

iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



D3.2 Tender Documents



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Executive Summary

This deliverable includes all the Call for Tender Documents. It is structures as follows:

- Tender Document 1 (TD1) is divided into six sections.
 - Section 1 explains the PCP approach and how it differs from traditional procurements. This section also provides an overview on of the budget, as well as the procurement approach. In addition, a general introduction to the procurers involved (also referred to as Buyers Group) is provided.
 - Section 2 introduces the tender profile, with the visions, overall challenge must address and the motivation behind it. It explains the different phases of the PCP and the expected outcome of each phase and the timeline of the iProcureSecurity PCP. Finally, Intellectual Property Right (IPR) considerations are addressed.
 - Section 3 explains the preconditions for submitting Tenders, and an overview of the criteria to be used in the evaluation of the Tenders.
 - Section 4 describes the content and format of the Tenders, the opening of Tenders and the different Envelopes.
 - Section 5 addresses conditions of the contracts between the winning Tenderers and the Buyers Group, and payments based on satisfactory completion of milestones and deliverables of the phase, payment schedules and eligibility.
 - Section 6 includes the language, communication, data processing and confidentiality and cancellation of the Tender Procedure.
 - And Annexes:
- Annex 1. Checklist of documents and actions
- Annex 2. Information about the Public Buyers
- Annex 3: Challenge Brief
- Annex 4: Requirements, use cases and process models

In addition, following documents have been drafted, discussed and updated according feedback from the consortium during the first project period:

- Tender Document 2 (TD 2): Technical Offer
- Tender Document 3 (TD 3): Financial Offer and Cost Breakdown
- Tender Document 4 (TD 4): Declaration of Honour
- Tender Document 5 (TD 5): Consortia Statement
- Tender Document 6 (TD 6): Subcontracting Statement
- Tender Document 7 (TD 7): Legal Capacity of the Tenderer Statement
- Tender Document 8 (TD 8): Declaration of pre-existing rights
- Tender Document 9 (TD 9): Framework Agreement
- Tender Document 10 (TD 10): PCP Specific contract for Phase 1/2/3
- Tender Document 11 (TD 11): End of Phase (1, 2, 3) Report
- Tender Document 12 (TD 12): Contractor details and project abstracts



iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 1 (TD 1) Call for Tender

Deadline to submit a tender: 31-8-2022 at 12 p.m. (CEST)



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

This Call for Tenders, designated as Tender Document 1 (TD1), should be read in conjunction with other Tender Documents related to this Pre-Commercial Procurement (PCP), listed hereunder:

Tender Document 1a (TD 1a): Cover Letter

Tender Document 2 (TD 2): Technical Offer

Tender Document 3 (TD 3): Financial Offer and Cost Breakdown

Tender Document 4 (TD 4): Declaration of Honour

Tender Document 5 (TD 5): Consortia Statement

Tender Document 6 (TD 6): Subcontracting Statement

Tender Document 7 (TD 7): Legal Capacity of the Tenderer Statement

Tender Document 8 (TD 8): Declaration of pre-existing rights

Tender Document 9 (TD 9): Framework Agreement

Tender Document 10 (TD 10): PCP Specific contract for Phase 1/2/3

Tender Document 11 (TD 11): End of Phase (1, 2, 3) report

Tender Document 12 (TD 12): Contractor details and project abstracts

And Annexes:

Annex 1. Checklist of Tender Documents and actions

Annex 2. Information about the Public Buyers

Annex 3: Challenge Brief

Annex 4: Requirements, use cases and process models

PREFACE

This iProcureSecurity PCP Call for Tenders invites all interested parties to present their offers for R&D services in the form of a solution that will provide Triage Management Systems which will strengthen the resilience and interoperability of European Emergency Medical Services (EMS).

The procurement addresses the procurers' unmet needs relating to different EMS-related aspect, such as: planning and decision making, resource allocation, improved triage practices, data transmission and interoperability, usability of EMS solutions, evaluation and sustainability, data security and protection in standard crisis management systems.

iProcureSecurity PCP is a research & development (R&D) services procurement which is conducted through a Pre-Commercial-Procurement (PCP).

Tender Document 1 (TD1) is divided into six sections.

- Section 1 explains the PCP approach and how it differs from traditional procurements. This section also provides an overview on of the budget, as well as the procurement approach. In addition, a general introduction to the procurers involved (also referred to as Buyers Group) is provided.
- Section 2 introduces the tender profile, with the visions, overall challenge must address and the motivation behind it. It explains the different phases of the PCP and the expected outcome of each phase and the timeline of the iProcureSecurity PCP. Finally, Intellectual Property Right (IPR) considerations are addressed.
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And 4 Annexes:

- Annex 1: Checklist of documents and actions
- Annex 2: Information about the Public Buyers
- Annex 3: Challenge Brief
- Annex 4: Requirements, use cases and process models

CONTENTS

SECTION	N 1:	: THE PCP PROCEDURE				
1.1	Intro	Introduction6				
1.2	Proc	Procurer(s) and other parties involved in the PCP7				
1.3	Gen	eral context & background	7			
1.3	.1	Public procurement of R&D services	8			
1.3	.2	Competitive development in phases (multiple sourcing)	8			
1.3	.3	Risk-benefit sharing at market conditions	8			
1.3	.4	Creating growth and jobs in Europe	8			
1.4	Proc	curement approach	9			
SECTION	12:	TENDER PROFILE	9			
2.1	iPro	cureSecurity PCP Vision	9			
2.2	iPro	cureSecurity PCP Challenges	11			
2.3	iPro	cureSecurity PCP Procedure	13			
2.4	Expe	ected outcomes (per phase)	13			
2.5	Con	tracting approach	20			
2.6	Max	imum Total budget and budget distribution (per phase)	21			
2.7	Time	e schedule	23			
2.8	IPR issues27					
2.8	.1	Ownership of results (foreground)	27			
2.8	.2	Declaration of pre-existing rights (background IPRs)	27			
2.8	.3	Protection of the results	27			
2.8	.4	Commercial exploitation of results	27			
2.8	.5	Promotion of R&D by the Buyers Group	28			
SECTION	13:	EVALUATION OF TENDERS	28			
3.1	Eligi	ble tenderers, joint tenders and subcontracting	28			
3.1	.1	Joint Tenderers - Consortia Tenders	29			
3.1	.2	Subcontracting	29			
3.2	Excl	usion criteria	30			
3.3	Sele	ction criteria	34			
3.4	Awa	ırd criteria	36			
3.5	Scor	ing	48			
3.6	Eval	uation Overview	48			
3.7	Evaluation of the submitted Tenders and initial Contract Award					

3.8	Procedures for appeal	50
SECTION	4: CONTENT & FORMAT OF THE TENDERS	50
4.1	Tender submission - Content & Format	50
4.2	Opening of tenders	51
4.3	Administrative section (ENVELOPE A)	52
4.4	Technical section (ENVELOPE B)	52
4.5	Financial section (ENVELOPE C)	53
SECTION	5: CONDITIONS OF THE CONTRACTS	54
5.1	Contract implementation	54
5.2	Payments based on Satisfactory Completion of Milestones and Deliverables of	the Phase54
5.3	Payments Schedule	55
5.4	Eligibility for the next phase based on Successful Completion of the phase	56
5.5	Finalisation of Phase 3: Possible follow-up PPI	57
SECTION	6: MISCELLANEOUS	57
6.1	Language	57
6.2	Tender constitutes binding offer	57
6.3	Communication	57
6.4	Confidentiality	58
6.5	Freedom of Information	58
6.6	Data processing in EU / EEA	59
6.7	Cancellation of the tender procedure	59
ANNEXES	5	60
ANNE	K 1 CHECKLIST OF TENDER DOCUMENTS AND ACTIONS	60
ANNE	X 2 INFORMATION ABOUT THE PUBLIC BUYERS	63
ANNE	K 3 CHALLENGE BRIEF	68
	A RECHIREMENTS LISE CASES AND PROCESS MODELS	90

SECTION 1: THE PCP PROCEDURE

1.1 Introduction

The Contracting Authority invites Tenderers to submit offers for the provision of R&D Services for the iProcureSecurity PCP project.

This PCP will be conducted in accordance with the procedure explained in section 2.3 below.

The budget for the PCP amounts to a maximum of is 6.774.194,00 EUR excluding VAT (see section 2.6 below).

Tenderers should aim at a market introduction of their new solution at a maximum of four (4) years after the end of the PCP.

When tendering for this PCP, it should be considered that the offered price should reflect the fact that the Intellectual Property Rights (IPR) stay with the Contractor.

While every effort has been made to provide comprehensive and accurate information in all notices and documents prepared for the purposes of this PCP, the Contracting Authority does not accept any liability or provide any expressed or implied warranty in respect of any such information. Tenderers must form their own conclusions about the solution needed to meet the requirements set out in the Tender Documents and may wish to consult their legal advisers.

The Contracting Authority does not bind itself to accept the lowest priced or any Tender. The evaluation process is described in detail under section 3 of the present document.

The Call for Tenders does not constitute an offer or commitment to enter into a Framework Agreement.

No contractual rights in relation to the Contracting Authority will exist unless and until a formal written Framework Agreement has been entered into by the Contracting Authority.

Any notification of a successful Contractor status by the Contracting Authority shall not give rise to any enforceable rights by the Contractor.

The Contracting Authority may cancel this PCP procedure at any time prior to a formal written Framework Agreement and Specific Contract being executed by the Contracting Authority.

The Call for Tenders supersedes and replaces any and all previous documentation, communications and correspondence between the Contracting Authority (in its own name and on behalf of the Buyers Group) and Tenderers, and Tenderers should place no reliance on such previous documentation and correspondence.

This PCP is an open tendering procedure and participation is on equal terms to all types of operators from the countries provided under section 3.1 of the present document (eligible Tenderers, Joint Tenders and Subcontracting) regardless of their size or governance structure. There will, however, be a requirement relating to the place of performance of the R&D Services.

For Phases 2 and 3, participation is limited to Contractors that successfully completed the preceding Phase.

Tenders may be submitted by a single entity or in collaboration with others. The latter approach can involve either submitting a Joint Tender or Subcontracting, or a combination of the two approaches.

Participation in the Open Market Consultation is not a condition for submitting a Tender.

1.2 Procurer(s) and other parties involved in the PCP

This procurement relates to a joint PCP that will be carried out by the following **Contracting Authority**: KENTRO MELETON ASFALEIAS (KEMEA), Greece.

The Contracting Authority is appointed to coordinate and lead the joint PCP, and to sign and award the Framework Agreement and the specific contracts for all phases of the PCP, in the name and on behalf of the following **Buyers' Group**:

- EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES), Spain
- SERVICIO MADRILENO DE SALUD (SERMAS), Spain
- OSTERREICHISCHES ROTES KREUZ (ARC), Austria
- AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN), Italy
- AGENZIA REGIONALE EMERGENZA URGENZA (AREU), Italy
- ELLINIKOS ERYTHROS STAVROS (HRC), Greece
- ETHINKO KENTRO AMESIS VOITHEIAS (EKAB), Greece
- IZMIR BUYUKSEHIR BELEDIYESI (IBB), Turkey

See Annex 2. for more information.

1.3 General context & background

This procurement is a pre-commercial procurement (PCP).

PCP challenges innovative players on the market, via an open, transparent and competitive process, to develop new solutions for a technologically demanding mid- to long-term challenge that is in the public interest and requires new research and development.



In this context, PCP enables the co-creation of innovative solutions by R&D suppliers (e.g. technology providers, researchers) and contracting authorities.

Pre-Commercial Procurement is an approach to procure R&D services that involves competitive development in phases, risk-benefit sharing under market conditions and that aims to create growth and jobs in Europe.

1.3.1 Public procurement of R&D services

PCP addresses mid- to long-term public procurement needs for which either no commercially stable solutions yet exist on the market, or existing solutions exhibit structural shortcomings which require further R&D to resolve. PCP is a way for contracting authorities to trigger the market to develop new solutions that address these shortcomings. PCP focuses on specific identified needs and provides customer feedback to businesses from the early stages of R&D. This improves the likelihood of commercial exploitation of the newly developed solutions.

1.3.2 Competitive development in phases (multiple sourcing)

• PCP targets situations that require R&D and for which there are no solutions on or close to the market yet. Different market parties may have different ideas for solutions to the problem. As R&D is yet to take place, there is not yet any proof as to which of these potential alternative solutions would best meet customers' needs.

• PCP therefore awards R&D contracts to a number of competing contractors at the same time, in order to compare different approaches to solving the problem. It thus offers innovators an opportunity to show how well their solution compares with others and to obtain a first customer test reference.

• The phased approach progressively identifies the solutions that offer the best value for money and best meet the customer needs. It allows successful contractors to improve their solutions gradually based on lessons learnt and feedback from the contracting authority. It also makes it easier for smaller companies (including SMEs and start-ups) to participate in the PCP and to grow their business step-by-step throughout the PCP.

• PCP may include the purchase of the limited set of innovative solutions that were developed and tested during the PCP. Depending on the outcome of the PCP, contracting authorities may or may not decide to follow-up the PCP with a public procurement for wider diffusion of the innovative solutions (Public Procurement of Innovative solutions).

1.3.3 Risk-benefit sharing at market conditions

• PCP allocates to each contractor the ownership of the IPRs attached to the results it generates during the PCP so that contractors can widely exploit the newly developed solutions commercially. The contracting authority receives the rights to use the R&D results and licensing rights subject to certain conditions (see more details in the contract).

• PCP is not a grant or subsidy. It is a public procurement of R&D services at market price, thus providing contractors with a transparent, competitive and reliable source of financing for the early stages of their research and development.

1.3.4 Creating growth and jobs in Europe

• PCP procurements are exempted from the EU public procurement directives, the WTO Government Procurement Agreement (GPA) and the EU's other procurements agreements with third countries.

• PCP procurements can thus contain conditions, for example conditions that restrict access of third country bidders to the procurement and place of performance conditions that require selected contractors to locate a specific part of the R&D activities for the contract, including in particular the principal researcher(s) working for the PCP contract, in Europe.

1.4 Procurement approach

For the present procurement, the Open Procedure is adopted.

SECTION 2: TENDER PROFILE

2.1 iProcureSecurity PCP Vision

The vision of iProcureSecurity PCP builds the foundation for the development of novel triage management systems (iProcureSecurity PCP Solution), that are able to overcome fundamental shortcomings of currently used systems and which will allow to digitalize key processes and thereby strongly contribute to an improved quality of the service for all involved stakeholders.

In particular, the iProcureSecurity PCP Solution must be developed considering the needs of the EMS on the field, and it must aim to:

- (1) Digitalize the triage management operations on the field, and provide guidance and support to the EMS practitioners.
- (2) Facilitate the communication and the information sharing among EMS on the field and external stakeholders (Dispatch Centre and public actors, respectively categorized as Category E and Category D).
- (3) Facilitate the decision-making process of the actors involved, by proving them with key information in real time, as well as with alerting and notification systems.
- (4) Provide a hardware component (Triage Tag), that is attached to the casualty throughout the whole process (from first triage to hand over to the hospital) and which supports data collection and hand over procedures.
- (5) Allow the report and assessment of MCIs including performed activities on the field (data collected, decisions taken, actors and profiles involved).
- (6) Integrate data from and to third party systems.

Starting from the findings collected and analysed during the iProcureSecurity CSA project and in-depth assessments during the first months of the iProcureSecurity PCP project it can be stated that an innovative system must be developed in a way to enable **planning** and **decision-making**, taking into account all the existing variables faced by the EMS practitioners at the MCI area.

Likewise, the **allocation of resources** must be as efficient as possible to reduce the cost of each intervention while always ensuring casualty safety. In general, all emergency professionals the project consortium engaged with, claimed that the current **practices in the area of triage management** need to be improved and the development that is carried out by the industry has to go beyond the current state of the art.

A system that truly has an impact on the work of the emergency teams should allow a quick, easy and uninterrupted communication and information flow among the EMS practitioners on the field,

allowing them to exchange information in real time with the other stakeholders in the EMS ecosystem (e.g. information sharing with the Dispatch Centre and the hospitals).

Furthermore, part of the project vision is to connect the iProcureSecurity PCP solution with and to existing and upcoming third-party solutions and databases (e.g., casualty's medical history). The aforementioned necessity implies that the iProcureSecurity PCP Solution is able to exchange data directly with other information systems of the EMS organizations involved. The **interoperability** concept has to ensure that existing and upcoming third-party solutions can connect to the solution according clearly defined standards and thereby ensure sustainability of the solution.

A system for triage management that meets the challenges faced by the EMS practitioners across Europe should be digital and able to provide data that facilitates the **evaluation** of interventions between different teams on national or European levels. However, to achieve this goal, the iProcureSecurity PCP Solution needs to demonstrate also the capability to be used during MCI trainings.

Finally, as the health data of casualties that is transferred and updated between the different actors is concerned, **data protection** must be guaranteed at all times supported by putting in place all the necessary **cybersecurity** measures.

The image below gives a basic overview of the involved actors, connections and interfaces of an envisaged flexible and highly modular triage management system solution, that can be applied and adapted to different approaches and connected to existing systems in every of the procurers' country or region.



Figure 1: Triage management aspects

To reach the desired quality and efficiency improvements suppliers will have to take into account several aspects and make use of and combine innovative aspects and concepts in several domains. A critical success factor is to establish a balanced understanding for the technology components, the involved data domains, and the organisational processes and structures which build on the former. The focus areas of the technology perspective include means to continuously capture and update triage information, which is consolidated to streamline the triage management, including the handover of casualties to healthcare organisations. The aspect of "site intelligence" seeks to utilise the capabilities of modern sensor technologies, to aid in casualty tracking and treatment, but also identification of potential threats, as well as providing a data foundation for further decision support. The cross-cutting aspects for technologies are the functional capabilities of technology components,

their usability and practicality for a field deployment, as well as interoperability from a technical standpoint.

The concept of operations examines the roles, structures and processes established for a Mass Casualty Incident response, starting from the concrete initial triage process, and the consequential treatment and the hand over to the hospitals. It includes the continuous interaction with other EMS organisations, as well as with the Dispatch Center and hospitals, as well as the collaboration under different constellations, especially in Mass Casualty Incidents with heterogenous EMS from different nationalities involved. This also covers the aspects of a consistent incident documentation, the feedback of lessons learned into training concepts, but also the (potentially diverging) terminology and taxonomy used by involved organisations.

The data perspective covers the aspect of incident information, to understand the scope and impact of the situation, which is necessary to plan a suitable Mass Casualty Incident resolution and identify additional resource needs on site. Particular emphasis is also on any data regarding the casualties, which ranges from their triage history, the treatment they received, but also the potential of retrieving a casualty record or capacity data from healthcare organisations to further improve the routines on site. Due to the sensitive nature of the involved information, the aspect of data protection is an important cross-cutting aspect. Of similar importance is the semantic interoperability of data, which ties in with the syntactic interoperability for technical components, and the terminology and taxonomy established in the concept of operations.

The iProcureSecurity PCP triage management system can be considered as one of the core components for EMS digitalisation, as it has the vital role of receiving data from the involved endpoints (sensors, services, applications), complements it with contextual data and distributes it to downstream systems, while providing information to decision makers on- and off-site to support the management of the incident situation.

In addition to that, the different modules of the iProcureSecurity PCP Solution can be seen as building blocks for advanced information systems to be deployed in the routine EMS activities other than MCI.

2.2 iProcureSecurity PCP Challenges

Multiple challenges were identified, which have to be addressed by the iProcureSecurity PCP solution triage management system:

• The tracking of the triage situation involves information on the number of casualties, their classification, their treatment and their status. Carried out manually, it is a challenging task to collect the information for an initial overview, and to maintain it as the situation evolves, as it requires multiple roles on-site to continuously update this information. Outdated information or mistakes influence and delay decision making processes on an operational, tactical and strategic level, which can lead to a misallocation of resources, a delayed delivery of supplies or equipment, or subsequent mistakes in the management and treatment of casualties. By maintaining a digital record of each triaged casualty, beginning with the initial primary triage, continuing to the treatment, up to the handover to the hospital, a permanently updated data baseline is available for decision makers to produce an overview which satisfies a demand for an overall situational awareness, but it is also rich in detail to be suitable for specific use cases (such as the treatment or transportation) or to be further processed by downstream systems.

- Data interoperability between different organisations on-site, especially if multiple nationalities are involved, is a challenging aspect. Triage information is relevant for other organisations to aggregate a holistic overview of the Mass Casualty Incident situation, to keep track of the resolution of the incident, to react to unexpected changes of the situation, or to flexibly change priorities in resource allocation if bottlenecks are identified. A digitalisation of the triage procedure provides a reliable data basis for other organisations to work with and does not bind personnel on-site (such as liaison or communication officers) to convey this information. On a broader scale, this structured information is also an important factor to plan out the transportation logistics towards hospital facilities, or identify additional supplies, vehicles or specialised equipment required at the Mass Casualty Incident Area.
- The handover procedure of a casualty for transportation also includes information on their triage classification and treatment history. This is of relevance for the paramedic in the transportation vehicle to ensure a correct, continuous treatment of the casualty during the transportation, and it remains equally important in the handover from the transportation to the hospital facility for the hospital triage and further treatment. The goal of the information handover is to be as accurate as possible, while also consuming as little time as possible for the personnel involved, which can be a challenging task if factors such as a manually written or transcribed documentation, proprietary systems and potentially semantic or taxonomic difficulties are involved. A distribution of digitalised triage information to any authorised data consumer is efficient, consistent and reliable and does not bind human resources of the involved organisations. It also has the inherent advantage of providing a larger amount of information than what is strictly necessary for the supported process step, which would be well beyond the scope of an efficient manual handover. This way, information can be purposefully narrowed down or retrieved depending on the usage scenario, providing an appropriate flexibility to adjust to an evolving MCI situation.
- In a Mass Casualty Incident, the situation can evolve rapidly, involving multiple organisations, carrying out a large subset of routines involving multiple decision points. A manual documentation of these activities is challenging, as it binds valuable resources and is often carried out under stress, impacting the accuracy, thoroughness and correctness of captured information. A digitalisation provides a consistent, chronological, documentation on the triage classification, the treatment received on site, and the handover for transportation. Furthermore, by using consistent reference objects and adhering to standardised data formats, a comprehensive data basis is created, which supports the analysis on how the MCI evolved on site, and derive insights on how to continuously improve the triage procedure from a long-term perspective. These insights can also feed back into the training of EMS personnel, or provide profound information which future research activities can build on. Furthermore, the evaluation, combined with the creation of training, can provide libraries of cases/scenarios, based on real or dummy data ("simulation mode"), which can be used by the procurers for the creation of customizable and evaluable scenarios.

The triage management system can be considered as one of the core components for digitalisation, as it has the vital role of receiving data from the involved endpoints (sensors, services, applications), complements it with contextual data and distributes it to downstream systems, while providing information to decision makers on- and off-site to support the management of the incident situation.

2.3 iProcureSecurity PCP Procedure

The PCP shall follow the phased PCP model described by the European Commission in the Communication referred to in the 1.2 section, aiming at conducting R&D services up to the development of a limited volume of first products.

This PCP will be divided into three Phases. Each Phase will result in a competition between the Tenderers in such a way that the number of Tenderers shall decrease from one Phase to the next one to ensure selecting those that best address the technical challenge on which this PCP is based.

- PCP PHASE 1 Solution Design
- PCP PHASE 2 Prototype Development
- PCP PHASE 3 Development and Testing of Pilot Systems

2.4 Expected outcomes (per phase)

Phase 1: Solution Design

During this phase, the awarded R&D providers are asked to develop an overall conceptual architecture and technical specifications for each of the system components and their interfaces based on the requirements, use cases and service process models.

During Phase 1, the Buyers Group will request from the contractors a series of deliverables in order to evaluate their progress based on a predefined set of criteria.

The Evaluation Committee and the Technical Committee will be responsible for achieving an effective monitoring. Monitoring meetings can be held physically or online and will be agreed between the Contractor and the Contracting Authority at least on a monthly basis.

So, the technical progress of the Contractors will be monitored through the Solution Design Phase by way of a monthly meeting, which shall commence upon signature of the Contracts. In these meetings the Contractor shall give monthly progress presentations that will be used for reviewing against the expected outcomes (milestones, deliverables and output or results) for the Solution Design Phase. If there are issues to be discussed or clarified with the Contractors, separate online meetings will be organised, according to the principles of transparency and equal treatment.

For more information on the assessment of the satisfactory completion of the End of Phase Reports, please see section 5.2 Payments based on Satisfactory Completion of Milestones and Deliverables of the Phase.

Phase 2: Prototype Development

Qualified contractors will develop and test prototypes in two iterations. The first iteration aims at developing non- or partly functional prototypes of key systems 1 components. Test outcomes will be collected and analysed for design, to serve as input for the suppliers' development of the second iteration. Outcomes of version 2 prototype testing will also be used for the evaluation of the phase outcomes (identical with the version 2 prototypes).

The interim payment for the said phase will be connected with specific deliverables and milestones. On completion of Phase 2, the R&D providers will each deliver the End of Phase 2 deliverables requested by the Consortium, describing the performed activities and the obtained results of Phase 2, the IPR, ethics and security handling and an updated business/commercialisation plan.

The Evaluation Committee and the Technical Committee will be responsible for achieving an effective monitoring. Monitoring meetings can be held physically or online and will be agreed between the Contractor and the Contracting Authority at least on a monthly basis. So, the technical progress of the Contractors will be monitored through the Prototype Development Phase by way of a monthly meeting, which shall commence upon signature of the Contracts. In these meetings the Contractor shall give monthly progress presentations that will be used for reviewing against the expected outcomes (milestones, deliverables and output or results) for the Prototype Development Phase. If there are issues to be discussed or clarified with the Contractors, separate online meetings will be organised, according to the principles of transparency and equal treatment.

For more information on the assessment of the satisfactory completion of the End of Phase Reports, please see section 5.2 Payments based on Satisfactory Completion of Milestones and Deliverables of the Phase.

Phase 3: Development and Testing of Pilot Systems

During Phase 3 further development of the selected prototype solutions to a state where they can be piloted under real-life conditions, involving patients, EMTs, and health professionals, will take place in the 5 countries (Greece, Italy, Spain, Austria and Turkey).

The systems will be finalised and introduced at the piloting partners' premises in each country / region while the piloting itself may take place in different locations depending on the piloting partners' choice for this activity. As part of this, suppliers will be required to provide all systems and end-user devices for the pilots. Systems will then run the pilot with the real users, while suppliers provide full helpdesk and technical support functionalities. The pilot operation will be prepared by the project partners in each country in terms of the development of a suitable evaluation framework and the recruitment of users. The trial evaluation will be used to collect data for the final assessment of the pilot systems and to serve as a data reference for future procurers.

The interim payment for the said phase will be connected with specific deliverables and milestones. On completion of Phase 3, the R&D providers will each deliver the End of Phase 3 deliverables requested by the Consortium, describing the performed activities and the obtained results of Phase 3, the IPR, ethics and security handling and an updated business/commercialisation plan.

The Evaluation Committee and the Technical Committee will be responsible of achieving an effective monitoring. Monitoring meetings can be held physically or online and will be agreed between the Contractor and the Contracting Authority at least on a monthly basis.

So, the technical progress of the Contractors will be monitored through the Solution Design Phase by way of a monthly meeting, which shall commence upon signature of the Contracts. In these meetings the Contractor shall give monthly progress presentations that will be used for reviewing against the expected outcomes (milestones, deliverables and output or results). If there are issues to be discussed or clarified with the Contractors, separate online meetings will be organised, according to the principles of transparency and equal treatment.

For more information on the assessment of the satisfactory completion of the End of Phase Reports, please see section 5.2 Payments based on Satisfactory Completion of Milestones and Deliverables of the Phase.

Expected outcomes					
Phase 1: Solution design					
		Perform research and develop	ment to:		
		 elaborate the solution design develop the innovative solution 	n and determine the approach to be taken to ns.		
	Objective:	• demonstrate the technical, medical, financial and commercial feasibility of the proposed concepts and approaches to meet the procurement requirement.			
		• incorporate the recommendations made by the Buyers Group in their assessment of the bids			
Output and results:		A solution design, including a clear and feasible plan on how to develop the solution successfully and formulate a preliminary business plan, which includes evidence of meeting the requirements outlined in the PCP challenge.			
Milestones		By when?	How?		
M1.1	Kick-off meeting	At the beginning of Phase 1	Physical Meeting or Online Meeting Presentation of Phase 1 action plan between TB and Contractors and Q&A		
M1.2	Interim-review meeting	At the end of month 2 of Phase 1	Video conference / submission of intermediate progress report		
M1.3	Submission of Phase 1 Final Report	At the end of Phase 1	Submission of report		
Deliverables		By when?	How?		
D1.1	Contractor details & project abstracts	At the end of month 1 of Phase 1	EU template (TD12)		

For each Phase, the indicative expected outcomes, milestones and deliverables are the following:

				Final report Phase 1, including:
				- Detailed Technical Report for the achievements of Phase 1
				- Updated commercialisation plan.
		At the end of		-Compliance with the ethics requirements.
D1.2	End of Phase		Phase 1	-Updated innovation impact plan
	1 Report			-Data management plan
				-IPR management plan
				-Risk mitigation plan for GDPR related issues
				-List the names and location of personnel that carried out the R&D activities.
	Report main			
D1.3	results and lessons learned	At the end of	Phase 1	Report EU template main results (TD11)
	for publication (EU template)			
	(

Phase	Phase 2: Prototype Development				
				Develop, demo	onstrate and validate prototypes in lab conditions.
	Objective:		• Development of prototype systems v.1: Prototypes at this stage are conceived of as non- or partly functional prototypes of key system components		
			• Development of prototype systems v.2: Prototypes at this stage are conceived of as functional prototypes, demonstrating component behaviour and system-wide interaction.		
	Output and results:		The prototypes v1 and v2 are subject to testing with end-users. A suitable number of individuals (n>10) will be involved in each pilot location. V2 prototypes will be presented by suppliers at each procurer site. Testing will take place according to common protocols. Progress of the work is monitored in status calls. Written report and on-site presentations		
Miles	tone	S	By when?		How?
M2.1		Kick-off meeting	At the beginning of Phase 2		Physical and/or online meeting
M2.2		Prototype System v1	At month	3	Physical meeting Presenting achieved levels of the prototype and demonstration of the results

M2.3	Prototype System v2	At the month 8	Physical meeting Presenting achieved levels of the prototype and demonstration of the results
M2.4	Submission of End of Phase 2 Report	At the end of month 8 of Phase 2	Prototype delivery Evaluation report per contractor-Update of technical and commercialisation plan
Deliverabl	es	By when?	How?
D2.1	Contractor details & project abstracts	At the end of month 1 of Phase 2	EU template (TD12)
D2.2	Presentation of prototypes of key system components	At the end of month 2 of Phase 2	Presentation of prototypes of key system components
D2.2a	Protocol of testing v1	At the end of month 3 of Phase 2	Protocol of testing v1
D2.3	Intermediate progress report	At the end of month 4 of Phase 2	Intermediate progress report
D2.4	Presentation of functional prototypes, demonstrating component behaviour and systemwide interaction	At the end of month 6 of Phase 2	Presentation of functional prototypes, demonstrating component behaviour and system-wide interaction
D2.4a	Protocol of testing v2	At the end of month 8 of Phase 2	Protocol of testing v2
D2.5	GDPR compliance report	At the end of month 8 of Phase 2	Presentation of conformance of the solutions with GDPR
			Final report Phase 2, including:
			- Detailed Technical report for the achievements of Phase 2
D2 6	End of Phase	At the end of month 8 of	- Updated commercialisation plan.
52.0	report	Phase 2	-Compliance with the ethics requirements.
			Updated innovation impact plan
			-Data management plan
			-IPR management plan

			-Risk mitigation plan for GDPR related issues
			- Test plan description of Phase 3 with detailed documentation of the steps that need to be done in order to run the test
			-List the names and location of personnel that carried out the R&D activities.
	Report main		
	results and		
D2.7	lessons learned	At the end of Phase 2	Report EU template main results (TD11)
	for publication		
	(EU template).		

Phase 3: D	Phase 3: Development and Testing of Piloting Systems			
			Devel condi	opment of pilot systems for an extended test under real-life tions at all procurer sites.
			• Pilot	t systems installed and tested in 5 pilot sites.
			• Ope	ration maintained in parallel at full quality.
	Objective:		• Hel opera	p service and maintenance response team set up and ted by suppliers.
			• Pilo metric	t systems evaluated using a commonly agreed protocol and cs.
	Output and results:		1) Dev life co	velopment of pilot systems for an extended test under real- onditions at all procurer sites for at least two days.
			2) Su collab introd trainin Before arising used a elimin	appliers install the pilot systems at each site in close poration with the respective site partner. System duction covers installation of central components, user ngs, and preparation of user devices, if any, for roll-out. e the pilot trial, on-site testing is done to reveal problems g from the particular situation of equipment, the networks and the organisational environment in which staff work, to nate problems in the full pilot.
			3) Ext per pr	ended test of the solutions. Involvement of 10-30 EMS staff rocurer at their sites.
			4) Sup respo at the	opliers set up and operate a help service and a maintenance nse service to address problems faced by the users involved sites. Help and support is provided at each site.
			5) Pro	gress of the work is monitored in status calls
Milestones By when			How?	

M3.1	Pilot systems ready	Atthebeginningofmonth1ofPhase 3	On site for pilots	
M3.2	Pilot operation start	At month 3	On site for pilots Technical training of dedicated end users	
M3.3	Pilot operations end	At month 7	Written confirmation of operations end	
M3.4	Submission of End of Phase 3 Report	At the end of Phase 3	Submission of reports	
Deliverabl	es	By when? ₌	How?	
D3.1	Signing of the GDPR Processing Agreement, if applicable for the pilot. See Annex X. * Testing can only start if the GDPR Processing Agreement has been signed. * The GDPR Processing Agreement depends on the actual pilot situation and the solution proposed by the Contractor with a maximum of four Agreements.	At the beginning of month 1 of Phase 3	Sent by e-mail to ipspcp-procurement@kemea-research.gr	
D3.2	Project abstract	At the end of month 1	EU template (TD12)	
D3.3	Progress report on system development	At the end of month 4	Written report	
D3.4	Presentation of pilot system and onsite testing results	At the end of month 7	Written report	

			- The analysis of the outcomes of the project and results of the physical tests including:
D3.5	End of Phase Report	At the end of Phase 3	 Summary of the main results achieved Installation & integration report Traceability Matrix Objective of the demonstrating Lists of names and location of personnel that carried out the R&D activities Summary of the features which were
			demonstrated and tested.
			-opdated commercialisation plan
			-Compliance with the ethics requirements
			-Updated innovation impact plan
			-Data management plan
			-IPR management plan
			-Risk mitigation plan for GDPR related issues
D3.6	Reportmainresultsandlessonslearnedfor publication	At the end of Phase 3	EU Template (TD11)

2.5 Contracting approach

The PCP will be implemented by means of a Framework Agreement with call-offs for specific contracts for each of the 3 R&D phases (altogether 'Contracts').

The law governing the Contracts is Greek law, because of the location of the Lead Procurer. However, the GDPR Processing Agreement – if applicable – will be governed by the law of the MS in which each pilot will take place during Phase 3.

The Framework Agreement will remain binding for the duration of all phases for which Contractors remain in the PCP. There will be no renegotiations.

KEMEA will be the Lead Procurer throughout all the phases of iProcureSecurity PCP.

Tenderers that are awarded a Framework Agreement will also be awarded a specific contract for Phase 1 (evaluation of tenders for the Framework Agreement and Phase 1 are combined). Tenderers are therefore asked not only to submit their detailed offer for Phase 1, but also to state their goals, and to outline their plans (including price conditions) for Phases 2 and 3.

1. Phase 1: Solution Design. Following the tendering stage, a Framework Agreement and a Specific Contract for Phase 1 will be awarded to at least six (6) contractors.

2. Phase 2: Solution Prototype. A call-off will be organised for Phase 2, with the aim of awarding at least four (4) Phase 2 contracts. Only offers from Contractors that successfully completed Phase 1

will be eligible for Phase 2. The procurers will validate the Phase 2 prototypes in the lab of the R&D provider.

3. Phase 3: Development and Testing of Piloting Systems. A second call-off will be organised for Phase 3, with the aim of awarding a minimum of two (2) Phase 3 contracts. Only offers from Contractors that successfully completed Phase 2 will be eligible for Phase 3. The procurers will validate the Phase 3 prototypes in the 5 pilot sites.

Offers for the next phase will be requested together with the End of Phase deliverables of the previous phase. I.e., all Contractors of the previous phase have the right to submit offers for the next phase (together with their End of Phase Report).

All possible complaints during the tendering process will be solely submitted to the Lead Procurer within five (5) days following the notification of the final decision – as described in step 7 of section 3.7 - of the Evaluation Committee. Complains will not be addressed to the other members of the Buyers Group or the iProcureSecurity PCP Consortium or the EC.

Possible complaints against any final decision of the Evaluation Committee may be reviewed by the Greek Administrative Court of Appeal of Athens.

A Contractor must have been awarded a Specific Contract for Phase 1 in order to be considered eligible for Phase 2. Likewise, a Contractor must have been awarded Specific Contracts for Phases 1 and 2 in order to be considered eligible for Phase 3.

2.6 Maximum Total budget and budget distribution (per phase)

The maximum total budget for this PCP is 6.774.194,00 EUR excluding VAT.

The minimum number of Contractors that are expected to be selected per phase, the maximum budget per phase and the maximum budget per bidder (including VAT) are given in the table below:

PCP Phase	#of Contractors	Subcontracting cost per contractor	Total subcontracting cost per phase
Phase 1 - Solution Design	At least 6	140.000,00€	840.000,00€
Phase 2 - Prototype Development	At least 4	735.000,00€	2.940.000,00€
Phase 3 - Development and Testing of Piloting Systems	At least 2	2.310.000,00€	4.620.000,00€

The minimum number of Contractors that are expected to be selected per phase, the maximum budget per phase and the maximum budget per bidder (excluding VAT) are given in the table below:

PCP Phase	#of Contractors	Subcontracting cost per Contractor	Total subcontracting cost per phase
Phase 1 - Solution Design	At least 6	112.903,2258€	677.419,3548€
Phase 2 - Prototype Development	At least 4	592.741,9355€	2.370.967,742€

Phase 3 -Development	At least 2	1.862.903,226€	3.725.806,452€
and Testing of Piloting			
Systems			

Since all Contractors will be paid by the Lead Procurer by way of centralised payments, and as KEMEA is based in Greece, EU rules and the valid Greek VAT legislation will be applied¹.

KEMEA may be entitled to a deduction for input VAT.

In case of suppliers from EU Member States, the reverse charge process, i.e., invoicing without VAT will be applied.

For suppliers from Greece (in the case of joint consortia, the consortium coordinator' headquarters are of relevance) national VAT procedures apply.

In case of suppliers from third countries, the VAT is calculated and reported by KEMEA. If the supplier upon import is obliged to report VAT according to the rules of the home country and the invoice contains VAT, that VAT is non-deductible in Greece. Instead, VAT amount is to be considered as a cost of the service.

For Phase 1, contracts will be financed until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. The lower the offered price of tenders, the more contracts can be awarded. However, the total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria.

Unless otherwise stated in the Call Off for Phase 2, contracts will be financed until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. The lower the offered price of tenders, the more contracts can be awarded. However, the total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria.

Unless otherwise stated in the Call Off for Phase 3, contracts for Phase 3 will be financed until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. The lower the offered price of tenders, the more contracts can be awarded. However, the total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria.

As leftover budget from the previous phase can be transferred to the next phase(s), the total budget available for Phases 2 and/or 3 may eventually be higher than stated here (but the maximum budget per Contractor for Phases 2 and 3 will remain the same).

¹ See indicatively, VAT Council Directive 2006/112/EC and Law No 2859/2000 Greek VAT Code. According to the later, the 24% VAT applies.

2.7 Time schedule

The general duration of each phase is as follows:

- Phase 1: Solution Design (4 months)
- Phase 2: Prototype Development (8 months)
- Phase 3: Development and Testing of Piloting Systems (7 months)

The estimated planned schedule for the iProcureSecurity PCP is presented in the following time schedule

Date	Activity
16-11-2021	Publication of PIN in TED
1-6-2022	Publication of Contract Notice in TED
30-7-2022	Deadline for submitting questions about Tender Documents
5-8-2022	Deadline for Contracting Authority to publish replies to questions (Q&A document)
31-8-2022	Deadline for submission of Tenders for the Framework Agreement and Phase 1
31-8-2022	Opening of Tenders
23-9-2022	Tenderers notified of the contract award decision
30-9-2022	End of the standstill period
30-9-2022	Signing of Framework Agreements and Phase 1 Contracts
30-9-2022	Publication of Contract Award Notice in TED
PHASE 1	
1-10-2022	Start of Phase 1 - Solutions Design

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Date	Activity		
1-10-2022	Names of winning Phase 1 Contractors and their project abstracts will be sent to the EU and will be published on the project's website (pcp.iprocuresecurity.eu)		
12-1-2023	Deadline for Phase 1 final milestone(s)/final report/deliverable(s)		
26-1-2023	Assessment of Phase 1 final milestone(s)/final report/deliverable(s)		
26-1-2023	Phase 1 Contractors notified as to whether they have completed this phase satisfactorily and successfully		
31-1-2023	End of standstill period		
31-1-2023	End of Phase 1 - Solutions Design		
31-1-2023	Summary of the results and conclusions achieved by each contractor during the phase sent to the EU		
2-3-2023	Payment of balance for Phase 1 to contractors that completed this phase satisfactorily		
PHASE 2 - Prototype Dev	relopment		
2-12-2022	Launch call-off for Phase 2 (only offers from Contractors that successfully completed Phase 1 are eligible)		
16-12-2022	Deadline for submitting questions on Phase 2 Call-off documents		
23-12-2022	Deadline for Contracting Authority to circulate replies to questions to Phase 2 tenderers		
5-1-2023	Deadline for submitting Phase 2 offers		
5-1-2023	Opening of Phase 2 offers		
26-1-2023	Contractors notified of decision on awarding Phase 2 contracts		
31-1-2023	End of standstill period		
31-1-2023	Signing of Phase 2 specific contracts		

Date	Activity
1-2-2023	Start of Phase 2 - Prototype Development
1-2-2023	Names of winning Phase 2 Contractors and their project abstracts will be be sent to the EU and will be published on project's website (<u>https://pcp.iprocuresecurity.eu/)</u>
31-3-2023	Deadline for Phase 2 interim milestone(s)/deliverable(s)
28-4-2023	Interim payments
31-08-2023	Deadline for submission of Phase 2 final milestone(s)/final report /deliverable(s)
23-09-2023	Assessment of Phase 2 final milestone(s)/final report/deliverable(s)
23-09-2023	Phase 2 Contractors notified as to whether they have completed this phase satisfactorily and successfully
30-09-2023	End of standstill period
30-09-2023	End of Phase 2
30-09-2023	Summary of the results and conclusions achieved by each contractor during the phase sent to the EU
30-10-2023	Payment of balance for Phase 2 to Contractors that completed this phase satisfactorily
PHASE 3 - Development	and Testing of Piloting Systems
1-9-2023	Launch call-off for Phase 3 (only offers from Contractors that successfully completed Phase 2 are eligible)
8-9-2023	Deadline for submitting questions about Phase 3 Call-off documents
15-9-2023	Deadline for Contracting Authority to circulate replies to questions to Phase 3 tenderers
22-09-2023	Deadline for submitting Phase 3 offers
22-09-2023	Opening of Phase 3 offers

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Date	Activity		
25-09-2023	Contractors notified of decision to award Phase 3 contracts		
29-09-2023	End of standstill period		
29-09-2023	Signing of Phase 3 specific contracts		
1-10-2023	Start of phase 3 - Development and Testing of Piloting Systems		
1-10-2023	Names of winning Phase 3 contractors and their project abstracts will be be sent to the EU and will be published on project's website (pcp.iprocuresecurity.eu)		
31-1-2024	Deadline for Phase 3 interim milestone(s)/deliverable(s)		
29-2-2024	Interim payments		
31-3-2024	Deadline for submission of Phase 3 final milestone(s)/final report/ deliverable(s)		
25-4-2024	Assessment of Phase 3 final milestone(s)/final report/deliverable(s)		
25-5-2024	Phase 3 Contractors notified as to whether they have completed this phase satisfactorily		
30-4-2024	End of standstill period		
30-4-2024	End of Phase 3		
30-4-2024	Summary of the results and conclusions achieved by each Contractor during the PCP sent to the EU for publication purposes		
30-6-2024	Payment of balance for Phase 3 to contractors that completed this phase satisfactorily		

The iProcureSecurity PCP Buyers' Group reserves the right to adjust the time schedule under specific and fully justified conditions. This will be communicated in writing and in a timely manner to all Tenderers/Contractors.

2.8 IPR issues

2.8.1 Ownership of results (foreground)

Each Contractor will keep ownership of the Intellectual Property Rights (IPRs) attached to the results they generate during the PCP implementation. The tendered price is expected to take this circumstance into account.

The ownership of the IPRs will be subject to the following:

- the Buyers' Group has the right to:
 - access the results, on a royalty-free basis, for their own use.
 - grant upon notification of the contractors (or to require the contractors to grant) nonexclusive licences to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license).
- the Buyers' Group has the right to require the contractors to transfer ownership of the IPRs back to the Buyers' Group if the contractors fail to comply with their obligation to commercially exploit the results (see below) or use the results to the detriment of the public interest (including safety and security interests).

2.8.2 Declaration of pre-existing rights (background IPRs)

The ownership of pre-existing rights will remain unchanged.

In order to be able to distinguish clearly between results and pre-existing rights (and to establish which pre-existing rights are held by whom) Tenderers are requested to list the pre-existing rights for their proposed solution in their offers following the template provided in TD 8: Declaration of pre-existing rights.

Subject to pre-existing obligations that may apply to background IPRs, the Tenderer grants the members of the Buyers Group a royalty-free, non-exclusive, irrevocable and non-sub-licensable license to use its background IPRs for the execution of the contract.

If applicable, subject to pre-existing obligations that may apply to background IPRs, the members of the Buyers Group grant the Contractor a royalty-free, non-exclusive, irrevocable and non-sublicensable license to use its background IPRs for the performance of the contract.

2.8.3 Protection of the results

The Contractor shall be responsible for the management of all the rights on the results that it holds and shall bear any associated costs including for the protection, examination, grant, maintenance, defense and litigation of the rights on the results.

The Lead Procurer shall be entitled to monitor the management of all rights on the results held by the Contractor. The Contractor shall respond at any time to requests for information from the Lead Procurer about the handling of the rights on the results.

2.8.4 Commercial exploitation of results

The Contractors are expected to start commercial exploitation of the results at the latest four years after the end of the Framework Agreement.

These provisions on Intellectual Property Rights apply regardless of whether the Contractor participates in all phases of the PCP or only in some of them, and that the provisions that extend beyond the duration of the Framework Agreement remain in force even if the Contractor is not selected for the next phase of the PCP and the agreement with the Contractor is terminated.

The Contractors are required to undertake specific activities beyond product development to commercially exploit the results, by building a concrete exploitation plan, including a commercialisation strategy, that should explain the proposed approach to commercially exploit the results of the PCP in order to bring a viable product to market. Contractors should prepare a detailed market analysis providing a first outlook on the cost/benefit ratio in the transition towards full scale deployment.

Contractors must consider the future certification of their solutions or contribution to standardisation. The feasibility of the commercialisation plan to commercially exploit the R&D results (Technical Offer) will be assessed as part of the Award Criteria. Furthermore, the commercialisation plan will be part of the End-of-Phase reports of all three phases, as well as of the offers for the Phases 1, 2 and 3.

2.8.5 Promotion of R&D by the Buyers Group

In addition to the commercialisation activities performed by the Contractors, the Buyers Group Members will promote the R&D results. The Buyers Group Members will also actively disseminate the Contractors' results at the end of each phase via relevant public and industry related activities. It is the Buyers' Group objective to help develop a working market for such type of solutions in order to ensure their usability and sustainability and to help overcome possible, commonly defined deployment barriers.

After the PCP, the Buyers Group will make their best efforts to support the Contractors and help remove barriers to the introduction onto the market of the solutions to be developed during the PCP (e.g., promotion of R&D results among other public procurers).

SECTION 3: EVALUATION OF TENDERS

3.1 Eligible tenderers, joint tenders and subcontracting

Participation in the tendering procedure is open on equal terms to all types of operators, regardless of their size or governance structure.

Tenders may be submitted by **a single entity** or in collaboration with others. The latter can involve either submitting **a Joint Tender or Subcontracting**, or a combination of the 2 approaches.

Concretely:

-Natural persons residing in one of the following countries:

• EU and EEA (European Economic Area) member states.

• H2020 Associated Countries having signed a Bilateral Agreement with the EU on security procedures for exchanging and protecting classified information

-Legal entities established under the law of the following countries and having their central administration or principal place of business or registered office (seat) in one of the following countries:

- H2020 Associated Countries
- H2020 Associated Countries

-Groups of economic operators of the above natural persons or legal entities, submit.

Participation in the **open market consultation** is not a condition for submitting a tender.

Å Attention:

For Phases 2 and 3, participation is limited to tenderers that successfully completed the preceding phase.

3.1.1 Joint Tenderers - Consortia Tenders

A Consortium (a combination of firms) may submit a Joint Tender. Any type of natural or legal persons (including non-profit entities properly registered like universities) shall be entitled to submit Tenders either individually or by way of an association or consortium comprising several Tenderers set up temporarily for the purposes of this PCP.

For Joint Tenders:

- The group of Tenderers must assume joint and several liability for the performance of the Contract.
- The group of Tenderers must mandate one of them with the power to sign the Framework Agreement and Specific Contracts provide in their name and on their behalf ('Lead Contractor').
- To this single authorised representative (Lead Tenderer) all communications shall be directed and accepted until this competition has been completed or terminated. Correspondence from any other person or entity will NOT be accepted, acknowledged or responded to.
- Prior to and as a condition of award of the Contracts, the successful Tenderer shall be required to designate a single authorised representative (Lead Contractor), who will carry overall responsibility for the Contracts irrespective of whether or not tasks are to be performed by a Subcontractor (see below) or another consortium member. The Lead Contractor shall sign the Tender and Contracts in the name of and on behalf of all members, and shall be responsible for all aspects and execution of the Contracts without prejudice to the existence of joint powers that they may grant for receiving and making payments of a significant amount. All members of the consortium shall be jointly and separately bound to fulfil the terms of the Framework Agreement and Specific Contracts. The Lead Contractor shall be mandated to act on behalf of the consortium for the purposes of the Contracts and shall have the authority to bind the consortium.

3.1.2 Subcontracting

Subcontracting refers to any contract or agreement between the Tenderer and a Third Party, whereby that Third Party agrees to provide services to the Tenderer to enable or assist the Tenderer to provide the R&D services or any part thereof to the Contracting Authority.

Subcontracting is permitted in each phase of this competition. However, no essential parts of the Contracts can be subcontracted, nor the management of the PCP.

The Tender must mention which parts of the Contract will be subcontracted.

The Contractors remain fully liable to the procurers for the performance of the Contract (and that is the reason why subcontracts must reflect the rules of the H2020 grant agreement, including as relates

to the place of performance, the definition of R&D services, confidentiality, results and IPRs, the visibility of EU funding, conflicts of interest, language, obligation to provide information and keep records, audits and checks by the EU, the processing of personal data, liability for damages, ethics and security requirements).

In case a Tenderer wishes to rely on the resources of a Third Party for the fulfilment of the requirements to participate in the PCP, this Third Party should be part of the Consortium (unless it is a hosting environment). I.e., if hardware or software from a Third Party is needed for the solution, they do not need to be part of the Consortium, but the Contractor needs to demonstrate that these resources will be available to him (e.g., by providing a licensing agreement).

The Tender that wishes to subcontract any part of the R&D services to be provided or to rely on the capabilities of Third Parties must fill in, sign – by duly authorised person and submit the Subcontracting Statement (TD 6).

Each of the Subcontractors and/or Third Parties participating must fill in, sign – by duly authorised person and submit the Declaration of Honour (TD4) and the Legal Capacity of the Tenderer Statement (TD 7).

The Subcontractor on whose experience the Contractor has relied on to satisfy the technical competence is obliged to perform the relevant work. This means that the execution of tasks assigned to a Subcontractor may not be subject of further subcontracting.

Subcontractors cannot participate in more than one Tender. Failure to do so leads to the automatic exclusion of the bids in which it participates, irrespective of its role in the bids.

Due to the short duration of the PCP no changes on Consortia or in Subcontractors will be allowed unless exceptional reasons that could not be foreseen apply.

3.2 Exclusion criteria

The exclusion criteria are as follows:

Exclusion criteria	Evidence
A) Conflict of Interest	TD 4 Self declaration
B) Bankruptcy & professional misconduct	TD 4 Self declaration
C) Criminal offences	TD 4 Self declaration
D) Proposed solution already available in the market	TD 4 Self declaration

- Tenderers that do not comply with these criteria will be excluded.
- In case of Joint Tenders, all members of the Consortium or group of bidders must fill in and submit TD 5, signed by an authorised representative.
- In case of subcontracting, all Subcontractors must fill in and submit TD 6, signed by an authorised representative.

A) Conflict of interest

Tenderers that are subject to a conflict of interest may be excluded. If there is a potential conflict of interest, Tenderers must immediately notify the Contracting Authority in writing.

A conflict of interest covers both personal and professional conflicts.

Personal conflicts can arise in any situation where the impartial and objective evaluation of Tenders and/or implementation of the Contract is compromised for reasons relating to economic interests, political or national affinity, family, personal life *(e.g. family of emotional ties)* or any other shared interest.

Professional conflicts might occur in situations where the contractor's (previous or ongoing) professional activities affect the impartial and objective evaluation of Tenders and/or implementation of the Contract.

Attention: If an actual or potential conflict of interest arises at a later stage (*i.e. during the implementation of the contract*), the Contractor must contact the Contracting Authority, who is required to notify the EU and take all necessary steps to rectify the situation. The EU may verify the measures taken and require additional information to be provided and/or further measures to be taken.

B) Bankruptcy & professional misconduct

A Tenderer or Contractor can be excluded from further participation in the PCP in any of the following situations of the former or any Subcontractor or Third Party on whose resources it relies upon in this procurement:

- Where the Contracting Authority can demonstrate by any appropriate means a violation of applicable obligations referred to in Article 18(2)Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014.
- Where the bidder is bankrupt or is the subject of insolvency or winding-up proceedings, where its assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under national laws and regulations.
- Where the Lead Procurer can demonstrate by appropriate means that the bidder is guilty of grave professional misconduct, which renders its integrity questionable.
- Where the Lead Procurer has sufficiently plausible indications to conclude that the bidder has entered into agreements with other economic operators with the intention of distorting competition.
- Where the bidder has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity or a prior concession contract which led to early termination of that prior contract, damages or other comparable sanctions.
- Where the bidder has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria.
- Where the bidder has undertaken to unduly influence the decision-making process of the Lead Procurer, to obtain confidential information that may confer upon it undue advantages

in the procurement procedure, or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.

• Where the bidder has failed and maintained relevant licensing or membership of an appropriate trading or professional organisation where required by law.

Attention: Should there be any doubt as to any of these criteria, Tenderers may be requested to provide additional information such as an extract of the local chamber of commerce.

C) Criminal offences

If the Procuring Entity becomes aware that a tenderer, or a representative of the Tenderer, or Sub-Tenderer, under a judgment that has entered into final legal force has been sentenced for a criminal offence listed below, such Tenderer can be excluded from the PCP. Tenderers must confirm by signing the Declaration of honour in TD 4 that they are not subject to any of the criminal offences indicated below:

Participation in a criminal organisation; this includes the following conduct: Conduct by any person who, with intent and with knowledge of either the aim and general criminal activity of the organisation or the intention of the organisation to commit the offences in question, actively takes part in:

- Activities of a criminal organisation, which shall be taken to mean a structured association, established over a period of time, of more than two persons, acting in cooperation with a view to committing offences which are punishable by deprivation of liberty or a detention order of a maximum of at least four years or by a more serious penalty, whether such offences are an end in themselves or a means of obtaining material benefits and, where appropriate, of improperly influencing the operation of public authorities, even where that person does not take part in the actual execution of the offences concerned and, subject to the general principles of the criminal law of the Member State concerned, even where the offences concerned are not actually committed;
- The organisation's other activities in the further knowledge that its participation will contribute to the achievement of the above-mentioned criminal activities;
 - Conduct by any person consisting in an agreement with one or more persons that an activity should be pursued which, if carried out, would amount to the commission of an offence as mentioned above, even if that person does not take part in the actual execution of the activity;
 - Corruption; corruption shall be considered as deliberately promising or giving, directly or through an intermediary, an advantage of any kind whatsoever to a public official, for himself or for a third party to act or refrain from acting in accordance with his duty or in the exercise of his functions in breach of his official duties; or in the private sector, directly or through an intermediary, deliberately promising, offering or giving an undue advantage of any kind whatsoever, for himself or for a third party, in the course of business activities of that person in order that the person should perform or refrain from performing an act, in breach of his duties;
 - •Fraud; fraud meaning both expenditure fraud and revenue fraud. This means any act or deliberate omission involving the use or presentation of false, incorrect or incomplete statements or documents which has as its effect the misappropriation or wrongful retention of funds from, or the illegal diminution of the resources of the general budget of the European

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Communities or budgets managed by, or on behalf of, the European Communities, nondisclosure of information in violation of a specific obligation, with the same effect, the misapplication if such funds for the purpose other than those for which they were originally granted or the misapplication of a legally obtained benefit with the same effect;

- Money laundering or terroristic financing, which shall be taken to mean:
 - The conversion or transfer of property, knowing that such property is derived from criminal activity or from an act of participation in such activity, for the purpose of concealing or disguising the illicit origin of the property or of assisting any person who is involved in the commission of such activity to evade the legal consequences of his actions;
 - The concealment or disguise of the true nature, source, location, disposition, movement, rights with respect to, or ownership of property, knowing that such property is derived from criminal activity or from an act of participation in such activity;
 - The acquisition, possession or use of property, knowing, at the time of receipt, that such property was derived from criminal activity or from an act of participation in such activity;
 - Participation in, association to commit, including attempts to commit, aiding, abetting, facilitating and counselling the commission of any of the actions mentioned in the foregoing three paragraphs;
- Terrorist offences or offences linked to terrorist activities
 - Child labour and other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA.

The exclusion criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for the Phases 2 and 3.

D) Proposed solution already available on the market

Tenderers whose proposed solution is already available on the market may be excluded.

Attention:

- Tenderers that do not comply with these criteria will be excluded.
- In case of Joint Tenders, all members of the Consortium or group of bidders must fill in, sign and submit the Declaration of Honour (TD4) signed by an authorised representative; fill in, sign and submit the Legal Capacity of the Tenderer Statement (TD 7).
- In case of subcontracting, all Subcontractors must fill in and submit the Declaration of Honour (TD4); fill in, sign and submit the Legal Capacity of the Tenderer Statement (TD7).
- All the documents must be signed by a duly authorised person with the powers to bind the legal/natural person.
- Modifications of the Declaration of Honour (TD4) and the Legal Capacity of the Tenderer Statement (TD7) are not allowed. Any of such modifications will lead to automatic exclusion of the Tenderer.

- The exclusion criteria will remain unchanged for the entire duration of the PCP, thus applying also for the Call-offs for the Phases 2 and 3. If there are any changes the Contractor needs to immediately inform the Lead Procurer.
- Should there be a missing document, the Lead Procurer has the right to ask for the missing information. If the Contractor does not submit the necessary information within five 5 (five) days from the written request of the Lead procurer, it will lead to automatic exclusion.
- Should there be any doubt as to any of these criteria, Tenderers may be requested to provide additional information.

3.3 Selection criteria

The purpose of the Selection Criteria is to determine whether a Tenderer has the financial, economic, technical and professional capacity necessary to carry out and perform the work.

The selection criteria are as follows:

Selection criteria	Evidence
Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, <i>including intangible</i> <i>results in particular IPRs</i>	Description of the capacity, materials and equipment that are available to the Tenderer for research, prototyping and limited production and supply of the first set of products or services.
Medical capacity in relation to triage management systems	Description of the capacity to create a solution in the field of Triage Management Systems and to judge the quality of triage algorithms and learning material and understand medical procedures and practices.
eHealth capacity	Description of the capacity to develop clinical solutions and SaMD
Demonstration of expertise and working experience required to undertake an innovative R&D project that entails relevant technology	Description of the expertise and working experience required to undertake an innovative R&D project that entails relevant technology.
Ability to commercially exploit the results of the PCP, including intangible results in particular IPRs	Description of the availability of financial and organisational structures for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results.

1 Tenderers that do not comply with these criteria will be excluded.

Ability to perform R&D up to original development of the first products

Tenderers must have:

- the capacity, tools, material and equipment to:
 - o carry out research and lab prototyping.

 produce and supply a limited set of first products or services and demonstrate that these products or services are suitable for production or supply in quantity and to quality standards defined by the procurers.

Medical capacity in relation to Triage Management Systems

Tenderers must have the capacity to create a solution in the field of Triage Management Systems and to judge the quality of triage algorithms and learning material and understand medical procedures and practices.

eHealth capacity

Tenderers must have the capacity to develop clinical solutions and SaMD (Software as a Medical Device).

Demonstration of expertise and working experience are required when undertaking an innovative R&D project that entails relevant technology

Tenderers must:

 provide a description of relevant reference and /or previous projects (executed during the last 5 years) which reflect the competences and capacity of the Tenderer in the different phases and domains of the iProcureSecurity PCP project, such as research, development, prototyping, testing and commercialisation. These references will be based on previous projects of the Tenderers and /or other members of the Joint Consortia and Subcontractors who will be working on the project.

To describe these projects, the Tenderers will provide proof of the capacity, tools, materials and equipment to carry out research and lab prototyping and proof of the capacity to produce and supply a limited set of first products or services. Tenderers will also have to demonstrate that these products or services are suitable for production or supply in quantity and to quality standards defined by the procurers.

In addition, the Tenderers will have to prove that they are able to manage, exploit and transfer or sell the results of the PCP (including tangible and intangible results, such as new product designs and IPRs) and able to generate revenue by marketing commercial applications of the results (directly or through subcontractors or licensees).

Finally, Tenderers will have to provide the necessary competences to ensure that they are able to complete this PCP project on time.

- Demonstrate the expertise and working experience required to undertake an innovative R&D project by providing a number of CVs of key personnel and competences, which they consider necessary to complete the project.
- Confirm that their organisation has a Business Continuity / Disaster Recovery / Risk Management plan which ensured that the described services will be delivered in the event of a disruption affecting their business and will ensure continuity of supply / service from critical suppliers.
- Confirm that they will take the appropriate level of insurance cover in case they are successful in winning the contract.

Ability to commercially exploit the results of the PCP, including intangible results in particular IPRs

Tenderers must have:

- the financial and organisational structures to
 - manage, exploit and transfer or sell the results of the PCP (including tangible and intangible results, such as new product designs and IPRs).
 - generate revenue by marketing commercial applications of the results (directly or through subcontractors or licensees).

Attention: Should there be any doubt as to any of these criteria, Tenderers may be requested to provide additional information.

3.4 Award criteria

There are 2 types of award criteria (on/off criteria and weighted criteria).

> On/off award criteria

These are the criteria that can only have value 0 or 1 and the score of the other award criteria must be multiplied by this value (so that the total score becomes 0 if a tender scores 0 on an on-off award criterion).

Tenders must comply with the following on/off award criteria:

On/off award criteria	Evidence	
A) Compliance with the definition of R&D services	Declaration of Honour including the evidence	
	required below	
B) Compatibility with other public financing	Declaration of Honour	
C) Compliance with the requirements regarding the place of	Declaration of Honour including the evidence	
performance of the contract	required below	
D) Compliance with ethics requirements	Declaration of Honour	
E) Compliance with security requirements	Declaration of Honour	
F) Compliance with GDPR	Declaration of Honour	
G) Compliance with usability and interoperability	Declaration of Honour	
requirements		
H) Compliance with data management requirements	Declaration of Honour	

• Tenders that do not comply with these criteria will be excluded. The offers for each phase will be evaluated against these criteria.

A) Compliance with the definition of R&D services

Tenders that go beyond the provision of R&D services will be excluded.

R&D covers fundamental research, industrial research and experimental development, as per the definition given in the <u>EU R&D&I state aid framework²</u>. It may include exploration and design of solutions and prototyping up to the original development of a limited volume of first products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and to demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards.³ R&D does not include quantity production or supply to establish commercial viability or to recover R&D costs. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements. The purchase of commercial volumes of products or services is not permitted.

The definition of services means that the value of the total amount of products covered by the contract must be less than 50 % of the total value of the PCP framework agreement.

A Declaration of Honour and the following evidence is required:

• the financial part of the offer for the Framework Agreement must provide binding unit prices for all foreseeable items for the duration of the whole Framework Agreement.

• the financial part of the offer for each phase must give a breakdown of the price for that phase in terms of units and unit prices for every type of item in the contract, distinguishing clearly the units and unit prices for items that concern products.

• the offers for all 3 phases may include only items needed to address the challenge in question and to deliver the R&D services described in the request for Tenders.

• the offers for all 3 phases must offer services matching the R&D definition above.

• the total value of products offered in Phase 1, respectively Phase 2, must be less than 50 % of the value of the Phase 1, respectively Phase 2, contract and the total value of products offered in Phase 3 must be so that the total value of products offered in all phases (1,2 and 3) is less than 50% of the total value of the PCP Framework Agreement.

B) Compatibility with other public financing

Tenders that receive public funding from other sources will be excluded if this leads to double public financing or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules.

A Declaration of Honour confirming that there is no incompatible public financing is requested as to demonstrate compliance with this criterion.

C) Compliance with requirements relating to the place of performance of the Contract

Tenders will be excluded if they do not meet the following requirements relating to the place of performance of the contract:

² See Point 15 of the <u>Commission Communication on a framework for state aid for research and</u> <u>development and innovation</u> (C(2014) 3282).

³ See Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

- At least 50% of the total value of activities covered by each Specific Contract for PCP Phase 1 and 2 must be performed in the EU Member States or in H2020 associated countries. The principal R&D staff working on each specific contract must be located in the EU Member States or H2020 associated countries.
- At least 50% of the total value of activities covered by the Framework Agreement (i.e., the total value of the activities covered by Phase 1 + the total value of the activities covered by Phase 2 + the total value of the activities covered by Phase 3) must be performed in the EU Member States or H2020 associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or H2020 associated countries.

The percentage is calculated as the part of the total monetary value of the Contract that is allocated to activities performed in the EU Member States or in other countries associated to Horizon 2020. All activities covered by the Contract are included in the calculation (i.e., all R&D and operational activities that are needed to perform the R&D services, e.g., research, development, testing and certifying solutions). This includes all activities performed under the contract by Contractors and, if applicable, their Subcontractors.

The principal R&D staff are the main researchers, developers and testers responsible for leading the R&D activities covered by the Contract.

The countries associated to Horizon 2020 are those listed as associated countries in the Participant Portal <u>Online Manual⁴</u>.

A Declaration of Honour and the following evidence is required:

- the financial part of the offer must provide binding unit prices for all foreseeable items for the duration of the whole Framework Agreement and give a breakdown of the price for the current phase in terms of units and unit prices (hours and unit price per hour), for every type of item in the Contract (e.g. junior and senior researchers).
- a list of staff working on the Specific Contract (including for Subcontractors), indicating clearly their role in performing the Contract (i.e. whether they are principal R&D staff or not) and the location (country) where they will carry out their tasks under the Contract.
- a confirmation or Declaration of Honour that, where certain activities forming part of the contract are subcontracted, Subcontractors will be required to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that has to be performed in the EU Member States or in countries participating in Horizon 2020 is respected.

D) Compliance with ethics requirements

Tenders will be excluded if they:

- do not comply with the following rules:
 - ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity⁵, and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct),
 - $\circ \quad$ applicable international, EU and national law.

⁴ List of H2020 associated countries.

⁵ The European Code of Conduct for Research Integrity of ALLEA (All European Academies).

- include plans to carry out activities in a country outside the EU if they are prohibited in all Member States or plans to destroy human embryos.
- include activities whose aim is to:
 - carry out human cloning for reproductive purposes,
 - modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads),
 - create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
- include activities that do not focus exclusively on civil applications.

If the Tender involves activities that raise ethical issues, the Tenderer must submit an ethics selfassessment that:

- describes how the Tender meets the legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out.
- explains in detail how the Tenderer intends to address the ethical issues identified, in particular as regards:
 - \circ objectives (e.g. dealing with vulnerable populations and dual-use goods⁶),
 - methodology (e.g. *involvement of children and related consent procedure and protection of data collected*),
 - the potential impact (e.g. issues relating to the dual use of goods, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing and malevolent use of results).

☑ For information on ethics issues, see the guidance for EU grant beneficiaries <u>How to complete your</u> <u>ethics self-assessment.</u>

A Declaration of Honour is requested as evidence.

1 Attention:

Call-offs for Phases 2 and 3 may request that this information shall be updated in the offers submitted for these phases.

Before starting the particular task that raises ethical issues, contractors must provide a copy of:

- any ethics committee opinion required under national law; and
- any notification or authorisation for activities raising ethical issues required under national law.

The Framework Agreement contains a provision on ethics.

E) Compliance with Security Requirements

Tenders will be excluded if they do not:

- comply with
 - EU, national and international law on dual-use goods or dangerous materials and substances, and

⁶ See Article 2(1) EU Export Control Regulation No 428/2009.

 the security aspect letter (SAL) annexed to the H2020 grant agreement and the Decision No 2015/444⁷.

Tenders themselves must not contain any classified information.

If the output of activities or results proposed in the Tender raise security issues or uses EU-classified information, the Tenderer must show that these issues are being handled correctly. In such a case, Tenderers are required to ensure and provide evidence of the adequate clearance of all relevant facilities. They must examine any issues (such as those relating to access to classified information or export or transfer control) with the national authorities before submitting their offer. Tenders must include a draft security classification guide (SCG), indicating the expected levels of security classification.

A Declaration of Honour is requested as evidence.

F) Compliance with GDPR

During the process, the Contractor, the members of the Consortium (if applicable) and the Subcontractors (if applicable) will have to comply with Article 28(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council and Article 29(7) of Regulation (EU) 2018/1725 of the European Parliament and of the Council (on standard contractual clauses between controllers and processors).

G) Compliance with usability and interoperability requirements

The solutions must be usable in the countries of the iProcureSecurity PCP Buyers Group and preferably all over the EU. In regard to this, the solutions can be easily modified to communicate with local customer information systems. The requirements regarding ICT standards that have to be observed in the development of the solution are as follows:

1. Technical frameworks of integration and systems architecture: a. IHE should be used as an implementation guide in the profiles that are applicable to the standard (www.ihe.net) or any other recognised technological framework that may be applicable. In this regard, the requirements of EU 2015/1302 of 28 of July 2015, and updates thereof, as well as new standard references which may appear during the project, should be taken into account. b. Continua alliance standards should be applied for personal health devices integration.

2. Messaging and data exchange standards: a. HL7: Electronic message format for administrative, financial and clinical data.

3. Semantic and terminology standards: a. SNOMED-CT for clinical terms. b. LOINC for laboratory results. c. ICD for medical diagnosis (ICD-9-MC, ICD10)

4. Clinical Document Standards: a. CCR (Continuous Care Record) provides a standard format for communication among health professionals which includes patient identification information, medical history, medication, allergies, and recommendations for the healthcare plan. b. CDA (Clinical Document Architecture): exchange standard for clinical documents, such as discharge reports, evolutionary reports, etc. c. CCD (Continuity of Care Document): project between HL7 and ASTM which represents the CCR data in an XML CDA.

⁷ Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information

5. Standards for user authentication: a. OpenID for patient-oriented applications. b. LDAP systems for the authentication of health professionals. In case of developing functionalities that require secure authentication and a digital signature, digital certificates recognised in accordance with the applicable European regulations will be used: currently, REGULATION (EU) No 910/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on electronic identification and trustworthy services for electronic transactions in the internal market. The general list of health-related standards to be taken into account in the event of their being applicable in the project can be found on the EIP AHA Standards web site: (https://ec.europa.eu/eip/ageing/standards/kind-of-resource).

E) Compliance with data management requirements

One of the main concerns of the iProcureSecurity PCP consortium is the management of data (mainly related to patients) of the solutions, both during the field testing phase and as a final solution. Data Management is related not only to technology, but to ethical, legal and organisational aspects. This is the reason why iProcureSecurity PCP bidders are requested to include a specific Data Management Plan during the Phase 2 to be presented to each regional Ethical Committee so as to get the approval before the beginning of the field testing at each site. These are examples of some of the principles that contractors in the iProcureSecurity PCP Framework should consider in their Data Management Plan:

1. Generic Principles: The data collected, generated and managed must be adequate, relevant and not excessive in terms of the scope and within the specific and legitimate final purpose for which they are to be handled. Rights to access, rectify and cancel data must be guaranteed to participants. The solutions might collect, generate and manage personal data and personal data related to health, so they must be compliant and demonstrate compliance with the EU normative (specifically Data Protection Regulation (EU) 2016/679 and Directive (EU) 2016/680), and also with the corresponding national and regional legal frameworks. A first approach to Data Management (e.g., the architecture of the solution, the sources and the storage of data) must also be included in the end of phase report for phase 1.

A Data Management Plan for the field-testing phase must be included in the request of approval that each bidder must present to the local ethics committees during the phase 2.

2. Data Management Plan. The Data Management Plan will include a detailed description about the collection, storage, management, generation and preservation of data during and after the field testing phase of iProcureSecurity PCP. It will also include the specification of the data and the justification for its use. This description should also incorporate the data management related differences (if any) between the testing phase and the potential commercial solutions that might result in the future. For the elaboration of the Data Management Plan the Guidelines of Horizon 2020 should be further considered. The Data Management Plan will be evaluated by the regional ethical committees who will ensure its compliance not only with the legal framework but also with the ethical principles within each region. The consent form included presented to the ethical committees must also include a detailed information of any relevant issue related to data management.

3. Data for evaluation. The DMP should guarantee that the data used for the assessment of the proposals is accessible by the bidders and available on time and in form to allow the evaluation. The format of this data will be specified at the call-off for Phase 2, but one standard format as .csv might be applicable.

1 Attention:

If necessary for the Tender procedure or for performing the Contract itself, Contractors will be requested to ensure appropriate security clearance for Third Parties (e.g., for personnel).

Call-offs for Phases 2 and 3 may request that this security information shall be updated in the offers submitted for that phase.

Before starting the particular task that raises security issues, Contractors must provide a copy of any export or transfer licences required under EU, national or international law.

The Framework Agreement and/or the specific contracts contain a provision on security.

☑ For information on security, see the guidance for EU grant beneficiaries: *Guidelines for the handling of classified information in EU research projects.*

Attention: Should there be any doubt as to any of these criteria, Tenderers may be requested to provide additional information.

> Weighted Award Criteria

Weighted award criteria	Maximum points	Weighting	Thresholds (40%)
Phase 1: Solution design			
1.Contract Implementation	10	10%	4
1.1 Methodology of the Project, including risk management and quality assurance	4		
1.2 Quality and completeness of the work-plan as well as detail of task and result descriptions	3		
1.3 Feasibility of the Project plan and resources to meet the objectives specified	3		
2.Functional Quality Criteria	40	40%	16
2.1 - Quick and accurate overview of casualties and their status	18		
C2.1.1 Overview on Casualties and Casualty Identification 2			
C2.1.2 Triage Tags - Basics 2			
C2.1.3 Triage Tags - Treatment 4			
C2.1.4 Triage Tags – Essential & Extended Information 4			
C2.1.5 Casualty Profile 5			
C2.1.6 Triage Algorithm 1	-		
2.2 Decision support for better allocation of available resources and quicker support for casualties;	14		
C2.2.1 Onsite Management 6			
C2.2.2 Decision Support 5			
C2.2.3 Staff Management and Guidance 2			
C2.2.4 Logistics 1			
2.3 Improved coordination and communication among the different EMS actors	2		
2.4 Reduced handover times between ambulance transport and hospitals (Data Sharing with EMS)	2		
2.5 - Insights for quality assurance and training measures	4		
3.Non-Functional Quality Criteria	15	15%	6
3.1 – Interoperability (and adaptation to local context)	6		
3.2 - Connectivity and Security	2		
3.3 – Usability (and configurability)	5		
3.4 – Scalability	2		

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3.5 – Performance	1		
4. Commercial Feasibility	5	5%	2
Exploitation Plan - Short to Mid-Term exploitation plan, including a commercialisation strategy. Completeness, sense of reality and feasibility of the commercialisation plan including the market analysis and risk management	3		
Commercial Viability. Sense of reality and feasibility of the principles for licensing, pricing, packaging, distribution	2		
5. Evaluation of the solution and sustainability of testing	10	10%	4
Level of innovativeness and ability to go beyond the state-of-the-art	4		
Impact of the proposed solution (Value of benefits due to the solution innovation for patients and procurers)	4		
Describe your vision and plan on executing prototype and pilot testing.	2		
6.Price	20	20%	
Binding contract Price for carrying out the work in the present Phase	20		

Weighted award criteria	Maximum points	Weighting
Phase 2: Prototype Development		
1.Contract Implementation	10	10%
1.1 Methodology of the Project, including risk management and quality assurance	4	
1.2 Quality and completeness of the work-plan as well as detail of task and result descriptions	3	
1.3 Feasibility of the Project plan and resources to meet the objectives specified	3	
2.Functional Quality Criteria	36	36%

-		-	-
2.1 - Quick a	and accurate overview of casualties and their status	16	
C2.1.1	Overview on Casualties and Casualty Identification 1		
C2.1.2	Triage Tags - Basics 2		
C2.1.3	Triage Tags - Treatment 4		
C2.1.4	Triage Tags – Essential & Extended Information 4		
C2.1.5	Casualty Profile 3		
C2.1.6	Triage Algorithm 2		
2.2 Decision casualties;	support for better allocation of available resources and quicker support for	12	
C2.2.1	Onsite Management 5		
C2.2.2	Decision Support 4		
C2.2.3	Staff Management and Guidance 2		
C2.2.4	Logistics 1		
2.3 Improve	ed coordination and communication among the different EMS actors	2	
2.4 Reduced EMS)	d handover times between ambulance transport and hospitals (Data Sharing with	2	
2.5 - Insight	s for quality assurance and training measures	4	
3.Non-Func	tional Quality Criteria	12	12%
3.1 – Intero	perability (and adaptation to local context)	4	
3.2 - Connee	ctivity and Security	2	
3.3 – Usabil	ity (and configurability)	4	
3.4 – Scalab	ility and Performance	2	
4. Commerc	cial Feasibility		8 %
Exploitation strategy. Co including th	Plan - Short to Mid-Term exploitation plan, including a commercialisation ompleteness, sense of reality and feasibility of the commercialisation plan e market analysis and risk management	5	
Commercial packaging, c	l Viability. Sense of reality and feasibility of the principles for licensing, pricing, distribution	3	
5. Evaluatio	on of the solution and sustainability of testing		14%
Level of inno	ovativeness and ability to go beyond the state-of-the-art	6	
Impact of th and procure	ne proposed solution (Value of benefits due to the solution innovation for patients ers)	4	

Describe your vision and plan on executing prototype and pilot testing.	4	
6.Price		20%
Binding contract Price for carrying out the work in the present Phase	20	

Weighted award criteria		Weighting
Phase 3: Development and Testing of Piloting Systems		
1.Contract Implementation	10	10%
1.1 Methodology of the Project, including risk management and quality assurance	3	
1.2 Quality and completeness of the work-plan as well as detail of task and result descriptions	3	
1.3 Feasibility of the Project plan and resources to meet the objectives specified	4	
2.Functional Quality Criteria	30	30%
2.1 - Quick and accurate overview of casualties and their status	12	
C2.1.1 Overview on Casualties and Casualty Identification 0.5		
C2.1.2 Triage Tags - Basics 1.5		
C2.1.3 Triage Tags - Treatment 3		
C2.1.4 Triage Tags – Essential & Extended Information 3		
C2.1.5 Casualty Profile 3		
C2.1.6 Triage Algorithm 1		
2.2 Decision support for better allocation of available resources and quicker support for casualties	10	
C2.2.1 Onsite Management 4		
C2.2.2 Decision Support 3		
C2.2.3 Staff Management and Guidance 2		
C2.2.4 Logistics 1		
2.3 Improved coordination and communication among the different EMS actors	2	
2.4 Reduced handover times between ambulance transport and hospitals (Data Sharing with EMS)		
2.5 - Insights for quality assurance and training measures	4	
3.Non-Functional Quality Criteria	10	10 %
3.1 – Interoperability (and adaptation to local context), Connectivity and Security	6	
3.2 - Usability , Scalability and Performance	4	

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4. Commercial Feasibility	12	12 %
Exploitation Plan - Short to Mid-Term exploitation plan, including a commercialisation strategy. Completeness, sense of reality and feasibility of the commercialisation plan including the market analysis and risk management	8	
Commercial Viability. Sense of reality and feasibility of the principles for licensing, pricing, packaging, distribution	4	
5. Evaluation of the solution and sustainability of testing	18	18%
Level of innovativeness and ability to go beyond the state-of-the-art	6	
Impact of the proposed solution (Value of benefits due to the solution innovation for patients and procurers)	6	
Describe your vision and plan on executing prototype and pilot testing.	6	
6.Price	20	20%
Binding contract Price for carrying out the work in the present Phase	20	

1 Attention:

Additional sub-criteria may be added for the call-offs for Phases 2 and 3, as a way of making the award criteria more precise, provided that they do not substantially change the existing criteria.

Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

The table below contains the Scoring Model that will be used by the TC and EC to assess and score the extent to which a Tender/Offer is meeting the Award Criteria.

Score	Textual Description
0	The description fails to address the Objective or cannot be assessed due to missing or incomplete information.
0,2	Poor – Objective is inadequately addressed or there are serious inherent weaknesses.
0,4	Fair – The description broadly addresses the Objective, but there are significant weaknesses.
0,6	Good – The description addresses the Objective well, but a number of shortcomings are present.
0,8	Very good – The description addresses the Objective very well, but a small number of shortcomings are present.
1	Excellent – The description successfully addresses all relevant aspects of the Objective. Any shortcomings are minor.

• **Explanation:** Every score per quality criterion (all, will be multiplied with the weight for the criterion). For example, if a tender scores 0,8 points (Very good) for sub criterion X, this means

this tender receives 0,8 points *5 = 4 points in total for this criterion out of a maximum of 5 points. Per criterion, this same methodology will be used. If a tender would score the maximum number of points for every criterion, a total maximum technical score of 80 points can be given.

3.5 Scoring

Awarded points for each criterion will be multiplied by weighting percentage for particular criteria leading to a final score per criteria. Final score for Tenderer is a sum of all final criteria scores.

The maximum scoring obtained after the proposal evaluation shall be 100 points, where:

- 20 percentage of the points correspond to the Financial Offer, and
- 80 percentage of the points correspond to the Technical Offer
- Following the Scoring Model:

Li = 80 * (Ti /Tmax) + 20 * (Fmin/Fi)

- Where Tmax Technical Score of the Best Technical Tender
- Ti Technical Score of the Tender i
- Fmin Lower Price of all Tenders
- Fi Price of the Tender i
- Li Total Score of the Offer i rounded to two decimals places.

3.6 Evaluation Overview

For the purpose of the evaluation of the received Tenders, the Lead Procurer shall appoint the following Committees:

- 1. The Evaluation Committee is the ultimate decision-making Board for the procurement. It analyses, makes proposals and sets guidelines for the whole PCP tendering process. It monitors the elaboration and approves the tender documentation. The Evaluation Committee, by taking into account the decision of the Technical Committee, will evaluate the Tenders received, accept milestones and decide on the release of the relative payments and decides on any complaints received throughout the overall procurement procedure. It is composed by one member of each Buyer Group representative, chaired by the Lead Procurer. The work of this Board is assisted by the project Coordinator and empirica.
- 2. The Technical Committee assists in their activities the Procurement Committee. It formulates the tender specifications, the evaluation and award criteria. Additionally, the Committee evaluates the complaints submitted by the economic operators during the tendering process. The TC is responsible for monitoring the contractors progress throughout the PCP implementation, reviewing the documentation submitted and verifying the compliance of the products with the technical requirements. The TC consists of one representative of the Buyers Group, assisted by the Project Coordinator, empirica and AAHD.
- 3. The Administrative Board which is composed by three members of KEMEA procurement department dealing with administrative aspects of the procurement (e.g., receiving and opening the Tenders, evaluations against exclusion grounds etc.). The scope of this Board © 2022 iProcureSecurity PCP | H2020-SU-SEC-2020 | 101022061

is to facilitate and fasten the procurement procedure. It passes this opinion to the Evaluation Committee for final decision.

Tenders will be evaluated in a non-discriminatory and transparent manner.

3.7 Evaluation of the submitted Tenders and initial Contract Award

The evaluation process and initial contract award will be carrying out the following eight steps:

- Step 1 Checking exclusion criteria per Tenderer. Performed by KEMEA Administrative Board. All the related documents shall be submitted in ENVELOPE A.
- Step 2 For Tenderers passing Step 1, checking selection criteria per Tenderer. Performed by KEMEA Administrative Board. All the related documents shall be submitted in ENVELOPE A.
- Step 3 For Tenderers passing Step 2, checking on/off award criteria per Tender. Performed by KEMEA Administrative Board. All the related documents shall be submitted in ENVELOPE A.
- Step 4 For Tenderers passing Step 3, evaluating the tender based on the weighted award criteria.
- Step 5 Opening of the Economical Offers.

Formal Approval by EC of the outcome of the two prior steps.

- Step 6 Final ranking.
- Step 7 Provisional award decision.
- Step 8 Signing of Framework Agreements and Phase 1 Contracts.

The iProcureSecurity PCP Buyers Group will proceed with the Tenderers' eligibility based on the information provided in the Administrative Section of the proposal (exclusion, selection and on/off award criteria, all related documents submitted in ENVELOPE A). This will be followed by the technical evaluation (all related documents submitted in ENVELOPE B) and the financial evaluations (all related documents submitted in ENVELOPE B) and the financial evaluations (all related documents submitted in ENVELOPE C).

Then the Technical Committee and the Evaluation Committee will proceed to the scoring, according to the criteria and procedures described above. At the end of the evaluation procedure, a ranking will be drawn up, in which the tenders will be inserted based on the overall score achieved, in descending order.

In case that Tenders of two or more tenderers obtain the same overall score, but with different partial scores for the price and for all the other different evaluation elements, the Tenderer who obtained the best score on the Technical Offer will be placed first in the ranking.

Å Attention:

- Tenders not complying with the Tender conditions on the content and format (Technical Offer (TD2) and Financial Offer and Cost Breakdown (TD3) will be excluded from the tender evaluation.
- Completeness and formal correctness of the tender procedure will be checked; in case of lack of documents, incompleteness and any other non-essential irregularities of the Tender, the Lead Procurer may request the necessary additions and clarifications. The Lead Procurer may conduct the necessary regularisation by requesting the information from the Tenderer. If the Contractor does not submit the necessary information within five 5 (five) days from the written request of the Lead Procurer, it will lead to automatic exclusion
- All the documents must be signed by a duly authorised person with the powers to bind the legal/natural person.

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- Modifications to the Technical Offer (TD 2), the Financial Offer and Cost Breakdown (TD3), the Declaration of Honour (TD4), the Consortia Statement (TD5), the Subcontracting Statement (TD6), the Legal Capacity of the Tenderer Statement (TD7), the Declaration of pre-existing rights (TD8), are not allowed. Any of such modifications will lead to automatic exclusion of the Tenderer.
- All cost and risk of preparing and submitting a Tender of the iProcureSecurity PCP are born by the Tenderers.

3.8 Procedures for appeal

The submission of a tender implies unconditional acceptance of all terms and conditions contained in this Request for Tender. Under penalty of exclusion, Tenders must not contain any reservation in relation to any point in the Tender terms and conditions.

All possible complaints during the tendering process will be solely submitted to the Lead Procurer within FIVE (5) days following the notification of the final decision – as described in step 7 of section 3.7 - of the Evaluation Committee. Complains will not be addressed to the other members of the Buyers Group or the iProcureSecurity PCP Consortium or the EC.

Submission of complaints shall not lead to unreasonable delays in the evaluation and award procedures.

The Lead Procurer, the members of the Buyers Group, the iProcureSecurity PCP Consortium and/or the EC will not be liable for any loss or damage that the Tenderer may suffer in preparing and submitting a bid for this PCP.

The Lead Procurer will forward the complaints to the Technical Committee which is responsible to evaluate the complaints and to submit its opinion to the Evaluation Committee for final decision.

Possible complaints against any final decision of the Evaluation Committee may be reviewed by the Greek Administrative Court of Appeal of Athens⁸. The Tenderers are mandated to notify the Lead Procurer in writing that they are submitting an appeal to challenge a decision of the Evaluation Committee.

Any dispute or claim arising in connection with the execution of the contracts shall be heard by Greek Administrative Court of Appeal of Athens.

SECTION 4: CONTENT & FORMAT OF THE TENDERS

4.1 Tender submission - Content & Format

All Tenderers must use the iProcureSecurity PCP Tender Documents, which can be accessed along with all of the other Tender Documents and related annexes by following the instructions in the Contract Notice on TED.

The Tender Documents are also available to be downloaded on the iProcureSecurity PCP website: pcp.iprocuresecurity.eu and on the Innovation Procurement Platform https://innovationprocurement.com/

⁸ <u>https://europa.eu/youreurope/business/selling-in-eu/public-contracts/request-review-public-procurement-procedure/index_en.htm</u>

The Tenders should be submitted within the deadline established in section 2.7 via the Innovation Procurement Platform, no later than the 12:00 (Athens time) on 31-8-2022.

The Cover Letter (TD 1a) should be also send by post and should be received by no later than the 12:00 (Athens time) on 31-8-2022. The Cover Letter should indicate that it relates to the dossier (R&D Services within the iProcureSecurity PCP Project) and be addressed to the Lead Procurer: Center for Security Studies (KEMEA), Hellenic Ministry of Interior, 4, P. Kanellopoulou str. 10177, Athens, Greece. Att to Ms Panagiota Benekou

The Cover Letter should be submitted no later than the 12:00 (Athens time) on 31-8-2022 and should be delivered by one of the following ways:

-By hand at the official registry office of KEMEA at the above mentioned address

-By registered post services with shipment notice. In such case, bidders should inform the Contracting Authority of the dispatch of the tender by fax or email on the same day, attaching a proof of the date of shipment, which must be before the deadline for the submission of tenders.

The Cover Letter should be signed by the Tenderer or its duly accredited representative, stating the full name (or entity name) of both and identifying the tender, a telephone number and an email address for contact.

All Tenders must be submitted in three separate and independent envelopes (A, B and C), in a way that allows the secrecy of the content of each one to be guaranteed until their formal opening.

Envelopes are digital and will only submitted via the Innovation Procurement Platform https://innovationprocurement.com/

1 Attention:

- In Annex 1, a detailed explanation of the documents, actions to be taken and related envelopes can be found.
- More detailed information about the final layout requirements for the Phases 2 and 3 offers will be provided in the subsequent Call-offs.
- The period of validity of the Tenders is six (6) months from the deadline indicated above (shorter validity period is not admissible and shall conduct to the rejection of the offer).
- Tenders and supporting documents must be written in English or a full English translation shall be provided at no cost to the Lead Procurer.
- Tenders must not be qualified or accompanied by statements or a covering letter that might be construed as rendering the tender equivocal. Unauthorised alterations or additions must not be made to any component of the tender documents.

4.2 Opening of tenders

Opening of the envelopes will take place on 31-8-2022, 12:00 CEST at the following location:

Center for Security Studies (KEMEA), Hellenic Ministry of Interior, 4, P. Kanellopoulou str. 10177, Athens, Greece.

Opening of the envelopes will be carried out by the iProcureSecurity PCP - KEMEA Administrative Board. An authorised representative of each Tenderer may attend the opening. The information provided during the opening will be solely the names of the companies who have submitted a Tender.

Companies wishing to attend are requested to notify their intention by sending an e-mail to <u>ipspcp-procurement@kemea-research.gr</u> at least 48 hours in advance. This notification must be signed by an authorised officer of the Tenderer and specify the name of the person who will attend the opening of the Tenders on the Tenderer's behalf.

Person of the Contracting Authority to provide all relevant information/clarification is: Panagiota Benekou, Phone: +030 2107710805 int. 364, Fax: +030 2111004499, Email: <u>ipspcp-procurement@kemea-research.gr</u>

4.3 Administrative section (ENVELOPE A)

Envelope A shall contain information and evidence on the legal capacity, non-disqualification from exclusion criteria, economic and financial standing of the bidder, technical and professional eligibility and fulfilment of the compliance criteria, to be provided by means of the documents and forms described below:

- The legal capacity and the representation of the Tenderer, all the members of the Consortium (if applicable), Subcontractors (if applicable) and Third Parties (if applicable) shall be proved by filling, signing – by duly authorised person – and submitting the Legal Capacity of the Tenderer Statement (TD7).
- In the case of a Joint Tender, all the members of a Consortium will have to fill in, sign by duly authorised person and submit the Consortia Statement (TD5).
- In the case of Subcontracting, the Subcontracting Statement (TD6) will have to be filled in, signed- by duly authorised person and submitted.
- To prove compliance with the exclusion, selection and on/off award criteria the Tenderer, all the members of the Consortium (if applicable), Subcontractors (if applicable) and Third Parties (if applicable) shall fill in, sign - by duly authorised person – and submit the Declaration of Honour (TD4).

4.4 Technical section (ENVELOPE B)

Tenders must include a **technical offer**, containing:

- a technical plan that outlines: I. the Tenderer's idea for addressing all the requirements given in the PCP challenge description; II. technical details of how this would be implemented and III. a project management plan that outlines the execution and monitoring approach, including a Gantt chart. This part should clearly address all the weighted award criteria, namely 1. Contract implementation, 2. Functional Quality Criteria, 3. Non-Functional Quality Criteria, 4. Commercial Feasibility and 5. Evaluation of the solution and sustainability of testing.
- a draft business plan that explains the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market.
- a risk assessment and risk mitigation strategy.

- a reply to the question "Does this tender involve **ethical issues**? (YES/NO)" and if YES, an ethics self-assessment, with explanations how the ethical issues will be addressed.
- A Declaration of pre-existing rights (*background IPRs*) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed, following the template provided in TD8.

Å Attention:

- Tenders failing to meet these requirements will be excluded.
- The technical part must provide a *detailed* technical offer for Phase 1 (*including an explanation of the methodology, a work plan and details of deliverables and milestones*), and must specify the plans for and objectives of the subsequent Phases 2 and 3 and beyond (*including a plan for commercial exploitation of the results*).
- The information provided in the technical section of the Tender will be used to evaluate the Tenders, on the basis of the technical award criteria and the on/off award criteria A, C and D.
- Maximum limit 50 pages. Minimum font size (11pt) and page margins (15mm).

4.5 Financial section (ENVELOPE C)

The Tender must include a detailed financial offer specifying:

- binding **unit prices** for all items needed for carrying out Phase 1 and binding unit prices for items that are expected to be needed for Phases 2 and 3 (given in euros, excluding VAT but including any other taxes and duties).
- a fixed **total price** for phase 1 and an estimated total price for Phases 2 and 3, broken down to show unit prices and the number of each unit needed to carry out Phase 1 (given in euros, excluding VAT but including any other taxes and duties).

In addition, the financial section must include:

- a **price breakdown** that shows the price for R&D services and the price for supplies of products (to demonstrate compliance with the definition of R&D in on/off award criterion A).
- a **price breakdown** that shows the location or country in which the different categories of activities are to be carried out (*e.g., x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour)* (to demonstrate compliance with the requirement relating to place of performance in on/off award criterion C).
- the **financial compensation** valuing the benefits and risks of the allocation of ownership of the **IPRs** to the contractor (*i.e.*, *IPRs generated by the contractor during the PCP*), by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e., the price that would have been quoted were IPR ownership to be transferred to the procurers).

1 Attention:

• The unit prices quoted for each category of items (e.g., hourly rates for junior and senior researchers, developers and testers) remain binding for all phases (i.e. for the duration of the Framework Agreement).

• The financial compensation for IPRs must reflect the market value of the benefits received (i.e., the opportunity that the IPRs offer for commercial exploitation) and the risks assumed by the contractor (e.g. the cost of maintaining IPRs and bringing the products onto the market).

The price that will be evaluated is the Actual Price offered.

The information provided in the financial section of the Tender will be used to evaluate the Tenders on the basis of the price award criteria and the compliance criteria A and C.

More detailed information for the Phase 2 and 3 offers will be provided in the Call-offs.

The price for Phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the Framework Agreement. Where new units/unit prices (e.g., for new tasks or equipment) are subsequently added to the Phase 2 or 3 offers, they will become binding for the remaining phases.

Similar price breakdowns will be requested for the call-offs for Phase 2 and 3.

SECTION 5: CONDITIONS OF THE CONTRACTS

5.1 Contract implementation

Successful Tenderers will be requested to sign both a Framework Agreement (TD9) and Specific Phases 1, 2 and 3 Contracts (TD10).

Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes for the phase. Each Contractor will be assigned a main contact person (their supervisor) appointed by the Lead Procurer.

There will be regular monitoring meetings between the Contractor and the TC. The intensity of monitoring and communication between the Buyers Group and the Contractors will increase from Phase 1 to Phase 3. Monitoring meetings can be held physically or online and will be subject to agreement between the parties. The Contractor will be asked to discuss the results achieved in the preceding period and present an updated work plan. The supervisor, or any party designated by it, is entitled to visit the premises of the Contractor.

The Technical Committee and/or supervisor will provide written feedback on paper or electronically to contractors after meetings or visits. Detailed information on the role of the supervisor will be provided after the award of a Specific Phase Contract. The role is intended to allow contractors to improve the way in which their solutions address the problem set out in the PCP challenge.

5.2 Payments based on Satisfactory Completion of Milestones and Deliverables of the Phase

Payments corresponding to each PCP phase will be subject to the satisfactory completion of the deliverables and milestones for that phase. Satisfactory completion will be assessed by the Technical Committee composed of members of the Buyers' Group.

Satisfactory completion will be assessed according to the following requirements:

- if the work corresponding to that milestone/deliverable has been carried out.
- if a reasonable minimum quality has been delivered.
- if the reports have been submitted on time.
- if the money has been allocated to the planned objectives.
- if the money has been allocated and the work has been carried out according to the on/off award criteria (place of performance, public funding and R&D definition criteria)
- if the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective phase).

'Reasonable minimum quality' of a report means that:

- the report can be read by somebody who is familiar with the topic, but not an expert.
- the report gives insight in the tasks performed in and the results.
- the report is made using the end of phase report form or if applicable the milestone report form and the requirements of this form have been met.

'Reasonable minimum quality' of a demonstration (for phase 2 or 3) means:

- the demonstration can be understood by somebody who is familiar with the topic, but not an expert (for instance, somebody with operational but not technical knowledge).
- the demonstration shows how the innovation works, how it can be used and if applicable how it is operated and maintained.
- the demonstration is accessible to parties appointed by the procurers, unless these are direct competitors of the contractor.

Satisfactory completion in each of the phases does not mean successful completion.

Invoices must be submitted to the Lead Procurer, once contractors are notified for the satisfactory completion. Contractors' invoices must provide:

- a price breakdown showing the price for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D in on/off award criterion A).
- a price breakdown showing the location or country in which the different categories of activities were performed (e.g. x hours of senior researchers in country L at y euro/hour, a hours of junior developers in country M at b euro/hour) (in order to demonstrate compliance with the requirement relating to the place of performance in on/off award criterion C).

5.3 Payments Schedule

For the payments schedule described below the Contractor is requested to provide the Contracting Authority along with the respective invoice, the following documentation, accompanied by their official translation in English:

- Tax Clearance certificate (payment of tax evidence) or equivalent.
- Social Security Contributions Payment Certificate or equivalent.

- Criminal Record of the legal representative(s) or equivalent.
- Company Legal Documents (i.e., statute/modifications/legal documents for the Representation of the company, all approved and registered by the Competent Authority, if applicable).
- Official Document with the bank account details.

Official documents must be issued within 30 working days prior to their submission and be valid when submitted (if a validity period is indicated). If a document has no expiration date, it must be issued within 30 working days prior to their submission and be accompanied by a declaration certifying that the respective document has no expiration date.

The Lead Procurer can only pay if all these above-mentioned documents have been attached to the invoice.

Once the deliverable has been evaluated as satisfactory, the Contractor will be asked to submit an invoice. Once the invoice and the additional documents have been accepted, the payment is due within 30 (thirty) days.

PHASE I: payment of the Price for Phase I shall be made in one part. The payment of 100% shall be paid within 30 calendar Days from the date of the decision of the Evaluation Committee confirming that the Contractor has complied with the Performance Conditions as described in section 5.2 of the applicable to such phase and is thus considered to have completed the phase satisfactorily.

PHASE II: payment of the Price for Phase II shall be made in two parts. The Contractor shall be paid a first payment of 50% of the Price for Phase II within 30 calendar Days from the date of the decision of the Evaluation Committee to accept the successful completion of the interim deliverables of the Contractor to Phase II The second payment of 50% shall be paid within 30 calendar Days of the decision of the Evaluation Committee confirming that the Contractor has complied with the Performance Conditions as described in section 5.2 applicable to such phase and is thus considered to have completed the phase satisfactorily.

PHASE III: payment of the Price for Phase III shall be made in three parts. The Contractors shall be paid a first payment of 45% of the Price for Phase III within 30 calendar Days from the date of the decision of the Evaluation Committee to accept the successful completion of the interim deliverables of the Contractor to Phase III (three). The second payment of 40% shall be paid within 30 calendar Days from the date of the decision of the Evaluation Committee confirming that the Contractor has complied with the Performance Conditions as described in section 5.2 applicable to such Phase and is thus considered to have completed the Phase satisfactorily. The third payment of 15% shall be paid within 30 calendar Days form the date of the decision of the Evaluation Committee confirming that iProcureSecurity PCP project has successfully concluded.

5.4 Eligibility for the next phase based on Successful Completion of the phase

Eligibility for participation in the next phase (Phase 2 and 3) will be subject to successful completion of the current phase.

Successful completion of a phase will be assessed by the TC and submits its opinion to the EC for final decision against the following requirements:

• if all milestones have been successfully completed.

- If the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency improvements which the procurers set forward for the innovative solutions to achieve).
- if the results of the R&D are considered to be promising.

'Promising' means:

- for Phase 1, that the feasibility is convincing.
- for Phase 2, that the feasibility, the application in an operational setting and the potential impact of the product are convincing.

Only contractors classified as "satisfactory" are eligible to have their work produced during a certain phase considered as "successful".

5.5 Finalisation of Phase 3: Possible follow-up PPI

Follow-up PPI for a limited set of prototypes and/or test products developed during this PCP procurement ('limited follow-up PPIs') may be awarded.

Follow-up PPI for a commercial volume of the innovative solutions developed in this PCP procurement will be subject to a new call for tenders.

SECTION 6: MISCELLANEOUS

6.1 Language

All communication (relating to either the tender procedure or the implementation of the Contract) must be carried out in English.

Tenders as well as offers for Phase 2 and 3 Call-offs (and all related necessary documents) must be submitted in English. Deliverables must also be submitted in English.

6.2 Tender constitutes binding offer

A signed Tender will be considered to constitute a firm, irrevocable, unchangeable and binding offer from the tenderer. The Tenderer's signatory must have the proven power and capacity to bind the tenderer/contractor.

The signature of an authorised representative will be considered as the signature of the Tender (and will be binding on the tenderer or, for joint tenders, the group of tenderers).

6.3 Communication

All questions or requests for clarification must be received by the Lead Procurer in English. Any questions received after this deadline will not be answered. The questions or requests for clarification must be addressed to: <u>ipspcp-procurement@kemea-research.gr</u>.

Please mention the iProcureSecurity PCP Procurement in the subject line of your emails. With each question the correct document reference and page number should be clearly stated.

The summary of all questions and answers will be presented in an anonymised Q&A document that will be published on the project's website (<u>pcp.iprocuresecurity.eu</u>) in English. For Phases 2 and 3, the

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Q&A will not be published, but distributed to all Contractors that successfully completed the previous Phase. Unless otherwise instructed, please do not use any other contact addresses or means or contact any other persons in connection with this procurement.

6.4 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure *(including EU-classified information⁹)*. All documentation, data, statistics, drawings, information, samples or material disclosed or furnished by the Lead Procurer to Tenderers during the course of this Competition:

- 1. are furnished for the sole purpose of replying to this PCP only;
- 2. may not be used, communicated, reproduced or published for any other purpose without the prior written permission of the Contracting Authority;
- 3. shall be treated as confidential by the Tenderer and by any third parties (including Subcontractors) engaged or consulted by the Tenderer; and
- 4. must be returned immediately to the Contracting Authority upon cancellation or completion of this PCP if so required by the Contracting Authority.

In respect of any Trade Secrets such as business plans, R&D maps or trajectories, customer lists etc. that it may receive from the Tenderer, the Lead Procurer undertakes to keep secret and strictly confidential and to ensure that all members of the Group of Procurers will be bound by the same confidentiality obligations towards the Contractor.

6.5 Freedom of Information

The principle of public access to official documents means that public documents and records (with a few exceptions) should be made available to whoever asks for them. The principle is balanced by the obligation of professional secrecy, that stipulates that public authorities are obliged to protect business secrets of others, if disclosure may seriously harm their interests.

Without prejudice to the confidentiality provisions included in the Framework Agreement (TD9), Tenderers are asked to consider if any of the information supplied by them in their Tender should not be disclosed because of its confidentiality or commercial sensitivity. If Tenderers consider that certain information is not to be disclosed because of its confidentiality or commercial sensitivity, Tenderers must, when providing such information, clearly identify the specific sections of their Tender containing such information and specify the reasons for its confidentiality or commercial sensitivity.

Tenderers should, however, be aware that the Lead Procurer reserves the right to publish public summaries of the results of the iProcureSecurity PCP Project (Phase 1, 2 and 3), including information of the key R&D results attained and lessons learned by the iProcureSecurity PCP Consortium. Details that will harm the legitimate business interest of the Contractors involved in the iProcureSecurity PCP or that would distort fair competition on the market will not be disclosed. The Lead Procurer will also

⁹ Commission Decision <u>2015/444/EC, Euratom</u> of 13 March 2015 on the security rules for protecting EUclassified information.

distribute and publish the following information about the Contractors that are awarded with contracts:

- The name of the organisation
- Their location
- The title of the project
- A short summary of the project
- Contract value as an exception to the confidentiality obligation of the NDA

6.6 Data processing in EU / EEA

The processing of data by the contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

In case the Contractor has to process personal data, the localisation of and access to the personal data processed by the Contractor shall comply with the following:

- The personal data shall only be processed within the territory of the European Union and will not leave that territory.
- The data shall only be held in data centres located with the territory of the European Union.
- No access shall be given to such data outside of the European Union.
- The Contractor may not change the location of data processing without the prior written authorisation of the contracting authority.
- Any transfer of personal data under the PCP to third countries or international organisations shall fully comply with the requirements laid down in Chapter V of Regulation (EU)2018/17252.

6.7 Cancellation of the tender procedure

The Lead Procurer (on behalf of the Buyer Group) may, at any moment, stop the tender procedure and cancel it. The Lead Procurer (on behalf of the Buyer Group) reserves the right not to award any Contracts at the end of the Tender procedure.

The members of the Buyer Group, the partners of the iProcureSecurity PCP Consortium and the EU are not liable for any expense or loss the tenderers may have incurred in preparing their offer.

iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Annex 1

Checklist of Tender Documents and Actions

Checklist of Tender Documents and Actions

See below a checklist of tender documents and actions to be taken by a Tenderer.

			Mandatory
ENVELOPE	TD	Action to be taken by tenderer	submission
			_
Cover Letter	TD 1a: Cover Letter	To be filled in, signed and sent to the LP by the Tenderer.	YES
		To be filled in and submitted by the Tenderer on the Innovation Procurement Platform.	
ENVELOPE B	TD 2: Technical Offer	To be filled in and submitted by the Tenderer submitted by the Tenderer on the Innovation Procurement Platform.	YES
ENVELOPE C	TD 3: Financial Offer and Cost Breakdown	To be filled in and submitted by the Tenderer submitted by the Tenderer on the Innovation Procurement Platform.	YES
ENVELOPE A	TD4:DeclarationofHonour	To be filled in and submitted by Tenderer, on the Innovation Procurement Platform.	YES
ENVELOPE A	TD 5: Consortia Statement	To be filled in and submitted d by the Tenderer on the Innovation Procurement Platform.	YES (ONLY IF THE TENDERER IS CONSISTING OF A CONSORTIUM)
ENVELOPE A	TD 6: Subcontracting Statement	To be filled in and submitted by the Tenderer on the Innovation Procurement Platform.	YES (ONLY IF THE TENDERER HAS SUBCONTRACTORS)
ENVELOPE A	TD 7: Legal Capacity of the Tenderer Statement	To be filled in and submitted by Tenderer on the Innovation Procurement Platform.	YES
ENVELOPE B	TD8:Declarationofpre-existingrights	To be filled in and submitted if pre-existing rights of the Tenderer, the members of a Consortium (if applicable), the subcontractors (if applicable) and third parties (if applicable) will be part of the solution to be developed for the Prevent PCP challenge, by the Tenderer on the Innovation Procurement Platform.	YES

Attention:

Tenderers that do not submit the mandatory documents will be excluded.

Should there be a missing document, the Lead Procurer has the right to ask for the missing information. If the Contractor does not submit the necessary information within five 5 (five) days from the written request of the Lead Procurer, it will lead to automatic exclusion.

Should there be any doubt as to any of these documents, Tenderers may be requested to provide additional information. If the Contractor does not submit the necessary information within five 5 (five) days from the written request of the Lead Procurer, it will lead to automatic exclusion.

iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Annex 2

Information about the Public Buyers

Information about the Public Buyers

KENTRO MELETON ASFALEIAS (KEMEA), Greece.

The Center for Security Studies (Kentro Meleton Asfaleias – KEMEA), founded in 2005 by Law 3387, is a scientific, consulting and research organisation overseen by the Minister of Citizen Protection, governed by common law and annually audited by chartered accountants. Its principal purpose is to conduct theoretical and applied research and studies, particularly at strategic level, on security topics and policies. Moreover, it is the think-tank of the Ministry of Citizen Protection on numerous policies such as public order, correctional services, terrorism prevention, crime prevention, integrated border management and civil protection as well as on various other security and societal issues; it also provides advisory and consulting risk-management services to an array of public and private organisations.

Currently, KEMEA employs one hundred and seventy-five (175) scientific and research associates with a broad range of high-calibre academic backgrounds and professional expertise. Of them, forty-four (44) are in active service at the domestic law enforcement, civil protection and defense agencies.

To meet the growing needs of the security and law enforcement practitioners and related academia, KEMEA has participated in research projects of the Horizon 2020 – the Research and Innovation Framework Programme of the European Commission – ever since it was launched; part of the H2020 is devoted to "Secure Societies – Protecting freedom and security of Europe and its citizens". KEMEA's objective in this context, is not only the development of new technologies or the application of emerging technologies, but also the understanding of associated phenomena and the development of more effective policies.

EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES), Spain

EPES is part of the Andalusian Health System founded in 1994. Its mission is to manage and provide out-of-hospital emergency healthcare in the region covering a population of more than 8 million inhabitants. EPES has 799 employees, 8 Health Emergency Co-ordination Centres, 1 Call Center "Salud Responde", 38 land-based Emergency Teams and 5 Emergency Helicopter Teams, which are used to provide support and help for victims of traffic accidents, cardiac arrests, and strokes.

EPES is also in charge of managing and providing medical support for mass casualty incidents. EPES manages, annually, more than 3 million calls at our Coordination Centers of Emergency through the emergency number 061. Our health emergency teams attend more than 65.000 citizens as well as the transfer of critical patients between hospitals around Andalusia region.

EPES is also involved in other areas such as training, research, quality control and management, information society technologies for health (eHealth), telemedicine, international cooperation in the health sector and health emergency consulting.

SERVICIO MADRILENO DE SALUD (SERMAS), Spain

The organisation Servicio Madrileño de Salud (SERMAS) is the administrative and management structure that integrates all public hospitals, primary care centres and every public health service of the Madrid Regional public Health System. SERMAS, in the FP7 and HORIZON 2020, is the legal representative (beneficiary) of every public medical centre of the Madrid Regional Health System. Usually SERMAS delegates authority to the Research Foundations in order to manage the research project favorably evaluated by the Commission.

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In this project, SERMAS (beneficiary) is the legal representative of Fundación de Investigación e Innovación Biomédica de Atención Primaria (FIIBAP) and delegate authority to the Director of said Foundation. So FIIBAP is an affiliated linked third party to SERMAS: Third party making their resources available to a beneficiary free of charge (Art.14). Collaboration between SERMAS and FIIBAP is carried out through a prior collaboration agreement, by means of which the latter handles the financial and administrative aspects of the Emergency services involved in research projects, including all issues relating to the employment and payment of additional personnel, purchase of equipment and consumables, etc. The Foundation depends on the Healthcare Coordinator General Directorate within SERMAS.

The organisation Servicio Madrileño de Salud (SERMAS) is the administrative and management structure that integrates almost all public hospitals, primary care centres, emergency medical services and every public health service that comprises the Madrid Regional Public Health System. SERMAS is the legal representative (beneficiary) of the Madrid Regional Health System. Madrid Health Regional Services (SERMAS) represents in this proposal its emergency department (SUMMA 112). SUMMA 112 is the emergency medical service that intervene in both emergency situations and catastrophes. SUMMA 112 is in charge of non-hospital or primary health care emergencies in Madrid region, including ordinary and urgent health transport services. SUMMA 112 also coordinates the health emergency services, having successfully managed 1.100.701 calls in 2017. Around 6.5 million people receive the SERMAS services every year.

OSTERREICHISCHES ROTES KREUZ (ARC), Austria

The Austrian Red Cross (ARC) is a non-profit organisation based on the Red Cross law in Austria. It is guided by the fundamental principles of the Red Cross Movement and it implements its humanitarian activities with the help of volunteers and employees. Through its activities, ARC aims to help the most vulnerable in society, both at national as well as at international level. In Austria, ARC has a network of around 75.000 volunteers, 10.200 employees and 88.000 registered Team Österreich spontaneous volunteers, and at the headquarters it employs around 600 staff members. ARC is the Austrian member of the International Red Cross and Red Crescent Movement.

ARC is mandated by authorities at all levels (district, regional, national) to be in charge of command & control of emergency medical and psychosocial situation.

In the field of civil protection ARC is providing the following services to the public – mandated by law – all over Austria: Emergency Medical Services, Ambulance Services, First-Responder Services, Humanitarian Disaster Relief, Psychosocial Support, First Aid-Training for the population, Paramedic-Training and relevant research activities. ARC is the biggest provider of emergency medical service (EMS) dispatch in Austria with more than 3 million operations per year – out of it 500.000 rescue operations. It is a very active actor in civil protection in Europe.

The department of National Disaster Management & Research is responsible for coordinating not only emergencies at national level, but participating in European research projects, fostering innovation into the organisation while providing feedback and concept validation to participating projects. In the last years, ARC has been involved in several research projects from research programmes such as FP7, Horizon 2020, European Civil Protection, among others.

AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN), Italy

Azienda Sanitaria Locale Benevento (ASL BN) is one of the 7 Local Health Agencies of the Campania Region. It is a public entity with managerial, technical and financial autonomy.

This kind of public entities have been created by the Italian Public Administration so as to manage the health issues at regional level. Indeed, ASL BN carries out the tasks of the national health system in the geographical area of the province of Benevento.

AGENZIA REGIONALE EMERGENZA URGENZA (AREU), Italy

Agenzia Regionale Emergenza Urgenza (AREU) Regional Emergency Agency was instituted on April 2nd 2008 with the Deliberation no. 6994 issued by Regione Lombardia. AREU is the Regional Healthcare Agency aimed to the governance and operational management of all the extra-hospital emergency medical activities in the Region, to develop the integration of the intra and extra-hospital healthcare emergency, to coordinate the organs and tissues transportation service and to coordinate the regional blood transfusion and hematic components activities.

Furtherly AREU has been appointed to define and implement the two stages 112 EEN model, develop the 116117 and the non-urgent healthcare patient transportation services. One of the AREU's main objective is to unify and to coordinate all the EMS activities carried out on the regional territory. This involves: people, processes, organisation, technology and knowledge.

AREU's activity covers more than 10 million citizens over Lombardy.

ELLINIKOS ERYTHROS STAVROS (HRC), Greece

The Hellenic Red Cross, as a member of the Red Cross and Red Crescent Movement, is the country's largest humanitarian organisation. Since its inception in 1877, it has been demonstrating a lasting dynamic presence in every country's emergency, but also in everyday life, through Primary Health Care and Health Education programs, which are at the heart of their interest. At the global level, the Red Cross is the leading Organisation in the provision of certified First Aid training and is the largest International Organisation to prepare citizens for crisis management.

The provision of the HRC services is based to a great extent on voluntary work through its national volunteer network and on direct response to the citizens. It is always active aiming to alleviate human suffering in times of war and peace, to support wounded, sick people, refugees, elders, people facing economic difficulties and people from all vulnerable parts of society. Its work is connected to constant alert, solidarity and altruism.

ETHINKO KENTRO AMESIS VOITHEIAS (EKAB), Greece

The National Centre for Emergency Care (EKAB) is the public provider of prehospital emergency services. It has been established in 1985 (Law 1579/1985) under the administration of the Ministry of Health and is the sole national provider of emergency prehospital services. The headquarters are based in Athens and the rest of the country is covered by 12 Branches (Athens, Thessaloniki, Patras, Heraklion, Larissa, Kavala, Ioannina, Lamia, Alexandroupoli, Tripoli, Kozani and Mytilene) with each Branch being developed in Sectors, thus covering a population of more than 10 million inhabitants. Our aim is to respond to all health emergencies in every part of the country 24/7 by:

- Receiving all emergency callsI
- Implementing life saving measures for people at risk

- Coordinating hospital and pre-hospital care in emergencies and crises
- Monitoring and coordinating the NHS hospital on-call system

EKAB has developed a Special Unit for Disaster Medicine – ETIK to deal with disasters and catastrophic situations in Greece and abroad which has been activated many times for national and international deployments (EQ in Armenia, Turkey, tsunami in Indonesia, "Helios Air" plane crash in Athens, forest fires in Peloponese, etc). According to the new law 4662/2020 in case of a major emergency that threatens human lives and property there is a complex response involving different bodies (Fire services, Police and Ambulance service – EKAB) all of which are coordinated by the National Crisis Management and Risk management Mechanism and are acting in concordance with the plans of the General Secretariat of Civil Protection.

IZMIR BUYUKSEHIR BELEDIYESI (IBB), Turkey

Izmir, also known Smyrna historically, is Turkey's third largest city and the second most important port city in Turkey. Having a history of 8,500 years and encompassing 3,500 years of recorded urban history, the city is situated by the gulf and is located in the west of Anatolian peninsula. The economically fertile atmosphere stemming from its ports, economic variety, skilled manpower and its geographic location has turned Izmir into the 3rd largest economy in Turkey. Our city, Izmir, is vibrant and dynamic – fast growing metropolitan economies in the World.

Izmir Metropolitan Municipality (legal name is Izmir Büyükşehir Belediyesi) holds a very important place in local administration organisation of Izmir, being the third largest city in Turkey with a population of around 4,4 million people. Its area of responsibility encompasses the entire provincial territory, which spans a total area of 12.000 km square, including 30 districts.

In terms of responding accidents, disasters, and other emergencies Directorate of Search and Rescue and Disaster Affairs operates under İzmir Fire Department. The Directorate established in 2014, is responsible for all kinds of accidents, collapses, explosions, intervenes in situations where technical rescue is required and conducts first aid services. It performs all kinds of search and rescue work on the surface, underwater and above water; participates in rescue operations in natural disasters and emergencies. Intervenes with the permission of the municipality if intervention is required for search and rescue activities outside the borders of the municipality. There are 14 search and rescue stations and 63 paramedic personnel affiliated to the directorate with 7 fully equipped rescue vehicles, 3 ambulances, 34 search and rescue emergency health response vehicles, 10 ATVs, motorcycle and 4×4 pioneer vehicles, 1 robotic response and transport vehicle, 1 live broadcast vehicle, 1 mountain Search and Rescue Vehicle, 1 water search and rescue vehicles.

iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Annex 3 Challenge Brief

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Contents

1.	. Introduction		
	1.1.	Terms and Definitions	70
:	1.2. Abbreviation		71
2.	Sho	rtcomings	72
3.	Visi	on	74
4.	. Narrative description of the overall process		78
5.	The	iProcureSecurity PCP change management strategy framework	79
!	5.1.	CM Models and tools overview	80
6.	Sum	nmary of the iProcureSecurity PCP Change Management recommendations	88

Figures

Figure 1: Triage management aspects	75
Figure 2: Change management framework	80
Figure 3: Lewin's change model	81
Figure 4: McKinsey 7S model	83
Figure 5: Nadler Tushman Congruence model	84
Figure 6: Kotter's change management history	85
Figure 7: ADKAR model	86
Figure 8: Beckhard and Harris change equation	87
Figure 9: Kanter's "Big Three" model	88

1. Introduction

Emergency Medical Services (EMS) in Europe are characterised by a heterogeneous landscape with diverse organisational setups, technology standards, coordination mechanisms and actors. This is the result of different historical and institutional contexts. However, these EMS are united by the common aim of providing timely care to casualties of sudden and life-threatening emergencies or disasters in cross-border settings and international humanitarian missions. Fostering the response capacities and increasing the cooperation of the Emergency Medical Services Systems (EMSS) is of decisive importance for strengthening the resilience of European societies.

During the prior iProcureSecurity (CSA) project, a large number of EMS were involved to identify, evaluate and prioritise future challenges and needs. The creation of an interoperable, flexible triage management system supported by modern technologies was among the most requested solutions in the context of security-related scenarios.

This iProcureSecurity PCP action is a result of those intense participatory processes. The action will lead to an innovative triage management system that provides a) quick and accurate overview of casualties and their status; b) decision support for better allocation of available resources and quicker support for casualties; c) improved interoperability with other first responders and relevant actors; d) reduced handover times between ambulance transport and hospitals; and e) insights for quality assurance and training measures.

Following the EC Guidelines on Pre-Commercial Procurement (PCP), through a competitive series of design, prototype and pilot steps, the iProcureSecurity PCP will contract suppliers to deliver the creation and deployment of the envisaged triage management system.

Term	Definition
Casualty	It refers to the people who have been involved in the Mass Casualty Incident.
Casualty Profile	The Casualty Profile is a digital profile which shows all the collected information on the single casualty. It shall contain both information manually entered by the actors, and automatically collected by the iProcureSecurity PCP Solution
Dispatch Centre	It refers to permanent institutions for management of emergency call, messages, as well as alarming and coordination relief units. The Dispatch Centre has different responsibilities, depending on the county. It is identified as Category E.
iProcureSecurity PCP Solution	It refers to the final, comprehensive technical solution developed within the iProcureSecurity PCP project.
Mass Casualty Incident Area	It refers to the area where the Mass Casualty Incident happened.
Mass Casualty Incident	It refers to "an event that overwhelms the local healthcare system, where the number of casualties vastly exceeds the local resources and capabilities in a short period of time", following ISO 22300:2021
	The Mass Casualty Incident will be identified from the <i>iProcureSecurity PCP Solution</i> through a Mass Casualty Incident Profile.

1.1. Terms and Definitions

Mass Casualty Incident Profile	It refers to the profile of the specific <i>Mass Casualty Incident</i> . The <i>Mass Casualty Incident Profile</i> will be identified from the <i>iPS PCP Solution</i> through a unique ID Reference Number and comprises all the information collected on the specific incident.
Treatment	It refers to the phase of the treatment, coming after the Simple Triage. The treatment phase begins as soon as the casualty is brought to the Advanced Medical Site (after being triaged) and it applies only in case a treatment is needed. The treatment phase may continue – if needed – in the ambulance, while the casualty is being transported to the hospital. The treatment phase ends as soon as the casualty is handed over to the hospital.
Triage Area(s)	It refers to the areas created at the <i>Mass Casualty Incident Area</i> , where the triaged casualties are located according to the status/colour code.
Triage Tag	It refers to the hardware component (Tag) which will be applied on the casualty after being triaged. The term <i>Triage Tag</i> is independent from the nature of the Tag, i.e., it could be an electronic tag, a bracelet, a badge, etc.
Simple Triage	The term Triage refers to an organised process that matches needs with available resources according to a priority scheme designed to achieve the end objective (i.e., goal) of the specific triage system.
	The Simple Triage in iProcureSecurity PCP project refers to the initial triage performed at the Mass Casualty Incident Area, as soon as the actors arrive. The Simple Triage follows an algorithm (e.g., START Algorithm).

1.2. Abbreviation

Abbreviation	Meaning
AMS	Advanced Medical Site
СМ	Change Management
EMS	Emergency Medical Services
EMSS	Emergency Medical Services System
MCI	Mass Casualty Incident
РСР	Pre-Commercial procurement
R&D	Research and Development
UC(s)	Use Case(s)

2. Shortcomings

This section highlights the shortcomings of the current state of the art and thus elucidates why existing solutions do not fully meet the needs of the EMS organisations in the field and a PCP process is needed to acquire new R&D services.

Table 1: Current shortcomings of available	systems
--	---------

Area	Shortcoming
Planning and decision making	 Lack of clarity for the head of operations on the ground and for command-and- control structures and dispatch centres in the background based on missing or unclear data.
	 Missing innovative geolocation and cartographic tools for onsite planning.
	 Missing information on environmental conditions (traffic conditions and weather conditions).
	 No data for decision support to improve resource allocation and casualty transport.
	 Lack of centralized clinical information that would allow an early distribution of casualties according to their pathology and the availability of hospital resources.
	 The information flow directly depends on human performance. In a stressful situation the professional can forget important data or be easily distracted by tasks that do not generate value.
	 Lack of integrated solutions for the management of major events.
	 Miscoordination in deciding which units to deploy depending on the event – i.e., how many persons, types and number of ambulances, other devices, logistic resources, which stakeholders to activate.
On-Site Data	 Lack of proper information of the location, i.e., which size of the area should be isolated, how many people are in the area, what is the accessibility of the area.
	• Lack of risk assessment of the emergency area.
	Lack of mapping of the location
Resource	Resource allocation is sometimes inefficient due to missing interoperability of
allocation	used systems.
	 An exhaustive analysis of the data generated in the incident is required, both in real time and afterwards, in order to improve resource allocation.
	 Automated monitoring of already assessed casualties can free up human resources to care for other casualties.
Triage practice	• Current triage is not very flexible e.g., START algorithm is used in scenarios or
	cases where it doesn't fit e.g., for children, blast injuries because of ease of use.
	 Improvement of re-triage, i.e., a monitoring of the condition and vital signs of already triaged casualties on site, setting up a common platform for the data interchange with electro medical equipment (defib-monitor, ultrasound etc) and triage system to improve interoperability on the field and in hospital.
	 Missing ability to connect with telemedicine applications.
	 Currently there is a high clinical variability in the triage process. Turning it into a homogeneous process increases casualty safety and serves the professional as a support for clinical decision making.

	 Triage practice is a handwritten process and therefore slow, unreliable, and not efficient.
Casualty	 Lack of identification systems for the casualties.
Identification	• Lack of access to the casualty medical history.
Data transmission	 In many cases it is still necessary for the staff on the ground to collect the handwritten information and report this information via radio. In some cases, information is still forwarded through so called "runners", who transport paper-based information from one place to another. Communication between different first responders is based on telephone or radio, and could be improved and less time consuming if those organizations
	share a common information exchange platform, including the vision of the scene at different levels.
	 Radio messages are prone to confusion and only one casualty data can be transmitted at a time.
	 Outage of usual communication network (mobile communication), due to overwhelmed networks or critical geographical locations.
Interoperability	 Missing interoperability (missing APIs) between existing EMS systems.
	 Missing interoperability between all the actors participating in the emergency (EMS, first responders).
	• The clinical information generated in MCIs currently cannot be easily shared
	with other healthcare providers, even in the same region.
	 Missing interoperability with national Electronic Health Record systems.
Usability	 Available systems are not providing necessary ergonomics and usability.
	 Many systems can only be operated by professionals after intensive training.
Evaluation	 Missing performance and risk assessment during incidents due to missing, incomplete or unavailable data.
	 Lack of benchmarking to provide accurate performance evaluations. Missing systems which allow to record what is happening in the emergency areas in order to use the data for evaluation and training.
Sustainability	 Isolated applications create a lock-in situation which hinders EMS to seamlessly connect them with current and potential future applications.
Reproducibility	 Lack of protocols that make the procedures ad hoc and too much cultural dependent.
	 Lack of common vocabulary and terminology in different relief units.
Data Protection	 Missing complete compliance with the dispositions of the GDPR: 1. Authentication and authorization; 2. Pseudonymisation and Encryption; 3. Backups and Business Continuity; 4. Infrastructure security (physical protection); 5. Applications security. Missing compliance to cybersecurity yuperabilities and risks
	• Wissing compliance to cybersecurity vulnerabilities and risks.

3. Vision

The vision of iProcureSecurity PCP builds the foundation for the development of novel triage management systems (iProcureSecurity PCP Solution), that are able to overcome fundamental shortcomings of currently used systems and which will allow to digitalize key processes and thereby strongly contribute to an improved quality of the service for all involved stakeholders.

In particular, the iProcureSecurity PCP Solution must be developed considering the needs of the EMS on the field, and it must aim to:

- (1) Digitalise the triage management operations on the field, and provide guidance and support to the EMS practitioners.
- (2) Facilitate the communication and the information sharing among EMS on the field and external stakeholders (Dispatch Centre and public actors, respectively categorized as Category E and Category D).
- (3) Facilitate the decision-making process of the actors involved, by proving them with key information in real time, as well as with alerting and notification systems.
- (4) Provide a hardware component (Triage Tag), that is attached to the casualty throughout the whole process (from first triage to hand over to the hospital) and which supports data collection and hand over procedures.
- (5) Allow the report and assessment of MCIs including performed activities on the field (data collected, decisions taken, actors and profiles involved).
- (6) Integrate data from and to third party systems.

Starting from the findings collected and analysed during the iProcureSecurity CSA project and in-depth assessments during the first months of the iProcureSecurity PCP project it can be stated that an innovative system must be developed in a way to enable **planning** and **decision-making**, taking into account all the existing variables faced by the EMS practitioners at the MCI area.

Likewise, the **allocation of resources** must be as efficient as possible to reduce the cost of each intervention while always ensuring casualty safety. In general, all emergency professionals the project consortium engaged with, claimed that the current **practices in the area of triage management** need to be improved and the development that is carried out by the industry has to go beyond the current state of the art.

A system that truly has an impact on the work of the emergency teams should allow a quick, easy and uninterrupted communication and information flow among the EMS practitioners on the field, allowing them to exchange information in real time with the other stakeholders in the EMS ecosystem (e.g. information sharing with the Dispatch Centre and the hospitals).

Furthermore, part of the project vision is to connect the iProcureSecurity PCP solution with and to existing and upcoming third-party solutions and databases (e.g. casualty's medical history). The aforementioned necessity implies that the iProcureSecurity PCP Solution is able to exchange data directly with other information systems of the EMS organizations involved. The **interoperability** concept has to ensure that existing and upcoming third-party solutions can connect to the solution according clearly defined standards and thereby ensure sustainability of the solution.

A system for triage management that meets the challenges faced by the EMS practitioners across Europe should be digital and able to provide data that facilitates the **evaluation** of interventions

between different teams on national or European levels. However, to achieve this goal, the iProcureSecurity PCP Solution needs to demonstrate also the capability to be used during MCI trainings.

Finally, as the health data of casualties that is transferred and updated between the different actors is concerned, **data protection** must be guaranteed at all times supported by putting in place all the necessary **cybersecurity** measures.

The image below gives a basic overview of the involved actors, connections and interfaces of an envisaged flexible and highly modular triage management system solution, that can be applied and adapted to different approaches and connected to existing systems in every of the procurers' country or region.





To reach the desired quality and efficiency improvements suppliers will have to take into account several aspects and make use of and combine innovative aspects and concepts in several domains. A critical success factor is to establish a balanced understanding for the technology components, the involved data domains, and the organisational processes and structures which build on the former. The focus areas of the technology perspective include means to continuously capture and update triage information, which is consolidated to streamline the triage management, including the handover of casualties to healthcare organisations. The aspect of "site intelligence" seeks to utilise the capabilities of modern sensor technologies, to aid in casualty tracking and treatment, but also identification of potential threats, as well as providing a data foundation for further decision support. The cross-cutting aspects for technologies are the functional capabilities of technology components, their usability and practicality for a field deployment, as well as interoperability from a technical standpoint.

The concept of operations examines the roles, structures and processes established for a Mass Casualty Incident response, starting from the concrete initial triage process, and the consequential treatment and the hand over to the hospitals. It includes the continuous interaction with other EMS organisations, as well as with the Dispatch Centre and hospitals, as well as the collaboration under different constellations, especially in Mass Casualty Incidents with heterogenous EMS from different nationalities involved. This also covers the aspects of a consistent incident documentation, the feedback of lessons learned into training concepts, but also the (potentially diverging) terminology and taxonomy used by involved organisations.

The data perspective covers the aspect of incident information, to understand the scope and impact of the situation, which is necessary to plan a suitable Mass Casualty Incident resolution and identify additional resource needs on site. Particular emphasis is also on any data regarding the casualties, which ranges from their triage history, the treatment they received, but also the potential of retrieving a casualty record or capacity data from healthcare organisations to further improve the routines on site. Due to the sensitive nature of the involved information, the aspect of data protection is an important cross-cutting aspect. Of similar importance is the semantic interoperability of data, which ties in with the syntactic interoperability for technical components, and the terminology and taxonomy established in the concept of operations.

The iProcureSecurity PCP triage management system can be considered as one of the core components for EMS digitalisation, as it has the vital role of receiving data from the involved endpoints (sensors, services, applications), complements it with contextual data and distributes it to downstream systems, while providing information to decision makers on- and off-site to support the management of the incident situation.

In addition to that, the different modules of the iProcureSecurity PCP Solution can be seen as building blocks for advanced information systems to be deployed in the routine EMS activities other than MCI.

Multiple challenges were identified, which have to be addressed by the iProcureSecurity PCP solution triage management system:

- The tracking of the triage situation involves information on the number of casualties, their classification, their treatment and their status. Carried out manually, it is a challenging task to collect the information for an initial overview, and to maintain it as the situation evolves, as it requires multiple roles on-site to continuously update this information. Outdated information or mistakes influence and delay decision making processes on an operational, tactical and strategic level, which can lead to a misallocation of resources, a delayed delivery of supplies or equipment, or subsequent mistakes in the management and treatment of casualties. By maintaining a digital record of each triaged casualty, beginning with the initial primary triage, continuing to the treatment, up to the handover to the hospital, a permanently updated data baseline is available for decision makers to produce an overview which satisfies a demand for an overall situational awareness, but it is also rich in detail to be suitable for specific use cases (such as the treatment or transportation) or to be further processed by downstream systems.
- Data **interoperability between different organisations on-site**, especially if multiple nationalities are involved, is a challenging aspect. Triage information is relevant for other organisations to aggregate a holistic overview of the Mass Casualty Incident situation, to keep track of the resolution of the incident, to react to unexpected changes of the situation, or to flexibly change priorities in resource allocation if bottlenecks are identified. A digitalisation of the triage procedure provides a reliable data basis for other organisations to work with and does not bind personnel on-site (such as liaison or communication officers) to convey this information. On a broader scale, this structured information is also an important factor to plan out the transportation logistics towards hospital facilities, or identify additional supplies, vehicles or specialised equipment required at the Mass Casualty Incident Area.
- The handover procedure of a casualty for transportation also includes information on their triage classification and treatment history. This is of relevance for the paramedic in the transportation vehicle to ensure a correct, continuous treatment of the casualty during the

transportation, and it remains equally important in the handover from the transportation to the hospital facility for the hospital triage and further treatment. The goal of the information handover is to be as accurate as possible, while also consuming as little time as possible for the personnel involved, which can be a challenging task if factors such as a manually written or transcribed documentation, proprietary systems and potentially semantic or taxonomic difficulties are involved. A distribution of digitalised triage information to any authorised data consumer is efficient, consistent and reliable and does not bind human resources of the involved organisations. It also has the inherent advantage of providing a larger amount of information than what is strictly necessary for the supported process step, which would be well beyond the scope of an efficient manual handover. This way, information can be purposefully narrowed down or retrieved depending on the usage scenario, providing an appropriate flexibility to adjust to an evolving MCI situation.

In a Mass Casualty Incident, the situation can evolve rapidly, involving multiple organisations, carrying out a large subset of routines involving multiple decision points. A manual documentation of these activities is challenging, as it binds valuable resources and is often carried out under stress, impacting the accuracy, thoroughness and correctness of captured information. A digitalisation provides a consistent, chronological, documentation on the triage classification, the treatment received on site, and the handover for transportation. Furthermore, by using consistent reference objects and adhering to standardised data formats, a comprehensive data basis is created, which supports the analysis on how the MCI evolved on site, and derive insights on how to continuously improve the triage procedure from a long-term perspective. These insights can also feed back into the training of EMS personnel, or provide profound information which future research activities can build on. Furthermore, the evaluation, combined with the creation of training, can provide libraries of cases/scenarios, based on real or dummy data ("simulation mode"), which can be used by the procurers for the creation of customizable and evaluable scenarios.

Based on these aspects the iProcureSecurity PCP consortium summarized the main challenge to be tackled as follows:

Improve triage scenarios through a flexible triage management system that provides:

a) quick and accurate overview of casualties and their status,

b) decision support for better allocation of available resources and quicker support for casualties,

- c) improved interoperability with other first responders and relevant actors,
- d) reduced handover time between ambulance transport and hospitals, and
- e) insights for quality assurance and training measures.

4. Narrative description of the overall process

In order to better explain the type of support which will be expected by the iProcureSecurity PCP Solution, this chapter describes the overall processes of a Mass Casualty Incident, having as main thread the Use Cases developed within the project, described in detail in the next paragraph.

A Mass Casualty Incident (MCI) has occurred. The Dispatch Centre starts receiving numerous emergency calls, all describing a large incident involving several casualties in need of rescue. A Mass Casualty Incident is officially declared. The Dispatch Centre activates the Operation Site Management and send the first actors to the MCI area. The iProcureSecurity PCP Solution allows the responsible actors (either the Dispatch Centre or the Operation Site Management, depending on the country) to assign the roles and responsibilities for the management of the specific MCI, as well as to create a unique MCI ID and MCI Profile, on which all the data in regard to the specific MCI will be stored, monitored and updated (**UC1**). Actors - who have been granted with particular roles - access the iProcureSecurity PCP Solution and, depending on their profile and category, they will have access to specific interfaces, and thus, to a specific range of information. Based on their role/responsibility, they will be able to perform specific actions and share specific information with the iProcureSecurity PCP Solution. (**UC3**).

The first actors arrive at the Mass Casualty Incident Area and start the simple triage and rapid treatment. The iProcureSecurity PCP Solution supports the actors in their triage activities, by providing them with guidance on how to conduct the triage algorithm, as well as with a "hardware component" (Triage Tag) able to measure specific vital parameters, automatically create the Casualty ID and Casualty Profile, and continuously geolocating the casualty. Finally, the iProcureSecurity PCP Solution proposes and displays the status/colour of the casualties, based on the applied triage algorithm and collected and continuously monitored vital parameters (UC2). After the primary triage (UC2), each casualty is automatically identified through a unique ID and Casualty Profile, which includes all the information about the casualty (e.g., continuous updated of vital parameters, ID and photos of the casualty - if available -, data coming from the HER etc.). Dependent on the size of the incident the casualty is transported to the Advanced Medical Site for treatment before being taken to the hospital. The iProcureSecurity PCP Solution provides support for the management of the activities planned in the Advanced Medical Site, supporting in the treatment and prioritization of the casualties. It will provide customizable guidance on the treatments (for example CGS - Glasgow Coma Scale, or RTS -Revised Trauma Score), enabling the update of the Casualty Profile, after the stabilisation of the patient's clinical conditions. The updated data will be shared in real time with the other EMS practitioners (UC4). Furthermore, in case of relevant changes of the casualty vital parameters, the iProcureSecurity PCP Solution enables an alerting and notification system, ultimately helping to determine the priority of treating or transporting the casualty to the hospital (UC3).

In parallel to the first triage and treatment procedures, the Category C (i.e., the Operatives, such as head of the triage, onsite manager, head of the advanced medical site etc.) is performing the Initial MCI assessment, and taking main decisions (for example where to locate the parking and triage areas).

All the information gathered by the Category C actor, must be then transmitted to other stakeholders. The iProcureSecurity PCP Solution quickly and (semi) automatically collects information on the geography and environmental conditions of the MCI area, as well as on traffic and weather conditions, thus facilitating the decision-making process. Also, it enables a smooth flow of the collected information with other EMS practitioners on the field as well as with external stakeholders involved in

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the MCIs (Category E) in order to properly manage the event accordingly to the national procedures **(UC6)**. Parallelly to the organisation of the area and the collection of the information, the Category C is also responsible for the management of the vehicles and resources, deciding on the number and type of human resources, equipment and vehicles. The iProcureSecurity PCP Solution supports the actors in managing the resources available, based on the continuous update and flow of information coming from the simple triage and rapid treatment (UC2), from the Advanced Medical Site (UC4) and from the Operation Site Management (UC6). The iProcureSecurity PCP Solution supports the Category C actor by providing information on vehicle availability, the casualties' health condition, traffic, types and availability of hospitals (e.g., free ICU beds) **(UC7)**.

All the sensitive data on the casualty – including personal information and vital parameters - are continuously collected, updated and stored within the iProcureSecurity PCP Solution. This functionality allows the EMS personnel in having continuous monitoring and update of clinical parameters. In case of relevant changes of the vital parameters, the iProcureSecurity PCP Solution will send alerts and notifications to the interested actor (UC3). The collected vital information is shared on the Casualty Profile, and on the Triage Tag, allowing all involved healthcare personnel to establish diagnostic and therapeutic procedures (UC5).

Once MCI operations have been completed, the iProcureSecurity PCP Solution provides a tool to monitor and evaluate the quality of the intervention and the management of emergency scenarios. It generates an automatic report, which assesses all the collected data, actions, decisions taken and highlights good and best practises. The iProcureSecurity PCP Solution will allow a fully customizable and editable reporting so that each procurer will be able to adapt the structure, format, and size of the evaluation report and prepare the debriefing for the training efficiently. The information provided by the report will be used for the creation of training modules and curricula. Furthermore, the iProcureSecurity PCP Solution supports the different actors during simulated emergency management activities and automatically evaluate the MCI trainings **(UC8)**.

Overall, the iProcureSecurity PCP Solution must be open and flexible enough to integrate data from and to third party systems (**UC9**).

5. The iProcureSecurity PCP change management strategy framework

The iProcureSecurity PCP Solution is expected to be innovative and influence current ways the eight procurers innovate existing Triage Management practices, therefore certain changes on the procurer's side might be required. This section reviews existing related literature to managing change in organisations and outlines an approach to change management (CM) to be used in the project.



Figure 2: Change management framework

The modern healthcare CM literature builds on the existing traditional models of CM. It seeks to identify the good practices that these models share. The evidence base for the practices is then evaluated and a set of recommendations is issued. The same approach is used in materials regarding resistance to change. A set of barriers is often identified and different ways to overcome them are compared. These change frameworks build from the business-oriented CM models to integrate different aspects of micro, meso and macro level of organizational change.

The traditional models of CM which emphasised the role of organisation's management in assuring the desired change takes place have been criticised for being unperceptive of the complexity of relations within and outside of the organization. They have also been described as top-down and authoritarian.

The predominant viewpoint shared today is one where organizations and systems are seen as complex dynamic systems. They also have many actors with different intentions. The approach to change with these presuppositions is therefore reactive to the ever-changing environment, "real-time" and iterative. It has been recognised that sometimes great results can come from a small change in the right environment or "climate". This implies that change cannot be pre-planned as many factors might emerge in the process that are uncontrollable. A change framework or strategy is what helps guide change as new needs arise from different actors. These models are collectively referred to as emergent change models. However, some of the traditional models of planned change management that have proved to be useful tools in guiding and understanding the process of change have a longer track record and still get to keep their place in the CM toolbox.

5.1. CM Models and tools overview

5.1.1. Lewin's Change Management Model

Named after Kurt Lewin, one of the pioneers of modern organizational, behavioural and applied psychology. The model describes change as a three-stage process. The first stage, called "unfreezing" is characterised as a "survive or die" situation where old habits, processes, mindset and defence

mechanisms (resistance to change) all must be surpassed in order to allow for the change process to take place. The second stage is the change or transition or "moving" itself. This is described as a period of uncertainty and confusion where the "old ways" are challenged but the new way to do things is has not yet settled. The third and final stage is "freezing". In this period the new habits "sink in" and the system comes back to balance.



Figure 3: Lewin's change model

Communication between EMS staff and supervisors needs to be encouraged and enabled during the change period. Actors performing triage need to get answers about all uncertainty and misunderstandings that they are faced with. After a certain time, it is assumed that a new way of triage management is established, and EMS staff should be able to have relevant information about the casualty - including vital parameters, status, condition, treatment and potential additional personal information – as well as about the overall MCI – including geographical and environmental conditions, resources, vehicles, staff etc.

5.1.2. Lippitt, Watson, and Westley Phases of Change Theory

Created in 1958 as an extension of the Lewin's three stage model, Lippitt's model is seven-stage process. The model introduces the role of change agent- the outside factor (e.g. a consultant) that can identify the need for change within the institution and act as a catalyst to that change. The consultant can then create a plan for change and facilitate the overall process. Another option is that the system itself identifies the need for change, but this process is much slower happens only when the system is severely malfunctioning.

The seven steps of the model are:

- 1. Diagnose the problem (done by the change agent of by the organization itself)
- 2. Assess the motivation and capacity for change
- 3. Assess the resources and motivation of the change agent. This includes the change agent's commitment to change, power and stamina.

4. Choose progressive change objects. In this step, action plans are developed, and strategies are established.

The role of the change agents should be selected and clearly understood by all parties so that expectations are clear.

Maintain the change. Communication, feedback and group coordination are essential elements in this step of the change process.

Gradually terminate from the helping relationship.

A possible example would be a group of change agents among the provider teams who are highly motivated to improve the triage management in different groups of EMS actors, in different conditions (e.g., rural areas that are far from the hospitals), and in different ways (communication tools and available structure of the providers). Change agents need to be aware of the obstacles and limitations of the management practices and be persistent in establishing a working routine.

Besides doctors, change managing teams need to include Category B (health-care actors), Category C (operatives), Category D (state actors) and Category E (Dispatch Centre) as well as other actors who would facilitate the implementation of change through organizing individual or group educations for digital triage management. Good organization plan and highly motivated healthcare staff, after the period of adaptation, should encourage collaborative relationships during the whole MCI management.

5.1.3. McKinsey 7 S Model

The model was developed by the McKinsey Consulting company in the 1980s. It has been created to assess the internal status of companies for use in different cases of merger and acquisition of companies. The model can be applied more broadly to analyse the different elements of performance in organizations. The aim is to create more balance between the 7 elements and the resulting status should have increased performance.

A distinction is drawn between the "hard" and "soft elements" in the McKinsey 7s model.

The hard elements include structure, systems and strategy of the organization. These are available to the management and can easily be changed.

- **Structure** refers to the internal organization, hierarchy and reporting pathways within the organisation
- **Systems** are the processes that take place in the organization e.g., tasks that are performed by staff to do a certain task
- **Strategy** is the planned path that the organization follows to achieve its goals in the market

The soft elements are shared values, style, skill and staff. These are more difficult to pinpoint and assess and control by the management and therefore it more difficult to influence their change by the management.

- Shared values the overarching principles shared by all members of the organization
- **Style** refers to style of leadership and its influence on the performance, resistance and motivation.
- Skill the competency of the employees
- **Staff** numbers and abilities of staff in different positions

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Systems

Figure 4: McKinsey 7S model

What is described in the diagram that is commonly associated with the McKinsey 7s model is the central location of Shared values, and the influence that it has on all the other elements of the model. The other elements are also interrelated and change in one lead to an effect in the others. The common approach to the use of this model in practice is stepwise:

- 1. Checking the congruence of shared values with the hard elements: strategy, systems and structure and assessing the soft elements and their relation to the hard elements. The hard elements should support the soft elements. If they don't, they need to be changed.
- 2. Finding the optimal organizational design to fit with the shared values
- 3. Finding a way to balance the identified problematic elements- creating a plan or a strategy
- 4. Implementing the necessary changes to achieve a balance of the elements
- 5. Re-evaluating the balance of the elements in the newly created system

This model puts in the centre a shared value, in this case performing triage with digital tools, which influences and connects different elements. Hard elements include structure (EMS staff), system (ways of communication within structure and education), and strategy (actions and tools that would be used to perform and manage triage).

5.1.4. Nadler Tushman Congruence Model



Figure 5: Nadler Tushman Congruence model

Nadler and Tushman's congruence model (1997) seeks to explore the dynamic ecosystem within the organisation it is trying to change. The concept proceeds to define the "input" variables (such as resources, strategy and the environment) that are transformed within the organization's machinery into desirable "outputs" in terms of change in the people's behaviour, working processes etc. Four variables describe the organization: the work (processes), the people (workforce and skills), the formal organization (structures or frameworks) and the culture (values and norms). The higher the level of congruence between these variables the higher the success of change will be. The "balancing" of these variables can be presumed to improve the outcome which is shared with McKinsey's 7s model.

The envisioned solution should seek to integrate seamlessly into the working processes and their culture and norms - the desired output of change, in this case, a qualitative and quantitative increase in triage efficiency and quality of care together with the advanced monitoring solutions should be viewed a product of change. The management of change in the workforce skills and influencing the desire to change could be seen as challenges in the change process.

5.1.5. Kotter's change management theory

John P. Kotter is a thought leader in organizational management from Harvard Business School. His theory of change management is divided into eight steps. Each step is related to one key principle that is deemed important to achieve positive response of people to change.

Create a sense of urgency	Clearly communicate the opportunity an the urgency to act now to all stakeholders
Build a guiding coalition	 Engage, include and empower the stakeholders to create a guiding force for change
Form a strategic vision and initiatives	Paint a picture of how the future will look and create initiatives that work towards that
Enlist a volunteer army	 Implement a strategy that will enlist a large number of actors that are rallied around a common goal
Enable action by removing barriers	 Get rid of unnecessary and ineffective processes. Eliminate silos of information.
Generate short-term wins	Celebrate small victories as they happen to track progress and boost morale
Sustain acceleration	Use the small victories and the gained credibility to press harder and achieve even grater victories
Institute change	 Reinforce the connection between the new processes and organizational success. This helps sustain the new practices

Figure 6: Kotter's change management history

The Kotter's model creates a step-to-step guide that is easy to follow. It recognises the importance of involvement of different actors and their role in delivering the change. It is in this sense different than Lewin's model and McKinsey's 7s where change is something that the management is tasked to deliver.

In regard to other CM theories, Kotter's theory recognises the importance of involving different actors, in this case, EMS staff with different roles within the scenario, who have realised the necessity and opportunity to implement the principles of change management in triage management. It is important to clearly communicate the main goals which are to be achieved and have an exact vision who will take a certain role in that process

The existing processes in triage management should be identified and replaced by efficient processes that promote the importance of digital tools and data. Positive feedback on treatment and triage efficiency from EMS actors would encourage other professionals to sustain a new CM plan.



Figure 7: ADKAR model

The ADKAR model is a tool that can help the organization management to sequentially focus their efforts into providing the right stimulus in order to progress change. It implies that each of the change stages: Awareness, Desire, Knowledge, Ability and Reinforcement must be achieved before advancing to the next one in sequence. The change stages signify the following:

- 1. Awareness is understanding the urgency to change
- 2. Desire to participate in the movement
- 3. Knowledge on how to implement change
- 4. Ability to implement change
- 5. Reinforcement to keep the change going once established

The ADKAR model shares many features with other described models- it recognises the importance of the people dimension in change and it pairs it well with the management stages of change implementation.

The ADKAR model shares many features with other described models. It recognises the importance of the people dimension in change and it pairs it well with the management stages of change implementation.

This model suggests that first of all, EMS actors need to recognise a need for a change, in this case performing and managing triage, and initiate the change movement. It is necessary to indicate people on the importance of readily available data on patient status and resources. That process is facilitated thanks to many digitals' tools, but still there are individuals who are not proficient with digital and online platforms. That makes ability to implement change depended on local decision makers and actors who have desire to participate in this CM movement. Good organisations and enough highly motivated staff can make it possible to establish change and reinforce to keep it going on.

5.1.7. Beckhard and Harris Change Equation



Figure 8: Beckhard and Harris change equation

A notable take on pinpointing the factors that contribute to the success of a change initiative comes from Beckhard and Harris's (1987) work. It is conceptualised here that in order for a change initiative to be successful, the change factors (dissatisfaction with the current state, a guiding vision for change and the feasibility of the steps towards change) must be greater than the resistance to change. This in turn implies that all three factors must be present (not equal to zero) in order for change to have an effect.

EMS actors need to develop a vision of digital triage management. They need to create a change plan and argue the necessity of change. Mitigating circumstances to change would be to the dissatisfaction of EMS staff with the current way of triage management.

5.1.8. Kanter's "Big Three" Model of organisation change

The "Big Three" model of organisational change stems from 5 major acknowledgements relating to the complexity of change:

- 1. It is hard to make changes stick
- 2. There are clear limitations to managerial action in making change
- 3. Attempts to carry out programmatic continuing change through isolated single efforts are likely to fail because of the effects of system context
- 4. The need for change may make it harder for change to occur
- 5. Some of those best at new practices in one realm may show limitations in others

Overall, these acknowledgements fall in line with other emergent change models in suggesting that change occurs incessantly in modern day organisations and the organisational contexts and broader environmental factors limit management's ability to control, predetermine, and plan for change. The Big Three model proposes that there are three kinds of motion, three forms of change, and three roles in the change process.



Figure 9: Kanter's "Big Three" model

This theory considers that the precondition of establishing CM of triage management is to make organizational change. That means that the health care system needs to make a change within itself so that the new way of performing triage can be effective. Furthermore, it is important to have a firm organisation that will mobilise medical staff with various other stakeholders, such as, EMS organisations, dispatch centre, etc. The last step is individuals, who have sufficient experience in the field of triage management, that would put an effort and make it possible to achieve the positive result of the change. Moreover, it is important to have a well-designed change plan, in this case, change in managing triage. It should be coordinated by EMS supervisors who also represent change implementers. The change should be controlled through feedback to triage workflows for EMS staff who represents change recipient and their motivation and commitment to the change are key to success in CM.

6. Summary of the iProcureSecurity PCP Change Management recommendations

Effective change management enables the successful and timely implementation of the desired change. To assure the uptake and scalability of the iProcureSecurity PCP Solution, a well-thought-out implementation strategy is required, one that is based on the sound principles of change management theoretical models. With this in mind, individual change management strategies should be developed and implemented by the iProcureSecurity PCP solution developers as well as the procuring regions.

This chapter has outlined some of the existing change management models and described potential applications for each one within the scope of the iProcureSecurity PCP project. This includes the considerations that are part of the development process of the iProcureSecurity PCP Solution as well as those that are directly linked to the phase of iProcureSecurity PCP Solution testing and implementation in procurer regions' existing systems. These CM considerations include the individual "micro" scale- e.g., how the iProcureSecurity PCP Solution will be presented to the user to foster both the uptake of the solution and also the sustained inputs that are required. On the "macro" or © 2022 iProcureSecurity PCP | H2020-SU-SEC-2020 | 101022061

population scale, the CM considerations deal with the uptake of the solution in procurer regions from the perspectives of leadership, systems affected by the change, and EMS staff that is taking part in the change. The chapter includes the tools to help develop a strong CM strategy for the iProcureSecurity PCP Solution.

The theoretical framework of CM presented aims to help assist the development and testing phases of iProcureSecurity PCP. The outlined CM models are in no way prescriptive - each development team and each procurer region will face specific challenges that require a tailored CM approach. The described CM models should, therefore, serve as a rough guide towards developing a pilot and solution-specific CM strategy. The outlined examples joined to each theoretical model represent an example of change need as recognised by the procurer regions and interpreted in the light of the studied CM model. This is to serve the development teams in their efforts to create the most aligned solution - the one that has the greatest chance to be accepted well in the pilot sites. It also serves as a reminder and a guide for the procurers to coordinate well their CM efforts to ensure good solution uptake and sustainability including their systems change and staff change needs.

iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Annex 4

Requirements, Use Cases and Process Models

Contents

1		Terms and Definitions			94
2		Abbreviation			
3		Requirements			95
	3.	1	Brief	Methodology	95
	3.	2	Func	tional Requirements	96
		3.2.1	L	Quick and accurate overview of casualties and their status	96
		3.2.2 casualtie		Decision support for better allocation of available resources and quicker support o	f
		3.2.3	3	Improved coordination and communication among EMS stakeholders	101
		3.2.4	1	Reduced handover time between ambulance transport and hospitals	102
		3.2.5	5	Insights for quality assurance and training measures	102
	3.	3	Non-	Functional Requirements	103
		3.3.1	L	Interoperability	103
		3.3.2	2	Connectivity	104
		3.3.3	3	Usability	105
		3.3.4	1	Performance	105
		3.3.5	5	Scalability	106
		3.3.6	5	Language	106
	3.	4	Para	meters/Measuring Units Requirements	106
	3.	5	Lega	l and Regulatory Requirements	107
		3.5.1	L	Security	107
		3.5.2	2	Privacy	108
		3.5.3	3	Regulations	109
	3.	6	Orga	inisational Staff and Business Requirements	109
		3.6.1	L	Installation of prototypes and systems	109
		3.6.2	2	Procurement Reporting	110
		3.6.3	3	Pilot Feedback	111
4		Proc	urers	IT System Interoperability	112
5		Lega	l and	Regulatory Environments	117
	5.	1	EMP	RESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES)	117
	5.	2	SERV	/ICIO MADRILENO DE SALUD (SERMAS)	117
	5.	3	ÖSTE	ERREICHISCHES ROTES KREUZ (ARC)	118
	5.	4	AZIE	NDA SANITARIA LOCALE BENEVENTO (ASLBN)	119
	5.	5	AGEI	NZIA REGIONALE EMERGENZA URGENZA (AREU)	120

	5.6	ELLINIKOS ERYTHROS STAVROS (HRC) / ETHNIKO KENTRO AMESIS VOITHEIAS (EKAB)	. 121
	5.7	IZMIR BUYUKSEHIR BELEDIYESI (IBB)	. 121
6	Orga	anisational Staff and Business Environment	. 123
	6.1	EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES)	. 123
	6.2	SERVICIO MADRILENO DE SALUD (SERMAS)	. 127
	6.3	ÖSTERREICHISCHES ROTES KREUZ (ARC)	. 134
	6.4	AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN)	. 138
	6.5	AGENZIA REGIONALE EMERGENZA URGENZA (AREU)	. 142
	6.6	ELLINIKOS ERYTHROS STAVROS (HRC) / ETHNIKO KENTRO AMESIS VOITHEIAS (EKAB)	. 149
	6.7	IZMIR BUYUKSEHIR BELEDIYESI (IBB)	. 154
7	Use	Cases and Process Models	. 160
	7.1	Use cases development methodology	. 160
	7.2	Use cases elements	. 160
	7.3	Service process models development methodology	. 161
	7.4	Service process models elements	. 162
8	Gen	eral narrative of the overall process	. 164
9	iPro	cureSecurity PCP use cases and service process models	. 166
	9.1	UC1: Central Information System	. 168
	9.2	PM1: Central Information System	. 170
	9.3	UC2: Simple Triage and Rapid Treatment	. 170
	9.4	PM2: Simple Triage and Rapid Treatment	. 172
	9.5	UC3: Data Visualisation System	. 172
	9.6	PM3: Data Visualisation System	. 174
	9.7	UC4: Advanced Medical Site Management	. 174
	9.8	PM4: Advanced Medical Site Management	. 176
	9.9	UC5: Clinical Parameters Collection System	. 176
	9.10	PM5: Clinical Parameters Collection System	. 177
	9.11	UC6: Operation Site Management	. 178
	9.12	PM6.1: Operation Site Management	. 180
	9.13	PM6.2: Operation Site Management	. 181
	9.14	UC7: Vehicle and Resource Management	. 181
	9.15	PM7: Vehicle and Resource Management	. 183
	9.16	UC8: Evaluation and Training	. 183
	9.17	PM8: Evaluation and Training	. 185
	9.18	UC9: Systems Integration	. 186
	9.19	PM9: Systems Integration	. 188

Figures

Figure 1: Human-driven use cases	167
Figure 2: System-driven use cases	167
Figure 3: Process Model 1 – Central Information System	170
Figure 4: Process Model 2 – Simple Triage and Rapid Treatment	172
Figure 5: Process Model 3 – Data Visualisation System	174
Figure 6: Process Model 4 – Advanced Medical Site Management	176
Figure 7: Process Model 5 – Clinical Parameters Collection System	178
Figure 8: Process Model 6.1 – Operational Site Management	180
Figure 9: Process Model 6.2 – Operation Site Management	181
Figure 10: Process Model 7 – Vehicle and Resource Management	183
Figure 11: Process Model 8 – Evaluation and Training	185
Figure 12: Process Model 9 – Systems Integration	188

Tables

Table 1: Service process model elements	163
Table 2: Use Case 1 - Central Information System	168
Table 3: Use Case 2 - Simple Triage and Rapid Treatment	170
Table 4: Use Case 3 - Data Visualisation System	172
Table 5: Use Case 4 - Advanced Medical Site Management	174
Table 6: Use Case 5 - Clinical Parameters Collection System	176
Table 7: Use Case 6 - Operation Site Management	178
Table 8: Use Case 7 - Vehicle and Resource Management	181
Table 9: Use Case 8 - Evaluation and Training	183
Table 10: Use Case 9 - Systems Integration	186

1 Terms and Definitions

Term	Definition
Casualty	It refers to the people who have been involved in the Mass Casualty Incident.
Casualty Profile	The Casualty Profile is a digital profile which shows all the collected information on the single casualty. It shall contain both information manually entered by the actors, and automatically collected by the iProcureSecurity PCP Solution
Dispatch Centre	It refers to permanent institutions for management of emergency call, messages, as well as alarming and coordination relief units. The Dispatch Centre has different responsibilities, depending on the county. It is identified as Category E.
iProcureSecurity PCP Solution	It refers to the final, comprehensive technical solution developed within the iProcureSecurity PCP project.
Mass Casualty Incident Area	It refers to the area where the Mass Casualty Incident happened.
Mass Casualty Incident	It refers to "an event that overwhelms the local healthcare system, where the number of casualties vastly exceeds the local resources and capabilities in a short period of time", following ISO 22300:2021
	The Mass Casualty Incident will be identified from the <i>iProcureSecurity PCP Solution</i> through a Mass Casualty Incident Profile.
Mass Casualty Incident Profile	It refers to the profile of the specific <i>Mass Casualty Incident</i> . The <i>Mass Casualty Incident Profile</i> will be identified from the <i>iPS PCP Solution</i> through a unique ID Reference Number and comprises all the information collected on the specific incident.
Treatment	It refers to the phase of the treatment, coming after the Simple Triage. The treatment phase begins as soon as the casualty is brought to the Advanced Medical Site (after being triaged) and it applies only in case a treatment is needed. The treatment phase may continue – if needed – in the ambulance, while the casualty is being transported to the hospital. The treatment phase ends as soon as the casualty is handed over to the hospital.
Triage Area(s)	It refers to the areas created at the <i>Mass Casualty Incident Area</i> , where the triaged casualties are located according to the status/colour code.
Triage Tag	It refers to the hardware component (Tag) which will be applied on the casualty after being triaged. The term <i>Triage Tag</i> is independent from the nature of the Tag, i.e., it could be an electronic tag, a bracelet, a badge, etc.
Simple Triage	The term Triage refers to an organised process that matches needs with available resources according to a priority scheme designed to achieve the end objective (i.e., goal) of the specific triage system.
	The Simple Triage in iProcureSecurity PCP project refers to the initial triage performed at the Mass Casualty Incident Area, as soon as the actors arrive. The Simple Triage follows an algorithm (e.g., START Algorithm).

2 Abbreviation

Abbreviation	Meaning
ΑΡΙ	Application Programming Interface
AMS	Advanced Medical Site
СМ	Change Management
EHR	Electronic Health Record
EMS	Emergency Medical Services
EMSS	Emergency Medical Services System
ICT	Information and Communication Technologies
MCI	Mass Casualty Incident
РСР	Pre-Commercial procurement
R&D	Research and Development
UC(s)	Use Case(s)

3 Requirements

The following sections present an overview of final requirements that were identified by the consortium. This ensures that suppliers understand clearly what is expected of them and there are no ambiguities in the way requirements are documented.

3.1Brief Methodology

Each requirement consists of an ID, name, a clear description and the defined priority for the Buyers Group. Most of the requirements was given a priority between 0 - 10. 0 represents not applicable and 10 represents the highest priority (must have). Those requirements which do not indicate a priority, are considered essential requirements, and they must be considered as such.

Most requirements are common to all procurers, but there are also some procurer-specific requirements included in the list (e.g., language requirements).

The iProcureSecurity PCP project has created a glossary of terms and definitions which is available as part of this document, in Chapter 1. The Terms and Definition table will facilitate the suppliers in understanding the requirements, but also the use cases and process models. It will therefore, increase the consistency of the document prepared by the consortium to avoid misinterpretation among relevant stakeholders (e.g., suppliers, experts).

The requirements are divided into:

Functional requirement

Functional requirements capture the intended behaviour of the system, i.e., what the system is expected to do. The functional requirements were structured according to the main challenges of the project.

Non-functional requirement

Non-functional requirements, or system qualities, capture required properties of the system, i.e., how well a given behavioural or structural aspect of the system should be accomplished. Non-functional requirements were allocated to one of the following categories: interoperability, connectivity, usability, performance, scalability, language. Furthermore, the set of vital parameters and measures is outlined.

Legal and Regulatory requirement

Legal requirements (e.g., data protection) include regulatory and standard aspects of the system. The section legal and regulatory requirements include aspects such as privacy, security and international regulations and certifications to be considered.

Organisational, staff and business requirements

The section organisational, staff and business requirements focus on topics such as installation of prototypes, procurement reporting and pilot feedback.

3.2 Functional Requirements

3.2.1 Quick and accurate overview of casualties and their status

ID	Requirement name	Related Use Case(s)	The iProcureSecurity PCP Solution shall	Priority
R 1.1.1	Role Management	UC1	differentiate between casualties and EMS practitioners, and between different roles of EMS practitioners.	10,0
R 1.1.2	Number of Casualties	UC3	display the number of casualties live, as they are being registered in the system.	10,0
R 1.1.3	Casualties Status	UC3	give an overview on casualty status (e.g. white, green, yellow, red, black).	10,0
R 1.1.4	Casualties Process Steps	UC3	give an overview on casualty process steps (e.g. field, triage tent, waiting for transport, in transport, hospital)	9,6
R 1.1.5	Location of casualties - Geolocation	UC2	show the actual geolocation of each registered casualty (e.g. on a map).	9,6
R 1.1.6	Casualty Identification - Scan ID Card	UC4	provide the possibility to scan ID Cards of casualties (e.g. after initial triage, before transport).	7,3
R 1.1.7	Casualty Identification - Save ID Photo	UC4	allow to include a photo of the casualty.	6,3
R 1.1.8	Casualty Identification - EHR Access	UC1, UC2, UC4, UC9	access casualties' medical history/EHR (electronic health record).	6,1
R 1.1.9	Triage Tags - Basics - Device	UC2	include a device that can be attached easily to the casualty in any condition.	10,0
R 1.1.10	Triage Tags - Basics - Triage Conducted	UC2	show if the casualty was already triaged.	10,0
R 1.1.11	Triage Tags - Basics - Allocate Unique ID	UC2	automatically provide a unique identifier for each casualty (one casualty one ID).	9,9
R 1.1.12	Triage Tags - Basics - Visible Dark	UC2	be visible in dark environments.	8,3
R 1.1.13	Triage Tags - Basics - Visible Afar	UC2	be visible from afar.	7,0

R 1.1.14	Triage Tags - Basics - Voice Commands	UC2, UC4	recognize voice commands.	6,6
R 1.1.15	Treatment - Central Information System	UC2, UC4	allow that the collected data on the casualty is sent to a central information system (to be further visualised and processed).	10,0
R 1.1.16	Treatment - Triage Guidance	UC2	guide the user (e.g. paramedic) through the triage algorithm.	9,6
R 1.1.17	Treatment - Dashboard	UC2, UC4	show the relevant information to EMS staff (primary triage, treatment, transfer).	9,6
R 1.1.18	Treatment - Triage Suggestion	UC4, UC5	support treatment based on vital signs.	8,9
R 1.1.19	Treatment - Triage Status Change	UC2, UC4	change status/colour based on vital signs.	8,6
R 1.1.20	Treatment - Triage History Offline Mode	UC2, UC4, UC5	have an integrated medical history of the case documenting all triage steps which can also be accessed when there is no network connection.	8,6
R 1.1.21	Treatment - Capture Vital Signs	UC2, UC5	be able to automatically determine the casualties' vital signs (see List of Parameters R 3.1.1 to R3.1.15).	8,3
R 1.1.22	Treatment - Vital Sign Change Alert	UC2, UC4, UC3, UC5	be able to alert EMS staff in case of status or vital signs get worse.	8,3
R 1.1.23	Treatment - EHR Connection	UC1, UC9	be able to connect to and include information of EHR if available.	7,1
R 1.1.24	Treatment - Store Casualty Injury Photos	UC4	be able to store photos of casualties and their injuries.	6,3
R 1.1.25	Treatment - Speech to Text Recording	UC2, UC4	be able to perform speech to text/ natural language processing (e.g. to support the documentation)	5,9
R 1.1.26	Treatment - Audio Warnings	UC4	provide audio warnings (e.g. casualty was already triaged).	5,7
R 1.1.27	Treatment - Blood Loss Alert	UC2, UC4, UC5	be able to indicate if casualty suffers from blood loss/internal bleeding.	5,4
R 1.1.28	Treatment - Augment Photos with Comments	UC4	be able to highlight photos of casualty with additional comments.	5,3

Triage Tag	g Essential Information			
R1.1.29	Triage Tag - Colour/status	UC2, UC4	display the colour/status of the casualty after having performed the first triage	10,0
Triage Tag	g Extended Information			
R1.1.30	Triage Tag - Heart Rate	UC2, UC4	display the heart rate values displayed of the casualty	8,0
R1.1.31	Triage Tag - Respiratory Rate	UC2, UC4	display the respiratory rate of the casualty	8,0
R1.1.32	Triage Tag - Arterial Oxygen Saturation	UC2, UC4	display the arterial oxygen saturation of the casualty	8,0
R1.1.33	Triage Tag - Blood Pressure	UC2, UC4	display the blood pressure of the casualty	8,0

What has to be visible in the casualty profile (e.g. mobile or tablet) that reads and saves data on the triage tag

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Casualty Profile Information	
cusually r rojne mjormation	

It indicates additional	information through	h the interface of	of device that reads	/writes data on the	e triage tag.
	,	,			5 5

R 1.1.34	Casualty Profile - Read/Write Stabilization	UC2, UC4	indicate information on what has been done to stabilize the casualty for transportation	10,0
R 1.1.35	Casualty Profile - Read/Write Airway	UC2, UC4	indicate information on airway (airway blockage, cervical spine injury)	10,0
R 1.1.36	Casualty Profile - Read/Write Breathing	UC2, UC4	indicate information on breathing (Tension pneumothorax, pulmonary oedema, bronchospasm)	10,0
R 1.1.37	Casualty Profile - Read/Write Circulation	UC2, UC4	indicate information on circulation (Shock - hypovolemic, obstructive, disruptive, cardiogenic)	10,0
R 1.1.38	Casualty Profile - Read/Write Disability	UC2, UC4	indicate information on disability (Seizure, hypoglycaemia, meningitis, intracranial haemorrhage or infarction, intoxication)	10,0
R 1.1.39	Casualty Profile - Read/Write Exposure	UC2, UC4	indicate information on exposure (Hypothermia or hyperthermia, critical skin conditions)	10,0
R 1.1.40	Casualty Profile - Read/Write Neurological Condition	UC2, UC4	indicate information on neurological condition	10,0
R 1.1.41	Casualty Profile - Read/Write Pain / Sedation for Pain	UC2, UC4	indicate information on pain / sedation for pain	10,0
R 1.1.42	Casualty Profile - Read/Write Bleeding / Fractures/ Injuries	UC2, UC4	indicate information on bleeding / fractures/ injuries conditions	10,0
R 1.1.43	Casualty Profile - Read/Write Child/Adult	UC2, UC4	indicate information on distinction child/adult	10,0
R 1.1.44	Casualty Profile - Read/Write CBRN	UC2, UC4	indicate information on CBRN conditions	10,0
R 1.1.45	Casualty Profile- Read/Write Injury Location	UC2, UC4	indicate information on the location of the injuries	10,0
R 1.1.46	Casualty Profile - Read/Write Pregnancy	UC2, UC4	indicate information on pregnancy status	10,0
R 1.1.47	Triage Algorithm - Switch Algorithm	UC1	be able to perform different standard algorithms for adults and children (START, JumpSTART etc.).	10,0
R 1.1.48	Triage Algorithm - Adapt Algorithm	UC1	allow procurer to easily adapt triage algorithm according to own needs (incl. using own terminology).	10,0
R 1.1.49	Triage Algorithm - Step by Step	UC2	be able to perform triage algorithms step by step.	9,3
R 1.1.50	Triage Algorithm - Select Algorithm	UC1	allow procurer to select from existing triage algorithms.	9,8

3.2.2 Decision support for better allocation of available resources and quicker support of casualties

ID	Requirement name	Related Use Case(s)	The iProcureSecurity PCP Solution shall	Priority
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D 4 2 4		1161	allow users to set preferences (e.g. language) which are	10.0
R 1.2.1	User Preferences	001	stored with the user account and / or as cookies.	10,0
R 1.2.2	User Enrolment and Roles Allocation	UC1, UC6	allow the enrolment of new users and the allocation of roles.	10,0
R 1.2.3	Onsite Management - Highlight Areas	UC6	automatically highlight areas to go / not to go.	10,0
R 1.2.4	Onsite Management - Central Data Collection/Access	UC6	collect all relevant data and allow particular roles to access it.	9,7
R 1.2.5	Onsite Management - Display Casualties Vital Signs	UC3, UC5	display the vital signs of the casualty (see List of Parameters R 3.1.1 to R3.1.15).	9,1
R 1.2.6	Onsite Management - Roles Checklist	UC6	include checklists of important actions and things to take into account for EMS staff onsite.	9,1
R 1.2.7	Onsite Management - Aggregated Information	UC6, UC7	provide a dashboard with main information (e.g. casualties, staff, resources).	9,1
R 1.2.8	Onsite Management - Save/Display Casualty Journey	UC1, UC2, UC4	captures and saves data from beginning of triage until casualties arrive in hospital (hand over process).	8,9
R 1.2.9	Onsite Management - Save/Display Location	UC6	show the exact location of the emergency.	8,7
R 1.2.10	Onsite Management - Save/Display Resources/Materials	UC7	provide an overview on all resources coming in and go out.	8,6
R 1.2.11	Onsite Management - Map Tool	UC6, UC7	provide cartographic tools using aerial images for onsite planning (e.g. to mark important areas).	8,3
R 1 2 12	Onsite Management - Save/Display Location of Resources/Materials	UC7	geolocate all resources and visualise them on a man	83
R 1.2.13	Onsite Management - Collect/Display Information on Place	UC6	provide information on the place (e.g. possible accesses, recommended traffic detours, existence of inhabited, industrial places, waterways).	7,9
R 1.2.14	Onsite Management - Share Information on Place	UC6	provide information on the scene (e.g. area designated, boundaries, AMP with tents for each category, etc) also to other actors at the scene.	7,9
R 1.2.15	Onsite Management - Request new Resources/Materials	UC7	allow to request new materials and operational resources.	7,4
R 1.2.16	Onsite Management - Map Triage Areas	UC6	clearly show the triage areas.	7,4
R 1.2.17	Onsite Management - Save/Display Scenario Guidelines	UC6	highlight specific approaches/guidelines to be considered for different scenarios.	7,3
R 1.2.18	Onsite Management - Save/Display Staff Objectives	UC6	indicate objectives and priorities to the different actors involved.	7,1
R 1.2.19	Onsite Management - Guide Advanced Medical Site Setup	UC6	support the setup and maintenance of Advanced Medical Site (small hospital) in the major incident area.	7,1

R 1 2 20	Onsite Management - Display Casualties Injuries		display photos of casualties and their injuries	7.0
N 1.2.20	Onsite Management -	000,004		7,0
R 1.2.21	Share Information on Surroundings	UC6	provide a connection to other first responders (e.g. to inform persons living in the surrounding)	6,7
R 1.2.22	Onsite Management - Display Weather Conditions	UC6	provide information on weather conditions.	6,4
R 1.2.23	Onsite Management - Display Traffic Conditions	UC6, UC7	provide information on traffic conditions.	6,3
R 1.2.24	Decision Support - Casualties Status	UC6, UC7	provide decision support based on status of the casualty.	10,0
R 1.2.25	Decision Support - Required Hospitals	UC6, UC7	provide decision support on required type of hospital infrastructure (e.g. specialists for particular emergency/injuries).	10,0
R 1.2.26	Decision Support - Transportation	UC6, UC7	provide decision support which means of transportation (land, air) should be used.	9,4
R 1.2.27	Decision Support - Number of Hospitals	UC6, UC7	provide decision support on required number hospital infrastructure (e.g. ICU beds).	9,4
R 1.2.28	Decision Support - Number of Vehicles	UC6, UC7	provide decision support on required number of vehicles.	9,0
R 1.2.29	Decision Support - Types of Vehicles	UC6, UC7	provide decision support on required types of vehicles.	7,7
R 1.2.30	Decision Support - Number of Personnel	UC6, UC7	provide decision support on required number of personnel.	7,6
R 1.2.31	Decision Support - Type of Personnel	UC6, UC7	provide decision support on required types of personnel.	7,1
R 1.2.32	Decision Support - Quantity of Resources	UC6, UC7	provide decision support on required quantity of logistic resources (supplies).	6,9
R 1.2.33	Decision Support - Type of Resources	UC6, UC7	provide decision support on required type of logistic resources (supplies).	6,9
R 1.2.34	Decision Support - Environmental Conditions	UC6	provide decision support based on environmental conditions (e.g. weather).	6,4
R 1.2.35	Decision Support - Surroundings	UC6	provide decision support based on surrounding population, buildings and other vulnerable elements.	6,3
D 1 2 20	Decision Support -	1166		6.2
R 1.2.36	Perimeter	UC6	propose the perimeter of the area to be isolated.	6,3
R 1.2.37	Suggest Zones	UC6	zoning (e.g. distinction between red and green zone).	6,3
R 1 2 38	Decision Support - Display Incident Assessment		automatically make an assessment of the MCI based on type of event, location and environmental conditions (e.g., weather traffic)	6.0
11 1.2.30	Staff Management -		visualize the position of staff in the area on a map (only	0,0
R 1.2.39	Display Staff Location	UC6	onsite during triage management).	8,0
R 1.2.40	Staff Management - Define Staff Types	UC6	be able to capture special groups, staff and volunteers.	6,4

R 1.2.41	Staff Management - Check-in/Check-out Staff of Location	UC7	provide the possibility to register (check-in/check-out) staff entering or leaving the site.	5,9
R 1.2.42	Staff Guidance - Initial MCI Assessment	UC1	allow customizable initial MCI assessments (example METHANE Assessment)	9,5
R 1.2.43	Staff Guidance - Read/Write Checklist/Guidance Cards	UC3	allow to check off completed tasks (interactive checklists with alerts).	9,4
R 1.2.44	Staff Guidance - Display Staff Guidance	UC2	give easy to follow "first-aid" guidance for staff.	9,4
R 1.2.45	Staff Guidance - Task Reminder	UC3	trigger certain tasks from the checklist and remind staff.	9,3
R 1.2.46	Staff Guidance - Adapt Checklist/Guidance Cards	UC1	provide customizable digital version of guidance cards and checklists for all actors.	9,1
R 1.2.47	Logistics - Updates	UC4, UC6, UC7	help to update the logistics department to provide new supplies.	7,0
R 1.2.48	Logistics - Database Connection	UC1, UC9	be able to connect to material database and synchronize with iProcureSecurity PCP Solution.	7,0
R 1.2.49	Logistics - Provide Resource Overview	UC4, UC6, UC7	provide real time information on available materials.	6,9
R 1.2.50	Logistics - Supply Chain Support	UC4, UC6, UC7	help the supply chain.	6,7
R 1.2.51	Logistics - Write Resource Usage	UC4, UC6, UC7	record usage of materials for each casualty.	5,4

3.2.3 Improved coordination and communication among EMS stakeholders

ID	Requirement name	Related Use Case(s)	The iProcureSecurity PCP Solution shall	Priority
R 1.3.1	Data Sharing with EMS - Record Casualty Journey	UC1	record all steps performed on the casualties.	10,0
R 1.3.2	Data Sharing with EMS - Share Information Red Zone	UC1	share information about red zones / danger zones.	8,4
R 1.3.3	Data Sharing with EMS - Dispatch Centre	UC1	be able to store and exchange images (e.g. to share it with Dispatch Centre).	7,9
R 1.3.4	Data Sharing with EMS - Push to Talk	UC1	provide push to talk functionality.	7,4
R 1.3.5	Data Sharing with EMS - Guidance on Treatment	UC1	provide remote medical guidance to healthcare teams in the field.	6,6
R 1.3.6	Communication - Fail Safety Store Data	UC1, UC2, UC4, UC6, UC7	store messages/data when communication is blocked.	10,0
R 1.3.7	Communication - Fail Safety Timestamps	UC1, UC2, UC4, UC6, UC7	show clear timestamps for all main information.	9,0
R 1.3.8	Communication - Fail Safety Timestamp Alert	UC1, UC2, UC4, UC6, UC7	highlight if timestamps are outdated (e.g. due to missing network connection).	7,9

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ID	Requirement name	Related Use Case(s)	The iProcureSecurity PCP Solution shall	Priority
R 1.4.1	Data Sharing with EMS - Share Information on Hospitals	UC3, UC9	show available hospital infrastructure (number, types).	10,0
R 1.4.2	Data Sharing with EMS - Share Information on Hospital Capacity	UC3, UC9	show current capacity of hospitals (e.g. free ICU beds, operating theatres etc.).	10,0
R 1.4.3	Data Sharing with EMS - Alert Hospitals	UC3	alert hospitals which casualties are transported to them.	9,0
R 1.4.4	Data Sharing with EMS - Share Information on Casualties	UC3, UC9, UC5	be able to send clinical information of casualties to hospitals before they arrive.	9,0

3.2.5 Insights for quality assurance and training measures

ID	Requirement name	Related Use Case(s)	The iProcureSecurity PCP Solution shall	Priority
R 1.5.1	Evaluation - Report Number of Casualties	UC8	reports on number of casualties and their status.	10,0
R 1.5.2	Evaluation - Store Data	UC8	store all data that allows evaluation after the MCI.	10,0
R 1.5.3	Evaluation - Store Internal Communication	UC8	document/report internal communication.	10,0
R 1.5.4	Evaluation - Report Hospital Number and Type	UC8	be able to report on the available/used hospitals in the area, their occupancy rate and their focus for certain injuries/treatments.	10,0
R 1.5.5	Evaluation - Report Event Timeline	UC8	be able to store and visualize the timeline of the MCI.	9,1
R 1.5.6	Evaluation - Automatic Standardized Reports Internal	UC8	provide automatically a standardized report after the end of the MCI.	8,6
R 1.5.7	Evaluation - Store External Communication	UC8	document/report external communication (e.g. with other First Responders).	8,3

R 1.5.8	Evaluation - Automatic Standardized Reports External	UC8	create automatic reports that can be shared with externals (e.g. civil protection board).	8,3
R 1.5.9	Evaluation - Map View	UC8	be able to show a map of the scene with allocation of different areas (e.g. triage tent, transport etc.).	7,7
R 1.5.10	Evaluation - Report Vehicle Number and Type	UC8	be able to report on the number and type of vehicles used in the MCI.	7,6
R 1.5.11	Evaluation - Operational Structure	UC8	report on the operational structure that was applied.	7,6
R 1.5.12	Evaluation - Environmental Factors	UC8	report on environmental factors (e.g. areas that are hard to reach, weather, routes/traffic).	6,6
R 1.5.13	Evaluation - Voice Commands	UC8	be able to collect data also by voice commands.	6,6
R 1.5.14	Evaluation - Report Equipment	UC8	report on the used equipment.	5,9
R 1.5.15	Evaluation - Store/Display Scene Images	UC8	show in the report images from the scene.	5,4
R 1.5.16	Evaluation - Store/Display Emergency Calls	UC8	be able to save the number of emergency calls for the MCI.	4,4
R 1.5.17	Evaluation - Operation Efficiency	UC8	report on the efficiency of the operation.	3,6
R 1.5.18	Evaluation - Operation Role Performance	UC8	report on the performance of particular roles.	3,4
R 1.5.21	Training - Simulation Mode	UC8	offer a simulation mode which uses dummy data for the training	10,0
R 1.5.19	Training - Interactive Checklists	UC8	use interactive checklists for training.	7,7
R 1.5.20	Training - Simulation of MCI	UC8	offer data for disaster simulation to be used on the training field.	7,7
R 1.5.22	Training - Extended and Interoperable Training Solutions	UC8	offer machine readable data coming from the evaluation to be used for external training solutions (i.e. MR/AR/VR etc.)	6,4

3.3 Non-Functional Requirements

3.3.1 Interoperability

ID	Requirement name	The iProcureSecurity PCP Solution shall	Priority
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R 2.1.1	Interoperability - Harmonized Terminology	use a harmonized terminology, following ISO 22320:2018 and ISO 22300:2018.	9,7
R 2.1.2	Interoperability - Data Sharing From Third Parties	allow open and flexible data sharing (e.g API) from third parties existing or upcoming solutions	9,7
R 2.1.3	Interoperability - Data Sharing To Third Parties	allow open and flexible data sharing (e.g API) to third parties existing or upcoming solutions	9,7
R 2.1.4	Interoperability - Central Information System API Endpoint	be able to instantly share information with all other EMS stakeholders via a central information system.	9,6
R 2.1.5	Interoperability - Information Flows	improve information flows between the different levels of care (primary care, specialized care and emergencies).	9,6
R 2.1.6	Interoperability - Mobile Application	allow to collect data with a mobile application.	9,4
R 2.1.7	Interoperability - Data Sharing Hospital	ensure a quick and complete handover of data to the hospital (using machine readable format)	9,4
R 2.1.8	Interoperability - Real-Time Updates	constantly update the data based on the evolution of the scenario.	9,4
R 2.1.9	Interoperability - Data Sharing EMCC	have real time connection with Dispatch Centre.	9,3
R 2.1.10	Interoperability - Data Sharing EMS	have an integrated communication system for emergency management.	9,1
R 2.1.11	Interoperability - Automatised Data Collection	facilitate automatisation of data collection to prepare/manage the site.	9,0
R 2.1.12	Interoperability - Data Sharing EMS Crews	support handover processes between EMS crews.	8,7
R 2.1.13	Interoperability - Data Sharing Other First Responders	collect harmonized data.	8,7
R 2.1.14	Interoperability - Data Sharing Other First Responders	be able to instantly share information with other First Responders (e.g., fire rescue, police, military).	8,0
R 2.1.15	Interoperability - Telemedicine Tools	be able to connect to existing telemedicine and e-diagnostic tools.	7,7
R 2.1.16	Interoperability - Telemedicine Support	allow remote medical support of healthcare teams in the field (e.g. video calls).	6,6
R 2.1.17	Interoperability - EHR	provide connection with available EHR.	6,3

3.3.2 Connectivity

ID	Requirement name	The iProcureSecurity PCP Solution shall	Priority
R 2.2.1	Connectivity - Mobile Network	use available mobile networks.	10,0
R 2.2.2	Connectivity - Local Network	be able to run without public networks (e.g., can establish local network).	9,7
R 2.2.3	Connectivity - 5G	be compatible with 5G.	9,0
3.3.3 Usability

ID	Requirement name	The iProcureSecurity PCP Solution shall	Priority
R 2.3.1	Usability - Device Support	run on mobile phones, tablets and laptops.	10,0
R 2.3.2	Usability - Ease of use	be easy to use and maintain.	10,0
R 2.3.3	Usability - No Training	be usable without the need for special training.	10,0
R 2.3.4	Usability - Flexible Scenarios	be usable in any kind of scenario.	10,0
R 2.3.5	Usability - Triage Tag Environmental Conditions	be unaffected by environmental conditions (e.g darkness, fluids, dust, extreme temperatures, resistant to physical impacts etc.).	9,6
R 2.3.6	Usability - Triage Tag Reusability	be reusable after use.	9,4
R 2.3.7	Usability - Triage Tag Hygiene	be easy to clean.	9,4
R 2.3.8	Usability - Triage Tag Non- Allergic	be non-allergic (skin contact).	9,4
R 2.3.9	Usability - Visualizations	offer all data in a visual easy to digest way.	9,4
R 2.3.10	Usability - Quick Decision Making	support quick decision making.	9,4
R 2.3.11	Usability - Flexible Checklists	provide an easily adaptable checklist.	9,4
R 2.3.12	Usability - Central Monitoring	allow central monitoring of all data including casualties' vital signs (e.g. to minimize staff for re-triage).	9,3
R 2.3.13	Usability - Triage Tag Undisturbed	not interfere with the treatment.	8,7
R 2.3.14	Usability - Triage Tag Small Size	have a small size/form factor (especially the triage tag).	8,7
R 2.3.15	Usability - Language	provide multi language support.	8,3
R 2.3.16	Usability - Primary Triage and Treatment	be used for primary triage and treatment.	7,9
R 2.3.17	Usability - Guide Triage	provide advice to the actors performing triage steps.	7,6
R 2.3.18	Usability - Scenario Evaluation	shall support optimization of handling Mass Casualty Incidents (MCIs).	7,6

3.3.4 Performance

ID	Requirement name	The iProcureSecurity PCP Solution shall
R 2.4.1	Performance - Capacity Users	support a sufficient number of simultaneous users accessing the iProcureSecurity PCP Solution.
R 2.4.2	Performance - Capacity Data (any)	support a sufficient number of data entries of any kind without loss of data and without restrictions to any user type.
R 2.4.3	Performance - Latency and Response Time	be usable with low latency and reasonable response time.
R 2.4.4	Performance - Actors	support different roles/actors.
R 2.4.5	Performance - Offline Behaviour	work well when there is no internet connection (e.g. caching of changes).

3.3.5 Scalability

ID	Requirement name	The iProcureSecurity PCP Solution shall
R 2.5.1	Scalability - Extendibility	be able to allow for new functionality (e.g. adding a new parameter) to be included in one or more parts of the solution.
R 2.5.2	Scalability - Instantiating	be able to be reproduced in a similar setting in form of a new instance (e.g. another EMS provider).
R 2.5.3	Scalability - Reproducibility	be easily reproducible/replicable to large amounts of users across different geographic regions.
R 2.5.4	Scalability - Interfaces	provide the necessary interfaces based on the different user roles.

3.3.6 Language

ID	Requirement name	The iProcureSecurity PCP Solution shall
R 2.6.1	Language - English	be available in English.
R 2.6.2	Language - German	be available in German.
R 2.6.3	Language - Greek	be available in Greek.
R 2.6.4	Language - Italian	be available in Italian.
R 2.6.5	Language - Spanish	be available in Spanish.
R 2.6.6	Language - Turkish	be available in Turkish.
R 2.6.7	Language - Flexibility	allow to add additional languages easily.
R 2.6.8	Language - Terminology	allow to change terminology easily.

3.4 Parameters/Measuring Units Requirements

ID	Requirement name	Measure
	(Desirably) automatically	measured vital parameters
R 3.1.1	Casualty Respiration	Yes/No
R 3.1.2	Casualty Respiratory Rate	Breaths per minute (bpm)
R 3.1.3	Casualty Airway Condition	Patent /Not Patent
R 3.1.4	Casualty Radial Pulse	Yes/No
R 3.1.5	Casualty Blood Oxygen Saturation	SpO2 (SAT02)
R 3.1.6	Casualty Blood Pressure	mm Hg

R 3.1.7	Casualty Body Temperature	٥C
R 3.1.8	Casualty Cardiac Frequency	Beats per minute (bpm)
	Manually measure	ed vital parameters
R 3.1.9	Casualty CBRN Status	Yes/No (chemical, biological, radiological, or nuclear)
R 3.1.10	Casualty Walking	Yes/No
R 3.1.11	Casualty Consciousness	Yes/No
R 3.1.12	Casualty Follow Simple Commands	Yes/No
R 3.1.13	Casualty Capillary Refill	Less than 2s/ More than 2s
R 3.1.14	Casualty Pregnancy Status	Yes/No
R 3.1.15	Casualty Pain Measurement	1 - 10 (Low - high)

3.5 Legal and Regulatory Requirements

3.5.1 Security

ID	Requirement Name	The iProcureSecurity PCP Solution shall
R 4.1.1	Security - Confidentiality	information is not made available or disclosed to unauthorized individuals, entities, or processes
R 4.1.2	Security - Integrity	ensure highest data security and data integrity.
R 4.1.3	Security - Availability	the IT systems used to store and process the information, the security controls used to protect it, and the communication channels used to access it must be functioning correctly
R 4.1.4	Security - Access Control: Authentication & Authorization	enable authentication using existing or preferred authentication techniques of the eight procurers. be able to ensure only the authorized roles have access to data that is relevant for them.
R 4.1.5	Security - Policy	develop a security policy with respect to the processing of personal data.
R 4.1.6	Security - Risk Impact Assessment and mitigation plans	The solution shall undertake an impact assessment of potential security and privacy risks arising because of the use of each service provided. The bidding companies should ensure that: • they follow the privacy-by-design and security-by-design approach to secure their complete infrastructure and building blocks. • services are not vulnerable to attacks which might interrupt their operation and cause data theft or data damage; and • they are compliant with the legal requirements and obligations regarding data protection and privacy acknowledging the risks to privacy from advanced data processing and analytics.
R 4.1.7	Security - Strategy	develop a strategy for the case that, despite the security measures, a breach of security occurs (e.g. this can be theft, deliberate attack on the systems, unauthorised use of data by staff members, etc.).

R 4.1.8	Security - Measure Encryption	provide necessary equipment and measures to ensure user and data privacy by encrypting to recent standards all account related information and / or other databases.
R 4.1.9	Security - Measure Firewall	provide necessary equipment and measures to ensure user and data privacy by installing a firewall.
R 4.1.10	Security - Measure HTTPS	provide necessary equipment and measures to ensure user and data privacy by only allowing access to data through a https-encrypted web connection.
R 4.1.11	Security - Measure Intranet	provide necessary equipment and measures to ensure user and data privacy by allowing access to data only within a restricted domain and / or intranet.
R 4.1.12	Security - Measure VPN	provide necessary equipment and measures to ensure user and data privacy by allowing access to data, if applicable inside and / or outside of the restricted domain, via a virtual private network (VPN).
R 4.1.13	Security - Authentication	enable authentication using existing or preferred authentication techniques of the eight procurers.
R 4.1.14	Security - Measure Secure Network protocol	The solution shall provide the use of secure network protocols for accessing applications and secure applications for data transmission
R 4.1.15	Security - Record and audit	The solution shall provide a logging system for keeping evidence of policy breaches e.g., unauthorized access to personal and/or health information of old adults and caregivers.
R 4.1.16	Security - Breach Notification	notify the users in case of security breaches by explaining the nature of the breach, contact information about the organisation and how the users can mitigate any possible adverse impact of the breach.
R 4.1.17	Security - Business Continuity and Disaster Recovery	The solution shall provide to put in place the procedures needed for functions to operate after a disastrous event and bring all functions back to normal the earliest possible.
R 4.1.18	Security - Incident	ensure a timely response to incidents reported by the national Computer Emergency Response Team (CERT).
R 4.1.19	Security - Profile	develop a security profile which can be certified according to Common Criteria for Information Technology Security Evaluation (ISO/IEC 15408).

3.5.2 Privacy

ID	Requirement Name	The iProcureSecurity PCP Solution shall
R 4.2.1	GDPR Compliance	ensure full compliance with GDPR.
R 4.2.2	Privacy - Policy	develop a privacy policy with respect to the processing of personal data, inc. pseudonymised data.
R 4.2.3	Privacy - Policy Communication	provide the user with complete information on its privacy and security policies during registration and later through navigation in the user interface.
R 4.2.4	Policy - Enforcement	ensure disciplinary measures will be adopted in cases where any breach of the policy occurs
R 4.2.5	Privacy - Access Control	govern access to the solution by username and secure password (in compliance with regional/national/European data protection legislation).
R 4.2.6	Privacy - Access Record	create an audit trail of access, and provide access to such audit trail if requested by the casualty.
R 4.2.7	Privacy - Casualty Access	have the capacity to provide casualties with access to data concerning them or their care in an understandable and shareable format.
R 4.2.8	Privacy - Consent Form	provide a consent form in either written and / or in electronic form for the pilot and testing phases.

R 4.2.9	Privacy - Consent Treatment	Consent to use of iProcureSecurity PCP tool will be informed, explicit, unambiguous and recorded for the pilot and testing phases.
R 4.2.10	Privacy - Consent Research	Consent to re-use data for research purposes will be collected separately from consent to use data for care purposes. Data used for research purposes will be anonymised or pseudonymised format if possible.
R 4.2.11	Privacy - Consent Withdrawal	allow for withdrawal of the individual's consent either written and / or in electronic form. A policy in deletion or not if already collected information will be adopted, for the pilot and testing phases.
R 4.2.12	Privacy - Data Correction	allow for any individual requesting to correct data related to his or her data where an error is found, such correction should be visible.
R 4.2.13	Privacy - Consent Marketing	require specific cornet to provide marketing material in any form prior to inclusion in any marketing action.
R 4.2.14	Privacy - Cookies	provide the user (prior to a successful registration and users' acceptance) with information about the purpose of storage or access to information gathered by cookies and ask for the user's consent to use such type of devices.
R 4.2.15	Privacy - Disclosure	use disclosure due to its nature of being a project involving different partners and the need of evaluation on an international level.
R 4.2.16	Privacy - Data Breaches	report any breaches of the data system.
R 4.2.17	Privacy - Data subject's rights	guarantee the management of requests to exercise the rights of the interested party, in a standardized manner and in compliance with the provisions of the GDPR
R 4.2.18	Privacy - processing activity register	All Data Controllers and Data Processors must establish the Register of processing activities, the contents of which are indicated in article 30 of the GDPR
R 4.2.19	Privacy - Identification of IT security measures	guarantee the identification and application of technical measures aimed at guaranteeing the confidentiality, integrity and availability of data and system resilience

3.5.3 Regulations

ID	Requirement Name	The iProcureSecurity PCP Solution shall	Priority
R 4.3.1	Regulations - Organisation MCI Protocols	comply with the existing protocols and regulations for MCIs in each organization.	10,0
R 4.3.2	Regulations - European MDR	use sensors to measure and collect certain parameters. In such cases, the devices offered shall be in line with the European Medical Device Regulation (REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL)	10,0

3.6 Organisational Staff and Business Requirements

3.6.1 Installation of prototypes and systems

ID	Requirement Name	The iProcureSecurity PCP Solution developers will

R 5.1.8	Interoperability - Pilot API Legacy Software	be compatible with existing software in the procurers' organisations.
R 5.1.7	Interoperability - Pilot API Legacy Systems	be able to exchange information (read and write data) with the systems of the Austrian/Greek/Italian /Spanish/Turkish procurers. Details about the relevant systems are provided in the challenge brief and further details can be obtained during the PCP.
R 5.1.6	Interoperability - Pilot Servers	be hosted on servers physically located in EU and/or the countries of the pilots according to GDPR and national laws.
R 5.1.5	Helpdesk and Maintenance Support	set-up and operate a help service and maintenance response team during the pilot operation to address problems faced by end-users. This service will be provided at each of the sites.
R 5.1.4	Pilot Operation Maintenance	maintain the operation of all systems at each site at full quality for the duration of the pilot. A team will be available to the site management to physically and/or remotely resolve any issues and problems that prevent the system from working as desired.
R 5.1.3	Pilot System Introduction	introduce the pilot system at the premises of each of the procurers in close collaboration with procurer representatives. System introduction includes installation of the solution and preparation of all necessary equipment and processes that are necessary for the solution to work. On-site testing will be done to reveal and resolve any issues that prevent the system from working properly at the premise (e.g. during exercises).
R 5.1.2	Prototype Installation V2	install and demonstrate the necessary prototype system v2 at the premises of each of the procurers. Alternatively, the developer will provide access to a lab environment in order to test the prototype by at least 10 users of each of the eight procurers.
R 5.1.1	Prototype Installation V1	install and demonstrate the necessary prototype system v1 at the premises of each of the procurers. Alternatively, the developer will provide access to a lab environment in order to test the prototype by at least 10 users of each of the procurers.

3.6.2 Procurement Reporting

ID	Requirement Name	The iProcureSecurity PCP Solution developers will
R 5.2.1	Procurement Reporting - Phase 1 Status Updates	report on the progress of "Phase 1: iProcureSecurity PCP Service Models & Specifications" in monthly status calls.
R 5.2.2	Procurement Reporting - Phase 2 Status Updates	report on the progress of "Phase 2: iProcureSecurity PCP Prototype Systems" in monthly status calls. This applies to both periods - prototype v1 and v2.

R 5.2.3	Procurement Reporting - Phase 3 Status Updates	report on the progress of "Phase 3: iProcureSecurity PCP Implementation & Operational Testing" in monthly status calls.
R 5.2.4	Procurement Reporting - Helpdesk	report on the progress of the work related to running a helpdesk and a response team to address problems faced by end-users in monthly status calls. This service will be provided at each of the procurer sites.
R 5.2.5	Procurement Reporting - Quality Management	provide a quality management strategy which may also support for certifying the solution as medical device (if necessary). International standards may apply.

3.6.3 Pilot Feedback

ID	Requirement Name	The iProcureSecurity PCP Solution shall
R 5.3.1	Pilot Feedback - Evaluation Section	contain a section which can be easily adapted in order to implement various modes of evaluation and feedback instruments.
R 5.3.2	Pilot Feedback - Evaluation Questionnaires	enable the display and answering of evaluation questionnaires to be filled out by end users.
R 5.3.3	Pilot Feedback - Bug reports	enable a simple, easy to use error/bug reporting and general feedback module that allows end users to almost instantly submit feedback on the solution.
R 5.3.4	Pilot Feedback - FAQ	contain a section with an FAQ.

4 **Procurers IT System Interoperability**

The "Procurers IT Systems Checklist" reports the current systems used by the procurers, which are wished to be integrated as part of the iProcureSecurity PCP Solution. Each procurer provided one or more systems.

Procurer	Services AREA (drop-down list)	Information system – description (free record)	Functionality Description (free record)	Management level (drop-down list)	DATA Type (Dataset) (drop- down list)	IT System Architectur e (drop- down list)	IT System Architecture (NOTE) (free record)	Interoperability Standard (drop-down list)	Interoperability Standard (NOTE) (free record)	Authorization and authentication Method (free record)	Data encrypting (drop- down list)	Pseudony mization of personal data
EPES	Emergency	112 calls management software		REGIONAL	Generic Data				most likely not open	user/password in active directory		
EPES	Emergency	EMCC management software		REGIONAL	Generic Data				most likely not open	user/password in active directory		
EPES	Emergency	EMS clinical records system		REGIONAL	Health Data				most likely not open	user/password in active directory		
SERMAS	Emergency	112 calls management software		REGIONAL	Generic Data				most likely not open	user/password in active directory		
SERMAS	Emergency	EMCC management software		REGIONAL	Generic Data				most likely not open	user/password in active directory		
SERMAS	Emergency	EMS clinical records system		REGIONAL	Health Data				most likely not open	user/password in active directory		
ARC	Emergency	Management Health Emergency	An open interface should be created where other systems can output data ("GET") or deliver data		Generic Data				e.g. based on JSON			

			("PUT") according to specified calls.								
ARC	Emergency	Management Health Emergency	A WEB-interface should be created for the Information System, which hospitals or control centres can call up via the Internet and, after user authentication (authorisation system), can view or call up the necessary data		Generic Data						
ARC	Emergency	ECG System	ECG systems that can transmit data to an IT system and thus, integrate it into the system		Health Data						
ASLBN	Administrative	Digital Identity Card (CID)	Citizens Digital Identification	NATIONAL	Identificati on Data	Web Application - Provider Cloud	HL7 - XML		Username/password SPID (Public System Identity Digital)	Yes	Yes
ASLBN	Administrative	Assisted Registry - Health Card	Healthcare Patient identification and Registry	NATIONAL	Identificati on Data	Web Application - Provider Cloud	HL7 - XML		Username/password SPID (Public System Identity Digital)	Yes	Yes
ASLBN	Administrative	Assisted Regional Registry (ARA) – Healthcare Facilities Registry (ASS) – Healthcare Operators Registry	Assisted Regional Registry (ARA) – Healthcare Facilities Registry (ASS) – Healthcare Operators Registry	REGIONAL	ldentificati on and Health Data	Web Application - Provider Cloud	HL7 - XML		Username/password	Yes	Yes
ASLBN	Healthcare	National Electronic		NATIONAL / REGIONAL	Identificati on and	Web Application	HL7 - Other:	Italian health report standard - CDA2	Different access method for citizen: SPID (Public System Identity Digital)	Yes	Yes

		Health Record (FSE)			Health Data	- Provider Cloud				Admin.Operetators: Username/password Health Operators: Username/password/ pincode		
ASLBN	Healthcare	Territorial Clinical Record		CORPORATE	Identificati on and Health Data	Web Application - Provider Cloud		HL7 - XML - DICOM		Username/password	Yes	Yes
ASLBN	Emergency	Management Health Emergency Call	Management Health Emergency Call	CORPORATE / REGIONAL	Identificati on and other sensitive Data	Web Application - Provider Cloud		XML		Username/password	No	No
AREU	Emergency	Computer Aided Dispatching and Emergency Management	Management of all the activities in the EMS chain: from the call to the delivery to the hospital, including the management of resources and of clinical data/information	REGIONAL	Identificati on and other sensitive Data	Web Application / App - Private Cloud	The interface with external system is realised through a specific "broker"	Other	The communication is through web services and JSON messages	Username/password	No	No
AREU	Healthcare	Territorial Clinical Record		CORPORATE	Identificati on and Health Data	Web Application - Provider Cloud		HL7 - XML - DICOM		Username/password	Yes	Yes
HRC	Administrative	A set of mobile tools to conduct surveys and collect data	HRC Beneficiaries Digital Identification	NATIONAL	Identificati on and other sensitive Data	Web Application / App - Company Server		XML		User Name/Password	Yes	Yes
HRC	Healthcare	A set of mobile tools to conduct surveys and collect data	Digital health and protection records	NATIONAL	Identificati on and Health Data	Web Application / App - Company Server		XML		User Name/Password	Yes	Yes

HRC	Social care	A set of mobile tools to conduct surveys and collect data	Digital social and protection records	NATIONAL	Identificati on and other sensitive Data	Web Application / App - Company Server	XML		User Name/Password	Yes	Yes
HRC	Emergency	A set of mobile tools to conduct surveys and collect data	Management Emergency and Information calls	NATIONAL	Generic Data	Web Application / App - Company Server	XML		User Name/Password	Yes	Yes
HRC	Emergency	A set of web tools to collect data	Individual and family records	NATIONAL	Identificati on and other sensitive Data	Web Application - Company Server	Other:	PDF	User Name/Password/OTP	Yes	Yes
HRC	Emergency	A system to securely move files and folders of any size	Sensitive Information Documents	NATIONAL	Identificati on and other sensitive Data	Client/Serv er - Company Server	Other:	PDF	User Name/Password	Yes	Yes
HRC	Emergency	A set of mobile tools to conduct surveys and collect data	Identification, protection and financial records	NATIONAL	Financial Data	Web Application / App - Company Server	XML		User Name/Password	Yes	Yes
HRC	Information Communication	A set of mobile tools to conduct surveys and collect data	CEA records	NATIONAL / REGIONAL	Generic Data	Web Application / App - Company Server	XML		User Name/Password	Yes	Yes
EKAB	Emergency	Management Health Emergency Call	Management Health Emergency Call	NATIONAL / REGIONAL	Identificati on and other sensitive Data	Client/Serv er - Company Server	XML		Username/password	Yes	No

Annex 4 Requirements, Use Cases and Process Models

ЕКАВ	Information Communication	Telematics commanding control	Telematics commanding control of ambulance	NATIONAL / REGIONAL	Identificati on and other sensitive Data	Client/Serv er - Company Server	XML		Username/password	Yes	No
IBB	Emergency	112 Emergency Call Center Management System	112 Emergency Call Center Management	NATIONAL / REGIONAL	Identificati on and other sensitive Data	Client/Serv er - Company Server	XML	112 Single Number (Police, Ambulance, Fire)	Username/ Password	Yes	No

5 Legal and Regulatory Environments

This section shows the current legal and regulatory environment per procurer.

5.1 EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES)

LAWS AND REGULATIONS	Law or Regulation
Please list any law or official regulation that need to be	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive
considered when your organisation implements a new software or	2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
hardware.	
Please list any internal regulation that needs to be considered	
when your examination implements a new software or hardware	Internal available
when your organisation implements a new software of hardware.	

DATA PROTECTION AND DATA PRIVACY	Description
Please describe if and which data protection and privacy policies	REGLAMENTO (UE) 2016/679 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 27 de abril de 2016, relativo a la protección de las personas físicas en lo
are applied during triage management in your country/region.	que respecta al tratamiento de datos personales y a la libre circulación de estos datos y por el que se deroga la Directiva 95/46/CE (Reglamenteo
	general de protección de datos)
Consider following aspects:	
Collation and use of personal information	
Monitoring of information	
Protection of personal information	
Collection of personally identifiable information and	
cookies	

5.2 SERVICIO MADRILENO DE SALUD (SERMAS)

LAWS AND REGULATIONS	Law or Regulation
Please list any law or official regulation that need to be	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
considered when your organisation implements a new software	of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and
or hardware.	Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC https://eur-lex.europa.eu/legal-
	content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN

Please list any <u>internal regulation</u> that needs to be considered when your organisation implements a new software or hardware.	The regional health ministry has its own requirements for approved software. Details have been asked for.	
DATA PROTECTION AND DATA PRIVACY	Description	
Please describe if and which data protection and privacy policies are applied during triage management in your country/region.		
 Consider following aspects: Collation and use of personal information Monitoring of information Protection of personal information Collection of personally identifiable information and cookies 	All information is collected in compliance with the GDPR	

5.3 ÖSTERREICHISCHES ROTES KREUZ (ARC)

LAWS AND REGULATIONS	Law or Regulation
Please list any <u>law or official requlation</u> that need to be considered when your organisation implements a new software or hardware.	Datenschutz-Grundverordnung (EU) 2016/679, Medizinproduktegesetz – MPG, Medizinproduktebetreiberverordnung – MPBV

DATA PROTECTION AND DATA PRIVACY	Description
 Please describe if and which data protection and privacy policies are applied during triage management in your country/region. Consider following aspects: Collation and use of personal information Monitoring of information Protection of personal information Collection of personally identifiable information and cookies 	All information is collected in compliance with the GDPR

5.4 AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN)

LAWS AND REGULATIONS	Law or Regulation	Comment
Please list any <u>law or official regulation</u> that need to be considered when your organisation implements a new software or hardware.	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	This regulation replaces the EU Medical Devices Directive (93/42/EEC) and the EU Active Implantable Medical Devices Directive (90/385/EEC). The software used within digital health apps can be classified either as medical devices within the meaning of the Legislative Decree no. 46/1997, which has implemented Directive 93/42/EEC, or as simple consumer product to which the regulations on general product safety apply.
	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)	The identification and process of the patient's health data will be managed compliance with the regulatory framework (particularly GDPR). A Data Protection Impact Assessment (DPIA) of new data processing will be required . The controller shall seek the advice of the data protection officer when carrying out a data protection impact assessment. In the case DPIA give a high risk value, the controller shall consult the supervisory authority prior to processing and he will seek higher security measures taken by the controller to mitigate the risk.
	Italian CEI 62-237 : 2021 - GUIDANCE FOR SOFTWARE MANAGEMENT AND IT - NETWORKS IN MEDICAL ENVIRONMENT - PART 1: SOFTWARE MANAGEMENT	
	ISO/IEC 27001:2013 Information technology — Security techniques — Information security management systems — Requirements	ISO/IEC 27001:2013 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system within the context of the organization. It also includes requirements for the assessment and treatment of information security risks tailored to the needs of the organization
	IEC 80001-1:2021 - Application of risk management for IT-networks incorporating medical devices - Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software	IEC 80001-1:2021 specifies general requirements for ORGANIZATIONS in the application of RISK MANAGEMENT before, during and after the connection of a HEALTH IT SYSTEM within a HEALTH IT INFRASTRUCTURE, by addressing the KEY PROPERTIES of SAFETY, EFFECTIVENESS and SECURITY whilst engaging appropriate stakeholders.
Please list any <u>internal regulation</u> that needs to be considered when your organisation implements a new software or hardware.	General Manager Resolution no. 391 of 05/08/2019 - EU Regulation 679/2016 relating to the protection of personal data (GDPR). Adoption of the Data Protection Management System and approval of the relative manual.	Below is a link to all the actions taken for data protection and security http://www.aslbenevento1.it/modules.php?name=Sections&op=viewarticle&artid=297

DATA PROTECTION AND DATA PRIVACY	Description
	As of 25 May 2018, the new European Privacy Regulation, approved on 27 April 2016 and published in the Official Journal of the European Union on 04 May 2016, has
	been directly applied on the national territory.
	In particular, the data processed by this Company are personal information (e.g. personal data, address, health card, tax code, etc.) and sensitive information (e.g.
	information on the state of health) essential for the provision and management of services and the services requested.
Please describe if and which data protection and	The treatments necessary for the provision of services are used by the staff in compliance with professional secrecy, office secrecy and the rights of the interested
privacy policies are applied during triage	party (articles 12 to 22 of the GDPR) and therefore based on principles of legitimacy, correctness, lawfulness.
management in your country/region.	The ASL Management has determined the need to adapt the company policy, procedures and regulations in order to ensure compliance with the indications of EU
	Regulation 679/2016 (GDPR).
Consider following aspects:	the General Manager, as Data Controller, with the support of the Company Data Protection Manager, having verified the congruity with the company objectives and
· Collation and use of personal information	with the national and European legislative provisions, has identified the methodological path described in ASLBN Data Protection Management System Manual.
Monitoring of information	Security measures, adopted ASL BN, are a set of technological, procedural and organizational requirements aimed at implementing an adequate level of security in
Protection of personal information	data processing, in order to guarantee the confidentiality, integrity and availability of data and the resilience of the systems. information (analog and digital). These
Collection of personally identifiable	technical-organizational measures are aimed at minimizing the risks of:
information and cookies	destruction or loss, even accidental, of data,
	unauthorized access;
	processing that is not permitted or does not comply with the purposes of the collection,
	 modification of data as a result of unauthorized or non-compliant interventions.
	The identification of the appropriate security measures adopted by the Data Controller is the result according to a path of analysis, assessment and risk management.

5.5 AGENZIA REGIONALE EMERGENZA URGENZA (AREU)

LAWS AND REGULATIONS	Law or Regulation	Comment
	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	In Italy, medical devices - and among them also software and hardware
Please list any law or official regulation that need	of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No	- were regulated until May 26,2021 at EU level by the Directive 93/42/
to be considered when your organisation	178/2002 and	ECC, which corresponds to the Italian D. Lgs. 46/97. From May 2021,
implements a new software or hardware.	Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	medical devices are regulated by the new EU Regulation MDR
	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN	2017/745, in Italy Law 53/2021.

DATA PROTECTION AND DATA PRIVACY

Description

Ple	ase describe if and which data protection and privacy policies are	
ap _l Col	olied during triage management in your country/region. Insider following aspects:	For data management, compliance with GDPR requirements, AREU has adopted the "REGOLAMENTO 32 REGOLAMENTO IN MATERIA DI
	Collation and use of personal information	PROTEZIONE DEI DATI PERSONALI in applicazione del Codice in materia di protezione dei dati personali ex D.Lgs. n. 196 del 30 giugno 2003 e s.m.i.".
•	Monitoring of information	This document, approved by the General Director is available on request.
	Protection of personal information	

5.6 ELLINIKOS ERYTHROS STAVROS (HRC) / ETHNIKO KENTRO AMESIS VOITHEIAS (EKAB)

LAWS AND REGULATIONS	Law or Regulation
Please list any <u>law or official regulation</u> that need to be considered when your organisation implements a new software or hardware.	Greek Law 4727/2020 (article 88 , paragraphs 1- 2) for new software implementations
	Greek Law 4727/2020 (article 88 , paragraph 4) for hardware (no permission for buying new servers)
	Greek Law 4727/2020 (articles 85-87) for cloud hosting policy
	Greek Law 4412/2016 (with the updates) about public procurement of projects, supplies and services (adaptation to Directives 2014/24 / EU and 2014/25 / EU)
Please list any internal regulation that needs to be considered when	There is no specific internal regulation, but as the experiment is a government convice, the greak laws and processes must be considered. In
your organisation implements a new software or hardware.	general, the IT department passes a suggestion for a new software/hardware to the administrative council for making the final decision

DATA PROTECTION AND DATA PRIVACY		Description
Ple app	ase describe if and which data protection and privacy policies are Ilied during triage management in your country/region.	
Сог	nsider following aspects:	
·	Collation and use of personal information	GDPR and Greek Law 4624/2019
·	Monitoring of information	
·	Protection of personal information	
•	Collection of personally identifiable information and cookies	

5.7 IZMIR BUYUKSEHIR BELEDIYESI (IBB)

LAWS AND REGULATIONS	Law or Regulation	Comment
Please list any <u>law or official requlation</u> that need to be considered when your organisation implements a new software or hardware.	Medical Devices,	In accordance with the Decree Law No. 554, it must be registered by the Turkish Patent and Trademark Law and produced in accordance with the Medical Device regulations.
	Medical Device Management Regulation	Organizations that will provide after-sales service to medical devices are required to have a service adequacy certificate for the device to be serviced in accordance with the "TS12426 Authorized Services - Rules for Medical Devices" standard or "TS13703 Special Services - Rules for Medical Devices"

DATA PROTECTION AND DATA PRIVACY	Description	Comment
Please describe if and which data protection and privacy policies are applied during triage management in your country/region.		
 Consider following aspects: Collation and use of personal information Monitoring of information Protection of personal information Collection of personally identifiable information and cookies 	KVKK (Must be in accordance with the Personal Data Protection Law)	Protection of personal data became official with the law numbered 6698, which entered into force on April 7, 2016. The purpose of the personal data protection law is to protect the fundamental rights and freedoms of individuals, especially the privacy of private life, in the processing of personal data, and the obligations of natural and legal persons who process personal data, and the procedures and principles they will comply with.

6 Organisational Staff and Business Environment

This section shows the current organisational, staff and business environment per each procurer.

6.1EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage
Which EMS staff is involved in the triage scenario?	Operational Health Command	Medical Doctor. Director of Provincial Centre	The highest authority of the health group in the LDC and liaison with the EUMC.
	Health Command	Medical Doctor 1º EE 061	The person most responsible for the assistance at the scene of the incident
	Triage Manager	Nurses 1º EE 061	Responsible for 1st basic triage and casualty grouping.
	Evacuation Manager	EMERGENCY HEALTH TECHNICIAN 1º EE 061	Responsible for ambulance parking and regulates the evacuation of victims.
	Assistance Manager	Medical Doctor 2º EE 061	Organises advanced triage and Advanced Health Post
	Logistics Manager	Emergency Health Technician	Responsible for Logistic Support Vehicle material and for the deployment of communications between health managers.
	Collective Emergency Coordinator	Medical Coordinator 1º EE 061	Coordinator responsible for the Collective Emergency in the Coordinator Centre.
	Health group	6 Medical Doctor, 7 Nurses, 8 EHT	Under the orders of the health officials assigned to triage, assistance or evacuation.

Materials/Equipment	Name	Туре	Used to	Example
	Triage sling bag		1 unit for basic triage in wounded group	
	Disaster Kit		40 triage cards, 80 triage bracelets, and health officer's bibs	
	Paediatric bag		2 units for paediatric Advanced Life Support	
	Care bag		7 units for Advanced Life Support	

Assistant tent	Advanced Life Support Capability for 8 patients simultaneously	
Set catastrophes EE	yellow (1), red (1), green (1), grease pens (5), identification bracelets (evacuation, medical, triage (1)), documentation folder (1), medical and triage command waistcoats (1), hospital dispersal sheet (2), permanent markers (3), flag holders (3), patient triage card (50).	triage

Triage algorithm	Description	Comment			
Which triage algorithm is used during triage?	Basic Triage	Carried out in the intervention area. Classification of victims according to START triage with the possibility of life-saving manoeuvres (control of exsanguinating haemorrhages and airway patency). Marks the priority for rescue and transfer to the rescue area (PSA).			
Does it differ between scenarios?	Advanced stabilisation triage	Carried out at the Advanced Health Post. It consists of the XABCDE Primary Assessment of severe trauma patients developed by the ATLS to prioritise care.			
	Advanced evacuation triage	Carried out at the Advanced Health Post. The Triage-Revised Trauma Score (T-RTS) version is used as triage to mark the order of evacuation of assisted patients.			

Communication Hardware/Software	Hardware/Software Name (Product Name)	Туре	Format	Used mainly (by which roles)	to communicate with whom	Special features
Which communication hard and software is used in the	TETRA 1	Radio	Voice	Operational Health Command	Health management y Coordination Centre	digital radio, encrypted
environment?	TETRA 2	Radio	Voice	Health Command	Health management y Coordination Centre	digital radio, encrypted
	TETRA 3	Radio	Voice	CCUE's EC co-ordinating doctor	Health management y Coordination Centre	digital radio, encrypted
	Mobile 1	Mobile phone	Voice	Health operational command	Coordination Centre (as an alternative)	Digital phone
	Mobile 2	Mobile phone	Voice	Health Command	Coordination Centre (as an alternative)	Digital phone

Terminales (1,2,3,4)	Radio	Voice	Health Command	Responsible for triage, assistance and evacuation	Analogical radio, encrypted
Terminales embarcados	Dispositivos embarcados	Data	Mobile Units (EE061, VAL y EM)	Coordination Centre	Digital (envío de datos y localización por GPS)
Sistema	Sistema informático	Voice y data	Coordination Centre	Hospitals, Health Care managers and CECEM- 112	Digital
Fixed Radio Equipment	Radio	Voice	Coordination Centre	CECEM-112 (as an alternative)	Analogical radio, encrypted
Communications in the Logistic Support Vehicle		1 TETRAPOL terminal and 1 mobile terminal for the health command and 4 handheld radios for the health officers.			

External Data Sources	Digital Data Source Name	Description	Who needs the data?	Restricted access (open or only available for EMS/first responders)
Which external data sources are/can be used during the triage management process	CECEM-112	112 emergency centres	Its function is to collect all relevant information on the emergency through the commanders of the different operational groups in the WFP.	yes
	Coordination Centre	061 health emergency centre		

Vehicles	Vehicle Name	Туре	Staff (roles and number of people on board)
List vehicles that are available and would/could be used durina triage	EE 061 1	class C ambulance	1 doctor/ 1NURSES/1TES
scenarios. Ensure that you include also different versions of similar vehicles (e a	EE 061 2	class C ambulance	2 doctor/ 1NURSES/1TES
ambulance Car with different equipment configurations)	EE 061 3	class C ambulance	3 doctor/ 1NURSES/1TES
	Logistic Support Vehicle	class C ambulance	4 doctor/ 1NURSES/1TES
	EM Axarquia 1	class C ambulance	5 doctor/ 1NURSES/1TES
	EM Axarquia 2	class C ambulance	6 doctor/ 1NURSES/1TES

Annex 4 Requirements, Use Cases and Process Models

EM Axarquia 3	class C ambulance	7 doctor/ 1NURSES/1TES
EM. Axarquia 4	class C ambulance	8 doctor/ 1NURSES/1TES
RTU CRE 1	class B ambulance	2 TES
RTU CRE 2	class B ambulance	2 TES
RTU Protección Civil 1	class A1 ambulance	1 TES
RTU Protección Civil 2	class A2 ambulance	1 TES
HELMA 061	medical helicopter	1 doctor/1 NURSES/ 1pilot/ 1 mechanic

Stakeholders	Organisation	Department	Role	Main Tasks
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation	Emergency Coordination Centre 112		Coordinator at the Advanced Control Post	Coordination of the operational groups involved.
has to be in contact with).	Fire Brigade Operational Group Chief		Operational Rescue Task Force at the Advanced Control Post	Rescue and neutralisation of hazards at the incident
	National Police, Guardia Civil, Local Police		Command of the security task force in the Advance Control Post	Safety and traffic control in the scenario involved.
	Malaga`s Civil Protection	Protección Civil Velez Málaga	Logistics Task Force Command in the Advance Control Post	Evacuation, provisioning and accommodation.
	Delegación Provincial	Delegación de Salud de Málaga	Health Delegate of Malaga	Head of the Health Group
	Andalusian Health Service	Hospital Axarquía	Disaster plan manager	Organisation of the hospital in the event of a collective emergency
	Andalusian Health Service	Hospital Regional de Málaga	Disaster plan manager	Organisation of the hospital in the event of a collective emergency
	Andalusian Health Service	Distrito extrahospitalario Axarquía	Responsible for the EM de la Axarquía	Coordina el personal de los EM según lo dispuesto por el mando sanitario
	Spanish Red Cross	Sanitario	Responsible for the Spanish Red Cross	Coordination of CRE care unit staff as mandated by the health command

Local Police	Policia Local Velez Málaga	Security Task Force	Traffic regulation
Guardia Civil	Guardia Civil	Security Task Force	Traffic regulation and incident safety.
National Police	Policia Nacional	Security Task Force	Incident safety.
Emergencies 112	GREA	Coordination of task forces	Communications at the advanced command post
Firefighters	Consorcio Provincial de Bomberos de Málaga	Intervention Task Force	Rescue and neutralisation of hazards at the incident
Colegio de Psicólogos Málaga	GIPCE	Logistics Task Force	Psychological support for those affected and their families
Protección Civil	PC Vélez Málaga	Logistics Task Force	Evacuation, provisioning and accommodation
Spanish Red Cross	Logística	Logistics Task Force	Evacuation, provisioning and accommodation

6.2 SERVICIO MADRILENO DE SALUD (SERMAS)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage	Education
Which EMS staff is involved in the triage scenario?	Coordinating Centre of SUMMA 112	It constitutes the basic pillar for the operation of EMS, since all the resources that SUMMA 112 puts into operation on a daily basis are coordinated from it. In addition, it is the place where calls are received from citizens requesting not only urgent and emergency health care, but also calls seeking medical and health advice. Taking advantage of the technological platform and the 24-hour operational space, the PAL 24 is located in the coordinating centre, continuous care of patients in palliative care. From the coordinating centre, the activity of the SUAP is monitored and, in turn, they are given the necessary support.	EMCC	
	Sanitary transport board	In the Coordinating Centre of SUMMA 112, the Programmed Health Transport management, attention to user demand, support to prescribers, monitoring of incidents and monitoring of the provision of the service is also carried out	Transport management of EMS	

DeparatorsInteger are the professionals whore requires the sufficiency and with the support of a logical computer tree, with closed questions, priority is assigned to the call to enter the doctor or nurse. In advanced resource is assigned by software and is managed by the Technicians - Speakers, in turn, the call with the highest priority is assigned to the doctor to obtain more data and, where appropriate, is give precise instructions.EMS calls reception and first all sociationPhysicians - Regulatorsgymeans of a clinical telephone interview, they determine whether which health resources is appropriate, as well as the type of resource and the priority. In addition, in cases where it is not of Cardiorespriatory Arrest, they give CPR instructions over the phone until the arrival of thes professionals at the site.Medical management of incidentsNurses:Arrong their multiple functions, they manage hospital aller's requested by EMS resources for critical professionals at the site.Nurse care managementTechnicians in HealthThey are health professionals, who are donation of the code (stricks, ST-elvedox AM). Segmession: Joine they receive the call from our resources, requesting the activation of the code and following the service of the corresponding hospital. They manage incidents and resources. Drace the priority and the type of resource and monitor it, carry out coordination tasks with other services and bodies (firefighters, police, etc.).In other EMS systems they are called parameticsPharmacy support servicesShe is the head of SUMMA 112 they are in charge of supervising all the activity not of the coordinating centre, and drain the resources SIMMA 112 they have the incourse and bodies (firefighters, police, etc.).In other EMS systems they are called parametics<				
By means of a clinical telephone interview, they determine whether which health resource is appropriate, as well as the type of resource and the priority. In addition, in cases where it is case where it is cases where it is ca	Operators	These are the professionals who receive the call in the first instance. They are responsible for collecting basic data, such as where the patient is, affiliation and with the support of a logical computer tree, with closed questions, priority is assigned to the call to enter the doctor or nurse. In the detected cases of pathologies of an emergency nature, an advanced resource is assigned by software and is managed by the Technicians - Speakers, in turn, the call with the highest priority is passed to the doctor to obtain more data and, where appropriate, give precise instructions.	EMS calls reception and first allocation	
NursesAmong their multiple functions, they manage hospital alter's requested by XBP securces for ritical preceive the call from our resources, requesting the activation of the code and following the protocois included in the codes, threy search for the ideal hospital and carry out the altert at the protocois included in the codes, they search for the ideal hospital and carry out the altert at the protocois included in the codes, they search for the ideal hospital transfers and neonatal transfers. Among its functions is also the attention of citizen calls, to offer health advice.Nurse care managementIn other EMS systems they are called paramedicsFechnicians in Health Emergencies - AnnouncersThey are health professionals, who are in charge of managing incidents and resources. Once the priority and the type of resource to be displaced have been determined, the Technicians look forth services and bodies (firefighters, police, etc.).In other EMS systems they are called paramedicsFehrergencies - AnnouncersS/he is the head of SUMMA 112 during his watch. They are in charge of supervising all the activity not only of the coordinating centre, but of all the resources of SUMMA 112. They have the coarded in the coordinating centre, but of all the resources of SUMMA 112. They have the coarded in the coordinating centre and during the daytime there is an additional guard chief on the steechical spokespersons for SUMMA 112. resources and supervising the activity. They act all resources and supervising the activity. They act all resourcesmanagement of medicamentsPharmacy support servicesIn coordinating centre and during the daytime there is an additional guard chief on the resourcesmanagement of supplies and resourcesa specific training that is periodically accredited of at least 40 hours of	Physicians - Regulators	By means of a clinical telephone interview, they determine whether which health resource is appropriate, as well as the type of resource and the priority. In addition, in cases where it is not necessary to displace a resource, they refer to other services and provide health advice. In the cases of Cardiorespiratory Arrest, they give CPR instructions over the phone until the arrival of EMS resources and in all cases, they offer advice and guidelines for action until the arrival of the professionals at the site.	Medical management of incidents	
Technicians in Health Emergencies - AnnouncersThey are health professionals, who are in charge of managing incidents and resources. Once the priority and the type of resource to be displaced have been determined, the Technicians look for the called paramedicsIn other EMS systems they are called paramedicsImage: Temergencies - AnnouncersS/he is the head of SUMMA 112 during his watch. They are in charge of supervising all the activity not only of the coordinating centre, but of all the resources of SUMMA 112. They have the command within the management of urgency and health emergencies. They support complex interventions and incidents that occur. On a permanent basis, 24 hours a day there is a guard chief located in the coordinating centre and during the daytime there is an additional guard chief on the street giving support to the different SUMMA 112 resources and supervising the activity. They act as technical spokespersons for SUMMA 112.management of medicamentsPharmacy support servicesmanagement of supplies and resourcesa specific training that is periodically accredited of at least 40 hours of training per yearAmbulance doctorsDoctors assigned to ambulancesMedical triagea specific training that is periodically accredited of at 	Nurses	Among their multiple functions, they manage hospital alerts requested by EMS resources for critical patients. They play a fundamental role in the Codes (stroke, ST-elevation AMI, Sepsis) since they receive the call from our resources, requesting the activation of the code and following the protocols included in the codes, they search for the ideal hospital and carry out the alert at the service of the corresponding hospital. They manage interhospital transfers and neonatal transfers. Among its functions is also the attention of citizen calls, to offer health advice.	Nurse care management	
S/he is the head of SUMMA 112 during his watch. They are in charge of supervising all the activity not only of the coordinating centre, but of all the resources of SUMMA 112. They have the command within the management of urgency and health emergencies. They support complex interventions and incidents that occur. On a permanent basis, 24 hours a day there is a guard chief located in the coordinating centre and during the daytime there is an additional guard chief on the street giving support to the different SUMMA 112 resources and supervising the activity. They act as technical spokespersons for SUMMA 112.management of medicamentsPharmacy support servicesmanagement of supplies and resourcesmanagement of supplies and resourcesAmbulance doctorsDoctors assigned to ambulancesMedical triagea specific training that is periodically accredited of at least 40 hours of training per year	Technicians in Health Emergencies - Announcers	They are health professionals, who are in charge of managing incidents and resources. Once the priority and the type of resource to be displaced have been determined, the Technicians look for the resource closest to the incident, activate and monitor it, carry out coordination tasks with other services and bodies (firefighters, police, etc.).	In other EMS systems they are called paramedics	
Pharmacy support services management of medicaments Logistics services management of supplies and resources Ambulance doctors Doctors assigned to ambulances Medical triage Ambulance doctors Doctors assigned to ambulances	Chief of watch	S/he is the head of SUMMA 112 during his watch. They are in charge of supervising all the activity not only of the coordinating centre, but of all the resources of SUMMA 112. They have the command within the management of urgency and health emergencies. They support complex interventions and incidents that occur. On a permanent basis, 24 hours a day there is a guard chief located in the coordinating centre and during the daytime there is an additional guard chief on the street giving support to the different SUMMA 112 resources and supervising the activity. They act as technical spokespersons for SUMMA 112.		
Logistics services management of supplies and resources Ambulance doctors Doctors assigned to ambulances Medical triage a specific training that is periodically accredited of at least 40 hours of training per year	Pharmacy support services		management of medicaments	
Ambulance doctors Doctors assigned to ambulances Doctors assigned to ambulances Ambulance doctors Doctors assigned to ambulances Doctors assigned to ambula	Logistics services		management of supplies and resources	
	Ambulance doctors	Doctors assigned to ambulances	Medical triage	a specific training that is periodically accredited of at least 40 hours of training per year

Nurses in ambulance	Nurses assigned to ambulances	Medical triage	a specific training that is periodically accredited of at least 40 hours of training per year
Emergency technicians and technical drivers	Technicians (paramedics) assigned to ambulances		a specific training that is periodically accredited of at least 40 hours of training per year
Disasters, MCI and catastrophes management roles according to regional and national regulations:			
	Operations Coordination Centre (CECOP/CECOPI)		
	Operations Manager (Fire Brigades Chief)		
	Experts Committee		
	Information Office	Collects, coordinates and channels the information generated in relation to the emergency.	
	Plan Manager	Determines the most appropriate telecommunications system to be used in the emergency, in each case. Authorize and, if necessary, order the use of remotely piloted aircraft for emergency management.	
Four Action Groups for MCI management			
	Interventions Group		
	Logistic Support Group		
	Advanced Command Post		
	EMS Group		

Name

Туре

Materials/Equipment

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Which materials are specifically used during triage scenarios.	Triage Tags	There is an integrated platform in the coordinating centre that allows monitoring the activity of the SUAPs, allowing, when necessary, to move professionals to reinforce and reduce both the care burden and the waiting for patients. Likewise, there is a security system that allows viewing of the closed-circuit TV cameras of the SUAPs to guarantee the safety of the professionals. The activation of alarms for the activation of the bodies and security forces is monitored from Anthracite.	<complex-block></complex-block>
	Tablet		Collect personal health data from the EMCC
	Pulse oximetry		allows the non-invasive estimation of the body's oxygenation, through spectral analysis: the absorption of the spectrum of oxygenated and reduced haemoglobin differs, allowing its percentage quantification.
	Capnometry		is the measurement of the CO2 concentration in a gas mixture, presented in a curve, which is capnography. The most common capnography uses infrared spectrometry (absorption of infrared light) or mass spectrometry.
	Pulse oximetry		allows the determination of carboxyhaemoglobin levels
	Pulse methaemoglobimetry		allows the reading of peripheral methaemoglobin saturation, which may be abnormally increased in different congenital or acquired pathologies.

Example

	The coordinating centre has a state-of-the-art technological platform, the entire process being computerized from the moment the call is received, ensuring traceability
Technological platform	and monitoring of the activity at all times. All SUMMA 112 mobile resources are geolocated and for this the professionals of the coordinating centre have a GIS system for their location and a tool that allows them to help decision-making on the resource closest to the incident, including deciding the hospital nearest ideal.

Triage algorithm	Description	Comment
Which triage algorithm is used during triage?	Dual Extraction Triage	Start TRIAGE is the standard but when there are multiple victims the first step is to locate who is dead and who is alive
Does it differ between scenarios?	When the health workers cannot work in the focus, the Intervention Group would do a dual triage to extract the victims:	
		NOT TRAPPED rather than trapped.
		WITH EVIDENT VITAL SIGNS rather than without obvious vital signs.
		A SANITARY RESCUE Technician (TES of the VEC) may be appointed by the JDS to assist the Intervention Group in this dual triage in focus.
	When the health workers can work in the focus	
		First triage or care triage: determination of the priority of each victim in receiving stabilization health care. It is done in the focus (if it is safe) or in the Wounded Concentration Zone.
		Second triage or evacuation triage: determination of the priority of each victim in being evacuated to a suitable health centre to receive definitive treatment. It is done in the Relief Zone (after stabilization).
	Labelling	
		The resulting priority for each victim is marked with Tassica 2 cards, colour coded pentapolar:
		- BLACK: Deceased.
		-BLUE or GRAY: Goner
		-RED: Priority 1 (immediate)
		-YELLOW: Priority 2 (delayed)
		-GREEN: Priority 3 (low priority)

Assistance Ferris Wheel	
	Coordinated by the Triage Command, the victims will be transferred to the Relief Zone according to their first triage
	priority:
	RED: On a stretcher to the Advanced Health Post
	YELLOW: On a stretcher after to the Advanced Health Post
	GREEN: Led to the Green Zone by the Green Manager.
	BLUE or GRAY: Compassionate medication on site (they would only be transferred to the Advanced Health Post
	when it was cleared)
	BLACK: They remain in situ or will be taken to the Morgue

Communication Hardware/Software	Hardware/Software Name (Product Name)	
Which communication hard and software is used in the environment?	Various radio systems are used in the Coordination Centres:	Medical warnings
	PMR: Personal Mobile Radio. Radio communication system for personal use.	Medication
	ANALOGUE TRUNKING: Analogue mobile radio communications system	Date and signature
	DIGITAL TRUNKING: TETRA. Digital radio communication system	Main pathology
	Telephony / Radio Integration Subsystem	
	Thanks to this configuration, each operator who requests it can make use of the shared resources available at that moment, optimizing resources and making daily work more flexible.	In case of evacuation, the second triage is carried out, which marks the priority and the Revised Trauma Score (T-RTS) used
	This system allows to treat radio communications in a similar way to how telephone calls are treated, which allows	
	recording; conference calls between different devices, voice communication between a voice call and a radio call.	Breathing frequency
	GPS	Systolic blood pressure
	TELEPHONE CONTROL UNIT	Glasgow scale score (0-15)
	GPRS (General Packet Radio Services)	The data of the evacuation vehicle is also filled in
	MOBILE SATELLITE COMMUNICATIONS	

External Data Sources	Digital Data Source Name	Description	Who needs the data?
Which external data sources are/can be used during the triage			Practitioners on the field, EMCC doctors and
management process.	Embarked Health Care Records		nurses
	GPS Positioning		EMCC
	Weather data	Data from national meteorological agency	Medical watch board
	Available beds in all hospitals in the	Every hospital in the region is polled every morning for	
	region	available beds	Medical watch board

Vehicles	Vehicle Name	Description
List vehicles that are available and would/could be used during triage scenarios. Ensure that you include also different versions of similar	28 Mobile ICUs.	24 hours, 365 days a year
vehicles (e.g. ambulance Car with different equipment configurations)	16 Rapid Intervention Vehicles	from 8:30 a.m. to 8:30 p.m., 365 days a year
		4 from Monday to Friday, from 4:00 p.m. to 9:00 a.m. weekends and holidays 24 hours (Lozoyuela,
	38 Medical Home Care Units.	Perales de Tajuña, Daganzo and Chapineria). The rest operate from Monday to Friday, from 8:30 pm to 8:30 am; weekends and holidays 24 hours.
	2 Nursing Homo Caro Units	1 from Monday to Friday, from 4:00 p.m. to 9:00 a.m. weekends and holidays 24 hours
	S Nursing Home Care Onits.	holidays 24 hours.
	Ambulances A1 (Concessionaire company)	
	Basic Life Support Ambulances	
	(Concessionaire Company)	

Stakeholders	Organisation
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has to be in contact with).	National Police
	Local Police
	Guardia Civil
	Civil Protection

Fire Brigades
Primary Care Centres
Hospitals

6.3 ÖSTERREICHISCHES ROTES KREUZ (ARC)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage	Education	Comments
Which EMS staff is involved in					
the triage scenario?	First MD				
	arriving on	Medical			if MD is not available, paramedics are doing the triage. Non injured persons will be
	scene	Doctor	Triage	MD	separated from the scene and will be getting support by crisis intervention teams later.
	Officer in				
	charge/head			EMT or Paramedic + internal	
	of operation		command and control	training, level 3	responsible for the whole operation
					responsible for the allocated part of the operation - biorarchic structure; head of operation
					(Finsatzleiter) -> head of medical (Leiter Sanitätshilfsstelle), head of triage, head of
			command and control.	FMT or Paramedic + internal	treatment, head of transport 1 + head of support (Leiter Betreuung), head of crisis
	Team leader		team leading	training. Level 1 to 2	intervention, head of reception centre, head of uniniured
					······································
	Chief Medical				
	Doctor		team leading, support,		
	Medical				
	Doctor		treatment	MD	
	Doctor		licatiliciti		
			Triage, treatment,		
	Paramedics		transport,	Paramedic	
	Emergency				
	medical		Triage, treatment,		
	technician		transport,	EMT	

Annex 4 Requirements, Use Cases and Process Models

Crisis Intervention member		Psychosocial first aid, psychosocial support	specific internal training for crisis intervention (72 h education + exam + advanced training)	
Ambulance Car drivers	Driver		EMT or Paramedic + internal drivers training	





Communication Hardware/Software	Hardware/Software Name (Product Name)	Туре	Format	Used mainly (by which roles)	to communicate with whom	Special features
Which communication hard and software is used in the environment?	TETRA	Radio	Voice	Team leaders, ambulance car drivers	leader, dispatch centre, other organizations	digital radio, encrypted
	Mobile Phone	Smartphone	Voice	Officers in charge, team leaders, Ambulance car driver		
	Mobile data collection	e.g. tablet	Data	EMT, Paramedic	Dispatch centre, Hospitals, insurance company	

External Data Sources	Digital Data Source Name	Description	Who needs the data?
Which external data sources are/can be used during the triage management process.	ZAMG	Austrian weather forcast	eg. Helicopter pilot
	Media Broadcast	traffic information	Emergency driver

KatWarn	Warning App Ministry of the interior	head of operation, staff and volunteers
ТӦ Арр	Warning App Austrian Red Cross	head of operation, staff and volunteers

Vehicles	Vehicle Name	Туре	Staff (roles and number of people on board)	Description	Comments
List vehicles that are available and would/could be used during triage scenarios.				in bus accident scenario	EN 1789 only for transport of
Ensure that you include also different versions of similar vehicles (e.g. ambulance Car	Ambulance Car			there will be min. 10 Type	non-injured or very light injured
with different equipment configurations)	(Sanitaetstransportfahrzeug)	A	min. 2 EMT (1 driver)	A	persons
	Ambulance Car		min. 2 EMT or 1 Paramedic	in bus accident scenario	
	(Rettungsfahrzeug)	В	+ 1 EMT (driver)	there will be min. 5 Type B	EN 1789
	Ambulance Car			in bus accident scenario	EN 1789 without the possibility
	(Notarzteinsatzfahrzeug)	С	1 MD + 1 Paramedic/Driver	there will be min. 2 Type C	for patient transport
				additional min. 1	
	Helicopter		1 Pilot, 1 MD, 1 Paramedic	helicopter	Equipment similar to C
				in bus accident scenario	
				there will be min. 2 Cl	
	Passenger car PKW		crisis intervention team	teams	one team = 2 members
				additional materials for	
	Trailer			mass casualties	
	Logistic vehicles				

Stakeholders	Organisation	Main Tasks
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has to be in contact with).	Police	marking with barrier tape, road block, documentation, identification
·····,····,·	Hospitals	preparation of arriving of server injured, treatment
		freeing severe injured, extinguish the fire, protect the scene from public (gawkers who stares)
	Fire brigade	with blankets,
	Mountain rescue	support saving injured at mountainous terrain
	Dispatch centre	call taker, dispatcher
	Healthcare	
	authority	on different levels (municipality, district, federal)

6.4 AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage	Education
Which EMS staff is involved in the triage scenario?	Health Aid Director (DSS)	Emergency Doctor	He is the doctor responsible for any medical intervention in the areas of operations.	Medical Doctor. Resuscitation and intensive care specialist
	Triage Manager	Medical Doctor/Nurse	coordinating triage	
	Recovery and Triage Team Director	Emergency Nurse / Physician		
	Transport Manager	Emergency technician		
	Advanced Medical Site Manager	Emergency Doctor	Role carried out by a doctor who is responsible for the management of the Advanced Medical Post.	
	Acute Care Doctor	Acute Care Doctor		
	Emergency Field Doctor (EFD)	Emergency Doctor		
	Emergency Filed Nurse (EFN)	Emergency Nurse		Bachelor in Nurse University
	EMT	Emergency medical technician (EMT)		EMTs must have 120 hours of training, attending an additional 80- or 100-hour course. Italian EMTs are able to provide non-invasive pre-hospital care, including PBLS, PTLS and automated external defibrillation
	Volunteers	Emergency Volunteers		have 20 or 40 hours of BLS training
	Emergency Driver	Driver		
	Emergency Operational Center Manager	Emergency Physician Manager		
	Emergency Operational Center Operator	Operational Center - Emergency Physician		
	Fire brigade command manager			
	Police command manager			

Civil protection command		
manager		

Materials/Equipment	Name	Туре	Used to	Example
Which materials are specifically used during triage scenarios.	Triage Wristbands (used only during the maxi emergency)	bracelets used as patients tag during maxi emergencies	bracelets used as patients tag during maxi emergencies	
	Defibrillator with rhythm and patient data recording	Equipment for Management of Life- Threatening Problems	Management of Life- Threatening Problems	
	Cardiac Monitor	Equipment for Management of Life- Threatening Problems	Management of Life- Threatening Problems	
	External Cardiac Pacing	Equipment for Management of Life- Threatening Problems	Management of Life- Threatening Problems	

Triage algorithm	Description	
Which triage algorithm is used during triage?		Without terminal the Statest Advect the Statest Distance Medity
Does it differ between scenarios?	<text><list-item><list-item><list-item><list-item><section-header><section-header><text><list-item><list-item><section-header></section-header></list-item></list-item></text></section-header></section-header></list-item></list-item></list-item></list-item></text>	Image: constrained by the second se

Communication Hardware/Software	Туре	
Which communication hard and software is used in the environment?	Mobile Radio Transceiver	
	Portable Radio Transceiver	
	Access to the public telephone network by mobile (cellular) telephone	
	Internal communication between driver and patient compartment	
	Video Conference Application	
External Data Sources	Digital Data Source Name	Description
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Which external data sources are/can be used during the triage management process.	SIRES - Regional Emergency Health Service	Regional Emergency Medical Service management system
	Internal Early Warning System	Regional Warning System
	Public Safety Common Dashboard (E015)	A dashboard managed by the Prefecture

Vehicles	Vehicle Name	Туре	Staff (roles and number of people on board)	Description
List vehicles that are available and would/could be used during triage scenarios.	Ambulance Car Example	Car	1x Role A / 1x Role B	Anything that is special (e.g., equipment)
Ensure that you include also different versions of similar vehicles (e.g. ambulance Car with different equipment configurations)	type A road ambulance - patient transport ambulance	Car	Emergency Driver Emergency Volunteers / EMT	vehicle designed and equipped for the transport of patients who are not expected to become emergency patients
	type B road ambulance - emergency ambulance	Car	Emergency Driver Emergency Volunteers / EMT / Emergency Nurse Emergency Physician	vehicle designed and equipped for the transport, basic treatment and monitoring of patients
	type C road ambulance - mobile intensive care unit	Car	Emergency Driver Emergency Volunteers / EMT / Emergency Nurse Emergency Physician / Acute Care Physician	vehicle designed and equipped for the transport, advanced treatment and monitoring of patients
	emergency helicopter	helicopter	Emergency Pilot Emergency Volunteers / EMT / Emergency Nurse Emergency Physician / Acute Care Physician	
	fire brigade vehicles	Firefighting Vehicles / Fire engine		
	police / armed forces vehicles	Police vehicles		
	civil protection vehicles	Cars / trucks		

Stakeholders	Organisation	Department	Role
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has to be in contact with).	Italian Civil Protection	Interior Ministry	Technical Rescue
	Campania Region - Emergency Team (Crisis Unit)	Regional Healthcare Authority	Healthcare situation supervision
	Healthcare Local Authority	Regional Healthcare Authority	Healthcare situation management
	Campania Region - Hospitals Network	Regional Healthcare Authority	Healthcare situation management
	Fire Brigades	Interior Ministry	Technical Rescue
	Prefecture	Interior Ministry	Responsible of the emergency
	Police command	Interior Ministry	
	Municipality		
	Local Transportation Company		

6.5 AGENZIA REGIONALE EMERGENZA URGENZA (AREU)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage	Education
Which EMS staff is involved in the triage scenario?	Director of Medical Rescue (DSS)	Emergency Doctor	He is the doctor responsible for any medical intervention in the areas of operations.	Medical Doctor. Resuscitation and intensive care specialist, Emergency Medicine
	Major Incident Coordinator (CIM)	Emergency operator: doctor / technician / nurse	Collaborates in the technical-sanitary management of the event. Together with the DSS it coordinates operational staff and relations with other rescue agencies	Profession specific, Disaster Medicine
	Triage Director	Emergency nurse	A nurse in charge of coordinating triage. Responsibility covers: the performance of triage, the sectorialisation, supervision of operations, communications, definition of usage of the Advanced Medical Post, coordinate the supply of resources	Emergency Medicine, Disaster Medicine
	Transport Director	Emergency rescuer / technician	Determine the position of the checkpoint(s): the compulsory point of passage for all vehicles entering and leaving the site. Taking stock of the available resources by communicating and adjusting their movement according to the	Technical / Engineer

		requests of the Advanced Medical Post and the DSS; taking stock of the available human resources Registering incoming and outgoing vehicles using special forms and more. He is also responsible for recording patient identity and hospital destination.	
Director of the Advanced Medical Post	Emergency Doctor	Role carried out by a doctor who is responsible for the management of the Advanced Medical Post. Liaises continuously with the DSS/CIM/Transport Director for the provision of material or human resources. He/she agrees with the triage director the dispatch of patients from the collection area to the Advanced Medical Post. Liaises with transport director for evacuation of casualties to hospitals. He/she does not normally carry out medical treatment of patients	Medical Doctor. Resuscitation and intensive care or Emergency Medicine specialist
Field doctor	Emergency Doctor	Conducts patient assessments and proceeds with patient stabilization	Medical Doctor. Resuscitation and intensive care or Emergency Medicine specialist
Field nurse	Emergency nurse	Cooperates with the fields doctors to assess and stabilize patients	Emergency Medicine, Disaster Medicine
Field rescuer	Emergency rescuer / technician	Performs the sweeping triage and performs life-saving manoeuvre on the patients and	profession-specific
Alpine rescuer technician	Alpine rescuer	Operating special manoeuvre during Helicopter activity	rescuer in hostile environment, qualified for rope work, avalanche rescue
Driver	Emergency Rescuer	is available for transporting patients or materials	
EMS Medical Director of the Territory	Emergency Doctor	is at the control centre and follows the progress of the event giving advice for a smooth operation	Medical Doctor. Resuscitation and intensive care or Emergency Medicine specialist
EMS Medical Coordinator of the Territory	Emergency Nurse	is at the control centre and follows the progress of the event giving advice for a smooth operation	Emergency Medicine, Disaster Medicine
EMS Command Centre Operating Manager	Emergency operator: rescuer / technician	Coordinate the activity of the Command Centre with particular attention to the need on the event field	Technical / Engineer
EMS Command Centre Operator	Emergency operator: rescuer / technician	Receives calls from the citizens, including the citizens calling from the scene of the event	Technical / Engineer
EMS Command Centre Doctor	Emergency Doctor	Receives calls from the doctors and nurses from the scene of the event and manages the transport of patients to Hospitals	Medical Doctor. Resuscitation and intensive care or Emergency Medicine specialist
EMS Command Centre Nurse	Emergency Nurse	Receives calls from physicians, nurses from the scene of the event and helps manage patient destination	Emergency Medicine, Disaster Medicine
EMS Command Centre Logistic operator	Emergency operator: rescuer / technician	Coordinates the dispatch of emergency vehicles to and from the event field	Technical / Engineer
AREU Strategic Directors	General, Medical, Admin Directors of the complete AREU organization	Stay at the AREU headquarter and are in contact with all the institutions involved (CP, PS, FB etc.)	Profession specific

AREU Maxi Emergency Coordinator	AREU central Maxi Emergency Coordinator	Is in staff to the strategic directors	Emergency Medicine, Disaster Medicine
Urban Safety And Rescue (USAR) team	Doctors, Nurses, Technicians specialized in UASR activities	Intervenes in specific situations like building collapses	Emergency Medicine, Disaster Medicine
NBC (CBRN) team	Doctors, Nurses, Technicians specialized in NBC activities	Intervenes in specific situations of contaminated sites	Technical / Engineer
AREU ICT staff	ICT specialists	Supports all the actors in using telecommunication and informatic systems.	Technical / Engineer
AREU Field Communication Operator	Radio communications specialist	Operates in the field to provide radio equipment to the people on the site	Technical / Engineer
AREU Central Command Centres Director	Medical Director coordinating all the EMS Command Centres	Supervises the situation of all the EMS Control Centres in the region	Emergency Medicine, Disaster Medicine
AREU Central Command Centres Coordinator	Nurse Director coordinating all the EMS Command Centres	Cooperate with the Command Centres Director	Emergency Medicine, Disaster Medicine
AREU Central Admin	Admin manager and employees	Available to support the team	Admin / MBA
AREU Media & Communication personnel	communication professional	Maintains contact with the press and the media	public relations expert
AREU Logistic Dept.	Engineers	Supports the provision of resources: vehicles and other needed goods	Technical / Engineer
Helicopter Command Centre	AREU HEMS Command Centre personnel	Coordinates the usage and dispatch of the HEMS in the region and provides the needed means to the site	Technical / Engineer
Unified Emergency Response Centre (112 PSAPs)	AREU PSAPs (112 Response Centre) Personnel and Managemnet	Receives all the emergency calls from the citizens and forward the relevant for the site to the EMS Control Centres	Technical / Engineer

Materials/Equipment	Name	Туре	Used to	Example	
Which materials are specifically used during triage scenarios.	Instruction Envelop	Paper Card	Provide standard first-hand instructions to the first emergency teams to arrive on scene.	<image/>	
	Triage Wristband and Box	Colourful plastic bracelets and containment box	Patient Severity Classification		

Triage Registration Cards	Paper Card	Record data for the START algorithm and collection of other patient data and situation	
EKG	Standard portable EKG machine	Acquire EKG trace	
Monitor Defib	Defibrillator-Monitor Manual and/or automatic	Provide Defib shock. Continuous monitoring of patient	
Portable Ultrasound Machine	Ultrasound	Perform rapid ultrasound evaluation (fast thoracic)	
Automatic External Defib	AED	Apply defib shock	
Advanced Medical Post	field hospital	Host victims in a first stage	
Stock Lot	Container	contains all the material needed for an Advanced Medical Post A. Non-sanitary material (yellow colour) B. Material for cardiovascular support (red) C. Respiratory support material (blue) D. Different materials (green colour)	
Drones	UAV	Survey the area of the emergency	

Triage algorithm	Description	Comment	
Which triage			
algorithm is used	The triage system used in the Lombardy Region is the S.T.A.R.T.		
during triage?	system The questions that arise are:	The START results are substantially over triaged. This over triage is compensated for by the ease of applicat	tion by most
	1) The patient walks/is able to walk	operators. START has many positive aspects, such as being easy to teach and simple to use in the field. Wh	en performing
Does it differ between	2) The patient is breathing, and if so, respiratory acts will be assessed.	START, the only treatment manoeuvres to be done are opening the airway in the non-breathing patient an	d direct
scenarios?	3) The patient has a radial pulse	compression of an external haemorrhage.	
	4) The patient carries out simple orders (consciousness)		

Communication Hardware/Software	Hardware/Software Name (Product Name)	Туре	Format	Used mainly (by which roles)	to communicate with whom	Special features
Which communication hard and software is used in the environment?	Radio	Tetra	Audio and simple data	everyone	Between them and Control Centre	Single network at Regional Level and connected to neighbours region
	Mobile Phones / Smartphone	Mainly Android phones	Audio Video and data	everyone	Between them and Control Centre	
	Communication App (INPRIMIS)	Mobile App	Data	rescuers	EMS Control Centre	Receive dispatch data and send patient data to EMS Centre
	Remote CAD system Workstation	Laptop with sw.	Everything	technician	EMS Control Centre	Remote station of CAD system
	LTE Public Safety	Network	Audio Video and data	experimental	EMS Control Centre	Special usage of public Mobile Network
	Mobile Video Conference App	Mobile App	Bi-directional video communication between actors on the field or between field and Control Centre	Get in visual contact with EMS Centre to show the scene and have hints	EMS Control Centre	Remote cooperation

External Data Sources	Digital Data Source Name	Description	Who needs the data?	Restricted access (open or only available for EMS/first responders)
Which external data sources are/can be used during the triage management	Internal Early Warning System	A function included in the PSAP CAD system able to early spot possible critical situations	Every stakeholder interested in Emergency	YES
process.	Weather Now Casting	Centro Meteo Lombardo	PSAPs EMS Control Centre, Teams on the field	NO
	Regional Hospital & ER Dashboard	EUOL (Emergenza Urgenza On Line) is a system collecting automatically the data and information related to the load of any single Er in the region, as well as the situation of critical hospital resources (Ors, CathLab, ICUs etc.)	EMS Control Centre and Coordinators at the Field	YES
	Public Safety Common Dashboard (E015)	A dashboard managed by the Prefecture showing the situation of the territory	EMS Control Centre and Coordinators at the Field	YES
	Media broadcasting	TV - Radio - WWW	All	NO

Vehicles	Vehicle Name	Туре	Staff (roles and number of people on board)	Description
List vehicles that are available and would/could be used during triage scenarios. Ensure that you include also different versions of similar	Basic Life Support Vehicle	Ambulance (Van)	2 or 3 Rescuers	Ambulance with standard equipment and basic support crew: only rescuers.
vehicles (e.g. ambulance Car with different equipment configurations)	Advanced Life Support Vehicle	Car/Ambulance	1 Doctor + 1 nurse + 1 Rescuer	Vehicle (car or van) with medical equipment: e.g. patient monitor, ultrasound machine and at least 1 doctor

Middle Life Support Vehicle	Car/Ambulance	1 Nurse + 1 or 2 Rescuers	Vehicle (car or van) with medical equipment: e.g. patient monitor, ultrasound machine and at least 1 nurse
HEMS	Helicopter	2 Pilots + 1 Doctor +1 Nurse + 1 Rescuers + 1 Alpine Technician	Helicopter with full equipment aimed to operate in specific territories (e.g. alpine) to to carry out specific rescue manoeuvres. The presence of a specialized technician permits to operate winch manoeuvres also in an urban environment
Specialized Vehicles	Van	Specialized Teams	Van equipped with specific tools aimed to counteract critical situations like NBC.
Emergency Train	Train	Various Doctor + Nurse + Rescuers and Train drivers	A train ready to be moved near t an emergency place. Every single carriage is equipped with 4 intensive care beds.
Advanced Medical Post		1 or more Doctors, some nurses + 1 technician	A field hospital. Very different in terms of size ad equipment in relation to the magnitude of the event. At the time of the triage activity is usually a basic structure aimed to host immediately victims impossible to transfer at the moment.

Stakeholders	Organisation	Department	Role	Main Tasks
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has	Fire Brigades	Interior Ministry	Technical Rescue	Various depending on the real situation and on the nature of the emergency
to be in contact with).	Low Enforcement	Interior Ministry	Secure the scene	Ensure that the rescuers are able to operate in a secured situation
	Prefecture	Interior Ministry	Responsible of the emergency	High level responsibility of the emergency situation
	Healthcare Local Authority	Regional Healthcare Authority	Healthcare situation supervision	Monitoring the situation and provide hospital and other healthcare resources
	Regional Healthcare Authority	Regional Government	High level monitoring	Assure all the resources outside the normality
	County - Municipality	Prefecture	Cooperating	Assure local authority support
	Railways Company / Entity	Traffic Management	Cooperating	Manage train traffic to clear the scene
	Motorway Company / Entity	Traffic Management	Cooperating	Manage train traffic to clear the scene
	Airport Management	Many	Cooperating	Control tower guarantees free access by air
	Local Transportation Company	Management	Cooperating	Provide transportation resources
	Hospital Network	Many	ER and Surgical Depts	Accept and treat patients
	Civil Protection	Control Centre and teams	Supervision and help on the scene	
	Crisis Unit		High level monitoring and political decision	

6.6 ELLINIKOS ERYTHROS STAVROS (HRC) / ETHNIKO KENTRO AMESIS VOITHEIAS (EKAB)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage	Education
Which EMS staff is involved in the triage scenario?	Triage manager	Medical Doctor	He has the main role in the triage process, head of the triage team - composed of one medical doctor and two or more EMT	emergency medicine course, ATLS and internal courses
	Auxiliary triage staff	EMT's	They assist the doctor in the triage procedure	PHTLS and internal courses
	AIA EKAB medical base staff	Doctors, nurses, EMT's	They receive and stabilize the seriously injured	emergency medicine course, ATLS, PHTLS, ILS, etc
	Ambulance staff	Doctors, EMT's	They undertake the main process of transporting the injured to the appropriate hospitals.	emergency medicine course, ATLS, PHTLS, ILS, etc
	Medical motorcycles staff	EMT's	They act as auxiliaries	emergency medicine course, ATLS, PHTLS, ILS, etc
	EKAB Coordination centre	Doctors, EMT's	They Coordinate the available resources	emergency medicine course, ATLS, PHTLS, ILS, etc
	Dispatch Centre Manager	EMT's	supervises the whole process, coordination of all involved ambulances	emergency medicine course, ATLS, PHTLS, ILS, Vocational School for EMT's, etc
	Dispatch Centre Operator	EMT's	receives all emergency calls	emergency medicine course, ATLS, PHTLS, ILS, Vocational School for EMT's, etc
	Dispatch Centre Doctor	MD	supervises all operations	emergency medicine course, ATLS, PHTLS, etc
	ETIK special unit	Doctors, EMT's, administrative staff	They respond to all the mass casualty situations	emergency medicine course, ATLS, PHTLS, ILS, etc
	КЕРҮ ЕКАВ	Doctors, nurses, EMT's, administrative staff	coordination of hospitals	different medical specialties - is not mandatory to have emergency medicine course, ATLS, PHTLS, ILS, etc (optional)
	HRC National Disaster Response Team	nurses, social workers, staff trained in crisis management, trained volunteers	Triage and treatment to assist EKAB, first aid psychosocial first aid, psychological support	Nursing, Social Working, Emergency and paramedic internal training
	Team Leader of HRC NDRT	Staff trained and experienced in emergencies	Coordination of HRC National Disaster Response Team, cooperation with team leader of EKAB as HRC role is auxiliary and complementary	HRC internal training in emergencies

HRC Dispatch Centre Coordinator	Staff trained and experienced in emergencies	Information collection from the field, analysis of the data and coordination of the whole situation from HRC side (human resources involvement, vehicles e.t.c)	HRC internal training in emergencies
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Materials/Equipment	Name	Туре	Used to	Example	Comment
Which materials are specifically used during triage scenarios.	Triage Bracelets	Bracelet	tag priority of receiving care		no data registration possibility
	Triage Tags	Paper tag	tag priority of receiving care		not suitable for different weather conditions, not possible to change category during secondary triage, tagged with rubber band - can be easily detached
	AMP tents				

Triage algorithm	Description	
Which triage algorithm is used during triage?		The second second second
Does it differ between scenarios?		
	S.T.A.R.T Triage	2 A 2 A

Communication Hardware/Software	Hardware/Software Name (Product Name)	Туре	Format	Used mainly (by which roles)	to communicate with whom
Which communication hard and software is used in the environment?	VHF				back up radio system
	Mobile phones				
	TETRA	radio	voice	airport services	all services that work inside the airport
	EKAB TETRA	radio	Voice	EKAB dispatch	EKAB ambulances
	DMR	radio	voice	EKAB ETIK	EKAB ambulances/dispatch/other organizations involved
	Network radio- Push to Talk over cellular (ZELO)	radio	voice	EKAB dispatch	EKAB ambulances
	Mobile phone and data collection	Cell phones/tablets	Voice/Data	HRC staff	

External Data Sources	Digital Data Source Name	Description	Who needs the data?	Restricted access (open or only available for EMS/first responders)
Which external data sources are/can be used during the triage management process.	Hellenic National Meteorological Service	Weather Forecast Information	All members	no
p	MoH (Ministry of Health)			
	social media applications	twitter/FB/viber/whats app	All members	no
	112	phone/data/emergency information		no
	Media broadcasting			
	Ministry of citizen protection data sources of the area where the incident occurred	Accurate and real time information	Coordinator of the operation, HRC staff and volunteers involved	

Vehicles	Vehicle Name	Туре	Staff (roles and number of people on board)	Description
List vehicles that are available and would/could be used during triage scenarios. Ensure that you include also different versions of similar vehicles (e.g. ambulance Car with different equipment	Ambulances	В	2 EMT's	
	Mobile medical units	С	2 EMT's + 1 MD	
configurations)	Medical emergency motorcycles	Motorcycle	1 EMT	
	Rescue VAN	Van	3 EMT's (1 DTL, 2 members)	Vehicle That carries medical equipment
	Rescue VAN	Van	2 EMT's (Unit members)	Vehicle That carries medical equipment
	Command & Communication Vehicle	Van	1 MD, 2 EMT (TL)	Vehicle That is equipped with communication equipment
	Personnel Van + Trailer	Van	6 EMT's, nurses, MD's (LO, and personnel)	Van that carries personnel and Base of Operations Equipment
	Rescue Van + Trailer	Van	2 EMT's	Vehicle That carries medical equipment and Base of operation equipment
	Rescue and Passenger Cars	Van	HRC staff and volunteers	Delivery of staff, volunteers and relevant equipment for the operation

Stakeholders	Organisation	Department	Role	Main Tasks	
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has to be in contact with).	Fire Service	Special Unit for Disasters (EMAK), Regional Fire Services	Coordination (Incident command), Safety	fire extinguishing, SAR operations, transportation of victims to the triage zone, HazMat & CBRNe incidents	communication for airport all services involved is through common TETRA system
	Civil protection	command coordination center	Incident command - auxiliary staff	In charge to coordinate all involved services in all levels of operations (bronze-silver-gold command)	phone communications or messages through 112
	Hellenic Police	Road Traffic Police	Security	facilitation for arrival and departure of ambulances, traffic control, perimeter control	phone communications or messages through 112
	Hellenic Police	Special Units: Anti- terrorism, Explosives, Rapid Responce	Security issues	Neutralize terrorists - control the perimeter - control of explosives	
	Hellenic Coast Guard		Security	SAR operations - perimeter control - terrorism control (incidents taking place in the sea or coastline)	phone communications or messages through 112
	Hellenic Armed Forces	Military Medical Services		Medical operations in collaboration with EKAB	
	EKAB - Emergency Medical Services	Special Disasters Unit	Medical Services	is in charge to coordinate all medical operations on scene - Triage Treatment Transport (MEDEVAC)	there is no common communication channel for the different services
	EKAB dispatch center		dispatch for ambulances and coordinates hospital response	communicates with other dispatch centres	phone and radio communication
	NGOs - Voluntary Organisations		auxiliary staff		on site communication
	Airport	Airport staff	Auxiliary staff	supportive to main staff	
	Airport	ASOC member	chief officer on scene (in case of emergency incident in the airport area)	is in charge to coordinate all involved services	
	MUNICIPALITIES	civil protection representative	supportive	offers supportive services or materials	phone communications

REGIONS	civil protection representative	supportive	offers supportive services or materials	phone communications
public transport authorities		supportive	offers supportive services or materials	through Civil Protection CC
hospitals and medical centres	ED	coordination regarding patients' transfers	facilitation for arrival and departure of ambulances, patients' reception, data exchange,	
Hellenic Red Cross	National Disaster Response Unit	Auxiliary to the State Organizations	First Aid and Psychosocial First Aid (PFA),PFA to the injured and to the families of the victims, dealing with vulnerable groups and treatment of rescuers and volunteers	

Stakeholders	Organisation	Department	Role	Main Tasks
List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has to be in contact with).	Airport	Airport Fire department	Coordination, Safe and secure	fire extinguishing, SAR operations, transportation of victims to the triage zone
	Airport	Airport Police department	Safe and secure	
	Airport	Airport staff	Auxiliary staff	supportive to main staff
	Airport	ASOC member	chief officer on scene	is in charge to coordinate all involved services
	Civil protection		Auxiliary staff	
	Hellenic Police	road traffic	auxilliary	facilitation for arrival and departure of ambulances
	Fire Service	local	auxilliary	support of the airport fire service
	Airport medical staff	airport EKAB department	Medical evaluation	is in charge to coordinate all medical operations on scene
	EKAB dispatch center		dispatch for ambulances and coordinates hospital response	communicates with other dispatch centers FS, HP, GSCP

6.7 IZMIR BUYUKSEHIR BELEDIYESI (IBB)

EMS roles, profession and educational background	Role	Profession	Main Tasks during Triage	Education
Which EMS staff is involved in the triage				
scenario?	Emergency and Disaster Manager	Emergency Manager	Provides scene coordination	Emergency and Disaster Management Training

Incident Health Manager	Medical doctor	Provides management of healthcare teams (UMKE)	BLS, ALS, PHTLS, paediatric ALS, Emergency and Disaster Management Training
Triage Manager	Medical doctor	Responsible for 1st basic triage	BLS, ALS, PHTLS, paediatric ALS,
Triage Assistant	Paramedic	Responsible for 1st basic triage	BLS, ALS, PHTLS, paediatric ALS,
Treatment Area Manager	Medical doctor	Responsible for 2st basic triage and treatment	BLS, ALS, PHTLS, paediatric ALS,
Treatment Area Staff	Medical doctors, paramedics, EMT's	Responsible for 2st basic triage and treatment	BLS, ALS, PHTLS, paediatric ALS,
Logistic Manager	Paramedic	Responsible for triage and treatment equipment.	BLS, ALS, PHTLS, paediatric ALS,
112 Emergency Call Centre Call Taker	Officer	Asses first incoming calls to 112	Call answering, communication and working under stress training
112 Emergency Call Centre Dispatcher	Paramedic/Nurse/ EMT	Directs incoming health calls to 112	Call answering, communication, BLS, ALS, PHTLS, paediatric ALS,
112 Emergency Call Centre Consultant Doctor	Medical doctor	Asses incoming health calls to 112	BLS, ALS, PHTLS, paediatric ALS,
112 Emergency Call Centre Manager Doctor	Medical doctor	Asses incoming health calls to 112	BLS, ALS, PHTLS, paediatric ALS,
Paramedic			
EMT			
Firefighter			
Driver			
Technical Staff			

Materials/Equipment	Name	Туре	Used to	Example
Which materials are specifically used during triage scenarios.	Triage tags		tag priority of receiving care	
	EKG			
	Monitor Defibrillator	Biphasic		
	Automatic External Defib	Heart Save AED (ED300)		
	Mobil Triage Tent			
	Mobil Treatment Tent			





Communication Hardware/Software	Hardware/Software Name (Product Name)	Туре	Format	Used mainly (by which roles)	to communicate with whom	Special features
Which communication hard and software is used in the environment?	Radio	VHS	audio ve. simple data	EMS and Firefighter	inter-team and emergency call centre	encrypted
	Mobile and smart phone	mainly android	audio/image	everyone	call centre and all stakeholders	Digital
	Satellite phone		Audio	Team leader	between other country and city	
	Acilizmir mobile app.	mainly android		everyone	between rescuer and survivor	Public Mobile network
	Citizen Communication Centre	HIM	audio and social media	everyone		Public Mobile network
	Amateur Radio (TRAC)	HF	Audio and simple data	Members	between the scene and the 112 call centre	encrypted
	112 Emergency app.	Android		everyone		
	Radio	UHF	Audio and simple data	Train crews	between Train Command Control and train crews	encrypted

External Data Sources	Digital Data Source Name	Description	Who needs the data?	Restricted access (open or only available for EMS/first responders)
Which external data sources are/can be used during the triage management process.	Personnel information system	EMS and firefighter personnel information	112 Emergency Call Centre Manager doctor, Incident Health Manager	Yes
	Hospital information system	Information of public and private hospitals (patients, beds, medical devices and staff).	112 Emergency Call Centre Consultant and Manager doctor, Incident Health Manager, Triage Manager	Yes
	Vehicle information system	Location and vehicle information of ambulances, fire trucks and police teams.	112 Emergency Call Centre Manager Doctor, Incident Health Manager	Yes
	Media broadcasting	TV, Radio and www.	Everyone	No

Vehicles	Vehicle Name	Туре	Staff (roles and number of people on board)	Description
List vehicles that are available and would/could be used during triage scenarios. Ensure that you include also different versions of similar vehicles	Emergency Ambulance	ALS	3 staff: 1 doctor/paramedic, 1 paramedic/EMT, 1 EMT/driver	for patients with red and yellow codes
(e.g. ambulance Car with different equipment configurations)	Patient Transport Ambulance	BLS	2 staff: 1 paramedic/EMT/Nurse 1 EMT/ driver	for patients with yellow and green codes
	Helicopter Ambulance	HEMS	4 staff: 1 doctor, 1 paramedic, 2 pilot	for patients with red codes
	Mobile Command Control Vehicle	МККА	5 staff: 1 Manager, 1 paramedic, 2 Firefighter, 1 Driver	for scene management
	Rescue Ambulance	AKS	5 staff: 2 paramedic/EMT, 2 Firefighter, 1 Driver	combi vehicle ambulance
	Rescue Vehicle		6 staff: 1 Chief, 4 firefighter, 1 driver	for rescue
	Fire Truck		6 staff: 1 Chief, 4 firefighter, 1 driver	for firefighting
	Logistics Vehicle		3 staff: 1 Chief, 1 firefighter, 1 driver	for rescue equipment, triage and treatment tents

Stakeholders	Organisation	Department	Role	Main Tasks
	Ambulance Service	Provincial Health Directorate	medical support	health care
	UMKE	Provincial Health Directorate	medical support	health care

List all other stakeholders which are involved during triage management scenarios (especially the ones that your organisation has to be in contact with).	Fire Department	Metropolitan Municipality		health care, search and rescue, fire response
	Hospitals	public and private	support	support
	Train command and control centre officers.	Metropolitan Municipality	support	support
	Suburban Train (IZBAN)	Metropolitan Municipality (IBB) & State Railways (TCDD)	support	support
	Police	Provincial Police Department	security	security in urban area
	train station security guards	Metropolitan Municipality	security	security in train stations
	TRAC	amateur radio association	communication	Long distance and different communication

7 Use Cases and Process Models

In order to allow the drafting and creation of the use cases, the consortium needed to strongly work on the definitions not only of the use cases and service process models, but also on agreeing on common glossary which will be used as basis for the next phases and development of the project. In this paragraph only those terms are reported, which are central for the methodology. All the other terms and definitions are part of the "Term and Definition" chapter (Chapter 1.1).

Use Case: Tabular description of the interaction between a role and a system to achieve a goal. The actor can be a human or group of humans. In iProcureSecurity PCP, the actors have been subdivided into six categories. Each category includes specific profiles, which can different from country to country as well from procurers to procurers. (More information on the categories on paragraph 2.3).

System Process Model: A visual representation of a business process or workflow and its related subprocesses. Process modelling generates comprehensive, quantitative activity diagrams and flowcharts containing critical insights into the functioning of a given process.

In iProcureSecurity PCP each process model describes a use case and is used to identify basic principles of the system or activity, which the suppliers need to implement.

7.1Use cases development methodology

The use cases follow a methodology, which is used in system analysis to identify, clarify, and organize system requirements. The use case is built from a set of possible **sequences of interactions between systems and users** in a particular environment and related to a particular goal.

Specifically, the iProcureSecurity PCP Solution is considered as a "black box", and the interactions with external systems, including system responses, are as perceived from outside the solution.

Furthermore, a complete set of use cases specifies the key functionalities the system should develop. Within the iProcureSecurity PCP project, each use case is described in full detail with one (or more) corresponding process models, which have the same name and ID.

Use Case development includes the following activities:

- Identification of all the different categories of actors and their responsibilities and roles within the iProcureSecurity PCP Solution.
- Creation of a user profile for each category of user, including all the roles the users play that are relevant to the system.
- For each category, the identification of all the relevant goals and needs, the system will support.
- Creation of a use case for each goal, following a use case template. It is important to note, that the consortium tried to maintain the same level of abstraction throughout all the use cases.

7.2Use cases elements

The following elements have been identified for the creation of the use cases (also proposed as ANNEX A "Use Cases Template").

ID: Each use case has an ID number to allow for easy referencing.

Title: Each use case should have a unique title suggesting its purpose.

Summary: The summary gives an overview over the purpose of the use case and provides the ideal outcome (result) of the use case.

Actors: This field contains the relevant and active actors.

The actors have been subdivided into six categories. Each category has customized access to information as well as responsibilities. Furthermore, each category includes specific profiles, but it should be noticed that the roles and responsibility of these profiles differ change from country to country and even from procurer to procurer:

- CATEGORY A) Non-Health Care Actors (first aider, bystander);
- CATEGORY B) Health Care Actors (EMS Practitioners, doctors, nurses, paramedics, ambulance crew);
- CATEGORY C) Operative Actors (head of triage, head of transport, head of operation site management);
- CATEGORY D) State Actors (fire brigades, law enforcement agencies, regional and or national authorities, Civil Protection authorities);
- CATEGORY E) Dispatch Centre Actors;
- CATEGORY F) Technical Administration and Maintenance.

Each category includes different profiles, which have different roles and responsibilities.

Preconditions: In all use cases, certain conditions and factors need to be present for the use case to be applied. They are described in this field.

Key functionalities: The key functionalities describe the main aspects of the envisioned system, implying steps that the actors and the system go through to accomplish the goal of the use case.

The most important functional flows will also be represented in the service process models, which depict more details and also further steps and artefacts (e.g., pieces of data necessary for the step to be carried out).

Post conditions: Clearly describes the end state or outcome of the use case.

Triggers: Triggers describe the entry criteria for the use case. This becomes especially important in semi-automatic or automatic processes which apply to services.

Frequency: The frequency describes whether the interaction takes place once or is repeated. In this field, it is described how and in which conditions the interaction repeats itself.

Open issues / Notes: Free text to report issues and make comments is also available for each use case.

7.3 Service process models development methodology

The Service Process Model development included the following actions:

- For each use case, create a first outline of the process model set based on the developed use cases.
- Refine the process model set based on feedback from the procurers (as by definition BPMN should be understandable and utilised by all business users). If needed, generalise or further specify models so that they fit all procurers' service processes.

• Create a final set of process models. Validate their technical accuracy against the BPMN specification.

Process models for iProcureSecurity PCP project have to cover the necessities of the eight procurers who are using different organisational model, approaches and systems. In order to simplify the structure for the suppliers and for the external stakeholders, but also to simplify the traceability of requirements among the different approaches the following principles will be applied to the service process models:

- Chronological approach the process models are mainly oriented on a timeline (from left to right);
- All tasks or activities are assigned to one of the category types;
- The notation can make use of colours to suit the purpose of the modeller or tool;
- The service process models elements can be of any size to suit the purpose of the modeller or tool;
- "Simplicity in modelling" approach:
 - New modelling elements are introduced only if there's no possible way of modelling a process with the basic elements.

If there are different ways of modelling a task or method, the simplest is chosen to minimise the size of the process.

Standards used

Techniques to model service process models such as the flow chart, functional flow block diagram, control flow diagram, Gantt chart, PERT diagram, and IDEF have emerged since the beginning of the 20th century. Business Process Model and Notation (BPMN) together with Unified Modelling Language (UML) are among the most often used modern methods of modelling business processes.

The process models follow the BPMN 2.0 open specification maintained by the Object Management Group (OMG)¹. It is based on previous notations such as EPC, UML activity diagrams and Petri Nets.

The primary goal of BPMN is to provide a notation that is readily understandable by all business users, from the business analysts that create the initial drafts of the processes, to the technical developers responsible for implementing the technology that will perform those processes, and finally, to the business people who will manage and monitor these processes. Thus, BPMN creates a standardised bridge for the gap between the business process design and process implementation.

The process models that are created for iProcureSecurity PCP are based on the use of BPMN 2.0 – the newest version that was released in January 2009.

The main advantages of BPMN 2.0 method are:

- Neutral notation, adopted by many solution providers;
- Growing number of tools available;
- Diversified usage from process visualisation to process automation;

7.4Service process models elements

Process Model ID: Each process model has an individual ID that always starts with "PM" (for process

¹ http://www.omg.org/spec/BPMN/index.htm

model) followed by a number corresponding to the use case number (e.g., PM2 for UC2 "Simple Triage and Rapid Treatment"). If there is more than one Process Model related to the same use case, following numbering scheme will be used PM n.1 and PM n.2.

Process Model Name: The name of the model matches the name of the corresponding use case.

Process Modelling Elements: The service process models share the workflow description format in a horizontal flow of activities that are contained in pools (see below) and are to be read from left to right. The following elements will be used in the development of the process models. The intention is to use as few elements as possible to cover all procurers' processes.

The table below presents a summary of elements/symbols and their graphic representation used for the modelling in iProcureSecurity PCP:

Symbol name	Туре	Symbol	Description
Start	Event		The Start indicates the start of a state.
End	Event	0	The End indicates the end of a state.
Action	Activity		The Action indicates that an action is performed by the category.
Gateway	Gateway		When splitting , it routes the sequence flow to exactly one of the outgoing branches. When merging , it awaits one incoming branch to complete before triggering the outgoing flow.
Sequence flow	Connection object	Sequence flow	Defines the connection between actions.
Association	Connection object	Association	Associations are used to connect activities, comments, actions or database.
Comments	Other		Comments are used to provide additional information for the reader of the diagram.

Table 1: Service process model elements

Use Case	Other	UC	The Use Case is used to connect the data coming or generated by the use cases.
Database**	Other	MCI DB User DB Casualty DB	The database is used to understand where the data are going to or taken from.
***External Database	Other	External EHR DB (if existing)	The external Database shows where integration from external database is needed.

**Database:

To highlight main data that needs to be captured, recorded and processed the process models mention following three main data bases:

- User Database (User DB): Contains information about users, their roles and permissions for different parts of the solution.
- Mass Casualty Incident Database (MCI DB): Contains all information on the MCI (e.g., MCI profile, initial assessment of MCI, location, environmental conditions, etc.)
- Casualty Database (Casualty DB): Contains all information on the casualty (e.g., Casualty profile, treatment, vital Parameters, etc.).

However, this should structure shall not dictate the actual data base architecture to be used by the suppliers.

***External Databases:

The iProcureSecurity PCP Solution should be able to exchange data with external databases (e.g., EHR database). The information coming from other databases will feed into the iProcureSecurity PCP Solution, following the IT interoperability requirements requested by the procurers (see ANNEX B).

8 General narrative of the overall process

In order to better explain the type of support which will be expected by the iProcureSecurity PCP Solution, this chapter describes the overall processes of a Mass Casualty Incident, having as main thread the Use Cases developed within the project, described in detail in the next paragraph.

A Mass Casualty Incident (MCI) has occurred. The Dispatch Centre starts receiving numerous emergency calls, all describing a large incident involving several casualties in need of rescue. A Mass Casualty Incident is officially declared. The Dispatch Centre activates the Operation Site Management

165

and send the first actors to the MCI area. The iProcureSecurity PCP Solution allows the responsible actors (either the Dispatch Centre or the Operation Site Management, depending on the country) to assign the roles and responsibilities for the management of the specific MCI, as well as to create a unique MCI ID and MCI Profile, on which all the data in regard to the specific MCI will be stored, monitored and updated (**UC1**). Actors - who have been granted with particular roles - access the iProcureSecurity PCP Solution and, depending on their profile and category, they will have access to specific interfaces, and thus, to a specific range of information. Based on their role/responsibility, they will be able to perform specific actions and share specific information with the iProcureSecurity PCP Solution. (**UC3**).

The first actors arrive at the Mass Casualty Incident Area and start the simple triage and rapid treatment. The iProcureSecurity PCP Solution supports the actors in their triage activities, by providing them with guidance on how to conduct the triage algorithm, as well as with a "hardware component" (Triage Tag) able to measure specific vital parameters, automatically create the Casualty ID and Casualty Profile, and continuously geolocating the casualty. Finally, the iProcureSecurity PCP Solution proposes and displays the status/colour of the casualties, based on the applied triage algorithm and collected and continuously monitored vital parameters (UC2). After the primary triage (UC2), each casualty is automatically identified through a unique ID and Casualty Profile, which includes all the information about the casualty (e.g., continuous updated of vital parameters, ID and photos of the casualty – if available -, data coming from the HER etc.). Dependent on the size of the incident the casualty is transported to the Advanced Medical Site for treatment before being taken to the hospital. The iProcureSecurity PCP Solution provides support for the management of the activities planned in the Advanced Medical Site, supporting in the treatment and prioritization of the casualties. It will provide customizable guidance on the treatments (for example CGS - Glasgow Coma Scale, or RTS -Revised Trauma Score), enabling the update of the Casualty Profile, after the stabilisation of the patient's clinical conditions. The updated data will be shared in real time with the other EMS practitioners (UC4). Furthermore, in case of relevant changes of the casualty vital parameters, the iProcureSecurity PCP Solution enables an alerting and notification system, ultimately helping to determine the priority of treating or transporting the casualty to the hospital (UC3).

In parallel to the first triage and treatment procedures, the Category C (i.e., the Operatives, such as head of the triage, onsite manager, head of the advanced medical site etc.) is performing the Initial MCI assessment, and taking main decisions (for example where to locate the parking and triage areas).

All the information gathered by the Category C actor, must be then transmitted to other stakeholders. The iProcureSecurity PCP Solution quickly and (semi) automatically collects information on the geography and environmental conditions of the MCI area, as well as on traffic and weather conditions, thus facilitating the decision-making process. Also, it enables a smooth flow of the collected information with other EMS practitioners on the field as well as with external stakeholders involved in the MCIs (Category E) in order to properly manage the event accordingly to the national procedures **(UC6)**. Parallelly to the organisation of the area and the collection of the information, the Category C is also responsible for the management of the vehicles and resources, deciding on the number and type of human resources, equipment and vehicles. The iProcureSecurity PCP Solution supports the actors in managing the resources available, based on the continuous update and flow of information coming from the simple triage and rapid treatment (UC2), from the Advanced Medical Site (UC4) and from the Operation Site Management (UC6). The iProcureSecurity PCP Solution supports the Category

C actor by providing information on vehicle availability, the casualties' health condition, traffic, types and availability of hospitals (e.g., free ICU beds) **(UC7)**.

All the sensitive data on the casualty – including personal information and vital parameters - are continuously collected, updated and stored within the iProcureSecurity PCP Solution. This functionality allows the EMS personnel in having continuous monitoring and update of clinical parameters. In case of relevant changes of the vital parameters, the iProcureSecurity PCP Solution will send alerts and notifications to the interested actor (UC3). The collected vital information is shared on the Casualty Profile, and on the Triage Tag, allowing all involved healthcare personnel to establish diagnostic and therapeutic procedures (UC5).

Once MCI operations have been completed, the iProcureSecurity PCP Solution provides a tool to monitor and evaluate the quality of the intervention and the management of emergency scenarios. It generates an automatic report, which assesses all the collected data, actions, decisions taken and highlights good and best practises. The iProcureSecurity PCP Solution will allow a fully customizable and editable reporting so that each procurer will be able to adapt the structure, format, and size of the evaluation report and prepare the debriefing for the training efficiently. The information provided by the report will be used for the creation of training modules and curricula. Furthermore, the iProcureSecurity PCP Solution supports the different actors during simulated emergency management activities and automatically evaluate the MCI trainings (**UC8**).

Overall, the iProcureSecurity PCP Solution must be open and flexible enough to integrate data from and to third party systems (**UC9**).

9 iProcureSecurity PCP use cases and service process models

The purpose of the use cases and service process models is to help suppliers to better understand the expected functionalities. Specific conditions may deviate slightly from what suppliers will offer. It is however essential that the overall functionalities and procurers' expectations will be met by the suppliers' envisaged solution.

Below, some important methodological notes on the use cases:

Note 1

It should be noticed that some of the key functionalities of the use cases are described with the verb "must", while some others with "shall/should or may". Must refers to the high importance of developing the key functionality, while "shall/should or may" refers to a desired wish of the procurers. The verbs used for the key functionalities mirrors therefore the prioritization given to the requirements.

Note 2

Furthermore, the iProcureSecurity PCP use cases have the characteristic of being related either to *human-driven processes* & *their management* or to *system-driven activities*.

The use cases dealing with *human-driven processes and their management,* are those which mainly foresee active actions from the category of actors (e.g., performing triage algorithms, treatments, decision-making processes etc.).

Human-driven use cases includes:

- Use Case 2 Simple Triage and Rapid Treatment;
- Use Case 4 Advanced Medical Site Management;
- Use Case 6 Operation Site Management;
- Use Case 7 Vehicle and Resource Management;
- Use Case 8 Training and Evaluation.



Figure 1: Human-driven use cases

System-driven use cases do not foresee and active engagement of the categories of actors (besides system administrators), but rather demonstrate fundamental structure and functionalities of the iProcureSecurity PCP Solution.

The consortium has decided to include the system driven activities as part of the use cases, as those components are particularly important to understand general procurer expectations to the solution.

System-driven use cases includes:

- Use Case 1 Central Information System;
- Use Case 3 Data Visualisation System;
- Use Case 5 Clinical Parameter Collection System;
- Use Case 9 Systems integration.



Figure 2: System-driven use cases

Note 3

The use cases and the process models are to be updated based on the outcomes of the next project phases. This will allow the use cases and process models (and thus, also the iProcureSecurity PCP Solution) to be partially flexible and adaptable to potential changes or unforeseeable new needs. However, the structure of the use cases and the process models which is outlined in this deliverable, should be considered as final and comprehensive as possible.

The use cases and the process models are to be updated based on the outcomes of the next project phases. This will allow the use cases and process models (and thus, also the iProcureSecurity PCP Solution) to be partially flexible and adaptable to potential changes or unforeseeable new needs. However, the structure of the use cases and the process models which is outlined in this deliverable, should be considered as final and comprehensive as possible.

9.1UC1: Central Information System

Table 2: Use Case 1 - Central Information System

ID	UC 1
TITLE	Central Information System
SUMMARY	The Central Information System (UC1) is a system-driven use case. It is the main system component of the iProcureSecurity PCP Solution. UC1 ensures real-time sharing of data and information, and has the scope to enable effective distributed collaboration during the evolution of the Mass Casualty Incident (MCI).
	Having access to the Central Information System (UC1), the selected actors (e.g. Onsite Management, Dispatch Centres and/or any other relevant actors, depending on the procurers' needs) grant access to all relevant information and will therefore, effectively support the decision-making process. The information gathered within the Central Information System (UC1) is sent to and elaborated by the Data Visualisation System (UC3). The latter - as described in UC3 - provides the elaborated information to the particular actors. The Central Information System (UC1) authorises the actors to assign roles and responsibilities within the MCI operation.
	The Central Information System (UC1) must be open and flexible enough to allow data sharing from and to existing and upcoming third-party solutions, in order to allow the proper Systems Integration (UC9).
ACTORS	• CATEGORY F - Technical Administration and Maintenance
PRE-CONDITIONS	 PRE CONDITION 1) A Mass Casualty Incident takes place. PRE CONDITION 2) The Central Information System (UC1) must be able to work without public internet coverage. PRE CONDITION 3) The Central Information System (UC1) must be open and flexible enough to allow data sharing from and to existing and upcoming third parties solutions, in accordance with Systems Integration (UC9) - e.g. such as EHR, medical devices or other solutions such as UAVs.

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KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Central Information System (UC1) must be accessible to authorised actors only.
	KEY FUNCTIONALITY 2) The Central Information System (UC1) must allow roles and responsibilities management. The role and responsibilities allow access to and management of the various functionalities of the iProcureSecurity PCP Solution to specific actors.
	KEY FUNCTIONALITY 3) The Central Information System (UC1) has to store all data and information in real-time (e.g. User, MCI and Casualty database).
	KEY FUNCTIONALITY 4) The Central Information System (UC1) must record and gather all the different data as well as actions, and activities which have been performed throughout the whole Mass Casualty Incident. Thus, it will allow a detailed reporting and check of the activities - in line with UC8.
	KEY FUNCTIONALITY 5) The Central Information System (UC1) must allow users to set preferences (e.g. language) which are stored with the user account and / or as cookies.
	KEY FUNCTIONALITY 6) The Central Information System (UC1) must allow customisation of main components (for example triage algorithm, initial assessment, guidance cards and checklists, user roles, terminology etc.)
	KEY FUNCTIONALITY 7) The Central Information System (UC1) must gather information from all the other UCs.
POST-CONDITIONS	POST CONDITION 1) All the UC1 collected information must be shared in real time with the Data Visualisation System (UC3).
TRIGGERS	MCI has been declared.
FREQUENCY	The Central Information System (UC1) is always active and continuously updated throughout the whole Mass Casualty Incident operation. The collected data must be recorded and stored.

9.2 PM1: Central Information System



Figure 3: Process Model 1 – Central Information System

9.3UC2: Simple Triage and Rapid Treatment

Table 3: Use Case 2 - Simple Triage and Rapid Treatment

ID	UC 2
TITLE	Simple Triage and Rapid Treatment
SUMMARY	The Simple Triage and Rapid Treatment (UC2) is a human-driven use case. It supports the actors in their triage activities. The Simple Triage and Rapid Treatment (UC2) follows a triage algorithm (for example START triage) that collects and uses consistent parameters. This allows the division and the selection of casualties into categories/groups/priority classes (regarding recovery, treatment and transport/evacuation), based on the severity of injuries encountered. The Simple Triage and Rapid Treatment (UC2) allows fast identification, tracking and geolocation of each casualty and supports and records continuously all the procedures performed throughout the whole MCI. It also assists the decision-making process for the prioritisation of one casualty over the other.

ACTORS	 Category A - Non-Health Care Actors (first aider, bystanders) Category B - Health Care Actors (EMS Practitioners, doctors, nurses, paramedics, ambulance crew)
PRE-CONDITIONS	PRE CONDITION 1) Mass Casualty Incident is declared and the Mass Casualty Incident Profile activated.
	PRE CONDITION 2) Actors responsible for the primary triage operations approached the casualty.
	PRE CONDITION 3) All actors involved within this UC are authorised to access the iProcureSecurity PCP Solution.
	PRE CONDITION 4) The Simple and Rapid Treatment (UC2) must not slow down the triage operations of the casualties by burdening the actors with additional tasks.
	PRE CONDITION 5) The Key Functionality 6 of UC1 must be fulfilled (components' customization).
	PRE CONDITION 6) The key functionalities of the UC2 must work even in absence of network communication.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Simple Triage and Rapid Treatment (UC2) must include a hardware component (Triage Tag), which automatically creates the Casualty Profile. All the information gathered on the Casualty Profile must be available on the casualty (Triage Tag) from the first triage until the hospitalisation.
	 KEY FUNCTIONALITY 2) The Triage Tag must be able to: (a) measure specific vital signs (see requirements), (b) comprise the whole casualty profile, (c) display the colour/status of the casualty, (d) indicate geolocation of casualties (e) (optionally) display extended parameters/information.
	KEY FUNCTIONALITY 3) The Simple Triage and Rapid Treatment (UC2) must include a guidance system that assists the actors conducting the triage algorithm step-by-step.
	KEY FUNCTIONALITIES 4) The Simple Triage and Rapid Treatment (UC2) must suggest - on the basis of the (manually and/or automatically) collected information -, the status of the casualties. All casualties have a colour code (depending on the system used in each country).
	KEY FUNCTIONALITY 5) The Simple Triage and Rapid Treatment (UC2) must allow the collection and monitoring of the vital parameters identified in the requirements list.
	KEY FUNCTIONALITY 6) The Simple Triage and Rapid Treatment (UC2) allows data on the casualty to be collected automatically (e.g. by the triage tag), but also gives the possibility to enter information manually (on the Casualty Profile) in a fast and reliable way, using mobile phone, tablets or laptops.
	KEY FUNCTIONALITY 7) The Simple Triage and Rapid Treatment (UC2) / Triage Tag must be mobile/easy to handle/operate, affordable, easy to maintain, as

	well as unaffected by environmental conditions (e.g darkness, fluids, dust, extreme temperatures, resistant to physical impacts etc.) KEY FUNCTIONALITY 8) The actors must be able to regularly update the triaged casualty status.
POST-CONDITIONS	POST CONDITION 1) Data sharing with Central Information System (UC1), and therefore, Data Visualisation System (UC3) is mandatory. POST CONDITION 2) Fulfil the KEY FUNCTIONALITY 4 of UC1.
TRIGGERS	Mass Casualty Incident Profile activated and actors are on the field.
FREQUENCY	Simple Triage and Rapid Treatment (UC2) is active after the first MCI assessment until all casualties are triaged.

9.4PM2: Simple Triage and Rapid Treatment



Figure 4: Process Model 2 – Simple Triage and Rapid Treatment

9.5UC3: Data Visualisation System

Table 4: Use Case 3 - Data Visualisation System

ID	UC 3
TITLE	Data Visualisation System
SUMMARY	The Data Visualisation System (UC3) is a system-driven use case. It is a system component of the iProcureSecurity PCP Solution. The scope of the UC3 is to present to the different actors the collected and elaborated information coming from the Data Visualisation System (UC1). The Data Visualisation System (UC3) also provides interfaces for manual data collection (such as the data collected from the initial MCI assessment or during the simple triage) which are fed into the Data Visualisation System (UC1). The information presented by the UC3 is

	continuously updated in real time. Furthermore, the Data Visualisation System (UC3), indicates alerts to the specific actors, based on data processed from Data Visualisation System (UC1).
ACTORS	All Categories
PRE-CONDITIONS	PRE CONDITION 1) The Data Visualisation System (UC3) must receive data from UC1.
	PRE CONDITION 2) The Data Visualisation System (UC3) must be able to share elaborated information with all the other UCs.
	PRE CONDITION 3) The Data Visualisation System (UC3) must be able to work without public internet coverage.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Data Visualisation System (UC3) must provide a system which is able to organise and aggregate data coming from the Central information System (UC1).
	KEY FUNCTIONALITY 2) The Data Visualisation System (UC3) enables category C (Operative Actors) and E (Dispatch Centre) to optimise the decision-making processes (e.g. dashboards).
	KEY FUNCTIONALITY 3) The Data Visualisation System (UC3) must indicate notifications (e.g. trigger certain tasks from the checklist and remind staff) and alerts to the relevant actor categories, based on the data processed from UC1. Thus, quickly and reliably supporting the immediate decision-making process. In addition, the UC3 should provide informed suggestions based on the available data on how to properly address the alerts.
	KEY FUNCTIONALITY 4) The Data Visualisation System (UC3) must present all the relevant information in an intuitive and uncomplicated way.
	KEY FUNCTIONALITY 5) The Data Visualisation System (UC3) must provide highly intuitive graphical user interfaces (based on the actors' categories), in order to allow the proper manual data entries into the system.
	KEY FUNCTIONALITY 6) The Data Visualisation System (UC3) must share information with:
	(a) UC2 - Simple Triage and rapid Treatment: data on casualty profiles (b) UC4 - Advanced Medical Site: data on treatments
	(c) UC6 - Operation Site Management: data of active actors (including their role) and number of triage casualties and their status (number of casualties, priority, geolocation, assistance provided, status of rescue).
	(d) UC7 - Vehicle and Resource Management: data on vehicles involved (number of vehicles, free/busy status, geolocation), stocks of care equipment (drugs, medical devices, first aid equipment).
	(e) UC8 - Evaluation and Training: evaluation report and training modules
POST-CONDITIONS	POST CONDITION 1) Fulfil the KEY FUNCTIONALITY 4 of UC1.
TRIGGERS	When iProcureSecurity PCP Solution is active.
FREQUENCY	The Data Visualisation System (UC3) is always active and continuously updated until the iProcureSecurity PCP Solution is running.

9.6PM3: Data Visualisation System



Figure 5: Process Model 3 – Data Visualisation System

9.7UC4: Advanced Medical Site Management

Table 5: Use Case 4 - Advanced Medical Site Management

ID	UC 4
TITLE	Advanced Medical Site Management
SUMMARY	The Advanced Medical Site Management (UC4) is a human-driven use case. It must provide support for selection, treatment and re-evaluation of the casualties identified in the simple triage. Therefore, the Advanced Medical Site Management (UC4) must support all the activities in regard to medical treatment and stabilisation of the casualties, as well as prioritisation of the casualties for the transport. The Advanced Medical Site is established especially in large and complex Mass
	Casualty Incidents.
ACTORS	 Category B - Health Care Actors (EMS Practitioners, doctors, nurses, paramedics, ambulance crew) Category C - Operative Actors (head of triage, head of transport, head of operation site management)
PRE-CONDITIONS	PRE CONDITION 1) After Simple Triage and Rapid Treatment (UC2), the casualty is recognised and his/her (first) status is ascertained.PRE CONDITION 2) The Operation Site Management (UC6) decided to establish
	the Advanced Medical Site. PRE CONDITION 3) The casualty is transported to the Advanced Medical Site for treatment.

	PRE CONDITION 4) Information coming from the Central Information System (UC1) through the Data Visualisation System (UC3) are shared.
	PRE CONDITION 5) The key functionalities of the UC4 must work even in absence of network communication.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Advanced Medical Site Management (UC4) supports the actors in treating casualties, according to status/colour-code priority (red, yellow, etc.).
	KEY FUNCTIONALITY 2) During the treatment procedures the Advanced Medical Site Management (UC4) must consider the re-evaluation of the casualty, who has been already classified during the simple triage. The re-evaluation can be performed through "medical" triage protocols, for example: - CGS (Glasgow Coma Scale) - RTS (Revised Trauma Score) - or similar.
	KEY FUNCTIONALITY 3) The Advanced Medical Site Management (UC4) must enable the update of the casualty status/colour, in order to facilitate the transportation to the hospitals.
	KEY FUNCTIONALITY 4) The Advanced Medical Site Management (UC4) must support the actors in identifying and monitoring major injuries and casualties at risk of sudden health deterioration. This functionality is supported by the Data Visualisation System (UC3) - alerting and notification system.
	KEY FUNCTIONALITY 5) The Advanced Medical Site Management (UC4) must be able to connect with the Casualty Profile in order to: (a) access all the necessary information on the casualty (e.g. including external EHR information if available);
	(b) update, record and store treatment and personal information on the casualty. This must be ensured also during the transportation to the hospital.
	KEY FUNCTIONALITY 6) The Advanced Medical Site Management must allow management of status/colour change based on Clinical Parameter Collection System (UC5).
	KEY FUNCTIONALITY 7) The Advanced Medical Site Management (UC4) must provide the capability of connecting with external devices that can capture vital parameters from casualties in a (semi) autonomous way.
	KEY FUNCTIONALITY 8) The Advanced Medical Site Management (UC4) must be able to share information on both resources available and needed. (UC6 and UC7).
	KEY FUNCTIONALITY 9) The Advanced Medical Site Management (UC4) must support the decision-making process of the Operation Site Management (UC6) and Vehicle and Resource Management (UC7) - e.g. finding the most suitable hospital for the specific injury/pathology of the casualty; supporting the decision making process for the transportation of injured-casualty; resource allocation.
	KEY FUNCTIONALITY 10) The Advanced Medical Site Management (UC4) shall enable the provision of remote medical guidance to Category A (non health-care actors) and Category B (health-care actors) in the field.
POST-CONDITIONS	POST CONDITION 1) The collected data are sent and stored in real time to the Central Information System (UC1). This automatically feeds into the Data Visualisation System (UC3).
	POST CONDITION 3) Fulfil the KEY FUNCTIONALITY 4 of UC1

TRIGGERS	The Advanced Medical Site Management (UC4) must be activated by the Operation Site Management (UC6), in case of particularly large and complex Mass Casualty Incidents.
FREQUENCY	As part of the field operations, after the Simple Triage is conducted and until all casualties have been properly treated and handed over to the transport area.

9.8PM4: Advanced Medical Site Management



Figure 6: Process Model 4 – Advanced Medical Site Management

9.9UC5: Clinical Parameters Collection System

Table 6: Use Case 5 - Clinical Parameters Collection System

ID	UC 5
TITLE	Clinical Parameters Collection System
SUMMARY	The Clinical Parameters Collection System (UC5) is a system-driven use case. It is a system component of the iProcureSecurity PCP Solution. UC5 enables the gathering of information on the casualties' health condition and monitoring of vital and clinical parameters (further details of vital parameters can be found in the list of requirements), in order to facilitate the decision-making process of the Categories A, B, C (ultimately supporting the treatment and transport prioritisation of casualties). The Clinical Parameters Collection System (UC5) continuously exchanges data
	with the Casualty Profile.
ACTORS	 Category B - Health Care Actors (EMS Practitioners, doctors, nurses, paramedics, ambulance crew) Category C - Operative Actors (head of triage, head of transport, head of operation site management) Category E - Dispatch Centre
PRE-CONDITIONS	PRE CONDITION 1) Mass Casualty Incident is declared.
---------------------	---
	PRE CONDITION 2) The actors are carrying out triage and providing medical care to the casualties.
	PRE CONDITION 3) The Clinical Parameter Collection System (UC5) must be able to work without public internet coverage.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Clinical Parameter Collection System (UC5) enables the actors to record casualty clinical parameters during simple triage and treatment operations. The recording of data is done through validated medical devices, which automatically uploads the data to the solution.
	KEY FUNCTIONALITY 2) The Clinical Parameter Collection System (UC5) must allow continuity of parameters' monitoring even when the casualty moves or is moved, or during transport to hospital. Continuity of monitoring must occur even when staff devices (mobiles, laptops, tablets) are replaced.
	KEY FUNCTIONALITY 3) Actors must have access to the clinical parameter values already stored in the system. Highest cybersecurity measures must be in place to prevent misuse of or attacks on collected medical data.
	KEY FUNCTIONALITY 4) The Clinical Parameter Collection System (UC5) must ensure the reliability of the measured medical parameters.
	KEY FUNCTIONALITY 6) The Clinical Parameter Collection System (UC5) must monitor the clinical parameters even during temporal interruptions of communication with the central servers.
	KEY FUNCTIONALITY 7) The Clinical Parameter Collection System (UC5) must trigger the alerting system if the casualty's clinical parameters worsen and lead to a change in the priority of care. (Connected with the Data Visualisation System UC3).
	KEY FUNCTIONALITY 8) The data collected by the actors on the casualty's clinical status will have to be handed over to the hospital staff (emergency room) once the casualty has been brought to the hospital.
POST-CONDITIONS	POST CONDITION 1) Data sharing with Central Information System (UC1), and therefore, Data Visualisation System (UC3) is mandatory.
	POST CONDITION 2) All Clinical Parameter Collection System (UC5) activities, vital signs and parameters must be anonymised in order to be shared with the Training and Evaluation (UC8).
TRIGGERS	The Simple Triage starts being conducted (clinical parameters are collected through the Casualty Profile).
	The Clinical Parameter Collection System (UC5) is further triggered any time there is an update or exchange of clinical parameters.
FREQUENCY	The Clinical Parameter Collection System (UC5) is always active until all casualties are transferred to the hospital.

9.10 PM5: Clinical Parameters Collection System



Figure 7: Process Model 5 – Clinical Parameters Collection System

UC6: Operation Site Management 9.11

Table 7: Use Case 6 - Operation Site Management

ID	UC 6
TITLE	Operation Site Management
SUMMARY	The Operation Site Management (UC6) is a human-driven process model. In case of Mass Casualty Incidents, it is necessary to create the rescue chain, starting with the recovery of the casualty and ending with his/her transfer to hospital. To do this, it is necessary to quickly build structures capable of properly handling casualties and actors during rescue operations. It is therefore essential to rely on an efficient, quick and precise decision-making process. This starts by providing the Initial MCI Assessment (e.g. METHANE Assessment), in order to collect relevant data on the situation on the field. This initial assessment procedure must be customizable by each procurer. In addition, the assessment must be constantly updated, depending on the evolution of the MCI. Based on the Initial MCI assessment and on the collected information from the Central Information System (UC1) and thus, from the Data Visualisation System (UC3), the Operation Site Management (UC6) facilitates and supports the actors in taking the right decisions. Decisions may include for example, geographical and environmental conditions of the Mass Casualty Area; the distance from connecting roads; the establishment of the triage areas, Advanced Medical Site and the transport areas. This requires precise and continuous coordination of operational staff and relations with other EMS personnel involved in the MCI.

	In addition to that, the Operation Site Management is responsible for the communication channels with Category E (Dispatch Centre) and Category D (State actors), in order to properly manage the MCI.
ACTORS	• Category C - Operative Actors (head of triage, head of transport, head of operation site management)
PRE-CONDITIONS	PRE CONDITION 1) The Mass Casualty Incident is declared and the Mass Casualty Incident Profile is created.
	PRE CONDITION 2) Data Sharing from the Central Information System (UC1) and thus, with the Data Visualisation System (UC3).
	PRE CONDITION 3) Active exchange of information with the Dispatch Centre must be ensured.
	PRE CONDITION 4) The key functionalities of the UC6 must work even in absence of network communication.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Operation Site Management (UC6) supports all the actors for technical and logistical activities in the MCI Areas (e.g highlight specific approaches/guidelines to be considered for different MCIs; indicate objectives and priorities to the different actors involved; provide decision support on required type of hospital infrastructure).
	KEY FUNCTIONALITY 3) The Operation Site Management (UC6) provides guidance to carry out the Initial MCI Assessment (e.g. METHANE Assessment).
	KEY FUNCTIONALITY 4) The Operation Site Management (UC6) must support the actors in the management of the functional and structural works that allow the overall management of the casualties of a Mass Casualty Incident.
	KEY FUNCTIONALITY 5) The Operation Site Management (UC6) must allow the visualisation and update of roles and responsibilities on the field.
	KEY FUNCTIONALITY 6) The Operation Site Management (UC6) must show an interactive map of the location to sketch the sectionalisation of the MCI Areas.
	KEY FUNCTIONALITY 7) The Operation Site Management (UC6) must support the decision-making process for the identification and co-ordination of the various areas, such as:
	 distinction between Red and Green zones; the Triage Areas; the Advanced Medical Site; the Transport Areas (vehicles parking and/or helicopter landing site); additional relevant areas.
	KEY FUNCTIONALITY 8) The Operation Site Management (UC6) must provide all available information about the event location: geographical and environmental conditions, traffic situation, weather conditions, etc.
	KEY FUNCTIONALITY 9) The Operation Site Management (UC6) must include checklists of important actions and things to take into account for EMS staff onsite.

	KEY FUNCTIONALITY 10) The Operation Site Management (UC6) must provide a continuously updated dashboard with the main information (e.g. nr. and status of casualties, staff, resources), in order to facilitate the decision-making process.
POST-CONDITIONS	POST CONDITION 1) Data Sharing to the Central Information System (UC1) and Data Visualisation System (UC3) is mandatory. POST CONDITION 2) Fulfil the KEY FUNCTIONALITY 4 of UC1.
TRIGGERS	The Mass Casualty Incident is declared and the Mass Casualty Incident Profile is created.
FREQUENCY	From the beginning to the end of the Mass Casualty Incident.

9.12 PM6.1: Operation Site Management



Figure 8: Process Model 6.1 – Operational Site Management



Figure 9: Process Model 6.2 – Operation Site Management

9.14 UC7: Vehicle and Resource Management

Table 8: Use Case 7 - Vehicle and Resource Management

ID	UC 7
TITLE	Vehicle and Resource Management
SUMMARY	The Vehicle and Resource Management (UC7) is a human-drive use case. It maps, organises and plans the number and types of incoming and on-site resources, distinguishing between available and needed resources (staff, vehicles, materials and equipment).
ACTORS	• Category C - Operative Actors (head of triage, head of transport, head of operation site management)
PRE-CONDITIONS	 PRE CONDITION 1) A Mass Casualty Incident is declared and the Mass Casualty Incident Profile is created. PRE CONDITION 2) Information coming from the Central Information System (UC1) through the Data Visualisation System (UC3) are shared. PRE CONDITION 3) Communication with the Operation Site Management (UC6) and with the Category E (Dispatch Centre) is established. PRE CONDITION 4) The key functionalities of the UC7 must work even in absence of network communication.

KEY FUNCTIONALITIES	 KEY FUNCTIONALITY 1) The Vehicle and Resource Management (UC7) must support the actors in the management of vehicles available for the transport of goods and persons based on the requests of the Operation Site Management (UC6) - taking into consideration the information provided by the Simple Triage and Rapid Treatment (UC2) and Advanced Medical Site (UC4). KEY FUNCTIONALITY 2) The Vehicles and Resources Management (UC7) must help to update the logistics department to provide new supplies. KEY FUNCTIONALITY 3) The Vehicle and Resource Management (UC7) must provide real time information on stock of material and equipment. KEY FUNCTIONALITY 4) The Vehicle and Resource Management (UC7) must recognise and record all incoming and outcoming resources from and to the Mass Casualty Incident Area (vehicles, equipment, goods, personnel, etc.). KEY FUNCTIONALITY 5) The Vehicle and Resource Management (UC7) must geolocate resources and visualise them on a map. KEY FUNCTIONALITY 6) The Vehicle and Resource Management (UC7) must exchange information on: number and status of the casualties to be transported; number and type of vehicles available; number and type of hospitals available (and free ICU beds) traffic conditions
POST-CONDITIONS	POST CONDITION 1) Data Sharing to the Central Information System (UC1) and Data Visualisation System (UC3) is mandatory.
	POST CONDITION 2) Fulfil the KEY FUNCTIONALITY 4 of UC1.
TRIGGERS	Initial MCI Assessment is conducted. Casualties must be treated and transported to hospitals.
FREQUENCY	During the whole MCI duration.

9.15 PM7: Vehicle and Resource Management



Figure 10: Process Model 7 – Vehicle and Resource Management

9.16 UC8: Evaluation and Training

Table 9: Use Case 8 - Evaluation and Training

ID	UC 8
TITLE	Evaluation and Training
SUMMARY	The Evaluation and Training (UC8) is a human-driven use case. For EMS personnel, the knowledge of protocols and procedures in the field of disaster medicine is pivotal. The UC8 aims to provide a tool to monitor and assess the quality of the rescue intervention and the management of emergency scenarios. Based on the Evaluation Report, good and best practices for training must be provided. Evaluation The Evaluation Report will be automatically created by the iProcureSecurity PCP Solution, as soon as the MCI is concluded. Also, the Evaluation Report must be fully customisable and editable.

	Training The Training component allows simulating an MCI, based on realistic scenarios. The scenarios can be built upon evaluation results or individual procurers' needs. The overall scope of the training is to create specific competences and skills in the management of MCIs. Similarly, to the Evaluation Report, the Training must be fully customizable and editable.
ACTORS	 Category B - Health Care Actors (EMS Practitioners, doctors, nurses, paramedics, ambulance crew)
	• Category C - Operative Actors (head of triage, head of transport, head of operation site management)
	• Category D - State Actors (fire brigades, law enforcement agencies, regional and or national authorities, Civil Protection authorities).
	Category E - Dispatch Centre
	• Specific role "Trainer" which could be a staff member from either of the previous categories (depending on the procurer) and who has been assigned responsibility for managing / moderating / conducting training sessions.
PRE-CONDITIONS	Evaluation
	PRE CONDITION 1) The Evaluation starts when the Mass Casualty Incident Profile is closed.
	Training
	PRE CONDITION 1) Trainer (or instructor) defined, customised and scheduled a training session.
	PRE CONDITION 2) Personal and sensitive data collected through real MCI operations and used for training purposes must be anonymised.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) Evaluators, trainers (instructors) and trainees are allowed to access the Evaluation and Training according to their user rights.
	Evaluation
	KEY FUNCTIONALITY E.1) The Evaluation must allow the automated assessment and reporting of all the collected data, actions, decisions taken during the specific MCI operation.
	KEY FUNCTIONALITY E.2) The Evaluation Report must be:
	- customisable for each procurer, i.e. adaptability of modules, structures, format, etc.
	 editable, i.e. procurers must be able to add comments and inputs manually and, generally, to work on the automatically created Evaluation Report. able to provide elaborated inputs for the Training. The inputs can be further refined by the procurers/trainers.
	KEY FUNCTIONALITY E.3) The Evaluation Report should (ideally) provide an automated identification of criticalities and errors committed during the MCI (for example based on national or international protocols; real data from previous MCIs elaborated by the iProcureSecurity PCP Solution). KEY FUNCTIONALITY E. 4) The Evaluation Report shall be available also for training.
	trainings.

	Training
	KEY FUNCTIONALITY T.1) The iProcureSecurity PCP must include a "Simulation Mode", based on (anonymised) real or dummy data, which allows simulating MCIs for training purposes.
	KEY FUNCTIONALITY T.2) The Training component shall allow to define curricula according to the training needs of personnel involved in MCIs.
	KEY FUNCTIONALITY T.3) The Training component shall allow dedicated training programmes in order to provide specific competences and skills to the different profiles and provides libraries and testing tools (interactive checklist).
	KEY FUNCTIONALITY T.4) The Training component must be fully customisable for each procurer, i.e., adaptability of modules, structures, format, etc.
	KEY FUNCTIONALITY T.5) The Training component must offer machine readable data coming from the evaluation to be used for external training solutions (i.e., MR/AR/VR etc.).
POST-CONDITIONS	POST CONDITION 1) The iProcureSecurity PCP Solution shall be able to improve based on collected and processed data (e.g., data coming from real MCIs, Evaluation Reports and Trainings).
TRIGGERS	Evaluation - A MCI took place and the Mass Casualty Incident Profile is closed.
	Training - The Trainer sets up and starts the Training.
FREQUENCY	The Evaluation starts as soon as the Mass Casualty Incident Profiles is closed. The Evaluation is closed when the Evaluation Report is complete (e.g., after edits and additions made by the actor).
	The Training takes place within scheduled timeframes, based on the organisation decisions.

9.17 PM8: Evaluation and Training



Figure 11: Process Model 8 – Evaluation and Training

Table 10: Use Case 9 - Systems Integration

ID	UC 9
TITLE	Systems Integration
SUMMARY	The Systems Integration (U9) is a system-driven use case. It is a component of the iProcureSecurity PCP Solution. Interoperability with existing systems and other devices is necessary to capture relevant data. The selection of data depends very much on the characteristics of the proposed iProcureSecurity PCP Solution and the data it requires for its algorithms. A data integration platform which ensures interoperability is required. Decision support systems and analytic tools need to compute coherent and easily collected data (UC1).
ACTORS	Category F - Technical Administration and Maintenance
PRE-CONDITIONS	PRE CONDITION 1) Procurers' existing IT/EHR systems and other data source systems (medical devices, personal devices, etc). The existence of local CAD systems for managing calls and coordinating rescue activities.
	PRE CONDITION 2) The compliance of existing CAD systems with data communication standards (XML, HL7, etc.)
	PRE CONDITION 3) The Systems Integration (UC9) must be able to work without coverage of public networks.
KEY FUNCTIONALITIES	KEY FUNCTIONALITY 1) The Systems Integration (UC9) must integrate data from different sources and use them in an innovative way to support and share information among EMS actors, Dispatch Centre, Hospital and other entities. There should be a strategy to ensure interoperability in order to integrate and use the data.
	KEY FUNCTIONALITY 2) The Systems Integration (UC9) must use a harmonised terminology, able to communicate through APIs with existing/legacy systems.
	KEY FUNCTIONALITY 3) The Systems Integration (UC9) must be able to instantly share information with the Central Information System (UC1) and with all other actors, improving information flows between the different profiles of actors.
	Data may come from/go to:
	 the existing CAD systems of procurers; casualties' health records; hospitals' medical records; Devices such as smartphones, tablets, medical devices, GPS; Existing telemedicine and e-diagnostics tools; Platforms for monitoring weather, traffic; Other procurers' databases or platforms; Other third-party applications.

	KEY FUNCTIONALITY 4) The Systems Integration (UC9) must ensure real-time connection among the Dispatch Centre and Operation Site Management and other actors, even in the absence of public internet coverage.
	KEY FUNCTIONALITY 5) Automatic data upload will be the preferred choice for any data that the solution has to handle. Depending on the proposed solution, developers will have to define what data they need in order to ensure that it is included in the system.
	KEY FUNCTIONALITY 6) The Systems Integration (UC9) must be hosted on servers physically located in EU and/or pilots' countries according to GDPR and national laws.
	KEY FUNCTIONALITY 7) All data should be gathered, transformed and stored using an international data standard format (example: IEEE 11073 PHD, LOINC and/or SNOMED) as possible by the data type. Data exchange protocols with a future perspective such as HL7/FHIR should be implemented in a separate and exchangeable interoperability layer.
	KEY FUNCTIONALITY 8) The Systems Integration (UC9) must comply with ethical and legal requirements.
POST-CONDITIONS	The Systems Integration (UC9) allows access and sharing data from different types of systems and continuously updates them.
TRIGGERS	Need of data exchange between iProcureSecurity PCP Solution and third-party solution.
FREQUENCY	Every time an actor needs to access the iProcureSecurity PCP Solution data.

9.19 PM9: Systems Integration



Figure 12: Process Model 9 – Systems Integration



iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 1a (TD 1a) Cover Letter



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Cover Letter

I declare that I have examined, and I accept without reserve or restriction the entire content of the PCP Tender Documents for the tender procedure in the framework of the iProcureSecurity PCP project Call for Tenders.

Name of the company	
Lead Tenderer/ Single Tenderer	
Name Authorised Signatory	
Position	
Signature	
Date	
Stamp, if available	



iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 2 (TD 2) Technical Offer



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Technical Offer

This form is related to the technical offer for Phase 1/2/3. Each section is required and shall be completed as stated below. Please, note that specific description should be done to implement Phase 1/2/3 of the iProcureSecurity PCP.

You may use up to 50 pages (this includes cover page, table of contents, etc.).

Minimum font size (11pt) and page margins (15mm)

Part 1

A technical plan that outlines: I. the Tenderer's idea for addressing all the requirements given in the PCP challenge description; II. technical details of how this would be implemented and III. a project management plan that outlines the execution and monitoring approach, including a Gantt chart. This part should clearly address all the weighted award criteria, namely 1. Contract implementation, 2. Functional Quality Criteria, 3. Non-Functional Quality Criteria, 4. Commercial Feasibility and 5. Evaluation of the solution and sustainability of testing.

Part 2

A draft business plan that explains the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market.

Part 3

A risk assessment and risk mitigation strategy.

Part 4

A reply to the question "Does this tender involve **ethical issues**? (YES/NO)" and if YES, an ethics self-assessment, with explanations how the ethical issues will be addressed.

Part 5

A list of the pre-existing rights (*background*) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed following the template provided in TD8.

Single Tenderer / Lead Tenderer confirmation Statement:

The contact person being the authorised signatory of the above Tenderer hereby declare that I, or my company, provided accurate information.



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 3 (TD 3) Financial Offer and Cost Breakdown



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Financial offer and Cost Breakdown

The purpose of this Annex is to provide the Buyers Group with:

A) A fixed total Price for Phase 1, broken down to show unit prices and the number of each unit needed to carry out phase 1 (given in euros, excluding VAT but including any other taxes and duties).

B) and set binding unit prices for the entire duration of the Framework Agreement.

C) An estimated total price for phases 2 and 3

For the above purpose a Total Cost and a Cost Breakdown shall be submitted.

Financial Offers which are not submitted using this Annex will be excluded. All six sections of this document must be presented. Tenderers should however add further fields (rows and columns) with additional cost elements, as needed. Full justifications and details must always be provided.

Declaration

The Lead Tenderer is assumed to have discussed the tender within their own company and any other body whose co-operation will be required to deliver the project.

The Lead Tenderer will need to obtain consent from an authorised officer or appropriate signatory who will sign the contract if successful. The contract is a legally binding document and subject to the outcome of this competition.

By submitting the Tender, you are confirming that the information given in this application is complete, that you are actively engaged in this project and responsible for its overall management and agree to administer the contract if made.

You are confirming that

- your organisation is prepared to carry out this project at the stated price,
- you are not subject to the Exclusion criteria, and
- that the services offered are within Research and Development as mentioned, and
- that you comply with the Compliance criteria stated in the iProcureSecurity Call for Tenders.

Name of Lead Tenderer	
Name of Authorised Signatory	
Function	
Signature	
Date	
Stamp, if available	

GENERAL INSTRUCTIONS - Mandatory reading

Please read section 4.5 'Financial Section of the Tender' of the Request for Tenders.

Tenderers must specify binding unit prices for all items needed for carrying out Phase 1 and for items that are expected to be needed for Phases 2 and 3 (given in euros, excluding VAT, but including any other taxes and duties).

Tenderers must quote binding unit prices for each category of R&D resources needed, e.g. junior, senior researchers, developers, product owner, testers, etc. (hourly rates) and specify other costs. Tenderers must also quote binding unit prices for their own resources for Phases 2 and 3 that are not expected to be used in Phase 1 and quote estimated unit costs for resources of third parties to be used in Phases 2 and 3.

The unit prices quoted for each category of item s rem ain binding for all Phases (i.e. for the duration of the Fram ework Agreement).

Tenderers must provide a cost breakdown for Phase 1, resulting in a fixed total price for Phase 1 and an estim ated total price for Phases 2 and 3 broken down to show unit prices and the num ber of each unit needed to carry out the Phases (given in euros, excluding VAT, but including any other taxes and duties).

The Cost Breakdown shall provide:

- 1 a % of the labour price allocated to R&D services. Note that the price must comply with the R&D definition and the total sum of the material/equipment/other Costs offered in each Phase must be less than 50 % of the total value of Total Price of each Phase)
- 2 the location or country in which the different categories of activities are carried out (e.g. x hours of senior researchers in country L at a euro/hour; y hours of junior developers in country M at b euro/hour). Dem onstrate com pliance with the com pliance criteria related to the place of perform ance.
- **3** a financial compensation valuing the transfer of ownership of the IPRs generated during the PCP to the Tenderer, by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e. the price that would have been quoted if the IPR ownership would have been kept by the Buyers Group).

The financial compensation for IPRs must reflect the market value of the benefits received (i.e. the opportunity that the IPRs offer for commercial exploitation) and the risks assumed by the contractor (e.g. the cost of maintaining IPRs and bringing the products onto the market).

To ensure that a fair market price is offered, Tenderers must state two prices:

- the "virtual" price that they would have quoted if all Intellectual Property Rights, including the ownership of results under the PCP, would be fully retained by the Buyers Group and tenderers would not have the possibility to exploit the results; and
- 2
- the "actual" price that takes into account the fact that the Tenderers keep ownership of the Intellectual Property Rights attached to the results under PCP, in accordance with the provisions of the contracts, and that they can exploit these results.

Note that the price must comply with the R&D definition and the total sum of non Personnel costs (such as material/Travelling/Subcontracting/Other costs) offered in each Phase must be less than 50 % of the total value of Total Price of each Phase.

Actual prices quoted for each phase must respect the maximum budgets specified per Contractor per each Phase. All offers above those amounts shall be excluded from the process.

Estimation of market price

Indicate, by means of a calculation/explanation, an estimation of future market price of the developed solution and exploitation of interims results

[add text here]

Binding unit prices

Provide the unit prices for all item s needed for carrying out Phase 1 and for item s that are expected to be needed for Phases 2 and 3 (given in euros, excluding VAT but including any other taxes and duties). This unit prices are binding, not subject to change during the entire duration of the Framework Agreem ent, by means of a calculation/explanation, an estimation of future market price of the developed solution and exploitation of interims results

Perso	Personnel unit prices							
A.	Category	R&D cost? (Yes/No)	Description	Price per hour				
A1	[e.g. Senior Researcher]	[e.g. Yes]	[e.g. Prepare solution design and prototype creation]	€/hour				
A2	[e.g. Junior Developer]	[e.g. Yes]	[e.g. Prepare solution design and protot ype creation]	€/hour				
A.3	[e.g. Marketing expert]	[e.g. No]	[e.g. Preparation of business model for concept solution]	€/hour				

add rows as needed

Materials & Equipments

Materials & Equipments								
В.	Category		Description	Unit price				
B.1	[e.g. Hardware, licenses, storage,]		[describe what the cost consist of, overall intended usage or application for such type of cost, and if applicable, the your unit price definition]	€/unit				
B.2								
add row	/s as needed							

Subcontracting

subcontracting									
С.	Category	R&D cost? (Yes/No)	Description	Unit price					
C.1	[e.g. Testbed set-up]	[e.g. Yes]	[describe what the cost consist of, overall intended usage or application for such type of cost, and if applicable, the your unit price definition]						
C.2	[e.g. Graphic designer]	[e.g. Yes]							

add rows as needed

Other	Jther costs									
D.	Category		Description	Unit price						
D.1	Travel cost		Average cost per trip	€/unit						
			[describe what the cost consist of, overall intended usage or							
D.2	General and administration cos	ts (overheads)	application for such type of cost, and if applicable, the your							
			unit price definition]							
D.3										

add rows as needed

Tender Document 3 (TD 3): Financial Offer and Cost Breakdown

Provic This ii	rrovide the cost breakdown for your proposed solution for Phase 1. This information will be used to check if you are indeed proposing R&D Services. It will also be used for the overall Tender evaluation.								
						Virtual Price	e		
Туре	A. Personnel costs	Principal R&D staff Y/N	Description of activities	Price per hour	Amount of hours	Total price	% of labour allocated to R&D services	Country or location of performance	Actual Price
A.1	[e.g. Senior Researcher -1]		[short desrciption of activities to be untertaken by this person]				[e.g. 100%]	[eg BE]	
A.2	[e.g. Senior Researcher - 2]						[e.g. 100%]		-
A.3	Commercial representative-1						[eg.0%]		-
						≻addrowsasn	æded	+	-
			Sub-Total Personnel costs		0,0	- €		1	€ -
					-1-	Virtual Price	2		-
Type	B. Materials & Equipments		Description of activities	Unitprice	Amount	Total price			Actual Price
в.1	[e.g. Hardware, li censes, storage,]								
B.2							4		
B.3							4		
						≻addrowsasn	æded		
		Sub-	Total Materials & Equipments		0,0	€ -			
						Virtual Price	2		
Туре	C. Subcontracting		Description of activities	Unitprice	Amount	Total price	Country of perfo	· location of mance	Actual Price
C.1	[e.g. Graphic designer]		[link to proposed work activities]						-
						> add rows as n	æded		1
			Sub-Total Subcontracting	•	0,0	-€			€ -
						Virtual Price	2		
Туре	D. Other costs		Description of activities	Unitprice	Amount	Total price			Actual Price
D.1	[Travel cost]						4		
D.2	[General and administration costs (overheads)]						1		
D.3							4		
						≻addrowsasn	eded		
			sub-Total Other costs		0,0	-€			€ -
				Phase 1 TOI	AL Coste				
				11113011101			Virtua	l Price (exc. VAT)	1
							Actua	l Price (Exc. VAT)	
							Actual Pri	ce (inc. 24% VAT)	

Comments, clarifications and remarks

	COST BREAKDOWN - Phase 2: Solution Prototype (Estimated)									
Provi This i	Provide envisioned cost breakdown for your proposed solution for Phase 2. Only unit prices are binding. Overall resources are merely estimations. This information will be used to check if you are indeed proposing R&D Services. It will also be used for the overall Tender evaluation.									
	Virtual Price									
Туре	A. Personnel costs	Principal R & D staff Y/N	Description of activities	Price per hour	Amount of hours	Total price	% of labour allocated to R&D services	Country or location of performance	Actual Price	
A.1	[e.g. Senior Researcher - 1]		[short desrciption of activities to be untertaken by this person]				[e.g. 100%]	[e.g. BE]		
A.2	[e.g. Senior Researcher - 2]						[e.g. 100%]			
A.3	Commercial representative - 1						[e.g. 0%]		-	
						> add nows as ne	eded		-	
Sub-Total Personnel costs 0,0 - € €								€ -		
Type B. Materials & Equipments Description of activities			Unit price	Amount	Virtual Price	e		Actual Price		
B.1	[e.g. Hardware, licenses, storage,]]			
B.2										
B.3							-			
						> add nows as ne	eded			
		Sub-	Total Materials & Equipments		.0,0	-€			€ -	
						Virtual Price				
Туре	C. Subcontracting		Description of activities	Unit price	Amount	Total price	Country or perfor	location of mance	Actual Price	
C.1	[e.g. Graphic designer]		prink to proposed work activities]							
]	
						> add rows as ne	eded			
			sub-Total Subcontracting		0,0	- 6			e -	
Туре	D. Other costs		Description of activities	Unit price	Amount	Total price			Actual Price	
D.1	[Travel cost]									
D.2	[General and administration costs (overheads)]									
							1			
						> add nows as ne	eded			
			Sub-Total Other costs		0,0	- €			£ -	
_			Phase 2	TOTAL Cos	ts - Estimat	ed				
				- Contractions	es esciniac	ou	Virtua	Price (exc. VAT)		
							Actua	Price (Exc. VAT)		
	Actual Price (inc. 24% VAT)									

Comments, clarifications and remarks

	COST BREAKDOWN - Phase 3: Operational Validation(Estimated)									
Provia This in	Provide envisioned cost breakdown for your proposed solution for Phase 3. Only unit prices are binding. Overall resources are merely estimations This information will be used to check if you are indeed proposing R&D Services . It will also be used for the overall Tender evaluation.									
Virtual Price										
Туре	A. Personnel costs	Principal R& D s taff Y/N	Description of activities	Price per hour	Amount of hours	Total price	% of labour allocated to R&D services	Country or location of performance	Actual Price	
A.1	[e.g. Senior Researcher - 1]		[short desrciption of activities to beuntertaken by this person]				[eg.100%]	(eg. BE)		
A.2	[e.g. Senior Researcher - 2]						[eg.100%]			
A.3	Commercial representative-1						[eg.0%]			
						> add rowsasne	eded			
			Sub-Total Personnel costs		0,0	- €			£	-
						Virtual Price				
Туре	B. Materials & Equipments		Description of activities	Unit price	Amount	Total price			Actual Price	
B.1	[e.g. Hardware, licenses, storage,]									
B.2										
B,3										
						> add rowsasne	eded			
		Sub-	Total Materials & Equipments		0,0	-€			€	-
						Virtual Price				
Туре	C. Subcontracting		Description of activities	Unit price	Amount	Total price	Country or perform	location of mance	Actual Price	
C.1	[e.g. Graphic designer]		[linkto proposed work activities]							
						> add rowsasne	eded			
	•		Sub-Total Subcontracting		.0,0	-€			€	-
						Virtual Price				
Туре	D. Other costs		Description of activities	Unit price	Amount	Total price			Actual Price	
D.1	[Travel cost]									
D.2	[General and administration costs (overheads)]									
0.3										
						> add rowsasne	eded			
			Sub-Total Other costs		0,0	- €			€	-
_			Dia area 21			-				
			Phase 3 I	UTAL LOSTS	- Estimate	u	Virtual G	tice (exc. VAT)		
							Actual F	rice (Exc. VAT)		
	Actual Price (Inc. 24% VAT)									

Comments, clarifications and remarks



iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 4 (TD 4) Declaration of Honour



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Declaration of Honour (TD 4)

I, the undersigned (name and surname)¹

As an individual (or position within the legal entity)

Of the following legal entity (hereafter the 'Tenderer') (name of legal entity)

With registered office in

Street address

Post code

In the City of

Telephone

Fax

E-mail

VAT reg. no.

IF APPLICABLE:

Acting in the context of a consortium or association of several entities together with the following entities:

Attention: Please ensure that the others concerned provide a separate form.

HEREBY STATE AND DECLARE

under my own personal responsibility, fully aware of the infringements and penalties provided by the Greek Law in case of fraudulent statements,

THAT

SECTION 1

The Tenderer fulfils the selection criteria set out under section 3.4 of the Tender.

Accordingly, the undersigned formally declares that the information stated and the certificates and other forms of documentary evidence provided are accurate and correct and that they have been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declares to be able, upon request and without delay, to provide other certificates or forms of documentary evidence referred to, except where the contracting authority has the possibility of obtaining the supporting documentation concerned directly by accessing a national database of a Member State that is available free of charge. (This should be possible on the condition that the economic operator has provided the necessary information, thus allowing the contracting authority to have access. Where required, this must be accompanied by the relevant consent to do so).

SECTION 2

Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, *including intangible results in particular IPRs*

Has the economic operator the ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs? Yes / No

 Provide a description of relevant reference and /or previous projects (executed during the last 5 years) which reflect the competences and capacity of the Tenderer in the different phases and domains of the iProcureSecurity PCP project, such as research, development, prototyping, testing and commercialisation. These references will be based on previous projects of the Tenderers and /or other members of the joint consortia and subcontractors who will be working on the project.

- Demonstrate the expertise and working experience required to undertake an innovative R&D project by providing CVs of key personnel and competences, which they consider necessary to complete the project.
- Confirm the Business Continuity / Disaster Recovery / Risk Management plan that ensures that the described services are delivered in the event of a disruption affecting your business and ensures continuity of supply / service from your critical suppliers.
- Confirm the appropriate level of insurance cover if the tenderer is to be successful in winning the contract.

SECTION 3

The Tenderer fulfils the compliance criteria set out under section of the Tender.

Accordingly, the undersigned formally declares that the information stated and the certificates and other forms of documentary evidence provided are accurate and correct and that they have been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declares to be able, upon request and without delay, to provide other certificates or forms of documentary evidence referred to, except where the contracting authority has the possibility of obtaining the supporting documentation concerned directly by accessing a national database of a Member State that is available free of charge. (This should be possible on the condition that the economic operator has provided the necessary information, thus allowing the contracting authority to have access. Where required, this must be accompanied by the relevant consent to do so).

SECTION 4

1. COMPLIANCE WITH THE DEFINITION OF R&D SERVICES

Does the economic operator guarantee that it is in compliance with the requirements regarding the definition of R&D services as set out in the Tender? Yes / No

Please note that according to the Tender this circumstance must be accredited by the presentation of the financial part of the offer, which must contain the following information:

- 1. The financial part of the offer for the framework agreement must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement.
- 2. The financial part of the offer for each phase must give breakdown of the price for that phase in terms of units and unit prices for every type of item in the contract, distinguishing clearly the units and unit prices for items that concern products.
- 3. The offers for all three phases may include only items needed to address the challenge in question and to deliver the R&D services described in the request for tenders.
- 4. The offer for all the three phases must offer services matching the R&D definition above.
- 5. The total sum of the value of products offered in each phase and all previous phases must be less than 50% of the value of the framework agreement.

2. COMPLIANCE WITH OTHER PUBLIC FINANCING

Does the economic operator guarantee that it is not receiving any public funding not permitted by EU legislation from other sources, including EU state aid rules, in areas of work related to the scope of the provision of services for the procurement in the terms established in the Tender? Yes / No

3. COMPLIANCE WITH REQUIREMENTS RELATING TO THE PLACE OF PERFORMANCE OF THE CONTRACTS

Does the economic operator guarantee that in case of selection it will comply with the requirements stated in the Tender Document regarding the place of performance of the contracts? Yes / No

Please note that according to the Tender the following evidence is required:

- 1. A list of staff working on the specific contract (including for subcontractors), indicating clearly their role in performing the contract (i.e. whether they are principal R&D staff or not) and the location (country) where they will carry out their tasks under the contract.
- 2. A confirmation or declaration of honour that, where certain activities forming part of the contract are subcontracted, subcontractors will be required to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that has to be performed in the EU Member States or in countries participating in Horizon 2020 is respected.

4. ETHICS, DATA PROTECTION AND RESEARCH INTEGRITY

Does the economic operator guarantee that in case of selection it will comply with the rules regarding ethics, data protection and research integrity set out in the Tender? Yes / No

SECTION 5

The Tenderer is not involved in any of the exclusion grounds set out under section 3.4 of the Tender (or, if existing, under similar regulations in the country in which it is established).

Accordingly, the undersigned formally declares that the information stated and the certificates and other forms of documentary evidence provided are accurate and correct and that they have been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declares to be able, upon request and without delay, to provide other certificates or forms of documentary evidence referred to, except where the contracting authority has the possibility of obtaining the supporting documentation concerned directly by accessing a national database of a Member State that is available free of charge. (This should be possible on the condition that the economic operator has provided the necessary information, thus allowing the contracting authority to have access. Where required, this must be accompanied by the relevant consent to do so).

SECTION 6

1. EXCLUSION GROUNDS RELATING TO THE CONFLICT OF INTEREST

Is the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control involved in any current or potential conflict of interest, as indicated in the Tender documents, due to its participation in the procurement procedure or for any other reason? Yes // No

Please describe it:

2. EXCLUSION GROUNDS RELATING TO BANKRUPTCY & PROFESSIONAL MISCONDUCT

Is the economic operator itself bankrupt or is being wound up, is under compulsory administration or is the subject of a composition or has indefinitely stopped its payments or is subject to a prohibition on conducting business? Yes \Box / No \Box

Please describe it:

Is the economic operator itself the subject of proceedings for a declaration of bankruptcy, for an order for compulsory winding up or administration by the court or composition or any other similar proceedings? Yes \Box / No \Box

Please describe it:

Has the economic operator itself been convicted by a judgment which has the force of *res judicata* for an offence relating to professional practice? Has the economic operator been guilty of grave professional misconduct and can the procuring agencies prove this? Yes \Box / No \Box

Please describe it:

Has the economic operator not fulfilled its obligations relating to social insurance charges or tax in its own country? Yes \square / No \square

Please describe it:

3. EXCLUSION GROUNDS RELATING TO CRIMINAL OFFENCES

a) Participation in a criminal organisation

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgement for participation in a criminal organisation, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Yes \Box / No \Box

Date of conviction

Reason

Who has been convicted

Length of the period of exclusion

b) Corruption

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgement for corruption, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Yes \Box / No \Box

Date of conviction:

Reason:

Who has been convicted:

Length of the period of exclusion:

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c) Fraud

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgement for fraud, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Yes \Box / No \Box

Date of conviction:

Reason:

Who has been convicted:

Length of the period of exclusion:

d) Terrorist offences or offences linked to terrorist activities

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgement for terrorist offences or offences linked to terrorist activities, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Yes \Box / No \Box

Date of conviction:

Reason:

Who has been convicted:

Length of the period of exclusion:

e) Money laundering or terrorist financing

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgement for money laundering or terrorist financing, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Yes \Box / No \Box

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Date of conviction:

Reason:

Who has been convicted:

Length of the period of exclusion:

f) Child labour and other forms of trafficking in human beings

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgement for child labour and other forms of trafficking in human beings, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Yes \square / No \square

Date of conviction:

Reason:

Who has been convicted:

Length of the period of exclusion:

4. EXCLUSION GROUNDS OF PROPOSED SOLUTION ALREADY AVAILABLE ON THE MARKET

Does the economic operator undertake that the tendered solution presented is not already available on the market? Yes \Box / No \Box

In witness whereof I confirm this statement.

Place and date



iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 5 (TD 5) Consortia Statement



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Consortia Statement (TD 5)

I, the undersigned (name and surname), acting in the name of (name of the one of the members of the consortium), a company duly incorporated under the law of ______, with registered office _____, with VAT no. _____, in my capacity as _____;

I, the undersigned (name and surname), acting in the name of (name of the one of the members of the consortium), a company duly incorporated under the law of ______, with registered office _____, with VAT no. ______, in my capacity as ______;

I, the undersigned (name and surname), acting in the name of (name of the one of the members of the consortium), a company duly incorporated under the law of ______, with registered office _____, with VAT no. ______, in my capacity as ______;

I, the undersigned (name and surname), acting in the name of (name of the one of the members of the consortium), a company duly incorporated under the law of ______, with registered office ______, with VAT no. ______, in my capacity as ______;

Acting in the context of a consortium or association of several entities (hereafter the **'Consortium'**) (name of the consortium or the association)

HEREBY STATE AND DECLARE

under our own personal responsibility, fully aware of the infringements and penalties provided by the Greek Law in case of fraudulent statements,

THAT

1.- In connection with the iProcureSecurity PCP Procedure, we have agreed to set up a team to participate jointly in the above-mentioned Procedure, undertaking to form and to maintain a designed temporary Consortium of Bidders, in order to comply jointly with the purposes of the PCP Procedure and with the contracts. Within this Procedure, the team may be awarded to the Consortium in the event of being selected to have access/to access to Phase 1. During the whole period of validity of the commitment to maintain the Consortium of Bidders, which shall coincide with the period of time during which the Consortium is participating in the iProcureSecurity PCP Procedure, each of the members of the Consortium shall assume the following participation:

Bidder Participation (%)

2.- All of the members of the Consortium shall remain jointly and severally liable towards the Procuring Entity.

3.- During the period of the PCP Procedure, the Consortium will be represented by (the name of the single authorized representative of the Consortium), with sufficient powers to exercise the rights and comply with the obligations that arise from the iProcureSecurity PCP Procedure.

4.- We also state that during the management of the Proposal selection, for the purposes of communications that may be necessary for its development, the team will be represented by (name, address, telephone, email).

The undersigned persons apply for admission to the above-mentioned PCP Procedure, having expressed their acceptance of all the provisions and conditions set out in the iProcureSecurity PCP Call for Tenders (CfT).

Place and date



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 6 (TD 6) Subcontracting Statement



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.
Subcontracting Statement (TD 6)

I, the	undersigned	(name and	surname)
.,	anacioignea	(manne ane	a barnanne,

As an individual (or position within the legal entity)

Of the following legal entity (hereafter the 'Bidder') (name of legal entity)

With registered office in

Street address

Post code

In the City of

Telephone

Fax

E-mail

VAT reg. no.

IF APPLICABLE:

Acting in the context of a consortium or association of several entities together with the following entities:

HEREBY STATE AND DECLARE

under my own personal responsibility, fully aware of the infringements and penalties provided by the Greek Law in case of fraudulent statements,

THAT

According to the provisions set out in the Tender Documents, the Bidders intent on subcontracting the following parts of the scope of the iProcureSecurity PCP Procedure:

ACTIVITY TO BE SUBCONTRACTED / %	NAME OF THE SUBCONTRACTOR / LOCATION	STATEMENT (According to Section 2)

THAT

I rely on the capacities of the proposed Subcontractors to perform part of the work in compliance with the requirements stated in the Call for Tenders and in its related documentation.

AND THAT

I hereby acknowledge and unconditionally state that the Subcontractor(s) is/are fully aware of the provisions set out in the Tender Documents, that it/they meet(s) the qualification requirements for the subcontracted service and that it/they have/has its/their resources at the Bidder disposal for the entire duration of the contract.

In witness whereof I sign this statement

Place and date



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 7 (TD 7) Legal Capacity of the Tenderer Statement



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Legal Capacity of Tenderer Statement (TD 7)

I, the undersigned (name and surname),

As an individual (or position within the legal entity)
Of the following legal entity (hereafter the 'Tenderer')
With registered office in
Street address
Post code
In the City of
Telephone
Fax
E-mail
VAT reg. no.
IF APPLICABLE:
Acting in the context of a consortium or association of several entities together with the following entities:

Attention: Please ensure that the others concerned provide a separate form.

HEREBY STATE AND DECLARE

under my own personal responsibility, fully aware of the infringements and penalties provided by the Greek Law in case of fraudulent statements,

THAT

SECTION 1

The Tenderer is empowered to contract with the Procuring Entity as, being free to act, is not involved in any of the exclusion grounds set out under section 3.2 of the Tender (or, if existing, under similar regulations in the country in which it is established).

Accordingly, the undersigned formally declares that the information stated, and the certificates and other forms of documentary evidence provided are accurate and correct and that they have been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declares to be able, upon request and without delay, to provide other certificates or forms of documentary evidence referred to, except where the contracting authority has the possibility of obtaining the supporting documentation concerned directly by accessing a national database of a Member State that is available free of charge. (This should be possible on the condition that the economic operator has provided the necessary information, thus allowing the contracting authority to have access. Where required, this must be accompanied by the relevant consent to do so).

SECTION 2

The Tenderer (just in case of legal persons), is registered at the following register of legal persons according to the law of the country of establishment:

The activity performed is
The registration number is
The Tenderer has run from
The Iegal form of the Tenderer is
The social object of the Tenderer is
The nationality of the Tenderer is

The address of the Tenderer is		
And specifically, list:		
Title:	Name:	Surname:

In witness whereof I sign this statement.

Place and date



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 8 (TD 8) Declaration of pre-existing rights



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Declaration of pre-existing rights (TD 8)

I, the undersigned, _______ representing [insert name of the tenderer] ('the Tenderer') declare that the following list contains all the pre-existing rights of the Tenderer as whole (including all members of the group in a Joint Tender, Subcontractors and Third Parties on which the Tenderer relies to fulfil some selection criteria) that are attached to the proposed solution or parts of the proposed solution in my technical offer for this Call for Tender.

Please fill in the table-one line per pre-existing right.

Part / aspect of the proposed solution concerned	Pre-existing material concerned	Rights to pre-existing material	Holder

Date:

Place:



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 9 (TD 9) PCP Framework Agreement



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

PCP Framework Agreement

PREAMBLE

This is a PCP Framework Agreement ("Agreement" or "PCP Framework Agreement") between the following parties:

on the one part,

the "Contracting Authority", KENTRO MELETON ASFALEIAS (KEMEA), established in P KANELLOPOULOU 4 ST, ATHINA 10177, Greece.

acting in the name and on behalf of the procurers in the Buyers Group (together with the Contracting Authority: "procurers"):

2. EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES), established in CALLE SEVERO OCHOA 28, CAMPANILLAS 29590, Spain, VAT number: ESQ2900463G,

3. SERVICIO MADRILENO DE SALUD (SERMAS), established in PLAZA CARLOS TRIAS BERTRAN 7, MADRID 28020, Spain, VAT number: ESQ28012211,

4. OSTERREICHISCHES ROTES KREUZ (ARC), established in WIEDNER HAUPTSTRASSE 32, WIEN 1041, Austria, VAT number: ATU16370905, ZVR: 432857691 ,

5. AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN), established in VIA ODERISIO 1, BENEVENTO 82100, Italy, VAT number: IT01009680628,

6. AGENZIA REGIONALE EMERGENZA URGENZA (AREU), established in VIALE MONZA 223, MILANO 20125, Italy, VAT number: IT11513540960,

7. ELLINIKOS ERYTHROS STAVROS (HRC), established in LYKAVITTOU 1, ATHINA 106 72, Greece, VAT number: 090001670,

8. ETHINKO KENTRO AMESIS VOITHEIAS (EKAB), established in TERMA ODOU YGEIAS, ATHINA 11527, Greece, VAT number: EL090073326,

9. IZMIR BUYUKSEHIR BELEDIYESI (IBB), established in CUMHURIYET BULVARI 1 KONAK, IZMIR 35251, Turkey, VAT number: TR4840008254

and on the other hand, the "Contractor", [insert details of the contractor],

[OPTION for Joint Tenders: acting in the name and on behalf of the other members of group of Tenderers:

1. [insert the details of the members of the group of Tenderers]

2.

The members of the group of Tenderers are hereafter collectively referred to as "the Contractor" and will be jointly and severally liable vis-à-vis the Contracting Authority for the performance of this PCP Framework Agreement and the Specific Contracts.]

The Contracting Authority, Buyers Group and the Contractor(s) shall be referred to together as "parties", unless otherwise specified.

By signing this Agreement, the parties agree to implement the pre-commercial procurement in accordance with the Agreement and all the obligations it sets out.

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The Agreement is composed of:

- Preamble
- Terms and Conditions

TERMS AND CONDITIONS

Article 1 — Subject of the agreement

This PCP Framework Agreement defines the general terms and conditions for the implementation of the PCP procurement of R&D services set out in Article 3 and for the Specific Contracts that will be awarded for each of the 3 PCP phases.

Article 2 — Duration

The PCP Framework Agreement becomes effective upon signing by both parties and shall remain in effect (unless terminated in accordance with Article 16) until the Completion Date (as defined below) of Phase I or of a later Phase that has been awarded to the Contractor. However, confidentiality obligations and provisions shall remain applicable for 5 years after the end of the PCP Framework Agreement in accordance to Article 6. Please note that Contractors who are awarded contracts for the Phases II and III shall sign a formal assignment for that particular phase.

The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

Article 3 — R&D services to be provided

The Contractor shall provide the R&D services (tasks, deliverables and milestones) to develop solutions to tackle the challenge set out in the Tender and the Specific Contracts.

Article 4 — Pricing, payment and accounting

The price for the R&D services to be implemented for each PCP phase will be set out in the Specific Contracts.

The prices shall be based on the binding unit prices in the tender and the following price conditions:

- if new units/unit prices are added to Phase 2 or 3 offers, they shall become binding for the remaining phases
- if offered unit prices from Phase 1 are changed in Phase 2 and / or Phase 3 offers, this should be duly notified and explained by the Contractor. The next payment conditions will apply:

4.1 The total amount to be paid by the procurement entity to the Contractor shall not exceed the relevant amounts detailed in Section 2.8. of the PCP Request for Tenders document. Subject to these limits the Contractor is free to administer received payments within the terms of this PCP Framework Agreement without further reference to the Procuring Entity.

4.2 Payment for the Contractor's Services for each Phase will be made according to the following provisions:

4.2.1 PHASE I: payment of the Price for Phase I shall be made in one part. The payment of 100% shall be paid within 30 calendar Days from the date of the decision of the Evaluation Committee confirming that the Contractor has complied with the Performance Conditions as described in section 5.2 of the

CfT document applicable to such Phase and is thus considered to have completed the Phase satisfactorily.

4.2.2 PHASE II: payment of the Price for Phase II shall be made in two parts. The Contractor shall be paid a first payment of 50% of the Price for Phase II within 30 calendar Days from the date of the decision of the Evaluation Committee to accept the successful completion of the interim deliverables of the Contractor to Phase II The second payment of 50% shall be paid within 30 calendar Days of the decision of the Evaluation Committee confirming that the Contractor has complied with the Performance Conditions as described in section 5.2 of the CfT document applicable to such Phase and is thus considered to have completed the Phase satisfactorily.

4.2.3 PHASE III: payment of the Price for Phase III shall be made in three parts. The Contractors shall be paid a first payment of 45% of the Price for Phase III within 30 calendar Days from the date of the decision of the Evaluation Committee to accept the successful completion of the interim deliverables of the Contractor to Phase III (three). The second payment of 40% shall be paid within 30 calendar Days from the date of the decision of the Evaluation Committee confirming that the Contractor has complied with the Performance Conditions as described in section 5.2 of the CfT document applicable to such Phase and is thus considered to have completed the Phase satisfactorily. The third payment of 15% shall be paid within 30 calendar Days form the date of the decision of the Evaluation Committee confirming that iProcureSecurity PCP project has successfully concluded.

In case of Default, any payment already made may be reclaimed, including for the case in which the Contracting Board comes to the conclusion that Phase III was not even satisfactorily completed.

4.3 The Contractor accepts, upon first request from the Procuring Entity, to provide the Procuring Entity with complete, relevant and clear information as well as documentary evidence about the allocation of monies paid by the Procuring Entity.

4.4 Payments to third parties employed or hired by the Contractor, if any, shall remain the responsibility of the Contractor who shall ensure that such payments are made promptly and shall hold the Procuring Entity harmless against any claim of such third parties.

4.5 During the Project Period, payments will be made by the Procuring Entity pursuant to invoices issued to the Procuring Entity; the Procuring Entity may suspend this payment at any time if, in the view of the Procuring Entity, acting reasonably, satisfactory progress on the Project has not been maintained, or reports have not been submitted as required under Article 6.

4.6 Subject to the confidentiality obligations set forth in Article 6, the Contractor grants to the Procuring Entity, acting, as the case may be, through agents authorized for that purpose, and to any statutory or regulatory auditors of the Procuring Entity, a right to access (and, if necessary to copy) the relevant financial records during normal business hours.

4.7 The Contractor shall provide all reasonable assistance at all times during the term of the Agreement and during a period of ten years after termination or expiry of this Agreement for any reason whatsoever, for the purposes of allowing the Procuring Entity to obtain such information as is necessary to fulfil the Procuring Entity's obligations to supply information for national or supranational parliamentary, governmental, judicial or other administrative purposes and/or to carry out an audit of the Contractor's compliance with this Agreement including all activities, performance, security and integrity in connection therewith. 4.8 If at any time an overpayment has been made to the Contractor for any reason whatsoever, the amount of such overpayment shall be considered when assessing any further payments or shall be recovered from the Contractor at the Procuring Entity's discretion.

4.9 The Contractor shall keep and maintain, up until at least ten years after this Agreement has been completed, full and accurate records of the Project including:

4.9.1 all aspects of the Project;

4.9.2 all expenditure paid by the Procuring Entity; and

4.9.3 all payments made by the Procuring Entity, and the Contractor shall allow upon request by the Procuring Entity or the Procuring Entity's representatives such access to those records as may be required in connection with the Agreement.

4.10 Where the Contractor enters into a Sub-Contract with a supplier or Contractor for the purpose of performing the Contract, it shall cause a term to be included in such a Sub- Contract that requires payment to be made of undisputed sums by the Contractor to the Sub- Contractor within a specified period not exceeding 30 calendar Days from the receipt of a valid invoice, as defined by the Sub-Contract requirements.

4.11 Wherever, under the Contract, any sum of money is recoverable from or payable by the Contractor (including any sum that the Contractor is liable to pay to the Procuring Entity in respect of any breach of the Contract), the Procuring Entity may unilaterally deduct that sum from any sum then due, or which at any later time may become due to the Contractor under the Contract or under any other agreement with the Procuring Entity.

4.12 The Contractor shall make any payments due to the Procuring Entity without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise, unless the Contractor has a final and enforceable court order requiring an amount equal to such deduction to be paid by the Procuring Entity to the Contractor.

4.13 The Procuring Entity presume that the intention is to prevent abnormal price offers, price estimation for research prices, and calculations of future market price of solutions. In case of suspicion of abnormal price offers the robustness of calculation has to be declared to the IPROCURESECURITY PCP consortium or advisory board.

Article 5 — Ownership of the results (foreground), pre-existing rights (background) and sideground (including intellectual and industrial property rights)

5.1 Rights and obligations concerning all (fore-, back- and sideground) Intellectual Property Rights.

5.1.1. Contractor shall take all appropriate and necessary measures to ensure the proper management of the Project Intellectual Property Rights.

5.1.2 Each contractor is responsible for the management (including protection) of its Intellectual Property Rights as stated in 5.1.1 and bears the costs associated with this.

5.1.3 If the Contractor becomes aware of any product or activity of any third party that involves or may involve infringement or other violation of the Project Intellectual Property Rights, or any other proprietary right on the Results, the Contractor shall promptly notify the Procuring Entity of the infringement or violation.

5.1.4 The procurers have the right to monitor the management of the IPRs.

5.1.5 The contractor must inform the buyers group (via the Contracting Authority) of results that can be exploited, regardless of whether they can be protected or not, within 30 days from when they are generated. The information submitted to the Contracting Authority must include information about the contents of the results, the confirmation by the contractor to protect them and the planned timing for protection.

5.1.6 For Results that are not IPRs, like prototypes and first products resulting from the R&D, design, prototype and first product/service specifications, simulations, data models, drawings, source code, the same rules as for IPR's will apply.

5.1.7 The Contractor will provide each of the iProcureSecurity PCP consortium members an irrevocable, indefinite, worldwide, royalty-free and non-exclusive license to use all Results, including Project Intellectual Property Rights and the Pre-existing rights *that are needed to perform the Project for the purpose of executing the Project* as well as for non-commercial research purposes, including trials set up to test the validity of the Results. In case of Results that constitute software, the non-commercial research license will extend to all updates and upgrades thereof during the trials set up to test the validity.

5.2 Rights and obligations concerning foreground Intellectual Property Rights.

5.2.1 Each contractor that generates Results owns the attached (foreground) IPRs.

5.2.2 If a contractor does not seek protection for results that should be protected, the Buyers Group has the full rights on all IPRs. The Contracting Authority will request to transfer the results and IPR to them.

5.2.3 The contractor grants to the buyers group irrevocable, royalty-free, non-exclusive, world-wide access rights to use the results, for their own purposes (for IPRs: until their expiry date).

5.2.4 The Buyers Group has the right to require the contractor to grant — within a reasonable time period specified in the request — non-exclusive licenses to third parties to commercially or non-commercially exploit the results under fair and reasonable conditions, without the right to sub-license.

5.2.5 The contractor may grant non-exclusive licenses to third parties allowing them to exploit the results (or otherwise give the right to exploit them) — unless this impedes the access rights of the buyers group.

5.2.6 The contractor may transfer ownership of its results — unless this is prohibited (or restricted) by the security obligations and provided that it ensures that its obligations (in respect of the results) apply to the new owner and that this new owner is obliged to pass them on any subsequent transfer (e.g., by including a requirement to do so in their arrangements with the new owner).

5.2.7 The contractor is required to deposit copies of Results (e.g. the source code and design specifications) to guarantee for the buyers group a continued access to results in case of financial bankruptcy of the contractor (or any of its subcontractors).

- Under an ESCROW agreement for Software.

- As a copy to the buyers group in case of designs, drawings, reports and specifications.

- As a copy of the original in the case of hardware (and prototype).

5.2.8 If a contractor wants to transfer its IPR to another party, and the procurers in the buyers group still have rights or requests regarding the IPR, the contractor must give at least 45 days prior notice of

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its intention to transfer ownership of the results. Furthermore, this notification must include sufficient information on the new owner to enable the procurers to assess the effects of their access rights. A procurer can object within 30 days of receiving such a notification if it is demonstrated that the transfer would adversely affect access rights and the transfer may not take place until an agreement has been reached between the parties concerned.

5.3 Rights and obligations concerning background and sideground Intellectual Property Rights.

5.3.1 The property rights of background IPRs do not change under this PCP Framework Agreement. All Pre-existing rights remain the property of the party introducing the same (or any third party supplier that owns it) and nothing contained in this PCP Framework Agreement or any license contract pertaining or pursuant to the Project shall affect the ownership rights of either party (or any third party) in its Pre-existing rights.

5.3.2 Parties must inform each other about the generation of/changes in pre-existing rights and sideground within 30 days from the generation /change.

5.3.3 The contractor introducing background must within 14 days of the signing of the PCP Framework Agreement provide the Contracting Authority with a list of the pre-existing rights it holds and/or has access to (e.g. via its subcontractors) (at the date of the agreement) and a list of the software necessary for the operation of the prototype and first [products][services] that will be developed during the PCP, specifying which software is closed source software. An updated list (to the extent necessary) must be provided with each bid for the next phase.

The access that the parties must grant each other to each other's pre-existing rights and sideground for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes (normally at least to the buyers group). The conditions for access should be fair and reasonable to all parties,

- on a royalty-free, non-exclusive basis, access to each other's background, solely for carrying out the tasks assigned to them in the PCP

- under fair and reasonable conditions and on non-exclusive basis, access to each other's background, for exploitation of results generated in the PCP and for using the results for their own purposes

- under fair and reasonable conditions and on non-exclusive basis, access to each other's sideground, for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes.

5.3.4 The Contractor shall, within four (4) years after the end of the PCP Framework Agreement, take measures to ensure that the Project Results are exploited commercially (directly or indirectly, in particular through licensing). Contractor will report on request of the Procuring Entity about the progress on the commercial exploitation of the results during the 4-year period aforementioned (max. twice per year).

5.3.5 If the Contractor fails to commercially exploit the Results within this period or uses the Results to the detriment of the public interest, the Contractor shall, at Procuring Entity's request, transfer the ownership of the Results to the Procuring Entity free of costs or sub-licenses IPRs to third parties indicated by the Procuring Entity. 'Failure to commercially exploit Results' means not marketing a commercial application of the Results (directly or indirectly, through a subcontractor or licensee).

5.3.6 The contractor must ensure that it complies with its obligations under the PCP Framework Agreement and specific contracts if it uses subcontractors; that it must obtain all necessary rights (transfer, licences or other) from subcontractors, as if they were generated by itself; that it should refrain from using subcontractors if obtaining those rights is impossible.

Article 6 — Confidentiality

The parties shall keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed. This applies during the implementation of the PCP Framework Agreement and Specific Contracts and up to 5 years after their end. If information has been identified as confidential only orally, it shall be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure. The parties may disclose confidential information to their staff or to third parties involved in the PCP implementation only if:

(a) they need to be aware of this information in order to implement the PCP activities under the PCP Framework Agreement and Specific Contracts; and (b) they are bound by an obligation of confidentiality. The procurers may disclose confidential information to the EU if required under their Horizon 2020 grant agreement. The confidentiality obligations cease to apply if:

(a) the disclosing party agrees to release the other party from the obligation;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was produced without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation; or

(e) the disclosure of the information is required by EU or national law.

This does not change the security obligations, which still apply. Stricter confidentiality obligations apply for information that is EU-classified or subject to a security recommendation.

Article 7 — Promotion, publicity and communication

7.1 The contractor shall undertake communication activities to create publicity about its participation to the procurement, and to promote the objectives and the results of the R&D carried out under the PCP.

All communication activities shall comply with the applicable confidentiality and security restrictions.

During the implementation of the contract and for a period of 5 years after the end of the contract, the contractor shall inform the Contracting Authority 28 days in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the services or results. Information on communication activities expected to have a major media impact shall be provided sufficiently in advance to allow the Contracting Authority to inform the EU.

All communication activities *(including in electronic form and via social media)* and infrastructure, equipment and major results financed by the PCP shall display the EU emblem and include the following text:

 for communication activities: 'This is part of the iProcureSecurity PCP project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme';

- for infrastructure, equipment and major results: 'This solution is part of the iProcureSecurity PCP project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme'. When displayed together with another logo, the EU emblem shall have appropriate prominence. The contractor may use the EU emblem without first obtaining approval from the EU. This does not, however, give the contractor the right to exclusive use. Moreover, the contractor may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means. All communication activities shall indicate that they reflect only the author's views.

7.2 The Procuring entity and the buyers group may use, for the purposes of communication and publicity, all information relating to the PCP, documents (notably summaries) and deliverables, and any other material (such as pictures or audio-visual material) from the contractor (including in electronic form). The procurers may, in particular, publish the names of the participating contractor and its project abstracts, the summaries of the main results from the R&D and the lessons learnt during the PCP (e.g., relating to the feasibility of the different approaches to meeting the procurers' requirements that were explored, and the lessons learnt for potential future use of the solutions proposed). This does not change the confidentiality obligations under Article 6. Moreover, before publishing this information, the procurers shall consult the contractor, in order to avoid harm to legitimate business interests (e.g. regarding aspects of the solutions that could be IPR-protected) or distortion of competition.

7.3 The EU may use, for the purposes of communication and publicity, information relating to the PCP, documents (*notably summaries*) and deliverables, and any other material (*such as pictures or audiovisual material*) from the contractor (*including in electronic form*). If the EU's use of these materials, documents or information would risk compromising legitimate interests, the contractor may, however, ask the Contracting Authority to request the EU not to use it. The right to use the contractor's materials, documents and information includes:

(a) use for its own purposes (in particular, making them available to staff working for the EU (including for the European Commission, EU executive agencies, other EU institutions, bodies, offices or agencies) or for EU Member State institutions or bodies; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) editing or redrafting for the purposes of communication and publicity (including shortening, summarizing, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts or using in a compilation);

(d) translation;

(e) giving access in response to individual requests made under EU Regulation No 1049/2001, without the right to reproduce or exploit;

- (f) storage in paper, electronic or other form;
- (g) archiving, in line with applicable rules on document management, and
- (h) authorising third parties to act on its behalf or sub-licensing the modes of use set out in points
- (b), (c), (d) and (f) to third parties if needed for the purposes of communication and publicity.

If the right of use is subject to rights of a third party *(including the contractor's staff)*, the contractor shall ensure that it obtains the necessary approval from the third parties concerned.

Article 8 — Commercial exploitation of results

The contractor shall, for at least four (4) years after the end of the PCP Framework Agreement and the Specific Contracts, take measures to ensure that its results are exploited commercially (directly or indirectly, in particular through transfer or licensing).

If the contractor fails to commercially exploit the results within this period (or uses the results to the detriment of the public interest, *including security interests*), the Buyers Group has the right to require that ownership of the results be transferred to them.

'Failure to commercially exploit results' means not marketing a commercial application of the results (directly or indirectly, through a subcontractor or licensee).

Article 9 — Conflicts of interest

9.1 The contractor shall take all measures necessary to prevent a situation arising where the impartial and objective implementation of the PCP Framework Agreement or a Specific Contract is compromised for reasons involving economic interests, political or national affinity, family, personal life or any other shared interest.

The contractor shall also take all measures necessary to prevent a situation in which its (previous or ongoing) professional activities affect the impartial and objective implementation of the PCP Framework Agreement or a Specific Contract.

9.2 The contractor shall notify the Contracting Authority without delay of any situation constituting or likely to lead to a conflict of interest *(including changes of ownership)* and shall immediately take all steps necessary to rectify this situation.

The Contracting Authority may instruct the contractor to take specific measures to remedy the situation.

Article 10 — Ethics and research integrity

10.1 The contractor shall carry out the tasks assigned to it in the PCP Framework Agreement and Specific Contracts in compliance with:

(a) ethical principles *(including the highest standards of research integrity)* and (b) applicable international, EU and national law.

The contractor may not:

 carry out activities in a country outside the EU, if they are prohibited in all EU Member States or

- - destroy human embryos. The contractor may not carry out activities whose aim is to:
- (a) carry out human cloning for reproductive purposes;

(b) modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads) or

(c) create human embryos solely for the purpose of research or for the purpose of stem cell procurement, *including by means of somatic cell nuclear transfer*.

The contractor may not carry out activities that do not focus exclusively on civil applications. The contractor shall respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity. This implies compliance with the following essential principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts. This means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

10.2 Before starting any activity that raises an ethical issue, the contractor shall submit to the Contracting Authority a copy of:

- (a) any ethics committee opinion required under national law and
- (b) any notification or authorisation for activities raising ethical issues required under national law.

Article 11 — Security-related obligations

11.1 Activities involving dual-use goods or dangerous materials and substances shall comply with applicable EU, national and international law. Before starting the activity, the contractor shall provide the Contracting Authority with a copy of any export or transfer licenses required.

11.2 Classified information shall be treated in accordance with the security aspect letter (SAL) annexed to the H2020 grant agreement and EU Decision No 2015/444 until it is declassified. Tasks involving classified information may not be subcontracted without prior written approval from the Contracting Authority. The contractor shall inform the Contracting Authority of any changes relating to security and, if necessary, request an amendment.

Article 12 — Processing of personal data

12.1 The Contracting Authority and the buyers group shall process personal data in compliance with the applicable EU and national law on data protection.

12.2 The contractor shall process personal data in compliance with the applicable EU and national law on data protection *(including information as well that relates to authorisations and notification requirements)*.

12.3 The contractor may grant its staff access to data only in so far as it is strictly necessary for implementing, managing and monitoring the PCP Framework Agreement and Specific Contracts.

12.4 The contractor must inform the staff whose personal data are collected and processed by the procurers and/or the EU. For this purpose, the contractor must provide them with the privacy statements of the procurers and the EU, before transmitting their data. If explicit prior consent from the data subjects is needed, the contractor must obtain such a consent.

Article 13 — Obligation to provide information and keep records

13.1 The contractor must, at any time during the implementation of the PCP Framework Agreement and Specific Contracts or afterwards, provide any information requested by the Contracting Authority or the buyers group in relation to the PCP Framework Agreement or related contracts concerning the commercialisation of the Results.

13.2 The contractor must keep, for a period of up to 10 years after the end of the PCP Framework Agreement and Specific Contracts, records and other supporting documentation relating to their implementation.

This obligation includes records and other supporting documentation on scientific and technical implementation (in line with the accepted standards in the field) and on the price charged and the costs incurred by the contractor.

The contractor must keep the original documents. Digital and digitalised documents are considered originals if they are authorised under national law.

Should there be ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims *(including claims by a third party against the procurers)*, the contractor must keep all records and other supporting documentation until the end of these procedures.

Article 14 — EU checks, reviews, audits and investigations

Should the EU (including the European Court of Auditors or the European Anti-Fraud Office (OLAF)) decide to carry out a check, review, audit or investigation, the contractor must make available all information, records and other supporting documents relating to the implementation of the PCP Framework Agreement and Specific Contracts.

Should there be a visit on-the-spot, the contractor must allow access to its premises and must ensure that the information requested is readily available.

Article 15 — EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the procurers), the contractor must make available all information, records and other supporting documents relating to the implementation of the PCP Framework Agreement and Specific Contracts.

Article 16 — Breach of contract / Termination

16.1 Without prejudice to any other provision of this PCP Framework Agreement, this PCP Framework Agreement may be terminated by either party giving three months' notice in writing to the other, unless the time remaining to the end of the relevant Phase is less than three Months, in which case the notification time shall be all the remaining time till the end of that Phase. Should the option to terminate be exercised by the Procuring Entity, it shall indemnify the Contractor from and against all

and any actual loss unavoidably incurred by reason or in consequence of the termination provided that the Contractor takes all immediate and reasonable steps to minimize the loss.

16.2 With regards to Article 16.1, the Procuring Entity will not pay any amount which will exceed the total sums which otherwise should have been paid under this PCP Framework Agreement once the Contractor had fulfilled its obligations under the Agreement.

16.3 The Procuring Entity may at any time and from time to time by formal notification terminate this PCP Framework Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if there is a change of control in the Contractor which the Procuring Entity can reasonably demonstrate is prejudicial. The Procuring Entity shall only be permitted to exercise its rights pursuant to this clause for 6 (six) months after any such change of control and shall not be permitted to exercise such rights where the Procuring Entity has agreed *a priori* in writing to the particular change of control and such change of control takes place as proposed. The Contractor shall notify the Procuring Entity within 2 (two) weeks if a change of control takes place.

16.4 The Procuring Entity may at any time and from time to time by formal notification terminate this PCP Framework Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if:

- any approvals consent or licenses required under this PCP Framework Agreement are not given unconditionally within 6 (six) months of the commencement of the Project Period;

- the Contractor is subject to an Insolvency Event;

- any provision of this PCP Framework Agreement (other than as previously specified in the preceding provisions of this Article 24) expressly entitles the Procuring Entity to terminate this PCP Framework Agreement;

- the Contractor, or any sub-Contractor on whose resources he has relied in the procurement that has preceded this PCP Framework Agreement, becomes subject to any exclusion criteria listed in the PCP Request for Tender document;

- the Services are not in compliance with requirements on Research and development Services as defined in the most recent version of the Frascati Manual (Proposed Standard Practice for Surveys on Research and Experimental Development OECD, 6th Edition, 2002, ISBN 978-92-64- 19903-9, pp 29-50) and, where applicable its latest annexes or in case of non-compliancy with any other requirement mentioned in the PCP Request for Tender document and declared in the signed declaration that is part of the tender.

16.5 Termination of this PCP Framework Agreement by the Procuring Entity under the preceding provisions of this Article 16 shall (at the option of the Procuring Entity) terminate this PCP Framework Agreement with immediate effect as from the date of service of the notice of that termination or from the expiry of a period (not exceeding 6 (six) Months) specified in that notice.

16.6 The contractor must compensate the Contracting Authority and the Buyers Group if they are held liable by the EU for damage it sustained as a result of the implementation of the PCP Framework Agreement or a specific contract or because it was not implemented properly.

16.7 The EU cannot be held liable for any damage caused to the contractor or caused by the contractor in connection with the implementation of the PCP Framework Agreement or a specific contract.

Article 17 — Amendments

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18.1 If at any time, it appears likely that any provision of the Agreement or the Project, needs to be amended, the Contractor shall immediately inform the Procuring Entity requesting in writing a Variation to the Agreement, giving full details of the justification for the request and giving proposals for the Variation to the Agreement. Upon receipt of such a request the Procuring Entity may:

18.1.1 agree to amend the Agreement provided such Variation is non-discriminatory and does not amount to a substantial change of the Agreement, the scope of services or the scope of the Results, as allowed following the existing case-law of the European Court of Justice;

18.1.2 amend the Project in a manner which the Contractor agrees can be carried out within the Project Period and within the Price with regard to the relevant phases;

18.1.3 refuse the request and require the continuation of the Project in accordance with the PCP Framework Agreement.

Article 18 — Interpretation

19.1 The terms set out in the PCP Framework Agreement have precedence over those in annexes.

19.2 The terms set out in Annex 1 have precedence over those set out in Annex 2 (contractor's tender).

19.3 The same applies to the specific contracts.

Article 19 — Subcontracting, Transfer, Assignment & Interpretation

20.1 The Contractor will allow the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 Grant Agreement (*mutatis mutandis*) and will comply with Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 Grant Agreement (*mutatis mutandis*).

20.2 The Contractor will ensure that in all Sub-Contracts the conditions from the Grant Agreement set out in the above clause 20.1 are imposed upon the subcontractor.

20.3 A third party may replace a Contractor or a member of the Contractor in case of a consortium activity as a result of universal succession in the position of the Contractor following corporate restructuring, including takeover, merger, acquisition or in an Insolvency Event, provided that the third party meets all exclusion, selection, compliance and minimal technical criteria and the succession does not entail a substantial modification.

20.4 The Contractor is allowed to replace a subcontractor, provided that the new subcontractor meets all exclusion, selection, compliance minimal technical criteria and the replacement does not entail a substantial modification.

20.5 The PCP Framework Agreement constitutes the entire agreement between the parties relating to its subject matter. Each party acknowledges that it has not entered into this PCP Framework Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this PCP Framework Agreement. Each party waives any claim for breach of this PCP Framework Agreement, or any right to repeal this PCP Framework Agreement in respect of, any representation which is not stated in this PCP Framework Agreement. However, this Article does not exclude any liability which either party may have to the other (or any right which either party may have to repeal this PCP Framework Agreement) in respect of any fraudulent misrepresentation or fraudulent concealment prior to the execution of this PCP Framework Agreement. In case of

discrepancy between the PCP Framework Agreement, on the one hand, and the PCP Request for Tender Document, on the other hand, the documents shall prevail in the following order:

- PCP Framework Agreement;
- PCP Call for Tender Document;
- Other Tender Documents; and
- Contractor's Tender in the Tendering Stage.

Article 20 — Applicable law and dispute settlement

This PCP Framework Agreement and the specific contracts are governed by the Greek Law. The place of jurisdiction shall be the competent court of Athens. Any legal claim, petition or application for judicial review, with regard to the present procurement procedure, shall be made in Greece. By submitting a tender, the Contractor accepts the exclusive jurisdiction of Greek courts.

Article 21 — Entry into force

This PCP Framework Agreement shall enter into force between Parties on the day on which KEMEA has received a signed duplicate of this Agreement of the authorized representative of each of the Parties.

SIGNATURES

The Contracting Authority signs for the Buyers Group and — in case of joint tenders — the lead contractor for the group of contractors.



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 10 (TD 10) PCP Specific Contract for Phase 1/2/3



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

PCP Specific Contract for Phase 1/2/3

This is a Contract between the following parties:

on the one part,

the "Contracting Authority", KENTRO MELETON ASFALEIAS (KEMEA), established in P KANELLOPOULOU 4 ST, ATHINA 10177, Greece.

acting in the name and on behalf of the procurers in the Buyers Group (together with the Contracting Authority: "procurers"):

2. EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES), established in CALLE SEVERO OCHOA 28, CAMPANILLAS 29590, Spain, VAT number: ESQ2900463G,

3. SERVICIO MADRILENO DE SALUD (SERMAS), established in PLAZA CARLOS TRIAS BERTRAN 7, MADRID 28020, Spain, VAT number: ESQ2801221I,

4. OSTERREICHISCHES ROTES KREUZ (ARC), established in WIEDNER HAUPTSTRASSE 32, WIEN 1041, Austria, VAT number: ATU16370905, ZVR: 432857691 ,

5. AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN), established in VIA ODERISIO 1, BENEVENTO 82100, Italy, VAT number: IT01009680628,

6. AGENZIA REGIONALE EMERGENZA URGENZA (AREU), established in VIALE MONZA 223, MILANO 20125, Italy, VAT number: IT11513540960,

7. ELLINIKOS ERYTHROS STAVROS (HRC), established in LYKAVITTOU 1, ATHINA 106 72, Greece, VAT number: 090001670,

8. ETHINKO KENTRO AMESIS VOITHEIAS (EKAB), established in TERMA ODOU YGEIAS, ATHINA 11527, Greece, VAT number: EL090073326,

9. IZMIR BUYUKSEHIR BELEDIYESI (IBB), established in CUMHURIYET BULVARI 1 KONAK, IZMIR 35251, Turkey, VAT number: TR4840008254

and on the other hand, the "Contractor", [insert details of the Contractor],

[OPTION for joint tenders: acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of Tenderers]

2.

The members of the group of Tenderers are hereafter collectively referred to as "the Contractor" and will be jointly and severally liable *vis-à-vis* the Contracting Authority for the performance of this Contract.

The Contracting Authority, Buyers Group and the Contractor(s) shall be referred to together as "parties", unless otherwise specified.

By signing this Contract, the parties agree to implement the pre-commercial procurement in accordance with the Contract and all the obligations set out.

TERMS AND CONDITIONS

Article 1 — Subject of the Contract

This Specific Contract defines the specific terms and conditions for the implementation of the PCP procurement of R&D services set out in Article 3 — for the $[1^{st}][2^{rd}][3^{rd}]$ PCP phase.

Article 2 — Duration

The Services with regard to Phase 1/2/3/shall be provided and delivered in full within the timetable set out in the Tender Documents. For the purpose of Phase 1/2/3, the "completion date" shall be

Article 3 — R&D services to be provided

The R&D services to be provided will be in accordance to the Call for Tenders and the Offer.

The contractor will design and submit for technical evaluation its individual views of the solution that meets iProcureSecurity requirements and will verify the technical, economic and organizational feasibility of their solution approach to address the PCP challenge.

The contractor will provide a detailed design of all the components, algorithms and processes of the proposed solution.

The works carried out will also encompass the definition of verification procedures for the evaluation of the performance of the solutions according to technical parameters, thus leading to an evaluation of the level of compliance of the solutions with respect to the specification from a technical standpoint.

A detailed planning for further stages of development will also be requested.

Article 4 — Price and payment arrangements

The price to be paid by KEMEA for the R&D services set out in Article 3 shall be [EUR] [amount in figures and in words] excluding VAT and [EUR] [amount in figures and in words]VAT included.

The Contractor is free to administer received payments within the terms of the Framework Agreement and this Contract.

The Contractor is requested to provide the Contracting Authority along with the respective invoice, the following documentation, accompanied by their official translation in English:

- Tax Clearance certificate (payment of tax evidence) or equivalent.
- Social Security Contributions Payment Certificate or equivalent.
- Criminal Record of the legal representative(s) or equivalent.
- Company Legal Documents (i.e. statute/modifications/legal documents for the Representation of the company, all approved and registered by the Competent Authority, if applicable).
- Official Document with the bank account details.

Official documents must be issued within 30 working days prior to their submission and be valid when submitted (if a validity period is indicated). If a document has no expiration date, it must be issued within 30 working days prior to their submission and be accompanied by a declaration certifying that the respective document has no expiration date.

The Lead Procurer can only pay if all these above-mentioned documents have been attached to the invoice.

Once the deliverable has been evaluated as satisfactory, the Contractor will be asked to submit an invoice. Once the invoice and the additional documents have been accepted, the payment is due within 30 (thirty) days.

Article 5 — Entry into force

The Contract shall enter into force between Parties on the day on which KEMEA has received a signed duplicate of this Contract of the authorized representative of the contractor and shall remain in effect until the Completion Date set out in article 2 "Duration" above. In any case, the duration of the Contract shall be conditioned to the duration of the Framework Agreement. So, in the event of an early termination of the Framework Agreement, this Contract shall be also terminated automatically.

SIGNATURES

The Contracting Authority signs for the Buyers Group and — in case of Joint Tenders — the Lead Contractor for the group of Contractors.



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 11 (TD 11) End of Phase (1/2/3) Report



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

End of Phase Report - Results & Conclusions

Contactors

1. The innovative solution

Provide a short description (that is suitable for publication purposes) of:

The innovative solution (in its current form)

Where exactly lies the innovation in the solution: In which ways and to which extent does the solution go beyond what existing solutions can achieve?

The degree of innovation: indicate if your innovative solution is (a) a totally new product / service / process / method; (b) an improvement to an existing product / service / process / method; (c) a new combination of existing products / services / processes / methods and (d) a new use for existing products / services / processes / methods).

2. Commercialisation success

Provide a short description (mark parts that are not suitable for publication purposes) of:

How mature is the innovative solution in terms of its readiness to commercialise widely: Which steps towards wide scale commercialisation have been completed so far? (*Do not forget: IPR protection, certification, CE marking, attracting additional investors to grow the business, setting up sales / distribution channels / marketing activities to expand sales to other countries etc.*)

What is the current commercialisation success of the solution: e.g. awards / other forms of recognitions obtained, sales / increase in market share already achieved, licensing agreements already concluded, collaboration agreements with other partners (e.g. retailers) to commercialise the solutions already signed, additional investments attracted to further commercialise the solution.

3. Other benefits obtained

Provide a short description (mark parts that are not suitable for publication purposes) of any other benefits that you obtained from participating in the procurement, e.g.

Getting easier access to (a new segment of) the public procurement market (e.g., did the procurement enable you to work with procurers / end-users that you were not working with beforehand?)

Growing your business across borders and/or to other markets (*e.g., private markets*) due to the first customer references provided by the procurement

Shortening the time-to-market for your innovation due to early customer / end-user feedback

Other benefits / lessons learnt: complete if applicable

4. Business growth

Provide a short description (mark parts that are not suitable for publication purposes) of:

How much has your business already grown during the procurement?

In terms of (a) personnel growth; (b) turnover growth; (c) growth in market share etc.

What are the prospects to grow your business via wider commercialisation of the solution:

- 1. How large is the potential market for your solution? Is it a growing / steady / declining market?
- 2. By when can commercialisation start (now / in 1 / in 3 / in 5 / in more than 5 years)?
- 3. Is competition patchy (no major players) / established (but no comparable offering) / fierce?

Which future steps do you plan to take to further grow your business? (e.g., attracting additional investors to grow your business, mergers / acquisitions / joint ventures / spin-offs / IPO, setting up sales / distribution channels / marketing activities, expanding to other countries etc.)

5. Final remarks (not for publication purposes, to assess how further EU support could best help you)

What are the remaining bottlenecks to commercialise your solution? (e.g., certification, legislation etc.)

What type(s) of assistance do you need to address those bottlenecks and grow your business / commercialise your solution more widely? (e.g., EU regulation on x, finding investors, IPR help etc.)

How important was the procurement for your business? (Would/could you have done it on your own?)



iProcure Security VPCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Tender Document 12 (TD 12) Contractor details and project abstracts



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Contractor details and project abstracts

Document type	Deliverable
Document version	Final
Document Preparation Date	[complete]
Classification	Public
Author(s)	All project partners
File Name	[Project Name] [PCP Phase 1] [PCP Phase 2] [PCP Phase 3] — Contractor details and project abstracts

For PCPs: complete this table for each contractor that was awarded a PCP Phase 1, 2 or 3 contract.

Contactor Details	Type/ size of legal entity	Place of performance of contract activities	Logo
Main contractor Name legal entity Address legal entity Name contact person Phone nr contact person E-mail address contact person	SME, larger company, natural person, university / research institute, other	% of contract value allocated to main contractor: [complete] % % of activities for the contract performed by the main contractor in EU Member States or countries associated with Horizon 2020: [complete] %	Main contractor logo
Other consortium member(s) (if applicable) Name legal entity Address legal entity Name contact person Phone nr contact person E-mail address contact person Complete as many times as there are other consortium members	SME, larger company, natural person, university / research institute, other	% of contract value allocated to contractor [x]: [complete] % % of activities for the contract performed by contractor [x] in EU Member States or countries associated with Horizon 2020: [complete] %	Other contracto r(s) logo(s)

Subcontractors (if			
<u>applicable)</u> Name legal	SME, larger	% of contract value	Subcontracto
entity	company,	allocated to	r(s) logo(s)
Address legal entity	natural person,	subcontractor [x]:	
Name contact person	university /	[complete] %	
Phone nr contact	research		
person E-mail address	institute, other	% of activities for the contract	
contact person		performed by subcontractor [x]	
		in EU Member States or	
		countries associated with	
		Horizon 2020: [complete] %	
Complete as many times			
as there are			
subcontractors			
54500111400015			

Project abstract (+/- 1000 characters maximum)

[Add an abstract of the winning tender, giving a brief project description agreed with the contractor that is suitable for publication purposes]

Previous EU funding

Is the project based on / a continuation of R&D activities that were previously funded by the EU?: YES/NO If yes, identify this EU funding: [name EU funding programme] — [project name] — [grant number]



iProcure Security PCP

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services



Contract Notice



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 101022061.

Contract Notice

ESENDER_LOGIN:	ENOTICES	
CUSTOMER_LOGIN:	ECAS_n0083c8y	
NO_DOC_EXT:	2022-XXXXX	
SOFTWARE VERSION:	13.2.0	
ORGANISATION:	ENOTICES	
COUNTRY:	EU	
PHONE:	1	
E_MAIL:	notices@kemea-research.gr	

LANGUAGE:	EN
CATEGORY:	ORIG
FORM:	F02
VERSION:	R2.0.9.\$05
DATE EXPECTED PUBLICATION:	1

1/7

Contract notice

Services

Legal Ba	nsis:
Directive	2014/24/EU
Section	I: Contracting authority
1.1)	Name and addresses
	Official name: KENTRO MELETON ASFALEIAS (KEMEA)
	Postal address: P. KANELLOPOULOU 4
	Town: Athens
	NUTS code: EL30 Αττική / Attiki
	Postal code: 10177
	Country: Greece
	Contact person: Panagiota Benekou
	E-mail: p.benekou@kemea-research.gr
	Telephone: +30 2107710805
	Fax: +30 2111004499
	Internet address(es):
	Main address: http://kemea.gr/en/
1.1)	Name and addresses
	Official name: OSTERREICHISCHES ROTES KREUZ (ARC)
	Postal address: WIEDNER HAUPTSTRASSE 32
	Town: Wien
	NUTS code: AT13 Wien
	Postal code: 1041
	Country: Austria
	Contact person: Monika Stickler
	E-mail: monika.stickler@roteskreuz.at
	Telephone: +43 158900134
	Fax: +43 5890098319
	Internet address(es):
	Main address: https://www.roteskreuz.at
1.1)	Name and addresses
	Official name: AGENZIA REGIONALE EMERGENZA URGENZA (AREU)
	Postal address: VIA ALFREDO CAMPANINI 6
	Town: Milano
	NUTS code: ITC4C Milano
	Postal code: 20124
	Country: Italy
	Contact person: Piero Maria Brambilla
	E-mail: p.brambilla@areu.lombardia.it
	Telephone: +39 3355465655
	Fax: +39 0267129002
	Internet address(es):
	Main address: https://www.areu.lombardia.it/
2/7

1.1)	Name and addressesOfficial name: AZIENDA SANITARIA LOCALE BENEVENTO (ASLBN)National registration number: IT01009680628Postal address: VIA ODERISIO 1Town: BeneventoNUTS code: ITF32 BeneventoPostal code: 82100Country: ItalyContact person: Alberto LombardiE-mail: alberto.lombardi@aslbenevento1.itTelephone: +39 824308560Fax: +39 82456340Internet address(es):Main address: http://www.aslbenevento1.it/
1.1)	Name and addresses Official name: ETHNIKO KENTRO AMESIS VOITHEIAS (EKAB) Postal address: TERMA ODOU YGEIAS Town: Athens NUTS code: EL3 Atruxń / Attiki Postal code: 11527 Country: Greece Contact person: KOUTSOUMPELIS PANAGIOTIS E-mail: p.koutsoumpelis@ekab.gr Telephone: +30 2132143530 Fax: +30 213214337 Internet address(es): Main address: https://www.ekab.gr/
1.1)	Name and addresses Official name: EMPRESA PUBLICA DE EMERGENCIAS SANITARIAS (EPES) Postal address: CALLE SEVERO OCHOA 28 Town: Campanillas Malaga NUTS code: ES617 Málaga Postal code: 29590 Country: Spain Contact person: Fernando Ayuso Baptista E-mail: direccion.epes@juntadeandalucia.es Telephone: +34 951042200 Internet address(es): Main address: http://www.epes.es/
1.1)	Name and addresses

1.1)

1.1)

1.2)

3/7

Official name: SERVICIO MADRILEÑO DE SALUD (SERMAS) Postal address: Paseo Castellana 280 Town: Madrid NUTS code: ES300 Madrid Postal code: 28046 Country: Spain Contact person: Teresa Chavarría Giménez E-mail: dgidoc@salud.madrid.org Telephone: +34 915867657 Fax: +34 915867658 Internet address(es): Main address: https://www.comunidad.madrid/centros/consejeria-sanidad Name and addresses Official name: IZMIR BUYUKSEHIR BELEDIYESI (IBB) Postal address: CUMHURIYET BULVARI 1 KONAK Town: Izmir NUTS code: TR310 İzmir Postal code: 35251 Country: Turkey Contact person: Senol Dereköy E-mail: senolderekoy@gmail.com Telephone: +90 5368112938 Fax: +90 2322938929 Internet address(es): Main address: https://itfaiye.izmir.bel.tr/ Name and addresses Official name: ELLINIKOS ERYTHROS STAVROS (HRC), Postal address: LYKAVITTOU 1 Town: Athens NUTS code: EL30 Αττική / Attiki Postal code: 10672 Country: Greece Contact person: Karafyllis Ioannis E-mail: general-director@redcross.gr Telephone: +30 6974464013 Internet address(es): Main address: http://www.redcross.gr/ Information about joint procurement The contract involves joint procurement

In the case of joint procurement involving different countries, state applicable national procurement law: Greek

L3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at: https://pep.iprocuresecurity.eu/

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: https://innovationprocurement.com/

4/7

1.4) Type of the contracting authority Body governed by public law

1.5) Main activity

Other activity: National Agency for Research and Homeland Security

Section II: Object

II.1) Scope of the procurement

II.1.1) Title:

Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services

II.1.2) Main CPV code

73100000 Research and experimental development services

II.1.3) Type of contract

Services

II.1.4) Short description:

iProcureSecurity PCP Call for Tenders invites all interested parties to present their offers for R&D services in the form of a solution that will provide Triage Management Systems which will strengthen the resilience and interoperability of European Emergency Medical Services (EMS).

The procurement addresses the procurers' unmet needs relating to different EMS-related aspect, such as: planning and decision making, resource allocation, improved triage practices, data transmission and interoperability, usability of EMS solutions, evaluation and sustainability, data security and protection in standard crisis management systems.

iProcureSecurity PCP is a research & development (R&D) services procurement which is conducted through a Pre-Commercial-Procurement (PCP).

This PCP procurement is a joint procurement by different procurers across Europe that are all facing the same common challenge and are thus looking for similar solutions (so-called 'buyers group').

II.1.5) Estimated total value Value excluding VAT: 6 774 194.00 EUR

II.1.6) Information about lots

This contract is divided into lots: no

II.2) Description

II.2.2) Additional CPV code(s)

32441000 Telemetry equipment

- 32441100 Telemetry surveillance system
- 32441300 Telematics system
- 33000000 Medical equipments, pharmaceuticals and personal care products
- 33100000 Medical equipments
- 33190000 Miscellaneous medical devices and products
- 33195000 Patient-monitoring system
- 33197000 Medical computer equipment
- 34221200 Mobile emergency units
- 35000000 Security, fire-fighting, police and defence equipment
- 35100000 Emergency and security equipment
- 35111200 Firefighting materials
- 48000000 Software package and information systems

5/7

- 48180000 Medical software package
 48211000 Platform interconnectivity software package
 48814000 Medical information systems
 48814200 Patient-administration system
 48814400 Clinical information system
 72210000 Programming services of packaged software products
 72220000 Systems and technical consultancy services
 72230000 Custom software development services
 72260000 Software-related services
 73200000 Data services
 73200000 Design and execution of research and development
 75122000 Administrative healthcare services
 80320000 Medical education services
- II.2.3) Place of performance
 - NUTS code: AT Österreich NUTS code: EL Ελλάδα / Elláda NUTS code: ES España NUTS code: IT Italia NUTS code: TR Türkiye

80420000 E-learning services 80561000 Health training services 85140000 Miscellaneous health services

II.2.4) Description of the procurement:

The procurement will take the form of a pre-commercial procurement (PCP) under which R&D service contracts will be awarded to R&D providers in parallel in a phased approach. This will make it possible to compare competing alternative solutions. Each selected operator will be awarded a framework agreement that covers three R&D phases. The three phases are: solution design, prototype development, original development and validation and testing of a limited volume of first products or services. After each phase, intermediate evaluations will be carried out to select the best of the competing solutions. The contractors with the best value-for-money solutions will be offered a specific contract for the next phase.

The selected operators will retain ownership of the intellectual property rights (IPRs) that they generate during the PCP and will be able to use them to exploit the full market potential (estimated at 40 million people in need of pre-hospital care in the five countries in the project) of the developed solutions.

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 101022061 – iProcureSecurity PCP (https://pcp.iprocuresecurity.eu/). The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6) Estimated value

Value excluding VAT: 6 774 194.00 EUR

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system Duration in days: 19

This contract is subject to renewal: no

II.2.10) Information about variants Variants will be accepted: no

II.2.11) Information about options

Options: no

II.2.13) Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: yes Identification of the project:

This PCP is part of iProcureSecurity PCP project that received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No.101022061

II.2.14) Additional information

- Section III: Legal, economic, financial and technical information
- III.1) Conditions for participation
- III.1.1) Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions: $\ensuremath{\mathsf{n/a}}$

III.1.2) Economic and financial standing

Selection criteria as stated in the procurement documents

III.1.3) Technical and professional ability

Selection criteria as stated in the procurement documents

III.2) Conditions related to the contract

III.2.2) Contract performance conditions:

Successful tenderers will be requested to sign both a Framework Agreement and Specific phases 1, 2 and 3 Contracts.

At least 50% of the total value of activities covered by each specific contract for PCP phase 1 and 2 must be performed in the EU Member States or in H2020 associated countries. The principal R&D staff working on each specific contract must be located in the EU Member States or H2020 associated countries.

At least 50% of the total value of activities covered by the framework agreement (i.e. the total value of the activities covered by phase 1 + the total value of the activities covered by phase 2 - the total value of the activities covered by phase 3) must be performed in the EU Member States or H2020 associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or H2020 associated countries.

III.2.3) Information about staff responsible for the performance of the contract

Obligation to indicate the names and professional qualifications of the staff assigned to performing the contract

Section IV: Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

- IV.1.3) Information about a framework agreement or a dynamic purchasing system The procurement involves the establishment of a framework agreement Framework agreement with several operators Envisaged maximum number of participants to the framework agreement: 12
- IV.1.8) Information about the Government Procurement Agreement (GPA) The procurement is covered by the Government Procurement Agreement; yes

6/7

VI.1

- IV.2.1) Previous publication concerning this procedure Notice number in the OJ S: 2021/S 222-584993
- IV.2.2) Time limit for receipt of tenders or requests to participate Date: 31/08/2022 Local time: 12:00
- IV.2.3) Estimated date of dispatch of invitations to tender or to participate to selected candidates
- IV.2.4) Languages in which tenders or requests to participate may be submitted: English
- IV.2.6) Minimum time frame during which the tenderer must maintain the tender Tender must be valid until: 28/02/2023
- IV.2.7) Conditions for opening of tenders Date: 31/08/2022 Local time: 12:00

Section VI: Complementary information

- Information about recurrence
- This is a recurrent procurement: no
- VI.2) Information about electronic workflows Electronic invoicing will be accepted

VI.3) Additional information:

The PCP procurement is exempted from the WTO Government Procurement Agreement (GPA), the EU public procurement directives and the national laws that implement them (because it concerns the procurement of R&D services where the benefits do not accrue exclusively to the contracting authority for its use in the conduct of its own affairs). This PIN is published to announce an open market consultation on a future procurement procedure. The PIN is not a commitment to procure.

The contracting authority involved in the iProcureSecurity PCP project is not legally bound in any way by the outcome of the market consultation.

Offers will be accepted in English.

All communication will be carried out in English. The questions or requests for clarification must be addressed to: ipspcp-procurement@kemea-research.gr.

All information provided during the open market consultation and other background information will be published online in English

VI.4) Procedures for review

VI.4.1) Review body

Official name: Administrative Court of Appeal Town: ATHENS Country: Greece

VI.5) Date of dispatch of this notice:

7/7