HORIZON 2020 | PRE-COMMERCIAL PROCUREMENT (PCP) | SU-GM02-2020

Request for tenders

iProcureSecurity PCP

Pre-Commercial Procurement of Innovative Triage Management Systems

Strengthening Resilience and Interoperability of Emergency Medical Services

Topic: Strategic Pre-Commercial Procurement of Innovative, Advanced Systems to Support Security

Deadline to submit an offer:
[insert date]

The iProcureSecurity PCP tender documents have been prepared as part of the iProcureSecurity CSA project (Grant Agreement 833291). Sections which cannot be completed due to the need for decisions being made by the Buyers Group in the first months of the PCP, or due to points which require further elaboration and agreement among the Buyers Group, are marked with blue boxes detailing the *open points*, which will be addressed in the PCP project.

PREFACE

This iProcureSecurity PCP Call for Tenders invites all interested parties to submit their offers to provide Research and Development (R&D) services to address the Common Challenge of a novel, modular and highly flexible triage management system to consequently increase effectiveness and efficiency of EMS services.

iProcureSecurity PCP project is a research & development (R&D) project, which takes form as a Pre-Commercial-Procurement (PCP). Based on the insights and comprehensive assessment established by iProcureSecurity CSA project (GA 833291), covering more than 340 challenges, gaps and innovation needs in the field, the follow up iProcureSecurity PCP aims to address the Common Challenge for Emergency Medical Services (as analyses in section 4.1.3.). This will be jointly tackled by the participating procuring organizations and awarded contractors.

This PCP follow the Phased PCP model described by the European Commission in the Communication referred to in section 2 below, aiming at conducting R&D services up to the development of a limited volume of systems in the form of a test series.

The budget for the PCP Competition amounts 8,400,000.00 Euro (including VAT). Please see section 1.5 below for details.

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 Lead Procurer does not accept any liability or provide any express 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 Lead Procurer does not bind itself to accept the lowest priced or any Tender. The evaluation process is described in detail under section 4 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 Lead Procurer will exist unless and until a formal written Framework Agreement has been executed by the Lead Procurer.

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

The Lead Procurer may cancel this PCP Competition at any time prior to a formal written Framework Agreement and Specific Contract being executed by the Lead Procurer.

The Call for Tenders supersedes and replaces any and all previous documentation, communications and correspondence between the Lead Procurer (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 4.1 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.

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

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

Tender Document 2 (TD 2): Challenge Brief

Tender Document 3 (TD 3a): Declaration of Honour - Exclusion Criteria

Tender Document 3 (TD 3a): Declaration of Honour - Compliance Criteria

Tender Document 4 (TD 4): Power of Attorney

Tender Document 5 (TD 5): Tender Application Template - Administrative

Tender Document 6 (TD 6): Tender Application Template - Technical

Tender Document 7 (TD 7): Tender Application Template - Financial

Tender Document 8 (TD 8): TD8 PCP Framework Agreement

Tender Document 9 (TD 9): TD9 PCP Specific contract for phase 1-2-3

All documents are available on the <include where the documentation will be made available>.

TABLE OF CONTENT

1. GENERAL CONTEXT

1.1. Introduction to Pre-Commercial Procurement

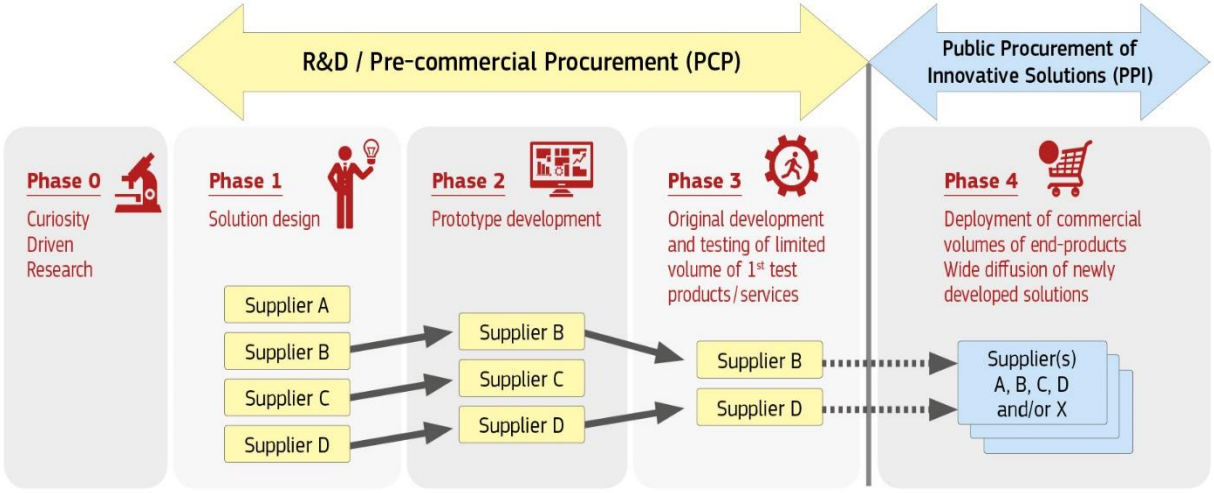
This procurement is a pre-commercial procurement (PCP). This PCP is co-funded by the European Commission and is divided into competitive phases, in which suppliers develop their solutions to address the Common Challenge. In Pre-Commercial Procurement (PCP), public procurers challenge innovative players on the market, via an open, transparent and competitive process, to develop new solutions (not available on the market yet) for a technologically demanding mid- to long-term challenge that is in the public interest and requires new R&D services. PCP is characterised by the following **four features**:

1. COMPETITIVE DEVELOPMENT IN PHASES TO IDENTIFY THE SOLUTIONS OFFERING THE BEST VALUE FOR MONEY

PCP targets situations that require radical innovation or R&D and for which there are typically no solutions on or close to the market yet. Different competing providers 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. It also allows a first customer test reference to be obtained from countries of the procurers that will test the solutions.

The R&D is split into 3 phases as presented below. During the complete PCP process, selection of suppliers entering the next phase will be based on transparent and objective criteria. In this regard, evaluations after each phase progressively identify the solutions that offer the best value for money and meet the customers' needs. This phased approach allows successful contractors to improve their offers for the next phase based on lessons learnt and feedback from procurers in the previous phase. Using a phased approach with gradually growing contract sizes per phase also makes it easier for smaller companies to participate in the PCP and enables SMEs to grow their business step-by-step with each phase.



Depending on the outcome of the PCP, procurers may or may not decide to follow-up the PCP with a public procurement to deploy the innovative solutions (PPI).

2. 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 that it requires further R&D to resolve. PCP is a way for procurers to trigger the market to develop new solutions that address these shortcomings. It 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.

An in-depth explanation of PCP can be found in the PCP communication COM/2007/799 [1]and the associated staff working document SEC/2007/1668[2]. The R&D services can cover research and development activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series. R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs[3]. 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.

3. OPEN, TRANSPARENT, NON-DISCRIMINATORY APPROACH — NO LARGE-SCALE DEPLOYMENTS

PCP is open to all operators on equal terms, regardless of the size, geographical location or governance structure. There is, however, a place of performance requirement that they must perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon 2020 associated countries.

Any subsequent public procurement of innovative solutions (PPI), for the supply of commercial volumes of the solutions, will be carried out under a separate procurement procedure. Providers that did not take part in this PCP (or were not chosen to go through as far as the last phase) will thus still be able to compete on an equal basis in any subsequent procurement looking for contractors to provide a solution on a commercial scale.

4. SHARING OF IPR-RELATED RISKS AND BENEFITS UNDER MARKET CONDITIONS

PCP procures 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. Giving each contractor the ownership of the IPRs attached to the results it generates during the PCP means that they can widely exploit the newly developed solutions commercially. In return, the tendered price must contain a financial compensation for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price must be the 'nonexclusive development price'; see section 4.7.4). Moreover, the procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.

For more information, see PCP on the Europa website[4].

1.2. Exemption from EU procurement directives, the WTO Government Procurement Agreement (GPA) and EU state aid rules

This procurement procedure is exempted from the EU public procurement directives because procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).[5]

It is also exempted from the WTO Government Procurement Agreement (GPA) because this Agreement does not cover R&D services[6] (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement).

[1] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0799:FIN:EN:PDF
[2] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007SC1668:EN:HTML
[3] See also Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.
[4] https://ec.europa.eu/digital-single-market/en/innovation-procurement
[5] See Article 25 of Directive 2014/23/EU, Article 14 of Directive 2014/24/EU, Article 32 of Directive 2014/25/EU and Article 13(f)(j) of Directive 2009/81/EC.
[6] See the EU's Annex IV of Appendix I to the WTO GPA.

This Pre Commercial Procurement does not constitute state aid under the EU state aid rules[7] because it is implemented as defined in the PCP communication[8], following an open, transparent, competitive procedure with risk- and benefit-sharing at market price. (The division of all rights and obligations (including IPRs) and all selection and award criteria for all phases are published at the outset; the PCP is limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors are not given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.)

1.3. EU funding

The information about the PCP project's Grant Agreement number and website will be finalised once the PCP project is started.

This Pre-Commercial Procurement (PCP) action is part of a project funded by the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No *[insert number]* - iProcureSecurity PCP (see *[insert PCP project website]*).

The procurement must therefore comply with the provision of the iProcureSecurity PCP grant agreement[9].

✕ **Attention**: **The EU is not a contracting authority in this procurement**.

1.4. The iProcureSecurity PCP Procedure

The figure in the section will be adjusted to cover only the PCP phases and exclude phase 0 of the PCP, which might be confusing to the tenderers.

The minimum suppliers per phase are provision and will be agreed by the Buyers Group when the PCP starts.

This PCP shall follow the Phased PCP model described by the European Commission in the Communication referred to in section 1.1. above, aiming at conducting R&D services up to the development of a limited volume of systems in the form of a test series. SERVICIO MADRILEÑO DE SALUD is the Lead Procurer and in this regard shall act as a procuring entity to launch the iProcureSecurity PCP Tender process in its own name and on behalf of the Public Buyers Group. This PCP shall 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, as summarised below:

[7] See Point 33 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

[8] Commission Communication: Pre-Commercial Procurement: driving innovation to ensure sustainable, high quality public services (COM(2007) 799) and PCP staff working document (SEC(2007)1668).

[9] For more information, see 'innovation procurement' and 'links to regional policy' in the Funding & Tenders Portal Online Manual

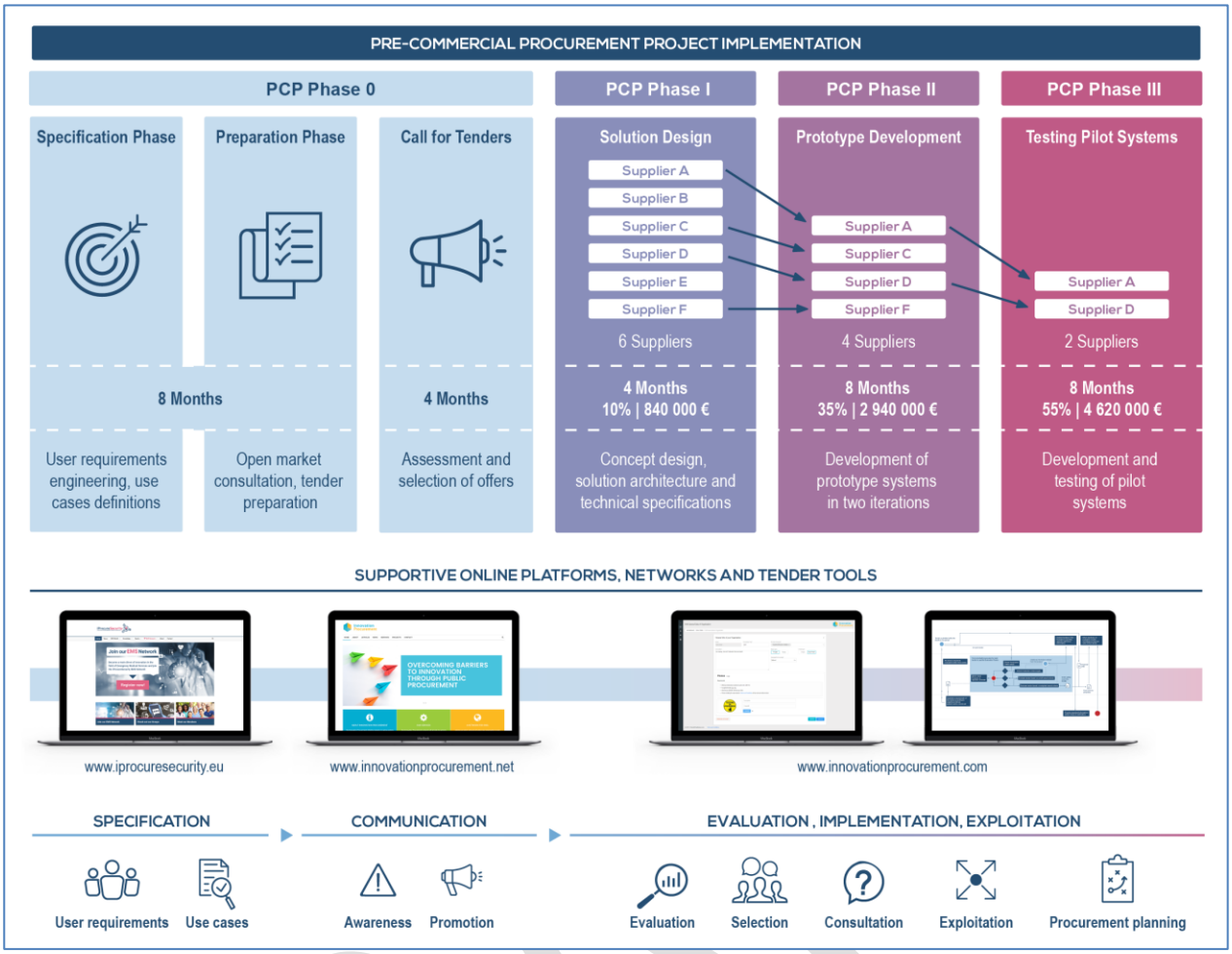


Figure 1: Overall Project Concept and Structured Approach

Which Phases are Planned?

1. SOLUTION DESIGN

During Phase 1, a minimum of six suppliers will be selected to develop their solutions. This Phase is a feasibility study of the selected technologies and proposals, which aims to verify the technical, economic and organisational feasibility of each Tender.

2. PROTOTYPE DEVELOPMENT

Participants who have successfully completed Phase 1 will be invited to Phase 2. At least four suppliers will be awarded to develop their solutions into working prototypes.

3. PROTOTYPE DEVELOPMENT ORIGINAL DEVELOPMENT & OPERATIONAL TESTING

Finally, participants who have successfully completed Phase 2 will be invited to Phase 3 where a minimum of two suppliers will be selected to test their prototypes under real-life situations on the basis of the prototypes delivered at the end of Phase 2.

1.5. Overview: contracting, budget and schedule

1.5.1. Total budget and budget distribution (per phase)

The budget table in this section (especially the distribution of funds between PCP phases 1 and 2) will be finalised by the Buyers Group when the PCP starts.

The Buyers Group will discuss the two options for the PCP subcontracting budget (decentralised vs. centralised) and make a decision as to the approach that will be used in the PCP. In a centralised

procurement, the VAT-related information provided in this section will be reviewed, as the VAT rules of the Lead Procurer would apply.

The total maximum budget for this PCP is 8,400,000.00 Euro (including VAT). The Public Buyers Group has contributed 840,000.00 Euro, which represents a 10% contribution into the overall budget. The maximum duration per phase, 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 and including other taxes and duties that may be applicable to the supplier) are described in the section below.

Table 1: Budget & number of Contractors

iProcureSecurity PCP	Total Budget (VAT excluded)	Minimum Number of contractors expected to be selected	Maximum Budget per contractor (VAT excluded)	Maximum Phase duration (in months)
Phase 1 Solution Design	840,000.00 Euro	6	140,000.00 Euro	4
Phase 2 Prototype Development	2,940,000.00 Euro	4	735,000.00 Euro	8
Phase 3 Operational Validation	4,620,000.00 Euro	2	2,310,000.00 Euro	8
Total	8,400,000.00 Euro			

Short outline of each project's phases

1. Phase 1: Phase 1 contracts will be 4 months and a minimum of 6 bidders will be awarded with a maximum total budget per bidder of 140,000 Euro (excluding VAT and including other taxes and duties that may be applicable to the supplier) against a total Phase budget of 840,000 Euro. Phase 1 aims to verify the feasibility proposed by bidders. It also aims to achieve a good understanding of the impact of such technologies, not only on Emergency Medical Services (EMS) organisations but also on the health market in general. The expected output of phase 1 is detailed in section 3.2. Phase duration and main activities are detailed in section 1.5.3.
2. Phase 2: Phase 2 contracts will be 8 months and a minimum of 4 bidders will be awarded, with a maximum total budget per bidder of 735,000 Euro (excluding VAT and including other taxes and duties that may be applicable to the supplier) against a total Phase budget of 2,940.000 Euro. Phase 2 aims to develop and verify the main features exhibited by the technology prototype. Expected outcomes involve a prototype specification and initial demonstration, as well as a plan for limited first product development, involvement of both EMS practitioner organisations and patients, and, above all, a detailed field testing plan for phase 3 (including all the necessary requirements and certificates for field testing activities). The expected output of phase 2 is detailed in section 3.2 and phase duration and the principal activities are detailed in section 1.5.3.
3. Phase 3: Phase 3 contracts will be 8 months and a minimum of 2 bidders will be awarded, with a maximum total budget per bidder of 2,310,000 Euro (excluding VAT and including other taxes and duties that may be applicable to the supplier) against a total Phase budget of 4,620,000 Euro. In this phase, a first batch of devices/technologies will be developed and subsequently evaluated through field tests. Phase 3 aims to verify and compare technology performance in real scenarios involving patients and healthcare professionals. The main output of this phase includes a test of technology that should provide evidence of its impact and benefits on both quantitative and qualitative measures. The required R&D services will end here with a report on the field-testing activities conducted by each contractor at the different test sites. The expected output and duration of phase 3 are detailed in section 3.2 and 1.5.3, respectively.

Since all Contractors will be paid by the Lead Procurer by way of centralised payments, and as <Lead Procurer> is based in <city/country of the Lead Procurer>, EU rules and the valid <include legislation(s)> VAT legislation (s) will be applied.

In the event of the above-mentioned minimum number of bidders for each phase not being reached, the contracting authority may decide to continue with the PCP procedure providing that there are a minimum of three initial tenders and that the principle of competitive development in phases is guaranteed.

The contracting authority may transfer leftover budget from one phase to the next phase if bidders present offers with prices lower than expected. For Phases 1 and 2, contracts are funded 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. As leftover budget from the previous phase will be transferred to the next phase, the total budget available for phases 2 and 3 may eventually be higher than stated herein (but the maximum budget per contractor for phases 2 and 3 will remain the same). The lower the average price of tenders, the more contracts can be awarded. 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.

1.5.2. iProcureSecurity PCP Contracting approach

The information about field testing in this section will be refined once the Buyers Group assesses the most suitable format for the testing.

This PCP will be implemented by means of a Framework Agreement (TDx) with Specific Contracts for each of the three R&D phases (TDx) (altogether: 'Contracts').

The Framework Agreement regulates all the terms and conditions for the entire duration of the PCP (covering all Phases). There will be no renegotiation of the Framework Agreement and the Phase Specific Contracts, which will apply for the duration of all phases for which contractors participate in the PCP. The law governing the Contracts is Spanish law. Research is defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. In the iProcureSecurity PCP the Research and Development (R&D) will focus on the interaction of new Triage Management System with emergency medical patients and EMS practitioner organisations. The new solution must gather and provide valuable information through a friendly, automatically and intelligent technology. The solutions must also be deployed and tested with patients in their own environment. With reference to the Deliverables set out in section 3.3, it is important to know that knowledge will build up across the phases, so that the solution is defined in Phase 1, a full working prototype is operational in Phase 2 and then field trials to test in Phase 3.

Following the tendering stage, a Framework Agreement and a Specific Contract for Phase 1 are expected to be awarded to a minimum of six contractors. Bidders 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). Bidders are therefore asked not only to submit their detailed offer for phase 1 in their tender, but also to state their goals, and to outline their plans (including price conditions) for phases 2 and 3, thus giving specific details of the steps that would lead to commercial exploitation of the R&D results.

Phase 1 will start after Framework Agreement and Specific Contract have been signed.

A call-off will be organised for Phase 2, with the aim of awarding a minimum of four contracts. Only offers from contractors that successfully completed Phase 1 will be eligible for Phase 2. Phase 2 will start as soon as Specific Contracts are concluded with the selected suppliers. The procurers will validate the phase 2 prototypes in the procurers' organisations.

A second call-off will be organised for phase 3, with the aim of awarding a minimum of two phase 3 contracts. Only offers from contractors that successfully completed phase 2 will be eligible for phase 3. Phase 3 will start after Specific Contracts have been concluded. The phase will last as described in the time

schedule below. Phase 3 field- testing is expected to take place in *CITY (COUNTRY OF LEAD PROCURER), CITY(COUNTRY OF PROCURER) and CITY(COUNTRY OF PROCURER).*

The PCP starts with the publication of the call for tender. The call will remain open from then until the deadline shown in the time schedule below. After the deadline the tenders will be evaluated, and results will be announced. The standstill period for each phase is at least 10 days and begins from the award decision and notification and lasts until date of signature by the Lead Procurer. At the end of the standstill period, a framework contract and a specific Phase 1 contract will be signed with the winning tenderers.

Award of a contract for a specific phase does not mean that contracts will be awarded for subsequent phases. A Contractor must have been awarded a Specific Contract for Phase 1 in order to be considered for Phase 2; a Contractor must have been awarded Specific Contracts for Phases 1 and 2 in order to be considered for Phase 3. Tenderers will be requested to submit their offer for the next phase together with the end-of phase deliverables. In this case all contractors of the previous phase will be invited to make offers for the next phase.

A brief overview of the overall **indicative** timing of the PCP (including the expected start and end dates) and of the individual phases follows in the next section.

1.5.3. iProcureSecurity PCP time schedule

The time schedule in this section can only be completed once the start date of the PCP project is clear following the evaluation by the European Commission and the Grant Agreement Preparation.

All requirements and dependencies between items in the time schedule need to be prepared holistically.

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

Planned time	
Date	**Activity**
DD.MM.YYYY	*Publication of PIN in TED*
DD.MM.YYYY	*Publication of contract notice in TED*
DD.MM.YYYY	*Deadline for questions by tenderers*
DD.MM.YYYY	*Deadline for replies to questions by tenderers*
DD.MM.YYYY	*Deadline for submission of tenders*
DD.MM.YYYY	*Opening of tenders*
DD.MM.YYYY	*Award decision and notification*
DD.MM.YYYY	*Contracts sent for signature by tenderers*
DD.MM.YYYY	*End of Standstill period*
DD.MM.YYYY	*Deadline for receipt of signed contracts*
DD.MM.YYYY	*Date of signature by Lead Procurer*
DD.MM.YYYY	*Signed contracts sent to tenderers*
DD.MM.YYYY	*Publication of contract award notice in TED*
Implementation of phase 1, call-off / tendering for phase 2	
DD.MM.YYYY	*Start of phase 1*
DD.MM.YYYY	*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*
DD.MM.YYYY	*Deadline for phase 1 final milestone(s)/final report/deliverable(s)*

DD.MM.YYYY	*Phase 1 contractors notified as to whether they have completed this phase satisfactorily and successfully*
DD.MM.YYYY	*End of standstill period*
DD.MM.YYYY	*End of phase 1*
DD.MM.YYYY	*Payment of balance for phase 1 to contractors that completed this phase satisfactorily*
DD.MM.YYYY	*Summary of the results and conclusions achieved by each contractor during the phase sent to the EU*
DD.MM.YYYY	*Launch call-off for phase 2 (only offers from contractors that successfully completed phase 1 are eligible)*
DD.MM.YYYY	*Deadline for submitting questions on phase 2 call-off documents*
DD.MM.YYYY	*Deadline for Contracting Authority to circulate replies to questions to phase 2 tenderers*
DD.MM.YYYY	*Submission of offer (tender) for next phase*
DD.MM.YYYY	*Opening of tenders*
DD.MM.YYYY	*Award decision and notification*
DD.MM.YYYY	*End of standstill period*
DD.MM.YYYY	*Contracts sent for signature by tenderers*
DD.MM.YYYY	*Deadline for receipt of signed contracts*
DD.MM.YYYY	*Date of signature by Lead Procurer*
DD.MM.YYYY	*Signed contracts sent to tenderers*
Implementation of phase 2, call-off / tendering for phase 3	
DD.MM.YYYY	*Start of phase 2*
DD.MM.YYYY	*Notification of permission to offer (tender) for next phase*
DD.MM.YYYY	*Opening of tenders*
DD.MM.YYYY	*Award decision and notification*
DD.MM.YYYY	*Contracts sent for signature by tenderers*
DD.MM.YYYY	*Deadline for receipt of signed contracts*
DD.MM.YYYY	*End of phase*
DD.MM.YYYY	*Date of signature by Lead Procurer*
DD.MM.YYYY	*Signed contracts sent to tenderers*
Implementation of phase 3	
DD.MM.YYYY	*Start of phase*
DD.MM.YYYY	*End of phase*

2. PROCURERS AND OTHER PARTIES IN THIS PCP

The iProcureSecurity PCP Buyers Group comprises experienced public procurers from four EU Member States and H2020 Associated Countries. All procuring partners will take further steps towards large-scale

procurement of ICT-enabled Triage Management System given a positive outcome of iProcureSecurity PCP. Partners are committed to ensuring a maximum of market participation and wide dissemination of project results to potential future procurers in Europe and worldwide. Combined, the iProcureSecurity PCP procurers represent attractive national markets, as well as an overall market. They represent 8 countries and are responsible for the pre-hospital care of over 16,3 million people.

2.1. The iProcureSecurity PCP Lead Procurer

The details of the procurers will be added to the final tender documents.

SERMAS as lead procurer and member of the Buyers Group, has been appointed to coordinate and lead the joint PCP, as well as to sign and award the Framework Agreement and the Specific Contracts for all phases of the PCP, in the name and on behalf of iProcureSecurity PCP Buyers Group:

iProcureSecurity PCP Buyers Group members				
Name	Address	Region	Country	Website
SERVICIO MADRILEÑO DE SALUD **(SERMAS)**	*STREET No, CITY*	*REGION*	SPAIN	*URL*
ANDALUSIAN PUBLIC COMPANY FOR HEALTH EMERGENCIES **(EPES)**	*STREET No, CITY*	*REGION*	SPAIN	*URL*
AUSTRIAN RED CROSS **(ARC)**	*STREET No, CITY*	*REGION*	AUSTRIA	*URL*
AZIENDA REGIONALE EMERGENZA URGENZA **(AREU)**	*STREET No, CITY*	*REGION*	ITALY	*URL*
AZIENDA SANITARIA LOCALE ASL BENEVENTO **(ASLBN)**	*STREET No, CITY*	*REGION*	ITALY	*URL*
HELLENIC RED CROSS **(HRC**	*STREET No, CITY*	*REGION*	GREECE	*URL*
HELLENIC NATIONAL CENTRE FOR EMERGENCY CARE **(EKAB)**	*STREET No, CITY*	*REGION*	GREECE	*URL*
IZMIR MUNICIPALITY **(IBB)**	*STREET No, CITY*	*REGION*	TURKEY	*URL*

2.2. The Buyers Group

The Buyers Group will be asked to provide their short profile and motivation for participating.

The procurers in the Buyers Group have the following background and motivation.

SERMAS

Profile: *[provide information]*

Motivation: *[provide information]*

EPES

Profile: *[provide information]*

Motivation: *[provide information]*

ARC

Profile: *[provide information]*

Motivation: *[provide information]*

AREU

Profile: *[provide information]*

Motivation: *[provide information]*

ASLBN

Profile: *[provide information]*

Motivation: *[provide information]*

HRC

Profile: *[provide information]*

Motivation: *[provide information]*

EKAB

Profile: *[provide information]*

Motivation: *[provide information]*

IBB

Profile: *[provide information]*

Motivation: *[provide information]*

The following entities are participating as preferred partners, having a special interest in closely following the PCP, but without being part of the Buyers Group or giving in-kind contributions for carrying out the PCP:

- SYNYO GMBH (SYNYO)
- AMBULANCE AND EMERGENCY PHYSICIANS ASSOCIATION (AAHD)
- KEMEA CENTER FOR SECURITY STUDIES (KEMEA)
- EMPIRICA GESELLSCHAFT FÜR KOMMUNIKATIONS- UND TECHNOLOGIEFORSCHUNG MBH [EMPIRICA]

The preferred partners will be informed of all aspects of the PCP and will be afforded access to all information concerning the PCP as they will support the Buyers Group regarding the collection of requirements, the translation of requirements into tender specifications and evaluation criteria / KPIs, the evaluation of tenders and call-offs, the evaluation of interim deliverables, and the validation of the outcomes in the last PCP phase. However, they will not assume the results or IPRs.

The roles of the preferred partners are the following:

SYNYO	The Project Co-ordinator: Directs the PCP project and is responsible for achieving the project results according to the Grant Agreement.
AAHD	Lead Implementation and operational testing.
KEMEA	Lead Evaluation and impact assessment in the PCP.
EMPIRICA	Lead Open Market Consultation and PCP coordination support alongside SYNYO.

3. TENDER PROFILE

3.1. Description of Services to be procured

3.1.1. PCP Background

This section elaborates on the shortcomings of the current the state of the art as identified in the iProcure Security CSA project and thus elucidate why existing solutions do not meet the needs of the EMS organisations in the field. Public Buyers as a whole believe 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 site of the incidence.

Likewise, the **allocation of resources** must be as efficient as possible to reduce the cost of each intervention while always ensuring patient safety. In general, emergency professionals 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 connect the EMS practitioners with the other stakeholders in the EMS ecosystem enabling continuous and reliable communication with the EMCC and the hospital where the patient is going to be transferred to as well as a quick access to the patient's medical history. The beforementioned necessity implies that the triage system can communicate directly with the other information systems of the EMS organizations involved. This **interoperability** has to be guaranteed so that **data transmission** is possible, as well as **sustainable** so that in the future it can be updated and improved without obstacles.

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 the solution needs to demonstrate the capability of **reproducing** interventions and decisions. Finally, if we are talking about the health data of victims that is transferred and updated between the different actors, **data protection** must be guaranteed at all times. The following table gives a brief overview on current shortcomings of available systems in the mentioned areas:

Table 2: 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 victims 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 maxi (epidemiological) emergencies and major events.
Resource allocation	• Resource allocation is sometimes inefficient due to missing interoperability of 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 victims.
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 victims on site setting up a common platform for the data interchange with electro medical equipment (defib-monitor, ultrasound etc.) and triage system to quicken interoperability on the field and in hospital. • Ability to involve telemedicine aspects e.g. for quick consultation during re-triage. • Currently there is a high clinical variability in the triage process. Turning it into a homogeneous process increases patient safety and serves the professional as a support for clinical decision making.
Data transmission	• In many cases it´s 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" move 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. • Tetra messages are prone to confusion and only one patient data can be transmitted at a time.
Interoperability	• Missing interoperability (missing APIs) between applied EMS systems • Missing interoperability between all the actors participating in the emergency (both health workers and law enforcement) • The clinical information generated in MCIs cannot currently be easily shared with other healthcare providers, even in the same region. • Missing interoperability with national Electronic Health Record.

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.
Sustainability	• Isolated applications create a lock-in situation which hinders EMS to seamlessly connect them with current and potential future applications.
Reproducibility	• Be able to use the system by different First Responders and that the result is practically the same. • Lack of protocols that make the procedures ad hoc and too much cultural dependent.
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.

3.1.2. Motivation and Preparation for the PCP

This section might be split into two separate topics covering the motivation and preparation of the PCP. This will be decided in the beginning of the PCP.

Fostering the response capacities and increasing the cooperation between the European Emergency Medical Services Systems (EMSS) is of decisive importance for strengthening the resilience of European societies in the light of multiple hazards. Recent events such as the COVID-19 pandemic proved that the vulnerability of Emergency Medical Services across Europe during a health crisis is a factor which affects not only people's lives but also destabilizes countries' health care systems and even threatens the global economy. Against this background practitioner organisations and relevant stakeholders from across Europe with experience and knowledge in the Emergency Medical Services (EMS) field joined forces with the goal to identify major issues of the EMS ecosystem, increase the capability of working together and stimulate R&I uptake to face current innovation needs. The initiative consequently resulted in the creation of the iProcureSecurity Horizon 2020 project (GA 833291). As a Coordination and Support Action (CSA), the project built the foundation for and represents the preparation of the Pre-Commercial Procurement (PCP) project at hand. It achieved this goal by comprehensively collecting and analysing practitioner insights and information on technological advancements to ultimately define the requirements for an innovative solution tackling a major problem inherent in the EMS sector across Europe. More than 500 EMS practitioners and decision makers from all organisational levels from across Europe provided their insights through surveys, conferences, workshops and webinars. The project established a full overview on the EMS ecosystem and established 9 comprehensive scenarios based on EMS main tasks including frequent as well as rare events. Furthermore, close cooperation with other R&D projects in the domain were established and more than 100 innovative solutions were mapped to capture the state of the art as well as new technological domains which will become of relevance to the EMS field. The iProcureSecurity CSA consortium finally screened more than 340 challenges, gaps and innovation needs. Based on detailed analysis of the gathered data and in-depth discussions and workshops with the practitioners the iProcureSecurity consortium made an informed decision and selected the area of Triage Management Systems as most relevant to be tackled during a follow-up PCP project. Compared to other relevant areas the demand for innovation in triage management is not only complex but also holds the key for an

increased interoperability of practitioners that should be able to work in concert in critical and rapidly changing scenarios. This affects not only the cross-border level but is already of relevance in many cases on a regional basis where different EMS organisations and further first line responders have to work together more efficiently. Specific gaps the PCP addresses lie in the market availability of proven and standardised technologies to support in the entire triage management process, including the initial triage classification, the continuous health monitoring, but also the capability to connect with healthcare organisations to understand their pathology and resource situation to optimise the hospitalisation of victims. iProcureSecurity has delivered key outcomes which are essential for the preparation and success of the upcoming PCP action including a detailed overview on capability gaps and challenges in main EMS areas combined with insights from the market on latest technological developments, prioritisation of opportunities for innovations and capabilities in the EMS ecosystem in Europe, identification of connected ethical, legal and societal aspects to be considered in the preparation of the PCP as well as technical requirements to be kept into account.

Multiple challenges were identified upfront, which will be addressed by the realisation of the Common Challenge on a functional, use-case oriented level:

- The **tracking of the triage situation** involves information on the number of victims, 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 involves, as it requires multiple roles on site to continuously update this information. Outdated information or mistakes influence and delay decision making 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 victims. By maintaining a digital record of each triaged victim, beginning with the initial primary triage, up to the handover for transportation, a permanently updated data foundation is available for decision makers to derive an overview which satisfies a demand for an overall situational awareness, but also is 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 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 incident location.
- The **handover procedure of a victim 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 victim during transportation, and remains equally important in the handover from the transportation to the hospital facility for a hospital triage and further treatment. The objective for 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 incident situation.

In a **large-scale 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. By using consistent reference objects and adhering to standardised data formats, a comprehensive data basis is created throughout an incident, which supports in analyse how the incident situation 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.

3.1.3. Open Market Consultation

Exact information about the Prior Information Notice can only be added at a later stage during the PCP.

The start of this PCP was preceded by an Open Market Consultation (OMC), which commenced with the publication of the PIN *[include PIN URL]*. Participation (or non-participation) in OMC activities does not preclude or disadvantage/ advantage any tenderer's ability to participate in this PCP. Participation in the Open Market Consultation is not a condition for submitting a tender. For more information on the OMC, tenderers are asked to refer to the project website *[include project website]*.

3.1.4. PCP Challenge

For the iProcureSecurity procurers, the key common challenges which were identified and discussed during the iProcureSecurity CSA project can be summarised 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 times between ambulance transport and hospitals, and

e) insights for quality assurance and training measures.

The triage management system is the core component 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.

3.2. Expected outcomes (per phase)

While initial discussions among the Buyers Group about the necessary deliverables and milestones have begun, this section will be finalised after the start of the PCP. Only minimum deliverables have been added thus far. Additions of kick-off meetings will be discussed. The description of phase 3 will be enriched.

It will be discussed if the end of phase reports should include further information such as a business and exploitation plan, a data management plan and compliance with the ethics requirements (currently D2.4 and the technical sections of the tenders are addressing these issues, but via separate deliverables they might be addressed more effectively).

Phase 1: Solution Design

During this phase, selected contractors will design and submit for technical evaluation their individual views of the solution that meets requirements and functional specifications, and will verify the technical, economic and organizational feasibility of their solution approach to address the PCP challenge. The

contractors will provide a detailed design of all the components, algorithms and processes of the proposed solution. A detailed planning for further stages of development will also be requested.

The Evaluation Committee will be responsible in order to achieve effective monitoring. Monitoring meetings can be held physically or online and will be agreed between the Contractor and the Evaluation Committee 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 organized, 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 6.2 Payments based on Satisfactory Completion of Milestones and Deliverables of the Phase.

Phase 2: Prototype Development

Qualified contractors will develop a first prototype based on the design documents delivered in the previous phase and test their solutions in lab conditions (lab of the R&D provider). Prototypes will be tested and verified to provide a measure of the technical performance of each solution in a controlled environment, and their readiness for a pre-operational deployment.

Phase's 2 evaluation plan will also include Factory Acceptance Tests (FAT) that will be performed at the contractors' premises. These tests will check if the solution meets each one of the specifications.

In this phase interim evaluation from an independent review board to continuously improve the prototypes while developing them.

The Evaluation Committee will be responsible in order to achieve effective monitoring. Monitoring meetings can be held physically or online and will be agreed between the Contractor and the Evaluation Committee at least on a monthly basis.

For more information on the assessment of the satisfactory completion of the End of Phase Reports, please see section 6.2 Payments based on Satisfactory Completion of Milestones and Deliverables of the Phase.

Phase 3: Operational Validation

For the purpose of the validation by the end users of the two solutions, each Phase 3 contractor shall provide identical solutions.

Phase 1		
Objective:	Perform research and development to: • elaborate the solution design and determine the approach to be taken to develop the innovative solutions. • 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 Fine-tuned solution design completed	M4	All phase deliverables submitted
Deliverables	By when?	How?
D1.1 Improved solution design	M3	Detailed technical description and specifications of the solution.

D1.2 Publishable project phase abstract	M4	Written report to be published on the project website, following EU templates.
D1.3 End of phase report.	M4	A summary of the main results achieved by each contractor and conclusions from phase 1 (in the format required by the EU for publication). Description of the foreground IPRs and measures to protect the IPRs and the results of this Phase. List the names and location of personnel that carried out the R&D activities.
Phase 2		
Objective: Develop, demonstrate and validate prototypes in lab conditions. • 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.	
Milestones	By when?	How?
M2.1 Prototype system v1 ready	M7	
M2.2 Prototype system v2 ready	M11	
Deliverables	By when?	How?
D2.1 Presentation of prototypes of key system components	M7	Presentation of prototypes of key system components
D2.1a Protocol of testing v1	M8	Protocol of testing v1
D2.2 Presentation of functional prototypes, demonstrating component behaviour and system-wide interaction	M10	Presentation of functional prototypes, demonstrating component behaviour and system-wide interaction
D2.2a Protocol of testing v2	M11	Protocol of testing v2
D2.3 Publishable project phase abstract	M10	Written report to be published on the project website
D2.4 GDPR compliance report	M12	Presentation of conformance of the solutions with GDPR
D2.5 End of phase report	M12	A summary of the main results achieved by each contractor and conclusions from phase 2 (in the format required by the EU for publication). Description of the foreground IPRs and measures to protect the IPRs and the results of this Phase. List the names and location of personnel that carried out the R&D activities.
Phase 3		

Objective: • Development of pilot systems for an extended test under real-life conditions at all procurer sites. • Pilot systems installed and tested in each pilot site. • Operation maintained in parallel at full quality. Help service and maintenance response team set up and operated by suppliers. Pilot systems evaluated using a commonly agreed protocol and metrics.		
Output and results:	1) Development of pilot systems for an extended test under real-life conditions at all procurer sites. 2) Suppliers install the pilot systems at each site in close collaboration with the respective site partner. System introduction covers installation of central components, user trainings, and preparation of user devices, if any, for roll-out. Before the pilot trial, on-site testing is done to reveal problems arising from the particular situation of equipment, the networks used and the organisational environment in which staff work, to eliminate problems in the full pilot. 3) Extended test of the solutions. Involvement of at least 30 EMS staff per procurer at their sites. 4) Suppliers set up and operate a help service and a maintenance response service to address problems faced by the users involved at the sites. Help and support is provided at each site. 5) Progress of the work is monitored in status calls.	
Milestones	By when?	How?
M3.1 Pilot systems ready	M15	
M3.2 Pilot operations start	M16	
M3.4 Pilot operations end	M20	
Deliverables	By when?	How?
D3.1 Progress report on system development	M14	Written report
D3.2 Presentation of pilot system and onsite testing results	M15	Written report
D3.3 Final report (end of phase report) including final system documentation**, business and commercialisation plan	M20	Written report
D3.4 Publishable project phase abstract	M18	Written report to be published on the project website
D3.5 Summary of the lessons learnt and the results achieved by each contractor during the PCP	M20	Written report

Notes:

- Each end-of phase report shall contain
  - an overview of work done during the phase
  - a description of any results generated (incl. technical results and any videos submitted)

  - a declaration of the resources expended, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report.
  - IPRs management plan including the measures taken to protect results
  - a declaration that at least 50% of the work was carried out within the EU28 or a country associated to Horizon 2020
  - Business and exploitation plan and
  - Data management plan
  - Compliance with the ethics requirements
- The offer in phase 1 for phase 2 and in phase 2 for phase 3 shall be an update of the original tender. All revisions and additions possible through work in the completed phase shall be made. The offer shall therefore include inter alia:
  - updated assessment of patient benefits and procurer benefits
  - updated exploitation business plan
  - updated list of Background
  - any new evidence of the feasibility of achievement of technical objectives and benefits to patients and procurer health systems
- The final report shall include an updated assessment of patient benefits, procurer benefits and updated information on the evidence on which this assessment is made, including evidence generated by the contractor in phase 3 of PCP implementation.
- In phase 3 each Contractor is to provide for the duration of the pilot full specification access to the innovative system to at least the number of users as listed in the table below.

Table 3: Minimum pilot users

Pilot Site	Number of EMS staff involved
SERMAS	30
EPES	30
ARC	30
AREU	30
ASLBN	30
HRC	30
EKAB	30

- The minimum number of users at a pilot site is the multiple of the numbers in the table above, given by the number of suppliers taking part in phase 3.
- User recruitment is the responsibility of the Buyers Group representing the procuring regions.
- The Buyers Group is responsible for evaluation.
- "Final system documentation" above includes all information required for technically qualified personnel not taking part in the PCP implementation to be able to use the results autonomously (without assistance by the contractor) to directly implement a system conforming to the specification of the phase 3 prototype.
- At the end of the PCP phase 3, contractors must agree on the text for a summary of overall lessons learnt and results achieved from the PCP, for publication. (until <*include month that Phase 3 ends*>)

3.3. Evaluation overview

There are two types of evaluations under this PCP:

Evaluation process intended to rank the Tenderers in order to award Contracts to the best ranked Tenders (see section 4.6);

- Evaluation process intended to assess the outcome of the work executed in a particular Phase. This evaluation will lead to the decision of payments and regarding the eligibility of a Contractor to bid for the next Phase (see section 6).

3.4. IPR — Commercial exploitation of the results — Declaration of pre-existing rights

3.4.1. 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 into account. More information about the ownership of results is specified in the Framework Agreement (TD8).

3.4.2. Commercial exploitation of results

The contractors are expected to commercially exploit the results of the R&D undertaken in the PCP within a period of four years after the end of the Framework Agreement. Contractors are obliged to prepare in good time for exploitation as follows:

1. If certification for the developed solution is necessary, the contractor must apply for certification at the earliest possible opportunity;
2. if extension or modification of existing standards, or new standards, are required for or would promote exploitation, contractors must take any opportunity to offer their contributions to the relevant standards bodies;

Given the expected, attractive business case (positive cost-benefit relation), procurers intend to procure operational systems from the PCP contractors. The commercial exploitation of the results includes confirming offers to all members of the Buyers Group to deliver an operational system at a price equal to or less that the total cost of ownership documented in the phase 3 offer "Phase 3 total offered price". This price may only be exceeded by an increase in price for third party components agreed for inclusion in Results.

Procurers will promote the R&D results among other procurers and assist in widely disseminating the results of the contract.

The feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria (see section 4.5).

3.4.3. Declaration of pre-existing rights (background)

A list of pre-existing rights held by the procurers and contractors will be established and included in TD8.

A complete list of all Background and planned Sideground must be provided with the Tender, including its ownership and the commercial conditions for use of Background and Sideground for any Member of the Buyers Group a) to use the Results and the proposed solution for their own purposes b) to exploit the Results as provided for in the Framework Agreement.

Procurers and contractors will be requested to establish a list of pre-existing rights to be used before the start of the contract. The list of pre-existing rights held by the procurers are presented in TD8.

The estimated price for any use of third party Background and the full annualised charge for the tenderers' own Background and Sideground must be full included in the calculation of total cost of ownership for procurers.Ownership and obligations regarding Background and Sideground is further specified in the Framework Agreement.

4. CONDITIONS OF TENDER PARTICIPATION

4.1. Eligible bidders, joint tenders and subcontracting

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

There will, however, be a requirement relating to the place of performance of the R&D services (see below).

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 two approaches.

Tender entities may not participate in more than one tender, be it as single entities or as part of a consortium submitting a joint tender. The Buyers Group reserves the right to exclude any tender in breach of this provision.

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:

• 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

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

Participation in the Open Market Consultation is not a pre-condition for submitting a tender.

For phases 2 and 3, participation is limited to tenderers that successfully completed the preceding phase. For the present procurement, the Open Procedure is adopted.

4.1.1. Joint 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. It is required for joint tenders that:

- 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 other consortium member.
- each member of the group of tenderers assumes joint and several liability for the performance of the contract
- To this single authorised representative (Lead Contractor) 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.
- the group of tenderers must mandate one of them with the power to sign the Framework Agreement and Specific Contracts provided in their name and on their behalf ('lead contractor') 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.

To meet these requirements, each of the members of a group of tenderers except the lead contractor must provide with the tender an originally signed power of attorney conforming to the template provided.

There may be no change in the composition of a group that tendered at the beginning of the iProcureSecurity PCP procedure.

The Buyers Group may exceptionally authorise changes in the composition of a group that tendered at the beginning of the iProcureSecurity PCP procedure (during the proposal selection) and/or the formation of a new group different from the one that tendered at the beginning of the tendering process. Nevertheless, any such authorisation, to be provided in writing at the discretion of the Buyers Group, shall not apply if:

- It implies the entry of new participants different from those tendering individually or jointly at the beginning of the iProcureSecurity Procedure, or of participants previously withdrawn or excluded from said procedure or in default under the Framework Agreement or under a Specific (phase) Contract.
- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set in Section 1.5.1. iProcureSecurity – PCP Request for tenders
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e. if associated participants selected for Phase 1 decide to continue as individual entities or to join other consortia).
- The new bidder resulting from the change no longer meets the selection criteria required under section 4.3.
- It occurs during the execution of a specific (phase) contract, except in the event of the insolvency of one of the members of the consortium, corporate restructuring operations affecting one or several of the members of the tendering group or the merger, take-over, transformation or assignment of a company or business unit.

In addition, the new consortium composition will have to prove that it has at least the same competencies as previous composition they replace and that they comply with all the other contractual conditions, rights and obligations that are in the Contracts e.g. complying with the place of performance conditions, respecting the same IPR conditions, the *binding unit prices*.

4.1.2. Subcontracting

The Buyers Group will discuss the option of using the European Single Procurement Document (ESPD) self-declaration form, if it covers the exclusion, selection and compliance criteria listed below.

Another discussion with the Lead Procurer will be about whether to add a declaration for subcontracting statement as a requirement (in case of subcontracting).

The provision of TD3a for subcontracts will be discussed, more specifically whether to lift the 30% suggestion in the current text and require a declaration from all subcontractors.

Subcontracting refers to any contract or agreement between the tenderer and any third party whereby that third party agrees to provide services to the tenderer to enable or assist the tenderer to provide all or any part of the R&D services offered to the Buyers Group in the tender.

The selection of a subcontractor to provide more than 10% of the work to be performed under any Specific Contract is subject to the approval of the Buyers Group unless such subcontractor was identified in the tender or in the tenderer's offer for a phase as the entity to deliver the work concerned.

The tenderer remains fully liable to the Buyers Group for the performance of the Framework Agreement and each Specific Contract.

The tender must mention which parts of the contract will be subcontracted. However, neither essential parts of the Contracts can be subcontracted, nor the management of the PCP.

Before subcontracted work begins in any Specific Contract, the tenderer must provide the Buyers Group with the originally signed agreement contained in TD8 PCP Specific contract for phase 1-2-3 with the subcontractor including a clear description of the work to be subcontracted and a declaration that the subcontractor:

- agrees to be bound vis-a-vis the tenderer by the provisions of the Framework Agreement and Specific Contract (in particular in relation to IPR) mutatis mutandis
- meets the qualification requirements for the subcontracted services,
- has placed the required resources at the tenderer's disposal for the full duration of the Specific Contract,
- agrees to be bound by and complies fully with obligations imposed on subcontractors under the iProcureSecurity PCP Grant Agreement, including those relating 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 and ethics and security requirements,
- will not subcontract any of the work so subcontracted.

No addition of subcontractor or change in subcontractor shall be possible if:

- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set out in Section 1.5.1.
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e. if associated participants selected for Phase 1 decide to continue as subcontractor for another bidder).
- It prevents the tenderer from meeting the selection criteria required under section 4.3.

The approach to subcontracting (selection of subcontractors and management) is to be described in the tender.

4.2. Exclusion criteria

Exclusion criteria	Evidence
Conflict of interest	Declaration of honour (TD3a)
Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 (consolidated version 01/01/2020)	Declaration of honour (TD3a)
Proposed solutions already available on the market	Declaration of honour (TD3a)

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

Bidders shall explicitly assure that they are not subject to any of the exclusion criteria listed above by presenting a duly signed and stamped declaration of honour, using for this purpose the template provided in Declaration of Honour on Exclusion Criteria (TD3a).

In case of joint tenders, all members of the consortium or group of bidders must accredit their compliance with the above-mentioned criteria by providing a signed Declaration of Honour on Exclusion Criteria (TD3a).

In case of subcontracting, all subcontractors whose share of the contract is above 30 % or whose capacity is necessary to fulfil the above-mentioned criteria must provide a Declaration of Honour on Exclusion Criteria (TD3a) signed by an authorised representative.

Should there be any doubt as to any of these criteria, bidders may be requested to provide additional information and/or evidence.

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.

4.2.1. 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 lead procurer in writing.

A conflict of interest covers both personal and professional conflicts.

A conflict of interest is any situation where the impartial and objective implementation of the 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.

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 lead procurer, who is required to notify the EU and to take 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.

4.2.2. Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014

Grounds relating to criminal convictions

The lead procurer shall exclude a bidder if it has been the subject of a conviction by final judgement for one of the following reasons:

- Participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;
- Corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union and Article 2 of Council Framework Decision 2003/568/JHA (34), as well as corruption as defined in the national law of the lead procurer or the economic operator;
- Fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests;
- Terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of the aforesaid Framework Decision;
- Money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
- 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.
- Is guilty of serious misrepresentation in supplying the information required under this section or has not supplied such information.

The obligation to exclude a bidder shall also apply where the person convicted by final judgement is a member of the administrative, management or supervisory body of that bidder or has powers of representation, decision or control therein.

Grounds relating to the payment of taxes or social security contributions

A bidder shall be excluded from participation in this procurement procedure where the lead procurer is aware that the bidder is in breach of its obligations relating to the payment of taxes or social security contributions, and where this has been established by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of the country in which it is established or with those of the country of the lead procurer.

Furthermore, the lead procurer may exclude from participation in this procurement procedure a bidder where the lead procurer can demonstrate by any appropriate means that the bidder is in breach of its

obligations relating to the payment of taxes or social security contributions. This paragraph shall no longer apply when the bidder has fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines.

Grounds of insolvency or professional misconduct

The lead procurer may exclude a bidder in any of the following situations:

- 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 a conflict of interest cannot be effectively remedied by other less intrusive measures;
- Where a distortion of competition from the prior involvement of the bidder in the preparation of this procurement procedure cannot be remedied by other, less intrusive measures;
- 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.

4.2.3. Proposed solutions already available on the market

Bidders will be excluded from this procurement process if their proposed solutions are already available on the market. If parts of their solution are already on the market, they need to mention this as background.

4.3. 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.

These selection criteria will be evaluated on a pass/fail basis. “Fail” means that the evidence given does not provide sufficient indication of the tenderer’s expertise, ability and/or equipment to meet project’s objectives. Any tenderer that cannot meet all requirements in this Section will not be selected.

The selection criteria are as follows:

Selection criteria	Evidence
Ability to perform R&D up to original development of the first products or services.	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 (Software as a Medical Device)
Ability to commercially exploit the results of the PCP, including intangible results in particular IPRs	Description of the financial and organisational structures that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results
Economic and financial solvency	Declaration of honour (Section 2) and relevant additional documentary evidence (see below)
Technical and professional solvency	Declaration of honour (Section 2) and relevant additional documentary evidence (see below)

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

4.3.1. Ability to perform R&D up to original development of the first products or services.

Tenderers must have the capacity, tools, material and equipment to:

- 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.

4.3.2. Medical capacity in relation to triage management systems

The evidence required for the medical capacity of the tenders needs to be discussed with the Buyers Group more extensively.

4.3.3. eHealth capacity

The evidence required for the eHealth capacity of the tenders needs to be discussed with the Buyers Group more extensively.

4.3.4. 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).

To measure these criteria, tenderers are asked to provide the following evidence:

- Provide a description of relevant reference and /or previous projects (executed during the last 5 years)
- Demonstrate the expertise and working experience required to undertake an innovative R&D project by providing a number of CV of key personnel and competences, which they consider necessary to complete the project.

- Confirm that the tenderer organization has a Business Continuity / Disaster Recovery / Risk Management plan that ensure 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 that the Tenderer will take the appropriate level of insurance cover if it's to be successful in winning the contract.

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

4.3.5. Economic and financial solvency

Following the specific requirements of the H2020 General Annex E, PCPs do not request any selection criterion related to the turnover of the potential interested bidders. It will be discussed if point c) in this section should not be removed, as guarantees generally limit competition.

Bidders shall demonstrate that they have the necessary economic and financial solvency to perform R&D up to the original development of the first products or services and to commercially exploit the results of the PCP, including intangible results, in particular IPRs. The economic and financial solvency to assure the coverage of the costs related to the execution and implementation of the project must be accredited by means of at least one of the following forms of evidence:

a) The annual accounts presented in the corresponding official Commercial Register referring to the last three available years. Bidders not obliged to present the accounts in an official Register may, as an alternative means of accreditation, provide duly legalised accounting books. Solvency shall be understood as accredited by those bidders whose annual net profits on the profit and loss account give an average of equal to or greater than 50,000 euros.

b) Statement issued by an accredited financial institution attesting the availability by the bidder of an amount equal or greater than 50,000 euros or the existence of a credit granted for the same amount.

c) Statement made by one of more investors providing a financial guarantee in an amount equal or greater than 50,000 euros for the performance of the contract. In spite of the above, for recently established businesses which have not yet existed for three financial years for which accounts have been closed, the annual accounts for one year only –if available– and a simple declaration on turnover will be required but supplemented by at least one of the following declarations providing a financial guarantee for the performance of the contract: bank declaration or declaration from an insurance company.

4.3.6. Technical and professional solvency

The Buyers Group will work further on this criterion, to focus on Demonstration of expertise and working experience that are required when undertaking an innovative R&D project that entails relevant technology.

It will also be discussed whether the approach listed in this section with respect to start-ups should be applied for the whole tender

Bidders shall demonstrate that they have the necessary technical and professional solvency to perform the contract to an appropriate quality standard. More precisely, bidders shall accredit that they possess the necessary experience and human and technical resources to perform R&D up to the original development of the first products or services and to commercially exploit the results of the PCP, including intangible results, in particular IPRs. This technical and professional solvency must be accredited by means of the following evidence:

A list of the main services or works similar to the present contract (see the last paragraph of this section) made by the bidder in the last five years, including amounts, dates and the recipients, public or private. In the description of the services or works carried out, bidders should detail the results obtained and the way in which they were commercially exploited. In the case of bidders whose activity period does not cover the last five years, the list of services or works will be those of the period corresponding to the bidder's

activity. The required solvency shall be understood to be accredited by the satisfactory completion of at least one service or work on the indicated fields.

In spite of the above, recently established businesses such as start-ups may also compete in this PCP procedure, even if they have not satisfactorily completed any service or work similar to the purpose of the present contract provided that the personnel assigned to the execution of the project do have the required experience. In such cases, in addition to the list of the services or works referred to in the previous paragraph performed during their period of activity, bidders shall submit a list of the services and works carried out by the staff allocated to the performance of the project in the previous five years and the profiles and curricula of said personnel, which shall contain a detailed description of their academic background and their previous professional experience. In this case, the required solvency shall be understood to be accredited by the satisfactory completion by the personnel allocated to the project of at least one service or work in the aforementioned areas or by the execution of a research project in an academic field similar to the purpose of the present contract.

NOTE: iProcureSecurity PCP considers a service or work similar to the present contract the previous realisation of R&D services or R&D projects in the following fields: R&D services or R&D projects that pursue to develop ICT technologies that support Triage systems for medical emergencies' management.

R&D services or R&D and e-health.

R&D services or R&D projects performed in other sectors or markets that pursue to develop technologies based on artificial intelligence (AI) or telemedicine.

4.4. Compliance criteria

The purpose of the compliance criteria is to determine whether the Tender is compliant with the principles of PCP, public financing, place of performance, research integrity and security.

The offers for each phase will be evaluated against the compliance criteria A to G.

Tenders must comply with the following compliance criteria:

Compliance criteria	Evidence
A) Compliance with the definition of R&D services	Declaration of Honour on Compliance Criteria (TD3b)
B) Compatibility with other public financing	
C) Compliance with the requirements regarding the place of performance of the contract	
D) Compliance with ethics requirements	
E) Compliance with security requirements	
F) Compliance with usability and interoperability requirements	
G) Compliance with data management requirements	

Tenders that do not comply with these criteria will be excluded.

4.4.1. 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 EU R&D&I state aid framework[10]. 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[11]. 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 any products covered by the contract must be less than 50 % of the total value of the PCP Framework Agreement. 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 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
- the offers for all three phases must offer services matching the R&D definition above
- the total sum of the value of products offered in each phase and all previous phases must be less than 50 % of the total value of the Framework Agreement

4.4.2. 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.

4.4.3. 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:

- At least 50% of the total value of activities covered by the Framework Agreement 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.
- 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 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.

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.

[10] See Point 15 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

[11] See Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014

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 Online Manual[12] .

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

4.4.4. D) Compliance with ethics and research integrity

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 Integrity[13] , and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
  - applicable international, EU and national law
  - detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation including General Data Protection Regulation (GDPR)
- include plans to carry out activities that are prohibited in all Member States or in a country outside the EU (where those activities are allowed)
- 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
- do not comply with the ethics requirements specified in the Framework Agreement.

If the tender involves activities that raise ethical issues, the tenderer must submit an ethics self-assessment 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:

[12] List of H2020 associated countries

[13] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

- objectives (e.g. dealing with vulnerable populations and dual-use goods and 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 How to complete your ethics self-assessment.

Attention:

Call-offs for phases 2 and 3 may request that this information 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.

4.4.5. 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.
- the security aspect letter (SAL) annexed to the H2020 grant agreement and the Decision No 2015/444[14]

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 to 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.

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 external experts needed to evaluate the proposal).

Call-offs for phases 2 and 3 may request that this security information 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 licenses required under EU, national or international law.

The Framework Agreement contains a provision on security aspects.

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

Attention: Tenders will be excluded if they do not comply with data protection requirements as provided under the GDPR

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

4.4.6. F) 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.
5. 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).

4.4.7. G) 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 (DMP).

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.

4.5. Award criteria

The award criteria, points and thresholds will be finalised during the first months of the PCP.

A tender will be evaluated against the award criteria set out here only if the tenderer is not excluded through application of the exclusion criteria, and only if the requirements in the selection criteria, the compliance criteria, and the administrative instructions are met.

The Award Criteria table below specifies maximum points and thresholds for each of the criteria. Points will be given per criterion based on the following Assessment table.

Assessment		Description	
5-point criteria	10-point criteria	15-point criteria	
0	0	0	Insufficient (fails to address the criterion under examination or cannot be judged due to missing or incomplete information)
1	2	3	Poor (the criterion is addressed in an inadequate manner, or there are serious inherent weaknesses)
2	4	6	Fair (while the criterion is broadly addressed, there are some weaknesses
3	6	9	Good (the criterion is addressed well, although improvements would have been necessary)
4	8	12	Very good (the criterion is addressed well, although certain improvements are still possible)

5	10	15	Excellent (all relevant aspects of the criterion are successfully addressed; any shortcomings are minor)

Award criteria[15]	Maximum points	Threshold
Excellence of the proposed solution		
Understanding of the iProcureSecurity PCP domain	5	
Extent to which the solution matches the iProcureSecurity vision	10	5
Extent to which the proposed solution meets the requirements documented in the Call	15	8
Evidence of effectiveness	10	
Total for excellence	40	20
Impact of the proposed solution		
Value of benefits for patients	10	5
Value of benefits for procurers	10	5
Total cost of ownership	5	2
Sustainability of supplier business case	5	
Soundness of the approach to integration with procurer systems	10	5
Total for impact	40	20
Implementation of the proposed solution		
Quality and completeness of the work-plan as well as detail of task and result descriptions	5	
Feasibility of plan and resources to meet the objectives specified	10	5
Relevance of the proposed way to involve clinicians and patients in design and development	5	
Total for implementation	20	10
Overall total score for tender	100	60

Additional sub-criteria may be added and maximum point distribution adjusted for the call offs for phases 2 and 3. These will be to make the award criteria more precise and to take account of improved information

[15] This table is valid for evaluation of Tenders and selection for phase 1

available relevant to addressing the Challenge without making substantial changes to the criteria presented here.

Should there be any doubt as to the application of any of these criteria to a tender / offer, tenderers may be requested to provide additional information.

4.6. Evaluation of tenders

The involvement of an Expert Board requires more discussions in the Buyers Group.

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

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

Expert Board: An Expert Board will do a prior assessment of the tenders, informing the Evaluation Committee, which is not bound to this pre-assessment.

Evaluation Committee: The Evaluation Committee shall respect the general principles settled in relevant provisions under Spanish regulations, specifically *[COUNTRY OF LEAD PROCURER] Code of Public Procurement (No XX)*, and work in accordance with all the provisions and content of the Contract Notice. In order to guarantee fairness and transparency, the appointment of the members of the Committee and its establishment shall take place in good time for meeting deadlines set for the evaluation of tenders.

Procurers nominate Committee members by forwarding information on the identity, education, professional qualifications and experience of the relevant nominee to the Lead Procurer. When doing so, the Procurers shall use the form provided by the Lead Procurer. It is a duty of each Procurer to ensure the person appointed is in accordance with the requirements provided by the law in force and there are no reasons for excluding the candidate.

The Lead Procurer will appoint an Evaluation Committee consisting of clinical, technical and business experts. Each procurer will nominate three experts they wish to represent them. The experts must come from the iProcureSecurity PCP consortium organisations and must reflect the necessary expertise areas – procurement, clinical, technical, business. The Committee will carry out the selection of tenders and apply exclusion, selection and compliance criteria, and then evaluate tenders eligible for evaluation on the basis of the award criteria.

The Lead Procurer draws up a list of the members of the Evaluation Committee, based on persons appointed by the other Procurers.

Note: Each member of the Committee and of the expert board will sign in advance a Declaration of absence of conflict of interest and protection of confidentiality and in addition specifically notify the Lead Procurer if there is any conflict of interest with any of the tenderers.

The Lead Procurer will keep duly certified copies of the Declaration of absence of conflict of interest and protection of confidentiality, signed by such persons. The Lead Procurer will refuse to accept a nomination if a conflict of interest is stated in the above-mentioned Declaration.

Members of the Committee are appointed ad personam. When carrying out their tasks, they shall not seek or take instructions from the Lead Procurer institutions, bodies, offices or agencies, from any government of a Procurer or from any other body. The Committee shall, within two weeks, issue its reports on selection and award, respectively. The Committee will reach its decision by a Simple Majority vote. It is however expected that the members make their best endeavours to reach unanimous decisions as to the content and conclusions of the reports.

The Procurers will not influence the members of the Committee in the performance of their tasks.

The Evaluation Committee will carry out the following six steps:

Step 1 — Checking whether the tenderer is not in one of the situations covered by the exclusion criteria

Step 2 — For tenderers passing Step 1, assessing whether the tenderer has the capacities necessary to perform the contract, on the basis of the selection criteria

Step 3 — For tenderers passing Step 2, evaluating the tender based on the compliance criteria

Step 4 — For tenders passing Step 3, evaluating the tender based on the award criteria.

Step 5 — Opening of the Economical offers

Step 6 — Final ranking

The proposal by the experts will be reviewed by each member of the evaluation committee and discussed. The scoring for each tender and a final ranking list of all tenders will be defined by majority vote by the Procurer delegate members as described above.

The tenderers will receive written justification including the scoring and their rank.

For phases 2 and 3, no differences in the composition of the evaluation committee or in the procedure are to be expected apart from the fact that the evaluation will have only two steps: evaluating the offers based on the compliance and award criteria.

The Buyers Group headed by the Lead Procurer will evaluate the tenders and offers for the call-offs for phase 2 and 3 jointly and make a joint award decision.

4.6.1. Ranking of tenders

The price-quality ratio will be discussed and decided by the Buyers Group in the first months of the PCP Project.

Tenders must score above the thresholds given, for each threshold (please refer to section 5.5.). Tenders that do not reach the minimum quality thresholds will be rejected.

The contract will be awarded to the most economically advantageous tender, i.e. the tender scoring above all thresholds and offering the best price-quality ratio determined in accordance with the formula below. The price applied is to be the total offered price relating to the next Specific Contract (contract for each phase) in the PCP. For the first tender, the price for phase 1 will be applied.

A weight of 70/30 is given to quality and price, respectively.

$$Total\ Score_{Tender\ i} = 70\% * Quality\ Score_{Tender\ i} + 30\% * \left(\frac{lowest\ price\ of\ all\ tenders}{Price_{Tender\ i}} * 100\right)$$

The tender ranked first after applying the formula will be awarded the contract.

4.7. Submission content and format

4.7.1. Submission and format of tenders, tender closing time

Partner SYNYO will discuss with the Buyers Group the best approach to submitting the tenders, which might include a dedicated tender submission platform instead of submission via email.

Tenderers shall submit tenders electronically not later than *xx:00h* (GMT +1) *DD MONTH YEAR*. Tenders where the electronically submitted and the signed paper copy diverge will be excluded. Tenderers should take full account of all the tender documents which must be downloaded from the project website *[WEBSITE]*.

The following documents must be submitted as part of the tender: TD3a, TD3b and TD4 (not required for a single organisation as tenderer) TD5, TD6 and TD7

For electronic submission:

1. an email must be sent to *[EMAIL]* by the deadline specified above

2. the email must contain three PDF attachments, clearly named using the terms "administrative", "technical" and "financial".

For postal or courier submission:

1. one originally signed complete paper copy of the administrative, technical and financial sections of the tender must be sent by registered mail by the deadline above to *[POSTAL ADDRESS]*
2. In such case, bidders should inform the Lead Procurer of the dispatch of the tender by email on the same day, attaching a proof of the date of shipment, which must be before the deadline for the submission of tenders. Evidence of the date of dispatch shall be constituted by the postmark. In any case, the Lead Procurer must receive the documentation within five days of the deadline for submission. Failing this requirement, offers will not be admitted.
3. Tenders must be placed inside two sealed envelopes. The inner envelope, addressed as above, should be marked: "CALL FOR TENDERS - NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT". If self-adhesive envelopes are used, they must be sealed and the sender must sign across this tape.
4. The inner envelope must contain three sealed envelopes, clearly marked "technical", "administrative" and "financial" respectively.

All offers must indicate their minimum validity period from submission (at least three months).

Any questions on the request for tender, tender documents or tendering process must be sent to *[EMAIL]* before the deadline set in the timeline in this document.

Tenders that do not comply with the formal requirements described in this section will be excluded.

Tenders are secret and the submission thereof implies unconditional acceptance of all terms and conditions contained in this Call for tender. Under penalty of exclusion, tenders must not contain any reservation in relation to any point in the Tender terms and conditions.

4.7.2. Administrative section of the tender

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

1. The legal capacity and the representation of the bidders shall be proved by a signed Legal Entity Form with its supporting evidence. All tenderers (including all members of the group in case of joint tender) must provide this form. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm
2. In the case of a joint tender, the documentation referred to in section 4.6.1 of this Call for tender shall be provided.
3. In the case of subcontracting, the documentation referred to in section 4.1.2 of this Call for tender shall be provided.
4. The non-subjection of the bidder to any of the exclusion grounds contained in section 4.2 of this Call for tender shall be proved by means of the types of evidence referred to in that section.
5. The fulfilment of the bidder of the selection criteria contained in section 4.3 of this Call for tender shall be proved by means of the types of evidence referred to in that section.
6. The fulfilment of the bidder of the compliance criteria contained in section 4.4 of this Call for tender shall be proved by means of the types of evidence referred to in that section.
7. The tenderer (or the leader in case of joint tenders) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed for subcontractors and other members of the group in case of joint tender. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm
8. The documentation to be included in the administrative section may be submitted in English, or in a language other than the previous ones, provided that, in the latter case, the original documents are

accompanied by their translation into English and a duly signed and stamped copy is annexed to the bid.

9. Should there be any doubt as to any of these requirements, bidders may be requested to provide additional information and/or evidence.
10. More detailed information for the phase 2 and 3 offers will be provided in the call-offs (in particular on the technical implementation plan, updated business plan and list of IPRs).

4.7.3. Technical section of the tender

Tenders must include a technical offer, containing:

- technical plan that outlines: 1. the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and non- functional, data, organisational and legal requirements; 2. technical details of how this would be implemented, and 3. a project management plan that outlines the execution and monitoring approach, including a Gantt chart.
- 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 list of the pre-existing rights (background) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed
- 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 (see section 4.2)
- a reply to the question "Does this tender involve: activities or results that may raise security issues and/or EU-classified information[16] as background or results? (YES/NO)" and if YES information on how these issues will be addressed (see section 4.2)

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).

Tenderers are requested to use the tender template TD6 and follow the instructions therein.

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 compliance criteria A, D and E.

More detailed information for the phase 2 and 3 offers (in particular on the technical implementation plan, updated business plan and list of IPRs) will be provided in the call-offs.

4.7.4. Financial section of the tender

VAT aspects in this section will be reviewed pending the decision to centralise the PCP budget with the Lead Procurer.

The tender must include a detailed financial offer specifying:

- 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)
- 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).
- For that please use the breakdown of the financial bid template TD7

[16] See Decision 2015/444/EC, Euratom on the provisions on security of EU-classified information.

- As the payments to contractors are centralised through the lead procurer, the *[COUNTRY OF LEAD PROCURER] VAT regime shall apply*
- Bids from any country but *[COUNTRY OF LEAD PROCURER]* shall not include VAT. *Bids from [COUNTRY OF LEAD PROCURER] shall include VAT, but shall also itemize the base fare and VAT.* Comparison of the price will be exclusive of VAT.

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 compliance 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 compliance criterion C)
- the financial compensation valuing the allocation 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 were IPR ownership to be transferred to the procurers)

in order to ensure compliance with the EU R&D&I state aid framework.

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-off. 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.

4.8. Opening of tenders

Opening of the envelopes will take place *xx:00h (Spanish time) on <Date>* .

Tenders will be evaluated in a non-discriminatory manner in accordance with the legal requirements provided for in relevant provisions under Spanish regulations.

The Lead Procurer will open the tenders submitted before the deadline and register them.

Bidders are welcome to attend the opening and registration of the electronic tender submissions. The procedure will be conducted fully electronically. A video webinar session may be provided and interested tenders provided with login data.

4.9. Other tender conditions

4.9.1. Signed tenders

A signed tender will be considered to constitute a firm, irrevocable, unchangeable and binding offer from the tenderer.

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).

4.9.2. Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure (including EU-classified information[17]).

All documentation, data, statistics, drawings, information, samples or material disclosed or furnished by the Contracting Authority 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 Buyers Group will be bound by the same confidentiality obligations towards the Contractor.

4.9.3. Language

Tenders as well as offers for phase 2 and 3 call-offs must be submitted in English.

Deliverables must be submitted in English. The PCP language is English and the Framework Agreement and the specific phase contract must be signed in English version.

Communication (relating to either the tender procedure or the implementation of the contract) must be carried out in English.

For field testing in phase 3 the ability to speak the local languages is not mandatory but (Spanish, Italian, German and Turkish) will be an advantage.

With the submission of their proposals, tenderers accept these requirements.

4.9.4. Cancellation of the tender procedure

The procurers may, at any moment, cease to proceed with the tender procedure and cancel it.

The procurers reserve the right not to award any contracts at the end of the tender procedure.

The procurers are not liable for any expense or loss the tenderers may have incurred in preparing their offer.

[17] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information.

5. PROCESS RULES AND INFORMATION

5.1. Communication — Q&A

The Q&A from the open market consultation can be found on *[WEBSITE].*

For further questions, you may contact the lead procurer via email *[EMAIL]* in English until the deadline specified in the time schedule.

The summary of all questions and answers will be presented in an anonymised Q&A document that will be published on *[WEBSITE]* in English on *[Date]*. For phases 2 and 3, the answers 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 contact any other persons in connection with this procurement.

Attention: All other contacts (or attempted contacts) will be considered unauthorised and may lead to the exclusion of your tender.

5.2. Procedures for appeal

The Lead procurer will incorporate a voluntary standstill period. The standstill period of not less than 10 days for each phase begins from the award decision and notification and lasts until date of signature by the Lead Procurer.

Any clarification or questions must be submitted in writing to *[EMAIL]* before the end of the standstill period.

Any legal claim, petition or application for judicial review with regard to the iProcureSecurity PCP Procedure, whether before civil law courts or administrative courts, shall be made only before the Spanish courts. By submitting a Tender, the Tenderer accepts the exclusive jurisdiction of Spanish courts.

Decisions taken with regard to the selection of tenders may be challenged only by means of an administrative remedy before the court.

Tenderers are referred to the Framework Agreement on the subject of dispute resolution in the performance of a Framework Agreement.

5.3. Data Protection

The contractor shall process personal data in the proposal documentation in compliance with the applicable EU and national law on data protection (including information related to authorisations and notification requirements).

The contractor may grant its staff access to data only in so far as it is strictly necessary for implementing the Tender proposal.

The contractor must inform the staff whose personal data are collected and processed by the procurer. For this purpose, the contractor must provide them with the privacy statements of the procurer, before transmitting their data. If explicit prior consent from the data subjects is needed, the contractor must obtain such consent.

Please refer to Article 11 — Processing of personal data of the Framework Agreement for the data protection handling during the contracts' implementation.

5.4. 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 rules under Article 6 of the Framework Agreement, 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 PCP (Phase 1, 2 and 3), including information of the key R&D results attained and lessons learned by the Consortium. Details will not be disclosed that will harm the legitimate business interest of the Contractors involved in the PCP or that would distort fair competition on the market. The lead Procurer will also 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

The above award information will be sent to the "contact information details" stated in the Tender. Experts, employees of the Lead Procurer and other persons contracted to aid in the tendering and award process will handle all information confidentially in compliance with the above procedure. Experts with a conflict of interest with one or more of the tenders will not assess these Tenders.

6. CONDITIONS OF THE CONTRACTS

Successful tenderers will be requested to sign both a Framework Agreement and Specific Contracts for phases 1, 2 and 3 (see the models given in TD8 and TD9).

6.1. Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, deliverables and output or results) for the phase.

Each contractor will be assigned a main contact person (their supervisor) from the monitoring team appointed by the procurers.

There will be monthly monitoring online meetings between each contractor and the supervisor/monitoring team.

The contractor will be asked to discuss the results achieved in the preceding period and present an updated work plan. The monitoring team and supervisor are allowed to visit the contractor's premises to monitor progress. The contractor can also visit the procurer's premises, at its own expense.

The contractors are asked to obtain all information necessary for their performance. The procurers will do their best to provide the contractors with information required. The contractor must cover its own costs and thus foresee personnel and travel budgets in its offer.

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

6.2. Payments based on satisfactory completion of milestones and deliverables of the phase

The payment instalments will be further discussed in light of the expectation that many tenderers are SMEs and might benefit from advanced and intermediate payments.

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 Evaluation Committee composed of representatives 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 monies have been allocated to the planned objectives
- if the monies have been allocated and the work has been carried out according to the compliance criteria (place of performance, public funding and R&D definition criteria) and
- 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 uses any reasonable template or form provided to the tenderer

'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. (A PCP could, for instance, be satisfactorily completed even if it concludes that the innovation is not feasible.)

The assessment will consider the efforts made by contractors to take into account the feedback from the supervisor or the monitoring team. The Buyers Group aims to approve as 'satisfactory' or reject submitted deliverables within 15 calendar days.

Where the Technical Committee judges the completion of deliverables or milestones to be unsatisfactory, the Buyers Group may decide to reduce or withdraw payments for that deliverable and/or may terminate the contract according to Article 17 of the Framework Agreement.

Invoices must be submitted to the Lead Procurer.

Contractors must notify the Lead Procurer in good time of the bank account to which payments are to be made in a document bearing the signature of the authorised signatory of the contractor following procedures reasonably required by the Lead Procurer.

Contractors' invoices must provide a price breakdown showing the number of units and resulting price for each of the unit prices defined in the offer and showing the location or country in which the different categories of activities were performed in a format agreed with the Lead Procurer (in order to verify compliance with the definition of R&D, compliance criterion A and C).

Payment Schedule

- Payment for Phase 1: 100% of the total price offered by the contractor will be accepted for invoicing from the date the lead procurer declares satisfactory completion.
- Payment for Phase 2: 50% of the total price offered by the contractor will be accepted for invoicing from the date the lead procurer declares the satisfactory completion of the Phase 2 *D2.1*

Presentation of prototypes of key system components. 50% of the total price offered by the contractor will be accepted for invoicing from the date on which the lead procurer declares the satisfactory completion of Phase 2.

- Payment for Phase 3: 50% of the total price offered by the contractor will be accepted for invoicing from the date on which the lead procurer declares the satisfactory completion of *D3.2* Presentation of pilot system and onsite testing results. 50% of the total price offered by the contractor will be accepted for invoicing from the date on which the lead procurer declares the satisfactory completion of Phase 3. Payments will be made to the bank account provided by the contractor within 30 days from the date of receipt, by the lead procurer, of a correct and approved invoice.

6.3. Eligibility for the next phase based on successful completion of the phase

Eligibility for participation in the next phase will be subject to successful completion of the current phase.

Successful completion of a phase will be assessed by the assessment committee 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 forth 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 applicability in an operational setting and the potential impact of the product is convincing

Note: Note the difference between satisfactory completion (requirement for payment) and successful completion (prerequisite for passing from one phase to the next).

6.4. Finalisation of phase 3: link with possible follow-up PPI procurement

A new call for tenders may be launched for a follow-up public procurement of innovative solutions (PPI) to deploy a commercial volume of innovative solutions.

HORIZON 2020 | PRE-COMMERCIAL PROCUREMENT (PCP) | SU-GM02-2020

Challenge brief

iProcureSecurity PCP

Pre-Commercial Procurement of Innovative Triage Management Systems

Strengthening Resilience and Interoperability of Emergency Medical Services

Topic: Strategic Pre-Commercial Procurement of Innovative, Advanced Systems to Support Security

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1. iProcureSecurity PCP vision to guide requirements

This section might be moved up to TD1 section 4 to enrich the motivation for the PCP.

A vision is necessary in iProcureSecurity PCP in order to consolidate the iProcureSecurity PCP buyers and their wishes into one single view within the project. This ensures that suppliers understand clearly what is expected of them and there are no ambiguities in the way requirements are documented. A shared vision document was drafted based on the iProcureSecurity PCP proposal which has identified the building blocks of a Triage Management System. It has the style of a story using the various viewpoints.

From the initial triage classification victims, over the treatment, up to the handover to hospitals, a large number of information objects are either explicitly or implicitly generated, enriched, processed by various roles in different process steps, on- and off-site. The figure below shows the information flows and type of information throughout the triage procedure. This is a simplified perspective for explanatory purpose instead of a holistic view of all information objects which would well exceed the scope of the document at hand.

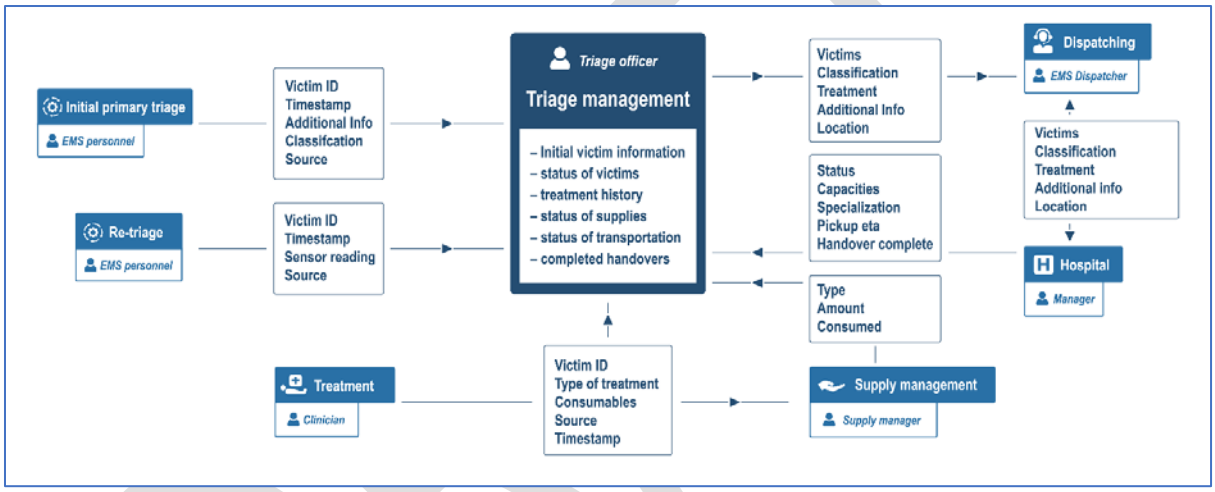

Figure 1: Neutral overview of formal and informal information flows during triage

The information generated in the initial triage classification is a unique identifier (number, barcode) for the victim, a classification, the location of the victim, and the triage is taken at a specific time, by a specific person. Additional information can include CBRN-related data, burns, trauma or the age of the victim (elderly/infant). During re-triage, the information relates to the unique identifier of the victim, and includes information on the victim's condition, alongside a timestamp for the last measurement and information on the source of information. Any treatment on-site, usually performed by clinicians, again relates to a specific victim, and includes information on which type of treatment was performed, alongside any consumables used during the treatment. These three information objects together form the core data relevant on the victim's situation, which is aggregated by the triage officer. In an aggregated view, this information provides a consistent overview of the number of victims on site, their condition and treatments. This information is invaluable for organising the transportation logistics to hospitals. Multiple dispatchers in a control centre organise the logistic aspects, working with the number of victims and their classification. They provide the feedback to the "transportation manager" on site on estimated times of arrival and capacities of ambulances, so the victims can be brought to the transportation pick-up location on site in advance. The triage information and any kind of treatment they received on site is carried over to the paramedics in the ambulance, and to the hospital. Dispatching can be reactively, i.e. by gathering information from hospitals on their capacities and treatment capabilities (e.g. for burns, traumas, CBRN victims), or proactively by having hospitals

provide this information upfront, to optimise the communication procedure for arranging transportation.

A side aspect is that a tracking of supplies, especially consumables on site can be derived as a by-product of the treatment information, so if the locally available stock is known beforehand, or a significant demand on a specific supply exists, additional supplies can be requested in time.

The status quo is that major parts of this information management on site is carried out manually, as highlighted in the figure below:

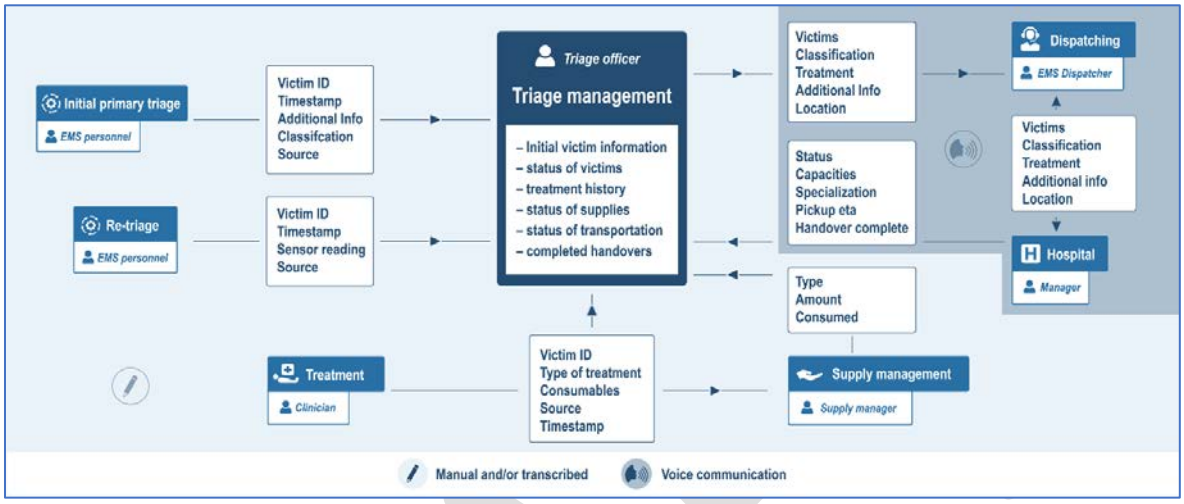

Figure 2: Status quo of formal and informal information flows during triage

The large amount of manually generated, enriched and transcribed information has advantages and disadvantages. A basic requirement is to keep the advantages of the manual procedure, while exploring possibilities to eliminate the disadvantages by incorporating modern technologies into the triage procedure. A progress towards a commonly accepted digitalisation of certain aspects of the triage procedure will therefore well exceed the current state-of-the art.

This governs **four main objectives**:

- The development, integration and evaluation of digital devices, to support in the initial triage classification, and the continuous and management of triaged victims
- The development, integration and evaluation of sensor technologies to assist in the continuous monitoring of victims (re-triage)
- The development of a central, on-site management platform to consolidate and manage information from the triage and re-triage of victims
- The development of an interoperability model for a standardised data exchange between devices, sensors, management- and communication systems relevant during the triage procedure.

The image below gives a basic overview of involved actors, connections and interfaces of an envisaged flexible and highly modular triage management system that can be applied and adapted to different approaches and connected to existing system 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.

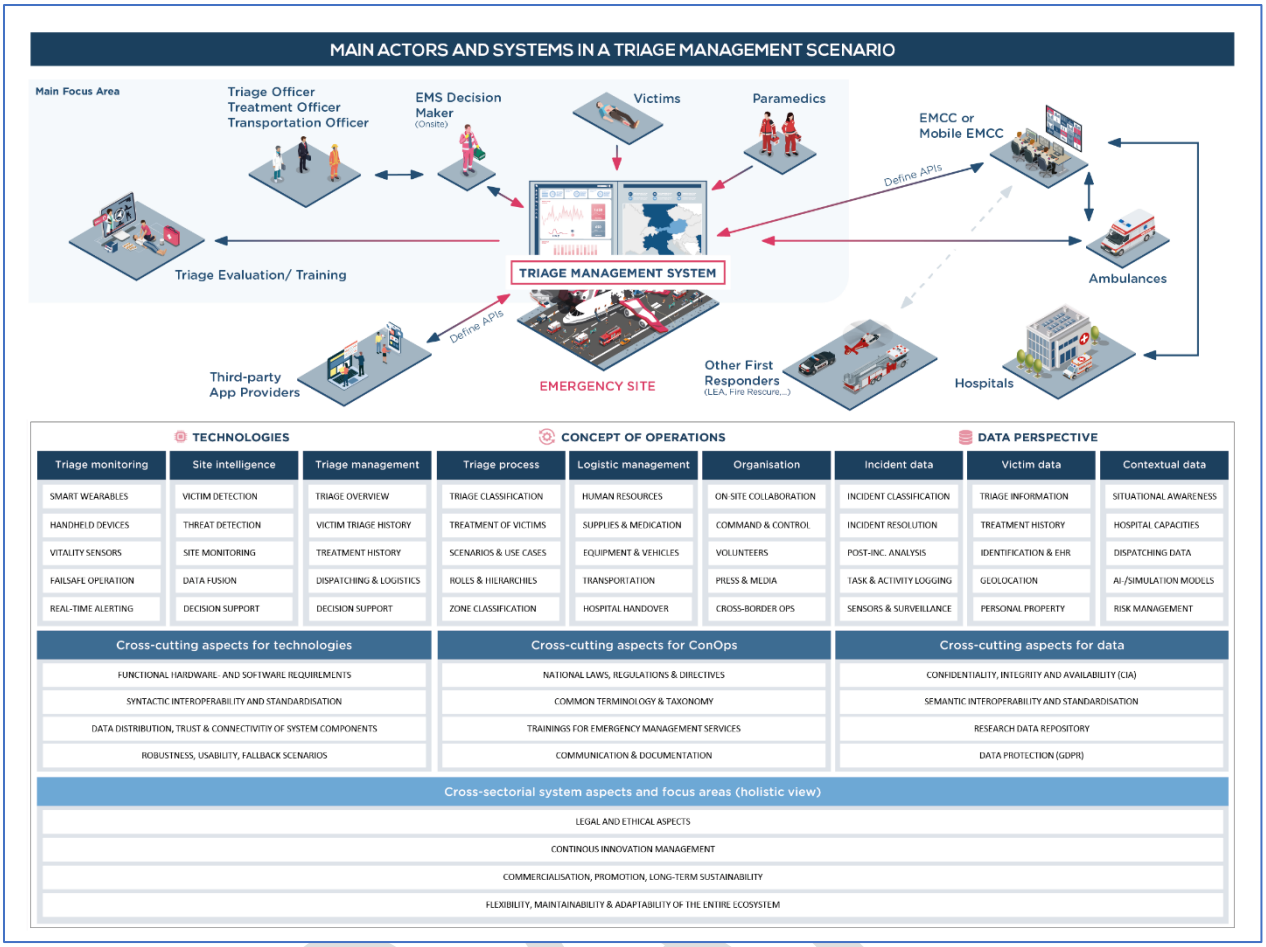

Figure 3: Triage management aspects

Figure 3 details the main perspectives for the technology development and implementation. 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 victims to healthcare organisations. The aspect of "site intelligence" seeks to utilise the capabilities of modern sensor technologies, to aid in victim detection, but also in threat identification to prevent further harm on victims or EMS workers, 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 and structures established for an incident response, the concrete initial and re-triage processes, relevant process interfaces to other EMS, emergency dispatching centres and hospital organisations, as well as the collaboration under different constellations, especially in large scale 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 incident resolution and identify additional resource needs on site. Particular emphasis is also on any data regarding the victim, which ranges from their triage history, the treatment they received, but also the potential of retrieving a patient 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.

As planned progress in iProcureSecurity PCP, suppliers will be expected to deliver a framework and actual technologies to solve the issues at hand. To fulfil the unmet needs identified, during the iProcureSecurity CSA project, procurers have set an ambitious framework for requirements to be met by R&D delivery with the following technological domains:

The **field of sensor technologies** provides benefits in multiple use cases. Sensor technologies can support in the continuous monitoring of triaged victims**,** by reading their vital signs by combining blood pressure monitors, pulse oximeters, heart rate and respiration rate monitors, but also evaluating the tilt and spatial movement of the victim. The challenges for further research and development in this technology field lie in the product development towards consumer-oriented, affordable and disposable devices suitable for MCIs, the robustness and usability of the devices, a miniaturization of the hardware, an appropriate mix of sensor technologies, a continuous power supply, as well as scenarios how the monitoring device is applied to a victim. In addition, it needs to tie into the operational procedures to alert first responder personnel on site, be it by a visual/audible alarm or data connection, in cases of a critical change of the victim's condition or an impending malfunction of the device. In the initial assessment of an incident location, it is critical to gather information on the incident type, scope, remaining risk factors and the location of victims to articulate an effective incident response. Shortcomings due to external factors (weather, time of day, line of sight), the amount of first responders and threats invisible to human sensing can be addressed by taking advantage of different sensor types to support in an **assessment and surveillance of the incident site.** CBRNE sensors are important to prevent further harm to EMS personnel, victims and the local infrastructure, and to determine the necessity for specialized equipment, treatment, medication and personnel on site. Infrared cameras can pick up gas leakages and provide thermal imagery to support in victim detection under poor visibility conditions (night-time, smoke, foliage), which can be further supplemented by acoustic sensors or radio direction finders to triangulate the location of victims. Lidar scanners allow a terrain analysis of the incident site, which not only is a baseline for an accurate situation picture combined with a geographic information system, but can also be used for simulation models (flooding, spread of fires and gasses etc.), for logistic planning, but can be used for virtual reality use cases to convey the incident situation to a control centre for increased situational awareness and decision support.

The advantages of **private blockchains** show potential to support in setting up data networks on site, and in the data exchange between different components. The main benefits are shifting from a centralized to a decentralized authorization mechanism to trust individual components of a network, a decentralized tracing of transactions, and a data replication over distributed nodes of the blockchain[19]. This way, the common challenges in setting up an ad-hoc network in the field, which means establishing a trust between heterogenous devices, sensors, applications, network components, etc. and ensuring security, validity and integrity of the information flow between these components as well as to external systems from emergency dispatching centers and hospitals, can be addressed, while taking advantage of the robust architecture for information storage and distribution throughout multiple decentralized nodes. Blockchain data is also a valuable information source in a post-incident evaluation to understand the sequence of events during resolution.

The utilisation of **AI algorithms** supports in decision making and planning activities of the incident response on a tactical and strategic level. In the initial establishment of safety zones, algorithms can support in identifying high risk areas based on GIS imagery, terrain information, sensor data and metrological prediction models. Vice versa, in can support in identifying the suitable locations for the

transportation of victims or supply routes, which can further incorporate data on the infrastructure, traffic situation and required hospitals, related to the incident location. In the evaluation of the incident situation, AI algorithms can be used for scenario-based (cause and effect) simulations to find the correct approach to resolve an incident, e.g. by factoring in the capacities of the healthcare system, the available personnel and resources, the circumstances of the incident, which helps to proactively identify resource bottlenecks or prioritise limited resources, and optimise the transportation of victims to the correct healthcare facilities. In addition, AI algorithms also impact other technology fields related to the triage process, such as autonomous navigation and driving capabilities for UxVs to aid site logistics and surveillance, simulation-based modelling for the calculation of search patterns for victim localisation or real-time sensor fusion to homogenise and correlate raw sensor data into human-readable form for command and control systems. The exploitation of these technologies, if it stays coherent within the concept of values to utilize them in an ethical, human-centric, secure, transparent, privacy conscious and socially driven way, provides a considerable benefit in terms of the efficiency, capability and expandability of the technologies and further research initiatives building on them, ultimately leading to a lasting and positive societal and economic impact.

Especially the exploitation of the capabilities of **natural language processing**, combined with text-to-speech capabilities, used in the documentation of the steps taken during a victim's triage and treatment, can provide an operational benefit by requiring less attention and time effort that a manual documentation or haptic user interface interaction would demand. A uniform taxonomy and semantic interpretation capabilities support an interoperability model by normalizing the information gathered from heterogenous, distributed sources throughout the incident resolution, which also benefits the application of AI algorithms which utilize the data, for example for decision support, for simulation models or as planning parameters for logistic operations. This approach also reinforces the interoperability in MCIs involving first responder- and healthcare ecosystems from different nationalities, which potentially use different natural languages, dialects, abbreviations or professional terminologies for the same information objects. In addition, natural language processing can be used to actively monitor and analyze social media information to potentially become aware of or localize (impending) MCIs before an active emergency call or distress signal is set off.

The application of **telemedicine** to support in mass casualty incidents by allowing a near-real-time interaction off-site physicians with EMS on site is valuable for secondary triage measures on site, when specialized medical knowledge is necessary for an accurate classification (such as CBRN incidents or uncommon diseases), or the amount of victims is too large to manage with the quantity of present qualified personnel. Furthermore, videoconferencing systems and data streams (concerning incident data, victim's condition monitoring, applied treatment etc.) will open the possibility of quickly pooling expert knowledge on site without requiring physical presence, which opens the field for new cooperation models in MCIs where experts around the globe can virtually assist in the consultation and resolution of the incident. Telemedicine will also synergize with other technology fields. The digital health monitoring of a victim provides a constant near-real-time data stream off-site, to further support in the diagnosis and treatment, while augmented reality technologies provide a visual data stream of the victim, but also allow overlying information in the augmented reality device.

The availability of rich, structured incident data is the base for **big data analysis to optimise the triage process**. The captured incident data provides a thorough sequence of concrete activities in the localisation, triage and treatment of victims, and the timing of events. This information can be correlated with other information repositories on raw sensor readings, metrological information, statistical data (demographic, environmental, healthcare system), unstructured social media data, but also with other historic incidents. This information can provide valuable insights, for example, to identify optimisation potential in the triage and treatment of victims, the training of EMS, the deployed

technologies or for dispatching, logistics and resource management. In a larger scope, the information is also beneficial for the disaster preparedness of societies by better understanding the necessary capacities and capabilities of the healthcare systems to respond to MCIs, and the long-term impact such events can have from an economic, environmental, societal, demographic, political or technological perspective.

Finally, also cybersecurity aspects have to be considered by suppliers in detail during the development of their prototypes. Currently, multiple ISO standards for IT security of medical devices are under development, specifically ISO/IEC 81001-1[20] which governs the entire system lifecycle management, i.e. the system development, patch and update management as well as decommissioning, including system security and data protection. IEC/CD 80001-5-1[21] includes security aspects for the entire development lifecycle of software deployed on medical devices, or interfacing with related IT system.

2. Overview of requirements for a solution in the area of Triage Management

The requirements documented here represent the best attempt of the iProcureSecurity PCP procurers to define features of future system which, individually and in total, represents significant innovation beyond the state of the art in the area of Triage Management. Nevertheless, the procurers will not accept into clinical practice any approach or system which has not shown cost-effectiveness. Cost-effectiveness will in all cases requires proper evidence of reliable positive outcomes and absence of patient risk. It follows that, where requirements go beyond state-of the-art, it is the tenderers' responsibility to ensure that evidence for positive outcomes is available or will be provided. If the latter, tenderers with clear plans to provide such evidence at or before completion of the iProcureSecurity PCP procurement execution will be favoured over those hoping unnamed third parties will deliver the necessary evidence.

All requirements share the description format in a tabular form. The following fields will be used in the tables. Some fields are only applicable to functional and non-functional requirements as indicated in brackets.

Requirement ID and type

Each requirement has an individual ID starting with R and containing three digits separated by dots (e.g. R1.3.1). The first digit indicates the type the requirement belongs to:

- R1.[...]: Functional Requirements
- R2.[...]: Non Functional Requirements
- R3.[...]: Parameters/measuring units requirements
- R4.[...]: Organisational, staff and business requirements
- R5.[...]: Legal and regulatory requirements

The second digit indicates the group within the requirement type (e.g. R1.1 would be the first group – Triage Management Plan). The third digits denominate the specific requirement within a group (e.g. R1.1.1 Shared Care Plan concept).

Requirement name

Each requirement has a unique name suggesting its purpose.

Description

The requirement summary briefly describes the functionality or purpose the requirements shall cover.

Priority

The priority rates the relevance of a given requirement for the procurers. The range is between 0 (not applicable) and 10 (highest priority). The mean priority across the procurers is used as the overall priority for each requirement. The priority serves the purpose of indicating preferences when developing different functionalities (applicable to the functional requirements, whereas the non-functional, organisational, legal etc. requirements are mandatory and therefore do not need prioritisation). Different vendors will suggest solutions with different focus and functional scope, but they all need to match the preferences of the procurers as much as possible.

2.1 The iProcureSecurity PCP functional requirements

The requirements will be finalised in phase 0 of the PC project.

Monitoring (Quick and accurate overview of casualties and their status)

Decision Making (Decision support for better allocation of available resources and quicker support for casualties)

Interoperability (Improved interoperability with other first responders and relevant actors)

Handover (Reduced handover times between ambulance transport and hospitals, and)

Evaluation (Insights for quality assurance and training measures.)

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

2.2 The iProcureSecurity PCP non-functional requirements

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

Existing systems of the *[COUNTRY OF THE LEAD PROCURER/PROCURER]* **procurer**

Relating to *R2.1.2*, the following tables describe the systems of the *[COUNTRY OF THE LEAD PROCURER/PROCURER] procurer.*

[COUNTRY OF THE LEAD PROCURER/PROCURER]Electronic Health Record characteristics	
Please describe how the Electronic Health Record is built within your region. Provide an overall graph architecture.	
What technology is used to produce the EHR? Please describe platforms the EHR is available on, as well as databases used.	
Is the data in the EHR in one system, or a collection of systems presented in a single portal? Please describe it	
What other information systems contribute information to the EHR?	
Are the systems linked to the EHR with live data feeds, or are they based on file sharing, or broadcast messaging?	
What messaging interface standards does the EHR adhere to (e.g. HL7, Edifact, XML, or proprietary)? Please provide sufficient details about the standards – types, versions, etc. Please provide a diagram, if available.	

Please describe the user authentication model in use.	
How is the EHR made available to staff? What platform and application environment(s) is used for log-in and use of the EHR?	

Requirements related to language availability of the iProcureSecurity PCP solution

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

Requirements related to the scalability of the iProcureSecurity PCP solution

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

Requirements related to the User Interface Design of the iProcureSecurity PCP solution

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

Requirements related to the performance of the iProcureSecurity PCP solution (R2.6)

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

2.3 The iProcureSecurity PCP requirements for parameters/measuring units

Requirements related to the parameters/measuring units recorded by the iProcureSecurity PCP solution

ID	NAME	DESCRIPTION	PRIORITY
X.X	*TBD*	*TBD*	*TBD*

X.X	*TBD*	*TBD*	*TBD*
X.X	*TBD*	*TBD*	*TBD*

2.4 The iProcureSecurity PCP legal and regulatory requirements

As these are essential requirements, no prioritisation is given.

Requirements related to privacy

ID and name	Summary
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*

Requirements related to security

ID and name	Summary
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*

2.5 The iProcureSecurity PCP organisational, staff and business requirements

As these are essential requirements, no prioritisation is given.

Requirements related to installation of prototypes and systems

ID and name	Summary
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*

Requirements related to procurement reporting

ID and name	Summary
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*
RX.X.X TBD	*TBD*

The organisational, staff and business environment of the *[COUNTRY OF LEAD PROCURER/PROCURER] procurer*

Organisational, staff and business environment in [COUNTRY OF LEAD PROCURER/PROCURER]

Please list all actors involved in delivering triage during medical emergencies *[PROVIDE EXAMPLES FOR DIFFERENT EMS PRACTITIONERS AND OTHER STAKEHOLDERS INVOLVED].* For each actor, explain the role/tasks related to management of triage during medical emergencies. How does each actor use the current services and technologies? Please provide, if available, a diagram illustrating how each actor interacts with the services and systems in your pilot.	
What is the process available at your site for identification of emergency patients where triage is to be applied? What patient data is used for this? Please describe and provide references.	
Is there a shared electronic document between the EMS practitioner and the patient that is used to manage and track the condition? What are its functions and scope? What standards does it comply to? What other systems does it connect to?	
How is training for EMS practitioners conducted at your pilot? Is there an international standard and/or programme for training delivery? Please cover the following aspects:	
How do the different EMS practitioner organisations involved in the triage management communicate?	
What parameters are recorded per patient which are relevant for emergency patients. What devices are used to capture certain parameters?	
Is there a community which the EMS practitioner can join?	

2.6 Gap analysis of the current state of the art in the area of Triage Management in the iProcureSecurity PCP procurer regions

Emergency Medical Services (EMS) in Europe use a variety of triage systems, which are often adapted to local circumstances of the most likely event requiring a primary triage, and the resource capabilities of their healthcare system. The triage systems are often based on the START triage, i.e. an algorithmic classification of a victim based on the factors if the victim can walk, has the ability to follow commands, the presence of a radial pulse and the presence of breathing. The "Sieve and Sort" triage developed and applied by EMS in the UK differs to the START triage by having a primary triage procedure ("Sieve") and a secondary triage procedure ("Sort"), based on a trauma injury scoring system.

Studies on the efficiency of triage procedures themselves are limited due to the scarcity of related events. A recent study comparing START, Sieve and Sort and CareFlight triage systems highlighted differences in the accuracy of the triage classification, with a discrepancy in the classification of priority 1 (colour red – "immediate") and priority 2 (colour yellow - "delayed") tagged victims, which is a sign of over- or under-triage. The outcome for the triage classification for priority 3 (colour green – "minor") and dead or expectant (colour black) was the same for the three systems.

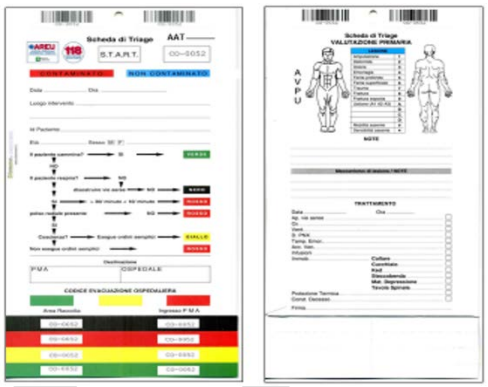

Figure 4: Example of triage paper tag

An extensive stakeholder consultation among **more than 320 EMS practitioners** and decision makers **from more than 10 European Countries** during the iProcureSecurity CSA project provided a consolidated overview on the triage routine in response to mass casualty incidents. In addition, insights on different triage scenarios (such as Subway Blast or Earthquake) were collected from EMS practitioners. Due to the large number of variables, this does not present a strict chronological sequence, as the nature of the incident, geographic circumstances, the involvement of other organisations (such as LEAs or CBRN units), the capacities of firsts responders, the vicinity of hospitals etc. will heavily influence the resolution of the incident.

Figure 5: Triage-related activities during incident resolution

The first objective after arriving at an incident location is to establish an initial situational awareness of the scope and nature of the incident and to establish a zone concept to prevent further harm and prepare the ground for setting up makeshift infrastructure which is necessary to resolve the incident. The top-level zone classification are safe and unsafe zones, with semi-safe zones that act as gateway between safe and unsafe zones, for example for decontamination, or for emergency treatment and further triage classification if the geographic distance to a safe zone is too far. Depending on the organisation, the zones can be colour coded into red/yellow/green, or titled as hot/warm/cold, non-permissive/semi-permissive/permissive, exclusion/contamination reduction/support zones. These zones can shift during the resolution, for example due to landslides, contamination, spreading fires or additional unforeseen incidents. The entry to unsafe zones is limited to personnel on site with the necessary training and protection equipment, and in the context of triage activities, focusses on transporting victims into the safe zone.

The safe zones will be further segmented into areas for gathering victims for triage, treatment or transportation (ambulances and helicopters), decontamination, morgue, supply areas, parking, designated command and communication posts as well as sanitary and dining areas for the personnel on site. Zones are logically set-up, for example triage, treatment and transportation areas are in close vicinity to shorten the times for shifting victims to different zones.

The initial primary triage is commonly based on the START triage scheme (or JumpSTART for pediatric triage), carried out by first responders, while a secondary pre-hospital triage is oriented on a numeric classification (Sieve and Sort, CRAMS), and either is carried out by a trained clinician or physician on site or at the hospital facility. The secondary triage on-site supports an efficient distribution of victims to the correct healthcare facilities depending on the type and severity of their injuries. EMS personnel is in vicinity of triaged victims awaiting transportation, so they can oversee their condition and react if it worsens, to change the treatment or prioritize them.

The organisation of the transportation of victims to hospitals is initiated immediately as part of the initial medical emergency dispatching as soon as the incident is reported, and is further expanded and optimised as more information on the scope and type of situation is available, factoring in the geographic circumstances and the route to the incident site, the type of hospital treatment and the logistic capacities for transportation and hospitalisation. The majority of work is carried out by a centralised emergency management- or dispatching centre, which maintains constant communication with healthcare facilities (to poll their capacities and capabilities) and a designated liaison officer on site (for the amount and treatment of victims) to organise the transportation logistics. The treatment history of a victim, which is maintained paper-based or electronically transcribed, is handed over at latest before the transport to a hospital facility, so that paramedics in the vehicle can continue the treatment if necessary, thus the updated information is also available at the hospital itself latest when the transports arrives at the facility.

A common factor for the triage classification is that it is carried out mainly in a manual, paper-based procedure. This means that after the assessment of a victim, the triage form is filled out by hand, and a corresponding triage tag is applied to the victim. The triage form is handed over to a centralised role (referred to as “triage officer”), who is responsible for organising any further treatment and the transportation of victims. The paper-based approach has the inherent advantage of being a proven and robust procedure which works autonomously and is familiar due to training exercises to first responders from emergency management services. A digitalisation of the triage process prerequires robust and reliable hardware devices, a sufficient wireless connection, an appropriate battery, and a high usability of the hardware and software components for users under stress or fatigue. This digitalisation circumvents flaws of the paper-based approach, which relies on the materials and information written on a triage form and tag to be resilient against external factors (weather, dirt, blood, decontamination agents). From an administrative perspective, the physical handover of the triage form to a triage officer, as well as the consolidation of the information so it can be processed by a central emergency centre, dispatching centre or hospitals requires a resource commitment and delays tactical planning on site. As the information is hand-written by people in high stress situations, potentially also under harsh environmental conditions, the procedure is prone to errors or mistakes in association to the correct victim, which is further reinforced by changing the communication medium from hand-written text to voice communication or transcription to a digital system.

3. iProcureSecurity PCP use cases

The purpose of the following chapter of the document is to help suppliers better understand the expected functionality. Individual characteristics described however may deviate from what suppliers offer. Important is that the overall functionality suppliers will offer meets the functionality expectations of the procurers. Through the dialogue planned in iProcureSecurity PCP suppliers will have the opportunity to adjust their plans, request further information from the procurers (e.g. about their legacy systems) and shape the solutions together.

The envisioned progress beyond the state-of-the art documented here represent the best attempt of the iProcureSecurity PCP procurers to define features of future systems which, individually and in total, represent significant innovation in the area of Triage Management. Nevertheless, the procurers will not accept into clinical practice any approach or system which has not shown cost-effectiveness. Cost-effectiveness will in all cases requires proper evidence of reliable positive outcomes and absence of patient risk. It follows that, where requirements go beyond state-of the-art, it is the tenderers' responsibility to ensure that evidence for positive outcomes is available or will be provided. If the latter, tenderers with clear plans to provide such evidence at or before completion of the iProcureSecurity PCP procurement execution will be favoured over those hoping unnamed third parties will deliver the necessary evidence.

From a data perspective, the scope of the PCP is to establishing an interoperability concept for the mentioned systems on-site, and defined, clean handovers points towards emergency dispatching and healthcare organisations, as outlined in the figure below:

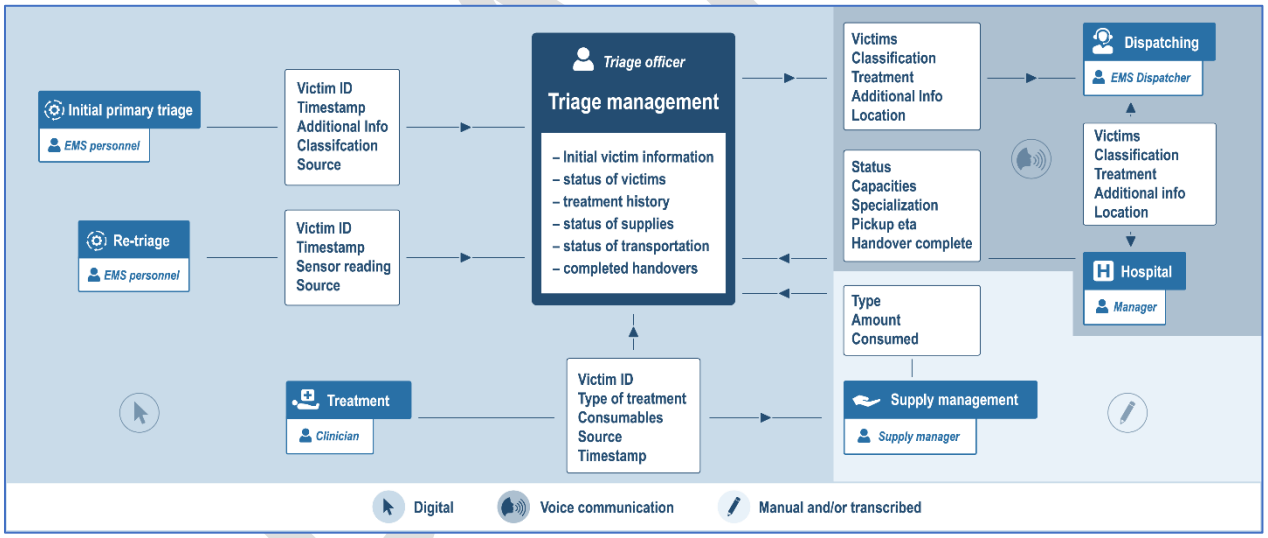

Figure 6: Scope of Formal and informal information flows during triage

In addition to increasing the efficiency of the triage routing on site, indirect benefits can be derived from the digitalisation. It is possible to create a consistent, chronological tracking of a victim's history on site, ranging from their initial triage classification, the treatment they received on site, how their condition developed on site, and their handover for transportation, which can prove helpful for the further treatment. Long-term, the data will also prove beneficial for a structured analysis of how the incident situation evolved on site, which is important to identify potential weaknesses in the current operational procedures, to adjust the routines and incorporate into trainings.

A shortcoming in the current triage procedures, which is not properly addressed, is the **need for a re-triage**, i.e. a monitoring of the condition and vital signs of already triaged victims on site. This is especially important for victims which were initially classified as green/minor or yellow/delayed, but if their condition worsens, they would fall into a different triage classification. To counteract this risk, routines on site need to be established to regularly control these victims, which also binds valuable

human resources on site. In a digitalised environment, sensor technologies (e.g. wearable sensors for remote health monitoring) can carry out the necessary routine checks instead and broadcast the victim's data to a central management instance, which gives the triage officer an overview of the condition of the victims on site and reallocate his or her resources accordingly, thus allowing a reactive and resource-optimised re-triage. The feasibility of this approach has been evaluated from a technical and process perspective in multiple studies[1][2][3].

A concluding aspect is **data interoperability**, which encompasses information generated on the triage situation and victims on site or an overall situation assessment, which is vital for other emergency services – but also governs digital support to formulate local resource demands for medication, equipment, personnel or logistical support. Interoperability standards for message exchange in emergency situations exist, such as the OASIS Emergency Data Exchange Language (EDXL)[4] or the Emergency Management Shared Information (EMSI) message format described in ISO/TR 22351:2015[5] which offer a rich domain model and taxonomy suited for the use cases of a mass casualty situation. However, as the support of these standards is not mandatory for national emergency management systems, and grown, legacy emergency management systems often build on bespoke system interfaces, the proliferation of these standards for data exchange of emergency management systems is not progressed enough to rely on a seamless integration between different emergency management services on site. Retrieving patient data in healthcare-specific formats, such as HL7 (ISO/HL7 27931:2009[17]) or based on the SNOMED CT[6]terminology model can prove valuable to gather patient data for victims in case they can be identified, for example on allergies or medications to improve their treatment. These standards can also fulfil a vital role in describing the condition of a victim to optimise the handover to hospitals.

Establishing standards for data interoperability in the triage process is a **major enabler** to support in streamlining the entire administrative procedure and related resource planning and disposition activities, and will reduce the complexity and costs of system integration for industrial companies and suppliers. Furthermore, cross-border disaster relief operations, especially if multiple emergency organisations from different countries are involved, would greatly benefit from this standardisation.

Most importantly, it will provide **the technical foundation for any further digitalisation**, such as optimising handover of victims to the hospital environment, increasing the efficiency of dispatching activities, or allowing the integration of advanced sensor technologies to assess the incident situation and prevent further harm to EMS and victims on site[7][8]. Lastly, geotagging metadata provides the foundation to integrate data in a superordinated situation pictures for tactical decision support.

[1] Killeen, J.P., Chan, T.C., Buono, C., Griswold, W.G. and Lenert, L.A. (2006). A wireless first responder handheld device for rapid triage, patient assessment and documentation during mass casualty incidents. In AMIA annual symposium proceedings (Vol. 2006, p. 429). American Medical Informatics Association.

[2] Rodriguez Martinez, J.D. (2018). A Wearable Platform for Patient Monitoring During Mass Casualty Incidents. KIT Scientific Publishing.

[3] Albahri, O.S., Albahri, A.S., Mohammed, K.I., Zaidan, A.A., Zaidan, B.B., Hashim, M. and Salman, O.H. (2018). Systematic review of real-time remote health monitoring system in triage and priority-based sensor technology: Taxonomy, open challenges, motivation and recommendations. Journal of medical systems, 42(5), p.80.

[4] Emergency Data Exchange Language (EDXL) Distribution Element Version 2.0, Committee Specification 02, 19 September 2013, http://docs.oasis-open.org/emergency/edxl-de/v2.0/edxl-de-v2.0.html retrieved on 04.08.2020

[5] ISO/TR 22351:2015, Societal security — Emergency management — Message structure for exchange of information, September 2015, https://www.iso.org/standard/57384.html retrieved on 04.08.2020

[6] SNOMED CT International Edition 2020-07-31, July 2020, http://www.snomed.org/; https://browser.ihtsdotools.org/ retrieved on 05.08.2020

3.1 Use Case 1

[USE CASE DESCRIPTIONS]

ID	*UC XX*
TITLE	*TBD*
SUMMARY	*TBD*
ACTORS	*TBD*
PARENT	*TBD*
CHILDREN	*TBD*
PRE-CONDITIONS	*TBD*
KEY FUNCTIONALITIES	*TBD*
POST-CONDITIONS	*TBD*
TRIGGERS	*TBD*
FREQUENCY	*TBD*
OPEN ISSUES / NOTES	*TBD*

3.2 Use Case n

[USE CASE DESCRIPTIONS]

ID	*UC XX*
TITLE	*TBD*
SUMMARY	*TBD*
ACTORS	*TBD*
PARENT	*TBD*
CHILDREN	*TBD*
PRE-CONDITIONS	*TBD*
KEY FUNCTIONALITIES	*TBD*
POST-CONDITIONS	*TBD*
TRIGGERS	*TBD*
FREQUENCY	*TBD*
OPEN ISSUES / NOTES	*TBD*

4. The iProcureSecurity PCP change management strategy framework

The iProcureSecurity PCP solution is expected to be innovative and influence current ways the eight procurers provide triage management to emergency patients, 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 to be used in the project.

4.1 Literature overview

The change management literature reflects two core modes of change management: planned change management and emergent change management. Planned change management dominates the academic literature and owes much to the work of Kurt Lewin. The planned change approach views change as a transitional process between fixed states. Throughout this process, a series of pre-planned steps are employed, thereby making this approach amenable to research analysis. The planned change approach recognises that, in order to successfully adopt new behaviours within an organisation, old behaviours must be relinquished. It should be noted that planned change makes an assumption that, overall, the change targets within an organisation will agree with management's vision of change and the steps designed to transition towards the "changed" state. In practice, this scenario rarely exists as workers within an organisation come from different backgrounds and have varying attitudes, beliefs, and needs. This reality makes a state of complete agreement on a course of action virtually impossible. Moreover, planned change places too much emphasis on the role of managers and obscures the contributions of employees in the change process. By placing an emphasis on pre-planned processes, timetables, and objectives, all of which are developed by management, this approach obscures the impacts employees have on change initiatives. Emergent change is a newer concept and lacks a single theoretical alternative to planned change. Rather, the emergent change field consists of many unrelated theories presenting varying approaches to change management. The emergent change approach views change as a less prescriptive and more analytical undertaking. While change will ultimately transition an organisation from one state to another, this approach places less emphasis on plans and projections to focus on understanding the complexity of the business environment and developing a range of alternatives to guide decision making. The emergent change approach recognises that change must be linked to market forces, work organisations, systems of management control, and the shifting nature of organisational boundaries and relationships. Unlike planned change, emergent change emphasises a "bottom up" approach to change management. While the planned change model emphasises preplanned processes and objectives that underscore the role of management, the emergent change approach argues that the pace and nature of change is so rapid and complex that management may have difficulties identifying changes and devising strategies to address them in a timely fashion. As a result, managers must cede some of the decision-making authority to employees and act as facilitators of change as opposed to controllers of change.

The Multilevel Approach

Individual Approach

Strategies focusing on individuals alone in efforts to improve quality are seldom effective by themselves. Educational strategies may be more powerful if used in conjunction with other interventions. This is because individual approaches fail to recognize that medicine is largely practiced as part of a group or team embedded within complex organisational structure.

Groups, Teams and Microsystems

Most health and medical services are delivered in groups or teams. Teams represent a potentially powerful lever for change and are a basic building block for Microsystems. A microsystem is the smallest replicable unit within an organisation; in the sense, that it contains within itself the necessary

human, financial, and technological resources to do its work. The microsystem concept is emerging as the focus for clinical quality-improvement work. There is evidence that effectively functioning teams or Microsystems are generally associated with higher quality of care, but the challenge is to develop effective teams.

Organisation level

The importance of the organisation as a lever of change to improve quality lies in the organisation's ability to provide an overall climate and culture for change through its various decision-making systems, operating systems and human resources practices. Pettigrew (1992) suggested that identifying receptive contexts for change may be more important than identifying effective levers for change that might work across all contexts. The underlying culture of the organisation may be an important conditioning factor for identifying those contexts. This organisational capacity can be built up over time, but it is a slow and complex task.

Large Systems and Environment

Strong change strategies may require that organisational-level shifts be reinforced by macrolevel changes in the wider political economy or market of health care.. The multilevel approach to change does not mean that every change effort must be directed to all four levels simultaneously. Rather, it means that a change aimed primarily at one level would be considered within the context of the other three levels. It is unlikely that health care organisations would be able to respond to the publication of such performance data without initiating secondary levels of change at the team and individual levels. Similarly inside/out approaches, such as collaborations aimed at improving the performance of individuals and teams, are unlikely to succeed without a supportive organisational environment and a favourable payment and regulatory environment. The issue is one of anticipating the barriers to change at levels proximate to the primary level of change intervention and to implement strategies for dealing with resistance.

Resistance to Change

Resistance to change is an ongoing problem. At both the individual and the organisational levels, resistance to change impairs concerted efforts to improve performance. Many corporate change efforts have been initiated at tremendous cost only to be halted by resistance among the organisation's employees. Organisations as a whole also manifest behaviour similar to that of individuals when faced with the need to change. The relationship between individual and organisational resistance to change is important. An organisation is a complex system of relationships between people, leaders, technologies, and work processes. From this interaction emerges organisational behaviour, culture, and performance. These emergent properties and behaviors are tightly linked in two directions to the lower-level interactions. Organisational resistance to change is an emergent property, and individual resistance to change can give rise to organisational resistance. A self-reinforcing loop of increasing resistance can develop as individuals create an environment in which resistance to change is the norm. That environment in turn encourages increased resistance to change among individual employees. The self-reinforcing nature of this loop can be tremendously powerful, defeating repeated attempts to break out of it.

Leaders and managers of change sometimes cannot understand why individuals and groups of individuals do not wholeheartedly embrace changes that are being introduced. They often label this 'resistance to change'. Schein suggests that there are two principles for transformative change to work: first, survival anxiety must be greater than learning anxiety, and second, learning anxiety must be reduced rather than increasing survival anxiety. Used in connection with Lewin's force field, the survival anxiety becomes a driving force and learning anxiety is a restraining force. Rather than attempting to increase the individual or group's sense of survival anxiety, Schein suggests reducing the individual's learning anxiety.

4.1.1 Change Management models

Planned change models

Phases of change by Kurt Lewin

Lewin's theory is a simple model, focusing on social changes within a community. The theory is seen as the starting point for other models regarding change management. Lewin talks about three different phases: Unfreezing, Moving and Freezing. The first phase (unfreezing) emphasizes the preparation for change. In this stage, plans are communicated and affected people are brought into the discussion in order to support the change process and to analyse the situation. The second phase (moving) leads over to the new circumstances. In this stage, new standards are implemented through the interventions of the authorities and training. The last phase (freezing) is to consolidate the change process. This is finished, when the changes have been implemented successfully into the affected group. To ensure the success of implementation, the whole process is supervised. Lewin's theory does not go deeper on the different phases of this process and is therefore only a starting point for more practical theories.

8-step process by John P. Kotter

Thirty years of research by leadership guru Dr. John Kotter have proven that 70% of all major change efforts in organisations fail, because organisations often do not take the holistic approach required to see the change through. The 8-step process for leading change, by John Kotter, shows organisations how to avoid failure and become adept to change. The 8 steps are explained below.

Step	Approach	Risks
1) Establish a sense of urgency	• Acquire the cooperation of individuals • Examine the firm's competitive realities, market trends, effects on financial performance • Communicate information gained in respect of potential crises	• Urgency rate might e not high enough to prevent internal problems • Underestimating the complexities and struggles from management shift • Tendencies become overwhelmed by the risk involved
2) Create the guiding coalition	• Form a powerful coalition in terms of titles, information, expertise, reputation and relationships • Operate outside of the normal hierarchy by definition, outside of formal boundaries, expectations, and protocol • Emphasis team work and whilst recognizing the power of a strong line management leadership within the coalition	• Maintaining the existing hierarchy where if that were working well, there would be no need for a major transformation • Coalition members having no history of teamwork at the top and therefore undervalue the coalitions importance • Not lead by a strong line manager
3) Develop a vision and strategy	• A vision beyond the numbers that clearly defines where the organisation is going.	• Plans, directives, and programs with no vision, but confused staff.

	• Clear and precise project plans that take the organisation in the direction it needs to move to achieve the vision	• List of confusing and incompatible projects and activities that can take the organisation in the wrong direction or nowhere at all
4) Communicate the change vision	• Brighten up the company's existing communications methods. Try new and different methods for sharing the vision. • Use every vehicle possible to communicate the strategies for achieving it. • Emphasise and teach new behaviors by the example of the guiding coalition	• A vision is developed, but only a single form of communication is used. • Management not walking the talk. Deeds speak louder than words. • Not enough communication to remind of the desired behaviours
5) Empower employees to broadband action	• Action is essential in getting rid of obstacles to change and in time, the big ones must be confronted and removed. • Empower people to maintain the credibility of the change effort as a whole, to try new approaches, to develop new ideas, and to provide leadership. • Change Systems and structures that seriously undermine the vision. • Encourage risk taking and nontraditional ideas, activities, and actions	• Failing to remove powerful individuals who resist the change effort and who resist individual employees who want to help make it happen. • Organisational structures such as human resource systems that remain intact even when there are clearly inconsistent compensation or performance-appraisal structures.
6) Generate short term wins	• Develop clear performance improvements goals and measurement systems and reward the people involved when they are achieved. • Maintain commitments to achieve short term goals to help maintain a high urgency level and force deep thinking that can clarify visions	• Without short-term wins, too many people give up or actively join the ranks of those people who have been resisting change. • Absence of defined and measured short term goals - urgency levels can drop • Leaving results to chance
7) Consolidate Gains and Produce More Change	• Use increased credibility from early wins to change 'the old way we do things around here' systems, structures, and	• Declaring victory before the changes and business improvements have sunk

	policies that are undermining the vision and have not been confronted before. • Understand that renewal efforts take not just months but often years. • Promote, hire, develop employees and use change agents who can implement the vision.	deeply into a company's culture. • Having premature victory celebrations that kill ongoing momentum • Allowing the powerful resistors and use change agents who can implement the vision. associated with tradition take over
8) Anchor New approaches in the Culture	• Communicate frequently how the new approaches, behaviors, and attitudes have improved performance • Create leadership development and succession plans consistent with the new approach	• New behaviors not rooted in social norms and shared values; they are subject to degradation as soon as the pressure for change is removed. • Not ensuring that the next generation of top management understand the transformation that has taken place and personify themselves, the new approach • Poor succession decisions because boards of directors are not an integral part of the renewal effort

Lewin	Bullock and Batten	Kotter	Lippitt
Unfreezing	*Phase 1 - Exploration*: The organization has to make a decision on the need for change	*Step 1*: Establish a sense of urgency	*Phase 1:* Diagnose the problem
			Phase 2: Assess motivation and capacity for change
	Phase 2 - Planning: Understand the problem	*Step 2*: Create a guiding coalition	*Phase 3:* Assess change agent's motivation and resources
		Step 3: Develop a vision and strategy	
Moving	*Phase 3 - Action*: Changes identified are agreed upon and implemented	*Step 4*: Communicate the change vision	*Phase 4:* Select a progressive change objective
		Step 5: Empower employees for broad-based action	
		Step 6: Generate short-term wins	*Phase 5:* Choose appropriate role of the change agent
		Step 7: Consolidate gains and produce more change	
Refreezing	*Phase 4 - Integration*: Stabilize and embed change	*Step 8*: Anchor new approaches in the culture	*Phase 6:* Maintain change
			Phase 7: Terminate the helping relationship

Figure 7: Bullock and Batten, Kotter, and Lippitt Change Management Models as they relate to the Lewin's 3-Step Mode

PDCA cycle by Walter Andrew Shewhart PDCA (plan–do–check–act or plan–do–check–adjust, also known as the Deming circle/cycle/wheel and Shewhart cycle) is an iterative four-step management method used in business for the control and continual improvement of processes and products.

Plan: Establish the objectives and processes necessary to deliver results in accordance with the **expected output (the target or goals).**

Do: Implement the plan, execute the process, make the product. Collect data for charting and analysis in the following "CHECK" and "ACT" steps.

Check: Study the actual results (measured and collected in "DO" above) and compare against the expected results (targets or goals from the "PLAN") to ascertain any differences. Look for deviation in implementation from the plan and also look for the appropriateness and completeness of the plan to enable the execution.

Act: If the CHECK shows that the PLAN that was implemented in DO is an improvement to the prior standard (baseline), then that becomes the new standard (baseline) for how the organisation should ACT going forward (new standards are enACTed). If the CHECK shows that the PLAN that was implemented in DO is not an improvement, then the existing standard (baseline) will remain in place. In either case, if the CHECK showed something different than expected (whether better or worse), then there is some more learning to be done, and that will suggest potential future PDCA cycles.

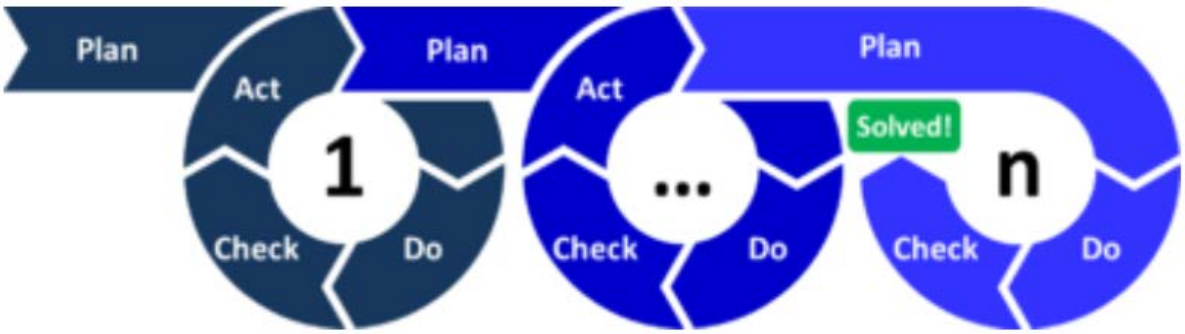

Figure 8: Multiple iterations of the PDCA-cycle by Walter Andrew Shewart and William Edwards Deming

Emergent change models

The emergent approach to change management is relatively new and currently lacks a principle theoretical foundation. Supporters of this approach are more united in their stance against planned change than in agreement about any particular alternative. Currently, the most commonly cited models of emergent change management include: Hinings and Greenwood's model of change dynamics; Kanter et al.'s "Big Three" model of organisational change; and Pettigrew's process/content/context model.

Hinings and Greenwood's Model of change dynamics

Change involves a complex interaction of organisational context and internal organisational processes. Change, as per this model, is an unfolding series of circumstances and actions stemming from unanticipated consequences and a moving context. The model of change dynamics posits that change occurs through the interplay of five factors: situational constraints, interpretive schemes, interests, dependence of power, and organisational capacity. Each of these factors is dynamic and managers must recognize and determine appropriate responses to each:

- **Situational constraints are environmental:** technological and size-related factors that may necessitate change, or enhance or thwart an organisation's ability to achieve successful change
- **Interpretive schemes:** are ideas, beliefs, and values that underlie the operations of an organisation. These form the foundation upon which organisational design arrangements and structures are built.
- **Interests:** represent the orientation and motivation of members of an organisation to maintain and enhance their sectional claims. While organisational subunits are, in theory, interdependent, interactions between units may become disruptively competitive.
- Dependencies of power: represent the power relations within an organisation. These relations determine which organisational actors have the capacity to determine outcomes and influence decisions.
- Lastly, the ability of an organisation to achieve successful change is dependent on the skill of its leadership to generate commitment and excitement over the prospect of change, that is, the extent of transformational leadership, and its ability to construct and communicate its vision of change. These two capabilities define an organisation's capacity.

Kanter's "Big Three" Model of organisational 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.

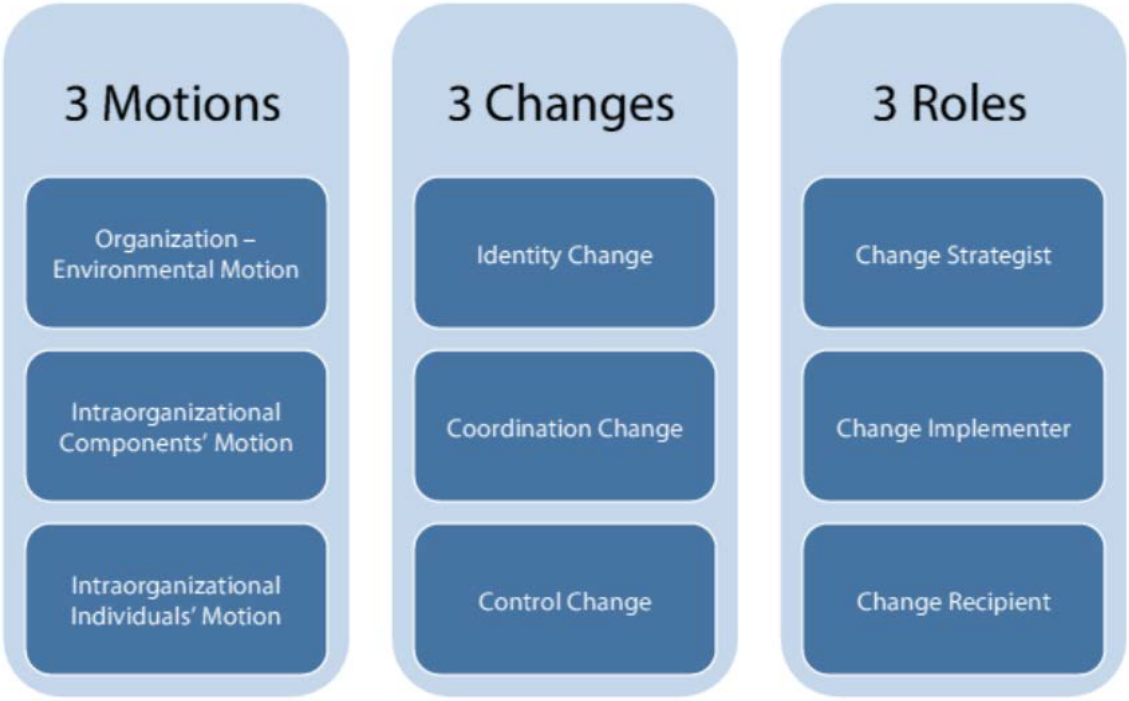

Figure 9: The Big Three model

Pettigrew's Context/Content/Process model

Pettigrew's Context/Content/Process model acknowledges the complexity and incessancy of change, but also perceives change as purposive because it is undertaken in search of a competitive advantage and not merely as a tool to keep up with the external environment. In this model, context consists of an organisation's internal environment – its structures, culture, power distributions, skill base, and resources – as well as its external environment – the economic, legal, and social circumstances under which it operates. As external environments change, internal environments must also be changed to accommodate the external changes. Content entails the components of change and draws on both internal and external logics. Thus, the content of change should respond to the factors in the external environment, such as market opportunities, as well as to those within the organisation, such as improving operational efficiency. Management must exhibit leadership in the ability to conceptualize change and inspire others in the organisation towards achieving this vision of change.

The process of change includes the operational activities undertaken to materialize change. This component of Pettigrew's model can be divided into three factors that managers must address: development of the logic of change implementation, managing the change transition, and curtailing resistance to change. Process represents the final stage of the conceptual model of change. As such, process can only be determined after a thorough understanding of the

organisational context has been attained and the perspectives of all individuals involved in the change process have been considered in the content stage.

The Context/Content/Process model encourages change leaders to be well aware of the organisational context, including internal structures and external constraints, in order to improve the likelihood of success of their change initiatives. Furthermore, managers should ensure the content of change resonates with all those involved in the change process. Only after these prerequisites are met can the process of change implementation be mapped out.

4.2 Learning from existing change management knowledge gathered by EU projects

[TBD]

4.3 Approach to change management in iProcureSecurity PCP

[TBD]

Project Acronym: **iProcureSecurity PCP**

Grant Agreement number: **XXXXXX**

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

PCP Framework Agreement
Declaration of Honour on Exclusion Criteria

The undersigned [insert full name of the signatory of this form], representing:

(only for natural persons) himself or herself:	**(only for legal persons) the following legal person:**	
ID or passport number: [insert ID/passport number] ('the person')	Full official name:	[...]
	Official legal form:	[...]
	Statutory registration number:	[...]
	Full official address:	[...]
	VAT registration number:	[...]
	('the person')	

1 Exclusion grounds relating to the conflict of interest

(1)	declares that a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers company directors, members of management or supervisory bodies, and cases where one natural person holds a majority of shares):	Yes	No
	is involved in any current or potential conflict of interest, as indicated in the Call for tender under section 5.2, due to its participation in the procurement procedure or for other reasons.	☐	☐

2 Situation of exclusion concerning the person

(2)	declares that the above-mentioned person is in one of the following situations:	Yes	No
(a)	it is bankrupt, subject to insolvency or winding up proceedings, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;	☐	☐
(b)	it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract;	☐	☐
(c)	it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility	☐	☐

	where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		
	(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract;	☐	☐
	(ii) entering into agreement with other persons with the aim of distorting competition;	☐	☐
	(iii) violating intellectual property rights;	☐	☐
	(iv) attempting to influence the decision-making process of the contracting authority during the award procedure;	☐	☐
	(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;	☐	☐
(d)	it has been established by a final judgement that the person is guilty of the following:		
	(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	☐	☐
	(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;	☐	☐
	(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;	☐	☐
	(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;	☐	☐
	(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;	☐	☐
	(vi) child labour or 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;	☐	☐
(e)	the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;	☐	☐
(f)	it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	☐	☐

(g)	for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to: i. facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; ii. non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics; iii. decisions of the ECB, the EIB, the European Investment Fund or international organisations; iv. decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or v. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.	☐	☐

3 Situations of exclusion concerning natural persons with power of representation, decision-making or control over the legal person

(3)	declares that a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers company directors, members of management or supervisory bodies, and cases where one natural person holds a majority of shares) is in one of the following situations:	Yes	No	N/A
	Situation (c) above (grave professional misconduct)	☐	☐	☐
	Situation (d) above (fraud, corruption or other criminal offence)	☐	☐	☐
	Situation (e) above (significant deficiencies in performance of a contract)	☐	☐	☐
	Situation (f) above (irregularity)	☐	☐	☐

4 Situations of exclusion concerning natural or legal persons assuming unlimited liability for the debts of the legal person

(4)	declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations:	Yes	No	N/A

	Situation (a) above (bankruptcy)	☐	☐	☐
	Situation (b) above (breach in payment of taxes or social security contributions)	☐	☐	☐

5 Grounds for rejection from this procedure

(5)	declares that the above-mentioned person:	Yes	No
(h)	has distorted competition by being previously involved in the preparation of procurement documents for this procurement procedure.	☐	☐

6 Remedial measures

If the person declares one of the situations of exclusion listed above, it must indicate measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

7 Evidence upon request

Upon request and within the time limit set by the contracting authority the person must provide information on the persons that are members of the administrative, management or supervisory body. It must also provide the following evidence concerning the person itself and concerning the natural or legal persons which assume unlimited liability for the debt of the person:

> For situations described in (a), (c), (d) or (f), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.
>
> For the situation described in point (a) or (b), production of recent certificates issued by the competent authorities of the State concerned is required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure. The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	Full reference to previous procedure
[Insert as many lines as necessary.]	

[Insert as many lines as necessary.]	

8 Evidence for selection

The signatory declares that the above-mentioned person is able to provide the necessary supporting documents listed in the relevant sections of the tender specifications and which are not available electronically upon request and without delay.

The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	Full reference to previous procedure
[Insert as many lines as necessary.]	
[Insert as many lines as necessary.]	

The above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

Full name(s)	Date	Signature(s)

Project Acronym: **iProcureSecurity PCP**

Grant Agreement number: **XXXXXX**

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

PCP Framework Agreement
Declaration of Honour on Compliance Criteria

I, the undersigned (name and surname)[1]

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. CIF nº

[1] If the bidder is a consortium or group of bidders, each member shall submit this statement.

HEREBY STATE AND DECLARE

Under my own personal responsibility, fully aware of the infringements and penalties provided for in Spanish law in case of fraudulent statements,

THAT

COMPLIANCE CRITERIA

The Bidder complies with compliance criteria set out under section 4.4 of the Call for tender.

Accordingly, the undersigned formally declares that the information stated below 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 requested.

1.1.1 COMPLIANCE WITH THE DEFINITION OF R&D SERVICES

Does the bidder guarantee that it is in compliance with the requirements regarding the definition of R&D services as set out in the clause 4.4.1 of the request for tender?

Yes / No

Attention: please keep in mind that the presentation of the evidences set out in Section 4.4.1 of the Call for tender is required.

1.1.2 COMPATIBILITY WITH OTHER PUBLIC FINANCING

Does the bidder 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 clause 4.4.2 of the Call for tender?

Yes / No

1.1.3 COMPLIANCE WITH THE REQUIREMENTS RELATING TO THE PLACE OF PERFORMANCE OF THE CONTRACT

Does the bidder guarantee that in case of selection it will comply with the requirements stated under the clause 4.4.3 of the Request for tender regarding the place of performance of the contracts?

Yes / No

Attention: please keep in mind that the presentation of the evidences set out in Section 4.4.3 of the Call for tender is required.

1.1.4 COMPLIANCE WITH ETHICS AND RESEARCH INTEGRITY REQUIREMENTS

Does the bidder guarantee that in case of selection it will comply with the rules regarding ethics, data protection and research integrity set out in the clause 4.4.4 of the Request for tender?

Yes / No

Attention: please keep in mind that the presentation of the evidences set out in Section 4.4.4 of the Call for tender is required.

1.1.5 COMPLIANCE WITH SECURITY REQUIREMENTS

Does the bidder guarantee that in case of selection it will comply with the provisions regarding security set out in the clause 4.4.5 of the Call for tender?

Yes / No

Attention: please keep in mind that the presentation of the evidences set out in Section 4.4.5 of the Call for tender is required.

1.1.6 COMPLIANCE WITH USABILITY AND INTEROPERABILITY REQUIREMENTS

Does the bidder guarantee that in case of selection it will comply with the provisions regarding usability and interoperability set out in the clause 4.4.6 of the Call for tender?

Yes / No

Attention: please keep in mind that the presentation of the evidences set out in Section 4.4.6 of the Call for tender is required.

1.1.7 COMPLIANCE WITH DATA MANAGEMENT REQUIREMENTS

Does the bidder guarantee that in case of selection it will comply with the provisions regarding data management set out in the clause 4.4.7 of the Call for tender?

Yes / No

Attention: please keep in mind that the presentation of the evidences set out in Section 4.4.7 of the Call for tender is required.

In witness whereof I sign this affidavit.

[DATE AND PLACE]

..... [Name of the institution]

Signature(s)

Name(s)

Title(s)

Project Acronym: **iProcureSecurity**

Grant Agreement number: **XXXXXX**

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

Power of Attorney

POWER OF ATTORNEY

mandating one of the partners in an iProcureSecurity PCP joint tender as Lead Contractor

The undersigned:

– Signatory: (please enter Name, Function, Company, Registered address, VAT Number)

having the legal capacity required to act on behalf of his/her company,

HEREBY AGREES TO THE FOLLOWING:

1) To submit a tender as a partner in the group of partners constituted by [NAMES OF ALL SUPPLIERS IN CONSORTIUM] and led by [LEAD CONTRACTOR NAME], in accordance with the conditions specified in the iProcureSecurity PCP Request for Tender and the terms specified in the tender to which this power of attorney is attached.

2) If the iProcureSecurity PCP Buyers Group represented by their Lead Procurer (the Buyers Group) awards a Specific Contract under the iProcureSecurity PCP Framework Agreement to the group of partners constituted by [NAMES OF ALL SUPPLIERS IN CONSORTIUM] and led by [LEAD CONTRACTOR NAME], on the basis of the joint tender to which this power of attorney is attached, all the partners shall be co-signatories of the Framework Agreement and Specific Contract in accordance with the following conditions:

(a) All partners shall be jointly and severally liable towards the Buyers Group for the performance of the Framework Agreement and Specific Contract.

(b) All partners shall comply with the terms and conditions of the Framework Agreement and Specific Contract and ensure the proper delivery of their respective share of the services and/or supplies subject to the Framework Agreement and Specific Contract.

3) Payments by the Buyers Group related to the services and/or supplies subject to the Specific Contract shall be made through the Lead Contractor's bank account:

[NAME AND ADDRESS OF BANK]

[ACCOUNT IBAN]

[ACCOUNT SWIFT CODE]

4) The partners grant to the Lead Contractor all the necessary powers to act on their behalf in the submission of the tender and conclusion of the Framework Agreement and Specific Contract, including:

(a) The Lead Contractor shall submit the tender on behalf of the group of partners.

(b) The Lead Contractor shall sign any contractual documents — including the Framework Agreement and Specific Contract, and Amendments thereto — and issue any invoices related to the services on behalf of the group of partners.

(c) The Lead Contractor shall act as single point of contact with the Buyers Group in the delivery of the services and/or supplies subject to the Specific Contract. It shall co-ordinate the delivery of the services and/or supplies by the group of partners to the Buyers Group, and shall see to a proper administration of the Framework Agreement and Specific Contract.

Any modification to the present power of attorney shall be subject to the express approval of the Buyers Group. This power of attorney shall expire when all the contractual obligations of the group of partners towards the Buyers Group under the Framework Agreement and for the delivery of the

services and/or supplies subject to the Specific Contract have ceased to exist. The parties cannot terminate it before that date without the consent of the Buyers Group.

Signed in …… on [dd/mm/yyyy]

Place and date

Name (in capital letters), function, company and signature:

Name (in capital letters), function, company and signature:

Name (in capital letters), function, company and signature:

Tender application for iProcureSecurity PCP

Project Acronym: **iProcureSecurity PCP**
Grant Agreement number: **XXXXXX**
Project Title: **Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services**

[Title of proposal]

ADMINISTRATIVE SECTION

List of participants

Participant No *	Participant organisation name	Country
1 (Coordinator)		
2		
3		

TABLE OF CONTENT

1 Overview

The following sections provide a framework for presenting all administrative information. Sections may be added if required.

Clarification or additional evidence may be requested where there is any doubt.

More detailed information for the phase 2 and 3 offers may be provided in the call-offs.

2 Identification of the tenderer

Provide here the documentary evidence necessary to identify the tenderer.

Provide a complete list of authorised signatories for the tenderer.

3 Declarations of honour

Please provide a Declaration of Honour on Compliance Criteria (TD3b).

Please provide Declarations of Honour on Exclusion Criteria (TD3a) for:

- in case of single tenderer, the contractor
- in case of joint tenders, the lead contractor and each member of the consortium or group
- In case of subcontracting, all subcontractors whose share of the contract is above 30 % or whose capacity is necessary to fulfil the selection criteria.

4 Power of Attorney for the lead contractor

(Joint bids only) Provide the mandate for the lead contractor using the power of attorney template (TD4) filled in for each member of the consortium or group.

5 Compliance with selection criteria

Provide the required evidence of your compliance with selection criteria A to D below. In addition to providing the evidence specified in each section below, please also:

- provide a description of relevant reference and /or previous projects (executed during the last 5 years);
- demonstrate the expertise and working experience required to undertake an innovative R&D project by providing CVs for key personnel and competences the tenderer considers necessary to complete the project;
- confirm that the tenderer has a Business Continuity / Disaster Recovery / Risk Management plan that ensures the described services are delivered in the event of a disruption affecting the tenderer's business and ensuring continuity of supply / service from critical suppliers;
- confirm that the tenderer will take the appropriate level of insurance cover if awarded the contract.

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

5.1 Criterion A: Ability to perform R&D up to original development of the first products or services

The evidence required is a 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.

5.2 Criterion B: Medical capacity in relation to Triage Management

The evidence required is description of the capacity to create a solution in the field of Triage Management Systems and to judge the quality of medical algorithms and learning material as well as to understand the medical procedures and practices.

5.3 Criterion C: eHealth capacity

The evidence required is description of the capacity to develop clinical solutions and SaMD (Software as a Medical Device)

5.4 Criterion D: Commercially exploit the results of the PCP, including intangible results in particular IPRs

The evidence required is description of the financial and organisational structures that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results

Tender application for iProcureSecurity PCP

Project Acronym: **iProcureSecurity PCP**
Grant Agreement number: **XXXXXX**
Project Title: **Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services**

[Title of proposal]

TECHNICAL SECTION (max. 100 pages in length)

List of participants

Participant No *	Participant organisation name	Country
1 (Coordinator)		
2		
3		

TABLE OF CONTENT

LIST OF TABLES

Executive Summary

Give a summary of the technical section to serve as abstract (max. 2,000 characters)

Indicate the validity of period of your offer (starting from the submission date) which cannot be less than six months.

The structure of this template must be followed when preparing your proposal. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the evaluation criteria. Sections 1, 2 and 3 each correspond to an evaluation criterion for a full proposal.

Page limit: For full proposals, the cover page and all sections together should not be longer than 100 pages. Any information exceeding the 100 pages will not be considered in the evaluation.

1 Excellence of the proposed solution

1.1 Understanding of the domain of iProcureSecurity PCP

Describe your understanding of the vision of iProcureSecurity PCP underlying the call for tenders, including issues involved in improving the Triage Management in healthcare systems in procurer countries.

Describe the constraints and opportunities of the PCP funding programme as they apply to your proposed work.

Check that the "proposed solution" is a solution to the problem, that is, not just an ICT system but its actual use (is a system, not used, a "solution"?)

Give an overview of relevant state of the art in supporting triage management using information and communication technology.

1.2 Detailed description of the proposed solution

Describe the proposed solution, including the main ideas, models and/or assumptions involved. Describe the functionalities supported / services provided by the ICT systems which are part of the proposed solution. Describe, to the extent possible, the processes in which systems are to be used, making as clear as possible how specific types of use of the systems by patients, EMS (Emergency Medical Services) practitioners and others can be expected to deliver benefits to patients and procurer health systems.

1.3 Matching the iProcureSecurity PCP vision

Describe how your approach will realise the iProcureSecurity PCP vision and matches the scope of iProcureSecurity PCP.

1.3.1 Level of innovation

Describe how your approach and solution represents an innovation compared to current systems and practice.

1.3.2 Added value beyond the iProcureSecurity PCP technical specification

Detail any added value of the proposed solution and its use beyond the requirements documented. Make specific reference to functionalities detailed in section 1.2 above.

1.4 Meeting the iProcureSecurity PCP requirements

It will be discussed in phase 0 of the PCP whether this section should include a table with the technical specifications (requirements, use cases) to ensure easier evaluation.

Explain how the proposed solution meets the requirements documented in the Call. Make specific reference to functionalities detailed in section 1.2 above.

We recommend structuring this along the use cases outlined in the PCP challenge and the following table.

Objective X:	Deliverable No.1	Where (page in offer) ?	Use of background?	Beyond the state of the art?
Req1				
Req2…				

1.5 Evidence for effectiveness

Describe any evidence available which helps show the effectiveness of the proposed solution.

2 Impact of the proposed solution

2.1 Benefits for patients

Describe the benefits EMS are expected to receive when the proposed solution is in operation. Benefits for EMS may include for example:

- Increased reduction of time between injury and medical intervention
- Increased accuracy in tagging patients
- Increased rapid transportation of the patients according to their status
- Ensures high level of protection of patients' personal (medical) data
- [INCLUDE FURTHER POINTS]

To assess the business case for acquisition of the proposed solution by health services, quantification of benefits will be necessary. Realistic estimates of benefit quantities should be provided where possible, expressed per [INCLUDE MEASURE].

2.2 Benefits for procurers

Describe the benefits a procurers are expected to accrue when the proposed solution is in place, over and above benefits to their patients. Benefits for a procurer and their staff may include:

- Quick assessment of the situation (e.g. number, location, status of casualties)
- Better and quicker planning onsite
- Reduced reaction time to changing situations
- Availability of data that help to make more informed decisions
- Reduction of the time to correctly tag victims
- Better interoperability with all relevant agencies in onsite/at disaster area
- Better distribution of resources at the scene
- Increase in rapid transportation of casualties (according to their status)
- Right distribution of patients to avoid overcrowded hospitals

To assess the business case for acquisition of the proposed solution by health services, quantification of benefits will be necessary. Realistic estimates of benefit quantities should be provided where possible, expressed as [INCLUDE MEASURE].

2.3 Annual cost of proposed solution

The total cost of deploying the proposed solution includes both payments to system providers, summarised as total cost of ownership, and additional time required by procurer staff, especially

clinicians, summarised as procurer annual operation costs. Please ensure that all additional costs incurred in deploying the proposed solution are included in one of these two sections.

2.3.1 Total cost of ownership

Provide here a breakdown of the total cost of ownership of the ICT systems for a procurer deploying the proposed solution. Different figures should be given for different scales of deployment. Please give figures for (scenario 1) and (scenario 2). One-off costs should be depreciated over a maximum of five years. All costs incurred by a procurer from third parties to reap the benefits from the proposed solution must be listed (licensing, maintenance, replacement, insurance, etc.). Costs may include:

- Implementation costs, set-up costs, including hardware, shipping, installation and configuration
- Operation and maintenance including hosting, security updates and upgrades
- Replacement of sensors and other components with short lifetimes
- Adaptation to existing IT systems, e.g. new EHR

2.3.2 Procurer annual operation costs

Provide a description of additional tasks providers and their staff must carry out to deliver benefits to patients. Estimate per [INCLUDE MEASURE].

- the additional time required for each member of staff by role or qualification (clinicians, nursing staff etc.).
- other internal costs, including for example, where relevant, additional laboratory costs.

2.4 Supplier business case

2.4.1 Sustainability of supplier offer

Explain the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market.

Describe the business strategy for commercialising the solution (including market expansion plans, business models, capital plan etc.).

2.4.2 Change management

Describe the proposed change management strategy to be followed and executed during the pilot operation phase. Detail the development of appropriate materials and where necessary planning of events as part of the strategy.

2.4.3 Quality management and certification

Describe the proposed quality management and certification strategy which may also allow for certifying the solution as medical device if necessary. Consider standards such as [INCLUDE STANDARDS]

3 Implementation of phases 1-3 of the iProcureSecurity PCP

3.1 Project plan - overall approach and work packages

List the work packages in the workplan, e.g. in the table below.

Describe the approach taken to each phase of the PCP and list the work packages active in each phase.

Provide a clear description of each task to achieve the work in a work package and complete the associated deliverables. Ensure it is clear why each WP is necessary to achieve the intended results and to the timely completion of deliverables.

Ensure the responsibility for each WP and deliverable is clear from the description.

Table the resources committed to each work package in person-months per organisation.

List the person-months committed by each organisation and all key staff members for each phase.

Quantify all other resources committed - number of person-days travel, licences etc.

Provide GANTT or similar timing information for all tasks across all Phases.

Table 1: List of work packages

Work package No.	Work package title	Lead participant No.	Lead participant short name	Person months	Start month	End month
WP1						
WP2						
WP3						
WP4						
WP5						
WP6						
WP7						
WP8						
WP9						
			Total months:			

The following table may be used for a work package description

Work package number	WP[Nr]			Start date or starting event		M[Nr]
Work package title	[WP title]					
Participant number	1	2	3	4	5	6
Participant short name						

PM per participant						
Objectives						
o to [describe objective] o o						
Description of Work						
T[Nr] [Task name] (M[Month Nr] – M[Nr]) - Lead: [short name] [Task description] T[Nr] [Task name] (M[Nr] – M[Nr]) - Lead: [short name] [Task description]						

In case of subcontracting, clearly mention which aspects and which tasks are planned to be subcontracted.

Detail each deliverable as to its key characteristics, size (where appropriate), maturity, usability etc. Provide a complete list of deliverables, the WP and organisation or key staff member responsible for delivery, e.g. as in the following table.

Table 2: List of Deliverables

No.	Title/description	WP	Responsible	Month
D1.1				
D1.2				
D1.3				
D1.4				

Describe any key milestones which are not deliverables.

3.2 Supplier description

3.2.1 Supplier(s) and key staff members

Describe the (lead) supplier organisation and all organisations in case of a supplier consortium, in each case (on approximately one page):

- a description of the organisation and its role in the proposed work;
- CV information for key staff members and their deliverable responsibilities;
- relevant previous projects;
- existing publications, products, services and/or other relevant achievements;

- any other particularly relevant aspect of the organisation and its resources

In case of a consortium describe the complementary role of the partners. Describe the contractual arrangements in place relevant to project execution and results exploitation.

3.2.2 Summary of supplier competence areas

Explain how the (lead) supplier organisation and all organisations in case of a supplier consortium jointly complement each other and bring in the necessary expertise to carry out all phases of the PCP.

Table 3: Competences of supplier (and partners)

Partner/ Expertise	Overall Management	Working with patients and professionals	Trials, pilots execution	Change management	IT systems Integration	Specification	Architecture design	Clinical expertise	Deployment Spain	Deployment Austria	Deployment Italy	Deployment Greece	Deployment Turkey

3.3 Management, compliance and user involvement

3.3.1 Management structure

Describe the structure and processes to be put in place to manage the project, including decision processes and conflict resolution, project communication, progress monitoring, quality assurance, management of resources and payments.

Describe the approach to selecting and managing subcontractors, if applicable.

3.3.2 Risks and risk mitigation

Describe your approach to risk management, your evaluation the key risks involved and the mitigation you envisage.

3.3.3 Involvement of EMS practitioners and patients

Explain how EMS practitioners and/or patients will be involved in the design and implementation phases.

3.3.4 Compliance to PCP requirements

Please summarise how your proposed workplan complies with the requirements of a PCP project

3.4 Legal and ethical issues

3.4.1 Ethical issues

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

3.4.2 Privacy and security

Describe policy and measures with respect to the processing of personal data and the protection of privacy of all concerned.

3.4.3 Pre-existing rights (background)

Describe any pre-existing rights (background which the supplier possesses) which any entity will have to acquire to deploy and use the proposed solution. Describe any background necessary for performance of the work in the workplan and completion of all deliverables.

iProcureSecurity PCP

Tender application for iProcureSecurity PCP

Project Acronym: iProcureSecurity PCP
Grant Agreement number: XXXXXX
Project Title: **Pre-Commercial Procurement of Innovative Triage Management Systems Strengthening Resilience and Interoperability of Emergency Medical Services**

[Title of proposal]

FINANCIAL SECTION

List of participants

	Participant organisation name	Country
1		
2		
3		
S1	(any subcontractors)	
S2	(any subcontractors)	

PRICE SUMMARY

Phase for current offer ("x"):	x		
1. Price for exclusive development (IPR are transferred to procurers)	0	0	0
2. Price reduction for retained IP (financial compensation)			
3. Total offered price (price where IPR can be exploited by suppliers freely on the market)	0	0	0

							Phase 1 (binding)		**Phase 2 (estimated)**		**Phase imated)**
A.	**FEES FOR STAFF**										
	Name / Staff category**	**Principal R&D staff (Y/N)**	**Within EU / H2020 associate countries**	**Participant/Subc ontractor*1**	**Hourly rate**	**No of hours**	**Total**	**No of**	**Total**	**No of hours**	
							0		0		
	…								0		
	…								0		
									0		
							0		0		
							0		0		
									0		
											0
											0
	…						0		0		0
	…						0		0		0
	…						0		0		0
	…						0		0		0
Sub-Total A							0		0		0

*1 number as in table on cover page
** Categories may not be used für principal R&D staff. The name of the individual must be given

							Phase 1 (binding		**Phase 2 (estimat**		**Phase 3 (estimated)**
B.	**OTHER ITEMS**										
	Description of item		**Supply of product*2**	**Participant/ ontractor*1**	**er unit**	**No of units**	**Total**	**nits**	**Total**	**No of units**	**Total costs**
							0		0		0
							0		0		0
							0		0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
									0		0
Sub-Total B							0		0		0

*2 related to the definition of R&D services

Phase Total							0		0		0

Project Acronym: **iProcureSecurity PCP**

Grant Agreement number: **XXXXXX**

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

PCP Framework Agreement

TABLE OF CONTENT

PREAMBLE

This is a framework agreement ("Agreement') between the following parties:

on the one part,

the Lead Procurer, NAME OF LEAD PROCURER ORGANISATION [ACRONYM, COUNTRY] , acting

in the name and on behalf of the other members of the Buyers Group (together with the Lead Procurer: "Procurers"):

- NAME OF PROCURER ORGANISATION [ACRONYM, COUNTRY]
- NAME OF PROCURER ORGANISATION [ACRONYM, COUNTRY]
- NAME OF PROCURER ORGANISATION [ACRONYM, COUNTRY]
- NAME OF PROCURER ORGANISATION [ACRONYM, COUNTRY]
- NAME OF PROCURER ORGANISATION [ACRONYM, COUNTRY]

[OPTION for single contractor: and on the other part, the Contractor, [insert details of the contractor],]

[OPTION for joint tenders: and on the other part, the Contractor, [insert details of the lead contractor],

acting in the name and on behalf of the other members of the group of tenderers:

1. [insert the details of the members of the group of tenderers.]

2.

The members of the group of tenderers are jointly and severally liable vis-à-vis the Lead Procurer for the performance of this agreement and of any specific contract which may be awarded.]

The Lead Procurer, the Buyers Group, and the Contractor shall be referred to together as the Parties, and individually as Party, unless otherwise specified.

By signing this agreement the Parties agree to implement the pre-commercial procurement in accordance with this agreement and all the obligations it sets out.

The agreement is composed of:

Preamble

Terms and Conditions

Annex 1 Ethical requirements for Field Testing

Annex 2 Request for Tenders

Annex 3 Contractor's tender

Annex 4 Grant Agreement

TERMS AND CONDITIONS

Article 0 — Definitions

1. Status of definitions

Without prejudice to Article 19, the definition in this Article of words and phrases with capital first letters shall have precedence over definitions of the same words or phrases in Annexes to this agreement and over definitions in an offer for a Specific Contract.

2. List of definitions

Results or Foreground means any tangible or intangible output, such as data, knowledge or information, that is Generated in the PCP, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights ('attached IPRs' or 'IPRs attached to the results').

Generated in the PCP means in activities described in this agreement and in the specific contracts defined here.

Pre-existing rights or **Background** means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('background IPRs') — that is held prior to the signing of this agreement and is needed for the implementation of the PCP, or needed to exploit the Results, or needed, by any member of the Buyers Group, to use the Results.

Sideground means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('sideground IPRs') — that is generated during the timespan of the PCP but is not Generated in the PCP and is needed for the implementation of the PCP, or needed to exploit the Results, or needed, by any member of the Buyers Group, to use the Results.

Third Party means any legal entity which is not a member of the Buyers Group, not a member of the iProcureSecurity PCP Consortium, not the Contractor and not member of the group of tenderers.

Specific Contract means a contract, of which this agreement forms an integral part, for supply of R&D services by the Contractor offered for one of the three phases of PCP implementation.

Fair and Reasonable Conditions means appropriate conditions, including financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access (for example, the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged).

Article 1 — Subject of the agreement

This agreement defines the general terms and conditions for the implementation of the PCP procurement of R&D services and for any Specific Contracts awarded for one or more PCP phase.

Award of Specific Contracts will take place according to the Contracting Approach documented in the Request for Tender. The Expected Outcomes to be achieved in Specific Contracts are documented in the Request for Tender.

Article 2 — Duration

This agreement shall come into force as of the date of signature of the last party and shall continue in full force and effect until terminated in accordance with Article 17 or after complete discharge of all obligations both under this agreement and under any Specific Contract tendered for by the Contractor.

The provisions of Articles 5, 6, 8, 12 and 20 shall survive the expiration or termination of this agreement to the extent needed to enable the Parties to pursue the remedies and benefits provided for in those Articles.

Article 3 — R&D services to be provided

The contractor shall provide the R&D services set out in in the tender and the Specific Contracts.

Article 4 — Pricing, payment and accounting

The total price offered for the R&D services to be implemented for each PCP phase shall be set out in any Specific Contract which may be awarded to the Contractor.

Prices shall take account of the requirements specified in chapter 4 of the Request for Tender.

The payment and invoicing conditions shall be as specified in chapter 6.2 of the Request for Tender.

The prices shall be based on the binding unit prices in the tender and the following price condition

- if new units/unit prices are added to phase 2 or 3 offers, they shall become binding for the remaining phases

The total amount to be paid by the Lead Procurer to the Contractor shall not exceed the relevant amounts detailed in Section X.X of the PCP Request for Tenders document. Subject to these limits the Contractor is free to administer received payments within the terms of this Framework Agreement without further reference to the Lead Procurer.

Payment for the Contractor's Services for each Phase will be made according the following provisions:

PHASE II: payment 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 of Phase II. The second payment of 50% 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 6.2 of the CfT document applicable to such Phase and is thus considered to have completed the Phase satisfactorily.

In case of Default, any payment already made may be reclaimed, including for the case in which the Evaluation Committee comes to the conclusion that Phase II was not even satisfactorily completed.

The Contractor accepts, upon first request from the Lead procurer, to provide the Lead procurer with complete, relevant and clear information as well as documentary evidence about the allocation of monies paid by the Lead procurer.

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 Lead Procurer’s discretion.

Article 5 — Ownership of the results (foreground), pre-existing rights (background) and sideground (including intellectual and industrial property rights)

Pre-existing rights (background) and sideground (including intellectual and industrial property rights)

The property rights of background IPRs do not change under this Framework Agreement. Ownership of Pre-existing Intellectual Property Rights IPR remains with the organisation that provide them. Ownership of Sideground IPR remains the property of the organisation which generates it. The Contractor grants the Parties herewith access, at no charge, to all Background and Sideground necessary to perform the iProcureSecurity PCP project for the purpose of executing the iProcureSecurity PCP 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 of the Results.

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 Lead Procurer of the infringement or violation.

The Contractor grants the Buyers Group herewith access, at the prices specified in the Tender or, should no specification be made and no written agreement reached, at no charge, to all Background and Sideground necessary to exploit Results whose ownership has transferred to the Buyers Group.

The Contractor grants each Member of the Buyers Group herewith access, at the prices specified in the Tender or in a Specific Contract, or, should no specification be made and no written agreement reached, at no charge, to all Background and Sideground necessary to use the Results for the purposes of that Member.

The Contractor shall provide in the Tender a complete list of Background and planned Sideground for implementation, exploitation and use, (the List) shall maintain the List throughout the performance of this agreement, shall make the List available to all Parties, and shall notify the Buyers Group immediately of any addition to or deletion from the List.

The Contractor shall not, without the express prior written agreement of the Buyers Group, generate Results whose exploitation or use relies on access to IPR not owned by the Contractor, or requires access to other rights not owned by the Contractor.

Rights and obligations relating to Results (Foreground)

The Contractor owns the Results generated by the activities of the Contractor.

The Contractor shall take appropriate measures to protect its Results and bear the costs associated with this.

The procurers have the right to monitor the management of the IPRs.

The Contractor shall inform the Buyers Group of all Results that can be exploited, regardless of whether they can be protected or not, without delay and at the latest within ninety (90) days from when they are generated (Protection Deadline). The information submitted by the Contractor to the Buyers Group shall contain a clear description of the Results, of their possible exploitation and of the measures taken to protect them.

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.

In respect of any Result of which the Buyers Group is not informed or which is not protected on expiry of the Protection Deadline, the Buyers Group has the right to require that ownership of the Result be transferred to them.

The Contractor herewith grants to each member of the Buyers Group irrevocable, royalty-free, non-exclusive, world-wide access rights to use the 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 their own purposes.

Access to Foreground, Sideground and Background is to include full documentation, comprising all information required for appropriately qualified personnel not taking part in the PCP implementation to be able to use these autonomously (without assistance by the contractor). Full documentation of the Results of phase 3 shall allow such qualified personnel autonomously to directly implement a system conforming to the specification of the phase 3 prototype. For the avoidance of doubt, full documentation for software includes source code and full documentation of any Result containing or using software includes all necessary software parts usable by such qualified personnel.

The access rights to Results that rely on access to rights not owned by the Contractor may be limited in time, provided such limit is contained in the written agreement with the Buyers Group reached to permit their generation.

The Lead Procurer may require the Contractor to grant non-exclusive licenses to any party including a Third Party to exploit the Results under Fair and Reasonable Conditions (without the right to sub-license).

The Lead Procurer may grant royalty-free access to Results to any party including a Third Party for the implementation of the PCP.

The Contractor may grant non-exclusive licenses to any party including a Third Party to exploit the Results (or otherwise give the right to exploit them) unless this would impede the access of the Buyers Group or rights have been transferred to another party pursuant to Article 8 or otherwise under this agreement. The Contractor may transfer ownership of the Results to any party including a Third Party

provided that

- the new owner is adequately bound to meet all obligations of the Contractor under this agreement and any Specific Contract in respect of the Results concerned, including the obligation to bind any subsequent owner to those obligations; and
- the Contractor has given the Buyers Group at least ninety (90) days advance notice of the intention to transfer ownership along with sufficient information on the new owner to enable the members of the Buyers Group to assess any effects on their access rights; and
- no objection is raised by any member of the Buyers Group within forty-five (45) days of receiving notification which shows that the transfer would adversely affect its access rights.

The contractor is required to deposit copies of Results to guarantee for the Buyers Group a continued access to results in case of financial bankruptcy of the Contractor (or any of its subcontractors).

Third Party rights and obligations

The Contractor must ensure:

- that any subcontractor complies with the Framework Agreement and Specific Contracts
- 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.

The Contractor shall obtain all rights to any Foreground owned by a subcontractor, and sufficient rights to Background or Sideground to allow the Contractor to comply fully with its obligations under this agreement and under Specific Contracts.

The requirements specified in the Request for Tender in respect of subcontracting shall be complied with.

ARTICLE 6 – PARTICIPATION OF PREFERRED PARTNERS

The Preferred Partners are entities that are neither the Lead Procurer, nor members of the Buyers Group, nor Third Parties providing in-kind contributions to the PCP, but that have a special interest in closely following the PCP. They may be entities involved in the EU grant (e.g. those involved in 'related additional networking activities') or not involved in the EU grant (e.g. other procurers on the market that are potential buyers for the solutions and have expressed an interest in closely following the PCP).

The preferred partners will be informed of all aspects of the PCP and will be afforded access to all information concerning the PCP as they will support the Buyers Group regarding the collection of requirements, and the translation of requirements into tender specifications and evaluation criteria / KPIs, the evaluation of interim deliverables, the validation of the outcomes in the last PCP phase.

However, they will not assume to results or IPRs and are committed to confidentiality on results, processing of personal data and communication for a period of five years after the end of project period.

Below it is presented a table with the preferred partners involved and their involvement:

SYNYO	The Project Co-ordinator: Directs the PCP project and is responsible for achieving the project results according to the Grant Agreement.
AAHD	Lead Implementation and operational testing.
KEMEA	Lead Evaluation and impact assessment in the PCP.
EMPIRICA	Lead Open Market Consultation and PCP coordination support alongside SYNYO.

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 this agreement and indefinitely after the end of this agreement.

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 staff of the iProcureSecurity PCP Consortium or to staff of the Buyers Group only if:

(a) they need this information in order to implement the Grant Agreement, this agreement or a Specific Contract; and

(b) they are bound by an obligation of confidentiality.

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 was received from a Third

Party without 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 the recipient

having breached 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.

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

1. The Contractor shall undertake communication activities to create publicity about its participation in the procurement, and to promote the objectives and the results of the R&D carried out under the PCP (in particular, to other potential customers beyond the Buyers Group with the objective to achieve commercial exploitation of the Results (see Article 8 – Commercial exploitation of results)).
    - 1.1 All communication activities shall comply with the applicable confidentiality and security restrictions.
    - 1.2 During the implementation of the agreement and for a period of 4 additional years, the contractor shall inform the Lead Procurer 45 days in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the implementation or Results. Information on communication activities expected to have a major media impact shall be provided sufficiently in advance to allow the Lead Procurer to inform the EU.
    - 1.3 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'.
    - 1.4 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.
    - 1.5 All communication activities shall indicate that they reflect only the author's views.
2. The Lead Procurer 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).
    - 2.1 The lead procurer and the buyers group may, in particular, publish the names of the Contractor and, in the case of a joint tender, the members of the group of tenderers, and the project abstract, summaries of the main results from the R&D and 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).

2.2 This does not change the confidentiality obligations under Article 6.

2.3 Moreover, before publishing this information, the lead procurer and the buyers group 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.

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 audio-visual material) from the contractor (including in electronic form).

3.1 If the EU's use of these materials, documents or information would risk compromising legitimate interests, the contractor may, however, ask the lead procurer to request the EU not to use it.

3.2 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, summarising, 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 Regulation EC 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.

3.3 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 4 years after the end of the Framework Agreement, 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).

In the event that the Buyers Group exercises the right to require transfer of ownership, the Contractor shall grant the Buyers Group access, at the prices specified in the Tender or, should no specification be

made and no written agreement reached, at no charge, to all Background and Sideground necessary to exploit the Results.

Article 9 — Conflicts of interest

The Contractor shall take all measures necessary to prevent a situation arising where the impartial and objective implementation of the 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 notify the Lead Procurer 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 lead procurer may instruct the Contractor to take specific measures to remedy the situation.

Article 10 — Ethics and research integrity

The Contractor shall carry out the tasks assigned to it in the Framework Agreement and in the 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 that are prohibited in all EU Member States in a country outside the EU (where those activities are allowed).

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 highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[1].

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that contractor must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;

[1] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — as much as possible and taking into account the legitimate interest of the contractor — access to research data, in order to enable research to be reproduced;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid conflicts of interest and misrepresentation of credentials or other research misconduct.

Before starting any activity that raises an ethical issue, the Contractor shall submit to the Lead

Procurer a copy of:

(a) any ethics committee opinion required under national laws and

(b) any notification or authorisation for activities raising ethical issues required under national laws.

In addition, the contractor shall comply with the following ethics requirements:

- following ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity[2], and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
- adhering to applicable international, EU and national law
- complying to ethical requirements for field testing, specified in Annex 2.

Article 11 — Processing of personal data

The Lead Procurer and the Buyers Group shall process personal data in compliance with the applicable EU and national law on data protection.

The Contractor shall process personal data in compliance with the applicable EU and national law on data protection (including as relates to authorisations and notification requirements).

The Contractor may grant its staff access to data only in so far as is strictly necessary for implementing, managing and monitoring the framework agreement and specific contracts.

The Contractor must inform the staff whose personal data are collected and processed by the Lead Procurer, the Buyers Group and/or the EU. For this purpose, the Contractor must provide them with the privacy statements of the Lead Procurer, the Buyers Group and the EU, before transmitting their data. If explicit prior consent from the subjects of the data is needed, the Contractor must obtain such consent.

Article 12 — Obligation to provide information and keep records

The contractor must, at any time during the implementation of the Framework Agreement and Specific Contracts or afterwards, provide any information requested by the Lead Procurer or other member of the Buyers Group in relation to the agreement or contracts.

[2] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

The contractor must keep, for a period of up 5 years after the end of the Framework Agreement, records and other supporting documentation relating to its implementation or the implementation of the Specific Contracts.

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 against the Lead Procurer or Buyers Group), the Contractor must keep the records and other supporting documentation relating to the implementation of the Framework Agreement and Specific Contracts until the end of these procedures.

Article 13 — EU checks, reviews, audits and investigations

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).

Should the EU (including as represented by 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 Framework Agreement and Specific Contracts. Should there be an on-the-spot visit, the contractor must allow access to its premises and must ensure that the information requested is readily available.

Article 14 — EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the Buyers Group), the contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.

Article 15 — Monitoring and reporting

During performance of any Specific Contract, the implementation by the Contractor of the R&D Services will be monitored periodically and reviewed against the deliverables agreed in the Specific Contract.

The Lead Procurer may request that it or any party designated by it witnesses any tests or measurements to be performed by the Contractor or his subcontractor(s), and the Contractor shall give the Lead Procurer reasonable prior notice in writing of the date(s) and place(s) of such tests and measurements. In the event of failure by the Contractor to give such notice, the Lead Procurer shall be entitled to demand at any time that such tests and measurements be repeated at the expense of the Contractor, who shall be liable for any delay resulting therefrom.

The monitoring team will provide feedback to the Contractor after meetings or visits

Article 16 — Breach of contract

1. The Contractor must compensate the Lead procurer and the Buyers group if they are held liable by the EU for damage it sustained as a result of the implementation of the Framework Agreement or a specific contract or because it was not implemented properly.
2. 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 Framework Agreement or a Specific contract.

3. The Contractor shall indemnify and hold the Lead Procurer and the other Buyers Group members free and harmless against loss and damage, including personal injury and death and related legal costs, arising from or in connection with its acts or omissions in relation to the Framework Agreement.
4. The Contractor's indemnity obligations under Clause 3 shall be without prejudice to any other rights and remedies available to the Lead Procurer, including the right to terminate the Framework Agreement or any Specific Contract.
5. If the Contractor fails to deliver Results or other deliverables compliant with the Framework Agreement, the Lead Procurer shall give the Contractor the opportunity to amend, within an appropriate period. If the Lead Procurer is still not satisfied after the expiry of such cure period it may (at its discretion):
   - Withhold payments until satisfactory delivery;
   - Cancel payments;
   - Exclude the Contractor from the any subsequent Phases on the basis that the Contractor has not successfully completed the present Phase; and/or
   - Terminate the Framework Agreement and/or any Specific Contract (see hereunder).
6. Acceptance by the Lead Procurer of any deliverable or Result shall not release the Contractor from liability in respect of such deliverable or Result subsequently being discovered to be non-compliant with the requirements of the Framework Agreement, nor for any loss or damage which may arise as a result.
7. Except in case of infringement of applicable laws, gross negligence or wilful misconduct on its part, a Party shall not be liable to the other for loss of the Framework Agreement, loss of income or revenue, loss of customers or reputation or any other indirect or consequential loss or damage.
8. Except in case of liability pursuant to clause 7 (IPR), infringement of applicable laws, gross negligence or wilful misconduct on its part, each Party's total liability in relation to the Framework Agreement shall be limited to the total value of the Specific Contract under the application of which the act or omission giving rise to the liability took place.
9. The Contractor shall take out insurance to cover its liability under the Framework Agreement and shall provide evidence of this insurance cover if so required by the Lead Procurer. The Contractor shall ensure that the same applies to its subcontractors involved in activities under the Framework Agreement. Any such insurance shall be maintained for the duration of the Framework Agreement and for a minimum of four (4) years thereafter.

Article 17 — Termination clauses and consequences of termination

1. The Lead Procurer shall be entitled to terminate this agreement at any time, including during performance of a Specific Contract, by notice in writing to the Contractor if:
   a) the Contractor is in breach of any of its confidentiality obligations
   b) the Contractor is in breach of any of its conflicts of interest obligations
   c) the Contractor is in breach of any of its ethics and research integrity obligations
   d) the Contractor is in breach of any of its data protection obligations
   e) the Contractor or a member of the Group of Tenderers undergoes any change in legal or beneficial ownership or control;
   f) the Contractor admits a new party to the Group of Tenderers
   g) the Contractor is in breach of an obligation set out in the Request for Tenders; h) any approvals, consents or licenses required under this agreement or to enable the services to be carried out lawfully are not granted, or lapse, terminate or otherwise cease to be of effect during the term of this agreement;
   h) the Contractor fails to deliver an Expected Outcome covered by a Specific Contract within ten (10) days of the date by which the relevant Expected Outcome was to be achieved, or

repeatedly fails over a period of three consecutive months to achieve Expected Outcomes by the date(s) on which those Expected Outcomes were to have been achieved.

2. The assignments and/or licenses granted under the Framework Agreement by the Contractor to the Lead Procurer, any Buyers Group member, the iProcureSecurity PCP Consortium or any Third Party shall continue notwithstanding any expiry or termination of this agreement.
3. Unless expressly stated to the contrary, the service of a notice to terminate this agreement shall operate as a notice to terminate any Specific Contract then in force.
4. Within thirty (30) days of the date of termination or expiry of this agreement, the Contractor shall return or destroy any personal data received from another Party and any Confidential Information belonging to another Party, either in its then current format or in a format nominated by the Lead Procurer.
5. Termination or expiry of this agreement shall be without prejudice to any rights, remedies or obligations of either Party accrued under this agreement before termination or expiry.

Article 18 — Amendments

The Parties may amend this agreement only in writing and only provided that the amendment not have the purpose or the effect of making changes which might call into question the decision awarding Framework Agreements or Specific Contracts or otherwise result in unequal treatment of tenderers.

A Party desiring an amendment to this agreement shall notify the other Parties providing a duly justified request and a full new version of this agreement clearly showing all the proposed changes. Without prejudice to the right to terminate in accordance with Article 17, the Buyers Group may notify the Party desiring the amendment of their rejection or agree with the other Parties that an amendment be executed.

Should the duration of the Grant Agreement be extended, the Lead Procurer may propose this agreement and any Specific Contract not completed be amended in respect of durations and deadlines. In such cases no Party shall not withhold agreement unless that Party can show that the proposed amendment would significantly and disproportionately harm that Party's interests. Should agreement be withheld, the Lead Procurer may invoke dispute resolution.

Article 19 — Interpretation

The interpretation and construction of this Framework Agreement and of any Specific Contract concluded under it shall be subject to the following provisions:

a) Terms defined in the Framework Agreement have precedence over those in annexes;
b) Terms set out in the Request for Tender have precedence over those in the Contractor's tender;
c) reference to any Act, Law, statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the Act, Law, statute, enactment, order, regulation or instrument as subsequently amended or re-enacted (regardless of whether or not expressly so stipulated);
d) Headings in this Framework Agreement are for ease of reference only and shall not affect its interpretation or construction;
e) References to conditions are references to conditions in the Article of this Framework Agreement in which they appear, unless otherwise stated;
f) Where the context allows, references to any gender include the other gender and the neuter, and the singular includes the plural and vice versa;
g) "including" means "including without limitation" (with related words being construed accordingly), in particular means "in particular but without limitation" and other general words shall not be given a restrictive interpretation by reason of their being;
h) Further definitions are given in Article 0.

Article 20 — Subcontracting, Transfer & Assignment

The Contractor will ensure that in all Sub-Contracts the conditions from the Grant Agreement set out in the clause 13 are imposed upon the subcontractor.

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. Nevertheless, any such replacement, to be provided in writing at the discretion of the Buyers Group, shall not apply if:

- It implies the entry of new participants different from those tendering individually or jointly at the beginning of the iProcureSecurity Procedure, or of participants previously withdrawn or excluded from said procedure or in default under the Framework Agreement or under a Specific (phase) Contract.
- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set in Section 1.5.1. of TD1 iProcureSecurity – PCP Request for tenders
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e. if associated participants selected for Phase 1 decide to continue as individual entities or to join other consortia).

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. No addition of subcontractor or change in subcontractor shall be possible if:

- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set out in Section 1.5.1. of TD1
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e. if associated participants selected for Phase 1 decide to continue as subcontractor for another bidder).
- It prevents the tenderer from meeting the selection criteria required under section 4.3 of TD1.

Article 21 — Applicable law and dispute settlement

1. Any legal claim, petition or application for judicial review with regard to the performance of this agreement on the implementation of the iProcureSecurity PCP, whether before civil, criminal or administrative courts, shall be made only before Spanish courts. In signing this agreement the Contractor accepts the exclusive jurisdiction of Spanish courts.
    - Decisions taken with regard to awarding a tenderer a Specific Contract for Phases 1, 2 or 3 or excluding them from a Specific Contract may be challenged by means of an administrative remedy before Madrid Courts.
    - Any dispute or claim arising out of or in connection with the execution of this agreement or of a Specific Contract shall be heard by Madrid Courts.
2. This agreement shall be considered as a contract made in Spain and be construed in accordance with and governed by Spanish Law, and no effect shall be given to any other choice-of-law or conflicts-of-laws rules or provisions. This agreement is outside the scope of Spanish procurement legislation.
3. Any dispute between the Contractor and another Party arising out of or in connection with this agreement shall in the first instance be referred to the Contractor Representative and the Lead Procurer Representative for resolution. These representatives shall work together in good faith to reach an agreed settlement of any such dispute. If, within 14 days of being referred to these representatives, the dispute has not been resolved, the Contractor and the Lead Procurer shall name a senior executive and a special representative respectively, who shall

meet within 7 days and work together in good faith to resolve the dispute. If, within a further 14 days, the dispute has not been resolved, the senior executive and the special representative may agree to submit the dispute to mediation by the International Chamber of Commerce in Paris. The fee for the appointed mediator shall be shared equally between the Parties in dispute.

4. Nothing in section 3 above shall preclude any Party from commencing an action for a legal remedy.
5. In case of discrepancy between the 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:
   – Framework Agreement;
   – PCP Request for Tender Document;
   – Other Tender Documents; and

– Contractor's Tender in the Tendering Stage.

Article 22 — Notices

Notices to the Buyers Group and notices to the iProcureSecurity PCP Consortium shall be sent to the Lead Procurer Representative:

Name: [insert details of the lead procurer]

Address: [insert details of the lead procurer]

The Lead Procurer may change representative by written notification to all Parties.

Notices to the Contractor shall be sent to the Contractor Representative:

Name: [insert details of the contractor]

Address: [insert details of the contractor]

The Contractor may change representative by written notification to all Parties.

Article 23 — Entry into force

The Framework Agreement becomes effective upon signing by both parties and shall remain in effect (unless terminated in accordance with article 17) until the Completion Date of Phase 1 or of a later Phase that has been awarded to the Contractor. However, confidentiality shall remain for four (4) years in accordance with the confidentiality clause.

An additional article relating to security obligations may be added in phase 0 of the PCP.

Annex 1 – Ethical requirements for Field Testing

The requirements for field testing are described further below:

- Requirements related to recruitment: research participants will be recruited by the buyers group via medical professionals who ask their individual patients to consider voluntary enrolment. Only certain people who have the target condition will be eligible to take part in the field test. Details on the procedures and criteria that will be used to identify/recruit research participants will be provided. During the PCP's Phase 3, the solutions awarded will be verified and compared against jointly defined criteria by the buyers group and other concerned final end-users in real-life operational conditions to verify fitness for purpose in view of potential conversion into permanent service of the solutions. Expected output from participating companies includes firstly field testing, secondly field test specification, thirdly specification of the final solution and other related technical documentation, and finally an updated cost/benefit evaluation.
- Field testing will be undertaken at four sites by the procurers, three EU countries and one non-EU country. No transfer of personal data is planned to exchange or transfer with non-EU countries. Previously collected data will NOT be used in the field tests. All Parties shall rigorously apply the ethical standards and guidelines of Horizon 2020, regardless of the country in which the research is carried out. Furthermore, copies of the relevant ethics approvals from the host EU country and non-EU country will be submitted to the Commission. The Contractor must be aware of this procedure and respect it.
- Informed consent procedures: Copies of templates of Informed Consent Forms and Information Sheets will be provided by the buyers group to the Commission. These will be drafted in a language and terms understandable to the participants. They will follow the Directive 2001/20/EC relating to the implementation of good field test practices. EMS organisations involved in the field testing will implement these procedures. The contractor must be aware of this procedure in each EMS organisation and respect it.
- Vulnerable individuals/groups will not be involved in the field tests: Details must be provided about the measures taken to avoid that vulnerable individuals/groups participate in the field-testing. The Contractor must ensure that this requirement is maintained.
- Details on incidental findings policy must be provided: Incidental findings are expected as a result of the nature of medical emergencies. iProcureSecurity PCP will NOT use invasive testing techniques, but monitor the functionalities of iProcureSecurity PCP solution. The Contractor will inform the Lead procurer in case of incidental findings identified.
- Copies of ethical approvals for the collection of personal data by the competent University Data Protection Officer / National Data Protection authority must be submitted. In principle, ethical review is not required for our proof-of-concept study as:
    - no diagnostic or monitoring procedures will be undertaken other than those ordinarily applied in clinical practice. (TBD)
    - However, during the implementation of the PCP, this procedure will be again reviewed and if necessary the procedure to obtain ethical approvals will be implemented. Each EMS organisation will initiate the procedure according to its own protocols and timings. The Contractor must be aware of the procedure and work together with the organisation if further information should be required.
    - Justification must be given in case of collection and/or processing of personal sensitive data: no personal sensitive data will be collected (i.e.: racial or ethnic origin of the data, political options, religious beliefs, membership of trade unions, sexual life, offences commission, sentences of any course for such offences, mental health condition). The Contractor must ensure that this requirement is respected in their solutions.
    - Detailed information must be provided on the procedures that will be implemented for
    - data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation: Data

collection/storage/protection/retention/destruction and confirmation will follow the EU Directives: Directive 95/46/EC21 (Data Protection Directive) harmonizing a common standard set of data protection among the member states. Article 17 of the Directive 95/46/EC establishes the rules to ensure that the data controller implements appropriate technical and organisational measures to protect personal data from destruction, loss, unauthorised alteration, unauthorised disclosure or access, whether by accident or by unlawful action. Directive 2002/58/EC (Directive on privacy and electronic communications) for data in the communication sector, and Directive 2006/24/EC (Data Retention Directive) regulating data management in the context of public services delivered electronically. The European Commission plans to unify data protection within the European Union (EU) with a single law, the General Data Protection Regulation (GDPR). According to the above explanation, the Contractor must clearly explain how he will meet this requirement by answering the compliance criteria D and E in the tender documents.

SIGNATURES

Authorised to sign for the Buyers Group and for the iProcureSecurity PCP Consortium

(Full Name, Date, Place, Signature)

Authorised to sign for the Contractor

(Full Name, Date, Place, Signature)

Project Acronym: **iProcureSecurity PCP**

Grant Agreement number: **XXXXXX**

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

PCP Specific contract for phase [1][2][3]

Template

1 PREAMBLE

This agreement is a Specific Contract executed and performed under the Framework Agreement concluded between the Buyers Group, the iProcureSecurity PCP Consortium and the Contractor. The provisions of the Framework Agreement form an integral part of this agreement. Annex 1: Framework Agreement Annex 2: Contractor's Offer / Tender

Annex 1: Framework Agreement

Annex 2: Contractor's Offer / Tender

2 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 [1st] [2rd] [3rd] PCP phase.

Article 2 — Duration

This contract shall come into force as of the date of signature of the last party and shall continue in full force and effect until terminated in accordance with the provisions of the Framework Agreement or until complete discharge of all obligations. 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) set out in the offer for this phase and deliver the Expected Outcomes specified for this phase in the Request for Tender

The individuals in charge of carrying out the R&D activities for the specific contract and their location (country where they carry out the R&D activities) must be specified in the Tender / Offer.

Article 4 — Price and payment arrangements

The price to be paid by NAME OF THE LEAD PROCURER ORGANISATION [ACRONYM, COUNTRY] for the R&D services set out in Article 3 shall be [EUR] [amount in figures and in words].

The following table is to be completed to specify the amount of any interim payment and of the final payment together with the expected date and short reference to all deliverables / milestones which must be accepted before the invoice is approved, as detailed for each phase in the Request for Tender.

Required deliverable/ milestone	Amount of payment	Expected date
Dx.y	€x0,000	dd.mm.yyyy

Approval of deliverables and invoicing shall proceed as specified in Section 6 of the Request for Tender.

SIGNATURES

Authorised to sign for the Buyers Group and for the iProcureSecurity PCP Consortium

(Full Name, Date, Place, Signature)

Authorised to sign for the Contractor

(Full Name, Date, Place, Signature)