Anti-SUPERBUGS
Pre-Commercial Procurement

ICT solution against *multi-resistant microorganisms*

ICT-36-2015 - Pre-commercial procurement open to all areas of public interest requiring new ICT solutions

H2020-EU.2.1.1. - INDUSTRIAL LEADERSHIP - Leadership in enabling and industrial technologies - Information and Communication Technologies (ICT)

Agència de Qualitat i Avaluació Sanitàries de Catalunya

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Pre-Commercial Procurement

Objectives

- *support and finance private R&D* activities in the field of advanced ICT solutions aimed at:
  - detecting microorganisms that may determine the incurrence of Hospital-Acquired Infection (HAI)
  - inform about the spreading of infections within healthcare facilities
- address the needs of healthcare providers regarding HAIs' associated care
- contribute in the development of a *new products in the life science and medical device industries*

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Consortium members

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Procuring entities

Lead Procurer

Generalitat de Catalunya
Departament de Salut

Agència de Qualitat i Avaluació Sanitàries de Catalunya
AGENCY FOR HEALTH QUALITY AND ASSESSMENT OF CATALONIA

award contracts on behalf of buyers

Buyers Group

VINCat
Vigilància de les infeccions nosocomials als hospitals de Catalunya

ICO
Institut Català d'Oncologia

PROVINCIA AUTONOMA DI TRENTO

Helios

Fundació Docència i Recerca MútuaTerrassa

UNIKLINIK RWTH AACHEN

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

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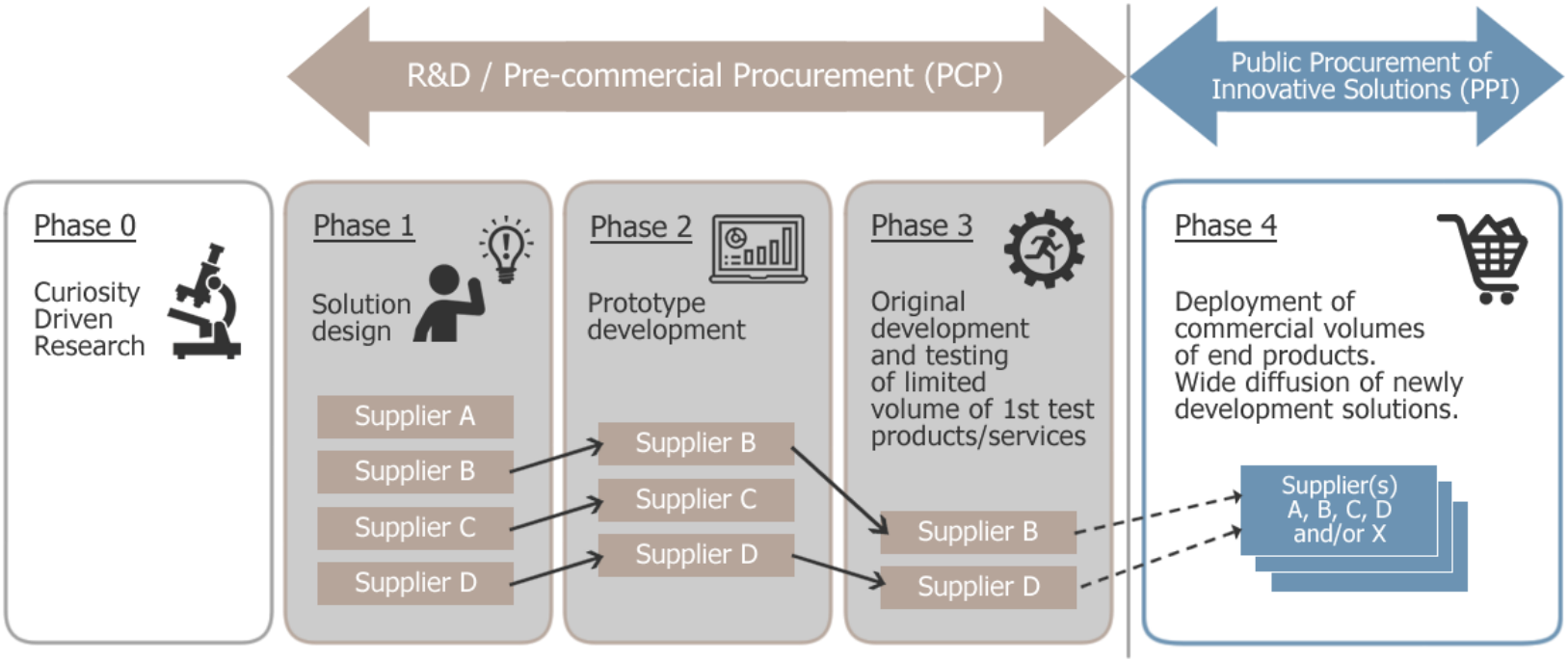
Description of Procurement



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	Phase 1 **Solution design**	*Phase 2* **Prototyping**	*Phase 3* Original development, **validation & testing** of a limited set of prototype devices or prototype services within the contracting authorities
Maximum number of selected Bidders	**5**	**4**	**2**
Maximum contract volume per phase (€)	≈450K	≈1,6 M	≈1M
	≈ 3,1 M		
Max contract volume per supplier (VAT incl.)	≈91k	≈420k	≈458k
Duration (months)	3	6	9
Regulation	Phase 1 Contract	Phase 2 Contract	Phase 3 contract
	Call for Tender/Invitation To Tender Challenge Brief Framework Agreement		

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Tender documents

Challenge Brief

Call for Tender/Invitation To Tender

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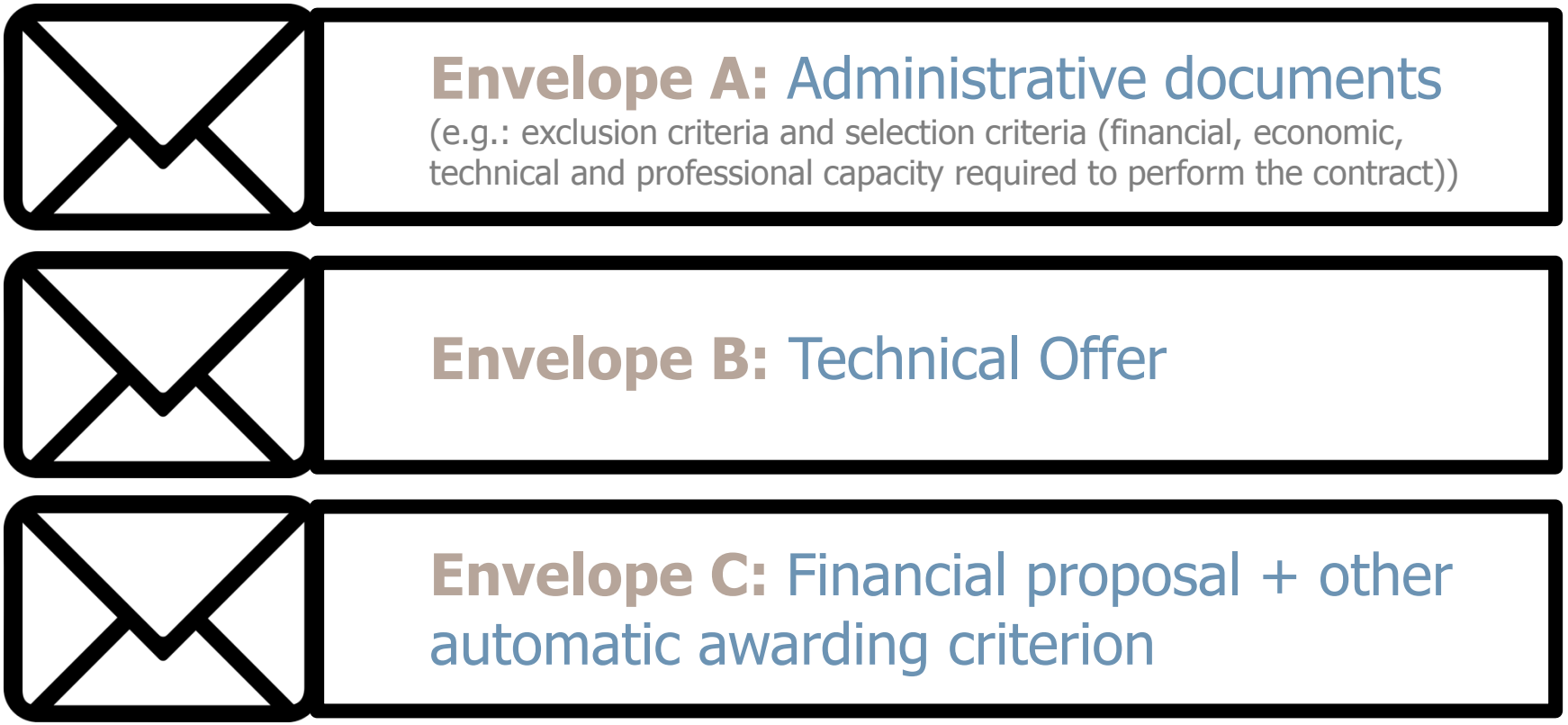
Bidder submissions



Envelope A: Administrative documents
(e.g.: exclusion criteria and selection criteria (financial, economic, technical and professional capacity required to perform the contract))

Envelope B: Technical Offer

Envelope C: Financial proposal + other automatic awarding criterion

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Challenge Brief

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Challenge

The ASB Technology is a medical device defined as a:

- **Volatile organic compound screening device that determines contaminations/colonisations of fomites and hospital environments on the following:**
  - ***Clostridium difficile* spores and/or microorganism (higher priority will be given to spore detection)**
  - **and either *Klebsiella pneumoniae* or *Acinetobacter baumannii* or both**

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Challenge

- **Additional points are given in case of:**
  - detection of antibiotic resistances in *Clostridium difficile*, *Klebsiella pneumoniae* (carbapenem & ESBL production) and/or *Acinetobacter baumannii* (carbapenem & ESBL production)
  - Additional Gram-negative pathogens bidders commit to detect

- **Triggering alert system in case of contamination/colonisation detection**

- **Local Surveillance & Infection Control System of the target microorganism(s)**

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Challenge

The ASB Technology comprises the following ICT elements:

- a **volatile organic compound screening device** able to detect the contaminations/colonisations from target microorganism(s) & the appropriate **software** (client & server) for the device's use

- a **local Surveillance & Infection Control System of the target microorganism(s)** able to:
  - store all the data collected by the screening device and all the laboratory results regarding contaminations/colonization found on patients that were screened as carriers of the specific microorganisms the ASB technology is able to detect
  - export data sets that other central Surveillance & Infection Control Systems (i.e. ECDC) can import and analyse
- an **interoperability engine** able to:
  - send screening outcomes and alerts on detections to HIS/LIS/HER, electronic hygiene control systems and indication-relation control systems
  - receive (1) confirmations from microbiology service and (2) compliancy if indication relevant actions have been undertaken by relevant clinical actors

- an **alert system** able (1) to identify patients at risk of infection after having analysed their health conditions, their patient history, the geolocalised area history and the staff indication-relation compliancy and (2) to generate alerts to be sent to the HIS/HER and recommend a patient screening

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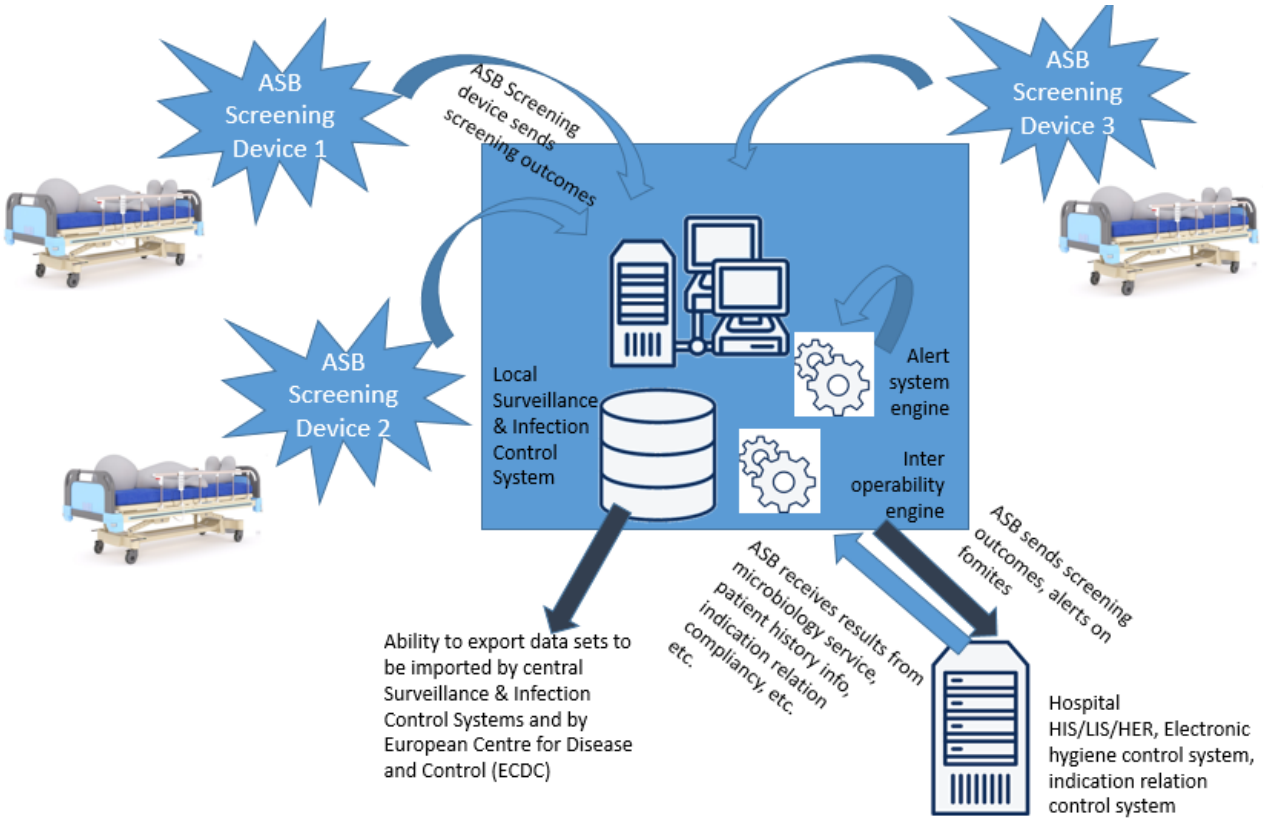
Challenge



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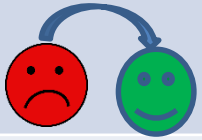
Challenge _ Beyond the current technologies

Requirements/characteristics	Microbiology Laboratory	PCRs	ASB
High sensitivity			
High specificity			
Environmental detection (no physical sample from the patient)			
Distant detection (enabling automatic and continuous detection with no user intervention)			
Real time (immediate/short turn-around time of test)			

 Not currently performed by technologies

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Challenge - Indicators

Technical/performance Indicators

- Turn-around time of test (task time)
- Sensitivity
- Specificity
- Distance of detection
- Task success rate / error rate

The committed values to these indicators will be used as automatic awarding criteria (to be submitted in the envelope C together with the price)

Technical solutions committing to best values will obtain higher scores

Procurers will not specify the minimums to be complied with

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Challenge - Indicators

Compliancy indicators

- Compliancy with the specifications and requirements for the ANTI-SUPERBUGS ICT platform
- Cost-effectiveness analysis that will include the structural cost of the clinical validation, the ASB screening device operating life costs and the forecasted ASB Platform pricing model, the ASB screening device range capabilities

User Experience Indicators

- Level of satisfaction of inpatients
- Level of patients' acceptability of ASB technology
- Level of satisfaction of clinicians
- Level of satisfaction of nurses
- Level of satisfaction of lab professionals
- Level of satisfaction of IT professionals

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Challenge - Indicators

Proposed clinical indicators (comparison with and without new ASB ICT solution)

- Period between ´detection at the patient´ to ´treatment´
- Period between ´detection at the patient´ to ´treatment-adjustment'
- Period between ´detection at the patient´ to patient discharge
- Amount of cases and cases with readmission within 28 days.
- Length of Stay

ANTI-SUPERBUGS PCP INVITATION TO TENDER

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USE CASE SCENARIOS

USE CASE SCENARIO *Klebsiella pneumoniae* (KPC)

A 68-year old patient is admitted at a hospital for a scheduled colon hemicolectomy due to a detected neoplasm. The surgery happens on May 20th, 2018. As surgical prophylaxis, the patient is prescribed ceftin and metronidazole. A urinary probe is introduced during the surgical procedure. Two days after the surgical procedure, the patient presents fever and suppuration on the surgical opening. The patient is diagnosed with suture unstitching and goes through another surgical intervention. Piperacillin-tazobactam is prescribed to the patient for a duration of 7 days. The surgical cultures show that the gut microbiota enterobacteria present no multi-resistance mechanisms. 18 days after the patient's admission, fever and urinary infection related to the urinary probe are diagnosed. Empirical antibiotic treatment with ceftazidime and amikacin is initiated. 18 hours after this diagnosis, the microbiology laboratory informs of a Gram-negative bacterial growth in the hemoculture. 36 hours later, a ***Klebsiella pneumonia*** with KPC production is detected in this patient. An anal swab is collected from all patients admitted to the same unit as this patient and two patients are found to be carriers.

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USE CASE SCENARIOS

USE CASE SCENARIO *Clostridium difficile*

A 74-year old patient is admitted at the internal medicine's unit from the ICU with severe community-associated pneumonia. Empirical antibiotic treatment starts with ceftriaxone and levofloxacin during 48h. On the 3rd day, due to the absence of behavioural diagnosis, ceftriaxone is suspended and the patient ends antibiotic treatment with 7 days of levofloxacin. On the 8th day of admission, the patient presents diarrhea (more than 5 stool deposition per day) with resurging of fever and abdominal pain. Stool samples are used to identify the presence of GDH and toxins A and B of ***Clostridium difficile***. Antibiotic treatment with oral vancomycin is initiated. The symptoms disappear in 48h and the patient is released. After being released, terminal cleaning of the room is done.

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Invitation To Tender

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Description of the procurement

The PCP procurement is exempted from the WTO Government Procurement Agreement (GPA), the EU public procurement directives and the national laws that implement them. This is because it concerns the procurement of R&D services where the benefits do not accrue exclusively to the contracting authorities for its use in the conduct of their own affairs.

Source: Annex E. Specific requirements for innovation procurement (PCP/PPI) supported by Horizon 2020 grants of the HORIZON 2020 — Work Programme 2014-2015

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Pre-Commercial Procurement

Bidders

-The Call for Tender/Invitation To Tender will be open to any type of natural or legal persons

- It will be possible to submit bids **either** individually **or** in association or consortium with other bidders
(under no circumstances it will be allowed to any natural or legal person to submit more than one bid)

- Subcontracting will be possible but limited to a %

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Place of performance

-It will be required to perform the majority of the contract volume within the EU Member States or H2020 associated countries.

-It will be required to have the principal R&D staff working on the PCP located within the EU Member States or H2020 associated countries.

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Language

-The official language of the procedure will be English

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PCP legal framework

PCP exempted from EU Procurement Directives:
article 14 of Dir 2014/24/EU (Public Sector Directive)

The Directives only apply to contracts for research and development services provided that both of the following conditions are fulfilled:

- (a) the benefits accrue exclusively to the contracting authority for its use in the conduct of its own affairs, and
- (b) the service provided is wholly remunerated by the contracting authority.

The fundamental principles of the Treaty for the Functioning of the European Union (TFEU) and the principles deriving therefrom are applicable.

PCP doesn't consitute State Aid (if implemented according to COM(2007) 799)

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Anti-SUPERBUGS Pre-Commercial Procurement

PCP legal framework

A competitive procurement designed to exclude State aid (1)

the procurement does not give any of the participant providers any preferential treatment in the supply of commercial volumes of the final products or services to a public purchaser in the Member State concerned

The scope is R&D services only (before commercialization): solution exploration , design , prototyping, up to the original development of a limited volume of first products or services in the form of a test series 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.

R&D does not include commercial development activities such as quantity production, supply to establish commercial viability or to recover R&D costs, integration, customisation, incremental adaptations and improvements to existing products or processes.

PCP Services Procurement: 50 % of contract value must be R&D services

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Anti-SUPERBUGS Pre-Commercial Procurement

PCP legal framework

A competitive procurement designed to exclude State aid (2)

the price paid for the relevant services fully reflects the market value of the benefits received by the public purchaser and the risks taken by the participating providers.

In PCP the public purchaser does not reserve the R&D results exclusively for its own use.

- IPR ownership rights are assigned to companies participating in the PCP.
- In a way that does not give the companies any form of unfair advantage

To ensure that the risk-benefit sharing is done according to market conditions any R&D benefit shared by the public purchaser with a company participating in the pre-commercial procurement should be compensated by the company to the public purchaser at market price.
This can be achieved through:

- Price reduction compared to exclusive development cost that reflects the market value of the benefits received and the risks assumed by the company
- (Royalties on the sales)

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Anti-SUPERBUGS Pre-Commercial Procurement

PCP legal framework

A competitive procurement designed to exclude State aid (3)

- Challenge the market in an open and transparent and non discriminatory way, the envisaged contractual arrangements describing all rights and obligations of the parties, including with regard to IPR, are made available to all interested bidders in advance.
- Organise the procurement as a stepwise process, including evaluations after each R&D phase, in order to select progressively the best solutions.
- Increase efforts after each R&D phase to achieve interoperability and product inter-changeability between the alternative solutions under development.
- Retain at least two participating companies until the last phase to ensure a future competitive market and avoid lock in and the risks assumed by the company.

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Pre-Commercial Procurement

Market Consultation

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Open Market Consultation

The market consultation aims to:

— check the technological SoA concerning early detection of superbugs and/or other HAIs vectors and find out whether technologies are commercially available (and acquire information about the advantages and disadvantages) and the level of fulfilment of the desired functionalities;

— identify market risks that may endanger business goals and supplier performance;

– enable preliminary analysis of the operational contests where innovations will be introduced;

— enable and increase the opportunities for industry to form fit-for-purpose consortia.

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Open Market Consultation

- Participants in the OMC are not expected to submit tenders or proposals or ideas at this preliminary stage.
- OMC does not lead to any rights or privileges for the participants, and is not part of any pre-qualification or selection process.
- The market consultation does not lead to any rights or privileges for the participants.
- The competitive phase of the AntiSuperBugs joint and cross-border public procurement procedure will be conducted separately with an open and advertised procedure.
- The contracting authorities involved in the AntiSuperbugs project are not legally bound in any way by the outcome of the market consultation.

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Thank you

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