Developing non-invasive innovative technologies to monitor and detect multidrug resistant pathogens in clinical settings: ANTI-SUPERBUGS pre-commercial procurement project

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Background and Aim

The ANTI-SUPERBUGS (ASB) pre-commercial procurement (PCP) EU co-funded project aims to develop innovative solutions for the continuous monitoring and detection of multidrug resistant pathogens in hospital environment and patients, integrating state of art non-invasive detection methods with ICT tool for alert generation, traceability, geolocation and data integration into hospital informative system.

The three phases-based PCP process successfully completed firsts co-design and prototyping phases with the involvement of public and private cross-border procurers, and it is now being finalized by testing the prototypes in real clinical settings.

We report about specific challenges and opportunities for implementing clinical investigations with highly innovative and prototypical systems.

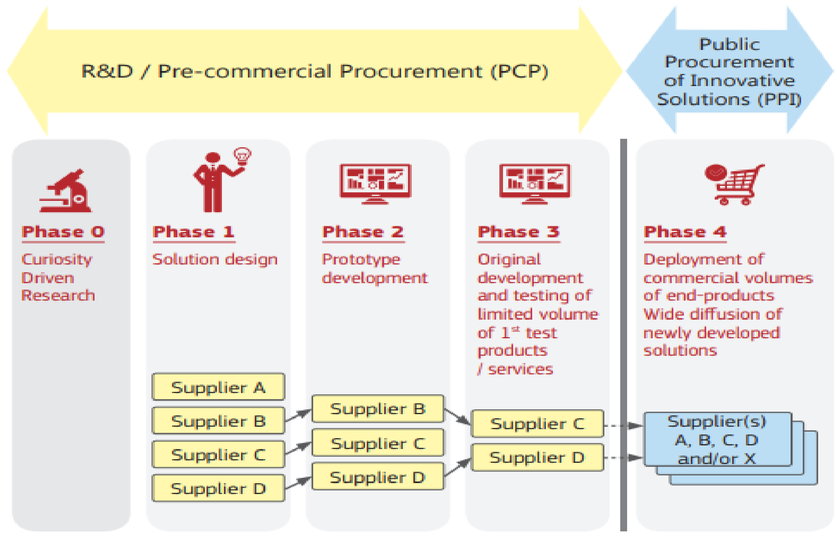


Figure 1: Schematic description of the main phases of the Pre-Commercial-Procurement (PCP), that could be followd by a Public Procurement of Innovative Solutions.
The whole process is a new tool for public and private entities (buyers) to drive innovation and procure innovative technologies designed according to their specific needs, by a continuous interaction with potential suppliers.

Materials and Methods

A public request for tender was issued in 2019 to identify the best value-for-money solutions among several competing suppliers. Six cross-border consortia composed of SMEs and technological centres participated to the call, from which four ended signing the PCP contract. The technologies proposed by two final consortia were finally selected as the most promising to address the needs of the procurers and to be assessed for performance in clinical setting.

The last piloting phase started on June 2021 and lasts 34 weeks, involving three pilot sites at the premises of Helios Klinikum, Germany (HELIOS), Provincia Autonoma di Trento, Italy (APSS), and Fundació Assistencial Mútua de Terrassa, Spain (MUTUA).

A list of recommendations and requirements for the best definition of the research protocol and the data management was defined by the lead procurer in collaboration with the pilot sites to address the two competing suppliers in the design of a multicenter clinical investigation protocol in line with GCP, ethics requirements and GDPR.

The AntiSuperBugs (ASB) project Framework design

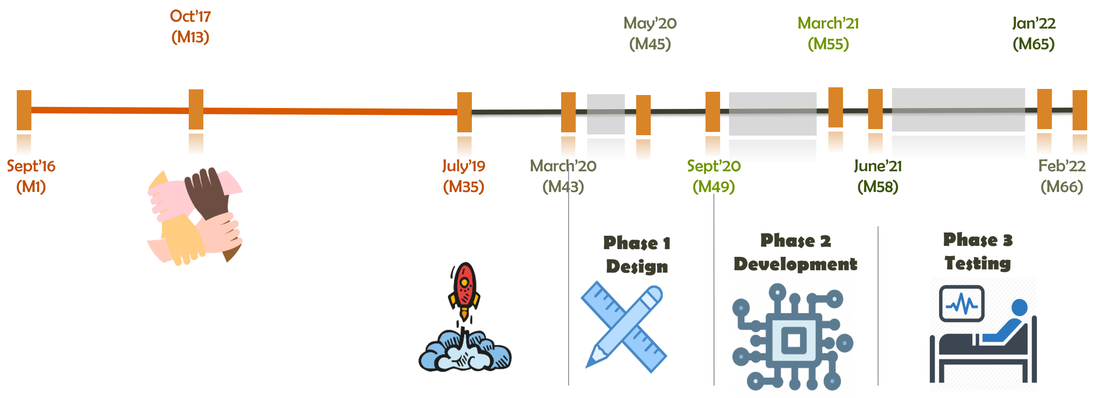
One joint PCP

1 procuring entity on behalf of the buyers group (AQUAS)

6 Commissioning Authorities (buyers group)

3 Pilot sites for field testing (part of the buyers group)

ASB-project timeline



The ASB solutions competing in Phase 3

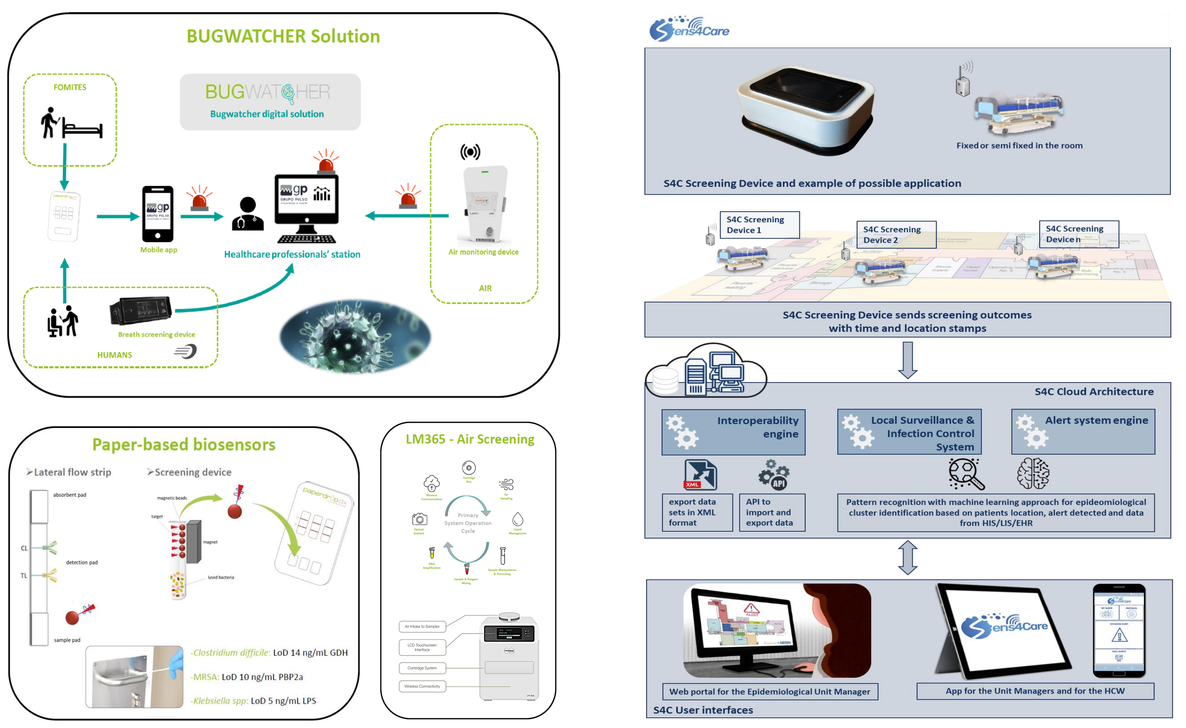


Figure 2: The Phase 3 competing solutions (BUGWATCHER, left and SENS4CARE, right) architecture and prototypes.

Results

The continuous collaborative interaction between procurers and suppliers, regulated by the terms of the request for tenders, provided a further opportunity of innovating the process of designing technologies for health according to the needs and priorities identified by the procurers.

Recommendations provided by the procurers to the suppliers to properly design their clinical investigation protocols included a common definition of primary and secondary study outcomes, the identification of two parallel study phases devoted respectively to testing diagnostic and screening performance of the prototypes, the minimum size of the study population, the clear identification of gold standard microbiological test to be performed as comparators, minimum number of prototypes per pilot sites and requirements for portability and non-intrusiveness, the need for caring about multilingual support trough the involvement of local CROs, and clear requirements about data protection and handling in agreement with GDPR with special provisions for correctly handling data within the supplier consortia, within the ASB project partners and in case open datasets are to be generated.

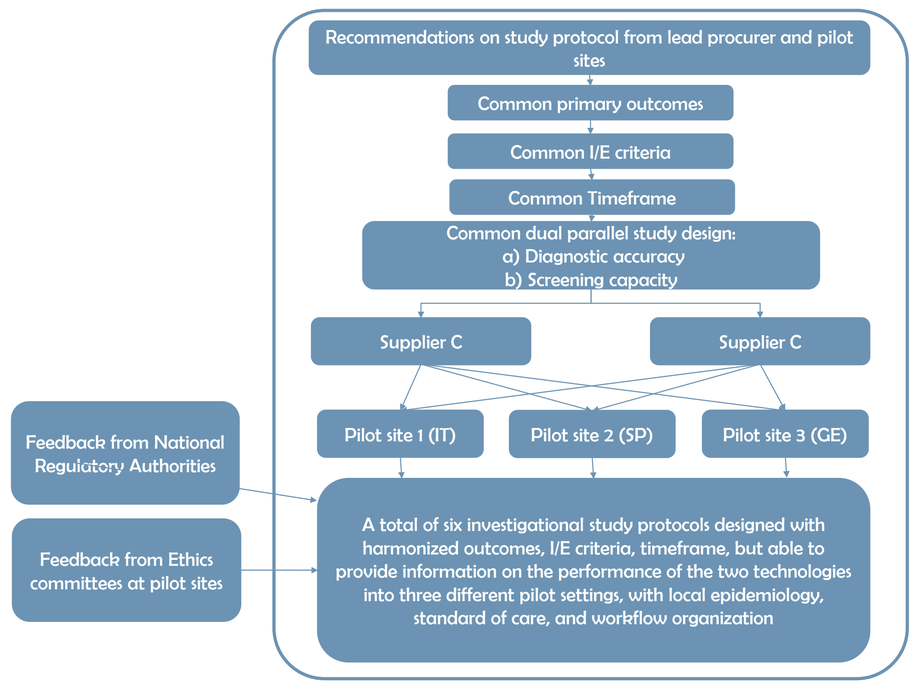


Figure 3: Flow-chart summarizing the main actions taken by buyers (pilot sites) and suppliers (competing for Phase III) to collaboratively proceed toward the completion of the Phase 3 clinical testing of the ASB technologies. All activities were performed within the the terms of the Call for tenders in the framework of the ASB PCP project.

Figure 4: The Phase 3 competing solutions installed at the three pilots sites (MUTUA, HELIOS, APSS) for the testing in the clinical field. The different technologies are visible in the circles

Conclusions

The testing in clinical settings of innovative technologies at a prototypical level poses several challenges including the complexity of properly classifying borderline devices as medical device, in vitro diagnostic tests or even electronic appliance. A joined effort has been performed by suppliers, acting as study sponsors; pilots sites, acting as procurers; ethics committee boards and National entities (e.g. Heath Ministry) to guarantee the best conditions allowing a rigorous testing of the innovative technologies in clinical setting preserving patient safety as well as allowing a quick testing of rapidly evolving and promising solutions for heath.

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