Grant Agreement no.: 688878

Technical Offer Assessment Report of the ANTI-SUPERBUGS PCP's submitted offers

File number: 3020170339

GENERAL INFORMATION:

- **Procedure:** Pre-Commercial Public Procurement
- **Tender budget:** 2,848,450.41 € (VAT excluded)
- **Maximum budget in the Phase "Call for Tender":** No monetary compensation at this stage
- **Date of publication of the Tender Announcement:** In the Public Contracts Platform website of the Government of Catalonia, 8 of July at 11.20 AM CET;
- **Last date for the submission of bids:** 28 of October at 13.00 CET.

BACKGROUND

The Envelope B ("Technical Offer") was opened by the Tendering Board at AQuAS headquarters on November 13th, 2019.

In agreement with section 4.2.2.3 of the Request for Tender (file name: Administrative Clauses), once opened, each technical offer was reviewed by three panels of 3 assessors of the Experts Board, in such a way that each Experts Board Panel includes at least one member of the Buyers Group (ICO, PAT, UKA, STH, HELIOS and FMT) and one external expert.

The Expert Board members were organized in the following Expert Panels:

I. Expert Panel 1:
- Mr. Francesco Tessarolo, Provincia Autonoma di Trento (PAT).
- Mr. Josep Trenado, Fundació Mutua de Terrassa (FMT).
- Ms. Sema Dumanli (Independent Expert).

II. Expert Panel 2:
- Mr. Beniam Ghebremedhin, HELIOS Universitätsklinikum Wuppertal (HELIOS).
- Mr. Dave Partridge, Sheffield Teaching Hospitals NHS Foundation Trust (STH).
- Ms. Meike Bomhof (Independent Expert).

III. Expert Panel 3:
- Mr. Enric Limón Cáceres, Institut Català d'Oncologia (ICO/VINCat).
- Mr. Vassilis Tsanidis (Independent Expert).
- Ms. Tram Trinh (Independent Expert).

All the panels assessed the technical offer according to the same evaluation criteria, based on the best value for money criteria. Each panel produced a report on each technical offer assessed, to be reached by consensus of the members of the panel.

The Expert Board adopts the following final assessment and scoring of the technical offers under the Criteria described in ANNEX VII.

RESULTS

The results are presented in two parts:

1. The Final Ranking scoring table
2. The technical offer assessment of each bidder
   a. TECH4CARE
   b. ERESULT S.R.L
   c. CULTURE (Bahia- Gradiant- INL)
   d. BUGWATCHER
   e. ASB-IMS2
   f. FASTINOV, S.A

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1. The Final Ranking Scoring Table

		Technical feasibility	ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority)	ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA	TECHNICAL/PERFORMANCE INDICATORS	ASB Volatile organic compounds detector COUID DTECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase)	ASB Volatile organic compounds detector COULD DTECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production	ASB Volatile organic compounds detector COUID DTECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance	ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling	ASB MUST comprise a local Surveillance & Infection Control System of the target microorganisms(s) able to store all the data and to export data sets	ASB MUST comprise an interoperability engine	ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any))	ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection	**Quality Plan**	**Business model & Plan**	**Financial feasibility**	Further Content (IPRs, ethics & security issues and % of R&D)	**TOTAL** ***(up to 90 points)***
1	Tech4care SRL	66,55	14,58	13,33	14,19	0,61	0,61	0,86	0,50	4,72	8,50	7,78	0,86	4,31	3,89	3,61	1,89	**80,24**
2	eResult SRL	61,51	13,75	12,50	12,98	0,53	0,53	0,67	0,11	5,00	7,00	7,56	0,89	4,17	3,19	2,78	1,33	**72,98**
3	CULTURE (Bahia-Gradiant-INL)	49,86	11,25	12,50	4,11	0,03	0,11	0,25	0,00	4,17	8,50	8,00	0,94	4,58	4,58	4,58	1,89	**65,50**
4	BUGWATCHER	47,27	8,75	10,00	13,00	0,00	0,00	0,00	0,42	4,72	5,75	4,22	0,42	4,58	4,58	4,03	1,83	**62,30**
5	ABS-IMS²	37,20	8,33	10,42	5,87	0,03	0,00	0,17	0,00	2,78	4,25	4,89	0,47	2,64	2,22	1,94	1,17	**45,17**
6	FASTINOV SA	4,70	2,50	Criterion NOT reaching the minimum	1,76	0,00	0,08	0,36	0,00	Criterion NOT reaching the minimum	Criterion NOT reaching the minimum	Criterion NOT reaching the minimum	0,00	2,36	3,75	2,92	0,94	**EXCLUDED**

Technical Offer Assessment - Summary

Bidder/s Tech4care SRL **Overall Score (up to 90 points)** **80,24**

I. Technical feasibility 66,55 / 73 points

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority) **14,58 / 15 points**

Technical feasibility is well defined and detailed.

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA **13,33 / 15 points**

Risk management needs to be detailed in terms of the MUST HAVEs (K.pneumoniae and MRSA)

TECHNICAL/PERFORMANCE INDICATORS **14,19 / 16 points**

The bidders do define the unmet needs and UCS of ASB, feasibilities should be more comprehensive and discussed along with the risks.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase) **0,61 / 1 point**

The technology requirements are considered. Additionally, the bidders propose a technique that enhances technic scattering by molecules (e.g. nucleic acids) adsorbed on surfaces, additional to VOC, which enables the detection different bacteria and their antimicrobial resistances.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production **0,61 / 1 point**

Citation: ASB ICT Solution COULD detect antibiotic resistances (carbapenem & ESBL production) in the contaminations/colonisations of fomites and inanimate hospital environment from Klebsiella pneumoniae. ASB ICT Solution COULD detect the contaminations/colonisations of fomites and inanimate hospital environment from any additional Gram-negative pathogen or any additional resistance. The requirement is not satisfactorily addressed...more details of the technical feasibility is expected and would be convictive for achieving the aims of the bidders.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance **0,86 / 1 point**

The requirement is not enough addressed. The technical approach should contain more details to rather follow the plan of the bidders.

ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling **0,50 / 1 point**

Technical approaches for the detection of the pathogens seems to be more detailed than the connectivities to to ICT. Therefore, the entire feasibility to develop the prototype is doubtful.

ASB MUST comprise a local Surveillance & Infection Control System of the target microorganism(s) able to store all the data and to export data sets **4,72 / 5 points**

This proposal lacks the risk management for the surveillance and infection control system of the targeted pathogens.

ASB MUST comprise an interoperability engine **8,50 / 9 points**

All the data exchange will be guaranteed by the interoperability engine. Specific process (as in case microorganisms' identification at molecular level) will be designed during phase one in order to provide a reliable data model and subsequent automatized time stamp features. The bidders should detail the risk assessment for this issue.

ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any)) **7,78 / 8 points**

The required elements are sufficiently addressed, but not totally satisfactorily.

ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection **0,86 / 1 point**

The bidders state that the ASB ICT Solution MUST interoperate with existing technologies/products/platforms/systems/developments and will enable alerts. However, more comprehensive risk management is of need.

II. Quality Plan **4,31 / 5 points**

The bidders did sufficiently detail the information about risk assessment and mitigation strategies (pages 28-31).

III. Business model & Pla **3,89 / 5 points**

The analysis of exploitability costs needs more details (sub-chapter 7.3)

IV. Financial feasibility **3,61 / 5 points**

Citation: At least eight intra-EU travels , 1.3% of costs will be allocated to ICT services. All costs will be incurred in EU countries and concern only items/products needed to address the ASB PCP challenge and to deliver the R&D services described in the request for tenders. But one can hardly see any description of the analysis of the business, marketing and sales plan costs structure in details, that is also true for the financing plan of the proposed solution...no tables, no graphs, no schematic / illustrative examples.

V. Further Content **1,89 / 2 points**

The total value of products offered in Phase 1 and Phase 2 is significantly lower than 50% of the value of the Phase 1 and 2 contracts. The evidences for these elements are rather incomprehensively described (patient data safety while bidirectional transfer etc.).

Technical Offer Assessment - Summary

Bidder/s eResult SRL **Overall Score (up to 90 points)** **72,98**

I. Technical feasibility 61,51 / 73 points

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority) **13,75 / 15 points**

The proposal sufficiently addresses the application of VOC-based identification of the MUST HAVE pathogen in details for all the elements 1-3.

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA **12,50 / 15 points**

All the elements 1-3 are sufficiently addressed

TECHNICAL/PERFORMANCE INDICATORS **12,98 / 16 points**

The bidders suggest solutions for the unmet needs & use case scenarios and the ability to achieve the large majority of the committed values. The technological feasibility is good, the development plan is clear and comprehensive. However, risk management is rather weak.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase) **0,53 / 1 point**

Citation: ….detect other pathogens by characterizing the peculiar chromatograph of spores and toxins. The bidders allude different technical approaches for the VOC detection. However, the risk management lacks mandatory details towards the specific detection of contamination/colonization with C.diff. (spores, toxins).

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production **0,53 / 1 point**

The risk management did not focus the antimicrobial resistance. Therefore, element was not sufficiently described.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance **0,67 / 1 point**

The work will be facilitated to extend the detection capability of our system in regard to additional Gram-negative pathogen or any additional resistance. We admit that the risk management was not directly described for these issues, but in general. The technology works for other bacteria if it functions for K. pneumoniae or S. aureus. The bidders do have detailed few risk potentials mitigation likelihood and the contingency plan for alternative approaches to detect the bacteria.

ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling **0,11 / 1 point**

We cannot conclude proposal the bidders' proposal that the nucleic acid-based detection methods for the microorganisms via non-invasive sampling is achievable.

ASB MUST comprise a local Surveillance & Infection Control System of the target microorganism(s) able to store all the data and to export data sets **5,00 / 5 points**

The local surveillance and infection control system of the MUST HAVE pathogens is able to store the data and bidirectional data transfer (incl. different file formats) is aimed (more than a page). They also address the NICE TO HAVE technical specifications for use case scenarios (ca. one page). Possible main risks to be managed are detailed in a table on pages 24-25.

ASB MUST comprise an interoperability engine **7,00 / 9 points**

Development of the interoperability platform for interfacing with VOC detector is described in the proposal. The risk management needs additional details. Especially, potential technical obstacles are not fully explored in the risk assessment.

ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any)) **7,56 / 8 points**

The risk management needs additional details. Especially, potential technical obstacles are not fully explored in the risk assessment.

ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection **0,89 / 1 point**

The bidders intend to apply Big Data paradigm to the ingestion of large volume of data from devices in real time mode. Server platform will store all screening data with details (page15). The schemes and illustrations in the proposal visualize the big data pyramid which covers data engineering, data science and analytics activities. The bivalent proposed system will detect fomites both in patients and in inanimate environments and in case of contamination/colonization, the system will transmit an alert according to the rules set forth in a specific configuration table previously populated by function masks. It will also send out alerts to the connected HIS/LIS/EHR systems.

II. Quality Plan **4,17 / 5 points**

QUALITY PLAN including the MANAGEMENT STRUCTURE, MILESTONES AND PROCEDURES and RISK MANAGEMENT are sufficiently detailed.

III. Business model & Pla **3,19 / 5 points**

SWOT Analysis of the related business is provided in the proposal. However, the elements 2 & 3 are marginally addressed, especifically risk management should be detailed.

IV. Financial feasibility **2,78 / 5 points**

Costs for the marketing, investments and sales plan structure are not sufficiently detailed.

V. Further Content **1,33 / 2 points**

The security issues and evidence that at least 50% of the proposal regards R&D service are not well detailed. No security issues apart from bacteria manipulation or classified information are foreseen.

Technical Offer Assessment - Summary

Bidder/s CULTURE (Bahia-Gradiant-INL) **Overall Score (up to 90 points)** **65,50**

I. Technical feasibility 49,86 / 73 points

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority) **11,25 / 15 points**

The offer presents a clear explanation of the background R&D that plans to be based upon. It also provides a comprehensive State of the Art analysis highlighting the limitations that the existing solutions present in relation to the buyer's needs. The progress beyond the State of the Art by addressing the existing limitations through the development of the Culture innovative solution is clearly explained. The offer allows for the detection of certain microorganisms based on their gaseous byproducts, but it is also necessary to specify if the spores are also included in that detection, and in the offer there is no reference to the detection of spores and their VOC profile. The required tech specifications are addressed, but the risk mitigation plan and the development plan are not sufficiently described.

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA **12,50 / 15 points**

The offer presents a clear explanation of the background R&D that plans to be based upon. It also provides a comprehensive State of the Art analysis highlighting the limitations that the existing solutions present in relation to the buyer's needs. The offer justifies the detection system based on VOC of several microorganisms and some resistant mechanisms and uses gaseous profiles as the definition of such microorganisms (with literature research that validates their claims). However, even though MRSA is mentioned, most of the explanation and justification is done towards the two other microorganisms (C. diff. and Kleb. pneumoniae). There is a lack of how the different microorganisms will be characterized and how the detection of such microorganisms, specifically, will be made. The technological risk management is addressed.

TECHNICAL/PERFORMANCE INDICATORS **4,11 / 16 points**

The offer defines a research of industrial design in a prototype-testing phase. Therefore, the technology has been adapted to show off its detection capabilities and how it is ready for the market. However, the fact that it is in this early phase means there are no percentages regarding the requested requirements. The offer is viable but has no backing regarding its use. Despite this, the antibiotic optimization program is integrated in plus the patient manager leads us to believe the knowledge in the area and the acknowledgement of the professional's needs is clear. The development program is also adequate and provides a real possibility of establishment of the technology in the clinical environment. There is no risk management analysis tailored to the achievement of the technical/performance indicators of the developed through the PCP innovative solution.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase) **0,03 / 1 point**

The capability of toxin detection is not described in this offer and, although spore detection is mentioned as one of the objectives of joining this tender, no further commitment is made.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production **0,11 / 1 point**

Carbapenemase and ESBL were not addressed in this proposal, however, the offer does mention that its plan is to combat resistances by including antimicrobial information in a surveillance system that will be able to monitor the efficacy of the actions taken against the detections of the microorganisms the offer commits to detect (i.e Klebsiella pneumoniae, Clostridium difficile and Staphylococcus aureus (MRSA)).

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance **0,25 / 1 point**

The offer mentions it's already possible to detect several microorganisms, such as Staphylococcus aureus, Streptococcus pneumoniae, Enterococcus faecalis, Pseudomonas aeruginosa, Klebsiella pneumoniae, and Escherichia coli, via their VOC signatures. However, as it is stated in the offer, the focus will be on the priority multi-resistant microorganisms defined in Section 3 of the Challenge Brief (i.e Klebsiella pneumoniae, Clostridioides difficile and Staphylococcus aureus (MRSA)). Regarding the resistances, seeing as the offer evaluates the gaseous byproducts to identify the microorganisms, but not the resistant ones, it remains unclear whether they will analyze or detect resistances.

ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling **0,00 / 1 point**

The offer does not mention the ability to detect nucleic acids or any other enzymatic complexes.

ASB MUST comprise a local Surveillance & Infection Control System of the target microorganism(s) able to store all the data and to export data sets **4,17 / 5 points**

One of this offer's strongest points is its Surveillance and Infection Control System. The continuous monitoring of the environment along with a patient management system is very valuable. The offer's engine contemplates the possibility of interoperability and ease of communication, seeing as it'll be fluent in most used data formats, between these two systems: monitoring and patient management. Healthcare workers are treated as consulting agents regarding the management of the alert system. The offer demonstrates knowledge of the management of MDROs because of the concept that is used: "lifecycle of the alerts". They stratify the risk of infection in patients based on a checklist. The offer contains sufficient information on the local Surveillance and Infection Control System especially on the background R&D, the current State of the Art and how it will go beyond it. The development and risk plans seem incomplete.

ASB MUST comprise an interoperability engine **8,50 / 9 points**

The offer's engine contemplates the possibility of interoperability and ease of communication, seeing as it'll be fluent in most used data formats, between these two systems: monitoring and patient management. There is a self-explanatory diagram in the offer that shows the connections made between the VOC device, the surveillance system and the healthcare workers. The experience the companies in this offer confirms its viability seeing as they collected all the necessary options for the system to be interoperable via the specified engine. The proposal indicates a system with a three-dimensional interoperability: technical, syntactic and semantic. Interoperability standards comply with a the module to provide an extensive variety of connectors and a custom connector to adapt new standards as HL7 easily. The members explicitly list the targetted information systems used by different healthcare organizations to interoperate (such as Health Record -EHR-, Electronic prescribing -eRx-, Microbiology Laboratory Information System -LIS-, etc.).

8,00 / 8 points

ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any))

The team is knowledgeable in multiresistant management and the industrial research senior team's previous research is robust, and, therefore, new advances can be planned to address the clinician's needs. Integration architecture is well-described and thought out and the amount of variables able to be correlated in time and space make it a very interesting proposition. The offer provides satisfactory information on the definition of alerts, priority assignment and alert tracking. There are technological and risk management options presented in the offer.

ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection **0,94 / 1 point**

A checklist was made to stratify the risk of infection. An algorithm is necessary to prevent that the sole presence of a microorganism in the environment is enough to generate an alert. Therefore, a patient triage based on risk of infection would be optimal. Because of their knowledge in the surveillance of MDROs, there is a planned continuous review of the scoring system that will be determined by the patient and center description and characteristics. The data capture to alert programming and interfacing with existing hospital ICT systems is well articulated. The risk mitigation plan needs to be detailed further.

II. Quality Plan **4,58 / 5 points**

The offer shows the description of all the necessary data to evaluate the viability of the project on several levels: management, adaptability and schedule. Project governance, project management and change management are described in sufficient detail with clear role allocations (e.g clear tasks for the project coordinator, the project manager etc.) and there is a note regarding the confidentiality of the clinical data. The project includes gender research: "The objective is to maintain, and if possible, increase, the participation rate of women throughout the Project". There is a detailed quality monitoring plan that is based on a set of KPIs. The selected KPIs cover the whole spectrum of the solution design and development (e.g regulatory and legal aspects). Some minor inconsistencies are present in the total duration of the project when matched with the PCP's timeline, requiring the technology validation at buyer sites to go beyond the proposed months. There is a clear risk assessment and risk mitigation strategy.

III. Business model & Pla **4,58 / 5 points**

The business plan is well described, as are the investments that were made so that the project can be commercialized, but it is somewhat incomplete regarding the value proposition and targeted go-to market (customer segments, channels and relationships) along with the future activities of the entity. The analysis of the exploitability of costs is presented in sufficient detail. It lacks however information on some aspects (e.g cost for the protection of IPRs). A SWOT analysis was present. The offer presents a business model definition that is based on a SWOT analysis containing sufficient detail. There is also a thorough business plan that explains how the innovative solution will be commercialized. Risk management in case the investment is not accomplished would be necessary.

IV. Financial feasibility **4,58 / 5 points**

The offer contains sufficient explanation on the different types of expenditure stressing that staff costs will be the main category of expenditure (71% of the total PCP costs). Work management from each partner is well established, with two subcontracting activities planned which fall outside the capacity of the members: CROs. It is highlighted that the majority of the activities (86% in average for all PCP phases) will be R&D services. The SWOT, market potential, sales forecasts and selling offer are described but the business model value proposition and targeted go-to market (customer segments, channels and relationships) along with the future activities of the future entity are incomplete.

V. Further Content **1,89 / 2 points**

The offer will apply for a Class 2b medical device, following the CULTURE protocol. There is confirmation that the confidentiality of the clinical data will be followed. The offer contains a section with sufficient detail on the background IPRs that are relevant to the tenderers proposed solution. All the legal requirements are fulfilled. It is necessary, however, to understand what the legislation is regarding paying a prototype that has not been tested at all, because of the possible risks, be they health or environmental. Although the Ethics protocol of the offer does not start with the question "Does this tender involve ethical issues (Yes/No)", as the template requests, there is a self-assessment on the ethical issues that may be arise. Furthermore, the offer contains enough information on how the ethical issues will be addressed (e.g appointment of ethics manager). The offer contains a section on the security issues protocol that - as it happens with the ethics protocol - does not start by answering the following question "Does this tender involve...." as the template requests. There is, however, info on a self-assessment that there will be no security issues. There is information on the % of the activities that could be regarded as R&D services (85%) as well as confirmation that items/products included in all 3 offered services in all PCP phases will be needed to address the challenge in question and deliver the R&D services. There is also information on the estimation of the budget % allocated to consumables (only in phase 1 and 2 of the PCP). Some points of element 4 must be developed further.

Technical Offer Assessment - Summary

Bidder/s BUGWATCHER **Overall Score (up to 90 points)** **62,30**

I. Technical feasibility 47,27 / 73 points

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority) **8,75 / 15 points**

The offer describes the detection system as one capable of volatile detection via microorganism-specific cartridges. Due to it being a system based on two mechanisms of detection, it would be possible for this offer to analyze both the air and direct samples from patients, such as urine, salive, blood and sweat, and detect the microorganisms it commits to. The system addresses both air monitoring to detect VOCs with its sensor and device, and screening patients through paper-based sensors composed of nanomaterials which are very effective methods. Surface-based sensors such as the surface plasmon resonance are compact, versatile, respond in real time, can be fabricated at low cost, and do not require molecular labeling. According to the offer, the two mechanisms will be cross-checked for every sample, meaning there will be a need for a technical healthcare worker to be able to collect the sample, analyze it, interpret it and report it. Spore detection is not mentioned in this document. A technological development and risk plans are present and clear.

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA **10,00 / 15 points**

According to the offer, all microorganisms requested by the PCP will be monitored. The offer describes the detection system as one capable of volatile detection via microorganism-specific cartridges. Due to it being a system based on two mechanisms of detection (one uses cartridges while the other uses reactive strips), it would be possible for this offer to analyze both the air and direct samples from patients, such as urine, salive, blood and sweat, and detect the two microorganisms. According to the offer, the two mechanisms will be cross-checked for every sample, meaning there will be a need for a technical healthcare worker to be able to collect the sample, analyze it, interpret it and report it. The technological development plan is well structured and described and there is a risk management description, albeit more detail is needed.

TECHNICAL/PERFORMANCE INDICATORS **13,00 / 16 points**

The offer bases its R&D on the development of cartridges for the devices that are already available in the market. The offer focuses on the development of three new cartridges that will allow for the detection of the microorganisms mentioned in this tender. The offer also determines the use of nanosensors, as stated in the literature, that will detect the three microorganisms via the detection of specific biomarkers. The system requires patient collaboration and a technician to be able to do the test, gather the results and interpret them. These results must then be added to the system and a complementing detection in the hospital's hygiene system. The software this offer mentions will unify these results and present a single read. The offer mentions 100% percentages regarding the detection of microorganisms and the detection of the requested microorganisms and given square meters of distance in detection. The time of detection varies depending on the specific use-case. Future commitment is bold and feasible.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase) **0,00 / 1 point**

The offer does not mention in any part of the document that it will be able to detect spores or toxins from C. difficile.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production **0,00 / 1 point**

The offer does not mention it will be able to detect any resistant forms of the mentioned microorganisms.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance **0,00 / 1 point**

The offer does not mention any type of possibility to detect additional resistances or, specifically, any extra gram-negative microorganisms.

ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling **0,42 / 1 point**

The offer mentions the ability to detect a target DNA biomarker and, "by means of new nanomaterials currently under development", to decrease the amount of sample needed to detect the target microorganisms it is already able to detect. The detection will be made via paper-sensors on non-invasive samples. There are development and risk management plans present in the offer.

ASB MUST comprise a local Surveillance & Infection Control System of the target microorganism(s) able to store all the data and to export data sets **4,72 / 5 points**

The offer states that there will be a software platform connected to the internal HIS/LIS/EHR which will receive alerts based on the information input in the devices after colonization/contamination has been detected. The process of continuous surveillance and preventive actions seems well-crafted.

ASB MUST comprise an interoperability engine **5,75 / 9 points**

Interoperability is mentioned but not detailed. The proposal comprises an interoperability engine using various standards for the integration with the HIS and other ICT systems of the hospital. These companies have experience in integrating technologies in clinical environments. Their clinical experience allied with their PCP knowledge and experience allows for an offer that could be well integrated in the HIS/LIS/EHR, which they mention will be via specific software design, albeit with the limitation that it's all dependent on the technician. Sufficient details of how the engine is going to operate are provided for this stage of the procurement. The consortium is also aware of the challenge of multi-language interoperation and and the fact that some functionalities should be adapted to each different hospital. Although a development plan tailored to the integration engine is incomplete, there is reference to technological risk management of this matter.

4,22 / 8 points

ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any))

The offer states that an alert will be generated by the introduction of a detection by the technician in the technology, which will be directly connected to the HIS. It notifies the HIS and also uses the location record to gather further information on the outbreak. However, it does not use the existing data in order to assess the risk of infection. The information flow is mainly one-way. The offer lacks sufficient detail on the background R&D that the alert system will be based upon, the SoA and the relevant clinical situations.

ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection **0,42 / 1 point**

This requirement is addressed in the proposal. However, the proposal platform does not utilize all the existing resources in order to assess the risk of infection. It mainly relies on the freshly collected data coming from the proposed sensors. Cloud-based software, daily reports with current level of risk and automated detection reports and analysis are briefly mentioned but need to be comprehensive.

II. Quality Plan **4,58 / 5 points**

The project management's description is quite good, albeit slightly too personalized regarding some of the participants' previous experiences. This project will have a long lifecycle pre- and post-production. The fact that they already have an agreement with a multi-national company regarding the sale of their device gives the offer a lot of credibility. Strong project management team and thorough analysis of the solution design and development plans that include compliance and regulation approvals, as do the risk assessment and mitigation strategies. A clear Gantt diagram is proposed, however, no time-points are set for deliverable and milestones.

III. Business model & Plan **4,58 / 5 points**

The experience of the partners present in this offer shows as they present their business model and inherent risks. The presented plan not only highlights the virtues of the offer but also evaluates the risks commonly associated to a project of this caliber. The offer presented a SWOT diagram and a Business Model Canvas. The offer presents a clear business model definition and a convincing preliminary business plan. It lacks, however, details on cost exploitation (e.g there are no costs for IPRs protection, maintenance, scale up production costs etc.). Business model canvas needs additional work. Once the paying targets are well identified, the specific criteria for selecting commercial channels (not just our identified distributor is present in X countries in healthcare) will need to be defined and a more thorough list of options for GTM needs to be established.

IV. Financial feasibility **4,03 / 5 points**

Sufficient description of R&D costs analysis and business, marketing and sales plan costs structure, but the financing plan needs to be more robust.

V. Further Content **1,83 / 2 points**

All the elements are considered. The proposal states that 72.30% of the overall project costs regards R&D services. However, no specific references are provided to show that the proposal match the definition offered by both the OECD Frascati Manual standard definition, 2015 Edition, and Article 2.1 (22) of Directive 2014/24/EC. The total value of products offered in Phase 1 and Phase 2 is claimed to be 28%, and that is significantly lower than 50% of the value of the Phase 1 and Phase 2 contracts. Also the total value of products offered in all Phases 1, 2 and 3 is 27.3%, which is significantly less than 50% of the total value of the PCP framework agreement. Security issues appears to be easily handled by the consortium while taking into consideration the design of the proposed technology. Ethic aspects are sufficiently considered and an ethics checklist is included in the proposal.

Technical Offer Assessment - Summary

Bidder/s ABS-IMS²

Overall Score (up to 90 points) **45,17**

I. Technical feasibility

37,2 / 73 points

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority) **8,33 / 15 points**

Must have tech specifications are addressed for C. difficile. However, no specific details are provided for the C. difficile spores detection. References to the literature are made to contextualize the technology and its possible use. Use-case scenarios on the collection of the samples and the technical specifications and requirements for the sampling methods and the VOC profile are present, however, a technological development plan and risk management is poorly described, as are the technical specifications and requirements.

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA **10,42 / 15 points**

The requirement is addressed for both Klebsiella pneumoniae and MRSA. The proposal describes how the technology will address the must have tech specifications and requirements. However, it is not specified which kind of volatile organic compounds will be detected for each microorganism. Technological development plan is sufficiently detailed but technological risk management is not included in the proposal. The proposed technology is based on the current state of art and aims to go beyond it allowing the detection of the target microorganisms. The technology is based on VOC detection as requested by the call for tender, but the technical specifications and requirements are not described in details.

TECHNICAL/PERFORMANCE INDICATORS **5,87 / 16 points**

The proposal demonstrate Bidder's understanding of ANTI-SUPERBUGS unmet needs & use case scenarios and its ability to achieve the majority of the committed values. The technological feasibility is good, the development plan is present but not enough details are provided. Risk management is not sufficient. Estimated tourn around time is reported and is of interest for the ASB applications. Moreover, a non exhaustive analysis of possible detection bias or errors is present.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase) **0,03 / 1 point**

The requirement is partly addressed via the explanation of the technical specifications for the infected/colonized patients and contaminations on surface. However, there is no description of how the VOC offer will detect spores or toxins from this microorganism.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production **0,00 / 1 point**

There is no description of how the VOC offer will detect the resistant forms of this microorganism. Even though there is some allusion to the state of the art, there is no real development of the idea or the research behind the necessary claims.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance **0,17 / 1 point**

This requirement is poorly addressed. The technology appears to be suitable to be extended to the detection of other potential multidrug resistant microorganisms in the future, but no information is provided on how this requirement could be addressed by the bidder.

ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling **0,00 / 1 point**

According to the offer, the detection will be made via the VOC profiles of the microorganisms rather than via any enzymatic or proteic detection. The detection of nucleic acids, be it enzymes, proteins or aminoacids is not contemplated in the offer.

ASB MUST comprise a local Surveillance & Infection Control System of the target microorganism(s) able to store all the data and to export data sets **2,78 / 5 points**

The offer proposes the use of an integrated surveillance system that will address data storage and exportation expertly and fluently and presents a sufficient overview of the background R&D, the SoA and how the developed solution will go beyond it. The consortium has a strong partner to handle the data storage with a proven track record. They have ensured that the EU General Data protection regulation will be adhered to. Point 3 is not addressed.

ASB MUST comprise an interoperability engine **4,25 / 9 points**

The offer shows commitment towards a system that will be able to interoperate with HISs, allowing it to be a bridge between the presented technology and the ones already in place at hospitals. The offer describes the system and how it will connect and store data in HISs, devising a technological development plan that pertains to the system's capabilities. Despite all this, the offer does not thoroughly address the way in which it will be compatible with other systems.

ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any)) **4,89 / 8 points**

The offer describes an alert system and commits to how it will be integrated in the healthcare workers' daily workflow. The system links to the different IT platforms, could be adjusted to the already exsisting systems and is capable to assess the riks for infection or colonization. However, the background R&D and the SoA on the matter is insufficient, making it unclear how the alert system will work in details and how it will affect the HIS. Technological development plan and technological risk management are not sufficiently addressed.

ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection **0,47 / 1 point**

The offer mentions a possible risk algorithm that, if well applied, could have an impact in the local hospital where it is integrated. However the document do not explain in sufficient details how the technology will address performance requirements related to the implementation of a system capable to assess the risk of infection. The risk assessment aspect has not been thoroughly discussed. The link between the existing health records and the monitored data is planned to be established. However, the proposal lacks details of how it is going to be tackled.

II. Quality Plan 2,64 / 5 points

The requirement is addressed in part. The work plan is well structured in three phases and adherent to the ASB PCP phases and time plan. Task, deliverable and milestones are provided for each phase. A clear Gantt diagram is proposed. However, risk assessment and mitigation strategies are not reported. There is no information on change management, Moreover phase three of the project, consider the installation of the technology in only two clinics among the buyer network, thus limiting testing in different settings. The description of the quality aspects of the solution design and development lacks sufficient detail (e.g. there is no detailed reference to the verification and validation of the proposed technology, personal and material resources, regulatory and legal aspect etc.). Risk assessment and risk mitigation strategies are not addressed.

III. Business model & Plan 2,22 / 5 points

The business model plan is reported. However, the offer lacks sufficient detail on business model definition (e.g absence of a business model canvas, SWOT analysis or detalied definition of the competitive advantage and value proposition). Although some general data on the potential market of the solution are present, the commercialization process is not detailed enough (e.g lack of info on pricing strategy, commercial alliances, distribution, etc.) . There is a high level estimation on the budget that is needed to achieve full scale commercialization but the offers lacks detail on the analysis of these costs (e.g patent cost, licenses, certification, ect.) There is a reference to a US and European patent at the end of the project but it lacks further detail (cost, process etc).

IV. Financial feasibility 1,94 / 5 points

The offer provides information on the R&D services costs as % of the total bid (this figure is not the same however in all parts of the offer). However, the document does not provide sufficient detail on the categories of the expenditure. The provided information is limited only to the subcontracting costs allocation - there is no comparison with other types of expenditure. The offer does not compare current methodologies with their own. There is no cost discrimination regarding the analysis of current antibiotic stewardship and the offer's implementation. Point 2 is not addressed in the offer. The information for point 3 is provided in superficial manner.

V. Further Content 1,17 / 2 points

The offer presents a list of background IPRs and open source databases. There is an ethics protocol reported, however it lacks of some essential details (e.g in phase 3 of the PCP it is assumed that the hospitals' ethics committee will allow the tests - there is no risk assessment/mitigation). The offer contains a security issue protocol. Although it is declared that the PCP will not raise any security issue, the offer lacks sufficient detail on how security issues may be tackled in case they arise. There is an inconsistency in the amount of the % of the offer for the R&D services among different sections of the document. Although it is derived from the rest of the figures that the majority of the PCP activities will be R&D services - there is no presentation on how these activities (presented as R&D services) match the OECD definition and the definition of the Directive 2014/24/EC.

Technical Offer Assessment - Summary

Bidder/s FASTINOV SA **Overall Score (up to 90 points)** **EXCLUDED**

I. Technical feasibility 7,12 / 73 points

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Clostridium difficile spores and/or microorganism (spore detection is considered of higher priority) **2,50 / 15 points**

The offer does not provide sufficient information regarding the contamination/colonisation of C. difficile. The offer plans to apply the same methodology they applied to blood samples in urine samples, however, the detection of spores is not contemplated on the document and neither is the microorganism, even though the group of microorganisms it belongs to (Gram-positive bacteria) is mentioned as detectable. No mention is made to any species of Clostridium in this Gram-positive detection, rather, only Gram-positive bacteria. The technological development plan exists but lacks sufficient detail. There is no technological risk management approach.

ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from Klebsiella pneumoniae OR/AND ASB Volatile organic compounds detector MUST DETECT the contaminations/ colonisations from MRSA **Criterion NOT reaching the minimum / 15 points**

The technology does not perform detection of microorganisms, but provide antibiotic susceptibility testing (AST) to already isolated microorganisms. More specifically the bidders do not commit to detecting via VOC, rather, via urine, even though it does detect these microorganisms. The document do not indicate how to detect Klebsiella pneumoniae. The technological development plan exists, but is not directed at the requested technology by the ASB team. There is no technological risk management approach.

TECHNICAL/PERFORMANCE INDICATORS **1,76 / 16 points**

The offer specify the turn around time for AST, but is lacking of information about detection of the microorganisms of interest. Sensitivity and specificity data, although of relevance, are referred only to AST testing phase. The categorical agreement with reference methods found in EUCAST and CLSI is of over 90%, with most major errors revolving around 0,02% of the samples. There is no distance detection due to the fact that the offer is dependent on contact with a physical sample. The technological development plan exists, but is not directed at the requested technology by the ASB team. There is no technological risk management approach. Development plan is sufficiently structured.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Clostridium difficile Spores, Toxins A and B, and Binary toxin (transferase) **0,00 / 1 point**

The detection of toxins and spores of Clostridium difficile is not mentioned in the offer.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from Klebsiella pneumoniae Carbapenem & ESBL production **0,08 / 1 point**

The offer is not a VOC sensor, but the document mentions the possibility of detecting resistance mechanisms in gram-negative bacteria. Although point 1 is sufficiently described, the rest is not. Resistances are mentioned but are not applied to the specific microorganism; rather, the offer generalizes this detection with the use of a specific device for the detection of resistances in urine. The technological development plan exists, but is not directed at the requested technology by the ASB team. There is no technological risk management approach.

ASB Volatile organic compounds detector COULD DETECT the contaminations/ colonisations from any additional Gram-negative pathogen or any additional resistance **0,36 / 1 point**

The proposed technology aims to detect a large amount of other Gram-negative bacteria. The addition of extra resistances and gram-negative pathogens is not contemplated in the offer, albeit it already covering a vast number of both, though such requirements are not a part of this tender.

ASB ICT Solution COULD detect nucleic acid-based detection of the target microorganisms using non-invasive sampling **0,00 / 1 point**

The offer does not mention the detection of nucleic acid-based, enzyme, protein or aminoacid detection of the target microorganisms, though the sampling method, if we consider the urine sampling, is non-invasive. According to the document, the offer is based on using large quantities of bacteria, which then, via fluorescent probes, are determined as a specific microorganism based on the cell lesions caused by antimicrobials

ASB MUST comprise a local Surveillance & Infection Control System of the target microorganism(s) able to store all the data and to export data sets **Criterion NOT reaching the minimum / 5 points**

A software components realizing the automatic analysis of the flow cytometry data is described, giving possibilities for further software enhancements. However, no specific tools for local surveillance and infection control system are described. The offer does not describe how the results will be integrated in the HIS, or into the clinical hospital workflow. All controls appear to be focused on the patient, the antibiotic therapy and the collected samples

ASB MUST comprise an interoperability engine — **Criterion NOT reaching the minimum / 9 points**

Interface link to various laboratory information systems and quality control features is reported but not sufficiently detailed. More specifically, the offer does not demonstrate that the proposed solution can be interoperable with HIS systems or that it will be, even though integration in the hospital environment has already been done previously with a similar device.

ASB MUST comprise an alert system engine (it generates alerts, based on the information retrieved by the screening device, to be sent to the HIS/LIS/EHR/users and it interoperates with existing technologies/products/platforms/systems/developments capable to assess the risks of infection (if any)) — **Criterion NOT reaching the minimum / 8 points**

The offer does not describe how the proposed system will generate an alert and, therefore, a surveillance mechanism, nor how it will define the different alarm coding necessary to handle patients. The technology is described as an isolated system not integrated into the overall IT system of the hospital.

ASB COULD comprise existing technologies/products/platforms/systems/developments capable to assess the risks of infection — **0,00 / 1 point**

The offer does not determine any way of calculating the risk nor what is the clinical algorithm that determines the collection of the samples, only when there is already a determined risk by a previous test (e.g. resistance detection) does the offer mention how to proceed (in this case, towards another technology called FASTInov FAST MAR). The overall system within hospitals is not capable of assessing the risks of infection at a hospital level.

II. Quality Plan — 2,36 / 5 points

The overall quality plan is well conceived, but do not fit the objectives of the ASB PCP call for tender. The validation of the prototype is planned to be performed only on residual urine samples. Validation of the prototype is expected to be performed at three sites of the consortium, not including any of the ASB buyers. The offer lacks sufficient information about risk assessment and mitigation strategies.

III. Business model & Plan — 3,75 / 5 points

The offer describes its business plan based on its experience with the previous H2020 in order to be able to commercialize the devices it presents. The offer contains a business model definition (e.g convincing business model canvas and SWOT analysis). It also contains a preliminary business plan that tackles issues such as the pricing strategy , the targeted markets, scale up activities, strategic alliances, but the customer segments are not identified yet. The business model is the one of a medical device flow cytometry assay testing only. The offer however lacks sufficient detail on the analysis of the exploitability of costs (e.g .plan to protect the generated through the PCP IPRs - there is info only on the pre-existing rights/licenses and not on the new IPRs developed through the PCP). Although there is information on some barriers that may prohibit/delay the entry of the solution into the market the offer lacks necessary information (e.g. on specific costs).

IV. Financial feasibility — 2,92 / 5 points

The offer describes how the resources that had been used for blood sample testing have been optimized for urine and will be used in the proposed methodology as well. Point 1 is sufficiently described, although the percentage of R&D that will be implemented by the staff -and not subcontracted - presents a risk for the success of the project. A realistic commercialization cost strategy is proposed based on partnership with large diagnostic companies. However, the description of the financing plan of the solution lacks sufficient detail.

V. Further Content — 0,94 / 2 points

Preexisting rights and IPR dependencies are properly identified and described in the offer. There is a list of patents that the bidder possesses exclusive licenses to, though they can be used in the PCP but cannot be transferred or licensed out. Ethics issues are addressed, however the exempt from informed consent in using residual urine samples for validating the technology appears to be inappropriate. No hazardous or security issues is recognized in the offer. The offer states that a 52.4% for R&D is calculated for the activities. However, no sufficient evidence is provided to support this statement.

This report is approved and signed by all Expert Board members:

Francesco Tessarolo	Josep Trenado
Beniam Ghebremedhin.	Dave Partridge
Enric Limón	Sema Dumanli
Vassilis Tsanidis	Meike Bomhof
Tram Trinh	