Rapid Detection and Control Systems for Antimicrobial

Responses to questions arising during the RaDAR Market Sounding and Consultation

Version 1
27 March 2023

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Version 1

Introduction

During the RaDAR market sounding and consultation taking place between November 2022 and April 2023, the supply chain representatives and other interested parties were invited to submit questions to the consortium relating to aspects of the need, clinical demand, procurement process etc.

This document is a collation of these questions together with answers agreed among the buyers group and wider consortium.

Version 1 of this document reflects the questions raised during the market sounding. The document will be up-dated as new questions arise during the Open market Consultation and Bi-lateral meetings.

A final version is anticipated in May 2023.

For all of the most up-to-date information about RaDAR see our website.

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12. Can you specify including/excluding criteria to participate in the tendering process? Form company representation point of view/from product/technologies specification point of view (regulatory)?

13. Could you elaborate on the correlation between innovative technology selection and reimbursement possibilities? Do you consider this aspect in your selection criteria?

14. Do you consider a value-based approach to evaluate the financial impact of an innovative technology in the Healthcare system?

1. **How much in advance of the award date are the tenders announced for AST solutions?**

   The Call(s) for Tender(s) will aim to leave sufficient time for the potential tenderers to prepare their offer. Tentatively, each Buyer will leave up to 60 days for the companies to present their offer(s). The tender's dates and timelines will be announced in advance of the tender being published.

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2. **We would request an open dialogue during the tendering process, including a timely response to formal questions**

   At this point the type of procedure to be adopted by each buyer has not been decided. However, the buyers will take into consideration feedback from the OMC process. No matter the procedure, each candidate will have time to request for more information.

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3. **We are a young company developing novel devices, but we are in the pre-approval phase. We expect to obtain approval in two years. Can we still participate in the tendering process? We are happy to participate in a clinical validation study with users of the buyer to establish clinical added value of our intervention.**

   In agreement with the section 5 of the Market Sounding Prospectus, the solution would need to have a sufficient level of technological maturity to be deployed in the healthcare facilities by the time the contracts are signed and by this time meet the required and obligatory standards in relation to quality, approvals, interoperability, ethics and data protection. The RaDAR project is a PPI (Public Procurement of Innovation) project in which we are looking for innovative solutions available on the market (No R&D or development to be done). Therefore, only companies with innovative solutions already approved (CE mark) and available on the market will be able to submit an offer to one of the 4 public tenders that will be launched at the end 2023.

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4. **What are the additional criteria the innovative solution would have to meet?**

   The details of the awarding criteria have yet to be decided. But quality and price will be taken into account.

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5. **Are the tenders dedicated to, for example, only one method, or are they combined?**

   The buyers may take different approaches and it also depends on their assessment of the market readiness to provide a complete solution.

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6. **Will the buyers provide data to develop AMR predictive models? If yes, is this data structured?**

   The details of how buyers will make accessible their data to the suppliers is still under progress. All information related to this matter will be duly described in the Call for Tender documentation. Candidates will be given all information deemed relevant by the buyers. In

the event they consider that information is missing, there will be time to request more data.

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7. Have you identified the pathogens on which they intend to focus, the diagnostic methodologies of choice, the volumes of their project, the participating countries, the time frame?

The target pathogens, the participating countries, and timeframes are set out in the MSP. The buyers are focussing on outcomes rather than specifying methodologies.

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8. What are the requirements of the PoC device (number of target analytes, Lod, Specificity, etc.)?

The details of the final functional requirements to be met by the solution have not still been decided. But the solution should be market ready as RaDAR is a public procurement of innovation.

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9. What is the target budget of the PPI?

The RaDAR project has an overall budget for procurement of €2.4M. However, the buyers have yet to finalise and define their budgets. The estimated budget will be precised in the tender documents for each buyer including the EU financing part.

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10. Is it possible that for the same tender several companies are awarded since they present specific solutions that are separated by lots in the specifications? We would like more information about the concept of "shared risk" that was discussed at the meeting on January 27.

Each buyer will determine their own approach to the procurement after the OMC concludes, it is unclear at this time if the tenders will be divided into lots by one or all of the buyers.

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11. Verification of technological needs, budget available and procedure at the base of the report of contract.

The tender specification will be prepared taking on board feedback collected during the OMC events.

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12. Can you specify including/excluding criteria to participate in the tendering process? Form company representation point of view/from product/technologies specification point of view (regulatory)?

Companies of all countries and/or sizes are welcome to participate in the tender process. However, the details of the awarding criteria have yet to be decided. See Q3 for information

related to regulatory aspects.

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13. Could you elaborate on the correlation between innovative technology selection and reimbursement possibilities? Do you consider this aspect in your selection criteria?

The details of the awarding criteria have yet to be decided. At this stage, we cannot give all the details regarding awarding criteria but the reimbursement won't probably be a criterion. Award criteria will focus on quality and price. The reimbursement status of the solution might not be one of the criteria as we are looking for innovative solutions. In this sense, this type of solution might be available on the market, efficient, but not reimbursed for the moment.

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14. Do you consider a value-based approach to evaluate the financial impact of an innovative technology in the Healthcare system?

At this stage we cannot answer this question.
