Rapid Detection and Control Systems for Antimicrobial Resistance

Responses to questions arising during the RaDAR Market Sounding and Consultation

Version 2
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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.

The current version of the document has been updated to include the new questions from the Open market Consultation and Bi-lateral meetings.

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

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22. Due to the broad spectrum of AMR's issues identified as rapid detection of MDROs or the communication with the IT systems, will there be an common call for tender for all the needs?

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38. Has UNINA already chosen the procedure to implement the tender? If yes which one? 2) Is the participation of economic operators through the telematic purchasing platform envisaged?

39. The origin of AMR has a strong territorial thrust, from the community, where antibiotics are misused and often self-prescribed. Do you think to create a hospital-territory alliance, in terms of education/appropriateness interventions/monitoring?

40. Will the call for tender involve the submission of a single project or individual requests in which each company can respond according to its field of expertise?

41. Imagining that the call for tenders envisages the purchase of various services (sensors and sw as we said), will there be a matchmaking platform for companies?

42. Your organisation already has innovative solutions with an impact on AMS. With such a call, do you expect alternative proposals or will those be maintained for traditional channels?

43. The results of the PCP were mentioned earlier. Is it expected that the proposed solutions will be an improvement on them (i.e. that the solutions implemented at the time will be the mandatory minimum requirements in these tenders)?

44. At one point you mentioned the development of new payment and reimbursement models, it is not clear to me which economic operator is interested in this type of research and development.

45. What would be the duration of the contracts?

46. Do you confirm that the AMR Radar contrast management is only and exclusively opsedaliero setting and will not be contemplated the territory with instruments that could use a specific parameter to distinguish in the first instance if virus/bacterium (Primary care/ COT setting, CDC..) to facilitate the prescriptive appropriateness in these contexts?

47. Can a technology that is not 100% ready for sales, but can be started with a pilot data collection for evaluation, good to participate in the PPI?

48. Regarding needs identification and tender specifications, we would need to know if each tender will demand a solution that includes all targets, or the targets will be reduced considering companies feed-back to the buyers group?

49. Is the budget presented at the OMCs all the budget that will be available for the project in every centre? Will this budget need to cover 1 year's patients full AMR testing for the described hospitals? Or will this amount be the budget allocation for a testing pilot experience for a limited time in a limited group of patients?

50. If everything is certified except the notification platform at the time of the offer, can a consortium make an offer?

51. For a solution that includes AI models, fine-tuning on local data may be necessary to obtain reliable results. Could you please confirm if any data (e.g., clinical data, susceptibility testing data, etc.) will be made available at some point in the procurement process?

52. Are there any specific constraints regarding the composition of the consortium? Would (public and private) healthcare organizations and universities be eligible to participate?

53. Are there any constraints or limits for participating consortia regarding the procurement of consultancy services (e.g., data providers, domain-specific experts, etc.)?

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.

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15. Where will the contracts be implemented?

The contracts are anticipated to be implemented by each of the Buyers in the buyers group (see MSP). Three of the buyers will implement on their hospital sites, in the case of Resah, the contract could be implemented all over the French State.

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16. Do the solutions need to be ready by the time the contract is signed?

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, inter-operability, ethics and data protection.

This is a procurement of innovation, which means that there is no research and development during the procedure. The solution should be market ready and operational. It should be directly usable in hospital or other facilities like laboratories.

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17. Will there be any budget allocated for company research? How does the clinical study validation system work? Do we have to finance it? Or do you have to do another issuer of the clinical study?

RaDAR project is not a research and development project. As a consequence, there will be no funds dedicated to research. The solution should be market ready and directly usable in Hospital and laboratories. Please refer to Q2 answer.

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18. Everything is focused on detection, but not treatment. Treatment too?

Please refer to the MSP description of Smart AMR Management which includes clinical decision making on treatment, 'Facilitate gold standard antimicrobial decision-making on the part of clinicians and provide easily referenced visual access to guidelines and protocols (e.g., dashboards).

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19. Could it be an innovation to have a treatment that is not an antibiotic?

So far, alternative treatment options are not explicitly being sought currently in RaDAR.

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20. Will the needs between buyers and the requirements be very different?

While all the buyers share the common unmet need described in the MSP, they are operating in different healthcare systems and environments and consequently have their own priorities. These are summarised in the MSP and were expanded upon in the local open market consultation workshops in March 2023.

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21. If it is finally a solution developed by a consortium of companies or a technology that has to incorporate any element to cover the buyers need, it will be a new technology. Will this technology have to be certified with the European certificate? Because this has to be taken into account when the solution is deployed to ensure there is enough time.

Please refer to Q2 answer.

22. Due to the broad spectrum of AMR's issues identified as rapid detection of MDROs or the communication with the IT systems, will there be a common call for tender for all the needs?

Please refer to Q6 answer.

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23. What will be "coordinated" in the execution of the contracts?

The coordinated aspect in this phase will be the sharing of good practice and, to the extent possible, aggregated data between the members of the Buyers group. The coordinated aspect of the contract enforcement process will only concern the buyer group and will not have an impact on suppliers or the contract execution.

Buyers will be sharing good practice, and common methodology.

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24. Are there any other pathogens identified?

The needs are not defined yet, they can be developed or extended after the bilateral meetings. The objective of the Market Open Consultation Events is to probe the Market and refine the needs, if necessary. Other pathogens exist and could be included.

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25. Will the suppliers have the opportunity to demonstrate their solution(s) to the Buyers group or to organise on premise meetings with end-users?

We do not plan to hold on premise meetings with companies and with end-users as part of the Market consultation. The timeframe for organising such meetings in the preparatory phase of the RaDAR project is too short. Therefore, the solution(s) proposed by the companies will be detailed by the company itself through a questionnaire available on the RaDAR website and presented during the bilateral meetings.

The solutions will be assessed based upon the provided offer's templates content (documentation, technical requirements etc.).

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26. Might it be interesting to have different timetables for participating in all calls for tenders?

One alternative option to keep the same calendar for the 4 tenders would be to extend the minimum publication period (from 60 days to 90 days). This will be considered by the buyers when developing their procurement strategies.

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27. Is there a quantified need?

There are no minimum quantities but the maximum about which is a mandatory legal requirement will be defined in the Tender Documentation.

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28. Where have the needs been identified? Are clinical needs or specifications?

The unmet needs and initial clinical demand definition is set out in the Market Sounding Prospectus a statement of need. At this stage it is not a specification.

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29. Are the needs common for all the buyers?

Please refer to Q6 answer.

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30. Is the budget different for each buyer?

Yes. According to current project planning, the budget is divided in the following way: Resah (900.000€); ICO (800.000€); Osakidetza (500.000€) and UNINA (150.000€). However, please note that these amounts might vary by the time the tenders are launched.

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31. How long will the validation/evaluation of the solution last? Will it be the same in all the buyers?

The validation / evaluation of each of the buyers solutions will follow a common methodology, while being adjusted based on the individual requirements that they have specified.

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32. How long the duration of the contract will be for the different buyers?

It is not clear at this stage and will be informed by the market consultation process.

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33. Would the tender documents be common? Will they follow the same criteria?

Complementing Q6 answer, each Buyer will launch their own tender. Although following a commons structure is planned, some sub criteria may be different depending on the buyers as well as the weighting. If we answer like that we will be bound.

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34. Bilateral meetings with different buyers to show the value proposition of the companies: How the interviews will be? Do we have the opportunity to speak with all the buyers?

This information was already provided to all the parties that expressed their interest in participating in Bilateral Meetings.

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35. How is it possible to call “innovation” if the solutions are almost in the market?

Innovation procurement includes the procurement of innovative solutions that do exist, but are not yet widely available on the market. Innovation in this case is related to the adoption of solutions that respond to Buyers Group unmet needs and add value to the healthcare system.

In accordance to the Article 2 from the Procurement Directive 2014/24: "‘innovation’ means the implementation of a new or significantly improved product, service or process, including but not limited to production, building or construction processes, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations inter alia with the purpose of helping to solve societal challenges or to support the Europe 2020 strategy for smart, sustainable and inclusive growth.

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36. Will we have access to necessary samples before validation?

Always in respect to Q2 answer, the contract foresees a validation and implementation phase in which the solution is progressively activated in Buyers Group facilities.

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37. How will the bilateral meetings be organised? Will they be in presence in Naples?

Please refer to Q20 answer.

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38. Has UNINA already chosen the procedure to implement the tender? If yes which one? 2) Is the participation of economic operators through the telematic purchasing platform envisaged?

The procedure for implementing the tender has not yet been defined as we are still in the preparatory and consultative phase of the PPI process. After the market consultation phase, the members of the Buyers Group will define the tender documents with the specific demand of each procurer.

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39. The origin of AMR has a strong territorial thrust, from the community, where antibiotics are misused and often self-prescribed. Do you think to create a hospital-territory alliance, in terms of education/appropriateness interventions/monitoring?

The services and products required by the tender will cover processes related to the rapid identification and management of AMR in the context of the different buyers.

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40. Will the call for tender involve the submission of a single project or individual requests in which each company can respond according to its field of expertise?

The structure of the call for tender has not yet been determined and will take into account the feedback from the OMC process. Companies could submit an offer as individual candidate or as a consortium of bidders as long as they meet requirements of capacity and economic and financial conditions. The procurement documentation will provide any relevant requirement to submit an offer. In the event that bidders need more information, they will be given time to ask their questions and get more information.

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41. Imagining that the call for tenders envisages the purchase of various services (sensors and sw as we said), will there be a matchmaking platform for companies?

The RaDAR project provides companies with a networking tool to help them submit joint offers. Please consult the project website for more information.

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42. Your organisation already has innovative solutions with an impact on AMS. With such a call, do you expect alternative proposals or will those be maintained for traditional channels?

With reference to the OMC in Naples: We expect innovative solutions that fit into the current AMR management processes at the Federico II University Hospital. We intend to improve existing services, avoiding duplication or replacement of existing solutions.

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43. The results of the PCP were mentioned earlier. Is it expected that the proposed solutions will be an improvement on them (i.e. that the solutions implemented at the time will be the mandatory minimum requirements in these tenders)?

The PCP Antisuperbugs demonstrated the possibility of integrating innovative technologies to improve communication between professionals, and identify antibiotic-resistant microorganisms in humans and environments at an early stage. Although a same topic, developed technologies will not necessarily be part of the RaDAR solution. The solutions to be provided need to answer to RaDAR Buyers Group specific needs, independently from ANTI-SUPERBUGS' procurement procedure.

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44. At one point you mentioned the development of new payment and reimbursement models, it is not clear to me which economic operator is interested in this type of research and development.

Based on the conclusions of the preparatory phase, each member of the Buyers Group will consider defining a limited number of outcome-based payment clauses, conditioning the payment of specific actions on its completion and committed results. If this is the case, all information will be well expressed in the respective Call for Tender documents.

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45. What would be the duration of the contracts?

Please refer to Q18 answer.

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46. Do you confirm that the AMR Radar contrast management is only and exclusively an hospital setting and will not be contemplated the territory with instruments that could use a specific parameter to distinguish in the first instance if virus/bacterium (Primary care/ COT setting, CDC etc.) to facilitate the prescriptive appropriateness in these contexts?

The services and products required by the four tenders will cover processes related to the rapid identification and management of AMR in the context of each of the buyers.

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47. Can a technology that is not 100% ready for sales, but can be started with a pilot data collection for evaluation, good to participate in the PPI?

Please refer to Q2 answer.

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48. Regarding needs identification and tender specifications, we would need to know if each tender will demand a solution that includes all targets, or the targets will be reduced considering companies feed-back to the buyers group?

Buyers Group will take into consideration market feedback and considerations. The final requirements defined by each member of the Buyers Group will be duly expressed in their respective Call for Tender specifications.

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49. Is the budget presented at the OMCs all the budget that will be available for the project in every centre? Will this budget need to cover 1 year's patients full AMR testing for the described hospitals? Or will this amount be the budget allocation for a testing pilot experience for a limited time in a limited group of patients?

Please refer to Q21 answer. The way in which budget will be allocated will be duly expressed in Buyers Group respective Call for Tender specifications.

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50. If everything is certified except the notification platform at the time of the offer, can a consortium make an offer?

Please refer to Q2 answer.

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51. For a solution that includes AI models, fine-tuning on local data may be necessary to obtain reliable results. Could you please confirm if any data (e.g., clinical data, susceptibility testing data, etc.) will be made available at some point in the procurement process?

Buyers Group is aware that AI models will need fine-tuning on local data, and, therefore, time to the models to be fed. The final requirements defined by each member of the Buyers Group will be duly expressed in their respective Call for Tender specifications.

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52. Are there any specific constraints regarding the composition of the consortium? Would (public and private) healthcare organizations and universities be eligible to participate?

In general terms, any natural or legal person, European or foreign, can participate in a public bidding process in tenders as long as they meet certain general requirements of capacity and economic and financial solvency.

In some cases, there will be specific requirements present in the corresponding specifications in each of the published tenders.

The final requirements defined by each member of the Buyers Group will be duly expressed in their respective Call for Tender specifications.

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53. Are there any constraints or limits for participating consortia regarding the procurement of consultancy services (e.g., data providers, domain-specific experts, etc.)?

Please refer to Q27 and Q39 answers.
