Rapid Detection and Control Systems for Antimicrobial Resistance

Market Report Summary and Project Update

October '23

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Foreword

The RaDAR consortium would like to extend their sincere thanks to all those that have expressed interest in the forthcoming tender and participated in the market sounding and consultation process.

We have been greatly encouraged by the level and quality of responses from across the supply chain and feel able to proceed with confidence into the tendering and evaluation stages of the project.

This short summary report provides only a general overview as the market responses were provided in confidence.

Introduction

Four European healthcare buyers have identified an unmet need for rapid detection of multi-drug resistant microorganisms (MDROs) and antimicrobial resistance (AMR) management and control systems to combat a serious and growing global problem.

At the end of 2023 the buyers will launch tenders for innovative solutions to address this challenge. Before launching the tenders, the buyers wished to give the supply chain advance notice and consult potential suppliers on the demand definition. In order to progress to tender in the most effective way, we wanted to understand the markets ability to respond and also how the buyers could facilitate supply chain innovation to deliver what is needed.

Figure 1. The four buyers of the RaDAR collaborative buyers group

The broad aims of the market engagement and consultation process were to provide early market notification on the buyers' needs, prime the market ahead of the market consultation and tendering, assess the appetite, capacity, and capability of the supply chain to respond the buyers unmet need for rapid detection, management, and control solutions for antimicrobial resistance (AMR), and understand the supply-side challenges and barriers to market.

The feedback received from the market consultation process has been used to help both to refine the clinical requirements for each buyer and finalise their clinical demand definition. The aim is to define ambitious but credible requirements that accurately reflect the buyers' needs and have scope for scalability and impact.

This document is a summary report of the process and findings of the market engagement and consultation process undertaken over the period 25 November 2022 and 22 April 2023.

The need for innovation

Antimicrobial Resistance (AMR) is a growing problem globally. According to recent research[1], at least 1.27 million people died directly as a result of antibiotic-resistant infections with an estimated 4.95 million indirect deaths associated with AMR in 2019. This means that it is already the third most common underlying cause of death, after heart disease and stroke. AMR happens when pathogens such as bacteria, viruses, fungi or parasites mutate over time and stop responding to medicines. As a result, the infections they cause become harder to treat and contain. AMR is a problem that will continue to get worse unless we acquire the tools that are needed to enable us to take effective action. Annual deaths resulting from antimicrobial-resistant infections could potentially be up to 10 million a year in 2050.

Hospitals and specialist healthcare units are at the frontline of the battle with AMR and innovation is necessary if we have to combat antimicrobial resistance. While investment in the development of new antibiotics is crucial, another important area where innovation is urgently needed is the rapid detection, management, and control of AMR in clinical settings and the healthcare environment. This includes the means to minimise over prescription of antibiotics and target their use, at point-of-care diagnostics, rapid, affordable, continuous, and autonomous multi-pathogen diagnostics, as well as Antibiotic Susceptibility Testing (AST) diagnostic technologies to identify all the resistance phenotypes and / or genotypes present within a clinical sample, together with information management and clinical decision support. Innovative solutions are urgently needed to be developed, adopted, their clinical and cost effectiveness demonstrated and then widely adopted across Europe and beyond.

[1] Published in The Lancet medical journal

Market Sounding and Consultation Process

A four-stage open market consultation (OMC) process was adopted:

- **Early notification:** The first stage was early market notification involving the publication of a Prior Information Notice (PIN) in the Official Journal of the European Union calling for expressions of interest at the start of the project (March 2022). The purpose was to alert and prime the market for the forthcoming consultation and tender.
- **Market Sounding:** The second stage was market sounding involving remote consultation with the market and collection of feedback via a response form where the market actors responded to the initial clinical demand definition. A second PIN announced this stage.
- **OMC Workshops:** The third stage involved four open market consultation events held at a local level (online and in person formats) and an international online event.
- **Bi-lateral meetings:** The final stage involved bi-lateral online market consultation meetings with the Buyers Group, supported by the expert partners.

All documentation relating to the market consultation can be found on the dedicated Procurement section of the RaDAR website.

The call was widely communicated, and responses were invited from all parts of the supply chain. The broad aim was to assess the appetite, capacity, and capability of the supply chain to respond the buyers' unmet need for rapid detection, management, and control solutions for antimicrobial resistance (AMR) and was designed to open a dialogue with the supply chain to:

- Explore what solutions are or could be available given the right market conditions to address the unmet needs and requirements identified by the buyers group (i.e. the initial Clinical Demand Definition).
- Understand the timeframes over which these solutions can be mobilised or become available.
- Inform the buyers group as to how they can support suppliers and innovators to deliver innovative solutions to meet these needs.

The market engagement and consultation process was designed to support adherence to the principles of transparency and equal access to information throughout. All input from companies is being held in accordance with the project privacy policy. The personal data provided in response to the market sounding and consultation has been compiled by The International Network for SMEs (INSME) as part of the RaDAR-PPI project's (GA:101036228) activities in compliance with the General Data Protection Regulation law (2016/679).

RaDAR Market Challenge: Initial Clinical Demand

The RaDAR Challenge as presented in the Market Sounding Prospectus (MSP) and at the OMC events was the basis for the market consultation and is summarised below:

- The RaDAR buyers group have identified an unmet need for a *holistic* solution that enables gold standard AMR management and control[2].
- The RaDAR solution would include *rapid detection* tools and / or systems and the means by which the results and information they produce can be *managed effectively* and *transferred* to the right people in 'real time' in a way that *elicits the necessary and correct action and decisions* within the clinical and AMR management workflow, and which correlates with and references *pertinent information regarding a patients AMR status*.
- The solution would provide clinicians with *easy visual access to guidance* on testing and treatment according to gold standard guidelines and protocols. The accumulated *data* would be collated and would help to inform future action and decision making.
- As the situation regarding AMR changes over time, the solutions should be *dynamic and remain up to date* with regard to the changing AMR environment and epidemiological data.
- As healthcare facilities have different systems and IT environments, it will be important that all elements of the solution are *customisable* to the specific healthcare environment and the workflow and priorities of the user, and able to interface with their existing IT systems.
- Rapid Detection and Smart AMR Management and Control would *together* significantly and demonstrably improve both the detection and management of multi-resistant microorganisms. In other words, while it may be ambitious in scope, the overall and ultimate unmet need in time is for an integrated package of measures that can be tailored to the healthcare facility and be flexibly deployed for the effective and pro-active detection and control of multidrug-resistant organisms.

At this stage, this market challenge was considered an 'initial' or 'preliminary' clinical demand definition to be refined through the open market consultation and further consultation with internal stakeholders and AMR experts. Taken together, the buyers finally arrived at a 'final clinical demand definition' that will directly inform their tender specification.

Figure 2. Overview of the RaDAR process: from needs identification to coordinated tenders.

[2] By control we mean surveillance and prevention.

Market Response

Overview

The market engagement and consultation actions attracted considerable interest from across the supply chain, including larger companies and Tier 1 suppliers, SMEs and micro companies. The high number, level of detail, and quality of response was unprecedented in the experience of the consortium:

- 67 good quality responses were received during the market sounding, the majority of which were SMEs.
- 164 supply-chain representatives attended the market consultation events.
- > 48 companies were represented in the bi-lateral meetings.

The list of responding companies can be found in the Directory of Market Respondents, which also includes a short description[3] of the companies.

There was a good level of representation from all parts of the relevant supply chain and the consortium is satisfied that the market sounding responses reflects feedback from the main sectors and areas of expertise needed to address the RaDAR challenge.

The RaDAR consortium conclude from the high level of market response and considerable level of interest expressed that the market is primed to respond to challenge of AMR testing and management and has moreover been mobilised by the market challenge presented by the RaDAR consortium. The quality and detail of market responses clearly demonstrate that the market is actively investing and solutions are rapidly developing across all areas of the buyers' needs. The market assessment also indicates a growing interest and active exploration in the development and implementation of integrated solutions for AMR management and control.

The supplier feedback strongly suggests that there is both capacity and appetite in the market to respond to the different requirements highlighted relating to both Rapid and Accurate Detection and Smart AMR management. These solutions are already available in the market or near to market, and there are many ongoing developments, some nearer to the market than others. While some of the promising solutions will not be available or will not have an approved CE mark within the RaDAR procurement timeframe, there are opportunities for adoption of relatively new solutions and combining solutions in a novel way to deliver organisational and process innovation within the buyers healthcare environment. It is also clear from the market response, that there are ways that the buyers can enable and support innovation within the tendering process.

[3] NOTE that 6 companies declined to be included in the directory.

Availability of solutions

The consortium is encouraged to see that all aspects of the buyers needs can be addressed by the supply chain and that solutions would be available within the timeframe of the project. Some of these solutions are indeed already on the market, while others are anticipated, some within months while others are still in the early stages and not anticipated for several years. Nonetheless, the latter provide a valuable insight into the future solutions that will be emerging which are likely to offer ongoing improvements and progress in the field. The intention of demand led innovation measures like PPI is to articulate unmet needs to the market and present a credible market demand to encourage suppliers to invest in developing new solutions to meet these needs. The sounding therefore asked if responding companies would consider developing new solution to meet the RaDAR buyers' needs and over 70% of respondents said that they would.

Regarding the supply of an integrated solution as set out in the MSP, the market response indicates that it has the ability to offer several solutions that combine different elements of the AMR detection and control workflow. The responses also suggest that a fully integrated solution is likely to require collaboration and a consortium of companies working together, with the market responses showing a willingness to do so on the part of some market players.

All the questions raised, and the answers provided during the market sounding and consultation are publicly available in the RaDAR Market Sounding and Consultation Q&As document on the project website.

NOTE. The detailed responses on the type of solutions and developments are subject to confidentiality.

Enabling innovation and supporting SME participation

The market responses provided insights into how the consortium could enable innovation and create the necessary market conditions to deliver the required outcomes:

- Developing detailed use cases
- Supporting the development of an evidence base, both clinical and return on investment (ROI)
- Being first or early adopters of solutions
- Creating opportunities for trials and demonstrations
- Co-creation / co-development via a living lab
- Helping to accelerate any approvals process (e.g. HTA, regulatory)
- Understanding and addressing the need for innovating companies to have confidence in the market, for example even a light, non-binding forward commitment, contractual terms, etc.
- Stakeholder engagement to support uptake, being proactive in raising awareness and engaging stakeholder and users of the solution to support adoption.
- Becoming champions of the solutions and helping to build market demand.
- Adopting innovation friendly procurement (see below). This was the most common recommendation made by respondents.
- Support demand both locally by mandating or encouraging use of solutions and more widely by proactive communication and sharing of value driven results among other potential buyers.
- Public awareness campaigns and outreach to wider stakeholders.

Similarly, insights into supporting SME participation were suggested in the market responses:

- Support supplier networking (a networking tool was launched by the end of May 2023 in advance of the tendering process).
- Build and evidence a wider market demand.
- Articulate their needs as clearly and accurately as possible.
- Exclude any pre-qualification criteria that could unintentionally exclude SMEs or young companies (e.g., years of accounts, turnover, healthcare references).
- Keep documentation simple and easy to access, write tender documents that are easy to understand and streamline the tender process.
- Allow alternatives to be proposed.
- Investigate and assess the pros and cons of dividing tenders into lots, which could support SMEs.
- Adopt pro-innovation / innovation friendly procurement procedures (see below).
- Use balanced award criteria that are not price based but quality and value based.
- Carefully consider the impact of contract terms on SMEs; for example, have payment terms that are short in duration, flexible terms and progressive expansion of delivery of new solutions (territorial and qualitative).
- Consider contracts that enable co-development and progressive innovation.
- Allow 90 days for tender submissions.
- Ask suppliers to submit video presentations / demonstrations of products during the tender process.
- Be proactive in providing information and guidance to suppliers during and prior to the tender launch. This could include for example a web presentation on how to complete the tender documents, use the e-portal etc.

Next steps

Enabling supplier networking and collaboration

In response to positive feedback from the supply chain regarding the idea of a RaDAR networking tool, one was created and launched in May 2023 and widely advertised. The RaDAR Matchmaking Tool will remain open throughout the tendering process.

To further support wide dissemination of the call for tender and supply chain networking, a RaDAR Information Day (InfoDay) will be held on the 21 November 2023. The RaDAR Consortium is inviting interested suppliers to present the latest information on the project and give the opportunity to potential suppliers to pitch their company, solutions and needs against AMR for Matchmaking purposes. Suppliers can participate without pitching. The event will be exclusively online.

Coordinated calls for tender

Over the last months the consortium has been carefully analysing the market response and further consulting stakeholders and experts in order to arrive at the RaDAR final demand definition and evaluation framework. This has provided a firm basis on which each of the four buyer organisations can further refine and determine their individual requirements in the form of a tender specification.

Information videos will be posted in early November giving the status of the four individual tenders.

It is anticipated that the coordinated publication of the four calls for tender will be by the end of 2023 and the tender is expected to be open for 90 days.

The calls will be advertised in the OJEU and local platforms and through the RaDAR social media channels, dedicated webpage, and Newsletter.

How to keep in touch

The RaDAR Website is the go-to place for up-to-date information and access to all market consultation and procurement related documents, FAQs and contact points.

RaDAR is a European Commission co-funded Public Procurement of Innovation (PPI) project which aims to address the European urgent need of a rapid detection and effective infection control system for antimicrobial resistance (AMR) through the implementation of a value-based cross-border collaborative procurement of innovative solutions.

RaDAR brings together buyers in the healthcare sector with expert partners to present a market challenge for the global problem of antimicrobial resistance and work with supplies to demonstrate value-based solutions.

Sign up for the RaDAR *newsletter* and connect via social media