# Rapid Detection and Control Systems for Antimicrobial Resistance

*Call for innovative solutions*

## Market Sounding Prospectus

November 2022

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# 1. 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 (figure 1) will launch tenders for innovative solutions to address this challenge. Before launching the tenders, the buyers wish 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 want to understand the market's ability to respond and also how the buyers can facilitate supply chain innovation to deliver what is needed.


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

## Antimicrobial Resistance (AMR) - a growing problem

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[2].

## The need for innovative solutions

Hospitals and specialist healthcare units are at the frontline of the battle with AMR and innovation is necessary if we are 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.

[1] Published in The Lancet medical journal
[2] Published in O'Neill Institute for National and Global Health Law or Georgetown University

## Open Market Consultation

This document is the second step in an Open Market Consultation (OMC) that began in March 2022 with the publication of a prior information notice (PIN) in the Official Journal of the European Union providing advance notice of a forthcoming tender concerning the collaborative procurement of innovative solutions to address the urgent need for rapid detection and effective infection control systems for antimicrobial resistance (AMR). The PIN invited all parts of the supply chain and other interested parties to register their interest. This process is now closed, and we are entering a new phase of detailed consultation.

To this end, a second PIN was published in November 2022 to launch a period of market sounding and open market consultation based on a more detailed presentation of the preliminary requirements of the four buyers involved in this collaborative procurement. (Note: there is no requirement to have registered prior interest in order to respond to this current call for solutions).

## The global market opportunity

According to Research&Markets[1], the global antimicrobial resistance (AMR) market was valued at US$ 9.39 billion in 2020, and is estimated to reach US$ 13.8 billion in 2027, with a Compound Annual Growth Rate (CAGR) of 4.68% from 2021 to 2027. New AMR diagnostic[2] technologies, beyond gene sequencing, are currently under development.

In particular, the global antimicrobial susceptibility testing (AST) market is expected to grow at a CAGR of 5,8% from 2022 to reach 4,7 Billion in 2030, according to Bloomberg[3]; at a CAGR of 4.9% from 2019 to 2027, according to TransparencyResearch[4] and at a CAGR of 6.4% from 2021 to 2028 to reach $5.99 billion by 2028, according to Research&Markets[5].

Major factors driving the growth of the AST market are rising prevalence of infections caused by bacterial pathogens, antibiotic overuse, which leads to antibiotic resistance in bacterial organisms, the development of better standards for fungal susceptibility and the growing use of rapid commercial AST systems for fungal testing.

The global AST market is driven by the increase in the occurrence of hospital-acquired infections, a spike in the patient population base (particularly in developing nations), and increased government awareness of the urgency to combat antibiotic resistance.

## Collaborative and coordinated innovation procurement

This is a collaborative and coordinated innovation procurement initiative to address an important challenge area and to procure innovative solutions to address our unmet needs.

What does this mean in practice?

- *Collaborative needs definition*. The buyers have come together to determine their unmet needs with regard to AMR detection and control and define a preliminary clinical demand. This will be refined following this market consultation and validation with wider stakeholders.
- *Collaborative market engagement:* A period of joint market engagement has been launched by the buyers group to validate and refine the clinical demand and seek supply chain feedback to inform their procurement strategies for the forthcoming tenders.
- *Coordinated tenders:* Four individual tenders reflecting the specific needs of each buyer will be launched in a coordinated approach to the market in the second half of 2023.
- *Innovation procurement:* The buyers will adopt good practice pro-innovation and pro-SME procurement processes to support and enable innovation and adoption of innovative solutions.

# 2. Market sounding and call for innovative solutions

## Purpose

The aim of this market sounding and call for innovative solutions is 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 (see the Clinical Demand Definition in section 3)
- 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.

Having conducted an initial state of the art review we believe that the supply chain has the information, insights and creativity to address the challenges outlined in this document. We are open to all ideas, from all parts of the supply chain, that could contribute to addressing this important challenge area.

## Open Market Consultation Workshops

The market sounding will be followed by a series of Open Market Consultation (OMC) events, which will be held both in person and online (figure 2).


*Figure 2. Dates of the RaDAR Open Market Consultation events. Register using the Market Response Form.*

## How to participate

- **Read** this Market Sounding Prospectus
- **Complete and submit** the online *Market Response Form*

  You can also use the Market Response Form to:

  - **Register** for one or more of the Open Market Consultation events
  - **Express interest** in bi-lateral meetings between buyers and supplier

- Check out the **FAQs** on the market consultation landing page on the *RaDAR website*

## How we will use your feedback

Responses are invited from all parts of the supply chain to enable the buyers group to refine their clinical demand specification and design a procurement strategy to support and enable innovative solutions to be presented and considered on an equal playing field with existing solutions.

The feedback we receive from the supply chain will be used to refine the clinical demand of the four buyers and inform our collaborative tender specification and strategy.

# 3. Clinical demand definition

## The process of definition

### Defining the preliminary clinical requirements

To determine their clinical requirements, the buyers have worked collaboratively over the last year in consultation with their internal stakeholders and end-users to understand the problems, strategic pains, and opportunities for reducing, detecting, and controlling AMR and improving overall stewardship.

This needs identification process also drew on the findings and rationale of ANTI-SUPERBUGS PCP[3], EU and national AMR Action plans, and the developments and experience arising from the recent pandemic.

Together, this comprehensive work has led to the identification of both unmet needs in common and unmet needs specific to each buyer organisation and has enabled the *preliminary* definition of the clinical requirements.

### Final clinical demand definition

To arrive at the *final* clinical demand definition more insight and information is needed. The buyers are therefore undertaking this consultation with the market. The aim is to understand the solutions that are or could be available in the future, the challenges and opportunities, and critically how we as buyers can support the delivery of innovative solutions.

In parallel the buyers will also consult a wider range of healthcare stakeholders, AMR experts and interest groups in a demand consultation and validation process.

The feedback received from this dual consultation process will 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.

The feedback from the market, stakeholders and experts will also inform the tendering approach the buyers will adopt to procure innovative solutions to meet our needs.

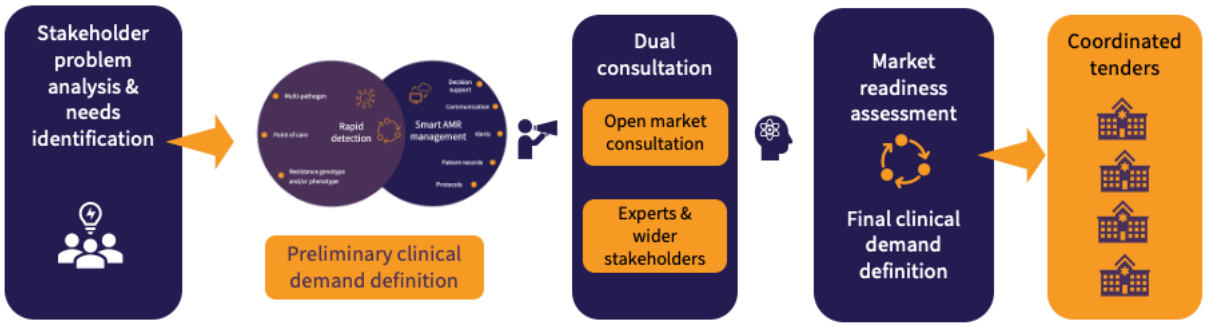


*Figure 3. Overview of the RaDAR process: from needs identification to coordinated tenders.*

[3] Antisuperbugs PCP

## The problem

AMR occurs when bacteria, viruses, fungi, and parasites change over time and no longer respond to medicines, making infections harder to treat and increasing the risk of diseases spreading, and severe illness and death. The situation differs between countries and regions, and even between different health institutions in a region. However, we can see similarities in the experience of healthcare providers facing the challenge of AMR detection, management, and control.

The detection of multidrug-resistant organisms (MDROs) takes time and is costly as the detection process usually relies on culture-dependent methods requiring technical equipment and qualified staff. The results can take from 24 to 72 hours to arrive, and it is often not possible to wait for the results to treat the patient with what may turn out to be inadequate or broad-spectrum treatment.

Often clinicians must decide on treatment without knowing if, or which, MDRO is involved, and therefore which antibiotics would be most effective. In the case of vulnerable patients, accurate and up-to-date information can be the difference between recovery or otherwise. Moreover, the lack of information often translates into the prescription of broad-spectrum antibiotics to try to cover many microorganisms, which in turn increases the selection of MDROs and may not address the true cause of the infection, affecting patient outcomes. Moreover, some healthcare facilities such as primary care centres, long-term facilities or small hospitals don't have their own laboratories, hence it is not always possible to test patients or it is difficult, for example due to limitations in testing or diagnosis of patients.

Sometimes it is difficult to differentiate between a viral and bacterial infection based solely on signs and symptoms, which means that antibiotics may well be over prescribed for viral infections where the prescription of antibiotics is only justified on suspicion of a secondary bacterial infection. This is a problem seen particularly in primary care and emergency departments.

There is considerable scope for improvement in the accessibility of information, from protocols to test results, and provision of 'real time' decision support systems to improve prevention and control of and accurate and timely prescription of antimicrobials. AMR management and control is hindered by limitations in the access and management of information across the AMR workflow. For example, the lack of joined up systems and lack of functionality in the detection and diagnosis workflow and patient journey. Health professionals experience difficulties accessing information about the patients AMR status and in being able to get easy access to relevant and up-to-date information about treatment, management and control protocols, local and regional epidemiological information, and guidance on the prescription antimicrobials.

## The unmet need

### Towards an integrated solution for the detection, management, and control of AMR

An important outcome of the needs identification process undertaken by the buyers is that rather than a single and discrete area of need for AMR detection and control, unmet needs were found right across the clinical workflow, relating to both the detection and subsequent management of AMR situations. It is also clear that AMR and its control is a complex, multi-faceted problem that is subject to regional and temporal variations.

The conclusion the buyers have therefore reached is that, while rapid detection is certainly key to improving antimicrobial stewardship and effective prevention and control of AMR, rapid detection alone would not fully address the very real challenges of AMR management as a whole experienced in our healthcare facilities. To address these challenges effectively, what is needed are rapid detection systems that may be standalone or may be implemented together with smart AMR management mechanisms that enable effective information flow, automatic alerts, decision support and easy access to epidemiological data, status reports and procedural guidelines. This would transform the management of AMR and enable gold standard AMR stewardship.

## Preliminary clinical demand

The buyers have worked together with their expert partners to present a *technology agnostic* definition of our needs, focussing on the outcomes we need to deliver. The following presents our best effort to present to the market what buyers need:

The RaDAR buyers group have identified an unmet need for a *holistic* solution that enables gold standard AMR management and control[4].

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.

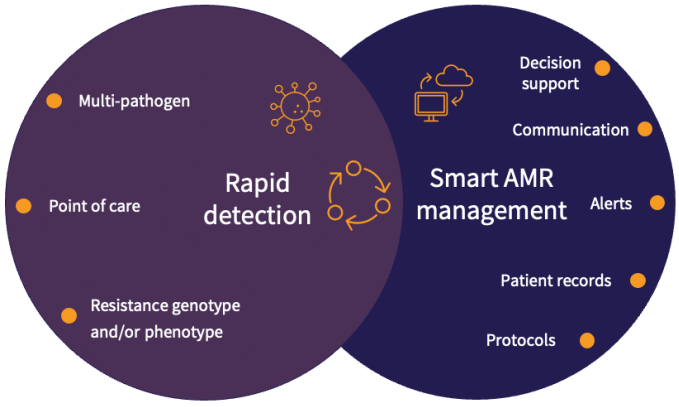


*Figure 4. An integrated solution would combine rapid detection with smart AMR management and control systems*

[4] By control we mean surveillance and prevention.

Rapid detection would identify MDRO in patients and the environment and have the following outcome and features:

- Rapid and accurate detection of multi-drug resistant organisms (MDROs) identifying the specific MDRO and the determinant of resistance, and ideally antibiotic susceptibility patterns (sensitivity profiles) of the detected MDROs (Antibiotic Susceptibility Testing).
- Tests would be based on human tissue or environmental samples requiring the minimum need for preparation and ideally requiring no preparation.
- Enable rapid differentiation between viral, bacterial, fungal and parasitic infections.
- Provide clinically relevant additional information about the target microorganisms. (For example, be able to accurately detect virulence factors like toxins in *C. difficile*).
- Enable clinicians and microbiologists to select the right means of detection at the right time and to use detection systems correctly to support the accuracy of results.
- Include solutions for application in some or all of the following areas: in microbiology laboratories (both within hospitals and / or in external labs), at the point of care (e.g., in a primary care setting, at admission to hospital, at the bedside), in the environment (e.g., within a hospital room, ICU, clinical zone or ward).
- Detect and control as many microorganisms as possible. In the first instance, solutions should focus on antibiotic-resistant pathogens prioritised for detection (based on WHO priority pathogens list for R&D of new antibiotics[5] and RaDAR consortium clinical needs) which present a particular threat in hospitals and nursing homes, to vulnerable patients, and to those whose care requires invasive devices such as ventilators and blood catheters. (See figure 5).
- Be easy to use and minimally invasive for patients, while maintaining safely and accuracy of results.

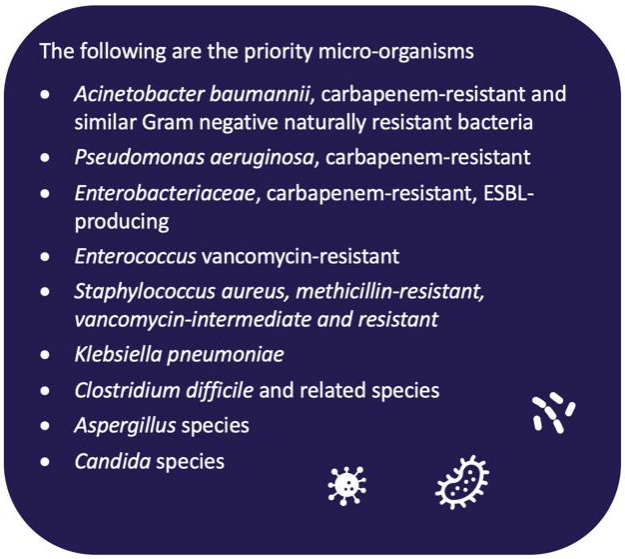


*Figure 5. Microorganisms that have been identified as a priority by the RaDAR consortium*

[5] Published by World Health Organisation

Smart AMR Management and Control would enable the best possible action and decision making in response to the detection results in order to control the spread of AMR and would provide a real-time information pathway across the AMR management and clinical workflow.

The solution would:

- Transfer detection results automatically to the right people within the clinical and AMR management workflow in 'real time' in a way that elicits a prompt and informed response (e.g., via targeted messaging, visual dashboards, alerts, alarms).
- Facilitate gold standard antimicrobial decision-making on the part of clinicians and provide easily referenced visual access to guidelines and protocols (e.g., dashboards).
- Enable the secure storage and clinical access to pertinent information about a patient's AMR status (i.e., previous exposure, treatments, outcomes) to inform decision making and action
- Optimise decision making based on the microbial ecology status of the hospital or clinic concerned and on epidemiological information related to the wider region (for example endemic microorganisms, outbreaks, antimicrobial susceptibility patterns).
- Be integrated within the organisations clinical and AMR management workflow and interface with existing IT systems and in line with procedures and be integrated into an organisations health information system.
- Store and analyse data on detected infections and colonisation episodes of the target microorganisms and enable data collection and interrogation in a standardized way for data analysis and surveillance to inform decision making.

# 4. Introducing the buyers

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

## The Reseau des Acheteurs Hospitaliers IDF (Resah)

Created in 2007, GIP Resah (https://www.resah.fr/) is a public Central Purchasing Body (CPB) that leverages the purchasing power of hospitals and nursing homes in France. GIP Resah is the only CPB specialized in both healthcare and medical-social sectors in France. It offers more than 4 000 public contracts, from 700 suppliers, which cover all healthcare procurement segments: medical and non-medical. In 2021, the total group procurement realised through Resah's contracts was over 1.8 billion €. Today the public organization has more than 700 members, including almost all French public and non-profit hospitals, nursing homes but also other public organisations.

## Institut Català d'Oncologia (ICO)

The Institut Català d'Oncologia (ICO) is a public non-profit centre working exclusively in the field of cancer. ICO is currently the cancer centre for almost 50% of the adult population of Catalonia and its approach to the disease is comprehensive, combining, all in one organisation, prevention, patient care, specialised training and research. Structured as a network, it comprises four centres (ICO L'Hospitalet, ICO Girona, ICO Badalona and ICO Tarragona i Terres de l'Ebre) that work in cooperation with university hospitals (Bellvitge, Dr. Josep Trueta, Germans Trias i Pujol and Joan XXIII), local hospitals, non-profit health research institutes and universities.

The needs and priorities of ICO are heavily influenced by their patient population i.e., those being treated or monitored for cancer. Cancer patients, or those living with cancer, often do not show symptoms of infection due to their suppressed immune systems. This means that when symptoms do appear the infection is already well advanced and therefore prompt and accurate treatment is essential to save lives. Moreover, cancer patients are usually taking multiple antibiotics which means that they are AMR susceptible, and detection needs to be highly sensitive if it is to provide accurate information. In the current situation so called 'rapid' tests take many hours to process, are conducted off site which can add to logistical delays, they rely on cultures and are insufficiently sensitive for this vulnerable patient population.

## Università degli Studi di Napoli Federico II, Department of Public Health (DiSaP)

The Department of Public Health of the University of Naples "Federico II" (UNINA) is born with a vision of medicine focused on the concept of health prevention in living and working environments, on the study of bio-morphological and molecular mechanisms, on the management of health services in an interdisciplinary and social conception of Public Health. It promotes multidisciplinary research with the aim of developing innovative models and solutions for the effectiveness of the management and governance of Healthcare Services and Systems.

The priority here is to target multimorbid older adults with complex care needs with a focus on rapid detection of MDROs in the different settings of their care journey (out-patients, in-patients, and ICU). Several tools are required in combination with a smart AMR management solution: tools to retrieve selected patients information from current dataflows, antimicrobial decision-making support tools & managing protocols, detection systems for patient samples and environment. They may be deployed in different areas, namely rapid point of care detection in out-patients and in-patients and environmental detection in the ICU with associated information management and decision support.

## Servicio Vasco de Salud Osakidetza (OSAK)

Osakidetza is the Basque Public Health Service provider of health care to more than 2 million inhabitants living in the Basque Country – a region located in the north of Spain, formed by three provinces: Biscay, Alava and Gipuzkoa. Osakidetza, a public body and financed by the Health Department of the Basque Government, is formed by a network of health centres (including hospitals, primary care centres, and mental health centres).

The Basque Public Health Service (composed by Primary Care health centres and hospitals) has a common database that includes an electronic patient record system that connects all levels of care, and so primary care and hospital care have shared records for each patient. The requirements for Osakidetza align very closely with the collaboratively defined unmet; namely rapid detection and diagnostics combined with a smart management and control system. Specifically, the requirement here is that the solution would interface with existing communication systems and electronic patient records.

What is envisaged is a system where the results of detection and diagnostics of MDROs creates, automatically and in real time, alerts into the system and provides decision guidance regarding prescriptions, care pathways and protocols and where this in turn links to the MDRO ecology of the region.

A priority unmet need identified by the clinicians at Osakidetza is for rapid tests at point of care at the primary care level that distinguishes viral and bacterial infections. This would significantly reduce the unnecessary prescription of antibiotics in these type of health centres.

## Voices from the front line

Clinicians and microbiologists also face some very practical problems that hinder their effective management and control of AMR in their day-to-day operations. Below we include some insights from those working on the front line.

"Up to date protocols, easily accessible through electronic devices and "user friendly" would allow a better management of the patient and MDROs"

"We need access to accurate information quickly, particularly when treating vulnerable patients. Antibiograms can take about 24 hours to give results"

"An improvement on a standardized collection of Health-Care Associated Infections and MDROs would allow a more optimal surveillance"

"Decision-making tools would help clinicians to choose the right test for the right patient at the right moment"

"Both rapid tests and tools to facilitate the interface between microbiologists and clinicians are needed"

# 5. The procurement timeline

Following this consultative phase the buyers group will refine their specific requirements in line with the market feedback, anticipated innovation timelines and wider stakeholder validation. Four individual but coordinated tenders will be launched during the autumn of 2023. The tendering process will be informed by the market feedback and will be designed to enable and support the procurement of innovative solutions and the participation of SMEs.

## Indicative procurement timeline


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.

## Value based contracts

The contract will follow a value-based approach that will enable buyers and suppliers to demonstrate the real value of the adopted solutions to a wider market as well as to patients, health care professionals, health care institutions, health care services and, ultimately, to the society as whole.

## How to keep in touch

The *RaDAR open market consultation landing page* 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.

Learn more about the Consortium *here* and visit the *market consultation* landing pages for up-to-date information.

*Keep in touch!*

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

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