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Open tender for integrated IT management service and antibiotic resistance monitoring

1. SUBJECT

This Technical Elaborate summarises the minimum characteristics of the supply of integrated IT services for the rapid detection of multidrug-resistant microorganisms and for the intelligent management and control of antibiotic resistance, at the Department of Public Health of the University of Naples 'Federico II', in patients admitted to certain wards of the AOU Federico II.

The provision of the integrated IT management service consists of:

- Intelligent software system for the clinical management of antibiotic-resistant patients;
- Stations for rapid identification of specific micro-organisms at the patient's bedside;
- Integration with the information systems in use at the AOU Federico II.

This technical paper is part of the activities of the RaDAR project - 'Rapid Detection and control system for Antimicrobial Resistance' (Grant Agreement No. 101036228), a Public Procurement for Innovative Solutions (PPI) aimed at procuring an IT-based solution to address Europe's urgent need for a rapid detection and effective control system for antimicrobial resistance (AMR) infections. PPI is a procurement process in which public authorities act as customers for the launch of innovative goods and services that are not yet available on a large-scale commercial basis, through the implementation of a cross-border collaborative procurement. The RaDAR project involved the joint identification of needs by a cross-border group of 4 contracting authorities, located in France, Spain and Italy, supported by the clinical and technical experts of the project consortium. During the open market consultation phase, potential suppliers capable of providing answers to the specific needs of the RaDAR project were sounded out. Finally, the co-ordinated preparation of the individual tenders in the local contexts was carried out, with the joint definition of the technical specifications of the required solution and the use cases, ensuring that each contracting station purchased according to the needs of the local context and according to national laws.

1.1 Current and future workflow including RaDAR solution

Thanks to the work carried out previously, we can summarise the current global workflow (Figure 1), the current stages of the workflow for each patient with suspected infection and the main difficulties encountered by the parties involved at each stage of the pathway.

Figure 1. Workflow for patients with suspected infection before implementation of the RaDAR solution

The RaDAR integrated IT management service will support healthcare professionals during the pathway from screening and/or suspicion of infection to patient follow-up (Figure 2).

Figure 2. Workflow after implementation of the RaDAR integral solution

1.2 Overall subject matter of the contract

The objective of the supply is to implement and maintain an integrated solution for the rapid screening and/or detection of community infections and certain care-related infections (C. difficile colitis) and support through a guided pathway for healthcare professionals to optimise prescribing and to prevent, control infections and rapidly identify community microorganisms, respiratory viruses and C. difficile with the aim of reducing unnecessary antibiotic prescribing. The integrated solution will have to meet the following requirements of the contracting authority, in particular:

1) Rapid detection of community micro-organisms;
2) Improved access and integration of information;
3) Organisational integration for intelligent antimicrobial resistance management;
4) Clinical decision support.

The RaDAR integrated IT management service (Figure 3) comprises several technologies to improve the management of patients, pathogens, samples and prescriptions, to provide integrated intelligent antimicrobial resistance management. The RaDAR solution integrates several services:

1) Rapid detection system for priority micro-organisms. The rapid detection system must include Point of Care (PoC) devices for testing on the ward, outside the laboratory environment, in close proximity

to the patient, by a healthcare professional. These are easy-to-use, accurate, sensitive and specific rapid testing devices that detect the priority micro-organism at the point of care.

2) The solution shall include devices for rapid, accurate, sensitive and specific tests performed close to the patient (Point of Care) for the detection of priority microorganisms and their resistance, in no. 6 wards of the Azienda Ospedaliera Universitaria Federico II. The devices must make it possible to detect whether a patient is infected or colonised. The wards and the micro-organisms to be detected are shown in Table 1 below.

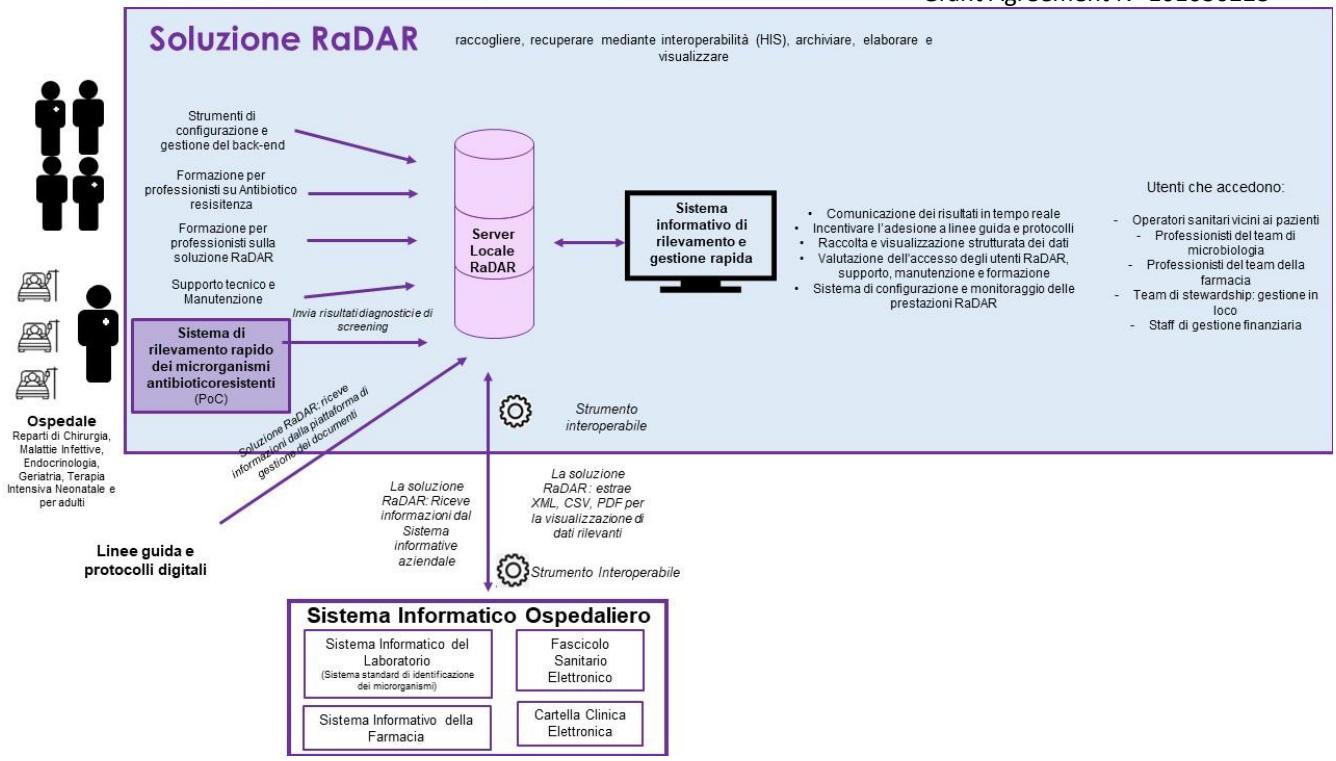
Table 1. Micro-organisms to be detected for each of the departments involved

Departments	Microorganisms
Adult Intensive Care	*Legionella and Pneumococcus (on urine), SARS-CoV-2 and influenza* (on nasopharyngeal swab); *Clostridioides difficile (on faeces)*; *C-reactive protein* (on capillary blood);
Infectious diseases	
Geriatrics	
Endocrinology	
Surgery	
Neonatal intensive care	*Influenza, SARS-CoV-2, RSV* (on nasopharyngeal swab); *C-reactive protein* (on capillary blood), *Haemochrome* (white blood cells and pyatrins), *Procalcitonin* (on capillary blood).

3) The rapid detection and patient management information system must include the following activities:
   a) Guided digital pathway for the implementation of protocols and guidelines, allowing the retrieval of up-to-date documentation along the patient's pathway and encouraging professionals to adhere to them.
   b) Real-time communication system for intuitive transmission of information retrieved from the rapid microorganism detection system and laboratory examinations, for tracking of studied samples and communication of results to interested parties.
   c) The performance monitoring system enables visualisation of data repositories, dashboards and analyses based on local data for monitoring the performance of the RaDAR solution.
   d) Support, maintenance and training on the use of the platform and evaluation of adherence to protocols by RaDAR users.

4) The Rapid Detection and Patient Management Information System Database must include:
   a) key patient data and digital guidelines, protocols or other information of interest for the rapid patient detection information system
   b) interoperability and integration with the hospital information system (HIS), the laboratory information system (LIS), the pharmacy information system (PIS), the electronic patient record (EHR) and any other local information systems.
   c) On-site support system and pathogen database, including archiving of the entire history of local contamination, colonisation and infection, based on local data of the target micro-organism(s) (including surveillance, long-term treatment impact and process, cost and/or sustainability)
   d) Health worker communication system database and RaDAR performance monitoring system database.

Figure 3. RaDAR solution



2. PLACE OF INSTALLATION

The supply object of this Technical Elaborate will be installed at the Federico II University Hospital Complex located in via Sergio Pansini n.5, in particular in certain Departments of the following Departments of the University of Naples Federico II:

- Department of Public Health
- Department of Clinical Medicine and Surgery (Endocrinology, Surgery and Infectious Diseases)
- Department of Neuroscience (Adult Intensive Care)
- Department of Translational Medical Sciences (Neonatal Intensive Care Unit, Geriatrics)
- Department of Molecular Medicine and Medical Biotechnology

3. DURATION OF THE CONTRACT

The object of the contract will be for a maximum duration of 18 months, starting from the awarding of the contract and in any case no later than 31 December 2025, during which the bidder will implement, deploy and maintain the RaDAR integrated IT solution.

4. RADAR PROCUREMENT RESULTS: THEORY OF CHANGE

This tender adopts the theory of change to analyse the relationship between the activities of the intervention to be implemented through the tender process for innovative solutions (PPI) and the identified unmet needs, their outcomes and the demonstration of long-term improvements compared to traditional healthcare service delivery modes.

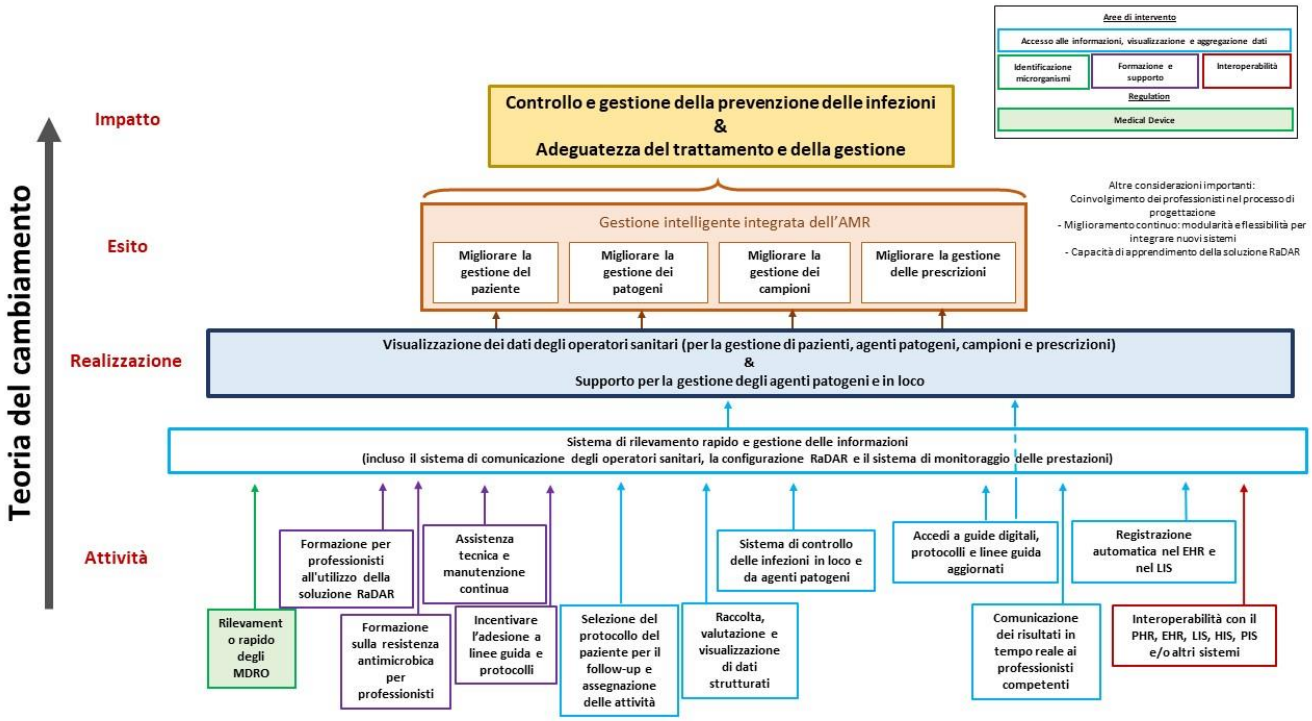
The theory of change will be used to define the appropriate 'results chain' and the correct demonstration of the impact of the RaDAR intervention.

The following activities (Figure 5) were defined by the contracting authority to meet their clinical needs. The activities were classified into 4 groups considering the areas of intervention and the responsiveness of the economic operators (including market feedback):

- rapid detection of community micro-organisms;
- staff training and support;
- access to information, visualisation and aggregation of data;
- interoperability.

The implementation of the different activities achieved by the RaDAR solution will lead to the achievement of the results and impact shown in Figure 4.

Figure 4. Theory of change applied to RaDAR at the contracting station



To assess the impact of the contract, the implemented solution will be monitored and evaluated. The monitoring of the contract consists of the fulfilment of activities, timely achievement of milestones and deliverables detailed in Section 8 of this Technical Workbook. During the contract and at the end of the contract, the deliverables specified in the contract or in the test generation plan to be provided by the supplier will be collected and evaluated.

<u>Impact</u>: infection prevention and control, treatment appropriateness and management

Overall, through intelligent integrated management of patients, specimens and prescriptions for antimicrobial resistance, the impact achieved will be timely and targeted prescribing, increased treatment efficacy and appropriate prevention and control of microorganisms that will help combat antimicrobial resistance.

Antimicrobial optimisation, which can be achieved through targeted antimicrobial prescribing (avoiding broad-spectrum prescribing or limiting it when not necessary), is critical in combating AMR and also helps in treatment follow-up. Ensuring a good patient prognosis and also stopping the selection and expansion of antibiotic-resistant clones is essential to check whether the antimicrobial can be removed, maintained or increased. Thus, ensuring the proper application of hygiene, prevention and control measures is crucial to prevent the spread of these microorganisms. These two points are key to the fight against antimicrobial resistance.

Outcome: timely, intelligent and integrated antimicrobial resistance management for patient, sample and prescription management.

The expected outcome of the RaDAR project will be the integrated intelligent management of antimicrobial therapy in the different departments of the contracting station, improving the management of patients, pathogens, samples and prescriptions. The improved visualisation, communication and surveillance of data and recommendations for pathogen and ward management will help healthcare professionals to follow the patient and specimen pathway following an evidence-based and well-informed protocol. RaDAR will support the implementation of necessary infection prevention and control measures.

Realisation: visualisation and communication of health worker data (for the management of patients, pathogens, samples and prescriptions)

The main achievements of the RaDAR project are better and more timely data sharing for patient and prescription management, pathogen identification, and sample tracking. All the activities described will feed a customised system that will support healthcare professionals along the diagnostic-therapeutic pathway to visualise and manage patient, pathogen, sample and prescription information.

1. Rapid detection of priority micro-organisms

This activity includes the rapid, accurate, sensitive and specific tests performed close to the patient used for the detection of priority micro-organisms for the choice of antimicrobial therapy, and the data set generated from the results of these tests that will feed the integrated RaDAR system.

2. Training and support

2.1. Training for professionals on the use of the RaDAR solution

This activity includes the training and updating of the different professional profiles that will interact and work with the RaDAR solution. This training will be carried out by providing access to training modules to facilitate the use of the RaDAR solution and ensure its adoption by healthcare professionals. It may include training material, videos, demonstrations, support and interactive tutoring including the use of the tools and technologies.

2.2. Technical support and ongoing maintenance

This activity includes the continuous availability (24/7) of a support system (live, on-site and/or virtual) to provide help and advice. It also includes physically on-site support to resolve any critical incidents and/or faults that cannot be solved by the contracting station's staff.

2.3. Antimicrobial resistance training for professionals

This activity includes access to training modules on antimicrobial resistance available at the Federico II University, or provided by recognised institutions or organisations (e.g: World Health Organisation, Ministry of Health, AGENAS, Istituto Superiore di Sanità, etc.).

2.4. Incentivising the correct use of guides, guidelines and protocols

This activity supports easy access to and periodic updating of user-friendly digital technology guides, guidelines and protocols for AMR.

3. Interoperability

This activity includes the interoperability between the different IT systems currently in use at the contracting station to enable the RaDAR solution to work properly and the correct tracking of information and results in all the required systems. In particular, the systems involved are the following: Electronic Health Record (PHR), Electronic Health Record (EHR), Laboratory Information System (LIS), Hospital Information System (HIS), Centralised Pharmacy Information System (PIS) and Repository dedicated exclusively to antibiotic resistance monitoring.

4. Access to information, visualisation and aggregation of data

4.1. Access to up-to-date digital guides, protocols and guidelines

This activity includes accessing and displaying smart digital guides, protocols and guidelines along the way (test selection, sample collection, test execution, diagnosis, therapeutic decision and/or follow-up...). The selection of up-to-date protocols and recommended and accessible guidelines will be made by each purchaser. This may include guides, protocols, guidelines and/or other documentation to support the selection and performance of tests, isolation, hygiene measures, cleaning and disinfection, prescribing, data and/or maps of local/regional antimicrobial susceptibility/resistance and other information when necessary.

4.2. Automatic registration in the electronic medical record and in the Laboratory Information System

This activity involves the automatic integration of the diagnosis results and outcomes collected by RaDAR into the electronic medical record and the laboratory information system.

4.3. Structured data collection, evaluation and visualisation

This activity includes the structured data collection, extraction, evaluation and visualisation of selected results at the contracting station that will enable the operation of the RaDAR performance monitoring system.

4.4. Real-time communication of results to appropriate professionals

This activity includes 'real time' communication to healthcare professionals appropriately identified by the contracting authority within the clinical management workflow of the antibiotic-resistant patient to enable rapid and well-informed communication of investigation results in the event of a suspected or positive infection result.

5. Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)

This activity includes the use of data from the Hospital Information System (HIS) and data from the RaDAR Rapid survey system to support the decision-making process of the healthcare provider. The Rapid Sensing and Management Information System will facilitate the visualisation of relevant information, improve communication between different profiles and highlight relevant information. This system will enable a more efficient implementation of infection prevention and control measures

and stewardship interventions. All the information described will be used to create an easy-to-use and visual rapid detection information system.

Table 2. Application of the theory of change and results to be obtained at the contracting station.

	ACTIVITIES	EVALUATION
Rapid detection of community micro-organisms	Rapid detection of community micro-organisms	OBLIGATORY
Rapid detection and management information system	Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)	OBLIGATORY
	Automatic registration in the electronic medical record and in the Laboratory Information System	OBLIGATORY
	Structured data collection, evaluation and visualisation	OBLIGATORY
	Real-time communication of results to appropriate professionals	OBLIGATORY
Training and support	Training for professionals on the use of the RaDAR solution	OBLIGATORY
	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
	Technical support and ongoing maintenance	OBLIGATORY
	Antimicrobial resistance training for professionals	OBLIGATORY
	Incentivising the correct use of guides, guidelines and protocols	*OPTIONAL*
Interoperability	Interoperability	OBLIGATORY

Expected overall results: improvement for stakeholders

- **Improvements for patients:** earlier and better diagnostic and therapeutic decisions, better follow-up, better short- and long-term results, reduction of unnecessary isolations and antibiotic/anti-fungal treatments, better patient and caregiver experience.
- **Improvements for health professionals:** improved patient follow-up, improved decision-making for diagnosis and treatment, better working environment, more professionals with access to evidence-based medical information, better guidelines for accession professionals and training.
- **Improvements for the healthcare professional**: improved workflow in the infected patient pathway, reduced patient isolation and length of stay, reduced antibiotic/antifungal consumption and less variability between professionals.
- **Improvement for the healthcare system**: better long-term results, reduced costs of antimicrobial resistance and possibility to assess the impact of antimicrobial resistance in the long term
- **Improving the social system:** reducing the impact of antimicrobial resistance on temporary and permanent sick leave of patients and their caregivers.

5. MONITORING

The monitoring process will determine how the RaDAR contract will be executed by the successful bidder. The impact will be assessed against the requirements outlined by the contracting authority taking into account the expected impact on health (technology and innovation, operability and implementation, quality, impact and evidence generation) and the benefits of the contract based on the value to the stakeholders detailed above (patients, health professionals, health organisation, health system and socio-economic).

The successful tenderer will have to provide three (3) Deliverables during the 18-month performance of the contract:

- Deliverable 1. Approval Report
- Deliverable 2. Interim Report on Results
- Deliverable 3. End-of-project report

The **Deliverable 1. Approval Report** (M6) shall include:

1. Supplier information table.

2a. Passed acceptance test for all activities (demonstration of the overall performance of the solution in the contracting authority's approved sanitary environment).

2b. Follow-up in Change Management, on-site adaptation, including:

- Achievements during phase 1.
- Report on the incidence of integration.
- Support and Maintenance System Report: Incident Reporting.
- Change Management Report.
- Changes to the plan: description of the changes, risks identified and actions to mitigate them.

3. Follow-up of the operational and quality plan, including:

- Report on project management and contract governance.
- Quality Incidence Report.
- Risk Management Report.
- Achievements during this phase.
- Changes to the plan: description of the changes, risks identified and actions to mitigate them.

4. Follow-up of the Impact Generation Plan, including the RaDAR performance report and monitoring system and suggestions for improvement:

- Report on the results of the implementation of the RaDAR solution
- Impact and Evidence Report

It also includes:

- Description of the questionnaires used to assess user satisfaction (preferably a validated questionnaire)
- Evaluation of local basal results (at M6);
- Achievements during this phase;

- Changes to the plan: description of changes, risks identified and actions to mitigate them.

5. Implementation of the recommendations of the contractor's monitoring group. Description of the implementation status.

The **Deliverable 2. Interim Report on Results** (M12) should include:

1. Supplier information table.

2. Follow-up in Change Management, on-site adaptation, including:

- Achievements during phase 2.
- Report on the incidence of integration.
- Support and Maintenance System Report: Incident Reporting.
- Change Management Report.
- Changes to the plan: description of the changes, risks identified and actions to mitigate them.

3. Follow-up of the operational and quality plan, including:

- Report on project management and contract governance.
- Quality Incidence Report.
- Risk Management Report.
- Achievements during this phase.
- Changes to the plan: description of the changes, risks identified and actions to mitigate them.

4. Follow-up of the Impact Generation Plan, including the RaDAR performance report and monitoring system and suggestions for improvement:

- Report on the results of the implementation of the RaDAR solution
- Impact and Evidence Report

It also includes:

- Description of the questionnaires used to assess user satisfaction (preferably a validated questionnaire)
- Evaluation of local results at 12 months.
- Achievements during this phase
- Changes to the plan: description of changes, risks identified and actions to mitigate them.

5. Implementation of the recommendations of the contractor's monitoring group. Description of the implementation status.

The **Deliverable 3. End of Project Report** (M17) should include:

1. Supplier information table.

2. Change management, solution integration and implementation follow-up of progress in each section, including:

- Achievements during this phase.
- Report on the incidence of integration.
- Report on support and maintenance system: incident reporting.
- Change Management Report

- Changes with respect to the plan: description of changes, risks identified and actions to mitigate them.

3. Follow-up of the operational and quality plan, including:

- Project Management and Contract Governance Report
- Quality Incidence Report
- Risk Management Report
- Achievements during this phase
- Changes with respect to the plan: description of changes, risks identified and actions to mitigate them.

4. Follow up on the impact plan and generation of evidence, including the RaDAR performance report and monitoring system and suggestions for improvement:
   - Report on the results of the implementation of the RaDAR solution
   - Impact and Evidence Report

It also includes:

Description of the questionnaires used to assess user satisfaction (preferably a validated questionnaire)

Evaluation of local results at 17 months.

Achievements during this phase

Changes to the plan: description of the changes, risks identified and actions to mitigate them.

5. Implementation of the monitoring team's recommendations. Description of the implementation status.

Table 3 shows the 18 months of the RaDAR project contract.

Table 3. Procurement schedule for the RaDAR project

Year	2024				2025			
Phase	1T	2T	3T	4T	1T	2T	3T	4T
1. Change management, on-site adaptation and acceptance testing								
2. Execution								
3. Project execution and completion								

From June 2024 to December 2024, the 'Change Management, On-site Adaptation and Acceptance Testing' phase will take place to enable the successful integration of the RaDAR solution at AOU Federico II. From January to June 2025, Phase 1 of 'Execution' will begin, when the RaDAR solution will start to operate in the daily routine of the hospital. Finally, from July to December 2025, Phase 2 of 'Execution and End of Project' will take place.

The following table describes the activities, results, and milestones of each phase of the RaDAR contract execution.

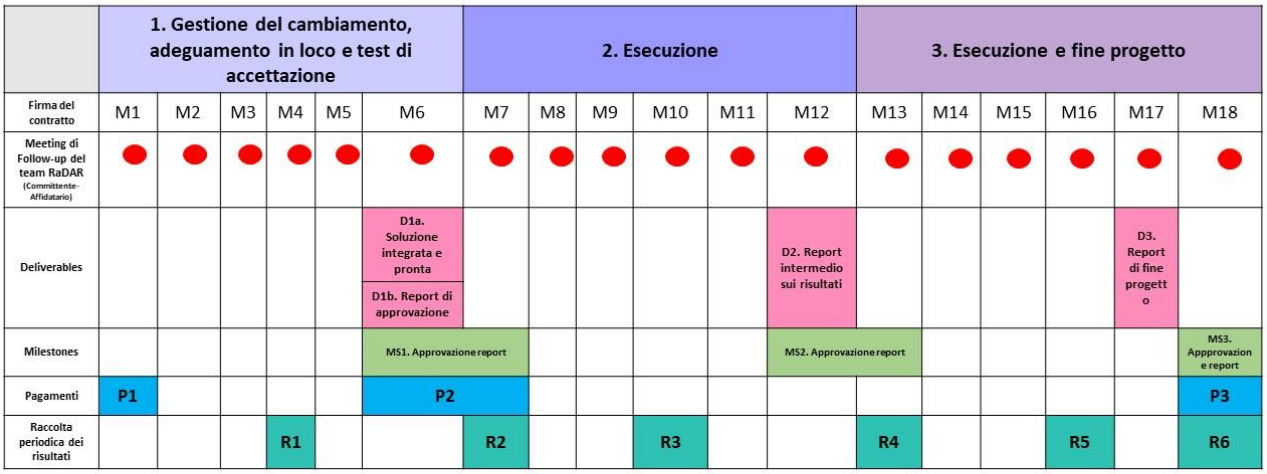
Table 4. Phases, activities, results and milestones of the RaDAR tender.

Phase	Duration	Activities	Results	Milestones
1. Change management, on-site adaptation and acceptance testing	M1-M6	1.1 Gathering information in a real context and planning the execution of the contract 1.2 RaDAR solution integration plan and change management 1.3 Solution Integration and Use Case Validation	Result 1. Approval Report (M6) Result 1. Integrated solution ready to operate in daily practice. Acceptance test passed, functioning and approved by the RUP (M6)	MS1. Approved Approval Report
2. Execution	M7-M12	2.1 Implementation of the solution in daily practice 2.2 Execution of the test generation plan	Final Results 2. Interim Report on Results (M12)	MS2. Interim Report on Approved Results (IOR) (M12)
3. Project Execution and Termination	M13-M18	3.1 Follow-up of implementation 3.2 Follow-up of the execution of the test production plan, including aggregated data	Final results 3. End of project report (M17)	MS3. Approved End of Project Report (EOR) (M18)

After the contract has been signed, the contracting authority will also organise a kick-off meeting with the contractor to start the contract monitoring process. The purpose of the kick-off meeting will be to detail to the supplier how the monitoring process will be implemented during the execution of the contract.

Several meetings will be held during the project implementation phase (Figure 5). Monthly local follow-up meetings (M1 to M18) will be organised between the client and the supplier to follow and monitor the implementation of the RaDAR project.

Figure 5.



Before the deadlines at Month (M) 6, M12 and M17 from the signing of the contract, the supplier shall submit the following documents:

- D1a. Integrated and ready solution (M6);
- D1b. Approval report (M6);
- D2. Interim report on results (M12);
- D3. End-of-project report (M17).

to reach the end of the MS1, MS2 and MS3 phases with the approval of the reports by the Contracting Authority's RaDAR Project Working Group.

Phase 1 of 'Change Management, On-site Adaptation and Acceptance Testing' will close with the approval and acceptance by the RaDAR project team of the implementation of the RaDAR solution. Monitoring will have two further milestones:

- MS2, the acceptance by the RaDAR Working Group of the Interim Results Report, to M12 after the signing of the contract;

- MS3, at the end of the project, the acceptance by the RaDAR Working Group of the End of Project Report, to M17 after the contract has been signed.

Finally, every 3 months (end of M3, M6, M9, M12, M15 and M18) the supplier's team will provide the required results, at the end of the phases the results will be included in each deliverable (impact section), while at M3, M9 and M12 they will be presented separately.

Monitoring Indicators

Table 5. Monitoring indicators

Outcome	Result	Key Performance Indicator
Improved patient management	Percentage of practitioner adherence to clinical guidelines/ Number of professionals with access to evidence-based medical information and training to benefit from its use	Number of health professionals with access to guidelines and protocols provided by the RaDAR solution
		Number of views of guidelines and protocols provided by the RaDAR solution
		% patients treated according to treatment guidelines
	Identification of cases of over-treatment or inadequate treatment	% of diagnostic appropriateness
	Workflow	Time since isolation
	Number of admissions	Total number of isolated patients
		Ratio number of cases of infection/total admissions
		Ratio of number of patients not admitted/total admissions
Improved pathogen management	Hospital infections	Number of hospital-acquired infections by priority micro-organism and type of resistance
	Screening	Total number of tests performed using the RaDAR solution
		Sensitivity rate (+ diagnosed patients / total positive patients)
Improved sample management	Workflow	RaDAR detector response time (from sample extraction until results are available in the detector)
		RaDAR detector response time (from the sample in the detector to the results available in the HIS)
		RaDAR detector response time (from the results available in the HIS to the treatment plan for the patient)
Improved prescription management	Reducing errors / Increasing accuracy Diagnostic/prescriptive adequacy	% of appropriate therapeutic prescription
		% of appropriate antibiotic prescription
		% of appropriate broad-spectrum antibiotic prescription
		% of the appropriate antifungal prescription (if fungi are included as priority microorganisms)
	Reducing drug consumption	Total amount of prescription of broad-spectrum antibiotics
	Workflow	RaDAR detector response time (from the results available in the HIS to the treatment plan for the patient)
General	Acceptability and usability of the solution by the health professional	Acceptability and usability of the solution by the health professional
		User satisfaction with the solution (healthcare professionals and patients)
		Number of health workers with access to the RaDAR solution
		Number of health workers using the RaDAR solution

	Effectiveness of training for health workers	Total number of professionals trained in the use of the RaDAR solution
	Maintenance	Total number of incidences per service level
		Time until resolution of incidence by service level
	Level of involvement in the design process	Number of health professionals who participated in the design and visualisation of the solution

Intellectual property rights and commercial exploitation of results

The supplier will retain ownership of the intellectual property rights (IPR) of the results generated during the RaDAR monitoring plan and may use them to exploit the potential market for the innovative solution beyond this contract. The Contract signed following this tender is for the provision of IT services protected by an intellectual or industrial property right (IPR). The supplier shall expressly declare that it owns the intellectual property rights or legal rights for the commercialisation of such products and shall submit supporting documentation if requested to do so by the Contracting Authority. The ownership of pre-existing rights remains unaffected by this tender.

The supplier shall be liable for any claims relating to intellectual, industrial and/or commercial property, in such a way that, should any claim be made against the Contracting Authority based on the breach of the obligations described above, the supplier shall bear any judicial or extrajudicial defence costs that may be incurred.

If, as a consequence of such a claim, the Contracting Authority is prevented from using the solution, it may request from the supplier, even after final receipt of the service, the total replacement and reimbursement of the costs of the materials, computer programmes, procedures or equipment affected by the claim of others, having the same characteristics and quality to be defined by the Contracting Authority, within a prudentially fixed term. Once this term has expired and the supplier has not provided for the replacement of the corresponding items, the Contracting Authority, without the need for any further prescription, shall replace the materials, procedures, computer programmes or equipment affected at its own expense, or through third parties. All this, without prejudice to the penalties and compensation for damages that shall proceed in accordance with the provisions of this Tender Rules.

6. REQUIREMENTS AND SPECIFICATIONS ACCORDING TO THE LIFE CYCLE OF THE CONTRACT

Table 6. Installation and delivery specifications and requirements

ID	DESCRIPTION	Activities	Evaluation
Rapid detection of priority micro-organisms			
RADAR -ID-001	The rapid detection system MUST be installable and ready for use in the rooms, in the wards of infectious diseases, geriatrics, endocrinology and surgery, and in neonatal and adult intensive care units (ICUs).	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-002	The solution should include devices for rapid, accurate, sensitive and specific tests performed close to the patient (Point of Care) for the detection of priority micro-organisms (see section 1.2)	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-003	The rapid detection system MUST identify, close to the patient (point of care), infected or colonised patients without requiring processing or minimal sample preparation; by direct detection from whole blood samples, urine samples, nasal/rectal swabs, faeces) without culture for priority micro-organisms	Rapid detection of priority micro-organisms	OBLIGATORY

RADAR -ID-004	The rapid detection system MUST perform in adult intensive care units, geriatrics, infectious diseases, endocrinology and surgery, close to the patient (point of care), tests for Legionella (on urine), SARS and FLU (on nasopharyngeal swab), Clostridium difficile (on faeces)	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-005	The rapid detection system MUST perform in the neonatal intensive care unit, close to the patient (point of care), tests for FLU, SARS, RSV (on nasopharyngeal swab)	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-008	The instruments must have very short activation, operation and maintenance times. The devices must be easy for healthcare workers (nurses, doctors, microbiologists and laboratory technicians) to use and simple to integrate into their work routines, without the need for special skills or preparation.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-009	The RaDAR rapid detection system MUST transmit and store the patient ID, results and timestamp in the RaDAR information system.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-010	The test must be simple and inexpensive for the micro-organisms identified.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-011	The supply of the devices will have to include kits to be able to perform rapid tests on an estimated population of 2,000 patients/year.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-012	The kits must be complete with all the material needed to carry out the analysis.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-013	Rapid test devices must comply with international standards such as IEEE 11073 PHD and have proven accuracy levels comparable to medical devices with similar functions.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-016	The RaDAR rapid detection system MUST detect in between 15 minutes and 5 hours (POSSIBLY in less than 3 hours), with minimal sensitivity, specificity and VPN, priority micro-organisms using any technique.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-017	The RaDAR Rapid Detection System MUST allow efficient sample processing in order to also perform the standard sample collection and laboratory detection process and subsequent tests routinely used in laboratories in parallel.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-018	The sensitivity of the rapid test MUST not depend on environmental conditions (temperature, humidity and kinetic saturation) nor be adversely affected to the point where the committed relative sensitivity is reduced by more than 50%.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-019	The response time, sensitivity, specificity and accuracy of the rapoid test SHOULD NOT be subject to degradation due to interference from devices commonly used in hospital rooms.	Rapid detection of priority micro-organisms	OBLIGATORY
RADAR -ID-020	The limitations of use of the RaDAR rapid detection system (environmental interference that could reduce the performance capabilities of the detector (response time, sensitivity, specificity and accuracy) MUST be declared.	Rapid detection of priority micro-organisms	OBLIGATORY
Rapid detection and management information system			
RADAR -ID-021	The RaDAR information system MUST be a web-based application for monitoring and decision support, able to monitor the epidemiological situation in the hospital setting, to support healthcare personnel in the management of patients and in decisions about antibiotic therapies on the basis of best practices for the responsible use of antibiotics (antimicrobial stewardship).	Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)	OBLIGATORY
RADAR -ID-022	The RaDAR information system MUST provide multiple user interfaces according to professional profiles (microbiologist, infectious disease specialist, nurse, etc.). Different users should have access to specific content.	Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)	OBLIGATORY
RADAR -ID-023	The RaDAR information system MUST provide tools to configure interfaces and content according to job profiles.	Rapid detection and management information system (including health	OBLIGATORY

		worker communication system and RaDAR configuration and performance monitoring system)	
RADAR-ID-024	The RaDAR information system should automatically collect the results of the screening test performed at the patient's bedside (Point-of-Care) and should support healthcare personnel in collecting the biological material to be sent to the microbiology laboratory for diagnostic confirmation and antibiogramming.	Real-time communication of results to appropriate professionals	OBLIGATORY
RADAR-ID-025	If infection/contamination/colonisation is detected, the RaDAR information system MUST store the relevant data (patient identifier, room where the patient is staying and timestamp of the patient's rapid test) on the server.	Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)	OBLIGATORY
RADAR-ID-026	The RaDAR information system MUST send the result of the rapid test and its timestamp to the LIS and the departments concerned.	Real-time communication of results to appropriate professionals	OBLIGATORY
RADAR-ID-027	In the event that the infection is confirmed and the HIS can send molecular-level micro-organism identification data (epidemic strains), resistance(s) and degree of virulence, the RaDAR information system MUST receive this information from the HIS and store it together with the date and time of confirmation.	Automatic registration in the electronic medical record and in the Laboratory Information System	OBLIGATORY
RADAR-ID-028	The RaDAR information system MUST send the confirmed infection/colonisation/contamination information (patient identifier (if any), the localised room where the patient is staying, timestamp of the patient's screening and identification of micro-organisms at the molecular level (epidemic strains), resistance(s), the degree of virulence and the timestamp of the microbiological test results, if available) to the local data server.	Automatic registration in the electronic medical record and in the Laboratory Information System	OBLIGATORY
RADAR-ID-031	The RaDAR information system MUST archive all infections and colonisation/contamination incidents of target micro-organisms detected by the RaDAR solution at the contracting authority's premises, including: patient identifiers, rooms the patients stayed in, timestamps of infection/colonisation/contamination detection, timestamps of infection/colonisation/contamination confirmation and the source of the information (RaDAR rapid detector, HIS/LIS, end-user identification, automatic upload from a file).	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR-ID-032	The RaDAR information system MUST correctly manage all episodes and allow duplicate episodes to be merged.	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR-ID-034	In the event that an infection/contamination/colonisation is detected, the information system MUST send an alert to the affected users.	Real-time communication of results to appropriate professionals	OBLIGATORY
RADAR-ID-035	The solution shall include a sample tracking system, from collection to delivery to the laboratory, and shall be integrated with existing systems. The solution shall allow the laboratory staff to upload the results of the analyses performed, giving the ward staff a complete overview of the patient care pathway.	Real-time communication of results to appropriate professionals	OBLIGATORY
RADAR-ID-036	The solution shall include an epidemiological monitoring system, with dashboards and data visualisation and aggregation tools to identify correlations and trends. The solution shall enable the tracking and monitoring of antibiotic-resistant microorganisms and trends in bacterial infections over time, identifying any outbreaks, most affected areas and departments.	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR-ID-038	The RaDAR information system MUST provide dashboards for retrospective analysis based on local data, statistics on target micro-organism detections: (1) number of detections/day/week/month/year, species detected, etc.; (2) Detection and identification of molecular biology (epidemic strains); (3) Detection of endemic or epidemic levels of colonisation/infection.	Structured data collection, evaluation and visualisation	OBLIGATORY

RADAR -ID-039	The RaDAR information system MUST create a user-friendly summary of the patient's data in PDF format to make it visible in the electronic medical record.	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR -ID-040	The patient summary of the RaDAR information system containing data/information MUST be co-designed together with healthcare professionals, considering the different user profiles.	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR -ID-041	The final decision on results will always be made by the practitioner. The RaDAR solution MUST allow the practitioner to accept/reject the results and MUST record the practitioner's decision.	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR -ID-042	The information system MUST periodically collect, extract and standardise in-patient data from the HIS (different sources): the frequency will be determined by the contracting station and will be, at least, daily; access will be according to the contracting station's ICT policies (either by querying the source database directly or by importing an export file containing all relevant INSERT/UPDATE for in-patients).	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR -ID-043	The data visualisation model of the RaDAR information system, including data from the rapid detection system and pathogen data MUST be co-designed together with healthcare professionals, considering the different user profiles.	Structured data collection, evaluation and visualisation	OBLIGATORY
RADAR -ID-044	The RaDAR ICT solution MUST be able to aggregate anonymised data. The information system MUST provide retrospective analysis dashboards based on aggregated data, statistics on the detection of target microorganisms for the needs of the RaDAR project.	Structured data collection, evaluation and visualisation	OBLIGATORY
Training and Support System			
RADAR -ID-046	The solution should support healthcare personnel in implementing antibiotic-resistant patient management protocols, providing a checklist of the different steps and useful information for patient isolation, room sanitisation, and the safety of other patients and ward staff.	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
RADAR -ID-048	The solution should include modules for continuous training of healthcare personnel on international protocols to be implemented and best practices in infection management and antibiotic resistance prevention.	Antimicrobial resistance training for professionals	OBLIGATORY
RADAR -ID-049	The RaDAR contractor MUST ensure access, registration and follow-up through the RaDAR solution of basic antimicrobial resistance training programmes.	Antimicrobial resistance training for professionals	OBLIGATORY
RADAR -ID-050	The RaDAR solution provider MUST submit a proposal for user training	Antimicrobial resistance training for professionals	OBLIGATORY
RADAR -ID-052	The provider of the RaDAR solution MUST describe and organise user training and the user support centre.	Antimicrobial resistance training for professionals	OBLIGATORY
RADAR -ID-053	The RaDAR information system MUST provide access to guides, clinical guidelines and protocols selected by the contracting authority through different user profiles.	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
RADAR -ID-054	The RaDAR information system MUST easily and frequently update guides, guidelines and protocols. The frequency will be determined by the purchasers' ICT policies and will be at least monthly.	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
RADAR -ID-055	The RaDAR information system MUST provide access to appropriate digital documents at each stage of the patient journey (from diagnostic test to execution, sample collection guide, test results, diagnosis and prescription).	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
RADAR -ID-059	Training modules and protocols must be in Italian	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
RADAR -ID-060	The user guide for the RaDAR solution MUST be provided in the Italian language.	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
RADAR -ID-061	Access guidelines and protocols MUST be easy. The guidance, guidelines and protocols included in the RaDAR ICT solution MUST be easy to use.	Access to up-to-date digital guides, protocols and guidelines	OBLIGATORY
Interoperability			

RADAR -ID-062	The supplier MUST prepare an implementation and operational plan including the strategy for integrating the solution by analysing the status of the situation at the contracting authority's site.	Interoperability	OBLIGATORY
RADAR -ID-063	The RaDAR solution MUST be integrated with the hospital information systems at the contracting station. The implementation MUST be carried out following the instructions of the contracting station's staff.	Interoperability	OBLIGATORY
RADAR -ID-064	The solution will be hosted on servers physically located within the AOU Federico II or on cloud in the geographical/legal area of the contracting station.	Interoperability	OBLIGATORY
RADAR -ID-065	The solution shall adopt international interoperability standards and code systems to ensure sustainable and reliable interoperability. The solution shall comply with HL7, FHIR, FHIR XML, IHE XDS, etc. standards for data integration and transmission of health-related information.	Interoperability	OBLIGATORY
RADAR -ID-067	The RaDAR ICT solution MUST provide the ability to query and export data in XML format.	Interoperability	OBLIGATORY
RADAR -ID-068	The RaDAR solution MUST be integrated into normal healthcare routines by including all the professionals involved, working close to the patient and the laboratory, pharmacy and stewardship team members.	Interoperability	OBLIGATORY
RADAR -ID-069	The RaDAR solution MUST be able to exchange information with the following systems: Electronic Health Record (PHR), Electronic Health Record (EHR), Laboratory Information System (LIS), Hospital Information System (HIS), Centralised Pharmacy Information System (PIS) and Repository dedicated exclusively to antibiotic resistance monitoring.	Interoperability	OBLIGATORY
General			
RADAR -ID-070	The RaDAR solution MUST be easy to install and implement. The introduction of the RaDAR solution MUST involve as little adaptation as possible to existing environments and facilities. In particular, the solution MUST not involve procurement from specific energy sources and energy-related equipment. The impact on energy consumption shall be minimal.	General	OBLIGATORY
RADAR -ID-071	No specific network infrastructure is required for the use of the RaDAR solution, but existing LAN and WiFi access points should be used	General	OBLIGATORY
RADAR -ID-072	No specific internal settings (temperature, humidity, lighting, air quality and flows) shall be required for the use of the RaDAR solution; its operation shall not be influenced by the opening/closing of windows and doors; its operation shall not be influenced by the movement of staff and patients.	General	OBLIGATORY
RADAR -ID-073	The solution with all its interfaces (medical, microbiologist, administrative, etc.) will be available on both desktop and mobile devices (tablets, smartphones). The interfaces must be easy to use. For this reason, they must be adapted to the needs of different user groups. The goal should be a certain degree of conformity with IEC 62366.	General	
RADAR -ID-074	Users MUST authenticate themselves securely to access the RaDAR solution	General	OBLIGATORY
RADAR -ID-075	The secure authentication of the RaDAR solution MUST comply with the methods used by the contracting authority (such as access (password, barcode, smartcard, biometric, etc.), network access authentication (IPSec, remote, single sign-on, etc.).	General	OBLIGATORY
RADAR -ID-076	Data MUST be protected from external misuse (servers MUST be installed according to the purchaser's ICT security procedures (e.g. firewalls)).	General	OBLIGATORY
RADAR -ID-077	The RaDAR solution MUST comply with the EU General Data Protection Regulation	General	OBLIGATORY
RADAR -ID-078	The RaDAR solution MUST be risk-free for patients.	General	OBLIGATORY
RADAR -ID-079	The RaDAR solution MUST be risk-free for users.	General	OBLIGATORY
RADAR -ID-080	The RaDAR solution MUST NOT include or generate any toxic material to be handled and transported by personnel.	General	OBLIGATORY

RADAR-ID-081	Consumables (if any) MUST be non-toxic and environmentally friendly.	General	OBLIGATORY
RADAR-ID-082	The RaDAR solution MUST not interfere with devices in use in hospital premises.	General	OBLIGATORY
RADAR-ID-083	The RaDAR solution MUST comply with EU safety, health and environmental protection requirements by assessing the conformity of all products used with EU directives, EU guidelines, EU standards and national occupational health and safety legislation.	General	OBLIGATORY
RADAR-ID-084	The technologies used by the RaDAR solution MUST comply with the following EU directives: - REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC - REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	General	OBLIGATORY
RADAR-ID-085	The RaDAR solution provider MUST ensure the proper functioning of the system by responding to operational incidents within the service time.	General	OBLIGATORY
RADAR-ID-086	The RaDAR solution provider MUST answer to the user for incidents and alterations to the system.	General	OBLIGATORY
RADAR-ID-087	RaDAR solution operations MUST be guaranteed every day during 24 hours (24x7)	General	OBLIGATORY
RADAR-ID-088	The RaDAR solution provider MUST support incident management: - Solving malfunctions in the solution. - Record the requests, keeping the information updated weekly. - Plan requests according to priorities. - Examine and analyse problems in order to propose solutions. - Follow-up with the service manager appointed by the contracting station.	General	OBLIGATORY
RADAR-ID-089	In user support, the priority criterion is determined by the following parameters, such as the impact of the incident, based on the volume of users affected, the frequency of the incident, the dates on which it occurred, and the application or module affected. Incidents are therefore prioritised as follows: - No service (down): problems to be resolved immediately because they prevent the solution from functioning in its entirety. The user cannot take any action until the incident is resolved. The critical level is considered very high. - Very Urgent: incidents that, due to their type, prevent the correct functioning of the solution. It is possible to perform part of the actions, but it is not possible to complete the procedure in its entirety. The critical level is considered very high. - Urgent: incidents affecting a low number of users or only one module of the solution. The incident can be temporarily resolved by other means. The critical level is high. - Moderate: incidents that, due to their type or the date on which they occurred, are not critical. - Low: few critical issues that do not seriously affect the proper functioning of applications. The critical level is considered low. The level of service established for each priority is detailed below: Priorities | Maximum Time for Resolution | Level	General	OBLIGATORY

	Low	7 working days	80%		
	Moderate	3 working days	80%		
	Urgent	1 working day	80%		
	Very urgent	8 working hours	100%		
	No Service	2 working hours	100%		
RADAR -ID-090	The RaDAR solution provider MUST provide a unique email address (which must be generic, not personal) that will be the buyer's point of contact with the company. At least two contact telephone numbers will also be required. For its part, the contracting authority will provide the supplier of the RaDAR solution with the telephone numbers and e-mail addresses of the project manager.			General	OBLIGATORY
RADAR -ID-091	Requests will be made through a single contact person at the contracting station and through the user support service.			General	OBLIGATORY
RADAR -ID-092	The RaDAR solution MUST have live and physically on-site support when required, particularly in urgent, very urgent and service interruption cases that cannot be resolved remotely.			General	OBLIGATORY
RADAR -ID-094	The RaDAR solution MUST guarantee the following terms in terms of data security and privacy: - Implementation and assurance of information security through the entire lifecycle of the RaDAR solution. - Monitoring the policy established by regional/national agencies to ensure the correct implementation of the security model in application maintenance, involving data security teams from the beginning of the service, carrying out the necessary tests and following certain guidelines. - Implementation of the necessary measures to comply with current security regulations based on the classification of application information. Given the changing nature of data security threats, technological development and changes that may occur, the RaDAR solution provider MUST adapt security controls and measures during the execution of the service, if necessary. In general, it is essential that the security measures to be taken enable threats of the following types, as a minimum: - Theft of information, with the resulting business and legal impact (e.g. violation of the EU General Data Protection Regulation (henceforth, GDPR). - PC intrusion, configuration/security changes to take over. - Theft of user credentials. - Exploitation of vulnerabilities in developed or evolving applications. - Interrupting network traffic to acquire information (DNS spoofing, HTTPS spoofing, among others). - Legal violation. For example, non-compliance with the GDPR, due to access to users' personal data. - Causing a refusal of service. - Access by unauthorised administrators/developers or for illegitimate use. Unauthorised use of resources. - Errors by the administrators/developers of the service. For example, incorrect configurations, poorly applied security measures, etc. - Uncontrolled remote access. Attackers could exploit weak remote access mechanisms (e.g. VPNs with weak passwords). - Social engineering to access the confidential information of the personnel providing the service.			General	OBLIGATORY

Table 7. OPTIONAL specifications and requirements

ID	DESCRIPTION	Activities	Evaluation

Rapid detection of priority micro-organisms			
RADAR-ID-006	The rapid detection system MUST perform in adult intensive care units, geriatrics, infectious diseases, endocrinology and surgery, close to the patient (point of care), tests for pneumococcus (on urine), PCR (on capillary blood)	Rapid detection of priority micro-organisms	OPTIONAL
RADAR-ID-007	The rapid detection system MUST perform in the neonatal intensive care unit, close to the patient (point of care), tests for PCR, Haemochrome (white blood cells and platelets), Proclacitonin (on capillary blood)	Rapid detection of priority micro-organisms	OPTIONAL
RADAR-ID-014	The RaDAR rapid detection system MUST be flexible/modular to integrate detection capabilities for additional micro-organisms or future tests or possible evolution of micro-organisms.	Rapid detection of priority micro-organisms	OPTIONAL
RADAR-ID-015	The RaDAR rapid detection system MUST allow the use of vendor-neutral consumables (e.g. plastic tubes, reagents), for vendor-neutral commercial solutions	Rapid detection of priority micro-organisms	OPTIONAL
Rapid detection and management information system			
RADAR-ID-029	The solution should use antimicrobial susceptibility data to predict resistance and suggest validated models and approaches, supporting clinicians in choosing the appropriate treatment.	Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)	OPTIONAL
RADAR-ID-030	The solution should help clinicians to quickly and accurately identify high-risk patients and anticipate antibiotic sensitivity test results, allowing for more targeted treatment selection.	Rapid detection and management information system (including health worker communication system and RaDAR configuration and performance monitoring system)	OPTIONAL
RADAR-ID-033	The RaDAR information system MUST allow real-time display of relevant data in the HIS (if any) after checking the patient's history (any previous infections, health/social care centre of reference (if any), previous hospitalisation (if any), etc.).).	Structured data collection, evaluation and visualisation	OPTIONAL
RADAR-ID-037	The solution should include evidence-based predictive models of bacterial resistance that can analyse patient clinical data, collected samples, antibiogram results and ward characteristics to provide a prediction of the likelihood of a bacterium being resistant or susceptible to a given substance.	Structured data collection, evaluation and visualisation	OPTIONAL
RADAR-ID-045	The RaDAR information system MUST periodically collect and extract data from the HIS (various sources) to fulfil the RaDAR project's impact and evidence generation plan.	Structured data collection, evaluation and visualisation	OPTIONAL
Training and Support System			
RADAR-ID-047	The solution should allow self-assessment of the effectiveness of protocols and actions implemented by healthcare personnel for the management of antibiotic resistance in the hospital setting.	Incentivising the correct use of guides, guidelines and protocols	OPTIONAL
RADAR-ID-051	The RaDAR solution provider MUST present a proposal for change management and involvement of key stakeholders in the process	Antimicrobial resistance training for professionals	OPTIONAL
RADAR-ID-056	The RaDAR information system MUST include technologies/products/platforms/systems/developments capable of at least evaluating, supporting and alerting on the risks of infection or other events per site and per pathogen at the population level after having processed all the data entered/updated the information related to the Electronic Health Record of the hospitalised patients together with the data related to all the histories of the hospitalised patients (previous infection, health/social care centre of reference (if any), previous hospitalisations (if any), etc.), the geo-localised area history, the staffing/reporting compliance (if any), etc. selected after having	Access to up-to-date digital guides, protocols and guidelines	OPTIONAL

	analysed the state of the art and considered the overall requirements of the system, the state of the art and the overall requirements of the system, the state of the art and the overall requirements of the system, the geo-localised area history, the staffing/reporting compliance (if any), etc.), geo-localised area history, staff-compliance report (if any), etc. selected after analysing the state of the art and taking into account the overall system requirements, clinical insights for relevant clinical processes/situations (e.g. referring to hygiene/sanitary protocols and clinical staff survey requirements).		
RADAR-ID-057	The RaDAR computer system MUST at least be able to provide on-site and pathogen decision support to the priority micro-organism in an explanatory manner (probability and criteria).	Access to up-to-date digital guides, protocols and guidelines	OPTIONAL
RADAR-ID-058	The RaDAR solution MUST involve health workers and include measures to encourage protocol adoption by health workers	Incentivising the correct use of guides, guidelines and protocols	OPTIONAL
RADAR-ID-066	The RaDAR information system MUST interoperate with existing technologies/products/platforms/systems/developments capable of assessing at least the infection risks per site and per pathogen, after processing together all entered/updated information from the electronic medical records of hospitalised patients, such as all inpatient histories (previous infection, health/social care centre of reference (if any), previous hospitalisations (if any), localised area history, adequacy of staff reports (if any)), etc.	Interoperability	OPTIONAL
General			
RADAR-ID-093	The RaDAR solution provider MUST prepare and describe an impact and evidence generation plan that contributes to generating clinical knowledge about the solution to be implemented.	General	OPTIONAL

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Table 8. Specifications and requirements for maintenance

ID	DESCRIPTION	Activities	Evaluation
RADAR-MAN-001	The covering materials of the entire device MUST be cleanable.	General	OPTIONAL
RADAR-MAN-002	The RaDAR rapid detector MUST be environmentally friendly, with a limited amount of disposable material.	General	OBLIGATORY
RADAR-MAN-003	The RaDAR solution MUST be easy to maintain; self-manageable by maintenance personnel.	General	OBLIGATORY
RADAR-MAN-004	The RaDAR solution MUST be easy to update and renew.	General	OBLIGATORY
RADAR-MAN-005	The RaDAR rapid detector MUST require little or no recalibration, which means that the drift of the RaDAR rapid detector MUST be minimal. In the event that the RaDAR rapid detector needs recalibration, it MUST be performed by professionals from the reference laboratory or, if this is not possible for them, the	Rapid detection of antibiotic-resistant	OBLIGATORY

	calibration should be covered by the RaDAR contractor's maintenance service.	micro-organisms	
RADAR-MAN-006	The RaDAR ICT solution MUST provide an online instruction manual with a quick guide to operating and maintenance instructions.	Antimicrobial resistance training for professionals	OBLIGATORY
RADAR-MAN-007	The RaDAR solution MUST be integrated into the normal support routines of health workers.	General	OBLIGATORY
RADAR-MAN-008	The data integrity of the RaDAR information system MUST be ensured during the storage and processing of all data collected by the RaDAR Rapid Relay System and all data received from computer systems with which it interacts.	General	OBLIGATORY
RADAR-MAN-009	The data integrity of the RaDAR information system MUST be guaranteed during export to and transmission between all technologies and computer systems with which it interacts.	General	OBLIGATORY
RADAR-MAN-010	The data integrity of the RaDAR solution MUST be ensured during calibration and during maintenance activities of the different technologies included.	General	OBLIGATORY
RADAR-MAN-011	The RADAR information system MUST facilitate, through electronic audit-trail records, the reconstruction of the course of events relating to the creation, modification and deletion of any electronic data, including the "who, what, when and why".	General	OBLIGATORY
RADAR-MAN-012	The RaDAR information system MUST be compatible with common third-party backup software packages.	General	OBLIGATORY
RADAR-MAN-013	User guidance for maintaining the RaDAR solution MUST be provided and MUST include instructions for backup and recovery.	General	OBLIGATORY
RADAR-MAN-014	The RaDAR fast detection system MUST not require complex equipment or a large volume of physical storage.	Rapid detection of antibiotic-resistant micro-organisms	OBLIGATORY
RADAR-MAN-015	The supplier of the RaDAR solution MUST ensure the maintenance and operation of the solution during the performance of the contract.	Antimicrobial resistance training for professionals	OBLIGATORY
RADAR-MAN-016	The RaDAR ICT solution MUST be disposed of in accordance with the EC Directive on Waste Electrical and Electronic Equipment (WEEE) and the EC Waste Directive.	General	OBLIGATORY

5.3 Implementation and Operation

Table 9. Specifications and requirements for implementation and operation

ID	DESCRIPTION	Activities	Evaluation

RADAR-ATT-001	The supplier MUST submit a **'Technology and Innovative Excellence Plan'** containing a detailed description of the proposed overall solution, how the solution will fit into the contracting authority's organisational context, and the strategy for IT integration of the solution. The detailed information to be included can be found in Section 7 of this Technical Drawing	General	OBLIGATORY
RADAR-ATT-002	The supplier MUST describe the **'Operational Implementation Plan'**, including the strategy for integrating the solution. The detailed information to be included can be found in Section 7 of this Technical Document.	General	OBLIGATORY
RADAR-ATT-003	The supplier MUST describe an **'Impact Generation Plan'** to contribute to the clinical knowledge generation of the solution. Detailed information to be included can be found in Section 7 of this Technical Paper	General	OBLIGATORY
RADAR-ATT-004	The contractor MUST support the production of evidence during the implementation phase to support the contracting authority in conducting the experimental study approved in the research protocol and the monitoring team in supervision and coordination	General	OBLIGATORY
RADAR-ATT-005	The successful tenderer MUST follow the schedule for monitoring the RaDAR Innovative Procurement described in section 8 of this Technical Workbook, including the solution implementation phases, partial results, final results, milestones and the request for results to be submitted.	General	OBLIGATORY

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