Call for Applications for the Designation of an EU Reference Laboratory for Public Health in the field of Antimicrobial Resistance (AMR) in bacteria

Terms of Reference

Version 1.3
29 November 2023

Version	Publication Date	Change
1.0	02.10.2023	▪ Initial version.
1.1	13.10.2023	▪ Section 2.3: Correction of internal reference (from section 0 to 2.4.2) ▪ Section 2.3.1: Correction of internal reference (from section 2.2.2.1 to 2.3)
1.2	27.10.2023	▪ Section 2.4.1.1: Task 1: Clarification on total volume of isolates for testing
1.3	29.11.2023	▪ Submission deadline changed to 5 January 2024.

CALL FOR APPLICATIONS FOR THE DESIGNATION OF AN EU REFERENCE LABORATORY FOR PUBLIC HEALTH IN THE FIELD OF ANTIMICROBIAL RESISTANCE (AMR) IN BACTERIA

TABLE OF CONTENTS

LIST OF ACRONYMS

AMR	Antimicrobial Resistance
AST	Antimicrobial Susceptibility Testing
CCB	Coordinating Competent Body
CRAb	Carbapenem-resistant *Acinetobacter baumannii*
CCRE	Carbapenem- and/or colistin-resistant Enterobacterales
CRPa	Carbapenem-resistant *Pseudomonas aeruginosa*
dEQA	Digital EQA
DNCC	Disease Network Coordination Committee
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EQA	External Quality Assessment
EU	European Union
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EURL	EU Reference Laboratory
EVA	ECDC Virtual Academy
GDPR	General Data Protection Regulation
ISO	International Organization for Standardization
IVD	In vitro diagnostics
NFP	National Focal Point
OCP	Operational Contact Point
PT	Proficiency testing
SRM	ECDC's Stakeholder Relationship Management system
WGS	Whole Genome Sequencing
WHO	World Health Organization
WHO CC	World Health Organization Collaborating Centre

1 INTRODUCTION

1.1 PURPOSE

The purpose of this call for applications is for the European Commission to invite laboratories in the EU Member States and EEA countries to submit applications in view of their possible designation as EU reference laboratory (EURL) for public health in the field of Antimicrobial Resistance (AMR) in bacteria (except for AMR issues related to *Salmonella* spp., *Campylobacter* spp. and *Neisseria gonorrhoeae*), in accordance with Article 15 of Regulation (EU) 2022/2371 on serious cross-border threats to health, adopted on 23 November 2022 (1).

1.2 LEGAL FRAMEWORK

The legal basis for the EURLs for public health is set out primarily in Article 15 of Regulation 2022/2371 (1). The ECDC role for coordination of dedicated networks is described in Regulation 2022/2370 (2).

1.2.1 Activity areas and characteristics of the EURLs

EURLs in the area of public health should provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

Article 15(2) states that the EU reference laboratories shall be responsible for coordinating the network of national reference laboratories, in particular, in the following areas: (1)

(a) reference diagnostics, including test protocols;

(b) reference material resources;

(c) external quality assessments;

(d) scientific advice and technical assistance;

(e) collaboration and research;

(f) monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and

(g) training.

Article 15(3) states that the network of EU reference laboratories shall be operated and coordinated by the ECDC, in cooperation with the WHO reference laboratories. The governance structure of that network shall cover cooperation and coordination with existing national and regional reference laboratories and networks (1).

1.2.2 Designation of EURLs

In accordance with Article 15(1), the European Commission may, by means of implementing acts, designate EU reference laboratories in the area of public health or for specific areas of public health relevant for the implementation of Regulation 2022/2371 or of the national prevention, preparedness and response plans.

The designations provided shall follow a public selection process, be limited in time, with a minimum period for designation of four years, and be reviewed regularly (1).

1.3 GENERAL INFORMATION

The call is available in English only. English will be the working language for this call, and applications must be completed in English. If requested, supporting documents should as much as possible be provided in English, except where it would be unavailable, such as national accreditation certificates or other proof of competence in the form of certificates.

Submission of an application following this call implies acceptance by the applicant(s) and the endorsing national competent authority/-ies of all provisions and conditions stipulated in this call.

No reimbursement will be provided for any expenses incurred in the preparation and submission of applications under this call.

This call does not constitute an obligation on the European Commission to designate an EURL in this field.

2 SCOPE OF THE CALL

2.1 EURL TOPIC

The field in which the EURL for public health is to be selected under this call is Antimicrobial Resistance (AMR) in bacteria[1].

2.2 DESCRIPTION OF THE EURL AND RELEVANT DISEASE / LABORATORY NETWORK(S)

2.2.1 Description of the EURL

With the establishment of the EURL for public health in the field of AMR in bacteria, the European Commission aims to strengthen and support work in this field. The future EURL shall provide support to the members of the laboratory sub-networks of ECDC's European Antimicrobial Resistance Surveillance Network (EARS-Net) and the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) on issues related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

Both EARS-Net and EURGen-Net support the prevention and control of antimicrobial resistance among bacterial pathogens with particular importance to healthcare settings.

As Regulation 2022/2371 designates ECDC to coordinate the EURLs' work, the selected EURLs will be integrated into and form an integral part of ECDC's existing networks and structures. For the implementation of the activities under their agreed workplan, the EURL for AMR in bacteria shall have a coordination function for the laboratory sub-networks of EARS-Net and EURGen-Net consisting of the National Focal Points (NFPs) for AMR and the Operational Contact Points (OCPs) for Microbiology for the pathogens covered by EARS-Net and EURGen-Net.

The nomination of laboratory network members is done by the Coordinating Competent Bodies (CCBs) through the ECDC Stakeholder Relationship Management (SRM) system as part of ECDC's agreed process for managing the disease networks and Member State contacts (3).

Routine and emergency diagnostic and reference laboratory services are necessary to detect, identify, characterise, and type human pathogens of public health

[1] Except for AMR issues related to *Salmonella* spp., *Campylobacter* spp. and *Neisseria gonorrhoeae*

significance. Maintaining and developing this alert and response support capacity requires action at local, regional, national, and supranational levels.

Core functions of national microbiology reference laboratories for public health have been described by ECDC (4) and form the basis for EU work to monitor and support microbiology laboratory capacity in the fields of prevention of communicable diseases and the fight against AMR (5). Maintaining and building capacities, particularly in Member States where capacities are less well developed, is essential to support the implementation of effective action to combat AMR (1) (6) (7). In particular, there is a need for activities, which have the overall aim of raising standards and improving the quality of microbiology laboratory functions in the field of AMR throughout the EU, with a particular focus on support to Member States with less developed capacities through:

(a) building capacity of national AMR reference laboratory functions in all the key roles required for national reference laboratories in the field of AMR; and

(b) specific activities aimed at supporting the role of national reference laboratories, and associated structures to strengthen regional and local laboratory capacities in AMR within their countries; and

(c) specific activities aimed at enabling modernisation of diagnostic and molecular typing tests using whole genome sequencing (WGS) towards improved and more uniform standards of diagnosis and characterisation of AMR across the EU.

In so doing, the EURL shall complement but not duplicate any activities already implemented or planned by ECDC in this area, such as those carried out through EARS-Net and EURGen-Net.

2.2.2 Description of the relevant disease / laboratory network(s)

2.2.2.1 European Antimicrobial Resistance Surveillance Network (EARS-Net)

EARS-Net (8) is the largest publicly funded system for antimicrobial resistance surveillance in Europe. Data from EARS-Net play an important role in raising awareness at the political level, among public health officials, in the scientific community, and among the general public. The network has representatives from all EU/EEA countries reporting AMR surveillance data, which are stored in the European Surveillance Portal for infectious diseases (EpiPulse) (9) hosted by ECDC.

The objectives of EARS-Net are to collect comparable, representative and accurate AMR data; to analyse temporal and spatial trends of AMR in Europe; to provide timely AMR data for policy decisions; to encourage the implementation, maintenance and improvement of national AMR surveillance programmes; and to support national systems in their efforts to improve diagnostic accuracy by offering annual external quality assessments (EQAs). Data are based on routine antimicrobial susceptibility test results collected from a network of clinical laboratories. At present, the pathogens included in EARS-Net surveillance are *Acinetobacter* spp., *Enterococcus faecalis*, *Enterococcus faecium, Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Streptococcus pneumoniae*.

2.2.2.2 European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net)

EURGen-Net (10) is a network for genomic-based surveillance of healthcare-associated multidrug-resistant bacteria of public health importance coordinated by ECDC. National reference laboratories or equivalent expert laboratories currently

participate in EURGen-Net. They are located in 37 countries, including the 30 EU/EEA countries and seven EU candidate countries (Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, Serbia, and Türkiye). The public health objectives of the European WGS-based surveillance within EURGen-Net are to determine the geographic distribution and population dynamics of multidrug-resistant clones and transmissible resistance elements to inform risk assessment, prevention and control polices, and to support countries in developing their technical capability and proficiency for genomic-based surveillance of multidrug-resistant bacteria with epidemic potential.

The network started its activities in 2018 with cross-border outbreak investigations of carbapenem-resistant Enterobacterales (CRE) and related rapid risk assessments, and the Europe-wide structured survey of carbapenem- and/or colistin-resistant Enterobacterales (CCRE survey), which focused on carbapenem-resistant *K. pneumoniae* and *E. coli* (10). In 2022, the ECDC National Focal Points for AMR identified, through a prioritisation exercise, carbapenem-resistant *Acinetobacter baumannii* (CRAb) and carbapenem-resistant *P. aeruginosa* (CRPa) as two 'priority pathogens' for establishment of molecular surveillance within EURGen-Net. It is likely that additional healthcare-associated multidrug-resistant pathogens will be included within the EURGen-Net surveillance activities in the coming years.

Since 2021, laboratory capacity building activities for laboratories participating in EURGen-Net have been implemented within the European Antimicrobial Resistance Genes Reference Laboratory Capacity Building (EURGen-RefLabCap) project, funded by the European Commission (11).

2.3 SCENARIOS FOR EURL FOR PUBLIC HEALTH IN THE FIELD OF AMR IN BACTERIA

The applicant is requested to present proposed tasks and activities based on two different scenarios for the EURL for public health in the field of AMR in bacteria. **Please note that the scenarios as well as the funding amounts presented below are fictitious and presented for the purpose of this application procedure alone, and therefore do not constitute a commitment on the duration or amount of funding for the EURL designated under this procedure.**

For each scenario below, the applicant should present a workplan with short descriptions of the tasks and activities that they would execute under the scenario, considering the following requirements:

- The hypothetical workplan must include all the mandatory tasks described under section 2.4.1 below, as these tasks are all deemed essential for the EURL for public health in the field of AMR in bacteria.
- In addition to the mandatory tasks, an applicant's hypothetical workplan should also include descriptions of additional activities that the applicant deems to be the most important and useful for the laboratory network(s), whilst feasible for implementation under the scenario parameters.
    - Such additional activities may be more ambitious (e.g., with higher frequency or volume) versions of the mandatory tasks, or new activities proposed by the applicants. However, please note that all additional activities need to fall under one of the activity areas as described under section 1.2.1 above, or be a coordination and communication-related activity.
    - Some potential additional activities are provided in section 2.4.2 below.

- Justifications of the proposed added value of workplan tasks and explanations of task dependencies should be provided within the responses to the scenarios.

All activities and services provided by the EURL shall be free-of-charge for the laboratory network participants. This includes costs related to shipping of materials required for the implementation of EURL activities, both to and from the EURL. When required by the nature of the EURL activity, the EURL must also cover participants' costs for travel and accommodation.

The EURL is not requested to provide routine WGS services to the laboratory network members, as such support is already available through a WGS support contract operated by ECDC.

2.3.1 Fictitious Scenario 1

The applicant is requested to present a cohesive hypothetical workplan with brief descriptions of the tasks and activities that they could execute in a **two year period** with a total amount of **1,500,000 EUR** of funding available for that two year period, taking into account the general instructions included under section 2.3 above.

2.3.2 Fictitious Scenario 2

The applicant is requested to present a brief hypothetical description of the additional tasks and activities (i.e. in addition to the tasks and activities already included under the workplan for scenario 1) that they could execute under a **two year period** with a total amount of **2,000,000 EUR** of funding available for that two year period (in other words, 500,000 EUR more than in Scenario 1, for the same duration), taking into account the general instructions included under section 2.3 above.

The tasks and activities described under the workplan for scenario 2 should make a cohesive workplan together with the tasks and activities from scenario 1; however, tasks and activities described under the workplan for scenario 1 do not need to be described again under the workplan for scenario 2, unless they are changed or updated in a way that impacts on the scenario 2 workplan description.

2.4 TASKS AND ACTIVITIES OF THE EURL

2.4.1 Mandatory tasks for the EURL for public health in the field of AMR in bacteria

List of mandatory EURL tasks and activities

Task no	Task / Activity	Timing	Minimum volume over the two-year scenario period
Reference diagnostics, including test protocols			
1	Provision of phenotypic and functional reference testing including confirmation of resistance mechanisms (EURGen-Net)	Upon request	Testing of 1000 isolates per year, i.e., approx. 2000 isolates to be tested for the scenario period

Task no	Task / Activity	Timing	Minimum volume over the two-year scenario period
2	Provision of harmonised laboratory methods and protocols for diagnostic and characterisation purposes of priority pathogens, including guidance for specific standardised surveys and updates of guidance developed for the CCRE survey and under the EURGen-RefLabCap project (EURGen-Net)	Upon request	2 items /year, i.e., 4 items over the scenario period
Reference material resources			
3	Provision of (i) physical reference material to the laboratory network, including (ii) repository listing reference material resources (EURGen-Net)	(i) Upon request (ii) Quarterly updates	(i) 1 shipment / year to approx. 37 network laboratories (full network) i.e., 74 shipments over the scenario period (ii) Quarterly updates i.e., 8 updates over the scenario period
External quality assessments (EQAs)			
4	Conducting phenotypic AMR EQA for local clinical laboratories (EARS-Net)	Annually	EQA for approx. 1000 network laboratories per year i.e., 2 EQAs for approx. 2000 laboratories over the scenario period
5	Provision of phenotypic EQAs and genomic proficiency testing (PT) to the national reference laboratories (EURGen-Net)	Annually	EQA and PT combined for approx. 37 network laboratories per year i.e., 2 rounds of EQA and PT combined for approx. 74 laboratories over the scenario period
Scientific advice and technical assistance			
6	Assessment of laboratory capacity and development of plans for capacity strengthening (EURGen-Net)	Biennially	1 capacity survey report and 1 capacity building plan over the scenario period
7	Support to capacity building through bespoke consultations and advice, including remote or on-site visits as required (EURGen-Net)	Annually	At least 8 hours of support / country and year for 37 countries i.e., 16 hours of support / country over the scenario period covering 37 countries
Collaboration and research			

Task no	Task / Activity	Timing	Minimum volume over the two-year scenario period
8	Coordination of collaborative research studies within EURL mandate (EURGen-Net)	Upon request	1 report of a study over the scenario period
Monitoring, alert notifications and support in outbreak response			
9	Support to national surveillance as well as national and cross-border outbreak investigations (EURGen-Net)	Upon request	8 investigations over the scenario period
Training			
10	Provision of training workshops, webinars, simulation exercises and pilot surveillance exercises (virtual or on-site) (EURGen-Net)	Annually	At least 4 trainings (including 1 workshop) per year i.e., 8 trainings and 2 workshops over the scenario period
11	Conducting training, including tailored technology transfer for continued integration of WGS to national AMR surveillance and outbreak investigation (EURGen-Net)	Annually	At least 2 trainings involving 37 persons from EURGen-Net over the scenario period
Coordination and communication			
12	Coordination with (i) laboratory network members and (ii) ECDC	Continuous	(i) Continuous coordination with the network; (ii) Continuous coordination with ECDC (i.e., 24 teleconferences; 2 annual progress reports; participation in 2 ARHAI meetings over the scenario period)
13	Coordination with other EURLs or relevant initiatives	Continuous	1 meeting per network if necessary over the scenario period
14	Communication and dissemination	Continuous	At least 4 consultations over the scenario period
15	Organisation of laboratory network meetings	Biennially	1 physical meeting per network (EARS-Net and EURGen-Net) over the scenario period

Description of mandatory EURL tasks and activities

2.4.1.1 Reference diagnostics, including test protocols

Task 1 – Provision of phenotypic and functional reference testing, including confirmation of resistance mechanisms (EURGen-Net)

As part of national or EU-level outbreak investigations on priority pathogens and other emerging resistance threats, the EURL shall provide phenotypic and functional reference testing on selected isolates. A detailed testing strategy needs to be agreed with ECDC before the start of the laboratory activities. EURL may also need to interact and coordinate with the ECDC contractor for the strain collection to store isolates collected during outbreak or emerging resistance investigations. Related shipments to the strain collection should be executed and paid by the EURL. Indicative volumes of reference testing that will be requested are approximately 1000 isolates per year (2000 isolates per scenario period) that are to be tested in the following ways:

i. Phenotypic AST including disk diffusion and/or broth microdilution, according to the European Committee on Antimicrobial Susceptibility Testing (EUCAST) standard methods for antimicrobials listed in the CCRE survey protocol (12) as well as additional relevant antimicrobial substances as agreed with ECDC;

   AND

ii. Functional testing of isolates for drug resistance mechanisms, including methods specified in the 'EUCAST guidelines for the detection of resistance mechanisms and specific resistances of clinical and / or epidemiological importance v2.0' (or an updated version) (13).

Task 2 – Provision of harmonised laboratory methods and protocols for diagnostic and characterisation purposes of priority pathogens, including guidance for specific standardised surveys and updates of guidance developed for the CCRE survey and under the EURGen-RefLabCap project (EURGen-Net)

The EURL shall evaluate relevant methods for pathogen detection, phenotypic susceptibility testing and confirmation of resistance mechanisms currently used for priority pathogens in laboratories participating in EURGen-Net. The evaluation should also include new methodologies relevant for detection, phenotypic and genomic characterisation and surveillance of CCRE, CRAb, and CRPa to ECDC and EURGen-Net. The EURL shall review information on and test new bioinformatic tools as well as reference functional gene databases for the detection and prediction of resistance determinants and give recommendations regarding their use to identify the key genetic determinants for EU level surveillance.

The EURL shall update or develop protocols for species identification and characterisation for future surveys of CCRE, CRAb, and CRPa, that reflect current knowledge on phenotypic susceptibility testing and characterisation of carbapenemase production as well as genomic confirmation of AMR mechanisms. The EURL shall also develop similar protocols for phenotypic susceptibility testing and genomic detection of resistance mechanisms for other relevant antimicrobial substances for the CCRE, CRAb, and CRPa surveys.

The EURL shall identify and prepare guidance for common WGS-based genome analysis methods and standard protocols for national priority pathogen surveillance and integrated outbreak investigations for CCRE, CRAb, and CRPa. These activities

shall be carried out in close coordination with ECDC and taking into account ongoing EU and global research and development projects, EU case definitions (14), EUCAST guidance (13), recommendations from the CCRE study and existing guidance developed under the EURGen-RefLabCap project (15).

Over the scenario period it is expected that four protocols/guidance documents are delivered.

2.4.1.2 Reference material resources

Task 3 – Provision of (i) physical reference material to the laboratory network, including (ii) repository listing reference material resources

The EURL shall:

i. distribute physical reference strains to laboratories participating in EURGen-Net upon request (shipment costs to be covered by the EURL). The EURL shall distribute one shipment per year to approximately 37 network laboratories, i.e., distribution to a total of approximately 74 laboratories over the study period; and

ii. develop the electronic repository accessible to EURGen-Net members and ECDC containing

   a. guidance documents, protocols, training, and capacity building materials, internal quality control schemes (based on EUCAST guidelines and the latest relevant ISO standards (ISO 17025 (16), ISO 15189 (17), ISO 20776 (18)), lists of bioinformatics tools and similar; and

   b. catalogues of physical materials, such as reference strains of relevant pathogens with defined antimicrobial resistance phenotypes and genotypes.

   The EURL shall update the electronic repository quarterly, i.e., eight times over the scenario period.

2.4.1.3 External quality assessments

Task 4 – Conducting phenotypic AMR EQA of local clinical laboratories (EARS-Net)

The EURL shall plan, organise, execute, and conclude a phenotypic AMR EQA exercise of local clinical laboratories, including common pathogens reported to EARS-Net. The EQA exercise should follow the recommendations in the internationally recognised guidelines and the latest standards (i.e., ISO 15189 (17)). Up to a maximum of 1200 EARS-Net laboratories must be invited to participate in the EQA, and the EURL should run EQA exercise twice over the scenario period.

The EURL shall prepare a selected specimen panel, perform quality control and organise confirmatory testing. The EURL shall collect and compile the EQA results and provide individual feedback to participating laboratories. A survey shall be conducted to participating laboratories for collection of feedback and certificates of participation should be distributed to participants. A comprehensive EQA technical report for the EQA exercise including the multiannual cumulative report of several EQA exercises shall be produced.

The EURL must define the overall scope and a detailed plan for the EQA activities,

which should be in alignment with the ECDC Strategy for the external quality assessment of public health microbiology laboratories (19) and must be agreed with ECDC before implementation of the EQAs.

EQA participation may help laboratories to meet some of the requirements needed for national accreditation. Therefore, an applicant's ISO certification as EQA providers (e.g., ISO 17043 (20)), would be advantageous.

Task 5 – Provision of phenotypic EQAs and genomic proficiency testing (PT) to the national reference laboratories (EURGen-Net)

The EURL shall perform the EQA schemes/proficiency testing (PT) exercises for phenotypic and genomic testing of EURGen-Net priority pathogens (CCRE, CRAb, and CRPa). These EQAs/PT exercises should include phenotypic AST as well as an evaluation of national bioinformatics pipelines currently used for WGS-based AMR detection and preferentially performed on the same panel of strains.

The EURL shall select panels of bacterial strains performing quality control and organising confirmatory testing and then distribute the panels to the EURGen-Net laboratories. The EURL shall collect and analyse the EQA/PT results by producing and distributing individual feedback of the results to each participating laboratory. The EURL shall prepare and distribute the EQA/PT participant feedback survey, certificate of participation to the participating laboratories. A comprehensive report for the EQA/PT exercise including participant feedback after completion shall be drafted. The EURL shall perform two rounds of combined phenotypic EQA and genomic PT involving approximately 37 laboratories over the scenario period.

The EURL must define the overall scope and a detailed plan for the EQA activities, which should be in alignment with the ECDC Strategy for the external quality assessment of public health microbiology laboratories (19) and must be agreed with ECDC before implementation of the EQAs.

EQA participation may help laboratories to meet some of the requirements needed for national accreditation. Therefore, an applicant's ISO certification as EQA providers (e.g., ISO 17043 (20)), would be advantageous.

2.4.1.4 Scientific advice and technical assistance

Task 6 – Assessment of laboratory capacity and development of plans for capacity strengthening (EURGen-Net)

The EURL shall map current AMR phenotypic testing, molecular AMR prediction and strain typing methods used in the national reference laboratories for public health for each priority pathogen (CCRE, CRAb, and CRPa) for both national surveillance and integrated support to outbreak response of hospital or community outbreaks via a detailed laboratory capacity survey following previous published examples (21) (22). A summary report based on the results of the survey shall be produced to identify technical and analytical capacity gaps at national level. The report shall be used as basis for the development of laboratory capacity strengthening plans. The EURL shall produce one such report over the scenario period.

After the consultation of the EURGen-Net members as well as ECDC on the capacity survey report, a capacity building plan shall be produced and implemented. Subsequently, the EURL shall evaluate the implementation of the activities and discuss the results with the network members. Based on the received feedback, the activities shall be adjusted and refined. The EURL shall draft one report as well as produce and update one plan for national laboratory capacity strengthening over the

scenario period.

Task 7 – Support to capacity building through bespoke consultations and advice, including remote or on-site visits as required (EURGen-Net)

The EURL shall implement the action plan described in task 6 for each country to strengthen national reference laboratory capacities. On the basis of the action plans and the identified needs for capacity building, the EURL shall provide tailored technical support to each country's national reference laboratories for public health (at least eight hours annual support per country and year) to strengthen and build capacities, including piloting of pathogen specific AMR genomic surveillance and outbreak investigations for priority pathogens. Tailored operational support (based on the identified gaps/needs) shall include the provision of access to reference material, bioinformatics software to initiate national genomic surveillance studies in countries with limited levels of capability/capacity to investigate outbreaks of priority pathogens. Over the scenario period the EURL shall provide 16 hours of support to each EURGen-Net laboratory.

2.4.1.5 Collaboration and research

Task 8 – Coordination of collaborative research studies within EURL mandate (EURGen-Net)

The EURL shall select new/not sufficiently evaluated methods for phenotypic susceptibility testing or genomic resistance detection or bioinformatic tools for joint evaluation in EURGen-Net laboratories using a suitable panel of phenotypically susceptible/resistant strains with defined resistance mechanisms. A protocol for laboratory testing of these methods in comparison to the agreed expert standard protocol shall be written and data from all participating laboratories shall be collected into one database. Statistical analysis of the data shall be performed and a report or manuscript for publication in a peer-reviewed open access journal shall be prepared (to be discussed with ECDC). The EURL shall deliver a report from one study over the scenario period.

2.4.1.6 Monitoring, alert notifications and support in outbreak response

Task 9 – Support to national surveillance as well as national and cross-border outbreak investigations (EURGen-Net)

The EURL shall provide ad hoc advice and reference testing for phenotypic and genomic methods required for national outbreak investigations and cross-border investigations for emerging resistance related to priority pathogens. Additionally, the EURL shall assist EURGen-Net laboratories with related microbiological and bioinformatic data analysis and support operational contact points with reporting relevant data on national or potential cross-border outbreaks to EpiPulse. Furthermore, the EURL shall provide advice to national reference laboratories regarding analysis and reporting of molecular surveillance data for monitoring of priority pathogens.

In case of a confirmed multi-country outbreak or other unusual event, the EURL will be asked to provide information, guidance and/or support to ECDC on microbiology-related matters relevant to the outbreak / event. The EURL shall, upon request, contribute to ECDC risk assessments in scope of the EURL. The requests may consist of preparing sections of these documents related to the pathogen properties and its detection and characterisation. The EURL contribution will be acknowledged in the documents produced; however, ECDC will be responsible for the final content of the document. Depending on the urgency for ECDC to produce the document, the EURL

may be required to provide its contribution within 24 hours (one working day). Approximately four requests for support in outbreak investigations are estimated per year, i.e., approximately eight requests over the scenario period.

Under this task the EURL may be requested by ECDC to contribute to presentations to the Health Security Committee and/or the Advisory Committee on Public Health meetings convened and coordinated by the European Commission, in coordination with ECDC.

2.4.1.7 Training

All training activities should be aligned with and fall under the overall training programme on prevention, preparedness, and response to serious cross-border health threats, that is currently developed to implement Article 11 of the Regulation 2022/2371 (1).

Task 10 – Provision of training workshops, webinars, simulation exercises and pilot surveillance exercises (virtual or on-site) (EURGen-Net)

The EURL shall train at least one participant from each national expert / reference laboratory (one per country) on the agreed expert consensus protocols. An agenda for the training outlining all topics to be covered prior to the training workshop shall be provided. A virtual or on-site workshop shall be organised and training materials as well as a summary of the training workshop shall be provided to all participants and ECDC. An evaluation of satisfaction of participants with this training workshop shall be carried out at the end of the workshop. Over the scenario period, eight training activities (including two workshops) should be organised involving 37 persons from EURGen-Net.

Task 11 – Conducting training, including tailored technology transfer for continued integration of WGS to national AMR surveillance and outbreak investigation (EURGen-Net)

The EURL shall develop and execute multidisciplinary training activities complementary with ongoing EU training programmes to disseminate skills across EU/EEA countries in applying standard microbiological (phenotypic), genomic and epidemiological methods for priority pathogen genomic surveillance and outbreak investigations using data generated during national and EU-level outbreak investigations ongoing at that time. Training activities may be delivered through face-to-face workshops or webinars or blended learning methods and may involve the laboratories of all participating 37 countries or a subset of laboratories with specific training needs. Over the scenario period, at least two training activities should be organised.

The training should include especially (but not exclusively) the areas of standard epidemiological data analysis and visualization, strategies for selection of isolates warranting further testing including WGS, identification of outbreaks in endemic settings, integrated epidemiological and genomic data analysis and visualization, choice of appropriate bioinformatic tools as well as communication and reporting to policy makers and the public. The training should also for example include analysis sessions on national data part of larger EU-surveys, discussion sessions on how to address findings from the EURGen-Net phenotypic EQAs and genomic PT for quality improvement and training on specific bioinformatic tools.

Additionally, the EURL shall propose other training activities, such as webinars on interesting research findings and ongoing parallel international initiatives with respective invited speakers and on examples of good practice and relevant results

from NRLs participating in the network, video and audio conference and online training resources in English, disseminated through the repository, including outbreak exercises as required.

2.4.1.8 Coordination and communication

Task 12 – Coordination of activities with laboratory network members and ECDC

The EURL is expected to be an integral part of the disease and/or laboratory network(s) that are under the overall coordination by ECDC. The EURL will have a coordination function with network members with regards to the implementation of the activities under its agreed work plan and should interact independently with the laboratory network members to carry out this work. Where applicable, EURL representatives will be invited to participate as observers in the ECDC Disease Network Coordination Committee (DNCC) meetings of the laboratory network(s) that they are supporting. ECDC will also provide the EURL with the relevant contact information for the laboratory network(s) members from the ECDC Stakeholder Relationship Management (SRM) system. Appropriate GDPR-compliant measures must be put in place by the EURL to ensure adequate data protection for this personal data.

The EURL must coordinate the implementation of their tasks with ECDC to ensure alignment with other relevant activities coordinated by ECDC. This coordination should be done through regular coordination meetings, participation in meetings and events on relevant topics etc. Within their application, the applicant is expected to present their plan for how this coordination would be best organised.

Task 13 – Coordination with other EURLs or relevant initiatives

Overlap and redundancy in activities between EURL and other laboratory support activities at supra-national level in the EU/EEA should be avoided whenever possible. The EURL will therefore be required to, in consultation with ECDC, exchange information and (where relevant) coordinate activities with other bodies carrying out work in similar areas. These bodies include the EUCAST Development Laboratory, other public health EURLs supporting the same networks, EURLs for food, feed and animal health (i.e., EU Reference Laboratory – Antimicrobial Resistance in bacteria of animal origin) or in vitro diagnostics (IVD) addressing the AMR issues, the Global Antimicrobial Resistance and Use Surveillance System, the Central Asian and European Surveillance of Antimicrobial Resistance network, WHO Collaborating Centres (WHO CCs; i.e., WHO Collaborating Centre for Surveillance of Antimicrobial Resistance; WHO Collaborating Centre for Antimicrobial Resistance Epidemiology and Surveillance; WHO Collaborating Centre for Antimicrobial Resistance, Consumption and Health Care-Associated Infections; WHO Collaborating Centre for Antimicrobial Resistance Containment), and other relevant projects/initiatives.

Task 14 – Communication and dissemination

The EURL must communicate on a regular basis with the members of the laboratory network(s) that they are supporting, to inform the network members of their work and planned EURL activities, and get feedback on the EURL activities.

The exact nature, frequency and mode(s) of communication depends on the planned activities, and the applicant is expected to present a plan for their communication and dissemination activities within their application. Within this plan, applicants should also consider what communication with other relevant stakeholders would be beneficial to the successful execution of their activities.

In serious outbreak situations, in particular if several EU/EEA countries are involved or an EU public health emergency is declared, the EURL may be requested by ECDC to support ECDC and the European Commission on risk communication.

Task 15 – Organisation of laboratory network meetings

The EURL must plan for the organisation of one face-to-face network meeting per laboratory network within the scenario period (one meeting for EARS-Net and one meeting for EURGen-Net). Invited participants must include at least one representative from each country that participate in the networks, as well as invited speakers (if applicable) and relevant ECDC contact points.

The network meetings should enhance networking activities and collaboration between laboratories, discuss achievements and results, review upcoming tasks and allow network members to provide feedback on these, and/or the exchange of scientific and technical expertise on relevant selected topics. Agendas for the network meetings shall be prepared by the EURL, and the EURL shall also prepare meeting minutes and share presentations and minutes with all participants.

Should full disease network meetings be organised by ECDC during the EURL's designation period, the EURL will be expected to contribute to content and agenda of these meetings but will not have operational meeting organisation responsibility. By agreement with ECDC it may be possible to organise EURL laboratory network meetings back-to-back or even incorporated into these full disease network meetings.

2.4.2 Potential additional activities for the EURL for public health in the field of AMR in bacteria

The following activities are not mandatory to be covered in the application, but should serve as an inspiration for the applicant to use or develop further activities in their application.

Conduct ad hoc surveys (EARS-Net and EURGen-Net)

The applicant may consider performing surveys in the form of electronic questionnaires on a secure platform, administer the survey to clinical laboratories participating in EARS-Net or national reference or expert laboratories participating in EURGen-Net and compile as well as report the results to ECDC. If implemented, the content of the surveys should be developed by the applicant in collaboration with ECDC, and other relevant organisations indicated by ECDC, such as ESCMID (e.g., EUCAST, ESGARS) or WHO. The technical report of such surveys should include the methods used, the results from the survey, and interpretation of the results.

Development and implementation of an online tool for interpretation of raw phenotypic AMR data, often referred to as 'digital EQA' or dEQA (EARS-Net)

The applicant may consider developing and annually updating an online dEQA tool regarding species identification and/or phenotypic AST of the most common bacterial pathogens for human health in the EU/EEA, including the eight species under surveillance in EARS-Net. In the first dEQA, the technical content could assess whether participants correctly apply current EUCAST guidance and recommendations (23), including AST methodology and implementation, and the interpretation of AST results.

For subsequent updates of the dEQA, the EURL can include content to educate participating laboratories in their ability to correctly process scenarios that are known to be difficult for EU/EEA clinical laboratories; develop a methodology to define 'best

practice' for aspects of phenotypic AST and educate participating laboratories in that 'best practice' through an update of the dEQA tool. The analysed results of dEQA could be compiled in reports providing laboratory-level feedback, national-level feedback, and results of the whole dEQA exercise.

Organisation of additional[2] meetings on topics under EURL remit

An applicant could, where deemed necessary and appropriate, plan for the organisation of additional meetings on specific topics for laboratory network members. While ECDC should be kept informed of all such plans, the EURL would be expected to organise and execute such meetings independently.

2.5 USE AND PUBLICATION OF DATA AND RESULTS

Beyond the contractually agreed reports and deliverables of the EURL, the use of data or data analysis results obtained or made by the EURL in their role as an EURL shall require written agreement by the laboratories that generated and/or shared the data, and by ECDC, prior to publication. Such publications may include peer-reviewed manuscripts, and/or disclosure of information to third parties.

Manuscripts for submission to relevant peer review scientific journals shall follow the ECDC authorship policy according to the guiding principles described in the ECDC authorship policy (24) and the Internal Policy on open access publication of scientific content, including articles submitted to peer review journals (25).

2.6 DESIGNATION PERIOD

The EURL for public health in the field of AMR in bacteria will be designated for a period of seven (7) years. However, should the designated EURL fail to meet their obligations, the European Commission may proceed to de-designate the EURL before the end of the designation period.

2.7 ELIGIBILITY CRITERIA

Laboratories to be designated as an EURL for public health must meet all of the eligibility criteria listed below. For consortium applications (see section 4.1.4 below), each individual laboratory within the consortium must meet all of the eligibility criteria.

Eligible candidate laboratories must:

- Be based in an EU Member State or an EEA country
- Play an active role in a national public health microbiology system

In addition, the designated EURLs shall meet the requirements specified in Article 15(5) of Regulation 2022/2371:

(a) be impartial, free from any conflict of interest, and, in particular, not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;

(b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;

(c) possess, or have access to, the infrastructure, equipment and products

[2] I.e. in addition to the mandatory laboratory network meeting task described under section 2.4.1

necessary to carry out the tasks assigned to them;

(d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices, and that the latest developments in research at national, Union and international levels are taken into account in their work;

(e) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and

(f) where relevant, be equipped to comply with relevant biosecurity standards.

Clarifications on these requirements:

Regarding requirement (a): The aim is to ensure that the designated EURLs do not have any relevant conflict of interest which may affect the impartiality of their professional conduct or commitment as regards the exercise of their tasks as EURL. Such conflicts of interest may exist due to reasons involving economic interest, political affinity, family or any other shared interest. While some conflicts of interest are direct, applicants should also consider any other situation that could cast doubt on their ability to perform the EURL tasks impartially, or that could reasonably appear to do so in the eyes of an outside third party.

Applicants are required to self-assess what relevant conflicts of interest may exist for them with regards to the required tasks of each EURL and document this assessment in the application. Should applicants find that such potential conflicts of interest exist, they are requested to declare these in the application form for further assessment by the evaluation panel.

Regarding requirements (b) and (c): While outsourcing of minor parts of activities is not excluded, applicants are expected to carry out the main elements of the EURL activities within their own organisations.

Regarding requirement (d): It is up to each national competent authority to determine what international standards and practices are relevant for the requested work of the EURL, and to ensure that the applicant appropriately meets these standards.

Regarding requirement (f): It is up to each national competent authority to determine what biosecurity standards are relevant for the requested work of the EURL, and to ensure that the applicant appropriately meets these standards.

2.8 SELECTION CRITERIA

The selection criteria are intended to allow evaluating the scientific excellence of the applicant, as well as applicant's ability and capacity to perform the role of an EURL for public health in the field of AMR in bacteria. Up to 100 points may be awarded for the four criteria below. There is a threshold of 60% for each individual criterion in order to pass the selection criteria.

Submission of supporting documents for the selection criteria is not necessary at the application stage. Applicants may however be requested to submit this additional documentation at a later stage.

Criterion	Sub-criteria	Max points (pass threshold)
Understanding of the EURL purpose and role	**Purpose** – This sub-criterion assesses the extent to which the applicant demonstrates an appropriate understanding of the purpose of laboratory support activities within the EU-level public health landscape **Role** – This sub-criterion assesses the extent to which the applicant appropriately identifies and describes the role of the EURL with regards to the relevant stakeholders at the EU and national level public health systems	**15 (9)**
Quality of the proposed activities and impact	**Quality of the workplans –** This sub-criterion assesses the quality and appropriateness of the applicant's proposed workplans, i.e. the scope and ambition of the workplans, the relevance and pertinence of the included activities, the quality and appropriateness of the proposed methods for carrying out the tasks and actions, and the logic and cohesion of each workplan as a whole **Organisation of the work –** This sub-criterion assesses the overall organisation of the work, i.e. overall planning (including, where relevant, within the consortium), and risk identification and mitigation **Impact** – This sub-criterion assesses potential impact of the applicant's proposed activities, i.e. how EU-level public health as well as the different stakeholders would benefit from the proposed activities	**45 (27)**
Team composition, knowledge and experience	**Scientific and technical qualifications and experience** – This sub-criterion assesses the degree to which the applicant demonstrates that their team possesses the scientific and technical qualifications required for carrying out the proposed activities, including any relevant experience of carrying out similar work **Team composition and resource availability** – This sub-criterion assesses the degree to which the applicant demonstrates that organization of the team will allow the use of the appropriate resources (including equipment and infrastructure) to deliver the proposed activities as planned	**25 (15)**
Coordination capacity	**Coordination with the members of laboratory network(s)** – This sub-criterion assesses the quality and appropriateness of the applicant's approach and plan for the coordination with the members of the laboratory network(s) **Coordination with ECDC** – This sub-criterion will assess the quality and appropriateness of the applicant's approach and plan for the coordination with ECDC	**15 (9)**
Total maximum points		**100 (60)**

3 TIMETABLE AND DEADLINES

Timetable and deadlines (indicative)	
Call publication:	2 October 2023
Deadline for submission of applications:	5 January 2024 17:00 CET
Evaluation:	January 2024
Information on evaluation results:	January - February 2024

4 APPLICATION, EVALUATION, DESIGNATION AND FUNDING PROCEDURES

4.1 APPLICATION PROCEDURE

4.1.1 Publication of call for applications

The call for application is published by the European Commission on its website and advertised via social media. ECDC will equally promote the call via social media.

4.1.2 Preparation of EURL application

An applicant to the call may be a single laboratory or a consortium of laboratories. However, please note that a laboratory may only apply to each topic once, i.e. either as a single laboratory applicant or as a member of a consortium applicant. For information specifically related to consortium applicants, please see section 4.1.4 below.

Applicants must complete the application form in EUSurvey, including the Technical Description whose template is found under Annex III. Please note that some sections of the application form have page limits, and that any application texts exceeding these page limits will be disregarded.

In their applications, applicants must include the relevant information to demonstrate how well they meet the selection criteria described under section 2.8 above. Please see Annex III for more detailed instructions on filling out the Technical Description.

4.1.3 Endorsement of candidate laboratories by national competent authorities

All applicants, whether they are single laboratories applying separately or members of a consortium applying jointly, must be endorsed by a national competent authority. The ECDC Coordinating Competent Bodies (CCBs) (26), that have already been nominated by Member States as national competent authorities in public health, are proposed as the main competent authorities for endorsement of applicants. However, other authorities such as the Ministry of Health can also endorse applicants, if the country so decides. In certain cases, further documentation may be required regarding the endorsing body's position as a national competent authority in public health (to be assessed on a case-by-case basis).

Prior to endorsing an applicant, each national competent authority is required to confirm that the applicant meets the eligibility criteria of the call. It is up to each

national competent authority to determine if, and if so what, supporting documentation they may require from applicants in this process.

To endorse an applicant, the national competent authority fills out and signs the endorsement form found in Annex I. The signed endorsement form is then attached to the application by the applicant. Please see Annex I for more detailed instructions on filling out the endorsement form.

A national competent authority may endorse more than one applicant per topic, provided that each applicant meets the eligibility criteria set out in section 2.7 above.

4.1.4 Modalities relevant to EURL applications by a consortium

4.1.4.1 General

For the purpose of this call, a "consortium" is defined as "between two and five eligible entities in one or more EU Member States and/or EEA countries working together to perform the tasks of the EURL for public health in the field of AMR in bacteria". Each consortium must designate a coordinator that is submitting the proposal on behalf of the consortium.

If designated, the consortium members will be jointly and severally liable for carrying out the tasks of the EURL. If one consortium member were to fail to implement its part of the tasks, the other members would become responsible for implementing this part. The application of a consortium must be accompanied by (an) agreement letter(s) regarding the joint and several liability and the authorisation for the coordinator to submit the application on behalf of the consortium and represent the consortium during the application and evaluation phases of the selection procedure. This is done by each non-coordinator consortium member filling out and submitting a copy of the letter found in Annex II together with the rest of the application documents.

The coordinator will be the administrative contact point of the consortium and the sole contact point for the European Commission. Depending on the areas of responsibility within the consortium, ECDC may make direct contacts with other consortium members on scientific and/or technical matters, in particular in outbreak situations.

Each member of the applicant consortium has to meet the eligibility criteria, and be endorsed by their respective national competent authorities (see sections 2.7 and 4.1.3 above). Consortium applications must therefore include the same number of endorsement form as there are total members of the consortium (including the coordinator).

The consortium as a whole must cover the all the tasks of the EURL, and the work programme of the consortium must contain a demonstration of coherence and complementarity within the consortium members including division of tasks and responsibilities and the exchange of knowledge.

A single, jointly elaborated, application must be submitted for a consortium, and the application must be submitted by the coordinator on behalf of all the consortium members.

4.1.4.2 Finding consortium partners

While it is assumed that some consortia may be formed directly between laboratories on the basis of previous or existing collaborations, ECDC will operate a service to put laboratories in contact with other laboratories potentially interested forming a

consortium and submitting an EURL application in a specific field.

Eligible laboratories interested in this service should send an email to ECDC using the contact email address specified under section 5 below, indicating the following:

- The call ID and EURL field
- Laboratory name and contact details (name, email address and phone number) of the main contact person

ECDC will then place this information on a restricted access website (or similar) that is only accessible to the laboratories that have expressed an interest in finding partners for a consortium application in the same field. Laboratories will receive separate emails informing them on how to access this information.

4.1.5 Submission of EURL application

Applications are submitted through EUSurvey, and the link to the application form for the EURL for public health in the field of Antimicrobial Resistance (AMR) in bacteria is:

https://ec.europa.eu/eusurvey/runner/Call_for_Applications_EU_Reference_Laboratory_for_Public_Health_AMR_in_bacteria

The password for accessing the application form is "EURL2023".

Certain application information, such as administrative information about the applicant and information about potential conflicts of interest, must be entered directly in the application form in EUSurvey, whereas other information is entered into the different application templates and, when completed, uploaded to EUSurvey as files.

Applications will only be considered as complete if all sections of the application form in EUSurvey have been filled out, all required files have been successfully uploaded, and the application has been successfully submitted in EUSurvey by the main contact person of the single lab / consortium applicant before the application submission deadline specified under section 1 above. Applicants are strongly encouraged not to wait until deadline day with their submissions in order to ensure minimise the risk of submission issues.

No modification to the application is allowed once the application has been submitted in EUSurvey or after the deadline for submission has passed. However, if there is a need to clarify clerical or obvious errors, such as the uploading of the wrong file etc, the applicant may be contacted during the evaluation procedure.

4.2 EVALUATION PROCEDURE

The evaluation panel consists of the European Commission staff members, ECDC staff members as well as of independent, external experts.

The evaluation panel confirms the eligibility of the applicants, as well as evaluates each application against the selection criteria set out in section 2.8 above. For each application an application evaluation report is drawn up, which includes the scores given on the selection criteria as well as comments made by the evaluation panel.

The successful applicant is the eligible applicant whose application is awarded individual criterion scores that exceed all pass thresholds for the selection criteria <u>and</u> is awarded the highest total score against the selection criteria out of all the applications evaluated in this field. Where

relevant, successful applicants may also be requested to demonstrate that they have the capacity to carry out all their activities across all EURL fields for which their applications have been successful.

Each applicant will receive their application evaluation report together with an evaluation result letter with information on whether their application has been successful or unsuccessful. If an applicant believes that the evaluation procedure is flawed, they may submit a complaint following the deadlines and procedures set out in the evaluation result letter.

4.3 DESIGNATION OF EURL

Once the evaluation is concluded, ECDC will notify the European Commission of the outcome of the evaluation and propose that the successful applicant is designated as an EURL for public health in the field of the call. The European Commission will further proceed with the designation of the EURL following the procedure for an implementing act, i.e. a secondary legislation following a Regulation.

4.4 FINANCIAL SUPPORT FOR EURL ACTIVITIES

The EURL selected through this call and then designated through an implementing act, will be able to apply for a grant under the EU4Health 2023 work programme, topic CP-g-23-05-01 (27).

Designated EURLs will be invited to apply for funding when their designation through the implementing act has been processed by the European Commission. A specific call for proposals will be prepared for this purpose.

5 CONTACTS AND FURTHER INFORMATION

All contacts on this call should be made in writing only, to the following email address:

EURL-PH@ecdc.europa.eu

with "EURL-PH-2023-01" in the subject line.

Applicants are particularly requested not to discuss or seek to elicit any further information on this procedure through contacts that they may need to have with European Commission or ECDC staff on matters other than EURLs for public health during the call application and evaluation period.

All questions received to the above e-mail address for which answers are provided that are of interest to all possible applicants will be published as a Q&A on the website below:

https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en

Once the information has been published on this website, it is considered to have been made available to all applicants. It is the responsibility of the applicants to regularly check and review the Q&A to use the information there during the preparation of their application.

6 REFERENCES

1. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23

November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. [Online] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371.
2. Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control. [Online] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R2370.
3. Coordinating Competent Bodies: structures, interactions and terms of reference, 1 January 2020. [Online] https://www.ecdc.europa.eu/sites/default/files/documents/Coordinating-Competent-Bodies-Structures-Terms-of-reference-and-interactions_2023.pdf.
4. Core functions of microbiology reference laboratories for communicable diseases. [Online] https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf.
5. EU Laboratory Capability Monitoring System (EULabCap) - Report on 2016 survey of EU/EEA country capabilities and capacities. [Online] https://www.ecdc.europa.eu/sites/default/files/documents/2016_EULabCap_EUreport_web_300418_final.pdf.
6. Communication from the Commission to the Council and the European Parliament (COM/2017/0339) A European One Health Action Plan against Antimicrobial Resistance (AMR). [Online] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52017DC0339.
7. Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01. [Online] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023H0622%2801%29.
8. European Antimicrobial Resistance Surveillance Network (EARS-Net). [Online] https://www.ecdc.europa.eu/en/about-us/networks/disease-networks-and-laboratory-networks/ears-net-data.
9. EpiPulse - the European surveillance portal for infectious diseases. [Online] https://www.ecdc.europa.eu/en/publications-data/epipulse-european-surveillance-portal-infectious-diseases.
10. European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net). [Online] https://www.ecdc.europa.eu/en/about-us/who-we-work/disease-and-laboratory-networks/EURGen-net.
11. European Antimicrobial Resistance Genes Reference Laboratory Capacity Building project. [Online] https://www.eurgen-reflabcap.eu/.
12. ECDC study protocol for genomic-based surveillance of carbapenem-resistant and/or colistin-resistant *Enterobacteriaceae* at the EU level. [Online] https://www.ecdc.europa.eu/en/publications-data/ecdc-study-protocol-genomic-based-surveillance-carbapenem-resistant-andor.
13. EUCAST guideline for the detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance. [Online] https://www.eucast.org/resistance_mechanisms.
14. Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological. [Online] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945.
15. European Antimicrobial Resistance Genes Reference Laboratory Capacity Building project protocols and guidance. [Online] https://www.eurgen-reflabcap.eu/resources/protocols-and-guidelines.
16. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. [Online] https://www.iso.org/standard/66912.html.
17. ISO 15189:2022 Medical laboratories — Requirements for quality and competence. [Online] https://www.iso.org/standard/76677.html.

18. ISO 20776-1:2019 Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1. [Online] https://www.iso.org/standard/70464.html.
19. ECDC strategy for the external quality assessment of public health microbiology laboratories. [Online] https://www.ecdc.europa.eu/en/publications-data/strategy-external-quality-assessment-public-health-microbiology-laboratories.
20. ISO/IEC 17043:2023 Conformity assessment — General requirements for the competence of proficiency testing providers. [Online] https://www.iso.org/standard/80864.html.
21. Worsening epidemiological situation of carbapenemase-producing *Enterobacteriaceae* in Europe, assessment by national experts from 37 countries, July 2018. Brolund, Alma, et al.: Eurosurveillance, 2019, Vol. 24.
22. Epidemiological situation, laboratory capacity and preparedness for carbapenem-resistant *Acinetobacter baumannii* in Europe, 2019. Lötsch, Felix, et al.: Eurosurveillance, 2020, Vol. 25.
23. EUCAST antimicrobial susceptibility testing. [Online] https://www.eucast.org/ast_of_bacteria.
24. Internal Policy on authorship and acknowledgement of contribution to scientific work and related outputs – ECDC/IP/104. [Online] https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-authorship-internal-policy.pdf.
25. ECDC policy on open access publication of scientific content, including articles submitted to peer review journals. [Online] https://www.ecdc.europa.eu/en/publications-data/ecdc-policy-open-access-publication-scientific-content-including-articles.
26. List of ECDC Coordinating Competent Bodies. [Online] https://www.ecdc.europa.eu/en/about-ecdc/who-we-are/governance/competent-bodies.
27. EU4Health 2023 Work Programme. [Online] https://health.ec.europa.eu/publications/2023-eu4health-work-programme_en.

ANNEX I: TEMPLATE FOR LETTER OF ENDORSEMENT

Template for letter of endorsement

[Header:]

[Name of institution e.g. national competent authority]

[Date]

[Addressee (i.e. the applicant)]

This letter of endorsement is provided to the above-mentioned addressee (i.e. applicant) in accordance with the requirements of the "Call for applications for designation of an EU Reference Laboratory (EURL) for public health in the field of AMR in bacteria" (ref: EURL-PH-2023-01), hereafter referred to as "the Invitation".

I, undersigned, as representative of the national competent authority [name of national competent authority] of [name of country], confirm endorsement of the applicant [name of the applicant] submitting an application for EURL for public health in the field of AMR in bacteria.

By ticking the boxes below, I specifically confirm that the applicant:

☐ Is based in an EU Member State or an EEA country

☐ Plays an active role in a national public health microbiology system

☐ Is impartial, free from any conflict of interest, and, in particular, not in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as an EU reference laboratory;

☐ Has, or has contractual access to, suitably qualified staff with adequate training in their area of competence;

☐ Possesses, or has access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;

☐ Ensures that their staff and any contractually engaged staff have good knowledge of international standards and practices, and that the latest developments in research at national, Union and international levels are taken into account in their work;

☐ Is equipped, or has access to, the necessary equipment to perform their tasks in emergency situations; and

☐ Where relevant, is equipped to comply with relevant biosecurity standards.

[Signature, name(s) and function(s) of signatory, name of national competent authority represented]

ANNEX II: TEMPLATE FOR AUTHORISATION OF COORDINATOR BY BENEFICIARY, AND CONFIRMATION OF JOINT AND SEVERAL LIABILITY FOR THE EXECUTION OF THE TASKS

For consortium applications, one copy of this form must be filled out by **all members of the consortium that are not identified as the Coordinator**.

These authorisations should be signed by the respective contact persons of the beneficiaries as identified under Part A section 1.2.

[Header]

[Name of institution]

[Date]

This is provided in accordance with the requirements of the "Call for applications for designation of an EU Reference Laboratory (EURL) for public health in the field of AMR in bacteria (ref: EURL-PH-2023-01)", hereafter referred to as "the Invitation".

I, undersigned, hereby authorise [coordinator organisation full name], as represented by [name of coordinator main contact person] and hereafter referred to as "the Coordinator", to submit an application with my organisation as one of the beneficiaries. I also mandate the Coordinator to represent my organisation in contacts with the European Commission and/or ECDC on issues directly related to the above-mentioned application during the application and evaluation processes.

In addition, I confirm my understanding and acceptance that, should our application be successful, my organisation and the other members of the consortium (including the Coordinator) will be jointly and severally liable for the technical implementation of the tasks of the EURL.

[Signature, Date, Name and function(s), Institution represented]

ANNEX III: TEMPLATE FOR TECHNICAL DESCRIPTION

Technical Description

Annex III to the Call for applications for the Designation of an EU Reference Laboratory for Public Health

GENERAL INSTRUCTIONS AND GUIDELINES

Please follow the structure of this template when preparing your Technical Description. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the evaluators to make an effective assessment of your application against the selection criteria. Please read carefully also the guidance provided for each section on the information expected within that section.

Please be aware that applications will be evaluated as they were submitted, rather than on their potential if certain additions / changes were to be made. This means that only applications that successfully address all the required aspects will have a chance of being successful.

⚠ *Applicants should take note of the page limits for each section, and strike the right balance between necessary detail and conciseness. Excess pages will be disregarded.*

⚠ *Fill in the template with text in black font colour of minimum font size 12.*

⚠ *When referring to the applicant organisation(s), please use the same organisation name(s) and acronym(s) as in the Administrative Information sections in EUSurvey.*

⚠ *Please read carefully all the documents and instructions provided.*

⚠ *These guidelines and all text in <blue>* in the subsequent sections *are instructions on how to use the template.* ***Please ensure that you delete this section and all text in <blue> from the final document prior to submission****.*

Application for the designation of an EURL for public health in the field of Antimicrobial Resistance (AMR) in bacteria (ref: EURL-PH-2023-01)

Applicant / Coordinator: <organisation name of single laboratory applicant or coordinator of consortium applicant>

1. PURPOSE AND ROLE OF THE EURL

<Describe your vision for the purpose and role of the EURL, in line with the requirements of the call.

This description should include a description of the EU-level public health landscape that the EURL will operate within, and how EURL fits in within it.

This section is limited to maximum two pages of text. Excess pages will be disregarded.>

[Your text here…]

2. COMPLEMENTARITY WITH OTHER ACTIONS — EUROPEAN ADDED VALUE

<Illustrate the EU added value of the proposed activities, and explain how the proposed activities are complementary to other supra-national activities carried out by other organisations, in particular relevant EURLs for food, feed and animal health and/or for in vitro diagnostics (IVD); relevant World Health Organization (WHO) Collaborating Centres (CCs) etc.

It is expected that applicants address the relevant organisations identified in the calls for applications, but applicants should also include additional activities / organisations as they find appropriate.

This section is limited to maximum two pages in total. Excess pages will be disregarded.>

[Your text here…]

3. SCENARIO WORKPLANS

<This section must describe the proposed workplans of the EURL in response to each of the two scenarios described in the call for applications, i.e. the tasks and activities that the applicant would implement as EURL over a two year period if the amount of funding specified in each scenario was made available.

Each workplan should include the following components:

- *An outline of the approach and methodology behind the workplan. Explain why the proposed approach and methodology are the most suitable.*

- *Descriptions of and justifications for the proposed activities included in the workplan.*
    - *Where relevant, this should also include the proposed methods for carrying out the tasks and actions*
    - *It is required that the mandatory tasks included under section 2.4.1 of the call for applications are covered by both scenarios; however, tasks and activities described under the workplan for scenario 1 do not need to be described again under the workplan for scenario 2, unless they are changed or updated in a way that impacts on the scenario 2 workplan description*
- *Information on interlinking and dependencies between activities, and how the included tasks and activities form a cohesive workplan*
- *(For consortium applications) Information on what consortium partner will lead on which activities / parts of the work plan*
- *Please mention any foreseen outsourcing of minor parts of the planned activities outside of the applicant's organisation(s)*

Please note that applicants are not obliged to organise their proposed workplans into formal work packages, nor present lists of reports and deliverables within their workplan descriptions.>

3.1 PROPOSED WORKPLAN UNDER SCENARIO 1

<The description of this section is limited to maximum eight pages in total. Excess pages will be disregarded.>

[Your text here…]

3.2 PROPOSED WORKPLAN UNDER SCENARIO 2

<The description of this section is limited to maximum five pages in total. Excess pages will be disregarded.>

[Your text here…]

4. RISK MANAGEMENT

<The applicant should provide a simple risk analysis, to predict the risks that could prevent the successful execution of the workplans. Identify the most relevant external and internal risks and briefly describe some proposed risk mitigation actions.

The description of this section is limited to maximum one page in total. Excess pages will be disregarded.>

[Your text here…]

5. RESOURCES AND KNOWLEDGE

<Provide a brief description of the applicant's organisation(s), and how the profile(s) and expertise(s) of the organisation(s) fit(s) with the requirements of the proposed activities and of the call for applications, including access to the equipment and infrastructure needed for carrying out the proposed work. Include also a description of any experience that the organisation(s) has of carrying out similar work, and how this experience would benefit the implementation of the proposed activities.

Describe the applicant team and how the members of this team will work together to implement the proposed workplans. List the required functions by expertise, and provide short descriptions of the profiles of the key team members for these functions, with a focus on demonstrating the scientific and technical expertise and competence needed for carrying out the proposed work.

This section is limited to maximum two pages per applicant organisation, i.e. a single laboratory applicant has a maximum of two pages whereas a consortium of five laboratories has a maximum of ten pages. Excess pages will be disregarded.>

[Your text here…]

5.1 CONSORTIUM SET-UP

<Only for consortium applications. Single laboratory applicants should leave this section blank.

Describe how each organisation has a clear role in the consortium, how the organisations in the consortium complement each other in terms of the required expertise, and how they will work together to implement the proposed workplans.

This section is limited to maximum one page in total. Excess pages will be disregarded.>

[Your text here…]

6. IMPACT

<Define the short, medium and long-term effects of the proposed work. Identify the key stakeholder groups that would be impacted by the work of the EURL, and explain how they would benefit concretely from the proposed workplan activities.

This section is limited to maximum two pages in total. Excess pages will be disregarded.>

[Your text here…]

7. COMMUNICATION AND DISSEMINATION

< Describe the communication and dissemination activities which are planned in

order to communicate with the key stakeholders, promote the activities/results, and maximise the impact (to whom, which format, how many, etc.). Clarify how you will reach the relevant stakeholders and policymakers and explain the choice of communication and/or dissemination channels.

At minimum, a communication plan for

a) the relevant laboratory network(s) members, and
b) ECDC

must be presented.

This section is limited to maximum two pages in total. Excess pages will be disregarded.>

[Your text here…]