Information Session for applicants:
2024 calls for application for EU reference laboratories for public health

15 May 2024 13:30 - 15:00

European Commission, Directorate-General for Health
SANTE-CONSULT-B2@ec.europa.eu

ECDC
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ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

European Commission

Agenda

13.30 – 13.35	**Welcome** European Commission - Directorate-General for Health
13.35 – 14.10	**Presentation by DG SANTE and ECDC – Introduction to EURLs for public health and published calls for applications** European Commission - Directorate-General for Health European Centre for Disease Prevention and Control
14.10 – 14.55	**Q&A focusing on application procedures and other issues faced by candidate laboratories** European Commission - Directorate-General for Health European Centre for Disease Prevention and Control
14.55 – 15.00	**Closing remarks** European Commission - Directorate-General for Health

The legal base

- **Entered into force 26 December 2022:**
  - 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
    - Regulations are binding in their entirety and directly applicable in all EU Member States
    - **Article 15 – EU reference laboratories**
  - 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**
    - **Article 5** - Operation of dedicated networks and networking activities
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Article 15

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2. The EU reference laboratories shall be **responsible for** coordinating the network of national reference laboratories, in particular, in the following areas:

1. reference diagnostics, including test protocols;
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3. The network of EU reference laboratories shall be **operated and coordinated by the ECDC**, in cooperation with the **WHO reference laboratories**.

4. The EURLs will be designated for a minimum period of **four years** and be reviewed regularly.

5. The EURLs shall be **impartial**, have suitably qualified **staff** with adequate training, have the necessary **infrastructure, equipment and products** to carry out the assigned tasks, take into account research at **national, Union and international levels**, be able to perform tasks in **emergency situations**, comply with **biosecurity standards** and be **accredited** (Regulation (EC) No 765/2008).

6. **Grants** may be awarded to the EURLs for the costs that they incur - EU4Health Programme.

Overall plan: iterative cycle of designation

- EURLs for public health will be gradually **designated over the next few years**
- Neither operationally nor financially feasible to implement all EURLs on a single year
- Number of EURLs and order of implementation, i.e. EURL designation, will be dependent on several factors, including EU public health priorities and budget
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  - AWP 2024: EUR 7.5 million
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  - **Antimicrobial Resistance (AMR) in bacteria**
  - **Vector-borne viral pathogens**
  - **Emerging, rodent-borne and zoonotic viral pathogens**
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  - ***Legionella***
  - **Diphtheria and pertussis**
- The EURLs are designated for seven years (March 2031)
- Link to the Implementing Regulation:

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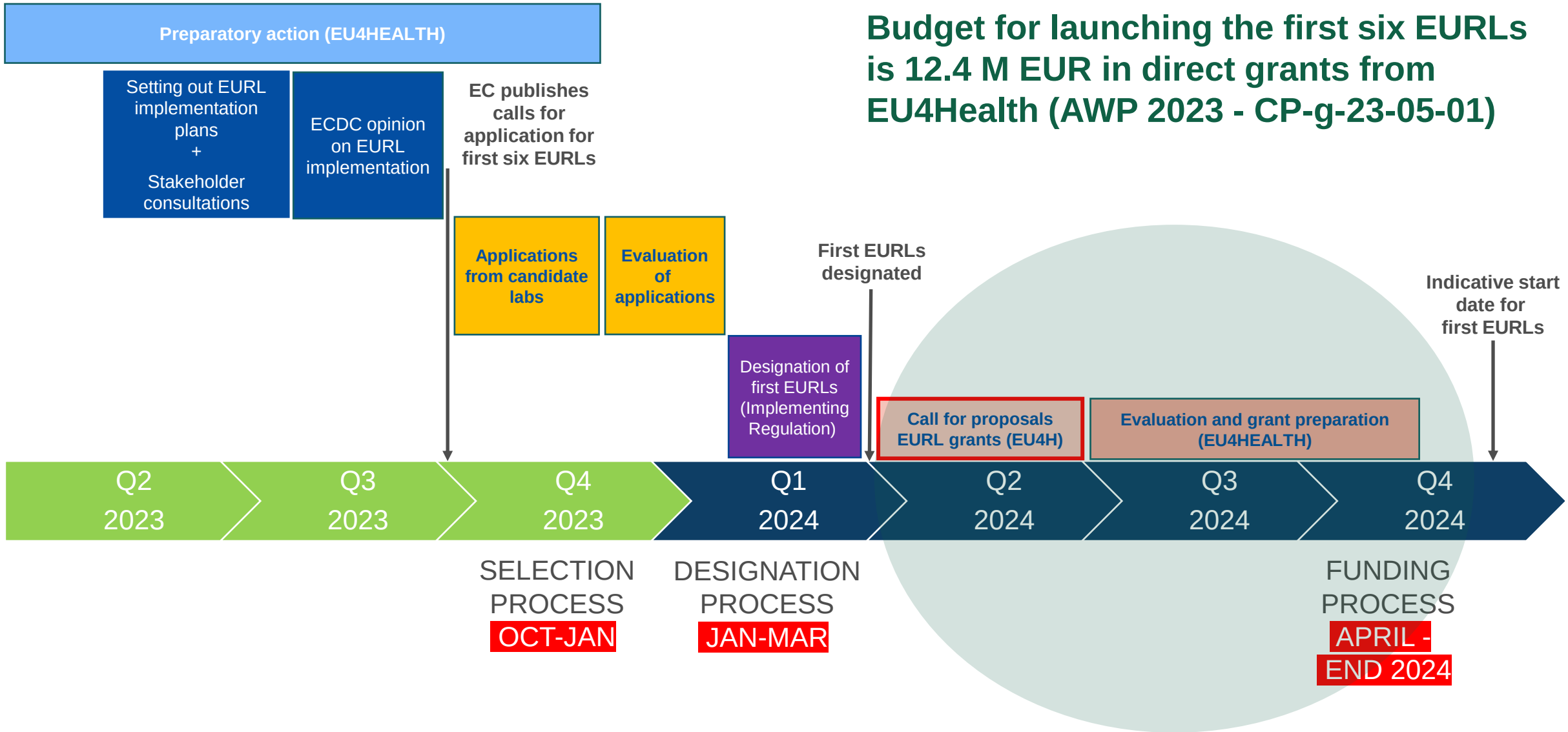

Calls for applications 2024

Based on ECDC expert opinion 2024

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- Information about these calls available here: https://health.ec.europa.eu/consultations/eu-reference-laboratories-public-health-2024-calls-applications_en

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EURL second round of applications
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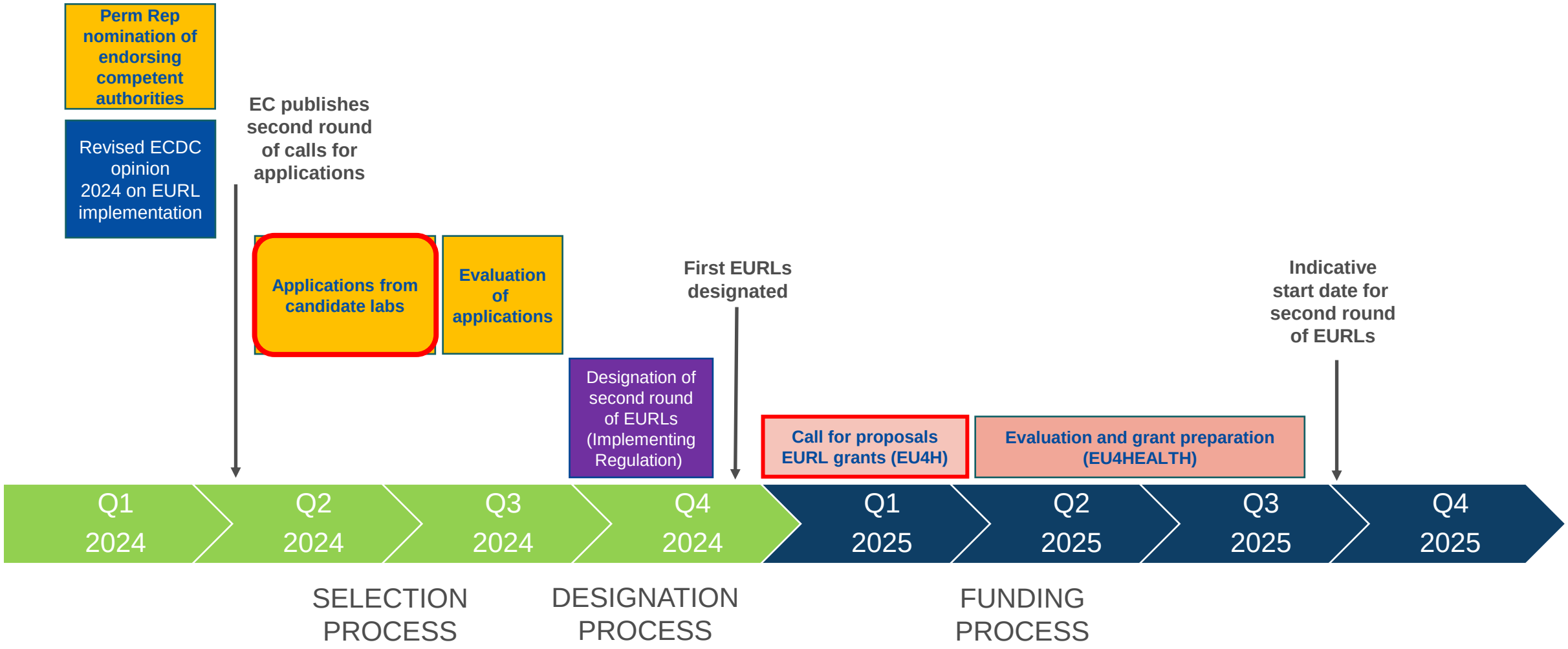

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Network member laboratories that do not apply to be an EURL for public health will remain members of the network, and will at a later date receive laboratory support from the EURL for public health designated for their particular pathogen / health issue.

Guide for applicants v1.0; p. 7

2024 calls for application – Applicants

Q: Who can submit an application?

A: The call for applications is aimed at laboratories in the EU Member States and EEA countries that play an active role in a national and/or EU-level public health microbiology system.

An applicant to the call may be a single laboratory or a consortium of up to five laboratories. Please note that a laboratory may only apply to each topic once, i.e. either as a single laboratory or as a member of a consortium.

All laboratories applying to the call, whether as a single laboratory or as a member of a consortium, must be endorsed by a national competent authority that will confirm that each laboratory meet the eligibility criteria.

Guide for applicants v1.0; p. 9

2024 calls for application – 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 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.

The compliance of candidate laboratories with these eligibility criteria must be supported by a national competent authority in public health (e.g. the ECDC Coordinating Competent Bodies) in the form of an endorsement

Call for applications; section 2.7

2024 calls for application – Clarifications on eligibility criteria

(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.

(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.

(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.

(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.

Call for applications; section 2.7

2024 calls for application – Endorsements of candidate laboratories (I)

All applicants, whether they are single laboratories applying separately or members of a consortium applying jointly, must be endorsed by a national competent authority in public health. The Permanent Representations of the Member States of the European Union have each nominated one national competent authority that will be responsible for endorsing candidate laboratories from their country; the list of nominated national competent authorities and their contact information is found in here:

https://health.ec.europa.eu/document/download/a0d90025-720d-44ca-b181-ef0fb88c22e0_en

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.

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.

Call for applications; section 4.1.3

2024 calls for application – Endorsements of candidate laboratories (II)

Q: Which are the national competent authorities able to endorse applicants?

A: The Permanent Representations of the Member States of the European Union have each been asked to nominate one national competent authority that is responsible for endorsing candidate laboratories from their country; the list of nominated national competent authorities and their contact information can be found here:

https://health.ec.europa.eu/document/download/a0d90025-720d-44ca-b181-ef0fb88c22e0_en

Q: What do I do if my country has not (yet) nominated a national competent authority to endorse EURL applicants?

A: SANTE is sending reminders to all Permanent Representations of the Member States of the European Union that have not yet nominated a national competent authority as requested. Please check the link regularly for updates and we thank you for your patience until this information is provided.

Guide for applicants v1.0; p. 12

2024 calls for application – Endorsements of candidate laboratories (III)

Q: Can a nominated national competent authority endorse itself as a candidate for an EURL for public health?

A: In principle, yes. However, a national competent authority may endorse more than one applicant per topic. In their role as national competent authorities, they are therefore expected to, in a fair and transparent manner, also endorse other national laboratories that are interested in applying and that meet the eligibility criteria.

Q: Can one laboratory apply to more than one EURL topic?

A: Yes, one laboratory may apply to one or more EURL topics if they have the capacity and expertise. However, please note the following:

- A separate endorsement is needed for each of the EURL topics that a laboratory submits an application for. This is because the staff qualifications, equipment, infrastructure required for each topic is different, and separate confirmations of eligibility are therefore needed from the national competent authority.
- Applicants those applications are successful for more than one topic may 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.

Guide for applicants v1.0; pp. 11-12

2024 calls for application – Consortia

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”.

If designated, the consortium members will be jointly and severally liable for carrying out the tasks of the EURL, i.e. if one consortium member were to fail to implement its part of the tasks, the other members would become responsible for implementing this part.

Each member of the applicant consortium has to meet the eligibility criteria, and be endorsed by their respective national competent authorities. 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.

Call for applications; section 4.1.4.1

2024 calls for application – Forming a consortium

Q: Is there a way for laboratories potentially interested in forming a consortium for a specific EURL topic to get in contact with other interested laboratories?

A: Yes – ECDC is operating a service to put laboratories in contact with other laboratories interested in forming a consortium and submitting a joint EURL application in a specific field.

Eligible laboratories interested in this service should send an email to ECDC at EURL-PH@ecdc.europa.eu, 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. Those laboratories will receive separate emails informing them on how to access this information.

Q: Do applicants have to use the ECDC-provided service to find consortium partners?

A: No, not at all – eligible laboratories are perfectly free to form their own consortia based on direct contacts with other eligible laboratories. There is no requirement to inform the European Commission or ECDC of the formation of a consortium prior to the submission of the application.

Guide for applicants v1.0; p. 15

2024 calls for application – Scenarios (I)

Q: What is the purpose of the scenarios?

A: The scenarios give two different sets of constraints (i.e. limited budget and defined time period) within which the applicants must prepare and submit workplans that, in their views, would provide the laboratory network members with the best and most relevant laboratory support whilst still respecting the scenario constraints. This will facilitate the evaluation of the applications, by making the workplans submitted by the applicants more easily comparable.

Guide for applicants v1.0; p. 11

2024 calls for application – Scenarios (II)

- All calls require applicants to submit applications with proposed workplans in response to two scenarios
  - Same scenario period – two years
  - Different scenario budget – higher in Expanded Scenario than in Basic Scenario
- Both workplans for Basic and Expanded scenarios must include all the mandatory tasks described under section 2.4.1 of the call for applications
- Applicants should also include additional activities that they deem to be feasible for implementation under the scenario parameters
- Justifications of the proposed added value of workplan tasks and explanations of task dependencies should be provided
- All activities and services provided by the EURL shall be free-of-charge for the laboratory network participants.

Please note that the scenarios as well as the funding amounts presented in the scenarios 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

Call for applications; section 2.3

2024 calls for application – Mandatory tasks

Q: Why are there mandatory tasks in the call for applications?

A: There are a number of laboratory support tasks that are considered so essential to the network members, or to other on-going work at the EU level, that an EURL for public health will be required to provide them. These essential activities are included in the calls for applications as mandatory tasks, and their number and scope vary between the different calls for applications.

All workplans prepared in response to the scenarios must include all the mandatory tasks required for the EURL for public health in the specific field.

Guide for applicants v1.0; pp. 16-17

2024 calls for application – Additional activities

Q: Why are potential additional activities listed in the call for applications?

A: These are activities that ECDC have identified as being potentially valuable to the laboratory network and complementary to the mandatory tasks of the EURL. These activities should be seen as suggestions, and it is up to each applicant to propose a set of additional activities within the scope of the EURL responsibility. This may include some of the potential additional activities listed in the call, and/or additional activities that the applicant deems to be of greater value to the network members.

Guide for applicants v1.0; p. 17

2023 calls for application – Description of workplan activities

Q: What level of detail is expected in the description of tasks in the workplan?

A: Each application should describe the workplan as a whole, the activities included under it, and how the activities relate to each other. The activities should be described with a focus on why the activity is useful for the network members and/or EU-level public health, what the main outcomes of the activity would be, if/how the activity builds on other activities, etc. However, applicants are not obliged to organise their proposed workplans into formal work packages, nor present lists of reports and deliverables within their workplan descriptions.

Applicants are expected to strike the right balance between necessary detail and conciseness in their descriptions of the activities, and the page limits of the different parts of the Technical Description template have been set to give applicants enough room to describe the above, while avoiding excessive detail.

Guide for applicants v1.0; p. 17

2024 calls for application – Selection criteria

Criterion	Sub-criteria	Max points (pass threshold)
Understanding of the EURL purpose and role	**Role and purpose** – This criterion assesses the extent to which the applicant demonstrates an appropriate understanding of the role of the EURL with regards to the relevant stakeholders at the EU and national level public health systems, and of the purpose of laboratory support activities within the EU-level public health landscape	**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)**

Call for applications; section 2.8

Key documents and links

- Calls for applications (one per EURL field)
- Links to application forms in EUSurvey (one per EURL field)
- Guide to applicants (one for all EURL fields)

All available on:

https://health.ec.europa.eu/consultations/eu-reference-laboratories-public-health-2024-calls-applications_en

Please check back regularly, as revisions of documents (in particular the Guide to applicants, but also the calls for applications) may be published

Thank you

European Commission:
Directorate-General for Health, Unit B2 - Health security, LU-1882 Luxembourg, DRB A1/035
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European Centre for Disease Prevention and Control: The ECDC Microbiology team
EURL-PH@ecdc.europa.eu

ecdc
EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

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Information Session for endorsing authorities:

2024 calls for application for EU reference laboratories for public health

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Dr Rita Figueira – Policy Officer - European Commission, Directorate-General for Health
SANTE-CONSULT-B2@ec.europa.eu

Karin Johansson – Principal Expert Molecular Surveillance - ECDC
EURL-PH@ecdc.europa.eu

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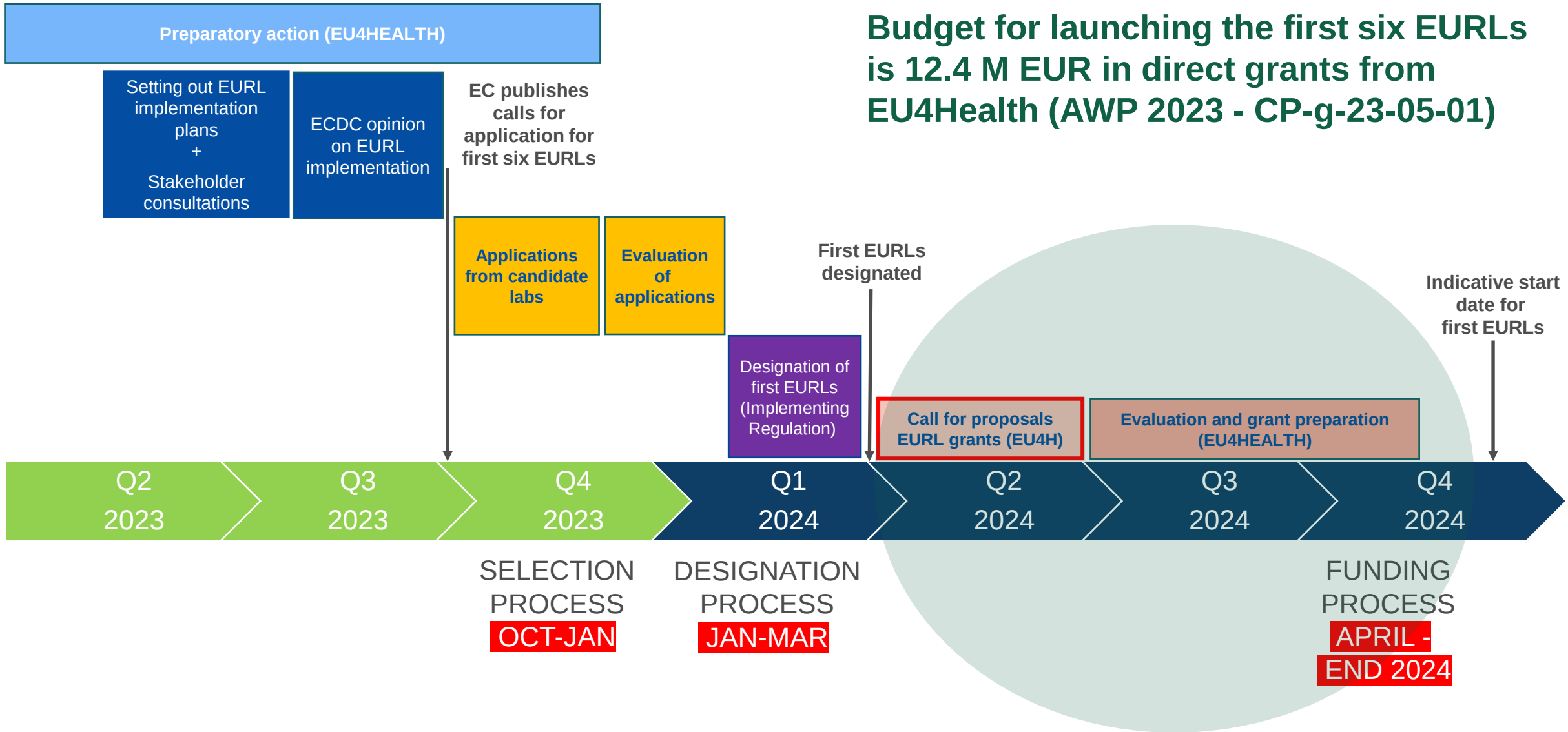

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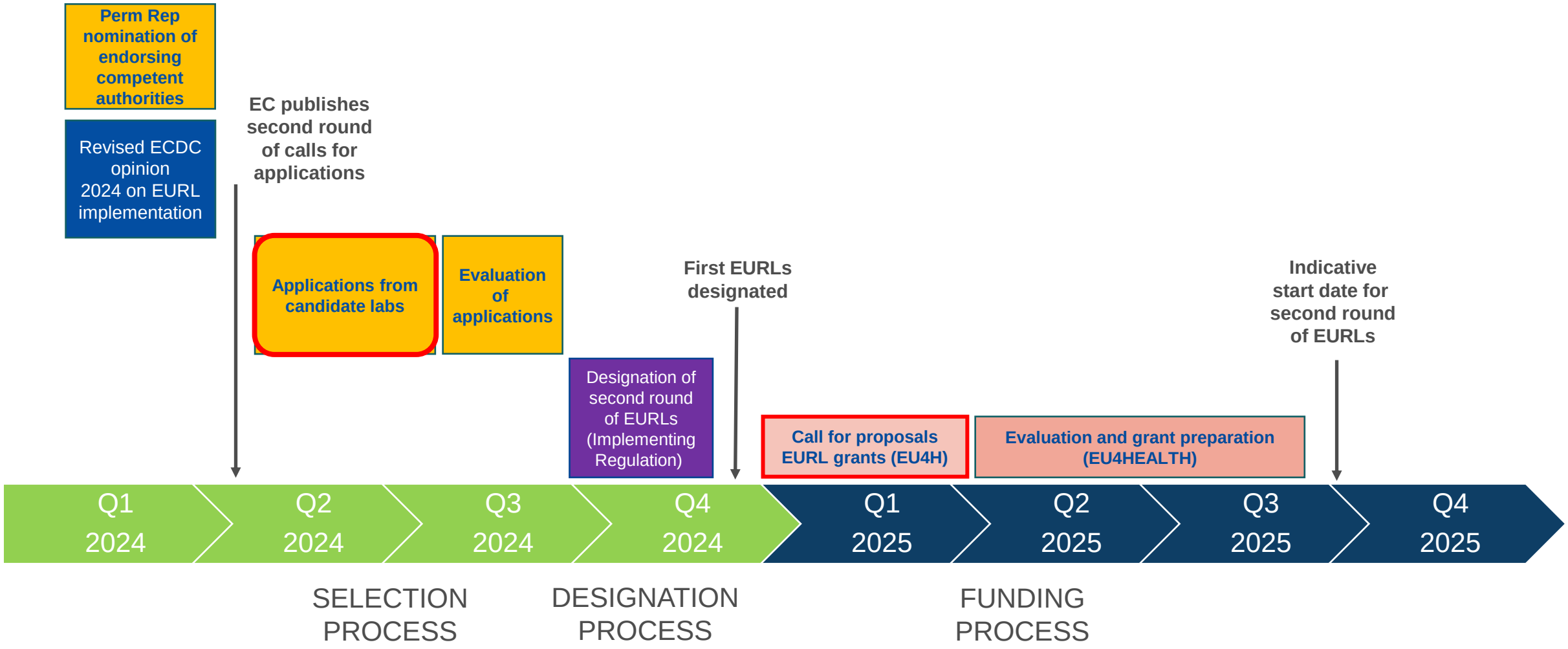

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All applicants, whether they are single laboratories applying separately or members of a consortium applying jointly, must be endorsed by a national competent authority in public health. The Permanent Representations of the Member States of the European Union have each nominated one national competent authority that will be responsible for endorsing candidate laboratories from their country; the list of nominated national competent authorities and their contact information is found in here:

https://health.ec.europa.eu/document/download/a0d90025-720d-44ca-b181-ef0fb88c22e0_en

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.

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.

Call for applications; section 4.1.3

2024 calls for application – Endorsements of candidate laboratories (II)

Q: Which are the national competent authorities able to endorse applicants?

A: The Permanent Representations of the Member States of the European Union have each been asked to nominate one national competent authority that is responsible for endorsing candidate laboratories from their country; the list of nominated national competent authorities and their contact information can be found here:

https://health.ec.europa.eu/document/download/a0d90025-720d-44ca-b181-ef0fb88c22e0_en

Q: What do I do if my country has not (yet) nominated a national competent authority to endorse EURL applicants?

A: SANTE is sending reminders to all Permanent Representations of the Member States of the European Union that have not yet nominated a national competent authority as requested. Please check the link regularly for updates and we thank you for your patience until this information is provided.

Guide for applicants v1.0; p. 12

2024 calls for application – Endorsements of candidate laboratories (III)

Q: Can a nominated national competent authority endorse itself as a candidate for an EURL for public health?

A: In principle, yes. However, a national competent authority may endorse more than one applicant per topic. In their role as national competent authorities, they are therefore expected to, in a fair and transparent manner, also endorse other national laboratories that are interested in applying and that meet the eligibility criteria.

Q: Can one laboratory apply to more than one EURL topic?

A: Yes, one laboratory may apply to one or more EURL topics if they have the capacity and expertise. However, please note the following:

- A separate endorsement is needed for each of the EURL topics that a laboratory submits an application for. This is because the staff qualifications, equipment, infrastructure required for each topic is different, and separate confirmations of eligibility are therefore needed from the national competent authority.
- Applicants those applications are successful for more than one topic may 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.

Guide for applicants v1.0; pp. 11-12

2024 calls for application – Assessment of eligibility for endorsement

Q: Are there defined criteria for the national competent authorities to assess the suitability of laboratories to be endorsed before their application??

A: Yes – they are the eligibility criteria listed in section 2.7 of the call for applications.

Each national competent authority is required to confirm that laboratories applying to the call meet 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 the laboratories in this process.

Q: Is there a template for the endorsement letter?

A: Yes – it's Annex I of the call for applications. It's also available as a Word file here:

https://health.ec.europa.eu/document/download/9ac8009b-8835-4c37-b57c-837d5e4ff8df_en?filename=security_2024-eurl-call_annex1_en.docx

Guide for applicants v1.0; p. 9

Key documents and links

- Calls for applications (one per EURL field)
- Links to application forms in EUSurvey (one per EURL field)
- Guide to applicants (one for all EURL fields)

All available on:

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

Please check back regularly, as revisions of documents and/or a Q&A may be published

Thank you

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