

RAPID SCIENTIFIC ADVICE

Rapid ECDC advice on the designation of future European Reference Laboratories for public health, June 2025

1. Summary

- ECDC proposes to issue the 2025 call for application for EURLs for public health in the area of respiratory viruses to ensure continued laboratory support and capacity-building activities for Europe on these high importance/high impact pathogens.
- The area of respiratory viruses is suggested to be covered in one EURL by a consortium of up to five partner institutes.
- A list of EURLs for implementation in subsequent calls beyond 2025 is proposed and in addition a list of diseases/health issues under consideration for EURL implementation is provided.
- Changes to the processes for application, evaluation and designation of EURLs are proposed.

2. Background

In July 2023, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) requested that ECDC provide it with advice on the establishment of EURLs for public health (from here on 'EURLs'), in order to support DG SANTE in implementing responsibilities in this area as set out in Regulations 2022/2370 and 2022/2371 [1,2].

The request asked for advice both on general processes for the implementation of EURLs, as well as a list of proposed EURLs for communicable diseases. In response, ECDC issued an opinion on the implementation of EURLs for public health in July 2023, with a revised version issued in April 2024 [3,4]. While these documents were drafted by ECDC, the National Microbiology Focal Points (NMFPS) were consulted on the contents prior to the documents being shared with DG SANTE.

Since the general process for the implementation of EURLs for public health is now largely stable, the previous opinion has been split into two documents:

- A technical report on the '[Establishment of EU Reference Laboratories for public health in Europe](#)'. This technical report contains a description of the general EURL implementation process, as well as a list of already established EURLs.
- This rapid scientific advice on the designation of future EURLs for public health. This document contains recommendations on the EURL(s) for public health to be implemented under the next EU4Health Annual Work Programme as well as in future years, and a list of diseases/health issues for which the implementation

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of EURLs is still under consideration. When relevant, it also contains recommendations for changes to the steps of the general EURL implementation process.

A list of all currently designated EURLs, including all consortium members and coordinators, is available on the DG SANTE website [5].

Decisions on which EURL(s) to be implemented and on general EURL implementation processes are made by DG SANTE.

3. Proposed EURL(s) for implementation

3.1 Proposed EURL for implementation in 2025/2026

The ECDC proposal on the diseases/health issues for EURL implementation in 2025/2026 is listed in Table 1. This is based on an assessment according to the methodology described under Methods (section 6.1) below. Weighing the factors described for all remaining disease/health issues where EURLs have not yet been designated, respiratory viruses were identified as the best candidate for implementation in 2025/2026.

Table 1. ECDC proposal on diseases/health issues for EURL implementation in 2025/2026

EURL	Disease(s)/health issues	Supporting disease network(s)	Rationale
Respiratory viruses	Influenza virus (seasonal, emerging/pandemic and human infections of zoonotic influenza virus), SARS-CoV-2 and RSV. The scope of the EURL should also include other respiratory viruses of epidemic and/or pandemic potential, such as SARS-CoV, MERS-CoV, enterovirus D68, adenovirus and human metapneumovirus.	Viral respiratory diseases networks of ECDC.	Respiratory viruses are a high priority for EU-level surveillance due to existing high burden of disease and pandemic potential; ensuring adequate laboratory support as well as training and capacity-building are essential to continued pandemic preparedness and high-quality EU surveillance activities for public health.

3.1.1 Related changes to the networks supported by the proposed EURL to be implemented in 2025/2026

Should a decision be made to implement the EURL for respiratory diseases as proposed in section 3.1 above, ECDC would explore the possibility of merging the two networks ERLI-Net and ECOVID-LabNet. This is mainly due to strong synergy effects identified between the network activities and a high degree of overlap between network members. In addition, ECDC would also propose to Member States that Operational Contact Points are also nominated for RSV, to ensure that the EURL would be able to contact the relevant Member State representatives for activities focusing on RSV.

Once a decision has been made by SANTE, in-depth discussions with the two networks should be initiated with the goal to discuss and agree on a plan for how these network merges should be managed.

3.2 Proposed EURLs for implementation in coming years

ECDC recommends that over the coming years, EURLs should also be established for the diseases/health issues listed in Table 2. Recommendations for specific timepoints for implementation of these EURLs will be assessed according to the methodology described under Methods (section 6.1) below.

Table 2. Proposed for implementation in coming years

EURL	Disease(s)/health issues*	Supporting network(s)
Healthcare-associated infections caused by <i>Clostridioides</i> (<i>Clostridium</i>) <i>difficile</i>	<i>Clostridioides</i> (<i>Clostridium</i>) <i>difficile</i> infections	HAI-Net CDI
(Antimicrobial-resistant) Gonorrhoea	Gonorrhoea	Euro-GASP
Tuberculosis	Tuberculosis	ERLTB-Net
Invasive Bacterial Diseases	Meningococcal Disease, <i>Haemophilus influenzae</i> Type B Infection, Invasive Pneumococcal Disease	IBD-LabNet

4 Additional diseases/health issues under consideration for EURL implementation

In addition to the proposed list of EURLs for implementation, Table 3 contains a list of additional diseases/health issues/pathogens or their vectors under consideration for EU-level laboratory support under the EURL system.

Depending on the stakeholders' opinion on the usefulness and public health added value of laboratory support for these diseases, these may be added to the list of EURLs for implementation in future revisions of this rapid scientific advice.

ECDC recommends that in 2025 SANTE and ECDC should carry out a structured stakeholder consultation to assess the need for, potential benefits and estimated costs of implementing EURLs for these diseases/health issues/pathogens or their vectors. Stakeholders to be consulted should include Member States (disease network members, National Focal Points for Microbiology, ECDC Advisory Forum, Health Security Committee) as well as other relevant initiatives relevant to these topics.

Table 3. Additional diseases/health issues under consideration for EURL implementation

Potential EURL function	Disease(s)/health issues	Supporting disease network(s)	Rationale
Arthropod vectors	Arthropod vectors, including mosquitoes, ticks, sand flies, and biting midges; lice, fleas, mites, etc.	EVD-Net	With climate change, arthropod vectors' distributions have been expanding, and the risk of disease outbreaks have been increasing. The lack of an EU reference laboratory for vector species identification, assessment of vector competence and vectorial capacity, as well as monitoring of insecticide resistance, is a barrier to adequate preparedness and response to vector-borne diseases. As many vector-borne diseases are zoonotic, this EURL should be developed taking a One Health approach, and cover arthropods of both public health and animal health relevance. Ideally, this EURL should be mandated to evaluate and monitor cost-effectiveness of vector control methods and contribute to the detection of pathogens in vectors in cooperation with pathogen-specific EURLs.
Prions	All prion diseases, including variant Creutzfeldt-Jakob Disease	FWD-Net	Given that prion diseases are rare, but with potential high public health impact, an EURL providing expertise and reference laboratory services can be of high added value for EU Member States. ECDC has provided laboratory support for variant Creutzfeldt-Jakob Disease in the past.
Fungal pathogens	Fungal diseases, e.g. diseases caused by infections of pathogenic	Not yet defined	Public health significance of fungal pathogens has increased with higher rate of drug resistance detected and thereby higher clinical burden of these infections. An EURL for fungal diseases has

Potential EURL function	Disease(s)/health issues	Supporting disease network(s)	Rationale
	species of <i>Candida</i> , <i>Aspergillus</i> etc		the potential to significantly strengthen diagnostic capability for such infections and improve data comparability.
Mycoplasma	Mycoplasma pneumoniae infections	Not yet defined	Increased number of cases have been reported in 2024 by several Member States with increased burden in health care systems. However, Mycoplasma pneumonia infections are not listed as EU-notifiable diseases and no EU-level surveillance is currently carried out routinely.
Wastewater surveillance	Multi-pathogen	Not yet defined	ECDC will take on a leading role in the wastewater-based surveillance of infectious diseases building on previous and ongoing projects such as EU-WISH. Going forward an EURL for WBS is an optional solution to ensure laboratory support and capacity-building to the future WBS network of ECDC.

5. Proposed changes in the processes for application, evaluation and designation of EURLs

Based on the lessons learned from the previous EURL application, evaluation and designation processes, ECDC recommends the following changes and improvements to the different steps of the general EURL implementation process compared to the process used in 2024. This is based on methodology described under Methods (section 6.2) below.

Below, the only process steps listed are the ones where one or more changes are recommended. For a detailed description of all the steps of the 2024 implementation process, please see one of the 2024 calls for applications [6].

5.1 Application process

5.1.1 Application form

For some EURLs, health crisis and/or pandemic preparedness capacity is of high importance, and for these EURLs it would be beneficial that this was more directly addressed by the EURL applicants in their application.

Based on the proposal in section 3.1 above that an EURL should be selected and designated for respiratory diseases where the issue of crisis preparedness is highly relevant, ECDC recommends that the application form (included as Annex III of the calls for application document) is revised accordingly.

5.1.2 Selection criteria

In previous EURL documentation, the concept of a 'laboratory network' as a subset of the disease network has caused confusion for applicants and other stakeholders. To emphasise the EURLs' supporting role in relation to the officially established disease networks and their members, all EURL documentation should be updated to eliminate the phrase 'laboratory network'.

For the selection criteria, ECDC therefore recommends that the selection criterion on 'Coordination capacity' is updated as follows (proposed changes indicated in red):

Coordination with the **laboratory members of **disease network(s)**** – This sub-criterion assesses the quality and appropriateness of the applicant's approach and plan for the coordination with the **laboratory** members of the **disease** 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

5.2 Funding process

5.2.2 Change to description of associated EU4Health annual work programme

Previous calls for applications have stated explicitly that 'The EURL selected through this call and then designated through an implementing act, will be able to apply for a grant under the EU4Health 202x work programme, topic XXX'. While this has been true so far, there may come a time where EURLs cannot immediately be funded for the entire designation period, and will need to apply for EU4Health funding more than once. The calls for application should therefore not limit the financial support options to one specific EU4Health annual work programme.

ECDC recommends that the text under section 4.4 of the calls for applications is updated as follows (proposed changes indicated in red):

The EURL selected through this call and then designated through an implementing act, will be able to apply for **one or more grants** under the EU4Health **programme, as specified through its annual work programmes**.

5.2.3 Annex added for mandatory deliverables

Due to ongoing discussions about the future format of the EU4Health calls for proposals issued by the European Health and Digital Executive Agency (HaDEA) to invite designated EURLs to apply for funding, there is a risk that the new format will not allow for the specification of mandatory deliverables in the same manner that was used for the 2023/2024 and the 2024/2025 calls for proposals.

ECDC therefore recommends that an annex with mandatory deliverables is added to all calls for applications to ensure that this information would be available to the successful EURL applicants when preparing their EU4Health proposals.

6 Methods

6.1 Prioritisation of disease areas or health issues for (potential) EURL implementation

The proposed topic(s) for the next call(s) for applications for EURL(s) for public health as well as the additional diseases/health issues under consideration for EURL implementation are identified by ECDC by considering several inputs and factors. These include:

- Internal discussion with the relevant ECDC experts working on specific diseases/health issues;
- Needs of the ECDC disease networks, as collected through:
 - The August 2023 survey of the disease network members to identify specific public health needs and priority tasks for future EURLs in the respective disease areas (for more details, please see the ECDC technical report on the [Establishment of EU Reference Laboratories for public health in Europe](#)); and
 - Feedback from network meetings and other discussions with network members.
- Input from stakeholders, including the Health Security Committee, ECDC's Management Board, ECDC's Advisory Forum, and NMFPs, since these groups are regularly updated on the EURL implementation progress;
- The contractual status and duration of relevant ECDC laboratory support contracts; and
- Preliminary budget allocated to EURL implementation under the next EU4Health annual work programme.

6.2 Collection of issues for improvement related to the general EURL implementation process

ECDC collects inputs and suggestions for improvements of the general EURL implementation process in several ways. This includes:

- Feedback from EURL applicants. This includes questions asked by applicants during the application process, which were collected and published by DG SANTE on the application website in a Frequently Asked Questions format;
- Feedback from ECDC and DG SANTE staff members who are involved in the EURL implementation initiative;
- Feedback from experts involved in the evaluation committees responsible for the evaluation of the submitted EURL applications;

- Feedback from stakeholders, including the Health Security Committee, ECDC's Management Board, ECDC's Advisory Forum, and NMFPs, since these groups are regularly updated on the EURL implementation progress; and
- Needs identified due to changes in related processes, e.g. the EU4Health funding process.

7 Conclusion and recommendations

- ECDC recommends that DG SANTE select and designate an EURL for public health on the topic of respiratory viruses.
- ECDC recommends that DG SANTE revise the general EURL implementation process with the changes proposed in this document.
- ECDC recommends that in 2025, DG SANTE and ECDC should carry out a structured stakeholder consultation to assess the need for and potential benefits and estimated costs of implementing EURLs for the 'under consideration' diseases/health issues/pathogens or their vectors.

References

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