EURL-PH-LEGI

EU Reference Laboratory for public health in the field of Legionella

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Project website	www.eurl-legi.eu

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LIST OF ACRONYMS

AWP	Annual Work Plan
CC BY	Creative Commons Attribution License
CDC	Center for Disease Control and Prevention
cgMLST	Core genome Multi-locus Sequence typing
DG SANTE	Directorate General For Health and Food Safety
DNA	Deoxyribonucleic Acid
DNCC	Disease Network Coordination Committee
ECDC	European Centre for Disease Prevention and Control
EC	Executive Committee
EEA	European Economic Area
EQA	External Quality Assessment
ELDSNet	European Legionnaires' Disease Surveillance Network
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
ESGLI	European Study Group for Legionella Infections
EU	European Union
EURL	EU Reference Laboratory
EURL-PH-LEGI	European Union Reference Laboratory for Public Health for Legionella
GA	Grant Agreement
GDPR	General Data Protection Regulation
HCL	Hospices Civils de Lyon
INSA	Instituto Nacional de Saude
ISS	Instituto Superiore di Sanita
LD	Legionnaires' Disease
MTT	Molecular Typing Tool
MS	Milestone
NFP	National Focal Point
NRL	National Reference Laboratory
OCP	Operational Contact Point
(q)PCR	(Quantitative) Polymerase Chain Reaction
SCo	Steering Committee
SNP	Single Nucleotide Polymorphism
SRM	Stakeholder Relationship Management
ST	Sequence Type
UKD	Uniklinikum Carl Gustav Carus Dresden
UKSHA	United Kingdom Health Security Agency
wgMLST	Whole Genome Multi-Locus Sequence Typing
WGS	Whole Genome Sequencing
WP	Work Package

1 OVERVIEW OF PLANNED EURL ACTIVITIES AND OUTPUTS FOR 2026

Work package 1: Project management and coordination

Task 1.1 – Management of Consortium activities

The Hospices Civils de Lyon (HCL) is responsible of ensuring continuity, coherence and compliance with the commitments of the grant proposal for all EURL-PH-LEGI actions. The project manager, Camille Jacqueline, ensures efficient and smooth management of the consortium activities. In addition, the HCL are supported for administrative, legal and financial aspects by its subsidiary Lyon Ingénierie Projets. In 2026, the HCL will continue to organize exceptional and trimestral Steering Committee (SCo) meetings (HCL elaborates and communicates the agenda, monitor the meeting and take the minutes).

In the second year of the EURL-PH-LEGI actions, the consortium will provide the first progress report. The HCL will lead the planning of activities for 2027.

Expected output(s):

- SCo meetings are planned in March, June, September and December 2026
- D1.5 – Progress report delivered (by the end of January 2026, M13). This document will respect the redaction plan provided by ECDC/HaDEA. It will provide an update on the activities in 2025 and plans for 2026. It will include a report on training and scientific webinar progresses.
- D1.6 – Annual Work Plan for 2027 (by end of October, M22).

Task 1.2 – Coordination with network laboratories and ECDC

HCL will continue to assume the coordination function for the implementation of the activities/tasks for the laboratory members of ELDSNet in coordination with ECDC. HCL/consortium manager and ECDC will continue to meet on demand by email or videoconference to coordinate on the different EURL-PH-LEGI actions. Finally, the consortium will also interact with the other EURL-PH through the EURL network meeting and a dedicated SharePoint hosted at ECDC.

Expected output(s):

- Attendance to the monthly EURL/ECDC catch-up meetings involving all EURL-PH.
- Attendance to the EURL network meeting organized by ECDC and DG SANTE.
- Technical coordination meetings with ECDC on demand

Task 1.3 – Coordination with other supra-national organizations

EURL-PH-LEGI has a key role to interconnect all organizations/bodies that can have laboratory support activities at supra-national level in the EU/EEA. During the second year, the consortium will focus on coordination with two main organizations: ESGLI and World Health Organization Collaborative Centres (WHO CC).

The project manager presents yearly the missions and activities of the EURL-PH-

LEGI during the ESGLI conference (around 100 members). The consortium also holds quarterly conference calls with the ESGLI Executive Committee (EC).

During the second year, the consortium aims to establish a collaboration with the WHO CC for microbial water safety (https://www.rivm.nl/en/who-collaborating-centre-risk-assessment-of-pathogens-in-food-and-water/fields-of-expertise/microbial-water-safety). One of the outcomes of this collaboration will be the co-organization of a webinar of the Guidelines for Water-borne Disease and Water Quality Surveillance from WHO for ELDSNet members.

Expected output(s):

- Quarterly meetings with ESGLI Executive Committee to discuss specific EURL-PH-LEGI actions.
- Webinar on Guidelines for Water-borne Disease and Water Quality Surveillance from WHO for ELDSNet members (December 2026, M24 not a deliverable)

Work package 2: Dissemination and communication

Task 2.1 – Website development and continuous updates

The EURL-PH-LEGI website will be continuously updated to serve as a central way of communication where general information, reports, recordings of webinars, method handbook, newsletter, EQA information, and planned activities are provided.

Task 2.2 – Communication plan and Dissemination strategy

The Communication and dissemination strategy was published in 2025. No specific actions for 2026. The WP2 leader will continue to provide support for the production of documents, newsletters and infographics to optimize the communication strategy of each WP.

Task 2.3 – Organisation of laboratory network meetings

A face-to-face meeting with ELDSNet network members will be organized in 2026. The EURL will invite at least one participant from each country that participates in the network (approximately 30 countries), as well as invited speakers and relevant ECDC contact points. Additional participants may be invited as observers, but at their own expenses. On that occasion, all the activities carried out by the EURL-PH-LEGI will be presented, and evaluations of the work carried out. Suggestions for increasing or improving the activities will be collected. The first meeting will be organized in Rome at the ISS in September 2026.

Expected output(s):

- D2.3 - Plan for laboratory network meeting (due by the end of July 2026, M19). This plan will contain the proposed date and time of the meeting, description and number of intended attendees, and a draft agenda. Invitation will be sent end of June-early July 2026.
- D2.4 – Network meeting report (due by the end of November, M23). This

report will include the minute of the meeting and the results of the satisfaction survey conducted among participants.

Work package 3: Evaluation

Task 3.1 – Design of an evaluation plan

The Evaluation plan was published in 2025. No specific actions for 2026.

Task 3.2 – Monitor the progress of each WPs

This task will be maintained during the whole duration of the EURL-PH-LEGI and based on the principles described in the evaluation plan. The project manager and the coordinator will be responsible of identifying issues at early stage and ways of improvements through an active communication strategy among the consortium members. First, the timetable of implementations and the deliverables of each WPs will be reviewed regularly during ad-hoc and SCo meetings. Regular technical coordination meetings between EURL consortium and ECDC will be organized to assess progress in the work plan and to give updates on the tasks started.

Second, evaluation surveys will be designed for all the events organised by the EURL in 2026. Survey questionnaires will be produced, in collaboration with other WPs, to include a set of standard questions to collect the feedback of different stakeholders. The data produced by these surveys will be analysed to ensure that the activities performed met the needs of the target audience and the objectives of the WPs.

Expected output(s):

- SCo meetings are planned in March, June, September and December 2026
- Coordination of surveys for other WPs including satisfaction surveys.

Task 3.3 – Analyses and generation of evaluation reports

Evaluation report will be delivered at the end of the action. No action for 2026.

Work package 4: Sustainability

Task 4.1 – Development of a Sustainability Plan

By the end of the action of the EURL-PH-LEGI, the consortium aims to provide a sustainability plan that will describe the priority outcomes of the EURL-PH-LEGI and envision ways to implement them and preserve them beyond the timeframe and scope of the program. Especially it will detail where (at what level: national, EU or regional/global) and how (what actions are necessary) to sustain these priority outcomes. No specific action for 2026.

Task 4.2 – Promote accessibility to EURL outcomes

Across the whole duration of the project, WP4 will work with WP2 to ensure the sustainability of the deliverables of the EURL. During the second year, this will

particularly concern the webinars organised by WP8. This task is in support to other tasks so there is no specific output.

Work package 5: Reference diagnostics

Task 5.1 – Elaboration of a laboratory handbook

The laboratory handbook is intended to be published in 2025. Further updates will be provided to cover the aspects of whole genome sequencing and antimicrobial susceptibility testing.

Task 5.2 – Pan-European study on performance characteristics of PCR methods for diagnosis of LD

There is increasing evidence that the introduction of real-time PCR as a routine diagnostic method improves the diagnosis of LD. In this context, the ECDC/ELDSNet technical proposal is studying a revised LD surveillance case definition that would include Legionella PCR-positive patients as confirmed cases for *Legionella pneumophila* serogroup 1. However, it is still unknown how many laboratories have the capacity to perform PCR on clinical samples and to which extent. Therefore, the EURL-PH-LEGI will first develop a questionnaire to establish what is the capacity of ELDSNet laboratories to perform PCR on clinical samples and what are the PCR tools available in network laboratories.

In parallel, ISS will lead the evaluation of several real-time PCR kits marketed in Europe for LD diagnosis to determine the performance and ability of these kits to detect *L. pneumophila* and *Legionella* spp. The study will involve ELDSNet laboratories with the aim to analyse artificial and fresh samples using commercially available Real Time PCR kits CE marked (Directive 98/79/EC of the European Parliament on *in vitro* diagnostic medical devices). The kits needed for this study will be provided free of charge by the producers. The protocol will be non-negotiable. Each real-time PCR kit will be used according to the manufacturer's instructions. Each laboratory will collect the anonymised data and ISS will conduct the data analysis to evaluate intra- and inter-laboratory agreement as well as the sensitivity, specificity and the rate of positive and negative predictive values (PPV and NPV).

<u>Expected output(s):</u>

- Identification of participating laboratories for the pan-European study on performance characteristics of PCR methods for diagnosis of LD (not a deliverable, M14)
- Shipment of kits to participating laboratories (not a deliverable, M18)
- MS11 – Questionnaire on PCR capacity (due by the end of June 2026, M18). This questionnaire will be conducted as online survey together with WP3. They will include questions such as: kits used, home-made PCRs, PCR instruments, number of PCRs performed, type of samples analyzed.
- Data collection and analyses for PCR capacity survey report (M21, not a deliverable)

Publication of the data from the survey and the inter-laboratory assays will be

published in 2027 (M36).

Task 5.3 – Develop or quality assure additional relevant antisera for monoclonal subgrouping

Monoclonal antibody-based subgrouping (Mab-subgrouping) serve as a fast and reliable first screening method to analyse *L. pneumophila* isolates. Even though, several laboratories perform WGS routinely, the subgrouping is a prominent method throughout Europe as it allows a fast pre-screening. The antibodies are produced in cell lines, purified and quality checked. Currently, the Mabs are used in an ELISA-based method. UKD established a protocol for a continuous and robust production of Mabs including quality control. The EURL-PH-LEGI will therefore produce and deliver free of charge the Mabs to 16 countries in total in three batches (2026, 2027, 2028, 2029).

Expected output(s):

- Call for expression of interest in receiving the monoclonal antibodies (Mabs) for *L. pneumophila* serogrouping among ELDSNet members (not a deliverable, M13). Results will be discussed with ECDC and 4 laboratories will be prioritized to receive the Mabs in 2026.
- MS10 – Production of Mabs to type *L. pneumophila.* Shipment will be made to the 4 identified laboratories.
- Report for production delivery and utility of Mabs to type *L. pneumophila*

Work package 6: Improving and assessing quality of laboratory surveillance methods

Task 6.1 – Provision of external quality assessment schemes

The EURL-PH-LEGI will provide external quality assessment (EQA) schemes to the ELDSNet network laboratories in EU/EEA, for supporting the surveillance of LD at European level. The EQA program will be organized by the National Reference Centre for Legionella in the HCL. In February 2026, a survey will be launched for National Focal Points for Legionnaires' Disease and Operational Contact Points for Microbiology – Legionellosis to nominate participating laboratories. The EQA scheme will be offered to one laboratory (or two laboratories if clinical and environmental testing services are provided separately) per country. In parallel, an EQA plan will be drafted and will be delivered by the end of June 2026. It will contain information on EQA objectives, participants, preparation and methodology including data analysis and reporting of results. In 2026, the EQA program will be composed of three schemes:

i) **Outbreak investigation using bioinformatics methods**: Whole genome sequence data of approximately 15 isolates will be shared with participants as short reads (Illumina) sequence (fastq format) on a server. Participants will have to perform species identification, sequence-based typing, and cluster analysis by tool of choice (e.g. cgMLST or SNP). The scheme will be launched in June 2026 and participating laboratories will be given 6 weeks to report their results through an online form.

ii) **Outbreak scenario using diagnostic clinical methods**: Participants laboratories will be asked to perform urinary antigen testing on five human urine samples. Additionally, they will be asked to perform detection, isolation and characterisation of *Legionella* spp. by culture and PCR as well as subtyping (including molecular typing) on five simulated sputum samples. Finally, three strains will be sent to evaluate the characterisation of *Legionella* spp. by subtyping (including molecular typing). The scheme will be launched in September 2026 (concomitantly with scheme 3) and participating laboratories will be given 6 weeks to report their results through an online platform.

iii) **Outbreak scenario using water samples for *Legionella* testing**. Participants laboratories will be asked to perform detection and enumeration by culture and PCR as well as subtyping (including molecular typing) on five simulated water samples. The scheme will be launched in September 2026 (concomitantly with scheme 2) and participating laboratories will be given 6 weeks to report their results through an online platform.

According to the norm ISO 17043, we will use a reference laboratory outside of the targeted participants, who will perform exercise concomitantly with the participants and for whom we will use the results to confirm assigned values.

Expected output(s):

- D6.5 - EQA report for 2025 EQA schemes in collaboration with ECDC in January 2026. This report will describe the results of the scheme 1, 2 and 3 from 2025. The results will be analysed and recommendation will be made based the performance of the laboratories.
- Survey for nomination of participating laboratories in February 2026
- Piloting of the scheme 1 with Germany and Portugal in April 2026
- D6.6 - Detailed EQA laboratory and reporting protocol plan by end of May 2026 (M17)
- Implementation of the 2026 EQA scheme 1 (M18)
- Piloting of scheme 2 and 3 with Italy and Portugal in June/July to test the EQA panel and logistics
- Individual reports for the EQA scheme 1 in August 2026
- Validation study report in August 2026
- MS12 – Implementation of the 2026 EQA scheme 2 and 3 in September 2026 (M21)
- Individual report for the EQA scheme 2 and 3 in November 2026
- Satisfaction survey for participant and stakeholders in December 2026
- The report summarising the EQA activities for publication (D6.8) is due in January 2027 (M25) and will be covered in the 2027 AWP.

Task 6.2 – Country visits to review, evaluate, and improve laboratory

surveillance

The EURL-PH-LEGI aims to conduct country visits to support the network member countries to review, evaluate, and improve laboratory surveillance for cases and outbreak detection.

Using the results of the call for expression of interest launched in 2025, the consortium together with ECDC will select two countries for visits in 2026 by two consortium members and for a maximum of 5 days. Another call for expression of interest will be launched by the end of 2026, beginning of 2027. A pre-visit conference call will be organized to identify the needs and establish pre-visit recommendations with each country. Based on the needs and recommendation, the plan for country visit will be redacted to outline the purpose and objectives, expected duration and participants and the planned actions, recommendations and expected outcomes. Finally, visits will be followed by conference calls with the participating laboratories to monitor and assess the impact of the activity.

Expected output(s):

- Pre-visit conference calls in January (M13) and June (M18) 2026
- D6.4 (January, M13) and D6.7 (July, M19) – Plans for country visits
- Country visit #3 before the end of March (M15)
- Country visit #4 before the end of September (M21)
- Post-visit conference calls and surveys in April and October 2026

Work package 7: Scientific advice and technical assistance

Task 7.1 – Provision of reference diagnostic services for network laboratories

The EURL-PH-LEGI will provide, upon request, centralised and accredited reference services to the laboratory members of ELDSNet for the diagnosis and characterization of Legionella. This service can include validation and confirmation of test results, support and advice in the investigation of atypical specimens, and assistance in characterisation of new *Legionella* species. It can be provided as a supplementary service to national reference laboratories, or to laboratory members of ELDSNet where national reference services are not available or do not exist.

A communication will be made to the ELDSNet members to remind them about this service and explain the processes to request assistance. Request will be made by email to the coordination email address (HCl.eurlphlegi@chu-lyon.fr). The request of the laboratory members of ELDSNet will be analysed by the consortium in articulation with ECDC. Depending on the expertise required, the project manager may send the request to a specific member.

Following the provision of the service, the EURL-PH-LEGI will discuss with the network laboratory and with ECDC the possibility to assist the laboratory members of ELDSNet in the implementation of such service.

A summary of the reference services provided will be available to ECDC and is meant to be used for evaluation purposes. In addition, it will serve to identify gaps in the capacity of the laboratory members of ELDSNet.

Expected output(s):

- Promotion of the service by email to the network in February (M14)
- Service available for an expected 50 specimens in 2026
- D7.2 - Summary of the reference service and assistance provide to ECDC and laboratory network 2 by the end of 2026 (M24)

Task 7.2 – Advice and technical support to network laboratories

The EURL-PH-LEGI aims to provide advice and technical support to laboratory members of ELDSNet on diagnostic techniques, characterisation methods including genomic typing and other methods, upon request. It could concern details on the handbook diagnostic methods, interpretation of water quantification using culture or qPCR method, WGS wet lab protocols such as library preparation or on bioinformatic analyses.

A communication will be made to the ELDSNet members to remind them about this service and explain the processes to request support. Request will be made by email to the coordination email address (HCl.eurlphlegi@chu-lyon.fr). The request of the laboratory members of ELDSNet will be analysed by the consortium in articulation with ECDC. Depending on the expertise required, the project manager may send the request to a specific member.

Advice and technical support will be provided by email, virtual consultation, or telephone. A summary of the reference services provided will be available to ECDC and is meant to be used for evaluation purposes. In addition, it will serve to identify gaps in the capacity of the laboratory members of ELDSNet.

Expected output(s):

- Promotion of the service by email to the network in January (M13)
- Service available for an expected 10 requests in 2026.
- D7.2 - Summary of the reference service and assistance provide to ECDC and laboratory network 2 by the end of 2026 (M24)

Task 7.3 – Scientific advice and technical support to ECDC

The EURL-PH-LEGI aims to provide technical support and advice to ECDC on issues related to the diagnosis of LD, environmental aspects and genomic typing, by providing guidance on the most appropriate and up-to-date methods and approaches, upon request. In this context, the EURL-PH-LEGI could help the ECDC to determine the definition of genomic clustering for strain relatedness in terms of allelic differences for cgMLST or single nucleotide polymorphisms (SNP) differences for phylogenetic analyses, especially for STs of particular interest. Consortium members could also share their expertise on WGS data information such as resistance, genomic markers or virulence determinants.

Finally, the consortium can also act as a link between the ECDC and the LD community members outside ECDC Network regarding development, evolution and standardisation of genotyping practices as well as databases creation and sharing at the international level.

A summary of the reference services provided will be available to ECDC and is meant to be used for evaluation purposes.

Expected output(s):

- Approximately 5 requests are estimated in 2026.
- D7.2 - Summary of the reference service and assistance provide to ECDC and laboratory network 2 by the end of 2026 (M24)

Task 7.4 – Provide information, guidance and/or support to ECDC in outbreak responses

The EURL-PH-LEGI aims to provide information, guidance and/or support to ECDC in outbreak situations, including contributions to ECDC risk assessments.

ISS will support ECDC on the basis of knowledge of established procedures of European and national guidelines such as for example the application of the water safety plan. Depending on the outbreak situations and the involved Legionella, all consortium members could participate. Online meetings of EURL members will be quickly organised depending on the emergency for ECDC to provide its input.

Under this task, ISS 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.

A summary of the reference services provided will be available to ECDC and is meant to be used for evaluation purposes.

Expected output(s):

- D7.2 - Summary of the reference service and assistance provide to ECDC and laboratory network 2 by the end of 2026 (M24)

Work package 8: Training

Task 1 – Assessment of training needs in the laboratory network

The training activity plan was published in 2025. The EURL-PH-LEGI will continue to assess training needs based on EQA outcomes and country visits. In addition, the EURL-PH-LEGI remains opened to suggestions from ELDSNet members and additional or complementary trainings might be proposed to cover suggested areas.

Task 2 – Organisation and delivery of wet lab trainings

One wet lab training will be delivered at the HCL in accordance with the handbook on reference methods and will combine practical and in-class teachings by experts in the field. They will be delivered in person to a maximum of 8 participants. The EURL-PH-LEGI will cover travel, accommodation and *per diem* for the participants. 2026's topic will be "Antimicrobial susceptibility testing" and the participants are expected to:

- Understand the principles and importance of antimicrobial susceptibility

testing for *Legionella*

- Apply standardized laboratory methods for AST (broth microdilution)
- Interpret AST results in the context of clinical management and outbreak investigations.
- Recognize challenges, limitations, and quality control requirements in AST for Legionella.
- Integrate AST findings into laboratory reporting and public health decision-making.

The training will be hosted by Lyon and on ECDC Learning Portal and will last 3 days.

Specific needs and feedbacks surveys on wet lab trainings (using pre- and post-test questionnaires) will be performed.

Expected output(s):

- Call for expression of interest for participation in wet-lab training in July 2026 (M19)
- Wet-lab training in November 2026 (M23)
- Satisfaction survey to identify areas of improvement in December 2026 (M24)
- Presentations and/or video will be available for the participants on the ECDC Learning Portal for Infectious Diseases by the end of 2026.

Task 3 – Organisation and delivery of scientific webinars

The EURL-PH-LEGI aims to organize and deliver a virtual webinar on a laboratory topic related to general diagnosis of *Legionella spp*, including typing, new molecular surveillance methods and laboratory outbreak analysis tools. 2026's topic will be "Detection and genomic investigation of *Legionella longbeachae* cases and outbreaks". The learning objectives will be for the participants to:

- Understand the epidemiology and clinical significance of *L. longbeachae* in Europe
- Recognize current diagnostic methods and their limitations in detecting *L. longbeachae* in clinical and environmental samples
- Appreciate the role of whole genome sequencing (WGS) and other genomic tools in investigating *L. longbeachae* outbreaks.

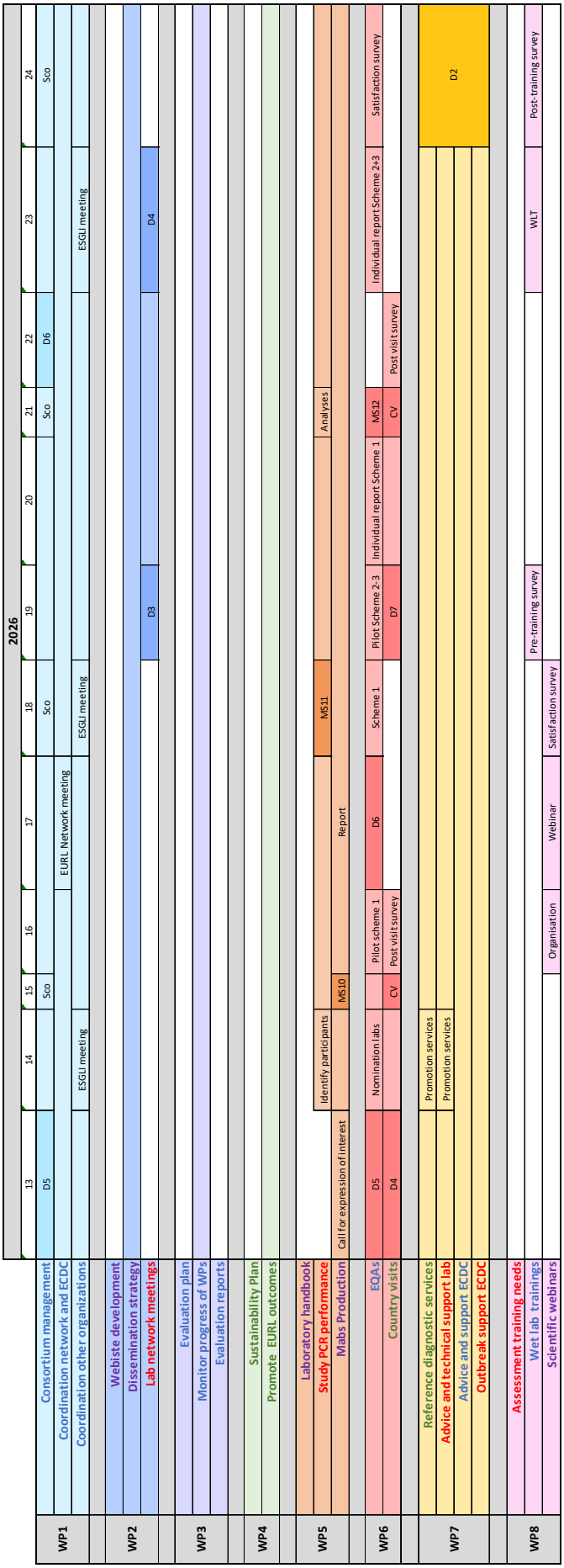
The webinar will be organized by UKD on the ECDC Learning Portal for Infectious Diseases and is envisioned to last 1:30 hours and the recording will be made accessible via the portal. An approximate number of 50 participants are expected to attend the webinars.

Expected output(s):

- Webinar before the end of September 2026
- Presentations and/or video will be available for the participants on the ECDC Learning Portal for Infectious Diseases by September 2026.

- Satisfaction survey to identify areas of improvement in October 2026

2 TIMELINE FOR ACTIVITIES AND OUTPUTS PLANNED FOR 2026



NRL-Lyon, NRL-Rome, NRL-Lisbon, NRL-Dresden

Deliverables

- D1.5 Progress report 1
- D1.6 Annual WP 3
- D2.3 Plan for laboratory network meeting (mandatory)
- D2.4 Network meeting report 1
- D6.4 Plan for country visits (mandatory)
- D6.5 EQA report published in collaboration with ECDC
- D6.6 Detailed EQA laboratory and reporting protocol plan (mandatory)
- D6.7 Plan for country visits (mandatory)
- D7.2 Summary of the reference service and assistance provide to ECDC and laboratory network 2

Milestones

- MS10 Production of Mabs to type L. pneumophila
- MS11 Questionnaire on PCR capacity
- MS12 Implementation of EAQ 2

3 ANY OTHER RELEVANT INFORMATION

We do not foresee any changes to the overall workplan or deviation from the tasks. Satisfaction survey was not carried after the kick-off meeting due to its planning early on in the implementation of EURL activities and the lack of time and structure to design the survey.