



## ECDC CORPORATE DOCUMENT

# ECDC public health microbiology strategy 2018–2022

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## Abbreviations

AF	ECDC Advisory Forum
AMR	Antimicrobial resistance
EQA	External Quality Assessment
EU	European Union
EEA	European Economic Area
IHR	International Health Regulations
MB	ECDC Management Board
NMFP	ECDC National Microbiology Focal Points
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
WGS	Whole genome sequencing
WHO	World Health Organization

# Executive summary

Microbiology laboratories provide a first line of defence against health threats from communicable diseases and antimicrobial resistance. The ECDC provides scientific advice, capacity building activities and operational support to foster capable and responsive public health microbiology services for the European Union and beyond. ECDC's vision is that by 2022 communicable disease and antimicrobial resistance threat detection, risk assessment, public health surveillance, and response in the EU/EEA will be underpinned by reliable and comparable microbiology data, shared and used in a timely manner. To this end, based on opportunities identified by monitoring laboratory capabilities in EU Member States since 2013 and progress achieved until 2017, ECDC will focus on five priorities for 2022:

- facilitating the technology transition to optimise EU-wide use of whole genome sequencing;
- benchmarking public health microbiology services and promoting best practices across the EU and beyond;
- further strengthening the EU public health microbiology capacity;
- strengthening the cross-sectorial and inter-agency integration of laboratory-based EU surveillance; and
- developing synergies with EU innovative laboratory methods and eHealth initiatives.

This report outlines the microbiology strategy as well as actions, outcome indicators and performance targets for the delivery and evaluation of its execution over the period 2018–2022.

# EU health security depends on its collective laboratory capacity

Strengthening Europe's defences against communicable diseases is essential to a high level of health security within the EU and forms the core of ECDC's mission [1]. Microbiology laboratories are a first line of defence against health threats from communicable diseases and rising multi-drug resistance of human pathogens. Adequate laboratory capacity is a critical component of health system preparedness by allowing rapid detection of infectious disease and identification of transmissible agents. This service is crucial for guiding appropriate patient treatment and providing early warnings of epidemics in order to control them effectively. Similarly, laboratory identification and molecular tracing of the spread of antimicrobial drug resistance to and among human populations are pivotal to the design and assessment of policies to contain its dissemination.

EULabCap monitoring by ECDC shows that by 2016 not all EU Member States had deployed the desired range of up-to-date laboratory capabilities at sufficient levels of capacity for effective public health surveillance and response to the main infectious disease threats faced by Europe (Annex 1). Gaps and inefficiencies were most significant for clinical use of diagnostic tests, molecular characterisation of epidemic agents and connectivity of laboratory information systems with public health monitoring and alert systems.

In accordance with its mandate, ECDC can help address these challenges by benchmarking capacities and sharing best practices, supporting the modernisation and harmonisation of laboratory-based surveillance methods and strengthening capacity by providing technical support within EU disease-specific networks. ECDC can help EU/EEA countries foster sufficient laboratory capacity to be better prepared to prevent, detect, and respond to disease, thereby strengthening health security in Europe.

In the area of microbiology ECDC has a specific mandate for 'encouraging cooperation between expert and reference laboratories' to 'foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterization of infectious agents which may threaten public health' (Founding Regulation EC 851/2004, Article 5, Point 3) [1]. Furthermore, the Centre 'will support Community preparedness planning, strengthening links with and between the clinical and public health sectors, reinforcing the public health laboratory capacity for rapid diagnosis and supporting and coordinating training programmes' (Recital, Point 10). It will also 'support the networking of the competent bodies recognized by the Member States' (Article 5, Point 1) and 'ensure the integrated operation of dedicated surveillance networks' for EU surveillance of communicable diseases and antimicrobial resistance' (Article 5, Point 2). These activities are undertaken in close cooperation with other laboratory support initiatives by the EU and the World Health Organization (WHO), as well as extending technical cooperation with EU enlargement and neighbourhood countries, in accordance with ECDC international policy.

ECDC's first Public Health Microbiology Strategy and Action Plan (2012-16) [2] and Strategic Multi-annual Plan (2014-20) [3] both aim at strengthening microbiological support for communicable disease prevention and control in the EU. These were set out in consultation with the National Microbiology Focal Point (NMFP), the Advisory Forum (AF) and the Management Board (MB). All of the strategic objectives set out for 2012–16 have been met successfully. In 2014, ECDC's Second External Evaluation indicated stakeholder satisfaction with specific ECDC microbiology activities such as External Quality Assessments (EQA) and selected disease network outputs. The evaluation recommended improvement in external visibility and transparency of ECDC laboratory support activities, assessment of national microbiology capacity, guidance on microbial genomics and other laboratory innovations and clarification of the respective roles of ECDC and the Commission in this area. Following endorsement of these recommendations by the Management Board, the Commission clarified the strategic goals and respective contributions of the Commission and ECDC in 2017 (4).

ECDC has progressed with implementation of the External Evaluation recommendations by mapping national microbiology capabilities in EULabCap surveys 2013–15; strengthening its microbiology communication strategy; reporting activity-based costing and outputs of microbiology support activities; adopting a strategy for managing EQA schemes in a cost-effective manner; gathering multidisciplinary expert opinion and mapping capacity for public health applications of whole genome sequencing (WGS)-based typing and updating its molecular surveillance roadmap accordingly. ECDC also contributed to laboratory system assessment and capacity building in the EU enlargement countries as part of the implementation of international policy.

Recently, a cost-benefit analysis by the Commission has concluded that the benefits of maintaining a system of EU reference laboratory networks are likely to outweigh the costs, both from a Member State and from an EU perspective [4]. EU laboratory network contributions that have demonstrated EU added value include development, harmonisation and validation of novel laboratory methods, EQA and training activities and, for some networks, expert and operational contributions to outbreak preparedness and response activities.

In 2017, Member States' laboratory vulnerabilities identified through the EULabCap surveys 2013–15 were reviewed in consultation with the National Microbiology Focal Points to help identify potential opportunities for ECDC support and build upon the many strong national assets already in place. The top nine priorities for ECDC support were:

- Service organisation: laboratory quality management and accreditation; laboratory contribution to epidemic investigations; diagnostic testing guidance and utilisation; national public health microbiology system organisation and updated guidance on core functions of national reference laboratories.
- Technology development: technical capability for identification of emerging pathogens/drug resistance; technical and bioinformatics management of WGS-based typing data for public health applications; harmonisation of laboratory methods for EU surveillance and machine-to-machine automated reporting of laboratory data to surveillance and alert systems.

# ECDC public health microbiology strategy 2022

To address the challenges and opportunities, ECDC has updated its public health microbiology strategy, defining a new vision, priorities and objectives, building upon the achievements of past activities, and laying out a new action framework for 2018–2022.

## Vision for 2022

By 2022, communicable disease and antimicrobial resistance threat detection, risk assessment, public health surveillance, and response in the EU/EEA will be underpinned by reliable and comparable microbiology laboratory data. The data will be based on quality-assured modern diagnostic and reference typing methods, used by a coordinated network of national laboratories operating to agreed standards and supported with relevant technical materials and electronic communication systems.

To achieve this vision, ECDC's public health microbiology strategy 2022 will be implemented with the focus on the following five priorities:

- Facilitating technology transition to optimise EU-wide use of whole genome sequencing for bacterial and viral disease and drug resistance detection and surveillance, and epidemiologic investigations of cross-border outbreaks by providing EU scientific and technical leadership, capacity building and operational support to Member States.
- Benchmarking the capacity and capabilities of public health microbiology services across the EU through EU LabCap indicators to identify potential vulnerabilities, promote effective policies and practices and follow up on corrective actions.
- Further strengthening the EU public health microbiology capacity by coordinating public health laboratory support activities to improve the quality of threat detection, surveillance and risk assessment of infectious diseases and antimicrobial resistance at Member-State and EU level. This includes continuing quality assessment, technical harmonisation and training provided through disease- dedicated networks of reference laboratories in collaboration with competent bodies and the European Commission.
- Strengthening collaboration and integration between the public health microbiology networks coordinated by ECDC and those coordinated by other relevant bodies, including the European Commission, the European Food Safety Authority (EFSA) and WHO, with a particular focus on One-Health integration of laboratory activities underpinning EU surveillance of foodborne diseases, emerging zoonoses and antimicrobial resistance.
- Developing synergies with innovative laboratory support, eHealth initiatives and open science infrastructure within the European Union, strengthening links with the clinical health sector and improving electronic connectivity and inter-operability between laboratory and public health information systems for near real time data sharing.

# How to deliver on these priorities?

## Strategic objective 1 – Facilitating technology transition to optimise EU-wide use of whole genome sequencing for surveillance and outbreak investigations

### Strategic coordination

ECDC will continue monitoring the Member States' operational WGS capacity and support the public health implementation of inter-operable genomic technologies, thereby increasing the effectiveness of surveillance and outbreak investigations. ECDC will review annual progress with implementation of its roadmap 2016–18 to integrate genomic typing into European-level surveillance and epidemic preparedness. It will evaluate the public health benefits gained and operational performance achieved in order to revise the roadmap accordingly for the next three year rolling period 2019–21 [9,10].

### Operational delivery and support

In line with the ECDC Strategy and roadmap for integration of molecular and genomic typing into European-level surveillance [9,10], and as part of its surveillance system reengineering project, ECDC will provide leadership and technical coordination in the development of easy- to-use and automated systems for upload of microbial pathogen genomic sequence data by the Member States. This will allow EU-wide comparable data sharing and integrated epidemiological and genomic data analysis, taking into account the need for inter-operability with international systems and global databases, where relevant. Solutions will be agreed with Member States to ensure that WGS data storage is performed in accordance with EU and international law.

Multidimensional analysis, visualisation, interpretation and interactive reporting of validated results according to the epidemiological context should be provided in near real-time to those stakeholders to enable them to draw the correct risk assessment conclusions and take risk management decisions.

For genomic surveillance of human infections with multidrug-resistant pathogens, as defined in the ECDC roadmap for integration of molecular and genomic typing into European-level surveillance, appropriate systems will be implemented, such as structured pan-European surveys with representative sentinel sampling among EU, EEA and EU enlargement countries performed in collaboration with epidemiological and laboratory contact points. Validated results will be made available through the appropriate ECDC online surveillance database search, interactive analysis and results visualisation interface. This development work on WGS-based analysis of antimicrobial resistance determinants will be done in coordination with the Commission, the Joint Research Centre, EFSA, EUCAST and the US CDC as part of the TATFAR<sup>1</sup> initiative.

## Strategic objective 2 – Benchmarking public health microbiology services and promoting best practices across the EU and beyond

### Strategic coordination

Together with the National Microbiology Focal Points, ECDC will continue monitoring trends in the capacities and capabilities of primary and national public health reference laboratories by EULabCap surveys. This benchmarking process will provide pragmatic evidence for policy-makers to enable them to measure the impact of national health system modernisation and EU preparedness support initiatives, and to identify and share best practice for national public health laboratory service management.

In line with its international policy and plan, ECDC will build upon the lessons learned from the EULabCap process to adapt laboratory capacity and capability performance indicators for use in voluntary monitoring of public health microbiology systems in the EU enlargement countries. This will enable them to evaluate the impact of national reform and capacity building action towards meeting the EU acquis.

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<sup>1</sup> Transatlantic Taskforce on Antimicrobial Resistance

## Strategic objective 3 – Strengthening further the EU public health microbiology capacity

### Strategic coordination

ECDC will continue to promote further harmonisation of methods for laboratory-based surveillance; pool reference microbiology expertise among EU laboratory networks and improve the quality of microbiology testing. It will also encourage wider use of innovative laboratory methods in public health to add value by implementing the Disease Programme Strategies (in preparation) and the EQA Strategy [11].

Based on this review and assessment of pragmatic experience, ECDC will provide scientific advice on optimised delivery of core public health functions of primary and reference laboratories, obtaining expert opinions by networking with national focal points, academic associations and international partners [5,6]. ECDC's expert opinion on the core public health functions of national reference laboratories [6] will be updated in collaboration with the Commission and the competent bodies. It will be extended to include the role of EU reference laboratory networks in the context of EU legislation on cross-border health threats. ECDC will continue to advise the Commission on how to ensure laboratory capacities for EU threat detection and communicable disease monitoring in the context of implementing the International Health Regulations (IHR) and Decision 1082/2013 EU [7].

### Operational delivery and support

Exchange and dialogue between Member States on best practices will be facilitated by ECDC to address potential vulnerabilities documented by EULabCap surveys, compare national laboratory system management models and share the lessons learned from laboratory response to cross-border infectious threats [8]. This evidence-based review process may take several formats, depending on Member State needs and priority topics, from interactive workshops on service delivery models to observer visits to Member States, or systematic literature reviews.

The ECDC Disease Programmes will continue to invest in EU public health laboratory network support activities to improve the quality, comparability and usability of laboratory information for specific disease or resistance threat detection and surveillance. This will be achieved through a continued quality improvement process by cost-effective EQA schemes and capacity development activities using various formats, including guidance on EU laboratory-based surveillance protocol, laboratory twinning exercises; senior expert exchanges and targeted in vitro or in silico training courses to address specific proficiency gaps. It could be extended to laboratories' participation in EU health preparedness simulation exercises.

## Strategic objective 4 – Strengthening cross-sectorial and inter-agency integration of laboratory activities underpinning EU surveillance

### Strategic coordination

Synergies will be sought in collaboration with WHO, the European Biosafety Association, the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and the European Committee on Antimicrobial Susceptibility Testing (EUCAST) regarding laboratory method standardisation, laboratory bio-risk management and quality improvement initiatives.

ECDC will continue to develop and implement 'One-Health' harmonised surveillance standards for antimicrobial resistance and laboratory characterisation of foodborne or zoonotic pathogens together with EFSA.

### Operational delivery and support

In execution of the Commission mandate for surveillance of foodborne disease and in coordination with the Commission and EFSA, ECDC will first contribute to designing WGS data collection standards and analytical methods for foodborne pathogens by 2019 and subsequently operate the joint ECDC-EFSA genomic typing database. This will permit integrated inter-agency analysis of WGS-based typing surveillance data originating from clinical, public health, animal health and food safety laboratories, as per its collaborative agreement with EFSA.

## **Strategic objective 5 – Developing synergies with EU initiatives on innovative laboratory methods and eHealth**

### **Strategic coordination**

As part of a broader range of initiatives to harness eHealth, solutions for laboratory-based surveillance can and should go beyond unidirectional data reporting to EU level. They should enable near real time sharing of laboratory and epidemiological data in a secure and customised manner among the data providers/users who assess and manage risks at local, national and cross-national levels, with due protection of patient personal data in accordance with Regulation (EU) 2016/679. ECDC will foster exchange between Member States of 'best practice' models of national electronic data sharing that bring together online operational communities of laboratory experts, local and national public health officials and statutory authorities participating in surveillance, alert and response activities.

### **Operational delivery and support**

In synergy with relevant Commission-supported eHealth initiatives, and as part of the work of implementing the ECDC Long-Term Surveillance Strategy 2014–2020 and the surveillance system re-engineering project, cross-unit projects will be undertaken to identify and disseminate solutions for automated machine-to-machine transfer of microbiology data between laboratory and surveillance information systems from the local to national and EU surveillance levels.

Specifically for laboratory-produced information, multidisciplinary work shall define standards and solutions for the capture and validation of point-of-care (POC) test results, WGS data storage/curation and interactive queries by Member States authorities, and microbiological data sets to be captured by e-health systems for public health purposes. These developments will be designed and operated with due protection of patient personal data in accordance with Regulation (EU) 2016/679.

## Strategic indicators and targets

Outcome indicators and targets for each of the ECDC microbiology priorities are shown in Table 1.

**Table 1. Performance indicators and targets for the ECDC microbiology priorities**

Priorities	Indicator(s)	Target(s) 2022
<b>1. Facilitating the technology transition to optimise EU-wide use of whole genome sequencing for surveillance</b>	1) Implementation of ECDC genomic surveillance roadmap 2019–2021.	- Top eight EU priority diseases in genomic surveillance roadmap in operation with >75% participation of Member States.
	2) Proportion of EU/EEA Member States using WGS typing for national surveillance.	- 90 % of Member States using WGS typing.
<b>2. Benchmarking the capacity and capabilities of public health microbiology services across the EU</b>	1) EULabCap country score.	- 95% of EU/EEA Member States have national public health microbiology system with average to high overall EULabCap score capability level.
	2) Proportion of EU/EEA Member States reporting corrective actions on EULabCap documented country capacity gaps.	- 70% EU/EEA of Member States having addressed gaps.
<b>3. Further strengthening the EU public health microbiology capacity</b>	1) EULabCap targets 2.3, 2.4, 3.1, 3.3 and 3.4 on laboratory capabilities for outbreak detection, surveillance and risk assessment.	-90% EU/EEA of Member States with average to high target specific capability levels.
	2) cross-disease programme annual proportion of EU/EEA participating laboratories reporting corrective/quality maintenance actions based on weaknesses identified through EQA results.	- 50% of laboratories reporting EQA-based actions.
<b>4. Strengthening the 'One-Health' integration of laboratory activities underpinning EU surveillance</b>	1) Joint ECDC-EFSA food and waterborne disease molecular WGS-based typing database in operation.	- Source attribution confirmed/corroborated for at least five food and water-borne outbreaks.
	2) Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report.	- JIACRA report published as scheduled.
<b>5. Developing synergies with innovative laboratory methods and eHealth initiatives</b>	1) EULabCap indicator 3.12: automated electronic notification of diagnostic laboratory data to national surveillance databases.	- 90% of Member States using automated electronic notification.

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## Annex 1. Level of laboratory system capacity and capability based on EULabCap country Index 2016, EU/EEA countries (N=30)

