



Laboratory networks in the field of diagnostics

Interplay between DG HERA's lab network DURABLE, EURLs under Regulation on serious cross-border threats to health and IVDR EURLs

IVD WG meeting, 30 March

DG HERA – Lab Network DURABLE

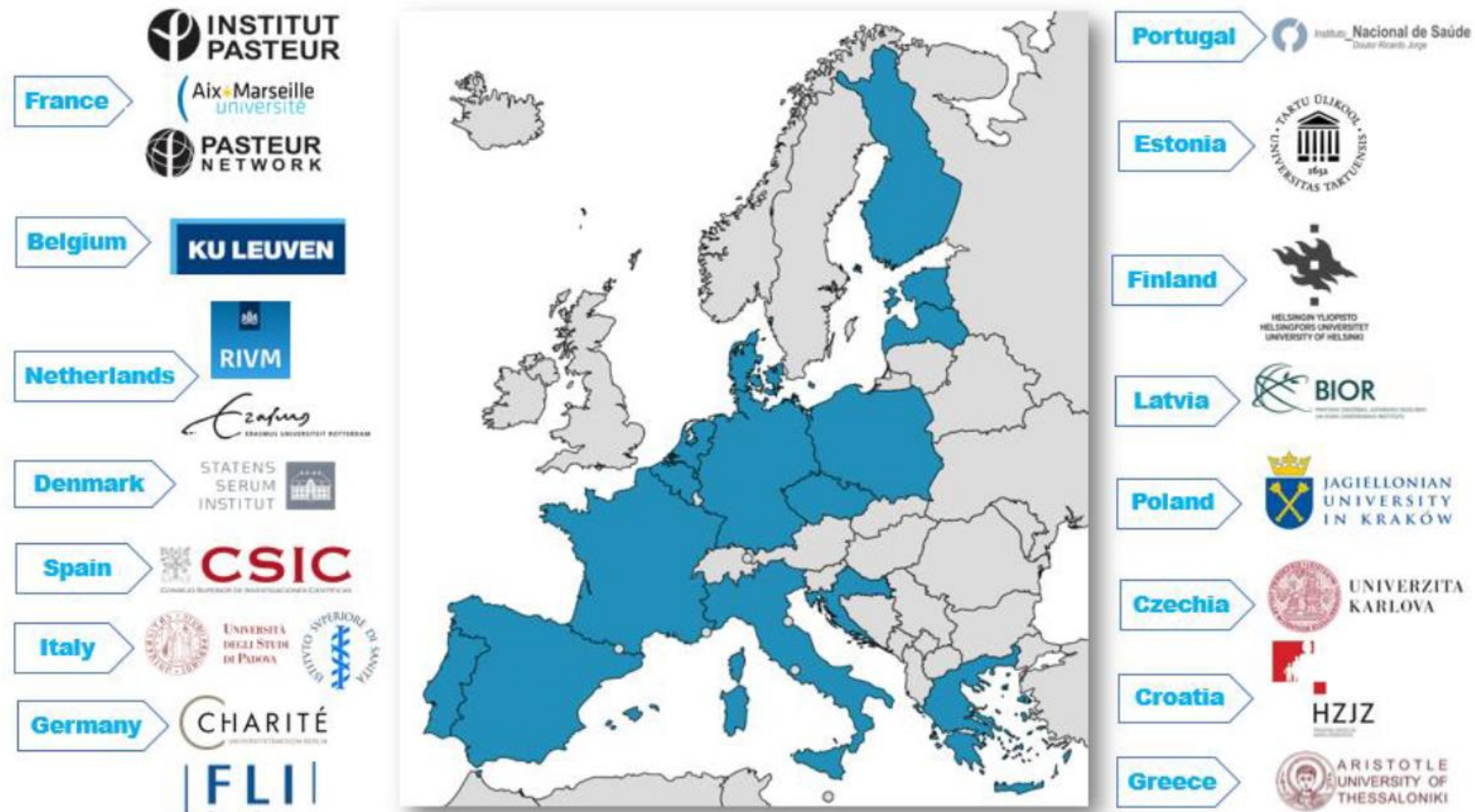
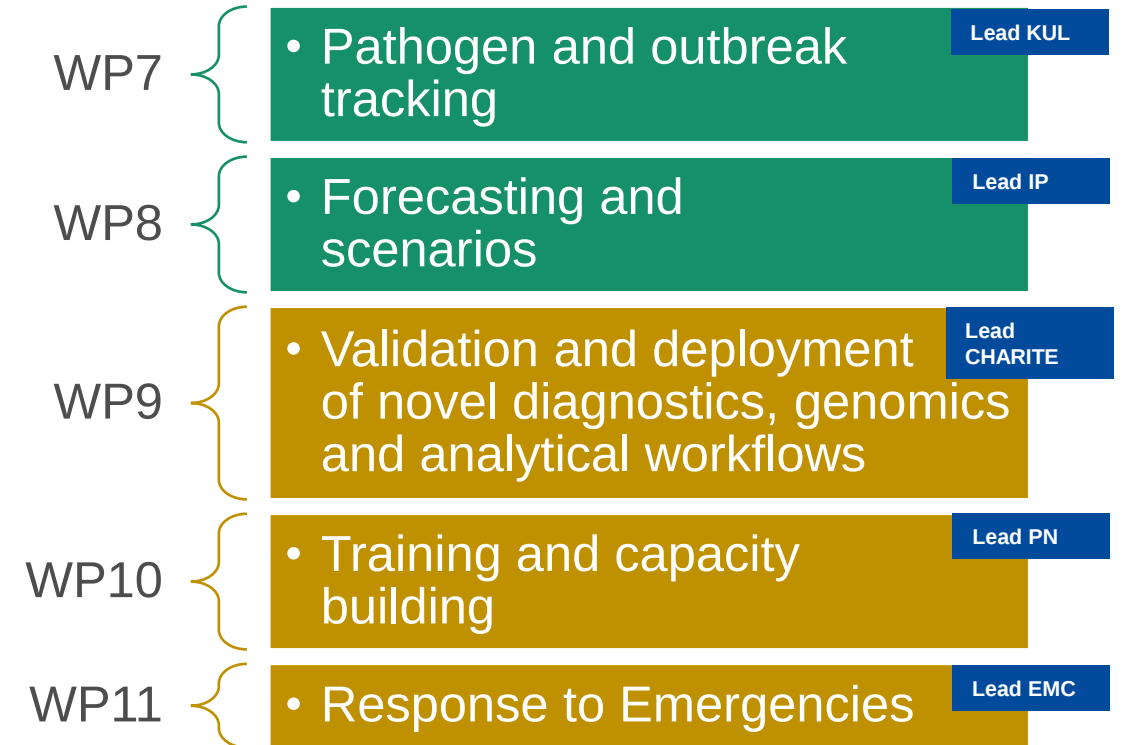
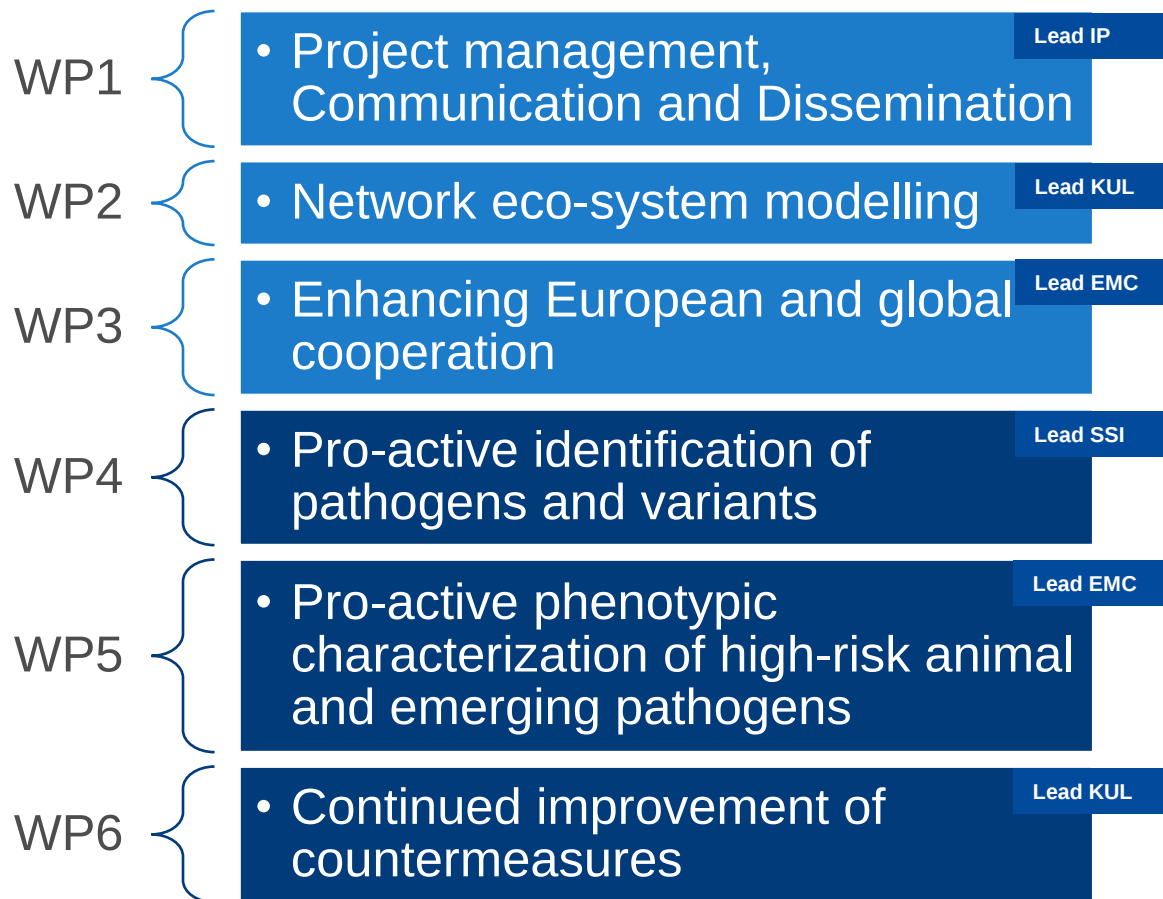


Figure 1: DURABLE consortium

DG HERA lab network

- EU4Health-funded project – € 25 Mio | 48 months
- HERA Lab network **DURABLE** = **D**elivering a **U**nified **R**esearch **A**lliance of **B**iomedical and public health **L**aboratories against **E**pidemics
- Objectives
 - **pathogen properties + interaction** with animal and human **hosts**
 - Increase understanding of **population immunity**
 - Development of anti-flavivirus **drug compounds**
 - Develop **modelling** of disease outbreaks based on lab data
 - Develop + deploy **diagnostics** for emergencies
 - Improve **collaboration** within network + outside stakeholders

DG HERA lab network - Work Packages



EURLs for public health: Legal base



- **23 November 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

- Published in the OJ on 6 December 2022, *entry into force 26 December 2022*
- **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
- **Article 11** - Support for international and field preparedness and response



EURLs for public health: Article 15 (I)



1. The Commission may, by means of **implementing acts**, designate EURLs in the area of public health or for specific public health areas relevant for the implementation of the SCBTH Regulation. **The aim** is to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by MS.

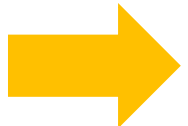
2. The EU reference laboratories shall be **responsible for** coordinating the network of national reference laboratories, in particular, in the following areas:

1. reference diagnostics, including test protocols;
2. reference material resources;
3. external quality assessments;
4. scientific advice and technical assistance;
5. collaboration and research;
6. monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and
7. training.

EURLs for public health: Article 15 (II)

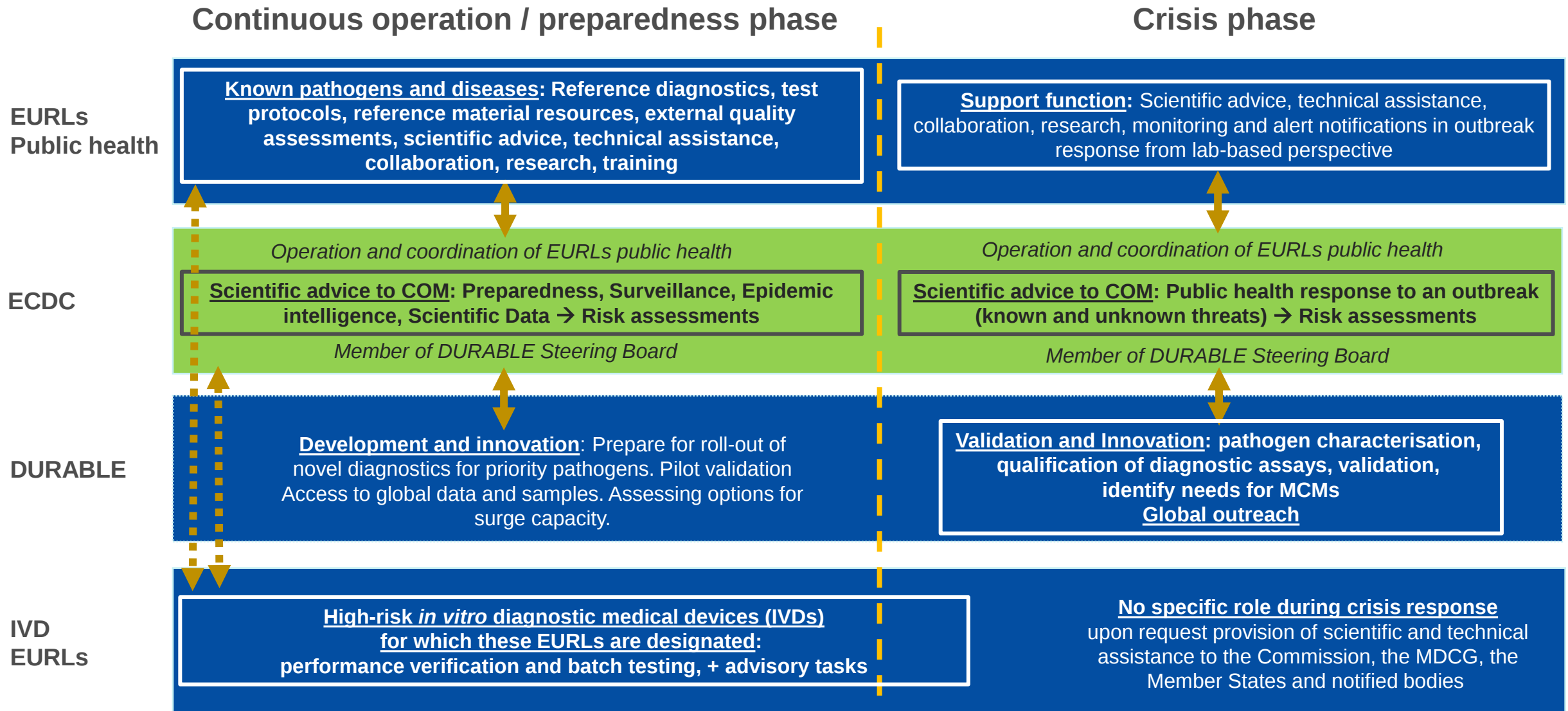


3. The network of EU reference laboratories shall be **operated and coordinated by the ECDC**, in cooperation with the **WHO reference laboratories**.
4. The EURLs will be designated for a minimum period of **four years** and be reviewed regularly.
5. The EURLs shall be **impartial**, have suitably qualified **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**, are able to perform tasks in **emergency situations**, comply with **biosecurity standards** and are **accredited** (Regulation (EC) No 765/2008).
6. **Grants** may be awarded to the EURLs for the costs that they incur - EU4Health Programme.



EU4Health WP2023: CP-p-23-05-02 (prep action) and CP-g-23-05-01 (direct grants)

Continuous operation/preparedness phase vs Crisis phase – Responsibilities



Indicative timeline ongoing work & next steps

