

**Herman Goossens and Marc Bonten**  
ECRAID-Plan Coordination Team  
University Medical Center Utrecht



# Short history of ECRAID

## High-level design completed in November 2016

### Coordination Team



Herman Goossens



Marc Bonten



Frank Deege



Chantal van Litsenburg

### Working Group



Christopher Butler



Peter Horby



Oliver Cornely



Menno de Jong



Bruno François



Jesús Rodríguez Baño



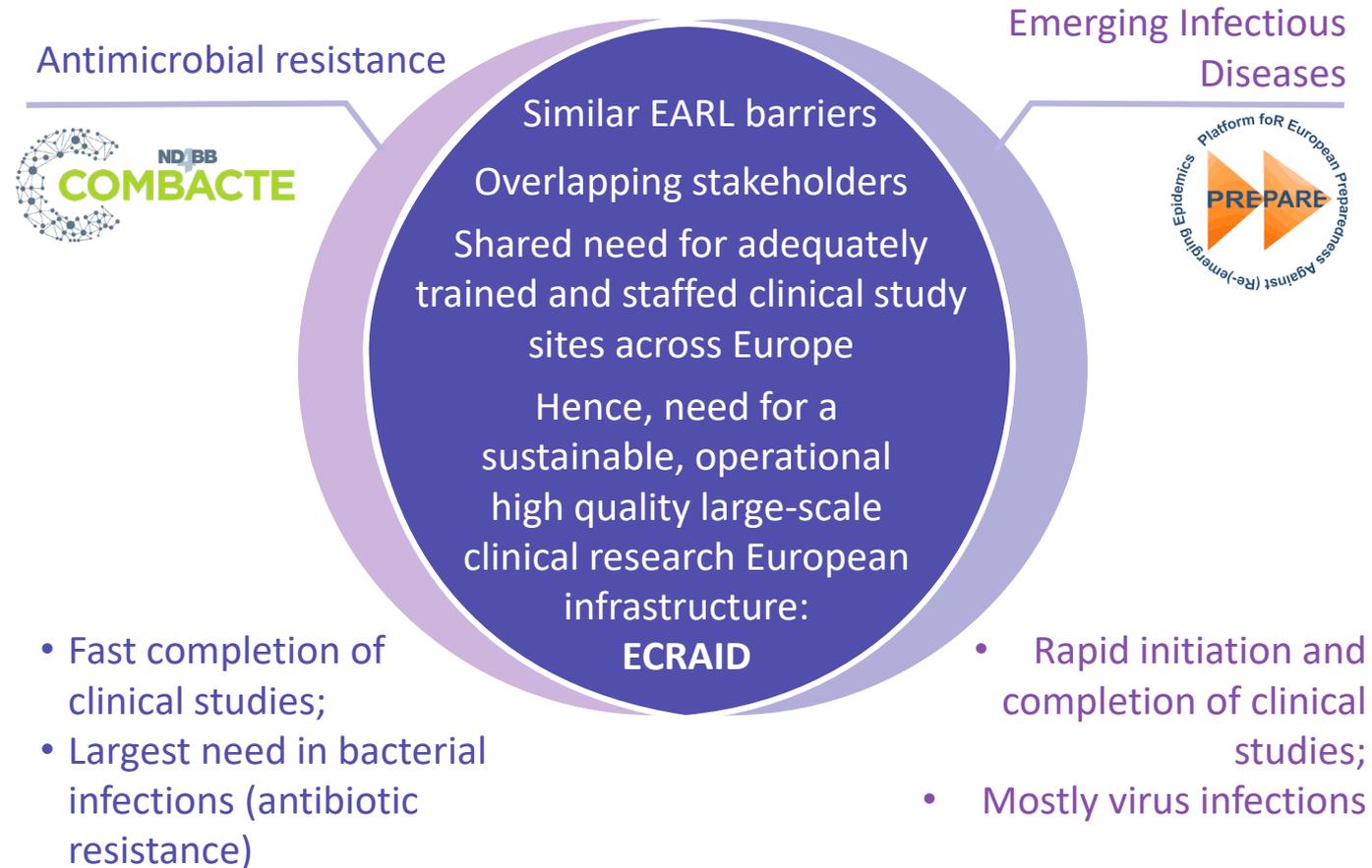
Stephan Harbarth



Evelina Tacconelli



# Leveraging EU/IMI investments in clinical research on AMR and EID



# ECRAID acronym: the European Clinical Research Alliance on Infectious Diseases.

## Our mission

To reduce the impact of infectious diseases on individual and population health, by efficiently generating rigorous evidence for new or improved diagnosis, prevention and treatment of infections and to better respond to infectious disease threats.

## Our vision

To establish a sustainable, single-point-of-access, coordinated, pan-European, clinical research network on infectious diseases building on the infrastructures and processes of PREPARE and COMBACTE.



# Core service is clinical research

## Clinical research design, execution and reporting



- ✓ **Phases:** Phase I - IV
- ✓ **Scope:** Prospective and retrospective
- ✓ **Source:** industry-driven and investigator driven
- ✓ **Pathogens:** viruses, bacteria, protozoa, fungi
- ✓ **Interventions:** vaccines, diagnostics, therapeutics, medical devices, routine care
- ✓ **Objectives:** Prevention, treatment, diagnosis, screening, quality of life, health economic evaluation, epidemiological, etc.
- ✓ **Types:** observational (analytical and descriptive), randomized controlled trials, database, perpetual trials (“warm base”, adaptive platform), ...

Encouraged by  
the Public  
sector support

## Kobé Communique



G7 Health Ministers' Meeting  
11-12 September 2016

*“we encourage governments to consider the need for establishing a global clinical studies network on drug resistance that provides access to a large clinical research infrastructure for the design, coordination and conducting of clinical trials and studies in cooperation with the existing global experts networks to ensure the common benefit of the outcomes”*

References: 1) Shiozaki et al. Lancet. 2016;388 (10051):1262-3. 2) [Kobe Communiqué](#) by G7 Kobe Health Ministers' Meeting. Sep 11-12, 2016.

Encouraged by  
the Private  
sector support

Industry Roadmap  
for Progress on  
Combating  
Antimicrobial  
Resistance

20 September 2016

*“... we commit to:*

*Support the creation of open and **sustainable clinical trial networks globally**, with our expertise and experience.*

*As proposed by the AMR Review, this would build on work started in Europe and US with the goal of improving the speed and efficiency of conducting clinical trials”*

Reference: [Industry Roadmap for Progress on Combating Antimicrobial Resistance](#). Sep 20, 2016



## **Creation of a European wide sustainable clinical research network for infectious diseases**

### **Specific Challenge:**

**There is a need to establish a clinical research network across Europe that has the capacity and capability to directly enrol patients with infectious diseases, to increase efficiency for testing and developing new diagnostic, preventive and/or therapeutic strategies and therapies.**

**This should allow generating rigorous evidence to improve the diagnosis, prevention and treatment of infections and to better respond to infectious disease threats,**

**and contribute to the G7 aim concerning the need to establish a global clinical studies network on drug resistance**

**that provides access to a large clinical research infrastructure for the design, coordination and conducting of clinical trials and studies.**

## **Creation of a European wide sustainable clinical research network for infectious diseases**

### **Scope:**

Proposals should build on successful European collaborative initiatives such as PREPARE and COMBACTE and further advance clinical research in the field of infectious disease by supporting the establishment of a European wide multidisciplinary clinical research network.

Such a network should be capable of performing all clinical trial aspects encompassing study design, execution and reporting. It should develop and allow for innovative research approaches and enable flexibility in responding to unpredictable events and signals.

The network should provide clear and direct access for stakeholders including academic organizations, SMEs and larger industry to perform clinical studies.

The proposal should develop a business plan to ensure the sustainability of the network. The network should actively disseminate information and contribute to awareness rising. Furthermore, it should also create synergies with global initiatives, enabling quick and smooth interactions and collaboration across the world.



### Overall goal:

Developing the detailed business plan for ECRAID, building on the high-level design developed in 2016 by the ECRAID Working Group

#### I. To develop the detailed business plan for ECRAID, based on COMBACTE and PREPARE.

The ECRAID Business Plan will serve three main purposes:

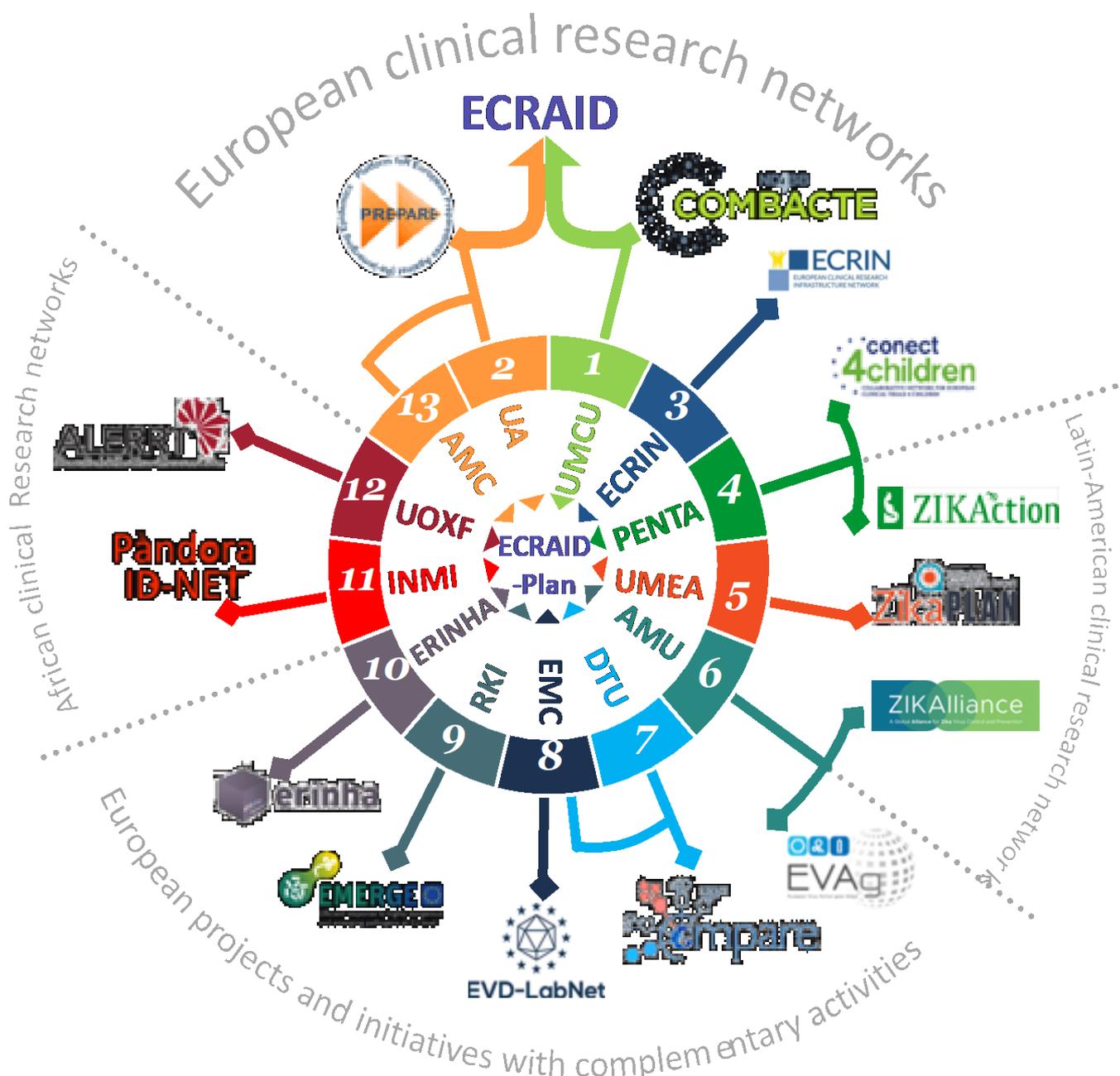
- Function as the central guiding document presenting the agreed strategy for the development of ECRAID;
- Serve as a means to build awareness of and support for ECRAID amongst stakeholders;
- Attract sufficient start-up funding/income to commence operations in ECRAID.

#### II. To align the ECRAID business plan to the activities, roles, mandates and ambitions of relevant other initiatives and organisations active in clinical research or complementary research on ID.

#### III. To build awareness of and create support for the ECRAID initiative amongst the broader group of stakeholders.

# ECRAID-Plan

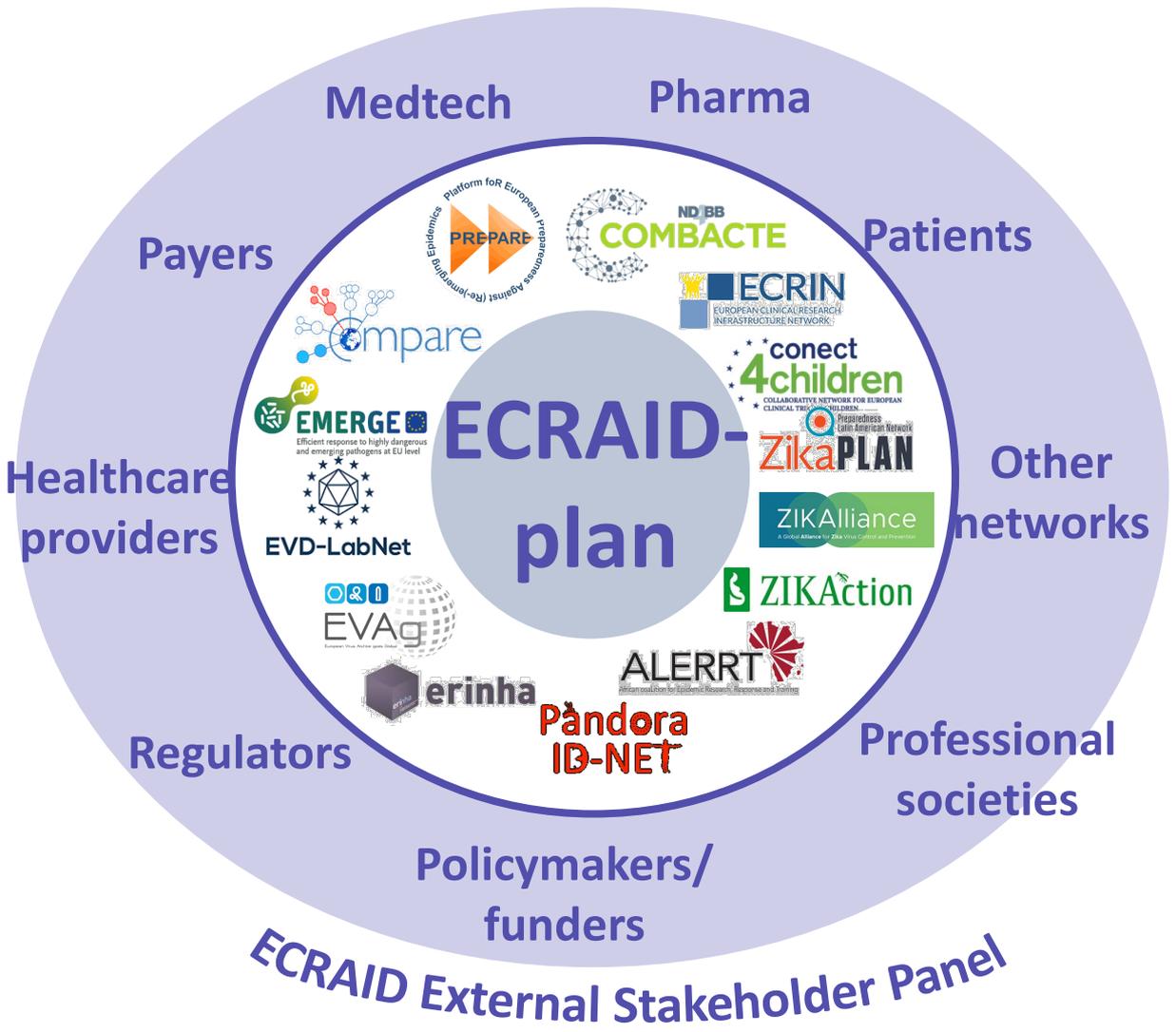
*Direct involvement of relevant other EU funded projects, networks and organisations*



# ECRAID-Plan

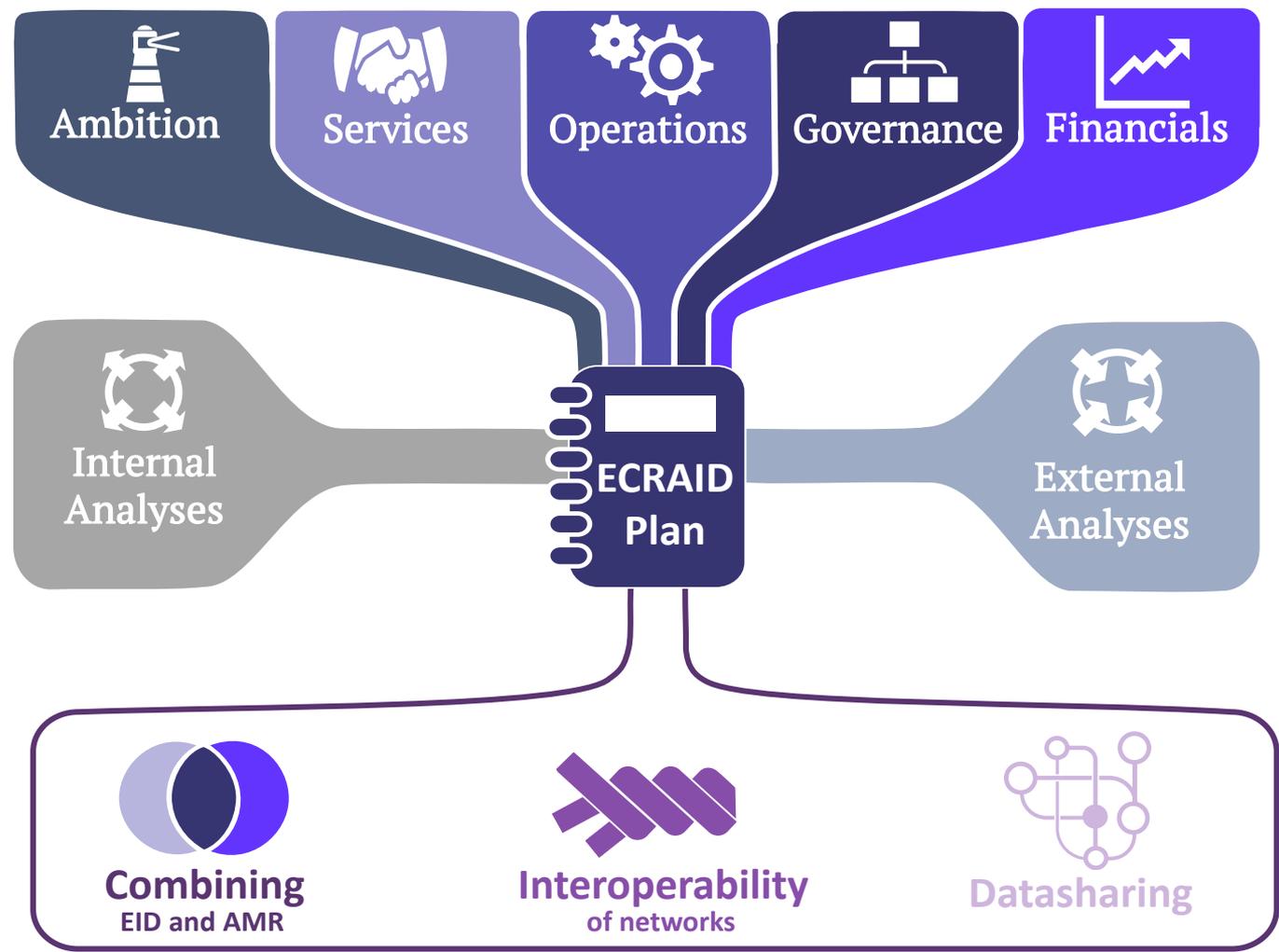
## Multi-Actor Approach

built-in consultation with key stakeholder groups, comprising the health system



# ECRAID-Plan

## Components of the plan



## Strategic themes



# ECRAID-Plan

**a** Internal and external analyses by WP1 and WP2 teams, consisting of representatives of European Clinical Research Networks + External consultancy



**b** WP 3-4-5 teams, consisting of representatives of all partners draft components of the ECRAID-Plan

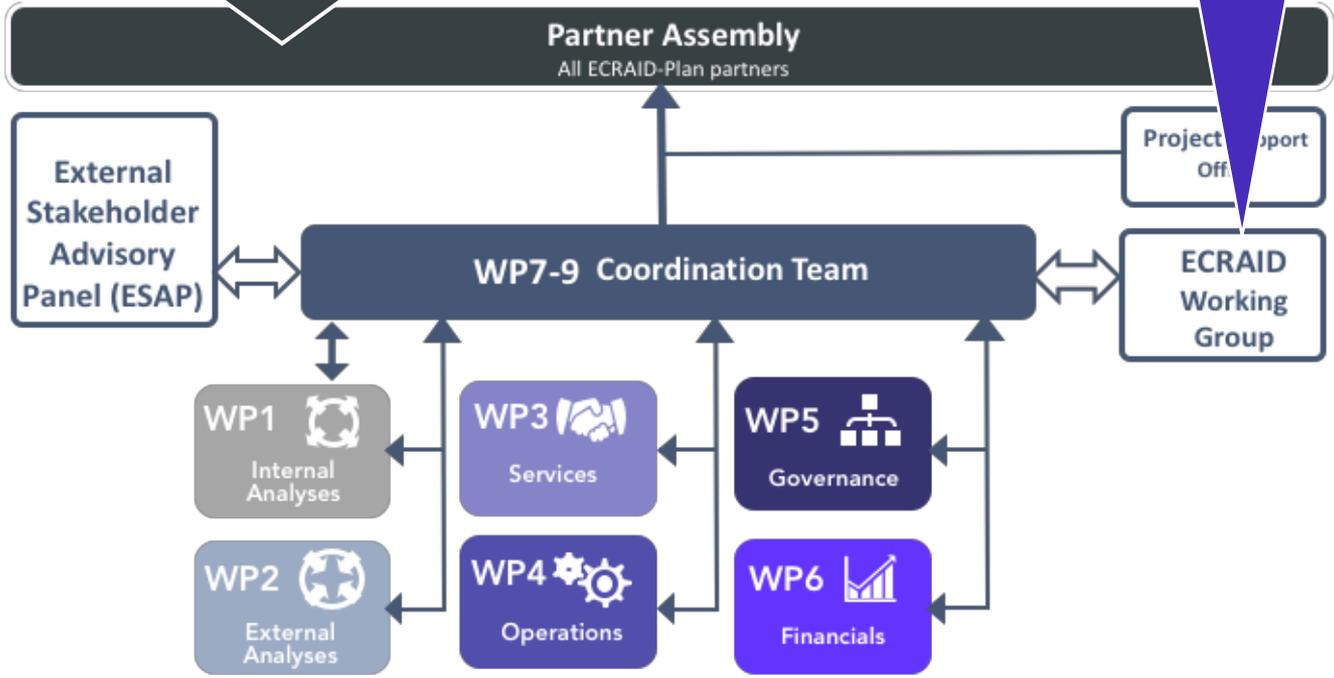
- Services
- Operations
- Governance

**c** Coordination Team assembles the interim reports from the WP team 3-5 into one coherent draft Business Plan

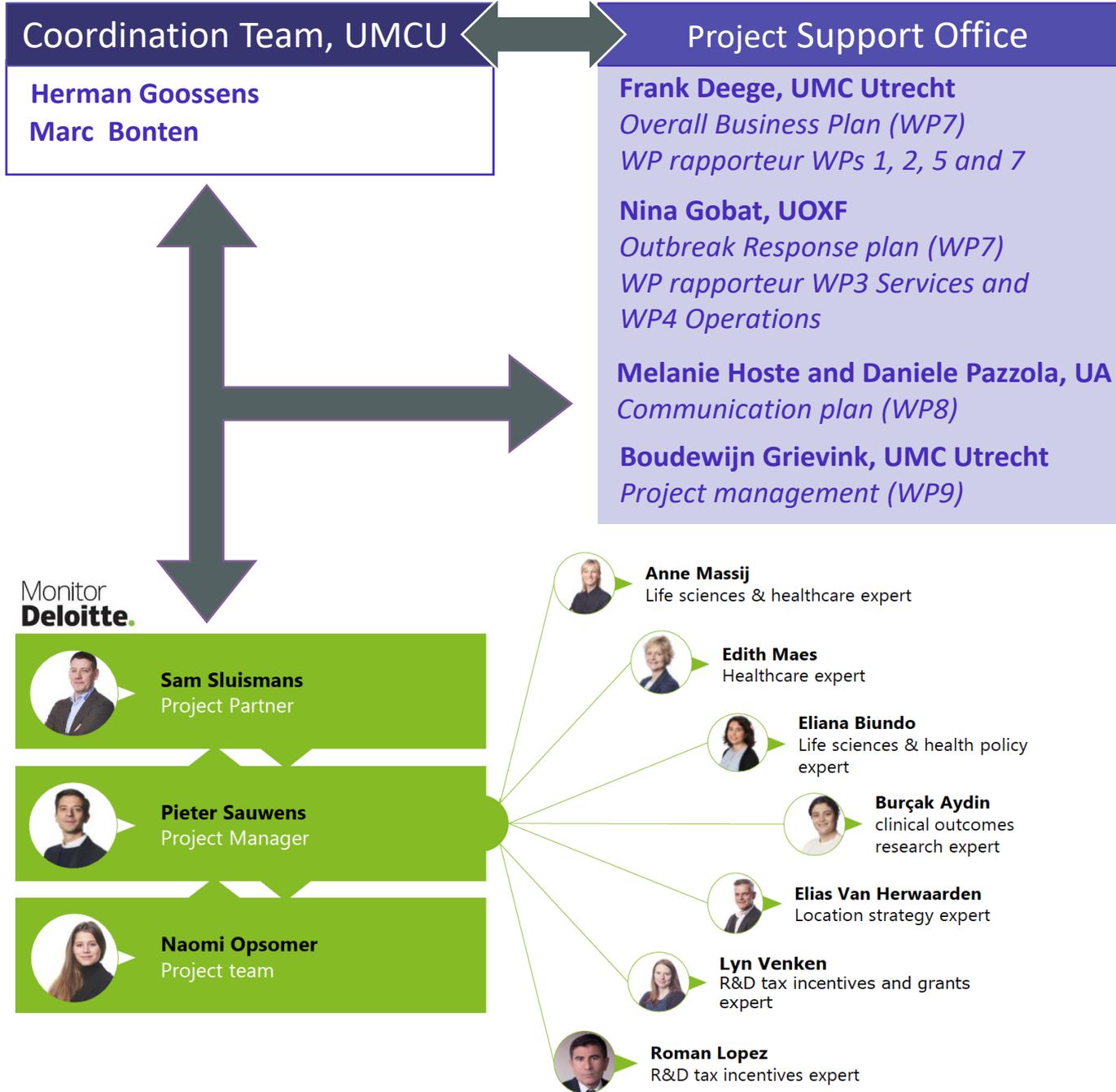
**ECRAID-Plan partners, Working Group and ESAP review and comment on version of the Business Plan**



# Project management structure of ECRAID-Plan



# Project management structure of ECRAID-Plan



*"It is amazing what  
you can accomplish if  
you do not care who  
gets the credit." -  
Harry Truman*

# ECRAID-Plan

## *Kick-off 16 January*

- 13:00** | Consortium and Working Group  
*1-2 minutes Introduction of each participant (introduce yourself, network you represent and role in the network and ECRAID-Plan)*
- 13:45** | **Herman Goossens**, University Medical Center Utrecht  
*ECRAID and ECRAID-Plan, towards a sustainable infrastructure for clinical research of infectious diseases*
- 14:30** | **Melanie Hoste & Daniele Pazzola**, University of Antwerp  
*Communication Workshop*
- 15:30** | **Marc Bonten**, University Medical Center Utrecht  
*Summary of Communication Workshop*
- 15:45** | Coffee break
- 16:00** | **Frank Deege and Boudewijn Grievink**, University Medical Center Utrecht  
*ECRAID-Plan*
- 16:15** | **Nina Gobat**, University of Oxford  
*Making Progress with ECRAID-Plan Task 4.5: Outbreak Preparedness*
- 17:00** | **WP Plans, Distribution of tasks, Role of Consultant, Kick-off meeting, Next meetings**  
*ECRAID-Plan Coordination Team*



# ECRAID-Plan

## *Big issues*

Scientific independence



Public-Private collaboration

Coordination



Autonomy

Clinical research on AMR



Clinical research on EID



*Core  
messages  
capturing the  
big issues*

## **Core Message 1:**

Forging a sustainable European clinical research infrastructure stemming from PREPARE and COMBACTE

## **Core Message 2:**

Boosting cooperation and dismantling silos between disciplines

## **Core Message 3:**

Building public-private alliances in clinical research on infectious diseases and AMR

# ECRAID-Plan

*To be clear...*

*ECRAID is the **logical step** to evolve from two publicly (PREPARE) and publicly-privately (COMBACTE) funded project-based ad-hoc collaborations, **to one integrated pan-European clinical research network, with appropriate governance and legal structures, generating sustainable source of income***



# ECRAID-Plan

*To be clear...*

ECRAID is **inclusive** to those partners that share its mission, vision and values, *but is **not** meant to integrate or take over other networks*

ECRAID focuses **on clinical research**, *that is linked to pre-clinical and public health research (networks).*

ECRAID focuses **on Europe**, *but aims to be globally linked.*

ECRAID focuses **on AMR and EID**, *but recognises the inherent differences in clinical research in both*



# ECRAID-Plan

## *What ECRAID could offer*

- ✓ Clinical Trial Network for infectious diseases in hospital care and primary care, adults and children
- ✓ Rapid access to target European patient populations
- ✓ Globally embedded
- ✓ Single-point of access into a high quality, business oriented clinical research network
- ✓ Focus on services that alleviate the Ethical, Administrative, Regulatory and Logistical (EARL) barriers to clinical research (faster start-up, reduce timelines, lower costs)
- ✓ Direct access to leading expertise on Infectious Diseases
- ✓ An active network, continuously including patients in platform trials, allowing rapid clinical research response in the event of an EID or pandemic threat



# ECRAID-Plan

*Hugely  
ambitious,  
we might fail,  
but...*

This is a **once-in-a-lifetime opportunity** to gear up the public and private resources already invested in COMBACTE and PREPARE (and other projects that will be discussed today!).

If we don't **collaborate**, we will fail and stand **accused of having turned our back** on the prospect of tackling pandemic infectious diseases, and effective investigations and treatments of infections for our citizens.



# VALUE-Dx

**In anticipation of signature of the Consortium Agreement and Grant Agreement!!**

**Starting date: 1 March – Kickoff: 1 - 4 April, Madrid**

# Objectives of VALUE-Dx:

*Helping to build the economic case for rapid diagnostics as a public good in the fight against AMR*

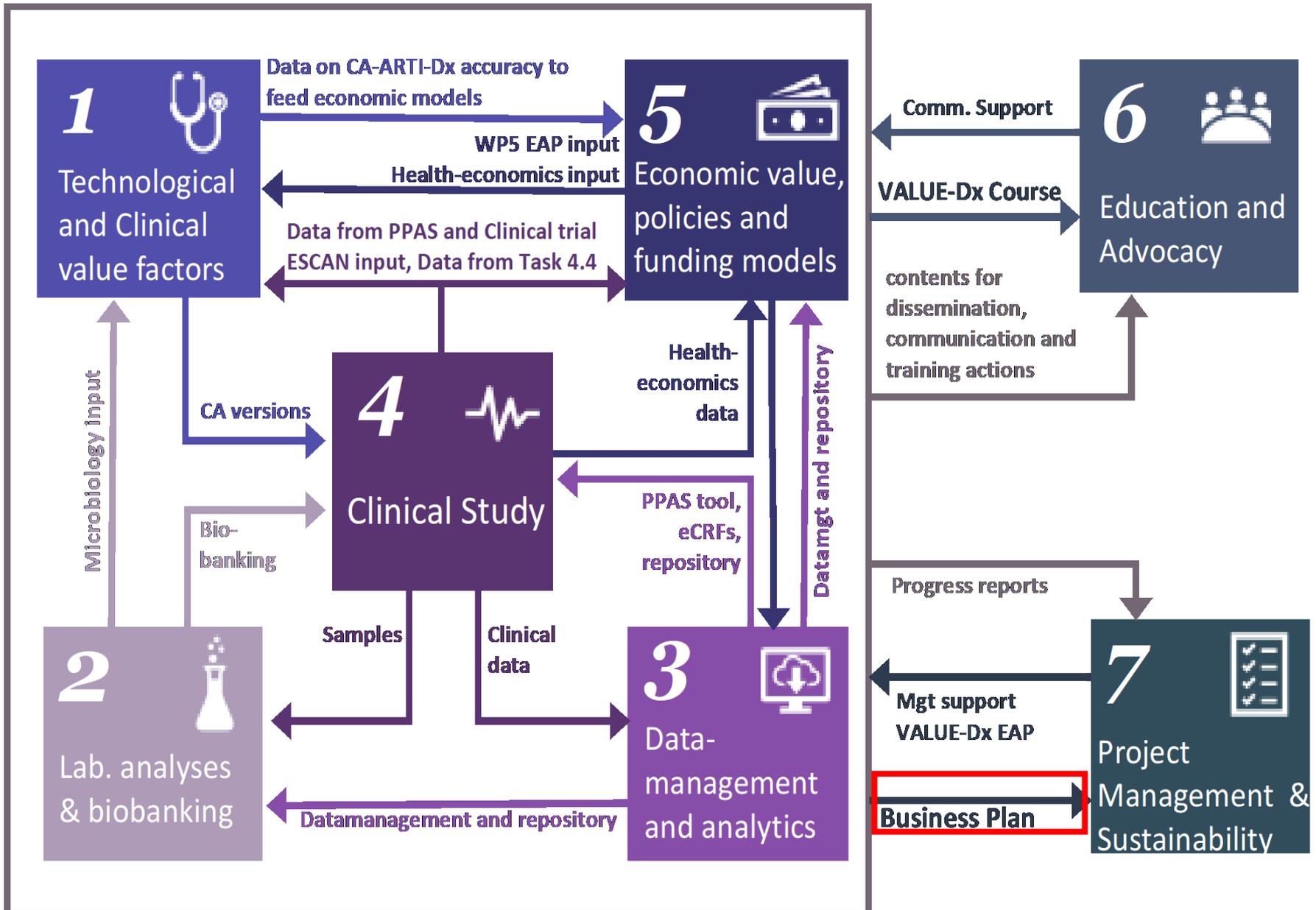
1. To **design a health-economic framework (HEF)** to assess and demonstrate the value of diagnostics both for individual patients and for public health impact by reducing antibiotic use and subsequent antibiotic resistance among patients.

2. To **establish a sustainable European Standardised Care Network** adequately trained and resourced to conduct clinical trials evaluating the value of diagnostics.

3. To **design and implement clinical studies to demonstrate the value of diagnostics** in the optimal management of Community-Acquired Acute Respiratory Tract Infections (CA-ARTIs)

4. To **explore, define and attempt to resolve the psychological, ethical and social barriers** which prevent the more widespread adoption of diagnostics delivering healthcare to the population.

# Interaction between the Workpackages



# Access to Clinical Trial Networks



**Primary  
care** +

>200 primary care  
practises in >20  
European countries



Genetics to combat Resistance against  
Antibiotics in Community-acquired STI in Europe

- ✓ Recruited over 20,000 patients into clinical studies on ARTI
- ✓ Randomised 3,268 participants in a response-adaptive platform trial of a drug for a CA-ARTI

**Chris Butler**



**Hospital  
care + Labs** +

>800 hospitals and  
>600 labs in >40  
European countries



ND/BB  
COMBACTE

- ✓ To date, this network is managing 17 trials, including phase I – III trials for 6 new compounds against multi-resistant bacteria, and recruited over 12,000 patients.

**Marc Bonten (Clin)  
Herman Goossens (Lab)**



+ **Pediatric  
care** +

90 paediatric clinical  
sites in 18 countries



www.penta-id.org

- ✓ Active a.o in ZIKACTION, PREPARE, C4C (IMI2)

**Carlo Giaquinto**



+ **Long Term  
Care**

Nursing homes and  
rehabilitation centres  
in 11 countries in  
Europe and Israel  
with more than  
14,000 LTCF beds

- ✓ Experience in clinical trials on antibiotic use, influenza epidemiology and vaccines, microbiome and more.

**Evelina Tacconelli  
Mical Paul** <sup>28</sup>



# General Assembly (GA)

EFPIA partners , IMI-JU Associated Partners, Beneficiaries

## Executive Board (EB)

### Coordination Team (CT)

 <b>Herman Goossens</b> Coordinator and Project Leader	 <b>Philippe Cleuziat</b> Industry Leader	 <b>Tim Jinks</b> Wellcome Leader
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## Academic (top row) and industry (bottom row) WP co-leads

WP1	WP2	WP3	WP4	WP5	WP6
 <b>Evelina Tacconelli</b>	 <b>Surbhi Malhotra</b>	 <b>Frank Leus</b>	 <b>Chris Butler</b>	 <b>Maarten Postma</b>	 <b>Murat Akova</b>
 <b>Jorge Villacian</b>	 <b>Carine Malcus</b>	 <b>Jean-Francois Gorse</b>	 <b>Kieran Clarke</b>	 <b>Isabelle Tongio</b>	 <b>Renuka Gadde</b>

## WP teams

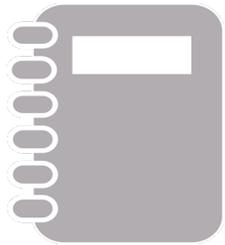
 Technological and Clinical value factors	 Lab. analyses & biobanking	 Data Management and analytics	 Clinical Study	 Economic value, policies and funding models	 Education and Advocacy
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### VALUE-Dx External Advisory Panel (EAP)

-  patients
-  healthcare providers
-  diagnostic industry
-  scientific experts
-  HTA bodies
-  payers
-  regulators
-  government / funders

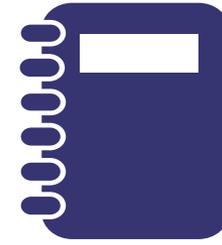
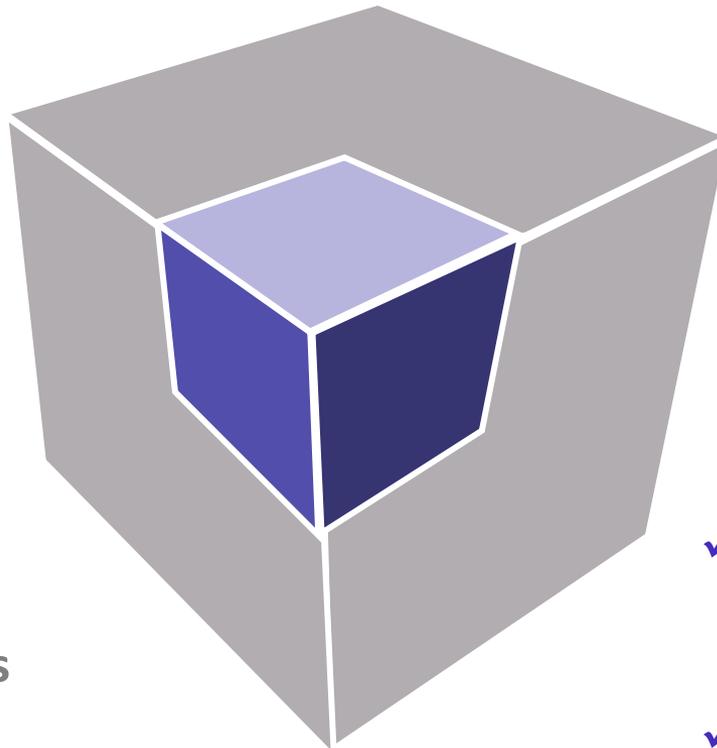
Project Management Office (PMO)

# Integration of sustainability plans of ECRAID-Plan and VALUE-Dx projects



## ECRAID-plan sustainability plan

- ✓ Building infrastructure for clinical trials in all clinical care settings



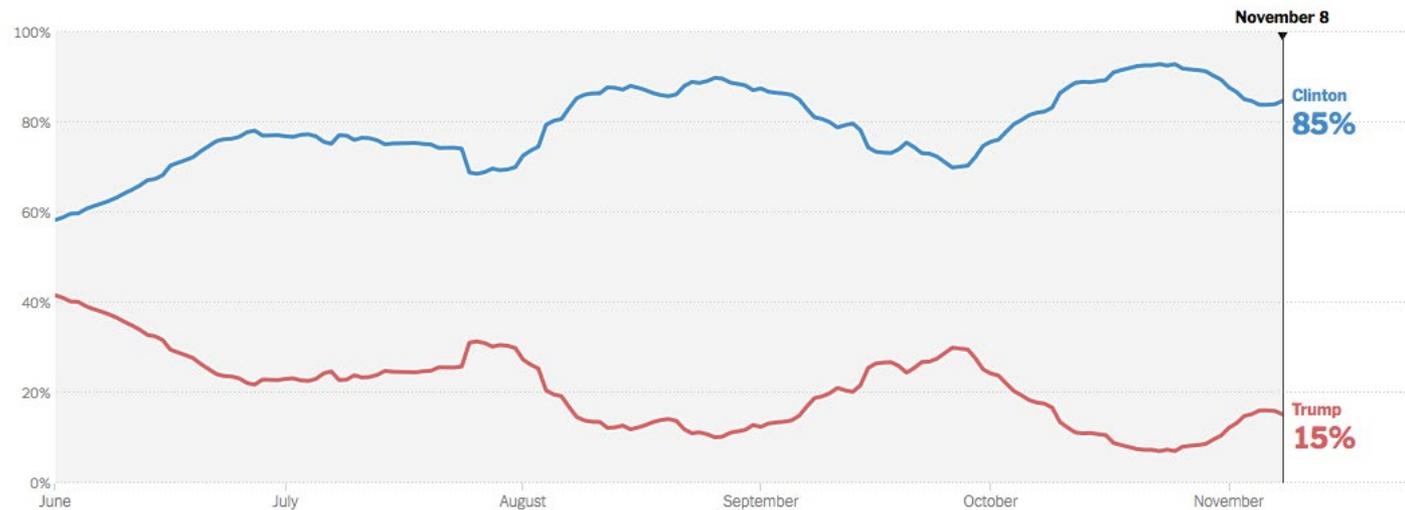
## VALUE-Dx sustainability plan

- ✓ Building infrastructure for clinical trials and labs on diagnostics
- ✓ Biobank
- ✓ Database

# ECRAID



*Against the odds?*



New York Times, Tuesday, November 8, 2016 at 10:20 PM ET

ECRAID-Plan Kick-off meeting  
16-17 January 2019



ECRAID-Plan is funded by the European Commission under Grant Agreement 825715

# ECRAID- Dream

*“The European Dream emphasizes community relationships over individual autonomy, cultural diversity over assimilation, quality of life over the accumulation of wealth, sustainable development over unilateral material growth, deep play over unrelenting toil, universal human rights and the rights of nature over property rights, global cooperation over the unilateral exercise of power”*

The European Dream, by Jeremy Rifkin



**Thank you**