ECRAID

European Clinical Research Alliance on Infectious Diseases

Herman Goossens & Marc Bonten

ECRAID-Plan Coordinators

University Medical Center Utrecht

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

European Clinical Trial Networks

Primary care

>200 primary care practises in >20 European countries

- ✓ 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

>900 hospitals and >750 labs in >40 European countries

- ✓ This network is/was managing 26 trials, including phase I – III trials including many new compounds against multi-resistant bacteria, and recruited 17,735 patients.

Miquel Ekkelenkamp (Clin)
Herman Goossens (Lab)

Pediatric care

90 paediatric clinical sites in 18 countries

- ✓ 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

Short history of ECRAID and ECRAID-Plan

Timeline

November 2016	High Level ECRAID design by the coordination team & working group
Summer 2017	H2020 CSA Call for 2-year project developing a business plan for CRN
Spring 2018	Application H2020 project (ECRAID-Plan)
Fall 2018	Grant awarded by European Commission
17 January 2019	Kick-Off of ECRAID-Plan
December 2020	*Finalized business plan for ECRAID*

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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

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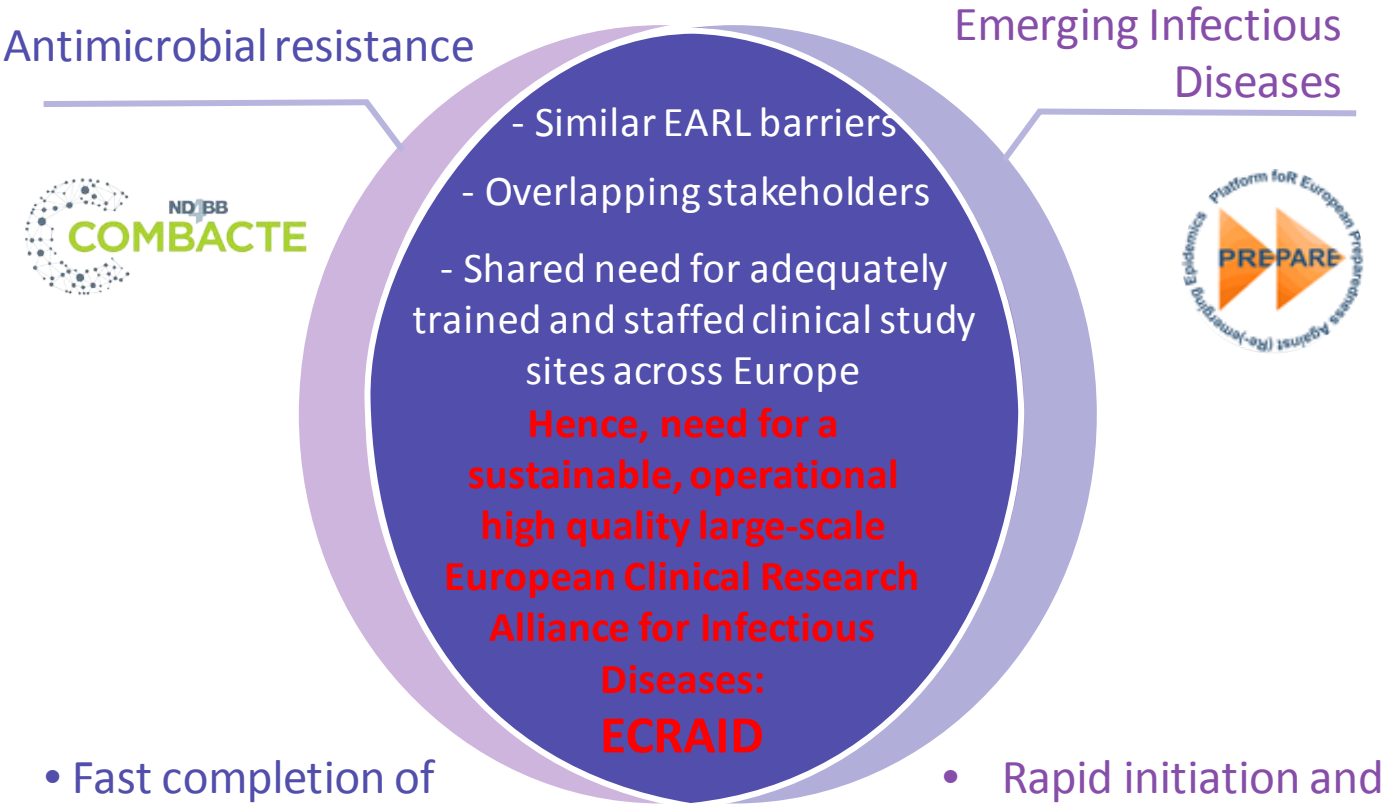
Leveraging EU/IMI investments in clinical research on AMR and EID



- Fast completion of clinical studies;
- Focus on bacterial infections and antibiotic resistance

- Rapid initiation and completion of clinical studies;
- Focus on viral infections

H2020 CSA call text

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.

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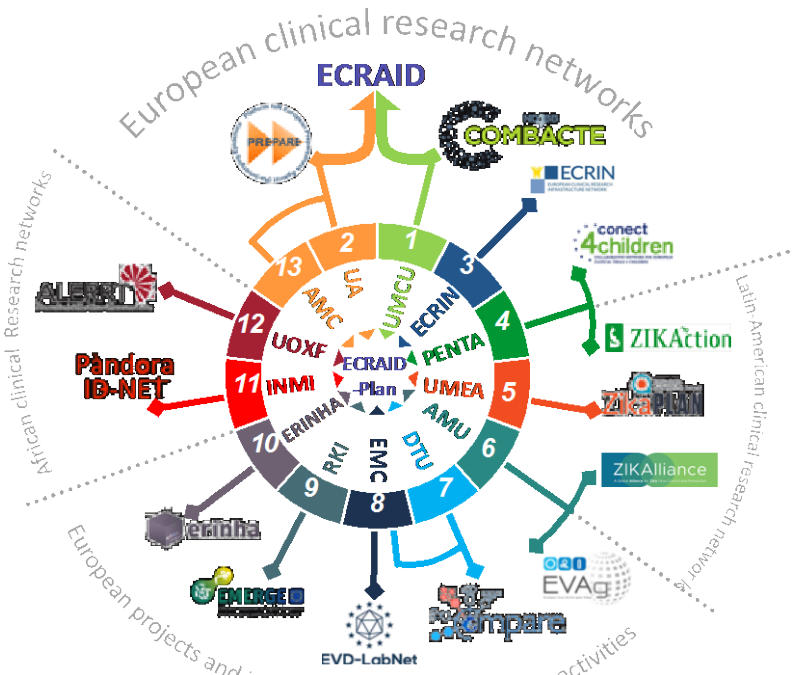
ECRAID-Plan Partners and Working Group

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



Consortium partners

Working Group

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ECRAID-Plan *Goal and Objectives*

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.**

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ECRAID-Plan

Project management structure

Coordination Team, UMCU

Herman Goossens
Marc Bonten

Project Support Office

Frank Deege, UMC Utrecht
Overall Business Plan (WP7)
WP rapporteur WPs 1, 2, 5 and 7

Nina Gobat, UOXF
Outbreak Response plan (WP7)
WP rapporteur WP3 Services and WP4 Operations

Melanie Hoste and Daniele Pazzola, UA
Communication plan (WP8)

Boudewijn Grievink, UMC Utrecht
Project management (WP9)

Monitor Deloitte.

Sam Sluismans
Project Partner

Pieter Sauwens
Project Manager

Naomi Opsomer
Project team

Anne Massij
Life sciences & healthcare expert

Edith Maes
Healthcare expert

Eliana Biundo
Life sciences & health policy expert

Burçak Aydin
clinical outcomes research expert

Elias Van Herwaarden
Location strategy expert

Lyn Venken
R&D tax incentives and grants expert

Roman Lopez
R&D tax incentives expert

ECRAID-Plan

Recently kicked off on 17 January 2019

"We expect the ECRAID-Plan to come up with a business plan that offers concrete solutions and prepares Europe to better deal with antimicrobial resistance and large infectious diseases outbreaks"
–EU commissioner Carlos Moedas,

"an inspiring vision of a pan-European infrastructure for patients and communities, bringing public health, clinical and laboratory, science, innovation and society together." – Sir Jeremy Farrar.

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ECRAID-Plan

Process of developing a business 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

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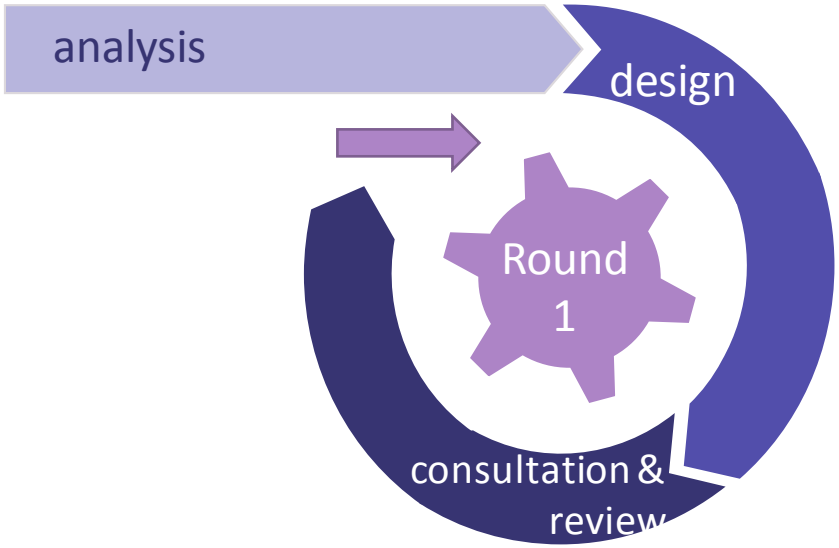
Where are we now?



Planning 2019

March – April 2019

- **Stakeholder Interviews, desk research & SWOT by Deloitte**

May 2019

- **First round consultation & review with ECRAID-Plan Partners and Working Group**

May to August

- **Stakeholder Interviews, desk research & SWOT by Deloitte**

September 2019

- **Stakeholder meeting with industry at ASM/ESCMID in Boston**
- **Second round consultation & review**

December 2019

- **Third round consultation & review**

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ECRAID

Why?

*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***

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ECRAID

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

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Thank you