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

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Working Group

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

Antimicrobial resistance

Emerging Infectious Diseases

Similar EARL barriers
Overlapping stakeholders
Shared need for adequately trained and staffed clinical study sites across Europe
Hence, need for a sustainable, operational high quality large-scale clinical research European infrastructure: ECRAID

• Fast completion of clinical studies;
• Largest need in bacterial infections (antibiotic resistance)

• Rapid initiation and completion of clinical studies;
• Mostly virus infections

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

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

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.
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”

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”

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

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Multi-Actor Approach

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

Strategic themes

Combining EID and AMR

Interoperability of networks

Data sharing
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ECRAID-Plan analysis & review

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

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
ECRAID-Plan Kick-off meeting
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Project management structure of ECRAID-Plan
"It is amazing what you can accomplish if you do not care who gets the credit." - Harry Truman
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>13:00</td>
<td><strong>Consortium and Working Group</strong>&lt;br&gt;1-2 minutes introduction of each participant (introduce yourself, network you represent and role in the network and ECRAID-Plan)</td>
</tr>
<tr>
<td>13:45</td>
<td><strong>Herman Goossens</strong>, University Medical Center Utrecht&lt;br&gt;<em>ECRAID and ECRAID-Plan, towards a sustainable infrastructure for clinical research of infectious diseases</em></td>
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<tr>
<td>14:30</td>
<td><strong>Melanie Hoste &amp; Daniele Pazzola</strong>, University of Antwerp&lt;br&gt;<em>Communication Workshop</em></td>
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<tr>
<td>15:30</td>
<td><strong>Marc Bonten</strong>, University Medical Center Utrecht&lt;br&gt;<em>Summary of Communication Workshop</em></td>
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<tr>
<td>15:45</td>
<td><strong>Coffee break</strong></td>
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<tr>
<td>16:00</td>
<td><strong>Frank Dege and Boudewijn Grieving</strong>, University Medical Center Utrecht&lt;br&gt;<em>ECRAID-Plan</em></td>
</tr>
<tr>
<td>16:15</td>
<td><strong>Nina Gobat</strong>, University of Oxford&lt;br&gt;<em>Making Progress with ECRAID-Plan Task 4.5: Outbreak Preparedness</em></td>
</tr>
<tr>
<td>17:00</td>
<td><strong>WP Plans, Distribution of tasks, Role of Consultant, Kick-off meeting, Next meetings</strong>&lt;br&gt;<em>ECRAID-Plan Coordination Team</em></td>
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Big issues

- Scientific independence
- Public-Private collaboration
- Coordination
- Autonomy
- Clinical research on AMR
- Clinical research on EID

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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 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.
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**.
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
Hugely ambitieus, 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.
Access to Clinical Trial Networks

**Primary care**
- >200 primary care practices 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

**Hospital care + Labs**
- >800 hospitals and >600 labs in >40 European countries
- 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.

**Pediatric care**
- 90 paediatric clinical sites in 18 countries
- Active a.o in ZIKACTION, PREPARE, C4C (IMI2)

**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.

**Chris Butler**
**Marc Bonten (Clin)**
**Herman Goossens (Lab)**
**Carlo Giaquinto**
**Evelina Tacconelli**
**Mical Paul**
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
Against the odds?

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