



## EXECUTIVE SUMMARY BUSINESS PLAN

THIS EXECUTIVE SUMMARY DESCRIBES THE CURRENT STATUS OF THE ECRAID BUSINESS PLAN. ALL CONTENTS ARE SUBJECT TO FURTHER AMENDMENT BASED ON ONGOING DISCUSSIONS AMONGST THE ECRAID-PLAN PARTNERS AND CONSULTATIONS WITH EXTERNAL STAKEHOLDER ORGANISATIONS.

October 2019

ECRAID-Plan is funded by the European Commission under grant agreement 825715



# 1. Introduction

The European Clinical Research Alliance for Infectious Diseases (ECRAID) is the working title of an envisaged European clinical research network for infectious diseases that is to emerge from the EU FP7 funded PREPARE project ([www.prepare-europe.eu](http://www.prepare-europe.eu)) and the IMI-funded COMBACTE project ([www.combacte.com](http://www.combacte.com)).

ECRAID-Plan is a two-year project (January 2019-Dec 2020) that will develop the business plan for ECRAID. Funded by the European Commission's H2020 programme (grant number 825715), ECRAID's business plan will:

- Detail the scope, services, operations, governance, financial and business model for ECRAID and will attract start-up investment for ECRAID operations.
- Set out a strategy that aligns with the mandates, activities and ambitions of other relevant organisations, including European public health and pre-clinical networks and international clinical research networks. These networks are strategic partners in ECRAID-Plan.
- Build awareness and create support for ECRAID among a broad group of stakeholders.

ECRAID-Plan:

- Involves direct involvement of relevant EU funded projects, networks and organisations. These strategic partners meet regularly in face-to-face workshops to feed into iterations of ECRAID's business plan.
- Involves a multi-actor approach that engages key stakeholder groups in the health system, including industry partners, patient groups, regulators, policy makers, professional societies, healthcare providers and funders.

ECRAID-Plan was launched at a high-level kick off meeting in January 2019, Brussels. The project started with a detailed stakeholder analysis conducted together with consultants from Monitor Deloitte, including an "inside-out" gap-analysis and an "outside-in" analysis of external stakeholder needs and wants from ECRAID. Following the kick-off meeting, an interviewee list and questionnaire were developed. With ECRAID's aim to bring together the entire ecosystem, a broad list of both internal and external stakeholders have been interviewed (to date, more than twenty interviews were conducted). The objective of these interviews was to:

- Understand how the market is evolving;
- Understand the opportunities and threats in the industry that ultimately should shape ECRAID's mission and concept;

- Understand the strengths and weaknesses of the current networks that should form ECRAID;
- Discuss how we can align the needs and expectations of the stakeholders (today and tomorrow) with the value proposition of ECRAID;
- Discuss the potential relationship to ECRAID stakeholders see for themselves;
- Discuss the potential risks and pitfalls for ECRAID, and how we can navigate these.

The input from the interviews has been reported back to the ECRAID Coordination and Support team, and processed into the draft business plans.

## 2. ECRAID-Plan partners

The table below lists the partners in ECRAID Plan.

	<b>Participant organisation name</b>	<b>Country</b>
1	University Medical Center Utrecht (( <b>UMCU</b> ))	The Netherlands
2	University of Antwerp ( <b>UA</b> )	Belgium
3	European Clinical Research Infrastructure Network ( <b>ECRIN</b> )	France
4	Fondazione PENTA ( <b>PENTA</b> )	Italy
5	Umeå Universitet ( <b>UMEA</b> )	Sweden
6	Aix-Marseille Université ( <b>AMU</b> )	France
7	Technical University of Denmark ( <b>DTU</b> )	Denmark
8	Erasmus University Medical Center ( <b>Erasmus MC</b> )	The Netherlands
9	Robert Koch Institut ( <b>RKI</b> )	Germany
10	ERINHA AISBL ( <b>ERINHA</b> )	Belgium
11	National Institute for Infectious Diseases Lazzaro Spallanzani ( <b>INMI</b> )	Italy
12	University of Oxford ( <b>UOXF</b> )	United Kingdom
13	Academic Medical Center ( <b>AMC</b> )	The Netherlands
14	UniversitätsKlinikum Heidelberg ( <b>UKH</b> ) ( <b>partner to be added</b> )	Germany

ECRAID will build on the foundations of the European consortia COMBACTE and PREPARE (see textbox 1), represented in ECRAID Plan by the coordinating entities UMCU and UA respectively.

### About COMBACTE

COMBACTE (Combatting Bacterial Resistance in Europe) is part of the IMI funded programme ND4BB (New Drugs for Bad Bugs) and focuses on improving the clinical development of antibiotics.

The goals are to create a self-sustaining antibacterial development network and to increase the efficiency of antimicrobial drug development. To this purpose it has established an infrastructure consisting of four high-quality networks: CLIN-Net, LAB-Net, STAT-Net and EPI-Net. By June 2019, COMBACTE is active in 42 European countries, with a total of 966 clinical sites and 766 laboratories. To date, close to 30 trials are being managed with over 20,000 patients included. This includes phase I – III trials for 8 new compounds against multi-drug resistant bacteria. For more information about COMBACTE visit [www.combacte.com](http://www.combacte.com).

### About PREPARE

The Platform for European Preparedness Against (Re-)emerging Epidemics (PREPARE) is a large scale European network, including 27 beneficiaries and is funded by the EU FP7 Programme. PREPARE started its activities in February 2014.

PREPARE aims for the creation of operational readiness for rapid deployment of harmonised European clinical studies for any infectious disease and effective spread of evidence-based clinical guidelines via public health agencies to healthcare centres over the globe. In addition, within PREPARE inter-epidemic research will be performed to study questions to allow for optimal clinical management of patients suffering with infectious diseases. For more information about PREPARE visit [www.prepare-europe.eu](http://www.prepare-europe.eu).

ECRAID will provide sustainability for the clinical research networks and infrastructures currently funded through COMBACTE and PREPARE. Other clinical research networks that are able to contribute to ECRAID's mission are welcome to participate. In addition to the clinical research networks in PREPARE and COMBACTE, there are many other relevant networks, projects and initiatives with highly complementary roles in European ID clinical research, preparedness and response and combatting AMR, and associated capabilities and resources. We welcome opportunity to discuss partnerships with these networks.

A core set of projects, networks and initiatives with highly complementary roles and capabilities in clinical research on EIDs and AMR in Europe are involved as partners in the development of the Business Plan (see partners 3-15 in the table above). These include:

#### European clinical research networks

- The ECRIN ERIC (European Research Infrastructure Consortium), funded through EU Member States;
- The c4c network, which includes the PENTA ID network, covering paediatric clinical research, funded by IMI, represented by the coordinator PENTA;

#### Latin-American, EU H2020 funded clinical research networks

- ZIKAPLAN, represented by the Coordinator UMEA;
- ZIKAlliance, represented by the Coordinator AMU;
- ZIKAction, represented by the Coordinator PENTA;

#### African EDCTP-funded clinical research networks:

- ALERRT, represented by the Coordinator UOXF;



- PANDORA, represented by the co-Coordinator INMI;

#### Networks and organizations with complementary roles/activities to ECRAID

- The VEO network, funded through H2020, represented by the Coordinator Erasmus MC and co-Coordinator DTU;
- The EMERGE network, funded through EU DG SANTE, represented by the Coordinator RKI and co-Coordinator INMI;
- The EVD-LabNet network, funded through ECDC; represented by the Coordinator Erasmus MC;
- The EVAg network, funded through H2020, represented by the Coordinator AMU;
- The ERINHA AISBL (Association Internationale Sans But Lucrative) funded by Member States and institutes;
- The RECODID network, funded through H2020, represented by the Coordinator UKH;

## 3. Purpose, vision and values of ECRAID

### ECRAID's purpose

Our purpose is to reduce the impact of infectious diseases on individual and population health.

### ECRAID's Vision

Our vision is to efficiently generate rigorous evidence to improve the diagnosis, prevention and treatment of infections and to better respond to infectious disease threats. This is facilitated by a European multidisciplinary clinical research network and innovative research approaches.

The network will function as the backbone of clinical research activities in the field of infectious diseases, providing an efficient European infrastructure capable of performing all aspects of clinical studies, from design to dissemination. All activities will be coordinated by a lean organisation, allowing direct and single access for all relevant stakeholders to the network and to world-leading infectious disease experts and researchers.

### ECRAID's Values

ECRAID will operate on the basis of a shared set of essential and enduring values that set out our aspirations and guide our decision-making, our activities and how we will interact and collaborate within the network and with our stakeholders.

Our values are:

#### *Scientific independence*

Our research is based on scientific and clinical interests, ensuring the generation of credible new knowledge that is useful to society and delivered with the highest possible scientific and ethical standards.

### *Excellence*

Clinical research excellence is at the heart of all our activities. Patient safety and the interests of research participants always receive the highest priority. Quality assurance, essential for robust data and efficient clinical research, is never compromised. A well-trained workforce is key to the continuous development of research excellence within the network.

### *Responsiveness*

We react with appropriate rapidity to the needs of society in relation to infectious disease threats. We proactively seek out and pursue the opportunities for novel and impactful research projects. We actively engage with relevant partners and stakeholders, including members of the public.

### *Transparency*

We operate with transparency, communicate clearly, and promote open debate. Ongoing scrutiny is encouraged, by internal and external stakeholders about the rationale of the clinical research projects, study design, research implementation, and analysis and dissemination of findings. We make all data and outcomes available in the public domain in a fair and balanced way.

### *Efficiency*

The efficiency of our clinical research is optimised through continuous improvement of the entire research process, from idea generation to research completion and dissemination of evidence into practice.

### *Sharing credits and benefits*

We operate on the basis of equity, integrity, collaboration, and collegiality. There are fair, transparent publication policies for all scientific activities.

### *Not-for profit*

All income and funds generated by ECRAID's activities flow back into the clinical research network and supporting services.

## 4. Strategic focus

ECRAID is a *European* clinical research network. Our clinical network covers the following countries:

- **All Member States (MS) of the European Union (EU)**
- **Associated Countries to the European H2020 programme**

Although the clinical research network of ECRAID does not cover the outmost regions and Overseas Countries and Territories linked to the Members States of the EU<sup>1</sup>, ECRAID

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<sup>1</sup> Anguilla, Aruba, Bermuda, British Antarctic Territory, British Indian Ocean Territory, British Virgin Islands, Cayman Islands, Falkland Islands, French Polynesia, French Southern and Antarctic Territories, Greenland, Montserrat, Netherlands Antilles (Bonaire, Curaçao, Saba, Sint Eustatius, Sint Maarten), New Caledonia, Pitcairn Islands, Saint

partners have direct access to some sites in these regions. If and when needed, ECRAID will seek to expand its presence to other countries on the European continent, notably those covered by WHO Europe (Andorra, Azerbaijan, Chechnya, Kazakhstan, Kyrgyzstan, Monaco, Rep of Moldova, Russian Federation, San Marino, Tajikistan, Turkmenistan, Uzbekistan). When needed ECRAID will seek to link to its global strategic partners that have a local presence in regions outside of Europe.

### Clinical research settings

The ECRAID clinical research network includes **primary care settings** (general practitioners), **hospital settings** (including emergency rooms (ERs) and intensive care units (ICUs)), **pediatric care settings**, **long-term care facilities** and **laboratories**.

The **primary care network** of ECRAID consists of over 600 primary care sites in more than 20 European countries. The network has its origin in the GRACE study, funded by the European Commission. It has functioned as the network for the primary care studies in PREPARE and VALUE-Dx (an IMI2 funded public private partnership on diagnosis of community-acquired respiratory infections).

The **hospital care network** of ECRAID consists of over 900 hospital sites in 42 European countries. The network has its origin in the COMBACTE-CLIN-Net project, funded by IMI. It also functions as the network for the hospital care studies in PREPARE and VALUE-Dx.

The **pediatric network** of ECRAID consists of over 90 pediatric sites in 18 European countries. The network is provided through partner PENTA-ID. It also functions as the network for the paediatric care studies in C4C, PREPARE and VALUE-Dx.

The clinical research sites are supported by a European network of clinical laboratories based on the laboratory network established in COMBACTE (COMBACTE LAB-Net). LAB-Net comprises of the Good Laboratory Practice (GLP) compliant laboratory sites of ECRAID and currently also functions as the lab network in PREPARE and VALUE-Dx.

ECRAID's European clinical research network is **globally connected** and can facilitate access to clinical sites and patients from clinical research networks outside of Europe, directly and through its strategic partners.

### Focus on infectious diseases indications

ECRAID focuses on infectious diseases that are of public health relevance to Europe. This includes infectious diseases caused by viruses, bacteria and protozoa. The ECRAID network can support clinical research on a broad range of infectious diseases of public health interest to Europe, including infectious diseases caused by antimicrobial resistant pathogens, acute infectious diseases caused by (re-) emerging pathogens with epidemic potential, and chronic infectious diseases.

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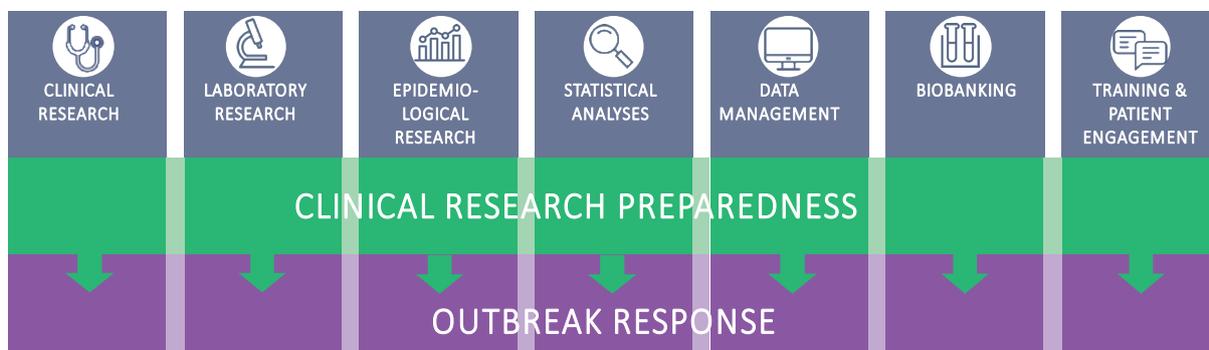
Barthélemy, Saint Helena, Saint Pierre and Miquelon, South Georgia and the South Sandwich Islands, Turks and Caicos Islands, Wallis and Futuna.



## 5. Service offering

ECRAID offers access to a ‘warm-base’ pan-European clinical research network experienced in delivering observational or intervention studies related to diagnosis, natural history, therapy or prevention in multiple or individual patients or healthy volunteers.

At the core of our services are the design, execution and reporting of clinical research studies. It includes, but is not limited to, clinical trials as defined in the EU Clinical Trials Directive (2001/20/EC). The core clinical research services are underpinned by a range of supporting services (figure 1).



*Figure 1: overview of the components of the ECRAID service offering.*

These include laboratory analyses, epidemiological analyses, statistical analyses, data management, biobanking and training, education and capacity building and patient engagement. These service components are described in detail in the following paragraphs. The service offering by ECRAID include novel design features that allow for a rapid research response in the event of a public health emergency.

ECRAID operations will ensure a “warm base” of ongoing clinical research activity at key sites across Europe. The warm base will include Perpetual Observational Studies that are fundamental to ECRAID’s clinical research services offering. These studies are multifunctional and serve multiple needs of the network.

ECRAID aims to start its operations with a selected number of clinical studies, partially building on operational clinical studies in PREPARE and COMBACTE. Within these networks, there is extensive experience with designing and implementing large European perpetual observational studies, Randomised Clinical Trials (RCTs), Response adaptive RCTs as well as platform trials. Within ECRAID, some of these studies will be continued and expanded, forming the platform for adding new demand-driven industry and/or investigator-initiated clinical research studies.

Using its Warm Base clinical research network, ECRAID can conduct clinical research at higher speed, and lower cost thanks to using combinations of seven design elements

Our studies can involve one or more of seven design elements contributing to our value proposition. These design elements are:

- A. Use of the ECRAID **warm base** clinical research network;
- B. **Continuous enrolment of patients**, strengthening the warm base;
- C. Use of a **shared control group**;
- D. Use of **response adaptive randomisation**;
- E. **Nested trials**;
- F. Application of a **Platform design**;
- G. Use of **Master protocols**;

In the medium term (5 years), we aim to build a clinical research portfolio that consists of a broad range of investigator-driven and industry-driven clinical studies, each including one or more of these seven design features.

**By preparing its warm base, ECRAID can offer clients access to clinical research sites able to start rapidly research during a public health emergency event**

In the absence of any unusual infectious diseases outbreaks in Europe, ECRAID is operating in a so-called '*inter-epidemic*' mode, implementing clinical research and supporting activities for our clients. During this '*inter-epidemic* mode', emerging outbreaks of epidemic-prone infectious diseases are continuously occurring, including those of potential public health concern to Europe.

The Perpetual Observational Studies conducted in the ECRAID network will be designed to routinely enrol patients with syndromic presentations of likely candidate pathogens for a widespread, severe, and high-impact epidemic in Europe: i.e. a(re)emerging respiratory pathogen or arbovirus. These studies provide daseline data for signaling unusual infectious disease activity and for evaluating the impact of new outbreaks and pathogen variants. The Perpetual Observational Study also provides a basis for operational clinical research preparedness for outbreak-relevant studies. For example, select ECRAID sites will be involved in annual simulation training and preparedness exercises to practice re-orienting their activities to deliver a research response in the event of a widespread ID threat.

## 6. Creating awareness and support

One of the main objectives of ECRAID-Plan is to build awareness of and create support for the ECRAID initiative at our broader group of stakeholders.

### *ECRAID's brand identity*

A new ECRAID logo was designed in April 2019. The logo serves as the visual identity of ECRAID and performs as a means of being recognisable in order to create awareness, interest, and trust in the project. Tying in with the ambition of ECRAID, the idea of sustainability and continuous cooperation was key in the design of the logo.

### *Message house*

To ensure that ECRAID's external messages to relevant stakeholders are clear and consistent, we started taking the steps to create a message house to exhibit the main messages of what ECRAID is. This message house allows ECRAID to position itself in the field and allows members of ECRAID to succinctly communicate what ECRAID is to targeted stakeholders in a concise manner.

### *Website*

The [ECRAID website](#) was launched in May 2019. This website acts as both a business card, with information on ECRAID, including news, publications, future events, and contact information. In addition, this website will serve as a means of legitimising ECRAID and giving a platform to raise awareness on the initiative.

### *Media relations*

We engaged with the media by writing a press release on the ECRAID-Plan Kick-Off Meeting on 17 January 2019. Journalists were previously identified and selected on basis of their professional background and interests. The press release generated positive coverage on the ECRAID initiative. Articles were written by [The Joint Programming Initiative on Antimicrobial Resistance](#), the [Pharma Letter](#), [PR News Wire](#) and [MarketWatch](#). An article was published and shared with POLITICO Pro subscribers across Europe.

### *Video*

During the ECRAID-Plan Kick-Off Meeting, we developed a [video](#) with five on-camera interviews that were conducted to discuss what ECRAID is and its ambitions.

### *Social media*

The [ECRAID Twitter account](#) has been in use since May 2019 with the launch of the website. This Twitter account is used to share latest news, events, and milestones achieved by ECRAID and act as a means of engaging in a discourse with the community.