Annual Report 2022

ecraid

“In 2022, we laid a solid foundation”

The flying start of Ecraid

2022 was the year in which Ecraid moved from the drawing board to the reality of a vital organisation. That went very well! And I can only hope that everything will continue to move as smoothly as this in the future. But let's not forget that we can build upon the foundations laid in PREPARE, COMBACTE and ECRAID-Plan.

We're on our own feet now, with an extensive team at the Ecraid headquarters and with about 20 leading European scientists in the field of infectious diseases in our Coordinating Committee. All highly motivated to ensure the success of Ecraid. In 2022, we laid a solid foundation, and 2023 will be the year in which we will reinforce the international collaboration with all stakeholders.

The importance of the fight against infectious diseases has never been so clear: the world is recovering from a pandemic and the threat of antimicrobial resistance is constantly growing. These threats to human health can only be fought successfully with international collaborations, between scientists, between academia and the pharmaceutical industry, and between investigators and authorities. I'm convinced Ecraid can be an accelerator in this environment. It's an honour to be the first CEO of Ecraid, and to present to you the first Annual Report of Ecraid.

I invite everyone to join forces and – as we say it – become part of the solution.

Marc Bonten
Chief Executive Officer

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An introduction to Ecraid

Ecraid is a not-for-profit organisation focused on reducing the impact of infectious diseases on individual health and on society as a whole. Started in January 2022, Ecraid builds on the legacies of major EU-funded projects: the COMBACTE projects – NET, CARE, MAGNET and CDI –, the PREPARE project and ECRAID-Plan. These projects demonstrated the value of collaboration between academia and industry. Ecraid now offers services both for industry- and investigator-driven research on infectious diseases. Several academic centres of excellence across Europe collaborate through Ecraid, which is headquartered in the Netherlands.

Full breadth

Ecraid provides the full breadth of clinical studies on infectious diseases: observational studies and interventional studies in three trial phases (II, III and IV). Ecraid can do this from the study design to protocol development, site selection, and finally, clinical study report (see page 12). Ecraid also aims to improve the European scientific response to an infectious outbreak or a pandemic. With its specialised warm-base network Ecraid can respond to an outbreak more quickly. Ecraid will use any resources to accelerate research in case of an emerging pandemic.

Fast, efficient, high quality

Because of its warm-base network (see image), Ecraid can execute trials faster and more efficiently, with a high level of quality. In a warm-base network, sites are used to work with standardised processes and procedures, and are able to start up quickly with well-trained staff. A continuous flow of studies is needed to maintain the warm-base network. Ecraid has multiple studies running with sites from its own network participating (see overview page 16). Ecraid helps less-experienced sites to develop their potential for clinical research, thus expanding the number of experienced sites and augmenting the capabilities of the network to conduct more studies in parallel.

Perpetual basis

Among the studies being executed are the Perpetual Observational Studies (POS). These are multicentre observational clinical studies that include patients on a perpetual basis. With the present set of POS, data and clinical samples are systematically collected. Partners can make use of this data or plug in their own questions. With their perpetual character, POS enable continuity in clinical research. This also applies to the even more innovative concept of Adaptive Platform Trials (APT), with which Ecraid has experience through REMAP-CAP and ECRAID-Prime.

Ecraid is much more than an organisation aimed at carrying out clinical trials. Ecraid is a movement where knowledge of infectious diseases can be shared and new methods of clinical research can be developed together. It is a movement where young talent and experienced experts – from both academia and industry – connect to collaborate and learn.

Europe-wide coverage

Ecraid strives to create real Europe-wide coverage of its network, aggregating the potential European academia has to offer in research on infectious diseases. A broad European coverage also gives access to specific populations where the prevalence of a pathogen is high. This shortens the time needed to reach the required number of patients in a trial.

1,200

CLIN-Net (over 1,200 hospital sites)

900

LAB-Net (over 900 laboratories)

250

Primary Care network (over 250 GPs)

Report from the Management Board – the successful delivery of Ecraid

In 2022 Ecraid became a legal entity. This also marked the start of building the enterprise infrastructure according to the transition roadmap as described in the Ecraid Business Plan (June 2021). At the end of 2022 we could look back on a year in which Ecraid became operational.

We formed the team, established our headquarters and put into service and implemented a governance infrastructure. In addition, we also succeeded in securing new assignments – both public and private – and expanded our networks. It is great to see how the efforts of so many people led to these achievements. And we are proud that we were able to conclude this first year with a positive financial report.

In the transition to the sustainable organisation Ecraid aims to be, our focus is on three objectives: (1) developing an '*as one*' strategy, (2) professionalising the organisation and (3) strengthening the infrastructure.

'As one' strategy reflected in governance

Characteristic of Ecraid is the collaboration model in which academic centres come together for a common goal: to efficiently generate rigorous evidence to improve the diagnosis, prevention and treatment of infections and to better respond to infectious disease threats. For this, it is important that we operate as one organisation but leave enough space for autonomy. This idea is reflected in the installation of a Coordinating Committee that gives the academic partners a prominent place in our governance structure. This committee exists of 20 members. In 2022, several formal and informal meetings took place, with members of the Coordinating Committee discussing topics such as Ecraid's legal structure and the results that had been achieved.

The Management Board is responsible for the daily operational management of Ecraid. Marc Bonten is Chief Executive Officer (CEO) as of January 2022, and in June 2022, Nils Visser joined the Management Board as Chief Operational Officer (COO). At the end of 2022, there was still a vacancy for a Chief Scientific Officer (CSO), which was ultimately filled in April 2023 by Evelina Tacconelli. The Management Board is supervised by the Supervisory Board.

Building a new team and culture

We built our team in 2022 in a staged and controlled process. Employees already working on tasks and projects that would transfer to Ecraid mostly made the switch from their former employer (UMC Utrecht), a sign of trust we appreciate. In addition, we recruited new staff. As Ecraid aims to be a real pan-European organisation; we hired a substantial part of our staffing from multiple countries across Europe. At the end of 2022, roughly 25% of our employees came from outside of the Netherlands, a percentage we expect will increase even further. In April 2022, Ecraid moved to its first private office space, which is located in Utrecht.

People-centred is an important principle in Ecraid's strategy. This also reflects in the way we look at our own team. We aim for an open and inclusive culture that invites innovative thinking. Diversity is key in such an environment. With the arrival of an HR manager in October 2022, we provided an impetus for the professionalisation of the HR discipline within Ecraid. We strengthened the involvement of employees of Ecraid in a number of ways, such as so-called town hall meetings, and helped them to find their place within the organisation, both socially and in their work.

"We aim for an open and inclusive culture that invites innovative thinking."

Networks incorporated and expanded within Ecraid

At the heart of our operations is the clinical research infrastructure. This consists of a hospital network (CLIN-Net), a laboratory network (LAB-Net) and the access to a primary care network. The first two networks were initially part of COMBACTE and were incorporated in Ecraid. Sites involved in these networks were informed about this transition. Now it's important to develop a strategy to help these sites become more involved and to feel like a part of our warm-base network. The first steps have already been taken, like an Ecraid Clinical Liaisons (ECLs) strategy and infrastructure (see page 15) and implementing site-selection-process improvements for CLIN-Net. Another step will be to raise awareness among the CLIN-Net team and operational teams that they are part of Ecraid and as such, act as ambassadors to the sites. In 2022, the hospital network expanded with 32 hospitals and the laboratory network with 24 laboratories. The start of ECRAID-Prime also enhanced the ties with the primary care network to which Ecraid gives access.

First assignments for industry fulfilled

Part of our strategy is expanding the collaboration between academia and private partners such as pharmaceutical companies and clinical research organisations (CROs). COMBACTE demonstrated the opportunities and added value of such collaborations. In the first year, Ecraid attracted the interest of multiple private organisations, and we even fulfilled the first assignments for industry. We were pleasantly surprised by the great interest of CROs in our services. As the Perpetual Observational Studies started to enrol patients in August 2022, we expect to see the first plug-in trials initiated by the industry making use of these permanent studies in 2023.

Milestones in research

Though there was a strong focus on building the organisation, we also achieved important milestones in the context of research. REMAP-CAP, designed and rolled out in PREPARE and RECOVER, and continued in Ecraid, saw several high-impact publications in 2022. Furthermore, two major projects within Ecraid – ECRAID-Base and ECRAID-Prime – made considerable progress in 2022. We look forward to 2023 with great confidence: The POS-VAP and POS-cUTI studies enrolled their first patients in 2022. For ECRAID-Prime the first agent to be studied (start 2023) was selected.

In 2022, Ecraid's *pandemic preparedness* was tested. In response to the global monkeypox outbreak we announced several phases of alertness, with the highest mode (response mode 3) in August. The availability within Ecraid of dedicated funding allowed a task force to prepare the EPOXI trial, meant to assess safety and efficacy of treatments for patients with monkeypox. Yet, it is fair to say that evoking a rapid international research response remains a challenge. Ecraid will continue to work with regulatory and other authorities to better streamline processes.

Sharing knowledge and insights is one of the ways in which we will be able to enhance the fight against infectious diseases. In August 2022, for example, several members of the Ecraid community contributed to peer-reviewed articles on the challenges of clinical research during the COVID-19 pandemic and about the concept of Perpetual Observational Studies. In October 2022, Ecraid and ESCMID joined forces for a workshop on clinical research methods.

2023

In 2022, we built the Ecraid organisation according to our transition roadmap. In 2023, we will proceed to professionalise the organisation and strengthen its infrastructure. We will create a more visible presence throughout Europe by establishing the Ecraid Chief Offices (ECHOs) and the Ecraid Clinical Liaisons (ECLs). We also aim to implement more (and also more innovative) studies and improve connections with sites in our *warm-base network*. All these actions will lead to the strong, unique and attractive academic clinical research network-organisation with broad European support that we want to be, with the ultimate goal being to reduce the impact of infectious diseases on individuals and the greater population.

Marc Bonten, CEO Ecraid
Nils Visser, COO Ecraid

2022

The year Ecraid became operational

“It was clear that such a network was needed”

Kelly Johnson Senior Principle Scientist MSD

“I had worked with members of the Ecraid team before its creation, by partnering with them to use the COMBACTE network to conduct the PNEUMO* study. But the first time I really learned about Ecraid was during a meeting with members of the Ecraid team, where Marc Bonten presented the goal and purpose of the network. My initial impression? It was clear that such a network was needed.

Ecraid is needed to provide access to a European clinical research network for infectious diseases to fully understand the impact clinical interventions have on reducing the morbidity and mortality associated with these diseases. And I truly think the Ecraid network includes knowledgeable experts that could help make it a success. Currently, many of the clinical studies are done in silo and are faced with several issues that contribute to inefficiencies and delays. Ecraid could help to mitigate those issues.

Also, the industry is always faced with pressure to accelerate clinical research so that those who need the interventions the most have access to them. I believe Ecraid could help with this by collaborating with the industry to accelerate clinical research and provide the data needed to demonstrate the value of the interventions. It is also what Ecraid promises: “...build a permanent, not-for-profit, pan-European clinical research network capable of rapidly initiating and completing high-quality clinical studies with greater speed and efficiency.” In my opinion Ecraid has made a great deal of progress since it has been created. During our investigator’s meeting in September of 2022, I learnt of the many projects that the team has advanced and the exciting plans that they have for the future. And it was also great to see how big Ecraid’s presence was at this year’s ECCMID conference in Copenhagen.”

* PNEUMO: Pneumococcal pNeumonia Epidemiology, Urine serotyping, Mental Outcomes. The primary objective of PNEUMO is to estimate the incidence of pneumococcal pneumonia and serotype prevalence among adults with community acquired pneumonia. Kelly Johnson is the MSD Lead for the PNEUMO study.

Highlights

January

Ecraid becomes a legal entity

19 January
Supervisory Board officially appointed

CEO Marc Bonten installed

19 January
Kick-off ECRAID-Prime

20 January
Official launch of Ecraid

April

1 April
Headquarters in Utrecht installed

23-26 April
First participation ECCMID as Ecraid

June

General Assembly ECRAID-Base in Antwerp

1 June
COO Nils Visser installed

August

First patients POS-studies enrolled

Launch multi-country study of monkeypox (MOSAIC)

1 August
Ecraid added as partner from RECoVER

5 August
Project's start date: MPX-Response (Ecraid is a partner)

25 August
Ecraid augments response to monkeypox outbreak

September

1 September
Ecraid added as partner from ECRAID-Base, ECRAID-Prime and COMBACTE-CARE

October

1 October
First employee

17-19 October
Postgraduate Education Course with ESCMID

20-22 October
Postgraduate technical workshop with ESCMID

November

30 November
ECRAID-Base consortium meeting in Verona

December

First country visit CLIN-Net

Business Development – Ecraid's value acknowledged

Ecraid Business Development aims to acquire new assignments and is building new and strengthening existing relations with both public and private sponsors. It turns out that our proposition is very attractive, also or maybe especially for the pharmaceutical industry. Our network is the first of its kind in Europe and is coordinated by Europe's leading experts in infectious diseases. We offer a unique single point-of-access in this field, to a pan-European warm-base clinical research network.

Time is of the essence

Time is of the essence in clinical trials. Patients, healthcare providers and policy makers are best served when the potential benefits of new diagnostic, treatment strategies, or preventive strategies are identified as quickly as possible. They share this interest with the industry, for which shorter time-to-market results in faster return-on-investment.

While efficiency is a crucial factor in clinical research, it should go hand in hand with a focus on quality, because reliable and solid conclusions are the ultimate goal.

Warm-base as a competitive advantage

A key capability of the warm-base network is rapid adaptation, either through rapidly implementing new trials or through rapidly responding to new infectious disease threats. Through this warm-base, Ecraid offers significant competitive advantages over other, often fragmented, isolated and ad-hoc clinical research networks.

Majority of assignment from CROs

Ecraid's clinical network, expertise and knowledge has made us a sought-after partner for clinical research organisations (CROs). Business Development noted that the majority of private leads and assignments in 2022 were from CROs. They ask our help to fast-track research processes or overcome tough challenges. The share of CROs in our sales funnel – related to pharmaceutical companies – exceeded our expectations. We think that an important reason for this is also that CROs see us as a complementary partner rather than a competitor, and thus are willing to collaborate with us.

Where we differ

Though part of our services (see box) overlaps with those of CROs, we also clearly differ from a CRO. We are a not-for-profit organisation, an investigators network and have direct access to research-oriented infectious diseases specialists throughout Europe. Making profits is a company's legitimate and ultimate goal. Ecraid's aim is to produce as much high-quality data as possible to improve the prevention and treatment of infectious diseases. Besides CROs, Ecraid therefore also invests in own research and in sharing knowledge.

Activities Business Development

In 2022, Business Development started to create awareness about Ecraid's services among (potential) private and public partners and ECHOs (Ecraid's own network of expert centres). It developed promotional materials together with Corporate Communications, like a slide deck, factsheet and a white paper. Business Development also attended congresses and symposia on infectious diseases with high exposures from pharma companies, like ECCMID 2022. During Ecraid General Assemblies Business Development connected with study teams, ECRAID-Prime sites and Adaptive Platform Trial teams.

Results

During 2022 Business Development explored 41 initial leads from industry. This led to 11 service agreements at the end of 2022. For these agreements 70% of the potential value came from CROs. The 2022 numbers significantly exceed the current yearly target.

Business Development Results		Distribution in %	
	Number	Pharma	CRO
Leads	41	33%	67%
Proposals**	14	29%	71%
Agreements signed	11	30%*	70%*

* related to budget potential

** types of services requested: 71% participating and coordinating centre, 29% site selection and participating centre

Service portfolio

- **Coordination and execution of trials**
  From the design of a trial through to the reporting of the study outcomes. Our experts advise sponsors about the best study design. And our operational team is at their side in all stages of the trial execution and can take care of all coordination tasks.

- **Site selection**
  Our CLIN-Net team uses a highly standardised process to streamline site selection and optimise the start-up of new trials. With our site selection process we help to select those sites that will enable trials to quickly and cost-effectively include the required patients.

- **Laboratory research and biobanking**
  With a network of over 900 laboratories, Ecraid can provide state-of-the-art laboratory diagnostic and research services, closely linked with and supporting its clinical research services.

- **Epidemiological research**
  We collect and analyse patient-level and regional data on emerging infectious diseases, including antibiotic resistance. This supports smart site selection for fast patient inclusion.

- **Statistical analyses**
  Ecraid can provide both standard and innovative statistical support to improve efficiency and scientific originality of studies.

At the heart of Ecraid: CLIN-Net

At the heart of Ecraid are its clinical hospital network (CLIN-Net) and laboratory network (LAB-Net). CLIN-Net was built within the IMI-funded projects of COMBACTE and has a track record of 10 years of coordinating and executing trials. Since 1 June 2022, CLIN-Net has been sustained in Ecraid. Within Ecraid in 2022, we took further steps to optimise CLIN-Net: the introduction of Ecraid Clinical Liaisons (ECLs), a survey on training wishes and a new start with country visits.

Delivering high-quality evidence

The aim of CLIN-Net is to have a network in place that is delivering high-quality evidence to improve patient care in the field of infectious diseases and to transparently select the most suitable sites for clinical trials, both commercial studies and investigator-driven studies and supporting the execution of clinical trials. Providing a regular flow of study activities and a broad portfolio of studies may help sites to build and maintain their local research infrastructure. In 2022, 478 sites participated in 17 studies. At present, the network encompasses over 1,200 hospitals, and more than 4,000 contacts spread across 42 European countries.

Data-driven site selection

Over the years, CLIN-Net had collected data on country specifics, sites, contacts, communication, performance and obtained data through feasibility questionnaires. In Ecraid, CLIN-Net has continued with the collection of performance data on previously defined quantitative performance indicators and will further improve the collection of qualitative performance data to support site selection. As more studies commence and active studies are completed, performance data enables CLIN-Net to differentiate between the capabilities of study sites. This allows for transparently matching of study sites to studies and for establishing a core network of well-performing participating sites and investigators. Choosing the best sites for recruitment of patients is essential for ensuring the quality of the collected data, realising ambitious study timelines, and limiting the costs of the project.

Much attention to training needs

Ecraid aims to provide investigators and research staff with regular training opportunities. Besides an online Good Clinical Practice (GCP) training, which over 1,100 researchers participating in CLIN-Net have completed so far, the network will be offered post-graduate courses, educational programs, on-site trainings, a virtual learning platform, as well as the upcoming Ecraid Academy – a series of training opportunities for young scientists. To assess training and educational needs, CLIN-Net sent out a training needs assessment questionnaire at the end of 2022 to 750 principal investigators that are participating in Ecraid supported studies. This survey primarily showed an interest in GCP training, research methodology and data management. In 2023, CLIN-Net will further explore how these training needs can be met in collaboration with partners from ECRAID-Base.

Ecraid Clinical Liaisons for local insights

CLIN-Net collaborates with Ecraid Clinical Liaisons (ECLs) throughout Europe, highly motivated specialists in the field of Infectious Diseases and/or Intensive Care Medicine who have insight in local legislation and contracting procedures and who are collaborating with research networks and other specialists in their region or country. The ECLs expertise, knowledge and experience with the sites is of great value for the optimisation of the CLIN-Net network. The official ECL Kick off meeting will take place on 5 June 2023 in Zagreb, Croatia. Ecraid CLIN-Net will offer ECLs a formal role within Ecraid by setting up an Ecraid Clinical Liaison Council (ECLC) and offering them a consultancy agreement that is covering the consultative and advisory services to Ecraid.

The benefits for the Ecraid Clinical Liaison

By establishing this cross-country collaboration, our liaisons are given the opportunity to centrally discuss current global trends or issues and needs within their country, region, or hospitals, to share knowledge and input on clinical research topics and to introduce study initiatives and protocols. They will receive regular updates on upcoming studies and will support decision-making regarding country feasibility. The ECLs can share the study overview with their network, speeding up the site selection process. Input from the ECL is imperative to select appropriate sites for ongoing and future studies and to get sites interested in participation.

"highly motivated specialists in the field of Infectious Diseases"

Greece – Ecraid's first country visit

CLIN-Net aims to proceed with country and site visits, that provide an opportunity to meet local contacts and investigators. In November 2022, CLIN-Net organised a visit to Athens, including a meeting with our two Greek ECLs and visits to five hospitals active in CLIN-Net. The aim was to better understand the local healthcare infrastructure, including its challenges and the opportunities, to identify hurdles in conducting research, both at a national level and at the site level, to discuss ongoing studies and upcoming studies supported by Ecraid and to provide in-depth information about CLIN-Net and the benefits of being part of this network. In 2023, CLIN-Net will keep investing in strengthening the relationships with investigators and ECLs, and, for example, increase its presence on ECCMID 2023 and the annual Intensive Care Medicine conference in Czech Republic.

We expect to foster a strong and sustainable clinical research network by having an ECL strategy and infrastructure in place, by providing training opportunities, the implementation of an user-friendly network & questionnaire application and by evaluating, redesigning and implementing site-selection process improvements.

Overview studies

RECOVER | COMBACTE - CARE | COMBACTE - NET

REMAP-CAP

Adaptive Platform Trial evaluating multiple treatment options in patients admitted to intensive care with severe community-acquired pneumonia

Type: APT
Domain: Community-Acquired Pneumonia in ICU, including COVID-19
Test subject: Multiple **Pts enrolled:** 12,090

HORIZON-HEALTH | First patient: 2018 | Completion date: perpetual

REVISIT

A Phase III, clinical trial to determine the efficacy and safety of aztreonam-avibactam (ATM-AVI) for the treatment of serious bacterial infections caused by Gram-negative bacteria

Type: RCT, Phase III
Domain: Hospitalized patients with Gram-negative infection
Test subject: Aztreonam-avibactam **Pts enrolled:** 418

ND4BB IHI | First patient: Apr 2018 | Completion date: Oct 2023

PNEUMO

Observational study to determine incidence, seroprevalence and disease burden of pneumococcal CAP and invasive pneumococcal diseases

Type: Observational
Domain: Patients with Acute Respiratory Infections in Emergency Rooms
Test subject: None **Pts enrolled:** 2,490

Merck | First patient: Feb 2020 | Completion date: 2025

SAATELLITE-2

A Phase III, randomized, double-blind, placebo-controlled study evaluating safety and efficacy of suvratoxumab in prevention of pneumonia caused by S. aureus in mechanically-ventilated subjects in ICU

Type: RCT, Phase III
Domain: ICU patients at risk for S. aureus HAP/VAP
Test subject: suvratoxumab **Pts enrolled:** 12

ND4BB IHI | First patient: Sep 22 | Completion date: 2024

ECRAID-BASE VACCELERATE MPX-RESPONSE

POS-VAP

Perpetual observational study to determine incidence and outcome of patients at risk for Ventilator-Associated Pneumonia in European ICUs

Type: Observational
Domain: ICU patients at risk for HAP/VAP
Test subject: None **Pts enrolled:** 170

HORIZON-HEALTH | First patient: Aug 2022 | Completion date: perpetual

POS-cUTI

Perpetual observational study to determine etiology and and outcome of patients with complicated Urinary Tract Infcetions in European hospitals

Type: Observational
Domain: Complicated urinary tract infections
Test subject: None **Pts enrolled:** 40

HORIZON-HEALTH | First patient: Oct 2022 | Completion date: perpetual

COVACC

A Phase II, Comparative Randomised Trial to Evaluate the impact of reduced COVID-19 mRNA vaccination regimens on immunological responses and reactogenicity in paediatric subjects (5-12 years) with and without prior SARS-CoV-2 infection

Type: RCT, Phase II
Domain: Healthy children (5-12 yrs)
Test subject: Tozinameran **Pts enrolled:** 20

HORIZON-HEALTH | First patient: Aug 2022 | Completion date: 2024

Epoxi

A randomized controlled double-blinded placebo-controlled trial evaluating safety and efficacy of tecovirimat, with adaptive design allowing future interventions

Type: RCT
Domain: MPX infections
Test subject: Tecovirimat **Pts enrolled:** 0

HORIZON-HEALTH | First patient: - | Completion date: Aug 2026

ECRAID-BASE ECRAID-PRIME

POS-ARI-ER

Perpetual observational study to determine etiology and and outcome of patients with Acute Respiratory Tract Infcetions in Emergency Rooms European hospitals

Type: Observational
Domain: Patients with Acute Respiratory Infections in Emergency Rooms
Test subject: None **Pts enrolled:** 0

HORIZON-HEALTH | First patient: - | Completion date: perpetual

POS-ARI-PC

Perpetual observational study to determine etiology and and outcome of patients with Acute Respiratory Tract Infcetions in Primary Care settings

Type: Observational
Domain: Patients with Acute Respiratory Infections in Primary Care
Test subject: None **Pts enrolled:** 0

HORIZON-HEALTH | First patient: - | Completion date: perpetual

POS-disX

Perpetual observational study to determine etiology and and outcome of immunocompromised patients hospitalized with unexplained febrile illness

Type: Observational
Domain: Immunocompromised hospitalized with unexplained febrile illness
Test subject: None **Pts enrolled:** 0

HORIZON-HEALTH | First patient: - | Completion date: perpetual

ECRAID-Prime

Adaptove platform trial comparing treatments for Acute Respiratory Tract infections in primary care

Type: APT
Domain: Patients with Acute Respiratory Infections in Primary Care
Test subject: Nitric oxide nasal spray (NONS) **Pts enrolled:** 0

HORIZON-HEALTH | First patient: - | Completion date: Nov 2024

NEO-IPC ZONMW

Neo-IPC

Cluster randomised controlled trial in neonatal intensive care units (NICU) to evalaute effectiveness of kangarooing in preventing infections and improving patient outcome

Type: cRCT
Domain: Neonates in ICU (neonatal intensive care)
Test subject: Kangarooing **Pts enrolled:** 0

HORIZON-HEALTH | First patient: - | Completion date: Mar 2026

VLA2001-307

Open-label Phase II/III clinical study to investigate safety and immunogenicity of single VLA2001 booster vaccination in adult volunteers, after receipt mRNA COVID-19 vaccines and/or natural SARS-CoV-2 infection

Type: RCT, Ph II/III
Domain: Healthy adults with prior COVID-19 vaccine
Test subject: VLA2001, COVID-19 vaccine **Pts enrolled:** 75

VALNEVA | First patient: Aug 2022 | Completion date: Aug 2023

SNAP

Adaptive platform trial evaluating multiple treatment and diagnostic option in patients with Staphylococcus aureus bacteremia

Type: APT
Domain: Staphylococcus aureus bacteremia
Test subject: Multiple **Pts enrolled:** 0

UMCU | First patient: - | Completion date: Dec 2025

“We must connect and involve people at all levels”

Bruno François University Hospital of Limoges, member Ecraid Coordinating Committee and Lead POS-VAP

“The threat of infectious diseases is a world-wide issue, there are no borders for bacteria. But national networks hardly dealt with clinical challenges in this field. So, there was truly an unmet need. Ecraid fulfilled this need and now offers a cross-border infrastructure for clinical research on infectious diseases. As a member of the Coordinating Committee, I can say we’re all on the same page now and agree on the objectives. The start of Ecraid in 2022 was an achievement. It’s time to go beyond that.

As we saw during COVID-19, the collaboration between academia and pharma is very important. We need each other, although we – understandably – have different drivers. The collaboration of academia within Ecraid offers pharma and government a full partner in clinical research on infectious disease. I think this also will balance the mutual discussions more and benefits everyone. To sustain this position, we will have to prove our capabilities.

Now the official launch is complete, the story must spread. We must connect and involve people at all levels. Explain the concept of Ecraid, which is new and not yet understood completely by everyone. Some colleagues ask me: ‘what interest is there for me to be in Ecraid?’. My answer is that they should be at the very start of the story. It’s innovative and at the forefront of science.

There is the intrinsic motivation to support our model, but we should not forget the daily life of the investigator. An investigator at a hospital has to pay the salary of the research staff. So our model should offer them sustainable and appropriate compensation. Both financial and non-financial. We reduce red tape and provide training and more opportunities to participate. So we must convince people that working through Ecraid is interesting and that they won’t lose money at the end of the day.

At a personal level, for me Ecraid is an amazing opportunity to connect on a European level. No doubt on that. As lead of the POS-VAP study, it’s my experience that this is much easier to do within Ecraid, because of these connections and the infrastructure. It probably would have taken me much more time if done alone. But at the level of participating sites, it is important that we keep them on board. That’s my challenge for 2023.”

Ecraid governance

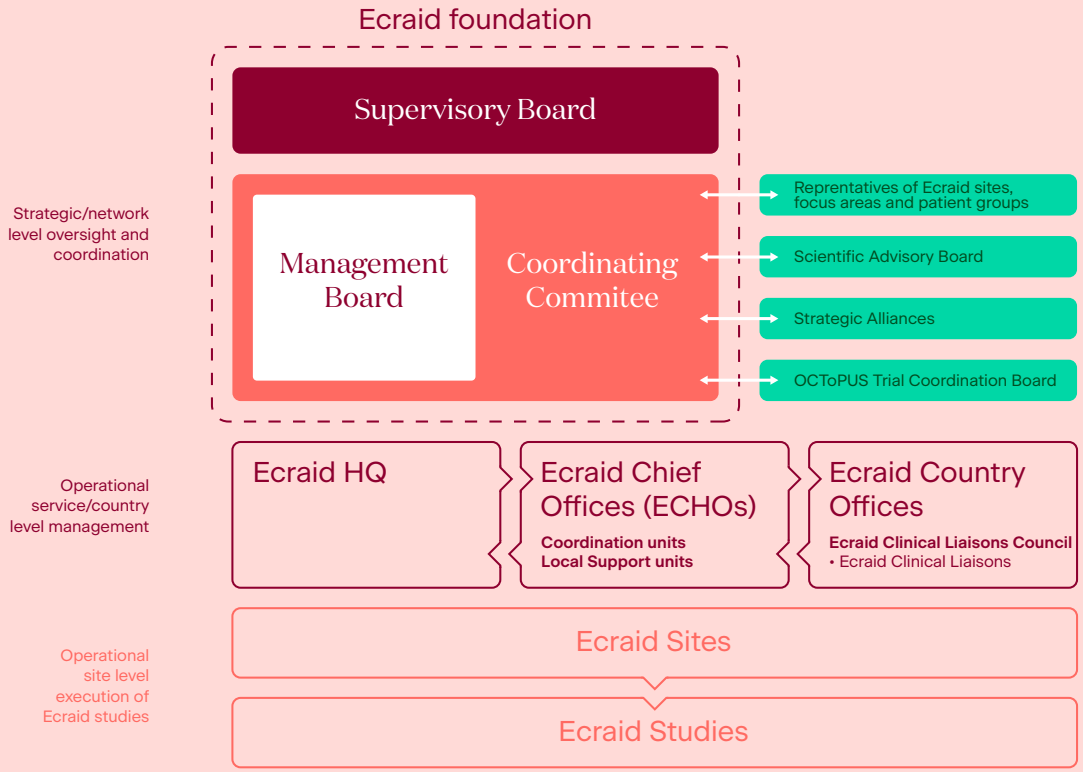
Before the start of activities in the foundation, Ecraid had put a lot of effort into structuring the governance in detail. The responsibilities and authorities of the various governing bodies within the foundation were well described. In addition to the articles of association, regulations were written for each individual body.

Ecraid has been established as a not-for-profit organisation under the Dutch Civil Law. The foundation employs the Management Board and central support staff of Ecraid. The Ecraid Management Board is responsible for the overall coordination and management of Ecraid. That board is supervised by the Supervisory Board.

Management Board

The Management Board is charged with the Foundation's management, including, but not limited to the general operations of the Foundation and representing the Foundation with regard to third parties.The Management Board consists of three persons Chief Executive Officer (CEO), Chief Scientific Officer (CSO), and Chief Operational Officer (COO). That board is supervised by the Supervisory Board. The Management Board meets on a weekly basis.

Marc Bonten	Chief Executive Officer
Nils Visser	Chief Operational Officer
Evelina Tacconelli	Chief Scientific Officer Vacant in 2022, per April 2023.



Central support staff

Ecraid's central support staff was designed as a matrix structure, a work structure in which team members report to multiple leaders. Team members report to a clinical trial project manager and also to their department head. In addition, Ecraid also has central departments, such as Finance, People & Culture, Office Management, Business Development, Grant Management, and Communications & Marketing.

Supervisory Board

The Supervisory Board ensures that the Management Board manages the foundation in accordance with the mission, identity, and objectives of Ecraid and that it acts and performs adequately. The Supervisory Board consists of global scientific experts and leading representatives of European and international scientific projects, networks and organisations with activities complementary to Ecraid. Three Supervisory Board meetings were held in 2022.

Arno Hoes	Chair, Executive Board member & dean University Medical Center Utrecht, the Netherlands
Ilaria Capua	Director One Health Center of Excellence, University of Florida, United States
Juan Emilio Echevarría	Laboratory Head, Instituto de Salud Carlos III, Spain
Bernard Pécoul	Former Executive Director Drugs for Neglected Diseases initiative, Switzerland
Momir Radulović	Board member EMA, Executive Director Slovenian Medicines Agency, Slovenia

Coordinating Committee

Ecraid's Coordination Committee functions as the central body in Ecraid responsible for the Europeanwide coordination of clinical studies on infectious diseases, strategy development, stakeholder management, and service and network development. Four Coordinating Committee meetings were held in 2022.

Marc Bonten	Chair, CEO Ecraid
Sybil Anthierens	Public Engagement – University of Antwerp, Belgium
Christopher Butler	POS on ARI in Primary Care, SOS-COVID, PRUDENCE, ECRAID-Prime – University of Oxford, United Kingdom
Oliver Cornely	VACCELERATE – University of Cologne, Germany
Jacques Demotes	ECRIN – Data Management, France
Lennie Derde	REMAP-CAP – University Medical Center Utrecht, the Netherlands
Bruno François	POS on VAP in ICUs – University Hospital of Limoges, France
Carlo Giaquinto	PENTA-ID, VERDI – University of Padova, Italy
Herman Goossens	LAB-Net – University of Antwerp, Belgium
Stephan Harbarth	STAT-Net – Geneva University Hospitals, Switserland
Peter Horby	POS on ARI in ER, MERMAIDS 2.0 – University of Oxford, United Kingdom
Thomas Jaenisch	RECoDid, Datasharing – Universität Heidelberg, Germany
Marion Koopmans	Outbreak Preparedness and Response Disease-X POS, VEO – Erasmus University Medical Center, the Netherlands
Jesús Rodriguez-Baño	POS on cUTI in ERs – Hospital Universitario Virgen Macarena, Spain
Jean-Louis Romette	European Virus Archive (EVA-g) – Aix-Marseille University, France

John-Arne Røttingen	Director General of the Research Council, Ambassador for Global Health, Ministry of Foreign Affairs, Norway
Evelina Tacconelli	EPI-Net, LOTTA-Net, ORCHESTRA – University of Verona, Italy
Arjana Tambić Andrašević	Capacity building Eastern Europe – University Hospital for Infectious Diseases Zagreb, Croatia
Nils Visser	COO Ecraid
Yazdan Yazdanpanah	EU-RESPONSE – INSERM and Bichat Hospital, France

Scientific Advisory Board

Ecraid's Scientific Advisory Board provides the Coordinating Committee with expert advice and feedback on its services, network composition, innovative trial designs, technologies, ethics, etc. First meeting is scheduled in 2023.

Marc Bonten	Chair, CEO Ecraid
Seamus O'Brien	Global Antibiotic Research and Development Partnership (GARDP)
Antonio di Caro	Unicamillus International University of Medicine Rome
Marco Cavaleri	European Medicines Agency
Vance Fowler	Duke University Durham
Nina Gobat	University of Oxford
Xavier de Lamballerie	Aix Marseille University
Nicole Lurie	Coalition for Epidemic Preparedness Innovations
Marc Mendelson	University of Cape Town
Frank Møller Aarestrup	Technical University of Denmark
David Paterson	University of Queensland
Hervé Raoul	Institut national de la santé et de la recherche médicale (INSERM)
Guy Thwaites	Oxford University Clinical Research Unit
Robert Weinstein	Rush University Chicago

Financial Report

Policy pursued

In the Ecraid Business plan (ECRAID-Plan) the road to establishing the Ecraid Foundation was described. A transition plan was developed with following objectives: provide an integrated view of the key capabilities for Ecraid to be operational, design how the Ecraid organisation will operate in the future, and develop a transition roadmap to ensure Ecraid can prioritise and implement these capabilities. This roadmap was further detailed into developing an as one strategy, professionalising the organisation and strengthening the infrastructure.

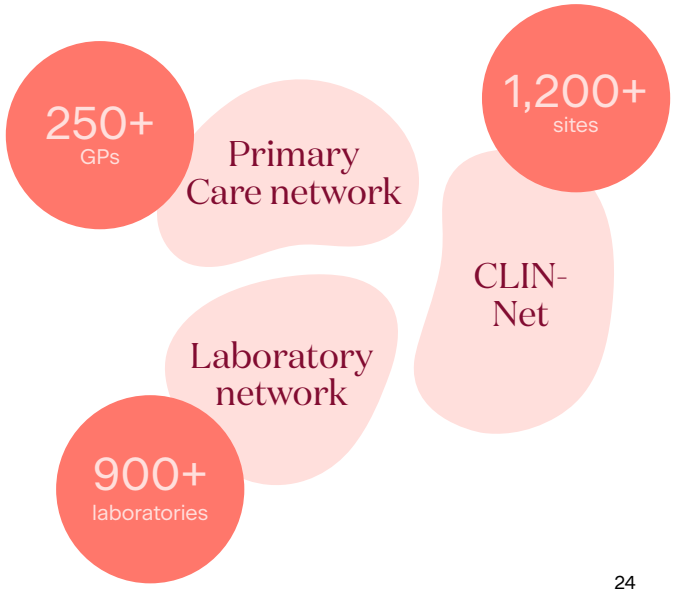
Financial position and risks

The financial statements reflect all the activities of the Ecraid Foundation. All activities were executed from Ecraid's head office in Utrecht, the Netherlands. Apart from the teams managing the trials and programmes, the head office was staffed with general management, financial management, people & culture management, communications & marketing management and office management. The publicly funded projects were prefunded by shifting actions, work packages and milestones from UMCU to Ecraid Foundation. Privately funded projects were trial project management activities performed on behalf of UMCU.

The foundation has been incorporated for the sole purpose of running the activities along the lines of the objectives as mentioned in the Management Board report. The foundation has no objective to gain reserves, but the margin reached will be used to professionalise the organisation, to strengthen the infrastructure and support or initiate research activities.

Given the nature of the organisation, risk assessment is addressed. The monitoring and managing of risks take place on the level of the Foundation. Risks have been categorised and prioritised on possibility and impact. The most significant risks that have been identified are:

- Financial risks – continuity of sufficient cashflow; mitigated by an option to effectuate a loan to cover late transfer of shifting funds.
- Financial risks – continuity of funding; (successfully) mitigated by business development and submitting proposals for new funding.
- Personnel risks – rapid start-up resulting in demotivated employees; mitigated by establishing clear communications and attractive employment conditions.
- Performance risks – availability of financial performance and overview; (successfully) mitigated by implementing an Enterprise Resource Planning (ERP) system before starting activities (e.g. the period between founding and starting activities).
- IT-related risks – continuity of IT systems and services; mitigated by continuing the current UMCU IT services as a vendor.



Financial Development

Income statement:

On 1 January 2022, Ecraid was formally registered as a Dutch not-for-profit organisation.

In the first three quarters of 2022, Ecraid focused mainly on preparational activities, whereas in the last quarter we started operational activities with the hiring of the first employees.

Financial Report 2022

Unaudited

Income	
Private-funded Studies and Projects	€747,982
Publicly-funded Studies and Projects	€706,738
TOTAL INCOME FOR 2022	**€1,454,720**
Expenditures	
Direct costs of Publicly-funded Studies and Projects	€264,785
Personnel and personnel related expenses	€611,395
Other staff expenses	€34,936
Office rent	€79,947
Sales expenses	€4,632
Office expenses	€68
Other expenses	€54,097
Income tax	€42,315
TOTAL EXPENDITURES FOR 2022	**€1,092,175**
TOTAL RESULTS FOR 2022	**€362,545**

The aforementioned figures have been extracted from the 2022 financial statements with a review report provided by BDO Accountants on 6 June 2023.

Abbrevations

APT	Adaptive platform trials
ARI	Acute respiratory infections
CEO	Chief Executive Officer
CLIN-Net	Clinical research network
COMBACTE	Combatting bacterial resistance in Europe
COMBACTE-CARE	Combatting bacterial resistance in Europe – carbapenem-resistance
COMBACTE-CDI	Combatting bacterial resistance in Europe – Clostridium difficile infections
COMBACTE-MAGNET	Combatting bacterial resistance in Europe – molecules against Gram negative infections
COMBACTE-NET	Combatting bacterial resistance in Europe – networks
COO	Chief Operational Officer
COVID-19	Coronavirus disease 2019
CRO	Clinical Research Organisation
CSO	Chief Scientific Officer
cUTI	Complicated urinary tract infections
EBIDTA	Earnings Before Interest, Tax, Depreciation and Amortisation
ECCMID	European Congress of Clinical Microbiology & Infectious Diseases
ECHOs	Ecraid Chief Offices
ECL	Ecraid Clinical Liaison
Ecraid	European Clinical Research Alliance on Infectious Diseases
ECRAID-Plan	European Clinical Research Alliance on Infectious Diseases – Business Plan
ECRAID-Prime	European Clinical Research Alliance on Infectious Diseases: Primary care adaptive platform trial for pandemics and epidemics
ECRIN	European Clinical Research Infrastructure Network
EMA	European Medicines Agency
EPOXI	European monkeypox randomised placebo-controlled, double-blinded platform trial
ER	Emergency room
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
EU	European Union
GARDP	Global Antibiotic Research and Development Partnership
GCP	Good clinical practice
ICU	Intensive care unit
IMI	Innovative Medicines Initiative
INSERM	Institut national de la santé et de la recherche médicale
LAB-Net	Laboratory network
LOTTA-Net	Long Term Care Facilities network
MERMAIDS	Multi-centre EuROpean study of MAjor Infectious Disease Syndromes
ND4BB	New Drugs for Bad Bugs
OCToPUs	Organisation for COVID-19 Trial Platforms in Europe
PENTA-ID	Paediatric European Network for Treatment of AIDS – Infectious Diseases
PNEUMO	Pneumococcal pNeumonia Epidemiology, Urine serotyping, Mental Outcomes
POS	Perpetual observational studies

PREPARE	Platform foR European Preparedness Against (Re-)emerging Epidemics
Prudence	Platform Randomised controlled trial of point of care Diagnostics for Enhancing the quality of aNtibiotic prescribing for Community acquired acute respiratory tract infection in ambulatory care in Europe
QMS	Quality management system
ReCoDID	Reconciliation of Cohort data in Infectious Diseases
REMAP-CAP	Randomised, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia
SOS COVID	SARS-CoV-2 Observational Study on Coronavirus Disease 2019
STAT-Net	Statistical network
UMC Utrecht	University Medical Hospital Utrecht
VACCELERATE	European Corona Vaccine Trial Accelerator Platform
VAP	Ventilator-associated pneumonia
VEO	Versatile Emerging infectious disease Observatory
VERDI	SARS-CoV-2 variants Evaluation in pRegnancy and paeDIatrics cohorts
ZonMW Netherlands	Organisation for Health Research and Development

ecraid

More information?
Mail us at jointhemovement@ecraid.eu or visit us at www.ecraid.eu

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