ANNUAL REPORT 2024

ecrin

Supporting clinical studies across borders

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Polish Medical Research Agency
Warsaw

Switzerland
SCTO
Bern

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Foreword

Management Team

For ECRIN, 2024 marks the transition to a new phase for the organisation. After celebrating its 10th anniversary at the end of last year ECRIN has launched its 2024-2027 Strategic Plan which builds on our experience and the expert knowledge existing within the organisation and its national partners, enabling ECRIN to consolidate its activities to continue serving the scientific community and its various stakeholders in an evolving clinical research ecosystem.

Stakeholders from across the organisation contributed to outlining the priorities for the coming years and identifying how *"in the next four years, ECRIN* ***will sustain****- the organisation, the activities, the community, the quality, and the collaborations;* ***will innovate****- to meet the new challenges and evolving clinical research ecosystem; and* ***will empower*** *-our staff, partners, and patients' community."*

A transition can also be noted in ECRIN's clinical study portfolio, with many of the first wave of clinical studies, from the early years after attaining its ERIC status, coming to a close and the progression from setup to running of the influx of studies that began in 2023. Within the context of the ERA4Health Partnership, this year also marked the launch of the pilot call for multinational investigator-initiated clinical studies (IICS).

Moreover, ECRIN increasingly contributes to European initiatives that align with its mission. These include, but are not limited to: Accelerating Clinical Trials EU (ACT EU), where ECRIN is involved in a variety of different activities, including the

ECRIN Management Team: Jacques Demotes, Marta Del Alamo, Sergio Contrino, Amélie Michon, Christine Kubiak and Alicja Szofer-Araya (left to right)

Multi-stakeholder Platform Advisory Group, to provide strategic advice on the ACT EU workplan and operational guidance on the ACT EU initiatives; EU-X-CT, which focuses on breaking down barriers to clinical trials through cross-border access; and the EFGCP eConsent initiatives to harmonise various aspects of eConsent.

Working with the different stakeholders of the clinical study community is at the core of what ECRIN does, and this is always exemplified in its big annual event, International Clinical Trials Day. In light of questions raised in previous years and the impending launch of the European Health Data Space, the focus of this year's event was Data Centric Clinical Research. Co-hosted with ECRIN's new Member, GreCRIN, in Thessaloniki, it brought together experts and stakeholders from across clinical research to discuss the challenges and the rapid progression of this field.

The importance of health data is highlighted in much of the work that has transpired in 2024 from the development of an open source statistical web application for validation and analysis of virtual cohorts in the SIMCor project to the continued development of our clinical research Data Sharing Repository (crDSR) in the BY-COVID project through to the inclusion of the first data set in the repository made available from the VACCELERATE project.

Other project highlights include the publication of the PERMIT project guidelines; the publication developed by ECRIN for the ERA4Health Partnership, guidelines for data sharing of IICS, a recommendation booklet for investigators and sponsors in multicountry IICS; the launch of the SENSITISE project which focuses on developing trainings on inclusive trial design; and the first international drug repurposing conference co-organised by REMEDi4ALL, to name a few.

ECRIN's commitment to supporting sponsors and investigators in the conduct of their clinical studies is demonstrated not only through their everyday activity but also through the maintenance of the ISO 9001:2015 certification, which allows the provision of high quality services ensuring user satisfaction.

The unity of the organisation and its national partners was highlighted through many of ECRIN's accomplishments this year. One example, with contributions from across the organisation and its national partners, is the successful launch of the updated version of ECRIN's Regulatory and Ethical Database, now known under the acronym RED. This has been developed as a central resource for information about clinical study regulatory and ethical requirements for submissions in Europe. It now provides freely available information on investigational products, medicinal devices and other studies for 16 countries.

For the national networks, ECRIN ran its Clinical Trial Unit Day, in December, which marked its 4th iteration. Moreover, with ongoing working groups in different subjects such as communications, we are working across Europe to build a cohesive approach to multinational IICS.

Assembly of members

Raphael DeAndres
(chair)

Oonagh Ward
(vice-chair)

Now with more than 10 years under its belt, ECRIN, a pillar of the EU clinical research community, continues to work to improve its capacity to answer the needs of its different stakeholders and partners. The organisation shared its ambitions for the next four years, which are outlined in the new Strategic Plan. This 2024-2027 Strategic Plan is focused on 5 goals touching on different aspects of its activities:

- ensure scientific excellence and public health relevance;
- cultivate a thriving and empowered ECRIN community;
- forge the path for future ECRIN services;
- consolidate and promote our visibility and awareness;
- sustain engagement with the research infrastructure ecosystem.

In line with a number of the goals, this year, ECRIN continued to work directly with its national networks to build understanding, share and collaborate on new opportunities, and create occasions for exchanging across the networks and with the greater clinical research community.

This includes a number of different activities from staples such as International Clinical Trials Day, which focused this year on Data Centric Clinical Research. Beyond the added support to clinical research, ECRIN's Member and Observer countries benefit from access to other services such as the Data Centre Certification program, which is seeing its value reinforced through the increasing number of requests for certification renewal.

ECRIN's Assembly of Members, December 2024

As the clinical research landscape continues to evolve, ECRIN is taking on a growing role in the European clinical research community, ensuring that the voice of academic researchers carries weight and is heard by large actors including regulatory bodies, funders, the pharmaceutical industry and that communication is open with all actors, including the public.

2024 Highlights

01 JANUARY

- APPEAL project kick off
- WHO Global Clinical Trial Forum
- CoMeCT project kick off
- BIOTOOL-CHF project kick off

02 FEBRUARY

- Close of ECRIN training series on EU proposal submissions
- ERA4Health workshop “Funding Mechanisms for IICS”
- INVENTS project kick off
- QUANTUM project kick off
- SENSITISE project kick off

03 MARCH

- EOSC ENTRUST project kick off
- REMEDi4ALL first International Drug Repurposing Conference (iDR24)

04 APRIL

- ECRIN launches 2024-2027 strategy plan
- INTEGRATE LMedC project kick off

05 MAY

- ICTD 2024: Data Centric Clinical Research
- canSERV challenge call for innovative approaches in research and clinical trials
- 2nd EU-Africa PerMed Summer School

06 JUNE

- ECRIN brochure released: general brochure and clinical operations

07 08 JULY-AUGUST

09 SEPTEMBER

- ERDERA partnership kick off
- SHARE-CTD propaedeutic course

10 OCTOBER

- ECRIN Summer School - *internal training*
- Launch of Regulatory and Ethical Database (RED)

11 NOVEMBER

- Publication of the PERMIT Guidelines
- ISO 9001:2015 certification maintained

12 DECEMBER

- CTU Day 2024

Mission & Vision

ECRIN MISSION

To support the conduct of multinational clinical research in Europe

ECRIN VISION

To generate scientific evidence to optimise medical practice.

ECRIN Strategy

- ECRIN as the reference for planning and management of multinational clinical research
- Anticipate changes in clinical research
- Build and maintain strong and balanced partnerships with users and patients that lead to more efficient and successful clinical research
- Enhance the recognition of ECRIN's corporate identity
- Create a cohesive cooperative pan-European CTU infrastructure
- Develop and strengthen collaboration of medical research infrastructures

ECRIN in Numbers

ECRIN as an organisation

11 years
that ECRIN has held its ERIC Status

13
Member & Observer countries

361 million
citizens living in ECRIN countries

130
clinical trial units

Scientific & Operational Activity

32
clinical studies supported by ECRIN in 2024 (with 4 new clinical studies)

79
total number of clinical studies supported to date

6.5
countries per ECRIN supported clinical study

26
infrastructure projects supported in 2024 (including 5 new projects)

Visibility & Outreach

5,904
LinkedIn followers
(+33% since 2023)

1,809
X followers
(+4% since 2023)

125
YouTube subscribers
(+28% since 2023)

ECRIN Overview

ECRIN-ERIC is a European Research Infrastructure facilitating multinational clinical research, through the provision of advice and services for the set-up and management of investigator or small and medium sized enterprise (SME) led clinical studies in Europe. ECRIN unites national networks of CTUs across Europe, through its scientific partners, to fulfil its vision of generating scientific evidence to optimise medical practice.

The core services provided by its staff are certified ISO 9001:2015, meet regulatory requirements and ensure user satisfaction. ECRIN is also involved in activities to enhance the ability of European institutions to successfully conduct multi-country clinical research (e.g., tools/database development, data centre certification). Moreover, ECRIN participates in projects aiming to develop its capacity, tools and services.

By supporting clinical studies across borders and advising and implementing policy, ECRIN advances knowledge flow, competitiveness and integration in European clinical research.

ECRIN's organisational model is based on country membership. With twelve Member countries (Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Spain, and Switzerland) and one Observer country (Slovakia).

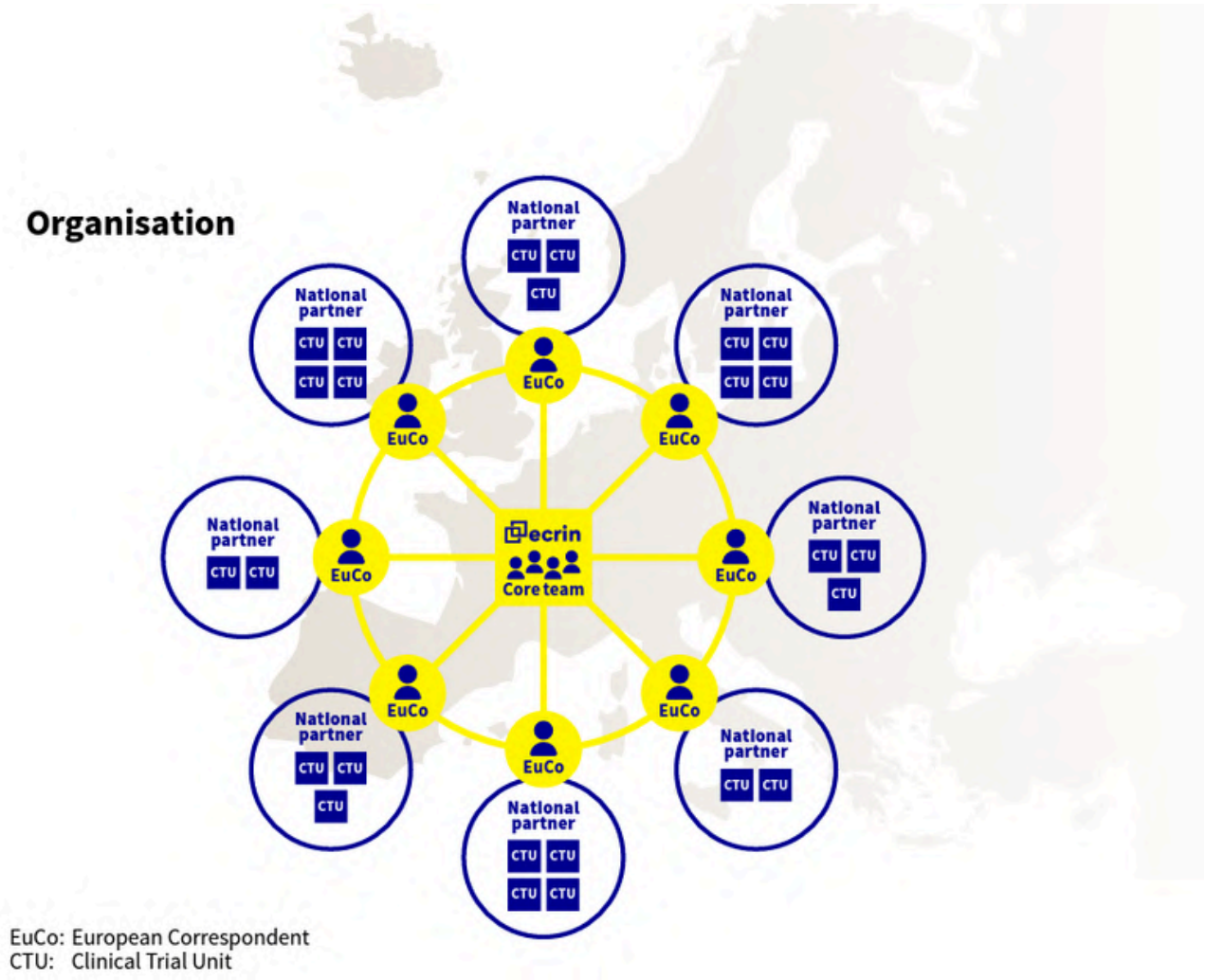


Figure 1: ECRIN's organisation structure.

Each country hosts a European Correspondent (EuCo) who is seconded to ECRIN by the national scientific partner, which is a network of academic CTUs located at, or affiliated to, national universities and hospitals. EuCos are clinical research experts with extensive knowledge of the national and European clinical research and regulatory landscape, operational management, and coordination of multinational studies.

They manage ECRIN's clinical trial portfolio in collaboration with the national scientific partner, the other EuCos and the Paris-based headquarters.

ECRIN's organisational model is based on country membership. With two new countries attaining member status, in 2023, it included twelve Member countries (Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Spain, and Switzerland) and one Observer country (Slovakia).

Strategy:

working with the community to build a better tomorrow

Interview on ECRIN's Strategic Plan 2024-2027

Jacques Demotes
General Director, ECRIN

Can you summarise the approach to the new ECRIN strategy?

The new ECRIN strategy plan was finalised and adopted in 2024, and will drive the design and implementation of the annual work plans until 2027. Consolidation is the keyword.

How does ECRIN situate itself?

ECRIN is now a mature organisation embedded in a dense research infrastructure ecosystem, and surrounded by new research instruments developed by the European Commission, together with the national funding bodies.

This includes, in particular, the concept of Missions (Cancer Mission) as well as Partnerships dedicated to specific health challenges (Rare diseases, Personalised Medicine, Brain Health, Pandemic Preparedness, ERA4Health, EDCTP etc), or supporting collaborations between academia and health industry (Innovative Health Initiative, IHI).

This changing environment requires ECRIN, as a generic research infrastructure, to adapt its strategy to the new research architecture, keeping a cross-fertilizing role across all medical disciplines while avoiding duplication of expertise and service provision.

What will be put in place for the 2024-2027 strategy?

Development of new tools and services will be promoted to maintain ECRIN at the leading edge of scientific excellence, while patient engagement and inclusivity will foster public health relevance of ECRIN activities.

As a pan-European federation of clinical trial units, ECRIN will take advantage of strengthening the ECRIN community and building harmonised and interoperable tools and procedures across ECRIN Member countries.

Methodological innovation, technological and regulatory opportunities to optimise the use of health and health research data, new trial designs and the opportunity of decentralised trials will require ECRIN to consider future services based on appropriate tools, procedures and know-how.

This also includes the promotion of innovative funding mechanisms to increase

the volume of multinational studies in Europe, and the development of CTUs and CTU networks in Europe to meet the WHO guidance and address the ECRIN Membership expansion.

In an increasingly complex ecosystem, communication and awareness is key to the success of ECRIN and its national partners, to attract the best clinical research projects and to optimise the use of ECRIN's tools and services.

Finally, partnership with the other research infrastructures supporting medical research, in particular the provision of joint services for complex projects, will broaden the scope of ECRIN services, while participating in European data initiatives such as EOSC and the EHDS will help ECRIN propose new solutions for data sharing and secondary use of health records.

Strategy

ECRIN woven into the clinical research landscape

The European infrastructure supporting investigator initiated clinical studies, ECRIN has a vital role in supporting the efforts carried out by academics and SMEs to advance medical knowledge. With its 2024-2027 Strategic Plan, ECRIN has built this continued support, through its actions, network, expertise and visibility as well as the space to reflect on future needs which could be integrated into its service offer.

Moreover, ECRIN is increasingly among the key players sitting around the table for a wide variety of initiatives, ensuring that the perspective of those from academia is taken into consideration. The largest of these is Accelerating Clinical Trials EU (ACT EU), where ECRIN is involved in different discussions on key topics for clinical research. ECRIN also participates in different initiatives driven by EFPIA and EFGCP which include the EU-X-CT endeavouring to make cross border clinical trials a reality and eConsent with the end goal of providing a fit for purpose eConsent framework.

Mapping priorities for the coming years

The ECRIN Strategic Plan 2024-2027 was developed by a dedicated ECRIN task force from October 2023 through to March 2024, and built based on the analysis of ECRIN's position in the environment, as well as of its strengths, weaknesses, opportunities, and threats. The feedback and suggestions from the ECRIN staff, ECRIN community and the governing body were actively collected during consultations.

These next four years represent a consolidation phase for ECRIN, building on the achievements accrued in the previous years and lessons learned. The main strategic objectives are:

- Strengthen ECRIN's position as a recognised infrastructure: demonstrate performance, impact, and the quality of services;
- Extend the scope of ECRIN's services and expertise, responding to the clinical research ecosystem evolution (i.e. new types of studies including adaptive platform trials);
- Maintain the infrastructure (operational services, staff, partners, collaborations);
- Continue building the community and engaging with national partners;
- Enhance patient engagement and collaboration with patient representatives;
- Consolidate and promote ECRIN's visibility and the awareness of the community (users, stakeholders, policy makers, regulators) through communication and training actions;
- Pursue collaboration with other research infrastructures and expand collaboration beyond Europe.

"In the next four years, ECRIN will sustain the organisation, the activities, the community, the quality, and the collaborations; will innovate to meet the new challenges and evolving clinical research ecosystem; and will empower our staff, partners, and patients' community."

Christine Kubiak - ECRIN's Operations Director

In response to these strategic objectives, the taskforce have defined five goals to drive ECRIN's activity for the 2024-2027 Strategic Plan.

The organisation will take action to ensure these goals become a reality and that ECRIN continues to serve the scientific community and its various stakeholders in an evolving clinical research ecosystem.

The voice of academic clinical research

As Europe's ambitions are set to improve and harmonise processes for clinical research across the continent, there is a surge in activity to unite stakeholders and collaborate on novel solutions. ACT EU, which launched in 2022 as a joint venture of the European Commission (EC), European Medicines Agengy (EMA) and Heads of Medicines Agencies (HMA), will support smarter clinical trials through regulatory, technological and process innovation. The ACT EU vision is to transform the EU into a region that supports clinical trial development and enables collaboration and innovation at all stages of the clinical research lifecycle, benefiting patients and healthcare in Europe in the process.

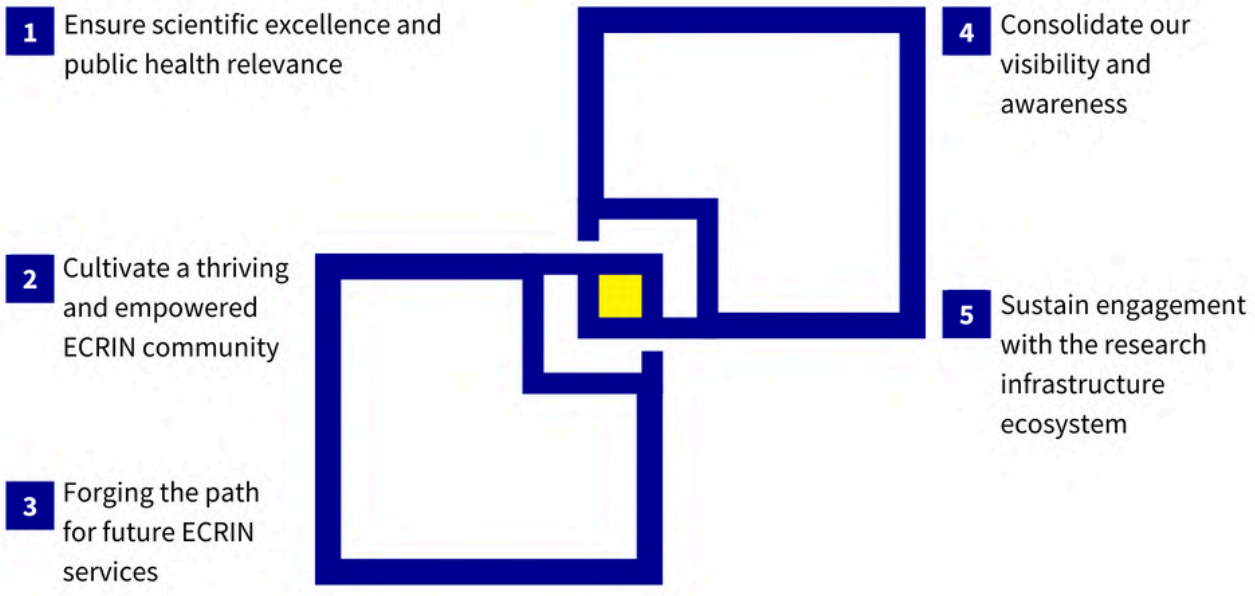


Figure 2: ECRIN's strategic goals as outlined in the 2024-2027 Strategic Plan

ACT EU will build on the Clinical Trials Regulation (CTR) and Clinical Trials Information System (CTIS). While the CTR officially launched in 2022, the transition period closes at the end of January 2025, leading to a very busy year in 2024 as all trials ensure that they have completed the transition process. To contribute to the discussions and improve the implementation of CTIS launch ECRIN participates in the CTR implementation working group coordinated by ACT EU as a representative of the academic user community.

ECRIN is also involved in another initiative housed under ACT EU, COMBINE. The COMBINE project addresses studies that include a medicinal product in parallel with a performance study of an in-vitro diagnostic or a clinical investigation of a medical device. The aim of which is to analyse root causes of the challenges encountered by sponsors in the conduct of these combined studies and to identify possible solutions.

ECRIN is a member of the Multi-stakeholder Platform (MSP) Advisory Group as a representative of academia. The MSP functions as a vehicle for clinical trials stakeholders and regulators to come together, share their points of view and collaborate to improve the clinical trials environment for European patients and citizens. Through the Advisory Group, ECRIN provides strategic advice on the ACT EU workplan and the identification of priorities as well as operational advice for the varied initiatives.

ACT-EU includes a focus on support to non-commercial sponsors that aligns closely with ECRIN's activities. It's dedicated webpage links to activities produced by stakeholders, including ECRIN's Regulatory and Ethical Database as well as several deliverables written by ECRIN for the ERA4Health Partnership.

Another example of the efforts to facilitate clinical research across Europe is EU-X-CT, cross-border access to clinical trials, which seeks to enable and facilitate access conditions in each European country and make it easier for clinical investigators to enrol patients from other European countries in their clinical trials. ECRIN has been contributing to this project since its inception in 2022 and over the course of the past year, participated in the public stakeholder's forum as the academic representative for this activity marking a significant milestone and outlining the way forward for the project.

Lastly, the eConsent Initiative, driven by EFGCP, focuses on the creation of practical tools and recommendations aimed at harmonising eConsent terminologies, study document requirements, and implementation methods. Over the course of the initiative, recommendations from a selection of the workstreams, have been made available. ECRIN continues to contribute to ensure that the perspective of academic investigators are considered.

At the global scale ECRIN joined the World Health Organization's (WHO) Global Clinical Trial Forum in Geneva and contributes to the discussions on the implementation of the World Health Assembly (WHA) resolution

75.8, aiming to strengthen clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination.

New funding opportunities launched

ECRIN has been working with the ERA4Health consortium to reflect on funding models that can provide funding from many national funders and make them available to multinational IICS. At the end of 2024, the first ERA4Health IICS call was launched, aiming to support randomised, interventional and pragmatic comparative-effectiveness multi-country IICS. All while encouraging and enabling transnational collaboration between clinical/public health research teams (from hospital/public health, healthcare settings and other healthcare organisations) that conduct comparative-effectiveness multi-country IICS.

Maintaining certification

In 2024, ECRIN maintained its ISO 9001:2015 certification for its quality management system (QMS). The QMS aims to coordinate and structure the organisation's activities to meet customer and regulatory requirements, and to improve effectiveness and efficiency on an ongoing basis.

ECRIN's current activities covered by its QMS and ISO 9001:2015 certification are as follows:

- Coordination of operational services to the management of multinational clinical trials in Europe
- Capacity development through participation in infrastructure development projects and Certification of Data Centres

The certification applies to activities carried out by ECRIN staff (both its core team and European Correspondents).

Interview on ECRIN's participation in ACT EU

Amélie Michon
Head of Clinical Operations, ECRIN

What is ACT EU?

ACT EU is a European initiative that has been jointly launched by the European Commission (EC), the European Medicine Agency (EMA) and the Heads of Medicines Agency in 2022 with the vision to create better, faster and smarter clinical trials in Europe. The overall goal is to make the European Union a region that supports clinical trial development and enables collaboration and innovation amongst trial stakeholders.

ACT EU is organised into different priority action areas. Among those, one that is important for us at ECRIN, is the one dedicated to the support of academic sponsors running multinational clinical trials, this fully aligns with ECRIN's mission.

We are also involved in priority actions dedicated to the clinical trial regulation and to the Multi-Stakeholder Platform Advisory Group.

What is the overarching goal of the Multi-Stakeholder Platform Advisory Group?

The goal is to create a vehicle where all clinical trials stakeholders can come together with regulators to share their vision, priorities and ideas on how to create a common space for clinical trials in Europe.

What is your role as an academic representative?

My role is to bring the academic perspective into the group to share ideas and operational advice to the initiative.

The Multi-Stakeholder Platform Advisory Group meets every three months. As a representative of the academic sector, I attend those meetings and use the opportunity to share our views and priorities.

What is also important for me as an academic representative is to promote ACT EU. For example we invited ACT EU representatives to join our ECRIN meeting with the objective of promoting and increasing the knowledge of ACT EU at the national level within our community.

ACT EU

Can you share some of the work that you have carried out to date?

I have been involved in several activities. In terms of focus groups, we are actively participating in one dedicated to improving CTIS training materials. We participate in meetings to contribute and give our perspective as users of this training material.

We are actively involved in the priority related to the CTR implementation in the CTIS focus group. Our role is to gather feedback from the academic sponsors and the academic community, then to share it with the group and EMA.

I've also been involved in consultations and surveys, where the objective is to, once again, provide our perspective as an academic community on specific topics. The next one will be dedicated to key performance indicators, on how the ACT EU initiative is going to be evaluated in the next years. It was important for us to share our views and needs on how we should measure the impact of this initiative in the academic community. We were also in another survey, which was dedicated to the training needs of academic stakeholders. This activity is very relevant, and we are very involved and dedicated to providing our feedback to ensure our voice is heard.

Finally, I have been involved in the organisation of the Multi-Stakeholder platform in-person meeting, providing advice on the content and the topics discussed. It is key that we are a part of this activity to ensure that our priorities are shared and presented to the community.

Amélie Michon and Jacques Demotes attending the Multi-Stakeholder Platform meeting in Amsterdam

Watch Amélie Michon's video interview on our YouTube channel

View Amélie Michon's interview

Special focus on Drug Repurposing

Special Focus: Drug repurposing

Drug repurposing is the process of identifying new therapeutic uses for existing medications. This strategy has gained significant attention in recent years due to its potential to accelerate the development of new treatments, reduce research and development costs, and improve patient outcomes.

Investigator-initiated clinical studies are well poised for exploring the repurposing of drugs, as they are often driven by the insights and expertise of researchers who identify promising candidates based on scientific evidence. This approach holds particular importance in the context of diseases with unmet medical needs, where traditional drug discovery can be a lengthy and expensive process.

A recent example that gripped the world was the significant role that drug repurposing played in the search for treatments during the COVID-19 pandemic and while some of the molecules did not prove effective, others were shown in clinical trials to reduce symptoms and shorten patients' hospital stays.

The advantage of drug repurposing lies in the fact that many existing drugs have already undergone extensive safety testing, and their pharmacokinetics and pharmacodynamics are well-understood. As a result, IICS can focus on evaluating the drug's efficacy for a new indication, potentially shortening the time to market for new treatments. In contrast to developing a novel drug from scratch, repurposing offers the potential to sidestep the early stages of preclinical testing and move directly into clinical trials, making it a more efficient and cost-effective approach.

In addition to reducing the time and cost associated with drug development, repurposing offers the opportunity to address therapeutic gaps in rare, complex, or underfunded diseases. IICS are often well-suited for investigating the potential of repurposed drugs in these areas. They can also lend themselves to direct collaboration with industry partners, fostering innovation and the rapid translation of scientific

discoveries into real-world treatments. ECRIN is available to support investigators and sponsors developing multinational IICS in the field of drug repurposing.

Identification of obstacles to drug repurposing

Within the EJP-RD Partnership ECRIN worked with patient organisations, researchers, regulators, funders, sponsors, CTU representatives and European Research Networks (ERNs) to identify obstacles hindering the development of IICS for drug repurposing on rare diseases. A dedicated workshop was hosted in 2022 in Prague, which led to a publication on the subject through the prism of six use cases.

Administrative burden and lack of harmonisation for trial-site agreements were deemed the major hurdle. Other key obstacles included the following: (1) complexity and restriction on the use of public funding, especially in a multinational set-up, (2) drug supply, including procurement tendering rules and country-specific requirements for drug stability, and (3) lack of harmonisation on regulatory requirements to get trial approvals.

With the main hurdles being more operational than scientific, a first step is to ensure that the existing support structures, such as ECRIN, guidance and support mechanisms and clinical research programs, are clearly visible and accessible to the community.

REMEDi4ALL is reshaping drug repurposing

ECRIN is participating in the Horizon Europe funded project, REMEDi4ALL which aims to develop a comprehensive, accessible and standardised platform that provides the expertise, tools and resources required in all stages of the

EJP-RD NSS Workshop, Prague 2022

repurposing journey. Moreover, the consortium aims to generate a more favourable policy environment by bringing together key stakeholders to identify current barriers and explore creative solutions and incentives. In parallel, the project is working to build a dynamic global repurposing community hosting a series of events and training, most notably the annual international drug repurposing conference (iDR24), whose first edition this year brought together over 250 experts. REMEDi4ALL has selected four medicine repurposing projects in different stages of development to demonstrate the viability of the newly created platform. Each project covers a different therapeutic area with high unmet medical needs– pancreatic cancer, COVID-19, rare diseases and ultra-rare diseases. These projects will serve to test all elements of the platform to optimise its tools, services and ensure a patient centric offer.

Clinical project manager, Sareema Javaid, judging the poster session at iDR24

ECRIN is leading the work package on clinical development and implementation, in which an inventory of resources and gap analysis will be carried out, recommendations and a blueprint for the establishment of a clinical repurposing platform will be developed, a dedicated services platform will be created. Provision of services for the clinical demonstrator(s) will be the opportunity to validate and refine the service offer.

Examples of drug repurposing trials

EU-SolidACT – Baricitinib

Drug repurposing was one of the principal routes in the search for treatment throughout the COVID-19 pandemic. Within the platform trial EU-SolidACT coordinated by ECRIN, one of the arms tested the molecule Baricitnib in patients with severe COVID-19. Identified as a drug with a high potential for repurposing in certain populations of COVID-19 trials this study looked to extend its applicability to those with severe cases of COVID-19.

TREOCAPA - Paracetamol

Similarly, the TREOCAPA trial took a well-known medication, paracetamol and tested its efficacy in extremely premature infants to determine its efficacy in closing patent ductus arteriosus.

LIVERHOPE - rifaximin and simvastatin

LIVERHOPE includes two separate trials LIVERHOPE SAFETY & LIVERHOPE EFFICACY. The aim of the LIVERHOPE SAFETY trial is to assess the safety and tolerability of oral administration of simvastatin plus rifaximin in patients with decompensated cirrhosis.
The aim of LIVERHOPE EFFICACY is to assess the efficacy of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis to prevent ACLF development.

REMEDi4ALL demonstrator projects

VESPA - valproic acid and simvastatin

This demonstrator is testing first-line gemcitabine and nab-paclitaxel-based regimens with or without valproic acid and simvastatin in advanced pancreatic ductal adenocarcinoma.

MOI-A - losartan

It aims to identify the dose of losartan that is effective in reducing circulating levels of CTX, a bone resorption (destruction) marker, without causing undue side effects in patients with osteogenesis imperfecta.

Interview on drug repurposing

Sareema Javaid
Clinical Project Manager, ECRIN

What is the REMEDi4ALL project and what is its aim?

The REMEDi4ALL project is a project about creating a platform for drug repurposing within Europe. It's led by EATRIS, and it brings together 26 organisations from all around Europe with diverse expertise.

Its aim is to create an accessible, comprehensive and a standardised platform where we can bring together expertise, tools and resources that are currently available to support the repurposing projects at all stages of the development, from pre-clinical to clinical.

How does the project support the research community?

REMEDi4ALL brings together a unique mixture of expertise throughout Europe and supports projects in various fields. Some examples include, in-silico computational methodology, in vitro in vivo clinical development, clinical development, drug screening, patient engagement activities and research funding.

We are also doing research on regulatory requirements and hurdles by involving different stakeholders and finding ways to improve. We support projects through health technology assessment research and project management, from the start of the project to the end. Our basic aim for the research community is to make the drug available to the patients.

"Our basic aim for the research community is to make the drug available to the patients."

How will the project impact patients and the larger population?

We consider patients at the heart of the REMEDi4ALL consortium. We have several demonstrator projects, one in pre-clinical and three in clinical stage, and in each of these, patients are at the centre, irrespective it's in pre-clinical or clinical, whether it's a

protocol development, whether it's a patient engagement plan development, whether it's the overall trial methodology development.

We are working very closely with patient communities, organisations and representatives to priorotise patients within clinical trials, to make their voices heard to the larger community.

REMEDi4ALL is running a Digital Academy where we have courses free of cost for all, irrespective of whether you are a patient, a researcher, a student or at a higher stage in your career. Please do visit our Digital Academy.

There is also the REMEDi4ALL Concierge; if you have a project or if you want to discuss anything about drug repurposing, reach out (to the concierge).

What is ECRIN's role in the project?

ECRIN is leading a work package on clinical development and implementation within the REMEDi4ALL consortium. We're supporting the clinical demonstrator projects as requested.

We are working across the consortium within all other work packages to bring together expertise and streamline the process of clinical development for repurposing projects, so it can help future projects to navigate the process more smoothly.

Watch Sareema Javaid's video interview on our YouTube channel

View Sareema Javaid's interview

National Scientific Partners:

Description and Highlights

CZECH REPUBLIC

Scientific Partner: CZECRIN - Czech Clinical Research Infrastructure Network
Full Member since 1 Jan. 2018
Host institution: Masaryk University
National hub: Brno
http://www.czecrin.cz/en/home/

CZECRIN is a national, large research infrastructure, included in the Czech Roadmap for Large Research, Development, and Innovation, facilitating academic clinical trials in the Czech Republic. Established as a unique infrastructure, connecting a network of major clinical sites, it is focused on clinical research, while also providing knowledge, development, production, and implementation capacities for the research and development of drugs and medical devices.

CZECRIN has put advanced solutions in place to ensure the effective provision and use of high-quality scientific data, implementing the FAIR (Findable, Accessible, Interoperable and Reusable) principles. In addition, CZECRIN organises annual educational events and conferences, including National Clinical Trials Day, further strengthening its role in promoting excellence in clinical research.

2024 Highlights

CZECRIN strengthened its international collaboration and data quality standards by hosting the first ECRIN-certified Czech data centre, Institute of Biostatistics and Analyses, Ltd.

CZECRIN has been an integral part of the new Central European Advanced Therapies and Immunotherapies Centre (CREATIC).

CZECRIN has reinforced patient engagement and training initiatives, serving as a pillar of the EUPATI National Platform and providing specialised training for representatives of patient organisations. The Czech-adapted EUPATI training course received the official patronage of the Minister of Health, reflecting its national importance in patient-centered education.

Eighty new clinical trials were initiated, bringing the total number of clinical trials supported to over 200, further strengthening CZECRIN's role in promoting non-commercial research. CZECRIN hubs continued to enhance the organisation's capacity, competencies and services, expanding collaborations with 28 hospitals and specialised centres and strengthening support for academic clinical trials.

The strategic expansion of Disease-Oriented Networks (DONets) further bolstered CZECRIN's engagement in disease-specific research initiatives.

The CZECRIN Academy continued its strong commitment to education, offering a wide range of training programmes tailored to different levels of expertise. In 2024, approximately 1,250 participants took part in its structured educational activities.

FRANCE

Scientific Partner: F-CRIN - French Clinical Research Infrastructure Network
Member since 29 Nov. 2013
Host institution: Inserm
National hub: Toulouse
www.fcrin.org/en

F-CRIN, created in 2012, is one of the single contact points facilitating France's participation in clinical studies. F-CRIN brings together the major academic and commercial stakeholders in clinical research in France, including clinical research and innovation departments from university hospitals, clinical investigation centers, and interregional groups for clinical research and innovation.

F-CRIN enables multinational, multi-centre, investigator-driven clinical trials and early-phase proof-of-concept studies. Clinical study support is provided through F-CRIN by:

- 17 national networks, which specialise in specific diseases or areas of medicine (e.g., cardiology, nutrition, inflammatory diseases, cardiorenal diseases, thrombosis, vaccinology, Parkinson's disease, sepsis, stroke, severe asthma, psychotic disorders and primary care)
- Two specific expertise networks (health technology / medical devices, rare diseases)
- One platform of professional services (EUCLID)
- One national coordination unit.

2024 Highlights

The F-CRIN network labeled "MUST" (Multidisciplinary University Research Network for Primary Care), a clinical research network in primary care, on 1 September 2024.

F-CRIN launched a fourth labeling campaign for new clinical research and investigation networks. The campaign consisted of two sections: the first was an "Open Campaign," where candidates were free to choose their network's theme, provided certain conditions were met. And the second was a "Targeted Campaign", which was aimed at labeling networks that were focused on women's health and innovative therapies. The selection of winners from the campaign will be decided by the Governance Council in 2025.

Two F-CRIN networks (NS-PARK : Parkinson's disease and CRICS-TRIGGERSEP: Sepsis/Intensive Care) running dedicated platform trials were selected for co-financing from F-CRIN national coordination to support sustainability.

GERMANY

Scientific Partner: KKSN - Netzwerk der Koordinierungszentren für Klinische Studien
Member since 29 Nov. 2013
Host institution: KKS-Netzwerk e. V.
National hub: Berlin
http://www.kks-netzwerk.de

Established in 1999, the KKS-Netzwerk e. V. (KKSN) is an association of currently 28 academic coordinating centres for clinical trials (KKS/ZKS) all over Germany. Members of the KKSN are competence hubs for quality-oriented clinical research and translation. They provide full trial services for medicinal products as well as for medical devices. Some KKS/ZKS provide CTU specific tasks for academic researchers.

The KKSN structure enables close collaboration between study centres in multicentric trials, facilitating a high level of quality. Network members are involved in various national and international clinical research projects and collaborate with diverse stakeholders on a national and European level.

2024 Highlights

The conduct of clinical trials in Germany under the CTR and MDR was significantly simplified in 2024 by the Medical Research Act. For many radiological procedures, only an ethics application is now required, which is processed by the Ethics Committee. Binding contractual clauses are another component of the Medical Research Act. Furthermore, “one study - one vote” principle requiring only the vote of one ethics committee for all trial sites in Germany has been accepted. KKSN has been actively engaged in these efforts to reduce bureaucracy for clinical studies in Germany.

Organised by KKSN Germany, the KKSN Austria and the SCTO Switzerland, more than 600 participants exchanged views on issues related to academic clinical trials during DACH Symposium in Berlin in September 2024.

Collaboration of the KKSN with the Network of University Medicine was extended as well as with other industrial and academic stakeholders on cost calculation and contract clauses to further improve the conduct of clinical trials and the use of data in Germany.

Eleven ECRIN projects are coordinated by the KKSN, support is also provided to 17 other ECRIN projects in which KKSN members are participating. Additionally, seven coordinating project proposals (three still in development from the previous year) and four participating project proposals were supported and processed by the EuCos.

GREECE

Scientific Partner: GRECRIN – Greek Clinical Research Infrastructure Network
Member since 18 April 2023
Host institution: CERTH
National hub: Thessaloniki
https://grecrin.gr/

Since its inception, GRECRIN has been working with stakeholders in academia and patient advocacy groups to build the necessary structure to support the Greek clinical research environment.

Alongside Centre for Research and Technology Hellas (CERTH), the national node for Greece in ECRIN, key research centers, six universities covering the entire country, patient organisations, and scientific collaborative groups have agreed to work together to realise the vision of GRECRIN.

The core partners of GRECRIN have worked to define the catalogue of services and tools to be offered to the clinical research ecosystem in Greece. More precisely, GRECRIN will provide services to support scientists in the conduct of clinical studies, addressing issues in all relevant stages (e.g., planning, risk management, operational coordination, and implementation).

2024 Highlights

On May 23rd, 2024, GRECRIN co-hosted ICTD 2024 “Data Centric Clinical Research” at its national hub in Thessaloniki. This hybrid event brought together 140 participants in the venue and hundreds of stakeholders from the international clinical research community who joined the online broadcast.

GRECRIN also contributed to the ECRIN Regulatory and Ethical Database (RED) and has collected the regulatory and ethical submission requirements to assist Greek and international investigators conduct clinical research in Greece. This information is available in English on RED and in Greek on the GRECRIN website.

HUNGARY

Scientific Partner: HECRIN – Hungarian European Clinical Research Infrastructure Network
Member since 5 November 2014
Host institution: HNHDA
National hub: Budapest
https://neku.org.hu/en/hecrin

The Hungarian National Healthcare Development Agency (HNHDA) was established by the competent Ministry in 2021 to strengthen Hungary's clinical trial infrastructure and enhance its international visibility. The agency's primary mission is to support the development of clinical research capabilities and attract a growing number of clinical trials to Hungary. Additionally, HNHDA provides continuous assistance to research centers and clinical trial sites, facilitating their scientific and research activities.

HNHDA actively engages in international collaborations, sharing its expertise in research, clinical trials, and pharmaceuticals in both bilateral and multilateral partnerships. The agency also serves as the host institution for HECRIN, which aims to support the conduct of investigator-initiated multinational clinical trials in Hungary.

2024 Highlights

In 2024, HNHDA continued to foster collaborations in the field of clinical research across Hungary. The agency played a key role in assisting several research institutions in establishing Phase I units, contributing to the expansion of early-stage drug development capabilities. As part of these efforts, a new clinical pharmacology unit was established within the National Korányi Institute of Pulmonology (OKPI). This facility enables the institute to participate in the early stages of innovative drug development, with a particular focus on medications for the treatment of lung diseases.

HNHDA also contributed to the organisation of clinical trial training programs, further supporting the professional development of researchers in the field.

HECRIN prioritised the expansion of Hungary's national clinical research network. Efforts were directed at strengthening ties with leading research sites and fostering new partnerships with research institutions, allowing the national network to grow in 2024. Additionally, in 2024, the HECRIN website was refreshed, and now contains information on HECRIN's objectives, clinical operations, and the services provided through ECRIN.

IRELAND

Scientific Partner: HRB NCTO – Health Research Board National Clinical Trials Office
Member since 20 November 2018
Host institution: University College Cork
National hub: Cork
https://ncto.ie/

The HRB National Clinical Trials Office, (HRB NCTO), established May 2021, is an independent, integrated, national clinical research network, providing centralised support to the conduct of multi-centre clinical trials and investigations/studies (both commercial and academic) across Ireland.

With the support of the Health Research Board, host institution University College Cork, Enterprise Ireland and in partnership with the seven University-based Clinical Research Facilities/Centres (CRFs/Cs) in the Republic of Ireland, the HRB NCTO was developed to build on the positive achievements of previous investments in clinical trials coordination and facilitate future investments in national clinical trials infrastructure in Ireland.

The central office provides overarching clinical research support and expertise, through a range of services and activities to academia, disease specific Clinical Trial Networks, and industry. Our partner University CRF/C's in Ireland provide the infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight programmes that are critical for the successful conduct of world-class patient-focused research.

2024 Highlights

- NCTO ran a communications and awareness campaign to highlight the NCTO and the clinical trial sector in Ireland leading to over 300% growth in LinkedIn followers via 46 unique articles.
- The National Study Feasibility support service carried out 113 feasibilities in 2024, with 33 relating to oncology feasibilities and 80 for other areas.
- The NCTO ICTD conference, "Advancing Healthcare in Ireland through Clinical Research", on May 9th, with more than 300 delegates attending, was the NCTO's largest ICTD conference to date.
- It hosted "Medtech Advance: Transforming Clinical Investigations in Ireland" a workshop in Galway attended by 120 delegates on October 3rd.
- Pursued the promotion of the Medtech Toolkit which provides all information for planning and carrying out clinical investigations in Ireland.
- "Enabling High Quality Clinical Trials in Ireland" was hosted by the HRB NCTO to increase the awareness of the great work delivered by its representatives.
- Established a Sponsor Working group along with other functioning working groups for Study Feasibility and Start Up, Pharmacovigilance and Quality.

ITALY

Scientific Partner: ISS - Istituto Superiore di Sanità / ItaCRIN - Italian Clinical Research Infrastructure Network
Member since 29 Nov. 2013
Host institution: Istituto Superiore di Sanità (ISS)
National hub: Rome
www.itacrin.it

The Italian Clinical Research Network is coordinated by the Istituto Superiore di Sanità (ISS) in Rome, where the national hub is located, and groups together 15 CTUs and Contract Research Organisations (CROs) covering the entire country.

The main objective of ItaCRIN is to promote non-profit clinical research in Italy and Europe by offering support to Italian clinical researchers in setting up and running multinational clinical trials to overcome hurdles and improve collaboration across borders. Network members are involved in various national and international clinical research projects through the provision of a full range of trial services.

In line with the ECRIN Strategic Plan, ItaCRIN prioritises training events for the national scientific community and collaboration with patient associations. These courses are conducted in accordance with the UNI EN ISO 9001:2015 certification issued by ISS.

2024 Highlights

As part of the ERA4Health Partnership, ItaCRIN and ECRIN have developed two key documents to support multinational clinical trials by non-commercial sponsors: Mapping of Funding Sources and Mapping of Existing Support Organisations. Both are promoted on the ACT-EU webpage.

ItaCRIN has the pleasure of coordinating a new ECRIN clinical study, sponsored by Istituto di Ricerche Farmacologiche Mario Negri.

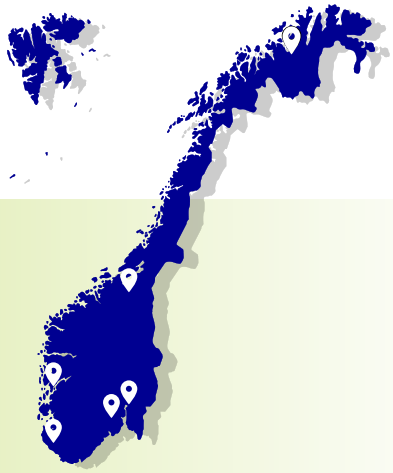
Two new CTUs, Azienda Ospedaliero Universitaria Careggi (Florence) and Azienda Ospedaliero Universitaria SS Antonio e Biagio e Arrigo (Alessandria) joined ItaCRIN in 2024.

ItaCRIN has updated regulatory and ethical guidelines for Italy, available in the RED.

In spring of 2024, ItaCRIN organised a series of trainings, together with the Italian National nodes of BBMRI and EATRIS to support over 100 researchers for preparing a successful research proposal.

ItaCRIN has also initiated patient engagement initiatives, including a collaboration with The Synergist, discussions with EUPATI Italy, and a partnership with Cancer Patients Europe for the national ICTD. Moreover, it has engaged in national scientific meetings concerning patient engagement and personalised medicine linked to the Coordination and Supporting Activities under the umbrella of Personalized Medicine Horizon Europe initiatives.

NORWAY



Scientific Partner: NorCRIN - Norwegian Clinical Research Infrastructure Network
Member since 18 May 2016
Host institution: Helse Bergen HF
National hub: Bergen
www.norcrin.no/en/

NorCRIN is a national network, with partners in the six university hospitals, covering all health regions of Norway. NorCRIN is currently funded by the Norwegian Research Council and with in-kind contributions by the partners, by original initiative of the Ministry of Health and Care Services.

NorCRIN's primary objective is to strengthen synergies and collaboration in clinical research in Norway and to ensure better quality by harmonising procedures and regulations.

NorCRIN has developed tools, courses and standard operating procedures (SOPs) to ensure adherence to best practice and to support clinicians in the planning and conduct of clinical trials. A great strength of NorCRIN is the close collaboration between the CTUs within the network – enhancing the distribution of clinical trial support to all regions of the country.

NorCRIN continues to be hosted by Helse Bergen HF, and the secretariat is located at Haukeland University Hospital in Bergen. NorCRIN aims to strengthen Norway's clinical research capabilities and knowledge of clinical trials in the general public as well as our position in the European research environment.

2024 Highlights

In 2024, NorCRIN has contributed to the revision of the Norwegian governments Action Plan for clinical studies and has also contributed to the WHO guidelines for clinical trials.

In August, NorCRIN participated at the annual democratic week in Arendal, hosting an event together with NorTrials and NorPedMed, where clinical trials stakeholders debated how to allow more and better clinical trials in Norway.

In 2024 NorCRIN finalised a report where the activities and capabilities of the nodes in the networks were categorised and evaluated. A part of the report also included visits to CTUs in other countries, to establish connections and compare practices. This led to the planning of a Nordic meeting for clinical research infrastructures to strengthen common practices and enable closer collaborations on clinical research.

NorCRIN's core platform for information and support is its website which was upgraded in 2024, in preparation for transfer to a common platform for the health care services in 2025, including an English version off all SOPs.

POLAND

Scientific Partner: PCTN - Polish Clinical Trials Network
Member since 30 September 2022
Host institution: Polish Medical Research Agency (MRA)
National hub: Warsaw
https://abm.gov.pl/en/polish-clinical-trialsnetwork/

The Polish Clinical Trials Network (PCTN) aims to implement uniform and, systemic solutions for quality and process management at institutions involved in conducting clinical trials in Poland. Continuous implementation of new solutions is expected to have a direct impact on reinforcing Poland's position in the clinical trial industry, boosting the competitive advantage of domestic infrastructure and its potential to support high-quality research to promote more effective international cooperation.

2024 Highlights

In 2024, the Medical Research Agency (MRA) launched a call for proposals for the creation and development of Clinical Trials Support Centres. The 10 public entities selected in the competition will receive funding and will soon become new members of the PCTN. This will increase the number of PCTN members to 33 entities.

In addition, five new entities have joined the PCTN as observers and one entity, the People4People foundation, as a partner.

The PCTN launched new social media channels, including a LinkedIn account that had nearly 800 followers at the end of the year. A bilingual catalogue of the Polish Clinical Trials Network was published, containing information about centres, equipment, infrastructure, experience, researchers and certificates. The catalogue is intended to make it easier to get to know the resources of the PCTN and to serve as a promotional and marketing tool.

A procedure for managing adverse events in clinical trials was developed. The document is public and available on the MRA website. Templates for tripartite and quadripartite agreements were updated, bringing them in line with new regulations and market needs.

The development of the PCTN ICT system, consisting of the PCTN portal and the MRA eCRF, continued.

In 2024, 11 ongoing projects were fully operational in the MRA eCRF system. In addition, the system was used for the MRA eCRF system as well as the first MRA research experiment, titled *'A comparative study evaluating the use of the non-invasive EndoRNA test in the diagnosis of endometriosis against laparoscopy*'.

PORTUGAL

Scientific Partner: PtCRIN – Portuguese Clinical Research Infrastructure Network
Member since 29 Nov. 2013
Host institution: Local Health Unit of Coimbra
National hub: Coimbra
www.ptcrin.pt

PtCRIN is an infrastructure dedicated to enhancing national clinical research by streamlining the implementation and conduct of IICTs across all disease areas. Its primary goal is to bolster both the quantity and quality of such trials by promoting international collaboration and fostering the generation of robust evidence crucial to support clinicians and decision-makers adopting safe and cost-effective therapeutic strategies.

PtCRIN is a consortium comprised of 26 esteemed national institutions, is included in Portuguese Roadmap of RIs, and represents the forefront of Portuguese clinical research. It serves as a central hub that facilitates a network of six academic CTUs, each providing a wide array of comprehensive trial services. These range from protocol design, regulatory and ethical submissions, to project management, pharmacovigilance, data management, monitoring, and reporting, for medical devices and medicinal product trials.

Additionally, PtCRIN remains committed to advancing the competencies of clinical investigators through initiatives like the CLIC (Clinical Investigator Certification) program and other tailored training programs, reinforcing itself as a strategic infrastructure to drive excellence and innovation in Portuguese clinical research.

2024 Highlights

This year marked the transition of PtCRIN's coordination from NOVA Medical School in Lisbon to the Local Health Unit of Coimbra and University of Coimbra. In November, a new CTU was welcomed to the network: CRU-RISE.

PTCRIN collaborated with ECRIN and its partners for the local onsite session of the training "Everything You Need to Know About Submitting a European Multinational Clinical Study Proposal". PtCRIN also actively participated in various national research initiatives, engaging with scientific institutions and patient associations to emphasise the importance of IICTs in the national research landscape. Moreover, PtCRIN facilitated meetings between its members and various regional development coordinators to discuss its role within the research investment framework.

Additionally, PtCRIN was involved in five ECRIN multinational clinical trials, with the participation of 15 national CRCs and four PtCRIN's CTUs, one of which served as the Lead CTU. The network carried out digital dissemination, updating the website and enhancing LinkedIn activity as well as sharing a monthly newsletter with members.

SLOVAKIA

Scientific Partner: SLOVACRIN – Slovak Clinical Research Infrastructure Network
Member since 1 Jul. 2018
Host institution: Pavol Jozef Šafárik University
National hub: Košice
www.slovacrin.sk/en

The national infrastructure SLOVACRIN aims to enhance both the quantity and quality of academic-initiated clinical trials in Slovakia by leveraging existing capacities, expertise, and advancements in medical research and development. Additionally, it seeks to establish a robust network of Clinical Trials Units. Since 2021, SLOVACRIN has been included in the Roadmap of Research Infrastructure SK VI Roadmap 2020–2030, the Slovak Republic's key strategic document for research infrastructures.

2024 Highlights

The SLOVACRIN infrastructure, in collaboration with key stakeholders in clinical research, organised its National Clinical Trials Day. The event featured a presentation on the upcoming national clinical research strategy and the country's support for ESFRI infrastructures. Representatives from the CZECRIN infrastructure introduced ECRIN, outlining its current vision and implementation across the EU.

Regulatory authorities provided updates on the Clinical Trials Regulation and, in this edition, also shared insights into medical devices. Commercial sponsors presented the results of their survey on the number of clinical trials conducted in Slovakia, offering an analysis of the research environment.

The event concluded with an open discussion, where participants addressed key challenges and proposed solutions for the future of clinical research in Slovakia.

SPAIN

Scientific Partner: SCReN - Spanish Clinical Research Network
Member since 29 Nov. 2013
Host institution: Instituto de Investigación del Hospital Universitario La Paz, IdiPaz
National hub: Madrid
www.scren.es

SCReN is the National Platform to support clinical trials in Spain, and it is funded by the National Institute for Health Carlos III (ISCIII). As of 1 January 2024, SCReN is composed of a network of 33 CTUs and 7 CTU-associated sites based in clinical centres of the Spanish National Health Service, covering the whole country. SCReN is organised in Working Groups (WGs) to cover all the areas of expertise and activity.

The SCReN General Coordination has been based in Madrid at La Paz University Hospital-IdiPAZ (Clinical Pharmacology Department and CTU) since 2021. Since August 2022, the ECRIN EuCos are hosted at the Virgen de la Victoria University Hospital (Clinical Pharmacology Service, IBIMA-Plataforma Bionand). The EuCos and SCReN coordination lead the Internationalisation WG under ISCIII directives, which represent the networks international collaboration strategy.

SCReN aims to foster excellence, leadership and quality in clinical research through networking, international cooperation, and support to clinical academic research projects, translating them into innovation for the Spanish National Health Service and European Society.

2024 Highlights

In 2024, SCReN's portfolio incorporated 19 new clinical trials projects and a capacity project. SCReN has established collaborations (e.g. CIBER-ISCIII, RICORS, public-private project consortia) enabling joint competition to calls and opportunities promoted by Spanish funding agencies (ISCIII and Agencia Estatal de Investigación) and acting as an advisor/facilitator of cross-cutting support. These collaborations have included both clinical trial projects (1) and capacity building (3). The collaborative strategy is aligned to the SCReN performance for joint interaction with the other ISCIII networks (ITEMAS, Biobanks & Biomodels), and also internationally with B&B and EATRIS ES as the national level of EU-AMRI .

To extend the scope of the network towards the use of AI and clinical data a dedicated SCReN WG was created and will be launched in the coming year now that the coordination team has been identified. In addition, May 2024, marked the arrival of a second EuCo.

SCReN hosted its second Annual Conference of ISCIII Platforms and the ECRIN Summer School in 2024.

SWITZERLAND

Scientific Partner: SCTO - Swiss Clinical Trial Organisation
Member since 22 May 2023
Host institution: SCTO
National hub: Bern
www.scto.ch/en

The Swiss Clinical Trial Organisation (SCTO) is a reference academic research infrastructure for high-quality, patient-oriented clinical research in Switzerland. Since 2017, it has been funded by the State Secretariat for Education, Research, and Innovation (SERI) and the Swiss National Science Foundation (SNSF). The SCTO supports academic clinical research across all medical disciplines to deliver new and better therapies to society. It consists of the Executive Office, seven CTUs and eight SCTO Platforms. The ECRIN EuCo for Switzerland is part of the Executive Office in Bern. The SCTO CTU Network includes the CTUs of the five university hospitals and two cantonal hospitals. The SCTO Platforms are centers of excellence and a pool of experts from the seven CTUs work to establish national standards and best practices in clinical research. The resources developed by the SCTO Platforms are publicly available on the SCTO Tools & Resources website.

2024 Highlights

New funding period and ECRIN projects
In 2024, the SCTO successfully completed the 2021–2024 funding period, securing renewed support for 2025–2028. This continued funding reflects the SCTO's pivotal role in advancing Switzerland's clinical research landscape by optimising processes and harmonising best practices, through its Platforms and CTUs. In 2024, the SCTO CTU Network supported 11 projects as an ECRIN partner, with nine ongoing and two newly initiated projects in areas such as oncology, infectious diseases and paediatrics.

Easy Guide to Clinical Studies (Easy GCS)
Easy GCS is a newly launched, interactive tool designed to help researchers plan and conduct clinical studies in compliance with regulations. The tool provides practical insights across eleven key research topics, offering step-by-step support. The tool has already attracted 10,161 users in 2024.

Outreach through events and websites
On 31 January 2024, the SCTO Forum on the Human Research Act's ordinances attracted nearly 80 participants. The 12th SCTO Symposium 2024 on "Working Towards Efficient Clinical Data-Driven Research in Switzerland," was attended by over 170 participants.

In 2024, the SCTO Tools & Resources website attracted 19k users and the main SCTO website 14k users representing 30% increase each.

Interview with the Italian European Correspondent

Maria Buoncervello
European Correspondent Italy - ItaCRIN

What is a day in the life of a EuCo like?

During my daily life as a EuCo, I work closely with my ItaCRIN colleagues to support various aspects of clinical trials management in which we are involved.

For ongoing trials, we provide support to overcome some hurdles that may arise during the trial work flow and manage several activities by relating with different stakeholders involved.

In my role as coordinating EuCo, I also make effort to be always in close contact with the Sponsor and lead CTU to prevent any delay in the study implementation.

Indeed, ensuring a prompt and clear communication is key for the good management of clinical trials. Moreover, I provide consultancy services for new contacts and also deepen contacts with the National network by organising meetings and preparing new documents.

I'm quite involved in the organisation of training initiatives on biomedical research also in collaboration with my EATRIS and BBMRI colleagues, as those activities are among the main scope of both ECRIN and the Italian Institute of Health where we are located.

How has ECRIN benefited Italy?

Italy, being a member of ECRIN since the beginning, had the opportunity to create its National clinical trial unit network, ItaCRIN, that offers to national clinical researchers diverse services in the methodological support, pharmacovigilance, monitoring and data management as well as overall project management.

In line with the mission of the Italian Institute of Health, where ItaCRIN is based, ECRIN's activities have enhanced Italy's capacity to conduct high-quality multinational clinical trials, generating benefits for the public health.

ISTITVTO SVPERIORE DI SANITÀ

ItaCRIN
ITALIAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

What achievement have you been proudest of since joining ItaCRIN/ECRIN?

Over the last five years the network grew significantly. Since our team has been renewed and thanks to a communication plan updated every year, new CTUs joined ItaCRIN, an increasing number of Principal Investigators contacted us to get our support for proposal preparation and for trial conduct when already funded.

Therefore, we were able to enlarge our stakeholders audience. As a result, we now count more and more projects submitted by Italian investigators who have requested ECRIN support and two new projects coordinated by Italy have been funded. We also organised several online and in-person events: all of them have been very well participated.

Tell us about Italy and what is planned for the next few years?

Italy has a strong community of researchers in the biomedical field. ECRIN is the best choice to support them in their clinical research activity. From my side, increasing the number of Italian clinical studies to manage means, both a challenge and a source of satisfaction.

As ItaCRIN, we are planning to strengthen collaboration with patient associations and we are also organising new training events.

Overall, we are working to place ItaCRIN as a landmark for the national scientific community, supporting researchers to conduct robust and impactful studies.

Watch Maria Buoncervello's video interview on our YouTube channel

View Maria Buoncervello's interview


Multicopy

Clinical Operations

Clinical Operations

In 2024, the ECRIN Clinical Operations team continued to support ECRIN's clinical study portfolio. The team worked diligently to enable the launch of the Regulatory and Ethical Database (RED).

Providing support on Regulatory and Ethical Submission

Despite efforts underway at the European level, the lack of harmonisation of regulatory approvals continues to be one of the main challenges for IICS as highlighted in the recent literature (Gumber et al, 2024[1]; Scarlett et al, 2024[2]). This builds on the OECD Global Science Forum report "Facilitating International Cooperation in Non-Commercial Clinical Trials", which reinforces the need for collaboration with international partners to address complex regulatory issues, share information and harmonisation for ethical, legal and logistical standards (2011).

The increasing number of IICS in Europe is leading to a growing need for tools to help sponsors investigators and the clinical trial team to plan and extend their research across countries. RED is one such tool which provides regulatory and ethical information coverage across an increasing number of European countries.

[1] Gumber L, Agbeleye O, Inskip A, et al. Operational complexities in international clinical trials: a systematic review of challenges and proposed solutions. BMJ Open. 2024 Apr 15;14(4):e077132. doi: 10.1136/bmjopen-2023-077132.

[2] Scarlett S, Hjelle SM, Hore N, del Alamo M, Nieto C, & Batoux M . D14.1. Report on bottlenecks to multicountry investigator-initiated clinical studies (IICS). 2024.

ECRIN has been working to redeploy RED, updating it to align with the current regulatory framework in Europe to ensure the content aligns with the present national information, in 2024 the clinical operations team made this a reality.

RED is the go-to platform for comprehensive information supporting stakeholders who are preparing a proposal for a multi-country study or expanding an ongoing study outside national boundaries.

RED provides in-depth coverage across European countries, ensuring that the user has access to detailed regulatory and ethical submission requirements that are tailored to a variety of key clinical study types.

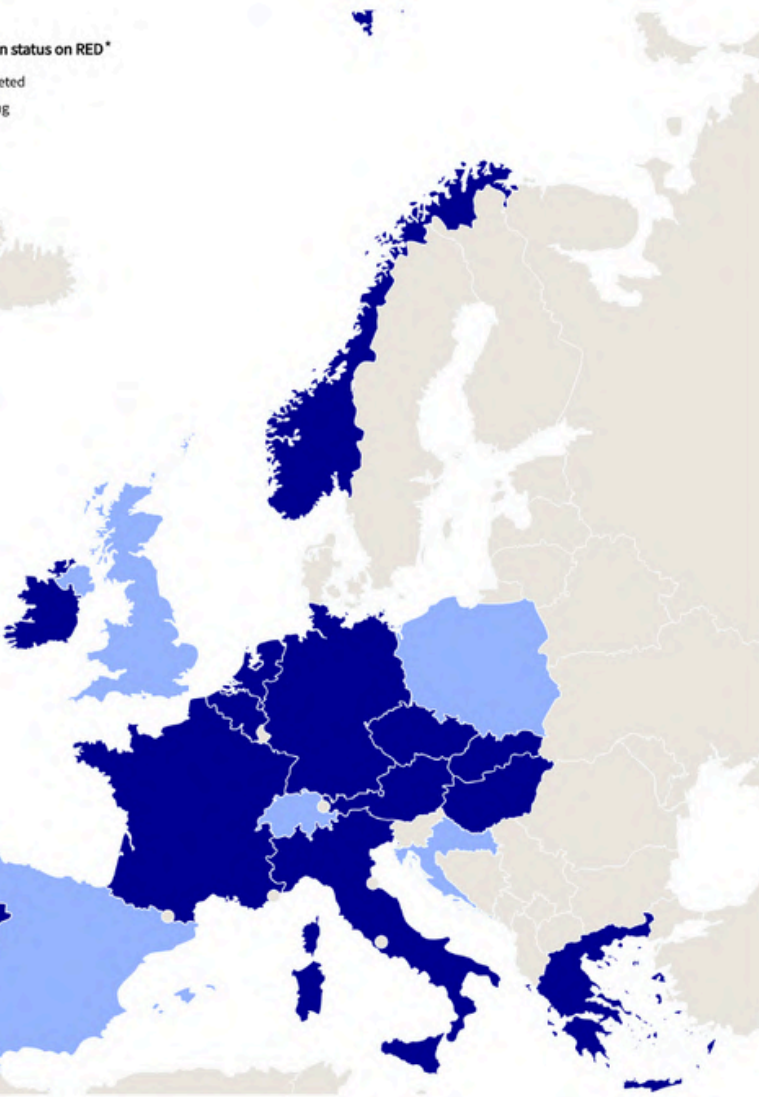
RED by ecrin
Regulatory & Ethical Database

Whether conducting research on pharmaceuticals, medical devices, or studies that do not fall into the first two categories, RED equips researchers with the critical information needed to work beyond their national boundaries and compare options to take their research to new horizons.

Filters are included to quickly access content tailored to the unique regulatory and ethical considerations for vulnerable populations, allowing users to negotiate the additional complexities involved in including these specific populations.

RED is supported by a network of professionals throughout Europe, with in-depth expertise in the regulatory and ethical frameworks of their respective countries, principally ECRIN's EuCos. They monitor the national situation and ensure major changes are integrated in a timely manner to keep the database up to date. They also ensure accessibility by providing translations of key legal information and national documents into English, where necessary. This commitment to sharing the national landscapes ensures that users are always informed of the most current and reliable information.

** Completion Status as of 2024*



RED in number

3
core types of studies available

18
countries updated by national experts

750
fields of information per country

4
population specific information

Access RED

ECRIN Scientific Board 2024 Review

The first step for a sponsor or investigator requiring ECRIN's support is to request access to ECRIN's services through the Scientific Board (SB). Access to ECRIN's operational services is based on scientific excellence. The SB Collaboration Committee (SB-CC) provides quick answers to proposals on ECRIN's capacity to support the development of funding applications and study design. It can also decide on support to running studies looking to expand to new countries. In 2024, 19 requests for collaboration were submitted to the ECRIN SB.

In 2024, the requests came from Germany, Ireland, Italy, Norway, Portugal, Spain and Denmark and the Netherlands.

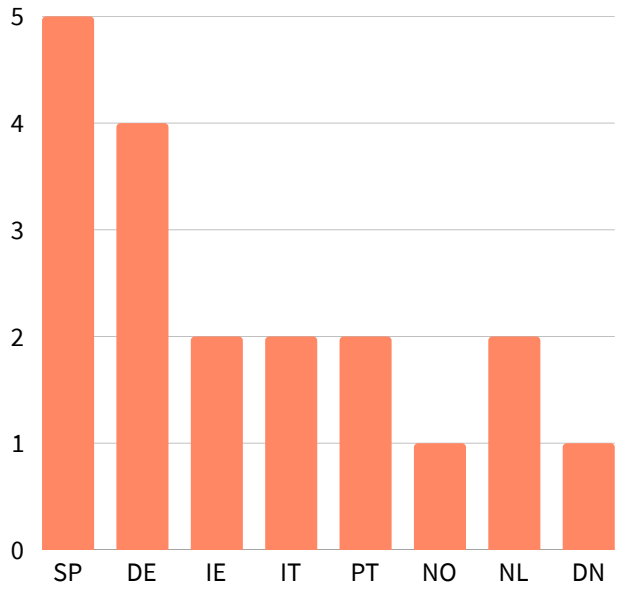


Figure 3. Number of collaborations request by country in 2024

Of the 19 requests for participation, ECRIN agreed to support 15. Four projects were already funded, one additional study received funding, three were funded but decided to advance without the support of ECRIN, three are pending funding approval at the end of 2024, and four projects were not funded.

Moreover, there were four Peer Reviews conducted by the SB Peer Review Committee (SB-PRC) over the course of the year.

A look at ECRIN's Clinical Study portfolio

Four new studies entered ECRIN's clinical study portfolio in 2024, bringing the total to 79 studies. Through the course of the year, ECRIN provided services to 32 studies.

There is a noted shift in ECRIN's study portfolio, as many of the early studies are coming to a close after many years of coordination and support by our staff across Europe. The projects from the last couple years cover greater geographical diversity, as four sponsor countries are represented in the set-up phase this year.

The portfolio continues to cover a wide range of medical fields and addresses different populations, including a new study, EPILOGUE, which focuses on Paediatric Oncology. We are also seeing an increase in diversity of funding models, which include different combinations from national organisations, charities and industry. Of the studies entering the portfolio this year, three are from Germany and one is from Italy.

The Italian study, AUSTRAL, stems from the ties that were developed at the launch of ECRIN as the Mario Negri Institute, present for the signature of ECRIN's ERIC status, is funding in part the study which focuses on a radiotherapy and drug regiment for to patients facing a relapse of non-small cell lung cancer.

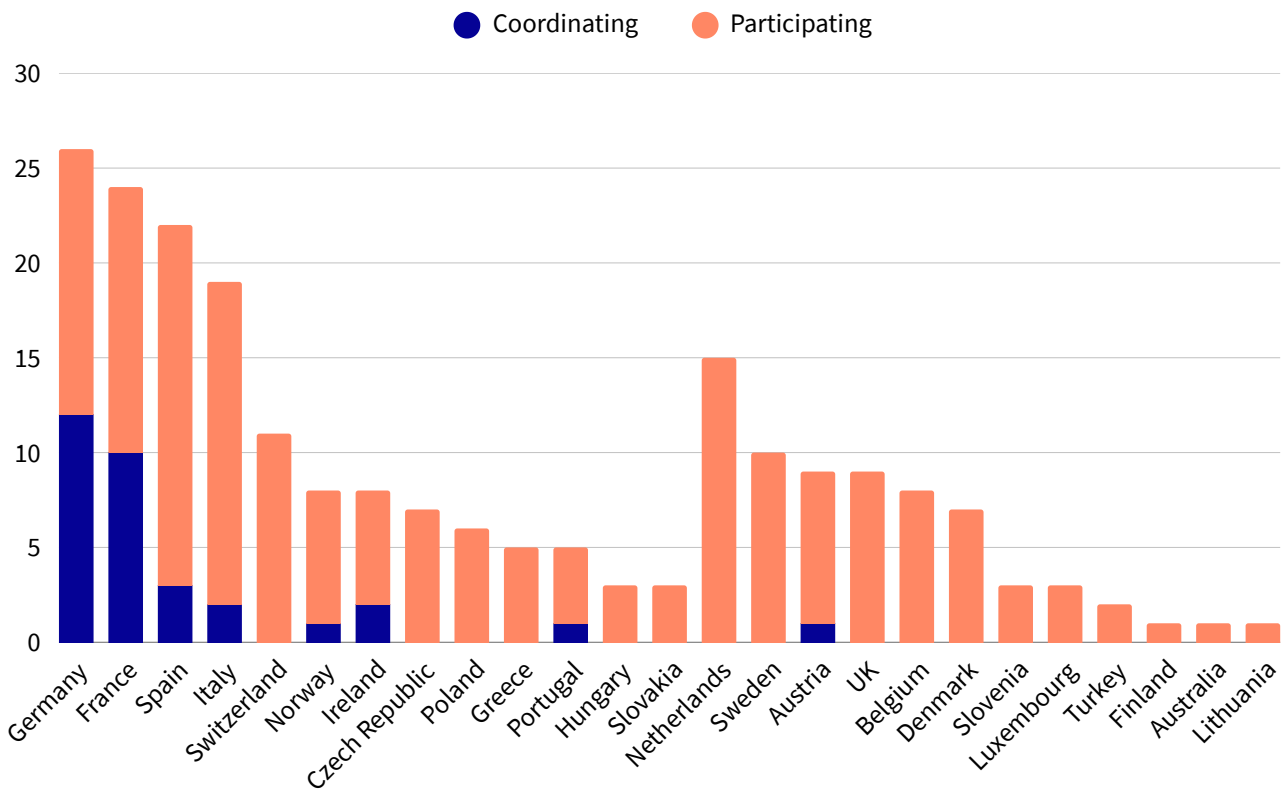
As previously mentioned, the EPILOGUE trial also focuses on cancer, with an umbrella trial focusing on relapsed paediatric low-grade gliomas. Its primary aim is to determine a safe starting dose in an intra-individual dose escalation regimen and to evaluate the activity and safety of the treatment arms. This study will be run in 10 countries and ECRIN will be responsible for supporting the activities in six of them.

ECRIN has also been brought in to support a running clinical study CABA-HFPEF, and help its expansion to two additional countries. The aim of this study is to assess whether catheter ablation for atrial fibrillation can prevent adverse cardiovascular outcomes in patients with heart failure with preserved or mildly reduced ejection fraction.

Lastly, the PreCoDe focuses on the fastest-growing neurodegenerative disorder, Parkinson's disease. It looks to identify a reduction in disease progression in those carrying a severe mutation of the GBA gene through a Prazinezumab treatment regimen. ECRIN will be supporting the coordination of the study in all EU countries, beyond the sponsor, of which there are five.

Key numbers

2024 ECRIN trial portfolio



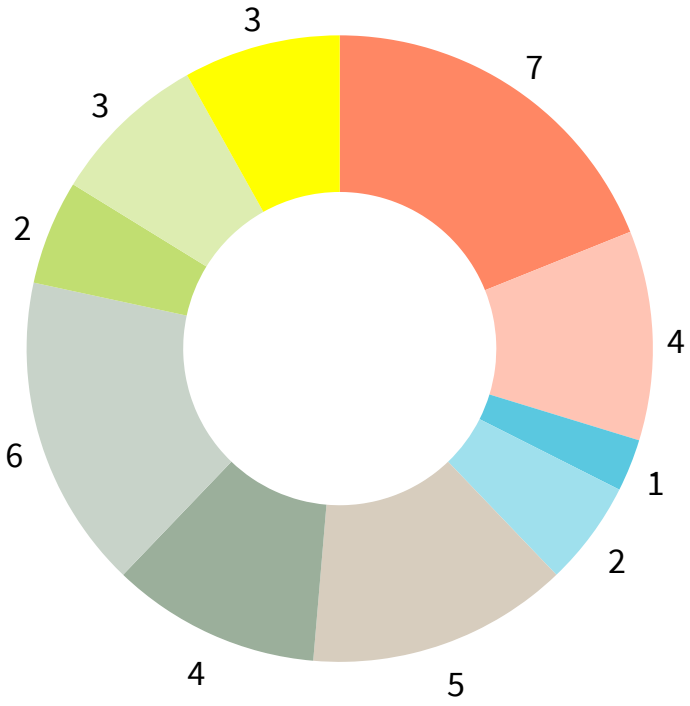
Feedback from ECRIN's service evaluation

*"ECRIN has a very **valuable clinical experience in different countries**, and it **eases the process** to build a **proposal** including a **multi-country clinical study**."*

*"Very **nice**, **proactive** and **professional** team willing to **find solutions to difficult project problems**."*

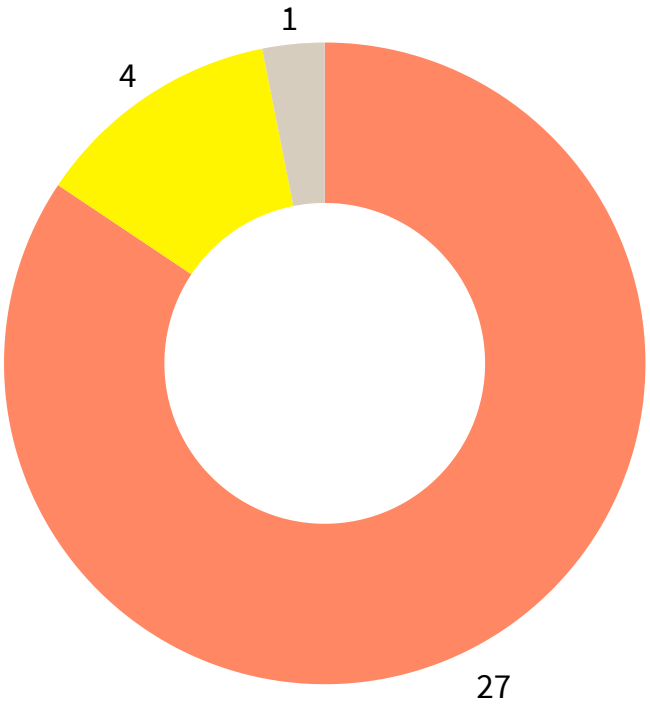
*"The support of ECRIN was **extremely valuable**. **I really appreciate it**."*

100% of respondents would collaborate with ECRIN again for the management of their clinical study



2024 portfolio by disease area

- Cardiovascular
- Infectious diseases
- Ophtalmology
- Rheumatology
- Urology/Nephrology
- Hepatology/Gastroenterology
- Neuroscience
- Orthopaedic/Surgery
- Immune disorders
- Oncology



2024 trial population

- Adult
- Paediatric
- Both

Interview with a principal investigator

Dr Jean-Christophe Rozé
Professor of Neonatology, Nantes University Hospital, France
Principal Investigator, TREOCAPA

What is the aim of TREOCAPA and how was it developed?

The TREOCAPA study was a phase 2/3 project, meaning it started with a phase 2, which was about finding the appropriate dose for extremely preterm infants.

I was in the process of writing up the results of a previous study on the ductus arteriosus using indomethacin. In that study, we clearly saw that the duct was closing properly, but overall, outcomes weren't improving. I thought, it could be because we were using a drug with too many side effects. While reviewing the literature, I thought that acetaminophen – paracetamol – might be a solution.

I discussed it with my colleagues, and also with the Finnish team who had published a first study in the Journal of Pediatrics, and that's how the project started attracting interest from several European groups. As a result, we submitted it to c4c.

We moved forward with a phase 3 trial to see whether a prophylactic treatment – meaning a systematic one – for babies born between 23 and 28 weeks would 1) close the ductus arteriosus. That had already been confirmed by earlier studies and our own phase 2 study. And most importantly, 2) whether it had an impact on discharge outcomes.

Why did you decide to develop a multinational study?

When you involve countries from Northern Europe like Sweden, Denmark, Norway, countries from the South like Greece and Portugal, and others in between like Ireland, France, and Belgium – you see, it's very broad. That's when you start thinking, okay, these are results that could be replicated elsewhere.

The great advantage is that if something is proven true across 14 countries, on such a large scale, it's very likely to be valid for most Western countries. That's a huge benefit. Secondly, people agreed to take part, which shows the question seemed relevant and cutting-edge.

But still, it's very complex. With the support of Inserm, ECRIN, and c4c, we were able to make it happen.

TREOCAPA
a c4c study

How did you work with the consortium to develop the project?

Even though COVID caused major delays at the start of the project, it also forced us to adapt to virtual tools.

We held regular meetings, we had a very supportive Steering Committee, a high-quality DSMB, regular investigator meetings, and above all, we published 24 newsletters – one every two months. We quickly found the right tone for the newsletters to show inclusion progress, answer questions, and I think that really contributed to the success.

This trial was built with input from the European parent representatives at EFCNI, who are scientifically competent. They wrote the information sheet for parents, and I think that by going down that road, we achieved a very high acceptance rate, almost 60%. I really believe that involving parents from the very beginning was a major factor. And I also think they truly have the scientific maturity, to take part and co-develop trials.

What are the key outcomes of the project, and the next steps?

So overall, we think we were able to identify the right dose for extremely preterm infants during the phase 2. In phase 3, the main result is negative in the sense that prophylactic treatment, even though it does close the ductus arteriosus, does not change the discharge outcomes.

In fact, this is completely true for babies born at 27 and 28 weeks – it has no effect. The relative risk is 1, meaning there's absolutely no change, even though the duct is closed. So it indirectly answers an old question: there's probably no benefit in closing the ductus arteriosus very early, as it doesn't change anything.

But there are two very interesting subgroups where we do see a difference, although not statistically significant because the study wasn't large enough. We are borderline significant in girls, with an 8% improvement and among the very extremely preterms – the 23-25 weekers, which also seems like a promising lead. Because, there too, we see improvements, I think 5 or 6%, and even 10% among very extremely premature girls . That means that clinically, it could be relevant.

It will need to be demonstrated in a new study. Given how difficult it is to recruit these extremely premature infants, the next step would be an international study, likely including Canada and the United States.

Watch Jean Christophe Roze's video interview on our YouTube channel

View Jean Christophe Roze's interview

Supporting the community:
tools, services, and knowledge

Supporting the community

In line with ECRIN's mission to support the conduct of multinational clinical studies in Europe much of the activity that is carried out by the organisation focuses on developing know how, resources, tools, training and ensuring clear dissemination of outputs to the clinical research community. In the next pages, we highlight the impact of these activities that took place in 2024.

Recommendations for investigators and sponsors

One of the key resources developed this year was a recommendations booklet for investigators and sponsors in multicountry IICS developed for the ERA4Health Partnership by ECRIN and its Portuguese partner, PtCRIN. It offered insights into challenges and solutions encountered in trials employing innovative methodologies, including trials within cohorts (TwiCs), umbrella trials, basket trials, adaptive platform trials, and decentralised clinical trials (DCTs). The report underscores the importance of collaborative efforts to overcome challenges and advance innovative trial methodologies in clinical research.

The deliverable contributed valuable insights to refine and enhance the landscape of clinical research, ultimately aiming to ensure equal access to modern healthcare for all Europeans.

Guidelines for Data Sharing

Similarly, ECRIN developed guidelines for data sharing of IICS for the ERA4Health Partnership based on ECRIN's experience in other clinical study projects. These provide guidance for preparing data sharing plan for clinical studies, including guidance on informed consent (ICF) for secondary use of data and long-term storage of data, especially Individual Participant Data (IPD) in repositories following the FAIR (Findable, Accessible, Interoperable and Reusable) principles.

The guidelines outlined the process of developing a GDPR compliant data sharing plan that is in alignment with the EU and international funders' expectations. They also provide practical guidance on how to meet them.

Data reuse – the clinical research Data Sharing Repository

ECRIN continues to contribute to the promotion of secondary use of clinical study data. This is exemplified by the clinical research Data Sharing Repository (crDSR). The repository provides a secure, ethical and GDPR compliant platform for sharing clinical trial data. It facilitates transparent and efficient research through data reanalysis, meta-analysis and secondary analysis.

The development of the latest version of the repository was made possible through the BY-COVID project, which ended in 2024, and is highlighted as one of the project's success stories. It aligned well with the project's aims which were, to make COVID-19 data accessible to scientists in laboratories but also to anyone who can use it, such as medical staff in hospitals or government officials.

"As a first pilot user of crDSR, I found the platform intuitive and efficient for uploading final data. The process went smoothly overall, and I appreciated the structured approach. Naturally, as with any pilot, there were learning experiences along the way, but the support provided by ECRIN was helpful in addressing them."

Elena Bardach, *Team Lead Data Management CTC Cologne, Medical Faculty, University of Cologne.*

The first clinical study data was entered into the crDSR in 2024 and came directly from one of the ECRIN coordinated trials within the VACCELERATE project.

Furthermore, ECRIN worked throughout the VACCELERATE project to apply FAIR principles in its real-world trials, setting a benchmark for future studies. Through its published methodology, the project provides a replicable model for data standardisation and interoperability, shaping clinical trial practices across Europe and beyond.

Leveraging electronic health records

Beyond reusing data obtained within clinical studies, ECRIN is working within the eCREAM project on the leveraging of electronic health records (EHRs) and the application of natural language processing to overcome the dearth of clinical research data in Emergency Room situations. This year a FAIRification strategy was published which details the data workflows within eCREAM, and outlines the strategy that will be used to FAIRify the project's outputs. The FAIRification approach is grounded in the process defined by the GO FAIR initiative and incorporates recommendations specific to healthcare data workflows.

Interview on the first use of the crDSR

Prof Dr. Oliver Cornelly
Coordinator VACCELERATE Consortium
Director, Institute of Translational Research, CECAD Cluster of Excellence, University of Cologne
Scientific Director, Center for Clinical Trials, University Hospital

Why did you decide to share your data in the crDSR as the project coordinator?

Basically, this is because ECRIN approached us spontaneously. They offered us direct access to existing data sharing infrastructure and were willing to support us throughout the entire process.

What are the benefits of future reuse and data sharing for a clinical study sponsor as well as for a clinical investigator?

By analysing existing data, i.e. accessible through crDSR, clinical investigators can refine their study designs, identify gaps in knowledge, and formulate more targeted research questions.

Through data sharing, trial sponsors can also gain reputational benefits by demonstrating their commitment to transparency.

Overall, data sharing for future reuse is a crucial tool for generating solid evidence way more efficiently.

As a first user of the crDSR, would you recommend it to other sponsors/clinical investigators?

Definitely so! Using crDSR ensures that our clinical trial data are shared via a state-of-the-art data repository. And we really appreciated ECRIN's support throughout the whole exercise, also on a personal level.

Can you elaborate on your experience using ECRIN's services?

We definitely appreciated the one-stop shopping offered by ECRIN. Our counterparts at ECRIN accompanied the whole process of data sharing right from the beginning.

To start with, ECRIN assisted in wording the separate informed consent form on data sharing.

For the anonymisation procedure, ECRIN leveraged internal and external expertise, which markedly alleviated our workload.

In addition, ECRIN facilitated all further steps, so everything went smoothly. The resulting upload to the data repository in Oslo was definitely hassle-free.

Of note, the entire sharing project was completed within the time frame specified upfront.

Defining the way forward for a federated digital cancer platform

Within the EOSC4Cancer project, a first draft of a roadmap towards a federated digital platform for advancing cancer research was developed. The roadmap outlines a federated digital platform for advancing European cancer research, which builds on EOSC4Cancer's outcomes and is linked to the work of current and upcoming synergy initiatives.

Validation of virtual cohorts for *in-silico* trials

A review of existing statistical tools revealed that currently no R-package exists that covers the needs of the SIMCor project. For this reason, ECRIN led a work package for the development of a new R-package, called R-statistical environment, allowing validation of virtual cohorts as well as application of validated cohorts in in-silico trials. It implements existing statistical techniques that can be applied to compare virtual cohorts with real datasets. It is fully open, generic and menu driven and provides user guidance and help.

Accessing ECRIN services through joint research infrastructure calls

The ISIDORe project offers free transnational access to research resources, services and expertise. Within the project, ECRIN provided a number of consulting services. Most notable was the service provided to an organisation, who had benefited from earlier services in the drug discovery pipeline of ISIDORe. Its chemical compound was brought to the Joint Access Advisory Mechanism, where it was suggested that for the next stage of clinical testing it be integrated into the ECRAID Prime platform trial.

The ECRAID-Prime project is implementing Europe's first adaptive platform trial on COVID-19 therapeutics in the primary care setting. The arm with the organisation's compound will launch in 2025.

ECRIN also made a selection of its services available within the canSERV project. CanSERV had numerous open calls in 2024, including one challenge call dedicated to “innovative approaches to research and clinical trials for improved treatment outcomes.”

Sara Raza Khan, canSERV project manager for ECRIN

Building a strong European Research Area

The ERIC Forum, including an ECRIN representative, was present at the European Research Area: Fostering Greater Integration. Advancing Competitiveness stakeholder conference in Brussels. It focused on discussing success stories and lessons learnt after four years of reshaping the European Research Area and exploring the role of Research Infrastructures (RI) policy in advancing European sustainable competitiveness. The ERICs were cited as an area where much progress has been made to provide the scientific community with a specialised legal framework for researchers.

Maria Alexandra Rujano, ERIC Forum project manager for ECRIN

Training

Training, both internal and external, has been taking a growing place at ECRIN over the past years, and this has been solidified with the role it can play in supporting many of the goals in the 2024-2027 ECRIN Strategic Plan. The training offer has been, and will continue to be, developed with the aim of complimenting the offer available at the national level and will maintain a focus on ECRIN's priority to support multinational clinical studies .

ECRIN Summer School

Organised annually to support staff development and growth, it was hosted by ECRIN's Spanish EuCos and took place in Malaga. It began with an overview of the national clinical trials organisation, its lead CTU and funding mechanisms by the SCReN coordination, followed by content on EU funding mechanisms.

A full-day workshop on time management had the team reflecting on their current organisation and ways to improve it.

There was also a focus on artificial intelligence from an introduction to the topic through to how it is applied in clinical research and information on further training. In addition, the team had the opportunity to visit the city, taste local delicacies and even learn about olive oil production.

Training for PIs and project managers

ECRIN offered the onsite portion of its hybrid training 'everything you need to know about submitting a European multinational clinical study proposal' in early 2024. Building on the six webinars offered throughout 2023, this allowed a select group of users to delve into more detail and work through additional case studies and exercises to better understand the key principles required in the submission process.

Two highly successful sessions were held onsite in Portugal and the Czech Republic, which brought together 23 and 15 learners, respectively. They represented a mix of nationalities and levels of experience, which led to very productive discussions. We also offered two sessions online to accomodate some learners.

Session 1 in Lisbon, Portugal

"The element I preferred was the group work because we have the opportunity to put in practice some of the lessons." **– Attendee**

Session 2 in Brno, Czech Republic

"The model of the budget and how to organise the work packages was really important for me to better plan a proposal" – **Attendee**

Raising awareness and building the CTU community

ECRIN hosted its 4th CTU Day on Friday 13 December 2024. This online event brought together more than 175 members from ECRIN's national partner networks.

It included an update of ECRIN's services and tools and then focused on two national partners, Slovakia (SLOVACRIN) and Italy (ItaCRIN). CTU Day is about keeping our community in the know of what is happening more largely in clinical research, with that in mind, ACT EU was invited and they presented their organisation, objectives, priority areas and shared the vision for clinical evidence in 2030.

To exemplify how CTUs and ECRIN collaborate, the NECESSITY project shared the actions taken for their transition to the CTIS and the relationship between the sponsor and ECRIN. To close this year's event, ECRIN introduced RED.

Online training for projects

ECRIN and its Czech partner contributed to training in the c4c consortium with a module focusing on the clinical trial protocol and another on safety data reporting. ECRIN also continued to deploy its training for the VACCELERATE network on the management of multinational clinical trials.

Mapping of existing training offer

Within the ERA4Health Partnership, ECRIN and its Czech partner CZECRIN put together a list of free online training courses which support European IICS.

The catalogue is directly available on the project website and includes an overview of, and links to, the existing free courses available online. They cover the following topics: proposal writing; GCP; Clinical Trial Methodology; Clinical Trial Management; Clinical Trial Regulation / Ethics; and Patient Engagement.

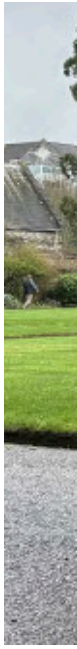
Webinar for the infectious disease community

2024 marked the first of a series of best practice webinars offered by ECRIN through the CoMeCT project. On 17 September 2024, ECRIN hosted a webinar which was dedicated to clinical operations, management and patient engagement.

The speakers addressed these issues through five insightful sessions, during which challenges and solutions were reported and actively discussed with the audience, paving the way to potential future developments.

Inclusive trial design training

In 2024, the SENSITISE project held its kick-off meeting, hosted by its coordinator,



University College Cork. Over two days, the consortium discussed the plans for developing a dedicated curriculum which will incorporate novel content from experts in the domain, emphasise the need to think more inclusively and be complemented by innovative learning methods to help participants develop transferable skills and reasoning.

The course is being developed for undergraduate biomedical and health professions students. It will require a minimum understanding of clinical trial design. For each learner module, a complementary teacher's guide will also be developed.

In addition, for those already working in the clinical trials environment, a dedicated one-day workshop will be developed to transfer the knowledge to the research community.

Events & Communications

ECRIN communications efforts continue to gather momentum since the rebrand. With a steady increase in followers on its principal social media account, LinkedIn and a near doubling of website visits when compared to the previous year, 2024 proved another successful year.

Key numbers

5,904 followers on LinkedIn	**1,809** followers on Twitter/X
47,433 visitors on the ECRIN website	**2,979** newsletter audience

International Clinical Trials Day

ECRIN organised International Clinical Trial Day (ICTD) 2024 together with its Greek national partner, GreCRIN, in Thessaloniki (Greece). ICTD 2024 was a hybrid event focusing on Data Centric Clinical Research. It brought together a full house of 140 participants in the venue and hundreds of stakeholders from the European and global international clinical research community who joined the online broadcast.

With the data revolution playing an increasing role in all aspects of clinical research, ICTD 2024 focused on some of the impacts, benefits and challenges of the rise of data and technology.

Different stakeholders from the community shared their experiences on topics ranging from the integration of the new technical assets, eHealth, data science, the data protection legislation and collaboration of academia and industry, among others.

"We should focus on the chances that new technology gives us and not the problems"
- **Timo Schinkothe**

"Trials and Real World Evidence complement each other"

- **Dani Prieto-Alhambra**

"We need to have a larger debate on what is coming up in the European Health Data Space"
- **Irene Schlünder**

Communication Working Group

The ECRIN Communication Working Group (CWG) was launched in 2020. The CWG unites key communication stakeholders from ECRIN's national partners.

In 2024, the group met for the first time in person. After updates from each country in attendance, a presentation was shared that highlighted how to make use of press releases for a large return on investment.

The group then took part in a world café where the current communication capacity and future needs at the national and European levels were pinpointed and discussed in further detail.

Supporting project communication and dissemination

In 2024, the role of ECRIN in supporting communications and dissemination in EU funded projects took a big step forward with the coordination of activities in the CoMeCT and SENSITISE projects.

For CoMeCT, this included but was not limited to, the development of the project communication, dissemination and exploitation strategy; the creation of the project website; and the continued sharing of information via the website and social media.

ECRIN Communication Working Group meeting in Thessaloniki, May 2024

Similarly, for SENSITISE, support to the project communication, development of dedicated campaigns and more was put in place throughout the year.

Workshop: Exploring Funding Mechanisms for IICS

The second ERA4Health workshop hosted by ECRIN was on Funding Mechanisms for IICS. It took place on 8 and 9 February 2024, in Brussels.

Models and funding strategies that were introduced throughout the first day of the workshop laid the foundation for the second day, which focused on discussions of possible adaptations of the current Joint Transnational Call funding mechanism planned for the ERA4Health Pilot Call on IICS.


The European Intermodal Freight Transport
State-of-the-art

Key players and financial report

ECRIN team

Core Team	
Marta Bastucci	Executive Assistant
Sergio Contrino	Head of Data Projects
Leopold Cudilla	Software Engineer
Marta del Alamo	Head of Capacity Projects
Jacques Demotes	Director General
Martina Esdaile	Communications and Training Manager
Sareema Javaid	Clinical Project Manager
Sarah Karam	Junior Communications Officer
Swarnalathaa Kichenassamy	Software Engineer
Takoua Khorchani	Data Scientist
Christine Kubiak	Operations Director
Alexandra Kuster	Communications Officer
Sabrina Lémeret	Project Manager
A Maitimo	Administrative Assistant
Salma Malik	Senior Project Manager, Paediatric and PPI specialist
Mihaela Matei	Legal Manager
Amélie Michon	Head of Clinical Operations
Samira Mokhtari	Quality Officer
Maria Panagiotopoulou	Senior Project Manager
Sara Raza-Khan	Project Manager
Maria Alexandra Rujano	Project Manager
Arthur Smaal	Information Systems Officer
Alicja Szofer-Araya	Head of Administration and Finance
Keiko Ueda	Clinical Scientist
Biljana Zafirova	Clinical Project Manager

European Correspondents	
Kateřina Nebeská	Czech Republic
Lenka Součková	Czech Republic
Jimena Bouzas	France
Véronique Chaigneau	France
Sarhan Yaïche	France
Linda Stöhr	Germany
Neshat Chareh	Germany
Thomas Chatzikonstantinou	Greece
Annamária Németh	Hungary
Niall Hore	Ireland
Maria Buoncervello	Italy
Elena Toschi	Italy
Maria Josefina Ruiz Alvarez	Italy
Sigrun Margrethe Hjelle	Norway
Maciej Janiec	Poland
Joana Batuca	Portugal
Simona Sonderlichová	Slovakia
Stefan Toth	Slovakia
Miriam Rol Garcia	Spain
Marina Mesa	Spain
Caecilia Schmid	Switzerland
Christina Huf	Switzerland

** Note: the staff lists include individuals who started working for ECRIN in 2024, as well as those who left the organisation*


SARA
ALEX

Organisational Bodies

Assembly of Members

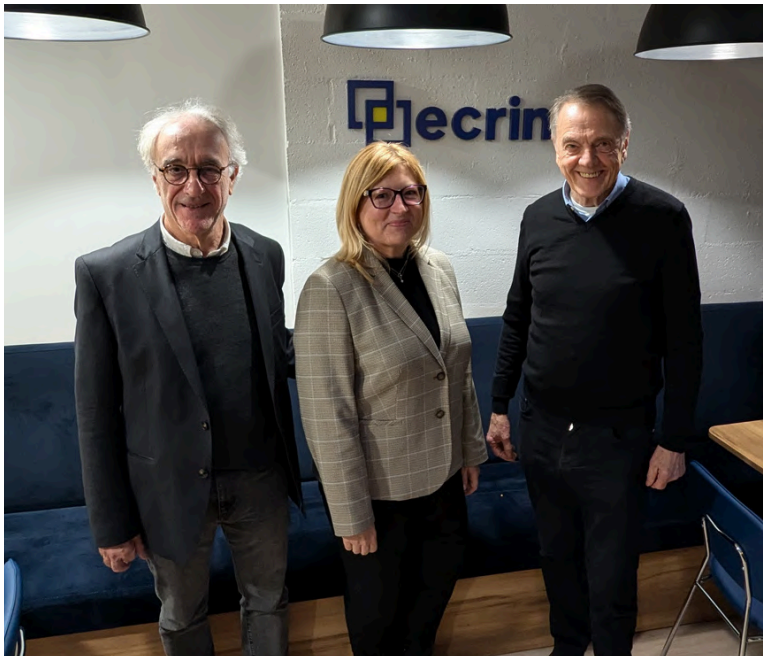
ECRIN is governed by an Assembly of Members (AoM), which is composed of a representative from the government of each Member or Observer country.

Rafael de Andrés	Chair
Oonagh Ward	Vice-Chair (Ireland)
Dalibor Valik	Czech Republic
Judita Klosakova	Czech Republic
Catherine Le Chalony	France
Svenja Krebs	Germany
Eva Müller-Fries	Germany
Kostas Stamatopoulos	Greece
Judit Tarnai	Hungary
Maria Ferrantini	Italy (end of term)
Luisa Minghetti	Italy (new member)
Øyvind Melien	Norway
Agnieszka Ryniec	Poland (end of term)
Elzbieta Bylina	Poland (new member)
Marta Abrantes	Portugal (new member)
Daniel Pella	Slovakia
Rosario Perona Abellon	Spain
Marina Lopez Perez	Spain
Deborah Studer	Switzerland

Network committee

The Network Committee represents the national scientific partners and provides advice to the AoM and Director General. It is composed of one senior delegate from each national scientific partner of the Member and Observer countries.

Christian Ohmann	Chair (Germany)
Regina Demlová	Vice-chair (Czech Republic)
Christine Trillou	France
Olivier Rascol	France
Britta Lang	Germany
Kostas Stamatopoulos	Greece
Judit Tarnai	Hungary
Robert O'Connor	Ireland
Elena Toschi	Italy
Camilla Tondel	Norway
Lukasz Szumowski	Poland (end of term)
Agnieszka Tycinka	Poland (new member)
Emília Monteiro	Portugal (end of term)
João Sargento de Freitas	Portugal (new member)
Daniel Pella	Slovakia
Beata Cecetkova	Slovakia
Alberto Borobia	Spain
Anja Eskat	Switzerland
Tatiana Terrot	Switzerland



Governance Meetings in 2024

Assembly of Members (AoM)
22 January 2024
5 April 2024
22 May 2024
20 September 2024
11 December 2024
Network Committee (NC)
22 May 2024
10 December 2024

Scientific Board

The Scientific Board Secretariat was run by Dr. Joaquin Saez-Penataro until April 2024 afterwhich Sabine Klager took on the role.

SB - Collaborative Committee

The Collaboration Committee of the ECRIN Scientific Board meets weekly to evaluate proposals for collaboration in a timely manner

Sabine Klager	Chair
Joaquin Saez-Penataro	Member (end of term)
Amélie Michon	Member
Jacques Demotes	Member
Christine Kubiak	Member
Keiko Ueda	Member (replacing outgoing member)
José Delgado Alves	Observer

SB - Peer Review Committee

The Peer Review Committee of the ECRIN Scientific Board is composed of external experts who provide expert feedback on the full protocols upon request.

José Delgado Alves	Chair (Portugal)
Cristina Avendaño-Sola	Spain
Declan Devane	Ireland
Ralf-Dieter Hilgers	Germany (end of term)
Raphaël Porcher	France
Sven Trelle	Switzerland (end of term)
Joaquin Saez-Penataro	Spain

Financial Report 2024

INCOME

Membership Core contributions	€ 1 602 002
Membership Local contributions	€ 1 160 930
Research projects	€ 2 165 173
Other income	€ 5 212
Financial income	€ 124 657
TOTAL INCOME FOR 2024	**€ 5 057 973**

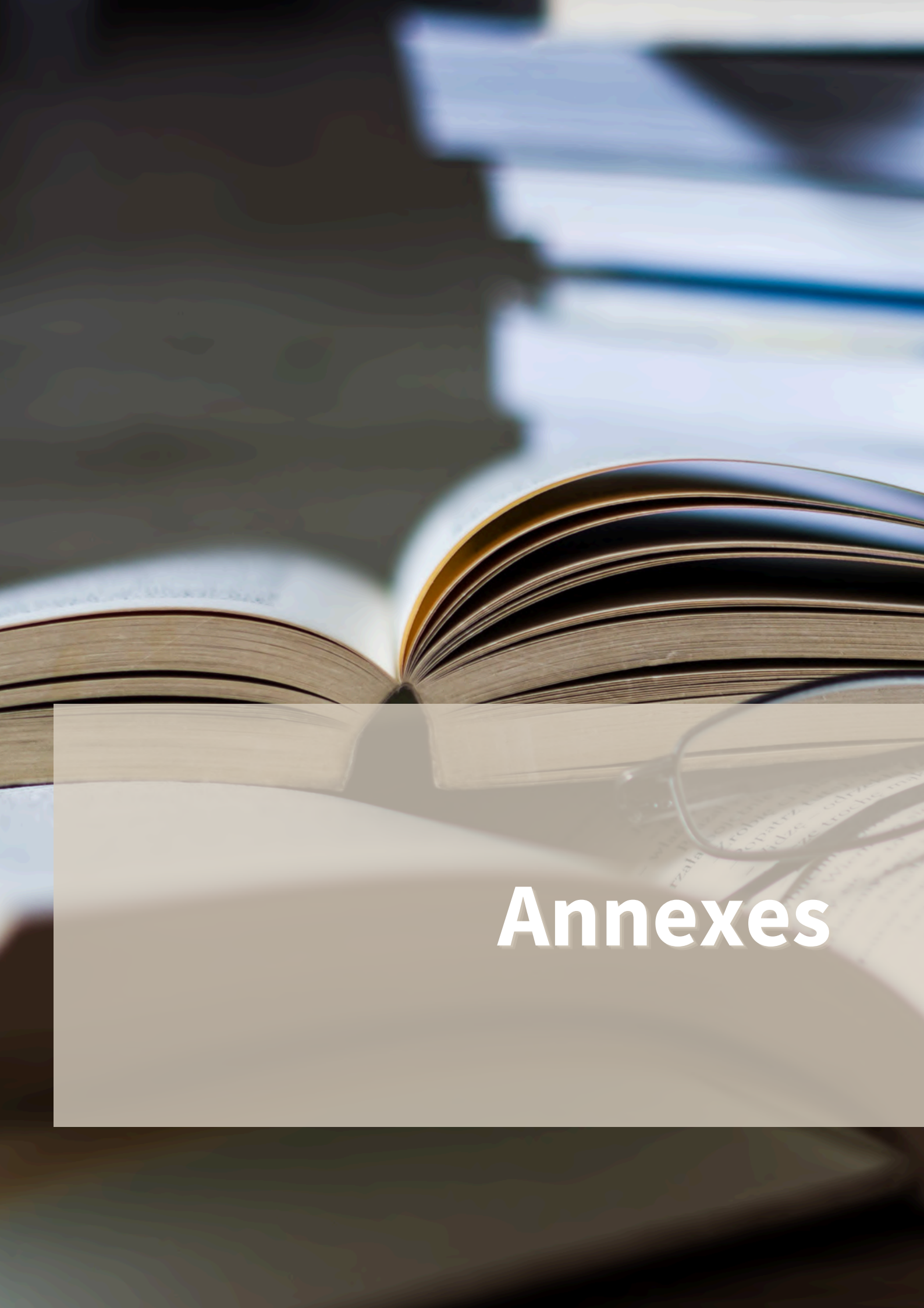
EXPENDITURES

Salaries & staff expenses	€ 2 330 150
Subcontracting	€ 1 008 572
Office and insurance	€ 35 301
Travel and meetings	€ 163 597
Information System	€ 138 235
Communication	€ 86 702
Amortization	€ 138 842
Other expenses	€ 247 528
Financial expenses	€ 62 766
Exceptional expenses	€ 1 014
Income taxes	€ 27 771
Local contribution provided in-kind	€ 1 053 586
TOTAL EXPENDITURE FOR 2024	**€ 5 294 065**

NET RESULT

NET RESULT FOR 2024	**€ - 236 092**

The financial figures are all rounded to the nearest Euro which has led to a small discrepancy in the addition of the numbers. The total displayed reflects the correct total rounded to the closest Euro.



Annexes

Annex 1: Acronyms

A

ACT EU: Accelerating clinical trials in the EU
AI: Artificial Intelligence
AoM: Assembly of Members
APPEAL: Antivirus Pandemic Preparedness EuropeAn pLatform
AUSTRAL: Phase II Study of Radiotherapy Followed by Durvalumab (MEDI4736) and Ceralasertib (AZD6738) in Stage III NSCLC Patients With Thoracic Relapses +/- Oligometastases After PACIFIC Regimen

B

BBMRI: Biobanking and Biomolecular Resources Research Infrastructure
BIOTOOL-CHF: BIOmarker based diagnostic TOOLkit to personalize pharmacological approaches in congestive heart failure
BY-COVID: BeYond-COVID

C

CABA-HFPEF: CAtheter-Based Ablation of atrial fibrillation compared to conventional treatment in patients with Heart Failure with Preserved Ejection Fraction
canSERV: Providing Cutting Edge Cancer Research Services Across Europe
CERTH: The Centre for Research & Technology, Hellas
CIBER: Centro de Investigación Biomédica en Red
CLIC: Clinical Investigator Certification
COMBINE: programme for clinical trials and medical devices
CoMeCT: Coordination Mechanism for Cohorts and Trials
COVID-19: Coronavirus Disease 2019
crDSR: Clinical Research Data Sharing Repository
CREATIC: Central European Advanced Therapy and Immunotherapy Centre
CRFs/CRCs: Clinical research facilities/Clinical research centres
CRO: Contract Research Organisation
CRU-RISE: Clinical Research Unit - RISE
CTIS: Clinical Trial Information System
CTR: Clinical Trial Regulation
CTU: Clinical Trial Unit
CWG: Communication Working Group
CZECRIN: Czech Clinical Research Infrastructure Network

D

DACH: Germany, Austria, Switzerland
DONets: Disease Oriented Networks
DSMB: Data Safety Monitoring Board

E

EATRIS: European Advanced Translational Research Infrastructure in Medicine
EC: European Commission
ECRAID-Prime: European Clinical Research Alliance for Infectious Diseases Prime
eCREAM: enabling Clinical Research in Emergency and Acute care Medicine
eCRF: Electronic Case Report Form
ECRIN: European Clinical Research Infrastructure Network
EFCNI: European Foundation for the Care of Newborn Infants
EFGCP: European Forum for Good Clinical Practice
EFPIA: European Federation of Pharmaceutical Industries and Associations
EHDS: European Health Data Space
EHR: Electronic Health Records

EJP-RD: European Joint Programme on Rare Diseases
EMA: European Medicines Agency
EOSC4Cancer: A European-wide foundation to accelerate data-driven cancer research
EOSC ENTRUST: A European Network of TRUSTed research environments
EPILOGUE: Phase I/II combination umbrella trial in relapsed pediatric low-grade glioma (pLGG)
ERA: European Research Area
ERA4Health: European Research Area for Health Research
ERDERA: European Rare Diseases Research Alliance
ERIC: European Research Infrastructure Consortium
ERIC-Forum: European Research Infrastructure Consortium Forum
ERN: European Reference Networks
ESFRI: European Strategy Forum on Research Infrastructures
EU: European Union
EU-Africa PerMed: Building links between Europe and Africa in personalised medicine
EU-AMRI: European Alliance of Medical Research Infrastructures
EUCLID: EUropean CLInical Trials Platform & Development
EuCo: European Correspondent
EU-X-CT: Cross-Border Access to Clinical Trials
EU-SolidAct: European DisCoVeRy for Solidarity: an Adaptive Pandemic and Emerging Infection Platform Trial.

F

F-CRIN: French Clinical Research Infrastructure Network
FAIR: Findable Accessible Interoperable, and Reusable

G

GCP: Good Clinical Practice
GCS: Guide to Clinical Studies
GDPR: General Data Protection Regulation
GreCRIN: Greek Clinical Research Infrastructure Network

H

HECRIN: Hungarian Clinical Research Infrastructure Network
HNHDA: Hungarian National Healthcare Development Agency
HRB: Health Research Board
HRB NCTO: Health Research Board National Clinical Trials Office

I

IBIMA: Biomedical Research Institute of Málaga and Nanomedicine Platform
ICTD: International Clinical Trials Day
IdiPAZ: Health Research Institute of La Paz University Hospital
ICF: Informed Consent Form
ICT: Information communication Technology
iDR24: International Drug Repurposing Conference
IICT: Investigator Initiated Clinical Trials
IICS: Investigator Initiated Clinical Studies
INTEGRATE LMedC: Concept development for a research infrastructure to manage, integrate and sustain large medical cohort studies
INVENTS: Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs
IPD: Individual Participant Data

I**SCIII:** National Institute for Health Carlos III
I**SIDORe:** Integrated Services for Infectious Disease Outbreak Research
ISO: International Standards Organisation
ISS: Istituto Superiore di Sanità
IT: Information Technology
ItaCRIN: Italian Clinical Research Infrastructure Network
ITEMAS: Platform for Innovation in Medical and Health Technologies

K

KKSN: Netzwerk der Koordinierungszentren für Klinische Studien
KKS: Koordinierungszentren für Klinische Studien

L

LIVERHOPE: Efficacy of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis to prevent ACLF development: a multicenter, doubleblind, placebo controlled randomized clinical trial

M

MDR: Medical Device Regulation
MOI-A: Matrix-Directed Therapy In Older Adolescents And Adults With Osteogenesis Imperfecta
MORPHEUS: Prognosis improvement of unprovoked venous thromboembolism using personalised anticoagulant therapy
MRA: (Polish) Medical Research Agency
MSP: Multi-stakeholder platform
MUST: Multidisciplinary University Research Network for Primary Care

N

NCTO: National Clinical Trials Office
NorCRIN: Norwegian Clinical Research Infrastructure
NSPARK: Réseau national de recherche clinique sur la maladie de parkinson
NSS: Networking Social Scheme

O

OECD: Organisation for Economic Co-operation and Development
OKPI: National Korányi Institute of Pulmonology

P

PCTN: Polish Clinical Trials Network
PERMIT : Personalised Medicine Trials
PI: Principal investigator
PPI: Patient and Public Involvement
Precode: Prevent Cognitive Decline
PtCRIN: Portuguese Clinical Research Infrastructure Network

Q

QUANTUM: Quality, Utility and Maturity Measured; Developing a Data Quality and Utility Label for HealthData@EU
QMS: Quality Management System

R

RED: Regulatory and Ethical Database
REMEDi4ALL: Building a sustainable European innovation platform to enhance the repurposing of medicines for all
RI: Research infrastructure
RNA: ribonucleic acid
RNIE: Portuguese Roadmap of Research Infrastructures

S

SB: Scientific Board
SB-CC: Scientific Board Collaboration Committee
SB-PRC: Scientific Board Peer Review Committee
SCReN: Spanish Clinical Research Network
SCTO: Swiss Clinical Trial Organisation
SENSITISE: Inclusive clinical trials: training and education
SERI: Secretariat for Education, Research and Innovation
SHARE CTD: Sharing and Re-using clinical trial data to maximise impact
SIMCOR: In-Silico testing and validation of Cardiovascular Implantable devices
SLOVACRIN: Slovak Clinical Research Infrastructure Network
SME: Small and Medium-sized Enterprise
SNSF: Swiss National Science Foundation
SOP: Standard Operating Procedure

T

TREOCAPA: Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen
TWiC: Trials Within Cohorts

V

VACCELERATE: European Corona Vaccine Trial Accelerator Platform
VESPA: Valproic Acid/Simvastatin Plus Gemcitabine/Nab-paclitaxel Based Regimens in Untreated Metastatic Pancreatic Adenocarcinoma Patients

W

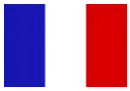
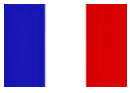
WG: Working Groups
WHA: World Health Assembly
WHO: World Health Organization

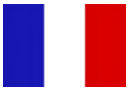
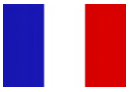
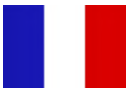
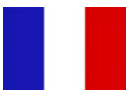
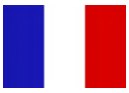
Z

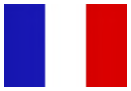
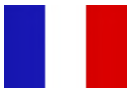
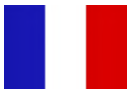
ZKS: Clinical Trials Unit

Annex 2: Clinical Study Portfolio in 2024 (current studies)

Throughout 2024 ECRIN provided support to 32 studies. At the end of the year 8 were in the set-up phase working towards the opening of all sites in all the participating countries, 10 were active meaning in the phase of recruitment (running), 9 were in completion mode (running), and 5 were completed. Additional information on the trials and associated registries are available on the ECRIN website.

Short title	Protocol title	Trial status	CT sponsor country	Funding source
AUSTRAL	An open-label, multicenter, phase II study of radiotherapy followed by durvalumab (MEDI4736) and ceralasertib (AZD6738) in stage III NSCLC patients with thoracic relapses +/- oligometastases after PACIFIC regimen.	Start up phase		Italian intitution & industry
BIOTOOL CHF	BIOmarker based diagnostic TOOLkit to personalize pharmacological approaches in congestive heart failure	Start up phase		101095653*
CABA-HFPEF	CAtheter-Based Ablation of atrial fibrillation compared to conventional treatment in patients with Heart Failure with Preserved Ejection Fraction)	Start up phase		German & International organisation
EPILOGUE	Phase I/II combination umbrella trial in relapsed pediatric low-grade glioma (pLGG)	Start up phase		Charity & Industry
LEOPARD	Liver Electronic Offering Platform with Artificial intelligence-based Devices	Start up phase		101080964*
LIVERATION	Unravelling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?	Start up phase		101104360*
ORTHO-ALLO-UNION	ORTHOpaedic treatment with ALLOgenic combined ATMP in long bone fracture delayed UNION and non-union	Start up phase		101137464*
PreCoDe	A randomized, double-blind, placebo-controlled, 104-week proof-of-concept study to evaluate the efficacy of intravenous Prasinezumab in participants with Parkinson's disease carrying a severe mutation in the GBA gene	Start up phase		Charity
CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	Running		German government
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults	Running		101015736°

ETAPA	Randomised Placebo-Controlled Trial of Early Targeted Treatment of Patent Ductus Arteriosus with Paracetamol in Extremely Low Birth Weight Infants	Running		Irish government
EU-COVAT-1	A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults (≥75) already Vaccinated Against SARS-CoV-2	Running		101037867°
EU-COVAT-2	An International Multicentre, Phase 2, Randomised, Adaptive Protocol to determine the need for, optimal timing of and immunogenicity of administering a 3rd homologous mRNA vaccination dose against SARSCoV-2 in the general population (18+ years) already fully vaccinated against SARS-CoV-2	Running		101037867°
EU-TRAIN RCT (IMPACT)	Randomized Controlled Multicenter Trial to quantify the benefits of biomarkers in routine patient care in kidney transplant recipients	Running		754995°
EU-TRAIN COHORT	Prospective cohort of kidney transplant patients	Running		754995°
IDEA-FAST COS	Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases	Running		IMI2 853981°
ImmunAID	Immunome project consortium for AutoInflammatory Disorders	Running		779295°
INFORM2 NIVENT	INFORM2 exploratory multinational phase I/II combination study of Nivolumab and Entinostat in children and adolescents with refractory high-risk malignancies	Running		Industry & German government
LIVERHOPE EFFICACY	Efficacy of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis to prevent ACLF development: a multicenter, double-blind, placebo controlled randomized clinical trial	Running		731875°
MACUSTAR	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention	Running		IMI 116076°
MORPHEUS	Prognosis improvement of unprovoked venous thromboembolism using personalised anticoagulant therapy	Running		101095698*
NECESSITY	NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifYing patients	Running		IMI 806975°
NISCI	Antibodies against Nogo-A to enhance plasticity, regeneration and functional recovery after acute spinal cord injury, a multicenter international randomized double-blinded placebo-controlled Phase II clinical proof	Running		681094°

SOLIDACT	European DisCoVeRy for Solidarity: An Adaptive Pandemic and Emerging Infection Platform Trial.	Running		101015736°
TENSION	Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window	Running		754640°
TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen Study type	Running		IMI 777389°
TTV Guide IT	A randomised and controlled trial to compare the safety, tolerability and preliminary efficacy between standard and Torque Teno virus-guided immunosuppression in stable adult kidney transplant recipients with low immunological risk in the first year after transplantation	Running		896932°
PAPA-ARTIS	Paraplegia Prevention in Aortic Aneurysm Repair by Thoracoabdominal Staging with 'Minimally-Invasive Segmental Artery Coil-Embolization': A Randomized Controlled Multicentre Trial	Completed		733203°
PROOF	Penumbral Rescue by Normobaric O=O Administration in Patients With Ischaemic Stroke and Target Mismatch ProFile: A Phase II Proof-of-Concept Trial	Completed		733379°
RESPINE	REgenerative therapy of intervertebral disc: a double blind phase 2b trial of intradiscal injection of mesenchymal stromal cells in degenerative disc disease of the lomber SPINE unresponsive to conventional therapy	Completed		732163°
R-Link	Optimizing response to Li treatment through personalized evaluation of individuals with bipolar I disorder: the R-LiNK initiative	Completed		754907°
SESAME	Safety and Effectiveness of SOFIA™/SOFIA™ PLUS when used for direct aspiration as a first line treatment technique in patients suffering an Acute Ischemic Stroke in the anterior circulation	Completed		Industry

° The clinical trial received funding from the European Union's Horizon 2020 research and innovation programme under the listed grant agreement.

* The clinical trial received funding from the European Union's Horizon Europe research and innovation programme under the listed grant agreement.

Annex 3: Infrastructure Development Projects Portfolio in 2024

Throughout 2024 ECRIN provided support to 26 projects, 5 of which were launched over the course of the year.

Acronym	Full name	Status end 2024	Logo	Funding source
BY-COVID	BeYond-COVID	Ended		101046203*
canSERV	Providing Cutting Edge Cancer Research Services Across Europe	Running		101058620*
CoMeCT	Coordination Mechanism for Cohorts and Trials	Running		101136531*
c4c	conect4children	Running		777389°
ECRAID-Base	European Clinical Research Alliance on Infectious Diseases - Base	Running		965313°
ECRAID-Prime	European Clinical Research Alliance on Infectious Diseases: PRIMary care adaptive platform trial for pandemics and Epidemics	Running		101046109*
eCREAM	Enabling Clinical Research In Emergency And Acute Care Medicine Through Automated Data Extraction	Running		101057726*
EJP-RD	European Joint Programme on Rare Diseases	Ended		825575°
EOSC4Cancer	A European-wide foundation to accelerate data-driven cancer research	Running		101058427*
EOSC-ENTRUST	A European Network of TRUSTed research environments	Running		101131056*
EOSC Future	European Open Science Cloud Future	Ended		101017536°
ERA4Health	Fostering a European Research Area for Health	Running		101095426*

ERDERA	European Rare Diseases Research Alliance	Running		101095426*
ERIC-Forum 2	ERIC-Forum Implementation project 2	Running		101124559*
EU-Africa PerMed	Building links between Europe and Africa in Personalised Medicine	Running		964333°
EU RESPONSE	European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases	Running		101015736°
EuroGCT	European consortium for communicating gene- and cell-based therapy information.	Running		965241°
INTEGRATE LMedC	Concept development for a research infrastructure to manage, integrate and sustain large medical cohort studies	Running		101131809*
INVENTS	Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs	Running		101136365*
ISIDORe	European consortium for communicating gene- and cell-based therapy information.	Running		101046133*
QUANTUM	Quality, Utility and Maturity Measured; Developing a Data Quality and Utility Label for HealthData@EU	Running		101137057*
REMEDi4ALL	Building a sustainable European innovation platform to enhance the repurposing of medicines for all	Running		101057442*
SENSITISE	Inclusive Clinical Trials: Training and Education to Increase Involvement of Under-Served Groups	Running		2023-1-IE02-KA220-HED-0001589532**
SIMCOR	In-Silico testing and validation of Cardiovascular Implantable devices	Ended		1101017578°
TESA III	Trials of Excellence in Southern Africa III	Running		EDCTP - GA 2020NoE-3104TESAIII
VACCELERATE	European Corona Vaccine Trial Accelerator Platform	Running		101037867°

° The project received funding from the European Union's Horizon 2020 research and innovation programme under the listed grant agreement.

* The project received funding from the European Union's Horizon Europe research and innovation programme under the listed grant agreement.

**The project received funding from the Erasmus+ Programme of the European Union under the listed grant agreement number.

Annex 4: 2024 Publications

Biavati, F., Saba, L., Boussoussou, M., Kofoed, K.F., Benedek, T., Donnelly, P., Rodríguez-Palomares, R., et al. 'Coronary Artery Calcium Score Predicts Major Adverse Cardiovascular Events in Stable Chest Pain'. Radiology 310, no. 3 (March 2024): e231557. https://doi.org/10.1148/radiol.231557.	DISCHARGE
Budillon, A., Leone, A., Passaro, E., Silvestro, L., Foschini, F., Iannelli, F., Serena Roca, M., et al. 'Randomized Phase 2 Study of Valproic Acid Combined with Simvastatin and Gemcitabine/Nab-Paclitaxel-Based Regimens in Untreated Metastatic Pancreatic Adenocarcinoma Patients: The VESPA Trial Study Protocol'. BMC Cancer 24, no. 1 (19 September 2024): 1167. https://doi.org/10.1186/s12885-024-12936-w.	REMEDi4ALL
Campana, M., Schneider-Axmann, T., Wobrock, T., Malchow, B., Langguth, B., Landgrebe, M., Eichhammer, P., et al. 'Assessing the Impact of Sex on High-Frequency Repetitive Transcranial Magnetic Stimulation's Clinical Response in Schizophrenia - Results from a Secondary Analysis'. The World Journal of Biological Psychiatry: The Official Journal of the World Federation of Societies of Biological Psychiatry 25, no. 4 (April 2024): 233–41. https://doi.org/10.1080/15622975.2024.2327028.	
de Jonge, J.C. , Sluis, W.M., Reinink, H., Bath, P.M., Woodhouse, L.J., Zweedijk, B., van de Beek, D., et al. 'Prevention of Infections and Fever to Improve Outcome in Older Patients with Acute Stroke (PRECIOUS): A Randomised, Open, Phase III, Multifactorial, Clinical Trial with Blinded Outcome Assessment'. The Lancet Regional Health - Europe 36 (1 January 2024): 100782. https://doi.org/10.1016/j.lanepe.2023.100782.	PRECIOUS
de Vente, C., Valmaggia, P., Hoyng, C.B., Holz, F.G., Islam, M.M., Klaver, C.C.W., Boon, C.J.F., et al. 'Generalizable Deep Learning for the Detection of Incomplete and Complete Retinal Pigment Epithelium and Outer Retinal Atrophy: A MACUSTAR Report'. Translational Vision Science & Technology 13, no. 9 (5 September 2024): 11. https://doi.org/10.1167/tvst.13.9.11.	MACUSTAR
del Álamo, M., Lémeret, S., Nieto, C., Pandya, L., Hagen, H., Walker, S., and Demotes, J. 'Funding Multinational Investigator-Initiated Clinical Studies in Europe: Why and How?' Trials 25, no. 1 (17 October 2024): 689. https://doi.org/10.1186/s13063-024-08548-1.	ERA4Health
Demotes, Jacques, Victoria Charlotte Simensen, Keiko Ueda, Sareema Javaid, Paula Garcia, Burç Aydin, and John-Arne Røttingen. 'Coordination of COVID-19 Platform Trials in Europe'. Trials 25, no. 1 (25 April 2024): 278. https://doi.org/10.1186/s13063-024-08126-5.	CoMeCT, EU RESPONSE, RECOVER, VACCELERATE, ECRAID-Prime
DISCHARGE Trial Group, Bosserdt, M., Serna-Higuita, L.M., Feuchtner, G., Merkely, B., Kofoed, K.F., Benedek, T., et al. 'Age and Computed Tomography and Invasive Coronary Angiography in Stable Chest Pain: A Prespecified Secondary Analysis of the DISCHARGE Randomized Clinical Trial'. JAMA Cardiology 9, no. 4 (1 April 2024): 346–56. https://doi.org/10.1001/jamacardio.2024.0001.	DISCHARGE

Felisi, M., Bonifazi, F., Toma, M., Pansieri, C., Leary, R., Hedley, V., Cornet, R., et al. ‘Mapping of Data-Sharing Repositories for Paediatric Clinical Research—A Rapid Review’. Data 9, no. 4 (April 2024): 59. https://doi.org/10.3390/data9040059. c4c

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Mancone, M., Vázquez Mézquita, A.J., Ilaria Birtolo, L., Maurovich-Horvat, P., Kofoed, K., Benedek, T., Donnelly, P., et al. ‘Impact of Smoking in Patients with Suspected Coronary Artery Disease in the Randomised DISCHARGE Trial’. European Radiology 34, no. 6 (June 2024): 4127–41. https://doi.org/10.1007/s00330-023-10355-2. DISCHARGE

Ohmann, C., Panagiotopoulou, M., Canham, S., Felder, G., and Emilio Verde, P. ‘An Assessment of the Informative Value of Data Sharing Statements in Clinical Trial Registries’. BMC Medical Research Methodology 24, no. 1 (9 March 2024): 61. https://doi.org/10.1186/s12874-024-02168-8. BY-COVID

Ohmann, C., Trillou, C., Klammt, S., Stamatopoulos, K., O’Connor, R., Toschi, E., Monteiro, E.C., Del Prado, G., and Schmid, C. ‘Survey by ECRIN about National Registries for Observational Studies and Sharing of Individual Participant Data’. Zenodo, 25 March 2024. https://doi.org/10.5281/zenodo.10868392.

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