ANNUAL REPORT 2025

ecrin

Supporting clinical studies across borders

Explore

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Toulouse

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Rome

Germany
KKS-Netzwerk e. V.
Berlin

Spain
Instituto de Investigación del Hospital Universitario La Paz
Madrid

Norway
Haukeland University Hospital
Bergen

Greece
CERTH
Thessaloniki

Poland
Polish Medical Research Agency
Warsaw

Switzerland
SCTO
Bern

Table of contents

Foreword

Management team

2025 has been a landmark year for ECRIN, with unprecedented interest in our clinical operations planning services and major new projects underway to assist those conducting clinical studies across Europe. We were also honoured to welcome Slovakia as a full ECRIN Member country.

ECRIN is well-positioned to respond to growing calls across Europe to strengthen the European Research Area and bring it to the forefront of global innovation. The Letta Report, the Draghi Report and the 2030 EU Life Science Strategy all highlight the importance of supporting multinational studies and advancing European innovation. In parallel, there is increased support for non-commercial sponsors through ACT-EU and the WHO Global Clinical Trial Forum.

With this surge in activity, including 71 clinical study proposals submitted to ECRIN's Scientific Board — almost three times the average of the last five years — the Clinical Operations team delivered substantial support not only to these new proposals but also to ongoing studies across the continent. Notably, the two new clinical projects launched in 2025 were both platform trials, bringing additional regulatory and organisational complexity for ECRIN to allay.

In 2025, it was particularly encouraging to see increasing attention across Europe on Equity, Diversity and Inclusion. Through ECRIN's International Clinical Trials Day focused on this theme, the launch of the new IHI project READI, and the progress achieved by the Erasmus+ SENSITISE project, it is clear that this topic is becoming central to European clinical trial discourse. ECRIN's growing involvement aims to break down barriers to participate in trials that exist in our different countries and support better trials that ultimately lead to better healthcare for all.

ECRIN is also continuing to invest in training to ensure that investigators, CTUs and sponsors are equipped to undertake multinational studies. Within EU-funded projects, dedicated training programmes are being delivered to specific communities: ERA4Health (supporting its IICS funding calls), ERDERA (focused on multicountry rare disease clinical research), REMEDi4ALL (sharing information on clinical trial research with the wider public), SENSITISE (supporting nclusive design), and, most recently, GREEN

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

-TRIALS (building capacity in sustainable trial design). In 2025, ECRIN also hosted the webinar portion of its training series, “Everything you need to know about submitting a multinational European clinical study proposal”.

Alongside this, we’re developing guidance documents to promote best practice. Through the ERA4Health project, ECRIN produced several practical guides for researchers, focusing on clinical trial data management plans and innovative study designs. ECRIN also continued to develop new tools, including the Master Protocol Toolbox within the canSERV project.

The importance of data sharing and reuse across Europe became even clearer following the publication of the EHDS in 2025, with the implementing acts expected in 2027. ECRIN is contributing to guidance for the EHDS through its involvement in the QUANTUM project, which is defining quality standards for data. Similarly, ECRIN is coordinating the development of guidelines for data preparation and reuse for cancer-related data within the CANDLE project. We also continue to advance the development of Trusted Research Environments (TREs), including through a dedicated workshop in the EOSC-ENTRUST project focused on supporting individual patient data meta-analyses within TREs.

To provide sponsors and investigators across Europe with the services they need, ECRIN maintains its ISO 9001:2015 certification, ensuring the consistent delivery of high-quality services and strong user satisfaction.

ECRIN is strengthened by the contributions of colleagues working within our national partner CTUs. These teams deliver essential in-country services. To ensure they remain informed not only about ECRIN’s activities but also about wider developments across Europe, ECRIN hosted its annual CTU Day. This year’s meeting focused on the implementation of ICH E6(R3), including feedback on training from Ireland, computerised systems validation policy for R from Switzerland, and operational implementation of the guideline from Spain.

The close work with the national partners is further strengthened by the guidance provided by its members on the ECRIN Network Committee, Assembly of Members and Scientific Board, as well as by those supporting daily activities through working groups on communications and CTU designation. This synergy is bidirectional not only opening the doors to Europe but also creating new opportunities to join consortia strengthening the European clinical research environment.

Assembly of Members

Oonagh Ward
(Chair)

Deborah Studer
(vice-chair)

This year marks an interesting turning point for multinational clinical trials in Europe ignited by the launch of the EU's first Life Sciences Strategy.

The continued calls and support to make Europe a competitive global player in key strategic areas, including the pharmaceutical and biotech industries, are bolstering the charge to drastically increase the number of multinational studies in Europe by 2030.

The ERA4Health Partnership pilot call "Effectrial" launched in 2025 to support the development of innovative, multinational clinical studies, encouraging data sharing, harmonised methodologies, and the inclusion of diverse patient populations - key factors for generating robust and generalisable evidence, increased opportunities for European investigators to work together. ECRIN played a crucial enabling role in this context. Its involvement supported the design and implementation of high-quality multinational clinical trials providing expertise in regulatory requirements, trial management, data standards, and quality assurance across different countries. ECRIN's infrastructure helps overcome common barriers in cross-border trials, such as regulatory complexity, ethical approvals, and operational inconsistencies.

Strengthened EU actions such as the Accelerating Clinical Trials in the EU (ACT EU) initiative, together with the ambitious target

ECRIN's Assembly of Members, December 2025

to increase the number of multinational clinical trials, marked a decisive step forward for Europe. These developments highlight the importance of coordinated, high-quality cross-border clinical research, an area where ECRIN plays a central role through its distributed infrastructure and strong national networks.

This year also brought notable changes within ECRIN membership and management. We were delighted to welcome Slovakia as a new Member Country. In parallel, ECRIN has expanded its international engagement by signing Memorandums of Understanding with organisations in countries eligible for Horizon Europe, recently including Canada and New Zealand, building on the growing list of collaborations (Australia, Korea and Japan), supporting the sharing of best practices and greater global alignment.

The Assembly of Members experienced its first transition in leadership since ECRIN's establishment as an ERIC, as the role of the Chair has been passed on. We would like to pay tribute to Rafael De Andres for his longstanding commitment and leadership. At the same time, a broader transition in leadership is taking place at ECRIN, with changes within the headquarters, including the ongoing recruitment of a new Director General, marking the beginning of a new phase for the organisation.

These important changes illustrate both the maturity and the ongoing positive transformation of ECRIN. The achievements presented in this report are a testament to the continued commitment of our Member Countries, partners, and staff.

As newly appointed Chair and Co-Chair to the Assembly of Members we look forward to supporting the organisation through some exciting changes that are on the horizon and beyond.

We will build on its existing momentum, ensuring that ECRIN continues to contribute decisively to Europe's ambition to strengthen multinational clinical research for the benefit of patients and society.

2025 Highlights

January

- ECRIN hosts EOSC-ENTRUST workshop
- READI Project Launches

February

- **Slovakia attains ECRIN full Membership**
- ECRIN signs Memorandum of Understanding with the Maternal Infant Child and Youth Research Network (MICYRN)

March

- REMEDI4ALL webinar series
- New ERA4Health booklet: Guidelines for data sharing of IICSs

April

- C4C final project meeting
- PEARLDIVER pre kickoff meeting

May

- **ICTD: 'Rethinking Clinical Trials: Inclusivity in Practice'**
- EOSC4Cancer project closes

June

- CANDLE project kicks off
- COMBINE programme launched
- ISIDORE project closes

July - August

September

- ECRIN Summer School in Slovakia
- Launch of the Global Clinical Trials Forum

October

- Master Protocol Toolbox launch
- Liveration meeting at ECRIN headquarters
- eCREAM consortium meeting at ECRIN headquarters

November

- **First webinar for the 2nd cohort of "Everything you need to know about submitting a European multinational clinical study proposal**
- SENSITISE workshop in Cork

December

- **ECRIN CTU Day 2026**
- GREEN-TRIALS project kick-off

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

12 years
that ECRIN has held its ERIC status

361 million
citizens living in ECRIN countries

130
clinical trial units

13
Member & Observer countries

Scientific and Operational Activities

29
clinical studies supported in 2025

81
total number of clinical studies supported to date

6.5
countries per ECRIN supported clinical study

26
infrastructure projects supported in 2025 (5 new)

Visibility and Outreach

7,577
followers on LinkedIn

62,281
visitors on the website

3,445
newsletter audience

167
YouTube subscribers

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. Slovakia transitioned to full ECRIN Membership in 2025, bringing the total to 13 Member countries (Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Slovakia, Spain, and Switzerland).

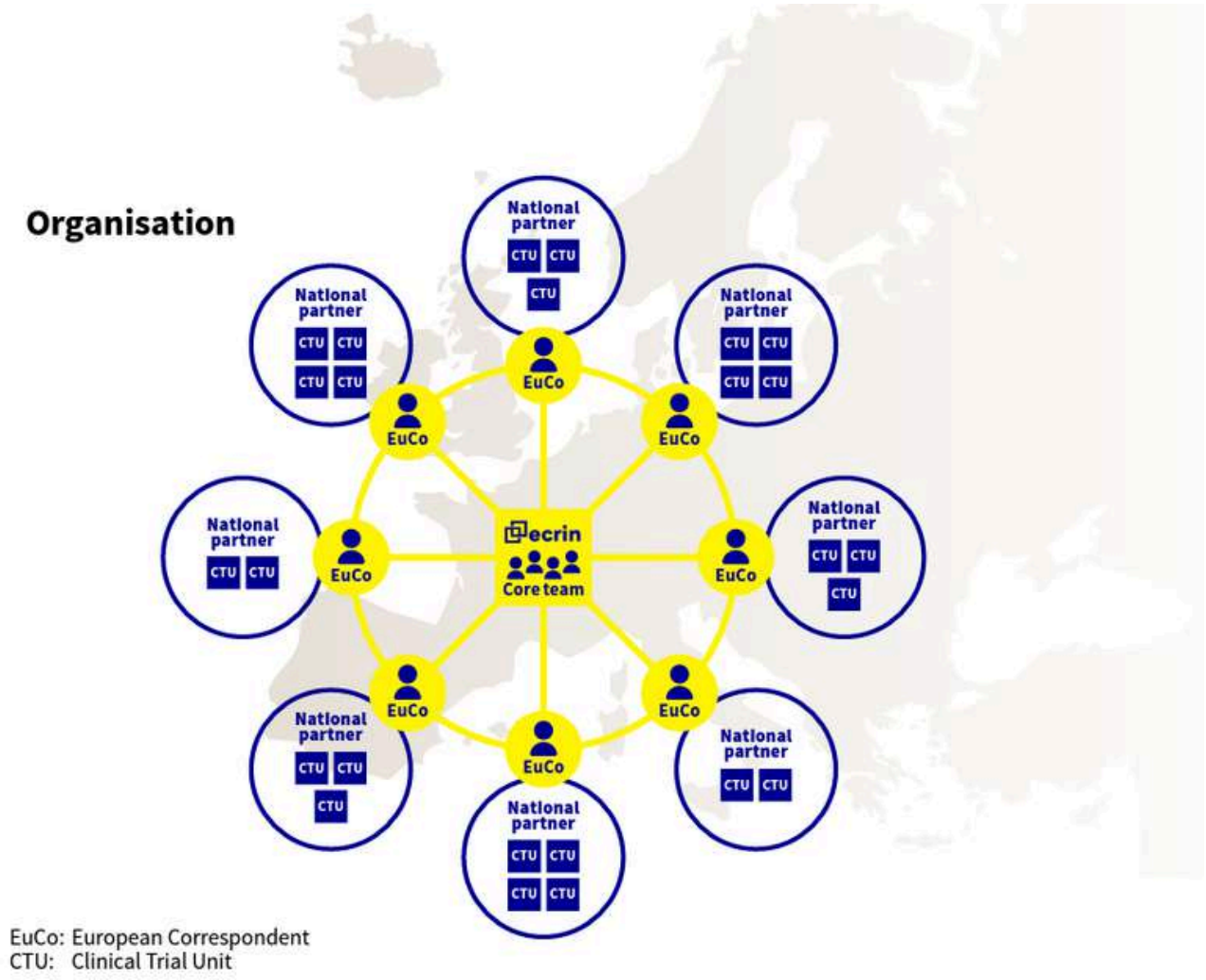

Figure 1: ECRIN's organisation structure.

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, hospitals and research institutions. 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.

The CTUs at the national partner carry out the study implementation in the different ECRIN countries with the support of their local EuCo for coordination with the Sponsor.

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Special focus on Inclusive Clinical Studies

Special focus on inclusive clinical studies

When clinical trials only sample some subsets of those with the condition under investigation, the results cannot be extrapolated to the full population concerned. The understanding of the need for greater inclusivity in clinical studies is growing in Europe, and there is an increasing obligation to progress. ECRIN has been working to unite different stakeholders from the clinical research community and shed light on why equity, diversity, and inclusion should be embraced in clinical research and where there are still hurdles to overcome.

In 2025, ECRIN selected “Rethinking Clinical Trials: Inclusivity in Practice” to be the topic of its annual International Clinical Trials Day (ICTD). ECRIN is participating in a number of important initiatives to address issues around inclusive design. The IHI-READI project and SENSITISE both being paramount.

ICTD 2025: Rethinking Clinical Trials: Inclusivity in Practice

ECRIN and its Spanish national partner, SCReN co-organised ICTD 2025 in Madrid (Spain) on the 20th of May at the Instituto de Salud Carlos III (ISCIII).

There was a resounding interest in the topic, with the 150 seats in the venue booked within weeks of opening and close to four hundred stakeholders from the European and global international clinical research community joining the online broadcast.

The event was particularly notable this year, as we celebrated 20 years of ICTD celebrations, which were originally launched by ECRIN in 2005 as part of the ECRIN Reciprocal Knowledge Programme or ECRIN-RKP (funded by European Union Framework Programme 6, FP6, "Societal challenges” health sub-programme [GA No. 511963]).

This was followed by different stakeholder perspectives on the subject: patient, regulatory, ethics, and industry. We then delved into use cases from academia and industry prior to closing with a panel on building a clinical trial environment in Europe that will support inclusivity and an introduction to the IHI-READI project.

This year's conference demonstrated where there remain hurdles to overcome, more importantly, what is underway to resolve these difficulties and how some people have overcome them.

ICTD International Clinical Trials Day 20 May 2025

With the aim of not only sharing theories and frameworks, yet to be tested the focus of this event was on examples that had been implemented. The meeting was opened by Tamás Bereczky who shared how his own experience as an under-represented individual has shaped his research and passion to make inclusion a must have in clinical trials, not just a box to optionally be ticked and Shaun Treweek, who explained that trial design is often overlooked as a crucial step in ensuring that a trial is truly inclusive.

"It's important for us to think about inclusion, because inclusion is better science."

-Shaun Treweek

20	***ICTD Celebrations***
150	***Attendees onsite***
387	***Attendees online***

Projects in focus

READI

The IHI-READI project aims to build an inclusive clinical research ecosystem to drive health equity in Europe. The project team will work to address these issues by connecting key stakeholders and equipping them with the necessary tools, training programs, and strategies essential for recruiting and retaining underserved and underrepresented patients in clinical studies.

ECRIN will contribute to the identification of barriers and facilitators for inclusivity in European clinical studies. We are further supporting elements related to protocol design and clinical operations with Novartis and Roche, which will include creating guidance on how to use key data to identify the study population; mapping of already identified design and operational features for inclusivity; evaluation of existing tools and development of new approaches; a framework for monitoring and evaluation of the impact of inclusive clinical study strategies; and the creation of a centralised toolkit.

ECRIN staff at SENSITISE Multiplier event in Cork, Ireland.

SENSITISE

Another exciting project underway is the ERASMUS+ funded SENSITISE project. The small expert consortium behind SENSITISE aims to provide education and training on the importance, conduct and impact of designing clinical trials to ensure appropriate representation of underserved groups.

The target audiences are undergraduate biomedical and health professions students, as well as individuals working in the field of clinical trials, including patient and public partners. ECRIN contributes to the content review and translation into French and German throughout the lifecycle of the project. We are also responsible for the tasks related to dissemination and evaluation. The full training content will be made openly available next year.

Liveration

The ECRIN-supported LIVERATION trial participated in an International Workshop on Designing and Implementing Inclusive Clinical Studies, organised by SHINE 2Europe. The event brought together over 50 experts with a shared goal: promoting inclusion in clinical trials. LIVERATION was presented as one of the highlighted projects, alongside initiatives such as REaDI, showing how innovation and equity can go hand in hand in clinical research.

We were pleased to host the consortium in our ECRIN headquarters for their 2025 general assembly.

Interview on equity, diversity and inclusion

Frances Shiely
Director of Education, University College of Cork

Sensitise
Inclusive Clinical Trials: Training and Education

What is the aim of the SENSITISE project?

The aim of the SENSITISE project is to develop an open-access training course on inclusion in clinical trials. And when we were designing the project as a team with ECRIN, University of Aberdeen and Masaryk University, we wanted to have two different types of training.

One, a module that is accessible around the world. It can be integrated into any learning management system. We hope that universities around the world or anybody that offers training in a modular format would be able to implement that. We also want to translate it. In the sense of being inclusive, we want to reach as many people as possible. We will have it available in Czech, German and French.

And the second type of training was workshop because people that are already working in trials and in the industry usually want bite-sized training. So we thought we'd also develop materials for this that would enable any trialist or trial team around the world to offer this to their colleagues as well.

Why is equity, diversity and inclusion important when thinking about clinical trial designs?

Well, we've learned many lessons from the past and that's why we know it's really important. And our most recent example is the COVID pandemic.

So I suppose the best thing I could say is when we looked at the vaccine trial, the UK particularly is a very good example, which is quite a multicultural country. Over 90% of the people in the COVID trials, it turned out, were white.

Okay, you'd say, what's the problem with that? The problem became very apparent when those in other ethnic groups said, how do I know these vaccines work for me? And so the UK government realised it had a problem with implementation because it had a low uptake for the vaccine trials. And, you know, we have many examples where trials need to reach the people who will benefit most from the outcome. But this was a perfect example and a very relatable one because it was so recent and I guess a very scary time for us all.

The real purpose of equity, diversity, inclusion is to make sure that our trials will benefit the people who will be served by the outcome.

Why is it important in the design? Well, because if we don't get it right in the design, we certainly can't get the outcome or the output right. So you've got to really think about equity, diversity and inclusion really early in your trial design. And, you know, some of the ways we can do that best is working with the people in the community that you want to reach with your trial outcome and so that will help them to enable an equitable, diverse and inclusive trial.

What can a student expect from this training ?

Well, if they're taking the module, they can expect a 12 unit course. It's nicely divided up into bite-sized pieces with a new piece of material or a new piece of information each day.

It's divided into three sections over the 12 weeks. We have setting the scene, inclusive design and then building for the future.

We go through things like the history of inclusivity and the ethical principles, defining who are the underserved groups, understanding barriers to inclusion. Then we also have some case studies.

When we talk about the design, we're looking at, well, who should be in our trial? Trying to think about how we would access these people or reach these underserved groups and going forward then building for the future, you know, working with the underserved communities and be more inclusive as a researcher.

What is being done to build knowledge in the current trial community?

I think people who are interested in inclusion and trial design are quite a connected group around the world. And so a lot is actually happening from education, but now, more importantly, implementation. We also have the very large READI IHI-funded project, which is reallygoing to focus on this. So taking it from where we know the problems are to implementation strategies going forward.

In the UK and Ireland, we work very closely in terms of this. We call it trials methodology research. We have a number of teams around the world involved in this type of work as well. I think the future is bright, but I think the challenge from establishing why we don't have inclusive research to how we implement it in trials is very strong. And I think that's where it's going in the next five to 10 years.

How can one access the learning materials developed by SENSITISE ?

We have a website and when the project is completed, everything will be available there. It will be available in English, German, French and Czech for both the workshop materials and the module materials. For the educators implementing the module, we have teacher's guides available for each unit and each lesson to help deliver these case studies or the different lectures.

Everything will be available free, open access on the SENSITISE website.

View Frances Shiely's interview


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LEBANON
ISRAEL
Tripoli
Benghazi
LIBYA
Marzuq
Cairo
EGYPT
Al Jawf
Aswān
SAHARA

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 clinical trials in the Czech Republic. It connects a network of major clinical sites and provides capacities for clinical research, as well as knowledge, development, production and implementation support for drug and medical device development.

CZECRIN continues to implement advanced data management solutions in line with FAIR principles and organises educational activities, including the National Clinical Trials Day.

2025 Highlights

CZECRIN further strengthened its international positioning through active participation in Horizon Europe and H2020 projects, contributing to seven European projects, including several in cooperation with ECRIN. CZECRIN supported a total of 197 clinical trials and initiated or prepared 36 new studies within its national network.

CZECRIN as a part of Centre of Excellence CREATIC, continued to expand its role in advanced therapies, including the development and GMP manufacturing of ATMP investigational medicinal products such as MyDendrix™ and FlyCellix™, supporting early-phase clinical trials. Its designation as an ECRIN ATMP Clinical Trials Node further reinforced its role in the European ATMP ecosystem.

The national network continued to grow, encompassing 18 Clinical Trial Units across major hospitals, 12 Disease-Oriented Networks aligned with national HEALTH 2030 priorities, and a coordinated network of GCP-certified Phase I units enabling first-in-human studies.

Education remained a core pillar, with the CZECRIN Academy delivering extensive training programmes, including the first Czech certified GCP course with over 2,000 certificates issued, EUPATI-based patient education, and specialised programmes for clinical research professionals and students.
Strategic collaboration was further enhanced with national and European partners, as well as with the Ministry of Health, SÚKL and other stakeholders. CZECRIN actively contributes to the development of the National Strategy for Clinical Trials and continues to strengthen its role in shaping the future of academic clinical research in the Czech Republic and Europe.

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 a hub of thematic research and investigation networks with a national scope. F-CRIN brings together the major academic and commercial stakeholders in clinical research in France, including clinical research and innovation departments in university hospitals, clinical investigation centres and teams in non-university hospitals, general practitioners and interregional groups for clinical research and innovation.

F-CRIN enables multinational, multicenter, investigator-driven clinical trials and early-phase proof-of-concept studies. Clinical trial support is provided through F-CRIN by:
- 23 national networks specialised in specific diseases or medical fields (e.g., cardiology, nutrition, inflammatory diseases, cardiorenal diseases, thrombosis, vaccinology, Parkinson's disease, sepsis, stroke, severe asthma, psychotic disorders, primary care, maternal health, etc.)
- 3 specific expertise networks (rare diseases, medical devices, innovative therapies)
- 1 platform supporting the setup and design of clinical trials
- 1 coordination unit, headquarters of the infrastructure and support services centre for the components of the infrastructure, based in Toulouse

2025 Highlights

The certification (labeling) of seven new clinical research and investigation networks: CLEIO (innovative therapies research and investigation), F-MOM (preventing severe pregnancy complications and improving the care of pregnant women), GRACE (research in cardiac amyloidosis), CONDOR (chronic obstructive pulmonary disease), FAMIREA (supporting relatives of intensive care patients), Myco-NET (treatment and prevention of non-tuberculous mycobacterial infections), and RENARCI (severe bacterial infections and antibiotic resistance).

The launch of two platform trials: Master Trial, to accelerate the identification of neuroprotective treatments for Parkinson's disease, and PALETTE, designed to efficiently study sepsis interventions within "treatable traits" across patients of all ages, for a fast evaluation of treatments during pandemics.

2025 included the organisation of new training initiatives of collective interest, "The F-CRIN webinars on clinical research", a new series dedicated to patient involvement and to sustainability in clinical research, as well as in-person training sessions on clinical research and innovation in hospitals.

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.

2025 Highlights

Throughout 2025, the KKSN continued advocating for the interests of academic clinical research in Germany.

With the focus on accelerating contract negotiations for clinical studies, KKSN, together with partner organisations, developed and published a contract template for academic clinical trials, a practical guidance on total service calculation at the trial site and a standard contract template for clinical trials with an industrial sponsor, aligned with the new regulatory requirements.

On 21 May 2025, KKSN marked its 25th anniversary with a symposium highlighting its longstanding commitment to improving the conditions for academic clinical research. At the end of the year, KKSN presented a comprehensively revised curriculum for the qualification of study coordinators, proposing a nationally harmonised standard and thereby further advancing the professionalisation of study coordination.

Nine ECRIN projects are coordinated by KKSN, support is also provided to four other ECRIN projects in which KKSN members are participating. Additionally, 20 new coordinating projects proposals and 20 participating 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).

2025 Highlights

In 2025, GRECRIN focused on expanding its educational reach and strengthening international partnerships to better support the Greek research community.

A key development was the launch of the Data-Centric Clinical Research webinars, a series running into 2026. These webinars provide practical guidance on data management and digital tools, helping local researchers stay updated on modern clinical trial standards.

Additionally, GRECRIN is stepping into a more active coordination role through the imminent launch of GenZ Trials project at the start of 2026. In collaboration with ItaCRIN, the network is co-leading a pragmatic Phase-IV clinical trial for patients with atrial fibrillation. This synergy demonstrates GRECRIN's growing capacity to manage multi-country studies and deliver meaningful results in real-world clinical settings.

HUNGARY

Scientific Partner: HECRIN – Hungarian European Clinical Research Infrastructure Network
Member since 5 November 2014
Host institution: OKFŐ – National Directorate General for Hospitals
National hub: Budapest
okfo.gov.hu/en

The National Directorate General for Hospitals (OKFŐ) is a central government body responsible for the coordination, management, and strategic development of Hungary's public healthcare system. Its core mission is to ensure the efficient operation of healthcare institutions, improve the quality of patient care, and support nationwide health system planning and implementation.

OKFŐ plays an important role in clinical research by overseeing and supporting healthcare providers that serve as clinical trial sites. Through its coordination of hospitals and integration of healthcare data systems, it helps create a structured and reliable environment for conducting clinical trials. This facilitates collaboration among clinical investigators, research organizations, and international partners, ultimately strengthening Hungary's participation in multinational clinical studies.

2025 Highlights

In 2025, a strong and targeted emphasis was placed on the domestic promotion of ECRIN, implemented through several professional forums and training programs across Hungary. As part of these efforts, ECRIN's activities and relevance were presented at multiple national-level events. These included a lecture at the University of Miskolc within CRA education, titled "Site Selection and Site Qualification in Clinical Trials," as well as a presentation at the Congress of the Hungarian Clinical Trial Management Society (MKVT) within GCP training, titled "Clinical Trials in Hungary and in the Surrounding Countries."

In addition, preparations for integration into the National Directorate General for Hospitals (OKFŐ) were initiated, which is expected to enable a more direct connection with hospitals, alongside the launch of several national training programs aimed at further supporting the professional development of experts working in the field of clinical research.

IRELAND

Scientific Partner: HRB Clinical Research Facility University College Cork
Member since 20 November 2018
Host institution: University College Cork
National hub: Cork
https://crf.ucc.ie/

As of May 1st 2025, CRF-UCC, acting through University College Cork (UCC) and supported by the Health Research Board (HRB), will serve as the National Scientific Partner, along with six other Clinical Research Facilities/Centres in Ireland: Children's Health Ireland Clinical Research Centre (CHI-CRC), Clinical Research Facility Galway (CRF-G), Health Research Institute Clinical Research Support Unit (HRI CRSU), Royal College of Surgeons Clinical Research Centre (RCSI CRC), University College Dublin Clinical Research Centre (UCD CRC), Wellcome Trust Clinical Research Facility St. James's Hospital (CRF-SJH).

As ECRIN's acting National Scientific Partner for Ireland, CRF-UCC has continued to host the European Correspondent role for Ireland, and the ECRIN Network Committee role to support the conduct of multi-centre clinical trials and investigations/studies (both commercial and academic) across Ireland. In total, the seven 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.

2025 Highlights

In 2025, Clinical Research Facilities/Centres in Ireland were involved in 5 active ECRIN multinational clinical trials and a part of 12 ECRIN multinational trial proposals.

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 Infrastructure Network is coordinated by the Istituto Superiore di Sanità (ISS) in Rome, where its national hub is located, and brings together 14 Clinical Trial Units (CTUs) and Contract Research Organisations (CROs) across Italy.

Its main objective is to support and promote non-profit clinical research in Italy and Europe by supporting Italian investigators in setting up and conducting multinational clinical trials. ItaCRIN contributes to overcoming operational challenges and strengthening cross-border collaboration. Network members contribute to a wide range of national and international projects by providing a full portfolio of clinical trial-related services.

In line with the ECRIN Consolidation Phase, ItaCRIN places strong emphasis on capacity building within the national scientific community and on collaboration with patient associations. Each year, ItaCRIN delivers high-level training initiatives for investigators, clinicians, and grant office staff, engaging more than 100 participants annually. All training activities are implemented in accordance with the UNI EN ISO 9001:2015 certification issued by ISS.

2025 Highlights

ItaCRIN held its 6th Annual Meeting in October, gathering partners from across the national network to discuss strategic priorities and reinforce collaboration in clinical research. The meeting also marked the official welcome of LATIS CRO, whose expertise further strengthens the network's capabilities.

Within the ProMIS Programme, ISS/ItaCRIN actively participated in initiatives aiming to provide an overview of Horizon Europe partnerships at the EU level and the Italian National Recovery and Resilience Plan. During these sessions, ECRIN and ItaCRIN/ISS presented their role in supporting multinational clinical studies—often funded under Horizon Europe—by offering methodological and operational guidance.

A key strength of ItaCRIN continues to be its close collaboration with the Italian nodes of BBMRI (BBMRI.it) and EATRIS (A_IATRIS). Together, the three nodes co-organise specialised training activities and, starting in 2025, have launched a joint newsletter, published every six months. The first special issue was released in December 2025.

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 was founded by the Norwegian Research Council, by original initiative of the Ministry of Health and Care Services, with the second funding period ending in fall 2025. The network will continue through in-kind contributions from the partners and a Coordinating Unit funded by the four regional health authorities.

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 to support clinicians in the planning and conduct of clinical trials. One of its great strengths is the close collaboration between CTUs within the network, enhancing the distribution of clinical trial support to all regions in Norway.

It is hosted by Helse Bergen HF, and the coordinating unit 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 its position in the European research environment.

2025 Highlights

In 2025, NorCRIN continued to strengthen national coordination of clinical trials, with a focus on harmonising procedures (SOPs) across institutions and aligning practices with updated international guidelines, including ICH-GCP R3.

Training and competence-building activities remained central, with continued delivery of national courses and e-learning programmes for research nurses and clinical trial personnel.

NorCRIN maintained its engagement with international partners, supporting knowledge exchange and ensuring that Norwegian clinical research remains aligned with developments in Europe.

Building on previous initiatives and relationships, NorCRIN continued efforts to strengthen Nordic collaboration between clinical research infrastructures and initiated the launch of Nordic Trial Connect in April 2025.This included dialogue and planning for closer cooperation across the Nordic countries, with the aim of harmonising practices, sharing expertise, and facilitating cross-border clinical studies.

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.

2025 Highlights

Infrastructure and capacity
In 2025, the MRA eCRF system was further developed, with 21 new projects launched on the platform. In total, the MRA eCRF system is now being used in 32 non-commercial projects conducted by PCTN members.

In 2025, three new entities joined the PCTN as Observers, and official invitations to partner were sent to several other organisations.

Promoting knowledge and best practice
In collaboration with external experts and specialists from Clinical Research Support Centres, a 'Guide to Best Practice for early-phase clinical research centres' was developed.

Communications and events
Representatives of PCTN have participated as exhibitors or speakers at numerous national and international events, including
- SCRS European Site Solutions Summit in Lisbon
- Conference celebrating International Clinical Trials Day in Warsaw
- Global Clinical Trials Connect conference in London

In November, the Medical Research Agency organised PCTN networking workshops, which took place in Warsaw. The event was attended by representatives of Clinical Research Support Centres, sponsor companies and CROs, MRA, patient organisations and other entities.

A series of promotional and informational activities were carried out via LinkedIn, covering both the PCTN's activities and those of its members and followers. Thanks to a high level of engagement, the PCTN's LinkedIn profile gained 5350 new followers in 2025 (more than five times as many as in the previous year).

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 a national research infrastructure dedicated to strengthening clinical research in Portugal by supporting the implementation, conduct, and management of Investigator-Initiated Clinical Trials (IICTs) across all disease areas. Its mission is to increase both the quantity and quality of academic clinical trials by fostering national and international collaboration, promoting best practices, and generating robust evidence to support safe, effective, and cost-efficient healthcare decisions.

PtCRIN is a consortium of 28 institutions included in the Portuguese Roadmap of Research Infrastructures (RNIE). It coordinates a network of six academic CTUs that provide comprehensive support to investigators and academic sponsors throughout all trial phases. Services include protocol development, budgeting, regulatory and ethics submissions, project and data management, monitoring, pharmaco-vigilance, and reporting, covering both medical device and medicinal product trials.

Through this integrated structure, PtCRIN strengthens the national research ecosystem, enhances operational efficiency, and facilitates the production of high-quality clinical evidence with direct impact on patient care and health policy.

2025 Highlights

PtCRIN organised, with ECRIN's support, a dedicated event on IICTs, titled "Fostering IICTs in Portugal: a multidisciplinary workshop across scientific societies," held at ULS Coimbra. It gathered researchers, scientific societies, and key stakeholders to discuss the future of IICTs and strategies to bolster national capacity and collaboration.

PtCRIN contributed to a national initiative, the policy brief "Strategies to Promote Research in Primary Health Care in Portugal". The network also collaborated with the national ethics authority (CEIC), developing a new standard informed consent form for clinical research. Furthermore, an internal CTU meeting initiated the development of a new strategic roadmap and improved coordination across CTUs. In November, ULS Santa Maria and Hospital de Cascais joined the consortium.

Throughout 2025, PtCRIN was involved in 3 ECRIN multinational trials (8 CRCs and 3 CTUs involved, one as the Lead CTU). The network also supported 12 Horizon Europe proposals (3 proposals as a coordinating country and 9 proposals as a participating country).

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.

2025 Highlights

Slovakia became an ECRIN full member
On January 27, 2025, Slovakia obtained full membership in ECRIN. Since 2018, it had participated as an ECRIN Observer, steadily strengthening national clinical research capacity. Representation is ensured through SLOVACRIN (the Slovak Clinical Research Infrastructure), headquartered at the Faculty of Medicine of Pavol Jozef Šafárik University in Košice. This milestone further strengthens Slovakia's integration into the European clinical research network and enhances opportunities for international collaboration.

SLOVACRIN National Clinical Trials Day 2025
SLOVACRIN, together with key stakeholders in the field of clinical research, hosted the National Clinical Trials Day. The agenda addressed current national and European challenges and opportunities, explored the importance of clinical research for Slovakia, and examined the state of the research environment from various perspectives. It also showcased examples of good practice and international experience to inspire further advancement. The event was attended by the Director General of ECRIN, Jacques Demotes, and concluded with a forward-looking discussion on future priorities and the continued development of clinical research in Slovakia.

Summer school 2025
In September 2025, SLOVACRIN organised and hosted the ECRIN internal Summer School in Košice. The three-day programme covered a range of topics, including medical devices, the use of artificial intelligence in clinical research, and a workshop focused on project management and conflict resolution. In addition to the professional sessions, participants took part in a short excursion to the High Tatras, fostering informal exchange and networking among colleagues.

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 (NHS), spanning 14 of the Spanish autonomous communities. 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 have been hosted at the Virgen de la Victoria University Hospital (Clinical Pharmacology Service, IBIMA-Plataforma Bionand). The EuCos and the SCREN coordination continue to lead the Internationalisation WG under ISCIII directives, which represent the network's 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 System and European Society.

2025 Highlights

In 2025, SCREN's portfolio incorporated 19 new clinical trial projects; 3 are ECRIN projects (2 from the ERA4Health partnership, EffecTrial call). 2025 also marked the start of the RICORS and AMRI Synergy capacity building projects (funded by ISCIII and AEI, respectively). A WG focused on Medical Devices and Regulatory Support was created through the RICORS project. SCReN restructured its paediatric clinical trial expert board into a new WG and signed a Memorandum of Understanding with RECLIP (Spanish paediatric clinical trials network). SCReN also provided advice and support in both national and international strategic activities and consultations.

Patient and citizen involvement was a key area, with several initiatives being promoted. The first steps of the READI project were shared at ICTD, co-organised by SCReN and hosted by the ISCIII in 2025. At national level, the Spanish branch of EUPATI and SCReN's Communication and Citizen Participation WG reviewed the main areas for collaboration and the needs to be addressed in the future.

SCREN participated in trainings, events and hosted the 3rd Annual Conference of ISCIII Platforms.

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 Switzerland's national reference infrastructure for high-quality, patient-centred academic clinical research. Funded since 2017 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 comprises the Executive Office, seven Clinical Research Centres (CRCs), and eight national Platforms. The ECRIN node for Switzerland is part of the Executive Office in Bern.

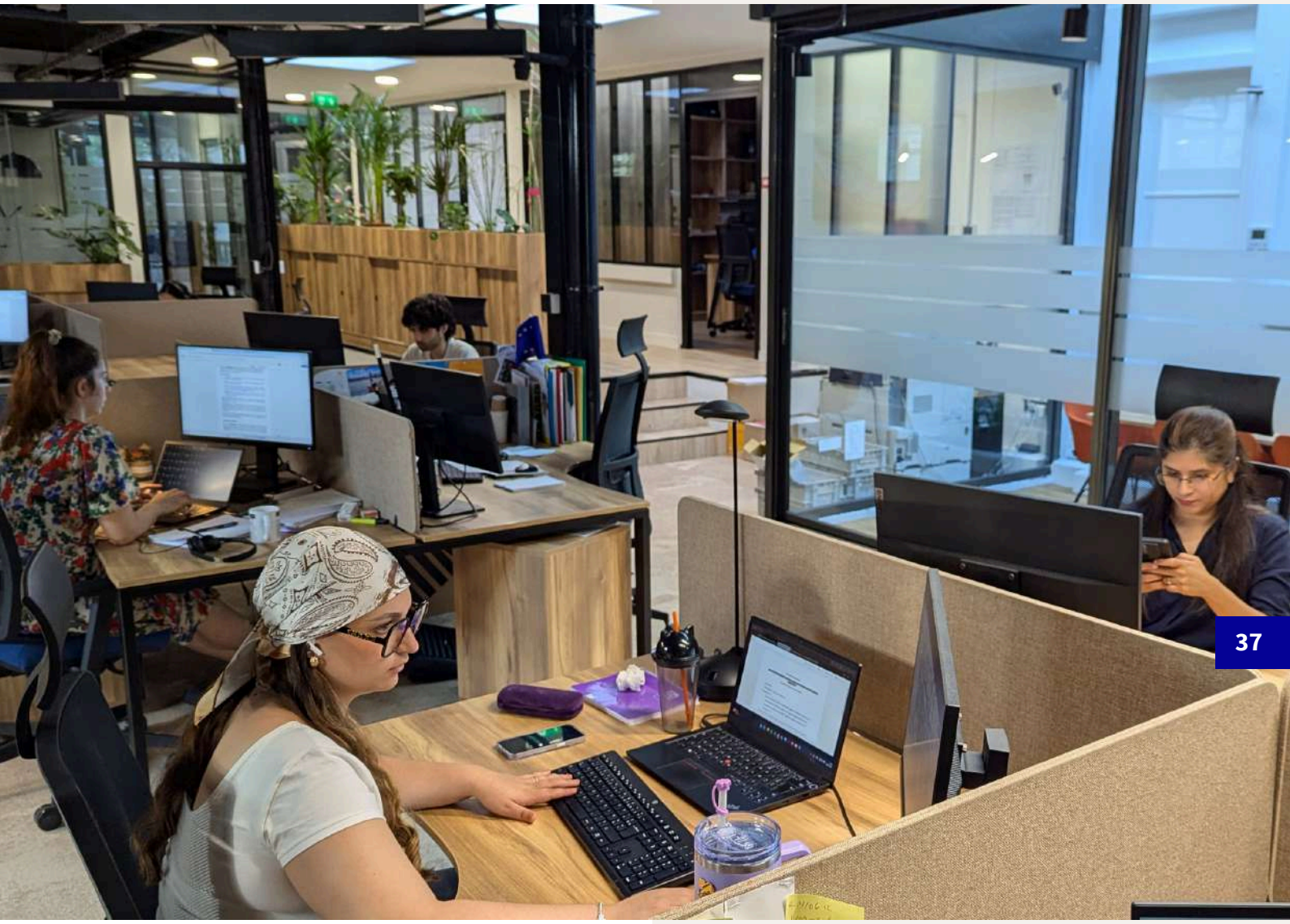
2025 Highlights

A year of strong performance
In 2025, the SCTO, with its CRCs Network, supported 2164 clinical research projects, delivered 4258 specialised services, trained 9374 professionals across 218 courses, and facilitated 352 international multicentre studies. CRC Network members co-authored 247 peer-reviewed publications, 77% of which appeared in top-tier (Q1) journals.

New tool output
A landmark achievement of 2025 was the delivery of 40 new or updated tools, templates, guidelines, statistical packages, and training resources by the SCTO. These resources, downloaded 7'788 times from the web, cover the full spectrum of clinical research practice.

Innovation and international engagement
The Research-on-Research (RoR) initiative launched five cross-Network projects to improve clinical research practices using evidence-based methods. Two new national working groups on Artificial Intelligence and Decentralised Clinical Trials were established. Six ECRIN-supported projects were active under the SCTO's responsibility, and nine new project proposals were prepared, with Swiss participation spanning oncology, paediatrics, and beyond.

Bringing the community together
The SCTO hosted two flagship events in 2025. The SCTO Forum focused on regulatory changes in clinical research, providing an essential space for dialogue between researchers and national authorities on the new ICH GCP E6(R3) guideline. The SCTO Symposium "Bridging the divide: Integrating clinical trials with medical care," bringing together clinicians, researchers, and policymakers to explore how academic trials can be more deeply embedded in routine healthcare. Together, these events reinforced the SCTO's role as a national convener for Switzerland's clinical research community.



Interview with the Slovak European Correspondent

Simona Sonderlichová
European Correspondent Slovakia - SLOVACRIN

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

SLOVACRIN is still relatively a very young and evolving research infrastructure. So a big part of my job focuses on strengthening our national network and also further building our network of CTUs. It's a very important, crucial point for our infrastructure.

I act as a contact point for all of our research community. I support communication across the network, for example, about important regulatory updates, interesting education and training opportunities, projects, clinical trials and so on.

Regarding the clinical trials, whether with or without ECRIN support, I'm involved in both phases, in the preparatory phase, but also in the implementation.

At the beginning, I identify all possible obstacles, and try to find a solution. I work very closely with the CTUs involved in these clinical trials to ensure that all regulatory requirements are met. This is very important.

Also, I'm part of the organising teams for our national meetings: our national clinical trials days and GCP courses. As we are very young, we're still developing, and I think training and education are a big and important part of our network. We see that this is crucial for us.

Another important part of my role is also to provide initial consultations to sponsors, researchers, and PIs, to provide them at the beginning with some guidance on how they should start clinical trials here in Slovakia.

Overall, I can say that my role is very comprehensive. It's a combination of coordination of our network, communication, training activities, organising a lot of events, but also, I'm deeply involved in clinical research. I think it's very important that I have a really broad spectrum of activities.

How has ECRIN benefited Slovakia?

Slovakia became a member of ECRIN in 2018 and we achieved a full membership at the beginning of the last year in 2025. ECRIN helped us raise awareness of non-commercial clinical research and why it is important to conduct these kinds of studies.

It also opened the door to discussions with policymakers, and we know that this is one of the most challenging parts - to discuss the importance of this kind of research.

Our membership helps us to continue building a network of CTUs. At the beginning of our journey in 2018, our Ministry of Health, in the Slovak Republic, issued an order to

establish these kind of units and also the position of clinical trial coordinators. This was a great thing for us because we can work together and build our network of CTUs. One of the biggest benefits of ECRIN membership is organising our national clinical trials days because it's a huge event every year. It brings together all relevant stakeholders, such as policy makers, regulators, sponsors, commercial and non-commercials, CTUs, physicians, and patients.

This is the biggest advantage of a small country, that we can organise one meeting where all relevant stakeholders can meet. We can raise questions and at the end of the meeting, we can at least try to find solutions.

Education and training are one of the key areas to really increase knowledge and expertise here in Slovakia. We are very happy because ECRIN provides a lot of kinds of training, free events, and knowledge sharing within the ECRIN network. We are very happy that we can participate in it.

Finally, the clinical trials and the infrastructure development projects that we can participate in bring some new studies here to Slovakia. As such, we can increase the visibility of our research community across Europe.

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

One of the achievements I am most proud of is the development of our roadmap for academic clinical research in Slovakia. It was the first comprehensive document to map the current situation across the hospitals, universities and research institutions here in Slovakia.

We analysed the current situation, the capacity of the established CTOs and evaluated what services they can provide. These documents identify the future needs of this institution, which is a clear starting point for improvement and strategic development.

This was a very long and quite demanding process, but I think it's worth it and in the next month, we would like to have some updates of this roadmap.

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

Recently, the Ministry of Health of Slovak Republic, launched the first call dedicated to clinical research. This call is a combination of network development and clinical studies. We see this as a very positive signal that the policy makers recognise the importance of clinical research and want to actively support its development. I think this is a milestone for Slovakia.

Although we don't know the results yet, we know that the whole community will be happy because this is the first time the money comes to this community.

Last year was the first time we received systematic funding from our Ministry of Education, which is great. This provides some stability for us and allows us to continue working towards our long-term goals. I think finance is always a very crucial step for each network, and we will see in the next couple of months how it will go.

View Simona Sonderlichová's interview


14:00
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Clinical Operations

Clinical Operations

Multinational Clinical Studies at the Heart of Political Reform

2025 saw a large influx of political support for multinational clinical studies in Europe. The Draghi Report placed a strong emphasis on Europe's global competitiveness and strategic autonomy, with a keen interest in the biotech and pharmaceutical sectors. Furthermore, the Letta Report pushed for a deeper integration of a single market, notably in health, data governance and regulatory harmonisation. The outcome of the two Reports is an increased incentive for investment in large-scale, multi-country trials in Europe to advance innovation.

Similarly, the 2025 Strategy for European Life Sciences, released by the European Commission in July, looks to ensure the EU is the world's most attractive place for life sciences by 2030. It includes flagship actions, including two of particular interest. The Clinical Research Investment Plan, to which ECRIN is contributing, will facilitate funding of multi-country clinical trials. The EU Biotech Act aims to reshape the landscape in particular where advanced therapies are concerned, through the simplification of regulatory predictability and better coordination between key actors.

These parallel actions are beneficial not just for ECRIN's activity but for that of the European Research Area as a whole. Accordingly, active participation in shaping these initiatives will remain a strategic priority for ECRIN, ensuring that the needs of academic research are appropriately represented and addressed.

ECRIN's contributions in Europe and beyond

Beyond the most recent calls to action listed above, ECRIN continues to participate in various initiatives in Europe and globally to advance the clinical research ecosystem.

ECRIN continues to play an active role in the Accelerating Clinical Trials in the EU (ACT EU) initiative from the European Commission, the Heads of Medicines Agencies and the European Medicines Agency. With a seat on the Multistakeholder Platform Advisory Group, ECRIN has contributed to shaping discussions and strategy for this year and beyond, with our focus on the community of non-commercial sponsors. Some key contributions this year were on issues related to training and Clinical Trial Regulation assessment.

The Cross-Border Access to Clinical Trials initiative (EU-X-CT) shared its consolidated recommendations from the first phase and aligned with stakeholders and policymakers on turning them into a clear, simple pathway for patients to join cross-border trials within Europe. It then launched into its second phase at the end of the year. ECRIN continues to participate in various workstreams supporting existing synergies, stakeholder engagement and the creation of key resources to support sponsors and researchers to build trials with cross-border access possibilities.

At international level, ECRIN was one of the original 27 organisations to join the WHO's Global Clinical Trials Forum (GCTF). The GCTF is a global, multi-stakeholder network that aims to strengthen the clinical trial environments and infrastructure at national, regional and global levels. It is in response to World Health Assembly Resolution WHA75.8, which called on the WHO to improve the quality and coordination of clinical trials to generate high-quality evidence for health decision-making. It is further guided by the Global Action Plan for Clinical Trial Ecosystem Strengthening, which translates the guidance into nine priority action areas addressing barriers across current clinical trial ecosystems.

Resources and funding opportunities for clinical studies

Horizon Europe included many calls this year, with funding for clinical studies available through open calls in Cluster 1 Health and Mission Cancer. Through Horizon Europe funding, a central budget is easily distributed to the various partners based on the needs of the consortium. This budget configuration, a central pot, facilitates ECRIN's contributions through the different phases of the clinical study. The breadth of this year's calls, being very large, led to record levels of interest in ECRIN's services.

ERA4Health Partnership

In 2025, the ERA4Health Partnership's first pilot call for investigator-initiated clinical studies (IICS), EffecTrial, closed in early 2025. It aimed to finance multi-country pragmatic comparative effectiveness trials for the treatment of non-communicable diseases. Sponsors were encouraged but not obliged to work with ECRIN. For those who did it proved fruitful as ECRIN is supporting the seven funded trials of this call.

Through the ERA4Health Partnership, ECRIN developed a unique resource: a standard clinical site agreement for Europe. This type of agreement is usually established at the start of a trial between the Sponsor of a clinical trial and the clinical site where the investigation takes place (typically, the hospital or any premises in which the clinical trial will be conducted). Several countries have developed national templates for clinical site agreements; to the best of our knowledge, none of them is tailored

Interview on ACT EU

Laura Pioppo
ACT EU Programme Manager

What is ACT EU doing for non-commercial sponsors?

We have an action plan that has been developed in collaboration with colleagues at the European Commission and the Heads of Medicine Agency to support academia and non-commercial sponsors in general to conduct clinical trials in the EU.

The interactive map on the ACT EU website is where we have compiled activities available at the Member States level, already in place in the different European countries, to support non-commercial sponsors.

Another major activity is the CTIS and CTR regulatory helpdesk, which was launched almost 18 months ago. This prioritises issues raised by non-commercial sponsors when they access CTIS and have technical issues or questions of a regulatory nature, in which case, we liaise with the national competent authorities in the Member States.

Together with the National Competent Authorities of the hosting country, we organise regular two-hour webinars where academic sponsors have the possibility to present their feedback and ask questions.

There is an explanatory analysis on funding opportunities to support non-commercial sponsors published on the ACT EU website. It highlights the importance of training and regulatory support, network development and collaboration, and the benefits of standard site agreements. All these points are being addressed by ACT EU.

Lastly, there are two other priority actions with a focus relevant to this group. The first one is about pilots on consolidated advice, where we bring together regulators and applicants to have an early dialogue on scientific or regulatory aspects in relation to clinical trial applications. The second priority is on training needs for academia and SME.

At ICTD 2025, you spoke about inclusive clinical research - what has ACT EU planned in this respect?

This is a very important topic and is becoming more and more of a priority for the regulatory network.

ACT EU is already trying to achieve more multinational clinical trials, so trials that are conducted in more than one country. This reflects an ambition to have a more inclusive approach and more representative populations recruited as trial participants at different clinical investigative sites.

One of the main tools that we have developed to achieve this objective was the launch of the trial map last year. This platform has been

developed, keeping in mind the needs of patient organisations and representatives, and healthcare professionals, enabling the identification of clinical trials running in the EU.

The ACT EU Steering Group has revised the objectives for the programme to make sure that they match the needs of the clinical trial environment. A new objective, included in the 2026-2027 workplan, is to have more inclusive clinical trials, looking particularly at children, women, not only but also pregnant and lactating women, and also rare diseases. Finally, I would like to mention the collaboration of EMA with the IHI-funded READI project.

What changes are anticipated in line with the BioTech Act?

The changes that the BioTech Act brings are quite broad. They refer to accelerated timelines for the assessment of clinical trial applications, strengthening the role of the reporting Member States in the assessment of the application, enabling the submission of parallel substantial modifications, etc.

Although the text is now under legislative review, we are considering how ACT EU could support change management activities to enable a smooth implementation and adoption of the final text of the BioTech Act. This will be through different means, such as the preparation of training materials and workshops.

What challenges have been addressed in Scientific Advice pre-CTA and consolidated for non-commercial sponsors?

This is one of the main deliverables and activities within the ACT EU program. We launched these pilots over 18 months ago. They are a good opportunity for applicants to have an early dialogue with the regulators.

We have seen two applications submitted to the SAWP CTCG pilot that focus on questions of a scientific nature: the design of the clinical trials, endpoints, and oriented to advanced phase clinical trials in the context of marketing authorisation.

Under the pre-CTA pilot, which is focused on regulatory or administrative questions, the two applications from non-commercial sponsors were on the design of complex clinical trials and how those should have been submitted to CTIS.

What are the key outcomes you are working towards in the next 5 years?

We want to be ambitious. We recognise that there is a need to become more competitive in the EU when it comes to clinical trials compared to other regions of the world. There is a willingness to collaborate to reach this goal, strengthen the governance, and streamline the process for submission and evaluation of clinical trial applications.

We launched a new initiative on the measurement of key performance indicators against two targets. One is to have 500 more clinical trials starting from 2026 until the end of 2030, leading to 100 more trials each year. The second KPI is to see 66% of the clinical trials recruiting patients at the first site within 200 days of submission of a CTA.

View Laura Pioppo's interview

specifically for EU multinational clinical trials. The template, addresses challenges such as legal compliance, negotiation complexities, and national variations, should improve efficiency, reduce administrative burden, and ensure compliance with applicable EU regulations. Ultimately, this template will foster better collaboration across European Member States for clinical trials.

Additional resources supporting the clinical researcher community can be found in the dedicated section of this report (p54).

Development of new European Platform trials

In 2025, the clinical operations team supported the development of two new European platform trials. One with a focus on infectious diseases and the second on major depressive disorder.

Platform trial: *A platform trial is a type of clinical study that tests multiple treatments at the same time within one ongoing framework. Instead of starting a new trial for each drug, researchers can add or remove treatments as results come in, making the process faster and more efficient. In a platform trial, several experimental treatments share a control group. This approach helps identify what works best more quickly, especially during urgent situations like disease outbreaks*

EU-PEARLDIVER

The IMI-funded EU-PEARL project (GA 853966-2) developed a reusable multinational infrastructure to run integrated platform trials. Using this infrastructure, EU-PEARLDIVER, funded by Wellcome, will test new and repurposed treatments for depression in six European countries. The trial has been co-designed with lived experience experts, who also play an active role as key collaborators who will vote on all decisions along the way.

The trial is designed to accommodate different types of drugs and may also include non-pharmacological treatments such as psychotherapy or non-invasive neuromodulation in the future.

PROACT-EU RESPONSE

Similar to EU-PEARLDIVER, PROACT-EU RESPONSE's origins are found within an existing EU-funded project, EU-RESPONSE. From the outset, PROACT EU-RESPONSE has displayed an ambitious vision: to strengthen Europe's capacity to respond effectively to future health emergencies by establishing a network of adaptive clinical trials capable of responding rapidly, ethically, and inclusively to emerging viral threats. Today, PROACT EU-RESPONSE is entering its operational phase with the trial named EU-SYNDACT1.

This new type of trial brings fast decision-making, scalability, improved comparison of results and encourages strong collaboration within the clinical research community. ECRIN looks forward to supporting these and future platform trials.

ECRIN's Clinical Trial Portfolio

ECRIN Scientific Board

The ECRIN portfolio relies on a first step, ECRIN's agreement to collaborate on a clinical proposal or project. This validation must come from ECRIN's Scientific Board (SB). Access to ECRIN's operational services is based on scientific excellence.

Access to ECRIN's clinical services *requires the following:*
- Trials must also be conducted in at least two ECRIN countries,
- Respect the transparency rules laid out by ECRIN to register the study and publish regardless of findings
- To recognise ECRIN's contribution as well as that of its national partners in trial registry and publications.

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 for running studies looking to expand to new countries. **This year, 96% of requests were addressed within 5 working days.**

2025 was a record year with **71 requests between January and September 2025**. This number also includes applications for the ERA4Health calls.

This jump highlights the increasing importance of collaboration with ECRIN to support the implementation of multinational clinical studies. Requests came from ECRIN Member Countries, including France, Germany, Italy, the Czech Republic, Poland, Portugal and Greece, with a record 18 requests from Spain.

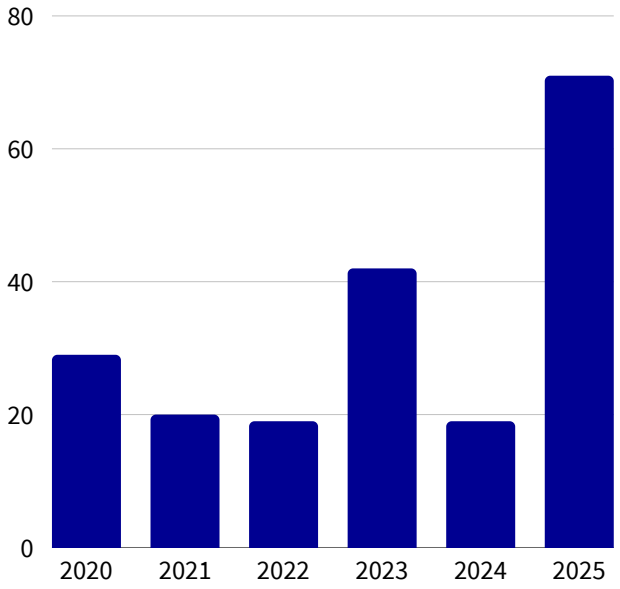


Figure 2. Number of collaboration requests per year.

A spattering of requests came from non-ECRIN countries, including Austria, Belgium, Denmark, Georgia, the Netherlands, Sweden, the UK and the US. Collaboration with non-ECRIN countries is possible, provided they include at least two ECRIN Member Countries in their study, or the request is made through the ERA4Health Partnership.

Within the first ERA4Health call, ECRIN supported 14 proposals of the 32 submitted and was included in all seven that received funding from the Partnership.

From other funding sources, ECRIN has confirmation of two funded proposals and is awaiting the response for nine others. The collaboration committee rejected 6 requests and 12 requests were later withdrawn.

Key Numbers

2025 ECRIN trial portfolio

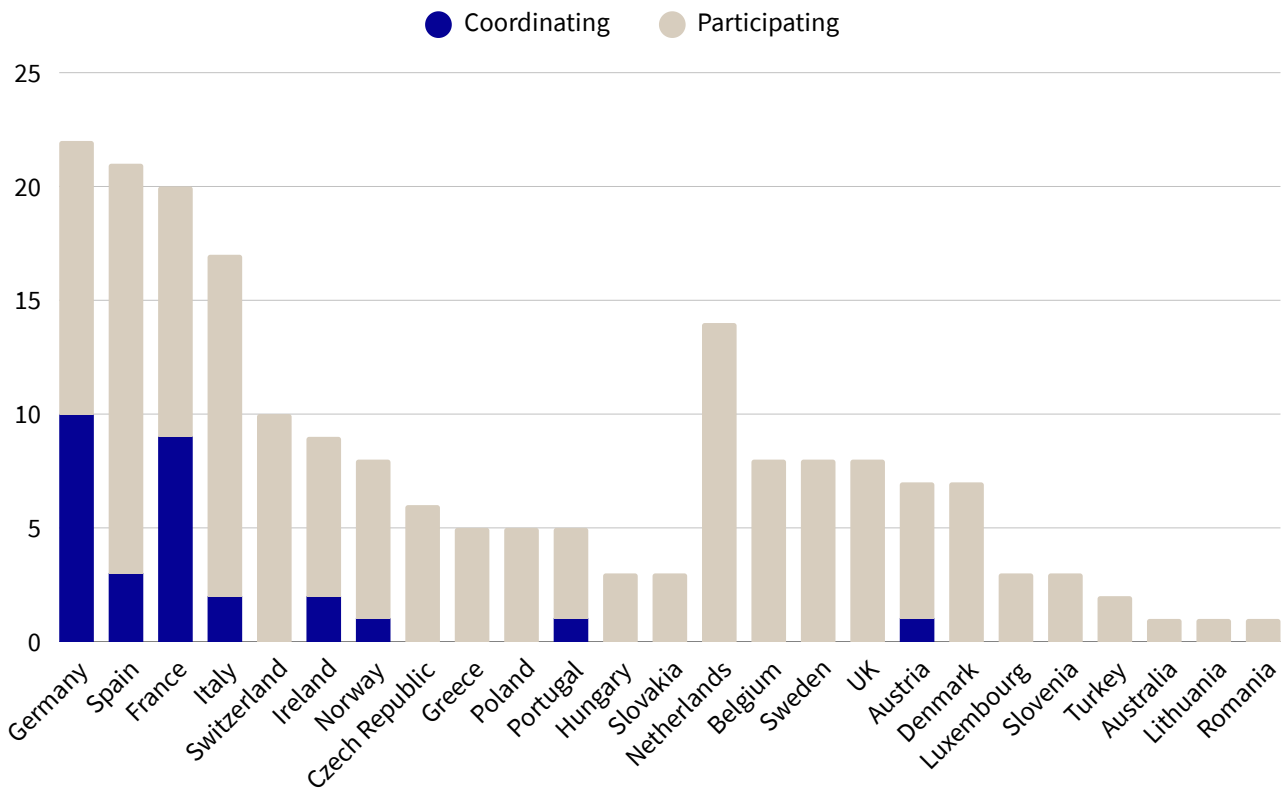


Figure 3. ECRIN's 2025 clinical trial portfolio showing both coordination and participation across countries

Feedback from ECRIN's 2025 proposal submission support survey

"ECRIN fills a real need in complex / multi-site academic clinical trials, where the sponsor is not looking for an industrial CRO, and has limited experience themselves of complex clinical trials."

"The expertise provided by ECRIN is invaluable. Even if I am located at a large university hospital, getting access to this expertise for a research project is not trivial."

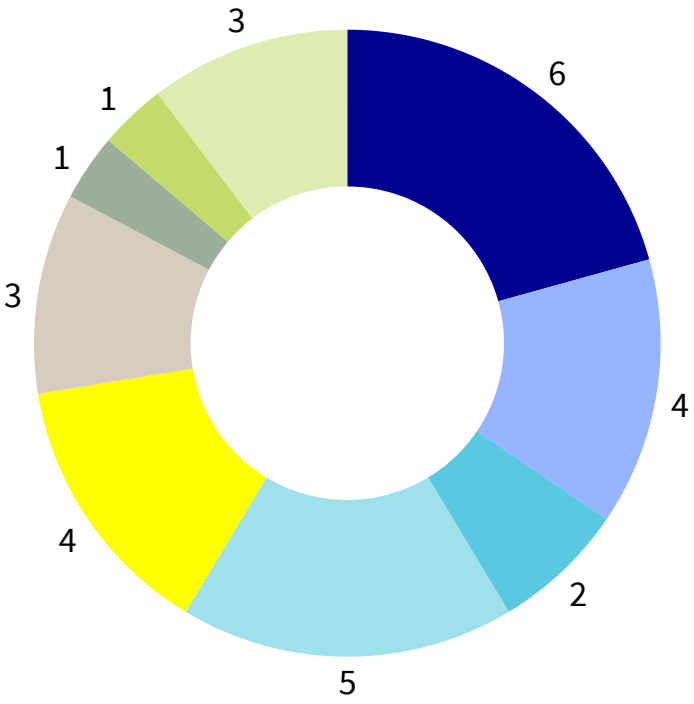


Figure 4.

2025 portfolio by disease area

- Cardiovascular
- Hepatology / gastroenterology
- Immune disorders
- Infectious diseases
- Neuroscience
- Oncology
- Ophthalmology
- Rheumatology
- Urology/nephrology

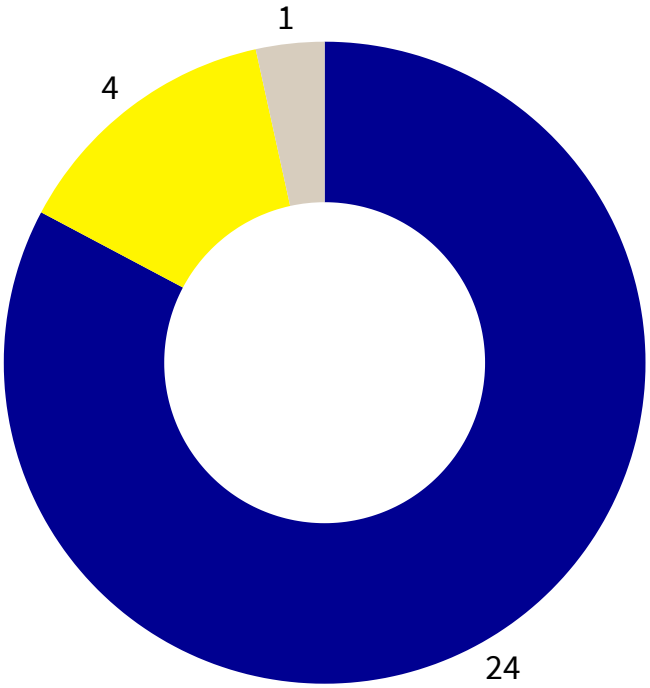


Figure 5.

2025 portfolio by population

- Adult
- Paediatric
- Both

Interview with a project coordinator

Dr Xavier Mariette
Head of Department, Paris-Saclay University & Bicêtre Hospital (AP-HP)
NECESSITY Project Coordinator

What is the aim of the NECESSITY Trial ?

I am the coordinator of a European project called NECESSITY and the goal is to set up new clinical outcome in a rare disease which is called Sjogren's disease. Sjogren's disease is an autoimmune disease which is very heterogeneous.

It is difficult to design a composite outcome for this disease and this is mandatory for running clinical trials. So the main aim of NECESSITY was to set up this composite outcome for running trials on the disease.

What is your relationship with ECRIN in this multinational clinical trial?

It is a rare disease so we have to involve different countries for working on these rare diseases. The first step was to set up these new clinical outcomes and once we have done that, it was mandatory to validate that. For validation, we needed a clinical trial, so this is the reason why we set up this new clinical trial across eight countries.

The other goal of running a clinical trial was to test a new type of treatment, which was a combination of classical immunosuppressive drugs, and to have enought power it was mandatory to design a multinational trial.

Why did you decide to build on a multinational clinical trial?

When you design a multinational trial as an academic entity, you need to have a sponsor and you need to have monitoring. As you know, it's more difficult than when a trial is sponsored by the pharma industry. So our institution, Assistance Publique Hôpitaux de Paris, was the sponsor of this trial, but we needed absolutely to have monitoring in the eight countries.

The structure of ECRIN is perfectly adapted for this task. So we decided to work with ECRIN for the monitoring of the clinical trial in the different countries.

What did you find easy and challenging in the realisation of the trial?

I must say a number of things were challenging. The first one was the role of the sponsor at the European level.

Academic sponsors are not used to running a clinical trial across Europe, and so we had a learning curve, but at the end of the day it went well. The second challenge was the collaboration with the sponsor, Assistance Publique Hôpitaux de Paris and ECRIN for the monitoring. So again there was a lot to learn but finally the relationship between both was very effective.

We had good leaders, both in APHP and in ECRIN, and so we could have a fluid process throughout the journey of the clinical trial. A final point was the relationships with different CROs in different countries because we have so many different CTUs, and ECRIN managed that very well. By coordinating the work of the different CTUs in those different countries.

So at the end of the day, it was not easy, but I think the process was very successful. And I think it's important in the future to be able to run clinical trials, notably international clinical trials with academic sponsors and academic monitoring.

What are the key outcomes of the trial and the next steps?

The last visit with the final patients ran just before Christmas. The database is now locked and we have just begun the statistic analysis. So we expect to have the first results of the statistic analysis around May 2026.

This analysis will have two objectives. The first one is to validate the new composite outcomes. And we have called this STAR (Sjogren's Tool for Assessing Response) to Treatments. So we will have the validation of STAR around then too.

And the second objective within the clinical trial is to have the results of the effect of the drugs that were tested.

As I said previously, we tested a combination of classical immunosuppressors, combination of hydroxychloroquine and leflunomide, and a combination of hydroxychloroquine and mycophenolate mofetil. If one of these combinations is successful, since these drugs are available in the market, they could be used very quickly on our patients with Sjogren's disease.

Do you have lessons learned to share with sponsors interested in working with ECRIN?

It is crucial to be able to run international clinical trials with an academic sponsor. It is the only way to be independent of the pharmaceutical industry, the only way to test therapeutic strategies and not only a new drug, to repurpose new drugs in new diseases. And for that, the academic sponsor needs to have help.

And a structure like ECRIN is very well adapted for helping the academic sponsors to run international studies by organising all the monitoring in different countries. So I think in the future, collaboration with ECRIN and academic sponsors will be crucial for developing new strategies in different domains of medicine.

View Xavier Mariette's interview

Supporting the community:

tools, services, and knowledge

Strengthening the clinical research community

Beyond the operational support to multinational trials, ECRIN accomplishes many additional activities to assist those conducting clinical studies in Europe. While some of these activities are covered by our Member contributions, many are also carried out in the framework of infrastructure development projects.

Infrastructure development projects *are structured activities designed to strengthen and expand the resources, tools, services, knowledge/expertise and training opportunities available to research stakeholders, ensuring they meet both current demands and future needs.*

Figure 6 highlights that through various activities, ECRIN works with partners and stakeholders across the clinical research ecosystem to build knowledge and expertise to bolster its main mission. Through collaborations with the research community, we gain a strong understanding of the existing elements and work to fill identified gaps. Moreover, ECRIN works with its fellow research infrastructure to build European capacity to respond to current and future needs.

Lastly, these projects help support open science, data sharing and reuse. The finality of which is often in the form of tools and services, training and education, as well as guidelines and recommendations that are made available to the larger community.

This year, we will focus on these outputs to showcase some of the key accomplishments of the organisation.

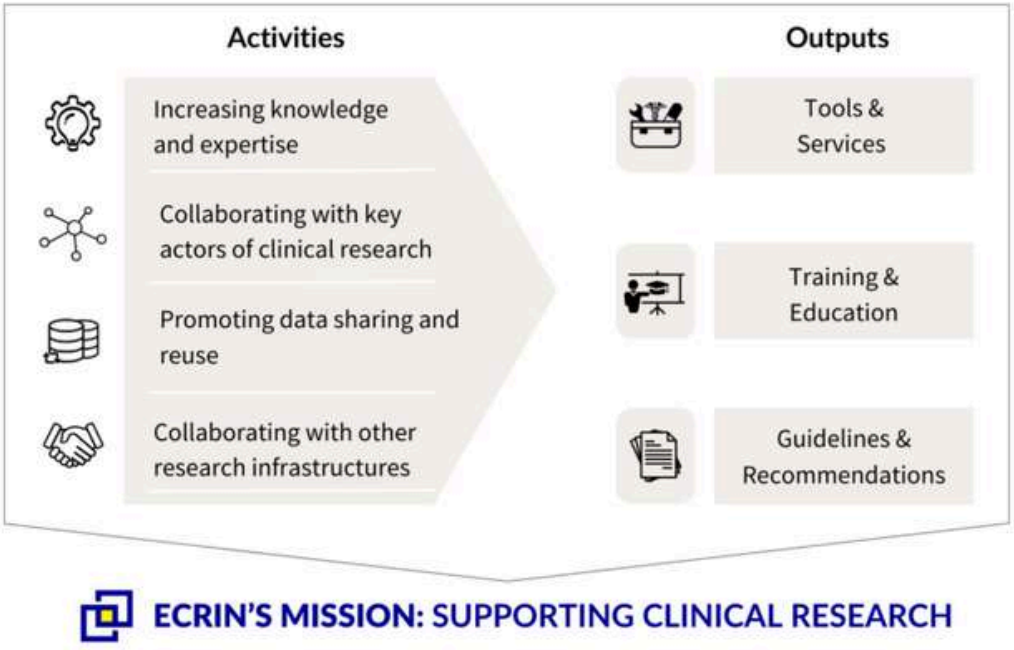


Figure 6 : ECRIN's infrastructure development project service and how it works to support clinical research

Tools and Services

Over the course of the past year, ECRIN has continued to create new tools, update existing ones and work on the creation of new services.

The MaP toolbox

ECRIN led the creation of a toolbox for conducting Master Protocol Trials – Basket, Umbrella, and Platform Trials within the canSERV project.

Master protocol clinical trials *are innovative study designs that allow multiple sub-studies to be conducted under a single overarching framework. They enable simultaneous investigation of multiple treatments or multiple conditions, providing faster, more flexible, and more efficient solutions for complex clinical research, particularly in areas such as oncology.*

The MaP Toolbox gathers a wide variety of tools (resources) to guide researchers at every stage of a master protocol trial, with resources organised into four main categories:

1. Planning and Design
2. Trial Conduct
3. Regulatory
4. Statistics and Data Management

It includes a wide range of contents and is designed for clinical researchers who wish to deepen their understanding of complex and innovative clinical trial methodologies. It may also serve as a valuable resource for sponsors, regulators, ethics committee members, and patients seeking clearer insights into these approaches.

The adaptive trials toolbox updated

With a narrower scope and different selection criteria from the MaP Toolbox, the Adaptive Platform Trial Toolbox was developed within a unique shared work package of EU RESPONSE, RECOVER (and later VACCELERATE and ECRAID PRIME). It operates as a practical and guided toolbox to facilitate planning and conduct of future adaptive platform trials in any therapeutic area. At the request of the EU-RESPONSE project, we have updated the toolbox with 80 recently published resources to better support complex clinical research and training purposes.

Interview on the QUANTUM project

Maria Alexandra Rujano
Project Manager

What is the aim of the QUANTUM project?

The QUANTUM project was designed to create and implement a standardised data quality and utility labelling mechanism for health datasets that can be widely used across the EU. This label serves two critical functions: first, it attests to the quality and utility of a dataset for secondary use (such as research, innovation, policy-making and healthcare improvements); and second, it assesses the maturity level of the data holder's internal quality management and assurance procedures.

Currently, researchers face significant challenges in determining if a dataset is fit-for-purpose before accessing it. QUANTUM addressed this challenge by providing a transparent, harmonised "badge" of trust.

What is ECRIN's role in the QUANTUM project?

ECRIN brings essential clinical research expertise to the project. Our role has been important in ensuring that the label is not just theoretically sound but practically applicable for real-world clinical trials and observational studies.

ECRIN has contributed to:
Specification of the Label: We helped define the specific quality dimensions and utility criteria that matter most to clinical researchers, ensuring the label captures the nuances of clinical data

Pilot testing and mid-scale implementation rounds: We participated in initial pilot tests to validate the label's methodology against real clinical datasets hosted in our meta(data) repositories, identifying gaps and refining the assessment metrics, and helping to validate the tool against real clinical data scenarios.

Guidelines and Recommendations: We contributed to drafting the practical guidelines and recommendations for data holders on how to use the tool and apply it to obtain the label, in alignment with future EHDS requirements and for researchers on how to interpret the label.

Our involvement ensures the labelling mechanism is not only technically sound but also fit for the realities of clinical research data reuse.

Where does QUANTUM fit in the context of the EHDS?

QUANTUM is strategically positioned with

respect to the EHDS. While the EHDS provides the legal and governance framework for data sharing, QUANTUM has provided a technical and operational mechanism to make that sharing trustworthy.

Specifically, QUANTUM addresses Article 78 of the EHDS regulation, which mandates that health data providers must label their datasets to indicate their quality and utility. Without a standardised label like the one QUANTUM has developed, the EHDS would lack a common language for data quality, making cross-border data exchange difficult and risky.

Moreover, QUANTUM has prepared the groundwork for the HealthData@EU portal that will host the catalogue of datasets made available for secondary use and is expected to include metadata indicating their quality and utility. The QUANTUM label is designed to serve as a standard metadata element attesting to this quality, allowing researchers to filter and select high-quality datasets more easily. Importantly, it also acts as a bridge to easier, more effective secondary health data use across borders and systems.

What can we expect from the outputs of QUANTUM?

QUANTUM has delivered a suite of outputs designed to support broad adoption and sustainability of the health data quality label.

Key outputs include:

- The Data Quality and Utility Label, which is standardised, machine-readable and that can clearly communicate a dataset's fitness for specific research purposes.
- The Maturity Model, a structured framework that allows data holders to self-assess and improve their internal data quality management processes, graded by maturity levels.
- Implementation Guidelines and Recommendations, which are practical, step-by-step documents for data holders on how to apply the label and for researchers on how to interpret it.
- A Community of Practice, Exchange Platform and capacity-building resources (templates, checklists, training materials) that will help accelerate adoption across Europe.

Collectively, these outputs go beyond research deliverables and serve as operational building blocks for the future EHDS infrastructure.

How can the data sharing community learn more about the application of these labels?

There were several pathways for the data sharing community to engage and learn from QUANTUM:

- The primary hub is the QUANTUM project website: quantumproject.eu
- Conferences, workshops, and public sessions were organised including a Patients and Citizens Forum
- QUANTUM produced training modules, case studies, and tools
- Zenodo community with project outputs

For data holders looking to adopt the label, the guidelines now published, provide a clear roadmap for the labelling process. Together, these avenues help ensure that data holders, HDABs, researchers and others can understand and apply the QUANTUM label, ultimately supporting informed, high-quality data sharing across Europe.

Focus on data services

The establishment of the European Health Data Space (EHDS) under Regulation (EU) 2025/327 this past year is an underlying driver for a plethora of new projects and initiatives. Projects are directly linked to both its development and implementation. ECRIN has a particular interest in how the EHDS will ensure the handling of sensitive health data.

The EHDS *is a flagship initiative of the European Union designed to create a secure, interoperable framework for sharing and using health data across Member States. It aims to empower individuals with greater control over their personal health data (such as accessing and transferring electronic health records across borders) while also enabling the secondary use of anonymised data for research, innovation, policymaking, and public health. By standardising data formats and governance rules, the EHDS seeks to improve healthcare delivery, support digital health services, and strengthen Europe's capacity for medical research and crisis response.*

With respect to the sharing of data, and the development of of the EHDS, the QUANTUM project aims to create a common label system for Europe that assesses and communicates the quality and utility of datasets in all countries for scientific and health innovation purposes. These labels will enable researchers, policymakers, and healthcare professionals to identify high-quality data for research and decision-making. ECRIN has contributed to QUANTUM notably in the piloting phase, wherein it participated in the testing of the data sets' quality and utility.

The CANDLE project, National CAncer data Node DeveLopErs, with its mission to build a robust cancer research infrastructure across EU Member States began in the second half of the year. CANDLE will play a strategic role in supporting the EHDS by establishing a federated network of national nodes in the cancer domain. These nodes will manage and share cancer data nationally and across borders, connecting different national actors. These nodes can be seen as demonstrators for national disease-specific implementation of the EHDS, aligning EU-wide health data policies with regional and national requirements. For this, ECRIN commenced its contribution to lead the effort to develop and share clear, practical guidelines for preparing and reusing cancer-related data.

As part of the EOSC-ENTRUST project, ECRIN, in collaboration with the University of Oslo, Health Data Research UK and the University of Dundee, hosted the workshop "Support of individual patient data meta-analyses through trusted research environments (TREs)" which focused on enabling secure, legally and ethically compliant cross-border re-use of clinical research data.

Over the course of the workshop, 42 participants explored opportunities and addressed challenges for improving meta-analysis of clinical trial data through faster, safer and more comprehensive data sharing within federated TREs.

Training and Education

ECRIN's current Strategy Plan 2024-2027 has a strong emphasis on the need to support training activities with different stakeholders. ECRIN is building its training infrastructure and resources, in particular as it relates to key aspects of multinational studies.

3

ECRIN hosted open access online courses

1

Training dedicated to our CTU network

11

Webinars for the clinical research community

3,783

Trainees

New Cohort of ECRIN EU-proposal training

After the success of the first edition, ECRIN decided to open a second edition of our Everything you need to know about submitting an EU multinational clinical study proposal training. The revised course structure included five weekly webinars where key experts from the field shared their experiences and key takeaways with the attendees.

The interest was immense, with over 500 registrants per training, and with over 250 attendees on average. The onsite sessions for this training will take place in some of ECRIN's national partner institutions in February of 2026.

Online course offer

Within the ERA4Health Partnership, ECRIN has developed an asynchronous interactive training course to familiarise investigators, personnel from clinical trial units and sites with the challenges of initiating and managing multinational studies. This course is solution-oriented to address the most common barriers in the European landscape.

Built with future applicants to the ERA4Health investigator-initiated clinical studies in mind,

it highlights some key aspects to consider when building the proposal to ensure the best possible outcome when the study is running.

"What I most appreciated in the training was the clarity of explanations and the practical examples that made complex aspects easier to understand"

– ERA4Health learner

In the second half of the year, a similar training, "Management of multi-national clinical trials for rare diseases" was launched by ECRIN within the ERDERA Partnership. The aim of the training is to help Europe's clinical research community run better, faster and more inclusive studies for people living with a rare condition. Designed around the needs of trials in rare diseases, the training tackles real-world bottlenecks that slow multinational trials and can limit patient access, strengthening trial readiness across Europe.

"The dynamic methods of teaching, including flash cards, questions and some videos, made it all so much easier to catch up with all the themes!!!"

- ERDERA learner

ECRIN has also contributed to training financed by the ECRAID Base project and available through ESCMID: Data and sample governance for biomedical research data. Composed of four discovery learning modules that include real-world scenarios, case studies, and interactive exercises to build understanding of data and sample governance frameworks, policies, and ethical and legal considerations.

Resources for post-graduates students and professionals

As highlighted in the focus on equity, diversity and inclusion early on in this report, the SENSITISE project has built a 12-week curriculum for postgraduate students to support the development of new learners in their capacity to think about key questions in clinical trial design, which ensures that all relevant people are included in a trial. The materials are also adapted to a workshop for those working in clinical trials who are looking to upskill. The piloting of these materials has begun. All materials are supported by teacher's guides and will be available in English, French, German and Czech.

Launched at the end of 2025 the GREEN-TRIALS project, will produce similar outputs to SENSITISE, but instead of focusing on inclusive design, it delves into ensuring a better understanding of the environmental impact of clinical trials. By focusing on how climate affects clinical trials and vice versa, and providing tools to address some of the issues, the project aims to generate resilient, environmental education and training for sustainable clinical trials.

Training for patients and trial participants

Within the REMEDi4ALL project, ECRIN co-hosted with Beacon for Rare Diseases, a 3-part webinar series to support those who are brought to participate in research. The aim was that they better understand the key components of a trial and have their questions answered. The series addressed topics including an introduction to clinical trials, clinical trials for rare diseases and the support and management of clinical trials.

Training for our CTU Community

ECRIN hosted its 5th CTU Day, an online event that brings together over 200 members of its CTU community. This year, the primary focus of the CTU Day was dedicated to giving CTUs a platform to discuss the implementation of ICH E6 R3. With representatives from three different ECRIN countries sharing their experiences and providing feedback on different areas from training for staff and investigators, to quality and a system validation policy for R (statistical software), to the concrete operational implementation and the necessary steps taken.

Staff training

To ensure that ECRIN and its staff are up to date on all the latest developments in clinical research, training is essential. While there are many roles requiring different skill sets across our team, both those in Paris and those in-country, it is essential that we all have some common ground to build on.

Every year, an ECRIN partner hosts a summer school to bring together the staff on topics important to all. In 2025, ECRIN colleagues from across Europe met in Košice, where we learned about the national infrastructure and their plans for the future.

The training then focused on the medical device regulatory framework, with case studies and a focus on quality by design. A full day was dedicated to project management skills. To close the meeting, we focused on AI tools for researchers and how to train AI models.

During our stay, we travelled to the High Tatras mountains and took a city tour of Košice.

ECRIN continues to offer scientific meetings to its staff, and now its CTUs on topics related to its activity among those covered in 2025 were: accessibility and accuracy of health information, a gene and cell therapy (ATMP) example; and non-pharmacological interventions, from research to practice.

To support our quality management system, continue to maintain our ISO 9001:2015 certification, and generally improve our process management, the process leads participated in a week-long training in Paris.

Additional trainings were made available in headquarters including training from our Gender Equality Plan on non-binary people, and a first aid training for the workplace.

Guidelines and Recommendations

ECRIN contributes to open consultations at the European level and develops guidelines and recommendations to support the different stakeholders it works with.

Planning and conducting clinical studies

Within ERA4Health ECRIN developed guidelines to support researchers in different aspects of their work.

The first guidelines developed in 2025 focus on data sharing. These guidelines are meant to promote and support data sharing and reuse among researchers, adequately inform trial participants and protect their rights and provide effective and efficient systems for preparing, storing and accessing data. By enforcing the implementation of these guidelines, funders of clinical trials contribute to the principle that publicly funded research data is a public good.

ECRIN then produced three additional recommendation booklets which aim to offer a comprehensive overview of the key aspects of new trial methodologies and to provide solutions to the main challenges in developing, implementing and conducting trials with new designs such as, master protocols with umbrella, basket, and adaptive platform design, trials within cohorts (or TwiCs) and decentralised clinical trials (DCTs).

Building recommendations for large medical cohorts

Within the INTEGRATE LMedC project, ECRIN contributed to the mapping European and selected international research infrastructures that support large medical cohorts. Partners compiled a comprehensive overview of available services, tools, and capacities spanning the entire research-data lifecycle, from study design and governance to long-term data use. In addition, partners highlighted six cross-cutting challenges that currently hinder service provision for large medical cohorts.

Interview on the EuCo role in projects

Joanna Batuca
Portuguese European Correspondent

How do EuCos collaborate on ECRIN capacity building projects?

The capacity building projects in which ECRIN collaborates are regularly presented to the entire ECRIN team during some of the operational meetings or monthly TCs. In these presentations, not only is the project introduced, but also how ECRIN will contribute to it. Although there is usually a project manager assigned to each project, there is always openness for team members to express their interest in contributing.

Depending on the project, different types of collaboration may be possible. For example, European Correspondents (EuCo) may share a survey within their national network, contribute to a national mapping exercise on a specific topic (e.g. EOSC-Life), test a tool being developed within the project, or contribute with examples of specific studies when ECRIN is responsible for organising a workshop, or even have a major contribution such as task leader.

Although each EuCo works in their respective country, we are all part of the ECRIN team and can therefore contribute to any project in which ECRIN is involved. I believe this also helps strengthen the team spirit and is one of the advantages of working within ECRIN: we are all part of ECRIN, whether we are based in Paris or in an ECRIN country.

How does this support your role as EuCo?

Participation in ECRIN capacity building projects reinforces the feeling that we are all part of the same team. It also helps us better understand different aspects related to investigator-initiated clinical studies by providing a broader perspective, not only on what happens in our own country, but also on the challenges and solutions identified in other countries.

Through these projects, we expand our knowledge on emerging topics such as innovative clinical trial designs, the secondary use of data, and personalised medicine. In some cases, EuCo can also contribute their own expertise.

Beyond being a personally enriching experience, because we collaborate with colleagues from different contexts, this participation helps me continuously learn and improve my role as a EuCo.

Ultimately, it strengthens the support we provide to investigators and academic sponsors. For example, we may be able to

share experiences from other countries, indicate how similar challenges have been addressed elsewhere, or point researchers to projects that have already explored a given topic and developed potential solutions or tools that could be applied in their context.

Can you describe your contributions to ERA4Health?

Within the ERA4Health partnership, ECRIN contributed to several activities related to innovative clinical trial methodologies. In particular, I was involved in a task aimed at identifying the main challenges associated with the implementation of new trial designs and proposing practical solutions.

As part of this work, we conducted five systematic literature reviews covering different innovative trial designs, including Trials within Cohorts, umbrella trials, basket trials, adaptive platform trials, and decentralised clinical trials. The goal was to analyse the challenges reported in the literature across the different stages of the trial lifecycle and identify potential solutions or mitigation strategies proposed in the literature.

The findings were first compiled in a detailed project deliverable, which is publicly accessible. However, since this document is quite extensive, the results were later transposed into a set of practical and user-friendly booklets. These booklets provide recommendations for planning and conducting clinical trials using these innovative designs, highlighting key considerations such as regulatory and ethical aspects, protocol design, sponsorship and governance, trial management, public and patient involvement , data management, and dissemination of results.

What makes these different study methodologies more complicated for researchers?

New trial methodologies, such as adaptive platform trials, basket and umbrella trials, Trials within Cohorts, and decentralised clinical trials, were developed to address the limitations of randomised control trials. They allow more flexibility, enable the evaluation of multiple interventions, and can be more patient-centred. However, this flexibility also brings additional complexity. These designs often require new regulatory and ethical approaches, more advanced statistical methods, and stronger coordination between multiple stakeholders.

These booklets were designed for a broad range of stakeholders in clinical research.

Are these study methodologies appropriate for multinational trials?

Yes, some of these methodologies have already been applied successfully in multinational trials, particularly in the context of COVID-19, where adaptive platform trials and decentralised trials were implemented across multiple countries. However, not all designs are suitable for every research question. The choice of methodology should always be guided by the scientific question, the target population, logistics, and overall trial objectives.

View Joana Batuca's interview

Key players and financial report

ECRIN Team

Core Team	
Marta Bastucci	Executive Assistant
Sergio Contrino	Head of Data Projects
Léopold 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
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

European Correspondents	
Kateřina Nebeská	Czech Republic
Lenka Součková	Czech Republic
Hana Blahynková	Czech Republic
Jimena Bouzas	France
Véronique Chaigneau	France
Sarhan Yaïche	France
Neshat Chareh	Germany
Lea-Jean Pietzke	Germany
Thomas Chatzikonstantinou	Greece
Annamária Németh	Hungary
Regina Gyuge	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
Christina Huf	Switzerland

** Note: the staff lists include individuals who started working for ECRIN in 2025, as well as those who left the organisation*

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.

In 2025, Rafael de Andrès did not represent himself for the role of Chair and a new Chair, Oonagh Ward, and Vice-Chair were elected. They will take on these new roles on February 1, 2026.

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
Sissy Kolyva	Greece
Judit Tarnai	Hungary
Milan Auer	Hungary
Luisa Minghetti	Italy
Øyvind Melien	Norway
Elzbieta Bylina	Poland
Marta Abrantes	Portugal
Daniel Pella	Slovakia (outgoing)
Jan Kociske	Slovakia (incoming)
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. The Chair and Vice Chair work with their counterparts in the AoM and the Director General to form the Steering Committee.

After staying on an additional year as Co-Chair following his last mandate as Chair, Christian Ohmann stepped down from the Network Committee. He has held this role since ECRIN attained its ERIC status. A solid succession is ensured in the hands of Regina Demlova and Britta Lang.

Christian Ohmann	Outgoing Co-Chair (Germany)
Regina Demlová	Chair (Czech Republic)
Britta Lang	Incoming Vice Chair (Germany)
Christine Trillou	France
Olivier Rascol	France
Kostas Stamatopoulos	Greece
Judit Tarnai	Hungary
Mila Auer	Hungary
Robert O'Connor	Ireland (outgoing)
Joanne Walsh-Crowley	Ireland (incoming)
Elena Toschi	Italy
Camilla Tondel	Norway
Agnieszka Tycinka	Poland
João Sargento de Freitas	Portugal
Daniel Pella	Slovakia
Beata Cecetkova	Slovakia
Alberto Borobia	Spain
Tatiana Terrot	Switzerland
Victoria Sarraf	Switzerland (new)

Governance Meetings in 2025

Assembly of Members (AoM)
27 January 2025
19 May 2025
28 November 2025
16 December 2025
Network Committee (NC)
19 May 2025
27 November 2025

Scientific Board

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

SB - Collaboration Committee

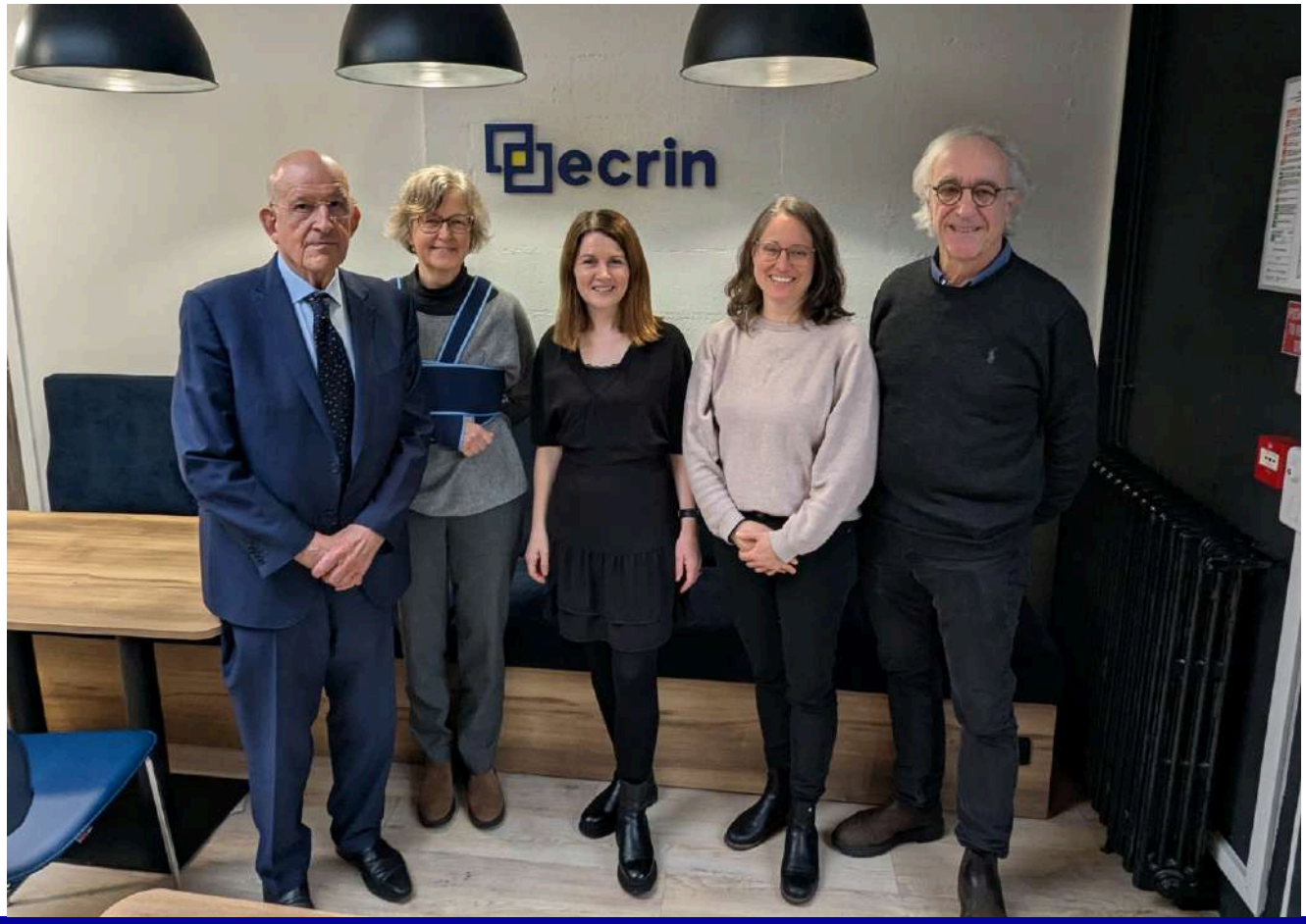
The Collaboration Committee of the ECRIN Scientific Board meets weekly to evaluate proposals for collaboration in a timely manner

Véronique Chaigneau	Chair (Jan-Jun)
Amélie Michon	Chair (Jul-Dec)
Jacques Demotes	Member
Christine Kubiak	Member
Keiko Ueda	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. No requests arose in 2025.

José Delgado Alves	Chair (Portugal)
Cristina Avendaño-Sola	Spain
Declan Devane	Ireland
Raphaël Porcher	France
Joaquin Saez-Penataro	Spain
Keiko	Ueda (Secretariat)



Financial report 2025

Income

Membership Core contributions	€ 1 642 002
Membership Local contributions	€ 1 247 283
Research projects	€ 1 985 319
Other income	€ 4 091
Financial income	€ 111 596
TOTAL INCOME FOR 2025	**€ 4 990 264**

Expenditures

Salaries & staff expenses	€ 2 185 873
Subcontracting	€ 772 800
Office and insurance	€ 47 598
Travel and meetings	€ 143 678
Information System	€ 75 561
Communication	€ 18 481
Amortization	€ 137 979
Other expenses	€ 189 904
Financial expenses	€ 68 387
Income taxes	€ 26 368
Local contribution provided in-kind	€ 1 132 793
TOTAL EXPENDITURE FOR 2025	**€ 4 799 422**

Net result for 2025

€ 190 842

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
AEI: Spanish State Research Agency
AI: Artificial Intelligence
A_IATRIS: Italian node of EATRIS
AoM: Assembly of Members
AMRI: Alliance of Medical Research Infrastructures
APHP: Assistance Publique Hopitaux de Paris
ATMP: Advanced Therapy Medicinal Product

B

BBMRI: Biobanking and Biomolecular Resources Research Infrastructure
BIOTOOL-CHF: BIOmarker based diagnostic

C

c4c: conect4children
CANDLE: National CAncer data Node DeveLopErs
CEIC: Portuguese national ethics authority
CERTH: The Centre for Research & Technology, Hellas
CHI-CRC: Children's Health Ireland Clinical Research Centre
CLEIO: Centres Labellisés d'Expertise en thérapies InnOvantes
COMBINE: programme for clinical trials and medical devices
CoMeCT: Coordination Mechanism for Cohorts and Trials
CONDOR: Chronic Obstructive Pulmonary Disease
COVID: Coronavirus Disease
CREATIC: Central European Advanced Therapy and Immunotherapy Centre
CRA: Clinical Research Associate
CRFs/CRCs: Clinical research facilities/Clinical research centres
CRF-G: Clinical research facility Galway
CRF-SJH: Clinical Research Facility St James's Hospital
CRO: Contract Research Organisation
CTA: Clinical Trial Application
CTCG: Clinical Trials Coordination Group
CTIS: Clinical Trial Information System
CTO: Clinical Trial Organisation
CTR: Clinical Trial Regulation
CTU: Clinical Trial Unit
CZECRIN: Czech Clinical Research Infrastructure Network

D

DCT: Decentralised Clinical Trial

E

EATRIS: European Advanced Translational Research Infrastructure in Medicine
EC: European Commission
ECRAID-Base: European Clinical Research Alliance for Infectious Diseases Base
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
EHDS: European Health Data Space
EMA: European Medicines Agency
EOSC4Cancer: A European-wide foundation to accelerate data-driven cancer research
EOSC ENTRUST: A European Network of TRUSTed research environments
ERA4Health: European Research Area for Health Research
ERDERA: European Rare Diseases Research Alliance

ERIC: European Research Infrastructure Consortium
EU: European Union
EuCo: European Correspondent
EUPATI: European Patients' Academy
EU-RESPONSE: European Research and Preparedness Network for Pandemic and Emerging Infectious Diseases
EU SYNDACT1: European Syndromic Adaptive Clinical Trial-1 (EU-SYNDACT-1): a Phase II randomized controlled, adaptive platform trial on antiviral treatments for viral respiratory infections in hospitalized patients
EU-X-CT: Cross-Border Access to Clinical Trials

F

FAMIREA: Supporting relatives of intensive care patients
F-CRIN: French Clinical Research Infrastructure Network
F-MOM: Preventing severe pregnancy complications and improving the care of pregnant women
FP: Framework Programme

G

GA: Grant Agreement
GCP: Good Clinical Practice
GCTF: Global Clinical Trials Forum
GenZ: Revolutionizing Clinical Trials to Optimize Assessment of Healthcare Innovations
GMP: Good Manufacturing Practices
GRACE: Research in cardiac amyloidosis
GreCRIN: Greek Clinical Research Infrastructure Network
GREEN-TRIALS: Generating Resilient, Environmental Education and Training for Sustainable Clinical Trials

H

H2020: Horizon 2020
HECRIN: Hungarian Clinical Research Infrastructure Network
HRB: Health Research Board
HRI-CRSU: Health Research Institute Clinical Research Support Unit

I

IBIMA: Biomedical Research Institute of Málaga and Nanomedicine Platform
ICTD: International Clinical Trials Day
ICH: International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IdiPAZ: Health Research Institute of La Paz University Hospital
IHI: Innovative Health Initiative
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
INSERM: French National Institute of Health & Medical Research
ISCIII: National Institute for Health Carlos III
ISIDORe: 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

K

KKSN: Netzwerk der Koordinierungszentren für Klinische Studien
KKS: Koordinierungszentren für Klinische Studien
KPI: Key Performance Indicator

L

LIVERATION: Unravelling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?

M

MaP: Master Protocol
MICRYN: Maternal Infant Child and Youth Research Network
MKVT: Congress of the Hungarian Clinical Trial Management Society
MRA: (Polish) Medical Research Agency
Myco-NET: Treatment and prevention of non-tuberculous mycobacterial infections

N

NC: Network Committee
NECESSITY: NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifYing patients
NHS: National Health Service
NorCRIN: Norwegian Clinical Research Infrastructure

O

OKFO: National Directorate General for Hospitals (Hungary)

P

PALETTE: Adaptive Platform Trial for Personnalisation of Sepsis Treatment in Children and Adults: a Multi-national, Treatable Traits-guided, Adaptive, Exploratory, Bayesian Basket Trial
PCTN: Polish Clinical Trials Network
PEARLDIVER: CAtheter-Based Ablation of atrial fibrillation compared to conventional treatment in patients with Heart Failure with Preserved Ejection Fraction)
PI: Principal investigator
Precode: Prevent Cognitive Decline
Proact EU RESPONSE: A European Proactive Adaptive Clinical Trials Network within EU-Responses
PtCRIN: Portuguese Clinical Research Infrastructure Network

Q

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

R

RCSI CRC: Royal College of Surgeons Clinical Research Centre
READI: Research in Europe and Diversity Inclusion
RECLIP: Spanish paediatric clinical trials network
RECOVER: Rapid European COVID-19 Emergency research Response
REMEDi4ALL: Building a sustainable European innovation platform to enhance the repurposing of medicines for all
RENARCI: REseau NAtional de Recherche Clinique en Infectiologie
RKP: Reciprocal Knowledge Programme
RNIE: Portuguese Roadmap of Research Infrastructures
RoR: Research on Research

S

SAWP: Scientific Advice Working Party
SB: Scientific Board
SB-CC: Scientific Board Collaboration Committee
SCReN: Spanish Clinical Research Network
SCRS: Society for Clinical Research Sites
SCTO: Swiss Clinical Trial Organisation
SENSITISE: Inclusive clinical trials: training and education
SERI: Secretariat for Education, Research and Innovation
SLOVACRIN: Slovak Clinical Research Infrastructure Network
SME: Small and Medium-sized Enterprise
SNSF: Swiss National Science Foundation
SOP: Standard Operating Procedure
STAR: Sjogren's Tool for Assessing Response
SUKL: Ministry of Health (Czech Republic)

T

TRE: Trusted Research Environement
TWiC: Trials Within Cohorts

U

UCC: University College Cork
UCD CRC: University College Dublic Clinical Research Centre
UK: United Kingdom
ULS: Unidade Local de Saude
US: United States

V

VACCELERATE: European Corona Vaccine Trial Accelerator Platform

W

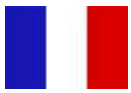
WG: Working Groups
WHA: World Health Assembly
WHO: World Health Organization

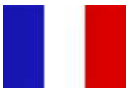
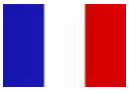
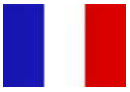
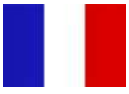
Z

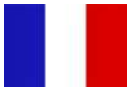
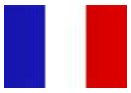
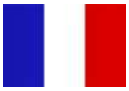
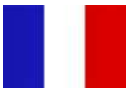
ZKS: Clinical Trials Unit

Annex 2: Clinical Study Portfolio in 2025 (current studies)

Throughout 2025, ECRIN provided support to 29 studies. At the end of the year, 4 were in the set-up phase working towards the opening of all sites in all the participating countries,13 were active, meaning in the phase of recruitment (running), or completion mode (running), 11 were completed and 1 was withdrawn. 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
BIOTOOL CHF	BIOmarker based diagnostic TOOLkit to personalize pharmacological approaches in congestive heart failure	Start up phase		101095653*
EPILOGUE	Phase I/II combination umbrella trial in relapsed pediatric low-grade glioma (pLGG)	Start up phase		Charity & Industry
EU-SYNDACT1	European Syndromic Adaptive Clinical Trial-1 (EU-SYNDACT-1): a Phase II randomized controlled, adaptive platform trial on antiviral treatments for viral respiratory infections in hospitalized patients	Start up phase		101156304*
PEARLDIVER	CAtheter-Based Ablation of atrial fibrillation compared to conventional treatment in patients with Heart Failure with Preserved Ejection Fraction)	Start up phase		303746/Z/23/Z Wellcome Trust
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.	Running		Italian intitution & industry
CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	Running		German government
ETAPA	Randomised Placebo-Controlled Trial of Early Targeted Treatment of Patent Ductus Arteriosus with Paracetamol in Extremely Low Birth Weight Infants	Running		Irish government
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°
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

LEOPARD	Liver Electronic Offering Platform with Artificial intelligence-based Devices	Running		101080964*
LIVERATION	Unravelling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?	Running		101104360*
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°
ORTHO-ALLO-UNION	ORTHOpaedic treatment with ALLOgenic combined ATMP in long bone fracture delayed UNION and non-union	Running		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	Running		Charity
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°
CABA-HFPEF	CAtheter-Based Ablation of atrial fibrillation compared to conventional treatment in patients with Heart Failure with Preserved Ejection Fraction)	Withdrawn		German & International organisation
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults	Completed		101015736°
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	Completed		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	Completed		101037867°

EU-TRAIN RCT (IMPACT)	Randomized Controlled Multicenter Trial to quantify the benefits of biomarkers in routine patient care in kidney transplant recipients	Completed		754995°
EU-TRAIN COHORT	Prospective cohort of kidney transplant patients	Completed		754995°
ImmunAID	Immunome project consortium for AutoInflammatory Disorders	Completed		779295°
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	Completed		731875°
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	Completed		681094°
SOLIDACT	European DisCoVeRy for Solidarity: An Adaptive Pandemic and Emerging Infection Platform Trial.	Completed		101015736°
TENSION	Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window	Completed		754640°
TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen Study type	Completed		IMI 777389°

° 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 2025

Throughout 2025, 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
CANDLE	National CAncer data Node DeveLopErs	Running		101214368*
canSERV	Providing Cutting Edge Cancer Research Services Across Europe	Running		101058620*
CoMeCT	Coordination Mechanism for Cohorts and Trials	Running		101136531*
c4c	conect4children	Ended		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*
EOSC4Cancer	A European-wide foundation to accelerate data-driven cancer research	Ended		101058427*
EOSC-ENTRUST	A European Network of TRUSTed research environments	Running		101131056*
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	Ended		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°
GREEN-TRIALS	Generating Resilient, Environmental Education and Training for Sustainable Clinical Trials	Running		2025-1-CZ01-KA220-HED-000355652**
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	Integrated Services for Infectious Disease Outbreak Research	Ended		101046133*
QUANTUM	Quality, Utility and Maturity Measured; Developing a Data Quality and Utility Label for HealthData@EU	Running		101137057*
READI	Research in Europe and Diversity Inclusion	Running		101166227°°
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**
SHARE-CTD	Sharing and Re-using clinical trial data to maximise impact	Running		2022-DN 101120360△
TESA III	Trials of Excellence in Southern Africa III	Running		EDCTP - GA 2020NoE-3104TESAIII
VACCELERATE	European Corona Vaccine Trial Accelerator Platform	Ended		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.

°° The project received funding by the Innovative Health Initiative Joint Undertaking (IHI JU) under the listed grant agreement. The JU receives support from the European Union's Horizon Europe research and innovation programme and other sources specific to the grant listed.

△The project received funding from the European Union's Marie Skłodowska-Curie Actions funding programme under the listed grant agreement.

Annex 4: 2025 Publications

Batuca J, del Alamo M, Buoncervello M, Hjelle SM, Hore N, Nebeska K, Ruiz Alvarez MJ, Sonderlichová S, Součková L, Toschi E, & Ueda K. (2025). Recommendations for planning and conducting clinical trials with master protocol designs: Umbrella, Basket and Platform Trials. https://zenodo.org/records/16086604	ERA4Health
Batuca J, del Alamo M, Lémeret S, & Monteiro EC. (2025a). Recommendations for planning and conducting decentralised clinical trials. https://zenodo.org/records/16096569	ERA4Health
Batuca J, del Alamo M, Lémeret S, & Monteiro EC. (2025b). Recommendations for planning and conducting Trials within Cohorts (TwiCs). https://zenodo.org/records/16094892	ERA4Health
David R, Liaskos N, Rybina A, Arvanitidis C, Bage AS, Carvajal-Vallejos PK, Das S, De Pascalis F, Dörr D, Exter K, Holub P, Gurwitz KT, Liberante F, Lieutaud P, Lister A, Lopez J, Madon B, Massimi M, Matteoni R, … Ewbank, J. (2025). Life Science Competence Centres: Open by Design. Zenodo. https://doi.org/10.5281/zenodo.17672046	ISIDORE
Declerck J, Lee J, Sen A, Palmeri A, Oostenbrink R, Giannuzzi V, Woodworth S, Malik S, Mahler F, Aurich B, Leary R, Kalra D, & Straub V. (2025). The Potential to Leverage Real-World Data for Pediatric Clinical Trials: A Proof-of-Concept Study. Journal of Medical Internet Research, 27(1), e72573. https://doi.org/10.2196/72573	c4c
del ÁlamoM, Zafirova B, Esdaile M, Karam S, Klager S, Kubiak C. Rare diseases clinical trials toolbox - public resources and main considerations to set up a clinical trial on medicinal products for humans in Europe. Rare Dis Orphan Drugs J. 2025;4:8. http://dx.doi.org/10.20517/rdodj.2024.49	
DISCHARGE Trial Group; Rieckmann N, Neumann K, Maurovich-Horvat P, Kofoed KF, Benedek T, Bosserdt M, Donnelly P, Rodriguez-Palomares J, Erglis A, Štechovský C, Šakalyte G, Adic NC, Gutberlet M, Diez I, Davis G, Zimmermann E, Kepka C, Vidakovic R, Francone M, Ilnicka-Suckiel M, Plank F, Knuuti J, Faria R, Schröder S, Berry C, Saba L, Ruzsics B, Kubiak C, Hansen KS, Müller-Nordhorn J, Merkely B, Knudsen AD, Benedek I, Orr C, Valente FX, Zvaigzne L, Suchánek V, Zajanckauskiene L, Adic F, Woinke M, Waters D, Lecumberri I, Thwaite E, Laule M, Kruk M, Neskovic AN, Birtolo LI, Kusmierz D, Feuchtner G, Pietilä M, Ribeiro VG, Drosch T, Delles C, Matta G, Fisher M, Szilveszter B, Larsen L, Ratiu M, Kelly S, Garcia Del Blanco B, Drobni ZD, Jurlander B, Regan S, Calabria HC, Boussoussou M, Engstrøm T, Hodas R, Napp AE, Haase R, Feger S, Mohamed MMA, Dreger H, Rief M, Wieske V, Estrella M, Michallek F, Mark DB, Martus P, Dodd JD, Sox HC, Serna-Higuita LM, Dewey M. Health Status Outcomes After Computed Tomography or Invasive Coronary Angiography for Stable Chest Pain: A Prespecified Secondary Analysis of the DISCHARGE Randomized Clinical Trial. JAMA Cardiol. 2025 Jul 1;10(7):728-739. doi: 10.1001/jamacardio.2025.0992. PMID: 40366703; PMCID: PMC12079563.	DISCHARGE

Ficany A, del Alamo M, Bernabeu C, Shovlin CL, & Rossi E. (2025). Epistaxis Prevention, Treatment, and Future Perspectives for Hereditary Hemorrhagic Telangiectasia. Journal of Clinical Medicine, 14(21), 7724. https://doi.org/10.3390/jcm14217724	EJP-RD
Hugova K, Mares J, Hakanson B, Repici A, von Rahden BHA, Bredenoord AJ, Bisschops R, Messmann H, Ruppenthal T, Mann O, Izbicki J, Harustiak T, Fumagalli Romario U, Rosati R, Germer CT, Schijven M, Emmermann A, von Renteln D, Dautel S, Fockens P, Boeckxstaens G, Rösch T, Martinek J, Werner YB. Per-oral endoscopic myotomy versus laparoscopic Heller's myotomy plus Dor fundoplication in patients with idiopathic achalasia: 5-year follow-up of a multicentre, randomised, open-label, non-inferiority trial. Lancet Gastroenterol Hepatol. 2025 May;10(5):431-441. doi: 10.1016/S2468-1253(25)00012-3. Epub 2025 Mar 17. Erratum in: Lancet Gastroenterol Hepatol. 2026 Feb;11(2):e1. doi: 10.1016/S2468-1253(25)00378-4. PMID: 40112837. (poem vs lvm)	POEM VS LHM
Luque Villalobos E, Ielpo B, Aldrighetti L, Anselmo A, Beghdadi N, Berardi G, Briceño F, Ciria R, Dorcaratto D, Durczynski A, Ettorre GM, Delvecchio A, Ferri V, Grąt M, Garces-Albir M, Grochola LF, Hogendorf P, Izzo F, Kobryn K, … Sánchez Velázquez, P (2025). LIVERATION trial: A multicentre European randomised study on radiofrequency margin coagulation and its impact on oncological outcomes after liver surgery - study protocol. BMJ Open, 15(11), e100518. https://doi.org/10.1136/bmjopen-2025-100518	LIVERATION
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CONTACT

ECRIN office: **30 Boulevard Saint Jacques, 75014 Paris, France**

For further information about ECRIN: **contact@ecrin.org**
or to contact your local European Correspondent: **www.ecrin.org/ecrin-staff**

Internet: **www.ecrin.org**
LinkedIN: **@ecrin**
YouTube: **@ecrin-clinicalresearchinfra**