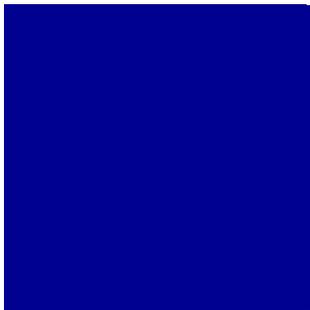
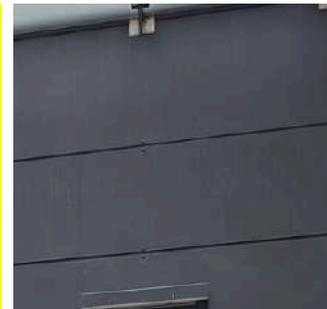
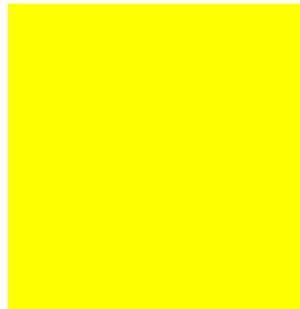
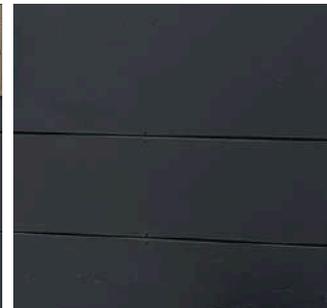




**Supporting clinical
studies across
borders**



Explore More



ANNUAL REPORT 2023



Czech Republic
Masaryk University
Brno



Hungary
Hungarian National Health
Research Agency
Budapest



Portugal
NOVA University
Lisbon



France
INSERM
Toulouse



Ireland
National Clinical Trials Office
Cork



Slovakia
Pavol Jozef Šafárik University
Košice



Italy
Istituto Superiore di Sanita
Rome



Spain
Instituto de Investigación del
Hospital Universitario La Paz
Madrid



Germany
KKS-Netzwerk e. V.
Berlin



Norway
Haukeland University Hospital
Bergen



Greece
CERTH
Thessaloniki



Poland
Polish Medical Research Agency
Warsaw



Switzerland
SCTO
Bern

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Foreword Management Team

Many milestones marked the year 2023 across the organisation. The credit for these achievements goes to our staff across Europe. We had the pleasure of uniting past and present collaborators in Paris in November to celebrate the 10-year anniversary of our ERIC status. Moreover, confirming our role even further as a European research infrastructure of reference, the organisation underwent a successful monitoring by ESFRI over the summer.

Among the big changes this past year, was the move to our new office space in June. The new

location provides the core team with a dedicated space for supporting ECRIN activities and also the capacity to invite our European Correspondents to join us for our annual meetings.

2023 brought two new Member countries to the ECRIN community: Greece, joining ECRIN and Switzerland transitioning from Observer to Member status.

In terms of operations, ECRIN confirmed its ISO 9001:2015 certification for its principal services. We saw a huge peak in activity, with a record number of requests to collaborate on proposals for clinical research projects and five new clinical studies added to our portfolio (two coordinated by France, two by Germany and one by Italy). To support our service on data centre certification an



Jacques Demotes (Director General), **Marta Del Alamo** (Head of Capacity Projects), **Sergio Contrino** (Head of Data Projects), **Amélie Michon** (Head of Clinical Operations), **Christine Kubiak** (Operations Director), **Alicja Szofer Araya** (Head of Finance and Administration)

upgrade of the ECRIN data standards was carried out and version 5.0 of the ECRIN Data Standards was published in June.

ECRIN CTU day, hosted online for the third time, and open to all of our 130 partner CTUs was an opportunity to get to know one another and share some training on key topics in clinical research.

ECRIN also worked with its national partners this year to develop new training activities, with a dedicated series open to investigators and project managers in ECRIN countries focussing on European clinical study proposal development. This training series united over 1300 participants across the six webinar sessions as well as hosting in depth workshops for a selection of candidates in four different ECRIN countries.

ECRIN was very active in many European projects including ERA4Health, where it hosted a two-day workshop in Paris uniting the consortium and concerned parties to discuss challenges in planning and designing investigator-initiated clinical studies. As part of the HealthyCloud project, ECRIN had the opportunity to present the Strategic Agenda for the Health Research and Innovation Cloud (HRIC). Similarly, at the end of the EOSC-Life project, ECRIN contributed to the recommendations for implementation of FAIR principles in life science data handling.

Together with our Polish partner, PCTN, ECRIN organised a successful International Clinical Trials Day which addressed questions on this year's theme “Decentralised Clinical Trials”. The event brought together diverse stakeholders from Europe and beyond both in Warsaw and online.

In 2023 ECRIN also strengthened its engagement with external stakeholders through participation in several European initiatives. For example, ECRIN is increasingly involved in ACT-EU, representing the academic clinical trial community in the Multi-stakeholder platform Advisory Board and several working groups.

As we look back on the year it is clear that ECRIN continues to make its mark on the challenging and changing landscape of European clinical studies both directly by supporting investigators and sponsors in the setup and implementation of their clinical studies but also in advocating for investigator-initiated clinical studies and in developing tools and training to facilitate this and other activities for the clinical research community. This is reflected in the 2024-2027 Strategic Plan developed throughout 2023 with the involvement of our stakeholders. It will pave the way forward in this next decade of activity where ECRIN will continue to sustain, innovate and empower our community.

Foreword Assembly of Members



Raphael DeAndres
(chair)



Oonagh Ward
(vice-chair)

In 2023 ECRIN achieved its ERIC status 10 year anniversary and on behalf of the entire Assembly of Members, we give thanks to those who worked in the preparatory phase from the initial idea and congratulate the current and past staff who worked to move it from the paper, with 5 founding countries, to a well-established European infrastructure with 13 countries, adding value to the academic clinical research pipeline.

It is with great satisfaction that we reflect on a very successful year for ECRIN, in which it demonstrated its capacity to adapt to the evolving needs of the clinical research community and the European research infrastructure landscape.

In a changing research landscape with new research infrastructures on the map, ECRIN proved its added value through its involvement in multinational academic clinical trials and infrastructure development projects in Europe and beyond.

Furthermore, we are thrilled to see that ECRIN has proven its ability to secure and reinforce the European network for clinical research, by welcoming Greece as a new Member country and by consolidating the long-term relationship with Switzerland that upgraded from an Observer to a Member country.



The Assembly of Members appreciated the recognition for all existing and new countries through a communication campaign on the ECRIN national partners and their CTU networks.

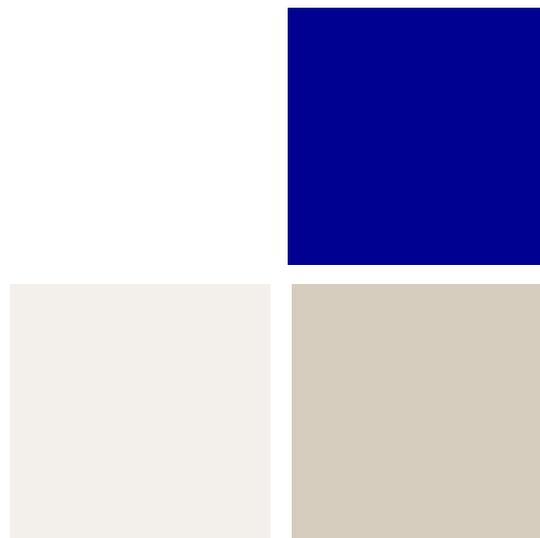
This year was also marked by the migration to a new headquarter office and the approval of significant changes to the ECRIN statutes and internal rules of procedures, for simplification and clarity, by changing the way countries participate in ECRIN activities leading to a better, and more congruous way forward for all members and their national partners.

The Assembly of Members were interested in the results of the monitoring of ECRIN by ESFRI and

acknowledged the level of maturity of the organisation and the suggestions for improvement and recommendations provided by the experts from the monitoring panel.

The Assembly of Members sincerely thanks Maria Ferrantini (its vice chair from 2015 to 2023) for all her work, devotion and contribution over the last 8 five years.

The year 2023 has shown a reinforced ECRIN on every front of European academic clinical research and the next strategic plan is in line with the ambition of ECRIN to strengthen its position at European level with its national partners.



ECRIN in Numbers



10

years that ECRIN has had ERIC Status



13

Member & Observer countries



361

million citizens living in ECRIN countries



34

studies supported by ECRIN in 2023



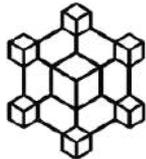
6.5

countries per ECRIN supported study



130

clinical trial units



28

infrastructure projects supported in 2023



8

new infrastructure development projects in 2023



4418

LinkedIn followers



1742

Twitter followers



98

YouTube subscribers

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 Strategic Goals

- 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



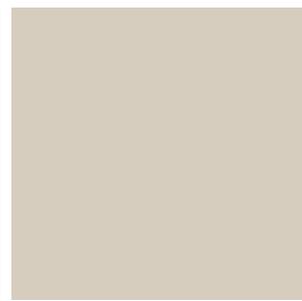
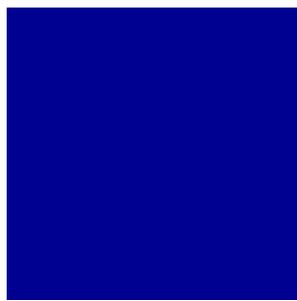
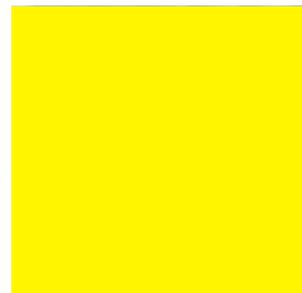
ECRIN Overview

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 clinical trial units (CTUs) across Europe, through its scientific partners, to fulfil its vision of generating scientific evidence to optimise medical practice.

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

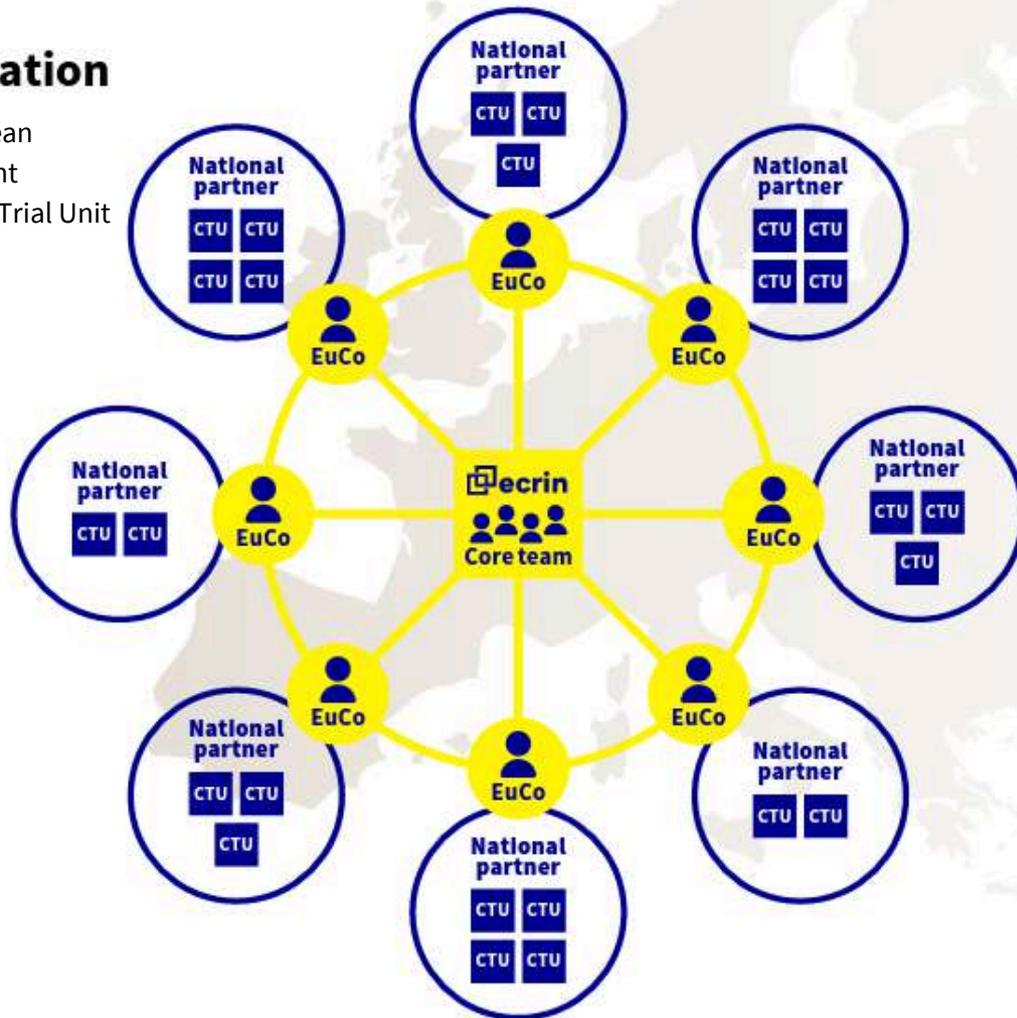
By supporting clinical studies across borders and advising and implementing policy, ECRIN advances knowledge flow, competitiveness and integration in European clinical research.

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



Organisation

EuCo: European Correspondent
CTU: Clinical Trial Unit



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

regulatory landscape, operational management, and coordination of multinational trials. They manage ECRIN's clinical trial portfolio in collaboration with the national scientific partner, the other EuCos and the Paris-based headquarters.

Highlights

January

- Launch of ERIC Forum toolkit

- EU-Africa PerMed Summer School

February

March

- EU-X-CT initiative press release

April

May

- Greece becomes ECRIN Member
- ICTD 2023 cohosted by PCTN – Decentralised Clinical Trials: Challenges & Opportunities
- IC PerMed together with PERMIT publishes brief
- Switzerland acquires ECRIN Member status
- ItaCRIN hosts meetings on FAIRifying clinical data and co-hosts a meeting on medical research infrastructures

- Version 5 of the Data Standards for Data Centre Certification published
- Kick off of LIVERATION project
- Kick off of European initiative: ACT-EU
- ECRIN moves into its new offices: 30 Boulevard St Jacques, 75014, Paris
- Health-RI/EOSC-Life workshop: Bridging the gap between researchers and the Health & Life Science research infrastructures

June

- ESFRI monitoring report

July

August

- Kick off of ERIC Forum 2 project
- ERA4Health workshop on bottlenecks and challenges in designing and conducting investigator-initiated multinational clinical studies
- 1st Sustainability workshop REMEDI4All
- ECRIN and its national partners launch the training series *Everything you need to know about submitting a European multinational clinical study proposal.*

September

- ECRIN in Spain for national research infrastructure joint meeting “Jornadas de las plataformas”

October

- ECRIN Summer School
- ECRIN Celebrates 10 years of ERIC Status
- ECRIN ISO 9001:2015 recertified
- EOSC-Life publication on sustainability of FAIR principles in life sciences.
- CRIGH General Assembly

November

December

- 3rd ECRIN CTU Day

10 Year Anniversary

Celebrating our ERIC status

On 29 November ECRIN united our staff, boards and past collaborators who have helped develop ECRIN to celebrate 10 years since ECRIN first attained its European Research Infrastructure Consortium (ERIC) status.

The festivities brought about fond memories of the last 10 years but also all the work that went into attaining the ERIC status in November 2013.

Some highlights of the first 10 years include:

- the 10 year celebration of our ICTD event in 2015
- the development of Data Centre Certification programme 2014
- attaining ESFRI landmark status in 2016
- PEDCRIN project coordinated by ECRIN, launched in 2017
- development of COVID-19 Taskforce in 2020
- ISO 9001:2015 certification in 2020

We sincerely thank the wider community for supporting us, and we look forward to the next 10 years and all our future collaborations.





ECRIN's
10
Year
Anniversary

The image features three European Union flags on tall poles, set against a background of a modern building with a grid-like facade. The entire scene is overlaid with a semi-transparent green filter. The text is centered and reads:

**National Scientific
Partners
Description and Highlights**



CZECH REPUBLIC

Scientific Partner: CZECRIN - Czech Clinical Research Infrastructure Network

Member since 1 Jan. 2018

Host institution: Masaryk University

National hub: Brno

<http://www.czecrin.cz/en/home/>

CZECRIN is the national, large research infrastructure, included in the Czech Roadmap for Large Research, Development and Innovation, that facilitates academic clinical trials in the Czech Republic. CZECRIN was built as a unique infrastructure, connecting a network of major clinical sites with a focus on clinical research and providing knowledge, development, production, and implementation capacities in the field of research and development of drugs and medical devices.

CZECRIN set up advanced solutions for the effective provision and use of high-quality scientific data, implementing the FAIR (Findable, Accessible, Interoperable, and Reusable) principles. CZECRIN also annually organises educational events and conferences, including National Clinical Trials Day.



2023 Highlights

In 2023, CZECRIN showcased impressive achievements across its operations. With 44 new clinical trials added in 2023, its portfolio over the decade expanded to over 200 studies, 83 of which are international, involving nearly 12,000 patients. The year also saw 281 access requests, serving over 800 users, highlighting CZECRIN's significant role in clinical research and education, reflecting both national and international collaboration.

The launch of the new CZECRIN hubs continues to strengthen the CZECRIN organisation and helps to significantly expand its capacity, competencies and services for non-commercial clinical research as well as its cooperation with 28 hospitals and specialised centres. CZECRIN is also strengthening its activities in the strategic area of DONets.

In 2023, CZECRIN significantly enhanced its educational offerings through the CZECRIN Academy, delivering an extensive range of educational activities designed to cater to participants of all ages and levels of expertise. The CZECRIN Academy saw the participation of approximately 1,250 individuals, engaging them in a comprehensive educational process tailored to diverse learning needs.



FRANCE

Scientific Partner: F-CRIN - French Clinical Research Infrastructure Network

Member since 29 Nov. 2013

Host institution: INSERM

National hub: Toulouse

www.fcrin.org/en

F-CRIN, created in 2012, is one of the single contact points facilitating the participation of France in clinical studies. 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 interregional groups for clinical research and innovation. F-CRIN enables multinational, multicentre, investigator-driven, clinical trials and early phase proof-of-concept studies. Clinical trial support is provided through F-CRIN by:

- 16 national networks specialised in specific diseases or areas of medicine (e.g., cardiology, nutrition, inflammatory disease, cardiorenal diseases, thrombosis, vaccinology, Parkinson's disease, sepsis, stroke, severe asthma, psychotic disorders)
- 3 specific expertise networks (methodology, health technology/medical devices, rare diseases)
- 1 platform of professional services (EUCLID)
- 1 national coordination unit



2023 Highlights

Launch of the five-year evaluation campaign for its 21 components.

Preparation and submission of the strategic F-CRIN project "2024/2028", with three main axes: expansion of the F-CRIN model through the labelling of new thematic national research and investigation networks; structuring of clinical research in primary care; and support for research projects with innovative designs.

Co-leadership of a national working group on "New Methodological Approaches in Clinical Research". F-CRIN and the French Ministry's Health Innovation Agency initiated a group of experts to accelerate the evaluation of health innovation using new methodologies throughout the development cycle of health innovation. This collaboration involves working with French regulatory authorities and opening up to Europe through collaboration with ACT-EU.

F-CRIN co-hosted, along with ECRIN, and other national partners, a training program on structuring multinational European projects under a new format ("Submitting a European Multinational Clinical Study"). The program included six webinars held in 2023 and four in-person sessions in various cities to come in 2024.



GERMANY

Scientific Partner: KKS - 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. (KKS) is an association of currently 28 academic coordinating centres for clinical trials (KKS/ZKS) all over Germany. Members of the KKS 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 KKS 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 national and European level.

Training is also a significant focus of KKS-Netzwerk. KKS members offer all required training courses for investigators and members of study teams. In addition, KKS-Netzwerk e. V. is organising workshops to train the employees of KKS CTUs.



2023 Highlights

Consented Model Contract Clauses for clinical trials v2.0 were published by KKS, German University Medicine and German industry and CRO associations. The model contract clauses are intended to facilitate faster and simplified contract negotiations between the involved parties. In the current version specific aspects of data protection and intellectual properties were consented. These contract clauses are available in English and might be a basis for the contract clauses for clinical trials funded by the German government.

KKS Fact Sheet (reporting period 2022)

- 1 095 clinical studies were substantially supported by KKS CTUs.
- 94 % of these clinical studies are investigator-initiated trials and 27 % are multinational.
- 14 233 scientists were trained by the members of the KKS in quality compliant conduct of clinical studies

Ten ECRIN projects are coordinated by KKS, support is also provided to 11 other ECRIN projects in which KKS members are participating. Additionally, 12 new coordinating project proposals and 10 participating project proposals were supported and processed by the EuCos.



GREECE

Scientific Partner: GRECRIN - Greek Clinical Research Infrastructure Network

Member since 18 Apr. 2023

Host institution: CERTH

National hub: Thessaloniki

<https://greclin.gr/>



In May 2023, Greece officially became a Member of ECRIN. Over the ensuing months, after several meetings with stakeholders in academia and patient advocacy groups, GRECRIN was established. Alongside 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 invested significant efforts in defining the catalogue of services and tools to be offered to the clinical research ecosystem in Greece. In more detail, 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).

In addition, GRECRIN will offer dedicated courses to help health scientists improve their skills and raise the awareness of the lay public about clinical trials.

Last, but not least, GRECRIN's website (www.greclin.gr) has been launched. The website will offer an overview of the services, training, and tools provided by GRECRIN.



HUNGARY

Scientific Partner: HECRIN – Hungarian European Clinical Research Infrastructure Network

Member since 5 Nov. 2014

Host institution: HNHRA

National hub: Budapest

<https://neku.org.hu/en/hecrin>

The Hungarian National Health Research Agency (HNHRA) was established by the competent Ministry in 2021. The mission and goal of the Agency is to support the development of clinical trial infrastructure in Hungary, and to advocate its capabilities to attract a higher number of clinical trials into the country.

Furthermore, HNHRA provides research centres and clinical trial sites with continuous support in their scientific and research activities. HNHRA shares its research, clinical trial, and pharmaceutical expertise in international cooperation, conveying the knowledge in bilateral and multilateral collaborations.

It currently comprises many hospitals and medical institutes in Hungary. HNHRA is also the host institution of HECRIN aiming at supporting the conduct of investigator-initiated multinational clinical trials in Hungary.



2023 Highlights

In 2023 HECRIN was involved in four ECRIN multinational clinical trials as a participating country.

Focusing on the development of the national network, HNHRA continued to build its relationship with leading research sites in Hungary. After a strategic agreement in 2022 with the University of Debrecen, in 2023 HNHRA signed a strategic agreement with the National Institute of Pulmonology and with the University of Szeged with the aim of establishing long-term cooperation in the field of clinical research and to open up opportunities for joint activities. HNHRA is devoted to continuing to build the clinical trial network in Hungary in 2024.

After the success of the Elementary Clinical Research Online Course organized by HNHRA in collaboration with the National Directorate General of Hospitals (OKFŐ) in 2022, the training was offered twice in 2023. The high number of participants showed that there is a need for such training programs in Hungary.



IRELAND

Scientific Partner: HRB NCTO - Health Research Board National Clinical Trials Office

Member since 20 Nov. 2018

Host institution: University College Cork

National hub: Cork

<https://ncto.ie/>

The HRB National Clinical Trials Office (HRB NCTO), established May 2021, is an independent, integrated, national clinical research network, providing centralised support to the conduct of multi-centre clinical trials and investigations/studies (both commercial and academic) across Ireland. With the support of funding agencies the Health Research Board and Enterprise Ireland, host institution, University College Cork, and in partnership with the seven University-based Clinical Research Facilities/Centres (CRFs/CRCs) in the Republic of Ireland, the HRB NCTO was developed to build on the positive achievements of previous investments in clinical trials coordination and facilitate future investments in national clinical trials infrastructure in Ireland. The central office provides overarching clinical research support and expertise and our partner University CRF/CRC'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.



2023 Highlights

- Dr. Robert O'Connor joined the HRB NCTO as the new director in summer, bringing a wealth of clinical research experience.
- NCTO Newsletters focused this year on events hosted by the NCTO, the growing Medtech sector in Ireland, and the work carried out by the Clinical Trial Networks operating in Ireland.
- The HRB NCTO National Study Feasibility support service carried out 77 feasibilities.
- Hosted the NCTO ICTD conference, "Advancing Clinical Research in Ireland 2023", with more than 140 delegates attending, the first in-person event since 2019.
- Hosted the HRB NCTO Medtech Workshop event in Dublin entitled: Clinical Investigations & Performance Studies in Ireland under the MDR/IVDR.
- Launched the Medtech Toolkit which provides all the information required for those planning on carrying out clinical investigations in Ireland.
- Hosted the HRB NCTO End of Year Meeting and Networking Event that brought together leading stakeholders from across the Irish clinical trials landscape to increase the awareness of the great work delivered by representatives enabling high quality trials.



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 National Network, coordinated by the Istituto Superiore di Sanità (ISS) in Rome, where the national hub is located, groups together 12 Clinical Trial Units (CTUs) and Clinical Research Organisations (CROs) covering the entire country.

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

Among others, training is also an important mission of ISS/ItaCRIN; in fact, ItaCRIN annually offers high level training courses for investigators, clinicians and grant office members according to the UNI EN ISO 9001:2015 certification supplied by ISS.



2023 Highlights

In May 2023, the ItaCRIN coordination team organised, together with the Italian National nodes of BBMRI and EATRIS, the training “Services offered by BBMRI, EATRIS, ECRIN to support European Projects preparation.” It was so successful that a second edition was held in December 2023.

In May 2023, ItaCRIN organised and hosted two days of training “FAIRifying sensitive data: technical, legal and practical considerations in the biomedical field” to introduce the principles of biological and medical sensitive data and medical applications, access to data resources and data FAIRification (especially for health research and health care data). The training received funding from EOSC-Life project.

Following an official request of the Polish Medical Research Agency, the ItaCRIN coordination team and the IRFMN and CD Pharma Italian CTUs jointly organised the training “Course for trial coordinators”. The training was held at the Mario Negri Institute, Milan, in June 2023.

ItaCRIN has the great pleasure of coordinating for ECRIN the clinical study under BIOTOOL-CHF project, sponsored by IRCCS Azienda Ospedaliero Universitaria of Bologna, Italy).



NORWAY

Scientific Partner: NorCRIN - Norwegian Clinical Research Infrastructure Network

Member since 18 May 2016

Host institution: Helse Bergen HF

National hub: Bergen

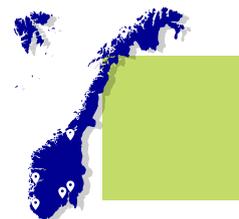
www.norcrin.no/en/

NorCRIN is a national network, with partners in the 6 university hospitals, covering all health regions of Norway. NorCRIN is funded by the Norwegian Research Council and in-kind contribution by the partners, by original initiative of the Ministry of Health and care services.

NorCRIN's primary objective is to strengthen synergies and collaboration in clinical research in Norway and to ensure better quality by harmonising procedures and regulations. NorCRIN has developed tools, courses and standard operating procedures (SOPs) to ensure adherence to best practices and to support clinicians in the planning and conduct of their clinical trials.

A great strength of NorCRIN is the close collaboration between the CTUs within the network – enhancing the distribution of clinical trials to all regions of the country.

2023 Highlights



NorCRIN aims to strengthen Norway's position in the European research environment through participation in projects and networks working towards increasing the quality and quantity of clinical research and healthcare development. NorCRIN is an observer in the CRIGH initiative and provided input to routines and guidelines for ethical international collaboration.

Norway, through NorCRIN was also invited to participate in the UK initiative "Group of Friends" in collaboration with WHO, contributing to identifying bottlenecks and developing the foundations towards best practice, ultimately to support the WHO guidelines. In 2023 NorCRIN, with EuCo Sigrun M. Hjelle, led the delivery of one of the tasks in the ERA4Health project, resulting in a report on bottlenecks to the planning and conduct of multinational IICT. The findings were presented at the ERA4Health workshop in September and published on the ERA4health website.

In 2023 NorCRIN has published bimonthly newsletters with relevant news from the work done within our network, we have hosted PPI workshops and developed a national course for study-nurses.



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-trials-network/>

The Polish Clinical Trials Network (PCTN) aims at implementing uniform, 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 in order to promote more effective international cooperation.

The PCTN is intended to ensure effective country-wide recruitment, streamline the feasibility process as well as support the training of dedicated clinical trial staff. Consolidating the procedures for clinical trial performance, pricing and billing as well as accelerating the contracting process, will contribute in the long term to optimising the costs of drug reimbursement and drug policies within the healthcare system.



2023 Highlights

In 2023, PCTN co-organized ICTD 2023, held in Warsaw, focusing on Decentralised Clinical Trials. It was a great opportunity to gather with experts from across Europe to discuss the state of the art, and the challenges and opportunities.

The MRA launched its eCRF (Electronic Case Report Form) system, offering a streamlined process for beneficiaries participating in MRA-organised calls.

The Polish Clinical Trials Network Portal, was also launched, a comprehensive repository fostering knowledge exchange and collaboration among PCTN members.

In addition, were developed a template clinical trial protocol, a template investigator brochure, a template informed consent form, instructions for preparation of Standard Operating Procedures and a template four-party clinical trial agreement to be used by PCTN members.



PORTUGAL

**Scientific Partner: PtCRIN - Portuguese
Clinical Research Infrastructure Network**

Member since 29 Nov. 2013

Host institution: NOVA University

National hub: Lisbon

www.ptcrin.pt

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

PtCRIN a consortium of 26 esteemed national institutions is included in the Portuguese Roadmap of Research Infrastructures (RNIE). PtCRIN serves as a central hub facilitating a network of academic Clinical Trial Units (CTUs), each providing a wide array of services. Additionally, PtCRIN is committed to advancing the competencies of clinical investigators through initiatives like the CLIC (Clinical Investigator Certification) program, Good Clinical Practice (GCP) training, and tailored training programs to ensure best practice.



2023 Highlights

In 2023, PtCRIN celebrated its 10th anniversary as one of the 5 founding member states of ECRIN. PtCRIN has actively participated in national working groups dedicated to strengthening Clinical Research in Primary Health Care and national research in Oncology through participation in the Stakeholders Group – National Cancer Hub.

PtCRIN has been engaged in various national scientific meetings concerning the funding of clinical research, promotion of international cooperation, and the European Health Data Space. PtCRIN collaborated with ECRIN and NorCRIN to co-organise the ERA4Health Partnership Workshop, which aimed to analyse bottlenecks and challenges in designing and conducting multicounty investigator initiated clinical studies. PtCRIN, in partnership with ECRIN, CZECRIN, F-CRIN, PCTN, and SLOVACRIN, organised the training program "Everything You Need to Know About Submitting a European Clinical Study Proposal".

Organised the Portuguese International Clinical Trials Day 2023 in collaboration with AICIB, APIFARMA, INFARMED, FCT, and HCP in Coimbra, focusing on "Clinical Research and Biomedical Innovation in Portugal."



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

SLOVACRIN is the national research infrastructure for non-commercial clinical trials in Slovakia. It represents a national distributed research infrastructure connecting hospitals, universities and scientific institutions involved in academic clinical research and is coordinated and funded by the Faculty of Medicine of the Pavol Jozef Šafárik University in Košice. SLOVACRIN supports the preparation and implementation of academic clinical trials, including international trials.

The aim of the national infrastructure is to increase the number and quality of academic initiated clinical trials in Slovakia using the available capacity and expertise, knowledge, research, and development in the field of medical sciences as well as to help build a network of Clinical Trials Units. Since 2021, SLOVACRIN has been listed on the Roadmap of Research Infrastructure SK VI Roadmap 2020 - 2030, which is the key document of the Slovak Republic for the field of Research Infrastructures.



2023 Highlights

SLOVACRIN National Clinical Trials Day 2023

The SLOVACRIN infrastructure in cooperation with the Ministry of Health of the Slovak Republic, the State Institute for Drug Control and the Association of Innovative Pharmaceutical Industry organised the National Clinical Trials Day. The central theme was the conduct of clinical trials from different perspectives. The participants of the conference discussed, among other topics, the development of the number of clinical trials in Slovakia and the possibilities of bringing innovative treatment options associated with ongoing research closer to Slovak patients. The conference also included a course on Good Clinical Practice for investigators and clinical trial coordinators.

Working Group of the Ministry of Health of the Slovak Republic on Clinical Trials

The Ministry of Health of the Slovak Republic has established a working group, of which SLOVACRIN is a member, representing academic clinical trials. The working group aims to identify obstacles in the conduct of clinical trials and to propose possible solutions.



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 supporting clinical trials in Spain. It is funded by the National Institute for Health Carlos III (ISCIII). In 2023, SCReN's network included 34 associated units based in clinical centres of the Spanish National Health Service spanning the 14 national autonomous communities. Through SCReN, these centres are organised into 8 Working Groups (WG) covering all the areas of expertise and activity.

SCReN's General Coordination is based in Madrid and since August 2022, the ECRIN EuCo has been hosted at Virgen de la Victoria University Hospital. The two work together to lead SCReN's Internationalisation WG, in alignment with and under ISCIII directives. Whether providing consultancy or services to clinical investigators, SCReN aims to foster excellence, leadership and quality in clinical research through networking, international cooperation, and support to clinical academic research projects, translating them into innovation for the Spanish National Health Service and globally for the European Society.



2023 Highlights

SCReN continues implementing new projects and capacities to enhance the growth and development of the Network and its associates. In 2023, SCReN's portfolio incorporated 19 new clinical trial projects, two programmes funded in national calls, and five new ECRIN trials, two of which are coordinated by Spain. The increased participation at the international level is seen through SCReN's submission of a CTU to become an ECRIN Certificated Data Centre (September).

A Communication and Citizen Participation WG was created to focus on the social awareness of clinical research and, internally, training, discussion forums and a newsletter have become monthly initiatives. SCReN collaborates with the ECRIN communications WG by promoting and participating in group actions and initiatives as well as the participation in ECRIN activities (i.e. ICTD, CTU Day, and training).

SCReN has worked on a proposal for joint interaction with the other ISCIII networks (ITEMAS, Biobanks & Biomodels), an approach similar to that of the European RIs (i.e. EU-AMRI) but at the national level. A preview was presented at the first ISCIII Platforms Conference, held in October 2023. The aim is to further develop this initiative over the next three years.

SWITZERLAND

Scientific Partner: SCTO - Swiss Clinical Trial Organisation

Member since 22 May 2023

Host institution: SCTO

National hub: Bern

www.scto.ch/en

The Swiss Clinical Trial Organisation (SCTO) is a national research infrastructure and an academic reference institution for high-quality, patient-oriented clinical research in Switzerland. In 2017, the SCTO was designated a research infrastructure of national importance, and it is funded by the State Secretariat for Education, Research and Innovation and the Swiss National Science Foundation. SCTO's primary objective is to catalyse valuable and innovative clinical research in Switzerland to make new and better therapies available to society. SCTO's CTU Network, comprising the CTUs of the five Swiss university hospitals and two cantonal hospitals, is a well-established and nationally coordinated clinical research infrastructure that provides all the services and support needed to conduct high-quality clinical research projects. Each of our eight SCTO Platforms focuses on a different key area of clinical research. As nationwide centres of excellence with pools of experts who develop tools and guidance resources, our platforms provide practical solutions for researchers involved in academic clinical research.



2023 Highlights

Switzerland acquired ECRIN Member status

Switzerland has been an ECRIN Observer country since December 2015, and its request for an ECRIN membership was approved at the Assembly of Members meeting held in Warsaw on 22 May 2023. A request by the Swiss Federal Council submitted on 13 April 2022. Switzerland is represented in the Assembly of Members by a delegate from the Swiss State Secretariat for Education, Research and Innovation (SERI). The Member status will enable Switzerland to have full access to ECRIN services. Since 2015, Switzerland has taken part in more than twenty multinational clinical trials or infrastructure projects, including platform trials on COVID-19.

Supporting best practices

The SCTO Platforms are an interconnected, nationwide network of experts that provide practical resources and innovative tools for clinical research professionals. Currently, the SCTO Platforms are focusing on clinical research governed by Switzerland's Human Research Ordinance (HRO). Several projects are underway, including tailored training for HRO projects. In 2023, the SCTO Platforms developed and shared eleven new products with the clinical research community in Switzerland and beyond, five tools and six publications.

Interview with the German EuCos



Linda Stöhr & Neshat Chareh

European Correspondents for Germany

What's a day in the life of a coordinating EuCo like?

Neshat: As a coordinating EuCo, for running projects, the most important role is that we should maintain close contact and collaborate with the sponsor and the lead CTU. We are also the contact person for our partner CTUs in participating countries, if they have any questions or issues regarding the project. We are their voice, reaching out to either the sponsor or lead CTU. Our main responsibility is to ensure effective communication and coordination between our partners in participating countries and the sponsors and lead CTU in Germany.

When we receive a collaboration request for services from ECRIN, here, in Germany, we are the first contact person for the sponsor and lead CTU. We obtain all the relevant information regarding the collaboration request. Then we prepare and introduce the project to the ECRIN Collaboration Committee. If the Collaboration Committee agrees on the collaboration, we start the next steps with the sponsor including finding partners in participating countries, preparing the budget and negotiating with the sponsor. However, there are different procedures depending on whether or not the proposal is Horizon Europe.

We also act as participating EuCo in a large number of studies but we won't get into the details here.

Linda: I think you summed it up perfectly. The important aspect is also that every day is different. You always have scheduled meetings and a plan of what you think you will be doing but then something comes up, like you get an urgent collaboration request. So, you're constantly adapting your priorities according to what's happening. It never gets boring and there's always something new. It also depends on the people you are working with: we have the sponsors, we have project managers, we have CRAs, we have people who are more familiar with the clinical study environment and then we have others who are not very familiar with it at all. Every day is so different.

How has ECRIN benefited Germany?

Linda: That is a good question, we come from a partner, the KKS Netzwerk, here in Germany that has been around for a longer time than ECRIN has existed. ECRIN has given some opportunities for CTUs in Germany to enter into collaborations that they might not have been able to do without ECRIN. We received feedback from the KKS Netzwerk that this is among the reasons some new CTUs are joining the network because they want this sort of opportunity.

Specifically, there's been a lot of interest in the Data Centre Certification programme. We currently have five CTUs in Germany that are certified. This has benefited them, because they are able to provide this sort of certified service. Also we get requests from sponsors outside of Germany to provide lead CTU services in the foreign country.

What achievements have you been the proudest of since joining ECRIN/KKS?

Linda: We do get repeat users and when we ask a new user, 'how did you come to find out about ECRIN?' they often say that ECRIN has been recommended by their peers. It is nice to have satisfied users.

There has also been this continuous interest for collaboration, with more than 20 requests in 2023

either from sponsors in Germany but also from other countries wanting to extend the services to Germany.

Personally, an accomplishment has been the change to the Berlin offices. We used to be located in Cologne and then we had to relocate and set up the new office in Berlin, whilst the majority of our projects were in their most busy phases. This was a challenge but, I think, it's taught me a lot.

Neshat: For me, most of the projects are quite big, involving different parties in different countries. So I am proud to work with, coordinate and communicate with different partners with different cultures. Further, since taking on this role two years ago, I have improved my knowledge about regulatory aspects in multinational clinical trials and also the management of multinational clinical trials.

Tell me about Germany and what is planned for the next few years?

Linda: We are always hoping to grow our portfolio. Personally, I would also like to grow our team, but that may be a different question (laughs).

At the national level, beyond the KKS network, there are some new national laws and changes in the national regulations coming up. So we are anticipating these changes as best possible.



**ECRIN, supporting the
rare disease clinical
research community**

Rare diseases affect an estimated 30 million people in Europe. There are believed to be 6000+ rare diseases, only a fifth of which have five or more documented cases in the literature. With only 230 orphan medicines authorised in the EU, there is a huge gap in clinical research that needs to be addressed.

Due to the low prevalence of each disease, the rarity of medical expertise, the scarcity of knowledge, inadequate care and limited research, rare diseases are among the areas where multinational investigator-initiated clinical studies (IICS) have a particularly important role. For all these reasons, ECRIN regards this field as an area of particular importance in its capacity to support clinical researchers and sponsors.

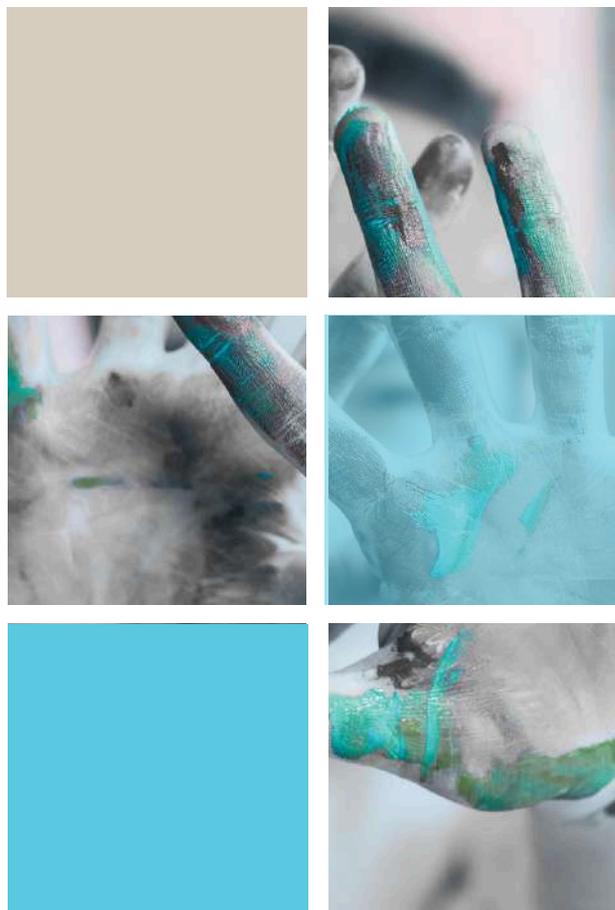
ECRIN has supported several studies working towards answers for this community. The PedCRIN project financed the expansion of, and ECRIN's support in, the OTBB3 trial which analysed the safety and efficacy of oxytocin treatment in neonates with Prader-Willi syndrome on oral and social skills and feeding behaviour. Another example is the NICOFA study which examined the efficacy and safety of nicotinamide in patients with Freidreich Ataxia.

Beyond supporting clinical researchers through the set-up and management of clinical studies, ECRIN also contributes to advance the rare

disease community through the creation of knowledge, tools, training and participation in partnerships.

■ *Uniting forces in Europe for rare diseases*

ECRIN has an active role in the European Joint Programme for Rare Diseases. As a partner of this project, ECRIN holds the secretariat of the Clinical

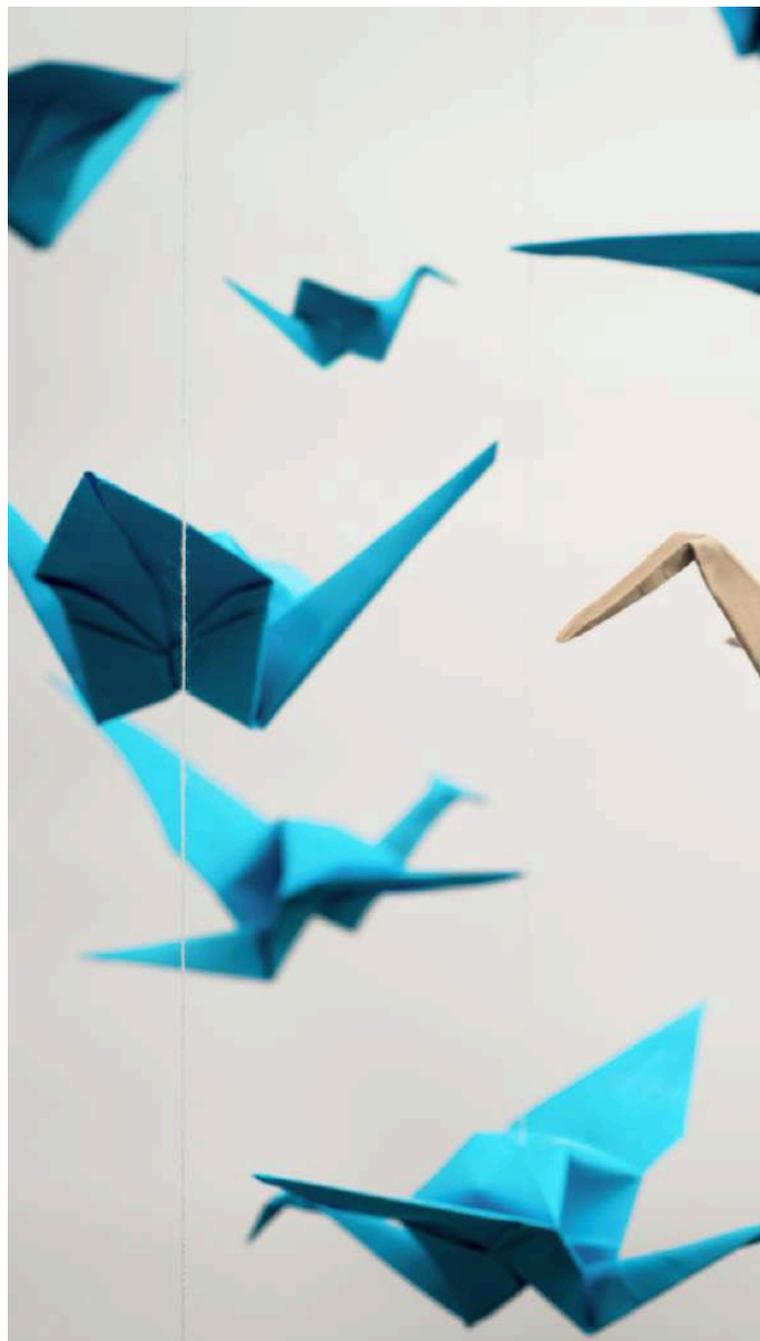


Studies Support Office (CSSO), has led the development of the Rare Diseases Clinical Trials Toolkit and organised a workshop to identify difficulties and solution to advance rare diseases research. These activities are highlighted in the next pages through an interview with ECRIN's rare disease expert, and Head of Capacity Projects, Marta del Alamo.

■ **Resources for neonates and paediatrics**

When we think about  strengthening the rare  disease community, we must consider how to advance paediatric clinical research as 75% of rare diseases are paediatric diseases. Within the ECRIN coordinated PedCRIN project, tools were developed to support researchers conducting trials on neonates and children.

These tools were created to train and support researchers and clinicians to establish, run, and manage both paediatric and neonatal multinational clinical trials more effectively and with greater ease.





■ **Drug repurposing, a pathway for new solutions**

One of the means of searching for answers in the rare disease field, as with other conditions currently with unmet medical needs, is to find new uses for existing medicines. Known as drug repurposing, this can lead to faster and less costly solutions than the classic drug discovery pipeline.

In the REMEDI4All project, this strategy is being supported through the development of a



comprehensive, accessible and standardised platform that provides the expertise, tools and resources required in all stages of the repurposing journey.

Moreover, the project looks to generate a more favourable policy environment for drug repurposing by bringing together key stakeholders in a forum of debate to identify current barriers and explore creative solutions and incentives.

ECRIN is part of this dynamic global community advancing drug repurposing with a focus on the elements that relate to ensuring clinical operations and trial management.

■ Ensuring clear communication gene and cell therapy

The majority of rare diseases have genetic origins opening the door for promising gene therapy treatments to fix or replace the defective gene. Through the EuroGCT project, which aims to provide reliable and accessible information about the use of cells and genetic material to treat diseases, including rare diseases, ECRIN assists in ensuring patients, people affected by various rare diseases and other conditions, healthcare professionals, and citizens have access to accurate scientific, legal, ethical and societal information on cell and gene-based therapies.



in silico trials, model based clinical trial design and evidence synthesis methods, all based on robust and mature computational models and qualified on extensive data from representative selected use cases. ECRIN, together with its Czech partner, has the essential role of ensuring the dissemination of the project outcomes through training and workshops to key stakeholders including its CTU community and regulators and health technology assessment (HTA) bodies.

■ Ensuring reliable regulatory decision-making



ECRIN is also working on a new project launched in 2023, INVENTS. It aims to provide clinical trial stakeholders with a generalisable framework encompassing methods, workflows and evidence tools to improve the level of evidence in regulatory decision-making in rare diseases. This will be achieved over the next years through the development and validation of improved extrapolation models, simulation and



■ **Public private partnerships to accelerate research**

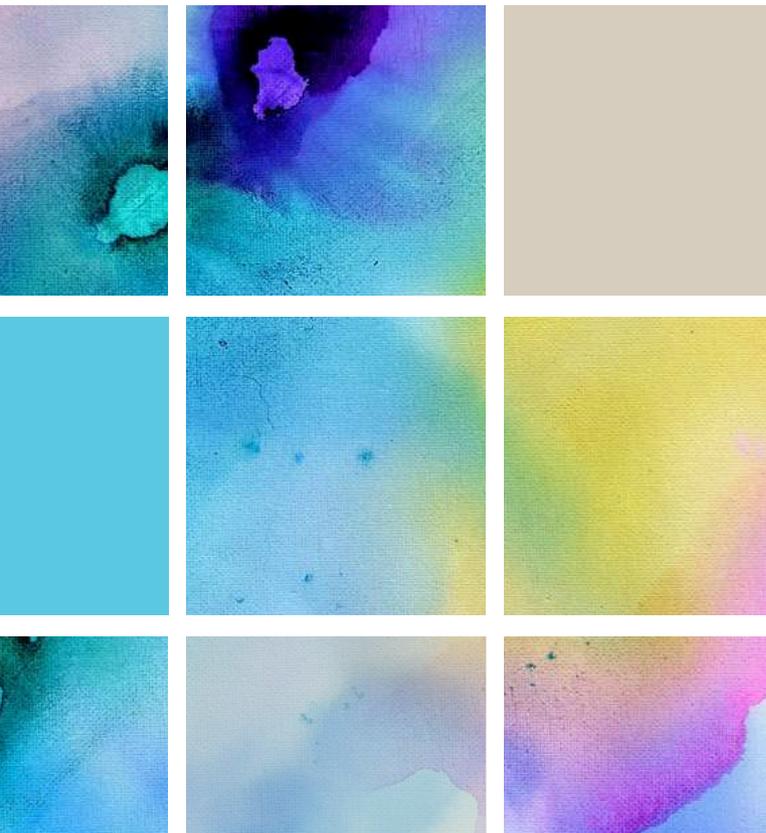
A new initiative to boost research and development in rare and paediatric diseases was launched at the end of 2022. The Rare Disease Moonshot is a public-private partnership which initially involved seven organisations, including ECRIN, and continues to grow. It aims to break down the



barriers to finding new treatments and cures for the world's rarest and most severe conditions which currently have no therapeutic options, and which often affect the youngest patients.

The partnership has identified three areas of actions where public-private collaborations can add the most value: diagnostic research, translational research and clinical trials.

As ECRIN looks back on 2023, it reaffirms its commitment to advancing research, improving access to treatment, and ultimately, transforming the lives of individuals and families affected by rare diseases. Through collaborative efforts and pioneering initiatives, ECRIN stands poised to make significant strides towards a future where rare diseases are no longer a barrier to health and well-being.



Interview on EJP-RD



Marta del Álamo,
Head of capacity projects,
ECRIN

What is the EJP RD project?

EJP RD's mission is to improve the rare disease research at European and international levels by overcoming fragmentation, enabling effective access and use of rare disease information, research data, and services to optimise exchange of knowledge between research and clinical practice.

Further goals are to foster rapid scientific progress in the field of rare diseases through funding of collaborative research projects, to accelerate the translation of high potential projects as well as to improve outcomes of clinical studies.

What has it accomplished in the 5 years since it began?

EJP actions and services included training and education, clinical research advice, development of data resources and funding.

EJP has developed three MOOCS (Massive Open Online Courses) on Rare Disease Diagnosis, Transnational research and Health Data and launched 5 Joint Transnational Calls covering a wide range of topics, including pre-clinical research, diagnostics, social and human sciences and natural history studies.

The Innovation Management Toolbox, the Clinical Trial Toolbox and the Virtual Platform are assets developed through the project that will be sustained upon the completion of EJP.

How does ECRIN support the EJP-RD project?

ECRIN was mainly involved in activities, dedicated to Innovation and Clinical Trials Support.

ECRIN coordinated the EJP Clinical Studies Support Office (CSSO), dedicated to supporting rare diseases investigators interested in setting up clinical studies. Over the past five years, the CSSO has given advice to academic investigators both on clinical trials methodology and clinical operations and supported applicants for the EJP Joint Transnational Call 2022 on "Natural History

Studies addressing unmet needs in rare diseases”.

As part of this task, ECRIN developed the Rare Diseases [Clinical Trial toolbox](#), an instrument that facilitates access to public resources relevant to the development of clinical trials for rare diseases.

ECRIN was also granted by the EJP [Networking Scheme Support Funding](#) to coordinate a Workshop on “Identifying obstacles hindering the development of academic-sponsored trials for drug repurposing on rare diseases”.

The workshop gathered investigators involved in rare-diseases academic-sponsored trials on drug repurposing and other RD clinical research stakeholders such as clinical research infrastructures, RD supporting programs representatives, patient organizations to identify systematic problems/challenges in the set-up of academic-sponsored international clinical trials and promote initiatives aiming to fill up the gaps (guidelines, recommendations, inventories of existing tools).

Outcomes of this workshop are summarized in a [peer reviewed publication](#).

How will ECRIN continue to support the rare disease community beyond the end of the project?

ECRIN will continue supporting the rare diseases community in different ways:

- As part of the [ERDERA partnership](#), the European Rare Diseases Research Alliance, an Horizon Europe project that will start in September 2024
- As part of the [Moonshot initiative](#), a coalition of partners joining forces to accelerate scientific discovery and drug development in rare and paediatric diseases. The Moonshot partners identified different areas of actions where public private collaboration can add more value, including [clinical trials research](#).

[View the interview](#)



**Clinical
Operations**

This year was a landmark year for ECRIN’s clinical operations. It included more solicitations for collaborations than ever before, with 5 new trials entering our portfolio and an evolving role in the clinical trial landscape.

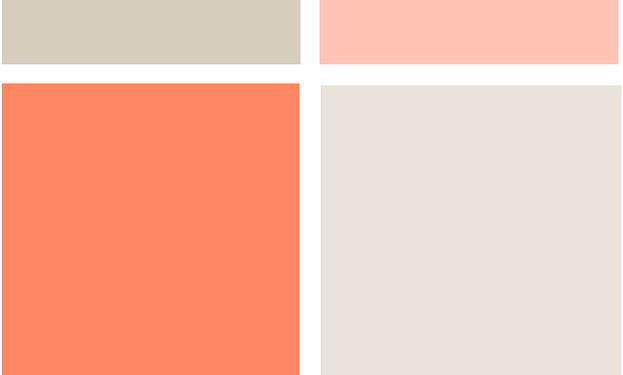
In this section, are described the changes made in 2023 to how the clinical operations service offer is presented. A zoom-in on the Scientific Board (the access board) shares the success and reach of ECRIN in 2023. Key numbers on ECRIN’s trial portfolio are included as well as the role ECRIN maintained in 2023 providing access to the EU funded COVID-19 adaptive platform trials.

A new way of looking at our service offer

In 2023 ECRIN updated the presentation of its clinical operations service offer. This change not only clarifies the clinical operations services provided by ECRIN and its network of CTUs, but also highlights the importance of our staff’s expertise and overarching support. This has always been at the heart of our offer but is now visibly displayed throughout the steps in which we accompany sponsors and investigators (Figure 1). There are now five principal services, each of which can be further broken down. For a full list of the ECRIN CTU services see the ECRIN [clinical operations brochure](#).



Figure 1. ECRIN clinical operations service offer



ECRIN offers all its clinical operation services at any time to academic investigators and sponsors in its Member and Observer countries. Select services can also be made available in specific disease areas to the larger clinical research community through TNA calls in which ECRIN participates. These are organised within projects centralising many research infrastructure activities in a given field. Lastly, operational coordination services are available to sponsors and investigators from across Europe (beyond ECRIN member countries).

■ **General information**



The acquisition of general information and support in the planning of a clinical study is of utmost importance in understanding the regulatory landscape, identifying funding opportunities and correctly defining the scope, roles and responsibilities of the work to include in the funding application. This assistance ensures initial clinical research questions become an operational reality.

■ **Planning**

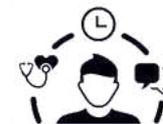
In the planning phase, ECRIN can support the preparation of EU funding proposals, regardless of the investigator or sponsor's level of experience with such applications. This service is available for our member and observer countries. The extent of ECRIN's participation will depend on our role.



While information may be freely provided to all, ECRIN can also be involved in designing and completing certain elements of the proposal related to the clinical study, subject to the approval of the collaboration committee.

■ **Operational coordination**

During project implementation, ECRIN offers various study management services, accompanying sponsors, investigators and project coordinators all the way from protocol finalisation to study close out.



ECRIN coordinates these services, performed by CTUs, in all participating countries. All CTUs involved in ECRIN projects are selected based on the location of the investigational sites, their competencies and/or expertise, the availability of resources and quality standards.

■ **Risk assessment**



As early as the planning phase through to study close out, ECRIN can accompany the sponsor and investigators to identify and mitigate risks. A feasibility study can be carried out to ensure that the scope of the study and the resource provisions outlined in the proposal align with the current and potential future situations.

ECRIN also offers its protocol peer review as a service. It is made available through the ECRIN Scientific Board. This is an independent assessment of the full protocol prior to operational services. It does not apply to all studies supported by ECRIN.

■ **Expertise and overarching support**

Through out ECRIN's clinical operations service provision, our expertise and overarching support are always present. This is the core of the EuCo role. They work directly with the investigators and sponsors in their country from the first contact to help them prepare for all the steps mentioned above, as they assist in structuring



the clinical study around the research question, taking into account local regulation, capacity and much more. They ensure a solid understanding of the different roles and responsibilities associated with the different steps and work to define a clear task distribution.

The tasks delegated by the sponsor to ECRIN are coordinated by the network of EuCos and implemented at CTU level in a harmonised manner and in keeping a streamlined communication flow.

Streamlined access to ECRIN's clinical operations services

Access to ECRIN operational services is based on scientific excellence. The ECRIN Scientific Board (SB) ensures that the project meets these criteria. The SB Collaboration Committee (SB-CC) provides quick answers to proposals on ECRIN's capacity to support the development of funding applications and study design. It can also decide on support to running studies looking to expand to new countries. This year a record 44 requests for collaboration were submitted to the ECRIN SB. This is more than double the number of requests from the previous year and more than any other year since the creation of the SB-CC (Figure 2).

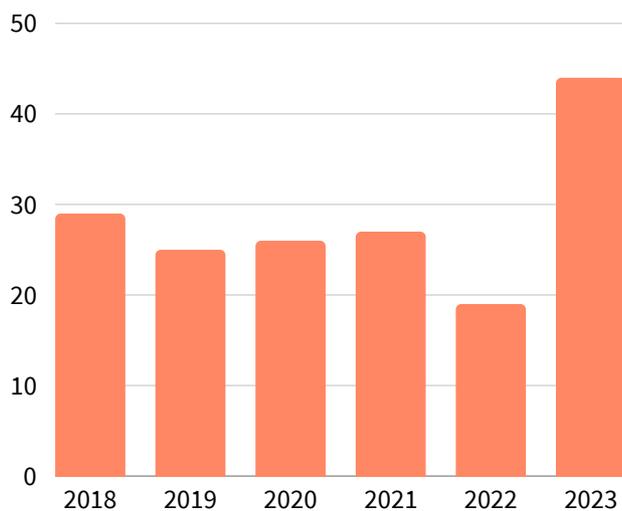


Figure 2. The number of collaborations request per year

ECRIN's Scientific Board in numbers

In 2023 the SB-CC received a record 44 requests for collaboration from seven different countries: France, Spain, Germany, Italy, Czech Republic, Ireland and non-ECRIN country (Netherlands) (Figure 3).

Of the 44 requests for collaboration ECRIN agreed to collaborate on 28. Of these four projects were already funded, three of which successfully

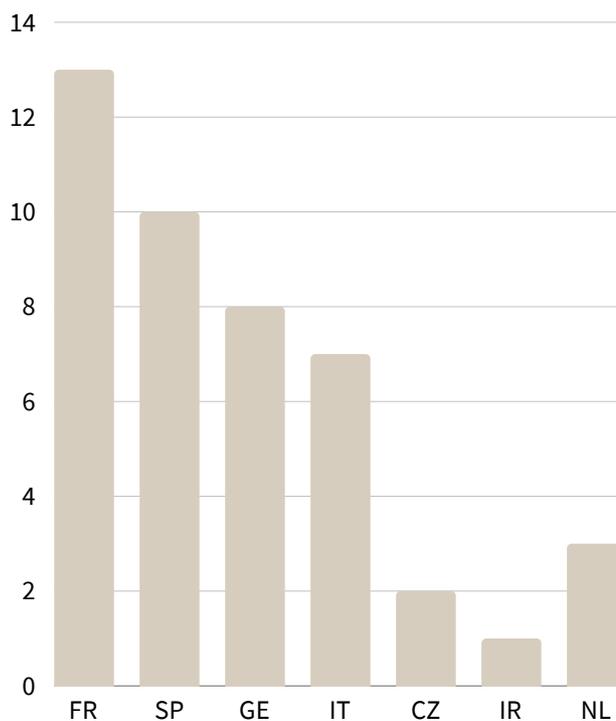
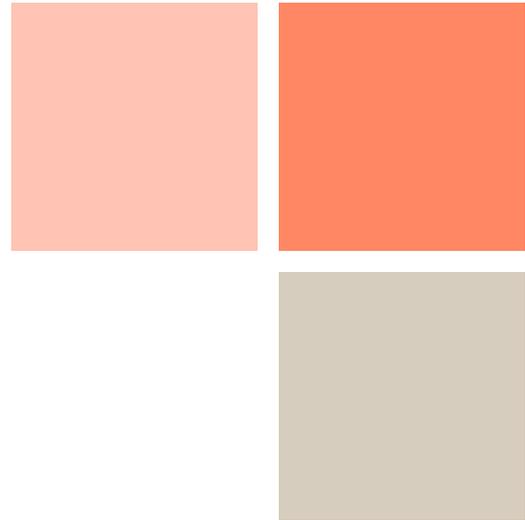


Figure 3. The number of requests for collaboration submitted to the ECRIN Collaboration Committee by country for 2023.

passed the ECRIN Scientific Board Peer Review Committee (SB-PRC) and one of which was pending review at the end of the year.

Sixteen were accompanied by ECRIN in part 1 of the proposal, of these 12 did not proceed to the second round but four have continued to the second round with ECRIN support. This demonstrates a 25% success rate in the first stage of the proposal when supported by ECRIN.

Eight were full proposals or submitted to the second stage, of these 50%, four, were funded.



Interview on BIOTOOL-CHF



Dr Luciano Potena

Director of the Heart Failure and Transplant Unit,
IRCCS University Hospital of Bologna

Tell me about the BIOTOOL project?

The BIOTOOL project is a wide and complex project that has been funded by a Horizon grant program and the main scope of the project is to develop an algorithm that is based on clinical data and biomarkers that can guide clinicians in the management of patient with heart failure and in particular in recognising congestion and managing more appropriately the congestion which is the main clinical feature of patients with chronic heart failure.

The target population are patients with heart failure and reduced ejection fraction. The goal is to start from a retrospective development phase

to develop the algorithm. Then the algorithm will be embedded in a software used in a prospective randomised clinical study in which patients will be randomised to be followed according to the algorithm or the standard clinical practice. In parallel we aim also to develop a point of care device that can assay the cytokines and the biomarkers that will be included in the algorithm.

So that ideally, we can have a pack of decision making tools plus point of care that could allow anyone in any outpatient clinic, remotely from a university centre to assess precisely and personalised the level of congestion of the patients in order to better manage the patient.

How did you learn about ECRIN and its services and how did you come to work with us?

I knew about ECRIN thanks to the project coordinators of my grant office. When we decided to run for this enterprise we started of course to work with the support of the grant office of my hospital and in the process of identifying the most suitable partner, ECRIN was on the list because of your reputation and because people had already worked with you in other projects.

Could you tell me about the working relationship setting up the different elements of the project?

Yeah as you said the project is at the very early stages so I cannot say that I have a real working experience in the field with your organisation. We will see. Up to now my impression is good, there is a lot of good will to collaborate and work well together.

When we started, we had a few preparatory meetings when we working on writing the project You know the drafting of these kind of projects is very complex and is very lengthy, you need to really work well as a team to put all the pieces together.

I have been involved as a partner in other projects where the CRO was not part of the project since the beginning but was included at a second stage as a contractor or as a third party but not as a proper partner and I can sense the difference. In particular, for the parts that need to be completed and for the deliverables that are specific to the clinical study monitoring and clinical study data analysis. The data analysis is not conducted by ECRIN but the data, how they are collected, the quality and how they are connected is part of your job. I think that having you on board as partner makes a difference.

Are there any lessons learned that you would like to share with other investigators that are drafting proposals?

I think that if there is the opportunity to engage with a CRO (or an organisation such as ECRIN) as a partner it is much better because it supports the building of a mutual trust relationship.

Of projects that are driven by the non profit scope and driven for investigating things that not necessarily have a commercial impact, I think it is important to this partner vibe, or this partner relationship.

[View the interview](#)

The ECRIN clinical study portfolio

ECRIN is pleased to have five new studies starting in its portfolio for 2023. The total ECRIN trial portfolio counts 75 studies with support provided to 34 throughout this year.

Of those that acquired ECRIN's support in 2023, at the end of the year five trials were in the set-up phase, 16 were running (12 openly recruiting and four in preparation of the close out visit), eight were in the completion, four were completed and one withdrew from ECRIN services. ECRIN's full 2023 study portfolio can be found in annex 2.

■ **Newest additions**

Of the newest studies two are coordinated by France, two are coordinated by Spain and one is coordinated by Italy. Both BIOTOOL-CHF



and MORPHEUS focus on cardiology, the former, described in detail in the dedicated interview, uses a biomarker-based diagnostic toolkit to personalise pharmacological approaches in congestive heart failure and the latter will develop a tool to be integrated into a shared decision-making process to optimise anticoagulation effectiveness.



LIVERATION and LEOPARD focus on liver diseases. LIVERATION works to determine whether additional ablated margins produced by radiofrequency can decrease the recurrence rate of colorectal cancer liver metastasis and liver cancer and improve patient survival. LEOPARD will design and test new multimodal AI predictive models of dropout/ mortality in hepato-cellular carcinomas and decompensated cirrhosis liver transplant candidates to improve stratification and patient outcomes on the waitlist.

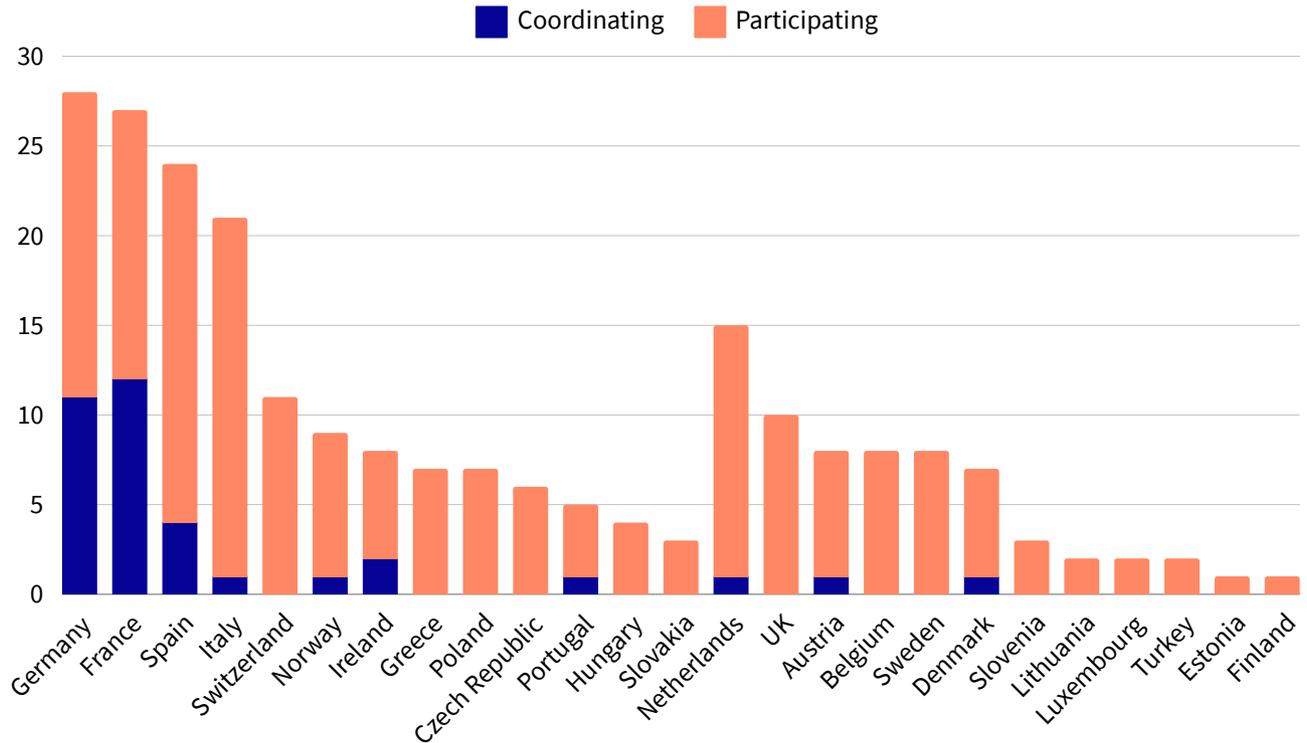
Lastly ORTHO-ALLO-UNION, a follow-up from the ECRIN coordinated ORTHOUNION, aims to develop effective therapy for fractures with delayed union or non-union that is economical for health systems and appropriate for use in a wide range of patients.





Key numbers

2023 ECRIN trial portfolio



Feedback from ECRIN's service evaluation

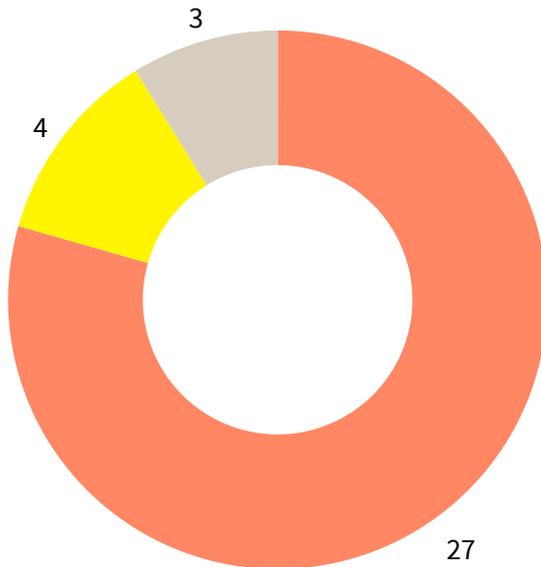
*“ECRIN offers **unparalleled professionalism** and emphasizes the value of international collaboration. The **diverse network of experts** enhances project outcomes and broadens our understanding of **global research dynamics**. Based on our positive past experiences, I would **eagerly collaborate with ECRIN again.**”*

*“The cooperation has **decreased our workload**”*



2023 portfolio by disease area

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



2023 trial population

- Adult
- Paediatric
- Both



Coordination across and access to platform trials

Launched in 2021, a joint work package between two EU-funded projects, EU-RESPONSE and RECOVER, each containing at least one adaptive platform trial was launched.



This endeavour sought to support EU adaptive platform trials on COVID-19 through better coordination (via the Trial Coordination Board - TCB) and a single access mechanism, known as the Joint Access Advisory Mechanism (JAAM) which is coordinated by ECRIN. Over time these entities have both expanded, with the addition of the ECRAID-Prime and VACCELERATE projects, new trials and a wider scope.

The TCB now gathers the main actors, playing a role in the successful implementation and development of the European adaptive platform trials (APTs) in infectious diseases with pandemic potential. The mission of the JAAM is to ensure, through an independent panel of experts, a solid scientific assessment of the most promising candidate treatments that meet the needs of the various patient populations and are adapted to the design and capacities of the EU-funded adaptive platform trials in emerging infectious diseases.





To support the expansion of the scope to all infectious diseases with pandemic potential and to unite these entities with similar mechanisms at work in other areas of infectious diseases the CoMeCT project kicked off at the end of this year.

Overcoming funding as a barrier

With a major aspiration of the ERA4Health project being to provide a funding mechanism for multicountry investigator initiated clinical studies (IICSs) coordination across Europe, ECRIN and its national partners have been working to support this aim. The initial steps consisted of identifying the bottlenecks to planning and conduct of IICSs and the mapping of organisations providing funding or support to multicountry IICSs.



Through these initial outputs, it is clear that some steps have been taken to address known barriers, such as the lack of harmonisation in the regulatory process with the introduction of the CTIS, but these steps remain limited. The retrieved information on funding will inform ERA4Health partners in the preparation of the future calls of the project, and the wide range of support for IICS will be useful for future applicants to IICS ERA4Health calls.

Interview on the JAAM



Sanjay Bhagani
JAAM Chair,
Professor and Consultant
Physician in Infectious
Diseases, Royal Free
Hospital



Jacques Demotes
Director General, ECRIN

What is the JAAM?

Sanjay: The JAAM is the Joint Access Advisory Mechanism that was set up during the COVID-19 pandemic for us to work through prioritisation of therapeutics that were coming in for COVID-19.

Jacques: The JAAM is an access board to provide access to the platform trials, considered as an infrastructure or an instrument, able to address multiple scientific questions. When the platform trial is created, we don't know what the next intervention arm will be. So, there is a need for an independent board to make the decision and to

prioritise what are the best options regarding the next intervention arms.

Sanjay: The JAAM consists of a number of experts from around Europe that encompass infectious diseases, virology, pharmacology, health economics experts, early therapeutics experts, et cetera. It was really important to have this group together, that would help us choose which therapeutics to prioritise for the studies that were coming through.

Why was the JAAM created?

Sanjay: Remember at the time, we were in the throws of a massive pandemic. A number of adaptive platform trials were being set up not only across Europe, but from around the world, too. Several drugs were being developed and being put forward as potential therapeutics for COVID-19. There was a real need to make sure that we prioritised antivirals or anti-inflammatories that were likely to be most effective. This was the “raison d'être” for the JAAM: to help set up a prioritisation process for the EU-funded adaptive platform trials.

Jacques: The JAAM provides access not to a single platform trial, but to a family of platform trials, addressing different aspects of the same disease. It is very important to sort out what is the best platform trial to address a new scientific question and to develop a new intervention arm.

How has the JAAM evolved since its inception?

Jacques: The JAAM started as the Access Board for two trials, EU SolidAct and REMAP-CAP. Then another trial was activated in 2021, ECRAID Prime, which is a clinical trial on COVID in primary care.

It was important to have this third trial because with this panel of three trials, one trial was focusing on the patients in the primary care, the other one in the hospitalised patients, and the third one in the ICU patients. They were able to address a broad range of scientific questions.

Now the JAAM is evolving again because first of all, we will cover also the access to other platform trials for pandemic preparedness that will be funded. There was a call in 2023. The final project was submitted to the Commission in April 2024, and the trial will start by end of 2024 or 2025. But this will correspond to new trials being also accessible through the same mechanism.

The second aspect is that the JAAM is now starting to perform a horizon scanning to identify the candidate drugs that are in the development pipeline. So we will be more proactive to interact with the developers, industry or academic developers, and to attract them to really enrich the potential of the platform trials.

How has the JAAM supported clinical research thus far?

Sanjay: The JAAM has been critically important in looking at a number of different therapeutic options that have been available for COVID-19. So we must have assessed probably an excess of at least 15 agents thinking very carefully about: A) whether they would be worth trialing in the context of COVID-19, and then B) where if we thought they were worth trialing, they would fit in, either within the primary care setting in the secondary setting in a hospital or in the intensive care setting.

I think this has been a really important exercise, not only for us that sit in the JAAM committee, but also for drug developers, because this gives us an opportunity to really explore the mode of activity of drugs and the likelihood of response, and then their best fit into an adaptive platform trial, taking into account all their early phase data, too.

We're clearly now at a hiatus. In other words, the COVID-19 pandemic has ceased, so to speak, in terms of a pandemic (COVID-19 is not over), but we now need to think about pandemic preparedness for other infections that will, no doubt, emerge in Europe. I think we've set a platform that will be really useful to be able to do exactly the same for new trials that come through across Europe in the next few years.

[View the interview](#)



**Supporting the
community:
tools, services, and knowledge**

ECRIN's mission is to support the conduct of multinational clinical studies in Europe and to do so beyond collaboration on clinical operations, we work to bolster the clinical research community in a wide variety of ways.

This includes the development and promotion of new trial methodologies; the promotion of open science and FAIR data, through tools that support access and data sharing and reuse; the update and promotion of the ECRIN data centre certification programme; and collaboration with the RI community to stay at the cutting edge.



New trial methodologies

The clinical research landscape is changing at a rapid rate. While the classic randomised clinical trial remains at the core of clinical research, we have seen an evolution in the design, execution and analyses of clinical trial results.

As highlighted in the earlier section, the platform trial, among others, has taken on an increasing space in the advancement of new and repurposed treatments. With this methodology, we can test multiple compounds simultaneously.

An emerging concept is the use of in silico methods which rely on modelling and simulation technology to advance our understanding of the physiological and pharmacological processes involved in drug discovery.



ECRIN has, since the start of the COVID-19 pandemic, had a very active role in the



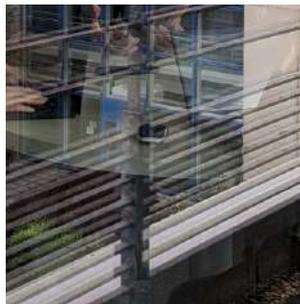
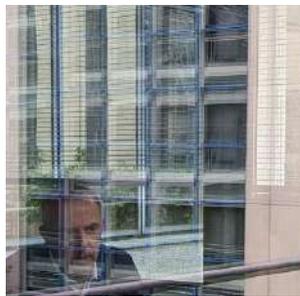
European adaptive platform trials. Its interests, however, were peaked well before this time. In 2019, ECRIN, as a consortium member of EU-PEARL, began to work towards transforming clinical trials to improve their efficiency and make them more patient-centric.

This project, which ended in 2023, with the support of ECRIN, developed many resources and tools to facilitate the implementation of platform trials. Some key outcomes consist of the suite of master protocol templates (master protocol template, intervention specific appendix, statistical analysis plan, data monitoring committee charter template, etc).

Moreover, through the shared work package that initially united the projects RECOVER and EU-RESPONSE, ECRIN was tasked with identifying and organising the accumulated knowledge, experience, and resources from multiple projects and trials into a practical and guided toolbox. The toolbox aims to facilitate the planning and conduct of future adaptive platform trials in any therapeutic area.



The toolbox was redesigned and the contents were updated in the fall of 2023. It now contains over 130 resources. Each tool listed has a brief presentation with an explanation, accompanied by other searchable elements and a direct link to the tool. In the most recent version, users can download the list of references of interest to them and store them for later use.



In 2023, ECRIN took a close look at the decentralised clinical trials and the advantages and challenges of organising trials where the patient does not need to travel (as much) to the trial site. As the theme of International Clinical Trials Day 2023 experts shed their insight on the subject for the benefit of the ECRIN community (more information in the events section).

We also have been contributing to other projects looking at the use of these new methodologies. For example, through canSERV we are working with partners to better support research proposal for complex clinical trials such as platform, basket and umbrella trials.



In the SIMCOR project we are responsible for developing a conceptual framework to model the effects of computer simulation for medical device testing on clinical trial planning and to assess the clinical impact of in-silico trials. This is detailed in the following interview.



Interview on SIMCOR



Maria Panagiotopoulou

Senior project manager

What do we mean by the term “in silico”?

Most scientists are already aware of the terms “in vitro” and “in vivo”. “In vitro” refers to experiments that are conducted in controlled laboratory settings outside of a living organism. They often employ isolated cells, tissues or organs. “In vivo” refers to experiments that are conducted within a living organism such as animals or humans.

The more recent term “in silico” refers to experiments or simulations performed on a computer. In silico techniques can be divided into two broad fields: models that predict only the average behaviour of populations (so-called population-specific) or models that predict the behaviour of each individual in a population (so called subject-specific).

What is an in silico clinical trial?

An in-silico clinical trial refers to the use of individualised computer simulations in a cohort of patients during the development or regulatory evaluation of a medicinal product, medical device, or medical intervention.

Different modelling and simulation methodologies can be used in in-silico trials. Some rely on pure computer science techniques like agent-based modelling and machine learning, while others are rather mathematical approaches like differential equations, finite elements, and regression analyses. In addition, both techniques can be combined in hybrid approaches.

How can in silico methods advance clinical trials in the coming years?

In silico methods are intended to support clinical or pre-clinical study planning in different ways.

- They contribute to the reduction of the duration and sample size of human clinical trials and preclinical animal studies.
- They can also indicate the best and most efficient design of a real clinical trial.
- and provide clearer and more detailed information on potential outcomes, including surrogate endpoints.

- In addition, they can lead to the reduction of adverse events due to predictions on failure patterns and greater explanatory power in detecting and interpreting adverse effects.
- In silico methods can predict long term or rare effects that clinical trials are unlikely to reveal.

Therefore, benefits in terms of clinical trial cost reduction, faster regulatory approval time, faster medicinal product development and reduced time-to-market, but also socio-economic benefits can be expected from a wider adoption of in silico methods in the coming years.

What are the remaining challenges for the wider adoption of in-silico trials?

Despite the promising advancements in the field, several challenges remain:

First, technological limitations, such as computational power, algorithm complexity, and data availability.

Second, the absence of standardised evaluation protocols and quality assurance measures complicates the process of model assessment and validation.

Third, there is currently an unmet need for regulatory guidance.

Fourth, misunderstandings stemming from conflicting terminologies, divergent expectations, and insufficient collaboration hinder progress.

How is the SIMCor project contributing to advancing the adoption of in silico methods?

SIMCor is a three-and-a-half year Horizon 2020 research and innovation action developing a computational platform for in-silico development, validation and regulatory approval of cardiovascular implantable devices. It started in January 2021.

The project's objectives include providing proof of validation for virtual cohorts and computer-based simulations of cardiovascular device implantation and performance. It also focuses on developing standards and protocols for in-silico testing, quantifying the benefits of such testing for healthcare, industry, and society, accelerating the integration of in-silico testing into medical device regulatory approval processes, and contributing to the EOSC by sharing data, virtual cohorts, simulation models, methodologies, standards, and guidelines.

ECRIN is tasked with providing evidence of benefits of in silico trial applications in real-world clinical research.

[View the interview](#)

Advancing data standards and the FAIR principles

This year was marked by some crucial work carried out by ECRIN and other RIs in furthering the adoption of FAIR (Findable, Accessible, Interoperable and Reusable) practices within their organisations and beyond. ECRIN's contribution focuses particularly on these elements as they relate to the sharing and secondary use of health and health research data.

■ **FAIR data resources, tools and trainings in life sciences: zoom in on the EOSC Life**

In 2023 the project focusing on the life sciences component of the European Open Science Cloud (EOSC) came to a close. Within EOSC-Life, ECRIN worked on improving the findability of clinical studies and associated data objects by continuing to build the ECRIN Clinical Research Metadata Repository (crMDR) containing information on more than 700 000 clinical studies and 1 000 000 associated data objects.



To tackle the research reproducibility crisis and accelerate scientific breakthroughs ECRIN designed and developed, together with the



University of Oslo, a secure and GDPR-compliant Clinical Research Data Sharing Repository (crDSR) for the sharing and reuse of individual participant data.

Finally, to help researchers navigate through different regulations, policies, best practices, and recommendations for sensitive data sharing, ECRIN partnered with five other life science infrastructures (EATRIS, BBMRI-ERIC, ERINHA, Euro-Biolmaging, EMBRC) to provide a demonstrator for an [EOSC-Life toolbox for sensitive data sharing](#).



■ **Finalising the Strategic Agenda for the European Health Research and Innovation Cloud**

ECRIN led the development of the Strategic Agenda for the Health Research and Innovation Cloud (HRIC). Developed with researchers, healthcare professionals, industry and policy makers across Europe in mind, the recommendations included five services identified for provision by the HRIC:

- A monitoring service for health-related research
- A legal/regulatory guidance service
- A metadata standards and data interoperability guidance service
- A health research community interface service, with the EOSC
- A health research community interface service, with HealthData@EU

It has been decided that a minimal coordination and orchestration body would be sufficient and minimise the administrative overload. A federated organisation based on existing partners, such as the European RIs is proposed.

■ **Forging the path forward for high quality standards for data management in clinical trials**

The ECRIN Data Centre Certification programme was launched in 2014. Since this time it has confirmed centres' abilities to provide compliant, effective, and efficient data management services for controlled clinical trials.

ECRIN's certification programme assesses the units for compliance with the published ECRIN data standards, performing an audit of the unit's data management activities and the IT infrastructure used to support those activities. To follow the current trends in data management, IT and statistics these standards are revisited as necessary.

Version 5.0 of the 'Requirements for certification of data centres', was released in June 2023 (the first version was produced in 2011, the second in 2012, third in 2015, and fourth in 2018). This latest version results from a review in 2022/2023 by experts and members of ECRIN's Independent Certification Board. The update of the standards was accompanied by training for the ECRIN data centre certification audit team.

Interview on data standards



Will Crocombe

RISG Consulting

Describe the ECRIN Data Centre standards and their use?

The standards have been around for quite a while, and actually originated from work Steve Canham and I did in the UK. They cover information systems and data management and provide practically useful interpretations of regulations and associated guidance.

The regulations are not always easy to interpret and we wanted some pragmatic guidance that would be useful to people who are actually running clinical trials, e.g. how do I secure a server, manage data, or validate bespoke code?

The standards are also used to certify ECRIN data centres themselves.

What was your role and the process used to make this current update?

In previous versions of the standards I had been a member of the review team. We all reviewed the current version and proposed updates in the light of feedback and changes in regulations and guidance. The review lead would coordinate the process, collate updates and draft the new version. For version 5.0 this was my job.

I re-read the current version of the standard, ploughed through all the recent guidance publications from regulators, and also reviewed useful feedback from data centres and auditors. This was quite a big piece of work, because the standards are long and detailed, and because there had been quite a large gap since the previous update – I think three or four years – in part due to COVID.

I updated the standards in the light of the documentation review and feedback, and circulated it to the review team for comments. We had a number of very useful meetings with each member of the team contributing and providing their own views – we had tech experts, researchers and auditors involved.

I tidied up the final version, added a new appendix listing the differences between this and the previous version, and the job was complete.

What are the big changes between version 5 and 4?

There are lots of minor changes but the biggest changes were around device management and statistical programming.

By device management, I mean the computers, the end devices, that people use, and which had been excluded from previous versions of the standards. These devices are often the source of vulnerabilities, hacking attempts etc. Ideally such devices should be managed by an organisation and subject to regular updates and patching, and also securely disposed of.

The second major, and possibly slightly controversial, change is statistical programming. The original guidelines included treatment allocation, but the actual statistical programming of analysis had not been included. If you were programming a database or application, there has long been an expectation of system validation but this had never really been applied to stats. You would spend all this time making sure the data was OK in the way it was collected and processed but when it came to stats, there was limited validation activity. We have introduced the idea of validation of stats software, what this means in terms of the installation and configuration of the software itself, and the writing of the bespoke stats programmes – the code that the statisticians write when they are doing the analysis.

What might be the next elements in version 5.1 or version 6?

I think there will continue to be developments in the approach to validation. When the regulations first came out, the validation of computer systems felt a bit heavy hitting and now there is a drive towards more pragmatic validation methods which I am hoping will continue to evolve.

The much harder thing to deal with will be AI. How this impacts things, we just do not know yet, and there is much activity underway with regulators. My sense of AI is that it is a very good tool for speeding up pattern matching and what humans can do themselves, but not very good at actually *thinking*, and a lot about computer systems and their validation is critical thinking. AI might well speed up creation of computer code though.

It feels that by the time you write guidance on the current situation its already moved on. I think we are probably going to go through a very rapid period of change and it is hard to be certain what the next iteration of the guidance will look like.

Any last thoughts?

I work with a number of trials units in the UK and I regularly recommend people read the standards, because they are pragmatically useful and pretty up to date. I think they are excellent, and not just because I had some part of writing them

Collaboration with the RI community

Research infrastructures (RI) have a clear role in supporting the advancement of science and their capacity to strengthen the European Research Area (ERA) is reinforced by their collaboration. In 2023, ECRIN participated in a large number of projects with other European RIs.

The ERIC Forum II project kicked off in September, otherwise known as the ERIC forum implementation project. It aims to strengthen coordination and networking, reinforcing the ERIC network; support thematic workshops focussing on shared challenges; support ERICs in preparation, based on best practices; and support common communication and outreach activities.



ECRIN will contribute as co-lead with CESSDA to Pillar 2 which focuses on the role of ERICs in European science policy and research strategy, the sustainability of ERICs, alignment with EU policy priorities and visibility, administrative challenges, their international dimension and progress towards the green and digital transition.

To support researchers' access to cutting-edge research services and resources, ECRIN participates in two projects (ISIDORE and canSERV) using the transnational access (TNA) model and developing open calls.

The ISIDORE project contributes to Europe's readiness for any epidemic-prone pathogen through a global, integrated and preparedness-driven approach, by providing free-of-charge access to cutting-edge resources and services to scientific user communities for supporting their research projects in the field of infectious.



Similarly, canSERV aims to defragment the landscape of European cancer research and will enable academia and industry access to cross-cutting services and support from basic science up to clinical translation to foster personalised medicine for cancer patients.

In both projects, ECRIN includes a number of its clinical operation services.



Training

ECRIN's national partners have demonstrated excellence in their ability to increase national capacity with training for the academic research community. ECRIN aims to support them by sharing its expertise across ECRIN Member and Observer countries. It also sees training as an essential means of uniting and building its community.

■ *EU proposal submission training*

ECRIN, together with some of its national partners, based on the experience of its French national partner developed a training dedicated to understanding the proposal submission process for multinational clinical studies.

The “Everything you need to know about submitting a European multinational clinical study proposal” training program was designed as a hybrid training. It consisted of six webinars and an onsite training to be hosted in four different ECRIN countries.

Investigators and project managers in all its member countries could request to attend the full training series or tune in for the webinars individually based on their interest and current understanding of the proposal submission process.

The webinars included:

- **Introduction session**, focusing on Horizon Europe, what it is and how it works.
- **General overview**, covering the different elements of the proposal and key insights for a successful proposal.
- **Regulatory and Ethical frameworks**, explaining the importance of these aspects, data protection and biobanking specifications.

EVERYTHING YOU NEED TO KNOW
**Submitting a European
Multinational Clinical
Study Proposal**



- **Study budget**, sharing the important elements needed to understand the application and some national specificities.
- **Organisation of the study**, highlighting how to include this in the proposal including task breakdown and more.
- **Data management**, showcasing data circulation in a project and the EU expectations for the proposal.

The success of the webinar series is visible from the number of registrations at times surpassing 500, and an attendance rate of over 50% at times.

These webinars will be followed by the onsite training for a select few. The one-day workshops, planned in the early months of 2024, will include use cases, additional information on the lump sum proposals and group work on the development of different elements of the proposal.

■ **CTU Day**

ECRIN also provides dedicated training to its CTU community through its scientific meeting series and most notably its annual CTU Day.

At CTU Day 2023, ECRIN focused on ensuring a solid understanding of its services, showcased its Irish and Norwegian national partners, and provided a continued emphasis on the Clinical Trial Information System (CTIS) with the latest updates provided by ECRIN's representative on the Clinical Trial Regulation Implementation working group.



■ *ECRIN staff training*

ECRIN continues to ensure new staff is up to speed through dedicated induction training. To support ongoing training needs the annual summer school, which this year was held conjointly with the ECRIN 10th anniversary in Paris, included focuses on the new lump sum funding model, literature review methods and platform trial methodology. A one-day workshop on leadership, critical thinking and problem-solving was topped off with a side of culinary adventure by our international team.

Events by ECRIN

2023 was assuredly a big year for ECRIN, with an event to mark its 10th anniversary (featured on page 12). This brought together ECRIN's staff, boards and some key collaborators from ECRIN's creation.

The larger clinical research community was, as always, invited to ECRIN's annual event, International Clinical Trial Day (ICTD). ECRIN also took on the organisation of project meetings, among which was a larger gathering uniting targeted members of the clinical research community with the European funders of clinical studies.



■ **ICTD 2023: Decentralised Clinical Trials - Challenges and Opportunities**

ECRIN, together with our Polish national partner, PCTN, represented by the Polish Medical Research Agency, organised ICTD 2023 in Warsaw, Poland. ICTD 2023 was a hybrid event focusing on Decentralised Clinical Trials: Challenges and Opportunities.

It was held in the heart of Warsaw and was also broadcast online. It brought together 700 stakeholders from the international clinical research community, from across Europe and the globe, with registered participants representing over 50 different nations and all continents.

Decentralised clinical trials are a hot topic at the moment, in the wake of the COVID-19 pandemic where classical trial modalities were not necessarily possible, where regulators made exceptional allowances and where funding was available, this trial methodology got the added boost needed to be launched to the forefront.

As a result, it was without hesitation that we proposed an exciting lineup of speakers to enable an open discussion from the different perspectives of the clinical research community.

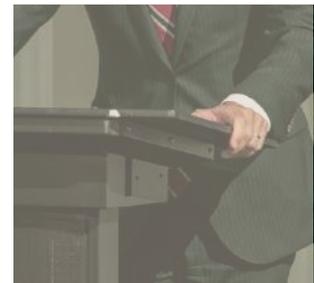




Some of the overarching conclusions of the day include:

- The importance of clear communication with all stakeholders. This involves communication with patients but also all the new stakeholders engaged in the trial, from the logistics through to data aspects.
- The use of technology can facilitate the implementation of the decentralised clinical trial - from electronic consent to devices that feedback data directly, or online questionnaire forms - but the selection of these tools must be made carefully and requires support from all stakeholders from beginning to end.

- The potential of decentralised trials to provide a more patient centric approach facilitating their participation in the trial in some cases from recruitment through to retention.



ERA4Health workshop: Bottlenecks and Challenges for Investigator Initiated Clinical Studies (IICS)

ECRIN had the honour of hosting the first ERA4Health Partnership-organised face-to-face workshop in Paris on September 14th & 15th. More than 65 participants came together to discuss the challenges in planning and designing IICs. They included representatives from the different institutions of the ERA4Health consortia and other relevant stakeholders, such as sponsors, investigators, EMA/ACT-EU and European Medicine Agencies, ethics committees, methodologists, and the European Commission.

The workshop kicked off with a presentation of the initial version of the report on obstacles and challenges to the planning and conduct of IICs which was based on a systematic literature



review. The findings were supplemented throughout the day with the feedback of different stakeholders who ensure the implementation of multinational clinical trials.

Over the second day the focus shifted to the advantages and difficulties associated with new trial methodologies such as basket, umbrella and platform trials, trials within cohorts (TWiCs) and decentralised trials.

It is expected that the work carried out over these two days will contribute to one of the main objectives of ERA4Health, establishing a framework to support multinational IICs.





**Operations, key
players and budget**

ECRIN adapting to the changing landscape

Taking into account the variety of activities described in the previous pages and the celebration of its 10th anniversary, it is clear that ECRIN continues to align its ambitions with its vision.

It works continuously to guarantee the necessary quality that is required in the highly regulated world of clinical trials and moves beyond to support new ways to use and reuse clinical study data and assist researchers taking on clinical study tasks.

To align these actions, it is important to evaluate our activities through regular monitoring and consider how to move forward by means of careful planning.

■ **ISO 9001:2015 certification renewed**

After an initial certification in 2020 by the French Association for Standardisation (AFNOR), this year marked a new certification cycle for ECRIN where in it has confirmed its ISO 9001:2015 for its principal services and quality management system.



The certification is concerns ECRIN's principal services: the coordination of operational services to the management of multinational clinical trials in Europe by the EuCos and core team, the capacity development through the participation in infrastructure development projects and the certification of data centres.

Among the key principles of the ISO 9001:2015 certification are the importance of the customer focus, the strength of the leadership, strong stakeholder relationship management and the engagement of competent staff, which are all important to ensure ECRIN continue to respond to the demands of the clinical research community.

The applied process-based approach enables the capacity to identify and act on areas of improvement as well as advance the system through evidence collection. The quality management system will continue to implement improvements to further these results and prepare for the upcoming follow-up audit in 2024.

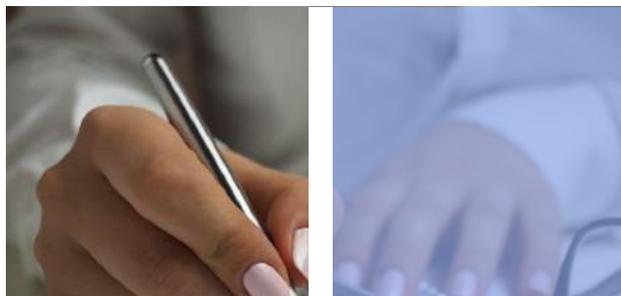
■ **Monitoring of ESFRI Landmarks**

In 2016 ECRIN was among the first RIs to attain the ESFRI Landmark status. As with the others who hold this title, it demarcates ECRIN as an RI of reference and a pillar in the ERA landscape, offering not only services to academic research but also supporting development and innovation.



To sustain further progress of the Landmarks and to achieve new insights into the functioning of the European RI ecosystem, ESFRI assigned a monitoring committee with the task of conducting a monitoring of all operational ESFRI Landmarks. ECRIN was among the first 12 Landmarks to undergo the monitoring, which took place in the first half of 2023.

ECRIN management worked hand in hand with the assigned monitors to ensure that the breadth of ECRIN's activities and ambitions were clearly understood. This led to a constructive discussion and useful suggestions to boost ECRIN's recognition further in the future.



■ **Increasing involvement in EU-wide initiatives**

ECRIN's role as a representative of the academic clinical trials community continues to be recognised as it is increasingly brought on to support the voice of this community in various EU-wide initiatives.

ECRIN is a member of the Multi-Stakeholder Platform Advisory Group, part of Accelerating Clinical Trials in the European Union (ACT-EU). The ACT-EU initiative will support smarter clinical trials through regulatory, technological and process innovation. Its vision is to transform the EU into a region that fosters clinical trial development and enables collaboration and innovation at all stages of the clinical research lifecycle.

Similarly, ECRIN is a permanent member of the ACT-EU group focussing on the implementation of the Clinical Trial Regulation.

Beyond these groups, ECRIN is also involved in more focused initiatives, the EFGCP eConsent initiative, for example, is developing a practical guideline for various aspects as they relate to eConsent, and the EU Cross-Border Clinical Trials initiative aims to systematically collect available information from all European countries and to develop recommendations for enabling cross-border access to clinical trials.



■ **Moving toward the new strategic plan**

The current ECRIN strategic planning period, 2021-2023, comes to a close and is marked by many achievements which allowed ECRIN to develop its capacity and increase its visibility and recognition of its expertise as has been highlighted in the pages of this review of 2023.

Throughout this three-year period, ECRIN successfully enhanced its collaboration with its national partners and optimised its internal processes as confirmed by the renewal of the ISO 9001:2015 certification. ECRIN also increased its involvement with regulators through participation in initiatives such as ACT-EU.

ECRIN's visibility has significantly grown in recent years, thanks to a revamped brand identity, website, and communication tools. The International Clinical Trials Day's audience and reach have expanded significantly following the adoption of a hybrid organisation.

A sustainable partnership has been established with EUPATI and will be the basis for our patient engagement activities at European and country levels. ECRIN continues to work with its partners in the European Alliance of Medical Research Infrastructures (EU-AMRI) and is pleased to see increasing activity between the three infrastructures at country level. Through the ERA4Health partnership ECRIN is building with

fundors support mechanisms for funding IICS.

The partnership with the user and medical communities is supported by participation in joint projects (c4c for paediatrics, EJP-RD for rare diseases, CoMeCT for infectious diseases, etc.) and by the development of dedicated national networks in several ECRIN countries.

The COVID-19 outbreak was an opportunity to demonstrate the capacity of ECRIN to rapidly adapt to a new research environment under a public health emergency. This resulted in the establishment of the COVID-19 taskforce and ECRIN's participation in the design and management of various platform trials on COVID-19 treatments and vaccines.

The achievements of the past three years have positioned ECRIN for an ambitious new strategic agenda.

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

ECRIN Team

Core Team

Marta Bastucci	Executive Assistant
Sergio Contrino	Head of Data Projects
Marta del Alamo	Head of Capacity Projects
Jacques Demotes	Director General
Martina Esdaile	Communications Officer
Paula Garcia	Project Manager
Sareema Javaid	Clinical Project Manager
Sarah Karam	Communications Assistant
Swarnalathaa Kichenassamy	Software Engineer
Takoua Khorchani	Data Scientist
Christine Kubiak	Operations Director
Aafke 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
Golbahar Pahlavan	Head of Infrastructure Development Projects Unit
Maria Panagiotopoulou	Senior Project Manager
Sara Raza-Khan	Project Manager
Maria Alexandra Rujano	Project Manager
Arthur Smaal	Quality Officer
Alicja Szofer-Araya	Head of Administration and Finance
Keiko Ueda	Clinical Scientist
Biljana Zafirova	Clinical Project Manager

European Correspondents

Kateřina Nebeská	Czech Republic
Lenka Součková	Czech Republic
Kristýna Nosková	Czech Republic
Jimena Bouzas	France
Sarhan Yaiche	France
Linda Stöhr	Germany
Neshat Chareh	Germany
Thomas Chatzikonstantinou	Greece
Zsolt Szabó	Hungary
Niall Hore	Ireland
Maria Buoncervello	Italy
Elena Toschi	Italy
Maria Josefina Ruiz Alvarez	Italy
Sigrun Margrethe Hjelle	Norway
Patrycja Klusek	Poland
Maciej Janiec	Poland
Joana Batuca	Portugal
Simona Sonderlichová	Slovakia
Stefan Toth	Slovakia
Miriam Rol Garcia	Spain
Caecilia Schmid	Switzerland

** Note: the staff lists include individuals who started working for ECRIN in 2023, as well as those who left the organisation*

Experts and Consultants

Steve Canham	Data Project Manager
Harrie Elzinga	Communication Consultant
Gerd Felder	Clinical Research Repository Manager
Sergei Gorianin	Data Scientist
Sabine Klager	Regulatory Expert
Christian Ohmann	Data Management Expert
Dr Joaquin Saez-Penataro	Medical Expert

In 2023 a big change, with a significant impact, particularly on the 24 core team staff located in Paris was the move to the new ECRIN headquarters. ECRIN now has its own offices, with a large open space for the staff to exchange and advance together as well as multiple meeting rooms to host the in country teams when they come for our regular meetings.



Boards

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 2023 it welcomed a new Vice-Chair, Oonagh Ward.

Rafael de Andrés	Chair (Spain)
Oonagh Ward	Vice-Chair (Ireland)
Marta Vandrovцова	Czech Republic (end of term)
Dalibor Valik	Czech Republic
Judita Klosakova	Czech Republic (new member)
Eric Guittet	France (end of term)
Catherine Le Chalony	France (new member)
Svenja Krebs	Germany
Eva Muller Fries	Germany
Kostas Stamatopoulos	Greece
Julianna Pantya	Hungary
Maria Ferrantini	Italy
Øyvind Melien	Norway
Agnieszka Ryniec	Poland
Andreia Feijão	Portugal (end of term)
Marta Abrantes	Portugal (new member)
Daniel Pella	Slovakia
Rosario Perona Abellon	Spain (new member)
Maria Pilar Gayoso	Spain (end of term)
Barbara Flueckiger	Switzerland

Additional Organisational Bodies

■ Network Committee

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

Christian Ohmann	Chair (Germany)
Regina Demlová	Vice-chair (Czech Republic)
Christine Trillou	France
Olivier Rascol	France
Britta Lang	Germany
Kostas Stamatopoulos	Greece
Judit Tarnai	Hungary
Fionnuala Keane	Ireland (end of term)
Robert O'Connor	Ireland (new member)
Elena Toschi	Italy
Camilla Tondel	Norway
Lukasz Szumowski	Poland
Emília Monteiro	Portugal
Daniel Pella	Slovakia
Antonio Carcas	Spain (end of term)
Alberto Borobio	Spain (new member)
Anja Eskat	Switzerland

Governance Meetings in 2023

Assembly of Members (AOM)

23 January 2023

22 May 2023

5 July 2023

15 September 2023

30 November 2023

20 December 2023

Network Committee

22 May 2023

29 November 2023

Scientific Board (SB)

The Scientific Board Secretariat is run by Dr. Joaquin Saez-Penataro who was reelected for a new term (2023-2025)



SB - Collaboration Committee

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

Sabine Klaber	Chair
Joaquin Saez-Penataro	Member
Amélie Michon	Member
Jacques Demotes	Member
Christine Kubiak	Member
José Delgado Alves	Observer
Takoua Khorchani	Observer

SB - Peer Review Committee

The Peer Review Committee of the ECRIN Scientific Board is composed of external experts who provide their expert feedback on the full protocols upon request. All members have been confirmed to continue for a three year term (2023-2025)

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

Financial Report 2023



INCOME

Membership Core contributions	1 470 000 €
Membership Local contributions	1 100 000 €
Research projects	2 423 696 €
Other income	728 €
Financial income	121 809 €

TOTAL INCOME FOR 2023 **5 116 233 €**

EXPENDITURES

Salaries & staff expenses	2 202 290 €
Subcontracting	917 607 €
Office rent and insurance	157 716 €
Communication & IS	206 079 €
Travel and meetings	223 131 €
Real estate transfer tax	227 733 €
Amortisation	71 208 €
Financial expenses	74 558 €
Other expenses	110 526 €
Income tax	28 654 €
Local contribution provided in-kind	1 000 000 €

TOTAL EXPENDITURE FOR 2023 **5 219 502 €**

NET RESULT

NET RESULT FOR 2023 **-103 269 €**

* 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

Annexes

Annex 1: Acronyms

A

ACT-EU: Accelerating clinical trials in the EU

AFNOR: Association Française de Normalisation

AI: Artificial Intelligence

AICIB: Agency for Clinical Research and Biomedical Innovation

AoM: Assembly of Members

APT: Adaptive Platform Trials

APIFARMA: Portuguese Association of Pharmaceutical Industry

B

BBMRI: Biobanking and Biomolecular Resources Research Infrastructure

BIOTOOL-CHF: BIOMarker based diagnostic TOOLkit to personalize pharmacological approaches in congestive heart failure

C

canSERV: Providing Cutting Edge Cancer Research Services Across Europe

CERTH: The Centre for Research & Technology, Hellas

CESSDA: Consortium of European Social Science Data Archives

CLIC: Clinical Investigator Certification

CoMeCT: Coordination Mechanism for Cohorts and Trials

COVID-19: Coronavirus Disease 2019

CRA: Clinical Research Associates

crDSR: Clinical Research Data Sharing Repository

CRFs/CRCs: Clinical research facilities/Clinical research centres

CRIGH: Clinical Research Initiative for Global Health

crMDR: Clinical Research Metadata Repository

CRO: Clinical Research Organisation

CSSO: Clinical Studies Support Office

CTIS: Clinical Trial Information System

CTU: Clinical Trial Unit

CZECRIN: Czech Clinical Research Infrastructure Network

D

DONets: Disease Oriented Networks

E

EATRIS: European Advanced Translational Research Infrastructure in Medicine

ECRAID-Prime: European Clinical Research Alliance for Infectious Diseases Prime

eCRF: Electronic Case Report Form

ECRIN: European Clinical Research Infrastructure Network

EFGCP: European Forum for Good Clinical Practice

EJP-RD: European Joint Programme on Rare Diseases

EMA: European Medicines Agency

EOSC-Life: European Open Science Cloud Life project

ERA: European Research Area

ERA4Health: European Research Area for Health Research

ERIC: European Research Infrastructure Consortium

ESFRI: European Strategy Forum on Research Infrastructures

EU: European Union

EU-Africa PerMed: Building links between Europe and Africa in personalised medicine

EU-AMRI: European Alliance of Medical Research Infrastructures

EUCLID: EUropean CLInical Trials Platform & Development

EuCo: European Correspondent

EUPATI: European Patients' Academy on Therapeutic Innovation

EU-PEARL: EU-Patient Centric Clinical Trial Platforms

EuroGCT: European Consortium for Communicating Gene and Cell Therapy Information

EU-RESPONSE: European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases

F

F-CRIN: French Clinical Research Infrastructure Network

FAIR: Findable Accessible Interoperable, and Reusable

FCT: Foundation for Science and Technology

G

GCP: Good Clinical Practice

GDPR: General Data Protection Regulation

GreCRIN: Greek Clinical Research Infrastructure Network

H

HCP: Health Cluster Portugal

HealthyCloud: Health Research and Innovation Cloud

HECRIN: Hungarian Clinical Research Infrastructure Network

HNHRA: Hungarian National Health Research Agency

HRB: Health Research Board

HRB NCTO: Health Research Board National Clinical Trials Office

HRIC: Health Research and Innovation Cloud

HRO: Human Research Ordinance

HTA: Health Technology Assessment

I

ICTD: International Clinical Trials Day

IICT: Investigator Initiated Clinical Trials

IICS: Investigator Initiated Clinical Studies

INFARMED: National Authority for Medicament and Health Products

INVENTS: Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs

IRFMN: Mario Negri Institute for Pharmacological Research

IRCCS: Istituto di Ricovero e Cura a Carattere Scientifico

ISCIH: 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

ITEMAS: Platform for Innovation in Medical and Health Technologies

J

JAAM: Joint Access Advisory Mechanism

K

KKSN: Netzwerk der Koordinierungszentren für Klinische Studien

L

LEOPARD: Liver Electronic Offering Platform with Artificial Intelligence-based Devices

LIVERATION: Unravelling the impact of radiofrequency in liver surgery

M

MORPHEUS: Prognosis improvement of unprovoked venous thromboembolism using personalised anticoagulant therapy

MRA: (Polish) Medical Research Agency

N

NCTO: National Clinical Trials Office

NICOFA: A randomized, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of nicotinamide in patients with Friedreich's Ataxia

NorCRIN: Norwegian Clinical Research Infrastructure

NSS: Networking Social Scheme

O

OKFŐ: National Directorate General of Hospitals (Hungary)

ORTHO-ALLO-UNION: ORTHOpaedic treatment with ALLOgenic combined ATMP in long bone fracture delayed UNION and non-union

OTBB3: Oxytocin Treatment in Neonates and Infants With Prader-Willi Syndrome

P

PCTN: Polish Clinical Trials Network

PedCRIN: Paediatric Clinical Research Infrastructure Network

PERMIT : Personalised Medicine Trials

PPI: Patient and Public Involvement

PtCRIN: Portuguese Clinical Research Infrastructure Network

R

RECOVER: Rapid European COVID-19 Emergency research Response

REMEDi4ALL: Building a sustainable European innovation platform to enhance the repurposing of medicines for all

RI: Research infrastructure

RNIE: Portuguese Roadmap of Research Infrastructures

S

SB: Scientific Board

SB-CC: Scientific Board Collaboration Committee

SB-PRC: Scientific Board Peer Review Committee

SCReN: Spanish Clinical Research Network

SCTO: Swiss Clinical Trial Organisation

SERI: Secretariat for Education, Research and Innovation

SIMCOR: In-Silico testing and validation of Cardiovascular Implantable devices

SLOVACRIN: Slovak Clinical Research Infrastructure Network

SME: Small and Medium-sized Enterprise
SOP: Standard Operating Procedure

T

TCB: Trial Coordination Board
TNA: Transnational Access
TWiC: Trials Within Cohorts

U

UK: United Kingdom

V

VACCELERATE: European Corona Vaccine Trial Accelerator Platform

W

WG: Working Groups
WHO: World Health Organisation

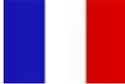
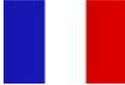
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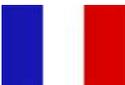
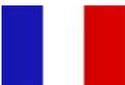
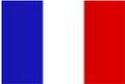
ZKS: Clinical Trials Unit

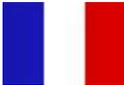


Annex 2: Clinical Trial Portfolio in 2023 (current trials)

Throughout 2023 ECRIN provided support to 34 studies. At the end of the year 5 were in the set-up phase working towards the opening of all sites in all the participating countries, 16 were active meaning in the phase of recruitment (running), 8 were in completion mode (running), 4 were completed and 1 withdrew its request for ECRIN services.

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*
LEOPARD	Liver Electronic Offering Platform with Artificial intelligence-based Devices	Start up phase		101080964*
LIVERATION	Unravelling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?	Start up phase		101104360*
MORPHEUS	Prognosis improvement of unprovoked venous thromboembolism using personalised anticoagulant therapy	Start up phase		101095698*
ORTHO-ALLO-UNION	ORTHOpaedic treatment with ALLOgenic combined ATMP in long bone fracture delayed UNION and non-union	Start up phase		101137464*
CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	Running		German government
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults	Running		101015736°
ETAPA	Randomised Placebo-Controlled Trial of Early Targeted Treatment of Patent Ductus Arteriosus with Paracetamol in Extremely Low Birth Weight Infants	Running		Irish government
EU-COVAT-1	A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults (≥75) already Vaccinated Against SARS-CoV-2	Running		101037867°

EU-COVAT-2	An International Multicentre, Phase 2, Randomised, Adaptive Protocol to determine the need for, optimal timing of and immunogenicity of administering a 3rd homologous mRNA vaccination dose against SARSCoV-2 in the general population (18+ years) already fully vaccinated against SARS-CoV-2	Running		101037867°
EU-TRAIN RCT (IMPACT)	Randomized Controlled Multicenter Trial to quantify the benefits of biomarkers in routine patient care in kidney transplant recipients	Running		754995°
EU-TRAIN COHORT	Prospective cohort of kidney transplant patients	Running		754995°
IDEA-FAST COS	Identifying Digital Endpoints to Assess FATigue, Sleep and acTivities daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases	Running		IMI2 853981°
ImmunAID	Immunome project consortium for AutoInflammatory Disorders	Running		779295°
INFORM2 NIVENT	INFORM2 exploratory multinational phase I/II combination study of Nivolumab and Entinostat in children and adolescents with refractory high-risk malignancies	Running		Industry & German government
LIVERHOPE EFFICACY	Efficacy of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis to prevent ACLF development: a multicenter, double-blind, placebo controlled randomized clinical trial	Running		731875°
MACUSTAR	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention	Running		IMI 116076°
NECESSITY	NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifying patients	Running		IMI 806975°
NISCI	Antibodies against Nogo-A to enhance plasticity, regeneration and functional recovery after acute spinal cord injury, a multicenter international randomized double-blinded placebo-controlled Phase II clinical proof	Running		681094°

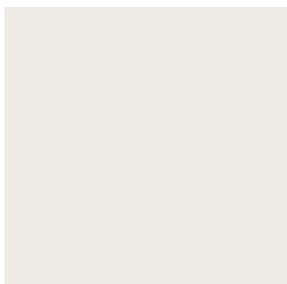
PAPA-ARTIS	Paraplegia Prevention in Aortic Aneurysm Repair by Thoracoabdominal Staging with ‘Minimally-Invasive Segmental Artery Coil-Embolization’: A Randomized Controlled Multicentre Trial	Running		733203°
PROOF	Penumbral Rescue by Normobaric O ₂ Administration in Patients With Ischaemic Stroke and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

PRECIOUS	Prevention of Complications to Improve Outcome in Elderly Patients with Acute Stroke	Completed	 	IMI 777389°
SWEET	Sweeteners and sweetness enhancers: Impact on health, obesity, safety and sustainability	Completed	 	774293°
TB MED BIOCERAMED	Prospective Multicenter Observational Study on the use of NEOCEMENT® for the Treatment of Bone Defects-Registry-based study	Completed		210487722°
TERIS	Multi-center, randomized, double-blinded study of Teriflunomide® in radiologically isolated syndrome (RIS)	Completed	 	Industry
SeeMyLife	Holistic mixed approaches to capture the real life of children with Rare Eye Diseases	Withdrawn	 	Joint Translational funding



° 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 2023

Throughout 2023 ECRIN provided support to 29 projects, 3 of which were launched over the course of the year.

Acronym	Full name	Status end 2023	Logo	Funding source
B1MG	Beyond 1 Million Genomes	Ended		951724°
BY-COVID	BeYond-COVID	Running		101046203*
canSERV	Providing Cutting Edge Cancer Research Services Across Europe	Running		101058620*
CoMeCT	Coordination Mechanism for Cohorts and Trials	Running		101136531*
c4c	conect4children	Running		777389°
CRIGH	Clinical Research Initiative for Global Health	Running		Member contributions
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	Running		101058427*
EOSC Future	European Open Science Cloud Future	Running		101017536°
EOSC-Life	Providing an open collaborative space for digital biology in Europe' – 'EOSCLife'	Ended		824087°
ERA4Health	Fostering a European Research Area for Health	Running		101095426*
ERIC-Forum II	ERIC-Forum Implementation project II	Running		101124559*
EU-Africa PerMed	Building links between Europe and Africa in Personalised Medicine	Running		964333°
EU-PEARL	EU Patient cEntric clinical tRial pLatform	Ended		853966-2°
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°
HealthyCloud	Health Research and Innovation Cloud	Ended		965345°
ISIDORe	European consortium for communicating gene- and cell-based therapy information.	Running		101046133*

RECOVER	Health Research and Innovation Cloud	Ended		101003589°
REMEDi4ALL	Building a sustainable European innovation platform to enhance the repurposing of medicines for all	Running		101057442*
SENSITISE	Inclusive Clinical Trials: Training and Education to Increase Involvement of Under-Served Groups	Running		2023-1-IE02-KA220-HED-0001589532**
SIMCOR	In-Silico testing and validation of Cardiovascular Implantable devices	Running		1101017578°
TB MED	A testing bed for the development of high-risk medical devices	Ended		814439°
TESA III	Trials of Excellence in Southern Africa III	Running		EDCTP - GA 2020NoE-3104TESAIII
TRANSVAC DS	Design study for a European vaccine infrastructure	Ended		951668°
TRANSVAC2	European Vaccine Research and Development Infrastructure	Ended		730964°
VACCELERATE	European Corona Vaccine Trial Accelerator Platform	Running		101037867°



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

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

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

2023 Publications

- Aydin, B., Kiely, E., & Ohmann, C. (2023). Feasibility Assessment of Using CDISC Data Standards for In Silico Medical Device Trials. *Journal of the Society for Clinical Data Management*, 3(3). <https://doi.org/10.47912/jscdm.230> SIMCOR
-
- Balligand, J.-L., Brito, D., Brosteanu, O., Casadei, B., Depoix, C., Edelmann, F., Ferreira, V., Filippatos, G., Gerber, B., Gruson, D., Hasenclever, D., Hellenkamp, K., Ikonomidis, I., Krakowiak, B., Lhommel, R., Mahmood, M., Neubauer, S., Persu, A., Piechnik, S., ... Pouleur, A.-C. (2023). Repurposing the β 3-Adrenergic Receptor Agonist Mirabegron in Patients With Structural Cardiac Disease: The Beta3-LVH Phase 2b Randomized Clinical Trial. *JAMA Cardiology*, 8(11), 1031–1040. <https://doi.org/10.1001/jamacardio.2023.3003> Beta3-LVH
-
- Bendszus, M., Fiehler, J., Subtil, F., Bonekamp, S., Aamodt, A. H., Fuentes, B., Gizewski, E. R., Hill, M. D., Krajina, A., Pierot, L., Simonsen, C. Z., Zeleňák, K., Blauenfeldt, R. A., Cheng, B., Denis, A., Deutschmann, H., Dorn, F., Flottmann, F., Gellißen, S., ... Zubel, S. (2023). Endovascular thrombectomy for acute ischaemic stroke with established large infarct: multicentre, open-label, randomised trial. *The Lancet*, 0(0). [https://doi.org/10.1016/S0140-6736\(23\)02032-9](https://doi.org/10.1016/S0140-6736(23)02032-9) TENSION
-
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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**

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