ecrin

Supporting
clinical studies
across borders

ANNUAL REPORT 2022

Czech Republic
Masaryk University
Brno

France
INSERM
Toulouse

Germany
KKS-Netzwerk e.V
Berlin

Hungary
Hungarian National Health
Research Agency
Budapest

Ireland
National Clinical Trials Office
Cork

Italy
Istituto Superiore di Sanita
Rome

Norway
Haukeland University
Hospital
Bergen

Poland
Polish Medical Research Agency
Warsaw

Portugal
NOVA University
Lisbon

Slovakia
Pavol Jozef Šafárik University
Košice

Spain
Instituto de Investigación del
Hospital Universitario La Paz
Madrid

Switzerland
SCTO
Bern

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Forewords

Jacques Demotes, Director General

2022 was another big year for ECRIN, with actions covering all domains from trial management, support to infrastructure projects, communication and outreach, and new opportunities arising on the horizon. We also had the opportunity to bring our staff and the clinical research community together in person to discuss essential and innovative aspects of clinical research. We continued to develop our clinical trial portfolio and support the COVID-19 platform trial coordination through the joint access advisory mechanism.

This year also marked the end of the ECRIN coordinated PERMIT project which brought about over 70 recommendations from across the personalised medicine pipeline to address the current gaps in the research and regulatory landscape.

EU-AMRI, the European Alliance of Medical Research Infrastructures that brings together BBMRI-ERIC, EATRIS-ERIC, and ECRIN-ERIC was officially launched in April of this year. Together with other key stakeholders, on stage for a live broadcast, the Directors of the three infrastructures discussed the direction the Alliance will take. EU-AMRI and ECRIN were present at ICRI 2022, held in Brno. Moreover, ECRIN participated in many different panels at ICRI 2022 ensuring that the needs for an ecosystem that enables and empowers academic investigators to conduct multinational trials were shared.

Towards the end of the year ECRIN embarked on a new strategic project for the funding of clinical studies, ERA4Health. In this project, ECRIN is responsible for contributing to updating the Strategic Research and Innovation Agenda with multinational Investigator Initiated Clinical Trials (IICTs). With the Italian Ministry of Health, eligibility and selection procedures will be defined, as well as, detailed rules for the funding of IICTs.

In short, after an extremely busy and productive year by ECRIN and its growing team, a new and ambitious line up of projects and activities will be setting the tone for 2023.

Christine Kubiak, Operations Director

In 2022 we continued to develop our support to the clinical research community through our services to multinational clinical studies to confirm ECRIN's position as the research infrastructure for high quality multinational clinical research. To stay at the leading edge in the domain, we also supported the development and improvement of our tools, services, and knowledge through new and existing projects in strategic areas such as drug repurposing, sharing and reuse of clinical and healthcare data.
The continued efforts of our team to ensure the best quality service has led to the confirmation of our ISO 9001:2015 certification. To support training on this and other elements of the organization, we were thrilled to finally unite our staff for the first summer school in over two years. The event was hosted by our Italian partner and provided an essential opportunity to integrate new team members and, to develop and maintain the link of our distributed team.
Similarly, for the greater clinical research community and our boards, we celebrated International Clinical Trials Day in person. This year, the event focused on recruitment in clinical trials. It was a hybrid event located in Berlin and co-hosted by our German partner, the KKS Netzwerk. Throughout the day, many key challenges were underscored including the importance of patient engagement, piloting small studies for proof of concept, development of trials through patient cohorts, better established trial networks, increase investment in trial methodology infrastructure and evidence, the use of new trial design, and the leveraging of technology to improve trial recruitment.
To support the strategic goal on enhancing the recognition of ECRIN's brand identity a corporate video was developed with the support of key players in our larger community. Moreover to facilitate access to the information on our organization and to better align with the times a new website was launched at the end of the year.

Amélie Michon, Head of Clinical Operations

The year 2022, was a big one for the ECRIN CTU community. It saw significant growth in the number of CTUs in the ECRIN network, which now counts over 120. The clinical study portfolio progressed with many studies moving from the startup phase to running and ten new proposals were supported and submitted for funding.

A key moment for clinical trials this year was the official launch of the new Clinical Trial Regulation on 31 January 2022. While not an obligatory step for clinical trials at this point, many of the first clinical trials to be approved using the new Clinical Trial Information System (CTIS) were academic, including two ECRIN coordinated trials which were the first multinational clinical trial to transition from EudraCT to CTIS, EU-SolidACT and the first academic multinational trial approved directly in CTIS, TTV Guide.

To support the CTU community we hosted the 2nd annual CTU Day bringing together members from our CTUs in all ECRIN countries. This year, given the context, the focus of the meeting was on the implementation of the new Clinical Trial Regulation. Moreover, working with our CTUs and sponsors we have been gaining meaningful insights and feedback on the use of CTIS and tips and tricks as well as identifying areas of vigilance.

In closing, I would like to extend a special thanks to Sabine Klager who stepped down as Head of Clinical Operations at the end of 2022 providing me with a solid portfolio to pilot into the next year.

Rafael de Andrés, Chair, Assembly of Members & Maria Ferrantini, Vice-chair, Assembly of Members

ECRIN marked another successful year demonstrating its capacity to adapt to the evolving needs of the European clinical research community. New projects were accepted, successful projects have left their mark and the principle services offered by ECRIN's staff are recertified ISO 9001:2015.

We have learnt to telework and host online meetings. These precious tools have both become common practice but what a pleasure to finally be able to meet again in person! The Assembly of Members meeting hosted in Berlin, Germany, which coincided with International Clinical Trials Day, saw some very exciting developments including the official application request by Poland to upgrade from Observer to full Member. This application was welcomed by the Network Committee, approved by the Assembly of Members on 30 September 2022, and became a reality on November 17th during the Polish Medical Research Agency meeting hosted in Warsaw: "An impulse for the development of science, health and innovation."

The ECRIN national scientific partners continue to work in close collaboration on a variety of different ECRIN coordinated working groups and taskforces. This year saw the creation of the taskforce for the development of key performance indicators. In alignment with the ESFRI KPIs, this taskforce is continuing to support revisions to adapt them to ECRIN's particular circumstances and to ensure that they are measurable and relevant.

ECRIN's involvement in the development of the Strategic Agenda for the Health Innovation Research Cloud, and its participation in the European Open Science Cloud are just two, among many other projects, that look to create a secure environment to encourage clinical data reuse and sharing.

The changing regulatory, ethical, and technical environment is opening new doors for ECRIN. The increased recognition of the actions at ECRIN, as seen through the enhanced relationship with stakeholders, the continued growth of the portfolio and the capacity to adapt, highlight many of the strengths of ECRIN.

2022 Highlights

January
- RI-VIS Final Meeting
- ERIC Forum Policy Brief release: Scaling-up Research Projects Through ERICs: Impact of Big Science on the Research Ecosystem

February
- Kick off of ISIDORe

March
- PERMIT Implementation workshop

April
- EU-AMRI Launch in Brussels
- First academic multinational clinical trial approval using CTIS – EU-SolidAct

May
- International Clinical Trials Day 2022 - Recruitment in Clinical Trials
- ECRIN unveils its corporate video

June
- Launch of the EJP-RD Rare Diseases Clinical Trial Toolbox
- PERMIT project Final meeting

July

August

September
- Kick off of REMEDi4ALL
- Kick off of CanSERV
- ItaCRIN hosts ECRIN Summer School in Rome
- Kick off of EOSC4Cancer

October
- Quality and Risk Council Meeting
- ECRIN attends ICRI 2022
- EJP-RD Networking Social Scheme Workshop on Identifying obstacles hindering the development of academic-sponsored trials for drugs repurposing on rare diseases.
- ERIC Forum Policy Brief release: Assessing the socio-economic impact of ERICs

November
- Kick off of eCREAM
- EULAC PerMed Technical Workshop
- Poland announces ECRIN Member status
- ECRIN confirmed its ISO 9001:2015 certification for its principal services

December
- ECRIN CTU Day
- ECRIN reveals its new website
- Launch of public-private initiative Rare Disease Moonshot

Mission, Vision, Focus Areas

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 in numbers

9
years that ECRIN has had ERIC status

10
Member countries

2
Observer countries

120+
CTUs

349M
number of European citizens in ECRIN Member and Observer countries

17
European Data Centres certified since 2014

35
number of trials supported by ECRIN throughout 2022

6.5
average number of countries per ECRIN supported trial

32
number of infrastructure development projects supported by ECRIN throughout 2022

1575
Twitter followers (+18%)

3126
LinkedIn followers (+62%)

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 SME led clinical studies in Europe. ECRIN is a distributed 'research infrastructure' (see highlighted text) that unites national networks of clinical trial units 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.

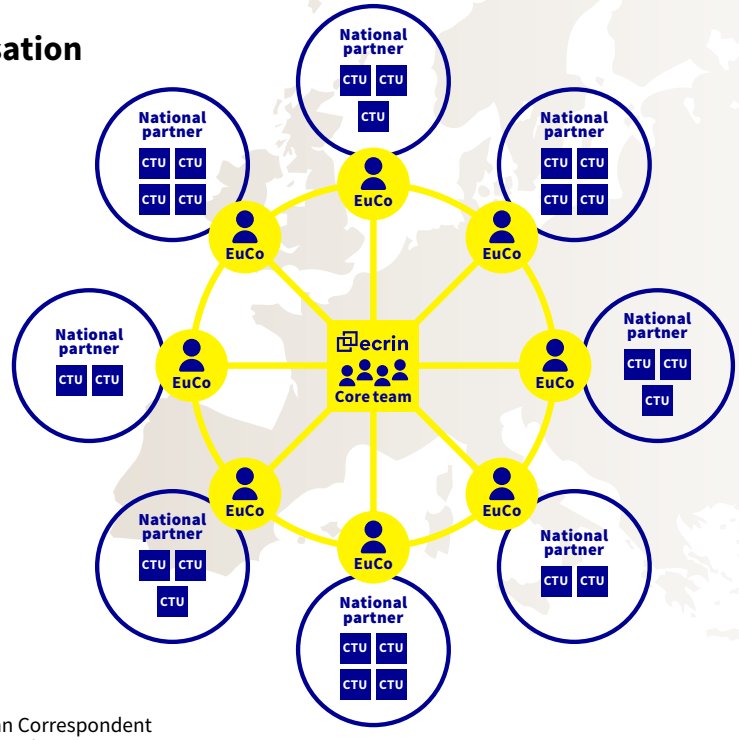
By supporting clinical studies across borders and advising and implementing policy, ECRIN advances knowledge flow, competitiveness and integration in European clinical research. Updates on ECRIN's trial support and project activities in 2022 can be found in the following pages.

RESEARCH INFRASTRUCTURES

Research Infrastructures (RIs) are defined by the European Commission as 'facilities that provide resources and services for research communities to conduct research and foster innovation'.

ECRIN is a RI and, more specifically, a "distributed RI". That means that it has a central coordinating office (located in Paris), and it brings together national scientific partners (networks of clinical trial units) across Europe.

Organisation



EuCo: European Correspondent
CTU: Clinical Trial Unit

ECRIN's organisational model is based on country membership. In 2022, it had ten Member countries (Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Poland, Portugal and Spain) and two Observer countries (Slovakia and Switzerland). Each country hosts a European Correspondent (EuCo) who is seconded to ECRIN by the national scientific partner, which is a network of academic clinical trial units (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 and the Paris-based headquarters.

National Scientific Partner: 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.

2022 Highlights

In 2022 CZECRIN celebrated its 5th year as an ECRIN full-Member country. The Government of the Czech Republic approved a new four-year funding from 2023 to 2026. The approval of the grant was preceded by an international evaluation of all national infrastructures, in which CZECRIN was again successful and achieved the highest possible rating confirming its long-term excellence. CZECRIN has thus received support and funding for the next period in which it will expand and deepen its activities briefly characterised by the motto “towards patient-centred medicine”.
In the past year, CZECRIN continued to strengthen its portfolio of services, which includes the “Knowledge Expertise Core Unit” for Regulatory Advice and Pharmacoeconomics (RAPHE). The belonging of the network of CZECRIN CTUs is still being strengthened and will be further consolidated by extending their competences and by establishing local hubs.
CZECRIN has also decided to strengthen its services in the field of education. Sharing of knowledge and experiences is an essential element for the development of biomedical research, which was also a fundamental factor for the establishment of the CZECRIN Academy educational platform.

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 or 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

2022 Highlights

2022 was a year of consolidation and communication for F-CRIN:

- Consolidation of its management and governance with the inclusion of University hospitals representation on its governing board, new component coordinators in its executive board and a continuing working group on common issues in the infrastructure. It's in compliance with the mission of F-CRIN to federate all the clinical research operators in France and to create a national community of expertise and projects.
- Reinforcing visibility of F-CRIN with a national event on 14 April 2022 in Paris ("Organisation with networks, a competitive advantage in clinical research") with 230 participants, the publication of an article on OLGA, in Therapy, a peer-reviewed journal ("OLGA, digital platform for the management of national health research networks: An effective model for complex organizations?") and 400 new publications mentioning F-CRIN.
- Strong involvement in clinical activity with 72 new projects and 15% of the selected projects initiated or with the association of F-CRIN labelled components in PHRC (programme hospitalier de recherche Clinique), the annual French Clinical research programme of the hospitals.

GERMANY

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

KKS-Netzwerk e. V. (KKSN) is an association of currently 27 academic coordinating centres for clinical trials (CTUs) all over Germany. Members of the KKSN are competence hubs for quality-oriented clinical research and translation. They provide full trial services ranging from consultancy on protocol design, budgeting, regulatory and ethical submissions to conducting trials, project management, site management, data management, monitoring, (pharmaco)vigilance, biometrical analysis and reporting for medicinal products as well as for medical devices. The KKSN structure enables close collaboration between study centres in multicentric trials, facilitating a high level of quality. Network members are involved in various national and international clinical research projects and collaborate with diverse stakeholders.
Training is also a significant focus of KKS-Netzwerk. KKSN members offer all required training courses for investigators and members of study teams. In addition, KKS-Netzwerk e. V. is organizing workshops to train the employees of KKSN CTUs.
KKS-Netzwerk e. V. was established in 2005 by the working group of Coordinating Centres for Clinical Studies. The KKSN headquarter is located in Berlin and hosts the German ECRIN office.

2022 Highlights

- KKS Netzwerk e. V. and ECRIN co-hosted International Clinical Trials Day 2022 in Berlin as a hybrid event.
- In 2022, KKSN became a consortium member of the DFG-funded project National Research Data Infrastructure for Personal Health Data (NFDI4Health). The mission of the NFDI4Health project is to open up new possibilities for the scientific use of personal health data while maintaining data protection.
- KKSN Fact Sheet (reporting period 2021):
  - 1 342 clinical studies were substantially supported by KKSN CTUs
  - 85% of these clinical studies are investigator initiated trials and 19% are multinational
  - 14 326 scientists were trained by the members of the KKSN in quality compliant conduct of clinical studies
- ECRIN projects: 12 ECRIN projects are coordinated by the KKSN, and support is also provided to 9 other projects in which KKSN is participating.

HUNGARY

Scientific Partner: HECRIN - Hungarian European Clinical Research Infrastructure Network
Member since 5 Nov. 2014
Host institution: Hungarian National Health Research Agency
National hub: Budapest
https://neku.org.hu/en/hecrin

Hungarian National Health Research Agency (HNHRA) was established by the competent Ministry at the end of 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. HECRIN central office is at the Hungarian National Health Research Agency.

2022 Highlights

In 2022 the Hungarian National Health Research Agency took over the direction of HECRIN. New representatives have been appointed including a EuCo, Zsolt Szabo, Network Committee, Judit Tarnai, and Assembly of Members, Julianna Pántya. The national hub is now located in Budapest.
The network members are involved in various national and international clinical research projects and collaborate with diverse stakeholders, HNHRA supported six projects in cooperation with ECRIN in 2022.
Training is also a significant focus of HNHRA, in collaboration with the National Directorate General of Hospitals (OKFŐ) organized the first ever Basic Clinical Investigation Online Course between 20-21 October 2022. The high number of participants - 235 - shows that there is a real demand for the training and also demonstrates the extent of the successful organisation.

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 the Health Research Board, host institution University College Cork, Enterprise Ireland and 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, through a range of services and activities to academia and industry. Our partner University CRF/CRC's provide the facilities, experienced research and specialist support staff.

2022 Highlights

- HRB NCTO team expanded in 2022 with the appointments of a Data Analyst, a Communications Officer, Clinical Industry Liaison Officer (CILO) and an ECRIN European Correspondent (EuCo), allowing the NCTO to forge new relationships and strengthen existing connections by dedicating staff resources to working with other organisations in our network.
- The HRB NCTO National Study Feasibility support service provided a streamlined service with a single point of contact for clinical trial feasibility for Ireland via *trials-feasibility@ucc.ie* with 80 feasibilities processed in 2022.
- HRB NCTO Working Groups delivered on Work Plans across areas such as Quality, Study Feasibility and Study start-up, Clinical Trial Budgets, Medtech and Pharmacovigilance. Their goal is the delivery of streamlined and transparent processes for clinical research across Ireland.
- The NCTO hosted its ICTD on May 12th, 2022, focusing on clinical research in Ireland during the COVID-19 Pandemic and the changing clinical research environment.
- A successful relaunch of HRB NCTO website *www.ncto.ie* took place in Oct 2022. The platform provides a central point of contact for the clinical trials ecosystem in Ireland and creates awareness of the value the NCTO's support provides.

ITALY

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

The ItaCRIN 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 Italian country. The main objective of the ItaCRIN National Network 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. ItaCRIN also annually organizes training in close collaboration with A_IATRIS and BBMRI_it.

2022 Highlights

- In May 2022, the ItaCRIN coordination team organized, together with BBMRI.it and A_IATRIS, the online meeting "BBMRI, EATRIS, ECRIN RESEARCH INFRASTRUCTURES: opportunity and services for researchers." The main purpose of this event was to introduce BBMRI, EATRIS, and ECRIN and their activities with the aim of supporting and facilitating biomedical research in the European landscape. More than two hundred participants attended.
- In September 2022, ItaCRIN organized and hosted three days of workshops and learning in Rome for the ECRIN internal Summer School. The team addressed a variety of issues, such as clinical research, patient engagement and considerations in the multicultural environment.
- ItaCRIN launched its first newsletter issue in June 2022 and will release new issues every six months.
- A new ItaCRIN brochure has been published with new content and information.
- Currently, the ItaCRIN Network is a participant in 29 ECRIN projects.

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, by original initiative of the Ministry of Health and care services, and is currently midway through its second funding period.
NorCRIN´s primary objective is to strengthen synergies and collaboration in clinical research in Norway and to ensure better quality by harmonizing procedures and regulations. NorCRIN has developed tools, courses and standard operating procedures (SOPs) to ensure adherence to best practice and to support clinicians in the planning of their clinical trials. A great strength of NorCRIN is the close collaboration between the CTUs within the network – supporting the spread of clinical trials to all regions of the country.

2022 Highlights

Since January 2022, the coordination of NorCRIN has been relocated to Haukeland University Hospital in Bergen. As a result a new EuCo, Sigrun Margrethe Hjelle was recruited from Bergen. Here the secretariat is a part of the Clinical Trials Unit that handles clinical research support for the whole western region of Norway and works with both academic and industry trials. NORCRIN is currently focusing of publicity and outreach to the clinical and scientific environments across the country together with other networks, to support local, national and international collaboration. NORCRIN aims to strengthen Norway´s position in the European research environment through participation in projects and networks working towards increasing the quality of clinical research and health care development. NORCRIN has also had the great pleasure of coordinating the EU-SolidAct study, Sponsored by Oslo University Hospital, Norway. The EU-SolidAct trial is part of EU-RESPONSE, a pan-European research project involved with rapid and coordinated investigation of new and repurposed medication to treat COVID-19 during the ongoing pandemic.

POLAND

Scientific Partner: POLCRIN - Polish Clinical Research Infrastructure Network
Member since 30 September 2022
Host institution: Polish Medical Research Agency (MRA)
National hub: Warsaw
www.polcrin.abm.gov.pl

POLCRIN is hosted by the Polish Medical Research Agency (MRA), a state institution responsible for the development of scientific research in the field of medical sciences and health sciences. The MRA is an entity whose purpose is to build an innovative healthcare system. The Agency helps to assess which new medical technologies and therapeutic methods should be used to meet society's needs. The Agency implements one of the first public grant programs with financing for non-commercial clinical trials in Poland. The research funded by MRA creates an opportunity for Polish patients to access the latest technologies, as well as a chance for Polish scientists to participate in global research. The Agency's main task is to lead analytical activities in the scope of assessment of undertaken decisions and their influence on the costs of functioning of the healthcare system. The compiled analysis will identify specific solutions that will allow the healthcare system to function more efficiently.

2022 Highlights

Poland has become a full Member of ECRIN-ERIC. The Assembly of Members unanimously decided to admit Poland to ECRIN. The decision was officially announced during the conference organized by the Medical Research Agency on November 17.
The National Institute of Cardiology, as the foremost CTU of POLCRIN, organized a conference and workshops for researchers and administrative teams from Polish clinical trials sites. Participants had the opportunity to gain knowledge, in the field of the planning and organization of multicenter, international clinical trials. Medical Research Agency is responsible for the establishment and development of the Polish Clinical Trials Network. In response to the increasing number of cancer cases, the Agency announced a competition for the development of Oncological Clinical Trials Support Centers in 2022. Seven applications received funding for a total amount of 11 M€. This initiative aims to make the clinical trials market in Poland more attractive, which will contribute to increasing patients' chances to access modern and innovative therapies, enable more frequent selection of research centers in our country by sponsors, as well as an increase in the number of trials conducted.

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 improving national clinical research by promoting more efficient implementation and conduct of investigator initiated clinical trials across all disease areas. PtCRIN aims to increase the number and quality of IICTs by promoting international cooperation, fostering the production of high-level evidence to support clinicians and decision makers in the adoption of safety and cost-effective therapeutic decisions.
PtCRIN is included in Portuguese Roadmap of Research Infrastructures (RNIE) but has no specific funds for infrastructure coordination and development. It is a consortium of 26 national institutions which represent the leading Portuguese clinical research institutions, and clinical investigators that are directly funded by regional, other public, or private funds, taking advantage of the label PtCRIN. PtCRIN fosters a network of academic CTUs that provide a full range of trial services from consultancy on protocol design, budgeting, regulatory and ethical submissions, project management and data management, monitoring, (pharmaco) vigilance, and reporting for medical as well as for medicinal products.

2022 Highlights

- Involved in seven ECRIN multinational clinical trials, with the participation of 17 national CRCs and four PtCRIN's CTUs, two of which as Lead CTU.
- Provided support to one Horizon Europe full proposal and two letters of intent for the first step of Horizon Europe calls through support to coordinators in developing the trial management section.
- Integrated the project ERAMUS + CONSCIOUS II - "Curriculum Development of Human Clinical Trials for the Next Generation of PhD Students and Early Career Researchers in the Medical, Science, Pharmacy and Health Professions" and the project ISIDORe.
- The CLIC - Clinical Investigator Certification, programme was updated taking into account the entry into force of the new European regulations on clinical trials with medicines (536/2014) and medical devices (745/2017).
- Held the Portuguese International Clinical Trials Day 2022 together with AICIB, INFARMED, APIFARMA and EUPATI-PT on "Future of Clinical Research in Portugal."

SLOVAKIA

Scientific Partner: SLOVACRIN - Slovak Clinical Research Infrastructure Network
Observer 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 and has been part of the ECRIN-ERIC consortium since 2018. 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 and 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.

2022 Highlights

SLOVACRIN continues to contribute to COVID-19 studies. The SolidAct study was the first academic multinational study approved in the new CTIS system.

SLOVACRIN has developed an updated logo that reflects the young, dynamic, expanding research infrastructure and launched a new website at the end of the year. The website provides an overview of the organisation, its projects and clinical trials, its services, news, events, and more information and is available in Slovak and English.

SLOVACRIN, in collaboration with the institutions involved in the national network, has prepared a Roadmap for Academic Clinical Research. This document presents a comprehensive description of the current state of clinical research in Slovakia, defines the scientific focus of hospitals, identifies clinical trial departments (units), and describes the available capacity, previous experience, and the range of services that these departments are able to provide.

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 for clinical trials in Spain. It is funded by the National Institute for Health Carlos III (ISCIII), and it is composed of a network of 34 CTUs based in clinical centres of the Spanish National Health Service spanning 14 of the Spanish autonomous communities, and which are currently organized in eight Working Groups (WGs) to cover all the areas of expertise and activity. The SCReN General Coordination is based in Madrid at La Paz University Hospital-IdiPAZ (Clinical Pharmacology Department and Clinical Trials Unit). Since August 2022, the ECRIN EuCo is hosted at Virgen de la Victoria University Hospital (Clinical Pharmacology Service, IBIMA-Plataforma Bionand). Both institutions and the EuCo lead SCReN's Internationalization WG. Whether providing consulting 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 to the Spanish National Health Service and globally to the European Society.

2022 Highlights

While 2021 was marked by defining the structure and strategy of the Network, several readjustments to SCReN's functional infrastructures were implemented in 2022 to enhance the growth and development of the network. First, a renewal for the EuCo role and the ECRIN National Hub occurred in August 2022.
Second, SCReN Working Groups (WG) were also redistributed to optimize the coverage of all the areas of expertise and activity. SCReN´s portfolio incorporated 13 new studies; one of which was a new ECRIN clinical trial from the VACCELERATE project. A new collaboration with ECRIN through the ERA4HEALTH- Pillar 2B project was added to the previous common collaborations (Network Committee, Quality and IS Unit, and Communication Working Group).
SCReN's communication activities have focused on strengthening the links between CTUs and the WGs (internal) and the other ISCIII networks at national level, and on consolidating the ECRIN partnership by participating in activities and events (i.e. ICTD 22, ECRIN CTU Day) at international level.

SWITZERLAND

Scientific Partner: SCTO - Swiss Clinical Trial Organisation
Observer since 18 Dec. 2015
Host institution: SCTO
National hub: Bern
www.scto.ch/en

The SCTO and its CTU Network were founded in 2009 to strengthen academic clinical research, to complement successful basic research in Switzerland, and to bring research results from bench to bedside.
The SCTO is a distributed clinical research infrastructure, it consists of a central hub (SCTO Executive Office) and a network of seven local CTUs. These units offer services for the operational implementation of trials locally at the SCTO's member institutions: the five Swiss university hospitals and at the cantonal hospitals in Ticino (EOC) and in St. Gallen.
The SCTO's mandate covers all types of research governed by the Human Research Act, including the broad spectrum of research projects starting from early entry into men, to late implementation into clinical care, and ranging from prospective interventional trials to research with data and bio samples.
The SCTO's strategic and operational priorities for 2021–2024 are:
- value and innovation
- education and the next generation
- visibility and transparency.

2022 Highlights

SCTO Platforms and their tools for clinical research
Administrative complexity, language barriers, and a tight budget place high demands on professionals in academic clinical research. Our thematic platforms, established in 2017, are developing and providing harmonised practical tools for clinical researchers nationally as well as internationally. These are made public on the distinct website SCTO Platforms Tools and Resources. Resources include templates, guidance documents, online training, and statistics packages, among others (*https://www.sctoplatforms.ch/*).

PPI activities in Switzerland
As one of its key strategic goals in the new 2021–2024 funding period, the SCTO is placing greater emphasis on the implementation of patient and public involvement (PPI) in academic clinical research. In pursuit of this strategic goal, the SCTO published a fact sheet on PPI in clinical research, a guidance document to support researchers with their PPI activities early on, and a remuneration policy to facilitate the compensation of patients and representatives of the public for their PPI contributions. To raise awareness of the concept of PPI, SCTO published an explanation video in lay language in German, French, Italian and English.

Interview with the Polish EuCos

Maciej Janiec
European Correspondent
Poland

What's a day in the life of EuCo like?
The day in the life of EuCo depends on the country in which EuCo works in and specific duties relevant to the national network. In Poland, EuCos act as the key contact point for ECRIN-ERIC and the network of EuCos in other ECRIN countries. We are in touch with our national and foreign colleagues. We provide advice and support concerning our trials and compile and distribute regular communication about the progress of ECRIN projects and details of new initiatives to the national network. Poland quite recently has started to cooperate with ECRIN. We became an Observer country in 2019 and full Member in the later part of 2022, so we haven't had a big portfolio of ECRIN clinical trials which Polish CTUs are participants or leaders in. Because of that, I have a little more time for additional activities. These last few years were also a time of rapid growth and professionalisation of the Polish non-commercial clinical trials market. In relation to this situation I have been focused on consolidating and developing our national network.

How has ECRIN benefited Poland?
ECRIN helps to conduct multinational trials through the provision of advice and services for the set-up and management of investigator or SME led clinical studies. By supporting clinical trials across borders, advising and implementing policy, ECRIN pushes knowledge flow, competitiveness, and integration in European clinical research. In Poland, we haven't started our own multinational clinical trials in collaboration with ECRIN yet, however, Polish CTUs took part in a few projects as participants. We gain knowledge, experience, and know-how from our European partners. At this stage, it is the most crucial aspect for us.

And I truly believe that in the future our cooperation will bring us to the next level of development of the non commercial clinical trials market.

What achievements have you been the proudest of since joining ECRIN/ PolCRIN?
I have been working in EuCo for almost 2 years. During this time the change of our status - from Observer to Member country was the most crucial for me and for the Polish network. Recently Poland has been asked to organize International Clinical Trials Day 2023 in collaboration with ECRIN. Of course, this event is ahead of us but we are now focusing on it. It will be a great opportunity to show our potential, capabilities, and to strengthen integration with other countries from ECRIN.

Tell me about Poland and what is planned for the next few years?
Poland is a beautiful country, and regarding the clinical trials, it's a great place to conduct them. Our main aim is to conduct the first multinational investigator-initiated clinical trial in cooperation with ECRIN and coordinated by Polish CTU. We would also like to increase the number of multinational clinical trials in which Polish CTUs are involved as participants.

Watch the full interview...

Opening of the Clinical Research Support Center, Warsaw, Poland.

ECRIN Team

Core Team	
Burç Aydin	Clinical Scientist
Marta Bastucci	Executive Assistant
Sergio Contrino	Data Engineer
Marta del Alamo	Project Manager
Jacques Demotes	Director General
Martina Esdaile	Communications Officer
Paula Garcia	Project Manager
Sergei Gorianin	Data Scientist
Sareema Javaid	Clinical Project Manager
Sarah Karam	Communications Assistant
Swarnalathaa Kichenassamy	Software Engineer
Sabine Kläger	Head of Clinical Operations Unit
Christine Kubiak	Operations Director
Aafke Maitimo	Administrative Assistant
Salma Malik	Paediatric Project Manager
Mihaela Matei	Legal Manager
Samira Mokhtari	Quality Officer
Golbahar Pahlavan	Head of Infrastructure Development Projects Unit
Maria Panagiotopoulou	Project Manager
Sara Raza-Khan	Project Manager
Arthur Smaal	Information Systems Officer
Alicja Szofer-Araya	Head of Administration and Finance
Christine Toneatti	Head of Quality and IS Unit
Keiko Ueda	Clinical Scientist
Biljana Zafirova	Clinical Project Manager

European Correspondents	
Kateřina Nebeská	Czech Republic
Lenka Součková	Czech Republic
Kristýna Nosková	Czech Republic
Amélie Michon	France
Jimena Bouzas	France
Sarhan Yaïche	France
Linda Stöhr	Germany
Neshat Chareh	Germany
Laura Vieweg	Germany
Hanna Schrinner-Fenske	Germany
Sabine Mofina	Germany
Zsolt Szabó	Hungary
Kata Bende	Hungary
Zita Tarjányi	Hungary
Niall Hore	Ireland
Maria Buoncervello	Italy
Elena Toschi	Italy
Maria Josefina Ruiz Alvarez	Italy
Sigrun Margrethe Hjelle	Norway
Bjarte Bergstrøm	Norway
Valentina Cabral Iversen	Norway
Patrycja Klusek	Poland
Maciej Janiec	Poland
Joana Batuca	Portugal
Simona Sonderlichová	Slovakia
Stefan Toth	Slovakia
Miriam Rol Garcia	Spain
Adriana Vives	Spain
Caecilia Schmid	Switzerland

** Note: the staff lists include individuals who started working for ECRIN in 2022, as well as those who left the organisation.*

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

As the workplace resumed a more 'normal' pace in 2022 there were some changes that followed in the composition of the team both at headquarters and across our national partners. The team worked hard to integrate the new arrivals and get them up to speed on ECRIN's activities. There was a total of 25 people in the ECRIN core team in 2022, including four people joining the team and four leaving. Furthermore, the reorganisation and relocation of some national partners has led to changes in the EuCos with 6 new EuCos joining the ECRIN team in 2022.

Members of ECRIN staff and board members at International Clinical Trials Day 2022.

ECRIN, Advancing Personalised Medicine Research

Personalised Medicine (PM) represents an exciting opportunity to improve healthcare, treatment and prevention for patients and citizens on an individual level, while simultaneously advancing public health. The current context has enabled advancements in personalised medicine at lightening speed. The elements that have sped up the clock include the big data revolution, with the capacity to process large quantities of data, and the increased precision and diversity of omics techniques available. Personalised medicine is increasingly being tested and applied in more medical domains. As new projects arise it is important that all stakeholders (from researchers, to regulators and through to the patients) can have access to best practices in the field.

The European Commission has prioritized PM since 2007. The funding of the PerMed project through 2013-2015 by the European Union's 7th Framework Programme was pivotal, as this project allowed the development of the first Strategic Research and Innovation Agenda for PM that gave way to the International Consortium for Personalised Medicine (ICPerMed), that was formed in 2016. Today the ICPerMed provides a platform to initiate and support communication and exchange on personalised medicine research, funding, and implementation. With over 40 member organizations in Europe and beyond, it helps to coordinate PM research and implementation across the globe. The ERA-PerMed, launched in 2018 is a co-funding initiative that allows funding bodies of multiple countries to fund collaborative PM research projects. To this day it has organized 5 annual co-funding calls, leading to the funding of more than 110 projects. In conjunction, these two initiatives bolster PM research and implementation, helping to drive PM priorities forward.

Image by Mahmoud Ahmed from Pixabay

PERMIT Final meeting, June 2022.

OVERARCHING RECOMMENDATIONS

1- Studies that allow the validation of research methods should be funded and promoted

2- Patients should be engaged as early as possible and through every stage of the personalised medicine research pipeline

3- Negative findings of personalised medicine research should be published and disseminated

4- The multidisciplinary nature of personalised medicine research will require sustained dialogue between all actors and stakeholders for the field to continue to advance

5- The regulatory framework must continue to advance to allow personalised medicine research to continue to be safe and innovative

Defining recommendations for the Personalised Medicine community

PERMIT
PERsonalised Medicine Trials

In 2020, ECRIN launched the EU Funded PERMIT project on methodological standards for personalised medicine research to establish recommendations ensuring the robustness of personalised medicine trials. Over the two and half year project, an analysis was carried out to identify the current methodological gaps in the personalised medicine research landscape after which experts were united to hone in on these missing elements and provide suggestions to overcome them. The project looked at the full personalised medicine pipeline: considerations were made for stratification and validation cohorts, machine learning for patient stratification, translational medicine and clinical trials. Over 70 recommendations were developed and disseminated. Of the recommendations, some are overreaching and can have a positive impact across the full personalised medicine pipeline (see bold text) and others are very specific to a particular stage of the pipeline.
The consortium has strived to widely disseminate the results and adapt them to different levels of learners. Six publications were made available

to date and more are in the works for the coming year (see annex, 2022 Publications). Meetings were organised through the project to bring stakeholders together to gain insights on how best to disseminate the information widely. Moreover trainings were organised. This includes the current PERMIT project online offer which addresses different publics: from the lay person, to a clinical researcher, funder, regulator etc interested in getting an overall understanding of the project, its methodology and the resulting recommendations. The last level of training is intended for those that specialise in the stage of the PM research pipeline in which the course is developed. Another dissemination opportunity was a webinar hosted by the Alliance of Academic Health Centers International (AAHCI) in December where the recommendations were presented by the topic leads.

Disseminating personalised medicine best practices internationally

ECRIN also works with different regions to promote knowledge sharing and best practices in personalised medicine. Through the EULAC PerMed project, ECRIN co-organised the second technical workshop in Panama which focused on Clinical Trials for Personalised Medicine. This meeting brought together 50 attendees from 19 EU and LAC countries. The workshop met its objectives, allowing experts from LAC and EU countries to exchange knowledge and experiences on innovative clinical trial designs in PM. It also provided a forum for networking and the establishment of future collaborations. In support of the project sustainability ECRIN is currently hosting the EULAC Clinical Trials HelpDesk which provides information on regulatory and funding agencies in Latin America and some select European examples.

2nd EULAC PerMed technical workshop co-organised by ECRIN

Similarly, through the EU Africa PerMed project, ECRIN is developing training and supporting the promotion of the PERMIT recommendations to this public. The first in-person training for the project will be co-organised by ECRIN in the winter of 2023. It will focus on standards in personalised medicine research and will bring together early career professionals from EU and Africa as well as speakers from both continents.

Supporting personalised medicine in cancer

ECRIN is currently involved in two projects that respond to the EU Mission Cancer the EOSC4Cancer project and the canSERV project. EOSC4Cancer will work to link genomic data for stratifying participants to ongoing clinical trials. canSERV is a service provision project where elements of personalised medicine are taken into consideration, notably with the creation of a molecular tumour board that looks to link patient with services.

The future of Personalised medicine

ECRIN, along with its partners in EU-AMRI, BBMRI & EATRIS, are well positioned to support the upcoming developments in the personalised medicine domain as they have the capacity to support researchers, institutions and SMEs that embark on complex projects. As EU-AMRI we hope to provide a one stop shop for access to relevant services in the medium term with a unified service catalogue and project management system. Furthermore, next year should mark the launch of the next European Partnership for Personalised Medicine. This ambitious initiative looks to be a prime driver for developing and implementing PM by establishing priorities for research funding, aligning PM strategies, developing educational and literacy strategies, and supporting policy development. It builds on the successes and lessons learned from the ICPerMed and the ERA-PerMed. The efforts for developing this future partnership have involved the creation of a Strategic Research and Innovation Agenda, through a collaborative process composed of interviews and a public consultation, and the drafting of a comprehensive 7 year work plan that will see the day in early 2024.

Interview on EP PerMed

Monika Frenzel
ICPerMed Secretariat
International coordinator
French National Research Agency

What do you think the future holds for PM in Europe?
Thanks to the high interest, PM is now proposed as a topic for a co-funded European Partnership under the Horizon Europe Framework programme. The European partnership for personalised medicine, in short, EP PerMed, is expected to perform research and research-supporting activities for 7 years with a budget of more than 300M€, including 30% co-funding through the European Union. The EP PerMed will coordinate funding and strategy development for PM research, innovation, and implementation, but especially, will act as a platform to create synergies between the different actors in the so-called Personalised Medicine system of health.

What have been the different development stages of the EP PerMed?
First preparations started in 2020, with a preparatory group supported by ICPerMed and ERA PerMed members that developed a concept paper, guidance documents and an information day. Finally, PM was validated by the Member States as a topic for a co-funded European partnership in Horizon Europe.
In 2021, a drafting group was formed that developed two important documents: a draft proposal that was published in February 2022, and the strategic research and innovation agenda (SRIA) for personalised medicine that will be published in April 2023. This so called SRIA for PM will support a wide range of stakeholders and experts to further develop programs, activities, and research towards PM and care, as well as prevention. Its main intention is of course to support the planned European Partnership for Personalised Medicine.
In 2022, in parallel of the SRIA development, the EP PerMed proposal was developed. If positively evaluated, the EP PerMed consortium will support personalised medicine research, innovation and implementation starting from the end of 2023. A first joint

transnational call is expected to be launched already in 2024.

Are elements from the PERMIT project taken into consideration in the development of the EP PerMed?
During the preparation of the partnership proposal and most importantly for the SRIA preparation, strategic documents of the ICPerMed family projects were consulted, including the recommendations developed by PERMIT on PM research methodology to ensure the scientific excellence, validity, robustness, reproducibility, and acceptability of results.
Furthermore, ICPerMed and PERMIT developed a joint document that will soon be published. It focuses on recommendations specifically directed to research funding agencies, regulators, and policy makers. The recommendations will provide guidance on the proper design and implementation of PM research programmes at every stage and will surely feed into the work of the partnership.

How could the research infrastructures, and in particular ECRIN, contribute to EP PerMed and the future of PM?
The SRIA for PM includes a dedicated chapter outlining the importance of infrastructures for PM per se but also the need for developing complementarities and synergies between research infrastructures. This is important to increase efficiency, sustainable and long-term integration of services and resources, and to prevent unnecessary duplications when addressing PM challenges and priorities.
The functioning of the broad research infrastructures landscape could be optimised, e.g. through coordinated efforts. A good example is the European Alliance of Medical Research Infrastructures, EU-AMRI, in that ECRIN, BBMRI and EATRIS work in parallel to provide complementary services to researchers in the field of biomedical sciences and support the development of PM and new treatments.
The SRIA also outlines the potential of ECRIN in facilitating multinational clinical research. Considering ECRIN's role and participation in the partnership ERA4Health, it may connect different partnerships, especially in the health sector and foster a balance in the coverage of clinical trials across fields.
I do see a great value if ECRIN and other RIs participate in EP PerMed activities, e.g. related to research, by providing support to the research communities, but also strategy development as well as education and training activities.
Only in joining forces, we can make PM a reality for all.

Watch the full interview...

Services

Clinical Operations

OVERVIEW

Supporting clinical studies across borders is the principal mission of ECRIN. This support is given to investigators and sponsors in ECRIN Member and Observer countries and beyond. It includes the preparation of European funding applications for ECRIN members and the coordination and management of multinational clinical studies. In 2022, ECRIN continued to invest in this core activity by increasing its capacity and recruiting additional clinical project managers and European Correspondents. Many of the more recent studies in the ECRIN portfolio, address different aspects of COVID-19 from prevention through to treatment and the effects of the pandemic continue to have implications on the role out of many other clinical studies, notably delays and increased workload, which the clinical operations unit works efficiently to accommodate. These efforts are of great importance and contribute to the high-quality standards set forth by ECRIN and consistent with the ISO 9001:2015 certification for its principal services carried out by its staff.

ECRIN ON THE CUTTING EDGE OF CLINICAL RESEARCH

In line with ECRIN's strategic aims, staying abreast of recent innovations and working to stay on the cutting edge requires training and constant implication in novel projects by our staff. ECRIN has invested its efforts, across the clinical research spectrum, with a particular interest in platform trials, personalised medicine, patient stratification, in-silico trials, use of artificial intelligence, protocols for data sharing and data reuse, as well as medical device investigations.

ECRIN continues to see an increase in the number of clinical studies in its portfolio that have adopted these new methodologies and works with investigators and SMEs to support their integration into already existing infrastructures. Moreover, ECRIN continues to provide the coordination of a single-entry point for new treatment arms to be included into the different European COVID-19 adaptive platform trials via the Joint Access Advisory Mechanism.

Staff from the ECRIN Clinical Operations Unit are engaged in the development of new policies and tools in the clinical studies area, including those that are underserved, through initiatives such as the Rare Disease Moonshot. ECRIN also has been working as stakeholder representatives in the EMA Clinical Trials Information System (CTIS) development and alongside clinical trial sponsors as they work through the growing pains that can be associated with a new system.

SCIENTIFIC BOARD

The ECRIN Scientific Board provides a thorough scientific and logistical assessment of any clinical study requesting ECRIN services. It is composed of two subcommittees:

(1) The Collaboration Committee decides on whether or not ECRIN should invest resources in the planning, design and funding application and/or participation in the project.

(2) The Peer-Review Committee is responsible for assessing the methodology and design of the pre-final protocol, as well as providing recommendations on the improvement of the final design.

Prof Jose Delgado Alves is the elected chair of the Scientific Board; Sabine Klager, Head of clinical operations took over the Scientific Board Secretariat in 2022. ECRIN's Medical Expert, Dr Joaquin Saez-Penataro, sits on both sub-committees and acts as a link, between the two.

- **Collaboration Committee**

The Collaboration Committee meets weekly to review collaboration requests, and to make transparent decisions on the support ECRIN will provide to the preparation of funding applications and planned operational services based on a trial synopsis and task requirements.

In 2022, a total of 19 requests for collaboration were reviewed, whereby 16 came from the ECRIN Member/Observer countries and three came from non-ECRIN countries. Ten requests for collaboration were approved, one is pending, while for eight a collaboration was not established for a variety of reasons (eligibility criteria, budget restraints, out of scope, decision from the Sponsor).

- **Peer-Review Committee**

The Peer-Review Committee (PRC) is composed of six independent, clinical and methodology experts, who elect a chair amongst themselves for a three year term. Three trial protocols were reviewed by the PRC in 2022

Access ECRIN's Clinical Study Operations Services

ECRIN's services are open to research projects in all clinical areas. Investigators and sponsors of ECRIN Member and Observer countries gain access to ECRIN clinical operations services by contacting their national EuCo. Key information on the proposed clinical study is collated and submitted by the EuCo to the Collaboration Committee. The Collaboration Committee reviews the proposal and decides on ECRIN's collaboration in the project. Upon collaboration agreement by the committee, the national EuCo or an ECRIN project manager will accompany and support the investigator and/or sponsor in the grant and budget preparation, ensuring regulatory requirements are being considered for the conduct of the clinical trial or study.

Access, via the Collaboration Committee, to ECRIN services can also be requested by investigators/sponsors for any already funded clinical study or for projects from investigators/sponsors located in non-ECRIN EU Member States.

Zoom in on Clinical Operations Services

1. PLANNING

- Trial design and methodology
- Regulatory, ethical, and insurance requirements
- Funding sources and cost
- Strategies for site selection and patient recriutment
- Task distribution for multinational study management
- Funding application support
- Medical expertise and support

2. RISK ASSESSMENT

- Protocol peer review
- Feasability and risk assessment

3. OPERATIONAL COORDINATION

- Study management and coordination
- Regulatory and ethical submission
- Selection and provision of qualified resources
- Monitoring
- Vigilance
- Data management

PLANNING

In the planning phase, ECRIN can give advice and provide input on the different aspects of funding applications such as work package structure, potential impact, governance, consortium composition, and multinational clinical study regulatory and ethical approval requirements, vigilance, and management. ECRIN can also advise on available (European) funding opportunities and how to best approach the application preparation. EuCos, who act as the intermediary between the sponsor and the ECRIN national partners as service providers (i.e., national networks and CTUs), provide information on the facilities that have the expertise, capacity and services needed to manage the study. They can also advise on all aspects of the clinical study, ranging from specific national ethical/regulatory requirements to study insurance, and conduct, logistical evaluation, and risk assessment of project plans.

RISK ASSESSMENT

Once funding has been secured, and before implementation of the projects, a risk assessment is performed according to ECRIN's risk assessment process. Through this process, solutions are provided to minimise any identified risks. Moreover, ECRIN, through the Peer Review Committee, can provide an independent peer-review of the pre-final protocol focusing on the methodology and design aspects contributing to the scientific excellence and research quality of the project.

OPERATIONAL COORDINATION

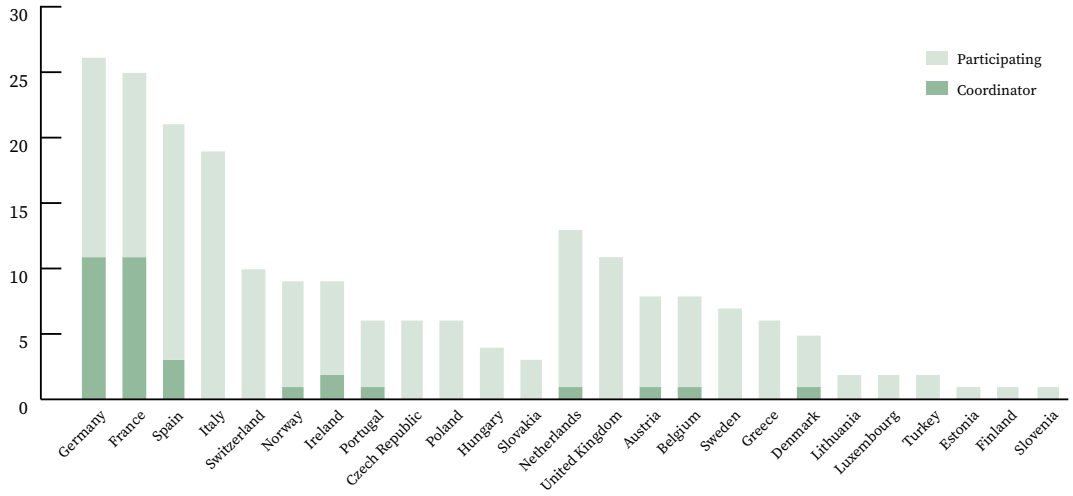
ECRIN's EuCos work closely with the investigator-sponsor team, coordinating the activities across the participating countries, with the key mission to implement the clinical study outside the sponsor's country. This includes operational coordination with a particular attention to obtaining all the necessary national approvals, site initiations, monitoring and close-down activities, as well as data management and vigilance as required by the sponsor.

Clinical Study Portfolio in 2022 (current studies)

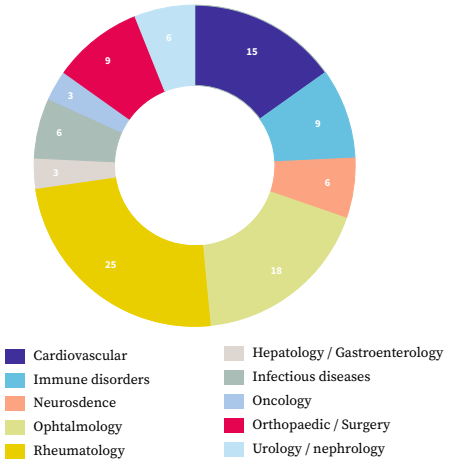
During 2022, ECRIN worked on a total of 35 clinical studies at different phases, whereby three clinical studies were in the start-up phase, six were opening sites, and 19 others were in the running phase, with recruitment, follow-up and/or close out activities. In 2022, one study was on hold, two studies were completed, and for three studies ECRIN's support came to an end. ECRIN's full study portfolio for 2022 can be found in the annex of this report.

The total ECRIN study portfolio, including past and current studies, consists of 70 studies.

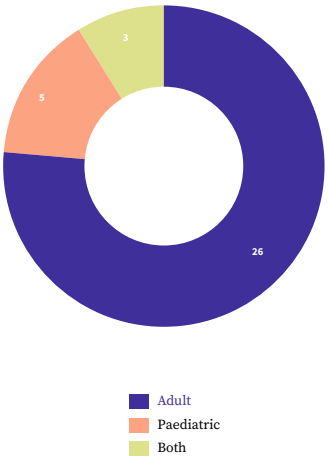
2022 ECRIN trial portfolio



2022 portfolio by disease area



2022 trial population



Interview with a Sponsor

Melanie Heiß, MSc
INFORM2 Project Management
Hopp Children's Cancer Center Heidelberg (KiTZ)
German Cancer Research Center (DKFZ)
Heidelberg University Hospital

Could you please introduce yourself/ INFORM2?

I am a project manager in the KiTZ Clinical Trial Unit at the Hopp Children's Cancer Center Heidelberg (KiTZ) in Germany.
One of the projects supported by the KiTZ Clinical Unit is the INFORM program. The INFORM2-NivEnt trial is part of the INFORM2 series.

As a project manager, I coordinate our investigator-initiated trials (IITs) such as the INFORM2-NivEnt trial as well as other planned INFORM2 trials.
In INFORM2-NivEnt trial titled "INFORM2 exploratory multinational phase I / II combination study of Nivolumab and Entinostat in children and adolescents with refractory high-risk malignancies" children and adolescents aged 6 to 21 years with relapsing / refractory or progressive high-risk cancers can be enrolled since August 2019. The aim is to investigate whether treatment with the checkpoint inhibitor Nivolumab and the HDACi Entinostat is a safe and effective treatment option for children and adolescents.
The sponsor of the trial is the Heidelberg University Hospital. Sites are open in Australia, Austria, France, Germany, Netherlands, Sweden and Switzerland. Currently, phase II is open for the older cohort (12-21 years) and phase I for the younger cohort (6-11 years). Phase I of the younger cohort will be completed soon and thereafter phase II can be started.

Could you explain the working relationship between yourself and ECRIN?

The task of a project manager while planning an IIT is to find a suitable partner for the execution of the clinical

monitoring. The trial was submitted to ECRIN to evaluate if ECRIN could conduct the monitoring in European countries. To set up the trial, the contract design, budget items, monitoring tasks, relevant documents for trial execution (e.g. protocol, monitoring plan) were discussed together with ECRIN. During the trial execution, updates on the trial and country-specific topics are discussed in regular meetings with the European Correspondent at ECRIN. In the future, for the termination of the trial, the tasks for site close-out will be discussed and tracked. Communication is the most important aspect of our working relationship as we need to exchange information on a regular basis to ensure proper execution of the trial.

What have you found easy/challenging?
There is very good communication between the ECRIN correspondent and our project management team and the response rate to questions and requests is very high. Furthermore, tasks are always tracked and executed from ECRIN side without us needing to intervene. While in the planning stage of the NivEnt trial, time coordination was a challenge. As there is always a long regulatory and administrative process for both ECRIN and our team, steps such as contract design, task distribution and protocol review took longer than expected.

What has been the impact of working with ECRIN on INFORM2?
Since we needed a partner for our trial to conduct the monitoring in the European countries, the cooperation with ECRIN was important to be able to start our INFORM2-NivEnt trial. The cooperation with ECRIN has decreased our workload by taking over tasks such as communicating with European sites and monitors as well as support with regulatory aspects. We have learned a lot from this collaboration, especially for the planning of future studies.

Do you have any lessons learned that you would like to share with other sponsors interested in working with ECRIN?
For working with ECRIN it is necessary to involve them as a partner at an early stage of a trial. This is especially important for the planning and during the trial to inform about updates, problems or timelines, to make sure all stakeholders are well informed about the current status. A precise definition of the tasks and the allocation between all involved partners facilitates the execution of the tasks. Furthermore, the experience and structured work of ECRIN can significantly support the planning and execution of a trial.

Read the full interview...

Infrastructure Development Projects

OVERVIEW

Through its participation in projects (most of them funded by the European Framework Programmes), ECRIN strengthens and or develops its capacity, tools, and services for the benefit of our user community. These projects further enable ECRIN to stay at the cutting edge of clinical research, enhance its the visibility, and develop synergies with the medical research and research infrastructure communities. This year ECRIN began work on 6 new projects:

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. The project will contribute to the EU Cancer Mission through the provision of innovative services. ECRIN will be working with other partners to provide clinical investigators in the cancer community with support in the planning and design of complex clinical trials and develop a secure and GDPR-compliant cancer clinical trial patient-level data sharing repository to link cancer related data across Europe.

eCREAM

Endeavours to enable clinical and quality of care assessment research using data extracted directly from electronic health records (EHR) of emergency departments (ED). It will do so through the development of technological solutions to extract structured and unstructured clinical data, the FAIRification of established databases and by piloting the exploitation of established databases in two relevant use cases. ECRIN will work to ensure that the project complies with the ELSI requirements in relations to the sharing of medical data.

EOSC4Cancer

Will make diverse types of cancer data accessible: genomics, imaging, medical, clinical, environmental and socio-economic. It will use and enhance federated and interoperable systems for securely identifying, sharing, processing

and reusing FAIR data across borders and offer them via community-driven analysis environments.

- **ERA4Health**

Brings the opportunity to increase European transnational collaborative research funding by creating a funding body for joint programming in priority areas addressing European public health needs. It aims to provide influential contributions as well as a sustainable model of funding for ground-breaking translational research in the health domain across Europe and beyond. ECRIN will contribute to updating the Strategic Research and Innovation Agenda with multinational Investigator Initiated Clinical Trials.

- **ISIDORe**

Aims to contribute 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 diseases in "peaceful times" as well as during outbreaks or epidemics. ECRIN is providing access to its clinical operations services and to the three COVID-19 platform trials.

- **REMEDi4ALL**

With the ambition of establishing a European research and innovation eco-system that facilitates fast and cost-effective patient-centric development and access to repurposed medicines, REMEDi4ALL will build a platform for expertise across the value chain, utilise big data, create a community of practice and train the next generation of stakeholders in medical repurposing. ECRIN will lead the activities on clinical trials with the aim of establishing a blueprint for the clinical repurposing platform.

Note: For funding information on the above projects, and all Infrastructure Development projects see the appendices or the ECRIN website.

Interview on ERA4Health Partnership

Marta Del Álamo
Project Manager
ECRIN

Can you describe the ERA4Health project in a few sentences?
This project aims to increase European transnational collaboration to fund research in Europe for areas addressing public health needs.
The EU-funded ERA4Health Partnership brings together 32 entities and 27 funding organisations from 21 countries.

Why is it important for IICTs to be integrated into this action plan?
Commercially sponsored clinical trials are responsible for bringing most of the new drugs to the market. Investigator Initiated clinical trials (or non-commercial clinical trials) have their own additional specific objectives, often focusing on refining or getting new indications of available treatments (drug repurposing) and/or optimizing therapeutic strategies that do not have as much financial gain for the pharmaceutical industry.
It is therefore very important to support academic institutions to explore these other options.
Some European national research programs support financially these non-commercial trials, but these funding programs are restricted at country-level, limiting the possibilities of setting up multinational trials. A typical example of the need for multinational trials is the rare diseases area, for which the scarcity of patients makes sometimes mandatory a multinational setting.
By joining forces, ERA4Health partners can support multinational projects avoiding duplication and fragmentation in Europe.

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What is ECRIN's role?
ECRIN leads one of the pillars of ERA4Health. It is called Pillar 2B. This Pillar 2B focuses on several activities aiming to improve the implementation of future calls funding investigator initiated clinical trials. Some of these activities are for instance the identification of current bottlenecks for the set up of these multinational clinical trials in Europe. Other activities are related to the identification of synergies with other initiatives at European or International level; the description and implementation of proactive and selective measures to improve the quality of the projects for future calls; and proposing alternative mechanisms of joint funding.

Watch the full interview...

Changing the health research data landscape

ECRIN has a rapidly growing portfolio of projects focusing on a variety of data components. This includes half of the new projects launched throughout 2022. The work mainly addresses the application of the FAIR principles in clinical research, ensuring that data and relevant resources are Findable, Accessible, Interoperable and Reusable. ECRIN strives to lift cultural, technical, ethical and legal barriers to data sharing by providing tools and guidelines and by coordinating policy initiatives.

Identifying the value add of new methodologies

Through the SIMCor project, which aims to establish an in-silico platform and simulation tools for the development, validation and regulatory approval of cardiovascular devices, ECRIN is responsible for creating 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 in real-world settings. This will allow an estimation of the benefits offered by in-silico technologies along several outcome dimensions, such as, a reduction in the duration and sample size of clinical trials, increased clinical efficacy and patient safety. In 2022, ECRIN started working on the practical application of the proposed impact assessment framework.

Optimising health-related cohort data

The SYNCHROS project, which wrapped up in June of this year, explored different ways for optimising European cohort research. In the project, a repository inventorying European and international population-based cohorts, patients' cohorts and clinical trials was developed. Moreover, it provided a comprehensive analysis of practical, methodological, ethical and legal challenges to cohort data sharing and a strategy to overcome them. This was outlined and supported by two policy briefs that were developed through discussion with a wide variety of stakeholders (e.g. cohort leaders, international research organizations, standardisation bodies, patient organisations, funding bodies, health administrations, the WHO, editors of peer-reviewed journals, European Research Infrastructures).

Improving the findability and interoperability of sensitive data resources

The digitisation of healthcare has brought new opportunities to complement and enhance the data traditionally utilized in regulatory decision-making through the exploitation of routinely collected real world data. Within the EOSC-Life project, ECRIN led an inventory of national health databases and registries covering 15

European countries (Austria, Czech Republic, France, Germany, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland). The access requirements for secondary use of this data for research purposes were described, highlighting the diverse and at times patchy European landscape due to differences in the governance and sustainability models of these data sources but also due to different local laws and access rules.
Furthermore, to address the findability of resources relevant for sharing and reusing sensitive data in a cross-domain scientific context, ECRIN collaborated with other life science research infrastructures to develop a sensitive data toolbox. The toolbox aims to support the FAIRification process of sensitive data resources through the discovery of relevant digital objects (e.g., regulations, guidelines, best practice, tools). Findability of such resources is enabled via the application of a community-approved categorisation system consisting of seven main categories (sensitive data type, resource type, research field, data type, stage in data sharing life cycle, geographical scope, specific topics). The toolbox demonstrator currently contains 110 resources that facilitate the sharing and reusing of sensitive data across scientific domains. In 2023 its content will be expanded, usability and user-friendliness aspects will be addressed and its long term sustainability discussed.

Paving the way for a pan-European Health Research and Innovation Cloud

This year ECRIN has continued to work within the HealthyCloud project to support the development of the strategic agenda for the Health Research and Innovation Cloud (HRIC) that the European Commission and Member States can implement. In June, ECRIN hosted members of the HealthyCloud consortium in its Paris office for a workshop to commonly identify the gaps and needs of the current European health research landscape and develop consensus on services that can be proposed to overcome current barriers. The feedback from the workshop is reflected in the first draft of the strategic agenda that was published in November. A series of stakeholder workshops was initiated in December, where the proposed services are being presented, discussed and refined together with different communities. In 2023, the final strategic agenda will be provided, following extensive feedback from internal and external stakeholders.

Ongoing projects

EJP-RD

The European Joint Programme on Rare Diseases (EJP RD) is a programme aiming to create an effective rare diseases research ecosystem for progress, innovation and for the benefit of everyone living with a rare disease. Within the context of the project ECRIN has developed the Rare Disease Clinical Trial Toolbox a practical aid for researchers developing clinical trials on medicinal products for human use regardless of therapeutic area. This year ECRIN also hosted an EJP-RD NSS workshop "Identifying obstacles hindering the development of academic sponsored trials for drug repurposing on rare diseases" in Prague with the help of its Czech Partner, CZECRIN.

ERIC Forum

The ERIC Forum Project brought together the ERIC community to strengthen its coordination and enhance its collaborations. Within the project ECRIN was responsible for a report on the scientific evaluation practices for pan-European RIs and the development of three policy briefs: the first focused on the different funding models that have been implemented to support ERICs, the second underscored the importance of involving ERICs in research projects to provide greater impact and the third looked at the socio-economic impact of ERICs. The project came to a close at the end of the year and the cumulated knowledge has been curated into an toolkit, an online platform to facilitate access to the project deliverables.

EJP-RD NSS Workshop: Identifying obstacles hindering the development of academic sponsored trials for drug repurposing on rare diseases.

Interview on the Clinical Research Repository

Gerd Felder
Clinical Research Repository Manager
ECRIN

What do we mean by clinical research data sharing and why is it important?
Clinical research data sharing makes the individual participant data or aggregated summary data from clinical trials and cohort studies available to other researchers for further use.
Recently, major stakeholders have shared their commitment towards more open and FAIR scientific research. The results of clinical trials are increasingly considered a public good and data sharing is justified on scientific, economic and ethical grounds. Sharing also squeezes more value from the original research investment, as well as helps to avoid unnecessary repetition of studies.
Ethically, data sharing provides a better way to respect clinical trial participants contribution, as it increases the utility of the data.
Despite these efforts in practice, only a small percentage of studies make their data available for re-use. As an example, less than 15% of clinical studies state upon registration that they will make data available for sharing. This percentage drops further when the principal investigators or sponsors are contacted with actual data sharing requests.

What is ECRIN doing to improve clinical research data sharing?
ECRIN has taken different actions to promote data sharing practices in clinical research.
Among them, we have: provided an evaluation of existing repositories for data sharing; produced policies and processes for individual participant data sharing; assessed the quality criteria for trusted repositories; designed and launched a Clinical Research Metadata Repository to increase the findability of clinical research studies and associated data objects; and more recently, ECRIN developed the Clinical Research

Repository (CCR) within the Horizon Europe EOSC-Life project as part of the response to the COVID-19 pandemic.

What is the CRR and who are the actors behind it?
The clinical research repository is a file based repository - capable of holding any type of 'digital object' - be it a data set, a document, a computer program, or a media file.
The secure infrastructure for file storage is provided by TSD, an established, secure, data infrastructure that is part of the University of Oslo.
The interface of the repository is provided by ECRIN. We liaise with both data providers, for the transfer of digital objects to the repository, and data requesters, browsing the objects under managed access. Both processes are governed by formal agreements, one for the data providers, and another for the secondary users. ECRIN uses a Repository Management System, developed in-house, to manage and record this activity.

What were the main highlights of the repository development in 2022?
The system developed so far is intended to provide and support: the management of repository content and its associated metadata; the transfer of data objects into the repository, including details of data contributors and their requirements; the quality control processes applied to uploaded data objects; the handling of data requests, in particular the responses of the repository in answering data requests; the usage of all types of stored data objects; the repository's performance against pre-agreed quality criteria; interfacing with other systems, for example TSD and ECRIN's MDR.
The aim of these efforts is to provide a single system to support and record all the workflows associated with managing the repository.

What is expected for the Clinical Research Repository in 2023?
2023 will be an important year for the Clinical Research Repository. In the first quarter, we will provide the alpha version of the repository and proceed with a soft launch for potential users. The initial user feedback will be used to improve the software for the beta release which will be made available to a wider public. Upon the beta release of the system, extensive discussions with stakeholders are planned to attract the first data providers and data re-users. The longer-term sustainability model of the repository will also be discussed. August 2023 will mark the end of EOSC-Life, but the development and operations of the repository will continue within the BY-COVID and canSERV projects. So, stay tuned!

Watch the full interview...

Data Centre Certification

OVERVIEW OF THE DATA CENTRE CERTIFICATION PROGRAM

The goal of the Data Centre Certification programme is to enhance high-quality data management services in non-commercial clinical trials and to contribute to the harmonisation of European practice in data management through the certification of non-commercial data centres from ECRIN Member and Observer countries.

UPDATE OF THE STANDARDS

A small group of experts started to review the standards to take into account the technical and regulatory changes. A new version is expected in Spring 2023.

BENEFITS FOR PARTICIPANTS

The potential rewards for Data Centre Certification recipients are numerous. Data centres can benefit from the ECRIN IT/DM standards as a reference guideline for leveraging competence, harmonisation, structuring and clarifying their working practice and implementing state-of-the-art good data management practice and latest technical developments. Training on data management and IT 'hot topics' (e.g., data sharing, clinical data management, Clinical Data Interchange Standards Consortium – CDISC) are regularly organised to the programme community of data centres.

Furthermore, auditors from CTUs involved in the certification programme receive advanced training on data management / IT, and thus may play a leading expert role in discussions on these topics in their respective countries. And finally, the programme provides a competitive advantage to the certified data centre with increased attractiveness to large-scale multinational projects, and trust in services quality from sponsors, authorities and partners.

2022 CALL FOR DATA CENTRE CERTIFICATION

On 9 June 2022, a call was launched for data centres to apply for certification. All interested centres had three months to complete an online questionnaire to confirm their readiness for audit with the aim of certification by the ECRIN Independent Certification Board. In 2022 two new centres applied for certification and a third centre applied for renewal.

Support Services

Quality

ECRIN QUALITY MANAGEMENT SYSTEM (QMS)

After its initial certification in 2020 by the French Association for Standardisation (AFNOR), ECRIN has completed its second follow-up audit and successfully confirmed its ISO 9001:2015 certification for its principal services and quality management system. The certification is applied to ECRIN's staff for the principal services: the coordination of operational services to the management of multinational clinical studies in Europe, the capacity development through the participation in infrastructure development projects and the certification of data centres. These services all have proven, effective processes to enable the best possible results to enhance our customer satisfaction.

ECRIN has, since its creation, applied the ICH GCP E6(R2) requirements and has worked to further enhance the standardization, effectiveness and performance of its QMS. The QMS at ECRIN is fit-for-purpose and has been adapted to the distributed infrastructure via an integrated, risk and process-based approach which ensures the highest services and process performance.

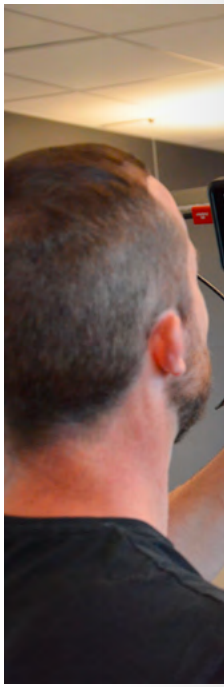
All staff are routinely trained on the various standard operating procedures to ensure a clear understanding and application of the "plan, do, check, act" approach. The quality management system will continue to implement improvements to ensure continued compliance and customer satisfaction.

Communications

ECRIN CORPORATE VIDEO & WEBSITE

After launching the new logo and visual charter in 2021, the rollout of the new ECRIN corporate identity continued in 2022 with the release of the ECRIN corporate video and the unveiling of the new website.

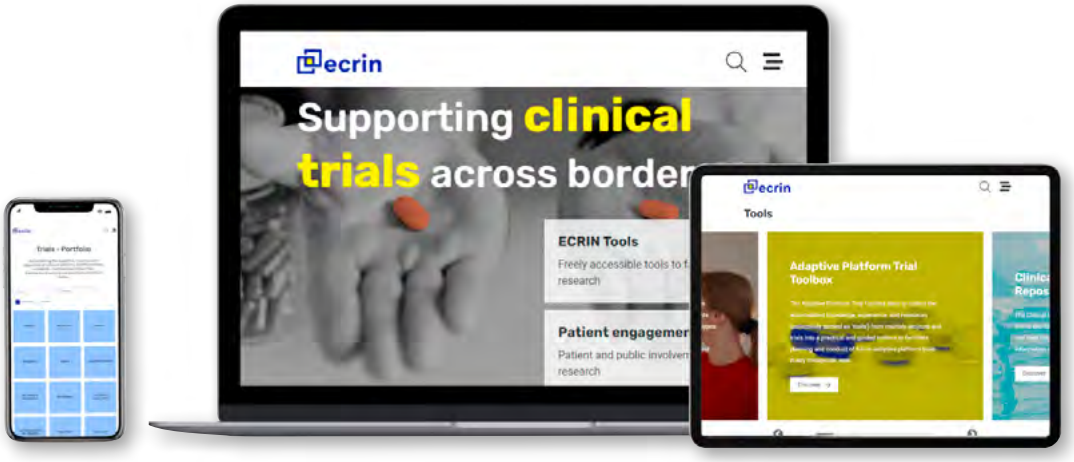
Working with key stakeholders in different ECRIN countries, a film crew travelled across Europe to conduct interviews as they weaved together the story 'ECRIN opening doors to clinical research'. The video highlights the various people who work with and rely on ECRIN's services in order to carry out their clinical research activities. It also features ECRIN personel who explain how these tasks are carried out. The video was launched at ECRIN's annual event, International Clinical Trials



Day and will remain a pillar of how ECRIN works with different parties for years to come. To complement the three minute video, a shorter one minute video was developed in parallel.

Filming the principal investigator of EU SolidACT and members of the local CTU in Oslo, Norway.

Film crew working with the Czech EuCo for the corporate video



One of the biggest tasks in communications at ECRIN this year was the development of the new website. The aim was to build a more modern website with better ergonomic functionalities and simplified content. The previous content was updated, reorganised and streamlined, where necessary new content was added, so that users can easily move around the website to learn more about ECRIN's various activities and quickly find the resources that are of use to them. Beyond the improved ergonomy with slideshows and tabs, a hashtag classification system was added as well as the standard word search which allows users to easily find all the related information on a given topic.

INTERNATIONAL CLINICAL TRIALS DAY 2022: RECRUITMENT IN CLINICAL TRIALS

Together with the KKS Netzwerk, ECRIN hosted International Clinical Trials Day 2022, which was live streamed from Berlin as a hybrid event. It built on the intentions of ICTD 2020 which was cancelled due to the pandemic. This event was a first opportunity to reunite ECRIN stakeholders in person after a couple of years of online meetings.

Over 100 participants were present in the Langenbeck-Virchow-Haus in Berlin, and more than 400 people connected from all across the world and followed the event via the online live stream. The keynote by Prof. Matthias Briel focused on the

Keynote address by Prof Matthias Briel

methodological studies undertaken on recruitment in clinical trials, or the lack thereof. He highlighted many of the issues that would be discussed throughout the day, including the importance of patient engagement, and the development of trials through patient cohorts.

Different perspectives on the importance of recruitment in clinical trials, including the impact on funding, patients involvement, and the use of new technologies were presented followed by use cases from clinical trials, cohorts and trial registries. To close the day a lively debate between the audience and some of the speakers brought to light some of the more contested issues that can be linked to recruitment. Some of the overarching conclusions of the day include:

- the need for patient involvement,
- the adoption of pilot trials to ensure trial feasibility,
- established infrastructures and networks for clinical trials and research methodology,
- the use of technology, including electronic health records, to support patient recruitments.

Panelists address the questions on recruitment in clinical trials at ICTD 2022.

Interview on ECRIN Communications

Martina Esdaile
Communication Officer
ECRIN

Could you briefly describe the role of Communications at ECRIN?
Communications at ECRIN are responsible for both external and internal communication, as well as, project communications.
In short, we support communication within the organisation via awareness of upcoming events, development of material for our staff and partners to use.
Our external communication is carried out by the communications staff via the regular communications channels including our website and social media but is strongly supported by the actions of our staff that are in constant contact with our different stakeholders.
The role of communications in projects can vary from support and dissemination of key messages to the development and execution of dedicated communication plans.

How do you work with the national partners?
ECRIN's distributed nature, developed on the principle of integrating existing clinical trial networks has provided it with a unique position to access the national clinical research landscape.
While our European Correspondents are our primary ambassadors within the different Member and Observer countries we also work directly with the communication professionals within the national network. With their support, we are capable of conducting direct dissemination within each country.
We organise quarterly meetings to support the development of messages that can be sent jointly. Through these meeting, we offer just-in-time training on best practices in communications.

Can you tell us more about the new ECRIN corporate identity?
ECRIN has been rolling out a new corporate identity. This all began with the launch of a new logo in November 2021. The logo was developed using the

core elements of the previous logo, the squares, and the importance of having users in the centre. These users can be patients, or the sponsors and investigators with whom we work. The new logo also can be interpreted to show our distributed nature which englobes not only our staff, the EuCos and the core team, but all those working across our national networks, in the different CTUs, to ensure operational coordination of clinical studies.
The aim of the new identity was to develop a modern take providing greater visibility to the brand while highlighting the maturity and important place ECRIN has developed for itself in the clinical research community. The colours are now more vibrant and can allow the brand to stand out among others.
In 2022 we continued to develop the rollout of this new identity and the last elements will be delivered in 2023.

What are new tools in your communication portfolio?
Over the past year, our communication team has been working to develop the necessary elements to support the new brand identity. In 2022 we have updated many of the ECRIN visuals for internal and external use. Among which are two key communication tools. The first is the development of a corporate video where key stakeholders across Europe were interviewed and explain the benefits of working with ECRIN. The second was the launch of a new website that centralises the essential information on ECRIN in a user-friendly format.

What will be the focus for the next year?
ECRIN has quite a lot planned for 2023. We will continue to support our key events, notably international clinical trials day for the clinical research community where we will focus on decentralised clinical trials: challenges and opportunities. And our CTU Day for the CTUs in our national partners. We will also have the pleasure of organising the celebration of the 10 years since ECRIN has attained its ERIC status.
To finalise the various elements of the new brand identity, the ECRIN brochures will be updated.
We also will look to highlight the work carried out by our national partners through the development of a communication campaign that will highlight them individually.
We will continue to build on the work done to date and support our staff to be sure that they have the necessary materials to communicate clearly on ECRIN and its missions.

Watch the full interview...

Training

INTERNAL TRAINING: ECRIN SUMMER SCHOOL

For the first time in 3 years, ECRIN staff from across its national networks and core team came together for a team building session in Rome. ECRIN's Italian partner, ItaCRIN, hosted 3 days of workshops and learning in the heart of Villa Borghese. This provided our staff time to learn about some more recent projects but also to work on the importance of understanding cultural differences in the workplace.

ECRIN summer school

ECRIN CTU TRAINING: SECOND EDITION

After the success of the first edition, on 2 December 2022 ECRIN hosted its second CTU Day uniting personnel from the CTUs in its national partners across Europe. Over 200 participants tuned in to learn about the latest updates at ECRIN and get to know our Czech and German national networks. Moreover, this year the event focused on feedback from the first multinational academic submission (TTV-Guide TX) & transition from VHP to CTIS (EU-SolidAct) approved in CTIS. The organization of CTIS, the timing of the various steps, the numerous documents requested, and tips to support others to successfully submit their trials were highlighted by Jette Rahn, Christiane Gaebel and Inge Christoffer Olsen.

ECRIN staff training at the Paris headquarters

EXTERNAL TRAINING

The PERMIT project developed numerous trainings to support the dissemination of the recommendations from webinars through to an asynchronous online training that is available on demand.

The trainings are available at three different levels to address different publics from the lay person through to the expert with a course dedicated to providing a full overview of the whole project.

Governance and strategy

Partnerships

EUPATI

Engaging and developing patient involvement in clinical research and medicines development, is one of the six goals in the ECRIN 2021-2023 Strategic Plan. Since the very beginning, ECRIN worked closely with patient representatives throughout its organisation. As the previous year closed with the signing of a strategic partnership with EUPATI, the European Patients' Academy on Therapeutic Innovation, this year was marked by the contributions to the organisation.
The collaboration with EUPATI is an important step in ECRIN's commitment to provide and improve education and training opportunities in clinical research for patients, patient representatives and patient engagement for clinical researchers. The partnership also aims to strengthen academic researchers' capacities to effectively engage with patients in their studies.
Christine Kubiak, ECRIN's Operations Director, has been elected as a Board member at EUPATI. In this role she will be representing the Academic cluster, reinforcing ECRIN's commitment to strengthen and develop balanced partnerships with users and patients, and to help get the best, reproducible results for tomorrow's patients.
During ICTD 2022, the patients' perspective was addressed by a EUPATI Fellow who shared her experience and vision on 'patient involvement in clinical research and its impact on patient recruitment.' The closing panel on new perspectives for patient recruitment also included a member of EUPATI who highlighted the importance of patient involvement, patient education and treating patients as equal partners for patient recruitment success.

EU-AMRI

The year 2022 has proven to be a busy and productive year for EU-AMRI, the collaboration between the European research infrastructures BBMRI-ERIC, EATRIS-ERIC, and ECRIN-ERIC. On April 5th, EU-AMRI was officially launched during a live broadcast from Brussels. The event brought together important stakeholders to discuss the European biomedical research landscape, and the needs for larger projects to work with the Alliance of research infrastructures. Professor Walter Ricciardi opened the

event, which was followed by a vivid roundtable discussion with a variety of stakeholders.
Furthermore, EU-AMRI organised a one-hour side event at ICRI 2022, held in Brno (Czech Republic). During this event case studies in the field of scientific health research were presented, shining a light on national and international collaborations creating synergies between Research Infrastructures.

EU AMRI Launch panel.

Beyond Europe: CRIGH

CRIGH, the Clinical Research Initiative for Global Health, aims to optimise clinical research programmes, develop global standards on clinical research, promote the uptake of innovative methodology and technologies, and encourage international cooperation to rapidly and efficiently respond to global health challenges. In November 2022, CRIGH submitted a response for the WHO stakeholder consultation on WHA Resolution 75.8 “Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination”. CRIGH and its actions are disseminated, via ECRIN and other partners, in support of clinical research capacity development.

Assembly of Members

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

Rafael de Andrés	Chair (Spain)
Maria Ferrantini	Vice-Chair (Italy)
Gonzalo Arevalo (end of term)	Spain
Maria Pilar Gayoso (new member)	Spain
Andreia Feijão	Portugal
Renáta Chudáčková (end of term)	Czech Republic
Marta Vandrovcova (new member)	Czech Republic
Dalibor Valik (new member)	Czech Republic
Svenja Krebs	Germany
Eric Guittet	France
Annette Magnin (end of term)	Switzerland
Barbara Flueckiger (new member)	Switzerland
Øyvind Melien	Norway
Daniel Pella	Slovakia
Julianna Pantya	Hungary
Agnieszka Ryniec	Poland
Oonagh Ward	Ireland

Jacques Demotes, ECRIN Director General with Network Committee Chair & Co-chair

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)
Annette Magnin (end of term October)	Vice-chair (Switzerland)
Regina Demlová (vice-chair as of December)	Vice-chair (Czech Republic)
Camilla Tondel	Norway
Anja Eskat	Switzerland
Lukasz Szumowski	Poland
Fionnuala Keane	Ireland
Judit Tarnai	Hungary
Emilia Montero	Portugal
Jesús Frías (replaced by)	Spain
Antonio Carcas (new member)	Spain
Lucia Palmisano (end of term)	Italy
Elena Toschi (new member)	Italy
Daniel Pella	Slovakia
Olivier Rascol	France
Christine Trillou (new member)	France
Heiko Von Der Leyen (end of term)	Germany
Britta Lang (new member)	Germany

Governance Meetings in 2022

ASSEMBLY OF MEMBERS (AOM)
19 January 2022
24 March 2022
16 May 2022
13 June 2022
30 September 2022
14 December 2022

NETWORK COMMITTEE
18 January 2022
26 April 2022
16 May 2022
13 December 2022

Steering Committee

ECRIN's Steering Committee oversees activities and provides advice on budget, work plan and scientific/technical matters. It is composed of the Chair and Vice-chair of the AoM, the Chair and Vice-chair of the Network Committee, as well as the Director General.

Scientific Board – Peer Review Committee

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

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

Advisory Board

The ECRIN Advisory Board is composed of individuals representing diverse areas related to clinical research, both in Europe and internationally. Members provide input and recommendations to the AoM on all matters related to the activities of the infrastructure and its further development.

Paul Avillach	Harvard Medical School
Patrick Bossuyt	University of Amsterdam
Frank Hulstaert	Belgian Health Care Knowledge Centre, KCE
Kaisa Immonen	European Patient's Forum
Michal Koščík	Masaryk University
Shaun Treweek	University of Aberdeen

Financial report 2022

INCOME

Membership Core contributions	1 355 002 €
Membership Local contributions	950 000 €
Research projects	2 296 480 €
Other income	111 €
Financial income	232 341 €
Extraordinary income	15 000 €
TOTAL INCOME FOR 2022	**4 848 933 €**

EXPENDITURES

Salaries & other staff expenses	2 060 803 €
Subcontracting	1 329 084 €
Office rent and insurance	305 955 €
Communication & IS	211 711 €
Travel and meetings	141 814 €
Financial expenses	8 181 €
Other expenses	373 913 €
Income tax	54 152 €
Local contribution provided in-kind	850 000 €
TOTAL EXPENDITURE FOR 2022*	**5 335 613 €**

NET RESULT

NET RESULT FOR 2022	**- 486 680 €**

* 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

Acronyms

AAHCI	Alliance of Academic Health Centers International
AFNOR	Association Française de Normalisation
A_IATRIS	Italian node of EATRIS
AICIB	Agency for Clinical Research and Biomedical Innovation
AoM	Assembly of Members
APIFARMA	Portuguese Association of Pharmaceutical Industry
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
canSERV	Providing Cutting Edge Cancer Research Services Across Europe
CDISC	Clinical Data Interchange Standards Consortium
CILO	Clinical Industry Liaison Officer
CLIC	Clinical Investigator Certification,
CONSCIOUS II	Curriculum Development of Human Clinical Trials
COVID-19	Coronavirus Disease 2019
CRC	Clinical research centre
CRFs/CRCs	Clinical research facilities/Clinical research centres
CRIGH	Clinical Research Initiative for Global Health
CRO	Clinical Research Organisation
CT	Clinical Trial
CTIS	Clinical Trial Information System
CTU	Clinical Trial Unit
CZECRIN	Czech Clinical Research Infrastructure Network
DCC	Data Centre Certification
DM	Data Management
EATRIS	European Advanced Translational Research Infrastructure in Medicine
EC	European Commission
eCREAM	Enabling Clinical Research In Emergency And Acute Care Medicine Through Automated Data Extraction
ECRIN	European Clinical Research Infrastructure Network
EHDS	European Health Data Space
EJP-RD	European Joint Programme on Rare Diseases
EMA	European Medicines Agency
EOC	Ente Ospedaliero Cantonale

EOSC	European Open Science Cloud
EOSC4Cancer	A European-wide foundation to accelerate data-driven cancer research
EOSC-Life	European Open Science Cloud Life project
ERASMUS+	EU programme for education, training, youth and sport
ERA4Health	European Research Area for Health Research
ERAPerMed	European Research Area for Personalised Medicine
ERIC	European Research Infrastructure Consortium
EU	European Union
EU-AMRI	European Alliance of Medical Research Infrastructures
EUCLID	EUropean CLInical Trials Platform & Development
EuCo	European Correspondent
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database
EU-Africa PerMed	Building links between Europe and Africa in personalised medicine
EULAC PerMed	Widening EU-LAC policy and research cooperation in Personalised Medicine.
EUPATI	European Patients' Academy on Therapeutic Innovation
EU-RESPONSE	European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases
EU-SolidACT	EUropean discovery for SOLIDarity Adaptive Clinical platform Trial
F-CRIN	French Clinical Research Infrastructure Network
FAIR	Findable Accessible Interoperable, and Reusable
GCP	Good Clinical Practice
HealthyCloud	Health Research and Innovation Cloud
HECRIN	Hungarian Clinical Research Infrastructure Network
HRB	Health Research Board
HRB NCTO	Health Research Board National Clinical Trials Office
HRIC	Health Research and Innovation Cloud
ICRI	International Conference on Research Infrastructures
ICH	International Conference on Harmonisation
ICPerMed	International Consortium for Personalised Medicine
ICTD	International Clinical Trials Day
IdiPaz	Instituto de Investigación del Hospital Universitario La Paz
IICT	Investigator Initiated Clinical Trials
IS	Information Systems

ISCIII	National Institute for Health Carlos III
ISIDORe	Integrated Services for Infectious Disease Outbreak Research
ISO	International Standards Organisation
ISS	Istituto Superiore di Sanità
IT	Information Technology
ItaCRIN	Italian Clinical Research Infrastructure Network
JAAM	Joint Access Advisory Mechanism
KCE	Belgian Health Care Knowledge Centre
KKSN	Netzwerk der Koordinierungszentren für Klinische Studien
LAC	Latin America and the Caribbean
MRA	(Polish) Medical Research Agency
NCTO	National Clinical Trials Office
NorCRIN	Norwegian Clinical Research Infrastructure
NSS	Networking Social Scheme
PERMIT	Personalised Medicine Trials
PHRC	programme hospitalier de recherche Clinique
PM	Personalised Medicine
POLCRIN	Polish Clinical Research Infrastructure Network
PPI	Patient and Public Involvement
PRC	Peer Review Committee
PT	Portugal
PtCRIN	Portuguese Clinical Research Infrastructure Network
QMS	Quality Management System
RAPHE	Regulatory Advice and Pharmacoeconomics
REMEDi4ALL	Building a sustainable European innovation platform to enhance the repurposing of medicines for all
RI	Research infrastructure
RI-VIS	Expanding research infrastructure visibility to strengthen strategic partnerships
SCReN	Spanish Clinical Research Network
SCTO	Swiss Clinical Trial Organisation
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
SYNCHROS	SYNergies for Cohorts in Health: integrating the Role of all Stakeholders
TTV-Guide	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. Short Title: TTV Guide IT
VACCELERATE	European Corona Vaccine Trial Accelerator Platform
WG	Working Groups
WHA	World Health Assembly
WHO	World Health Organisation

Clinical Trial Portfolio in 2022 (current trials)

During 2022 ECRIN provided support to 35 clinical trials in different phases; at the end of the year 4 were in the set-up phase working toward the opening of all sites in all participating countries; and 26 trials were active-meaning in the phases of recruitment, follow-up, close-down activities.

SHORT title	Protocol title	Trial_status	CT Sponsor country	Funding source
ETAPA	Randomised Placebo-Controlled Trial of Early Targeted Treatment of Patent Ductus Arteriosus with Paracetamol in Extremely Low Birth Weight Infants	Start-up phase		Irish government
NICOFA	A randomized, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of nicotinamide in patients with Friedreich's Ataxia	Start-up / on hold		ERA-Net & DFG
SeeMyLife	Holistic mixed approaches to capture the real life of children with Rare Eye Diseases	Start-up phase		Joint Translational funding
TB-MED – BIOCERAMED	Prospective Multicenter Observational Study on the use of NEOCEMENT ® for the Treatment of Bone Defects-Registry-based study	Start-up phase		210487722*
BETA3_LVH	A multi-centre randomized, placebo-controlled trial of mirabegron, a new beta3-adrenergic receptor agonist on the progression of left ventricular mass and diastolic function in patients with structural heart disease	Running phase		634559*
CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	Running phase		German government
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults	Running phase		101015736*
EU-COVAT-1	A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults (≥75) already Vaccinated Against SARS-CoV-2	Running phase		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 SARS-CoV-2 in the general population (18+ years) already fully vaccinated against SARS-CoV-2	Running phase		101037867*
EU-TRAIN RCT (IMPACT)	Randomized Controlled Multicenter Trial to quantify the benefits of biomarkers in routine patient care in kidney transplant recipients	Running phase		754995*
EU-TRAIN COHORT	Prospective cohort of kidney transplant patients	Running phase		754995*
IDEA-FAST – COS	Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases	Running phase		IMI2 853981*
ImmunAID	Immunome project consortium for AutoInflammatory Disorders	Running phase		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 phase		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 phase		731875*
MACUSTAR	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention	Running phase		IMI 116076
NECESSITY	NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifYing patients	Running phase		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 phase		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 phase		733203*
PRECIOUS	Prevention of Complications to Improve Outcome in Elderly Patients with Acute Stroke	Running phase		634809*
PROOF	Penumbral Rescue by Normobaric O=O Administration in Patients With Ischaemic Stroke and Target Mismatch ProFile: A Phase II Proof-of-Concept Trial	Running phase		733379*
RESPINE	REgenerative therapy of intervertebral disc: a double blind phase 2b trial of intradiscal injection of mesenchymal stromal cells in degenerative disc disease of the lomber SPINE unresponsive to conventional therapy	Running phase		732163*
R-Link	Optimizing response to Li treatment through personalized evaluation of individuals with bipolar I disorder: the R-LiNK initiative	Running phase		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 phase		Industry
SOLIDACT	European DisCoVeRy for Solidarity: An Adaptive Pandemic and Emerging Infection Platform Trial.	Running phase		101015736*
SWEET	Sweeteners and sweetness enhancers: Impact on health, obesity, safety and sustainability	Running phase		774293*
TENSION	Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window	Running phase		754640*
TERIS	Multi-center, randomized, double-blinded study of Teriflunomide® in radiologically isolated syndrome (RIS)	Running phase		Industry
TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen Study type	Running phase		IMI 777389*

TTV	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	Start-up phase		896932*
BETA3_LVH	A multi-centre randomized, placebo-controlled trial of mirabegron, a new beta3-adrenergic receptor agonist on the progression of left ventricular mass and diastolic function in patients with structural heart disease	Completed		634559*
ORTHOUNION	A multi-centre, open-label, randomized, comparative clinical trial of two different doses of bone marrow autologous human mesenchymal stem cells plus biomaterial versus iliac crest autologous graft, for bone healing in non-union after long bone fractures	Completed		733288*
ADIPOA2	Autologous Adipose-Derived Mesenchymal Stromal Cells in the Treatment of Mild to Moderate Osteoarthritis	No longer requires ECRIN services		643809*
EU-COVPT	A Phase 2, Comparative Randomised Trial to Evaluate the impact of reduced COVID-19 mRNA vaccination regimen on immunological responses and reactogenicity in paediatric subjects with prior SARS-CoV-2 immunity (CoVacc)	Withdrawn		101037867*
HIVACAR	Evaluating a Combination of Immune-based Therapies to Achieve a Functional Cure of HIV Infection	No longer requires ECRIN services		731626*

* 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 Framework Project 7 research and innovation programme under the listed grant agreement.

Infrastructure Development Projects Portfolio in 2022 (current projects)

ECRIN participated in a total of 32 projects this past year, of which 6 kicked off in 2022.

Acronym	Full name	Status (as of 12/2022)	Funding
B1MG	Beyond 1 Million Genomes	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 951724.
BY-COVID	BeYond-COVID	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101046203.
canSERV	Providing Cutting Edge Cancer Research Services Across Europe	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101058620.
c4c	conect4children	Running	The Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389. The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries & Associations (EFPIA).
CRIGH	Clinical Research Initiative for Global Health	Running	Funding through members' contributions.
ECRAID-Base	European Clinical Research Alliance on Infectious Diseases	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 965313.
ECRAID-Prime	European Clinical Research Alliance on Infectious Diseases: PRIMary care adaptive platform trial for pandemics and Epidemics	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101046109.
eCREAM	Enabling Clinical Research In Emergency And Acute Care Medicine Through Automated Data Extraction	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101057726.
EJP-RD	European Joint Programme on Rare Diseases	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825575.

EOSC4Cancer	A European-wide foundation to accelerate data-driven cancer research	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101058427.
EOSC-Future	European Open Science Cloud Future	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101017536.
EOSC-Life	Providing an open collaborative space for digital biology in Europe' — 'EOSC-Life'	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 824087.
ERA4Health	Fostering a European Research Area for Health	Running	Co-funded by European Union's Horizon Europe research and innovation proframme under grant agreement number 101095426.
ERIC- Forum	ERIC-Forum Implementation project	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 823798.
EU-Africa PerMed	Building links between Europe and Africa in Personalised Medicine	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 964333.
EU-PEARL	EU Patient cEntric clinical tRial pLatform	Running	The European Union's Horizon 2020 research and innovation programme and the Innovative Medicines Initiative (IMI) under grant agreement number 853966-2.
EU-RESPONSE	European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101015736.
EULAC-PerMed	Widenening Eu-CELAC policy and research cooperation in Personalised Medicine	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825173.
EuroGCT	European consortium for communicating gene- and cell-based therapy information.	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 965241.
HealthyCloud	Health Research and Innovation Cloud	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 965345.

ISIDORe	Integrated Services for Infectious Disease Outbreak Research	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101046133.
PERMIT	PERsonalised MedicIne Trials	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 874825.
RECoVER	Rapid European SARS Cov-2 Emergency Research response	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101003589.
REMEDi4ALL	Building a sustainable European innovation platform to enhance the repurposing of medicines for all	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101057442.
RI-VIS	Expanding research infrastructure visibility to strengthen strategic partnership	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 824063.
SIMCOR	In-Silico testing and validation of Cardiovascular Implantable devices	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101017578.
SYNCHROS	SYNergies for Cohorts in Health: integrating the Role of all Stakeholders	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825884.
TBMED	A testing bed for the development of high-risk medical devices	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 814439.
TESA III	Trials of Excellence in Southern Africa III	Running	European & Developing Countries Clinical Trials Partnership (EDCTP) under GA CSA 2020NoE-3104TESAIII
TRANSVAC-DS	Design study for a European vaccine infrastructure	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 951668.
TRANSVAC2	European Vaccine Research and Development Infrastructure	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 730964.
VACCELERATE	European Corona Vaccine Trial Accelerator Platform	Running	The European Union's Horizon 2020 programme under grant agreement number 101037867.

2022 Publications

Publication	Related project/trial
Ader F, Bouscambert-Duchamp M, Hites M, et al. Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomised, controlled, open-label trial. The Lancet Infectious Diseases. 2022;22(2):209-221. doi: 10.1016/S1473-3099(21)00485-0	Discovery / EU RESPONSE
Amstutz A, Speich B, Mentré F, et al. Effects of Remdesivir in Hospitalized Patients with COVID-19: Systematic Review and Individual Patient Data Meta-Analysis of Randomized Clinical Trials. Published online October 11, 2022. doi: 10.2139/ssrn.4244759	DisCoVeRy, EUSolidAct, EU-Reponse
Antikainen E, Njoum H, Kudelka J, et al. Assessing fatigue and sleep in chronic diseases using physiological signals from wearables: A pilot study. Frontiers in Physiology. 2022;13. Accessed November 14, 2022. https://www.frontiersin.org/articles/10.3389/fphys.2022.968185	IDEA-Fast
Aydin B. COVID-19 ve Platform Klinik Araştırmaları. Turkiye Klinikleri J Med Oncol-Special Topics. 2022;15(3):175-178.	
David R, Ohmann C, Boiten JW, et al. An iterative and interdisciplinary categorisation process towards FAIRer digital resources for sensitive life-sciences data. Sci Rep. 2022;12(1):20989. doi: 10.1038/s41598-022-25278-z	EOSC-Life
del Álamo M, Bührer C, Fisher D, et al. Identifying obstacles hindering the conduct of academic-sponsored trials for drug repurposing on rare-diseases: an analysis of six use cases. Trials. 2022;23(1):783. doi: 10.1186/s13063-022-06713-y	EJP-RD
Devos D, Labreuche J, Rascol O, et al. Trial of Deferiprone in Parkinson's Disease. New England Journal of Medicine. Published online November 30, 2022. doi: 10.1056/NEJMoa2209254	FAIRPARK II
Gagnat Y, Oudenhoven LM, Brændvik SM, Bardal EM, Roeleveld K. Energy cost of gait in children and the effect of speed, age, and body size. Gait & Posture. 2022;98:146-152. doi: 10.1016/j.gaitpost.2022.09.005	WE Study
Galasko D, Simuni T. Lack of Benefit of Iron Chelation in Early Parkinson's Disease. New England Journal of Medicine. 2022;387(22):2087-2088. doi: 10.1056/NEJMe2213120	FAIRPARK II
Haupenthal F, Rahn J, Maggi F, et al. A Multicentre, Patient- and Assessor-Blinded, Non-Inferiority, Randomised and Controlled Phase II Trial to Compare Standard and Torque Teno Virus-Guided Immunosuppression in Kidney Transplant Recipients in the First Year After Transplantation: Ttv Guide It.; 2022. doi: 10.21203/rs.3.rs-2337435/v1	TTV Guide IT (preprint)

Kjølbæk L, Manios Y, Blaak EE, et al. Protocol for a multicentre, parallel, randomised, controlled trial on the effect of sweeteners and sweetness enhancers on health, obesity and safety in overweight adults and children: the SWEET project. BMJ Open. 2022;12(10):e061075. doi: 10.1136/bmjopen-2022-061075	SWEET
Neuhann JM, Stemler J, Carcas A, et al. A multinational, phase 2, randomised, adaptive protocol to evaluate immunogenicity and reactogenicity of different COVID-19 vaccines in adults ≥75 already vaccinated against SARS-CoV-2 (EU-COVAT-1-AGED): a trial conducted within the VACCELERATE network. Trials. 2022;23(1):865. doi: 10.1186/s13063-022-06791-y	VACCELERATE & EU-COVAT-1-AGED
Ohmann C, David R, Abadia MC, et al. Pilot Study on the Intercalibration of a Categorisation System for FAIRer Digital Objects Related to Sensitive Data in the Life Sciences. Data Intelligence. Published online March 7, 2022:1-16. doi: 10.1162/dint_a_00126	
Panagiotopoulou M, Yaïche S, Michon A, et al. EOSC-Life Public database inventorying the national health databases and registries and describing their access procedures for reuse for research purposes. Published online October 5, 2022. doi: 10.5281/zenodo.7148861	EOSC-Life
Roustit M, Demarcq O, Laporte S, et al. Les essais plateformes. Therapies. Published online December 5, 2022. doi: 10.1016/j.therap.2022.11.011	
Rychlickova J, Nagy V, Shiely F, et al. Training clinical trial teams of the future: open online teaching programs. Eur J Clin Pharmacol. Published online November 23, 2022. doi: 10.1007/s00228-022-03426-8	
Salmanton-Garcia J, Stewart FA, Heringer S, et al. VACCELERATE: Volunteer Registry: A European Study Participant Database to Facilitate Clinical Trial Enrolment. Social Science Research Network; 2022. doi: 10.2139/ssrn.4016606	VACCELERATE
Seror R, Baron G, Camus M, et al. Development and preliminary validation of the Sjögren's Tool for Assessing Response (STAR): a consensual composite score for assessing treatment effect in primary Sjögren's syndrome. Annals of the Rheumatic Diseases. 2022;81(7):979-989. doi: 10.1136/annrheumdis-2021-222054	NECESSITY
Superchi C, Bouvier FB, Gerardi C, et al. Study designs for clinical trials applied to personalised medicine: a scoping review. BMJ Open. 2022;12(5):e052926. doi: 10.1136/bmjopen-2021-052926	PERMIT
Tarn J, Lendrem D, Barnes M, Casement J, Ng WF. Comorbidities in the UK Primary Sjögren's Syndrome Registry. Frontiers in Immunology. 2022;13. Accessed January 23, 2023. https://www.frontiersin.org/articles/10.3389/fimmu.2022.864448	NECESSITY

Terheyden JH, Pondorfer SG, Behning C, et al. Disease-specific assessment of Vision Impairment in Low Luminance in age-related macular degeneration - a MACUSTAR study report. British Journal of Ophthalmology. Published online March 29, 2022. doi: 10.1136/bjophthalmol-2021-320848	MACUSTAR
The Discharge Trial Group. CT or Invasive Coronary Angiography in Stable Chest Pain. New England Journal of Medicine. 2022;0(0):null. doi: 10.1056/NEJMoa2200963	DISCHARGE
The Discharge Trial Group. Comparative effectiveness of initial computed tomography and invasive coronary angiography in women and men with stable chest pain and suspected coronary artery disease: multicentre randomised trial. BMJ. 2022;379:e071133. doi: 10.1136/bmj-2022-071133	DISCHARGE
Torres Moral T, Sanchez-Niubo A, Monistrol-Mula A, et al. Methods for Stratification and Validation Cohorts: A Scoping Review. Journal of Personalized Medicine. 2022;12(5):688. doi: 10.3390/jpm12050688	PERMIT
Trutschel D, Bost P, Mariette X, et al. Variability of Primary Sjögren's Syndrome Is Driven by Interferon-α and Interferon-α Blood Levels Are Associated With the Class II HLA–DQ Locus. Arthritis & Rheumatology. 2022;74(12):1991-2002. doi: 10.1002/art.42265	NECESSITY

Notes

CONTACT
Management office:
30 Bd St Jacques 75014 Paris - France
For general information about ECRIN,
email us at: contact@ecrin.org

To contact your local European correspondent,
see here: https://ecrin.org/ecrin-staff
www.ecrin.org
Follow us on Twitter: @ECRIN_ERIC
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