SUPPORTING CLINICAL TRIALS ACROSS BORDERS

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Czech Republic
Masaryk University
Brno

France
INSERM
Toulouse

Germany
KKS-Netzwerk e. V
Berlin

Hungary
University of Pécs
Pécs

Ireland
Clinical Research
Development Ireland
Dublin

Italy
Istituto Superiore
di Sanita
Rome

Norway
St. Olav's Hospital
Trondheim

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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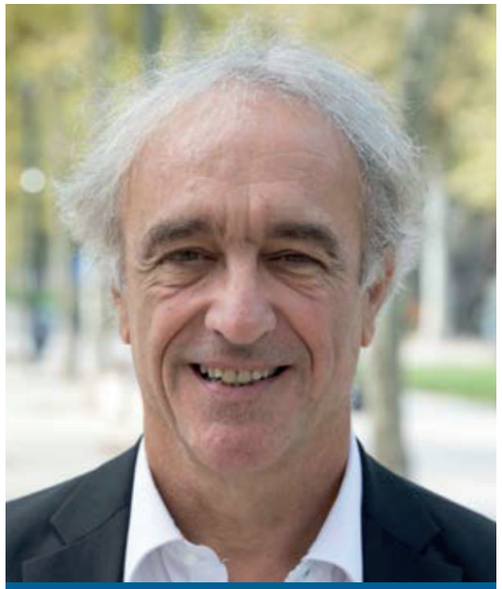
Letter from the Director General

The year 2020 was a challenging one as the Covid-19 outbreak had a tremendous impact on ECRIN's activities, cancelling all travel and face to face meetings while promoting working from home and video conferencing. It was also an opportunity for ECRIN to demonstrate its maturity as well as its capacity to adapt to a changing environment and to address new research questions, using innovative instruments and playing novel roles.



Jacques Demotes,
Director General of ECRIN

While the expanding spectrum of ECRIN's activities was reflected in the growth of its team (with currently 40 staff members, 20 at the headquarters in Paris and 20 European Correspondents in Member and Observer countries), the ISO 9001:2015 certification of its core services was awarded as a result of the continuous commitment of the whole team. ECRIN renewed its scientific board and the access procedures to operational multinational trial management services. The crisis led to closer cooperation with ECRIN national partners, in particular through the establishment of a Covid-19 taskforce, coordinating the involvement of ECRIN and its partners in project applications and implementation. Progress was made in the partnership with other ESFRI-roadmap medical research infrastructures through advancement in the model for an Alliance of Medical Research Infrastructures (EU-AMRI) with BBMRI and EATRIS.

While the PedCRIN project led to a strategic roadmap for partnership with the paediatric and rare disease community, experience in master protocols and adaptive platform trials derived from the IMI EU-PEARL project and the Covid-19 trials provided new models for partnership with medical specialties. The same applies to the personalised medicine research pipeline, as ECRIN develops in the PERMIT project, together with EU-AMRI partners, expertise on methodological standards for personalised medicine research that will foster partnerships in any disease area.

Substantial efforts were dedicated to the digital transformation of clinical research. A major achievement was the activation in April 2020 of the pilot version of the clinical research metadata repository, a global instrument for the identification of clinical trial metadata and related documents covering all the medical disciplines. In addition, an amendment to the EOSC-Life project was obtained to develop a secure and GDPR-compliant Covid-19 clinical trial data sharing platform, linked to the EU Covid-19 Data Portal. Furthermore, EOSC-Life also continues to support ECRIN in identifying the regulatory and data protection environment for secondary use of health and research data for clinical trials.

" The crisis led to closer cooperation with ECRIN national partners "

In the Covid-19 outbreak, ECRIN rapidly deployed support and services to the design, planning and conduct of clinical trials, built tools facilitating clinical research, and took on a role in the coordination of Covid-19 clinical research in Europe. ECRIN promoted large adaptive platform trials to test multiple interventions simultaneously, avoiding the duplication of trials. ECRIN and its national partners are now participants in all the EU-funded clinical trial initiatives, namely the EU-RESPONSE project funding both the DisCoVery and EU-SolidAct trials, the RECOVER project funding REMAP-COVID in Europe, and will be in 2021 part of the VACCELERATE project consortium establishing a pan-European vaccine network and designing master protocols for vaccine trials. ECRIN contributes to the design, planning, ethical and regulatory support, monitoring, data management and data sharing in these projects.

ECRIN also developed a toolbox to facilitate clinical research on Covid-19 including a literature review, data on Covid-19 trial registries, on funding calls, on fast-track regulatory approvals for Covid-19 trials, on the regulatory and ethical context during the pandemics, and other resources.

Finally, ECRIN leads a common work package acting as a bridge between RECOVER and EU-RESPONSE, in charge of coordinating the major Covid-19 trials. This includes the Trial Coordination Board fostering cooperation among the investigators of the large platform trials conducted in Europe, and promoting a dialogue with the major stakeholders (EMA, HTAs, CTFG, Ethics Committees, Industry) and policymakers (WHO, ECDC, EU Commission). This coordination mechanism also includes the exchange of unblinded information on safety between the DSMB chairs. A Joint Access Advisory Mechanism coordinates the activities of each trial's prioritization board, and provides a single entry point for investigator-initiated or industry-initiated arms requesting access to the large Covid-19 platform trials.

Although the Covid-19 turmoil undoubtedly disturbed the ECRIN 2020 work plan, it will result in a positive long-term impact as the team demonstrated its capacity to decide on relevant priorities and quickly react and adapt to the novel situation, offering new services, playing different roles and developing innovative technologies and methodologies.

Foreword from chair/co-chair of Assembly of Members

2020 marked an unexpected turning point for ECRIN. In 2020 ECRIN received its ISO 9001:2015 certification for its principal services: the coordination of operational services to the management of multinational clinical trials in Europe, capacity development through the participation in infrastructure development projects and the certification of data centres. This internationally recognised standard ensures for ECRIN's partners and users that ECRIN complies with rigorous quality standards and focuses on continuous improvement.

Rafael de Andrés,
Chair of ECRIN's Assembly of Members (Instituto de Salud Carlos III, ISCIII – Spain)

The ISO 9001:2015 certification, as well as the implementation of the recommendations of the external evaluation held in 2019, reinforce the main mission at ECRIN, which remains the provision of high-quality support for the conduct of multinational clinical research. ECRIN achieves this through the coordinated efforts with national scientific partners, as well as to partners elsewhere in Europe and beyond. For individual countries and to Europe as a whole, this cross-border collaboration is a huge advantage and its importance became evident through the Covid-19 pandemic: multinational clinical trials provided greater access to patients, expertise, resources, and more, which in turn provided faster and more robust results in the identification of prevention and treatments to Covid-19.

The Covid-19 pandemic impacted ECRIN and its services. It led to the participation of ECRIN in new projects and clinical trials in the search for preventative medicines, treatments and vaccines but also necessitated delays and extensions in some ECRIN supported trials and projects. Moreover, ECRIN and its networks came together early in the pandemic and developed the Covid-19 Taskforce to facilitate access to information enabling the advancement of clinical research on Covid-19 and to act as a united front in the aid.

Beyond the added support to clinical research ECRIN's Member and Observer countries benefit from access to other services such as the Data Centre Certification program and participation in projects that provide capacity development at the national level.

ECRIN services are available to all medical specialties but are particularly beneficial for rare diseases, paediatrics and personalised medicine where access to patients can be an obstacle. The participation in EULAC PerMed was supplemented with the launch of the ECRIN coordinated PERMIT project in January which will develop recommendations for robust and reproducible personalised medicine research. PEDCRIN, was granted a 6-month extension and will thus be continuing to disseminate results to the paediatric community through the first half of 2021.

ECRIN looks to remain on the cutting edge of clinical research methodology and is heavily invested through the large Covid-19 trials and EU-PEARL in the development of European adaptive platform trials which can be applied to all medical domains. The future of clinical research also looks to the secure and ethical secondary use of clinical data and ECRIN is developing toolbox through EOSC-Life for just this purpose.

The continuous growth of ECRIN in numbers of trials, projects, and staff underlines the strength and need of this unique organisation. Each piece contributes to the generation of scientific evidence through multinational clinical research which enhances medical practice, and ultimately, improves public health.

Maria Ferrantini,
Vice-chair of ECRIN's Assembly of Members (Istituto Superiore di Sanità, ISS – Italy)

2020 Highlights

January

- Kick-off of the ECRIN coordinated PERMIT project (PERsonalised MedIcine Trials)

February

- Inaugural meeting of the new Scientific Board
- Kick-off meeting for IDEA-FAST

March

- Launch of the ECRIN Covid-19 Taskforce
- Wrap-up meeting of CORBEL

April

- Launch of Clinical Research Metadata Repository (CRMDR)

May

- ICTD postponed
- Network Committee meeting
- Assembly of Members meeting

June

- Kick-off meeting for B1MG (Beyond 1 Million Genomes)

July

- Kick-off meeting for Transvac-DS

August

September

- ERIC Forum policy brief released
- Release of European Alliance of Medical Research Infrastructures (EU-AMRI) joint statement on Horizon Europe Mission Cancer
- Kick off meeting for EU-RESPONSE

October

- Clinical Research Initiative for Global Health (CRIGH) General Assembly
- Participation in the OECD Global Science Forum Workshop on the mobilisation of science to fight the Covid-19 crisis
- ECRIN joins the Covid-19 Clinical Research Coalition
- Quality and Risk Council meeting

November

- Network Committee meeting
- ECRIN awarded ISO 9001:2015 Certification for its principal services

December

- ECRIN joins the RECOVER project (Rapid European Covid-19 Emergency research Response)
- Assembly of Members meeting

PERMIT project kick-off meeting

3rd CRIGH General Assembly

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

Focus Areas Moving Forward

- ECRIN as the reference for planning and management of multinational clinical research
- Anticipate changes in clinical research
- Build and maintain strong and balanced partnership with users that lead to more efficient and successful clinical research
- Enhance the recognition of ECRIN's Corporate Identity
- Create a cohesive cooperative pan-European CTUs infrastructure
- Develop and strengthen collaboration of medical research infrastructures
- Support the European efforts to address Covid-19

ECRIN in numbers

7
Years that ECRIN has had ERIC status

9
Member countries

3
Observer countries

100
CTUs

346
Million European citizens in ECRIN member and observer countries

39
Number of trials supported by ECRIN throughout 2020

7
Average number of countries per ECRIN supported trial

24
Number of infrastructure development projects supported by ECRIN throughout 2020

5
Number of new infrastructure development projects

17
European Data centers certified since 2014

1110
LinkedIN followers (+58%)

1013
Twitter followers (+35%)

ECRIN Overview

Who we are

ECRIN is a sustainable, non-profit, distributed 'research infrastructure' (see box) with an ERIC legal status, that strives to overcome the obstacles to multinational trials in Europe. In particular, ECRIN supports sponsors and coordinating investigators in the preparation of their clinical trial projects and funding applications, and provides services for the management of multinational trials. It focuses on independent, multinational academic research as well as trials initiated by biotech and medical device small and medium-sized enterprises (SMEs).

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 infrastructure development projects aiming to develop its capacity, tools and services. Updates on ECRIN's trial support and project activities in 2020 can be found in the following pages (see 'Clinical Trial Operations' and 'Infrastructure Development' sections).

Organisation

ECRIN's organisational model is based on country membership. In 2020, it had nine member countries (Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Portugal and Spain) and three observer countries (Poland, 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 multi-national trials. They manage ECRIN's clinical trial portfolio in collaboration with the national scientific partner and the Paris-based core team.

Research Infrastructures

Research Infrastructures (RIs) are defined by the European Commission (EC) 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.

National Scientific Partner
Description & Highlights

Scientific Partner: CZECRIN
Czech Clinical Research Infrastructure Network
Czech Republic

Member since 1 Jan. 2018
Host institution: Masaryk University
National hub : Brno
www.czecrin.cz/en/home/

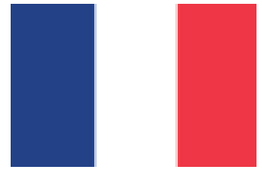
CZECRIN is a national, large research infrastructure, included in the Czech Roadmap for Large Research, Development and Innovation, that facilitates academic clinical trials in the Czech Republic. CZECRIN was built as a unique infrastructure, involving the network of most major clinical sites with a 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 provisioning and use of high-quality scientific data, implementing the FAIR (Findable, Accessible, Interoperable, and Reusable) principles. CZECRIN also annually organizes educational events and conferences, including International Clinical Trials Days.

2020 HIGHLIGHTS

In 2020 CZECRIN celebrated its 3rd year as an ECRIN full member country. In the last two years, CZECRIN significantly expanded its portfolio of services including the “Knowledge Expertise Core Unit” for Regulatory Advice and Pharmacoeconomics (RAPHE). It also expanded CZECRIN’s CTU network (consisting of 12 CTUs within the university hospitals) and completed Good Manufacturing Practice (GMP) facilitating the development of Advanced Therapy Medicinal Products (ATMP) for somatic cell therapies. CZECRIN decided to create disease-oriented networks in priority clinical research areas, in line with research topics within the strategy of the Ministry of Health of the Czech Republic HEALTH 2030.

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



Member since 29 Nov. 2013
Host institution: INSERM
National hub: Toulouse
www.fcrin.org/en

F-CRIN, created in 2012, is the single contact point 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:

- 12 national networks specialised in specific diseases or areas of medicine (e.g., cardiology, nutrition, inflammatory disease, cardiorenal diseases, thrombosis, vaccinology, Parkinson’s disease, sepsis: rare diseases, medical devices)
- 1 specific expertise networks (methodology)
- 1 platform of professional services (EUCLID)
- 1 national coordination unit

2020 HIGHLIGHTS

- FCRIN and Inserm coordinate the COVIREIVAC platform, developed to conduct and promote first-class clinical vaccination research in France, which was launched in October 2020: www.covireivac.fr.

- FCRIN launched a new campaign to expand its infrastructure. The call for applications opened in September 2020. The units selected will be added to the infrastructure at the start of 2022.

National Scientific Partner
Description & Highlights

Scientific Partner: KKSN - Netzwerk
der Koordinierungszentren für Klinische Studien
Germany

Member since 29 Nov. 2013
Host institution: KKS-Netzwerk e. V.
National hub: Berlin
www.kks-netzwerk.de/en/network/about-us.html

KKS-Netzwerk (KKSN), the German network of coordinating centres for clinical trials, was established in 2005 and currently comprises 25 academic coordinating centres for clinical trials all over Germany. The KKSN headquarters is located in Berlin and hosts the German ECRIN office. CTUs in KKSN provide full trial services ranging from consultancy on protocol design, budgeting, and regulatory and ethical submissions to conducting trials, including project management, site management, data management, monitoring, (pharmaco-)vigilance, biometrical analysis, and reporting for medical as well as for medicinal products. The KKSN structure enables close collaboration between study centres in multicentre trials, facilitating a high level of quality. Training is also a significant focus of the network. In addition, network members are involved in various national and international clinical research projects, and collaborate with diverse stakeholders.

2020 HIGHLIGHTS

Qualification and training are of great importance to KKSN. In 2020, due to the coronavirus pandemic, most of the KKS network members' classroom courses could not take place. In response to this, a working group of KKSN implemented within a few weeks eLearning courses for investigators: basic, advanced and refresher courses as well as a supplementary course for medical devices. The eLearning courses comply with the current national recommendations for curricular training of the Bundesärtzekammer (German Medical Association), the Arbeitskreis der Medizinischen Ethikkomissionen (German association of medical ethics committees) and the criteria for "blended learning" of the Bundesärtzekammer. By the end of 2020, more than 1.500 participants were successfully trained in the KKSN eLearning courses.

KKSN is actively supporting the CSA project "Strengthening Training of Academia in Regulatory Science – STARS". Working closely with the project coordination which is realized by the German NCAs KKSN supports the improvement of easily accessible regulatory knowledge and training in academia.

Scientific Partner: HECRIN
Hungarian European Clinical Research Infrastructure Network
Hungary

Member since 5 Nov. 2014
Host institution: University of Pécs
National hub: Pécs
www.hecrin.pte.hu/en

The HECRIN Consortium represents 125 university clinics and diagnostic institutes, as well as 100 hospital units, covering the entire Hungarian research network capable of innovative clinical research, with the exception of the county hospitals who will join at a later date. The HECRIN central office is at the University of Pécs.

The HECRIN Consortium received a government subsidy for the development of the integrated, harmonised clinical trial network at the trial sites of the four Hungarian universities. The goal is to accentuate Hungary's capabilities in innovative, high-quality clinical research, including research on medicines, clinical nutrition science, pharmaceutical drugs and medical devices. The Consortium supports the strengthening of the research potential and its translation into practice through accredited processes, promotes continuous professional training, and makes efforts to exploit the wealth of clinical data in research.

2020 HIGHLIGHTS

- HECRIN is currently participating in 5 international projects: EOSC-Life, PRECIOUS, TREOCAPA, EU-RESPONSE, and CONSCIOUS. Within the CONSIOUS project, for which HECRIN is the coordinator, the development of the e-learning courses is well underway. The course offer should be available in 2021.

- Through a mandate from the Ministry of Innovation and Technology, a Covid Committee was established by HECRIN. The aim is to select the most promising Hungarian research project to give them scientific, administrative and infrastructural support from HECRIN. Among these studies, HECRIN supported a non-interventional clinical trial for the identification of genetic factors determining the course of Covid-19 infection caused by a new type of coronavirus and for the preparation of pharmacogenetic applications.

National Scientific Partner
Description & Highlights

Scientific Partner: HRB CRCI - Health Research Board Clinical Research Coordination Ireland
Ireland

Member since 20 Nov. 2018
Host institution: Clinical Research Development Ireland
National hub: Dublin
www.hrb-crci.ie

HRB CRCI is an independent integrated national clinical research network, providing centralised support in the conduct of multicenter clinical trials and investigations/ studies (both commercial and academic) across Ireland. Operational since May 2015, it is funded by national extramural grants from the Health Research Board (HRB) and Enterprise Ireland (EI), supported by the six medical schools in Ireland. The HRB CRCI central office provides overarching support and expertise, through a range of services and activities to academia and industry. The partner University Clinical Research Facilities/Centres (CRF/CRCs) provide the infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight programs that are critical for the successful conduct of world-class patient-focused research.

2020 HIGHLIGHTS

- Ireland's EuCo coordinates a number of Irish led ECRIN-supported international clinical trials (e.g., POPART, CONVINCE) as well as acting as a liaison for several ECRIN-supported multinational clinical research projects in which Irish CRF/CRCs are providing services and supporting recruitment (e.g., TREOCAPA, IDEA-FAST, NECESSITY).
- Ireland's EuCo supported by HRB CRCI, co-led in 2020 the ECRIN Covid-19 Literature Review initiative whose purpose it is to curate an online resource of the most relevant articles presenting results from Covid-19 trials.
- The Irish EuCo chaired the ECRIN Quality Group, consisting of quality representatives from 6 ECRIN countries, during 2019/2020. The group drafted a business case in 2020 entitled "Impact of the Covid-19 Pandemic on Quality Aspects of Clinical Research" which they plan to implement in 2021.

Scientific Partner: ISS - Istituto Superiore di Sanità/ItaCRIN - Italian Clinical Research Infrastructure Network
Italy

Member since 29 Nov. 2013
Host institution: Istituto Superiore di Sanita (ISS)
National hub: Rome
www.itacrin.it

ItaCRIN National Network, coordinated by Istituto Superiore di Sanità (ISS), groups together 11 CTUs and Clinical Research Organisations (CROs) covering the whole Italian territory, and offers Italian clinicians and researchers the opportunity to coordinate or participate in international research projects. The national hub of ItaCRIN is located at the Istituto Superiore di Sanità (ISS) in Rome.

The specific objectives of the ItaCRIN National Network are to facilitate and sustain Italian participation in International clinical trials, to support the set-up and running of clinical trials, and to promote non-profit clinical research in Italy and in Europe

2020 HIGHLIGHTS

- The ItaCRIN Network has grown, with the addition of the CTU of University of Milan-Bicocca (BICRO).
- ItaCRIN contributed to the COVID-19 Clinical Trial Team at ISS in order to share a Clinical Trial Report related to the Coronavirus emergency, which was updated regularly. This report includes the interventional pharmacological clinical studies and vaccines for the treatment and prevention of SARS-CoV-2 infection from the most important sources of information worldwide.
- ItaCRIN actively participated in the National Covid-19 study 'TSUNAMI' based on the treatment of early diagnosed patients with the plasma from convalescent patients. The study was coordinated by ISS and involved about 80 Italian clinical sites.

National Scientific Partner
Description & Highlights

Scientific Partner: NorCRIN - Norwegian Clinical Research Infrastructure Network

Norway

Member since 18 May 2016
Host institution: St. Olav's Hospital
National hub: Trondheim
www.norcrin.no/en/

NorCRIN's primary objective is to offer research support within a broad spectrum of clinical studies – ranging from biomedicine and medical equipment to testing of new medicinal products. NorCRIN is a national network with partners in 6 university hospitals in Norway, covering all health regions of Norway. NorCRIN is currently funded by the Norwegian research council by original initiative of the Ministry of Health and Care services. NorCRIN is coordinated from St. Olavs hospital, Trondheim.

NorCRIN works to support both industry and academic studies, and the expectations with the establishment of NorCRIN was to increase the number of academic and industry financed studies, increase participation in international studies and to increase the speed of which all studies can be planned and conducted.

2020 HIGHLIGHTS

- NorCRIN2 was funded and initiated in 2020. NorCRIN2 is a continuation of the NorCRIN project and has secured funding for another 5 years of work to continue the improvements in the environment supporting clinical trials in Norway.

Scientific Partner: POLCRIN – Polish Clinical Research Infrastructure Network

Poland

Observer since 23 Aug. 2019
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 functioning shall also have concrete benefits for patients - it will help 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.

2020 HIGHLIGHTS

- Seven CTUs have signed the common cooperation agreement that allows to sign the Framework Agreement with ECRIN as POLCRIN.
- Two national meetings were organised. The first was aimed at Polish investigators included or interested in joining ECRIN and provided general information about ECRIN. The second meeting, held on the 1st anniversary of POLCRIN as an observer country, was an exchange on the experience of working with ECRIN for Polish investigators and with presentations from ECRIN colleagues from Germany, Hungary and Slovakia.
- POLCRIN contributes to the EU-RESPONSE project.

National Scientific Partner
Description & Highlights

Scientific Partner: PtCRIN - Portuguese Clinical Research Infrastructure Network
Portugal

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 a more efficient implementation of multinational investigator-initiated clinical trials, fostering access to international funds and making Europe a single area for clinical research through the link to its European counterpart infrastructure, ECRIN.

PtCRIN maintains a network of academic CTUs in Portugal that provide general services for clinical studies following the standards/certification of ECRIN, at a not-for-profit rate to public sponsors and Small Medium Enterprises (SMEs).

Currently, PtCRIN is a consortium of 24 national research and development institutions that host 5 CTUs or equivalent units limited to the provision of specific services (statistics, informatics), and health care units that work in close coordination, but are open to all.

2020 HIGHLIGHTS

- Portugal's renewed its ECRIN member status through to 2023.
- In its first maturity evaluation, PtCRIN obtained an overall classification of high, based on the progress of the infrastructure, relevance and context.
- PtCRIN was formally integrated into the Portuguese Roadmap of Research Infrastructures of Strategic Relevance in April.
- Portugal integrated the EU-RESPONSE project through PtCRIN. Within the scope of this project the DisCoVeRy trial extension started recruitment in Portugal in September.
- PtCRIN, EATRIS Portugal and the Agency for Clinical Research and Biomedical Innovation (AICIB) jointly organised the first workshop of a series called "Science Talks" on November 25th, addressing the topic: How are vaccines developed, approved and produced?

Scientific Partner: SLOVACRIN - Slovak Clinical Research Infrastructure Network
Slovakia

Slovakia Observer since 1 Jul. 2018
Host institution: Pavol Jozef Šafárik University
National hub: Košice
www.slovacrin.sk/en

SLOVACRIN is a national research infrastructure network connecting hospitals, universities and scientific institutions involved in academic clinical research. It is coordinated and funded by the Faculty of Medicine of the Pavol Jozef Šafárik University in Košice. The General Director of SLOVACRIN and the Dean of the Faculty of Medicine is Prof. Daniel Pella.

SLOVACRIN supports the preparation and implementation of academic clinical trials in Slovakia, including international trials. The aim is to increase the number and quality of academically initiated clinical trials in Slovakia through unique capacities of knowledge, expertise, research, development and implementation in the medical sciences in order to ensure compliance with regulatory, legislative and ethical requirements related to clinical research.

2020 HIGHLIGHTS

- SLOVACRIN participates in the EU-RESPONSE project
- SLOVACRIN coordinates the PREVCOVEAST study on herd immunity SARS-CoV-2 in the population of Eastern Slovakia. The primary goal is to perform a cross-sectional study on the representative population in Eastern Slovakia as well as on the certain selected subpopulations of high-risk individuals in order to detect the seroprevalence of circulating antibodies.
- The National Oncology Programme enables SLOVACRIN to support academic clinical trials in Slovakia in cooperation with the Ministry of Health of the Slovak Republic and the National Oncology Institute. SLOVACRIN was able to support 4 multicentre academic clinical trials in the field of oncology in the regulatory, monitoring and pharmacovigilance activities.
- SLOVACRIN participated in AKARDIO Covid-19 which analyses the cardiovascular and immunological response of patients after overcoming Covid-19 with a focus on research of new diagnostic markers and therapeutic agents.
- Participation in the DisCoVeRy study and the EU-SolidAct study will bring innovative therapy to Slovak patients with COVID-19.

National Scientific Partner
Description & Highlights

Scientific Partner: SCReN
Spanish Clinical Research Network
Spain

Member since 29 Nov. 2013
Host institution: Instituto de Investigación del Hospital Universitario La Paz, IdiPaz[1].
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, and it is formed by a network of Spanish CTUs based in clinical centres of the Spanish National Health Service. There are currently 34 CTUs in the network spanning 12 Spanish autonomous communities.

As of November 2020, SCReN´s Coordination Unit is based in Madrid at Instituto de Investigación del Hospital Universitario La Paz, IdiPaz, (previously based in Instituto de Investigación Sanitaria del Hospital Clínico San Carlos, IdISSC) and is progressing forward in the work developed over the past 7 years. The coordination with ECRIN is based in Barcelona at the Hospital Clinic which hosts the EuCo. Some of the updates in the strategy proposed by the current Coordination Unit include a structural re-organisation that aligns the experience and capacities with SCReN´s areas of activity resulting in 11 working groups (WG): Methodology (WG1), Regulatory, Ethics, & Data Protection (WG2), Monitoring (WG3), Pharmacovigilance (WG4), Data Management (WG5), Statistics (WG6), Training (WG7), Early Stage Phase studies (WG8), Paediatric studies (WG9), Observational studies (WG10), and Internationalization (WG11).

SCReN aims to foster excellence and quality in clinical research through networking, international cooperation, and support to clinical research projects, translating them into benefits for the Spanish National Health Service. SCReN also works on the education and training of clinical research professionals. SCReN´s portfolio totals 159 clinical trials which have been supported with an average of 9 sites per study. With regards to the recruitment objectives, SCReN ISCIII has recruited 17.022 out of the 25.983 planned potential patients.

2020 HIGHLIGHTS

- The network has recently incorporated 7 new Covid-19 studies.

1- The location of the coordination unit has changed since November. It is now based in Madrid at Instituto de Investigación del Hospital Universitario La Paz, IdiPaz, previously it was based in Instituto de Investigación Sanitaria del Hospital Clínico San Carlos, IdISSC.

Scientific Partner: SCTO
Swiss Clinical Trial Organisation
Switzerland

Observer since 18 Dec. 2015
Host institution: SCTO
National hub: Bern
www.scto.ch/en

The SCTO is committed to serving public health through excellent clinical research. The SCTO fosters cooperation and establishes networks to ensure that clinical research in Switzerland is

- of high value to patients,
- innovative by answering cutting-edge research questions, and
- visible by sharing research results with the public at large.

To this end, the SCTO advocates for clinical research that addresses issues relevant to patients and society. Furthermore, it establishes a trustful dialogue with its stakeholders and advocates for the involvement of the patient's and the public's perspectives in clinical research. Last but not least, it ensures that the Swiss clinical research community is interconnected with its counterpart in the EU.

The SCTO was established in 2009. Funded by the Swiss National Science Foundation (SNSF) and State Secretariat for Education, Research and Innovation (SERI), it has acted as an independent organisation since 2013.

2020 HIGHLIGHTS

- During the last four years of operation, the SCTO thematic platforms developed and conducted a number of projects, that vary from tools to guidance documents, templates, publications and periodic thematic newsletters and magazines such as the RA Watch.
- The Department of Clinical Research, University of Basel (DKF) is the first institution in Switzerland to achieve ECRIN data centre certification for its data management and IT standards.
- Since 2015, Switzerland has been an observer country of ECRIN. In July, the extension of Switzerland's observer status was granted by a unanimous vote of the ECRIN members.
- The paediatric clinical research infrastructure in Switzerland, SwissPedNet (hosted by the SCTO) is contributing partner to related ECRIN projects and other initiatives (IMI funded c4c and H2020 funded PEDCRIN and Id-EPTRI). Within c4c Switzerland contributes to the TREOCAPA trial. The CTU in Zurich recruited the first four babies in this study.
- The CTU Network is involved and contributes to the EU-RESPONSE project and the SwissPedNet participates in the RECOVERY trial.

An Interview
with the Portuguese Euco

Joana Batuca,
European Correspondent Portugal

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

As a EuCo I need to make sure that I have the most up to date information about the management of the ECRIN trials that are running in Portugal. During 2020 we had Portuguese partners involved in 6 multinational clinical trials, involving different teams and in different phases. Although each ECRIN trial has a coordinating EuCo who has the big picture of the trial and is in direct contact with the sponsors, the participating EuCos have an important role in assisting the coordinating EuCo by facilitating and supporting the participation of the national CTU/institutions. We have regular meetings with all ECRIN partners involved in each trial which also fosters multinational collaborations.

As a EuCo I'm also the key contact point in Portugal for ECRIN, so I´m responsible to establish the link between all national sponsors or investigators that wish to develop European multinational studies through ECRIN and its partners.

How has ECRIN benefitted Portugal?

Portugal is one of the founding members of ECRIN and has benefited a lot from its membership, through PtCRIN, the national hub of ECRIN in Portugal. We started with 2 CTUs in 2014 and in 2020 we now have 5 CTUs able to provide services in accordance with ECRIN quality standards. One of the CTUs, AIBILI has the ECRIN Data Centre Certification.

This benefit was even more emphasized during last year with the Covid-19 pandemic. Since we were already integrated in a well-established research infrastructure like ECRIN with solid networking capacity, we could quickly contribute to ECRIN Covid-19 taskforce and integrate very early into some of the most important EU H2020 projects in response to pandemic and emergency situation. Such as EU-RESPONSE project that allowed the extension of the DisCoVeRy trial to Portugal. As part of the scope of the EU-RESPONSE we are currently initiating the participation of Portugal in another platform trial, EU-SolidAct.

What achievement are you proudest of since joining ECRIN/PtCRIN?

One of the things that I'm proudest of was when PtCRIN was formally integrated in the Portuguese Roadmap of Research Infrastructures, in April 2020. It was also important to underline that in the first maturity evaluation, PtCRIN obtained an overall classification of high, based on the progress of the infrastructure, national relevance and context.

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

We would like to continue develop the CTU network by supporting the applications of our CTUs to the ECRIN Data Centre Certification. We also have had, for a few years, the goal to get the first ECRIN supported multinational study with a Portuguese Sponsor and I can say that we will finally achieve this goal in 2021. Our new goal is to increase the number of studies as a coordinating country, and continue to participate in ECRIN studies as participating country.

ECRIN Team

2020 was marked by the scaling up of activities, requiring changes in ECRIN's internal organisation and staff competencies. There was a total of 22 people in the ECRIN core team in 2020, including 8 people joining the team and 2 leaving. The core team now totals 20 staff in the Paris offices. Furthermore, four new EuCos joined ECRIN in 2020.

Core Team	
Burç Aydin	Project Manager
Marta Bastucci	Executive Assistant
Serena Battaglia	Capacity Program Manager
Steve Canham	Data Project Managerment
Marta del Alamo	Project Manager
Jacques Demotes	Director General
Martina Esdaile	Communications Officer
Sabrina Gaber	Communications Officer
Paula Garcia	Project Manager
Sergei Gorianin	Data Scientist
Sabine Kläger	Head of Clinical Operations Unit
Christine Kubiak	Operations Director
Aafke Maitimo	Executive 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
Arthur Smaal	Quality Officer
Alicja Szofer-Araya	Head of Administration and Finance
Safia Thaminy	Project Manager
Christine Toneatti	Head of Quality and IS Unit

Experts and Consultants	
Christian Ohmann	Data Management Expert
Dr Joaquin Saez-Penataro	Medical Expert
Harrie Elzinga	Communication Consultant

European Correspondents	
Kateřina Nebeská	Czech Republic
Lenka Součková	Czech Republic
Kristýna Nosková	Czech Republic
Amélie Michon	France
Jimena Bouzas	France
Luc Wasungu	France
Sarhan Yaïche	France
Linda Stöhr	Germany
Laura Vieweg	Germany
Hanna Schrinner-Fenske	Germany
Zita Tarjányi	Hungary
Kata Bende	Hungary
Suzanne Bracken	Ireland
Fiona Cregg	Ireland
Maria Buoncervello	Italy
Elena Toschi	Italy
Valentina Cabral Iversen	Norway
Bernadetta Wisniewska	Poland
Patrycja Klusek	Poland
Joana Batuca	Portugal
Simona Sonderlichová	Slovakia
Stefan Toth	Slovakia
Adriana Vives	Spain
Caecilia Schmid	Switzerland

*Note: the core team and European Correspondent lists include individuals who started working for ECRIN in 2020, as well as those who left the organisation.

ECRIN's response to Covid-19

In the beginning of 2020, the world was confronted with the rapid spread of the Covid-19 virus, leading to the worldwide pandemic. The Covid-19 crisis requires researchers to join forces worldwide to find effective treatments and vaccines, and sharing research data is a critical step in this global cooperation effort. ECRIN reacted promptly with the creation of the Covid-19 Taskforce, its role in the coordination module of the two European Union funded projects dedicated to clinical trials on Covid-19 (EU-RESPONSE and RECOVER), and with the launch of the Clinical Research Metadata Repository.

Covid-19 Taskforce

ECRIN established a Covid-19 Taskforce with its national partners to:

- Review and digest the scientific literature on Covid-19 randomised clinical trials.
- Develop a metadata repository for Covid-19 trials making all the non-sensitive Covid-19 trial data accessible.
- Develop a database on the regulatory, ethical and data protection fast track approvals across all European countries.
- Ensure preparedness of its national clinical trial unit (CTU) partners for Covid-19 trials.
- Combine and coordinate national initiatives to promote multinational rather than national trials, including through connections with national funders, sponsors, investigators and CTUs.
- Develop partnerships with national and pan-European investigation networks on infectious diseases and intensive care.
- Outreach to investigators, sponsors, patients, policymakers, funders, and citizens.
- International cooperation and outreach, including with the WHO through CRIGH and other initiatives.

Covid-19 Projects

By the end of March 2020, at the national level hundreds of clinical trials were underway across Europe to test potential SARS-CoV-2 treatments. However, except for the WHO's Solidarity trial, there was a marked absence of multinational clinical trials. ECRIN approached the European Commission and promoted the idea of supporting multinational, multi-arm platform trials (see box) to rapidly recruit patients and to test multiple treatment options.

Platform trials

Platform trials allow a multitude of different treatment options (arms) to be compared with a single control (arm) across a disease area. They are perpetual and enable ineffective arms to be stopped after an interim analysis and new treatment arms to be added. To date, they have been used principally in the field of oncology and more recently infectious diseases.

EU-RESPONSE

The EU-RESPONSE project, European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases, is funded by the European Union and coordinated by INSERM. ECRIN plays a role in the three key objectives. The first goal is the expansion of DisCoVeRy, a phase III, adaptive randomised, controlled multicentre clinical trial designed to evaluate the efficacy of repurposing medication in hospitalised adult patients diagnosed with Covid-19 to other European countries (Austria, Belgium, Czech Republic, France, Greece, Hungary, Italy, Luxemburg, Norway, Poland, Portugal, Slovakia, Spain, Switzerland, Turkey). Upon completion of the DisCoVeRy trial, the second goal is to build and implement a new European adaptive platform trial for Covid-19 and other emerging infectious diseases through EU-SolidACT. The third objective includes the coordination module with the second EU-funded project addressing clinical research on Covid-19.

ECRIN's response to Covid-19

RECOVER

ECRIN joined the RECOVER project, Rapid European SARS-CoV-2 Emergency Research Response, an EU funded project that aims to advance knowledge for clinical and public health responses to the Covid-19 pandemic. RECOVER includes the expansion to Europe of the REMAP-CAP for Covid platform trial. The objective is to include 200 hospitals across Europe with the participation of at least 15 countries and all regions. ECRIN's primary role is to lead the coordination module that links RECOVER to EU-REPONSE.

THE COORDINATION MODULE

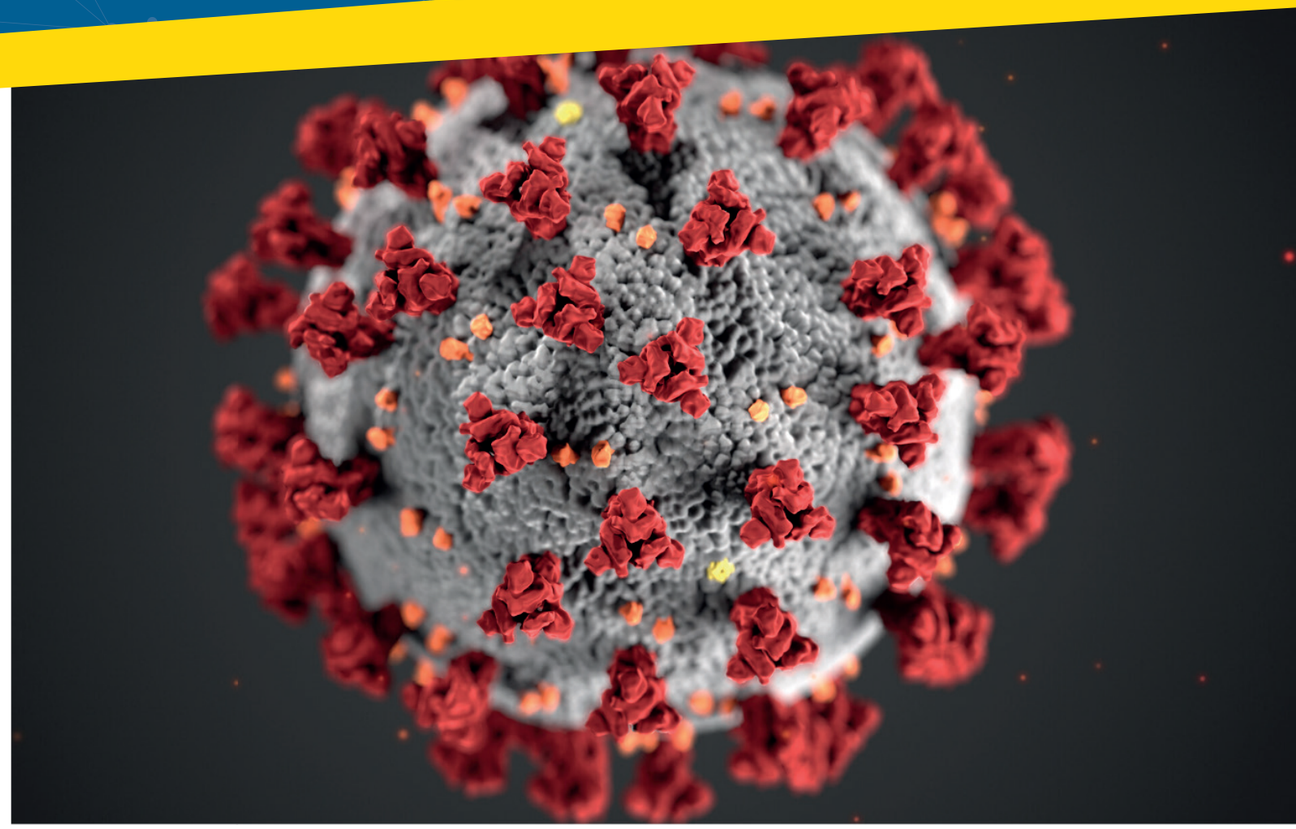
The coordination module is a shared work package present in both the EU-RESPONSE and RECOVER projects, led by ECRIN. Its aim is to enable the coordination and complementarity of the two large European Adaptive Platform Trials (APT) and it will set a precedent for future clinical trials, establishing structures and processes that can serve as a blueprint for coordination in other disease areas.

The coordination module comprises three primary functions: a Trial Coordination Board (TCB), a Joint Access Advisory Mechanism (JAAM) and a toolbox for the design and management of APTs.

Together with the Norwegian Institute of Public Health, ECRIN has established the TCB. The TCB gathers all key stakeholders involved in the implementation of trials and the successful integration of trial outcomes into clinical care. It will provide high-level strategic recommendations to avoid redundancies and promote cooperation and complementarity between the trials and to ensure that the core data can be analysed across both trials.

The JAAM is the single access point for the European Covid-19 adaptive platform trials. It is the single body, common to the DisCoVeRy, EU-SolidACT and REMAP-CAP for Covid trials, that assesses requests from investigators or industry looking to test their compound in one or more of these trials.

Lastly, the APT toolbox will centralise resources useful in the design, implementation and management of APTs. These tools will be developed through collaborations with the IMI project EU-PEARL and will be implemented in the development of the EU Covid-19 APT.



CLINICAL RESEARCH METADATA REPOSITORY

Clinical trials play a crucial role in the development of preventative medicine, treatments and vaccines. They also generate a lot of data that is made available in diverse locations. ECRIN has launched the Meta Data Repository, which includes Covid-19 trial data, allowing the discovery of clinical studies and related data objects. The related data objects can include study protocol, information sheet and consent form, data management plan, results, publications, and more.

The Metadata Repository allows scientific users to search freely and without registration for documents and data linked to a clinical research study, and to obtain information on the accessibility of those results. The Meta data Repository output is non-opinionated and non-curated, meaning that the data collected and aggregated is presented in a searchable form, without the use of 'expert input' or a quality filter.

SERVICES
Clinical Trial Operations

Overview

ECRIN provides support to investigators and sponsors in ECRIN Member and Observer countries and beyond for the preparation of European funding applications and management of multinational clinical research. ECRIN's core activity is the coordination of operational services for clinical trials, which continued to be the key focus in 2020. The Covid-19 pandemic resulted in major challenges for the provision of these services, requiring flexibility and adaptations to trial conduct. The impact directly affected the site initiations, on-site monitoring and patient recruitment which led to major delays in many clinical trials. The result of which includes extensions to the clinical trials and an increased workload for the clinical trial team.

As part of its activities, ECRIN also contributes to the development of tools designed to facilitate multinational clinical research. These tools are freely available on the ECRIN website.

ECRIN's Support in a Changing Research Landscape

In 2020, ECRIN's clinical trial activities, while impacted by the Covid-19 pandemic, continued to reflect an evolution in the clinical research landscape, including the rise of platform trials, personalised medicine, patient stratification, in-silico trials, artificial intelligence, big data, digital endpoints, and medical devices. ECRIN supported a significant number of applications for European funding (H2020) for multinational studies on Covid-19 treatments, prevention and vaccination. As such, ECRIN continued to shift from support for randomised clinical drug trials to support for new clinical research methodologies (e.g., platform trials) and new roles (coordination between different European clinical trials). Moreover, the clinical operations team had an instrumental role in the Covid-19 Taskforce (see ECRIN's response to Covid-19)

The sections below provide a closer look at the type of support ECRIN provides to clinical trials from preparation to implementation, conduct and completion, highlighting the number of grant applications and clinical trials ECRIN supported in 2020.

Scientific Board

The Scientific Board at ECRIN provides a thorough scientific and logistical assessment of any clinical trial requesting ECRIN services. There are two subcommittees: (1) The Collaboration Committee which decides on whether or not ECRIN should invest resources in the planning, design and funding application and/or participation in the project, and (2) the Peer-Review Committee which 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.

Collaboration Committee

The Collaboration Committee meets weekly to review collaboration requests and 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 2020, the Collaboration Committee reviewed 28 requests for collaboration from seven different ECRIN Member countries, as well as three requests from non-ECRIN countries. Seventeen requests for collaboration were approved, while for 11 a collaboration was not established for a variety of reasons (eligibility criteria, budget restraints, out of scope decision from the sponsor).

Of the 17 approved requests, three were for already funded projects; five were submitted as pre-proposal, of which one was invited for a full application and was subsequently funded. Nine additional full grant proposals resulted in three funded projects.

Peer-Review Committee

Six new, independent, clinical and methodology experts were appointed for a three-year term at the beginning of 2020:

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

ECRIN's Medical Expert, Dr Joaquin Saez-Penataro, is sitting on both sub-committees, acting with the chair of the Scientific Board as a link, between the two sub-committees.

In addition, Burç Aydin, ECRIN project manager, was appointed as the new Scientific Board Secretariat in 2020.

SERVICES
Clinical Trial Operations

Access ECRIN's Clinical Trial Operations Services

In 2020, ECRIN published a new policy on access to its services for clinical trial operations. In short, clinical trial operations services are accessed by reaching out to the national EuCo in the same way one would for the development of a new trial protocol and/or the planned grant application. The EuCo will submit the collaboration request for the planned protocol to the Collaboration Committee. This committee then decides on ECRIN's collaboration in the project. On agreement, the allocated EuCo will accompany the investigator and / or sponsor in the grant and budget preparation. In addition, any already funded clinical trial project can also access ECRIN services and agreement for collaboration via the Collaboration Committee.

A Closer Look at Trial Support Services

The figure below offers a more detailed look at the types of services that ECRIN can offer before and during multinational clinical trial implementation.

1. PLANNING

We offer advice on:
- Trial design and methodology
- Regulatory, ethical, data protection and insurance requirements
- Strategies for site selection
- Task distribution for multinational studies
- Cost evaluation
- Funding opportunities

2. RISK ASSESSMENT

We conduct:
- Independent protocol peer reviews
- Logistical evaluations of project plans

3. OPERATIONAL COORDINATION

We coordinate services for:
- Study management
- Regulatory and ethical approval
- Study monitoring
- Vigilance
- Data management

SERVICES
Clinical Trial Operations

Planning
In the planning phase, ECRIN can give input on the different aspects of funding applications such as work package structure, potential impact, management, governance, consortium composition, and multinational clinical trial 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 national partners as service providers (i.e., national networks and CTUs), provide information in particular on the facilities that have the capacity and services needed to manage the trial. They ensure that the selected CTUs have the necessary expertise and capacity. They can also advise on all aspects of the clinical trial ranging from specific national ethical/regulatory requirements, to trial insurance, and conduct, logistical evaluation and risk assessment (see below) of project plans.

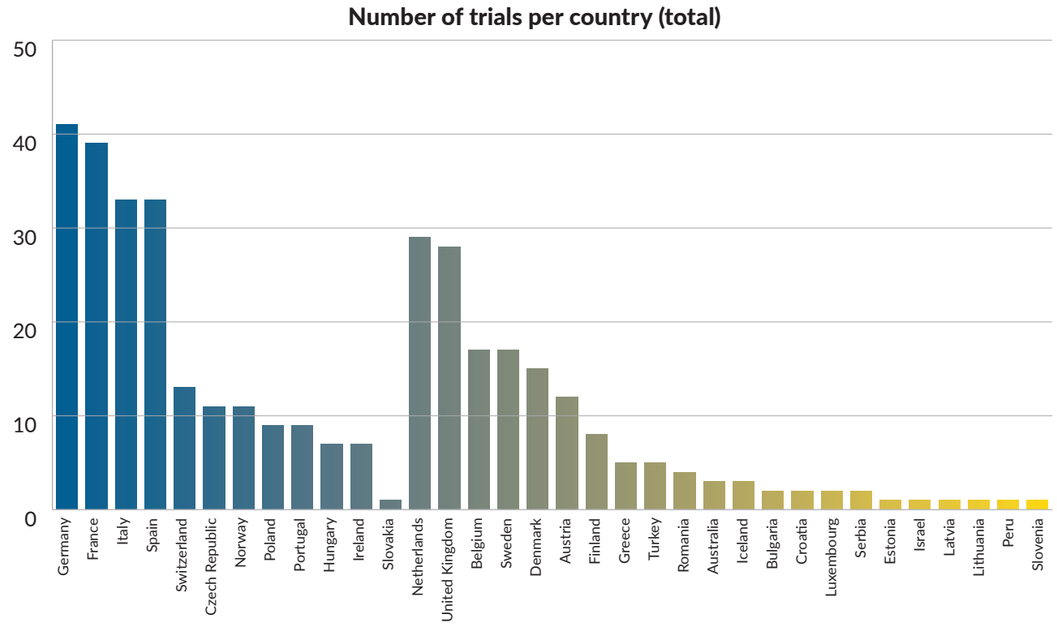
Risk Assessment
Once funding has been secured, and before implementation starts, projects are submitted to ECRIN for risk assessment. The coordinating EuCo and a nominated risk management team review the risk factors related to project implementation and conduct (e.g., patient recruitment, timelines, budget). They provide solutions to minimise any identified risks. Moreover, ECRIN can provide an independent peer-review of the pre-final protocol focusing on the methodology and design aspects to assess the risk of bias. The peer review is performed by the Peer Review Committee, a subcommittee of the Scientific Board.

Operational Coordination
ECRIN's EuCos work closely with the investigator-sponsor team, coordinating the activities across the participating countries, with the key mission to extend the clinical trial 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, until completion, as well as data management and vigilance as required by the Sponsor.

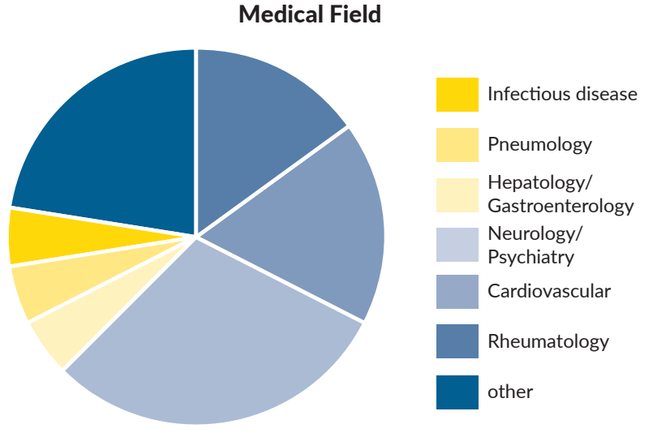
Clinical Trial Portfolio in 2020 (current trials)

Throughout the year, ECRIN participated in a total of 39 clinical trials at different phases, more precisely 16 clinical trials were in the start-up phase and 23 were in the running phase, which can include recruitment, follow-up and/or close out activities. During 2020, one trial was put on hold, one was completed, and a last trial withdrew its support request. ECRIN's full trial portfolio can be found in the appendix of this report.

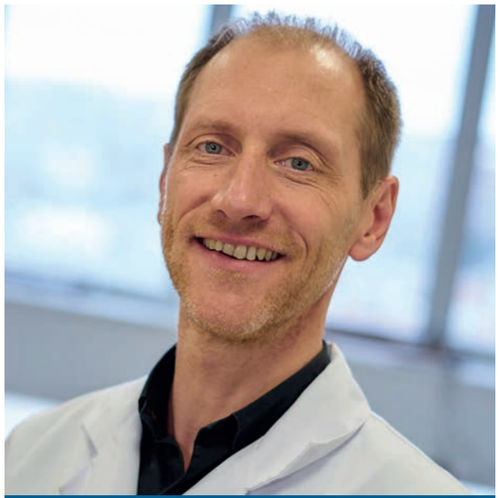
The total ECRIN trial portfolio, including past studies, reached 65 studies in 2020.



The chart provides a glimpse of the range of medical fields covered by the current ECRIN-supported trials portfolio. In effect, ECRIN works across all medical fields and disease areas.



An Interview
with the FAIRPARK II Principal Investigator



Dr. David Devos,
MD, Ph.D. neurologist, Prof. of Medical Pharmacology CHU of Lille, University of Lille, Lille Neuroscience and Cognition Inserm U1172

Can you tell me about FairParkII and how you came to work with ECRIN?

After demonstrating that an iron chelator, Deferiprone, was able to induce huge antioxidant effects and to block some type of cell death in a first trial in 40 Parkinson disease patients, we wanted to confirm (the findings) with a large phase II B clinical trial, FairPark II. When we built the project, I was involved in the F-CRIN, NS Park, (the French Network) and it seemed very interesting to have several centres in France and of course several centres in Europe, so we decided to contact our colleagues in Europe and to contact ECRIN.

What were the reasons you chose to work with ECRIN?

ECRIN is very important, because they have already developed skills, knowledge and they know the centres and the clinical assistant in each country. They also provide knowledge in the methodology of the trial as well as on the budget and that is the key part. They can develop all the monitoring, to try to keep the best quality for the clinical research, and notably for this trial, we want to show a very small difference. So, if the quality of the data is not great, we will miss it.

What can you tell me about your working relationship with ECRIN?

There is the structure, and behind the structure you have people, and it's the people that matter. It is a question of human relationships, and so when we started to build the application, we were connected to ECRIN. They were kind enough to review it and to challenge us on the statistical analysis plan, the number of centres, and some specific aspects of the clinical research to make sure that everything could be feasible.

What lessons would you share with another PI who is considering working with ECRIN?

My advice is that you need to go through ECRIN because you really need it, it's really important. I am really thankful that ECRIN was operational.

You also cannot just say "well ECRIN will work on that", you have to be involved also yourself. You have to go through ECRIN but also be directly connected to every centre: to send newsletters, to get people to answer the questions in case of adverse event or drop out effects. We succeed to do it thanks to the people involved. It is a small group of people that actively tried to do the best they can to move forward the recruitment.

SERVICES Infrastructure Development Projects

Overview

To strengthen its mission 'support the conduct of multinational clinical research in Europe', ECRIN develops its capacity through infrastructure development projects funded by the EU Commission (H2020 or IMI). The objective is to strengthen, upgrade, and develop tools, services, and expertise for the benefit of our user community and to stay at the cutting edge, enhance the visibility of the infrastructure, and develop synergies with the research infrastructure community.

In 2020 ECRIN coordinated one new EU-Funded project, PERMIT (PERsonalised MedicIne Trials), and contributed as a partner to the Covid-19 projects as well as two others that were launched:

B1MG (Beyond 1 Million Genomes)
TransvacDS (Design Study for a European Vaccine Infrastructure)

Note: for funding information on the above projects, and all infrastructure development projects see the appendices.

Focus on the Data Portfolio

The increased use of electronic health records and clinical data has led to the potential to use the data beyond its initial intended purpose. Data reuse can lead to reductions in unnecessary duplications and the associated costs, while increasing availability of the data, for example in a health crisis such as the Covid-19 pandemic, and in the long run, improve public health. In 2020, ECRIN contributed to several projects related to data management and data sharing, notably EOSC-Life, B1MG & Synchros. ECRIN's contributions include advancing the following goals:

- Development of policies and guidelines on secure and ethical data reuse which take into consideration data quality, standards, technical infrastructure, and Ethical, Legal and Social Implications (ELSI)
- Creation of tools to facilitate data-sharing (see example of the CRMDR)
- Coordination and support for the synchronisation of cohort and population data

An Interview

with a data management expert

Christian Ohmann
Data management expert consultant,
Chair of the ECRIN Network Committee

What is the aim of EOSC Life?

EOSC-Life brings together the 13 Research Infrastructures in the Health and Food domain of the ESFRI Roadmap to create an open, collaborative digital space for life science in the European Open Science Cloud.

EOSC-Life will be publishing life science data and tools as FAIR Data Resources, linking reusable tools and workflows to standardised computing services in national life-science clouds, connecting users across Europe to a single login authentication and resource authorisation system, and developing the data policies needed to preserve and deepen the trust given by research participants and patients volunteering their data and biosamples.
EOSC-Life also aims to provide the policies, guidelines and processes for secure and ethical data reuse and to enable data-driven research in Europe by connecting life scientists to EOSC via Open calls for participation.

What did ECRIN accomplish in EOSC-Life during 2020?

In 2020, ECRIN has been contributing to EOSC-Life through its involvement in the different Work Packages.

More precisely, ECRIN contributed by addressing policies and specifications for the storage, processing, access, sharing and reuse of biological and medical data for research purposes, with a special focus on sensitive data. This is an essential step to build the European Health Research and Innovation Cloud, able to handle health data and health research data in a transnational environment.

Key ECRIN achievements this past year are: the conceptualisation of a toolbox for sharing sensitive data and mapping, with partners, the national landscapes on sharing and re-using health data. The development of a new WP that focuses on development and implementation of a repository for Individual Participant Data from Covid-19 trials, enabling reporting and sharing to facilitate reanalyses, secondary analyses and patient-level data meta-analyses; and ECRIN has been working with partners on a Clinical Research Metadata Repository, linking metadata from clinical studies to related data objects (e.g. study protocol, statistical analysis plan, consent form).

What are some key deliverables expected from ECRIN in 2021?

In 2021, ECRIN will be working on the categorisation system of the toolbox for sensitive data sharing and an early demonstrator of the toolbox which will be tested by the scientific community to assess its usefulness and utility to determine its sustainability.

The national landscaping of ELSI requirements for data sharing is also expected to be concluded, guiding European researchers through the transnational data access opportunities. Moreover, ECRIN will also be exploring the interoperability of data standards between healthcare and research data, which is the main technical bottleneck in the secondary use of health data for scientific purposes.

With regards to the Covid-19 repository for Individual Participant Data from clinical trials, an early demonstrator will be launched in February 2021 and its full technical implementation will be a key deliverable in 2021.

SERVICES Infrastructure Development Projects

ECRIN Coordinated Projects

In 2020 ECRIN coordinated two projects in areas of particular interest to the organisation: Paediatrics and Personalised Medicine.

PedCRIN

Launched in 2017, PedCRIN (Paediatric Clinical Research Infrastructure Network) involves the development and testing of tools and services designed specifically to support paediatric trials and strengthen ECRIN capacity and expertise in the field.

PedCRIN encompasses three investigators initiated paediatric or neonatal clinical trials: 1) The WE-study–Walking Easier with cerebral palsy, 2) A randomised trial of prophylactic oropharyngeal surfactant for preterm infants: the POPART trial, 3) Oxytocin Treatment in Neonates/Infants with Prader-Willi syndrome: the OTBB3 study. Recruitment in this population is particularly complex, the sponsor of the WE-study, St Olav's University Hospital Norway, described in an interview : "The main challenge during implementation has been recruitment of study participants. First, the patient base is small and second, the possibility of receiving placebo may cause some reluctance to participate... The possibility to include two foreign sites (Poland and France) through the PedCRIN project has also been important in order to reach the planned number of participants."

Among the successes of the PedCRIN trials is the completion of the recruitment of 250 babies to the POPART trial. The consortium continued its efforts in patient and public involvement as well as the development of tools for the setup and management of paediatric and neonatal clinical trials. In an interview, University College Dublin (UCD), the sponsor of the POPART trial, explains how they included the parents in the study: "We received help with the design of the study and study materials (parent information leaflet and consent form) from the representative group for parents of premature babies in Ireland".

The tools, developed based on a needs assessment of the paediatric and neonatal investigation community carried out by PedCRIN, are in the process of publication. Professor Evelyne Jacqz-Aigrain, INSERM, explained when she sat down with PedCRIN : "Although the utility of the tools will need to be assessed by the researchers using these tools, the aim is to provide practical points to consider which will pull together information from key references."

A six-month extension was granted to PedCRIN, which will now close in June 2021.

Ongoing projects
ERIC-Forum

As lead of the work package that is structuring discussions to bring together the various stakeholders (science policymakers, funding agencies, ERIC governance bodies, research institutions and representatives of the research communities) to jointly address science policy issues raised by the development of science and technology, and by the impact of ERICs on the European research ecosystem, ECRIN contributed to the publication of a brief by the ERIC-Forum entitled "Funding models for access to ERIC multinational / transnational services." These recommendations are directed to the funding bodies at a national, regional and European level who support the operation of the ERICs and access to their services, and aim to stimulate a stronger, long-lasting dialogue and more efficient synergies between funding sources. This brief also provides insight into ERICs and other RIs for the optimal use of existing funding instruments, and for the advancement of their visibility in the research communities.

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An Interview

with the PERMIT project manager

Paula Garcia
ECRIN Project manager

What is the aim of PERMIT?

The aim of the PERMIT project is to build recommendations and identify standards for more robust and reproducible personalised medicine (PM) research. What we want to ensure is that PM research, treatments and technologies are developed and tested through clinical trials, in the most safe and effective way.

What was accomplished in the first year of the project?

During the first year, a series of scoping reviews were performed and the objective was to map the existing methodologies that are used today, throughout the different stages of the PM research pipeline. Scientific literature and grey literature were analysed to identify the research methods that are currently being applied and then an analysis was carried out to see where the gaps exist: gaps in terms of lack of harmonisation, lack of technical means or lack of clear regulatory guidelines.

How is PERMIT moving towards completing its goals in its second year?

In the second year of the PERMIT project, the aim is to address the gaps that were identified and to draft the recommendations that the project wants to put forward. In order to achieve this, the project is organising a series of workshops and working sessions, with the consortium members and also with external experts that represent all the key stakeholders in the PM research environment. The idea is to break down the gaps into questions and to address them and collectively come up with the recommendation. The idea of associating all the relevant stakeholders to the recommendations is to be sure that these recommendations help to meet the expectation of all the actors and that it will also help at a later stage to easily implement the recommendations.

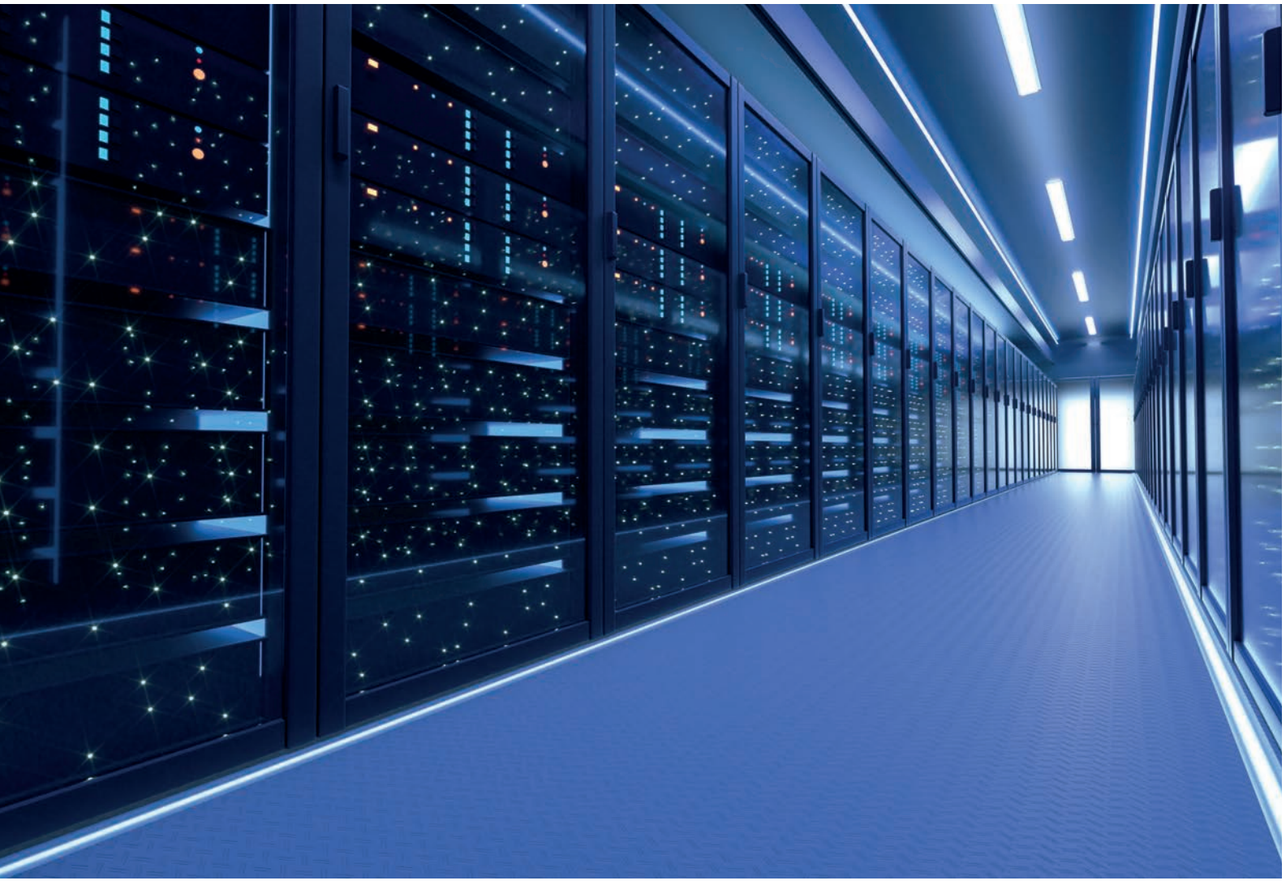
PERMIT
PERsonalised MedicIne Trials

SERVICES: Quality as a Service:
Data Centre Certification

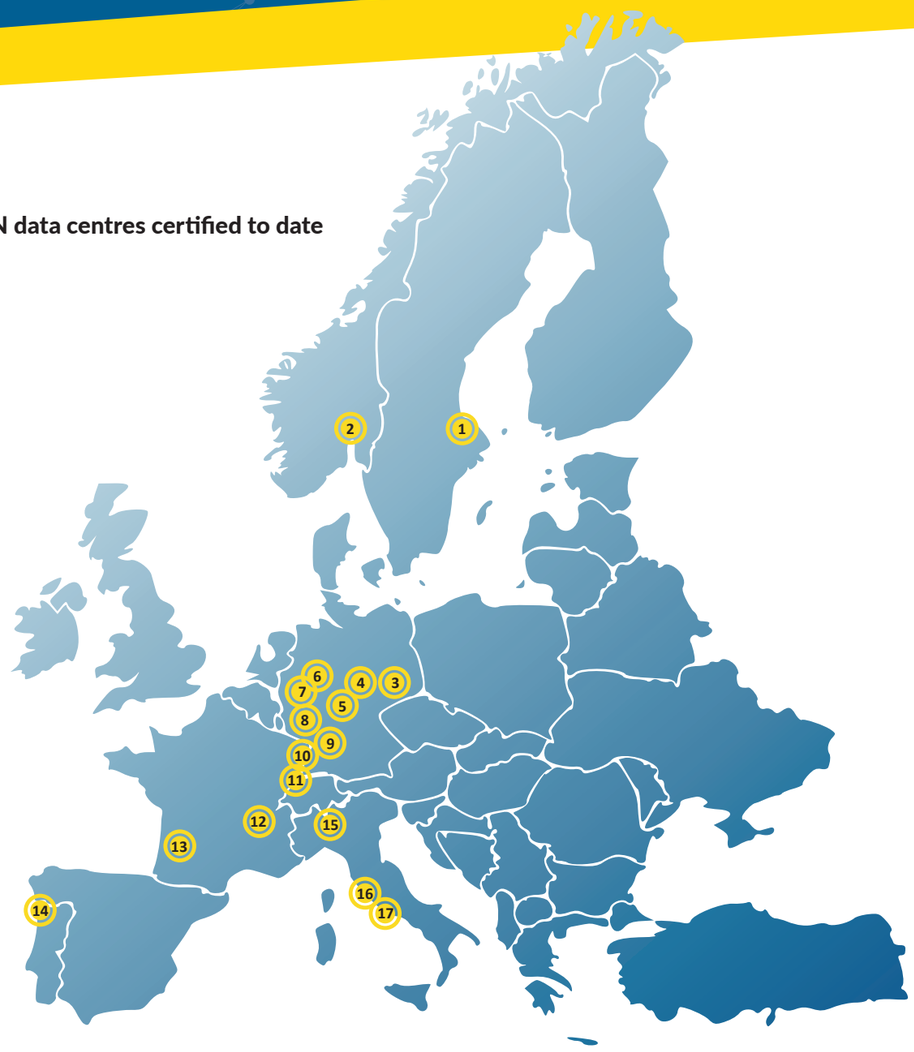
Overview of the Data Centre Certification program

ECRIN offers 'Quality as a Service' through its Data Centre Certification (DCC) programme. The goal of the Data Centre Certification 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.

Data centres can apply to the programme via their national partner through an annual call for applications. The 2020 call was cancelled due to the changing national travel regulations and restrictions caused by the Covid-19 pandemic, which limited the feasibility of some onsite audits.



ECRIN data centres certified to date



1. Uppsala Clinical Research Center (UCR)*
2. Dept. of Research Support for Clinical Trials (Clinical Trials Unit), Oslo University Hospital
3. KKS Dresden- Coordination Centre for Clinical Trials Dresden
4. Zentrum für Klinische Studien Leipzig (ZKS Leipzig)
5. KKS Marburg – Coordinating Center for Clinical Trials of the Philipps-University Marburg
6. KKS Düsseldorf- Coordinating Centre for Clinical Trials*
7. ZKS Köln, Clinical Trials Centre Cologne, University of Cologne
8. Interdisciplinary Centre for Clinical Trials (IZKS
9. KKS Heidelberg- Coordination Centre for Clinical Trials (KKS) Heidelberg
10. Clinical Trials Unit Freiburg
11. Department of Clinical Research (DKF), University of Basel
12. Clinical Pharmacology and Therapeutic Trials Service HCL, Laennec Faculty of Medicine
13. EUropean CLInical trials & Development (EUCLID)
14. AIBILI Data Centre
15. Data Centre of the Institute of Pharmacological Research "Mario Negri" (IRCCS
16. Group for Haematological Diseases in Adults (GIMEMA)
17. Ospedale Pediatrico Bambino Gesu

*certification lapsed in 2016

SERVICES: Quality as a Service:
Data Centre Certification

Two data centres were certified in 2020: Basel University Department Klinische Forschung (DKF) and Zentrum für Klinische Studien (ZKS) Köln. The certification of DKF marks the first certification in Switzerland and also the first certification of a Data Centre in an ECRIN observer country. Furthermore, certification renewal was awarded by the Independent Certification Board (ICB) to the Association for Innovation and Biomedical Research on Light and Image (AIBILI), Coimbra. The three centres met and continue to meet the ECRIN data management (DM) standards, as described in 'Requirements for Certification of ECRIN Data Centres, with Explanation and Elaboration of Standards, Version 4.0'. This brings the total number of centres certified to date to 17.

Benefits for Participants

The potential rewards for Data Centre Certification recipients are numerous. Data centres can benefit from the sharing of the latest technical developments (maintenance of up-to-date standards reflecting state-of-the-art practice) and training on data management / IT 'hot topics' (e.g., data sharing, clinical data management, Clinical Data Interchange Standards Consortium – CDISC). Finally, 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.

ECRIN audit closing meeting at
Medical Research Collaboration Centre

Programme expansion

Recognising the certification model's effectiveness, countries outside Europe and in particular in East and Southeast Asian (e.g., Singapore, Japan, South Korea, Taiwan) have expressed interest in adopting the programme. The first major steps for the pilot of the Data Centre Certification expansion were taken in 2017, with the translation of the DM standards (version 3.1) into Japanese, the training of Japanese auditors in February 2017 (at ECRIN's Paris office), and the inclusion of Asian auditors (as observers) in three on-site audits of European data centres.

In 2020, ECRIN continued to lay the groundwork for the expansion of the programme to Asia (and beyond), through the certification of the Medical Research Collaboration Center (MRCC) at Seoul National University Hospital in South Korea. It joins the Translational Research Centre for Medical Innovation (TRI) in Kobe and the National Hospital Organization (NHO), Nagoya Medical Centre Clinical Research Centre, Nagoya, Japan as the 3rd non-European centre to be awarded certification by the ICB.

SUPPORT SERVICES

Quality

ECRIN Internal Quality Management System (QMS)

The year 2020 marked a landmark for ECRIN's Internal Quality Management System (QMS): on 30 November ECRIN was awarded the ISO 9001:2015 certification by the French standards association (AFNOR) for its capacity to provide high-quality operational services. The certification is applied to ECRIN's three principal services: the coordination of operational services to the management of multinational clinical trials in Europe, capacity development through the participation in infrastructure development projects and the certification of data centres (Quality as a Service). 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 but in 2017 began work to further enhance the standardization, effectiveness and performance of its QMS. The major challenge related to this achievement being its application in a distributed research infrastructure.

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. Furthermore, it applies to the ECRIN core team based in the Paris head office, the European Correspondents based in the ECRIN member and observer countries, and more broadly to any external organization under contract to perform missions on behalf of ECRIN or external members of ECRIN Boards, where relevant to their mission for ECRIN. 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 post-certification to further these results and prepare for the ISO 9001:2015 follow-up audit.

afaq ISO 9001 Qualité AFNOR CERTIFICATION 2020/89236

Communications

For Communications the year 2020 marked a new start, beginning with the arrival of a new communications team. As identified as a need in the independent evaluation ECRIN underwent in 2019, the new communications team took on the challenge of changing the communication strategy, and launched a plan to shape the visibility of ECRIN for 2021 and beyond. Leveraging on past achievements, ECRIN will be repositioning itself in the communication landscape as a mature and modern, expert organisation. The primary communication target groups have been redefined, and to connect with them five communication pillars have been developed for 2021-2022: Communication tools, Visibility projects, EU-AMRI, Members and Observers outreach, and Communication projects.

Also, 2020 was the year where ECRIN responded quickly to help in the battle against the Covid-19 crisis. Through the Covid-19 Taskforce, adapted tools such as the Clinical Research Metadata Repository were launched as well as relevant literature reviews, funding calls, and fast track procedures. In part, due to this proactive approach and wide visibility, ECRIN has established a prominent, and sometimes even leading, role in the coordination of European clinical trials against Covid-19.

Achievements include a significant increase in website usage, and a leap in outreach via Twitter and LinkedIN. In 2020 ECRIN also supported the communications activities of various infrastructure development projects, such as EOSC, PedCRIN and RI-VIS.

ICTD Postponed

The International Clinical Trials Day (ICTD) is an opportunity to foster dialogue between all European and international stakeholders involved in clinical research, and to discuss new challenges raised by emerging methodologies. This event, held around May 20th, is ECRIN's annual event. Unfortunately, the ICTD 2020 in Berlin had to be postponed due to the worldwide sanitary crisis. In 2021 the ICTD will be a virtual event, and ICTD 2022 will replace the cancelled ICTD of 2020.

Training

Staff training

ECRIN hosts monthly scientific meetings that allow staff to share and discuss topics related to ECRIN's work. Hosted by a member of the staff or an expert in the field, they can analyse new trial methodologies, best practices in clinical research and aspects of the funded projects in which ECRIN is a partner. In 2020, many of the topics were related to Covid-19, from a review of the literature in the early months to the impact of the virus on non-Covid clinical trials and tools developed to support researchers.

External Training

EULAC PerMed

#EULAC PerMed

ECRIN co-coordinated the online Ethical Legal and Societal Aspects (ELSA) Workshop held virtually in September and contributed to the organisation of the 3rd EULAC PerMed Summer School, hosted online, "Implementing Personalised Medicine Research into Practice: Ethical Legal and Societal Aspects and perspectives."

An Interview

on ECRIN's Quality Management System

Christine Toneatti,
Head of Quality and IS, ECRIN

What does the ISO 9001:2015 certification mean for ECRIN and its partners?

ECRIN certification ISO 9001:2015 is a globally recognised standard that provides ECRIN customers and partners with the assurance that ECRIN services and processes are managed through recognised quality criteria which ensures the highest efficiency, embedding continuous improvement, and performance monitoring.

What were the key steps put in place to ensure that ECRIN successfully completed the certification?

Engagement of management and personnel are key to improve the internal integration of processes. It was especially important for ECRIN because we are a distributed research infrastructure. We are all based in different places in Europe, so it was important to use the same voice and the same processes. From the start of the ECRIN quality system, we established a risk-based approach to continuously anticipate risks to processes and services.

Structuring and increasing the awareness of process and process performance and making everyone accountable for this knowledge led ECRIN to more consistent results and better use of resources.

How do you ensure that all the personnel are aware of the necessary procedures?

From the very start, we organised continuous quality procedure training for the whole team. It is tailored to each role at ECRIN and anyone at ECRIN can get continuous access to effective procedures and training recordings. We are also using the feedback from the training to improve what we are delivering. The training and access to documentation are very efficient and make everyone aware of the common and standardized processes to apply.

What are the next steps for the Quality at ECRIN?

The next step is for us to confirm our certification through the follow-up ISO audit that we will have next October.

We have created a European quality network, among the ECRIN countries in order to join our quality efforts and develop, through an internal and informal quality group, the understanding of the new emerging regulation, and their practice through to application so that we can share and improve our way of working from a quality perspective.

GOVERNANCE AND STRATEGY
Partnerships

ECRIN highly values its partnerships with its scientific partners in its member and observer countries, as well as with diverse organisations and networks in Europe and beyond.

ECRIN Membership and Collaboration

The expansion of ECRIN membership remained a key priority in 2020. A plan has been developed to map all European countries, and to create strategies for a proactive approach of recruitment for potential new member and observer countries. The execution of this plan is scheduled for 2021 and beyond.

EU-AMRI: The Alliance of BBMRI, EATRIS and ECRIN

In February 2019 the medical research infrastructures BBMRI, EATRIS, and ECRIN signed an agreement to build a long-term, sustainable collaboration strategy. The three pan-European research infrastructures provide different, yet complementary, services to researchers in the field of biomedical sciences supporting the development of personalised medicine and new treatments.

The year 2020 has strongly been influenced by the worldwide pandemic, challenging the management of the Alliance to reposition the collaboration for the post-pandemic era. An updated implementation plan is foreseen for 2021. Furthermore, the Public Affairs team and the Communication team have been created. The Communications team established the name EU-AMRI, the European Alliance of Medical Research Infrastructures, and has started to prepare the dissemination plan as well as the official launch in 2021. The Public Affairs team has started monitoring opportunities for joint or concerted actions to increase policy influence and visibility. In 2020 this has resulted in requesting alignment input by ESFRI for the 2021 roadmap, and in joint publications and speaking opportunities.

Joint publications
5 recommendations to accelerate Covid-19 research (May 2020)
Scientific publication in Infectious Diseases (September 2020)
Cancer Mission: overview of capabilities (in collaboration with Elixir, September 2020)
Speaking opportunities
ESFRI Conference under Croatian Presidency (2020)
OECD Global Science Forum workshop (2020)

Projects to Promote International Partnership and Multinational Collaboration

ECRIN seeks to facilitate multinational clinical research on a global level and to engage through projects such as the Clinical Research Initiative for Global Health (CRIGH).

CRIGH

The Clinical Research Initiative for Global Health (CRIGH) was launched in October 2016 as a follow-up to the Organisation for Economic Co-operation and Development (OECD) Global Science Forum (GSF) initiative. The objective is to optimise clinical research programmes in participating countries, 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. To date CRIGH brings together 40 global health stakeholders and research institutions across the globe.

The Covid-19 crisis has further underscored the need to streamline international collaborative mechanisms for funding and implementing independent multinational clinical trials, the collection, sharing and access to quality data and adapted ethics and regulatory frameworks.

The third CRIGH General Assembly was hosted as a virtual event due to the Covid-19 restrictions. This format enabled the participation of over 100 CRIGH consortium members and observers as well as the WHO Chief Scientist. The objectives of the General Assembly were to underscore the role of CRIGH as a key partner for the co-development of independent clinical trials and to provide recommendations for global health actors and stakeholders to support independent, timely and equitable clinical trial implementation and access.

The meeting closed with a call for better harmonization and risk-based clinical trial regulation by bodies such as the WHO and the OECD as well as more effective instruments to coordinate and fund multinational clinical research. Moreover, the key role that could be played by entities such as the CRIGH Consortium and ECRIN by facilitating and streamlining multinational clinical trials' operations was highlighted. The 4th General Assembly shall be held in Mozambique next year, back-to-back with the 10th EDCTP Forum.

GOVERNANCE AND STRATEGY
Governance

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	Spain
Marta Abrantes	Portugal
Renáta Chudáčková	Czech Republic
Alexander Grundmann	Germany
Eric Guittet	France
Annette Magnin	Switzerland
Øyvind Melien	Norway
Daniel Pella	Slovakia
Attila Levente Szőcs	Hungary
Agnieszka Ryniec	Poland
Oonagh Ward	Ireland

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 member and observer countries.

Christian Ohmann	Chair (Germany)
Annette Magnin	Vice-chair (Switzerland)
Valentina Cabral Iversen	Norway
Regina Demlová	Czech Republic
Anja Eskat	Switzerland
Tomasz Hryniewiecki	Poland
Fionnuala Keane	Ireland
Gábor Kovács	Hungary
Emilia Montero	Portugal
Antonio Portoles	Spain
Lucia Palmisano	Italy
Daniel Pella	Slovakia
Olivier Rascol	France
Heiko Von Der Leyen	Germany

Governance Meetings in 2020

Body	Dates
Assembly of Members (AoM)	18 May 2020
	15 December 2020
Network Committee	18 May 2020
	30 November & 7 December 2020

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.

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. The main recommendations provided by the board members cover funding of clinical research, expansion, community building, and long-term sustainability and are integrated as actions in the 2021 work plan or in the next strategic plan.

Paul Avillach	Harvard Medical School
Maria Blettner	Johannes Gutenberg University Mainz
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
Effy Vayena	University of Zurich

Financial Report 2020

INCOME

Membership Core contributions	1 330 000 €
Membership Local contributions	950 000 €
Research projects	1 609 841 €
Other income	33 315 €
Financial income	108 692 €
Extraordinary income	138 635 €
TOTAL INCOME FOR 2020	4 170 483 €

EXPENDITURES

Salaries & other staff expenses	1 708 682 €
Subcontracting	671 951 €
Office rent and insurance	158 598 €
Travel and meetings	57 119 €
Financial expenses	13 138 €
Extraordinary expenses	22 460 €
Income tax	25 873 €
Other expenses	246 792 €
Local contribution provided in-kind	850 000 €
TOTAL EXPENDITURE FOR 2020	3 754 613 €

NET RESULT

NET RESULT FOR 2020	415 870 €

ECRIN is funded by the contributions of its member and observer countries. These funds are primarily dedicated to supporting the organisation and developing its core competencies. In addition, ECRIN receives funds from European funding bodies (e.g. Horizon 2020) that cover specific activities carried out as part of multinational clinical trials or infrastructure development projects.

APPENDIX
Acronyms

AFNOR	Association Française de Normalisation
AIBILI	Association for Innovation and Biomedical Research on Light and Image
AICIB	Agency for Clinical Research and Biomedical Innovation
AoM	Assembly of Members
APT	Adaptive Platform Trials
ATMP	Advanced Therapy Medicinal Products
B1MG	Beyond 1 Million Genomes
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
BICRO	University of Milan-Bicocca
c4c	connect 4 children
CDISC	Clinical Data Interchange Standards Consortium
CHU	Centre Hospitalier Universitaire
CONVINCE	Colchicine for Prevention of Vascular Inflammation in Non-Cardio Embolic Stroke
CORBEL	Coordinated Research Infrastructures Building Enduring Life-science Services
Covid-19	Coronavirus Disease 2019
CRC	Clinical research centre
CRFs/CRCs	Clinical research facilities/Clinical research centres
CRIGH	Clinical Research Initiative for Global Health
CRMDR	Clinical Research Metadata Repository
CRO	Clinical Research Organisations
CSA	Coordination and Support Action
CTFG	Clinical Trial Facilitation Group
CTU	Clinical Trial Unit
CZECRIN	Czech Clinical Research Infrastructure Network
DCC	Data Center Certification
DKF	Departement Klinische Forschung
DM	Data Management
DSMB	Data and Safety Monitoring Board
EATRIS	European Advanced Translational Research Infrastructure in Medicine
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECRIN	European Clinical Research Infrastructure Network
EDCTP	European & Developing Countries Clinical Trials Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
EI	Enterprise Ireland
EJP-RD	European Joint Programme on Rare Diseases
ELSA	Ethical, Legal and Social Aspects
ELSI	Ethical, Legal and Social Implications
EMA	European Medicines Agency
EOSC	European Open Science Cloud
EOSC-Life	European Open Science Cloud Life project
EPTRI	European Paediatric Translational Research Infrastructure
ERIC	European Research Infrastructure Consortium
ERIC Forum	ERIC Forum Implementation project
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
EULAC PerMed	Widening EU-CELAC policy and research cooperation in Personalised Medicine
EU-AMRI	European Alliance of Medical Research Infrastructures
EUCLID	European Clinical Trials Services Platform
EuCo	European Correspondent
EUnetHTA	European Network for Health Technology Assessment
EU-PEARL	EU Patent-cEntric clinical tRial pLatforms
EURORDIS	EURORDIS Reare Diseases Europe
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
GMP	Good manufacturing practice
GSF	(OECD) Global Science Forum

H2020	Horizon 2020
HECRIN	Hungarian Clinical Research Infrastructure Network
HRB	Health Research Board
HRB CRCI	Health Research Board Clinical Research Coordination Ireland
HTA	Health Technology Assessment
ICB	(ECRIN) Independent Certification Board
ICH	International Conference on Harmonisation
ICTD	International Clinical Trials Day
IDEA-FAST	Clinical observational study on the relationship between digital and clinical parameters of fatigue, sleep disturbances and activities of daily living in neurodegenerative disorders and immune-mediated inflammatory diseases
ID-EPTRI	Infradev - European Paediatric Translational Research Infrastructure
IdiPaz	Instituto de Investigación del Hospital Universitario La Paz
IdISSC	Instituto de Investigación Sanitaria del Hospital Clínico San Carlos
IMI	Innovative Medicines Initiative
INSERM	Institut National de la Santé et de la Recherche Médicale
IPD	Individual Participant Data
IS	Information systems
ISCIII	Carlos III Health Institute (Instituto de Salud Carlos III)
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
MRA	(Polish) Medical Research Agency
MRCC	Medical Research Collaboration Center
NECESSITY	New Clinical Endpoints in primary Sjögren's Syndrome
NHO	National Hospital Organization
NIH	(U.S.) National Institutes of Health
NorCRIN	Norwegian Clinical Research Infrastructure
OECD	Organisation for Economic Co-operation and Development
OTBB3	Oxytocin Treatment in Neonates/Infants with Prader-Willi syndrome
PedCRIN	Paediatric Clinical Research Infrastructure Network
PERMIT	Personalised Medicine Trials
PM	Personalised Medicine
POLCRIN	Polish Clinical Research Infrastructure Network
POPART	A randomised trial of prophylactic oropharyngeal surfactant for preterm infants
PRECIOUS	PREvention of Complications to Improve OUtcome in elderly patients with acute Stroke
PREVCOVEAST	Study on herd immunity SARS-CoV-2 in the population of Eastern Slovakia
PtCRIN	Portuguese Clinical Research Infrastructure Network
QMS	Quality Management System
RAPHE	Regulatory Advice and Pharmacoeconomics
RECOVER	Rapid European Covid-19 Emergency Research Response
REMAP-CAP	Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia
REMAP-COVID	Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia for COVID
RI	Research infrastructure
RI-VIS	Expanding research infrastructure visibility to strengthen strategic partnerships
SaaS	Software as a service
SARS-CoV-2	Severe Acute Respiratory Syndrome CoronaVirus-2
SCReN	Spanish Clinical Research Network
SCTO	Swiss Clinical Trial Organisation
SERI	State Secretariat for Education, Research and Innovation (Switzerland)
SLOVACRIN	Slovak Clinical Research Infrastructure Network
SME	Small and Medium sized Enterprise
SNSF	Swiss National Science Foundation
STARS	Strengthening Training of Academia in Regulatory Science
Synchros	SYNergies for Cohorts in Health: integrating the ROle of all Stakeholders
TCB	Trials Coordination Board
Transvac-DS	Design study for a European vaccine infrastructure
TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen
TRI	Translational Research Centre for Medical Innovation (Japan)
TSUNAMI	Italian National Covid-19 study 'TSUNAMI' based on the treatment of early diagnosed patients with the plasma from convalescent patients
UCD	University College Dublin
VACCELERATE	European Corona Vaccine Trial Accelerator Platform
WE-study	Walk Easier with cerebral palsy
WG	Working Groups
WHO	World Health Organisation
ZKS	Zentrum für Klinische Studien

APPENDIX
Clinical Trial Portfolio in 2020

During 2020 ECRIN provided support to 39 clinical trials in different phases; 16 were in the set-up phase working toward the opening of all sites in all participating countries; and 23 trials were active- meaning in the phases of recruitment, follow-up, close-down activities.

Short Title	Full Title	Trial status	Coordinating country	Funding source
CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	Set-up phase	Germany	German government
CLEARANCE	Randomized Comparison of interventional cLosure of the lEft atrial Appendage using a LAA closure device versus oRal Anticoagulation therapy in patients with Non-valvular atrial fibrillation and status post intraCranial bIEeding	Start-up phase	Germany	Industry
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults	Set-up phase	France	101015736*
EU-TRAIN RCT (IMPACT)	Randomized Controlled Multicenter Trial to quantify the benefits of biomarkers in routine patient care in kidney transplant recipients	Set-up phase	France	754995*
HIVACAR	Evaluating a Combination of Immune-based Therapies to Achieve a Functional Cure of HIV Infection	Set-up phase	Spain	731626*
IDEA-FAST-CVS	Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases	Set-up phase	Germany	IMI2 853981*
ImmunAID	Immunome project consortium for AutoInflammatory Disorders	Set-up phase	France	779295*
INFORM2 NivEnt	INFORM2 exploratory multinational phase I/II combination study of Nivolumab and Entinostat in children and adolescents with refractory high-risk malignancies	Set-up phase	Germany	Industry & German government
NECESSITY	NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifYing patients	Set-up phase	France	IMI 806975*
NICOFA	A randomized, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of nicotinamide in patients with Friedreich's Ataxia	Set-up phase	Germany	ERA-Net & DFG
OTBB3	Oxytocin Treatment in neonates and infants (BaBies) with Prader-Willi syndrome: effects of intranasal administrations of oxytocin in infants aged from 0 to 3 months vs. placebo on sucking and swallowing (phase III clinical trial)	Start-up phase	France	731036*
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	Set-up phase	France	732163*
TB-MED	An Open Innovation testing bed for the development of high-risk medical devices	Set-up phase	Spain	814439*
TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen Study type	Set-up phase	France	IMI 777389*
CONVINCE-IRL	Colchicine for Prevention of Vascular Inflammation in Non-cardio Embolic Stroke	Set-up phase in ECRIN countries running in Ireland	Ireland	National : Irish
ADIPOA3	Efficacy of knee injection of allogeneic adipose-derived MSC in subjects with mild to moderate knee OA unresponsive to conventional therapy	Set-up phase	France	Industry
ADIPOA2	Autologous Adipose-Derived Mesenchymal Stromal Cells in the Treatment of Mild to Moderate Osteoarthritis	Running	France	643809*
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	Belgium	634559*
BIOCHIP	Clinical Trial for the Regeneration of Cartilage Lesions in the Knee (NosetoKnee2)	Running	Switzerland	681103*
EU-TRAIN COHORT	Prospective cohort of kidney transplant patients	Running	France	754995*

APPENDIX
Clinical Trial Portfolio in 2020

FAIR-PARK II	Conservative Iron Chelation as a Disease-Modifying Strategy in Parkinson's Disease	Running	France	633190*
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	Spain	731875*
MACUSTAR	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention	Running	Germany	IMI 116076*
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 - on hold in 2020/21	Germany	681094*
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	Running	Spain	733288*
PAPA-ARTIS	Paraplegia Prevention in Aortic Aneurysm Repair by Thoracoabdominal Staging with 'Minimally-Invasive Segmental Artery Coil-Embolization': A Randomized Controlled Multicentre Trial	Running	Germany	733203*
POPART	Prophylactic oropharyngeal surfactant for preterm infants: a randomised trial	Running	Ireland	731046*
PRECIOUS	Prevention of Complications to Improve Outcome in Elderly Patients with Acute Stroke	Running	Netherlands	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	Germany	733379*
R-Link	Optimizing response to Li treatment through personalized evaluation of individuals with bipolar I disorder: the R-LiNK initiative	Running	France	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	Germany	Industry
SWEET	Sweeteners and sweetness enhancers: Impact on health, obesity, safety and sustainability	Running	Denmark	774293*
TENSION	Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window	Running	Germany	754640*
TERIS	Multi-center, randomized, double-blinded study of Teriflunomide® in radiologically isolated syndrome (RIS)	Running	France	Industry
WE Study	Walking Easier with cerebral palsy	Running	Norway	731046*
SCD-WELL	A Randomized Multicenter Clinical Trial in Patients with Subjective Cognitive Decline At Risk for Alzheimer's Disease to Assess the Short-term Effects of a Standardized Meditation Intervention vs. Active Control on Behavioral Measure	Running	France	667696*
HCQ4Surfdefect	Hydroxycholoroquine in paediatric ILD_START randomized controlled in-parallel group, then switch to placebo active drug, and STOP randomized controlled in-parallel group to evaluate the efficacy and safety of hydroxychloroquine (HCQ)	Running	Germany	ERA-Net
ALCHEMIST	ALdosterone antagonist Chronic HEModialysis Interventional Survival Trial	Withdrawn/ cancelled (2020)	France	Industry
DISCHARGE	Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies	Completed - ECRIN no longer involved (2020)	Germany	603266**

* 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

APPENDIX
Intrastructure Development Portfolio in 2020

At the end of 2020, ECRIN's infrastructure development portfolio included 21 open projects. However, ECRIN provided support to an additional three projects during the year, bringing the total number of projects ECRIN is contributing to in 2020 to 24.

Acronym	Full name	Status (Dec. 2020)	Funding
B1MG	Beyond 1 Million Genomes	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 951724
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)
CORBEL	Coordinated Research Infrastructures Building Enduring Life-science Services	Ended	The European Union's Horizon 2020 research and innovati on programme under grant agreement number 654248
CRIGH	Clinical Research Initiative for Global Health	Running	Funding through members' contributions
EBRA	The European Brain Research Area	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825348
ECRAID-Plan	European Clinical Research Alliance on Infectious Diseases (ECRAID) Business Plan	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825715
EJP-RD	European Joint Programme on Rare Diseases	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825575
EOSC-Hub	Integrating and managing services for the European Open Science Cloud	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 777536
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
ERIC- Forum	ERIC-Forum Implementation project	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 823798
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	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825173
MiRoR	Methods in Research on Research	Ended	European Union's Horizon 2020 Marie Sklodowska Curie Innovative Training Networks- European Joint doctorate (ITN-EJD) under grant agreement number 676207
PedCRIN	Paediatric Clinical Research Infrastructure Network	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 731046
PERMIT	PERsonalised MedicIne Trials	Running	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
RI-VIS	Expanding research infrastructure visibility to strengthen strategic partnership	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 824063
SYNCHROS	SYNergies for Cohorts in Health: integrating the Role of all Stakeholders	Running	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 82588
TESA II	Trials of Excellence in Southern Africa II	Running	European & Developing Countries Clinical Trials Partnership (EDCTP) under GA no.1051-TESAII EDCTP-RegNet-2015
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
XDC	eXtreme DataCloud	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 777367

APPENDIX
2020 Publications

Publication	Related project/trial
Ader, F. (2020) Protocol for the DisCoVeRy Trial: Multicentre, Adaptive, Randomised Trial of the Safety and Efficacy of Treatments for COVID-19 in Hospitalised Adults. BMJ Open 10, no. 9. https://doi.org/10.1136/bmjopen-2020-041437.	DisCoVeRy - study protocol
Aurich, B., Vermeulen, E., Elie, V., Driessens, M. H. E., Kubiak, C., Bonifazi, D., Jacqz-Aingrain, E. (2020). Informed consent for neonatal trials : practice points to consider and a checklist. BMJ Paediatrics Open, 4(1), e000847	PedCRIN
Banzi, R., Gerardi, C., Fratelli, M., Garcia, P., Teresa Torres, Josep Maria Haro Abad, Albert Sanchez Niubo, Enrico Glaab, Emanuela Oldoni, Florence Bietrix, Vibeke Fosse, Emmet McCormack, Raphael Porcher, Cecilia Superchi, & Jacques Demotes-Mainard. (2020). Methodological approaches for personalised medicine: Protocol for a series of scoping reviews. https://doi.org/10.5281/zenodo.3770937	PERMIT
Canham, S. (2020a). Design and Development of the Study Data System. In S. Piantadosi & C. L. Meinert (Eds.), Principles and Practice of Clinical Trials (pp. 1–29). Springer International Publishing.	
Canham, S. (2020b). Long-Term Management of Data and Secondary Use. In S. Piantadosi & C. L. Meinert (Eds.), Principles and Practice of Clinical Trials (pp. 1–30). Springer International Publishing	
Canham, S., Ohmann, C., Thomassen, G., Matei, M., Demotes, J., & Panagiotopoulou, M. (2020). EOSC-Life Strategic plan for the development of a COVID-19 repository including specification of technical requirements, policies and procedures. https://doi.org/10.5281/zenodo.4141619	EOSC-Life
Fabrellas, N., Carol, M., Palacio, E., Aban, M., Lanzillotti, T., Nicolao, G., Chiappa, M.T., et al. (2020) Nursing Care of Patients With Cirrhosis: The LiverHope Nursing Project. Hepatology 71, (3) 1106–16. https://doi.org/10.1002/hep.31117.	LIVERHOPE
Leers, J. M., Knepper, L., van der Veen, A., Schröder, W., Fuchs, H., Schiller, P., Hellmich, M. et al. (2020) 'The CARDIA-Trial Protocol: A Multinational, Prospective, Randomized, Clinical Trial Comparing Transthoracic Esophagectomy with Transhiatal Extended Gastrectomy in Adenocarcinoma of the Gastroesophageal Junction (GEJ) Type II'. BMC Cancer 20, no. 1: 781. https://doi.org/10.1186/s12885-020-07152-1.	CARDIA - study protocol
Magnin, A., Cabral Iversen, V., Calvo, G., Cecetkova, B., Dale, O., Demlova, R., Blasko, G., Keane, F., Kovacs, G. L., Levy-Marchal, C., Monteiro, E., Palmisano, L., Pella, D., Portoles, A., Rascol, O., Schmid, C., Tay, F., von der Leyen, H., Ohmann, C. (2020) European survey on national harmonization in clinical research. Learning Health Systems; 5:e10220	
Murphy, M. C., Galligan, M., Molloy. B., Hussain, R., Doran, P., O'Donnell, C. (2020) Study protocol for the POPART study – Prophylactic Oropharyngeal surfactant for Preterm infants: A Randomised Trial. BMJ Open 10:e035994.	PedCRIN/ POPART trial
Oldoni, E., van Gool, A., Garcià Bermejo, L., Scherer, A., Th Mayrhofer, M., Florindi, F., Demotes, J., Kubiak, C. Fauvel, A-C, Bietrix, F., Ussi, A., Andreu, A.L. (2020) Biomarker Research and Development for Coronarivus Disease 2019 (COVID-19): European Medical Research Infrastructures Call for Global Coordination. Clinical Infectious Diseases, ciaa1250	
Ohmann, C., Canham, S., Boiten, J.-W., Cano Abadía, M., Chassang, G., Chiusano, M. L., David, R., Mayrhofer, M. T., & Pireddu, L. (2020). EOSC-Life WP4 Toolbox: Categorisation system for resources to be referenced in the toolbox for sharing of sensitive data. Zenodo. https://doi.org/10.5281/zenodo.4311094	EOSC-Life
Stein, I. von, Wittenberg, M., Dijk, E., Huigen, F., Baxter, R., Nordling, J., Ohmann, C., Matei, M., Maria Panagiotopoulou, Manzi, A., Wildish, T., Carrillo, R., & Savini, G. (2020). D2.9—Final Data Policy recommendations https://doi.org/10.5281/zenodo.4305628	EOSC- Hub
Terheyden, J.H., Holz, F.G., Schmitz-Valckenberg, S., Lüning, A., Schmid, M., Rubin, G.S., Dunbar, H., Tufail, A., Crabb, D.P., Binns, A., Sánchez, C.I., Hoyong, C., Margaron, P., Zakaria, N., Durbin, M., Luhmann, U., Zamiri, P., Cunha-Vaz, J., Martinho, C., Leal, S., Finger, R.P., and on behalf of MACUSTAR consortium (2020) Clinical study protocol for a low interventional study in intermediate age-related macular degeneration developing novel clinical endpoints for interventional clinical trials with a regulatory and patient access intention—MACUSTAR. Trials 21:659	MACUSTAR - study protocol
Tilki, B., Schulenberg, T., Canham, S., Banzi, R., Kuchinke, W., & Ohmann, C. (2020). Assessment of a demonstrator repository for individual clinical trial data built upon DSpace. F1000Research, 9, 311. https://doi.org/10.12688/f1000research.23468.1	EOSC-Life
Van Tilburg, C.M., Witt, R., Heiss, M., Pajtler, K.W., Plass, C., Poschke, I., Platten, M., Harting, I., Sedlaczek, O., Freitag, A.,; Meyrath, D., Taylor, L., Balasubrumanian, G.P., Jäger, N., Pfaff, E., Jones, B.C., Milde, T., Pfister, S.M., Jones, D.T.W., Koppe-Schneider, A. & Witt, O. (2020) INFORM2 NivEnt: The first trial of the INFORM2 biomarker driven phase I/II trial series: the combination of nivolumab and entinostat in children and adolescents with refractory high-risk malignancies. BMC Cancer, 20, 523.	INFORM NivEnt – study protocol

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CONTACT

Management office:
5-7 rue Watt - 75013 - Paris - France

For general information about ECRIN, email us at: contact@ecrin.org

To contact your local European correspondent, see here: www.ecrin.org/contact/eu-co

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