



Supporting
clinical trials
across borders

ANNUAL REPORT 2021



Czech Republic
Masaryk University
Brno



France
INSERM
Toulouse



Germany
KKS-Netzwerk e.V
Berlin



Hungary
University of Pécs
Pécs



Ireland
National Clinical Trials Office
Cork



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

Table of Contents

Forewords.....	4
2021 Highlights	9
Mission, Vision, Focus Areas.....	10
ECRIN in Numbers	11
ECRIN Overview.....	12
National Scientific Partner: Description and Highlights	14
Interview with the Czech EuCos.....	26
ECRIN Team.....	28
ECRIN's Response to COVID-19	30
Interview with the EU-SolidAct Principal Investigator	34
Services	
Clinical Trial Operations.....	36
Infrastructure Development Projects.....	44
Interview on the PedCRIN project	46
Interview on the HealthyCloud project	50
Quality as a service: Data Centre Certification.....	52
Interview with an ECRIN certified Data Centre	54
Support Services	
Quality	56
Communications	56
Training	60
Interview with EMA on CTIS joint training session.....	62
Governance and Strategy	
Partnerships	64
Governance	66
Financial Report 2021.....	67
Annexes	
Acronyms.....	68
Clinical Trial Portfolio in 2021.....	72
Research Infrastructure Development Portfolio in 2021	76
2021 Publications.....	79

Forewords



**Jacques Demotes,
Director General**

For the second consecutive year, the challenges raised by the COVID-19 outbreak were the main drivers for ECRIN's activities in 2021. This was an opportunity to demonstrate the ability of ECRIN and ECRIN's team to work remotely and under strong time constraints on high-visibility, complex trial projects. This was illustrated by the launch of the EU-SolidAct platform trial for COVID-19 treatments in hospitalised patients, and the initiation of the VACCELERATE project including three COVID-19 vaccine platform trials on elderly, adult and children volunteers.

Though challenging, the COVID-19 crisis also opened new opportunities, such as

developing a capacity to manage platform trials as part of the sustainability plan of the IMI EU-PEARL. These COVID-19 projects also led ECRIN to play new roles, including the trial coordination board to promote cooperation across the large COVID-19 platform trials and establish a dialogue with regulators, industry and policymakers, or the joint access advisory mechanism operated by ECRIN, with an expert panel performing an independent scientific assessment of candidate intervention arms for COVID-19 platform trials.

Beyond the COVID-19 crisis, ECRIN provided high-quality services to its clinical trials portfolio and contributed to many projects on health research data sharing and reuse, including the HealthyCloud project where ECRIN is in charge of drafting the strategic research agenda for the Health Research and Innovation Cloud, at the interface between the European Open Science Cloud and the European Health Data Space.

Finally, preparatory work with BBMRI and EATRIS helped refine the objectives of the Alliance of Medical Research Infrastructures (EU-AMRI), as an integrated service workflow for complex projects requiring support from multiple research infrastructures, leading to a launch event early in 2022.



**Christine Kubiak,
Operations Director**

2021 marks the launch of the ECRIN strategic plan 2021- 2023. One of the strategic goals is to enhance the brand recognition and a first step was achieved with the launch at the end of November of the renewed ECRIN logo and corporate identity. This new visual identity relies on a simplified image and modern blue and yellow hues, nevertheless keeping the core elements of the previous logo, such as the square, the checkerboard and the idea of the people in the centre. The modernisation of the ECRIN brand will continue throughout 2022.

Patient involvement is another key priority in ECRIN's 2021-2023 strategic plan, contributing to the general goal

to make clinical research more efficient and successful. ECRIN has engaged in a strategic partnership with EUPATI, the European Patients' Academy on Therapeutic Innovation. With this collaboration, both ECRIN and EUPATI wish to elaborate on their commitment to provide and improve education and training opportunities in clinical research for patients and patient representatives. Also, they aim to strengthen academic researchers' capacities to effectively engage with patients in their studies.

An important date on the ECRIN calendar is International Clinical Trials Day (ICTD) which brings together clinical research stakeholders to exchange on various trial topics and to acknowledge the achievements that result from clinical research. ICTD 2021 was organised as a virtual event. The topic was "Platform trials: shift in testing, treatment & collaboration". Over 800 people with an interest in clinical research and in platform trials registered from across the world, making the day a success, and confirming ECRIN's position in the clinical research landscape.

ECRIN will continue to build on these achievements and more as it works to fulfil the actions outlined in the current strategic plan.



**Sabine Klager,
Head of Clinical Operations Unit**

2021 proved to be a very busy year for the Clinical Operations Unit at ECRIN. Through its ongoing support for a portfolio of 39 multi-national clinical trials in diverse clinical specialities, and despite the added difficulties of the current pandemic, ECRIN has demonstrated its capacity to deliver, be prepared and adapt as necessary. The continued contributions to European clinical trial projects assisted in the search for solutions in the current public health crisis.

The ECRIN trial portfolio grew by five new trials, one in the field of nephrology, one new platform trial for the treatment of COVID-19 and three COVID-19 vaccine trials; whereby one trial is set in the

paediatric population and two platform trials in different adult populations sharing one master platform trial template. It also marked the end of one of the first trials in which ECRIN has participated from the very early proposal stage to trial completion, FAIRPARK II.

This year was marked by a closer engagement with the CTUs and affiliated organisations of the ECRIN Network Members & Observers Countries. Two back-to-back dedicated events were organised online. The first, ECRIN CTU Day brought together members from the CTU community to get to know one another, exchange information and best practices, and through a use case demonstrated ECRIN trial management from the ECRIN and CTU perspective. The second was an exclusive training event organised jointly with the European Medicines Agency (EMA) which provided hands on demonstrations and Q&A on the implementation of the Clinical Trials Information System (CTIS) in the academic setting.

Fostering closer collaborations and better understanding of the activities conducted at all levels by members of ECRIN is a great step towards strengthening the ECRIN community for future joint projects.



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

ECRIN continued throughout 2021 to demonstrate its capacity to meet the needs of the European clinical research community and continued to hone its service offer. ECRIN confirmed its ISO 9001:2015 certification in 2021. This year the actions undertaken were also guided by the 2021-2023 strategic plan. This new strategic plan highlights six goals for the coming years including ensuring ECRIN's place in the clinical research landscape, anticipating changes, strengthening and developing partnerships, enhancing brand recognition, building the ECRIN community and the EU-AMRI collaboration.

The ongoing pandemic has had a large impact on ECRIN's activities (both its

services and projects):

- ECRIN has defined a new role for itself in the clinical research landscape as a coordinator at the intersection of many critical COVID-19 clinical trial projects funded by the EU.
- It has also served to reinforce the relationship of the ECRIN Member and Observer countries through their close collaboration in the COVID-19 Taskforce.
- A new call for the Data Centre Certification program was launched for ECRIN Member and Observer countries in 2021 after cancelling the 2020 call and adapting the audit process to the COVID-19 pandemic situation.

ECRIN continues its efforts to stay on the cutting edge of clinical research and developed its capacity, in particular in personalised medicine, platform trials and rare diseases. This year also marks the end of the successful ECRIN coordinated project PedCRIN. Among the outcomes of the project are the sustainability plan and the development of a collaboration agreement with the paediatric community.

The increased recognition of the actions at ECRIN, as seen through the enhanced relationship with stakeholders at all levels, the continued growth of the portfolio and the capacity to adapt, highlight many of the strengths of ECRIN.

2021 Highlights

January

- Kick-off of SIMCor

February

March

- Kick-off of HealthyCloud
- Kick-off of EU-Africa PerMed
- Kick-off of ECRAID Base
- Kick-off of VACCELERATE

April

- Launch of ECRIN Covid-19 Marketplace
- 2021-2023 Strategic Plan released
- PedCRIN Webinar: Methods for the engagement of youth and families in paediatric clinical trials – Towards patient-centred studies
- PedCRIN Webinar: Tools for the management of paediatric trials – handling biosamples and assessing causality of adverse events

May

- International Clinical Trials Day 2021 - Platform Trials: shift in testing, treatment & collaboration
- Kick-off of TTV Guide
- EU-AMRI endorses Porto Declaration on Cancer Research
- PedCRIN Webinar: Practical points to consider for neonatal trials – An introduction to the PedCRIN neonatal tools
- Launch of EU-SolidAct

June

- PedCRIN final meeting
- Launch of COVID-19 coordination module website (<https://covid19trials.eu/en>)

July

- IC PerMed focus on PERMIT project

August

September

October

- Quality and Risk Council Meeting
- Clinical Trial Helpdesk developed by EULAC PerMed
- Kick-off of BY-COVID

November

- Unveiling of the new ECRIN logo
- ECRIN CTU Day
- EU-COVAT-1 AGED study launched within VACCELERATE
- ECRIN confirmed its ISO 9001:2015 certification for its principal services



December

- CTIS Training event co-hosted by ECRIN and EMA
- Signature of strategic partnership between ECRIN and EUPATI

Mission, Vision, Focus Areas

ECRIN MISSION

To support the conduct of multinational clinical research in Europe

ECRIN VISION

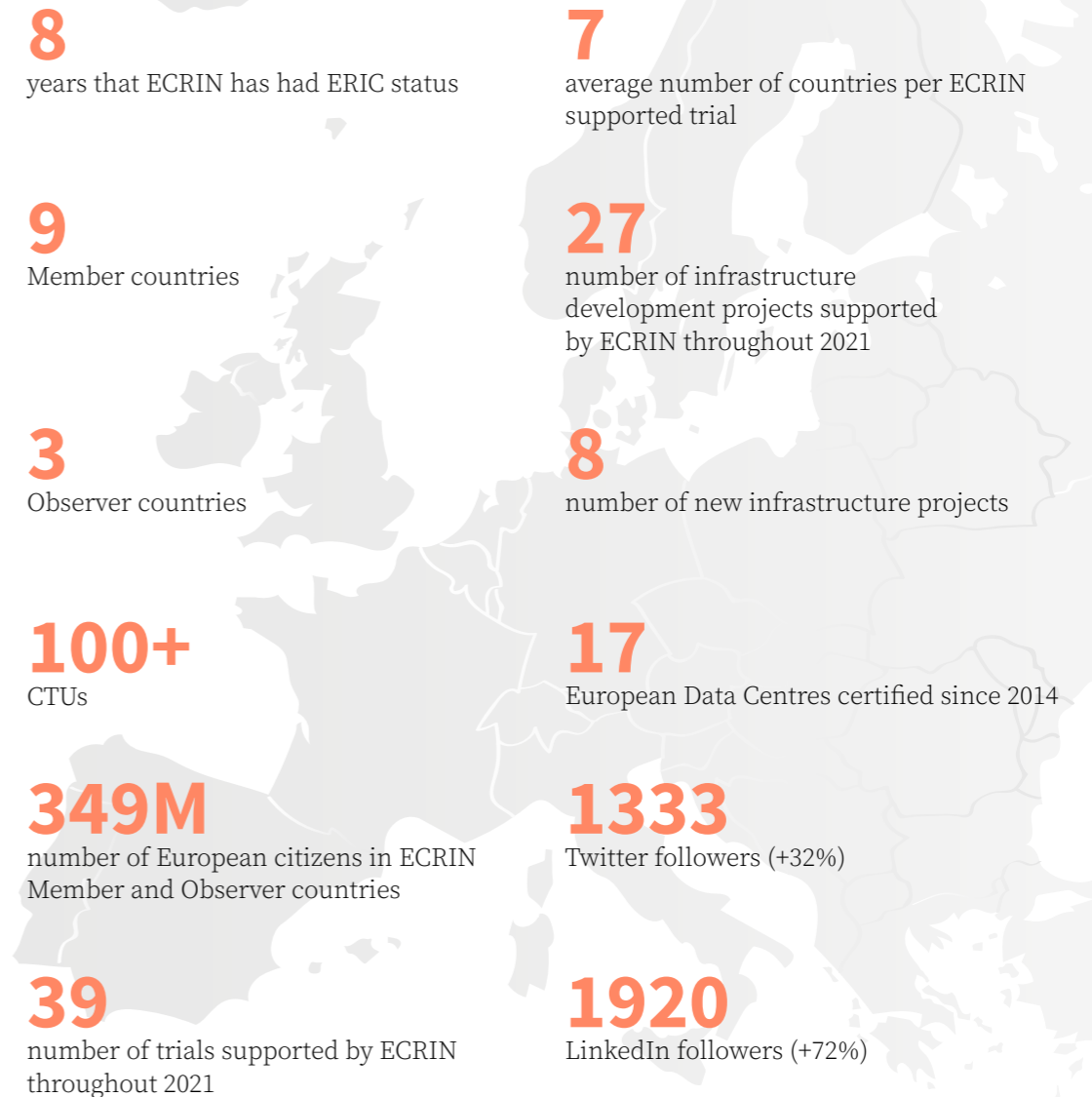
To generate scientific evidence to optimise medical practice

ECRIN Strategic Goals

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



ECRIN in numbers



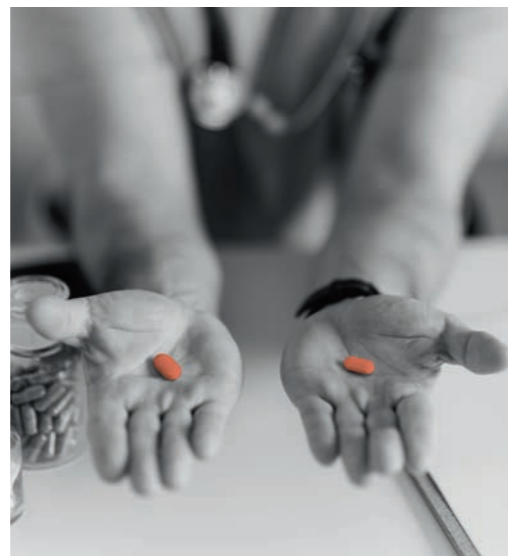
ECRIN Overview

ECRIN-ERIC is a European Research Infrastructure facilitating multinational clinical research, through the provision of advice and services for the set-up and management of investigator or SME led clinical studies in Europe. ECRIN is a distributed 'research infrastructure' that unites national networks of clinical trial units across Europe, through its scientific partners, to fulfil its vision of generating scientific evidence to optimise medical practice. It is certified ISO 9001:2015 for its principal services. ECRIN is also involved in activities to enhance the ability of European institutions to

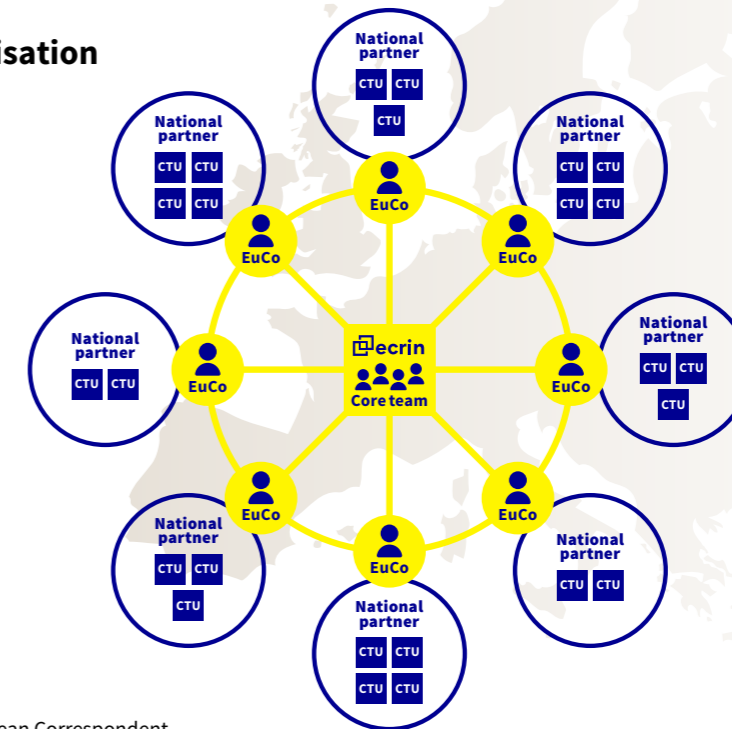
successfully conduct multi-country clinical research (e.g., tools/database development, data centre certification). Moreover, ECRIN participates in projects aiming to develop its capacity, tools and services.

By supporting clinical trials across borders and advising and implementing policy, ECRIN advances knowledge flow, competitiveness and integration in European clinical research. Updates on ECRIN's trial support and project activities in 2021 can be found in the following pages.

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.



Organisation



EuCo: European Correspondent
 CTU: Clinical Trial Unit

ECRIN's organisational model is based on country membership. In 2021, 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, research organisations, and hospitals. EuCos are clinical research experts with extensive knowledge of the national and European clinical research and regulatory landscape, operational management, and coordination of multinational trials. They manage ECRIN's clinical trial portfolio in collaboration with the national scientific partner and the Paris-based core team.

National Scientific Partner: Description and Highlights



CZECH REPUBLIC

Scientific Partner: CZECRIN - Czech Clinical Research Infrastructure Network

Member since 1 Jan. 2018

Host institution: Masaryk University

National hub: Brno

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

CZECRIN is the national, large research infrastructure, included in the Czech Roadmap for Large Research, Development and Innovation, that facilitates academic clinical trials in the Czech Republic. CZECRIN was built as a unique infrastructure, connecting a network of major clinical sites with a focus on clinical research and providing knowledge, development, production, and implementation capacities in the field of research and development of drugs and medical devices. CZECRIN set up advanced solutions for the effective provision and use of high-quality scientific data, implementing the FAIR (Findable, Accessible, Interoperable, and Reusable) principles. CZECRIN also annually organises educational events and conferences, including National Clinical Trials Day.



2021 Highlights

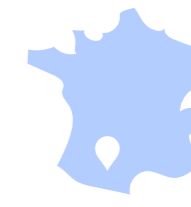
CZECRIN introduced a new website and logo at the beginning of 2021. It also launched its newsletter this year, to keep stakeholders informed about all highlights on the Czech science scene. Moreover, the new covivac website was launched for the general public to raise awareness of COVID-19 and vaccines.

The national multicentric clinical trial REMED was started in January, and the CoVigi study was launched in May both facilitated by CZECRIN.

Beyond its activities in COVID, CZECRIN achieved excellent results in the international evaluation of research infrastructures in the Czech Republic and introduced the first Disease Oriented Networks – STROCZECH, ONCONet, and EPILEPSY Network.

The CONSCIOUS II project, of which CZECRIN will be coordinator was approved.

CZECRIN is proud to support 114 projects, of which 10 are H2020 projects in cooperation with ECRIN as well as 78 publications in 2021. CZECRIN organised the annual research conference, CZECRIN Networking, and seven scientific workshops.



FRANCE

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

Member since 29 Nov. 2013

Host institution: INSERM

National hub: Toulouse

www.fcrin.org/en

F-CRIN, created in 2012, is one of the single contact points facilitating the participation of France in clinical studies. F-CRIN brings together the major academic and commercial stakeholders in clinical research in France, including clinical research and innovation departments in university hospitals, clinical investigation centres, and interregional groups for clinical research and innovation. F-CRIN enables multinational or multicentre, investigator-driven, clinical trials and early phase proof-of-concept studies. Clinical trial support is provided through F-CRIN by:

- 17 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, stroke, severe asthma, psychotic disorders)
- 2 specific expertise networks (methodology; health technology/medical devices)
- 1 platform of professional services (EUCLID)
- 1 national coordination unit

2021 Highlights

F-CRIN, ECRIN's French national scientific partner, certified 4 new research and investigation networks on pathologies of national interest:

- Fraden, an atopic dermatitis research network
- PSYnet, a psychotic disorders research network
- ACT4ALS-MND, the Alliance of Clinical trials for Amyotrophic Lateral Sclerosis and Motor Neurone Disease
- Strokelink, research network on heart disease and stroke.

An increase in its activity as demonstrated through:

- its participation in major projects on COVID-19 such as COVIDOSE which brought together the INNOVTe and INI-CRCT networks,
- the association of the FCRIN4MS (SLA) to the project "Recherche Hospitalo-Universitaire (RHU) "PRIMUS",
- the increase in the number of publications mentioning F-CRIN (411 compared to 322 in 2020)
- and the number of ongoing projects launched by an F-CRIN partner or where they are contributing (390 compared to 369 in 2020).



GERMANY

Scientific Partner: KKS - Netzwerk der Koordinierungszentren für Klinische Studien
Member since 29 Nov. 2013

Host institution: KKS-Netzwerk e. V.

National hub: Berlin

<http://www.kks-netzwerk.de/en/network/about-us.html>

KKS-Netzwerk e. V. (KKS), is currently an association of 26 academic coordinating centres for clinical trials (CTUs) all over Germany. Members of the KKS are competence hubs for quality-oriented clinical research. They 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 KKS structure enables close collaboration between study centres in multicentre trials, facilitating a high level of quality.

Training is also a significant focus of KKS-Netzwerk. In addition, network members are involved in various national and international clinical research projects and collaborate with diverse stakeholders. KKS-Netzwerk e. V. was established in 2005 by the working group of Coordinating



Centres for Clinical Studies. The KKS headquarter is located in Berlin and hosts the German ECRIN office.

2021 Highlights

- KKS-Netzwerk e. V. has prepared intensively for the new EU Regulation 536/2014 on clinical trials. Expert working groups with representatives of all KKS members joined forces to facilitate the practical implementation of the Regulation which will take place on 31.01.2022.
- Launch and coordination of the ECRIN activities in IMI-project IDEA-FAST.
- Currently, 11 ECRIN projects are coordinated by the KKS, support is also provided to 11 other projects in which the KKS is participating.
- Seven out of 17 ECRIN certified data centres in Europe are members of the KKS. With the expertise of KKS data management and IT working groups, the EMA Draft Guideline on computerised systems and electronic data in clinical trials was commented in the public consultation period by the KKS-Netzwerk e. V. to represent the view of academic data centres.
- During the COVID-19 pandemic, KKS has established online GCP trainings for investigators to guarantee appropriate qualifications.



HUNGARY

Scientific Partner: HECRIN - Hungarian European Clinical Research Infrastructure Network

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 capacity in innovative and 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, promotion of continuous professional training, and efforts to utilise the wealth of clinical data in research.



2021 Highlights

In 2021 the HECRIN Consortium was awarded the title of Hungarian Research Infrastructure of Excellence by the Ministry of Innovation and Technology and the NRDI. HECRIN will be able to use the title "Centre of Excellence" in the future. It also expanded with the addition of one new member.

HECRIN has continued to manage five research projects in the field of COVID-19, of which three are clinical trials of medical products in COVID-19 indication, the fourth is a study that aims to identify genetic factors determining the disease course of the infection and to prepare pharmacogenetic applications, and the last one is a support program which aims to select high potential ideas in the field of prevention, diagnosis and treatment of COVID-19.



IRELAND

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

Member since 20 Nov. 2018

Host institution: University College Cork

National hub: Cork

<https://ncto.ie/>

The HRB National Clinical Trials Office, (HRB NCTO), has recently been established (May 2021) as an independent, integrated, national clinical research network, providing centralised support to the conduct of multi-centre clinical trials and investigations/studies (both commercial and academic) across Ireland. With the support of the Health Research Board, host institution University College Cork, Enterprise Ireland and the seven University-based Clinical Research Facilities/Centres (CRFs/Cs) in the Republic of Ireland, the HRB NCTO was developed to build on the positive achievements of previous investments in clinical trials coordination, and future investments in national clinical trials infrastructure in Ireland. With a change in host institution in 2021, HRB NCTO has replaced HRB CRCI and the new central office provides overarching clinical research support and expertise, through a range of services and activities to academia and industry. The partner University CRF/CRCs in Ireland



provide the infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight programmes that are critical for the successful conduct of world-class patient-focused research.

2021 Highlights

- The HRB National Clinical Trials Office (NCTO) was established in May 2021 with a new host institution for the central coordination office in Ireland, University College Cork
- The HRB NCTO began recruiting staff in summer 2021.
- It launched its new website www.NCTO.ie in Dec 2021 and will further grow and develop this website throughout 2022
- The HRB NCTO National Study Feasibility support service has been re-established providing a streamlined service with a single point of contact for clinical trial feasibility for Ireland via the trials-feasibility@ucc.ie email address.
- HRB NCTO Working Groups were re-established with the new organisation in 2021 to deliver on Work Plans across areas such as quality, study feasibility and study start-up, clinical trial budgets, Medtech and pharmacovigilance. Ultimately, the aim of the working groups is the delivery of streamlined transparent processes for clinical research across the institutions in Ireland.



ITALY

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

Member since 29 Nov. 2013

Host institution: Istituto Superiore di Sanità (ISS)

National hub: Rome

www.itacrin.it

ItaCRIN National Network is coordinated by Istituto Superiore di Sanità (ISS) in Rome where the national hub is located. It groups together 11 Clinical Trial Units (CTUs) and Clinical Research Organisations (CROs) covering the whole Italian area. The main objective of the ItaCRIN National Network is to promote non-profit clinical research in Italy and Europe by offering support to the Italian clinical researchers in the set-up and running of multinational clinical trials to overcome hurdles and improve collaboration across borders.



2021 Highlights

In April 2021, the ItaCRIN coordination team organised a successful and well attended annual meeting with the CTUs/CROs of the national network. This was useful to define a common strategy focused on the quality implementation of our services and the organisation of training activities primarily dedicated to clinical researchers. In addition, a price list of all the services offered has been discussed and jointly agreed upon. Throughout 2021, a framework agreement has been finalised and signed with our CTUs/CROs.

Three out of 17 ECRIN certified data centres in Europe are members of ItaCRIN and one more is currently under certification.

With regard to the COVID-19 pandemic, ItaCRIN contributes to EU-SolidAct included in the EU-RESPONSE project. In addition, the ItaCRIN coordination team took part in a survey on national and international COVID-19 clinical studies which has led to a publication.



NORWAY

Scientific Partner: NorCRIN - Norwegian Clinical Research Infrastructure Network
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. Until the end of 2021, NorCRIN was coordinated from St. Olav's hospital, Trondheim. NorCRIN works to support both industry and academic studies, the expectation with the establishment of NorCRIN was to increase the number of academic and industry financed studies, to increase participation in international studies and to increase the speed at which all studies can be planned and conducted.



2021 Highlights

As the NorCRIN 1 project ended and NorCRIN 2 was financed and started up in 2021, coordination of the national network is preparing to move from St. Olav's Hospital in Trondheim to Haukeland Universitetssykehus in Bergen on 1 January 2022. The Haukeland node of NorCRIN has been one of the most active in ECRIN-supported clinical trials in 2021, including participation in the EU-COVAT-1 AGED and EU-COVPT-1 CoVacc trials. We welcome them aboard as the new national ECRIN hub for Norway.



POLAND

Scientific Partner: POLCRIN - Polish Clinical Research Infrastructure Network
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 helps to assess which new medical technologies and therapeutic methods should be used to meet society's needs. The Agency implements one of the first public grant programs with financing for non-commercial clinical trials in Poland. The research funded by MRA creates an opportunity for Polish patients to access the latest technologies, as well as a chance for Polish scientists to participate in global research. The Agency's main task is to lead analytical activities in the scope of assessment of undertaken decisions and their influence on the costs of functioning of the healthcare system. The compiled analysis will identify specific solutions that will allow the healthcare system to function more efficiently.



2021 Highlights

The most significant change in clinical trial area in Poland was the establishment of the Polish Clinical Trial Network (PCTN) in March, 2021. After two editions of the open call organised by Medical Research Agency, PCTN is comprised of 16 standardized Clinical Research Support Centres, which will improve patients' knowledge and access to innovative therapies. In the first open call 10 applications received funding for a total amount of 22 million euros (five from universities and five from institutes). In the second open call six applications received funding for a total amount of 12 million euros (four from universities and two from institutes). The centres will be staffed by highly qualified employees, which will have an impact on the efficiency and quality of the conducted research. Nine of the sixteen centres obtained funding for Early Phase Clinical Sites. At the end of 2021, MRA organised the third edition of the open call and seven new members will join the PCTN as Oncological Research Support Centres next year.



PORTUGAL

Scientific Partner: PtCRIN - Portuguese Clinical Research Infrastructure Network
Member since 29 Nov. 2013
Host institution: NOVA University
National hub: Lisbon
www.ptcrin.pt

PtCRIN is one of the infrastructures on the Portuguese Roadmap of Research Infrastructures of strategic relevance, dedicated to the improvement of 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 is a distributed consortium of 26 national institutions, Health Care Units, Universities, Research Institutes that host academic CTUs, clinical research centres (CRCs) and clinical investigators. PtCRIN CTUs provide general services for the management of the clinical studies, according to ECRIN's high standards, at a not-for-profit rate to public sponsors and SMEs. PtCRIN CRCs provide technical support to clinical investigator teams to conduct clinical studies in their health units.



2021 Highlights

- PtCRIN consortium update: currently it represents a distributed consortium of 26 national institutions with 15 Health Care Units, 6 Universities and Research Institutes that host 5 academic CTUs;
- 2021 marks the beginning of the first ECRIN supported multinational clinical study with a Portuguese Sponsor;
- Portugal participated in two EU COVID-19 clinical trials via the PtCRIN network: EU-SolidAct – a pan-European platform for pandemic research and preparedness and VACCELERATE – a pan-European backbone for the acceleration of phase 2 & 3 COVID-19 vaccine trials.
- Publication of two articles: Investigator Initiated Clinical Trials (IICTs): A Systematic Search in Registries to Compare the Czech Republic and Portugal in Terms of Funding Policies and Scientific Outcomes and Portuguese Authorship in Published Clinical Trials: Differences in Industry and Investigator Initiated Trials



SLOVAKIA

Scientific Partner: SLOVACRIN - Slovak Clinical Research Infrastructure Network
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 academic 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.



2021 Highlights

Covid-Vaccine-Monitor study: SLOVACRIN participates in the Cohort Event Monitoring of safety of COVID-19 vaccines in special populations (pregnant and lactating women, children and adolescents, immunocompromised, people with a history of allergy, people with prior SARS-CoV-2 infection) with the primary aim of generating and comparing incidence rates of patient-reported adverse reactions from different COVID-19 vaccines. SLOVACRIN was formally integrated into the Slovak Roadmap of Research Infrastructures “SK VI Roadmap 2020 – 2030” in April. EU RESPONSE: SLOVACRIN contributes to the EU-RESPONSE project. Participation in the Discovery and the EU-SolidAct study brings innovative therapy to Slovak patients with COVID-19.



SPAIN

Scientific Partner: SCReN - Spanish Clinical Research Network

Member since 29 Nov. 2013

Host institution: Instituto de Investigación del Hospital Universitario La Paz, IdiPaz.

National hub: Madrid

www.scren.es

SCReN is the National Platform for clinical trials in Spain. It is funded by the National Institute of Health Carlos III, and it is composed of a network of 34 CTUs based in clinical centres of the Spanish National Health System spanning 14 Spanish autonomous communities. The SCReN Coordination Unit is based in Madrid at Institute of Biomedical Research of La Paz University Hospital, IdiPaz. The coordination with ECRIN is based in Barcelona at the Hospital Clinic which hosts the EuCo. Whether offering consulting or service provision to clinical research professionals, 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.



2021 Highlights

2021 marked the incorporation of 5 new CTUs to the SCReN network and the redistribution of personnel which was accompanied by a thorough mapping of personnel and capacities in the first months of 2021. SCReN's governance and management organigram were constituted in alignment with the new strategic approach of the Coordination Unit. SCReN Working Groups (WG) for areas of activity and provision of services were launched and a WG in Advanced Therapies was incorporated. SCReN's SOPs and portfolio (41 new studies; 4 ECRIN studies, which include VACCELERATE and EU-RESPONSE projects) were updated and the participation and collaboration in ECRIN activities (Network Committee, Quality and IS Unit, and Communication Working Group) and events (ICTD 21, ECRIN CTU Day, and CTIS training) was consolidated. Finally, updates in communication technologies (new website) and social media (new Twitter account) were implemented.



SWITZERLAND

Scientific Partner: SCTO - Swiss Clinical Trial Organisation

Observer since 18 Dec. 2015

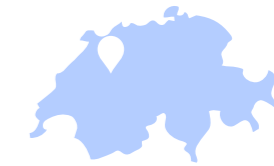
Host institution: SCTO

National hub: Bern

www.scto.ch/en

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

- . value and innovation
- . education and the next generation
- . visibility and transparency.



2021 Highlights

Tools & Resources: The new SCTO Platforms' website provides ready-to-use, up-to-date resources that are publicly available and can help take research projects over the finish line. They include templates, guidance documents, online training, and statistics packages, among others.

Poland meets Switzerland: The SCTO and its CTU network were happy to welcome representatives from the Polish Medical Research Agency for a two-day visit to Switzerland. Among others, ideas were exchanged on how to best establish a national clinical Research Infrastructure (RI), including considerations from a governance point of view and how to overcome potential challenges. Involving patients in academic clinical research: as one of its key strategic goals in the new 2021–2024 performance period, the SCTO is placing greater emphasis on the implementation of patient and public involvement (PPI) in academic clinical research. This began with a survey sent out to relevant stakeholders to identify and characterise all PPI initiatives and projects in Switzerland. The results of the survey are published on the SCTO's website.

Interview with the Czech EuCos



Kristýna Nosková
European Correspondent
Czech Republic



Lenka Součková
European Correspondent
Czech Republic



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

Lenka: I would say that EuCo's job description varies considerably

from country to country. In the case of the Czech Republic, we still focus on consolidating and further developing our national network, CZECRIN. We are aware that only a strong national network can successfully support its investigators. *Kristýna:* We are both based at the Masaryk University in Brno. Masaryk University is the Scientific Partner of ECRIN and consequently the national hub of CZECRIN, which cooperates with the St. Anne's University Hospital also in Brno. We are still waiting on our first multinational clinical trial coordinated

by the Czech Republic, so we have a little bit more time for additional activities. For example, we organise conferences and educational seminars focused on our investigators and study teams to encourage them to make their project international. We are also trying to show them that using ECRIN's services is a much easier way to reach this goal. We are also participating in different ECRIN working groups including communication, quality, and pharmacovigilance.

And last but not least, it has been already 2 years since we started with the COVID literature review published every 2 weeks on the ECRIN website. Currently, we have over 500 records of clinical trials focused on COVID-19. To sum up, the EuCo's job is really variable and never boring!

How has ECRIN benefited the Czech Republic?

Lenka: ECRIN is a developed and well-recognised infrastructure. At the beginning of our observership period, we learnt a lot about the infrastructure as such. How it works, which activities and services are in the ECRIN portfolio and this know-how we took over and implemented at the national level. Being an ECRIN partner has other advantages, of course. It is absolutely clear that to get the value and impact

of data from clinical trials within a reasonable time, it is necessary to carry out the multi-site, multinational clinical trial. We have seen it in the case of coronavirus vaccine development. If we do things together it is faster and more efficient. The impact of one site trial is very low today.

Kristýna: More benefits, cost savings, access to greater expertise, greater patient diversity, facilitation of all these administrative and regulatory processes and much much more.

What achievements are you the proudest of since joining ECRIN/CZECRIN?

Lenka: I remember in the autumn of 2014 when CZECRIN was established and got support from the Ministry of Education, Youth and Sports. We started as an observer for 3 years because CZECRIN was not yet well recognised. We took this as an opportunity to build a strong national infrastructure. We used our previous experience in the clinical trials field and supported around 20 national clinical trials and we also cooperated on European clinical projects under the ECRIN umbrella.

Kristýna: I've been part of ECRIN since 2019, however, I've been working for CZECRIN since 2018 when we achieved the next great success, we became an ECRIN full Member!

When speaking about achievements, CZECRIN is evaluated every two years by the international committee, the two previous periods we got the highest excellence score which is also quite a success.

Lenka: Additionally, thanks to our national network we contributed to the multinational clinical trials with the Czech participants. Our investigators were proud to be a part of these European projects as FP7 or H2020 and we are happy to help them to get approval from the regulatory authority, ethics committee and offer other services such as monitoring, and pharmacovigilance, etc.

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

Kristýna: Our main goal is pretty clear, we would like to start the multinational clinical trial across Europe within the ECRIN collaboration. But for that, it is necessary to get financial support. In the Czech Republic, we don't have any grant support for multinational projects, so we have to apply for European grants. And currently, we are waiting on a decision on one of our projects, so let's keep our fingers crossed.

Lenka: At a national level, within CZECRIN, we plan to enlarge the disease-oriented networks.

[Watch the full interview...](#)

ECRIN Team

2021 was marked by a continued progress in ECRIN's activities, which benefitted from the solidification of the core team through staff retention and recruitment on a few key positions. There was a total of 22 people in the ECRIN core team in

2021, including two people joining the team and two leaving. Furthermore, the reorganisation and relocation of some national partners has led to changes in the EuCos with four new EuCos joining the ECRIN team in 2021.

Core Team	
Burç Aydın	Project Manager
Marta Bastucci	Executive Assistant
Steve Canham	Data Project Manager
Marta del Alamo	Project Manager
Jacques Demotes	Director General
Martina Esdaile	Communications Officer
Paula Garcia	Project Manager
Sergei Gorianin	Data Scientist
Swarnalatha Kichenassamy	Software Engineer
Sabine Kläger	Head of Clinical Operations Unit
Christine Kubiak	Operations Director
Aafke Maitimo	Administrative Assistant
Salma Malik	Paediatric Project Manager
Mihaela Matei	Legal Manager
Samira Mokhtari	Quality Officer
Golbahar Pahlavan	Head of Infrastructure Development Projects Unit
Maria Panagiotopoulou	Project Manager
Arthur Smaal	Quality Officer
Alicja Szofer-Araya	Head of Administration and Finance
Safia Thaminy	Clinical Project Manager
Christine Toneatti	Head of Quality and IS Unit
Biljana Zafirova	Clinical Project Manager
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
Sarhan Yaïche	France
Linda Stöhr	Germany
Laura Vieweg	Germany
Hanna Schrunner-Fenske	Germany
Zita Tarjányi	Hungary
Kata Bende	Hungary
Suzanne Bracken	Ireland
Fiona Cregg	Ireland
Anne-Marie Miller	Ireland
Maria Buoncervello	Italy
Elena Toschi	Italy
Maria Josefina Ruiz Alvarez	Italy
Bjarte Bergstrøm	Norway
Valentina Cabral Iversen	Norway
Bernadetta Wisniewska	Poland
Patrycja Klusek	Poland
Maciej Janiec	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 2021, as well as those who left the organisation.



ECRIN's response to Covid-19

2021 has been another challenging year with regards to the COVID-19 pandemic. On the other hand, it has also once again proven to be a strong example of worldwide collaboration in the research community to develop diagnostics, vaccines and treatments through the open and rapid sharing of data and information. When it comes to COVID-19 clinical research data, ECRIN, like many other scientific organisations, funders and publishers, is committed to making them FAIR.

The COVID-19 outbreak provided ECRIN with the opportunity to demonstrate its readiness to rapidly deploy support and services for the design, planning and conduct of multinational clinical trials and to coordinate COVID-19 clinical research in Europe. Moreover, ECRIN reacted promptly in the early months of the pandemic with the creation of its COVID-19 Taskforce, its central 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 Meta Data Repository.

In 2021 it continued to support these initiatives and has taken on an important role in VACCELERATE, the EU-funded project for the acceleration of phase 2 & 3

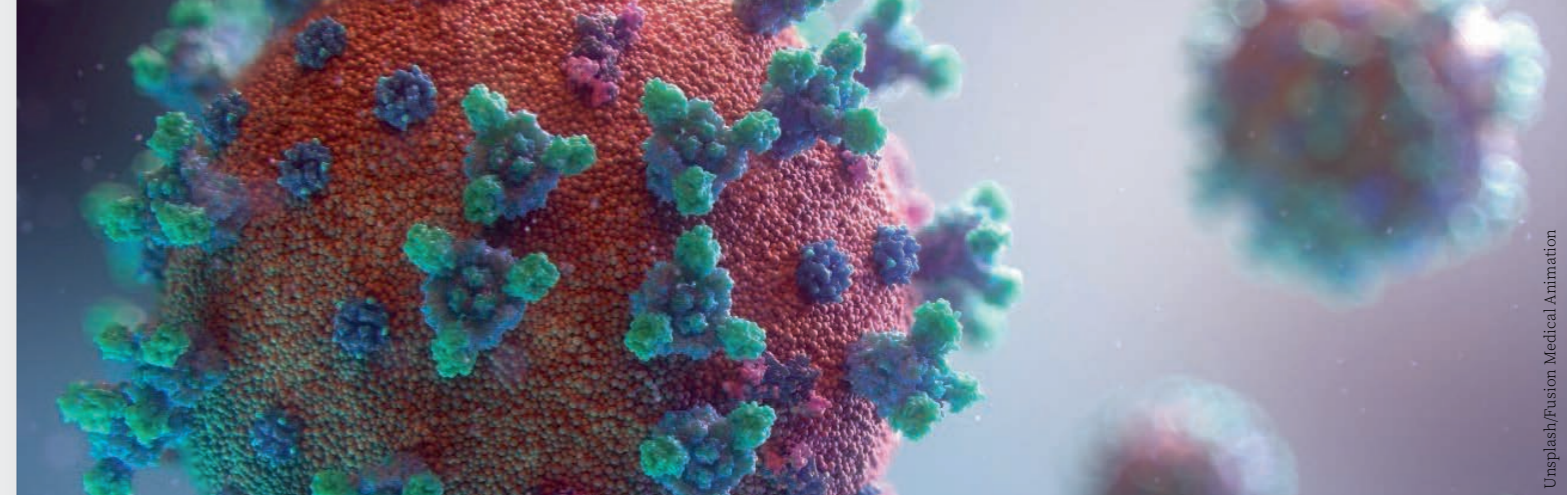
COVID-19 vaccine trials. The development of a COVID-19 Data Repository is also underway. ECRIN also launched the COVID-19 Marketplace to help researchers identify collaboration opportunities and expand their research beyond national borders as well as a website dedicated to the coordination module between the different EU-funded COVID-19 platform trials.

Covid-19 Taskforce

<https://ecrin.org/covid-19-taskforce>

ECRIN established a COVID-19 Taskforce with its national partners early in 2020 and has maintained this initiative to:

- Review and digest the scientific literature on COVID-19 randomised clinical trials.
- Develop a meta data 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



Unsplash/Fusion Medical Animation

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 DATA REPOSITORY

In response to the need for timely and accurate collection, reporting and sharing of data within and between research communities as part of the EOSC-Life project, ECRIN has partnered with the University of Oslo to jointly design, develop, implement and operate a repository for individual participant data from COVID-19 clinical research studies that is compliant with European regulations and in particular with the GDPR. The data sharing policy for the repository was published in 2021. Currently in the development phase, the repository will be part of the EU COVID-19 data portal.

ECRIN Covid-19 Marketplace

<https://marketplace.ecrin.org/en/search/trial>

Effective and efficient clinical research must curb redundant efforts in different countries, reduce trial costs and boost patient recruitment by promoting the cooperation of clinical scientists across Europe. The ECRIN COVID-19 Marketplace is the free online tool to help investigators find researchers engaged in similar COVID-19 trial questions to collaborate with. It looks to avoid duplication of trials and to promote cooperation across borders, and has been created to facilitate and promote collaboration by providing access to planned and ongoing clinical trials.



Pexels/Alexander Suhorucov

Launch of the covid19trials.eu website



In 2021, ECRIN was responsible for launching the covid19trials.eu website which centralises information on the coordinated pan-European approach, essential for tackling the COVID-19 pandemic, and finding the most effective therapeutic solutions. More specifically, two ambitious EU-funded projects, EU-RESPONSE and RECOVER, share a joint coordination module that allows them to evaluate potential therapeutics for COVID-19, while avoiding duplications and maximizing the use of resources. The coordination module, composed of the Trial Coordination Board (TCB), the Joint Access Advisory Mechanism (JAAM) and the Adaptive Platform Trial Toolbox, ensures optimal coordination of trials in the EU and abroad and provides a single-entry point for new study arms in the European COVID-19 adaptive platform trials.

The TCB gathers the main actors, playing a role in the successful implementation and development of the European COVID-19

adaptive platform trials. It aims to ensure collaboration and cooperation between the European COVID-19 adaptive platform trials, and to create and maintain a constructive dialogue with regulatory bodies, policy makers and global COVID-19 trials. Through this dialogue, the TCB provides recommendations for the strengthening of the European COVID-19 platform trials and identifies opportunities for synergies between trials.

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

THE ADAPTIVE PLATFORM TRIAL TOOLBOX

The Adaptive Platform Trial Toolbox aims to collect the accumulated knowledge, experience, and resources from multiple projects and trials into a practical and guided toolbox to facilitate planning and conduct of future adaptive platform trials in any therapeutic area. The toolbox has been structured with different categories for different trial steps. Each tool is presented with a brief explanation and a resource type, indicating the tool's format and level of validation.

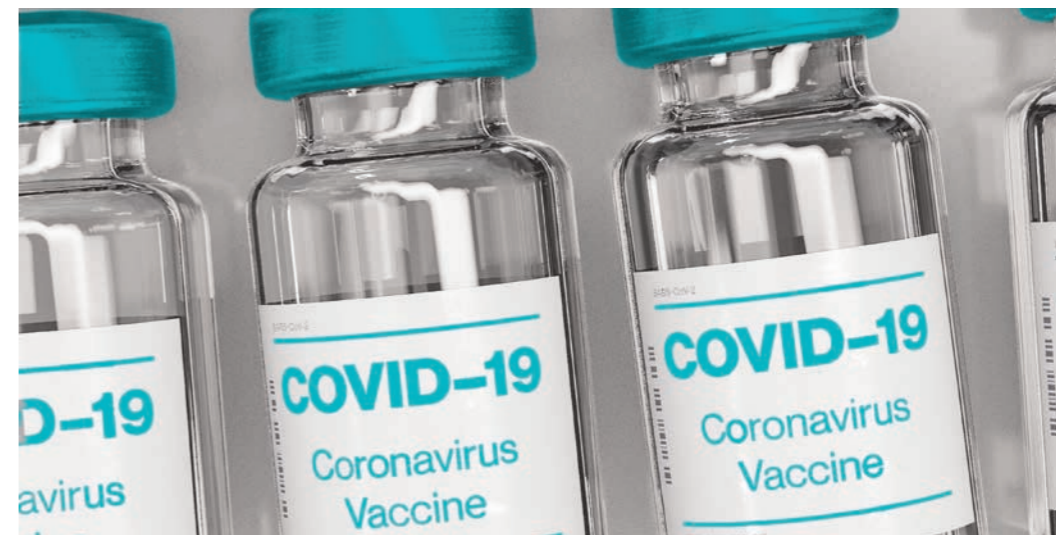
VACCELERATE



VACCELERATE is an academic, pan-European platform that accelerates phase II & III trials of clinical COVID-19 vaccine development in Europe. The network brings together experts from the areas of clinical trial design and conduct, immunology, laboratory standardization and public health from 23 European countries, and lends its expertise to all stakeholders involved in vaccine development. A long-term goal is to pool expertise and accelerate procedures for future pandemics.

ECRIN leads the workpackage “Data Management, Standards and Sharing”. In short, it focuses on developing a data management toolbox to enable standardised data management and promote data interoperability across the vaccine trials using the VACCELERATE network.

ECRIN is also providing its trial management services to the vaccine trials that will be deployed within the VACCELERATE project. Through the provision of this principal service, ECRIN will be facilitating the implementation of the trials in the different European countries.



Unsplash/Daniel Schudi

Interview with the EU-SolidAct Principal Investigator



Marius Trøseid, MD, PhD
Group Leader, Associate Professor,
Oslo University Hospital



Could you briefly describe EU-SolidAct?

EU-SolidAct is a platform trial for COVID-19 but

also for future pandemics. It is part of European preparedness for pandemics.

How did you come to work with ECRIN?

ECRIN was a partner in this project, called EU-RESPONSE, which runs the DisCoVeRY Trial and EU-SolidAct. ECRIN has been part of the project from the beginning and the planning phase.

Could you explain the working relationship with ECRIN?

ECRIN is a very important partner of the

project. ECRIN is the focal point for all the CTUs and CROs in Europe and is vital for the national regulatory proposals and also for orchestrating monitoring across the European countries.

What has been the impact of working with ECRIN on EU-SolidAct?

It has been necessary for an academic sponsor to have the support of ECRIN, to run EU-SolidAct. We have needed the operational network, we have needed the help to organise the monitoring in so many countries and we have needed the help for the facilitation of the national applications for the regulatory authorities across Europe.

How has the Trial Coordination Board (TCB) supported EU-SolidAct?

The TCB is very important for all platform trials, I think. It allows us to meet every 14 days to exchange information and to exchange experiences, with regards to the regulatory hurdles, the biobanking, and the data integrity, all common topics that all the platform trials face and work with. The TCB is very valuable for pandemic research in Europe.

Do you have any lessons to share with other PIs interested in working with ECRIN?

I think if you are an academic sponsor

and you want to start a multinational trial within Europe, ECRIN is a very good starting point. It has been necessary to have ECRIN on board in order to run EU-SolidAct in so many countries. It has been vital for establishing an operational

network, it has been vital for allowing monitoring to a certain standard in so many countries and also for the national regulatory applications.

[Watch the full interview...](#)



Services

Clinical Trial Operations

OVERVIEW

Supporting clinical trials across borders is the key mission of ECRIN. This support is given to investigators and sponsors in ECRIN Member and Observer countries, including the preparation of European funding applications and the coordination and management of multinational clinical research projects. In 2021, ECRIN continued to invest in this core activity by increasing its capacity in recruiting additional clinical project managers and European Correspondents.

Throughout the year, the COVID-19 pandemic was still a major challenge for

the provision of ECRIN services, with a direct impact on site initiations, on-site monitoring, and patient recruitment. Addressing these problems for the ECRIN portfolio trials required a certain level of flexibility and necessary adaptations, often resulting in an increased workload for the clinical trial teams and trial coordinators. In particular, the necessary extensions to project duration caused by the COVID-19 pandemic delays, required additional work for the related amendments to budgets and contracts. These efforts carried out efficiently by the clinical operations unit are of great importance and contribute to the high-quality standards set forth by ECRIN and in line with the ISO 9001:2015 certification for its principal services.

ECRIN ON THE CUTTING EDGE OF CLINICAL RESEARCH

The clinical research landscape is currently evolving at an incredible rate, by means of and albeit the ongoing pandemic. Specifically, the progress in this context includes the rise in platform trials, personalised medicine, patient stratification, in-silico trials, use of artificial intelligence, protocols for data sharing and data reuse, as well as medical device investigations.

In 2021 ECRIN saw an increase in the number of clinical trials in its portfolio that have adopted these new methodologies. The clinical operations team had an instrumental role in the ECRIN COVID-19 Taskforce

activities. ECRIN continued to deliver coordination of services across borders for set-up and actively recruiting clinical trials. Moreover, ECRIN provided the coordination of a single-entry point for new treatment arms to be included into the different European COVID-19 adaptive platform trials.

Staff from the ECRIN clinical operations unit are engaged in the development of new policies and tools in the clinical trials area, participating in the Roadmap Initiative led by EFPIA and EFGCP developing the Good Lay Summary Practices Guide, as well as stakeholder representatives in the EMA Clinical Trials Information System (CTIS) development.



■ **SCIENTIFIC BOARD**

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

- (1) The Collaboration Committee decides on whether or not ECRIN should invest resources in the planning, design and funding application and/or participation in the project.
- (2) The Peer-Review Committee is responsible for assessing the methodology and design of the pre-final protocol, as well as providing recommendations on the improvement of the final design.

Prof. José Delgado Alves is the elected chair of the Scientific Board; Burç Aydin, ECRIN project manager, was appointed as the Scientific Board Secretariat in 2021. ECRIN’s Medical Expert, Dr Joaquin Saez-Penataro, sits on both sub-committees and acts as a link, between the two.

• **Collaboration Committee**

The Collaboration Committee meets weekly to review collaboration requests, and to make transparent decisions on the support ECRIN will provide to the preparation of funding applications and planned operational services based on a trial synopsis and task requirements. In 2021, a total of 26 requests for collaboration were reviewed, whereby 22

came from the ECRIN Member/Observer countries and four came from non-ECRIN countries. Seventeen requests for collaboration were approved, while for nine a collaboration was not established for a variety of reasons (eligibility criteria, budget restraints, out of scope decision from the Sponsor).

• **Peer-Review Committee**

The Peer-Review Committee (PRC) is composed of six independent, clinical and methodology experts, who elect a chair amongst themselves for a three year term. Three trial protocols were reviewed by the PRC in 2021, including two protocols for adaptive platform trials – one for COVID-19 treatment regimens and new medicines, and one for vaccination regimens.

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



Access ECRIN's Clinical Trial Operations Services

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

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



Zoom in on Clinical Trial Operations Services

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



PLANNING

In the planning phase, ECRIN can give advice and provide input on the different aspects of funding applications such as work package structure, potential impact, 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 ECRIN national partners as service providers (i.e., national networks and CTUs), provide information on the facilities that have the expertise, capacity and services needed to manage the trial. 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 of project plans.



RISK ASSESSMENT

Once funding has been secured, and before implementation of the projects, a risk assessment is performed according to ECRIN’s risk assessment process. The coordinating EuCo and a nominated risk management team review the risk factors related to project implementation and conduct (e.g., national ethical and regulatory approvals, contracting, patient recruitment, data protection, timelines, budget). They provide solutions to minimise any identified risks. Moreover, ECRIN, through the Peer Review Committee, can provide an independent peer-review of the pre-final protocol focusing on the methodology and design aspects contributing to the scientific excellence and research quality of the project.



OPERATIONAL COORDINATION

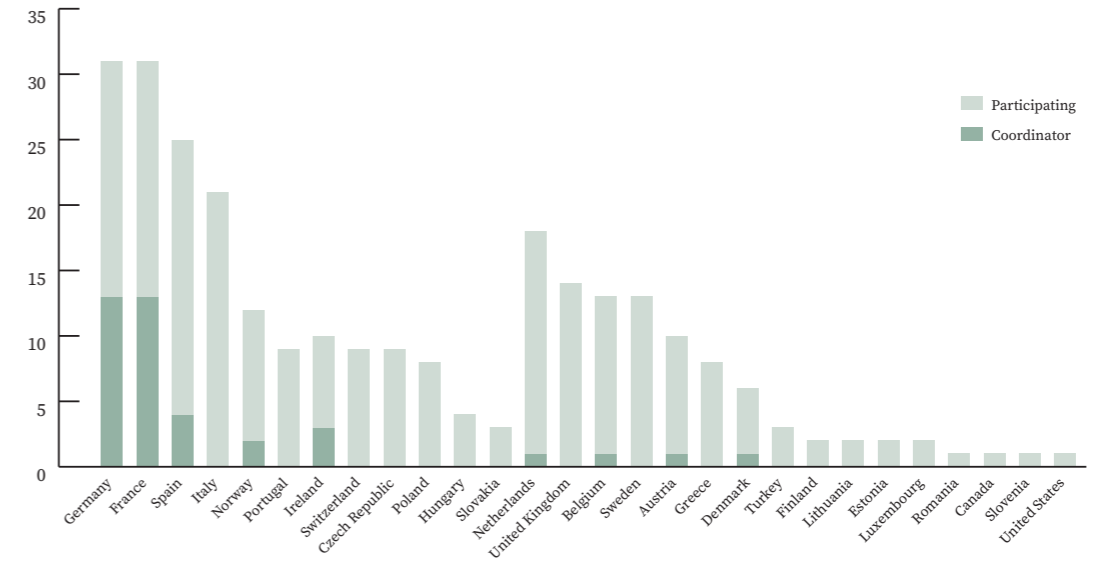
ECRIN’s EuCos work closely with the Investigator-Sponsor team, coordinating the activities across the participating countries, with the key mission to implement the clinical trial outside the Sponsor’s country. This includes operational coordination with a particular attention to obtaining all the necessary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

Clinical Trial Portfolio in 2021 (current trials)

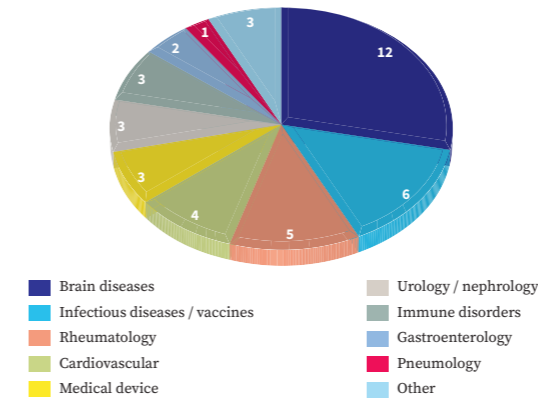
During 2021, ECRIN worked on a total of 39 clinical trials at different phases, whereby 11 clinical trials were in the start-up phase; seven trials moved from start-up to recruitment phase, and 15 others were in the running phase, with recruitment, follow-up and/or close out activities. In 2021, one trial was put on hold, three trials were completed, and for three trials ECRIN’s support came to an end. ECRIN’s full trial portfolio of 2021 can be found in the appendix of this report. The total ECRIN trial portfolio, including past and current studies, reached 70 studies in 2021.



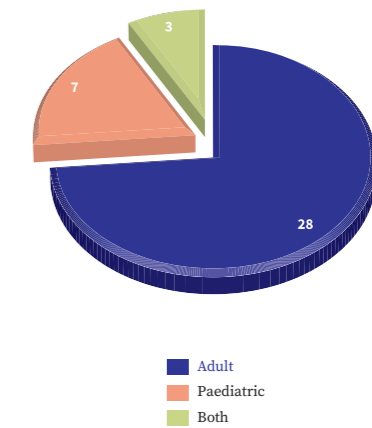
2021 ECRIN trial portfolio



2021 trial portfolio disease area



2021 trial population



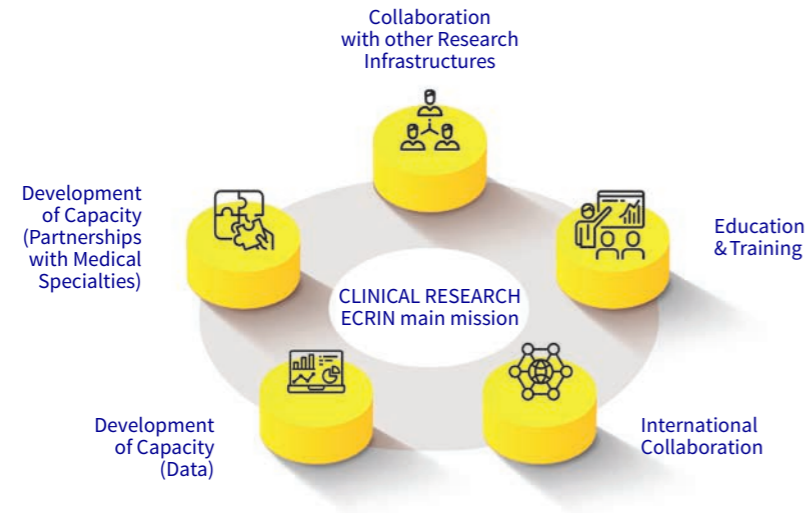
Infrastructure Development Projects

OVERVIEW

Through its participation in projects (most of them funded by the European Framework Programmes), ECRIN strengthens and or develops its capacity, tools, and services for the benefit of our user community. These projects further enable ECRIN to stay at the cutting edge of clinical research, enhance its the visibility, and develop synergies with the research infrastructure community. These types of projects fall into five different possible domains (see above).

In 2021 ECRIN coordinated two projects, the PedCRIN project which ended in June and the PERMIT project which received a six-month extension and will close in June 2022.

ECRIN also began work on eight new projects:



- **ByCOVID** (BeYond-COVID) - aims to tackle the data challenges that can hinder effective pandemic response.
- **ECRAID Base** (European Clinical Research Alliance for Infectious Diseases) - intends to efficiently generate rigorous evidence to improve the diagnosis, prevention and treatment of infections and to respond to infectious diseases (ID) threats effectively and rapidly.
- **EOSC Future** (European Open Science Cloud Future) - aims to implement EOSC which will give European researchers access to a wide web of FAIR data and related services.
- **EU-Africa PerMed** (Building links between Europe and Africa in personalised medicine) - aims to integrate organizations from the African continent into ICPeMed activities, as a means to contribute to the implementation of personalised medicine (PM) in the global context, fostering joint PM projects and programmes between

Europe and Africa, and strengthening bilateral EU-Africa Union science, technology and innovation in health.

- **HealthyCloud** (Health Research and Innovation Cloud) - aims to define the Strategic Agenda for the European Health Research and Innovation Cloud (HRIC).
- **SIMCOR** (In-Silico testing and validation of Cardiovascular Implantable devices) - aims to develop an in-silico platform and simulation tools for the development, validation and regulatory approval of cardiovascular devices, providing tangible value to patients and clinicians, device manufacturers, clinical researchers, medical authorities and regulatory bodies.
- **TESA III** (Trials of excellence in southern Africa III) – will build capacity and strengthen less established institutions, including infrastructure for conducting clinical trials.
- **VACCELERATE** (European Corona Vaccine Trial Accelerator Platform) – ambitions to connect all European stakeholders involved in vaccine development to provide a pan-European platform for clinical trial design and conduct, to accelerate phase 2 & 3 COVID-19 vaccine trials.

Note: For funding information on the above projects, and all Research Infrastructure Development projects see the annexes.

ECRIN Coordinated project

PERMIT



In its endeavour to define recommendations for robust and reproducible personalised

medicine, the PERMIT project hosted 14 workshops, focus groups, and working sessions to develop the guidelines that stem from the gap analysis conducted in the first year of the project. Encompassing the full personalised medicine pipeline, the different work packages each brought together experts and relevant stakeholders to develop pertinent and applicable guidance for their field of personalised medicine.



Interview on the PedCRIN project



Christine Kubiak
Operations Director
ECRIN

Salma Malik
Project Manager
ECRIN



Why paediatrics clinical research?

Salma: The multinational paediatric clinical trials are very

important to boost paediatric research, and to ensure that children receive appropriate, safe, and effective treatment and care.

We should not forget that clinical trials in children are challenging because of additional complexities due to the safety concerns, the ethical considerations, informed consent, lower prevalence of the disease, and specifically different age groups which makes it more complicated. We need to have a tailored study

design and also appropriate medicine formulations. In addition, conducting clinical trials in children requires specific competencies and infrastructure.

Why PedCRIN?

Christine: The objective of the PedCRIN project, that was funded by the EU Framework Programme Horizon 2020, was to develop and enhance the existing ECRIN capacity for the setup and management of academic paediatric clinical trials. The project started in January 2017, was coordinated by ECRIN, and involved key paediatric stakeholders. It ended in June 2021 with a lot of positive outcomes for the paediatric community.

What are the outcomes of the PedCRIN project ?

Salma: The outcomes of PedCRIN were remarkable. This includes the support that was provided by PedCRIN through a competitive call to three clinical trials for their multinational expansion, in the countries other than the sponsor country (the country where the trial originated). The support was provided by PedCRIN / ECRIN partners: clinical trials units and their experienced staff. This covered the regulatory and ethical approvals, the quality control (through on site monitoring) and trial management, which was key to the setup and conduct of the



trial and the completion in accordance with all the regulatory requirements. The support that was provided by PedCRIN and the services that were included in that support were acknowledged and appreciated by the investigators of the three trials. They thought that without PedCRIN support the multinational expansion of these trials would not have been possible. Another important achievement of PedCRIN is the development of tools and procedures to support the setup and management of multinational neonatal and paediatric trials in Europe. These tools have been developed to train and support researchers and paediatric clinicians so they can run, and manage both paediatric and neonatal multinational clinical trials in a more effective and easier way.

What is the sustainability plan for PedCRIN?

Christine: In addition to the outcomes already mentioned, the PedCRIN project was a great opportunity to develop a partnership with the paediatric research community and to better understand and fulfil their needs.

PedCRIN sustainability is really important to avoid duplication, fragmentation and overlaps, and to clarify the role of the generic research infrastructures such as ECRIN versus paediatric investigator networks.

The next step is to establish a stable partnership at operational and governance levels to ensure efficient coordination and optimal use of resources and competencies.

[Watch the full interview...](#)

Supporting efficient use of clinical trial data

ECRIN contributed to six European projects that look to define data standards, sharing and governance, improve and ensure safe and ethical data use, as well as support our users through the development of new tools. Over the past year much work has gone into the development of the Toolbox for sharing of sensitive data, which began user testing with members of the EOSC-Life Consortium.

Other activities included uniting stakeholders through these projects to identify the best way forward: From the development of in silico trials and the creation of stakeholder portal, to the development of secure cross-border health data sharing reality.

Beyond these projects and those listed in ECRIN's response to COVID-19, ECRIN also supported the data management, standards and data sharing in various other projects that coordinate multiple clinical trials. In effect, developing a toolbox to enable standardised data management and encourage interoperability across trials.

Ongoing projects

■ EU-PEARL



EU-PEARL, a strategic alliance between the public and private sectors, aims to transform the way clinical trials are conducted. ECRIN has contributed to the development of the platform trials clinical operations checklist and protocol templates development activities, as well as sustainability, sponsorship, and business planning for future platform trials. The project also had tight ties to ICTD 2021 and expert input from different stakeholder was provided.

■ RI-VIS



The RI-VIS project, designed to increase the visibility of European Research Infrastructures to new communities, held three symposia with African, Latin American and Australian partners and stakeholders to increase awareness of activities on both sides and improve bilateral relations. These symposia were preceded by the publication of three White Papers that provide recommendations on increasing collaboration between European Research Infrastructures and their counterparts.



Interview on the HealthyCloud Project



Maria Panagiotopoulou
Project Manager
ECRIN



Jacques Demotes
Director General
ECRIN



What is the HealthyCloud Project?

Maria: HealthyCloud is a 30-month, EU-

funded, Coordination and Support Action that kicked off this year, in March 2021, and it will go until the end of August 2023. Its principal aim is to prepare the Strategic Agenda for establishing a pan-European Health Research and Innovation Cloud and make sure that it includes the views of all the relevant European actors. The project has some objectives, apart from including the voices of the stakeholders, we would also like to include ELSI aspects, Ethical,

Legal and Societal Issues in the design of the future HRIC, the Health Research and Innovation Cloud. We would also like to ensure that we have sustainable access, use and re-use of health data by progressively adopting the FAIR principles. Lastly, we will ensure that we have the most appropriate technological solutions in place to make this happen. For example, having the computational power in place when needed and making sure that we have the distributed data analysis for the health data in place.

What is the strategic aim of HealthyCloud?

Jacques: The objective is to prepare the Strategic Research Agenda for the Health Research and Innovation Cloud which is the instrument for open science in health research as part of the European Open Science Cloud dedicated to health research, data sharing, and secondary use under the General Data Protection Regulation and also under the European Health Data Space Regulation. The Health Research and Innovation Cloud will include a protected environment to store, to share, and to process the health research data.

How is ECRIN contributing to HealthyCloud?

Maria: HealthyCloud involves 21 partners from 11 European countries and some of them are ERICs like ECRIN, such as BBMRI and EATRIS, who are contributing to the project.

ECRIN has a very strategic role as the work package 8 leader. Work package 8 is tasked with preparing the Strategic Agenda for this Health Research and Innovation Cloud. So we are the ones that need to crystallise the different voices of the stakeholders into concrete requirements for this Health Research and Innovation Cloud.

We kicked off the activity this spring by first organising a big joint workshop with other big projects and initiatives that aim to make cross-border health data sharing a reality. We invited the leaders of EOSC-Life, B1MG, PHIRI and TEHDAS joint action to have a common discussion with HealthyCloud and identify ways to tackle common challenges. This workshop was attended by over 100 participants from all over Europe and it gave us an idea of how we can start progressing on our task. To make sure that the outcomes of the workshop could be broadcast to a wider audience, we also attended one of the biggest eHealth events this summer, the eHealth Summit Portugal.

What is planned for the coming year in the HealthyCloud project?

Maria: In 2022, ECRIN has under its responsibility one of the most important deliverables in the project, which is to provide the first draft of the Strategic Agenda. For this, we need to get into the discussions with the consortium partners, and the work package leaders, and try to align our visions.

As a first step, ECRIN has provided a discussion paper to facilitate this process of feedback collection within the HealthyCloud Consortium. We are expecting to give the first version in October 2022. This first draft of the Strategic Agenda will further be refined through a series of stakeholder workshops, together with thematic stakeholders that will help us address issues such as the legal uncertainties that we face, ethics and trust, metadata and findability, data quality and interoperability, also how to choose the technical infrastructure and how to address aspects on sustainability. The ultimate aim of ECRIN will be to include this input and provide the last version of the strategic agenda for the Health Research and Innovation Cloud for the final project outcome in 2023.

[Watch the full interview...](#)

Quality as a service: Data Centre Certification

OVERVIEW OF THE DATA CENTRE CERTIFICATION PROGRAM

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

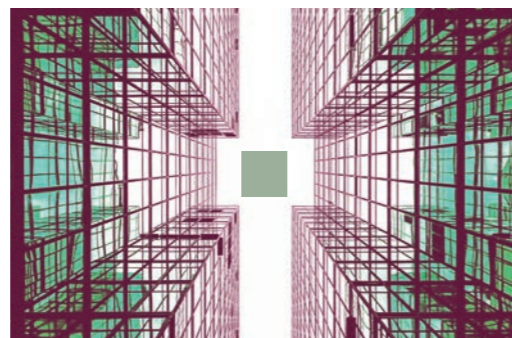
BENEFITS FOR PARTICIPANTS

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

data management/IT, and thus may play a leading expert role in discussions on these topics in their respective countries. And finally, the programme provides a competitive advantage to the certified data centre with increased attractiveness to large-scale multinational projects, and trust in the quality of services for Sponsors, authorities and partners.

2021 CALL FOR DATA CENTRE CERTIFICATION

On 10 June 2021, a call was launched for data centres to apply for certification. All interested centres had three months to complete an online questionnaire to confirm their readiness for audit with the aim of certification by the ECRIN Independent Certification Board Secretariat. Two data centres completed this initial step. In addition, two data centres are in the process of renewing their Data Centre Certification.



ECRIN data centres certified to date



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

*certification lapsed in 2016

Interview with an ECRIN certified Data Centre



Roland John
Head of Quality Development
Department Klinische Forschung
Universität Basel



Tell me about your role in the Data Centre Certification?

I was responsible for the ECRIN

certification project in our organisation in 2020. The Department of Clinical Research is one of seven clinical trial units in Switzerland that provides a whole range of services for academic clinical research in Switzerland. The seven Swiss CTUs are organised in the Swiss Clinical Trial Organisation, SCTO.

How did you learn about the ECRIN's Data Centre Certification programme?

The SCTO started to discuss the ECRIN certification for the Swiss CTUs several years ago. When I joined the Department of Clinical Research in Basel in 2018 the project was already started at the DKF. So, I learned from my collaborators about the ECRIN Certification.

Could you explain the working relationship with ECRIN?

The collaboration with ECRIN was always in a very friendly, supporting and professional atmosphere. The well elaborated ECRIN Data Centre Certification standards always served as a guidance document which was actually very helpful for the whole collaboration.

What are some of the things that you found easy or challenging when working ECRIN?

The data certification standards definitely made everyone's life much easier during the certification process. The clear structure, the well defined requirements and examples helped a lot. The examples even take into consideration the academic setting and the integration into the hospital infrastructure which is always a challenge. On the other hand, the start of the pandemic in early 2020 delayed the finalisation of the certification process but



Pexels/Manuel Geissinger

luckily and with the help of ECRIN we could finalise the certification in an online audit.

What has been the impact of the Data Centre Certification?

The ECRIN certification helps to strengthen the position of the DKF within the academic network here in Basel. It is easy to run a clinical data management system or environment and services, but it is very difficult to maintain GCP compliant structure. This certification proves that the DKF is compliant with the regulations. Internally at the DKF, the ECRIN standard is the accepted reference. If we optimise our process and infrastructure, we challenge the solutions against this standard.

Do you have any lessons to share with others interested in Data Centre Certification?

It is always worthwhile to check the ECRIN standards if you develop your data management process and IT infrastructure, and if you provide services in academic clinical research. Even if you are still in an early stage of maturity, the ECRIN standards provide a good collection of topics and best practices for IT operation and data management. But don't underestimate the effort it takes to get the certification: take your time, prepare yourself well and develop your systems and process before you start the certification process.

[Watch the full interview...](#)

Support Services

Quality

■ ECRIN QUALITY MANAGEMENT SYSTEM (QMS)



After its initial certification in 2020 by the French Association for Standardisation (AFNOR), ECRIN

has completed its first follow-up audit and successfully confirmed its ISO 9001:2015 certification for its principal services and quality management system. The certification is applied to ECRIN's 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 and has worked to further enhance the standardization, effectiveness and performance of its QMS. The QMS at ECRIN is fit-for-purpose and has been adapted to the distributed infrastructure

via an integrated, risk and process-based approach which ensures the highest services and process performance. It applies to the ECRIN staff, both the core team based in Paris and the EuCos located in the ECRIN Member and Observer countries and more broadly to external organizations under contract to perform missions on behalf of ECRIN as well as members of ECRIN's 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 to ensure continued compliance and customer satisfaction.

Communications

■ NEW ECRIN LOGO & IDENTITY

In 2021 a new communication strategy was launched to renew and modernise the ECRIN brand. The cornerstone of the project completed in 2021 is the new ECRIN logo. It embodies the core values of ECRIN and carries its ambitions as ECRIN takes on new roles and responsibilities. The new ECRIN logo includes the core elements of the previous logo (the square,

the checkerboard and the idea of the people in the centre) with a modern twist, through the simplification of the image and the greater saturation of the colours. While it was important for ECRIN to maintain the two principal colours (yellow & blue) the new logo can also be displayed as a monochromatic white on the different supporting colours. Furthermore, lower case lettering was selected to encourage a more accessible brand.

In its new form, the logo can be used with the acronym, or just represented through the symbol. The 2021 annual report represents one of the first publications to be developed in the new visual charter. The new corporate identity can be found on the dedicated brand guidelines page on the ECRIN website. More updates are planned for 2022 to ensure outreach to all stakeholder groups is clear and optimised. <https://ecrin.org/ecrin-brand-guidelines>



INTERNATIONAL CLINICAL TRIALS DAY 2021: A SUCCESSFUL VIRTUAL EVENT ON PLATFORM TRIALS

International Clinical Trials Day 2021 was hosted by ECRIN online and entitled “Platform trials: shift in testing, treatment & collaboration.” It provided key players in clinical research insight on the impact of this new trial methodology. The platform trial’s theme was chosen by the ICTD scientific advisory board, composed of members from ECRIN national partners from the Czech Republic, Ireland and Switzerland.

“These kinds of trials can challenge our concept of what is a clinical trial.”

- Dr. Fergus Sweeney (panellist), Head, Clinical Studies and Manufacturing Taskforce, European Medicines Agency

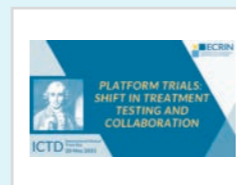
Platform trials allow a multitude of different treatment options (arms) to be compared with a single control (arm). They enable ineffective arms to be stopped after an interim analysis and new treatment arms to be added. To date, they have been used principally in the field of oncology and more recently infectious diseases. They represent the clinical approach selected by the European Commission to find a treatment for COVID-19.

Over 800 people registered from all across the world. The keynote by Dr. Marion Mafham addressed the advantages and the rollout of large simple trials. She explained the factors that contributed to the success of RECOVERY *“Top-down instructions, bottom-up enthusiasm and efforts from the coordinating centre to build and maintain collaboration.”* Throughout the day, many questions on platform trials were addressed from different angles including, from clinical researchers, statisticians, funders, methodological experts, regulators, industry, and patient groups. Most presentations are available online and can be viewed on the ECRIN YouTube channel.



Marion Mafham, ICTD Keynote: The power of large simple trials

Panel session from ICTD 2021



on Statistical, regulatory & ethical issues related to the trial design and implementation’



Cecile Spiertz, Senior Director, External Innovation Clinical Trial Platforms, Johnson & Johnson



Franck Hulstaert, Senior Researcher, Belgium Health Care Knowledge Centre (KCE)



Martin Posch, Professor Medical University of Vienna



Fergus Sweeney, Head, Clinical Studies and Manufacturing Taskforce, European Medicines Agency



Marco Cavaleri, Head of Biological Health Threats and Vaccine Strategy, European Medicines Agency



Valentina Stramiello, Head of Programmes European Patient Forum

FIRST EDITION OF ECRIN CTU DAY

On 26 November 2021 ECRIN hosted its first CTU Day bringing together 225 members of its CTU community from all 12 of its national networks. The objectives of the meeting included encouraging staff of ECRIN National Network affiliated organisations to get to know one another, exchanging information and best practices, discussing training opportunities and synergies.

During this meeting, ECRIN presented its services offer. While national networks shared how they collaborate with ECRIN and how they would like to see things as we move forward. A use case with an



ECRIN supported project, FAIRPARK II, was presented by the coordinating

European Correspondent and the Project Manager based at the Lead CTU/Sponsor. From this use case attendees were then divided into breakout groups to get to know one another and discuss how to address some of the challenges that arise and identify improvements in the course of a clinical trial.

Training

■ TRAINING FOR THE ECRIN CTU COMMUNITY: JOINT TRAINING BY EMA & ECRIN



On 3 December 2021 EMA and ECRIN offered a joint training session to the ECRIN CTU

community, Implementation of the Clinical Trial Regulation (EU) No 536/2014 for academia: Live demonstration of CTIS and Q&A session.

Over 275 participants connected during the event and watched demonstrations on CTIS Access & User Management, Completion of an initial application, Modifications to an initial application – under evaluation via RFI (request for information) and Modifications to an authorised initial application via modifications & adding a new Member State Concerned (MSC).

■ EXTERNAL TRAINING

Through the PedCRIN project, ECRIN organised three separate webinars to train users on a selection of the paediatric tools developed throughout the project. These focused on neonatal tools, paediatric tools and patient and participant involvement in clinical trials.



ECRIN also develops trainings with its national partners to provide information on multinational clinical trials to their user communities. In 2021 ECRIN joined forces with F-CRIN on two separate occasions and trained over 125 project managers.



Interview with EMA on CTIS joint training session



Laura Pioppo
Scientific Officer
European Medicines Agency



Can you briefly explain CTIS?

CTIS is a new IT system that serves as a single entry point for the submission, assessment, and supervision of clinical trials data, for clinical trials conducted in the EU and EEA*. It includes two secure domains, one for Sponsor users and another accessible to members of the national competent authorities and the ethics committees. There is also a public website, which is freely accessible to the public.

The launch of CTIS and the application of the Clinical Trials Regulation (EU) No 536/2014 represents a major change in the clinical trial landscape. Before the application of the Regulation, Sponsors had to submit individual clinical trial applications to each Member State. Now, all the collection of clinical trial data occurs in one place.

How did you take into consideration the academic clinical trials in the development of CTIS?

EMA is committed to engaging with academic Sponsors to work together on one of the main objectives of the clinical trial Regulation, to make the EU an attractive place for clinical research. As part of the development of the system functionalities, we have appointed product owners from academic Sponsors. This is important as the product owners are involved in all the design steps, validation and testing of the system functionalities. Having academic Sponsors on board was key to understanding their needs and identifying some areas and functionalities of the system that could have been complex to use. We also had academic sponsors represented in the CTIS stakeholder group, a group that meets four times a year and provides input on the CTIS project in general.

A joint training session was developed with ECRIN in December for its CTU community. What was the approach taken for this training?

One of the main factors was the close collaboration with ECRIN in preparation for this event. We worked together in defining the agenda and the topics to be covered during the event, as well as the format. It was important to know that the preference of the audience was to have a hands-on experience, rather than a long detailed presentation of the system functionalities. We proposed a format including a short introductory presentation for each system functionality presented, time to dive into the functionalities and see how the system looked in practice. We also made sure that we had sufficient time for Q&A to make the event more interactive.

What were the benefits of running this training session?

The benefits of running this training session were the modality and the fact that we had a live demo which allowed the users to raise questions during the event and ask the speakers to provide a better look at some of the system functionalities that were presented. This was a complimentary event to the existing material and the catalogue published on the EMA corporate website.

Are there any important messages to share on the roll-out of CTIS?

We now have a system that has been launched, that is being used by different Sponsors when submitting their clinical trial applications. There is, however, a three year transition period and Sponsors can choose whether they want to submit during this first year of transition the new clinical trials applications using CTIS or the previous database, EudraCT. Starting from the 31st of January 2023, all new clinical trial applications will have to be submitted in CTIS and clinical trials that are ongoing under the regime of the Directive (2001/20/EC) can continue up to the 31st of January 2025. This will mark the end of the three year transition period after which all clinical trial applications will have to be migrated to CTIS. Another important point is that the very first clinical trial that we received in CTIS was submitted by an academic Sponsor. I would like to conclude on the ACT-EU initiative, launched in January 2022. It concerns accelerating clinical trials in the EU and it is a new initiative that builds on the momentum of the launch of CTIS and the applicability of the Clinical Trials Regulation. It aims to bring together the different partners involved in clinical trials.

** This interview was conducted a few months after the December 2021 joint training session.*

[Watch the full interview...](#)

Governance and strategy

Partnerships

EUPATI



In December 2021 ECRIN engaged in a strategic partnership with EUPATI, the European Patients'

Academy of Therapeutic Innovation. Through this collaboration, both parties anticipate an increased commitment to training in clinical research for patients and patient representatives and an emphasis on strengthening academic researchers' capacities to effectively engage with patients in their clinical trials. Patient involvement is a key priority in ECRIN's 2021-2023 strategic plan, contributing to the general goal to make clinical research more efficient and successful. The partnership with EUPATI is a major step to achieve this goal, as collaborating and exchanging with patient communities will increase the benefits for all involved in clinical research.

EU-AMRI



EU-AMRI, the European Alliance of Medical Research Infrastructures, is the collaboration between the

European research infrastructures BBMRI-ERIC, EATRIS-ERIC, and ECRIN-ERIC. EU-AMRI aims to provide complementary services to researchers in the field of biomedical sciences.

Although the year 2021 was still dominated by the worldwide pandemic, EU-AMRI managed to work on its strategic positioning, by means of two extensive internal workshops exploring possibilities to collaborate and to define concrete solutions to tackle common issues in the biomedical research field.

Furthermore, the Public Affairs team and the Communication team have drafted the communication plan and put the corporate identity in place. The soft-launch of EU-AMRI took place right after the summer holidays, while preparing for the official, hybrid launch event. Although planned for the beginning of December, the launch event had to be postponed due to the increase in COVID-19 numbers in Europe.

The Public Affairs team also organised joint or concerted actions to increase policy influence and visibility. In 2021 this resulted in several joint publications and speaking opportunities.

Beyond Europe: CRIGH



CRIGH, the Clinical Research Initiative for Global Health, aims to optimise clinical research programmes,

develop global standards on clinical research, promote the take-up of innovative methodology and technologies, and encourage international cooperation to rapidly and efficiently respond to global health challenges. As co-chair of CRIGH, ECRIN hosted its 4th General Assembly in 2021 at the heart of the 10th EDCTP (European & Developing Countries Clinical Trials Partnership) Forum held online.

CRIGH and its actions are disseminated, via ECRIN and other partners, in support of clinical research capacity development. At the Europe Science and Innovation Summit held in June a session cochaired by ECRIN and the EDCTP



led to the development of 11 recommendations for clinical research infrastructure and capacity development in Africa.



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 (end of term 11/2021)	Portugal
Andreia Feijão (new member)	Portugal
Marta Vandrovcová	Czech Republic
Svenja Krebs	Germany
Eric Guittet	France
Annette Magnin	Switzerland
Øyvind Melien	Norway
Daniel Pella	Slovakia
Attila Levente Szócs (end of term 09/2021)	Hungary
Agnieszka Ryniec	Poland
Oonagh Ward	Ireland

Governance Meetings in 2021

ASSEMBLY OF MEMBERS (AOM)

28 January 2021

21 May 2021

8 July 2021

22 October 2021

15 December 2021

Additional Organisational Bodies

Network Committee

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

Christian Ohmann	Chair (Germany)
Annette Magnin	Vice-chair (Switzerland)
Valentina Cabral Iversen (end of term 09/2021)	Norway
Regina Demlová	Czech Republic
Anja Eskat	Switzerland
Tomasz Hryniewiecki	Poland
Fionnuala Keane	Ireland
Gábor Kovács	Hungary
Emilia Montero	Portugal
Jesús Frías	Spain
Lucia Palmisano	Italy
Daniel Pella	Slovakia
Olivier Rascol	France
Heiko von der Leyen	Germany

NETWORK COMMITTEE

19 May 2021

29 November 2021

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 board members mandates are up for renewal and exiting board members will be replaced in 2022.

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 2021

INCOME

Membership Core contributions	1 330 000 €
Membership Local contributions	950 000 €
Research projects	1 829 087 €
Other income	11 161 €
Financial income	111 994 €
Extraordinary income	1 402 €

TOTAL INCOME FOR 2021 4 233 644 €

EXPENDITURES

Salaries & other staff expenses	1 972 725 €
Subcontracting	889 946 €
Office rent and insurance	164 807 €
Communication & IS	151 728 €
Travel and meetings	5 879 €
Financial expenses	6 330 €
Income tax	25 702 €
Other expenses	112 549 €
Local contribution provided in-kind	850 000 €

TOTAL EXPENDITURE FOR 2021* 4 179 668 €

NET RESULT

NET RESULT FOR 2021 53 976 €

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

Annexes

Acronyms

ACT4ALS-MND	Alliance of Clinical trials for Amyotrophic Lateral Sclerosis and Motor Neurone Disease
AFNOR	Association Française de Normalisation
AoM	Assembly of Members
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
BIH QUEST	Berlin Institute of Health Quality Ethics Open Science Translation
ByCOVID	BeYond-COVID
CDISC	Clinical Data Interchange Standards Consortium
CONSCIOUS II	Curriculum Development of Human Clinical Trials
COVID-19	Coronavirus Disease 2019
COVIDOSE	A Phase II Clinical Trial of Low-Dose Tocilizumab in the Treatment of Noncritical COVID-19 Pneumonia
CoVigi	Post authorisation phase IV effectiveness and safety multicentric study of COVID-19 vaccines
CRC	Clinical research centre
CRFs/CRCs	Clinical research facilities/Clinical research centres
CRIGH	Clinical Research Initiative for Global Health
CRO	Clinical Research Organisation
CT	Clinical Trial
CTIS	Clinical Trials Information System
CTU	Clinical Trial Unit
CZECRIN	Czech Clinical Research Infrastructure Network
DCC	Data Centre Certification
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults
DM	Data Management
EATRIS	European Advanced Translational Research Infrastructure in Medicine
EC	European Commission
ECRAID	European Clinical Research Alliance for Infectious Diseases
ECRAID Base	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults
ECRIN	European Clinical Research Infrastructure Network
EDCTP	European & Developing Countries Clinical Trials Partnership
EEA	European Economic Area
EFGCP	European Forum for Good Clinical Practice









EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	European Health Data Space
EMA	European Medicines Agency
EOC	Ente Ospedaliero Cantonale
EOSC	European Open Science Cloud
EOSC-Life	European Open Science Cloud Life project
ERA4Health	European Research Area for Health Research
ERIC	European Research Infrastructure Consortium
EU	European Union
EU-AMRI	European Alliance of Medical Research Infrastructures
EUCLID	European Clinical Trials Services Platform, European Clinical trials & Development
EuCo	European Correspondent
EU-COVAT-1	A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults (≥75) already Vaccinated Against SARS-CoV-2
AGED	
EU-COVPT-1	A Phase 2, Comparative Randomised Trial to Evaluate the impact of reduced COVID-19 mRNA vaccination regimen on immunological responses and reactogenicity in paediatric subjects with prior SARS-CoV-2 immunity (CoVacc)
CoVacc	
EU-Africa	Building links between Europe and Africa in personalised medicine
PerMed	
EULAC PerMed	Widening EU-LAC policy and research cooperation in Personalised Medicine.
EUPATI	European Patients' Academy on Therapeutic Innovation
EU-PEARL	EU Patient-centric clinical tRial pLatforms
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
FCRIN4MS	F-CRIN for Multiple Sclerosis
FAIRPARK II	Conservative iron chelation as a disease-modifying strategy in Parkinson's disease: a multicentric, parallel group, placebo-controlled, randomized clinical trial of deferiprone
Fraden	Atopic dermatitis research network
GCP	Good Clinical Practice
H2020	Horizon 2020
HealthyCloud	HRIC, Health Research and Innovation Cloud
HECRIN	Hungarian European Clinical Research Infrastructure Network










HRB	Health Research Board
HRB CRCI	Health Research Board Clinical Research Coordination Ireland
ICH	International Conference on Harmonisation
IC PerMed	International Consortium for Personalised Medicine
ICTD	International Clinical Trials Day
ID	Infectious Diseases
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
IdiPaz	Instituto de Investigación del Hospital Universitario La Paz
IICT	Investigator Initiated Clinical Trials
IMI	Innovative Medicines Initiative
INI-CRCT	Investigation Network Initiative Cardiovascular and Renal Clinical Trialist
INNOVTe	INvestigation Network On Venous Thrombo-Embolism
INSERM	Institut National de la Santé et de la Recherche Médicale
IS	Information Systems
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
MSC	Member State Concerned
NCTO	National Clinical Trials Office
NorCRIN	Norwegian Clinical Research Infrastructure
NRDI	National Research, Development and Innovation Office
ONCONet	Czech National Cancer Control Programme
PCTN	Polish Clinical Trial Network
PedCRIN	Paediatric Clinical Research Infrastructure Network
PERMIT	Personalised Medicine Trials
PM	Personalised Medicine
POLCRIN	Polish Clinical Research Infrastructure Network











PPI	Patient and Public Involvement
PRC	Peer Review Committee
PRIMUS	PRojection In MULTiple Sclerosis
PSYnet	Psychotic disorders research network
PtCRIN	Portuguese Clinical Research Infrastructure Network
Q&A	Question and answer
QMS	Quality Management System
RECOVER	Rapid European Covid-19 Emergency Research Response
RECOVERY	A randomised trial of treatments to prevent death in patients hospitalised with COVID-19 (coronavirus)
REMAP-CAP	Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia
REMED	Effect of dexamethasone in patients with ARDS and COVID-19 – prospective, multi-centre, open-label, parallel-group, randomized controlled trial
RFI	request for information
RI	Research infrastructure
RI-VIS	Expanding research infrastructure visibility to strengthen strategic partnerships
SARS-CoV-2	Severe Acute Respiratory Syndrome CoronaVirus-2
SCReN	Spanish Clinical Research Network
SCTO	Swiss Clinical Trial Organisation
SIMCOR	In-Silico testing and validation of Cardiovascular Implantable devices
SLOVACRIN	Slovak Clinical Research Infrastructure Network
SME	Small and Medium sized Enterprise
SOP	Standard Operating Procedure
STROCZECH	Czech Stroke Research Network
Strokelink	Research network on heart disease and stroke
TCB	Trials Coordination Board
TESA III	Trials of excellence in southern Africa III
TTV-Guide	A randomised and controlled trial to compare the safety, tolerability and preliminary efficacy between standard and Torque Teno virus-guided immunosuppression in stable adult kidney transplant recipients with low immunological risk in the first year after transplantation. Short Title: TTV Guide IT
VACCELERATE	European Corona Vaccine Trial Accelerator Platform
WG	Working Groups
WHO	World Health Organisation

Clinical Trial Portfolio in 2021 (current trials)

During 2021 ECRIN provided support to 39 clinical trials in different phases; 11 were in the set-up phase working toward the opening of all sites in all participating countries; and 28 trials were active- meaning in the phases of recruitment, follow-up, close-down activities.

SHORT title	Protocol title	Trial status	CT Sponsor country	Funding source
EU-COVAT-1	A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults (≥75) already Vaccinated Against SARS-CoV-2	Start-up phase		101037867*
EU-COVat-2	An International Multicentre, Phase 2, Randomised, Adaptive Protocol to determine the need for, optimal timing of and immunogenicity of administering a 3rd homologous mRNA vaccination dose against SARS-CoV-2 in the general population (18+ years) already fully vaccinated against SARS-CoV-2	Start-up phase		101037867*
EU-COVPT	A Phase 2, Comparative Randomised Trial to Evaluate the impact of reduced COVID-19 mRNA vaccination regimen on immunological responses and reactogenicity in paediatric subjects with prior SARS-CoV-2 immunity (CoVacc)	Start-up phase		101037867*
EU-TRAIN RCT (IMPACT)	Randomized Controlled Multicenter Trial to quantify the benefits of biomarkers in routine patient care in kidney transplant recipients	Start-up phase		754995*
HIVACAR	Evaluating a Combination of Immune-based Therapies to Achieve a Functional Cure of HIV Infection	Start-up phase		731626*
IDEA-FAST – COS	Identifying Digital Endpoints to Assess FATigue, Sleep and aCTivities daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases	Start-up phase		IMI2 853981*
NECESSITY	New Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifying patients	Start-up phase		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	Start-up / on hold		ERA-Net & DFG

SeeMyLife	Holistic mixed approaches to capture the real life of children with Rare Eye Diseases	Start-up phase		Joint Translational funding
TB-MED – BIOCERAMED	Prospective Multicenter Observational Study on the use of NEOCEMENT® for the Treatment of Bone Defects-Registry-based study	Start-up phase		210487722*
TTV Guide IT	A randomised and controlled trial to compare the safety, tolerability and preliminary efficacy between standard and Torque Teno virus-guided immunosuppression in stable adult kidney transplant recipients with low immunological risk in the first year after transplantation	Start-up phase		896932*
ADIPOA2	Autologous Adipose-Derived Mesenchymal Stromal Cells in the Treatment of Mild to Moderate Osteoarthritis	Running phase		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 phase		634559*
CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	Running phase		German government
DisCoVeRy	Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults	Running phase		101015736*
EU-TRAIN COHORT	Prospective cohort of kidney transplant patients	Running phase		754995*
ImmunAID	Immunome project consortium for AutoInflammatory Disorders	Running phase		779295*
INFORM2 NivEnt	INFORM2 exploratory multinational phase I/II combination study of Nivolumab and Entinostat in children and adolescents with refractory high-risk malignancies	Running phase		Industry & German government
LIVERHOPE EFFICACY	Efficacy of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis to prevent ACLF development: a multicenter, double-blind, placebo controlled randomized clinical trial	Running phase		731875*

MACUSTAR	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention	Running phase		IMI 116076*
NISCI	Antibodies against Nogo-A to enhance plasticity, regeneration and functional recovery after acute spinal cord injury, a multicenter international randomized double-blinded placebo-controlled Phase II clinical proof	Running phase		681094*
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 phase		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 phase		733203*
PRECIOUS	Prevention of Complications to Improve Outcome in Elderly Patients with Acute Stroke	Running phase		634809*
PROOF	Penumbra Rescue by Normobaric O ₂ Administration in Patients With Ischaemic Stroke and Target Mismatch ProFile: A Phase II Proof-of-Concept Trial	Running phase		733379*
RESPINE	REgenerative therapy of intervertebral disc: a double blind phase 2b trial of intradiscal injection of mesenchymal stromal cells in degenerative disc disease of the lomber SPINE unresponsive to conventional therapy	Running phase		732163*
R-Link	Optimizing response to Li treatment through personalized evaluation of individuals with bipolar I disorder: the R-LINK initiative	Running phase		754907*
SESAME	Safety and Effectiveness of SOFIA™/SOFIA™ PLUS when used for direct aspiration as a first line treatment technique in patients suffering an Acute Ischemic Stroke in the anterior circulation	Running phase		Industry
SolidAct	European DisCoVeRy for Solidarity: An Adaptive Pandemic and Emerging Infection Platform Trial.	Running phase		101015736*

SWEET	Sweeteners and sweetness enhancers: Impact on health, obesity, safety and sustainability	Running phase		774293*
TENSION	Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window	Running phase		754640*
TERIS	Multi-center, randomized, double-blinded study of Teriflunomide® in radiologically isolated syndrome (RIS)	Running phase		Industry
TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen Study type	Running phase		IMI 777389*
FAIR-PARK II	Conservative Iron Chelation as a Disease-Modifying Strategy in Parkinson's Disease	Completed		633190*
POPART	Prophylactic oropharyngeal surfactant for preterm infants: a randomised trial	Completed		731046*
WE Study	Walking Easier with cerebral palsy	Completed		731046*
ADIPOA3	Efficacy of knee injection of allogeneic adipose-derived MSC in subjects with mild to moderate knee OA unresponsive to conventional therapy	No longer requires ECRIN services		Industry
CONVINCE-IRL	Colchicine for Prevention of Vascular Inflammation in Non-cardio Embolic Stroke	No longer requires ECRIN services		National : Ireland
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)	No longer requires ECRIN services		731046*



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

Research Infrastructure Development Portfolio in 2021 (current projects)

At the end of 2021, ECRIN's infrastructure development portfolio included 25 open projects. However, ECRIN coordinated one project that ended and provided support to an additional two projects during the year, bringing the total number of projects ECRIN is contributing to in 2021 to 27.

Acronym	Full name	Status (as of Dec. 2021)	Funding
B1MG	Beyond 1 Million Genomes	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 951724.
BY-COVID	BeYond-COVID	Running	The European Union's Horizon Europe research and innovation programme under grant agreement number 101046203.
c4c	conect4children	Running	The Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389. The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries & Associations (EFPIA).
CRIGH	Clinical Research Initiative for Global Health	Running	Funding through members' contributions.
ECRAID-Base	European Clinical Research Alliance on Infectious Diseases	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 965313.
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-Future	European Open Science Cloud Future	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101017536.
EOSC-Hub	Integrating and managing services for the European Open Science Cloud	Ended	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-Africa PerMed	Building links between Europe and Africa in Personalised Medicine	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 964333.
EU-PEARL	EU Patient cEntric clinical tRial pLatform	Running	The European Union's Horizon 2020 research and innovation programme and the Innovative Medicines Initiative (IMI) under grant agreement number 853966-2.
EU-RESPONSE	European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101015736.
EULAC-PerMed	Widenening Eu-CELAC policy and research cooperation in Personalised Medicine	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 825173.
EuroGCT	European consortium for communicating gene- and cell-based therapy information.	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 965241.
HealthyCloud	Health Research and Innovation Cloud	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 965345.
PedCRIN	Paediatric Clinical Research Infrastructure Network	Ended	The European Union's Horizon 2020 research and innovation programme under grant agreement number 731046.
PERMIT	PERsonalised Mediclne 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.

SIMCOR	In-Silico testing and validation of Cardiovascular Implantable devices	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 101017578.
SYNCHROS	SYnergies for Cohorts in Health: integrating the Role of all Stakeholders	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 814439.
TESA III	Trials of Excellence in Southern Africa III	Running	European & Developing Countries Clinical Trials Partnership (EDCTP) under GA CSA 2020NoE-3104TESAIII
TRANSVAC-DS	Design study for a European vaccine infrastructure	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 951668.
TRANSVAC2	European Vaccine Research and Development Infrastructure	Running	The European Union's Horizon 2020 research and innovation programme under grant agreement number 730964.
VACCELERATE	European Corona Vaccine Trial Accelerator Platform	Running	The European Union's Horizon 2020 programme under grant agreement number 101037867.



2021 Publications

Publication	Related project/trial
Ader F, Peiffer-Smadja N, Poissy J, Bouscambert-Duchamp M, Belhadi D, Diallo A et al. Antiviral drugs in hospitalized patients with COVID-19 - the DisCoVeRy trial. medRxiv 2021.01.08.20248149; doi: https://doi.org/10.1101/2021.01.08.20248149	Discovery / EU RESPONSE
Ahern C, Beatrix F, Panagiotopoulou M, Biziou L. EOSC-Life Strategic Marketing and Stakeholder Mapping Report. Published online February 24, 2021. doi:10.5281/zenodo.4560453	EOSC-Life
Anthony N, Pellen C, Ohmann C, Moher D, Naudet F. Social media attention and citations of published outputs from re-use of clinical trial data: a matched comparison with articles published in the same journals. BMC Medical Research Methodology. 2021;21(1):119. doi:10.1186/s12874-021-01311-z	
Bellivier F, Young AH, Scott J, Etain B, Cousins DA; R-LiNK Consortium. Make lithium great again - Precisely! Bipolar Disord. 2021 Mar;23(2):209-210. doi: 10.1111/bdi.13023.	R-Link
Bofill Roig M, Krotka P, Burman CF, Glimm E, Hees K, et al. On model-based time trend adjustments in platform trials with non-concurrent controls, ArXiv.org, Cornell University (2022) November 2021, arxiv.org/abs/2112.06574	EU-PEARL
Boiten JW, Ohmann C, Adeniran A, et al. EOSC-LIFE WP4 TOOLBOX: Toolbox for Sharing of Sensitive Data - a Concept Description. Zenodo; 2021. doi:10.5281/zenodo.4483694	EOSC-Life
Canham S, Ohmann C, Boiten J-W, Panagiotopoulou M, Hughes N, David R, et al. EOSC-Life Report on data standards for observational and interventional studies, and interoperability between healthcare and research data. Published online December 30, 2021. doi:10.581/zenodo.5810612	EOSC-Life
Cash-Gibson L, Pericàs JM, Spiertz C, van de Ketterij E, Molero E, et al. Changing the paradigm of clinical trials in Europe, European Journal of Public Health, Volume 31, Issue Supplement_3, October 2021, ckab165.657,	EU-PEARL
Colombo C, Mayrhofer MT, Kubiak C, et al. The CORBEL matrix on informed consent in clinical studies: a multidisciplinary approach of Research Infrastructures Building Enduring Life-science Services. BMC Medical Ethics. 2021;22(1). doi:10.1186/s12910-021-00639-x	CORBEL
Dhaenens BAE, Ferner RE, Evans DG, Heimann G, Potratz C, van de Ketterij E et al. Lessons learned from drug trials in neurofibromatosis: A systematic review, European Journal of Medical Genetics, 64 (9), 2021. doi.org/10.1016/j.ejmg.2021.104281.	EU-PEARL
Dhaenens BAE, Ferner RE, Bakker A et al. Identifying challenges in neurofibromatosis: a modified Delphi procedure. Eur J Hum Genet 29, 1625–1633 (2021). https://doi.org/10.1038/s41431-021-00892-z	EU-PEARL

Diallo A, Trøseid M, Simensen VC, et al. Accelerating clinical trial implementation in the context of the COVID-19 pandemic: challenges, lessons learned and recommendations from DisCoVeRy and the EU-SolidAct EU response group. <i>Clin Microbiol Infect.</i> Published online November 8, 2021:S1198-743X(21)00612-1. doi:10.1016/j.cmi.2021.10.011	EU-RESPONSE
Glaab E, Rauschenberger A, Banzi R, Gerardi C, Garcia P, Demotes J. Biomarker discovery studies for patient stratification using machine learning analysis of omics data: a scoping review. <i>BMJ Open.</i> 2021;11(12):e053674. doi:10.1136/bmjopen-2021-053674	PERMIT
Goossens H, Derde L, Horby P, Bonten M. The European clinical research response to optimise treatment of patients with COVID-19: lessons learned, future perspective, and recommendations. <i>Lancet Infect Dis.</i> 2021 Dec 21:S1473-3099(21)00705-2. doi: 10.1016/S1473-3099(21)00705-2. Epub ahead of print. PMID: 34951954; PMCID: PMC8691848.	RECOVER / REMAP CAP
Kim M. Recommendations towards Cooperation between African and European Research Infrastructures. Zenodo; 2021. doi:10.5281/zenodo.4475595	RI-VIS
Kim M. Recommendations towards Cooperation between Australian and European Research Infrastructures. Zenodo; 2021. doi:10.5281/zenodo.4546173	RI-VIS
Kim M. Recommendations towards Cooperation between Latin American and European Research Infrastructures. Zenodo; 2021. doi:10.5281/zenodo.4544374	RI-VIS
Magnin A, Iversen VC, Calvo G, et al. European survey on national harmonization in clinical research. <i>Learning Health Systems.</i> 2021;5(2):e10220. doi: https://doi.org/10.1002/lrh2.10220	
Madeira C, Hořavová L, dos Santos F, Batuca J, Nebaska K, Součková L, et al. Investigator Initiated Clinical Trials (IICTs): A Systematic Search in Registries to Compare the Czech Republic and Portugal in Terms of Funding Policies and Scientific Outcomes. <i>Therapeutic Innovation & Regulatory Science</i> 55: 966-978.	
Kyr M, Svobodnik A, Stepanova R, Hejnova R. N-of-1 Trials in Pediatric Oncology: From a Population-Based Approach to Personalized Medicine—A Review. <i>Cancers.</i> 2021; 13(21):5428. https://doi.org/10.3390/cancers13215428	CZECRIN
Lê MP, Peiffer-Smadja N, Guedj J, Neant N, Mentré F, et al. Rationale of a loading dose initiation for hydroxychloroquine treatment in COVID-19 infection in the DisCoVeRy trial-authors' response. <i>J Antimicrob Chemother.</i> 2021 Jan 1;76(1):277-279. doi: 10.1093/jac/dkaa415.	Discovery / EU RESPONSE
Maccari S, Buoncervello M, Ascione B, Stati T, Macchia D, Fidanza S, et al. α -Adrenoceptor stimulation attenuates melanoma growth in mice. <i>Br J Pharmacol.</i> 2022 Apr;179(7):1371-1383. doi: 10.1111/bph.1573	ItaCRIN
Meyer, E.L., Mesenbrink, P., Mielke, T. et al. Systematic review of available software for multi-arm multi-stage and platform clinical trial design. <i>Trials</i> 22, 183 (2021). https://doi.org/10.1186/s13063-021-05130-x	EU-PEARL

Naudet F, Siebert M, Pellen C, Gaba J, Axfors C, Cristea I, et al. Medical journal requirements for clinical trial data sharing: Ripe for improvement. *PLOS Medicine* 18 (10) : e1003844. <https://doi.org/10.1371/journal.pmed.1003844>

Ohmann C, Moher D, Siebert M, Motschall E, Naudet F. Status, use and impact of sharing individual participant data from clinical trials: a scoping review. *BMJ Open.* 2021;11(8):e049228. doi:10.1136/bmjopen-2021-049228

Pinheiro Andrade, M., Matias, D., Batuca, J., Gouveia, N., Mota-Filipe, H., Carreira Monteiro, E., & Madeira, C. (2021). Portuguese Authorship in Published Clinical Trials: Differences in Industry and Investigator Initiated Trials. *Acta Médica Portuguesa*, 34(11), 733-740. doi:http://dx.doi.org/10.20344/amp.14554

Riad A, Pokorná A, Attia S, Klugarová J, Koščík M, Klugar M. Prevalence of COVID-19 Vaccine Side Effects among Healthcare Workers in the Czech Republic. *Journal of Clinical Medicine.* 2021; 10(7):1428. <https://doi.org/10.3390/jcm10071428>

Riad A, Pokorná A, Mekhemar M, Conrad J, Klugarová J, Koščík M, et al. Safety of ChAdOx1 nCoV-19 Vaccine: Independent Evidence from Two EU States. *Vaccines.* 2021; 9(6):673. <https://doi.org/10.3390/vaccines9060673>

Rodríguez-Laso Á, Rico-Urbe LA, Kubiak C, Haro JM, Rodríguez-Mañas L, Ayuso JL. A Map of the Initiatives That Harmonize Patient Cohorts Across the World. *Front Public Health.* 2021;0. doi:10.3389/fpubh.2021.666844

Ruggieri L, Ceci A, Bartoloni F, et al. Paediatric clinical research in Europe: an insight on experts' needs and perspectives. *Contemporary Clinical Trials Communications.* 2021;21:100735. doi:10.1016/j.conctc.2021.100735

Sforzini L, Worrell C, Kose M et al. A Delphi-method-based consensus guideline for definition of treatment-resistant depression for clinical trials. *Mol Psychiatry* (2021). <https://doi.org/10.1038/s41380-021-01381-x>

Terheyden JH, Behning C, Lüning A, et al. Challenges, facilitators and barriers to screening study participants in early disease stages-experience from the MACUSTAR study. *BMC Medical Research Methodology.* 2021;21(1):54. doi:10.1186/s12874-021-01243-8

The REMAP-CAP Investigators* Interleukin-6 Receptor Antagonists in Critically Ill Patients with Covid-19. *N Engl J Med* 2021; 384:1491-1502 DOI: 10.1056/NEJMoa2100433

The REMAP-CAP, ACTIV-4a, ATTACC Investigators, Zarychanski R. Therapeutic Anticoagulation in Critically Ill Patients with Covid-19 – Preliminary Report doi: <https://doi.org/10.1101/2021.03.10.21252749>

Trøseid M, Hites M, Barratt-Due A, Ader F, Yazdanpanah Y. Assessing the evidence on remdesivir. *Lancet Infect Dis.* 2021 Dec;21(12):1630-1631. doi: 10.1016/S1473-3099(21)00695-2.

Notes



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
www.ecrin.org

 Follow us on Twitter: [@ECRIN_ERIC](https://twitter.com/ECRIN_ERIC)
 www.linkedin.com/company/ecrin