



ECRIN ANNUAL REPORT 2019

Supporting clinical trials across borders



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Table of Contents

Letter from the Director General	4
Foreword from the Assembly of Members Chair and Vice Chair	6
Mission, Vision and Focus Areas	8
2019 in Numbers	9
2019 Highlights	10
ECRIN Overview	12
Clinical Trial Operations	16
Infrastructure Development	22
Partnerships	26
Quality	28
Training	32
Communications	34
ECRIN Team	36
National Scientific Partners	38
Governance	48
Financial Report for 2019	50
Acronyms	51
Clinical Trial Portfolio in 2019 (current trials)	56
Project Funding and Other References	60
Publications	62

**EUROPEAN CLINICAL RESEARCH
INFRASTRUCTURE NETWORK**
5 rue Watt - 75013 Paris France

Letter from the Director General

Throughout 2019, we continued to grow our clinical trial portfolio, supporting the management of multinational, academic clinical trials covering diverse medical fields and diseases.

Dear reader,

We are proud to present ECRIN's Annual Report for 2019. A major highlight this year was ECRIN's external and independent scientific evaluation, which took place five years after ECRIN was granted the status of a 'European Research Infrastructure Consortium' (ERIC). The evaluation was carried out by a multinational consortium of independent evaluation bodies, the European Research Infrastructure Evaluation Consortium (ERIEC).

The report is divided into three areas: Positioning and strategy, Governance and management, and ERIC activities. It includes general

conclusions and recommendations, which were incorporated into ECRIN's 2020 work plan and strategy plan. Some recommendations, as well as the comments provided by ECRIN, have a broader significance and may affect the research infrastructure community as a whole, as well as national and European science policymakers. ECRIN is the first ERIC to have done this type of fully independent evaluation with an external body.

Another highlight for 2019 was the addition of a new observer country: Poland, with the Polish Medical Research Agency (MRA) as national scientific partner. This brought our total number of member countries

to nine and observer countries to three, for a total of 12.

Throughout 2019, we continued to grow our clinical trial portfolio, supporting the management of multinational, academic clinical trials covering diverse medical fields and diseases. We also continued to work on infrastructure development projects that aim to further develop the European clinical research community and to facilitate multinational trials.

We expanded our core team in Paris to meet the needs of a growing number of projects and ECRIN-supported trials, as well as quality activities, especially as we finalise

We are excited to continue striving to achieve our vision: the generation of scientific evidence through multinational clinical trials to enhance medical practice, and ultimately, to improve public health.

”



Jacques Demotes
Director General of ECRIN

the preparation phase for ISO 9001: 2015 certification. The Chair (Rafael de Andrés) and Vice Chair (Maria Ferrantini) of our Assembly of Members were re-elected.

We are proud of what we have accomplished with our many European and international partners so far, and are excited to continue striving to achieve our vision: the generation of scientific evidence through multinational clinical trials to enhance medical practice, and ultimately, to improve public health.

Moving forward, we will focus on enhancing our financial resources to continually improve our ability to provide the highest quality support

services. This report provides an overview of how we used these resources in 2019 to achieve our goals. We thank you for your interest and continued support.

Sincerely,

Jacques Demotes

Foreword from chair/co-chair of Assembly of members

Overall 2019 has been an important year for continuing, focussing, and adjusting the road to the future of ECRIN.

2019 - another busy and constructive year for ECRIN.

It was the year of finalising the execution of the goals set out in the 2016-2019 strategy plan, and also the year when a research infrastructure – ours – was assessed for the first time by the European Research Infrastructure Evaluation Consortium (ERIEC²) and its recommendations immediately after started their implementation. Overall 2019 has been an important year for continuing, focussing, and adjusting the road to the future of ECRIN, led by the 2020 work plan and strategy plan.

An important step for the ECRIN network is the addition of Poland as a new observer country. With twelve member and observer countries, the core existence of ECRIN remains of course the provision of high-quality support services to its participating countries, helping

its national scientific partners to connect to partners in other ECRIN members and observer countries, as well as to partners elsewhere in Europe and beyond. For individual countries and to Europe as a whole, this cross borders' collaboration is a huge advantage as multinational clinical trials mean greater access to patients, expertise, resources, and more, which in turn means faster and more robust results.

We thank the French Senate for hosting on 20th May the International Clinical Trial Day (ICTD) at the magnificent Palais du Luxembourg in Paris with the welcome address by its President, Mr Larcher. It was followed, the day after, by the business combined meeting of the Network Committee (NC) -Assembly of Members (AoM), a sign of the regular work and interaction of the different ECRIN constituencies.

With ECRIN's support, countries can gain easier access to other national networks (composed of clinical trial units) and coordinated services, and to research communities. Collectively, they can develop and implement innovative research projects to tackle the pressing questions that might otherwise go unaddressed in clinical studies involving paediatric patients (now 20% of ECRIN's portfolio) or adult patients – and which may have a potentially great impact on public health.

A particular benefit for researchers is access to the 346 millions of European inhabitants and potential patients. This is especially relevant in Personalized Medicine and for rare diseases, whereby a single country may only have a handful of cases, making a clinical trial extremely difficult (or slow) to conduct.

The continuous growth of the ECRIN



Rafael de Andrés

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



Maria Ferrantini

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

clinical trial portfolio, highlights the underlying strength of this unique organisation and the need to support the management of multinational, academic clinical trials covering diverse medical fields and diseases. One of the focusses for ECRIN is to continue the path to attract additional member and observer countries. An important asset in that perspective is the future ISO 9001:2015 certification.

ECRIN is also active partner in other projects related to clinical research, often started within the ECRIN field of operations. In 2019, ECRIN supported amongst others actively the projects PedCRIN for the paediatric related clinical research, EULAC-PerMed on the collaboration with Latin America and Caribbean countries to foster the participation of their policy makers and researchers in the International

Consortium on Personalized Medicine (ICPerMed) and the ERANet on Personalized Medicine (ERAPerMed) and the PERMIT project to develop recommendations for robust and reproducible personalised medicine research. Within the collaboration with other research infrastructures in the field of biological and medical sciences, ECRIN continued its co-operation and visibility in major projects as CORBEL, EOSC-LIFE and EJP-RD. In this context, steps have been set to advance on the long-term cooperation with ERIC's BBMRI and EATRIS in a non-bureaucratic mode.

The continuous growth of ECRIN in numbers of trials, projects, member/observer countries, and the continuing route of collaboration between research infrastructures, underline the strength and need of

this unique organisation. Each small step is an important link to create a leap in the generation of scientific evidence through multinational clinical trials to enhance medical practice, and ultimately, to improve public health.

Sincerely,

Rafael de Andrés, chair of ECRIN's Assembly of Members

Maria Ferrantini, vice chair of ECRIN's Assembly of Members

²ERIEC was established in April 2019 to evaluate European research infrastructures. Learn more: www.eriec.eu/missions

Mission, Vision and Focus Areas

ECRIN MISSION

To support the conduct of multinational clinical research in Europe

ECRIN VISION

To generate scientific evidence to optimise medical practice

Focus Areas Moving Forward³

- ✓ Increasing the number of ECRIN supported trials.
- ✓ Expanding the number of member / observer countries.
- ✓ Promoting quality inside the organisation.
- ✓ Further developing partnerships.
- ✓ Increasing our involvement in strategic / science policy actions.
- ✓ Developing tools / services adapted to the clinical research context.



³Focus areas are adapted from those in the 2019 work plan..

2019 in Numbers

6

Years that ECRIN has had 'ERIC' status

9

Member countries

3

Observer countries

346M

Number of European citizens in ECRIN member and observer countries

45

Number of trials supported by ECRIN throughout 2019⁴

6

Average number of countries per ECRIN-supported trial

10

Number of new infrastructure development projects

1

New infrastructure development project coordinated by ECRIN funded

15

Data centres certified since 2014

11

Number of scientific articles (co)authored by ECRIN and published

750

Twitter followers

⁴This figure includes all trials that received ECRIN support (or were approved to receive support) during 2019. For the full list of trials and their exact status as of 31 Dec. 2019, see the Clinical Trial Operations section below. The 45 figure includes trials that were ongoing or in the set-up stage; new trials (i.e. with a projected start date in 2020); and trials that closed/terminated in 2019.

2019 Highlights



International Clinical Trials Day (ICTD)



Signature of the Alliance



Economic Forum, Poland

Jan.

- Kick-off of new infrastructure development projects: **SYNCHROS** (SYnergies for Cohorts in Health: integrating the Role Of all Stakeholders)ⁱ, ECRAID-Plan (European Clinical Research Alliance on Infectious Diseases Business Plan)ⁱⁱ, and ERIC Forum Implementation projectⁱⁱⁱ
- Kick-off meeting of new ECRIN-supported clinical project: 'NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifying patients (NECESSITY)^{iv} in Paris (16-17 Jan.)
- Host two MiRoR students^v

Feb.

- Signature of an agreement with the Biobanking and BioMolecular resources Research Infrastructure (BBMRI), and the European Research Infrastructure for Translational Medicine (EATRIS) for long-term sustainable collaboration strategy
- Kick-off meeting of new ECRIN-supported clinical project: 'An Open Innovation testing bed for the development of high-risk medical devices' (TB-Med)^{vi} in San Sebastian, Spain (21-22 Feb.)

Mar.

- 'Management Office'⁵ face-to-face meeting (27-28 Mar.)
- Participation in kick-off of the EOSC-Life (Providing an open collaborative space for digital biology in Europe) project^{vii}.

Apr.

- Advisory Board Meeting (1 Apr.)
- Training session held for auditors involved in ECRIN's Data Management (DM) Centre Certification programme (10 Apr.)
- Joint training session with CDISC as part of DM certification programme (11 Apr.)

May

- International Clinical Trials Day (ICTD) meeting in Paris (20 May)
- HRB CRCI⁶ Celebration of ICTD 2019: 'Enabling Ireland as a Clinical Research Leader' (13 May)
- CZECRIN's⁷ 4th National Clinical Trials Day in Prague (14 May) focusing on source data for pharmaco-economic evaluation and data sharing
- Slovakian Celebration of ICTD in Bratislava (30 May)
- Joint meetings: ECRIN Assembly of Members (AoM) and Network Committee; Network Committee and Management

Jun.

- Clinical Research Initiative for Global Health (CRIGH) General Assembly (20-21 Jun.)
- ECRIN's external and independent scientific evaluation (24-27 Jun.)

Jul.

- Launch of 2019 Data Centre Certification call
- EFPIA, EATRIS, ELIXIR, BBMRI and ECRIN issue a statement on the role of research infrastructures to boost patient-centred research and innovation in Europe

Aug.

- Poland joins ECRIN as an observer country (23 Aug.)

Sep.

- ECRIN Summer School (internal) meeting in Balatonfüred, Hungary (11-13 Sept.)

Oct.

- New publication on ECRIN-supported LIVERHOPE-Safety trial^{viii}

Nov.

- Management Office face-to-face meeting (27-28 Nov.)
- Network Committee meeting (15 Nov.)

Dec.

- Finalisation of 2020 work plan
- Assembly of Members meeting (17 Dec.)
- Support for the organisation of a week of events on personalised medicine as part of the EULAC-PerMed (Widening EU-CELAC policy and research cooperation in Personalised Medicine) project^{ix}

⁵ As per the ECRIN Statutes, the Management Office is defined as the ECRIN core team and European correspondents (EuCos).

⁶ Health Research Board Clinical Research Coordination Ireland (HRB CRCI) is ECRIN's Irish national partner.

⁷ CZECRIN is the Czech Clinical Research Infrastructure Network, ECRIN's Czech national partner.



Who we are

ECRIN is a sustainable, non-profit, distributed ‘research infrastructure’ (see box) with an ERIC⁸ legal status, that strives to overcome the obstacles to multinational trials in Europe.

In particular, ECRIN supports sponsors and coordinating investigators in the preparation of their clinical trial projects and funding applications, and provides services for the management of multinational trials. It focuses on independent, multinational academic research as well as trials initiated by biotech and medical device small and medium-sized enterprises (SMEs).

ECRIN is also involved in activities to enhance the ability of European institutions to successfully conduct multi-country clinical research (e.g. tools/database development, data centre certification). Moreover, ECRIN participates in infrastructure development projects aiming to develop its capacity, tools and services. Updates on ECRIN’s trial support and project activities in 2019 can be found in the following pages (see ‘Clinical Trial Operations’ and ‘Infrastructure Development’ sections).

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.

⁸ERIC: European Research Infrastructure Consortium

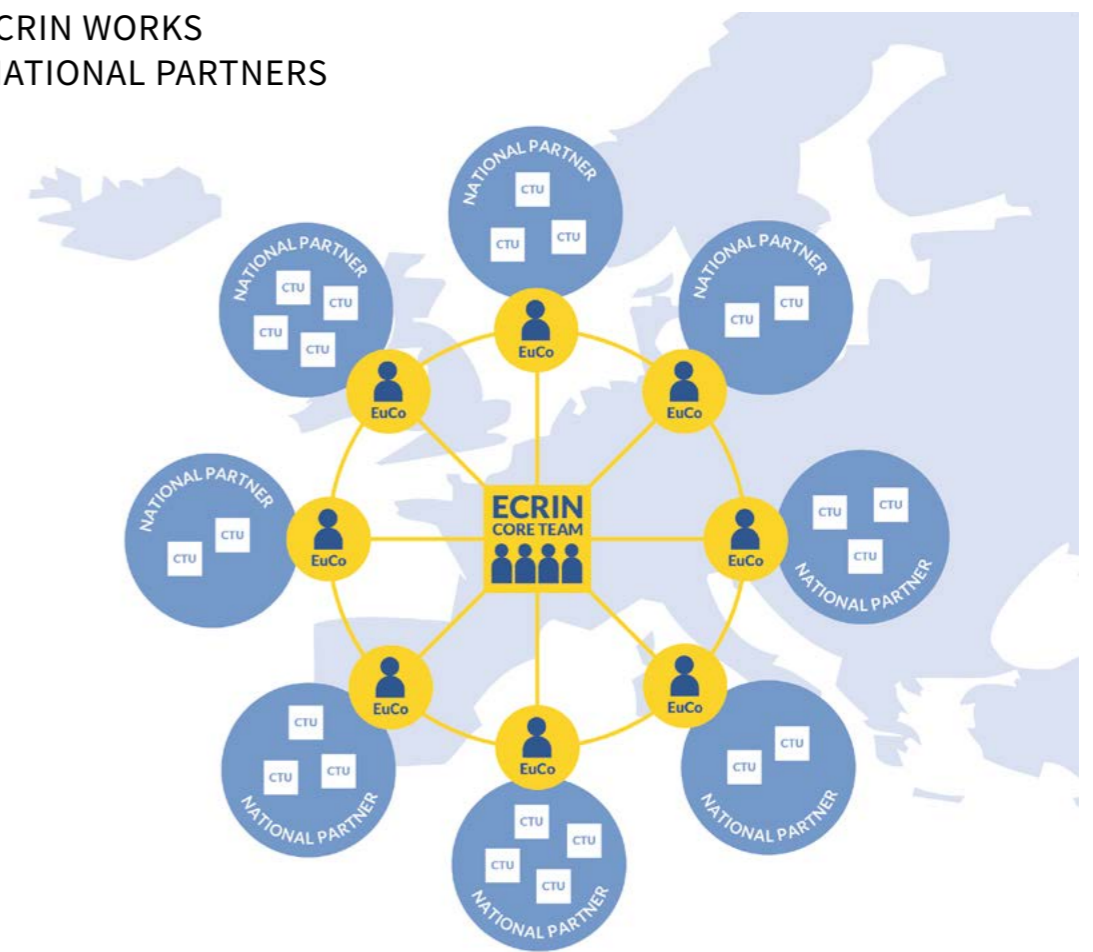
Organisation

ECRIN’s organisational model is based on country membership. In 2019, it had nine member countries (Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Portugal and Spain) and three observer countries (Poland, Slovakia and Switzerland).

Each country hosts a European correspondent (EuCo) who is seconded to ECRIN by the national scientific partner, which is a network of academic

clinical trial units (CTUs) located at or affiliated to national universities and hospitals. EuCos are clinical research experts with extensive knowledge of the national and European clinical research and regulatory landscape, operational management, and coordination of multi-national trials. They manage the ECRIN clinical trial portfolio in collaboration with the national scientific partner and the Paris-based core team.

HOW ECRIN WORKS WITH NATIONAL PARTNERS



EuCo European Correspondent CTU Clinical Trial Unit

⁷ Documents available here: www.ecrin.org/who-we-are/organisation-funding

An Interview with the Irish EuCos

Ireland joined ECRIN as a member country in 2018. In this interview, the country's two European correspondents (Suzanne Bracken and Fiona Cregg), discuss their background, their roles, the benefits of ECRIN for Ireland, and more.

ECRIN's Irish EuCos have been 'friends for ages', according to Fiona Cregg. Their friendship grew from a professional relationship, starting 14 years ago when she and Suzanne Bracken were starting out at a biotech diagnostic company. They parted ways, however, when Cregg took a position at the University of Dublin working on marine biology. She then branched out to clinical research in 2012, managing a project on the entire clinical trial lifecycle. In 2017, a regulatory/quality role came up at Health Research Board Clinical Research Coordination Ireland (HRB CRCI), where Bracken had joined in 2011 to facilitate translational research, and the two former colleagues and friends were reunited again. Shortly after that, Ireland joined ECRIN, and the EuCo position was created, which the two now split (with Bracken assuming most daily tasks and Cregg focusing on tasks related to quality).

interview

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

For Bracken, a typical day involves 'lots of emails!' She is a coordinating EuCo for the PedCRIN-supported 'Prophylactic oropharyngeal surfactant for preterm infants: a randomised trial' (PopArt), which, she says, makes the job more than worthwhile. Bracken is also involved in the EOSC-Life project to create an open collaborative space for digital biology. This draws on her experience coordinating a data protection-working group in Ireland. 'The GDPR has created a lot of confusion', she explains. 'So I help to navigate through that confusion: to identify best practices' and to ensure that researchers in hospitals, health research regulators, and other parties are on the same page, she adds.

One of Cregg's main roles is to chair the ECRIN quality group for this year. The goal is to share expertise across ECRIN partner organisations (i.e. the national scientific partners). For example, she says, the group looks at how GDPR has been implemented in clinical research facilities across countries and discusses changes in regulation across countries.

What's the best part of being a EuCo?

For Cregg, it's 'being aware of what's happening in Europe'. Bracken seconds that, adding that 'you get the perspective of what else is going on in Europe. You can see that others are encountering similar challenges' – which makes you feel less alone.

How has ECRIN benefitted Ireland?

Bracken says that 'The experience clinical trial units gain [from being involved in ECRIN-supported trials] will surely benefit them for future multinational trials. They are learning all sorts of things that go into multinational trials: the tasks, roles, what you can do to facilitate the trial, and so on'. Cregg hopes that Ireland's involvement in ECRIN will lead to greater recognition [of Irish researchers/CTUs] among the European scientific community, leading to increased involvement in multinational trials in the future.

What is their vision for future collaboration with Europe/ECRIN?

Bracken sees a future in medical devices, stating that 'Given the new regulations, the EU is putting out more calls. There is a lot of potential for more trials on med tech', an area where Ireland has significant experience, she says. Cregg concludes, 'It's early days for Ireland', and the future for multinational collaboration is bright.



Suzanne Bracken
European Correspondent,
Ireland.



Fiona Cregg
European Correspondent,
Ireland.



Funding

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

Clinical Trial Operations



Overview

ECRIN's core activity is clinical trial operations, which continued to be its focus in 2019. ECRIN provides support to investigators and sponsors in ECRIN member and observer countries for the preparation of European funding applications and the validation of study protocols.

Given that projects meet ECRIN's eligibility criteria⁹, ECRIN can also provide various trial management services to sponsors / project coordinators.

As part of its operations activities, ECRIN also contributes to the development of tools designed to facilitate multinational clinical research.

ECRIN's Support in a Changing Research Landscape

In 2019, ECRIN's clinical trial activities continued to reflect an evolution in the clinical research landscape, including the rise of personalised medicine, patient stratification, artificial intelligence, big data, digital endpoints, medical devices, and more. ECRIN supported a significant number of applications for European funding (H2020) for multinational studies on patient stratification (as part of personalised medicine programmes). As such, ECRIN continued to shift from support for randomised clinical drug trials to support for new clinical research areas and methodologies (e.g. the identification of biomarkers, prospective cohorts and medical device investigations).

The sections below provide a closer look at the type of support ECRIN provides from preparation to implementation, and highlights the number of applications that ECRIN supported in 2019. The ECRIN clinical trial portfolio (of 36 on-going trials as of 2019) is also presented.

A Closer Look at Trial Support Services

The figure offers a more detailed look at the types of services that ECRIN can offer before and during multinational clinical trial implementation. These services are described in greater detail, with information specific to 2019, in this section.

Collaboration Committee

ECRIN has an internal Collaboration Committee which meets weekly to discuss whether or not to move forward with proposals. The goal is to make an early, transparent decision on the support to be provided to funding applications based on a project synopsis and task requirements.

In 2019, the Collaboration Committee reviewed 37 requests for collaboration. Seventeen requests for project participation were rejected, while 20 requests for collaboration were approved. Of these 20 requests, nine grant submissions were rejected; four collaboration requests already had funding security; one full proposal was funded; and six proposals were invited to go for a full (step-2) proposal (outcome to be announced in 2020).

Planning

In the planning phase, ECRIN can give input on the different aspects of funding applications such as work package architecture, potential impact, management, governance, consortium composition, and multinational clinical trial management. ECRIN can also advise on the types of available (European) funding and how to go about applying. EuCos, who act as the intermediary between the sponsor and service providers

(i.e. national networks and CTUs), can provide information in particular on the facilities that have the capacity and services needed to manage the trial. They ensure that the CTUs selected for the study are an appropriate fit, both in their country and in other European countries. They can also advise on anything from ethical/regulatory requirements to trial insurance, and can provide a logistical evaluation and/or risk assessment (see below) of project plans.

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

Figure: ECRIN Support Services

⁹ECRIN member countries benefit from the full range of ECRIN services for multinational trial planning, risk assessment, and operational coordination. To be eligible for ECRIN support, projects must involve at least two ECRIN member or observer countries; the protocol and trial plans must be reviewed and approved by ECRIN. ECRIN can provide support services even if the trial's coordinating country is not a member or observer, provided that the project involves at least two member and observer countries. In this case, one of ECRIN's EuCos or the core team is assigned to the trial.

Risk Assessment

Once funding has been secured, and before implementation, projects are submitted to ECRIN for risk assessment. EuCos and nominated risk management team assess the risk related to project implementation (e.g. patient recruitment, timelines, budget). They give suggestions and alternatives to minimise any identified risk factors. Moreover, ECRIN can provide independent peer-review of the pre-final protocol to assess risk of bias, with recommendations on how to reduce this risk. This review is done by ECRIN's independent Scientific Board of clinical research and methodology experts.

Operational Coordination

During project implementation, ECRIN delivers various trial management services to sponsors / project coordinators. ECRIN coordinates these services, some of which are performed directly by CTUs in ECRIN's member and observer countries.

As indicated in the previous illustration, these services range from study management to monitoring, vigilance, and data management.

Trial Support in 2019

In 2019, ECRIN proposed comprehensive support to investigators and sponsors for funding applications. While the majority of support was provided for H2020 calls, ECRIN also assisted with applications to projects such as conect4children (c4c) (funded by the Innovative Medicines Initiative, IMI). It was also contacted directly by other academic institutions.

In addition, various existing projects contacted ECRIN throughout the year to see if the organisation could provide trial management support services.



ECRIN proposed comprehensive support to investigators and sponsors for funding applications.

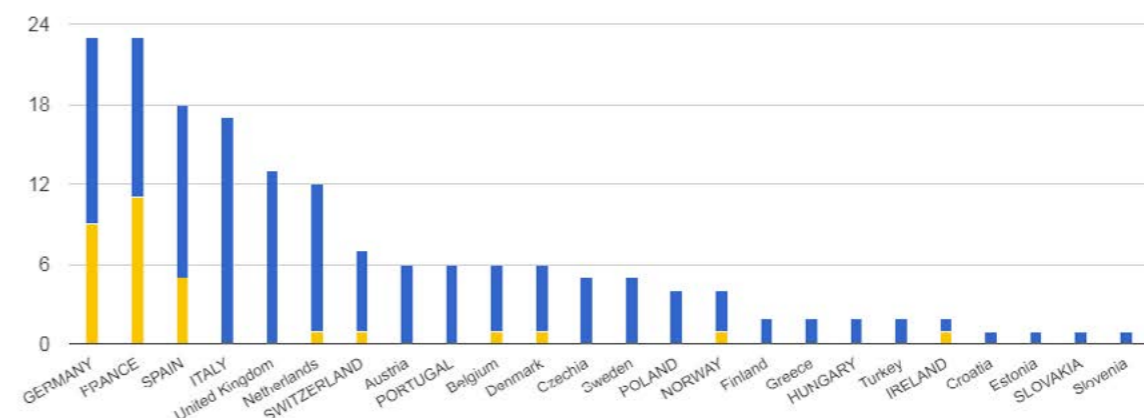
Clinical Trial Portfolio in 2019 (current trials)

At the end of 2019, ECRIN's trial portfolio included 36 'current' trials. However, ECRIN provided support to an additional nine trials during the year, bringing the total number of trials having received ECRIN support in 2019 to 45.

The trial portfolio below illustrates the country coordination / participation for ECRIN-supported trials as of 31 December 2019.

Clinical Trial Portfolio (all trials)

The total ECRIN trial portfolio, including past studies, reached 58 studies in 2019.

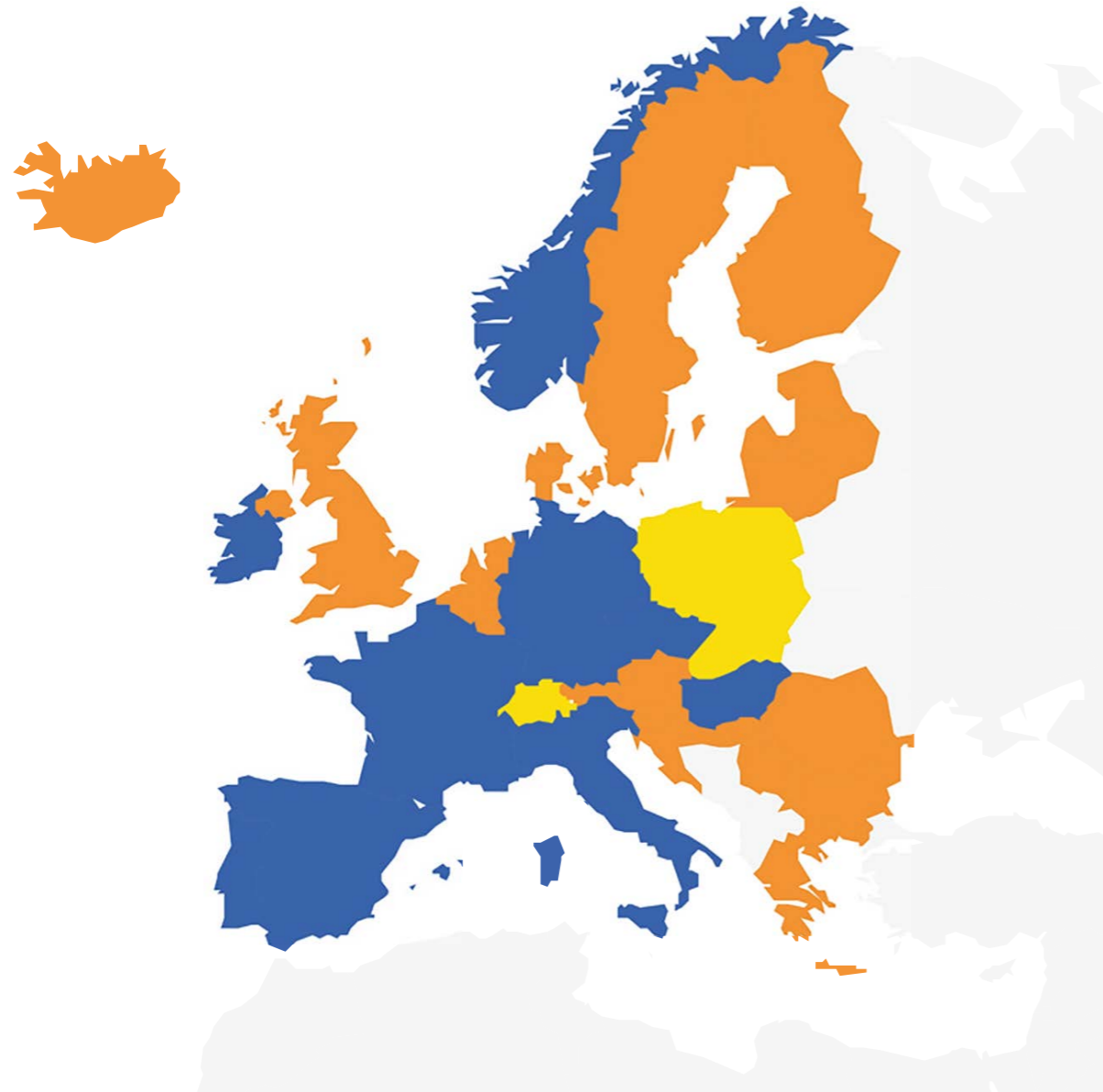


Number of Trials Per Country (current)

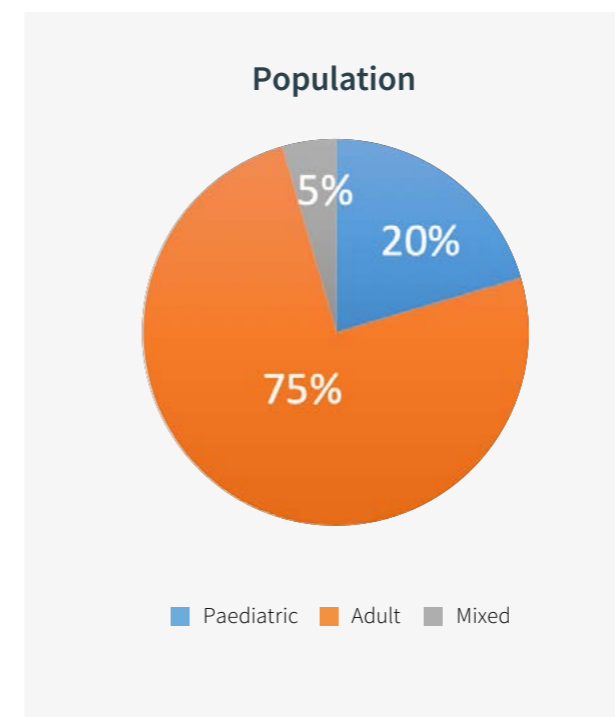
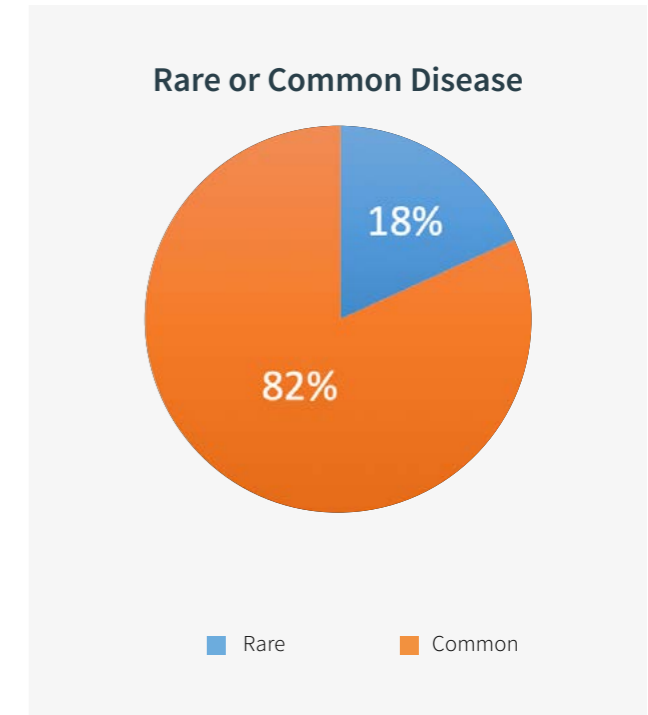
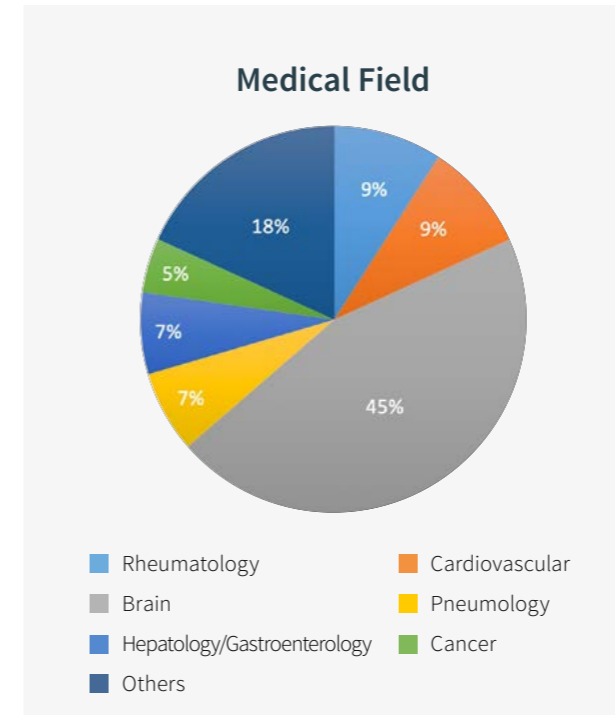
ECRIN member/observer countries listed in capital letters

■ Coordinating country ■ Participating country

Countries involved in clinical trials (current and past)



■ ECRIN member country ■ ECRIN observer country ■ Other country



The charts provide a glimpse of the range of medical fields covered by ECRIN-supported trials (current) and type of population. In effect, ECRIN works across all medical fields and disease areas.

Infrastructure Development

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

ECRIN Membership and Collaboration

In 2019, new infrastructure development projects involving ECRIN as a partner were launched:

Partnerships with medical specialties:

- **EBRA** (European Brain Research Area)
- **ECRAID-Plan** (European Clinical Research Alliance on Infectious Diseases Business Plan)
- **EJP-RD** (European Joint Programme on Rare Diseases)
- **TB-Med** (A testing bed for the development of high-risk medical devices)
- **EU-PEARL** (EU Patient centric clinical trial Platforms)



Data:

- **EOSC-Life** (Providing an open collaborative space for digital biology in Europe)
- **SYNCHROS** (SYnergies for Cohorts in Health: integrating the Role of all Stakeholders)

International cooperation:

- **EULAC-PerMed** (Widening EU-CELAC policy and research cooperation in Personalised Medicine)
- **RI-VIS** (Expanding research infrastructure visibility to strengthen strategic partnerships)

Strategy, policy, development:

- **ERIC Forum** (ERIC Forum Implementation project)

Note: for funding information on the above projects, see the endnotes. Reference numbers for aforementioned projects can be found in the highlights section (and not in the current section).

Focus on Personalised Medicine

In 2019, ECRIN's focus on personalised medicine was seen in particular through its involvement in the EULAC-PerMed project. The H2020-funded project aims to:

- Map existing programmes, capacities and expertise and gaps in the Community of Latin American and Caribbean States (CELAC) countries;



Featured EULAC-PerMed Events

EULAC-PerMed organised the 'Great Week of Personalised Medicine' (PM) in Montevideo, Uruguay, from 9 to 13 December 2019. The events were hosted by the Agency for Research and Innovation in Uruguay (ANII), a partner of EULAC-PerMed.

Event 1: 2nd Summer School on 'Health Technology Assessment (HTA) Research & PerMed' (9-10 Dec.)

Forty participants from EU and LAC countries learned about HTA and its relevance for personalised medicine, addressing topics such as psychiatry, oncology screening, diagnostic and therapy, e-rare diseases, clinical trials, and genomics.

Event 2: Stakeholder Workshop (11-12 Dec.)

A Stakeholder Workshop, inaugurated by the Uruguayan Minister of Health, Dr. Jorge Bassó, brought together more than 70 participants (EULAC-PerMed consortium members; representatives from ministries of health, science and technology; R&I funding organisations; research centres; private companies, etc.). Participants learned about different PM activities in LAC countries, and discussed

opportunities and challenges to develop PM in the region and options to strengthen collaboration with Europe. Funding agencies from LAC countries were also able to discuss directly with the ICPPerMed Secretariat.

Event 3: Technical Workshop (12-13 Dec.)

Finally, a Technical Workshop entitled 'Innovative methodologies for data use and management in Personalised Medicine research' brought together 75 participants from Guatemala, Chile, Uruguay, Argentina, Italy, Brazil, Peru, The Netherlands, Spain, Costa Rica, Panama, and Colombia. Discussion topics included interoperability of data from multiomics studies, cohort integration, patient stratification through machine learning, optimisation of diagnosis through medical imaging, text mining of patient records and more.

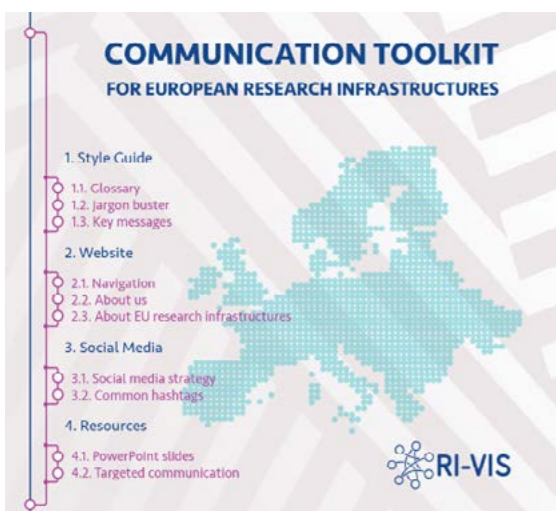
Meeting with the President of Uruguay

An EULAC-PerMed delegation (including ECRIN's Director General) was received by the President of the Republic of Uruguay, Dr. Tabaré Vázquez, who expressed his thanks to the consortium for the week of events.

View the project website: www.eulac-permed.eu

- Facilitate the incorporation of CELAC countries in the International Consortium on Personalized Medicine (ICPerMed) and in the ERA-Net ERAPerMed;
- Foster the participation of CELAC countries in research mobility and transnational projects on PerMed, and create a platform for EU-CELAC collaboration on PerMed-focused clinical trials
- Promote cross-border learning from Research & Innovation (R&I) and Ethical, Legal, Social Aspects (ELSA) for implementing innovations between research capacities based in the EU and CELAC countries.

Other New Projects in 2019



Example: RI-VIS

In a different area of activity, ECRIN also worked to strengthen its own communication and collaboration with other European RIs in the context of the RI-VIS project. Throughout the year, ECRIN participated in two communications working groups, which contributed to the development of a draft communications toolkit at the end of the year. This tool (pictured above) will help ECRIN and other participating RIs to enhance their communication in view of increasing their international visibility.

Learn more: <https://ri-vis.eu/network/rivis/home>

Ongoing Projects

In 2019 ECRIN continued to be involved, as coordinator or participant, in various other H2020 projects. Updates on select projects and activity areas are provided below.

PedCRIN

Launched in 2017, PedCRIN^{xv} (H2020-funded Paediatric Clinical Research Infrastructure Network, www.pedcrin.org) involves the development and testing of tools and services designed specifically to support paediatric trials and strengthen ECRIN capacity and expertise in the field.

Throughout 2019, PedCRIN continued to develop tools and services and to provide support to three investigator-initiated paediatric or neonatal interventional clinical studies on medicinal products: 1) The WE-study–Walking Easier with cerebral palsy, 2) A randomised trial of prophylactic oropharyngeal surfactant for preterm infants: the POPART trial, 3) Oxytocin Treatment in Neonates/Infants with Prader-Willi syndrome: the OTBB3 study.

PedCRIN is one of the initiatives¹¹ funded by the EU Commission with the objective to foster the development and the access to medicines for the paediatric patients and the development and implementation of multinational clinical research.

ECRIN-ERIC, as other ESFRI biomedical infrastructures was designed as a generic, disease-agnostic instrument. ECRIN provides generic services to trial management tasks, supporting the sponsor in multinational trials, and PedCRIN was designed to strengthen ECRIN capacity to manage paediatric clinical trials. Stable partnership with the paediatric investigation network (as with any disease-specific investigation network) will streamline the interface with investigators, providing the scientific content and access to patients. In such a partnership, a clear distribution of roles is needed to avoid overlap and duplication, to optimise the use of resources, enable cross-fertilization across countries and across disciplines, and benefit the paediatric community.

CORBEL

CORBEL (www.corbel-project.eu) is another H2020-funded project that remained a focus in 2019. The project aims to establish shared services between the ESFRI Biological and Medical Sciences Research Infrastructures (ESFRI BMS RIs)–which includes ECRIN–for the biomedical research community. This is achieved through the creation of ‘cross-infrastructure scientific workflows’, development of common services, and development of partnerships with user communities.

One highlight in 2019 was the 2nd CORBEL Service Operator and User Meeting, which was held in Heidelberg, Germany from 1 to 2 October. The event brought together European scientists who have received CORBEL support to advance their various projects, and the RIs providing the support services. ECRIN was involved in one of these projects in the medical area.

In the context of CORBEL, ECRIN also continued to lead the work package for the Medical Infrastructure User Forum (MIUF). This is a unique forum that enables dialogue and action planning between various stakeholders involved in European clinical research including medical research communities, funding bodies, and medical RIs.

Data Sharing

Data sharing and optimal reuse of data are key challenges for the clinical research community. In 2019, ECRIN continued to address data-sharing issues through its involvement in

various projects. For example, in CORBEL, ECRIN worked on clinical trial data sharing and reuse, and participates in the development of solutions for multimodal data management. Upon the completion of the project in 2020, much of this data work will be continued as part of the European Open Science Cloud projects.

The analysis and re-use of data is addressed by the European Open Science Cloud pilot project (EOSCpilot)^{xvi}, which supports the first phase in the development of the European Open Science Cloud (EOSC). ECRIN is involved in the EOSCpilot work package on policy, and is the lead, along with BBMRI, of the task on ethics. ECRIN is also part of the EOSC-hub^{xvii} project that aims to define the governance of the EOSC. EOSC-Life builds off of the work achieved with CORBEL partners to create an open collaborative space for digital biology.

Another data-related project is the H2020-funded eXtreme DataCloud (XDC)^{xviii} aimed at developing scalable technologies for federating storage resources and managing data in highly distributed computing environments. The services provided will be capable of operating at the unprecedented scale required by the most demanding, data intensive, research experiments in Europe and worldwide.

For the full list of ECRIN-supported infrastructure development projects, see here: www.ecrin.org/activities/projects

¹¹ c4c: conect4children - Collaborative Network for European Clinical Trials For Children (funded by IMI under GA n° 777389)
 EPTRI : European Paediatric Translational Research Infrastructure funded by H2020 under GA n° 777554
 EJP RD: European Joint Programme on Rare Diseases funded by H2020 under GA n° 525575
 PedCRIN: paediatric clinical research infrastructure network. Funded by H2020 under GA no. 731046

Partnerships

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

ECRIN Membership and Collaboration

The expansion of ECRIN membership remained a key priority in 2019. As mentioned above, Poland joined as an observer country on 23 August 2019.

Following the addition of Poland, Annex II of the ECRIN statutes (list of members and observers) was updated on 23 August 2019. *These documents are available here:* www.ecrin.org/who-we-are/organisation-funding

An Alliance to Empower the European Biomedical Community: BBMRI, EATRIS and ECRIN

BBMRI, EATRIS, and ECRIN signed an agreement in Brussels in February 2019 to build a long-term, sustainable collaboration strategy. By joining forces, the three pan-European RIs hope to facilitate user access to their services (i.e. biobanking – BBMRI, multinational clinical trial support – ECRIN, translational medicine – EATRIS), and to support the development of joint tools, services, and approaches. This in turn will support a more cost-effective research and development process.

In a press release that was issued following the signing of the agreement, EATRIS's scientific director, Toni Andreu, said: 'It is very exciting to work more closely with these other infrastructures to jointly tackle pressing issues in medicines development for the benefit of patients, particularly in the field of personalised medicine'. BBMRI's director general, Erik Steinfeldt, added: 'Increasing our collaboration will also decrease isolation and fragmentation of efforts. Most importantly, such an alliance will significantly increase the impact of activities and minimise waste of precious resources'. Finally, ECRIN's director general, Jacques Demotes, noted: 'The digital revolution and the new regulatory framework of patient-centred research results in complex and multidisciplinary research programmes, requiring tight cooperation between infrastructures supporting translational research, biobanking and clinical research to provide joint services for cross-border transfer of data and biosamples, cohort integration, multimodal data management, machine learning, and multinational trials'.

By facilitating the use of their services by the European research community, and developing new and joint tools/services to overcome pressing research challenges, the three RIs ultimately hope to enable more robust, evidence-based science that will have a long-term positive impact on public health. The three organisations will lay out an implementation plan for the agreement in 2020.

Projects to Promote International Partnership and Multinational Collaboration

ECRIN also seeks to facilitate multinational clinical research on a global level through various projects, one example being the Clinical Research Initiative for Global Health (CRIGH), launched in 2017. A follow-up to the Organisation for Economic Co-operation and Development (OECD) Global Science Forum (GSF)

¹² An OECD Global Science Forum (GSF) initiative started in 2008 with the aim of fostering international cooperation in non-commercial trials, leading to a report in 2011, followed in 2012 by the 'OECD Recommendation on the Governance of Clinical Trials'.

initiative¹², CRIGH aims to serve as a support structure for international collaboration on clinical research for the benefit of patients, healthcare professionals, and health systems. The CRIGH secretariat is shared by the US National Institutes of Health (NIH) and ECRIN, and the project brings together research institutions across the globe.

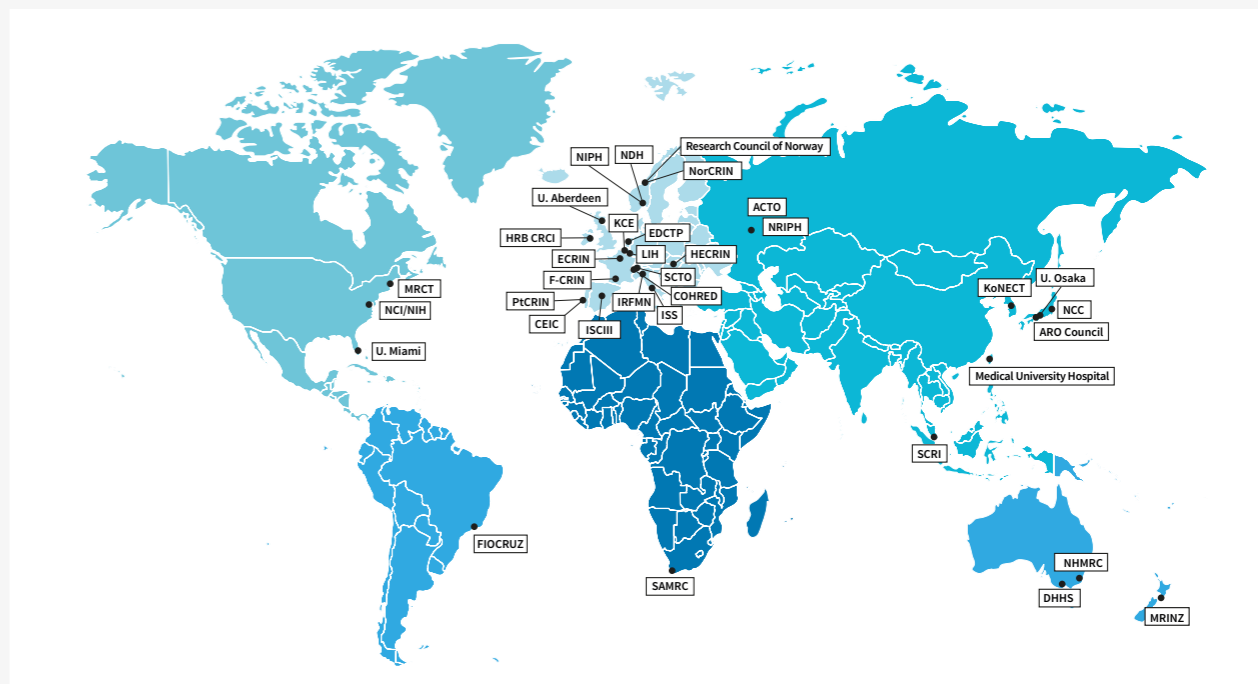
Learn more: www.crigh.org

The second CRIGH General Assembly held on the 20 and 21 June 2019 in Paris. Organised back-to-back with the 4th Global ARO¹³ meeting, it was an opportunity to discuss the progress of the various activities and establish a roadmap for the future actions to be developed. Breakout sessions enabled in-depth discussion within each project and coordination of activities across the projects. Transversal and overarching aspects related to international clinical research were presented to feed the discussion.

Participation in the International Health Technology Assessment conference in Cologne (HTAi) was an opportunity to reach out to the global HTA community, and to present both ECRIN and CRIGH as instruments to generate scientific evidence addressing questions raised by HTAs, while HTAs identify research gaps relevant for public health.



CRIGH General Assembly 2019 © ECRIN



Map of CRIGH Participants across the Globe¹⁴

¹³ ARO: Academic Research Organisation, Japan

¹⁴ For the full list of CRIGH participants, see here: <https://crigh.org/members-observers>

Quality

This section presents the challenges, opportunities and achievements for quality in 2019 and beyond.

ECRIN Internal Quality Management System (QMS)

Following the decision in early 2017 to apply for ECRIN ISO 9001:2015 certification, ECRIN continued to make the upgrading of its quality management system (QMS) a strategic priority throughout 2019.

ECRIN's QMS is fit-for-purpose and has been adapted to its distributed infrastructure. It follows a risk and process-based approach, which is founded on the recommendations of the ISO 9001:2015 standard and the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP; document E6(R2)). It aims to coordinate and structure the organisation's activities to meet customer and regulatory requirements, and to improve effectiveness and efficiency on an ongoing basis.

In 2019, ECRIN continued to adapt to changes in the clinical trial regulatory environment and other requirements such as: the European adoption in June 2017 of the aforementioned ICH E6(R2) GCP Guideline, EU Clinical Trial Regulation 536/2014, and the EU General Data Protection Regulation (GDPR) 2016/679.

ECRIN also made significant progress in 2019 in the preparation of its QMS for ISO 9001: 2015 certification. In particular, it formalised processes



related to user satisfaction, infrastructure development project management and agreements management. Pursuing its optimisation of ECRIN electronic infrastructure, it formalised its strategy for information systems architecture, data privacy and confidentiality, and security requirements.

ECRIN's Quality and Risk Council met for its annual meeting to review overall quality performance. In particular, the Council evaluated the pre-defined key performance indicators (KPIs) for ECRIN's processes, as well as its risk-based internal auditing programme. Recommendations and adjustments were made to improve the overall QMS.

Finally, in order to fulfil its coordination role and the responsibility given to it by the clinical trial sponsor, ECRIN continued to collect information from its partners to ensure that they meet the highest capacity and quality standards. This was achieved through a self-assessment questionnaire, which must be completed before the provision of services begins.

¹⁵ The Quality and Risk Council is chaired by the Head of Quality and Information Systems (IS) and is composed of the ECRIN Director General, Operations Director, Head of Clinical Operations, Supervisor of processes, a European Correspondent representative, and ad hoc representatives (upon request).

¹⁶ The periodic assessment of KPIs is performed to monitor the performance of each process in order to continuously improve the overall quality of ECRIN services.

Quality as a Service: Data Management Centre Certification Programme

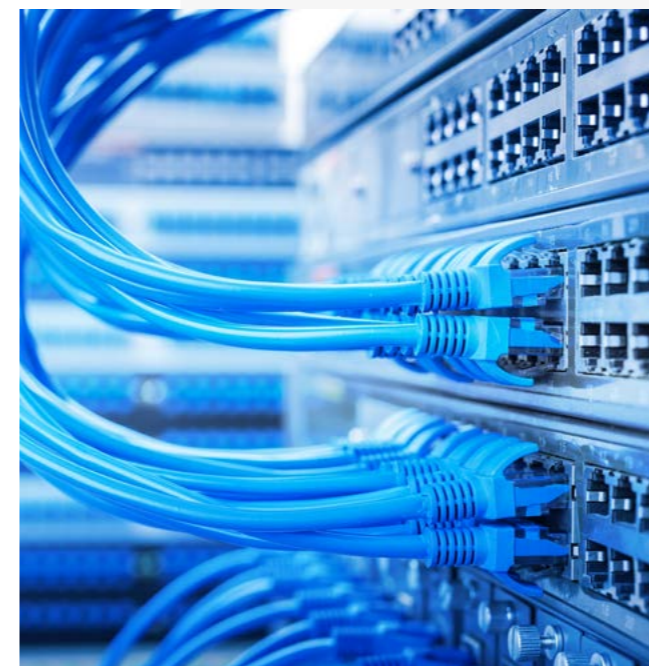
ECRIN also offers 'Quality as a Service' through its Data Management Centre Certification programme. The programme certifies non-commercial data centres from ECRIN member and observer countries which have demonstrated that they can provide safe, secure, compliant and efficient management of clinical research data. Data centres can apply to the programme through an annual call for applications. Applications are assessed by the ECRIN Independent Certification Board (ICB)¹⁷.

An on-site audit is performed to assess the centre's data management activities and IT infrastructure. This is done using published ECRIN data management (DM) standards¹⁸, as described in 'Requirements for Certification of ECRIN Data

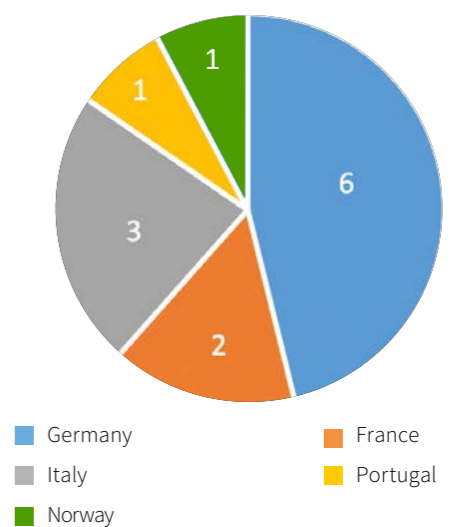
Centres, with Explanation and Elaboration of Standards, Version 4.0'. Key to the programme's effectiveness is the broad acceptance of the DM standards as well as a high-quality process to ensure adherence.

Given the significant changes in recent years for clinical trial data management (e.g. increasing use of cloud-based infrastructure and 'software as a service' (SaaS), new regulatory requirements for data integrity), the ECRIN DM standards underwent a comprehensive review in 2017. The new revised version 4.0 of the standards was published in 2018. These standards were applied for the audits conducted in 2019.

During the year, two European additional centres received a positive certification decision, bringing the total number of ECRIN-certified centres to 15¹⁹.



Current certified data centres



¹⁷ The ICB is composed of a chair and six (as of end 2018) independent expert members, all of whom are senior staff with significant experience in clinical research. They are nominated by ECRIN countries. The ICB conducts an objective, independent assessment of audit results and auditor reports, and awards certification or requests a re-audit or document review (after which the certification decision is re-considered).

¹⁸ The ECRIN DM standards comprise 106 criteria.

¹⁹ The certification period for two of the data centres has lapsed, bringing the total number of currently certified centres to 13.

Programme Expansion

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

- Assess compliance of the data centres with ECRIN's DM standards
- Oversee and approve the appointment of Japanese auditors
- Contribute to the training of auditors and preparation for the future implementation of a regional certification programme in Asia

In 2019, ECRIN continued to lay the groundwork for the expansion of the programme to Asia (and beyond), and launched a pilot programme in South Korea in collaboration with the Medical Research Collaboration Center (MRCC) at Seoul National University Hospital.

Following audits of two non-commercial Japanese data centres in the fall of 2018, the Translational Research Centre for Medical Innovation (TRI) at Kobe was certified.



Harmonisation of good practices and enhancing of high-quality data management in European non-commercial clinical trials.

⁹ Learn more: www.ecrin.org/news/corbel-miuf-meeting

The presentation of ECRIN data management and data sharing services at the European Quality Assurance Conference (6-8 Nov.) triggered high interest from participants and European authority representatives. Its contribution to the harmonisation of good practices and enhancing of high-quality data management in European non-commercial clinical trials was recognised.

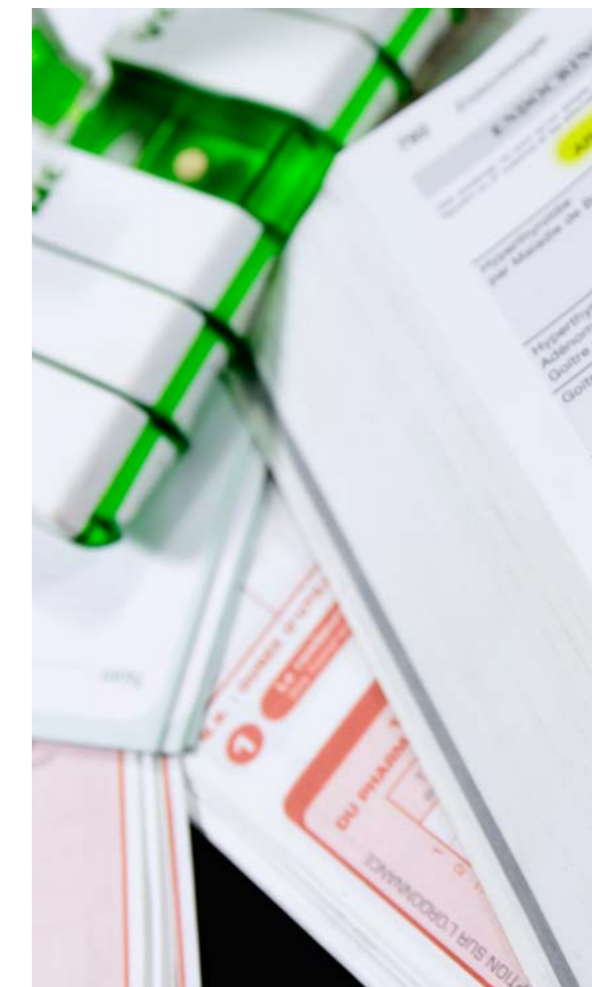
Benefits for Participants

The potential rewards for Data Management Centre Certification programme participants are numerous. Data centres can benefit from the sharing of the latest technical developments (maintenance of up-to-date standards reflecting state-of-the-art practice) and training on data management / IT 'hot topics' (e.g. data sharing, Clinical Data Interchange Standards Consortium - CDISC), clinical data management). Finally, auditors from CTUs involved in the certification programme receive advanced training on data management / IT, and thus may play a leading expert role in discussions on these topics in their respective countries.

Pharmacovigilance Qualification and Compliance

In 2019, ECRIN continued to develop its project (initiated in 2018) to develop pharmacovigilance qualification and compliance standards. This entails 1) creating a fit-for-purpose set of pharmacovigilance (PV) standards which interpret regulatory and good practice requirements, in the context of academic central pharmacovigilance in Europe, and 2) identifying the CTUs within ECRIN member or observer countries that are capable of running central PV services in compliance with the current EU requirements.

For this purpose, ECRIN set up a working group in 2018 composed of 19 experts, with at least one representative from each ECRIN member/observer country (individuals were selected by ECRIN's Network Committee). In 2019, the group continued to meet monthly and presented its work to the Network Committee. The group is currently working on the development of a set of standards that will be used to evaluate pharmacovigilance centres' compliance and ability to provide high-quality central pharmacovigilance tasks.



Training

Staff Training

Summer School

One of ECRIN's main internal training events is the annual Summer School, targeted at the Management Office (i.e. core team and EuCos). In particular, the Summer School aims to provide training in areas related to the tasks performed by EuCos and the core team; to foster discussion on issues related to these tasks in a constructive environment; and to agree on potential courses of action to address potential problems.

ECRIN held its Summer School in Balatonfüred, Hungary from 11 to 13 September 2019.

The Summer School involved workshops and presentations, and addressed topics such as costing, clinical trial training in university education (e.g. as part of the Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students, or



CONSCIOUS project), e-learning, education of clinical trial teams, ECRIN member country practices, and training of multinational coordinating investigators. There were also team-building exercises such as a boating race (see one of the victorious teams pictured above).

Mentorship Programme

Also in 2019, ECRIN continued its mentorship programme, which was introduced in 2017. Through the programme, one of the most experienced EuCos provides regular mentoring to the other EuCos, in addition to the support they receive from management staff in Paris.

Training as a Service (external training)

MiRoR

As partner of the Marie Curie MiRoR (Methods in Research on Research) project, ECRIN hosted two PhD students in 2019.

Learn more: <http://miror-ejd.eu/>

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An excellent opportunity to support EuCos, including new ones and more experienced staff



Meet the Mentor: Amélie Michon

'The mentoring programme has been an excellent opportunity to support EuCos, including new ones and more experienced staff, to overcome the hurdles to multi-national trials', said Amélie Michon, senior EuCo and EuCo mentor. 'In 2019,

I worked with EuCos from the Czech Republic, Italy, Portugal, Norway and Ireland on various topics. For example, one time a EuCo needed information on how to proceed when a sponsor/principal investigator contacts ECRIN with a collaboration request. I organised a specific training session with the EuCo to explain all the necessary steps to have the project evaluated by ECRIN's Collaboration Committee (signature of confidentiality agreement, discussion with the PI to define the support they need, reference to the appropriate forms to complete, and so on). I also organised four training sessions with new European Correspondents as well as European Correspondents undertaking the development of proposals and the coordination of clinical projects'.

Communications

The optimisation of internal and external communications activities was a continued focus in 2019. Achievements included the optimisation of the website, and the increasing use of social media, with the number of Twitter followers reaching more than 700. In 2019 ECRIN also supported the communications activities of various infrastructure development projects, such as CORBEL, PedCRIN and RI-VIS.

Scientific communication in particular was a central activity throughout 2019. ECRIN organised ICTD 2019, and participated in various European and international scientific conferences.

Scientific Publications

ECRIN contributed to multiple scientific publications (see below) in 2019. ECRIN's scientific publications are generally related to the trials that it supports, the projects it participates in or leads, its quality initiatives, and/or the activities of its national networks. In addition, ECRIN-supported trials generated six papers in peer-reviewed journals in 2019. Both categories of publications (i.e. those ECRIN directly contributed to as well as those related to ECRIN-supported trials) are listed in appendix.



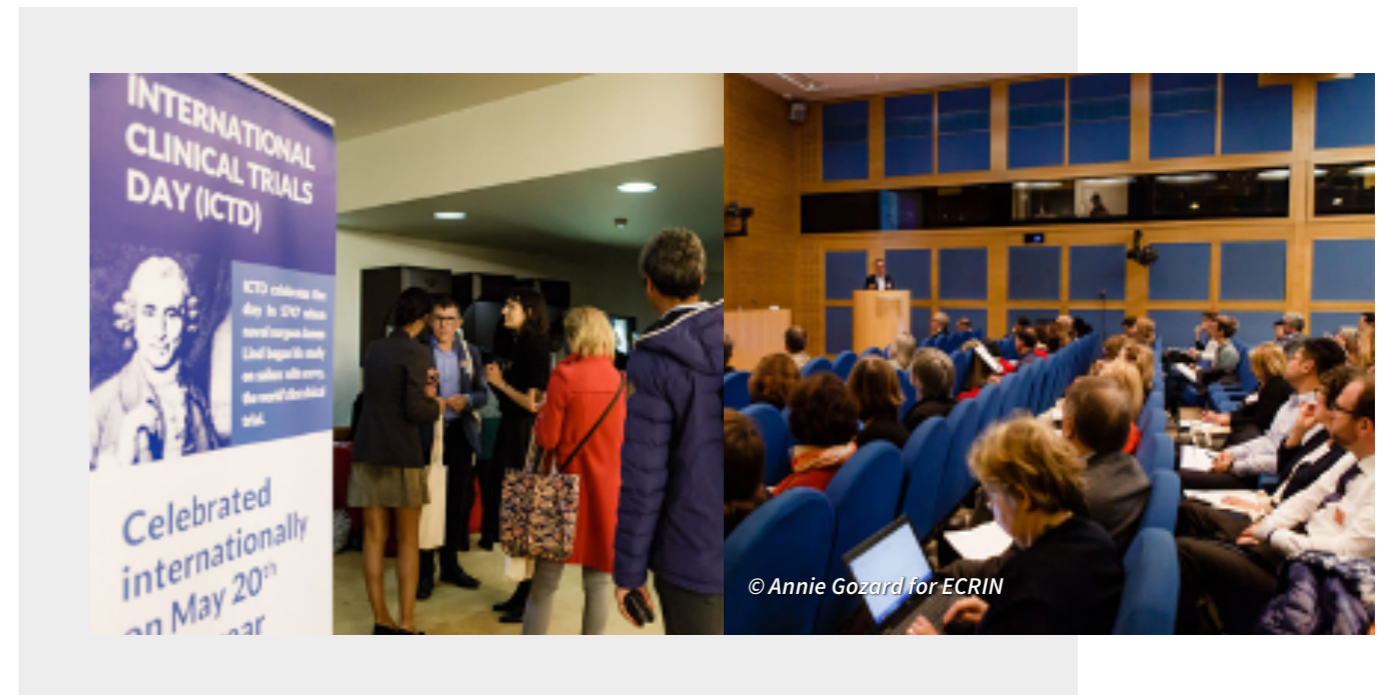
Personalised medicine

Personalised medicine aims to deliver the best and most appropriate healthcare strategy to each patient subgroup. This requires the

identification of patient groups based on the understanding of disease mechanisms (hypothesis-driven approach) or following mechanism-agnostic clustering (data-driven approach). Although both approaches can co-exist, the data-driven approach is now made easier because of the availability of large multimodal datasets combining clinical, imaging and multiomics data from broad patient populations, collected either prospectively or retrospectively in the context of observational or interventional studies. Such large datasets are exploited by machine-learning algorithms to stratify the patient population.

Regardless of the approach used to

stratify patients, randomised clinical trials are necessary to compare and validate treatment strategies. Depending on the nature of the biomarker signature underpinning stratification, and the understanding of the drug's mechanism of action, linking a biomarker profile with a treatment option may be a relatively easy or very difficult task. New designs (i.e. basket and umbrella trials) are becoming more widespread in randomised trials in order to validate proposed treatment options. Although these approaches were first designed and implemented in the field of cancer, they have now spread rapidly to other disease areas.



ICTD 2019: Patient Stratification Studies, Paris, 20 May

ECRIN and its French scientific partner, the French Clinical Research Infrastructure Network (F-CRIN), organised a conference in Paris, France on May 20th, 2019 to celebrate International Clinical Trials Day (ICTD).

ICTD 2019 brought together ECRIN's internal stakeholders and partners, and additional scientists and policymakers from France, the rest of Europe, and beyond. The meeting objective was to engage participants in discussion on issues related to multinational clinical trials and the clinical research landscape in Europe. ICTD 2019 focused on challenges raised by patient stratification studies. For background information on personalised medicine, see the box on the left page.

The meeting took place at Luxembourg Palace in Paris from 10:30 to 16:30 CET.

For the full draft agenda, see here: <https://www.ecrin.org/events/ictd>

Speaker Topics and Background

Opening comments were made by Gérard Larcher, president of the French Senate, Gilles Bloch, CEO of the French National Institute of Health and Medical Research (Institut national de la santé et de la recherche médicale, INSERM), and professors Jacques Demotes (ECRIN Director General) and Olivier Rascol (coordinator of F-CRIN).

The conference then featured a talk about an ongoing patient stratification study entitled 'Taxonomy of Neurodegenerative Diseases: Observational Study in Alzheimer's Disease and Parkinson's Disease' ('AETIONOMY'). The investigator-led study, which is currently supported by ECRIN, served as a 'use case', illustrating the various issues and challenges that arise from a multinational clinical study using patient stratification. Subsequent talks then addressed these issues and challenges, proposing paths forward to take advantage of the opportunities created by patient stratification and patient-centred research in the age of big data. The ultimate goal is to develop the best therapeutic solution for specific subgroups of patients.

ECRIN Team

2019 was marked by the scaling up of activities, requiring changes in ECRIN's internal organisation and staff competencies. New hires joined the organisation in during the year.

Core Team	
Marta Bastucci	Executive Assistant
Serena Battaglia	Capacity Program Manager
Marta del Alamo	Project Manager
Jacques Demotes	Director General
Sabrina Gaber	Communications Officer
Paula Garcia	Project Manager
Sergei Gorianin	Data Scientist
Sabine Kläger	Head of Clinical Operations Unit
Christine Kubiak	Operations Director
Patricia Le Mouel	Assistant
Salma Malik	Paediatric Project Manager
Mihaela Matei	Legal and Regulatory Officer
Arthur Smaal	Quality Officer
Alicja Szofer-Araya	Head of Administration and Finance
Christine Toneatti	Head of Quality and IS Unit
Experts and Consultants	
Vittorio Bertelé	Scientific Board Secretariat
Chiara Gherardi	Scientific Board Secretariat
Steve Canham	Data Management Consultant
Christian Ohmann	Data Management Expert
Joaquín Sáez Peñataro	Medical Expert

European Correspondents	
Kateřina Nebeská	Czech Republic
Kristýna Nosková	Czech Republic
Lenka Součková	Czech Republic
Amélie Michon	France
Luc Wasungu	France
Sarhan Yaïche	France
Linda Stöhr	Germany
Laura Vieweg	Germany
Zita Tarjányi	Hungary
Suzanne Bracken	Ireland
Fiona Cregg	Ireland
Maria Buoncervello	Italy
Elena Toschi	Italy
Valentina Cabral Iversen	Norway
Agata Smoleń	Poland
Bernadetta Wisniewska	Poland
Joana Batuca	Portugal
Catarina Madeira	Portugal
Simona Sonderlichová	Slovakia
Stefan Toth	Slovakia
Juan Ferrero-Cafiero	Spain
Adriana Vives	Spain
Caecilia Schmid	Switzerland

**Note: the core team and European correspondent lists include individuals who started working for ECRIN in 2019, as well as those who left the organisation.*



National Scientific Partners

Country	National Scientific Partner (CTU Network)	Host Institution	National Hub ²⁰
Czech Republic	CZECRIN	Masaryk University	Brno
France	F-CRIN	INSERM	Toulouse
Germany	KKS Network	KKS-Netzwerk e. V.	Berlin
Hungary	HECRIN	University of Pécs	Pécs
Ireland	HRB CRCI	Clinical Research Development Ireland (CRDI)	Dublin
Italy	ItaCRIN	Istituto Superiore di Sanita (ISS)	Rome
Norway	NorCRIN	St. Olaf's Hospital	Trondheim
Poland*	POLCRIN	Polish Medical Research Agency (MRA)	Warsaw
Portugal	PtCRIN	NOVA University	Lisbon
Slovakia*	SLOVACRIN	Pavol Jozef Šafárik University	Košice
Spain	SCReN	Instituto de Investigación Sanitaria del Hospital Clínico San Carlos	Madrid
Switzerland*	SCTO	SCTO	Bern

*Observer country

²⁰ 'Hub' refers to the city where the national CTU network (i.e. national scientific partner) is headquartered. The hub generally provides central management services to the network of CTUs.



Czech Republic

Member since 1 Jan. 2018

Scientific Partner: CZECRIN - Czech Clinical Research Infrastructure Network

CZECRIN is a national research infrastructure network that facilitates academic clinical trials in the Czech Republic. In 2019 CZECRIN celebrated the 2nd year as an ECRIN member country. CZECRIN is included in the Ministry of Education, Youth and Sports' Roadmap for Large Research, Development and Innovation Infrastructures. It provides full services for clinical research, including knowledge, training activities, methodological and service support for investigator-initiated clinical trials. It encourages national and international clinical research collaboration for the benefit of patients, habitants and healthcare. CZECRIN also

annually organise the educational events and conferences including International Clinical Trials Days. Masaryk University as CZECRIN's national hub, coordinate the university module, with St. Anne's University Hospital Brno as a partner that coordinate the clinical module. The university module brings together clinical trial centres (CTCs) located in Czech universities. The clinical trials module has grown by 2 CTCs and currently includes 10 CTCs within the university hospitals.

Website: www.czecrin.cz/czecrin-en



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France

Member since 29 Nov. 2013

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

F-CRIN, created in 2012, is the single contact point facilitating the participation of France in clinical studies. F-CRIN brings together the major academic and commercial stakeholders in clinical research in France, including clinical research and innovation departments in university hospitals, clinical investigation centres, and interregional groups for clinical research and innovation.

F-CRIN enables multinational or multicentre, investigator-driven, clinical trials and early phase proof-of-concept studies. Clinical trial support is provided through F-CRIN by:

- 12 national networks specialised in specific diseases or areas of medicine (e.g. cardiology,

nutrition, inflammatory disease, cardiorenal diseases, thrombosis, vaccinology, Parkinson's disease, sepsis)

- 4 specific expertise networks (methodology, medical devices, rare diseases)
- 2 platforms of professional services (EUCLID and PARTNERS)

2019 HIGHLIGHTS

-After its positive evaluation in 2019, F-CRIN has been extended until 2025 and refunded

-In 2019, F-CRIN was involved in several ECRIN clinical projects

-F-CRIN and ECRIN organised together, in France (Paris), ICTD (International Clinical Trials Day) 2019

-F-CRIN also began to prepare for a training session on data for 2020, as a follow-up to a session that was held in France in November 2018 (organised with ECRIN)

Website: www.fcrin.org



Germany

Member since 29 Nov. 2013

Scientific Partner: KKS - Netzwerk der Koordinierungszentren für Klinische Studien

KKS-Netzwerk (KKS), the German network of coordinating centres for clinical trials, was established in 2005 and comprises 24 academic coordinating centres for clinical trials (as of December 2019). The KKS headquarters are located in Berlin, next to the German ECRIN office. CTUs in KKS 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 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 the network. In addition, network members are involved in various national and international clinical research projects, and collaborate with diverse stakeholders.

Website: www.kks-netzwerk.de



Hungary

Member since 5 Nov. 2014

Scientific Partner: HECRIN - Hungarian Clinical Research Infrastructure Network

HECRIN currently comprises 17 hospitals and medical institutes in Hungary. Its goal is to extend membership nationally and to establish clinical trial coordinating centres at member sites. The HECRIN central office is at the University of Pécs.

HECRIN Consortium developed a Hungarian national clinical trial unit network with four CTUs at the Universities and one CTU for the paediatric studies in Hungary that are able to provide management support for clinical trials.

Further aims are to extend membership nationally and to improve the landscape for clinical research in Hungary, tapping into the innovation potential of Hungarian academic partners. The Consortium provides support to national investigators through the accredited processes in strengthening the potential of the clinical research and in the transposition of research into practice and seeking to internationalize clinical trials, and to involve their country in clinical trials initiated by investigators in other European countries. In addition, the Consortium promotes the continuous professional training of the study team and the supporters, as well as it strives with special efforts for the utilization of clinical data assets for research purposes.

2019 HIGHLIGHTS

-Celebrated 5 years as an ECRIN full member country

-Organised the ECRIN annual internal Summer School in Balatonfüred, Hungary. The most relevant topics were metadata repositories, data management, data centres, education of clinical teams, member country activities, GDPR and trial costing.

Website: www.hecrin.pte.hu/en



Ireland

Member since 20 Nov. 2018

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

HRB CRCI is an independent integrated national clinical research network, providing centralised support in the conduct of multicentre clinical trials and investigations/studies (both commercial and academic) across Ireland 'for the benefit of people's health and the economy'. Operational since May 2015, it is funded by extramural grants from the Health Research Board (HRB) and Enterprise Ireland (EI), supported by the six medical schools in Ireland, and is hosted by Clinical Research Development Ireland (CRDI).

The HRB CRCI central office provides overarching support and expertise, through a range of services and activities to academia and industry. CRDI provides corporate support services to the central office. The partner university clinical research facilities/centres (CRFs/CRCs)²¹ 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.

Website: www.hrb-crci.ie



Italy

Member since 29 Nov. 2013

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

ItaCRIN is the national clinical research infrastructure in Italy. ItaCRIN currently comprises 10 participants capable of providing services for clinical research. The network includes academic CTUs and CTUs with 'IRCSS' (Istituto di Ricovero e Cura a Carattere Scientifico)²² accreditation, as well as clinical research organisations (CROs) dedicated to independent clinical studies. The national hub of ItaCRIN is located at the Istituto Superiore di Sanità (ISS) in Rome. The main purpose of ItaCRIN is to promote, through international networking, excellent non-profit clinical research focused on identifying advanced therapeutic strategies for the benefit of public health.

2019 HIGHLIGHTS

- Organised a meeting entitled 'Facilitating high-quality multinational clinical research in Europe: ECRIN mission and vision' at the Istituto Superiore di Sanità (ISS)
- Published the new website: www.itacrin.it
- Increased the ItaCRIN network with a new CTU

Website: www.itacrin.it

²¹ HRB CRI's partner CRFs/CRCs include: HRB CRF Cork at University College Cork and Mercy University Hospital; HRB CRF Galway at University Hospital Galway; Royal College of Surgeons Ireland CRC at Beaumont Hospital; University College Dublin CRCs at Mater Misericordiae University Hospital and St. Vincent's University Hospital; Wellcome Trust – HRB CRF at St. James's Hospital; HRI-CRSU: Health Research Institute Clinical Research Support Unit at University Hospital Limerick, Co Limerick; NCRC: National Children's Research Centre at Our Lady's Children's Hospital, Crumlin, Dublin 12.

²² IRCSS status is awarded to biomedical institutions of relevant national interest, which drive clinical assistance in strong relation to research activities. Their mission is the continuous upgrade of healthcare. The IRCSS title is granted by Italian Department of Health to a very limited number of institutes.



Norway

Member since 18 May 2016

Scientific Partner: NorCRIN - Norwegian Clinical Research Infrastructure

NorCRIN's aim is to facilitate clinical research by supporting the many complex elements of this type of research, such as study design, the application process, trial conduct, and GCP reporting. The main objective is to strengthen and simplify collaboration within all categories of clinical research in Norway.

The Ministry of Health and Care Services in Norway initiated the founding of NorCRIN, and Trondheim University Hospital (St. Olav's Hospital) is responsible for coordinating and operating the network.

Website: www.norcrin.no/in-english



Poland

Observer since 23 Aug. 2019

Scientific Partner: POLCRIN - Polish Clinical Research Infrastructure Network

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 aims to create an innovative healthcare system and to bring tangible benefits to patients. This will be achieved through the assessment of which new medical technologies and therapeutic methods should be used to meet the needs of society.

MRA will analyse decisions and their impact on the costs of the functioning of the healthcare system. These analyses will make it possible to present specific solutions, thanks to which the healthcare system will be able to function in a more efficient way.

The development of medical sciences and health sciences and contribution to the growth of innovation of Polish medicine are the most important goals that have been set before the newly established MRA. Its main role will be to provide funding for analyses and clinical trials in healthcare, with a specific focus on non-commercial trials (which constitute approximately 2% of all registered research).

2019 HIGHLIGHTS

- In August 2019, Poland, with its entity POLCRIN, became a part of the ECRIN community, with the status of observer country
- In 2019, POLCRIN worked to develop and support international, non-commercial clinical trials, and to create a strong collaborative environment for the CTU network

Website: <https://polcrin.abm.gov.pl/>

¹⁹ A user survey was conducted in September 2018, with a total of 149 respondents. Users indicated their involvement in academic vs. industrial studies (75% and 46%, respectively); means by which they became aware of NorCRIN; and satisfaction with NorCRIN services (+72% of users indicating they were satisfied or very satisfied).

²⁰ Official start early 2019.



Portugal

Member since 29 Nov. 2013

Scientific Partner: PtCRIN - Portuguese Clinical Research Infrastructure Network

PtCRIN is the national research infrastructure for clinical research in Portugal. PtCRIN is composed of 14 members which represent the leading Portuguese clinical research institutions, including hospitals, medical centres, universities and a research organisation.

PtCRIN is currently working on the development of a network of academic CROs and clinical sites. PtCRIN will position Portugal strategically in the rapidly evolving field of clinical research, giving Portuguese investigators an opportunity to influence the development of ethical guidelines, best practices, and new standards. In addition, European researchers will have access to Portugal as a clinical research venue.

Website: www.ptcrin.pt



Slovakia

Observer since 1 July 2018

Scientific Partner: SLOVACRIN - Slovak Clinical Research Infrastructure Network

SLOVACRIN is a national research infrastructure network connecting hospitals, universities and scientific institutions involved in academic clinical research. It is coordinated 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 studies in Slovakia, including international studies. The aim is to increase the number and quality of academically-initiated clinical trials in Slovakia, using the available capacity and expertise to ensure compliance with regulatory, legislative and ethical requirements related to clinical research. SLOVACRIN currently comprises 12 hospitals and 1 clinical trial centre at the Slovak Academy of Science.

2019 HIGHLIGHTS

-1st national SLOVACRIN meeting (22 March 2019), organised by the Faculty of Medicine of Pavol Jozef Šafárik University in Košice: this meeting was held on the occasion of the establishment of the Slovak academic research infrastructure (part of ECRIN)

-Course for Coordinators and Heads of Clinical Trials Departments in Medical Facilities (25-26 April 2019, in Bratislava): attended by nearly 80 participants, mainly from hospitals under the authority of the Ministry of Health, as well as other health care providers, representatives of research institutions and universities.



- Slovak International Clinical Trials Day 2019 (Slovak ICTD 2019): took place on May 30th, 2019 in Bratislava with the participation of ECRIN's Director General Jacques Demotes and leaders of national infrastructures within 'V4' countries, i.e. CZECRIN, which based at the Masaryk University in Brno, HECRIN, based at the University of Pécs in Hungary, and representatives from Poland. The CEO of SLOVACRIN and the Dean of the Faculty of Medicine of P. J. Šafárik University in Košice prof. Daniel Pella represented Slovakia. Representatives of the Ministry of Health of the Slovak Republic and the State Institute presented the direction of Slovakia in the area of support for academic clinical trials and biomedicine for drug control.

Websites:

<https://www.upjs.sk/en/faculty-of-medicine/research-department/slovacrin/>
<https://slovacrin.sk/en/>



Spain

Member since 29 Nov. 2013

Scientific Partner: SCReN - Spanish Clinical Research Network

SCReN is the National Platform on Clinical Trials in Spain. It is funded by the National Institute for Health Carlos III, and it is formed by a network of Spanish CTUs based in clinical centres of the Spanish National Health Service. There are currently 30 CTUs in the network spanning 12 Spanish autonomous communities.

The SCReN coordinator is based in the Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC) in Madrid, while the coordination with ECRIN is based in Barcelona at the Hospital Clinic, hosting this latter one the EuCo. Three working groups specialise in regulation and monitoring; methodological assessment, data management and statistics; and pharmacovigilance.

SCReN aims to foster excellence and quality in clinical research through networking, international cooperation, and support to clinical research projects, translating them into benefits for the Spanish National Health Service. SCReN also works on education and training of clinical research professionals.

Website: www.scren.es



Switzerland

Observer since 18 December 2015

Scientific Partner: SCTO - Swiss Clinical Trial Organisation

Our vision: To serve patients and society through excellent clinical research.

Our mission: To get the best minds collaborating on optimising clinical research.

The SCTO intends to achieve its mission by: promoting a high-quality and nationally harmonised study culture; supporting the creation of a national network; boosting integration of national clinical research into international networks; and building bridges between patients and public, academia, industry and public authorities. The SCTO advocates for favourable framework conditions in the field of clinical research, and coordinates and acts as an intermediary in multicentre studies.

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

2019 HIGHLIGHTS

SCTO thematic platforms

Pools of expertise in key areas of clinical research

During the first three years of operation, the [SCTO thematic platforms](#) developed and conducted a bounty of projects, all of national relevance and publicly accessible to the Swiss clinical research community and the CTU Network.



SCTO turns 10

[The SCTO celebrated its 10th anniversary with a special project](#) to foster the dialogue at eye level with the clinical research community and the public.

Paediatric clinical research infrastructure

[SwissPedNet](#) is hosted by the SCTO and is the linking partner for international paediatric clinical research. It is part of the paediatric clinical research infrastructure as well as the contributing partner to related and resulting projects and initiatives (IMI funded c4c and H2020 funded PEDCRIN and Id-EPTRI)

PUBLICATIONS

The SCTO led the publication of results of ECRIN survey on national harmonisation and learning activities:

-Magnin, A., Iversen, V.C., Calvo, G. et al. European survey on national training activities in clinical research. *Trials* 20, 616 (2019)

[DOI:10.1186/s13063-019-3702-z](https://doi.org/10.1186/s13063-019-3702-z)

- Magnin, A., Iversen, V.C., Calvo, G. et al., European survey on national harmonisation activities in clinical research. *Learning health systems* (2020), 2020:1-9. [DOI: 10.1002/lrh2.10220](https://doi.org/10.1002/lrh2.10220)

Website: www.scto.ch/en

Governance



Jacques Demotes and AoM Chair Rafael de Andrés Medina
(© Australian embassy in Belgium)

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. The AoM is chaired by Rafael de Andrés Medina, Spain, and the vice chair is Maria Ferrantini (Italy).

Members

- Marta Abrantes (Portugal)
- Renáta Chudackova (Czech Republic)
- Alexander Grundmann (Germany)
- Eric Guittet (France)
- Annette Magnin (Switzerland)
- Øyvind Melien (Norway)
- Daniel Pella (Slovakia)
- Csaba Vadadi-Fülöp (Hungary, until Nov. 2019); Attila Levente Szócs (appointed 1 Nov. 2019)
- Oonagh Ward (Ireland)
- Anna Bajera (Poland)
- Rafael de Andrés (Spain) replaced by Gonzalo Arevalo in November 2019 after his retirement

Additional Organisational Bodies

Network Committee

The Network Committee represents the national scientific partners and provides advice to the AoM and Director General. It is composed of one senior delegate from each national scientific partner of member and observer countries. In 2019 the Network Committee was chaired by Christian Ohmann (Germany). The vice chair was Annette Magnin (Switzerland) and members included Ola Dale (Norway), Regina Demlova (Czech Republic), Gabor Kovacs (Hungary), Emilia Monterio (Portugal), Lucia Palmisano (Italy), Daniel Pella (Slovakia), Antonio Portoles (Spain), Olivier Rascol (France), Fabian Tay (Switzerland) and Heiko Von Der Leyen (Germany).



Network Committee Chair Christian Ohmann (© Annie Gozard)

Governance Meetings in 2019

Body	Dates
Assembly of Members	21 May 2019
	17 December 2019
Network Committee	21 May 2019 (joint with AoM)
	15 November 2019

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 development²³.

As of 2019, members include: Paul Avillach (Harvard Medical School), Patrick Bossuyt (University of Amsterdam), Frank Hulstaert (Belgian Health Care Knowledge Centre, KCE), Kaisa Immonen (European Patient's Forum), Michal Koščík (Masaryk University), Shaun Treweek (University of Aberdeen), Effy Vayena (University of Zurich), and Maria Blettner (Johannes Gutenberg University Mainz).

The main recommendations provided by the board members cover funding of clinical research, expansion, community building, and long term sustainability and are integrated as actions in the 2020 workplan or in the next strategic plan.

Scientific Board

To integrate the required scientific and logistical assessment in a step-wise procedure, the Scientific Board involves two committees: a collaboration committee, making an early and rapid decision on whether or not ECRIN should get committed to invest in the planning, design and funding application of a given project and, a peer-review committee, in charge of ensuring the methodological quality of the pre-final protocol and to make recommendations to improve the final version.

The peer review committee is currently under renewal and a new committee composed of 6 nominated independent experts and the ECRIN Medical Expert will be operational beginning of 2020.

²³ In particular, the Advisory Board may provide input/recommendations on ECRIN's strategy and future strategic development; scientific and technical development; ethical and personal data protection issues raised by ECRIN's activities; access to data and transparency policies; and methodological recommendations.

Financial Report for 2019

Income	
Membership Core contributions	€ 1 280 000
Membership Local contributions	€ 925 000
Research projects	€ 1 648 370
Financial income	€ 86 865
Total Income for 2019	€ 3 940 235
Expenditures	
Salaries, social expenses and taxes	€ 1 532 395
Services	€ 1 061 105
Travel and meetings	€ 218 689
Rent and insurance	€ 194 071
Scientific Board	€ 47 300
Fees for consultants	€ 236 401
Other expenses	€ 70 512
Income tax	€ 19 457
Local contribution provided in-kind	€ 825 000
Total Expenditure for 2019	€ 4 204 930
Net Results	
Net Results for 2019	-€ 264 695

Acronyms²⁴

ACC	Alliance Against Cancer (Italy)
AoM	Assembly of Members
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
BMS RIs	Biological and Medical Sciences Research Infrastructures
c4c	conect4children
CDISC	Clinical Data Interchange Standards Consortium
CONSCIOUS	Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students
CORBEL	Coordinated Research Infrastructures Building Enduring Life-science Services
CoRi	Coordination and Support Service (Italy)
CRC	Clinical research centre
CRDI	Clinical Research Development Ireland
CRFs/CRCs	Clinical research facilities/Clinical research centres
CRIGH	Clinical Research Initiative for Global Health
CTU	Clinical trial unit
CZECRIN	Czech Clinical Research Infrastructure Network
DM	Data management
EATRIS	European Advanced Translational Research Infrastructure in Medicine

²⁴ Note: only select acronyms are presented here; the acronyms for ECRIN-supported trials, in particular, are not listed here (see the table in the Clinical Trials Operations section for this information).

EBRA	European Brain Research Area
ECRAID-Plan	European Clinical Research Alliance on Infectious Diseases Business
ECRIN	European Clinical Research Infrastructure Network
EFPIA	European Federation of Pharmaceutical Industries & Associations
EI	Enterprise Ireland
EJP RD	European Joint Programme on Rare Diseases
ELSA	Ethical, Legal, Social Aspects
EOSC	European Open Science Cloud
EOSC-hub	European Open Science Cloud hub
EOSC-Life	European Open Science Cloud Life project (Providing an open collaborative
EOSCpilot	European Open Science Cloud pilot
EPTRI	European Paediatric Translational Research Infrastructure
ERIC	European Research Infrastructure Consortium
ERIC Forum	ERIC Forum Implementation project
ERIEC	European Research Infrastructure Evaluation Consortium
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
EuCo	European Correspondent
EuLac-PerMed	Widening EU-CELAC policy and research cooperation in Personalised Medicine
EU-PEARL	EU Patent-centric clinical tRial pLatforms

F-CRIN	French Clinical Research Infrastructure Network
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GMP	Good manufacturing practice
GSF	(OECD) Global Science Forum initiative
H2020	Horizon 2020
HECRIN	Hungarian Clinical Research Infrastructure Network
HRB CRCI	Health Research Board Clinical Research Coordination Ireland
HRB	Health Research Board (Ireland)
ICB	(ECRIN) Independent Certification Board
ICH	International Conference on Harmonisation
ICTD	International Clinical Trials Day
IdISSC	Instituto de Investigación Sanitaria del Hospital Clínico San Carlo Carlos
IMI	Innovative Medicines Initiative
IRCSS	Istituto di Ricovero e Cura a Carattere Scientifico
ISCIII	Carlos III Health Institute (Instituto de Salud Carlos III)
ISS	Istituto Superiore di Sanita
ItaCRIN	Italian Clinical Research Infrastructure Network
KKSN	Netzwerk der Koordinierungszentren für Klinische Studien
KPI	Key performance indicator

MiRoR	Methods in Research on Research (project)
MIUF	Medical Infrastructure/ Users Forum
MoH	Ministry of Health
MoU	Memorandum of understanding
MRA	(Polish) Medical Research Agency
NIH	(U.S.) National Institutes of Health
NorCRIN	Norwegian Clinical Research Infrastructure
OECD	Organisation for Economic Co-operation and Development
OPBG	Ospedale Pediatrico Bambino Gesu
PedCRIN	Paediatric Clinical Research Infrastructure Network
POLCRIN	Polish Clinical Research Infrastructure Network
PtCRIN	Portuguese Clinical Research Infrastructure Network
PV	Pharmacovigilance
QMS	Quality management system
RI	Research infrastructure
RI-VIS	Expanding research infrastructure visi+bility to strengthen strategic partnerships
SaaS	Software as a service
SCReN	Spanish Clinical Research Network
SCTO	Swiss Clinical Trial Organisation

SERI	State Secretariat for Education, Research and Innovation (Switzerland)
SLOVACRIN	Slovak Clinical Research Infrastructure Network
SNSF	Swiss National Science Foundation
SYNCHROS	SYNergies for Cohorts in Health: integrating the Role of all Stakeholders
TBMed	A testing bed for the development of high-risk medical devices
XDC	eXtreme DataCloud

Clinical Trial Portfolio in 2019 (current trials)

At the end of 2019, ECRIN's trial portfolio included 36 'current' trials. However, ECRIN provided support to an additional nine trials during the year, bringing the total number of trials receiving ECRIN support in 2019 to 45.

1	ADIPOA2 research centre	Autologous Adipose-Derived Mesenchymal Stromal Cells in the Treatment of Mild to Moderate Osteoarthritis	running-ending end of 2020
2	BETA3_LVH	A multi-centre randomized, placebo-controlled trial of mirabegron, a new beta3-adrenergic receptor agonist on the progression of left ventricular mass	running
3	BIOCHIP	Clinical Trial for the Regeneration of Cartilage Lesions in the Knee (Nose-toKnee2)	running / extension
4	DISCHARGE	Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery	running-extended
5	EUTRAIN	The EUROpean TRAnsplantation and INnovation (EU-TRAIN) consortium for improving diagnosis and risk stratification	running
6	FAIR-PARK II	Conservative Iron Chelation as a Disease-Modifying Strategy in Parkinson's Disease	running / asking for extension
7	HCQ4Surf-defect	Hydroxychloroquine in paediatric ILD. START randomized controlled in-parallel group, then switch to placebo active drug, and STOP randomized controlled in-parallel group to evaluate the efficacy and safety of hydroxychloroquine (HCQ)	running / on hold
8	HIVACAR	A phase I/IIa, randomized study to evaluate the safety and the effectiveness of a Combination of Therapeutic Vaccine, the Broadly Neutralizing Antibody and 10-1074 and the Latency Reversing Agent Romidepsin to Achieve a Functional Cure of HIV in chronic	running

9	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
10	MACUSTAR	Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention	running
11	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 trial	running
12	ORTHO-UNION	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	running
13	PAPA-ARTIS	Paraplegia Prevention in Aortic Aneurysm Repair by Thoraco-abdominal Staging with 'Minimally-Invasive Segmental Artery Coil-Embolization': A Randomized Controlled Multicentre Trial	running
14	POPART	Prophylactic oropharyngeal surfactant for preterm infants: a randomised trial	running
15	PRECIOUS	Prevention of Complications to Improve Outcome in Elderly Patients with Acute Stroke	running / extension
16	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
17	R-Link	Optimizing response to Li treatment through personalized evaluation of individuals with bipolar I disorder: the R-LiNK initiative	running
18	RESPINE	REgenerative therapy of intervertebral disc: a double blind phase 2b trial of intradiscal injection of mesenchymal stromal cells in degenerative disc disease of the lumbar SPINE unresponsive to conventional therapy	running
19	WEstudy	Walking Easier with cerebral palsy	running
20	ALCHEMIST	ALdosterone antagonist Chronic HEModialysis Interventional Survival Trial	set-up
21	CARDIA	Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy	set-up - start Dec19

22	CYST-FIB	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy of Tezacaftor/Ivacaftor Combination Therapy in Subjects With Cystic Fibrosis Who Have an R334W-CFTR Mutation	set-up
23	EMPA-ALP-ORT	Phase 3, multicentre, randomized, parallel group, double-blind, placebo-controlled clinical trial to assess the effect of EMPAgliflozin, on the progression of chronic kidney disease in patients diagnosed with ALPORT syndrome	set-up
24	Endo-Low	ENDO-LOW (Endovascular Therapy for Low NIHSS Ischemic Strokes)	set-up
25	IDEA-FAST	Identifying Digital Endpoints to Assess Fatigue, Sleep and activities daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases	set-up in 24 months
26	ImmunAID	Immunome project consortium for AutoInflammatory Disorders	set-up
27	INFORM2	INFORM2 exploratory multinational phase I/II combination study of Nivolumab and Entinostat in children and adolescents with refractory	set-up
28	NECESSITY	NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifying patients	set-up
29	NICOFA	A randomized, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of nicotinamide in patients with Friedreich's Ataxia	set-up
30	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	set-up
31	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	set-up
32	SWEET	Sweeteners and sweetness enhancers: Impact on health, obesity, safety and sustainability	set-up
33	TBMed	An Open Innovation testing bed for the development of high-risk medical devices	Set-up- TBA- currently only Pilots
34	TENSION	Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window	set-up

35	TERIS	Multi-center, randomized, double-blinded study of Teriflunomide® in radiologically isolated syndrome (RIS)	set-up
36	TREOCAPA	Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen Study type	set-up
37	AETIONOMY	Taxonomy of Neurodegenerative Diseases: Observational Study in Alzheimer's Disease and Parkinson's Disease	closed
38	EUROHYP-1	Cooling Plus Best Medical Treatment Versus Best Medical Treatment Alone for Acute Ischaemic Stroke	closed
39	LIVERHOPE SAFETY	Safety and tolerability of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis: a multi-	closed
40	MENAC	Multimodal Intervention for Cachexia in Advanced Cancer Patients Undergoing Chemotherapy	closed
41	POEM VS LHM	Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial (POEM rcpmt)	closed
42	RESCUE ESES	A Randomized European trial of Steroids versus Clobazam Usage for Encephalopathy with Electrical Status Epilepticus in Sleep	closed
43	SCD-WELL	A Randomized Multicenter Clinical Trial in Patients with Subjective Cognitive Decline At Risk for Alzheimer's Disease to Assess the Short-term Effects of a Standardized Meditation Intervention vs. Active Control on Behavioral Measures	ECRIN's support services completed
44	TRIHEP 3	A Comparative Phase 2 Study Assessing the Efficacy of Triheptanoin, an Anaplerotic Therapy in Huntington's Disease	closed
45	VISION DMD	A Phase IIb Randomized, Double-blind, Parallel Placebo- and Active-controlled Study to Assess the Efficacy and Safety of VBP15 in Ambulatory Boys with Duchenne Muscular Dystrophy (DMD)	ECRIN's support services completed

For more information, and trial websites (if available), see <https://ecrin.org/activities/trial-portfolio>

Project Funding and Other References

ⁱ **SYNCHROS** is funded by Horizon 2020 (H2020) under grant agreement number (GA no.) 825884.

ⁱⁱ **ECRAID-Plan** is funded by the European Commission under GA no. 825715.

ⁱⁱⁱ **ERIC Forum** is funded by H2020 under GA no. 823798.

^{iv} **The NECESSITY** project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under GA no. 806975. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries & Associations (EFPIA).

^v **MiRoR** is funded by the H2020 Marie Skłodowska Curie Innovative Training Networks- European Joint doctorate (ITN-EJD) under GA no. 676207.

^{vi} **TB-Med** is funded by H2020 under GA no. 825884. by service providers of the EGI Federation.

^{vii} **EOSC-Life** is funded by H2020 under GA no. 824087.

^{viii} **LIVERHOPE-Safety** is supported through Societal Challenges (Health, demographic change and well-being) of the European Community's H2020 GA no. 731875.

^{ix} **EULAC-PerMed** is funded by H2020 under GA no. 825173.



^x **c4c** is funded by the Innovative Medicines Initiative (IMI) 2 Joint Undertaking under GA 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).

^{xi} **EBRA** is funded by H2020 under GA no. 825348.

^{xii} **EJP-RD** is funded by H2020 under GA no. 825575

^{xiii} **EU-PEARL** is funded by H2020 and the Innovative Medicines Initiative (IMI) under GA no. 853966-2.

^{xiv} **RI-VIS** is funded by H2020 under GA no. 824063.

^{xv} **PedCRIN** is funded by H2020 under GA no. 731046.

^{xvi} **EOSCpilot** is funded by H2020 under GA no. 739563.

^{xvii} **EOSC-hub** is funded by H2020 under GA no. 777536. The generous EU funding received by the project is complemented with a contribution from the EGI Foundation and its participants, and in-kind contributions made available by service providers of the EGI Federation.

^{xviii} **eXtreme - DataCloud (XDC)** is funded by H2020 under GA no. 777367.

^{xix} **ISO 9001:2015**. Quality management systems - Requirements. Available at: www.iso.org/standard/62085.html

^{xx} **ICH Harmonised Guideline**. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Current Step 4 version dated 9 November 2016. Available at: <https://bit.ly/2K5uFev>

^{xxi} **Regulation (EU) No 536/2014** of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Available at: <https://bit.ly/2DrFuTG>

^{xxii} **Regulation (EU) 2016/679** of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Available at: <https://bit.ly/2s7bupy>

^{xxiii} **Canham et al.**: Requirements for Certification of ECRIN Data Centres, with Explanation and Elaboration of Standards, Version 4.0. 27 April 2018. DOI: 10.5281/zenodo.1240941. Available at: <https://bit.ly/2Gyg7QT>


^{xxiv} **CONSCIOUS** is funded by the Erasmus+ Programme of the European Union under GA no. KA2-FSO-00018-009/2018.

Publications

Publication Reference (2019)	ECRIN-supported trial or project
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