

# ECRIN ANNUAL REPORT





**ECRIN  
ANNUAL  
REPORT  
2015**



# OUR MISSION

## TO SUPPORT THE CONDUCT OF MULTINATIONAL CLINICAL TRIALS IN EUROPE

ECRIN's vision is a society where decisions in medical practice are made based on sound scientific evidence from high-quality clinical research. To achieve this vision, ECRIN supports the conduct of multinational clinical trials in Europe.

By managing and supporting clinical trials across borders, connecting scientific networks, and providing investigators and sponsors with tools and other resources, ECRIN aims to enhance the flow of knowledge and increase the competitiveness of the European Research Area.



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# LETTER FROM THE DIRECTOR GENERAL



I am pleased to share ECRIN's 2015 Annual Report with our friends and partners.

2015 was a year of growth, as we enlarged our Paris-based Core Team, consolidated the organisation, welcomed a new Observer Country (Switzerland), and added new clinical trials to our portfolio.

We also wrapped up key activities in our fourth major project, the ECRIN Integrating Activity or ECRIN-IA project, funded by European Union Framework Programme 7 (grant agreement no. 284395). Involving 23 countries and covering three main areas of expertise (rare diseases, medical devices and nutrition), it brought together diverse stakeholders to build capacity and tools for multinational clinical trials in Europe (ESCALE, IMPACTT, MENAC, POEM vs LHM, and RESCUE ESES). Originally planned for four years (2012 to 2015), the clinical trials work package was extended until 2017.

In 2015, several ECRIN-IA “structuring activities” were completed and presented at ECRIN’s meeting on “Conducting Independent, Multinational Clinical Trials in Europe”, held from December 7th to 8th, 2015 in Paris. One such activity was the development of the CAMPUS database ([campus.ecrin.org](http://campus.ecrin.org)). Launched in December 2015, CAMPUS is a central resource for information on clinical trial regulatory and ethical requirements for multiple study types in 22 European countries.

In addition, we began to work on new collaborative projects funded by the European Union Horizon 2020 programme such as CORBEL<sup>1</sup> and Rltrain<sup>2</sup>, involving all the biological and medical science research infrastructures (BMS RIs) listed on the European Strategy Forum on Research Infrastructures (ESFRI) Roadmap. Also, in 2015, I was elected the first Chair of the ESFRI-BMS RI Strategy Board.

We focused not only on strengthening our European partnerships but also on increasing collaboration with international stakeholders. Collaboration agreements were signed with the Korea National Enterprise for Clinical Trials (KoNECT) and the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) in the United States. In April 2015, ECRIN hosted a workshop to draft the Clinical Research Initiative for Global Health (CRIGH) multilateral collaborative project.

We are proud of the work we have achieved with our partners so far, and are aware of the significant challenges that still lie ahead. To meet these challenges, we know we must make the best possible use of our human and financial resources. This report provides an overview of how we devote these resources to achieve our mission.

It is an honour to do our work and to team up with outstanding partners in Europe and internationally to overcome obstacles to multinational trials. Together, we hope to make progress towards more evidence-based medical decisions.

Sincerely,

A handwritten signature in blue ink, appearing to be 'J. Demotes', written over a horizontal line.

Jacques Demotes

<sup>1</sup>CORBEL has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 654248).

<sup>2</sup>RITRAIN (Research Infrastructures Training Programme) has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 654156).



# 1 / ECRIN OVERVIEW

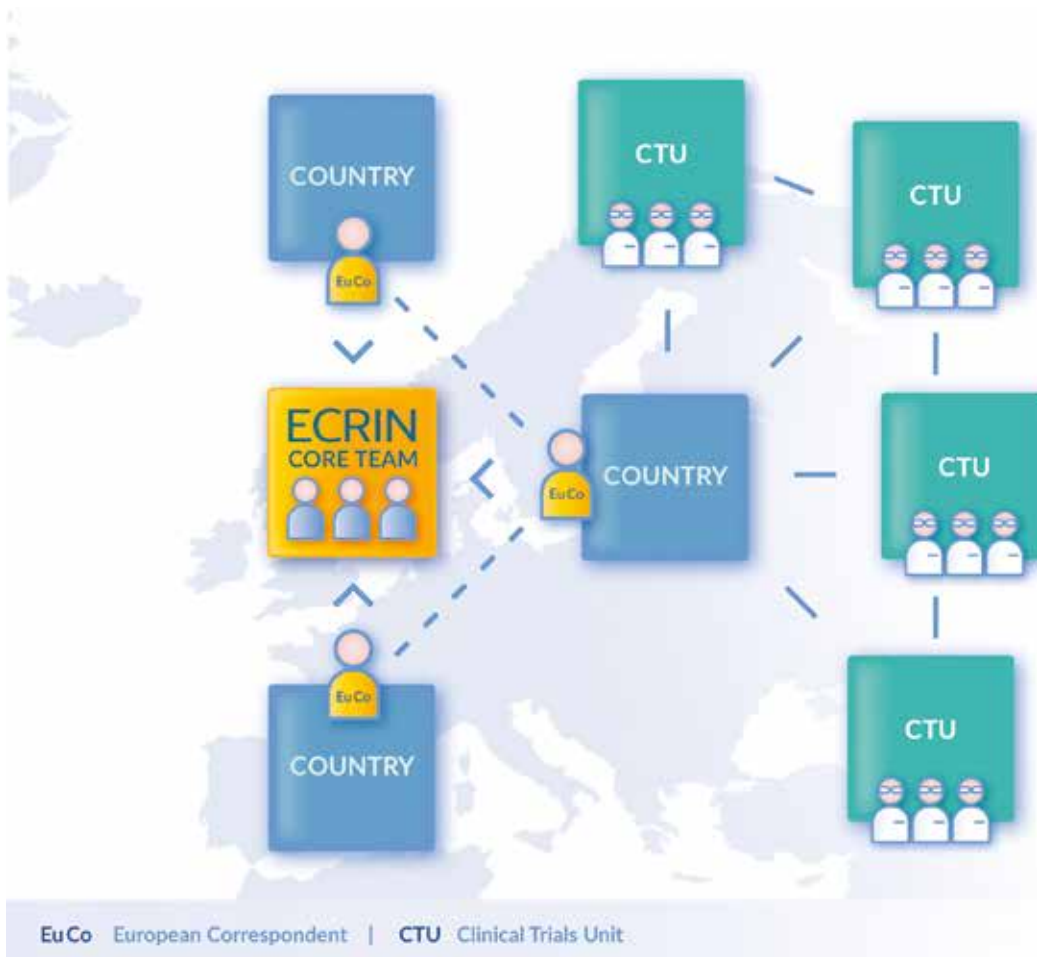
Since its creation in 2004, the European Clinical Research Infrastructure Network (ECRIN) has been striving to overcome the obstacles to multinational trials in Europe. Multi-country trials mean greater access to patients, resources, and expertise, and, in turn, potentially more robust trial results and greater public health impact.

A non-profit intergovernmental organisation, ECRIN offers support for trial preparation, validation and especially implementation.

## ORGANISATION

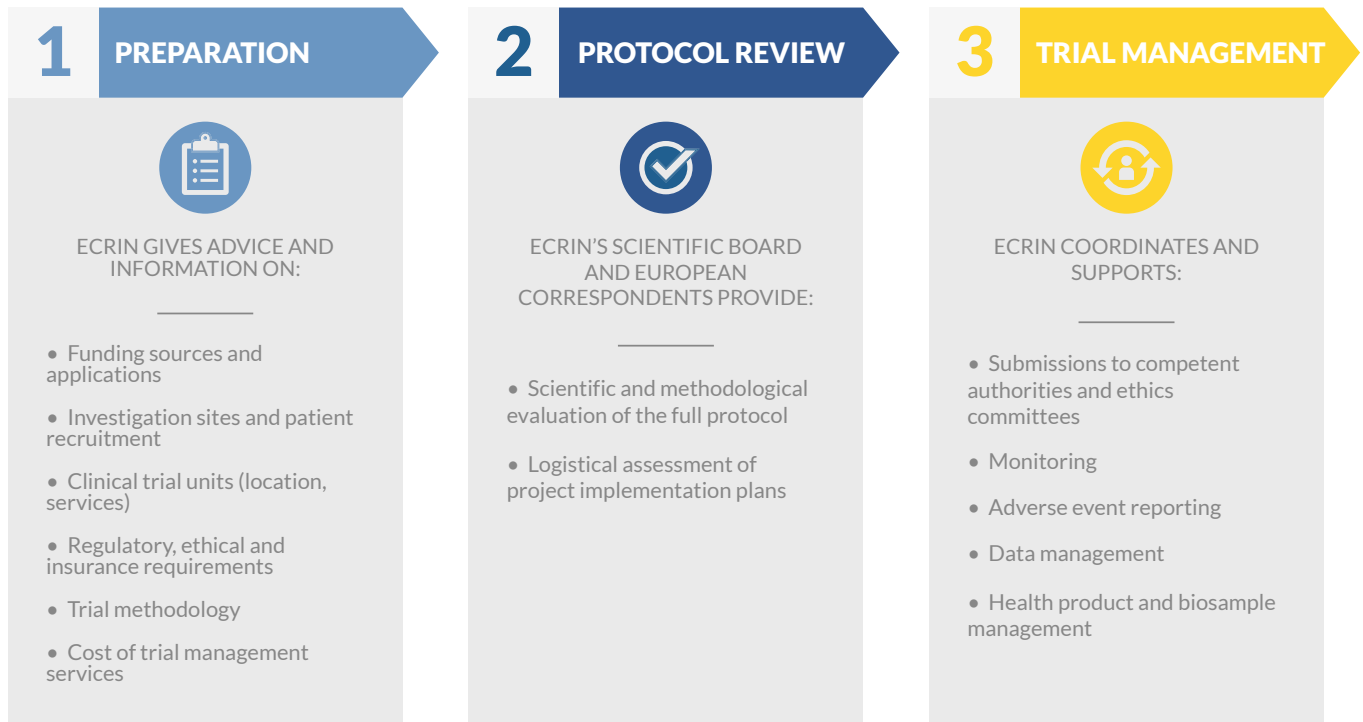
ECRIN's organisational model is based on country membership. In 2015, it had six Member Countries (France, Germany, Hungary, Italy, Portugal and Spain) and two Observer Countries (Czech Republic and Switzerland, which joined at the end of the year).

Each country hosts a European Correspondent (EuCo), an ECRIN staff member who manages the clinical trial portfolio and coordinates with the national scientific partner (i.e., network of clinical trial units, or CTUs), with support from the Paris-based Core Team.



# SUPPORT TO MULTINATIONAL CLINICAL TRIALS

ECRIN provides support to sponsors in investigator-initiated trials for trial preparation, the validation of study protocols, and trial management. It focuses on independent, multinational academic research as well as trials initiated by biotech and medical device small and medium enterprises (SMEs).



## PREPARATION

In the preparation phase, ECRIN's EuCos (see box "Zoom on EuCos", page 6) 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. Moreover, EuCos can provide information on the facilities that have the capacity and services needed to manage the trial, as well as on investigator sites and networks in their countries. As such, they act like "matchmakers", ensuring that the clinical trial units (CTUs) selected for the study are an appropriate fit, both in their country and in other European countries. Also in the preparation stage (or in parallel to protocol review), EuCos can assess the practicality of trial plans in each country and give suggestions and alternatives to ensure that the trial runs smoothly.

## PROTOCOL REVIEW

ECRIN can provide methodological consulting and an independent review of study protocols. This evaluation is done by ECRIN's Scientific Board, which is composed of clinical research and methodology experts.

## TRIAL MANAGEMENT

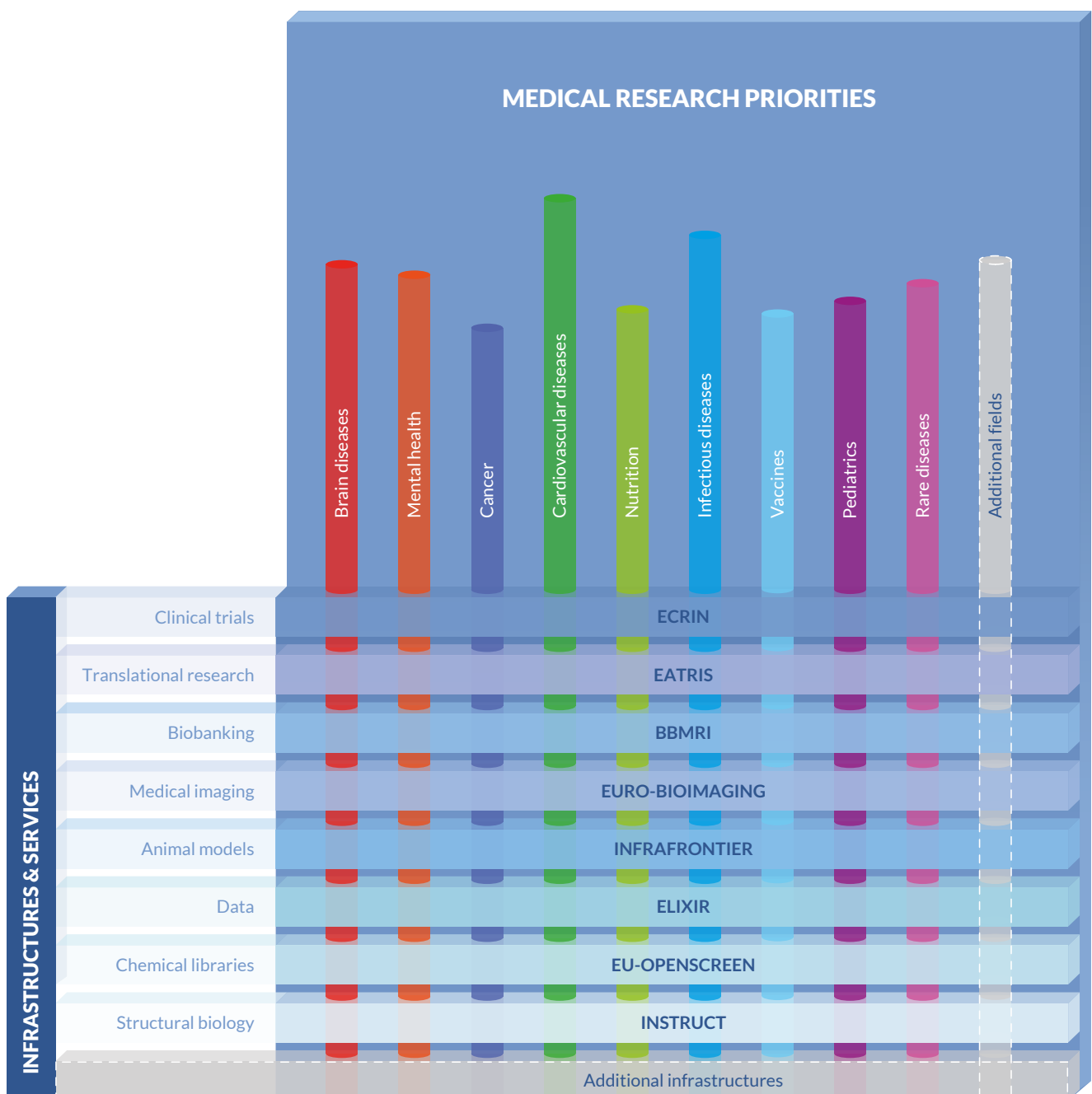
In the project implementation phase, ECRIN offers investigators and project coordinators various trial management services. Through its national partners (networks of CTUs), ECRIN can perform project management (central and local); handle submissions to regulatory and ethics authorities in participating countries; provide on-site monitoring in the different countries; and conduct local pharmacovigilance tasks. We can also provide centralised activities such as data management (through our certified data centres) and central pharmacovigilance. In addition, we can provide support with trial insurance (national or multinational) and provide contacts for medicine and sample handling across countries.

As part of its trial-support activities, ECRIN develops and maintains freely accessible tools such as databases on regulatory and ethical requirements, outcome measures, and risk-based monitoring.

# COLLABORATIVE PROJECTS: WORKING ACROSS MEDICAL FIELDS WITH RESEARCH INFRASTRUCTURES

In addition, ECRIN contributes to collaborative projects aiming to establish shared services in biomedical areas, further develop its own infrastructure and that of partner organisations, and foster international cooperation in non-commercial trials.

Such collaborative projects typically involve other European research infrastructures (RIs) providing resources and services to a wide range of medical research communities, as illustrated below. The goal of these partnerships is to identify the needs of scientific users and to develop the tools and services that best meet these needs.



# ECRIN IN NUMBERS: 2015

- 33** Number of multinational trials in the ECRIN portfolio (current/past projects)
- 7** Average number of countries per ECRIN-supported trial
- 9** Core Team members (based in Paris)
- 9** European Correspondents (one per country with two for Spain)
- 6** Member Countries
- 2** Observer Countries

## 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 (Horizon 2020, Innovative Medicines Initiative – IMI, or other sources) that cover specific activities carried out as part of multinational clinical trials or collaborative projects.





## ZOOM ON EUROPEAN CORRESPONDENTS (EUCOS)

EuCos are at the heart of ECRIN's unique ability to successfully work across borders, coordinating CTUs and other stakeholders from multiple countries. Typically seconded to ECRIN by their local research institution, these clinical research experts work directly in-country and are deeply familiar with the national clinical trial landscape.

EuCos can provide investigators and sponsors with highly valuable knowledge on ethical and regulatory requirements for multinational trials, not only in the coordinating country (where the EuCo is usually working) but also in participating countries. This is achieved through ECRIN's network of EuCos, who regularly communicate and work together, providing essential information and support throughout the clinical trial lifecycle. (Although we do not have EuCos in non-Member/Observer Countries, we have local contacts through our previous and current collaborative activities; these individuals can be mobilised to advise on and identify appropriate resources in-country.)

More than just a resource for information, EuCos are the ones who coordinate ECRIN's trial management support on a daily basis (following the acceptance of projects by ECRIN based on recommendations from the ECRIN Scientific Board and results of logistical assessment). They collaborate closely with the trial management team, national partners and stakeholders in other countries, making sure that tasks are performed as planned, on time and according to the highest standards of quality.

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## 2 / WHY ECRIN?



### MULTI-COUNTRY TRIALS: IMPORTANCE AND CHALLENGES

Clinical trials are an essential step in evaluating the efficacy and safety of innovative treatments, exploring new indications for authorised drugs, and comparing the efficacy and safety of approved healthcare strategies.

International collaboration is important for clinical research, as it maximises access to patients and leads to faster results. It also enables the sharing of medical and scientific expertise, tools, procedures and costs; increases the applicability of research findings; reduces duplication; and enhances methodological standards. The evidence from multinational trials can support enhanced health policy-making, optimal resource use, and improved patient care across borders.

Despite these advantages, just 3% of academic trials (vs. 30% of industry trials) are multinational. In Europe, the relative scarcity of multinational academic trials can be explained, in part, by restrictions with current cross-border funding options. Other general barriers to multi-country collaboration include different legal, regulatory and ethical requirements; difficulties in locating CTUs; and linguistic, insurance, contracting, and managerial and administrative issues.

Due to these obstacles, investigators may forgo multinational trials in favour of trials conducted in a single centre, or in multiple centres within one country. This limits the scope of research and reduces its potential impact on global public health.

# THE ECRIN ADDED VALUE AND IMPACT

ECRIN helps investigators to be successful in their multinational trials from preparation to publication. A unique partner, ECRIN provides the expertise and resources to manage multinational clinical trials using the same standards. It also provides the necessary links between the investigator/sponsor and CTUs across countries, facilitating dialogue and coordination between parties, and, ultimately, leading to more effective trials.



## Q&A: MEMBERSHIP BENEFITS AND ELIGIBILITY FOR ECRIN SUPPORT

### **Q. What services do Member and Observer Countries receive?**

A. ECRIN Member and Observer Countries can benefit from the full range of ECRIN services for multinational trial preparation, protocol evaluation and/or trial management. Advice and information are freely provided by the ECRIN Core Team and EuCos. Trial management services are provided at not-for-profit rates.

### **Q. Are all trials in Member and Observer Countries automatically eligible for ECRIN support?**

A. No. To be eligible for ECRIN support, projects must involve at least two Member or Observer Countries; the protocol and trial plans must be reviewed and approved by ECRIN's Scientific Board and EuCos, respectively.

### **Q. Can ECRIN support a trial that is coordinated by a country that is not a Member or Observer?**

Yes, 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.

### **Q. Do investigators have to use ECRIN-certified data centres in ECRIN-supported trials?**

A. This is not an absolute requirement, but it is strongly recommended to use such centres for trial data management.

# 3 / ADMINISTRATION AND COMMON SERVICES

2015 was the second year that ECRIN operated with the status of a European Research Infrastructure Consortium (ERIC), which was awarded by the European Commission in December 2013. In 2015, ECRIN continued to build on the work accomplished in 2014 to develop its legal, administrative and financial organisation, as well as other core support services (communications, quality, human resources).

## GENERAL ADMINISTRATION AND FINANCE

The development of general administration and financial tasks was led by the Administrative Manager, hired on 1 January 2015 following an internal recruitment procedure.

The financial contributions from Member Countries were received for 2015. Observer Countries, which make in-kind contributions only, paid for the cost of their respective local European Correspondents. In 2015, an appendix to the rules of internal procedures was added describing how to report and validate in-kind contributions.

Following discussions in 2014 within the Assembly of Members to draft Article 7 of the Rules of Internal Procedure regarding the procurement/sourcing policy, the document was adopted in February 2015 and the procedure tested throughout the year.

## COMMUNICATIONS AND TRAINING

Internal and external communications activities were developed in 2015 through the hiring of a Communications Officer in March. The website was redesigned and launched end July, communications materials were developed, and a Twitter account was created, among others. The Communications Officer also supported the organisation of meetings including the International Clinical Trials Day celebration in Trondheim, Norway in May and the meeting on “Conducting Independent, Multinational Clinical Trials in Europe” held in Paris, France in December.

ECRIN participated in numerous European and international scientific conferences, with around 30 presentations made in 2015 by the Director General.

In terms of project communications, ECRIN became involved in the communications work package of the CORBEL project. Led by the German biological resource centre DSMZ<sup>3</sup>, the work package supports effective documentation, communication and outreach to internal and external stakeholders including the participating BMS RIs, infrastructure users, funding networks, and more.

<sup>3</sup> Stands for The Leibniz-Institut DSMZ (Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH), or German Collection of Microorganisms and Cell Cultures GmbH. It is coordinated by the Microbial Resource Research Infrastructure (MIRRI).



As part of the ECRIN-IA project, ECRIN also organised a workshop with the Carlos III Health Institute (Instituto de Salud Carlos III, ISCIII) in Madrid in January 2015 to discuss possible ways to fund independent, multinational trials using a combination of national funding sources.



## HUMAN RESOURCES AND STAFF TRAINING

Based on the organisation chart adopted in the 2015 work plan, ECRIN continued to distinguish activities in two major areas: Capacity and Operations, with a Director leading each work stream (see next section).

ECRIN further expanded its Paris-based Core Team with the hiring of a Quality Manager (February 2015), a Communications Officer (March 2015), a Clinical Operations Project Manager (October 2015), an Administrative Assistant (October 2015), and a Capacity Project Manager (October 2015).

Finally, ECRIN held a Summer School for its European Correspondents in Brno, Czech Republic in September.

## LEGAL

A priority in 2015 continued to be the signing of framework agreements with each Member and Observer Country. A task force was created in 2014, chaired by the Capacity Director and supported by the Legal Officer, to finalise a template framework agreement to be signed by ECRIN's scientific partners. The framework agreement is essential as it sets out the terms for collaboration between ECRIN and its national scientific partners for the provision of joint support to clinical studies. It also establishes the roles and responsibilities of the EuCos (typically seconded by the national partner to ECRIN) and helps to define the status of the national partner in H2020 or IMI projects. Following the task force's work, the template was validated and the first framework agreements were signed early 2015.

In addition, ECRIN developed various model agreements in order to support and facilitate the contracting process in multinational clinical trials. These include, for example, models for delegation, subcontracting and confidentiality agreements. This work has enabled ECRIN to identify and address the main legal and practical issues in international contracting (letters of intent, memorandums of understanding, dispute resolution mechanisms, different legal systems, laws governing contracts, cultural differences in contract management, etc.).

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# 4 / CAPACITY DEVELOPMENT AND CLINICAL TRIAL OPERATIONS

## TWO MUTUALLY REINFORCING WORK STREAMS

ECRIN's Capacity department works to develop and improve the infrastructure, tools and procedures that support high-quality, multinational trials; structure and bring together disease-oriented investigation networks in Europe; contribute to improving the organisation of national scientific partners; encourage additional countries to join as Members and Observers; and promote international collaboration.

The Operations department strives to optimise the support that ECRIN provides for multinational clinical trials in Europe. While there is overlap with the Capacity team's work, the Operations department is more specifically focused on providing management support to the actual trials themselves, as opposed to developing the underlying infrastructure, tools and resources (i.e., the clinical trial landscape).

For both capacity and operations activities, the EuCos continued to play a key role in 2015 for in-country implementation, with oversight from the Capacity or Operations Director as appropriate.

## QUALITY ASSURANCE AND CERTIFICATION POLICY

Upgrading the quality management system (QMS) used within ECRIN and its national partners was an essential task in 2015. A main achievement was the addition of several new standard operating procedures for ECRIN's internal QMS. This work was led by the organisation's new Quality Manager.

In order to discuss the overall ECRIN quality strategy, taking into account national approaches, a multinational working group of quality experts was set-up.

In addition, the data centre certification expert group revised the "requirements for certification of data centres" with the publication of a third version in October 2015.

The 2015 data centre certification campaign was launched in May with updated criteria, and four data centres from Member Countries applied. Site audits, led by an independent certification board, evaluated compliance with ECRIN data standards.

A report evaluating the certification programme and providing recommendations for future calls was submitted to the governing body in September.

# CONNECTION TO INVESTIGATION NETWORKS

ECRIN provides support to multinational trials regardless of the type of disease being investigated. However, it values the establishment of partnerships with disease-specific networks, as they represent potential users of ECRIN support services and provide ECRIN with efficient and pan-European investigation capacity.

In 2015, ECRIN continued to develop partnerships with pan-European investigation networks and hubs on rare diseases, medical devices and nutrition as part of the ECRIN-IA project. Links were also established with investigator communities on paediatrics and ophthalmology, for example, with a framework agreement being signed with the European Vision Institute Clinical Research Network (EVICR.net).

## EXPANSION OF MEMBERSHIP AND INTERNATIONAL PARTNERSHIPS

The expansion of ECRIN membership was a key priority in 2015, and progress was made in attracting new countries. As mentioned before, Switzerland came on board as an Observer in December 2015, a status that lasts three years. Additional countries, particularly among those which had been involved in ECRIN-IA, expressed strong interest in joining soon as well. By the end of 2015, the application process was initiated in Norway, Ireland, Turkey and Luxembourg.

The development of international partnerships was also an important activity in 2015. This work is in line with the Organisation for Economic Co-operation and Development (OECD) initiative to foster international cooperation in non-commercial trials.<sup>4</sup> ECRIN signed a memorandum of understanding (MoU) with the Korea National Enterprise for Clinical Trials (KoNECT) in April 2015, opening channels for greater cooperation between Korea and Europe in clinical research. This enlarged the geographic scope of ECRIN's international partnerships, which already included Therapeutic Innovation Australia (TIA) as of 2014. Collaboration letters were also prepared to support collaboration with the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) in the United States, and signed in August 2015.

Finally, in April 2015, ECRIN hosted a workshop to draft the CRIGH multilateral collaborative project – a follow-up of the OECD initiative. CRIGH aims to facilitate global collaboration in clinical research.<sup>5</sup>

## TOOLS

In 2015, ECRIN continued to develop common tools as part of the ECRIN-IA project. This led, for example, to the launch in December 2015 of the CAMPUS database ([campus.ecrin.org](http://campus.ecrin.org)), which provides European regulatory and ethical information for studies on medical devices, medicinal products for human use, and nutrition. CAMPUS can be used to locate country-specific competent authorities and ethics committees, consult the summary of requirements for each country, compare country information, and browse related documents (e.g., regulations and guidelines).

<sup>4</sup> 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".

<sup>5</sup> In particular, CRIGH will seek to maximise impact and return on investment of research programmes in participating countries and organisations, and will develop global standards and promote the take-up of cutting-edge methodologies and technology for clinical research.



Other tools finalised in 2015 as part of ECRIN-IA include a risk-based monitoring toolbox, an outcome measure database for medical devices, and a mapping of nutrition centres. The data management tool (VISTA) developed as part of ECRIN-IA will be finalised in 2016.

## TRIAL SUPPORT AND COLLABORATIVE PROJECTS

In 2015, ECRIN supported numerous investigators for the preparation and validation of their applications for multinational funding. In regards to H2020 specifically, ECRIN submitted 20 clinical trial proposals, and seven applications for collaborative projects.

In all, 16 projects were reviewed by ECRIN's Scientific Board, 11 of which went through the new "ECRIN-On-Board" (EoB) initiative. EoB aims to improve the quality of applications for EU funding through early support on the protocol and the logistical/operational aspects of project design. Similar to traditional ECRIN support, ECRIN's Scientific Board provides a methodological review of the protocol, while ECRIN advises on issues including work package organisation. This logistical support is particularly useful for investigators who are less experienced in drafting H2020 applications. In 2015, 11 projects used the EoB initiative.

A noteworthy development in 2015 was the start of four new clinical projects funded by H2020 (MEDIT-AGEING, BIOCHIP, NISCI, VISION-DMD), adding to the four H2020 projects already funded in 2014 (ADIPOA2, FAIR-PARK II, BETA3\_LVH, PRECIOUS). The total number of ongoing clinical trials (all funding sources) in ECRIN's portfolio increased to 21 in 2015. Moreover, ECRIN started additional H2020 collaborative projects: Rltrain and PRO4VIP.<sup>6</sup> The next section provides more detailed information on ECRIN's clinical trials and projects in 2015.

<sup>6</sup> PRO4VIP (Innovative Procurement for Visual Impaired People) has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement number 645584.

# 5 / CLINICAL TRIAL AND PROJECT UPDATES

## NEW CLINICAL TRIALS

**BIOCHIP<sup>I</sup>** (Clinical Trial for the Regeneration of Cartilage Lesions in the Knee (NosetoKnee2): ECRIN started to work on the BIOCHIP trial, which aims to investigate the efficacy of an engineered cartilage transplant (N-TEC) in comparison to a cell-activated matrix (N-CAM) for the treatment of articular cartilage lesions in the knee. ECRIN is a work package leader and is involved as well in regulatory and ethical submission and monitoring.

Countries: Croatia, Germany, Italy, Switzerland\*

Medical field: Orthopaedics / cell therapy

**NISCI<sup>II</sup>** (Antibodies against Nogo-A to enhance plasticity, regeneration and functional recovery after acute spinal cord injury, a multicentre European clinical proof of concept trial): work also began on NISCI, which will enrol patients with various degrees of acute spinal cord injury for a double-blind, placebo-controlled trial to test the efficacy of antibody therapy against Nogo-A (a protein inhibiting axonal growth) to improve motor outcome and quality of life of tetraplegic patients. ECRIN's role involves regulatory and ethical submission, as well as monitoring.

Countries: Czech Republic, Germany\*, Italy, Spain, Switzerland

Medical field: Neurology

**PRECIOUS<sup>III</sup>** (Prevention of Complications to Improve Outcome in Elderly Patients with Acute Stroke): after having provided funding application support, ECRIN began to support this Horizon 2020 project in 2015. PRECIOUS aims to find out whether a pharmacological strategy to prevent complications after stroke can reduce the risk of death or long-term disability<sup>IV</sup>. ECRIN is providing coordination support, and will provide monitoring.

Countries: Estonia, France, Germany, Hungary, Italy, Netherlands\*, Norway, Poland, United Kingdom

Medical field: Neurology

**VISION-DMD<sup>V</sup>** (Phase 2 Clinical Trials of VBP15: An Innovative Steroid-like Intervention on Duchenne Muscular Dystrophy): began participation in this study, aiming to assess the safety and toxicity (phase 2a) and safety and efficacy (phase 2b) of the orphan drug VBP15 in ambulatory boys with Duchenne muscular dystrophy (DMD).

Countries: Australia, Belgium, Czech Republic, Denmark, France, Germany, Israel, Italy, Netherlands, Poland, Spain, Sweden, Turkey, United Kingdom\*

Medical field: Neurology / rare diseases / paediatrics

Note: the "\*" symbol designates the trial coordinating country

<sup>I</sup>BIOCHIP has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement number 681103.

<sup>II</sup>NISCI has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 681094).

<sup>III</sup>PRECIOUS has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 634809).

<sup>IV</sup>PRECIOUS will recruit 3.800 patients in 80 hospitals, and patients aged 66 years or older will be randomised to a strategy to prevent complications in the first four days of their hospitalisation, or to standard care.

<sup>V</sup>VISION-DMD has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement No 667078).

# ONGOING CLINICAL TRIALS #1

**ADIPOA2<sup>VI</sup>** (Clinical Trial of Autologous, Adipose-Derived Mesenchymal Stromal Cells (ASCs) in the Treatment of Mild-to-Moderate Osteoarthritis, OA): ECRIN continued to provide support for project management, regulatory and ethical submission, data management, monitoring and pharmacovigilance in this phase 2b study. Funded by H2020, ADIPOA2 aims to assess the safety and efficacy of autologous (patient-derived) ACSs in the treatment of advanced OA of the knee.

Countries: France\*, Germany, Ireland, Italy, Netherlands, United Kingdom  
Medical field: Orthopaedics / cell therapy

**AETIONOMY<sup>VII</sup>** (Taxonomy of Neurodegenerative Diseases: Observational Study in Alzheimer's Disease and Parkinson's Disease): continued to provide support for regulatory and ethical submission, as well as monitoring on this IMI-funded study which is now in the recruitment/follow-up phase. AETIONOMY aims to validate the mechanism-based taxonomies of Alzheimer's and Parkinson's disease for two biomarkers for each disease.

Countries: France\*, Germany, Spain, Sweden  
Medical field: Neurology

**BETA3\_LVH<sup>VIII</sup>** (A multi-center randomized, placebo-controlled trial of mirabegron, a new beta3-adrenergic receptor agonist on left ventricular mass and diastolic function in patients with structural heart disease): ECRIN continued to support the implementation of this phase 2b trial, which aims to evaluate mirabegron (a new  $\beta$ 3-specific agonist) over 12 months as an add-on to standard treatment compared to standard treatment alone.

Countries: Austria, Belgium\*, France, Greece, Germany, Italy, Poland, Portugal, United Kingdom  
Medical field: Cardiology

**BIO-RAIDS<sup>IX</sup>** (Biomarker Evaluation in Advanced Stage Cervical Cancer by an International Working Group. Tumor Stages (1B1 - 4)): ECRIN continued to be involved in this FP7-funded study, which aims to identify predictive biomarkers of standard treatment response using an integrative approach combining exome sequencing, proteomics and tumour micro environment analyses.

Countries: Belgium, France\*, Germany, Moldova, Netherlands, Romania, Serbia  
Medical field: Oncology

**DISCHARGE<sup>X</sup>** (Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies): ECRIN provided monitoring support for this FP7-funded trial, which hypothesizes that coronary computed tomography (CT) is superior to invasive coronary angiography (ICA) for major adverse cardiovascular events in a given population.

Countries: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany\*, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Romania, Serbia, Spain, United Kingdom  
Medical field: Cardiology

<sup>VI</sup>ADIPOA2 has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 643809).

<sup>VII</sup>AETIONOMY has received funding from the Innovative Medicines Initiative (IMI) under grant agreement number 115568.

<sup>VIII</sup>BETA3\_LVH has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement number 634559.

<sup>IX</sup>BIO-RAIDS has received funding from the European Union's 7th Framework Programme for research and technological development under grant agreement number 304810.

<sup>X</sup>DISCHARGE has received funding from the European Union's 7th Framework Programme for research and technological development under grant agreement number 603266.

## ONGOING CLINICAL TRIALS #2

**ESCALE<sup>XI</sup>** (Efficacy Study of Antimicrobial Catheters to Avoid Urinary Infections in Spinal Cord Injured Patients): in the follow-up phase in 2015, this ECRIN-supported trial (funded as part of ECRIN-IA with additional funding from Fundacio la Marata de TV3) aims to make a comparison between the use of antiseptic silver alloy-coated silicone urinary catheters and the use of conventional silicone urinary catheters in spinal cord injured patients to prevent urinary infections. ECRIN's role includes monitoring, pharmacovigilance and project management.

Countries: Italy, Netherlands, Portugal, Spain\*, Turkey  
Medical field: Infectiology / medical device

**EUROHYP-1<sup>XII</sup>** (Cooling Plus Best Medical Treatment Versus Best Medical Treatment Alone for Acute Ischaemic Stroke): in the recruitment/follow-up phase in 2015, this FP7-funded study seeks to determine if systemic cooling to a target temperature of 34 to 35°C, started within six hours of symptom onset and maintained for 24 hours, improves functional outcome at three months in patients with acute ischaemic stroke. ECRIN is involved in monitoring.

Countries: Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany\*, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Romania, Spain, Sweden, Turkey, United Kingdom  
Medical field: Neurology

**FAIR-PARK II<sup>XIII</sup>** (Conservative Iron Chelation as a Disease-Modifying Strategy in Parkinson's Disease): this H2020-funded trial aims to demonstrate an effect of deferiprone (DFP) on the course of PD (including both disease modifying and symptomatic effects). In December 2015, it received voluntary harmonisation procedure (VHP) approval. ECRIN is in charge of pharmacovigilance, regulatory, and ethical submission and monitoring.

Countries: Austria, Czech Republic, France, Germany, Netherlands, Portugal, Spain, United Kingdom  
Medical field: Neurology

**IMPACTT<sup>XIV</sup>** (Efficacy Study of IgY (Antibody Against Pseudomonas) in Cystic Fibrosis Patients): ECRIN's support role on this ECRIN-IA phase 3 trial includes regulatory and ethical submission, monitoring, pharmacovigilance, and advice. The study aims to prolong the time to reinfection with *Pseudomonas aeruginosa* after successfully treated acute or intermittent infection.

Countries: Austria, Belgium, France, Germany\*, Hungary, Italy, Poland, Spain, Sweden  
Medical field: Pneumology / rare diseases

**MEDIT-AGEING<sup>XV</sup>** (Investigating the Impact of Meditation Training on Mental Health and Wellbeing in the Ageing Population): a H2020 project to promote mental well-being, MEDIT-AGEING involves a randomised multicentre clinical trial (RCT) in patients with subjective cognitive decline (SCD) at risk for Alzheimer's disease to assess the short-term effects of a standardised meditation intervention vs. active control on behavioural measures. ECRIN is involved in pharmacovigilance, regulatory and ethical submission, and monitoring.

Countries: France\*, Germany, Spain, United Kingdom  
Medical field: Neurology

<sup>XI</sup> ESCALE has received funding as part of the ECRIN-IA project from the European Union's 7th Framework Programme for research and technological development under grant agreement number 284395; additional funding is provided by Fundacio la Marata de TV3.

<sup>XII</sup> EUROHYP-1 has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 278709).

<sup>XIII</sup> FAIR-PARK II has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 633190).

<sup>XIV</sup> IMPACTT has received funding from the European Union's 7th Framework Programme for research and technological development under grant agreement number 261095; it has received additional funding from another FP7-funded project, ECRIN-IA (grant agreement number 284395).

<sup>XV</sup> MEDIT-AGEING has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 667696).

## ONGOING CLINICAL TRIALS #3

**MENAC<sup>xvi</sup>** (A Randomised, Open-label Trial of a Multimodal Intervention (Exercise, Nutrition and Antiinflammatory Medication) Plus Standard Care Versus Standard Care Alone to Prevent/Attenuate Cachexia in Advanced Cancer Patients Undergoing Chemotherapy): ECRIN continued to provide support to this ECRIN-IA phase 3 study aiming to prevent the development of cachexia early on rather than providing treatment late in the disease trajectory.

Countries: Norway\*, Switzerland, United Kingdom  
Medical field: Medical oncology / nutrition

**POEM vs LHM<sup>xvii</sup>** (Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial (POEM rcpmt)): another ECRIN-IA study, it aims to compare short and long-term feasibility, safety and efficacy of peroral endoscopic myotomy (POEM) with laparoscopic Heller myotomy (LHM) in the treatment of achalasia. In 2015, ECRIN continued to provide support for pharmacovigilance and monitoring.

Countries: Belgium, Czech Republic, Germany\*, Italy, Netherlands, Sweden  
Medical field: Gastroenterology / rare disease / surgery trial

**RESCUE ESES<sup>xviii</sup>** (A Randomized European trial of Steroids versus Clobazam Usage for Encephalopathy with Electrical Status Epilepticus in Sleep): ECRIN continued to support this trial (regulatory and ethical submissions, monitoring, pharmacovigilance, project management), which is part of the ECRIN-IA project. The aim is to establish which treatment is best for children with ESES syndrome.

Countries: Belgium, Bulgaria, Denmark, Finland, France, Germany, Italy, Netherlands\*, Romania, Spain, United Kingdom  
Medical field: Neurology / rare diseases / paediatrics

**TRIHEP 3** (A Comparative Phase 2 Study Assessing the Efficacy of Triheptanoin, an Anaplerotic Therapy in Huntington's Disease): with support ranging from regulatory and ethical submission to monitoring, ECRIN continued to support the implementation of this study. It asks whether the administration of triheptanoin can effectively improve Huntington's disease as assessed by MRI, in vivo spectroscopy and clinical evaluation.

Countries: France\*, Netherlands  
Medical field: Neurology / rare diseases

<sup>xvi</sup> MENAC has received funding as part of the ECRIN-IA project from the European Union's 7th Framework Programme for research and technological development under grant agreement number 284395.

<sup>xvii</sup> POEM vs LHM has received funding as part of the ECRIN-IA project from the European Union's 7th Framework Programme for research and technological development under grant agreement number 284395.

<sup>xviii</sup> RESCUE ESES has received funding as part of the ECRIN-IA project from the European Union's 7th Framework Programme for research and technological development under grant agreement number 284395; it has received additional funding from the Wilhelmina Research Fund, Dutch National Epilepsy Fund (NEF).



# NEW COLLABORATIVE PROJECTS

**CORBEL<sup>xix</sup>**: ECRIN became involved in this Horizon 2020 (H2020) project, aiming to establish shared services between the European Strategy Forum on Research Infrastructures Biological and Medical Sciences Research Infrastructures (ESFRI BMS RIs)–which includes ECRIN–for the biomedical research community. ECRIN is in charge of the third work package (WP3), involving the development of common tools to be used by biomedical research institutions to develop innovative prevention, diagnostic, and treatment solutions.

As part of CORBEL WP3, ECRIN is also leading the Medical Infrastructure/Users Forum (MIUF), which brings together medical research infrastructures and communities to:

- Identify needs of medical research communities in terms of infrastructure and services
- Drive the development of tools and services by the infrastructures
- Share a consistent strategy for the structuring of medical research in Europe, avoiding duplication and gaps

**Rltrain<sup>xx</sup>** (Research Infrastructures Training Programme): began to work on this H2020 project, which aims to develop a flagship training programme enabling research infrastructures (RIs) across all domains to gain expertise on governance, organisation, financial and staff management, funding, intellectual property (IP), service provision and outreach in an international context. ECRIN is involved in work packages on project management; definition of competencies required by RIs; and continuing professional development for managers of RIs.

**EuroStemCell<sup>xxi</sup>**: ECRIN became involved in another H2020 project, European Consortium for Communicating Stem Cell Research (EuroStemCell). The project unites 33 partner institutions, that collectively represent >400 stem cell research groupings across Europe. The goal is to provide trusted high-quality information on stem cells accessible to citizens and stakeholders across Europe, through support and further development of the multi-lingual EuroStemCell Information Portal ([www.eurostemcell.org](http://www.eurostemcell.org)).

**PRO4VIP<sup>xxii</sup>**: ECRIN contributed to this H2020 project, which aims to: create a European-wide network of procurers; define a common innovation procurement roadmap in the short and long term; and define the public procurement of innovation procedure(s) that best meet needs and support the early detection and screening of functional low vision conditions, or would support the provision for low vision services. ECRIN is involved in work packages on information management, online engagement/dissemination, and resources for decision-making and the media.

<sup>xix</sup> CORBEL has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 654248).

<sup>xx</sup> RITRAIN (Research Infrastructures Training Programme) has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 654156).

<sup>xxi</sup> EuroStemCell has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement number 652796).

<sup>xxii</sup> PRO4VIP (Innovative Procurement for Visual Impaired People) has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement number 645584.

# 6 / GEOGRAPHIC DISTRIBUTION

**31**  
COUNTRIES

## ECRIN MEMBER COUNTRIES (as of 31 December 2015)

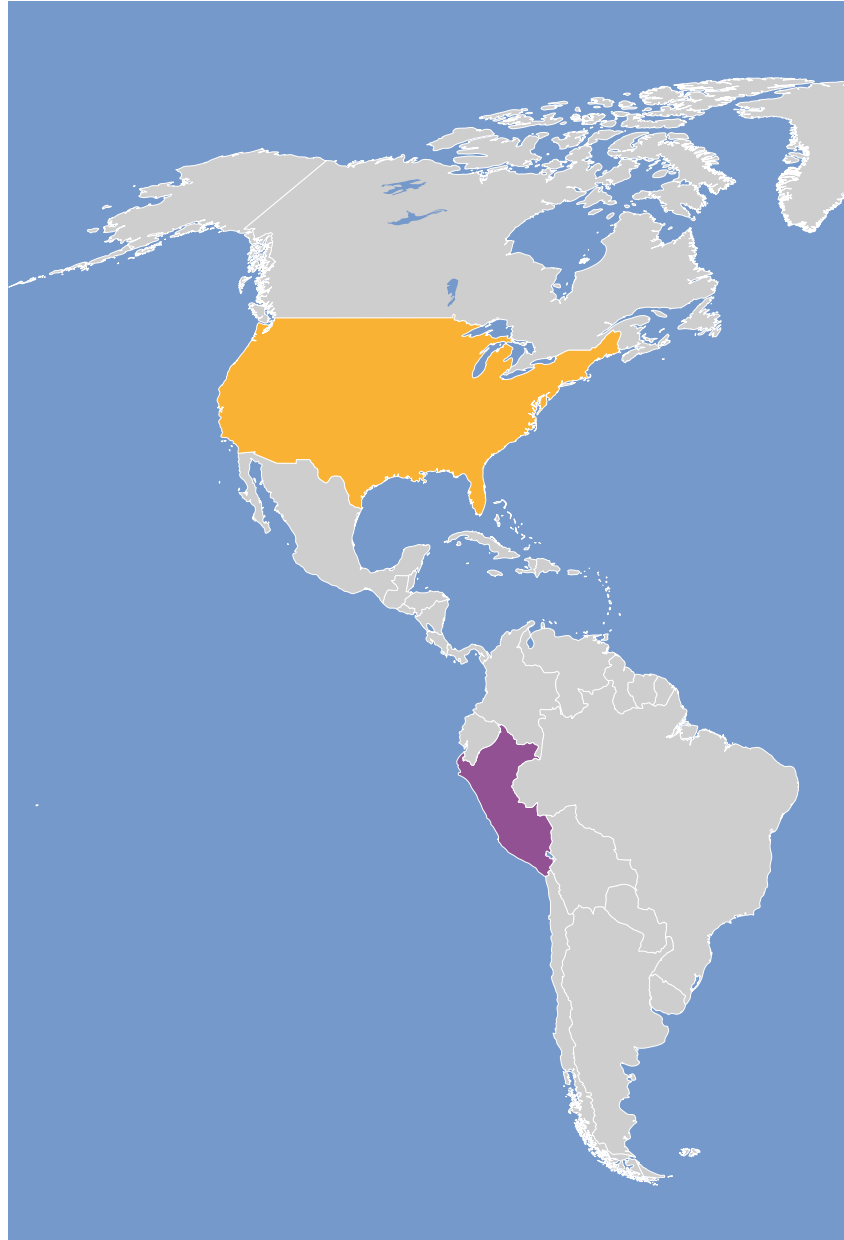
France  
Germany  
Hungary  
Italy  
Portugal  
Spain

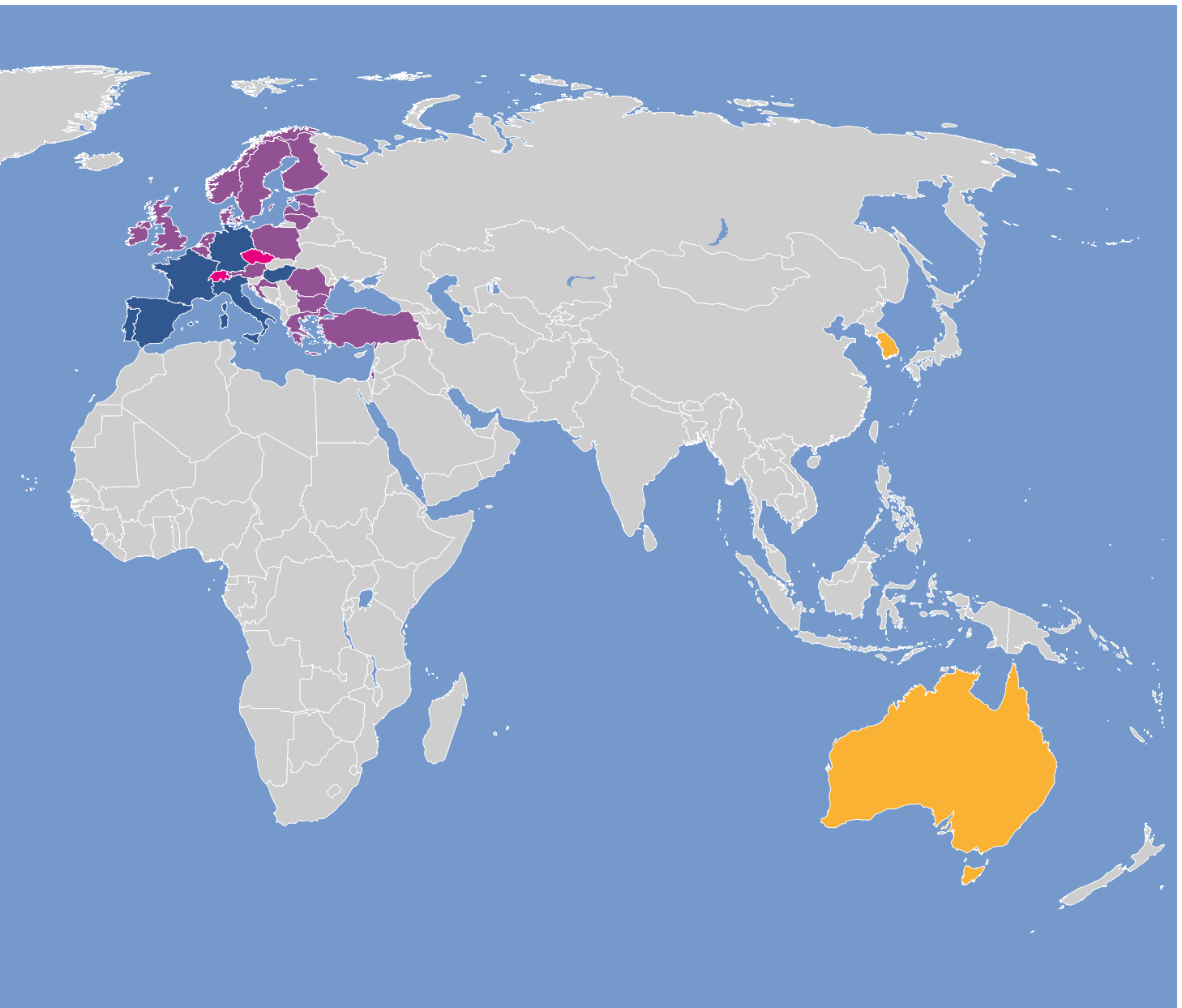
## ECRIN OBSERVER COUNTRIES (as of 31 December 2015)

Czech Republic  
Switzerland

## OTHER COUNTRIES IN ECRIN-SUPPORTED TRIALS / COLLABORATIVE PROJECTS

Austria	Denmark	Ireland	Netherlands	Romania
Belgium	Estonia	Israel	Norway	Sweden
Bulgaria	Finland	Latvia	Peru	Turkey
Croatia	Greece	Lithuania	Poland	United Kingdom





**ECRIN INTERNATIONAL PARTNER COUNTRIES**  
(with whom we have collaboration agreements)



- Australia** (Therapeutic Innovation Australia, TIA)
- Korea** (Korea National Enterprise for Clinical Trials, KoNECT)
- USA** (National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH))



## GOVERNANCE: ASSEMBLY OF MEMBERS

ECRIN is governed by an Assembly of Members (AoM), which is composed of a representative from the government of each Member or Observer Country. In 2015, the AoM was chaired by Rafael de Andres Medina of Carlos III Health Institute (*Instituto de Salud Carlos III, ISCIII*), Spain. Filippo Belardelli (Italy) served as vice chair, and additional members included Alexander Grundman (Germany), Andreia Feijao (Portugal), Claire Levy-Marchal (France), Gabor Kovacs (Hungary), Jan Burianek (Czech Republic), and Annette Magnin (Switzerland).

## ADDITIONAL ORGANISATIONAL BODIES

### NETWORK COMMITTEE

The Network Committee represents the national scientific partners and provides advice to the AoM and Director General. It is composed of one senior delegate from each national scientific partner of Member and Observer Countries. In 2015, the Network Committee was chaired by Christian Ohmann (Germany). The vice chair was Emilia Monteiro (Portugal) and members included Olivier Rascol (France), Gonzalo Calvo (Spain), Flavia Pricci (Italy), Gyorgy Blasko (Hungary), Regina Demlova (Czech Republic), and Annette Magnin (Switzerland).

### 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, two members from the Network Committee, as well as the Director General.

### ADVISORY BOARDS

As part of the ECRIN-IA project, ECRIN had Scientific and Ethical Advisory Boards in 2015, which provided external input on project development and strategy.

## KEY DATES

- 2004** | Creation of ECRIN  
| Began its first project, ECRIN Reciprocal Knowledge Programme or ECRIN-RKP<sup>xxiii</sup> (funded by European Union Framework Programme 6, FP6, "Societal challenges" health sub-programme), involving six countries; ECRIN-RKP aimed to determine bottlenecks to multinational collaboration in academic clinical studies
- 2006** | Started its second project, ECRIN Transnational Working Group or ECRIN-TWG<sup>xxiv</sup> (also funded by FP6), involving 10 countries, to develop procedures and guidelines for investigators and sponsors involved in multinational clinical research in Europe  
| Listed on the European Strategy Forum on Research Infrastructures (ESFRI) roadmap
- 2008** | ECRIN's third project, ECRIN Preparatory Phase for Infrastructure or ECRIN-PPI<sup>xxv</sup> (funded by European Union Framework Programme 7, FP7, for which ECRIN was now eligible given its ESFRI status) was launched in 2008 with 14 countries. The goal was to define the necessary organisational and legal structure for ECRIN to support the establishment and implementation of multinational clinical trials in Europe.
- 2009** | Began to provide services to multinational clinical studies
- 2012** | ECRIN embarked on its fourth project, ECRIN Integrating Activity or ECRIN-IA<sup>xxvi</sup> (also funded by FP7), involving 23 countries and covering three main areas of expertise: rare diseases, medical devices and nutrition
- 2013** | Awarded the status of European Research Infrastructure Consortium (ERIC) by the European Commission

<sup>xxiii</sup> ECRIN-RKP received funding from the European Union's 6th Framework Programme for research and technological development under grant agreement number 511963.

<sup>xxiv</sup> ECRIN-TWG received funding from the European Union's 6th Framework Programme for research and technological development under grant agreement number 37199.

<sup>xxv</sup> ECRIN-PPI received funding from the European Union's 7th Framework Programme for research and technological development under grant agreement number 211738.

<sup>xxvi</sup> ECRIN-IA has received funding from the European Union's 7th Framework Programme for research and technological development under grant agreement number 284395.

# 7 / ECRIN PUBLICATIONS IN 2015



Berge E, Ford GA, Bath PM, Stapf C, van der Worp HB, Demotes-Mainard J, Broderick J, Al-Shahi Salman R, Lees KR; the ESO Trials Network Committee. Regulation and governance of multinational drug trials in stroke: barriers and possibilities. *Int J Stroke*. 2015 Jan 12. doi: 10.1111/ijvs.12427

Burgun A, Oksen DV, Kuchinke W, Prokosch HU, Ganslandt T, Buchan I, van Staa T, Cunningham J, Gjerstorff ML, Dufour JC, Gibrat JF, Nikolski M, Verger P, Cambon-Thomsen A, Masella C, Lettieri E, Bertele P, Salokannel M, Thiebaut R, Persoz C, Chêne G, Ohmann C. Proposal for a European Public Health Research Infrastructure for Sharing of health and Medical administrative data (PHRIMA). *Stud Health Technol Inform*. 2015;216:1005.

De Moor G, Sundgren M, Kalra D, Schmidt A, Dugas M, Claerhout B, Karakoyun T, Ohmann C, Lastic PY, Ammour N, Kush R, Dupont D, Cuggia M, Daniel C, Thienpont G, Coorevits P. Using electronic health records for clinical research: the case of the EHR4CR project. *J Biomed Inform*. 2015; 53:162-73.

Hyttel-Sorensen S, Pellicer A, Alderliesten T, Austin T, van Bel F, Benders M, Claris O, Dempsey E, Franz AR, Fumagalli M, Glud C, Grevstad B, Hagmann C, Lemmers P, van Oeveren W, Pichler G, Plomgaard AM, Riera J, Sanchez L, Winkel P, Wolf M, Greisen G. Cerebral near infrared spectroscopy oximetry in extremely preterm infants: phase II randomised clinical trial. *BMJ*. 2015 Jan 5;350:g7635.

Kerpel-Fronius S, Rosenkranz B, Allen E, Bass R, Demotes Mainard J, Dodoo A, Dubois DJ, Hela M, Kern S, Massud J, Silva H, Whitty J. Education and training for medicines development, regulation, and clinical research in emerging countries. *Front. Pharmacol.*, 2015 | doi: 10.3389/fphar.2015.00080

Ohmann C, Canham S, Danielyan E, Robertshaw S, Legré Y, Clivio L, Demotes J. 'Cloud computing' and clinical trials: report from an ECRIN workshop. *Trials*. 2015 Jul 29;16(1):318.

Wykes T, Haro JM, Belli SR, Obradors-Tarragó C, Arango C, Ayuso-Mateos JL, Bitter I, Brunn M, Chevreul K, Demotes-Mainard J, Elfeddali I, Evans-Lacko S, Fiorillo A, Forsman AK, Hazo JB, Kuepper R, Knappe S, Thornicroft G, van der Feltz-Cornelis C, van Os J, Wahlbeck K, Walker-Tilley T, Wittchen HU; ROAMER consortium. Mental health research priorities for Europe. *Lancet Psychiatry*. 2015 Nov;2(11):1036-42.

# 8 / FINANCIAL REPORT FOR 2015

## INCOME

<b>Member Country Contributions</b> (France, Germany, Italy, Spain, Portugal, Hungary)	€1,310,000
<b>European Commission Projects</b>	€165,540
<b>Financial Income</b>	€12,300
<b>TOTAL INCOME FOR 2015</b>	<b>€1,487,840</b>

## EXPENDITURES

<b>Salaries and Taxes</b>	€720,660
<b>General Administration</b>	€132,030
<b>Other Operational Costs</b> (legal, IT, communication, other)	€153,740
<b>Travel and Meetings</b>	€152,370
<b>Scientific Board Secretariat</b>	€124,000
<b>TOTAL EXPENDITURE FOR 2015</b>	<b>€1,282,800</b>

## NET RESULT

<b>NET RESULT FOR 2015</b>	<b>€205,040</b>
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# 9 / THE YEAR IN REVIEW – HIGHLIGHTS FROM 2015

With new multinational clinical trials and projects launched, additional staff members and an Observer Country, and milestones achieved on various activities, 2015 was an overall success for ECRIN.

## SUPPORT WHERE IT COUNTS

At the heart of ECRIN's activity is support for the management of multinational clinical trials in Europe. In 2015, ECRIN's portfolio of current trials reached 21, with an average of seven countries per trial. Since its creation in 2004, ECRIN has been involved in 33 trials. The potential scientific and public health impact for such cross-country collaboration is considerable, as access is granted to greater numbers of patients, resources and medical expertise.

An additional support area continued to be the preparation and validation of multinational trials. This activity gained visibility with the launch of ECRIN-On-Board (EoB), aiming to optimise support to investigators for the development of EU funding proposals (e.g., H2020, IMI, E-Rare calls) including protocol review and logistical assessment.

## FROM TOOLS TO CAPACITY BUILDING

ECRIN's support to multinational clinical trials or collaborative projects is not limited to management, advice or information alone. ECRIN recognises that to be successful, countries need to enhance their ability to design and conduct multinational trials. This means having the right tools, resources, infrastructure and capabilities. That is why, in 2015, ECRIN continued to develop freely-accessible common tools and to strengthen national clinical trial infrastructure. Much of this work was done through the ECRIN-IA project, which impressively brought together 23 countries to build capacity in rare diseases, medical devices and nutrition.

## DATA CENTRE CERTIFICATION

Another key activity in 2015 was ECRIN data centre certification, part of ECRIN's quality programme. New criteria, developed by ECRIN, were introduced in May and site audits followed. This shows ECRIN's commitment to high-quality data management and harmonised standards.



## **ADDITIONAL PROJECTS AND ECRIN'S DUAL ROLE**

ECRIN plays a dual, yet perhaps lesser-known role. In addition to supporting trials themselves (and building the tools and capacity to implement them), it is an active player in European collaborative projects related to clinical research. This was shown in 2015 through its involvement (as a work package leader or participant) in new H2020 projects, particularly CORBEL and Rltrain.

## **ORGANISATION AND GROWTH**

In 2015, ECRIN's Paris-based Core Team nearly doubled in size, welcoming staff to develop its operations, communications, quality, administrative and project management capacity. With six Member and two Observer Countries as of the end of 2015, ECRIN plans to increase its membership and to develop additional partnerships with European and international stakeholders.

## **A EUROPEAN AND INTERNATIONAL ACTOR**

Not just focused on Europe, ECRIN seeks to facilitate multinational clinical research on a global level. This was seen in 2015 through its involvement in the CRIGH initiative and the development of new and existing international partnerships.

## **LOOKING FORWARD: A COMMITMENT TO SCIENCE AND SOCIETY**

Looking ahead, ECRIN plans to continue to develop and expand projects across its various domains of activity. In 2016 and beyond, we can expect to see additional multinational clinical trials in diverse disease areas, stronger partnerships with investigation networks, international collaboration on clinical research issues, and more.

In general, ECRIN will strive to make a greater scientific and socio-economic impact on health and the economy. This will be mainly achieved by providing support to large, multinational comparative effectiveness trials testing various authorised preventive, diagnostic or therapeutic solutions for a disease condition, leading to evidence-based medical decisions. This benefits patients and healthcare systems, by comparing the safety, efficacy and effectiveness of each option in real life, thus optimising medical decisions and healthcare strategies while containing the cost of treatments.





