



Strategic Plan

2024 - 2027



OUR MISSION

To support the conduct of multinational clinical trials in Europe

OUR VISION

To generate scientific evidence to optimise medical practice

The ECRIN Strategic Plan 2024-2027 has been developed by a dedicated ECRIN task force from October 2023 to March 2024, based on the analysis of ECRIN's position in the environment, and analysis of its strengths, weaknesses, opportunities, and threats. The feedback and suggestions from the ECRIN staff, ECRIN community and the governing body were actively collected during consultations.

“ECRIN supporting clinical studies across borders”

ECRIN's vision is to generate scientific evidence to optimise medical practice.

To achieve this vision, ECRIN supports investigator-initiated multinational clinical research in Europe. By managing and supporting clinical studies across borders, connecting networks, and advising and implementing policy, ECRIN advances knowledge flow, competitiveness and integration in European clinical research.

This strategy outlines ECRIN's ambitions for the next four years. The specific actions, timelines and indicators to measure the implementation of these goals will be included in the ECRIN annual workplans.

Introduction

ECRIN celebrated its 10 year anniversary on November 29th 2023. This marked the first decade since ECRIN was awarded its European Research Infrastructure Consortium (ERIC) legal status in 2013. With this status, ECRIN can collect Member country contributions, which sustains the organisation's core budget.

Prior to this, ECRIN was listed on the 2006 European Strategy Forum on Research Infrastructures (ESFRI) roadmap, and was developed and matured through a series of five EU-funded projects (FP6, FP7, and H2020) to successfully become a pan-European research infrastructure providing a full range of services to support the conduct of multinational clinical research in Europe.

Building on this experience and the expert knowledge existing and developed within the organization and its national partners, ECRIN can now consolidate its activities to continue to serve the scientific community and its various stakeholders in an evolving clinical research ecosystem.



Strategic Plan 2021-2023: key results

Many achievements resulted from the previous strategic plan (2021-2023) and allowed ECRIN to develop its capacity and increase its visibility and recognition of its expertise.

Throughout this period, ECRIN successfully enhanced its collaboration with its national partners, implemented “CTU Day” for enhanced knowledge exchange with the clinical trial units involved in the national partners, and optimised its internal processes as confirmed by the renewal of the ISO certification. ECRIN also increased its involvement with regulators through participation in initiatives such as ACT-EU and ERA4Health¹ project.

With regards to the development of new areas of interest, and expanding the scope of activities, ECRIN participated in several EU-funded projects enabling an increase of its knowledge and expertise, and the

development of new services: EU-PEARL² (platform trials), EJP RD³ (Rare Disease Toolbox), EOSC-Life⁴ and BY-COVID⁵ (clinical research metadata repository, and clinical research data sharing repository), Healthy Cloud⁶ (Strategic Agenda for a Health Research and Innovation Cloud), among others.

ECRIN’s visibility has significantly grown in recent years, thanks to a revamped brand identity, website, and communication tools. This heightened visibility is further amplified by a synergistic collaboration with the national partners through a joint communication working group fostering the exchange of information, best practices, and the alignment of actions.

The International Clinical Trials Day’s audience and reach have expanded significantly following the adoption of a hybrid organisation, enabling remote participation of a broader audience.

A sustainable partnership has been established with EUPATI and will be the basis for our patient engagement activities at European and country level in collaboration with our national partners through the EUPATI National Platforms (ENPs).

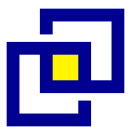
“ECRIN’s visibility has significantly grown in recent years”

The partnership with the user and medical communities is supported by participation in joint projects (c4c⁷ for paediatrics, EJP-RD for rare diseases, CoMeCT⁸ for infectious diseases, etc.) and by the development of national networks in several ECRIN countries.

The COVID-19 outbreak was an

opportunity to demonstrate the capacity of ECRIN to rapidly adapt to a new research environment under a public health emergency. This resulted in the establishment of the COVID-19 taskforce and ECRIN’s participation in the design and management of various platform trials on COVID-19 treatments and vaccines. Moreover, a new service to the clinical research community arose, where ECRIN contributed to the coordination and governance of the COVID-19 platform trials, in particular acting as the secretariat of the Joint Access Advisory Mechanism (JAAM), functioning as the gatekeeper providing independent scientific assessment for candidate intervention arms.

The achievements of the past three years have positioned ECRIN for an ambitious new strategic agenda.



Overview

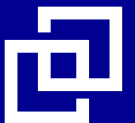
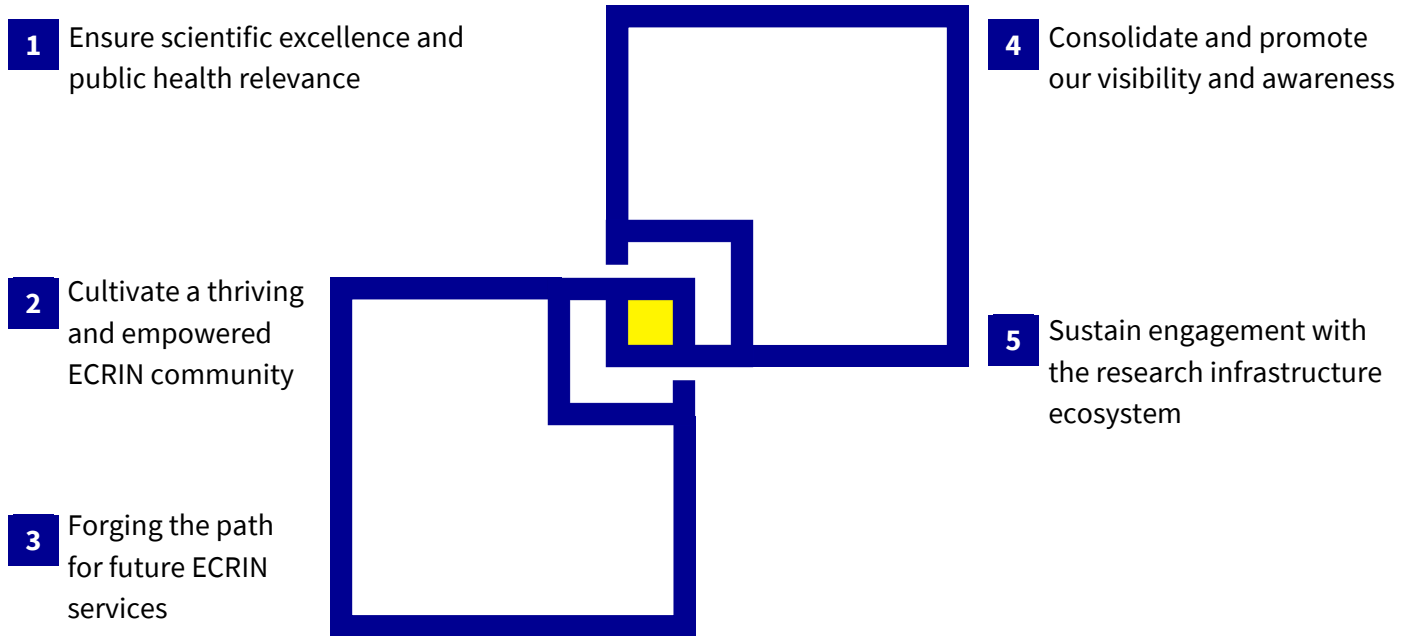
2024 to 2027 represents a consolidation phase for ECRIN, building on the achievements accrued in the previous years and the lessons learned. The main strategic objectives are:

- Strengthen our position as a recognised infrastructure: demonstrate our performance, impact, and the quality of services;
- Extend the scope of our services and expertise, responding to the clinical research ecosystem evolution (i.e. new types of studies including adaptive platform trials);
- Maintain the infrastructure (operational services, staff, partners, collaborations);
- Continue building our community and engaging with our national partners;
- Enhance patient engagement and collaboration with patient representatives;
- Consolidate and promote our visibility and the awareness of our community (users, stakeholders, policy makers, regulators) through communication and training actions;
- Pursue collaboration with other research infrastructures and expand collaboration beyond Europe.

*“In the next four years, ECRIN will **sustain**- the organisation, the activities, the community, the quality, and the collaborations; will **innovate**- to meet the new challenges and evolving clinical research ecosystem; and will **empower** -our staff, partners, and patients’ community.”*

Our Goals

In response to these strategic objectives we have defined five goals to drive ECRIN's activity for the 2024-2027 strategic plan:



1

Ensure scientific excellence and public health relevance

To maintain its position as a dynamic force driving excellence and quality in clinical research while actively contributing to improving public health outcomes, ECRIN commits to a multifaceted strategy, addressing critical aspects ranging from stakeholder collaborations to patient-centric methodologies and continuous innovation.

To this end, ECRIN is committed to mapping and analysing the ever-evolving landscape of **scientific innovation, research methodologies, and quality assured clinical data registries and repositories.**

The organisation and partners participate in conferences, initiatives, and workshops across relevant fields. By staying at the forefront of advancements, ECRIN ensures that its practices and policies align with the latest developments in clinical research, fostering an environment of continuous improvement and adaptability.

ECRIN recognizes the pivotal role of **collaboration and advocacy** in shaping the future of clinical research. The organisation is dedicated to enhancing interactions with key stakeholders, including national experts, regulators, ethics committees, and policy makers at both national and EU levels. By fostering these connections, ECRIN aims to create an environment conducive to the evolution of clinical research methodologies and the development of impactful policies.

To ensure the inclusivity and diversity of clinical studies, ECRIN prioritizes strengthening **patient engagement.** The organisation seeks to improve accessibility to clinical studies and implement a patient-centric approach in the design, development, and reporting of clinical research. By continuing to place patients at the heart of the process, ECRIN aims to enhance the quality and relevance of clinical studies while promoting equal access for all.

ECRIN recognises the paramount importance of **internal expertise and the quality of services** to further enhance the value and reliability of clinical research. The organisation commits to reinforcing its internal capabilities through standards, guidelines, best practices, and certification programmes as well as leveraging national expertise and training initiatives.

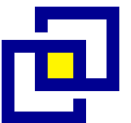
“To ensure the inclusivity and diversity of clinical studies, ECRIN prioritizes strengthening patient engagement.”

To contribute meaningfully to the resolution of critical health challenges, ECRIN aims to develop policy statements and white papers to provide insight into key areas of interest.

In the pursuit of excellence, ECRIN acknowledges the need to continually

evaluate the impact of clinical studies, ensuring that the knowledge generated translates into tangible benefits for citizens. This will be achieved through collaborative efforts with its national partners, scientific boards and stakeholders. Regular assessments and adjustments will be made to ensure alignment with the evolving research landscape and public health priorities.

ECRIN’s comprehensive strategy, spanning stakeholder engagement, patient-centric approach, innovation, policy alignment, expertise reinforcement, and impact evaluation reflects a commitment to advancing clinical research in Europe with a focus on excellence, inclusivity, and continuous improvement. Through these initiatives, ECRIN aims to play a pivotal role in shaping the future of European clinical research and contributing to improved public health outcomes.



2

Cultivate a thriving and empowered ECRIN community

As a distributed infrastructure, ECRIN is only as strong as its network. It is essential not only that the network be cohesive on a national level but that those in the CTUs also understand what the organisation is and how it benefits them. Efforts have been made to establish a sense of belonging on all levels for some time, and with this new strategic agenda, we aim to boost such endeavours through increased outreach, training, networking and new opportunities to participate in EU initiatives and projects.

Among the top assets of the existing ECRIN community is the diversity of its national networks with their different strengths and expertise. Supporting the various partners and continuing to develop new means of sharing this information is a wonderful example of

how ECRIN is and will be **stronger together. Webinars and training** activities, as they exist today, through the annual ECRIN CTU Day, or open scientific meetings, should continue and benefit from the feedback of those who already partook. To bolster this activity,

“ECRIN community has among its top assets the diversity of its national networks with different strengths and expertise”

new means of reaching even more members of the CTU network will be carried out by both ECRIN and its national partners. Moreover, a feedback loop will be reinforced to ensure that ECRIN is aware of our community's needs and continues to develop resources to support them.

To bolster the sense of belonging, other means of sharing expertise across the network will be organised through dedicated meetings both in person or online, networking events, mentoring, or staff exchanges.

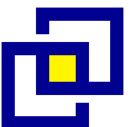
By **connecting national investigation networks** in specific disease areas, ECRIN should contribute to the establishment of pan-European investigator networks. These groups as users and partners of ECRIN would be able to design and conduct, with the support of ECRIN, large pan-European studies or platform trials.

ECRIN will continue to support the core management skills of its CTU community, as well as, develop and deploy its **identification of expert and specialised CTUs**. The Data Centre Certification Programme, which now benefits from the version 5.0 of the ECRIN Data Standards, will continue to audit and certify data

centres in ECRIN countries that meet its standards for supporting academic clinical research. Similarly, the vigilance standards will be developed to offer the possibility of certification.

ECRIN will also focus on building the community through the creation of new opportunities for the national partners. Notably, this can include initiatives such as their inclusion in new calls and projects, or the co-creation of resources and publications to increase awareness of timely issues for the European clinical research community.

Last, but not least, **outreach beyond the existing community** is necessary to onboard new ECRIN member countries. Work will continue to be carried out to better identify their needs, capacity and objectives to support them in overcoming the existing barriers to membership.



3

Forging the path for the future ECRIN services

Facilitating pan-European studies requires ECRIN to operate across the whole clinical research ecosystem. To propel ECRIN to new heights in the realms of collaborative and impactful clinical research, we need to be the catalyst for cutting-edge methodologies that not only uphold the highest standards of scientific excellence but also directly address the pressing needs of European citizens.

Emerging trends in synthetic data, in silico trials, AI, and related areas identified through a comprehensive landscape analysis will be assessed regarding their technological and methodological considerations, and by gauging their **potential impact on ECRIN's services**.

To better serve the research community, ECRIN maps their requirements, needs, and expectations,

aligning them with the capabilities of the organisation to ensure the adoption of its services. To **develop future services** tailored to meet the specific needs identified by the research community, a co-creation approach will be implemented with the users and the stakeholders.

ECRIN also identifies potential **resources and capacity from its partners**, strategically leveraging them to enhance service development and expand ECRIN's capabilities.

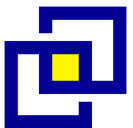
To stay at the forefront of evolving services and technologies, ECRIN strategically **grows its team and invests in training programs**. This ensures that team members are adequately equipped to handle new challenges and deliver high-quality services to the research community.

Funding remains a critical issue. ECRIN develops a proactive strategy for securing funding to support infrastructure growth and services, ensuring sustainability and continuity in providing essential support to the research community, however, for multi-country investigator initiated clinical studies this remains a critical point. To this end, ECRIN **actively promotes, designs and supports new funding mechanisms** and initiatives for multi-country investigator-initiated clinical studies fostering innovation and collaboration across borders.

ECRIN promotes the development and implementation of **platform trials**, engaging different member countries for collaborative efforts. This approach fosters efficiency and synergy in conducting multi-country clinical studies.

Furthermore, ECRIN prioritizes the development of clinical studies and services that align with the requirements of Health Technology Assessment (HTA), particularly in the context of the HTA Regulation, which emphasizes increased EU cooperation for generating evidence from comparative effectiveness and treatment optimization/combination trials. ECRIN also promotes the implementation of the World Health Assembly (WHA) 75.8 Resolution through the CRIGH initiative and the dissemination of the ECRIN model of regional clustering for clinical research capacity to other world regions.

ECRIN actively contributes to pandemic preparedness and to the coordination of research under public health emergencies.



4

Consolidate and promote our visibility and awareness

For this new strategic plan, the goal is to consolidate the visibility and awareness while maintaining the current momentum and quality of activities. To respond to this need ECRIN will look to optimise the current tools and improve the impact of its communication actions. Central items to the realisation of this goal include the existing communication channels, building national capacity, participation at both ECRIN hosted and external events, the development of a training offer, and scientific outreach.

At the heart of ECRIN's outreach is its website. All relevant information and tools are made available to the general public here, and social media and bimonthly newsletters are used to support the dissemination.

For this strategic agenda, ECRIN will work to increase its visibility in the

scientific community by **ensuring the necessary recognition** of its work in clinical studies. ECRIN's presence will also be better represented through advocacy and support to policy via its response to public consultations. Moreover, ECRIN will endeavour to increase its dissemination with the lay scientific press and patient groups to ensure a wider understanding of its services and the benefits of participation in clinical studies.

To increase the impact of its communication and ensure visibility at national level, ECRIN **works directly with its national partners to develop and share messaging**. This is crucial as the national partners are linked to their local research communities. Furthermore, ECRIN looks to support the national partners to develop their capacity. Encouraging this initiative can only enhance our visibility in Europe.

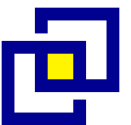
ECRIN will continue to **demonstrate how it supports the research community** through success stories. These will highlight various aspects of ECRIN's role from internal and external points of view. ECRIN will continue to **expand the reach of the events that it hosts** through hybridisation and communication tactics. It will continue to participate in events held by various stakeholders and disease areas across Europe and beyond.

From an outreach perspective, training should not be overlooked. Through training, ECRIN can demonstrate its strengths and increase the overall level of understanding of the European community on clinical studies. Training provides not only visibility but also enables interactions between ECRIN stakeholders and its staff, paving the way for future collaborations and upskilling the next generation of clinical researchers.

Throughout these 4 years, **ECRIN will develop its training capacity.** At the end of the previous strategic agenda, ECRIN began working with its national scientific partners to offer widescale training to all its Member countries based on an identified need. With this in

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mind, work will be carried out with the national partners to map the current capacity, gaps and goals and identify the areas where ECRIN's expertise will be of most use to support them nationally, and where larger-scale training can be developed.



5

Sustain engagement with research infrastructure ecosystem

To be positioned as an important partner in the research infrastructure ecosystem, ECRIN actively engages in overarching initiatives and programmes. To fortify connections within the Research Infrastructures (RIs), and partake in opportunities, ECRIN is working to identify common strengths, prevent overlaps, and to **foster collaboration with the Life Science RIs, ERICs, ESFRI, and EOSC.**

“ECRIN actively engages in overarching initiatives and programs”

In an effort to **enhance internal knowledge**, ECRIN is integrating the “RIs ecosystem” into the induction course for newcomers.

ECRIN strategically leverages established collaborations, such as those with EATRIS on repurposing and personalized medicine, BBMRI on infrastructure support to cohorts, and ELIXIR on sensitive data FAIRification and sharing. Moreover, EU-AMRI will continue to support the joint efforts of the medical research infrastructures.

This collaborative approach not only broadens but also reinforces the ECRIN service portfolio, ultimately benefiting the entire European clinical research community.

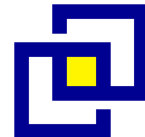
References and abbreviations

REFERENCES

1. ERA4Health is co-funded by the European Union's Horizon Europe programme under grant agreement N101095426
2. EU-PEARL has received funding from the IMI & the European Union's H2020 programme under grant agreement N853966-2.
3. EJP-RD has received funding from the European Union's H2020 programme under grant agreement N825575.
4. EOSC-Life has received funding from the European Union's H2020 programme under grant agreement N824087.
5. BY-COVID has received funding from the European Union's H2020 programme under grant agreement N101046203.
6. HealthyCloud has received funding from the European Union's H2020 programme under grant agreement N965345.
7. c4c has received funding from the European Union's H2020 through the Innovative Medicines Initiative 2 grant agreement N777389
8. CoMeCT has received funding from the European Union's Horizon Europe programme under grand agreement N101136531

ABBREVIATIONS

- ACT-EU** Accelerating Clinical Trials in the EU
- BBMRI** Biobanking and Biomolecular Resources Research Infrastructure
- COVID-19** Coronavirus Disease 2019
- CRIGH** Clinical Research Initiative for Global Health
- CTU** Clinical Trial Unit
- EATRIS** European Advanced Translational Research Infrastructure in Medicine
- ECRIN** European Clinical Research Infrastructure Network
- ELIXIR** European life science infrastructure for biological information
- ENP** EUPATI National Platform
- EOSC** European Open Science Cloud
- ERIC** European Research Infrastructure Consortium
- ESFRI** European Strategy Forum on Research Infrastructures
- EU** European Union
- EU-AMRI** European Alliance of Medical Research Infrastructures
- EUPATI** European Patients' Academy on Therapeutic Innovation
- HTA** Health Technology Assessment
- JAAM** Joint Access Advisory Mechanism
- RI** Research Infrastructure
- WHA** World Health Assembly





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