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COMMISSION IMPLEMENTING DECISION (EU) 2025/410

of 26 February 2025

amending Decision 2013/713/EU setting up ECRIN-ERIC

(notified under document C(2025) 1189)

(Only the Czech, English, French, German, Greek, Hungarian, Irish, Italian, Polish, Portuguese, Slovak and Spanish texts are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) ([1]), and in particular Article 11(1) thereof,

Whereas:

(1) Regulation (EC) No 723/2009 has been incorporated in the Agreement on the European Economic Area (EEA) by Decision of the EEA Joint Committee No 72/2015 ([2]).

(2) The European Clinical Research Infrastructure Network was set up as a European Research Infrastructure Consortium (ECRIN-ERIC) by Commission Decision 2013/713/EU ([3]).

(3) ECRIN-ERIC submitted on 25 September 2023, on 23 November 2023 and on 17 May 2024 a proposal to the Commission to amend its Statutes in accordance with Article 11(1) of Regulation (EC) No 723/2009.

(4) Some amendments concerning minor changes in the rights of members and observers, governance, data policy, amendment procedure, definition of scientific partners, updated list of members and observers and updated list of financial contributions (a list with the financial contributions of each member and observer), entered into force in accordance with Article 11(4) of Regulation (EC) No 723/2009.

(5) Some other amendments, introducing minor changes in the description of tasks and activities, governance affecting the scientific evaluation policy, description of the winding up procedure and dissemination policy, require the Commission's approval.

(6) The Commission has, pursuant to Article 5(2) of Regulation (EC) No 723/2009, assessed the application and concluded that it meets the requirements set out in that Regulation.

(7) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 20 of Regulation (EC) No 723/2009,

([1]) OJ L 206, 8.8.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/723/oj.

([2]) Decision of the EEA Joint Committee No 72/2015 of 20 March 2015 amending Protocol 31 to the EEA Agreement, on cooperation in specific fields outside the four freedoms [2016/755] (OJ L 129, 19.5.2016, p. 85, ELI: http://data.europa.eu/eli/dec/2016/755/oj).

([3]) Commission Implementing Decision 2013/713/EU of 29 November 2013 on setting up the European Clinical Research Infrastructure Network (ECRIN) as a European Research Infrastructure Consortium (ECRIN-ERIC) (OJ L 324, 5.12.2013, p. 8, http://data.europa.eu/eli/dec_impl/2013/713/oj).

HAS ADOPTED THIS DECISION:

Article 1

The Statutes of the ECRIN-ERIC annexed to Decision 2013/713/EU are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Czech Republic, the French Republic, the Federal Republic of Germany, the Hellenic Republic, Hungary, Ireland, the Italian Republic, the Kingdom of Norway, the Republic of Poland, the Portuguese Republic, the Slovak Republic, the Kingdom of Spain and the Swiss Confederation.

Done at Brussels, 26 February 2025.

For the Commission
Ekaterina ZAHARIEVA
Member of the Commission

ANNEX

The Statutes of the ECRIN-ERIC annexed to Decision 2013/713/EU are amended as follows:

(1) Article 3 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The principal task of ECRIN-ERIC shall be to establish and operate a research infrastructure supporting multi-national collaboration in clinical research, to make Europe a single area for clinical studies.';

(b) paragraph 3 is replaced by the following:

'3. Information, advice and services proposed by ECRIN-ERIC shall particularly cover support to clinical study management, reducing the fragmentation of health and legislative systems in Europe: submissions to ethics committees and competent authorities, adverse event reporting, study monitoring, data management, support with insurance contracting.';

(2) Article 9(2) is amended as follows:

(a) point (b) is replaced by the following:

'(b) be composed of one senior Delegate of each Scientific Partner from Member and Observer countries. The ECRIN-ERIC Director-General shall attend the meetings of the Network Committee. The ECRIN-ERIC Management Office shall act as the Secretariat for the Network Committee;';

(b) point (e) is replaced by the following:

'(e) support the coordinated implementation, at national level, of decisions, strategies, rules, and procedures set out by the ECRIN-ERIC Director-General and the Assembly of Members in the pluri-annual work plan;';

(3) Article 20 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. The intangible assets of ECRIN-ERIC (scientific assets) shall be transferred after its winding up to an entity that shall be agreed by a more than two thirds majority of the Members representing a more than two thirds majority of the mandatory contributions.';

(b) the following paragraph 4 is added:

'4. The tangible assets of ECRIN-ERIC (cash and cash equivalent, real estate, equipment, other) shall be redistributed to ECRIN-ERIC current Members at the time of winding up in proportion to their share in the ECRIN-ERIC assets. Detailed rules on winding up procedure are defined in the Internal Rules of Procedure.';

(4) The following Article is inserted after Article 20:

'*Article 20a*

Dissemination policy

1. ECRIN-ERIC shall take all appropriate action to promote the infrastructure and its use in research and education.

2. ECRIN-ERIC shall promote the dissemination and sharing of results obtained by multinational clinical studies supported by ECRIN-ERIC, and of any tool, procedure or methodology developed with a contribution of ECRIN-ERIC.

3. Without prejudice to any property rights ECRIN-ERIC shall request its users to make their research results publicly available, and to make results available through ECRIN-ERIC.

4. The dissemination policy shall identify the various target groups, including patients, and ECRIN-ERIC shall use several channels to reach the target audiences, such as web portals, social media, newsletters, workshops, presence at conferences, articles in journals and daily newspapers.

5. ECRIN-ERIC shall promote an Open Science policy, as well as the sharing and secondary use of all data generated with the support of ECRIN-ERIC according to the FAIR (Findable, Accessible, Interoperable and Reusable) principle, and in compliance with national and European data protection legislations.'.

CONSOLIDATED STATUTES OF THE EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

(ECRIN-ERIC)

COMMISSION IMPLEMENTING DECISION

of 29 November 2013

on setting up the European Clinical Research Infrastructure Network (ECRIN) as a European Research Infrastructure Consortium (ECRIN-ERIC)

(2013/713/EU)

Amended on:
February 27th, 2017 (Amendment No.1)
and on December 9th, 2019 (Amendment No.2)
and on November 22nd, 2023 (Amendment No.3)
and on February 26th, 2025 (Amendment No.4)

ANNEX I

STATUTES OF THE EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK (ECRIN-ERIC)

THE FEDERAL REPUBLIC OF GERMANY

THE KINGDOM OF SPAIN

THE FRENCH REPUBLIC

THE ITALIAN REPUBLIC

THE PORTUGUESE REPUBLIC

Hereinafter referred to as 'the Founding Members'

DESIRING to strengthen Europe's and the Founding Member countries' position in clinical research in the world, and to intensify cooperation across national boundaries;

CONSIDERING that multinational clinical research is currently hampered by the fragmentation of health and legislative systems in Europe, an obstacle for multinational cooperation in investigator driven, as well as industry-sponsored clinical research (particularly in the biotechnology and medical device sectors), European countries must unlock latent scientific potential and access to patients and expertise, thus strengthening the competitiveness of Europe in clinical science and its attractiveness for the development of preventive, diagnostic and therapeutic procedures — this is of particular importance for rare diseases, paediatrics, personalised treatments, for the development of biotherapy, and for independent clinical trials that are pivotal instruments for evidence-based medicine;

BUILDING on the ESFRI roadmap that identified the European Clinical Research Infrastructure Network (ECRIN) as the distributed infrastructure supporting, based on scientific excellence, clinical research in Europe through information, consulting and services to investigators and sponsors in multinational studies, acting through correspondents hosted in national clinical research hubs and networks, also contributing to the structuring of national infrastructures, harmonising training, tools and practice and high quality standards, fostering transparency and data sharing, promoting a harmonised regulatory system and shared ethical standards;

RECOGNISING that, for each Member country, participating in ECRIN enables the initiation of, and the participation in multinational clinical research projects, taking advantage of the population size of the European Union, therefore strengthens the attractiveness and competitiveness of the national clinical research infrastructure and its ability to support high quality clinical research in line with European standards, with a strong impact on research capacity, on innovation, and on health;

EXPECTING other countries to participate in the activities undertaken together under the following Statutes;

HAVE AGREED AS FOLLOWS:

Article 1

Establishment of ECRIN-ERIC

1. There shall be a distributed European Research Infrastructure called the European Clinical Research Infrastructure Network ECRIN).

2. The name of the European Research Infrastructure Consortium (ERIC) - European Clinical Research Infrastructure Network shall be 'ECRIN-RIC'.

Article 2

Objectives

1. ECRIN-ERIC shall constitute a Pan-European distributed clinical research infrastructure with as objectives to provide advice and services to multinational clinical research, in any medical field and for any category of clinical research, observing high scientific, ethical and quality standards, in order to strengthen the capacity of the European Union to explore the determinants of diseases and to develop and optimise the use of diagnostic, prevention and treatment strategies.

2. ECRIN-ERIC shall:

(a) provide support to multicentre clinical studies involving at least two countries;

(b) be primarily accessible to investigator-initiated clinical research, but also open to industry sponsored clinical research projects, originating from any country;

(c) encourage cooperation and harmonisation;

(d) be a distributed infrastructure, based on the connection of existing national or regional clinical research networks;

(e) promote common standards, tools and practice that will impact on the structuring of national networks;

(f) promote training of investigators and all categories of professionals and lay persons involved in clinical research;

(g) promote quality, transparency and optimal use of clinical research data;

(h) communicate with patients and citizens on the challenges and opportunities raised by clinical research.

Article 3

Tasks and activities

1. The principal task of ECRIN-ERIC shall be to establish and operate a research infrastructure supporting multi-national collaboration in clinical research, to make Europe a single area for clinical studies.

2. ECRIN-ERIC shall provide information, advice and services to clinical investigators and sponsors of multinational studies, as well as advice to national and European authorities and policymakers, as described in the Scientific and Technical Annex accompanying the ERIC application documents.

3. Information, advice and services proposed by ECRIN-ERIC shall particularly cover support to clinical study management, reducing the fragmentation of health and legislative systems in Europe: submissions to ethics committees and competent authorities, adverse event reporting, study monitoring, data management, support with insurance contracting.

4. ECRIN-ERIC shall pursue its principal task on a non-economic basis. However it may carry out limited economic activities, provided that these are closely related to its principal task and that do not jeopardise the achievement thereof.

5. ECRIN-ERIC shall record the costs and revenues of the economic activities referred to in paragraph 4 separately and shall charge market prices for them, or if these cannot be ascertained, full costs plus reasonable margin.

Article 4

Members and Observers

1. The following entities may become Member or Observer of ECRIN-ERIC:

(a) Member States;

(b) Associate Countries;

(c) Third Countries other than Associate Countries; and

(d) Intergovernmental Organisations.

2. ECRIN-ERIC shall have at least three Member States as Members. Members of ECRIN–ERIC of which membership commenced with the ECRIN-ERIC foundation will be hereinafter referred to as Founding Members. European Union Member States shall hold jointly the majority of voting rights in the Assembly of Members.

3. The admission of candidate Members, or candidate Observers, shall be subject to the approval of the Assembly of Members.

4. Members and Observers of ECRIN-ERIC are listed in Annex II. This Annex shall be updated by the ECRIN-ERIC Director-General after revocation or withdrawal of memberships, or approval of candidate Members or Observers by the Assembly of Members.

5. Withdrawal from Membership

(a) Members may, by giving a minimum of three years' notice, withdraw from ECRIN-ERIC by writing to the Chair of the Assembly of Members stating: (1) the reasons for withdrawal and (2) the requested date of withdrawal.

(b) All outstanding payments and obligations must be paid and fulfilled before the withdrawal of membership can become effective.

(c) The Assembly of Members shall be notified of any request for withdrawal during the next meeting and the Membership shall be put on hold on that date.

(d) The provisions set out in point (a) in the present paragraph apply also for the withdrawal of Observers, but with a minimum of one year's notice.

6. Revoking Membership

(a) The Assembly of Members may revoke the membership of a Member if the following conditions are met:

(i) the Assembly of Members considers that the Member is in substantial breach, of one or more of its obligations under these Statutes or that the Member brings ECRIN-ERIC into disrepute, and the Member has failed to rectify such breach within 30 days after it has received notice of the breach by the Director-General in writing; or

(ii) the Chair of the Assembly of Members or the Director-General has submitted to the Assembly of Members a motion to revoke the relevant Membership; and

(iii) the motion for revocation receives the consent from two thirds of the voting members representing two thirds of the contributions, excluding the Member concerned.

(b) The provisions set out in point (a) shall apply also for the revocation of Observers.

Article 5

Rights of Members and Observers

1. Members shall make full contribution to ECRIN-ERIC as specified in Annex III (4) and according to the pluri-annual workplan and the relative indicative contribution.

2. Observers shall make a partial contribution to ECRIN-ERIC budget for sustainable operation of ECRIN-ERIC as specified in the Annex III(5) and may remain as Observer of ECRIN-ERIC for a maximum period of three years; after this period the Observer has to either apply for Membership or withdraw from ECRIN-ERIC. Observers shall attend the meeting of the Assembly of Members without voting rights.
Under exceptional circumstances, based on a decision of the Assembly of Members (approved by consensus or if no consensus can be found by a vote of more than two thirds of ECRIN-ERIC Members representing more than two thirds of the contributions of the Members), the Observer Status may be extended beyond the 3-years period, according to the procedure set out in the Rules of Internal Procedure (Article 1.3).

3. Members and Observers may be represented by an appointed body delegate as regards the exercise of specified rights and the discharge of specified obligations as a Member or Observer of ECRIN-ERIC. Members and Observers shall ensure that their delegates comply with the rules, obligations and agreements governing their membership or status as Observer of ECRIN-ERIC as provided under these Statutes.

Article 6

Partners

1. In order to fulfil its role as a distributed European infrastructure, ECRIN-ERIC shall establish links with partners offering centralised or distributed services to ECRIN-ERIC. Such partnerships shall be based on permanent contracts including provisions on the delivery of services and on the quality assurance.

2. Scientific Partners

(a) Scientific Partners are National Clinical Research Networks that:

(i) are composed of academic clinical research centres or clinical trial units with a national coordinating centre, or a coordination of disease-oriented networks;

(ii) have developed shared tools, procedures and practices to facilitate multi-centre studies, have reached the critical mass and represent the standard in the country;

(iii) are able to provide support to investigators and sponsors for any category of clinical research, in any disease area.

(b) The following entities may become Scientific Partners of ECRIN-ERIC:

(i) National Clinical Research Networks proposed by Members of ECRIN-ERIC;

(ii) National Clinical Research Networks proposed by Observers of ECRIN-ERIC;

(c) The Assembly of Members shall define the rules and conditions for establishing scientific partnerships with candidate Scientific Partners.

(d) The rights and obligations governing the scientific partnership shall be set out in the Internal Rules of Procedure that shall be adopted by the Assembly of Members on proposal by the ECRIN-ERIC Director-General.

(e) Scientific Partners shall assign a Senior Scientist that represents the National Clinical Research Network in the Network Committee as provided for under Article 9(1) of the present Statutes. In absence of the delegate, a proxy shall be designated.

(f) Scientific Partners shall assign a coordinating centre (National Clinical Research Hub), which acts as the national contact point of ECRIN-ERIC.

(g) Additional details in relation to the general cooperation policy among the Scientific Partners shall be set out in the Internal Rules of Procedure.

(h) The rights and obligations governing the partnership of a Scientific Partner shall be set out in individual contracts agreed between the ECRIN-ERIC Director-General and the candidate Scientific Partner.

(i) Scientific Partners of ECRIN-ERIC are listed in Annex IV. The Annex IV shall be updated by the ECRIN-ERIC Director-General.

Article 7

Bodies

1. The bodies of ECRIN-ERIC shall be:

(a) The Assembly of Members

(b) The Director-General

(c) The Steering Committee

2. Assembly of Members:

(a) The Assembly of Members shall be the governing body of ECRIN-ERIC and shall be composed of representatives of Members and Observers. Each Member and Observer shall appoint up to two representatives who shall be deemed to be duly authorised to discuss and where appropriate to vote on all matters listed in Article 7(2)(c) of the present Statutes. A proxy shall be designated to the Chair of the Assembly of Members by the Member or Observer if a representative would be absent for a meeting. Meetings through remote participation, including video-conferences and any other agreed electronic means, shall be possible.

(b) The ECRIN-ERIC Director-General and the Chair and Vice-Chair of the Network Committee may attend the meetings of the Assembly of Members, without voting rights.

(c) The Assembly of Members shall meet at least once a year and shall:

(i) note and approve minutes from the past meeting;

(ii) discuss, amend and adopt changes in the strategic plan, governance structure, annual or pluri-annual work plan, and annual budget of ECRIN-ERIC;

(iii) decide on proposals for amendments to the Statutes of ECRIN-ERIC and notify the European Commission for approval;

(iv) approve the Internal Rules of Procedure;

(v) approve the annual activity report;

(vi) approve the audited accounts and budget of ECRIN-ERIC;

(vii) decide on the contribution of Members or Observers of ECRIN-ERIC and the annual budget proposed by the Director-General;

(viii) decide on changes of the composition of ECRIN-ERIC (candidate Member, candidate Observer, as well as withdrawals and revocations of Members and Observers);

(ix) elect, approve and revoke the Chair and Vice-Chair of the Assembly of Members;

(x) nominate and revoke, upon recommendation of the Network Committee, the ECRIN-ERIC Director-General; and

(xi) decide on any other issue necessary for the fulfilment of the objectives of ECRIN-ERIC.

(d) Joint meetings of the Assembly of Members with the Network Committee may be convened upon request by the ECRIN-ERIC Director-General, the Chair of the Assembly of Members, or by one fourth of the Members.

(e) Additional meetings of the Assembly of Members may be convened upon request of the Director-General, of the chair of the Assembly of Members, or of at least one fourth of the Members if issues of importance arise that cannot be delayed until the next scheduled Assembly of Members meeting.

3. Chair and Vice-Chair of the Assembly of Members:

(a) The Chair and a Vice-Chair shall be elected by the members of the Assembly of Members. The Chair and Vice-Chair shall be appointed for a three years period.

(b) Any member may propose a vote of no-confidence against the Chair or Vice-Chair. A vote of no-confidence shall be treated as a regular proposition and must include the reason for the proposal of a vote of no-confidence.

(c) The Chair shall call, prepare and organise the Assembly of Members meetings.

(d) The Chair shall delegate its duties to the Vice Chair in the event of his or her absence, or if a vote of no-confidence in the Chair is being discussed.

(e) The Chair and Vice-Chair may make use of the ECRIN-ERIC Management office for operational issues.

4. Proceedings of the Assembly of Members:

(a) The Assembly of Members shall approve the agenda at the beginning of each meeting. Any change to the agenda can be proposed by a voting member of the Assembly of Members.

(b) The Chair shall rule on any point of order raised during the meeting by a voting member. Rulings of the Chair shall stand unless overruled by a majority of those present and voting.

(c) The Assembly of Members may set up working committees to accomplish its tasks. Additional details in relation to the operational procedures of the Assembly of Members shall be set out in the Internal Rules of Procedure.

(d) Voting procedure and voting rights

(i) Each Member of ECRIN-ERIC shall have one vote. Observers shall have no voting rights. A quorum of two thirds of Members shall be required for having a valid Assembly of Members meeting.

(ii) If the quorum is not met, then the meeting of the Assembly of Members shall be adjourned and shall be repeated within 15 calendar days, following a new invitation by the Chair of the Assembly of Members. The issues on the agenda of the repeat meeting shall be the same as the issues on the agenda of the original meeting. In the repeat meeting of the Assembly of Members, the quorum shall be considered met, if one third of Members are present or represented.

(iii) Unless otherwise expressly stated to the contrary in these Statutes or in any Rules, a simple majority of those in attendance and voting at any Assembly of Members meeting whether in person or by a proxy shall be sufficient to pass a resolution. In the event of tie votes, the Chair shall have the casting vote.

(iv) The consolidated audited accounts and the annual budget must be agreed by a vote of more than half of ECRIN-ERIC Members representing more than half of the contributions of the Members in accordance with the agreed annual contribution as provided for under Article 5(1).

(v) Changes in the national contributions, proposals for amendments of the Statutes, and adoption of the initial version and subsequent amendments of the Internal Rules of Procedure shall be approved by consensus or if no consensus can be found by a vote of more than two thirds of ECRIN-ERIC Members representing more than two thirds of the contributions of the Members in accordance with the agreed annual contribution as provided for under Article 5(1).

5. ECRIN-ERIC Director-General:

(a) The Director-General shall be responsible for the overall management of the Infrastructure with the support of the ECRIN-ERIC Management Office and will function as the intermediary between the Scientific Partners, Management Office, and the Assembly of Members.

(b) The ECRIN-ERIC Director-General shall be nominated and revoked by the Assembly of Members, based on recommendations by the Network Committee.

(c) The ECRIN-ERIC Director-General shall attend, without voting rights, all meetings of the Assembly of Members (except for items concerning the employment or supervision of the Director-General).

(d) The ECRIN-ERIC Director-General shall attend all meetings of the Network Committee.

(e) The Director-General shall be the legal representative of ECRIN-ERIC and may conclude contracts and conduct other legal and administrative proceedings as appropriate in accordance with the decisions of the Assembly of Members and the Internal Rules of Procedure.

6. Steering Committee:

(a) A Steering Committee shall be established by the Assembly of Members to strengthen the link between the Assembly of Members and the Director-General. It shall oversee the activities of ECRIN-ERIC and prepare the meetings of the Assembly of Member.

(b) The membership, responsibilities and procedures of the Steering Committee shall be set out in the Internal Rules of Procedure.

Article 8

ECRIN-ERIC Management office and staff

1. The infrastructure shall be managed by the ECRIN-ERIC Management Office. This office shall include:

(a) the ECRIN-ERIC Director-General;

(b) the core team;

(c) the European Correspondents.

2. The ECRIN-ERIC Director-General shall define, based on the pluri-annual work plan and the budget adopted by the Assembly of Members, the composition of the Management Office, hire the relevant collaborators and shall be responsible for the management of the ECRIN-ERIC staff.

3. The ECRIN-ERIC Core Team shall:

(a) provide the necessary support for day-to-day management (including the financial management) as well as reporting activities to the Assembly of Members and the European Commission;

(b) be in charge of the coordination of support to individual clinical research projects, as described in the scientific and technical description of ECRIN-ERIC;

(c) further develop and maintain the organisation, knowledge base, know-how and procedures, allowing each Scientific Partner to efficiently support multinational clinical studies throughout the European Union;

(d) update and upgrade the quality assurance system, and ensure that ECRIN-ERIC maintains the capacity to effectively deliver high quality services.

4. The ECRIN-ERIC European Correspondent shall represent the ECRIN collaborator hosted at each national hub. The work of the ECRIN-ERIC European Correspondent shall be under the management authority of the ECRIN-ERIC Director- General, with a functional link to the national hub, and he/she shall act as relay to the national clinical research network and hub for the various ECRIN-ERIC activities such as structuring activities and provision of coordinated services.

5. ECRIN-ERIC is an equal opportunity employer and shall be committed to affirmative action consistent with the applicable labour laws and regulations and shall in accordance with the Internal Rules of Procedure select the best qualified individuals for the ECRIN-ERIC Management office.

Article 9

ECRIN-ERIC activities

1. ECRIN-ERIC activities require the involvement of its network of national Scientific Partners represented in the Network Committee, and of the Scientific Board in charge of providing access to the infrastructure.

2. The Network Committee shall:

(a) represent the Scientific Partners of ECRIN-ERIC, and shall have an advisory role for the Assembly of Members and the Director-General;

(b) be composed of one senior Delegate of each Scientific Partner from Member and Observer countries. The ECRIN-ERIC Director-General shall attend the meetings of the Network Committee. The ECRIN-ERIC Management Office shall act as the Secretariat for the Network Committee;

(c) under the direction of the Assembly of Members coordinate the policies, procedures, tools and practices across the Scientific Partners, make proposals to the ECRIN-ERIC Director-General to optimise the quality and efficiency of services, and monitor the performance of the ECRIN-ERIC Scientific Partners to ensure the high quality of service provision;

(d) on request of the ECRIN-ERIC Director-General assist in the preparation of annual strategic documents including the pluri-annual work plan and annual budgets to submitted by the ECRIN-ERIC Director-General to the Assembly of Members;

(e) support the coordinated implementation, at national level, of decisions, strategies, rules, and procedures set out by the ECRIN-ERIC Director-General and the Assembly of Members in the pluri-annual work plan;

(f) upon request of the Assembly of Members make recommendations for the nomination or revocation of the ECRIN-ERIC Director-General;

(g) upon request of the ECRIN-ERIC Director-General make recommendations on the capability of candidate Partners;

(h) be consulted by the ECRIN-ERIC Director-General for the nomination of the members of the Scientific Board;

(i) convene a face-to-face meeting at least twice a year;

(j) elect a Chair who will call, prepare and organise the Network Committee meetings, and a Vice-Chair. They shall hold office for three years renewable and attend the meetings of the Assembly of Members, without voting rights;

(k) Additional details in relation to the general operational procedures of the Network Committee are set out in the Rules of Internal Procedure.

3. The Scientific Board shall:

(a) select and prioritise the clinical projects supported by ECRIN-ERIC and evaluate submitted projects through defined acceptance criteria and rules of access to services for the academic and industry scientific community, as agreed upon by the Assembly of Members;

(b) be composed of a minimum of four members, with a majority of external members (not involved in the governance of ECRIN-ERIC), appointed by the ECRIN-ERIC Director-General upon recommendation of the Network Committee, and approved by the Assembly of Members. They shall be appointed for a three years renewable period and make decisions based on the assessment by external scientific experts in the relevant field.

4. An External Advisory Board, composed of experts appointed by the Director-General after approval by the Assembly of Members for a three years mandate, shall meet annually in the presence of the Director-General and of the Chair and Vice-Chair of the Network Committee, providing strategic input to the Assembly of Members on the scientific and technical development of ECRIN-ERIC.

5. Ethical Advisory Board, composed of experts appointed by the Director-General after approval by the Assembly of Members for a three years mandate, shall meet annually in the presence of the Director-General and of the Chair and Vice-Chair of the Network Committee, providing input and recommendations to the Assembly of Members on the ethical and personal data protection issues raised by the activities of ECRIN-ERIC.

Article 10

Annual report and reviews

1. The ECRIN-ERIC Director-General shall draw up, with the Network Committee, an annual activity report containing the scientific, operational and financial aspects of ECRIN-ERIC. The Assembly of Members shall approve the annual activity report and transmit the report to the European Commission. After approval, the annual activity report shall be made publicly available through the ECRIN-ERIC website.

2. ECRIN-ERIC shall undergo every five years a scientific review performed by international experts appointed by the Assembly of Members, providing guidance and recommendations on the ECRIN-ERIC development strategy.

Article 11

Effective access to services and data policy

1. Effective access for researchers to ECRIN-ERIC services shall be provided based on scientific excellence and shall not be restricted to Members or Observers of ECRIN-ERIC.

2. Access shall be based on internal and external expertise: services are provided pending acceptance of the project by the Scientific Board, based on the scientific assessment by external peer-reviewers. The decision to provide services shall be made by the Director-General upon recommendation of the Network Committee, taking into account:

(a) the assessment by the Scientific Board;

(b) the logistical assessment performed by the Scientific Partners as reflected in the recommendation of the Network Committee.

3. Application, assessment procedures and evaluation criteria shall be defined by the Scientific Board and made publicly available at the ECRIN-ERIC website and Rules of Internal Procedure.

4. ECRIN-ERIC shall provide services at a not-for-profit rate for non-economic activities.

5. Access criteria shall include a commitment to optimise the use of the clinical trial data through registration of the clinical trial protocol before inclusion of patients in a publicly available registry approved by the World Health Organization (WHO), and through a commitment to report the study results. ECRIN-ERIC shall promote FAIR individual patient-level clinical trial data sharing, in compliance with the relevant European and national data protection regulations and patient informed consent.

Article 12

Intellectual property rights

1. Nothing in these Statutes shall be read to alter the scope and application of Intellectual Property Rights and benefit sharing agreement as determined under relevant laws, regulations and international agreements of the Members of ECRIN-ERIC.

2. ECRIN-ERIC may own appropriate Intellectual Property Rights whenever the ECRIN-ERIC contribution covers the innovation process. Further details in relation to the intellectual property policy of ECRIN-ERIC shall be set out in the Internal Rules of Procedure.

3. Income generated by Intellectual Property produced by ECRIN-ERIC shall be used for the operations of the ERIC.

4. Intellectual property shall mean property as defined in Article 2 of the Convention Establishing the World Intellectual Property Organization, done at Stockholm on 14 July 1967.

Article 13

Accounts

1. All items of revenue and expenditure of ECRIN-ERIC shall be included in estimates to be drawn up for each financial year and shall be shown in the budget. The budget shall be approved by the Assembly of Members.

2. The accounts of ECRIN-ERIC shall be accompanied by a report on budgetary and financial management of the last financial year. The accounts shall be submitted to periodical external financial audits. The Assembly of Members shall approve the appointment of an external auditor to examine the accounts of ECRIN-ERIC, with specification of the duration of the appointment. The external auditor shall submit a report on the annual accounts to the Assembly of Members.

3. ECRIN-ERIC shall be subject to the requirements of the laws and regulations of the State where ECRIN-ERIC has its Statutory Seat as regards the preparation, filling, auditing and publication of accounts.

Article 14

Procurement

ECRIN-ERIC shall treat procurement candidates and tenderers equally and without discrimination, regardless whether or not they are based within the European Union. The ECRIN-ERIC procurement policy shall respect the principles of transparency, non-discrimination and competition. Detailed rules on procurement procedures and criteria are defined in the Internal Rules of Procedure.

Article 15

Liability and insurance

1. The financial liability of the Members and Observers for the debts of ECRIN-ERIC shall be limited to their respective annual contribution as set out in Annex III.

2. ECRIN-ERIC shall take appropriate measures to insure the risks specific to its activities.

Article 16

Value Added Tax (VAT)

VAT exemption based on Articles 143(1)(g) and 151(1)(b) of Council Directive 2006/112/EC (1) and in accordance with Articles 50 and 51 of Council Implementing Regulation (EU) No 282/2011 (2) shall be limited to the value added tax for such goods and services which are purchased for official use by ECRIN-ERIC, exceed the value of EUR 150, and are wholly paid and procured by ECRIN-ERIC. Procurement by individual members shall not benefit from these exemptions. VAT exemption shall apply to purchases related to non-economic activities of ECRIN-ERIC, not to its economic activities. VAT exemption will be applied to goods and services for the scientific, technical and administrative operations undertaken by ECRIN-ERIC in line with its principal tasks. This also includes expenses for conferences, workshops and meetings directly linked to the official activities of ECRIN-ERIC. However travel and accommodation expenses shall not be covered by VAT exemption.

Article 17

Internal Rules of Procedure

1. The Internal Rules of Procedure shall specify the organisation of the work between the Members, Observers, Bodies and Partners of ECRIN-ERIC, organise the management of ECRIN-ERIC, and define the respective rights and obligations of the Members, Observers, Bodies and Partners.

2. The Internal Rules of Procedure shall be prepared by the ECRIN-ERIC Director-General and approved by the Assembly of Members.

3. The Internal Rules of Procedure shall be updated if necessary by the ECRIN-ERIC Director-General and approved by the Assembly of Members following the procedures established in it.

Article 18

Language

1. The working language of ECRIN-ERIC shall be English.

2. An official language of the host country ECRIN-ERIC statutory seat may also be used for the relation to the host country authorities.

3. These Statutes shall be deemed authentic in German, Spanish, French, Italian, Portuguese, English and in all other official EU languages. No linguistic version shall prevail.

Article 19

Statutory seat

ECRIN-ERIC shall have its statutory seat in Paris, France.

Article 20

Duration and winding-up of ECRIN-ERIC

1. The duration of ECRIN-ERIC shall be indeterminate.

2. The winding up of ECRIN-ERIC shall be decided by a two thirds majority vote of all members of the Assembly of Members.

3. The intangible assets of ECRIN-ERIC (scientific assets) shall be transferred after its winding up to an entity that shall be agreed by a more than two thirds majority of the Members representing a more than two thirds majority of the mandatory contributions.

4. The tangible assets of ECRIN-ERIC (cash and cash equivalent, real estate, equipment, other) shall be redistributed to ECRIN-ERIC current Members at the time of winding up in proportion to their share in the ECRIN-ERIC assets. Detailed

rules on winding up procedure are defined in the Internal Rules of Procedure.

Article 20a:

Dissemination policy

1. ECRIN-ERIC shall take all appropriate action to promote the infrastructure and its use in research and education.

2. ECRIN-ERIC shall promote the dissemination and sharing of results obtained by multinational clinical studies supported by ECRIN-ERIC, and of any tool, procedure or methodology developed with a contribution of ECRIN-ERIC.

3. Without prejudice to any property rights ECRIN-ERIC shall request its users to make their research results publicly available, and to make results available through ECRIN-ERIC.

4. The dissemination policy shall identify the various target groups, including patients, and ECRIN-ERIC shall use several channels to reach the target audiences, such as web portals, social media, newsletters, workshops, presence at conferences, articles in journals and daily newspapers.

5. ECRIN-ERIC shall promote an Open Science policy, as well as the sharing and secondary use of all data generated with the support of ECRIN-ERIC according to the FAIR (Findable, Accessible, Interoperable and Reusable) principle, and in compliance with national and European data protection legislations.

Article 21

Amendments

1. Any proposed amendment of the Statutes shall be notified to the European Commission and shall take only effect in accordance with Article 11 of the ERIC Regulation.

2. The date of any amendment shall be recorded in these Statutes.

3. The Annexes to these Statutes may be amended according to Article 11 of the ERIC Regulation, by approval of the Assembly of Members followed by notification to the Commission.

([1]) OJ L 347, 11.12.2006, p. 1.
([2]) OJ L 77, 23.3.2011, p. 1.

Article 22

Consolidated version of the Statutes[1]

1. These Statutes shall be kept up to date and made publicly available on the website of ECRIN-ERIC and at its statutory seat.

2. Any amendment to the Statutes shall be clearly indicated with a note specifying whether the amendment concerns an essential or non-essential element of the Statutes in accordance with Article 11 of Regulation (EC) No 723/2009 and the procedure followed for its adoption.

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[1] The Statutes were amended based on a decision of the ECRIN-ERIC Assembly of Members:

1. Amendment N°1: based on a decision of the Assembly of Members on February 17th, 2017, the amendment entered into force on February 27th, 2017. The amendment only affected Annex III, and consisted of replacing USD by EUR in the thresholds used to calculate the local contribution (Article 3(a), 2 substitutions) and the core contribution (Article 3(b), 4 substitutions).

2. Amendment N°2: based on a decision of the Assembly of Members on December 11th, 2018, the amendment entered into force on December 9th, 2019.This amendment concerns a non-essential element of the Statutes in accordance with Article 11 of Regulation (EC) No 723/2009. The amendment affected the rights and obligations of members and observers, and consisted of addition to the article 5, the clause about extension of the Observer Status under exceptional circumstances.

3. Amendment N°3: based on a decision of the Assembly of Members on September 15th, 2023. The amendment concerns non-essential elements of the Statutes in accordance with Article 11 of Regulation (EC) No 723/2009. The amendment affected the Articles 5, 6, 7, 11 and 21, to the Annexes II and III and an addition of Annex IV. The amendment entered into force on November 22nd, 2023.

4. Amendment N°4: based on three decisions of the Assembly of Members: First decision on December 14th, 2022 affected the winding up procedure, and consisted of modification to the Article 20; Second decision on September 15th, 2023 affected description of the tasks and activities and consisted of modification to the Article 3 and 9. Third decision on April 5th, 2024 concerning adding an article on dissemination as Article 21 and adjusting the numbers of the following articles. The amendment concerns essential elements of the Statutes in accordance with Article 11 of Regulation (EC) No 723/2009. The amendment entered into force on February 26th, 2025.

ANNEX II

LIST OF MEMBERS AND OBSERVERS[2]

Members

Founding Members

The Federal Republic of Germany (since 29 November 2013)

The Kingdom of Spain (since 29 November 2013)

The French Republic (since 29 November 2013)

The Italian Republic (since 29 November 2013)

The Portuguese Republic (since 29 November 2013)

Other Members

Hungary (since 5 November 2014)

The Kingdom of Norway (since 18 May 2016)

The Czech Republic (since 1 January 2018)

The Republic of Ireland (since 20 November 2018)

The Republic of Poland (since 30 September 2022)

The Hellenic Republic (since 24 April 2023)

The Swiss Confederation (since 22 May 2023)

The Slovak Republic (since 27 January 2025)

[1] Updated on January 27th, 2025

ANNEX III

FINANCIAL CONTRIBUTION

1. This Annex describes the mechanism of calculation of the annual contribution to ECRIN-ERIC.

2. After the setting up of ECRIN-ERIC, the Assembly of Members shall decide on the financial contribution as stated in Article 5(1). The Assembly of Members shall review the provisions set out in Annex III every four years.

3. The ECRIN-ERIC annual budget shall be covered by the contribution of ECRIN-ERIC Members and Observers. It consists of:

(a) a local contribution to cover the activities of ECRIN-ERIC staff in each national hub (salary of the European Correspondent and related operation expenses) with an equivalent value of three times the national adjusted gross disposable income of household per capita, plus 30% for operation costs, travels and overhead.

(b) a core financial contribution to cover the activities of the ECRIN-ERIC core team, stratified according to the GDP:

EUR 250 000 if GDP > EUR 1 000 billion

EUR 125 000 if EUR 1 000 billion > GDP > EUR 700 billion

EUR 100 000 if EUR 700 billion > GDP > EUR 350 billion

EUR 50 000 if EUR 350 billion > GDP > EUR 200 billion

EUR 20 000 if GDP < EUR 200 billion

(c) an annual financial contribution of EUR 150 000/year to ECRIN-ERIC provided by the Member State of the ECRIN-ERIC statutory seat (Article 19).

4. Members of ECRIN-ERIC shall contribute to the annual budget with the local and the core contribution as defined in points (a) and (b) of Annex III (3) to these Statutes.

5. Observers of ECRIN-ERIC shall contribute to the annual budget with the local contribution as defined in point (a) of Annex III (3) to these Statutes.

6. The detailed mechanism used to calculate the Member and Observer contributions are set out in the Rules of Internal Procedure (Article 9.4).

7. A European Correspondent may be seconded to ECRIN-ERIC and be under its management authority, with a functional link to the national hub. The selection of such a correspondent shall be based on guidelines set out in the Internal Rules of Procedure, and shall necessitate the agreement of both ECRIN-ERIC and the Member, Observer or Partner. If no suitable candidate can be identified, the respective Member, Observer or Partner shall provide the financial contribution to ECRIN-ERIC enabling it to recruit directly.

8. The annual contributions must be received by ECRIN-ERIC upon calls issued by ECRIN-ERIC based on agreed financial schedules in the financial year concerned. Interest based on interest rates of the European Central Bank as published in the Official Journal shall be charged as defined in the Internal Rules of Procedure to a late contributor.

9. The budget will be adapted with the addition of new Members, based on the principle that integration of a new Member results in an increase in the total budget of the core team equivalent to 80% of the expected core contribution of the new Member. The remaining 20% are used to decrease the contribution of the Members, proportionate to their core contribution.

ANNEX IV

LIST OF NATIONAL SCIENTIFIC PARTNERS

Member / Observer country	*National Scientific Partner*	*Legal entity*
The Czech Republic	CZECRIN	Masaryk University
The Federal Republic of Germany	KKSN	KKSN
The Kingdom of Spain	SCREN	ISCIII
The French Republic	F-CRIN	INSERM
The Hellenic Republic	GRECRIN	CERTH
Hungary	HECRIN	HNHDA
The Republic of Ireland	HRB	University College Cork
The Italian Republic	ITACRIN	ISS
The Kingdom of Norway	NORCRIN	Helse Bergen University Hospital
The Republic of Poland	POLCRIN	ABM
The Portuguese Republic	PtCRIN	NOVA Medical School
The Swiss Confederation	SCTO	SCTO
The Slovak Republic	SLOVACRIN	UPJS