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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.'.