Press Release

25 September 2024

The European CRO Federation (EUCROF) announces that after the European Data Protection Board (EDPB) adopted the opinion 12/2024 on June 18th and the CNIL[1] adopted resolution no.2024-064, the EUCROF Code for service providers in clinical research is now approved.

On June 18th, the European Data Protection Board (EDPB) adopted the opinion 12/2024 on the draft decision of the French Supervisory Authority regarding the "Code of Conduct for Service Providers in Clinical Research" submitted by EUCROF, opening the way to the final approval of the EUCROF Code.

On its plenary meeting of September 12, 2024, the CNIL adopted the resolution no. 2024-064, which approves this code, thus completing the formal approval process of the EUCROF Code. The decision of CNIL will be published on the website of Legifrance.

Marie-Laure Denis, the President of CNIL, informed EUCROF of this decision in a letter dated September 19th addressed to Yoanni Th. Matsakis, chairman of the EUCROF Code Task Force and member of the Executive Board with the following remarks:

> *This accessible tool, of European dimension and intended for clinical research service providers, will allow a harmonised dissemination of good practices to many stakeholders. The work carried out by the working group has made it possible to consolidate, in this code, pragmatic and concrete responses, adapted to the challenges of professionals in the sector.*
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> *This is why, aware of the involvement required to successfully carry out such a project, I wanted to salute the investment of the EUCROF in this process, which demonstrates its commitment and that of its members to providing more legal security to their activities involving personal data.*

As reminded in EDPB's opinion, the EUCROF Code is transnational and applies across the whole European Union, as per Article 40 (7) GDPR; All European Union supervisory authorities are listed as concerned SAs, making it the 1st transnational code in the area of health with such a territorial scope.

"This decision is the result of an immense collaborative effort, not only within EUCROF and all of its members, but also with many other stakeholders and of course, with CNIL and all concerned SAs. It is an indication that, when joining efforts, Europeans can not only create innovative regulations to foster trust and transparency, but also convert them into competitive advantages through practical and consensual approaches", says Yoanni Th. Matsakis.

"*With this decision, the task force can now focus on establishing the monitoring body of the Code and obtaining its accreditation"* says Ekaterina Smirnova, co-chairman of the EUCROF task force.

"*Many CROs have already initiated their request for adherence and we are targeting the first approvals by the end of the first quarter of 2025*" adds Anastassia Negrouk, one of the main contributors to the drafting of the accreditation dossier.

EDPB's opinion 12/2024 can be downloaded from: https://www.edpb.europa.eu/our-work-tools/our-documents/opinion-board-art-64/opinion-122024-draft-decision-french-supervisory_fr

[1] *Commission National Informatique et Libertés*

Article 40 of Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, also known as "GDPR", "*[…] encourages drawing up of code of conducts intended to contribute to the proper implementation of this Regulation, taking account of the specific features of the various processing sectors and the specific needs of micro, small and medium-sized enterprises*."

Clinical research is a field with highly specific features, where a number of dedicated Regulations apply, and the vast majority (over 90%) of Service Providers for Clinical Research, also known as "CROs" – Contract Research Organizations" are micro, small, and medium-sized enterprises.

About EUCROF

EUCROF is a not-for-profit legal entity registered in the Netherlands whose objectives are, among others, to contribute to high quality Clinical Research in humans and to promote the excellence of European Clinical Research to the public and the media, as well as on the international stage.

The members of EUCROF are national CRO associations as well as individual CROs established in one or more European countries or outside Europe, as defined in its Bylaws. Today EUCROF has more than 450 affiliated companies, in 31 countries. The list of EUCROF members, as well as EUCROF Bylaws, are public and can be freely downloaded from EUCROF's website (www.eucrof.eu).

About the EUCROF Code International Task Force

The EUCROF Code has been drafted by a dedicated international task force, established under the umbrella of the New Technologies Working Group of EUCROF. This task force has widely consulted the EUCROF affiliates, as well as representatives of other stakeholders: pharmaceutical industry, patient associations, medical devices companies, representatives of ethics committees, representatives of various academic organizations, lawyers specialised in electronic health systems, as well as experts in ISO certifications.

Chairman: Yoanni Th. Matsakis[2], member of the EUCROF Executive Board, AFCROs - France

Co-chairman: Ekaterina Smirnova, DPO at PSI CRO AG, Switzerland

Members: Victoria Watts (Vice President, Privacy and Global DPO, Premier Research – UK), Anastassia Negrouk (Chief Operating Officer, DPO, MyData-Trust – Belgium), Thierry Lepoutre (Chief Compliance Officer, Telemedicine Technologies – Belgium), Emmanuel Damigos (ISO Auditor & Consultant – Greece), Witra (Tim) Chulindra (Global Privacy and Product Counsel, Malwarebytes - USA), Ilaria Colussi (BBMRI ERIC – Austria), Natasa Spasic (Associate Director, Privacy & Data Protection, Allucent (DE) - Germany), Guiomar M. León Salvatierra (Compliance Officer, Sermes CRO – Spain) and the many who contributed to the work of the task force for some period of time.

More info at: www.eucrof.eu

Contacts:
Please send an email to info@eucrof.eu, at the attention of **Yoanni Th. Matsakis & Kate Smirnova** and with subject "EUCROF Code".

[2] *CEO of Telemedicine Technologies - France*