FEB. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

New European Regulation on Clinical Trials

Regulation (EU) 536/2014 of the Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use ("**Regulation**") came into force on 31 January 2022. The Regulation was adopted by the European Parliament in 2014 and released in May of the same year. It was subsequently officially published in the Official Journal of the European Union on 31 July 2021 and came into force six months after that date.

The Regulation repeals Directive 2001/20/EC and makes sweeping changes to the European rules on conducting clinical trials.

The Regulation introduces substantial amendments to the regulatory framework applicable to clinical trials in the EU. Up to this point, the regulations were essentially the responsibility of the authorities and ethics committees of each Member State. The implementation of this Regulation will have an impact on the authorisation, conduct and supervision of clinical trials in the European Union ("**EU**"), as it will harmonise the procedures relating to clinical trials within the EU and in countries belonging to the European Economic Area ("**EEA**"), specifically Iceland, Lichtenstein and Norway.

The fundamental objective of the publication of the Regulation is to create a favourable environment for conducting clinical trials and to make these processes more efficient and attractive to sponsors.

The great innovation is the creation of an electronic platform at EU level. This is provided for in Articles 80 and following of the Regulation and it is called the Clinical Trials Information System ("**CTIS**"). The CTIS will centralise all procedures for obtaining authorisations to conduct clinical trials in the EU and EEA. The European Medicines Agency ("**EMA**"), together with the Member States and the European Commission, will be responsible for maintaining this platform, so that it becomes the single entry point to submit data and information relating to clinical trials to be conducted in the states covered by the Regulation.

Eduardo Nogueira Pinto
Ricardo Rocha
Bartolomeu Soares de Oliveira
Healthcare, Life Sciences & Pharmaceuticals team

"The fundamental objective is to create a favourable environment for conducting clinical trials and to make these processes more efficient and attractive to sponsors."

The CTIS will work in tandem with the other centralised information systems in the EU to support the integrated analysis of safety reports when conducting clinical trials. This will increase the monitoring of the risks and benefits associated with medicines that are either already on the market or in the process of obtaining a marketing authorisation ("**MA**"). In parallel, the CTIS will also simplify the recruitment of participants in clinical trials by extending clinical trials to EEA countries. This will enhance knowledge sharing and achieve more reliable results.

"Transparency is also one of the key points in the new Regulation. It requires that all information stored in the database incorporated in the CTIS is publicly available."

Transparency is also one of the key points in the new Regulation. It requires that all information stored in the database incorporated in the CTIS is publicly available unless it is exempt under the Regulation. Exemptions exist to protect *(i)* personal data, *(ii)* commercially confidential information, in particular the marketing authorisation status of the medicinal product, unless there is an overriding public interest, *(iii)* confidential communications between Member States in preparation for their assessment and, *(iv)* supervision of clinical trials by Member States. This means that citizens or interested parties will be able to consult information on clinical trials taking place in the states covered.

Therefore, as a result of the entry into force of the Regulation and the CTIS, sponsors of clinical trials can apply for authorisation to conduct clinical trials in up to 30 countries through a single application. This contrasts with the situation existing until now, with the need to apply for authorisation separately to the competent authority and ethics committee of each Member State. Nevertheless, the authorisation and supervision of clinical trials remain the responsibility of the states covered by the Regulation.

The states covered by the Regulation will have to start using the CTIS as soon as this system is made available. However, the Regulation does provide for a transitional period of three years. During the first year, sponsors can choose to submit their applications for authorisation to conduct a clinical trial under the previous directive or under the new Regulation. After 31 January 2023, application will have to be submitted under the new Regulation and, finally, on 31 January 2025, all clinical trials that have been approved under the current Directive will have to transfer to the CTIS.

To implement the Regulation and the CTIS in Portugal, Infarmed, I.P. (the Portuguese National Authority for Medicines and Healthcare Products) and the Ethics Committee for Clinical Research (*Comissão de Ética para a Investigação Clínica* - "CEIC") have developed a methodology for the pilot phase of the national coordinated assessment procedure between both bodies. This is very similar to the future regulatory framework still under development. This methodology is the guiding standard for clinical trial applicants and sponsors wishing to integrate their applications for authorisation into the pilot phase, pursuant to the Joint Informative Circular of Infarmed, I.P. and CEIC 003/CD/100.20.200 of 26 February 2021. However, participation in the pilot phase by clinical trial applicants and sponsors is, at this stage, optional.

PLMJ

In conclusion, the new Regulation will make it possible to (i) harmonise the rules and procedures for conducting clinical trials in the countries covered, and (ii) enhance the safety of trial participants while ensuring greater reliability and quality of the information collected. The harmonised electronic submission and assessment process for clinical trials conducted in several Member States will facilitate the conduct of clinical trials within the European Union and improved cooperation, information sharing and decision making between Member States. It will also make it simpler to conduct multinational trials and expand existing trials to other CTIS states. This will make the EU/EEA a more attractive location for clinical research and this is essential for scientific development. ■

"It will also make it simpler to conduct multinational trials and expand existing trials to other CTIS states."