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BY VICKY VLONTZOU

On 31 January 2022 the Regulation (EU) 536/2014 on clinical trials on medicinal products for human use ("CTR") entered into application. The CTR has repealed the Directive 2001/20/EC regarding good clinical practice in the conduct of clinical trials on medicinal products for human use "Directive 2001/20/EC" and brings significant changes in the way that clinical trials are conducted in the EU. The purpose of the CTR is to ensure that the EU offers a favorable environment for the conduct of clinical trials by harmonizing the process for their assessment and supervision. It also aims to foster innovation and research in the EU by facilitating the conduct of larger clinical trials in multiple EU Member States/EEA countries.

The key benefits of the CTR include the following:

- Optimization of information-sharing and collective decision-making on clinical trials;
- Ensuring high standards of safety for all participants of EU clinical trials;
- Expansion of trials to other EEA countries;
- Possibility for national regulators to collaboratively process clinical trial applications in more than one country, request further information, authorize or refuse a trial and oversee an authorized clinical trial;
- Avoidance of unnecessary repetition of clinical trials and/or repetition of unsuccessful trials;
- Increased transparency through access to information for any party interested in clinical trials conducted in the EEA through a searchable public website.

Clinical Trial Information System

One of the main "breakthroughs" introduced by the Regulation is the Clinical Trial Information System ("CTIS"). The CTIS contains the centralized EU portal and database for clinical trials provided in Article 80 of the CTR and will be used as the single EU entry point for submitting, assessing, authorizing, supervising and reporting a

clinical trial in all Member States of the EU as well as in the European Economic Area (EEA).

The CTIS is structured in two workspaces only accessible to registered users (one for sponsors and one for National Competent Authorities, ethics committees, the European Commission, and the European Medicines Agency ("EMA")) as well as a website openly accessible to the general public.

Pursuant to the previous regime, sponsors wishing to conduct clinical trials in multiple Member States ("multinational clinical trials") were obliged to submit separate applications to the National Competent Authorities and Ethics Committees of each one of the Member States involved in order to gain regulatory approval.

With the entry into application of the CTR, the multiple submission of largely identical information has now been **replaced by the submission of one application dossier to all the Member States concerned through the CTIS.** This enables sponsors to apply for a clinical trial authorization in up to 30 EU/EEA countries simultaneously with a single online application.

Moreover, according to the CTR **clinical trials carried out only in a single Member State should also be submitted through the CTIS.** The authorization and supervision of clinical trials, however, remains the responsibility of the Member States.

Supporting materials and relevant guidance

It should be noted that the EMA had previously issued a handbook on the Clinical Trials Information System ("CTIS"). The purpose of the handbook was to provide references to key guidance, technical information, recommendations, training materials, and supportive documentation regarding the use of the CTIS. It also provided instructions regarding product registration and data transmission. The EMA has also published various training and support materials, which can be found on EMA's website.

It should be noted that on 1 February 2022, the European Commission issued an updated version of the Questions & Answers Document – Regulation (EU) 536/2014 – Version 5 following the entry into application of the CTR.

Finally, EOF has recently issued an announcement with a brief overview of the CTIS system and the relevant changes it initiates for sponsors and National Competent Authorities.

Transitional period

The CTR provides for a three-year transitional period. More specifically, until 31 January 2023, sponsors may submit clinical trial applications under either the previous regime, namely that of Directive 2001/20/EC or the CTR regime. Clinical trials, whose application has been submitted under the Directive 2001/20/EC, will continue to be regulated under the previous regime until 31 January 2025. From 25 January 2025 onwards, however, ongoing clinical trials that have been approved under the Directive 2001/20/EC will need to comply with the CTR.

Contact Us

Irene Kyriakides
PARTNER
i.kyriakides@kglawfirm.gr

Victoria Mertikopoulou
PARTNER
v.mertikopoulou@kglawfirm.gr

Follow Us

ATHENS OFFICE

28, Dimitriou Soutsou Str.,
115 21 Athens

T +30 210 817 1500
F +30 210 685 6657-8
E kg.law@kglawfirm.gr

THESSALONIKI OFFICE

31, Politechniou Str.,
551 34 Thessaloniki

T +30 2310 441 552
E kg.law@kglawfirm.gr

www.kglawfirm.gr