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What You Need to Know About EU Clinical Trials Regulation (CTR) No. 536/2014 and Clinical Trials Information System (CTIS)

Starting from 31 January 2022 the EU Clinical Trials Regulation No 536/2014 (CTR) became applicable in all EU/ European Economic Area (EEA) Member States replacing the EU Clinical Trials Directive (2001/20/EC) (CTD). On the same day the Clinical Trials Information System (CTIS), go-live version was opened for users to submit clinical trials on medicinal products for human use under coordination authorisation procedure.

Without a doubt, the CTR application has an impact on the clinical trials environment. Among others, the CTR harmonises the approval process for clinical trials, increases coordination between Member States, as well as maintains the highest level of standards for patient safety, and increases transparency of clinical trial information.

Sponsors should be prepared to comply with the CTR requirements and proactively plan their initial submissions for new clinical studies and/ or transition of ongoing clinical trials to CTIS.

The CTR foresees a 3-year transition period for sponsors to use CTIS. Sponsors will be able to choose whether to apply for a new Clinical Trial Application (CTA) under the regime of the CTD or to apply under the new legislation, the EU CTR, using CTIS.

CROMSOURCE is here to help you to understand what the CTR includes, how Member States interpret the Regulation, how to submit the study via CTIS and how to prepare the dossier for ongoing study to be smoothly transferred to CTIS .

3-Year transition period

31st January 2022

- CTIS Go-Live
- Clinical Trial can be submitted under the Directive (through national portals)

OR

- New Regulation (via CTIS)

31st January 2023

- All new Clinical Trial Applications must be submitted under new Regulation through CTIS
- Ongoing Clinical Trials authorised under Directive may remain

31st January 2025

- All ongoing Clinical Trials must be transferred through CTIS

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What you need to know starting your submission under CTR via CTIS

- **Single online submission via CTIS for all Member States**
  - Part I (scientific review) common to all Member States Concerned (MSC)
  - Part II (ethical review) country specific for each MSC
  - Single Decision per Member States (Part I + II)
- **Communication electronically via CTIS**
- **Single contact per Clinical Trial: Reporting Member Sate (RMS)**
- **One fee per Member State (if applicable)**
- **Increased availability of data to the public via the CTIS public website**
- **Strictly defined deadlines:**
  - RMS assigned within 6 working days
  - 10 calendar days for validation for Clinical Trials Application (CTA), 6 calendar days for Substantial Modification (SM)
  - 45 calendar days for assessment report by Member States and Ethics Committee for CTA (+50 days, if Advanced Therapy Medicinal Products - ATMPs), 38 calendar days for SM
  - If a Request for Information (RFI) comes in during assessment, a maximum of 12 calendar days to respond by Sponsor
- **Streamlined reporting**
  - Simplified reporting procedures
  - Clinical trials lifecycle events

How can CROMSOURCE support you?

CROMSOURCE has been specialising in clinical development and staffing solutions for more than 25 years and provides outsourced services to the pharmaceutical, biotechnology and medical device industries. We offer a flexible approach to ensure that we are optimally supporting the unique needs of each client.

Our team of regulatory experts bring a wealth of knowledge to consult with our clients and help them navigate through the regulatory intricacies in the life sciences sector.

The EU Clinical Trials Regulation will usher in a new era in the way clinical trials are conducted for sponsors, Member States, CROs and especially for patients whose rights, safety, dignity and well-being will be better protected.

CROMSOURCE is here to support you with the changes coming with the EU Clinical Trials Regulation. If you want to learn more contact us at the below contact details or send an email to **cromsource@cromsource.com** to get in contact with our regulatory experts and get started today.

CROMSOURCE is an ISO-certified, international contract research organisation providing a comprehensive portfolio of services to the pharmaceutical, biotechnology, and medical device industries.

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