6 Key Implications Of The EU Clinical Trials Regulation

1. Streamlined Application and Authorisation Process

The EU Clinical Trials Regulation (CTR) No 536/2014 introduced a centralised system for trial submissions and authorisations across the European Union, via the Clinical Trials Information System (CTIS). From 2022 onwards, it replaced fragmented national submissions with one coordinated assessment and aligned timelines, with national decisions issued via CTIS. This unified procedure now allows sponsors to submit one dossier to CTIS for assessment, leading to a single conclusion on the trial design applicable across all involved member states, reducing administrative delays from months to more predictable timelines. By harmonising regulatory and ethics reviews, the CTR minimises duplication across countries, enabling faster trial startups and making the EU more attractive for global research. To allow for this, the submission dossier in CTIS is divided into Part I: involving trial design and protocol, and Part II: involving country-specific documents such as informed consent procedures. Part I is assessed only once in a coordinated assessment involving all member states concerned. Each member state assesses Part II themselves.

2. Increased Transparency of Clinical Trial Data

Under the CTR, all trial protocols, results, and key documents must be publicly accessible eventually through CTIS, fostering accountability and information sharing among researchers and the public. Sponsors are enabled to redact commercially confidential information (CCI) and protected personal data (PPD) under the EU General Data Protection Regulation (GDPR) within system-based deadlines to prevent unintended disclosures, while non-redacted elements like study life cycle milestones are published automatically. This transparency enhances trust in the research process but demands robust experience with the CTR, CTIS, and official guidance on the practical implications of both combined to comply with the Regulation while protecting the commercial interests of sponsors.

3. Enhanced Patient Safety and Rights

The CTR bolsters patient protection by mandating detailed informed consent processes, providing potential participants with comprehensive risk-benefit information, and requiring reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) to regulators. SUSARs are reported in EudraVigilance, whereas the mandatory Annual Safety Reports are yearly uploaded in CTIS in order to allow the Safety Assessing Member State (SaMS) maintaining its regulatory oversight. It emphasises a patient-centric approach, including plain-language summaries of results and encouraging greater involvement in trial design, which improves recruitment and ethical standards. These measures not only safeguard participants but also build public confidence, potentially accelerating innovation while ensuring trials prioritise well-being.

4. Facilitation of Multinational Trials

By enabling coordinated assessments across member states, the CTR simplifies multinational trial conduct, eliminating the need for separate approval processes in each country and fostering collaboration through shared assessment reports. This harmonisation reduces costs and timelines for large-scale studies, attracting international sponsors to Europe and promoting regulatory alignment that could influence global standards.

5. Impact on Sponsors and Researchers

Although established in 2014 and fully applicable since January 2023, the CTR remains novel in practice. This leaves many sponsors, especially smaller ones, unfamiliar with its demands, such as CTIS navigation and

redaction practices. Researchers benefit from efficiency gains and clarity on timelines but face challenges like stringent response timelines and risks of delays from submission errors, necessitating training and thorough expertise. Overall, CTR streamlines operations for multinational work while increasing compliance burdens, potentially requiring updated SOPs and partnerships with CROs to meet requirements effectively.

6. CRO selection

Selecting a CRO that truly understands the EU clinical trial landscape is critical because the CTR introduced a single, highly structured framework and the accompanying CTIS. Only teams with profound regulatory, operational, and in-depth expertise with CTIS can design submission strategies that will have your trial authorised within weeks and start recruitment immediately after. A knowledgeable CRO can proactively manage complex requirements like transparency rules, incorporate accurate safety reporting and advise on level of detail. In addition, a highly trained regulatory team will reduce the risk of errors in CTIS data entry, missed deadlines, or inconsistent communication with national authorities.

By contrast, non-compliance with the CTR can have serious consequences. Failing to register the trial, report results correctly or maintain ongoing obligations such as Annual Safety reporting may result in trials being deemed non-compliant and halted. Member states can impose corrective measures, significant administrative fines, and, in severe cases, civil or criminal liability for sponsors. Beyond formal penalties, non-compliance damages sponsor reputation, undermines patient trust and site relationships, and can delay or block future approvals, ultimately jeopardising the value of an entire development programme.

Centre for Human Drug Research

CHDR brings more than three decades of experience designing and running early-phase clinical trials in the Netherlands, operating as a full-service CRO that covers study design, regulatory submission, conduct, data analysis, and final reporting. This is accomplished within a robust framework of hundreds of internal SOPs and Good Clinical Practice training. Deeply embedded in the EU regulatory environment, CHDR's in-house regulatory team oversees submissions via CTIS, while maintaining close relationships with national authorities and ethics committees. CHDR routinely secures approvals on efficient timelines for both EU and non-EU sponsors, for both big and small pharma. CHDR partners with pharmaceutical companies to ensure the successful completion of their submissions and provides strategic guidance throughout each phase of the process until authorisation is achieved. This infrastructure is complemented by a dedicated clinical research unit, advanced pharmacodynamic and biomarker capabilities, and expertise in innovative and decentralised trial methods, allowing CHDR to execute complex studies across multiple therapeutic areas while ensuring full compliance with Dutch and European laws on performing clinical trials.