The Clinical Trials Regulation

Increasing transparency, efficiency and cooperation on clinical trials information in the EU

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

What is it?

Regulation (EU) No 536/2014 (the Clinical Trials Regulation) aims at creating an environment that is favourable for **conducting clinical trials (CTs) in the EU** with the highest standards of **safety** for participants and increased **transparency** of CTs **information**. It will replace and expand the scope of the existing EU Clinical Trials Directive 2001/20/EC.

What will the Clinical Trials Regulation do?

Ensure the highest **safety** standards for all participants in CTs

Strengthen reliability, robustness, and **transparency** of CTs data in the European Union

Increase the **efficiency** for the **submission** and **assessment** of CTs applications within established deadlines

Harmonise the **authorisation** process of CTs, through a coordinated assessment by the Member States concerned

Provide **common provisions** governing CTs across Member States

Improve the **cooperation** between Member States and sponsors, and among Member States in the assessment of a CT application

Establish more **detailed guidelines** at EU level for the **informed consent process** of participants in CTs, including for those who are unable to provide said consent

Introduce a **risk-adapted approach** with less stringent rules for those trials conducted with authorised medicines and low-risk CTs

Reinforce **supervision** of CTs by introducing Union Controls to ensure compliance with the Clinical Trials Regulation

Who will the Clinical Trials Regulation benefit?

Authorities

Member States national competent authorities, ethics committees, European Commission and EMA

Sponsors

Pharma industry and academia

General Public

Patients, scientists, healthcare professionals, clinical research associations, media, citizens

The implementation of the Clinical Trials Regulation will be supported by...

The Clinical Trials Information System (CTIS)

The rules established in the Regulation will be supported through a dedicated EU Portal and Database (the Clinical Trials Information System) that will become the **single entry point** for submitting CTs information in the EU and will support the **daily business processes** of Member States and sponsors throughout the life cycle of their CTs.