



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?



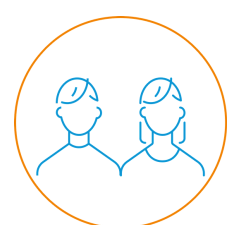
Authorities

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.