NEW CLINICAL TRIALS REGULATION (CTR) No 536/2014

Timeline

EU Portal and database audit → **Endorsement of audit by EMA MB** → **Notice in Official Journal** → **CTR applicable** → **All trials need to be submitted under CTRL rules** → **EC 2001/20 stops applying (end of transition period)**

6 months

Go Live Expected 31 January 2022

Year 1

- Sponsors may apply for a new trial authorization under old legislation (EudraCT, etc.) or new CTR (CTIS), at their own choice.
- Member States must all be ready to use CTIS from day 1 (and still run the old process as well).

Years 2 and 3

- Clinical trials authorized under the old directive may continue under that directive, but may already switch to the CTIS at sponsor choice.
- Any new clinical trial application must be submitted and managed via CTIS.
- By end of 2024 at latest all trials authorized under the old directive/legislation must end or have been transferred to CTIS by the sponsor.

Top changes

Implementation of Clinical Trials Regulation (CTR) No 536/2014

- Harmonization of the submission requirements and assessment processes of clinical trials conducted in the EU.
  - Part I: Coordinated assessment > Reference Member State.
  - Part II: National evaluation > Member States concerned.

  **Important to thoroughly review all updated requirements/timelines from the new Regulation.*
- Robust and agile approval process for clinical trials and close coordination between Member States for multi-country trials.

Digitalization

- Unique digital tool for harmonized submission, evaluation and supervision of clinical trial applications in the European Union.
- Fully electronic exchange of information between sponsors and Member States over the life cycle of a clinical trial.
  - CTIS users will have access to the CT system functions according to their role. User management will follow a hierarchical approach.
  - Notifications will be received within the system and not by email. Close monitoring of the portal Notices and Alerts will be required.
- Digital secured storage of structured data and documents on clinical trials.

Increased Transparency

- All documentation for the entire life cycle of the trial stored in the database will be publicly available, unless exempt according to Article 81(4) of CTR (see Disclosure rules: EMA/42176/2014).
  - Sponsors have options to defer the timing of publication of specific data/documents.
  - For some documents, two versions will be needed for publishing.
- Easy access to structured data and documents on clinical trials for patients, healthcare professionals, scientists and general public, including access to clinical trial results in lay language.

Enhanced patient safety

- Simplified safety reporting.
- Coordinated assessment of Suspected Unexpected Serious Adverse Reactions (SUSARs) and Annual Safety Reports (ASRs).

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