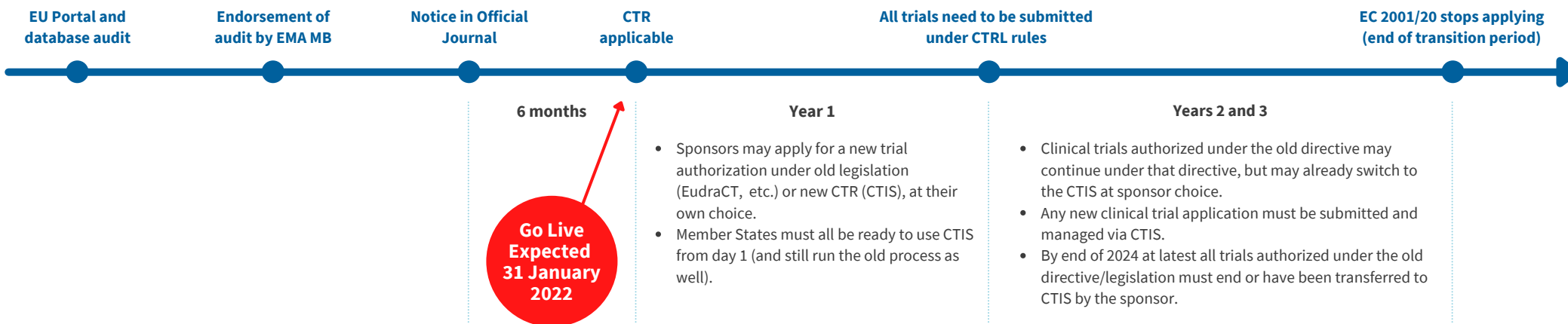


## Timeline



## 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).