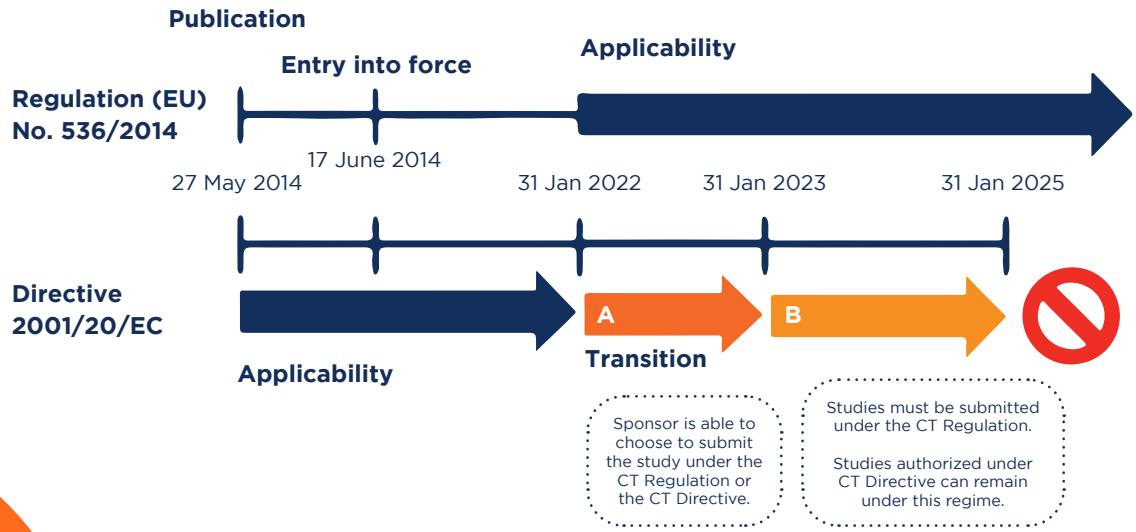
Are You Ready for EU Clinical Trials Regulation 536/2014 (CTR)?

- The EU Clinical Trials Regulation 536/2014 (CTR) entered into force on January 31, 2022, replacing the existing Directive 2001/20/EC at the end of the transition period, on January 31, 2025.
- EU-CTR aspires to overcome the limitations of EU-CTD to increase the EU's competitiveness in the drug development market.
- Nevertheless, sponsors must be aware of several significant changes it brings in transparency and reporting obligations, new safety reporting rules, and patient protection provisions that need to be followed.

When does the Clinical Trial Regulation apply?

It applies from 31 January, 2022 but allows for a 3-year transition period:



By 31 Jan 2025, all studies must switch to CT Regulation.

What changes does the Clinical Trials Regulation bring?

European Medicines Agency

Watch Video on "Clinical Trials in the EU"

- New clinical trial authorization process through Centralised electronic database (the Clinical Trial Information System (CTIS) and New timelines
- New definitions (e.g.: low intervention trials & risk-based approach)
- Improved patient protections for vulnerable subjects
- Notification and regulatory reporting are required (serious breach, etc.)
- Changes to safety reporting, surveillance processes for identifying potential new safety signals, start/end of reporting obligations
- Increased public transparency

Safety Reporting Rules **in transition period**

Clinical Trials (CTs) conducted under:	SUSAR reporting	DSUR reporting	ECs / Investigators reporting
Directive (old system)	Centralized to EVCTM only	Member States	As per CT-3 / national legislation
Regulation (new system)	Centralized to EVCTM only	CTIS only	Reporting to ECs not foreseen
CTs with same IMP but under CTD & CTR	Centralized to EVCTM only	CTIS only (cover letter)	As per CT-3 / national legislation for trials under Directive

How has PrimeVigilance prepared for CTR 536/2014?

- Assembled a **Specific Working Group** made of regulator experts, clinical trials leaders and safety specialists available to our customers to support their plan and strategy
- Developed an **Action Plan** to align procedures for ongoing and new projects during the transition phase and beyond
- **Implemented** new working procedures and updated all necessary existing processes, tools, and systems
- Delivered company-wide and department-specific **Training Modules**
- Supported our clients in preparing for the changes and provided **Strategic Advice** for the transitional period

STAY TUNED FOR FURTHER UPDATES!

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