EU Clinical Trial Regulation 536/2014

PPD enables a seamless lifecycle development of your product globally

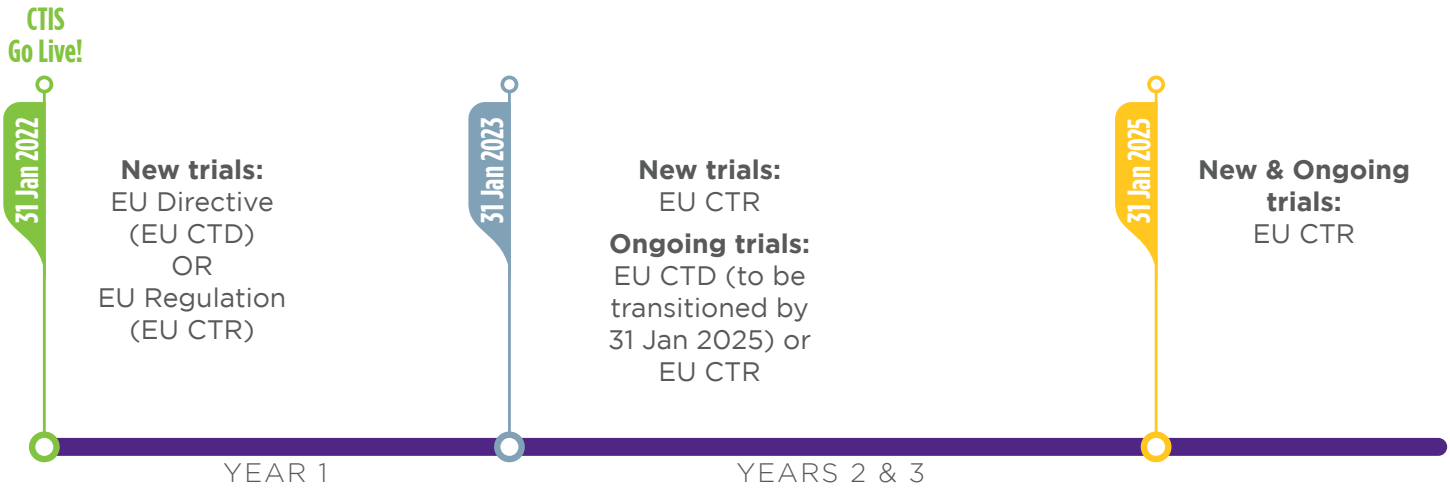
The EU Clinical Trial Regulation (CTR) 536/2014 will replace Directive 2001/20/EC and aims to simplify and harmonise procedures for the authorisation, assessment and supervision of clinical trials in the EU.

There are going to be big changes

The cross functional PPD EU CTR readiness team is ideally positioned to help you navigate these requirements.

The EU Clinical Trial Regulation ((EU) No_536/2014)) will be implemented on 31 January 2022 and aims to simplify and harmonise procedures for the authorisation, assessment and supervision of clinical trials between the EU Member States. The new CTR will allow sponsors to make one clinical trial application (CTA) for all EU Member States intended to participate in a given trial, via a centralised portal, the Clinical Trial Information System (CTIS).

Within the first year of the implementation of the EU CTR, sponsors will have the option of submitting new clinical trials under the current EU Clinical Trial Directive or the new EU CTR. This includes the addition of Member States for ongoing trials. After the first year of the implementation (after 31 January 2023), the trial will be required to transition to the EU CTR prior to adding the new Member States. Ongoing trials will need to transition to the EU CTR within a three-year transition period and by no later than 31 January 2025. Trials ending before the transition period will not be mandated to transition.



PPD has multiple cross functional teams dedicated to this regulation enabling us to deliver up to date intelligence on the impact of the changing regulation. With our patients in mind, all steps will be taken to assure that the EU CTR implementation will have no impact on patient safety and access to medicines.

An overview of the impact of the new regulation on global lifecycle management is outlined below.

Protocol Optimisation	Submission Strategy and Planning	Authorisation	Lifecycle Management	Post Trial Activities
• Ensuring that a **harmonised or consolidated protocol** is in place prior to transition • Protocol synopsis in **Lay Persons language** • Categorisation of your clinical trial: New **Low Interventional Trial** category	• **Directive or Regulation?** • **Transition strategy** • New definition: **Non-authorised Auxiliary Medicinal Products** • **Transparency Requirements** • **Redaction of**: – Commercially Confidential Information – Personal data – Confidential communication between Member States • Revised **labelling requirements**	• Clinical Trial Information System (CTIS) **registration and user management** • Selection of **Reporting Member State (RMS)** • **Single CTA submission** to the Competent Authorities and Ethics Committees for multi-national trials • **Parallel or sequential** Part I and Part II submissions	• **Directive or Regulation?** • **Single CTA submission** to the Competent Authorities and Ethics Committees for multi-national trials • **Planning and Management of mid-study modifications** • **Authoring and Submission of Annual Safety Reports**	• **Authoring, Publication and Submission of:** – **Lay Persons Summary** – **Summary of Results** • Submission of **Clinical Study Report**

Regulatory Challenges

- **Navigating around the Regulation** in line with your Global Development Plan
- **Limited country specific** guidelines
- Adhering to the **Transparency** requirements
- Responding to **agency requests** in a maximum of **12 calendar days**

PPD's Solution

- **Understand and manage the requirements** of leading and executing trials under the Regulation
- **Customised level of outsourcing** to meet your specific needs
- **Preparedness and Implementation**
  - IT Systems
  - SOPs
  - Training
- **Transition strategy** across book of work
- Apply and adapt EU strategy globally using our **Subject Matter Experts (SMEs)** and **strategic expertise**
- Build **efficiencies** in compiling core documents
- Provide a **flexible and skilled-cross-functional resource** pool

PPD will be carefully factoring in the transition of clinical trials from the Directive 2001/20/EC to the EU CTR as part of your clinical trial development plan to allow for a seamless lifecycle development of your product, while ensuring compliance with the required regulations.

PPD is focused on providing the support to progress and conduct the required regulatory strategies, assessment and submission activities so that companies are prepared and ready for these changes.

Learn more at **Regulatory Affairs | PPD Inc**

Contact your Business Product Lead or our Regulatory Policy and Advocacy Team **RISSM@PPD.COM**

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