PLG Clinical Trial Regulation: Updates & Services

Context:
The Implementation of the EU Clinical Trial Regulation 536/2014

On the 31st of January 2022, the European Union (EU) initiated the transition from the Clinical Trial Directive (CTD 2001/20/EC) to the Clinical Trial Regulation (CTR 536/2014). The main purpose is to streamline the Clinical Trial Application (CTA) and enhance the assessment and supervision of clinical trials among the EU Member States.

The European Medicines Agency (EMA) implemented the setup of the Clinical Trial Information System (CTIS).
The platform is to be used by Sponsors/ Contract Research Organisations (CROs) & Member States.
The portal allows for one single application to intended Member State and receive a single decision that covers both Regulatory Agencies & Ethics Committees.

Timeline for the implementation of 536/2014

Year 1	Year 2&3	Year 4
From 31 Jan 2022 to 31 Jan 2023	From 1 Feb 2023 to 31 Jan 2025	From 1 Feb 2025 onwards
New Trials can apply under CTD or CTR	New Trials must apply under CTR, Ongoing Trials currently under CTD must transition to CTR	New & Ongoing Trials should all be under CTR

The EMA has indicated that there will be a three (3) year transition plan

- **In Year 1** (31 Jan 2022 - 31 Jan 2023), sponsors for new clinical trials can apply under EU CTD or EU CTR. This would include the addition of Member States for ongoing trials.
- **Year 2 & 3** (1 Feb 2023 - 31 Jan 2025), new trials will have to apply through the CTR and any ongoing trials ending post 31 Jan 2025 will need to transition under the same regulations.
- **Year 4 & Beyond** (1 Feb 2025), all new & ongoing trials would be under EU CTR. Any trials ending before the three-year period will not need to transition to the new CTR.

Although these regulations have been around a while, the accelerated nature of the EMA's new initiative has created a significant shift in the landscape.

ProductLife Group is here to support companies though this transition for those seeking to submit new applications or those with ongoing trials.

PLG Services

With a multi-skilled and flexible clinical team of experts, we offer:

1. Clinical Strategy: CTD or CTR? Selection of Reporting Member State (RMS) & Member State Concerned (MSC)
2. Conversion of CTD to CTR
3. Application Preparation for CTD or CTR
4. Submission of Application via CTIS
5. Management of Submission: Communication with Regulatory Authorities on behalf of the sponsor
6. Clinical Study Management/High Level Project Management

PLG Added-value

In House Expertise

PLG's team of over 15 Subject Matter Experts (SME).

Our SMEs have intimate knowledge of EU Regulations.

They have experience with Biosimilars, New Biological & Chemical Entities, Combination & Generic products.

3rd Party Management & Oversight

PLG has a dedicated & experienced Project Management team who will oversee the entire clinical trial process.

Our Project Managers will provide timely updates & comprehensive reports.

Flexibility and Competitive Packaging

PLG can prepare packages catered to the unique requirements of each company.

We can provide full clinical support or individual services.

We can work with your existing team or create an entire in house team dedicated to your projects.

Want to learn more about these new regulations and how they will impact your ongoing or upcoming clinical trials? Click HERE and have one of our team members reach out to you to explore how PLG can help.

PLG ProductLifeGroup