EU CTR: Final Countdown, What You Need to Know

The end of the transition period is imminent. How can clinical trial sponsors and CROs ease the transition to CTIS?

Soon, the one-year transition period of the EU's Clinical Trials Regulation (CTR) will come to a close. EU CTR aims to harmonise the clinical application process across Europe and increase transparency. The regulation envisions a faster and more streamlined submission and approval process for larger multinational studies. Soon, biopharma sponsors, contract research organisations (CROs), the European Medicines Agency (EMA), and member states will use one system to manage all trial applications and authorisations.

Sponsors and CROs have spent the transition period learning how to navigate the Clinical Trials Information System (CTIS) for their study registration and approval activities, which will be a mandatory requirement from 31st January 2023. Having a common regulatory approach across the European Union will boost regional competitiveness. Patients are set to benefit from improved transparency of trial data, as data submitted within applications will be made public, making it easier for patients to identify and participate in ongoing trials.

To date, almost 100 studies have already been submitted under the new regulation, with Veeva customers accounting for at least half of these. The initial feedback from sponsors and CROs alike is that it is challenging to remain efficient while complying with legal responsibilities. Companies have had to improve communication, collaboration, and alignment across diverse global study stakeholders and departments.

Rethinking Our Approach to People, Processes, and Data

In its present format, the backbone technology of CTIS is not easy to integrate. Sponsors and CROs are collating data in their own technology environments. Each document in a study submission needs to be individually isolated and manually uploaded to the CTIS portal. Process timelines are getting longer, as companies spend more time collecting data points and information while managing translations and redactions. Once the submission has been made, companies often find they have a small window to respond to questions and requests for further information from the EMA.

How should companies address these challenges? Those that have successfully navigated the new process first had to attain internal alignment. This meant acknowledging that the old way of interacting with regulatory authorities was no longer

Checklist
Are you ready? Your EU CTR Checklist

- [ ] Processes: Review and re-define for tighter timelines
- [ ] Review processes for ethics committee submission, health authority interaction, and clinical trial disclosure
- [ ] Define new processes for document redaction, translations, and data collection
- [ ] Determine approach for upload to CTIS (who, what, when) and regulatory tracking
- [ ] Define clear RACI and ownership mapping
- [ ] Reduce redaction and mitigate user errors by updating forms and templates

People: Build alignment across your entire R&D organisation

- [ ] Coordinate closely with regulatory, quality, safety, and disclosure teams
- [ ] Include affiliates, as well as CRO partners
- [ ] Offer end-user system training for all relevant functions

Data & Systems: Future-proof your technology environment

- [ ] Review current technology landscape, existing capabilities, and future requirements
- [ ] Identify interim solutions until data formats and document requirements are determined by the EMA/CTIS team
- [ ] Visit the EMA/CTIS website for guidance (e.g. document naming), training material, and CTIS revision notes
- [ ] Contact a Veeva expert to support with Vault system evaluation, capabilities, and recommended configurations

sufficient and mapping out which internal stakeholders should be brought into the process, and when. Some created new roles to reflect the new reality, including managing translations or uploads to the portal. Others have redefined the RACI framework for clinical and regulatory study leads to maximise efficiency. All agree that technology plays a crucial role in improving collaboration across diverse stakeholders by making it easier to search for and extract data quickly, as well as draw on internal expertise during submission.

Without a doubt, managing high volumes of data and documents in the new process is very challenging. Few companies like their current approach of collecting data using internal tools, like spreadsheets. Nor do they think the current cross-functional efforts to complete reviews, quality checks, and translations are sustainable. Eventually, the industry expects further enhancements, such as integration with CTIS.

However, any sponsor or CRO submitting an application faces disclosure risks for two types of information: protected personal data (PPD, with privacy protection under GDPR) and commercially confidential information (CCI). The redaction effort required to make documents available for public consumption is significant, complex, and dynamic as redacted passages can change over time.

For the industry, CCI and PPD are serious pain points – perhaps the most acutely felt. And while there is consensus that automation could alleviate the redaction effort, there is a high barrier to entry before technology can offer more than just tactical support to human oversight and interventions. There are multiple languages in play, metadata to remove, and significant coordination effort, to name just a few hurdles.

A New Global Standard for Clinical Trials

The end state envisioned in the regulation is a faster, more consistent approach to clinical trials: not just for Europe but for global companies that want to sell products into the region. However, enterprise biopharma companies face more complexity than smaller sponsors (who tend to outsource to CROs). These global organisations are undertaking significant change management to harmonize their technology and processes and face the added complication of running studies under EU and non-EU regulations.

Setting an ambitious worldwide standard was never going to be easy. EU CTR challenges the industry to balance consistent processes and reporting with an excellent user experience, operational efficiency with inspection readiness. For now, companies of all sizes are focusing on ensuring their processes (including for EU and non-EU country studies) are well set up, which in turn requires significant people training.

Many will need to keep a manual approach to collecting data points for entry into CTIS for the interim period. However, their attention is turning to how software and end-to-end technology can work better to deliver on the stated aim of the regulation: accelerating innovation and research through improved efficiency.

As partners to the life sciences industry, we will need to rise to the same challenge of balancing opposing forces. Technology will get us there. But, like EU CTR, it will come in stages.

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Werner Engelbrecht, Senior Director Strategy at Veeva Systems, has extensive experience in the pharmaceuticals and life sciences industry, across a range of roles, with his career spanning over twenty years'. For the last twelve years, he has brought his in-depth industry knowledge to operational, and sales and account management teams at CROs (contract research organisations). In his current role as Senior Director Strategy at Veeva Systems, Werner heads up a team that is dedicated to using digital transformation to navigate the complexities of clinical trials and speed up development of new medicines.