Research Professionals-CRO Case Study:

Adapting to the Clinical Trials Information System (CTIS) Implementation in the EU

Research Professionals (RP) is a leading GCP compliant CRO based in Hungary (EU Member) with operations in Poland, Czechia, Romania, and Bulgaria, serving customers from across Europe and the globe. www.rp-cro.com

Introduction: The EU introduced the Clinical Trials Information System (CTIS) searchable public database in 2022 to support the flow of electronic information between clinical trial sponsors, European Union (EU) Member states, European Economic Area (EEA) countries and the European Commission. All clinical trial information including clinical sites, Principal Investigators (PIs), site personnel, study protocols, informed consent forms, study manual and more must be entered into the system for new clinical studies starting by January 2023. The CTIS is intended to provide a consistent and comprehensive platform for clinical study information that applies across the EU. This requires both the sponsors and the Clinical Research Organizations (CROs) managing their studies to adapt their current practices to meet both the local regulatory requirements and also more global EU level requirements imposed by the adoption of the CTIS electronic platform. For sponsors, finding a Clinical Research Organization (CRO) that understands the new CTIS and can efficiently manage clinical studies through it with a broader EU perspective, are critical to maintaining timelines of study programs and meeting the new compliance requirements.

Background:

Sponsors of clinical studies are increasingly seeking CROs with experience in managing CTIS requirements. This requires that CROs have strong expertise in clinical research fundamentals, as well as up to date technical and regulatory experience in successfully using the CTIS system. Clinical studies today are often conducted simultaneously at multiple sites, in multiple countries, all with varying levels of knowledge and understanding of the various stakeholders across the study. As the implementation of the CTIS is new for most CROs, such submissions can become more complex, require more time and effort when they lack practical experience using the CTIS. In the CTIS platform, either the sponsor or the contracted CRO is responsible for creating the study, uploading documents, data and maintaining contact with the relevant regulatory authorities. Part 1 of the CTIS (Global Regulatory Section) is typically managed by the central CRO office, while Part 2 of the CTIS (Local Regulatory Section) is managed by the local CRO affiliates. The local CRO affiliates are normally well-versed in the local administration of studies and the regulations but can have limited experience in the full administrative and regional/global regulatory environments. With the CTIS, CROs with a wider European perspective combined with strong local operational and regulatory knowledge is critical to efficiently managing clinical studies in the EU.

Strategy:

Research Professionals CRO (RP-CRO) brings long established experience in managing international studies across numerous EU member states and beyond. Our leadership teams are well versed in managing the added complexities of international studies and has been using modern electronic systems to create and share clinical study data and documentation for many years. RP-CRO started working within the CTIS system before the January 2023 implementation deadline and has therefore established documented internal processes that allow our network of operations to efficiently build the required clinical study in the CTIS. Applicable RP-CRO employees have undergone CTIS training and are knowledgeable regarding their role in complying with the new CTIS requirements at all operational locations. RP-CRO's mandate is to always stays up to date with both pending and current regulations so that it can adapt its practices to meet them, providing a simplified experience for its sponsor customers.

Research Professionals CRO - CTIS Submission Process Experience:

To date, RP-CRO has successfully submitted both Part 1 & 2 of customer clinical studies on behalf of four sponsors.

Study	Phase	Countries	Status (as of November 2023)
#1	Phase 1	Hungary	Approved
#2	Phase 1	Hungary	Approved
#3	Phase 1	Hungary, Slovakia	Approved
#4	Phase 1	Hungary	Approved

Key Points

- RP-CRO has demonstrated the capability to successfully submit single country and international clinical studies via the CTIS to the EU authorities.
- RP-CRO submitted four different clinical studies via the CTIS that received regulatory approvals, demonstrating its compliance with EU regulations and the requirements of the new CTIS.
- RP-CRO put the process and training in place to allow CTIS submissions to occur efficiently saving sponsors both time and resources without compromising quality.

Conclusion:

RP-CRO had the foresight to prepare for the implementation of CTIS in advance of the deadline. As RP-CRO had already established cooperative relationships with local authorities and had ample experience supporting international studies with global regulators, the transition to the CTIS was streamlined. Our CTIS experience to date includes acting in an admin role or application submitter, demonstrating that RP-CRO is well positioned to manage customer clinical studies within the requirements of the newly implemented EU Clinical Trials Information System (CTIS).