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Key to EU CTIS Success: Plan, Prepare, Participate

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ABSTRACT:

All new clinical trials within the European Union (EU) must be uploaded to the Clinical Trial Information System (CTIS). This requirement poses a significant challenge for many sponsors, as they must interpret the regulations accurately and act swiftly to meet stringent regulatory timelines.

This poster presentation delves into how sponsors can align their resources effectively. It emphasizes upon the importance of gathering a team of knowledgeable subject matter experts and meeting submission criteria. The presentation also highlights how a seasoned contract research organization (CRO) can offer invaluable advice on submission planning, enhancing process efficiency, and liaising with the EMA. This guidance ensures the smooth integration of teams for successful submissions and adeptly manages requests for information throughout the clinical trials' CTIS lifecycle.

METHODOLOGY:

We examined data from seven handpicked sponsors collected over a time frame of 11 months (January 2023-November 2023). Data was collected from 250 documents and evaluated for document complexity, type of request, and turnaround time (TAT) for EU CTIS redaction. The types of documents included for redaction were protocols (26%), Investigator Brochures (16%), informed consent forms (15%), and Investigational Medicinal Product Dossiers (5%). Approximately 30 unique plain language protocol synopses were also delivered for redaction. An average turnaround time of five days was achieved for preparing the initial redacted copies of 250 documents. Turnaround on RFIs received for 37 documents was expedited to <48 hours.

DISCUSSION:

Our collaboration as a CRO with sponsors has led us to understand the importance of a proactive approach in four key aspects of an EU CTIS submission process: planning, stakeholder alignment, project management, and consulting support.

PLANNING:

- Monthly meetings/reports to forecast upcoming clinical trial application (CTA) submissions.
- Scope assessment including types of trials (transition vs. new), types of documents, and identification of stakeholders ensures that the CTA has a solid foundation for success.

STAKEHOLDER ALIGNMENT:

- Establishing a Responsible, Accountable, Consulted, and Informed chart at the beginning of the project eliminates confusion and unnecessary work as all stakeholders understand their roles and responsibilities.
- All commercially confidential information (CCI) proposed by the CRO should be validated/reviewed by the sponsor experts before being presented to the health agency.
- Translation needs/process for CTA documents should be discussed and confirmed.
- Escalation mechanisms should be clearly delineated for all stakeholders.

PROJECT MANAGEMENT:

- Project timelines/milestones should be agreed with the sponsor team at the start of the project.
- A strategy for Request for Information (RFIs) should be in place before one occurs. RFI resolution meetings ensures that study team members availability to quickly resolve RFI queries.

CONSULTING SUPPORT:

- Confirm with the sponsor that all process documents and templates are up-to-date and compliant with EU-CTR regulations.
- Conduct CCI workshop to educate sponsor teams for CCI identification and review criteria.
- Train sponsor teams on lean authoring practices to avoid including unnecessary protected personal data (PPD) in document text/tables.

- Cross-functional collaboration among various departments boosts process-efficiency. For example, the CRO medical writing team and transparency teams should be in close communication as documents are written and redacted.

CONCLUSION:

The typical EU-CTIS submission requires efficient collaboration of various departments for all stakeholders to proactively address and remove roadblocks encountered along the clinical trial application (CTA) life cycle. After the successful submission of over 100 applications for the EU-CTIS portal, process challenges, CCI justifications, expedited timelines and managing multiple stakeholders, etc., were identified as common pitfalls. Partnering with a seasoned CRO mitigates these pitfalls by offering training to sponsor teams on the identification of CCI, consultation to ensure compliance, proactive planning, dedicated project teams to meet stringent EU-CTIS timelines and communicating effectively across departments to lead stakeholders.

The key to EU-CTIS success is to plan, prepare, and participate. The data presented in this poster have shown that all stakeholders benefit from partnership. Proactive planning and training facilitate preparation of successful submissions when all stakeholders participate, understand their roles and responsibilities, and actively comply on assigned tasks.

CONTACT INFORMATION:

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