Managing Compliance: New EudraCT Regulation

Multinational Pharmaceutical Company

Challenge

Revisions to the EudraCT legislation, released by the European Medicines Agency (EMA) in July 2014, now requires clinical trial sponsors to disclose trial results to the EudraCT database. The client was compliant with the previous registration requirements, and needed to address the new results disclosure requirements, retrospectively and prospectively. Preparing for this effort presented several challenges:

- Major gaps in their understanding of the new requirements embedded in detailed legislation
- Disparate and incomplete data sources from which to identify in-scope Clinical Trials
- Resource constraints to manage activities/issues/risks, gather data, and perform detailed analysis
- Potential for data inconsistencies across registries

Collaborative Approach

Acquis proposed an end to end approach to address the legislation changes. We worked with leaders cross-functionally to gain clarity on the requirements, develop a plan to meet the aggressive EMA timelines, manage and prepare for impacts to the organization, and ensure resources were in place to ensure compliance. As a team, we focused on:

- Understanding the **detailed disclosure criteria**, aligning interpretations between Clinical Registry, Regulatory, and Legal teams
- **Identifying the data sources and fields** needed, including triaging inconsistent or missing data
- Analyzing all company trials against the agreed-upon criteria to **determine the in-scope trial set**
- Developing a **retrospective roadmap** with processes, activities, and resources
- Implementing a **system for capturing retrospective trial data and triaging** data issues
- Managing the team of medical writers responsible for **retrospective results posting** to ensure timely completion of activities and consistency of data across registries
- Designing and implementing a **prospective disclosure process**

Drive Change

- Implemented an approach that allowed for **all required trials to be remediated** within the specified timeframe
- Prevented the client from realizing any ill-effects of non-compliance through **proactive issue and risk management**
- Developed a **thorough report of project activities** to aid in future remediation efforts
- **Remediated existing data gaps** which improved the overall quality of company clinical trial data and ensured consistency across registries
- Provided senior management with **confidence in their compliance risk level**
- Trained the client teams on the prospective process, allowing for **ongoing management and continued compliance**

THINK + DO

About Acquis

Acquis is a consulting firm specializing in strategy and implementation. We help ambitious organizations solve business challenges that enable sustainable growth and healthy efficiency. We do this by not just designing strategies but also putting them to work.

Key Contact:

Veenusha Santchurn – Manager
vsantchum@acquisconsulting.com
office: 212.609.2736