Clinical Trials Regulation (EU) 536/2014 advisory services

REGULATORY CONSULTING SERVICES

Our offerings include:

- Global Regulatory Leader who serves as a single point of contact for integration of EU submissions
- Partial or full outsourcing models to overcome short- or long-term capacity gaps
- Subject Matter Expertise (SME) to support process adaptations and development
- A dedicated global submission management organization, ensuring consistent high-quality global application services, while integrating EU CTR specifics
- Application management planning and strategy
- EU Clinical Trial Information System (CTIS) user and business task management
- Communication and change management support for organizational and procedural changes
- Integration of technical solutions: end-to-end processes or system interface options (application programming interface/API)

The European Union (EU) Clinical Trials Regulation 536/2014 is currently slated to become applicable in January 2022, introducing fundamental changes for Phase I to IV interventional clinical trials. It establishes a uniform approach to clinical trial applications, assessment, and reporting with consistent rules across the EU.

With the new regulation in force, all stakeholders will communicate and exchange clinical trial data via the Clinical Trial Information System (CTIS, previously known as EU Portal and Database) developed by the European Medicines Agency (EMA) to ensure the highest standards of safety for clinical trial participants, harmonizing approval processes and strengthening transparency and consistency. Via this single platform across the EU, sponsors will also be able to submit electronic annual safety reports.

Preparedness will require a wide-ranging cross enterprise business strategy including for both ongoing and new clinical trials to be set up correctly. This means a thorough assessment and adaptation of current business processes and technology to avoid disruption of timely trial start-up and maintenance.

Parexel is well-positioned to assist sponsors in preparing their readiness for this transition.

"As an association representative and product owner for EMA's CTIS delivery model, I am able to help clients interpret and implement the necessary requirements for the EU 536/2014 clinical trial regulations."

Rüdiger Pankow, PhD, Principal Consultant, Parexel

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Internally, Parexel has ongoing workstreams across all functional areas to drive procedural changes and information technology enhancements throughout the clinical trial lifecycle. In addition, Parexel has trained staff on EU and applicable local legislation and updates to standard operating procedures (SOPs) well in advance of the regulation's implementation.

Parexel has an unmatched EU and global footprint of experienced regulatory professionals, and provides seamless regulatory, clinical, medical, and logistics services. Parexel's proven record of first-time quality supports accelerated study start-up and regulatory pathways to ensure fast approvals, reimbursement, and patient access to treatments.

Preparing for the EU CT Regulation

Organizational Structure

- Business approach (in-house and outsourcing)

Implementation

- Communication
- Change management
- SOPs
- Training
- Metrics

IT Systems

- Future proof technology platforms and systems integration, e.g., CTMS, eTMF, RIM

Transition

- Strategy and prioritization for moving ongoing trials under EU CT Directive to EU CT Regulation

Operational Delivery

- Cross-departmental operational model
- SOP review
- Roles and responsibilities
- Process adaptation and integration (EU vs global)

Your Journey. Our Mission.®

Offices across Europe, Asia, and the Americas
www.parexel.com