EU Clinical Trials Regulation Published

On May 27, 2014, the long-awaited EU Clinical Trials Regulation was published in the EU Official Journal (full text available here).

Previous Sidley Updates (available here, here and here) have dealt with important aspects raised during the legislative process, and we also expect the implementation process to present its own challenges and opportunities.

Significant changes brought about by the new legislation include:

- Harmonized rules across the 28 EU Member States, whereas previously each country had different rules to implement the Clinical Trials Directive;
- A single EU portal for all applications, aiming not only at procedural simplification, but also more transparency throughout the whole process;
- A faster authorization procedure ensuring a single assessment outcome and extension of the tacit agreement principle;
- Clear rules governing provision of informed consent in emergency situations; and
- A better-defined role for Ethics Committees throughout the procedure with specific considerations for involvement of the pediatric population;
- Strengthened transparency approach with regard to disclosure of data related to clinical trials.

The Regulation will become applicable at the earliest on May 28, 2016. The exact date will depend on the completion of the necessary IT solutions (i.e., six months after the publication in the EU Official Journal of a notice by the European Commission acknowledging that the EU portal and database have achieved full functionality).

Industry should thoroughly consider the impact of the new Regulation, and start to put in place all relevant measures to ensure compliance with its provisions. Close attention should be paid to the upcoming implementing measures, such as:

- The adoption of Delegated and Implementing Acts focusing on inspections and safety reporting;
- Steps taken by the European Medicines Agency to establish the EU portal and database and in coordinating inspection activities (among EU Member States and third countries);
• New fee structures at national level for assessment activities performed by Member States and for appeal procedures in case a clinical trial application is refused; and
• New national rules to streamline the role and the procedural involvement of Ethics Committees.

CONTACTS

For more information regarding the content of this Sidley Update, please contact:

Maurits J.F. Lugard   Maarten Meulenbelt   Vincenzo Salvatore
+32.2.504.64.17   +32.2.504.64.67   +32.2.504.64.78
mlugard@sidley.com   mmmeulenbelt@sidley.com   vsalvatore@sidley.com

RELATED PRACTICES

Sidley EU Life Sciences Practice
Sidley Global Life Sciences Practice

To receive future copies of this and other Sidley updates via email, please sign up at www.sidley.com/subscribe