One Step Away: European Parliament Approves New Clinical Trials Regulation

On April 2, 2014, the European Parliament approved the new clinical trials regulation (the "Regulation") for the European Union ("EU"), with 594 votes in favor, 17 opposed and 13 abstentions. The European Parliament approved the Regulation in substantially the same form as the proposed draft regulation endorsed by the Committee of Permanent Representatives of the European Union on December 20, 2013.

For it to become law across the EU, the Regulation needs to be adopted formally by the European Council of Ministers. That is expected to occur on April 14, 2014. Significant changes are not anticipated at this final stage of the process. After formal approval by the European Council of Ministers, the Regulation is expected to be signed into law on April 16, 2014. Following the signing, the Regulation will be published in the Official Journal of the European Union Publication, which is expected to happen at the end of June. This Regulation will replace the existing clinical trials Directive 2001/20EC, and will be binding in its entirety and automatically incorporated into the national laws for all EU Member States.

Notably, the Regulation establishes a new streamlined application and review process for research sponsors wishing to site clinical trials in the EU, including a web-based portal for submission of all clinical trials applications (the "EU Portal"). Additionally, the Regulation increases transparency of data collected from clinical trials performed in the EU. The Regulation requires sponsors who have been approved to hold clinical trials within the EU to post detailed summaries of clinical trial data, including a plain-language summary, within one year of the termination of the clinical trial (*e.g.*, last visit by the last subject or as otherwise defined in the protocol). All summaries will be centralized on a publicly accessible, free and searchable database of all approved clinical trial data relating to medicinal products. On the same database, within 30 days of the marketing application's authorization, rejection or withdrawal, sponsors will be required to post full clinical study reports that were submitted to EMA in support of the marketing application. Failure to post the summaries or final clinical study reports will result in fines. For a summary on the other notable provisions of the Regulation, see our January alert.

The Regulation will not be enforced until six months after the EU Portal is fully functional. While the EU Portal is currently being developed by the European Medicines Agency, no deadline has been set. In light of that process, the Regulation is not expected to become effective until sometime in mid-2016, at the earliest.

The European Parliament stated its hope that the new Regulation will "streamline the rules on clinical trials across Europe, facilitating cross-border cooperation to enable larger, more reliable trials," and that "[b]y working at EU level we can reduce the huge cost and burden of conducting trials across borders." The EU Health Commissioner, Tonia Borg, announced that, in the aggregate, the Regulation would save research sponsors with clinical trials in the EU approximately $1.1 billion dollars in regulatory costs annually.

If you would like to discuss the foregoing or any other related matter, please contact Mark Barnes, Eve Brunts, David Peloquin, Shine Chen or your usual Ropes & Gray advisor.