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Goals For and Challenges to the Push for More Clinical Trials in the EU

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Background on Clinical Trials in the EU

Clinical trial research, like medicine more generally in the European Union (EU), is regulated by a network of national competent authorities from each of the Member States of the European Economic Area (EEA) working with the European Medicines Agency (EMA) and European Commission. Clinical trials are specifically controlled by the Clinical Trials Regulation (CTR), which was published in 2014 and replaces the Clinical Trials Directive. The CTR aims to maintain the highest standards of participant safety while also making the EU a hospitable environment for clinical research trials. The CTR replaces national laws and aims to create a streamlined approach for EU Member State participation in clinical research trials.

In January 2022, the CTR was amended to further improve efficiency by creating the Clinical Trials Information System (CTIS) to streamline authorizations from the different Member States, reporting, and public searches. The process of transitioning to the CTIS was completed as of January 30, 2025. At the same time, the Accelerating Clinical Trials in the EU (ACT EU) initiative was launched by the European Commission, the EMA, and the Heads of Medicine Agencies (HMA) to "build on the momentum" of the CTR and launch of the CTIS.

Recently Announced Expansion Goals and Challenges

With the CTIS now fully implemented, on September 23, 2025, ACT EU published a report on EU clinical trials during the three-year transition period that highlighted how 5,088 clinical trials were successfully transitioned to the CTIS and 5,001 new initial applications were also submitted during that time period. As of the report's publication, 8,521 clinical trials had been authorized. Along with this report highlighting the transition's success, ACT EU also published measurable goals of accomplishing the following in the next five years:

- Adding a total of ". . . 500 multinational clinical trials . . . (i.e., an estimated 100 per year)"; and
- Ensuring that "[t]wo thirds (66%) of clinical trials should begin recruiting patients within 200 calendar days or less from the date of application submission . . . in comparison to only 50% of clinical trials today."

With the background efforts described above, these goals seem achievable so long as the momentum behind administrative simplification of the clinical trial research application process is maintained.

ACT EU, through its Multi-stakeholder Platform Advisory Group (MSP AG), also identified the three main challenges currently facing cross-border clinical trials in Europe at the September meeting of the MSP AG. These three main challenges are (1) liability insurance conditions (with insurance coverage being limited to the host country for the clinical research trial), (2) import and delivery of investigational and authorized medicinal products (IMP/AMP), and (3) patient recruitment. At this meeting, the focus was on addressing the patient recruitment challenge, but future meetings will likely focus on how to additionally address the first two challenges.

Ongoing Guidance from ACT EU

In addition to providing a forum for addressing these main challenges, ACT EU plays a critical role in achieving the goals of expansion by publishing specific application guidance that is responsive to stakeholders' concerns.

In its most recent report published on October 29, 2025, it provided a list of those frequent application issues identified by national competent authorities and ethics committees. The publication then went on to provide targeted guidance for each issue so as to help sponsors in preparing their clinical trial applications. As a "multi-stakeholder platform" ACT EU has set forth a specific goal of engaging in "ongoing dialogue" with each of the stakeholders to address challenges and needs. Thus far, it appears to be achieving this goal.

Impact on Clinical Trial Sponsors

The relevant regulatory bodies in the EU have been working since 2022 to respond to the needs of clinical trial sponsors by simplifying the process through which sponsors interact with EU's Member States when setting up clinical research trials. ACT EU has put tangible numbers to the underlying goals of this simplification process by explicitly stating the numbers of clinical trials it hopes to add and initiate across the next five years. These numbers create a unique opportunity for clinical trial sponsors that have previously or have never considered performing clinical research trials in the EU to take advantage of a streamlined mechanism to engage in multinational clinical trial research. To the extent pervasive challenges to clinical trial research still exist in the EU, ACT EU appears to be proactively seeking to identify and address these problems – hopefully in a manner that is as effective as the CTIS program.

For more information or assistance with navigating the EU CTIS program, please contact Michael J. Halaiko, Daniel Abrams, Katherine Denney, or any member of the Baker Donelson Health Law Team.