



Report on webinar on contractual agreements

16 April 2026 – online

As part of the ACT EU workplan, the webinar on contractual agreements focused on agreements between sponsors and clinical trial sites, recognising contract negotiation as a persistent bottleneck in the start-up of clinical trials.

To better understand the current contractual landscape across Member States, the first session of the webinar presented the results of a survey conducted in February 2026, among the members of the Clinical Trials Coordination Group. The findings showed that most contractual templates available in the Member States are non-mandatory and more commonly available for commercial than non-commercial sponsors. This highlights the fragmentation across the EU in terms of clinical site agreements, confirming the need for information, further coordination and exchange of best practices.

The following session explored the different national experiences with template contracts, with presentations from Germany, France, Poland and the Netherlands.

Germany shared their experience with harmonising clinical site agreements through a joint initiative involving commercial and non-commercial sponsors. In 2019, a model contract clause was published, which was later expanded to cover intellectual property and data protection. Building on this, in 2024, Germany adopted binding standard contractual clauses under the Medical Research Act. The Act, which is applicable to commercial sponsors, provides standard templates and aligned cost calculation and remuneration recommendations. Since implementation a measurable reduction in contract negotiation timelines and start-up delays has been seen.

In France, the national "single contract" for commercial sponsors is mandatory under the French Public Health Code since 2017. The approach relies on a standardised national template with a non-modifiable core text, complemented by limited adaptable annexes; and contract finalisation timelines which are monitored by the Ministry of Health. Compliance with the template is linked to public funding, creating strong incentives for consistent and timely use.

In Poland, a voluntary national clinical site agreement template has been developed. While it supports contract negotiations for both commercial and non-commercial sponsors, the initiative primarily aims to strengthen consistency and capacity within publicly funded research institutions. The template is intentionally broad, designed to cover a wide range of scenarios while remaining adaptable to the specific needs of individual studies.



In the Netherlands, national harmonisation efforts have resulted in widely used, non-mandatory standard templates for clinical trial agreements, developed by stakeholders involved in the conduct of clinical research. Their use has led to more consistent processes, increased legal certainty, improved compliance, alignment with national and EU requirements and faster study start-up. However, institution-specific practices and deviations from standard contractual arrangements can still lead to delays.

At European level, ECRIN presented a model clinical site agreement developed within the Horizon Europe funded [ERA4Health partnership](#) to facilitate cross-border contracting in multinational clinical trials. The template combines a standardised core term of agreements, with country-specific annexes for national requirements. It is an annotated template and is currently being tested through pilot studies. Next steps include transforming the annotated version into a simplified form and publishing it.

From the perspective of EFPIA and EUCROF, the last presentation highlighted the results of an industry survey to understand better what the challenges in site contracting processes are. Results showed that complex financial negotiations and lengthy site review of the contracts are the main bottlenecks, followed by legal and administrative challenges. The findings suggest that greater use of standard country specific templates, reasonable timelines and efficient legal review processes can help streamline the contracting process.

Overall, the webinar confirmed that clinical site agreements are a strategic element in enabling faster, more efficient and collaborative clinical research. This webinar proved that there is a need for information, less fragmentation, clearer processes and practical tools and examples that help trials start faster and bring new treatments to European patients sooner.

The feedback provided by the participants in the registration survey will be considered together with the event feedback to define the next steps of activities covered by the ACT EU programme.

Possible follow up actions might include signposting of available national templates on the ACT EU page with a regular maintenance cycle, the organisation of additional convenings to continue with the knowledge sharing process, and in the long term the development of a European template.