Asphalion's support for Clinical Trials (CTs) transition to Clinical Trials Regulation EU 536/2014 and CTIS

CTIS BACKGROUND

Online system for the regulatory submission, authorization and supervision of Clinical Trials (CTs) **in the EU and the European Economic Area**.

Single-entry point for all Clinical Trial (CT) data. CTIS allows sponsors to apply to the 30 EU/EEA countries through a **single application**. It streamlines submission processes.

CTs authorised under previous Directive shall be **mandatorily transitioned** to the new CTR and CTIS prior to January 31st 2025.

KEY POINTS

- Type of study
- Objective of the study
- Number of participant countries
- Duration of the study
- End date
- Approved version of Protocol
- Differences across participant countries

ASPHALION SERVICES

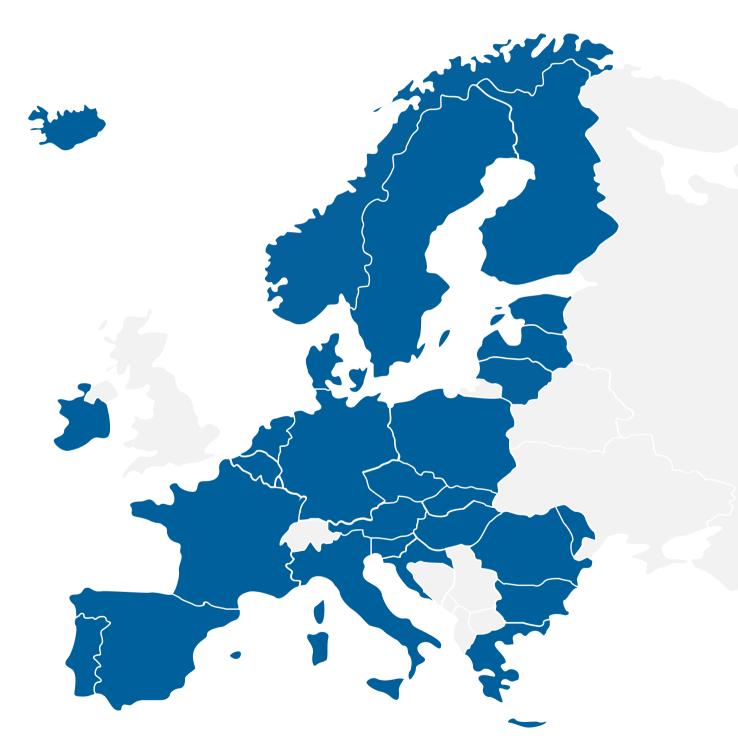
Asphalion counts with a service line specialized in CTIS platform and CTR EU 536/2014.

With deep knowledge in European Regulation, Asphalion provides a comprehensive, multidisciplinary, and transversal support for successful management of CTs; with experts involved in the management and coordination of the procedure and with technical expertise of non-clinical, clinical and CMC technical documents.

For a successful transition of a CT to CTIS, Asphalion can provide you with:

- **Transition strategy**: understanding of the trial context and Client's situation to determine complexity of the transition and requirements.
- Assistance in **prioritization of CTs for transition**, according to a defined strategy, evaluating the most effective transition plan and calendar in the case of sponsors managing multiple CTs.
- Analysis of documentation, including technical analysis, if appropriate, for their adaptation to CTR and for its homogenization in the case of multi-country CTs.
- Management of the transition process: set up of the project, appointment of roles and permissions, preparation and Review of documentation for Parts I and II, adaptation of documents to Transparency Regulation, management of Requests for Information, and follow-up with National Competent Authorities.
- CT lifecycle management.
- Ad-hoc consultancy.





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