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 i**nvolved in the management and coordination of the procedure and with technical expertise of non-clinical, clinical and CMC technical documents.**

F**or 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**.