Regulatory Factsheet

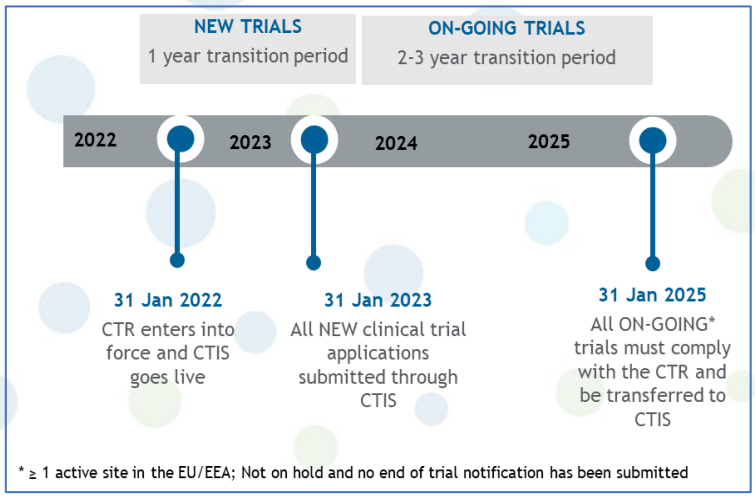
Preparing for the Clinical Trials Regulation (CTR)

What is the CTR?

- The CTR (Regulation (EU) No 536/2014) replaces the EU Clinical Trials Directive and local implementing legislation and provides the requirements for conducting clinical trials in member states of the European Union (EU)
- The CTR aims to harmonize EU clinical trial requirements and has a single point for communication with the competent authorities and ethics committees in the EU and the European Economic Area (EEA), the Clinical Trials Information System (CTIS)

Transition Period

- The Regulation came into force on 31 January 2022 with a transition period to 31 January 2023 for new clinical trials and up to 31 January 2025 for ongoing trials
- Ongoing trials can be transitioned at any point during the three-year transition period
- Sponsors are advised to do this early to ensure they have enough time before 31 January 2025 to complete all the necessary steps
- Clinical trials that are transitioned must meet all the mandatory data and document requirements of the CTR including a harmonized or consolidated protocol, taking into account all protocol versions in the EU; this may require substantial amendment in preparation for transition
- It is therefore imperative that all Sponsors of EU clinical trials are prepared for the CTR and have a clear strategy in place for the submission of new trials and transition of existing ones



Considerations for Trials Conducted Under the CTR

- The CTR represents a massive change in the way in which clinical trials are regulated in the EU
- Some of the key elements Sponsors should consider are highlighted below
- Please do reach out to us at Boyds for any help in determining your strategy for the transition to the CTR and in preparing for implementation

Documents and submissions	Reporting obligations	Transparency
• Core documents requirements harmonised • Local document requirements remain e.g. ICF, fees, translations, legal requirements etc • Single point of communication with CAs and ECs (CTIS)	• New obligations for reporting of milestones/actions during the trial, including both local and global milestones • Addition of safety reporting procedures • Reporting of serious breaches of GCP, protocols and the regulation	• By default, CTIS is publicly accessible • Provisions put in place to ensure legitimate interests protected • Publication of some elements can be deferred under certain circumstance but must be carefully identified in advance

If you would like to speak to a member of the Boyds team, contact **info@boydconsultants.com** or visit **www.boydconsultants.com** and we will be happy to help.