cencora
PharmaLex

Clinical trials regulation (CTR)

Time is rapidly running out to transition ongoing clinical trials in the EU to the new framework of the Clinical Trials Regulation (CTR). A key challenge for sponsors is ensuring they are proficient in the Clinical Trial Information System (CTIS) and understand the transition requirements.

Timelines need to be understood, including that review of the transition to CTR application takes up to 106 days and achieving compliance with all requirements prerequisite to performing the transition may take even longer.

* Our recommendation: start harmonisation AMDs in multi-MS trials at the very latest on 01-Apr-24, in order to ensure on-time transition
** Timeline: max. 22 days (provided no RFI is needed); Note: part II assessment timeline depends on MS

Cencora PharmaLex is part of Cencora, a leading global healthcare company centered on improving lives. Together, we offer end-to-end product commercialization, including global market access strategy and execution, to drive patients' healthier futures wherever they are in the world.

We service the pharma, biotech and medtech industries, guiding clients from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities. Our experts use technology-elevated solutions to support clients through the entire product lifecycle.

www.pharmalex.com