cencora
PharmaLex

Are you CTR and CTIS ready?

After 30 January 2025 all ongoing EU trials not transitioned to the clinical trials regulation will lose their legal basis.

We support you in defining and executing optimal strategies for the EU Clinical Trial Regulation implementation

- Adapt your global development and submission strategies
  - Establish a drug development strategy
  - Implement a clinical trial submission strategy
- Understand dossier requirements and plan for updated content
  - Start activities for the transition of your clinical trials approved under the old regulatory framework
- Ensure that staff, systems and processes are ready
  - Secure the availability of dedicated personnel
  - Implement SOPs and processes
  - Set up templates and trackers dedicated to CTR/CTIS
  - Adapt processes in medical and scientific writing to meet the strict transparency requirements
- Be aware of accelerated timelines
  - Put in place processes and contingency plans for the new and very short response timelines to CA/EC questions

Review of the transitional trial application takes up to 106 days!

Navigate through the CTR process | **Meet the timelines** | **Reach your development goal**

We have the expertise to support you from clinical trial applications to marketing authorization to support the development goal

- Regulatory support and guidance for every step of the global product development path
- Regulatory consultancy for clinical trials in the EU/EEA
- Global and local clinical trial coordination
- Operational CTIS support
- Clinical trial submission strategy to support team readiness
- In-house CMC, medical/ scientific writing and regulatory expertise

Let us be your trusted partner in achieving EU CTR readiness and improving processes beyond compliance

25+
years of industry experience and knowledge

9/10
of the top pharmaceutical companies are our clients

50+%
of our projects are global

200+
experienced and certified local representatives support our global coverage

CTR Clinical Trial Regulation
CTIS Clinical Trial Information System
CMC Chemistry, Manufacturing, and Controls
CA Competent Authority
EC European Commission

Have the right expertise by your side

www.pharmalex.com

Contact us