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European Medicines Agency

CTIS Task Force

Topics for analysis: Tracker

Topic	Status of analysis
Clinical Trial Application (CTA) Workflow a) Assessment timelines for initial CTAs and Substantial Modifications b) Removal of extension for advanced therapy medicinal products (ATMP) c) Part I/II alignment	Analysis ongoing
Collaboration space	Analysis ongoing
Submission rules (parallel Substantial Modifications)	Analysis ongoing
Low and minimum intervention trials	Analysis ongoing
Change of Reporting Member State (RMS) & RMS Selection	Analysis ongoing
Member State Application Programming Interface (API)	Analysis ongoing
Product core dossier	Full analysis pending delegated/implementing act

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Topic	Status of analysis
Combined devices	Full analysis pending delegated/implementing act
Public Health Emergencies	Full analysis pending delegated/implementing act
Use of artificial intelligence (AI)	Analysis pending
Environmental Risk Assessment	Analysis pending
Implementation of ICH M11 Guideline on clinical electronic structured harmonised protocol	Analysis ongoing
Sandbox	Analysis pending