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European Medicines Agency

CTIS Simplification Task Force

Topics analysed (2024-2026)

Topic	Status of analysis	Recommendation	Status of implementation
CTIS role matrix	Analysis complete.	The Task Force has recommended a revised roles matrix that reduces complexity by reducing the number of user roles.	To be planned
Safety	Analysis complete.	The Task force has recommended the creation of a new safety module, with the aim to simplify the overall business rules for the Annual Safety Report (ASR) while enabling the selection of the safety assessing Member State (saMS) in CTIS. The release of the new safety module is planned for Q3 2026.	Planned in 2026 CTIS Roadmap

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Topic	Status of analysis	Recommendation	Status of implementation
CTIS timetable visualisation	Analysis complete.	The Task Force has recommended to keep the timetable in CTIS and increase awareness on the functions of this feature.	N/A
Investigational Medicinal Product Dossier – Quality (IMPD-Q) only applications	Analysis complete.	The Task Force has recommended to keep the current process while closely monitoring whether there is a need to implement an alternative solution in the future.	N/A
User Management	Analysis complete.	The Task Force has recommended to implement key improvements that will provide immediate benefits to administrators, with the aim to make the user administration more efficient and user friendly.	Planned in 2026 CTIS Roadmap
Ad-hoc assessment	Analysis complete.	The Task Force has recommended to keep the current process with potential implementation of some improvements based on priorities and to **look into possibilities** to modernise the ad-hoc assessment of safety and non-safety notifications, serious breaches and quality issues in the future.	N/A
Lock mechanism	Analysis complete.	The Task Force has recommended reducing the number of locks only in the Request for Information (RFI) sections to streamline the RFI response process for sponsors.	To be planned
Clinical Trial Application (CTA) Workflow	Analysis ongoing, with the aim to introduce more flexibility for users in the submission of clinical trial applications.	a) The Task Force has recommended increasing flexibility in the rules for submission of clinical trial applications, prioritising Substantial Modifications/Non-	a) Planned as part of Biotech Act implementation

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	This topic includes the following sub-topics: a) Application submission rules b) Notices and alerts c) Workflow automatic business rules d) Tasks e) Requests for Information and considerations f) Cloning functionality	Substantial Modifications Part II and Additional Member State Concern applications. b) The Task Force has recommended deleting notices and alerts 90 days after receipt, reducing the number of Notices and Alerts, and introducing email notifications, among other recommendations. c) The Task Force has recommended keeping the workflow automatic business rules in the system as-is. d) The Task Force has recommended a revision of the RMS selection process. e) The Task Force has recommended key improvements in the Request for Information and Considerations tab to enhance user experience. The Task Force has also agreed to explore the use of a collaborative tool in the authority workspace, and analyse the need for a communication tool in CTIS (see topic below). f) The Task Force has recommended enhancements in the way the system clones sections when applications are created as well as to split SM types into smaller sections to facilitate parallel submissions.	b) Deletion of notices and alerts 90 days after receipt implemented Q3 2025, email notifications implemented Q2 2026 c) N/A d) To be planned e) To be planned f) Planned as part of Biotech Act implementation
Member State Application	Analysis ongoing.	N/A	N/A

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Programming Interface (API)			
Download management	Analysis complete.	The Task Force has recommended to implement key improvements in the "All documents" table and "Download" feature to improve the user experience and increase overall productivity.	Planned in 2026 CTIS Roadmap
Collaboration tool	Analysis ongoing. To be analysed in 2026.	Work continued under CTIS Taskforce	N/A
Review of structured data		Work continued under CTIS Taskforce	N/A