

eCTD 4.0: A Brave New World

eCTD 4.0 marks the latest milestone in the ongoing quest to make the global submission and review process more efficient, harmonized, and seamless for both publishing teams and reviewers.

Initially defined as an interface to facilitate the transfer of regulatory information from the regulated industry to regulatory authorities, the eCTD aims to **enhance the efficiency and effectiveness** of the regulatory review process for medicinal products. As more countries adopt eCTD, it is becoming the standard format for submitting regulatory information worldwide.

Implementing eCTD 4.0 represents a significant step forward for both industry and authorities, entailing new software and processes that will require companies to invest time and resources.

Implementation

This upgraded version introduces **considerable improvements** in the **submission process** for sponsors and regulatory bodies alike. All major regulatory authorities are gradually transitioning to this standard. The timeline for implementation varies by region, with **mandatory implementation dates** ranging **from 2026 to 2030** for the different health authorities.



The US FDA and Japan PMDA currently accept eCTD 4.0 on a voluntary basis, while other countries are in the process of implementation. Visit the ICH website for the latest updates on the eCTD v4.0 implementation schedule. [eCTD v4.0 Implementation Dates](#)



Services

At Asphalion, our Regulatory Operations consultants are ready to support clients in the timely adoption of eCTD 4.0 across their regulatory processes, offering a comprehensive range of [services](#).



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EMA Subject
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How to Prepare for eCTD v4.0

Proactive planning is crucial, as eCTD 4.0 introduces several new concepts that differ significantly from the previous version. Staying up-to-date with the latest changes is essential to ensure compliance with regulations.

Regulatory leaders will need to thoroughly review guidelines to adapt practices within their companies and teams in order to:



Provide team
training



Update submission
processes



Ensure publishing
software compliance



Establish an
implementation timeline



Review metadata
and keywords



Monitor regulatory
updates

Contact us!

Be Prepared! eCTD 4.0 is here, and it's time to capitalize on its benefits and position yourself to embrace this evolution.

Are you navigating complex regulations or challenges with compliance, quality systems, or regulatory submissions? Asphalion is here to help. Our expert team of consultants, with extensive experience across regulated industries, is ready to deliver tailored solutions designed to meet your unique needs.

Schedule a free meeting with our European Medicines Agency Subject Matter Expert for eCTD 4.0 and overcome your implementation challenges.