

eCTD 4.0: A Brave New World

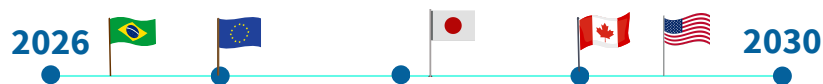
eCTD 4.0 marks the latest milestone in the ongoing quest to make the global submission and review process more efficient, harmonized, and seamless for both publishing teams and reviewers.

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 Asphaltion, with our team of Regulatory Operations consultants, we are prepared to assist our clients in the timely adoption of eCTD 4.0 within their regulatory processes, offering a diverse range of [services](#).



Leverage the latest software; self-developed, ISO-certified, project management tools



Decades of experience supporting all types of regulatory procedures and dossier types

