synteract®
BRINGING CLINICAL TRIALS TO LIFE

Synteract Offers
Comprehensive eCTD Services to Support Electronic Submission to Regulatory Authorities

eCTD: The Preferred Format

As electronic common technical document submission (eCTD) becomes the standard submission format many sponsors need the guidance of an experienced and knowledgeable team to support their regulatory requirements worldwide.

Synteract offers a comprehensive service that includes all aspects of eCTD publishing and submission management, running the entire program in-house for our sponsors.

eCTD submission offers several advantages over paper submissions:

- eCTD shortens the development timeline by simplifying drug life cycle management and quickens the move from the CTA/IND to MAA/NDA
- eCTD allows for company-wide sharing of regulatory information, which can improve regulatory information quality, management and visibility.

eCTD is already the preferred format for many Regulatory Authorities, and many are requiring it. It is widely used in Australia, Canada, China, Croatia, Japan, Saudi Arabia, Singapore, South Africa, Switzerland, US, and all EU/EEA Member States.

The FDA and the HMA are moving to making eCTD submissions mandatory for MAAs/NDAs and INDs

January 2009: eCTD became the required format for medicinal products submitted to the HMA in the centralized procedure.

January 2015: The HMA adopted Annex 2 to the HMA eSubmission Roadmap: Implementation of mandatory eCTD format for regulatory submissions

- July 2015: New MAAs in decentralized procedure (DCP)
- January 2017: New MAAs in Mutual Recognition Procedure (MRP)
- January 2018: eCTD for all regulatory activities in the EU (DCP/MRP)
- July 2018: New MAA in National Procedures (NP)
- January 2019: eCTD for all regulatory activities in the EU NP

May 2015: The FDA issued its final guidance: Regarding Mandating eCTD format

- May 2017: NDAs, Amendments and Supplements required in eCTD format
- May 2018: INDs, Amendments and Annual Reports required in eCTD format
- May 2019: Drug Master Files in eCTD format.

Who is the appropriate customer for eCTD?

Synteract's eCTD offering can be the solution for any customer, including:

- Companies with personnel or budget constraints
- Companies preparing to start investigational trials or marketing authorization submission
- Small to mid-sized research companies that don't have eCTD capability in-house
- Those who don't have the technology knowledge/expertise to ensure all documents meet the international standards and requirements established

What does Synteract's eCTD offering cover?

Synteract offers a comprehensive service that includes all aspects of electronic document preparation, document management, eCTD publishing, submission management and Regulatory Authority submission. We take into account both the "story" and the operational specifics that will help you to gain approval.

Sponsors also gain access to a full-service regulatory offering that includes:

- Strategic regulatory advice
- Content authoring
- Legal/authorized representation services
- Regulatory/scientific advice meeting request, preparation and support
- Technical gap analysis
- Regulatory submissions

What are the advantages of Synteract's eCTD offering?

Collaborative and experienced Synteract team members understand the technology and benefits of the platform – helping sponsors gain improved turnaround time and higher quality. Perhaps most important for our sponsors, we are committed to improving our sponsors' knowledge base and we walk them through the process, explain requirements, and handle gap analysis as needed.

- Synteract has the global knowledge required for multiple-country submissions
- Synteract team members care about accuracy and quality
- Pricing is competitive – when eCTD is outsourced to Synteract it allows our sponsor to gain the advantages of using the electronic method without having to make a significant investment in the software
- Going to eCTD makes it easier to share information both internally and externally, and ensures that the data always stays up-to-date
- Synteract helps companies with their own Regulatory Affairs Department to convert current paper submission docs to electronic; then we manage and house the eCTD
- Synteract completes submissions in a timely manner, meeting sponsors' timelines

About Synteract

With employees across 21 countries, Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of therapeutic expertise in oncology, dermatology, and neuro degenerative indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Services/Regulatory-Affairs or ContactUs@synteract.com.