CTI's Regulatory Experts Have Completed Hundreds of eCTD Submissions

CTI eCTD Publishing & Regulatory Submission Services:

Providing a seamless process from the earliest stages of drug development consulting through formal submission

CTI's Regulatory and Scientific Affairs team has developed dozens of Investigational New Drug (IND) applications utilizing electronic-Common Technical Document (eCTD) formats. The team has vast experience in preparing and submitting initial applications, serial submissions, and with converting submissions from paper to electronic. To date, the team has completed hundreds of various eCTD submissions.

The US Food and Drug Administration's (FDA) mandate for eCTD format and electronic submissions are now in effect. As of May 5, 2018, commercial INDs and Drug Master Files must be submitted using eCTD format,* joining previously mandated requirements for New Drug Applications (NDAs), Abbreviated NDAs (ANDAs), and Biologics License Applications (BLAs), which went into effect May 5, 2017.

CTI has licensed and trained eCTD publishers ready to professionally prepare, validate, and submit your regulatory applications to the FDA, European Union, Health Canada, Australia, Swissmedic, or other global regulatory agencies. CTI uses the same software used by many of these agencies, including the FDA, to view and validate all eCTD submissions, which ensures technical and quality excellence, leading to a faster approval time.

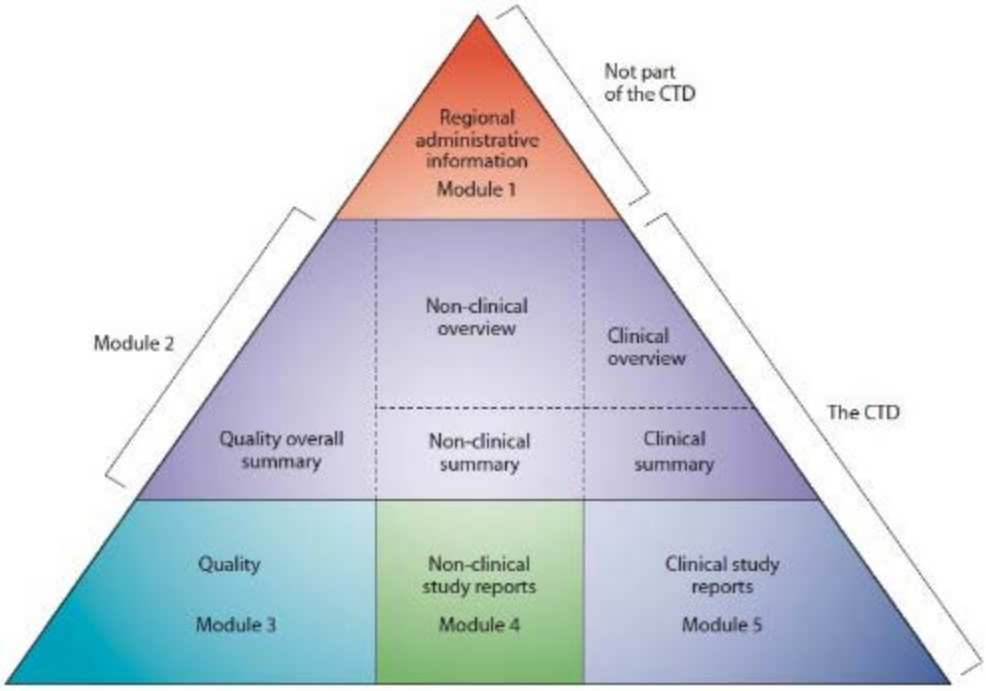
Our team members can electronically submit all applications to regulatory agencies around the world utilizing this eCTD software. Each deliverable includes expertise from our diverse team of regulatory, trial operations, data management, biostatistics, medical affairs, medical writing, and publishing experts. Throughout the development process, we use regulatory accepted document

templates, programs, and processes to produce compliant regulatory submission documentation, reports, and dossiers. We have an independent Quality Assurance team that ensures quality is the leading factor in all of our services and is reflected in all of our submissions to regulatory authorities.

CTI publishers are each set up with an FDA Electronic Submissions Gateway (ESG) account for securely submitting pre-market and post-market regulatory information. The FDA ESG is the central transmission point for sending information electronically to the FDA and is a conduit along which submissions travel to reach the proper FDA Center or Office.

Additionally, our team of regulatory and medical writing experts can assist with the development and tracking of application content from pre-IND to marketing application. We offer a seamless process from the earliest stages of drug development consulting through formal submission of documents electronically to regulatory agencies.

eCTD Structure:



The CTD triangle. The Common Technical Document is organized into five modules. Module 1is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

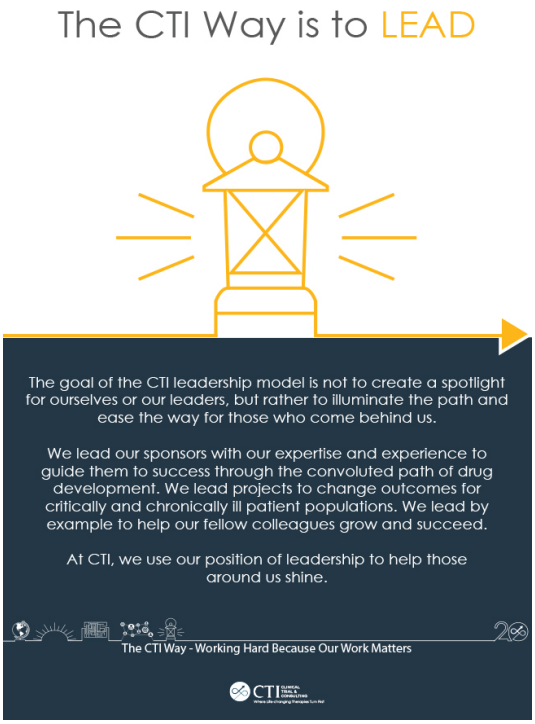
**EXCEPTION: Type III DMFs have been extended to May 5, 2019*

Additional Highlights

The CTI Way

There is a unique culture that exists at CTI, a method of approaching our work and interacting with our coworkers that we have come to refer to as "The CTI Way."

As we make our way towards our 20th year, each month we will be highlighting a different theme or aspect of "The CTI Way." The theme for the month of June is "Lead."The employee of the month is awarded to the candidate who exhibits strength in CTI's core values, best exemplifies "The CTI Way" theme of the month, and consistently demonstrates outstanding performance.



Employee of the Month

Sandra Wöhr

Sandra has been with CTI for nearly 5 years, and is currently a Clinical Systems Analyst in our Ulm office. While Sandra consistently exemplifies strength in CTI's core values and regularly demonstrates excellent performance, her ability to lead is second to none.

Sandra has been an instrumental leader in the development and implementation of CTI's electronic systems in Europe and Asia. With her proven expertise and extensive knowledge of the various electronic systems, Sandra is always willing to answer questions from colleagues all over the world and helps lead them through the difficulties in the use of the systems.

Sandra is an incredibly valuable asset to the CTI team, and her insight and experience has undoubtedly contributed to the success of the company. Congratulations, Sandra, on your well-deserved award!

Upcoming Meetings CTI is Attending

Non-alcoholic Steatohepatitis (NASH) Meeting
Paris, France
July 5-6
Outsourcing in Clinical Trials (OCT) Medical Device Conference
Minneapolis, MN
July 11-12

International Symposium on MPS
San Diego, CA
August 2-4

CAR-TCR Summit 2018
Boston, MA
September 4-7

Society of Hematologic Oncology (SOHO 2018)
Houston, TX
September 12-15

Outsourcing in Clinical Trials (OCT) Southern California
San Diego, CA
September 26-27

Cell and Gene Meeting on the Mesa
La Jolla, CA
October 3-5

IDWeek 2018
San Francisco, CA
October 3-7

American Society of Nephrology (ASN) Kidney Week 2018 San Diego, CA
October 23-28

Outsourcing in Clinical Trials (OCT) New England
Boston, MA
November 6-7

AASLD - The Liver Meeting 2018
San Francisco, CA
November 9-13

Join Our Team!

We are currently seeking qualified individuals to join our team!
Search Open Positions

CTI Cares

This month, the CTI family is raising money to support Sant Joan de Déu (SJD) Children's Cancer Center in Barcelona, Spain. SJD conducts research to find new and better treatments for pediatric diseases.
Learn more and donate

New Hires & Promotions

CTI is thrilled to welcome all of our new employees, and to congratulate our recently promoted employees!
View New Hires and Promotions

CTI in the News

CTI Named Top Workplace

CTI Clinical Trial and Consulting Services (CTI), a multi-national, privately held, full-service contract research organization was recognized as a Top Workplace in Cincinnati by The Enquirer Media. The award ceremony took place Thursday, June 7th.
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