

Review Article



US Electronic Common Technical Document (eCTD): An Overview

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ABSTRACT

The International Council for Harmonization (formerly, International Conference on Harmonization), ICH, has come up with uniform Technical Requirements for registration of pharmaceuticals for human use so as to avoid the redundancy in the work by the pharmaceutical manufacturer for submitting registration dossier to the regulatory authority of the intended market. Common Technical Document (CTD) format has now become the obligatory format for the EU, Japan, Canada, Switzerland and Australia, and the recommended format in the US. Even the derivatives of the CTD are becoming widely adopted in other regions like the ASEAN countries. Electronic Common Technical Document (e-CTD) is an extension form of CTD where structure is specified by XML based backbone (Extensible Mark-up Language). The e-CTD is an interface between industry and agency for knowing and sharing regulatory information and at the same time taking in to consideration of creating, reviewing the lifecycle of submission. It provides a harmonized solution to implement the Common Technical Document (CTD) electronically. An eCTD consists of individual documents in PDF format which are arranged in a hierarchical form as per the CTD structure. It also has an XML backbone which cross-links required documents and provides information regarding the submission.

Keywords: International Council for Harmonization (ICH), Common Technical Document (CTD), e-CTD (Electronic Common Technical Document), Dossier, Regulatory submission.

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INTRODUCTION

USFDA

The United States Food and Drug Administration (FDA or USFDA) is a federal agency of the Department of Health and Human Services. The Food, Drug, and Cosmetic Act was signed by President Franklin Delano Roosevelt on June 25, 1938. FDA headquarters is located in Maryland. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.¹

Regulatory authority of USA is: Food and Drug Administration (FDA)

Major Functions of USFDA:

To protect public health by confirming the safety, efficiency, and security of drugs, biological products,

medical equipment, as well as to ensure the safety of food items, cosmetics, and items that emit radiations.

To promote public health by supporting innovations or inventions that make drugs, medical devices, etc., safer, effective and affordable.²

ICH History and Formation:

In the 1980 the European Union began harmonizing regulatory requirements. In 1989, Europe, Japan, and the United States began creating plans for harmonization. **The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)** was created in April 1990 at a meeting in Brussels.

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration.

The mission of the ICH is to promote public health by achieving greater harmonization through the development of technical Guidelines and requirements for pharmaceutical product registration.

In 2015, ICH underwent several reforms and changed its name to the **International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use**.¹



The Need For ICH:

The international need to harmonize regulations quickly became obvious and was accelerated by concerns over rising costs of healthcare, escalation of the cost of R&D, and the need to reduce the delay in making safe and efficacious new drug products available to patients in need.³

Objective:

- To improve efficiency of new drug development and registration process
- Accomplished through the development and implementation of harmonized guidelines and standards.⁴

Common Technical Document:

The common technical document (often abbreviated as CTD) was developed by the ICH (International Conference on Harmonization) working group with representatives from regulatory bodies in Europe, Japan and the United States. The CTD is a set of specifications for the submission of regulatory data in the application for the right to market pharmaceuticals.

CTD Format:

In this region that recognize the CTD regulatory file format (specifically, the U.S., Europe, and Japan), CTD files are organized into dossiers that align with prescribed technical requirements for eventual submission to the appropriate regional regulatory authority as an application for the registration of pharmaceuticals intended for human use.

As illustrated in the accompanying CTD triangle, all well-structured CTDs are divided into five distinct modules that contain the proper arrangement of CTD files.⁵

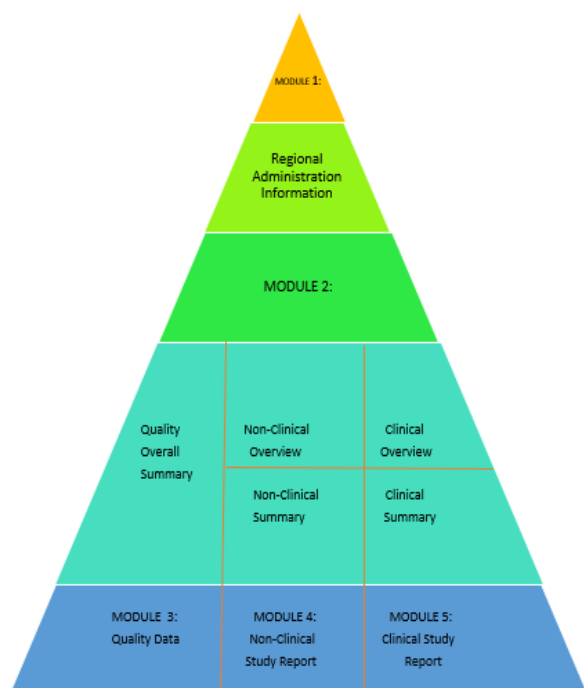


Figure 1: CTD Triangle⁶

eCTD:

overcoming the challenge of managing huge volumes of paper based product data and to enable faster and efficient submissions, an electronic equivalent of CTD was introduced as eCTD.⁷

The Electronic Common Technical Document (eCTD) is the standard format for submitting applications, amendments, supplements and reports to the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).⁸

The eCTD format provides support for all application types including:

Investigational New Drug Applications (INDs)

New Drug Applications (NDAs)

Biologics License Applications (BLAs)

Abbreviated New Drug Applications (ANDAs)

Drug Master Files (DMFs)⁹

There are two categories of modules:

1) Regional module: 1 (different for each region; i.e., country)

2) Common modules: 2–5 (common to all the region)¹⁰

eCTD Structure:-

eCTD has five Modules:

Module 1: Administrative and prescribing information

Module 2: summaries



Module 3: Quality

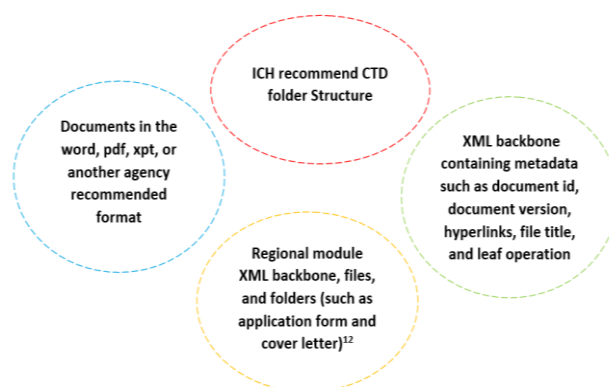
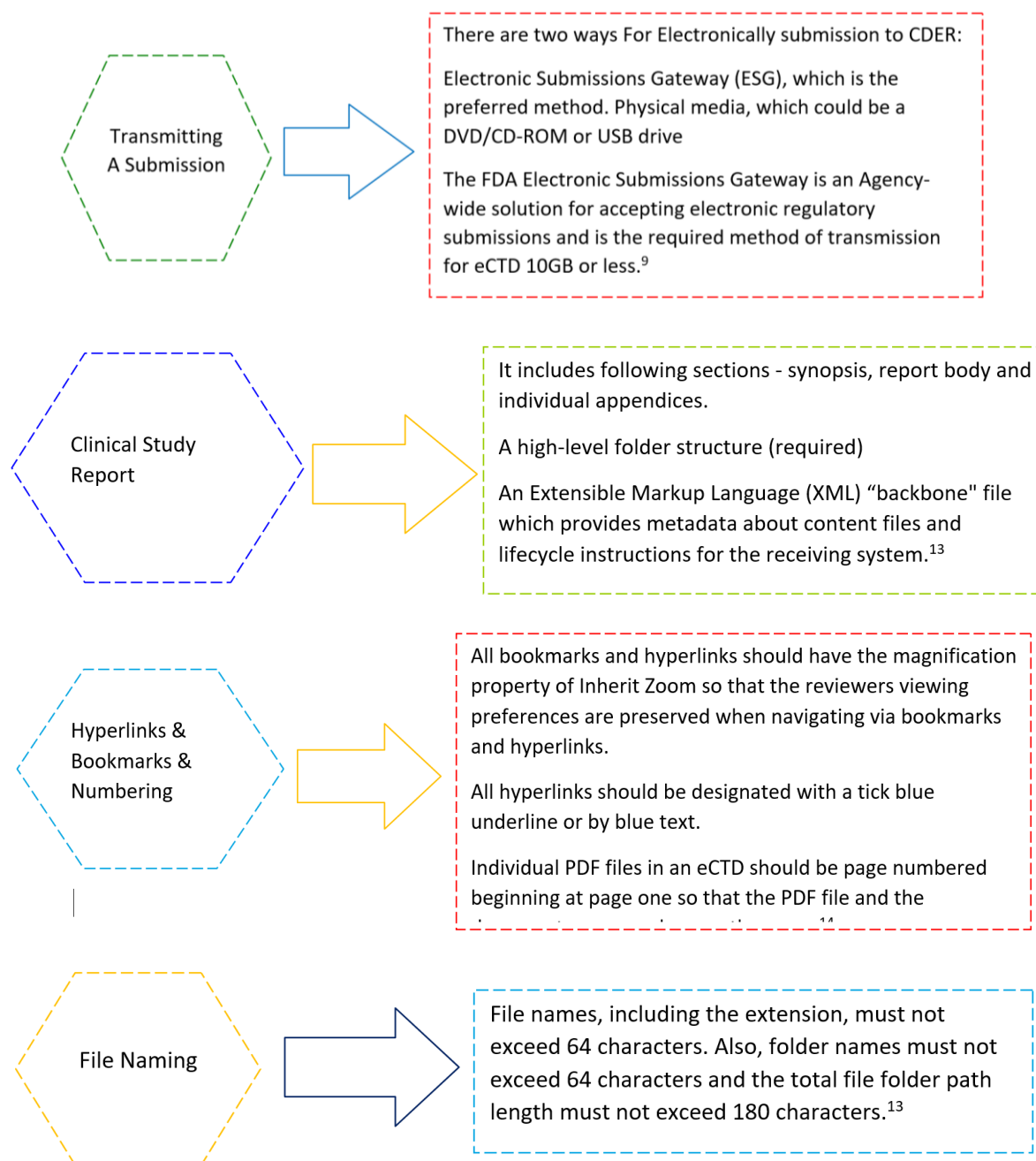
Module 4: Nonclinical study reports

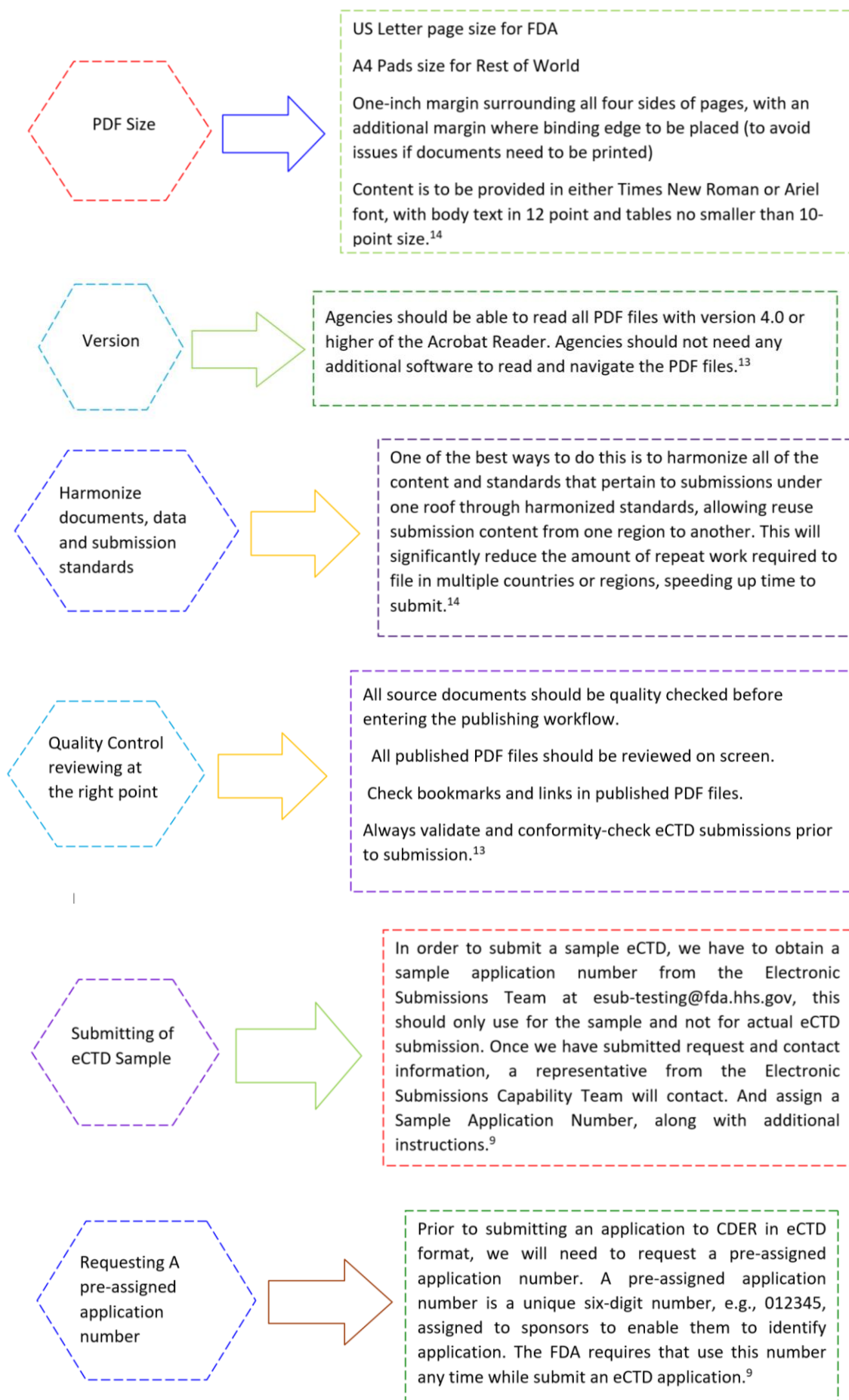
Module 5: Clinical study Report

Table 1: CTD Modules

	MODULE 1: Regional And Administrative Information : Regional module which includes only Module 1 - Administrative information and prescribing information - not harmonized - different for each region; i.e., country, defined by each of the ICH regions (USA, Europe and Japan).
	MODULE 2: Common Technical Document Summaries Module 2 summarizes the information that will be provided in the quality (Module 3), nonclinical (Module 4) and clinical (Module 5) modules of the dossier.
	MODULE 3: Quality Module 3 describes the format and organization of the chemical, pharmaceutical and biological data relevant to the application.

	MODULE 4: Module 4 describes the format and organization of the nonclinical (pharmaco-toxicological) data relevant to the application.
	MODULE 5: Module 5 describes the format and organization of the clinical data relevant to the application. ¹¹

Contents of eCTD:**Requirements to submission of eCTD Documents:**



Advantages:

- 1] More Efficient than Paper Submissions.
- 2] Superior Visibility of the Procedure.
- 3] Decreased Timeline and Faster Approvals.
- 4] A Standardized Process and Format for Submissions.
- 5] Market and Revenue Growth.
- 6] Improved Tracking Ability.⁷

If written as a single document, publishers may attempt to avoid validation issues by placing the annual report within a single node corresponding to one of the annual report sections (e.g., Summary for Nonclinical Studies). However, this approach risks confusion during the review, as the content will not properly align with the node description.¹³

CONCLUSION

The main role of eCTD in pharmaceutical industry is regulatory submissions. And it is done by harmonizing the blueprint and module-based format of pharmaceutical submission applications. This kind of submission ensures convenient and faster filing of applications.

Nowadays, CTD Technique widely used for documentation. It is implemented in various developing countries like united states, Europe, Japan. This technique is helpful for pharmaceutical companies.

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ABBREVIATIONS:

FDA: Food and Drug Administration

IND: Investigational New Drug

NDA: New Drug Application

BLA: Biologics License Application

ANDA: Abbreviated New Drug Application

DMF: Drug Master File

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