

What is CTD/eCTD ?

Common Technical Document (CTD): Its an format set by ICH which was agreed by the Regulatory Agencies of Europe, Japan & the US.



Its electronic version called as **electronic Common Technical Document (eCTD)**.



The CTD Triangle



CTD Modules

- ❑ Module 1 – Administrative Information (Region Specific)
 - ❑ Module 2 – CTD Summaries (QOS)
 - ❑ Module 3 – Quality (CMC)
 - ❑ Module 4 – Non-Clinical Study Reports
 - ❑ Module 5 – Clinical Study Reports
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Module 1

Administrative Information (Region Specific)

Should contain documents specific to each region

For USA

- Application form 356h
- Proposed label
- Patent certification / information
- Debarment certificate
- Letter of Authorization (LoA)/ DMF letter
- Labeling text

For EU

- Application form
- Summary of product characteristics
- Labelling text and mock-ups
- Information about the experts
- Environmental risk assessment
- Description of the pharmacovigilance system
- Risk management plan

Module 2

CTD Summaries (QOS)

It contain **7 sections** in the following order:

- 2.1 CTD TOC (Module 2-5)
 - 2.2 CTD Introduction
 - 2.3 Quality Overall Summary
 - 2.4 Non-clinical Overview
 - 2.5 Clinical Overview
 - 2.6 Non-Clinical Summary
 - 2.7 Clinical Summary
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Module 3

Quality (CMC)

- 3.1 TOC of Module 3
 - 3.2 Body of Data
 - 3.2.S - Drug substance
 - 3.2.P - Drug product
 - 3.2.A - Appendices
 - 3.2.R - Regional Information
 - 3.3 Literature references
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Module 4

Non-Clinical Study Reports

- 4.1 TOC of Module 4
- 4.2 Study reports
 - 4.2.1 Pharmacology
 - 4.2.2 Pharmacokinetics
 - 4.2.3 Toxicology
- 4.3 Literature References

Module 5

Clinical Study Reports

- 5.1 TOC of Module 5
 - 5.2 Tabular listing of Clinical Studies
 - 5.3 Clinical study reports
 - 5.3.1 Reports of Biopharmaceutical (BA-BE) Study
 - 5.3.2 Reports of Pharmacokinetic (**biomaterial**) study
 - 5.3.3 Reports of Pharmacokinetic (PK) Studies
 - 5.3.4 Reports of Pharmacodynamic (PD) Studies
 - 5.3.5 Reports of Efficacy and Safety studies
 - 5.3.6 Reports of Post-Marketing experience
 - 5.3.7 Case Report Forms & Individual patient listings
 - 5.4 Literature References
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eCTD

Its electronic version of CTD, so called as **electronic Common Technical Document (eCTD)**.

- eCTD composed of two types of specification
 - Content specification – As defined by ICH
 - Technical specification – Electronic software's



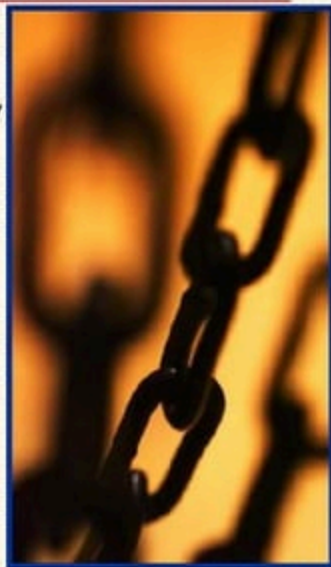
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- ❑ eCTD is highly recommended by USFDA for NDAs, BLAs, DMFs and INDs filing
 - ❑ From year 2010 European Union also make compulsory for electronic CTD submission to all procedures



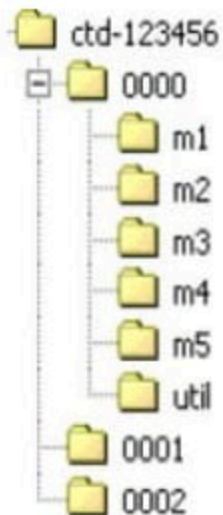
eCTD Characteristics

Structure

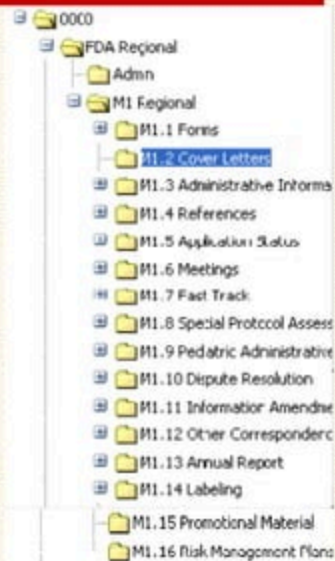
- All Modules 1 to 5 have granularity options.
- PDF documents linked via XML backbone
- Increased document granularity.
- Transparency of entire submission
- Ease of navigation and review



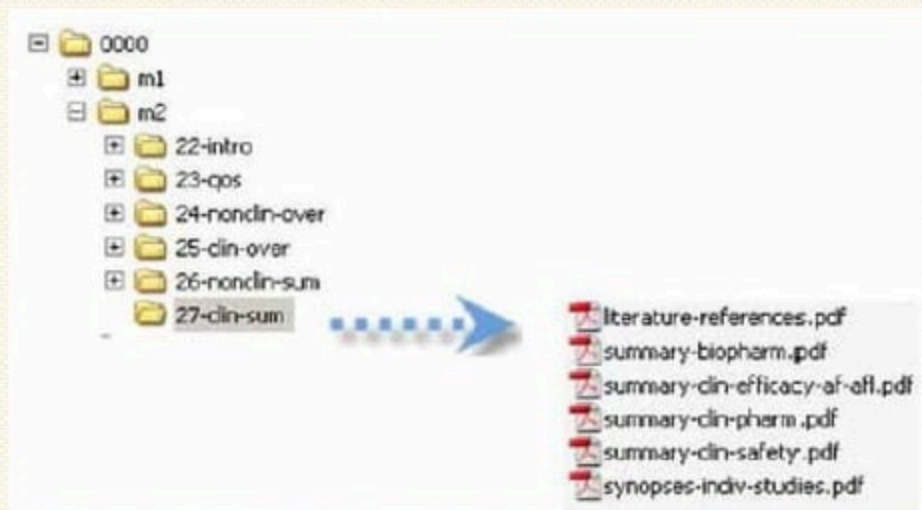
eCTD Template



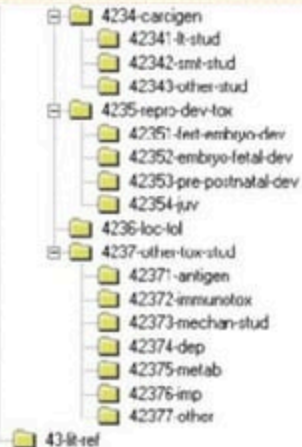
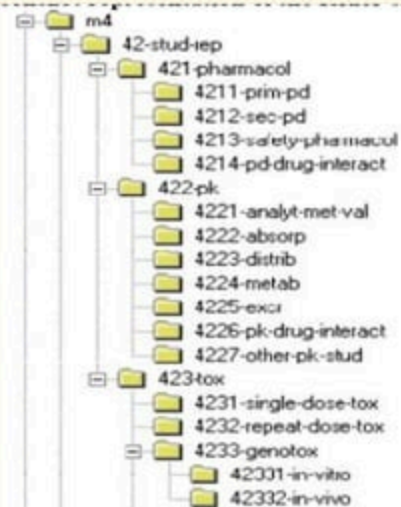
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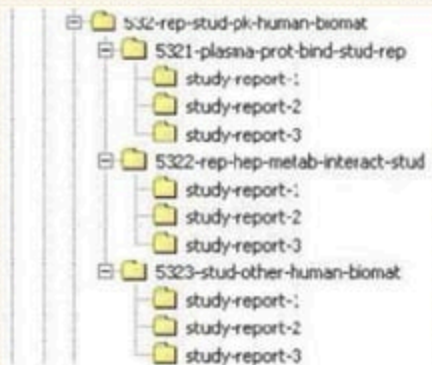
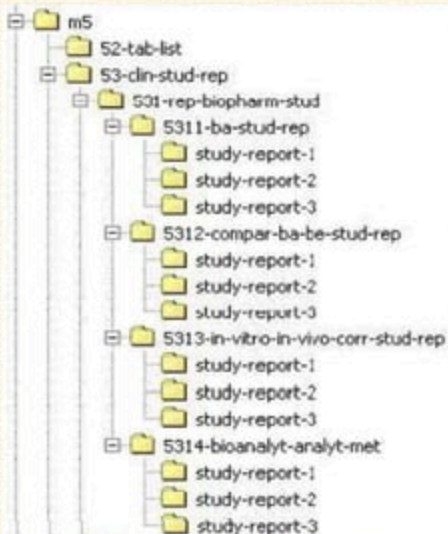
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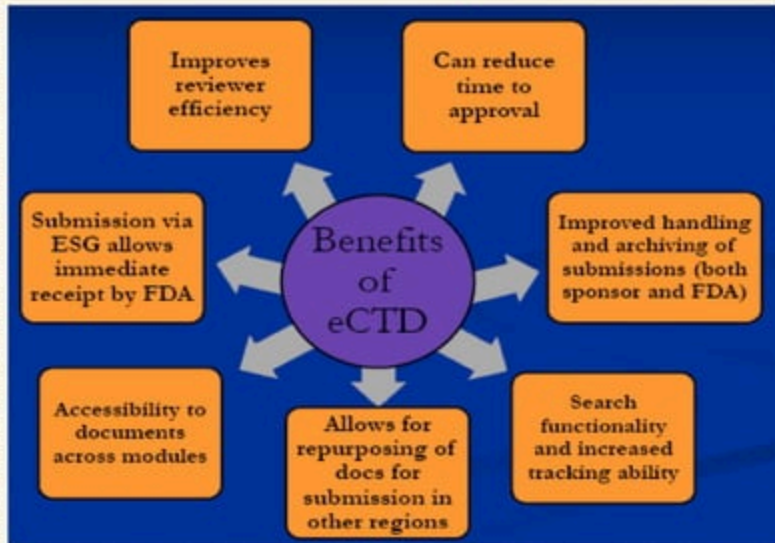
M4



M5



Benefits of eCTD



Thank you