

**E-CTD**

# 1. ECTD (ELECTRONIC COMMON TECHNICAL DOCUMENT)

## 1. Introduction

- ✓ After decades of using paper, the goal is the electronic transfer of drug applications and their review across submission formats, procedures, and reasons came in electronic common technical document.
- ✓ The steadiness of the submission format paper in the past might not apply for the electronic submission format in the future( six standards in the last 20 years –DAMOS, MERS, MANSEV, CANADA, ECTD, SEDAMM ).
- ✓ The Concept of electronic regulatory submissions is not new , and has been evolving in America and Europe since the late 1980s.

## 2. DEFINITION OF ECTD


- ✓ The electronic common technical document is an interface and international specification for the pharmaceutical industry to agency transfer of regulatory information.
- ✓ ECTD specification lists the criteria that will make an electronic submission technically valid.
- ✓ The focus of the specification is to provide the ability to transfer the registration application electronically from industry to a regulatory authority.

# 3. NEED FOR ELECTRONIC SUBMISSION

Designed with consideration that facilitate

- ✓ Creation
- ✓ Review
- ✓ Assist project management and information management
- ✓ Life cycle management (history of a product application)
- ✓ Archiving
- ✓ Drug development planning

## **4. BENEFITS OF IMPLEMENTING ECTD AND CHALLENGES**

- ✓ Allows regulatory to use computer based tools such as searching ,copying, and ,pasting text , review process.
  - ✓ Stream lines review process allow for multiple reviewers and there fore a more efficient review process.
  - ✓ Allow re use of document and submission components with more easy for several difference reasons by sponsors.
  - ✓ Enhance the ability to efficiently organize , prepare and management submission content.
  - ✓ Reduce storage cost associate with production and storing paper dossiers.
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## Before eCTD

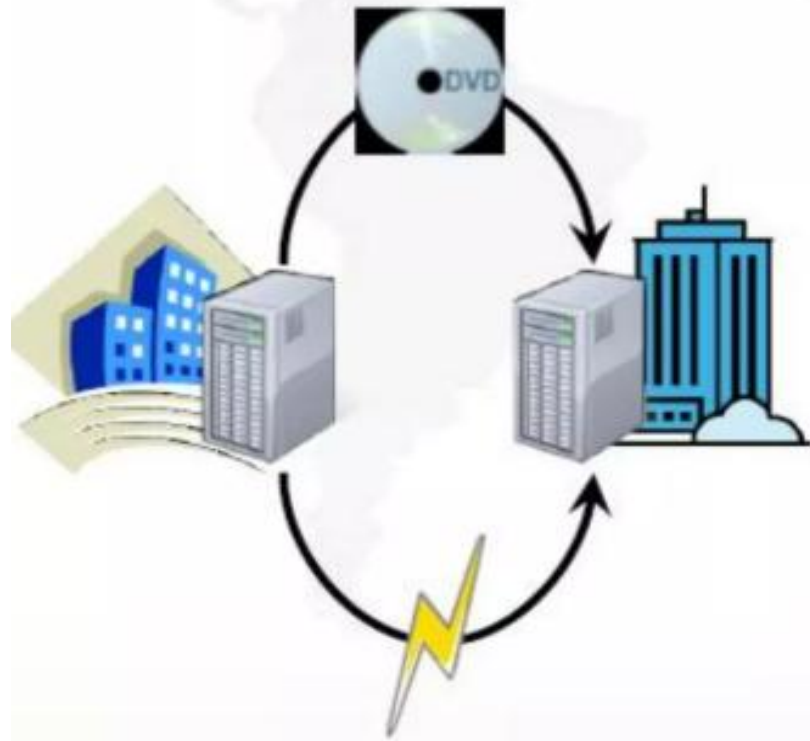


CTD dossier in bookrack



Reviewer's desk

# After eCTD

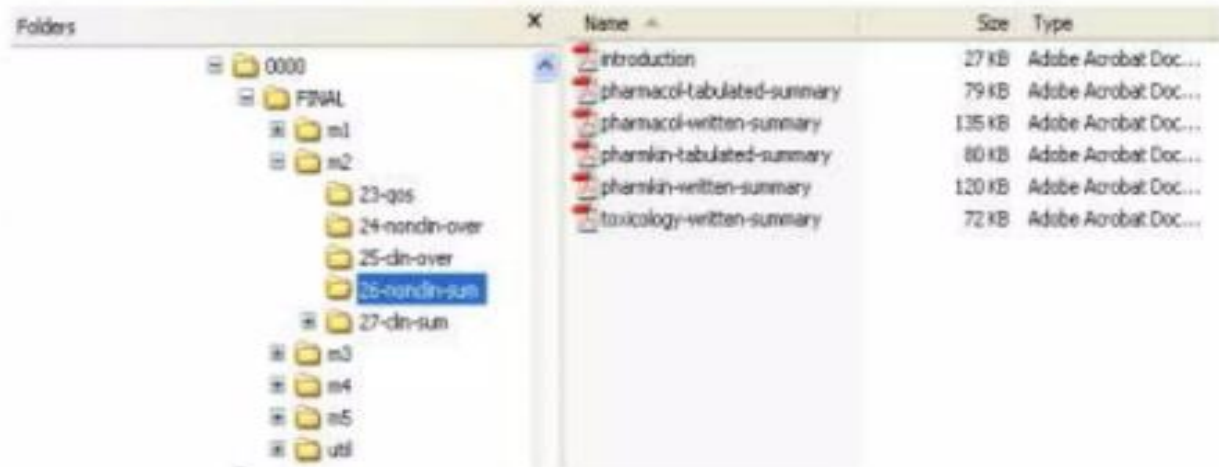
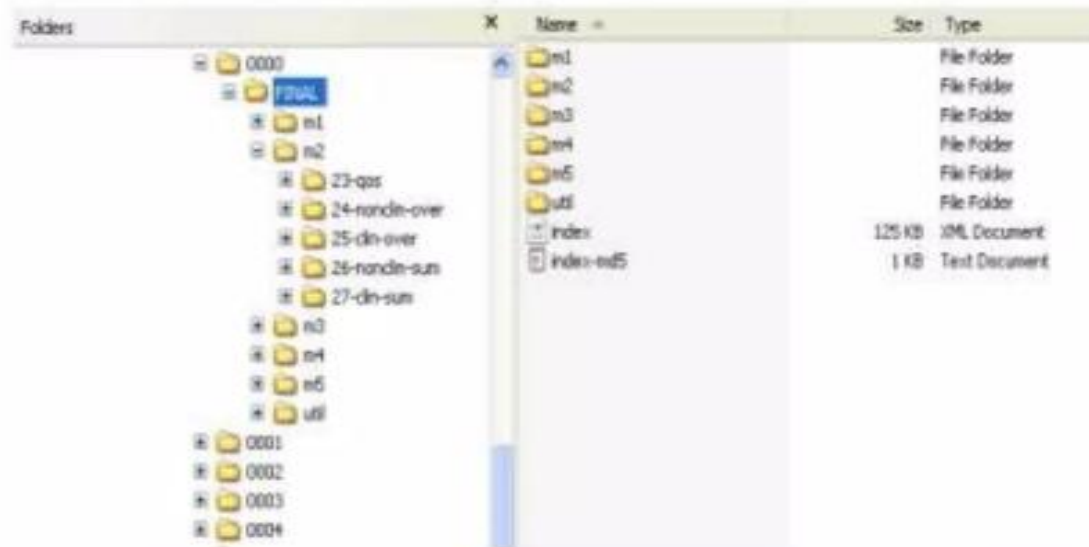
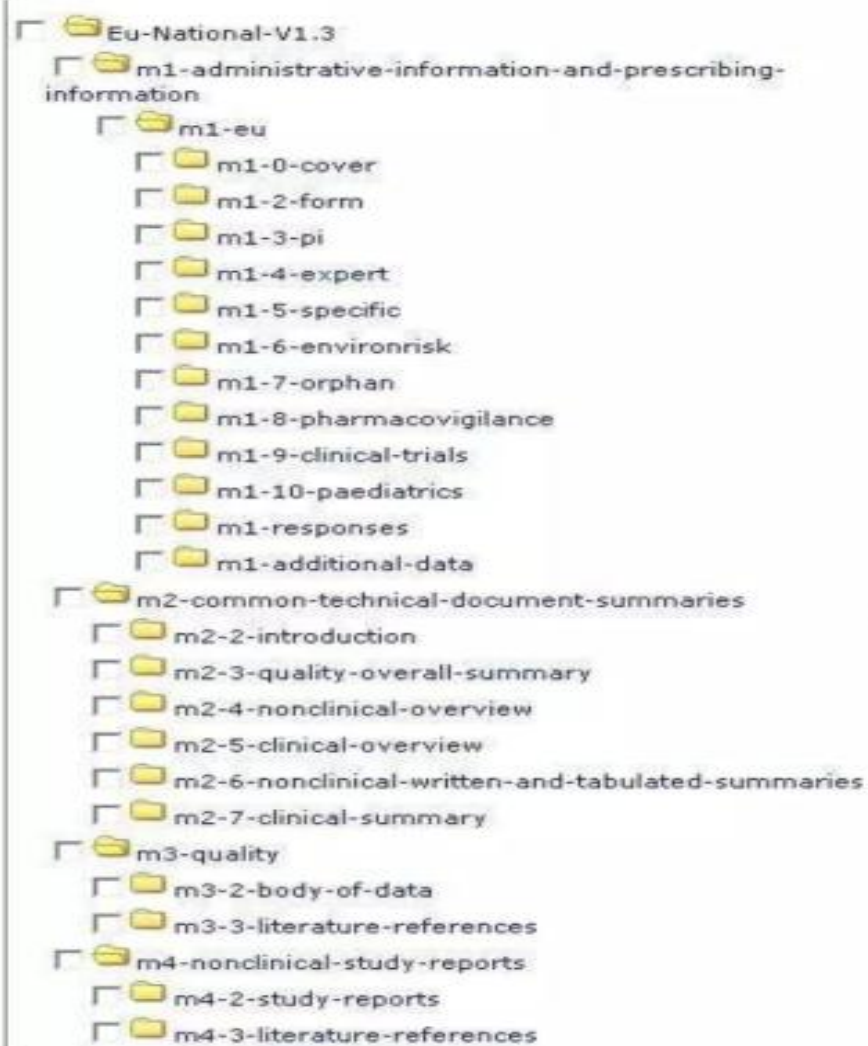


CTD dossier in server

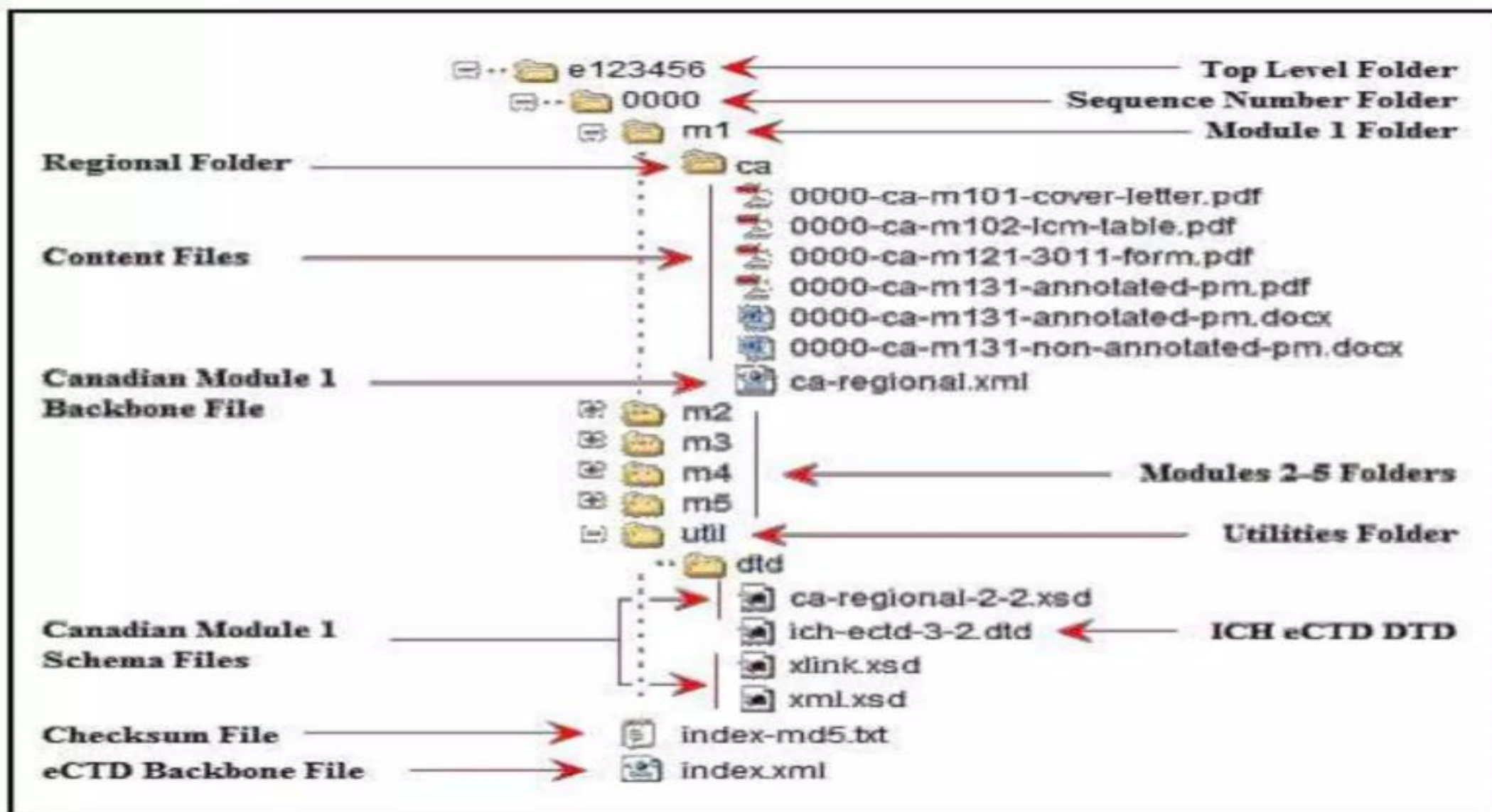


Reviewer's desk

# ECTD FILE STRUCTURE



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## 5. ECTD READY DOCUMENT

- ✓ It is important that ECTD ready document are prepared by authorization them in ECTD compliant templates.
- ✓ If it is not under taken , a large amount of the “publishing time ” is spent in document reformatting.
- ✓ Guidance on the preparation of ectd ready document is provide below.
- ✓ A) File organization for the ECTD (Granultority)
- ✓ B)specification for submission of formats.
  - 1.Directory structure
  - 2.XML,ECTD instance
  - 3.Content files

## 6. RISK INVOLVED IN ECTD PUBLISHING

- ✓ A) Source document incompatibility
- ✓ B) In sufficient information for publishers
- ✓ C) In correct document versions
- ✓ D) Short publishing timelines
- ✓ E) Non linear delays
- ✓ F ) In appropriate granularity
- ✓ G) technical problems with legacy files
- ✓ H) quality control review at right time
- ✓ I) In appropriate validation process

## **Benefits of eCTD**

- ✓ **Make the reviewing of each application more easy**
- ✓ **Avoid omission of critical data or analyses**
- ✓ **Save time**
- ✓ **Better information management**
- ✓ **Support of Life Cycle Management**
- ✓ **Immediate access to complete and up-to-date information**
- ✓ **Reduced workload**
- ✓ **Better use of resources**
- ✓ **Simplified business process**
- ✓ **Better communication with industry**

# CHALLENGES

- Advantages sometimes perceived as disadvantages
  - PDFs
  - Hyperlinks

**Requires tools and trained technical experts**

**Different implementation approach**

**Regional rules vary**

**Last minute changes not easy**

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