eCTD
is NOT just
an electronic CTD

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Files
PDF
XML
TIFF
IMAGE
Photograph
Digital imaging
SAS Transport Files
etc.......

Metadata
- Title
- CheckSum
- Checksum Type
- XML ID
- Keywords
- Operation
- Modified File
- **Links** (Path)

XML
(CTD TOC)

XML Backbone Model for Repository Data Interchange

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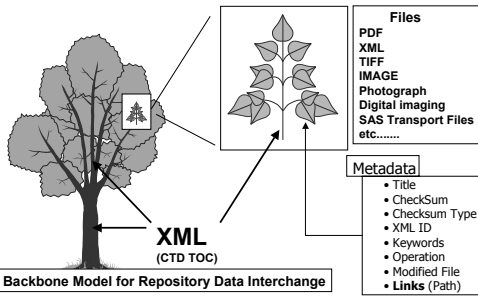
Structure of an eCTD Submission

1. XML eCTD Instance and DTD
2. XML Regional Instance(s) and Regional DTD(s)
3. Directory Structure with Files
4. eCTD instance Checksum(s)
5. Viewer or Style Sheet(s)

Files
PDF
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Photograph
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etc......

MetaData

XML

eCTD Checksum
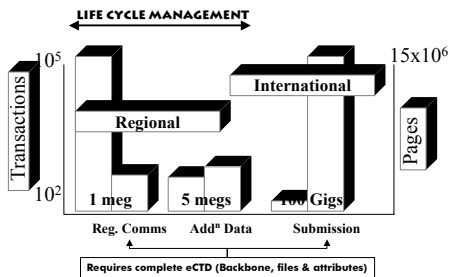
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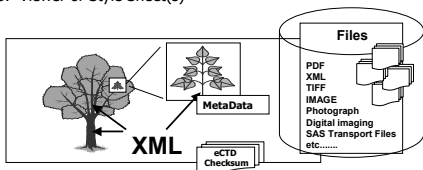
eCTD Concepts

- eCTD is a Transport Standard
- eCTD is Content Modeled to the CTD TOC
- XML Backbone Concept
- Supports Life Cycle Management
- Usable as delivered (with default style sheet)
- Designed for the Paperless Submission
- All supplements, amendments, and responses are electronic (eCTD)
- Once electronic (eCTD) always electronic (eCTD)

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eCTD Supports Life Cycle Management

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eCTD Supports Life Cycle Management

1. **XML Content Modeled Backbone DTD:**
   - Strict content modeling of the CTD in the eCTD.DTD ensures that:
   - *Each Leaf with its associated file can be unambiguously identified.*

2. **The OPERATION Attribute (Leaf):** creates
   - four (4) **CLEARLY DEFINED STATES**
   - (**N**ew, **R**eplace, **A**ppend, **D**elete)
   - that identify the **role** of the leaf(s) submitted.

3. **Metadata Attributes** at the LEAF level allow for automated submission use
   (i.e. Drug Substance or Study report Level)

Taxonomy Development

Standards	Standards	Standards
• MeDRA	• Document	• Data Integrity
• CTD	• Work Process	• Authentication
• eCTD	• Best Practices	• "Transmission"
• Clinical Trial Standards	• Internal Standards	• "Broker"
• ICSR		
• E / S / Q / M Topics		

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Benefits

- Knowledge Management
- Work Process Efficiency
- Reduced days to Filing
- Reduced Days to Market
- Increased Profitability

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THANK YOU!

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XML Applications…eCTD Tools…eCTD Readiness…eCTD Production…Regulatory IT Solutions

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