

# Transition to eCTD: Impact on industry business processes

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# Outline

- Submission Timelines
- Financial
- Data Management
- People

# Submission Timelines

- Adopting the eCTD format (Phase 2 and 3) will significantly reduce the amount of time needed to publish and submit a drug submission.
- Adopting eCTD reduces (Phase 2) or eliminates (Phase 3) the need to print the paper portion of a submission.
  - No need to spend time printing, creating tabs, loading binders etc.
- Preparation of both paper and electronic submissions, whether simultaneously or concurrently, consumes a considerable amount of time and resources.

# Submission Timelines

- Preparation of the paper submission alone is labor intensive.
  - Several people will be needed to prepare a large paper submission within a reasonable amount of time.
- With eCTD, resources can be used more efficiently
  - One person can create a large electronic submission within a reasonable amount of time.
  - Resources can be reallocated such that multiple electronic submissions, large or small, can be prepared and submitted at the same time.

# Submission Timelines

- Adopting the eCTD format also encourages other submittable Regulatory documents to be sourced in an electronic format.
  - Reduce or eliminate the need to scan documents (e.g. Documents sourced from Clinical trials).
  - Processing data from a paper source takes time. Electronic data can be sorted, processed and transferred quickly and easily using various software programs.
  - Electronic data and documents will proceed through the drug development process much faster than paper documents.

# Financial Impact

- Increased costs/new expenses:
  - Software and Hardware
    - Upgrade existing or purchase new:
      - Publishing software tools
      - Document management systems
      - Storage space
      - Systems to ensure data security/data integrity
      - General software tools  
(e.g. Acrobat, XML authoring, MS Office)
  - Personnel
    - Training
    - Time (installation, validation, testing etc.)
    - Increased dependency on IS/IT professionals

# Financial Impact

- Reduce costs/increase cost efficiency:
  - Sourcing documents in an electronic format can reduce costs associated with processing paper data.
  - Print materials
    - Reduced need for binders, paper, tabs etc.
  - Courier costs
    - Ship smaller packages rather than large bundles of binders .
  - No need for large and expensive high-tech printers
    - Printing M1 and M2 can be done on desktop printers or standard networked laser printers.
    - No need to use outsource print companies (reduced costs and enhanced logistics).
    - No need to keep and service expensive publishing printers (e.g. DocuTechs).

# Financial Impact

- Reduce costs/increase cost efficiency:
  - Office Space
    - Paper submissions take up a considerable amount of space.
    - Take advantage of virtual storage
    - Over time reclaim office space designated for paper submissions or space used for large publishing printers
  - Offsite storage
    - Can be expensive.
    - Retrieving stored information can be cumbersome and is not instant.
    - Take advantage of virtual storage
    - Retrieving virtual data is faster and more efficient than retrieving physical information.
    - Virtual data can be kept on site.



# Data Management

- Much easier to retrieve and reuse electronic submissions and submission data.
  - Much more efficient way to manage massive amounts of information
  - Easier to access, share and search data

# Data Management

- Increased dependency on electronic systems and associated infrastructure.
- Data integrity
- Data security
- Increased dependency on IS/IT personnel
- Focus on contingency plans

# Data Management

- Amount of information transferred will increase
  - Paper physically limits the amount of information that can be sent at one time.
  - DVDs currently hold up to 8.7GBs. More information can be sent electronically than on paper. (e.g. 1 binder of DVDs vs 1 binder of paper).
- The pace of information exchange will increase
  - The pace at which paper documents are sent and received is limited by having to physically transport the paper with couriers or through fax.
  - Eventually eCTD's will be send over secure file transfer systems. Information can be sent and received almost instantly.

# People

- There is a threat of becoming overwhelmed by the mass of information and the increased speed that the information will be sent and received.
- Focus intensely on training and support.
  - No longer acceptable for users to “just get by” with a basic knowledge of software tools.
  - Upgrade users software application skills (e.g. Word, Acrobat, XML software, Document Management systems etc).
  - Take full advantage of what the electronic environment offers by knowing what your options are.
- With proper training users of electronic systems are less likely to feel overwhelmed.

# People

- Learning to work without paper can be difficult, but is not impossible.
- Over time, the majority of people will become used to authoring and reviewing documents electronically.
  - Steadily wean yourself away from a dependency on paper.
- Although it is important to upgrade IS skills, it is very easy for RA professionals to be distracted from “the science” and Regulatory Affairs.
  - Focus on being an intermediate/advanced user not an IT expert.
  - Work very closely with IS/IT
  - Outline your wants and needs to your IS/IT department or to software vendors.
  - Let IT worry about the details while you worry about Regulatory Affairs

# Summary

- Reducing, and eventually eliminating, the need to print paper submissions will reduce submission preparation timelines.
- Reallocated resources can publish multiple submissions at the same time.
- Expenses associated with:
  - electronic data management will increase.
  - Printers and print materials will decrease

# Summary

- Increased dependency on electronic systems means companies must focus more intensely on data security and integrity (Viruses, security breaches etc).
- Personnel working in an electronic environment must have the appropriate training to ensure they have the skills to cope with the mass of information and the increasing speed of information exchange.