eCTD
Agency expectations and impact for the industry

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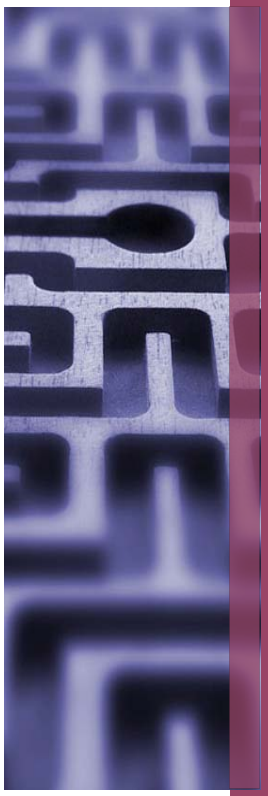
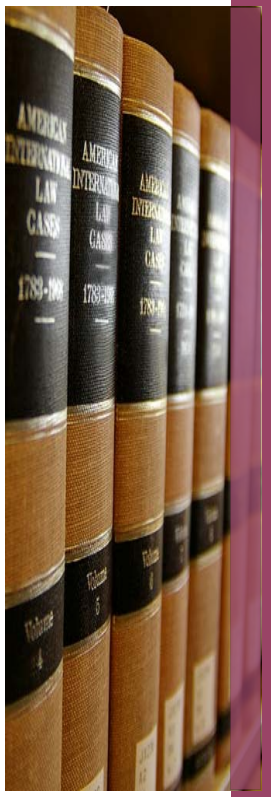
Agenda

- Agency Expectations
  - eCTD Background
  - Current Status & Timelines
- Impact for Industry
  - eCTD Capability – Drivers & Requirements
  - Implementation Scenarios
  - Factors Impacting Strategy
  - Outsourcing Opportunities
  - Conclusion – How to Proceed?

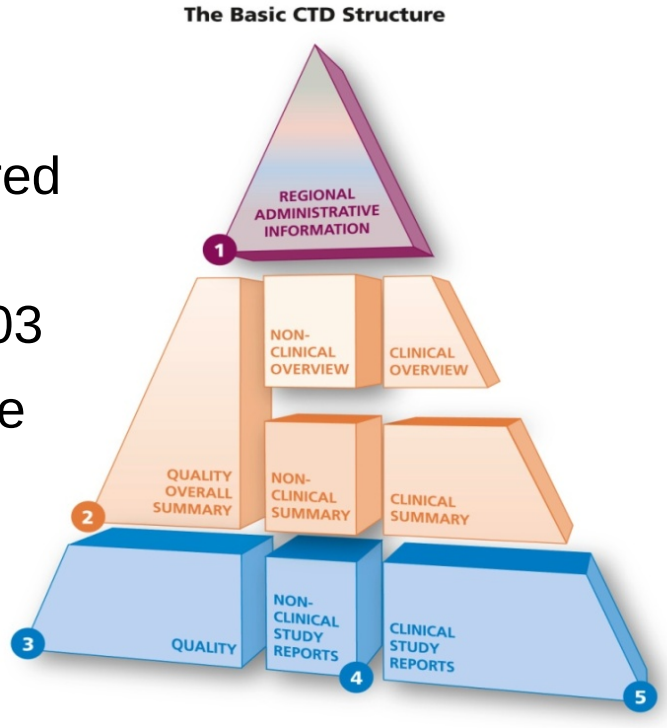


Agency Expectations



(e)CTD – electronic Common Technical Document

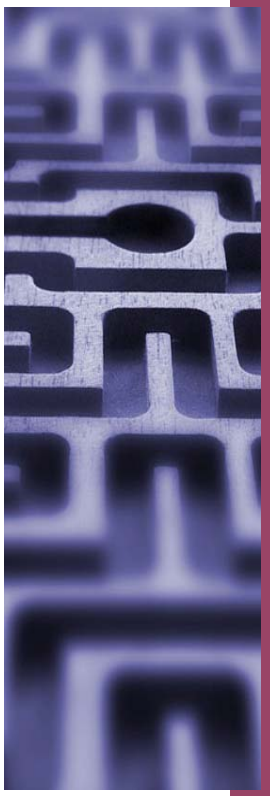
- The CTD
  - Represents a harmonized structured format of a registration dossier
  - Adopted by the ICH regions in 2003
  - Recognised as standard worldwide



- The eCTD
  - Represents the standardised electronic presentation of a CTD based on a XML “backbone”
  - Facilitates access, review, lifecycle, archiving for authorities and industry

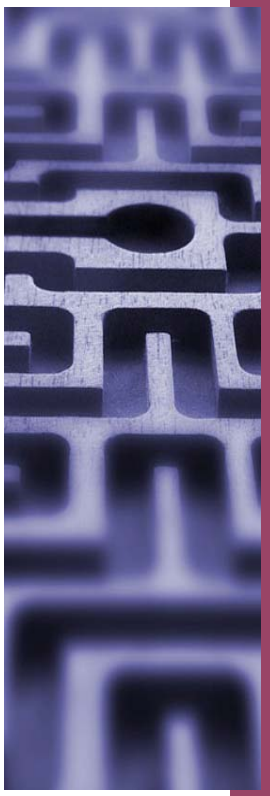
Status eCTD: EMEA and EU Member States

- EMEA: eCTD is the mandatory electronic format from Jan-2010
- EU: Members states committed to accept electronic-only submission from Jan-2010
  - eCTD is the recommended and increasingly mandatory electronic format
  - NeeS (Non eCTD electronic submission) is accepted by several EU member states during a transition period
  - Paper copies still required by some countries



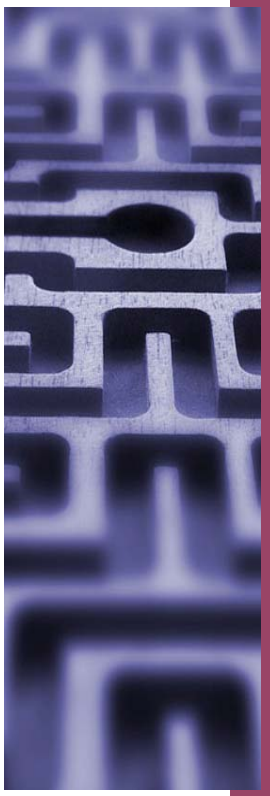
Status eCTD: US

- FDA: eCTD is the mandatory electronic format since Jan-2008
  - Applicable for all new applications (NDA, IND, ANDA, BLA, Annual Report and DMF)
  - In contrast to the EU the eCTD is the adopted format for clinical trial submissions (IND)
  - In Module 5 additional info is needed: Study data (e.g. SAS datasets, programs) and CRFs (Case Report Forms)
  - Electronic Submission Gateway (ESG) – submission of eCTD via the Internet



Status eCTD: CH

- CH: Announcement - electronic-only eCTD submissions accepted from Jan-2010
  - Project „SIMES“: Solution for the Implementation and the Management of Electronic Submissions
  - Final CH Module 1 specification announced for October 2009
  - eCTD is the only accepted format (NeeS requires paper -> regarded as paper submission)
  - Currently, same review timelines for paper and eCTD submission
  - Some M1 documents are still required in paper, e.g. cover letter, forms and product information (see Annex 3 of CH guidance for industry)

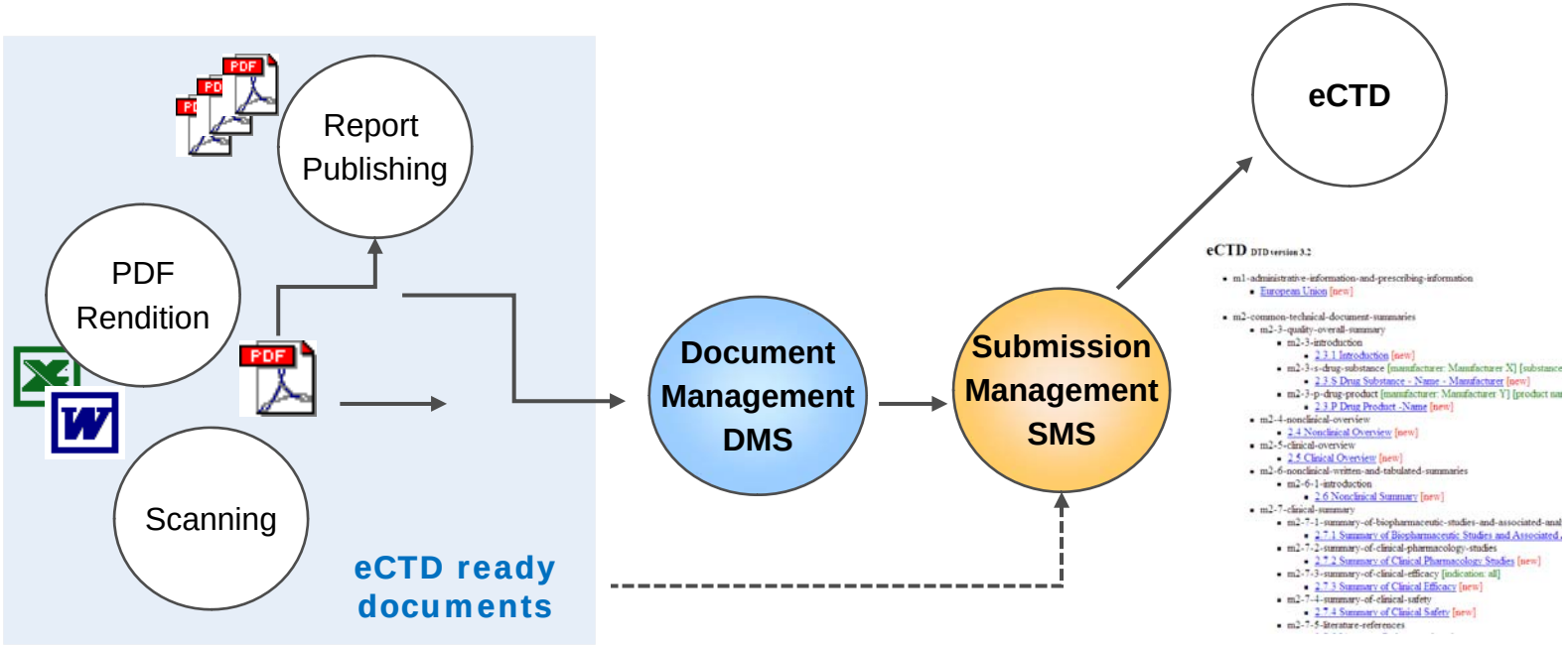


Impact for Industry

eCTD Capabilities - Drivers

- Compliance to regulatory requirements is the main driver for implementing eCTD capabilities
- Secondary drivers are
  - Opportunity to evaluate & optimise internal processes -> potential reduction in submission time -> time to market
  - Increased quality of documents & submissions
  - Ease of (global) access of information
  - Re-usability (cloning) of submissions
  - Facilitated transfer (agencies - portals, partners)

eCTD – Systems, Processes, People

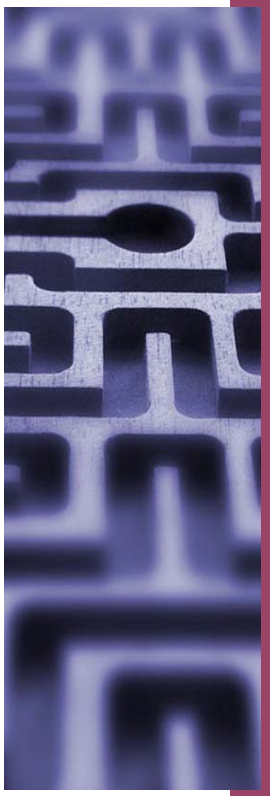


Documents
- Style guide, document templates
- Referencing approach
- Requirements for external partners
- Processing of legacy documents

People
- Specialised skills
- User training
- Support organisations: First, second level support
- Generally: Awareness about eCTD processes

eCTD – Implementation Scenarios

- A company has to identify their “best fit” solution
  - Document creation is frequently managed by internal document management systems (DMS) - or comparable controlled procedures
  - For the eCTD creation and lifecycle an internal submission management system (SMS) can be implemented
  - Alternatively, eCTD publishing can be managed with a service provider - no SMS implementation required

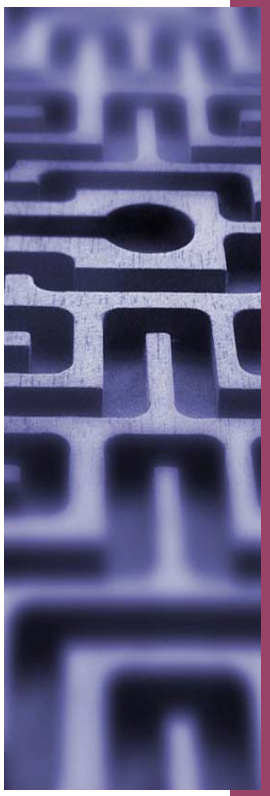


Factors Impacting Strategy

- Number of products that ..
  - Reach phase III and MAA (Marketing Authorisation Application)
  - Are submitted without the support of a strategic partner
- General company strategy regarding outsourcing
- Time, costs and resources for system ...
  - Selection, implementation, deployment, maintenance
  - Both, implementation of DMS and SMS represent a significant effort

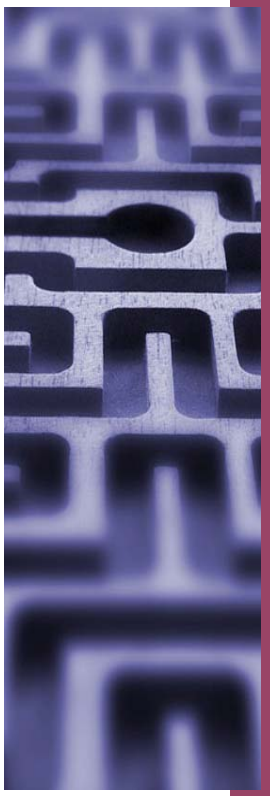
SMS Implementation – Cost Factors

- Main cost factors – system implementation
  - Vendors selection process, project management
  - Initial software licenses & annual maintenance fees
  - Hardware, incl. backup and recovery
  - Implementation, configuration
  - System validation (initial and ongoing)
- Main cost factors – system deployment "make people work with the system"
  - SOPs, user manuals, training
  - Specialized staff (key users, helpdesk, administration)



SMS Implementation – Potential Costs

- Average costs for the implementation of a SMS (internal & external costs, smaller companies)
  - Implementation and deployment ~ 200 T€
  - Especially for SMEs software licenses often represent ~ 20 - 30% of the overall costs
  - Ongoing annual costs ~ 80 - 100 T€

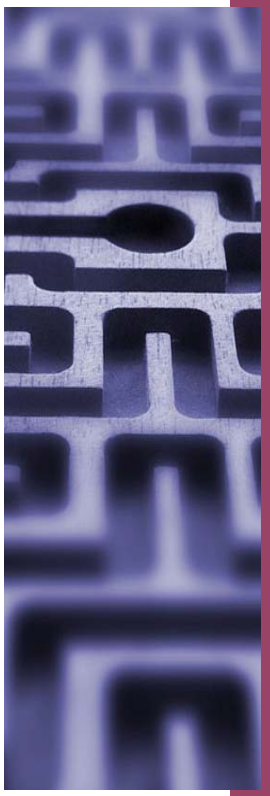


SMS – Outsourcing Opportunities (1)

- Focus on core competences
  - Focus on regulatory content
  - Regulatory affairs avoids becoming involved in discussions on IT systems
  - The eCTD represents a "generic process“: no specific product know-how needed -> outsourcing opportunity
- Access to specialised skills and expertise
  - The eCTD requirements follow specific rules that leave room for best practise interpretations; requirements are also changing
  - Ongoing experience with eCTD generation is required to deliver a high quality result

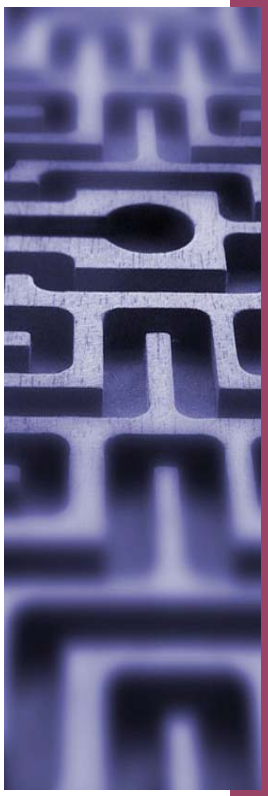
SMS – Outsourcing Opportunities (2)

- Financials
  - No costs and investments for implementing a new system and the required organization
  - No costs of ownership
  - Costs can clearly be to allocated to specific projects
- Time
  - An eCTD submission can be realized from today on, no significant lead-time required
- Flexibility
  - eCTD services are only contracted when needed



Conclusion - How to Proceed

- How to proceed for eCTD implementation – some key activities
  - Assure common awareness
  - Gap analysis – what needs to be done?
  - Evaluation of options – how can it be done?
  - Decision for systems / partners
  - Implementation of technology / processes



Thank You – Questions?

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eCTD-EXPERTS

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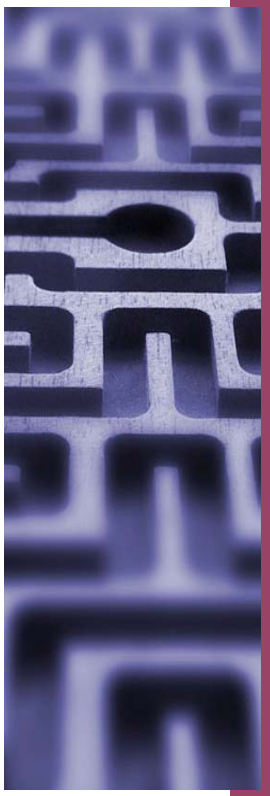

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