

# Realising eCTD Capability with External Providers

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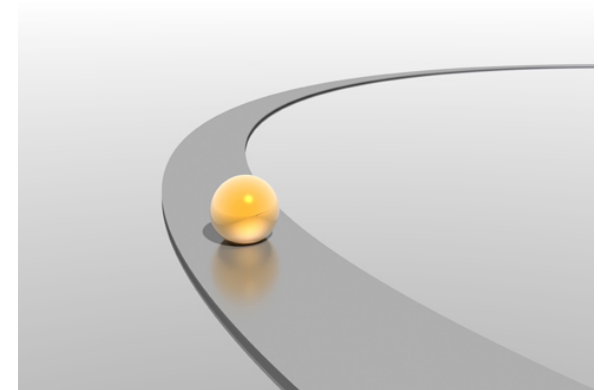
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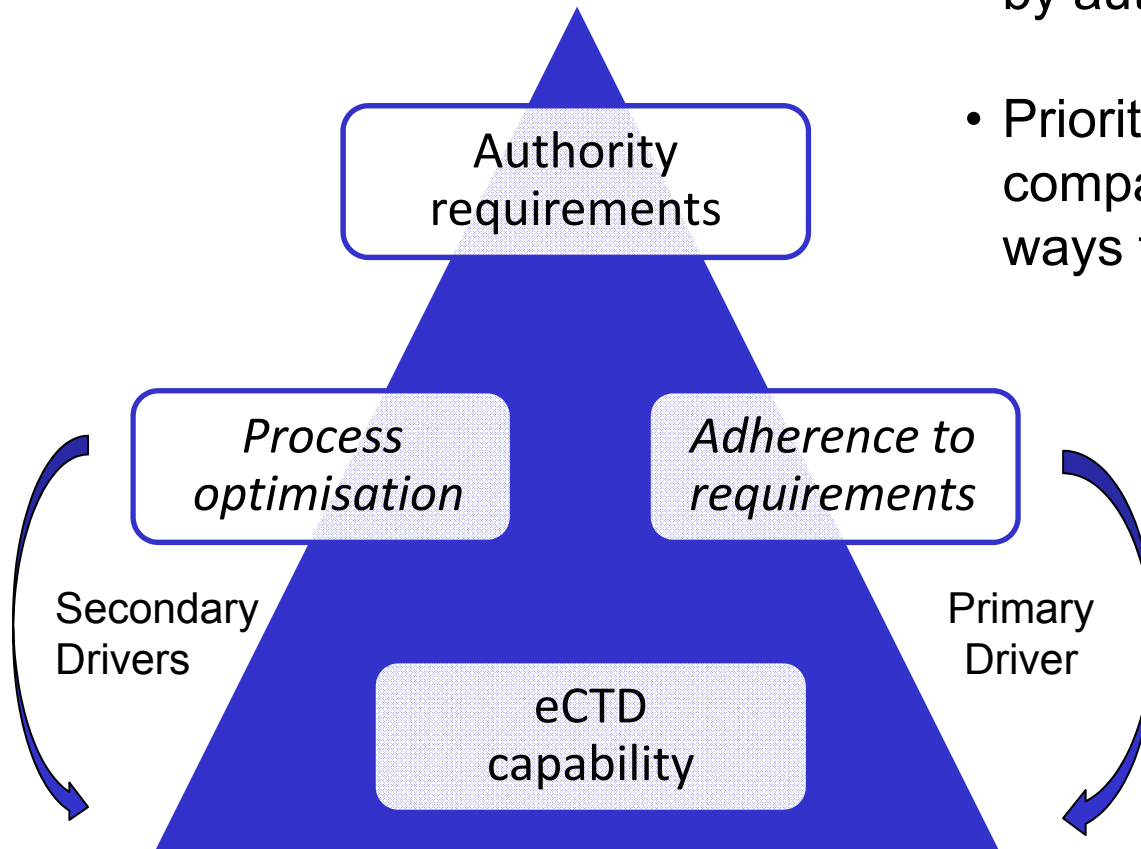
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- eCTD Strategy
  - Drivers & Influencing Factors
  - eCTD Implementation Scenarios
- Outsourcing Process
  - Process Overview
  - Points to Consider
  - Typical Questions / Concerns
- Conclusions




- eCTD is increasingly requested by authorities
- Priority of drivers depends on company strategy – as well as ways for eCTD implementation






How to  
achieve eCTD  
capability?



Let's select  
and implement  
software



Let's think  
what solution  
is best for my  
company!



Spontaneous  
reaction

Recommended  
reaction

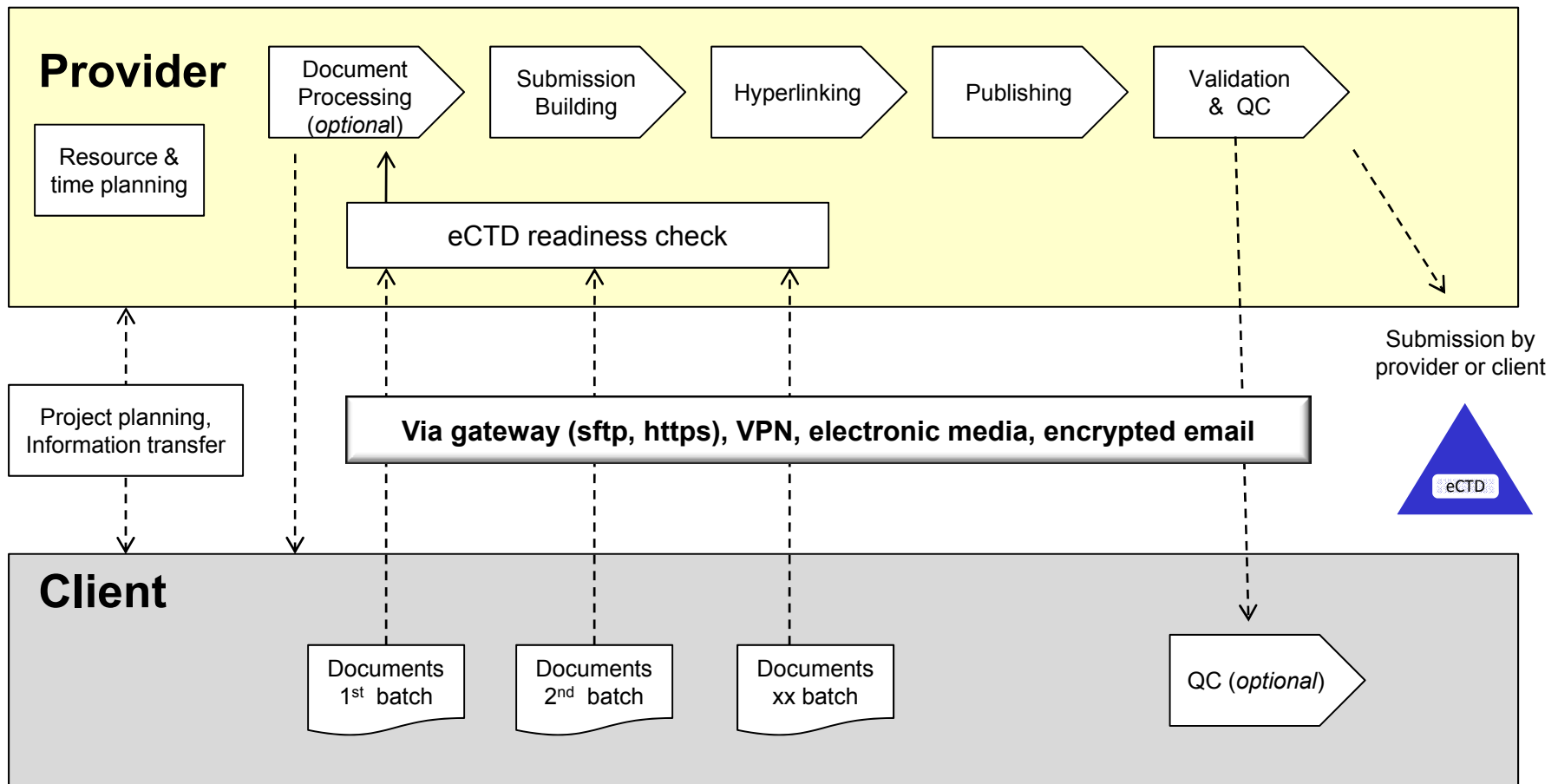
- **Number of products that ..**
  - reach the stage of marketing application
  - are submitted by a strategic partner
  - are on the market
- **Company strategy**
  - Outsourcing as integral part of business strategy
  - Focus on (regulatory) core competence

- **Costs**
  - For system implementation, deployment, maintenance
- **Time**
  - Time required for system implementation and first project (*when is first eCTD needed?*)
- **Resources**
  - Staff and know-how for software implementation and handling of eCTD process (*hiring of experienced professionals is not evident*)

Implementation Item	Internal System Implementation	Software as a Service (Cloud Computing)	eCTD Outsourcing
Vendor Selection	yes	yes	yes
Hardware / Software	yes	managed by provider	managed by provider
Validation (e.g. URS)	yes	reduced	no
Ongoing Operations	yes	limited	no
SOPs	yes	reduced	limited
Training	yes	yes	no
Specialised staff	yes	yes	no
Implementation Time	~ 1 - 2 years	~ < 6 months	~ < 1 month
Implementation Costs	high	medium	low

A company has to identify what solution covers best their needs  
The following slides focus on outsourcing





- **Communication**
  - Good personal and trust based communication
  - Project changes to be communicated immediately
- **Experience of provider**
  - Combination of technical and regulatory knowledge
  - Who will be the contact person for the project?
- **In-house contact aware of eCTD principals**
  - Supports straight-forward project discussions
  - Knowledge-transfer offered by provider

- **Contractual framework**

- Long-term relationship:  
Master Service Agreement defining conditions of collaboration
- Task orders for single submission projects (smaller activities often initiated via email request)
- Single projects can be based on a NDA (Non-Disclosure Agreement) and an agreed proposal

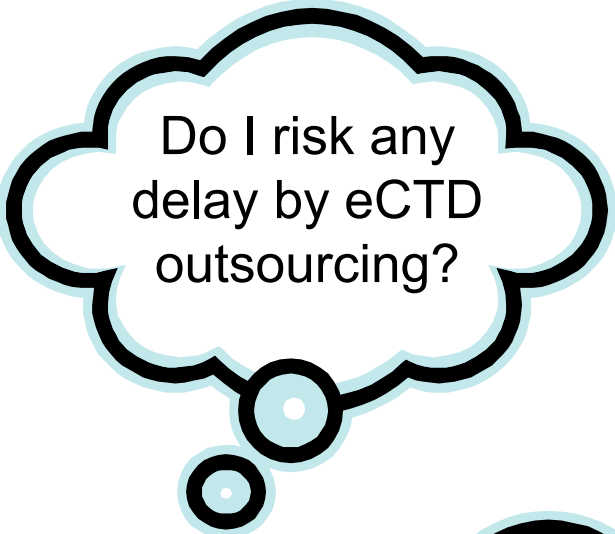


- **Project conditions**


- Provider should ask the right questions to clarify project scope, timelines and client interaction (e.g. review)
- If available draft versions of documents help to identify required activity (eCTD ready?)
- There details are also needed for appropriate proposal




- **eCTD ready documents positively impact cost**
  - Adherence to expected granularity
  - Bookmarks & internal hyperlinks available
  - Indication of cross-doc hyperlinking (e.g. blue text)
- **Consideration of costs for**
  - eCTD lifecycle (e.g. sequences for key-milestones during authority review)
  - Shipment (can be more expensive than compilation e.g. for small sequences sent to ~ 30 recipients)



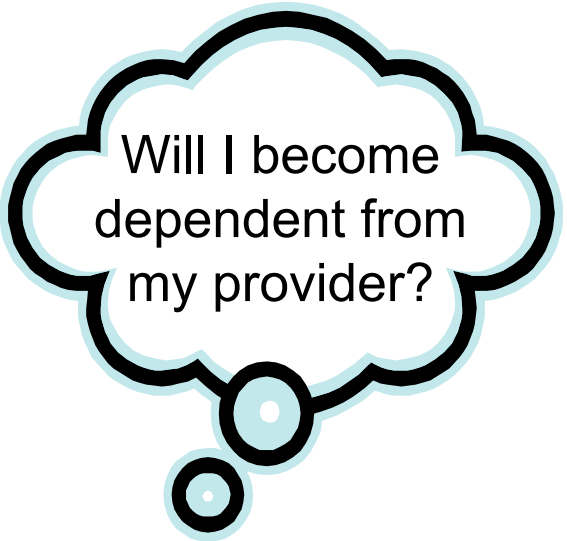
Do I risk any  
delay by eCTD  
outsourcing?



Can I track  
submitted  
documents?



Is my  
information  
protected?



Will I become  
dependent from  
my provider?

- **Processing and reaction times**

- Last document 1 week prior to submission (about 80% should be available 2 weeks prior submission)
- Provider should be prepared for last minute changes
- Small sequences available within 1-2 days

- **Dispatch of submission**

- Provider can manage dispatch of electronic media (and paper) to authorities
- Direct submission via portals (e.g. FDA ESG)

- **Information exchange**
  - Exchange of documents and submissions via e.g. sFTP gateway, VPN connection
- **Information processing**
  - Established publishing software
  - Validated systems
  - Controlled access and processes (SOPs)
  - Backup and disaster scenarios



- **Document information**

- If available the DMS document IDs can be forwarded to provider (part of document plan)
- A submission content report then includes the IDs  
⇒ searchable for client

- **Published version**

- The published PDFs are always different to original versions (same for internal or outsourced publishing)
- Internal process for storage of submissions is independent from outsourcing model

- **eCTD - a non-proprietary format**
  - Exchange of eCTD sequences possible (between providers, between provider – sponsor)
  - Process should be discussed with provider (to estimate time and costs)
- **Relationship**
  - eCTD lifecycle benefits of long-term relationship, (frequent change of providers should be avoided)
- **Knowledge**
  - The provider has no critical business knowledge as the eCTD is a generic process

- **Outsourcing of eCTD Publishing is an interesting (and proven) alternative for system implementation**
- **In case of long-term relationship the provider acts similar to an internal department**
- **Document and submission exchange procedures have to be well defined**
- **The individual situation of a company should be considered for an appropriate eCTD solution**

Think open-minded how to implement eCTD capability  
time- and cost-efficiently



**Thank you!**

**Questions / Comments / Discussions ?**