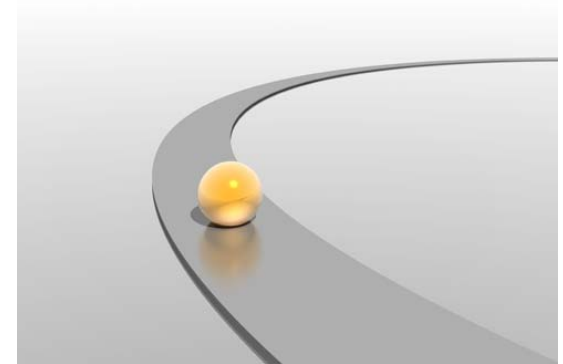15.04.2010 eCTD Conference Istanbul

Realizing eCTD capability with external providers:
Points to consider
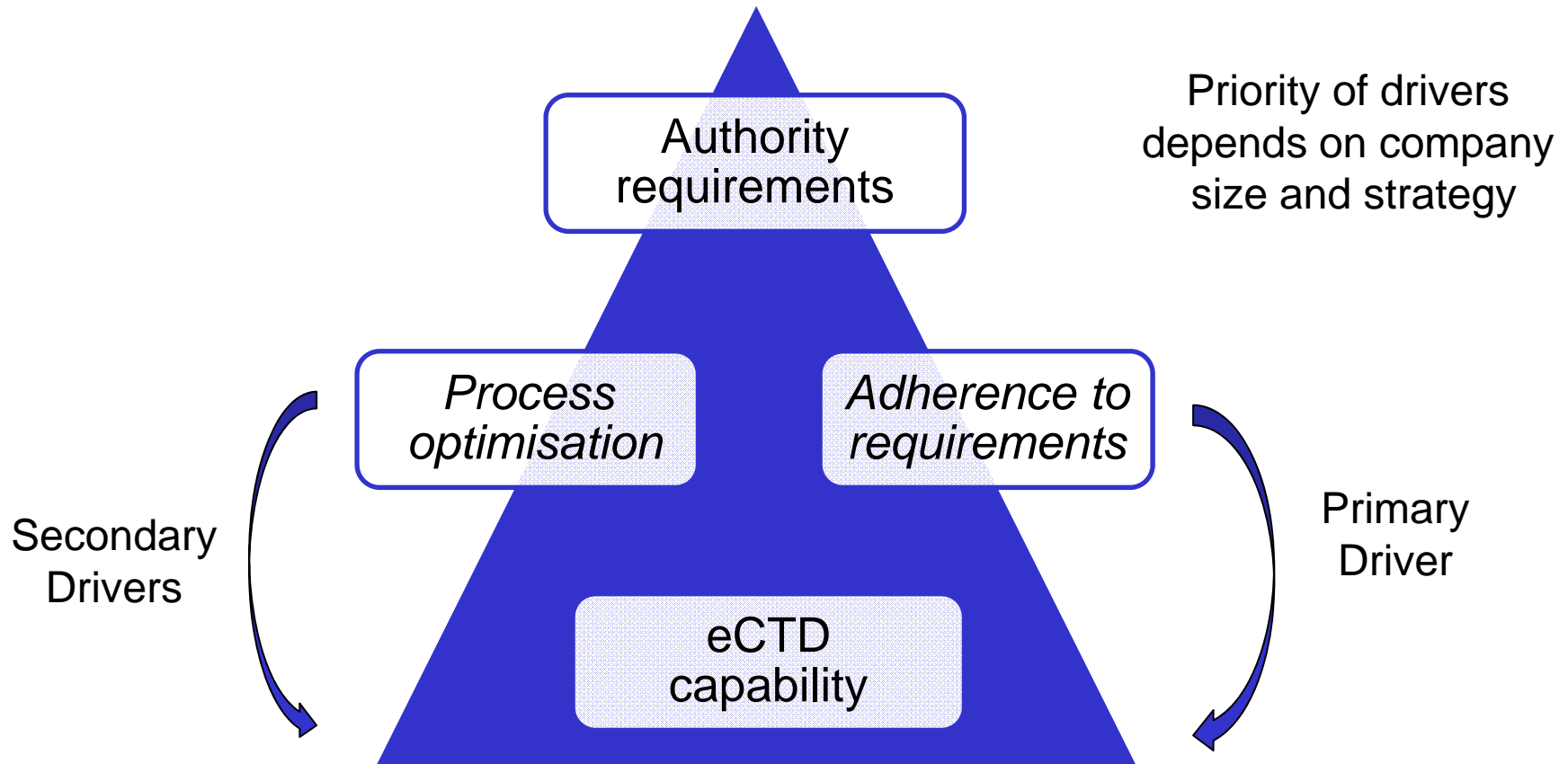
Sibylle Teuchmann
Exalon GmbH

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eCTD-Experts

Topics

▸ eCTD drivers and strategy

▸ eCTD implementation scenarios

▸ Outsourcing process

▸ Points to consider - typical questions

▸ Conclusion

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eCTD Drivers

▶ Primary driver - regulatory requirements

▶ Secondary drivers are

- ▶ Opportunity to evaluate & optimise internal processes
  ⇨ potential reduction in submission time ⇨ time to market
- ▶ Increased quality of documents & submissions
- ▶ Re-usability (cloning) of submissions
- ▶ Ease of (global) access of information
- ▶ Facilitated transfer (agencies, partners, due diligence)
- ▶ Increasing aversion regarding "tree-killing" aspect of paper

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eCTD Drivers

Authority requirements

Process optimisation

Adherence to requirements

eCTD capability

Priority of drivers depends on company size and strategy

Secondary Drivers

Primary Driver

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eCTD Strategy

Factors Impacting Strategy

▶ Number of products that ..

- ▸ reach the stage of marketing application
- ▸ are not submitted by a strategic partner
- ▸ are on the market

▶ Company strategy

- ▸ Outsourcing as integral part of business strategy
- ▸ Focus on (regulatory) core competence

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Factors Impacting Strategy

- Costs
  - For system implementation, deployment, maintenance

- Time
  - Time required for system implementation and first project
  - How much time left until first eCTD is needed?

- Resources
  - People and know-how for software implementation and handling of eCTD process
  - Hiring of experienced professionals can be difficult

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A company has to identify their "best fit" solution,
the alternatives are

- ▸ System implementation
  - ▸ In-house system
  - ▸ Software as a Service (SaaS)

- ▸ eCTD outsourcing

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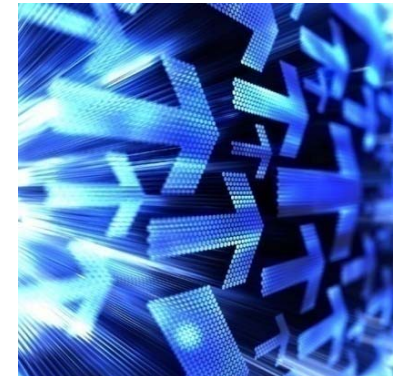
System Implementation
In-house

▶ System implementation & maintenance

  ▶ Vendor selection process

  ▶ Initial software licenses (may represent only ~ 20% of costs) and future licenses (named or concurrent?)

  ▶ Hardware incl. backup and recovery

  ▶ System validation (effort frequently underestimated)

  ▶ Maintenance activities and costs

▶ People

  ▶ Training - "make people use the system" (SOPs, user manuals)

  ▶ Specialized staff (key users, helpdesk, administration)
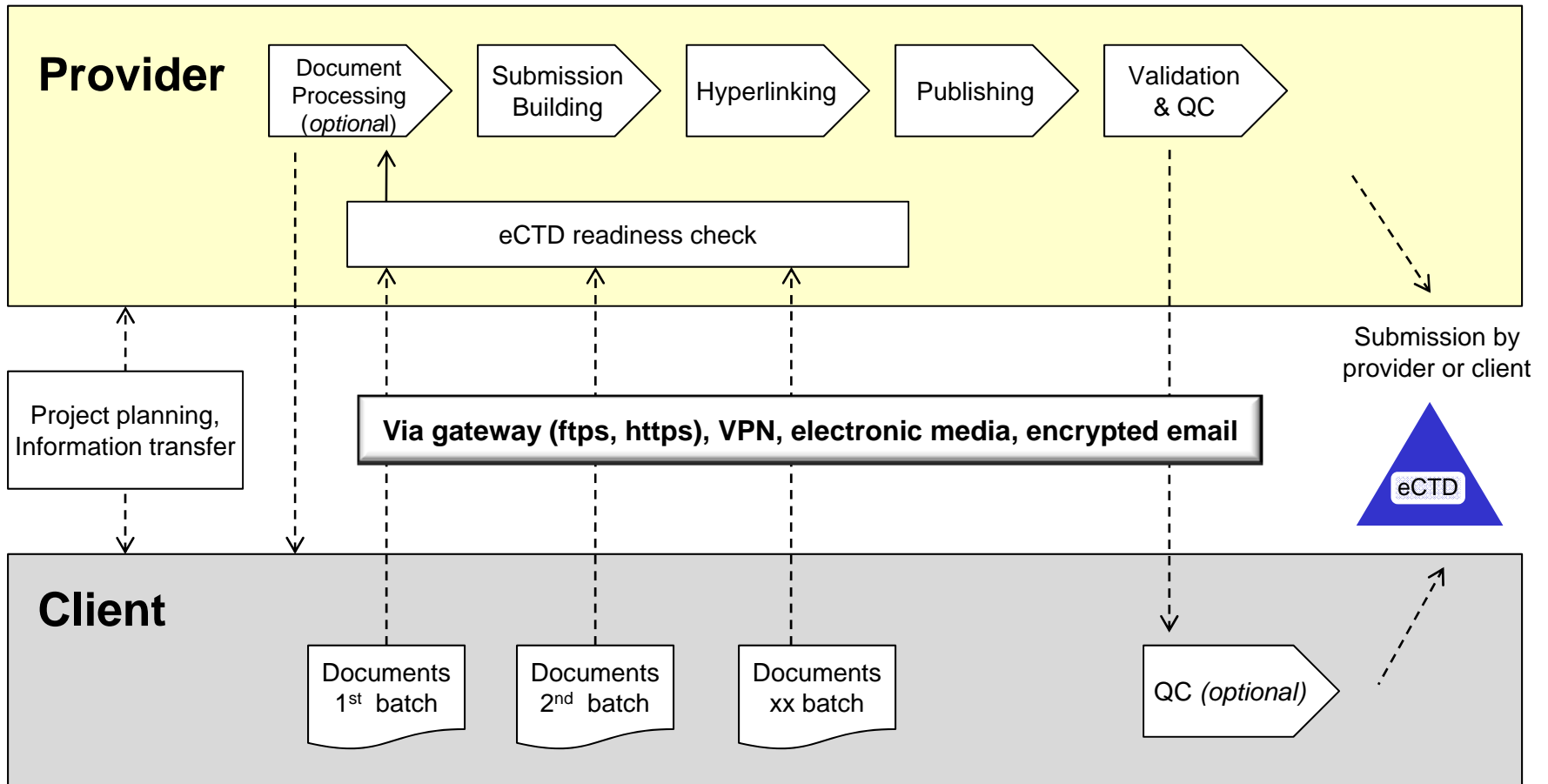
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System Implementation
SaaS

▸ **System selection & access**

  ▸ Vendor selection

  ▸ User requirements (e.g. system configuration, process for transferring documents and submissions)

  ▸ Costs depending on pricing models (e.g. initial setup, user and software licenses, maintenance)

▸ **People**

  ▸ Training - "make people use the system" (SOPs, user manuals)

  ▸ Internal helpdesk complemented by vendor support

  ▸ Resources and competence for eCTD required in-house

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eCTD Outsourcing

▶ Partner instead of system selection

- ▸ Selection of external partner
- ▸ No software and hardware requirements
- ▸ Costs arise for actual projects

▶ People

- ▸ No internal resources for eCTD compilation and system maintenance
- ▸ Outsourcing partner guides client through regulatory and formal eCTD requirements
- ▸ Creation of eCTD ready documents is supported (if needed)

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Example
Full eCTD Outsourcing

Provider

Document Processing (*optional*) → Submission Building → Hyperlinking → Publishing → Validation & QC

eCTD readiness check

Submission by provider or client

Project planning, Information transfer

Via gateway (ftps, https), VPN, electronic media, encrypted email

eCTD

Client

Documents 1st batch

Documents 2nd batch

Documents xx batch

QC (*optional*)
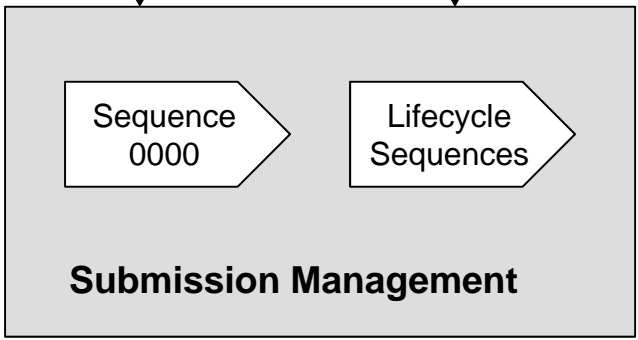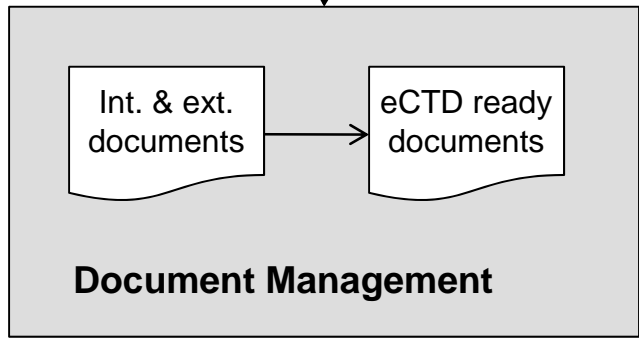
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Outsourcing Options

Outsourcing Options

- Document templates
- Style guides
- Scanning
- Report publishing
- Document formatting

- eCTD for initial MAA
- Baseline submission

- Complete lifecycle
- Selected sequences

On-site support

Processes

Document Management

Int. & ext. documents → eCTD ready documents

Submission Management

Sequence 0000 → Lifecycle Sequences

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Points to consider
People

▶ Communication

  ▶ Good personal and trust based communication

  ▶ Project changes to be communicated immediately

▶ Experience of provider

  ▶ Efficient support only possible by sound technical and regulatory knowledge

  ▶ Who will be the contact person for the project?

▶ In-house contact understanding the eCTD principals

  ▶ Supports straight-forward project discussions

  ▶ Knowledge-transfer offered by provider

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Points to consider
Project Initiation

▸ Contractual framework

  ▸ Master service agreement covering confidentiality and pricing conditions

  ▸ Task orders for single submission projects (smaller activities often initiated via email request)

▸ 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
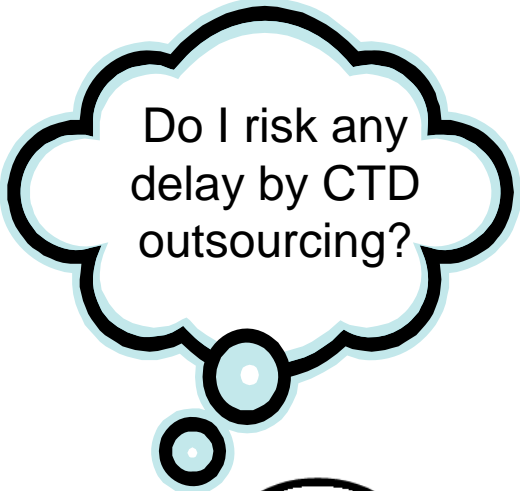
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Points to consider
Costs

▸ **eCTD ready documents positively impact compilation cost**

  ▸ Adherence to expected granularity

  ▸ Bookmarks & internal hyperlinks available

  ▸ Clear indication of cross-document hyperlinking (e.g. blue text)

▸ **Clear definition of services included in and excluded from cost proposal**

▸ **Consider costs for eCTD lifecycle (e.g. sequences for key-milestones during authority review)**

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Typical questions
Timelines

▸ Processing and reaction times

  ▸ M5, M4 and M3 should be provided prior to M2 and M1 (last document 1-2 weeks prior to submission)

  ▸ Provider should be prepared for last minute changes and urgent authority request

▸ Dispatch of submission

  ▸ Provider can manage dispatch of electronic media (and paper) to authorities

  ▸ Direct submission via portals (e.g. FDA ESG)

> Do I risk any delay by CTD outsourcing?

> **No**

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Typical questions
Security

- **Information exchange**
  - Exchange of document and submissions via gateways (https, ftps), VPN connection, encrypted email

- **Information processing by provider**
  - Established publishing software
  - Validated systems
  - Controlled access and processes (SOPs)
  - Backup and disaster scenarios

Is my information secured and protected?

**Yes**

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Typical questions
DMS connectivity

▶ Document information

  ▸ If available the DMS IDs can be forwarded to provider (part of document plan)

  ▸ A submission content report includes IDs
    ⇨ searchable for client

▶ Published version

  ▸ The publishing process changes PDFs (cross-document hyperlinks, PDF settings)

  ▸ Internal process for storage of submission (documents) is independent from outsourcing model

Can I track submitted documents?

Yes

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Typical questions
Relationship

- **eCTD - a non-proprietary format**
  - Exchange of sequences possible
  - Process should be discussed with vendor
  - eCTD lifecycle benefits of long-term relationship

- **Gain of flexibility**
  - Opportunity to start eCTD today and acquire first experience
  - Systems can be implemented in parallel if needed
  - Submission peaks can be managed with provider

Will I become dependent from my provider?

No

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Conclusion
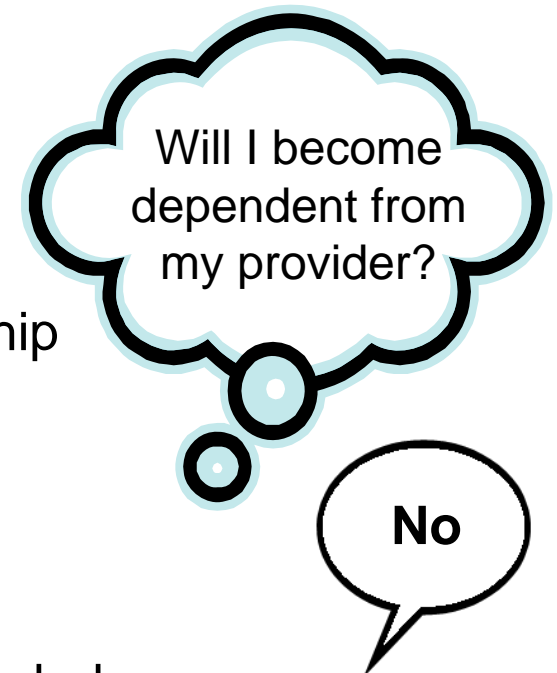
▶ How to proceed for eCTD implementation – key activities

- ▶ Assure common awareness
- ▶ Identify stakeholders including upper management
- ▶ Evaluation of options by considering company strategy
- ▶ Selection of systems / partners
- ▶ Implementation of technology / processes

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Conclusion

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

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Thank you
Any questions?

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eCTD-Experts

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