

A Case Study for a Global Submission eArchiving System

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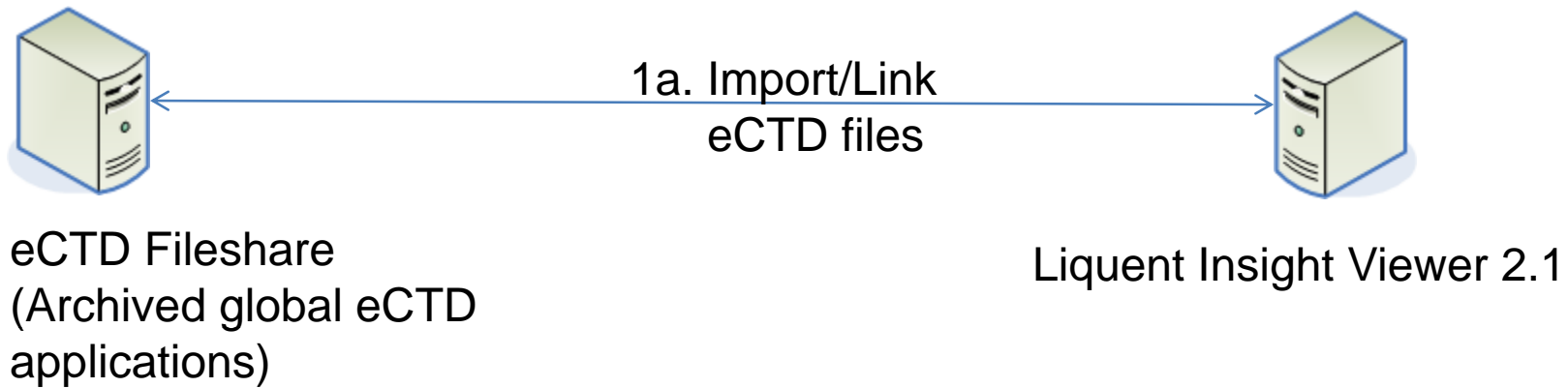
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- Project Overview
- Challenges
- Solutions
- Considerations for Success

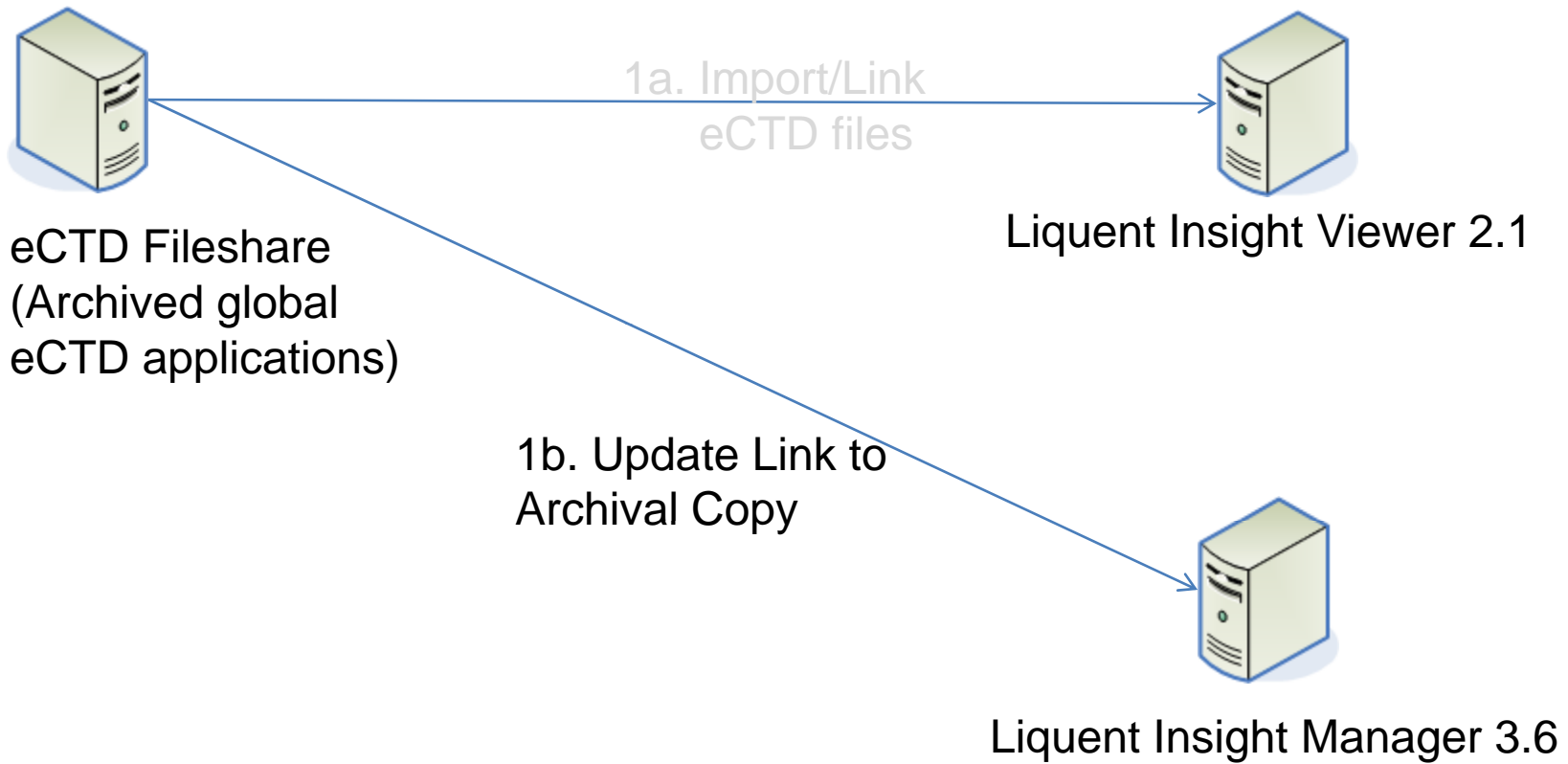
- Purpose
- Scope
- Data Analysis
- Metadata Mapping
- Migration Efficiency
- Final Points of Entry

- Define the eArchival Purpose
 - Streamline archival data for multi-functional use
 - Consolidate multiple archival applications into single repository
 - Leverage archival applications for future submissions
 - Local and Global content
 - Begin locally, expand globally
 - Two major phases
 - eCTD and non-eCTD

Data Migration Path: eCTD Phase 1a



Data Migration Path: eCTD Phase 1b



- Identify the desired, combined end result
 - Technology drivers
 - Regulatory drivers
- Identify the business processes
 - Archivist business processes to retain data
 - Current processes to access archival data
 - Identify vision for the future processes

- Identify the existing systems
 - Locations
 - Electronic availability of data
 - Security and permissions settings/groups
- Identify the final repository
 - Existing, new, or upgraded technology
 - Home-grown or commercially available
 - Limited or global access

- Identify the migration path
 - Quantity of unique systems (5)



Documentum 4



Insight Viewer



eCTD Fileshare



Insight Manager

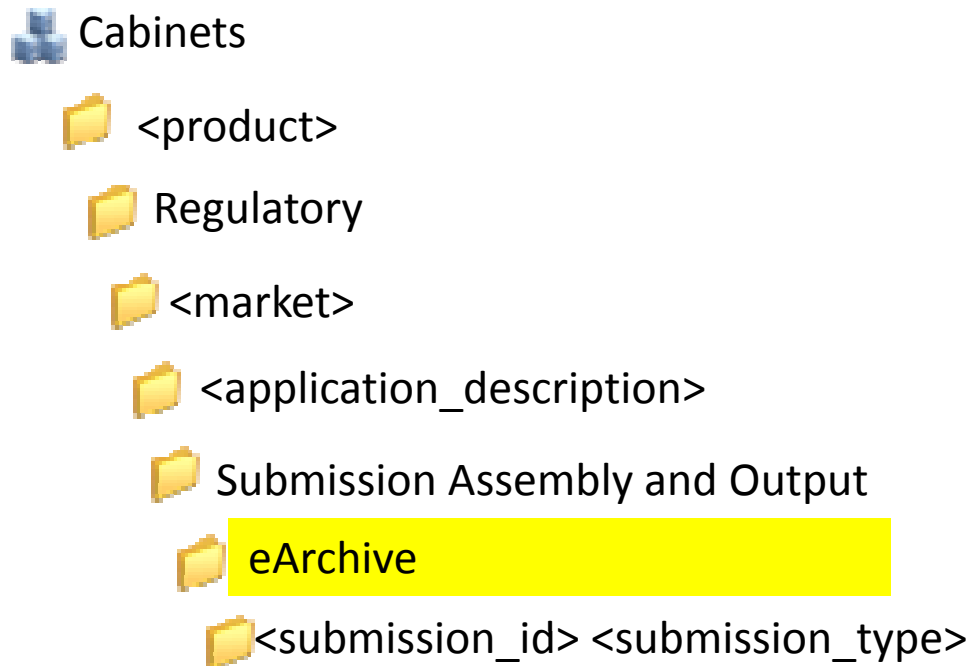


FirstDoc

- Relationships between systems
- Quantity of data; applications vs. submissions

- Identify the migration destination
- <document_unit> = eArchive

FirstDoc structure:

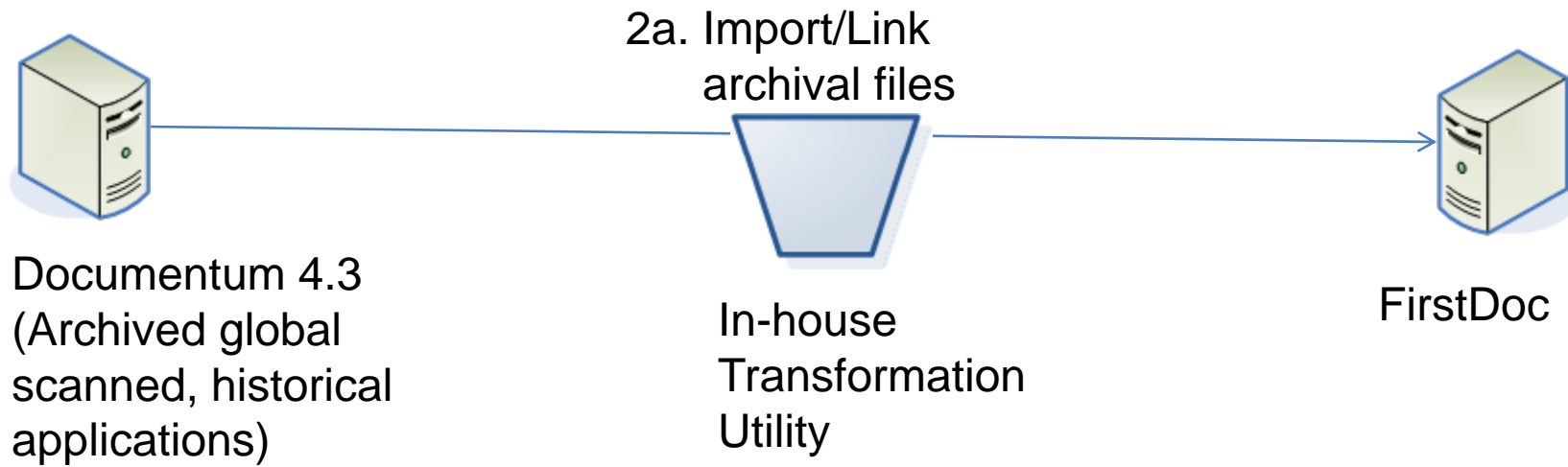


- Quantity of Documents
 - Duplicates
 - Linked documents
 - Concurrent content
- Quality of Documents
 - Organization
 - Structure
 - Locations

- Document Content
 - Regulatory applications and submissions
 - Non-regulated administrative documents
 - Internal documents
- Document Format
 - Scanned files
 - Electronic source files
 - eSubmission or eCTD files

- Editing Document Properties
 - File extensions
 - Date formats
 - Searchable attributes
 - Where to edit?

Data Migration Path: non-eCTD Phase 2a



- Primary fields

FirstDoc Property	Documentum Field
Short Title	Object Name
Full Title	Title
Product	Product Family
Market	Country

- Naming conventions
 - Ideal Short Title naming convention
 - not to exceed 32 or 60 characters
 - *YYYY-MM-DD <submission-type abbreviation> <keywords> <volume number>*
 - Text issues
 - Redundant Text: Product Family, Country, Application Type, Submission Type
 - Variable Text: Agency, Dosage Strength

Metadata Mapping (continued)



```

/<product>/Regulatory/<market>/<application_description>
/Submission Assembly and Output/eArchive
/<submission_id> - <submission_type>/
    
```

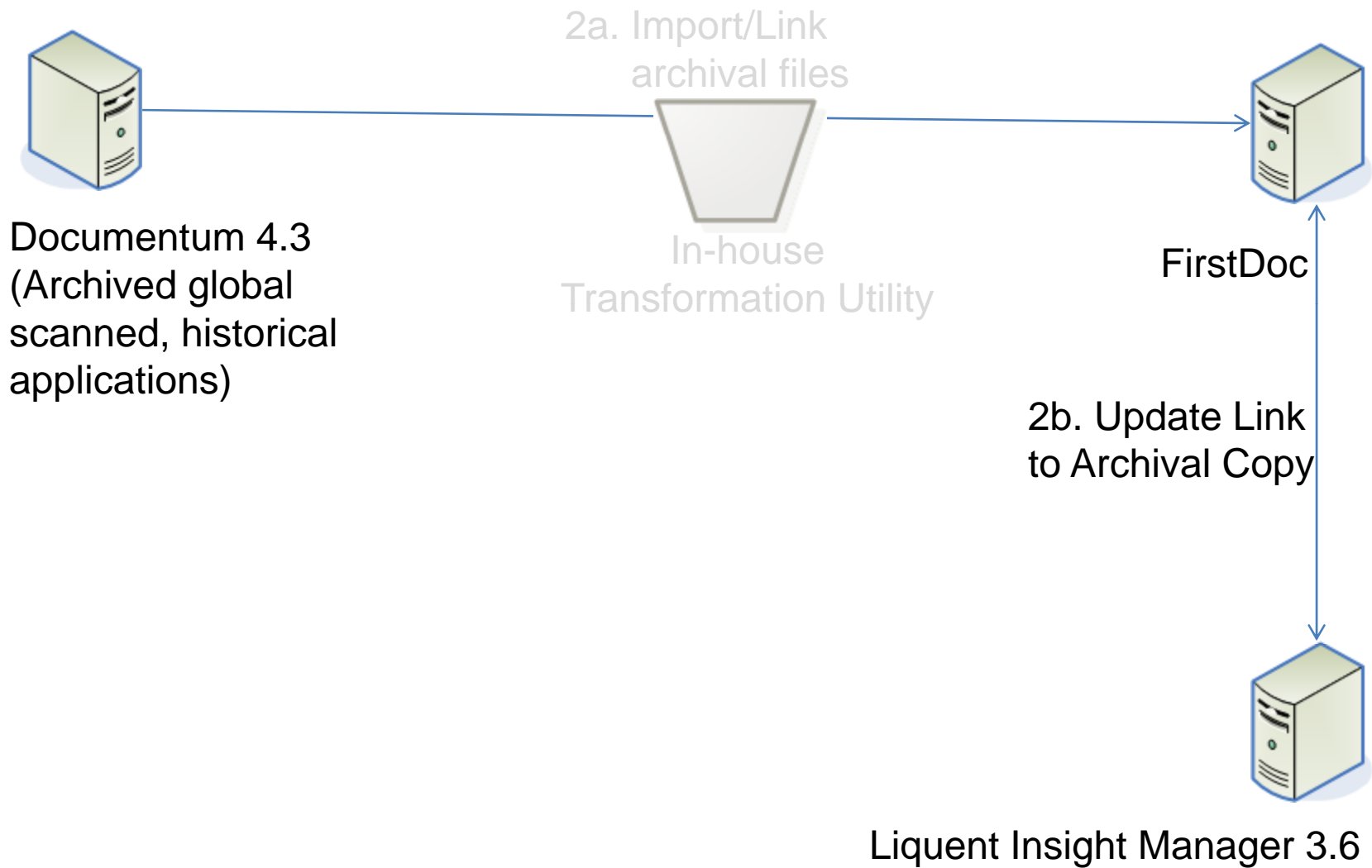
FirstDoc	Documentum
Cabinets	
<product>	<product_family>
Regulatory	<document_type>
<market>	<country>
<application_description>	[<application> <application_number>]
Submission Assembly and Output	<document_subtype>
eArchive	<document_unit>
<submission_id> <submission_type>	[<YYYY-MM-DD> <submission_type>]

- Secondary fields
 - Submission ID
 - Unique identifier; e.g. date or sequence number
 - Date of Submission
 - Date: YYYY-MM-DD
 - Submission Type
 - Data dictionaries
 - Redundancy with Application Type
 - Level of detail

- Region/Market
 - Same as country, ISO codes
- EU Filing Procedure/EU Procedure Role
- Health Authority
- Optional fields
 - Indication
 - Dosage Form
 - Dosage Strength
 - Route of Administration

- Migration Success
 - Fully populated fields
 - Ability to test on demand
 - Error resolution process
 - New content alerts
 - Version and upgrade plans

Data Migration Path: non-eCTD Phase 2b



- Post-migration
 - (2) points of entry
 - Searchable metadata fields
 - End-user requirements met
 - Security models (product, RA, other)
 - Implementation
 - Training
 - Revised eArchival business processes



Documentum 4.3.1
Retired or re-purposed

User Community: Options to access eArchival content



FirstDoc



Liquent Insight Manager

Thank you!

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