

Submissions and Business Technology:  
A Case Study on Achieving Submission  
Readiness Through Innovative  
Technology and Standards

## **The Deconstructed Workflow - Providing Flexibility to the Document Lifecycle Process**

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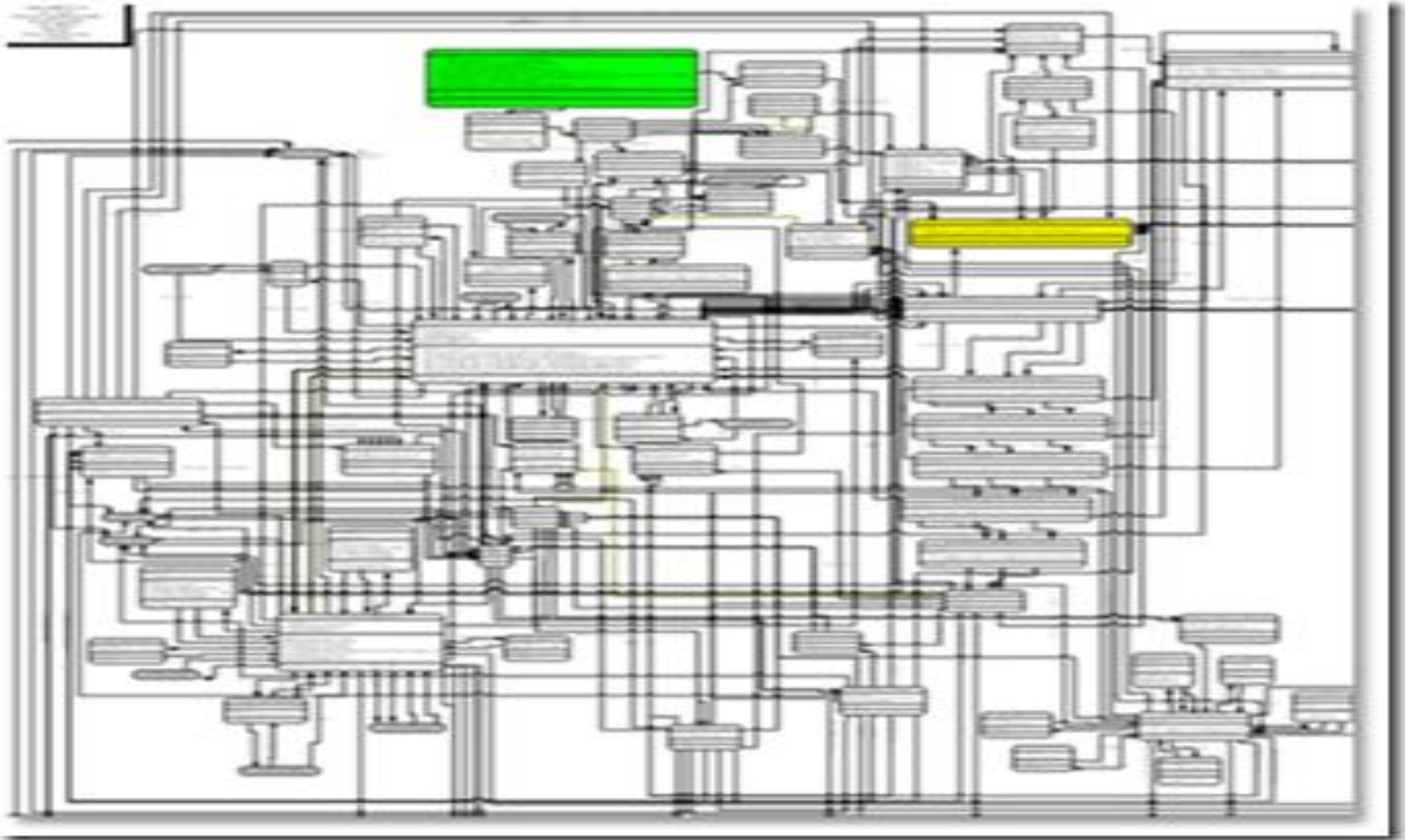
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# Why the Deconstructed Workflow?



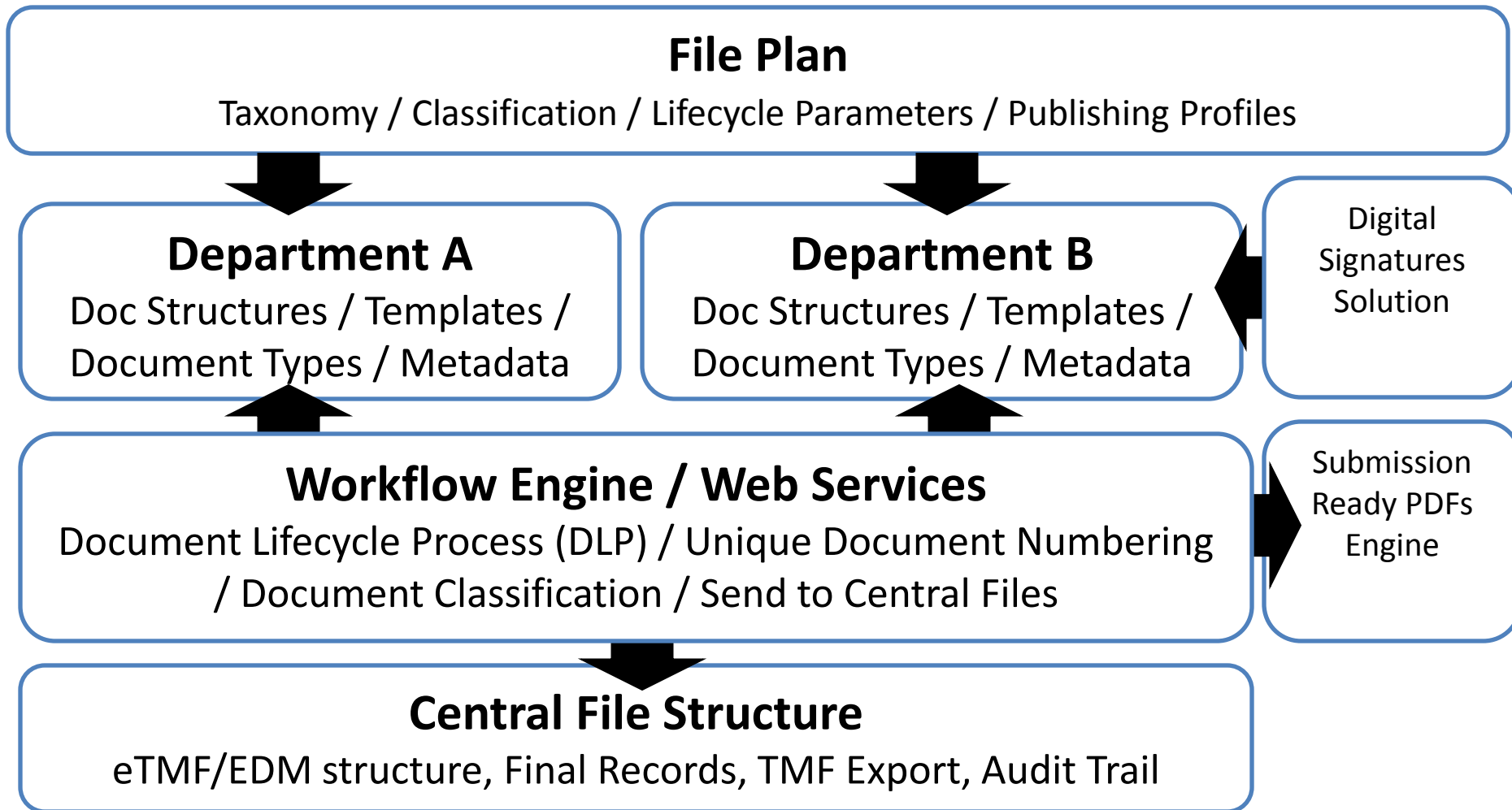
# Why the Deconstructed Workflow?



- Business needs
- System Architecture
  - File Plan
  - Classification
  - UDI – Unique Document Identifier
  - Publishing Templates
  - Approvals
  - Governance
- DLP – Document Lifecycle Process

- Create/upload regulated documents in departmental EDMS workspaces
- Automatically number and classify controlled documents
- Automate review and editing cycle(s) of draft documents and incoming records
- Implement an automated publishing process to produce submission ready PDFs
- Automate the approval and QC cycle of final records
- Automatically file final approved records in EDMS Central Files based on predefined schema

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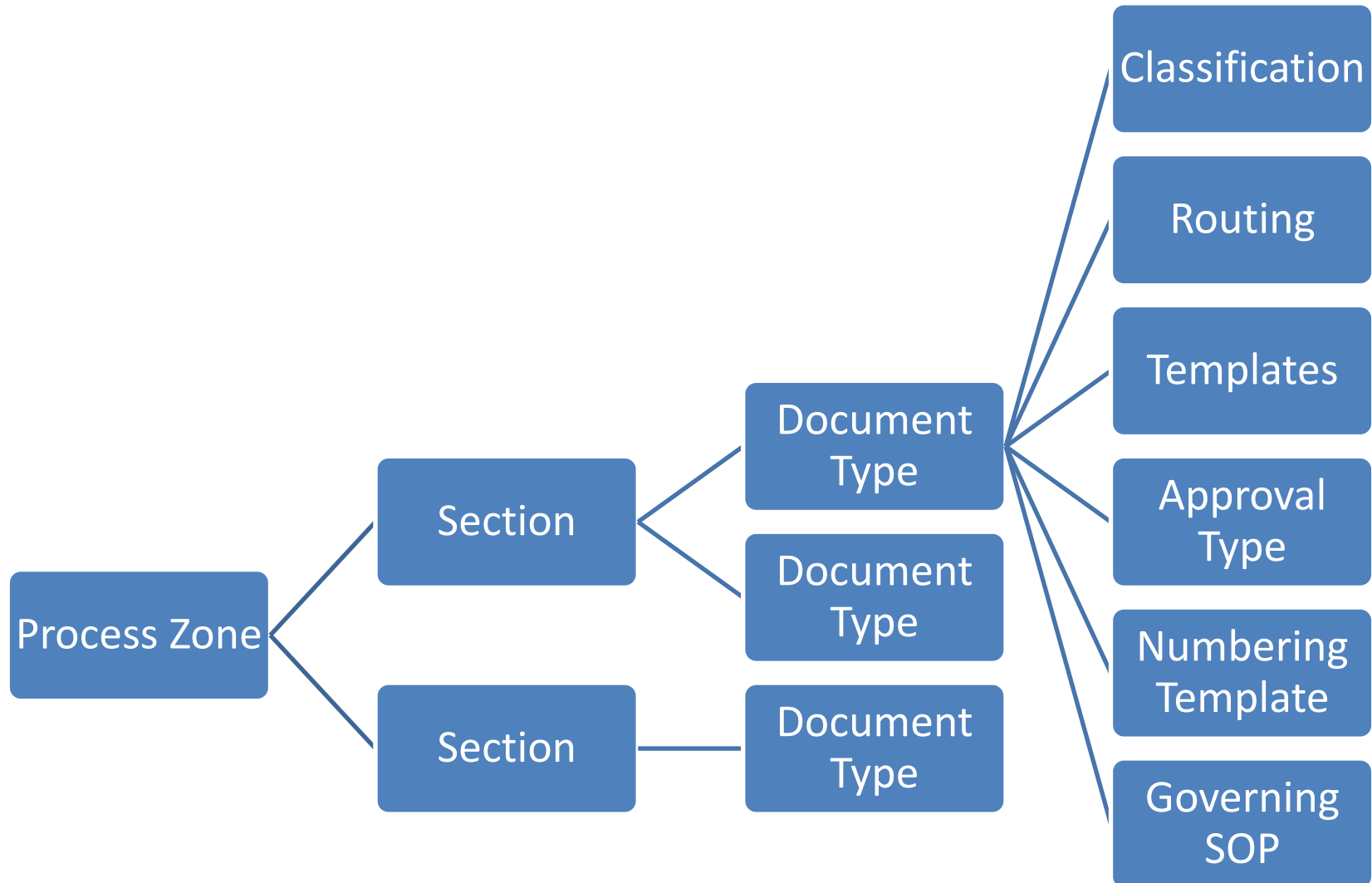


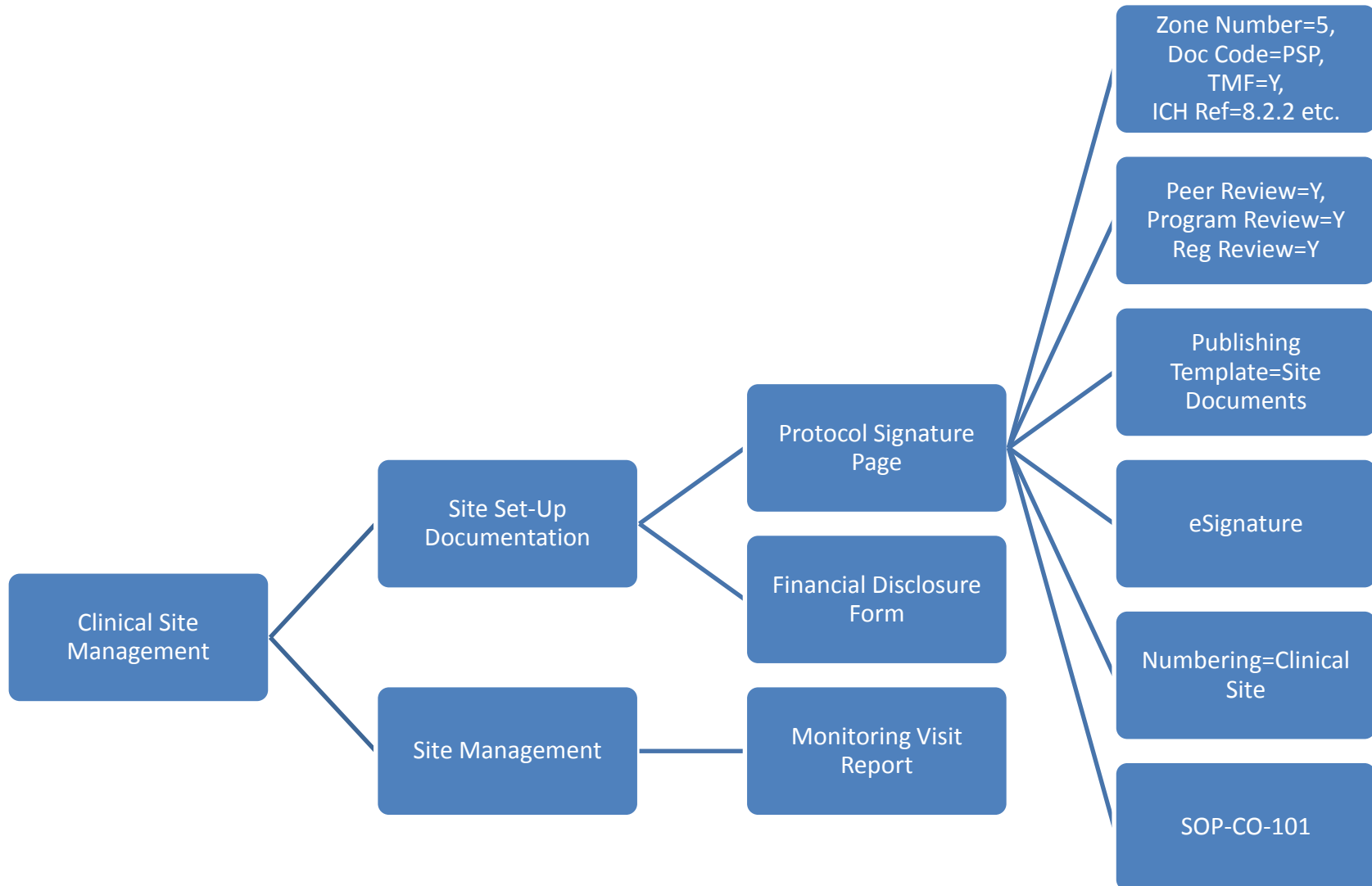
- Allows the construction of a central taxonomy for all records
- This taxonomy is used to:
  - Create all document management structures for each department
  - To create document types and associated metadata
  - To automatically classify and identify documents
  - To determine document lifecycle through the use of metadata
  - To apply PDF publishing templates
- Baseline taxonomy inspired by EDM/TMF Reference Model

# File Plan - Example



Zone Number	Process Zone	Section Number	Section	Document Type	Doc Code	Artefact Name	Department	Approval Type	Numbering Format	TMF	Peer Review	Program Review	Reg Ops Review	Publishing Template
1.0	Trial Management	1.1	Trial Oversight	Audit Certificate	ACRT	Audit Certificate	Clinical Operations	eSignature	Clinical Study	Yes	Yes	No	No	Clinical Study
1.0	Trial Management	1.1	Trial Oversight	List of SOPs	SOPL	List of SOPs Current During Trial	Clinical Operations	No Approval	Clinical Study	Yes	Yes	No	No	Clinical Study
1.0	Trial Management	1.1	Trial Oversight	Monitoring Plan	CMP	Monitoring Plan	Clinical Operations	Paper Approval	Clinical Study	Yes	Yes	No	No	Clinical Study
1.0	Trial Management	1.2	Trial Team	Trial Team CV	TTCV	Trial Team Curriculum Vitae	Clinical Operations	No Approval	Clinical Study	Yes	Yes	No	No	Clinical Study
2.0	Central Trial Documents	2.1	Trial Documents	CRO Transfer of Obligations	XOB	CRO Transfer of Obligations	Clinical Operations	Paper Approval	Clinical Study	Yes	Yes	Yes	No	Clinical Study
2.0	Central Trial Documents	2.1	Trial Documents	Financial Disclosure Summary	FDS	Financial Disclosure Summary	Clinical Operations	Paper Approval	Clinical Study	Yes	Yes	Yes	No	Clinical Study
2.0	Central Trial Documents	2.1	Trial Documents	Insurance	SIN	Insurance	Clinical Operations	No Approval	Clinical Study	Yes	Yes	Yes	No	Clinical Study
2.0	Central Trial Documents	2.1	Trial Documents	Investigator Brochure	IB	Investigator Brochure	Clinical Operations	Paper Approval	Clinical Study	Yes	Yes	Yes	No	Clinical Study
5.0	Clinical Site Management	5.2	Site Set-up Documentation	Protocol Amendment Signature Page	PASP	Protocol Amendment Signature Page	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.2	Site Set-up Documentation	Protocol Signature Page	PSP	Protocol Signature Page	Clinical Operations	eSignature	Clinical Site	Yes	Yes	Yes	Yes	Clinical Site
5.0	Clinical Site Management	5.2	Site Set-up Documentation	Regulatory Compliance Review Package	RCRP	Regulatory Compliance Review Package	Regulatory	Electronic Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.2	Site Set-up Documentation	Signed Investigator Budget	SIB	Signed Investigator Budget	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.2	Site Set-up Documentation	Signed Investigator CDA	SCDA	Signed Investigator CDA	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.3	Site Initiation	Site Training Documentation	STD	Site Training Documentation	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.3	Site Initiation	Site Training Material	STM	Site Training Material	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.3	Site Initiation	Initiation Monitoring Report	IMR	Trial Initiation Monitoring Report	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.4	Site Management	Final Trial Close Out Monitoring Report	FTCMR	Final Trial Close Out Monitoring Report	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.4	Site Management	Investigator Newsletter	IN	Investigator Newsletter	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.4	Site Management	Monitoring Visit Report	MVR	Monitoring Visit Report	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site
5.0	Clinical Site Management	5.4	Site Management	Protocol Deviations	PD	Protocol Deviations	Clinical Operations	Paper Approval	Clinical Site	Yes	Yes	Yes	No	Clinical Site

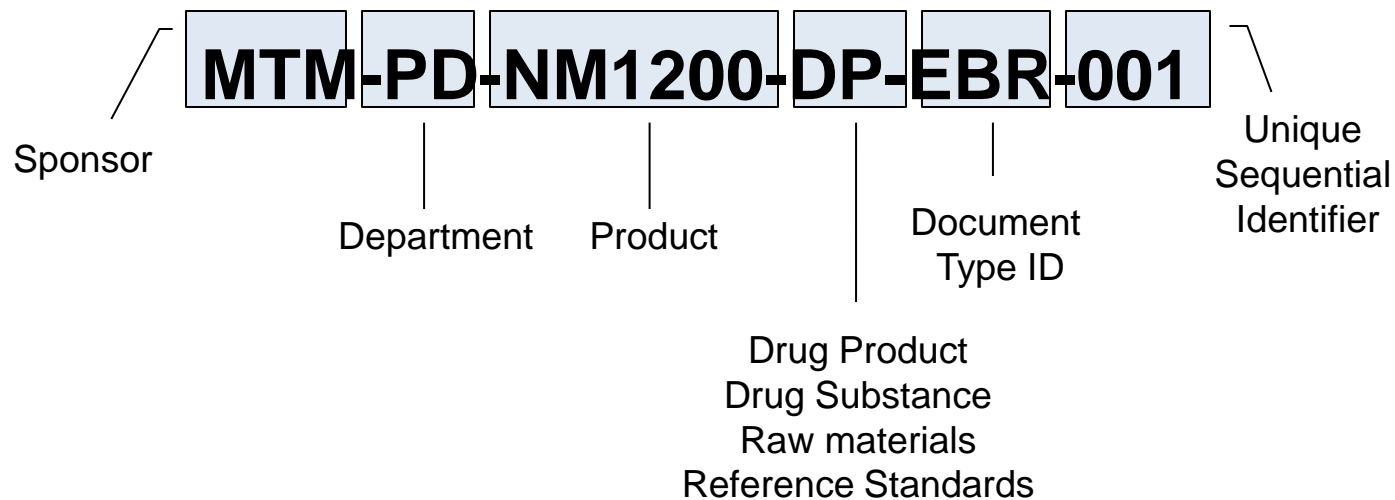




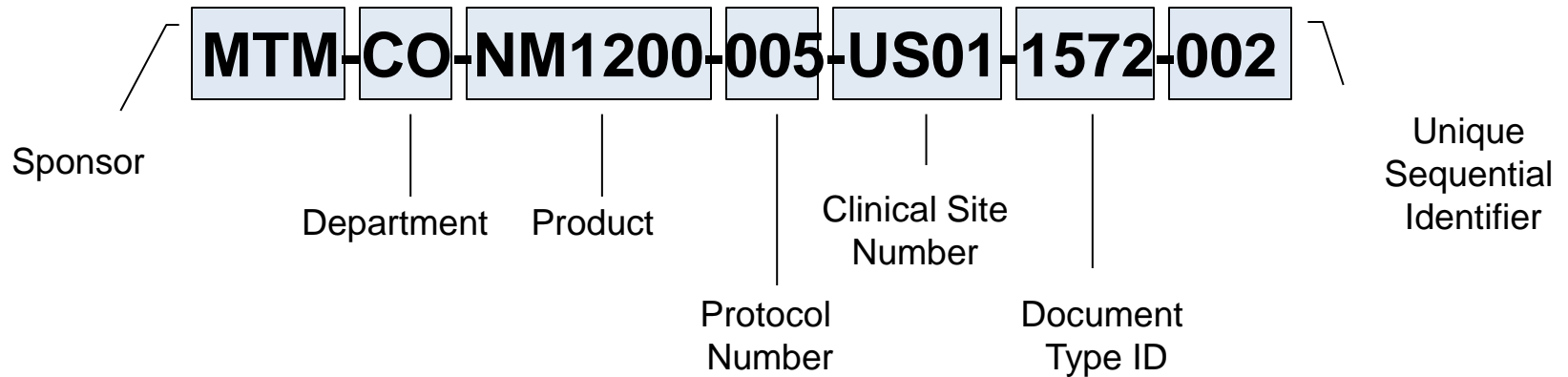
- UDI - Automatically generates a unique identifier for each document based on a predefined nomenclature
- One of the challenges with the technology that was used was the lack of an automatic numbering function
- Nomenclature is composed of concatenated metadata values and unique sequential numbers
- If a document type changes, it should be renumbered
- Unique identifiers cannot be reused
- Nomenclature standards are linked to numbering tags which are then associated to document types in the file plan

- For each document type we need to define a naming standard
- This naming standard is a concatenation of metadata values and number sequences

## Example of record number for CMC document:



## Example of record number for clinical site document:



- Predefined PDF publishing parameters are centrally stored in XML templates
- Document types are associated to publishing templates in the file plan
- Publishing templates are submitted automatically with documents to the PDF Conversion server
- Publishing parameters include:
  - TOC
  - Hyperlinks
  - Formatting
  - Watermarks

- With EDMS there are several approval methods to consider:
  - No Approval Required
  - Electronic Approval
  - Digital Signature
  - Scanned Wet Ink Signature
- Through the use of the File Plan we can define which method to be used by document type
- This ensure a smooth transition from paper to electronic approval processes

- Ensure that a document lifecycle process follows governing SOP by document type
- Facilitate adherence to SOP by guiding end-users step by step through tasks and alerts
- Can track deviations from SOP and rationale for deviation
- Metrics can be obtained automatically from system

- Series of automated workflows to manage the lifecycle of each document/record
- Document Status and Routing is managed automatically
- Routing can be dictated by governing SOP
- Links automatically generated PDF renditions to source documents
- Automatically sends final records to Central Files structure
- Improves control and enhances collaboration

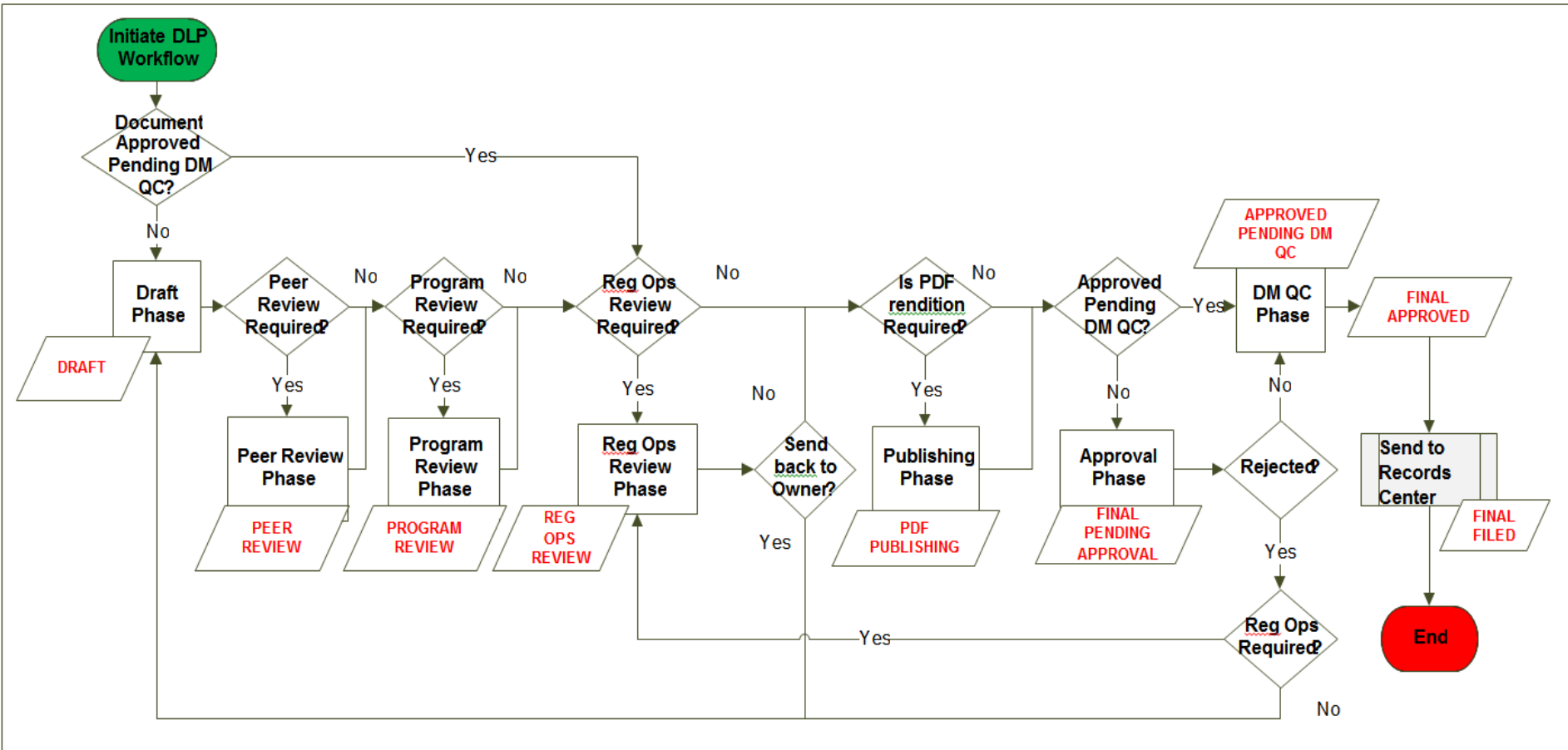


- Each sub-process was represented by a sub workflow in the system
- Document Lifecycle was broken down into a series of sub-processes
- A document can enter the process at any phase / status of the workflow through the use of metadata

- Built-in flexibility to accommodate default routing per document type based on the central file plan
- State model allows a document to be uploaded at any point in the lifecycle based on its status and choice of governing metadata
- Default routing can be overridden for a specific instance of a document albeit with adequate control/permission in place if it's a controlled document
- Easy to maintain and grow

- Document Owner
- Peer Review Required
- Program Review Required
- Peer Reviewers
- Program Reviewers
- Reg Ops Reviewers
- DM (Document Management) Reviewers
- Approvers
- Approved Pending DM QC
- Document Status

# High-level Process flow



Phase:	<u>Draft</u>	<u>Peer Review</u>	<u>Program Review</u>	<u>Reg Ops Review</u>	<u>Publishing</u>		<u>Approval</u>		<u>DM QC</u>		<u>Archiving</u>
<b>Statuses</b>	Draft	Draft, Peer Review	Draft, Program Review	Draft, Reg Ops Review	Locked Source	PDF Publishing	Final Pending Approval	Rejected	Approved Pending DM QC	Final Approved	Final Filed
<b>Description</b>	A new document has been created or initial versions uploaded in the system, metadata assigned, routing assigned	Review within <i>Document Owners</i> Department or other Departments. Includes QC of data to source as defined by current process or SOP	Review by program managers and senior development team members and or QA, as defined by current process or SOP	Review by Reg Ops group to ensure that document meets publishing Std	The source document is locked and cannot be edited	The PDF document is undergoing "Publishing" by the Reg Ops group	The PDF document is deemed final waiting for the approval based on approval type	The PDF document has been rejected by one or many of the document approvers	The document has been signed by the Approvers and is undergoing DM QC	The document has been approved and QC by DM and is considered a final record	The document has been sent to the Central Files/Records Center
<b>Roles</b>	Document Owner, DLP Initiator	Document Owner, Peer Reviewer	Document Owner, Program Reviewer	Document Owner, Reg Ops Group	Document Owner, Reg Ops Group		Document Owner, Reg Ops Group, Approver/s		Document Owner, Documentation Management (DM) Group, Reg Ops Group		

- Executed Batch Records – EBR, which is received as a Final PDF record.
  - File Plan will indicate that by default, “Approved Pending DM QC” is checked for this document type
  - When a document of that type is created, the workflow automatically routes the document directly to last sub-workflow for “Document Management QC Phase” thus bypassing all other phases before being filed as a record
- In-house Pharmacology Report
  - Default values in File Plan will call for multiple reviews and in-house approval
  - An instance of that document type will start as draft and go through the whole lifecycle within the EDMS (unless end-user decides otherwise!)

# THANK YOU!



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