

Leveraging Documentation Management Standards for Continuous Clinical Trial Process Improvement

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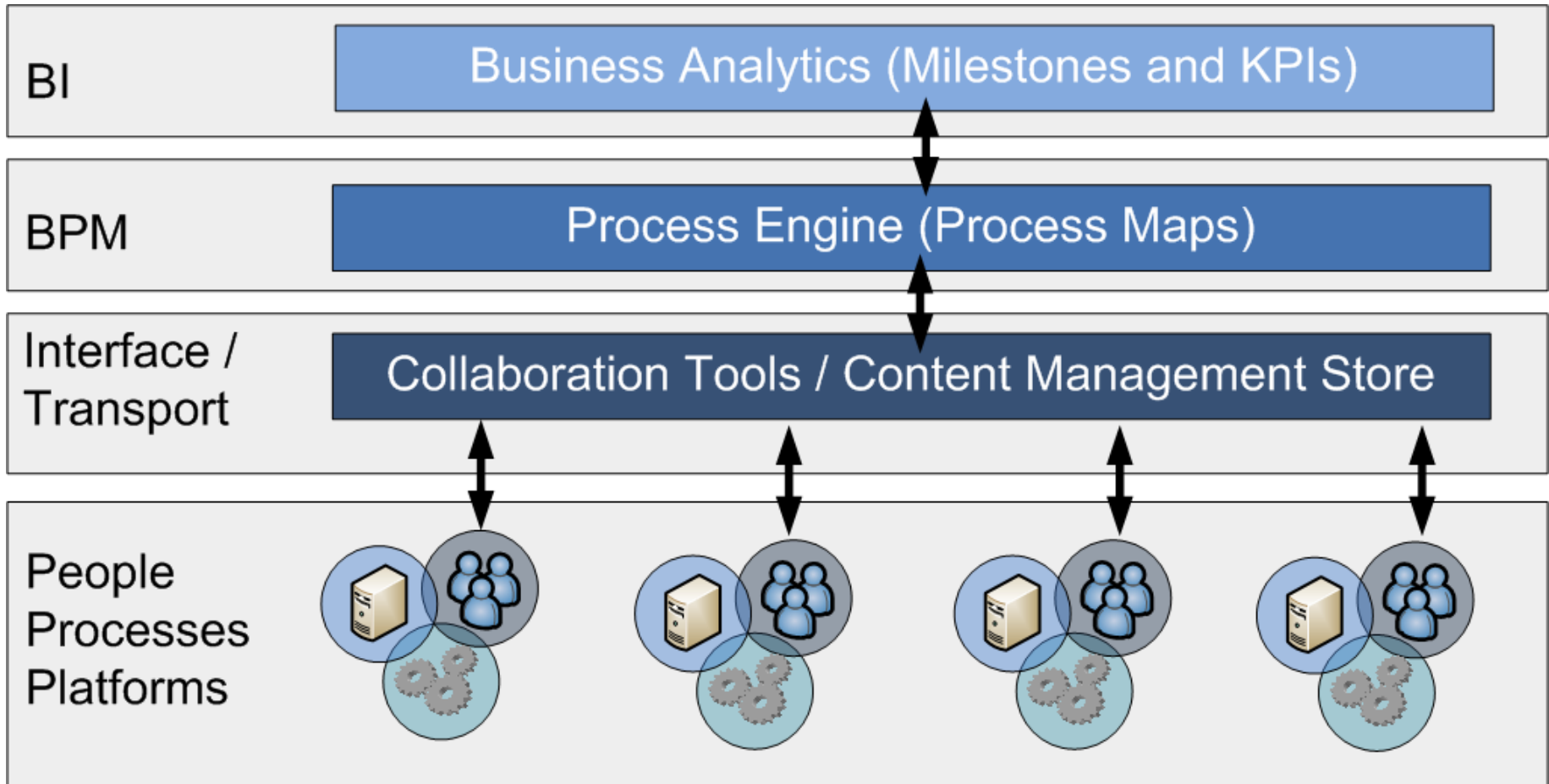
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- Current Situation
- The efficient, integrated clinical trial system
- Establishing a taxonomy
- The importance of documents as process drivers
- Clinical Process Mapping
- Operational knowledge through KPIs

- Many companies have **implemented EDMS** over the years
- These EDMS systems have traditionally **mimicked file shares** for document management
- There is an **emergence** of a **new breed** of EDMS which focuses more on **collaboration** and **automation through metadata**
- Emergence of new document management **models**
- EDMS is ripe for exploiting documents and metadata to **drive processes**

- **Technology** is now available to **integrate** document management with process management
- We need to think of **documents** as **process drivers**
- The effective use of **metadata** can help us make more **informed decisions**
- We need to **apply standards** to facilitate this decision making
- A **new construct** is emerging which enables us to combine **people, processes and platforms**

The efficient, integrated clinical trial system



Definition:

•tax·on·o·my (tk-sn-m)*n. pl. tax·on·o·mies*

1. The classification of organisms in an ordered system that indicates natural relationships.

•**2. The science, laws, or principles of classification; systematics.**

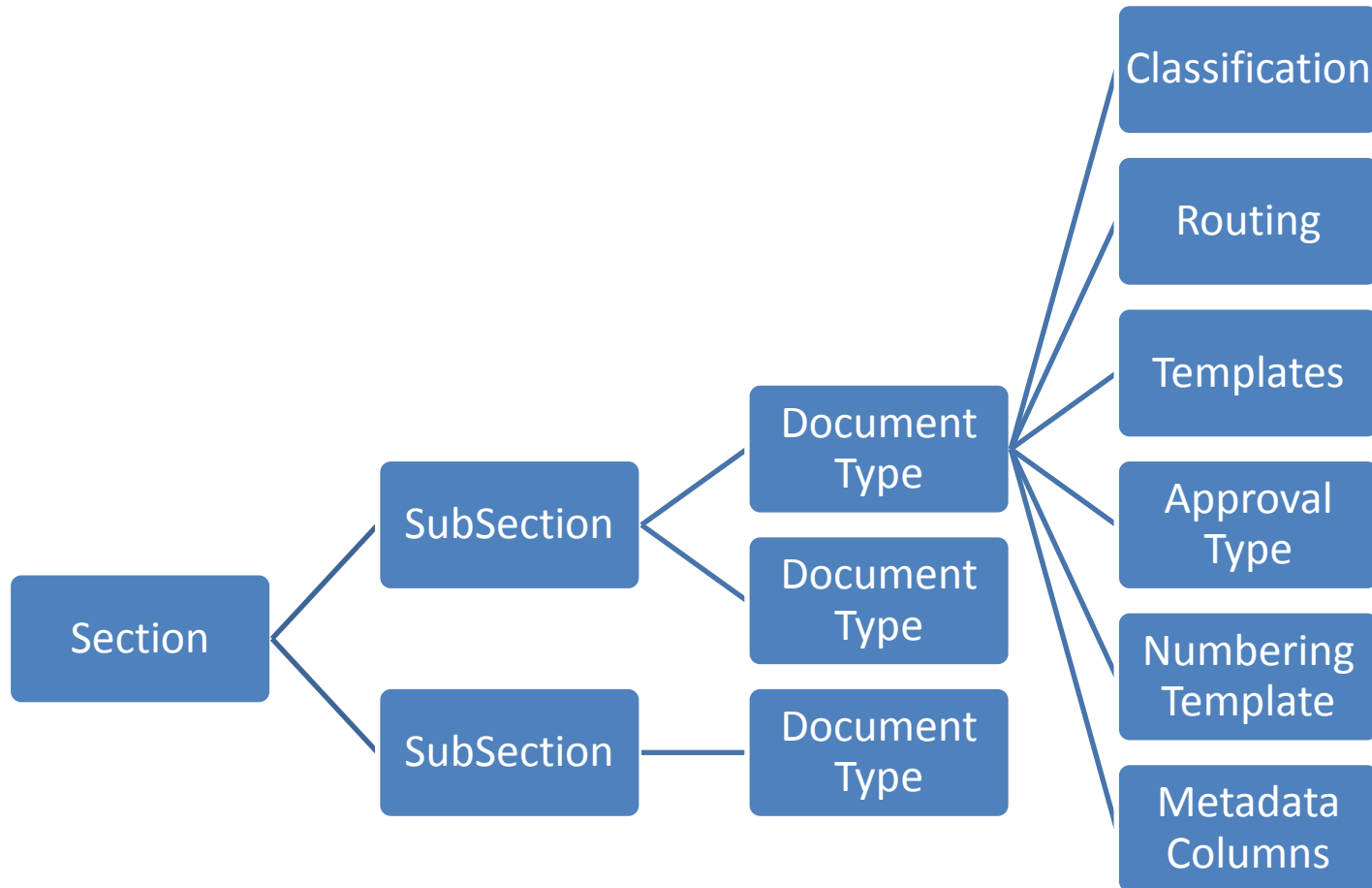
•**3. Division into ordered groups or categories**

Source: The Free Dictionary

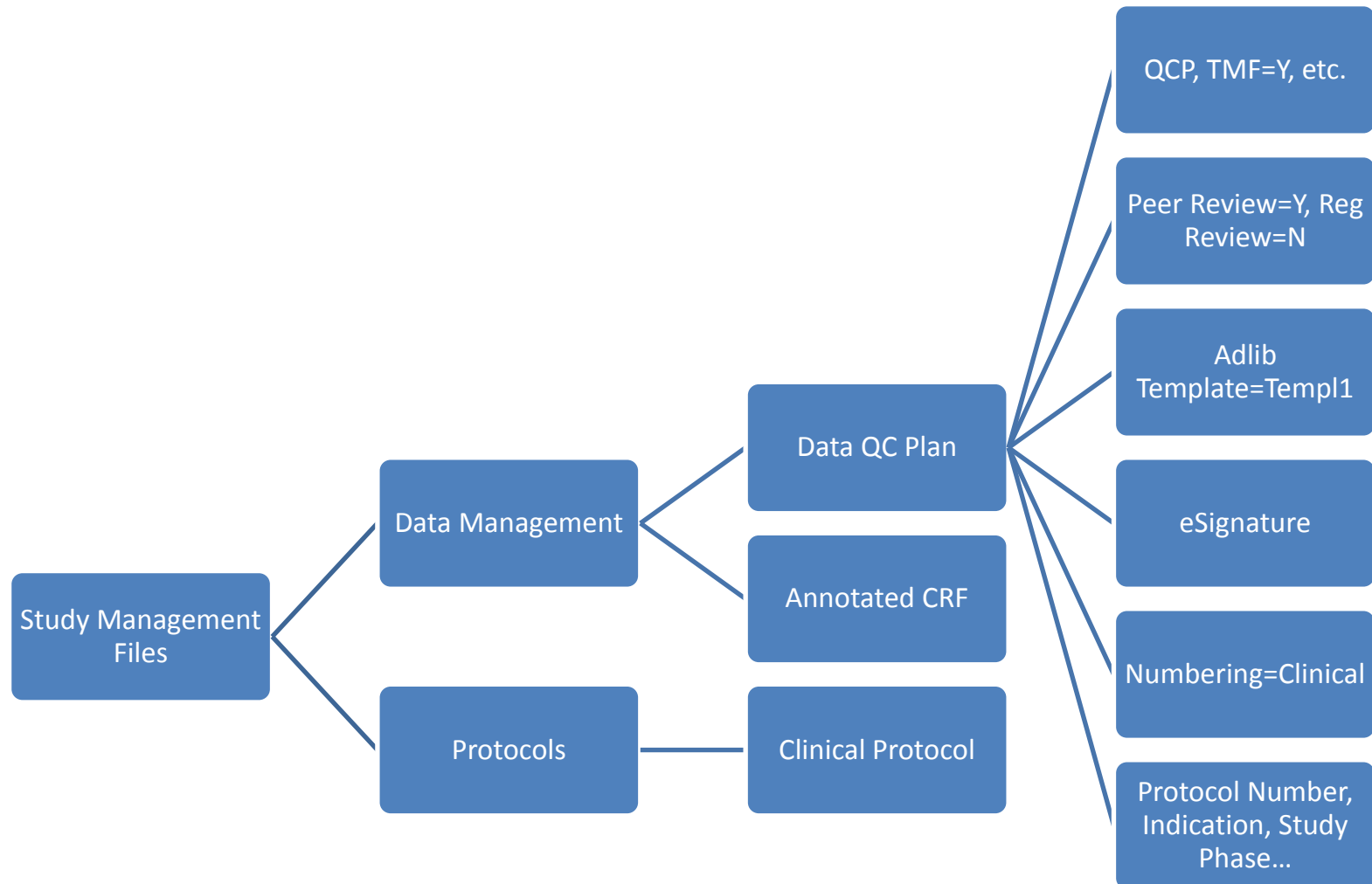
- Industry standards can provide a **foundation** on which to build a **taxonomy**
- Standards allow us to **describe artifacts** in the same way across systems and processes
- The **more** we adhere to standards the **easier** it becomes to **interoperate**
- Standards **empower** process automation

- DIA EDM Reference Model
- DIA TMF Reference Model
- ICH M2 – eCTD
- ICH E2 – E2B(M)
- CDISC Standards

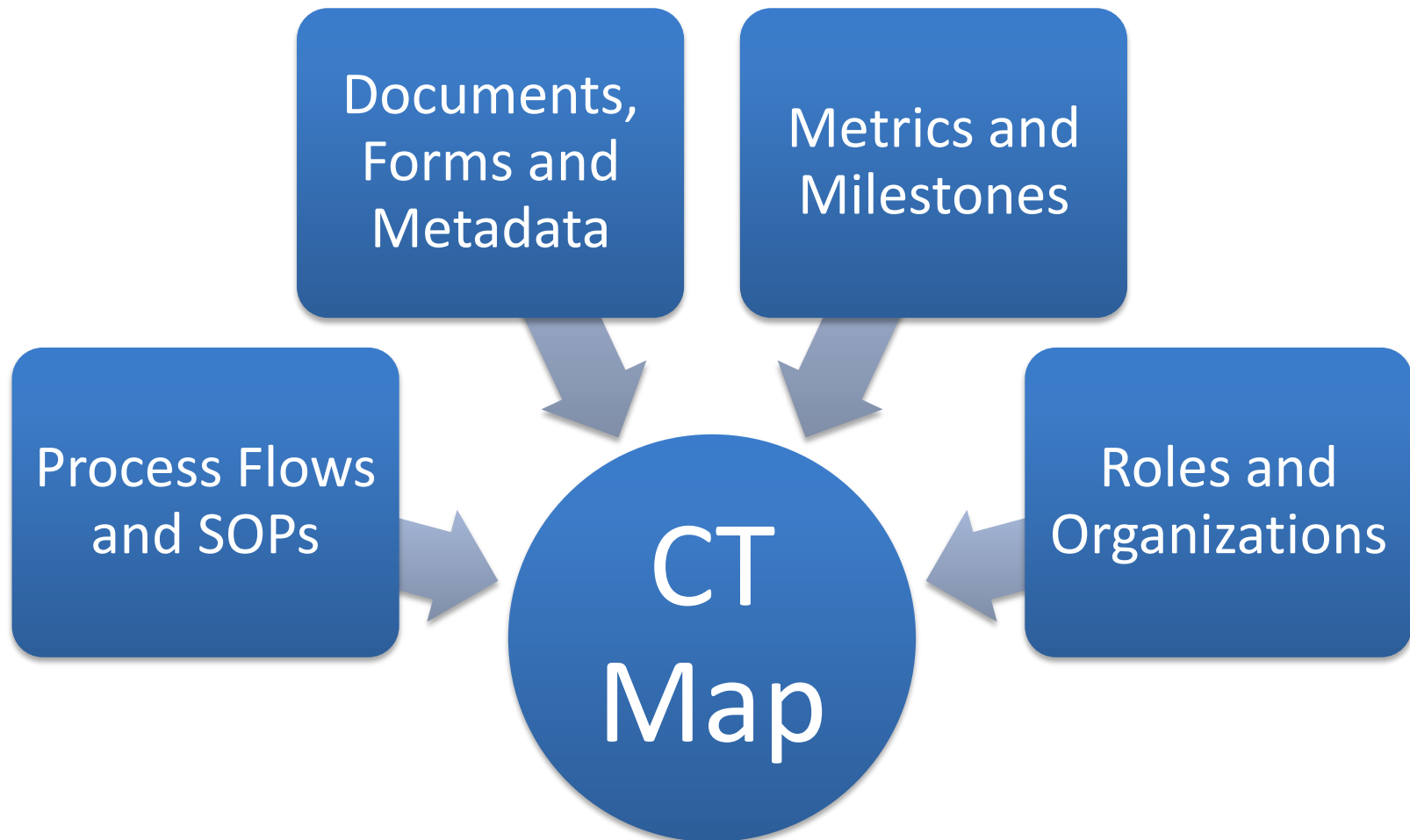
- **Centralize** terms and classification **across systems** to facilitate integration and **improve standardization**
- **Implement** document and information management **systems**
- **Automate processes** through use of metadata and classification
- **Identify** documents/records
- Manage records **lifecycle** and **retention**
- **Search** for and **view** information based on predefined classification
- Generate **metrics** and **KPIs**



Example of use of eTMF with Taxonomy



- All **activities** in clinical trials tend to be **documented** in one form or another
- Different **operations** on documents can be recorded as metadata
- Document **status / lifecycle** is an important **indicator** of process advancement
- Document **metadata** can be used to make **decisions** and to **drive workflows**



- To **define, standardize and optimize** CT operations (reduce time to market, reduce cost, improve quality, etc.)
- **Identify and exploit deliverables** and metadata that drive processes
- Create **automated workflows** from the CT map
- Exploit operational data produced from deliverables and workflow to **better control processes**
- Create **operational intelligence and knowledge** through standard metrics and KPIs to drive **continuous improvement**

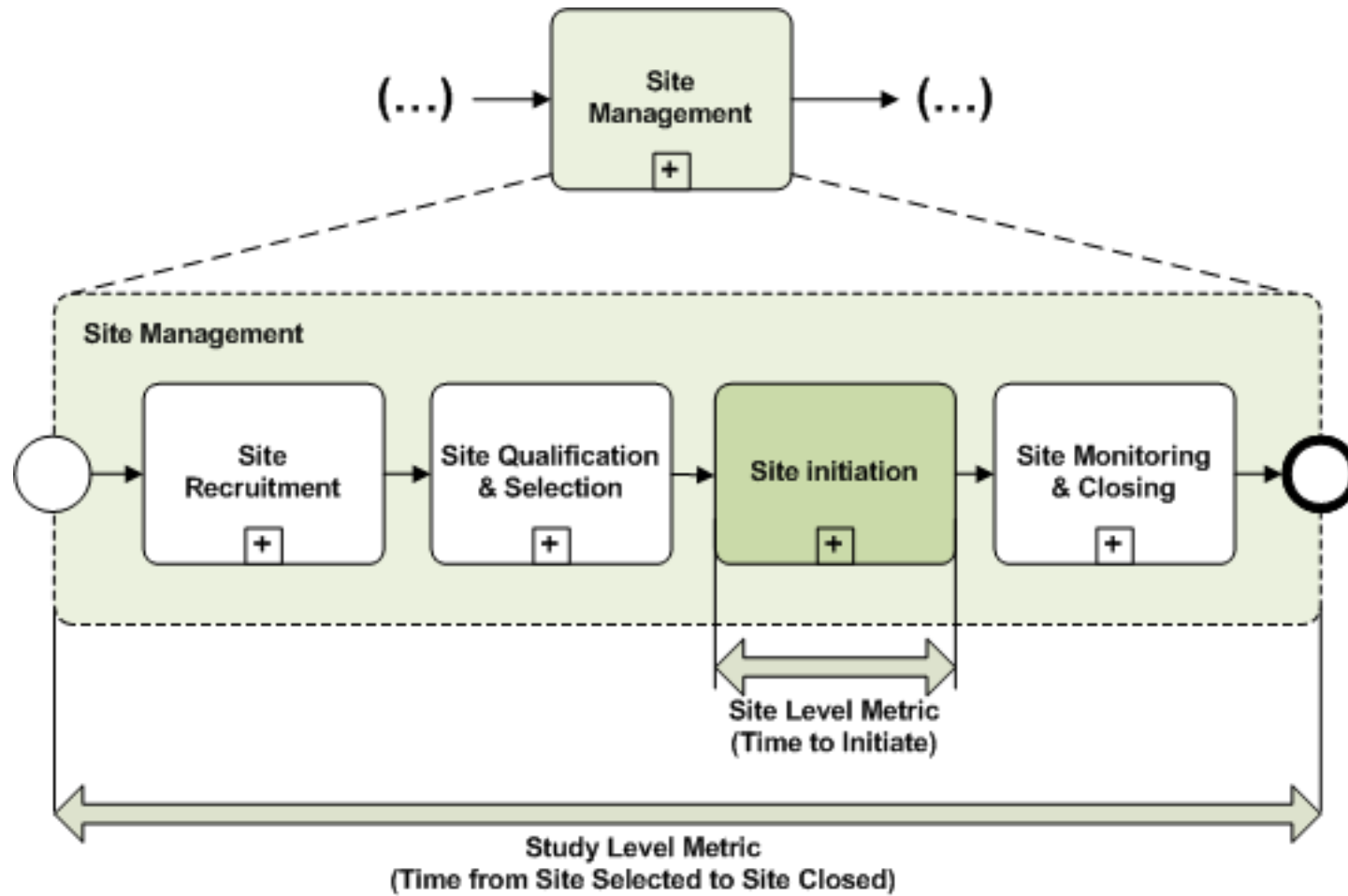
1. Identify all **processes** from the highest level and then drill down
2. Identify **relationships** and **dependencies** between processes
3. Identify **milestones** and **metrics** as processes are defined
4. Identify **document deliverables** that are required for the different processes
5. Identify **metadata** which is used to drive process and generate metrics

6. Identify **roles** who are responsible for process steps
7. **Map** CT Map to BPM system to automate
8. **Develop and deploy** automated workflows and online forms in EDMS / BPMS
9. Create **KPIs / Dashboards / Scorecards**
10. **Improve** processes and **update** map

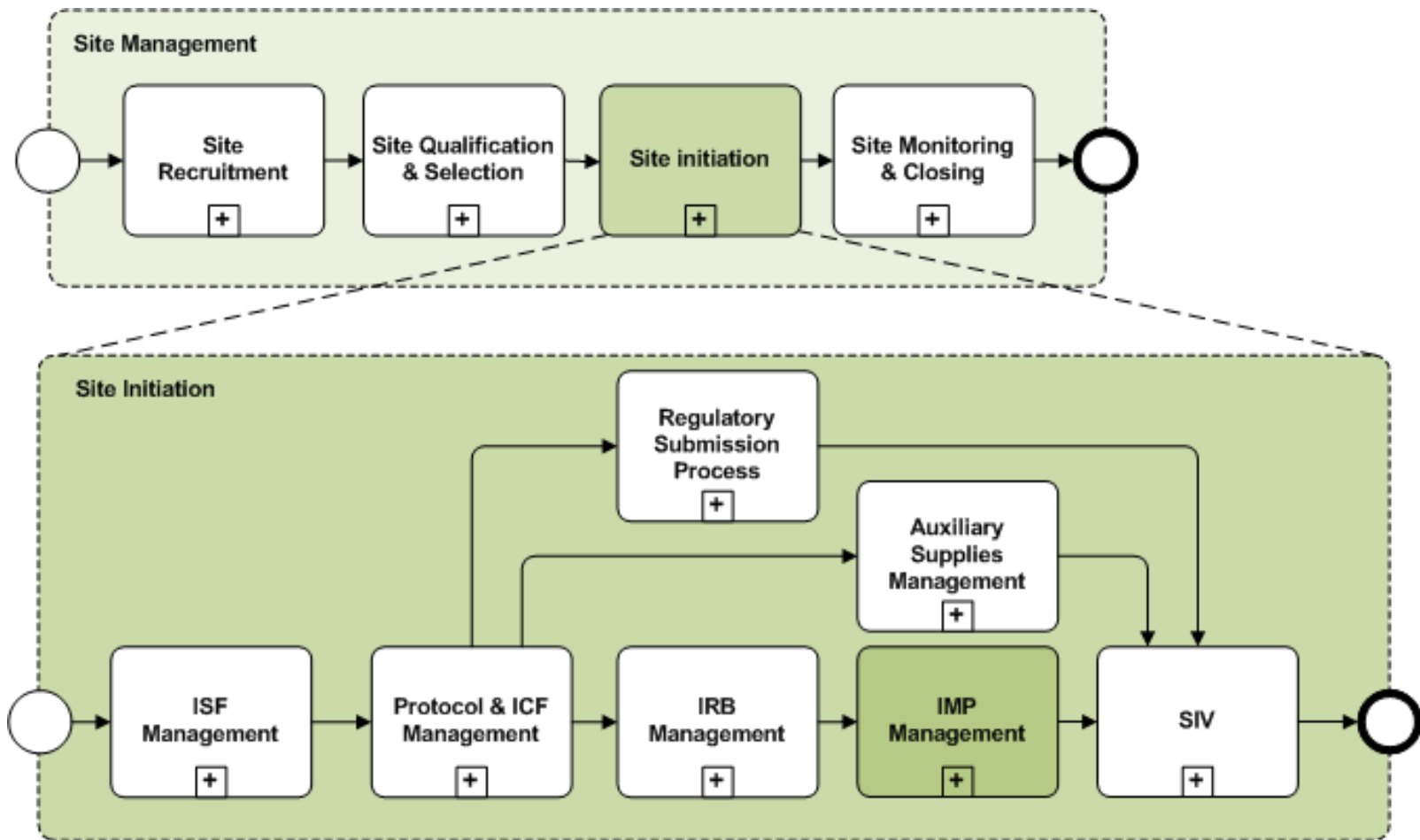
Example: Authorization to Ship Drug

- Part of the **Site Initiation** process
- Is very **dependent** on **document** deliverables and status
- **High volume** process which involves multiple individuals and many documents
- Example uses documents, milestones, forms and workflow

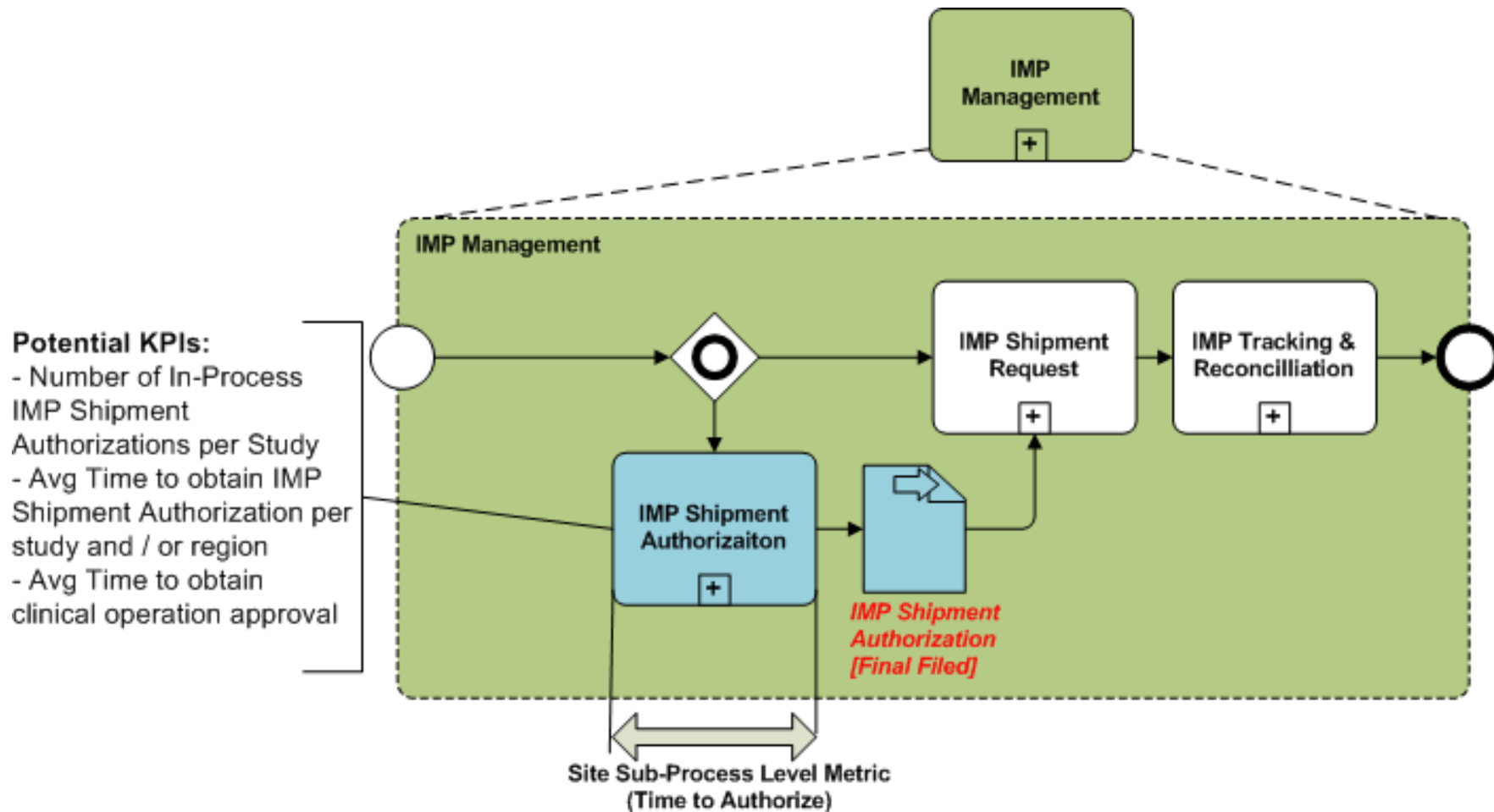
Example : Site Initiation



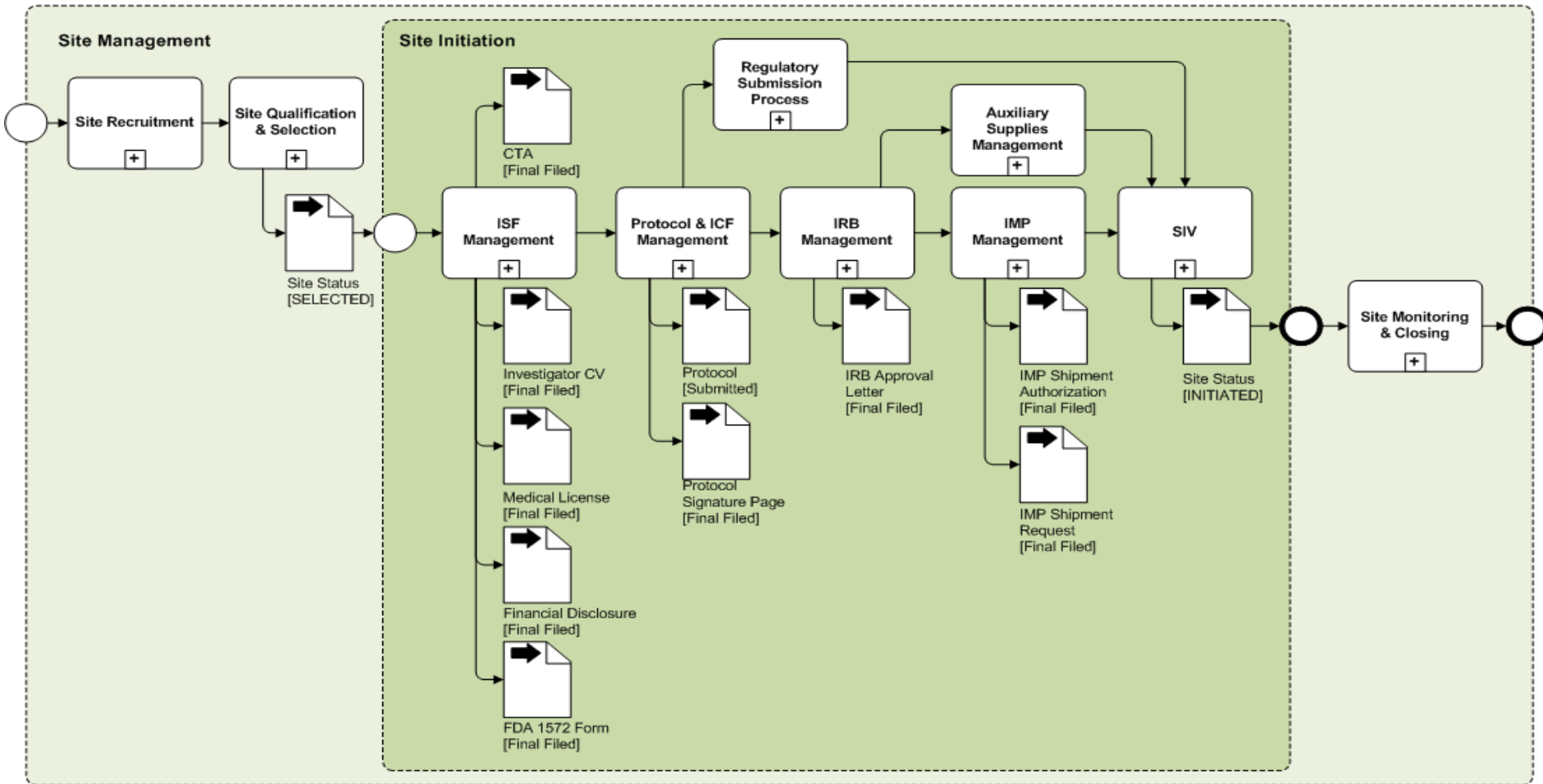
Example : IMP Shipment Authorization (Site Initiation)



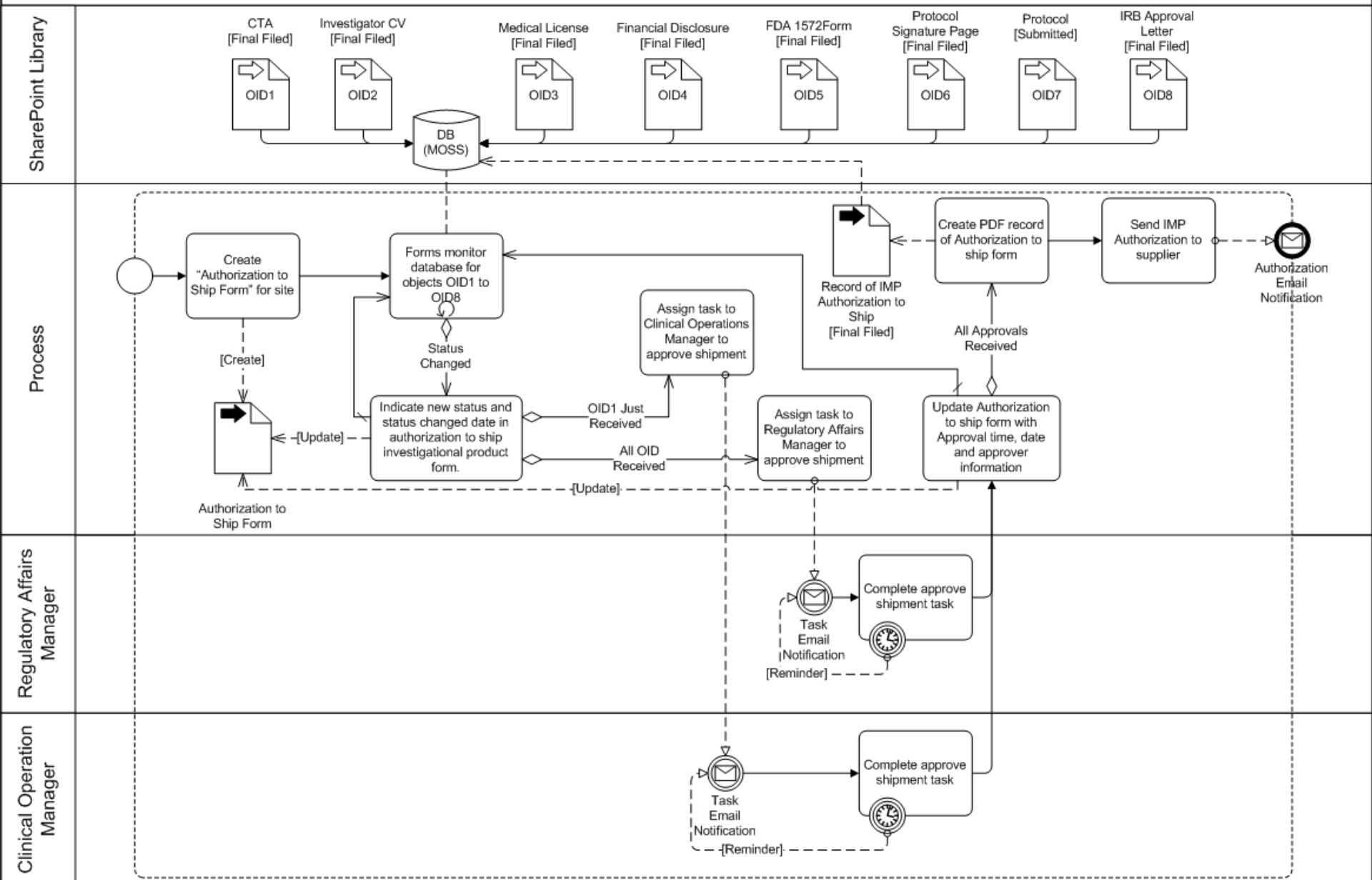
Sub-Process Breakdown (IMP Management)



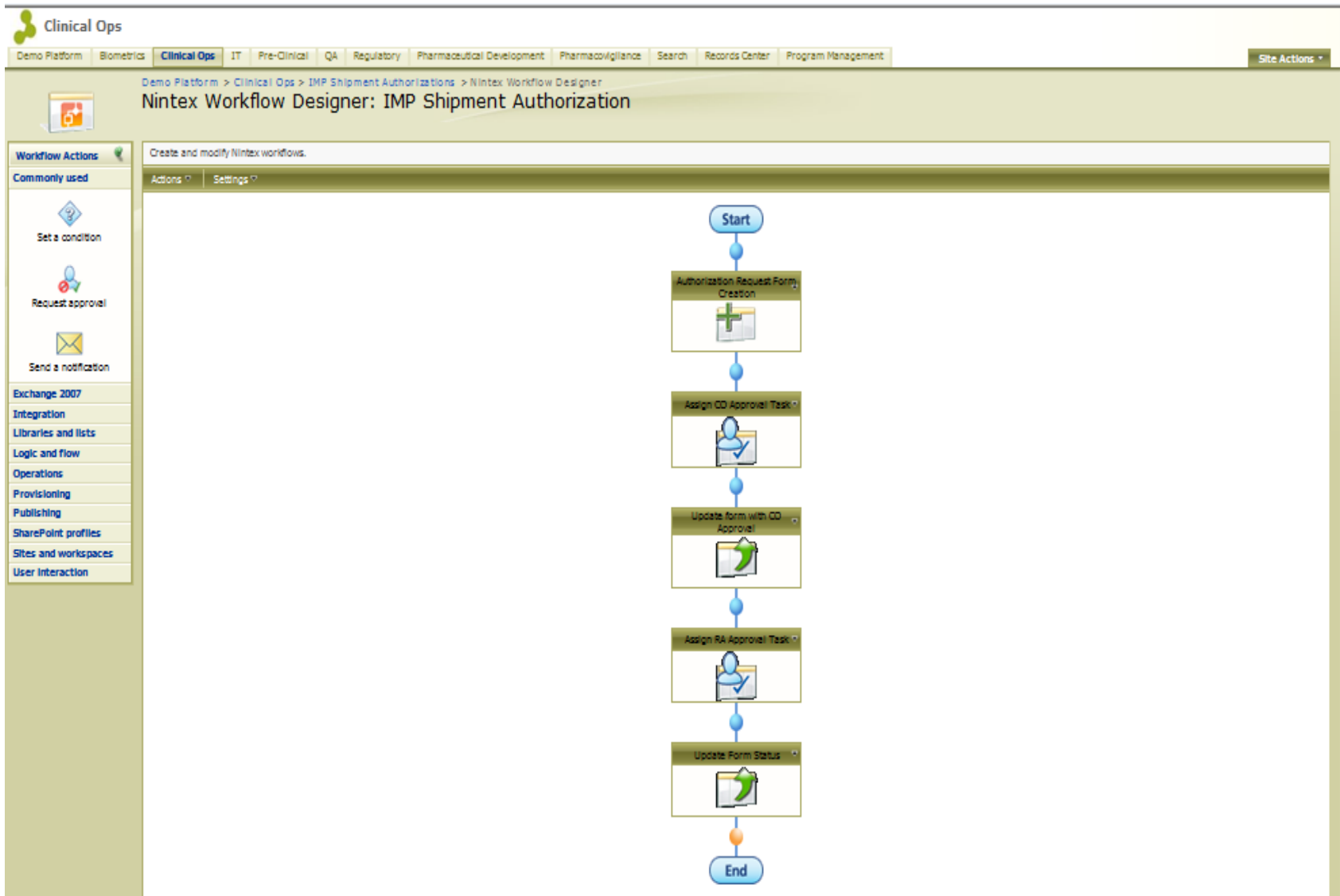
IMP Authorization Process Dependencies



IMP Authorization Sub-Process



IMP Shipment Authorization Workflow



IMP Authorization Form



Authorization to ship Investigational Products

Status: *Authorized*

Example of an online form where document deliverables, metadata and workflow process status can be used to establish if a site is authorized to receive drug.

1. Investigator Information	
Product Number:	Product- 103
Protocol Number:	Study- 103
Site Number:	105
Investigator Name:	Arthur Poch
Investigator Shipping Address:	3217 Mabel
Investigator Shipping Contact Telephone Number:	318-525-3233

2. Clinical Operations Authorization:				
Site Status	Selected	Date:	1/15/2010	<input checked="" type="checkbox"/>
Debarment Check	Final Filed	Date:	2/1/2010	<input checked="" type="checkbox"/>
Clinical Trial Agreement(CTA)	Final Filed	Date:	2/16/2010	<input checked="" type="checkbox"/>
Print Name:	Tevin Pathareddy			
Clinical Ops Approval	<input checked="" type="checkbox"/>	Date:	2/24/2010	<input checked="" type="checkbox"/>

3. Regulator Affairs Authorization:				
Form FDA 1572	Final Filed	Date:	3/3/2010	<input checked="" type="checkbox"/>
Investigator CV	Final Filed	Date:	3/3/2010	<input checked="" type="checkbox"/>
Investigator Medical License	Final Filed	Date:	3/7/2010	<input checked="" type="checkbox"/>
Financial Disclosure for PI and Sub-Investigator	Final Filed	Date:	3/3/2010	<input checked="" type="checkbox"/>
Signature Page of most Recent version of Protocol	Final Filed	Date:	3/11/2010	<input checked="" type="checkbox"/>
IRB Approval Letter	Final Filed	Date:	3/31/2010	<input checked="" type="checkbox"/>
Most recent version of Protocol submitted to FDA	Submitted	Date:	4/2/2010	<input checked="" type="checkbox"/>
Print Name:	John Smith			
Regulatory Affairs Approval	<input checked="" type="checkbox"/>	Date:	4/5/2010	<input checked="" type="checkbox"/>
*This form must be completed prior to shipment				

Parent Document	MTM-SOP-012	Shipment of Investigational Product(s) to clinical investigators		
Form Number MTM-SOP-012-FA	Revision 00	Effective Date MAR 28 2009	Page Number 1 of 1	

Clinical Study Dashboard

- View All Site Content
- Clinical Dashboards**
 - ClinOps Dashboards
 - ClinicalStudyDash
- Clinical Documents**
 - Product-101
 - Product-102
 - Product-103
- Monitoring**
 - Monitoring Visits
 - Issues Log
 - Monitoring Dashboard
- IMP Management**
 - IMP Shipment Authorizations
 - IMP Shipment Requests
 - IMP Management
- Trackers**
 - Site Activation Tracker
- Lists**
 - Tasks
 - Clinical Team Calendar
 - KPI-IMP Shipment Authorization

Excel Web Access - ClinicalSiteScorecard

Open ▾ | Update ▾ | Find View: **ScoreC**

	Goal:	70	14	30	5	21	5	20	14	5	80%	20%
	Alert:	80	21	45	10	28	10	30	21	10	60%	35%
Row Labels	Values											
	Average of Days to Initiation	Average of Days to ISF Completion	Average of Days to IRB Approval	Average of Days to Drug Shipment	Average of Days to FSFV	Average of Months to LSV	Average of Days to DB Lock	Average of Days to Site Closure	Average of Target Open Query Rate (per subject)	Average of % Target Recruitment Achieved	Average of % Screen Failure Rate	
Study-101	70	17	36	6	17	5	25	15	5	80%	35%	
FRA	74	18	40	7	21	6	29	17	7	94%	39%	
FR-001	73	13	56	2	21	4	27	12	5	86%	29%	
FR-002	77	21	39	9	19	7	53	38	14	100%	54%	
FR-003	76	29	43	8	19	3	16	9	1	113%	18%	
FR-004	68	10	23	10	26	9	19	8	7	78%	53%	
GER	61	18	33	5	15	6	20	15	2	89%	27%	
DE-001	59	27	22	3	12	4	9	5	1	76%	41%	
DE-002	27	17	7	6	19	9	21	13	2	100%	33%	
DE-003	81	13	55	3	23	9	10	2	3	106%	33%	
DE-004	77	16	48	9	5	5	40	39	1	75%	0%	
USA	74	15	36	6	16	5	26	14	7	89%	37%	
US-001	73	13	56	2	21	4	27	12	5	86%	29%	
US-002	77	21	39	9	19	7	53	38	14	100%	54%	
US-003	76	29	43	8	19	3	16	9	1	113%	18%	
US-004	68	10	23	10	26	9	19	8	7	78%	53%	
US-005	82	1	51	8	14	3	27	9	8	92%	0%	
US-006	80	5	17	3	3	4	28	19	11	80%	64%	
US-007	59	27	22	3	12	4	9	5	1	76%	41%	
Study-102	65	16	37	5	17	5	17	10	4	85%	22%	
Overall Average	68	17	37	6	17	5	22	13	5	89%	30%	

- Take a **Step by Step** approach to process automation
- Try and use existing **internal taxonomies** and **industry standards**
- Align to **SOPs** and QS
- Try and identify **metadata** that is required to generate KPIs and metrics in advance
- Identify **collaborative technology** which will allow you to automate easily
- Leverage **BI** to build in **continuous improvement**

- Documents **drive processes** and can generate significant intelligence
- Mapping **documents to processes** and automating these processes using BPM tools can generate **significant benefits**
- Adopting **industry standards** facilitates this process and also enables cross organizational interaction

THANK YOU

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