The Power of Content Reuse within Clinical and Labeling Documentation

- A Global Pharma Case Study

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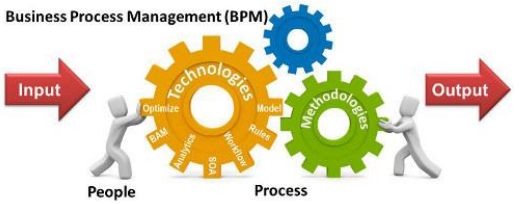
Agenda

- Program Charter
- Business Drivers
- Scope:
  - Clinical Documentation
  - Labeling
- Information Design
  - Reuse across compendium of documents
  - Reuse within same document
  - Benefits
  - Challenges
- Lessons Learned

Program Charter

Delivery of a highly adaptable and accountable service based platform enabled by innovative knowledge management tools and efficient, reusable processes.



Structured authoring and re-use of both content and processes as well as separating content from presentation while proactively ensuring compliance

Reduction of the effort required to prepare, compile and analyse content and documents through a synergy of optimized processes and enabling technology proactively scoped for value by a defined service catalog

Business Drivers

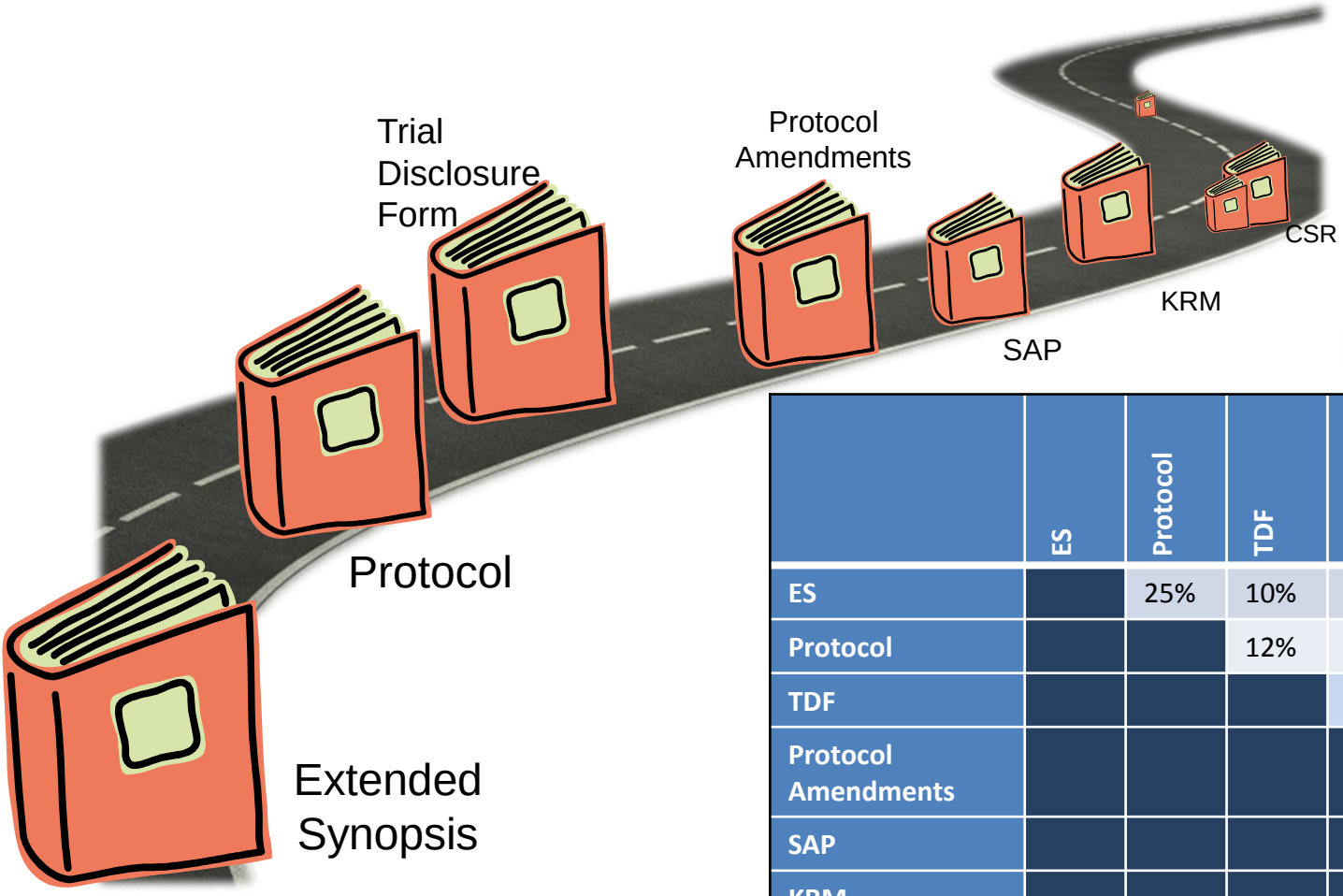
BUSINESS **DRIVERS**

- ENSURE CONSISTENCY WITHIN THE ORGANIZATION AND BETWEEN PUBLIC DISCLOSURE AND REGULATED REPORTS (NDA, IND, CTA, PSUR...) AGAINST DATABASES
- QUICKLY ASSESS VALUE AND NON-VALUE ADD ACTIVITIES AND MANAGE THE SOURCING OF THOSE ACTIVITIES WITHIN THE CAPABILITIES PORTFOLIOS BALANCING FIXED AND VARIABLE COSTS
- REDUCE CYCLE TIMES, ENABLE EARLIER AND MORE EFFECTIVE DECISION-MAKING AROUND CLINICAL DEVELOPMENT PROGRAMS, AND REDUCE TIME TO MARKET
- SHARE KNOWLEDGE BY MOVING TOWARD REUSABLE COMPONENTS OF INFORMATION THAT CAN BE MANAGED AND REUSED ACROSS PUBLICATIONS, DEPARTMENTS AND AUDIENCES.

PROGRAM PRINCIPLES

- Deliver a highly adaptable and accountable service based platform enabled by innovative knowledge management tools and efficient, reusable processes.
- Perform structured authoring by enabling re-use of both content and processes as well as separating content from presentation while proactively ensuring compliance
- **Reduce the effort required to prepare, compile and analyse content and documents**
- **Lead, change and innovate within the transforming enterprise**

Scope – Clinical Documentation



Reuse Scope

	ES	Protocol	TDF	Protocol Amendments	SAP	KRM	CSR
ES		25%	10%	10%	21%	26%	21%
Protocol			12%	40%	37%	7%	31%
TDF				0%	0%	0%	0%
Protocol Amendments					0%	0%	1%
SAP						1%	12%
KRM							15%
CSR							

Scope - Labeling

- CCDS *(reference document)*
- CCSI
- EU SmPC
- USPI

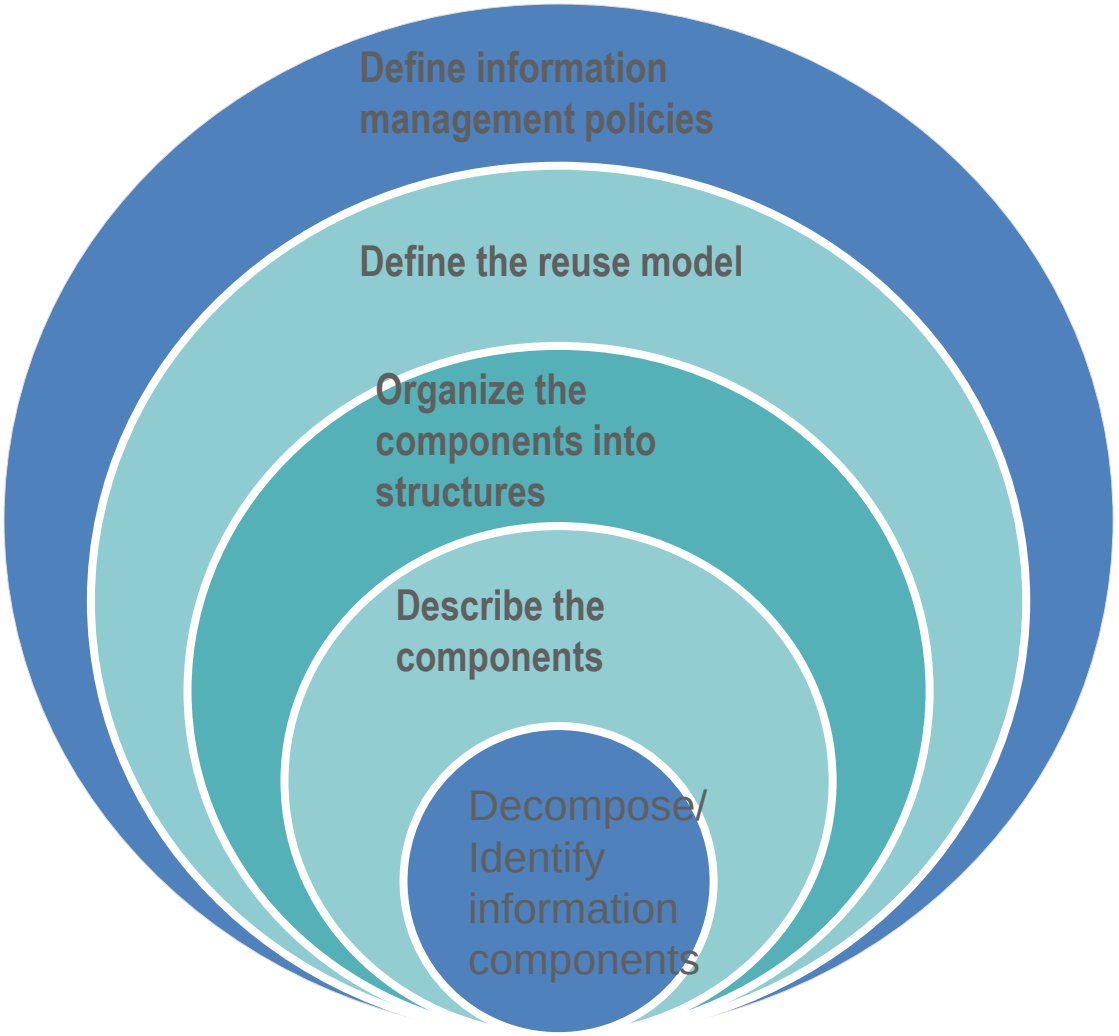
Reuse Scope

	CCDS	CCSI	EU SmPC	USPI
CCDS		85%	76%	79%
CCSI				
EU SmPC				
USPI				

Information Design

- What is Information Design in this context?
  - Information design is the process used to develop models that represent structured content within the clinical or labeling deliverables.
  - The are used to specify how content is created, described, managed, and used/reused in outputs.

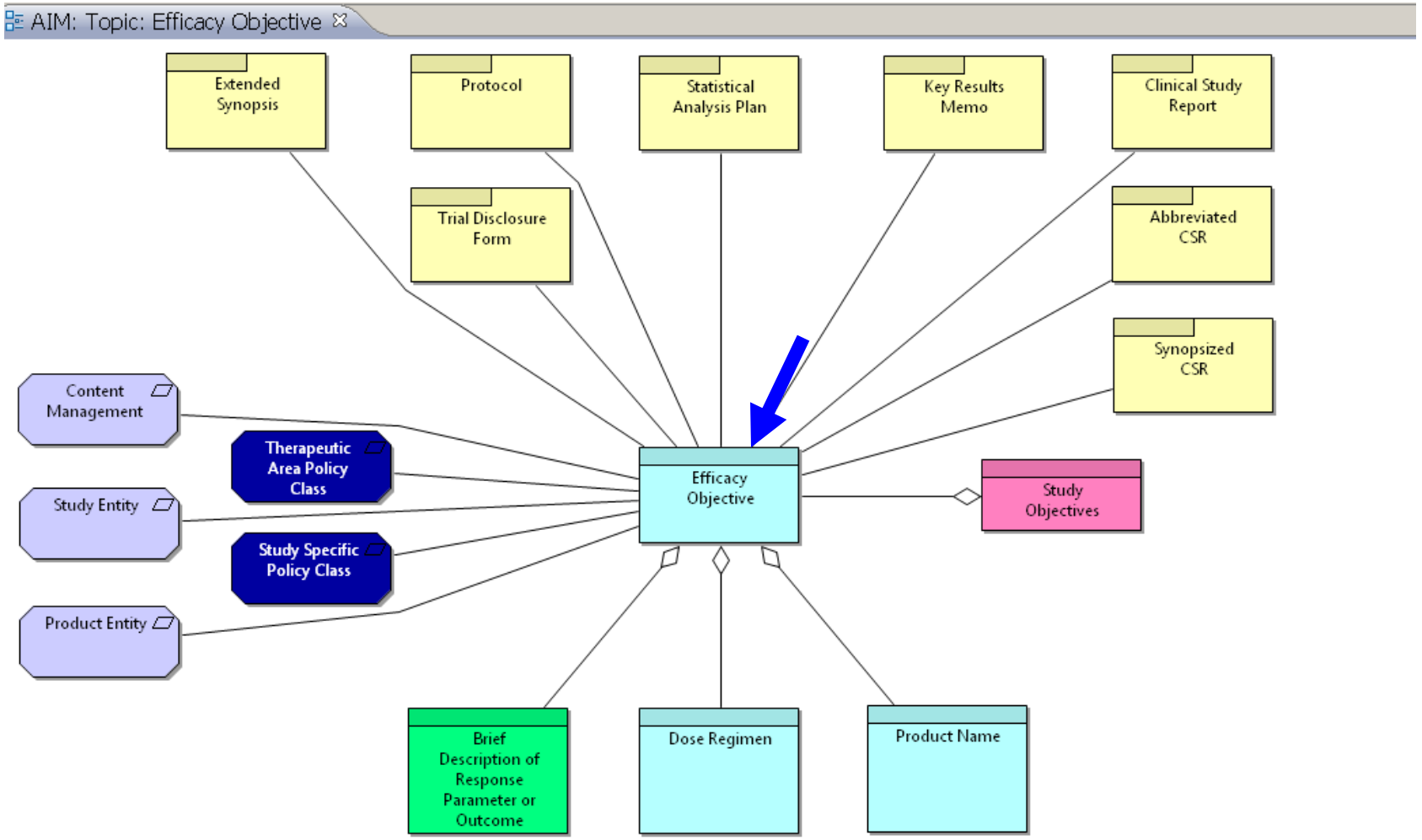
The design process



Identifying and Describing information

- Identify topic chunks
  - Self-contained textual content
  - Potential for reuse
- Define the metadata (topic attributes)
  - Elements: small units of information used within topics
  - Metadata: enables searching for topic and tracking of information about topic
- Organizing topics into structured maps
  - Topics are ordered into small maps with related content, which can be ordered into larger maps
  - Structured maps describe the order of content that will be reused
  - Goal: Provide content for reuse in a semi-automated fashion

Topic Example: Efficacy Objective



Structure Content Management – Labeling Example

- Creation of a Structured Content Management and Information hub for Labeling
  - to reduce risk by streamlining information flow
  - to reduce time between submission approval to label by reuse and automation
  - to improve quality by reuse
- Adoption of SCM to support reduction in duplicate of content through reuse
- IDC* research study indicated that an average of 26% of the time and cost of clinical study is due to document and compliance issues. SCM is seen as having the best potential to significantly reduce document quality, compliance time and related cost
- Based on experience of industries outside pharmaceuticals, a 15-20% reduction of duplicate content is readily achievable using structured content management

* Louie, Alan, Research Study "Managing Paper at Its Roots: Extending Beyond Document Management to Enterprise Content Compliance", Health Industry Insights, 2010
conducted across a group of 26 global pharmaceutical & biotechnology companies, medical device companies and CRO's

Benefit Drivers

Improving Labeling quality, transparency, scale, speed and efficiency

BENEFIT	KEY BENEFIT DRIVERS
Improved Data Quality and Knowledge Velocity	• Efficiency – reduce duplicate content (authoring) • Consistency – single version of "truth" • Quality via reducing error prone copy/paste efforts
Improved Interoperability: Internally and with Clinical Partners	• Reduce translation cost/effort • Improve consistency of translated content • Expand business value by supporting other submission procedures • Expand business value by increasing content
Improved Flexibility, Speed and Productivity of Labeling	• Efficiency – propagate changes in corporate label content to USPI and EU SmPC • Improve cycle times and effort e.g. to produce artwork
Reduced Risk of Regulatory and Compliance Issues	• Compliance with regulatory deliverables increased as a result of content use rules • Quality improved via traceability of alignment between CCDS/CCSI and USPI/SmPC

Roadmap

What critical capabilities need to be assessed in order to finalize a business case?

If outcome of capabilities are met , based on vision and business objectives a roadmap of incremental service extensions (focus on high value/low effort first)

Vision:
First in Class Content Management for Class Product Information

Service Foundation

Information Design
Foundation
Content reuse #1

Versioning
Verification
Content versioning #2

Document-based review process #3

Business Case preparation Incl. capability roadmap

Collaboration

Review and approval

Support local procedure

Operationalization
Global labeling content

Content Publication
(publish content in different formats)

Content mgt national labels

Manage label claims

Content translation

Annotations

Content reuse

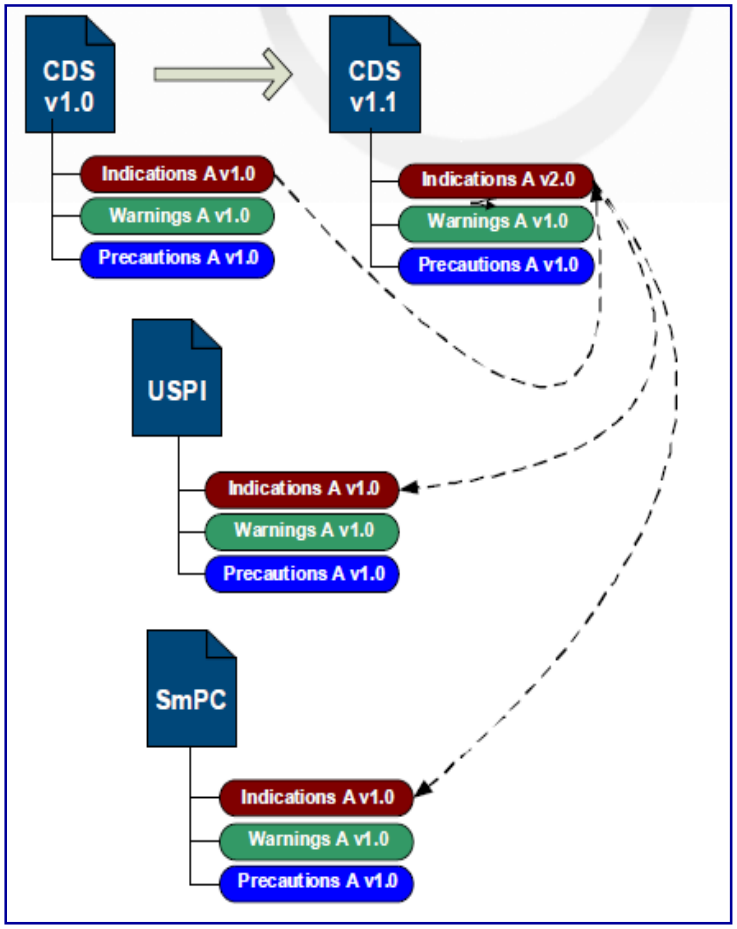
Topic Versioning

Ingestion

Content maintenance ops

Business Objectives
reduce duplication of content
Improve consistency of global labeling content
Improve traceability of content and content history
Improve efficiency and collaboration within global labeling and other stakeholders

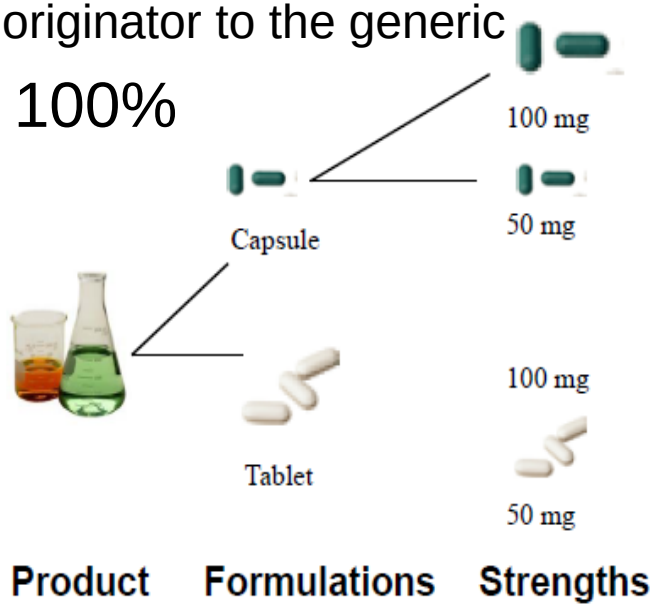
Information Design for Labeling



- CCDS *(reference document)*
  - 78 topics
  - 20 elements
- CCSI
  - 47 topics (39 reused from the CCDS)
  - 7 elements (7 reused from the CCDS)
  - → 85% reused information
- EU SmPC
  - 83 topics (66 reused from the CCDS)
  - 18 elements (11 reused from the CCDS)
  - → 76% reused information
- USPI
  - 82 topics (65 reused from the CCDS)
  - 20 elements (16 reused from the CCDS)
  - → 79% reused information

Reuse across SmPC

- For one single product
  - Up to 37 SmPC (need to repeat per formulation and strength)
  - Reuse of information across SmPC
    - Estimation: 70-90%
- For duplicate application
  - Reuse of information from the originator to the generic
    - Estimation: close to 100%



Critical Success Factors

Many factors used determine the overall program effectiveness. The learning program will be considered successful if:

- Business understanding of the value of structured content and buy-in
- Authors need to relate to and find the value of writing for reuse, and writing content as “topics” – contextual and strategic is important
  - Reuse across a compendium, but also within the same output/ document
- Work very closely with the business
  - Champions are trained and develop the information model for their content
  - Business champions work very closely with technology team – Product Owners
  - Business is part of the IT, product vendor and operations planning activities
- Business ownership of the standardized content
  - Creation and tagging of the content
  - Assigned ownership, and buy-in on it’s value
  - They drive adoption by directing the change, IT does not own this

Rolling out a SCM Solution Suite to Operations

Structured a Services organizational model for business and IT:

- IT Services
  - Maintain and enhance SCM solution suite for business services
  - Competency in design, tool configuration, test, deployment
  - Level 1, 2, and 3 support for operations
- Business Services
  - Scope of deliverables for operational needs (clinical pipeline, labeling pipeline)
  - Competency in onboarding and enabling new groups/ units to leverage SCM suite to author and publish required outputs
  - Support to business units to develop harmonized content libraries to be used for the authoring processes

Business Services

Business

Model –
Service focus

Business structured as a Service Delivery Team

SERVICE

*** Scoping Service**

*** Service Release Planning Information and Content Service**

SERVICE DEFINITION

*** Define services**

*** Define service/scope of work**

*** Ownership of service scope**

SERVICE DELIVERY

*** Engagement Model**

*** Service Delivery Model**

*** Refresh Service Catalogue**

SERVICE ROLES

***Define roles & responsibilities for delivery of services to customer**

Content Harmonization

Business Model – Content Management

Roles, ownership and governance established and operational

CONTENT

Content creation and preparation

Create, manage and use standardized content

Populate and configure libraries

Review/approval of text

Content Owner Roles:

Define roles and responsibilities

Define scope of work

Governance: Establish a governance structure to manage content

Lessons Learned

- Know the real users
- Having the right advocates to sponsor program
  - Crucial to business adoption
  - Needed to engage and move organization for change
  - Top-down buy-in
- Having the right people in the key roles
  - During the Program Development
  - On the business side for Services:
    - Service Managers, Service Delivery
  - Ensuring right level of engagement (not a part-time activity for key roles)

- People need to have the right skills
  - Ramp-up & train on needed knowledge/ expertise
  - Business owns the Information and Content Models
- Governance – standards alignment; standardized text; templates and models
  - Tap into existing governance bodies

Thank you

QUESTIONS?