

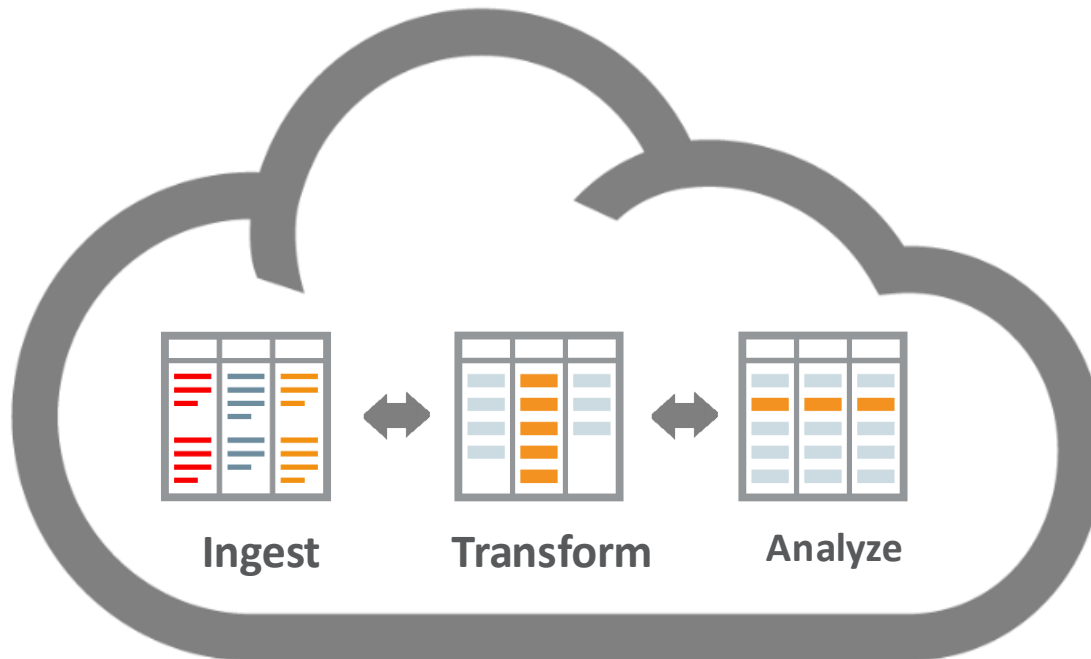
A network diagram consisting of numerous blue circular nodes of varying sizes connected by thin blue lines. The nodes are arranged in a complex, interconnected web, with some nodes having more connections than others. The diagram is positioned in the upper left quadrant of the slide, partially overlapping the white background and the blue header area.

Turbocharge Your Trials

Transform CRF Creation and CDISC Standardization Process with Smart Metadata Repositories and AI/ML Innovations.

Harinarayan Gopichandran

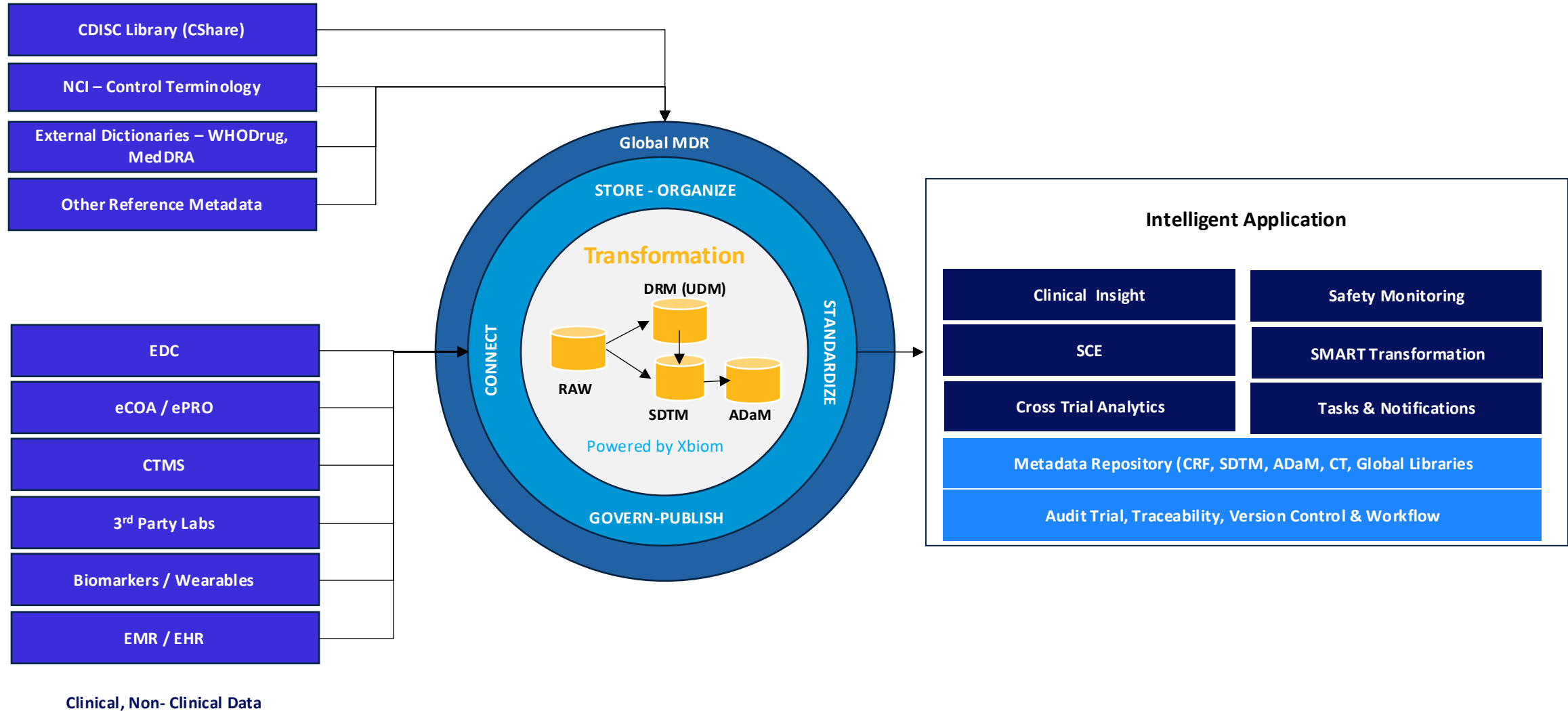
17th Mar 2025



Xbiom™ Platform

- Share one platform
- Share one process
- Share one library
- Increase reusability
- Reduce timelines
- Decrease study costs
- Improve study quality

Life Sciences Digital Transformation



Xbiom Solutions Platform

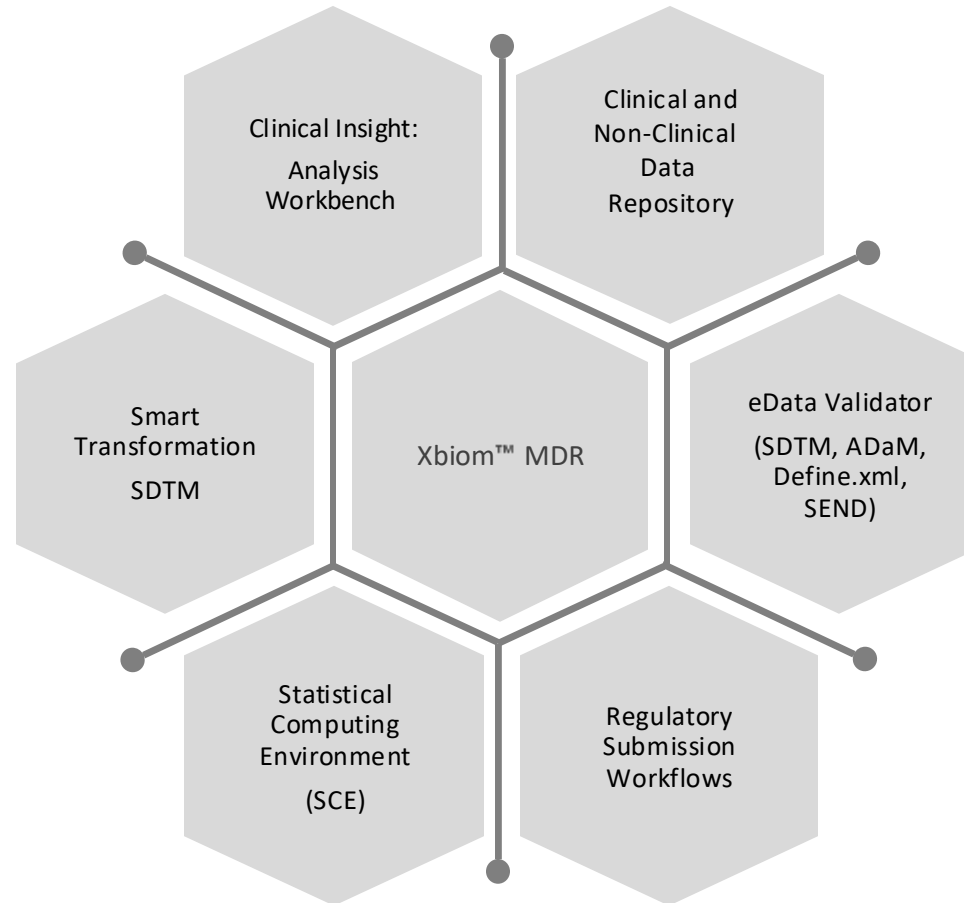
Capability

60 Clients across
Biotech & Pharma

7500+ studies from
Xbiom for SEND
Submission

10000+ User using
eDV across US, Asia
& Australia

XBIOM™ Solutions Platform



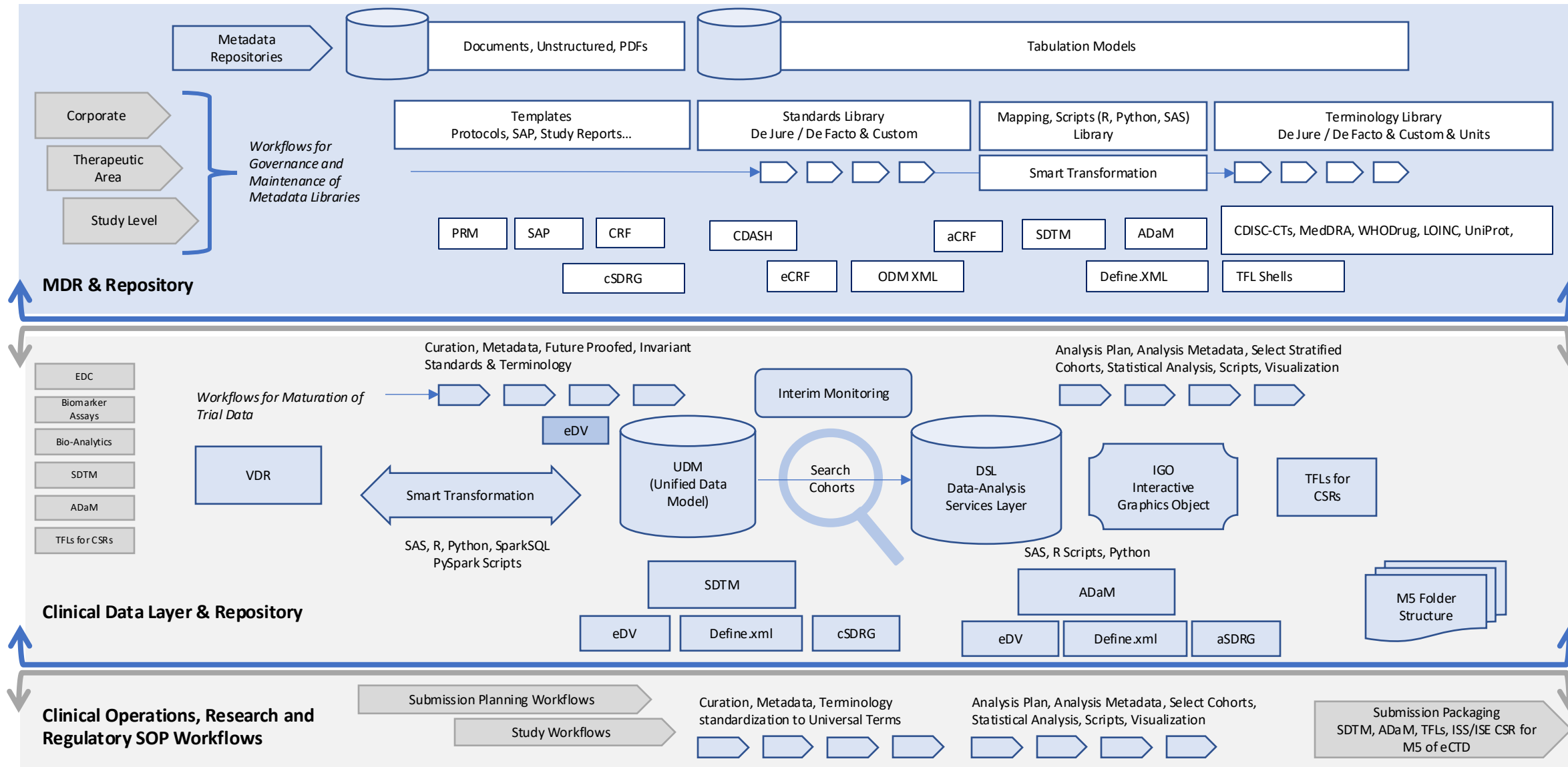
R&D Business Value

Regulatory, role-
based workflows
with 21 CFR Part 11
compliance

Fully integrated
Platform

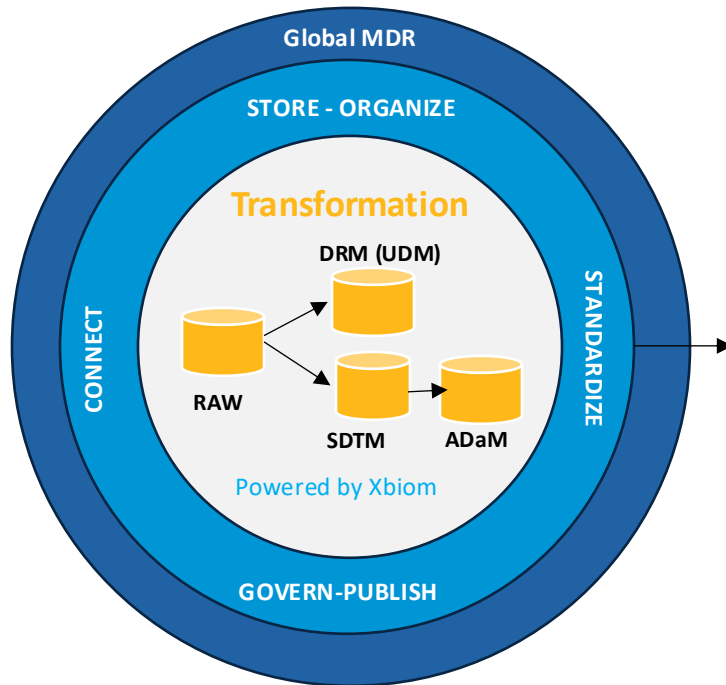
Scalable,
Interoperable &
Secured Cloud
based Platform

Xbiom – Under the Hood view



Life Sciences Digital Transformation – Business Painpoints

Xbiom Value Proposition – “Accelerate time to collect, review and submit clinical data”



1

Reduce the Time and Effort for Study Data Collection *(Weeks to Days)*

2

Centralize Pre-Clinical, Clinical datasets into one common place
(No more Manual discovery of data)

3

Accelerate Study Data Review and Analysis with ready TA specific packages
(Months to weeks)

4

Accelerate Submission Dataset Creation for Pre-Clinical and Clinical Studies
(Months to Weeks)

Xbiom MDR Demo

Pre-deployed models and controlled terminologies

AutoSave ☐ Off     Use case 2 • Saved to this PC

File Home Insert Draw Design Transitions Animations Slide Show **Record** Review View Help

 Preview  Cameo  From Beginning  From Current Slide  Screen Recording  Audio

 Clear Recording  Reset to Cameo  Save as Show  Export to Video  Learn More

Preview Camera Record Edit Export Help

1 

2 

Describe and show how multiple MDR standard models and STD versions can be simultaneously governed and consumed.

Standard steward (Developer & Approver)

- Showcases how different standards are supported and managed in MDR
 1. Pre-deployed models and controlled terminologies
 2. Managing CRF models
 3. Managing SDTM models
 4. Accessing and managing Global Mapping templates
 5. Maintaining Global Programming templates.

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Managing CRF forms

Dashboard

Model Management

insightsaastest.xbiom.com/modelmanagement?CrpID=10#modelsList

Test | Surya Padmini, Sowmya | 19-FEB-2024 2:04:25 PM (UTC +05:30) |  Business Base : Xbiom MDR

Model Templates

CRF

SDTM

ADaM

Therapeutic Area

Custom

Import History

Notifications

Study Models

Programming Templates

Mapping Templates

Terminologies

Folder Templates

Model Templates

Refresh

Create Model

Copy Model

Edit Properties

Delete

Obsolete

Activate

Diff Report

Blank Template

Export

Audit Trail Report

Q

		Source Model Type	Model Name	Tags	Model Status	Model Version	IG Version	IG Status
☐		CDASH	CDASHIG-2.1		Published	3.00000	CDASHIG-2.1 (CDASH-1.1)	Final
☐		ADaM	ADaMIG-OCCDS-1.1		Published	6.00000	ADaMIG-OCCDS 1.1	Final
☐		ADaM	ADaMIG-OCCDS-1.0		Published	5.00000	ADaMIG-OCCDS 1.0	Final
☐		ADaM	ADaMIG-MD-1.0		Published	4.00000	ADaMIG-MD 1.0	Final
☐		ADaM	ADaMIG-NCA-1.0		Published	3.00000	ADaMIG-NCA 1.0	Final
☐		ADaM	ADaMIG-1.3		Published	6.00000	ADaMIG 1.3 (ADaM 2.1)	Final
☐		SDTM	SDTMIG-3.4		Published	6.00000	SDTMIG 3.4 (SDTM 2.0)	Final
☐		SDTM	SDTM-2.0		Published	11.00000		
☐		SDTM	SDTM-1.8		Published	7.00000		
☐		ADaM	ADaMIG-1.2		Published	10.00000	ADaMIG 1.2 (ADaM 2.1)	Final
☐		SDTM	SDTMIG-PGX-1.0		Published	9.00000	SDTMIG-PGX 1.0	Final
☐		SDTM	SDTMIG-MD-1.1		Published	8.00000	SDTMIG-MD 1.1	Final
☐		SDTM	SDTMIG-MD-1.0		Published	9.00000	SDTMIG-MD 1.0 SDTMIG-MD 1.1	Final
☐		SDTM	SDTMIG-AP-1.0		Published	8.00000	SDTMIG-AP 1.0	Final
☐		SDTM	SDTMIG-3.3		Published	17.00000	SDTMIG 3.3 (SDTM 1.7)	Final
☐		SDTM	SDTM-1.7		Published	14.00000		
☐		ADaM	ADaMIG-1.1		Published	14.00000	ADaMIG 1.1 (ADaM 2.1)	Final
☐		SDTM	SDTMIG-3.2		Published	17.00000	SDTMIG 3.2 (SDTM 1.4)	Final
☐		SDTM	SDTM-1.6		Published	26.00000		
☐		SDTM	SDTM-1.4		Published	15.00000		
☐		SDTM	SDTMIG-3.1.3		Published	17.00000	SDTMIG 3.1.3 (SDTM 1.3)	Final

Total Count : 22

Managing SDTM models

Dashboard

Model Management

insightsaastest.xbiom.com/modelmanagement?CrpID=10#SDTM

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Model Templates

CRF

SDTM

ADaM

Therapeutic Area

Custom

Import History

Notifications

Study Models

Programming Templates

Mapping Templates

Terminologies

Folder Templates

Refresh

Create Model

Copy Model

Edit Properties

Delete

Obsolete

Activate

Diff Report

Blank Template

Export

Audit Trail Report

Q

		Source Model Type	Model Name	Tags	Model Status	Model Version	IG Version	IG Status
☐		SDTM	GLOBAL SDTM	#Global SDTM	Draft	2.00000R	SDTMIG 3.3 (SDTM 1.7) SDTMIG 3.4 (S...	
☐		SDTM	DS MODEL FOR SDTM 3.4	#globalSDTM	Draft	1.00000R	SDTMIG 3.4 (SDTM 2.0)	
☐		SDTM	SDTMIG-3.4		Published	6.00000	SDTMIG 3.4 (SDTM 2.0)	Final
☐		SDTM	SDTM-2.0		Published	11.00000		
☐		SDTM	SDTM-1.8		Published	7.00000		
☐		SDTM	SDTMIG-PGX-1.0		Published	9.00000	SDTMIG-PGX 1.0	Final
☐		SDTM	SDTMIG-MD-1.1		Published	8.00000	SDTMIG-MD 1.1	Final
☐		SDTM	SDTMIG-MD-1.0		Published	9.00000	SDTMIG-MD 1.0 SDTMIG-MD 1.1	Final
☐		SDTM	SDTMIG-AP-1.0		Published	8.00000	SDTMIG-AP 1.0	Final
☐		SDTM	SDTMIG-3.3		Published	17.00000	SDTMIG 3.3 (SDTM 1.7)	Final
☐		SDTM	SDTM-1.7		Published	14.00000		
☐		SDTM	SDTMIG-3.2		Published	17.00000	SDTMIG 3.2 (SDTM 1.4)	Final
☐		SDTM	SDTM-1.6		Published	26.00000		
☐		SDTM	SDTM-1.4		Published	15.00000		
☐		SDTM	SDTMIG-3.1.3		Published	17.00000	SDTMIG 3.1.3 (SDTM 1.3)	Final
☐		SDTM	SDTMIG-3.1.2		Published	17.00000	SDTMIG 3.1.2 (SDTM 1.2)	Final
☐		SDTM	SDTM-1.5		Published	16.00000		
☐		SDTM	SDTM-1.3		Published	13.00000		
☐		SDTM	SDTM-1.2		Published	13.00000		

Total Count: 22

Accessing and managing Global Mapping and Programming templates

Dashboard

Model Management

Curation & Transformation Faci

insightsaastest.xbiom.com/modelmanagement?CrpID=10#SDTM

MDR

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Model Templates

Study Models

Programming Templates

Mapping Templates

Terminologies

Folder Templates

Refresh

Create Model

Copy Model

Edit Properties

Delete

Obsolete

Activate

Diff Report

Blank Template

Export

Audit Trail Report

Q

		Source Model Type	Model Name	Obsolete/Active	Context		Validation Report	Approved Object Report	Created By
☒		SDTM	GLOBAL SDTM	Active	Other		Errors 2 Warnings 281	Errors 0 Warnings 280	padmini, sowmya
☐		SDTM	GLOBAL SDTM	Active	Other		Errors 0 Warnings 283		padmini, sowmya
☐		SDTM	GLOBAL SDTM	Active	Other		Errors 0 Warnings 247		padmini, sowmya
☐		SDTM	DS MODEL FOR SDTM 3.4	Active	Other		Errors 0 Warnings 1652	Errors 0 Warnings 1652	h, arpitha
☐		SDTM	SDTMIG-3.4	Active	Other				Administrator, System
☐		SDTM	SDTM-2.0	Active	Other				Administrator, System
☐		SDTM	SDTM-1.8	Active	Other				Administrator, System
☐		SDTM	SDTMIG-PGX-1.0	Active	Other				Administrator, System
☐		SDTM	SDTMIG-MD-1.1	Active	Other				Administrator, System
☐		SDTM	SDTMIG-MD-1.0	Active	Other				Administrator, System
☐		SDTM	SDTMIG-AP-1.0	Active	Other				Administrator, System
☐		SDTM	SDTMIG-3.3	Active	Other				Administrator, System
☐		SDTM	SDTM-1.7	Active	Other				Administrator, System
☐		SDTM	SDTMIG-3.2	Active	Other				Administrator, System
☐		SDTM	SDTM-1.6	Active	Other				Administrator, System
☐		SDTM	SDTM-1.4	Active	Other				Administrator, System
☐		SDTM	SDTMIG-3.1.3	Active	Other				Administrator, System
☐		SDTM	SDTMIG-3.1.2	Active	Other				Administrator, System
☐		SDTM	SDTM-1.5	Active	Other				Administrator, System
☐		SDTM	SDTM-1.3	Active	Other				Administrator, System

Total Count : 228 Selected Record(s) : 1



Thank you

Xbiom™ makes data useful

Quality is never an accident. It's always the result of intelligent effort -John Ruskin

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