

“Hermes SDD Platform Project”

***An integrated platform for
efficient standards
management
and
study conduct***

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Janssen (*Pharmaceutical companies of
Johnson & Johnson*)



DRIVE YOUR PERFORMANCE

Agenda

1

Introduction

2

Application Modules – Key Functionalities

3

Demo

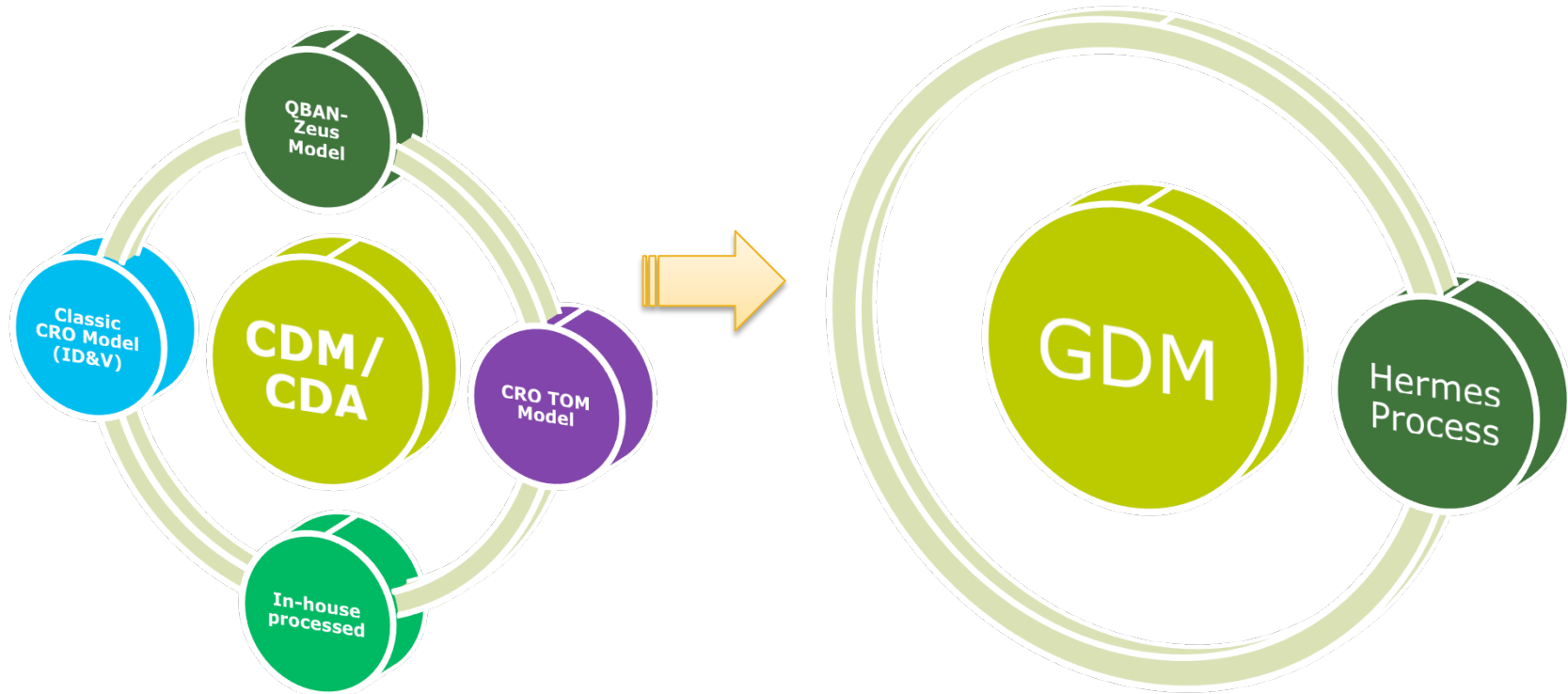
4

What does the future hold?

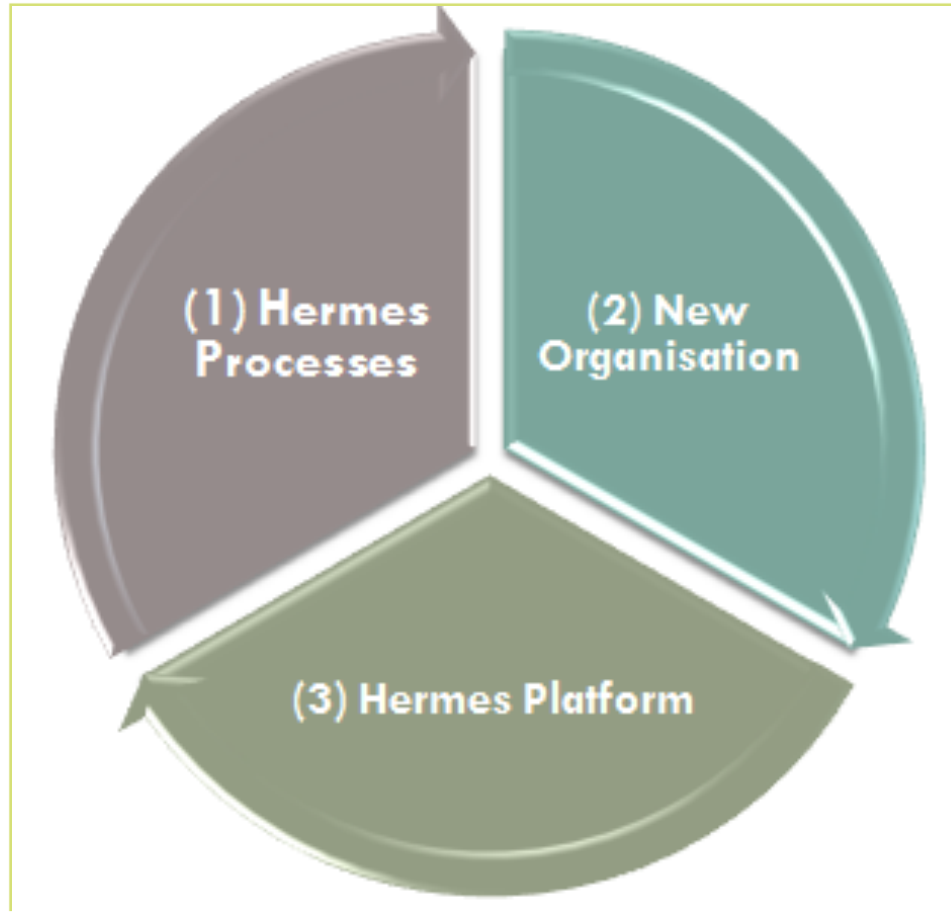
Janssen Hermes Project Strategy

Project HERMES objective

- ✓ In order to deliver against customer requirements, Hermes will design a global end to end approach to deliver quality data on time and within budget
- ✓ The Hermes project team will design and implement a future proof and deliverable based outsourcing model with internal J&J oversight and accountability

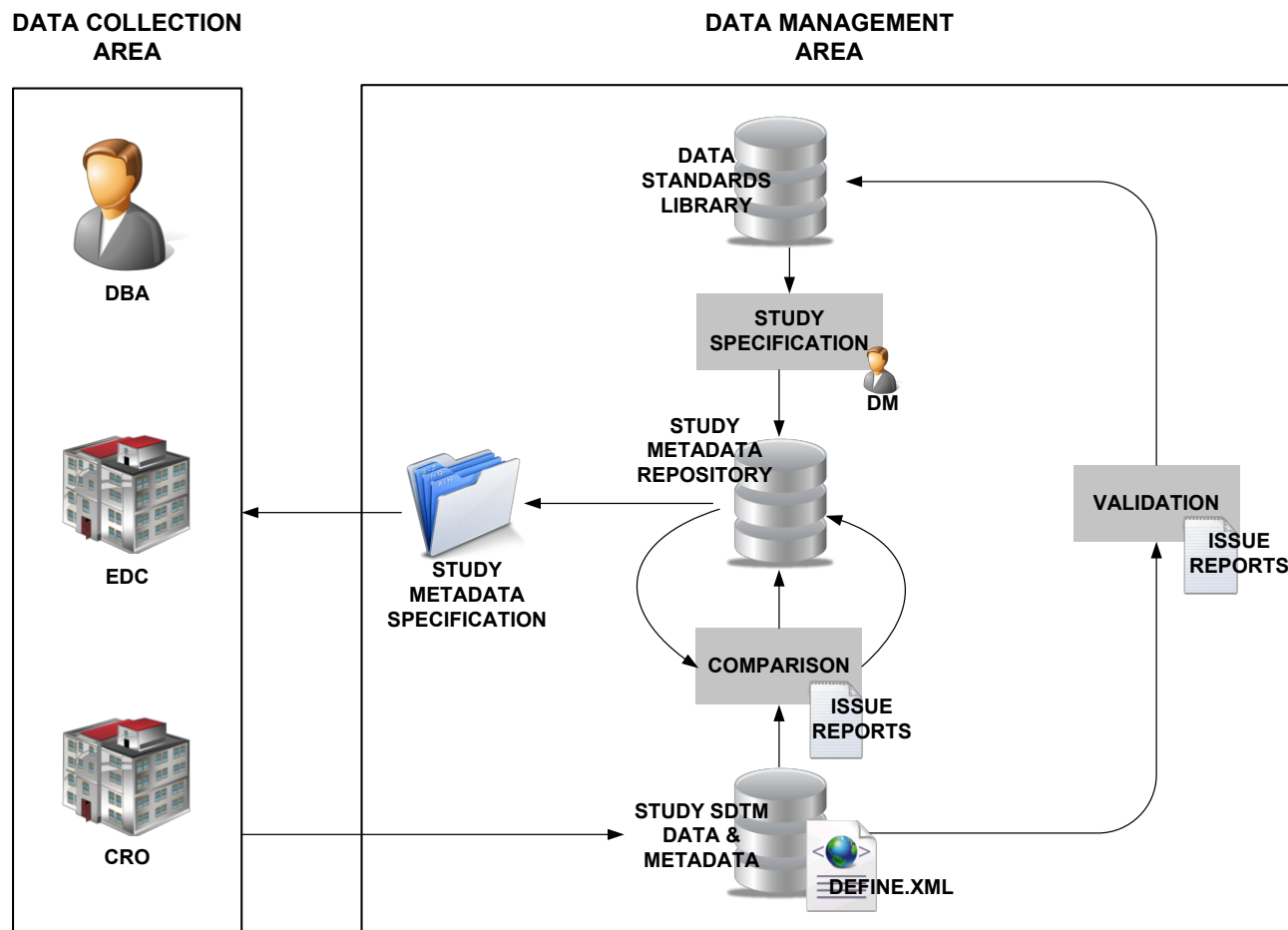


Janssen Hermes Project Strategy

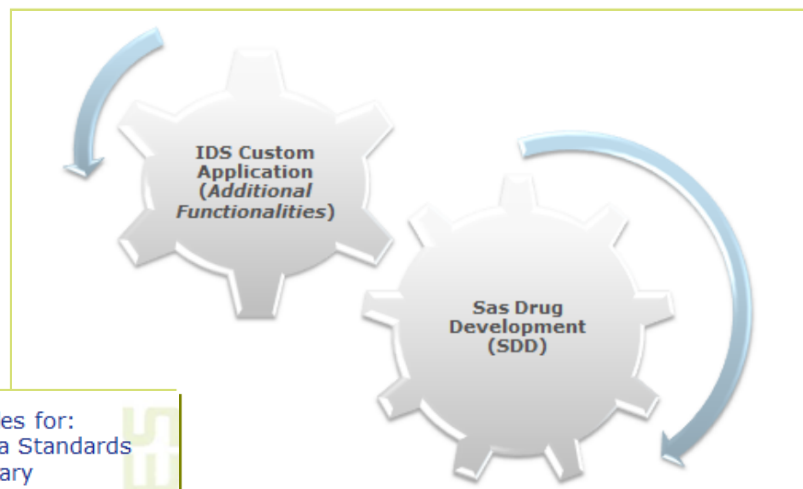


Platform: Process Overview

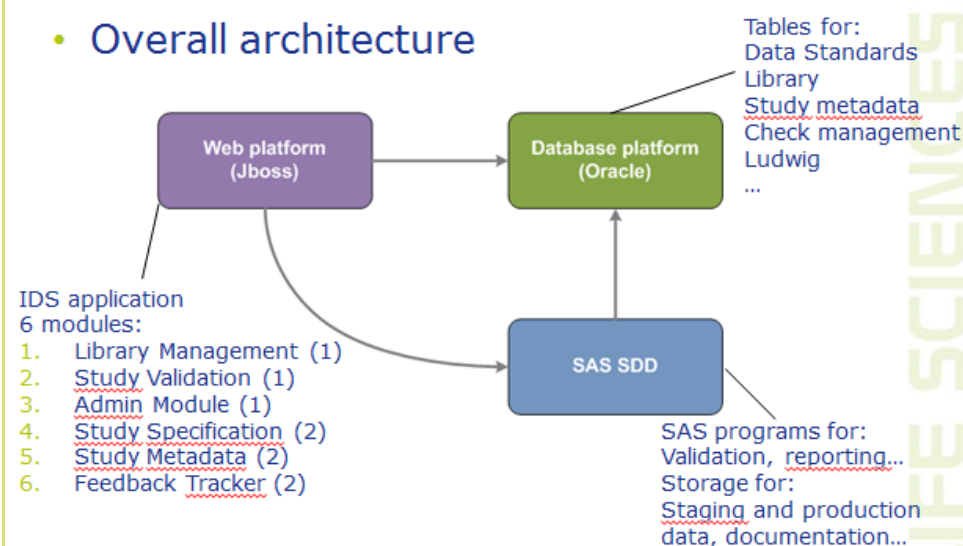
‘Data Standards Implementation Approach’



Platform: Partnering for Innovation



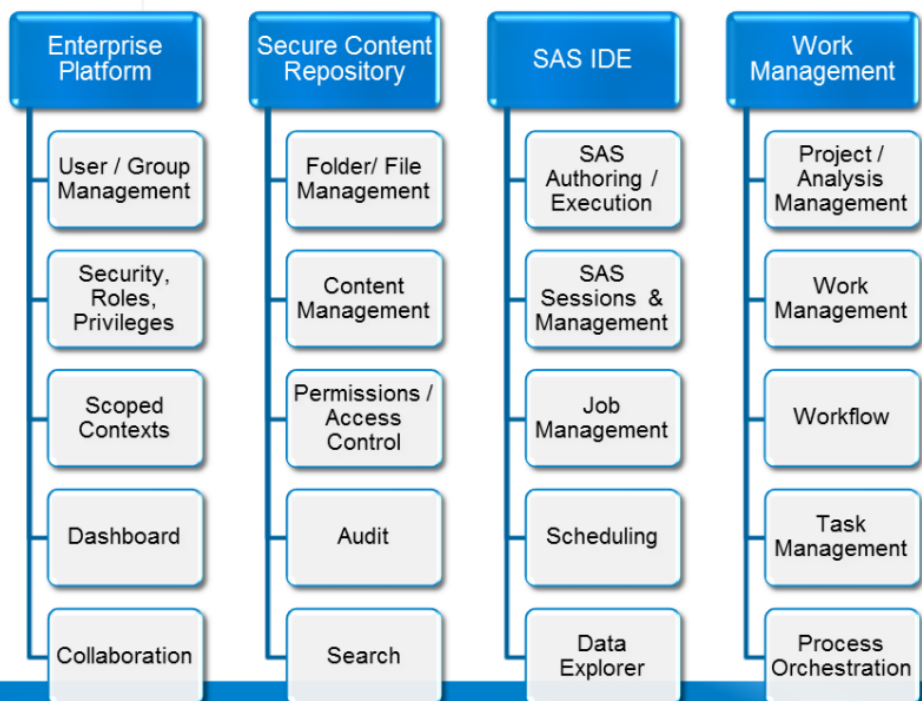
• Overall architecture



Platform: SDD Major Components

SAS DRUG DEVELOPMENT

MAJOR COMPONENTS



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sas THE POWER TO KNOW.

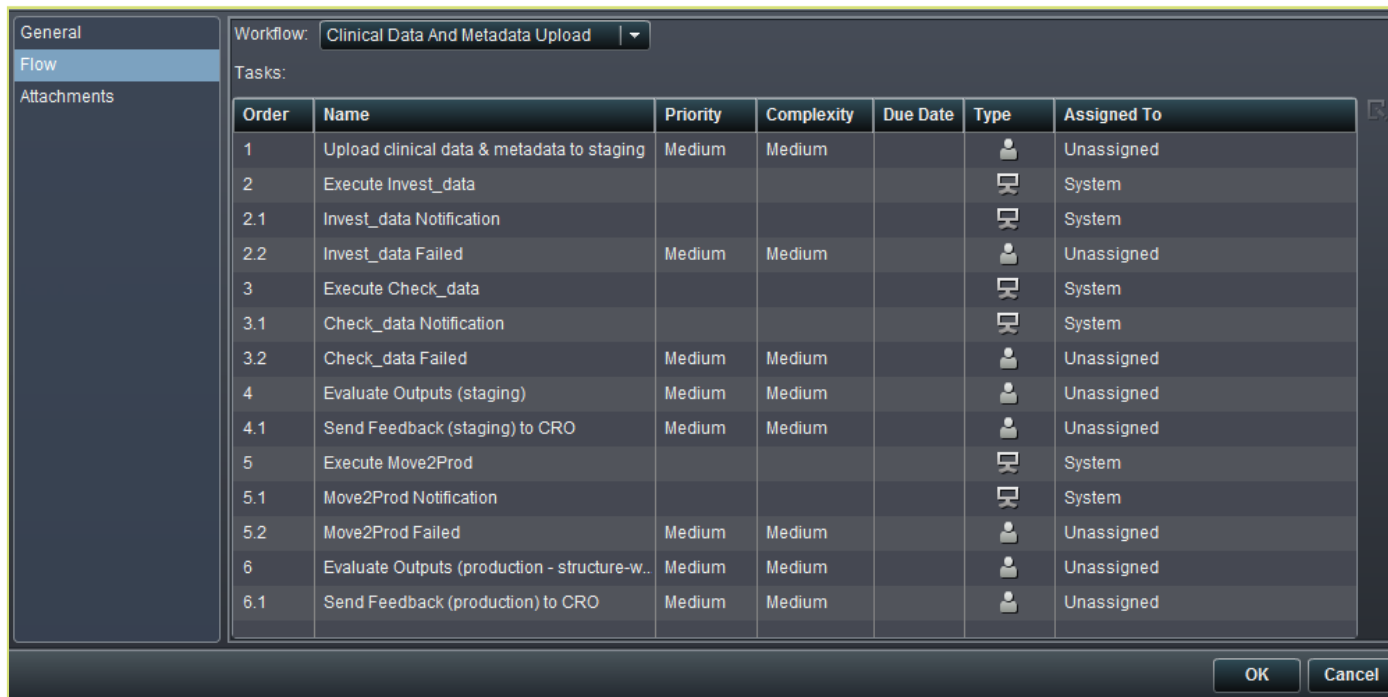
LIFE SCIENCES

Platform: SDD Major Components

Workflows

Workflow 1: Upload data and metadata into SDD
([screenshot below – example](#))

Workflow 2a: PK flow before database lock
Workflow 2b: PK flow after database lock

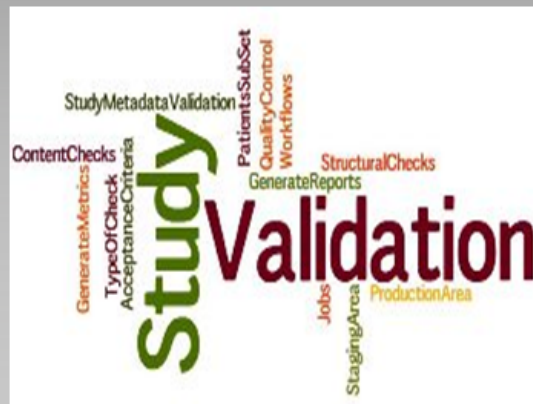


The screenshot displays a software interface for configuring workflows. On the left, a sidebar contains three tabs: 'General', 'Flow' (which is selected), and 'Attachments'. The main area shows a dropdown menu for 'Workflow:' set to 'Clinical Data And Metadata Upload'. Below this, a 'Tasks:' section contains a table with the following data:

Order	Name	Priority	Complexity	Due Date	Type	Assigned To
1	Upload clinical data & metadata to staging	Medium	Medium			Unassigned
2	Execute Invest_data					System
2.1	Invest_data Notification					System
2.2	Invest_data Failed	Medium	Medium			Unassigned
3	Execute Check_data					System
3.1	Check_data Notification					System
3.2	Check_data Failed	Medium	Medium			Unassigned
4	Evaluate Outputs (staging)	Medium	Medium			Unassigned
4.1	Send Feedback (staging) to CRO	Medium	Medium			Unassigned
5	Execute Move2Prod					System
5.1	Move2Prod Notification					System
5.2	Move2Prod Failed	Medium	Medium			Unassigned
6	Evaluate Outputs (production - structure-w..	Medium	Medium			Unassigned
6.1	Send Feedback (production) to CRO	Medium	Medium			Unassigned

At the bottom right of the interface are 'OK' and 'Cancel' buttons.

Platform: Application Modules



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What does the future hold?

Library Objects - Data Standards Library Module



Hermes SDD Platform

Standards Library | Specification Study | Metadata | Study Validation | Feedback Tracker | Administration

DCM | Domain | Variables | Computational Algorithm | Controlled Terminology | DVR | Reports

Domain

- CDASH Metadata
- SDTM Metadata

Code List

- Code Value
- VLM Name
- VLM Value

Completion Guidelines

- Implementation Guides

Import (xls) | New Item | With selection... | Default filter

1 2 25

Locked	Invalid	Consistency Check result	SDTM keys	Dataset	Description	Class	Struc
All	All	Text to filter		Text to filter	Text to filter	Text to filter	Text to filter

One record p
pharmacokin

Key Features of Data Standards Library Module

Key features **Data Standards Library Module**

- Versioning of the Library Objects
- Linking of the Library Objects
- Integrity Checks
- Consistency Checks
- Comparison Report

Versioning through dates

All records versioned through dates

- Fields 'Active from' and 'Active to'
- There can be no overlap of dates

Linking of Library Objects

DCM → **CDASH metadata***

CDASH metadata → **Domain***
→ **SDTM metadata**
→ **VLM/Code List**

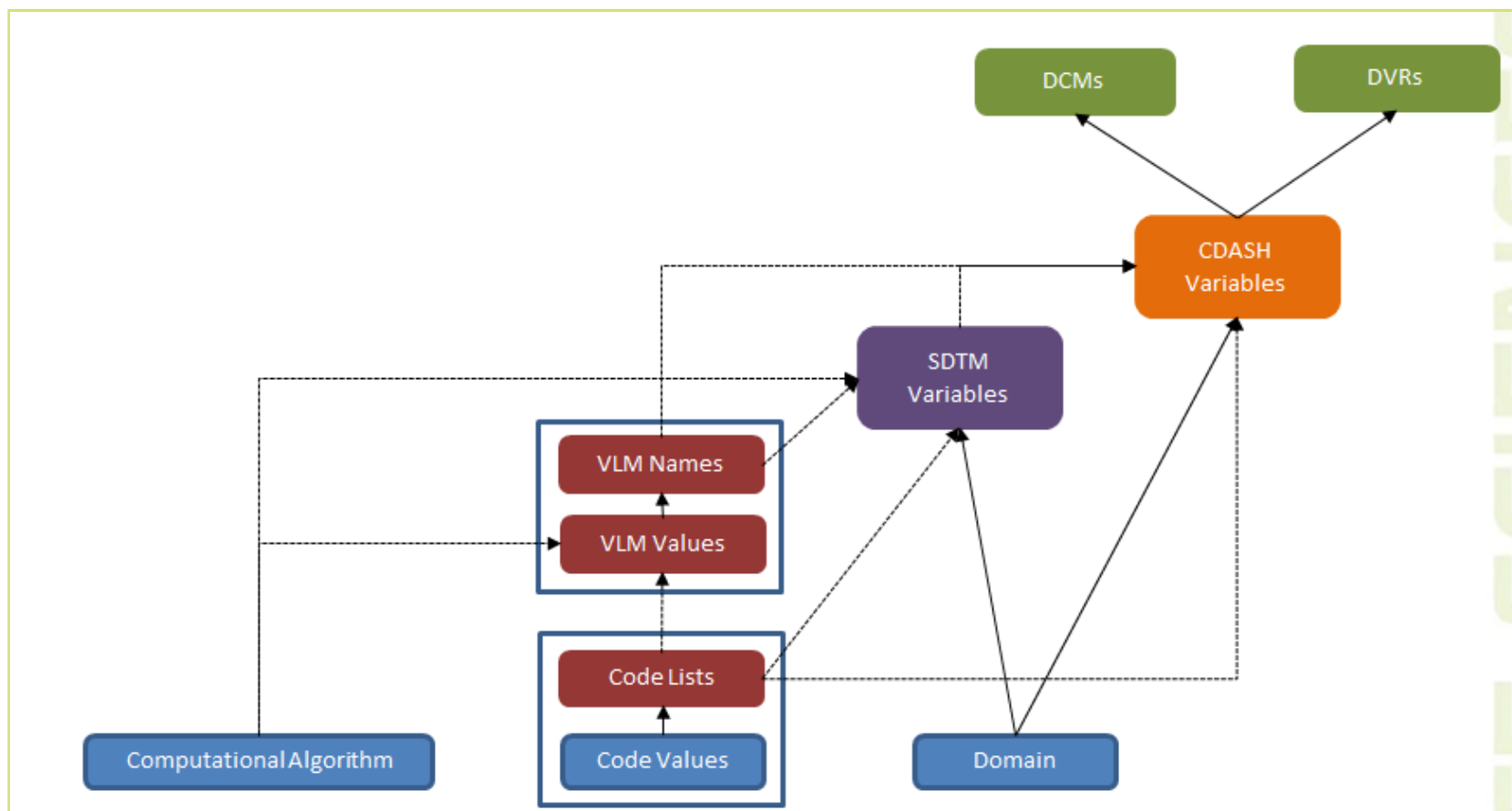
SDTM metadata → **Domain***
→ **Computational Algorithm**
→ **VLM/Code List**

VLM Name → **VLM Value***

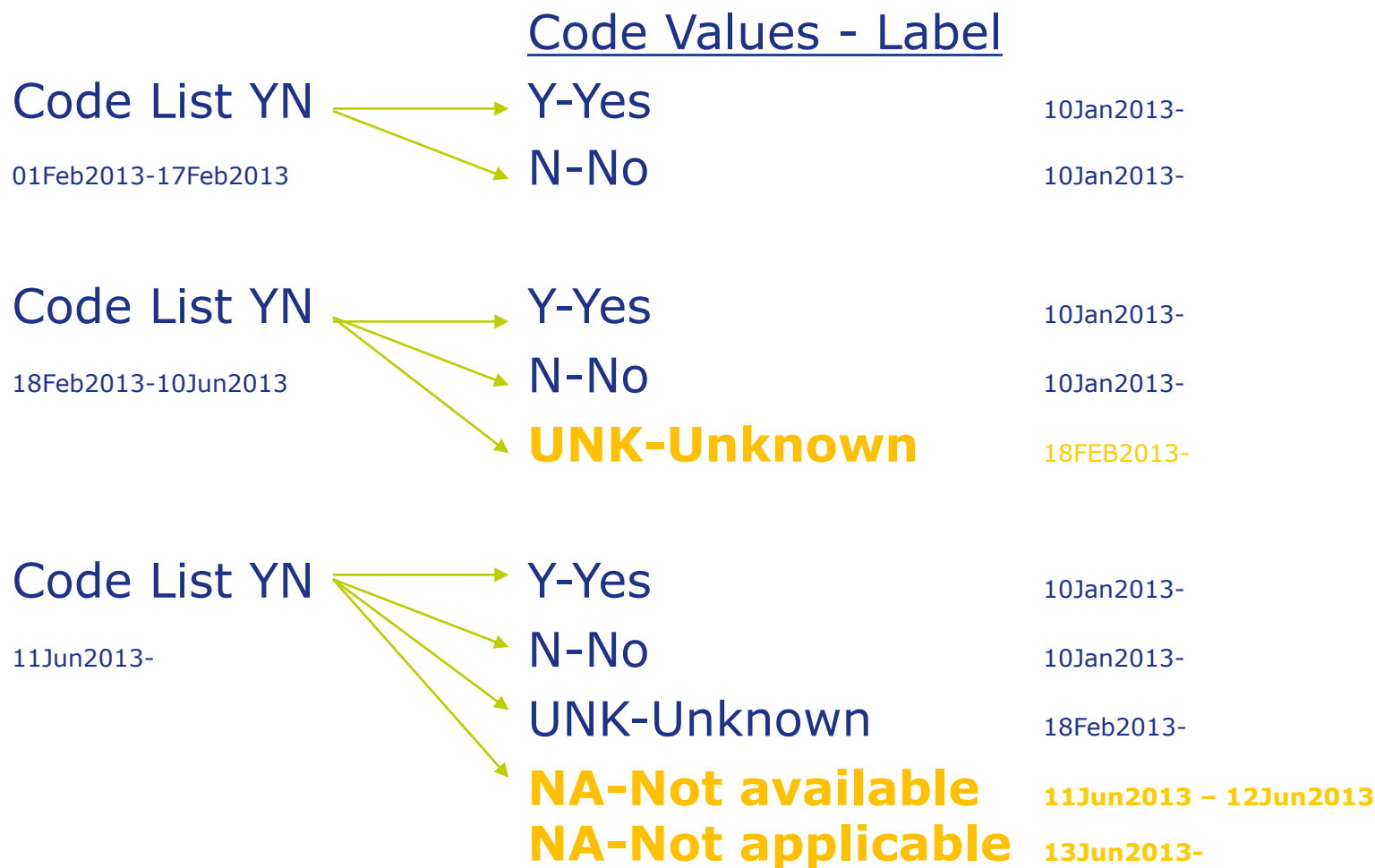
Code list → **Code Value***

(*) mandatory linking

Linking of Library Objects



Linking & versioning Example Codelist



Linking & versioning Example Codelist



Checks in the LM module

➤ Integrity Checks

System integrity checks will ensure that the system requirements per Library Object Type are met prior to promoting the library object to the repository.

➤ Consistency Checks

Programmatic checks to identify Library Objects that do not comply with applicable metadata rules.

Comparison reports in the LM module

➤ Comparison Reports

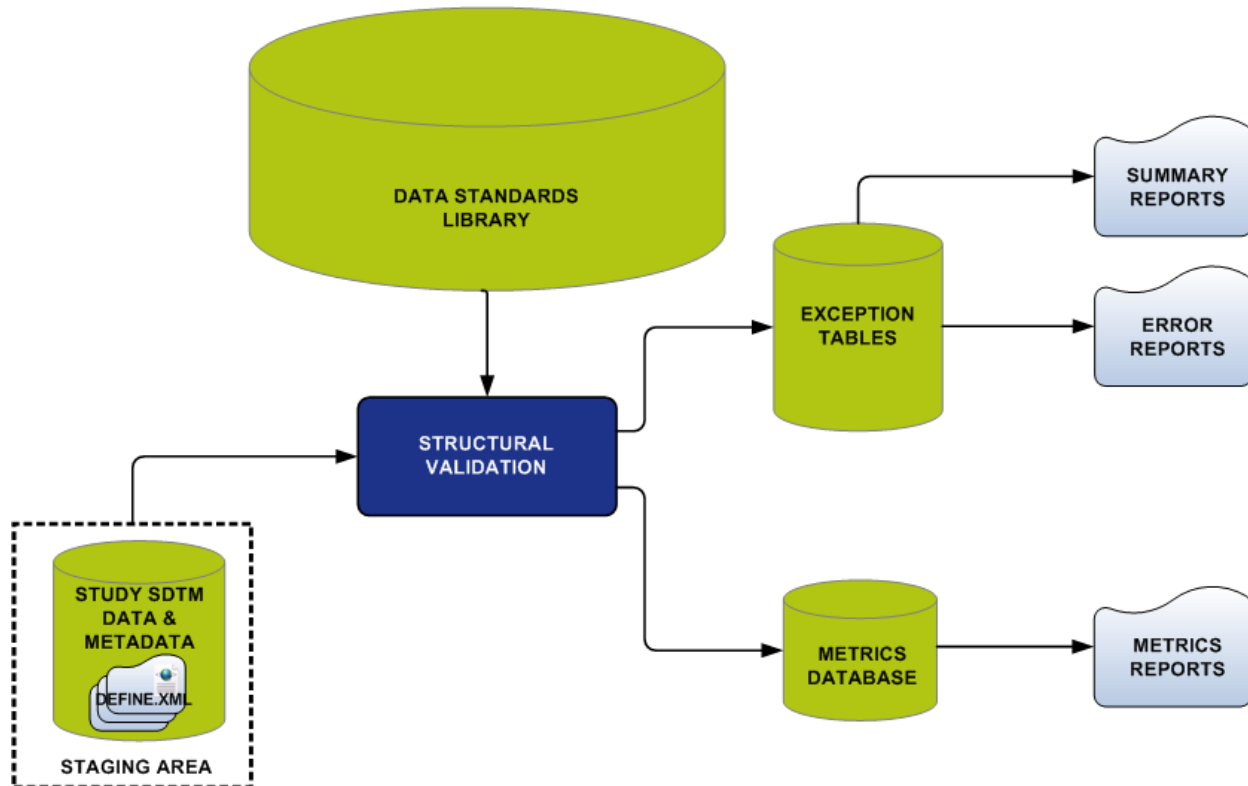
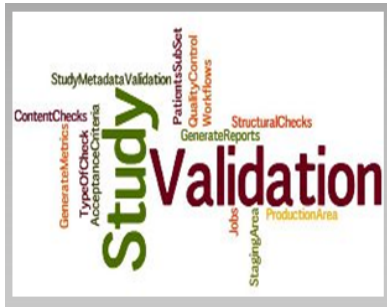
The comparison reports provide the possibility to report the differences between library object types from two different dates within one library.

CHECK	AID	DATASET	NAME	DESCRIPTION	DOMAINORDER	NAME	REFDATA	REPEATED	STRUCTURE	OLD	NEW
Ok	bd3f0432-7536-4afc-9cef-5a0ca3d292fd	SUPPCM	Relationship	Supplemental Qualifiers for CM	.	Tabulation	N	Y	One record per IDVAR, IDVARVAL, QNAM per subject	X	X
Ok	bd474f89-1e3e-4879-9343-e8968dba90d2	TE	Trial Design	Trial Elements	.	Tabulation	Y	N	One record per planned Element	X	X
Difference	e0567b90-93df-4766-a700-14388b0e2520	QS	Events	Questionnaires	.	Tabulation	N	N	One record per question per time point per visit per subject		X
Difference	e0567b90-93df-4766-a700-14388b0e2520	QS	Findings	Questionnaires	.	Tabulation	N	N	One record per question per time point per visit per subject	X	

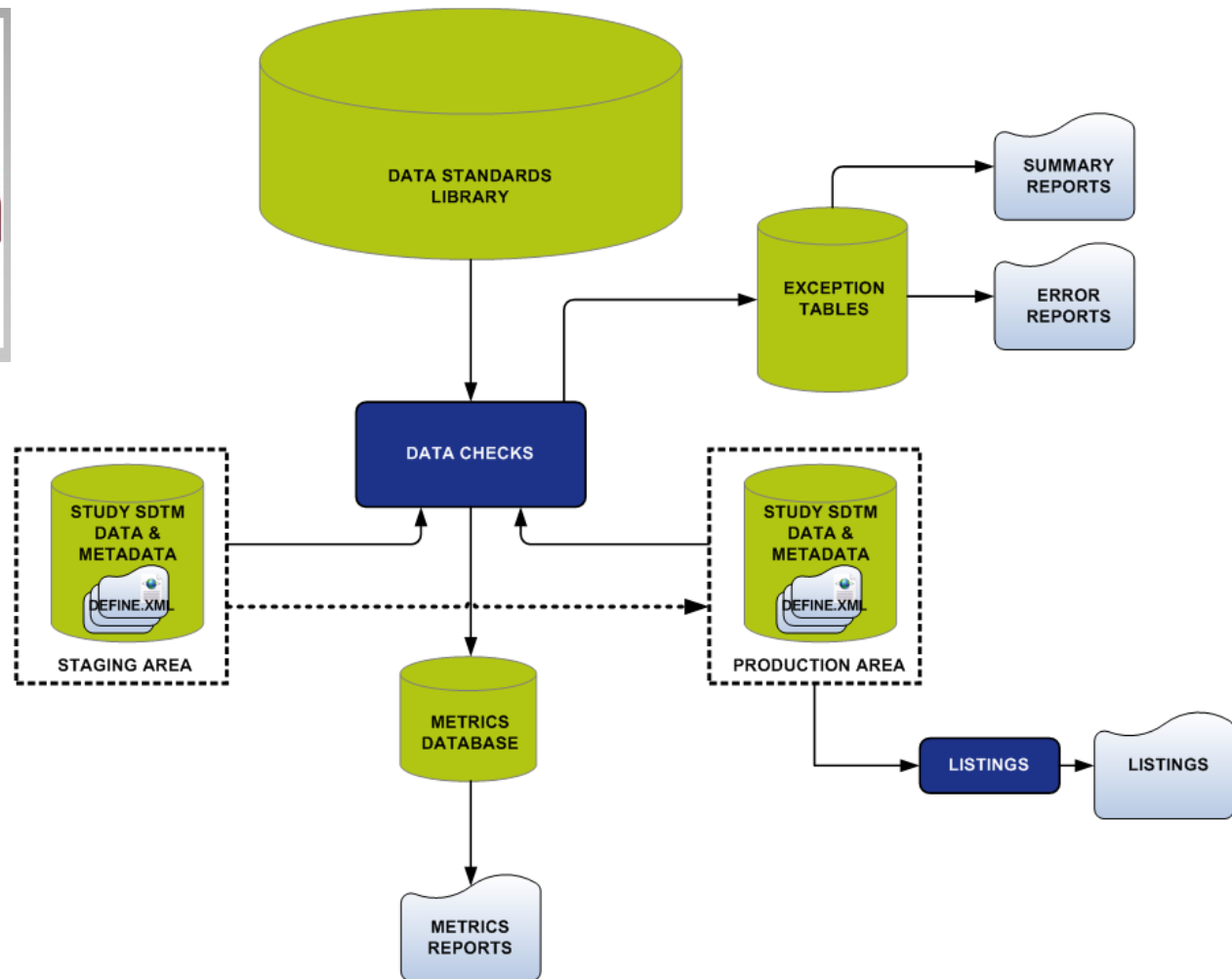
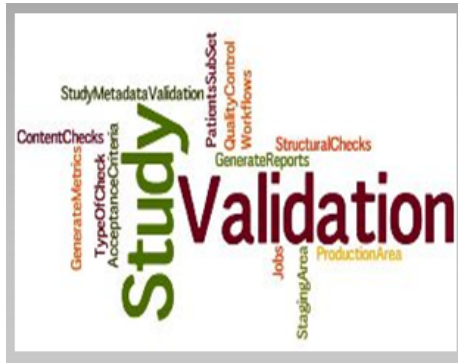
The comparison reports provide the possibility to report the differences between trial Define.XML and the library.

CHECK	SDTM_Value	SDTM_CodelistName	SDTM_Text	GLLIBRARY	DEFINEXML
Difference	%	UNIT	%		X
Difference	%	UNIT	Percentage	X	
Difference	%	UNIT	Percentage	X	

Study Validation Module - Structural Checks



Study Validation Module - Data Checks



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Custom Application Modules – Key Functionalities

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What does the future hold?

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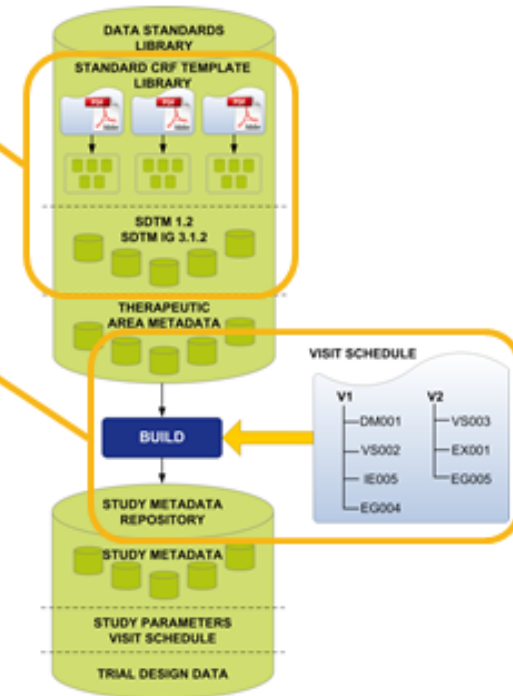
4

What does the future hold?

Platform: What does the future hold?



- **Global Standards Library:** metadata clusters corresponding to the CRF templates
- **Generation of study metadata by a *Pick & Select Module* requires:**
 - Visit/Time Point schedule & CRF Templates
 - Study Parameters
 - Trial Design Domains
 - Trial Arms (TA)
 - Trial Elements (TE)
 - Trial Inclusion/Exclusion Criteria (TI)
 - Trial Summary (TS)
 - Trial Visits (TV)



Platform: What does the future hold?



- Study Specifications Module

- Pick and Select Janssen DCM - Data Collection Modules
- Complete Visit & Time Point Information
- Complete XML parameter info
- Complete Trial Design Domains in close collaboration with Biostatistics & Reporting (BaR) Trial Summary (TS); Trial Criteria (TI); Trial Arms (TA); Trial Elements (TE); Trial Visits (TV)

Trial Design Visits **DCM** XML Parameters Study Build Study select

Successfully added The DCM was successfully added to the study

Data Collection Module (DCM)

Visit: Period 2_Day 1

Library: SDTM 3.1.2 A1 | 2

Domain: EX

DCM: - Select DCM -
EX_900

View DCM

Tick to Exclude	Question	Type	Order
☐	Start Date	BODY	11.0
☐	Start Time	BODY	12.0
☐	Treatment end date	BODY	13.0
☐	Treatment end time	BODY	14.0
☐	Was the dose administered?	BODY	15.0
☐	What was the reason the dose was not administered?	BODY	16.0
☐	Was the dose adjusted from planned?	BODY	17.0

TimePoint: PRE-DOSE

DCM order: 7

Add

Study overview

Copy from

	Visit	DCM	Questions	TPTNUM	TPT	TPTREF	ORDER
 	Screening	DM_900		1	PRE-DOSE	AM DOSE	1
 	Period 1_Day 1	AE_900		1	PRE-DOSE	AM DOSE	2
 	Period 1_Day 1	CM_900		1	PRE-DOSE	AM DOSE	3
 	Period 1_Day 1	CO_900		1	PRE-DOSE	AM DOSE	4
 	Period 1_Day 1	EX_900		1	PRE-DOSE	AM DOSE	5
 	Period 2_Day 1	AE_900		1	PRE-DOSE	PM DOSE	6
 	Period 2_Day 1	EX_900		1	PRE-DOSE	PM DOSE	7

Temporary build

Platform: What does the future hold?



- Study Metadata Repository Module

- Study Metadata build (automatically) based on Study Specifications
- Comparison of Study Metadata within a Trial (different versions)
- Comparison of Study Metadata between Trials
- Comparison of Study Metadata between Compounds
- Sharing of Study Metadata (Define.xml) with DM-CRO or other partners early in the Setup Phase

Study MetaData

Project:

Study:

Study version:

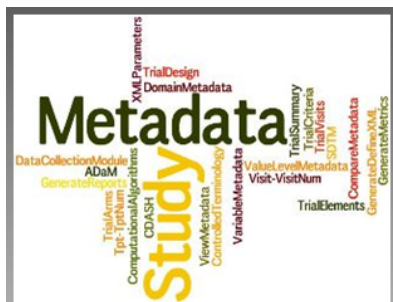
Run CreateDefine.job

Description:

Parameters:

Label	Value
The study name	AAAA-00001
The installation path	/SAS/Files/Global Files/Programs/Define Creator
The output folder	/SAS/Files/Global Files/Programs/Define Creator/Define Output

Platform: What does the future hold?



Run MetadataCompareStudies.job X

Description:

Parameters:

Label	Value
Path of the programs	/SAS/Files/Global Files/Programs/Comparison
Path of the report	/SAS/Files/Global Files/Programs/Comparison/Report
Metadata Level (DOMAIN,VARIABLE,CODELIST..	TABLE_METADATA
Name of the first study	AAAA-00001
Name of the second study	AAAA-00002
Name of source one	AAAA_00001
Name of source two	AAAA_00002

CHECK	DATASET	STRUCTURE	AAAA_00001	AAAA_00002
Ok	AE	One record per adverse event per subject	X	X
Difference	CM	One record per recorded intervention occurrence or constant-dosing interval per subject	X	
Difference	CM	One record per recorded intervention occurrence or constant-dosing interval per subject		X
Ok	CO	One record per comment per subject	X	X
Ok	DM	One record per subject	X	X

Platform: What does the future hold?



- Feedback Management Module

- Follow-Up on Output of Validation (manual and automated)
Automated Status Updates for Trial Oversight/Quality Control validation checks between different runs !
- Communication tool with our stakeholders (e.g. DM-CRO ...)
- Replaces Feedback Tracker (SharePoint) from Release 2 onwards.

Project : * Study : *

(1 of 6) 1 2 3 4 5 6 25

	Actions	Id	Modified Date	Status	Check	Sub Check Id	Description	ErrorMsg	Assigned Group	Assigner User	Documentation	Metadata Data Source	Severity	Iss
☐	view edit	100003	2013-07-30 13:09:20	NEW	Check1438		Check the dataset description in the define is consistent with SDTM Datasets.	The dataset description in the define is not consistent with the SDTM Dataset.					low	
☐	view edit	100003	2013-07-30 13:09:20	NEW	Check1438		Check the dataset description in the define is consistent with SDTM Datasets.	The dataset description in the define is not consistent with the SDTM Dataset.					low	
☐	view edit	100003	2013-07-30 13:09:20	NEW	Check1438		Check the dataset description in the define is consistent with SDTM Datasets.	The dataset description in the define is not consistent with the SDTM Dataset.					low	

Thank you for your attention

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