

InForm and DMW Standards End to End

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Reading, UK
June 2015

Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

Regulatory background

FDA Binding Guidance sets the clock running for 2017

- FDA Submission Guidance
 - SDTM Submissions: Binding by 2017
- FDA Submission Gateway
 - 75% of trials in SDTM by 2015
- FDA Data Standards Catalog
 - Support for SDTM 3.1.1 ended
 - SDTM 3.2 not yet supported
- PMDA to follow
 - PMDA binding guidance
- EMA

Providing Regulatory Submissions In Electronic Format — Standardized Study Data

Guidance for Industry

FDA Data Standards Catalog v4.3 (05-27-2015) - Supported and Required Standards

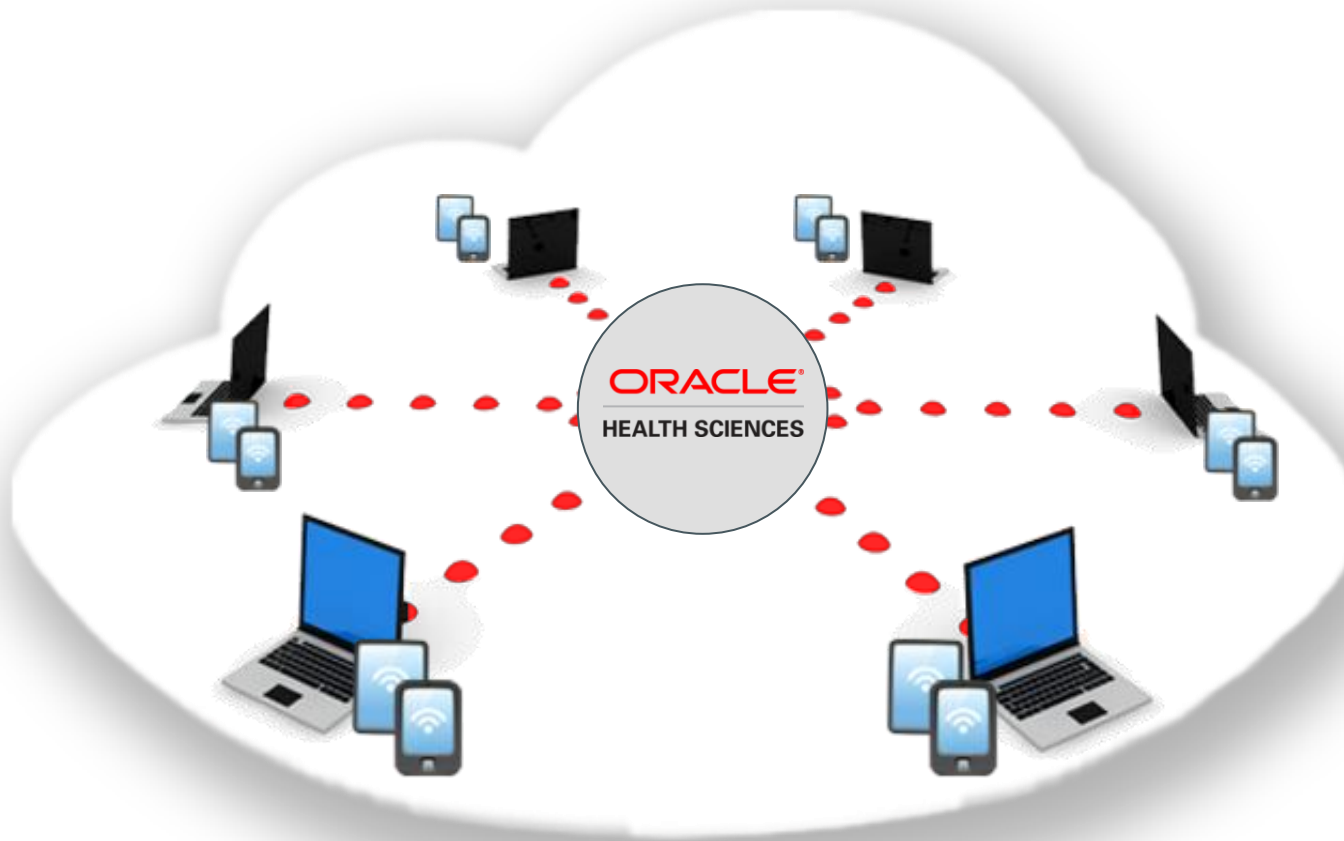
This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, *Providing Regulatory Submissions in Electronic format-Standardized Study Data* (<http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf>). A separate catalog will be published in the future that will contain a listing of standards that are in the development, testing, adoption or research & development (R&D) phases.

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Regulatory Reference and Information Sources
Clinical study datasets	Study Data Tabulation Model (SDTM)	XPT	Clinical Data Interchange Standards Consortium (CDISC)	1.3	3.1.3	CDER, CBER	12/01/2012		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	30/10/2009		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.1	3.1.1	CDER, CBER	Ongoing	01/28/2015	12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC	2.1	1.0	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - ADaM

December 2014
Electronic Submissions

Oracle Health Sciences InForm

Integrated into the secure and scalable Oracle Health Sciences Cloud



Global performance, scalability, and security



HIPAA certification



Enables 21 CFR Part 11 compliance



Optimized for each individual customer



Secure data and application management across organizations and geographies



Scale from smallest to largest enterprises

Cloud services built for life sciences applications. Owned and managed by Oracle.

Comprehensive Support for CDISC Standards

Speeds trial setup, increases efficiency and data quality, and ensures compliance

- CDISC Registered Solutions Provider for:
 - ADaM
 - CDASH
 - Define-XML
 - ODM
 - Study/Trial Design Model
 - LAB
 - SDTM
- CDISC ODM certified
 - ODM data import API
 - ODM-based clinical data exchange
 - ODM-based study design metadata exchange
- Member and active participant of:
 - CDISC Advisory Council
 - European CDISC Coordination Committee (E3C)
 - CDISC UK Network
 - CDISC technical teams e.g. Define-XML and Protocol Representation

Oracle Central Designer CDASH Library

Completely customizable library includes all 16 domains

- Quickly set up studies with ready-to-use CDASH Library
- Use the standardized library to securely edit and build upon
- Facilitate compatibility with the CDISC SDTM Submission Standard

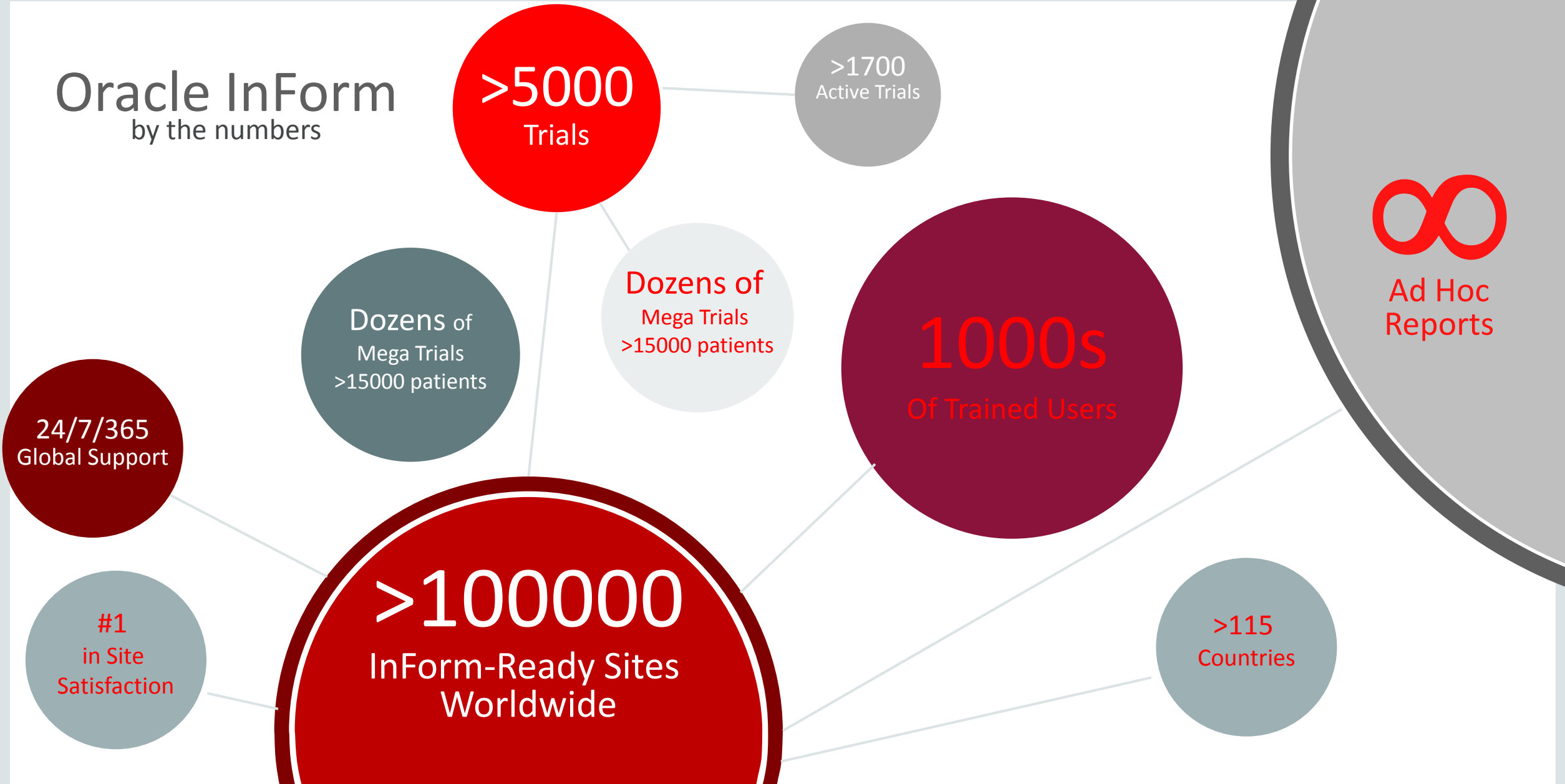
The screenshot displays the Oracle Central Designer interface for designing an 'Adverse Event' form. The main window shows a form with fields for 'Were any Adverse Events Experienced?', 'AE Number', 'Adverse Event', 'Start Date', 'Start Time', 'End Date', 'End Time', 'Is this AE ongoing?', 'Severity', and 'CTC Grade'. A 'Preview Annotated Form' window is overlaid, showing a table with columns for 'Any AEs Experienced?', 'AE Number', 'Adverse Event', 'Start Date', 'Start Time', 'End Date', 'End Time', 'Ongoing', 'Severity', 'CTC Grade', 'Serious Event', 'Serious - Congenital Anomaly', and 'Serious - Disability'. The preview table contains data for a specific adverse event, including a start date of 2008-2010 and a start time of 24-hour clock.

Significantly cut study build time and help ensure adherence to standards.



Oracle InForm

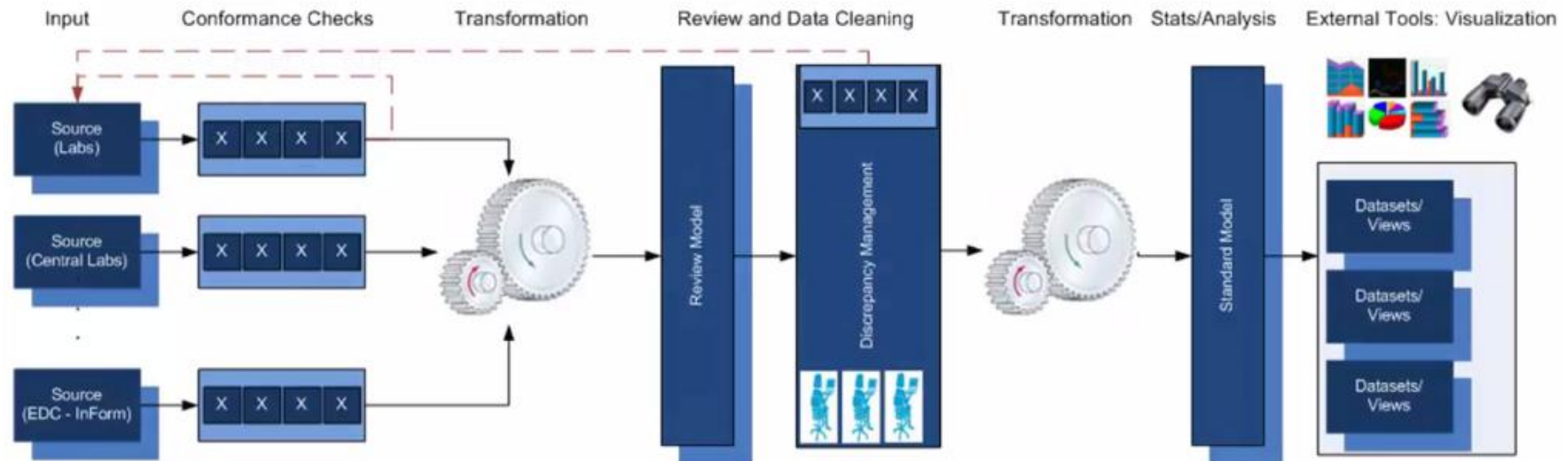
by the numbers



Oracle Health Sciences Data Management Workbench (DMW)

Fully integrated end-to-end clinical data management solution

- Accelerates trial conduct and submissions, improves data quality, and reduces development cost by automating manual processes required to load, transform, and clean trial data
- New per trial licensing model: DMW Enterprise (DMWE)



Oracle DMW Study Definition

Load InForm data

- Seamless Integration with InForm:
 - Minimal Set Up
- Incremental Loads
 - DMW can be set to check for new data every 15 minutes
- Full Change Control:

ORACLE[®] DMW DMW Sales Demo Study 04Mar2015 (Cardiology) Development

The screenshot displays the Oracle DMW Study Configuration interface. The main window is titled "Clinical Data Model : 01 Inform". It shows the following details:

- Version: 2
- Validation Status: Development
- Model Type: Input
- Status: Installable
- Checked-Out Status: Checked In
- Checked-Out by:
- Install Job Status: Success
- Installed Status: Success
- Installable Version: 2

Below the details, there is a "Tables" section with an "InForm Configuration" tab. A table lists the following data:

Table Name	Oracle Name	SAS Name	SAS Label	Aliases	SDTM Identifier
AE	AE	AE	AE		
CHD	CHD	CHD	CHD		
CHEM	CHEM	CHEM	CHEM		
CM	CM	CM	CM		
CONT	CONT	CONT	CONT		
DEATHREP	DEATHREP	DEATHREP	DEATHREP		
DM	DM	DM	DM		
SSOC	DMW_FORM_ASSOC	DMW_FORM_ASSOC	DMW_FORM_ASSOC		
DOSE	DOSE	DOSE	DOSE		

Metadata Comparison Report

All required metadata in InForm Data Model : 01 InForm - Development and InForm Trial : SDECARDIODMW710UID - UAT are the same.

OK

Oracle DMW Data Cleaning

Integration with InForm

- DMW Data Cleaning is tightly integrated with InForm:
- Queries raised in either application can be closed in either
 - DMW discrepancies can be sent back to InForm after DM review
 - Inform discrepancies are visible in Listings for all Data Models

ORACLE[®] DMW DMW Sales Demo Study 04Mar2015 (Cardiology) Development

Home | Listings | Discrepancies | Study Configuration | Library | Administration

ModelName: 01 Inform

Default Listing: AE

Showing rows from 1 to 28. Estimated row count: 47

Page 1 of 2

	AETERM	AETERM_ND	AETERMEN	AETERMEN_ND	AETERMJP	AETERMJP_ND	AESTDTC
	Fever		Fever				5/4/2013
	Upper GI Pain		Upper GI Pain				5/5/2013
	頭痛				頭痛		4/30/2013
	Constipation		Constipation				5/15/2013
	Rash on left arm		Rash on left arm				5/20/2013
	Acute Pain in left knee		Acute Pain in left knee				5/20/2013
	Headache		Headache				4/8/2013
	Fever		Fever				3/28/2013
	Back Pain		Back Pain				5/1/2013
	Shortness of Breath		Shortness of Breath				4/15/2013
	Abdominal pain		Abdominal pain				4/25/2013
	Acute Myocardial Infarction		Acute Myocardial Infarction				4/12/2013

Oracle DMW Consolidation and Transformation

Powerful transformation interface

- InForm and External Data can be transformed in DMW
 - To aid data review
 - To prepare data for Submission or Visualization
- Wide range of transformations including pivot / unpivot and custom programs
- Automapping feature for tables and variables
- Data can be transformed multiple times
- End to end traceability allows discrepancies to be routed to InForm even when the data has been transformed

Oracle DMW Validation Checks

Complex Validation Checks made simple

- DMW can create complex Validation Checks
- Validation Checks can span data sources
- InForm discrepancies include link to source
- Validation Queries are automated in batches
 - can be directly routed to InForm or extracted to Excel and sent to data provider

Detail ⓘ

Subject	013-004	Days in State	1
Visit	AE/CM	Category	From InForm
Discrepancy	DMW8430;Please check date Created by CLAUDIO.GARUTTI@ORACLE.COM	Created	DMW_QUERY (InForm) 04-Mar-2015 04:15:03 PM
Table	AE	Modified	DMW_QUERY (InForm) 04-Mar-2015 04:15:03 PM
Model	01 InForm	Tag	
Item	AESTDTC	New Data	No
Value	12-APR-13	View Query in InForm	
State	Open	View Data in InForm	

Home | Listings | Discrepancies | Study Configuration | Library | Administration

Studies

Filter Studies:

Model: 01 InForm

Validation Check Batches for Model: 01 InForm

View

Batch Name	Description	Ordered?	Can be Triggered?	Version	Upgradeable	Reason	Installed	Install Job Log	Installed
CM_Checks		No	Yes	1	No		Yes		Success

Oracle DMW Medical Coding

Integration with Oracle TMS

- Assign dictionaries for AE / MH / CM
- Terms are applied when data is transformed
- Omission management in DMW

Discrepancy Management

Discrepancies on blinded cells are not displayed. Use the Unlock icon (Show Sensitive Data) to see them.

Tg	St	Discrepancy Id	Subject	Visit	Discrepancy	Latest Comment	Table	Item	Validation-Check	Days in State
		8136	013-002		Pain YN	Needs site to correct AE		AETERM	Pain YN	22
		18582	013-002	AE/CM	This study excludes subjects suffering chronic Pain		AE	AETERM	AE001	6

Detail

Subject 013-002
Visit AE/CM
Discrepancy This study excludes subjects suffering chronic Pain. Please confirm Pain reported is not chronic
Table AE
Model 01 InForm
Item AETERM
Value Back Pain
State Candidate

Days in State 6
Category QC:Protocol Violation
Created MIKE.COLLINSON@ORACLE.COM 11-Mar-2015 12:53:22 PM
Modified MIKE.COLLINSON@ORACLE.COM 11-Mar-2015 01:02:40 PM
Tag NeedsDMReview
New Data No
View Data in InForm

History

Action Name	Comment	State	Tag	User
Create Discrepancy	This study excludes subjects suffering chronic Pain. Please confirm Pain reported is not chronic	Candidate		MIKE.COLLINSON@ORAC

Add Study

Study Details TMS

Oracle Thesaurus Management System
Domain Elements

View Force Rederivation Detach

TMS Base Terminology	TMS Domain	Terminology
Meddrapp	MedDRa latest ver	Meddrapp
Who-Drug	Who-Drug	Who-Drug

OK Cancel

Oracle DMW Protects Sensitive Data Throughout

Data Blinding / Unblinding

- Data blinding maintained throughout the system as the data are transformed
- Accessing the data in any model will prompt the user to confirm the blind break
- Blinding privileges are based on user role
- Blind break is audited in the system
- Data remains blinded in downstream systems

mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	xxxxx	1	15
xx	xx	QD	TRANSDERMAL	WEEK 2	4	14	xxxxx	16	56
mg	PATCH	QD	TRANSDERMAL	WEEK 24	12	168	xxxxx	169	
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	xxxxx	1	
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	xxxxx	1	
mg	PATCH	QD	TRANSDERMAL	WEEK 24	12	168	xxxxx	174	
xx	xx	QD	TRANSDERMAL	WEEK 2	4	14	xxxxx	20	
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	xxxxx	1	
xx	xx	QD	TRANSDERMAL	WEEK 2	4	14	xxxxx	16	16
xx	xx	QD	TRANSDERMAL	WEEK 2	4	14	xxxxx	18	16
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1			

Confirmation

Do you want to access the blinded data?

Yes No

mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	2013-11-14	1
mg	PATCH	QD	TRANSDERMAL	WEEK 2	4	14	2013-12-11	16
mg	PATCH	QD	TRANSDERMAL	WEEK 24	12	168	2013-08-09	169
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	2013-02-15	1
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	2013-11-07	1
mg	PATCH	QD	TRANSDERMAL	WEEK 24	12	168	2013-11-03	174
mg	PATCH	QD	TRANSDERMAL	WEEK 2	4	14	2013-06-13	20
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	2014-01-01	1
mg	PATCH	QD	TRANSDERMAL	WEEK 2	4	14	2013-12-05	16
mg	PATCH	QD	TRANSDERMAL	WEEK 2	4	14	2014-08-30	18
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	2013-07-16	1

Oracle DMW Traceability

Transformations and Data Lineage

- End to End traceability allows data to be traced through transformations

STUDYID	DOMAIN	USUBJID	AESEQ	AEGRPID	AEREFID	AESPID	AETERM	AEMODIFY	AELLT	AELLTCD	AEDECOD
Study 06Feb2015	AE	35490	1	1			Sinus Conqestion	Sinus Conqestion	Sinus conqestion	10040742	Sinus conqestion

Name	Is Masked	Is Staging	Value	Datatype	Preferred Path	Primary Key
20 SDTM.AE.AETERM			Ear Ache	VARCHAR2(200)	No	STUDYID:Study 06Feb2015,USUBJID:35490,AE
01 InForm.AE.AETERM			Ear Ache	VARCHAR2(200)	Yes	SUBJECTID:35490,VISITID:9365,VISITINDEX:1,

- Enables discrepancies to be raised on any model and sent back to source
- Simplifies blank CRF annotation
- Simplifies define.xml

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt	
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dgm.xpt	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide

Oracle DMW Methods of Adoption

InForm2DMW Quick Start – a single point of contact for combined services

- A new way of engaging with our software and services
- DMW, LSH and TMS, hosted in the Oracle Cloud, configured by HSC and supported by SaaS Services under a combined Service Description
- Pricing aligned to size, length and complexity, simplified by Accelerators
- Get up and running today with SDTM accelerator
 - Additional accelerators to be added
- Accelerators also available for HSC on premise / Enterprise Adoption model

InForm2DMW Quick Start SDTM Libraries

Completely customizable library includes all versions, up to 43 domains

- Quickly set up studies with ready-to-use SDTM Libraries
- Use the standardized library to securely edit and build upon, without affecting existing studies
- Facilitate submissions in CDISC SDTM

Significantly cut study build time and help ensure adherence to standards.

The screenshot displays the InForm2DMW software interface. The main window shows the 'Library Data Model' section with a list of models on the left and a table of tables in the center. The 'Add Clinical Data Model' dialog box is open on the right, showing configuration options for a new model.

Library Data Model

Therapeutic Area: Global Standards

Filter Library Data Models:

- SDTM 3.1.1x
- SDTM 3.1.2x
- SDTM 3.1.3x
- SDTM 3.2x
- SubjectVisit

Library Data Model

SDTM 3.1.1x

Version: 1

Validation Status: Development

Tables

Table Name	Oracle Name	SAS Name
AE	AE	AE
CM	CM	CM
CO	CO	CO
DM	DM	DM
DS	DS	DS
EG	EG	EG
EX	EX	EX
IE	IE	IE

Columns Hidden: 1 | Columns Frozen: 1

Columns

Column Name	Order	Oracle Datatype
STUDYID	1	VARCHAR2
DOMAIN	2	VARCHAR2
USUBJID	3	VARCHAR2

Add Clinical Data Model

* Clinical Data Model: SDTM 3.1.2

Description: SDTM 3.1.2 Data for Submission

* Model Type: Target

Input Type: InForm

File Input Type: SAS TEXT

Select from Source

None

Load from file

Library Data Model

Study Data Model

Therapeutic Area	Library Data Model
Cardiology	Central Lab
Allergy	Central Lab
Cardiology	Labs
Oncology	Metadata Change Test
Cardiology	Review Model
Cardiology	SDTM 3.1.2

Business Area

Business Area:

Business Area Schema Name: BA_SD TM 3.1.2

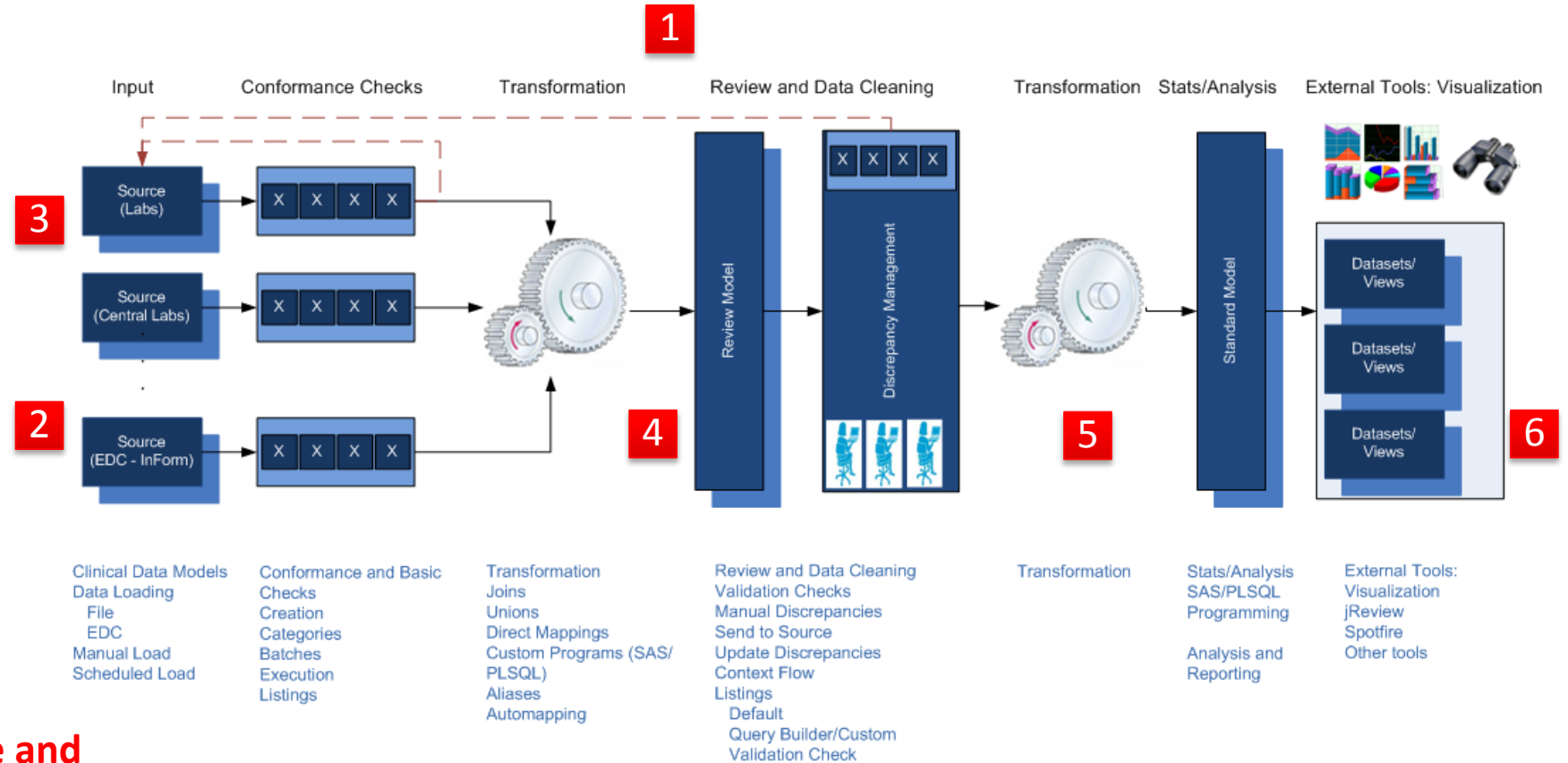
OK Cancel



InForm2DMW Quick Start

HSC and SaaS continue to expand on standards based accelerators

1. Security
2. CDASH Input
3. Laboratory Data
4. Review Model
5. SDTM Models
6. Data Extract



Significantly cut study build time and help ensure adherence to standards.



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