

ORACLE®

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.

Software to Support eSubmissions

- 1 Study Closeout, Submission and Decommissioning in InForm
- 2 InForm and Data Management Workbench (DMW)
- 3 DMW Value Add
- 4 DMW Traceability, Medical Coding, Libraries and Templates
- 5 DMW Study Closure and Data Extract

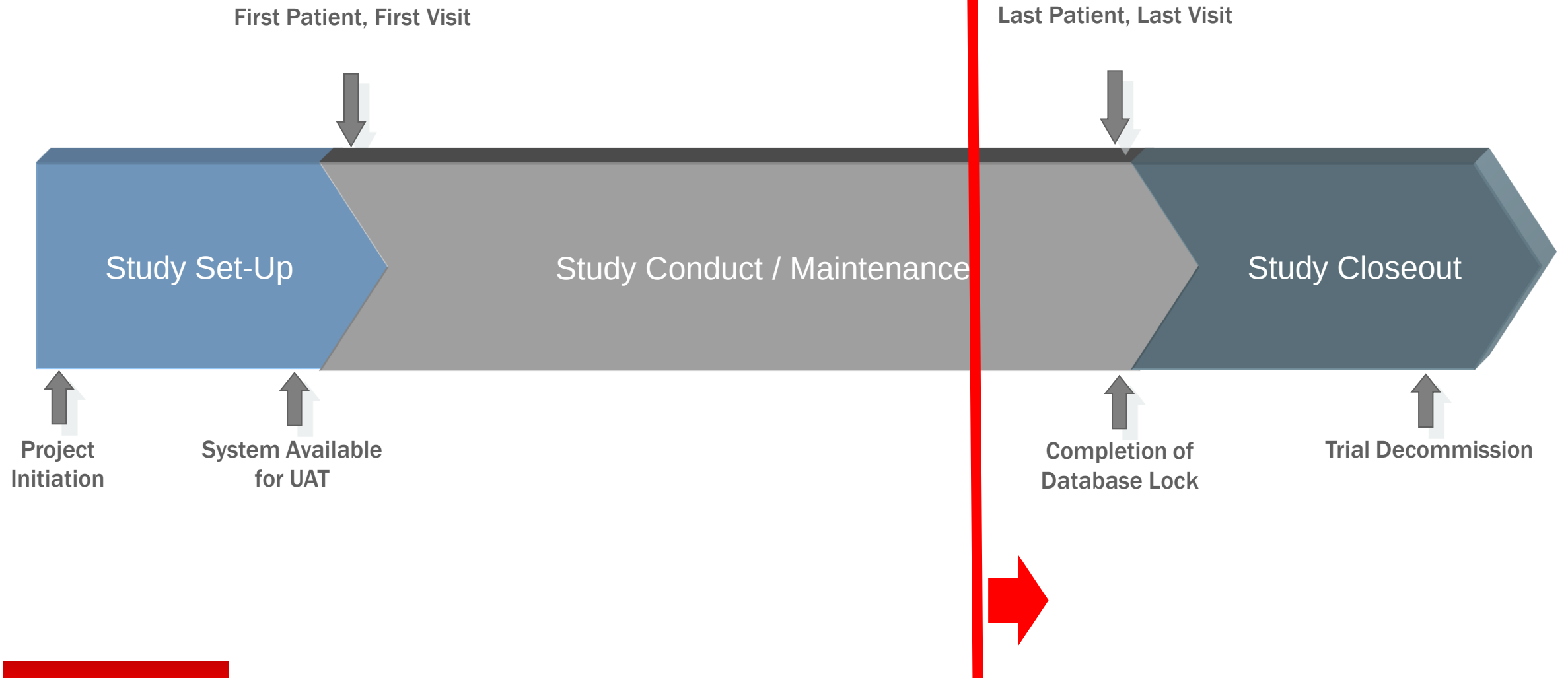
Software to Support eSubmissions

Ben Parkes, Directing Project Consultant
Mike Collinson, Life Sciences Architect

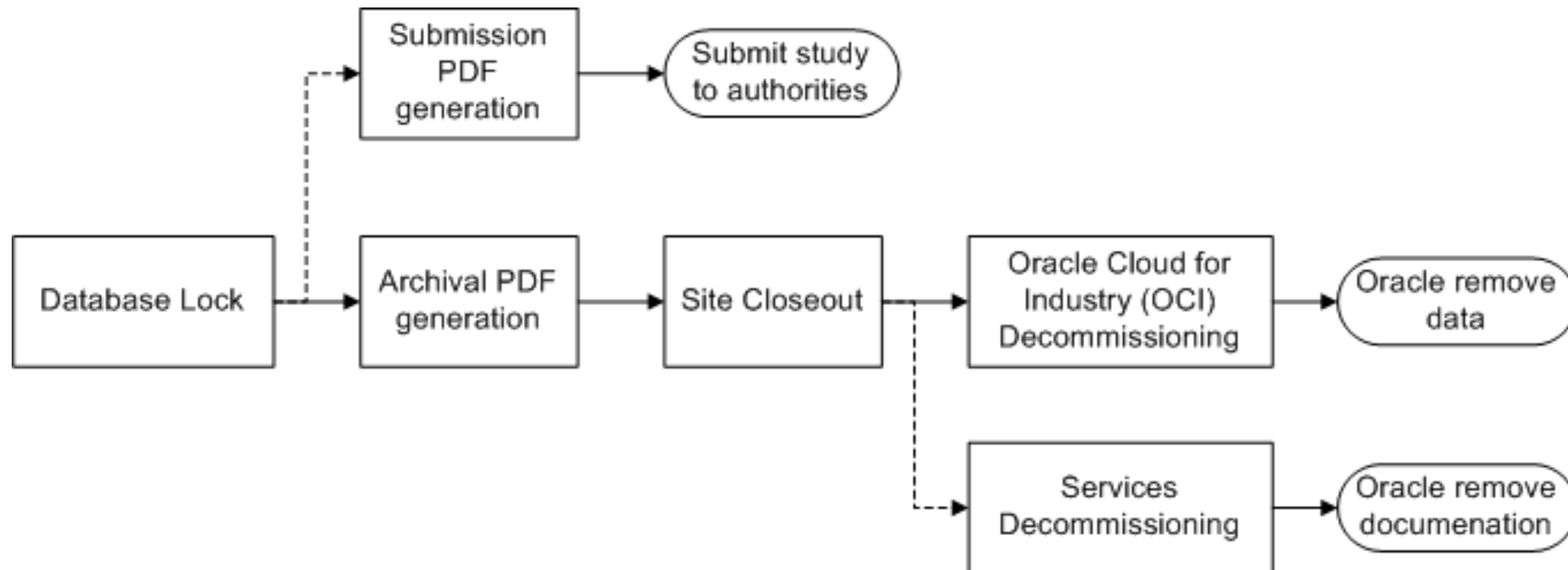
Oracle Health Sciences

PhUSE SDE London
May 2015

InForm Trial Lifecycle



InForm Study Closeout and Submission



InForm Archiving

- Physical media created containing PDF subject casebooks and blank forms
 - Couriered between vendor of CD -> Sponsor -> Site
 - Risks associated with physical media
- Not clearly an independent copy if handled or generated by sponsor
- Site confirmation of receipt prior to decommissioning

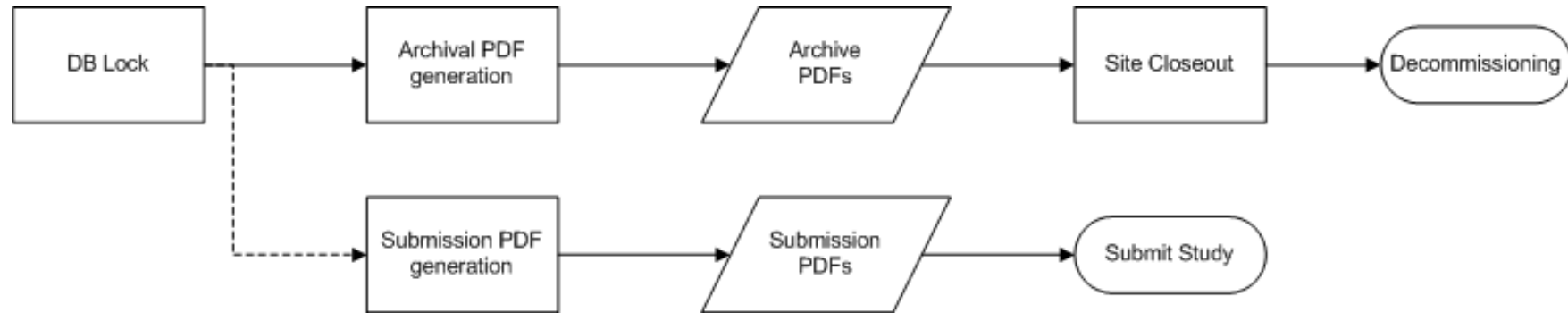


InForm Decommissioning – OCI Hosted

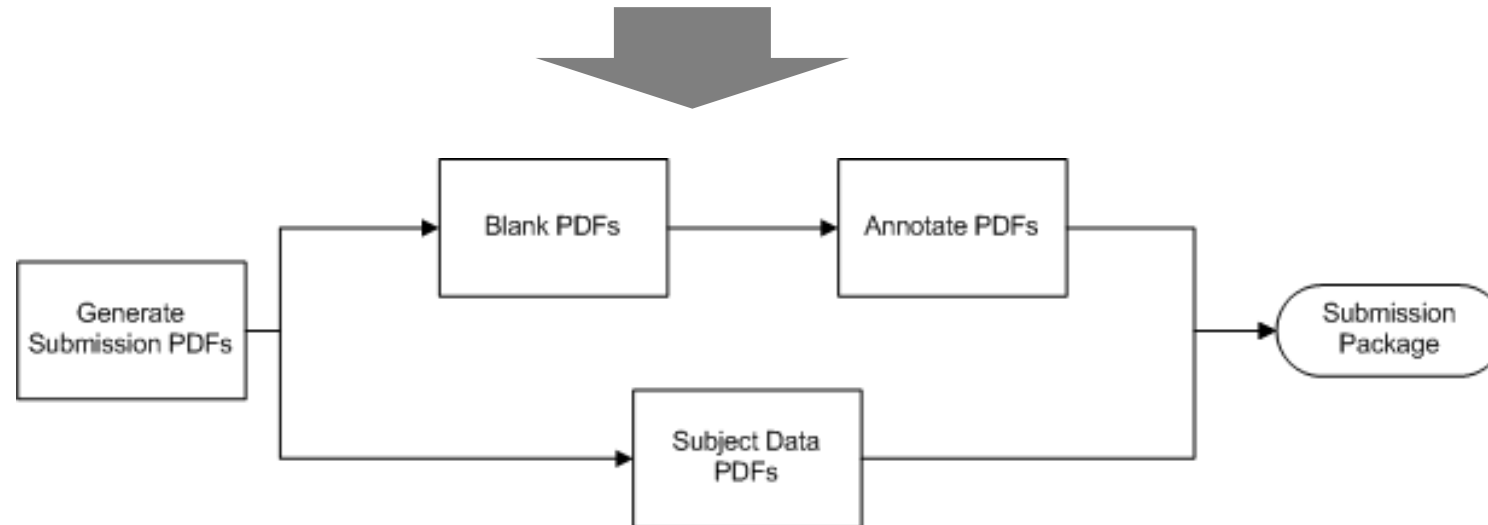
- Remove access to the Production trial
- Remove UAT and Training instances
- Create the Decommissioning Package and transfer to customer
 - The aim of the Decommissioning Package is to handover the files needed to re-create the trial to the customer for archival.
- Oracle removes InForm trial data
- Environments fully decommissioned and recycled



InForm Submission

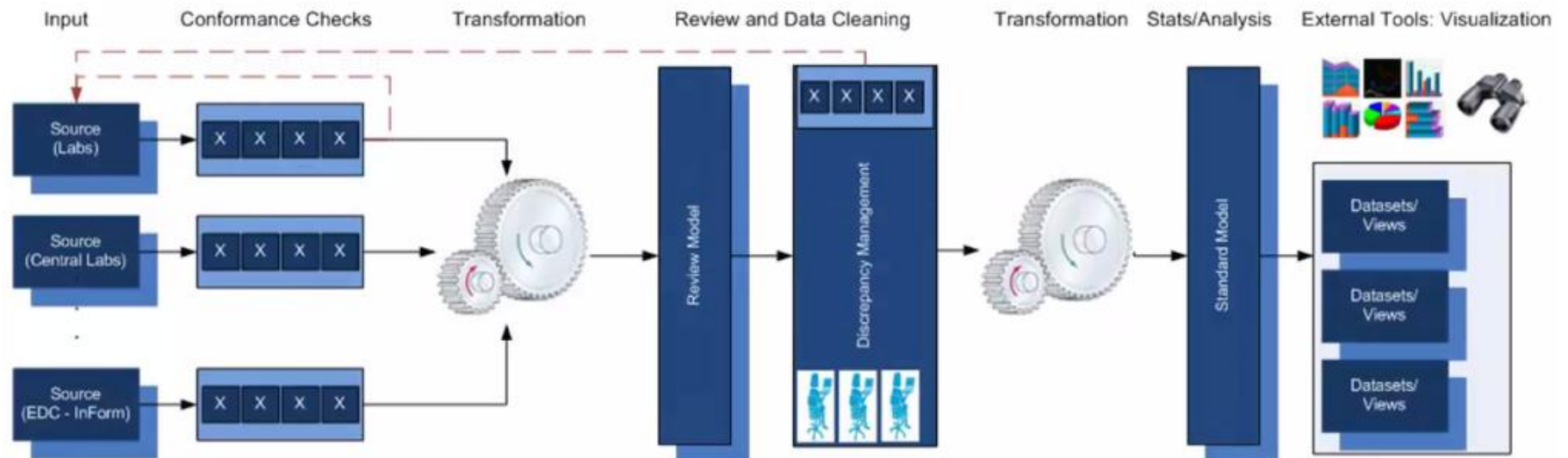


- Submission ready PDFs generated, including Blank Forms and Subject Casebooks



An End to End Solution for Data Management

- Oracle Health Sciences Data Management Workbench (DMW) is a fully integrated end-to-end clinical data management solution
- The software accelerates trial conduct and submissions, improves data quality, and reduces development cost by automating manual processes required to load, transform, and clean trial data



DMW Study Definition

Load InForm Data

- DMW data model is created directly from InForm
- Data can then be loaded automatically
- DMW can be set to check for new data as required, e.g. every 15 minutes

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

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

Study Template
Clinical Data Model
Filter Clinical Data Models:
01 Inform

Clinical Data Model : 01 Inform

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

Tables InForm Configuration

View

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		
DMW_FORM_ASSOC	DMW_FORM_ASSOC	DMW_FORM_ASSOC	DMW_FORM_ASSOC		
DOSE	DOSE	DOSE	DOSE		

DMW Study Definition

Load InForm Data

- InForm data is immediately visible in DMW
- InForm discrepancies are visible automatically

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

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

ModelName 01 Inform

Default Listings

Filter Default Listings:

AE

CHD

CHEM

CM

CONT

DEATHREP

DM

DMW_FORM_ASSOC

DOSE

DOSEVS_SCTDOSEVS

DOSE_SCTDOSE

DS

EG CENT

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
	Open anal pain		Abdominal pain				4/25/2013
	Acute Myocardial Infarction		Acute Myocardial Infarction				4/12/2013

DMW Data Cleaning

Integration with InForm

- DMW data cleaning is tightly integrated with InForm
- Queries raised in either application can be closed in either:
 - InForm queries are visible in Listings
 - DMW discrepancies can be sent back to InForm after DM review

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

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

ModelName: 01 Inform

Default Listing: AE

Filter Default Listings:

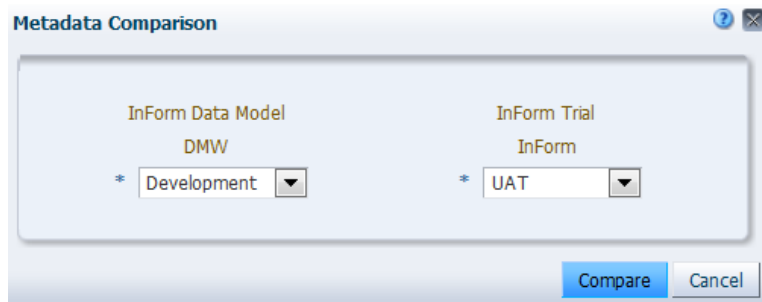
Showing rows from 1 to 28. Estimated row count: 47
Page 1 of 2

	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
	Open anal pain		Abdominal pain				4/25/2013
	Acute Myocardial Infarction		Acute Myocardial Infarction				4/12/2013

InForm Deployment and DMW Lifecycle

InForm Metadata Comparison

- When you promote a DMW Study to Production, the system will compare Oracle DMW metadata and the InForm metadata
- The system will report any differences. Where differences are found, promotion cannot not take place
- Differences are seen on the metadata comparison report



DMW Value Add - Data Consolidation

Laboratory / External Data Loading

- Central laboratory data is loaded directly into DMW
- Multiple external data sources can be configured in a single study
- Data is loaded automatically using filewatcher functionality:
 - Data files are detected automatically
 - Wildcards are supported in filenames
 - Can trigger downstream processes

DMW Value Add - Transformations

Transformations

- 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 regardless of transformations

DMW Value Add – Validation Checks

Validation Checks

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

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		
Table	AE	Created	DMW_QUERY (InForm) 04-Mar-2015 04:15:03 PM
Model	01 InForm	Modified	DMW_QUERY (InForm) 04-Mar-2015 04:15:03 PM
Item	AESTDTC	Tag	
Value	12-APR-13	New Data	No
State	Open	View Query in InForm	
		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

DMW Value Add – Validation Checks

View in InForm

- Where a query exists, on any data model, the user can launch InForm using their Data Manager credentials to view:
 - the source data
 - the query in InForm
- Validation checks can be written against any model

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

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

Discrepancy Management

View Actions

Tg	St	Discrepancy Id	Subject	Visit	Discrepancy	Latest Comment	Table
	?	9102	013-002	AE/CM	DMW8136;Pain YN		AE
	?	9101	013-003	AE/CM	DMW8454;check value Created by TODD.CORNEL	Response satisfies qu	AE
	?	9099	013-004	AE/CM	DMW8430;Please check date Created by CLAUDIC		AE
	?	9097	013-005	AE/CM	DMW8234;Check AE severity Created by CLAUDIC		AE
	?	9096	013-004	AE/CM	DMW8214;Please check this data point Created by		AE
	?	9095	002-001	AE/CM	DMW8196;Check value Created by TODD.CORNEL	Response satisfies qu	AE
	?	9094	009-001	AE/CM	DMW8195;test Created by TODD.CORNELIUS@Of		AE
	?	9093	016-003	AE/CM	DMW8194;test Created by TODD.CORNELIUS@Of		AE
	?	9092	007-001	AE/CM	DMW8181;test Created by TODD.CORNELIUS@Of	Response satisfies qu	AE
	?	9090	003-001	AE/CM	DMW8178;test Created by TODD.CORNELIUS@Of		AE
	?	9088	014-004	AE/CM	DMW8159;test Created by TODD.CORNELIUS@Of		AE
	?	9087	015-001	AE/CM	DMW8158;check value Created by TODD.CORNEL		AE
	?	9073	014-004	AE/CM	Please recheck and reconfirm the relationship of ti		AE
	?	9072	014-004	AE/CM	Start date is equal or prior to the Baseline date of		AE

Rows Selected 1

Detail

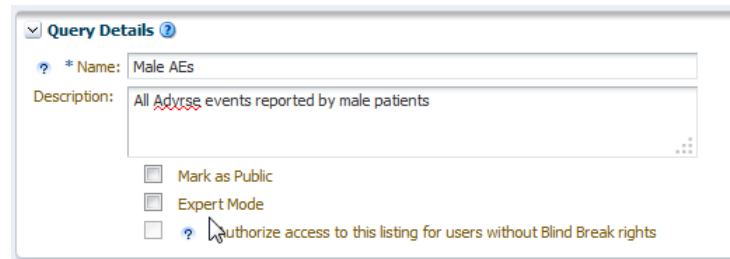
Subject	013-004	Days in State	1
Visit	AE/CM	Category	From InForm
Discrepancy	DMW8430;Please check date Created by CLAUDIO.GARUTTI@ORACLE.COM	Created	DMW_QUERY (InForm) 04-Mar-2015 04:15:03 PM
Table	AE	Modified	DMW_QUERY (InForm) 04-Mar-2015 04:15:03 PM
Model	01 Inform	Tag	
Item	AESTDTC	New Data	No
Value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

> Display Full Record View Data in InForm

DMW Value Add - Data Review

Custom Listings

- Custom listings allow users to access all the data in a single table, allowing users to
 - Review comments
 - Evaluate reported values
 - Identify missing data
- Can be shared with other users
- Flexible filtering
- Filters can persist across data models



Query Details

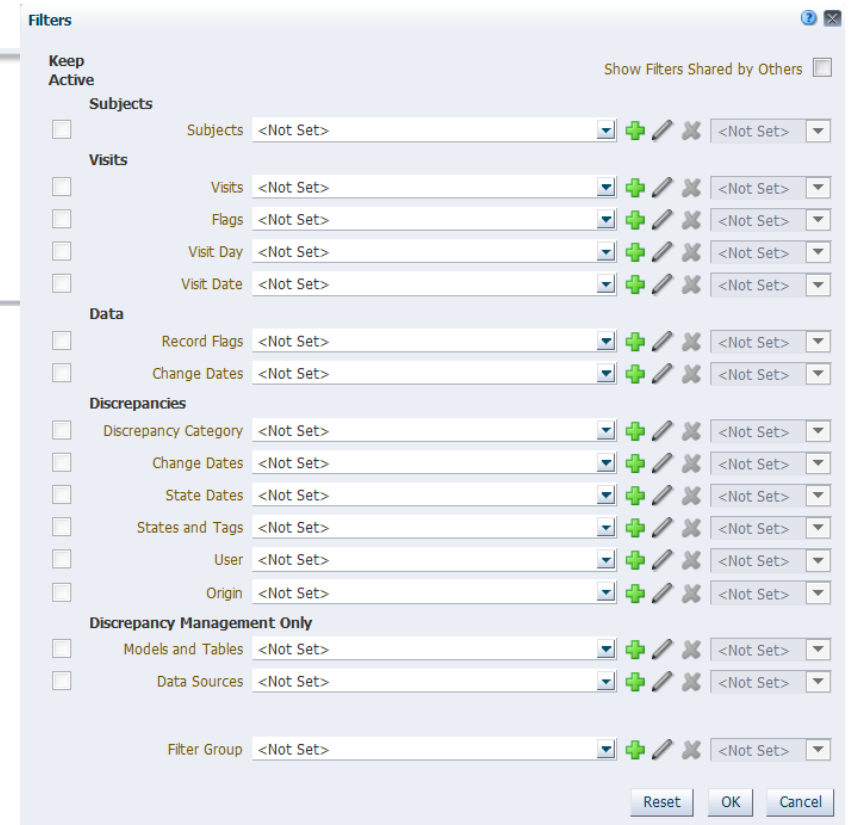
Name: Male AEs

Description: All Adverse events reported by male patients

☐ Mark as Public

☐ Expert Mode

☐ ? authorize access to this listing for users without Blind Break rights



Filters

Keep Active ☐ Show Filters Shared by Others ☐

Subjects

☐ Subjects <Not Set> + - x <Not Set>

Visits

☐ Visits <Not Set> + - x <Not Set>

☐ Flags <Not Set> + - x <Not Set>

☐ Visit Day <Not Set> + - x <Not Set>

☐ Visit Date <Not Set> + - x <Not Set>

Data

☐ Record Flags <Not Set> + - x <Not Set>

☐ Change Dates <Not Set> + - x <Not Set>

Discrepancies

☐ Discrepancy Category <Not Set> + - x <Not Set>

☐ Change Dates <Not Set> + - x <Not Set>

☐ State Dates <Not Set> + - x <Not Set>

☐ States and Tags <Not Set> + - x <Not Set>

☐ User <Not Set> + - x <Not Set>

☐ Origin <Not Set> + - x <Not Set>

Discrepancy Management Only

☐ Models and Tables <Not Set> + - x <Not Set>

☐ Data Sources <Not Set> + - x <Not Set>

Filter Group <Not Set> + - x <Not Set>

Reset OK Cancel

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

Confirmation

Do you want to access the blinded data?

YesNo

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
mg	PATCH	QD	TRANSDERMAL	BASELINE	3	1	2013-03-03	1

DMW Traceability

Transformations and Data Lineage

- End to End traceability allows data to be traced through any associated transformations
- Enables discrepancies to be raised on any model and sent back to source
- Simplifies blank crf annotation

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

Trace Data Lineage

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,AESQ:1
01 InForm.AE.AETERM			Ear Ache	VARCHAR2(200)	Yes	SUBJECTID:35490,VISITID:9365,VISITINDEX:1,INFORM:01

DMW Traceability

Submission

SDTM-IG 3.1.2

- Annotated Case Report Form
- Reviewers Guide
- Complex Algorithms
- Tabulation Datasets
- Value Level Metadata
- Controlled Terminology
- Computational Algorithms
- Comments

Date of document generation: 2013-03-03T17:04:44

Stylesheet version: 2013-04-24

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	dm.xpt	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide

DMW Medical Coding

Integration DMW / 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.

View	Actions	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

View	Actions	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

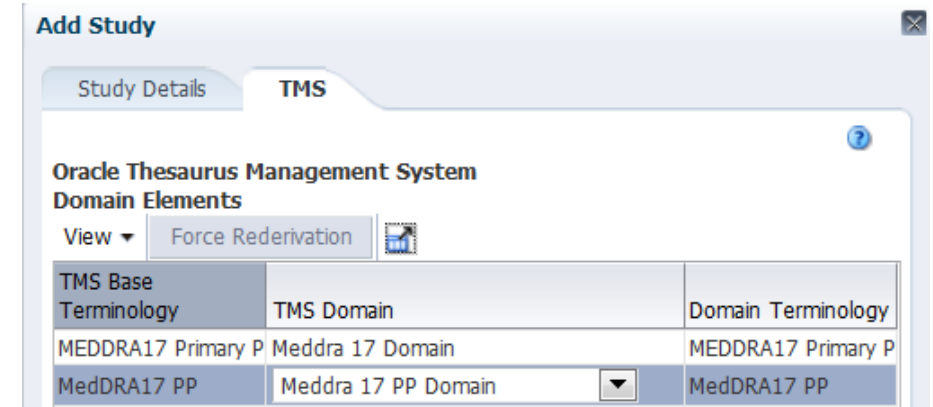
TMS Base Terminology	TMS Domain	Terminology
Meddrapp	MedDRA latest ver	Meddrapp
Who-Drug	Who-Drug	Who-Drug

OK Cancel

DMW Medical Coding

Integration DMW / TMS and Force Rederivation

- Medical Dictionaries are associated at study set up
- Studies may also have to be up-versioned as required for submission
- The new version can be applied to the study by selecting Force Rederivation



DMW Libraries and Templates

Simplify Study Set Up

- Study objects can be based on pre-existing Libraries
- A study can also be set up as a Template
- Templates include
 - Data Models
 - Transformations
 - Listings
 - Validation Checks

Add Clinical Data Model

* Clinical Data Model:

Description:

* Model Type:

Input Type:

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: ☒

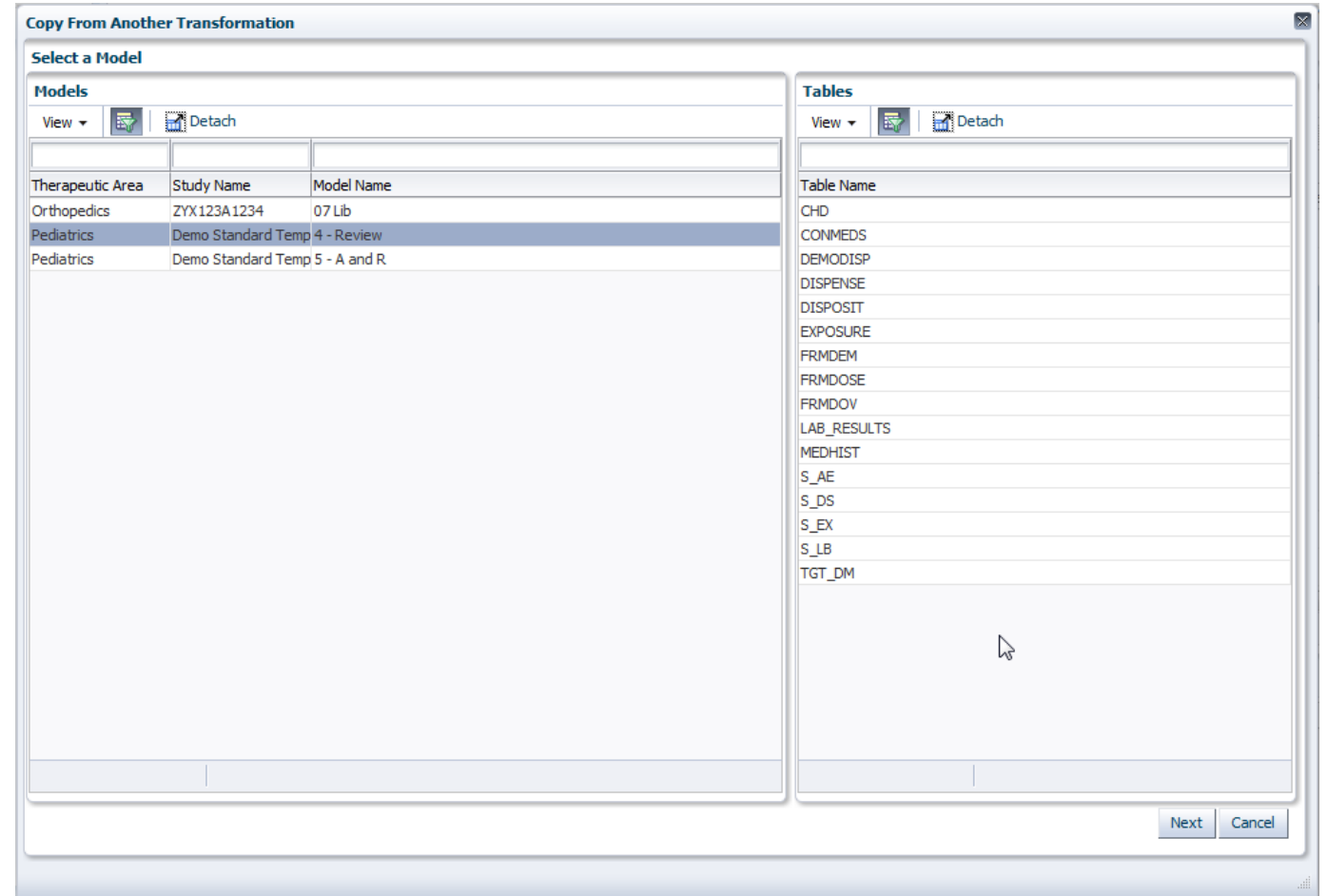
Business Area Schema Name:

OK Cancel

DMW Libraries and Templates

Simplify Study Set Up

- Studies can be created directly from Templates
- Data Models, Listings, Transformations and Validation Checks can be copied from Templates and Studies
- Objects can be updated in the target study, without impacting the source

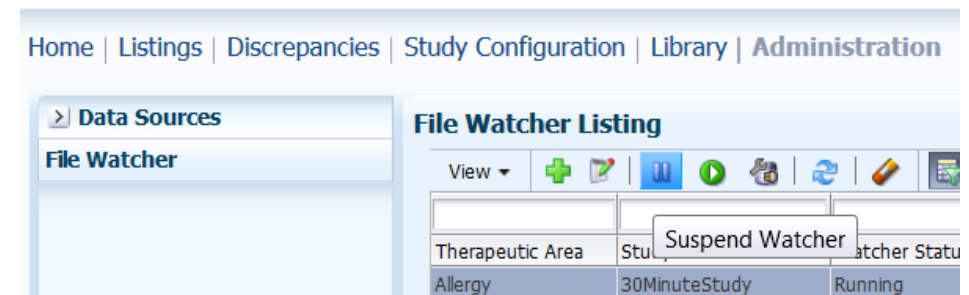


DMW Study Closure

Finalize and Suspend DMW Operations in Production

- Suspend all Filewatchers in Production
- Manually submit transformations and collect and store the log file
- Manually submit validation checks and collect and store the log file to confirm that no new discrepancies are created
- Retire all work area objects
- Study is closed in DMW, but the data remains available in LSH

ORACLE[®] DMW DMW Sales Demo Study 06Feb2015 (Cardiology)



The screenshot displays the Oracle DMW Administration interface. The top navigation bar includes links for Home, Listings, Discrepancies, Study Configuration, Library, and Administration. The left sidebar shows a tree view with 'Data Sources' expanded and 'File Watcher' selected. The main content area is titled 'File Watcher Listing' and contains a table with columns for Therapeutic Area, Study, and Watcher Status. A tooltip labeled 'Suspend Watcher' is visible over the 'Study' column of the first row.

Therapeutic Area	Study	Watcher Status
Allergy	30MinuteStudy	Running

DMW Data Extract

DMW / LSH Data Extract Functionality

All of the current LSH data extract functionality is available:

- SAS Data Marts can create zipped datasets, xpt and cport files
- GVA Business Areas:
 - Secure database access to DMW data
 - Visualization tools connect directly to DMW
 - Can access Blinded / Non Blinded data as per DMW role
- Text Data Marts can create zipped text files
- Oracle Data Marts can create zipped Oracle dmp files

Beyond Submission

DMW / LSH Pooling, Visualization and Reconciliation

- Cross Study Pooling in LSH
- OBIEE for Clinical Ad-hoc Reporting
- JReview
- Periodic Reporting using BI Publisher
- Argus Data Load
- Reconciliation

The image displays two screenshots from the Oracle Business Intelligence (OBIEE) environment. The top screenshot shows the 'Criteria' window for a query. The 'Subject Areas' pane on the left lists various data sources under 'Business Area : BA_Therapeutic_'. The 'Selected Columns' pane on the right shows columns like TCD_DM, STUDYID, USUBJID, SEX, RACE, COUNTRY, and AETERM. The 'Filters' pane at the bottom shows a filter: 'STUDYID is equal to / is in TEST_STUDY'. The bottom screenshot shows the 'OTS_RECONCILIATION_DASHBOARD'. It has a header with 'No Match Records' and a timestamp 'Time run: 8/11/2014 6:40:12 AM'. Below this is a table with columns: SOURCE, STUDY, PATID, PTMT, STRTDT, ENDDT, LLT_TXT, PT_TXT, AETXT, AESOC, SERIOUS, OUTCOMES, ACTION, RELATED, MEDORA, STATUS, Enter A, and COMMENTS. The table contains six rows of data, each representing a patient record with various clinical and safety details.

SOURCE	STUDY	PATID	PTMT	STRTDT	ENDDT	LLT_TXT	PT_TXT	AETXT	AESOC	SERIOUS	OUTCOMES	ACTION	RELATED	MEDORA	STATUS	Enter A	COMMENTS
Clinical	315XYZ-002	013	SRM	10-MAY-13	15-MAY-13	Poly	Poly	POLY	Renal disorders	Not Serious	RECOVERED/RESOLVED	WITHDRAWAL BY SUBJECT	RELATED	16.0DW	P		/
Safety	315XYZ-002	013	SRM	10-MAY-13	15-MAY-13	Poly	Poly	poly	Renal disorders	Not Serious	Recovered/Resolved	Drug withdrawn	Related	17.0	P		/
Clinical	315XYZ-002	013	SRM	11-MAY-13	14-MAY-13	Fatigue	Fatigue	FATIGUE	General disorders	Not Serious	RECOVERED/RESOLVED	DOSE NOT CHANGED	RELATED	16.0DW	P		/
Safety	315XYZ-002	013													P		/
Clinical	315XYZ-002	013	SRM	11-MAY-13	14-MAY-13	Fatigue	Fatigue	FATIGUE	General disorders	Not Serious	RECOVERED/RESOLVED	DOSE NOT CHANGED	RELATED	16.0DW	P		/
Safety	315XYZ-002	013													P		/

ORACLE®