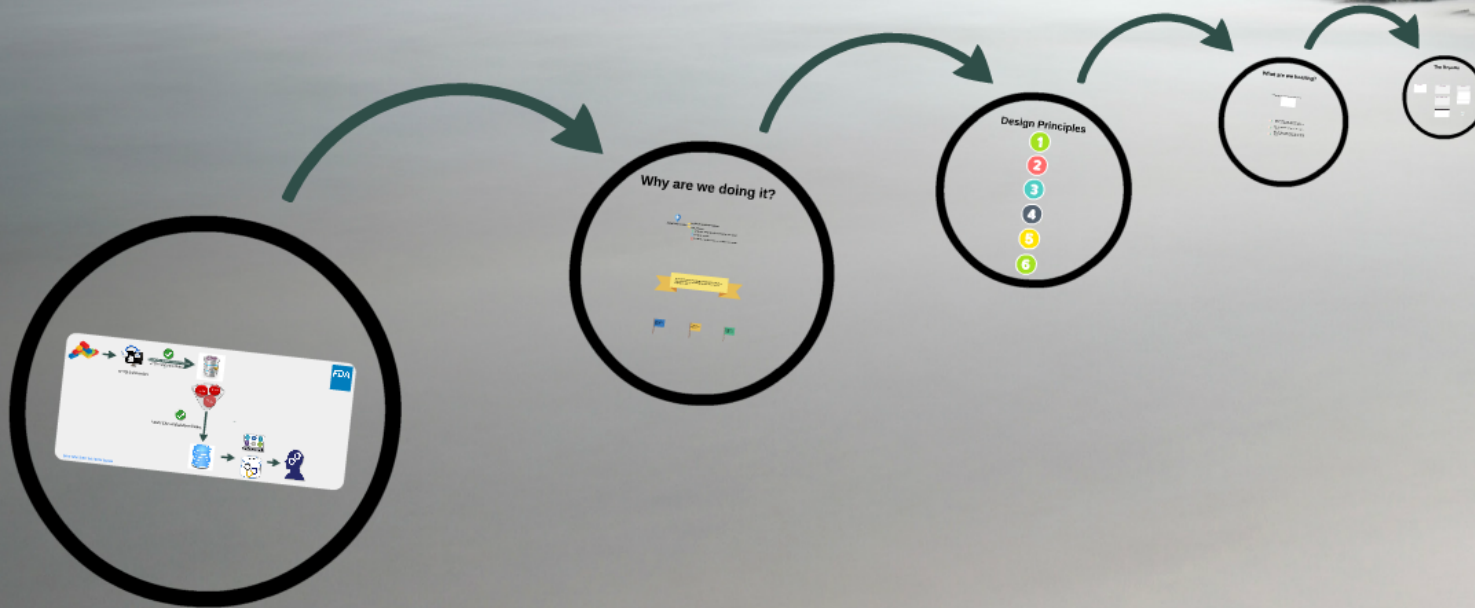


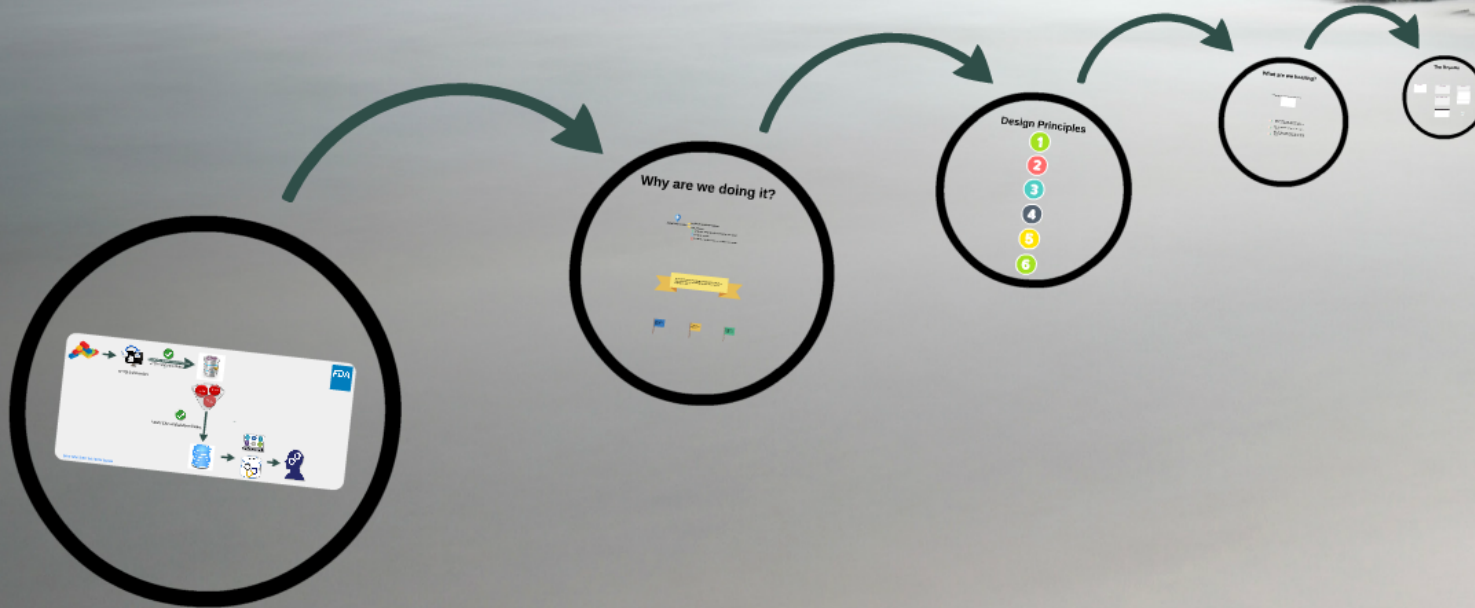
CoreDF

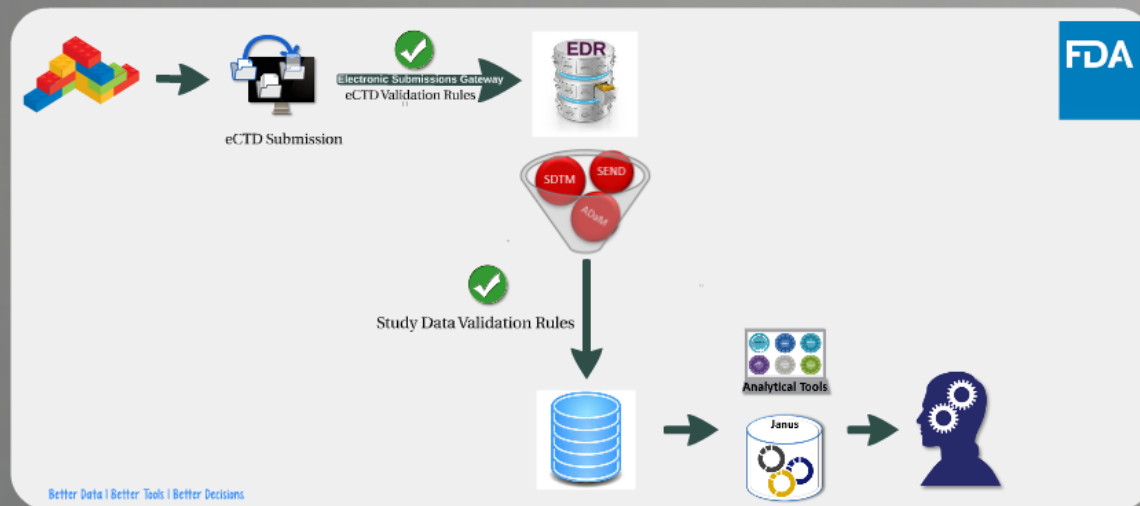
Core DataFitness Assessments



CoreDF

Core DataFitness Assessments



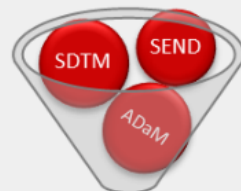




eCTD Submission



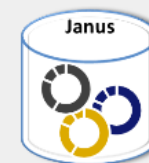
Electronic Submissions Gateway
eCTD Validation Rules

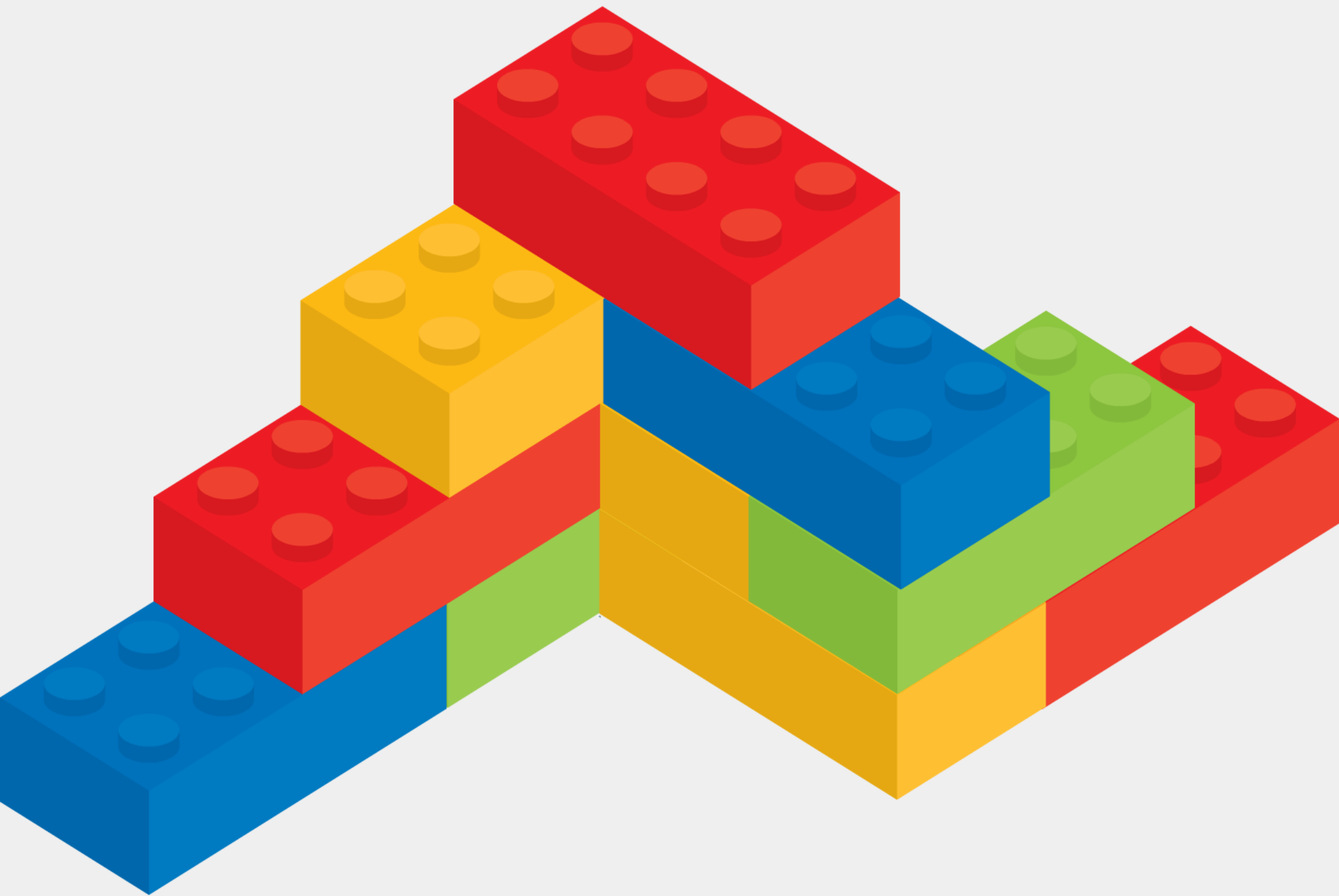


Study Data Validation Rules



Analytical Tools





**Final Published
Dec 17, 2014**

FDASIA Guidance

**Final Published
May 5, 2015**

24 months after
final guidance,
sponsors must use
standards identified
by FDA (NDAs,
ANDAs, BLAs)

eStudy Guidance

Binding Guidance – Requires that studies are compliant with the standards outlined in the FDA Data Standards Catalog.



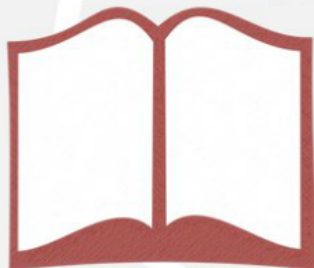
eCTD Guidance

Binding Guidance – Requires that content be submitted to the agency electronically in the format specified in the guidance.



Data Standards Catalog

Lists supported and/or required standards.



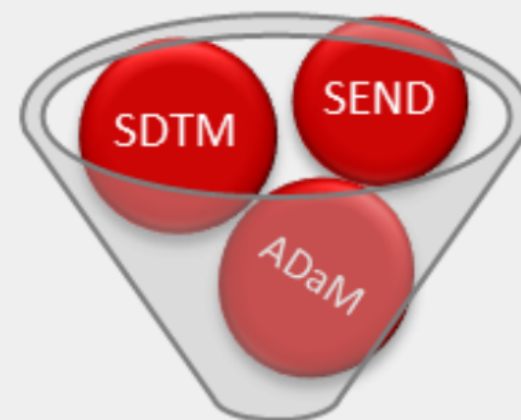
Technical Conformance Guide

Provides specifications, recommendations, and general considerations on how to submit standardized study data.





eCTD Submission



For More Information:

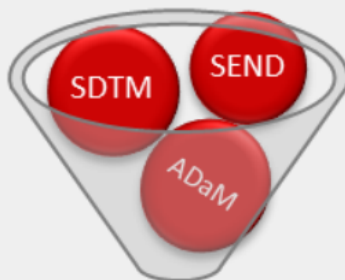
- **RG09: FDA View: Technical Rejection Criteria for Study Data – FDA**
 - **Ethan Chen, OBI/FDA, Wednesday June 6, 9-9:30**
- **RG08: "What's Rules Got to Do with It?" – FDA**
 - **Helena Sviglin, OCS/FDA, Tuesday, June 5, 13:30-14:00**



eCTD Submission



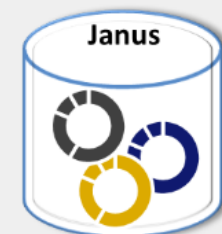
Electronic Submissions Gateway
eCTD Validation Rules



Study Data Validation Rules

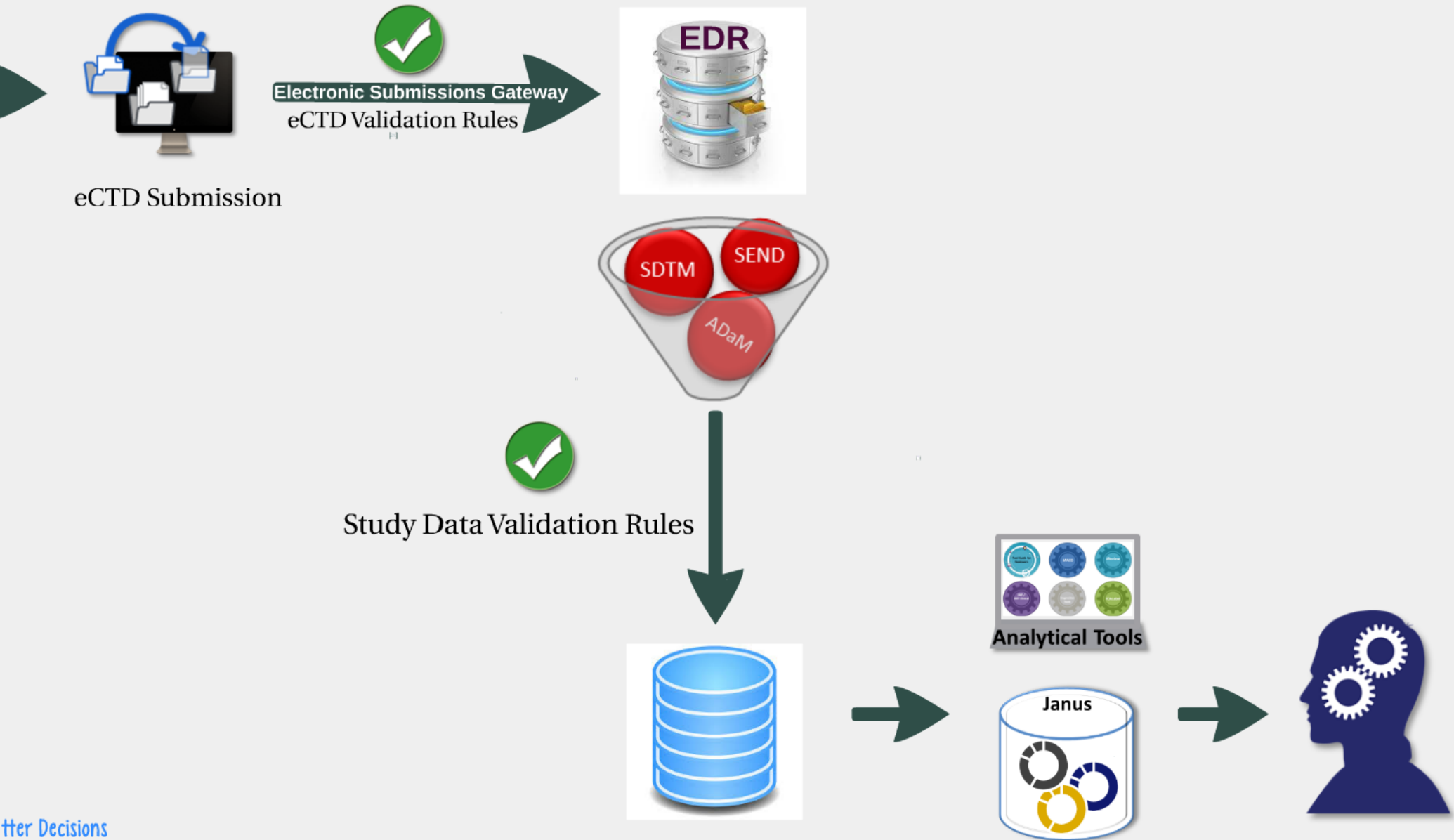


Analytical Tools



For More Information:

- **DH10: Janus Clinical and Nonclinical Loading: The Most Common Issues Identified from Sponsor Submissions**
 - **Kendra Worthy, OCS/CDER, Wednesday June 6th, 11-11:30**



Set of automated reports from DataFit

Application: OCS Data

Study: PhUSE US Connect 2018

Generated: 2018-04-18T14:02:59

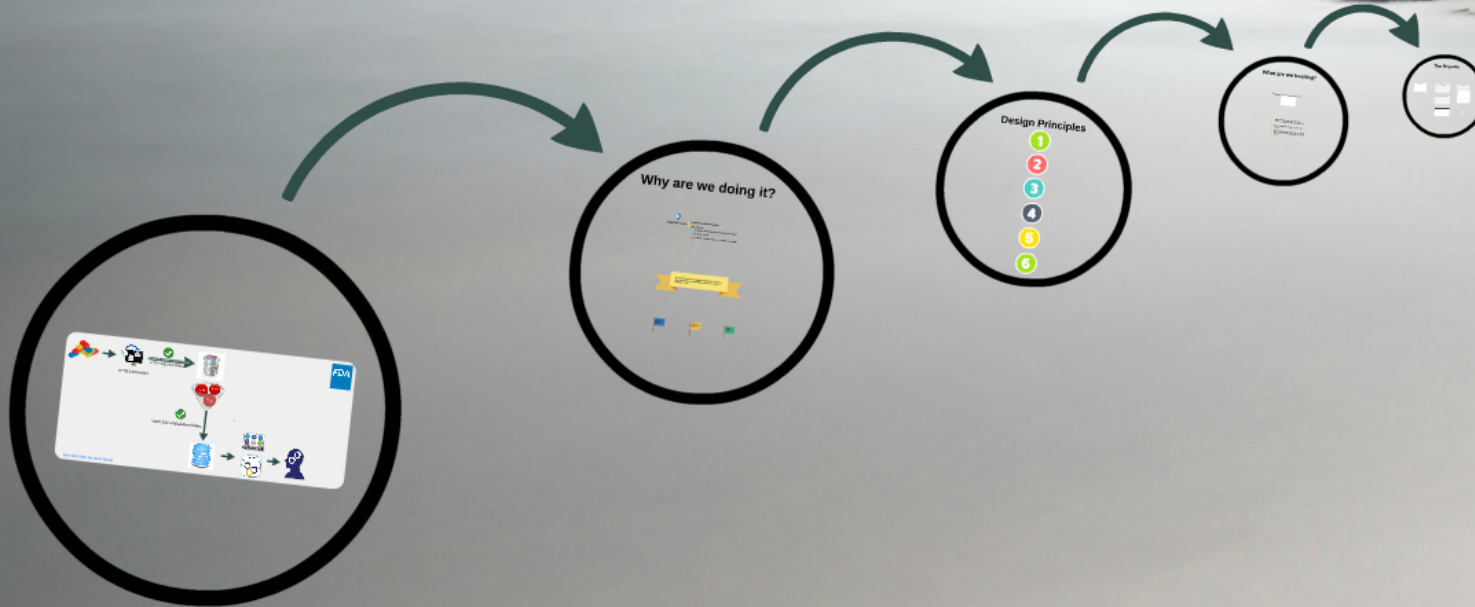
[Data Standards Training](#)

Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimers Disease.

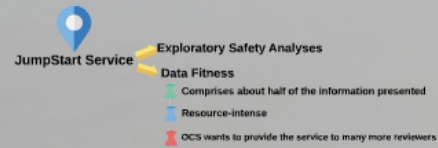
Summary	Findings
Standards / Dictionaries SDTM-IG 3.1.2 SDTM-CT 2017-09-29 MedDRA 8.0	Adverse Events 36 (92.3%) of serious adverse events are not flagged as serious 473 (39.7%) of events are missing end time-point 230 (19.3%) of adverse events are potential duplicates
Subjects / Actual Arms 306 - Subjects 86 - Placebo (28.1%) 52 - Screen Failure (17.0%) 72 - Xanomeline High Dose (23.5%) 96 - Xanomeline Low Dose (31.4%)	Disposition No significant findings
Datasets 22 - Total Datasets 0 - Custom Datasets 4 - Suppqual Datasets	Supplemental Info No significant findings
	Terminology No significant findings
	Laboratory 2,041 (3.5%) of observations are missing Reference Range Upper Limit in Standard Units (LBSTNRHI) 318 (0.6%) of Standard Units (LBSTRESU) are missing when Standard Results (LBSTRESC) are provided
	Vital Signs No significant findings
	Demographics No significant findings
	Exposure No significant findings
	Other EPOCH variable was not provided Study day (AEDY) variable is missing when the Study Date/Time (AEDTC) variable is provided 1 (0.4%) of subjects are missing baseline test results in LB Study day (CMDY) variable is missing when the Study Date/Time (CMDTC) variable is provided 234 (100.0%) of RELREC domain records reference non-existent data in related domain 64,403 (100.0%) of SUPPLB domain records reference non-existent data in related domain Study day (DSDY) variable is missing when the Study Date/Time (DSDTC) variable is provided
Reports	
Deaths Death Summary Death Details Death Reconciliation	
Adverse Events Adverse Events Coding Quality	
Disposition Disposition Coding Quality	
Supplemental Info Supplemental Contents	
Laboratory Upper Limit Normal Summary	

Core DataFitness Assessments

Core DataFitness Assessments



Why are we doing it?



The CoreDE reports provide approximately 75% of the data quality information previously provided only through a JumpStart Service.

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JumpStart Service



Exploratory Safety Analyses

Data Fitness



Comprises about half of the information presented



Resource-intense



OCS wants to provide the service to many more reviewers

A decorative yellow banner with a central text box. The banner has a light yellow background and is flanked by two darker yellow, stylized arrow-like shapes pointing outwards. The text is centered within the light yellow box.

The CoreDF reports provide approximately 75% of the data quality information previously provided only through a JumpStart Service.



Focuses on relevant findings that will help a reviewer quickly identify areas for further exploration



**Helps reviewers
understand whether
the data for a study is
analysis-ready**



**Helps reviewers
use their time
exploring quality
findings**

Design Principles

1

2

3

4

5

6

Automated

- Run automatically with a tool
- Minimize human intervention

Review Relevance

- Will not focus on conformance to a standard,
- Will focus on findings that will provide valuable information to a clinical reviewer

Reviewer Focused Language

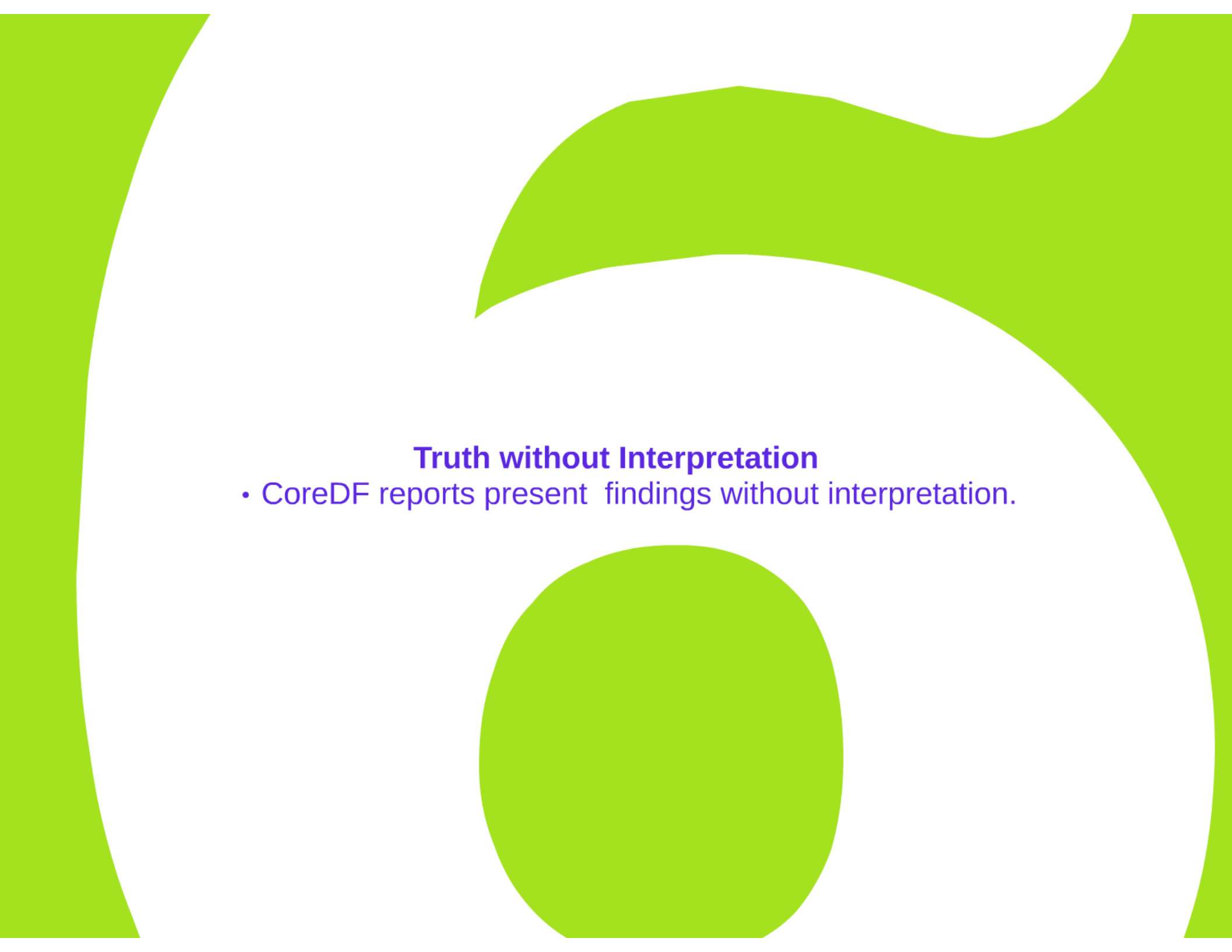
- Use language that a reviewer will understand without a list of acronyms or dictionary.
- Ideally, utilize reports without receiving training on any specific data standard

Actionable

- Provide sufficient information to understand how to explore a finding
 - Determine next steps

Exploratory

- Provide findings such that reviewers have the information they need to explore relevance.
- Do not prescribe relevance nor tell a reviewer what to think about a particular finding.

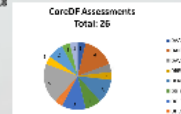
The background features several large, organic, lime-green shapes that resemble stylized leaves or abstract forms, set against a white background. These shapes are positioned around the central text, with one large shape on the left, another on the top right, and a large oval shape at the bottom center.

Truth without Interpretation

- CoreDF reports present findings without interpretation.

What are we hearing?

CoreDF Assessments were provided to 26 JumpStart applications November 2017 through April 2018



100% of reviewers said information within reports was easy to navigate and understand.

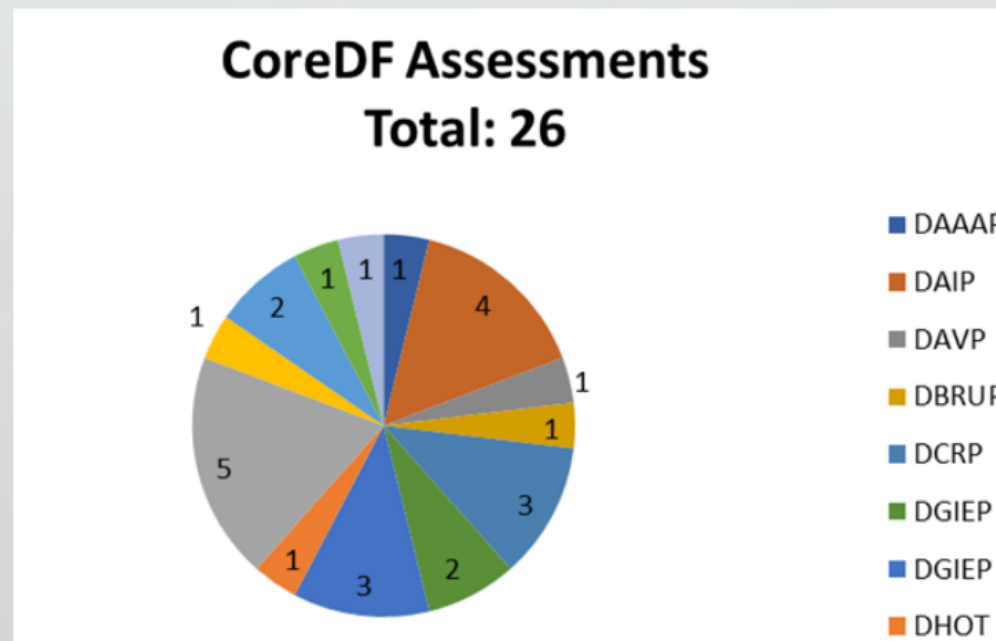


90% of reviewers felt nothing was missing from reports



85% of medical reviewers found the information within reports relevant for that time point in their review

CoreDF Assessments were provided to 26 JumpStart applications November 2017 through April 2018





100% of reviewers said information within reports was easy to navigate and understand.



90% of reviewers felt nothing was missing from reports



85% of medical reviewers found the information within reports relevant for that time point in their review

The Reports

Summary Report

Category	Count
Admission	1
Discharge	1
Transfer	1
Death	1
Other	1

AE Coding Report

AE	ICD-9	ICD-10	Count
Acute Myocardial Infarction	410.9	I21.9	1
Heart Failure	402.9	I50.9	1
Stroke	430.9	I63.9	1
Pneumonia	480.9	J62.9	1
Diabetes Mellitus	250.9	E11.9	1

Death Reports

ICD-9	ICD-10	Count
410.9	I21.9	1
402.9	I50.9	1
430.9	I63.9	1
480.9	J62.9	1
250.9	E11.9	1

1. What is distinct about the non-perfect matches?

AE	ICD-9	ICD-10	Count
Acute Myocardial Infarction	410.9	I21.9	1
Heart Failure	402.9	I50.9	1
Stroke	430.9	I63.9	1
Pneumonia	480.9	J62.9	1
Diabetes Mellitus	250.9	E11.9	1

2. Let's look at the coding for a specific AE

AE	ICD-9	ICD-10	Count
Acute Myocardial Infarction	410.9	I21.9	1
Heart Failure	402.9	I50.9	1
Stroke	430.9	I63.9	1
Pneumonia	480.9	J62.9	1
Diabetes Mellitus	250.9	E11.9	1



Summary Report

Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimers Disease.

Summary	Findings
Standards / Dictionaries	Adverse Events
SDTM-IG 3.1.2	36 (92.3%) of serious adverse events are not flagged as serious
SDTM-CT 2017-09-29	473 (39.7%) of events are missing end time-point
MedDRA 8.0	230 (19.3%) of adverse events are potential duplicates
Subjects / Actual Arms	Disposition
306 - Subjects	No significant findings
86 - Placebo (28.1%)	Supplemental Info
52 - Screen Failure (17.0%)	No significant findings
72 - Xanomeline High Dose (23.5%)	Terminology
96 - Xanomeline Low Dose (31.4%)	No significant findings
Datasets	Laboratory
22 - Total Datasets	2,041 (3.5%) of observations are missing Reference Range Upper Limit in Standard Units (LBSTNRHI)
0 - Custom Datasets	318 (0.6%) of Standard Units (LBSTRESU) are missing when Standard Results (LBSTRESC) are provided
4 - Suppqal Datasets	Vital Signs
	No significant findings
	Demographics
	No significant findings
Reports	Exposure
Deaths	No significant findings
Death Summary	Other
Death Details	EPOCH variable was not provided
Death Reconciliation	Study day (AEDY) variable is missing when the Study Date/Time (AEDTC) variable is provided
Adverse Events	1 (0.4%) of subjects are missing baseline test results in LB
Adverse Events Coding Quality	Study day (CMDY) variable is missing when the Study Date/Time (CMDTC) variable is provided
Disposition	234 (100.0%) of RELREC domain records reference non-existent data in related domain
Disposition Coding Quality	64,403 (100.0%) of SUPPLB domain records reference non-existent data in related domain
Supplemental Info	Study day (DSDY) variable is missing when the Study Date/Time (DSDTC) variable is provided
Supplemental Contents	
Laboratory	
Upper Limit Normal Summary	

AE Coding Report

Adverse Events Coding Quality

Description

This report will help you methodically select a sample of adverse events to examine coding quality. The algorithm uses approximate string matching and does not have medical background. The score represents similarity between Reported Term (AETERM) and either MedDRA PT (AEDECOD) or MedDRA LLT (AELLT) in the submitted data. A score of 100 means the strings are identical, while a score of 0 means that algorithm was unable to determine sufficient similarity. Many terms that have 0 or low scores will, in fact, be coded properly. Using this report will allow you to cut down on the number of terms to review by cutting out those with higher scores.

MedDRA 8.0

MedDRA version used for this report was pulled from define.xml. Report could show additional mismatches if there is a discrepancy between the MedDRA version in define.xml and the actual MedDRA version used to code adverse events.

Reported Term (AETERM)	MedDRA LLT (AELLT)	MedDRA PT (AEDECOD)	Match Details	Score	Number of Rows
ABDOMINAL DISCOMFORT	ABDOMINAL DISCOMFORT	ABDOMINAL DISCOMFORT	Direct match to PT	100	1
ABDOMINAL PAIN	ABDOMINAL CRAMPS	ABDOMINAL PAIN	Direct match to PT	100	6
ACROCHORDON EXCISION	SKIN TAG REMOVAL	ACROCHORDON EXCISION	Direct match to PT	100	1
ACTINIC KERATOSIS	ACTINIC KERATOSIS	ACTINIC KERATOSIS	Direct match to PT	100	1
AGITATION	AGITATION	AGITATION	Direct match to PT	100	5
ALCOHOL USE	ALCOHOL USE	ALCOHOL USE	Direct match to PT	100	1
ALLERGIC GRANULOMATOUS ANGI	ALLERGIC GRANULOMATOSIS	ALLERGIC GRANULOMATOUS ANGI	Direct match to PT	100	1
ALOPECIA	HAIR LOSS	ALOPECIA	Direct match to PT	100	1
AMNESIA	SHORT-TERM MEMORY LOSS	AMNESIA	Direct match to PT	100	2
ANXIETY	FEELING ANXIOUS	ANXIETY	Direct match to PT	100	6
APPLICATION SITE BLEEDING	APPLICATION SITE BLEEDING	APPLICATION SITE BLEEDING	Direct match to PT	100	1
APPLICATION SITE DERMATITIS	APPLICATION SITE RASH	APPLICATION SITE DERMATITIS	Direct match to PT	100	36
APPLICATION SITE DESQUAMATION	APPLICATION SITE DESQUAMATION	APPLICATION SITE DESQUAMATION	Direct match to PT	100	1
APPLICATION SITE DISCHARGE	APPLICATION SITE DISCHARGE	APPLICATION SITE DISCHARGE	Direct match to PT	100	1
APPLICATION SITE DISCOLOURATIO	APPLICATION SITE DISCOLORATION	APPLICATION SITE DISCOLOURATIO	Direct match to PT	100	1

1. What is distinct about the non-perfect matches?

Adverse Events Coding Quality

Description

This report will help you methodically select a sample of adverse events to examine coding quality. The algorithm uses approximate string matching and does not have medical background. The score represents similarity between Reported Term (AETERM) and either MedDRA PT (AEDECOD) or MedDRA LLT (AELLT) in the submitted data. A score of 100 means the strings are identical, while a score of 0 means that algorithm was unable to determine sufficient similarity. Many terms that have 0 or low scores will, in fact, be coded properly. Using this report will allow you to cut down on the number of terms to review by cutting out those with higher scores.

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ABDOMINAL DISCOMFORT	ABDOMINAL DISCOMFORT	ABDOMINAL DISCOMFORT	Direct match to PT	100	1
ABDOMINAL PAIN	ABDOMINAL CRAMPS	ABDOMINAL PAIN	Direct match to PT	100	6
ACROCHORDON EXCISION	SKIN TAG REMOVAL	ACROCHORDON EXCISION	Direct match to PT	100	1
ACTINIC KERATOSIS	ACTINIC KERATOSIS	ACTINIC KERATOSIS	Direct match to PT	100	1
AGITATION	AGITATION	AGITATION	Direct match to PT	100	5
ALCOHOL USE	ALCOHOL USE	ALCOHOL USE	Direct match to PT	100	1
ALLERGIC GRANULOMATOUS ANGI	ALLERGIC GRANULOMATOSIS	ALLERGIC GRANULOMATOUS ANGI	Direct match to PT	100	1
ALOPECIA	HAIR LOSS	ALOPECIA	Direct match to PT	100	1
AMNESIA	SHORT-TERM MEMORY LOSS	AMNESIA	Direct match to PT	100	2
ANXIETY	FEELING ANXIOUS	ANXIETY	Direct match to PT	100	6
APPLICATION SITE BLEEDING	APPLICATION SITE BLEEDING	APPLICATION SITE BLEEDING	Direct match to PT	100	1
APPLICATION SITE DERMATITIS	APPLICATION SITE RASH	APPLICATION SITE DERMATITIS	Direct match to PT	100	36
APPLICATION SITE DESQUAMATION	APPLICATION SITE DESQUAMATION	APPLICATION SITE DESQUAMATION	Direct match to PT	100	1
APPLICATION SITE DISCHARGE	APPLICATION SITE DISCHARGE	APPLICATION SITE DISCHARGE	Direct match to PT	100	1
APPLICATION SITE DISCOLOURATIO	APPLICATION SITE DISCOLORATION	APPLICATION SITE DISCOLOURATIO	Direct match to PT	100	1

2. Let's look at the coding for a specific AE

Adverse Events Coding Quality

Description

This report will help you methodically select a sample of adverse events to examine coding quality. The algorithm uses approximate string matching and does not have medical background. The score represents similarity between Reported Term (AETERM) and either MedDRA PT (AEDECOD) or MedDRA LLT (AELLT) in the submitted data. A score of 100 means the strings are identical, while a score of 0 means that algorithm was unable to determine sufficient similarity. Many terms that have 0 or low scores will, in fact, be coded properly. Using this report will allow you to cut down on the number of terms to review by cutting out those with higher scores.

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ACTINIC KERATOSIS	ACTINIC KERATOSIS	ACTINIC KERATOSIS	Direct match to PT	100	1
AGITATION	AGITATION	AGITATION	Direct match to PT	100	5
ALCOHOL USE	ALCOHOL USE	ALCOHOL USE	Direct match to PT	100	1
ALLERGIC GRANULOMATOUS ANGI	ALLERGIC GRANULOMATOSIS	ALLERGIC GRANULOMATOUS ANGI	Direct match to PT	100	1
ALOPECIA	HAIR LOSS	ALOPECIA	Direct match to PT	100	1
AMNESIA	SHORT-TERM MEMORY LOSS	AMNESIA	Direct match to PT	100	2
ANXIETY	FEELING ANXIOUS	ANXIETY	Direct match to PT	100	6
APPLICATION SITE BLEEDING	APPLICATION SITE BLEEDING	APPLICATION SITE BLEEDING	Direct match to PT	100	1
APPLICATION SITE DERMATITIS	APPLICATION SITE RASH	APPLICATION SITE DERMATITIS	Direct match to PT	100	36
APPLICATION SITE DESQUAMATION	APPLICATION SITE DESQUAMATION	APPLICATION SITE DESQUAMATION	Direct match to PT	100	1
APPLICATION SITE DISCHARGE	APPLICATION SITE DISCHARGE	APPLICATION SITE DISCHARGE	Direct match to PT	100	1
APPLICATION SITE DISCOLOURATIO	APPLICATION SITE DISCOLORATION	APPLICATION SITE DISCOLOURATIO	Direct match to PT	100	1

Death Summary

Description

A high-level summary of which domains contain death information for each subject. All domains were searched for terms associated with death (e.g., "death", "fatal", "dead", "died", "autopsy", "dth") and only those domains where death information was identified, for any subject, have been included. The counts of these terms are based on individual terms, not records (or rows).

USUBJID	AE	DM	DS
01-701-1211		5	2
01-704-1445		2	2
01-710-1083		2	2

Death Details

Description

Detailed information regarding the terms associated with death that were identified for each subject. Record numbers are also provided for easy reference to the rows in the datasets.

USUBJID	Domain	Record	Variable	Label	Value
01-701-1211	AE	121	AEENDTC	End Date/Time of Adverse	2013-01-14
01-701-1211	AE	121	AEOUT	Outcome of Adverse Even	FATAL
01-701-1211	AE	121	AESDTH	Results in Death	Y
01-701-1211	AE	121	AESTDTC	Start Date/Time of Advers	2013-01-14
01-701-1211	AE	121	AETERM	Reported Term for the Ad	SUDDEN DEATH
01-701-1211	DM	25	DTHDTC	Date/Time of Death	2013-01-14
01-701-1211	DM	25	DTHFL	Subject Death Flag	Y
01-701-1211	DM	25	RFSTDTC	Subject Reference Start D	2012-11-15
01-701-1211	DS	52	DSDECOD	Standardized Disposition	DEATH
01-701-1211	DS	52	DSDTC	Date/Time of Collection	2013-01-14
01-701-1211	DS	52	DSSTDTC	Start Date/Time of Dispos	2013-01-14
01-701-1211	DS	52	DSTERM	Reported Term for the Dis	DEATH
01-704-1445	AE	409	AEENDTC	End Date/Time of Adverse	2014-10-31
01-704-1445	AE	409	AEOUT	Outcome of Adverse Even	FATAL
01-704-1445	AE	409	AESDTH	Results in Death	Y
01-704-1445	AE	409	AESTDTC	Start Date/Time of Advers	2014-10-31
01-704-1445	AE	409	AETERM	Reported Term for the Ad	COMPLETED SUICIDE
01-704-1445	DM	96	DTHDTC	Date/Time of Death	2014-11-01
01-704-1445	DM	96	DTHFL	Subject Death Flag	Y
01-704-1445	DM	96	RFSTDTC	Subject Reference Start D	2014-05-11
01-704-1445	DS	195	DSDECOD	Standardized Disposition	DEATH

Death Reconciliation

Description

Reconciliation of death records across AE, DS, and other related domains. The purpose is to show where dates may differ between the domains (subjects will be highlighted in red when the death dates do not match between the Start Date/Time of Disposition Event [DSSTDTC] and either the Start Date/Time of Adverse Event [AESTDTC] and End Date/Time of Adverse Event [AEENDTC]). Additionally, this report can show where a subject had a death record in the AE domain but not in the DS domain or vice-versa. This tab also includes any death information found in the Comments domain (CO).

USUBJID	RFSTDTC	DTHFL	DTHDTC	AETERM	AEOUT	AESDTH
01-701-1211	2012-11-15	Y	2013-01-14	SUDDEN DEATH	FATAL	Y
01-704-1445	2014-05-11	Y	2014-11-01	COMPLETED SUICIDE	FATAL	Y
01-710-1083	2013-07-22	Y	2013-08-02	MYOCARDIAL INFARCTION	FATAL	Y

Death Reports

Death Summary

Description

A high-level summary of which domains contain death information for each subject. All domains were searched for terms associated with death (e.g., "death", "fatal", "dead", "died", "autopsy", "dth") and only those domains where death information was identified, for any subject, have been included. The counts of these terms are based on individual terms, not records (or rows).

USUBJID	AE	DM	DS	
01-701-1211		5	2	2
01-704-1445		2	2	2
01-710-1083		2	2	2

Death Details

Description

Detailed information regarding the terms associated with death that were identified for each subject. Record numbers are also provided for easy reference to the rows in the datasets.

Death Details

Description

Detailed information regarding the terms associated with death that were identified for each subject. Record numbers are also provided for easy reference to the rows in the datasets.

SUBJID	Domain	Record	Variable	Label	Value
1-701-1211	AE	121	AEENDTC	End Date/Time of Adverse	2013-01-14
1-701-1211	AE	121	AEOUT	Outcome of Adverse Even	FATAL
1-701-1211	AE	121	AESDTH	Results in Death	Y
1-701-1211	AE	121	AESTDTC	Start Date/Time of Advers	2013-01-14
1-701-1211	AE	121	AETERM	Reported Term for the Ad	SUDDEN DEATH
1-701-1211	DM	25	DTHDTC	Date/Time of Death	2013-01-14
1-701-1211	DM	25	DTHFL	Subject Death Flag	Y
1-701-1211	DM	25	RFSTDTC	Subject Reference Start D	2012-11-15
1-701-1211	DS	52	DSDECOD	Standardized Disposition	DEATH
1-701-1211	DS	52	DSDTC	Date/Time of Collection	2013-01-14
1-701-1211	DS	52	DSSTDTC	Start Date/Time of Dispos	2013-01-14
1-701-1211	DS	52	DSTERM	Reported Term for the Dis	DEATH
1-704-1445	AE	409	AEENDTC	End Date/Time of Adverse	2014-10-31
1-704-1445	AE	409	AEOUT	Outcome of Adverse Even	FATAL
1-704-1445	AE	409	AESDTH	Results in Death	Y
1-704-1445	AE	409	AESTDTC	Start Date/Time of Advers	2014-10-31
1-704-1445	AE	409	AETERM	Reported Term for the Ad	COMPLETED SUICIDE
1-704-1445	DM	96	DTHDTC	Date/Time of Death	2014-11-01
1-704-1445	DM	96	DTHFL	Subject Death Flag	Y
1-704-1445	DM	96	RFSTDTC	Subject Reference Start D	2014-05-11
1-704-1445	DS	195	DSDECOD	Standardized Disposition	DEATH

01-701-1211	DS	52 DSTERM	Reported Term for the DS DEATH
01-704-1445	AE	409 AEENDTC	End Date/Time of Adverse 2014-10-31
01-704-1445	AE	409 AEOUT	Outcome of Adverse Even FATAL
01-704-1445	AE	409 AESDTH	Results in Death Y
01-704-1445	AE	409 AESTDTC	Start Date/Time of Advers 2014-10-31
01-704-1445	AE	409 AETERM	Reported Term for the Ad COMPLETED SUICIDE
01-704-1445	DM	96 DTHDTC	Date/Time of Death 2014-11-01
01-704-1445	DM	96 DTHFL	Subject Death Flag Y
01-704-1445	DM	96 RFSTDTC	Subject Reference Start D 2014-05-11
01-704-1445	DS	195 DSDECOD	Standardized Disposition DEATH

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Death Reconciliation

Description

Reconciliation of death records across AE, DS, and other related domains. The purpose is to show where dates may differ between the domains (subjects will be highlighted in red when the death dates do not match between the Start Date/Time of Disposition Event [DSSTDTC] and either the Start Date/Time of Adverse Event [AESTDTC] and End Date/Time of Adverse Event [AEENDTC]). Additionally, this report can show where a subject had a death record in the AE domain but not in the DS domain or vice-versa. This tab also includes any death information found in the Comments domain (CO).

USUBJID	RFSTDTC	DTHFL	DTHDTC	AETERM	AEOUT	AESDTH
01-701-1211	2012-11-15	Y	2013-01-14	SUDDEN DEATH	FATAL	Y
01-704-1445	2014-05-11	Y	2014-11-01	COMPLETED SUICIDE	FATAL	Y
01-710-1083	2013-07-22	Y	2013-08-02	MYOCARDIAL INFARCTION	FATAL	Y

Death Reporting Mock-Up

Application: NDA209401
Study: 301
Data Standards Training

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Sequence: 0033

Overview

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PHASE III, MULTICENTER, RANDOMIZED, TRIAL OF CPX-351 (CYTARABINE/DAUNORUBICIN) LIPOSOME INJECTION VERSUS CYTARABINE AND DAUNORUBICIN IN PATIENTS 60-75 YEARS OF AGE WITH UNTREATED HIGH RISK (SECONDARY) AML

Summary	Findings
Documents	Demographics
Study Data Reviewer's Guide	149 (100.0%) of screen failure subjects do not have information in Inclusion/Exclusion Criteria Not Met (IEL) domain
Define.xml	31 (6.8%) of RACE values not found in CDISC codelist
	5 (1.1%) of subjects have a different actual arm than planned
Standards / Dictionaries	Disposition
SDTM-IG 3.2	No significant findings
SDTM-CT 2017-06-30	Exposure
MedDRA 16.0	648 (28.9%) of exposure records are missing timing information
	Adverse Events
Subjects / Actual Arms	157 (69.2%) of serious adverse events are missing seriousness criteria
458 - Subjects	7 (0.1%) of adverse events are potential duplicates
153 - CPX-351 (33.4%)	35 (17.8%) of serious adverse events are not flagged as serious
151 - CYTARABINE/DAUNORUBICIN (33.0%)	13 (0.2%) of adverse events have started after the last disposition date
149 - Likely Screen Failures (32.5%)	Laboratory
5 - Likely Not Treated (1.1%)	9,250 (2.6%) of observations are missing Reference Range Upper Limit in Standard Units (LBSTRNHU)
	175 (0.2%) of Standard Units (LBSTRSU) are missing when Standard Results (LBSTRSC) are provided
	503 (0.3%) of laboratory test results are potential duplicates
	503 (0.4%) of observations use inconsistent values for Standard Units (LBSTRSU)
Datasets	Vital Signs
49 - Total Datasets	160 (2.2%) of vital sign results are potential duplicates
3 - Custom Datasets	Other
17 - Suppquel Datasets	Study day (OSDY) variable is missing when the Study Date/Time (OSDTC) variable is provided
	1 (0.3%) of subjects are missing baseline flag record in Laboratory Test Results (LB)
	EPOCH variable was not provided
	6 (2.0%) of subjects are missing baseline flag record in ECG Test Results (EG)
Reports	
Deaths	
Death Summary	
Death Details	
Adverse Events	
Adverse Events Coding Quality	
Disposition	
Disposition Coding Quality	
Supplemental Info	
Supplemental Contents	

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Study: 301

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Death Summary

Number of reported subject deaths and potentially unreported deaths by summarized by Actual Arm

Actual Arm	Reported Subject Deaths	Potentially Unreported Deaths
Magic Drug	60	1
Potion #9	35	2
Eternal Youth Cream	55	0
Placebo	89	0
Likely Sreen Failures	0	0
Likely Not Treated	0	0
Totals	239	3

Number of subjects with Subject Death Flag value of "Y" or Date/Time of Death value populated in Demographics (DM) dataset and/or Disposition Event of "DEATH" in Disposition (DS) dataset.

Number of subjects with potential death information in other datasets, but not identified in previous column. These were found by searching all datasets for terms associated with death (e.g., "death", "fatal", "dead", "died").

[more details](#)[more details](#)

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Death Details

Detailed death information for each subject with Subject Death Flag value of "Y" or Date/Time of Death value populated in Demographics (DM) dataset and/or Disposition Event of "DEATH" in Disposition (DS) dataset. Death related information found for subjects whose deaths were not reported in Demographics (DM) and/or Disposition (DS) datasets is identified in this report with Unreported Death Flag = "Y" might not mean the subject has died, for example a death related term found in Comments (CO) dataset could mean that a family member died instead. Report includes data found by searching all domains for terms associated with death (e.g., "death", "fatal", "dead", "died", "autopsy", "dth").

Subject	Actual Arm	Dataset	Values	Inconsistencies?	Potentially Unreported?	Comments
ABC-01001	Magic Drug	Death Details (DD)	Died in Presence of Active Leukemia: YES	N	N	
			Primary Cause of Death: PROGRESSIVE LEUKEMIA			
ABC-01001	Magic Drug	Demographics (DM)	Is Death Study Drug Related: NOT RELATED	N	N	
			Death Associated with Another Cause: NO			
ABC-01001	Magic Drug	Disposition (DS)	Date/Time of Death: 2015-02-02	N	N	
			Subject Death Flag: Y			
ABC-01001	Magic Drug	Subject Status (SS)	Reference Start Date/Time: 2013-04-22	N	N	
			Reported Term: DEATH			
ABC-01001	Magic Drug	Demographics (DM)	Standardized Term: DEATH	N	N	
			Category: DISPOSITION EVENT			
ABC-01001	Magic Drug	Disposition (DS)	Subcategory: END OF FOLLOW-UP PHASE	N	N	
			Start Date/Time: 2015-02-02			
ABC-01001	Magic Drug	Subject Status (SS)	Survival Status: DEAD	N	N	
			Date/Time of Death: NULL			
ABC-01003	Magic Drug	Demographics (DM)	Subject Death Flag: NULL	N	Y	
			Reference Start Date/Time: 2017-03-02T13:00			
ABC-01003	Magic Drug	Disposition (DS)	Disposition Event of DEATH: Missing	N	Y	
			Survival Status: DEAD			
ABC-01003	Magic Drug	Subject Status (SS)	Date/Time of Collection: 2017-08-01	N	Y	

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Overview

PHASE III, MULTICENTER, RANDOMIZED, TRIAL OF CPX-351 (CYTARABINE:DAUNORUBICIN) LIPOSOME INJECTION VERSUS CYTARABINE AND DAUNORUBICIN IN PATIENTS 60-75 YEARS OF AGE WITH UNTREATED HIGH RISK (SECONDARY) AML.

Summary	Findings
Documents Study Data Reviewer's Guide Define.xml	Demographics 149 (100.0%) of screen failure subjects do not have information in Inclusion/Exclusion Criteria Not Met (IE) domain 31 (6.8%) of RACE values not found in CDISC codelist 5 (1.1%) of subjects have a different actual arm than planned
Standards / Dictionaries SDTM-IG 3.2 SDTM-CT 2017-06-30 MedDRA 16.0	Disposition No significant findings
Subjects / Actual Arms 458 - Subjects 153 - CPX-351 (33.4%) 151 - CYTARABINE/DAUNORUBICIN (33.0%) 149 - Likely Screen Failures (32.5%) 5 - Likely Not Treated (1.1%)	Exposure 648 (28.9%) of exposure records are missing timing information
Datasets 49 - Total Datasets 3 - Custom Datasets 17 - Suppqual Datasets	Adverse Events 157 (49.2%) of serious adverse events are missing seriousness criteria 7 (0.1%) of adverse events are potential duplicates 35 (17.8%) of serious adverse events are not flagged as serious 13 (0.2%) of adverse events have started after the last disposition date
Reports	Laboratory 3,250 (2.6%) of observations are missing Reference Range Upper Limit in Standard Units (LBSTNRHI) 175 (0.2%) of Standard Units (LBSTRESU) are missing when Standard Results (LBSTRESC) are provided 503 (0.3%) of laboratory test results are potential duplicates 503 (0.4%) of observations use inconsistent values for Standard Units (LBSTRESU)
Deaths Death Summary Death Details	Vital Signs 160 (2.2%) of vital sign results are potential duplicates
Adverse Events Adverse Events Coding Quality	Other Study day (QSDY) variable is missing when the Study Date/Time (QSDTC) variable is provided 1 (0.3%) of subjects are missing baseline flag record in Laboratory Test Results (LB) EPOCH variable was not provided 6 (2.0%) of subjects are missing baseline flag record in ECG Test Results (EG)
Disposition Disposition Coding Quality	
Supplemental Info Supplemental Contents	

ing Mock-Up

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Death Summary

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Totals	239	3

Number of subjects with Subject Death Flag value of "Y" or Date/Time of Death value populated in Demographics (DM) dataset and/or Disposition Event of "DEATH" in Disposition (DS) dataset.

[more details](#)

Number of subjects with potential death information in other datasets, but not identified in previous column. These were found by searching all datasets for terms associated with death (e.g., "death", "fatal", "dead", "died").

[more details](#)

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Details

[If subjects are missing baseline flag record in Laboratory Test Results \(LB\)](#)
[variable was not provided](#)
[If subjects are missing baseline flag record in ECG Test Results \(EG\)](#)

Number of subjects with Subject Death Flag value of "Y" or Date/Time of Death value populated in Demographics (DM) dataset and/or Disposition Event of "DEATH" in Disposition (DS) dataset.

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Death Details

Detailed death information for each subject with Subject Death Flag value of "Y" or Date/Time of Death value populated in Demographics (DM) dataset and/or Disposition Event of "DEATH" in Disposition (DS) dataset. Death related information found for subjects whose deaths were not reported in Demographics (DM) and/or Disposition (DS) datasets is identified in this report with Unreported Death Flag = 'Y' might not mean the subject has died, for example a death related term found in Comments (CO) dataset could mean that a family member died instead. Report includes data found by searching all domains for terms associated with death (e.g., "death", "fatal", "dead", "died", "autopsy", "dth").

Subject	Actual Arm	Dataset	Values	Inconsistencies?	Potentially Unreported?	Comments
ABC-01001	Magic Drug	Death Details (DD)	Died in Presence of Active Leukemia: YES Primary Cause of Death: PROGRESSIVE LEUKEMIA Is Death Study Drug Related: NOT RELATED Death Associated with Another Cause: NO	N	N	
ABC-01001	Magic Drug	Demographics (DM)	Date/Time of Death: 2015-02-02 Subject Death Flag: Y Reference Start Date/Time: 2013-04-22	N	N	
ABC-01001	Magic Drug	Disposition (DS)	Reported Term: DEATH Standardized Term: DEATH Category: DISPOSITION EVENT Subcategory: END OF FOLLOW-UP PHASE Start Date/Time: 2015-02-02	N	N	
ABC-01001	Magic Drug	Subject Status (SS)	Survival Status: DEAD	N	N	
ABC-01003	Magic Drug	Demographics (DM)	Date/Time of Death: NULL Subject Death Flag: NULL Reference Start Date/Time: 2017-03-02T13:00	N	Y	
ABC-01003	Magic Drug	Disposition (DS)	Disposition Event of DEATH: Missing Survival Status: DEAD	N	Y	
ABC-01003	Magic Drug	Subject Status (SS)	Date/Time of Collection: 2017-08-01	N	Y	

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1. So how many deaths? What was the cause of

1. So how many deaths? What was the cause of any uncertainty?

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Death Summary

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[more details](#)

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[more details](#)

CoreDF

Core DataFitness Assessments

