A large, stylized teal graphic on the left side of the slide, consisting of several thick, wavy lines that curve and flow downwards, resembling a ribbon or a signal waveform.

Accelerate Database Lock, Sample Management and Submission Readiness using Data Science

**Philip Ross, Ph.D.
Strategic Clinical Analytics**

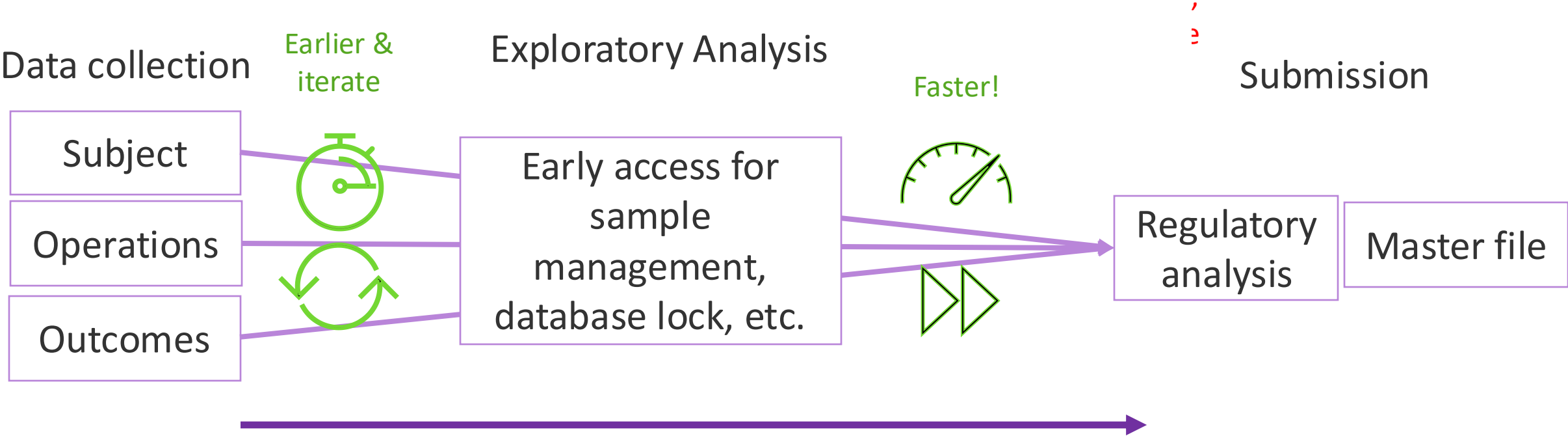
**revvity
signals**

The Speaker

- Strategic Clinical Analytics Lead at Revvity Signals
- Formerly led work at Pfizer and Bristol-Myers Squibb in clinical data pipelines and analytics.
- Brings deep pharmaceutical experience in visualization of clinical data to drive clinical decision-making.
- Ph.D. in Pharmacology from The Ohio State University.

- The opinions expressed are those of Philip Ross and he welcomes robust discussion as we seek to define emerging AI/ML solutions to drive clinical trial execution.

Clinical trials suffer from lack of access to analysis ready data & reproducible decision-making



- Data science and automation accelerate access to data
- Visualizations and workflows drive quality and task completion

DATA

PEOPLE

DECISIONS

Real-time data access

Connect to all data

Reusable data maps

Transform any data

Robust self-service analytics

Interactive Visualizations

 Spotfire integration

Cross-study analysis

Traceable decisions

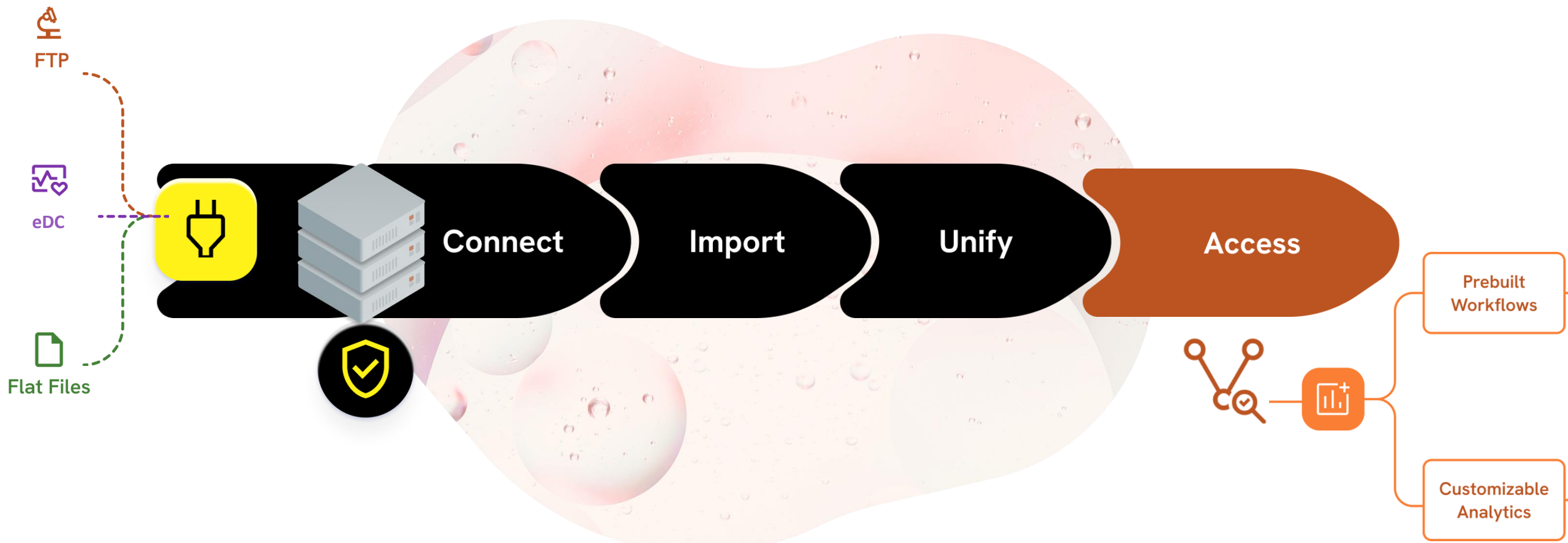
Track data changes

Query Workflow

Issue Management

- How can we automate data mapping and transformation?

Automate Access to Clinical Trial Data



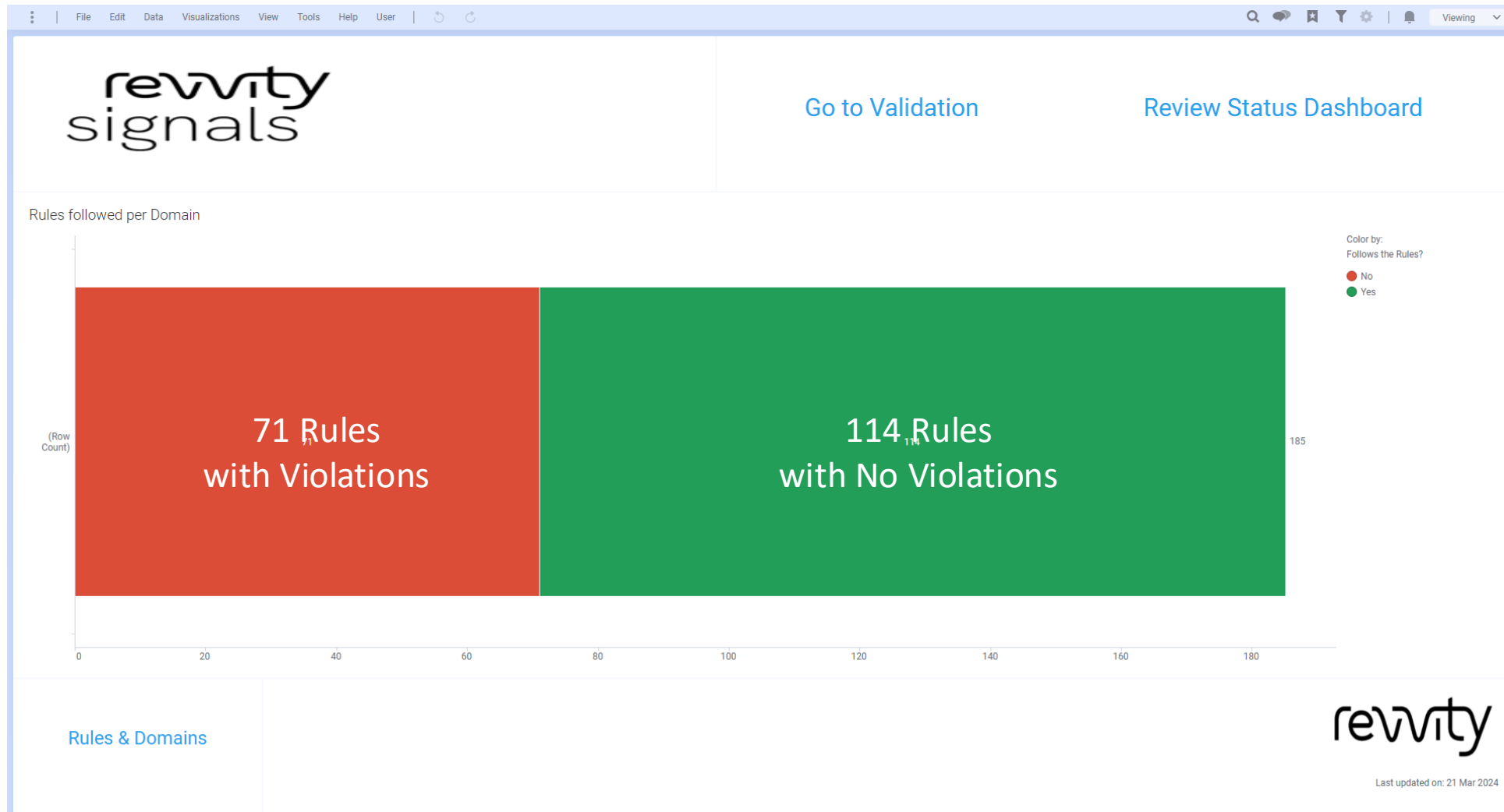
Examples of FDA Validation, database lock and sample management dashboards

FDA Validation Rules

FDA Rules from Agency

- FDA Validation Rules 1.6 at <https://www.fda.gov/media/103587/download>
- Can dashboard visualizations drive FDA data compliance during study execution?

Automated Daily Update to FDA Validation Rule Violation Status



Validation Page – Rules Violated by Domain

Select a Rule and Domain of Interest

[Get Table](#)

Results

No

Yes

Rules

Type to search in list

(All) 41 values

Rule 1

Rule 2

Rule 3

Rule 4

Rule 5

Rule 5.1

Result per FDA Rule ID, FDA Validator Rule Message and Domain

FDA Rule ID	FDA Validator Rule Message	Domain											
		AE	CM	DD	DM	DS	EG	EX	IE	IS	LB	MH	
Custom 1	Missing Value for MHCAT	-	-	-	-	-	-	-	-	-	-	-	Yes
Custom 2	Missing End Time-Point value	No	Yes	-	-	-	-	-	No	-	-	-	Yes
Custom 3	Missing Start Time-Point value	No	Yes	-	-	-	-	No	No	Yes	-	-	Yes
Custom 4	Result of Finding in Original Units (--ORRES) should not be NULL, ...	-	No	-	-	-	-	No	Yes	-	No	No	-
Custom 5	Missing value for --ORRES, when --STAT or --DRVFL is not populat...	-	-	-	-	-	-	Yes	-	-	Yes	Yes	-
	Missing value for --STRESC, when --STAT is null	-	-	-	-	-	-	Yes	-	-	Yes	No	-
	No baseline flag record in Domain for subject	-	-	-	-	-	-	No	-	-	-	No	-
SD0006		-	-	-	-	-	-	-	-	-	-	-	-
SD0013	--STDTDC is after --ENDTC	No	No	-	-	-	-	-	Yes	-	-	-	No
SD0014	Negative value for --DOSE	-	No	-	-	-	-	No	No	-	-	-	-
SD0022	Missing Start Time-Point value	Yes	No	-	-	Yes	-	No	-	-	-	-	No
SD0023	Missing value for --STAT, when --REASND is provided	-	-	-	-	Yes	-	-	-	No	Yes	-	-
SD0030	Missing value for --STRESC, when --STRESU is provided	-	-	-	-	-	-	No	-	-	No	No	-
SD0035	Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is ...	-	No	-	No	-	-	No	No	-	-	-	-
SD0047	Missing value for --ORRES, when --STAT or --DRVFL is not populat...	-	-	-	-	-	Yes	-	-	-	Yes	No	-
SD0070	No Exposure record found for subject	-	-	-	Yes	-	-	-	-	-	-	-	-
SD0085	Mismatch between IORRES and IESTRESC values	-	-	-	-	-	-	-	-	No	-	-	-
SD1002	RFSTDTDC is after RFENDTC	-	-	-	Yes	-	-	-	-	-	-	-	-
SD1021	Unexpected character value in variable	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SD1036	Missing value for --TOXGR, when --TOX is populated	No	-	-	-	-	-	-	-	-	-	-	No
SD1037	Missing value for --TOX, when --TOXGR is populated	No	-	-	-	-	-	-	-	-	-	-	No
SD1117	Duplicate records	-	-	-	-	-	-	No	-	-	No	No	-
SD1122	Missing value for --STRESN	-	-	-	-	-	-	-	-	-	Yes	-	-
SD1123	--ORRES value is populated, when --STAT is 'NOT DONE'	-	-	-	-	-	Yes	-	-	-	Yes	No	-
SD1208	RFXSTDTDC date is after RFXENDTC	-	-	-	Yes	No	-	-	-	-	-	-	-
SD1210	Missing value for RFICDTC	-	-	-	No	-	-	-	-	-	-	-	-
SD1240	No Informed Consent Obtained record in DS domain for subject	-	-	-	Yes	-	-	-	-	-	Yes	-	-
SD1247	ECDOSE is not greater than 0 when ECOCCUR does not equal 'N' a...	-	-	-	-	-	-	No	-	-	-	-	-
SD1248	ECDOSE is not null or greater than 0 when ECOCCUR = 'N'	-	-	-	-	-	-	No	-	-	-	-	-
SD1254	DTHFL does not equal 'Y' when AE.AEOUT = 'FATAL'	No	-	-	-	-	-	-	-	-	-	-	-
SD1255	DTHFL does not equal 'Y' when AE.AESDTH = 'Y'	No	-	-	-	-	-	-	-	-	-	-	-
SD1261	SSDTC is not greater than or equal to DTHDTC, when SSSTRESC = ...	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes
SD1272	--TESTCD equals 'OTHER'	-	-	-	-	-	-	-	-	-	Yes	-	-
SD1319	--STDTDC is before RFICDTC	-	-	-	Yes	No	-	-	-	Yes	-	-	-
SD1446	Exposure start date is after the latest Disposition date	-	-	-	-	-	-	Yes	-	-	-	-	-
SD1449	Missing values for one or more variables: --LLTCD, --PTCD, --HLTC...	No	-	-	-	-	-	-	-	-	-	-	No
SD2007	Value for --PTCD is less or equal to 8 characters	Yes	-	-	-	-	-	-	-	-	-	-	Yes
SD2009	Value for --LLTCD is less or equal to 8 characters	Yes	-	-	-	-	-	-	-	-	-	-	Yes
SD2011	Value for --HLTCD is less or equal to 8 characters	Yes	-	-	-	-	-	-	-	-	-	-	Yes
SD2013	Value for --HLGTCDC is less or equal to 8 characters	Yes	-	-	-	-	-	-	-	-	-	-	Yes
SD2016	Value for --SOCCD is less or equal to 8 characters	Yes	-	-	-	-	-	-	-	-	-	-	Yes
SE2277	Variable length exceeds 200 characters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Review Status Dashboard

Rules & Domains

Rules Status

Domains Status

Result

Validation Page – Filter to Rules Violated by Domain

File Edit Data Visualizations View Tools Help User
Viewing

Select a Rule and Domain of Interest

[Get Table](#)

Results

No
 Yes

Rules

Type to search in list

- (All) 26 values
- Rule 1
- Rule 2
- Rule 3
- Rule 4
- Rule 5
- Rule 6

Result per FDA Rule ID, FDA Validator Rule Message and Domain

FDA Rule ID	FDA Validator Rule Message	Domain											
		AE	CM	DM	DS	EG	EX	IE	IS	LB	MH	PC	
Custom 2	Missing End Time-Point value	No	-	-	-	-	No	-	-	-	-	-	-
Custom 3	Missing Start Time-Point value	No	-	-	-	-	No	-	-	-	-	-	-
Custom 4	Result or Finding in Original Units (-ORRES) should not be NULL, ...	-	No	-	-	No	-	-	No	No	-	-	No
Custom 5	Missing value for --STRESC, when --STAT is null	-	-	-	-	-	-	-	-	No	-	-	-
SD0006	No baseline flag record in Domain for subject	-	-	-	-	No	-	-	-	No	-	-	-
SD0013	--STDTC is after --ENDTC	No	No	-	-	-	-	-	-	-	No	-	-
SD0014	Negative value for --DOSE	-	No	-	-	-	No	-	-	-	-	-	-
SD0022	Missing Start Time-Point value	-	No	-	-	-	No	-	-	-	No	-	-
SD0023	Missing value for --STAT, when --REASND is provided	-	-	-	-	-	-	No	-	-	-	-	-
SD0030	Missing value for --STRESC, when --STRESU is provided	-	-	-	-	No	-	-	No	No	-	-	No
SD0035	Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is ...	-	No	No	-	-	No	No	-	-	-	-	-
SD0047	Missing value for --ORRES, when --STAT or --DRVFL is not populat...	-	-	-	-	-	-	-	-	No	-	-	-
SD0085	Mismatch between IEORES and IESTRESC values	-	-	-	-	-	-	-	No	-	-	-	-
SD1036	Missing value for --TOXGR, when --TOX is populated	No	-	-	-	-	-	-	-	-	No	-	-
SD1037	Missing value for --TOX, when --TOXGR is populated	No	-	-	-	-	-	-	-	-	No	-	-
SD1117	Duplicate records	-	-	-	-	No	-	-	No	No	-	-	No
SD1123	--ORRES value is populated, when --STAT is 'NOT DONE'	-	-	-	-	-	-	-	-	No	-	-	No
SD1208	RFXSTDTC date is after RFXENDTC	-	-	-	No	-	-	-	-	-	-	-	-
SD1210	Missing value for RFICDTC	-	-	No	-	-	-	-	-	-	-	-	-
SD1247	ECDOSE is not greater than 0 when ECOCCUR does not equal 'N' a...	-	-	-	-	-	No	-	-	-	-	-	-
SD1248	ECDOSE is not null or greater than 0 when ECOCCUR = 'N'	-	-	-	-	-	No	-	-	-	-	-	-
SD1254	DTHFL does not equal 'Y' when AE.AEOUT = 'FATAL'	No	-	-	-	-	-	-	-	-	-	-	-
SD1255	DTHFL does not equal 'Y' when AE.AESDTH = 'Y'	No	-	-	-	-	-	-	-	-	-	-	-
SD1261	SSDTC is not greater than or equal to DTHDTC, when SSSSTRESC = ...	-	-	-	No	-	-	-	-	No	-	-	-
SD1319	--STDTC is before RFICDTC	-	-	-	No	-	-	-	-	-	-	-	-
SD1449	Missing values for one or more variables: --LLTCD, --PTCD, --HLT...	No	-	-	-	-	-	-	-	-	No	-	-

[Review Status Dashboard](#)

[Rules & Domains](#)

[Rules Status](#)

[Domains Status](#)

Validation Page – Choose AE Violations of Start Date Rule

File Edit Data Visualizations View Tools Help User
Viewing

Select a Rule and Domain of Interest

Get Table

Results

No

Yes

Rules

Type to search in list

(All) 26 values

- Rule 1
- Rule 2
- Rule 3
- Rule 4
- Rule 5
- Rule 6

Review Status Dashboard

Rules & Domains

Rules Status

Domains Status

Result per FDA Rule ID, FDA Validator Rule Message and Domain

FDA Rule ID	FDA Validator Rule Message	Domain											
		AE	CM	DM	DS	EG	EX	IE	IS	LB	MH	PC	
Custom 2	Missing End Time-Point value	No	-	-	-	-	No	-	-	-	-	-	-
Custom 3	Missing Start Time-Point value	No	-	-	-	-	No	-	-	-	-	-	-
Custom 4	Result or Finding in Original Units (-ORRES) should not be NULL, ...	-	No	-	-	No	-	-	No	No	-	-	No
Custom 5	Missing value for --STRESC, when --STAT is null	-	-	-	-	-	-	-	-	No	-	-	-
SD0006	No baseline flag record in Domain for subject	-	-	-	-	No	-	-	-	No	-	-	-
SD0013	--STDTC is after --ENDTC	No	No	-	-	-	-	-	-	-	No	-	-
SD0014	Negative value for --DOSE	-	No	-	-	-	No	-	-	-	-	-	-
SD0022	Missing Start Time-Point value	-	No	-	-	-	No	-	-	-	No	-	-
SD0023	Missing value for --STAT, when --REASND is provided	-	-	-	-	-	-	No	-	-	-	-	-
SD0030	Missing value for --STRESC, when --STRESU is provided	-	-	-	-	No	-	-	No	No	-	-	No
SD0035	Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is ...	-	No	No	-	-	No	No	-	-	-	-	-
SD0047	Missing value for --ORRES, when --STAT or --DRVFL is not populat...	-	-	-	-	-	-	-	-	-	No	-	-
SD0085	Mismatch between IEORES and IESTRESC values	-	-	-	-	-	-	-	No	-	-	-	-
SD1036	Missing value for --TOXGR, when --TOX is populated	No	-	-	-	-	-	-	-	-	No	-	-
SD1037	Missing value for --TOX, when --TOXGR is populated	No	-	-	-	-	-	-	-	-	No	-	-
SD1117	Duplicate records	-	-	-	-	No	-	-	No	No	-	-	No
SD1123	--ORRES value is populated, when --STAT is 'NOT DONE'	-	-	-	-	-	-	-	-	-	No	-	No
SD1208	RFXSTDTC date is after RFXENDTC	-	-	-	No	-	-	-	-	-	-	-	-
SD1210	Missing value for RFICDTC	-	-	No	-	-	-	-	-	-	-	-	-
SD1247	ECDOSE is not greater than 0 when ECOCCUR does not equal 'N' a...	-	-	-	-	-	-	No	-	-	-	-	-
SD1248	ECDOSE is not null or greater than 0 when ECOCCUR = 'N'	-	-	-	-	-	-	No	-	-	-	-	-
SD1254	DTHFL does not equal 'Y' when AE.AEOUT = 'FATAL'	No	-	-	-	-	-	-	-	-	-	-	-
SD1255	DTHFL does not equal 'Y' when AE.AESDTH = 'Y'	No	-	-	-	-	-	-	-	-	-	-	-
SD1261	SSDTC is not greater than or equal to DTHDTC, when SSSSTRESC = ...	-	-	-	No	-	-	-	-	No	-	-	-
SD1319	--STDTC is before RFICDTC	-	-	-	No	-	-	-	-	-	-	-	-
SD1449	Missing values for one or more variables: --LLTCD, --PTCD, --HLT...	No	-	-	-	-	-	-	-	-	No	-	-

Validation Page – Right Click on AE to Raise a Query

Return to Validations Matrix Review Status Dashboard ▾ Reset Filters ▾

FDA Validation Results

Adverse Event	Start Date	Is Adverse Event Ongoing	Is Adverse Event Ongoing_D	End Date	Toxicity Grade	Toxicity Grade_D	Is Adverse Event Serious	Is Adverse Event Serious_D	Outcome	Relationship to Drug 1	Drug Withdrawn
Urinary Incontinence		Y	Yes		2	Moderate (Gra...	N	No	RECOVERING/RESOLVING	NOT RELATED	N
pressure - right ear		Y	Yes		1	Mild (Grade 1)	N	No	NOT RECOVERED/NOT RESOLVED	NOT RELATED	N
numbness - right ear		Y	Yes		1	Mild (Grade 1)	N	No	NOT RECOVERED/NOT RESOLVED	NOT RELATED	N
Right Axillary Lesion		Y	Yes		1	Mild (Grade 1)	N	No	UNKNOWN	RELATED	Y
Dyspnea		Y	Yes		2	Moderate (Gra...	N	No	UNKNOWN	NOT RELATED	N
Dyspnea		N	No		1	Mild (Grade 1)	N	No	NOT RECOVERED/NOT RESOLVED	NOT RELATED	N
ASTHENIA		Y	Yes		1	Mild (Grade 1)	N	No	NOT RECOVERED/NOT RESOLVED	RELATED	N
DRY COUGH		Y	Yes		1	Mild (Grade 1)	N	No	NOT RECOVERED/NOT RESOLVED	RELATED	N
Bruising Increased		Y	Yes		1	Mild (Grade 1)	N	No	NOT RECOVERED/NOT RESOLVED	NOT RELATED	N

Filters ↻ ↑ ×

Type to search filters

ae ^

Subject

Type to search in list

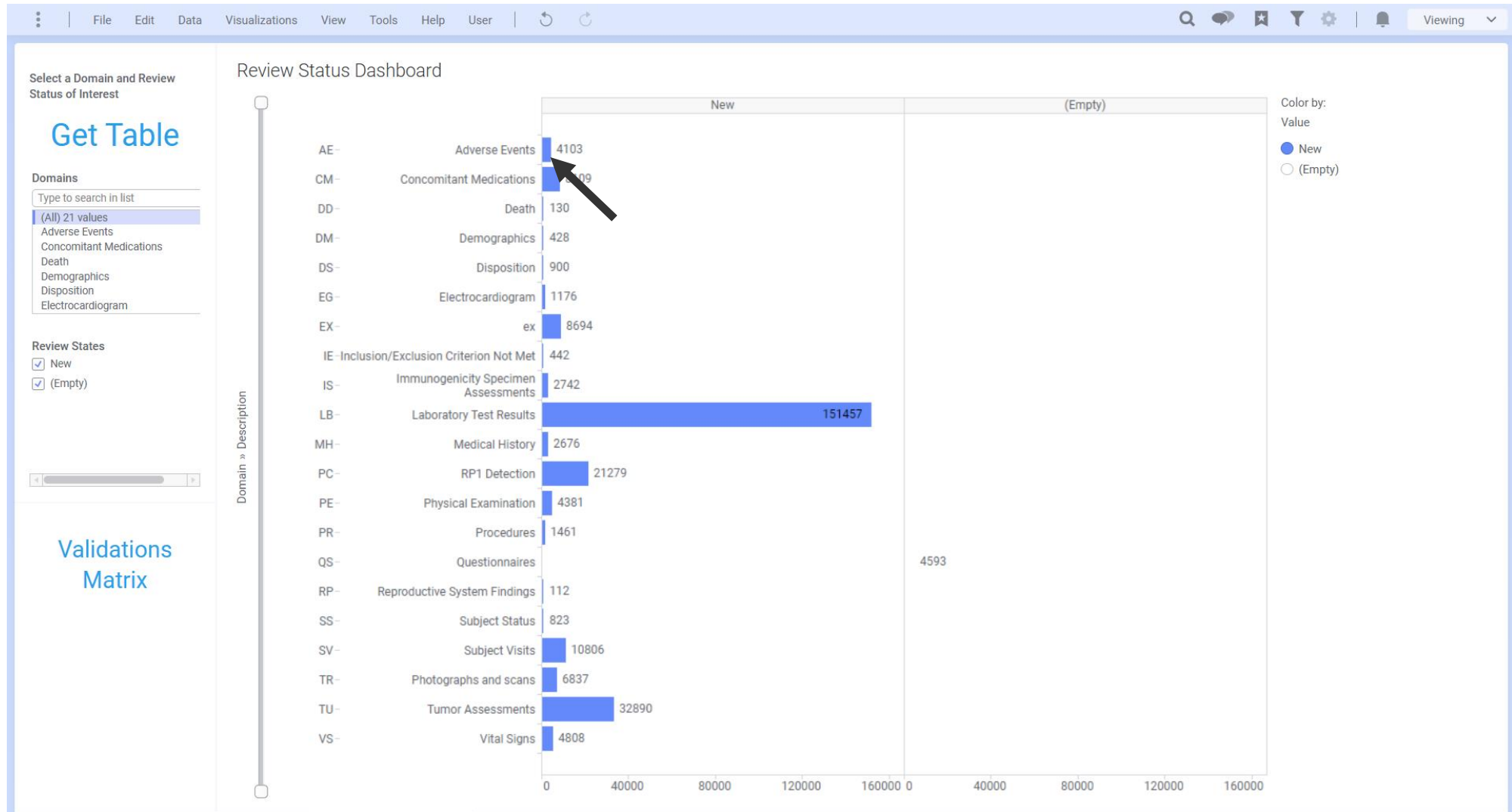
- (All) 6 values
- Fake Study-z1152-x2004
- Fake Study-z1172-x2004
- Fake Study-z3308-x2001
- Fake Study-z4403-x2003
- Fake Study-z4405-x2011
- Fake Study-z4405-x2012

Medical Review State

New

Medical Review Date/Time

Review Status Page – Click on AE to Review New AEs



Review New AE records – Raise Queries with a Right Click

Return to Validations Matrix Review Status Dashboard Reset Filters

FDA Validation Results

Adverse Event	Start Date	Is Adverse Event Ongoing	End Date	Toxicity Grade	Toxicity Grade_D	Is Adverse Event Serious	Outcome_D	Relationship to Drug 1	Dose Not Changed
diarrhoea	11/14/2020	N	1/16/2021	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y
Generalized muscle Weakness	9/16/2019	N	9/20/2019	3	Severe (Grade 3)	Y	Recovered/Resolved	NOT RELATED	N
Rash legs	3/18/2021	N	3/22/2021	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y
bleeding at tumor site	8/10/2020	N	9/6/2020	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y
Urinary Frequency	11/20/2020	Y		2	Moderate (Grade 2)	N	Not Recovered/Not Resolved	NOT RELATED	Y
Exematous rash on both hands	9/24/2020	Y		1	Mild (Grade 1)	N	Not Recovered/Not Resolved	NOT RELATED	Y
Constipation	1/14/2021	N	1/15/2021	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	N
Fever	5/2/2020	N	5/8/2020	2	Moderate (Grade 2)	Y	Recovered/Resolved	RELATED	N
Pneumothorax	10/10/2019	N	10/31/2019	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y
Iron deficiency anemia	12/28/2020	N	1/10/2021	2	Moderate (Grade 2)	N	Recovered/Resolved	NOT RELATED	Y
Iron deficient anemia	11/16/2020	N	12/13/2020	2	Moderate (Grade 2)	N	Recovered/Resolved	NOT RELATED	Y
chills	12/21/2020	N	12/21/2020	1	Mild (Grade 1)	N	Recovered/Resolved	RELATED	Y
Pain from right nostril	11/4/2020	Y		1	Mild (Grade 1)	N	Not Recovered/Not Resolved	NOT RELATED	Y
flu like symptoms	7/28/2020	N	7/29/2020	2	Moderate (Grade 2)	N	Recovered/Resolved	RELATED	Y
Nausea	7/15/2020	N	7/15/2020	1	Mild (Grade 1)	N	Recovered/Resolved	RELATED	Y
Fever	11/2/2019	N	11/3/2019	2	Moderate (Grade 2)	N	Recovered/Resolved	RELATED	N
Generalized Muscle Weakness	10/29/2019	N	11/1/2019	1	Mild (Grade 1)	N	Recovered/Resolved	RELATED	N
Upper respiratory infection	1/11/2021	N	2/8/2021	2	Moderate (Grade 2)	N	Recovered/Resolved	NOT RELATED	Y
Inmuno mediated colitis	2/7/2020	N	2/12/2020	3	Severe (Grade 3)	Y	Recovered/Resolved	NOT RELATED	N
Musculoskeletal other - hip dislocation	11/2/2020	N	11/2/2020	2	Moderate (Grade 2)	N	Recovered/Resolved	NOT RELATED	Y
Abdominal cramping	11/3/2020	N	11/8/2020	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	N
Severe lower thoracic spine pain due to cancer pain	12/9/2019	N	12/30/2019	3	Severe (Grade 3)	Y	Recovered/Resolved	NOT RELATED	N
Right lower extremity swelling	12/10/2019	N	1/7/2020	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y
Anxiety	11/26/2019	N	11/26/2019	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y
Fatigue	10/27/2019	N	10/28/2019	2	Moderate (Grade 2)	N	Recovered/Resolved with Sequelae	RELATED	N
Nephritis	3/3/2020	Y		2	Moderate (Grade 2)	N	Not Recovered/Not Resolved	NOT RELATED	N
Rigors	12/23/2019	N	12/23/2019	2	Moderate (Grade 2)	N	Recovered/Resolved	RELATED	Y
Anorexia	10/27/2019	N	12/12/2019	2	Moderate (Grade 2)	N	Recovered/Resolved	RELATED	N
Fatigue	9/14/2020	N	8/25/2021	1	Mild (Grade 1)	N	Recovered/Resolved	RELATED	Y
Diarrhea	4/16/2020	N	4/16/2020	1	Mild (Grade 1)	N	Recovered/Resolved	RELATED	Y
Pruritus- intermittent	9/21/2020	N	12/15/2020	1	Mild (Grade 1)	N	Recovered/Resolved	NOT RELATED	Y

Filters

Type to search filters

ae

Subject

Type to search in list

(All) 321 values

- Fake Study-z1103-x2001
- Fake Study-z1103-x2002
- Fake Study-z1103-x2004
- Fake Study-z1103-x2005
- Fake Study-z1103-x2006
- Fake Study-z1103-x2007

Medical Review State

New

Medical Review Date/Time

5/6/2024 11:00:00 5/6/2024 11:00:00

1 filter changed

ae

Medical Review State: (New)

Setup - Rules by Domain

Return to Validations Matrix

Rules Status

Implemented Rules

Rules	FDA Validator Rule Message	FDA Validator Rule Description
Rule 1	No baseline flag record in Domain for subject	All subjects should have at least one baseline observation PC and VS domains, except for subjects who failed screening were not fully assigned to an Arm (ARMCD = 'NOTASSGN')
Rule 2	--STDTC is after --ENDTC	Start Date/Time of Event, Exposure or Observation (--STDTC) should be greater than or equal to End Date/Time of Event, Exposure or Observation (--ENDTC).
Rule 3	Negative value for --DOSE	Non-missing Dose (--DOSE) value must be greater than or equal to 0.
Rule 4	Missing Start Time-Point value	One Start Time-Point variable is expected to be populated for each event. (E.g., Start Date/Time of Event or Intervention (--STRF), or Start Relative to Reference Period (--STRF), or Start Relative to Reference Period (--STRF)).
Rule 5	Missing value for --STAT, when --REASND is provided	Completion Status (--STAT) should be set to 'NOT DONE', 'PENDING', or 'COMPLETED' when Reason (--REASND) is populated.
Rule 5.1	Missing Value for MHCAT	If Body System Category is null then Flag=No
Rule 6	Missing value for --STRESC, when --STRESU is provided	Character Result/Finding in Std Units (--STRESC) should be populated when Result or Finding in Original Units (--STRESU) is provided.
Rule 7	Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is provided	Dose Units (--DOSU) must be populated, when Dose per Administration (--DOSE), Dose Description (--DOSTXT) or Total Daily Dose (--DOSTOT) is provided.
Rule 8	Missing value for --ORRES, when --STAT or --DRVFL is not populated	Status (--STAT) should be set to 'NOT DONE' or Derived Flag (--DRVFL) should be set to 'Y', when Result or Finding in Original Units (--ORRES) is provided.
Rule 9	No Exposure record found for subject	All Demographics (DM) subjects (USUBJID) participating in the study should have at least one record in the Exposure table, except for subjects who failed screening (ARMCD = 'SCREENING')

Domains Status

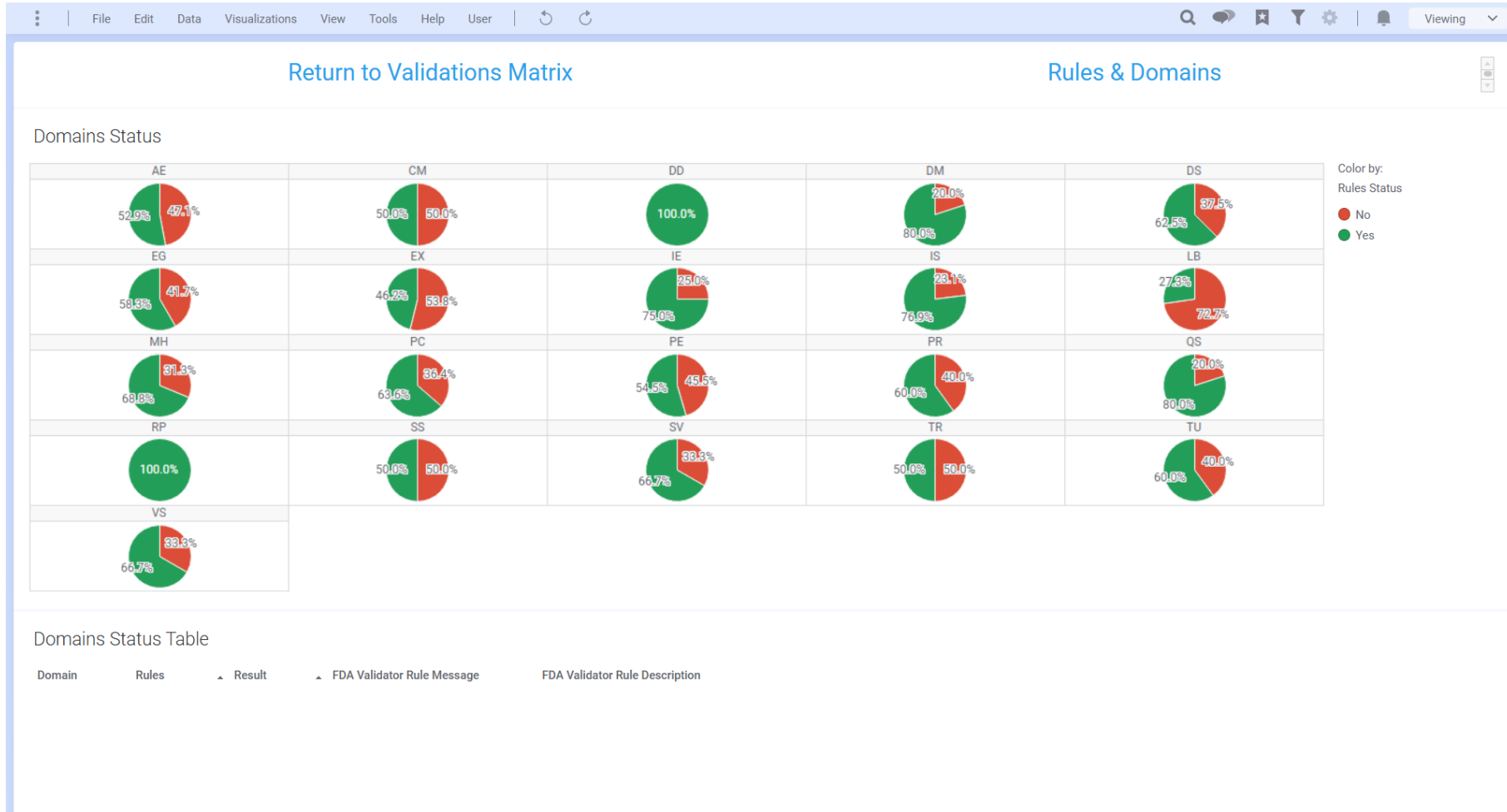
Relevant Domains

Domains	Abbreviation	Tables
Demographics	DM	dm
Subject Visits	SV	sys_evt
Laboratory Test Results	LB	Lbchem, lbchem_tsh, lbchem_crp, lbchem_lbsfh, trop
Concomitant Medications	CM	cm, prior radiotherapy(pat), subsequent therapy(pat), PATAM, PATPR
Exposure	EX	ex2, ex2a, ex
Procedures	PR	pr, ps
Adverse Events	AE	ae
Disposition	DS	dses, dset_rp1, dset_nivo, informed consent(enroll), dm
Medical History	MH	mh
Death Details	DD	dth
ECG Test Results	EG	eglr
Inclusion/Exclusion Criterion Not Met	IE	ie
Immunogenicity Specimen Assessments	IS	HERP, HSVA, external data eurofins, external data viracor
RP1 Detection	PC	RP1 detections, external data viracor
Physical Examination	PE	pe
Questionnaires	QS	Qs, ecog
Reproductive System Findings	RP	wornh

Rule Status Page – Violation Status for each Rule



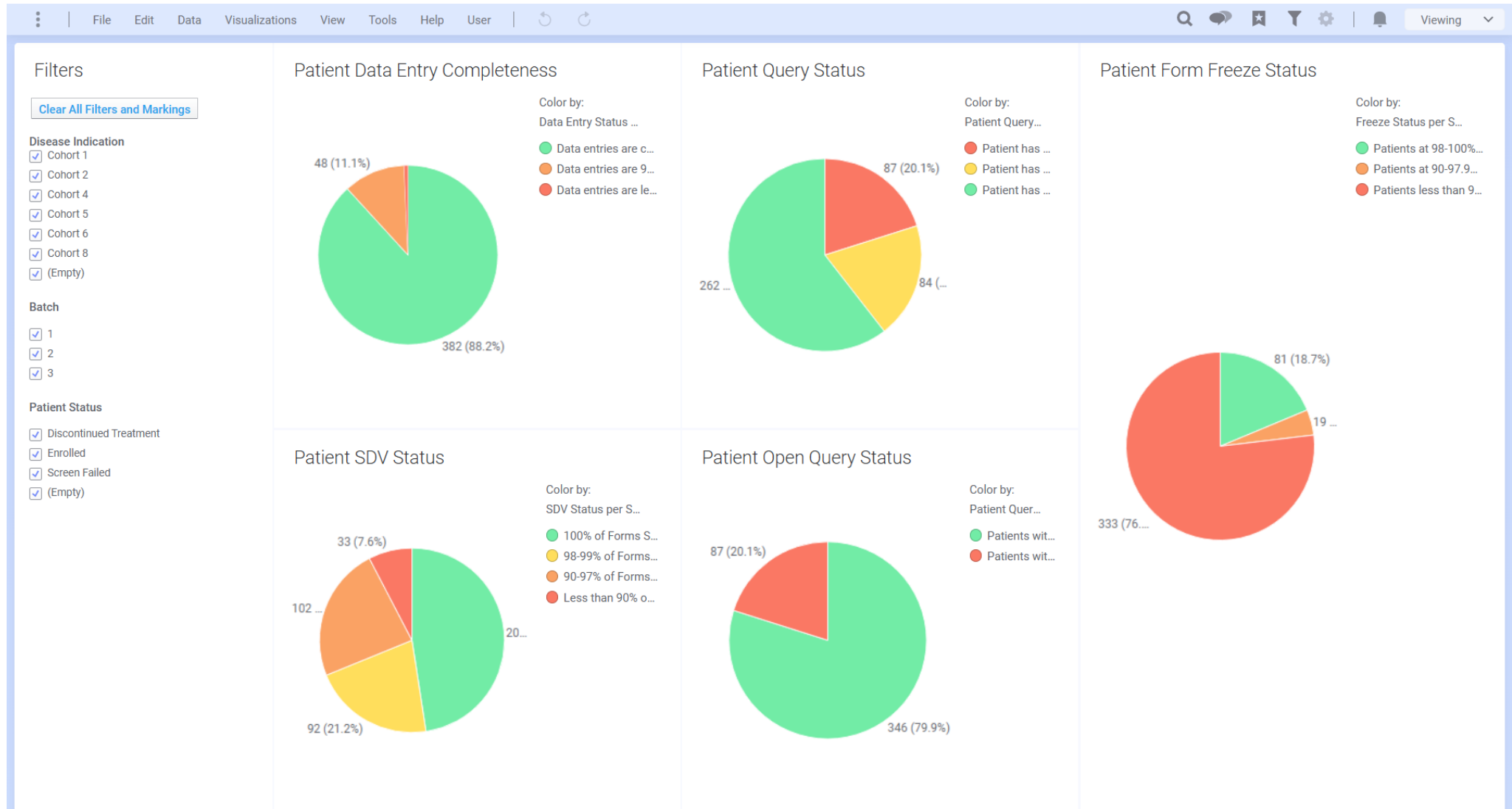
Domain Status Page – Violation Status for each Domain



Database Lock

- Automated real-time data access
 - Drives Database Lock activities
 - How can dashboard visualizations drive database lock?

Automated Daily Update to Database Lock Status



EDC Data Metrics and Patient Status towards Database Lock

File Edit Data Visualizations View Tools Help User
Viewing

Filters

[Clear Filters and Markings](#)

Disease Indication

- Cohort 1
- Cohort 2
- Cohort 4
- Cohort 5
- Cohort 6
- Cohort 8
- (Empty)

Batch

- 1
- 2
- 3

Patient Status

- Discontinued Treatment
- Enrolled
- Screen Failed
- (Empty)

EDC Data Metrics with Batch Breakdown

Disease Indication	Batch	# Patients with SDV Completed Forms	% SDV Complete	Open Queries	# Patients with Open Queries	Queries Open > 30 Days	# Patients with Queries Open > 30 Days	Answered Queries	# Patients Ready for Freeze	# Patients Frozen	% Patients Frozen	
Cohort 1	1	3	36	98.2%	24	12	1	1	38	9	0	0.0%
	2	2	28	99.0%	21	10	4	4	45	10	0	0.0%
	3	9	77	96.9%	38	13	10	5	113	18	0	0.0%
Cohort 2	1	0	7	98.8%	16	4	1	1	5	0	1	14.3%
	2	5	3	99.1%	0	0	0	0	0	1	0	0.0%
Cohort 4	1	3	2	95.1%	2	1	0	0	1	0	1	50.0%
	2	4	6	98.6%	5	2	2	1	5	2	0	0.0%
	3	7	15	98.9%	4	2	0	0	9	8	0	0.0%
Cohort 5	1	2	39	97.6%	35	13	5	4	20	11	1	2.6%
	2	0	16	96.9%	9	4	0	0	37	3	0	0.0%
	3	1	54	96.4%	36	11	16	6	55	12	0	0.0%
Cohort 6	1	0	1	96.9%	0	0	0	0	4	0	0	0.0%
	3	9	1	97.8%	2	1	0	0	0	0	0	0.0%
Cohort 8	1	9	11	98.1%	6	3	0	0	3	1	0	0.0%
	2	0	3	100.0%	0	0	0	0	1	3	0	0.0%

Detailed Patient Status

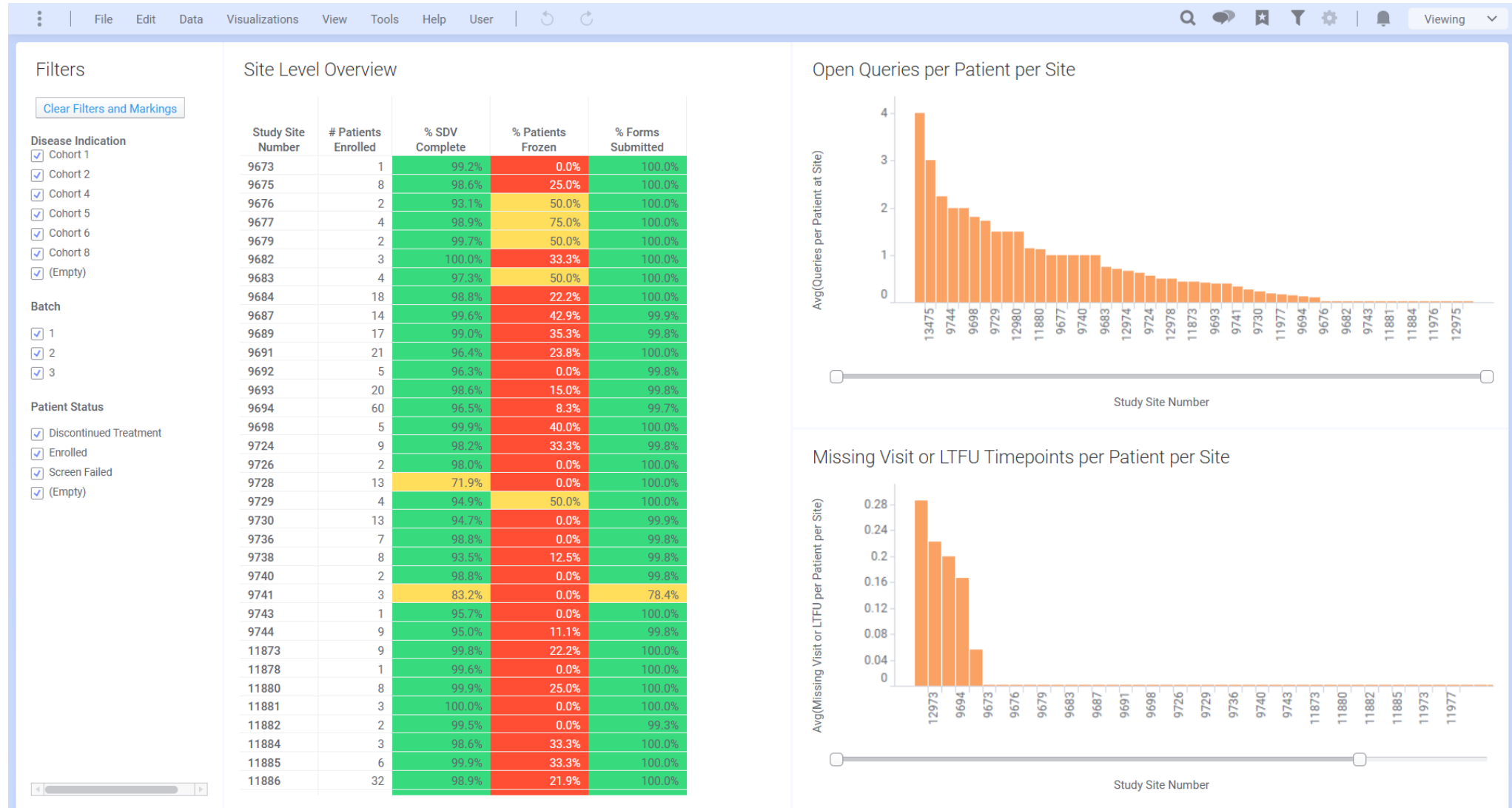
Patient Status	Cohort 1	Cohort 2	Cohort 4	Cohort 5
Discontinued Treatment	129	10	22	0
Enrolled	12	0	1	0
Screen Failed	0	0	0	0
(Empty)	0	0	0	0
Grand total	141	10	23	0

Patient Status

Color by: IRT Patient Status

- Discontinued Treat...
- Enrolled
- Screen Failed

SDV and Query Status towards Database Lock



Patient Details towards Database Lock

File Edit Data Visualizations View Tools Help User | Refresh | Search | Filter | Settings | Notifications | Viewing

Filters

[Clear Filters and Markings](#)

Subject ID

Type to search in list

(All) 433 values

- 22369859
- 22409859
- 22409861
- 22409863
- 22409865
- 22409867

Site ID

Type to search in list

(All) 51 values

- Royal Hope Hospital 1
- Royal Hope Hospital 10
- Royal Hope Hospital 11
- Royal Hope Hospital 12
- Royal Hope Hospital 15
- Royal Hope Hospital 16

Disease Indication

- Cohort 1
- Cohort 2
- Cohort 4
- Cohort 5
- Cohort 6
- Cohort 8
- (Empty)

Batch

- 1
- 2
- 3

Patient Status

- Discontinued Treatment

Patient Details

Subject	Disease Indication	Detailed Patient Status	Site	Batch	Blank or In Progress Forms	Submitted Forms	Total Expected Forms	% Forms Submitted	Missing Visit or LTFU Timepoints	Missing Visits	Missing LTFU Timepoints	For
22689861	Cohort 1	Follow-Up	9689	2	0	377	377	100.0%	0	0	0	
22689863	(Empty)	Off Study	9689	2	0	6	6	100.0%	0	0	0	
22689865	(Empty)	Screen Failed	9689	2	0	6	6	100.0%	0	0	0	
22689867	Cohort 1	Off Study	9689	2	0	268	268	100.0%	0	0	0	
22689869	Cohort 1	Screen Failed	9689	2	0	482	482	100.0%	0	0	0	
22689871	Cohort 1	On Study	9689	2	0	104	104	100.0%	0	0	0	
22689873	Cohort 1	Follow-Up	9689	2	0	126	126	100.0%	0	0	0	
22689875	Cohort 5	On Study	9689	2	5	389	394	98.7%	0	0	0	
22689877	(Empty)	Screen Failed	9689	2	0	7	7	100.0%	0	0	0	
22689879	Cohort 5	Follow-Up	9689	2	0	123	123	100.0%	0	0	0	
22689881	Cohort 5	On Study	9689	2	0	58	58	100.0%	0	0	0	
22689883	(Empty)	On Study	9689	2	0	7	7	100.0%	0	0	0	
22689885	Cohort 1	On Study	9689	2	0	84	84	100.0%	0	0	0	
22689887	(Empty)	Off Study	9689	2	0	7	7	100.0%	0	0	0	
22689889	(Empty)	On Study	9689	2	0	20	20	100.0%	0	0	0	
22689891	Cohort 5	On Study	9689	2	5	219	224	97.8%	0	0	0	
22729859	Cohort 8	On Study	9691	1	0	353	353	100.0%	0	0	0	
22729861	Cohort 6	On Study	9691	1	0	300	300	100.0%	0	0	0	

Missing Cycles and Lost to Follow Up towards Database Lock

Subject Number	Site ID	Visit	Visit Date	Expected Visit Date	Missing in EDC per Subject
68409861	11975	Cycle 27 Day 603	5/25/2018	5/24/2018	2
68409861	11975	Cycle 28 Day 631	6/22/2018	6/22/2018	2
88409865	12975	Cycle 15 Day 281	8/11/2015	6/30/2015	1

Data limiting: Marking
Data table: missing cycles (ba...)

Subject	# of FU	# FU Expected	# Missing FU	Missing LTFU per Subject	Date of Drug One Discontinuation	Willing to Continue Follow Up Drug ...	Date of Drug Two Discontinuation	Did the Patient Complete the Study?	Status_EOS	Visit Truly Occurred	Last Visit	IRT Patient Status
88369861	4	8	4	4	8/20/2014	Y	11/25/2014		Consented	Visit Did Not T...	11/25/2014	Discontini...
88369883	7	8	1	1	3/21/2015	Y	11/19/2016		Consented	Visit Did Not T...	11/19/2016	Discontini...
22789887	8	11	3	3	5/21/2015	Y	4/7/2016		Consented	Visit Did Not T...	4/7/2016	Discontini...
22789881	7	10	3	3	3/25/2015	Y	4/1/2016		Consented	Visit Truly Occ...	7/13/2016	Discontini...
22789909	8	11	3	3	10/5/2016	Y	2/10/2016		Consented	Visit Did Not T...	2/10/2016	Discontini...
22749861	4	5	1	1	9/12/2017	Y	9/27/2017		Consented	Visit Truly Occ...	9/27/2017	Discontini...
22789907	10	11	1	1	3/10/2016	Y	3/10/2016		Consented	Visit Did Not T...	3/10/2016	Discontini...
88369911	3	4	1	1	6/30/2017	Y	12/22/2017		Consented	Visit Did Not T...	12/22/2017	Discontini...

Data limiting: Marking
Data table: missing ltfu (base)

Missing Page Details towards Database Lock

Study	Site Name	Study Site Number	Subject	Principal Investigator	Event Date	Form	Form Status	Intentionally Left Blank	SDV Required	Disease Indication	IRT Patient Status	Batch
Fake Study	Royal Hope Hospital 55	12973	88369867	Dr. Martha Jones 54		Concomitant Medications	In Progress/In Progress Post Submit	No	Yes	Cohort 6	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 15	9687	22649871	Dr. Martha Jones 15		Drug One End of Treatment	In Progress/In Progress Post Submit	No	Yes	Cohort 4	Discontinued Treatment	2
Fake Study	Royal Hope Hospital 32	9738	23669861	Dr. Martha Jones 32	12/31/2018	Follow-Up	Blank		Yes	Cohort 5	Enrolled	3
Fake Study	Royal Hope Hospital 32	9738	23669861	Dr. Martha Jones 32	12/31/2018	Photography	Blank		No	Cohort 5	Enrolled	3
Fake Study	Royal Hope Hospital 32	9738	23669861	Dr. Martha Jones 32		Drug Two End of Treatment	Blank		Yes	Cohort 5	Enrolled	3
Fake Study	Royal Hope Hospital 59	12977	88449879	Dr. Martha Jones 58	11/22/2017	Drug One Detection Follow Up	Blank		Yes	Cohort 2	Discontinued Treatment	2
Fake Study	Royal Hope Hospital 57	12975	88409881	Dr. Martha Jones 56	9/28/2017	Drug One Detection Follow Up	Blank		Yes	Cohort 1	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 44	11886	66629867	Dr. Martha Jones 44	5/30/2017	Brain Scan - CT/MRI	Blank		No	Cohort 1	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 32	9738	23669865	Dr. Martha Jones 32		Drug One End of Treatment	In Progress/In Progress Post Submit		Yes	Cohort 1	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 34	9741	23729861	Dr. Martha Jones 34		Drug Two End of Treatment	Blank		Yes	Cohort 1	Enrolled	1
Fake Study	Royal Hope Hospital 21	9694	22789887	Dr. Martha Jones 21	11/20/2018	Evaluation of Response (RECIST 1.1)	In Progress/In Progress Post Submit		Yes	Cohort 1	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 21	9694	22789887	Dr. Martha Jones 21	11/20/2018	Target Lesions	In Progress/In Progress Post Submit		Yes	Cohort 1	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 21	9694	22789919	Dr. Martha Jones 21		Drug Two End of Treatment	In Progress/In Progress Post Submit		Yes	Cohort 1	Discontinued Treatment	3
Fake Study	Royal Hope Hospital 32	9738	23669859	Dr. Martha Jones 32		Drug One End of Treatment	In Progress/In Progress Post Submit		Yes	Cohort 5	Discontinued Treatment	3

Sample Management

- How can automated third party data visualizations accelerate sample management data quality?

Automated Listing – Sample Biopsy

The screenshot shows a software interface with a menu bar (File, Edit, Data, Visualizations, View, Tools, Help, User) and a toolbar with search, refresh, and filter icons. On the left, there are filter panels for Subject ID, Site, EDC Event, Record Missing in EDC?, Record Missing in PPD?, and Disagreement on Visit Scheduling?. The main area displays a table with the following data:

Medical Review State	Latest Medical Reviewer	Medical Review Date/Time	Record Missing in EDC	Record Missing in PPD	Disagreement on Visit Scheduling	Subject ID	EDC Event	PPD Visit Description	EDC Event Date	According to EDC, Was a Tumor Tissue ...	EDC Reason Collection
Reviewed	UserA@email.com	1/31/2022 7:00:00 PM			EDC and PPD in conflict over unscheduled ...	4401-0016	C4	Unscheduled [1]	11/4/2020	Yes	For Biomark Testing

A callout box with a black border and white background is positioned over the table, containing the text: "Conflict in EDC and 3rd Party Visit".

Automated Listing – Saliva/Mucosa and Injection Site Swab Samples

Reset All Filters and Markings

Subject ID
Type to search in list
(All) 67 values
3403-0001
3403-0002
3403-0003
3403-0004
3403-0006
3403-0008

Site
Type to search in list
(All) 7 values
3403
3412
3413
4401
4402
4403

EDC Event
Type to search in list
(All) 32 values
C10
C11
C12
C13
C14
C1D1

Record Missing in EDC?
 Missing in EDC
 (Empty)

Record Missing in PPD?
 Missing in PPD
 (Empty)

Disagreement on Visit Scheduling?
 EDC and PPD in conflict over un

Medical Review State	Record Missing in EDC	Record Missing in PPD	Sample Count Errors at PPD	Subject ID	EDC Event	EDC Event Date	EDC Sample Collected?	EDC Sample Type	EDC Date/Time of Collection	PPD Collection Date	EDC Timepoint	PPD Description
Reviewed				4411-0001	C1D1	3/28/2023	Yes	Saliva/Mucosa	3/28/2023 9:45:00 AM	3/28/2023	Pre RP2 Dose	RP2 Det Oral Sw
New				4411-0001	C1D1	3/28/2023	Yes	Saliva/Mucosa	3/28/2023 5:55:00 PM	3/28/2023	6 hr Post RP2 Dose	RP2 Det Oral Sw
In Progress				4411-0001	C1D1	3/28/2023	Yes	Injection Site Swab	3/28/2023 5:55:00 PM	3/28/2023	6 hr Post RP2 Dose	RP2 Det InjSite 6
In Progress				4411-0001	C1D1	3/28/2023	Yes	Dressing Swab	3/28/2023 5:55:00 PM	3/28/2023	6 hr Post RP2 Dose	RP2 Det Ext Dr 6
Reviewed		Missing in PPD		4411-0001	C1D1	3/28/2023	Not Applicable	Injection Site Swab			Pre RP2 Dose	
Amended (In Progress)		Missing in PPD		4411-0001	C1D1	3/28/2023	Not Applicable	Dressing Swab			Pre RP2 Dose	
Amended (In Progress)				4411-0001	C1D2	3/29/2023	Yes	Saliva/Mucosa	3/29/2023 8:50:00 AM	3/29/2023	21 hr Post RP2 Dose	RP2 Det Oral Sw Post
In Progress				4411-0001	C1D2	3/29/2023	Yes	Injection Site Swab	3/29/2023 8:51:00 AM	3/29/2023	21 hr Post RP2 Dose	RP2 Det InjSite 2
In Progress				4411-0001	C1D2	3/29/2023	Yes	Dressing Swab	3/29/2023 8:51:00 AM	3/29/2023	21 hr Post RP2 Dose	RP2 Det Ext Dr 2
Reviewed				4411-0001	C1D3	3/30/2023	Yes	Saliva/Mucosa	3/30/2023 8:11:00 AM	3/30/2023	48 hr Post RP2 Dose	RP2 Det Oral Sw Post
Reviewed				4411-0001	C1D3	3/30/2023	Yes	Injection Site Swab	3/30/2023 8:11:00 AM	3/30/2023	48 hr Post RP2 Dose	RP2 Det InjSite 4
Reviewed				4411-0001	C1D3	3/30/2023	Yes	Dressing Swab	3/30/2023 8:11:00 AM	3/30/2023	48 hr Post RP2 Dose	RP2 Det Ext Dr 4
Reviewed				4411-0001	C2D15	4/11/2023	Yes	Saliva/Mucosa	4/11/2023 10:19:00 AM	4/11/2023	Pre RP2 Dose	RP2 Det Oral Sw
Reviewed				4411-0001	C2D15	4/11/2023	Yes	Injection Site Swab	4/11/2023 10:19:00 AM	4/11/2023	Pre RP2 Dose	RP2 Det InjSite P
Amended (In Progress)				4411-0001	C2D15	4/11/2023	Yes	Dressing Swab	4/11/2023	4/11/2023	Pre RP2 Dose	RP2 Det

Missing Records in 3rd Party Data

Automated Listing – Blood and Urine Samples

File Edit Data Visualizations View Tools Help User

Reset All Filters and Markings

Subject ID
Type to search in list
(All) 67 values
3403-0001
3403-0002
3403-0003
3403-0004
3403-0006
3403-0008

Site
Type to search in list
(All) 7 values
3403
3412
3413
4401
4402
4403

EDC Event
Type to search in list
(All) 32 values
C10
C11
C12
C13
C14
C1D1

Record Missing in EDC?
 Missing in EDC
 (Empty)

Record Missing in PPD?
 Missing in PPD
 (Empty)

Disagreement on Visit Scheduling?
 EDC and PPD in conflict over unsch...

PPD Visit Description	EDC Was Sample Collected?	EDC Date/Time of Collection	PPD Date of Collection	EDC Sample Type	EDC Timepoint	PPD Barcode	PPD Description	PPD Description Type	EDC Samples Collected at This Visit of...	Samples Received by PPD at This...	PPD Sample Status	PPD
C1D1	Yes	3/28/2023 8:30:00 AM	3/28/2023	Blood	Pre RP2 Dose	1G003239956	RP2 Detection Blood Pre 1	Whole Blood (EDTA)	1	2	Shipped	VIR. LAE KAI
C1D1	Yes	3/28/2023 8:30:00 AM	3/28/2023	Blood	Pre RP2 Dose	1G003166336	RP2 Detection Blood Pre 2	Whole Blood (EDTA)	1	2	In Storage	GCL
C1D1	Yes	3/28/2023 9:40:00 AM	3/28/2023	Urine	Pre RP2 Dose	1G003231872	RP2 Detection Urine Pre 1	Urine	1	2	Shipped	VIR. LAE KAI
C1D1	Yes	3/28/2023 9:40:00 AM	3/28/2023	Urine	Pre RP2 Dose	1G003240064	RP2 Detection Urine Pre 2	Urine	1	2	In Storage	GCL
C1D1	Yes	3/28/2023 6:00:00 PM	3/28/2023	Blood	6 hr Post RP2 Dose	1G003239952	RP2 Detection Blood 6h Post 1	Whole Blood (EDTA)	1	2	Shipped	VIR. LAE KAI
C1D1	Yes	3/28/2023 6:00:00 PM	3/28/2023	Blood	6 hr Post RP2 Dose	1G003231764	RP2 Detection Blood 6h Post 2	Whole Blood (EDTA)	1	2	In Storage	GCL
C1D1	Yes	3/28/2023 6:30:00 PM	3/28/2023	Urine	6 hr Post RP2 Dose	1G003166356	RP2 Detection Urine 6h Post 1	Urine	1	2	Shipped	VIR. LAE KAI
C1D1	Yes	3/28/2023 6:30:00 PM	3/28/2023	Urine	6 hr Post RP2 Dose	1G003174548	RP2 Detection Urine 6h Post 2	Urine	1	2	In Storage	GCL
C1D2	Yes	3/29/2023 8:30:00 AM	3/29/2023	Urine	21 hr Post RP2 Dose	1G003700752	RP2 Detection Urine	Urine	1	2	Shipped	VIR. LAE KAI
C1D2	Yes	3/29/2023 8:30:00 AM	3/29/2023	Urine	21 hr Post RP2 Dose	1G003692564	RP2 Detection Urine	Urine	1	2	In Storage	GCL
C1D2	Yes	3/29/2023 8:46:00 AM	3/29/2023	Blood	21 hr Post RP2 Dose	1G003692544	RP2 Detection Blood 21h Post 1	Whole Blood (EDTA)	1	2	Shipped	VIR. LAE KAI
C1D2	Yes	3/29/2023 8:46:00 AM	3/29/2023	Blood	21 hr Post RP2 Dose	1G003700736	RP2 Detection Blood 21h Post 2	Whole Blood (EDTA)	1	2	In Storage	GCL
C1D3	Yes	3/30/2023 7:50:00 AM	3/30/2023	Urine	48 hr Post RP2 Dose	1G003700868	RP2 Detection Urine 48h Post 1	Urine	1	2	Shipped	VIR. LAE KAI
C1D3	Yes	3/30/2023 7:50:00 AM	3/30/2023	Urine	48 hr Post RP2 Dose	1G003692688	RP2 Detection Urine 48h Post 2	Urine	1	2	In Storage	GCL
C1D3	Yes	3/30/2023	3/30/2023	Blood	48 hr Post RP2	1G003758100	RP2 Detection	Whole Blood	1	2	Shipped	VIR.

3rd Party Sample Status

Summary

- Data access automation – accelerates data preparation for submission and data review
 - Data science drives automation of data mapping, transformation and access
- Workflows with listings, visualizations and tracking improve data quality and consistency
 - FDA Validation Rule, Database Lock and Sample Management good examples
- Together, these are a powerful tool for data managers and data scientists
 - Maximize the power of clinical trial data
 - Accelerate clinical drug submission

Thank you!

For more information:

<https://revvitysignals.com/products/clinical-development/signals-clinical>

Come see us at the Revvity Booth #30!

