



EXPERTISE

SAFETY

SOLUTIONS

Get Ready in one Click: Clean SDTM datasets by Using Library Backend Rules

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WHEN YOU NEED TO BE SURE

SGS

DISCLAIMER AND DISCLOSURES

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the opinions of PHUSE members, respective companies or organizations.*



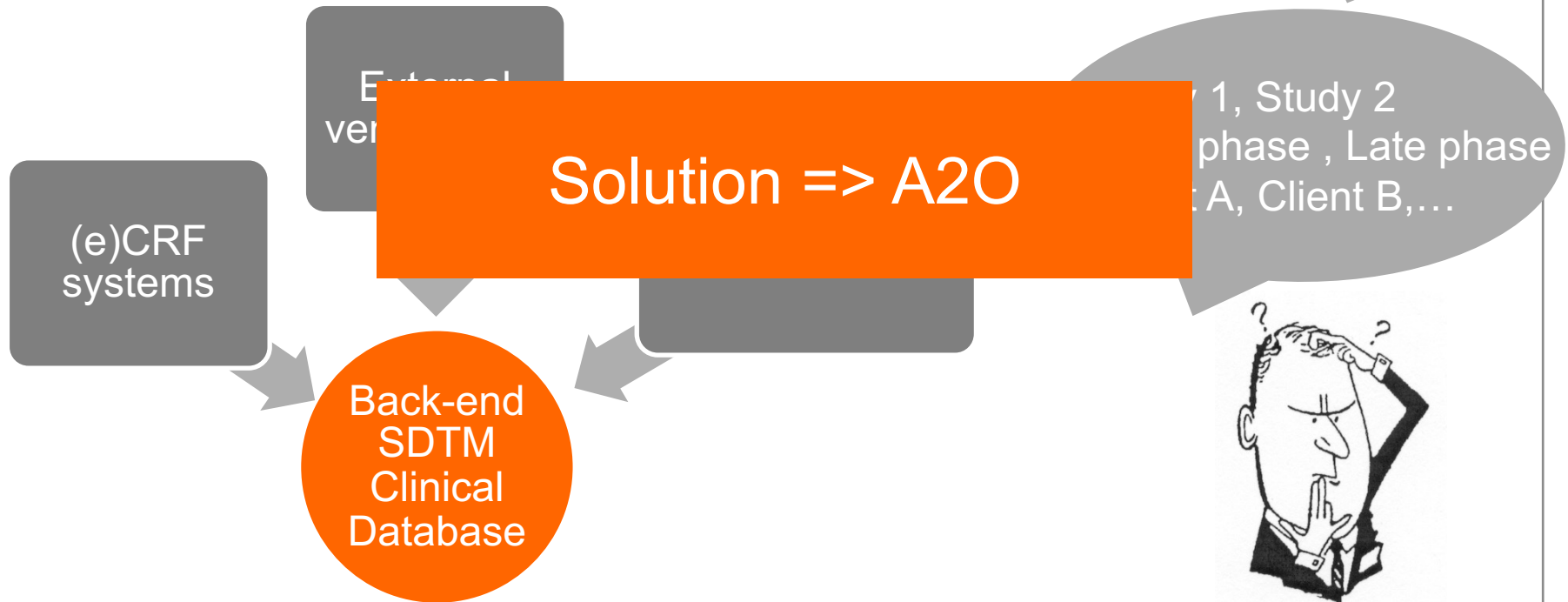
Rules

- Data cleaning challenges
- All2One Tool
- Case study
 - Selecting back-end rules
 - Creating new rules
 - Use of help tables
- Automated creation Data Validation Plan
- Future plans
- Conclusion

Rules

Data cleaning challenges

DATA CLEANING CHALLENGES



Rules

All2One Tool

- In-house developed application for data cleaning
- First Release in 2011
- Contains a master cleaning library that can be applied to trials
- Library populated with rules that have been validated (controlled validation process, no study validation needed)
- A2O rules will run on the backend SDTM database
- Used by both Clinical Data Manager (CDM) and Clinical Data Programmer (CDP)
- CDM is able to select relevant rules for a trial from the library
- CDM is able to create new rules

CASE STUDY

- New trial
- Use protocol, eCRF/aCRF and DTA's
- Determine data cleaning needs
- Create data cleaning package
 - Selecting all appropriate back-end library rules
 - Create new study specific rules
 - Update help tables
 - Create manual rules



EXPERTISE

Rules

Selecting back-end rules

SELECTING BACK-END RULES

- Rules are divided in Checks and Listings

Detail	Copy	Library ... ▲ ▼	Version	Panel	Type	Full Rule Type	Description	Message
Detail		AE_006_L	V01.00	AE	CHECK	CHECK	Check if adverse event outcome ([AEOUT]) = 'FATAL' that the AE is considered serious ([AESER] = 'Y'). Reported: [AETERM], [AESTDTC], [AEOUT], [AESER]	Adverse event outcome is fatal, but the adverse event is not considered serious. Please check and correct where necessary.



- All output needs to be investigated
- If all data is ok => no output in A2O

panel	rulename	ruletype	fullruletype	state	version	tot	new	ind	cie	qtp	chg	nan	hld
AE	AE_006_L	CHECK	CHECK	ACCEPTED	V01.00	0	0	0	0	0	0	0	0
AE	AE_007_L	CHECK	CHECK	ACCEPTED	V01.00	0	0	0	0	0	0	0	0
AE	AE_008_L	CHECK	CHECK	ACCEPTED	V02.00	0	0	0	0	0	0	0	0
AE	AE_020_L	CHECK	CHECK	ACCEPTED	V01.00	0	0	0	0	0	0	0	0
AE	AE_039_L	CHECK	CHECK	ACCEPTED	V01.00	0	0	0	0	0	0	0	0
AE	AE_061_L	CHECK	CHECK	ACCEPTED	V01.00	0	0	0	0	0	0	0	0
AE	AE_064A_L	CHECK	CHECK	ACCEPTED	V01.00	3	3	0	0	0	0	0	0

Rules are divided in Checks and Listings

Detail	Copy	Library Rule ...	Version	Panel	Type	Full Rule Type	Description	Message
Detail		VS_026_L	V02.00	VS	LISTING	LISTING_WITH_IND	List per subject, visit and time point all vital signs results ([VSSTRESN]) and the corresponding clinical significance ([QVAL] where [QNAM] = 'VSCLSIG' and [IDVAR] = 'VSSEQ'). Add a first indication when a value is out of range and the corresponding clinical significance is not completed. Add a second indication when the clinical significance is completed but the corresponding value is not out of range. Refer to table [ZZ_VSRANGES] for specifications on vital signs reference ranges. Reported: [VISITNUM], [VSTPT], [VSTPTNUM], [VSDTC], [VSPOS], [VSTESTCD], [VSTEST], [VSORRES], [VSORRESU], [VSSTRESN], [VSSTRESU], [QNAM], [QVAL], [VSSTAT], [VSREASND], [IND#1], [IND#2] Order by: [SITEID], [USUBJID], [VSTESTCD], [VSDTC]	



- Always output
- Uses indications to facilitate cleaning

	panel	rulename	ruletype	fullruletype	state	version	tot	new	ind
	VS	VS_004_L	LISTING	LISTING	ACCEPTED	V02.00	957	76	0
	VS	VS_008_L	LISTING	LISTING_WITH_IND	DATED	V03.00	1271	117	4
▶	VS	VS_026_L	LISTING	LISTING_WITH_IND	ACCEPTED	V02.00	10974	6446	211
	VS	VS_511A_L	LISTING	LISTING_WITH_IND	ACCEPTED	V01.00	4743	462	0

Rule Package

New Rules All Trials

Copy Library Rule

Add New Rule

Rule Package Statistics

Copy From Trial: No Trial Selected

☐ Copy DVP Info

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	Detail	Copy	Library Rule Na...	Version	Panel	Type	Full Rule Type	Description	Message
	Detail	☐	AE_003_L	V01.00	AE	CHECK	CHECK	Check that end date of adverse event ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSSCAT] = 'TRIAL TERMINATION'). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSTERM], [DSSTDTC]	The adverse event end date is after the da trial termination ([DSTERM]). Please check a necessary.
	Detail	☐	AE_003A_L	V01.00	AE	CHECK	CHECK	Check that the end date of the adverse event ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSCAT] = 'DISPOSITION EVENT'). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSTERM], [DSSTDTC]	The adverse event end date is after the da trial termination ([DSTERM]). Please check a necessary.
	Detail	☐	AE_003B_L	V01.00	AE	CHECK	CHECK	Check that end date of AE ([AEENDTC]) <= study discontinuation date ([DSSTDTC] where [DSCAT] = 'DISPOSITION EVENT' and [EPOCH] <> 'TREATMENT' or not completed). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSSTDTC#STUDY]	End date of AE ([AEENDTC]) is after the stu ([DSSTDTC#STUDY]). Please check and con If the AE was ongoing at the time of study c tick the according option.
	Detail	☐	AE_003C_L	V01.00	AE	CHECK	CHECK	Check that end date of adverse event ([AEENDTC]) >= minimum administration start date of primary medication (min [EXSTDTC] where [EXTRT] = [TRT#ZZ_EX]) and <= current date. Refer to table [ZZ_EX] for specifications about primary medication. Reported: [AESPID], [AETERM], [AEENDTC], [TRT#ZZ_EX], [EXSTDTC]	End date of adverse event is prior to the fir [TRT#ZZ_EX] or is a future date. Please ch necessary.
	Detail	☐	AE_003D_L	V02.00	AE	CHECK	CHECK	Check that the end date of AE ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSSCAT] = [DSSCAT] of the record in [ZZ_DS] where [EVENT] = 'TRIAL TERMINATION'). Refer to table [ZZ_DS] for specifications about termination records. Reported: [AETERM], [AESTDTC], [AEENDTC], [DSSTDTC], [X1SPID#ZZ], [X1TESTCD#ZZ], [X1ORRES#ZZ]	The adverse event end date ([AEENDTC]) is trial termination ([DSSTDTC]). Please check necessary.
	Detail	☐	AE_003E_L	V01.00	AE	CHECK	CHECK	Check that end date of adverse event ([AEENDTC]) >= minimum administration start date of primary medication (min [ECSTDTC] where [ECTRT] = [TRT#ZZ_EC]) and <= current date. Refer to table [ZZ_EC] for specifications about primary medication. Reported: [AESPID], [AETERM], [AEENDTC], [TRT#ZZ_EC], [ECSTDTC]	End date of adverse event is prior to the fir [TRT#ZZ_EC] or is a future date. Please ch necessary.
	Detail	☒	AE_006_L	V01.00	AE	CHECK	CHECK	Check if adverse event outcome ([AEOUT]) = 'FATAL' that the AE is considered serious ([AESER] = 'Y'). Reported: [AETERM], [AESTDTC], [AEOUT], [AESER]	Adverse event outcome is fatal, but the ad considered serious. Please check and correc
	Detail	☒	AE_007_L	V01.00	AE	CHECK	CHECK	Check if concomitant therapy is not given because of adverse event ([AECONTRT] = 'N') or if concomitant therapy given ([AECONTRT]) is not completed, that no linking with a concomitant therapy record exists in [RELREC]. Reported: [AETERM], [AESTDTC], [AECONTRT]	There was no concomitant therapy given be event, but there is a link with a concomitant Please check and correct where necessary.

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Edit Filter

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Refresh

Close

FileRulesCleanerDCFsZZ TablesSDTM RulesDVPReportsWindows

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Copy DVP Info

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Detail	Copy	Library Rule Na...	Version	Panel	Type	Full Rule Type	Description	Message
Detail	☐	AE_003_L	V01.00	AE	☐ SUPPAE ☐ SUPPDM ☐ SUPPDS ☐ SUPPEX ☐ SUPPSS ☐ SV ☐ TR ☐ TU ☒ VS ☐ X1 ☐ XA ☐ XZ ☐ YY_CONV_MISS ☐ YY_DP_DM ☐ YY_EG_DM OK Cancel	Check that end date of adverse event ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSSCAT] = 'TRIAL TERMINATION'). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSTERM], [DSSTDTC]	The adverse event end date is after the da trial termination ([DSTERM]). Please check a necessary.	
Detail	☐	AE_003A_L	V01.00	AE			Check that the end date of the adverse event ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSCAT] = 'SPOSITION EVENT'). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSTERM], [DSSTDTC]	The adverse event end date is after the da trial termination ([DSTERM]). Please check a necessary.
Detail	☐	AE_003B_L	V01.00	AE			Check that end date of AE ([AEENDTC]) <= study discontinuation date ([DSSTDTC] where [DSCAT] = 'DISPOSITION ENT' and [EPOCH] <> 'TREATMENT' or not completed). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSSTDTC#STUDY]	End date of AE ([AEENDTC]) is after the stu ([DSSTDTC#STUDY]). Please check and con If the AE was ongoing at the time of study tick the according option.
Detail	☐	AE_003C_L	V01.00	AE			Check that end date of adverse event ([AEENDTC]) >= minimum administration start date of primary medication (min [STDTC] where [EXTRT] = [TRT#ZZ_EX]) and <= current date. Refer to table [ZZ_EX] for specifications about primary Reported: [AESPID], [AETERM], [AEENDTC], [TRT#ZZ_EX], [EXSTDTC]	End date of adverse event is prior to the fir [TRT#ZZ_EX] or is a future date. Please ch necessary.
Detail	☐	AE_003D_L	V02.00	AE			Check that the end date of AE ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSSCAT] = [DSSCAT] of the ord in [ZZ_DS] where [EVENT] = 'TRIAL TERMINATION'). Refer to table [ZZ_DS] for specifications about termination ords. Reported: [AETERM], [AESTDTC], [AEENDTC], [DSSTDTC], [X1SPID#ZZ], [X1TESTCD#ZZ], [X1ORRES#ZZ]	The adverse event end date ([AEENDTC]) is trial termination ([DSSTDTC]). Please check necessary.
Detail	☐	AE_003E_L	V01.00	AE	CHECK	CHECK	Check that end date of adverse event ([AEENDTC]) >= minimum administration start date of primary medication (min [ECSTDTC] where [ECRT] = [TRT#ZZ_EC]) and <= current date. Refer to table [ZZ_EC] for specifications about primary medication. Reported: [AESPID], [AETERM], [AEENDTC], [TRT#ZZ_EC], [ECSTDTC]	End date of adverse event is prior to the fir [TRT#ZZ_EC] or is a future date. Please ch necessary.
Detail	☒	AE_006_L	V01.00	AE	CHECK	CHECK	Check if adverse event outcome ([AEOUT]) = 'FATAL' that the AE is considered serious ([AESER] = 'Y'). Reported: [AETERM], [AESTDTC], [AEOUT], [AESER]	Adverse event outcome is fatal, but the ad considered serious. Please check and correc
Detail	☒	AE_007_L	V01.00	AE	CHECK	CHECK	Check if concomitant therapy is not given because of adverse event ([AECONTRT] = 'N') or if concomitant therapy given ([AECONTRT]) is not completed, that no linking with a concomitant therapy record exists in [RELREC]. Reported: [AETERM], [AESTDTC], [AECONTRT]	There was no concomitant therapy given be event, but there is a link with a concomitant Please check and correct where necessary.

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QC sync: 20/04/2021 10:01:21 | Live sync: 27/04/2021 4:48:14

FileRulesCleanerDCFsZZ TablesSDTM RulesDVP SAEReportsWindows

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☐ Copy DVP Info

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Detail	Copy	Library Rule Na...	Version	Panel	Type	Full Rule Type	Description	Message
Detail	☒	VS_003_L	V03.00	VS	LISTING	LISTING	List per subject and visit the height, weight, BMI, Waist Circumference, Arm Circumference, Hip Circumference and Waist-to-hip ratio results ([VSSTRESN] where [VSTESTCD] = 'HEIGHT', 'WEIGHT', 'BMI', 'WSTCIR', 'ARMCIR', 'HIPCIR' or 'WAISTHIP'). Reported: [VISITNUM], [VSDTC], [VSTESTCD], [VSORRES], [VSORRESU], [VSSTRESN], [VSSTRESU] Order by: [SITEID], [USUBJID], [VSTESTCD], [VISITNUM], [VSDTC]	
Detail	☒	VS_003A_L	V01.00	VS	LISTING	LISTING	List all height, weight, BMI and growth percentile records per visit ([VSSTRESN] where [VSTESTCD] = 'HEIGHT', 'WEIGHT', 'BMI' or 'GROWTH'). Reported: [VISITNUM], [VSDTC], [VSTESTCD], [VSORRES], [VSORRESU], [VSSTRESN], [VSSTRESU] Order by: [SITEID], [USUBJID], [VSTESTCD], [VISITNUM], [VSDTC]	
Detail	☐	VS_004_L	V02.00	VS	LISTING	LISTING	List 10 minimum and maximum results ([VSSTRESN]) for all distinct positions, vital signs tests ([VSPOS], [VSTESTCD]) from [VS]. Reported: [VISITNUM], [VSTPTNUM], [VSTPT], [VSPOS], [VSTESTCD], [VSORRES], [VSORRESU], [VSSTRESN], [VSSTRESU] Order by: [VSTESTCD], [VSPOS], [VSSTRESN], [SITEID], [USUBJID], [VISITNUM], [VSTPTNUM]	
I Detail	☒	VS_004A_L	V01.00	VS	LISTING	LISTING	List 10 minimum and maximum results ([VSSTRESN]) for all distinct vital signs tests ([VSCAT], [VSSCAT], [VSPOS], [VSTESTCD]). Reported: [VISITNUM], [VSTPTNUM], [VSTPT], [VSCAT], [VSSCAT], [VSPOS], [VSTESTCD], [VSORRES], [VSORRESU], [VSSTRESN], [VSSTRESU] Order by: [VSTESTCD], [VSPOS], [VSSTRESN], [SITEID], [USUBJID], [VISITNUM], [VSTPTNUM]	
Detail	☐	VS_006_L	V01.00	VS	LISTING	LISTING_WITH_IND	List per subject and visit the distinct date of vital signs ([VSDTC]) and the screening visit date ([SVSTDTCT] where [VISIT] = 'SCREENING'). Add an indication when [VSDTC] < [SVSTDTCT] or [VSDTC] > current date. Reported: [VISITNUM], [VSDTC], [SVSTDTCT#SCREENING], [IND] Order by: [SITEID], [USUBJID], [VISITNUM]	
Detail	☐	VS_008_L	V04.00	VS	LISTING	LISTING_WITH_IND	List per subject and visit the distinct date of vital signs ([VSDTC]*) and the corresponding visit date ([SVSTDTCT]). Add an indication when date of vital signs* is not completed, when date of vital signs* <> visit date or when there is no corresponding visit date. *For [VSDTC] use only the date part. Reported: [VISITNUM], [VSDTC#DATE], [SVSTDTCT], [IND]	

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Detail	Copy
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Trial Name	TrialId	Library	Sponsor Name	Compound Name
	1803831	SDS32_SGSIG50	Client A Client B	
	1502009	SDS32_SGSIG50		
	1507300	SDS32_SGSIG50		
	1507302	SDS32_SGSIG50		
	1605772	SDS32_SGSIG50		
	1805324	SDS32_SGSIG50		
	1601039	SDS32_SGSIG50		
	1801534	SDS32_SGSIG50		
	1801535	SDS32_SGSIG50		
	1901116	SDS32_SGSIG50		
	1803871	SDS32_SGSIG50		
	2000229	SDS32_SGSIG50		

☒ [Library] = 'SDS32_SGSIG50' Edit Filter

☒

AE_003E_L	V01.00	CHECK	AE	Check that end date of adverse event ([AEENDTC]) >= minimum adminis [ECSTDTC] where [ECTRT] = [TRT#ZZ_EC]) and <= current date. Refer primary medication.
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Trial Name	TrialId	Library	Sponsor Name	Compound Name
	1803831	SDS32_SGSIG50		
	1502009	SDS32_SGSIG50		
	1507300	SDS32_SGSIG50		
	1507302	SDS32_SGSIG50		
	1605772	SDS32_SGSIG50		
	1805324	SDS32_SGSIG50		
	1601039	SDS32_SGSIG50		
	1801534	SDS32_SGSIG50		
	1801535	SDS32_SGSIG50		
	1901116	SDS32_SGSIG50		
	1803871	SDS32_SGSIG50		
	2000229	SDS32_SGSIG50		

☒ [Library] = 'SDS32_SGSIG50' Edit Filter
☒

AE_003E_L	V01.00	CHECK	AE	Check that end date of adverse event ([AEENDTC]) >= minimum adminis [ECSTDTC] where [ECTRT] = [TRT#ZZ_EC]) and <= current date. Refer primary medication.
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Detail	Copy	Library Rule Na...	Version	Panel	Type	Full Rule Type	Description	Message
Detail	☐	AE_003A_L	V01.00	AE	CHECK	CHECK	Check that the end date of the adverse event ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSCAT] = 'DISPOSITION EVENT'). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSTERM], [DSSTDTC]	The adverse event end date is after the da... trial termination ([DSTERM]). Please check a necessary.
Detail	☐	AE_003B_L	V01.00	AE	CHECK	CHECK	Check that end date of AE ([AEENDTC]) <= study discontinuation date ([DSSTDTC] where [DSCAT] = 'DISPOSITION EVENT' and [EPOCH] <> 'TREATMENT' or not completed). Reported: [AETERM], [AESTDTC], [AEENDTC], [DSSTDTC#STUDY]	End date of AE ([AEENDTC]) is after the stu... ([DSSTDTC#STUDY]). Please check and con... If the AE was ongoing at the time of study c... tick the according option.
Detail	☐	AE_003C_L	V01.00	AE	CHECK	CHECK	Check that end date of adverse event ([AEENDTC]) >= minimum administration start date of primary medication (min [EXSTDTC] where [EXTRT] = [TRT#ZZ_EX]) and <= current date. Refer to table [ZZ_EX] for specifications about primary medication. Reported: [AESPID], [AETERM], [AEENDTC], [TRT#ZZ_EX], [EXSTDTC]	End date of adverse event is prior to the fir... [TRT#ZZ_EX] or is a future date. Please ch... necessary.
Detail	☐	AE_003D_L	V02.00	AE	CHECK	CHECK	Check that the end date of AE ([AEENDTC]) <= trial termination date ([DSSTDTC] where [DSSCAT] = [DSSCAT] of the record in [ZZ_DS] where [EVENT] = 'TRIAL TERMINATION'). Refer to table [ZZ_DS] for specifications about termination records. Reported: [AETERM], [AESTDTC], [AEENDTC], [DSSTDTC], [X1SPID#ZZ], [X1TESTCD#ZZ], [X1ORRES#ZZ]	The adverse event end date ([AEENDTC]) is... trial termination ([DSSTDTC]). Please check... necessary.
Detail	☐	AE_003E_L	V01.00	AE	CHECK	CHECK	Check that end date of adverse event ([AEENDTC]) >= minimum administration start date of primary medication (min [ECSTDTC] where [ECTRT] = [TRT#ZZ_EC]) and <= current date. Refer to table [ZZ_EC] for specifications about primary medication. Reported: [AESPID], [AETERM], [AEENDTC], [TRT#ZZ_EC], [ECSTDTC]	End date of adverse event is prior to the fir... [TRT#ZZ_EC] or is a future date. Please ch... necessary.
Detail	☒	AE_006_L	V01.00	AE	CHECK	CHECK	Check if adverse event outcome ([AEOUT]) = 'FATAL' that the AE is considered serious ([AESER] = 'Y'). Reported: [AETERM], [AESTDTC], [AEOUT], [AESER]	Adverse event outcome is fatal, but the ad... considered serious. Please check and correc...
Detail	☒	AE_007_L	V01.00	AE	CHECK	CHECK	Check if concomitant therapy is not given because of adverse event ([AECONTRT] = 'N') or if concomitant therapy given ([AECONTRT]) is not completed, that no linking with a concomitant therapy record exists in [RELREC]. Reported: [AETERM], [AESTDTC], [AECONTRT]	There was no concomitant therapy given be... event, but there is a link with a concomitant... Please check and correct where necessary.
Detail	☐	AE_007D_L	V01.00	AE	CHECK	CHECK	Check if concomitant therapy is not given because of adverse event ([AECONTRT] = 'N') or if concomitant therapy given ([AECONTRT]) is not completed, that no linking with a concomitant therapy record exists (no linking via [AEGRPID] and [CMSEQ] exists in [RELREC]).	There was no concomitant therapy given be... event, but there is a link with a concomitant... Please check and correct where necessary.

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Edit Filter

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File

Rules

Cleaner

DCFs

ZZ Tables

SDTM Rules

DVP

SAE

Reports

Windows

Help

Rule Name

AE_006_L

Version

V01.00

Library Name

AE_006_L

Domain

AE

Responsible

DCF

Rule Type

CHECK

Rule State

ACCEPTED

Comments

Rule accepted by LIB team

☐ Trial Specific Rule

Description

Check if adverse event outcome ([AEOUT]) = 'FATAL' that the AE is considered serious ([AESER] = 'Y').
Reported: [AETERM], [AESTDTC], [AEOUT], [AESER]

Message

Adverse event outcome is fatal, but the adverse event is not considered serious. Please check and correct where necessary.

BRANDT

No code review

☐

Code reviewed

☐

Reviewer

SELECT AE.RECID, AE.SITEID, AE.USUBJID, AE.ARMCD, AE.AETERM, AE.AESTDTC,
AE.AEOUT, AE.AESER
FROM CTSS\$PROTOCOL.AE AE
WHERE AE.AEOUT = 'FATAL' AND AE.AESER <> 'Y'

Communication

Reason Change Request

Change Request Rejected

Save

Save/Next

Save/New

Accept

Close

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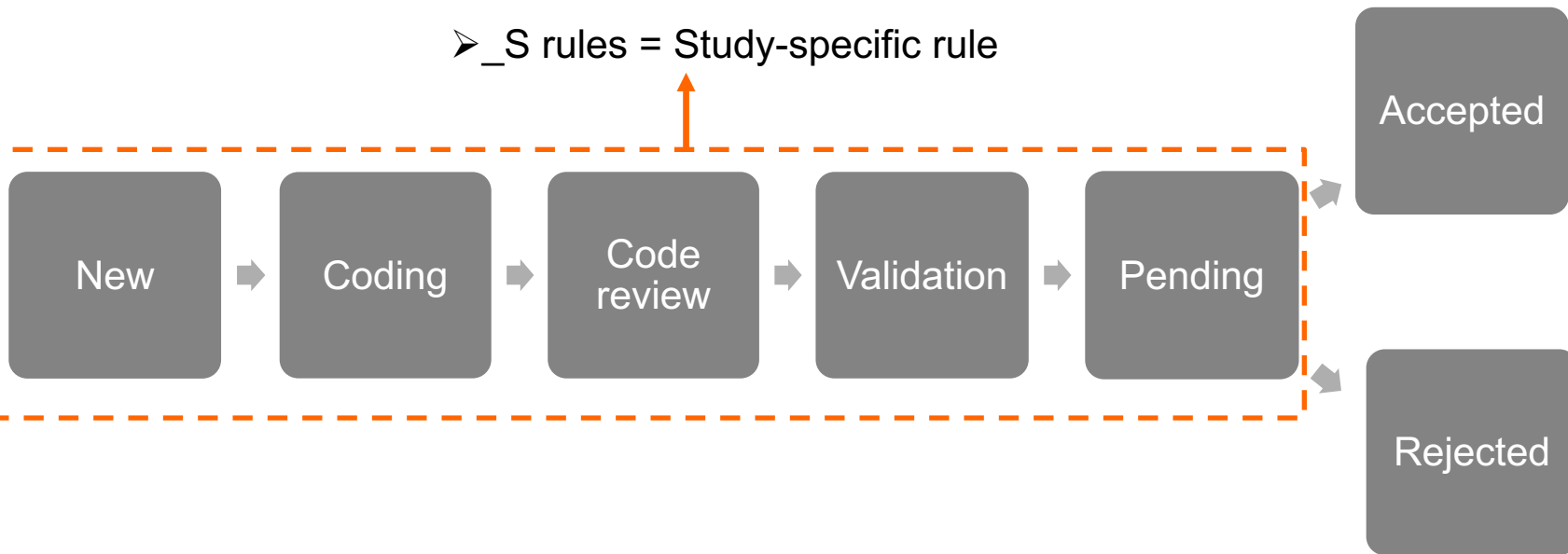
19

Rules

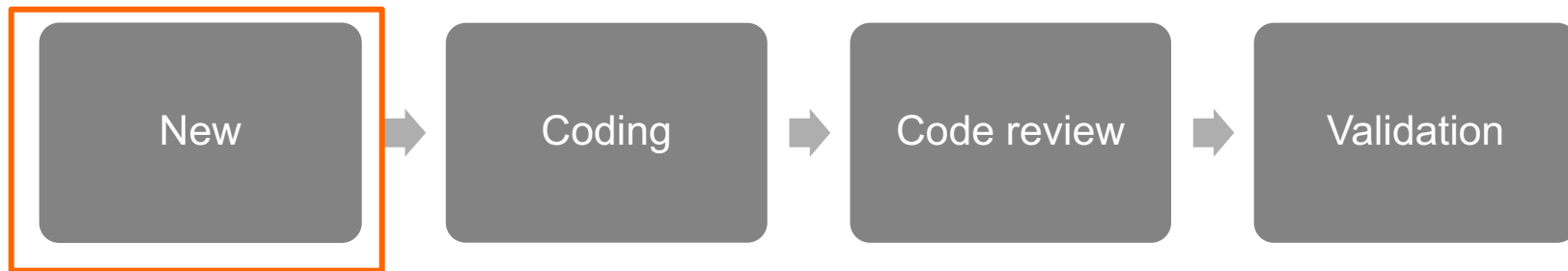
Rule creation flow

RULE CREATION FLOW

➤ _S rules = Study-specific rule



RULE CREATION FLOW



- CDM defines new rule

Rule Name		Version		Library Name	
Domain		Responsible			
Rule Type		Rule State		Comments	

☐ Trial Specific Rule

Description

Message

No code review

Code reviewed

Reviewer

Communication

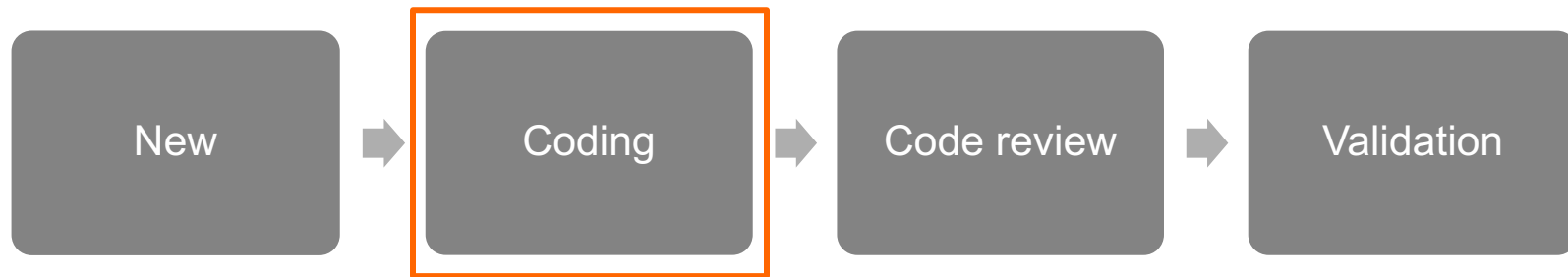
Reason Change Request

Change Request Rejected

Save Save/Next Save/New Delete Change Request Accept Close

QC sync: 3/09/2020 7:49:28 | Live sync: 17/03/2021 13:27:16

RULE CREATION FLOW



- CDM defines new rule
- CDP programs SQL

RulesCleanerDCFsZZ TablesSDTM RulesDVP
SAEReportsWindowsHelp

Rule Name

Version

Library Name

Domain

Responsible

Rule Type

Rule State

Comments

☐ Trial Specific Rule

Description

Message

No code review

Code reviewed

Reviewer

Communication

Reason Change Request

Change Request Rejected

Save

Save/Next

Save/New

Delete

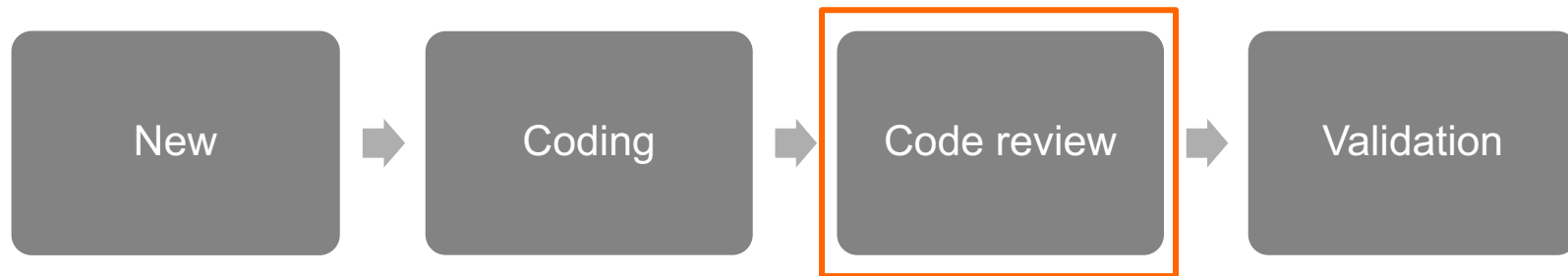
Change Request

Accept

Close

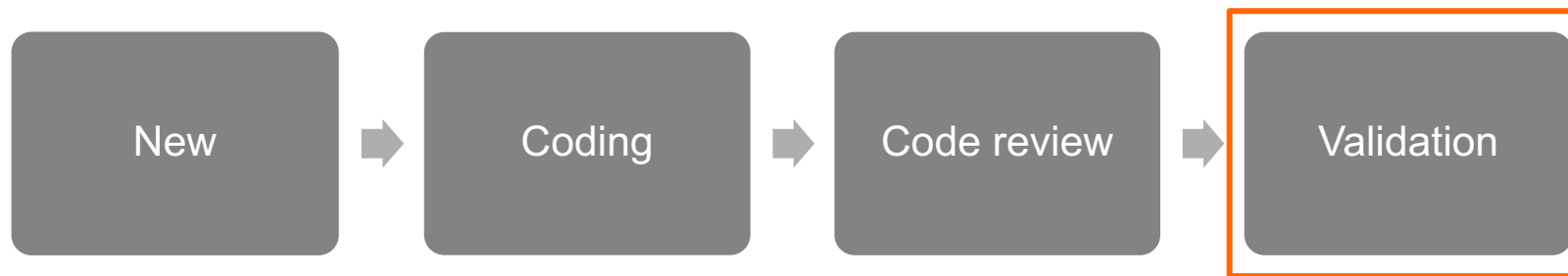
QC sync: 3/09/2020 7:49:28 | Live sync: 17/03/2021 13:27:16

RULE CREATION FLOW



- CDM defines new rule
- CDP programs SQL
- Code review by 2nd CDP

RULE CREATION FLOW



- CDM defines new rule
- CDP programs SQL
- Code review by 2nd CDP
- Validated by CDM

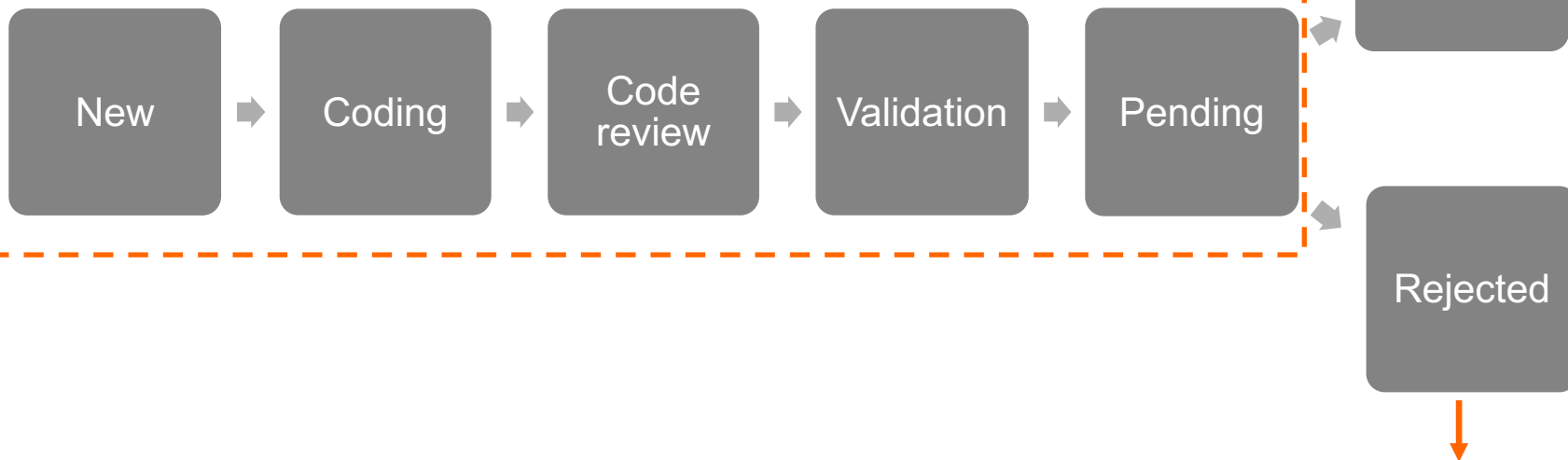
Validation for checks:
The SQL code and the pre-defined discrepancies match.
The SQL code meets the All2One criteria.

Validation for listings:
The SQL code meets the All2One criteria

RULE CREATION FLOW

➤ _L rules = Library rule

➤ _S rules = Study-specific rule



➤ _S rules = Study-specific rule

■ L rules = Library rules

Name	Type	Main Domain	PD	Description	Notes	Annotated Description	Proposed Query Text
LB_614_L	LISTING	LB		02. Inconsistent data - Check that the clinical significance is completed when a value is out of range. - Check that lab normal range indicator is completed.	The second indication does not necessarily require action; a value can be within ranges and still have clinical significance completed, e.g. in case of hemolytic sample.	List per subject, visit and time point all lab test results [LBSTRESC] and the corresponding clinical significance ([QVAL] where [QNAM] = 'LBCLSIG' and [IDVAR] = 'LBSEQ'). Add a first indication when a value is out of range ([LBNRIND] <> 'NORMAL') and the corresponding clinical significance is not completed. Add a second indication when the clinical significance is completed but the corresponding value is not out of range. Add a third indication when reference range indicator ([LBNRIND]) is not completed. Reported: [VISITNUM], [LBTPPT], [LBTPPTNUM], [LBOTC], [LBOTAT], [LBOTCAT], [LBTESTCD], [LBTEST], [LBORRES], [LBORRESU], [LBORNRLLO], [LBORNRI], [LBSTRESC], [LBSTRESU], [LBSTNRLO], [LBSTNRHI], [LBSTNRC], [LBNRIND], [QNAM], [QVAL], [LBSTAT], [LBREASND], [IND#1], [IND#2], [IND#3] Order by: [SITEID], [USUBJID], [LBTESTCD], [LBOTC]	

RULE CREATION FLOW

- _L rules = Library rules
- _S rules = Study-specific rule

Name	Type	Main Domain	PD	Description	Notes	Annotated Description	Proposed Query Text
AE_001_S	LISTING	AE		02. Inconsistent data Check if the information in QNAM -Panel 1 (AEACNS1/2/3/4 and AERELS1/2/3/4) -Panel 2 (AEACNS5/6/7 and AERELS5/6/7) is completed correctly: - If a subject never received study drug, action taken must always be 'not applicable' and relation 'not related'. - If the AE starts and ends before first intake of study treatment or after the last intake of study treatment, the relationship is expected to be 'not related' and action taken 'not applicable'. - All other scenarios (AE duration overlaps partially/entirely with period of first-to-last study drug intake) require an action: • DOSE NOT CHANGED • DOSE INCREASED • DOSE REDUCED • DRUG WITHDRAWN (=administration study medication terminated permanently) • UNKNOWN -> If action taken is 'unknown', it is expected that subject is 'lost to follow-up' (reason for withdrawal) -> If action taken is 'Dose reduced/drug interrupted/drug withdrawn', it is expected that relation is 'related'		List per subject all adverse events ([AETERM]) with start date ([AESTDTC]), end date/ongoing ([AEENDTC]), [AEENRPT]), severity ([AESEV]), seriousness ([AESER]), outcome ([AEOUT]), stabilization date ([QVAL] where [QNAM] = 'AESBDTC'), concomitant therapy taken ([AECONTRT]), action taken regarding study drug ([QVAL] where [QNAM] = 'AEACNS1', 'AEACNS2', 'AEACNS3', 'AEACNS4', 'AEACNS5', 'AEACNS6', 'AEACNS7') and relation to study drug ([QVAL] where [QNAM] = 'AERELS1', 'AERELS2', 'AERELS3', 'AERELS4', 'AERELS5', 'AERELS6', 'AERELS7'). Reported: [AETERM], [AESTDTC], [AEENDTC], [AEENRPT], [AESEV], [AESER], [AEOUT], [QNAM#AESBDTC], [QVAL#AESBDTC], [AECONTRT], [QNAM#AEACNS1], [QVAL#AEACNS1], [QNAM#AEACNS2], [QVAL#AEACNS2], [QNAM#AEACNS3], [QVAL#AEACNS3], [QNAM#AEACNS4], [QVAL#AEACNS4], [QNAM#AEACNS5], [QVAL#AEACNS5], [QNAM#AEACNS6], [QVAL#AEACNS6], [QNAM#AEACNS7], [QVAL#AEACNS7], [QNAM#AERELS1], [QVAL#AERELS1], [QNAM#AERELS2], [QVAL#AERELS2], [QNAM#AERELS3], [QVAL#AERELS3], [QNAM#AERELS4], [QVAL#AERELS4], [QNAM#AERELS5], [QVAL#AERELS5], [QNAM#AERELS6], [QVAL#AERELS6], [QNAM#AERELS7], [QVAL#AERELS7] Order by: [SITEID], [USUBJID], [AETERM], [AESTDTC]	

RULE CREATION FLOW

- _L rules = Library rules
- _S rules = Study-specific rule
- _M rules = Manual rule (exceptional cases)
 - Normally no SAE reconciliation expected in early phase
 - Be prepared (pro-active approach)

AE_004_M	MANUAL	AE	 	08. Fatal Adverse Events For AEs with outcome Fatal: * Severity should be SEVERE * the AE record should be 1 day and no end date should be entered for the fatal AE		
----------	--------	----	---	--	--	--

■ Help tables

- For general rules that often vary between studies
- Enter/update study specific parameters
- For different parts/cohorts with different parameters
- To check on scheduled visits, timepoints

ZZ Tables list - LIVE

Drag a column header here to group by that column

	Edit	Copy to QC	Table Name	Row Count	Date Last Modified By	Last Modified By	Has Errors	Show Errors
▶	Edit	Copy	ZZ_AESPECIAL	0			☐	Show Errors
	Edit	Copy	ZZ_CMFORB	0			☐	Show Errors
	Edit	Copy	ZZ_CMSPECIAL	0			☐	Show Errors
	Edit	Copy	ZZ_CMSTIND	0			☐	Show Errors
	Edit	Copy	ZZ_COMPARE	0			☐	Show Errors
	Edit	Copy	ZZ_DAREFID	0			☐	Show Errors
	Edit	Copy	ZZ_DS	1	3/07/2020 9:42:19	SOFIE_STYNEN	☐	Show Errors
	Edit	Copy	ZZ_DSECTMIN	0			☐	Show Errors
	Edit	Copy	ZZ_EC	6	3/12/2020 11:31:59	SOFIE_STYNEN	☐	Show Errors
	Edit	Copy	ZZ_ECDOSE	0			☐	Show Errors
	Edit	Copy	ZZ_ECLBCRIT	0			☐	Show Errors
	Edit	Copy	ZZ_ECTIMERANGE	0			☐	Show Errors
	Edit	Copy	ZZ_EGRANGES	5	29/07/2020 9:29:01	SOFIE_STYNEN	☐	Show Errors
	Edit	Copy	ZZ_EX	0			☐	Show Errors
	Edit	Copy	ZZ_EXDM	1			☐	Show Errors
	Edit	Copy	ZZ_EXLB	0			☐	Show Errors
	Edit	Copy	ZZ_EXTIMERANGE	0			☐	Show Errors
	Edit	Copy	ZZ_FALB	0			☐	Show Errors
	Edit	Copy	ZZ_FARANGES	0			☐	Show Errors
	Edit	Copy	ZZ_FORMREFNAME	0			☐	Show Errors
	Edit	Copy	ZZ_IEAGE	2	8/07/2020 13:28:34	SOFIE_STYNEN	☐	Show Errors
	Edit	Copy	ZZ_IECM	0			☐	Show Errors
	Edit	Copy	ZZ_IEDM	0			☐	Show Errors

ZZ Tables list - LIVE																				
	VISIT	TPT	TPTNUM	TPTRF	CAT	SCAT	POS	TESTCD	GRPID	QNAM	QVAL	X1TESTCD	X1ORRES	VISIT_X1	X1SPID	X1TESTCD_2	X1ORRES_2	X1SPID_2	VISIT_X1_2	SGS_I
1	SCREENING				WEIGHT, HEIGHT AND BMI			HEIGHT												
2	SCREENING				WEIGHT, HEIGHT AND BMI			BMI												
3	SCREENING				WEIGHT, HEIGHT AND BMI			WEIGHT												
4	V1_P1_D-1				VITAL SIGNS STANDING		STANDING	DIABP												
5	V1_P1_D-1				VITAL SIGNS STANDING		STANDING	SYSBP												
6	V1_P1_D-1				VITAL SIGNS STANDING		STANDING	HR												
7	V1_P1_D-1				VITAL SIGNS SUPINE		SUPINE	HR												
8	V1_P1_D-1				VITAL SIGNS SUPINE		SUPINE	DIABP												
9	V1_P1_D-1				VITAL SIGNS SUPINE		SUPINE	TEMP												
10	V1_P1_D-1							WEIGHT												
11	V1_P1_D-1				VITAL SIGNS SUPINE		SUPINE	SYSBP												
12	V2_P1_D1	0H	0	MIDAZOLAM DOSE	VITAL SIGNS SUPINE		SUPINE	DIABP				PART	PART A		DM					
13	V2_P1_D1	0H	0	MIDAZOLAM DOSE	VITAL SIGNS SUPINE		SUPINE	HR				PART	PART A		DM					
14	V2_P1_D1	0H	0	MIDAZOLAM DOSE	VITAL SIGNS SUPINE		SUPINE	SYSBP				PART	PART A		DM					
15	V2_P1_D1	0H	0	MIDAZOLAM DOSE	VITAL SIGNS STANDING		STANDING	HR				PART	PART A		DM					
16	V2_P1_D1	0H	0	MIDAZOLAM DOSE	VITAL SIGNS STANDING		STANDING	DIABP				PART	PART A		DM					
17	V2_P1_D1	0H	0	MIDAZOLAM DOSE	VITAL SIGNS STANDING		STANDING	SYSBP				PART	PART A		DM					
18	V2_P1_D1	3H	180	MIDAZOLAM DOSE	VITAL SIGNS SUPINE		SUPINE	DIABP				PART	PART A		DM					
19	V2_P1_D1	3H	180	MIDAZOLAM DOSE	VITAL SIGNS SUPINE		SUPINE	HR				PART	PART A		DM					
20	V2_P1_D1	3H	180	MIDAZOLAM DOSE	VITAL SIGNS SUPINE		SUPINE	SYSBP				PART	PART A		DM					
21	V2_P1_D1	3H	180	MIDAZOLAM DOSE	VITAL SIGNS STANDING		STANDING	HR				PART	PART A		DM					
22	V2_P1_D1	3H	180	MIDAZOLAM DOSE	VITAL SIGNS STANDING		STANDING	DIABP				PART	PART A		DM					

- DVP (Data validation plan)
 - Contains all selected rules and help tables
 - Reviewed by 2nd CDM
 - Can be exported and reviewed by client if required

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Flags: ☐ Ready To Review ☐ Reviewed

Domain Name	Domain Description	Number Of Rules	Show On DVP
AE	Adverse Events	32	☒
AG	Procedure Agents	0	☐
APAE	Associated Persons Adverse Events	0	☐
APDM	Associated Persons Demographics	0	☐
APMH	Associated Persons Medical History	0	☐
APRELSUB	Associated Persons Related to Subjects	0	☐
BE	Biospecimen Events	0	☐
BS	Biospecimen	0	☐
CE	Clinical Events	0	☐
CM	Concomitant Medications	19	☒
CO	Comments	1	☒
DA	Drug Accountability	0	☐
DD	Death Details	0	☐
DE	Device Events	0	☐
DI	Device Identifiers	0	☐
DM	Demographics	8	☒
DO	Device Properties	0	☐
DR	Device to Subject Relationship	0	☐
DS	Disposition	22	☒
DT	Device Tracking and Disposition	0	☐
DU	Device-In-Use	0	☐

⏮

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⏭



Selected Rule

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Options

[Help Tables](#)

Help Tables<<

ZZ_SVVS

ZZ_WINDOWDSSV

ZZ_WINDOWECEC

ZZ_WINDOWECMAX

ZZ_WINDOWECMIN

ZZ_WINDOWECML

ZZ_WINDOWEGEC

ZZ_WINDOWEGML

ZZ_WINDOWLBEC

ZZ_WINDOWLBML

ZZ_WINDOWPCEC

ZZ_WINDOWPCML

ZZ_WINDOWSV

ZZ_WINDOWVSEC

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Help Tables Overview

Drag a column header here to group by that column

Help Table Name	Ready To Review Flag	Number Of Comments	Ready To Review Flag By	Reviewed Flag	Reviewed Flag By
▶ ZZ_DS	☒	0	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_ECTIMERANGE	☒	3	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_EGRANGES	☒	2	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_IEAGE	☒	0	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_IEVS	☒	0	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_LBGRADE	☒	9	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_SVEC	☒	3	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_SVEG	☒	4	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_SVLB	☒	6	GLENN_BORGMANS	☒	NATHALIE_COP
ZZ_SVML	☒	2	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_SVPC	☐	1		☐	
ZZ_SVPE	☒	1	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_SVVS	☒	12	SOFIE_STYNEN	☐	
ZZ_WINDOWDSSV	☒	2	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWECEC	☒	1	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWECMAX	☐	0		☐	
ZZ_WINDOWECMIN	☒	1	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWECML	☒	4	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWEGEC	☒	3	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWEGML	☒	2	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWLBEC	☒	3	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWLBML	☒	2	SOFIE_STYNEN	☒	NATHALIE_COP
ZZ_WINDOWPCEC	☒	9	SOFIE_STYNEN	☒	NATHALIE_COP

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Version	Date Creation	Created By	State	Reason For Update	Details
	23-apr-2021	Stynen Sofie	CURRENT		

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Adverse Events							
NAME	TYPE	MAIN DOMAIN	PD	DESCRIPTION	NOTES	ANNOTATED DESCRIPTION	PROPOSED QUERY TEXT
AE_074_L	CHECK	AE		01. Missing data		Check that the following items are completed for each adverse event: AE verbatim ([AETERM]), seriousness ([AESER]), action taken regarding primary medication ([AEACN]), relation to primary medication ([AEREL]), concomitant therapy taken ([AECONTRT]), severity/intensity ([AETOXGR]), start date ([AESTDTC]). Reported: [AETERM], [AESER], [AEACN], [AEREL], [AECONTRT], [AETOXGR], [AESTDTC]	Not all items have been completed. Please check and provide the missing information. Thank you.
AE_130A_L	CHECK	AE		02. Consistency		Check if adverse event outcome ([AEOUT]) or end of adverse event ([AEENRPT] or [AEENDTC]) is completed that adverse event outcome and end of adverse event are both completed. Reported: [AETERM], [AESTDTC], [AEOUT], [AEENDTC], [AEENRPT]	If AE [AETERM] has ended, both AE outcome and end of adverse event should be completed. Please check and correct where needed. Thank you.
AE_582_L	CHECK	AE		01. Missing data		Check that the dictionary-derived term ([AEDECOD]) is completed.	AEDECOD is missing.

Rules

Past improvements/
Future plans

EXPERTISE

■ Past improvements

- Added change request function
- Implementation of help tables
- Merging of different implementation guide libraries
- Automated checks on rule naming conventions
- Automatic assignment flow in A2O for new rules

EXPERTISE

■ Past improvements

- Added change request function
- Implementation of help tables
- Merging of different implementation guide libraries
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- Automatic assignment flow in A2O for new rules

■ In progress

- Option to clean on source or SDTM data
- Add tags to increase efficiency in proposing rules

EXPERTISE

■ Future plans

- Standard queries automatically populated in the eCRF system
- Keep expanding and streamlining the existing library

Rules

Conclusion

Rules

■ Drawbacks

- Library will never be finished
- Growing library can result in too much choice in rules -> pitfall for new users
 - ⇒ Important to use filter/search options (active/inactive rules)
 - ⇒ Maintenance is needed

Rules

■ Benefits

- No need to start from scratch for new studies
- Immediate release and use of validated library rules (clean data one click away)
- Allows fast set-up (without CDP)
- Client specific library: next study => easier to select rules and consistent data cleaning
- Allows more standardisation & automatization
- Less chance for human errors



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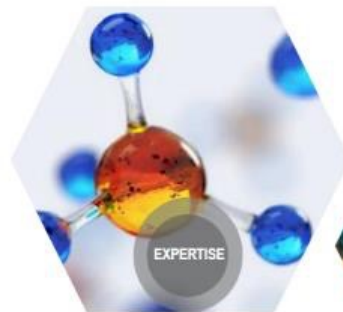


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