

# 30. CDISC DACH User Network Meeting Introduction to CORE – a COSA project 14-March-2023

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#### CORE – CDISC Open Rules Engine

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#### CORE

Overview	Planning and	Status	Program Governance	Participate	Presentations	FAQ	CORE on GitHub
		Latest <b>j</b>	page content update: 24 N	ov 2022			
	cdišč	Page N	ote:				
		The CO	RE project originated as a t	raditional CDISC	project with plannir	ng and vol	unteer/collaborator recruitment during spring & summer 2021
		and for	mal kickoff in Sept 2021. Du	ring summer 20	22, CDISC transition	ed CORE	development to an open-source framework. This page (tab)
EL.	Je Star	describ	es the project goals, object	ives, and high-le	evel roadmap; Please	e see the F	Program Governance page (tab) for description of the open-
41	ULES E	source	governance framework. Ple	ase see the Plar	nning & Status page	(tab) for th	ne latest CORE activity, which is now guided by the open-
•		source	CORE Roadmap Board.				

Development of open-source software for the global clinical research community to test study data for conformance to CDISC standards as well as to regulatory and sponsor-specific conformance rule sets.





- Create a set of unambiguous, executable Conformance Rules for each standard
- Ensure consistency across Conformance Rule implementations
- Expedite availability of Conformance Rules for new standards
- Create Rules vetted by the CDISC standard development teams
- Develop an open-source engine that serves as a Reference Implementation
- Publish rules in CDISC library
- Release of open-source engine under COSA





# **MVP** Engine

- Presentation of the CORE Minimum Viable Product (MVP)
   Engine early evaluation version on CDISC EU Interchange
   2022
- The MVP Engine was previously available via the CORE web page
- Provided with a basic user interface (UI) to allow users to quickly and easily run the Engine to provide early feedback on the Engine functionality to the CORE team



#### **CDISC CORE**

CDISC Open Rules Engine

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Ø	Plugin	Validate you	mance Validator ar study with the most recent Cor	nformance rules from the CDISC >	Rule Editor Create you own rules with the	Rule Editor		>	Plugin Create your own Plugin and use it within CORE
11.	View My Studies	Library							
~×)	Manage <mark>M</mark> y Rule Sets								
?	Help	Recent St	udies				£	See all >	Resources
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### View My Studies









#### View My Studies – Study Details

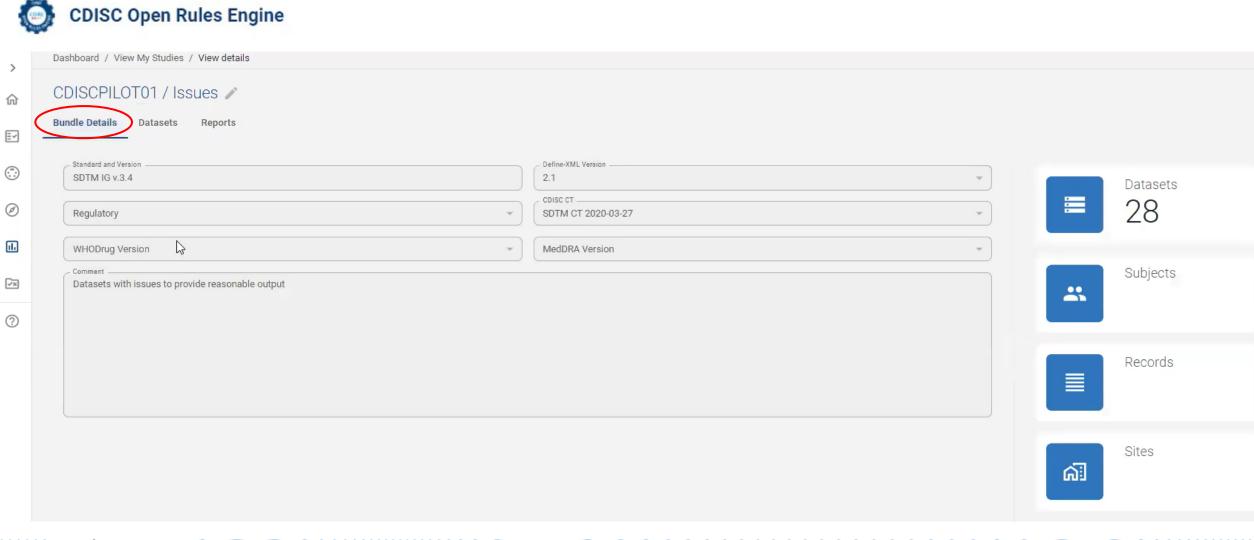


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#### CDISC Open Rules Engine

Dashboard / View My Studies / Study Details	
CDISCPILOT01 🖍	
Study Details Study Start Da 2012-10-06	Data Bundles       Data Bundle     SDTM       Data Bundle     SDTM
Therapeutic Area Alzheimer's Disease II	Data Bundle     SDTM     O     Data Bundle     SDTM       Issues     Issues     Issues     Clean Data     Issues       Last validation date:     Image: Clean Data     Image: Clean Data       2022-04-22T19:32:09     Image: Data Bundle     Image: Clean Data
Client CDISC Study Title	Validate
Safety and Efficacy of Zanomaline in Patients with Mild to Moderate Alzheimers Disease.	









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### **Conformance Validator**



	Dashboard / Conformance Validator / Choose Datasets		
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	DI Device Identifiers		16.4 kB



### **Conformance Validator**



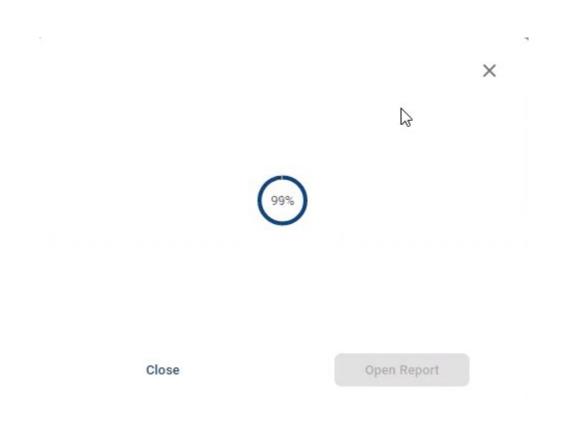
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( <u>.</u> )	Confe	ormance Rules	Q Search			Rule Type	👻 Rule Seve	erity 🗸 C 🗘
Ø		Rule ID	Rule Type	Description			Version	Rule Severity
11.		CDISC.SDTMIG.C	G0007 Value Presence	Raise an error when the date portion of –DTC is an incom	plete date and the date portion of DM.RFSTDTC is an incomplete date, butDY is not empty		1.0	Error
√×.		CDISC.SDTMIG.C	G0008 Value Presence	Raise an error whenTPTREF is empty, butELTM is not	empty		1.0	() Error
?		CDISC.SDTMIG.C	G0009 Range & Limit	Raise an error when EPOCH is not in TA.EPOCH			1.0	() Error
		CDISC.SDTMIG.C	G0026 Range & Limit	Trigger error whenTPTREF = null andRFTDTC is popu	ated		1.0	() Error
		CDISC.SDTMIG.C	G0027 Range & Limit	Trigger error whenSCAT is not null andSCAT is equal	o –CAT		1.0	Marning
	Versions							





## Validation









CDISCPIL	OT01 / Issues / 2	022-04-24T14:58:51 🛓				
ssue Summary	Issue Details Rule	s Reports				
Q See	arch					
Dataset 🛧	Rule ID	Error Message		Severity	# Issues	Explanation
AE	CDISC.SDTMIG.CG0041	At least one of the Seriousness criteria (AESCAN, A AESER = 'N' or empty.	AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE) = 'Y', but	Error	1	
AE	CDISC.SDTMIG.CG0042	If AESER = "N" then none of the seriousness criteri AESMIE) could be equal to "Y".	a (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD,	Warning	3	
AE	CDISC.SDTMIG.CG0050	AEDECOD should be populated when AEPTCD is p	opulated	() Error	1	
AE	CDISC.SDTMIG.CG0389	AESCONG is completed, but not equal to "N" or "Y"		() Error	1 <	This issue needs to be resolved





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Ø	Rule ID 个	Error Message	Severity	Dataset	USUBJID	Record	Sequence	Variable(s)	Value(s)		
	CDISC.SDTMIG.CG0008	FTTPTREF is empty and FTELTM is not empty	() E	rror FT	CDISC003	958	278	FTELTM, FTTPTREF	PT30M,		
√×	CDISC.SDTMIG.CG0008	FTTPTREF is empty and FTELTM is not empty	() E	ror FT	CDISC003	959	279	FTELTM, FTTPTREF	PT30M,		
0	CDISC.SDTMIG.CG0008	FTTPTREF is empty and FTELTM is not empty	() E	rror FT	CDISC003	960	280	FTELTM, FTTPTREF	PT30M,		
	CDISC.SDTMIG.CG0009	EPOCH is not in TA.EPOCH	() E	TTOT DS	CDISC002	6	3	EPOCH	TREATMENT1		

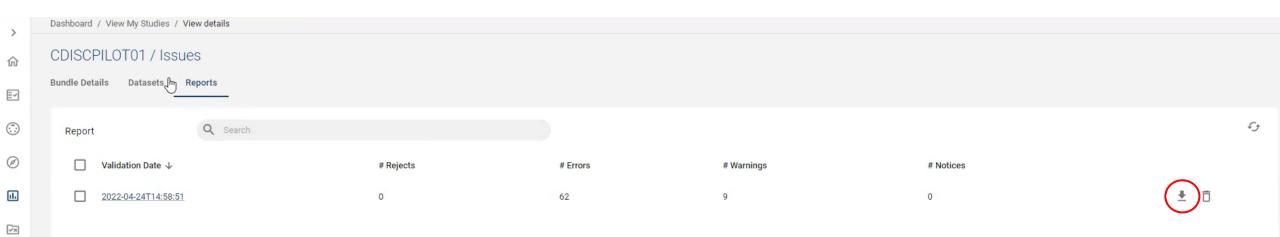




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	CDISCPILOT01 / Issue	es / 2022-04-24T14:58:51 🛓	
E.Y.	Issue Summary Issue Details	Rules Reports	
		Q Search	Status 🗸 C
Ø	Rule ID 🛧	Message	Status
	CDISC.SDTMIG.CG0007	The date portion ofDTC is not complete date or the date portion of DM.RFSTDTC is not complete date, butDY is not empty	Success
\×	CDISC.SDTMIG.CG0008	TPTREF is empty andELTM is not empty	Success
0	CDISC.SDTMIG.CG0009		Success
	CDISC.SDTMIG.CG0026	RFTDTC is populated whenTPTREF is null	Skipped













A	В
	Conformance Details
Study	CDISCPILOT01
Bundle	Issues
Report Generation	2022-04-24T14:58:51
Total Runtime	166 seconds
Transaction ID	71f9b9fa-df84-4f71-b519-a1cd477b81db
	Study Details
Therapeutic Area	Alzheimer's Disease
Phase	
Client	CDISC
Study Start Date	2012-10-06
1.0	
Chan dand	Bundle Details
Standard	SDTM
Version CT Version	V3.4 2020-03-27
Define-XML Version	2020-03-27
UNII Version	
Med-RT Version	Not configured Not configured
MedDRA Version	Not configured
WHODRUG Version	Not configured
SNOMED Version	Not configured
	Notcomgueu





# CORE on GitHub

- The CORE Engine Reference Implementation on GitHub is an advancement over the CORE Minimum Viable Product (MVP) Engine early evaluation version
- The GitHub-based Engine is updated to process additional Rule syntax (YAML) engaged to handle new processing conditions that were encountered as the CORE team developed additional Rules
- The GitHub-based Engine is provided with a command line interface (CLI)





#### CORE on GitHub

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#### CORE



#### **CORE Engine Reference Implementation in GitHub**

The CORE Engine Reference Implementation is the current version of the Engine. The CORE Engine Reference Implementation has been transversion on GitHub. The GitHub-based Engine is:

- Provided as open source with the permissive MIT license
- Registered with the CDISC Open-Source Alliance (COSA)
- Available to users for free
- Provided with a command line interface (CLI)
- Accessed at the GitHub CDISC-rules-engine repository, including special instructions in the Readme file





## CORE on GitHub

	Product Y Solutions Y	Dpen Source \vee Pricing	Search	
₽ <u>cdisc-or</u> g	g / cdisc-rules-engine (Public)			
<> Code 📀	) Issues 61 1 Pull requests 2	Discussions 📀 Actions 🗄 Projects 1	🕮 Wiki 🕕 Security 🗠 Insights	
	ি main → ৫০ branches ৫	<b>◇ 49</b> tags	Go to file Code -	
	nhaydel Update version.py		de14c5a last month 🕚 459 commits	
	📄 .github	fix paths for cli executables	5 months ago	
	cdisc_rules_engine	Rule schema updates (#246)	last month	
	cdisc-rules-en	gine		
	Open source offering of the	cdisc rules engine		





# Thank you!

# Questions?

#### **Contact Details**

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