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CDISC CORE and Real-Time Validation The Perfect Match

Presented by Bremer Louw, VP Operations, Bioforum



Meet the Speaker

Bremer Louw

Title: VP Operations

Organization: Bioforum

He is the Vice President of Operations at Bioforum. He has been in the industry for more than 16 years, involved with SAS programming in both Data Management and Statistical Programming departments. Most recently he is involved with the development of Bioforum's next generation SDTM automation platform.

“There's a way to do it better – find it.” – Thomas A Edison



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



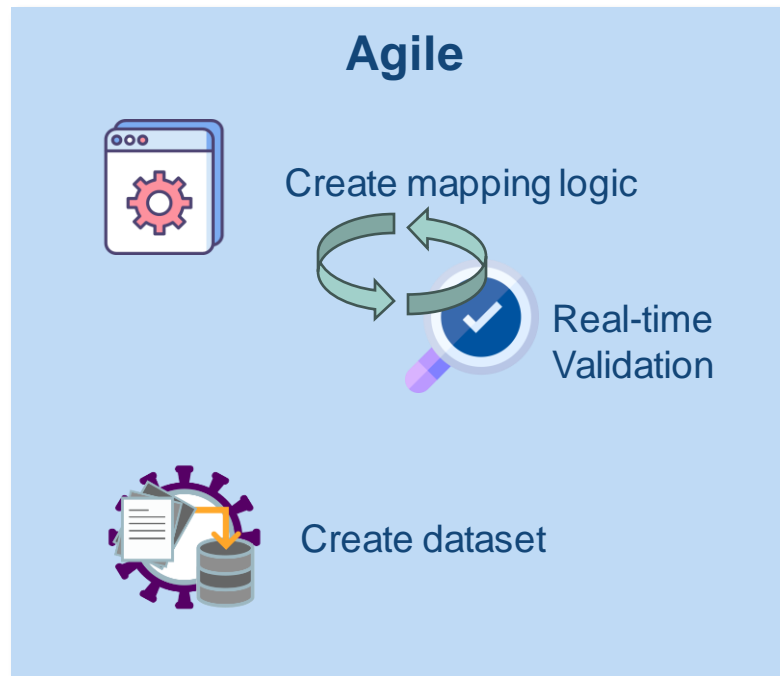
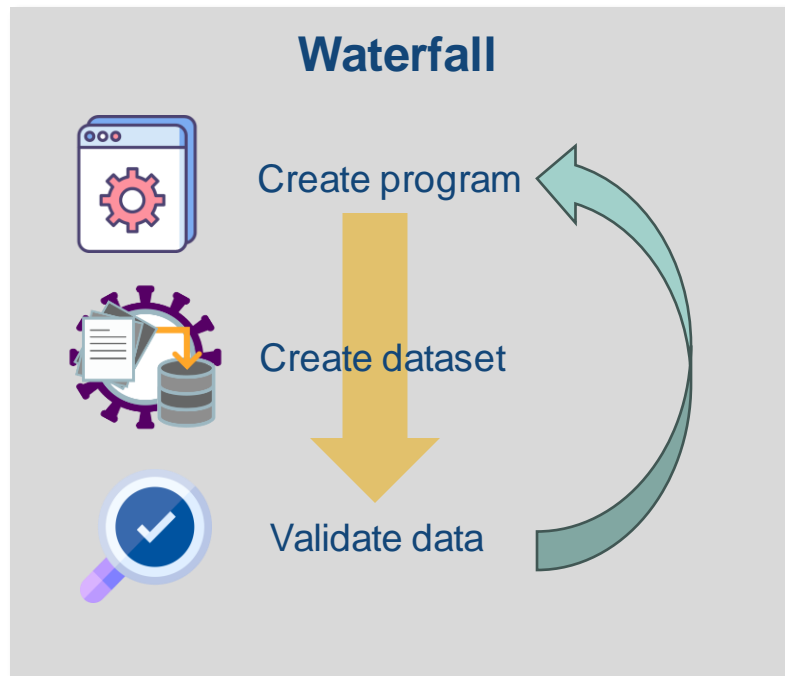
Agenda

1. What is real-time validation?
2. Real-time validation requirements
 - Existing validation rule library
 - Add custom validation rules
 - Integrated validation engine
3. Real-time validation in action



What is real-time validation?

What is real-time validation?



Why real-time validation?



No more repetitive
validation cycles



Better first-time quality

Requirements for a real-time validation system?



An existing **library** of validation rules



Add **custom** validation rules



Integrated validation engine



Real-time validation requirements

Existing validation rule library

CDISC CORE Validation Rule Library

Components	Status										
	OPEN	DONE	BLOCKED	UNIT TESTING	QC IN PROGRESS	READY TO PUBLISH	PUBLISHED	AWAITING QC	AUTHOR IN PROGRESS	BACK TO AUTHOR	T:
ADaMIG v1.0	314	0	0	0	0	0	7	0	0	0	321
ADaMIG v1.1	419	0	0	0	0	0	7	0	0	0	426
ADaMIG v1.2	591	0	0	0	0	0	7	0	0	0	598
ADaMIG v1.3	568	0	5	4	2	0	7	9	1	0	596
FDA SDTMIG v3.2	493	0	0	0	0	0	0	0	0	0	493
FDA SDTMIG v3.3	501	0	0	0	0	0	0	0	0	0	501
FDA SENDIG DART v1.1	350	0	0	0	0	0	0	0	0	0	350
FDA SENDIG v3.0	316	0	0	0	0	0	0	0	0	0	316
FDA SENDIG v3.1	330	0	0	0	0	0	0	0	0	0	330
FDA SENDIG v3.1.1	335	0	0	0	0	0	0	0	0	0	335
FDA SENDIG-AR v1.0	466	0	0	0	0	0	0	0	0	0	466
SDTMIG v3.2	279	37	14	0	3	0	74	0	5	4	416
SDTMIG v3.3	295	48	14	1	4	0	78	0	5	4	449
SDTMIG v3.4	7	60	51	10	4	0	272	2	35	3	444
SENDIG v3.0	259	0	0	0	4	0	1	0	0	0	264
SENDIG v3.1	174	2	2	3	4	9	1	96	11	1	303
SENDIG v3.1.1	307	0	0	0	4	0	1	0	0	0	312
SENDIG-DART v1.1	353	0	0	0	4	0	1	0	0	0	358
Total Unique Issues:	6357	147	86	18	29	9	456	107	56	12	7277

As presented by CDISC on 26-27 April 2023

FDA Validator Rules v1.6 (Dec 2022)

SDTMIG 3.3

Publisher	# of Rules	CDISC CORE syntax
FDA	192	135
CDISC	306	268
<blank>	3	2
TOTAL	501	405



Real-time validation requirements

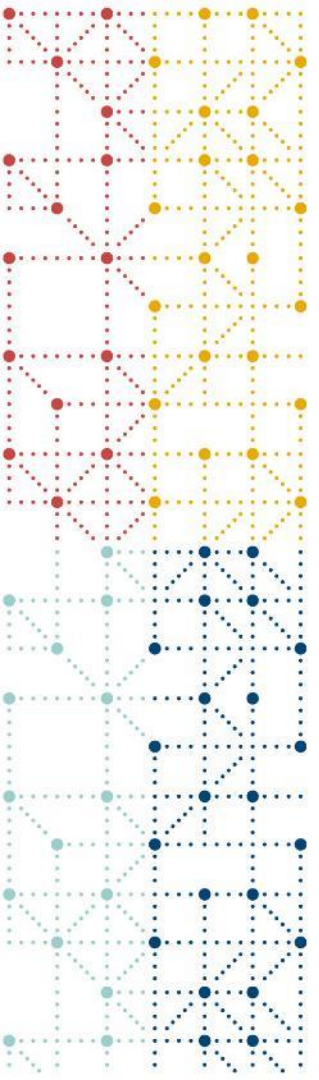
Add custom validation rules

CDISC CORE Custom Rules



Custom rules created per customer request

-
- Domain label does not match SDTMIG.
 - A value of --SEQ is being used in IDVAR, but should not be used per Guidelines.
 - A value is present that is not part of custom CT or SDTM specific CT.
 - A domain is present that should not be used per Guidelines.
 - A record is missing for medical coding information, but a response is required per Guidelines.
 - A value is present that is not uppercased per Guidelines.
 - The domain sort keys are not per Guidelines.
 - ...
-



Real-time validation requirements

Integrated validation engine



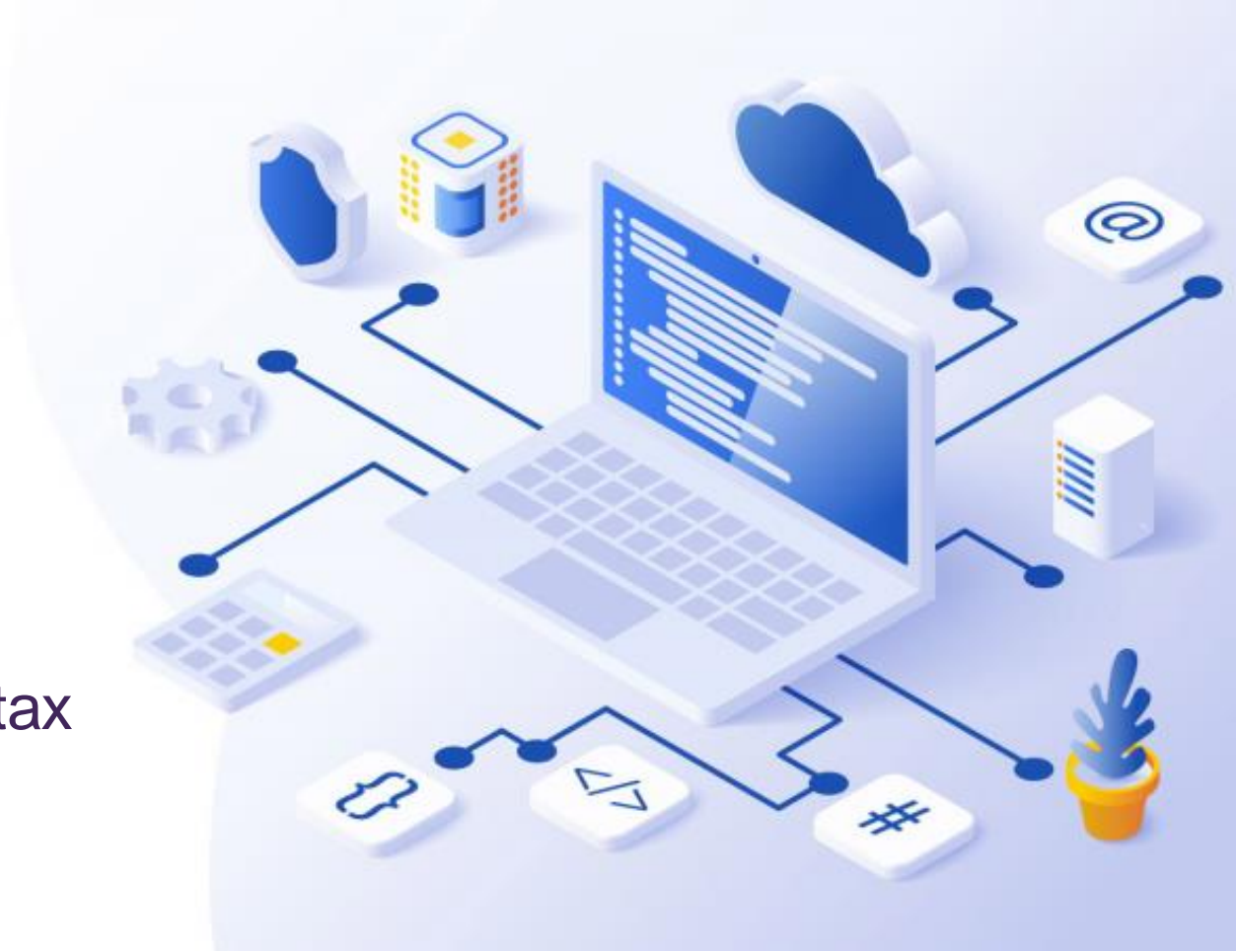
Integrated Validation Engine

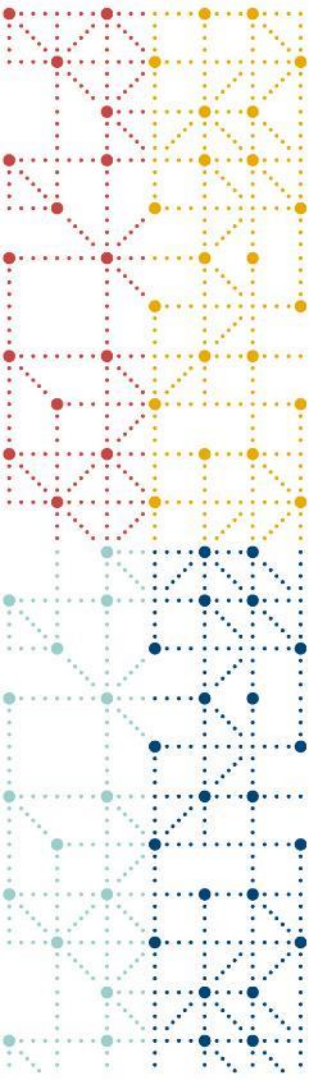
Implementation testing of CDISC CORE engine and challenges

- **Open-Source Integration:** How do we integrate open source in a commercial product, validation?
- **Performance:** 1-10 min validation needs to change to 3 seconds.
- **Repeated data access:** Build a mechanism to efficiently aggregate rules together to minimize repeated data access.
- **Specific Execution:** Develop a mechanism to identify fast which specific rules to run given the specific state of the mapping. Avoid 'blasting' the user with errors that are not important given the specific state.
- **Domain Dependencies:** All the SDTM domains are inter-related and there are complex dependencies across the datasets so changes in one domain can trigger a sequence of validation rules to be fired on other domains.

Bioforum Developed a New Validation Engine

CDISC CORE Syntax





Real-time validation in action

Real-time Validation

List of validation issues

Results Table 4,175 records Vital Signs / TEMP_VSORRES

2 Issues < 2/2 > View Log

STUDYID	DOMAIN	USUBJID	VSTEST	VSORRES	VSORRESU	VSSTAT	VISIT
Demo-ALS	VS	DEMO_ALS-8-000436	Temperature	36.9	C		Day 0 - Surgery
Demo-ALS	VS	DEMO_ALS-3-000437	Temperature	37.5	C		Screening
Demo-ALS	VS	DEMO_ALS-3-000437	Temperature	36.5	C		Day 1
Demo-ALS	VS	DEMO_ALS-3-000437	Temperature	36.8	C		Day 5
Demo-ALS		DEMO_ALS-3-000437	Temperature	36.9	C		Day 0 - Surgery
▲ Demo-ALS	VSSTAT Not Null When VSORRES Not Null		DEMO_ALS-3-000438	Temperature	36.9	NOT DONE	Screening
	Source FDA	ID SD1123 Instances 27 < 1/27 >	DEMO_ALS-3-000438	Temperature	36.6	C	Day 1
		View In Log	DEMO_ALS-3-000438	Temperature	37.1	C	Day 30
			DEMO_ALS-3-000438	Temperature	36.8	C	Day 5
			DEMO_ALS-3-000438	Temperature	36.7	C	Day 60/Termination
	VS	DEMO_ALS-3-000438	Temperature	36.3	C		Day 0 - Surgery
	VS	DEMO_ALS-3-000445	Temperature	36.6	C		Screening
	VS	DEMO_ALS-3-000445	Temperature	37.3	C		Day 1
	VS	DEMO_ALS-3-000445	Temperature	36.6	C		Day 14
	VS	DEMO_ALS-3-000445	Temperature	36.8	C		Day 5

Description of validation issue

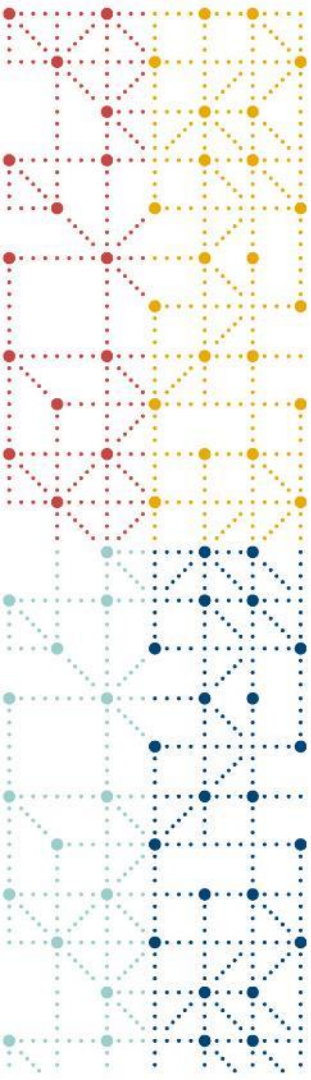
Highlight of relevant data



Conclusion

Conclusion

- Real-time validation is possible using CDISC CORE syntax.
- A large library of validation rules is already available and custom rules can be added.
- A custom validation engine is needed for specific use cases.
- The benefits include:
 - No more repetitive validation cycles.
 - Better first-time quality = Faster delivery.



Thank You!

