CDISC CORE Adoption and Certification
Presented by Bremer Louw, VP Operations, Bioforum\ BionData

Meet the Speaker

Bremer Louw

Title: VP Operations

Organization: BionData (a Bioforum company)

Bremer has been in the Clinical Research industry for 18 years, serving as SAS programmer in Data Management and Statistical Programming departments. He has been leading teams in Data Management and Statistical programing for more than a decade. Currently he is the Vice President of Operations at BionData, the technology department of Bioforum.

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.*

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Agenda

1. Our CDISC CORE journey
2. CORE Adoption Roadblock
3. Submit24
4. CDISC Certification
5. Submit24 Testing Results

Our CDISC CORE Journey

JetConvert.
SDTM Automation Platform

Real-time SDTM Validation → Validation Engine → Build Our Own

Our CDISC CORE Journey

Why did we decide on the CORE syntax?

➢ Community generated rules

➢ Allows organizations to add custom rules

➢ CDISC is actively working on expanding the library of rules that is freely available

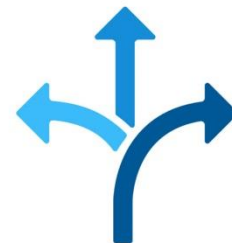# Our CDISC CORE Journey

Why not use the CORE engine?

JetConvert

Slow

We believe…

Universally Accessible

FREE

Flexible

CORE Adoption Roadblock

Lack of Software Solutions

➢ Cost Effective

➢ User Friendly

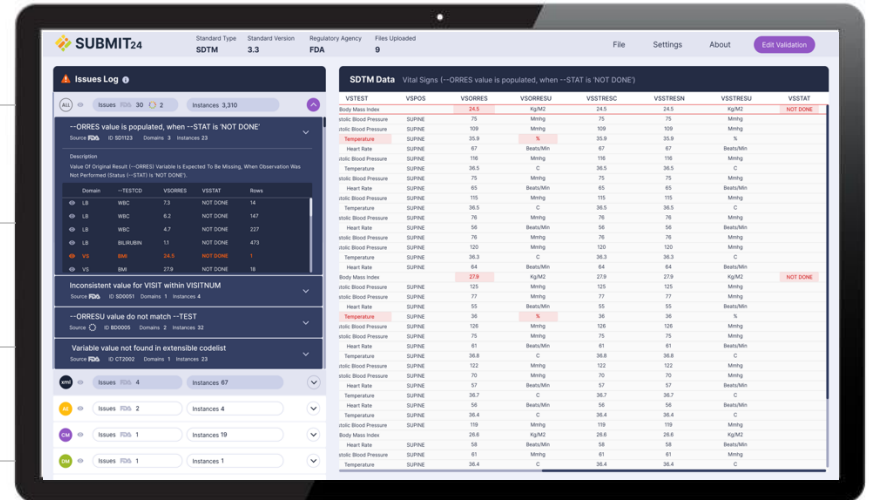➢ Feature Rich

➢ Efficient

BionData wants to bridge this gap…

Aspiring for broader industry adoption.

Standalone App

Innovative

Validated

Customizable

CDISC Certification

In progress…

- ✓ Agreement with CDISC on Certification process
- ✓ First test run – Issues identified
- ✓ Issue resolution
- ✓ Second test run – Successful
- ❏ Additional testing
- ❏ Certification run by CDISC
- ❏ Issue resolution iterations as needed

CDISC Certification

Why Certify?

Ensure a rules engine produce the same results as the CORE engine.

- ✓ Ensure data integrity
- ✓ Maintain credibility of CORE rules
- ✓ Ensure consistency between tools
- ✓ User transparency on tool accuracy

Current Testing Results

CDISC OPEN Rules

100 rules received & executed

Negative results 100/100 (100%)

Positive results 18/18 (100%)

FDA Validator Rules

100 rules created & executed

Negative results 100/100 (100%)

Positive results 100/100 (100%)

Conclusion

Open-source Syntax
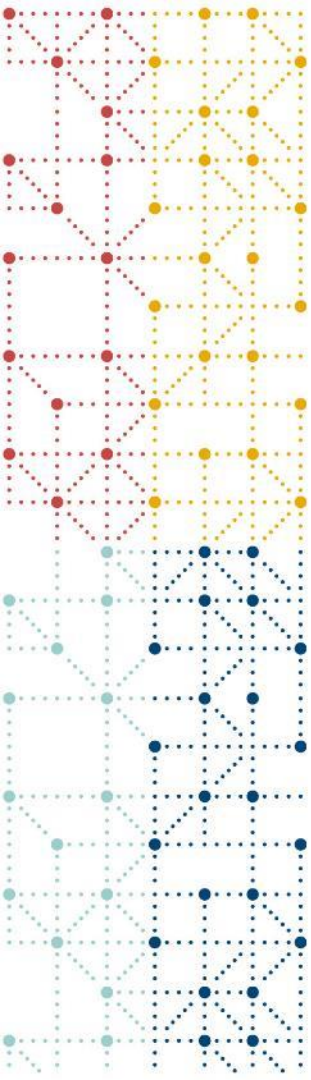**Open-source Engine**
Certification

Open Rules Library

Evaluate data conformity
with the freedom to select…

Which tool?
Which engine?
Which rules?

Thank You!