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How the new CDISC Open Rules Engine (CORE) can improve the speed and quality of dataset deliverables in clinical trials

Presented by Kevin Burges, Head of Product Management, Formedix
and James Conway, rzye Labs Developer, Formedix

Meet the Speakers

Kevin Burges

Title: Head of Product Management

Organization: Formedix

In his 24 years at Formedix, CDISC has been a core focus. He was a founding member of the CDISC XML Technologies Governance team, and currently sits on the Data Exchange Standards team helping drive the future technical direction of CDISC standards. He works closely with customers to define new feature enhancements for the ryze platform.



James Conway

Title: ryze Labs Developer

Organization: Formedix

James' role involves researching and developing prototypes for Formedix products. He's a passionate programmer with a Bachelor's degree in Computing and 12 years of programming experience. Whilst at University, he worked as a research assistant on a Biomedical project for Adrenal Gland research.





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. Overview of Formedix CORE
2. Advanced study workflows
3. Demo of Formedix CORE
4. Developer experience of working with the CORE engine



Overview of Formedix CORE

Overview of Formedix CORE



Why?

- CDISC wanted a desktop CORE application
- To make it simple for users to try out CORE, and speed adoption

How?

- Formedix built a downloadable application that bundled the CORE engine
- CDISC developed the CORE engine
- CDISC developed the rule sets (SDTM-IG etc)



Overview of Formedix CORE

Features

- Load data from local XPT datasets
- Select subset of datasets to validate
- Select rule set
- Select subset of rules to run
- Refresh rule sets from CDISC Library
- Sorting/filtering of results
- View Excel results report



Overview of Formedix CORE

Features

- Online help
- Formedix CORE community forum
- Notify users of updates to Formedix CORE
- Ability to drop in a new version of the CORE engine
- Windows only

- **Free download!**

<https://www.formedix.com/formedix-core-cdisc-core-open-rules-engine>



Overview of Formedix CORE

Future functionality

- Final production version of CORE engine
- Final production version of initial rulesets (e.g. SDTM-IG 3.4)
- Additional rulesets (SEND, ADaM, FDA business rules etc)
- Load data from CSV, Dataset-XML, Dataset-JSON
- Validate against MedDRA / WHODrug and other dictionaries
- (maybe) Linux / MacOS support



Overview of Formedix CORE

Timeline

April 2023

- Formedix CORE Technology preview
 - Please try it out – we'd love to hear your feedback!

<https://www.formedix.com/formedix-core-cdisc-core-open-rules-engine>

Q2 2023

- Production release
- Dependent on CORE engine and rulesets being finalized



Advanced study workflows



Advanced study workflows

Build CORE into an SDTM automation workflow

- Metadata driven SDTM automation
 - Daily conversions as soon as data comes in
 - Delivered COVID studies in super quick time
 - CORE integration will enhance this with immediate SDTM feedback



Advanced study workflows

Build CORE into an SDTM automation workflow

- Benefits
 - Early visibility of SDTM conformance
 - Early visibility of safety and efficacy data
 - Make informed decisions early on
 - Run more trials, focus on those showing promise
 - Ultimately, speed the delivery of life changing treatments



Advanced study workflows

Use CORE for validating source data

- Define and manage custom rulesets for validating your source data
 - TA-specific rules
 - Study-specific rules
- Ingest and validate source data on a schedule
- Add rules over time, increasing data quality



Advanced study workflows

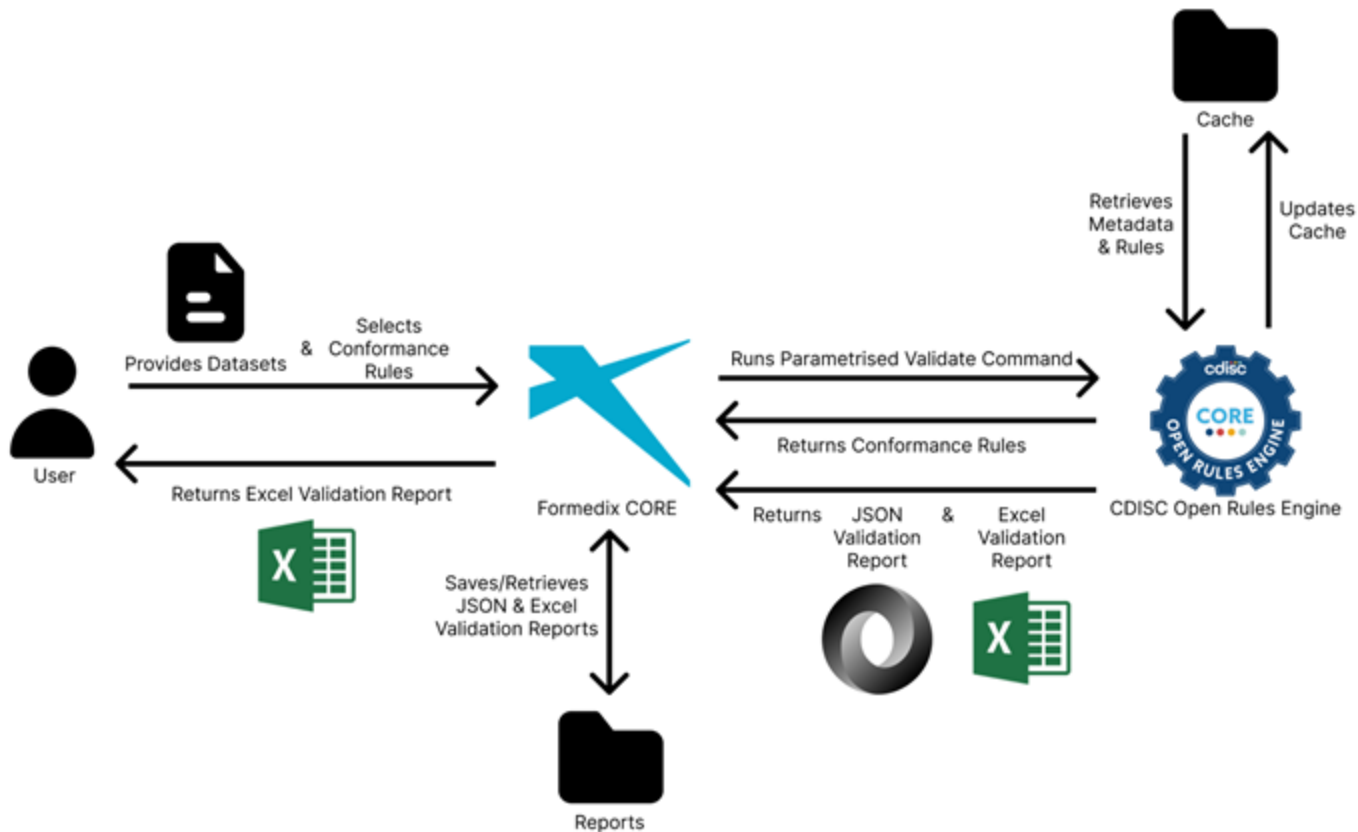
Other possibilities

- Issue tracking across multiple conversions
- Any other ideas?



Demo of Formedix CORE

System Overview



Demo of Formedix CORE

Show demo



Developer experience of working with CORE



Developer experience of working with CORE

The CORE engine is very easy to integrate with other software

- Available as a standalone executable for Linux, Mac, or Windows
- Uses an external cache folder that can easily be moved and replaced
- Can update a cache folder with latest rules from the CDISC library
- Produces validation reports as readable Exceles or easily parsable JSON files
- Outputs validation progress as readable progress bar or verbose listing of completed rules
- Open sourced, allowing developers to modify and extend as needed



Developer experience of working with CORE

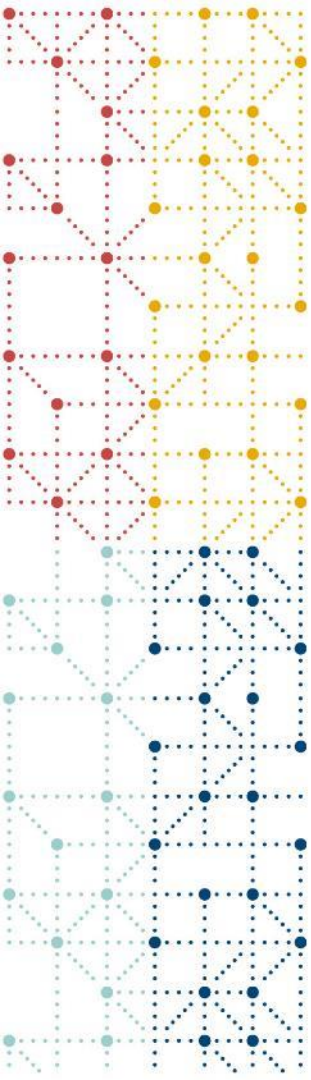
The CORE development team also delivered several features to support our own integration with the engine:

- Query to return available rule sets in the cache
- Query to return details of rules for each rule set
- Option to return validation report as both Excel and JSON
- Verbose validation progress logging
- Query to return current version of the CORE engine

Thanks to CDISC developers Nic Haydel and Aleksei Furmenkov for working with us to deliver these



Questions



Thank You!

cdisc