

The "Smart Submission Dataset Viewer" Support for Dataset-JSON and CDISC CORE Validation

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What is the "Smart Submission Dataset Viewer"?

- Open source Viewer for CDISC submission datasets (SDTM, SEND, ADaM)
- written in Java, source code and executables:
 https://sourceforge.net/projects/smart-submission-dataset-viewe/
- "Smart" in that it understands the CDISC standards (in contrast to regular XPT viewers)
- Supports CDISC Dataset-XML, Dataset-JSON and CSV as formats

Why not SAS-XPT?

- Outdated format, no Java libraries available
- Not vendor-neutral
- Discouraged by the <u>US Library of Congress</u>
- Many character limitations, making implementation complicate
- We don't want to encourage the FDA keeping mandating XPT with a smart tool for an outdated format ...

The "Smart Submission Dataset Viewer" and Dataset-JSON

- As a modern format, JSON is easy to implement in any modern software
- Users can easily transform XPT to Dataset-JSON anyway
- Dataset-JSON can also be used with APIs and RESTful Web Services
 - opening the usability of the Viewer for use with RESTful Web Services
- The "Smart Submission Dataset Viewer" now accepts Dataset-JSON as an input fomat.

The "Smart Submission Dataset Viewer" and CDISC CORE

 The CDISC Open Rules Engine ("CORE") has now been adapted for use with Dataset-JSON format

- The number of rules (SDTM, SEND, ADaM) implemented in CORE is growing on a weekly basis
- CORE has now been coupled to the "Smart Submission Dataset Viewer" for use with Dataset-JSON

Demo time!

Next steps

- Spreadsheet report of validation results
- Adaption of CORE for CSV format (used a lot in academics)
- Make all software publicly available by Christmas (nice Christmas present to the CDISC community and Regulatory Authorities such as FDA)
 - CORE engine will be update-able independent from the Viewer
- Your ideas ...