

A panoramic view of the Berlin skyline at sunset, featuring the TV Tower (Fernsehturm) and various city buildings under a clear blue sky.

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The Need for Speed: Why Dataset-JSON is so important

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Meet the Speaker

Jozef Aerts

Title: My Title

Organization: XML4Pharma

CDISC Volunteer for over 20 years.

Major contributions to ODM, Define-XML standards

Currently involved in the following projects:

- CDISC CORE
- Dataset-JSON



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Agenda

- 1 Demonstration movies
- 2 Dataset-JSON as enabler for better and faster Submissions and Reviews
- 3 The Need for Speed
- 4 Tools for Dataset-JSON
- 5 Conclusions



Demonstration movies

The demonstrations use the "**Smart Submission Dataset Viewer**", an open-source Viewer for submission datasets in Dataset-JSON, Dataset-XML and CSV format

<https://sourceforge.net/projects/smart-submission-dataset-viewer/>

An early implementation of the Dataset-JSON-API has been implemented on our server. See:

http://xml4pharmaserver.com/WebServices/Submission_Services_Dataset-JSON/

Demonstration Movies

What is possible using Dataset-JSON where we have no chance with SAS Transport (XPT)?

- Lifts all classic XPT limitations
- Really vendor-neutral
- Small footprint - ideal for use with APIs
- Embedded source records (EHRs - HL7- and CDISC-Lab messages ...)
- Audit records (not tried yet)
- Embedded images as data points
- RWS for "extras" like video, audio, ...
- API offers unbelievable opportunities
 - No need for "files" (and their management)
 - use databases (don't care about internals), single source of submission truth
 - Filtering before loading
 - All other advantages of using APIs ...



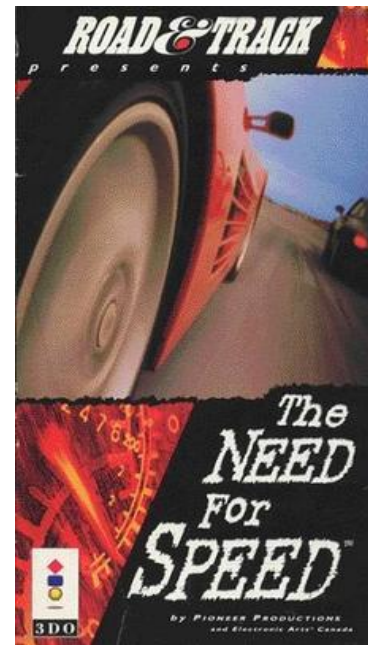
Demonstration Movies

API offers unbelievable opportunities

- No need for "files" (and their management)
- Use databases as source for RWS (single source of submission truth)
 - don't care on what the DB technology is
- Sharing data between partners (internal / external)
- Filtering before loading
- All other advantages of using APIs ...

The Need for Speed

- Dataset-JSON + APIs allow for much better and faster cooperation in the development of submissions
- One can think of a "shared zone" between sponsor and regular authority, where data is added early in the process
 - can be e.g. as soon as data has been collected and transformed to SDTM/ SEND, maybe ADaM
- Like this, communication and exchange can start much earlier in the process
- And ultimately, shorten "time to market" considerably





Tools for Dataset-JSON

- It is much easier to develop software tools for Dataset-JSON than for XPT
- Development of mapping tools for SDTM/SEND becomes much easier
 - No real need for SAS or R ...
 - For example, SDTM-ETL mapping software generates Dataset-JSON "out of the box"
- As Dataset-JSON is an open standard, it encourages the development of all kind of software tools for working with submission datasets (not necessarily as "files"). The only limitation is "lack of creativity"
- List of tools for working with Dataset-JSON at: <https://cosa.cdisc.org/hackathons/datasetJson>



Conclusions



Conclusions

- Dataset-JSON can revolutionize the electronic submissions process:
- Modern exchange format, perfect for use with APIs
- No need for "files" anymore
(but still possible)
- In principle, reviews could start (and be finalized) much earlier
- This can lead to considerable shorter "time to market"



Thank You!

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The logo for CDISC, featuring the lowercase letters "cdisc" in a dark blue sans-serif font. Above the letter "i" are three small colored dots: a red one on the left, a yellow one in the middle, and a light blue one on the right.