A Restful Web Service using Dataset-JSON

CDISC Dataset-JSON Hackaton Webinar
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APIs and RESTful Web Services

- RESTful Web Services (RWS) are about machine-machine communication for exchange of information
- Most of the dynamic content on the internet is based on RWS
- An RWS requires a "Application Programming Interface" (API), defining the "contract" between the applications
  Some of these APIs are public, e.g. the CDISC Library API.
- JSON is nowadays the first choice as the data format in RWS

A "Proof of Concept" API and RWS for Dataset-JSON

- We developed a simple "proof of concept" API for use with Dataset-JSON, and a demo RESTful Web Service that is publicly available:

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

- This API and RWS demonstrate the effectiveness and efficiency of Dataset-JSON for submissions to regulatory authorities in a modern way
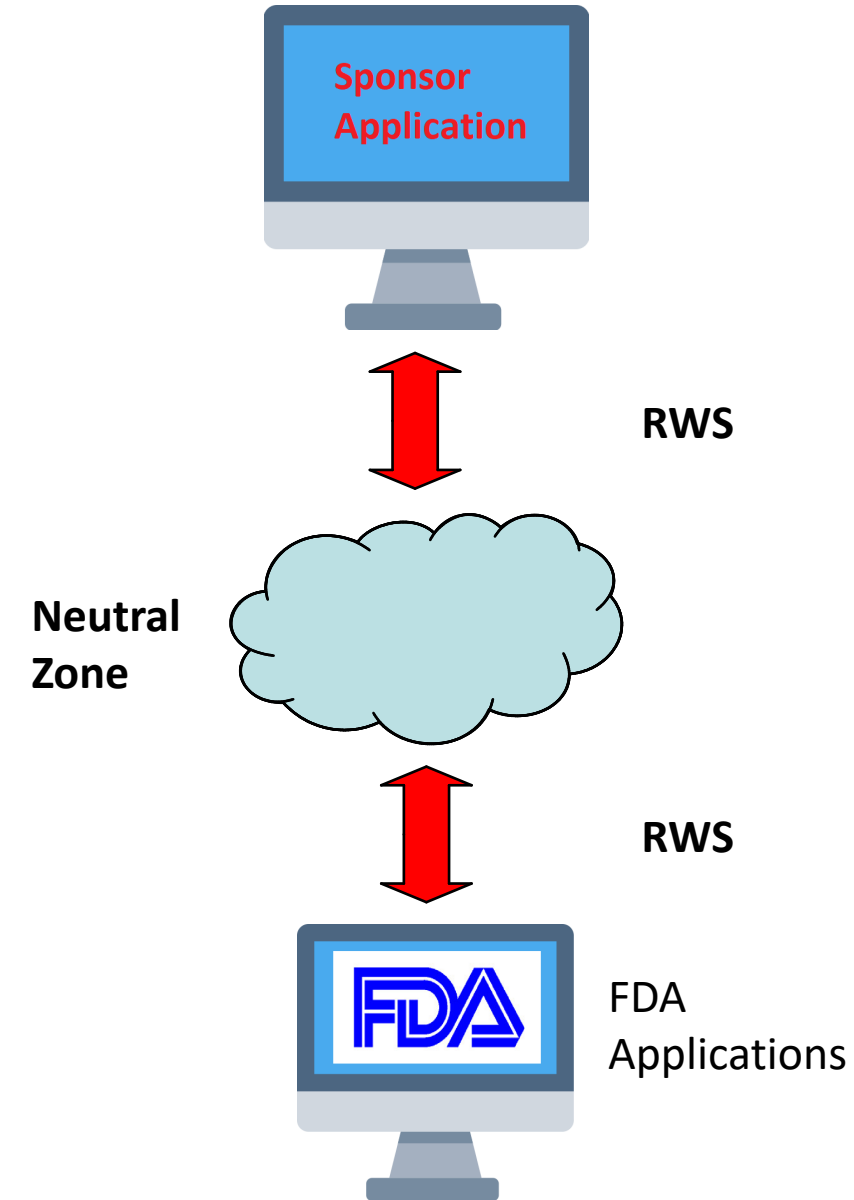
Short Demo!

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

Why is this important?

- Currently, FDA submissions are done through the "Electronic Submission Gateway" (ESG), and usually only AFTER study finalization
- The ESG is a classic portal requiring "files" to be uploaded
  - no machine-machine communication is possible
- The mandated file format is extremely inefficient, and does not allow for "smart", "dynamic" updates

- The consequence is an unnecessary delay (months to 1-2 years) in the approval process

The Neutral Zone

- We should come to "neutral zones" between sponsors and regulators based on RESTful Web Services and standardized APIs
- This would allow already starting (rolling) review once a certain percentage of the data has been collected, thus considerably improving and speeding up the approval process

Sponsor Application

RWS

Neutral Zone

RWS

FDA Applications

Next steps

- Add a few more example studies to the POC "neutral zone"-like server

- Extend (branch) the "Smart Submission Dataset Viewer" for use with the "proof of concept" API and RWS for demoing the concept

- CDISC is the perfect SDO for developing a standardized API for exchange of submission datasets between Regulatory Authorities and sponsors

Try it out yourself!

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