Dataset-JSON as Alternative Transport Format for Regulatory Submissions

Project Scope

The scope for the project covers twin objectives:

1. Demonstrate that Dataset-JSON can transport information with no disruption to business
2. Demonstrate the viability of Dataset-JSON as the primary transport option

Sub Teams

1. Pilot Submissions Report

- Consolidate feedback from the pilot submissions and develop report

2. Business Case

- Establish the overall business case for using Dataset-JSON for submissions to justify the investment needed to implement the changes

3. Technical Implementation

- Develop and document software tools to be used in the pilot to include updates to existing products

4. Strategy for Future Development

- Define a roadmap for future development and changes to the CDISC Foundational Standards

Project Impact

The XPT file format is outdated and imposes limitations on submission data due to the lack of modern features – for example, XPT files are limited to US ASCII Character encoding, have restricted variable names/sizes, inefficient use of storage space, use a non-extensible tabular structure and lack any integrated metadata. The impact of overcoming these limitations will be seen initially by regulators; however, by far the bigger impact will be seen in the medium to longer term, where, by lifting the restrictions of XPT, and moving to Dataset-JSON, new standards will be able to take advantage of these enhanced capabilities, and drive efficiencies, consistency and re-usability across the clinical research data life cycle.

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CURRENT STATUS Q1 2024

- Hosted a webinar to give a status update.
- Sub-teams working towards their work, which will form the end deliverable.
- Hosted a workshop at the US Connect.

Objectives & Deliverables	Timelines
PHUSE Team formation Engaged with collaboration partners (CDSIC, FDA etc.)	Q2 2023
Initial technical/ regulatory deliverables CSS workshop – Workstream roundtable	Q3 2023
Industry deliverables (PHUSE EU Connect)	Q4 2023
Standards deliverables	Q1 2024
All project deliverables published CSS workshops – Project findings and recommendations	Q2 2024

Resources
Summary of the pilot findings to date and recommended solutions
Pilot participation testing and reporting instructions

Dataset-JSON Webinar

Please find the recording and presentations from the Webinar that took place on 1 February.

Introduction, presented by Stuart Malcom, *Veramed*

Pilot Submissions Status Update, presented by Sam Hume, *CDISC*

Technical Implementation Topics, presented by Jesse Anderson, *FDA*

Business Case, presented by Marguerite Kolb, *Johnson & Johnson*

Strategy for Future Development, presented by Nicole Thorne, *BMS*