NORD®
National Organization for Rare Disorders

Alone we are rare. Together we are strong.®

June 9, 2025

Jacqueline Corrigan-Curay, J.D., M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10001 New Hampshire Ave
Silver Spring, MD 20903

Re: Docket No. FDA-2025-N-0129

Dear Dr. Corrigan-Curay,

On behalf of the more than 30 million Americans living with one of the over 10,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the U.S. Food and Drug Administration (FDA or Agency) for the opportunity to provide comments on the Agency's docket, "Electronic Study Data Submission; Data Standards; Clinical Data Interchange Standards Consortium Dataset-JavaScript Object Notation; Request for Comments."

With a more than 40-year history, NORD is the leading and longest-standing patient advocacy organization for the estimated 1-in-10 Americans living with a rare disease. An independent 501(c)(3) nonprofit, NORD is dedicated to caring for individuals with rare diseases and the organizations that serve them. NORD, along with its more than 355 patient organization members, is committed to improving the health and well-being of people with rare diseases by driving advances in care, research, and policy. NORD believes that all individuals with a rare disease should have access to high quality, affordable health care that is best suited to meet their medical needs.

NORD believes that moving to the Dataset-JSON format for sharing study data is a smart and necessary step toward making rare disease research more collaborative, transparent, and efficient. The mechanism in which researchers handle and exchange data has changed dramatically in recent years, and Dataset-JSON offers a much-needed update to the older SAS XPT format, which has been around for decades but no longer meets the demands of modern research.

As seen in the Appendix, one of the key advantages of Dataset-JSON lies in its accessibility and user-friendliness. In contrast to SAS XPT files, which are stored in a binary format and necessitate specialized software for access, Dataset-JSON is a plain text format. It can be viewed using a web browser, text editor, or a variety of modern, freely available tools. As a result, researchers, developers, and regulatory authorities can more readily access and interpret the data without the need for a SAS license or additional proprietary software.

Dataset-JSON is also more informative, as displayed in the Appendix when compared to SAS XPT. In addition to the data itself, it contains comprehensive metadata, including variable labels, data types, formats, and controlled terminology. This additional context facilitates more accurate interpretation, validation, and integration of the data across systems, particularly when working with heterogeneous datasets or collaborating across organizations.

From a technical standpoint, Dataset-JSON is well-aligned with the demands of the modern digital ecosystem. It integrates seamlessly with databases, web-based platforms, APIs, and widely used programming languages such as Python and R. This interoperability enables automation, expedites validation processes, and supports real-time collaboration. These are capabilities that are often difficult to achieve with legacy formats like SAS XPT.

Transitioning to a new standard is not without its challenges. As a text-based format, JSON files can be larger in size and may require more processing time, particularly when handling extensive datasets. Additionally, there is a learning curve for teams accustomed to working with traditional SAS tools and file types. Nonetheless, the advantages of adopting Dataset-JSON significantly outweigh these obstacles. Its flexibility, openness, and ease of integration represent a meaningful step forward for the research community. By lowering technical barriers and enhancing transparency, Dataset-JSON facilitates faster, more inclusive, and more impactful research, particularly in the rare disease research space.

For individuals involved in the collection, transfer, or analysis of study data, whether in research, technology, or regulatory domains, Dataset-JSON offers a more efficient, collaborative, and future-ready approach. For these reasons, NORD strongly supports this transition.

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NORD again thanks the Agency for the opportunity to provide comments on this important docket. We look forward to further opportunities to engage in ongoing dialogue around efforts to strengthen the streamlining of data for rare disease research. For questions regarding NORD or the above comments, please contact Prashant Goel, Vice President of Information Technology, at pgoel@rarediseases.org

Sincerely,

Prashant Goel
Vice President of Information Technology
National Organizations for Rare Disorders

Appendix: Comparison of High-Value Features Between Dataset-JSON and SAS XPT

Feature	Dataset-JSON	SAS XPT (Transport)
Human-readable	Yes - easily viewable in any text editor or browser	No - binary format requires specialized software
Modern tooling support	Yes - Works natively with Python, R, JavaScript, etc.	Limited - mostly SAS or specialized libraries
Metadata support	Yes - Rich support - includes labels, types, formats, controlled terms	Minimal - only basic variable info
Open standard	Yes - Open and license-free	No - Proprietary legacy format
Web integration	Yes - Ideal for APIs, dashboards, and cloud-based tools	No - Not suitable for web use
Extensibility	Yes - Highly extensible - new fields can be added without issues	Very limited - rigid structure
Schema validation	Yes - Validated using JSON Schema	No - Not supported