

M2 EWG Recommendation to the ICH Assembly

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

JavaScript Object Notation (JSON) Recommendation

Version 1.0 – 21MARCH2024

Title: JavaScript Object Notation (JSON)

Background:

JSON (JavaScript Object Notation) is an open standard file format and data interchange format that uses human-readable text to store and transmit data objects utilized in electronic data interchange. JSON is a language-independent data format which utilizes the *.json* extension.

Published specifications and print requirements for each code are available from the International Organization for Standardization (ISO).

- ISO/IEC 21778:2017- Information technology - The JSON data interchange syntax.
- The JavaScript Object Notation (JSON) Data Interchange Format", STD 90, RFC 8259, December 2017.

Recommendation:

- This recommendation is applicable to those regions that support *.json* extension implementation.
 - Examples may include the use of the *.json* extension in REST (or RESTful) APIs¹ and in support of message exchange standards.
- ICH M2 EWG recommends the *.json* extension per ISO/IEC 21778:2017 and STD 90, RFC 8259: December 2017.

Conditions:

- This document is not recommending the deprecation of other file formats (e.g., *.pdf*, *.doc*).
- Sponsors should adhere to the recommended standards/specifications as identified by the local/regional regulatory authority.

Remarks:

- Please refer to the ICH M2 Recommendations & Technical References for the latest ICH M2 ESTRI Recommendations for file formats.

¹ REST-Representational State Transfer