

Electronic Data Submission in Japan



Project Scope

To raise awareness of eData submission to PMDA globally, especially focusing on PMDA specific requirements and practical challenges. To provide ideas for improvements for eData submission process/deliverables and to discuss better solution for both for PMDA and sponsor/CRO.

Objectives:

1. Produce a white paper to clearly describe PMDA specific requirements, best practice and suggestion for improvements
2. Create a presentation on tips of eData submission to PMDA to be presented at a Webinar, SDE or Connect

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Published Deliverables	Date
Best Practices for the Submission of Data in Japan	09-June-2022
(E) Validation Error	03-May-2023