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ASIA EDITION

Submitting clinical data to the FDA and PDMA: An efficient and compliant approach

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Creating a single set of data that can be used in submissions for both countries is entirely do-able

In both the US and Japan, regulators provide an extensive set of resources detailing the rules and specifications governing submissions for marketing approval of new drugs and biologics. Fortunately, despite some differences, the regulations concerning clinical data have a surprising amount in common. It is possible that with a solid understanding of the requirements and an adherence to best practices, sponsors can develop some of the same material for submission to both countries.

Accessing technical references

The US Food and Drug Administration (FDA) and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan each maintain a comprehensive website of study standards with links to important documents for study sponsors. Notably, both agencies offer a searchable Data Standards Catalog to aid sponsors in finding only those standards and the correct versions that are applicable to a given study. Both also have published a Technical Conformance Guide, following a similar format.

In the US, sponsors should refer to two binding guidances:

- *FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug & Cosmetic Act.*
- *FDA Providing Regulatory Submissions in Electronic Format—Standardized Study Data (June 2021)*

The PDMA's guidance is laid out in *Notification on Handling Submission of Electronic Study Data for New Drug Applications.*

Selecting the appropriate standard

In the US, each standard listed in the Catalog has a beginning and ending support date. A standard can be used for a study if the first patient has provided informed consent after the support start date and before the end date. At times, there can be more than one acceptable version of a standard, in which case, sponsors can select the version they choose to use. In contrast, in Japan, the date that determines which standard applies is based on the study submission date.

There are also a few cases in which the FDA's expectations do not conform to Clinical Data Interchange Standards (CDISC). Sponsors should evaluate each such instance on a case-by-case basis to determine the best solution and then approach the FDA with a proposed strategy. The Reviewer's Guide should ultimately explain which of the conflicting standards was applied and why.

Checking for compliance

Agencies can reject data for non-compliance. To check for compliance, sponsors can use commercially available software to perform the same type of checks performed by the agencies. Some tools are free to download while others are enterprise tools that incur usage fees. Such automated checks are thorough, however human oversight is still required.

Adopting the most efficient approach

Creating a single set of data that can be used in submissions for both countries is entirely do-able. In striving for this consistency, we recommend that sponsors:

- Review each country's Data Standards Catalog to see where the implementation guides overlap.
- Follow the applicable US FDA Technical Specifications and CDISC Therapeutic Area User Guides (TAUGs), even though doing so is not required by the PMDA.
- Identify and cross-document conflicts and document why they were resolved as they were.
- Create separate files (in Define.xml format) for each country since the PDMA wants to receive ADaM Analysis Results Metadata (ARM), whereas the FDA does not.
- Prepare separate Reviewer's Guides for each country, considering that each will need explanations for any conformance findings.

Ensuring compliance with both agencies' specifications requires careful attention to selecting the appropriate standards and versions from the outset and making use of the available tools to check for conformance to expectations. With proper planning and adherence to best practices, sponsors can pursue the most efficient approach, thus accelerating the path to market for their products.

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