Key guidelines, Tricks and Experiences for PMDA and comparison with FDA and CDE submission

- **PharmaSUG 2025 - Paper SS-254**

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Agenda

FDA
CDE, NMPA

- Comparison of PMDA with FDA and CDE,NMPA.
- Standard Review timeline for PMDA.
- Best practices and tips for efficient PMDA submission.
- Q & A

Comparison of PMDA with FDA and CDE,NMPA

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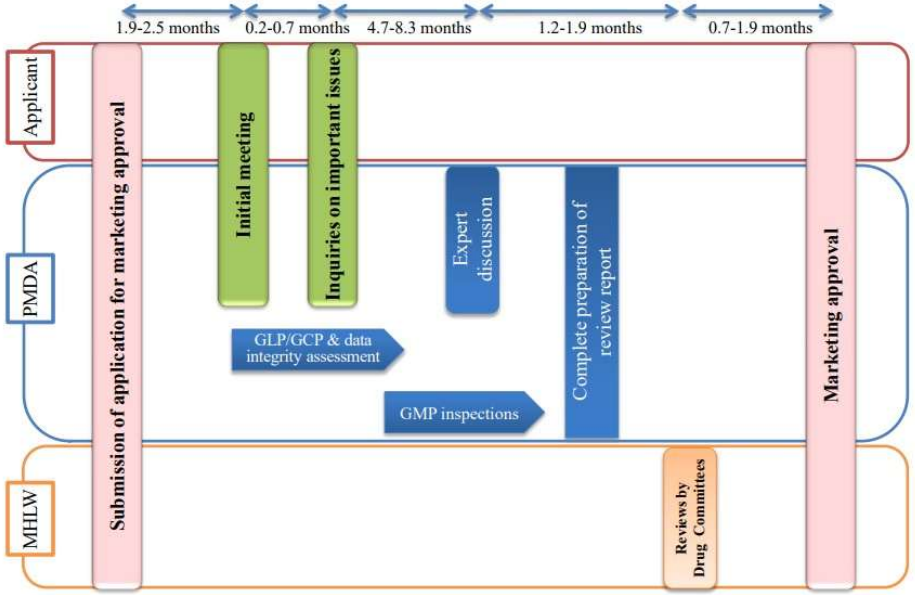
Causality/ Relationship Definitions	Causality categories may include related/not related, probable/possible/unlikely/unrelated. Only 'unlikely' is considered 'not related	Considering 'Unlikely related' as 'not related' is accepted by FDA.	Follows Causality/relationship definitions as FDA

STANDARD REVIEW TIMELINE FOR NEW DRUG APPLICATION FOR PMDA SUBMISSION



MHLW- The Ministry of Health, Labour and Welfare (MHLW) is a government ministry in Japan responsible for overseeing health, labor, and welfare policies.

Best practices and tips for efficient PMDA submission

DATA VALIDATION RULES

The PMDA website (New Drug Review with Electronic Data | Pharmaceuticals and Medical Devices Agency)

PMDA performs **independent validation** on submitted e-data

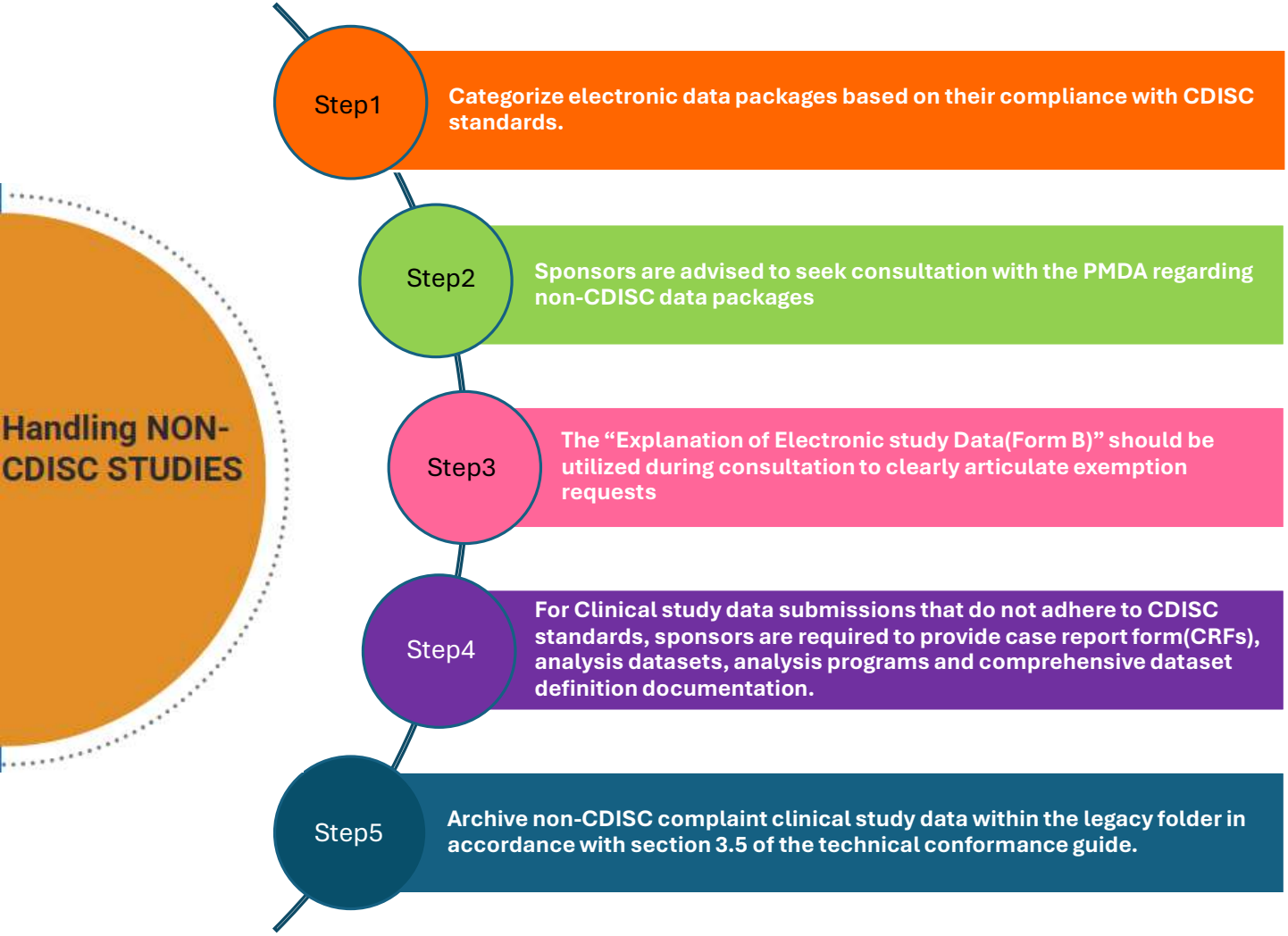
A **unified set of validation rules** must be applied for PMDA submissions across all e-data packages that comply with CDISC standards (SDTM/ADaM)

Data packages submitted to the FDA must be **revalidated against PMDA rules**.

UNDERSTANDING THE SCOPE OF STUDIES FOR SUBMISSION

- The regulatory team must collaborate with PMDA to define the required study electronic data packages.
- Categorize the Pivotal studies of the PMDA submission.
- Identifying the core focus of the e-data packages.
- Include integrated safety and efficacy analysis when applicable. Clear focus and scope aid in task assignment and management.

IDENTIFYING CDISC AND NON-CDISC STUDIES



M5 folder structure

ARM (Analysis results metadata)

Traceability	• Arm includes metadata for key analysis results, ensuring traceability to data and methods. It is typically in the define.xml file for ADaM datasets.
Pivotal analysis	• ARM is highly preferred for pivotal studies and for non-pivotal analyses, ARM is not required. Providing the relevant ADaM datasets and corresponding analysis programs is sufficient
Primary efficacy and critical safety	• The FDA views ARM as optional, While PMDA highly prefers it for Primary safety and critical efficacy of pivotal analysis.
Replication	• ARM helps PMDA reviewers understand the derivation of each results and facilitate analysis replication if needed.

INSPECTION READINESS

- Inspection preparation should be coordinated with the **quality function** and focus on the documentation based on **Good Clinical Practice** (**GCP) BIMO list**. Mock interviews are highly recommended to prepare for the real inspection.

CONCLUSION

A thorough understanding of PMDA regulatory requirements, early and meticulous planning, proper identification of CDISC compliance, clear documentation of analysis datasets and programs, and detailed preparation of Analysis Results Metadata (ARM) are essential elements for an efficient submission. By following these best practices and proactively preparing for potential inquiries, regulatory and programming teams can significantly streamline the PMDA submission process, facilitating timely approvals and enhancing overall submission quality.


Q & A

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THANK YOU