

Key Programmer Tasks for Japan Submission and Programmer Role Allocation

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Agenda



Introduction



Conclusion



Key Programmer Tasks for
Japan Submission



Q&A | Any Questions ?



Programmer Role Allocation

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Key Programmer Tasks for
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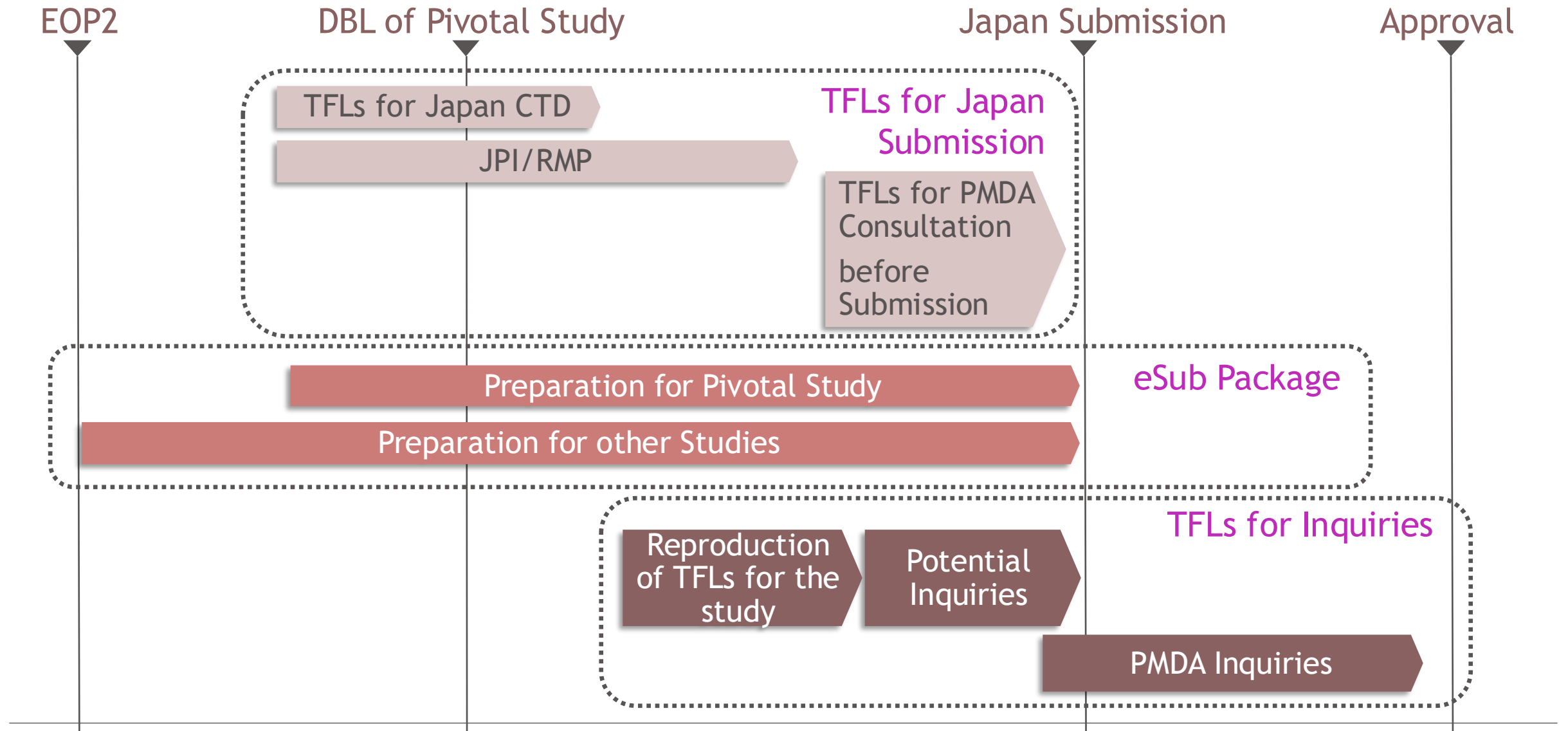


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Programmer Role Allocation

Illustrative Key Programmer Tasks for Japan Submission

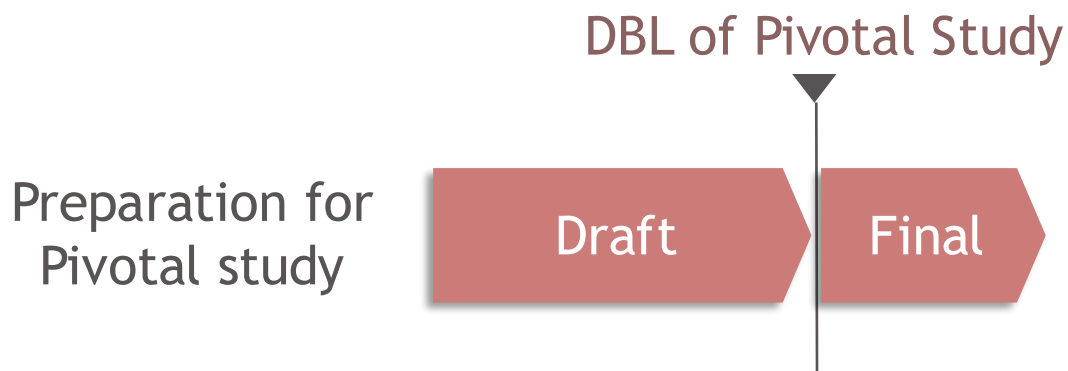


TFLs for Japan Submission - Key Points of Outputs

- Japan Subgroup Analysis is needed for CTD, JPI/RMP
- Align MedDRA version across studies for pooled outputs
- Display AE term in Japanese
- Specific safety TL requirements based on PMDA notifications on Japan CTD (called JIMUREN) have recently become less necessary
- PMDA pre-submission consultations may require analyses or lead to inquiries

eSub Package - Key Points of Package Preparation for Pivotal Study

- Perform PMDA validation for draft eSub before and after DBL
 - Resolve the “REJECT” issues related to data issues before lock
 - Resolve the “ERROR” issues as much as possible and make explanation for those can’t be resolved
 - Confirm mandatory requirements to avoid inquiries or any correction requests
 - Check that file names follow eCTD naming rules, not only the eSub rules
- Prepare Meeting material for PMDA consultation meeting if any



**Draft
validation
before lock is
important to
avoid REJECT**

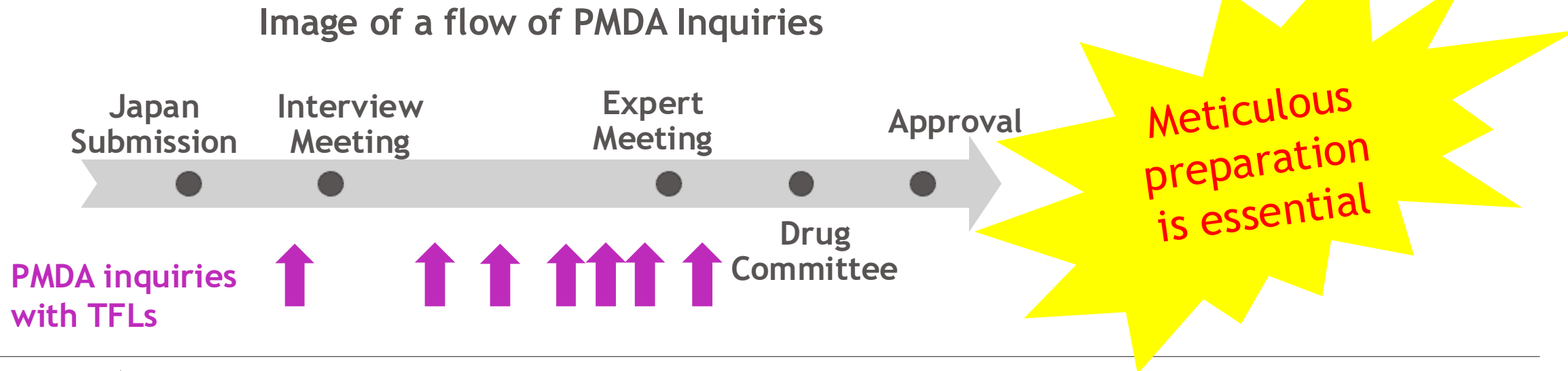
eSub Package - Key Points of Package Preparation for other Studies

- Identify the PMDA-required eSub studies based on PMDA notification* and make an agreement on the scope of eSub with PMDA at EOP2
- Ensure CSR version alignment and completeness of datasets, documents, and programs
- Estimate the need for legacy data conversion
- Prepare Meeting materials (e.g. BB, FormA, FormB) for PMDA consultation meeting if any
- Create eSub package for PMDA submission (the same as pivotal study)

* Notification on Handling of Submission of Electronic Study Data for New Drug Applications

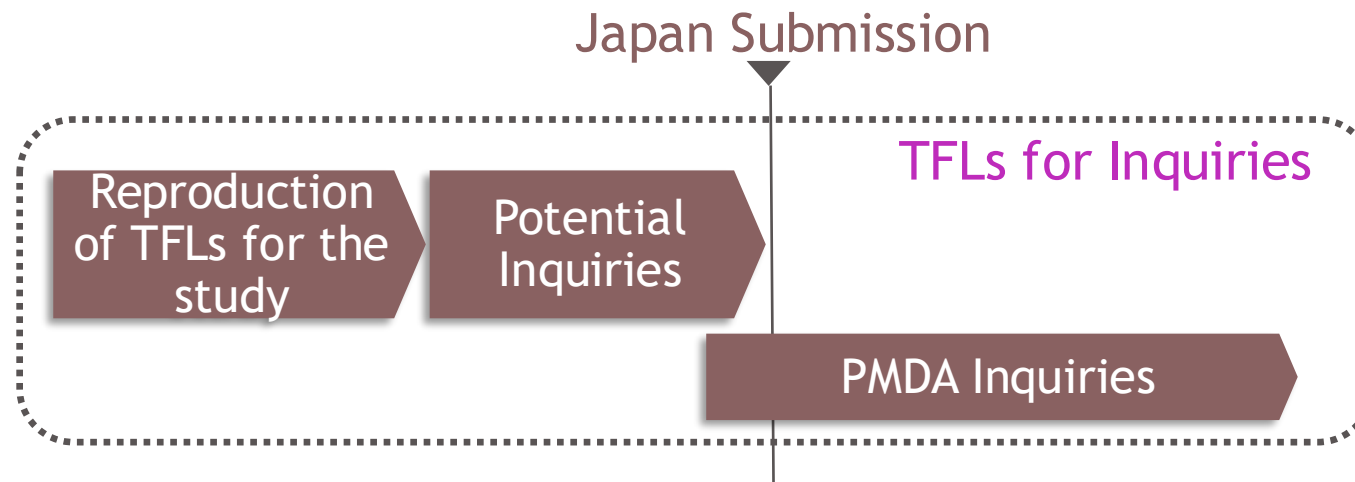
TFLs for Inquiries - Key Points of PMDA Inquiries

- Receive inquiries for multiple times
- Require immediate response
- Require a large volume of TFLs in a short period
- Later-phase inquiries require faster turnaround (1-2 days for program)



TFLs for Inquiries - Key Points of Preparation before Japan Submission

- Ensure programs can be executable and reproduce CSR, ISS, ISE result accurately
- Prepare potential inquiries
- Establish rules of collaboration with the Global team in advance:
 - Role allocation
 - Process for analysis requests



Examples of Programmer Tasks for an Oncology Product Submission

- Volume of Clinical data package
 - 24 studies (Pivotal study: 7, Reference study: 17), ISS, ISE
- Volume of eSub package
 - 18 packages
- TFLs for submission
 - JPI/RMP: 4 tables
 - Preparation for inquiries
 - Potential inquiries: 22 tables, 10 listings
 - Reproduced CSR output programs: 10-15 tables per study for 23 studies, prepared more than a year in advance
 - Modified CSR programs: About 50 tables to be executable for the pivotal Japan study
 - 1st important inquiries after submission: 762 tables & listings by 4 weeks
 - 4 rounds of additional inquiries after 1st inquiries: revised or newly created outputs within a short period

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Programmer Role Allocation

Role Allocation for Programming Tasks: Global and Japan

- As part of our stat programming department's basic approach, Global handled outputs for Japan submission and eSubmission packages for Global-led studies
- This approach is accurate and efficient due to Global's familiarity with the study
- Tight US/Japan timelines sometimes push more Priority Project tasks to Japanese programmers

Basic Approach		Possibilities for Priority Projects
TFLs for Japan Submission	Almost prepared by Global	Japan prepares outputs based on Global results
eSub for PMDA	Created by Global Japan checks PMDA requirements	Same as Basic Approach
TFLs for Inquiries	Efficacy: Global Safety & Others: Japan	All analyses by Japan; Global reviews if needed

Challenges of Japanese Programmers for Primary Project's Japan Submission

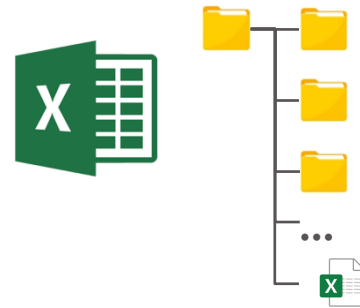
Possibilities for Priority Projects		Challenges of Japanese programmers
TFLs for Japan Submission	Japan prepares outputs based on Global results	• Need Frontloaded action before lock: Share global programs and be ready to perform analysis for Japan • Require more resources
eSub for PMDA	Created by Global Japan checks PMDA requirements	• Confirm compliance with PMDA requirements before DBL
TFLs for Inquiries	All analyses by Japan; Global reviews if needed	• Need deep SAP understanding for quick responses • Require time to learn the study • Require more resources for preparation

Advantages of Japanese Programmers for Japan Submission

- Regional location
 - Language
 - Time difference
- Familiarity with regional submission
 - Extensive experience with PMDA submission
 - Ability to make proposal
- Meticulousness for analysis readiness
 - Programs preparation
 - Resource estimation
 - Programmer training

Ideas for Efficient Work Management

- Establish a platform to manage various analysis requests by different departments for different purposes and at different times
 - Centralized one sheet to track and manage all requests
 - Well-organized and access-controlled folders
 - Streamline collaboration between Statisticians and Programmers
- This platform allows quick lookup and easy reuse of past work, improving efficiency and quality



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- Key deliverables for Japan submission: TFLs for Japan submission, eSub packages, and TFLs for Inquiries.
 - For TFLs for Japan submission, Japan subgroup analysis is needed.
 - For eSub preparation, early issue resolution in pivotal study and proactive checks in other studies ensure smooth submission.
 - To quickly respond to repeated, many inquiries, meticulous preparation and building relations with the Global team is important.
- Allocate roles between Global and Japan, and optimize as needed to maximize quality and speed.
- Japanese programmers face challenges such as the need for sufficient preparation and understanding of Global-led studies, as well as securing adequate resources.
- Thoughtful role allocation and strong autonomy at regional sites are essential for efficient multi-country submissions under tight schedules.

Q&A | Any Questions?

