

Awareness from Electronic Data Submission to PMDA and FDA

-- Lesson & Learnt from hands-on experiences --

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ABSTRACT

Pharmaceuticals and Medical Devices Agency (PMDA) has started accepting electronic study data (e-study data) submissions, beginning October 2016 with a 3.5 year transitional period. The requirement of PMDA is similar to that of U.S. Food and Drug Administration (FDA) e-study data submission requirements. However, there are some differences in the requirement between both health authorities. Because recent drug development should be done in a more globally integrated way and similar clinical data package should be used for submission to both PMDA and FDA, sponsors need to understand the differences precisely and consider efficient processes for a new drug application (NDA) to meet requirements of each health authority (HA).

In November 2016, Novartis submitted e-study data of global study including Japanese subjects in Clinical Data Interchange Standards Consortium (CDISC) formats to PMDA and FDA simultaneously. Because of different requirements of the two health authorities, there were several challenges in terms of e-study data preparation. Japanese and global teams worked closely to achieve simultaneous e-study data submission.

This paper explains experiences and challenges based on actual e-study data submission and proposes internal comprehensive processes for the e-study data submission, focusing on the differences between PMDA and FDA requirements.

INTRODUCTION OF PMDA E-STUDY DATA SUBMISSION

The initiation date of e-study data submission is October 1, 2016. There is the transitional period of 3.5 years from October 1, 2016 to March 31, 2020. Submission of standardized e-study data will be mandatory effective on April 1, 2020. On the other hand FDA will request standardized e-study data for studies which start after December 17, 2016. The difference between two agencies is that PMDA takes the submission date irrelevant of study start date whereas FDA takes the study start date.

Before starting preparation of e-study data submission, sponsors should refer below notifications and guidance published by MHLW, Ministry of Health, Labor and Welfare / PMDA as of March 2017.

- “Basic Principles on Electronic Submission of Study Data for New Drug Applications”, published on June 20, 2014, by MHLW. The first official announcement that MHLW / PMDA will require e-study data for NDA.
- “Notification on Practical Operations of Electronic Study Data Submissions”, published on April 27, 2015, by MHLW. This document mainly describes practical issues and announces start date of e-study data submission for NDA.
- “Technical Conformance Guide on Electronic Study Data Submissions”, published on April 27, 2015, by PMDA. Amendment version published on August 2016.
- Other related document / guidance such as Data Standard Catalog, Validation rules, FAQ document and web page and PMDA gateway manual. (in Japanese only)

Almost all clinical study data must be compliant to CDISC standard format for submissions on or after April 1, 2020. Conformity of the CDISC standards e-study data submission must be ensured under the responsibility of sponsors. The main targeted studies which should be submitted in e-study data submission are listed below;

- Data on results from all phase 2 and phase 3 studies (including long-term studies) that are generally regarded as major evidence for evaluation of efficacy, safety, and dosage and administration.
- For study results from phase 1 studies and clinical pharmacology (CP) studies, results from studies listed below are required to be electronically submitted.
 - Phase 1 studies of oncology drugs
 - Phase 1 studies that have been conducted in both Japanese and non-Japanese subjects (e.g. in case of a strategy of global clinical trials and bridging studies)
 - QT/QTc studies based on ICH E14 guideline

Phase 1 and CP studies other than listed above are requested only if PMDA deems necessary. Further detail of targeted studies and e-study data are summarized in “Question and Answer Guide Regarding Notification on Practical Operations of Electronic Study Data Submissions”, published by MHLW on April 2015, with relevant data format for clinical study data and analysis data.

PMDA TRANSITIONAL PERIOD

As mentioned above, from October 1, 2016 to March 31, 2020 will be the transitional period. During this period, e-study data submission is not mandatory, and sponsors can choose to submit e-study data per study level, not submission level. i.e., only one study can be submitted electronically in clinical data package. Note that for a partial e-study data submission, the NDA will be reviewed using the conventional review process.

CHALLENGES AND AWARENESS BASED ON ACTUAL EXPERIENCES

In November 2016, Novartis submitted e-study data of one clinical study formatted in CDISC standards to both PMDA and FDA simultaneously. This section presents challenges and awareness through this simultaneous e-data submission experience. Japanese and Global team had worked closely and kept communication from the beginning to the end.

PREPARATION OF E-STUDY DATA TO EACH HEALTH AUTHORITY

Here is the list of e-study data submitted to PMDA and FDA in our e-study data submission.

- Study Data Tabulation Model (SDTM) dataset**
- Analysis Data Model (ADaM) dataset
- Define-XML for SDTM** and ADaM dataset
- **Analysis Results Metadata (ARM) in PDF format***
- Annotated Case Report Form (aCRF)
- Study Data Reviewer’s Guide (SDRG)**
- Analysis Data Reviewer’s Guide (ADRG)**
- SAS® programs for creating ADaM dataset* and analyses

* Submitted to PMDA only

** Including different contents between PMDA and FDA

Initially, one common set of e-study data creation was planned for PMDA and FDA. But in fact, for some e-study data we had to prepare two versions for each HA with following reasons as below.

Analysis Results Metadata (ARM)

The FDA doesn’t specifically mention the necessity of ARM as one of the requirements. On the other hand, PMDA technical conformance guidance clearly mentions ‘the definition documents of the ADaM

datasets should preferably include Analysis Results Metadata'. Therefore ARM was created for PMDA submission purpose only. According to guidance, corresponding analyses covered by ARM will be

- Primary and secondary efficacy analysis
- Primary safety analyses and basic analysis for adverse events
- Analyses to investigate the effect of major factors on efficacy and safety.

These targeted analyses are also applied to ADaM datasets, SAS programs for ADaM and Table, Listing and Figures (TLF) when these are submitted.

Although ARM is generally included as a part of Define-XML for ADaM dataset in Define version 2.0, PMDA allows sponsors to submit ARM in PDF format because PMDA considers content is more important than a format of ARM (i.e. PDF, XML, etc.). In addition, because our Define-XML for ADaM was created with version 1.0 for both HA, ARM needed to be created in PDF format for PMDA as ARM is the new element for version 2.0.

Different content in SDRG and ADRG

There were 2 main differences in contents of reviewer's guide for PMDA and FDA.

Firstly a summary of conformance issues had to be described differently because of differences in validation level between PMDA and FDA. Even though both checks are basically implemented by Pinnacle 21 validation rules, severity of issues are different. PMDA categorizes validation severity as "Reject", "Error" and "Warning" to SDTM, ADaM and Define-XML whereas FDA defines "Error" and "Warning" to SDTM and SEND.

PMDA Severity	Rules
Reject	Rules which, if violated, will cause the review to be suspended until corrections are made. Very basic rules such as the presence/absence of necessary datasets for each clinical study.
Error	Rules which, if violated without any prior explanation, will cause the review to be suspended until corrections are made. In many cases, these rules are clearly stated in each standard and implementation guide, and if violated, sponsors should consult to the PMDA before the application on a reason for the violation and a reason why it is not possible to correct it. These rules must also be explained in the data reviewer's guide.
Warning	Rules which, even when violated, will not necessarily require any explanation.

Table 1. PMDA validation criteria

Secondly, SI unit conversion table was added in SDRG Appendix for as per PMDA request. The example of conversion unit table can be found in PMDA FAQ page.

LBTEST	Original Unit	Conversion Factor	SI unit
Albumin	g/dL	10	g/L
Bilirubin	mg/dL	17.1	umol/L
Glucose	mg/dL	0.05551	mmol/L
...

Table 2. Example of conversion unit table in SDRG.

Note that PMDA requests SI converted value not only for laboratory but also any test if SI unit is available. For example, kPa is SI unit for pressure and value in kPa for SBP and DBP should be included in SDTM.

SHARING CONFORMANCE ISSUES AT CONSULTATION ON DATA FORMAT

The “consultation on data format of the submission of electronic study data” is newly settled to discuss e-study data by PMDA. The main purpose of this meeting is to discuss not on data “contents” but on data “formats”. For example, if sponsors have concerns or questions about how to store collected information in CDISC standards, this consultation will help. Another main purpose for this consultation is to provide irresolvable validation results which are categorized in “Error”. Sponsors have to set up this consultation in face to face if sponsors have any concerns and conformance issue of “Error” criteria. As described in previous section (Table 1), a NDA review won’t be started while “Error” issues remain without explanation.

For this consultation sponsors need to describe not only discussion point but also e-study data information shown in Table 3 in PMDA specific template (Form 8).

Contents of Form 8		Description	Referred section in SDRG/ADRG
Basic information		Compound, product name, general name, drug form, dose regimen, ...	--
Clinical data package and overview of each clinical trial	Planned clinical study to be included in clinical submission.	Describe all planned studies (both evaluation and reference data) regardless of submission of e-data.	--
	Detail information of clinical study submitting e-study data	Study information (Protocol ID, target population, study design, treatment group, efficacy and safety endpoint, number of patients per arm, ...)	--
Information on submitted clinical study, Integrated Summary of Efficacy (ISE) / Integrated Summary of Safety (ISS), CP study in CDISC format		<ul style="list-style-type: none"> • CDISC compliant status for SDTM and ADaM. E.g.) “Data collection was performed in CDASH format?”, “Is ADaM created from SDTM?” • Data standards to be used. • File format • Total size of e-study data. • List of SDTM and ADaM dataset to be submitted and individual dataset description. • Pinnacle 21 validation result summary. 	<ul style="list-style-type: none"> • SDRG/ADRG 1.3 Study Data Standards and Dictionary Inventory. • SDRG 3.3 SDTM subject Domains (Table for list of SDTM). • ADRG 5.2 Analysis Datasets. • SDRG 4.2 / ADRG 6.2 Issues Summary. • ADRG 7 Submission of Programs.

Table 3. Constitution of Form 8

Since some contents in Form 8 are similar to SDRG and ADRG, usually each reviewer’s guide is the source of Form 8. It can be said that each reviewer’s guide should be finalized before consultation on data format and make sure the contents is valid, even any e-study data not supposed to be requested for this consultation.

Because our submission timeline was very tight, it was very hard to adjust the timing of finalization of these reviewer’s guides for consultation on data format. We had to set up multiple consultations to share issues before submission.

UNEXPECTED SPECIFICATION IN PMDA VALIDATION CHECKS

Sponsors must be careful when using multiple CDISC standard version in individual study.

Because we were still in the transitional period of SDTM version upgrading in Novartis, most of our SDTM datasets were implemented by SDTM IG v3.1.2 but only Trial Design Model (TDM) were SDTM IG v3.1.3 in order to use additional variable in v3.1.3. According to PMDA technical guidance, using multiple CDISC standard version within individual study should be noticed during consultation on data formats. Thus we had a consultation and agreed to use mix version. Then we checked SDTM, ADaM and Define-XML by Pinnacle 21 with corresponding CDISC version in order to confirm no “Reject” issues.

However we received rejection from PMDA.

DM	SD0056	SDTM Required variable ACTARMCD not found	Reject	1
DM	SD0056	SDTM Required variable ACTARM not found	Reject	1
DM	SD1121	Neither AGE nor AGEXT values are populated	Error	43

Display 1. Actual results from PMDA validation report

In general after submitting e-study data to PMDA gateway, PMDA validation check will be run. For PMDA e-study data submission, SDTM, ADaM and Define-XML will be checked by Pinnacle 21 Enterprise. As described in Table 1, since PMDA has provided their validation criteria, sponsors are able to run validation check to eliminate any “Reject” issues in advance.

As we were agreed with PMDA in terms of use of mix version, we expected the corresponding validation to be run to each SDTM and TDM and confirmed no reject issues in each study data. But in fact, CDISC standard version for SDTM, ADaM and Define-XML in validation checks are automatically extracted from each Define-XML source code and sponsor can’t choose when study data is submitted in gateway system.

```
<MetaDataVersion OID="MDV.ABC1234.SDTMIG.3.1.2.SDTM.1.2"
  Name="Study CDISC01, Data Definitions"
  Description="Study ABC1234, Data Definitions"
  def:DefineVersion="2.0.0"
  def:StandardName="SDTM-IG"
  def:StandardVersion="3.1.2" >
```

Display 2. CDISC standard version to be used in PMDA conformance check

For example, Define-XML for SDTM specifies standard version as “SDTM 3.1.3” in its XML code, then validation check for SDTM will be run by SDTM IG v3.1.3. There were two solutions at that time, one is to add above two variables ACTARMCD and ACTARM just to remove above reject errors, the other one is to downgrade TDM to v3.1.2. According to request from PMDA, we chose first option that adding above two variables in DM domain and update Define-XML for SDTM for PMDA as a “first aid”.

Important message here is, sponsor should specify single version of CDISC standard to each SDTM, ADaM, and Define-XML even though PMDA guidelines mentioned the acceptance of mixed versions of CDISC standards within single study. Now PMDA FAQ page clearly notices this discrepancy.

Also note that as long as PMDA uses Pinnacle 21 Enterprise version 3.0.5, sponsors will be requested to use Community version 2.1.3 in terms of compatibility.

SUGGESTIONS FOR SUCCESSFUL E-STUDY DATA SUBMISSION

COMMUNICATION WITH HEALTH AUTHORITIES WITH PROPER TIMING

One of the most important things in e-study data submission preparation is to define clinical data package for NDA as early as possible. For example, in Japanese NDA, it is usually discussed on clinical data

package in the end of phase 2 clinical consultation. Overall timeline of several consultations/meetings until NDA, which is related to e-data submission, is indicated in Figure 1. Sometimes, clinical data package to PMDA is different from that to other health authorities. From that point of view, sponsors should estimate overall cost and resource for e-study data submission to cover all NDAs to various health authorities. Especially when legacy data is possibly to be included, we should consider conversion plan (Legacy data conversion is described later). It may be not easy to decide on the clinical data package at the end of phase 2. However, it is extremely important for statisticians and programmers to keep reminding the team that e-study data submission is time consuming.

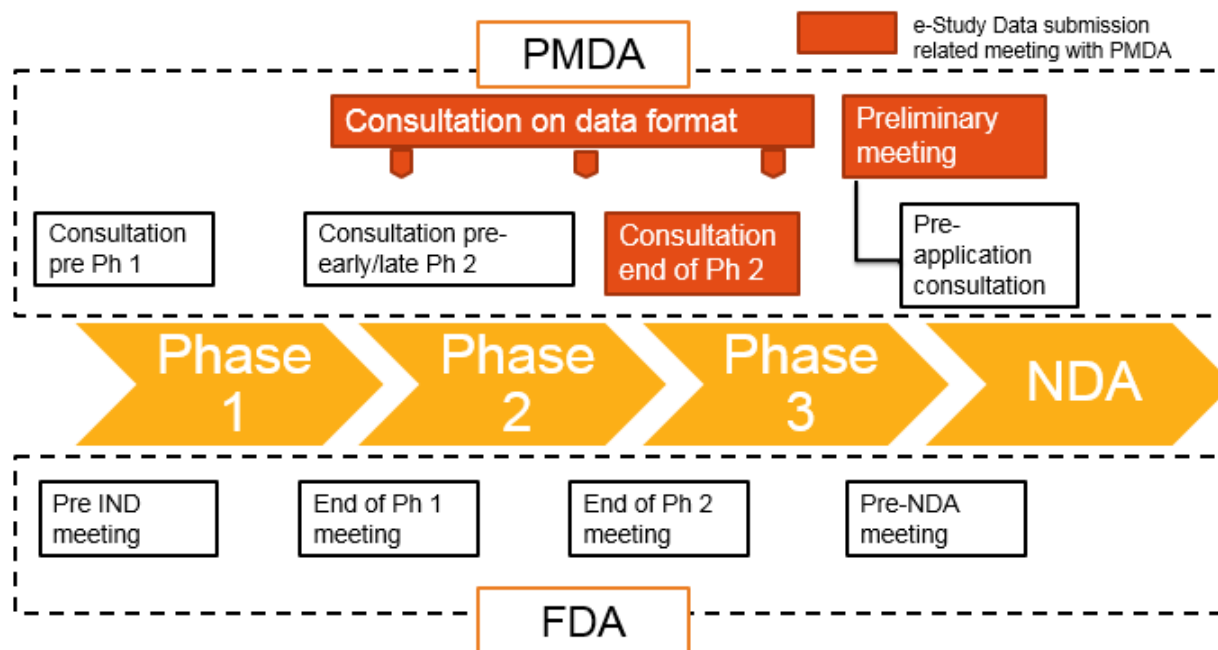


Figure 1. PMDA consultations for NDA

From our experiences, the biggest challenge was timelines. In terms of data preparation, timeline of PMDA e-study data submission was more difficult than FDA e-study data submission. For example, whereas e-study data for FDA is supposed to be prepared prior to NDA, data preparation for PMDA should estimate at least two months in terms of conformance issue sharing with PMDA.

PMDA gateway system is initiated for data submission one to five weeks prior to NDA. Because final version of Form 8 should be submitted at preliminary meeting which usually takes place one to three months prior to NDA, sponsors need to complete data preparation at least two months before NDA. Furthermore all conformance issues should be shared with PMDA at consultation data format before preliminary meeting. Thus at least 2 months should be taken into consideration. As a worse case, conformance results for SDTM, ADaM and Define should be prepared before final consultation on data format.

Also as PMDA doesn't provide test environment in gateway for now, sponsors should complete data preparation as soon as possible.

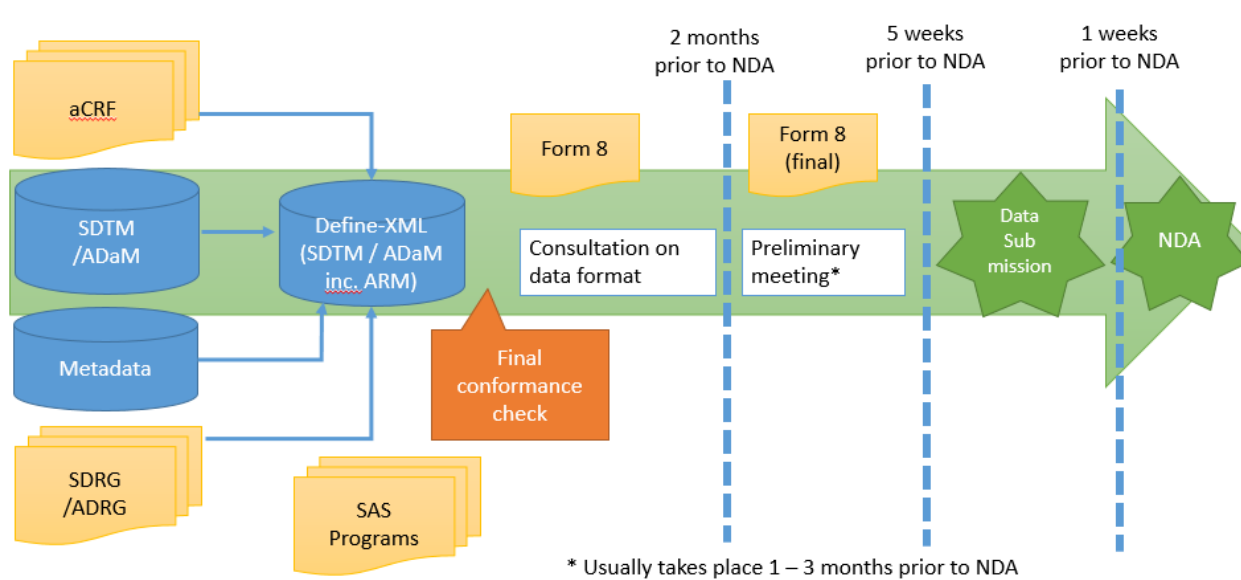


Figure 2. Best case scenario of e-study data submission to PMDA

However timeline after database lock to NDA is often challenging. If completion of data preparation is very close to NDA and it is not able to hold consultation on data format before preliminary meeting, then sponsors should discuss PMDA about switching these communication as an exception.

CREATING ONE SET OF E-STUDY DATA FOR PMDA AND FDA

As described in the above section, some deliverables were created as two versions, one for each health authority. However, submission deliverables of e-study data are not so different between PMDA and FDA. Therefore, sponsors could consider creating only one e-study data for both PMDA and FDA with meeting their requirements. Referring back to experience, we reaffirm the significance of well-structured standardized process and it is an important factor for the successful e-study data submission.

What makes the process simple? Standardization is one of the answers. In Novartis, we have tools and processes that help us to create and manage standards and the related metadata. It will also support data traceability, consistency and quality within submission data package especially aCRF, SDTM and ADaM dataset. When a new standard is required for a study, several steps will be followed. Generally,

1. Generate example for a standard CRF page by standard team.
2. Setup page model for SDTM annotation and review.
3. Pages are endorsed by standards governance.
4. Prepare metadata in data repository considering new elements and standard derivations.
5. Generate standard template programs from metadata.

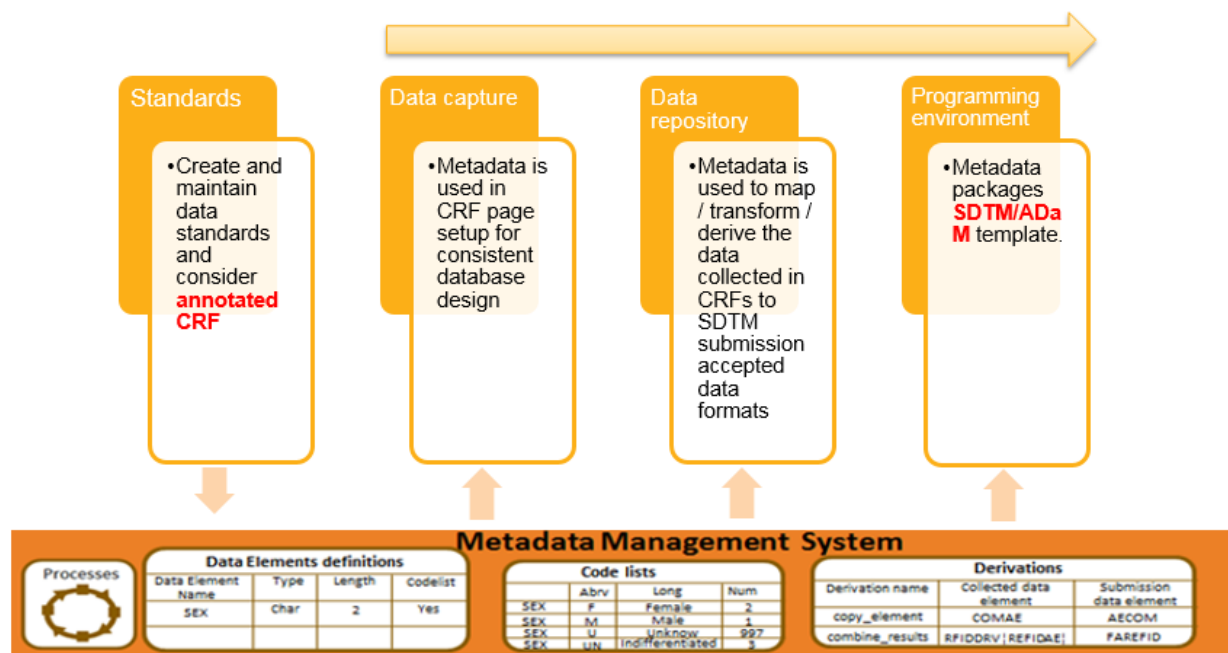


Figure 3. Metadata Management System

For other e-study data such as SDRG/ADRG and ARM, in Novartis, those template, QC checklist and training material are available for end users to prepare e-study data submission efficiently and will be updated based on actual experiences. For example, adding common SI unit conversion table in appendix of SDRG, updating conformance section in SDRG and ADRG to be able to describe both validation results of PMDA and FDA could be applied.

COLLABORATION BETWEEN JAPANESE AND GLOBAL TEAMS

Collaboration was very basic but most important factor for successful e-data submission.

The first step is to understand Japan specific requirements especially for global team who will support Japanese e-study data submission. Since majority of requirements are the same, it is better if Japanese/global teams have only one set of e-study data which meet both PMDA and FDA requirements including validation criteria if sponsors aim to submit them in PMDA and FDA simultaneously.

Second step is to discuss roles and responsibilities globally to optimize resources globally, for example,

- Who will check HA specific validation criteria
- Who will draft HA specific e-study data like Study data standardization Plan (SDSP) for FDA and ARM for PMDA
- Who will create SDTM/ADaM, Define-XML including ARM, and SDRG/ADRG

It is key to have this discussion and make decision in advance at high level to avoid big discussions in the busiest time of e-study data submission preparation. It is recommended that sponsors have a consistent policy so that it's not necessary to spend much time discussing the topic in each e-study data submission. In order to have successful PMDA e-study data submission, global collaboration is essential.

Global team needs to involve Japanese team from the beginning to get input, and Japanese team is also responsible to explain and input clearly what the PMDA specific requirements are.

FUTURE CONSIDERATIONS

LEGACY STUDY DATA CONVERSION

Legacy data conversion is one of the major concerns for sponsors. PMDA requires that e-study data must be submitted in CDISC standard formats (for submissions after April 1, 2020) as per 'Basic Principles on Electronic Submission of Study Data for New Drug Applications' published in June, 2014.

When sponsors plan to include legacy study data into clinical data package to PMDA,

- To keep traceability, convert legacy tabulation data to SDTM, then ADaM dataset is created from the converted SDTM.
- Prepare aCRF, Define-XML, SDRG and ADRG.
- Create SAS programs for selected TLFs which can reproduce in Clinical Summary Report (CSR).

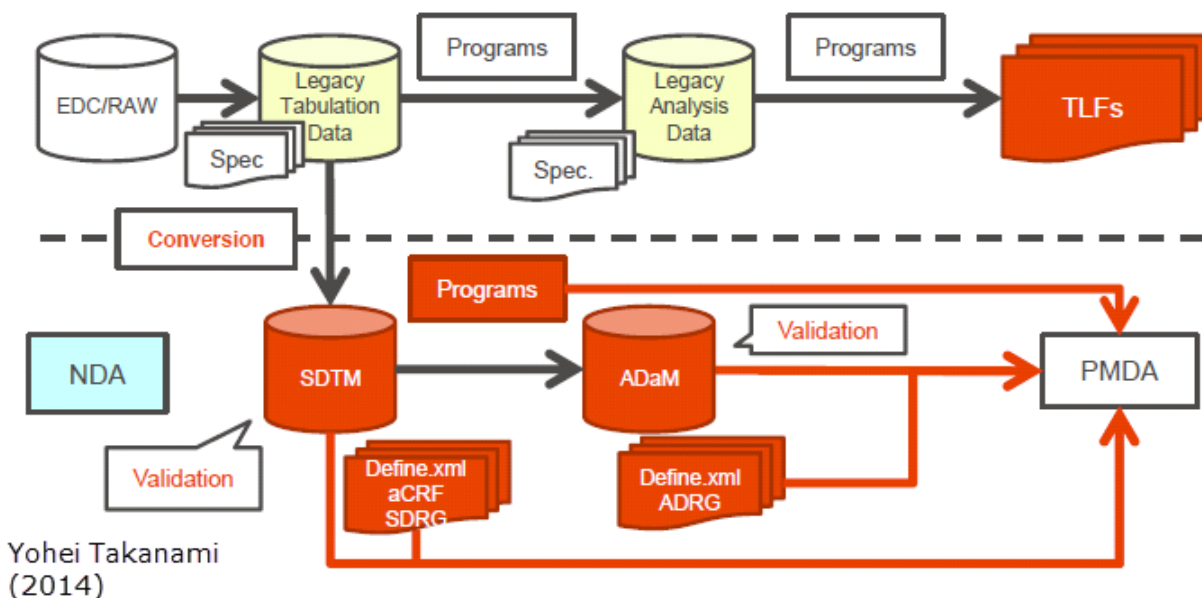


Figure 4. Workflow of legacy data conversion

One big challenge here is to develop new programs as a submission deliverable using converted data in order to check consistency with original CSR results. If CSR has already been created by legacy data, programs for TLFs need to be reproduced to use converted CDISC compliant data. As described in the previous section, not all of the programs will be required for submission, therefore it is strongly recommended to have an agreement on the scope of analyses for submission with PMDA at clinical consultation such as end of Phase 2 meeting beforehand in order to save time and resources to create ADaM dataset and reproduce TLFs such as primary/key secondary efficacy analysis and key safety analysis. Furthermore, if discrepancies are specified in data between converted data and legacy data, clarification must be explained in SDRG or ADRG as conversion issues.

CLINICAL PHARMACOLOGY (CP) STUDIES AND ANALYSES

For non-Japanese associate, it would be slightly difficult to get exact information of requirement in CP area. Especially clinical pharmacologists in pharma industry may not to be aware of this PMDA specific requirement of e-study data from CP studies and analyses. Regardless of e-study data is requested, clinical pharmacologist should be also involved in the discussion on e-study data preparation from an early stage.

Here is the list of targeted CP study and analysis, and corresponding e-study data possibly requested by PMDA. Note that electronic data of CP study or analysis will need to be submitted only when it is important as a clinical data package.

Content	Individual clinical study data	Efficacy and safety analysis	Pharmacokinetics (PK) or PK/PD analysis
Clinical studies where standard pharmacokinetic (PK) analysis was performed	SDTM	ADaM	ADaM is preferable, but other formats are acceptable
Population analysis (PPK)	May be submitted in formats other than CDISC standards		
Physiologically-based pharmacokinetic model analysis (PBPK)			

Table 4. Target CP study and analysis

To submit non-CDISC compliant analysis dataset (i.e. non-ADaM dataset) for those PK/PD analysis, sponsors need to use the electronic data depending on software to be used for PK analysis. For example,

- Phoenix Projects (*.phxproj), WinNonlin file (*.pmo, *.pwo) for standard CP study
- Control and output files of NONMEM dataset for PPK
- Simcyp PE input and output files (XML formats) for PBPK if the datasets are created or modified to be analyzed using a specific software

Regarding other e-study data for CP study, firstly, dataset definition file for non-CDISC compliant analysis dataset in pdf format also needs to be submitted. It includes at least the variable names and the explanation of the variables to be submitted (The example form of this document can be found in PMDA technical guide appendix). Secondly, sponsors should submit 1) either analysis plan or programming specification which can specify analysis algorithm for PK parameter for standard PK analysis, 2) either programs for simulation or programming specification / procedure document for program execution (See the example in PMDA technical guide appendix) for PPK. Those files also need to be part of electronic data. In addition, when sponsors submit PC and PP domain, RELREC domain is recommended to be prepared in order to clarify the relationship between these two domains. Otherwise information should be explained in SDRG instead.

SUMMARY OF KEY DIFFERENCES BETWEEN PMDA AND FDA FOR E-DATA SUBMISSION

In summary, the important differences for PMDA e-study data submission compared to FDA are listed in the below Table 5. Although most of e-study data can be similar to that of FDA, some PMDA requirements need to be considered in addition to FDA submission.

Differences	PMDA	FDA
Initiation date of e-study data submission	Studies that make a NDA after October 1, 2016 with a 3.5 years transitional period. To be mandatory after April 1, 2020.	Studies that start after December 17, 2016
CDISC compliance check by Pinnacle 21 with specific criteria	SDTM, ADaM, Define-XML with specific "Reject" criteria.	SDTM, Standard for Exchange of Nonclinical Data (SEND).
Communication with health authorities	Clinical consultation such as end-of-phase 2 and Consultation on data format of submission of e-study data and e-study data summary need to be documented in the PMDA specific form (Form 8)	FDA-sponsor meetings (e.g. pre-IND, and end-of-phase 2) and SDSP for discussions on data standards.
Legacy data conversion	Non-CDISC compliant data won't be accepted. Requirements for e-study	If study falls under FDA mandate (i.e., study started after Dec. 16,

Differences	PMDA	FDA
	data are same as other CDISC compliant study. If conversion issue is identified, it should be discussed with PMDA at consultation on data format.	2016), then data would have to be CDISC-compliant. If not collected in that way, then study would have to be converted. Issues during conversion need to be documented in the legacy data conversion plan and report.
ARM	Define-XML should preferably include ARM.	Not required (as of Mar 2017) but support of Define V1.0 will end on March 15, 2018.
CP studies	Specific documents are required in addition to e-study data.	Not specifically described in Study Data Technical Conformance Guide.
SI unit converted value	Basically any test with SI unit is applicable to be used.	Under evaluation of common and therapeutic area-specific lab tests to apply SI unit.

Table 5. Key differences between PMDA and FDA

CONCLUSION

Currently PMDA and FDA request sponsors to comply CDISC standard format for e-study data submissions, but there are some differences between requirements of PMDA and FDA. Based on actual e-study data submission to PMDA, first of all, understanding requirements of PMDA and differences between PMDA and FDA is necessary. Secondly, early preparation especially decision making of clinical data package is extremely important. Finally, input from Japanese team to global team on Japan specific requirements from early stage is essential particularly when legacy data conversion is needed only for Japan submission. Recent clinical development is conducted globally, and same or similar clinical data package can be used for submission to PMDA and FDA. In order to work productively, Japanese and global teams need to work together, share the knowledge of PMDA and FDA requirements each other, and incorporate Japan specific requirements into global submission package under standard processes.

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