

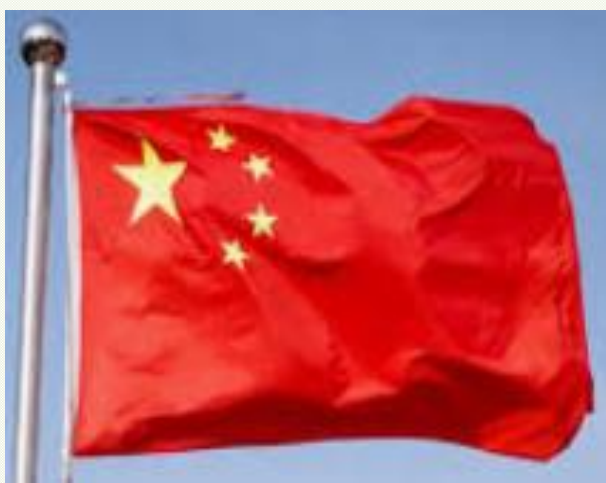
PP11

Does One Size Fit All?

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**Abstract**

Submitting data to the Health Authorities is a critical part of our business to obtain approval for our medicines. Currently, three agencies, namely FDA (USA), PMDA (Japan), and NMPA (China), require clinical trial data for filing. Preparing one set of data packages will not satisfy all agencies' needs. i.e., Variations DO exist. Hence, understanding the agency-specific requirements could help us to submit quality data packages to facilitate efficient review to get our medicines approved faster and get them to the patients sooner. This poster demonstrates variations across these agencies with respect to the submission requirements and recommendations. This is based on our interpretation of the data requirements across the agencies. It also highlights the importance of being aware of these variations to help adequately plan time, resources, and contents when considering filing to multiple agencies in parallel.

|                                                                                                                                                                                                 |                                                                                      |                                                                                                                                                                                                                                                                                                                                            |                                                                                       |                                                                                                                                                                                                                                                                                                                |                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
|                                                                                                                | <b>FDA (USA)</b><br>CDISC Mandate:<br>All studies started<br>after December 17, 2016 |                                                                                                                                                                                                                                                          | <b>PMDA (Japan)</b><br>CDISC Mandate:<br>All studies submitted<br>after April 1, 2020 |                                                                                                                                                                                                                             | <b>NMPA (China)</b><br>CDISC Recommended+:<br>All studies submitted<br>after October 1, 2020 |
| Tabulation / SDTM data                                                                                                                                                                          |                                                                                      | Tabulation / SDTM data                                                                                                                                                                                                                                                                                                                     |                                                                                       | Tabulation / SDTM data                                                                                                                                                                                                                                                                                         |                                                                                              |
| SDTM annotated Case Report Form (acrf.pdf)                                                                                                                                                      |                                                                                      | SDTM annotated Case Report Form (acrf.pdf)                                                                                                                                                                                                                                                                                                 |                                                                                       | SDTM annotated Case Report Form (acrf.pdf) <ul style="list-style-type: none"><li>Chinese version of CRF, current practice is to have SDTM dataset/variable names remain in English</li></ul>                                                                                                                   |                                                                                              |
| SDTM Define file (define.xml)                                                                                                                                                                   |                                                                                      | SDTM Define file (define.xml)                                                                                                                                                                                                                                                                                                              |                                                                                       | SDTM Define file (define.xml) or PDF (definel.pdf) <ul style="list-style-type: none"><li>Translation required : dataset label, variable label, codelists &amp; derivations</li></ul>                                                                                                                           |                                                                                              |
| SDTM SAS xpt's (*.xpt, split if >5GB) <ul style="list-style-type: none"><li>Conformance to FDA validation rules</li></ul>                                                                       |                                                                                      | SDTM SAS xpt's (*.xpt, No split criteria for file size but should consult with PMDA if datasets are >10GB) <ul style="list-style-type: none"><li>Conformance to PMDA validation rules</li><li>WHODrug must be used for drug coding</li><li>SI units should be used to standardized results of laboratory test (e.g. g/L → mol/L)</li></ul> |                                                                                       | SDTM SAS xpt's (*.xpt, split if >4GB for eCTD) <ul style="list-style-type: none"><li>Conformance to NMPA (same as FDA) validation rules</li><li>Translation required – dataset &amp; variable labels, text within variables, e.g. WHODrug, MedDRA terms</li><li>UTF8, and Chinese character encoding</li></ul> |                                                                                              |
| SDTM Reviewers Guide (csdrg.pdf) <ul style="list-style-type: none"><li>Explanation of the validation results against FDA validation rules (Errors only)</li><li>No Rejects acceptable</li></ul> |                                                                                      | SDTM Reviewers Guide (csdrg.pdf or study-data-reviewers-guide.pdf) <ul style="list-style-type: none"><li>Explanation of the validation results against PMDA validation rules (Errors only)</li><li>No Rejects acceptable</li><li>Coefficients required for conversion from original units to SI units</li></ul>                            |                                                                                       | SDTM Reviewers Guide (csdrg.pdf) <ul style="list-style-type: none"><li>Explanation of the validation results against NMPA validation rules [Errors only]</li><li>Translation required: whole document</li></ul>                                                                                                |                                                                                              |
| Analysis / ADaM data                                                                                                                                                                            |                                                                                      | Analysis / ADaM data                                                                                                                                                                                                                                                                                                                       |                                                                                       | Analysis / ADaM data                                                                                                                                                                                                                                                                                           |                                                                                              |
| ADaM Define file (define.xml)                                                                                                                                                                   |                                                                                      | ADaM Define file (define.xml)                                                                                                                                                                                                                                                                                                              |                                                                                       | ADaM Define file (define.xml) or PDF (definea.pdf) <ul style="list-style-type: none"><li>Translation required : dataset label, variable label, codelists &amp; derivations</li></ul>                                                                                                                           |                                                                                              |
| ADaM SAS xpt's (*.xpt, split if >5GB) <ul style="list-style-type: none"><li>Conformance to FDA validation rules</li></ul>                                                                       |                                                                                      | ADaM SAS xpt's (*.xpt, No split criteria for file size but should consult with PMDA if datasets are >10GB) <ul style="list-style-type: none"><li>Conformance to PMDA validation rules</li></ul>                                                                                                                                            |                                                                                       | ADaM SAS xpt's (*.xpt, split if >4GB for eCTD) <ul style="list-style-type: none"><li>Conformance to NMPA (same as FDA) validation rules.</li><li>Translation required - dataset/variable labels, text within variables (WHODrug &amp; MedDRA terms) codelists and derivations</li></ul>                        |                                                                                              |
| Software (i.e., SAS, R) programs [*.txt] <ul style="list-style-type: none"><li>Readable format, executable not necessary</li><li>Note: At Roche-Genentech we use pkglite R package</li></ul>    |                                                                                      | Software (i.e., SAS, R) programs (*.txt, *.sas) <ul style="list-style-type: none"><li>(e.g. SAS, R) - Readable format, executable not necessary</li></ul>                                                                                                                                                                                  |                                                                                       | Software (i.e., SAS, R) programs (*.txt) <ul style="list-style-type: none"><li>Readable format, (and Executable R code preferred)</li><li>Note: At Roche-Genentech we pkglite R package</li></ul>                                                                                                              |                                                                                              |
| ADaM Reviewers Guide (adrg.pdf) <ul style="list-style-type: none"><li>Explanation of the validation results against FDA validation rules (Errors only)</li><li>No Rejects acceptable</li></ul>  |                                                                                      | ADaM Reviewers Guide (adrg.pdf or analysis-data-reviewers-guide.pdf) <ul style="list-style-type: none"><li>Explanation of the validation results against PMDA validation rules (Errors only)</li><li>No Rejects acceptable</li></ul>                                                                                                       |                                                                                       | ADaM Reviewers Guide (adrg.pdf) <ul style="list-style-type: none"><li>Explanation of the validation results against NMPA validation rules (Errors only)</li><li>No Rejects acceptable</li><li>Translation required: whole document</li></ul>                                                                   |                                                                                              |
| Analysis Results Metadata (ARM) - Not required                                                                                                                                                  |                                                                                      | Analysis Results Metadata (ARM) - Strongly recommended                                                                                                                                                                                                                                                                                     |                                                                                       | Analysis Results Metadata (ARM) - Not required                                                                                                                                                                                                                                                                 |                                                                                              |

Blue and Green text indicates variations + Roche-Genentech's current approach