

## INSTRUCTIONS TO SELF-CHECK WORKSHEET FOR STUDY DATA PREPARATION

(The field numbers below correspond to the numbered boxes in each section of the Self-Check Worksheet for Study Data Preparation)

NOTE: The Agency performed a study data validation assessment utilizing the validation rules as specified in FDA's Technical Rejection Criteria for Study Data<sup>1</sup>. The checklist is for industry to validate the technical conformance of clinical and nonclinical study datasets included in a submission with study data.

The Self-Check Worksheet for Study Data Preparation is designed to check the validation criteria for newly submitted Study Data. Section 1 should be completed only once for a submission with study data. Section 2 through Section 5 can be repeated for each study included in the submission.

Technical specifications associated with this guidance are provided in FDA's Technical Rejection Criteria for Study Data<sup>2</sup> and other stand-alone documents that are updated periodically, which can be found on FDA's Study Data website<sup>3</sup>:

- Data Standards Catalog
- Study Data Technical Conformance Guide
- FDA Business Rules
- FDA Validator Rules

The following four high-level study data validation rules per FDA's Technical Rejection Criteria for Study Data<sup>4</sup> are checked:

<b>Validation Error Number 1734:</b>	A dataset named ts.xpt with information on study start date must be present for each study in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4, and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2
<b>Validation Error Number 1735:</b>	The correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4, and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2
<b>Validation Error Number 1736:</b>	For SEND data, a DM dataset and define.xml must be submitted in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4  For SDTM data, a DM dataset and define.xml must be submitted module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2  For ADaM data, an ADSL dataset and define.xml must be submitted in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2
<b>Validation Error Number 1789:</b>	A file has been submitted in a study section without providing an STF file. STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports

<sup>1</sup> eCTD Technical Rejection Criteria for Study Data

(<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM523539.pdf>).

<sup>2</sup> Ibid.

<sup>3</sup> Resources related to study data, including guidance documents, technical guides, business rules, and position statements, can be found on the FDA Study Data website (<https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>).

<sup>4</sup> See footnote 1.

## INSTRUCTIONS TO SELF-CHECK WORKSHEET FOR STUDY DATA PREPARATION

\*Required field

<b>Section 1: Application &amp; Submission Information</b>
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<b>Reference:</b> 21CFR 314.3(b)
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**Field 1a. FDA Center\*:** Identify the appropriate Center by which the application will be reviewed.

**Field 1b. Application Type\*:** Identify the appropriate application type.

**Field 1c. Application Number:** Provide the six-digit application number.

**Field 1d. eCTD Sequence Number:** Provide the four-digit eCTD sequence number.

**Field 1e. eCTD Submission Type:** Provide an appropriate submission type.

**Field 1f. eCTD Submission Sub Type:** Identify submission sub-types.

### SECTION 2 THROUGH SECTION 5 CAN BE REPEATED FOR EACH STUDY INCLUDED IN THE SUBMISSION

<b>Section 2: Study Information</b>
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<b>Reference:</b> N/A
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**Field 2a. Study ID\*:** Identify the study ID for the study being submitted. Study ID is the unique identifier across application documents. Therefore, the study ID must be consistent across all the files being submitted for the same study, i.e. STF File, ts.xpt, dm.xpt, etc. For the purposes of this worksheet, **Fields 2a, 3d, and 4c** should include the same study ID.

**Field 2b. Is This the First Time Study Data is Being Submitted for This Study as Part of This Application?\*** Indicate whether the study data is being submitted for the first time. The Self-Check Worksheet is designed for newly submitted study data.

**Field 2c. Title of the Study:** Provide title/name of the study that is being submitted.

**2d. Study Section - eCTD Heading (Example: m4-2-1-1)\*:** Identify study section/eCTD Heading that the Study Data is being submitted (Example m4-2-1-1).

**Field 2e. Module\*:** Identify an appropriate module that the Study Data is associated with. If nonclinical study data is being submitted, then select "Nonclinical (m4)". If clinical Study Data is being submitted, then select "Clinical (m5)".

**Field 2f. Study Dataset Type(s)\*:** Identify the Study Data (identified by the Study ID in **Field 2a**) as Tabulation and/or Analysis. If datasets are not in a CDISC Tabulation or Analysis format, select Other.

<b>Section 3: STF File Information</b>
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<b>Reference:</b> Validation Error Number 1789 <sup>5</sup>
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**Field 3a. Are Files Included in a Study Section? (Not Applicable to Sections 4.3, 5.2, 5.3.6, and 5.4)\*:** If the Study Data for the study identified in **Field 2a** contains files that are not included in sections 4.3, 5.2, 5.3.6, or 5.4, select 'Yes'. If the Study Data contains files in sections 4.3, 5.2, 5.3.6, or 5.4 *only*, select 'No.'

**Field 3b. Is STF File Included?\*** All study files submitted in Study Sections other than the ones listed in **Field 3a** should have an associated STF file. If the Study Data identified in **Field 2a** contains STF File, select 'Yes'. If the Study Data identified in **Field 2a** does not contain STF File, select 'No'.

**Field 3c. Does STF File Reference all Associated Study Files?\*** Identify whether all files associated with the study are referenced in an STF file.

**Field 3d. Study ID in STF File\*:** Identify Study ID in the STF File of the Study Data identified in **Field 2a**. Study ID in STF File in **Field 3d** should be identical to the Study ID identified in **Field 2a**.

**Field 3e. Does the Study ID in the STF File Match Field 2a?\*** Identify Study ID provided in **Field 2a** and **Field 3e** match. Study ID should be consistent across all the files being submitted for the same study.

<b>Section 4: TS File Information</b>
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<b>Reference:</b> Validation Error Number 1734 <sup>6</sup>
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**Field 4a. What Type of TS File is Required?\*** If files included in a Study Section in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4, and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2, then TS file is required.

Select "Full TS" (1) if Study Start Date is after December 17, 2016 for NDA, ANDA, or BLA submitted to CDER or CBER; (2) if Study Start Date is after December 17, 2017 for Commercial IND submitted to CDER or CBER.

<sup>5</sup> See footnote 1.

<sup>6</sup> Ibid.

Select "Simplified TS" (1) if Study Start Date for a clinical study containing an XPT dataset (other than the ts.xpt) is on or prior to December 17, 2016 for NDA, ANDA, or BLA submitted to CDER or CBER; (2) if Study Start Date for a nonclinical study is on or prior to December 17, 2016 for NDA, ANDA, or BLA submitted to CDER; (3) if Study Start Date for a nonclinical study is on or prior to December 17, 2017 for Commercial IND submitted to CDER.

If neither a full nor simplified TS file is required, select "Not Required". For more details on simplified and full ts.xpt, please refer to the Study Data Technical Conformance Guide<sup>7</sup>.

Study Start Date	Application Type	Data Type	Study Section	Required TS File Type (by Center)	
				CDER	CBER
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Simplified TS	
Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	
After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Full TS	
After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	

**Field 4b. Is TS File Included?\***: Identify whether the Study Data identified in **Field 2a** includes TS File.

**Field 4c Study ID in TS File\***: Identify the Study ID in the TS File.

**Field 4d. Does Study ID in STF (Field 3d) & TS Files Match?\***: Identify whether the Study ID in TS File in **Field 4c** is identical to Study ID in **Field 3d**.

**Field 4e. Study Start Date in TS File**: Identify Study Start Date as it appears in TS File of study identified in **Field 2a**. If the Study Start Date is not available, leave the field blank.

**Field 4f. If Study Start Date Exists, Is it Valid?**: If the Study Start Date is provided in **Field 4e**, identify whether the study start date is valid, i.e. in the correct format: yyyy-mm-dd.

**Field 4g. If Study Start Date does not Exist, What is the Stated Exception Code?**: Identify Study Start Date Exception Code as it appears in TS File of the study identified in **Field 2a**. The following exception codes, as specified in the ISO 21090 Standard, can be used in TSVLNF to indicate an exception to providing a study start date. If the Study Start Date is provided in **Field 4e**, leave the field blank.

Study Start Date Exception Codes			
<b>NI</b> – No information	<b>INV</b> – Invalid	<b>OTH</b> – Other	<b>PINF</b> – Positive infinity
<b>NINF</b> – Negative infinity	<b>UNC</b> – Unencoded	<b>DER</b> – Derived	<b>UNK</b> – Unknown
<b>ASKU</b> – Asked but unknown	<b>NAV</b> – Temporarily unavailable	<b>NASK</b> – Not asked	<b>QS</b> – Sufficient quantity
<b>TRC</b> – Trace	<b>MSK</b> – Masked	<b>NA</b> – Not applicable	

<sup>7</sup> See footnote 3.

**Section 5: Standardized Datasets (SEND, SDTM, ADaM)****Reference:** Validation Error Numbers 1735 & 1736<sup>8</sup>

**Field 5a. Are Standardized Datasets Required?\***: Identify whether the Standardized datasets are required or not required. Standardized Datasets are required: 1) if Study Start Date is after December 17, 2016 for NDA, ANDA, or BLA submitted to CDER or CBER; 2) if Study Start Date is after December 17, 2017 for Commercial IND submitted to CDER or CBER. **Fields 5b-5e** are applicable to non-clinical tabulation datasets (SEND), **Fields 5f-5i** are applicable to clinical tabulation datasets (SDTM), and **Fields 5j-5m** are applicable to clinical analysis datasets (ADaM). For more details on standardized dataset requirements, please refer to the Study Data Technical Conformance Guide<sup>9</sup>.

Study Start Date	Application Type	Standardized Data Set Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16		Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17		Required

**Nonclinical (m4): Tabulation (SEND datasets)**

**Field 5b. Is DM File Included?\***: Identify whether a DM dataset is included. DM dataset is required for submissions in Study Section module 4, section 4.2.3.1, 4.2.3.2, 4.2.3.4.

**Field 5c. Is Define File Included?\***: Identify whether a Define File is included. Define File is required for submissions in Study Section module 4, section 4.2.3.1, 4.2.3.2, 4.2.3.4.

**Field 5d. Are the STF File-Tags for the SEND Datasets “data-tabulation-dataset-send”?\***: Identify that all the datasets (XPT files) use the correct STF file-tags in module 4, section 4.2.3.1, 4.2.3.2, 4.2.3.4. Valid file tag for XPT files for module 4 is “data-tabulation-dataset-send”.

**Field 5e. Is the STF File-Tag for Define File “data-tabulation-data-definition”?\***: Define File is required for submissions in Study Section in module 4, section 4.2.3.1, 4.2.3.2, 4.2.3.4 of the tabulation dataset. Valid file tag for Define File for module 4 is “data-tabulation-dataset-definition”.

**Clinical (m5): Tabulation (SDTM datasets)**

**Field 5f. Is DM File Included?\***: Identify whether a DM dataset is included. DM dataset is required for submissions in Study Section module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 of the tabulation dataset.

**Field 5g. Is Define File Included?\***: Identify whether a Define File is included. Define File is required for submissions in Study Section module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 of the tabulation dataset.

**Field 5h. Are the STF File-Tags for the SDTM Datasets “data-tabulation-dataset-sdtm”?\***: Identify that all the datasets (XPT files) use the correct STF file-tags in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2. Valid file tag for XPT files for module 5 tabulation dataset is “data-tabulation-dataset-sdtm”

**Field 5i. Is the STF File-tag for the Define File “data-tabulation-data-definition”?\***: Define File is required for submissions in Study Section in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 of the tabulation dataset. Valid file tag for corresponding define.xml file for module 5 tabulation dataset is “data-tabulation-data-definition”.

**Clinical (m5): Analysis (ADaM datasets)**

**Field 5i. Is ADSL File Included?\***: Identify whether a ADSL dataset is included. ADSL dataset is required for submissions in Study Section module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 of the analysis dataset.

**Field 5g. Is Define File Included?\***: Identify whether a Define File is included. Define File is required for submissions in Study Section module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 of the analysis dataset.

<sup>8</sup> See footnote 1.<sup>9</sup> See footnote 3.

**Field 5h. Are the STF File-Tags for the ADaM Datasets “analysis-dataset-adam”?\***: Identify that all the datasets (XPT files) use the correct STF file-tags in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2. Valid file tag for XPT files for module 5 analysis dataset is “analysis-dataset-adam”

**Field 5j. Is the STF File-Tag for the Define File “analysis-data-definition”?\***: Define File is required for submissions in Study Section in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 of the analysis dataset. Valid file tag for corresponding Define File for module 5 analysis dataset is “analysis-data-definition”.

If you have further questions or need clarification, please contact [edata@fda.hhs.gov](mailto:edata@fda.hhs.gov).