SELF-CHECK WORKSHEET FOR STUDY DATA PREPARATION

Note: This Self-Check Worksheet is designed for newly submitted Study Data.
Required field

Section 1: Application & Submission Information

1a. FDA Center*:   CDER ☐   CBER ☐

1b. Application Type*:   NDA ☐   BLA ☐   ANDA ☐   Commercial IND ☐

1c. Application Number: _____   **1d. eCTD Sequence Number:** _____

1e. eCTD Submission Type: _____   **1f. eCTD Submission Sub Type:** _____

Note: Repeat Sections 2 through 5 for each study included in the submission.
Required field

Section 2: Study Information

2a. Study ID*: _____

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.

2b. Is This the First Time Study Data is Being Submitted for This Study as Part of This Application?*   Yes ☐   No ☐

*If you answered "No" in **Field 2b**, do not proceed. This self-check worksheet is designed for newly submitted study data.*

2c. Title of the Study: _____

2d. Study Section - eCTD Heading (Example: m4-2-1-1)*: _____

2e. Module*:   Nonclinical (m4) ☐   Clinical (m5) ☐

2f. Study Dataset Type(s)*:   Tabulation ☐   Analysis ☐   Other ☐

Section 3: STF File Information

3a. Are Files Included in a Study Section? (Not Applicable to Sections 4.3, 5.2, 5.3.6, and 5.4)*   Yes ☐   No ☐

*If you answered "No" in **Field 3a**, and no files are included in a study section, excluding sections 4.3, 5.2, 5.3.6, and 5.4, then Validation Rules 1734, 1735, 1736, and 1789 do not apply. Do not proceed.*

3b. Is STF File Included?*   Yes ☐   No ☐

3c. Does STF File Reference all Associated Study Files?*   Yes ☐   No ☐

> **Referenced Validation Error Number 1789**

*If you answered "No" in **Fields 3b or 3c**, Validation Rule 1789 FAILS. Do not proceed.*

3d. Study ID in STF File*: _____

3e. Does the Study ID in the STF File Match Field 2a?   Yes ☐   No ☐

*If you answered "No" in **Field 3e**, ensure the study ID is consistent across all the files being submitted for the same study.*

4a. What Type of TS File is Required?*   Full TS ☐   Simplified TS ☐   Not Required ☐

Refer to guidelines in chart below.

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**	

*If you answered "Not Required" in **Field 4a**, then Validation Rules 1734, 1735, and 1736 do not apply. Do not proceed.*

4b. Is TS File Included?*   Yes ☐   No ☐

Referenced Validation Error Number 1734

*If you answered "No" in **Field 4b**, Validation Rule 1734 FAILS. Do not proceed.*

4c. Study ID in TS File*:   _____

4d. Does Study ID in STF (Field 3d) & TS Files Match?*   Yes ☐   No ☐

Referenced Validation Error Number 1734

*If you answered "No" in **Field 4d**, Validation Rule 1734 FAILS. Do not proceed.*

4e. Study Start Date in TS File: _____

4f. If Study Start Date Exists, Is it Valid?   Yes ☐   No ☐

Referenced Validation Error Number 1734

4g. If Study Start Date does not Exist, What is the Stated Exception Code?   _____

*If you do not have a Study Start Date in **Field 4e** and you do not have a stated Exception Code in **Field 4g**, Validation Rule 1734 FAILS. Do not proceed.*

*Or, if you answered "No" in **Field 4f**, Validation Rule 1734 FAILS. Do not proceed.*

Section 4: TS File Information

Section 5: Standardized Datasets (SEND, SDTM, ADaM)

5a. Are Standardized Datasets Required?* Yes ☐ No ☐

	Study Start Date	Application Type	Standardized Datasets 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

*If you answered "No" in **Field 5a**, standardized datasets are not required and Validation Rules 1735 and 1736 do not apply. Do not proceed.*

Fields 5b-5e *are applicable to nonclinical tabulation datasets (SEND),* *Fields 5f-5i* *are applicable to clinical tabulation datasets (SDTM), and* *Fields 5j-5m* *are applicable to clinical analysis datasets (ADaM).*

Note: For clinical data in Commercial INDs standardized datasets are required if the study start data is after the date stated, however, study data technical rejection criteria will not be applicable until further notice.

Nonclinical (m4)

Tabulation (SEND datasets)

5b. Is DM File Included?* Yes ☐ No ☐

5c. Is Define File Included?* Yes ☐ No ☐

Referenced Validation Error Number 1736

*If you answered "No" in **Fields 5b or 5c**, Validation Rule 1736 FAILS. Proceed to **Fields 5d and 5e** for Validation Rule 1735.*

5d. Are the STF File-Tags for the SEND Datasets "data-tabulation-dataset-send"?* Yes ☐ No ☐

5e. Is the STF File-Tag for the Define File "data-tabulation-data-definition"?* Yes ☐ No ☐

Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5d or 5e**, Validation Rule 1735 FAILS.*

Clinical (m5)

Tabulation (SDTM datasets):

5f. Is DM File Included?* Yes ☐ No ☐

5g. Is Define File Included?* Yes ☐ No ☐

Referenced Validation Error Number 1736

*If you answered "No" in **Fields 5f or 5g**, Validation Rule 1736 FAILS. Proceed to **Fields 5h and 5i** for Validation Rule 1735.*

5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?* Yes ☐ No ☐

5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?* Yes ☐ No ☐

Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5h or 5i**, Validation Rule 1735 FAILS.*

Analysis (ADaM datasets):	
5j. Is ADSL File Included?* Yes No ☐ ☐ **5k. Is Define File Included?*** Yes No ☐ ☐	**Referenced Validation Error Number 1736**
*If you answered "No" in **Fields 5j or 5k**, Validation Rule 1736 FAILS. Proceed to **Fields 5l and 5m** for Validation Rule 1735.*	
5l. Are the STF File-Tags for the ADaM Datasets "analysis-dataset-adam"?* Yes No ☐ ☐ **5m. Is the STF File-tag for the Define File "analysis-data-definition"?*** Yes No ☐ ☐	**Referenced Validation Error Number 1735**
*If you answered "No" in **Fields 5l or 5m**, Validation Rule 1735 FAILS.*	

Click Here to Add Studies