CDER / CBER
Study Data Standardization Plan Recommendations

ABC Pharma Company

Study Data Standardization Plan

1. General Sponsor Information

Name of Product	SuperDrug
Indication(s)	Hypertension
IND	054321
Sponsor Name	ABC Pharma
Sponsor Contact	Joe Smith
Sponsor Contact Email	Joe.Smith@abcpharma.com

2. Product Information

Description of the product under development, its intended indication(s), and patient populations.

3. List of Completed Studies and Standards

A. Nonclinical

Study ID	Brief Title	Study Type	Exchange Standards	Terminology Standards
XYZ1	One month toxicity study in the Cynomolgus monkey	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology 2014-06-27
XYZ2	One month toxicity study in the Han Wistar rat	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology 2014-06-27

B. Clinical

Study ID	Brief Title	Study Design	Exchange Standards	Terminology Standards
Phase 1 Studies				
ABC#1	A randomized, open-label, single-dose, two-arm crossover, pharmacokinetic (PK), bioequivalence/bioavailability study in healthy adult volunteers, 18 to 45 years of age.	Comparative, randomized, open-label, 2-way crossover, single-dose, PK study	SDTM 1.2/SDTM I.G. v. 3.1.2 Define.xml v.2.0	CDISC Terminology MedDRA v.15 (Adverse Events) WHO-DD (Medications)

4. List of Planned Studies and Standards

A. Nonclinical

Study ID	Brief Title	Study Type	Exchange Standards	Terminology Standards
XYZ3	Three month toxicity study in the Cynomolgus monkey	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology (current version at study start)
XYZ4	Three month toxicity study in the Han Wistar rat	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology (current version at study start)
XYZ5	Two-year carcinogenicity study in the Han Wistar rat	Carcinogenicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology (version used in XYZ4)

B. Clinical

Study ID	Brief Title	Study Design	Exchange Standards	Terminology Standards
Phase 1 Studies				
ABC#1	A randomized, open-label, single-dose, two-arm crossover, pharmacokinetic (PK), bioequivalence/bioavailability study in healthy adult volunteers,	Comparative, randomized, open-label, 2-way crossover, single-dose, PK study	SDTM 1.2/SDTM I.G. v. 3.1.2 Define.xml v.2.0	CDISC Terminology MedDRA v.15 (Adverse Events) WHO-DD (Medications)

Study ID	Brief Title	Study Design	Exchange Standards	Terminology Standards
	18 to 45 years of age.			
ABC#2	An Open-Label Study of the Single-Dose Pharmacokinetics of SuperDrug in Patients with Hypertension	Open label, single dose PK	SDTM 1.2/SDTM I.G. v. 3.1.2 Define.xml v.2.0	CDISC Terminology MedDRA v.15 (Adverse Events) WHO-DD (Medications)
Phase 3 Studies				
ABC#3	Randomized, Double-Blind, Parallel Group Study Evaluating the Efficacy and Safety of SuperDrug in Subjects with Hypertension	Randomized, double blind, efficacy and safety study	To be determined	CDISC Terminology MedDRA v.XX (Adverse Events) WHO-DD (Medications) SNOMED CT (Indication) NDF-RT (Pharm Class) UNII (active moiety)
ABC#4	Open Label Efficacy and Safety of SuperDrug in Subjects with Hypertension	Open label safety extension	To be determined	CDISC Terminology** MedDRA v.16 (Adverse Events) WHO-DD** (Medications) SNOMED CT** (Indication) NDF-RT** (Pharm Class) UNII** (active moiety)

**same version as used for ABC#3

5. References

- Guidance to Industry: Providing Regulatory Submissions in Electronic Format – Standardized Study Data (See http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm)

- Study Data Technical Conformance Guide (See http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf)

- CBER Study Data Submissions Web page: (See http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm)

- CDER Study Data Resources Web page (See http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm)

May, 2015