Study Data Reviewer's Guide (SDRG)

DRAFT prepared by PHAXTON. It is not signed and not submitted; it requires review and sign-off by the responsible person before any use.

- Study: Synthetic 2x2 BE study (synthetic data)
- Protocol: SYN-BE-001
- Sponsor: Synthetic (no sponsor)
- Compound: Drug A
- Phase: Phase 1
- Indication: Not declared by the sponsor in this package
- Date generated: 2026-11-07

1. Introduction

This SDRG describes the structure, content and derivation rules of the 5 SDTM dataset(s) of study SYN-BE-001, as delivered in this package. Every number in this document is inserted from the package results; Appendix A lists each one with its origin.

2. SDTM datasets overview

Dataset	Label	Structure	Records	Subjects	Keys
PC	Pharmacokinetics Concentrations	One record per sample characteristic or time-point concentration per subject	176	8	STUDYID, USUBJID, PCSEQ
PP	Pharmacokinetics Parameters	One record per PK parameter per time-concentration profile per subject	96	8	STUDYID, USUBJID, PPSEQ
DM	Demographics	One record per subject	8	8	STUDYID, USUBJID
EX	Exposure	One record per constant dosing interval per subject	16	8	STUDYID, USUBJID, EXSEQ
TS	Trial Summary	One record per trial summary parameter value	4	n/a	STUDYID, TSPARMCD, TSSEQ

3. Dataset details

3.1 PC - Pharmacokinetics Concentrations

PC has 176 records and 12 variables. Structure: One record per sample characteristic or time-point concentration per subject.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	Identifier	Req	Collected	No
DOMAIN	Domain Abbreviation	character	2	Identifier	Req	Collected	No
USUBJID	Unique Subject Identifier	character	40	Identifier	Req	Collected	No
PCSEQ	Sequence Number	numeric	8	Identifier	Req	Derived	No
PCGRPID	Group ID	character	40	Identifier	Perm	Collected	Observed
PCTESTCD	Pharmacokinetic Test Short Name	character	8	Topic	Req	Collected	No
PCTEST	Pharmacokinetic Test Name	character	40	Synonym Qualifier	Req	Collected	No
PCORRES	Result or Finding in Original Units	character	40	Result Qualifier	Exp	Collected	No

Variable	Label	Type	Length	Role	Core	Origin	Value list
PCSTRESN	Numeric Result/Finding in Standard Units	numeric	8	Result Qualifier	Exp	Collected	No
PCSTRESU	Standard Units	character	20	Variable Qualifier	Exp	Collected	No
PCDTC	Date/Time of Specimen Collection	character	20	Timing	Exp	Collected	No
PCTPTNUM	Planned Time Point Number	numeric	8	Timing	Perm	Collected	No

3.2 PP - Pharmacokinetics Parameters

PP has 96 records and 10 variables. Structure: One record per PK parameter per time-concentration profile per subject.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	Identifier	Req	Collected	No
DOMAIN	Domain Abbreviation	character	2	Identifier	Req	Collected	No
USUBJID	Unique Subject Identifier	character	40	Identifier	Req	Collected	No
PPSEQ	Sequence Number	numeric	8	Identifier	Req	Derived	No
PPGRPID	Group ID	character	40	Identifier	Perm	Derived	Observed
PPTESTCD	Parameter Short Name	character	8	Topic	Req	Derived	Observed
PPTEST	Parameter Name	character	40	Synonym Qualifier	Req	Derived	Observed
PPORRES	Result or Finding in Original Units	character	40	Result Qualifier	Exp	Derived	No
PPSTRESN	Numeric Result/Finding in Standard Units	numeric	8	Result Qualifier	Exp	Derived	No
PPSTRESU	Standard Units	character	20	Variable Qualifier	Exp	Derived	Observed

3.3 DM - Demographics

DM has 8 records and 8 variables. Structure: One record per subject.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	Identifier	Req	Collected	No
DOMAIN	Domain Abbreviation	character	2	Identifier	Req	Collected	No
USUBJID	Unique Subject Identifier	character	40	Identifier	Req	Collected	No
SUBJID	Subject Identifier for the Study	character	20	Topic	Req	Collected	Observed
AGE	Age	numeric	8	Record Qualifier	Exp	Collected	No
AGEU	Age Units	character	10	Variable Qualifier	Exp	Collected	No
SEX	Sex	character	1	Record Qualifier	Req	Collected	Observed
ARM	Description of Planned Arm	character	40	Synonym Qualifier	Req	Collected	Observed

3.4 EX - Exposure

EX has 16 records and 10 variables. Structure: One record per constant dosing interval per subject.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	Identifier	Req	Collected	No
DOMAIN	Domain Abbreviation	character	2	Identifier	Req	Collected	No
USUBJID	Unique Subject Identifier	character	40	Identifier	Req	Collected	No
EXSEQ	Sequence Number	numeric	8	Identifier	Req	Derived	No
EXTRT	Name of Treatment	character	40	Topic	Req	Collected	Observed
EXDOSE	Dose	numeric	8	Record Qualifier	Exp	Collected	No
EXDOSU	Dose Units	character	10	Variable Qualifier	Exp	Collected	No
EXROUTE	Route of Administration	character	20	Variable Qualifier	Perm	Collected	No
EPOCH	Epoch	character	40	Timing	Perm	Collected	Observed
EXSTDTC	Start Date/Time of Treatment	character	20	Timing	Exp	Collected	Observed

3.5 TS - Trial Summary

TS has 4 records and 11 variables. Structure: One record per trial summary parameter value.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	Identifier	Req	Collected	No
DOMAIN	Domain Abbreviation	character	2	Identifier	Req	Collected	No
TSSEQ	Sequence Number	numeric	8	Identifier	Req	Derived	No
TSGRPID	Group ID	character	20	Identifier	Perm	Collected	No
TSPARMCD	Trial Summary Parameter Short Name	character	8	Topic	Req	Collected	Observed
TSPARM	Trial Summary Parameter	character	40	Synonym Qualifier	Req	Collected	Observed
TSVAL	Parameter Value	character	200	Result Qualifier	Exp	Collected	Observed
TSVALNF	Parameter Null Flavor	character	8	Result Qualifier	Perm	Collected	No
TSVALCD	Parameter Value Code	character	40	Result Qualifier	Exp	Collected	No
TSVCDREF	Name of the Reference Terminology	character	20	Result Qualifier	Exp	Collected	No
TSVCDVER	Version of the Reference Terminology	character	20	Result Qualifier	Exp	Collected	No

4. CodeLists

Value lists observed in the delivered data (inferred from the data, not a CDISC CT release). Identifier variables are not listed.

PC.PCGRPID

Code	Decode
TREATMENT PERIOD 1	TREATMENT PERIOD 1
TREATMENT PERIOD 2	TREATMENT PERIOD 2

PP.PPGRPID

Code	Decode
TREATMENT PERIOD 1	TREATMENT PERIOD 1
TREATMENT PERIOD 2	TREATMENT PERIOD 2

PP.PPTESTCD

Code	Decode
AUCIFO	AUCIFO
AUCLST	AUCLST
CMAX	CMAX
LAMZ	LAMZ
LAMZHL	LAMZHL
TMAX	TMAX

PP.PPTEST

Code	Decode
AUC Infinity Obs	AUC Infinity Obs
AUC to Last Nonzero Conc	AUC to Last Nonzero Conc
Half-Life Lambda z	Half-Life Lambda z
Lambda z	Lambda z
Max Conc	Max Conc
Time of CMAX Observation	Time of CMAX Observation

PP.PPSTRESU

Code	Decode
/h	/h
h	h
h*ng/mL	h*ng/mL
ng/mL	ng/mL

DM.SUBJID

Code	Decode
001	001
002	002
003	003
004	004
005	005
006	006
007	007
008	008

DM.SEX

Code	Decode
F	F
M	M

DM.ARM

Code	Decode
Reference-Test	Reference-Test

Code	Decode
Test-Reference	Test-Reference

EX.EXTRT

Code	Decode
Reference	Reference
Test	Test

EX.EPOCH

Code	Decode
TREATMENT PERIOD 1	TREATMENT PERIOD 1
TREATMENT PERIOD 2	TREATMENT PERIOD 2

EX.EXSTDTC

Code	Decode
2026-03-01T08:00	2026-03-01T08:00
2026-03-15T08:00	2026-03-15T08:00

TS.TSPARMCD

Code	Decode
ACTSUB	ACTSUB
SPONSOR	SPONSOR
SSTDTC	SSTDTC
TITLE	TITLE

TS.TSPARM

Code	Decode
Actual Number of Subjects	Actual Number of Subjects
Clinical Study Sponsor	Clinical Study Sponsor
Study Start Date	Study Start Date
Trial Title	Trial Title

TS.TSVAL

Code	Decode
2026-03-01	2026-03-01
8	8
Synthetic (no sponsor)	Synthetic (no sponsor)
Synthetic 2x2 BE study (synthetic data)	Synthetic 2x2 BE study (synthetic data)

5. Derivations

No derivation rule was declared for these datasets in this package.

6. Data conformance and deviations

• PC: 1 specification variable(s) absent in the source (written empty) (PCDTC); 0 source column(s) outside the specification (not delivered); 0 sequence variable(s) generated.

• PP: 0 specification variable(s) absent in the source (written empty); 0 source column(s) outside the specification (not delivered); 0 sequence variable(s) generated.

• DM: 0 specification variable(s) absent in the source (written empty); 0 source column(s) outside the specification (not delivered); 0 sequence variable(s) generated.

• EX: 0 specification variable(s) absent in the source (written empty); 0 source column(s) outside the specification (not delivered); 0 sequence variable(s) generated.

• TS: 0 specification variable(s) absent in the source (written empty); 0 source column(s) outside the specification (not delivered); 0 sequence variable(s) generated.

• PP: the list of NCA parameters excluded from the closed PK parameter list was not supplied to this guide; it is not known whether any were excluded.

• CDISC CORE 0.17.1: of 180 applicable rules, 123 were run (114 pass, 9 fail) and 57 could not be run. A rule that did not run gives no evidence in either direction; 'pass' is not 'conformant'.

• CDISC CORE did not validate ADNCA, ADPP: its cache has no rules for adamig 1-1. These datasets have no CORE evidence and are not in the counts above.

• CORE finding CORE-000334 on DM: 1 incidence(s) - At least one expected variable is missing from dataset

• CORE finding CORE-000355 on DM: 1 incidence(s) - At least one required variable is missing from dataset

• CORE finding CORE-000328 on EX: 1 incidence(s) - The Study Day of Start of Observation (--STDY) is not present in the dataset when Start Date/Time of Observation (--STDTC) is present.

• CORE finding CORE-000334 on EX: 1 incidence(s) - At least one expected variable is missing from dataset

• CORE finding CORE-000321 on PC: 1 incidence(s) - Study Day of Visit/Collection/Exam (--DY) variable is missing when Date/Time of Collection (--DTC) is present.

• CORE finding CORE-000334 on PC: 1 incidence(s) - At least one expected variable is missing from dataset

• CORE finding CORE-000701 on PC: 176 incidence(s) - EPOCH is missing for clinical subject-level observation.

• CORE finding CORE-000334 on PP: 1 incidence(s) - At least one expected variable is missing from dataset

• CORE finding CORE-000575 on PP: 1 incidence(s) - No timing variable is provided

• CORE finding CORE-000733 on TS: 4 incidence(s) - TSPARMCD = RANDQT record is not present

• CORE finding CORE-000740 on TS: 1 incidence(s) - A required value of TSPARMCD is not found

• CORE finding CORE-000741 on TS: 4 incidence(s) - The set ('INTMODEL', 'INTTYPE','PCLASS') is not in the list of TSPARAMCD with TSVAL populated.

• Protocol deviations: Not declared by the sponsor in this package.

7. Traceability of the delivered files

File	SHA-256 (start)	Reader A	Reader B	XPT arbitration (A, B and metadata)
PC.xpt	74c39195daa5b3ee...	foreign::read.xport	pandas.read_sas	passed
PP.xpt	04fc33d8b601854f...	foreign::read.xport	pandas.read_sas	passed
DM.xpt	13c266e91325ff18...	foreign::read.xport	pandas.read_sas	passed
EX.xpt	5eb25e6d61efd061...	foreign::read.xport	pandas.read_sas	passed
TS.xpt	ef57b56a32bab5b9...	foreign::read.xport	pandas.read_sas	passed

8. Conventions

• Datasets with a specification (PC, PP, DM, EX, TS) are SAS Transport v5 files written with xportr; variable names up to 8 characters, labels up to 40.

• Standards referenced by this package: SDTM Implementation Guide v3.2 (reference table: variables of DM, EX, PC and PP only; role and core are n/a elsewhere); CDISC Define-XML v2.0.

• Data listings of PC, PP, DM, EX, TS are delivered in docs/listados/ (one PDF per dataset, generated from the conformed data frame and checked against the rendered PDF, in cell order).

Appendix A. Numbers in this document and their origin

Key	Value	Origin
core.applicable	180	CDISC CORE 0.17.1: aplicables
core.fail	9	CDISC CORE 0.17.1: fallan
core.notrun	57	CDISC CORE 0.17.1: no_ejecutadas
core.pass	114	CDISC CORE 0.17.1: pasan
core.run	123	CDISC CORE 0.17.1: ejecutadas
n_datasets	5	SDTM datasets of the package
n_descartadas.DM	0	conformar(): source columns outside the spec, DM

Key	Value	Origin
n_descartadas.EX	0	conformar(): source columns outside the spec, EX
n_descartadas.PC	0	conformar(): source columns outside the spec, PC
n_descartadas.PP	0	conformar(): source columns outside the spec, PP
n_descartadas.TS	0	conformar(): source columns outside the spec, TS
n_generadas.DM	0	conformar(): derived --SEQ variables, DM
n_generadas.EX	0	conformar(): derived --SEQ variables, EX
n_generadas.PC	0	conformar(): derived --SEQ variables, PC
n_generadas.PP	0	conformar(): derived --SEQ variables, PP
n_generadas.TS	0	conformar(): derived --SEQ variables, TS
n_reg.DM	8	rows of the delivered DM dataset
n_reg.EX	16	rows of the delivered EX dataset
n_reg.PC	176	rows of the delivered PC dataset
n_reg.PP	96	rows of the delivered PP dataset
n_reg.TS	4	rows of the delivered TS dataset
n_suj.DM	8	distinct USUBJID in DM
n_suj.EX	8	distinct USUBJID in EX
n_suj.PC	8	distinct USUBJID in PC
n_suj.PP	8	distinct USUBJID in PP
n_vacias.DM	0	conformar(): spec variables missing from the source, DM
n_vacias.EX	0	conformar(): spec variables missing from the source, EX
n_vacias.PC	1	conformar(): spec variables missing from the source, PC
n_vacias.PP	0	conformar(): spec variables missing from the source, PP
n_vacias.TS	0	conformar(): spec variables missing from the source, TS
n_var.DM	8	variables of DM (spec)
n_var.EX	10	variables of EX (spec)
n_var.PC	12	variables of PC (spec)
n_var.PP	10	variables of PP (spec)
n_var.TS	11	variables of TS (spec)