Analysis Data Reviewer's Guide (ADRG)

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 ADRG describes the structure, content and derivation rules of the 2 ADaM 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. ADaM datasets overview

Dataset	Label	Structure	Records	Subjects	Keys
ADNCA	ADaM NCA Input Data	One record per subject per dose or concentration record	192	8	STUDYID, USUBJID, ASEQ
ADPP	ADaM PK Parameters Analysis	One record per subject per parameter per period	96	8	STUDYID, USUBJID, PARAMCD, APERIOD

3. Dataset details

3.1 ADNCA - ADaM NCA Input Data

ADNCA has 192 records and 36 variables. Structure: One record per subject per dose or concentration record.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	n/a	Req	Predecessor	No
USUBJID	Unique Subject Identifier	character	40	n/a	Req	Predecessor	No
ASEQ	Analysis Sequence Number	numeric	8	n/a	Perm	Derived	No
APERIOD	Period	numeric	8	n/a	Perm	Derived	No
PARAMCD	Parameter Code	character	8	n/a	Req	Derived	Observed
PARAM	Parameter	character	40	n/a	Req	Derived	Observed
AVAL	Analysis Value	numeric	8	n/a	Cond	Derived	No
AVALU	Analysis Value Unit	character	20	n/a	Req	Predecessor	Observed
EVID	Event ID	numeric	8	n/a	n/a	Assigned	Closed
AVISIT	Analysis Visit	character	40	n/a	Req	Derived	Observed
PCRFTDT	Reference Date of Dose for Analyte	numeric	8	n/a	Req	Derived	No
PCRFTTM	Reference Time of Dose for Analyte	numeric	8	n/a	Req	Derived	No
PCRFTDTM	Reference Datetime of Dose for Analyte	numeric	8	n/a	Req	Derived	No

Variable	Label	Type	Length	Role	Core	Origin	Value list
AFRLT	Act. Rel. Time from Analyte First Dose	numeric	8	n/a	Perm	Derived	No
ARRLT	Actual Rel. Time from Ref. Dose	numeric	8	n/a	Req	Derived	No
NFRLT	Nom. Rel. Time from Analyte First Dose	numeric	8	n/a	Perm	Derived	No
NRRLT	Nominal Rel. Time from Ref. Dose	numeric	8	n/a	Req	Derived	No
FRLTU	Rel. Time from First Dose Unit	character	10	n/a	Perm	Assigned	No
RRLTU	Rel. Time from Ref. Dose Unit	character	10	n/a	Req	Assigned	No
ATPTN	Analysis Timepoint (N)	numeric	8	n/a	Perm	Derived	No
ATPTREF	Analysis Timepoint Reference	character	40	n/a	Perm	Derived	Observed
DOSEA	Actual Treatment Dose	numeric	8	n/a	Req	Derived	No
DOSEU	Treatment Dose Units	character	20	n/a	Req	Predecessor	No
FANLDT	First Date of Dose for Analyte	numeric	8	n/a	Perm	Derived	No
FANLTM	First Time of Dose for Analyte	numeric	8	n/a	Perm	Derived	No
FANLDTM	First Datetime of Dose for Analyte	numeric	8	n/a	Perm	Derived	No
ROUTE	Route	character	20	n/a	Perm	Predecessor	No
PCGRPID	Group ID	character	40	n/a	Perm	Predecessor	Observed
PCSEQ	Sequence Number	numeric	8	n/a	Cond	Predecessor	No
PCSTRESU	Standard Units	character	20	n/a	Cond	Predecessor	Observed
BLQFL	Below Limit of Quantification Flag	character	1	n/a	n/a	Derived	Closed
NCAXFL	PK NCA Exclusion Flag	character	1	n/a	Perm	Derived	Closed
NCA1XRS	Reason 1 for PK NCA Exclusion	character	20	n/a	Perm	Derived	Closed
SRCDOM	Source Data	character	8	n/a	Perm	Assigned	Closed
SRCVAR	Source Variable	character	8	n/a	Perm	Assigned	Closed
SRCSEQ	Source Sequence Number	numeric	8	n/a	Perm	Predecessor	No

3.2 ADPP - ADaM PK Parameters Analysis

ADPP has 96 records and 14 variables. Structure: One record per subject per parameter per period.

Variable	Label	Type	Length	Role	Core	Origin	Value list
STUDYID	Study Identifier	character	20	n/a	Req	Predecessor	No
USUBJID	Unique Subject Identifier	character	40	n/a	Req	Predecessor	No

Variable	Label	Type	Length	Role	Core	Origin	Value list
ASEQ	Analysis Sequence Number	numeric	8	n/a	Perm	Derived	No
PARAMCD	Parameter Code	character	8	n/a	Req	Predecessor	Observed
PARAM	Parameter	character	40	n/a	Req	Predecessor	Observed
PARCAT1	Parameter Category 1	character	20	n/a	n/a	Derived	Closed
AVAL	Analysis Value	numeric	8	n/a	Cond	Predecessor	No
AVALU	Analysis Value Unit	character	20	n/a	n/a	Predecessor	Observed
APERIOD	Period	numeric	8	n/a	Perm	Derived	No
DOSEA	Actual Treatment Dose	numeric	8	n/a	Perm	Predecessor	No
DOSEU	Treatment Dose Units	character	20	n/a	Perm	Predecessor	No
SRCDOM	Source Data	character	8	n/a	Perm	Assigned	Closed
SRCVAR	Source Variable	character	8	n/a	Perm	Assigned	Closed
SRCSEQ	Source Sequence Number	numeric	8	n/a	Perm	Predecessor	No

4. CodeLists

Closed lists: the lists of the derivation rules of this package, the SAME as the CodeList elements of define_adam.xml. They are not a CDISC terminology release. An empty value is outside the list (not applicable, or not evaluable).

ADPP.PARCAT1

Code	Decode
PKPARMCD (CDISC CT)	Code found in the loaded CDISC PKPARMCD terminology
House criterion	Code outside the loaded terminology

ADPP.SRCDOM

Code	Decode
PP	Pharmacokinetics Parameters

ADPP.SRCVAR

Code	Decode
PPSEQ	PP sequence number

ADNCA.EVID

Code	Decode
0	Concentration record (PC)
1	Dose record (EX)

ADNCA.BLQFL

Code	Decode
Y	Yes
N	No

ADNCA.NCAXFL

Code	Decode
Y	Excluded from the PK NCA (empty: included)

ADNCA.NCA1XRS

Code	Decode
Missing time	No time for the concentration record
BLQ	Below the limit of quantification
Missing result	No numeric result

ADNCA.SRCDOM

Code	Decode
PC	Pharmacokinetics Concentrations
EX	Exposure

ADNCA.SRCVAR

Code	Decode
PCSEQ	PC sequence number
EXSEQ	EX sequence number

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

ADNCA.PARAMCD

Code	Decode
DOSE	DOSE
DRUGA	DRUGA

ADNCA.PARAM

Code	Decode
Dose	Dose
Drug A	Drug A

ADNCA.AVALU

Code	Decode
mg	mg
ng/mL	ng/mL

ADNCA.AVISIT

Code	Decode
Period 1	Period 1
Period 2	Period 2

ADNCA.ATPTREF

Code	Decode
Period 1 dose	Period 1 dose
Period 2 dose	Period 2 dose

ADNCA.PCGRPID

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

ADNCA.PCSTRESU

Code	Decode
ng/mL	ng/mL

ADPP.PARAMCD

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

ADPP.PARAM

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

ADPP.AVALU

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

5. Derivations

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

5.1 Variable-level derivations and origins

Origin types follow Define-XML 2.0 (Predecessor, Derived, Assigned). This table and the closed lists of section 4 are the same source as the MethodDef, Origin and CodeList elements of define_adam.xml. Derivations declared by the caller are listed in section 5, not here. On dose records the flags BLQFL, NCAXFL and NCA1XRS are empty (not applicable); BLQFL is also empty where PCORRES is absent (not evaluable). NCAXFL follows the ADaM IG for NCA: Y means the record is EXCLUDED from the NCA and empty means included.

Dataset	Variable	Origin type	Source	Method
ADNCA	STUDYID	Predecessor	PC.STUDYID / EX.STUDYID	STUDYID of the package (taken from the datasets; the protocol name when they carry none).
ADNCA	USUBJID	Predecessor	PC.USUBJID / EX.USUBJID	Copied from the SDTM record.
ADNCA	ASEQ	Derived	PC.PCSEQ, EX.EXSEQ	Ordinal of the record within USUBJID, ordered by APERIOD and ARRLT (missing times last), dose record before concentration record, then SRCDOM and SRCSEQ.

Dataset	Variable	Origin type	Source	Method
ADNCA	APERIOD	Derived	PC.PCGRPID, EX.EPOCH	Period number read from PCGRPID (concentration record) or EPOCH (dose record), both 'TREATMENT PERIOD n' (n integer >= 1); 1 when empty. Any other text is an error.
ADNCA	PARAMCD	Derived	PC.PCTESTCD, EX	PCTESTCD for a concentration record; DOSE for a dose record.
ADNCA	PARAM	Derived	PC.PCTEST, EX	PCTEST for a concentration record; Dose for a dose record.
ADNCA	AVAL	Derived	PC.PCSTRESN, EX.EXDOSE	PCSTRESN for a concentration record; EXDOSE for a dose record. Missing stays missing.
ADNCA	AVALU	Predecessor	PC.PCSTRESU, EX.EXDOSU	PCSTRESU for a concentration record; EXDOSU for a dose record. Empty when the source does not declare a unit.
ADNCA	EVID	Assigned	(constant)	0 for a concentration record (PC); 1 for a dose record (EX).
ADNCA	AVISIT	Derived	APERIOD	'Period n' for the analysis period of the record (n = APERIOD). The input contract carries no visits, so this is the period, not a clinical visit.
ADNCA	PCRFTDT	Derived	EX.EXSTDTC	Date of the dose of the record's period (the reference dose), from EXSTDTC, as a SAS date value (days since 1960-01-01), written with the SAS format DATE9. Empty when EXSTDTC is absent, unreadable or carries a time zone.
ADNCA	PCRFTTM	Derived	EX.EXSTDTC	Time of day of the reference dose, from EXSTDTC, in seconds since midnight, written with the SAS format TIME8. Empty when EXSTDTC has no time part or is not usable; a time is never invented.
ADNCA	PCRFTDTM	Derived	EX.EXSTDTC	Datetime of the reference dose, from EXSTDTC, in seconds since 1960-01-01T00:00:00, written with the SAS format DATETIME20. Empty when EXSTDTC has no time part or is not usable.

Dataset	Variable	Origin type	Source	Method
ADNCA	AFRLT	Derived	PC.PCTPTNUM, EX.EXSTDTC	Time from the FIRST dose of the subject: PCTPTNUM (planned time point in SDTM) plus the offset between the first dose and the dose of the record's period, from EXSTDTC and the declared time unit. Equal to PCTPTNUM in the period of the first dose; empty for later periods when EXSTDTC or the unit is not usable. For a dose record, the offset of its period.
ADNCA	ARRLT	Derived	PC.PCTPTNUM	Time from the dose of the record's period (the reference dose): PCTPTNUM; 0 for a dose record.
ADNCA	NFRLT	Derived	PC.PCTPTNUM, EX.EXSTDTC	Same value as AFRLT: the CSV carries a single time (no separate nominal schedule).
ADNCA	NRRLT	Derived	PC.PCTPTNUM	Same value as ARRLT (no separate nominal schedule); 0 for a dose record.
ADNCA	FRLTU	Assigned	time unit declared for the package	Unit of AFRLT and NFRLT: the time unit declared for the package (the same as RRLTU); empty when none is declared.
ADNCA	RRLTU	Assigned	time unit declared for the package	Time unit of the relative time variables when the package declares one; empty otherwise.
ADNCA	ATPTN	Derived	PC.PCTPTNUM	Same value as ARRLT (analysis time point, from the dose of the record's period); 0 for a dose record.
ADNCA	ATPTREF	Derived	APERIOD	'Period n dose': the reference of the relative time variables for the record's period.
ADNCA	DOSEA	Derived	EX.EXDOSE	Dose of the subject's EX record in the record's period (one dose per subject and period); missing when that period has no dose record.
ADNCA	DOSEU	Predecessor	EX.EXDOSU	Dose unit of the subject's EX record in the record's period; empty when not declared.
ADNCA	FANLDT	Derived	EX.EXSTDTC	Date of the subject's FIRST dose (the dose of the first period), from EXSTDTC, as a SAS date value, format DATE9. Empty when EXSTDTC is absent, unreadable or carries a time zone.
ADNCA	FANLTM	Derived	EX.EXSTDTC	Time of day of the subject's first dose, from EXSTDTC, in seconds since midnight, format TIME8. Empty when EXSTDTC has no time part; a time is never invented.

Dataset	Variable	Origin type	Source	Method
ADNCA	FANLDTM	Derived	EX.EXSTDTC	Datetime of the subject's first dose, from EXSTDTC, in seconds since 1960-01-01T00:00:00, format DATETIME20. Empty when EXSTDTC has no time part.
ADNCA	ROUTE	Predecessor	EX.EXROUTE	EXROUTE of the subject's EX record in the record's period (direct copy; empty when EX does not carry a route). Not inferred from the engine route.
ADNCA	PCGRPID	Predecessor	PC.PCGRPID	Direct copy of PCGRPID on a concentration record; empty on a dose record.
ADNCA	PCSEQ	Predecessor	PC.PCSEQ	Direct copy of PCSEQ on a concentration record (the PC record associated with AVAL); empty on a dose record.
ADNCA	PCSTRESU	Predecessor	PC.PCSTRESU	Direct copy of PCSTRESU on a concentration record; empty on a dose record (its unit is in AVALU and DOSEU).
ADNCA	BLQFL	Derived	PC.PCORRES	Y when PCORRES, trimmed and case-insensitive, starts with '<' or contains 'BLQ' (SDTM convention); N when PCORRES exists and does not; empty (not evaluable) when PCORRES is absent. Empty on dose records (not applicable).
ADNCA	NCAXFL	Derived	PC.PCORRES, PC.PCSTRESN, PC.PCTPTNUM	PK NCA exclusion flag (ADaM IG for NCA): Y = the concentration record is EXCLUDED from the NCA; empty = included. Y with NCA1XRS by precedence: missing time, then BLQ, then missing result. Empty on dose records (not applicable). A time before the dose is included, and a result of 0 is a result. Inverse meaning of the ANL01FL of admiral.
ADNCA	NCA1XRS	Derived	NCAXFL rule	Reason 1 for PK NCA exclusion. Closed list: Missing time, BLQ, Missing result; empty when NCAXFL is empty and on dose records.
ADNCA	SRCDOM	Assigned	(constant)	PC for a concentration record; EX for a dose record.
ADNCA	SRCVAR	Assigned	(constant)	PCSEQ for a concentration record; EXSEQ for a dose record.
ADNCA	SRCSEQ	Predecessor	PC.PCSEQ, EX.EXSEQ	Sequence number of the source record (SRCDOM, SRCVAR).
ADPP	STUDYID	Predecessor	PP.STUDYID	STUDYID of the package (taken from the datasets; the protocol name when they carry none).

Dataset	Variable	Origin type	Source	Method
ADPP	USUBJID	Predecessor	PP.USUBJID	Copied from the SDTM record.
ADPP	ASEQ	Derived	PP.PPSEQ	Ordinal of the record within USUBJID in the order of PPSEQ.
ADPP	PARAMCD	Predecessor	PP.PPTESTCD	PKPARMCD code of the PP record (PP built by PHAXTON uses the PKPARMCD terminology loaded from CDISC; an external PP may carry other codes: see PARCAT1).
ADPP	PARAM	Predecessor	PP.PPTEST	PKPARM name of the PP record.
ADPP	PARCAT1	Derived	pp_ct (PKPARMCD list)	'PKPARMCD (CDISC CT)' when PARAMCD is in the loaded terminology, 'House criterion' otherwise. Sponsor-defined variable: it states the provenance of the code.
ADPP	AVAL	Predecessor	PP.PPSTRESN	Numeric result of the PP record. A PP record without a numeric result produces no record here.
ADPP	AVALU	Predecessor	PP.PPSTRESU	Standard unit of the PP record.
ADPP	APERIOD	Derived	PP.PPGRPID	Period number read from the PPGRPID of the PP record ('TREATMENT PERIOD n'); 1 when empty.
ADPP	DOSEA	Predecessor	ADNCA.DOSEA	Dose of the subject's dose record in ADNCA for the same period (copied); missing when none.
ADPP	DOSEU	Predecessor	ADNCA.DOSEU	Dose unit of the subject's dose record in ADNCA for the same period (copied).
ADPP	SRCDOM	Assigned	(constant)	PP: every record comes from the PP domain.
ADPP	SRCVAR	Assigned	(constant)	PPSEQ: the source record is identified by its PPSEQ.
ADPP	SRCSEQ	Predecessor	PP.PPSEQ	Sequence number of the PP record.

5.2 Analysis decisions and data used

• ADNCA: of 176 concentration records, 176 are included in the NCA (NCAXFL empty). Excluded (NCAXFL = Y) with a reason (NCA1XRS): 0 BLQ, 0 missing result, 0 missing time. Precedence: missing time, then BLQ, then missing result.

• ADNCA: BLQ follows the SDTM convention on PCORRES ('<' prefix or 'BLQ'). Where PCORRES is absent the flag is empty (not evaluable): 0 concentration record(s).

• ADNCA: 16 dose record(s), one per subject (a second dose is not supported: no actual dates are available); 0 dose(s) without a value produced no dose record. 0 sample(s) before the dose are analysed, not excluded. 0 concentration record(s) carry no unit.

• ADNCA time: the input carries a single time (PCTPTNUM, the planned time point in SDTM), so if it is a nominal time AFRLT is not an actual time. ARRLT and NRRLT are counted from the dose of the record's period (APERIOD); AFRLT and NFRLT from the first dose of the subject, derived from EXSTDTC and the time unit when there are several periods (empty when they cannot be derived). FRLTU and RRLTU carry the same unit. Time unit: h.

• ADNCA: AVISIT (required by the IG) is the analysis period ('Period n'), because the input contract carries no visits. PCRFTDT, PCRFTTM and PCRFTDTM are the date, time and datetime of the dose of the record's period, read from EX.EXSTDTC as SAS values (days, seconds of the day and seconds since 1960-01-01), written with

the SAS formats DATE9., TIME8. and DATETIME20. They are empty where EXSTDTC is absent, unreadable or has a time zone, and the time and datetime are empty where EXSTDTC has no time: no value is invented.

• ADNCA: AVISIT, PCRFTDT, PCRFTTM and PCRFTDTM are Core Req in the IG, so the define marks them Mandatory; in this package 0 record(s) have no PCRFTDT and 0 have no PCRFTTM/PCRFTDTM. That is a known nonconformity while EXSTDTC is absent or has no time.

• ADPP: 96 record(s) for 8 subject(s) and 6 parameter(s) (AUCIFO, AUCLST, CMAX, LAMZ, LAMZHL, TMAX). One record per subject, parameter and period; APERIOD is read from PPGRPID of the PP record ('TREATMENT PERIOD n'; empty means period 1), and DOSEA is the dose of that period.

• ADPP: 382 of 388 PKPARMCD codes of the controlled terminology have no record (not emitted by the analysis; stated as missing, not as empty). 0 PP record(s) without a numeric result produced no record.

5.3 Verification against SDTM

• ADNCA was cross-checked row by row against PC.xpt and EX.xpt read back from the written XPT files: 192 row(s) checked, 0 problem(s). The check recomputes the analysis flags independently and requires each source record to appear exactly once. A package with a problem is not delivered.

• ADPP was cross-checked against PP.xpt and ADNCA.xpt read back from the written XPT files: 128 check(s), 0 problem(s). Cmax, Tmax, Tlast and Clast are recomputed from the analysable ADNCA records. This is an internal consistency check (PP and ADNCA come from the same concentrations), not an external validation.

• AUClast was compared with a linear trapezoid on ADNCA for 16 subject(s); 16 differ (the AUC method of the analysis is not recorded in the package, so a difference is reported, not treated as an error).

5.4 Limits of this guide

• The structure is inspired by the CDISC ADaM Implementation Guide for Non-compartmental Analysis Input Data; the official PDF could not be read (it requires a CDISC login). Variable names and labels follow the table of the IG for NCA 1.0 held in the CDISC CORE cache (also not checked against the PDF); BLQFL is a sponsor name, APERIOD and ATPTREF are used instead of the IG's ACYCLE (permissible), and PARCAT1 is a sponsor-defined variable.

• CDISC CORE has no ADaM rules in its cache and no second validator has been run on these datasets: there is no conformance evidence beyond the Define-XML schema check and the cross-checks above.

• Not emitted (absent, not empty): ARM/TRTA, ALLOQ, PARCAT1 for concentrations, real visits (AVISIT is the period), multiple doses within the same period, and time since the first dose across periods (no actual dates).

• ADPC carries the same parameter values as ADPP and is kept for compatibility; in CDISC ADPC names the concentrations dataset.

6. Data conformance and deviations

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

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

• 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)
ADNCA.xpt	18bb8688d81271bd...	foreign::read.xport	pandas.read_sas	passed
ADPP.xpt	a2be7c5b08b6f2aa...	foreign::read.xport	pandas.read_sas	passed

8. Conventions

• Datasets with a specification (ADNCA, ADPP) are SAS Transport v5 files written with xportr; variable names up to 8 characters, labels up to 40.

• Standards referenced by this package: ADaM Implementation Guide v1.1 (reference table: none for role (roles are not used in ADaM); ADaM core (Req/Cond/Perm) is the one of the ADaM IG for NCA 1.0 (ADNCA) and the ADaMIG 1.1 BDS table, as held in the CDISC CORE cache and not checked against the IG PDF; 'n/a' where no table lists the variable); CDISC Define-XML v2.0.

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

• The listing of ADNCA shows 20 of its 36 columns; not shown here (all are in the XPT): PCRFTDT, PCRFTTM, PCRFTDTM, NFRLT, NRRLT, FRLTU, ATPTN, ATPTREF, FANLDT, FANLTM, FANLDTM, ROUTE, PCGRPID, PCSEQ, PCSTRESU, SRCVAR.

Appendix A. Numbers in this document and their origin

Key	Value	Origin
adnca.analizables	176	audit.json adnca: analizables
adnca.blq_ne	0	audit.json adnca: blq_no_evaluable
adnca.conc	176	audit.json adnca: registros_conc
adnca.dosis	16	audit.json adnca: registros_dosis
adnca.dosis_sv	0	audit.json adnca: dose records without a value, not issued
adnca.excl_blq	0	audit.json adnca: excluded BLQ
adnca.excl_mr	0	audit.json adnca: excluded Missing result
adnca.excl_mt	0	audit.json adnca: excluded Missing time
adnca.neg	0	audit.json adnca: negative times
adnca.ref_sin_fecha	0	audit.json adnca: referencia_sin_fecha
adnca.ref_sin_hora	0	audit.json adnca: referencia_sin_hora
adnca.sin_unidad	0	audit.json adnca: no unit
adnca.verif_filas	192	audit.json adnca.verificacion: rows checked against PC.xpt and EX.xpt read back
adnca.verif_prob	0	audit.json adnca.verificacion: problems
adpp.auc_comp	16	audit.json adpp.verificacion: AUCLST compared with the linear trapezoid
adpp.auc_dif	16	audit.json adpp.verificacion: AUCLST that differ from the linear trapezoid
adpp.ct_sin_fila	382	audit.json adpp: CT codes without a row
adpp.ct_total	388	audit.json adpp: CT codes
adpp.npar	6	audit.json adpp: parameters issued
adpp.reg	96	audit.json adpp: records
adpp.sin_valor	0	audit.json adpp: PP records without a result, not issued
adpp.suj	8	audit.json adpp: subjects
adpp.verif_comp	128	audit.json adpp.verificacion: checks against PP.xpt and ADNCA.xpt read back
adpp.verif_prob	0	audit.json adpp.verificacion: problems

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	2	ADaM datasets of the package
n_descartadas.ADNCA	0	conformar(): source columns outside the spec, ADNCA
n_descartadas.ADPP	0	conformar(): source columns outside the spec, ADPP
n_generadas.ADNCA	0	conformar(): derived --SEQ variables, ADNCA
n_generadas.ADPP	0	conformar(): derived --SEQ variables, ADPP
n_reg.ADNCA	192	rows of the delivered ADNCA dataset
n_reg.ADPP	96	rows of the delivered ADPP dataset
n_suj.ADNCA	8	distinct USUBJID in ADNCA
n_suj.ADPP	8	distinct USUBJID in ADPP
n_vacias.ADNCA	0	conformar(): spec variables missing from the source, ADNCA
n_vacias.ADPP	0	conformar(): spec variables missing from the source, ADPP
n_var.ADNCA	36	variables of ADNCA (spec)
n_var.ADPP	14	variables of ADPP (spec)