One headache, seven artefacts

The same clinical observation, re-expressed at every step of the CDISC chain — and never once losing its link to where it came from.

A patient in a fictional Phase II diabetes trial reports a headache on study day 14 — mild, not serious, not related to treatment. Follow that single event left to right. Nothing about it changes; only the shape it is carried in. That is the whole idea behind clinical data standards.

COLLECTED

CDASH

01

eCRF · Adverse Events — entered

Study AB-201 Subject AB201-01-001

Adverse event term	Headache
Start date	2025-06-15
End date	2025-06-16
Severity	☑ Mild ☐ Moderate ☐ Severe
Serious?	☑ No ☐ Yes
Related to treatment?	☑ Not related ☐ Related

▸ *Illustrative — AB-201*

A site records the event on the case report form. The wording and the fields are standardised, so it looks like every other study's adverse event.

MAPPED

Annotated CRF

02

eCRF · Adverse Events — annotated

Study AB-201 Subject AB201-01-001

Adverse event term	Headache	AE.AETERM verbatim
Start date	2025-06-15	AE.AESTDTC ISO 8601
End date	2025-06-16	AE.AEENDTC ISO 8601
Severity	☑ Mild ☐ Moderate ☐ Severe	AE.AESEV CT SEVERITY
Serious?	☑ No ☐ Yes	AE.AESER CT NY
Related to treatment?	☑ Not related ☐ Related	AE.AEREL sponsor scale

▸ *Illustrative — AB-201*

The blank form is annotated to show where each field lands in SDTM. This is the bridge between collection and tabulation — and a submission deliverable in its own right.

TABULATED

SDTM

03

SDTM · AE domain — excerpt

STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AESTDTC	AESEV	AEREL
AB-201	AE	AB201-01-001	1	Headache	HEADACHE	2025-06-15	MILD	NOT RELATED

■ Required ■ Expected ■ Permissible

▸ *Illustrative — AB-201*

The event becomes one row in the AE domain. Column colour shows each variable's core: required, expected or permissible.

LINKED

SDTM · DM

04

SDTM · DM domain — excerpt

STUDYID	USUBJID	AGE	SEX	ARM
AB-201	AB201-01-001	58	M	AB-201 10 mg

↑ *USUBJID links the AE to its subject in DM.*

▸ *Illustrative — AB-201*

The subject identifier ties the event to the participant in the demographics domain. One value holds the whole submission together.

CONTROLLED

Terminology

05

Controlled Terminology · Severity/Intensity

Submission value	NCI code	Definition
MILD	C41338	Minimal / no intervention
MODERATE	C41339	Marked; local intervention
SEVERE	C41340	Severe / significant

Codelist: Severity/Intensity (C66769) · Extensible: No

▸ *Illustrative — verify against your CT release*

'Mild' is not free text. It is a fixed submission value with a code, so one study cannot write 'mild' while another writes 'Grade 1'.

ANALYSED

ADaM · ADAE

06

ADaM · ADAE — excerpt

USUBJID	TRTA	AEDECOD	ASTDT	ASEV	TRTEMFL
AB201-01-001	AB-201 10 mg	HEADACHE	2025-06-15	MILD	Y

▸ *Illustrative — AB-201*

The event gains what analysis needs: the treatment the patient received, merged in from the subject-level dataset, and a treatment-emergent flag.

REPORTED

Table 14.3.1

07

Output · Table 14.3.1 — TEAEs by treatment (Safety)

Preferred Term	AB-201 10 mg (N=3)	Placebo (N=3)
Any TEAE	3 (100.0)	3 (100.0)
Headache	2 (66.7)	1 (33.3)
Nausea	1 (33.3)	1 (33.3)
Diarrhoea	1 (33.3)	0 (0.0)

n (%) of subjects. Computed from the shipped datasets.

▸ *Illustrative — AB-201, Safety population*

The headache becomes a count and a percentage, next to the same figure for the comparator arm. An observation has become evidence.

AND DESCRIBED

Define-XML

Define-XML · stylesheet view — AE variable metadata

Variable	Label	Type	Codelist	Origin
AETERM	Reported Term	text	—	CRF
AEDECOD	Dictionary-Derived Term	text	MedDRA	Derived
AESEV	Severity/Intensity	text	SEVERITY	CRF
AESTDTC	Start Date/Time	ISO 8601	—	CRF

▸ *Illustrative — AB-201*

Every dataset is described in a machine-readable file: the variables, where each value came from, how anything derived was derived. This is what makes the chain readable by a stranger.

Read it right to left and you have traceability.

Take the count in the table and walk it back: to the analysis dataset, to the tabulation dataset, to the field on the form. If you can do that, a reviewer can trust the number.

Everything shown here is an illustrative mock-up from a fictional study. Coded terms are illustrative and are not a MedDRA extract.

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