Non-Clinical Psychedelic Exposure Record: Data Collection Form

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Companion form to: *Minimum Common Data Element Set for Non-Clinical Psychedelic Exposure Records*, version 1.1, draft for public comment (25 September 2026). Read the data element set and the completion guide before using this form. Where this form and the data element set differ in any way, the data element set governs.

What this form is, and what it is not

This form is a paper or on-screen layout of the 23 data elements of the set, in the order the set presents them, so that a source can capture a record without building its own form first. It is a draft for comment, not a finished or validated instrument.

- It records what happened. No field on this form asks how much of a substance to take, how to take it, when to take it, or whether to take it. Nothing on this form is guidance on use.
- It is not a clinical, screening or diagnostic tool.
- Filling in this form is not, by itself, a data collection under any law. Anyone who uses it to collect records is responsible for their own consent, privacy and legal review, as the data element set states in its section on privacy and re-identification.
- This form does not set privacy or consent rules. Follow the three-layer handling recommended in the data element set (restricted, coded, aggregate) and your own source's rules.

How to use this form

Complete one copy of the main record (Record header through PRV-02) for one index exposure of one person. Complete the separate **Source-record log** at the end once per source and cohort, not once per person. Some elements repeat inside a record: the form says so at the top of each of those elements. For guidance on what each field means and how to answer it, use the companion Completion Guide. For the formal definition of every field, use the Data Dictionary.

Missing-data codes (use in place of any substantive value)

Every field on this form, including every sub-field, accepts one of five codes in place of a substantive answer. A blank is never a valid entry.

Code	Meaning	Write this when
NR	Not recorded, not asked	Your source does not ask or collect this item at all.
NH	Not held	The item is collected somewhere, but this copy of

		the record does not have it (for example, it was lost in transfer).
DE	Declined	The person was asked and chose not to answer.
UK	Unknown	The item was asked, and the answer is not known to whoever is filling in the record.
NA	Not applicable	The item does not apply here, for example a conditional field whose condition is not met.

Where a field's own answer list already includes "prefer not to say" or "unknown," that option is the same as DE or UK respectively, and either wording may be used on paper.

Capture timing codes

Code	Meaning
B	Before exposure (baseline).
S	At the exposure or session, or as soon as practicable after it.
F	At follow-up, on the schedule below.

Follow-up schedule (counted in days from the start of the index exposure, day 0)

Period or window	Definition	Used by
Acute period	Start of exposure to 72 hours after it.	OUT-01
Subacute period	72 hours after the start of exposure to the end of day 29.	OUT-01
Window 7	Targeted at day 7, accepted from day 5 to day 10.	OUT-02 (symptom status only), OUT-03, OUT-04, OUT-05
Window 30	Targeted at day 30, accepted from day 30 to day 40.	OUT-02 to OUT-05
Window 90	Targeted at day 90, accepted from day 80 to day 110.	OUT-02 to OUT-05

Window 365	Targeted at day 365, accepted from day 335 to day 395.	OUT-02 to OUT-05

Always record the actual number of days since exposure, even when an assessment falls outside the accepted range.

Record model: what the paperwork consists of

A **record** describes one index exposure of one person. It has:

1. A **record header** (identifiers, completed once).
2. A value or a missing-data code for each of the **23 elements** below, completed once per record unless the element itself repeats.
3. **Repeating sub-records** inside some elements: one row per adverse event (OUT-01), one row per symptom and window (OUT-02), one row per window (OUT-03, OUT-04), one row per healthcare contact (OUT-05), one row per supervising or attending person (SET-02), one row per setting phase where more than one is recorded (SET-01), and one row per purpose-capture instance, before and after exposure (PUR-02).
4. A separate **source-record log**, filled in once per source and reporting period, never per person, holding the denominators (how many people were enrolled, how many completed each window). Records link to it by Source ID and Cohort ID, and never repeat the denominators themselves.

A later exposure by the same person is recorded as re-exposure (OUT-04) in this record and may also open a new record of its own, with its own record header and its own index exposure.

Record header

Completed once per record.

Field	Entry
Source ID	_____
Cohort ID (or NA if the source has no defined cohort)	_____
Person ID (pseudonymous only, never a name, government ID, or contact detail)	_____
Exposure ID	_____
Record version (increases each time this record is corrected or completed, with earlier versions kept)	_____
Specification version	1.1
Transformation note (recommended: was this record made directly under this set, or converted	_____

from another format? name and version of the conversion rule)	

Group 1. SUBSTANCE

SUB-01. Substance identity: as reported and as verified

Capture: S (reported), with verification at any time after S. Obligation: required, with method conditional on a test having been done.

- Reported substance (code from Annex B, or free text if unlisted): _____
- Verification status: ☐ Verified ☐ Not verified ☐ Not tested
- Verification method (only if a test was done): ☐ Laboratory assay of the same batch ☐ Laboratory assay of a sample of the material consumed ☐ Presumptive field test ☐ Other (specify): _____
- Substance detected (recommended, only if not verified: code from Annex B): _____
- Analytical platform (recommended, only if assayed: coded to the method used): _____
- Labelling (recommended): ☐ Labelled with a stated identity ☐ Not labelled
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SUB-02. Preparation form, quantity consumed with units, and route

Capture: S. Obligation: required, and "unknown" is a permitted value in every sub-field.

- Form: ☐ Dried whole material ☐ Fresh whole material ☐ Powdered or encapsulated material ☐ Brewed or steeped preparation ☐ Standardized extract ☐ Isolated compound ☐ Other ☐ Unknown
- Quantity consumed (number, or "unknown"): _____
- Unit: ☐ g dried material ☐ g fresh material ☐ mg of a named compound ☐ ml of preparation ☐ Other (specify) ☐ Unknown
- Route: ☐ Oral ☐ Sublingual or buccal ☐ Inhaled ☐ Other ☐ Unknown
- Basis of the quantity (recommended): ☐ Weighed ☐ Estimated ☐ Taken from a label ☐ Reported by another person
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SUB-03. Date and time of exposure

Capture: S, or B if planned and recorded in advance. Obligation: required. End-of-session value recommended.

- Start of exposure (date-time, ISO 8601): _____
- Precision: ☐ Full date-time ☐ Date only ☐ Month only ☐ Unknown

- End of session or release (recommended, where the exposure took place in a supervised session): _____
- Precision of end time: ☐ Full date-time ☐ Date only ☐ Month only ☐ Unknown
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SUB-04. Prior exposure history

Capture: B. Obligation: required.

- Lifetime count of prior exposures to any classic psychedelic: ☐ 0 ☐ 1 ☐ 2 to 5 ☐ 6 to 20 ☐ More than 20 ☐ Unknown ☐ Prefer not to say
- Interval since most recent exposure: ☐ No prior exposure ☐ Less than 30 days ☐ 30 to 89 days ☐ 90 to 364 days ☐ 1 year or more ☐ Unknown ☐ Prefer not to say
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Group 2. PERSON

PER-01. Age band, sex, and gender identity

Capture: B. Obligation: age band and sex at birth required. Gender identity recommended.

- Age band: ☐ 18-24 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 55-64 ☐ 65-74 ☐ 75 or older ☐ Prefer not to say
- Sex at birth: ☐ Female ☐ Male ☐ Intersex ☐ Prefer not to say
- Gender identity (recommended): ☐ Woman ☐ Man ☐ Non-binary ☐ Genderqueer ☐ Another identity, not specified ☐ Prefer not to say
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

PER-02. Comorbidities and risk-relevant history, from a closed list

Capture: B. Obligation: required. ("Other condition" text is held in the restricted layer and is not yet coded to a standard terminology.)

- Items present (select all that apply): ☐ Cardiovascular disease ☐ Psychosis ☐ Family history of psychosis ☐ Bipolar disorder ☐ Seizure disorder ☐ Suicidal ideation or behavior ☐ Other condition, specify (restricted layer): _____ ☐ None of these ☐ Unknown ☐ Prefer not to say
- Temporal status, per item selected (except family history): ☐ Current at time of exposure ☐ Past only
- Source of each item: ☐ Self-reported ☐ Clinician-recorded
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

PER-03. Concomitant medications and concomitant psychoactive exposure

Capture: B for current medications. S for same-day and preceding psychoactive exposure, with a 7-day window afterward. Obligation: the seven flags below are required. The full medication list is recommended.

Current use of (yes / no / unknown for each):

Class	Yes	No	Unknown
SSRI	☐	☐	☐
SNRI	☐	☐	☐
MAOI	☐	☐	☐
Lithium	☐	☐	☐
Tramadol	☐	☐	☐
Other serotonergic agent	☐	☐	☐
Agent with cardiac conduction effects	☐	☐	☐

- Basis of the flags above (recommended): ☐ Self-reported ☐ Medication record ☐ Both
- Concomitant psychoactive exposure: ☐ None ☐ Alcohol ☐ Cannabis ☐ Stimulant ☐ Other psychedelic ☐ Other (specify class): _____ ☐ Unknown ☐ Prefer not to say
- Timing of that exposure relative to the index exposure: ☐ Same day ☐ 1 to 7 days before ☐ 1 to 7 days after
- Full medication list (recommended, repeat rows as needed: coded to a standard drug vocabulary where supported, otherwise text flagged "uncoded"): _____
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

PER-04. Reproductive stage and hormonal status

Capture: B, confirmed at S. Obligation: required. Cycle phase is conditional on cycling.

- Hormonal status (select one or more): ☐ Cycling, regular ☐ Cycling, irregular ☐ Hormonal contraception ☐ Pregnant ☐ Postpartum ☐ Lactating ☐ Perimenopausal ☐ Postmenopausal ☐ Menopausal hormone therapy ☐ Gender-affirming hormone therapy ☐ Not applicable ☐ Unknown ☐ Prefer not to say
- Cycle phase at exposure (only if cycling): ☐ Menstrual ☐ Follicular ☐ Ovulatory ☐ Luteal ☐ Unknown ☐ Prefer not to say
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

PER-05. Concurrent non-drug intervention and its timing

Capture: B, updated at F. Obligation: required.

- Intervention: ☐ None ☐ Psychotherapy ☐ Structured rehabilitation (specify): _____ ☐ Meditation or contemplative program ☐ Other structured program (specify): _____ ☐ Unknown
- Timing: ☐ Ongoing before and after ☐ Started within 30 days before ☐ Started within 30 days after ☐ Other ☐ Unknown
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Group 3. PURPOSE

PUR-01. Clinical indication present

Capture: B where possible, otherwise S. Obligation: required. Basis and reason sub-fields conditional on "yes."

- Clinical indication diagnosed by a licensed clinician, present at time of exposure: ☐ Yes ☐ No ☐ Unknown
- Basis (only if yes): ☐ Clinician-recorded ☐ Self-reported ☐ Unknown
- Indication was a reason for this exposure (only if yes): ☐ Yes ☐ No ☐ Unknown
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

PUR-02. Purpose of use

Capture: B, or S/F with the timing field recorded. Obligation: required. A later instance never replaces an earlier one: keep both. This element repeats: complete one instance block for each time purpose is captured (typically once before exposure and, if asked again, once after).

Vocabulary (version 1.1, draft):

Code	Purpose
PU-01	Treatment of a diagnosed condition, clinician-directed
PU-02	Self-treatment of a symptom or condition, not clinician-directed
PU-03	Self-exploration or self-understanding
PU-04	Processing a specific life event (for example bereavement, trauma, a transition)
PU-05	Creativity, insight or problem-solving
PU-06	Interpersonal or relational purpose
PU-07	Spiritual or religious practice

PU-08	Ceremonial or cultural participation
PU-09	Performance or skill enhancement
PU-10	Recreation, social or enjoyment
PU-11	Other (free text required)
PU-12	Curiosity
PU-13	Connection with nature or the natural world
PU-14	Personal growth or self-improvement

Instance block (copy for each capture: before exposure / after exposure):

- Capture timing: ☐ Before exposure ☐ After exposure ☐ Unknown
- Capture date-time (proposal for comment, needed to decide if this instance counts as prospective): _____
- Primary purpose (one code, PU-01 to PU-14): _____
- Secondary purpose(s) (any number of codes): _____
- Free text (recommended, hold in the restricted layer): _____
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Group 4. SETTING

SET-01. Physical environment category

Capture: S. Obligation: required. Phase recommended. This element repeats: complete one row per setting phase if more than one is recorded for this exposure. Where no phase is stated, the row describes the exposure session.

Phase (recommended)	***Category***	***Row***
☐ Preparation ☐ Exposure session ☐ Integration ☐ Follow-up	*☐ Own home ☐ Another private residence ☐ Outdoors in nature ☐ Licensed service center or healing center ☐ Clinical or research facility ☐ Religious or spiritual setting ☐ Concert, festival or party ☐ Other public place ☐ Other ☐ Unknown*	*1*
☐ Preparation ☐ Exposure session ☐ Integration ☐ Follow-up	*☐ Own home ☐ Another private residence ☐ Outdoors in nature ☐ Licensed service center or healing center ☐*	*2 (add rows as needed)*

	Clinical or research facility ☐ Religious or spiritual setting ☐ Concert, festival or party ☐ Other public place ☐ Other ☐ Unknown	

Or code (if no setting record can be made): ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SET-02. Supervision: presence, role, and licensure

Capture: S. Obligation: required. Role and license conditional on "present." Never record the person's identity: role and license status only. This element repeats: one row per supervising or attending person.

- A supervising or attending person was present: ☐ Yes ☐ No ☐ Unknown

• **Person**	• **Role**	• **Health-professional license**
• 1	• ☐ Sober companion or sitter ☐ Licensed facilitator under a State program ☐ Guide or ceremonial leader ☐ Therapist or clinician ☐ Other ☐ Unknown	• ☐ Yes ☐ No ☐ Unknown
• 2	• ☐ Sober companion or sitter ☐ Licensed facilitator under a State program ☐ Guide or ceremonial leader ☐ Therapist or clinician ☐ Other ☐ Unknown	• ☐ Yes ☐ No ☐ Unknown

•

Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SET-03. Solitary or group, and number of persons present

Capture: S. Obligation: required.

- Configuration: ☐ Alone ☐ With others also using ☐ With others not using ☐ Mixed ☐ Unknown
- Number of others present (integer of 0 or more, or unknown): _____
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SET-04. Preparatory contact before exposure

Capture: B or S. Obligation: required. Number conditional on "yes."

- Preparatory contact with a supervising person, facilitator or clinician occurred before exposure: ☐ Yes ☐ No ☐ Unknown
- Number of contacts (only if yes, integer of 1 or more, or unknown): _____
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

SET-05. Pre-exposure screening

Capture: B. Obligation: required. Domain, instrument and role conditional on "yes." The result of screening is not recorded by this element.

- Screening performed: ☐ Yes ☐ No ☐ Unknown
- Domain screened (only if yes, select all that apply): ☐ Medical ☐ Psychiatric ☐ Current medications ☐ Other (specify): _____
- Instrument (only if yes): named instrument and version, or "unstructured interview": _____
- Performed by: ☐ Licensed clinician ☐ Facilitator or guide ☐ Self-administered ☐ Other ☐ Unknown
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Group 5. OUTCOME

OUT-01. Acute and subacute adverse events

Capture: S, and at each follow-up contact up to the end of day 29. Obligation: required, including an explicit "no adverse event" value. This element repeats: complete one event block per adverse event.

- No adverse event recorded, covering: ☐ Acute period ☐ Subacute period (state which periods were covered even when there is nothing else to report)

Event block (copy for each event):

- Term (a MedDRA term where used, a supplementary-list code once published, or the source's own term as text flagged "uncoded"): _____
- Terminology and version (only if a terminology is used): _____
- Onset (hours from the start of the exposure): _____
- Period (derived from onset): ☐ Acute ☐ Subacute
- Resolution: ☐ Resolved without lasting effect ☐ Resolved with lasting effect ☐ Ongoing at last contact ☐ Fatal ☐ Unknown, with time of resolution (hours or days from start): _____
- Severity (intensity): ☐ Mild ☐ Moderate ☐ Severe
- Seriousness: ☐ Serious ☐ Not serious
- Seriousness criterion (only if serious, select one or more): ☐ Results in death ☐ Life-threatening ☐ Requires inpatient hospitalisation or prolongs an existing hospitalisation ☐

Results in persistent or significant disability or incapacity ☐ Congenital anomaly or birth defect ☐ Other important medical event, or name another definition applied: _____

- Ascertainment: ☐ Observed during the session ☐ Reported spontaneously ☐ Elicited at a scheduled follow-up ☐ Found in existing records
- Relatedness to the exposure (recommended): ☐ Assessed as related ☐ Assessed as not related ☐ Not assessed, assessed by (reporter type, as PRV-01): _____
- Reporter (as in PRV-01): _____
- Reporting convention (the rule or protocol whose event definition and time window produced this record, for example a State rule or a study protocol): _____
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

OUT-02. Persisting effects at fixed observation windows

Capture: B (pre-exposure status and baseline severity, where possible), F. Obligation: required in each window the source operates. A window not operated is coded NR, never left blank. This element repeats per symptom and per window. In window 7 this element records symptom status only: no assessment at day 7 can meet the persisting-effect case definition below.

Per symptom, baseline (captured once, before exposure where possible):

- Pre-exposure status, in the 30 days before exposure: ☐ Present ☐ Absent
- Baseline severity (only if present): ☐ Mild ☐ Moderate ☐ Severe
- Basis of the baseline: ☐ Assessment before exposure ☐ Recall at follow-up

Per symptom, per window (copy for windows 7, 30, 90, 365 as operated):

- Window: ☐ 7 ☐ 30 ☐ 90 ☐ 365
- Days since exposure (integer): _____
- Recall period asked about (for example "since the last assessment" or "the past 7 days"): _____
- Presence: ☐ Present, new ☐ Present, worsened ☐ Present, not worsened ☐ Absent (assessment not made: code NR)
- Severity: ☐ Mild ☐ Moderate ☐ Severe, or named instrument and version: _____
- Functional impact (recorded separately from presence): ☐ None ☐ Mild ☐ Moderate ☐ Severe
- Reporting convention: ☐ Composite (any listed effect) ☐ By category
- Case status, derived under case definition CD-1.1 below: ☐ Case ☐ Not a case ☐ Not assessable
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Case definition CD-1.1 (proposal for comment), for deriving case status above:

5. Eligible record: start of exposure known at date precision or better, and a pre-exposure status recorded for the symptom.
6. Criteria: a persisting adverse effect is a symptom present at the assessment that is new (absent throughout the 30 days before exposure) or worsened (present before exposure, and at least one severity level higher than baseline, on the same scale).
7. Window: the assessment falls in window 30, 90 or 365, within its accepted range. (Window 7 is never used for case status.)
8. Case status: "Case" when the criteria are met. "Not a case" when the symptom was assessed and the criteria are not met. "Not assessable" when the pre-exposure status is NR/NH/UK/DE, a symptom present before exposure has no baseline severity, or no assessment falls in the window.
9. A case status is always reported together with the OUT-04 re-exposure status for that window.
10. Cases whose baseline rests on recall at follow-up are reported separately from cases whose baseline was assessed before exposure.
11. Composite counts and single-category counts are reported separately and are never interchanged.

OUT-03. Outcome referenced to the recorded purpose of use

Capture: B (purpose and baseline), F (outcome). Obligation: required. This element repeats per window.

- Instrument identifier: _____
- Instrument version: _____
- Window: ☐ 7 ☐ 30 ☐ 90 ☐ 365
- Purpose-referenced score(s), following the named instrument's own scoring rules: _____
- Computability: ☐ Computed ☐ Not computable, purpose was not recorded before exposure ☐ Not computable, the instrument was not administered
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

OUT-04. Re-exposure during the follow-up window

Capture: F. Obligation: required. This element repeats per window. Re-exposure here means any further exposure to a classic psychedelic, whether or not the same substance as the index exposure.

- Window: ☐ 7 ☐ 30 ☐ 90 ☐ 365
- Re-exposure occurred before this window closed: ☐ Yes ☐ No ☐ Unknown
- Date(s) of each re-exposure (precision as in SUB-03, add rows as needed): _____
- Substance of re-exposure (recommended, coded as in SUB-01): _____
- Status at the assessment (derived): ☐ Re-exposed before assessment ☐ Not re-exposed before assessment ☐ Unknown

- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Re-exposure rule, version 1.1 (proposal for comment): follow-up for the index exposure is censored at the date of the first re-exposure. An assessment made after that date stays in the record, marked "re-exposed before assessment," and is analyzed as a separate group. It is never deleted and never counted as an outcome of the index exposure alone. A record whose re-exposure status is unknown in a window is reported as its own group. A re-exposure may open a record of its own, with its own index exposure.

OUT-05. Healthcare contact attributable to the exposure

Capture: S and F, at every window. Obligation: required, including an explicit "none." This element repeats per interval, and per contact within an interval.

Per interval (acute period, then each follow-up window):

- Contact in this interval: ☐ Yes, one row below per contact ☐ None reported (the person or source was asked and reported no contact), if the interval was not asked about, code NR instead of choosing an option

Per contact (copy as needed):

- Level: ☐ None ☐ Telehealth ☐ Urgent care ☐ Emergency department ☐ Hospital admission ☐ Psychiatric admission
- Date (as in SUB-03): _____
- Attribution: ☐ Self-attributed ☐ Clinician-attributed
- Ascertainment (recommended): ☐ Self-report ☐ Health record ☐ Both
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Group 6. PROVENANCE

PRV-01. Capture mode, reporter type, and retention denominator

Capture: every record, at every capture point. Obligation: required. Both denominators must be reportable wherever the source has a cohort.

- Capture mode: ☐ Prospective (baseline values captured before the index exposure, later values at or near the time they describe) ☐ Retrospective (record created after the index exposure, from recall or existing records)
- Reporter type: ☐ Subject ☐ Supervising or attending person ☐ Clinician ☐ Other person, specify the relationship (for example family member or friend): _____
- Denominator link (held in the separate source-record log): Source ID _____ Cohort ID _____
- Window completion: Window 7 ☐ Completed ☐ Not completed · Window 30 ☐ Completed ☐ Not completed · Window 90 ☐ Completed ☐ Not completed · Window 365 ☐ Completed ☐ Not completed

- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

PRV-02. Jurisdiction and primary language of capture

Capture: every record. Obligation: required. Jurisdiction of exposure and first language recommended.

- Jurisdiction of capture (ISO 3166-1 alpha-2 country code, with an ISO 3166-2 subdivision code where one exists (use the subdivision code alone for places like Puerto Rico that have both)): _____
- Jurisdiction of exposure (recommended, only if different from capture): _____
- Language of capture (ISO 639-1, or ISO 639-3 where no two-letter code exists): _____
- Respondent's first language (recommended): _____
- Translation flag: ☐ Captured in the respondent's first language ☐ Captured through translation ☐ Unknown
- Or code: ☐ NR ☐ NH ☐ DE ☐ UK ☐ NA

Source-record log

Completed once per source and cohort, for each reporting period. Never repeated inside a person-level record: records link to this log by Source ID and Cohort ID. For a source with no defined cohort, the denominators are NA, and its records are counts without a rate.

Field	Entry
Source ID	_____
Cohort ID (or NA)	_____
Reporting period	_____
Source type	☐ State program ☐ Naturalistic survey ☐ Registry ☐ Adverse event reports ☐ Electronic health records ☐ Other
Number enrolled	_____
Enrolment definition	☐ Consented ☐ Completed baseline ☐ Other (specify): _____
Number completing window 7	_____
Number completing window 30	_____
Number completing window 90	_____
Number completing window 365	_____
Reporting conventions in operation (as recorded with events in OUT-01)	_____

Conformance reminder

A record conforms to version 1.1 when every one of the 23 elements above is present and holds either a substantive value or one of the five missing-data codes, and every conditional sub-field whose condition holds is filled in the same way. A source that does not collect an element records NR for it, never a blank. This set does not rank sources by how many substantive values they supply.

Reminders

This form records what was reported or observed. It gives no guidance on use, and it is not itself a request for anyone's exposure data. It is not a clinical, screening, or diagnostic instrument, and it does not replace medical, legal or regulatory advice. Comments on the underlying data element set close 2 December 2026. Send them to main@metanoia-ca.org with "CDE v1.1" in the subject line, citing the element ID.

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