Minimum Common Data Element Set for Non-Clinical Psychedelic Exposure Records

Records of human exposure that arise outside clinical trials. "Non-clinical" in this title does not refer to nonclinical (animal or laboratory) studies.

Version: 1.1, draft for public comment

Version date: 25 September 2026

Status: A draft specification released for comment. It is not yet an implementable standard. Section 4 lists what is not yet done, including a machine-readable data dictionary and the mappings to other standards.

Comments close: 2 December 2026

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Version history

Version	Date	Change
0.1 and 0.1.1	22 September 2026	Internal drafts. Not published.
1.0	23 September 2026	Prepared for public release and reviewed before publication. Not published.
1.1	25 September 2026	First public version, released for comment. Corrections after pre-publication review: a record model with identifiers, with the denominators moved

		to a source-level record. A follow-up schedule shared by the outcome elements, with a standard acute period and a subacute period. The persisting-effect case definition separates new from worsened and is stated as a named, versioned rule. OUT-01 separates severity from seriousness and adds resolution, ascertainment and relatedness. OUT-04 states the re-exposure censoring rule explicitly. The missing-data codes separate "not asked" from "not held", and PU-98 and PU-99 are withdrawn in favor of the set-level codes. New sub-fields in SUB-03, PER-02, PER-03, PUR-01, PUR-02, SET-01, SET-05, OUT-02, OUT-03, OUT-04, OUT-05, PRV-01 and PRV-02, each marked as a proposal for comment. A provisional substance list (Annex B). Corrected: the description of the hearing notice, the reading of two figures from Nayak et al. (2023), and the statement on data collection. The 23 element identifiers and the six groups are unchanged. Two element names are extended (PER-02, OUT-01).

1. Context

Metanoia is a California 501(c)(3) public charity advancing the science of natural psychedelics for personal growth and human flourishing in healthy adults. Not treating illness. Expanding potential.

In its written comment to the Food and Drug Administration on Docket No. FDA-2026-N-7542 (Topic 4, Best Practices for Data Collection and Standardization), submitted on 22 September 2026, Metanoia recommended that any Coordinated Registry Network or comparable

repository require a minimum set of common data elements, and stated that it was preparing a draft of that set for non-clinical exposure records. This document is that draft.

The problem it addresses is practical. Records of psychedelic exposure now come from State programs, naturalistic surveys, clinical registries, adverse event reports and electronic health records. They define adverse events on different clocks, report counts against different denominators, and record the reason for use in different words or not at all. For supervised psilocybin services, a three-phase e-Delphi of 36 experts has defined consensus process, outcome and structure measures (Korthuis et al., 2024). Those measures assess supervised services. This set is a cross-source element set for records that arise outside clinical trials. The two are meant to be mapped to each other, not merged, and element-level mapping is planned for a later version, after that study has been read in full text. Among the sources we have read, which are listed in section 8, we have not identified a shared minimum element set for psychedelic exposure in adopted use across the kinds of source listed above. This statement does not rest on a systematic search. Pooling such records without a shared set produces numbers that look comparable and are not.

The set has 23 elements in six groups. The first groups follow the categories for which the hearing notice seeks common data elements across data sources: "drug, dosage, indication, setting, and patient characteristics (e.g., comorbidities)" (91 FR 43097). The notice names these categories and does not publish a list of elements. The elements are Metanoia's proposal, and outcome and provenance groups are added. Each element below gives a definition, data type, permitted values or units, when it is captured, whether it is required, the external source it is aligned to, and a short rationale. Each element is a composite that holds several sub-fields. An atomic data dictionary, with one identifier per sub-field, will follow with the machine-readable dictionary (section 4).

Three design choices run through the whole set.

1. **Record, never recommend.** Every quantity field records what was reported or observed. Nothing in this set is guidance on how much of anything to take, how to take it, or whether to take it.
2. **The status of every field is recorded, and no answer is ever compelled.** Every person-level field can record that the person declined to answer (code DE, below). A declined answer is a recorded value. It is kept distinct from an item the source never asked (NR), from an item the source collects but this record does not hold (NH), and from an answer of "unknown" (UK).
3. **Missing is not a value.** The missing-data codes are kept separate from each other, because collapsing them corrupts denominators.

Terms used in this set

Term	Meaning in this set
Non-clinical exposure record	A record of a human exposure to a psychedelic substance that did not take place within a clinical trial, whatever the source of the record: a State-regulated program, a naturalistic survey,

	an adverse event report or an electronic health record. The term does not refer to nonclinical (animal or laboratory) studies, which is the sense in which the Agency's guidance cited in this set (source 10) uses the word.
Exposure	One occasion of use of a substance by one person, beginning at the time recorded in SUB-03.
Index exposure	The exposure a record is about. Every period and window is counted from it.
Re-exposure	A further exposure after the index exposure, as defined in OUT-04.
Record	Everything recorded under this set about one index exposure of one person (see "Record model and identifiers" below).
Source	The program, study, registry or system in which a record is created.
Source record	The record a source supplies about itself and its cohort, which holds the denominators (see "Record model and identifiers").
Repository	Any registry, coordinated registry network or database that pools records from more than one source.
Coordinated Registry Network	The term the hearing notice uses as an example of a data repository (91 FR 43097). This set does not propose one.
Reporter	The person who supplies the information in a record (PRV-01).
The comment	Metanoia's written comment on Docket No. FDA-2026-N-7542, cited above.
MedDRA	Medical Dictionary for Regulatory Activities, a medical terminology maintained by its own organization under its own terms.
ICH E2A	The International Conference on Harmonisation guideline on clinical safety data management, definitions and standards for expedited reporting (source 15).
ReSPCT	Reporting of Setting in Psychedelic Clinical Trials, a reporting guideline (source 3).

OPEN	Open Psychedelic Evaluation Nexus, the evaluation of Oregon's supervised psilocybin services (sources 4 and 7).
CDISC	Clinical Data Interchange Standards Consortium, a standards organization for clinical research data.
HL7	Health Level Seven, a standards organization for health data exchange.
ISO 3166, ISO 639	International standards for country and subdivision codes (ISO 3166) and for language codes (ISO 639).
UPLC-ESI-MS/MS	Ultra-performance liquid chromatography with electrospray ionization and tandem mass spectrometry, an analytical method (source 5).

Scope

In the Agency's final guidance on clinical investigations of psychedelic drugs, "psychedelic drug" covers classic psychedelics, "typically understood to be 5-HT2A receptor agonists such as psilocybin and lysergic acid diethylamide (LSD)", as well as entactogens or empathogens such as MDMA. This version of the set is written for records of adults (18 or older) exposed to classic psychedelics in that sense, including natural materials that contain them, such as psilocybin-containing fungi. Annex B lists the substances and materials the set treats as in scope, as a proposal for comment. Most elements are not specific to any substance. SUB-04 and OUT-04 are limited to classic psychedelics. Whether the set should extend to entactogens, or to records of minors, is an open question for comment (section 6).

Capture timing codes

Code	Meaning
B	Before exposure (baseline). Some elements lose most of their value if captured later.
S	At the exposure or session, or as soon as practicable after it.
F	At follow-up, on the schedule below.

Follow-up schedule

Every period and window is counted in days from the start of the index exposure (SUB-03), which is day 0. The schedule is shared by the outcome elements, so that every source refers to the same intervals.

Period or window	Definition	Used by
Acute period	From the start of the exposure to 72 hours after it.	OUT-01
Subacute period	From 72 hours after the start of the exposure to the end of day 29.	OUT-01
Window 7	Assessment targeted at day 7, accepted from day 5 to day 10.	OUT-02 (symptom status only), OUT-03, OUT-04, OUT-05
Window 30	Assessment targeted at day 30, accepted from day 30 to day 40.	OUT-02 to OUT-05
Window 90	Assessment targeted at day 90, accepted from day 80 to day 110.	OUT-02 to OUT-05
Window 365	Assessment targeted at day 365, accepted from day 335 to day 395.	OUT-02 to OUT-05

Each assessment records the actual number of days since exposure, so an assessment made outside the accepted range is still usable and is visibly out of range. Window 30 begins at day 30 because the persisting-effect case definition cannot be met earlier. The 72-hour boundary and the accepted ranges are proposals for comment. A source's own reporting period, for example Oregon's 72 hours from the client's release from an administration session (OAR 333-333-1010(59)), is recorded with each event in OUT-01 and is a different quantity from these standard periods.

Missing-data codes and what "required" means

Every element, and every sub-field within it, accepts five set-level codes in place of a substantive value.

Code	Meaning
NR	Not recorded because not asked. The source does not ask or collect this item.
NH	Not held. The source collects this item, but this record does not hold it, for example because it was lost in transfer or not supplied in an extract.
DE	Declined. The person was asked and chose not to answer ("prefer not to say").
UK	Unknown. The item was asked, and the answer is not known to the reporter.

NA	Not applicable. The item does not apply to this record, for example a conditional sub-field whose condition does not hold.

Where an element lists "prefer not to say" or "unknown" among its permitted values, these are the codes DE and UK. The codes PU-98 and PU-99 of version 1.0 are withdrawn, and PUR-02 uses these set-level codes like every other element.

"Required" means that the element is present in every record and holds either a substantive value or one of these codes. It does not mean that every source must be able to supply a substantive value. A blank is never a valid entry.

Conformance. A record conforms to this version when every element is present and holds a substantive value or one of these codes, and every conditional sub-field whose condition holds is filled in the same way. A source that does not collect an element conforms by recording NR for it. The set does not rank sources by how many substantive values they supply.

Obligation

All 23 elements are **required** at the element level, as recommended in the comment. Within an element, a sub-field may be **conditional** (required only when a stated condition holds) or **recommended** (collected where the data source can support it). Sub-fields, permitted values and scoping choices that go beyond the text of the comment are proposals for comment, and each is marked as one where it appears.

Record model and identifiers

A record describes one index exposure of one person. It has a record header, a value or code for each of the 23 elements, and repeating sub-records where an element says so: one per adverse event (OUT-01), per symptom and window (OUT-02), per window (OUT-03, OUT-04), per healthcare contact (OUT-05), per supervising or attending person (SET-02) and per setting phase (SET-01). A later exposure of the same person is recorded in OUT-04 and may also open a record of its own, with its own index exposure. The record model is a proposal for comment.

Record header (proposal for comment)

Field	***Content***
Source ID	*Identifier of the source, assigned by the repository.*
Cohort ID	*Identifier of the cohort or collection wave within the source, or NA for a source with no defined cohort.*
Person ID	*A pseudonymous identifier assigned by the source. Never a name, a government identifier or a contact detail.*

Exposure ID	*Identifier of the index exposure within the source.*
Record version	*Increases each time the record is corrected or completed. Earlier versions are kept.*
Specification version	*The version of this set the record was made under, for example 1.1.*
Transformation note	*Recommended. Whether the record was created directly under this set or converted from another format, and the name and version of the conversion rule.*

Source record (proposal for comment). Each source supplies, for each cohort and reporting period: the source type (State program / naturalistic survey / registry / adverse event reports / electronic health records / other), the number enrolled with the enrolment definition (consented / completed baseline / other, specify), the number completing each window, and the reporting conventions it operates (see OUT-01). Records link to it by Source ID and Cohort ID. For a source with no defined cohort, such as spontaneous adverse event reports, the denominators are NA, and records from that source are counts without a rate.

Versioning and change control

Element identifiers (for example PUR-02) and code values (for example PU-03) are stable. A later version may add or withdraw elements, sub-fields and codes, but will not reuse an identifier or a code for a different meaning. A withdrawn item keeps its identifier and is marked as withdrawn. New codes are added at the end of a list, so the order of codes is not a ranking.

Metanoia maintains the set. Changes are proposed through comments (section 5) or by Metanoia, and Metanoia decides on them after each comment period. Every version carries a change log, and the version after a comment period is published with a summary of how each comment was handled. A machine-readable version manifest will follow with the data dictionary.

2. The elements

Group 1. SUBSTANCE

SUB-01 Substance identity: as reported and as verified

Attribute	Specification
Definition	The substance the person or reporter states was used, and whether that identity was independently verified by a test.

Data type	Coded value plus text, a coded verification status, and conditional coded sub-fields.
Permitted values	Reported substance: coded to the provisional substance list in Annex B, with free text for unlisted entries. Verification status: verified (a test identified the reported substance) / not verified (a test was done and did not identify the reported substance, or was inconclusive) / not tested. Verification method (conditional, when 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, when not verified): coded as for the reported substance. Analytical platform (recommended, when assayed): coded to the method actually used. Labelling (recommended): labelled with a stated identity / not labelled. A label is recorded here and is never counted as verification.
Capture	S (reported). Verification at any time after S.
Obligation	Required. Method is conditional on "verified" or "not verified". Method, substance detected, platform and labelling values, and the Annex B list, are proposals for comment.
Alignment	Analytical methods for psychedelic compounds in botanical materials, including a single-laboratory validated UPLC-ESI-MS/MS method for 26 natural and synthetic psychedelic and psychoactive compounds in fungi, cactus and leaf matrices, brewed tea and simulated finished product (J AOAC Int. 2026, 109(1):61-74, PMID 41014027). Metanoia adopts the analytical standard as it develops and does not propose a competing one.
Rationale	The gap between reported and verified identity is itself an analyzable variable. Where no test was done, recording "not tested" per record turns a weak number into a documented weak number. A presumptive field test and a laboratory assay are not equally strong, which is why the method is recorded.

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

Attribute	Specification
Definition	The physical form of what was consumed, the amount consumed as recorded by the reporter, the unit of that amount, and the route.
Data type	Coded form, numeric quantity, coded unit, coded route.
Permitted values	Form: dried whole material / fresh whole material / powdered or encapsulated material / brewed or steeped preparation / standardized extract / isolated compound / other / unknown. Quantity: a non-negative 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.
Capture	S.
Obligation	Required. "Unknown" is a permitted value in every sub-field.
Alignment	Batch-to-batch variation in psilocybin and psilocin content has been documented in Psilocybe cubensis biomass cultivated under uniform conditions, and the authors recommend that each batch be tested (J AOAC Int. 2026, 109(1):51-60, PMID 40802522).
Rationale	This is a recording field. It records what was consumed and makes no statement about what should be consumed. Dried material by mass and a standardized extract are not interchangeable units, and a number without its unit and form cannot be compared with any other number.

SUB-03 Date and time of exposure

Attribute	Specification

Definition	When the exposure began and, where the exposure took place in a session, when the session ended.
Data type	Date-time (ISO 8601), with a precision flag, and a conditional second date-time.
Permitted values	Start of exposure: date-time. Precision: full date-time / date only / month only / unknown. End of session or release (recommended, where the exposure took place in an administration session or another supervised session, proposal for comment): date-time, with the same precision flag. A repository may store the values as offsets in days from a reference date held separately. A de-identified release should not carry full dates (section 4).
Capture	S, or B when the exposure is planned and recorded in advance.
Obligation	Required. The end-of-session value is recommended.
Alignment	Anchor for the follow-up schedule (section 1) and the re-exposure rule in OUT-04. Oregon counts a post-session reaction from "the client's release from an administration session" (OAR 333-333-1010(59)), which is why the end of the session is recorded where it applies.
Rationale	Required for any longitudinal linkage. Every period and window in this set is counted from the start of the exposure. A source whose own clock runs from the end of a session can be read against the standard periods only if both times are recorded.

SUB-04 Prior exposure history

Attribute	Specification
Definition	Lifetime number of prior exposures to any classic psychedelic (section 1), and the interval since the most recent one.
Data type	Two coded bands.
Permitted values	Lifetime count: 0 / 1 / 2 to 5 / 6 to 20 / more than 20 / unknown / prefer not to say. Interval

	since most recent: no prior exposure / less than 30 days / 30 to 89 days / 90 to 364 days / 1 year or more / unknown / prefer not to say.
Capture	B.
Obligation	Required.
Alignment	None external. The bands and the restriction to classic psychedelics are proposals for comment.
Rationale	Prior exposure is a candidate modifier of both acute and later effects. It also determines whether a baseline measurement is truly pre-exposure.

Group 2. PERSON

PER-01 Age band, sex and gender identity

Attribute	Specification
Definition	The person's age band, sex recorded at birth, and current gender identity, held as separate fields.
Data type	Three coded values.
Permitted values	Age band: 18 to 24 / 25 to 34 / 35 to 44 / 45 to 54 / 55 to 64 / 65 to 74 / 75 or older / prefer not to say. Sex at birth: female / male / intersex / prefer not to say. Gender identity: woman / man / non-binary / genderqueer / another identity, not specified / prefer not to say.
Capture	B.
Obligation	Required (age band and sex at birth). Gender identity is recommended.
Alignment	The comment lists "age band, sex". Gender identity is added as a separate field, as a proposal for comment, so that neither variable is lost by merging them. Oregon's aggregate client data include gender identity and age, and the list in that rule does not name sex recorded at birth (OAR 333-333-4910(2)(a)).
Rationale	Bands rather than dates minimize identifying detail. The set covers adults (section 1), so the lowest band begins at 18. Sex and gender are different variables, and a record that collapses

	them supports neither sex-stratified nor gender-stratified analysis.

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

Attribute	Specification
Definition	Conditions present at the time of exposure, relevant past history, and a family history of psychosis, from a closed list, each with its temporal status and its source.
Data type	Multi-select coded list, each item with a temporal status and a source flag.
Permitted values	Items: cardiovascular disease / psychosis / family history of psychosis / bipolar disorder / seizure disorder / suicidal ideation or behavior (proposed for comment) / other condition, specify (proposed for comment, the text held in the restricted layer) / none of these / unknown / prefer not to say. Temporal status per item (proposed for comment): current at the time of exposure / past only. The family-history item has no temporal status. Source flag per item: self-reported / clinician-recorded.
Capture	B.
Obligation	Required. Coding of "other condition" to a standard terminology is not yet specified (section 4).
Alignment	Under Topic 2 of the same notice, the Agency gives cardiovascular disease, psychosis and suicidality as examples of "medical and psychiatric conditions associated with greater risk of adverse outcomes" (91 FR 43097). The list covers all three. Bipolar disorder and seizure disorder are in the list as recommended in the comment. The suicidality value, the temporal status and the "other" value are additions to the comment and are offered for comment. The element name is extended from the comment's "Comorbidities from a closed list", because the list holds past history and a family history as well as current conditions.

Rationale	A closed list is poolable where free text is not. The temporal status keeps a current condition distinguishable from a past one, and the source flag keeps self-report distinguishable from a clinical record.

PER-03 Concomitant medications and concomitant psychoactive exposure

Attribute	Specification
Definition	Medications in current use at the time of exposure, with required structured capture of the interaction-relevant classes, and any other psychoactive substance used in the period around the exposure.
Data type	Structured flags plus an optional coded medication list.
Permitted values	Required yes / no / unknown flags: SSRI / SNRI / MAOI / lithium / tramadol / other serotonergic agent / agent with cardiac conduction effects. Basis of the flags (recommended, proposal for comment): self-reported / medication record / both. Concomitant psychoactive exposure: none / alcohol / cannabis / stimulant / other psychedelic / other (specify class) / unknown / prefer not to say, with timing relative to the exposure (same day / 1 to 7 days before / 1 to 7 days after). A further exposure to a classic psychedelic after the index exposure is recorded as re-exposure in OUT-04, not here. Full medication list (recommended): coded to a standard drug vocabulary where the data source supports one, otherwise text flagged "uncoded".
Capture	B for current medications. S for same-day and preceding psychoactive exposure. The 7-day window for psychoactive exposure after the index exposure.
Obligation	Required for the flags. The full list is recommended. The set does not define how recently a medication must have been taken to count as current use. The source states its own rule in its documentation.

Alignment	Classes as listed in the comment. The psychoactive co-exposure element responds to a request made by a presenter speaking for a State health department at the FDA public hearing of 14 September 2026 (as heard on the webcast, section 8).
Rationale	The interaction-relevant subset must be a structured field, not free text, or it cannot be searched or pooled.

PER-04 Reproductive stage and hormonal status

Attribute	Specification
Definition	The person's reproductive and hormonal state at the time of exposure.
Data type	Multi-select coded list, plus a conditional coded cycle phase.
Permitted values	Hormonal status (one or more): cycling, regular / cycling, irregular / hormonal contraception / pregnant / postpartum / lactating (proposed for comment) / perimenopausal / postmenopausal / menopausal hormone therapy (proposed for comment) / gender-affirming hormone therapy / not applicable / unknown / prefer not to say. Values may be combined, for example postpartum and lactating. Cycle phase at exposure (conditional, when cycling): menstrual / follicular / ovulatory / luteal / unknown / prefer not to say.
Capture	B, confirmed at S.
Obligation	Required. Cycle phase is conditional.
Alignment	Requested by a presenter speaking on women's health at the FDA public hearing of 14 September 2026 (as heard on the webcast, section 8).
Rationale	Recorded as a structured field so that safety signals are not lost inside population averages. The states are not mutually exclusive, so the field is multi-select. The field is short and cannot be added retrospectively to a cohort

	already enrolled. Self-reported cycle phase is a coarse proxy and is labelled as one.

PER-05 Concurrent non-drug intervention and its timing

Attribute	Specification
Definition	Any structured non-drug intervention the person is undergoing in the period around the exposure, and when it occurs relative to the exposure.
Data type	Multi-select coded list with timing.
Permitted values	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.
Capture	B, updated at F.
Obligation	Required.
Alignment	Requested by a presenter speaking on cochlear-implant rehabilitation at the FDA public hearing of 14 September 2026 (as heard on the webcast, section 8).
Rationale	A concurrent intervention that is not recorded is indistinguishable, downstream, from no intervention.

Group 3. PURPOSE

PUR-01 Clinical indication present

Attribute	Specification
Definition	Whether a clinical indication diagnosed by a licensed clinician was present at the time of exposure, and how that is known.
Data type	Coded value, plus conditional coded sub-fields.
Permitted values	Yes / no / unknown. Basis (conditional on yes, proposed for comment): clinician-recorded / self-reported / unknown. Indication was a

	reason for this exposure (conditional on yes, proposed for comment): yes / no / unknown.
Capture	B where possible, otherwise S.
Obligation	Required. The basis and reason sub-fields are conditional on "yes".
Alignment	Colorado's facilitator rules record "Whether the goal of facilitation was for clinical or experiential purposes (or both)" (4 CCR 755-1, Rule 6.22(C)(1)(i)). Colorado's healing center rules record whether the session "is intended to treat physical or behavioral conditions, or is for wellness services" (1 CCR 213-1, Rule 8035(C)(5)).
Rationale	Records from non-medical sources have no indication field, because no indication was assigned. If they enter a repository with that field empty, they cannot be told apart from records where the field was simply not collected. This field carries the medical versus non-medical distinction explicitly rather than by inference from a missing value. "No" is a legitimate, recordable state. A self-reported diagnosis and a clinician-recorded one carry different weight, which is why the basis is recorded. The conditional sub-fields are additions to the comment and are offered for comment.

PUR-02 Purpose of use

Attribute	Specification
Definition	The person's own purpose or purposes for the exposure, coded to a closed vocabulary, with one designated primary purpose, any number of secondary purposes, and the time of capture relative to the exposure. A purpose recorded before exposure and a purpose recorded after it are separate instances, each with its own timing.
Data type	Per instance: one coded primary value, a multi-valued coded secondary list, optional free text, a coded capture timing and a capture date-time.

Permitted values	Vocabulary, version 1.1 (draft): 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. PU-98 and PU-99 are withdrawn in version 1.1, and the set-level codes NR, NH, UK and DE are used instead. Capture timing: before exposure / after exposure / unknown. Capture date-time (proposed for comment): as in SUB-03.
Capture	B. Where the source cannot capture before exposure, the value is captured at S or F and the timing field says so.
Obligation	Required. A value recorded after exposure never replaces one recorded before it. Both are kept. Only an instance with capture timing "before exposure" and a capture date-time earlier than the start of exposure in SUB-03 counts as prospectively recorded, for OUT-03 and for any analysis. Free text is recommended, and should be held in a restricted layer because free text is the strongest re-identification risk in the record.
Alignment	Colorado's facilitator rules require "Reasons the participant sought natural medicine services, including whether the participant had any diagnosed physical or behavioral health condition for which the participant sought natural medicine services" (4 CCR 755-1, Rule 6.22(C)(1)(e)). Oregon's rules require service centers to report "The reasons, or reasons, for which clients requested psilocybin services" (OAR 333-333-4910(2)(b), quoted as published). This element supplies what those rules do not: a closed vocabulary, a capture-

	timing field, and a common code set across States. Annex A maps the reason categories of two published cohorts to this vocabulary.
Rationale	Multi-valued capture is required for the element to work at all. In a prospective naturalistic cohort, 1,802 respondents recorded 5,736 motivation endorsements, about 3.2 per person (Nayak et al., 2023). In Oregon's supervised program, 346 participants recorded 1,398 reasons, about four per person (Korthuis et al., 2026). A single-valued field would discard most of what was recorded. Timing is the substantive part: purpose recorded before exposure is a fixed reference point, and purpose recorded afterwards can be revised in light of the outcome. PU-01 always pairs with PUR-01 = yes and with the reason sub-field = yes. NR, UK and DE stay distinct. PU-07 and PU-08 are descriptive codes only and carry no position on the uses they describe. PU-12, PU-13 and PU-14 were added, as proposals for comment, after the vocabulary was mapped against the Oregon categories. Without them, the most frequently endorsed reason in that cohort, curiosity, had no code.

Group 4. SETTING

The setting fields decompose a definition of setting given in the review cited in OUT-03 (the culture, place and situation of use, including the other people present) into recordable values. They are a recording schema for non-clinical records. They are designed to map to the Reporting of Setting in Psychedelic Clinical Trials (ReSPCT) guidelines, an international Delphi consensus of 89 experts from 17 countries that specified 30 setting variables in four categories: physical environment, dosing session procedure, therapeutic framework and protocol, and subjective experiences (Pronovost-Morgan et al., 2025). ReSPCT is a reporting standard for trials, and these fields are designed to map to it and not to compete with it. In this version the correspondence is at the level of the four ReSPCT categories only. Item-level mapping will follow in a later version, once the full ReSPCT item checklist has been read against each field.

One exposure can carry more than one setting record. Each setting record states the phase it describes (SET-01).

SET-01 Physical environment category

Attribute	Specification
Definition	The kind of place where the exposure took place, and the phase the setting record describes.
Data type	Coded value, and a coded phase.
Permitted values	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. Phase described (recommended, proposal for comment): preparation / exposure session / integration / follow-up. Where no phase is stated, the setting record describes the exposure session.
Capture	S.
Obligation	Required. Phase is recommended.
Alignment	ReSPCT category: physical environment (category level only).
Rationale	A naturalistic cohort captured location in structured form from 1,551 respondents 1 to 3 days after exposure, most often at home (1,081, 69.7%) and outdoors in nature (245, 15.8%) (Nayak et al., 2023). Structured capture is feasible and yields a usable variable now, without waiting for a validated setting instrument.

SET-02 Supervision: presence, role, and licensure

Attribute	Specification
Definition	Whether a supervising or attending person was present, and for each such person, that person's role and whether that person holds a health-professional license.
Data type	One coded value, and a repeating pair of coded values, one pair per supervising or attending person.
Permitted values	Present: yes / no / unknown. For each person present: Role: sober companion or sitter /

	licensed facilitator under a State program / guide or ceremonial leader / therapist or clinician / other / unknown. Health-professional license: yes / no / unknown.
Capture	S.
Obligation	Required. Role and license are conditional on "present". The record holds each person's role and license status, never the person's identity.
Alignment	ReSPCT category: dosing session procedure (category level only). Role values are named so that State-program roles map without loss.
Rationale	In the naturalistic cohort cited in SET-01, 17 of the 1,551 respondents (1.1%) reported using psilocybin with a therapist, the only category in that survey that suggests a licensed clinician. Collapsed into one field, the distinction that matters most for risk characterization disappears. More than one person can attend, which is why role and license repeat per person.

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

Attribute	Specification
Definition	Whether the person was alone or with others, and how many others were present.
Data type	Coded value and integer.
Permitted values	Configuration: alone / with others also using / with others not using / mixed / unknown. Number of others present: integer of 0 or more, or unknown.
Capture	S.
Obligation	Required.
Alignment	ReSPCT category: dosing session procedure (category level only).
Rationale	Group size and whether others are also using are separate variables, and both appear in the structured setting data already collected at scale.

SET-04 Preparatory contact before exposure

Attribute	Specification
Definition	Whether any preparatory contact with a supervising person, facilitator or clinician occurred before the exposure, and how many contacts.
Data type	Coded value and integer.
Permitted values	Occurred: yes / no / unknown. Number of contacts: integer of 1 or more, or unknown.
Capture	B or S.
Obligation	Required. Number is conditional on "yes".
Alignment	ReSPCT category: therapeutic framework and protocol (category level only).
Rationale	Preparation is one of the few setting variables that is under the control of a program and can be recorded as a count.

SET-05 Pre-exposure screening

Attribute	Specification
Definition	Whether any screening was performed before the exposure, what it covered, with which instrument, and by whom. The result of the screening is not recorded by this element.
Data type	Coded value, coded domains, text or coded instrument, coded role.
Permitted values	Performed: yes / no / unknown. Domain screened (conditional, multi-select, proposal for comment): medical / psychiatric / current medications / other (specify). Instrument (conditional): named instrument and version, or "unstructured interview". Performed by: licensed clinician / facilitator or guide / self-administered / other / unknown.
Capture	B.
Obligation	Required. Domain, instrument and role are conditional on "yes".

Alignment	ReSPCT category: therapeutic framework and protocol (category level only).
Rationale	Whether screening happened, what it covered and who did it changes how any later adverse event should be read. The screening result is left out because this set is not a screening tool (section 4) and because a result adds identifying health detail to every record.

Group 5. OUTCOME

OUT-01 Acute and subacute adverse events

Attribute	Specification
Definition	Adverse events with onset in the acute period or the subacute period (section 1, follow-up schedule), that is, from the start of the exposure to the end of day 29.
Data type	Repeating record, one per event: coded term, terminology version, onset, period, resolution, severity, seriousness with criterion, ascertainment, relatedness, reporter, reporting convention.
Permitted values	Term: a MedDRA term where the source uses MedDRA and a term exists, otherwise a code from the supplementary list when it is published, otherwise the source's own term as text flagged "uncoded". Terminology and version (conditional, when a terminology is used). Onset: hours from the start of the exposure. Period (derived from onset): acute / subacute. Resolution (proposal for comment): resolved without lasting effect / resolved with lasting effect / ongoing at last contact / fatal / unknown, with the time of resolution in hours or days from the start of the exposure where known. Severity (intensity): mild / moderate / severe. Seriousness: serious / not serious. Seriousness criterion (conditional on serious, 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. A source that applies another definition of seriousness names it. Ascertainment (proposal for comment): observed during the session / reported spontaneously / elicited at a scheduled follow-up / found in existing records. Relatedness to the exposure (recommended, proposal for comment): assessed as related / assessed as not related / not assessed, with who assessed it (reporter types as in PRV-01). Reporter: as in PRV-01. Reporting convention: the rule or protocol whose event definition and time window produced the record, for example OAR 333-333-1010, 4 CCR 755-1 Rule 6.23, or a named study protocol.
Capture	S, and at each follow-up contact up to the end of day 29.
Obligation	Required, including an explicit "no adverse event recorded" value that states which periods were covered. The terminology version, reporting convention, resolution, ascertainment and relatedness sub-fields, and the extension to the subacute period, are proposals for comment.
Alignment	ICH E2A distinguishes severity, the intensity of an event, from seriousness, which rests on outcome or action criteria, and states that the two terms "are not synonymous". "Life-threatening" is one of its seriousness criteria, not a severity grade (source 15). It also lists the onset, the stop date or duration, the outcome and the source of the report among the details of a case. The Agency's final guidance states, for trials, that "It is important to characterize onset and resolution of psychedelic and other subjective effects." Oregon's rules define adverse reactions within an administration session, and a "post-session reaction" as one "occurring within 72 hours of the client's release from an administration session" that resulted in contacting emergency services or receiving care from a medical care provider (OAR 333-333-1010(2) to (4), (59) and (85)). Colorado requires a facilitator to report "every adverse health event that is life-threatening or serious within 24 hours" (4 CCR 755-1, Rule 6.23(B)), and a

	licensed business to report a possible adverse health event "no later than within two business days from being notified" (1 CCR 213-1, Rule 3015(A)). Neither Colorado deadline is measured from the session. The business rule runs from notification, and the facilitator rule fixes no starting point. Reporting deadlines are recorded as conventions and are not observation periods. MedDRA is maintained by its own organization under its own terms, and this set refers to its terms without reproducing them.
Rationale	The two State programs whose rules we have read count on different clocks. A repository that ingests both without recording which convention produced each count is pooling two different quantities, which is why the convention is a field, and why the standard periods are defined independently of it. Expected acute effects are recorded here and are never counted as persisting effects. An event that begins after the acute period and resolves before day 30 falls in the subacute period, so no event before day 30 is left without an element. The name of the element is extended from the comment's "Acute adverse events" for that reason. OUT-01 counts events. OUT-02 records whether a symptom is present at an assessment. The same symptom can appear in both, and the two are never summed.

OUT-02 Persisting effects at fixed observation windows

Attribute	Specification
Definition	A persisting adverse effect is a symptom, present at an assessment on or after day 30, that is either new (absent throughout the 30 days before exposure) or worsened (present in the 30 days before exposure, and at least one severity level higher at the assessment than at baseline, on the same scale). Persisting effects are assessed in windows 30, 90 and 365 (section 1). In window 7 this element records symptom status only, and no assessment at day 7 can meet the definition.

Data type	Per symptom: pre-exposure status and baseline severity. A repeating record per symptom and window: window, days since exposure, recall period, presence, severity, functional impact, convention flag, case status.
Permitted values	Pre-exposure status (per symptom, for the 30 days before exposure): present / absent. Baseline severity (conditional on present, proposal for comment): mild / moderate / severe. Basis of the baseline (proposal for comment): assessment before exposure / recall at follow-up. Window: 7 / 30 / 90 / 365. Days since exposure: integer. Recall period (proposal for comment): the period the question asked about, for example "since the last assessment" or "the past 7 days". Presence: present, new / present, worsened / present, not worsened / absent. An assessment that was not made is coded NR. Severity: mild / moderate / severe, the three levels of OUT-01, or a named instrument and version where the source uses one. Functional impact: none / mild / moderate / severe, recorded separately from symptom presence. Reporting convention: composite (any listed effect) / by category. Case status (derived under CD-1.1, below): case / not a case / not assessable.
Capture	B (pre-exposure status and baseline severity, where the source can capture them), F.
Obligation	Required in each window the source operates. A source that does not operate a window records NR for it, never a blank.
Alignment	The 365-day window matches the follow-up period in the Agency's final guidance on clinical investigations, which states that the most informative clinical trial design "would incorporate blinded long-term follow-up (typically 12 months) with prespecified criteria for retreatment", in the context of evaluating durability of response and repeat dosing. That guidance concerns trials. The window is adopted here so that non-clinical and trial records can refer to the same interval. The comment defines a persisting adverse effect as "a new or worsened symptom present at or beyond 30

	days after exposure and not present during the 30 days preceding exposure". A worsened symptom was present before exposure by definition, so version 1.1 states the two branches separately.
Rationale	The thresholds are proposals. What matters is that a definition be fixed in advance and shared across sources. The definition needs a pre-exposure reference, which is why pre-exposure status and baseline severity are captured at B, and why the basis of the baseline is recorded when it was not. In the Oregon program's prospective evaluation, three of the four serious behavioral adverse reactions were identified only through participant follow-up after the session, at one week in two cases and at three months in the third (Korthuis et al., 2026). The convention flag exists because of how such counts are extracted. In the naturalistic cohort (Nayak et al., 2023), 127 of 1,182 respondents (10.7%) reported at least one persisting negative effect at 2 to 4 weeks, and the most frequent single category, mood fluctuations, was reported by 55 (4.7%). These are different quantities. The first counts people with any listed effect, and the second counts people with one effect. The four categories drew 144 endorsements from 127 people, so they overlap and cannot be summed. A figure taken from such a table without the flag cannot be told apart from the other. Neither figure is a persisting effect in the sense of this set, since that survey asked at 2 to 4 weeks about effects that "lasted beyond the duration of the drug's effects".

Case definition CD-1.1 (proposal for comment). Every count of persisting adverse effects derived under this set names the case definition and its version. Two analysts who apply the same version to the same records obtain the same count.

4. **Eligible record.** A record with the start of exposure (SUB-03) at date precision or better, and a pre-exposure status for the symptom.
5. **Criteria.** The definition of a persisting adverse effect above, new or worsened.
6. **Window.** An assessment in window 30, 90 or 365, within the accepted range (section 1).
7. **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 or DE, when a symptom present before exposure has no baseline severity, or when no assessment falls in the window.

8. **Re-exposure.** The case status in each window is reported together with the OUT-04 status for that window, and the re-exposure rule in OUT-04 applies.
9. **Basis.** Cases whose baseline rests on recall at follow-up are reported separately from cases whose baseline was assessed before exposure.
10. **Convention.** Composite counts and single-category counts are reported separately and are never interchanged.

OUT-03 Outcome referenced to the recorded purpose of use

Attribute	Specification
Definition	An outcome measured at each follow-up window against the purpose recorded in PUR-02, using a named instrument and version.
Data type	Structured record per window: instrument identifier, instrument version, window, purpose-referenced score or scores, and a computability flag.
Permitted values	Computability: computed / not computable because purpose was not recorded before exposure / not computable because the instrument was not administered. Scores follow the scoring rules of the named instrument.
Capture	B (purpose and baseline), F (outcome).
Obligation	Required. Where purpose was not prospectively recorded (PUR-02), the purpose-referenced score is not computed and is never reconstructed retrospectively. The record remains valid for all other elements.
Alignment	Metanoia is developing an open outcome instrument referenced to this element, for non-clinical exposure records, and intends to publish it separately under the same license. No publication date is set, and nothing in this element depends on it. Any instrument that reports a score against a prospectively recorded purpose can populate this element.
Rationale	When the recorded purpose and the measured outcome come from different frames, the record cannot be interpreted without knowing both. This element records which instrument and version produced each score. Scores from

	different instruments are not comparable with each other and are never pooled as one quantity. Measurement in this field is not yet standardized even for the acute experience. A review of 93 trials of classical psychedelics found 17 different rating scales for the acute subjective experience and advised the development of a core outcome set (Hovmand, Poulsen and Arnfred, 2024).

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

Attribute	Specification
Definition	Whether any re-exposure occurred between the index exposure and the close of each follow-up window, with dates. In this set, re-exposure means any further exposure to a classic psychedelic (section 1), whether or not it is the substance of the index exposure. This scope is a proposal for comment.
Data type	Coded value per window, with a list of dates, and a derived status.
Permitted values	Yes / no / unknown, with the date of each re-exposure (precision as in SUB-03). Substance (recommended): as in SUB-01. Status at the assessment (derived, proposal for comment): re-exposed before assessment / not re-exposed before assessment / unknown.
Capture	F.
Obligation	Required.
Alignment	The re-exposure censoring rule of Recommendation 3 of the comment, under which records with re-exposure before a window closes "are flagged and analyzed separately". The rule below states how.
Rationale	Re-exposure rule, version 1.1 (proposal for comment). For the index exposure, follow-up is censored at the date of the first re-exposure. An assessment made after that date is kept in the record, marked "re-exposed before assessment", and analyzed as a separate group. It is never deleted, and it is 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. Without this rule, an effect attributed to one exposure may in fact follow a later one, and nothing in an unflagged record says which. In the naturalistic cohort, 26% of the participants remaining at the 2 to 4 week follow-up, and 50% of those at the 2 to 3 month follow-up, had taken at least one further dose of psilocybin (Nayak et al., 2023).

OUT-05 Healthcare contact attributable to the exposure

Attribute	Specification
Definition	Any contact with the healthcare system that the person or a clinician attributes to the exposure, recorded for the acute period and for each follow-up interval.
Data type	Per interval, a contact status. A repeating record, one per contact: level of contact, date, attribution source.
Permitted values	Contact in the interval (proposal for comment): yes, with one record per contact / none reported. "None reported" means that the person or the source was asked about the interval since the previous assessment and reported no contact. An interval that was not asked about is coded NR. Level: none / telehealth / urgent care / emergency department / hospital admission / psychiatric admission. Date: as in SUB-03. Attribution: self-attributed / clinician-attributed. Ascertainment (recommended, proposal for comment): self-report / health record / both.
Capture	S and F, at every window.
Obligation	Required, including an explicit "none".
Alignment	Oregon's rules count a contact with emergency services, care from a medical care provider, or transport to a hospital (OAR 333-333-1010(2) to (4), (59) and (85)). This element records the same kind of event on a common scale and

	extends it past 72 hours. Two kinds of Oregon event have no level of their own in this version: an emergency services contact that did not lead to transport, and care from a medical care provider outside the listed settings. Whether to add levels for them is an open question for comment.
Rationale	Gives a hard, linkable outcome that does not depend on any instrument. It is a utilization count and is reported as one, never interchanged with an incidence count derived from symptom reporting. "None" is meaningful only for an interval that was asked about, which is why the interval is recorded.

Group 6. PROVENANCE

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

Attribute	Specification
Definition	For every record: whether it was captured prospectively or retrospectively, who reported it, and the denominator it belongs to.
Data type	Two coded values, and a link to the source record, with a completion status per window.
Permitted values	Capture mode: prospective (baseline values were captured before the index exposure, and later values at or near the time they describe) / retrospective (the record was created after the index exposure, from recall or from existing records). Reporter type: subject / supervising or attending person / clinician / other person, specify the relationship, for example family member or friend (proposed for comment). Sources may use their own role names (for example facilitator, observer) provided each maps to one of these values. Denominator: held in the source record (section 1), which the record links to by Source ID and Cohort ID. Window completion (per window): completed / not completed.
Capture	Every record, at every capture point.

Obligation	Required. Both denominators must be reportable wherever the source has a cohort.
Alignment	Recommendation 4 of the comment, and the denominator convention in its Recommendation 3. The comment names three reporter values and states that the permitted values belong to the setting in which the record was created. The fourth value is an addition, offered for comment.
Rationale	In Oregon's prospective evaluation, facilitator and participant reports of adverse event type and severity often diverged, and neither record is simply wrong (Korthuis et al., 2026). In a naturalistic cohort, the same 127 participants with a persisting negative effect at 2 to 4 weeks are 10.7% of the 1,182 who completed that window, 4.5% of the 2,833 who completed baseline, or 1.6% of the 8,006 who consented (Nayak et al., 2023). That is why the definition of enrolment is recorded with the number. Denominators describe a cohort, not a person, so they are held once in the source record rather than repeated in every record. Adverse event reports and health records can come from people who are neither the subject, a supervising person nor a clinician, which is why a fourth value is proposed. Without these fields, records of different evidentiary weight are pooled indistinguishably.

PRV-02 Jurisdiction and primary language of capture

Attribute	Specification
Definition	The jurisdiction in which the record was captured, and the language in which it was captured.
Data type	Coded values and a flag.
Permitted values	Jurisdiction of capture (proposed): the jurisdiction in which the source that created the record operates, coded as an ISO 3166-1 alpha-2 country code with an ISO 3166-2 subdivision code where one exists, which covers States and territories. Where a place has both a country code and a subdivision code, as Puerto Rico and

	the other outlying areas of the United States do, records use the subdivision code (for example US-PR), so that one place is never coded two ways. Jurisdiction of exposure (recommended, proposed): where the exposure took place, coded the same way, when it differs from the jurisdiction of capture. This set does not record residence. Language of capture (proposed): the language of the questions or form, coded to ISO 639-1 where a two-letter code exists, otherwise to ISO 639-3. Respondent's first language (recommended, proposed): coded the same way. Translation flag: captured in the respondent's first language / captured through translation / unknown.
Capture	Every record.
Obligation	Required. Jurisdiction of exposure and first language are recommended.
Alignment	Requested by a presenter speaking for a research institute in Puerto Rico at the FDA public hearing of 14 September 2026 (as heard on the webcast, section 8). Oregon's aggregate client data include preferred spoken and written languages and, where applicable, county of residence (OAR 333-333-4910(2)(a)). The code systems are proposals, and we ask for comment on them.
Rationale	A repository whose sample frame omits a jurisdiction cannot report that omission unless the field exists. A record captured through translation is not evidentially identical to one captured in the respondent's first language.

3. Summary table

ID	Element	Capture	Obligation
SUB-01	Substance as reported and as verified	S	Required
SUB-02	Preparation form, quantity consumed with units, route	S	Required

SUB-03	Date and time of exposure, and end of session	S (or B)	Required (end of session recommended)
SUB-04	Prior exposure history	B	Required
PER-01	Age band, sex, gender identity	B	Required (gender identity recommended)
PER-02	Comorbidities and risk-relevant history, closed list	B	Required
PER-03	Concomitant medications and psychoactive exposure	B, S, F	Required
PER-04	Reproductive stage and hormonal status	B, S	Required
PER-05	Concurrent non-drug intervention and timing	B, F	Required
PUR-01	Clinical indication present	B (or S)	Required
PUR-02	Purpose of use, with capture timing	B (or S, F with timing recorded)	Required
SET-01	Physical environment category, and phase	S	Required
SET-02	Supervision, role, licensure	S	Required
SET-03	Solitary or group, number present	S	Required
SET-04	Preparatory contact	B, S	Required
SET-05	Pre-exposure screening	B	Required
OUT-01	Acute and subacute adverse events	S, F (to day 29)	Required
OUT-02	Persisting effects at fixed windows	B, F	Required
OUT-03	Outcome referenced to recorded purpose	B, F	Required

OUT-04	Re-exposure during follow-up	F	Required
OUT-05	Healthcare contact attributable to exposure	S, F	Required
PRV-01	Capture mode, reporter type, denominator	All	Required
PRV-02	Jurisdiction and language of capture	All	Required

4. What this set does not do

- It gives no guidance on use. No field suggests an amount, a route, a preparation or a setting. The quantity field records what was consumed.
- It does not endorse, oppose or evaluate any use, any substance, or any State or local program. It describes what their records contain.
- It is not a clinical instrument, a screening tool or a diagnostic tool.
- It is not a validated outcome instrument. OUT-03 names the element that an outcome instrument fills.
- It does not replace MedDRA, the ReSPCT guidelines, ICH E2A, or analytical method standards for the material. It refers to them.
- It is not an agency standard. It has not been adopted or endorsed by FDA, by any other federal agency, or by any State program.
- It makes no claim of interoperability with any other standard. That claim waits for the mappings listed below.
- It is not itself a data collection. Publishing it is not a request for anyone's exposure data, and comments on it (section 5) should contain none.
- Metanoia is developing an anonymous intake channel, with a report form derived from this set, for accounts of exposure that would otherwise go unrecorded. Its design principles, no direct identifiers, aggregate-only publication with small-cell suppression, and no collection of cultivation or sourcing methods, will be set out in a separate policy before the channel opens. The channel is not part of this document and is not yet accepting reports.
- It does not set privacy, consent or data-governance rules. Any collection under this set must follow the consent terms and the law that apply to the data source.

Privacy and re-identification

This set describes sensitive information. A record under it can describe conduct that is unlawful where it occurred, health conditions, pregnancy, medication use, and religious or spiritual practice. A few fields together can identify a person without a name: an exact date (SUB-03), a subdivision code (PRV-02), an age band with sex and gender identity (PER-01), a rare

substance (SUB-01), and the supervising roles of a small program (SET-02). A record can also describe people who are not its subject, such as a facilitator or a companion.

This section is not a de-identification standard, and following it does not make a data set de-identified under any law. The set does not set rules for privacy, but it recommends the following to any source or repository that uses it.

- Hold records in three layers. A restricted layer holds free text, full dates, and anything that describes a person other than the subject. A coded layer holds coded values, with dates as offsets. An aggregate layer holds counts only.
- Limit access to the restricted layer to named staff of the source, under the source's own rules.
- Store dates as offsets or shift them, and carry no full dates in a de-identified release.
- Suppress or combine small cells before any aggregate release, and state the threshold used in the release.
- Record the roles of other people, never their identities (SET-02, PRV-01).
- Link records across sources only under a written agreement that names the fields used for linkage.

Retention periods, key management and the legal role of each party are governed by the law and the consent terms that apply to each source, and this set does not specify them.

Not yet done in version 1.1

- Item-level mapping to the ReSPCT guidelines, and mapping to the consensus measures for supervised psilocybin services (Korthuis et al., 2024), which will follow a reading of that study in full text.
- Publication of the supplementary adverse event list for OUT-01. The substance list in Annex B is provisional.
- Coding rules for "other condition" in PER-02 and for the medication list in PER-03, to standard terminologies for conditions and medications.
- An atomic data dictionary with one identifier per sub-field, published in machine-readable form with a version manifest.
- Mapping to CDISC standards and to the format of the NIH Common Data Elements Repository, and a check of the missing-data codes against the HL7 NullFlavor code system.
- An assessment of the set against the Agency's guidance Data Standards for Drug and Biological Product Submissions Containing Real-World Data (December 2023).

These are planned for later versions.

5. How to comment

Send comments to **main@metanoia-ca.org** with "CDE v1.1" in the subject line, by **2 December 2026**. Comments that arrive later will still be read and considered for later versions. Please cite the element ID (for example PUR-02) and, where you propose a change, the reason and any source. We are also interested in comments from people who hold or work with records

like these outside supervised or State-regulated programs, under the same terms as any other comment in this section.

We are particularly interested in comments from State program staff, registry operators and investigators on four questions: whether the permitted values for SET-02 and PRV-01 map cleanly onto the roles your program uses, whether the proposed code systems in PRV-02 work for your jurisdiction, whether the follow-up schedule and the case definition CD-1.1 can be operated with your follow-up resources, and whether the record model in section 1 fits the records you hold. Section 6 lists further open questions.

What happens to comments. We read every comment. With the next version we will publish a summary of the comments received and of how each point was handled. The summary names no commenter unless the commenter asked to be acknowledged.

How we may use your comment. We read every comment and reflect each point in the published summary, in our own words. If you want us to be able to quote or incorporate your wording, mark your message "contribution" at the start. For a contribution you grant Metanoia a worldwide, royalty-free, non-exclusive and perpetual license to reproduce, adapt and incorporate the text in this set and in its later versions, and to publish the result under the Creative Commons Attribution 4.0 International license (CC BY 4.0), including the right to license the incorporated text to the public under CC BY 4.0 and nothing beyond that. You keep the copyright in your text and may use it anywhere else. You may withdraw a contribution by writing to us within 30 days of sending it. After that, or once the text appears in a published version, the license for the incorporated text continues, because a CC BY 4.0 license granted to the public cannot be withdrawn. Text that is not marked as a contribution is not reproduced. Please send only material you wrote yourself or have the right to share. Do not include items or text from proprietary instruments, information about any other identifiable person, or accounts of your own or anyone else's use of any substance. This process collects comments on a specification. It does not collect exposure data.

Acknowledgment. We name contributors only when they ask us to. If you would like to be acknowledged, tell us how your name, and your affiliation if you wish, should appear.

Privacy. We use your name, email address and message only to review and respond to comments and to prepare later versions. We do not publish email addresses. You may ask us at any time to delete your name and email address, and any comment or contribution that has not yet appeared in a published version. We will delete them from our comment records, except where the law requires us to keep them. Text already published under CC BY 4.0 stays published. Our Privacy Policy: https://metanoia-ca.org/privacy

6. Open questions for comment

11. Whether the 72-hour boundary between the acute and subacute periods, and the accepted ranges of the windows (section 1), can be operated.
12. How aggregate reports, such as quarterly State counts, should report against a set that is specified for person-level records. Oregon, for example, requires service centers to submit

aggregated counts of adverse reactions and of post-session reactions each quarter (OAR 333-333-4910(5) and (6)).
13. Whether the fourth reporter value in PRV-01 should be split further, for example into family member, friend and bystander.
14. Whether OUT-05 needs levels for an emergency services contact without transport and for other outpatient care.
15. Whether the set should extend formally to entactogens such as MDMA, and to records of persons under 18.
16. Whether the new values proposed in PER-02, PER-04 and PUR-02 (PU-12 to PU-14) should stay, whether Annex B lists the right substances and materials, and whether the case definition CD-1.1 and the re-exposure rule in OUT-04 are workable.

7. Disclaimer

This document is a proposed data specification, provided as is and without warranty. It is not medical, legal or regulatory advice, and it is not guidance on the use of any substance. References to the Food and Drug Administration, to ICH, to State programs and to published studies describe what their documents say. They do not imply that any agency, program or author has reviewed or endorsed this set. Metanoia does not provide, sell, or source any controlled substance, and does not provide therapy or medical services.

8. Sources

Literature

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Verification note. PubMed records for literature sources 1 to 7 were retrieved on 22 and 23 September 2026. The statements attributed to sources 1, 3, 5, 6 and 7 were checked against their abstracts on 23 September 2026. Source 7 is cited from its PubMed record, and its full text has not yet been read. The figures attributed to source 2 were checked against its full text in PubMed Central on 24 September 2026. The figures attributed to source 4 were checked against its full text on 15 September 2026. The totals of 5,736 endorsements, the averages per person, and the rates of 4.5% and 1.6% are arithmetic performed on counts reported in those articles. The passages quoted from sources 9 and 10 were read in the published documents on 23 and 24 September 2026. The definitions quoted from OAR 333-333-1010 and the text of OAR 333-333-4910 were read in the Oregon Secretary of State's Administrative Rules database

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Annex A. Provisional crosswalk of two cohorts' reason categories to PUR-02

The category names are those reported in the two cohorts (sources 2 and 4). The mapping is provisional and is offered for comment. Where one source category could fall under more than one code, both are given. These cohort-level categories cannot be resolved into one code without person-level data on whether a clinician had diagnosed the condition (PUR-01) and whether that condition was the reason for the exposure. That ambiguity is itself the case for recording PUR-01 and PUR-02 separately.

Naturalistic cohort (Nayak et al., 2023), seven motivation categories

Source category	PUR-02 code
Self-exploration	PU-03
Mental health	PU-01 or PU-02
Therapy	PU-01 or PU-02
Creativity	PU-05
Recreation	PU-10
Productivity	PU-09
Physical health	PU-01 or PU-02

Oregon supervised program (Korthuis et al., 2026), eleven reason categories

Source category	PUR-02 code
Curiosity	PU-12
To improve or change themselves	PU-14
To treat mental health symptoms	PU-01 or PU-02
To process trauma	PU-04
Connection with others, the Earth, or nature	PU-06 and PU-13
Spiritual reasons	PU-07
Professional burnout	PU-02 or PU-09

To reduce substance use	PU-01 or PU-02
Physical health symptoms	PU-01 or PU-02
Coping with death	PU-04
Fun, enjoyment, or celebration	PU-10

Annex B. Provisional substance list for SUB-01

The list names substances and materials, not products or suppliers. It is Metanoia's reading of the scope in section 1, it is not exhaustive, and it is offered for comment. The form of what was consumed (dried, fresh, brewed, extract) is recorded in SUB-02, not here. Whether entactogens are added is open question 5.

Code	Substance or material
SB-01	Psilocybin-containing fungi
SB-02	Psilocybin or psilocin as an isolated compound
SB-03	Lysergic acid diethylamide (LSD)
SB-04	Mescaline-containing cactus
SB-05	Mescaline as an isolated compound
SB-06	DMT-containing brew or preparation, for example ayahuasca
SB-07	DMT as an isolated compound
SB-08	Other classic psychedelic (specify)
SB-09	Material sold or described as a psychedelic, identity not known