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CDISC Controlled Terminology Release Management Playbook

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Executive Summary

Clinical Data Interchange Standards Consortium (CDISC) controlled terminology release management should separate published vocabulary updates from study adoption and submission validation. As of this report's **October 2026** source check, the latest retrieved CDISC announcement is **September 25, 2026, Package 62**, with approximately **102 new Questionnaire, Rating, and Scale (QRS) terms** and **656 new terms** across its named subsets. (www.cdisc.org) A quarterly-update assumption needs revision: CDISC's terminology lead describes **biannual** publications, while older terminology documentation retains quarterly language. (www.cdisc.org) (www.cdisc.org) Neither description supplies a universal rule for upgrading in-flight studies.

The operational recommendation is to archive exact source artifacts, calculate a semantic diff against the study's adopted baseline, inspect dependencies, and approve either adoption or retention. The National Cancer Institute (NCI) provides date-versioned archives and release change files. (www.cancer.gov) (www.cancer.gov) The **March 27, 2026** worked example uses the retrieved Study Data Tabulation Model (SDTM) changes file and publication stamp. The stamp records a **March 30 modification** adding definitions to **C48918** and **C53322** in **COLSTYP**; the change report records **C100469 merged into C100467** in the laboratory test-name and test-code codelists. (evs.nci.nih.gov) (evs.nci.nih.gov) These examples justify recording both a release label and an artifact fingerprint, and reviewing paired changes together.

Study freeze should preserve a reproducible configuration while allowing an explicitly assessed change. The Food and Drug Administration (FDA) technical guide is **October 2026, Final**. (www.fda.gov) It recommends the most recent dictionary available at study start, allows newer versions later, and recommends a single terminology version for pooled analyses. (www.fda.gov) (www.fda.gov) (www.fda.gov) A sponsor's manifest should distinguish collection, transformation, validation, and submission versions. The approval should cover **case report forms**, electronic data capture, SDTM, the Analysis Data Model (ADaM), **Define-XML metadata**, validation configuration, and pooled repositories, as applicable.

The playbook supplies a **release-diff schema**, a **study-by-release decision matrix**, and definitions for affected-value rate, metadata impact, unresolved exceptions, and downstream artifact coverage. Those are proposed management controls, with sponsor-defined thresholds rather than invented universal cutoffs.

Regression testing should assess previously validated behavior; Good Clinical Data Management Practice (GCDMP) guidance recommends planning that testing. (www.jscdm.org) Adoption is complete when the semantic decisions, updated artifacts, approved exceptions, declared versions, and retained evidence agree. Gross release counts alone cannot establish study impact or authorize automatic recoding.

Introduction and Background

CDISC controlled terminology release management is the controlled selection, adoption, and documentation of vocabulary versions across clinical data systems. The Clinical Data Interchange Standards Consortium (**CDISC**) develops terminology with the National Cancer Institute (**NCI**); NCI describes content development, public review, and distribution through its terminology services. (www.cancer.gov) Terminology is available by release date, with previous versions archived. (www.cancer.gov)

Controlled terminology (**CT**) supplies standardized values and meanings. A study also needs a data model, an implementation guide, variable-level metadata, derivation rules, and a submission strategy. CDISC publishes explicit relationships between terminology subsets and variables. (www.cdisc.org) The practical consequence is that adopting a vocabulary release should not silently select a different implementation guide or rewrite an analysis specification.

This report is an implementation reference for standards governance, data management, statistical programming, metadata repository, and submission teams. Its process recommendations are **editorial implementation choices**, to be adapted to sponsor procedures. Source-specific requirements and recommendations retain their original scope. The Society for Clinical Data Management (**SCDM**) publishes Good Clinical Data Management Practice (**GCDMP**) guidance covering collection instruments, software development, management plans, and electronic data capture (**EDC**). (scdm.org)

The systems-advisory perspective is consistent with IntuitionLabs' published data engineering services, which include pipelines, integration, warehousing, and business intelligence. (intuitionlabs.ai) It does not determine what a standards body or regulator requires.

The reference date is **October 13, 2026**. The Food and Drug Administration (**FDA**) landing page identifies its current Study Data Technical Conformance Guide as **October 2026**, Final. (www.fda.gov) The March release below is historical, not the latest available vocabulary. For every adoption decision, teams should revisit the applicable catalog, guide, and release artifacts rather than reuse this report's date as an enduring compliance conclusion.

Key Changes

Replace the quarterly assumption with verified release intake

The current announcement is **Package 62, September 25, 2026**, reporting approximately **102 new Questionnaire, Rating, and Scale (QRS) terms** and **656 new terms** across its named subsets. (www.cdisc.org) These are publisher-reported approximate figures, not a count of changes affecting any individual study.

Current cadence needs care. CDISC's terminology lead biography describes **biannual terminology publications**. (www.cdisc.org) An older terminology-relationships publication discusses quarterly terminology releases alongside less frequent foundational standards. (www.cdisc.org) Those statements concern different publication contexts and dates. The operational rule proposed here is to monitor the current announcement and publication schedule, not hard-code a quarterly adoption job or extrapolate future release dates from an older description.

NCI offers changes from the previous release in Excel and text formats, and a changes-file program for comparisons over different time spans. (www.cancer.gov) (www.cancer.gov) A study skipping releases therefore needs a comparison against its actual adopted baseline, rather than an assumption that the latest consecutive-release delta captures its exposure.

Treat a release date and an artifact revision separately

For the **March 27, 2026** SDTM release, the publication stamp records a **March 30, 2026 modified date** and definitions added to **C48918** and **C53322** in **COLSTYP**. (evs.nci.nih.gov) The Study Data Tabulation Model (**SDTM**) archive therefore supplies a concrete reason to preserve artifact identity beyond the release label.

Recommended practice is to retain the original bytes, checksum, retrieval timestamp, publication stamp, and import log. A later download carrying the same release date enters intake as a distinct artifact revision. Its effect should be assessed against the bytes actually imported into each study. This provenance approach is consistent with the World Wide Web Consortium (**W3C**) model of a revision as a derivation producing a revised entity. (www.w3.org)

Distinguish term changes from codelist and model changes

The March changes file records a merge of **C100469** into **C100467** affecting **LBTEST** and **LBTESTCD**. (evs.nci.nih.gov) The file retires **LBSTRESC** referring to **SDTM Implementation Guide (SDTMIG) v4.0**, and directs users of **RACE** to the appropriate regulatory-agency terminology. (evs.nci.nih.gov) (evs.nci.nih.gov) These instructions need their stated model and jurisdiction context; they do not authorize indiscriminate rewriting of historical data.

Backward compatibility requires release-specific reading. A CDISC SEND presentation states that replaced codelists remain in terminology for compatibility. (www.cdisc.org) The **Standard for Exchange of Nonclinical Data (SEND)** example shows why replacement, retention, removal, and future model treatment should be separate diff classifications.

Manage protocol terminology as a distinct transition

For the International Council for Harmonisation (**ICH**) M11 program, ICH owns terminology and approves updates, while CDISC handles public review, reconciliation, publication, and maintenance. (www.cdisc.org) (www.cdisc.org) FDA describes M11's harmonized terminology and standardized fields for electronic protocol exchange. (www.fda.gov)

The final ICH guideline was adopted **November 19, 2025**; regional implementation is a separate step. (database.ich.org) (database.ich.org) The European Medicines Agency (**EMA**) document gives **June 11, 2026** as its coming-into-effect date. (www.ema.europa.eu) Teams migrating historical protocol metadata should

reconcile its concepts with the applicable M11 artifacts and regional guidance. This report does not assign an unverified historical retirement date or imply that a terminology transition automatically changes an approved protocol.

Release Intake and Semantic Diffing

Build an immutable intake package

NCI's date-versioned archives are the release baseline. (www.cancer.gov) The proposed intake package should contain more than the vocabulary import: it should record the release files, change reports, supplementary mappings, paired views, and the sponsor's parser configuration. Record the source and its local interpretation. W3C provenance models source-to-output transformations. (www.w3.org)

- **Identify:** Record publisher, subset, dates, URL, filename, and checksum.
- **Archive:** Preserve source bytes, stamps, and supplements.
- **Normalize:** Record encoding, parsing, and missing-value rules.
- **Compare:** Use the study's baseline, including skipped releases.
- **Trace:** Link differences to source rows, dependencies, and decisions.
- **Reproduce:** Retain comparison code and configuration.

These proposed sponsor controls require version identification. Health Level Seven International (**HL7**) Fast Healthcare Interoperability Resources (**FHIR**) distinguishes a value set's canonical identity from an identified expansion and supports explicit code-system versions. (www.hl7.org) (www.hl7.org) (www.hl7.org) FHIR is an architectural analogy here, not a required CDISC implementation technology.

Compare identities, memberships, and meanings separately

Use a compound local key such as **subset**, **codelist code**, **term code**, **release**. NCI C-codes support pairing related submission values. (www.cdisc.org) Using codes as keys does not guarantee immutable meanings. March records a merge. (evs.nci.nih.gov)

Compare membership, submission value, preferred term, synonym, definition, extensibility, and status. Preserve original strings. FDA recommends exact case and spelling for submitted controlled terms, while the Unified Code for Units of Measure (**UCUM**) distinguishes incompatible case-sensitive and case-insensitive symbol systems. (www.fda.gov) (ucum.org) Keep text normalization separate from submission-value conversion.

Table 1 specifies a proposed **release-diff schema**. Its fields are implementation choices, informed by explicit version references and provenance rather than a new CDISC-required file format. (www.hl7.org) (www.w3.org)

Field group	Recommended fields	Decision enabled
Release identity	Baseline and candidate subset, release date, artifact revision	Compare the actual adopted sources.
Artifact evidence	Source URL, filename, checksum, retrieved time, parser version	Reproduce the import and detect replacement bytes.

Field group	Recommended fields	Decision enabled
Membership key	Codelist code, term code, membership before and after	Separate concept identity from list membership.
Semantic payload	Old and new submission value, definition, synonym, preferred term	Route meaning changes to domain review.
Governance state	Published status, inferred diff class, source instruction, successor if documented	Keep observed disappearance separate from stated retirement.
Codelist rules	Extensibility before and after, implementation-guide context	Assess extension and model compatibility.
Dependencies	Paired variable, mapping target, study, dataset, derivation, repository object	Identify downstream scope.
Disposition	Owner, decision, reason, approval, exception reference, target artifact	Make adoption or retention reviewable.

The schema separates **observations**, **publisher instructions**, and **sponsor decisions**. Missing membership does not establish retirement or a successor. A parser should preserve that uncertainty for review.

Check supplementary mappings independently

Reference vocabularies need their own baselines. The historical **Logical Observation Identifiers Names and Codes (LOINC) 2.81** release notes say its change snapshot covers field and status changes but excludes newly added terms. (loinc.org) (loinc.org) LOINC illustrates why a change file alone may not enumerate every new member.

UCUM documents generated artifacts and a versioned changelog. (ucum.org) (ucum.org) The Unified Medical Language System (**UMLS**), maintained by the National Library of Medicine (**NLM**), is updated in May and November. (www.nlm.nih.gov) Record such dependencies separately; a CDISC release date cannot identify every mapping vocabulary used by the pipeline.

Implementation Considerations and Process Changes

Classify each change before deciding its treatment

The proposed classification separates **addition**, **membership removal**, **payload update**, **documented retirement**, **documented merge**, and **unknown disappearance**. NCI provides release change reports; they should be reconciled to the independently calculated diff rather than replaced by it. (www.cancer.gov) For deprecated terms, retain the exact status evidence, release, successor if documented, and study disposition. A status or successor not present in retrieved source evidence should remain unresolved.

- **Addition:** Establish study relevance before expanding permissible values.
- **Label update:** Check mappings, displays, and meaning.
- **Definition update:** Review eligibility, interpretation, and derivation.
- **Membership removal:** Check surviving memberships and variable use.
- **Deprecation:** Distinguish local flags from published status.
- **Retirement:** Preserve instructions, model scope, and jurisdiction.

- **Merge:** Verify successor semantics before recoding.
- **Unknown status:** Block unsupported automatic mapping.

The review discipline is consistent with an authored PharmaSUG governance paper recommending documented approval and downstream-impact assessment. (pharmasug.org) (pharmasug.org) These conference recommendations are implementation guidance, not regulatory requirements.

Assess historical values against the pinned release, permitted set, guide, and submission context. Retention still needs review when the intended use changes.

Handle paired TEST and TESTCD as a dependency

CDISC's paired views bring related submission values together but are not the complete terminology distribution. (www.cdisc.org) Clinical Data Acquisition Standards Harmonization (**CDASH**) guidance illustrates vital-sign codes obtained from **VSTESTCD**. (www.cdisc.org) The operational proposal is to maintain paired relationships as reviewable dependencies, rather than deduce every relationship from similar labels.

Check each affected pair's identity, membership, submitted strings, case, and qualifiers against the applicable guide. Route laboratory name-and-code merges to paired review, with a documented source-to-output decision.

Treat PARAM and PARAMCD in their analysis context

An older PharmaSUG ADaM design paper describes a one-to-one **PARAM/PARAMCD** relationship and explains that PARAM lacks the accompanying qualifiers used with SDTM TEST. (pharmasug.org) (pharmasug.org) PARAM denotes an analysis parameter; PARAMCD denotes its code. That dated paper is technical guidance, not a substitute for the study's applicable current Analysis Data Model (**ADaM**) implementation guide.

Check parameter dictionaries, derivations, units, population relevance, and dataset-context consistency. Do not equate every sponsor-derived analysis parameter with a published NCI term. CDISC's ADaM primer identifies SDTM as the source and Define-XML as the metadata delivery standard, supporting examination of the full transformation chain. (www.cdisc.org)

Resolve extensibility before approving a custom value

The CDASH Implementation Guide (**CDASHIG**) permits additions to extensible lists for concepts not already represented by a submission value, synonym, or preferred term; non-extensible lists are used without additions. (www.cdisc.org) (www.cdisc.org) It also permits familiar collection wording that maps directly to a submission value. (www.cdisc.org) Collection synonyms differ from new submission terms.

- **Search equivalence:** Check existing submission values, definitions, preferred terms, and synonyms.
- **Check permission:** Determine the applicable codelist's extensibility and variable constraints.
- **Define meaning:** Specify the proposed concept and prevent overlap with existing values.
- **Request standardization:** Submit a genuinely missing concept early; older FDA guidance expressly recommends early requests. (www.hhs.gov)

- **Document use:** Identify unavoidable custom terms and explain them consistently, as the current FDA guide recommends. (www.fda.gov)

Record exception owner, scope, reason, mapping, approval, review trigger, and evidence. Sponsor-specific approval does not change the published extensibility flag or create a new official CDISC release.

Study Freeze and Version Selection

Make study adoption a separate controlled decision

A **study freeze** is the sponsor's defined boundary for changing selected study metadata and transformations. It is an implementation policy, not a universal quarterly-upgrade requirement. FDA recommends the most recent dictionary available at study start and permits use of a newer version after start. (www.fda.gov) (www.fda.gov) The distinction leaves room for controlled adoption, but does not establish a sponsor's acceptable operational risk.

Create a **study terminology manifest** recording sources, fingerprints, guides, permitted values, extensions, mappings, and validator configuration. Distinguish collection, tabulation, analysis, validation, and submission roles. FHIR supports exact code-system versions and a fixed date for otherwise unversioned references; that design pattern illustrates why ambiguous references should be eliminated. (www.hl7.org) (www.hl7.org)

Table 2 is a proposed **study-by-release decision matrix**. It supplies review questions and evidence. GCDMP guidance supports version control for case report forms (**CRFs**) and records of when sites change CRF versions. (www.jscdm.org) (www.jscdm.org)

Study situation	Default review posture	Evidence before a change
Study design, before collection	Consider the current applicable release.	Catalog and guide checks, permissible-set review, mappings, approved manifest.
Active collection	Preserve the baseline pending scoped assessment.	Site and CRF version plan, affected values, EDC behavior, rollback and communication.
Near database lock	Require an explicit benefit and controlled implementation plan.	Query implications, dataset reproducibility, analysis and metadata regression.
Locked study	Preserve original provenance; assess a separately versioned transformation.	Baseline outputs, approved recoding rules, derivation trace, before-and-after review.
Submission preparation	Reconcile declared and validated versions.	Current jurisdiction-specific rules, Define-XML, reviewer guide, validation evidence.
Pooled analysis	Assess a harmonized target independently of study baselines.	Cross-study mappings, meaning checks, unresolved exceptions, pooled lineage.
Same-date artifact correction	Assess the exact corrected bytes.	Checksum comparison, source correction evidence, targeted impact assessment.

Publication, lock, and submission are different triggers. Where approved downstream transformations use another target, document it separately from the collection baseline. FDA recommends explaining the impact of different terminology versions, where applicable. (www.fda.gov)

Distinguish catalog eligibility from CT adoption

FDA's [catalog](#) describes supported or required standards and their dates; its submission page ties supported study-data formats to study start. (www.fda.gov) (www.fda.gov) These statements should not be expanded into a requirement to adopt every terminology publication. Check applicable catalog rows, submission type, and current guidance.

Japan provides a validation example. The Pharmaceuticals and Medical Devices Agency (**PMDA**) March 2025 provisional English Frequently Asked Questions (FAQ) describes gateway validation using the entered CT version and asks applicants to validate against the intended version. (www.pmda.go.jp) (www.pmda.go.jp) It also asks for explanation where dataset-creation and validation terminology versions differ. (www.pmda.go.jp) This is a reason to track both roles, not evidence that every jurisdiction uses the same mechanism.

PMDA's electronic-data page describes rules for additional data submitted after an application. (www.pmda.go.jp) Health Canada's filing guidance distinguishes electronic Common Technical Document (**eCTD**) and non-eCTD formats by regulatory activity. (www.canada.ca) Check jurisdiction-specific obligations without inferring a Canadian CT freeze policy.

Keep pooling separate from historical provenance

FDA recommends pooled analyses use a single terminology version. (www.fda.gov) Use a versioned harmonization layer retaining study provenance. Review semantic preservation, derivation changes, and unmapped concepts before approving the pooled target.

Regeneration, Regression Tests, and Evidence

Regenerate the dependent artifacts as a connected system

Regenerate dependent artifacts or document their unaffected status. GCDMP's EDC maintenance chapter recommends considering related systems and programs during an upgrade. (www.jscdm.org) A PharmaSUG governance paper similarly recommends assessing downstream effects of standards changes. (pharmasug.org) The proposed control is an explicit dependency inventory.

- **CRFs:** Review labels, choices, synonyms, instructions, and direct submission mappings.
- **EDC:** Review configuration, edit checks, imports, exports, site deployment, and historical capture.
- **SDTM:** Review mapping specifications, values, paired fields, and permissible membership.
- **ADaM:** Review analysis-parameter dictionaries, derivations, traceability, and presentation labels.
- **Define-XML:** Reconcile declared versions, applicable values, and sponsor extensions with generated datasets.
- **Validation rules:** Pin terminology configuration and distinguish rule-engine upgrades from vocabulary updates.
- **Pooled repositories:** Review ingestion, cross-study mappings, provenance, and target terminology.

Define-XML **v2.1** added identification of referenced standards and CT versions. (www.cdisc.org) The operational recommendation is to generate declared versions from the approved manifest and compare them with actual transformation inputs. A declaration should identify any pipeline that resolves a live vocabulary behind the scenes.

Use the study's applicable guide for permissible-set details. Historical SDTMIG guidance includes planned but unobserved permissible values, restricts the set to planned collection, and excludes null as an explicit member. (www.cdisc.org) (www.cdisc.org) (www.cdisc.org) Thus, comparing only observed dataset values is insufficient to review the study metadata.

Test effects on previously validated behavior

The peer-reviewed GCDMP Software Development Life Cycle chapter recommends specifying regression testing in the test plan and examining impacts on previously validated requirements. (www.jscdm.org) (www.jscdm.org) Recommended CT tests should cover semantic dependencies and reproducibility, not only whether a file imports successfully.

- **Baseline reproduction:** Rebuild the previously approved outputs using their archived inputs and configuration.
- **Membership checks:** Evaluate candidate values against the correct subset, release, and codelist.
- **Pair checks:** Detect mismatched names and codes within applicable domain and dataset rules.
- **Mapping checks:** Find missing targets, unintended many-to-one collapses, and unexpected new custom terms.
- **Definition review:** Route substantive meaning changes to the responsible clinical or analysis specialist.
- **Case and units:** Compare exact submission strings and separately review unit semantics.
- **Metadata checks:** Compare planned permissible sets, actual data, declared versions, and annotations.
- **Output comparison:** Classify expected changes and investigate unexplained differences.

UCUM permits implementations with limited conformance to compare unit expressions literally, which may leave equivalent meanings undetected; it also permits flagging whitespace as an error. (ucum.org) (ucum.org) This supports separate tests for original submission strings, mapping behavior, and unit interpretation. It does not justify silently rewriting every stored unit into an assumed canonical form.

Approve a reproducible release, with a rollback path

The proposed approval package contains the archived candidate, calculated diff, impact inventory, unresolved exceptions, regression results, reviewer documentation, and a signed adoption or retention decision. A governance paper recommends version control, periodic reviews, and documented maintenance. (pharmasug.org) GCDMP's EDC maintenance guidance recommends establishing rollback or fallback before an upgrade. (www.jscdm.org)

Assign standards interpretation, collection, programming, metadata, and submission owners. Sponsor procedures determine approval authority. Automation may assemble evidence; unresolved clinical meaning should reach the designated owner.

Link the baseline, candidate, transformation, outputs, and approval as distinct evidence objects. W3C provenance describes both derivation and revision relationships. (www.w3.org) (www.w3.org) Reruns should identify each output's sources and approved decisions.

Data Analysis and Evidence

What the retrieved release figures can establish

A release-wide additions count describes publication scope. To assess the percentage of study records requiring recoding, calculate impact from the study's used concepts and data. Treat separate publisher totals as separate populations until their relationship is verified, rather than adding them into an unsupported combined figure.

The historical SEND presentation reports **32 new codelists** developed for **SEND Implementation Guide (SENDIG) v4.0** and identifies the **March 27, 2026** publication. (www.cdisc.org) (www.cdisc.org) Those facts provide dated nonclinical context, not an estimate of SDTM or ADaM workload. The archived SDTM stamp separately documents a same-release correction to definitions. (evs.nci.nih.gov) Counts, model scope, and artifact revision therefore require separate columns in an intake register.

The March SDTM merge example is more actionable than a gross additions count: the code-to-successor instruction identifies a concrete mapping dependency. (evs.nci.nih.gov) Even then, the change file does not supply the number of affected records in a sponsor's study. No conversion success rate, productivity estimate, cost saving, or universal adoption threshold is implied here.

Calculate study exposure from declared denominators

Table 3 provides **editorial calculation definitions** for the adoption review. These are proposed management metrics, not regulator-specified acceptance limits. The need to assess related systems and previously validated behavior is supported by GCDMP guidance. (www.jscdm.org) (www.jscdm.org)

Metric	Calculation	Interpretation and denominator control
Affected-value rate	Records using changed codes / coded records	Define dataset, variable, baseline, and change class; use distinct records when multiple changed fields occur.
Metadata impact	Affected codelists / codelists used	Count within the study's defined scope; include planned values and affected definitions.
Unresolved exceptions	Count of open exceptions at the decision time	Report reason, owner, disposition needed, and whether each blocks the intended use.
Downstream artifact coverage	Assessed artifacts / artifacts in scope	Include CRFs, EDC, SDTM, ADaM, Define-XML, validation configurations, and pooled repositories where applicable.

The formulas require **declared scope**. A coded-record denominator should not fluctuate because one run counted cells and another counted rows. Report a zero denominator as not applicable, rather than treating it as evidence of no impact. Artifact coverage should include a reviewed finding of no change, with evidence, rather than count only regenerated outputs.

Sponsor-defined thresholds should follow the proposed change's meaning, timing, and downstream dependencies. A small affected-value rate may involve an important endpoint definition; broad metadata impact may concern harmless display changes. Rate and coverage summarize exposure, while semantic review explains its consequences. No universal cutoff follows from the retrieved publications.

Separate evidence dates from adoption dates

FDA's current guide is **version 6.3, October 2026**, while its earlier June guide also allowed newer dictionary versions after study start. (www.fda.gov) (www.hhs.gov) The retrieved catalog identifies itself as **v11.0**. (www.fda.gov) Record guide and catalog snapshots alongside the sponsor's adoption date; publication recency alone does not prove that a study's proposed configuration is supported.

Implications and Future Directions

Make version resolution explicit across the metadata repository

The implementation priority is a reproducible version-resolution service. A study should request an approved manifest, not an unspecified latest codelist. HL7 distinguishes canonical identity, an expansion identifier, and a referenced code-system version. (www.hl7.org) (www.hl7.org) (www.hl7.org) A repository can apply the same separation without using FHIR or assuming that CDISC objects share every FHIR rule.

Reference terminologies will continue to need separate monitoring. NLM describes vocabulary-specific metadata in UMLS, and UCUM documents its own generated artifacts and release changes.

(www.nlm.nih.gov) (ucum.org) (ucum.org) Governance should preserve dependency versions and prevent a shared mapping service update from silently changing frozen study transformations.

IntuitionLabs' published information-layer approach emphasizes connecting AI to authoritative enterprise sources with permissions, retrieval, citations, and evaluation. (intuitionlabs.ai) In this setting, that perspective supports using automation to collect and trace release evidence while leaving adoption authority with the sponsor's designated standards and study owners.

Recheck regional implementation and evolving exchange formats

M11's template and technical specification are versioned documents, and the guideline says they do not supersede other protocol-content guidance. (database.ich.org) (database.ich.org) EMA identifies its current M11 guideline as adopted, while FDA's M11 materials are labeled **Final, May 2026**. (www.ema.europa.eu) (www.fda.gov) Protocol terminology governance should therefore track regional implementation separately from a central vocabulary import.

The same discipline applies to emerging exchange formats. FDA's **April 9, 2025** Federal Register notice requested comments on accepting **Dataset-JSON**, rather than announcing an immediate replacement mandate. (www.govinfo.gov) The notice describes linkage to Define-XML. (www.govinfo.gov) A historical consultation is not evidence of current catalog eligibility; implementation teams should verify current status before adoption.

SCDM distinguishes legacy GCDMP chapters from current guidance. (scdm.org) A sustainable release-management process should make that distinction equally visible in its own evidence register: current requirement, dated recommendation, historical example, or sponsor implementation choice.

Conclusion

CDISC controlled terminology release management should produce a reviewable decision and a reproducible study configuration. Release intake, study adoption, and submission validation are connected activities with different scopes. The proposed playbook gives each an explicit source, owner, baseline, and evidence package.

The central operating discipline is to compare meaning and dependency, not merely filenames or additions. Archive the exact artifacts. Separate membership changes from definition changes, documented retirement, and documented successors. Review paired fields within their applicable guides. Check extensibility before introducing a custom value. Keep each study's adopted baseline visible, including the mappings used when a downstream target differs.

For in-flight studies, decide whether to retain, migrate, or transform through a scoped approval. Include collection, tabulation, analysis, metadata, validation, and pooling in the assessment. Measure affected values, metadata exposure, unresolved exceptions, and evidence coverage with declared denominators. Use sponsor-defined acceptance criteria and document why the chosen action suits the study's timing and intended use.

Finally, retain the diff, regression results, exceptions, approvals, and rollback evidence together. A successful adoption is not simply a newer release installed in a repository. It is an explained change whose source artifacts, semantic decisions, resulting outputs, and submission declarations can be reconstructed. That is the practical purpose of a study freeze: controlled, evidenced change throughout the study lifecycle.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.cdisc.org/standards/terminology/controlled-terminology>
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IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

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