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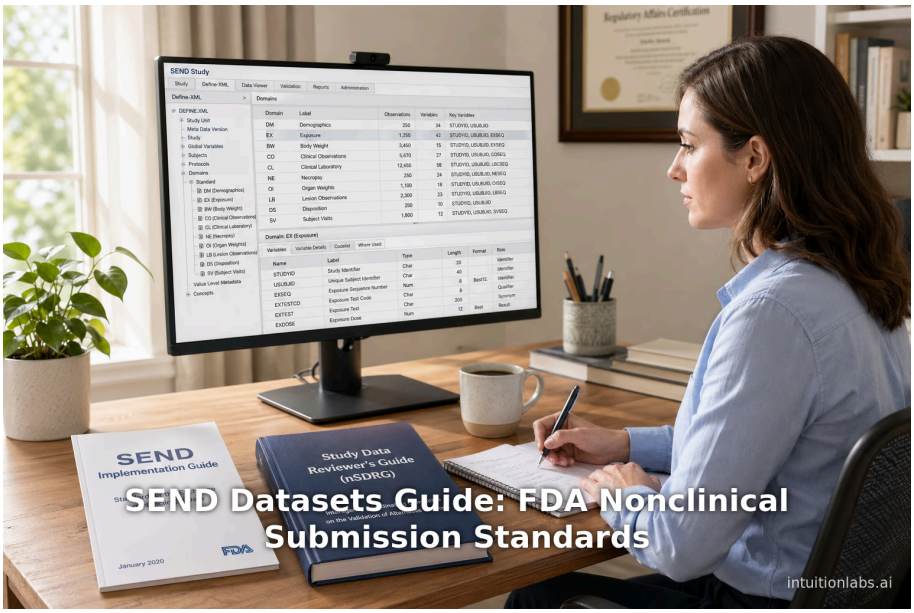
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SEND Datasets Guide: FDA Nonclinical Submission Standards

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Published by IntuitionLabs · 2026-04-20 · send datasets · fda nonclinical submissions · cdisc standards · sendig · sdtm framework · define-xml · toxicology data · nsdrg

Original article: https://intuitionlabs.ai/articles/send-datasets-fda-nonclinical-submissions



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Executive Summary

The **Standard for the Exchange of Nonclinical Data (SEND)** is the CDISC-endorsed standard for organizing nonclinical (toxicology, pharmacology, etc.) study data in regulatory submissions to the FDA. First released in 2011 (SENDIG v3.0) under SDTM v1.2, and subsequently updated (e.g. v3.1 in 2016 under SDTM v1.5, and v3.1.1 in 2021), SEND is explicitly built on the SDTM framework (www.cdisc.org). In practice, SEND provides an **"SDTM-like" Implementation Guide** tailored for animal studies, prescribing domains and variables that mirror clinical SDTM datasets but accommodate nonclinical study design (e.g. animals instead of human subjects, dosing periods, tissue findings, etc.) (www.cdisc.org). The FDA **requires** SEND datasets for in-scope nonclinical studies (for example single-dose and repeat-dose toxicity and carcinogenicity studies) started after the dates set in its Data Standards Catalog (FDA Study Data Technical Conformance Guide). Key components of a SEND submission include dataset files (datasets like TS, TA, TX, DM, DS, SE, EX, and any applicable findings datasets), a metadata Define-XML file, and a nonclinical Study Data Reviewer's Guide (nSDRG) (www.certara.com). Industry panels and FDA experts emphasize that the uniform format improves review efficiency and enables cross-study analysis of toxicology data (pubs.acs.org) (pointcrosslifesciences.com). For example, aggregated SEND data from nearly 1,900 studies has been used to quantify background lesion incidence in control animals, with 94% of microscopic-finding records in SEND v3.1 using standardized terms (pubs.acs.org). This report reviews the historical development of SEND, current FDA rules and timelines, the technical structure of SEND datasets, tools and processes for implementation, case examples of usage, and future directions for SEND and standardized nonclinical data submission.

Introduction and Background

Standardized Study Data has been required for clinical trials (CDISC SDTM and ADaM) for years. Under the Food and Drug Administration Safety and Innovation Act (FDASIA, 2012) and subsequent guidance, the FDA mandated that certain submissions (INDs/NDAs/BLAs etc.) include standardized tabulation data – specifically

SDTM for clinical studies and SEND for applicable nonclinical studies (www.certara.com). The FDA's *Data Standards Catalog* lists the required standards and effective dates. In brief, all in-scope nonclinical studies (e.g. general toxicology, carcinogenicity, safety pharmacology, and DART studies) **"started on or after"** the catalog's deadlines must be submitted in SEND format (www.certara.com). Sponsors should always check the Data Standards Catalog for the current requirements for each study type (FDA Study Data Technical Conformance Guide). In addition, submission files must meet the technical rejection criteria laid out in the FDA's Study Data Technical Conformance Guide (TCG) (www.certara.com).

SEND is a specialized implementation of the **CDISC Study Data Tabulation Model (SDTM)** for animal (nonclinical) data. In CDISC's own words, "SENDIG is developed in reference to a specific SDTM model. … The SDTM is cumulative – each new release builds on the previous model. Therefore, the models are backward compatible" (www.cdisc.org). In effect, SENDIG versions align with successive SDTM releases. For example, *SENDIG v3.0* (June 2011) was designed to be used with SDTM v1.2 (www.cdisc.org), while *SENDIG v3.1* (June 2016) is based on SDTM v1.5 (www.cdisc.org). By CDISC policy, "Each new SEND release must include an assessment and realignment with the SDTM model and the SEND standard" to maintain cross-domain alignment (www.cdisc.org). In practice, this means new SDTM features (e.g. new variables or conventions) flow into subsequent SENDIG releases, ensuring that SEND always remains an "SDTM-like" IG for nonclinical data.

SEND was developed collaboratively by CDISC, the FDA, and industry stakeholders beginning around 2007–2011. The first published SEND Implementation Guide (SENDIG v3.0) appeared on June 17, 2011 (www.cdisc.org). It covered single-dose and repeat-dose general toxicology and carcinogenicity studies. In the years since, new domains and IGs have been added: for example, SENDIG v3.1 added dedicated Safety Pharmacology domains (Cardiovascular and Respiratory), and updated vital signs and microscopic findings domains (www.cdisc.org). Specialized IGs have also been released for unique study types. **SENDIG-DART v1.2** (2023) covers data from developmental and reproductive toxicology (DART) studies, in particular embryo-fetal development (EFD) studies and toxicity studies conducted on juvenile animals (note that FDA's current SEND requirement is for SENDIG-DART v1.1 for EFD studies, and Appendix D of the FDA Study Data Technical Conformance Guide lists SENDIG-DARTv1.2 among the CDISC properties that CBER and CDER have evaluated and do not consider to align with their current business needs; the list may not be comprehensive, so consult the review division), and **SENDIG-AR v1.0** supports "Animal Rule" studies (where human trials are not ethical) (www.cdisc.org). **SENDIG-Genetox v1.0**, covering in vivo comet and micronucleus genetic toxicology tests, has also been published and is supported in the FDA Data Standards Catalog, as described in the FDA Study Data Technical Conformance Guide. In tandem, *controlled terminology* and *conformance rules* have been developed to ensure consistent data use. CDISC notes that controlled terms are used for fields like specimen and finding identifiers, and conformance rule sets codify the SENDIG's logic to support validation (www.cdisc.org).

In sum, SEND provides a rigorous, **machine-readable tabulation** of nonclinical study data, analogous to how SDTM provides standardized formats for clinical trials (www.certara.com) (www.cdisc.org). By submitting nonclinical datasets in SEND format with accompanying metadata (Define-XML) and documentation (nSDRG), sponsors enable regulatory review with powerful data analysis tools. As one industry author observes, standardized SEND data "allows regulatory agencies to streamline the review of the non-clinical sections of drug submissions" (www.certara.com) Sponsors also see benefits: consistent formatting and controlled

vocabularies mean that data from multiple studies (even from different CROs or from prior legacy studies) can be merged and queried easily, facilitating meta-analyses and historical control comparisons (pointcrosslifesciences.com) (pubs.acs.org). In this report, we detail the evolution, structure, regulatory requirements, implementation practices, and future directions of SEND data standards for FDA nonclinical submissions.

Regulatory Requirements and Timeline

FDA Standards Mandate

The FDA issued final guidance clarifying that submission of standardized study data would become mandatory under FDASIA 745A(a) for certain application types (www.fda.gov) (www.certara.com). Specifically, the *FDA Data Standards Catalog* (maintained by CDER/CBER/CDRH/CDV) lists which study types and effective dates apply. For **nonclinical (GLP/NGS) studies**, CDER's SEND requirement applies to studies started after **December 17, 2016** (NDAs/BLAs) and after **December 17, 2017** (commercial INDs) for SENDIG v3.0, and these rules have since expanded and been updated as new SEND IGs have been released (FDA Study Data Technical Conformance Guide). Per the October 2026 Technical Conformance Guide (always confirm against the current FDA Data Standards Catalog), the requirements include:

- **SEND IG v3.1.1** (the latest base SEND standard) became *required* for in-scope single-dose toxicity, repeat-dose toxicity, carcinogenicity and cardiovascular/respiratory safety pharmacology studies started after March 15, 2023, for both CDER NDAs/BLAs and commercial INDs (FDA Study Data Technical Conformance Guide).
- SEND datasets (v3.1 or v3.1.1) are required for nonclinical studies submitted to the FDA's Center for Biologics Evaluation and Research (CBER) that started after March 15, 2023, for NDAs, BLAs, ANDAs and commercial INDs, per the FDA Data Standards Catalog as reflected in the Technical Conformance Guide (FDA Study Data Technical Conformance Guide).
- The **SENDIG-AR (Animal Rule) v1.0** applies to CDER nonclinical natural history and efficacy studies for Animal Rule submissions: SEND datasets are required for studies initiated after March 15, 2022 for NDAs, ANDAs and BLAs, and after March 15, 2023 for certain INDs for which the CDER review division expects a full tabulation of data (FDA Study Data Technical Conformance Guide).
- The **SENDIG-DART (DART v1.1)** applies to CDER embryo-fetal development (EFD) studies: the SEND requirement applies to studies started after March 15, 2023 for NDAs/BLAs and after March 15, 2024 for commercial INDs (FDA Study Data Technical Conformance Guide).
- **Define-XML** (metadata spec): the Data Standards Catalog lists the currently supported version(s) (FDA Study Data Technical Conformance Guide).
- The **SENDIG-Genetox v1.0** (for in vivo genetic toxicology) is listed in the FDA Data Standards Catalog; the SEND requirement applies to studies started after 3/15/2025 (see the Technical Conformance Guide linked above).
- Additional requirements: CBER also requires SENDIG-AR for CBER submissions, for studies starting after 3/15/2027 (see the Technical Conformance Guide linked above).

Table 1 below summarizes selected FDA deadlines and scope for SEND standards. (These dates come from the FDA Data Standards Catalog, as reflected in the October 2026 Technical Conformance Guide (FDA Study Data Technical Conformance Guide).)

Standard / Guide	Requirement applies to studies started after	Regulatory Scope	Notes
SENDIG v3.1.1	Mar 15, 2023	CDER and CBER (NDAs/BLAs and commercial INDs)	Latest base SEND model (general tox, etc.)
SEND (v3.1 or v3.1.1)	Mar 15, 2023	CBER (NDAs, INDs)	Prior to this, only CDER required SEND.
SENDIG-AR v1.0	Mar 15, 2022 (NDA); Mar 15, 2023 (IND)	CDER (NDAs, INDs)	Animal Rule (nonclinical efficacy) studies
SENDIG-AR v1.0 (CBER)	Mar 15, 2027	CBER (NDAs, INDs)	(Animal Rule for biologics)
SENDIG-DART v1.1 (EFD)	Mar 15, 2023 (NDA); Mar 15, 2024 (IND)	CDER (NDAs, INDs)	Embryo-Fetal Development studies
SENDIG-Genetox v1.0	Mar 15, 2025	CDER (NDAs, INDs)	In vivo genetic toxicology data
Define-XML	See Data Standards Catalog	CDER and CBER	Catalog lists the currently supported version(s)

Table 1. Key FDA data standards requirements for nonclinical studies (from FDA Data Standards Catalog).

As the above shows, the FDA treats SEND very similarly to SDTM: once a standard is "required," *every* new study in scope must provide data in that format. The FDA's Study Data Technical Conformance Guide states that, per the FDA Data Standards Catalog, studies started after the listed dates require SEND datasets (FDA Study Data Technical Conformance Guide). For legacy nonclinical studies that began before the deadlines, sponsors may submit an abbreviated SEND package (TS dataset) with their original reports; in these cases the FDA allows an "abbreviated TS" in place of full datasets (www.certara.com).

In addition to the standards themselves, the FDA enforces separate business/validator rules and technical criteria on SEND data. The Study Data Technical Conformance Guide (TCG) contains business rules (e.g. v1.5) and validator rules (v1.6) that apply to both SDTM and SEND datasets (www.fda.gov). For example, FDA's *Business Rules v1.5 (May 2019)* document states it "applies to SDTM formatted clinical studies and SEND formatted non-clinical studies" (www.fda.gov). These rules check conformance of variable names, controlledTerminology, dates, and relationships across datasets (www.fda.gov). FDA staff and working groups (e.g. PhUSE) have also published additional clarifications – for instance, templates for the nSDRG have been circulated to help sponsors meet expectations (www.certara.com).

Regulatory Documents and Guidance

Key FDA guidances and resources include the *Providing Regulatory Submissions in Electronic Format – Standardized Study Data* guidance (Final, June 2021) and the Study Data TCG (www.fda.gov). These outline the overall requirement under FD&C Act Section 745A(a) to submit standardized data, and specify that after 24 months from the final guidance, certain submission types must include machine-readable data. The Data Standards Catalog is the FDA's reference for which standards are supported or required and from what dates. FDA also maintains quick-links pages for study data standards (www.fda.gov). Notably, as of 2025 the FDA and CDISC are evaluating a future move away from SAS XPT files to a **CDISC Dataset-JSON** format for submissions, indicating ongoing modernization (www.fda.gov).

Technical Structure of SEND Datasets

SEND data are delivered as **SAS XPT (transport) files**, one file per dataset (domain). The fundamental domains are analogous to SDTM's, but tailored to animal studies. Key core domains in every SEND package include *Trial Summary (TS), Trial Arms (TA), Trial Elements (TE), Trial Sets (TX), Demographics (DM), Disposition (DS), Subject Elements (SE),* and *Exposure (EX)* (www.certara.com). The variables in these domains (for example, USUBJID, STUDYID, domain-specific keys) largely mirror SDTM conventions, but there are also new variables and domains as needed for study design. For example, the **Trial Arms** (TA) and **Trial Elements** (TE) domains define the planned experimental arms and treatment sequences – trial-design datasets that describe the planned study design (www.certara.com).

Each study's SEND package also includes one or more **findings/observations domains** appropriate to that study's endpoints. For a general toxicology study, such endpoint domains might include *Body Weights (BW)*, *Clinical Observations (CL)*, *Laboratory Tests (LB)*, *Microscopic Findings (MI)*, etc. For example, in a simple repeat-dose rat study the SEND package might contain TS, TA, TE, TX, DM, DS, SE, EX, plus *BW.xpt* (for serial weights), *CL.xpt* (clinical signs), perhaps *LB.xpt* (clinical pathology), etc. (www.certara.com). In practice, the exact list of endpoints is study-specific and guided by the SENDIG's CoDEx mapping. Table 2 (below) illustrates a sample SEND file list and domains for a hypothetical toxicology study with body-weight and observation data (www.certara.com).

XPT File	Domain (abbr.)	Contents
ts.xpt	Trial Summary (TS)	High-level study info (objective, design, population) (www.certara.com)
ta.xpt	Trial Arms (TA)	Planned treatment sequences/arms
te.xpt	Trial Elements (TE)	List of treatment events (e.g. dosing regimens)
tx.xpt	Trial Sets (TX)	Group assignment information (treatment vs control)
dm.xpt	Demographics (DM)	Animal-level demographics (ID, sex, species, etc.)
ds.xpt	Disposition (DS)	Animal disposition (e.g. study completion status)
se.xpt	Subject Elements (SE)	Timing of study elements (exposure, observations) for each animal

XPT File	Domain (abbr.)	Contents
ex.xpt	Exposure (EX)	Dosing records (dates, amounts for each animal)
bw.xpt	Body Weights (BW)	Body weight measurements (study day vs weight)
cl.xpt	Clin. Observations (CL)	Qualitative/graded clinical signs for each animal

Table 2. Example SEND datasets for a nonclinical toxicology study (as per FDA example) (www.certara.com).

SEND datasets are accompanied by **Define-XML** metadata. This XML file describes all variables, labels, and controlled terms used in the XPT datasets, enabling FDA reviewers to navigate the datasets easily. The FDA's Study Data Technical Conformance Guide states that the Data Standards Catalog lists the currently supported version(s) of Define-XML (FDA Study Data Technical Conformance Guide). (Define-XML v2.1 allows multiple standard references and new constructs for empty datasets, but for SEND it is largely similar to v2.0 with incremental features.) The related *SAS XPT* files themselves follow the XPT v5 format, and the FDA reports that initial results from testing CDISC Dataset-JSON indicate potential use as a replacement for XPT v5 (FDA).

Another strongly recommended component is the **Nonclinical Study Data Reviewer's Guide (nSDRG)**. This is a PDF document written by the sponsor that explains the SEND datasets in relation to the study report. The FDA's Technical Conformance Guide states that the nSDRG is *"recommended as an integral part of a standards-compliant study data submission."* (www.certara.com). While the exact format is not mandated, it typically includes explanations of any nonstandard domains or variables, definition of analysis flags, handling of blanks or missing values, and any assumptions or derivations. Industry working groups (e.g. PhUSE Nonclinical WG) have published templates to guide nSDRG content. Thus, each SEND submission is not just raw data; it includes the XPT files, Define-XML, an XSL stylesheet (for human viewing of the define.xml), and an nSDRG, all packaged in the eCTD (module 4) of the application (www.certara.com).

Domain Definitions and Controlled Terminology

The SENDIG specifies a set of about 30+ **domains** that cover standard study data (Table 2 lists some core ones). Depending on study design, further findings domains are used beyond these. Each domain has a set of **variables**, many of which are identical or analogous to SDTM variables (e.g. `USUBJID`, `STUDYID`, `SPECIES`, `SEX`). Many variables in SEND are inherited from SDTM (e.g. the DM variables), and others are new or redefined for the animal context. Users must populate variables with values from the standardized **Controlled Terminology** (CDISC CT). For example, permissible values for `SPECIES` are drawn from the SEND CT lists (e.g. "Dog" or "Rat" identifiers) published by CDISC. Versions of CDISC Controlled Terminology are updated with each SEND release (e.g. new specimen terms for DART studies).

The use of controlled vocabularies is a key feature. For instance, in the SENDIG v3.1 standard a controlled term variable `MISTRESC` (Microscopic Finding Result, Char) was defined in the MI domain. A recent analysis showed that in submitted SEND v3.1 datasets, 94% of all microscopic finding records had the `MISTRESC` field populated with a term from the official CT list (pubs.acs.org). (By contrast, v3.0 had no defined terms for this field, so 0% of records were coded.) Controlled terms thus ensure that results can be reliably searched and aggregated across studies (pubs.acs.org).

SEND also incorporates **Supplemental Qualifiers (SUPP)** domains (e.g. `SUPPMI`) for more detailed data. For example, if a rat had multiple microscopic lesion findings for one slide, additional findings may be captured in SUPP or related records. The Implementation Guide provides rules for how to link records across domains using standard keys (e.g. `EXTRT`, `EXDOSE` in EX domain link to TA/TE). There are also **controlled timing variables** (e.g. `DY`, `DTC` for study day or date-time) to standardize time points. Overall, the SENDIG enforces a strict tabulated model – *unstructured text* is not allowed in the main datasets, and free-format narratives should be kept in the CSR text (although some study-level comments can go in **Comments** variables). This rigor ensures the datasets are fully machine-readable.

Implementation and Data Quality Processes

Implementing SEND in practice involves generating the required domains and ensuring all rules are met. Many sponsors work with CROs or standards vendors to extract data from study databases or legacy records and convert them to SEND XPTs. A typical workflow includes: mapping raw data (e.g. animal tables, assay outputs) to the SEND domains; applying controlled terms; populating any study-level (TS) parameters; and generating Define-XML and the nSDRG. Specialized software tools or ETL scripts (SAS, R, or commercial tools) are often used.

Quality control is critical. Because the FDA will technically “validate” the submission, sponsors must run *conformance checks* beforehand. CDISC publishes *SEND Conformance Rules* (separate from FDA’s Business Rules) which codify many SENDIG rules. These can be checked with validation tools (e.g. Pinnacle 21, SAS CRT). The FDA’s own Business Rules (v1.5) and Validator Rules add FDA-specific checks (e.g. required columns, code lists). Indeed, FDA reviewers have noted common errors in submitted SEND data, such as missing records or mis-spelled terminology. The agency even offered webinars on “common issues” when reviewing safety pharmacology SEND data (www.fda.gov). These errors can complicate review. The TCG’s eCTD technical rejection criteria (Appendix F) check items such as a valid study tagging file and a ts.xpt with the study start date, and whether studies started after the cut-off dates are submitted in a CDISC standard; other conformance discrepancies should be corrected or explained in the nSDRG. Sponsors therefore perform careful QC, often involving review of the nSDRG by nonclinical scientists to ensure alignment with the source study reports.

The **Nonclinical Study Data Reviewer’s Guide (nSDRG)** deserves special mention. While not strictly enforced, it is “recommended as an integral part” by the FDA (www.certara.com). In practice, the nSDRG is often the hardest document to prepare, because it requires explaining any deviations from pure SEND. For example, if a company adds a custom domain or leaves a SEND domain empty (because a particular endpoint was not measured), the nSDRG must note and justify this. A typical nSDRG will describe each domain file, define any custom columns, list the tables and listings produced by each dataset, and specify the controlled terminology versions used. The FDA's Technical Conformance Guide asks that the nSDRG be named nsdrg and provided as a PDF file (nsdrg.pdf) (FDA Study Data Technical Conformance Guide). In short, a SEND submission is more than just data files: it is a structured data package complete with metadata and documentation.

Analysis and Case Examples

One of the major motivations for SEND is to enable *analysis of aggregated toxicology data*. With standardized formats, repositories of pooled nonclinical datasets become possible; for example, FDA CDER maintains a repository of sponsor-submitted SEND studies. Researchers and reviewers can then query these data across studies and sponsors. A striking example comes from a cross-industry research report (Carfagna et al. 2020) that analyzed SEND data in the FDA repository (pubs.acs.org). In that study, analysts posed queries about nonclinical findings (e.g. “What are the most common microscopic findings in male beagle dogs age 12–18 months dosed by oral gavage?”) and succeeded in retrieving answers by leveraging SEND domain data. They found that in control dogs, findings in testis (mature), pituitary gland, parathyroid gland, and thymus were among the most frequently recorded terms – consistent with common background lesions described in dogs (pubs.acs.org). Crucially, they noted that the introduction of controlled terms in SEND v3.1 made this analysis possible: “Perhaps the most significant improvement facilitating cross-study analysis was the introduction of Controlled Terminology in SENDIG v3.1 for microscopic findings” (pubs.acs.org). Indeed, the paper reports that, for SEND v3.1 datasets, 487,216 of 516,007 microscopic-finding records (94%) had MISTRESC populated with a Controlled Terminology term (pubs.acs.org). Without the controlled terminology, automated queries would have failed or required manual coding.

These kinds of case studies illustrate the power of SEND data aggregation. They also provide quantitative insight: for instance, Carfagna et al. reported that the animal’s age at the time of a finding could be calculated for 3,735,312 of 3,803,024 findings records (98.2%), demonstrating that key metadata are usually present (pubs.acs.org). Analysis of such data can reveal incidence of rare findings, help set historical control ranges, or even support AI modeling. From the sponsor’s perspective, submitting good quality SEND data can therefore yield feedback and insights long after submission. In discussions, regulators have pointed to ongoing research leveraging SEND data for predictive toxicology and cross-study safety analysis.

In practice, sponsors have reported case-study successes. For example, large pharmaceutical companies have internally used SEND to consolidate data from legacy studies and to prepare integrated analyses. Converting legacy toxicology studies into SEND can be laborious; one consultant notes that converting older studies (pre-2016) is tedious but valuable, because it enables integration into overall safety summaries and helps avoid review delays (bioforumgroup.com). Moreover, SEND data are beginning to be used by sponsors to generate ADaM-like analysis datasets for toxicology (though ADaM is not currently required for nonclinical), pushing data analysis beyond regulatory compliance into research uses.

Implications, Benefits, and Challenges

Benefits: The uniform SEND standard brings multiple advantages. Regulatory reviewers no longer have to manually parse PDF tables; instead they can load the datasets and automatically run safety analyses (as was done in the Carfagna study). This makes reviews faster and potentially more thorough. For sponsors, having structured data upfront can simplify later life-cycle uses (e.g. additional analyses, regulatory reporting for post-approval studies). Standardization also facilitates data sharing between companies and with consortia (for example, aggregated SEND datasets are increasingly used in toxicogenomics and drug repurposing

research). In sum, experts echo that SEND **“improves the quality of the data”** and **“reduces the cost of implementing the standard”** in the long run (www.cdisc.org). In fact, industry sources note that submitting standardized data can “increase the likelihood of a successful review at the first attempt” by eliminating workflow bottlenecks and providing clear, consistent data to reviewers (pointcrosslifesciences.com).

Challenges: On the other hand, implementing SEND is nontrivial. Organizations must build or license tools to convert legacy data, map to new domains, and perform extensive QA. There is a learning curve: toxicologists, data managers, and programmers must all understand the SENDIG rules. Sponsors must also manage versioning (e.g. choosing v3.1 vs 3.1.1). In some cases, not all collected endpoints fit neatly into existing domains, leading to creation of *custom domains*. (SEND v3.1 added flexibility to define custom domains.) In rare cases, ambiguous data or missing information from old studies must be handled carefully; the nSDRG becomes critical here. Failure in internal QC can lead to submission delays or FDA queries. The FDA’s recent webinars on common SEND issues (www.fda.gov) underscore that even well-prepared sponsors sometimes submit incomplete or inconsistent datasets (missing records, incorrect timing, incorrect file formats, etc.).

It is also an organizational change. Pharmaceutical R&D groups have traditionally focused on narrative reports for GLP studies; transitioning to a data-centric approach requires process changes. Smaller companies or biologics firms (which faced SEND mandates only in 2023) may struggle more than large pharmas. Globally, the FDA has been ahead: requirements outside the US are less uniform, so check each agency's current guidance (though ICH PHS harmonization encourages CDISC standards, and discussions about nonclinical data standards are ongoing internationally). Nonetheless, experience with the FDA indicates that SEND becomes a permanent part of the nonclinical documentation ecosystem.

Future Directions

SEND standards continue to evolve. CDISC has been developing **SEND v4.0** (final publication was targeted for 2026; FDA support and requirement dates are set only after publication, so check the current status with CDISC and FDA) which is expected to incorporate new domains like *Immunogenicity Specimen Assessments (IS)* for antibody data (www.certara.com). This reflects feedback from CBER on including ADA (anti-drug antibody) data. The FDA is already providing interim guidance: until IS exists, CBER suggests placing immunogenicity results in the LB domain or a custom IS domain (www.certara.com). Similarly, updates to existing domains (e.g. for new assays or advanced assays) will come as the science advances.

Other technological trends are also shaping SEND’s future. As noted, FDA/CDER are exploring CDISC’s *Dataset-JSON* format to replace XPT (www.fda.gov), which could modernize how SEND data are packaged. Machine learning and AI from big data are another frontier: aggregated SEND repositories may feed models that predict toxicity. There are also efforts to streamline cross-center data flow – for example, using standardized SEND data for cross-study queries of sponsor-submitted studies, as in the CDER repository analysis described above.

On the regulatory side, enforcement remains a focus. The TCG and business rules continue to be updated, so sponsors must stay current. Meanwhile, the culture of clinical–nonclinical data integration is growing: with both arms of drug development using CDISC standards (SDTM/ADaM and SEND), cross-domain analyses (e.g.

linking PK from animals to humans) become more feasible. This “fit-for-use” principle of standards (www.cdisc.org) will likely encourage SEND to become a foundational asset not just for submission but for R&D analytics.

Finally, training and community support (PhUSE CONs, CDISC tutorials, etc.) will expand. The FDA’s outreach (webinars, KickStart/OCS services) and industry best practices (SAS tools, open-source scripts) mean that over time the barriers to SEND compliance will lessen. Academic research may also leverage SEND data. In all, the move to SEND is a step in the digital transformation of drug development. Its trajectory suggests deeper integration of data standards into both regulatory review and scientific innovation.

Conclusion

The SEND (SDTM-like) Implementation Guide has rapidly become the required standard for FDA nonclinical submissions. From its origins in 2011 through the latest 2021 and future releases, SEND has evolved to capture the complexity of animal studies in a structured, harmonized way (www.cdisc.org) (www.certara.com). The FDA requires SEND datasets for the in-scope study types listed in its Data Standards Catalog, reflecting a regulatory commitment to data standardization (FDA Study Data Technical Conformance Guide). This alignment between SEND and SDTM ensures that nonclinical and clinical data can be jointly understood and analyzed.

The practical impact is significant: sponsors who invest in SEND implementation benefit from more efficient FDA reviews and the ability to run powerful analyses across large datasets (www.certara.com) (pubs.acs.org). The FDA and CDISC’s continued collaboration – through controlled vocabularies, versioning, and new tool support – helps make SEND a living standard that keeps pace with science. At the same time, sponsors must contend with the challenges of converting legacy studies and meeting strict conformance. However, well-implemented SEND data can support smoother reviews and can even yield business intelligence (e.g. safety meta-analyses) that accelerates drug development.

Looking forward, SEND will likely expand (e.g. new domains in v4.0) and integrate with modern data ecosystems (JSON, analytics platforms). The foundational principle remains that standardized nonclinical data benefit all stakeholders – sponsors, regulators, and ultimately patients – by making safety data more transparent, comparable, and usable (pointcrosslifesciences.com) (pubs.acs.org). In conclusion, implementing the SEND “SDTM-like” standard is now an essential part of nonclinical research and regulatory strategy. All claims and guidelines cited here are drawn from FDA guidances, CDISC documentation, and published studies, and reflect the October 2026 FDA Technical Conformance Guide; confirm current requirements in the FDA Data Standards Catalog before relying on them (www.certara.com) (pubs.acs.org).

References: Registered eCitations from regulatory guidance, CDISC standards, and peer-reviewed literature as indicated (e.g. FDA Technical Guides, CDISC SENDIG releases (www.cdisc.org) (pubs.acs.org)).

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/foundational/send/sendig-v3-0

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About IntuitionLabs

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.

Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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