The Current Use and Future Vision of SEND at FDA

Stephanie Leuenroth-Quinn, PhD
Associate Director for Pharmacology and Toxicology
FDA/CDER/OND/IO

April 22, 2026

CDISC SEND Public Meeting

U.S. FOOD & DRUG ADMINISTRATION

Disclaimer

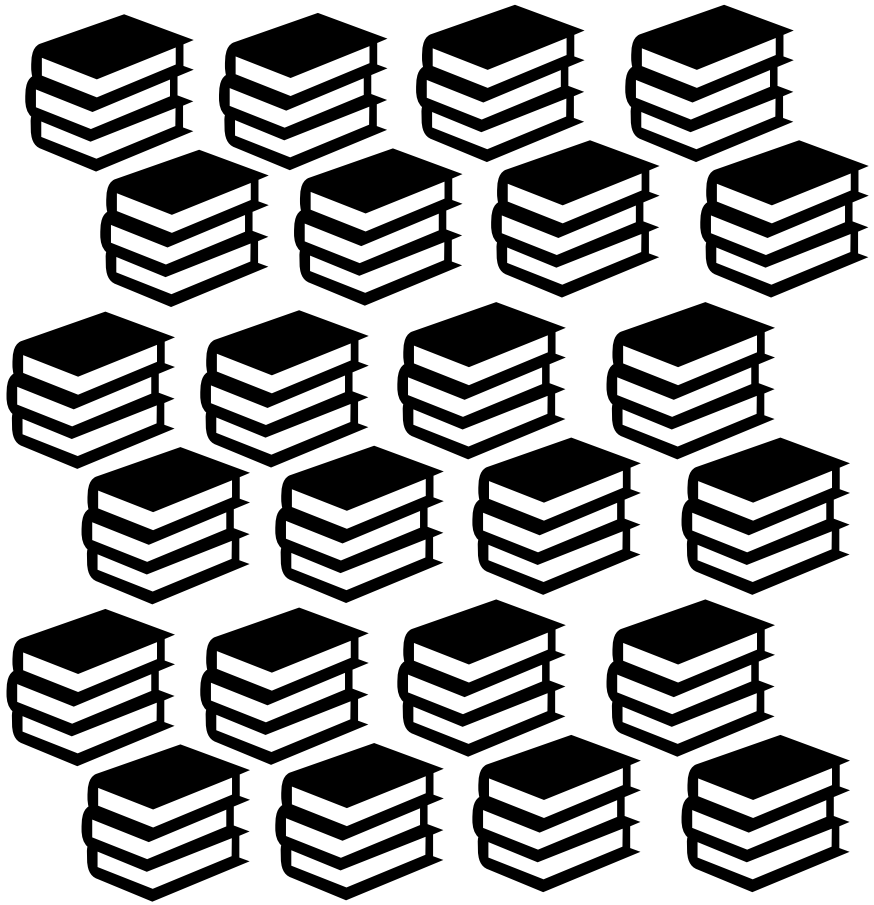
This presentation reflects the views of the speaker and should not be construed to represent FDA's views or policies.

Agenda

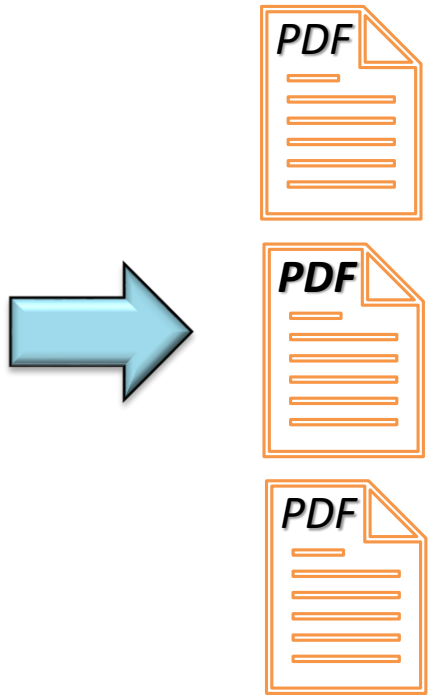
- Current Use of SEND at FDA
- Future Interest in SEND Development for In Vitro Studies
- Additional Brief Topics:
  - Request for Use of Specific TSPARMCDs
  - March Study Data TCG 2026
  - File Tags added to the March 2025 Study Data TCG

The Use of SEND at FDA

Paper Submissions



Electronic Study Reports



SEND

Standardized Study Data

SEND is used by the Pharm/Tox Discipline Across Roles:

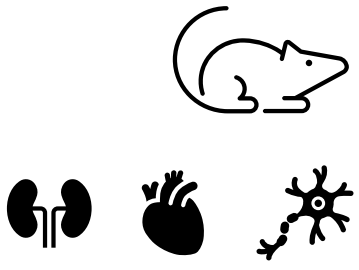
- Primary Reviewers
- Supervisors/Team Leads
- Division Directors
- Associate Directors

Nonclinical IND Review and SEND

Toxicology

SEND Requirements

General Toxicology
In vivo Genetox



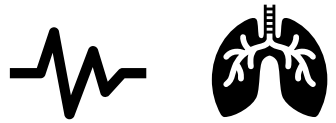
Nonclinical Safety Profile to Support Human Safety

Rodent Carcinogenicity
Reproductive Toxicology (EFD)
Future SENDIGs - TBD

Pharmacology

SEND Requirements

Safety Pharmacology (CV, RE)



Analyzing Study Results (30-Day IND): Using SEND

- Single Study: Assessing multiple study endpoints to determine target organs of toxicity (safety)

1-month study toxicology

BW, CL, FW, MA, OM, PP, LB, **MI**, etc.

e.g., Identification of cardiac toxicity in one species

- Multiple Studies: Assessing results (toxicities) of multiple studies within the same species (duration, dosing) and across species to determine risk to human subjects. Utilizing the concept of Cross-Study Analysis.

1-month study toxicology

1-month study toxicology

BW, CL, FW, MA, OM, PP, LB, **MI**, etc.

BW, CL, FW, MA, OM, PP, LB, **MI**, etc.

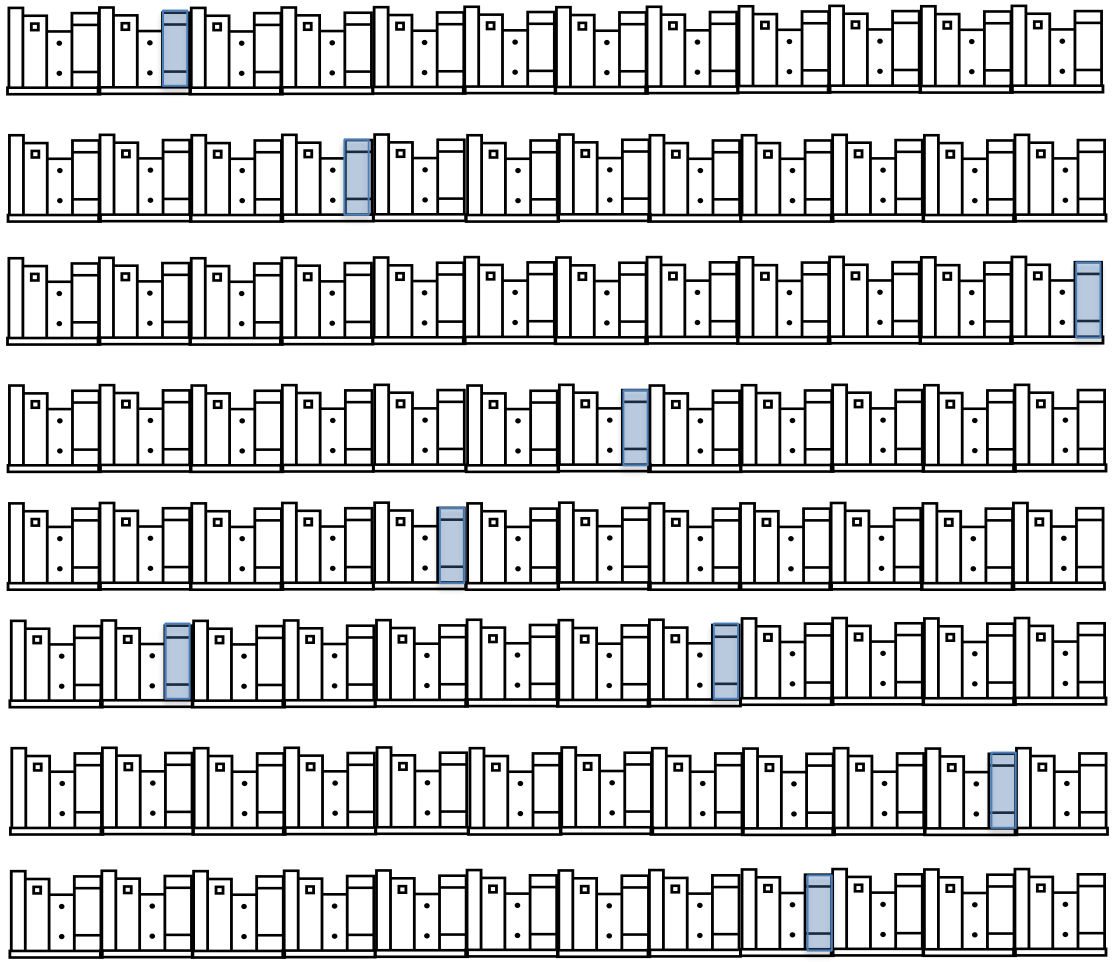
e.g., Identification of cardiac toxicity in two species

Advanced Uses of SEND – Present Day

Examples of How SEND Can be Used Beyond Primary Review:

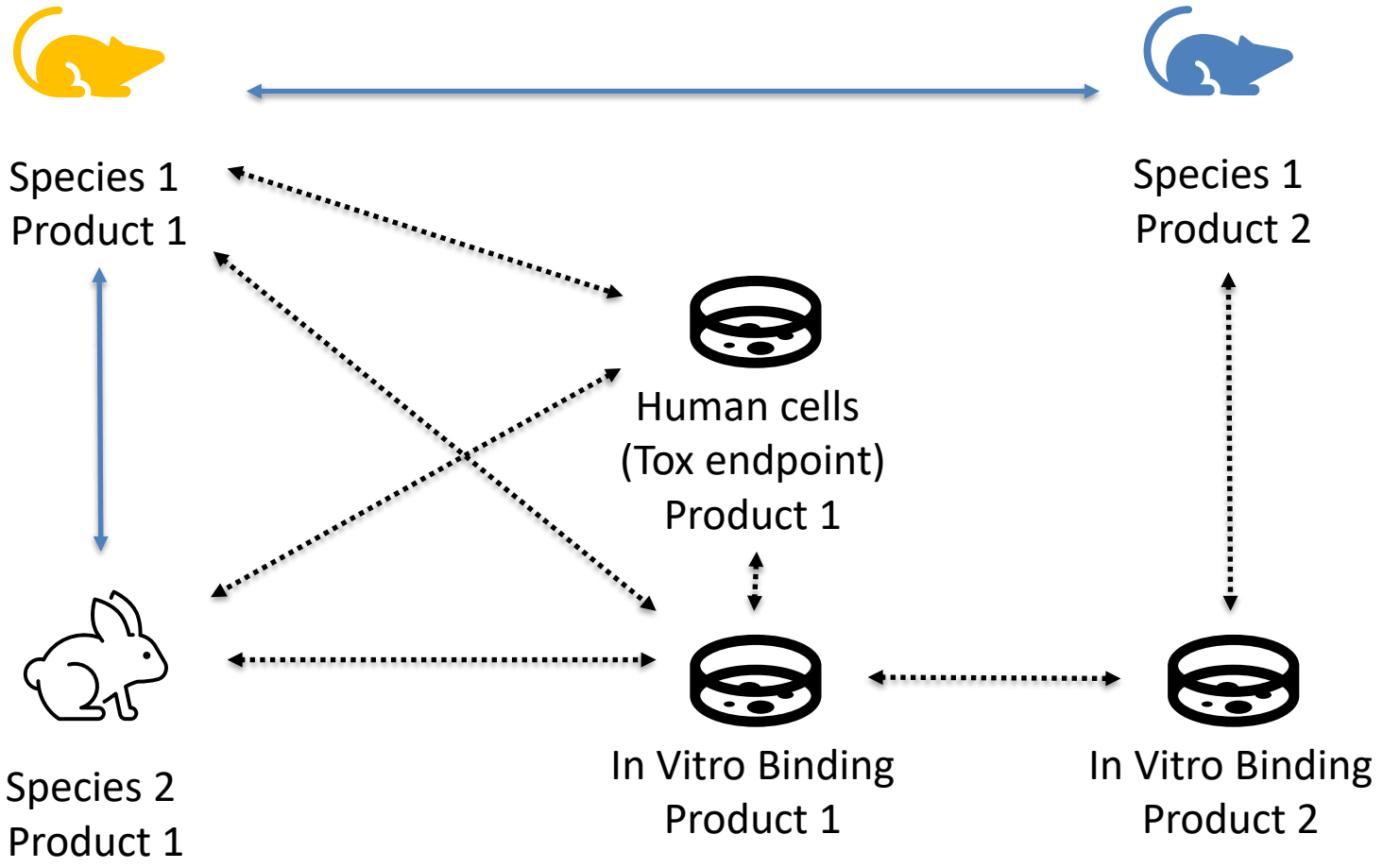
- Independent Analysis of Large Datasets
- Query toxicity profiles within the same pharmacologic class
- Species differences/ similarities in toxicity profiles
- Product type toxicity profiles (small molecule, biologic, oligo)
- Standardized information to be used to populate template information
- Data mining efforts to inform scientific publications, guidance and external communication

"Library" of SEND Datasets: Finding Information

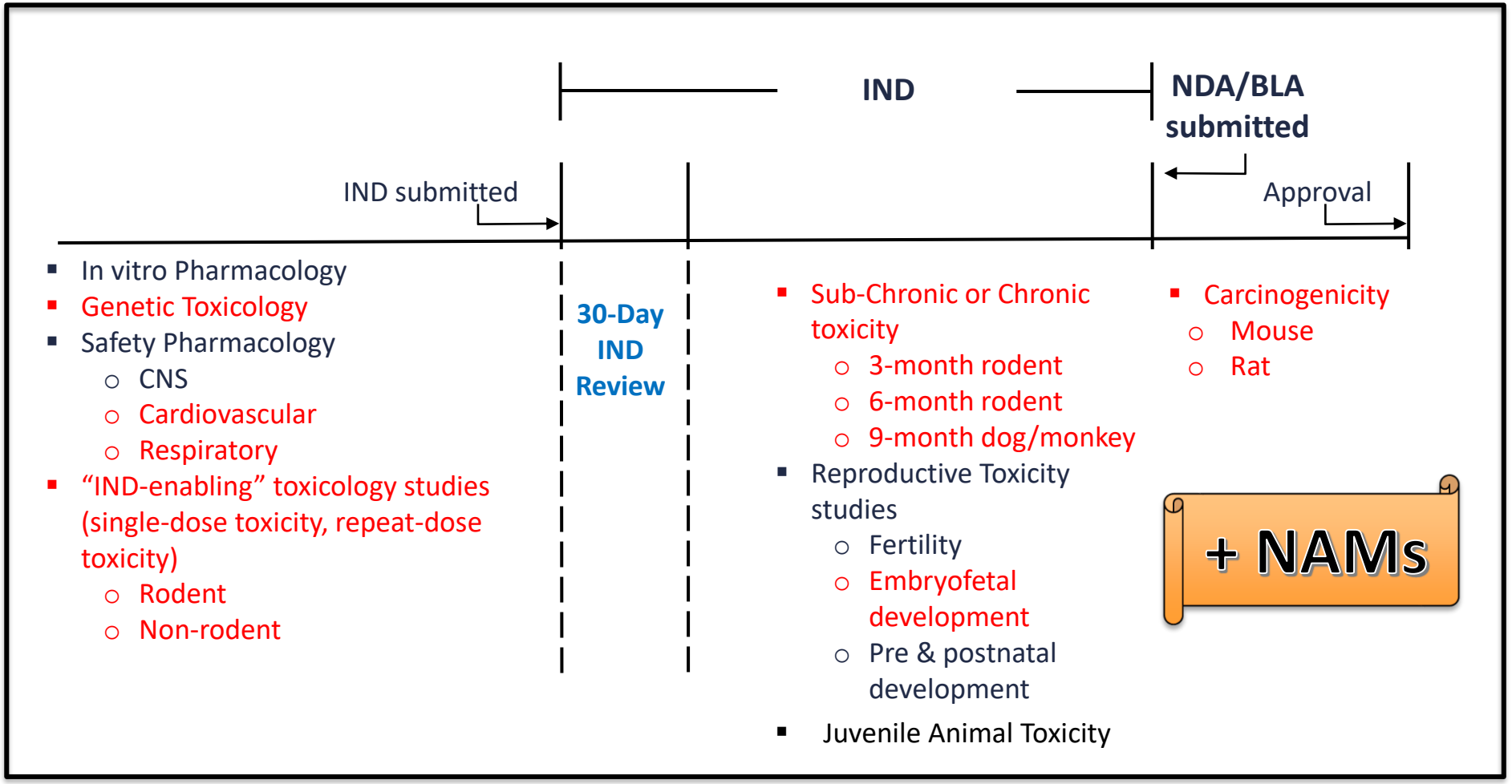


Standardized Data: Connecting Information

Integration and analysis of data not only between in vivo studies (current state) but linkage of information to in vitro studies as well (future vision)



SEND Submissions Throughout Development

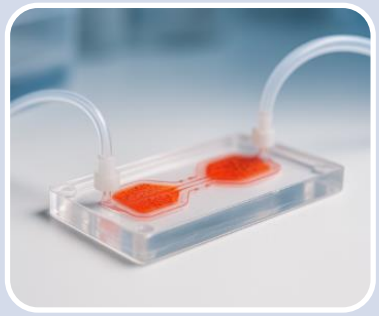


- In vitro Pharmacology
- Genetic Toxicology
- Safety Pharmacology
  - CNS
  - Cardiovascular
  - Respiratory
- "IND-enabling" toxicology studies (single-dose toxicity, repeat-dose toxicity)
  - Rodent
  - Non-rodent

- Sub-Chronic or Chronic toxicity
  - 3-month rodent
  - 6-month rodent
  - 9-month dog/monkey
- Reproductive Toxicity studies
  - Fertility
  - Embryofetal development
  - Pre & postnatal development
- Juvenile Animal Toxicity

- Carcinogenicity
  - Mouse
  - Rat

Examples of NAMs



In Vitro

3D models, microfluidic systems, organ chip

In Silico

Quantitative structure activity relationship (QSAR), artificial intelligence (AI)

In Chemico

Direct peptide reactivity assay

Nonhuman In Vivo

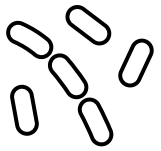
Alternative organisms, C. elegans, zebrafish

Other

Bioprinting, bioengineering, multi-electrode array (MEA)

Slide courtesy of Nakissa Sadrieh, PhD

In Vitro Assays, NAMs and SEND



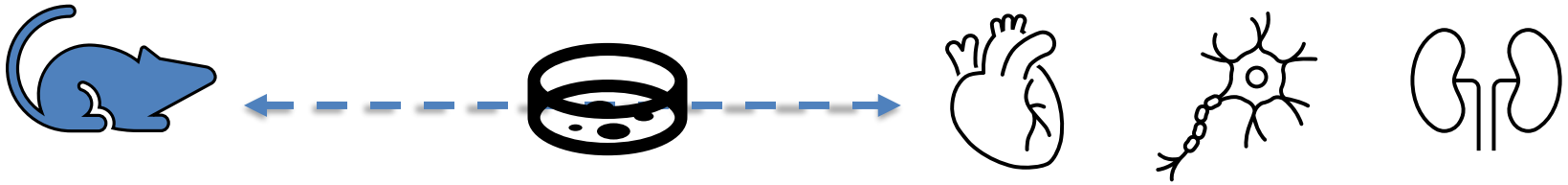
- Expansion of Genetic Toxicity to such in vitro assays as the Ames assays or in vitro Chromosome aberration assays.

- Safety Pharmacology (e.g., Cardiovascular)
- Reproductive Toxicity/ Teratogenicity

- Microphysiological Systems (MPS) (e.g., microfluidic systems)
- 3D model (e.g., organoid, spheroid, organ chip, organotypic)

- Stem cells (e.g., induced pluripotent stem cells (iPSCs) or human-induced pluripotent stem cells (hi-iPSC)
- Complex in vitro method (CIVM)

Future SEND Standards

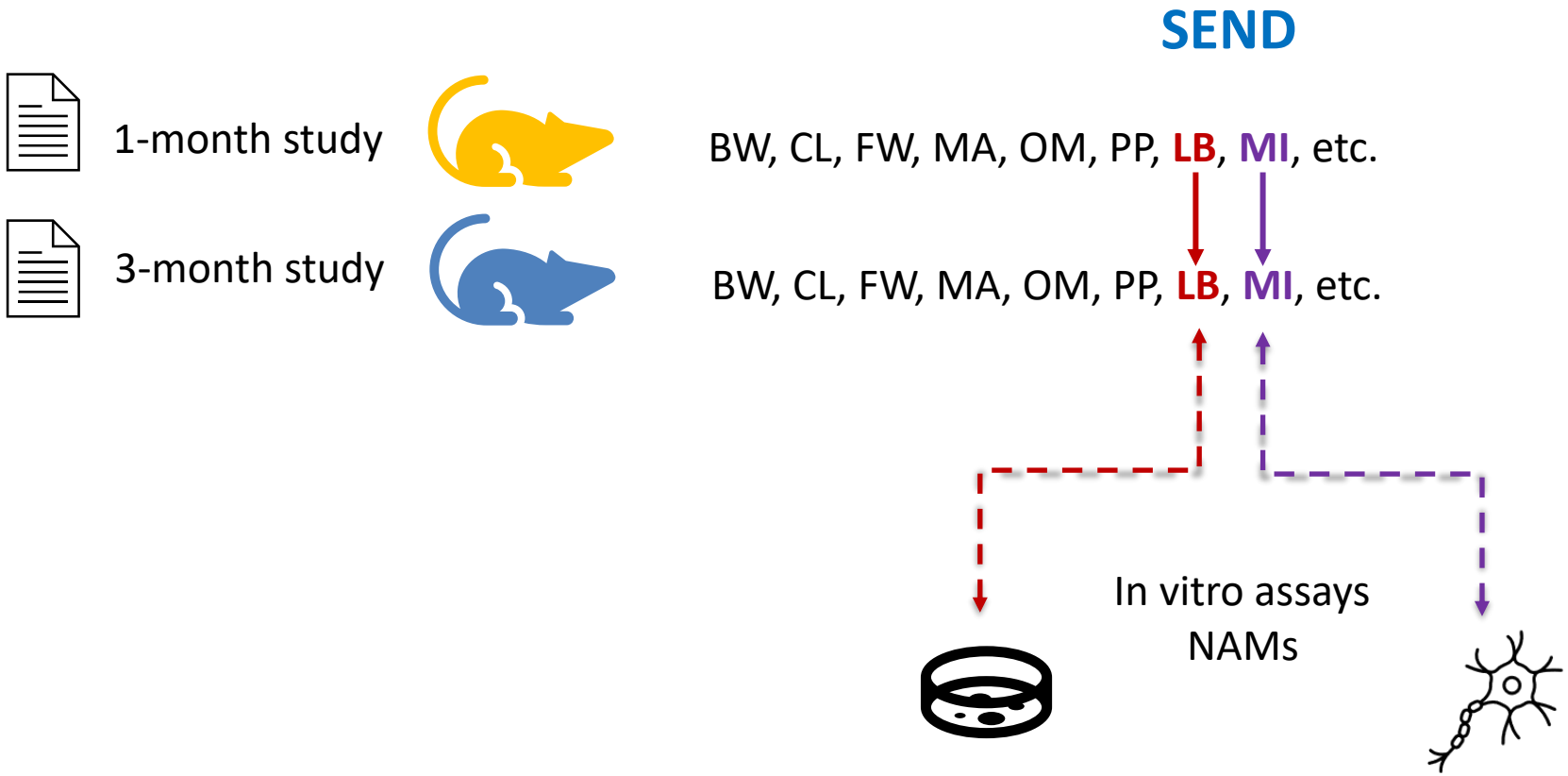


Current SEND:
General Tox
Carcinogenicity
Safety Pharm (CV, RE)
EFD
In vivo Genetox
Animal Rule

Future SEND:
In vitro
Pharmacology
Secondary Pharmacology
Safety Assessments

Continued Interest in the development of in vivo SEND standards:
Reproductive Toxicology Studies: FEED and PPND
Genetic Toxicology Battery of Studies (in vitro and in vivo)
CNS Safety Pharm

Bridging In Vivo and In Vitro Data



- Assessment of similar biomarkers between in vivo and in vitro studies
- Follow-up toxicity concern with in vitro safety assessments
- Standardized correlation between in vivo and in vitro endpoints

ADDITIONAL BRIEF TOPICS

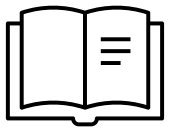
sdTCG – Appendix C - TSPARMCD

- PCLASS: Pharmacologic Class/ Class of Compound (Refer to MED-RT for terminology)
- PPTCNAM: Planned Pharmacologic Target Common Name
- PPTEGSYM: Planned Pharmacologic Target Entrez Gene Symbol
- PPTEGID: Planned Pharmacologic Target Entrez Gene Identifier
- PPTMDA: Planned Pharmacologic Target Mode of Action

Including information on the pharmacologic class, gene target and/or mode of action in SEND is useful to the Agency.

March 2026 Study Data TCG

- The March 2026 edition added a new Appendix (**Appendix I**): Best Practice – SEND Data Review Prior to Submission to CDER and CBER
- The intent of this section to convey minimal practices needed for the verification of SEND. This is not an exhaustive resource of detailed checks of every study type.
- Common issues have been identified over time that prevent the use of SEND datasets in certain circumstances.
- This section is subject to updates as needed (e.g., new standards are available).



Best Practice for SEND Data Review

- Background
- Common Issues:
  - Issues with submission
  - Issues with basic SENDIG conformance
  - Issues with representation of study design and data in SEND
- General Expectations for SEND Study Data Verification
- Best Practice Recommendations for Review of SEND Study Data Prior to Submission

File Tags (Nonclinical and Clinical)

The Study Data Technical Conformance Guide

File Tags Section 7.1.5 (Nonclinical and Clinical)

Study Data Technical Conformance Guide:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document

FDA Study Data Standards Resources:

https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources

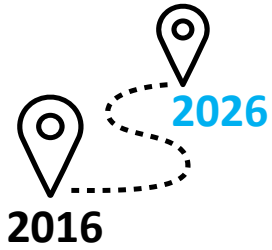
Applies to Study Reports/ Documents

Nonclinical File Tag	Intended Use
animal-rule-efficacy	Use to tag nonclinical efficacy studies conducted for products regulated under the Animal Rule
animal-rule-natural-history	Use to tag nonclinical natural history studies that are conducted with chemical, biological, radiological, or nuclear agents and used for animal model development for products regulated under the Animal Rule
weight-of-evidence	Use to tag nonclinical weight-of-evidence or risk assessment documents
study-data-reviewers-guide	**Use to tag SDRG for nonclinical data** **Use to tag SDRG for clinical data**

Nonclinical File Tags for NAMs

Applies to Study Reports/ Documents

Nonclinical File Tag	Intended Use
nonstandard-safety-study	Use to tag nonclinical studies conducted to provide complementary safety information to standard pharmacology and toxicology studies
PD-invivo-study	Use to tag in vivo nonclinical mechanism of action or proof of concept studies that supplement standard primary and secondary pharmacology studies
PD-invitro-study	Use to tag in vitro nonclinical mechanism of action or proof of concept studies that supplement standard primary and secondary pharmacology studies



Use of SEND at FDA

- Data Standards Requirements for FDA first implemented for Marketing Applications December 17, 2016 (SENDIG v3.0).
- The number of SEND datasets submitted to CDER are >20,000.
- Reviewers find great value in SEND and are disappointed when not available.
- Supervisors can quickly check data and confirm reviewer conclusions by using SEND visualizations.
- Use and interest has grown over time. Reviewer use remains high, as we move into an era of using SEND for data mining, and special projects.
- SEND allows for maintaining independent analysis of data, while saving time to find information in study reports (efficiency!)

Thank you, CDISC!


FDA
U.S. FOOD & DRUG
ADMINISTRATION