cdisc®

2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

SEND Framework: A Journey From Preclinical Raw Data to a Standardized Package for Submission. A Focus on Genetox Preclinical Studies

Matteo Cortivo, Associate Data Scientist & Data Analyst, Evotec
Sergio Garofalo, Research Data Scientist & Data Analyst, Evotec

Speakers

Matteo Cortivo
Associate Data Scientist & Data Analyst
Evotec

Sergio Garofalo
Research Data Scientist & Data Analyst
Evotec

Agenda

1. SEND-IG Overview
2. Preclinical Dashboard
    - Innovative and Interactive Report
    - In Life Report
3. GENETOX-IG

SEND-IG Overview

SEND-IG v3.1.1

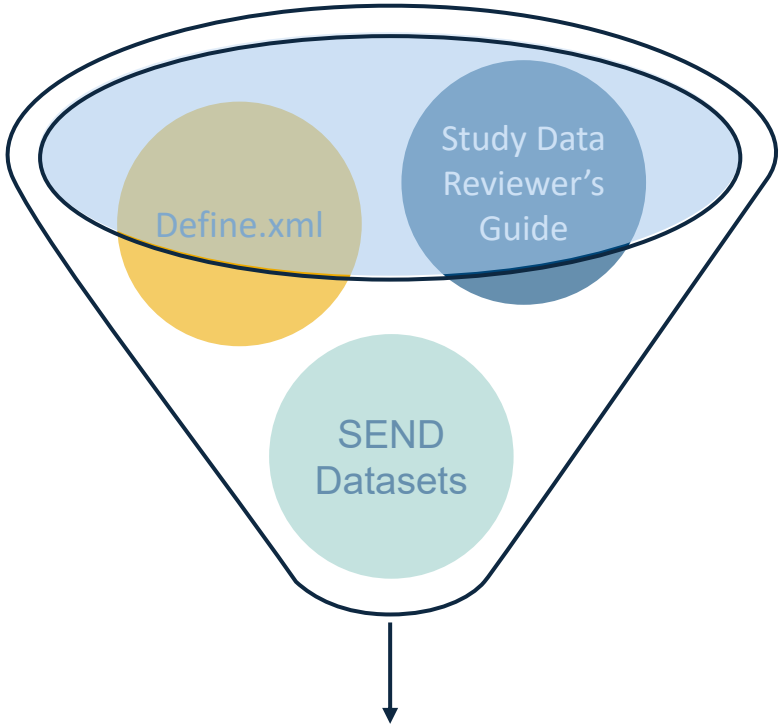
Required for studies started after 15MAR2023

SENDIG 3.1.1 covers

- General Toxicology
  - GLP / Non-GLP
  - Single-Dose / Repeat-Dose
- Carcinogenicity
- Safety Pharmacology
  - Cardiovascular (CV domain) to support non-ECG cardiovascular tests
  - Respiratory (RE domain)
- Custom Domains Permitted

SEND-IG v3.1.1 expands the standard to better support modern non-clinical study needs.

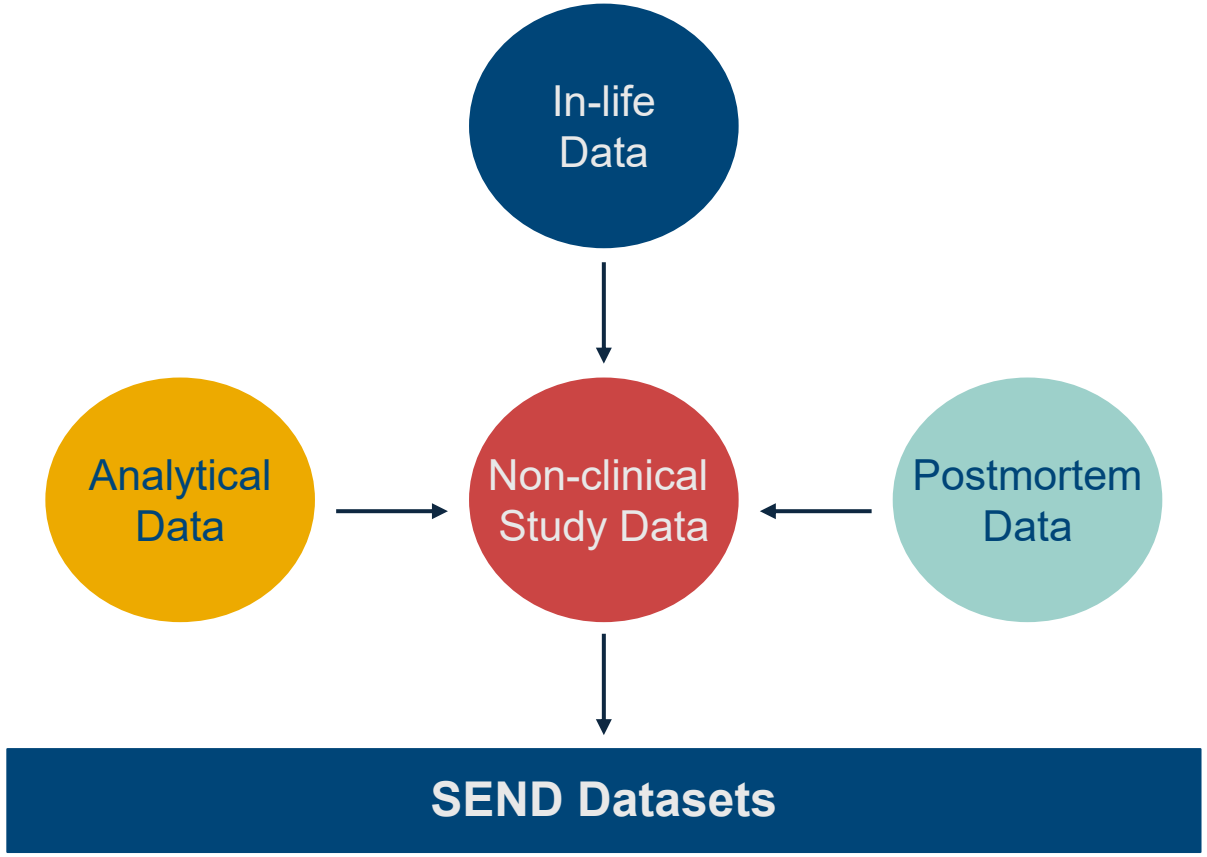
SEND Package



SEND Package

A unified bundle of standardized data and metadata for non-clinical study submissions.

Non-clinical Study Data



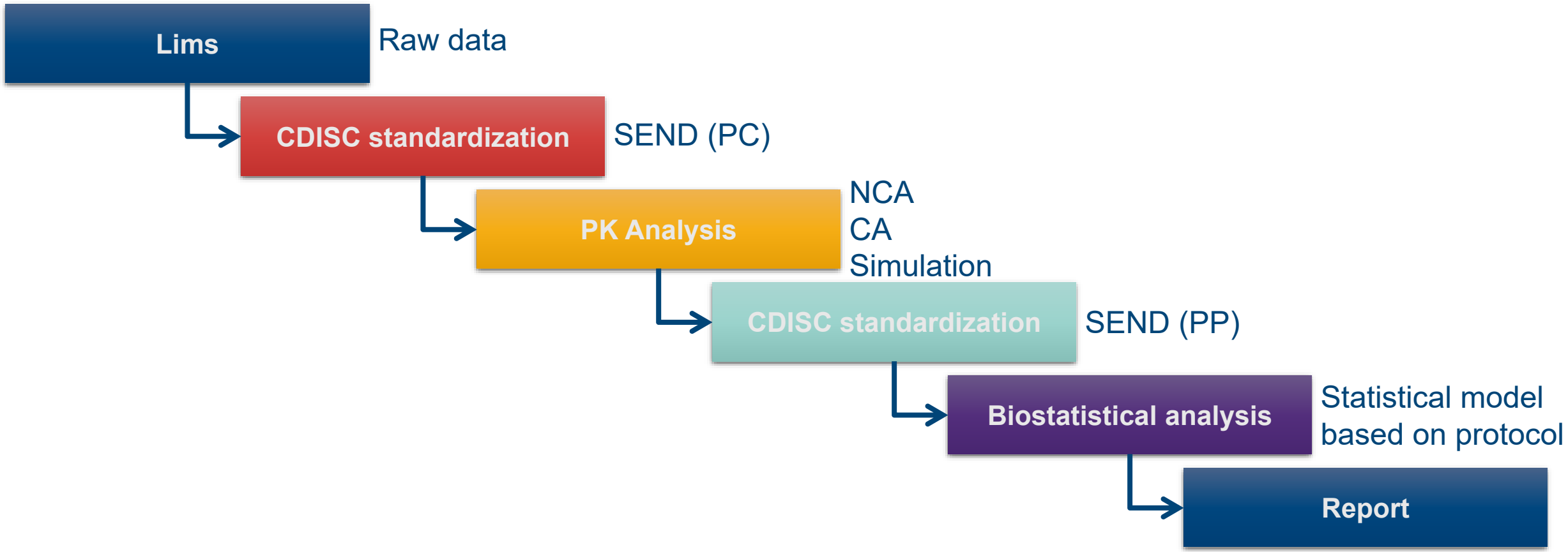
Different study phases generate different data streams: SEND packages bring them together into a unique, review-ready structure.

Data sources

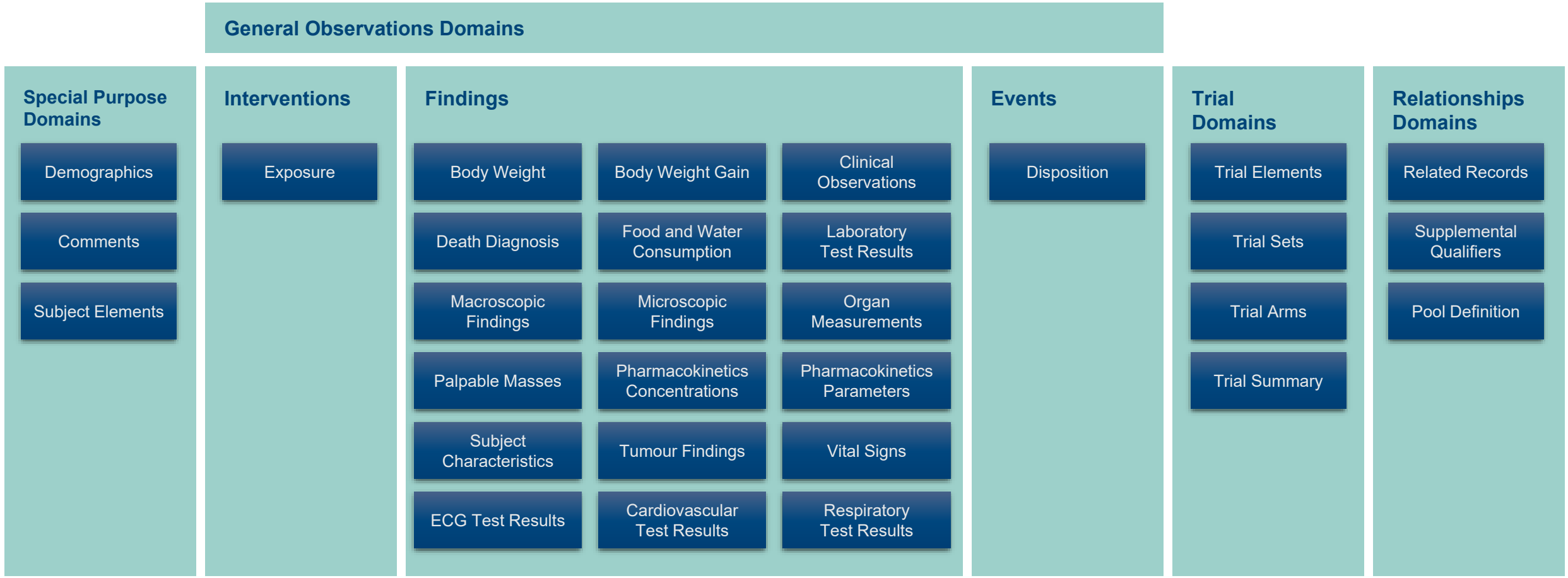
- Data comes from different scientists and sources:
- Study directors (In-Life Data)
- Study pathologists (Postmortem Data)
- Biostatisticians (Biostatistical Data)
- Bioanalytical scientists (TK Data)
- Pharmacokineticists (TK Data)

Data format could be different based on the different data source: SAS dataset, Excel format or XML format.

TK Data workflow



SEND Domains overview



Special Purpose Domains

Demographics (DM)

All the information regarding the study subjects.

Most of the information can be found in the study protocol or study report.

Comments (CO)

All free-text comments relating to different SEND domains can be found here.

Comments come from different data sources based on the parental domains.

Subject Elements (SE)

Contain the actual timing and sequence of study elements a subject experienced.[1]

Data can be collected through other SEND domains.

Special Purpose Domains represent information that does not fit any of the General Observation Classes.

[1] as per SEND-IG v3.1.1, Paragraph 5.3.1.1

General Observations Domains

Interventions

It captures investigational, therapeutic, and other treatments that are administered to the subject.[1] It can be actual or nominal.

These informations come directly from the Study Director.

Findings

All endpoints in this subclass include all assessments specified for the study.

These informations come from different sources (Study Director, Biostatistician, etc.).

Events

We can find information about the disposition of study subjects.

These informations come from the Study Director or the Lab Veterinarians.

General Observations Domains capture what happened to the subject during the study: treatments, results, and events.

[1] as per SDTM v1.5, Paragraph 2.2

Trial Domains

Trial Sets (TX)

It details information about planned groups of subjects that result as a combination of experimental factors of interest for a study.[1]

Trial Elements (TE)

It reports all the study elements with description and duration.

Trial Summary (TS)

Reports all the relevant study informations.

Trial Arms (TA)

It describes each planned Arm in the trial, which is described as an ordered sequence of Elements.[1]

Trial Domains describe the planned structure of a study, ensuring consistency in its elements, arms, and summaries.

[1] as per SDTM v1.5, Paragraph 3.1

Relationship Domains

Related Records (RELREC)

Some studies include subjects who are related to each other, and in some cases, it is important to record those relationships.[1]

Supplemental Qualifiers (SUPP--)

Represent a dependent relationship where data that cannot be represented by a standard variable within a general-observation-class dataset record (or records) can be related back to that record.[2]

Pool Definition (POOLDEF)

This dataset identifies individual subjects included in a pool of subjects for which a single observation record (pool level) is captured.[3]

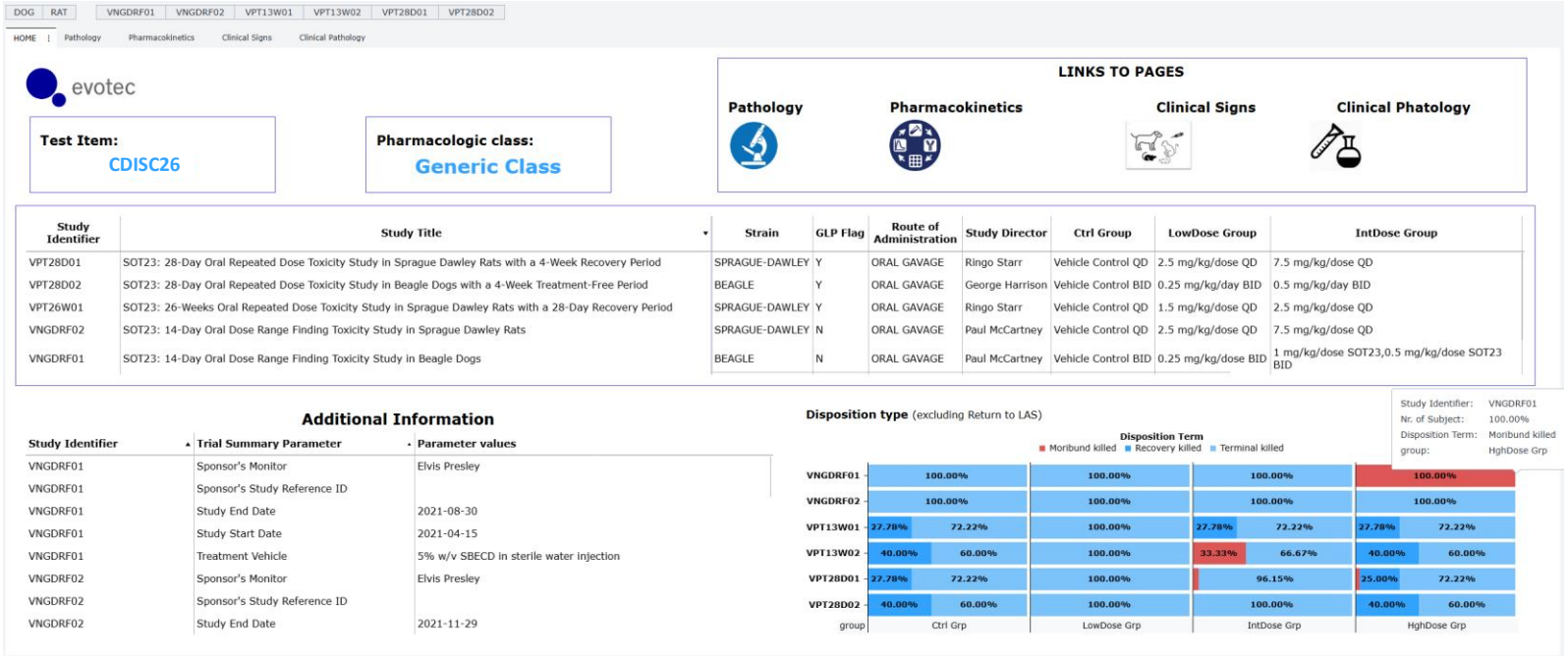
Relationship Domains capture associations between records, enabling relationships that extend beyond a single SDTM dataset.

[1] as per SDTM v1.5, Paragraph 4.1.4
[2] as per SDTM v1.5, Paragraph 4
[3] as per SDTM v1.5, Paragraph 4.1.3

Preclinical Dashboard

Innovative and Interactive Report

From SEND Package to Preclinical Dashboard

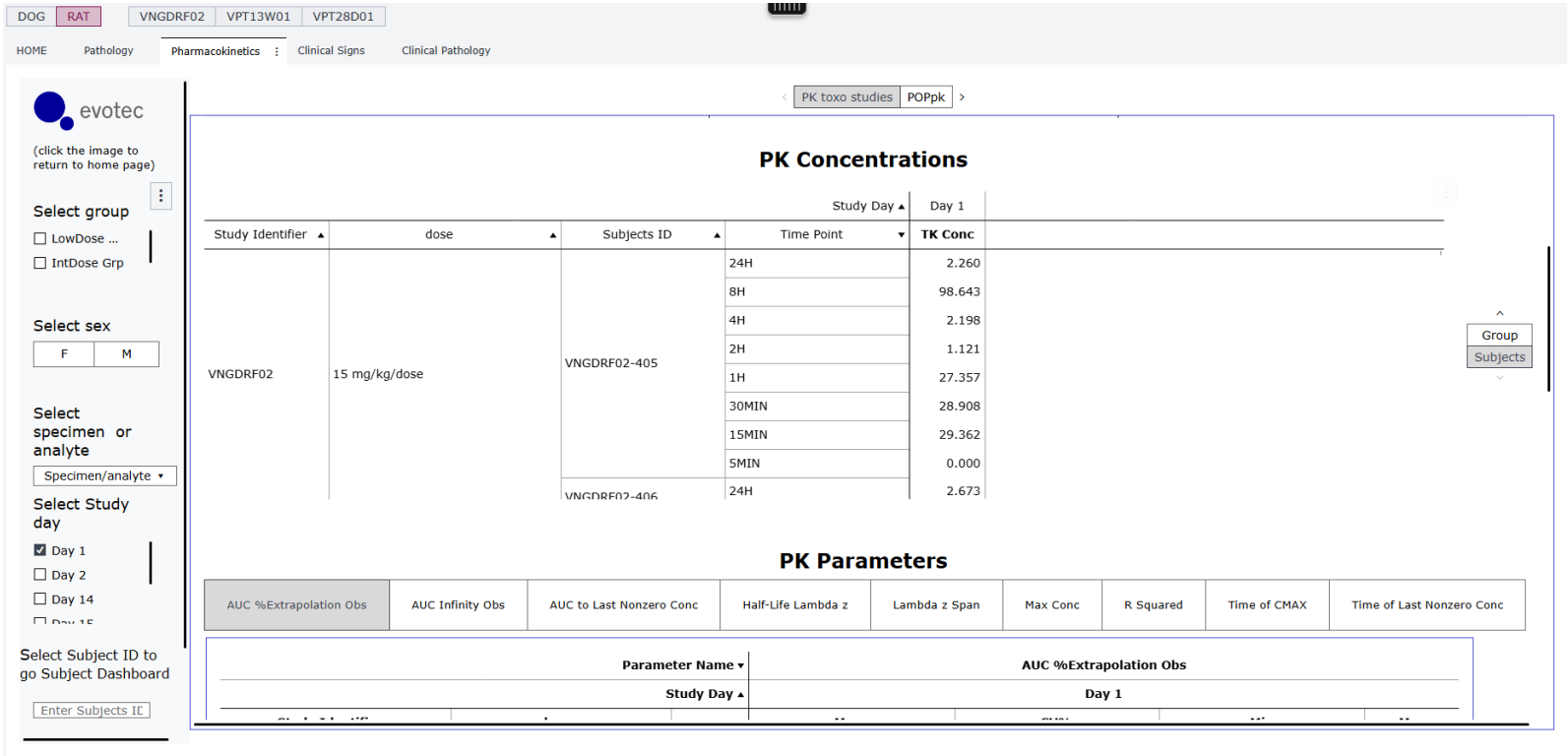


Data in SEND format are useful to create preclinical dashboards to compare different studies based on the same Test Item.

Cross-study Information

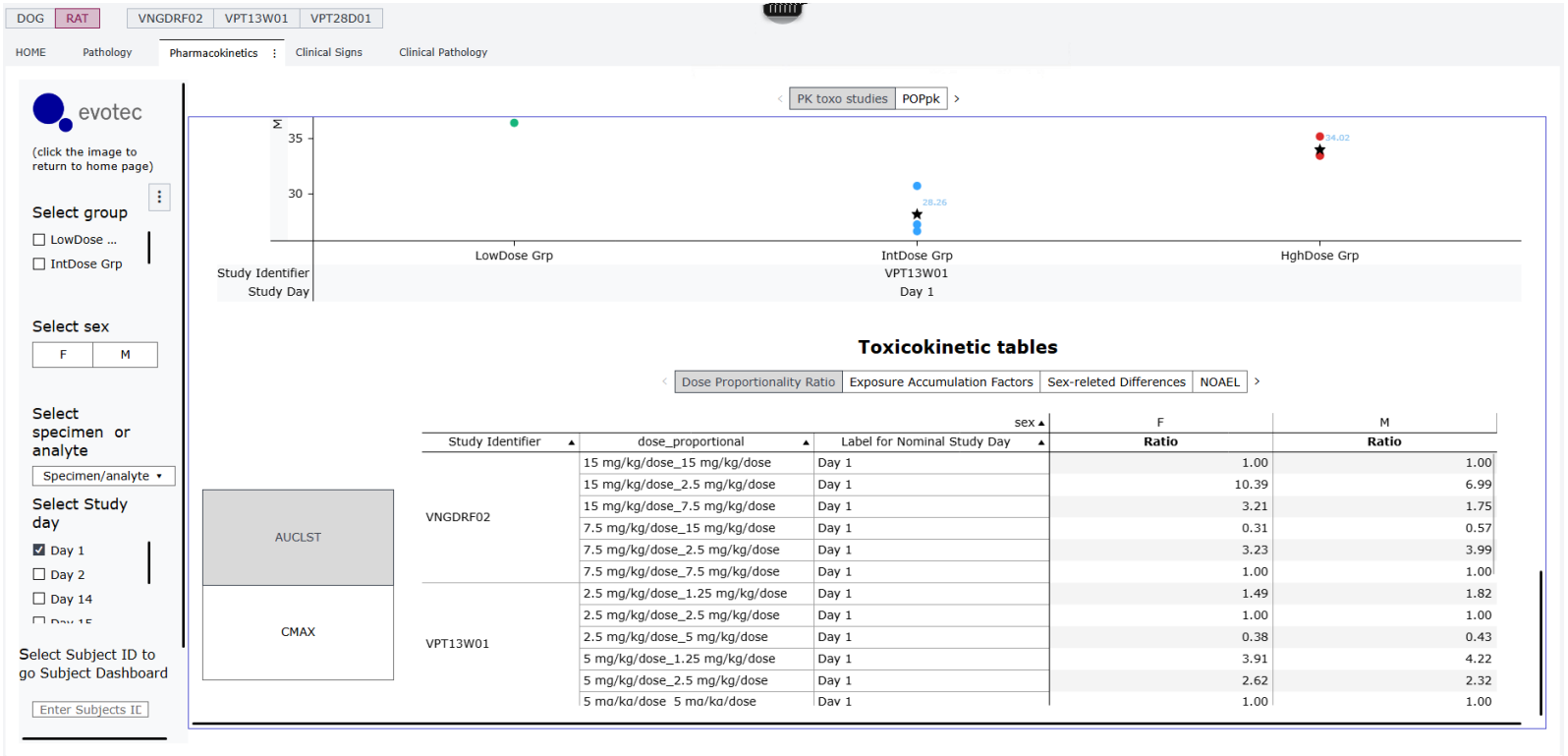
Comparing studies is not just about aligning dataset. It's about revealing insight that no single study can show.

Cross-study Information



Comparing studies is not just about aligning dataset. It's about revealing insight that no single study can show.

Cross-study Information



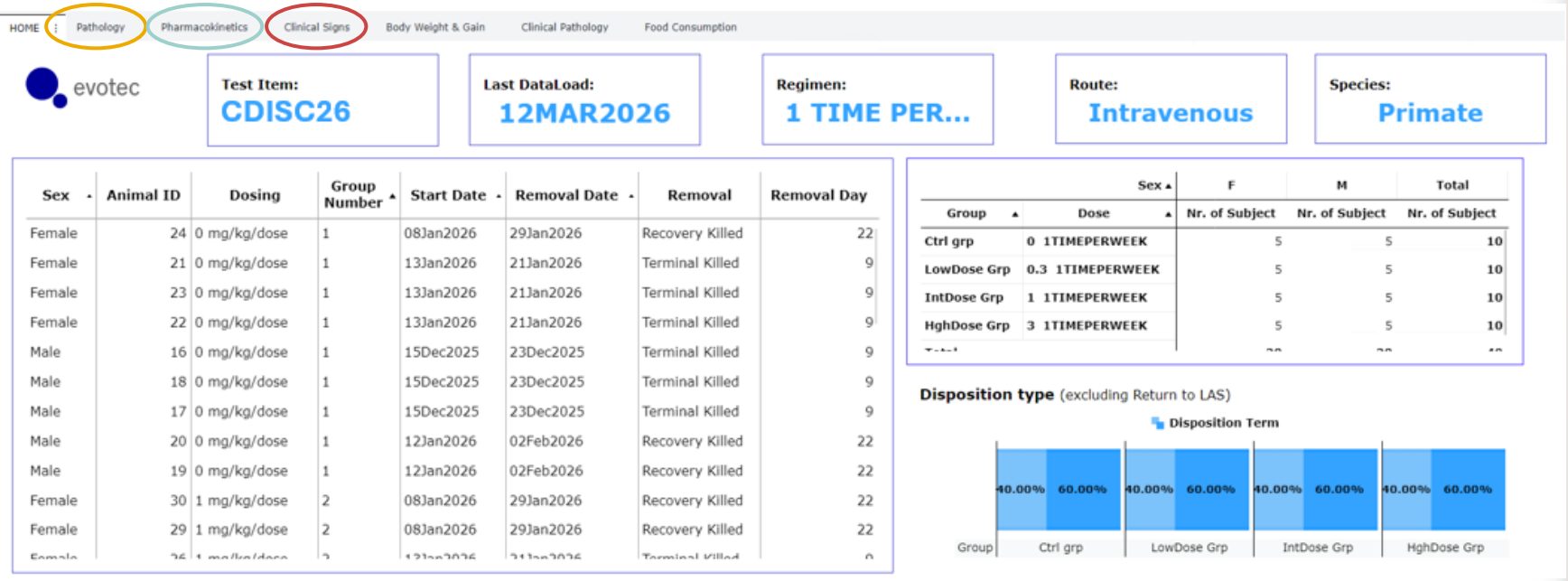
Comparing studies is not just about aligning dataset. It's about revealing insight that no single study can show.

Preclinical Dashboard

In Life Report

Real time In-life data

In life data structured as SEND-like format

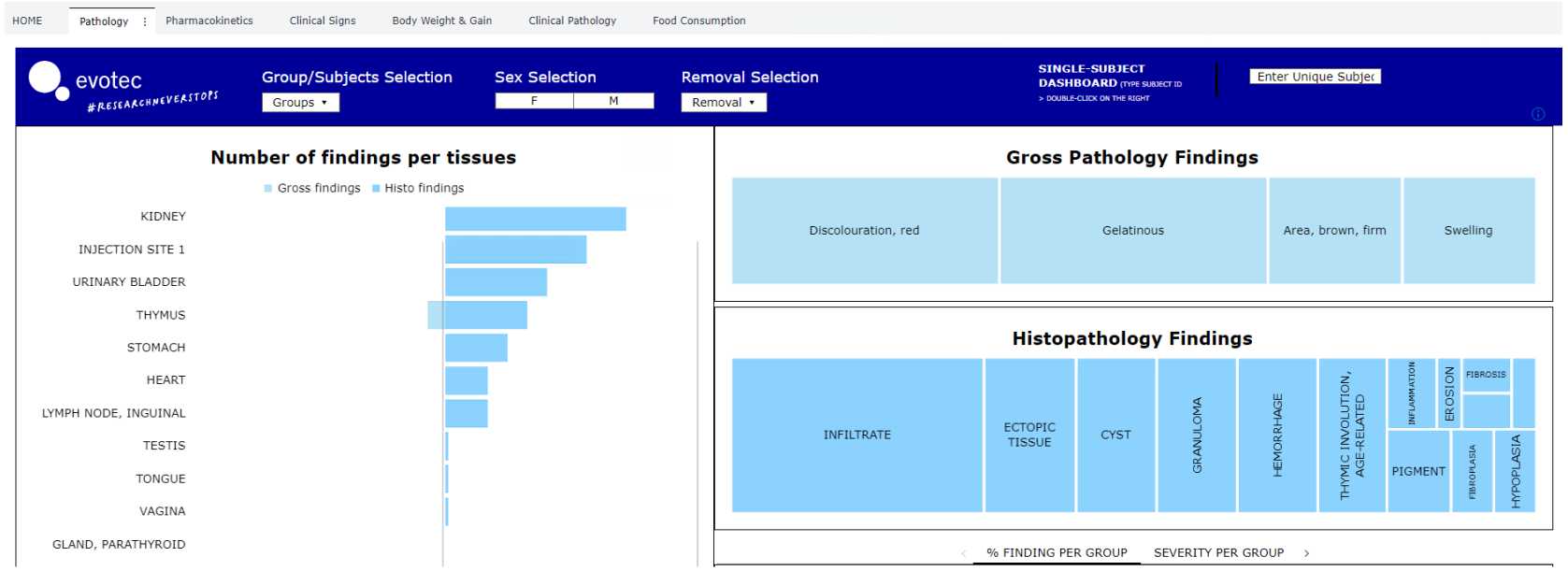


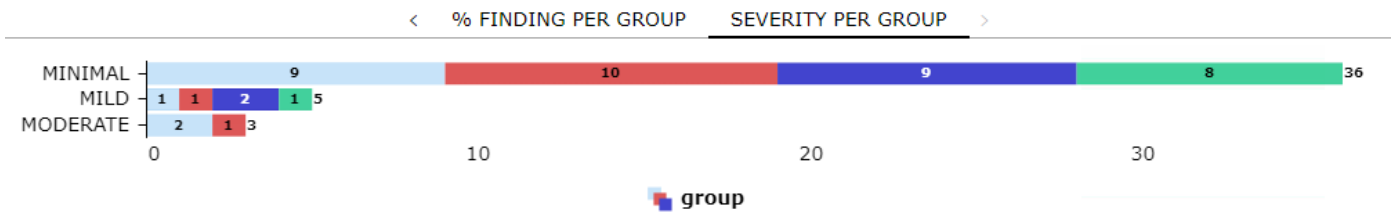
Sex	Animal ID	Dosing	Group Number	Start Date	Removal Date	Removal	Removal Day
Female	24	0 mg/kg/dose	1	08Jan2026	29Jan2026	Recovery Killed	22
Female	21	0 mg/kg/dose	1	13Jan2026	21Jan2026	Terminal Killed	9
Female	23	0 mg/kg/dose	1	13Jan2026	21Jan2026	Terminal Killed	9
Female	22	0 mg/kg/dose	1	13Jan2026	21Jan2026	Terminal Killed	9
Male	16	0 mg/kg/dose	1	15Dec2025	23Dec2025	Terminal Killed	9
Male	18	0 mg/kg/dose	1	15Dec2025	23Dec2025	Terminal Killed	9
Male	17	0 mg/kg/dose	1	15Dec2025	23Dec2025	Terminal Killed	9
Male	20	0 mg/kg/dose	1	12Jan2026	02Feb2026	Recovery Killed	22
Male	19	0 mg/kg/dose	1	12Jan2026	02Feb2026	Recovery Killed	22
Female	30	1 mg/kg/dose	2	08Jan2026	29Jan2026	Recovery Killed	22
Female	29	1 mg/kg/dose	2	08Jan2026	29Jan2026	Recovery Killed	22

		Sex	F	M	Total
Group	Dose		Nr. of Subject	Nr. of Subject	Nr. of Subject
Ctrl grp	0 1TIMEPERWEEK		5	5	10
LowDose Grp	0.3 1TIMEPERWEEK		5	5	10
IntDose Grp	1 1TIMEPERWEEK		5	5	10
HghDose Grp	3 1TIMEPERWEEK		5	5	10

Tool to support decision during the study and the definition of the final report for each involved scientist

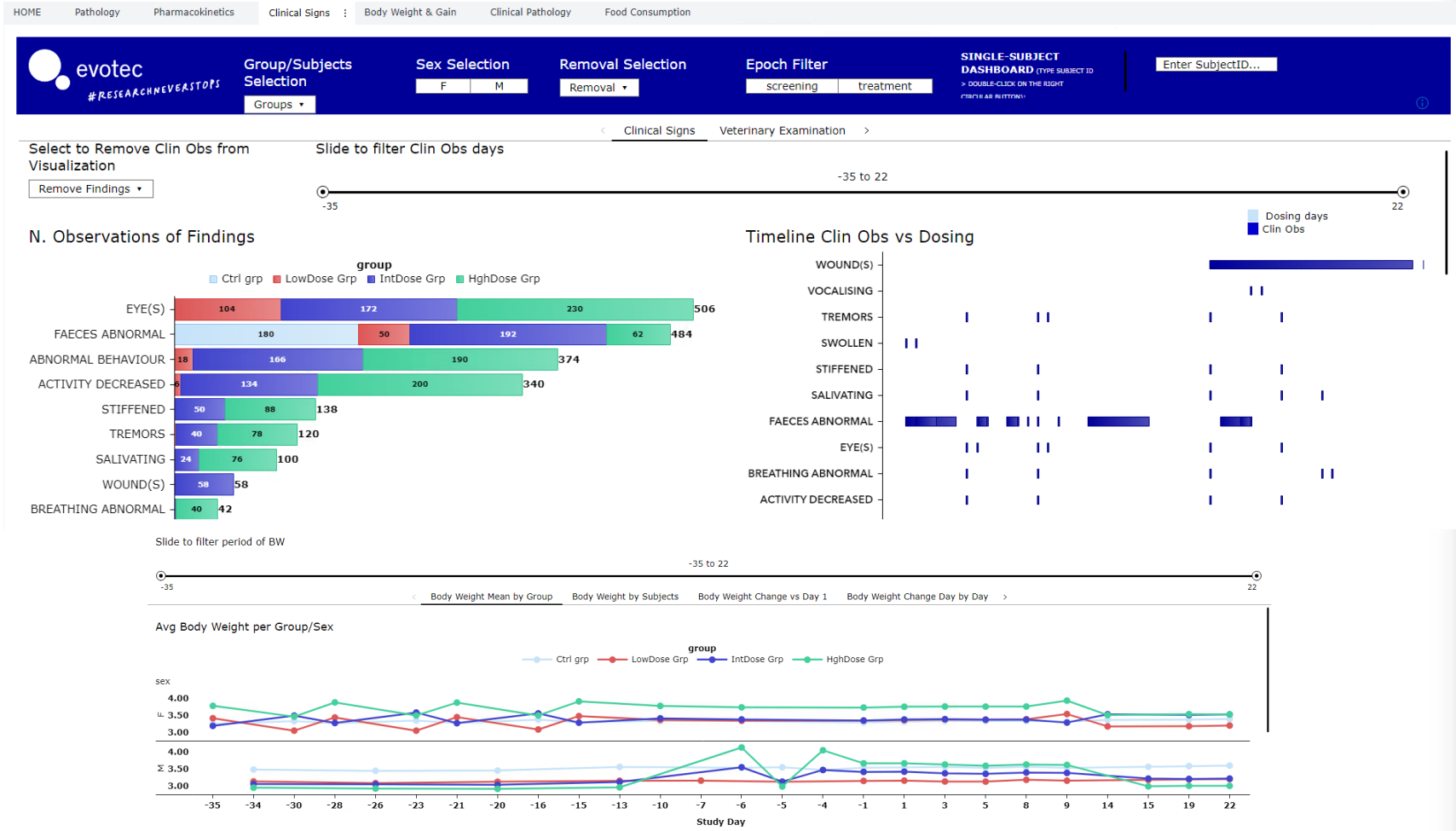
Real time In-life data





Support Pathologist to define the final report

Real time In-life data



Support Study director and Sponsor for decision making during the study.

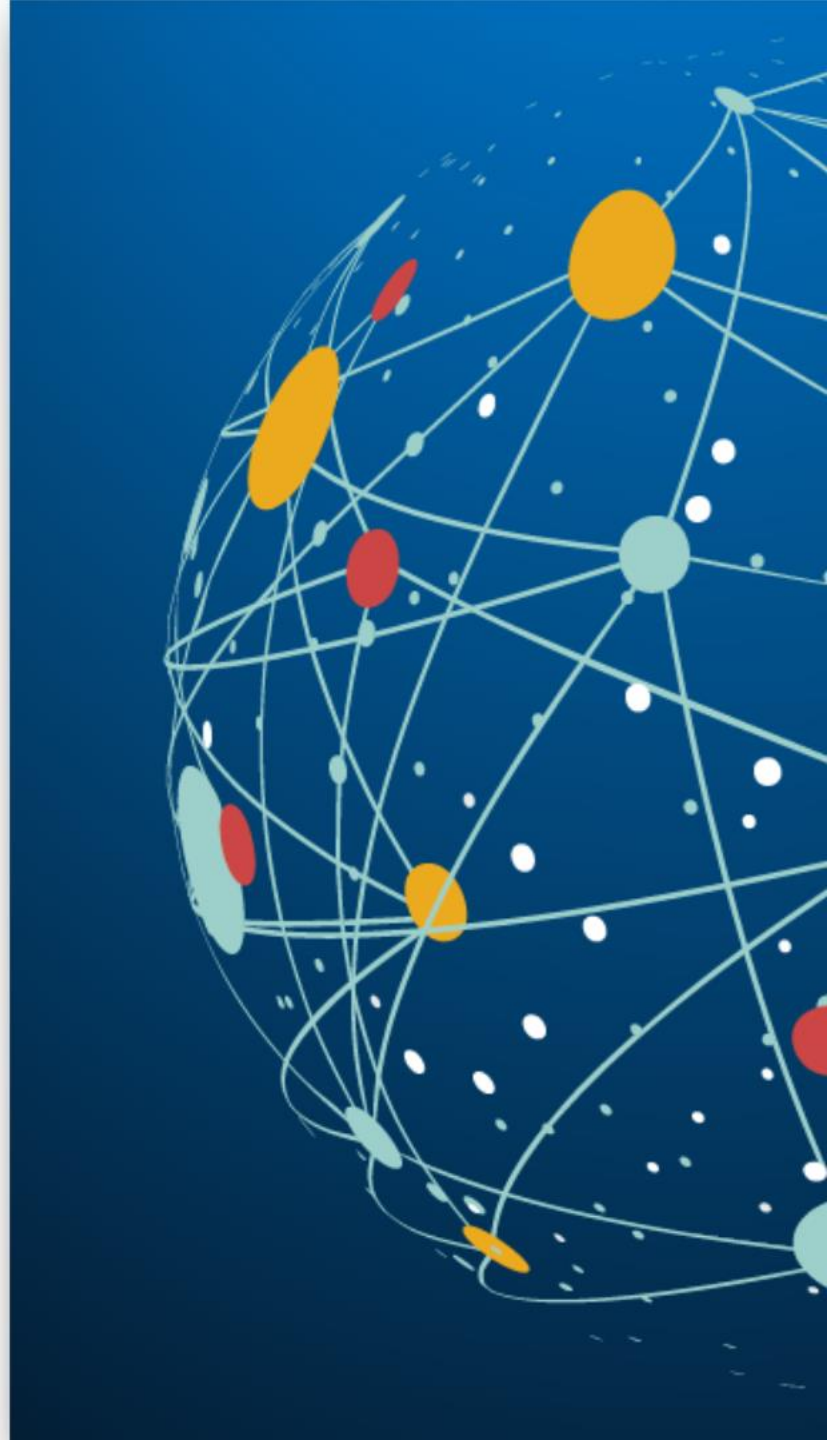
From Preclinical Data to Clinical trials

Preclinical Dashboards:

- Improve study comparability across multiple studies for the same test item.
- Provide a comprehensive view of the test item profile.
- Support decision-making on progression to clinical phases.
- Help assess whether clinical adverse events could have been predicted during the preclinical phase.

Clinical Dashboards:

- Enable real-time monitoring and summarization of study data
- Support safety review meetings by providing clear and up-to-date insights



GENETOX-IG

Other Non-clinical IG

SENDIG-DART 1.1

- Extends the SEND standard into Reproductive Toxicology by supporting study data typically found in embryo-fetal development (EFD) toxicity studies (DART IG 1.1)
- Fertility, Postnatal Development; Juvenile toxicology, Multi-generational will be covered in future releases (DART IG 1.2)

SENDIG-Genetox 1.0

- Genetic toxicology for non-clinical studies

These Implementation Guides are strictly related to SEND, acting as extensions of the core standard.

Genetic Toxicology Overview

"Genotoxicity testing for risk assessment has the aim to identify substances causing genetic alterations in somatic and/or germ cells. Genetic alterations in somatic cells may cause cancer and have also been related to degenerative conditions such as accelerated aging, immune dysfunction, cardiovascular and neurodegenerative diseases. In germ cells, DNA damage is associated with spontaneous abortions, infertility or heritable damage to the offspring."

https://www.iss.it/en/-/oecd-test-guidelines-for-genetic-toxicology

Erythrocyte micronucleus Assay

"The erythrocyte micronucleus test examines the ability of substances to cause chromosome damage in developing red blood cells inside bone marrow."

https://ntp.niehs.nih.gov/go/gt

Comet Assay

"The comet assay examines the ability of substances to cause DNA damage in cells from a variety of different tissues, such as liver, stomach, lung, or brain."

https://ntp.niehs.nih.gov/go/gt

cdisc®

SENDIG-Genetox 1.0

Genetic toxicology:

- In vivo micronucleus test
- Comet test

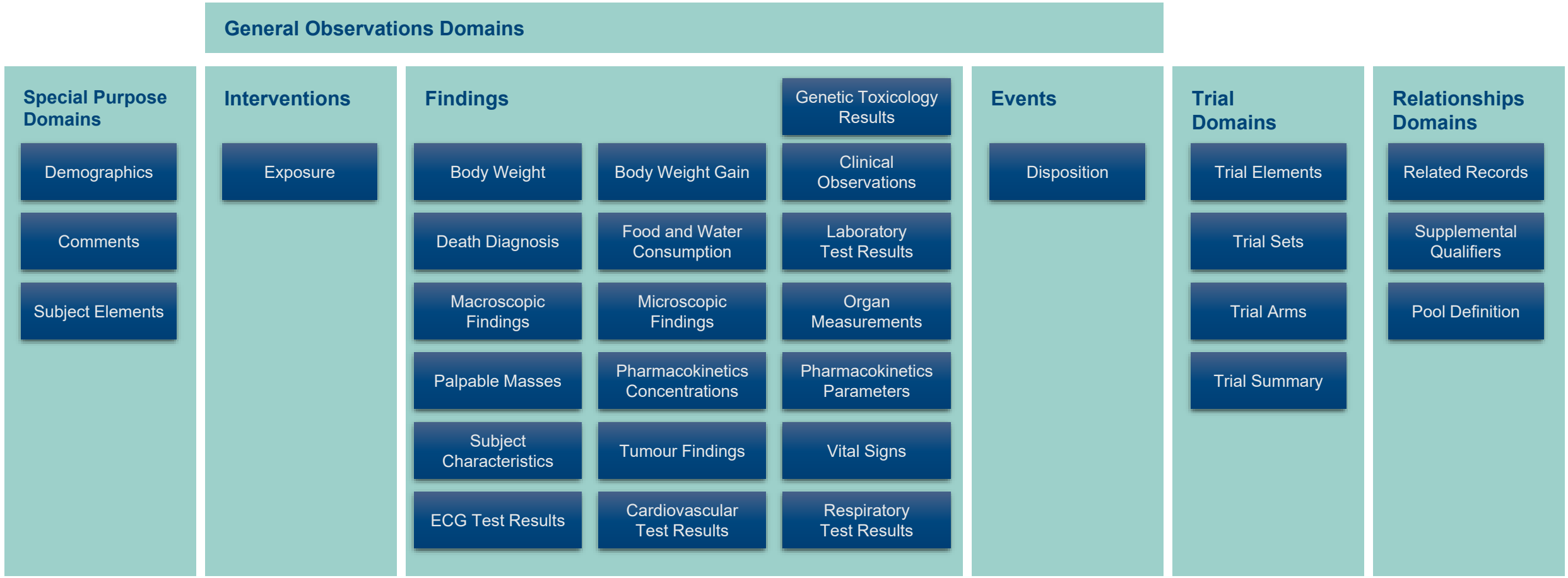
New Domain (GV) introduced

Updates to Trial Design

No change in the modeling assumptions

FDA Requirement for studies started after 15th March 2025.

SEND Domains overview



GV Domain

Dataset	Domain Name	Class	Structure	Purpose	Keys	Location
GV	Genetic Toxicology In Vivo Test Results	Findings	One record per test per specimen material type per observation time per subject	Tabulation	STUDYID, USUBJID, GVTESTCD, GVCAT, GVSCAT, GVSPEC, GVDTC	gv.xpt

Note: Define.xml must includes metadata related to GV dataset

cdisc®

Trial Domain update

Update required just for TSVAL variable in TS domain

TSPARM	TSVAL
SEND Implementation Guide Version	SEND GENETIC TOXICOLOGY IMPLEMENTATION GUIDE VERSION 1.0

Toxicology study with Micronucleus endpoint

TSPARM	TSVAL
Study Category	TOX
Study Type	REPEAT DOSE TOXICITY

Genetic toxicology study

TSPARM	TSVAL
Study Category	GENTOX
Study Type	GENOTOXICITY IN VIVO

cdisc®

GV Domain Dataset example

DOMAIN	USUBJID	GVTESTCD	GVTEST	GVCAT	GVSCAT	GVORRES	GVSPEC	GVMETHOD	GVDY
GV	CDISC26-1	ACE	Total Assessed Cells	IN VIVO MICRONUCLEUS	CYTOTOXICITY	1156	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-1	COMETCES	Comet Cells Scored	IN VIVO COMET, SLIDE	GENOTOXICITY	148	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-2	ACE	Total Assessed Cells	IN VIVO MICRONUCLEUS	CYTOTOXICITY	1213	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-2	NCESC	Normochromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	351	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-3	ACE	Total Assessed Cells	IN VIVO MICRONUCLEUS	CYTOTOXICITY	1078	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-3	COMETCES	Comet Cells Scored	IN VIVO COMET, SLIDE	GENOTOXICITY	155	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-4	ACE	Total Assessed Cells	IN VIVO MICRONUCLEUS	CYTOTOXICITY	1100	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4
GV	CDISC26-4	COMETCES	Comet Cells Scored	IN VIVO COMET, SLIDE	GENOTOXICITY	158	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	4

STUDYID	DOMAIN	TSPARMCD	TSPARM	TSVAL
CDISC26	TS	SNDIGVER	SEND Implementation Guide Version	SEND GENETIC TOXICOLOGY IMPLEMENTATION GUIDE VERSION 1.0
CDISC26	TS	SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2025-09-26
CDISC26	TS	STCAT	Study Category	TOX
CDISC26	TS	SSTYP	Study Type	REPEAT DOSE TOXICITY
CDISC26	TS	SDESIGN	Study Design	PARALLEL

GV Domain Dataset example

DOMAIN	USUBJID	GVTESTCD	GVTEST	GVCAT	GVSCAT	GVORRES	GVSPEC	GVMETHOD	GVDY
GV	CDISCINT-101	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	599	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	1
GV	CDISCINT-101	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	632	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	7
GV	CDISCINT-101	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	602	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	14
GV	CDISCINT-101	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	605	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	28
GV	CDISCINT-102	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	632	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	1
GV	CDISCINT-102	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	499	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	7
GV	CDISCINT-102	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	533	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	14
GV	CDISCINT-102	PCESC	Polychromatic Erythrocytes Scored	IN VIVO MICRONUCLEUS	CYTOTOXICITY	523	BONE MARROW	FLUORESCENT MICROSCOPY, MANUAL	28

STUDYID	DOMAIN	TSPARMCD	TSPARM	TSVAL
CDISCINT	TS	SNDIGVER	SEND Implementation Guide Version	SEND GENETIC TOXICOLOGY IMPLEMENTATION GUIDE VERSION 1.0
CDISCINT	TS	SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2025-09-26
CDISCINT	TS	STCAT	Study Category	GENTOX
CDISCINT	TS	SSTYP	Study Type	GENOTOXICITY IN VIVO
CDISCINT	TS	SDESIGN	Study Design	DOSE ESCALATION

SENDIG 4.0

New domains will be included

- Genetic Toxicology In Vivo Test Results (GV)
- Pharmacokinetics Input (PI)
- Skin Test Results (SK)
- Cell Phenotyping (CP)
- Nervous System Findings (NV)
- Non-Standard Variables (NS--)
- Immunogenicity Specimen Assessments (IS)
- Ophthalmic Examinations (OE)
- Scoring Scale (SX)

Deprecated domains

- Body Weight Gain (BG)
- Tumor Findings (TF)

Currently in Public Review.

Thank You!

Questions?