SEND for CBER

What You Need to Know

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Learning Objectives

- Describe CBER's requirement and support on SEND for CBER
- Understand the important data points for CBER non-clinical studies
- Understand the perspective from review's point of view
- Understand the future development on SEND for CBER

SEND for CBER Requirement Date

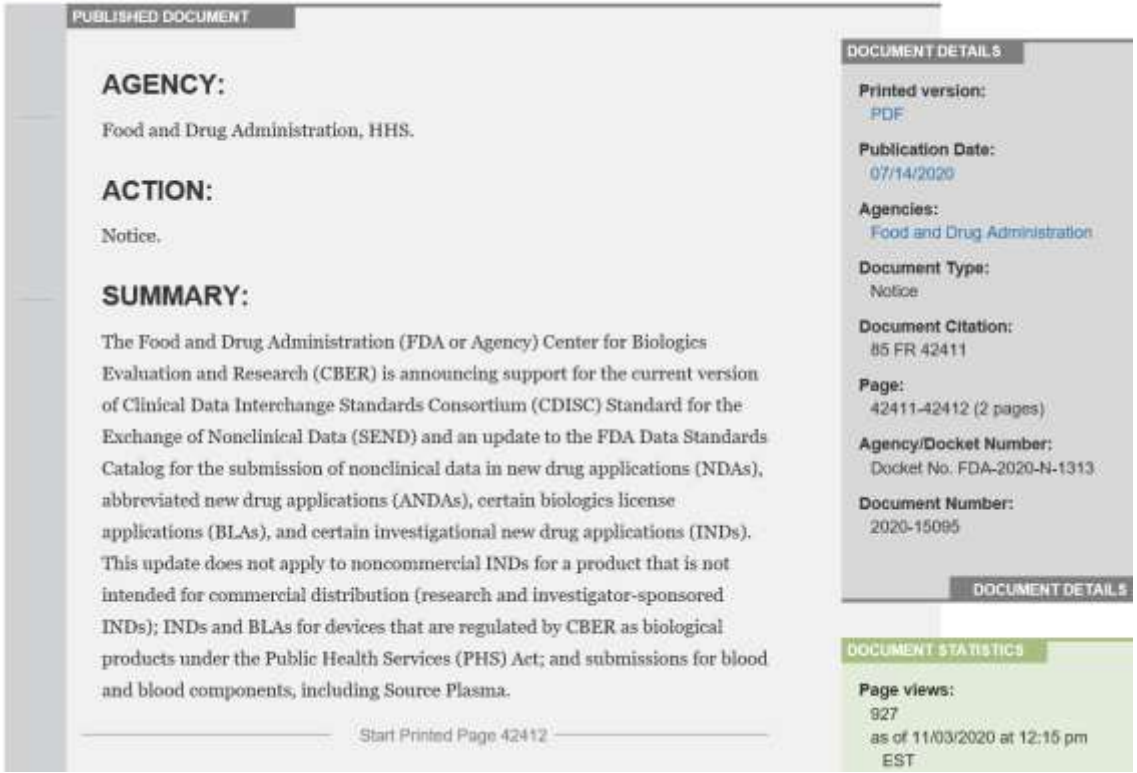
“The Center for Biologics Evaluation and Research (CBER) intends to receive SEND datasets in future submissions.”

Use	Data Exchange Standard	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)
Animal study datasets	SEND	3.1	CDER	08/21/2017		03/15/2019 [1] 03/15/2020 [2]
Animal study datasets	SEND	3.1	CBER	03/15/2021		03/15/2023

We are on the way!
Assessing, Analyzing, Recommending, Piloting, Implementing

[1] July 2020

Federal Register Notice was published in July 2020, announcing CBER's support and future requirement for SEND



PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing support for the current version of Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data (SEND) and an update to the FDA Data Standards Catalog for the submission of nonclinical data in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). This update does not apply to noncommercial INDs for a product that is not intended for commercial distribution (research and investigator-sponsored INDs); INDs and BLAs for devices that are regulated by CBER as biological products under the Public Health Services (PHS) Act; and submissions for blood and blood components, including Source Plasma.

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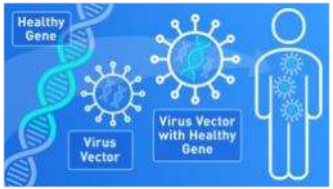
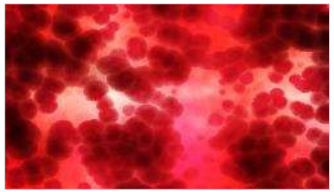
CBER Review Offices

- **Office of Vaccine Research and Review (OVRR)**

- **Office of Tissues and Advanced Therapies (OTAT)**



- **Office of Blood Research and Review (OBRR)**



Office of Vaccine Research and Review (OVRR)

- **Products Reviewed**
  - Vaccines for prevention or treatment of infectious disease indications only
  - Allergenics
  - Miscellaneous biologics:
    - Fecal microbiota transplants
    - Probiotics
    - Phage products

- **Nonclinical Studies**
  - **Single and repeat dose toxicology**
  - **Developmental and reproductive toxicology (DART)**
  - **Genotoxicity, safety pharmacology (allergenics)**
  - **Immunogenicity**
  - Proof-of-concept, efficacy
  - **Biodistribution**
  - No chronic toxicity or carcinogenicity

- **Data Consideration**
  - **Timing of endpoints following vaccinations**
  - **Draize Scoring**
  - **Body temperature**
  - **Acute phase reactants**
  - **Immunogenicity/Serology Assays**
  - **Injection site histology**

Study and data types well aligned with SEND roadmap

• Office of Tissues and Advanced Therapies (OTAT)

❖ **Products Reviewed**

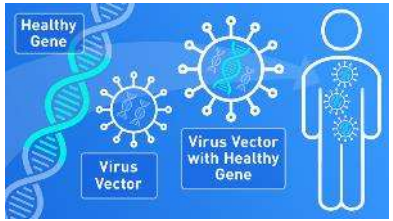
- Stem cell and stem-cell-derived products
- Somatic cell products
- Xenotransplantation products
- Certain devices and combination products
- Therapeutic vaccines
- Recombinant or plasma derived proteins
- Wound healing products
- Gene therapy

❖ **Nonclinical Studies**

- **Proof-of-concept/safety/toxicity**
- Cell-fate/biodistribution, typically no PK studies
- Differentiation/integration capacity
- Tumorigenicity: required for stem cell therapy
- Biocompatibility (implantable scaffolds)
- **Immunogenicity (therapeutic vaccines)**

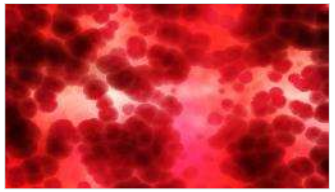
❖ **Data Consideration**

- Animal model of disease/injury
- Hybrid safety and activity studies
- Distribution/biodistribution assessments
- Biocompatibility of devices



SEND for CBER Team has been working closely with CDISC on developing IS Domain for Nonclinical Immunogenicity Data

- **Office of Blood Research and Review (OBRR)**
  - **Products Reviewed**
    - Modified blood components
    - Hemoglobin-based oxygen carriers
    - Container-closure systems
    - Process-related impurities
    - Excipients
    - Pathogen reduction systems
  - **Nonclinical Studies**
    - Focused on biocompatibility
    - Extractables and leachables testing
    - Container closure systems
    - Occasionally see developmental or embryo-fetal toxicology for replacement proteins
    - Proof-of-concept
    - **Carcinogenicity**
  - **Data Consideration**
    - **GLP-compliant toxicology studies only requested on a case-by-case**
    - Most nonclinical studies received are not amenable to SEND data
    - Systemic toxicity (biocompatability, hemoglobin-based oxygen carriers),
    - Mutagenicity (impurities, extractables, leachables)



Most Nonclinical studies are not amenable to SEND data

- Provide Training & Support for Reviewers
  - ❖CDISC study data standards
  - ❖Analysis tools including JMP, JMP Clinical, SEND Explorer
  - ❖Going through data standards validation check
  - ❖Exploring data by using tools and evaluating define.xml and non-clinical study data reviewers guide

SEND Importance in the View of a Reviewer

Precision
vs
Time

Nabil Al-Humadi, Ph.D. CBER/FDA

U.S. FOOD & DRUG ADMINISTRATION

Disclaimer:

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

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What is most important for reviewers to complete their job?

To review a large amount of data requires Time. This time is required for accuracy in summarizing the findings to reach the right conclusion.

Time Importance

- Time is very critical when it comes to an emergency situation. The best example is the corona virus pandemic. In this kind of situation, submission of the data in an organized, easy to evaluate way is very important. One of the most important features of SEND is that the reviewer will receive the data in very organized, easy to review modules.

What are the types and amount of data we receive to review??

Study designs for Tox studies

- Includes 2, 3, 4 or sometimes up to 8 groups
- Males and Females
- Main study sacrifice and Recovery sacrifice
- Termination might varies on the study design as some studies might include multiple termination time points (Days 3, 7, 15, 30, 45… etc.)

Table of general in-life assessments

Parameter	Frequency	Comments
Mortality/ Moribundity Checks[a]	Twice daily (morning and afternoon) beginning upon arrival through termination.	Animals were observed within their cage unless removal was necessary for identification or confirmation of possible findings.
Postdose Observations[a]	On each dosing days; predose and at 2 hours (±15 minutes) postdose after the end of each group for each sex (for exceptions, see appendix 1).	Cage side observation unless removal was necessary for identification or confirmation of possible findings.
Cageside Observations[a]	Once daily, on non-dosing days, during the dosing phase and recovery period.	Cage side observation unless removal was necessary for identification or confirmation of possible findings.
Detailed Clinical Observations[a]	At least every 2 weeks during the prestudy period then weekly starting day -1.	Animals were removed from the cage or handled in the cage.
Dermal Scoring[a]	Daily, starting day 1, predose on dosing days (for exceptions, see appendix 1).	Each animal had the dose injection sites examined according to the modified Draize scoring scale.
Individual Body Weights[a]	Once during week-2, two to three times during week -1, daily during week dosing, and twice weekly during the recovery period.	Fasted weight on the day of necropsy.
Food Consumption	Once daily; from at least week -1 and throughout the study	Quantitatively measured; daily measurement was reported.
Body Temperature[a]	Daily from day -5 to day -1, on dosing days: pre-dose and at 3, 6, and 24 hr postdose.	Collected using a subcutaneous implant. When the body temperature of any animal was over 39.5°C, it was recorded daily (only the animal concerned was recorded) until it returned to normal (for exceptions, see appendix 1). Body temperature was measured at approximately the same hour on every measurement day, between 7 and 9 AM during prestudy period and on non-dosing days (where applicable) (for exceptions, see appendix 1).
Ophthalmic Examinations	All animals: once prestudy. Group 1 to 4 on day 3 and the day prior to necropsy (scheduled animals only).	All animals were subjected to funduscopic (indirect ophthalmoscopy) and biomicroscopic (slit lamp) examinations. The mydriatic used was 1% tropicamide

[a] Minimum required frequency for this parameter indicated.

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Table of samples for clinical pathology evaluation

Group Nos.	Population	Occasion/ Time Point	Hematology	Coagulation	Clinical Chemistry	Biomarker (CRP)
All animals	-	Prestudy	X	X	X	X
1 to 4	Interim Recovery Study	Day 3	X	X	X	X

Group Nos.	Population	Occasion/ Time Point	Hematology	Coagulation	Clinical Chemistry	Biomarker (CRP)
1 to 4	Interim Main Study	At termination Day 3	X	X	X	X
1 to 4	Interim Recovery Study	Day 7	-	-	-	X
1 to 4	Interim Recovery Study	At termination Day 15	X	X	X	X
Overnight Fasting:			-	-	Yes	-
Method/Comments:			Appropriate auricular vessel	Appropriate auricular vessel	Appropriate auricular vessel	Appropriate auricular vessel
Target Volume[a] (mL):			0.7	1.2	0.7	0.5
Anticoagulant:			EDTA	Sodium citrate	None, in SST	None, in SST
Processing:			None	Plasma	Serum	Serum

Hematology Parameters

RED BLOOD CELLS	**Hematocrit (Hct)** **Hemoglobin Conc. (Hb)** **Mean Corp. Hb. (MCH)** **Mean Corp. Hb. Conc. (MCHC), Mean Corp. Volume (MCV)** **Total Erythrocyte Count (RBC)** **Reticulocytes**
WHITE BLOOD CELLS	Macrophage Lymphocyte count Large Unstained Cells (LUC) Basophils Neutrophil Monocyte Eosinophil
CLOTTING POTENTIAL	Prothrombin time Activated partial-thromboplastin time clotting time Platelet count Fibrinogen
OTHERS	Bone marrow cytology

Serum Chemistry Parameters

ELECTROLYTE BALANCE	Calcium, chloride, potassium, sodium, phosphorus
CARBOHYDRATE METABOLISM	Glucose
LIVER FUNCTION: A) HEPATOCELLULAR	Alanine aminotransferase (ALT or SGPT) Aspartate aminotransferase (AST or SGOT) Total bilirubin
B) HEPATOBILIARY	Alkaline phosphatase (ALP) GGT
ACUTE PHASE REACTANTS	Fibrinogen C-reactive protein (CRP)
KIDNEY FUNCTION	Blood Urea Nitrogen (BUN) Creatinine
OTHERS (ACID/BASE BALANCE, CHOLINESTERASES, HORMONES, LIPIDS, METHEMOGLOBIN, AND PROTEINS)	Albumin (A) Total protein Carbon dioxide Globulin A/G ratio Total Cholesterol Lactate dehydrogenase Fasting Triglycerides SDH Creatine kinase

Table of sample collection for immunogenicity

Group Nos.	Population	Occasion/Time Point	ADA	Investigation
All animals	-	Prestudy	X	X
1 to 4	Interim Recovery Study	Day 15	X	X
Method/Comments:			Appropriate auricular vessel	Appropriate auricular vessel
Target Volume (mL):			0.5	2
Anticoagulant:			None, in SST	None, in SST
Processing:			Serum	Serum

X = Sample collected; SST = Serum separator tube; ADA = Anti-drug antibody

Table of interim main and recovery study terminal procedures

Group No.	Scheduled Euthanasia Day		Necropsy Procedures			Histology Processing	Microscopic Evaluation
	Main	Recovery	Necropsy	Tissue Collection	Organ Weights		
1	Day 3	Day 15	X	Full List[a]	Full List[a]	Full List[a]	Full List[a]
2							
3							
4							

X = Procedure conducted.

[a] See tables below.

Table of organs weighed at necropsy

Brain	Heart
Epididymis[a]	Kidney[a]
Gallbladder[d]	Liver
Gland, adrenal[a]	Lung
Gland, seminal vesicle[b]	Ovary[a]
Gland, parathyroid[c]	Spleen
Gland, pituitary	Testis[a]
Gland, prostate	Thymus
Gland, thyroid[a]	Uterus/Cervix

[a] Paired organ weight.
[b] Weighed with prostate
[c] Weighed with thyroid
[d] Weighed with liver

Table of tissue collection and preservation

Animal identification	Large intestine, rectum
Artery, aorta	Larynx
Body cavity, nasal	Liver
Bone marrow smear[a]	Lung
Bone marrow, sternum	Lymph nodes draining administration sites: inguinal, iliac, and sacral
Bone, femur, right	Lymph node, mandibular
Bone, sternum	Lymph node, mesenteric
Brain	Muscle, skeletal (biceps femoris)
Bronchi (mainstem)	Nasopharynx
Diaphragm	Nerve, optic[c]
Epididymis[b]	Nerve, sciatic
Esophagus	Nerve, tibial
Eye[c]	Oropharynx
Gallbladder	Ovary
Ganglion, dorsal root, lumbar	Oviduct
Gland, adrenal	Pancreas
Gland, lacrimal	Site, administration: dorso-lumbar region[e]
Gland, harderian	Skin
Gland, mammary	Skin overlying the injection site
Gland, parathyroid	Small intestine, duodenum
Gland, pituitary	Small intestine, ileum
Gland, prostate	Small intestine, jejunum
Gland, salivary, submandibular	Small intestine, sacculus rotundus
Gland, salivary, sublingual	Spinal cord (cervical, thoracic, and lumbar)
Gland, salivary, parotid	Spleen
Gland, seminal vesicle	Stomach
Gland, thyroid	Testis[b]
Gross lesions/masses	Thymus
Gut-associated lymphoid tissue[d]	Tongue
Heart	Trachea
Joint, femorotibial, right	Ureter
Kidney	Urinary bladder
Large intestine, appendix	Uterus/Cervix
Large intestine, cecum	Vagina
Large intestine, colon	

[a] Three bone marrow smears collected from the 5th to 7th rib were prepared from each euthanized animal, air dried, fixed in methanol, and stained with Wright's Giemsa stain.
[b] Preserved in Modified Davidson's fixative.
[c] Preserved in Davidson's fixative.
[d] From small intestine: Peyer's patch or solitary lymphoid follicle.
[e] 3 sections collected per injection site.

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DART endpoints

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- Use ICH S5(R2) for each period's reproductive and developmental endpoints
- Mating period
  - Mating and Fertility Indices
- Gestational period
  - Maternal evaluation
    - corpora lutea
    - implantation sites
    - pre- & post-implantation losses
  - Fetal and placental weights

DART endpoints

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- Gestational period
  - Fetal external evaluation
  - Fetal visceral evaluation
  - Fetal skeletal evaluation plus ossification sites
- Lactational period
  - Litter evaluations
  - Lactation and Survival Indices
  - Pup Developmental Landmarks

Immunological endpoints

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- Serum antibody determination
  - F0 female – predose, end of gestation and lactation
  - F1 fetus – cord blood
  - F1 pup (PND 21)
- Additional assessments (case-by-case)
  - If vaccine-induced adverse effects, e.g. histochemical analysis for antibody depositions
  - Neurological assessments
  - Immunological endpoints in Developmental Immunotoxicity Study

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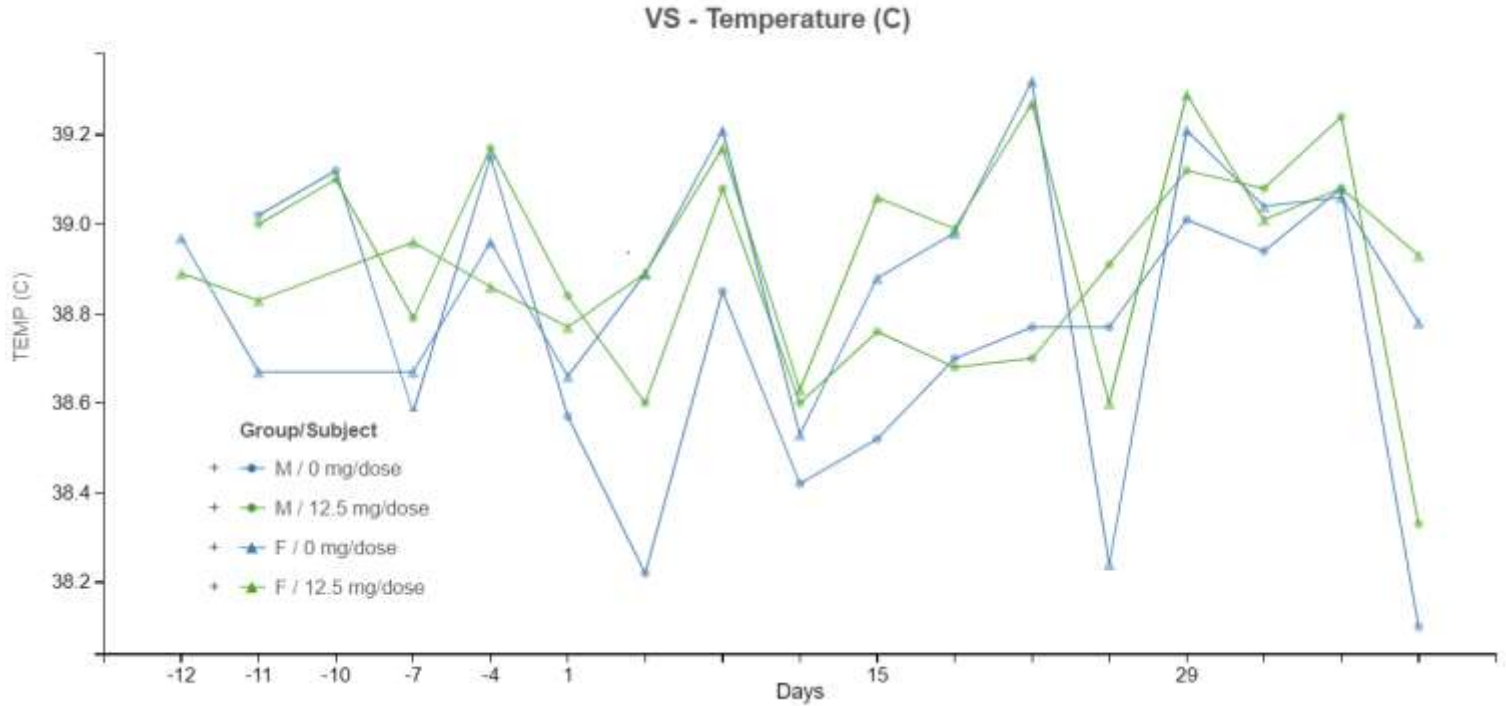
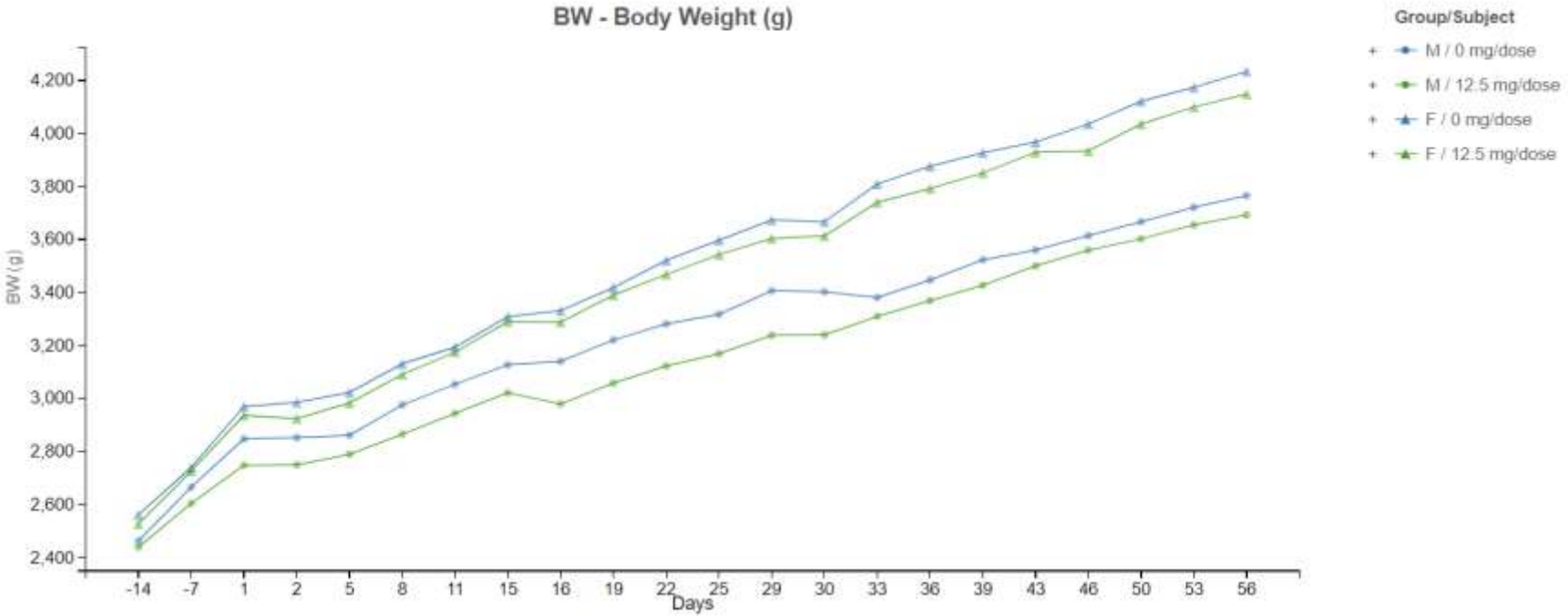
How could SEND help us?
Organize the data, help us review the data in an efficient way, and provide a tool to create tables and graphs to present the most important findings.

Temperature Levels



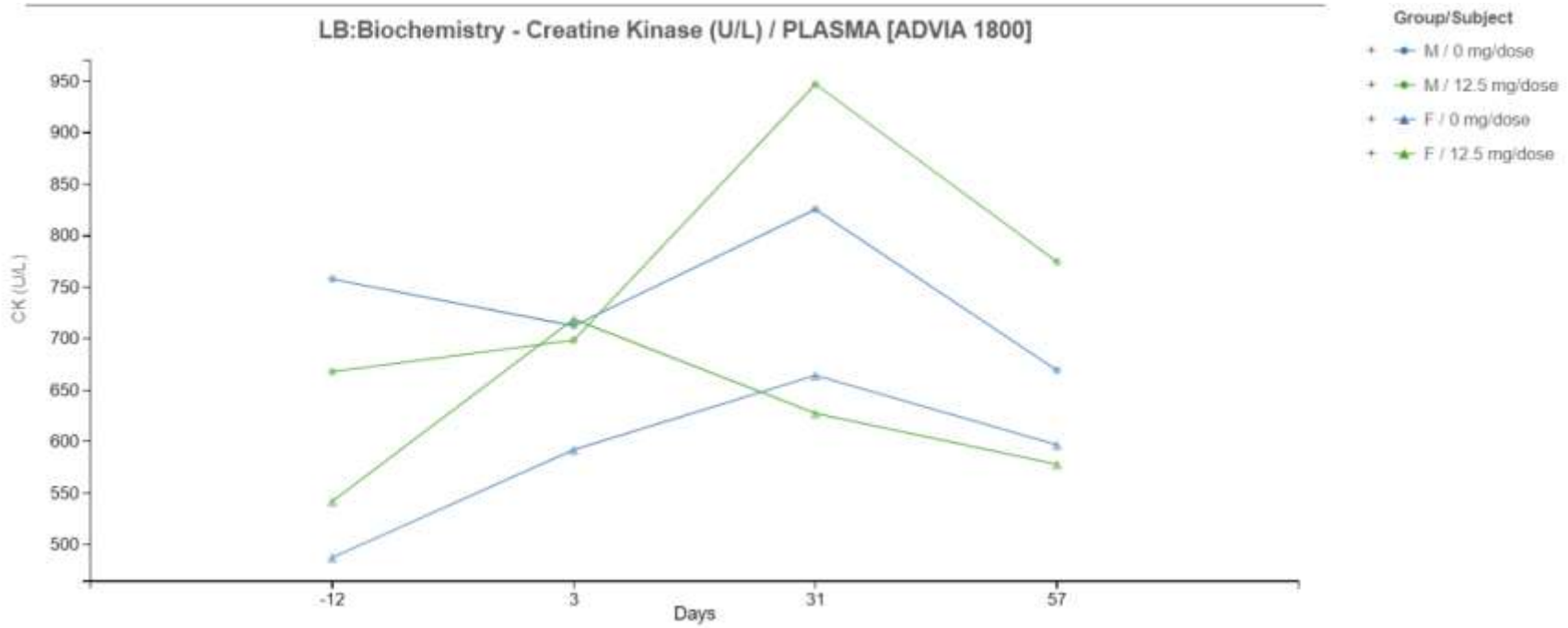
Cut off Temperature of 40 ºC is very easy to locate in any group from this graph.

Body Weight Changes



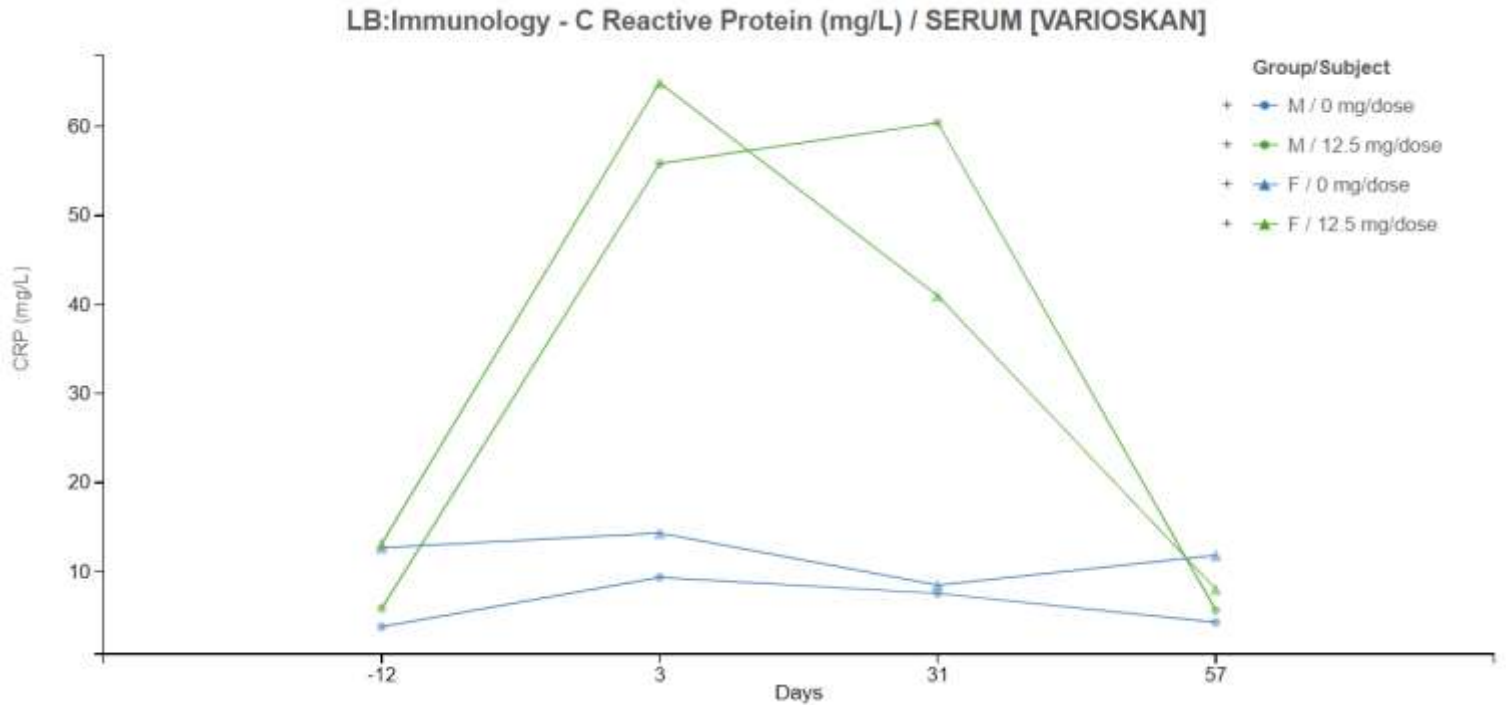
Body weight changes in test article-treated groups are easy to find when compared to the control groups

Creatine Kinase Levels



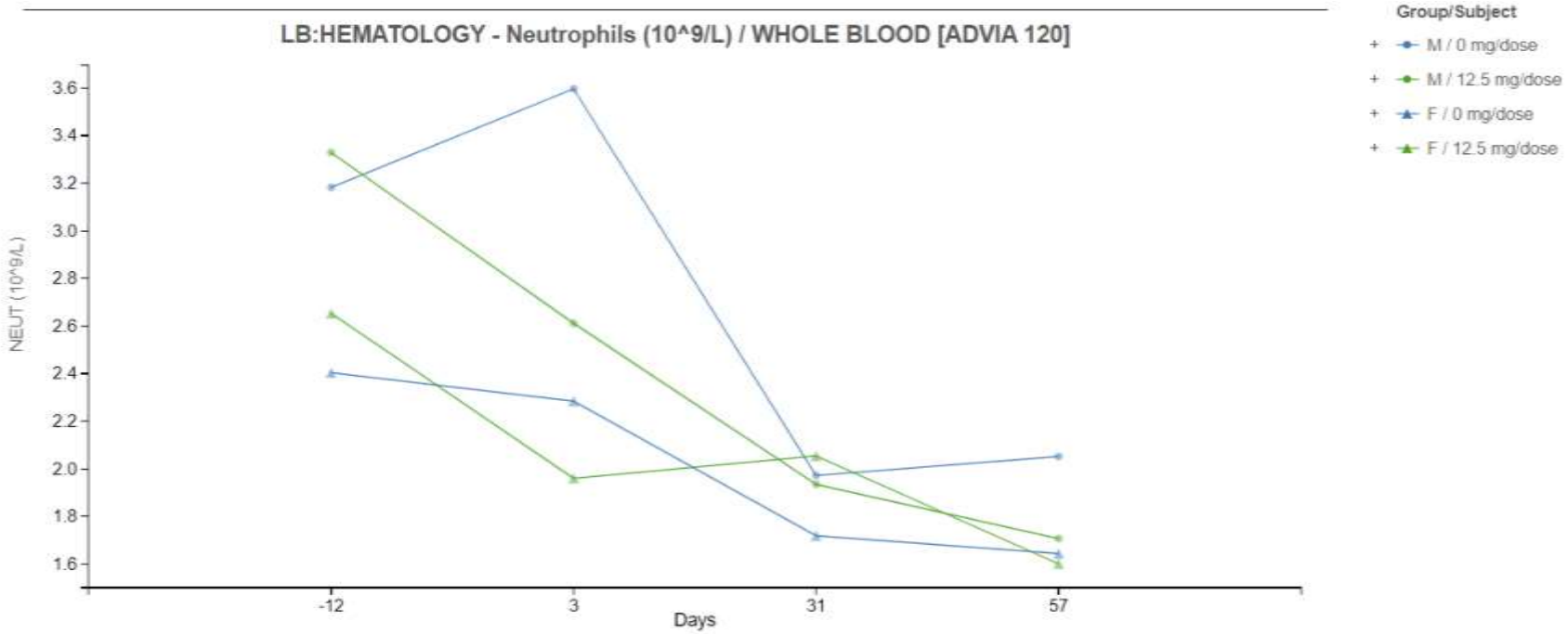
Creatine Kinase increases are markers of inflammation due to test article treatment

C-Reactive Protein Levels



Cut off level of 40 mg/L of the acute phase reactant [CRP] increases (another marker of inflammation) in any group is easy to read from this graph

Neutrophils count



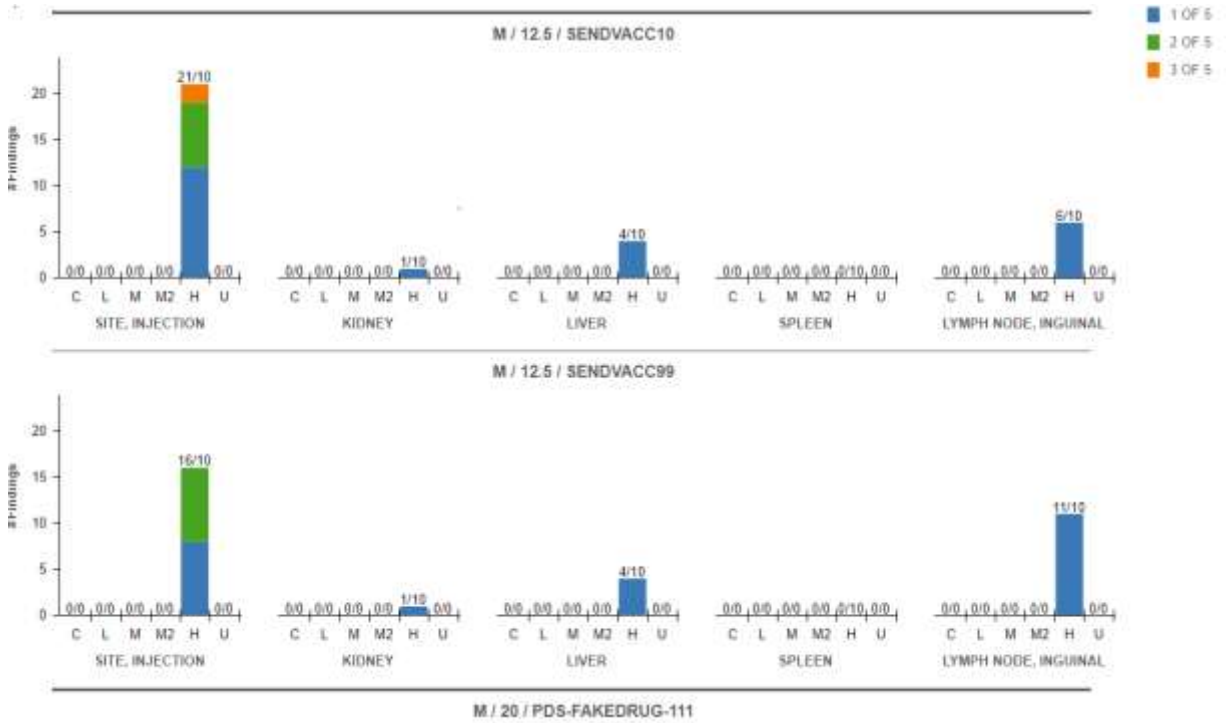
Clinical chemistry findings of neutrophil's levels is obvious in this graph

Microscopic Findings-Table

LYMPH NODE, ILIAC	UNREMARKABLE				11	1	1	1	1	1	1	1	1	1	1	10										1	1
LYMPH NODE, ILIAC	Erythrocytosis	NON-NEOPLASTIC	1 OF 5		1											0								1			1
LYMPH NODE, ILIAC	Increased cellularity	NON-NEOPLASTIC	1 OF 5		2											0						1	1				2
LYMPH NODE, ILIAC	Increased cellularity	NON-NEOPLASTIC	2 OF 5		7											0	1	2	1	2	1			1	1		7
LYMPH NODE, ILIAC	Increased cellularity	NON-NEOPLASTIC	3 OF 5		2											0			1		1						2
				LYMPH NODE, ILIAC Examined:	20	1	1	1	1	1	1	1	1	1	1	10	1	1	1	1	1	1	1	1	1	1	10
LYMPH NODE, MESENTERIC	UNREMARKABLE				18	1	1	1	1	1	1	1	1	1	1	10	1	1	1	1		1	1		1	1	8
LYMPH NODE, MESENTERIC				NOT DONE	2											0					1			1			2
				LYMPH NODE, MESENTERIC Examined:	18	1	1	1	1	1	1	1	1	1	1	10	1	1	1	1		1	1		1	1	8
SITE, APPLICATION	UNREMARKABLE				20	3	3	3	3	2	3	3	3	3	3	10	1	2	1	1	1	3	1	3	3	2	10
SITE, APPLICATION	Cellular debris	NON-NEOPLASTIC	1 OF 5		1											0	1										1
SITE, APPLICATION	HEMORRHAGE	NON-NEOPLASTIC	1 OF 5		1											0	1										1
SITE, APPLICATION	HEMORRHAGE	NON-NEOPLASTIC	2 OF 5		2											0		1			2						2
SITE, APPLICATION	Infiltration, mixed cell	NON-NEOPLASTIC	1 OF 5		3											0	1		1	1							3
SITE, APPLICATION	Infiltration, mononuclear cell	NON-NEOPLASTIC	1 OF 5		5											0			1	1	1		2			1	5
SITE, APPLICATION	Inflammation, mixed cell	NON-NEOPLASTIC	2 OF 5		2											0				1	1						2
SITE, APPLICATION	Inflammation, mixed cell	NON-NEOPLASTIC	3 OF 5		2											0		1			1						2
SITE, APPLICATION	Inflammation, mononuclear cell	NON-NEOPLASTIC	1 OF 5		1					1						1											0
SITE, APPLICATION	Necrosis	NON-NEOPLASTIC	2 OF 5		1											0				1							1
SITE, APPLICATION	Necrosis	NON-NEOPLASTIC	3 OF 5		2											0		1			1						2
				SITE, APPLICATION Examined:	20	1	1	1	1	1	1	1	1	1	1	10	1	1	1	1	1	1	1	1	1	1	10
SPLEEN	UNREMARKABLE				11	1	1	1	1	1	1	1	1	1	1	10								1			1
SPLEEN	Increased cellularity	NON-NEOPLASTIC	1 OF 5		4											0					1	1	1			1	4
SPLEEN	Increased cellularity	NON-NEOPLASTIC	2 OF 5		5											0	1	1	1	1					1		5
				SPLEEN Examined:	20	1	1	1	1	1	1	1	1	1	1	10	1	1	1	1	1	1	1	1	1	1	10

Histopathological findings in numbers are listed in one table using few clicks

Microscopic Findings-Graph



Different histopathological findings in different organs in one graph

THANK YOU

Proof of Concept Pilot Studies

Susan DeHaven
Translational Medicine & Early Development
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Roadmap to SEND for CBER

Key Activities	June 2018-Dec 2019	Nov 2019 - Jun 2020	Jul-20	Dec-20	Mar 15 2021	Mar 15 2023
SEND IG 3.1 Review	Deep review of domains, examples, terminology					
Conduct Proof of Concept		Donated studies w/ team analysis on CDISC WIKI				
Develop Gap Analysis and Recommendations				Assessment Summary Report on CDISC WIKI		
FDA Federal Register Notice Docket No. FDA-2020-N-1313			FRN published		SENDIG V3.1 Supported	SENDIG V3.1 Required

- SEND for CBER Team was a strong collaboration between FDA and CDISC SEND Experts

FDA

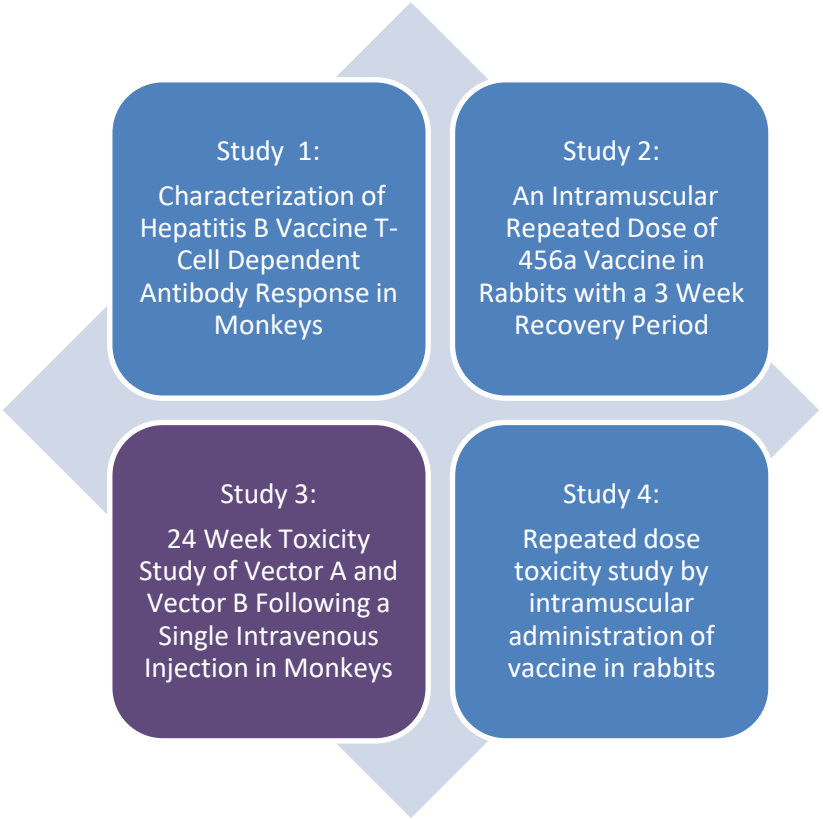
Drug/Vaccine Development Sponsors

CROs

Data Service Providers

Software Vendors

Proof of Concept Pilot Studies



- Four Studies in two modalities were donated to the Pilot:
  - 3 Vaccine
  - 1 Gene Therapy
- No study suitable for OBRR consideration was donated

https://wiki.cdisc.org/display/SEND/Proof+of+Concept+Study+Reviews

Proof of Concept Pilot Endpoints

Endpoints evaluated:

- Clinical observations
- Local tolerance
- Ophthalmoscopy
- Mortality
- Body weight, Food consumption
- Plasma activity and antigen levels
- Immunogenicity/Antibody development
- Clinical pathology – standard hematology , clinical chemistry, urinalysis
- Terminal procedures: comprehensive macroscopic and microscopic evaluation
- Organ weight
- Body temperature
- Specifically noted for Vaccines: C-reactive protein (in rabbits)

Pilot Studies: domains & endpoints

Endpoint	Domain Study 1	Domain Study 2	Domain Study 3	Domain Study 4
Clinical observations	cl	cl	cl	cl
Local reactions				cl
Ophthalmoscopy		cl		cl
Mortality		ds	ds	ds
Body weight, body weight gain	bw, bg	bw	bw	bw, bg
Food consumption		fw		fw
Antigen levels	is*			is*
Immunogenicity/Antibodies			is*	
Protein expression, transgene expression, vector conc.			pc	
Hematology	lb	lb	lb	lb
Clinical chemistry	lb	lb	lb	lb
Coagulation	lb	lb	lb	lb
Urinalysis	lb			
Macroscopic evaluation		ma	ma	ma
Microscopic evaluation		mi	mi	mi
Organ weights		om		om
Body temperature		vs		vs
C-reactive protein (rabbits)		lb		lb

Each pilot study included:

- study design
- nsdrg
- define file
- study report

**is – immunogenicity specimens domain, was piloted as a custom domain, based on SDTM model because it is not yet a SEND standard (current CDISC work in progress)*

Pilot Outcomes:
Study Findings Considerations

KEY BENEFITS

Quick data overview

Consistent terms and units

Original results available

Alignment with Study Report

- Using SEND data enables quick overview of data, such as:

  Seeing differences between scheduled body weight measurements, Identifying body temperatures above normal, Determining key timepoints of collection relative to dosing (i.e. was CRP measured 24, 48 hrs postdose?)
- Correct mapping to controlled terminology and consistent units within/between SEND data, Study Report and nSDRG is helpful
- Use of variables in the SEND data needs to be consistent with SEND IG definitions, for clarity and utility
- Original result values in SEND (--ORRES) are very useful to see the full text of the observation as collected. Standardization of --ORRES parses content into parent domain variables, with possibly comments and/or supplemental qualifiers, such that sometimes difficult to reconstruct.
- Quantification of LOQ or BLQ values are useful when included in supplemental qualifiers

Pilot Outcomes:
SEND "Package" Considerations

- **Study designs for single and repeat dose tox studies fit into SEND trial design domains**
  - Study design descriptions in nSDRG are very helpful
- **Important information dependencies:**
  - Clear description of differences between SEND dataset and study report in nSDRG
  - Consistency between Define file and dataset content
  - Explanation of extended terminology in nSDRG

Pilot Outcomes:
Other Considerations

- **Study "hybrid" e-data submissions are possible**
  - Nonclinical studies submitted to CBER can include some endpoints modeled in SEND and other endpoints not modeled in SEND
    - Efficacy endpoints within a tox study are not modeled in SEND IG 3.1
    - Not all endpoints for CBER studies are yet in scope of SEND
- **All data that can be submitted in SEND is helpful to the review**
  - Biodistribution data can be modeled using PC domain, though not specifically mentioned in SEND IG yet
  - "IS" Custom domain is not required, but can be accepted, or data (such as ADA) may fit in LB domain, under SEND IG 3.1
  - Clarify for Reviewers which data has been submitted in e-format or not, in nSDRG
- **As future SEND IG versions come into publication and adoption by CBER, e-data scope is expected to expand accordingly**

SEND For CBER Team Future
Ongoing Mission

- **Support CDISC SEND Team to include CBER considerations in standards development by:**
  - Participating in domain working groups for Exposure, Immunogenicity Specimens and modeling of dermal/ocular findings
  - Contributing to relevant controlled terminology development
  - Contributing to CDISC SEND IG version 3.2 scope decisions and development
  - Remain engaged, as future SEND IG versions come into publication and adoption by CBER, scope is expected to expand accordingly (i.e. repro studies)
- **Support FDA's data standards efforts by:**
  - Developing recommendations for Technical Conformance Guide
  - Considering conformance and business rules applied to CBER e-data submissions
  - Communicating Proof of Concept Pilot and other team deliverables to industry stakeholders

Resources

- *FDA Data Standards Catalog*
- *Federal Register Notice regarding SEND for CBER*
- *FDA Data Standards Program Action Plan*
- *SEND for CBER wiki site*

Summary

- CBER is ready to support SEND data for non-clinical study submissions
- Requirement date of CBER SEND submission is March 15, 2023
- Future development on SENDIG for CBER

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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