U.S. FOOD & DRUG ADMINISTRATION


# Optimizing Your Study Data Submissions to FDA: OVRR Data Submission

## May 8th 2018

Center for Drug Evaluation and Research (CDER)

# Submitting Clinical Trial Data Sets for Vaccines to the Office of Vaccines Research and Review, Center for Biologics Evaluation and Research

SBIA: Study Data Technical Conformance Webinar

May 8, 2018

Brenda Baldwin, Ph.D.

# Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review

## Guidance for Industry

*Technical Specifications Document*

**This guidance is for immediate implementation.**

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with docket number FDA-2018-D-1358.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or

# Goals of Presentation

- Preferred usage of CDISC SDTM domains and variables for vaccine clinical trial data:
  - Safety
    - Reactogenicity
    - Unsolicited Adverse Events (AEs), including Medically Attended AEs (MAAEs)
    - Death
    - Laboratory Safety Assessments
  - Effectiveness
    - Clinical Disease Endpoint
    - Immunogenicity
  - Maternal Immunization

❖ **SDTM v1.4/ STDMIG 3.2 or higher**

# FDA Data Standards Catalog v5.0 (Apr 20, 2018)- Supported Versions of SDTM

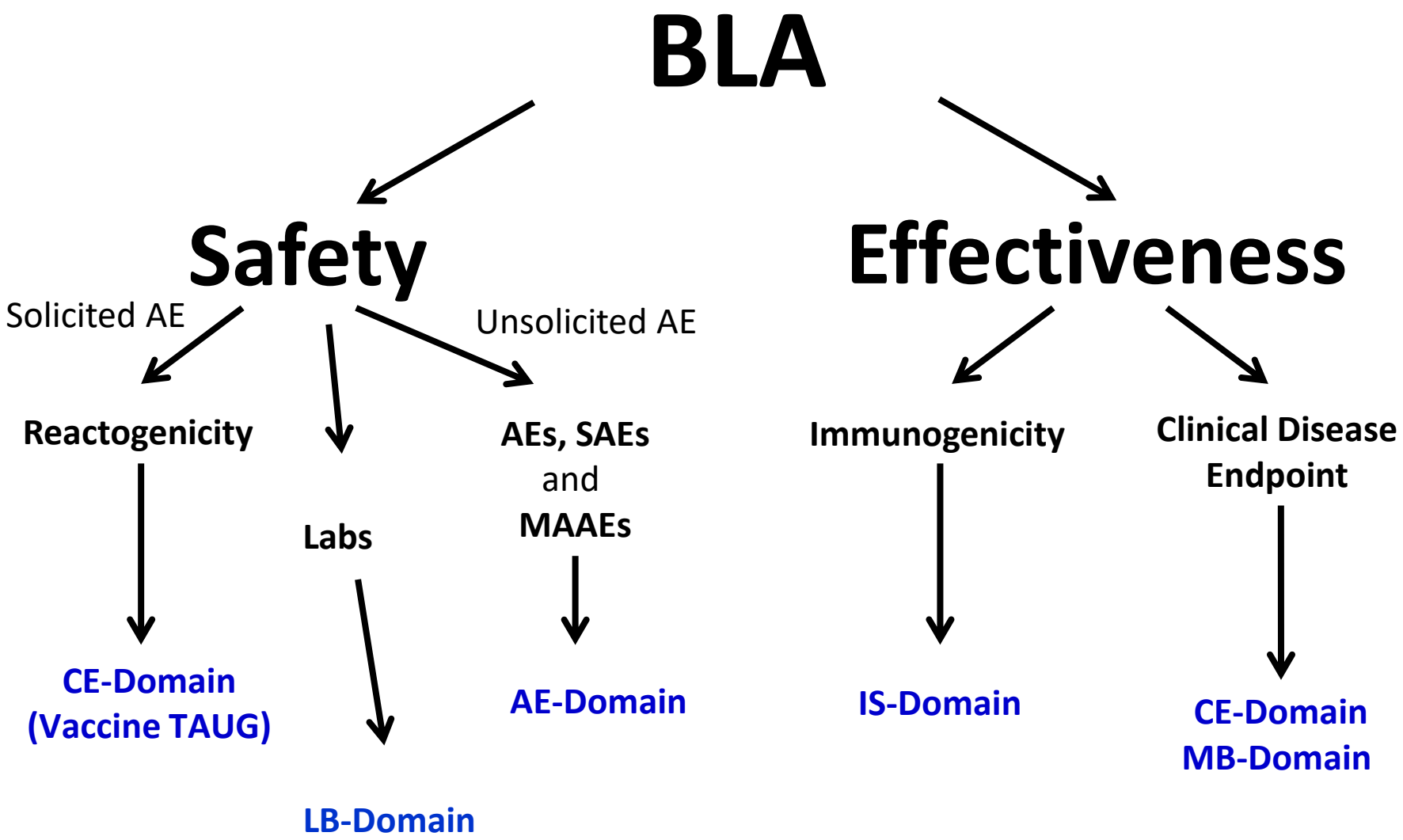
| Use | Data Exchange Standard | Exchange Format | Standards Development Organization (SDO) | Supported Version | Implementation Guide Version | FDA Center(s) | Date Support Begins (MM/DD/YYYY) | Date Support Ends (MM/DD/YYYY) | Date Requirement Begins (MM/DD/YYYY) |
|---|---|---|---|---|---|---|---|---|---|
| Clinical study datasets | Study Data Tabulation Model (SDTM) | XPT | Clinical Data Interchange Standards Consortium (CDISC) | 1.1 | 3.1.1 | CDER, CBER | Ongoing | 01/28/2015 | |
| Clinical study datasets | SDTM | XPT | CDISC | 1.2 | Version 3.1.2 Amendment 1 | CDER, CBER | 08/07/2013 | 03/15/2019 [1]<br>03/15/2020 [2] | 12/17/2016 [1]<br>12/17/2017 [2] |
| Clinical study datasets | SDTM | XPT | CDISC | 1.2 | 3.1.2 | CDER, CBER | 10/30/2009 | 03/15/2019 [1]<br>03/15/2020 [2] | 12/17/2016 [1]<br>12/17/2017 [2] |
| Clinical study datasets | SDTM | XPT | CDISC | 1.3 | 3.1.3 | CDER, CBER | 12/01/2012 | | 12/17/2016 [1]<br>12/17/2017 [2] |
| Clinical study datasets | (SDTM) | XPT | CDISC | 1.4 | 3.2 | CDER, CBER | 08/17/2015 | | 03/15/2018 [1]<br>03/15/2019 [2] |

# All submissions should contain

- Trial Summary (TS)
- Demographics (DM)
- Subject Visits (SV)
- Concomitant Medications (CM)
- Exposure (EX)
- Disposition (DS)
- Protocol Deviations (DV)
- Medical History (MH)
- Physical Examinations (PE) - if included in the protocol
- Laboratory Tests (LB) - if safety labs included in protocol

# Disposition (DS) Domain

- Should always include the DECOD, TERM, CAT and STDTC variables.
- If relevant (i.e., multiple doses administered over time) the DS domain should include the use of the TAETORD timing variable


BLA
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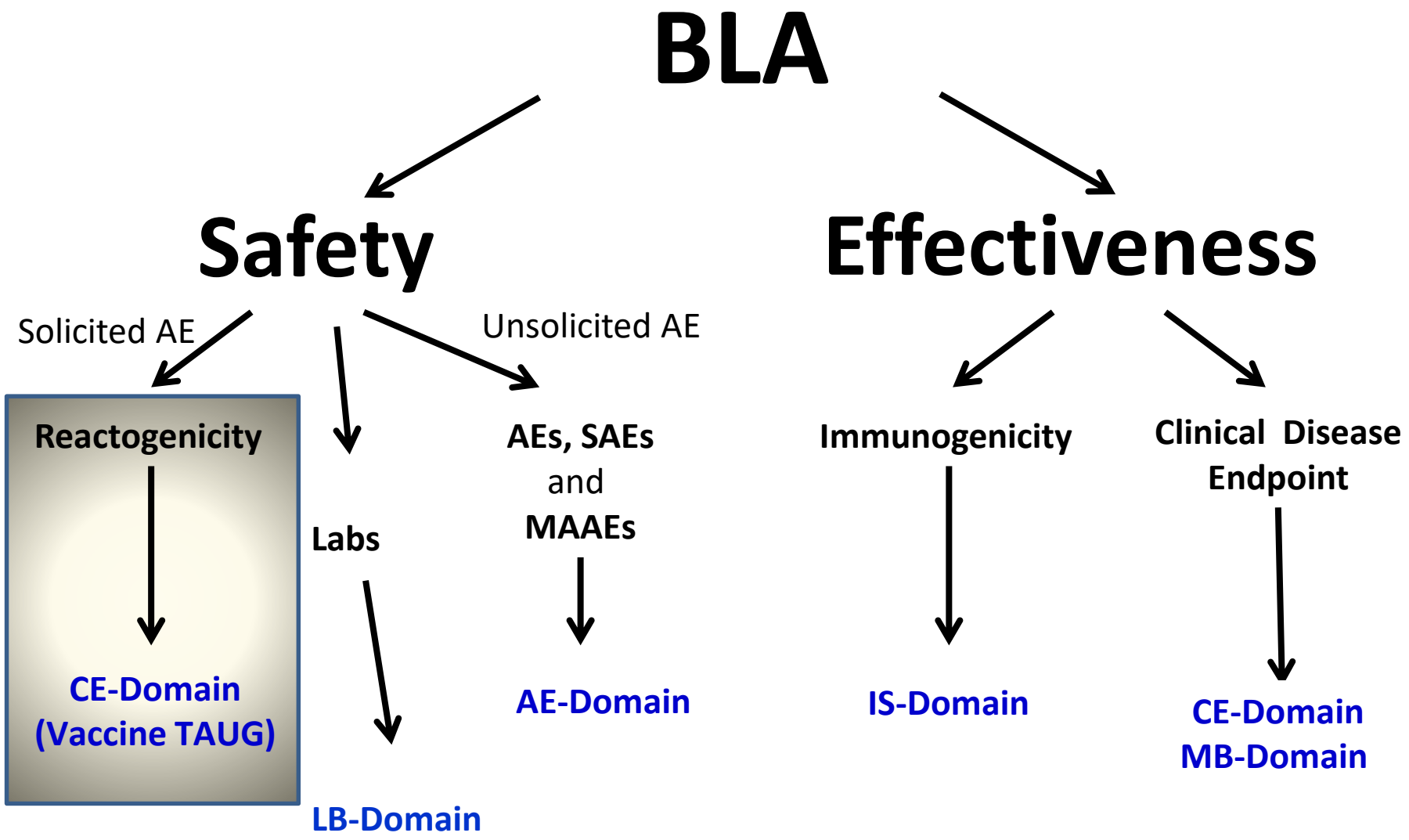
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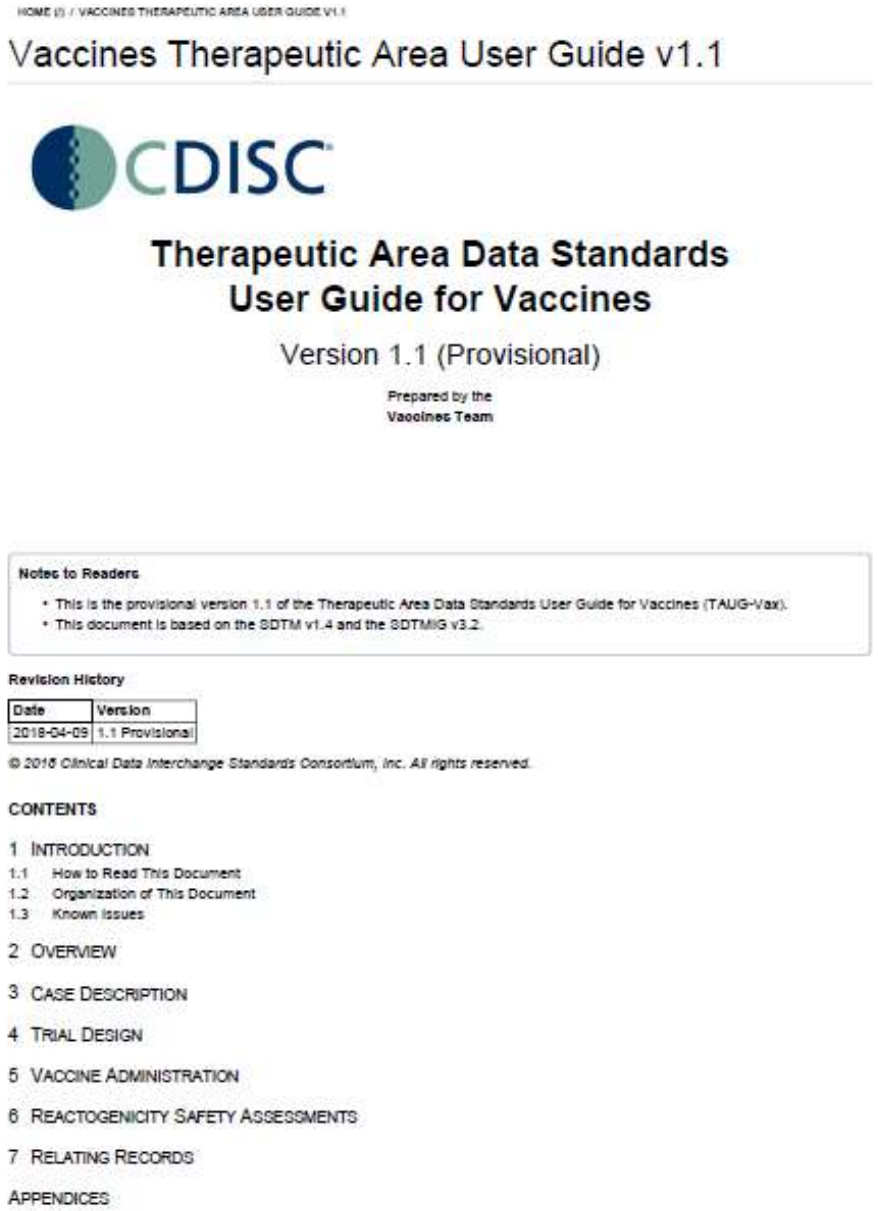
# Vaccine Therapeutic Area User Guide (TAUG)



HOME (/) / VACCINES THERAPEUTIC AREA USER GUIDE V1.1

Vaccines Therapeutic Area User Guide v1.1

CDISC

**Therapeutic Area Data Standards User Guide for Vaccines**

Version 1.1 (Provisional)

Prepared by the Vaccines Team

**Notes to Readers**

- This is the provisional version 1.1 of the Therapeutic Area Data Standards User Guide for Vaccines (TAUG-Vax).
- This document is based on the SDTM v1.4 and the SDTMIG v3.2.

**Revision History**

| Date | Version |
|---|---|
| 2018-04-09 | 1.1 Provisional |



**CONTENTS**



Can be found at: https://www.cdisc.org/standards/therapeutic-areas/vaccines

# Reactogenicity Data

- Domains to be utilized - Clinical Event (CE), Findings About (FACE) and Vital Signs (VS)
- CECAT "reactogenicity" and CESCAT "administration site" or "systemic"
- Prefer Flat Model, but may allow Nested Model – please discuss with review team

# Reactogenicity – Flat Model

- CE - record for each event for each subject
  - CETERM as the event name
  - CEOCCUR = "Y" or "N"
  - If “Y” - CESTDY/CESTDTC and CEENDY/CEENDTC should be collected and included
    - If dates unknown – CESTDY/CESTDTC and/or CEENDY/CEENDTC should be null, CO should provide reason
    - CEPATT can be noted if collected
- Daily records in FACE
- Daily temperature measurements in VS domain
- RELREC should be used to represent relationships

# Annotated Case Report Form (aCRF)

- Checkbox to indicate (Y/N) whether reactogenicity event did or did not occur during prespecified time frame
- Checkbox to indicate (Y/N) whether reactogenicity event was collected every day during assessment interval
  - If box is “N” the OCCUR variable is “Y” or “null”
  - the --STAT and --REASND variables in CE (covering the assessment interval), FACE and/or VS must be utilized

# Reactogenicity event extends beyond assessment interval

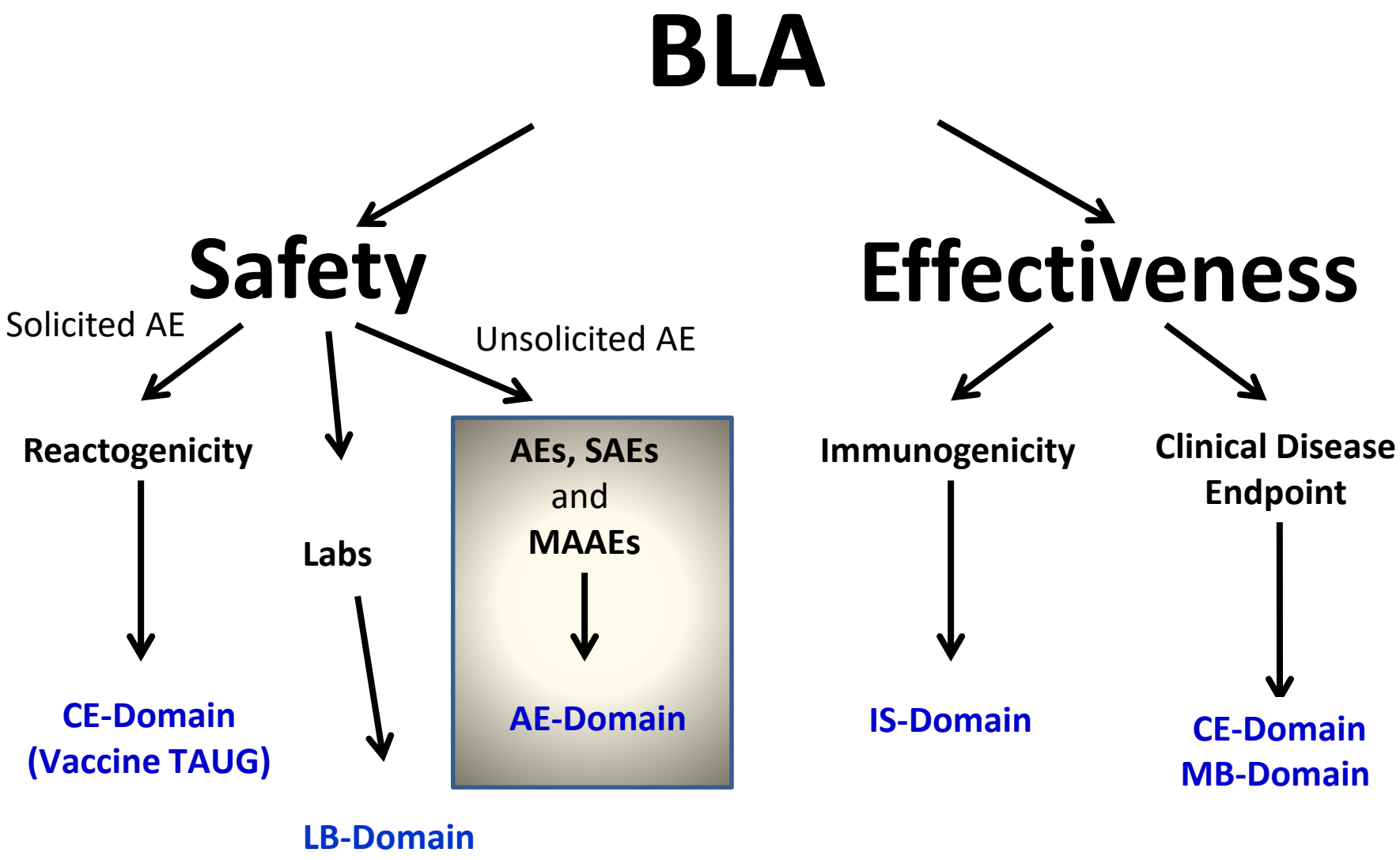
- In CE - use CEENTPT (e.g. “Day 7”) and CEENRTPT (“Ongoing”)
- Also record in AE - categorize (AECAT) as “reactogenicity”
- In both CE and AE - start day/date (--STDY/--STDTC) and end day/date (--ENDY/--ENDTC) should be identical
- Duration (--DUR) should capture the time that the event occurred as part of the assessment interval and as part of the continuance separately
  - e.g., an event that lasted 6 days in the assessment interval and 3 days beyond the assessment would be CEDUR= 6 days and AEDUR = 3 days
- A dataset-level relationship in RELREC should be used

# Reactogenicity event extends beyond assessment interval (cont)

- We recommend inclusion of checkboxes in the aCRF to indicate:
  - whether the reactogenicity event is ongoing after assessment period
  - duration of the reactogenicity event in the assessment period and the duration of the reactogenicity event beyond the assessment period

# Reactogenicity event becomes a Serious Adverse Event (SAE) during prespecified assessment interval

- CE domain indicates it became serious by a “Y” in CESER
- FACE should contain the daily records – SER as a nsv or as a suppFACE variable
- Record event in AE and categorize (AECAT) as “reactogenicity”
- In both CE and AE - start day/date (--STDY/--STDTC) and end day/date (--ENDY/--ENDTC) should be identical
- A dataset-level relationship in RELREC should be used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# Unsolicited AEs

- AE domain - one record per adverse event per subject for each unique event “collapsed” to the highest level of severity, causality, seriousness, and the final outcome
- AESTDY/AESTDTC and AEENDY/AEENDTC should be utilized
- Day-to-day details reported in FAAE and possibly VS
- CM, PR, HO and/or DD domains should be utilized if the corresponding variables in AE are marked as yes
- A dataset-level relationship in RELREC should be used

# Medically Attended Adverse Events (MAAEs)

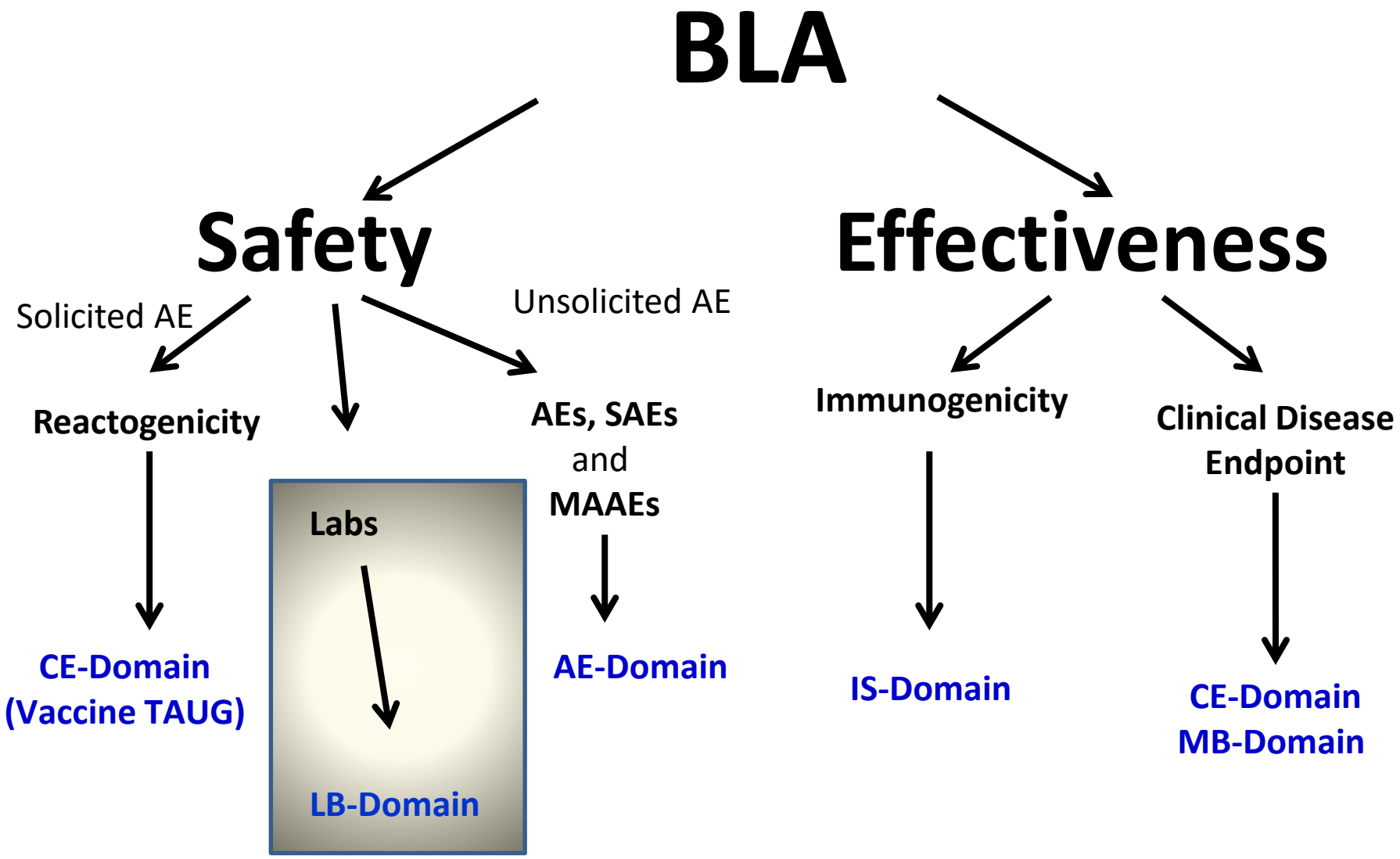
- Report in AE domain
  - Categorize (CAT) Potential immune-mediated medical conditions as "PIMMC"
  - Categorize (CAT) New onset of a chronic disease as "NOCD"
- Day-to-day details in FAAE and/or VS
- Additional data reported in HO and/or DD
- A dataset-level relationship in RELREC should be used

# MAAEs (cont)

- If a chronic disease is exacerbated following a vaccination, MH domain should contain data on the disease prior to the first day of vaccination and AE domain should contain data on the disease following vaccination
  - AECAT and AESCAT should be utilized - e.g., kidney failure would be categorized as “renal medical history” and subcategorized as “renal failure”

# Death

- Report in AE – use the AESDTH
- Report in DM - use the DTHFL (death flag) and DTHDTC (date/time of death)
- Supplemental information provided in the DD domain
- A dataset-level relationship in RELREC should be used.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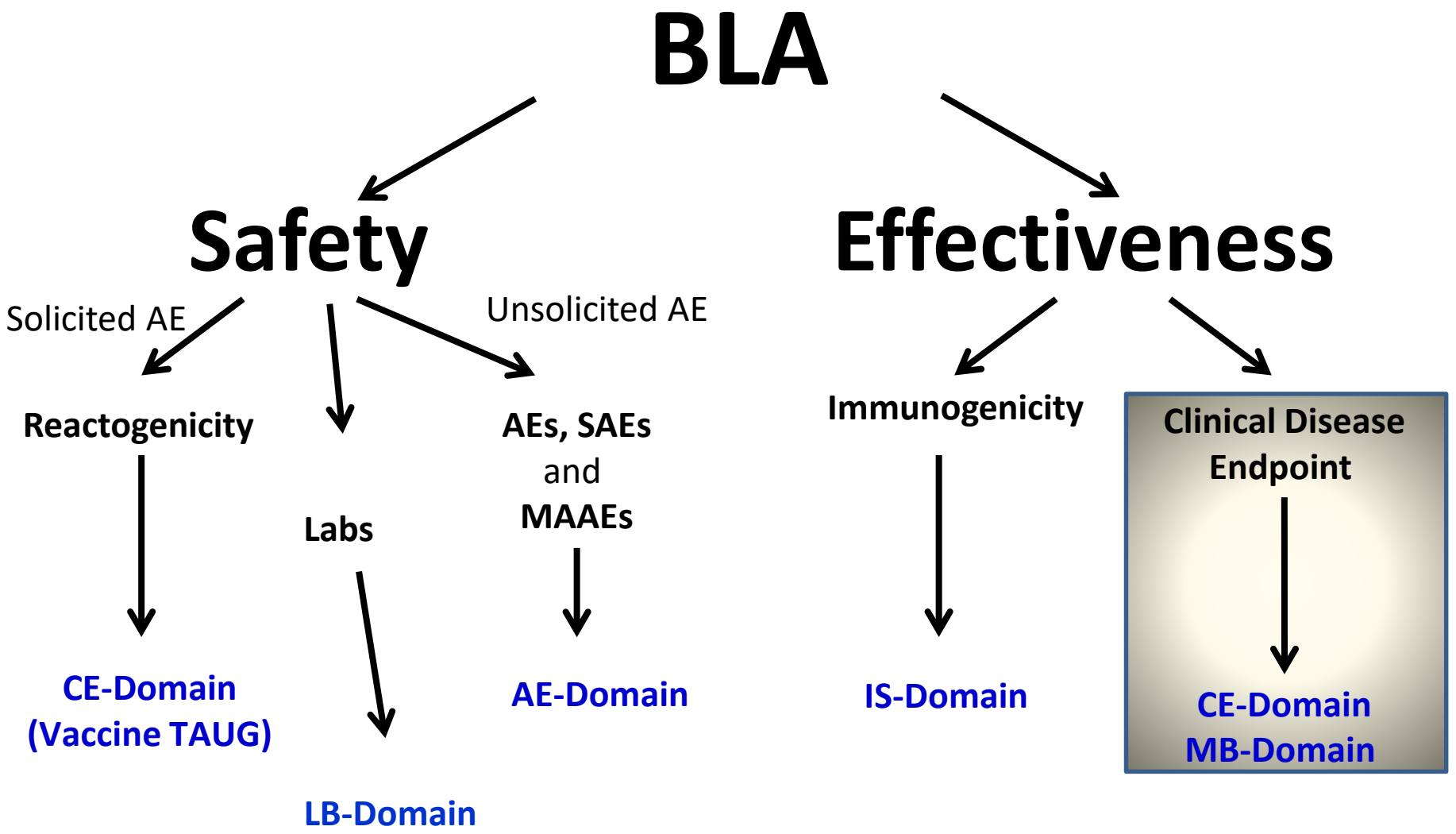
# Laboratory Safety Assessments

- Clinical chemistry, hematology and urine data should be included in the LB domain
- If the laboratory result for a particular assessment for a subject is outside the normal range, it should additionally be captured in the AE domain with the highest level noted
- A dataset-level relationship in RELREC should be used

# Data Traceability

- Sponsors should be able to clearly identify a “chain of custody” of the data. It should be clear who (e.g., subject, parent or custodian, investigator, sponsor) entered the data at all points and the source used (e.g., Diary Card, CRF).

- The use of variables --EVAL, --ACPTFL and --CLTYP (nsv for “Collection Type”) can be included in domains FA and VS to indicate the origin of each data line.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# Clinical Disease Endpoint

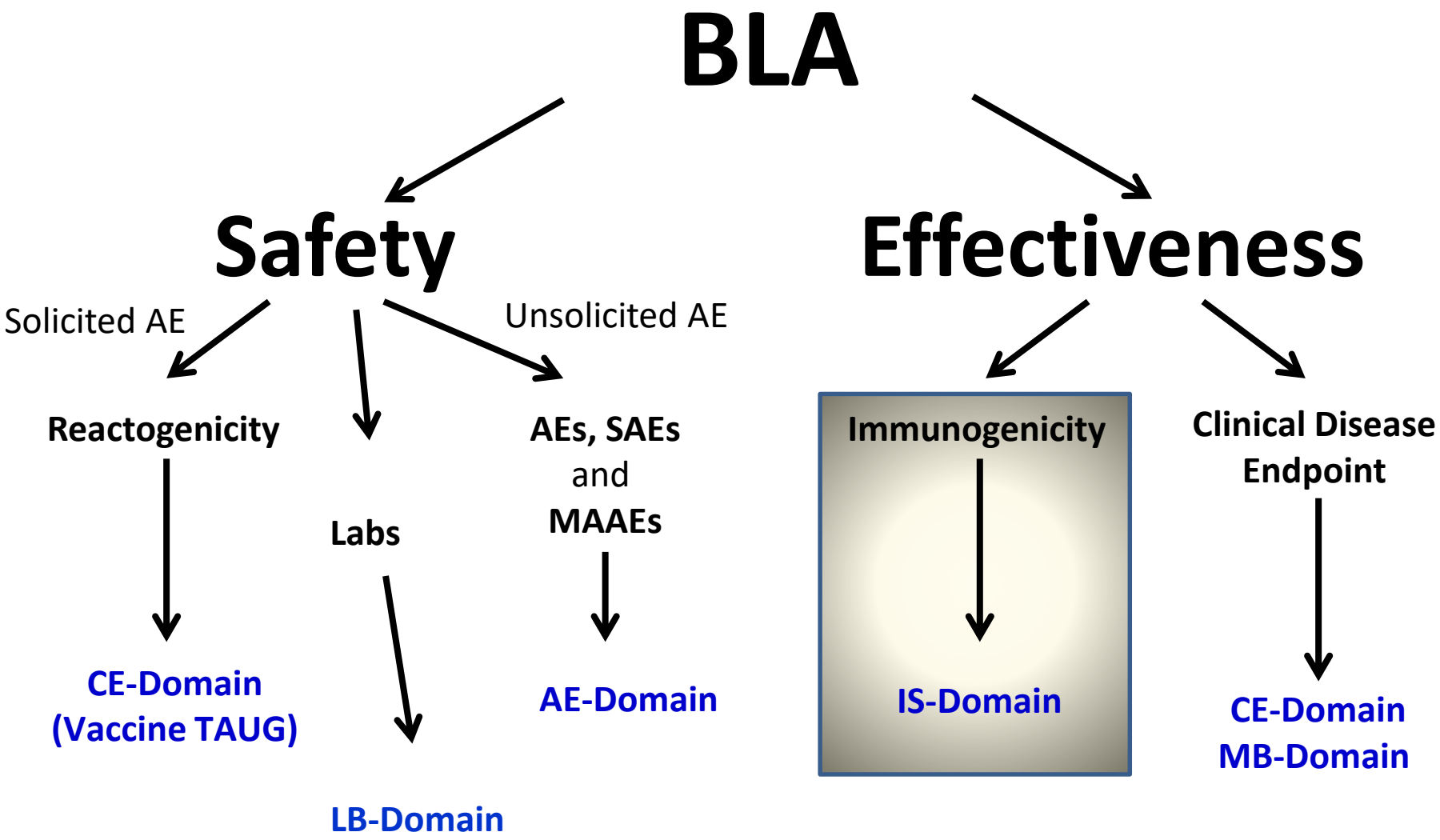
- CE
  - CECAT as “efficacy”
  - Because pre-specified - must use CEOCCUR, CESTAT and CEREASND
  - CETERM should be indicative of the disease, e.g., for an influenza vaccine it would be “Influenza-like illness or ILI”
  - Use CESHOSP and CECONTRT if hospitalization occurs or concomitant medication was taken to alleviate symptoms
- MB - Test results for microbe of interest (e.g., from PCR, ELISA, or cell culture)
  - if result is negative, use nsv “Control” to indicate status of result for control (e.g., β-actin positive/negative)
- FACE - Categorize (CAT) as “efficacy”
- VS
- PE (if part of protocol)

# Confirmation of Disease

- Flagged in DM
  - Use nsv of CECASE – indicate “Y” or “N”, or
  - In suppDM domain
    - If disease occurred - QNAM= “CECASE”, QLABEL= “Clinical endpoint case flag” and QVAL= “Y”
    - If disease did not occur - QNAM= “CECASE”, QLABEL= “Clinical endpoint case flag” and QVAL= “N”

# Confirmation of Disease (cont)

- The manner in which the occurrence of a disease of interest is confirmed (e.g., by an adjudication committee or by the clinical investigator or by another mechanism) should be clearly delineated in the clinical protocol
- CEEVAL and CEACPTFL variables should be used if relevant
- A check box in the CRF, indicating the status (i.e. confirmation or not) of the disease of interest, is recommended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# Immunogenicity

- Data related to the assessment of immunogenicity should be captured in the Immunogenicity Specimen (IS) domain (in SDTM v1.4 and higher)

- The LB domain should not be used for immunogenicity data

# Maternal Immunization Clinical Trials

- Relationship between mother and child should be represented in Relationship of Study Subjects (RELSUB)
  - Fetuses given a USUBJID value - appends an A or B to the mother's USUBJID
- In DM domain, the informed consent and vaccination administration date for the fetus are the same as for the mother.
  - Age of enrollment will be a negative number in weeks.
  - Birth date for the infant - reported in BRTHDTC

# Maternal Immunization Clinical Trials (cont'd)

- Since the amount of vaccine that reaches the fetus is unknown, the Dose Description (EXDOSTXT) should indicate "Fetal Exposure"
  - DOSE should be null
- Use reproductive findings (RP) domain to report maternal date of last menstrual period
  - Gestational age at exposure can be calculated

# Take Home Recommendations

- Utilize recommended domains and variables for vaccine clinical trial dataset submissions to OVRR
- Provide a clear, traceable pathway from the primary collection documents (e.g. Diary Cards, EHR, CRF) to the raw datasets (SDTM) to the analysis datasets (ADaM)

U.S. FOOD & DRUG ADMINISTRATION

# Submitting the Study Data Standardization Plan (SDSP) with the CBER Appendix to OVRR

SBIA: Study Data Technical Conformance Webinar

November 8, 2017

Kirk Prutzman, Ph.D.

# Goals of Presentation

- Reason for SDSP CBER appendix creation
- Timeline for submission
- Overview of SDSP CBER appendix
  - SDTM datasets
  - ADaM datasets
  - Integrated Summary of Safety and Integrated Summary of Efficacy
  - Supplemental qualifiers

# Reason for SDSP CBER appendix
## (Common dataset problems that result in delays)

- Clinical data discrepancies (e.g. numbers don't "add up" across tables, between sections, etc.)
- Additional clinical analyses needed
- Unclear clinical data presentation (e.g., terminology, controls, definitions, timing of events, etc.)
- Wrong statistical methods used - both in CMC assays and clinical data analysis
- Uninterpretable datasets
- Lack of follow-up info on subjects with AEs
- Overall disorganization

# Reason for SDSP CBER appendix
## (Delays and extra work due to data integrity issues)

Examples of poor quality data submitted to OVRR were presented [July 13, 2017 Webinar]

- Necessitate information request from CBER that took 2-4 weeks (or longer) for applicants to respond
  - Possibility of a Major Amendment (extend the review clock 3 months)
- Complete response (CR) letters that took 6 months to 2 years for an applicant to respond
  - Revised Datasets
  - Revised Clinical Study Report
- Additional 6 month review clock when a sponsor submits a response to a CR letter

# Timeline for submitting SDSP CBER appendix

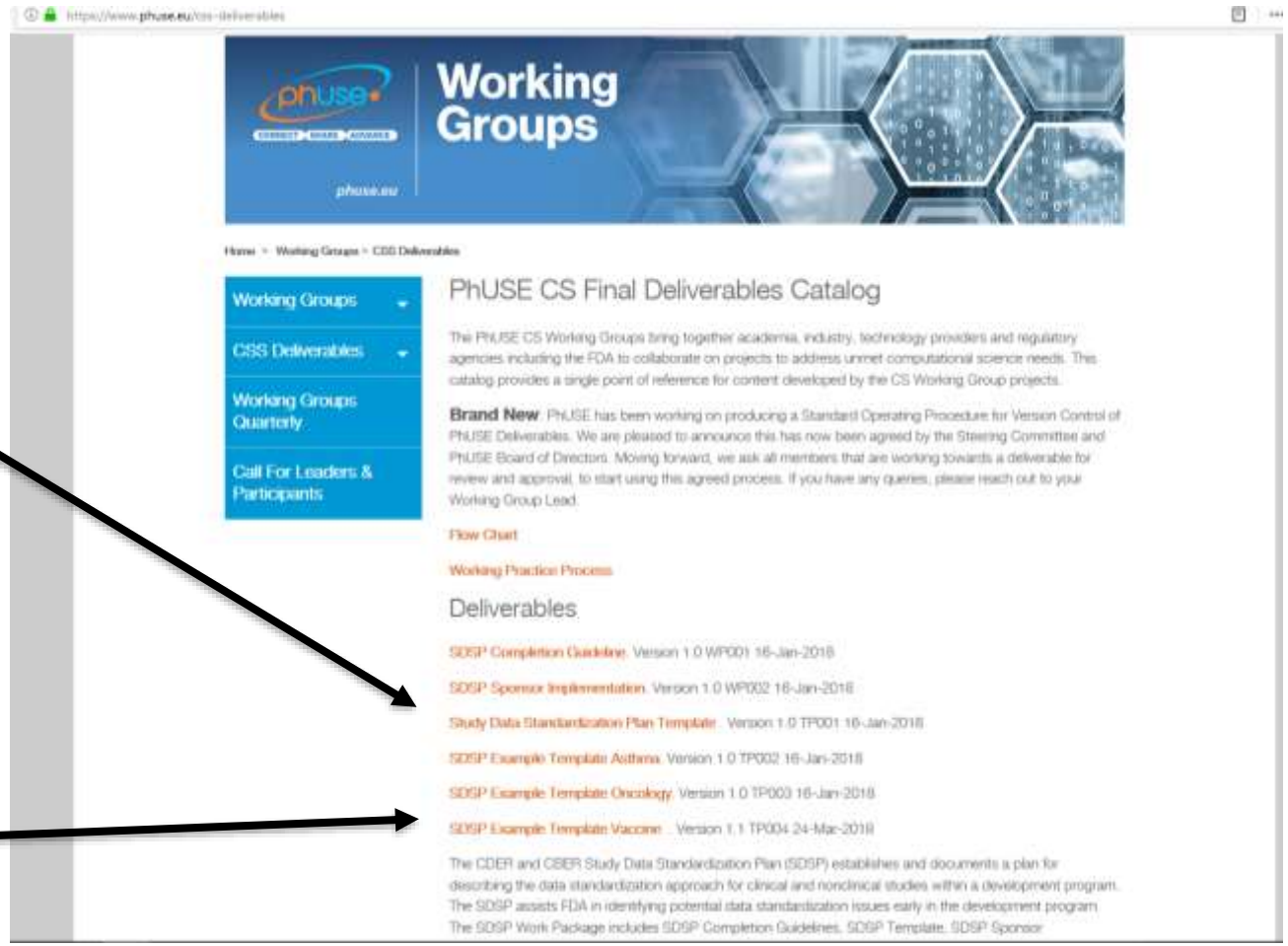
- Too late if at preBLA
  - Data already captured and datasets have been constructed
- We recommend submitting to CBER by End-of Phase 2 or earlier
  - Can be part of an EOP2 meeting package or,
  - Submit the SDSP in an amendment to your IND (eCTD Module 1.13.9 General Investigational Plan)
- We also recommend submitting an annotated Case Report Form (aCRF) with at least your phase 2 and phase 3 protocols
- **Incorporate OVRR comments into design of data collection**

# Overview of SDSP CBER appendix

## (Where to find a template and example)

**SDSP Template**

**SDSP Example Vaccine**




https://www.phuse.eu/css-deliverables

# Overview of SDSP (non-clinical)

## 4. List of Studies and Standards

### 4.1 Nonclinical

| Study Identifier | Brief Title | Study Type | Study Status | Study Start Date | Exchange Standards | Terminology Standards |
|---|---|---|---|---|---|---|
| If value is unknown, specify TBD | | Please See Completion Guidelines for more information<br><br>If value is unknown, leave blank or specify TBD | COMPLETED<br>ONGOING<br>PLANNED | ccyy-mm-dd <(forecasted Protocol sign)><br><br>TBD | LEGACY<br><br>SDTM v<version>/ SEND IG <version><br><br>SDTM vTBD/ SEND IG TBD<br><br>tumor.xpt<br><br>define.xml<version><br><br>define.xml TBD<br><br>No Electronic Data | Sponsor Defined Terminology<br><br>CDISC SEND Terminology <date><br><TBD><br><br>NONE |

# Overview of SDSP (clinical)

**4.2 Clinical**

| Study Identifier | Brief Title | Study Design | Study Status | Study Start Date | Exchange Standards | Terminology Standards |
|---|---|---|---|---|---|---|
| <Phase <x>> <Interventional/Observational/Expanded Access> Studies - <indication or Healthy Subjects or Healthy Volunteers> | | | | | | |
| If value is unknown, specify TBD | | Please See Completion Guidelines for more information<br><br>If values are unknown, leave blank or specify TBD | COMPLETED<br><br>ONGOING<br><br>PLANNED | ccyy-mm-dd <(forecasted Informed Consent)><br><br>TBD | ANALYSIS LEGACY<br><br>ADaM v<version>/ ADaM IG <version><br><br>ADaM define.xml <version><br><br>ADaM vTBD/ ADaM IG TBD<br><br>ADaM define.xml TBD<br><br>TABULATIONS LEGACY<br><br>SDTM v<version>/ SDTM IG <version><br><br>SDTM define.xml <version><br><br>SDTM vTBD/ SDTM IG TBD | Sponsor Defined Terminology<br><br>CDISC SDTM Terminology <date> <TBD><br><br>MedDRA (Adverse Events/ Medical History/ <other>) Initial <version> Final <version> Initial TBD Final TBD<br><br>WHO-DD (Medications) <version> <TBD><br><br>LOINC (Lab Test Term) <version> <TBD> |

**Indicate versions of ADaM/ADaMIG SDTM/SDTMIG and Define.xml**

**Indicate versions Of Terminology Standards**

# Overview of SDSP CBER appendix - SDTM datasets

## CBER Appendix

### 1. Introduction

#### 1.1 Purpose

The purpose of this appendix is to document additional study data information. This document should be submitted well in advance of any licensing application (ie, no later than the end of phase 2 meeting) to CBER. Receipt of this document in a timely manner will help to ensure an efficient review process.

#### 1.2 Scope

The scope of this document is to facilitate study data review by CBER reviewers.

### 2. SDTM Datasets

List all SDTM datasets used/planned for each clinical study in the submission.

| SDTM Version: | | | |
|---|---|---|---|
| STUDY ID: | TITLE: | | |
| DOMAIN | Select Domains to be Submitted X | Variables to be utilized (besides required) | Additional Comments |
| Trial Design | | | |
| TA (Trial Arms) | <X> | | |
| TE (Trial Elements) | <X> | | |
| TI (Trial Inclusion/ Exclusion Criteria) | <X> | | |
| TS (Trial Summary) | <X> | | |
| TV (Trial Visits) | <X> | | |
| TD (Trial Disease Assessments) | <X> | | |
| Special Purpose | | | |
| CO (Comments) | <X> | | |
| DM (Demographics) | <X> | | |
| SE (Subject Elements) | <X> | | |
| SV (Subject Visits) | <X> | | |

**Indicate non-Required (Exp, Perm) variables used**

**Check box for domain that will be submitted**

# Overview of SDSP CBER appendix SDTM datasets

- CBER Appendix includes all domains the subject classes
  - Special Purpose
    - Demographics, Trial Design, Comments, Subject Elements, Subject Visits
  - General Observation Classes
    - Interventions, Events, Findings, Findings About
  - Relationships
    - RELREC
  - Custom (discuss with review committee)
- SDSP may be revised by PhUSE as newer version of SDTM and SDTMIG become available

# Overview of SDSP CBER appendix - Supplemental qualifiers

### 3. Supplemental Qualifiers

List each SUPPQUAL variable in an individual row. Include one set per clinical study.

| SDTM Version: | | | |
|---|---|---|---|
| STUDY ID: | TITLE: | | |
| **Supplemental Qualifier Domain** | **Qualifier Variable Name (QNAM)** | **Qualifier Variable Label (QLABEL)** | **Corresponding CRF Question or Derivation information** |
| | | | |

- **The listing of SUPPQUAL variables should match what is indicated in Section 2 of the CBER Appendix.**
- **Non-Standard Variables (NSV) in Standard Domains will be available in new versions.**

# Overview of SDSP CBER appendix -ADaM datasets

Check box for domain that will be submitted

**4. ADaM Datasets**

List all ADaM datasets used/planned for each clinical study (if analysis is planned to be performed on the individual study).

| ADaM Version: | | | |
|---|---|---|---|
| STUDY ID: | TITLE: | | |
| **TYPE** | **DOMAIN** | **Select Domains to be Submitted X** | **Comments** |
| | ADSL (Subject Level Analysis Dataset) | <X> | |
| | BDS (Basic Data Structure) | <X> | |
| | OCCDS (Occurrence Data Structure) | <X> | |
| | <DOMAIN NAME> <(Domain Long Name)> | <X> | |

# Overview of SDSP CBER appendix - Integrated Summary of Safety and Integrated Summary of Efficacy

Provide definition of acronym for dataset label

Essential to list all contributing datasets

## 5. ISS and ISE

The following table summarizes the Integrated Summary of Safety and Integrated Summary of Efficacy using ADaM (ISS and ISE).

List all ADaM domains that will be used in the submission.

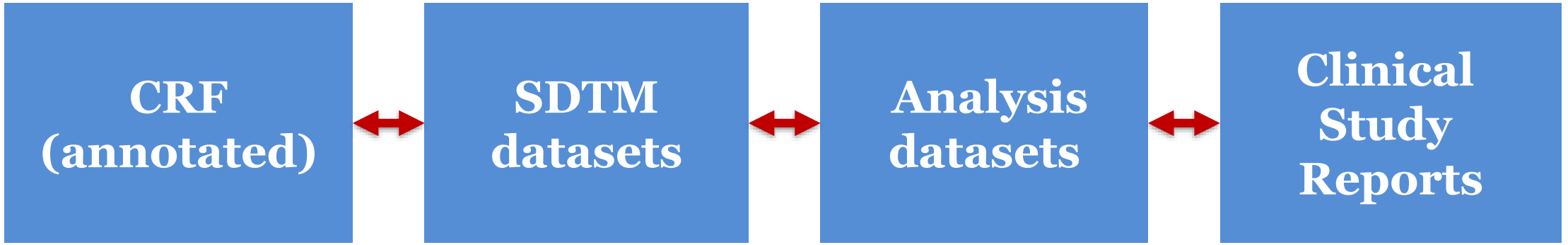
| Dataset Label | Efficacy | Safety | Other* | Included Studies | Phase | Contributing Datasets |
|---|---|---|---|---|---|---|
| <ADSL (Analysis Dataset – Subject Level)> | <X> | <X> | <X> | | <1/2/3> | |
| | | | | | | |

*other: endpoints not part of safety and efficacy (e.g. immunogenicity)

# Common Issues Identified in the submitted CBER Appendix

- Use of older version of SDTM and SDTMIG
  - OVRR prefers SDTM v1.4 and SDTMIG 3.2 or higher
- Use of Supplemental Qualifier variables when equivalent variables exists in standard domains
- Supplemental Qualifier variables listed in table 3 not represented in table 2 Supplemental Qualifiers
- Reactogenicity data reported in AE
  - Should be reported in CE
- Biological assay results reported in LB
  - Immunogenicity should be reported in IS
  - Other biological assays should be reported in MB
- aCRF and SDSP should match the protocol

# Data Traceability




One important goal of the submitting the SDSP with the CBER appendix to OVRR early in vaccine development is improved data traceability.

# What does an applicant do when submitting CDISC data to OVRR

- Validate raw data/analysis data and correct where possible before submission (validation follows the FDA specific SDTM Validation Rules)
- Provide a Study Data Regulatory Guide (SDRG) and Analysis Data Regulatory Guide (ADRG) –
  - It should describe any special considerations or directions that may facilitate an FDA reviewer's use of the submitted data and may help the reviewer understand the relationships between the study report and the data
  - Also should describe data conformance and issues summary
  - 1 SDRG/study and 1 ADRG/study (clinical and non-clinical)
- Provide a Define.xml file

# Take Home Recommendations

During the IND phase:

1. Annotated CRFs should be submitted with protocols
2. The Study Data Standardization Plan (SDSP) with CBER Appendix should be submitted by the End of Phase 2 Meeting

For the BLA:

1. Prior to submitting CDISC data to a BLA the sponsor should:
   - ✓ Validate the SDTM and ADaM datasets and correct warnings and errors
   - ✓ Warnings/errors that cannot be corrected should be identified and a rationale provided in SDRG/ADRG
2. The sponsor should have a clear, traceable pathway from the primary collection documents (e.g. Diary Cards, CRF to the raw datasets (SDTM) to the analysis datasets (ADaM).

# Q&A and Resources

Click for:

- Email any unanswered questions to: CDERSBIA@fda.hhs.gov
- Submitting Clinical Trial Data Sets for Vaccines to the Office of Vaccines Research and Review
- Vaccine TAUG
- Study Data Technical Conformance Guide
- FDA Data Standard Catalog
- Study Data Standardization Plan with CBER Appendix (PhUSE)
- SDSP Example Template Vaccine (PhUSE)
- Technical Rejection Criteria for Study Data
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