

CDASH SAE v2.0 Supplement Public Review

John Owen, Head of Partnerships and Development, CDISC



Tuesday, 10 NOV 2020
11:00AM – 12:00PM EDT



Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



Housekeeping

Housekeeping

- You will remain on **mute** for the entirety of the webinar
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
 - To access – make sure that you create a login for the CDISC website if you haven't already
 - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!

Submitting Questions

- To send a question, use the “QUESTIONS” function on your GoToWebinar app. (See red arrow)
- You can submit questions at any time during the presentation, we’ll answer them during the Q&A.
- If you have a question for a specific presenter, please indicate the presenter’s name at the beginning of the question
 - Examples:
 - John: ‘Question’
 - Alana: ‘Question’

A screenshot of the GoToWebinar app's 'Questions' interface. At the top, there is a dark blue header with a downward-pointing triangle and the word 'Questions'. Below the header is a large white text area for entering a question. Underneath that is a smaller white text input field with the placeholder text 'Type question here.'. At the bottom right of the interface is a grey button with a paper plane icon and the word 'Send'.



Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.



Our Presenters

- John Owen, Head of Partnerships and Development, CDISC

CDASH SAE v2.0 Supplement Public Review

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CDASH SAE V2.0

Public Review Webinar

10th November 2020

cdisc

CDASH SAE V1.0

2013

2019

2019

CDASH SAE V2.0
KICK-OFF

CDASH SAE V2.0
PUBLICATION

2021



CDASH SAE V1.0



CDASH Serious Adverse Event (SAE) Supplement v1.0

1.0 Release Date: 22 Nov 2013

This supplement expands the AE domain in CDASH to include additional data elements to capture information in an SAE form, facilitating Sponsor generation of an E2B message for electronic reporting of an Individual Case Safety Report (ICSR) to regulatory authorities.

Attachment	Size
 CDASH SAE Supplement v1.0	1.16 MB
 CDASH-SAE Addendum Public Review Comments	29.46 KB

<https://www.cdisc.org/standards/foundational/cdash>

This supplement expands the AE domain in CDASH to include additional data elements to capture information in an SAE form, facilitating Sponsor generation of an E2B message for electronic reporting of an Individual Case Safety Report (ICSR) to regulatory authorities.

TRANSCCELERATE COMMON SAE FIELDS PROJECT



A TransCelerate-led project designed to increase the quality and comprehensiveness of serious adverse event (SAE) reports. The project focused on the assessment of the common core fields collected and reported following a serious adverse event. Upon completion of this assessment, the team proposed a list of SAE fields that would better support a complete clinical picture of a serious adverse event..

<https://transceleratebiopharmainc.com/common-serious-adverse-events-sae-fields/>





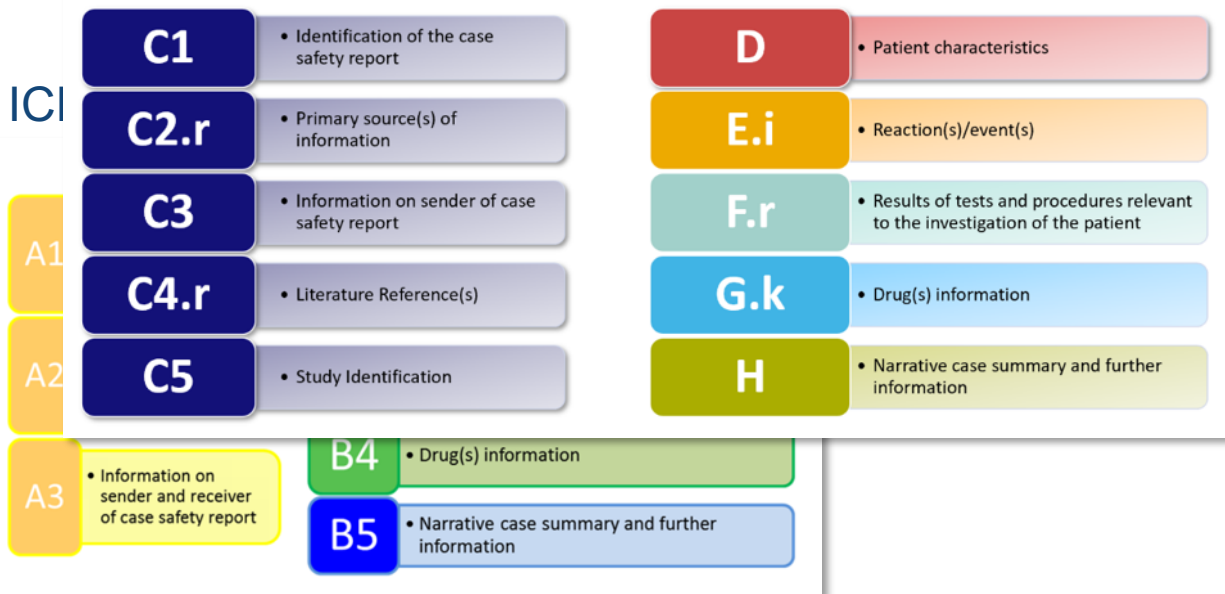
2019

CDASH SAE V2.0
KICK-OFF

- Develop version 2.0 of the CDASH SAE Supplement, an update to **CDASH SAE Supplement v1.0**, released in 2013.
- CDASH SAE Supplement v2.0 will capture how to structure serious adverse events (SAE) concepts for regulated clinical trials.
- Align with **E2B (R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide – Data Elements and Message Specification**
- Align the standard up to date with current CDISC standards.
<https://www.cdisc.org/cdash-sae-supplement-v20>

ICH E2B(R3) Individual Case Safety Report (ICSR) Specification

ICH E2B(R3)



This is a screenshot of a standard ICH E2B(R3) Individual Case Safety Report form. It features a header section for 'REPORT ADDRESS REACTION REPORT', followed by a grid for 'CASE IDENTIFICATION' and 'CASE CHARACTERISTICS'. Below this are sections for 'PATIENT CHARACTERISTICS', 'REACTIION(S)/EVENT(S)', 'RESULTS OF TESTS AND PROCEDURES RELEVANT TO THE INVESTIGATION OF THE PATIENT', 'DRUG(S) INFORMATION', and 'NARRATIVE CASE SUMMARY AND FURTHER INFORMATION'. The form includes various checkboxes and text input fields for detailed reporting.

This is a screenshot of a MedWatch Individual Case Safety Report form. It includes a header with the MedWatch logo and 'NATIONAL CENTER FOR MONITORING, EVALUATION AND RESEARCH'. The form is structured with multiple sections for 'CASE IDENTIFICATION', 'CASE CHARACTERISTICS', 'PATIENT CHARACTERISTICS', 'REACTIION(S)/EVENT(S)', 'RESULTS OF TESTS AND PROCEDURES RELEVANT TO THE INVESTIGATION OF THE PATIENT', 'DRUG(S) INFORMATION', and 'NARRATIVE CASE SUMMARY AND FURTHER INFORMATION'. It contains numerous checkboxes and text input fields for comprehensive data collection.

CDASH SAE V2 Project Team



CDISC Developers

CDASH Experts

**SAE Experts
(TransCelerate)**



CDASH SAE V2.0 Scope

- Protocol/Investigator
- Subject Demographics
- Relevant Medical History
- Relevant Medications
- Relevant Diagnostics and Labs
- SAE Attributes
- SAE Criteria (Death Supplement & Hospitalization)
- Pregnancy

**Cross Functional
Review**

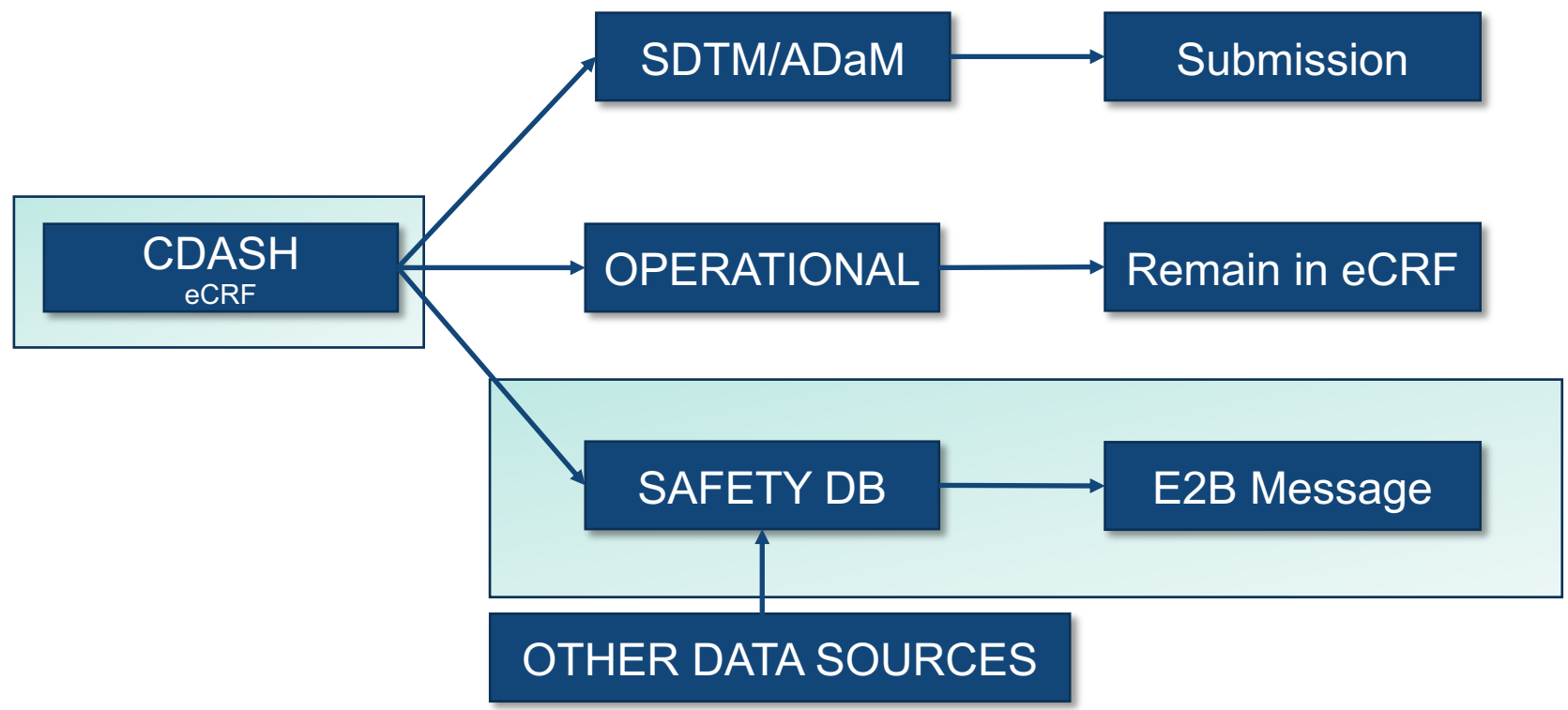
Clinical Database

Data Collection tool (eCRF)
and downstream data
aggregation systems usually
used for submission of data to
regulatory databases

Safety Database

Systems used by
Pharmacovigilance groups to
process Serious Adverse
Events and creation of ICSR
reports using E2B Messages

CDASH Data Journey



CDASH Variables

- Used for SDTM and Safety Database e.g.,
 - Birth Date – BRTHDAT
 - Race – RACE
 - Ethnicity – ETHNIC
 - Weight - WEIGHT_VSORRES
 - Height - HEIGHT_VSORRES
- Safety Database Only
- New CDASH Serious Adverse Events (SA) domain
- New Variables e.g.,
 - Serious adverse event/reaction start date – SASTDAT
 - Serious adverse event/reaction start time – SASTTIM
 - Causality assessment source – SACSTSCR
 - Causality assessment method – SACSTMTH
 - Dechallenge Result – SADCHLLT
 - Rechallenge Result – SARCHLLT
 - Narrative - SANARR

Overview of the CDASH SAE V2 Document

- › 1 Overview of Document
- › 2 Serious Adverse Event (SAE) Tables
 - 3 Introduction to Regulatory References
- › Appendices



- ▼ 1 Overview of Document
 - 1.1 Introduction
 - 1.2 Scope/Purpose
 - 1.3 Organization of this Document
 - 1.4 Data Privacy Laws
 - 1.5 CDISC Controlled Terminology
 - › 1.6 Alignment with Other Standards
 - 1.7 Explanation of Table Headers

Overview of the CDASH SAE V2 Document

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- ▼ 2 Serious Adverse Event (SAE) Tables
 - 2.1 SAE Report Administrative and Identifier Va
 - > 2.2 Patient/Subject Characteristics
 - 2.3 SAE Event/Reaction
 - > 2.4 Investigations and Results
 - > 2.5 Drug Information
 - 2.6 Narrative
 - 2.7 Hospitalization Supplemental (CDASH HO)

Overview of the CDASH SAE V2 Document

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- 3 Introduction to Regulatory References
- ▼ Appendices
 - A CDASH Serious Adverse Events Supplement I
 - B Data Elements from ICH E2B R2/R3
 - C Glossary and Abbreviations
 - D References
 - E SAE Narrative
 - F Representations and Warranties, Limitations c

CDASH Metadata

CDASH		E2B				CDASH						
1	2	3	4	5	6	7	8	9	10	11	12	13
CDASH Question Text	CDASH Prompt	E2B Variable Name	E2B (R2) Data Element	E2B (R3) Data Element	E2B (R3) Data Element Name	CDASH Variable Name	CDASH Definition	CDISC Controlled Terminology	CDASH SAE Form Completion Instructions	CDASH SAE Implementation Notes	CDASH SAE Core	SDTM Mapping Indicator (Y/N)



Demographics – (CDASH DM)

Created by CDASH, last modified by cdisc on 06/23/2014

CDASH Question Text	CDASH Prompt	E2B R2 Variable Name	E2B R2 Data Element	E2B R3 Data Element	E2B R3 Variable Name	CDASH Variable Names	CDASH Definition	CDISC Controlled Terminology	CDASH SAE Form Completion Instructions	CDASH SAE Implementation Notes	CDASH SAE Core	SDTM Mapping Indicator (Y/N)
What is the subject's date of birth?	Birth Date	patientbirthdate	B.1.2.1b	D.2.1	Date of birth	BIRTHDAT	A subject's date of birth (with or without the time of birth). The complete Date of Birth is made from the temporal components of Birth Year, Birth Month, Birth Day and Birth Time.		Record the date of birth to the level of precision known (e.g., day/month/year, year, month/year, etc.) in this format (DD-MON-YYYY).	This may be subset into the CDASH variables of BIRTHDO, BIRTHMO, BIRTHY, BIRTHTM as needed per specifications of the EDC system.	R/C	Y
What is the subject's age group?	Subject Age Group	patientagegroup	B.1.2.3	D.2.3	Patient age group (as per reporter)	AGEGRP	The Age Group of the patient when more precision is not available.			This section is only completed when the subject's age is not provided in any more precision.	O	N
What is the sex of the subject?	Sex	patientsex	B.1.5	D.5	Sex	SEX	Sex of the subject as determined by the investigator.	(SEX)	Record the appropriate sex	Collect the subject's sex or gender, as reported by subject or caretaker. This is a phenotypic assessment and a genotypic assessment.	HR	Y

Ongoing discussions with CDASH and Data Sciences Teams on handling of metadata for the CDISC library

CDASH SAE V2.0 – Public Review Documents

Home / Public Reviews

Public Reviews

Standard/Therapeutic Area	Comments Due
Controlled Terminology Relationships for SDTM v1.4 and SDTMIG v3.2	15 January 2021
ADaMIG for Non-compartmental Analysis v1.0 and Associated Conformance Rules	15 January 2021
CDASH Serious Adverse Event Supplement 2.0	6 January 2021
Therapeutic Area User Guide for Crohn's Disease: Work Package 2	4 December 2020
Study Data Tabulation Model Metadata Submission Guidelines v2.0	20 November 2020

On-Line demo to access documents and commenting

Home / CDASH Serious Adverse Event Supplement 2.0

CDASH Serious Adverse Event Supplement 2.0

Comments Due By
6 January 2021

CDISC invites you to provide comments on the CDASH SAE v2 Supplement. The CDASH SAE v2 Supplement is a key component of the CDASH Serious Adverse Event Supplement (CDASHSAE). CDISC will be hosting the public review of the CDASH SAE v2 Supplement. You will need to log in to CDISC to provide comments. Register for the CDASH SAE v2 Supplement. Public review is a key component of the CDASH Serious Adverse Event Supplement (CDASHSAE).

CDASH Serious Adverse Event Supplement

CDASH Serious Adverse Event Supplement

Created by Joe Ben Clark, last modified by John Owen on Oct 08, 2020

Instructions for Reviewers

Created by John Owen, last modified by Alana St. Clair on Oct 16, 2020

Reviewers are requested to provide comments via JIRA; wiki and JIRA use the same credentials, so if you can see this page, then you can use JIRA.

The project associated with the CDASH Serious Adverse Event Supplement is **CDASH Serious Adverse Event Supplement (CDASHSAE)**, located at: <https://jira.cdisc.org/projects/CDASHSAE>

- If you have no edits or comments to a page
- To add comments to JIRA from within the Wiki
- To add comments from within JIRA

If you have no edits or comments to a page

- Click "Like" at the bottom of the page. This will help us determine who has read each page.

To add comments to JIRA from within the Wiki

- Select the text (ideally, a short, unique phrase) to which you wish to attach the comment. After a moment, two icons should appear.
- Click on the 3 arrow JIRA icon on the right. This will trigger a Create Issue form.
- Choose the project associated with this document from the **Project** drop-down menu ("CDASH Serious Adverse Event Supplement").
- Choose "Review Comments" from the **Issue Type** drop-down menu.
- Fill out the form.
 - The **Summary** field will be pre-populated with the text that you selected. You can change this or leave it as is.
 - Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
 - In case of technical difficulties, please make sure to include a brief description of the context of your comment.
- Click the "Create" button in the bottom left corner of the form to submit your comment as an issue.



Thank You

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Upcoming Learning Opportunities

2021 CDISC Upcoming Events

February 2021 – TechniCon Virtual Events



TechniCon

- Tuesday, 2 February: Asia-Pacific Rim
- Wednesday, 3 February: EMEA
- Friday, 5 February: India
- Monday, 8 February: Americas

Submit Abstracts Now. Registration Open Soon!

April 2021 – Europe Virtual Event



2021 Europe Interchange

28-29 April

February 2021 – Abstract Submissions and Registration Coming Soon.

Free Upcoming Webinar Lineup – Registration Open!

CDISC Tabulate Certification Launch

16 NOV 2020, 11:00 AM - 12:30 PM
EDT

- Announcing the new CDISC Certification program: why you should take it, and how you can do it.

New Virtual Training Methods

- CDISC Provides Many Ways to Begin or Continue Growing Your Standards Knowledge.
 - Popular self-paced training plus new Blended Learning and Virtual Classroom settings.

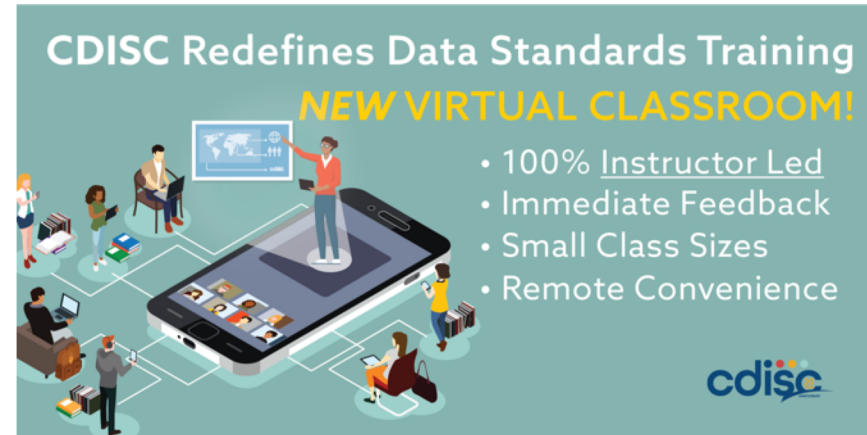


**Blended Learning
from CDISC**

Online Resources
+ In-Person Instruction
More Personalized Learning

Classes Starting Soon!

The graphic features a central laptop displaying a video call with a person's headshot. Surrounding the laptop are various icons: a lightbulb, a clock, a magnifying glass, a speech bubble, a play button, a calendar, and a person icon. The background is blue with white and yellow accents.



**CDISC Redefines Data Standards Training
NEW VIRTUAL CLASSROOM!**

- 100% Instructor Led
- Immediate Feedback
- Small Class Sizes
- Remote Convenience

The graphic shows a large smartphone in the center with a person standing on its screen pointing at a data visualization. Around the phone, several people are depicted in various work settings, connected by lines to the phone. The background is a light teal color.



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don't forget to fill out the feedback survey!

