SDTMIG v4.0 and SDTM 3.0 Public Review

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Agenda

1. Housekeeping
2. Background
3. Restructured Metadata and General Content
4. Nonstandard Variables
5. Multiple Subject Instances
6. Additional SDTM and SDTMIG Updates
7. Review Instructions

Housekeeping

Housekeeping

You will remain on **mute**

Housekeeping

Submit questions at any time via the Q&A section on your Teams app

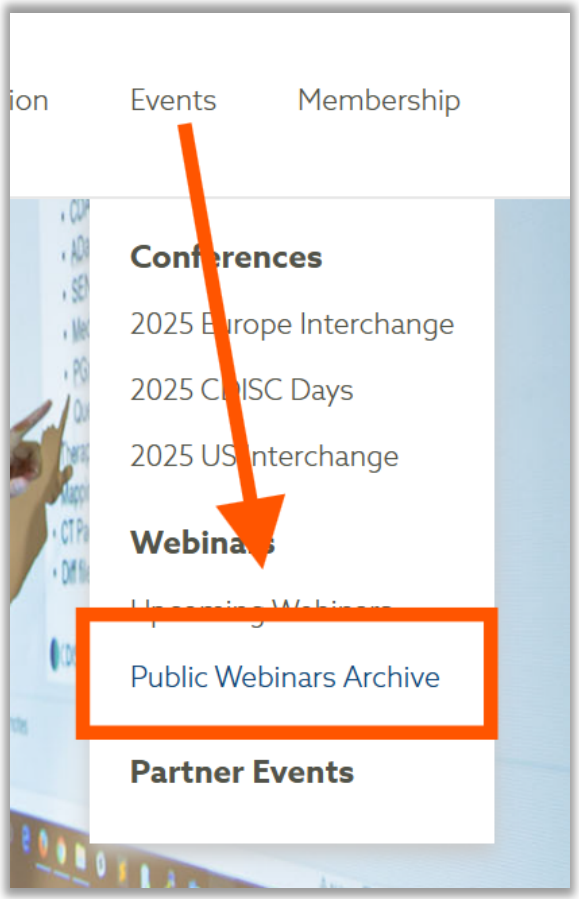
Housekeeping

Audio Issues?

First, close and restart your Teams App
Second, check your local internet connection strength

Housekeeping

Webinar Recording



A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.

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Main Conference: 20-21 May | Trainings & Workshops: 18, 19, & 22 May

SDTM and related topics will be covered during Interchange main conference!

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Register:

Training: SDTM Fundamentals in Practice (Beginner to Practitioner - Part I)

October 7, 2026 | 9:00 AM-6:00 PMMT

Course Description

This interactive training introduces the foundations of the Study Data Tabulation Model (SDTM) by demonstrating how clinical trial data is transformed from source data into SDTM datasets. The training emphasizes the conceptual process of transforming raw data, CRFs, and protocol requirements into SDTM datasets and documentation.

Through guided examples and hands-on activities, learners explore observation classes, timing concepts, and relationships, gaining a practical understanding of how and why data changes as it moves toward regulatory-ready SDTM. This training builds a strong foundation in SDTM v4.0 concepts and usage, preparing learners for *Part II: SDTM Implementation in Clinical Data Flow*, which will include much more detailed coverage of General Observation class domains and Special Purpose domains.

Learning Outcomes

1. Locate and use key SDTM documents, including the SDTM Model and Implementation Guide.
2. Explain how SDTM-structured data relates to the collected data.
3. Identify appropriate SDTM observation classes, timing concepts, and modeling approaches.

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Register:

SDTM Implementation in Clinical Data Flow (Practitioner to Experienced - Part II)

October 8, 2026 | 9:00 AM-6:00 PMMT

Course Description

This hands-on training focuses on the practical application of SDTM v4.0, guiding learners through the creation of SDTM-conformant datasets using the SDTM Implementation Guide. Building on foundational SDTM concepts (provided in Part I: SDTM Fundamentals in Practice), participants work through realistic implementation scenarios including CRF annotation, domain creation, timing variables, Findings About, relationship datasets, trial design domains, metadata, and conformance considerations.

Learning Outcomes

1. Create SDTM domains using the SDTM Implementation Guide v4.0.
2. Apply timing variables, standard and custom domains, non-standard variables (NSVs), and relationship datasets correctly.
3. Assess SDTM datasets for conformance prior to regulatory submission.

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Register:

Speakers

- **Dave** has been a programmer at Rho for 26 years, and has worked with CDISC data standards since 2010. As a CDISC volunteer since 2018, he has worked on the SDTM and SDS, including on the SDS subteams for multiple subject instances and Jira issue management. Dave currently serves as the Current Lead role on the CDISC SDS Leadership Team and lives in Durham, NC.

Dave Scocca
Title: Principal Statistical Programmer
Company: Rho, Inc.

Speakers

- **Dianna** has been with CDISC for 3 years and is the Project Manager for the SDS (SDTMIG), SDTM, SEND, Medical Devices, and Open Rules teams. Prior to CDISC, she has over 15 years experience in Clinical Data Management and vendor management on both the sponsor and CRO side.

Dianna DiRusso
Title: Project Manager
Company: CDISC

Speakers

- **Maria** is a Clinical Data Standards Lead at Merck with over 25 years of experience in the pharmaceutical industry. She has led initiatives across the entire clinical trial lifecycle and has developed hundreds of CDASH- and SDTM-compliant data collection specifications. Maria currently serves as the Future Lead role on the CDISC SDS Leadership Team and lives in Linden, NJ.

Maria Sekac
Title: Director, Clinical Data Standards
Company: Merck & Co., Inc., USA

Speakers

- **Michael** is the past lead of the CDISC Study Data Submissions (SDS) team and has over 20 years of experience in statistical programming for clinical research including, CROs, pharmaceuticals, biotech, and medical devices. Through the years, he has volunteered for multiple sub-teams within CDISC and had served as president for the Chicago chapter of the American Statistical Association.

Michael Wise

Title: Director, Statistical Programming

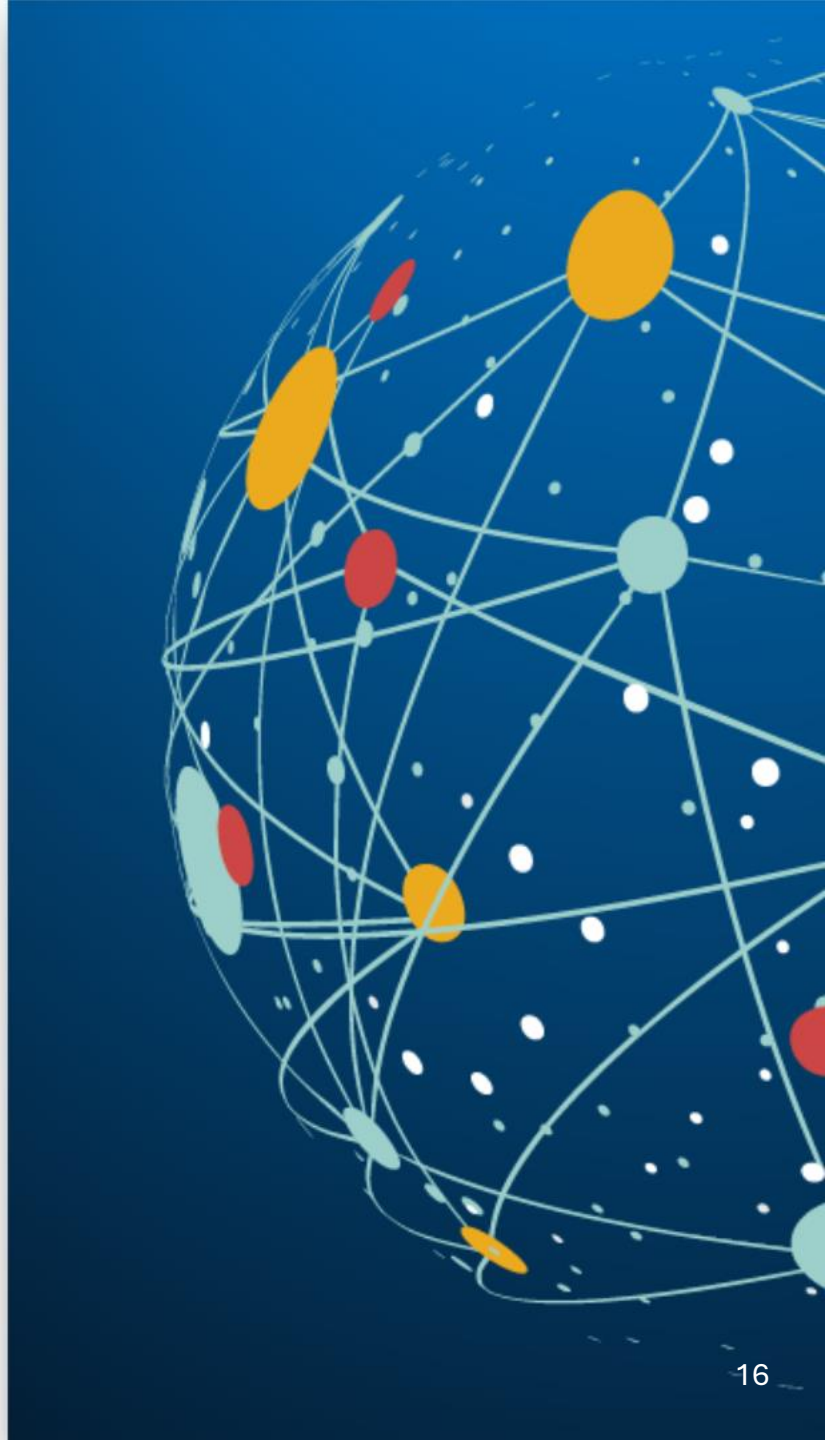
Company: Edwards LifeSciences

Background

SDTMIG 4.0 and SDTM 3.0

Background

- SDTMIG 4.0
  - Major revision to SDTMIG 3.4
  - Scoping started 2020
- SDTM 3.0
  - Revision to 2.0 (SDTMIG 3.4) and 2.1 (Tobacco)
  - Completed Variable Definitions
  - Added Variable Groups
  - Added Variable Relationships



Restructuring

Metadata and General Content

Metadata Restructuring

- Old Structure

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DD	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DDSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DDTESTCD	Death Detail Assessment Short Name	Char	(DTHDXCD)	Topic	Short name of the measurement, test, or examination described in DDTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DDTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). DDTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "PRCDTH", "SECDTH".	Req
DDTEST	Death Detail Assessment Name	Char	(DTHDX)	Synonym Qualifier	Long name for DDTESTCD. The value in DDTEST cannot be longer than 40 characters. Examples: "Primary Cause of Death", "Secondary Cause of Death".	Req

- New Structure

#	Variable Name	Variable Label	Type	Codelist	Allowed Controlled Terms	Format	Role	Variable Group	Root Variable C-code	Root Variable Definition	Notes	Examples	Core
1	STUDYID	Study Identifier	Char				Identifier	Study	C83082	A sequence of characters used to identify or name the study.			Req
2	DOMAIN	Domain Abbreviation	Char	(DOMAIN)	DD		Identifier	Domain	C49558	An abbreviation for a collection of observations, with a topic-specific commonality.	See Datasets and Domains.		Req
6	DDTESTCD	Death Detail Assessment Short Name	Char	(DTHDXCD)			Topic	Test Focus	C82503	The standardized or dictionary-derived short sequence of characters used to represent the measurement, test, or examination.	See Variable Lengths.	"PRCDTH"; "SECDTH"	Req
7	DDTEST	Death Detail Assessment Name	Char	(DTHDX)			Qualifier	Test Focus	C82541	The standardized or dictionary-derived name of the measurement, test, or examination.	See Test Name (--TEST) Greater than 40 Characters.	"Primary Cause of Death"; "Secondary Cause of Death"	Req

Where is the CDISC Notes Content?

- Moved to:
  - The new Variable Definition column
  - The new Allowed Controlled Terms column for CT restrictions
    - e.g. "Y" for --DRVFL, "NOT DONE" for --STAT
  - The new Examples column
  - The new Notes column
  - To general assumptions sections 1-4
  - To domain-specific assumptions list

Reorganization and Rewrite of Sections 1-4

- Sections 1-4 were rewritten to accommodate restructuring of the metadata tables, to add more clarity, improve the content's organization, and to ensure that general assumptions are consistent, and in one place, rather than dispersed within the CDISC notes for every domain's specification tables.

Non-standard Variables

No more SUPPQUAL

Non-Standard Variables (NS--)

Previous Versions	SDTM 3.0 and SDTMIG 4.0
Dataset named SUPP--, one per parent dataset	Dataset named NS--, one per parent dataset
Vertical: one row per populated nonstandard variable value	Horizontal: one row, per row in the parent dataset with at least one nonstandard variable populated
A row in SUPP-- may match more than one row in the parent dataset (IDVAR could be --GRPID) and IDVARVAL is character.	Each row in NS-- matches exactly one row in the parent dataset. IDVAR is always --SEQ and IDVARVLN is numeric.
QVAL is always a character field.	Nonstandard variable columns can be character or numeric.
Value-level metadata in Define-xml for QVAL, based on value of QNAM.	Variable-level metadata in Define-xml for nonstandard variables.
Merge requires transposing and often converting IDVARVAL from character to numeric.	Can merge without transposing or character-to-numeric conversion.

AE Example: Comparing SUPPAE to NSAE

ae.xpt

Convert IDVARVAL from character to numeric

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESEV	AESER	AESMIE	AESTDTC	AEENDTC
1	1996001	AE	99-401	1	UTERINE FIBROIDS	SEVERE	Y	Y	2023-01-05	2023-01-12
2	1996001	AE	99-567	1	FEVER	MILD	N		2023-09-25	2023-09-25

Transpose

suppae.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	AE	99-401	AESEQ	1	AESOSP	Other Medically Important SAE	SPONTANEOUS ABORTION	CRF	
2	1996001	AE	99-401	AESEQ	1	AETRTEM	Treatment Emergent Flag	Y	Derived	
3	1996001	AE	99-567	AESEQ	1	AETRTEM	Treatment Emergent Flag	N	Derived	

nsae.xpt

Row	STUDYID	DOMAIN	USUBJID	IDVAR	IDVARVLN	AESOSP	AETRTEM
1	1996001	AE	99-401	AESEQ	1	SPONTANEOUS ABORTION	Y
2	1996001	AE	99-567	AESEQ	1		N

NSAE metadata

Variable	Label	Type	Codelist	Role	Origin Type	Origin Source
AESOSP	Other Medically Important SAE	Char		Non-Standard Qualifier	Collected	Investigator
AETRTEM	Treatment Emergent Flag	Char	(NY)	Non-Standard Qualifier	Derived	Sponsor

Multiple Subject Instances

SUBJID Everywhere, and DC Domain

SUBJID Everywhere

- SDTM 3.0
  - SUBJID has been added to “Identifiers for all Classes”
- SDTMIG 4.0
  - SUBJID required in DM domain (and new DC domain)
  - SUBJID added as permissible variable in all subject domains
  - New section 4.4.3 about USUBJID and SUBJID
  - SUBJID is used when there are multiple enrollments
  - Uniqueness of --SEQ is still relative to USUBJID
  - SUBJID is not used in RELREC, RELSUB, or RELSPEC.

Multiple Participations: DM and DC

- FDA Request
  - “A custom domain with a structure similar to DM”
- New Special Purpose domain in SDTM 3.0 and SDTMIG 4.0
  - Model restricts use to human clinical trials
- DC Domain: Demographics for Multiple Participations
  - One record per participation for all subjects: no need to combine with DM
  - Structure matches DM
  - Required when (and only when) there are multiple enrollments
  - DM can often be derived from DC
    - Strategy 1: Always create DC and do not submit DC if not needed
    - Strategy 2: Create DM first and then only create DC when needed

Multiple Participations: DM and DC

- Shared Demographics Assumptions
  - All DM assumptions are shared
  - Additional assumptions specific to DC
- FDA: “the primary enrollment should be submitted in DM”
  - Per FDA, if multiple screenings and single enrollment, enrollment is “primary”
  - No CDISC definition of “primary” in other instances
    - Multiple screenings without enrollment
    - Multiple enrollments over time
- All study day variables are still derived from DM.RFSTDTC

Differences between DC and DM

- DCSEQ is required
  - NSDC will have IDVAR=DCSEQ
  - NSDM will still have IDVAR and IDVARVLN missing
- DC.SEX is expected (not required) because it may not be collected at re-screening
  - MULTIPLE can be used in DM when responses differ across participations for SEX, RACE, CRACE, ETHNIC, CETHNIC
- DC.RFSTDTC and DC.RFENDTC are permissible (not required)
  - If one is present, both must be present
- No DCDY (avoids DC depending on DM)

Effects in Other Domains

- All study days are still derived from DM.RFSTDTC
  - There is no DCDY to avoid interdependency
  - For other relative days, use NSVs or derive in ADaM
- Subject Visits (SV) now requires SVSEQ
  - Assigned in a chronological sequence
  - Cannot assume USUBJID and VISITNUM uniquely identify a record
- Subject Elements (SE) allows gaps between participations only

Additional SDTM and SDTMIG Updates

Additional updates to DM (and DC)

- Addition of CRACE and CETHNIC variables
  - Collected values
  - CRACE and CETHNIC have extensive, extensible codelists
  - RACE and ETHNIC no longer have assigned codelists
    - Previously had assigned codelists matching FDA requirements
    - Now will use terminology as defined by data recipient (e.g. FDA)
  - All four race and ethnicity variables are now permissible
- Age updates
  - Added AGERLO and AGERHI for when precise age is unknown
  - Removed AGETXT

Other New Domains

- Event Adjudication (EA)
  - Uses Findings About structure
  - EAOBJ is the event being adjudicated
  - Uses EAEVAL, EAEVALID, and EAACPTFL
  - Terminology will be available for EATEST and EATESTCD
  - Examples show adjudication of event occurrence, relationship to treatment, event start date, event type, event classification
- Gastrointestinal Findings (GI)
  - Additional morphology/physiology body system domain
  - Already used in Therapeutic Area User Guides

EA Domain Use Case

- This example depicts the adjudication of a study endpoint.

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Row	STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	AEDECOD	AEREL	AESTDTC	AEENDTC
1	ABC	AE	ABC-01-101	4	4	DRUG-INDUCED LIVER INJURY	Drug-induced liver injury	RELATED	2015-02-13	2015-03-13

ea.xpt

Row	STUDYID	DOMAIN	USUBJID	EASEQ	EASPID	EATESTCD	EATEST	EAOBJ	EAORRES	EASTRESC	EASTRESN	EAMETHOD	EAEVAL	EAEVALID	EAACPTFL
1	ABC	EA	ABC-01-101	1	4	REL	Relation to Study Treatment or Product	Drug-induced liver injury	PROBABLE	3	3	FONTANA DILIN NUMERIC SCORE 2009	ADJUDICATOR	ADJUDICATOR 1	
2	ABC	EA	ABC-01-101	2	4	REL	Relation to Study Treatment or Product	Drug-induced liver injury	HIGHLY LIKELY	2	2	FONTANA DILIN NUMERIC SCORE 2009	ADJUDICATOR	ADJUDICATOR 2	
3	ABC	EA	ABC-01-101	3	4	REL	Relation to Study Treatment or Product	Drug-induced liver injury	HIGHLY LIKELY	2	2	FONTANA DILIN NUMERIC SCORE 2009	ADJUDICATION COMMITTEE		Y
4	ABC	EA	ABC-01-101	4	4	EVSTDTC	Start Date/Time of Event	Drug-induced liver injury	2015-02-13	2015-02-13			ADJUDICATOR	ADJUDICATOR 1	
5	ABC	EA	ABC-01-101	5	4	EVSTDTC	Start Date/Time of Event	Drug-induced liver injury	2015-02-13	2015-02-13			ADJUDICATOR	ADJUDICATOR 2	Y

Updates to Protocol Deviations (DV)

- New variable, DVCLASI
  - Retrospective classification of deviations
    - No assigned Controlled Terminology
    - Examples: MAJOR/ MINOR, IMPORTANT/ NON-IMPORTANT, CRITICAL/ NON-CRITICAL
- Controlled terminology for DVDECOD and DVCAT

General Observation Class New Variables

Variable	Label	Observation Class	Definition
--RSCNT	Result Count	Findings, EG domain only	The number of occurrences of a result.
--CBRFL	Conditionally Branched Item Flag	Findings, Restricted to the QRS domains: QS, FT, RS	An indication that this instance of an item within a QRS instrument was conditionally branched. An item is conditionally branched when the instrument does not solicit a response from the respondent based on a given condition, although for certain instruments, the instrument may provide a result for the item.
--TRTCD	Standardized Treatment Code	Interventions, CM domain only	A standardized or dictionary-derived short sequence of characters used to represent the intervention.
--CLASI	Classification of Protocol Deviation	Events, DV domain only	A classification of protocol deviations based on the potential impact to the completeness, accuracy, and/or reliability of the study data, or to a subject's rights, safety, or well-being. (ICH E3 Q&As (R1))

Removed Variables

- Findings
  - --BLFL removed from model and from all domains
    - Deprecated in SDTMIG 3.4 in favor of --LOBXFL
  - --MODIFY and --BODSYS
    - No expectation that Findings results would be coded
- Events and Interventions
  - --PORTOT
- Trial Inclusion/ Exclusion Criteria (TI)
  - TIRL

Updated Conformance Rules

- Rules for multiple versions of SDTM and SDTMIG
  - Updated and new rules specific to SDTM 3.0 and SDTMIG 4.0
  - Format has been updated to a rules catalog template used across standards
- Separate review page and instructions
- Rules are in a spreadsheet
- Issues are in a separate Jira project

SDTMIG 4.0 Extended Scope Project

- A handful of tightly focused additional changes
  - Not yet posted for public review
  - Will have a separate public review period
  - Will be part of SDTMIG 4.0 release
  - Includes new LC domain

Knowledge Base Articles

- Three (3) draft Knowledge Base Articles related to SDTMIG v4.0 new content
- These articles will be finalized and published with SDTMIG v4.0
- Available in the SDTMIG v4.0 Wiki space and via links in the Instructions for Reviewers and Public Review announcement email

  - NS-- Datasets: Why they were built as they were.
  - Why change the structure of SDTMIG metadata?
  - Why does the DC domain differ from what's described in FDA's TCG?

Review Instructions

Submitting Comments

Public Review closes **06-April-2026**; targeted Publication: **Q4 2026**

- WIKI
  - https://wiki.cdisc.org/
  - The CDISC Wiki is a collaborative tool to share information relevant to the development and use of clinical research data standards. WIKI is built on Confluence. By creating a CDISC Wiki account and logging into the system, you are accepting our Terms of Use.
- JIRA
  - https://jira.cdisc.org/
  - Jira is an issue management system used for tracking comments on standards submitted from Staff, Volunteers, and the Public. It is also used for internal issue tracking of IT, and Project Management of Publications, Events, and Communication to name a few.

You only need **one account** to access both WIKI and JIRA

Submitting Comments – Best Practices

- Publication timeline is dependent on resolution of Public Review comments
- How you can help – provide specific, actionable feedback
  - Include section and subsection, if applicable
  - Be specific about proposed edits
    - Suggested wording, additions, or deletions
    - Identified gaps or inconsistencies
    - Clear recommendation for changes
  - Provide rationale for the proposed change where it may facilitate comment resolution

Clear, actionable comments increase the likelihood of the comment being addressed as intended

Thank you!

And Thank You to the Volunteers who have made this possible!

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Questions?