

## What's new in SDTM IG 3.1.2 ?



# Introduction

- New releases:
  - SDTM IG 3.1.2 (298 pages)
  - SDTM 1.2
- SDTM IG 3.1.2:
  - Additional guidance
  - More examples
  - Minor and major changes to the model

<http://www.cdisc.org/standards/index.html>

# Overview

## Major changes:

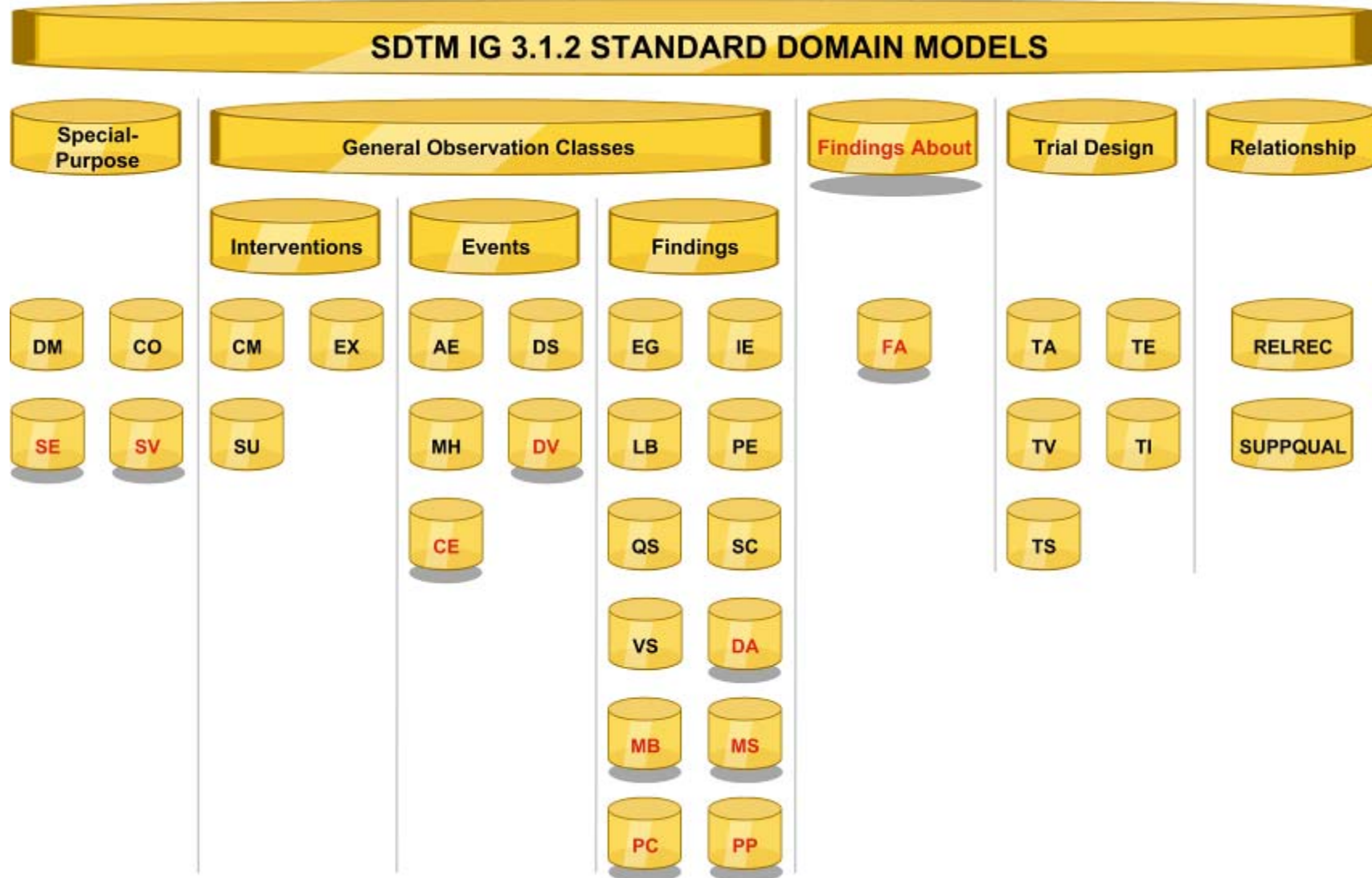
- SDTM Domains
- SDTM Variables
- Controlled Terminology
- Trial Design
- Additional Functionality
- Summary

# Overview

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- **SDTM Domains**
- SDTM Variables
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# SDTM Standard Domain Models



# New Published Domains

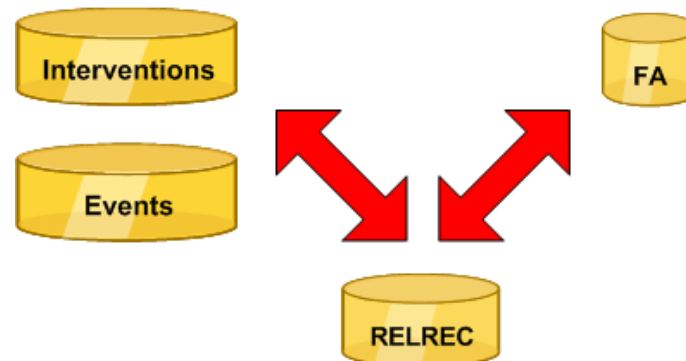
- PC = Pharmacokinetic Concentrations
- PP = Pharmacokinetic Parameters
- DA = Drug Accountability
- DV = Protocol Deviations
- MB = Microbiological Specimen
- MS = Microbiological Susceptibility
- CE = Clinical Events
- FA = Findings About Events/Interventions

# Clinical Events

- Clinical events of interest
- Not classified as adverse events
  - Stated in Protocol
  - Disease under study, 'Signs and Symptoms'
- Examples:
  - nausea, headache, ...

# Findings About (1)

- Solution for problems SUPPQUAL cannot handle
  - Additional information with different timing
  - To represent each measurement with its unit
- Only in combination with Events, Interventions
- Linked via RELREC
- New variable: --OBJ



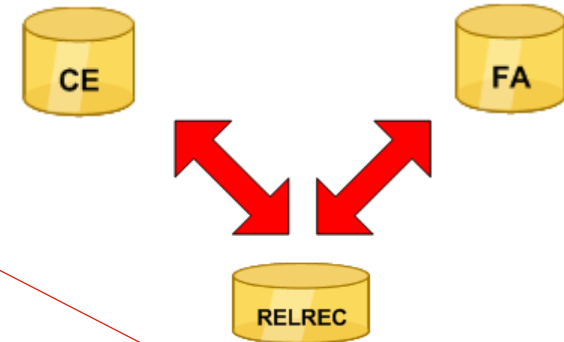
[SDTM IG 3.1.2 section 6.4.1](#)

# When to use findings About

- Data that do not describe an event or intervention as a whole
  - different timing, 'snapshot'
- Data that indicate the occurrence of related symptoms
  - Event: Migraine <-> related symptoms: sensitivity to light, headache
- Data for which no Event or Intervention record has been collected or created
  - pre-requisite for the study, not part of MH.
  - Ex: bone fractures not in MH.
  - No RELREC
- Data that indicate the occurrence of presp. AE's (not occurred → no AE record)
- Data having qualifiers that can be represented in Findings variables (units and methods)

# Findings About (2)

|                                                           |                                                                                            |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>Migraine Symptoms Diary</b> <b>CETERM</b>              |                                                                                            |
| Migraine Reference Number                                 | xx                                                                                         |
| When did the migraine start                               | DD-MM-YY <b>CESTDTC</b><br>HH-MM                                                           |
| Answer the following 5 Minutes BEFORE Dosing <b>FATPT</b> | <b>FAORRES where FATESTCD = "SEV"</b>                                                      |
| Severity of Migraine                                      | <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe     |
| Associated Symptoms:                                      |                                                                                            |
| Sensitivity to light                                      | <input type="radio"/> No <input type="radio"/> Yes                                         |
| Sensitivity to sound <b>FAOBJ</b>                         | <input type="radio"/> No <input type="radio"/> Yes <b>FAORRES where FATESTCD = "OCCUR"</b> |
| Nausea                                                    | <input type="radio"/> No <input type="radio"/> Yes                                         |
| Aura                                                      | <input type="radio"/> No <input type="radio"/> Yes                                         |



- CE

| STUDYID | DOMAIN | USUBJID | CESEQ | CESPID | CETERM   | CEDECOD  | CESTDTC          |
|---------|--------|---------|-------|--------|----------|----------|------------------|
| ABC     | CE     | ABC-123 | 1     | 90567  | Migraine | Migraine | 2007-05-16T10:30 |

- FACE

| Row | STUDYID | DOMAIN | USUBJID | FASEQ | FASPID | FATESTCD | FATEST             | FAOBJ                | FACAT             |
|-----|---------|--------|---------|-------|--------|----------|--------------------|----------------------|-------------------|
| 1   | ABC     | FA     | ABC-123 | 1     | 90567  | SEV      | Severity/Intensity | Migraine             | MIGRAINE SYMPTOMS |
| 2   | ABC     | FA     | ABC-123 | 2     | 90567  | OCCUR    | Occurrence         | Sensitivity To Light | MIGRAINE SYMPTOMS |
| 3   | ABC     | FA     | ABC-123 | 3     | 90567  | OCCUR    | Occurrence         | Sensitivity To Sound | MIGRAINE SYMPTOMS |
| 4   | ABC     | FA     | ABC-123 | 4     | 90567  | OCCUR    | Occurrence         | Nausea               | MIGRAINE SYMPTOMS |
| 5   | ABC     | FA     | ABC-123 | 6     | 90567  | OCCUR    | Occurrence         | Aura                 | MIGRAINE SYMPTOMS |

| Row        | FAORRES | FASTRESC | FADTC      | FATPT       | FAELTM | FATPTREF |
|------------|---------|----------|------------|-------------|--------|----------|
| 1 (cont'd) | SEVERE  | SEVERE   | 2007-05-16 | 5M PRE-DOSE | -PT5M  | DOSING   |
| 2 (cont'd) | Y       | Y        | 2007-05-16 | 5M PRE-DOSE | -PT5M  | DOSING   |
| 3 (cont'd) | N       | N        | 2007-05-16 | 5M PRE-DOSE | -PT5M  | DOSING   |
| 4 (cont'd) | Y       | Y        | 2007-05-16 | 5M PRE-DOSE | -PT5M  | DOSING   |
| 5 (cont'd) | Y       | Y        | 2007-05-16 | 5M PRE-DOSE | -PT5M  | DOSING   |

- RELREC

| STUDYID | RDOMAIN | USUBJID | IDVAR  | IDVARVAL | RELTYPE | RELID |
|---------|---------|---------|--------|----------|---------|-------|
| ABC     | CE      |         | CESPID |          | ONE     | 1     |
| ABC     | FA      |         | FASPID |          | MANY    | 1     |

# SDTM Domain Metadata

Logical keys have changed

Sponsor defined sorting  
keys allowed

**Table 3.2.1. SDTM Submission Dataset-Definition Metadata Example**

| Dataset | Description         | Class         | Structure                                                           | Purpose    | Keys                               | Location |
|---------|---------------------|---------------|---------------------------------------------------------------------|------------|------------------------------------|----------|
| SU      | Substance Use       | Interventions | One record per substance type per reported occurrence per subject   | Tabulation | STUDYID, USUBJID, SUTRT, SUSTDTC   | su.xpt   |
| AE      | Adverse Events      | Events        | One record per adverse event per subject                            | Tabulation | STUDYID, USUBJID, AEDECOD, AESTDTC | ae.xpt   |
| DS      | Disposition         | Events        | One record per disposition status or protocol milestone per subject | Tabulation | STUDYID, USUBJID, DSDECOD, DSSTDTC | ds.xpt   |
| MH      | Medical History     | Events        | One record per medical history event per subject                    | Tabulation | STUDYID, USUBJID, MHDECOD          | mh.xpt   |
| DV      | Protocol Deviations | Events        | One record per protocol deviation per subject                       | Tabulation | STUDYID, USUBJID, DVTERM, DVSTDTC  | dv.xpt   |
| CE      | Clinical Events     | Events        | One record per event per subject                                    | Tabulation | STUDYID, USUBJID, CETERM, CESTDTC  | ce.xpt   |

# Overview

## Major changes:

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# --PRESP

- Technique for pre-specified Events or Interventions

| Situation                             | Value of<br>--PRESP | Value of<br>--OCCUR | Value of<br>--STAT |
|---------------------------------------|---------------------|---------------------|--------------------|
| Spontaneously reported event occurred |                     |                     |                    |
| Pre-specified event occurred          | Y                   | Y                   |                    |
| Pre-specified event did not occur     | Y                   | N                   |                    |
| Pre-specified event has no response   | Y                   |                     | NOT DONE           |

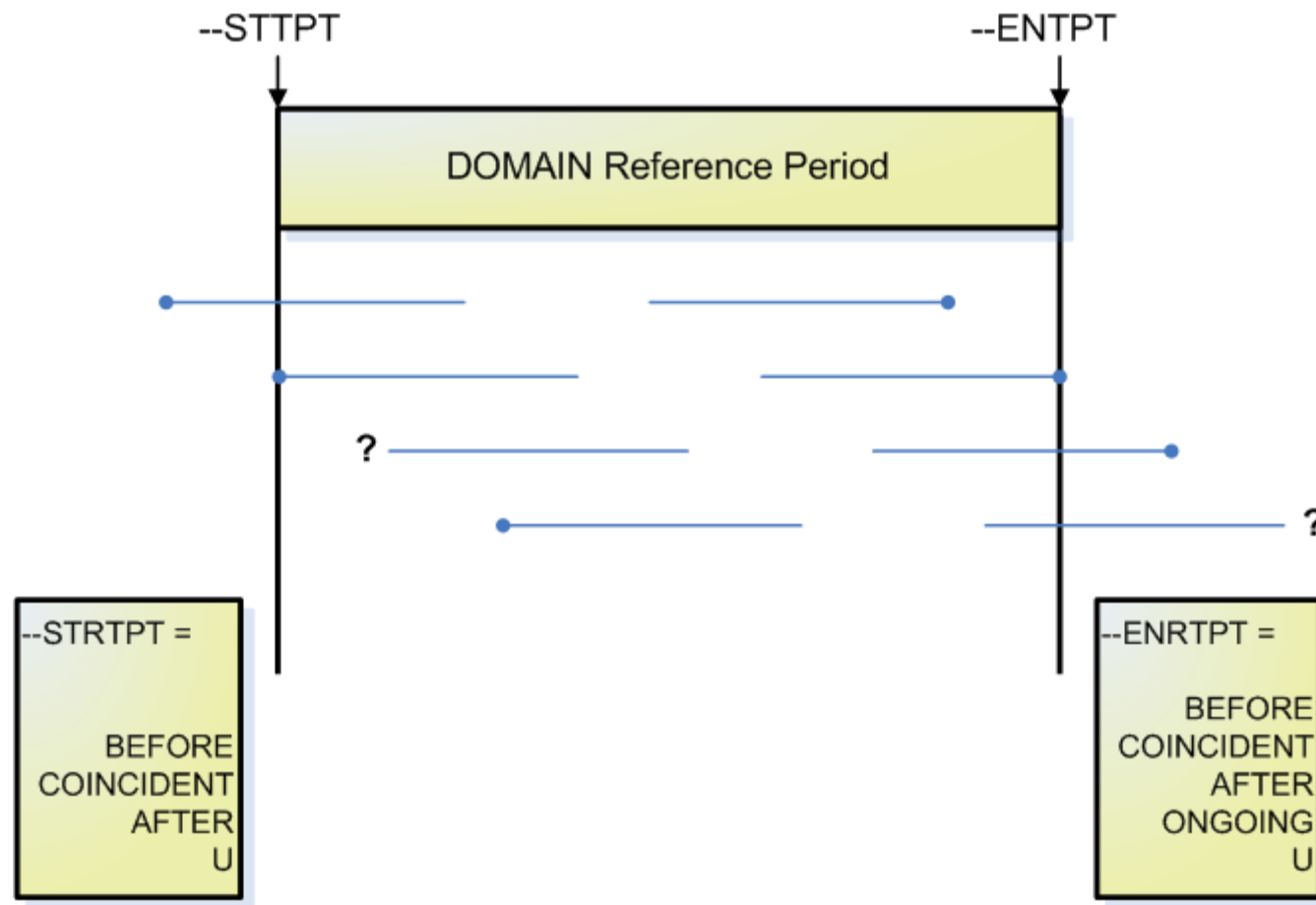
- Example:

| MEDICAL HISTORY                                       |                                         |                                        |
|-------------------------------------------------------|-----------------------------------------|----------------------------------------|
| <b>Conditions of interest:</b>                        | <b>MHOCCUR</b>                          |                                        |
| Diabetes <b>MHTERM</b>                                | <input type="checkbox"/> yes            | <input checked="" type="checkbox"/> no |
| Gastrointestinal disease                              | <input type="checkbox"/> yes            | <input checked="" type="checkbox"/> no |
| Hypertension                                          | <input checked="" type="checkbox"/> yes | <input type="checkbox"/> no            |
| <b>If other significant medical history, specify:</b> |                                         |                                        |
| <i>Migraines</i>                                      |                                         |                                        |
| <i>Nose bleeds</i>                                    |                                         |                                        |
|                                                       |                                         |                                        |
|                                                       |                                         |                                        |

| Row | STUDYID | DOMAIN | USUBJID | MHTERM                      | MHPRESP | MHOCCUR |
|-----|---------|--------|---------|-----------------------------|---------|---------|
| 1   | ABC     | MH     | 001     | DIABETES                    | Y       | N       |
| 2   | ABC     | MH     | 001     | GASTROINTESTINAL<br>DISEASE | Y       | N       |
| 3   | ABC     | MH     | 001     | HYPERTENSION                | Y       | Y       |
| 4   | ABC     | MH     | 001     | MIGRAINES                   |         |         |
| 5   | ABC     | MH     | 001     | NOSE BLEEDS                 |         |         |

# --STTPT, --STRTPPT, --ENTPT, --ENRTPT

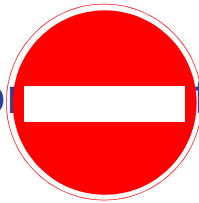
- SDTM IG 3.1.1: reference time points in DM
- SDTM IG 3.1.2: sponsor defined reference period per domain



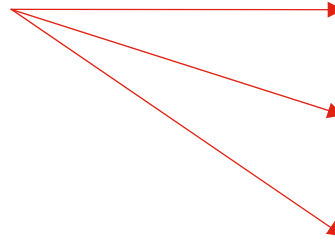
# Origin of Variables (1)

- SDTMIG 3.1.1

- CRF
- Derived
- Spontaneous



defined



- SDTMIG 3.1.2

- CRF
- Derived
- eDT
- Assigned
- Protocol

# Origin of Variables (2)

- CRF
  - Paper or electronic
- Derived
  - Calculated from other SDTM variables
- eDT: electronic Data Transfer
- Assigned
  - Individual judgement, adjudicator
  - Default values: DOMAIN, --TESTCD
- Protocol
  - Trial Design

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# Controlled Terminology (1)

| Variable Name | Variable Label             | Type | Controlled Terms, Codelist or Format | Role               |                                                                                                                                                                                                                                                                                                                                                                                                                                                 |      |                                |
|---------------|----------------------------|------|--------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------------------------------|
| BRTHDTC       | Date/Time of Birth         | Char | ISO 8601                             | Record Qualifier   | Date/time of birth of the subject.                                                                                                                                                                                                                                                                                                                                                                                                              | Perm | SDTMIG 4.1.4.1                 |
| AGE           | Age                        | Num  |                                      | Record Qualifier   | Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).                                                                                                                                                                                                                                                                                                | Exp  |                                |
| AGEU          | Age Units                  | Char | (AGEU)                               | Variable Qualifier | Units associated with AGE.                                                                                                                                                                                                                                                                                                                                                                                                                      | Exp  |                                |
| SEX           | Sex                        | Char | (SEX)                                | Record Qualifier   | Sex of the subject.                                                                                                                                                                                                                                                                                                                                                                                                                             | Req  |                                |
| RACE          | Race                       | Char | (RACE)                               | Record Qualifier   | Race of the subject. Ethnicity Data regarding the collection of ethnicity data (http://www.fda.gov/cder/guidance/5656fnd.htm) regarding RACE.                                                                                                                                                                                                                                                                                                   |      |                                |
| ETHNIC        | Ethnicity                  | Char | (ETHNIC)                             | Record Qualifier   | The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity (http://www.fda.gov/cder/guidance/5656fnd.htm).                                                                                                                                                                                                      | Perm |                                |
| ARMCD         | Planned Arm Code           | Char | *                                    | Record Qualifier   | ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20. | Req  | SDTMIG 4.1.2.1                 |
| ARM           | Description of Planned Arm | Char | *                                    | Synonym Qualifier  | Name of the Arm to which the subject was assigned.                                                                                                                                                                                                                                                                                                                                                                                              | Req  | SDTMIG 4.1.2.1, SDTMIG 4.1.2.4 |
| COUNTRY       | Country                    | Char | (COUNTRY) ISO 3166                   | Record Qualifier   | Country of the investigational site in which the subject participated in the trial.                                                                                                                                                                                                                                                                                                                                                             | Req  |                                |
| DMDTC         | Date/Time of Collection    | Char | ISO 8601                             | Timing             | Date/time of demographic data collection.                                                                                                                                                                                                                                                                                                                                                                                                       | Perm | SDTM 2.2.5, SDTMIG 4.1.4.1     |
| DMDY          | Study Day of Collection    | Num  |                                      | Timing             | Study day of collection measured as integer days.                                                                                                                                                                                                                                                                                                                                                                                               | Perm | SDTM 2.2.5, SDTMIG 4.1.4.1     |

Indicates which CDISC codelist should be used

Indicates variable may be subject to sponsor CT

\* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

# Controlled Terminology (2)

- CDISC CT: September 2008  
(<http://www.cdisc.org/standards/terminology/index.html>)

| <div> <div> <a href="#">ABOUT CDISC</a> <a href="#">CDISC MEMBERS</a> <a href="#">EVENTS</a> <a href="#">NEWS ROOM</a> <a href="#">PUBLICATIONS &amp; PRESENTATIONS</a> <a href="#">FAQ</a> <a href="#">INTERNATIONAL</a> <a href="#">CONTACT</a> </div> <div>  <div>CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM</div> <div>search: <input type="text"/> <a href="#">go</a></div> </div> </div> |      |               |                              |                                   |                        |                      |                                   |                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------------|------------------------------|-----------------------------------|------------------------|----------------------|-----------------------------------|------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | A    | B             | C                            | D                                 | E                      | F                    | G                                 |                                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Code | Codelist Code | Codelist Extensible (Yes/No) | Codelist Name                     | CDISC Submission Value | CDISC Preferred Term | CDISC Synonym(s)                  | CDISC Definition                                                 |
| Standards                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1    | C86767        | No                           | Action Taken with Study Treatment | ACN                    | ACN                  | Action Taken with Study Treatment | The reason that changes were                                     |
| Terminology                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2    | C49503        | C86767                       | Action Taken with Study Treatment | DOSE INCREASED         | DOSE INCREASED       |                                   | An indication that a medication frequency, strength or amount.   |
| Recent                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 3    | C49504        | C86767                       | Action Taken with Study Treatment | DOSE NOT CHANGED       | DOSE NOT CHANGED     |                                   | An indication that a medication                                  |
| The CDISC Labtest Relation (LBTEST) and SUP spreadsheets                                                                                                                                                                                                                                                                                                                                                                                                                            | 4    | C49505        | C86767                       | Action Taken with Study Treatment | DOSE REDUCED           | DOSE REDUCED         |                                   | An indication that a medication frequency, strength or amount.   |
| <a href="#">SDTM &amp; Public C</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 5    | C49501        | C86767                       | Action Taken with Study Treatment | DRUG INTERRUPTED       | DRUG INTERRUPTED     |                                   | An indication that a medication prescribed regimen of medication |
| The CDISC Package SDTM Package 2300. S direct d                                                                                                                                                                                                                                                                                                                                                                                                                                     | 6    | C49502        | C86767                       | Action Taken with Study Treatment | DRUG WITHDRAWN         | DRUG WITHDRAWN       |                                   | An indication that a medication                                  |

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# Trial Design

- SE and SV are now Special-Purpose domains
- Some new variables
  - TIVERS: Inclusion/Exclusion criteria version number
  - TIRL: Inclusion/Exclusion Criterion Rule

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# Additional Functionality (1)

- Splitting domains
  - 1 domain, multiple datasets
  - By --CAT or --OBJ
  - Examples:  
*FAAE, FACE, FASU*  
*QSAD, QS36*
- The value « multiple »
  - Only for non-result qualifiers
  - See example on next slide

# Additional Functionality (2)

**[DM]**

| Race                                      | Check all that apply                |
|-------------------------------------------|-------------------------------------|
| American Indian or Alaska Native          | <input checked="" type="checkbox"/> |
| Asian                                     | <input type="checkbox"/>            |
| Black or African American                 | <input checked="" type="checkbox"/> |
| Native Hawaiian or Other Pacific Islander | <input type="checkbox"/>            |
| White                                     | <input type="checkbox"/>            |
| Other, Specify: <i>Aborigine</i>          | <input checked="" type="checkbox"/> |

**RACE**

Multiple values checked

Checked values go into QVAL

## • DM

| Row | STUDYID | DOMAIN | USUBJID | RACE     |
|-----|---------|--------|---------|----------|
| 1   | ABC     | DM     | 001     | MULTIPLE |

## • SUPPDM

| Row | STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | QNAM    | QLABEL      | QVAL                             |
|-----|---------|---------|---------|-------|----------|---------|-------------|----------------------------------|
| 1   | ABC     | DM      | 001     |       |          | RACE1   | Race 1      | AMERICAN INDIAN OR ALASKA NATIVE |
| 2   | ABC     | DM      | 001     |       |          | RACE2   | Race 2      | BLACK OR AFRICAN AMERICAN        |
| 3   | ABC     | DM      | 001     |       |          | RACE3   | Race 3      | OTHER                            |
| 4   | ABC     | DM      | 001     |       |          | RACEOTH | Race, Other | ABORIGINE                        |

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# Summary

## SDTM 1.2 – SDTM IG 3.1.2

- Expanded model
- More functionality, usability
- More complex ?
- Correction of SDTM IG 3.1.1 errors
- Backward compatible
- Will become current FDA submission standard

Questions ?

