

# CDISC Standards Overview

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# World without Standardization



# Data without Standardization

## ► Demographics

Study#3 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Study#1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Study#3 – dmgph.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

# Big Data, Big Headache?

- Where is data needed?
- What dose it mean?!
- The data was coded in different way, pool them?!



# What's data standards about?

- ▶ A **standard** way to **organize** and **format** study data

dm.xml

STUDYID	DOMAIN	USUBJID	SUBJID	AGE	AGEU	SEX	RACE
CDE01	DM	CDE01-701-1015	1015	63	YEARS	F	WHITE
CDE01	DM	CDE01-701-1023	1023	64	YEARS	M	WHITE
CDE01	DM	CDE01-701-1033	1033	74	YEARS	M	WHITE
CDE01	DM	CDE01-701-1047	1047	85	YEARS	F	WHITE
CDE01	DM	CDE01-701-1097	1097	68	YEARS	M	WHITE
CDE01	DM	CDE01-701-1111	1111	81	YEARS	F	ASIAN
CDE01	DM	CDE01-701-1115	1115	84	YEARS	M	WHITE
CDE01	DM	CDE01-701-1118	1118	52	YEARS	M	WHITE
CDE01	DM	CDE01-701-1130	1130	84	YEARS	M	BLACK OR AFRICAN AMERICAN

# Standardized vs Non-standardized

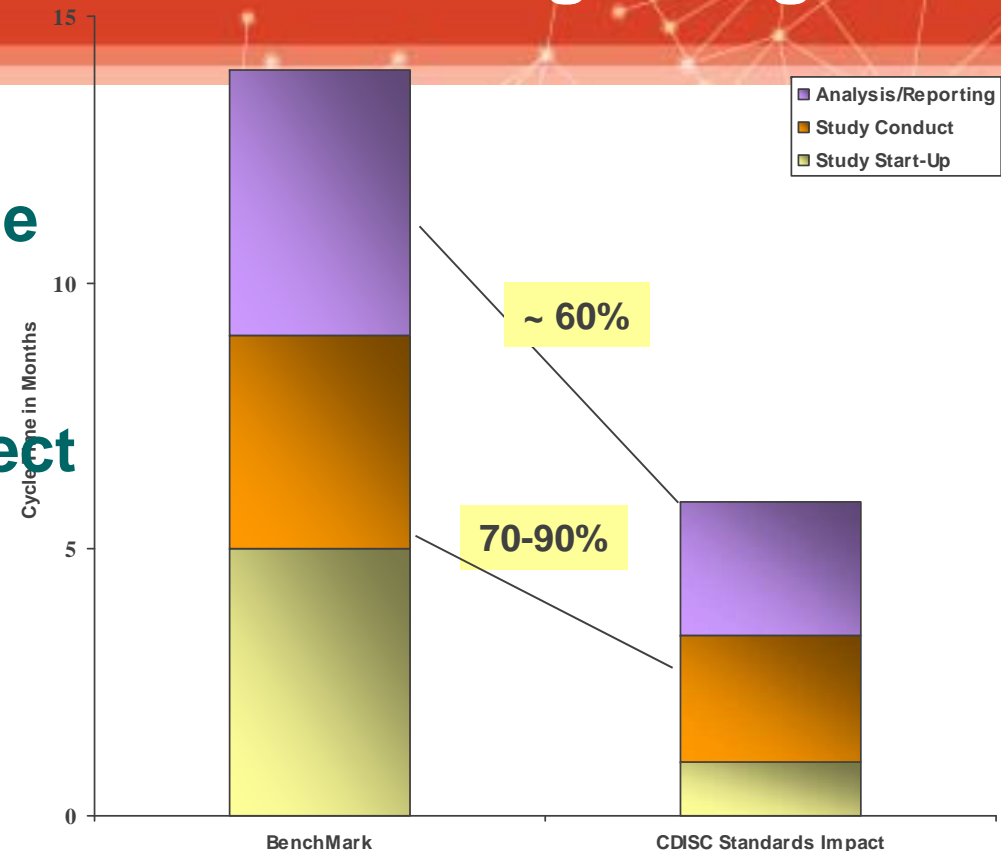
- Dataset level
  - Name
  - Description
  - Structure
  - Allowed Variables
- Variable level
  - Name
  - Label
  - Type
  - Format
- Value level
  - Controlled Terminology

Predictable  
vs  
Unpredictable



# Implement CDISC standards from beginning

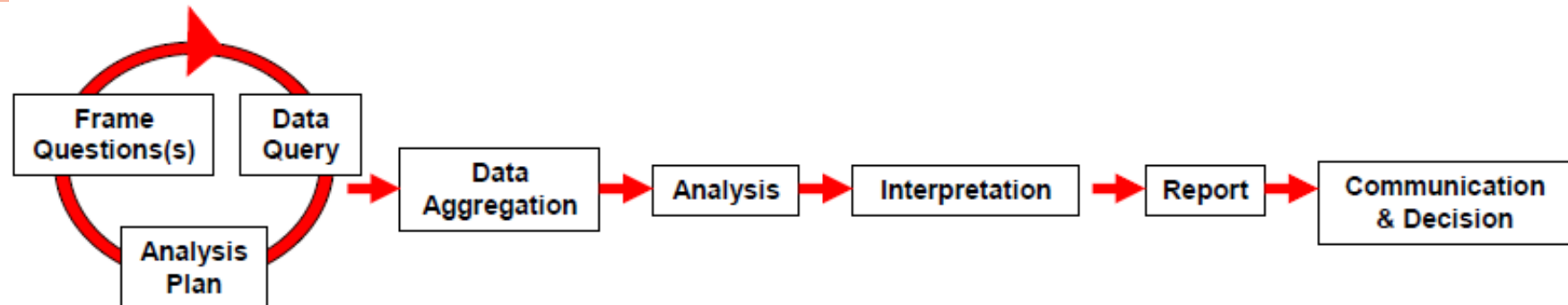
- 70-90% start-up stage
- 60% of the non-subject participation time



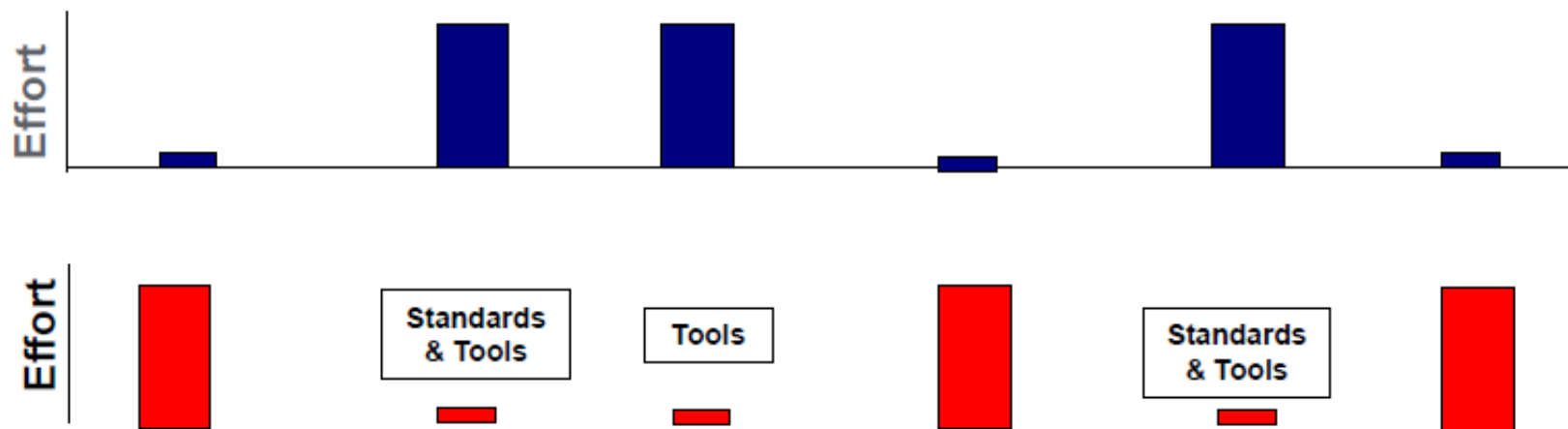
- + Better data quality and accuracy
- + Improve communication among project teams
- + Enable data integration, re-usability



# Time to spend on?



## Present Time Emphasis- 'Doing'

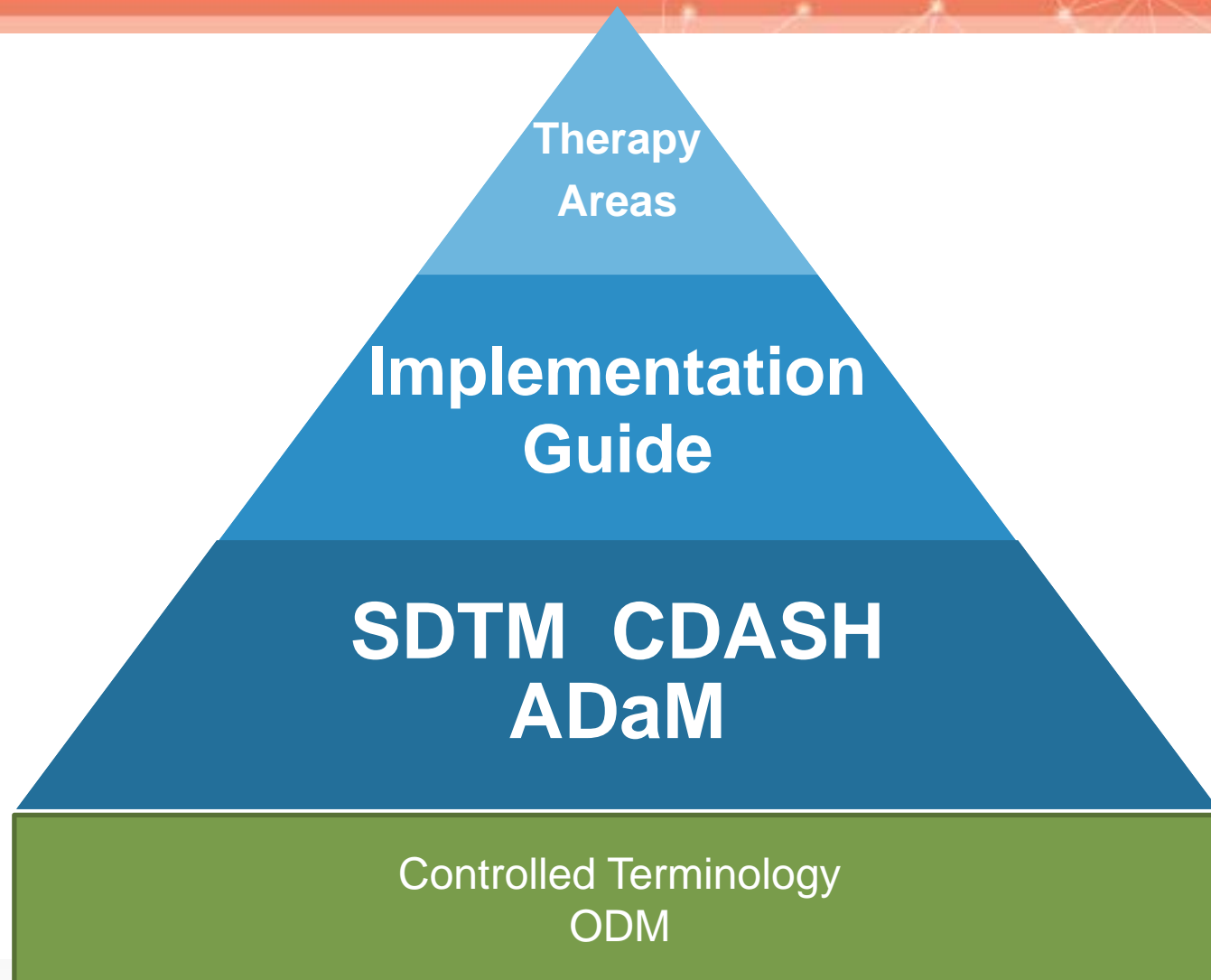


Source: Theresa Mullen, PhD, FDA CDER Associate Director

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# CDISC Standards and Implementation

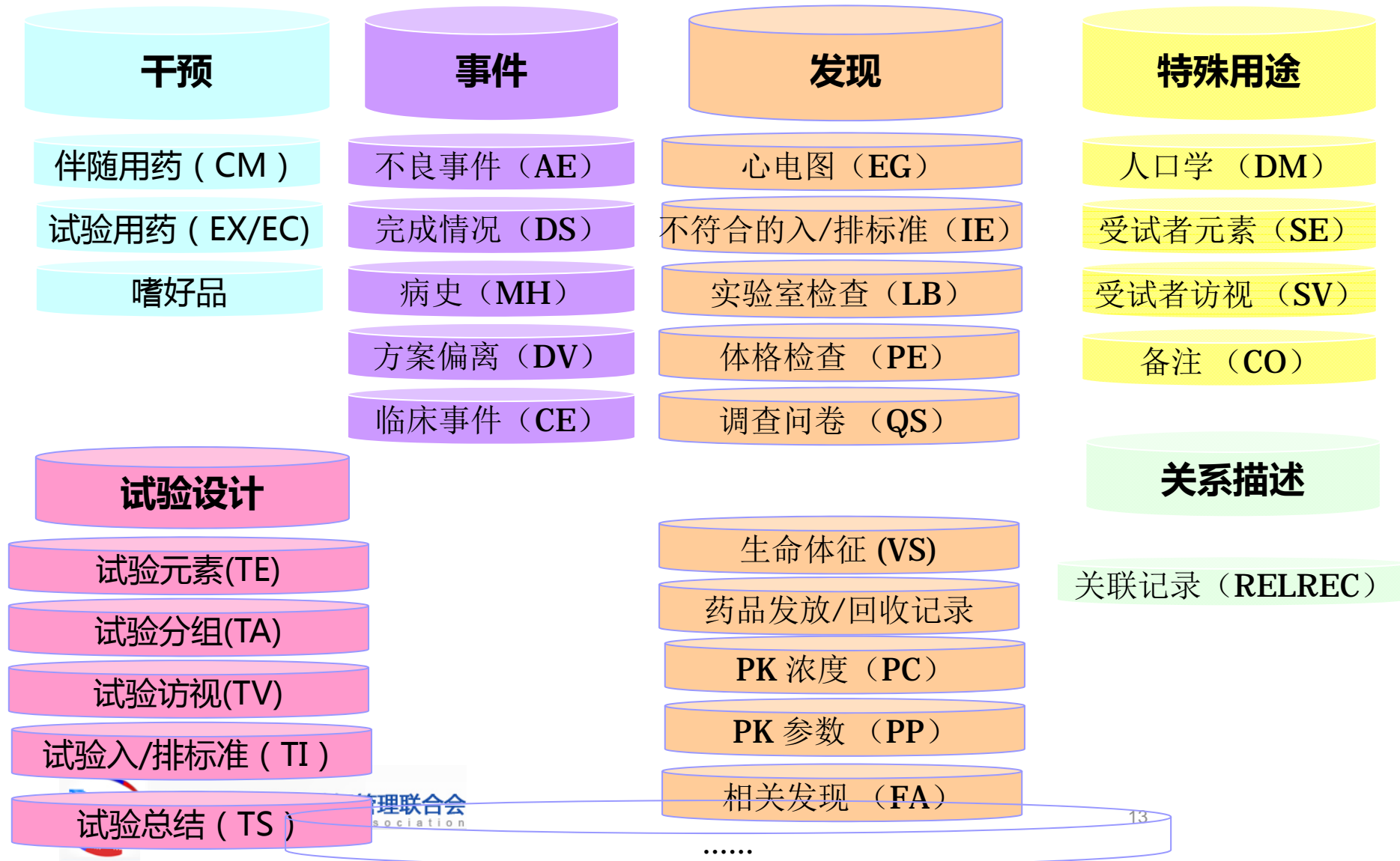


# CDISC Standards

- SDTM: S t u d y D a t a T a b u l a t i o n M o d e l
- CDASH: C l i n i c a l D a t a A c q u i s i t i o n S t a n d a r d s H a r m o n i z a t i o n
- ADaM: A n a l y s i s D a t a M o d e l
- CT: C o n t r o l l e d T e r m i n o l o g y
  - Allowed value list
- ODM: O p e r a t i o n a l D a t a M o d e l  
xml format for interchange and archive of clinical trials data

# SDTM IG 标准域

Domains are logical groupings of data



# SDTM Basic

- Domains are organized around a “Topic”

Identifier	Topic	Qualifier	Timing
<ul style="list-style-type: none"><li>• STUDYID</li><li>• DOMAIN</li><li>• USUBJID</li><li>• --SEQ</li></ul>	<ul style="list-style-type: none"><li>• --TRT</li><li>• --TERM</li><li>• --TESTCD</li></ul>	<ul style="list-style-type: none"><li>• --DOSE</li><li>• --DOSU</li><li>• --SEV</li><li>• --OUT</li><li>• --ORRES</li><li>• --ORRESU</li></ul>	<ul style="list-style-type: none"><li>• --STDTC</li><li>• --ENDTC</li><li>• --STDTC</li><li>• --ENDTC</li><li>• --DTC</li></ul>

# Variables by Role – Example

**Subject 101 had mild nausea starting on 07Dec2015**

<u>Identifier</u>	<u>Topic</u>	<u>Qualifiers</u>	<u>Timing</u>
<i>USUBJID</i>	<i>AETERM</i>	<i>AESEV</i>	<i>AESTDTC</i>
101	Nausea	Mild	2015-12-07



# CDASH

## ► Best Practice

- **NECESSARY DATA ONLY**
- **CLARITY**
- **COMPLETION GUIDELINES**
- **SITE WORKFLOW**
- CONTROL
- ADEQUATE REVIEW
- DEPLOY STANDARDS
- TRANSLATIONS
- Data Cleaning Prompts
- What to database

	Question Text	Prompt	SDTM or CDASH Variable Name	BRIDG	Definition	CRF Completion Instructions	Information for Sponsors	Core
10a	What was the severity of the adverse event?	Severity	AESEV	AdverseEvent.severity Code*	Description of the severity of the adverse event. {AESEV} (See <a href="#">Section 2.2.</a> )	The reporting physician/healthcare professional will assess the severity of the event using the sponsor-defined categories. This assessment is subjective and the reporting physician/healthcare professional should use medical judgment to compare the reported Adverse Event to similar type events observed in clinical practice. Severity is not equivalent to seriousness.	Either AESEV or AETOXGR <u>must</u> appear on the CRF. Some studies may mandate the collection of both.  Refer to ICH E3 guidelines for CSR Section 12.2.4.  * See the BRIDG model for complete path.	R/C

# ADaM Principles & Structure

## ➤ Fundamental Principles

- Clearly and unambiguously communicate 清晰无歧义
- **Traceability** 可溯源
- Readily usable with commonly available software tools 易用
- **Analysis-ready** 即可分析

## ➤ Structure

- **ADSL**: one record per subject
- **BDS**: one or more records per subject, per analysis parameter, per analysis timepoint
- **OCCDS**: one record per record in SDTM domain (optional: per coding path, per Analysis Period and/or Phase)

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# CDISC Implementation

- ***The earlier, the better (越早越好)***
  - ***At the start up stage (Protocol and CRF dev)***
  - ***CDASH → SDTM → ADaM***
- ***It is very easy to implement (容易实施)***

# CDASH example (CRF)

方案编号: CDE01

## 访视 1

访视日期: \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MMM/YYYY)

## 知情同意

知情同意签署日期: \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MMM/YYYY)

## 人口统计学

出生日期: \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MMM/YYYY)

性别:

☐ M 男

☐ F 女

种族:

☐ 1 白人

☐ 2 黑人/非洲裔美国人

☐ 3 亚洲人

☐ 4 夏威夷原住民或其它太平洋岛人

☐ 5 美洲印第安人或阿拉斯加原住民

☐ 99 其它, 请说明: \_\_\_\_\_

# aCRF example

方案编号: CDE01 STUDYID

访视 1 VISIT  
VISITNUM SVSTDTC DMDTC  
访视日期: \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MMM/YYYY)

知情同意 RFICDTC  
知情同意签署日期: \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MMM/YYYY)

人口统计学 BRTHDTC  
出生日期: \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MMM/YYYY)

性别: SEX  
☐ M 男  
☐ F 女

种族: RACE  
☐ 1 白人  
☐ 2 黑人/非洲裔美国人  
☐ 3 亚洲人  
☐ 4 夏威夷原住民或其它太平洋岛人  
☐ 5 美洲印第安人或阿拉斯加原住民  
☐ 99 其它, 请说明: \_\_\_\_\_

# SDTM example (DM)

STUDYID	DOMAIN	USUBJID	SUBJID	RFICDTC	BRTHTDTC	AGE	AGEU	SEX	RACE
CDE01	DM	CDE01-701-1015	1015	2013-12-26	1951-04-03	63	岁	F	白人
CDE01	DM	CDE01-701-1023	1023	2012-07-22	1948-10-26	64	岁	M	白人
CDE01	DM	CDE01-701-1033	1033	2014-03-10	1940-08-06	74	岁	M	白人
CDE01	DM	CDE01-701-1047	1047	2013-01-22	1928-04-03	85	岁	F	白人
CDE01	DM	CDE01-701-1097	1097	2013-12-23	1946-01-20	68	岁	M	白人
CDE01	DM	CDE01-701-1111	1111	2012-08-25	1931-11-02	81	岁	F	白人
CDE01	DM	CDE01-701-1115	1115	2012-11-23	1929-02-24	84	岁	M	白人
CDE01	DM	CDE01-701-1118	1118	2014-02-27	1962-09-02	52	岁	M	白人
CDE01	DM	CDE01-701-1130	1130	2014-02-09	1930-05-20	84	岁	M	白人



# ADaM example (ADSL)

USUBJID	TRT01P	TRT01A	AGE	AGEU	RACE	RACEN	SEX	SAFFL	ITTFL
CDE01-701-1015	安慰剂	安慰剂	63	岁	白人	1	F	Y	Y
CDE01-701-1023	安慰剂	安慰剂	64	岁	白人	1	M	Y	Y
CDE01-701-1033	CDE_001	CDE_001	74	岁	白人	1	M	Y	Y
CDE01-701-1047	安慰剂	安慰剂	85	岁	白人	1	F	Y	Y
CDE01-701-1097	CDE_001	CDE_001	68	岁	白人	1	M	Y	Y
CDE01-701-1111	CDE_001	CDE_001	81	岁	白人	1	F	Y	Y
CDE01-701-1115	CDE_001	CDE_001	84	岁	白人	1	M	Y	Y
CDE01-701-1118	安慰剂	安慰剂	52	岁	白人	1	M	Y	Y
CDE01-701-1130	安慰剂	安慰剂	84	岁	白人	1	M	Y	Y

Ask



# Thank You 谢谢!



**Strength** *through collaboration.*

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