

A wide banner featuring a panoramic view of the Shanghai skyline at dusk or dawn. The Oriental Pearl Tower is the central focus, with its distinctive spheres. The city's dense skyscrapers are visible in the background under a soft, hazy sky.

**2024** CDISC CHINA INTERCHANGE **SHANGHAI**

30-31 AUGUST: CONFERENCE & EXPO | 28-29 AUGUST: TRAININGS

## Do's and Dont's for CRF Mapping

Presented by Alice Liu



## Meet the Speaker

Alice Liu

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Alice Liu, has over 10 years SAS programming experience for phase I/II/III clinical trials in various therapeutic areas. Alice also has abundant experience in CDISC standard implementation, including developing annotated CRF, SDTM, ADaM and define-xml. Before join Hengrui, she had worked in IQVIA and PAREXEL for more than 7 years.



# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



# Agenda

1. Brief Introduction to SDTM-MSG
2. Basic Principles for Annotations
3. Appearance of Annotations
4. Comparison between MSG V2.0 and MSG V1.0
5. PDF Requirements
6. Common Confusion for CRF Mapping



# 1. Brief Introduction to SDTM-MSG

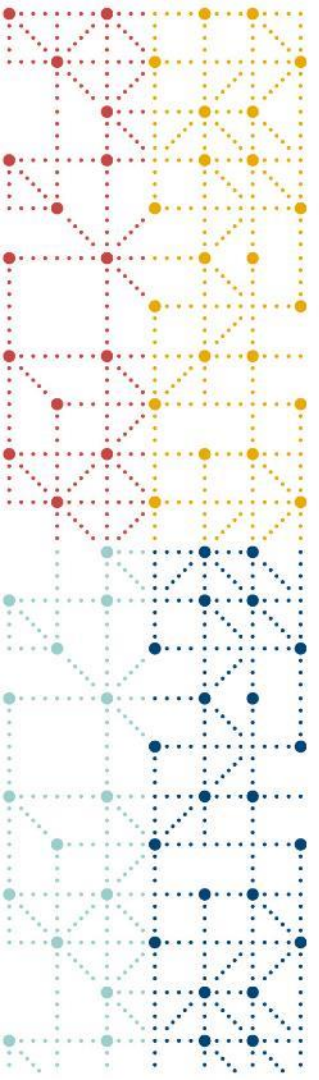
# 1. Brief Introduction to SDTM-MSG

- What is SDTM-MSG?  
Study Data Tabulation Model Metadata Submission Guidelines
- Available MSG Version

Date	Version
2021-03-30	2.0 Final
2011-12-30	1.0 Final

- Purpose of SDTM-MSG  
The purpose of the Study Data Tabulation Model Metadata Submission Guidelines: Human Clinical Trials (SDTM-MSG) is to provide guidance for preparing the components of the International Conference on Harmonisation (ICH) electronic Common Technical Document (eCTD) Module 5 (M5) Clinical Study Reports "sdtm" folder. This document and the associated example submission package illustrate the components recommended for electronic submission of SDTM data.

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## 2. Basic Principles for Annotations

## 2. Basic Principles for Annotations

- Filename: acrf.pdf (suggested by the FDA and the PMDA )
- Searchable
- Dual bookmarking (recommended)
- Annotating Unique CRF Pages (recommended)
- Partial CRF page annotations should be avoided
- Avoid covering up text on the CRF page or collection screen

### **Best Practice**

Developing the Define-XML and annotated CRF components early in the study development life cycle aids in overall efficiency, allowing study teams to manage potential incremental changes during the course of a study's development, and ensuring alignment between the various components. This is especially important when those components are intended for regulatory submission, thereby helping propagate a more expedited submission package compilation process.



# 2.1 Dual Bookmarking

## 2.2.1 Bookmark

Printable Table Of Contents	Forms
Visit	Adverse Events
Screening 1	Auditory Verbal Learning Test (AVLT-REY)
Screening 2	Concomitant Medications
Baseline	Death
Week 2	Running Records
Vital Signs (Weight And Temperature)	Demographics
Ophthalmic Examination	Electroencephalogram
Week 4	Eligibility
Week 6	End Of Treatment
Week 8	Exposure
Week 12	Hamilton Depression Rating Scale - 17 (HAMD-17)
Week 16	Informed Consent
Week 20	Injection Site Reactions
Week 24	Medical History
Week 26	Ophthalmic Examination
Early Discontinuation Retrieval	Patient Health Questionnaire-9 (PHQ-9)
Running Records	Baseline
Exposure	Week 12
Electroencephalogram	Week 16
Adverse Events	Week 20
Injection Site Reactions	Week 24
Concomitant Medications	Early Discontinuation Retrieval
Death Details	Patient Summary

Bookmarks by **chronology** should be ordered according to the study schedule of activities (SoA).

- ✓ Pages that are independent of visits (e.g., Adverse Events) should be presented last, under a "**Running Records**" bookmark.
- ✓ Within each chronological bookmark, topic bookmarks should appear **in the order that they appear in the annotated CRF**.

Bookmarks by topics can be ordered **alphabetically**, as is done in the SDTM-MSG sample submission package, or sponsors may choose to list the forms **in the order in which they appear in the CRF**.

- ✓ Within each topic bookmarks should be ordered **chronologically** according to the SoA schedule.
- ✓ For SDTM-MSG v2.0, the aCRF example showed "Domains" as the top level for these bookmarks, but SDTM-MSG v1.0 has changed that to "**Forms**," because "Domains" implies SDTM domains.

# 2.1 Dual Bookmarking

## 2.2.2 TOC

Bookmarking by Visits	Bookmarking by Forms
<b>Visits</b> Screening 1 Informed Consent Demographics Eligibility Medical History Vital Signs (Weight, Height and Temperature) Version 2 Version 1 Ophthalmic Examination Screening 2 Vital Signs (Temperature) Version 2 Version 1 Auditory Verbal Learning Test Ophthalmic Examination Baseline Vital Signs (Weight and Temperature) Version 2 Version 1 Patient Health Questionnaire-9 (PHQ-9) Satisfaction With Life Survey (SWLS) Hamilton Depression Rating Scale - 17 (HAMD 17) Ophthalmic Examination Week 2 Vital Signs Vital Signs (Weight and Temperature) Version 2 Version 1 Auditory Verbal Learning Test (AVL02) Ophthalmic Examination	<b>Forms</b> Adverse Events Running Records Auditory Verbal Learning Test (AVL02) Screening 2 Week 4 Week 8 Week 12 Week 16 Week 24 Early Discontinuation Retrieval Concomitant Medications Running Records Death Running Records Demographics Screening 1 Electroencephalogram Running Records Eligibility Screening 1 End of Treatment Week 26 Exposure Running Record Hamilton Depression Rating Scale - 17 (HAMD 17) Baseline Early Discontinuation Retrieval Informed Consent Screening 1

In the annotated CRF, the bookmarks essentially comprise a table of contents (TOC) for the reviewer. To facilitate a more efficient review process, a printable TOC may be included at the beginning of the annotated.

## 2.2 Unique CRF Pages

- > V0\_Screening
- > V1\_Randomization
- ▼ V2\_W2
  - Visit Date
  - Vital Signs
  - Dispense
  - Study Drug Administration
  - Body area for Psoriasis Area Severity Index(PASI)
  - Visual Analog Scale (VAS)
  - Dactylitis Assessment
  - Healthy Assessment Questionnaire (HAQ-DI)
  - Leeds Enthesitis Index(LEI)
  - Tender Joint Count
  - Swelling Joint Count
  - ESR Testing
  - CRP Sample Collection
- ▼ V3\_W4
  - Visit Date
  - Vital Signs
  - Dispense
  - Study Drug Administration

Repeat by VISIT

- Subject Identification
- Visit Date
- Demographics
- Height And Weight
- Tobacco Use History
- Alcohol Use History
- Medical History
- Psoriatic Arthritis History
- Psoriatic Arthritis Treatment History
- Virology
- Vital Signs
- Electrocardiogram
- TB-IGRA
- Chest Imaging
- HBV-DNA
- Eligibility
- Randomization
- Re-Randomization

Unique CRF

Sponsors who choose to submit the entire CRF rather than unique forms are responsible for determining the approach for their submission that best allows the reviewer to understand multiple occurrences of a given page.

## 2.3 Partial CRF Page Annotations

**VS (Vital Signs)**

**VITAL SIGNS** [NOT SUBMITTED]

Vital Signs Collected?  Yes  No VSSTAT = NOT DONE when VSTESTCD = VSALL

Visit: [ ] VISIT

Date: [ ] [ ] [ ] VSDTC

VSTESTCD = TEMP: Temperature  VSORRES  F  VSORRESU

**VSREPNUM = 1** 1st Measurement (Supine) [VSPOS]

VSTESTCD = PULSE: Pulse  VSORRES bpm VSORRESU

VSTESTCD = SYSBP: Systolic  VSORRES mmHg VSORRESU

VSTESTCD = DIABP: Diastolic  VSORRES mmHg VSORRESU

**VSREPNUM = 2** 2nd Measurement (Standing) [VSPOS]

VSTESTCD = PULSE: Pulse  VSORRES bpm VSORRESU

VSTESTCD = SYSBP: Systolic  VSORRES mmHg VSORRESU

VSTESTCD = DIABP: Diastolic  VSORRES mmHg VSORRESU

**VSREPNUM = 3** 3rd Measurement (Standing) [VSPOS]

VSTESTCD = PULSE: Pulse  VSORRES bpm VSORRESU

VSTESTCD = SYSBP: Systolic  VSORRES mmHg VSORRESU

VSTESTCD = DIABP: Diastolic  VSORRES mmHg VSORRESU

**VS (Vital Signs)**

**VITAL SIGNS** [NOT SUBMITTED]

Vital Signs Collected?  Yes  No VSSTAT = NOT DONE when VSTESTCD = VSALL

Visit: [ ] VISIT

Date: [ ] [ ] [ ] VSDTC

VSTESTCD = WEIGHT: Weight  VSORRES pounds VSORRESU

VSTESTCD = TEMP: Temperature  VSORRES  F  VSORRESU

**VSREPNUM = 1** 1st Measurement (Supine) [VSPOS]

VSTESTCD = PULSE: Pulse  VSORRES bpm VSORRESU

VSTESTCD = SYSBP: Systolic  VSORRES mmHg VSORRESU

VSTESTCD = DIABP: Diastolic  VSORRES mmHg VSORRESU

**VSREPNUM = 2** 2nd Measurement (Standing) [VSPOS]

VSTESTCD = PULSE: Pulse  VSORRES bpm VSORRESU

VSTESTCD = SYSBP: Systolic  VSORRES mmHg VSORRESU

VSTESTCD = DIABP: Diastolic  VSORRES mmHg VSORRESU

**VSREPNUM = 3** 3rd Measurement (Standing) [VSPOS]

VSTESTCD = PULSE: Pulse  VSORRES bpm VSORRESU

VSTESTCD = SYSBP: Systolic  VSORRES mmHg VSORRESU

VSTESTCD = DIABP: Diastolic  VSORRES mmHg VSORRESU

Partial CRF page annotations should be avoided. For example, if a CRF page has 1 or more collected data points than another similar page, it is recommended that both/all CRF pages be annotated. In this instance, annotating just the new collection point and referencing the annotations on another page (e.g., "See Page <n> for Annotations") makes reviewability more difficult.



### 3. Appearance of Annotations

# 3.1 Format of Annotation (cont.)

black text **with** bold formatting  
Arial font

**EC (Exposure as Collected)**

**EXPOSURE**

Did the subject take  
Zanomaline?

Yes  No

**ECOCCUR**

If No, Reason Not  
Administered

**ECREASOC in SUPPEC**

Exception Criterion Identifier

**IETESTCD = "EXCL" or "INCL", depending  
on IECAT, concatenated with exception  
criterion identifier padded to 2 digits**

black text **without**  
bold formatting  
Arial font/12-point

Variables and dataset codes  
should be capitalized

Instruction text and comments  
should be sentence case,  
excluding variables and  
dataset

# 3.1 Format of Annotation

BLUE	<b>DM (Demographics)</b>	191, 255, 255
YELLOW	<b>DS (Disposition)</b>	255, 255, 150
GREEN	<b>SC (Subject Characteristics)</b>	150, 255, 150
ORANGE	<b>VS (Vital Signs)</b>	255, 190, 155

**AE (Adverse Events)**

**FA (Findings About Events or Interventions)**

**ADVERSE EVENTS**

Did the subject have an injection site reaction?



[NOT SUBMITTED]

Colors are recommended not mandatory! But should use consistent colors and take color blindness into consideration.



# 3.2 Annotation of Domain (cont.)

Consistency in annotation placement based on their CRF design;  
Domain annotations should use black text **with** bold formatting

**AE (Adverse Events)** ←

**ADVERSE EVENTS**

Were any adverse events experienced?  Yes  No [NOT SUBMITTED]

If yes please provide details below.

AE Identifier

What is the adverse event term?

Start Date

Severity  Mild  Moderate  Severe

**CM (Concomitant and Prior Medications)** ←

**CONCOMITANT MEDICATIONS**

Were any medications taken?  Yes  No [NOT SUBMITTED]

Medication

Indication  Primary Study Condition  Prophylaxis or Non-Therapeutic Use

Dose  ✓

Dose Unit

Frequency

**AE (Adverse Events)** ←

**ADVERSE EVENTS**

Were any adverse events experienced?  Yes  No [NOT SUBMITTED]

If yes please provide details below.

AE Identifier

What is the adverse event term?

Start Date

Severity  Mild  Moderate  Severe

**CM (Concomitant and Prior Medications)** →

**CONCOMITANT MEDICATIONS**

Were any medications taken?  Yes  No [NOT SUBMITTED]

Medication

Indication  Primary Study Condition  Prophylaxis or Non-Therapeutic Use

Dose  X

Dose Unit

Frequency



## 3.2 Annotation of Domain (cont.)

Domain names, rather than dataset (including split dataset) names, are annotated

✓ **QS (Questionnaires)**      QSCAT = PHQ-9

**PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)**

QSEVLINT = -P2W  
Over the last 2 weeks, how often have you been bothered by any of the following problems?  
(Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day	QSORRES
QSTESTCD = PHQ0101 1. Little interest or pleasure in doing things	0	1	2	3	QSSTRES / QSSTRESN
QSTESTCD = PHQ0102 2. Feeling down, depressed, or hopeless	0	1	2	3	

X **QSPH (Questionnaires)**      QSCAT = PHQ-9

**PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)**

QSEVLINT = -P2W  
Over the last 2 weeks, how often have you been bothered by any of the following problems?  
(Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day	QSORRES
QSTESTCD = PHQ0101 1. Little interest or pleasure in doing things	0	1	2	3	QSSTRES / QSSTRESN
QSTESTCD = PHQ0102 2. Feeling down, depressed, or hopeless	0	1	2	3	

# 3.2 Annotation of Domain

**EC (Exposure as Collected)** ✓

**EXPOSURE**

Did the subject take Zanolamine?  Yes  No **ECOCCUR**

If No, Reason Not Administered  **ECREASOC in SUPPEC**

Date    **ECSTDTC**  
**ECENDTC**

Lot Number  **ECLTOT**

Dose **ECDOSE** 5 mL **ECDOSU**

**RELREC** when ECLINKID = EXLNKID

Supplemental qualifier domain names/RELREC do not need to be annotated ✓

**EC (Exposure as Collected)**

**SUPPEC (Supplemental Qualifiers for EC)** X

**EXPOSURE**

Did the subject take Zanolamine?  Yes  No **ECOCCUR**

If No, Reason Not Administered  **ECREASOC in SUPPEC**

Date    **ECSTDTC**  
**ECENDTC**

Lot Number  **ECLTOT**

Dose **ECDOSE** 5 mL **ECDOSU**

**RELREC** when ECLINKID = EXLNKID

**EC (Exposure as Collected)** X

**RELREC (Related Records)**

**EXPOSURE**

Did the subject take Zanolamine?  Yes  No **ECOCCUR**

If No, Reason Not Administered  **ECREASOC in SUPPEC**

Date    **ECSTDTC**  
**ECENDTC**

Lot Number  **ECLTOT**

Dose **ECDOSE** 5 mL **ECDOSU**

**RELREC** when ECLINKID = EXLNKID

# 3.3 Not Collected Data

**DS (Disposition)**

**INFORMED CONSENT**

Informed Consent Date

**DM (Demographics)**

**DEMOGRAPHICS**

Birth Year

Age

Sex  Female  Male

Race (Check all that apply)

White

Black or African American

Asian

**RACE**

**Annotations:**

- DS (Disposition):** DSCAT = PROTOCOL MILESTONE; DSTERM / DSDECOD = INFORMED CONSENT OBTAINED
- DM (Demographics):** BRTHDTC, AGE, AGEU, SEX, RACE
- RACE:** When multiple values are selected then RACE = MULTIPLE and individual responses are RACE1, RACE2, RACE3, etc. in SUPPDM

Assigned or Derived variables: the SDTM-MSG recommends the use of dashed annotation borders for annotations which do not represent collected data.

DSDECOD	<a href="#">VLM</a>	Standardized Disposition Term	text	Synonym Qualifier	29		
	<a href="#">DSSCAT</a> = ""	Standardized Disposition Term	text		29	<a href="#">Completion/Reason for Non-Completion</a> [13 Terms]	Collected (Source: Investigator) Annotated CRF <a href="#">[27]</a> <a href="#">[28]</a> <a href="#">[ ]</a>
	<a href="#">DSSCAT</a> = ""	Standardized Disposition Term	text		29	<a href="#">Protocol Milestone</a> • "INFORMED CONSENT OBTAINED" = "Informed Consent"	Assigned (Source: Sponsor) Annotated CRF <a href="#">[5]</a> <a href="#">[ ]</a>
DSCAT		Category for Disposition Event	text	Grouping Qualifier	18	<a href="#">Category for Disposition Event</a> • "DISPOSITION EVENT" = "Disposition Event" • "PROTOCOL MILESTONE" = "Protocol Milestone"	Assigned (Source: Sponsor) Annotated CRF <a href="#">[5]</a> <a href="#">[27]</a> <a href="#">[28]</a> <a href="#">[ ]</a> Variable is Assigned but there are annotations to help understand the data and so references to the proper pages are included

# 3.4 Supplemental References

Boxes, arrows, and lines—can be used to further clarify annotations

**QS (Questionnaires)**      **QSCAT = PHQ-9**

**PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)**

**QSEVLINT = -P2W**  
 Over the last 2 weeks, how often have you been bothered by any of the following problems?  
 (Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day	<b>QSORRES</b>
<b>QSTESTCD = PHQ0101</b> 1. Little interest or pleasure in doing things	0	1	2	3	<b>QSSTRESC / QSSTRESN</b>

**QS (Questionnaires)**      **QSCAT = SWLS**

Below are five statements that you may agree or disagree with. Using the 1 - 7 scale below, indicate your agreement with each item by placing the appropriate number on the line preceding that item. Please be open and honest in your responding.

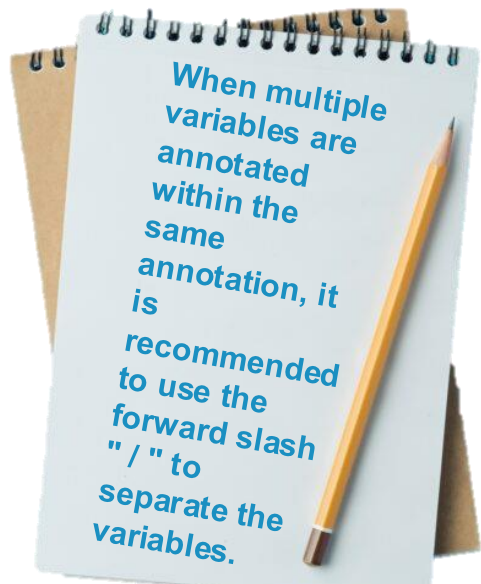
**QSSTRESC / QSSTRESN**      **QSORRES**

- 7 Strongly agree
- 6 Agree
- 5 Slightly agree
- 4 Neither agree nor disagree
- 3 Slightly disagree
- 2 Disagree
- 1 Strongly disagree



This method should be limited or avoided when not necessary.

## 3.5 Multiple Variables



**DS (Disposition)**

DSCAT = DISPOSITION EVENT

DSSCAT = STUDY TREATMENT

**END OF TREATMENT**

Disposition Event Date

DSSTDTC

What was the subject's treatment status?

- COMPLETED
- ADVERSE EVENT
- DEATH
- LACK OF EFFICACY

DSTERM / DSDECOD

# 3.6 Not Submitted

## AE (Adverse Events)

### ADVERSE EVENTS

Were any adverse events experienced?

Yes  
 No [NOT SUBMITTED]

If yes please provide details below.

AE Identifier

AELNKID

What is the adverse event term?

AETERM

Start Date

/ / AESTDTC

Severity

Mild  
 Moderate AESEV  
 Severe

For NOT SUBMITTED fields, there should be an explanation in the relevant RG stating why these data have not been submitted.

## 3.7 Use of Quotes



**DS (Disposition)**

**END OF TREATMENT**

DSCAT = DISPOSITION EVENT ✓  
DSSCAT = STUDY TREATMENT ✓

Disposition Event Date [ ] [ ] [ ]

DSSTDTC

What was the subject's treatment status?

COMPLETED DSTERM / DSDECOD

ADVERSE EVENT

DEATH

LACK OF EFFICACY



**DS (Disposition)**

**END OF TREATMENT**

DSCAT = "DISPOSITION EVENT" X  
DSSCAT = "STUDY TREATMENT" X

Disposition Event Date [ ] [ ] [ ]

DSSTDTC

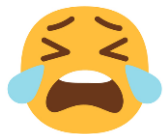
What was the subject's treatment status?

COMPLETED DSTERM / DSDECOD

ADVERSE EVENT

DEATH

# 3.8 Annotating Findings



Interpretation

- Normal **OEORRES**
- Abnormal

Abnormalities:

Location  **OELOC**

Abnormality  **OEORRES**



Interpretation

- Normal **OEORRES when OETESTCD = INTP**
- Abnormal

Abnormalities:

Location  **OELOC**

Abnormality  **OEORRES when OETESTCD = ABDETAIL**



Interpretation

- Normal **OEORRES** **OETESTCD = INTP**
- Abnormal

Abnormalities:

Location  **OELOC**

Abnormality  **OEORRES** **OETESTCD = ABDETAIL**



## 3.9 Supplemental Qualifiers

**EC (Exposure as Collected)**

**EXPOSURE**


Did the subject take Zanomaline?  Yes  No **ECOCCUR**

If No, Reason Not Administered  **ECREASOC in SUPPEC**

Date    **ECSTDTC**  
**ECENDTC**

Lot Number  **ECLOT**

Dose **ECDOSE** 5 mL **ECDOSU**



## 3.10 RELREC

### AE (Adverse Events)

### FA (Findings About Events or Interventions)

#### ADVERSE EVENTS

Did the subject have an injection site reaction?

Yes  
 No

[NOT SUBMITTED]

If yes please provide details below.

AE Identifier

AELNKID

FALNKGRP

RELREC when FALNKGRP = AELNKID

Date

FADTC

### OE (Ophthalmic Examinations)

#### OPHTHALMIC EXAMINATION

RELREC when OE.FOCID = AE.FOCID

OEMETHOD = SLIT LAMP

[NOT SUBMITTED]

Slit lamp examination performed?

Yes

No

Visit

VISIT

OESTAT = NOT DONE when  
OETESTCD = OEALL

Date

OEDTC

# 3.11 Replacement or Deprecated Pages

**VS (Vital Signs)**

**VITAL SIGNS** [NOT SUBMITTED]

Vital Signs Collected?  Yes  No VSSTAT = NOT DONE when VSTESTCD = VSALL

Visit: [ ] VISIT

Date: [ ] [ ] [ ] VSDTC

[VSTESTCD = TEMP] Temperature: [VSORRES] F [VSORRESU]

[VSTESTCD = PULSE] 1st Measurement (Supine) Pulse: [VSORRES] bpm [VSORRESU]

[VSTESTCD = SYSBP] Systolic: [VSORRES] mmHg [VSORRESU]

[VSTESTCD = DIABP] Diastolic: [VSORRES] mmHg [VSORRESU]

Version 1.0

**VS (Vital Signs)**

**VITAL SIGNS** [NOT SUBMITTED]

Vital Signs Collected?  Yes  No VSSTAT = NOT DONE when VSTESTCD = VSALL

Visit: [ ] VISIT

Date: [ ] [ ] [ ] VSDTC

[VSTESTCD = TEMP] Temperature: [VSORRES] F [VSORRESU]

[VSTESTCD = PULSE] 1st Measurement (Supine) Pulse: [VSORRES] bpm [VSORRESU]

[VSTESTCD = SYSBP] Systolic: [VSORRES] mmHg [VSORRESU]

[VSTESTCD = DIABP] Diastolic: [VSORRES] mmHg [VSORRESU]

[VSTESTCD = PULSE] 2nd Measurement (Standing) Pulse: [VSORRES] bpm [VSORRESU]

[VSTESTCD = SYSBP] Systolic: [VSORRES] mmHg [VSORRESU]

[VSTESTCD = DIABP] Diastolic: [VSORRES] mmHg [VSORRESU]

[VSTESTCD = PULSE] 3rd Measurement (Standing) Pulse: [VSORRES] bpm [VSORRESU]

[VSTESTCD = SYSBP] Systolic: [VSORRES] mmHg [VSORRESU]

[VSTESTCD = DIABP] Diastolic: [VSORRES] mmHg [VSORRESU]

Version 2.0

Bookmark

- ✓  Screening 2
- ✓  Vital Signs (Temperature)
  - Version 1
  - Version 2

TOC

- Screening 2
  - Vital Signs (Temperature)
    - Version 1
    - Version 2
  - Auditory Verbal Learning Test
  - Ophthalmic Examination



## 4. Comparison between MSG V2.0 and MSG V1.0

# 4 Comparison between MSG V2.0 and MSG V1.0 (cont.)

SDTM-MSG v1.0 Annotation Style	SDTM-MSG v2.0 Annotation Style
<p><b>DS=Disposition</b></p> <p><b>INFORMED CONSENT</b></p> <p>Informed Consent Date [ ] [ ] [ ] [ ]</p> <p><b>DM=Demographics</b></p> <p><b>DEMOGRAPHICS</b></p> <p>Birth Year [ ] <b>BRTHDTC</b></p> <p>Age [ ] years <b>AGE</b> <b>AGEU</b></p> <p>Sex <input type="radio"/> Female <input type="radio"/> Male <b>SEX</b></p> <p>Race (Check all that apply)</p> <p><input type="checkbox"/> White</p> <p><input type="checkbox"/> Black or African American</p> <p><b>RACE</b> <input type="checkbox"/> Asian</p> <p><input type="checkbox"/> Native Hawaiian or Other Pacific Islander</p> <p><input type="checkbox"/> American Indian or Alaskan Native</p> <p>Ethnic</p> <p><b>ETHNIC</b> <input type="radio"/> Hispanic or Latino</p> <p><input type="radio"/> Not Hispanic or Latino</p> <p><i>When multiple values are selected then RACE = MULTIPLE and individual responses are RACE1, RACE2, RACE3, etc. in SUPPDM</i></p>	<p><b>DS (Disposition)</b></p> <p><b>INFORMED CONSENT</b></p> <p>Informed Consent Date [ ] [ ] [ ] [ ]</p> <p><b>DM (Demographics)</b></p> <p><b>DEMOGRAPHICS</b></p> <p>Birth Year [ ] <b>BRTHDTC</b></p> <p>Age [ ] years <b>AGE</b> <b>AGEU</b></p> <p>Sex <input type="radio"/> Female <input type="radio"/> Male <b>SEX</b></p> <p>Race (Check all that apply)</p> <p><input type="checkbox"/> White</p> <p><input type="checkbox"/> Black or African American</p> <p><b>RACE</b> <input type="checkbox"/> Asian</p> <p><input type="checkbox"/> Native Hawaiian or Other Pacific Islander</p> <p><input type="checkbox"/> American Indian or Alaskan Native</p> <p>Ethnic</p> <p><b>ETHNIC</b> <input type="radio"/> Hispanic or Latino</p> <p><input type="radio"/> Not Hispanic or Latino</p> <p><i>When multiple values are selected then RACE = MULTIPLE and individual responses are RACE1, RACE2, RACE3, etc. in SUPPDM</i></p>

# 4 Comparison between MSG V2.0 and MSG V1.0

## Filename

blankcrf.pdf → acrf.pdf

"acrf.pdf" is the current filename suggested by the FDA and the PMDA. It describes the collected data in context by annotating the corresponding SDTM datasets, variables, and any associated notes identified on the CRF.

## Dashed Annotation Borders

SDTM-MSG recommends the use of dashed annotation borders for annotations which do not represent collected data. This will aid in reducing unnecessary cross-document referencing (e.g., between the define.xml and acrf.pdf).

## Domain

DM = Demographics → domain and variable annotations look very similar without clear visual distinction

DM (Demographics) → distinguish between domain and variable annotations



## Variable

MSG v1.0 → featured red, bold, and italicized text  
MSG v2.0 → black text without bold or italics  
Annotations were easier to read and covered less of the CRF page.



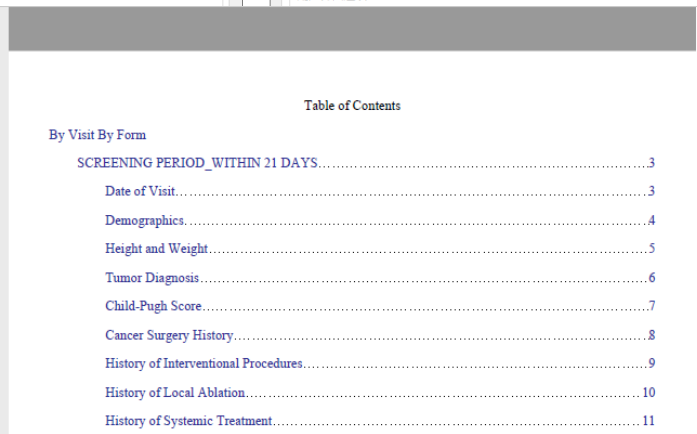
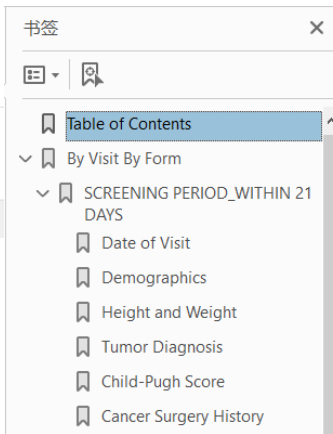
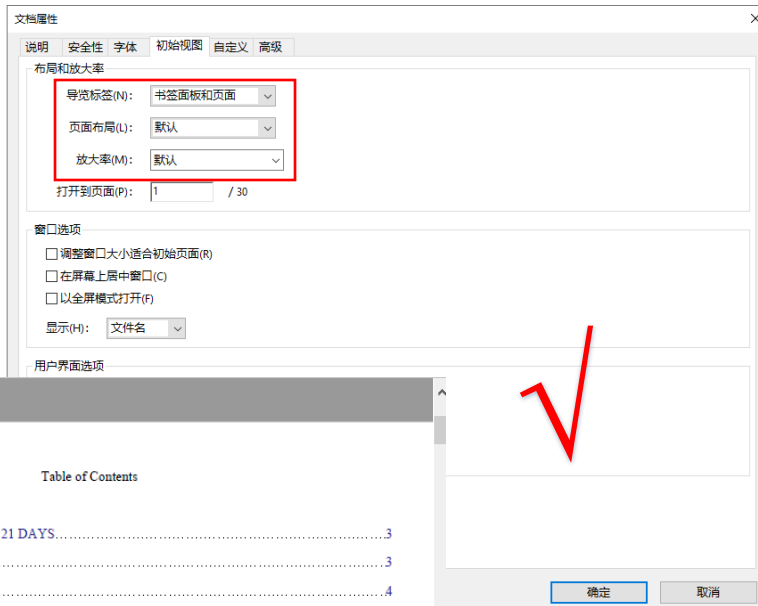
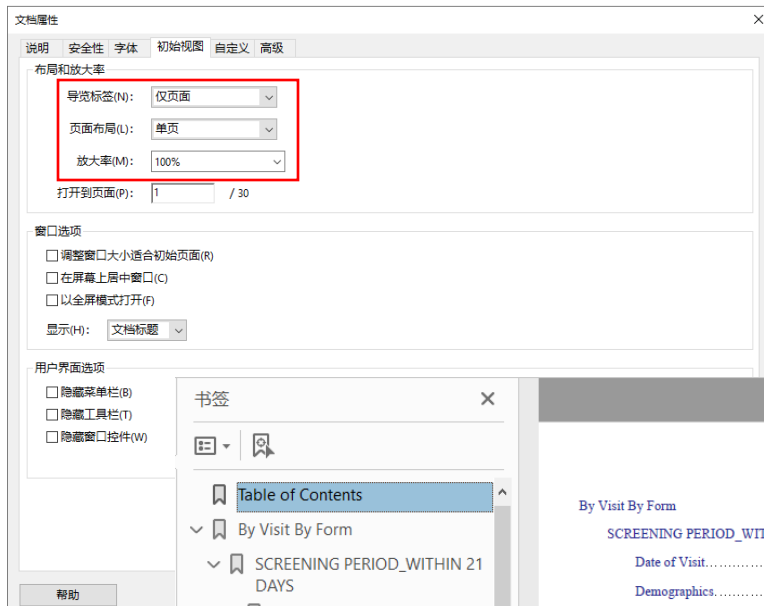
## 5. PDF Requirements

# 5 PDF Requirements

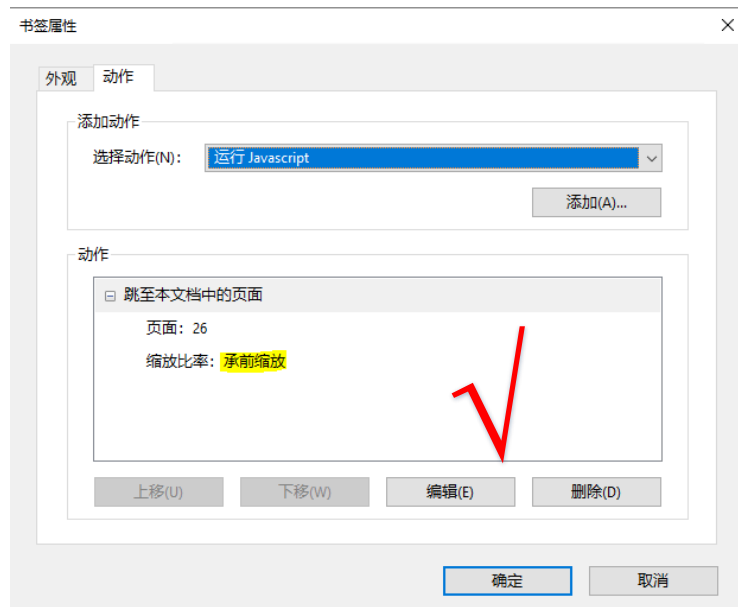
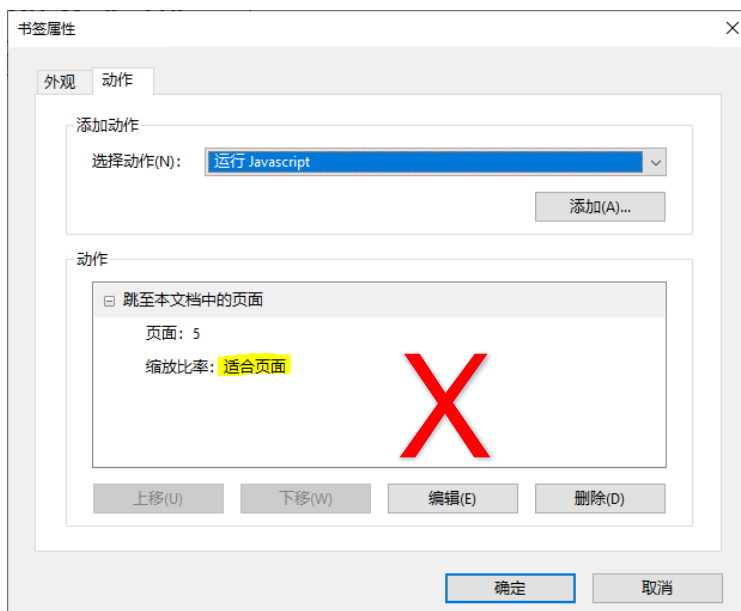
	 <b>U.S. FOOD &amp; DRUG ADMINISTRATION</b>	 <b>国家药品监督管理局</b> <small>National Medical Products Administration</small>
<b>PDF Initial View</b>	Set the Navigation Tab to open to “Bookmarks Panel and Page.” This sets the initial document view when the file is opened. If there are no bookmarks, set the Navigation Tab to “Page Only.” Page Layout and Magnification should be set to “Default.”	PDF初始视图正确 有书签的文件在初始视图中应显示书签。放大率和页面布局应设置为默认。
<b>Inherit Zoom</b>	When creating bookmarks and hyperlinks, set the magnification setting to “Inherit Zoom” so the destination page displays at the same magnification level used in the primary document.	书签必须承前缩放（Inherit Zoom）所有的书签的放大率设置应为承前缩放（Inherit Zoom）。 超文本链接必须承前缩放（Inherit Zoom）所有超文本链接的放大率设置应为承前缩放（Inherit Zoom）。
<b>Flatten the Annotations</b>	Do not include PDF annotations in documents. Note: Can be validated by LORENZeValidator.	文档中不应包含PDF注释。 注：电子申报资料制作软件无法验证。



# 5 PDF Requirements



# 5 PDF Requirements



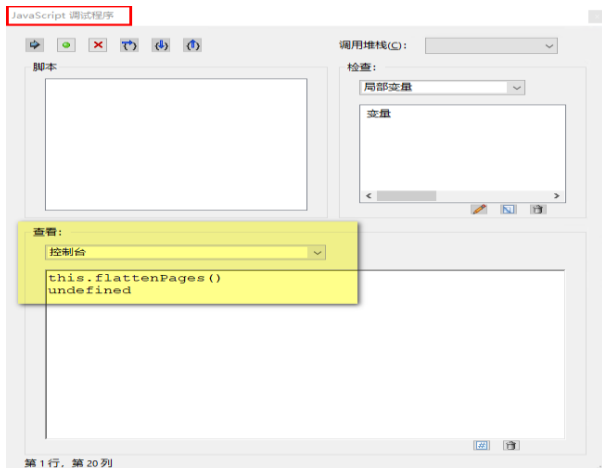
# 5 PDF Requirements

Other Frequency, Specify

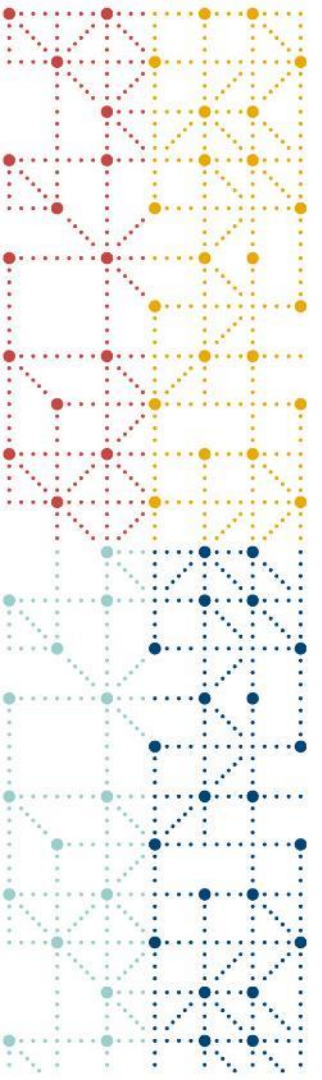
Start Date

End Date

Add New Record



- 打开未flatten的PDF，目前远程桌面的版本v1.7适用
- Ctrl + j 打开 JavaScript 调试程序
- 在查看控制台的框中输入“this.flattenPages()”
- Ctrl + enter，查看控制台的框中出现 undefined
- 另存为PDF保存



## 6. Common Confusion for CRF Mapping

## 6.1 --STAT & --OCCUR (cont.)



--STAT = NOT DONE (No response)

Situation	Value of --PRESP	Value of --OCCUR	Value of --STAT
Spontaneously reported event occurred			
Prespecified event occurred	Y	Y	
Prespecified event did not occur	Y	N	
Prespecified event has no response	Y		NOT DONE

The --OCCUR variable is used to indicate whether a prespecified intervention or event occurred or did not occur. It has controlled terminology of "Y" and "N" (for "Yes" and "No"). It is a permissible variable and may be omitted from the dataset if no topic-variable values were prespecified.

If a study collects both prespecified interventions and events as well as free-text events and interventions, the value of --OCCUR should be "Y" or "N" for all prespecified interventions and events, and null for those reported as free text.

The --STAT and --REASND variables can be used to provide information about prespecified interventions and events for which there is no response (e.g., investigator forgot to ask). As in Findings, --STAT has controlled terminology of NOT DONE.



--OCCUR = N (Response is No)

# 6.1 --STAT & --OCCUR

## Example 3

This is an example of a medical history CRF where the history of specific (prespecified) conditions is solicited. The conditions were not coded using a standard dictionary. The data were collected as part of the screening visit.

Rows 1-9: MHPRESP = "Y" indicates that these conditions were specifically queried. Presence or absence of the condition is represented in MHOCCUR.

Row 10: There was also a specific question about asthma, as indicated by MHPRESP = "Y", but this question was not asked. Because the question was not asked, MHOCCUR is null and MHSTAT = "NOT DONE". In this case, a reason for the absence of a response was collected, and this is represented in MHREASND.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHPRESP	MHOCCUR	MHSTAT	MHREASND	VISITNUM	VISIT	MHDTC	MHDY
1	ABC123	MH	101002	1	HISTORY OF EARLY CORONARY ARTERY DISEASE (<55 YEARS OF AGE)	Coronary Artery Disease	Y	N			1	SCREEN	2006-04-22	-5
2	ABC123	MH	101002	2	CONGESTIVE HEART FAILURE	Congestive Heart Failure	Y	N			1	SCREEN	2006-04-22	-5
3	ABC123	MH	101002	3	PERIPHERAL VASCULAR DISEASE	Peripheral Vascular Disease	Y	N			1	SCREEN	2006-04-22	-5
4	ABC123	MH	101002	4	TRANSIENT ISCHEMIC ATTACK	Transient Ischemic Attack	Y	Y			1	SCREEN	2006-04-22	-5
5	ABC123	MH	101002	5	ASTHMA	Asthma	Y	Y			1	SCREEN	2006-04-22	-5
6	ABC123	MH	101003	1	HISTORY OF EARLY CORONARY ARTERY DISEASE (<55 YEARS OF AGE)	Coronary Artery Disease	Y	Y			1	SCREEN	2006-05-03	-3
7	ABC123	MH	101003	2	CONGESTIVE HEART FAILURE	Congestive Heart Failure	Y	N			1	SCREEN	2006-05-03	-3
8	ABC123	MH	101003	3	PERIPHERAL VASCULAR DISEASE	Peripheral Vascular Disease	Y	Y			1	SCREEN	2006-05-03	-3
9	ABC123	MH	101003	4	TRANSIENT ISCHEMIC ATTACK	Transient Ischemic Attack	Y	N			1	SCREEN	2006-05-03	-3
10	ABC123	MH	101003	5	ASTHMA	Asthma	Y		NOT DONE	FORGOT TO ASK	1	SCREEN	2006-05-03	-3

## 6.2 Other, specify (cont.)

### CM (Concomitant/Prior Medications)

Form: Psoriatic Arthritis Drug Treatment :CMCAT = Psoriatic Arthritis Treatment History

Was any medication taken for psoriatic arthritis? [NOT SUBMITTED] Yes   
No

Treatment Type [CMSCAT]

- NSAIDs&Analgesis
- csDMARDs
- bDMARDs
- tsDMARDs
- Topical therapy
- Acitretin
- Phototherapy
- Systemic Glucocorticoids
- Other

Other treatment type, specify **Non-result qualifier**

Treatment Name [CMTRT]

- Loxoprofen
- Naproxen
- Piroxicam
- Meloxicam
- Celecoxib
- UVB
- Other

Other treatment name, specify **Topic variable**

### DM (Demographics)

### RP (Reproductive System Findings)

### SC (Subject Characteristics)

Form: Demographics

Date subject or legal guardian signed informed consent [RFICDTC]

Date of birth [BRTHDTC]

Sex [SEX] Male   
Female

Is the subject of childbearing potential [RPORRES] Yes   
[RPTTESTCD = CHILDPOT] No

Ethnicity [ETHNIC] Hispanic or Latino   
Not Hispanic or Latino

Eye Color [SCORRES] [SCTEST = Eye Color] Black   
Brown   
Blue   
Green   
Other

Other, specify **Result qualifier**



## 6.2 Other, specify (cont.)

### 6.2.1 Non-result Qualifier

If the sponsor wishes to maintain controlled terminology for the CMSCAT field and limit the terminology to the prespecified choices, then the free text is placed in SUPPCM.

#### CM (Concomitant/Prior Medications)

SHR-1314-204-V1.1-20211008: Unique

Form: Psoriatic Arthritis Drug Treatment **CMCAT = Psoriatic Arthritis Treatment History**

Was any medication taken for psoriatic arthritis? **NOT SUBMITTED** Yes   
No

Treatment Type **CMSCAT**

- NSAIDs&Analgesis
- csDMARDs
- bDMARDs
- tsDMARDs
- Topical therapy
- Acitretin
- Phototherapy
- Systemic Glucocorticoids
- Other

Other treatment type, specify **CMSCATO in SUPPCM**

Ref: SDTM IG V3.4, section 4.2.7.1

If the sponsor does not require that controlled terminology be maintained and stored wishes for all responses to be in a single variable, then CMSCAT will be used and SUPPCM is not required.

#### CM (Concomitant/Prior Medications)

SHR-1314-204-V1.1-20211008: Unique

Form: Psoriatic Arthritis Drug Treatment **CMCAT = Psoriatic Arthritis Treatment History**

Was any medication taken for psoriatic arthritis? **NOT SUBMITTED** Yes   
No

Treatment Type **CMSCAT**

- NSAIDs&Analgesis
- csDMARDs
- bDMARDs
- tsDMARDs
- Topical therapy
- Acitretin
- Phototherapy
- Systemic Glucocorticoids
- Other

**Note: When 'Other' is collected, the verbatim value specified is represented in CMSCAT.**

Other treatment type, specify **CMSCAT**



# 6.2 Other, specify (cont.)

## 6.2.2 Result Qualifier

If the sponsor wishes to maintain controlled terminology in the standard result field and limit the terminology to the 5 prespecified choices, then the free text is placed in --ORRES and the controlled terminology in --STRESC.

**DM (Demographics)**  
**RP (Reproductive System Findings)**  
**SC (Subject Characteristics)**  
 SHR-1314-204-V1.1-20211008: Unique  
 Form: Demographics

Date subject or legal guardian signed informed consent **RFICDTC**

Date of birth **BRTHDTC**

Sex **SEX** Male  Female

Is the subject of childbearing potential **RPORRES** Yes  No   
**RPTSTCD = CHILDPOT**

Ethnicity **ETHNIC** Hispanic or Latino  Not Hispanic or Latino

Eye Color **SCTEST = Eye Color**  
**SCORRES/SCSTRESC** Black  Brown  Blue  Green  Other   
**STRESC**

Other, specify **SCORRES**

SCTEST	SCORRES	SCSTRESC
Eye Color	BLUEISH GRAY	OTHER

If the sponsor does not require that controlled terminology be maintained, the verbatim value will be copied to --STRESC.

**DM (Demographics)**  
**RP (Reproductive System Findings)**  
**SC (Subject Characteristics)**  
 SHR-1314-204-V1.1-20211008: Unique  
 Form: Demographics

Date subject or legal guardian signed informed consent **RFICDTC**

Date of birth **BRTHDTC**

Sex **SEX** Male  Female

Is the subject of childbearing potential **RPORRES** Yes  No   
**RPTSTCD = CHILDPOT**

Ethnicity **ETHNIC** Hispanic or Latino  Not Hispanic or Latino

Eye Color **SCTEST = Eye Color**  
**SCORRES/SCSTRESC** Black  Brown  Blue  Green  Other

Other, specify **SCORRES/SCSTRESC**

SCTEST	SCORRES	SCSTRESC
Eye Color	BLUEISH GRAY	BLUEISH GRAY

## 6.2 Other, specify (cont.)

### 6.2.3 Topic Variables

#### Interventions

If a list of specific treatments is provided along with "Other, Specify", --TRT should be populated with the name of the treatment found in the specified text. If the sponsor wishes to distinguish between the prespecified list of treatments and those recorded in "Other, Specify," the --PRESP variable could be used.

CMPRESP	CMTRT
Y	Loxoprofen
	Golimumab

Ref: SDTM IG V3.4, section 4.2.7.3



#### CM (Concomitant/Prior Medications)

SHR-1314-204-V1.1-20211008: Unique

Form: Psoriatic Arthritis Drug Treatment :CMCAT = Psoriatic Arthritis Treatment History

Was any medication taken for psoriatic arthritis?  Yes   
No

Treatment Type  NSAIDs&Analgesis   
csDMARDs   
bDMARDs   
tsDMARDs   
Topical therapy   
Acitretin   
Phototherapy   
Systemic Glucocorticoids   
 Other

Other treatment type, specify

Treatment Name  Loxoprofen   
Naproxen   
Piroxicam   
Meloxicam   
Celecoxib   
UVB   
Other

Note: CMPRESP = Y when a pre-specified diagnosis is collected. CMPRESP is null when Other is collected.

Other treatment name, specify

# 6.2 Other, specify

## 6.2.3 Topic Variables

**Events**  
 "Other, Specify" for events may be handled similarly to Interventions. --TERM should be populated with the description of the event found in the specified text and --PRESP could be used to distinguish between prespecified and free-text responses.

**MH (Medical History)**  
 SHR-1314-204-V1.1-20211008: Unique  
 Form: Psoriatic Arthritis History :MHCAT = Psoriatic Arthritis History

Date of first diagnosis of PsA :MHSTDTC

Type of Psoriasis :MHTERM

Chronic plaque psoriasis   
 Generalized pustular psoriasis   
 Erythrodermic psoriasis   
 Guttate psoriasis   
 Other

Note: MHPRESP = Y when a pre-specified diagnosis is collected. MHPRESP is null when Other is collected.

If other, specify :MHTERM when Other is collected

MHPRESP	MHTERM
Y	Chronic plaque psoriasis
	Pustular psoriasis

**Findings**  
 "Other, Specify" for tests may be handled similarly to Interventions. --TESTCD and --TEST should be populated with the code and description of the test found in the specified text. If specific tests are not listed on the CRF and the investigator has the option of writing in tests, then the name of the test would have to be coded to ensure that all --TESTCD and --TEST values are consistent with the test controlled terminology

**LB (Laboratory Test Results)**  
 SHR-1314-204-V1.1-20211008: Unique  
 Form: Hematology :LBCAT = HEMATOLOGY

Lab Name: \_\_\_\_\_

Was the hematology performed :LBSTAT = NOT DONE when LBTESTCD = LBALL  No

Sample collection date :LBDTC

Hemoglobin(Hb) :LBTESTCD = HGB

Platelets(PLT) :LBTESTCD = PLAT

Other, specify :LBORRES

Note: LBTESTCD based on the collected value

LBTESTCD
HGB
PLAT
WBC

Ref: SDTM IG V3.4, section 4.2.7.3



# 6.3 Multiple Values for a Variable

## DM (Demographics)

## RP (Reproductive System Findings)

Form: Demographics

Date subject or legal guardian signed informed consent **RFICDTC**

Date of birth **BRTHDTC**

Sex **SEX** Male  Female

Is the subject of childbearing potential Yes  No   
**RPTESTCD = CHILDPOT** **RPPORRES**

Ethnicity **ETHNIC** Hispanic or Latino  Not Hispanic or Latino

Race (1) **RACE** American Indian or Alaskan Native  Asian  Black or African American  Native Hawaiian or Other Pacific Islander  White

Note:  
 Where one race value is collected, it is represented in RACE.  
 Where more than one race value is collected, RACE = 'MULTIPLE' and each value is represented in RACE1/RACE2/RACE3/RACE4 in SUPPDM.

Race(2) **RACE** American Indian or Alaskan Native  Asian  Black or African American  Native Hawaiian or Other Pacific Islander  White

RACE
MULTIPLE

RACE1	RACE2	RACE3	RACE4
AMERICAN INDIAN OR ALASKA NATIVE	ASIAN	BLACK OR AFRICAN AMERICAN	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER

### Additional Example

In some cases, values for QNAM and QLABEL more specific than these may be needed.

For example, a sponsor might conduct a study with 2 study drugs (e.g., open-label study of Abcicin + Xyzamin), and may require the investigator assess causality and describe action taken for each drug for the rash:

*ae.xpt*

AETERM	AEREL	AEACN
RASH	MULTIPLE	MULTIPLE

*suppae.xpt*

QNAM	QLABEL	QVAL
AERELABC	Causality of Abcicin	POSSIBLY RELATED
AERELXYZ	Causality of Xyzamin	UNLIKELY RELATED
AEACNABC	Action Taken with Abcicin	DOSE REDUCED
AEACNXYZ	Action Taken with Xyzamin	DOSE NOT CHANGED

In each of these examples, the use of SUPPAE should be documented in the Define-XML document and the annotated CRF. The controlled terminology used should be documented as part of value-level metadata.

If the sponsor has clearly documented that one response is of primary interest (e.g., in the CRF, protocol, or analysis plan), the standard domain variable may be populated with the primary response and SUPP-- may be used to store the secondary response(s).

For example, if Abcicin is designated as the primary study drug in the example above:

*ae.xpt*

AETERM	AEREL	AEACN
RASH	POSSIBLY RELATED	DOSE REDUCED

*suppae.xpt*

QNAM	QLABEL	QVAL
AERELX	Causality of Xyzamin	UNLIKELY RELATED
AEACNX	Action Taken with Xyzamin	DOSE NOT CHANGED

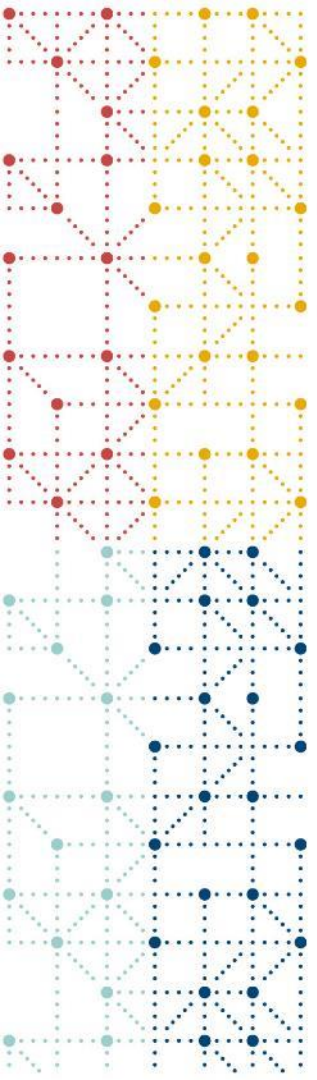
Note that in the latter case, the label for standard variables AEREL and AEACN will have no indication that they pertain to Abcicin. This association must be clearly documented in the metadata and annotated CRF.

Ref: SDTM IG V3.4, section 4.2.8

# Reference

- SDTM IG V3.4, <https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-4>
- MSG V2.0, <https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0>
- STUDY DATA TECHNICAL CONFORMANCE GUIDE , <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document>
- PDF SPECIFICATIONS, <https://www.fda.gov/media/76797/download>
- 电子申报资料制作软件, [关于更新电子申报资料制作软件的通知 \(cde.org.cn\)](#)





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