ADaM Structure for Occurrence Data (OCCDS)

Version 1.0

Prepared by the
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Notes to Readers

- This Analysis model uses the principles, structures and standards described in the CDISC Analysis Data Model Version 2.1 and Implementation Guide v1.1 documents.

Revision History

Date	Version	Summary of Changes
2016-02-12	1.0	Released version reflecting all changes identified during finalization of referenced document ADaMIG v1.1.
2015-06-01	1.0	Provisional release reflecting all changes and corrections identified during comment period.

See Appendix C for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1 Introduction

1 简介

1.1 Purpose

1.1 目的

The statistical analysis data structure presented in this document describes the general data structure and content typically found in occurrence analysis. Occurrence analysis is the counting of subjects with a given record or term, and often includes a structured hierarchy of dictionary coding categories. Examples of data that fit into this structure include those used for typical analysis of Adverse Events, Concomitant Medications, and Medical History. The structure is based on the ADaM Analysis Data Model V2.1 [1] and the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2].
本文档所呈统计分析数据结构描述了发生率数据分析的典型数据结构与内容。事件类数据分析是计算有某记录或词的受试者频数，通常包括结构化层级的词典编码归类。符合这种结构的数据示例，包括那些用于不良事件、伴随用药及病史的典型分析。这种结构是基于 ADaM 模型 V2.1[1]和 ADaM 分析数据模型实施指南（ADaM IG）V1.1[2]。

This document is based on the document titled "Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis" released by the CDISC ADaM team on May 10, 2012. It replaces this earlier document, making it more generic and applicable to analysis of more than just adverse event data.
本文档是基于 CDISC ADaM 团队 2012 年 5 月 10 日发布的名为"用于不良事件分析的分析数据模型（ADaM）数据结构" 的文档，该文档取代了它的早期文档，应用范围更加广泛，适用于不良事件数据以外的其它类型分析。

The table shows a summary of differences between the two documents:
下表展示了这二个文档之间的差异：

Table 1.1.1: Differences between Data Structures

	Data Structure for Adverse Events Analysis	**Data Structure for Occurrence Data**
Applications	Only adverse events	Adverse events plus other types of data
ADaM version	ADaM v 2.1, ADaMIG v1.0	ADaM v 2.1, ADaMIG v1.1
SDTM version	SDTM v1.2, SDTMIG v3.1.2	SDTM v 1.4, SDTMIG v3.2
Dataset metadata class	ADAE	OCCURRENCE DATA STRUCTURE
ANLzzFL label	"Analysis Record Flag zz"	"Analysis Flag zz"
AOCCFL label	"1st Occurrence of Any AE Flag"	"1st Occurrence within Subject Flag"
Study Drug Dose at Onset	Variable name "DOSEAEON" and label "Study Drug at AE Onset"	Variable name "DOSEON" and label "Treatment Dose at Record Start"
Treatment Dose Units	Separate variables named "DOSAEONU" and "DOSECUMU"	Variable name "DOSEU" and label "Treatment Dose Units"
Cumulative Actual Treatment Dose	Variable name "DOSECUM" and label "Cumulative Study Drug Dose"	Variable name "DOSCUMA" and label "Cumulative Actual Treatment Dose"
Original or Prior Coding Variables	Use of "y" suffix to represent prior version	Use of "w" suffix to represent prior version

Table 1.1.1: 两种数据结构间的差异

	不良事件的数据结构	事件类数据的数据结构
应用范围	仅仅是为不良事件的分析	包括不良事件和其它类型的事件类数据
ADaM 版本	ADaM v 2.1, ADaMIG v1.0	ADaM v 2.1, ADaMIG v1.1
SDTM 版本	SDTM v1.2, SDTMIG v3.1.2	SDTM v 1.4, SDTMIG v3.2
数据集元数据类别	ADAE	OCCURRENCE DATA STRUCTURE
ANLzzFL 标签	“Analysis Record Flag zz”	“Analysis Flag zz”
AOCCFL 标签	“1st Occurrence of Any AE Flag”	“1st Occurrence within Subject Flag”
开始时的研究用药剂量	变量名为“DOSEAEON”，变量标签为“AE 发生时的研究用药”	变量名为“DOSEON”，变量标签为 “事件发生时的研究用药剂量”
治疗用药剂量单位	两个单独的变量“DOSAEONU” 和 “DOSECUMU”	变量名为“DOSEU”，变量标签为“治疗用药剂量单位”
累积实际治疗剂量	变量名“DOSECUM”，变量标签为“累积研究用药剂量”	变量名为“DOSCUMA”，变量标签为“累积实际治疗剂量”
既往编码变量	运用后缀为‘y’的变量来代表既往的版本	运用后缀为‘w’的变量来代表既往的版本

As presented in the ADaMIG, many analysis methods can be performed using the ADaM Basic Data Structure (BDS) including Parameter (PARAM) and Analysis Value (AVAL). However, data analyzed as described above do not fit well into the BDS structure and are more appropriately analyzed using an SDTM structure with added analysis variables. Specifically, the data and analysis described in this document must meet these criteria:
如 ADaM IG 所述，很多分析方法可用 ADaM 基本数据结构（BDS）来实行，该结构包括参数（PARAM）与分析值（AVAL）。但上述数据分析难以纳入 BDS 结构，更适合使用添加了分析变量的 SDTM 结构进行分析。特别的是，本文中所述的数据与分析必须符合下面这些标准：

- There is no need for AVAL or AVALC. Occurrences are counted in analysis, and there are typically one or more records for each occurrence assessment.
  不需要 AVAL 或 AVALC。在分析中计算事件类数据的发生率，需要注意的是在每一事件类数据中常常有一条或者多条记录的数据。

- A dictionary is often used for coding the occurrence and typically includes a well-structured hierarchy of categories and terminology. Re-mapping this hierarchy to BDS variables PARAM and generic *CAT variables would lose the structure and meaning of the dictionary. Per the Study Data Tabulation Model Implementation Guide (SDTMIG) V3.2 [3], a dictionary is expected for Adverse Events and Concomitant Medications, and recommended for Medical History. Although not as common, Clinical Events, Procedures, and Substance Use may also be coded. (Data for a particular study that could have been coded but wasn't should use this structure because analysis results are similar, and this will allow analysis programming to work the same way – for example, Medical History data might be coded in one study, not coded in another, yet the analysis tables look very similar.)
  对于事件类数据，通常用包括结构良好的层级归类与术语的词典进行编码。。若将此种层级结构重新映射到 BDS 变量 PARAM 或通用的 *CAT 变量将失去词典的结构和含义。按照原始数据标准模型实施指南（SDTMIG）V3.2[3]， 不良事件、伴随用药期望使用词典，病史也推荐使用。尽管不那么通用，临床事件、操作和物质使用也可能进行编码。 (特定研究中应当编码而没有编的数据由于其分析结果的相似性也应当采用这种结构， 从而可以用相同的方法编程 -例如，病史数据可能在一

个研究中进行了编码，而在另一研究中没有，但分析表格还是很类似的。)

- The data content is typically not modified for analysis purposes. In other words, there is no need for analysis versions of the variables that hold the dictionary hierarchy or category terms.
  数据内容通常不会随分析的目的而改变。换言之，不需要存放为了分析而设置的词典层级或归类词变量。

This does not mean that all categorical data are appropriate for OCCDS. More standard categorical data that would never be mapped to a hierarchical dictionary, such as questionnaire responses, fit nicely in BDS and should not use OCCDS.
但这并不是说所有的分类数据都适用于 OCCDS。更标准的分类数据并不需要映射到层级结构的词典，如问卷结果，可以很好地纳入 BDS 结构，不应当用 OCCDS。

Typically, findings data fit nicely into BDS, while events and interventions fit nicely into OCCDS. However, this is not always the case: Exposure data, from an interventions SDTM structure, is quite often analyzed in BDS because that analysis isn't simply counting records, though there could be an OCCDS intermediate dataset used to help derive those BDS summary parameters. In all cases, it's the combination of input data and analysis needs that determines the dataset structure required.
通常，发现类数据可以很好地纳入 BDS 结构，而事件类和干预类数据可以很好地纳入 OCCDS 结构。但也有例外：暴露数据，来自 SDTM 干预类结构，但一般用 BDS 结构，因为其分析不是简单的记录计数，尽管有时会用 OCCDS 结构的中间数据集来帮助衍生 BDS 中的综合参数。在各种情况下都需要综合考虑输入数据和分析需求来决定采用哪种数据结构。

The structure presented in this document is built on the nomenclature of the SDTMIG V3.2 [3] standard for collected data, and adds attributes, variables, and data structures required for statistical analyses. The primary source domain for the structure is the SDTM domain plus the corresponding Supplemental Qualifier dataset. Many additional variables are added from Subject-Level Analysis Dataset (ADSL).
本文所呈结构是以 SDTMIGV3.2 标准建立和命名的术语基础上建立的，用来描述用于统计分析的所收集的数据及其属性、变量名、数据结构。其主要来源域是 SDTM 域及其相关的的修饰语数据集。许多额外的变量是从受试者水平分析集（ADSL）拷贝过来的。

In this document, the analysis datasets described are required when SDTM data aren't sufficient to support all analyses. Whether an analysis dataset is needed is left up to the producer (see ADaM Analysis Data Model V2.1 Section 4.1.1). If an analysis dataset is needed, and it meets the criteria listed above, it should use OCCDS.
当 SDTM 数据集不足以支持全部分析时，需要准备在本文档中所描述的分析数据集。是否需要创建分析数据集，取决于创建者（见 ADaM 分析数据模型 V2.1 第 4.1.1 节）。当需要分析数据集，并符合前文所列标准，就应当用 OCCDS。

The dataset and variable naming conventions and the dataset structure described in this document should be followed.
应当遵循本文所述数据集与变量命名规则、数据结构。

The structure for the occurrence analysis dataset is usually one record per each record in the corresponding SDTM domain. Examples of when the number of records in the analysis dataset would not match the number in SDTM include:
发生率分析数据集的结构，通常是一条记录对应于相应的 SDTM 域中一条记录。有时分析数据集中的记录数与 SDTM 不同，例如：

- SDTM data contain screen failures but screen failures are not analyzed. In this case, the screen failure records are not needed in the analysis dataset.
  SDTM 数据包含了筛选失败的受试者，但并不对之进行分析。这种情形下，分析数据集中就不需要

包含筛选失败者。

- The topic, such as an adverse event or concomitant medication, spans several treatment periods and needs to be counted in each. Based on the analysis need, a separate row might be required for each treatment period spanned and analyzed.
  当主题，如不良事件或伴随用药，跨越若干治疗阶段，且在各阶段均须单独计算。基于分析的需要，跨越、分析的各治疗阶段可能均单独需要一条记录。
- An adverse event needs to be analyzed along multiple coding paths. In this case, a row would be needed for each coding path analyzed. An alternate solution, if multiple coding paths are not needed together, would be to put records for each coding path into a separate analysis dataset.
  不良事件需要在多个编码路径下进行分析。这种情形下，每一分析的编码路径需要一条记录。另外一种解决方案是，如果多个编码路径不是同时需要的话，把每个编码路径放到单独的分析数据集中去。

This doesn't exclude a producer from creating additional datasets for other analyses, or even using a different structure if needed for analysis (e.g. time-to-event of adverse events of special interest).
这并不意味着创建者不可以创建额外的数据集用于其它分析，甚至在需要分析时使用不同的数据结构（如特殊兴趣不良事件的事件发生时间）。

1.2 Points to Consider When Interpreting this Document

1.2 解读本文档注意事项

In reviewing the metadata and examples in this document, some of the points to consider are:
在阅读本文中的元数据及例子时，需要注意以下几点：

- **Ordering of variables:** Within this document, no specific ordering of variables within the illustrated datasets is applied. The ADaM v2.1 [1] states that ideally the ordering of the variables in the analysis dataset follows a logical ordering (not simply alphabetic). The ADaM v2.1 [1] does not provide a specific recommendation for the ordering of the variables. Within this document, the author of each example applied their own logical ordering. Though there is not an across-example consistency of ordering of variables, within an example the ordering of the variables within the illustrated analysis dataset matches the order of the variables as presented in the associated metadata.
  变量的顺序：在本文档中，示例数据集中并未应用特定的变量顺序。ADaM v2.1 [1] 中申明分析数据集中理想的变量顺序是逻辑顺序（而不是简单的按字母排序）。ADaM v2.1 [1] 对变量顺序并无具体的推荐。本文档中，各示例的作者是应用自己的逻辑顺序。尽管各示例中的变量顺序并不一致，但在同一示例中所示分析数据集中变量的顺序与相关的元数据中的顺序是一致的。

- **Identification of source dataset:** When identifying the source dataset for a variable, the immediate predecessor is used, as described in the ADaM v2.1 [1]. For example, in ADSL the source is identified as DM.SUBJID in the analysis variable metadata. When SUBJID is used in the occurrence analysis dataset, the source is identified as ADSL.SUBJID.
  源数据集标识：如 ADaM v2.1 [1] 中所述，当标识一个源数据集中的变量时可以直接使用其前身数据集中的变量。例如 ADSL 中分析变量元数据来源标识为 DM.SUBJID， 并且事件类分析数据集中 SUBJID 的来源标识为 ADSL.SUBJID。

- **Analysis-ready:** The occurrence analysis dataset should be "analysis-ready," meaning it should contain all of the variables needed for the specific analysis, so that the analysis can be replicated by performing the actual statistical test without first having to manipulate data. Analysis-ready does not mean that a formatted display can be generated in a single statistical procedure. For typical occurrence analyses, unique subject counts are derived by running a standard statistical procedure (e.g., SAS PROC, S-PLUS function, etc.) on the occurrence analysis dataset, while denominator counts can be derived from ADSL.

即可分析：发生率分析数据集应当是 “即可分析” 的，意思是应当包括特定分析所需的所有变量，这样不需先操作数据就可以再现所做的实际的统计检验。即可分析并不是说用一个简单的统计过程就可以生成格式化的展示。典型的发生率分析是运行一个标准的统计程序（比如 SAP PROC， S-PLUS 函数等）来从发生率分析数据集里计算受试者个数， 而从 ADSL 里来推断所需分母。

- **Examples are for illustration only:** Note that the examples in this document are only intended as illustrations and should not be viewed as a statement of the standards themselves. In addition, the examples are intended to illustrate content and not appearance; it is understood that there are many different ways that data can be displayed. This document does not cover display formats.
  示例只是为了阐明: 请注意本文档中的示例仅是用于阐明标准，不应理解为标准本身的陈述。此外，示例仅是用于阐明内容，而不是呈现形式。众所周知，数据有多种不同的显示方式。本文档并不涵盖显示格式。

- **Display of metadata for illustration of content only:** Though the metadata elements have been defined in the ADaM v2.1 [1], how the metadata are displayed is a function of the mechanism used to display the content. The presentation formats used in this document are for the purposes of illustration of content only, and are not intended to imply any type of display standard or requirement. Additionally, the metadata examples just include the metadata necessary to understand the respective example datasets. Refer to Define-XML v2.0 [11] for additional information (e.g., variable length and origin) required when building a valid define.xml file according to the Define-XML v2.0 standard.
  元数据的展示也只是为了阐明内容: 尽管 ADaM v2.1 [1]中对元数据元素进行了定义，如何显示元数据是属于内容显示机制的范畴。文中所用的展示格式，只是为了满足阐明内容的目的，并不意味着是任何类型的显示标准或要求。此外，元数据示例仅包括了理解相关示例数据集所需的元数据。如需根据 Define-XML v2.0 创建有效的 define.xml, 所需更多信息（如变量长度与来源），请参见 Define-XML v2.0 [11] 。

- **Analysis results metadata:** Analysis results metadata have not been included for any examples in this document. As stated in the ADaM v2.1 [1], analysis results metadata are not required. However, best practice is that they be provided to assist the consumer by identifying the critical analyses, providing links between results, documentation, and datasets, and documenting the analyses performed.
  分析结果元数据：本文示例中均未包括分析结果元数据。正如 ADaM v2.1[1]中所申明，分析结果元数据不是必须的。当然，最好的做法是提供分析结果元数据，帮助使用者标识关键分析，提供结果、文档、数据集之间的关联，并对所做分析进行存档。

- **Examples not meant to be all inclusive regarding variables:** The examples describe some of the key variables and records that would be included in the dataset. They are not intended to illustrate every possible variable that might be included in the analysis dataset; for example core variables required for subgroup analyses are not included in all illustrations.
  示例中并未包括全部相关变量：示例中描述了数据集中的一些关键变量和记录。这些示例不是为了说明分析数据集中所有可能的变量，如示例中未包括亚组分析所需核心变量。

- **Source/Derivation Column:** The algorithms provided in the Source/Derivation column are for illustration purposes only and are not intended to imply universally accepted definitions or derivations of variables. Algorithms are producer-defined and dependent on trial and analysis design.
  来源/衍生列：来源/衍生列提供的算法目的只是为了举例说明用，并非意味着是普遍接受的变量定义或衍生规则。算法是创建者定义的，随临床试验与分析设计而不同。

- **No endorsement of vendors or products:** As with other ADaM documents, references to specific vendor products are examples only and therefore should not be interpreted as an endorsement of these vendors or products.
  没有对供应商或产品认可的意思：与其它 ADaM 文档相同，应用某供应商产品只是为了举例，因而不应理解为对这些供应商或产品的认可。

1.3 Conventions Used in this Document

1.3 本文档中应用的规则

Throughout this document the terms “producer” and “consumer” are used to refer to the originator/sender/owner/sponsor of the data and the user/reviewer/recipient of the data, respectively. These terms are used to simplify the document, and are not intended to imply that these examples only apply to analysis datasets in the context of electronic submissions to regulatory agencies.
贯穿本文的“创建者”和“使用者”是用于指数据的发起者/发送者/所有者/申办方和相应的数据使用者/审阅者/接受者。这些用语只是为了简化文档，并不意味着这些事例仅适用于向监管机构提交电子数据时的分析数据集。

2 Data Analysis and Coding

2 数据分析和编码

2.1 Statistical Analysis

2.1 统计分析

The most frequently used method for the comparison between treatment groups of data in this structure is the summarization of the number of subjects with at least one occurrence of a term. These counts and related percentages are presented at different levels of the dictionary hierarchy, when the hierarchy exists. The denominator used for the calculation of the percentages is often determined by a population flag, such as the total number of subjects at risk or number of subjects exposed to treatment. Note that some subjects in the population may not have any records, and therefore these subjects would not be represented in the SDTM domain nor the corresponding OCCDS analysis dataset. Thus, the denominators usually need to be obtained from ADSL (subject level analysis dataset) rather than directly from the occurrence analysis dataset.
治疗组之间的数据比较最常用的方法是汇总发生至少一次事件的受试者总数。当存在层级时，这些计数和相应百分比在字典层级的不同级别间进行汇总。用于计算百分比的分母通常是由某个特定人群决定，如处于风险或暴露于治疗的受试者总数。 需要注意的是该人群的部分受试者可能没有发生这些事件，所以无论是 SDTM 域还是相应的 OCCDS 分析数据集里都不会有他们的记录。因此，用于计算的分母需要从 ADSL(受试者水平分析数据集)得到，而不是直接从该发生率分析数据集来。

This ADaM model primarily discusses the creation of an analysis dataset that is needed for the presentation of frequencies and percentages. However, the analysis datasets presented here could be used to construct more in-depth analysis dataset, even in a different structure. For time-to-event analyses, see the ADaM Basic Data Structure for Time to Event Analyses appendix.
本 ADaM 模型主要是论述怎么创建需要用频数和百分比进行描述的分析数据集。但其实并不限于此，它也可用于构造更深入的分析数据集，甚至其他结构也可使用。对于事件发生时间的分析，可参见 ADaM 到事件发生时间的基本数据结构的附录。

2.2 Dictionary Coding

2.2 字典编码

Data are often collected in textual or ‘verbatim’ content, a short description of an event or intervention generally written in free text on the case report form. Verbatim content is then processed through a coding dictionary so that similar verbatim content is grouped together by classifying them into a hierarchy of medical granularity.
数据经常以原文或逐字填写的形式进行收集，事件或干预的简述经常以自由文本的形式填写在病例报告表里。然后用编码字典进行查询加工使得相同意思的内容被归到同一类医学粒度的层级里。

Medical Dictionary for Regulatory Activities (MedDRA) [4] has become widely recognized as a global standard for the coding of adverse events. Examples of other coding dictionaries include WHO Adverse Reaction Terminology (WHO-ART) [5] and International Classification of Disease (ICD) [6], and Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) [7] which was replaced by MedDRA but can still be found in older studies.
监管活动医学词典（MedDRA）[4] 已经成为编码不良事件的普遍公认的全球标准。其他编码字典有世界卫生组织不良反应术语集（WHO-ART）[5] 和国际疾病分类（ICD）[6], 和已被 MedDRA 取代但可能仍在比较老的研究项目里使用的不良反应词汇库标准编码（COSTART）[7]。

The coding dictionary is characterized by classifying each verbatim into a hierarchy of medical granularity. For example, if the verbatim content recorded was ‘stomach virus’, the COSTART coding hierarchy would place this

event in the 'Body as a Whole' body system, in the 'General' subcategory for this body system, and with the preferred term of 'Flu Syndrome'. Using MedDRA V12.0, this verbatim content would result in a System Organ Class (SOC) of 'Infections and infestations' and a preferred term (PT) of 'Gastroenteritis viral'.
编码字典的特点在于将每个描述文本归类到医学粒度的一个层级里。例如：如果一个事件的描述是"胃病毒"，COSTART 编码层级将其对应于身体系统"整个身体"，和其子类"常规"，和首选术语"流感症状"。使用 MedDRA V12.0，该事件将对应于系统器官分类"感染和侵染"和首选术语"病毒性胃肠炎"。

When using coding dictionaries, it is recommended that coding rules and guidelines be developed by the producer prior to the classification of terminology. The process of coding verbatim terms with a dictionary is outside the scope of this document. The objective of coding guidelines is to promote medical accuracy and consistency when using the controlled vocabulary of the dictionary. This consistency will support a variety of downstream analysis needs, such as when events need to be recoded to integrate data from two or more clinical studies.
使用编码字典之前，建议编码人员写好编码规则和指导原则。如何使用字典实施编码已经超出了本文的范畴。编码指导原则的目标是确保编码的精确性和一致性。一致性有助于下游的多种分析需要，比如需要将多个研究项目的事件整合在一起分析时。

2.2.1 Recoding of Occurrence Data

2.2.1 事件类数据的重新编码

In some situations, multiple study reports are created for a single study. For example, an initial study report may be created at the time of the primary analysis for the primary efficacy endpoint. If subjects are followed for safety, a second report may be created years later so that long term safety data can be incorporated. At this time, there may be a desire to update the coding dictionary so that all content is coded using the most recent version of a dictionary. In this situation, a recommendation is to provide the original coded terms along with the new coded terms so that the implications of the recoding can be more easily investigated.
某些情况下，一个研究项目可能需要产生多个研究报告。例如， 可以在主要疗效终点的初步分析时创建初步研究报告。如果对受试者进行安全性随访，则可能在几年后创建第二个报告，以便合并长期安全数据。这段时间内，可能会需要升级编码词典使得所有内容都可以使用最新的编码。这种情况下，建议同时提供原始的和新的编码结果，以利于解析重新编码的涵义。

It should be noted that a more common scenario involving the recoding of occurrence data is when data are recoded for an integrated analysis and submitted to a regulatory agency for marketing approval. However, neither the current version of the ADAMIG nor this document fully covers integration of multiple studies. The ADaM team is developing a document to address integration of multiple studies. Some of the suggestions included here for handling multiple dictionaries may be revised after this Integration document is released.
值得注意的是更常见的重新编码的情形是为了获得市场批件提交给相关监管机构的数据的整合分析。然而，最新的 ADaMIG 和本文件都没有完全涵盖多个研究项目的整合性分析。ADaM 团队正在着手开发处理多个研究项目整合分析的文档。 此文档发布后，本文的一些关于处理多个字典编码结果的建议可能会作相应修正。

2.3 Adverse Events

2.3 不良事件

The safety evaluation of a clinical trial includes the analysis of adverse events, and that analysis is typically done using this data structure. The definition of an adverse event, as presented in International Conference of Harmonization (ICH) E2A [8] guidelines, is:
临床试验的安全性评估包括不良事件的分析，该分析通常使用这种数据结构。不良事件在国际协调会议（ICH）E2A[8] 指导原则上是这样定义的：

> *Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with*

this treatment.

病人或临床研究受试者接受一种药品后出现的任何异常医学事件，但该事件不一定与治疗有因果关系。

Important attributes include the level of severity of the AE (Mild, Moderate, or Severe), whether the AE is considered to be related to the study product (Yes or No), and whether the AE is considered serious (Yes or No). Of particular importance in the analysis of AEs is the definition of 'treatment emergent'. The ICH E9 guidance [9] document defines treatment emergent as an event that emerges during treatment having been absent pre-treatment, or worsens relative to the pre-treatment state. Operationally, classifying AEs as treatment emergent will utilize, in part, the start or worsening date of the AE relating to the trial or treatment start. Other important attributes of AEs include the action taken in response to the event and whether the event led to permanent discontinuation of the investigational product.

不良事件重要的属性包括严重程度的级别（轻度，中度，重度），是否跟研究药物相关（是或不是），是不是严重不良事件（是或不是）。不良事件分析中尤其重要的是"治疗期"不良事件的定义。ICH E9 指导[9]文件定义治疗期事件为治疗前不存在但在治疗期间新发生的事件或者是相对于治疗前恶化的事件。治疗期不良事件的归类可用新事件的开始日期或事件恶化的日期与试验或治疗的开始日期进行比较来判定。不良事件的其他重要属性包括应对措施和是否导致研究中止。

2.4 Concomitant Medications Data

2.4 伴随用药数据

Concomitant medications data can be coded to a hierarchy such as WHO Drug and summarized by medication and/or ingredient within class.

伴随用药数据可用层级字典进行编码，如 WHO Drug，然后按类别内药物和/或成分进行汇总。

2.5 Pre-specified Data

2.5 预设数据

In some cases, data can be gathered on a case report form that contains a pre-specified category and a checkbox to indicate whether or not the subject had this event, condition, or treatment. This information is stored in these variables as described in the SDTMIG. --PRESP is used to indicate that the term is a pre-specified one, and --OCCUR is either Y or N to indicate whether the subject did or did not have the event, condition, or treatment. --TERM or --TRT will have a known and finite set of values, so these values may be adequate to use as a summarization category. Often these pre-specified terms are grouped into categories at collection using the --CAT and --SCAT variables, creating additional levels of summarization categories. In this situation, data are analyzed by variables such as --TERM, --TRT, --CAT and --SCAT, and dictionary coding might not be necessary. For example, medical history and clinical events data are often captured in this way.

某些情况下，数据的收集可以由 CRF 上预设的类别和勾选框指明受试者是否存在该事件、状况或治疗。按照 SDTMIG 的描述， 这些信息会存放于下面的一些变量里。 --PRESP 用于指明该术语是预设的， --OCCUR 的值是 Y 或 N， 用于指明受试者是否存在该事件、状况或治疗。--TERM 或 --TRT 将包含有限的可预知的值, 这些值可能已经足够充当汇总类别。通常这些预设值在收集的时候使用--CAT 和--SCAT 变量（也即额外的级别汇总分类）进行了归类。 这种情况下，将使用诸如变量--TERM，--TRT，--CAT，--SCAT 进行数据分析，没有必要再使用字典编码。例如，既往病史和临床事件经常以这样的方式收集数据。

Note that this pre-specified data option does not work well for Adverse Events because the Study Data Tabulation Model Implementation Guide (SDTMIG) V3.2 [3] does not permit the use of variable AEOCCUR. In other words, all records in SDTM AE must correspond to an actual occurrence of the event.

需要注意的是预设数据选项不适用于不良事件，因为 SDTMIG V3.2[3] 不允许使用 AEOCCUR。也就是说 SDTM AE 里的所有记录必须是试验中实际发生的事件。

2.6 Combining Spontaneous and Pre-specified Occurrences

2.6 合并自发和预设发生数据

It is technically feasible to apply the same coding dictionary to both collected and pre-specified data and combine these data for analysis. Whether or not to do so is a statistical judgment that should be carefully considered and described in programming specifications. A pre-specified question on a case report form makes it more likely to receive data, and would therefore increase the frequency in a summary. In deciding whether to pool pre-specified and spontaneous data, the statistician should consider the way data were gathered and weigh the possibility of over-reporting pre-specified data. The statistician should also carefully consider and describe the correct denominator for percentages.
将收集和预设数据使用同样的字典进行编码然后合并在一起用于分析在技术上是可行的。是否这么做是一个统计的判断，需要深虑并描述于编程说明文件里。CRF 上的预设值会产生期望获得该数据的假象，可能会因此增加其在汇总里的频率。在决定是否合并预设值数据和自发数据，统计师应当要考虑数据收集的形式和权衡预设值被过多报告的可能性。统计师还应当仔细考虑和描述用于计算百分比的正确分母。

If data are pooled in this way, take care that non-occurring data (--OCCUR=N) are properly excluded from the analysis.
如果是这样合并数据，需要注意分析时需排除“未发生”的数据（--OCCUR=N）。

2.7 Other Data

2.7 其他数据

Other similar data, with or without coding hierarchy, can be summarized similarly. An example of summarizing without a coding hierarchy can be seen in the example in Section 11.
其他类似数据，不管有无编码层级，都可以以类似的方式来汇总。无编码层级的汇总可参见 11 章的例子。

Some examples of other data that can also be summarized using OCCDS include:
一些其他可使用 OCCDS 进行汇总的数据包括

- Clinical Events, when collected by category and not mapped to a dictionary, but summarized in a similar way as Adverse Events.
- 临床事件，当按类别收集且不使用字典，但汇总方式和不良事件类似时。
- Protocol violations, when summarized by counting subjects with violations within each category.
- 方案偏离，当汇总是计数每类别里方案偏离的受试者个数时。
- Laboratory data containing National Cancer Institute Common Toxicity Criteria (NCI-CTC) [10] information that has been coded with MedDRA and summarized as laboratory events. When these events are summarized like adverse events, an extension of the adverse event examples that are shown in this document can be used.
- 实验室数据包含美国国家癌症研究所通用毒性判定标准（NCI-CTC）[10] 的已被 MedDRA 编码的信息并需要以实验室事件进行汇总时。当这些事件像不良事件一样被汇总，本文的不良事件例子可以被扩展进行使用。

In all cases, OCCDS should be used when a summary of the hierarchy is done, counting the number of subjects at each level of the hierarchy. Alternately, BDS should be used for counting when there isn't a hierarchy, when the terms are counted rather than the subjects, and when variables such as AVAL and PARAM are appropriate to include.

所有情况下，当层级完成并需要汇总受试者在各层级中的计数时应当使用 OCCDS。 当没有层级概念，计数事件而不是计数受试者，且使用 AVAL 和 PARAM 这些变量更适合记录数据时应使用 BDS。

3 ADaM Metadata

3 ADaM 的元数据

As described in the ADaM Analysis Data Model V2.1 [1], variables that are copied from SDTM must have the same variable name, label, values, and meaning as in SDTM. Because the Occurrence Data Structure (OCCDS) can be used for adverse events, concomitant medications, and other occurrence data, metadata shown in this section reference different SDTM domains. For clarity, the following conventions are used:
正如在 ADaM 分析数据模型 V2.1 中描述的，从 SDTM 复制来的变量必须保持与 SDTM 相同的变量名、标签、数值和含义。因为事件类数据结构(OCCDS)能够应用在不良事件、伴随用药或其他的事件类数据，本章节展示的元数据引用了不同的 SDTM 域。为了清楚起见, 使用以下约定:

- When referring to the 2-letter prefix in variable names, the standard convention is to use "--", as described in the Study Data Tabulation Model v1.4 [3].
- 当涉及到以 2 个字母为前缀的变量名时，标准的写法为用"--"表示，如 SDTM V1.4 中所述。
- The "--" convention was intended for variable names, not domain names, and "--" is difficult to read in the documentation for SDTM domain names. This document uses the convention of "XX" to represent a domain name, as was done in the Analysis Data Model (ADaM) Examples in Commonly Used Statistical Analysis Methods appendix document.
- "--"的约定用于变量名,不用于域名, 且"--"很难在文档中代表域名。本文档使用 "XX" 的约定来表示一个域名, 正如在常用统计分析方法附录文档中分析数据模型(ADaM)的示例所做。
- Variable labels that differ depending on SDTM domain are shown with the SDTM observation class label followed by an asterisk (*), referencing a note at the end of the table.
- 随 SDTM 域而不同的变量标签将显示为 SDTM 的观测类型标签， 并在其后加一个星号（*）标识来引用表格最后的一段注释。

Take care when creating actual metadata to replace "--", "XX", and generic variable labels with the actual 2-letter domain code and label from SDTM.
在创建真实元数据时请注意用 2 个字母的域名和来自 SDTM 的标签来替换 "--", "XX" 和通用的变量标签。

3.1 Dataset Metadata

3.1 数据集的元数据

Typically, the following Analysis Dataset Metadata is specified as follows: 通常情况下,以下分析数据集元数据详细说明如下：

Table 3.1.1 Example of ADaM OCCDS Dataset Metadata*,
表 3.1.1 ADaM OCCDS 数据集元数据示例

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset	Class of Dataset	Documentation
ADXXXXXX	<Dataset label>	adxxxxxx.xpt	one record per record in SDTM domain (optional: per coding path, per Analysis Period and/or Phase)	*List variables, such as USUBJID, --SEQ*	OCCURRENCE DATA STRUCTURE	*Example: Dictionary used is MedDRA V11.1*

3.2 ADaM Variables and Variable Metadata

3.2 ADaM 变量和变量元数据

As stated earlier, OCCDS is different from BDS. There is no PARAM nor AVAL, for example. However, some of the variables described for BDS in the ADaM Implementation Guide version 1.1 [2] can be used in OCCDS, as shown below.
如前所述，OCCDS 是不同于 BDS 结构的。 例如，它既没有 PARAM 也没有 AVAL。但是，有一些在 ADaM 实施指南 v1.1[2]中描述 BDS 的变量是可以被用在 OCCDS 中的，如下所示：

The more standardized variables commonly occurring in an ADaM OCCDS are described here in tabular format. In general, include all variables from the SDTM dataset and corresponding supplemental qualifiers that are needed for analysis or traceability. For traceability when copying variables from SUPPQUAL, it is recommended to use variable names that exactly match the corresponding SUPPQUAL.QNAM values. Additional study or therapeutic specific variables may be added as needed but should follow the standard variable naming conventions described in the ADaM Implementation Guide version 1.1 [2]. For example, variables with the 2-letter SDTM prefix are most commonly those that are copied from the SDTM or transposed SUPPQUAL dataset, or the numeric version of the SDTM variable, but not analysis versions of SDTM variables. Choose variable names with care to prevent unintended conflicts with standard names.
本章以表格的形式列出了 ADaM OCCDS 结构中常用的比较标准的变量。一般而言，它包括全部的 SDTM 变量和需要用于分析或可追溯性的相关补充限定信息。为了保留可追溯性，当从 SUPPQUAL 复制变量时，建议使用和 SUPPQUAL.QNAM 的值精确匹配的变量名字。 根据研究或治疗的需要， 可以添加额外的变量但要遵循 ADaM IG v1.1[2]中所属的标准变量命名规范。例如，以 2 个 SDTM 前缀开头的变量通常大部分都是从 SDTM 直接复制过来的或由 SUPPQUAL 数据集转置来的，再或是数值型的 SDTM 变量，但不是分析型的 SDTM 变量。在选择变量名的时候要注意以防与标准的名称冲突。

As described in the ADaM Analysis Data Model V2.1 [1], the two rightmost columns of metadata ("Core" and "CDISC Notes") provide information about the variables to assist users in preparing their datasets. These columns are not meant to be metadata. The "Core" column, as defined in the ADaM Implementation Guide version 1.1 [2], describes whether a variable is required (Req), conditionally required (Cond), or permissible (Perm). The "CDISC Notes" column provides more information about the variable. In addition, the "Type" column is being used to define whether the variable is character (Char) or numeric value (Num). More specific information will be provided in metadata.
如 ADaM 分析数据模型 v2.1[1]中所述，元数据最右边两列（"Core" and "CDISC Notes"）提供关于变量的信息来辅助用户准备他们的数据集。这几列并不意味是元数据。"Core"列按照在 ADaM 实施指南 v1.1[2]中的定义，用于描述一个变量是否是必须的（Req），有条件要求的（Cond），还是许可的（Perm）。"CDISC Notes"列则提供更多关于变量的信息。另外，"Type"列常常用于定义这个变量是否为字符型（Char）或数值型（Num）。元数据将提供更详细的信息。

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* The display presentation of the metadata should be determined between the producer and the consumer. The example is only intended to illustrate content and not appearance.
* 这个元数据的展示形式应该由制作者和使用者两者决定。这个例子仅仅是为了说明内容并不是说明形式。

See discussion near the end of the Introduction section of this document for examples of when the analysis data structure might not be one record per record in SDTM domain
详见本文档简介章节结尾讨论部分关于分析数据结构可能在 SDTM domain 中不是一个记录一条的实例。

3.2.1 ADSL Variables

3.2.1 ADSL 变量

Merge any ADSL variables needed for analysis or reference.
合并任何需要分析或引用的 ADSL 变量

Be aware that only subjects with an SDTM record would have an analysis record. For this reason, it is recommended that population indicators and denominator counts for percentages be derived from ADSL and not from the occurrence analysis dataset.
要注意只有受试者有一条 SDTM 记录才可能有一条可分析的记录。因此，建议我们人群指标和用于计算百分比的分母计数要从 ADSL 衍生而不要从发生率分析数据集产生。

3.2.2 Identifier Variables

3.2.2 标识变量

Include the identifier variables from SDTM:
包括从 SDTM 中来的标识变量

Table 3.2.2.1 OCCDS Identifier Variables

Variable Name	Variable Label	Type	Code List / Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	XX.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	XX.USUBJID
SUBJID	Subject Identifier for the Study	Char		Perm	ADSL.SUBJID
SITEID	Study Site Identifier	Char		Perm	ADSL.SITEID
--SEQ	Sequence Number	Num		Req*	XX.--SEQ This would be copied from the SDTM domain XX. This may be missing for derived rows. Required for traceability back to SDTM.

**Note that the only sequence number option shown is --SEQ, because it is unlikely that multiple SDTM domains would be used as input to a single OCCDS dataset.*

Table 3.2.2.1 OCCDS 标识变量

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
STUDYID	研究标识符	Char		Req	XX.STUDYID
USUBJID	受试者唯一标识符	Char		Req	XX.USUBJID
SUBJID	受试者标识符	Char		Perm	ADSL.SUBJID

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
SITEID	研究中心标识符	Char		Perm	ADSL.SITEID
--SEQ	序号	Num		Req*	XX.--SEQ This would be copied from the SDTM domain XX. This may be missing for derived rows. Required for traceability back to SDTM.

**注意只有序号选项被显示为"--SEQ"，因为多个 SDTM domains 不太可能被用在一个 OCCDS 数据集中。*

3.2.3 Dictionary Coding and Categorization Variables

3.2.3 字典编码和分类变量

Dictionary coding and categorization variables provided in SDTM should be included as needed for analysis, review, or traceability. Variables shown below are the common coding variables. If other coding variables are included in SDTM and pertinent for analysis, these should be included in ADaM using a similar naming convention as shown below. For any public versioned dictionary, the metadata for each coding variable should include both the name and version of the dictionary.
SDTM 中提供的字典编码和分类变量应该按照需要包含在分析数据集里用于分析，复审或支持数据的可追溯性。下面是常见的编码变量。如果其他编码变量被包含在 SDTM 并且和分析相关，那么应该用一个和如下所示相似的命名规则将这些变量保存在 ADaM 中。对于任何公开版本的字典，每一个编码变量的元数据都应该包含它的名字和字典版本。

Common Dictionary Coding Variables for MedDRA
MedDRA 中常见的字典编码变量

MedDRA coding is typically used for AEs and Medical History. Copy to the analysis dataset the needed MedDRA terms and codes from SDTM. It is recommended but not required that all levels of terms for the primary path in the MedDRA hierarchy [System Organ Class (SOC), High Level Group Term(HLGT), High Level Term (HLT), Lowest Level Term (LLT), and Preferred Term (PT)] be included, especially in the AE analysis dataset, as these are frequently useful in further analyses of events.
MedDRA 编码通常用于不良事件和既往病史。将需要的 MedDRA 术语和编码从 SDTM 复制到分析数据集。我们推荐但不是必须包含 MedDRA 层级主要路径上的所有层级术语[系统器官类(SOC)， 高位分组术语（HLGT），高位术语（HLT），最低位术语（LLT），和首选术语（PT）]， 特别是在 AE 分析数据集中，因为他们将被频繁的使用在将来的事件分析中。

Table 3.2.3.1 MedDRA Dictionary Coding Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
--TERM	Reported Term*	Char		Req	XX.--TERM This would be copied from the SDTM domain XX.

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
--DECOD	Dictionary-Derived Term	Char	MedDRA	Cond	XX.--DECOD This would be copied from the SDTM domain XX. It is typically one of the primary variables used in an analysis and would be brought in from the SDTM domain. Equivalent to the Preferred Term (PT in MedDRA). As mentioned above, all other SDTM domain variables and supplemental qualifiers needed for analysis or traceability should also be included. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for Adverse Event data.
--BODSYS	Body System or Organ Class	Char	MedDRA	Cond	XX.--BODSYS This would be copied from the SDTM domain XX. It is typically one of the primary variables used in an analysis and would be brought in from the SDTM domain. As mentioned above, all other SDTM domain variables and supplemental qualifiers needed for analysis or traceability should also be included. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for Adverse Event data.
--BDSYCD	Body System or Organ Class Code	Num	MedDRA	Perm	XX.--BDSYCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--LLT	Lowest Level Term	Char	MedDRA	Cond	XX.-- LLT This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis.
--LLTCD	Lowest Level Term Code	Num	MedDRA	Perm	XX.--LLTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--PTCD	Preferred Term Code	Num	MedDRA	Perm	XX.--PTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--HLT	High Level Term	Char	MedDRA	Cond	XX.--HLT This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether used for analysis.
--HLTCD	High Level Term Code	Num	MedDRA	Perm	XX.--HLTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--HLGT	High Level Group Term	Char	MedDRA	Cond	XX.--HLGT This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether used for analysis.
--HLGTCD	High Level Group Term Code	Num	MedDRA	Perm	XX.--HLGTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
--SOC	Primary System Organ Class	Char	MedDRA	Cond	XX.--SOC This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether a secondary SOC was used for analysis.
--SOCCD	Primary System Organ Class Code	Num	MedDRA	Perm	XX.--SOCCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.

** This variable label differs depending on the SDTM domain. See Study Data Tabulation Model V1.4 and Study Data Tabulation Model Implementation Guide (SDTMIG) V3.2 [3] for details.*

表 3.2.3.1 MedDRA 字典编码变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
--TERM	报告名称	Char		Req	XX.--TERM This would be copied from the SDTM domain XX.
--DECOD	标准化名称	Char	MedDRA	Cond	XX.--DECOD This would be copied from the SDTM domain XX. It is typically one of the primary variables used in an analysis and would be brought in from the SDTM domain. Equivalent to the Preferred Term (PT in MedDRA). As mentioned above, all other SDTM domain variables and supplemental qualifiers needed for analysis or traceability should also be included. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for Adverse Event data.
--BODSYS	系统器官分类	Char	MedDRA	Cond	XX.--BODSYS This would be copied from the SDTM domain XX. It is typically one of the primary variables used in an analysis and would be brought in from the SDTM domain. As mentioned above, all other SDTM domain variables and supplemental qualifiers needed for analysis or traceability should also be included. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for Adverse Event data.
--BDSYCD	系统器官分类编码	Num	MedDRA	Perm	XX.--BDSYCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--LLT	低位语	Char	MedDRA	Cond	XX.-- LLT This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis.
--LLTCD	低位语编码	Num	MedDRA	Perm	XX.--LLTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--PTCD	首选语编码	Num	MedDRA	Perm	XX.--PTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
--HLT	高位语	Char	MedDRA	Cond	XX.--HLT This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether used for analysis.
--HLTCD	高位语编码	Num	MedDRA	Perm	XX.--HLTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--HLGT	高位组语	Char	MedDRA	Cond	XX.--HLGT This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether used for analysis.
--HLGTCD	高位组语编码	Num	MedDRA	Perm	XX.--HLGTCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.
--SOC	主系统器官分类	Char	MedDRA	Cond	XX.--SOC This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Conditional on whether a secondary SOC was used for analysis.
--SOCCD	主系统器官分类编码	Num	MedDRA	Perm	XX.--SOCCD This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata.

**这个变量的标签会因为不同的SDTM域而不同。详见研究数据列表模型v1.4和研究数据列表模型实施指南（SDTMIG）v3.2[3]。*

NOTE: MedDRA allows for secondary paths for Lower Level Terms. One may be required to report on secondary paths along with primary paths. Please see section 8for an example layout for one possible way to handle this analysis need.
注：MedDRA 允许对低层术语使用次要路径。一个事件可能被要求在用主要路径报告的同时也使用次要路径来报告。请参照第八章节的一个案例，其展示了一种可能的方法来处理这种分析需要。

Common Dictionary Coding Variables for WHO Drug
WHO Drug 中常见的字典编码变量

WHO Drug coding is typically used for Concomitant Medications. Copy to the analysis dataset the needed WHO Drug terms and codes from SDTM CM and SUPPCM. The variables shown in this table 3.2.3.2 are intended for a single WHO Drug coding path.
WHO Drug 编码通常被用于伴随用药。 将需要的 WHO Drug 术语和编码从 SDTM 的 CM 和 SUPPCM 中复制到分析数据集中。 列在下表 3.2.3.2 中的变量仅用于单一的 WHO Drug 编码路径。

Table 3.2.3.2 WHO Drug Dictionary Coding Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
CMTRT	Reported Name of Drug, Med, or Therapy	Char		Req	CM.CMTRT
CMDECOD	Standardized Medication Name	Char	WHO Drug	Cond	CM.CMDECOD This is typically one of the primary variables used in CM analysis and would be copied from the SDTM CM domain. Include the dictionary version in the variable metadata. Conditional on whether coded and used for analysis.
CMCLAS	Medication Class	Char		Perm	CM.CMCLAS Include the dictionary version in the metadata.
CMCLASCD	Medication Class Code	Char		Perm	CM.CMCLASCD Include the dictionary version in the metadata.
ATCy	ATC Level y Text	Char	WHO Drug	Cond	Corresponds to the ATC Level Text for WHO Drug Conditional, based on analysis at multiple levels (y)
ATCyCD	ATC Level y Code	Char	WHO Drug	Cond	Corresponds to the ATC Level Code for WHO Drug Conditional, based on analysis at multiple levels (y)

表 3.2.3.2 WHO Drug 字典编码变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
CMTRT	治疗报告名称	Char		Req	CM.CMTRT
CMDECOD	标准化名称	Char	WHO Drug	Cond	CM.CMDECOD This is typically one of the primary variables used in CM analysis and would be copied from the SDTM CM domain. Include the dictionary version in the variable metadata. Conditional on whether coded and used for analysis.
CMCLAS	归类	Char		Perm	CM.CMCLAS Include the dictionary version in the metadata.
CMCLASCD	归类编码	Char		Perm	CM.CMCLASCD Include the dictionary version in the metadata.
ATCy	ATC 第 y 级	Char	WHO Drug	Cond	Corresponds to the ATC Level Text for WHO Drug Conditional, based on analysis at multiple levels (y)
ATCyCD	ATC 第 y 级代码	Char	WHO Drug	Cond	Corresponds to the ATC Level Code for WHO Drug Conditional, based on analysis at multiple levels (y)

Other Categorization Variables
其他分类变量

When categories are used for the intended analysis, instead of or in addition to MedDRA or WHO Drug, these generic categorization variables are commonly used:
当类别用于预期分析时，通常使用这些通用分类变量来代替或补充 MedDRA 或 WHO 药物词典变量。

Table 3.2.3.3 Other Categorization Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
--CAT	Category*	Char		Perm	XX.--CAT This would be copied from the SDTM domain XX.
--SCAT	Subcategory*	Char		Perm	XX.--SCAT This would be copied from the SDTM domain XX.
ACATy	Analysis Category y	Char		Perm	Category used in analysis. May be derived from --CAT and/or --SCAT. Examples include records of special interest like prohibited medications, concomitant medications taken during an infusion reaction, growth factors, antimicrobial medications, and other such categories not defined elsewhere or present in SDTM domains.

** This variable label differs depending on the SDTM domain. See Study Data Tabulation Model V1.4 and Study Data Tabulation Model Implementation Guide (SDTMIG) V3.2 [3] for details.*

表 3.2.3.3 其他分类变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
--CAT	类别	Char		Perm	XX.--CAT This would be copied from the SDTM domain XX.
--SCAT	子类	Char		Perm	XX.--SCAT This would be copied from the SDTM domain XX.
ACATy	类别 y-分析用	Char		Perm	Category used in analysis. May be derived from --CAT and/or --SCAT. Examples include records of special interest like prohibited medications, concomitant medications taken during an infusion reaction, growth factors, antimicrobial medications, and other such categories not defined elsewhere or present in SDTM domains.

** 这个变量的标签会因为不同的 SDTM domain 而不同。详见 SDTM v1.4 和 SDTM IG v3.2[3]。*

3.2.4 Timing Variables

3.2.4 时间变量

Timing variables are copied from SDTM and derived within ADaM. Included below are the common timing variables. If other timing variables are collected in SDTM and pertinent for analysis, these should be included in ADaM. Additional timing variables, such as those for analysis period or phase, can be included.

For more details on timing variables, see the BDS structure in the ADaM Implementation Guide version 1.1 [2].
时间变量是从 SDTM 复制来的并且在 ADaM 内部衍生。包括如下常见的时间变量。如果其他的时间变量收集在 SDTM 中并且和分析相关，那么这些变量应该被包含在 ADaM 中。额外的时间变量，例如那些分析周期或阶段，应该被包含进 ADaM。更多关于时间变量的信息，请详见 ADaM 实施指南 v1.1[2]中的 BDS 结构部分。

Table 3.2.4.1 Timing Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
--STDTC	Start Date/Time of Observation*	Char	ISO 8601	Perm	Copied from XX.--STDTC This would be copied from the SDTM domain XX.
ASTDT	Analysis Start Date	Num		Cond	Created from converting XX.--STDTC from character ISO8601 format to numeric date format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start date is pertinent for study and is populated in SDTM.
ASTTM	Analysis Start Time	Num		Cond	Created from converting XX.--STDTC from character ISO8601 format to numeric time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start time is pertinent for study and is populated in SDTM.
ASTDTM	Analysis Start Date/Time	Num		Cond	Created from converting XX.--STDTC from character ISO8601 format to numeric date-time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start date-time is pertinent for study and is populated in SDTM.
ASTDTF	Analysis Start Date Imputation Flag	Char	(DATEFL)	Cond	Created during conversion of XX.--STDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the start date.
ASTTMF	Analysis Start Time Imputation Flag	Char	(TIMEFL)	Cond	Created during conversion of XX.--STDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the start time.
--ENDTC	End Date/Time of Observation*	Char	ISO 8601	Cond	Copied from XX.--ENDTC This would be copied from the SDTM domain XX. Conditional on whether end date is pertinent for study and is populated in SDTM.
AENDT	Analysis End Date	Num		Cond	Created from converting XX.--ENDTC from character ISO8601 format to numeric date format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end date is pertinent for study and is populated in SDTM.
AENTM	Analysis End Time	Num		Cond	Created from converting XX.--ENDTC from character ISO8601 format to numeric time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end time is pertinent for study and is populated in SDTM.
AENDTM	Analysis End Date/Time	Num		Cond	Created from converting XX.--ENDTC from character ISO8601 format to numeric date-time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end date-time is pertinent for study and is populated in SDTM.

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
AENDTF	Analysis End Date Imputation Flag	Char	(DATEFL)	Cond	Created during conversion of XX.--ENDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the end date.
AENTMF	Analysis End Time Imputation Flag	Char	(TIMEFL)	Cond	Created during conversion of XX.--ENDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the end time.
ASTDY	Analysis Start Relative Day	Num		Cond	Example derivation: ASTDT – ADSL.TRTSDT + 1 if ASTDT ≥ TRTSDT, else ASTDT – ADSL.TRTSDT if ASTDT< TRTSDT This variable may instead be copied from --STDY. Conditional on whether analysis start relative day is pertinent to the study.
--STDY	Study Day of Start of Observation*	Num		Perm	XX.--STDY This would be copied from the SDTM domain XX. ASTDY may differ from --STDY due to date imputation and the option in ADaM to use a reference date other than SDTM's RFSTDTC. Including XX.--STDY in addition to ASTDY adds traceability.
AENDY	Analysis End Relative Day	Num		Perm	Example derivation: AENDT – ADSL.TRTSDT + 1 if AENDT ≥ TRTSDT, else AENDT – ADSL.TRTSDT if AENDT < TRTSDT This variable may instead be copied from --ENDY.
--ENDY	Study Day of End of Observation*	Num		Perm	XX.--ENDY This would be copied from the SDTM domain XX. AENDY may differ from --ENDY due to date imputation and the option in ADaM to use a reference date other than SDTM's RFSTDTC. Including XX.--ENDY in addition to AENDY adds traceability.
ADURN	Analysis Duration (N)	Num		Perm	Derive from ASTDT (or ASTDTM) and AENDT (or AENDTM).
ADURU	Analysis Duration Units	Char	(UNIT)	Cond	Conditional on whether ADURN is included and units are not included in the label of ADURN.
--DUR	Duration of XX	Char	ISO 8601	Perm	XX.—DUR This would be copied from the SDTM domain XX. Because --DUR is a collected field and ADURN is derived, the values will often differ. Including XX.--DUR in addition to ADURN adds traceability.
APERIOD	Period	Num		Perm	APERIOD is a record-level timing variable that represents the analysis period within the study associated with the record for analysis purposes. The value of APERIOD (if populated) must be one of the xx values found in the ADSL TRTxxP variables. See the ADaM Implementation Guide version 1.1 [2] for more information on this variable.
APERIODC	Period (C)	Char		Perm	Text characterizing to which period the record belongs. One-to-one map to APERIOD.
APHASE	Phase	Char		Perm	APHASE is a categorization of timing within a study, for example a higher-level categorization of APERIOD or an analysis epoch. For example, APHASE could describe spans of time for SCREENING, ON TREATMENT, and FOLLOW-UP. See the ADaM Implementation Guide version 1.1 [2] for more information on this variable.

** This variable label differs depending on the SDTM domain. See Study Data Tabulation Model V1.4 and Study Data Tabulation Model Implementation Guide (SDTMIG) V3.2 [3] for details.*
Code Lists in parenthesis are the names of CDISC Controlled Terminology.

表 3.2.4.1 时间变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
--STDTC	开始日期/时间	Char	ISO 8601	Perm	Copied from XX.--STDTC This would be copied from the SDTM domain XX.
ASTDT	开始日期-分析用	Num		Cond	Created from converting XX.--STDTC from character ISO8601 format to numeric date format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start date is pertinent for study and is populated in SDTM.
ASTTM	开始时间-分析用	Num		Cond	Created from converting XX.--STDTC from character ISO8601 format to numeric time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start time is pertinent for study and is populated in SDTM.
ASTDTM	开始日期时间-分析用	Num		Cond	Created from converting XX.--STDTC from character ISO8601 format to numeric date-time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start date-time is pertinent for study and is populated in SDTM.
ASTDTF	开始日期填补标记	Char	(DATEFL)	Cond	Created during conversion of XX.--STDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the start date.
ASTTMF	开始时间填补标记	Char	(TIMEFL)	Cond	Created during conversion of XX.--STDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the start time.
--ENDTC	结束日期/时间	Char	ISO 8601	Cond	Copied from XX.--ENDTC This would be copied from the SDTM domain XX. Conditional on whether end date is pertinent for study and is populated in SDTM.
AENDT	结束日期-分析用	Num		Cond	Created from converting XX.--ENDTC from character ISO8601 format to numeric date format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end date is pertinent for study and is populated in SDTM.
AENTM	结束时间-分析用	Num		Cond	Created from converting XX.--ENDTC from character ISO8601 format to numeric time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end time is pertinent for study and is populated in SDTM.
AENDTM	结束日期时间-分析用	Num		Cond	Created from converting XX.--ENDTC from character ISO8601 format to numeric date-time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end date-time is pertinent for study and is populated in SDTM.
AENDTF	结束日期填补标记	Char	(DATEFL)	Cond	Created during conversion of XX.--ENDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the end date.

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
AENTMF	结束时间填补标记	Char	(TIMEFL)	Cond	Created during conversion of XX.--ENDTC from character to numeric. Imputation flags are described in the ADaM Analysis Data Model Implementation Guide (ADaMIG) V1.1 [2] General Timing Variable Conventions. Conditional on whether any imputation is done for the end time.
ASTDY	开始日-分析用	Num		Cond	Example derivation: ASTDT – ADSL.TRTSDT + 1 if ASTDT ≥ TRTSDT, else ASTDT – ADSL.TRTSDT if ASTDT< TRTSDT This variable may instead be copied from --STDY. Conditional on whether analysis start relative day is pertinent to the study.
--STDY	开始日	Num		Perm	XX.--STDY This would be copied from the SDTM domain XX. ASTDY may differ from --STDY due to date imputation and the option in ADaM to use a reference date other than SDTM's RFSTDTC. Including XX.--STDY in addition to ASTDY adds traceability.
AENDY	结束日-分析用	Num		Perm	Example derivation: AENDT – ADSL.TRTSDT + 1 if AENDT ≥ TRTSDT, else AENDT – ADSL.TRTSDT if AENDT < TRTSDT This variable may instead be copied from --ENDY.
--ENDY	结束日	Num		Perm	XX.--ENDY This would be copied from the SDTM domain XX. AENDY may differ from --ENDY due to date imputation and the option in ADaM to use a reference date other than SDTM's RFSTDTC. Including XX.--ENDY in addition to AENDY adds traceability.
ADURN	持续时间(N)-分析用	Num		Perm	Derive from ASTDT (or ASTDTM) and AENDT (or AENDTM).
ADURU	持续时间单位-分析用	Char	(UNIT)	Cond	Conditional on whether ADURN is included and units are not included in the label of ADURN.
--DUR	持续时间	Char	ISO 8601	Perm	XX.—DUR This would be copied from the SDTM domain XX. Because --DUR is a collected field and ADURN is derived, the values will often differ. Including XX.--DUR in addition to ADURN adds traceability.
APERIOD	周期	Num		Perm	APERIOD is a record-level timing variable that represents the analysis period within the study associated with the record for analysis purposes. The value of APERIOD (if populated) must be one of the xx values found in the ADSL TRTxxP variables. See the ADaM Implementation Guide version 1.1 [2] for more information on this variable.
APERIODC	周期(C)	Char		Perm	Text characterizing to which period the record belongs. One-to-one map to APERIOD.
APHASE	分析期	Char		Perm	APHASE is a categorization of timing within a study, for example a higher-level categorization of APERIOD or an analysis epoch. For example, APHASE could describe spans of time for SCREENING, ON TREATMENT, and FOLLOW-UP. See the ADaM Implementation Guide version 1.1 [2] for more information on this variable.

** 这个变量的标签会因为不同的 SDTM 域而不同。详见研究数据列表模型 v1.4 和研究数据列表模型实施指南（SDTMIG）v3.2[3]。*
括号里的编码列表是 CDISC 受控术语中的名字。

3.2.5 Indicator Variables

3.2.5 标识变量

Some indicator variables can be copied from SDTM, while others are derived within ADaM. If indicator variables other than those shown here are included in SDTM and pertinent for analysis, these should be copied to ADaM. If other indicator analysis variables are needed for analysis, these can also be added.
一些标识变量可以从 SDTM 复制，而另外一些则是在 ADaM 中衍生的。如果除了此处列出的标识变量，还有其他 SDTM 中的标识变量与分析有关，那么他们也应该复制到 ADaM 中。如果另外一些指示分析变量需要用于分析，也可以添加到 ADaM 中。

Table 3.2.5.1 SDTM Indicator Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
--OCCUR	XX Occurrence	Char	(NY)	Cond	Copied from XX.--OCCUR This would be copied from the SDTM domain XX. Conditional on whether this content is pertinent for analysis and is populated in SDTM.
--PRESP	XX Pre-Specified	Char	(NY)	Cond	Copied from XX.--PRESP This would be copied from the SDTM domain XX. Conditional on whether this content is pertinent for analysis and is populated in SDTM.

Code lists in parenthesis are the names of CDISC Controlled Terminology.

表 3.2.5.1 SDTM 标识变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
--OCCUR	是否发生	Char	(NY)	Cond	Copied from XX.--OCCUR This would be copied from the SDTM domain XX. Conditional on whether this content is pertinent for analysis and is populated in SDTM.
--PRESP	预设	Char	(NY)	Cond	Copied from XX.--PRESP This would be copied from the SDTM domain XX. Conditional on whether this content is pertinent for analysis and is populated in SDTM.

括号里的编码列表是 CDISC 受控术语中的名字。

Table 3.2.5.2 OCCDS Indicator Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
ANLzzFL	Analysis Flag zz	Char	Y	Cond	The ANLzzFL flag is useful in many circumstances; an example is when there is more than one coding path included for analysis, in which case separate analysis flags could be used to denote primary coding path or the records used for analysis from each coding path. See the ADaM Implementation Guide version 1.1 [2] for more information on this flag variable. This variable is conditional on whether analysis records flags are needed for analysis.

表 3.2.5.2 OCCDS 标识变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
ANLzzFL	分析标帜 zz	Char	Y	Cond	The ANLzzFL flag is useful in many circumstances; an example is when there is more than one coding path included for analysis, in which case separate analysis flags could be used to denote primary coding path or the records used for analysis from each coding path. See the ADaM Implementation Guide version 1.1 [2] for more information on this flag variable. This variable is conditional on whether analysis records flags are needed for analysis.

With Adverse Events and Concomitant Medications, typically indicator flags are also assigned based on the timing of the analysis record in relation to the study. Below are some common indicator flags for these types of data.
对于不良事件和合并用药，通常指示标记是基于研究项目中分析记录的时间来制定的。以下是一些此类型数据中常见的指示标记。

Table 3.2.5.3 Adverse Events Indicator Variables

Variable Name	Variable Label	Type	Code List / Controlled Terms	Core	CDISC Notes
TRTEMFL	Treatment Emergent Analysis Flag	Char	Y	Cond	Treatment emergent flag as defined for analysis. Variable TRTEMFL is to be used for any analysis of treatment-emergent AEs. This variable is conditional on whether the concept of treatment emergent is a key feature of the AE analyses. Example derivation: If ADSL.TRTSDT≤ASTDT≤ADSL.TRTEDT + x days then TRTEMFL='Y' The number x is defined by the producer and often incorporates the known half-life of the drug. It should be consistent with variable APHASE (described above) if APHASE is also used.
AETRTEM	Treatment Emergent Flag	Char	(NY)	Perm	Treatment emergent flag from SDTM, if available. See the SDTMIG version 3.2 [3] for more information. Derivation: SUPPAE.QVAL where QNAM='AETRTEM'. TRTEMFL may differ from AETRTEM due to different definitions, date imputation and other analysis rules. Including AETRTEM in addition to TRTEMFL will add traceability.

Code lists in parenthesis are the names of CDISC Controlled Terminology.

表 3.2.5.3 不良事件标识变量

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
TRTEMFL	治疗期分析标帜	Char	Y	Cond	Treatment emergent flag as defined for analysis. Variable TRTEMFL is to be used for any analysis of treatment-emergent AEs. This variable is conditional on whether the concept of treatment emergent is a key feature of the AE analyses. Example derivation: If ADSL.TRTSDT≤ASTDT≤ADSL.TRTEDT + x days then TRTEMFL='Y' The number x is defined by the producer and often incorporates the known half-life of the drug. It should be consistent with variable APHASE (described above) if APHASE is also used.

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
AETRTEM	治疗期标帜	Char	(NY)	Perm	Treatment emergent flag from SDTM, if available. See the SDTMIG version 3.2 [3] for more information. Derivation: SUPPAE.QVAL where QNAM='AETRTEM'. TRTEMFL may differ from AETRTEM due to different definitions, date imputation and other analysis rules. Including AETRTEM in addition to TRTEMFL will add traceability.

括号里的编码列表是 CDISC 受控术语中的名字。

Table 3.2.5.4 Concomitant Medications Indicator Variables

Variable Name	Variable Label	Type	Code List / Controlled Terms	Core	CDISC Notes
ONTRTFL	On Treatment Record Flag	Char	Y	Cond	Character indicator of whether the observation occurred while the subject was on treatment. Example derivation: If ADSL.TRTSDT <= ASTDT <= ADSL.TRTEDT then ONTRTFL = 'Y' This variable is conditional on whether the concept of on-treatment is a feature of the study and used in analysis.

表 3.2.5.4 合并用药指示标量

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
ONTRTFL	治疗中记录标帜	Char	Y	Cond	Character indicator of whether the observation occurred while the subject was on treatment. Example derivation: If ADSL.TRTSDT <= ASTDT <= ADSL.TRTEDT then ONTRTFL = 'Y' This variable is conditional on whether the concept of on-treatment is a feature of the study and used in analysis.

Table 3.2.5.5 Adverse Events and Concomitant Medications Indicator Variables

Variable Name	Variable Label	Type	Code List / Controlled Terms	Core	CDISC Notes
PREFL	Pre-treatment Flag	Char	Y	Cond	Character indicator of whether the observation occurred before the subject started treatment. Example derivation: If ASTDT < ADSL.TRTSDT then PREFL='Y' This variable is conditional on whether the concept of pre-treatment is a feature of the study and used in analysis.
FUPFL	Follow-up Flag	Char	Y	Cond	Character indicator of whether the observation occurred while the subject was on follow-up. Example derivation: If ASTDT > ADSL.TRTEDT then FUPFL='Y' This variable is conditional on whether the concept of follow-up is a feature of the study and used in analysis.

表 3.2.5.5 不良事件和合并用药标识变量

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
PREFL	治疗前标帜	Char	Y	Cond	Character indicator of whether the observation occurred before the subject started treatment. Example derivation: If ASTDT < ADSL.TRTSDT then PREFL='Y' This variable is conditional on whether the concept of pre-treatment is a feature of the study and used in analysis.
FUPFL	随访期标帜	Char	Y	Cond	Character indicator of whether the observation occurred while the subject was on follow-up. Example derivation: If ASTDT > ADSL.TRTEDT then FUPFL='Y' This variable is conditional on whether the concept of follow-up is a feature of the study and used in analysis.

3.2.6 Occurrence Flag Variables

3.2.6 事件标记变量

Occurrence flags can be used to prepare data for analysis. They are typically created by sorting the data in the required order and then flagging the first treatment emergent record. The use of the word "first" in this section doesn't necessarily mean chronological, though that is an option. The more common occurrence flags and a structure for additional flags are shown below:
事件标记可以用来准备分析的数据。通常按照指定顺序来排序数据，然后标记第一个治疗期记录， 以此方法来创建事件标记。此处所用词汇'第一个'并不一定是需要按时间顺序排列的，尽管按时间排序是一种选择。更多常见的事件标记和其他额外的标记结构显示如下

Table 3.2.6.1 OCCDS Occurrence Flag Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
AOCCFL	1st Occurrence within Subject Flag	Char	Y	Perm	Character indicator for the first occurrence of any event/intervention/finding within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for each subject.
AOCCPFL	1st Occurrence of Preferred Term Flag	Char	Y	Perm	Character indicator for the first occurrence of the preferred term within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for each --DECOD for each subject.
AOCCIFL	1st Max Sev./Int. Occurrence Flag	Char	Y	Perm	Character indicator for the first occurrence of the event/intervention/finding with the maximum severity/intensity within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity for each subject.
AOCCPIFL	1st Max Sev./Int. Occur Within PT Flag	Char	Y	Perm	Character indicator for the first occurrence of the maximum severity/intensity within the subject and preferred term. Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity within preferred term for each subject.

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
AOCCzzFL	1st Occurrence of ….	Char	Y	Perm	Additional flag variables as needed for analysis. Derivation rules for these flags need to be described in the metadata.

表 3.2.6.1 OCCDS 事件标记变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
AOCCFL	受试者首次发生标帜	Char	Y	Perm	Character indicator for the first occurrence of any event/intervention/finding within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for each subject.
AOCCPFL	首选语首次发生标帜	Char	Y	Perm	Character indicator for the first occurrence of the preferred term within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for each --DECOD for each subject.
AOCCIFL	最严重首次发生标帜	Char	Y	Perm	Character indicator for the first occurrence of the event/intervention/finding with the maximum severity/intensity within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity for each subject.
AOCCPIFL	首选语最严重首次发生标帜	Char	Y	Perm	Character indicator for the first occurrence of the maximum severity/intensity within the subject and preferred term. Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity within preferred term for each subject.
AOCCzzFL	……首次发生标帜	Char	Y	Perm	Additional flag variables as needed for analysis. Derivation rules for these flags need to be described in the metadata.

Table 3.2.6.2 MedDRA Occurrence Flag Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
AOCCSFL	1st Occurrence of SOC Flag	Char	Y	Perm	Character indicator for the first occurrence of the system organ class within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for each body system for each subject.
AOCCSIFL	1st Max Sev./Int. Occur Within SOC Flag	Char	Y	Perm	Character indicator for the first occurrence of the maximum severity/intensity within the subject and system organ class. Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity within body system for each subject.

表 3.2.6.2 MedDRA 事件标记变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
AOCCSFL	SOC 首次发生标帜	Char	Y	Perm	Character indicator for the first occurrence of the system organ class within the subject. Example derivation: Sort the data in the required order and flag the first treatment emergent record for each body system for each subject.
AOCCSIFL	SOC 最严重首次发生标帜	Char	Y	Perm	Character indicator for the first occurrence of the maximum severity/intensity within the subject and system organ class. Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity within body system for each subject.

3.2.7 Treatment/Dose Variables

3.2.7 治疗/剂量变量

The treatment variable used for analysis must be included. Typically this would be TRTP, TRTA, TRTxxP, or TRTxxA. See the ADaM Implementation Guide version 1.1 [2] for more details on these variables. Additional dosing variables may also be included.
用于分析的治疗变量必须包含进来。代表性的有 TRTP, TRTA, TRTxxP 或者 TRTxxA。更多细节请参照 ADaM 实施指南 v1.1 版本[2]。其他额外的用药变量也可能包含进来。

Table 3.2.7.1 Treatment/Dose Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
DOSEON	记录开始时的治疗剂量	Num		Perm	Dose received at the point in time of the record start date. Example derivation: Obtained from EX.EXDOSE where --STDTC falls between the values of EX.EXSTDTC and EX.EXENDTC
DOSCUMA	累积实际治疗剂量	Num		Perm	Cumulative actual study drug dosage at the point in time of the record start date.
DOSEU	治疗剂量单位	Char	(UNIT)	Cond	Conditional on whether DOSEON and/or DOSCUMA are included.

表 3.2.7.1 治疗/用药变量

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
DOSEON	Treatment Dose at Record Start	Num		Perm	Dose received at the point in time of the record start date. Example derivation: Obtained from EX.EXDOSE where --STDTC falls between the values of EX.EXSTDTC and EX.EXENDTC

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
DOSCUMA	Cumulative Actual Treatment Dose	Num		Perm	Cumulative actual study drug dosage at the point in time of the record start date.
DOSEU	Treatment Dose Units	Char	(UNIT)	Cond	Conditional on whether DOSEON and/or DOSCUMA are included.

3.2.8 Descriptive Variables
3.2.8 描述变量

Variables that describe the record are often used in analysis. Include these and any other SDTM variables if used in analysis. If the analysis version of the variable differs from the version in SDTM, additional variables must be added using the conventions below and described in Section 3.2.
描述记录的变量经常用于分析中。 包括这些和其他需要在分析中使用的 SDTM 变量。 如果变量的分析版本与 SDTM 的版本不同，就需要按照以下惯例和 3.2 部分中的说明增加额外的变量。

Shown here are some common descriptive variables that are often included in ADAE. Any other SDTM variables should be included as appropriate (e.g. AEOUT, AESDTH).
这里显示的是一些 ADAE 中常见的描述变量。其他一些 SDTM 中的描述变量（例如: AEOUT, AESDTH）应该酌情包含进来。

Table 3.2.8.1 Adverse Event Descriptive Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
AESER	Serious Event	Char	(NY)	Req	AE.AESER
AESEV	Severity/Intensity	Char	(AESEV)	Perm	AE.AESEV
AESEVN	Severity/Intensity (N)	Num	1, 2, 3	Perm	Code AE.AESEV to numeric Low intensity should correspond to low value
ASEV	Analysis Severity/Intensity	Char	*	Perm	Apply imputation rules for missing severity of adverse events as specified in the SAP or metadata. May change case of text, such as from all uppercase in AESEV to mixed case in ASEV.
ASEVN	Analysis Severity/Intensity (N)	Num	1, 2, 3	Perm	Code ASEV to numeric Low intensity should correspond to low value
SEVGRy	Pooled Severity Group y	Char	*	Perm	Pooled grouping of AE Severity for analysis (e.g. mild/moderate or severe).
SEVGRyN	Pooled Severity Group y (N)	Num	*	Perm	Code SEVGRy to numeric Low intensity should correspond to low value
AEREL	Causality	Char	*	Perm	AE.AEREL
AERELN	Causality (N)	Num	*	Perm	Code AE.AEREL to numeric Low relation should correspond to low value
AREL	Analysis Causality	Char	*	Perm	Apply imputation rules for missing causality of study drug as specified in the SAP or metadata. May change case of text, such as from all uppercase in AEREL to mixed case in AREL.
ARELN	Analysis Causality (N)	Num	*	Perm	Code AREL to numeric
RELGRy	Pooled Causality Group y	Char	*	Perm	Pooled grouping of causality of study drug for analysis (e.g. related, Not related).

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
RELGRyN	Pooled Causality Group y (N)	Num	*	Perm	Code of RELGRy to numeric Low relation should correspond to low value
AETOXGR	Standard Toxicity Grade	Char	*	Perm	AE.AETOXGR
AETOXGRN	Standard Toxicity Grade (N)	Num	*	Perm	Code AETOXGR to numeric Low toxicity should correspond to low value
ATOXGR	Analysis Toxicity Grade	Char	*	Perm	Toxicity grade for analysis. May be based on AETOXGR or an imputed or assigned value. May change case of text, such as from all uppercase in AETOXGR to mixed case in ATOXGR.
ATOXGRN	Analysis Toxicity Grade (N)	Num	*	Perm	Code ATOXGR to numeric Low toxicity should correspond to low value
TOXGGRy	Pooled Toxicity Grade Group y	Char	*	Perm	Pooled grouping of toxicity grade for analysis.
TOXGGRyN	Pooled Toxicity Grade y (N)	Num	*	Perm	Code of TOXGGRy to numeric Low toxicity should correspond to low value
AEACN	Action Taken with Study Treatment	Char	(ACN)	Perm	AE.AEACN

** Indicates variable may be subject to producer-defined controlled terminology.*
Code Lists in parenthesis are the names of CDISC Controlled Terminology.

表 3.2.8.1 不良事件描述变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
AESER	严重事件	Char	(NY)	Req	AE.AESER
AESEV	严重程度	Char	(AESEV)	Perm	AE.AESEV
AESEVN	严重程度(N)	Num	1, 2, 3	Perm	Code AE.AESEV to numeric Low intensity should correspond to low value
ASEV	严重程度-分析用	Char	*	Perm	Apply imputation rules for missing severity of adverse events as specified in the SAP or metadata. May change case of text, such as from all uppercase in AESEV to mixed case in ASEV.
ASEVN	严重程度(N)-分析用	Num	1, 2, 3	Perm	Code ASEV to numeric Low intensity should correspond to low value
SEVGRy	严重程度合并分组 y	Char	*	Perm	Pooled grouping of AE Severity for analysis (e.g. mild/moderate or severe).
SEVGRyN	严重程度合并分组 y(N)	Num	*	Perm	Code SEVGRy to numeric Low intensity should correspond to low value
AEREL	相关性	Char	*	Perm	AE.AEREL
AERELN	相关性(N)	Num	*	Perm	Code AE.AEREL to numeric Low relation should correspond to low value
AREL	相关性-分析用	Char	*	Perm	Apply imputation rules for missing causality of study drug as specified in the SAP or metadata. May change case of text, such as from all uppercase in AEREL to mixed case in AREL.
ARELN	相关性(N)-分析用	Num	*	Perm	Code AREL to numeric
RELGRy	相关性合并分组 y	Char	*	Perm	Pooled grouping of causality of study drug for analysis (e.g. related, Not related).

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
RELGRyN	相关性合并分组 y(N)	Num	*	Perm	Code of RELGRy to numeric Low relation should correspond to low value
AETOXGR	毒性分级	Char	*	Perm	AE.AETOXGR
AETOXGRN	毒性分级(N)	Num	*	Perm	Code AETOXGR to numeric Low toxicity should correspond to low value
ATOXGR	毒性分级-分析用	Char	*	Perm	Toxicity grade for analysis. May be based on AETOXGR or an imputed or assigned value. May change case of text, such as from all uppercase in AETOXGR to mixed case in ATOXGR.
ATOXGRN	毒性分级(N)-分析用	Num	*	Perm	Code ATOXGR to numeric Low toxicity should correspond to low value
TOXGGRy	毒性分级合并分组 y	Char	*	Perm	Pooled grouping of toxicity grade for analysis.
TOXGGRyN	毒性分级合并分组 y(N)	Num	*	Perm	Code of TOXGGRy to numeric Low toxicity should correspond to low value
AEACN	对研究治疗采取的措施	Char	(ACN)	Perm	AE.AEACN

** 标识变量可能是用户自定义的受控术语*
括号里的编码列表是 CDISC 受控术语中的名字。

Medical History data typically does not contain descriptive variables. If needed for analysis, use variables as shown above for Adverse Events, replacing the prefix "AE" with "MH".
病史数据通常不包含描述变量。如果分析需要，可以使用以上不良事件中的变量，不过要把前缀'AE'换成'MH'。

Shown here are some common descriptive variables that are often included in ADCM. Any other SDTM variables should be included as appropriate.
这里显示的是一些 ADCM 中常见的描述变量。其他一些 SDTM 中的描述变量应该酌情包含进来。

Table 3.2.8.2 Concomitant Medications Descriptive Variables

Variable Name	Variable Label	Type	Code List / Controlled Terms	Core	CDISC Notes
CMSTAT	Completion Status	Char		Perm	CM.CMSTAT
CMINDC	Indication	Char		Perm	CM.CMINDC
CMDOSE	Dose per Administration	Num		Perm	CM.CMDOSE
CMDOSFRM	Dose Form	Char		Perm	CM.CMDOSFRM
CMDOSRGM	Intended Dose Regimen	Char		Perm	CM.CMDOSRGM
CMROUTE	Route of Administration	Char		Perm	CM.CMROUTE

表 3.2.8.2 合并用药描述变量

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
CMSTAT	未做状态	Char		Perm	CM.CMSTAT
CMINDC	适应症	Char		Perm	CM.CMINDC
CMDOSE	单次剂量	Num		Perm	CM.CMDOSE
CMDOSFRM	剂型	Char		Perm	CM.CMDOSFRM
CMDOSRGM	计划给药方案	Char		Perm	CM.CMDOSRGM
CMROUTE	给药途径	Char		Perm	CM.CMROUTE

3.2.9 Standardized MedDRA Query Variables

3.2.9 MedDRA 标准化查询变量

Standardized MedDRA Queries (SMQs) [13] are becoming increasingly common in clinical trial safety evaluations, particularly when known or suspected safety issues are associated with experimental compounds. In addition, Customized MedDRA Queries (CMQs) are often used to modify an SMQ or identify AdverseEvent or Medical History records of special interest. The following variables are used to identify SMQs and CMQs, where the 'zz' indicates a number starting with 01 for each SMQ or CQ of interest. This ordering can be based on importance or some other producer-defined criteria. It is recommended that the ordering be consistent across studies within a development program, but it is recognized that there may be situations where this is not possible or practical.
MedDRA 标准化查询（SMQs）[13]越来越普遍地用于临床试验的安全性评估中，特别是已知的或者可疑的安全性问题与实验化合物有关时。此外，自定义的 MedDRA 查询（CMQs）经常被用于修订 SMQ、识别特殊关注的不良事件或者病史记录。以下变量用来识别 SMQs 和 CMQs。此处的'zz'对每一个 SMQ 或者感兴趣的 CQ 代表一个从 01 开始的数字。 这种数字的排序可以基于重要性或者其他一些用户自定义的标准。推荐在一个开发方案中的不同研究项目中保持一致的排序，但也接受有的特殊情况下无法做到一致性.

Table 3.2.9.1 Standardized MedDRA Query Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
SMQzzNAM	SMQ zz Name	Char		Cond	The standardized MedDRA queries name. Would be blank for terms that are not in the SMQ. Therefore this variable could be blank for all records if no terms within the study were included in the SMQ. Conditional on whether SMQ analysis is done.
SMQzzCD	SMQ zz Code	Num		Perm	The standardized MedDRA queries number code.
SMQzzSC	SMQ zz Scope	Char	BROAD, NARROW	Cond	The search strategy for SMQs can be narrow or broad. The preferred terms that are narrow in scope have high specificity for identifying events of interest while the broad terms have high sensitivity. By definition, all narrow terms are also considered within the broad scope. Therefore, to summarize all broad terms, terms with either narrow OR broad would be considered. Will be null for terms that do not meet the criteria. Conditional on whether SMQ analysis is done.
SMQzzSCN	SMQ zz Scope (N)	Num	1, 2	Perm	Will be null for terms that do not meet the criteria.

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
CQzzNAM	Customized Query zz Name	Char		Cond	The customized query (CQ) name or name of the AE of special interest category based on a grouping of terms. Would be blank for terms that are not in the CQ. Conditional on whether CQ analysis is done. Examples: “DERMATOLOGICAL EVENTS” “CARDIAC EVENTS”, “IARS (INFUSION ASSOCIATED REACTIONS)”

表 3.2.9.2 MedDRA 标准化查询变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
SMQzzNAM	SMQ zz 名称	Char		Cond	The standardized MedDRA queries name. Would be blank for terms that are not in the SMQ. Therefore this variable could be blank for all records if no terms within the study were included in the SMQ. Conditional on whether SMQ analysis is done.
SMQzzCD	SMQ zz 编码	Num		Perm	The standardized MedDRA queries number code.
SMQzzSC	SMQ zz 范围	Char	BROAD, NARROW	Cond	The search strategy for SMQs can be narrow or broad. The preferred terms that are narrow in scope have high specificity for identifying events of interest while the broad terms have high sensitivity. By definition, all narrow terms are also considered within the broad scope. Therefore, to summarize all broad terms, terms with either narrow OR broad would be considered. Will be null for terms that do not meet the criteria. Conditional on whether SMQ analysis is done.
SMQzzSCN	SMQ zz 范围 (N)	Num	1, 2	Perm	Will be null for terms that do not meet the criteria.
CQzzNAM	自定义查询 zz 名称	Char		Cond	The customized query (CQ) name or name of the AE of special interest category based on a grouping of terms. Would be blank for terms that are not in the CQ. Conditional on whether CQ analysis is done. Examples: “DERMATOLOGICAL EVENTS” “CARDIAC EVENTS”, “IARS (INFUSION ASSOCIATED REACTIONS)”

3.2.10 Original or Prior Coding Variables

3.2.10 原始或既往的编码变量

The suite of variables used for the primary analysis is described in section 3.2.3. Variables described here are those from original (or prior) analyses, and not used directly for analysis from this data set.
这套用于主要分析的变量已经在 3.2.3 部分介绍过了。此处描述的变量是来自于原始（或者先前的）的分析，而不是直接从这个数据集里拿来分析。

Keeping multiple sets of mapping variables is not common, but there are a couple instances where it might be helpful:
保留多套映射版本的例子并不常见，下面两个例子可以帮助理解：

- When a study is mapped to one version of a mapping dictionary for an interim analysis and another for final analysis
  当一个研究映射到一个映射词典版本用于中期分析， 而映射到另一个版本用于终期分析

- When studies using different version of a mapping dictionary are pooled together for an integrated analysis
  当使用不同映射词典版本的研究合并在一起做整合分析时

The variables described below provide traceability to original (or prior) analysis(es). The suffix "w" represents an integer [1-9] corresponding to a previous version. Include the dictionary name and version as part of the metadata for each variable.
以下介绍的变量提供了可溯源性，可追踪到原始（或者先前）的分析。后缀"w"代表【1-9】的整数，这些整数是相对于先前版本号而言的。将词典名字和版本号作为每个变量的元数据的一部分

These variable names at this time are recommendations only. There is an ADaM sub-team currently working on integration, and this group may create different naming conventions for that type of analysis.
这里这些变量的名字仅仅是推荐使用的。 目前有一个 ADaM 的小组正在做整合，这个小组针对这种类型的分析，可能会创建一套不同的命名规则。

Table 3.2.10.1 Original or Prior MedDRA Coding Variables

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
DECDORGw	PT in Original Dictionary w	Char	MedDRAw*	Perm	Original preferred term coding of XX.--TERM using MedDRA or other dictionary version X.X.
BDSYORGw	SOC in Original Dictionary w	Char	MedDRAw*	Perm	Original body system coding of XX.--TERM using MedDRA or other dictionary version X.X.
HLGTORGw	HLGT in Original Dictionary w	Char	MedDRAw*	Perm	Original HLGT coding of XX.--TERM using MedDRA or other dictionary version X.X
HLTORGw	HLT in Original Dictionary w	Char	MedDRAw*	Perm	Original HLT coding of XX.--TERM using MedDRA or other dictionary version X.X.
LLTORGw	LLT in Original Dictionary w	Char	MedDRAw*	Perm	Original LLT coding of XX.--TERM using MedDRA or other dictionary version X.X.
LLTNORGw	LLT Code in Original Dictionary w	Char	MedDRAw*	Perm	Original LLT code of XX.--TERM using MedDRA or other dictionary version X.X.

** For each version of an external dictionary, a different reference name must be used. The individual reference names will point to a dedicated section in the data definition file where all external dictionaries used in the analysis are listed, including dictionary name and version.*

表 3.2.10.1 原始或既往的 MedDRA 编码变量

Variable Name	变量标签	Type	Codelist / Controlled Terms	Core	CDISC Notes
DECDORGw	词典 w 版中的标准化名称	Char	MedDRAw*	Perm	Original preferred term coding of XX.--TERM using MedDRA or other dictionary version X.X.
BDSYORGw	词典 w 版中的 SOC	Char	MedDRAw*	Perm	Original body system coding of XX.--TERM using MedDRA or other dictionary version X.X.
HLGTORGw	词典 w 版中的 HLTG	Char	MedDRAw*	Perm	Original HLGT coding of XX.--TERM using MedDRA or other dictionary version X.X
HLTORGw	词典 w 版中的 HLT	Char	MedDRAw*	Perm	Original HLT coding of XX.--TERM using MedDRA or other dictionary version X.X.
LLTORGw	词典 w 版中的 LLT	Char	MedDRAw*	Perm	Original LLT coding of XX.--TERM using MedDRA or other dictionary version X.X.
LLTNORGw	词典 w 版中的 LLT 编码	Char	MedDRAw*	Perm	Original LLT code of XX.--TERM using MedDRA or other dictionary version X.X.

** 对于外部词典的每一个版本，必须使用一个不同的参照名字。单独的参照名字将指向数据定义文件中专门的部分。这个专门的部分列出了所有用于分析的外部词典，包括词典名字和版本号。*

Table 3.2.10.2 Original or Prior WHO Drug Coding Variables

Variable Name	Variable Label	Type	Code List / Controlled Terms	Core	CDISC Notes
DECDORGw	Standardized Med Name in Orig Dict w	Char	WHODRUGy*	Perm	Original standardized medication name of CM.CMTRT using WHO Drug version X.X
CLASORGw	Medication Class in Orig Dictionary w	Char	WHODRUGy*	Perm	Original medication class of CM.CMTRT using WHO Drug version X.X
CLCDORGw	Medication Class Code in Orig Dict w	Char	WHODRUGy*	Perm	Original medication class code of CM.CMTRT using WHO Drug version X.X
ATyCORGw	ATC Level y Code in Orig Dictionary w	Char	WHODRUGw*	Perm	Original ATC Level y code of CM.CMTRT using WHO Drug version X.X
ATyTORGw	ATC Level y Text in Orig Dictionary w	Char	WHODRUGw*	Perm	Original ATC Level y text of CM.CMTRT using WHO Drug version X.X

** For each version of an external dictionary, a different reference name must be used. The individual reference names will point to a dedicated section in the data definition file where all external dictionaries used in the analysis are listed, including dictionary name and version.*

表 3.2.10.2 原始或既往的 WHO Drug 编码变量

Variable Name	变量标签	Type	Code List / Controlled Terms	Core	CDISC Notes
DECDORGw	词典 w 版中的标准化名称	Char	WHODRUGy*	Perm	Original standardized medication name of CM.CMTRT using WHO Drug version X.X
CLASORGw	词典 w 版中的归类	Char	WHODRUGy*	Perm	Original medication class of CM.CMTRT using WHO Drug version X.X
CLCDORGw	词典 w 版中的归类编码	Char	WHODRUGy*	Perm	Original medication class code of CM.CMTRT using WHO Drug version X.X
ATyCORGw	词典 w 版中的 ATC 第 y 级代码	Char	WHODRUGw*	Perm	Original ATC Level y code of CM.CMTRT using WHO Drug version X.X
ATyTORGw	词典 w 版中的 ATC 第 y 级	Char	WHODRUGw*	Perm	Original ATC Level y text of CM.CMTRT using WHO Drug version X.X

** 对于外部词典的每一个版本，必须使用一个不同的参照名字。单独的参照名字将指向数据定义文件中专门的部分。这个专门的部分列出了所有用于分析的外部词典，包括词典名字和版本号。*

3.3 Other Metadata

3.3 其他元数据

Because OCCDS does not use parameters, there is typically no need for Value Level Metadata.
因为 OCCDS 并没有使用参数，因此也不需要变量值水平的元数据。

The other type of ADaM metadata which may be included is the Analysis Results Metadata. The CDISC Analysis Results Metadata Version 1.0 for Define-XML Version 2 [14] has examples of how to represent Analysis Results Metadata.

其他类型的 ADaM 元数据也可能被包含在分析结果的元数据里。在 CDISC 分析结果元数据版本 1.0 的 Define-XML 版本 2 [14]中有如何展示分析结果元数据的例子。

4 示例 1： 关于治疗后不良事件的分析

The basic summary of adverse event frequencies described in section 12.2.2 (and located in section 14.3.1) of ICH Guideline E3 [12] report should be used to display frequencies in treatment and control groups.
ICH 指导原则 E3 类论题中第 12 条 12.2.2.2 部分（以及 14.3.1 部分）说的不良反应频率的基本总结应当用来体现治疗组和对照组中的频率

This example displays a simple summary of all treatment emergent adverse events. The example is based on a two treatment parallel design study. The display summarizes (1) the number of subjects in each treatment group in whom the adverse event occurred and (2) the rate of occurrence in each treatment group.
这个例子在两个平行组设计治疗研究的基础上简单体现了紧急治疗中所有不良反应的两个方面的总结：（1）每个发生不良反应的治疗组中的主体数量，（2）每个治疗组的发生率。

4.1 Analysis Display Example Layout

4.1 示例分析结果展示样式

Table 4.1.1 Example of Summary of Treatment Emergent Adverse Events*
表 4.1.1 关于治疗后的不良事件的总结的例子

Table 14.2.7.1
表 14.2.7.1
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term
由系统器官类别和首选术语对治疗中突发不良反应所进行的汇总
Analysis Population: Safety
分析人群：安全性

SYSTEM ORGAN CLASS **Preferred Term**	**Treatment A** **(N = xxx)** **n (%)**	**Treatment B** **(N = xxx)** **n (%)**
Number of subjects reporting at least one adverse event		
BLOOD AND LYMPHATIC SYSTEM DISORDERS	x (x.x)	x (x.x)
At least one event		
Anaemia		
…	x (x.x)	x (x.x)
	x (x.x)	x (x.x)
CARDIAC DISORDERS	x (x.x)	x (x.x)
At least one event		
Angina pectoris		
Coronary artery disease		
Ventricular tachycardia	x (x.x)	x (x.x)
Myocardial infarction	x (x.x)	x (x.x)
…	x (x.x)	x (x.x)
	x (x.x)	x (x.x)
<Other SOCs and PTs>	x (x.x)	x (x.x)
	x (x.x)	x (x.x)

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N = Safety subjects, i.e., subjects who received at least one dose of study drug

N=安全受试者，即那些至少使用一剂试验药物的受试者

n = Number of subjects reporting at least one treatment emergent adverse event
n=至少有一次治疗后不良事件的受试者的人数

% = n / N * 100
% = n / N * 100

Adverse events are presented by descending frequency within Treatment B
不良事件将按照治疗组 B 发生率降序排序

System organ classes and preferred terms are coded using MedDRA version x.x.
系统器官类别和首选术语使用医学用语词典版本 xx 进行表达

*The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。4.2 Sample ADaM Variable Metadata

4.2 ADaM 变量元数据样例

This example describes an adverse events ADaM dataset named ADAE. ADAE is not a required dataset name.
本例描述的是名为 ADAE 的不良反应 ADaM 数据集。ADAE 不是必须的数据集名称。

Table 4.2.1 Example of ADaM Variable Metadata
表 4.2.1 ADaM 变量元数据示例

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	STUDYID	Study Identifier	text		AE.STUDYID
ADAE	USUBJID	Unique Subject Identifier	text		AE.USUBJID
ADAE	AESEQ	Sequence Number	integer		AE.AESEQ
ADAE	AETERM	Reported Term for the Adverse Event	text		AE.AETERM
ADAE	AEDECOD	Dictionary-Derived Term	text	MedDRA	AE.AEDECOD MedDRA Version 11.1
ADAE	AEBODSYS	Body System or Organ Class	text	MedDRA	AE.AEBODSYS MedDRA Version 11.1
ADAE	TRTEMFL	Treatment Emergent Analysis Flag	text	Y	If ADSL.TRTSDT <= ASTDT<=(ADSL.TRTEDT +14) then TRTEMFL='Y'
ADAE	PREFL	Pre-treatment Flag	text	Y	If ASTDT < ADSL.TRTSDT then PREFL='Y'
ADAE	FUPFL	Follow-up Flag	text	Y	If ASTDT > ADSL.TRTEDT+14 then FUPFL='Y'
ADAE	AESTDTC	Start Date/Time of Adverse Event	date	ISO 8601	AE.AESTDTC
ADAE	ASTDT	Analysis Start Date	integer		<Producer will insert derivation here>
ADAE	ASTDTF	Analysis Start Date Imputation Flag	text	D, M, Y	If start date is completely missing or missing the year then ASTDTF='Y' Else if start date has month missing then ASTDTF='M' Else if start date has day missing then ASTDTF='D'
ADAE	AEENDTC	End Date/Time of Adverse Event	date	ISO 8601	AE.AEENDTC
ADAE	AENDT	Analysis End Date	integer		<Producer will insert derivation here>
ADAE	AENDTF	Analysis End Date Imputation Flag	text	D, M, Y	If end date is completely missing or missing the year then AENDTF='Y' Else if end date has month missing then AENDTF='M' Else if end date has day missing then AENDTF='D'
ADAE	AESER	Serious Event	text	Y, N	AE.AESER
ADAE	APHASE	Phase	text	PRE-TREATMENT, TREATMENT, FOLLOW-UP	If ASTDT<ADSL.TRTSDT, then APHASE='PRE-TREATMENT' Else if ASTDT > ADSL.TRTEDT + 14 days then APHASE='FOLLOW-UP', Else APHASE='TREATMENT'
ADAE	AESEV	Severity/Intensity	text	MILD, MODERATE, SEVERE	AE.AESEV

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	ASEV	Analysis Severity/Intensity	text	Mild, Moderate, Severe	If AE.AESEV='MILD' then ASEV='Mild' Else if AE.AESEV='MODERATE' then ASEV='Moderate' Else if AE.AESEV is equal to 'SEVERE' or Severity/Intensity is missing then ASEV='Severe'
ADAE	ASEVN	Analysis Severity/Intensity (N)	integer	1, 2, 3	Map ASEV to ASEVN in the following manner: 'Mild' = 1 'Moderate' = 2 'Severe' = 3
ADAE	AEREL	Causality	text	NOT RELATED, UNLIKELY RELATED, POSSIBLY RELATED, PROBABLY RELATED, DEFINITELY RELATED	AE.AEREL
ADAE	RELGR1	Pooled Causality Group 1	text	Not Related, Related	If AE.AEREL is equal to 'NOT RELATED' or 'UNLIKELY RELATED' then RELGR1='Not Related' Else if AE.AEREL is equal to 'POSSIBLY RELATED' or 'PROBABLY RELATED' or 'DEFINITELY RELATED' or Causality is missing then RELGR1='Related'
ADAE	RELGR1N	Pooled Causality Group 1 (N)	integer	0, 1	Map RELGR1 to RELGR1N in the following manner: 'Not Related' = 0 'Related' = 1
ADAE	SAFFL	Safety Population Flag	text	Y,N	ADSL.SAFFL
ADAE	AOCCFL	1st Occurrence within Subject Flag	text	Y	Subset ADAE to Treatment Emergent Adverse Events (TRTEMFL='Y') Sort by Subject (USUBJID), Analysis Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCCFL='Y') within each Subject
ADAE	AOCCSFL	1st Occurrence of SOC Flag	text	Y	Subset ADAE to Treatment Emergent Adverse Events (TRTEMFL='Y') Sort by Subject (USUBJID), System Organ Class (AEBODSYS), Analysis Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCCSFL ='Y') within each Subject and SOC
ADAE	AOCCPFL	1st Occurrence of Preferred Term Flag	text	Y	Subset ADAE to Treatment Emergent Adverse Events (TRTEMFL='Y') Sort by Subject (USUBJID), System Organ Class (AEBODSYS), Preferred Term (AEDECOD) Analysis Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCCPFL ='Y') within each Subject,
ADAE	TRTA	Actual Treatment	text	Drug A, Drug B	ADSL.TRT01A
ADAE	TRTAN	Actual Treatment (N)	integer	1, 2	ADSL.TRT01AN Drug A = 1 Drug B = 2

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	TRTSDT	Date of First Exposure to Treatment	integer		ADSL.TRTSDT
ADAE	TRTEDT	Date of Last Exposure to Treatment	integer		ADSL.TRTEDT
ADAE	AGE	Age	integer		ADSL.AGE
ADAE	AGEGR1	Pooled Age Group 1	text	<65, >=65	ADSL. AGEGR1
ADAE	SEX	Sex	text	M, F	ADSL.SEX
ADAE	RACE	Race	text	BLACK OR AFRICAN AMERICAN, AMERICAN INDIAN OR ALASKA NATIVE, ASIAN, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, WHITE	ADSL.RACE

4.3 Sample ADaM Data

4.3 ADaM 数据样例

Table 4.3.1 is an illustration of the adverse events analysis dataset (ADAE) defined above. The ADAE dataset illustrated in this example was designed to support some standard subsets and/or classifications of treatment emergent adverse events including seriousness, severity, and relationship to study drug. The example describes some of the key variables and records that would be included in the dataset.
表 4.3.1 是上面定义的不良事件分析数据集（ADAE）的图示。本实施例中说明的 ADAE 数据集旨在支持治疗相关不良事件的一些标准子集和/或分类，包括严重性，严重程度和与研究药物的关系。该示例描述了将包含在数据集中的一些关键变量和记录。

Key points to note in the example are:
示例中要注意的要点是：

1. The producer of the dataset chose to use record level actual treatment variable (TRTA) populated with the same value across all rows in the dataset rather than subject level treatment variable (TRT01A). For a parallel design either TRTA or TRT01A could be used as the actual treatment identifier. The producer interpreted TRTA as the treatment associated with the record for analysis display purposes and populated the pre-treatment records with treatment even though subjects had not yet received treatment at that time.
   数据集的制作人选择使用由具有相同值的行填充的记录级别实际治疗变量（TRTA），而不是受试者级别处理变量（TRT01A）。对于平行设计研究来说，TRTA 和 TRT01A 都可以用作实际治疗组标识符。制作人将 TRTA 作为与用于分析展示目的的记录联系在一起的治疗组，并

且在受试者尚未接受治疗时，就根据该治疗方法填写了治疗前记录。

2. Variables such as AESEQ, AETERM, and AESTDTC are copied in from SDTM AE domain to provide data point traceability.
一些变量，例如 AESEQ, AETERM,和 AESTDTC，都是从 SDTM AE 域复制得来，以提供数据点可追溯性。

3. Variables such as AEBODSYS, AEDECOD, AESER, AESEV, and AEREL are copied in from the SDTM AE domain for analysis purposes.
一些变量，例如 AEBODSYS, AEDECOD, AESER, AESEV 和 AEREL，都是从 SDTM AE 域复制得来，用于分析目的。

4. ASTDT is the AE timing variable used for analysis. Other timing variables such as AENDT/ASTDTF/AENDTF/ AESTDTC/AEENDTC/TRTSDT/TRTEDT are supportive variables for metadata traceability.
ASTDT 为用于分析的 AE 时间变量。其他时间变量，如 AENDT/ASTDTF/AENDTF/ AESTDTC/AEENDTC/TRTSDT/TRTEDT 是元数据可追溯性的支持变量。

5. The addition of ASEV and RELGR1 allow for the imputation of missing severity and grouping and imputation of Relationship to Study Drug as specified in the Statistical Analysis Plan.
ASEV 和 RELGR1 还可根据统计分析计划中所示的来对严重程度缺失值进行填补，还可以对与研究药物的关系进行分组或者缺失值填补。

6. The Occurrence Flags (AOCC*FL) are permissible. The main purpose of these flags is to facilitate data point traceability between records in the dataset and unique counts in the summary displays. In addition if a Time to Event (TTE) Analysis is built off of Adverse Events, the flags provide a crucial link between the summary records in the TTE BDS and the source of the records in ADAE.
发生标帜（AOCC*FL）是许可变量。这些标帜的主要目的是便于数据集中的记录和汇总展示中的单一计数值之间的数据点可追溯性。另外，如果事件发生时间（TTE）的分析是建立在不良反应的基础之上，这些标帜就可以在 TTE BDS 中的汇总记录和 ADAE 的记录来源之间提供重要连接。

7. The core variables of AGE, AGEGR1, SEX, and RACE are included in ADAE to facilitate subgroup analyses.
核心变量 AGE, AGEGR1, SEX, 和 RACE 都包含在 ADAE 之中以便于子类分析。

Table 4.3.1 Sample ADaM Data
表 4.3.1 ADaM 数据样例

Row	STUDYID	USUBJID	AESEQ	AETERM	AEDECOD	AEBODSYS	TRTEMFL	PREFL	FUPFL
1	XYZ	XYZ-001-001	1	HEADACHE	Headache	Nervous system disorders		Y	
2	XYZ	XYZ-001-001	2	CHRONIC BACK PAIN	Back pain	Musculoskeletal and connective tissue disorders		Y	
3	XYZ	XYZ-001-001	3	NOSE BLEEDING RIGHT NOSTRIL	Epistaxis	Respiratory, thoracic and mediastinal disorders		Y	
4	XYZ	XYZ-001-001	4	PROBLEMS OF HYPOTENSION	Hypotension	Vascular disorders	Y		
5	XYZ	XYZ-001-001	5	HEADACHE	Headache	Nervous system disorders	Y		
6	XYZ	XYZ-001-001	6	HEADACHE	Headache	Nervous system disorders	Y		
7	XYZ	XYZ-001-001	7	LOOSE STOOL	Diarrhoea	Gastrointestinal disorders	Y		
8	XYZ	XYZ-001-001	8	ABDOMINAL DISCOMFORT	Abdominal discomfort	Gastrointestinal disorders	Y		
9	XYZ	XYZ-001-001	9	DIARRHEA	Diarrhoea	Gastrointestinal disorders	Y		
10	XYZ	XYZ-001-001	10	ABDOMINAL FULLNESS DUE TO GAS	Abdominal distension	Gastrointestinal disorders	Y		

11	XYZ	XYZ-001-001	11	NAUSEA (INTERMITTENT)	Nausea	Gastrointestinal disorders	Y		
12	XYZ	XYZ-001-001	12	WEAKNESS	Asthenia	General disorders and administration site conditions	Y		
13	XYZ	XYZ-001-001	13	HEADACHE	Headache	Nervous system disorders	Y		
14	XYZ	XYZ-001-001	14	HEADACHE	Headache	Nervous system disorders	Y		
15	XYZ	XYZ-001-001	15	HYPOTENSIVE	Hypotension	Vascular disorders	Y		
16	XYZ	XYZ-001-001	16	HEADACHE	Headache	Nervous system disorders			Y

Row	AESTDTC*	ASTDT*	ASTDTF	AEENDTC*	AENDT*	AENDTF	AESER	APHASE	AESEV	ASEV	ASEVN	AEREL
1 (cont)	2006-01	01JAN2006	D	2006-01-22	22JAN2006		N	PRE-TREATMENT	MILD	Mild	1	NOT RELATED
2 (cont)	2006-01-21	21JAN2006		2006-01-28	28JAN2006		N	PRE-TREATMENT	MODERATE	Moderate	2	NOT RELATED
3 (cont)	2006-01-22	22JAN2006		2006-01-22	22JAN2006		N	PRE-TREATMENT	MILD	Mild	1	NOT RELATED
4 (cont)		23JAN2006	Y		15MAY2006	Y	N	TREATMENT	MILD	Mild	1	POSSIBLY RELATED
5 (cont)	2006-01-24	24JAN2006		2006-01	31JAN2006	D	N	TREATMENT	MODERATE	Moderate	2	PROBABLY RELATED
6 (cont)	2006-02	01FEB2006	D	2006-02-05	05FEB2006		N	TREATMENT	SEVERE	Severe	3	PROBABLY RELATED
7 (cont)	2006-03-05	05MAR2006		2006-03-06	06MAR2006		N	TREATMENT		Severe	3	DEFINITELY RELATED
8 (cont)	2006-03-05	05MAR2006		2006	15MAY2006	M	N	TREATMENT	MODERATE	Moderate	2	DEFINITELY RELATED
9 (cont)	2006-03-17	17MAR2006		2006-03-18	18MAR2006		N	TREATMENT	MODERATE	Moderate	2	DEFINITELY RELATED
10 (cont)	2006-03-17	17MAR2006		2006-03-19	19MAR2006		N	TREATMENT	MILD	Mild	1	DEFINITELY RELATED
11 (cont)	2006-04-20	20APR2006		2006-04-22	22APR2006		N	TREATMENT	MILD	Mild	1	PROBABLY RELATED
12 (cont)	2006-05-17	17MAY2006		2006-05-20	20MAY2006		N	TREATMENT	MILD	Mild	1	POSSIBLY RELATED
13 (cont)	2006-05-20	20MAY2006		2006-05-22	22MAY2006		N	TREATMENT	MILD	Mild	1	UNLIKELY RELATED
14 (cont)	2006-05-23	23MAY2006		2006-06-27	27JUN2006		N	TREATMENT	MILD	Mild	1	UNLIKELY RELATED
15 (cont)	2006-05-21	27MAY2006		2006-05-25	29MAY2006		Y	TREATMENT	SEVERE	Severe	3	UNLIKELY RELATED
16 (cont)	2006-06-01	01JUN2006		2006-06-01	01JUN2006		N	FOLLOW-UP	MILD	Mild	1	UNLIKELY RELATED

** Variables ending in suffix DTC are character date/time fields in the ISO8601 format. Variables ending in DT are numeric dates, here shown using SAS date format date9. Other numeric date formats can be used, but care should be taken with newer date formats which might not be understood by all statistical packages*

** 以 DTC 为后缀的变量为 ISO8601 格式的字符型日期/时间。以 DT 为后缀的变量为数值型日期，这里显示的使用了 SAS 日期格式 date9。其他日期时间格式也可以使用，但需要注意的是较新的格式可能不会被所有的统计软件识别。*

Row	RELGR1	RELGR1N	SAFFL	AOCCFL	AOCCSFL	AOCCPFL	TRTA	TRTAN	TRTSDT*	TRTEDT*	AGE	AGEGR1	SEX	RACE
1 (cont)	Not Related	0	Y				Drug A	1	23JAN2006	15MAY2006	54	<65	M	ASIAN
2 (cont)	Not Related	0	Y				Drug A	1	23JAN2006	15MAY2006	54	<65	M	ASIAN
3 (cont)	Not Related	0	Y				Drug A	1	23JAN2006	15MAY2006	54	<65	M	ASIAN
4 (cont)	Related	1	Y	Y	Y	Y	Drug A	1	23JAN2006	15MAY2006	54	<65	M	ASIAN
5 (cont)	Related	1	Y		Y	Y	Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
6 (cont)	Related	1	Y				Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
7 (cont)	Related	1	Y		Y	Y	Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
8 (cont)	Related	1	Y			Y	Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
9 (cont)	Related	1	Y				Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
10 (cont)	Related	1	Y			Y	Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
11 (cont)	Related	1	Y			Y	Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
12 (cont)	Related	1	Y		Y	Y	Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
13 (cont)	Not Related	0	Y				Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
14 (cont)	Not Related	0	Y				Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN
15 (cont)	Not Related	0	Y				Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN

16 (cont)	Not Related	0	Y				Drug A	1	23JAN 2006	15MAY 2006	54	<65	M	ASIAN

** Variables ending in DT are numeric dates, here shown using SAS date format date9. Other numeric date formats can be used, but care should be taken with newer date formats which might not be understood by all statistical packages.*

**以 DT 为后缀的变量为数值型日期，这里显示的使用了 SAS 日期格式 date9。其他日期时间格式也可以使用，但需要注意的是较新的格式可能不会被所有的统计软件识别。*

5 Example 2: Analysis of Hemorrhages (SMQ) among Treatment Emergent Adverse Events by Sex

5. 示例 2：按性别进行的治疗期不良事件时出血的分析（SMQ）

This example demonstrates how to incorporate SMQs into an AE analysis data set. In this example, an SMQ for hemorrhages is being used. This particular SMQ is hierarchical with only narrow-scope terms, including terms referring to different types of hemorrhage, hematoma, bleeding, etc. (For a full description of SMQs one may refer to the Maintenance and Support Services Organization (MSSO's) Introductory Guide for Standardized MedDRA Queries [13].)
本例演示了如何将 SMQs 纳入 AE 分析数据集中。在本出血例子中使用了 SMQ。这种特定的 SMQ 的层次结构为狭义范围的术语，包括指不同类型的出血、血肿、流血等的术语。（有关 SMQs 的完整说明，可以参考《维护和支持服务组织（MSSO）入门指南》对于标准化 MedDRA 查询的介绍指导。）

Key points to note in the example are:
本例中值得注意的关键点：

1. The exact name of the SMQ being used in this example is "Haemorrhages (SMQ)". This precise terminology is used throughout the example.
   1. 本例中使用的 SMQ 的确切名称为"出血（SMQ）"。在整个示例中都使用了此精确术语。

2. As mentioned above, this particular SMQ contains only narrow scope terms. However, in order to illustrate best practice, the scope is also specified when a reference is made to the SMQ. Although redundant in this particular case, it is important to show which scope is being used when providing SMQ-based summaries since the scope can often have a profound effect on the percent of subjects who meet certain SMQ criteria.
   2. 正如先前提到的，此处的 SMQ 只包含狭义范围的术语。然而，为了说明最佳做法，当在引用 SMQ 时要指定范围。尽管在本案例中有些多余，但是在提供基于 SMQ 的汇总示例时注明它的范围也是十分重要的，因为在通常情况下，这个范围可以对满足该范围的受试者占比产生重大的影响。

5.1 Analysis Display Example Layouts

5.1 分析结果展示样式示例

Table 5.1.1 Example of Summary of Haemorrhages (SMQ) (Narrow Scope) Adverse Events by Sex and Actual Treatment Group*

Table 14.2.7.3
Summary of Haemorrhages (SMQ) (Narrow Scope) Adverse Events by Sex and Actual Treatment Group
Analysis Population: Safety

	Gender n (%)			
	Females		Males	
Preferred Term	B (N=281)	A (N=166)	B (N=297)	A (N=158)
Any Haemorrhages (SMQ) (Narrow Scope) Event	36 (8.0)	48 (10.5)	26 (8.8)	31 (19.6)
Cerebral haemorrhage	11 (2.4)	15 (3.3)	6 (2.0)	13 (8.2)
Conjunctival haemorrhage	0	1 (0.2)	0	0
Ecchymosis	1 (0.2)	0	0	0
Epistaxis	0	1 (0.2)	0	0
Extradural haematoma	1 (0.2)	0	1 (0.3)	1 (0.6)
Gastrointestinal haemorrhage	10 (2.2)	4 (0.9)	8 (2.7)	6 (3.8)
Haematuria	1 (0.2)	2 (0.4)	0	3 (1.9)
Haemoptysis	1 (0.2)	1 (0.2)	0	0
Haemorrhage	1 (0.2)	2 (0.4)	0	0
Infusion site haemorrhage	1 (0.2)	4 (0.9)	2 (0.7)	2 (1.3)
Melaena	0	0	0	1 (0.6)
Petechiae	0	1 (0.2)	0	0
Subarachnoid haemorrhage	14 (3.1)	24 (5.3)	12 (4.0)	11 (7.0)
Subdural haematoma	2 (0.4)	2 (0.4)	0	0

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.

Table 5.1.1 Example of Summary of Haemorrhages (SMQ) (Narrow Scope) Adverse Events by Sex and Actual Treatment Group*
表 5.1.1 按性别和实际治疗组对出血（SMQ）（狭义范围）的不良反应进行的汇总

Table 14.2.7.3
Summary of Haemorrhages (SMQ) (Narrow Scope) Adverse Events by Sex and Actual Treatment Group
Analysis Population: Safety

	Gender n (%)			
	Females		Males	
Preferred Term	B (N=281)	A (N=166)	B (N=297)	A (N=158)
Any Haemorrhages (SMQ) (Narrow Scope) Event	36 (8.0)	48 (10.5)	26 (8.8)	31 (19.6)
Cerebral haemorrhage	11 (2.4)	15 (3.3)	6 (2.0)	13 (8.2)
Conjunctival haemorrhage	0	1 (0.2)	0	0
Ecchymosis	1 (0.2)	0	0	0
Epistaxis	0	1 (0.2)	0	0
Extradural haematoma	1 (0.2)	0	1 (0.3)	1 (0.6)
Gastrointestinal haemorrhage	10 (2.2)	4 (0.9)	8 (2.7)	6 (3.8)
Haematuria	1 (0.2)	2 (0.4)	0	3 (1.9)
Haemoptysis	1 (0.2)	1 (0.2)	0	0
Haemorrhage	1 (0.2)	2 (0.4)	0	0
Infusion site haemorrhage	1 (0.2)	4 (0.9)	2 (0.7)	2 (1.3)
Melaena	0	0	0	1 (0.6)
Petechiae	0	1 (0.2)	0	0
Subarachnoid haemorrhage	14 (3.1)	24 (5.3)	12 (4.0)	11 (7.0)
Subdural haematoma	2 (0.4)	2 (0.4)	0	0

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.

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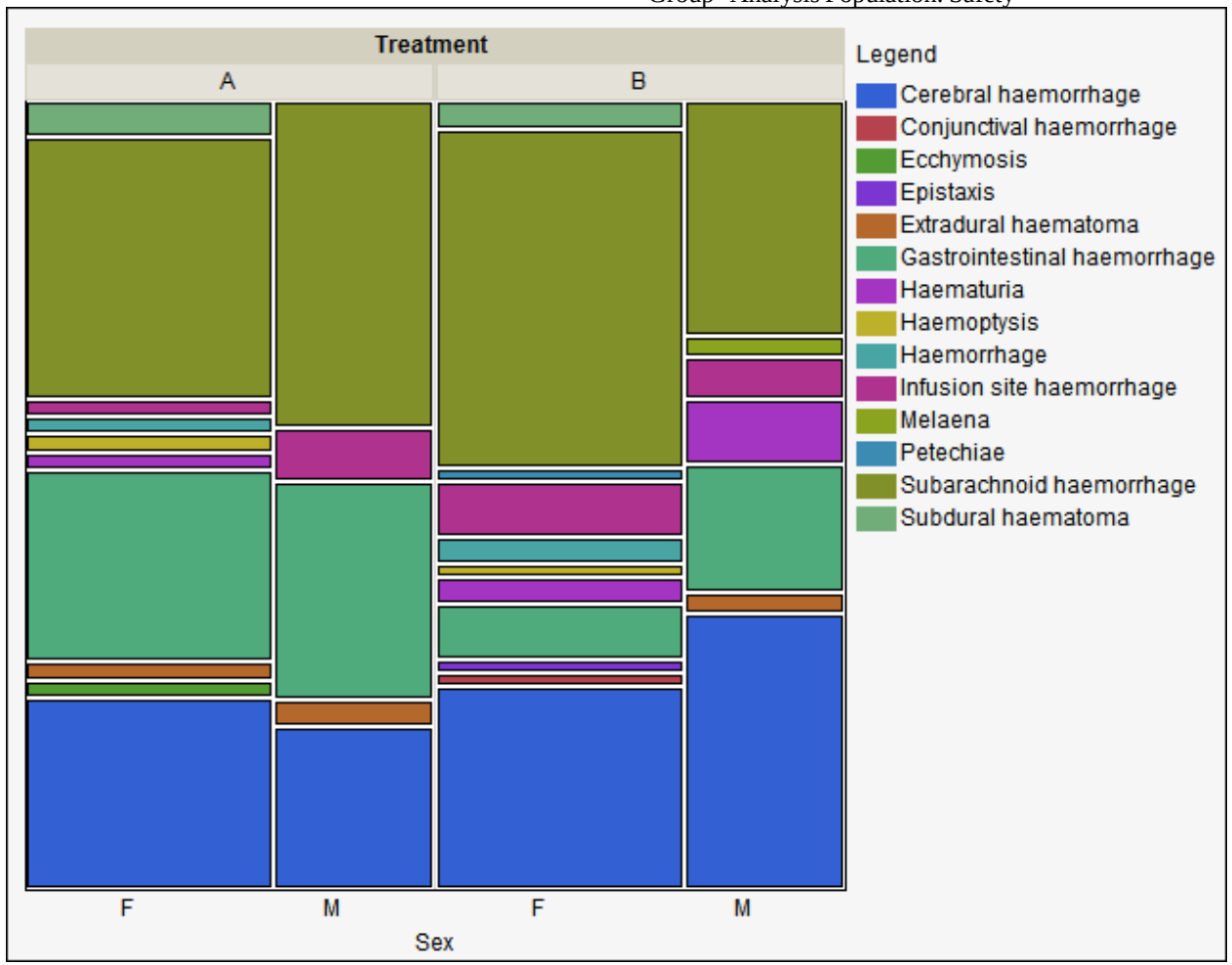
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

Figure 5.1.1 Example of Mosaic Plot of Haemorrhages (SMQ) (Narrow Scope) Preferred Terms by Sex and Actual Treatment Group*
图 5.1.1 按性别和实际治疗组对出血（SMQ）（狭义范围）的首选术语所绘制的马赛克图的实例

Figure 14.2.7.1
Mosaic Plot of Hemorrhagic (SMQ) Preferred Terms by Sex and Actual Treatment Group Analysis Population: Safety



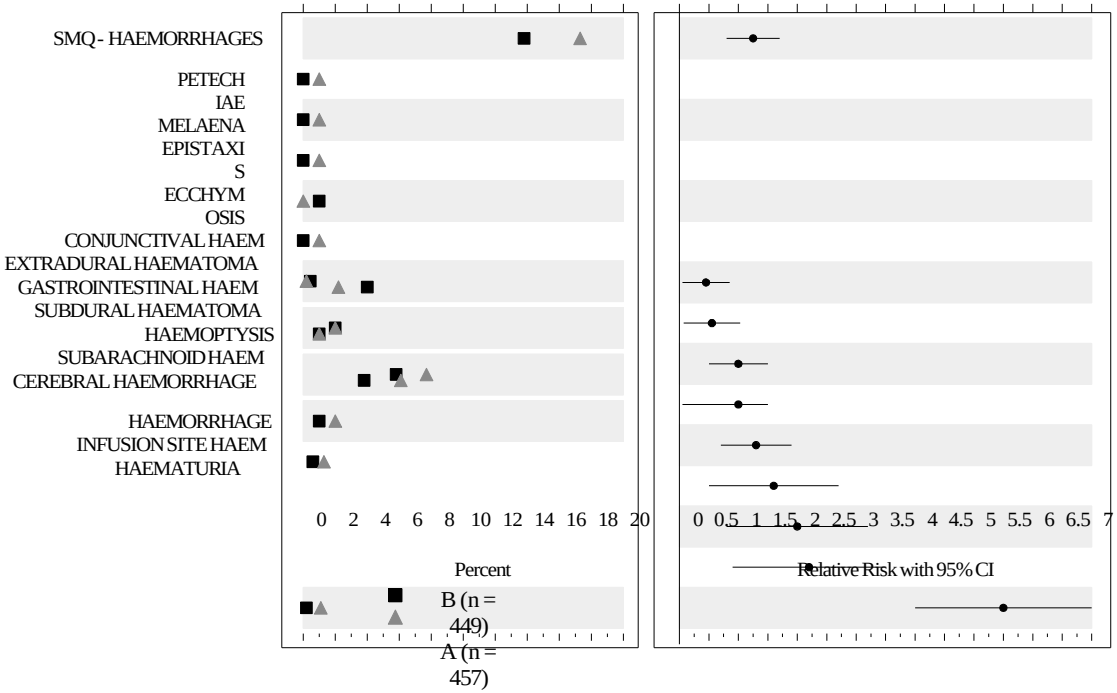
[4] The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.

此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

Figure 5.1.2 Example of Haemorrhages (SMQ) (Narrow Scope) Preferred Terms Sorted by Relative Risk*

图 5.1.2 按相对风险对出血（SMQ）（狭义范围）的首选术语进行排序的实例

Figure 14.2.7.2
Hemorrhagic (SMQ) Preferred Terms Sorted by Relative Risk Analysis Population: Safety Population



5.2 Sample ADaM Variable Metadata

5.2 ADaM 变量元数据样例

This example describes an adverse events ADaM dataset named ADAE. ADAE is not a required dataset name. In Table 5.2.1 below, four variables relate to our primary SMQ of interest (hemorrhage terms), SMQ01CD, SMQ01NAM SMQ01SC, and SMQ01SCN. The '01' indicates that this is the first SMQ and subsequent SMQs or subSMQs would be sequenced accordingly. Note that this ordering can be based on importance or some other producer-defined criteria. The first two of these variables, SMQ01CD and SMQ01NAM contain the numeric code and name for the SMQ from the MedDRA dictionary. The next two variables, SMQ01SC and SMQ01SCN, are character and numeric variables, respectively, that indicate not only whether or not the given AE meets the criteria for the given SMQ, but also whether the term meets the SMQ's broad or narrow scope (the 'SC' suffix is for "scope").
本例描述了名为 ADAE 不良反应的 ADaM 数据集。ADAE 不是必需的数据集名称。在下面的表 5.2.1 中，与我们最感兴趣的 SMQ（描述出血的术语）相关的变量有四个，分别为 SMQ01CD, SMQ01NAM，SMQ01SC 和 SMQ01SCN。"01"代表这是第一次 SMQ，且之后的 SMQs 或 subSMQs 都应该被相应排序。请注意，这种排序可以基于重要性或其他一些由制定者定义的标准。这些变量中的前两个，SMQ01CD 和 SMQ01NAM 包含数字编码，且以 MedDRA 字典中的 SMQ 命名。后两个变量，SMQ01SC 和 SMQ01SCN，分别为字符型及数值型变量，这就不仅显示了给定的 AE 是否达到给定 SMQ 的标准，而且还显示了该术语是否满足 SMQ 广义或狭义的范围（SC 后缀的含义为"scope"）。

Table 5.2.1 Example of ADaM Variable Metadata
表 5.2.1 ADaM 变量元数据的示例

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	USUBJID	Unique Subject Identifier	text		ADSL.USUBJID
ADAE	AETERM	Reported Term for the Adverse Event	text		AE.AETERM
ADAE	AEDECOD	Dictionary-Derived Term	text	MedDRA	AE.AEDECOD
ADAE	AEBODSYS	Body System or Organ Class	text	MedDRA	AE.AEBODSYS
ADAE	ASTDT	Analysis Start Date	integer		<Producer will insert derivation here>
ADAE	AEPTCD	Preferred Term Code	integer		AE.AEPTCD
ADAE	SMQ01CD	SMQ 01 Code	integer		SMQ01CD=20000039 if the AEPTCD is included in this SMQ.
ADAE	SMQ01NAM	SMQ 01 Name	text		SMQ01NAM='Haemorrhage terms (excl. laboratory terms) (SMQ)' if the AEPTCD is included in this SMQ.
ADAE	SMQ01SC	SMQ 01 Scope	text	BROAD, NARROW	For this given SMQ, all scopes are Narrow.
ADAE	SMQ01SCN	SMQ 01 Scope (N)	integer	1, 2	Map SMQ01SC to SMQ01SCN in the following manner: Broad = 1 Narrow = 2

*The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。5.3 Sample ADaM Data

5.3 ADaM 数据样例

Table 5.3.1: Sample ADaM Data Showing SMQ Variables
表 5.3.1 显示 SMQ 变量的 ADaM 数据样例

Row	USUBJID	AETERM	AEDECOD	AEBODSYS	ASTDT*	AEPTCD	SMQ01CD	SMQ01NAM	SMQ01SC	SMQ01SCN
1	0092017	SCLERAL BLEED RIGHT EYE	Scleral haemorrhage	Eye disorders	09JUN2009	10050508	20000039	Haemorrhage terms (excl laboratory terms) (SMQ)	NARROW	2
2	0112012	BRUISING OF LEFT UPPER ARM	Contusion	Injury, poisoning and procedural complications	27AUG2008	10050584	20000039	Haemorrhage terms (excl laboratory terms) (SMQ)	NARROW	2
3	0112012	BRUISING TO LEFT WRIST	Contusion	Injury, poisoning and procedural complications	22AUG2007	10050584	20000039	Haemorrhage terms (excl laboratory terms) (SMQ)	NARROW	2
4	0112013	NAUSEA	Nausea	Gastrointestinal disorders	16JUN2010	10028813				
5	0112014	NOSE BLEEDING	Epistaxis	Respiratory, thoracic and mediastinal disorders	22NOV2009	10015090	20000039	Haemorrhage terms (excl laboratory terms) (SMQ)	NARROW	2
6	0122006	EPISTAXIS	Epistaxis	Respiratory, thoracic and mediastinal disorders	06NOV2009	10015090	20000039	Haemorrhage terms (excl laboratory terms) (SMQ)	NARROW	2

** Variables ending in DT are numeric dates, here shown using SAS date format date9. Other numeric date formats can be used, but care should be taken with newer date formats which might not be understood by all statistical packages.*
**以 DT 为后缀的变量为数值日期，这里显示的使用了 SAS 日期格式 date9。其他数字日期格式也可以使用，但必须小心使用，因为新引进的日期格式可能不会被所有统计软件包识别。*

6 Example 3: Analysis of Peripheral Sensory Neuropathy (PSN) Adverse Events by Severity and Cumulative Dose Exposure

6 示例 3：按疾病严重程度和药物累积剂量对周围感觉神经病变（PSN）不良事件的分析

Some institutions and organizations use standardized coding guidelines for reporting of adverse events. Examples of such standardized scales are [NCI (National Cancer Institute) and ACTG (Antiviral therapeutic area)]. These scales may be based upon variables as collected on AE CRFs, such as a grading scheme based upon severity [AESEV/AESEVN]. Other guidelines may be so objective that some variables, for example, drug relatedness [AEREL/AERELN] are not captured.
一些研究机构和组织使用标准的编码指南来报告不良事件。这些标准化的规则例如：[NCI（美国国家癌症研究所）和 ACTG（抗病毒治疗领域）]。这些规则可能是基于 AE CRFs 上收集的变量，例如基于严重程度[AESEV/AESEVN]的分级准则。其他的指南可能过于客观，以致于某些变量，比如和药物相关性的变量[AEREL/AERELN]没有收集。

In this example the adverse event analysis dataset is used to summarize the frequency of peripheral sensory neuropathy (PSN) by cumulative dose exposure in an oncology study. In this study PSN was reported on the CRF at each cycle and at each 6-month follow-up visit, using the National Cancer Institute Common Toxicity Criteria (NCI CTC) version 4.03 [10] Peripheral sensory neuropathy (MedDRA v12.0 Code = 10034620):
此例为在一个肿瘤研究中，不良事件分析数据集按药物累积剂量对周围感觉神经病变（PSN）不良事件进行频数汇总分析。在这个研究中的每一个用药周期和间隔 6 个月的随访，PSN 会根据美国国家癌症研究所规定的常见毒性标准(NCI CTC)版本号 4.03 [10]被记录在病例报告表中。周围感觉神经病变(MedDRA 版本 12.0 编码 = 10034620)：

- Grade 0 = None;
  等级 0 = 无；
- Grade 1 = Asymptomatic; loss of deep tendon reflexes or paresthesia;
  等级 1 = 无症状；深层腱反射消失；
- Grade 2 = Moderate symptoms; limiting instrumental ADL;
  等级 2 = 轻度症状；有限的日常家务活；
- Grade 3 = Severe symptoms; limiting self care ADL;
  等级 3 = 严重症状；有限的日常自我照顾活动；
- Grade 4 = Life-threatening consequences; urgent intervention indicated;
  等级 4 = 后果危及生命；需要紧急医疗干预；
- Grade 5 = Death.
  等级 5 = 死亡；

As a result of using this means of reporting, the PSN events reported in this module were all coded to ‘paresthesia’.
作为使用这种报告方式的结果，在这个模块报告的 PSN 事件都被编码成“感觉异常”。

6.1 Analysis Display Example Layout

6.1 示例分析结果样式

Table 6.1.1 Example of Summary of Cumulative Dose Quartiles to First Onset for PSN by Severity Grade*
表 6.1.1 按严重程度汇总的 PSN 首次发病时累积剂量的四分位数示例*

Table 6.1.1 Example of Summary of Cumulative Dose Quartiles to First Onset for PSN by Severity Grade*

Table 14.2.7.4

Summary of cumulative dose quartiles to first onset for PSN by severity grade

Analysis population: Intent-to-treat

Cumulative dose	Number of patients Exposed	PSN grade			
		Number (%) of patients with grade ≥ 1	Number (%) of patients with grade ≥ 2	Number (%) of patients with grade ≥ 3	Number (%) of patients with grade 4 or 5
Total number of patients with PSN		x (x.x)	x (x.x)	x (x.x)	x (x.x)
1st quartile (3 cycles)	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2nd quartile (6 cycles)	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3rd quartile (9 cycles)	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4th quartile (12 cycles)	N	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Median cumulative dose to first onset (mg/m^2)		X	X	X	X

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。6.2 Sample ADaM Variable Metadata

6.2 ADaM 变量元数据示例

This example describes an adverse events ADaM dataset named ADAE. ADAE is not a required dataset name.
本例描述的是名为 ADAE 的不良反应 ADaM 数据集。ADAE 不是必须的数据集名称。

Table 6.2.1: Sample ADaM Variable Metadata for selected variables
表 6.2.1：示例 ADaM 对选定变量的元数据

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	USUBJID	Unique Subject Identifier	text		ADSL.USUBJID
ADAE	ITTFL	Intent-to-Treat Population Flag	text	Y,N	ADSL.ITTFL
ADAE	AEDECOD	Dictionary-Derived Term	text	MedDRA	AE.AEDECOD
ADAE	AETOXGR	Standard Toxicity Grade	text	1, 2, 3, 4, 5	AE.AETOXGR
ADAE	AETOXGRN	Standard Toxicity Grade (N)	integer	1, 2, 3, 4, 5	Code AE.AETOXGR to numeric
ADAE	DOSCUMA	Cumulative Actual Treatment Dose	float		Total all values of EX.EXDOSE for the subject up to the start of the AE.
ADAE	DOSEU	Treatment Dose Units	text	mg	EX.EXDOSEU
ADAE	DOSCMGR1	Cumulative Dose Group 1	text	Quartile 1, Quartile 2, Quartile 3, Quartile 4	Missing if DOSCUMA=0, else DOSCMGR1 = Quartile 1 if DOSCUMA is in the 1st Quartile, Quartile 2 if in the 2nd Quartile, Quartile 3 if in the 3rd Quartile and Quartile 4 if in the 4th Quartile.

6.3 Sample ADaM Data

6.3 示例 ADaM 数据

Key points to note in the example are:
例子中需要注意的关键点：

1. Variable DOSCMGR1 is not a standard variable. It has been added for analysis purposes and uses the naming conventions from the ADaMIG.
   变量 DOSCMGR1 不是一个标准的变量。它是出于分析目的而被加入的，并且使用来自 ADaMIG 的命名规则。

2. This is a simple example to only illustrate the cumulative dose variables that can be added to ADAE. It does not include additional variables that would also be needed for analysis like a flag to indicate the first occurrence for PSN.

这个简单的例子仅仅是用来说明累积剂量变量能够被添加到 ADAE。它不包括分析中也是需要的额外变量，如标记 PSN 第一次出现的标帜。

3. Row 3 and 7 include two patients who had no dose of study drug at the time of PSN and would not be included in the table.
   第 3 和 7 行包括这样的 2 个病人，他们在第一次出现 PSN 的时候没有使用试验药物，因此不应该出现在这个表格里面。

Table 6.3.1: Sample ADaM Data Showing Cumulative Dose Variables
表 6.3.1： 展示累积剂量变量的 ADaM 数据示例

Row	USUBJID	ITTFL	AEDECOD	AETOXGR	AETOXGRN	DOSCUMA	DOSEU	DOSCMGR1
1	101-002	Y	PARESTHESIA	3	3	247.06	mg	Quartile 1
2	101-003	Y	PARESTHESIA	2	2	674.02	mg	Quartile 3
3	101-005	Y	PARESTHESIA	1	1	0	mg	
4	101-006	Y	PARESTHESIA	2	2	900.00	mg	Quartile 4
5	101-008	Y	PARESTHESIA	4	4	493.30	mg	Quartile 2
6	101-010	Y	PARESTHESIA	3	3	894.29	mg	Quartile 4
7	101-012	Y	PARESTHESIA	1	1	0	mg	

7 Example 4: Analysis of Treatment Emergent Adverse Events in a Cross-Over Interaction Study

7 例 4： 在交叉设计试验中治疗期不良事件的分析

This example is a phase I, open-label, three period cross-over study. Subjects are treated for 7 days within each period with a 7 day wash-out between periods. In each period, subjects are to receive one of 3 treatments (A, B, or A + B combined) in order of the sequence they are randomized to. Treatment emergent AEs were defined as AEs that occurred or worsened from the start of the treatment period through 72 hours after the end of the treatment period. Non-treatment emergent AEs were those that occurred before the first treatment period or more than 72 hours after the end of the treatment period until the start of the next treatment period. Post-treatment emergent AEs were those that occurred more than 72 hours after the last treatment period.
该例是一个一期，开放性，分 3 个阶段的交叉设计试验。受试者接受每阶段为期 7 天的治疗，阶段之间会有 7 天的洗脱期。在每一阶段，受试者将按照他们随机获得的顺序接受 3 种治疗 (A, B, 或 A + B 组合)。治疗期的 AE 定义为从治疗阶段开始到结束后 72 小时内发生或加重的 AE。非治疗期的 AE 就是那些在治疗阶段之前发生或者在结束 72 小时之后并且在下阶段治疗开始之前发生的 AE。治疗后出现的 AE 是指发生在最后阶段治疗结束后 72 小时之后的 AE。

In addition to standard cross-over analysis, this example also includes analysis using both a primary and a secondary coding path.
除了标准的交叉试验分析之外，这个例子也包括同时使用主要和次要的代码路径。

7.1 Analysis Display Example Layout

7.1 分析结果样式示例

Table 7.1.1 Example of Summary of Treatment Emergent AEs by System Organ Class and Preferred Term and Treatment Group*
表 7.1.1 按系统器官类别和首选术语及治疗组汇总的治疗期不良事件的示例* 表 14.2.7.5

Table 14.2.7.5
表 14.2.7.5
Summary of Treatment Emergent AEs by System Organ Class and Preferred Term and Treatment Group
按器官系统类别和首选术语及治疗组汇总的治疗期不良事件
Analysis Population: Safety
分析人群：安全集

SYSTEM ORGAN CLASS Preferred Term	Treatment A (N = xxx)		Treatment B (N = xxx)		Treatment A + B (N = xxx)	
	n (%)	No. of events	n (%)	No. of events	n (%)	No. of events
Any TEAE	x (x.x)	x	x (x.x)	x	x (x.x)	x
GASTROINTESTINAL DISORDER	x (x.x)	x	x (x.x)	x	x (x.x)	x
Nausea	x (x.x)	x	x (x.x)	x	x (x.x)	x
Constipation	x (x.x)	x	x (x.x)	x	x (x.x)	x
Vomiting	x (x.x)	x	x (x.x)	x	x (x.x)	x
Diarrhoea	x (x.x)	x	x (x.x)	x	x (x.x)	x
INFECTIONS AND INFESTATIONS	x (x.x)	x	x (x.x)	x	x (x.x)	x
Pharyngitis	x (x.x)	x	x (x.x)	x	x (x.x)	x
NERVOUS SYSTEM DISORDERS	x (x.x)	x	x (x.x)	x	x (x.x)	x
Headache	x (x.x)	x	x (x.x)	x	x (x.x)	x
Dizziness	x (x.x)	x	x (x.x)	x	x (x.x)	x
Syncope	x (x.x)	x	x (x.x)	x	x (x.x)	x
<Other SOCs and PTs>						

TEAE = treatment emergent adverse event
TEAE= 治疗期不良事件

N = Safety subjects, i.e., subjects who received at least one dose of study drug in that particular period
N=符合安全集的受试者，即那些至少接受一剂试验药物的受试者

n = Number of subjects reporting at least one treatment emergent adverse event
n=至少有一次治疗后不良事件的受试者的人数
% = n / N * 100
% = n / N * 100

Adverse events are presented by descending frequency of SOC and PT within SOC within Treatment A+B
不良事件按在 A+B 组内系统器官类别的频数和系统器官类别内首选术语的频数降序排列来展示

System organ classes and preferred terms are coded using MedDRA version x.x.
系统器官类别和首选术语是使用 MedDRA x.x 版本编码

*The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
*此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

7.2 Sample ADaM Variable Metadata

7.2 ADaM 变量的元数据样例

This example describes an adverse events ADaM dataset named ADAE. ADAE is not a required dataset name.
本例描述的是名为 ADAE 的不良反应 ADaM 数据集。ADAE 不是必需的数据集。

Table 7.2.1: Sample ADaM Variable Metadata for selected variables
表 7.2.1：ADaM 对选定变量的元数据样例

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	USUBJID	Unique Subject Identifier	text		ADSL.USUBJID
ADAE	TRTA	Actual Treatment	text	Treatment A, Treatment B, Treatment A+B	ADSL.TRT01A if in the 1st period, ADSL.TRT02A if in the 2nd period, or ADSL.TRT03A if in the 3rd period
ADAE	TRTAN	Actual Treatment	integer	1, 2, 3	Code TRTA to numeric. Treatment A = 1 Treatment B = 2 Treatment A+B = 3
ADAE	SAFFL	Safety Population Flag	text	Y,N	ADSL.SAFFL
ADAE	AEBODSYS	Body System or Organ Class	text	MedDRA	AE.AEBODSYS
ADAE	AEDECOD	Dictionary-Derived Term	text	MedDRA	AE.AEDECOD
ADAE	ASTDTM	Analysis Start Date/Time	integer		Converting AE.AESTDTC from character ISO8601 format to numeric date format, applying producer defined imputation rules.
ADAE	ASTDTF	Analysis Start Date Imputation Flag	text	D, M, Y	The level of imputation done for the start date (D if day was imputed, M if month was imputed, or Y if year was imputed).
ADAE	ASTTMF	Analysis Start Time Imputation Flag	text	M, H	The level of imputation done for the start time (H if hour was imputed, M if minutes were imputed).
ADAE	TRTEMFL	Treatment Emergent Analysis Flag	text	Y	If ADSL.TR01SDTM LE ASTDTM LE (ADSL.TR01EDTM+72 hours) or ADSL.TR02SDTM LE ASTDTM LE (ADSL.TR02EDTM+72 hours) or ADSL.TR03SDTM LE ASTDTM LE (ADSL.TR03EDTM+72 hours) then TRTEMFL=Y
ADAE	PREFL	Pre-treatment Flag	text	Y	If TRTEMFL ^='Y' and FUPFL^='Y' then PREFL='Y'
ADAE	FUPFL	Follow-up Flag	text	Y	if ASTDTM GT (ADSL.TR03EDTM+72 hours) then FUPFL='Y'
ADAE	ASTDY	Analysis Start Relative Day	integer		Date portion of ASTDTM- date portion of ADSL.TRT01SDTM+1 day if date portion of ASTDTM is on or after date portion of TRT01SDTM, else date portion of ASTDTM- date portion of ADSL.TR01SDTM if date portion of ASTDTM precedes date portion of TR01SDTM

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADAE	EPOCH	Epoch	text	RUN-IN, FIRST TREATMENT, FIRST WASHOUT, SECOND TREATMENT, SECOND WASHOUT, THIRD	AE.EPOCH
ADAE	APHASE	Phase	text	RUN-IN, FIRST TREATMENT, FIRST	If AESDTM < ADSL.TR01SDTM then APHASE='RUN-IN', else ifADSL.TR01SDTM LE AESDTM LE(ADSL.TR01EDTM+72 hours)
				TREATMENT, SECOND WASHOUT, THIRD TREATMENT, FOLLOW-UP	then APHASE ='FIRST TREATMENT', else if(ADSL.TR01EDTM+72 hours) < AESDTM< ADSL.TR02SDTM then APHASE='FIRST WASHOUT', etc.
ADAE	APERIOD	Period	integer	1, 2, 3	If TR01SDTM LE ASTDTM LE (TR01EDTM+72 hours) then APERIOD=1, else if TR02SDTM LE ASTDTM LE (TR02EDTM+72 hours) then APERIOD=2, else if TR03SDTM LE ASTDTM LE (TR03EDTM+72 hours) then APERIOD=3,
ADAE	APERIODC	Period (C)	text	PERIOD 01, PERIOD 02, PERIOD 03	If APERIOD=1 then APERIODC='PERIOD 01', else if APERIOD=2 then APERIODC='PERIOD 02', else if APERIOD=03 then APERIODC='PERIOD 03'
ADAE	TR01SDTM	Datetime of First Exposure in Period 01	integer		ADSL.TR01SDTM
ADAE	TR01EDTM	Datetime of Last Exposure in Period 01	integer		ADSL.TR01EDTM
ADAE	TR02SDTM	Datetime of First Exposure in Period 02	integer		ADSL.TR02SDTM
ADAE	TR02EDTM	Datetime of Last Exposure in Period 02	integer		ADSL.TR02EDTM
ADAE	TR03SDTM	Datetime of First Exposure in Period 03	integer		ADSL.TR03SDTM
ADAE	TR03EDTM	Datetime of Last Exposure in Period 03	integer		ADSL.TR03EDTM

7.3 Sample ADaM Data

7.3 ADaM 数据样例

Table 7.3.1 is an illustration of the adverse events analysis dataset (ADAE) defined above.
表 7.3.1 图例说明上面定义的不良事件分析数据集（ADAE）。

Key points to note in the example are:
例子中需要注意的关键点：

1. The SDTM variable EPOCH was kept for traceability and to illustrate the differences between this variable and APHASE and APERIOD.

SDTM 的变量 EPOCH 是出于可追溯性的目的而被保留下来，并且用来说明它和变量 APHASE, APERIOD 之间的区别。

2. Treatment start and end datetimes for each period were kept and used to calculate APERIOD and TRTEMFL. Another option would have been to use ADSL variables relating to period start and end datetimes (APxxSDTM and APxxEDTM). However, if different periods for efficacy and safety were defined this latter option wouldn't work.
   每一个阶段的治疗开始和结束的日期和时间都被保留下来用来计算变量 APERIOD 和 TRTEMFL。另一种选择是可以使用 ADSL 里面关于阶段开始和结束的日期时间变量(APxxSDTM and APxxEDTM)。然而，对于疗效分析和安全性分析，如果阶段的定义是不同的，那么后面的这种选择就不可行。

3. The producer of the dataset chose to populate APERIOD as an analysis period where the wash-out and follow-up period were not populated for APERIOD. The same applied for the record level actual treatment variable (TRTA) which was left missing for records not associated with a treatment. However, this is left up to the producer.
   数据集的制作人选择用 APERIOD 作为分析阶段，其中洗脱期和随访期都不在 APERIOD 里面。相同的方法应用到了记录级别实际治疗变量(TRTA)，这个变量里面和治疗无关的记录都设置成缺失值。然而，这些都是由制作人来决定的。

4. Row 5 indicates an AE that occurs in the follow-up EPOCH, is post-treatment emergent and not related to any analysis period or treatment.
   第 5 行显示一个 AE 发生在随访阶段，属于治疗后出现的，且与任何分析阶段或治疗无关。

5. Row 8 indicates an AE that occurs in the follow-up epoch but within the third treatment phase and analysis period and associated with treatment A + B.
   第 8 行显示的是一个发生在随访阶段，但属于第三治疗期和分析阶段，且和治疗 A+B 有关的 AE。

Table 7.3.1: Sample ADaM Data
表 7.3.1: ADaM 数据样例

Row	USUBJID	TRTA	TRTAN	SAFFL	AEBODSYS	AEDECOD	ASTDTM*	ASTDTF	ASTTMF	TRTEMFL	PREFL	FUPFL	ASTDY	EPOCH
1	101-001	A	1	Y	GASTROINTESTINAL DISORDERS	VOMITING	05MAY08:16:00:00		M	Y			5	FIRST TREATMENT
2	101-001	B	2	Y	INFECTIONS AND INFESTATIONS	PHARYNGITIS	16MAY08:06:42:00			Y			16	SECOND TREATMENT
3	101-001	A+B	3	Y	NERVOUS SYSTEM DISORDERS	HEADACHE	01JUN08:15:30:00			Y			32	THIRD TREATMENT
4	101-001	A+B	3	Y	NERVOUS SYSTEM DISORDERS	CONSTIPATION	02JUN08:07:15:00			Y			33	THIRD TREATMENT
5	101-001			Y	INFECTIONS AND INFESTATIONS	ORAL HERPES	07JUN08:08:00:00					Y	38	FOLLOW-UP
6	101-002			Y	VASCULAR DISORDERS	HYPOTENSION	25MAY08:13:20:00				Y		26	SECOND WASHOUT
7	101-002	A+B	3	Y	NERVOUS SYSTEM DISORDERS	HEADACHE	27MAY08:22:10:00			Y			28	THIRD TREATMENT
8	101-002	A+B	3	Y	NERVOUS SYSTEM DISORDERS	HEADACHE	02JUN08:22:10:00			Y			34	FOLLOW-UP

** Variables ending in DTM are numeric datetimes, here shown using SAS format datetime16. Other numeric datetime formats can be used, but care should be taken with newer formats which might not be understood by all statistical packages.*

**以 DTM 结尾的变量是数值型日期格式的变量，这里是使用 SAS datetime16 格式显示。其他数值型日期时间格式也可以使用，但需要注意的是较新的格式可能不会被所有的统计软件识别。*

Row	APHASE	APERIOD	APERIODC	TR01SDTM*	TR01EDTM*	TR02SDTM*	TR02EDTM*	TR03SDTM*	TR03EDTM*
1 (cont)	FIRST TREATMENT	1	PERIOD 01	01MAY08:10:05:00	07MAY08:09:10:10	15MAY08:08:15:00	21MAY08:10:30:00	20MAY08:13:50:00	03JUN08:07:20:00
2 (cont)	SECOND TREATMENT	2	PERIOD 02	01MAY08:10:05:00	07MAY08:09:10:00	15MAY08:08:15:00	21MAY08:10:30:00	29MAY08:13:50:00	03JUN08:07:20:00
3 (cont)	THIRD TREATMENT	3	PERIOD 03	01MAY08:10:05:00	07MAY08:09:10:00	15MAY08:08:15:00	21MAY08:10:30:00	29MAY08:13:50:00	03JUN08:07:20:00
4 (cont)	THIRD TREATMENT	3	PERIOD 03	01MAY08:10:05:00	07MAY08:09:10:00	15MAY08:08:15:00	21MAY08:10:30:00	29MAY08:13:50:00	03JUN08:07:20:00
5 (cont)	FOLLOW-UP			01MAY08:10:05:00	07MAY08:09:10:00	15MAY08:08:15:00	21MAY08:10:30:00	29MAY08:13:50:00	03JUN08:07:20:00
6 (cont)	SECOND WASHOUT			30APR08:12:05:00	06MAY08:08:32:00	14MAY08:11:55:00	20MAY08:08:10:00	26MAY08:15:40:00	01JUN08:09:13:00
7 (cont)	THIRD TREATMENT	3	PERIOD 03	30APR08:12:05:00	06MAY08:08:32:00	14MAY08:11:55:00	20MAY08:08:10:00	26MAY08:15:40:00	01JUN08:09:13:00
8 (cont)	THIRD TREATMENT	3	PERIOD 03	30APR08:12:05:00	06MAY08:08:32:00	14MAY08:11:55:00	20MAY08:08:10:00	26MAY08:15:40:00	01JUN08:09:13:00

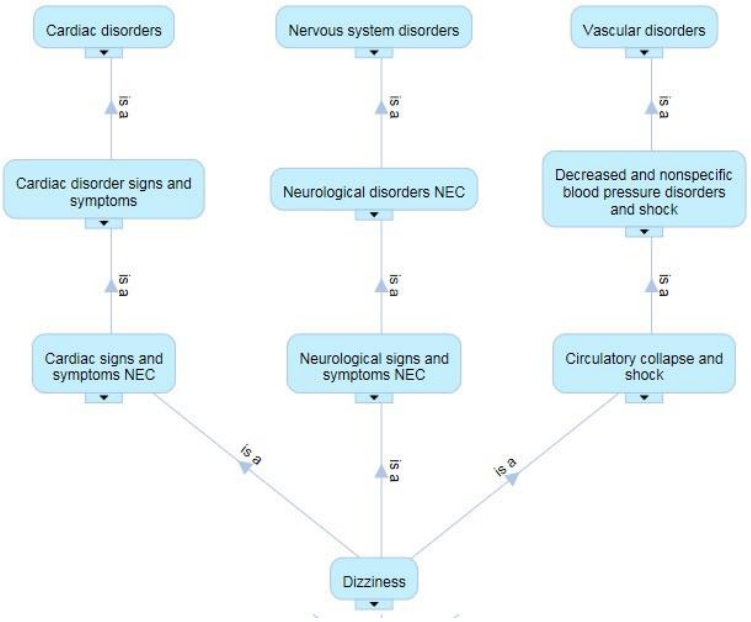
** Variables ending in DTM are numeric datetimes, here shown using SAS format datetime16. Other numeric datetime formats can be used, but care should be taken with newer formats which might not be understood by all statistical packages.*

**变量以 DTM 结尾的是数值型日期格式，这里是使用 SAS datetime16 格式显示。其他日期时间格式也可以使用，但需要注意的是较新的格式可能不会被所有的统计软件识别。*8 Example 5: MedDRA Secondary Path

8 示例：MedDRA 的次要编码路径

In MedDRA, a collected term can be mapped along more than one path, as shown in the diagram below.
如下图所示，在《ICH 国际医学用语词典》（MedDRA）中，一个收集的术语可以有不止一种路径进行编码。

Figure 8.1: Possible MedDRA Coding Paths for term "Dizziness" [15]
图 8.1：术语“眩晕”可能的 MedDRA 编码路径



Whenever more than one path is possible, there is always a primary coding path plus one or more secondary paths. When a secondary path will be used for analysis, SDTMIG version 3.2 allows for capture of both a primary and secondary System Organ Class (SOC), as described in the CDISC Notes column for these variables:
当有不止一种编码路径时，总会有一个主编码路径和一个或一个以上的次编码路径。当次编码路径需用于分析，SDTMIG 3.2 版本允许同时收集主、次系统器官分类（SOC），正如在“CDISC 注释”中对以下变量的描述：

- **AEBODSYS**: “Dictionary derived. Body system or organ class used by the sponsor from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor’s analyses and summary tables which may not necessarily be the primary SOC.”
  AEBODSYS：“词典衍生。申办方使用系统器官分类，源自编码词典（如 MedDRA）。当使用的词典为多轴时，如 MedDRA，本变量应包含用于申办者分析与总结表格的 SOC，不必是主 SOC。”
- **AESOC**: “Dictionary-derived text description of the primary System Organ Class. Will be the same as AEBODSYS if the primary SOC was used for analysis.”
  AESOC：“词典衍生的主系统器官分级的文本描述。当主 SOC 用于分析时，等同于 AEBODSYS。”

As with other SDTM variables, these are typically copied from SDTM to ADaM and used directly in the occurrence analysis. 和其他 SDTM 变量一样，这些变量通常是从 SDTM 复制到 ADaM 中，直接用于事件类数据的分析。

This section describes different ways to handle multiple coding paths and gives an example on how to create a single analysis dataset with two different coding paths.
这一章节将会描述处理多个编码路径的不同方法，并用一个示例来说明如何生成一个有两种不同编码路径的分析数据集。

Typically adverse event analysis includes only the primary coding path. However, some indications also perform analysis on the secondary path. For example in study of brain cancer, a headache might need to be analyzed according to a secondary path that attributes this to the cancer. This is why SDTM has the option of including two different paths.
通常不良事件分析只包含主编码路径。然而，一些适应症也会对次编码路径进行分析。例如在脑肿瘤的研究，头痛可能需要根据可将它归因于肿瘤的次编码路径进行分析。这也是 SDTM 有收集两种不同编码路径的选择的原因。

When a secondary path is used, often the analysis need is:

当需要用次编码路径时，通常是需要分析：

- One set of tables showing primary path, such as shown in section 4, using AESOC for analysis.
  一组展示主编码路径的分析表格，正如第四章所述，用 AESOC 进行分析。

- Another separate set of tables showing secondary path, similar to what is shown in section 4 but using AEBODSYS for analysis.
  另一组展示次编码路径的分析表格，和第四章所述类似，但用 AEBODSYS 进行分析。

For this type of analysis need, analysis can be made straightforward by creating one dataset for the primary path tables, and a separate dataset for the secondary path tables. The remainder of this section describes an analysis need beyond this, where both primary and secondary analyses are performed on the same table.
对这类分析需求，可以直接通过创建一个用于输出主编码路径分析表格的数据集和一个用于输出次编码路径分析表格的数据集来实现。本章节接下来会描述除此之外的一种分析需求，可以同时把主、次分析都放在同一个表格里。

8.1 Analysis Display Example

8.1 示例分析结果样式

The analysis need is to produce the following table:
分析的目的是为了输出下列的表格：

Table 8.1.1: Example Analysis Display*
表 8.1.1：示例分析结果展示*

Table 14.2.8.3
Treatment Emergent AEs by Primary and Secondary SOCs, Preferred Term (Population: Safety Subjects)

System Organ Class Preferred Term	Placebo (n=xxx)		Drug X (n=xxx)	
	Primary SOC	Primary + Secondary n (%) SOC n (%)	Primary SOC	Primary + Secondary n (%) SOC n (%)
CARDIAC DISORDERS	0 (x.x)	0 (x.x)	0 (x.x)	1 (x.x)
Dizziness [2]	0 (x.x)	0 (x.x)	0 (x.x)	1 (x.x)
ENDOCRINE DISORDERS	0 (x.x)	1 (x.x)	2 (x.x)	2 (x.x)
Autoimmune thyroiditis [1] Thyroid atrophy[1]	0 (x.x)	0 (x.x)	1 (x.x)	1 (x.x)
	0 (x.x)	1 (x.x)	1 (x.x)	1 (x.x)
NERVOUS SYSTEM DISORDERS	2 (x.x)	2 (x.x)	1 (x.x)	1 (x.x)
Dizziness [1]	2 (x.x)	2 (x.x)	1 (x.x)	1 (x.x)
VASCULAR	0 (x.x)	1 (x.x)	0 (x.x)	0 (x.x)
DISORDERS	0 (x.x)	1 (x.x)	0 (x.x)	0 (x.x)
Dizziness [2]				

SOC = System Organ Class;
[1] Preferred term comes from primary system organ class path
[2] Preferred term comes from secondary system organ class path

8.2 Sample SDTM AE Data

8.2 示例 SDTM AE 数据

As described above in the introduction to this section, both SDTM variables AEBODSYS and AESOC are included in the SDTM AE data, and each represents a different coding path used for analysis. In table 8.2.1 below, notice that AEBODSYS and AESOC are the same on some rows but different on others. When only a primary path is to be used, the values of AEBODSYS and AESOC are the same. When a secondary path is to be used, AEBODSYS and AESOC are different. For the purpose of this example we see that the AE Dizziness was coded to different MedDRA coding paths in different subjects based on further information available.
如本章前面介绍部分所述，SDTM 变量 AEBODSYS 和 AESOC 都会包含在 SDTM AE 数据集中，它们各自代表用于分析的不同编码路径。在下表

8.2.1 中，请注意 AEBODSYS 和 AESOC 在有些行中是相同的，而在其他一些行中是不同的。当只有主编码路径用于分析时，AEBODSYS 和 AESOC 的值是一样的。当次编码路径用于分析时，AEBODSYS 和 AESOC 的值则是不一样的。通过这个示例，我们可以看到，对不同的受试者，基于其可用补充信息，不良事件--眩晕可以按不同的 MedDRA 编码路径进行编码。

Table 8.2.1: Sample SDTM AE data for selected variables
表 8.2.1：SDTM AE 选定变量的示例数据

Row	STUDYID	USUBJID	AESEQ	AEDECOD	AEBODSYS	AESTDTC	AESOC
1	XYZ	XYZ-1-001	1	Autoimmune thyroiditis	Endocrine disorders	2008-05-13	Endocrine disorders
2	XYZ	XYZ-1-001	2	Dizziness	Cardiac disorders	2008-06-13	Nervous system disorders
3	XYZ	XYZ-2-002	1	Dizziness	Vascular disorders	2008-09-13	Nervous system disorders
4	XYZ	XYZ-3-003	1	Thyroid atrophy	Endocrine disorders	2008-09-13	Endocrine disorders
5	XYZ	XYZ-4-004	1	Dizziness	Nervous system disorders	2008-09-09	Nervous system disorders

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
*此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

8.3 Sample ADaM Data

8.3 示例 ADaM 数据

As mentioned earlier in this section, a typical way to analyze adverse event data with multiple paths is to split the different coding paths into separate analysis datasets. Each analysis dataset would contain the records from the SDTM AE dataset, but one dataset would use AEBODSYS for analysis and the other would use AESOC. Dataset metadata, including dataset labels and documentation, would explain the different datasets and their individual analysis purposes.
如前所述，对包含多种编码路径的不良事件数据分析的一种常规方式是按不同的编码路径分别划分不同的分析数据集。每一个分析数据集都包含来自 SDTM AE 的记录，但一个数据集会用 AEBODSYS 进行分析，而另一个数据集则会用 AESOC 进行分析。这些不同的数据集及其各自的分析目的将会在包括了数据集标签和文档的数据集元数据中加以说明。

In this case, the data were kept in a single analysis dataset, with rows for each coding path, as shown in table 8.3.1, to facilitate analysis for the table shown in table 8.1.1.
在本示例中，为了便于进行表 8.1.1 所示的分析，所有的数据会存放在一个包含有各种编码路径的分析数据集中，如表 8.3.1 所示。

Key points to note in the example are:
示例中需注意的要点：

1. The analysis record flag variables can be used to differentiate between primary path and secondary path records. In this example, ANL01FL is used to identify the primary coding path and ANL02FL is used to identify the secondary coding path.
   分析记录标识变量可用于区分主编码路径和次编码路径。在本示例中，ANL01FL 用于标识主编码路径，ANL02FL 用于标识次编码路径。

2. Row 2 and 3 represent a single adverse event of Dizziness from SDTM. It was coded to two system organ classes: Nervous system disorders (primary

SOC) and Cardiac disorders (original coding). Both rows in ADAE have the same value of AESEQ.
第2、3行观测代表来自SDTM的一个不良事件—眩晕。它出现在两种系统器官分类中：神经系统疾病（主SOC）和心脏疾病（原始编码）。在ADAE中，这两行观测对应的AESEQ的值是相同的。

3. Rows 4 and 5 represent a single adverse event of Dizziness. It was coded to two system organ classes: Nervous system disorders (primary SOC) and Vascular disorders (original coding). Both rows in ADAE have the same value of AESEQ.
第4、5行观测代表一个不良事件--眩晕。它出现在两种系统器官分类中：神经系统疾病（主SOC）和血管疾病（原始编码）。在ADAE中，这两行观测对应的AESEQ的值是相同的。

4. Rows 6-7 use only one path, so no additional records are necessary.
第6、7行观测只用一种编码路径，因此没有必要记录更多的观测。

5. AEBODSYS and AESOC are unchanged from SDTM. New variable ASOC is added as an analysis version of the body system to facilitate the analysis. ASOC is not a required name.
来自SDTM的AEBODSYS和AESOC保持不变。为便于分析，新增的一个变量ASOC会用于记录身体系统的分析版本。但ASOC不是一个必需的变量名。

6. The purpose of this example is not to state how MedDRA secondary paths are to be handled, only to provide an example.
本示例的目的不是为了陈述如何处理 MedDRA 次编码路径，只是提供一个示例。

Table 8.3.1: Sample ADaM ADAE data for selected variables
表 8.3.1：ADaM ADAE 选定变量的示例数据

Row	USUBJID	TRTA	AESEQ	AEDECOD	AEBODSYS	AESOC	ASOC	ANL01FL	ANL02FL
1	XYZ-1-001	Drug X	1	Autoimmune thyroiditis	Endocrine disorders	Endocrine disorders	Endocrine disorders	Y	
2	XYZ-1-001	Drug X	2	Dizziness	Cardiac disorders	Nervous system disorders	Cardiac disorders		Y
3	XYZ-1-001	Drug X	2	Dizziness	Cardiac disorders	Nervous system disorders	Nervous system disorders	Y	
4	XYZ-2-002	Placebo	1	Dizziness	Vascular disorders	Nervous system disorders	Vascular disorders		Y
5	XYZ-2-002	Placebo	1	Dizziness	Vascular disorders	Nervous system disorders	Nervous system disorders	Y	
6	XYZ-3-003	Drug X	1	Thyroid atrophy	Endocrine disorders	Endocrine disorders	Endocrine disorders	Y	
7	XYZ-4-004	Placebo	1	Dizziness	Nervous system disorders	Nervous system disorders	Nervous system disorders	Y	

9 Example 6: Analysis of Concomitant Medications

9 示例 6：合并用药的分析

This example displays a simple summary of all concomitant medications. The example is based on a two treatment parallel design study. The display summarizes (1) the number of patients in each treatment group who took a concomitant medication and (2) the rate of occurrence in each treatment group. In this example, analysis results metadata have not been included. As stated in the ADaMIG, analysis results metadata are not needed or even advisable for every analysis included in a clinical study report or submission.
此示例展示了一份对全部合并用药的简单汇总。该示例基于一项双治疗组平行设计试验。该示例展示汇总了（1）每个治疗组中具有某特定合并用药的受试者数目（2）每个治疗组中的发生率。此示例没有包括分析结果元数据。如 ADaMIG 中规定，每项分析不需要或甚至建议性的分析结果元数据包含于临床研究总结报告和提交中。

9.1 Analysis Display Example Layout

9.1 分析展示布局示例

Table 9.1.1 Example of Summary of Concomitant Medications*
表 9.1.1 合并用药示例

Table 14.1.5
Summary of Concomitant Medications by Medication Class
and Preferred Term Analysis Population: Safety
表 4.1.5 根据用药分类和首选术语的合并用药总结
分析人群：安全性数据集

Medication Class/Preferred Term	Treatment A(N=4)	Treatment B (N=5)	Total (N=9)
Any Concomitant Medication	4 (100.0%)	4 (80.0%)	8 (88.9%)
ANALGESICS	2 (50.0%)	2 (40.0%)	4 (44.4%)
PARACETAMOL	2 (50.0%)	2 (40.0%)	4 (44.4%)
ANTIBACTERIALS FOR SYSTEMIC USE	1 (25.0%)	1 (20.0%)	2 (22.2%)
AMOXICILLIN	1 (25.0%)	1 (20.0%)	2 (22.2%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (25.0%)	2 (40.0%)	3 (33.3%)
IBUPROFEN	1 (25.0%)	2 (40.0%)	3 (33.3%)
DRUGS FOR OBSTRUCTIVE AIRWAY	0	2 (40.0%)	2 (22.2%)
MONTELUKAST	0	1 (20.0%)	1 (11.1%)
SALBUTAMOL	0	2 (40.0%)	2 (22.2%)
NASAL PREPARATIONS	2 (50.0%)	0	2 (22.2%)
FLUTICASONE PROPIONATE	2 (50.0%)	0	2 (22.2%)
PSYCHOANALEPTICS	1 (25.0%)	0	1 (11.1%)
SERTRALIN	1 (25.0%)	0	1 (11.1%)

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

9.2 Sample ADaM Variable Metadata

9.2 示例 ADaM 变量元数据

This example describes an adverse events ADaM dataset named ADCM. ADCM is not a required dataset name.
此示例描述了一个命名为 ADCM 的不良反应 ADaM 数据集。ADCM 并非一个规定的数据集名称。

Table 9.2.1 Example of ADaM Variable Metadata
表 9.2.1 示例 ADaM 数据

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADCM	STUDYID	Study Identifier	text		CM.STUDYID
ADCM	USUBJID	Unique Subject Identifier	text		CM.USUBJID
ADCM	CMSEQ	Sequence Number	integer		CM.CMSEQ
ADCM	CMTRT	Reported Name of Drug, Med or Therapy	text		CM.CMTRT
ADCM	CMMODIFY	Modified Reported Name	text		CM.CMMODIFY
ADCM	CMDECOD	Standardized Medication Name	text	WHODRUG	CM.CMDECOD
ADCM	ATC1CD	ATC Level 1 Code	text	WHODRUG	ATC Level 1 Code
ADCM	ATC2CD	ATC Level 2 Code	text	WHODRUG	ATC Level 2 Code
ADCM	ATC3CD	ATC Level 3 Code	text	WHODRUG	ATC Level 3 Code
ADCM	ATC1	ATC Level 1 Text	text	WHODRUG	ATC Level 1 Text
ADCM	ATC2	ATC Level 2 Text	text	WHODRUG	ATC Level 2 Text
ADCM	ATC3	ATC Level 3 Text	text	WHODRUG	ATC Level 3 Text
ADCM	AOCCFL	1st Occurrence within Subject Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCC01FL	First Occurrence of ATC Level 1 Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCC02FL	First Occurrence of ATC Level 2 Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCC03FL	First Occurrence of ATC Level 3 Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCCPFL	1st Occurrence of Preferred Term Flag	text	Y	<Producer will insert derivation here>
ADCM	CMINDC	Indication	text		CM.CMINDC
ADCM	CMDOSFRM	Dose Form	text	TABLET	CM.CMDOSFRM
ADCM	CMDOSE	Dose per Administration	text		CM.CMDOSE
ADCM	CMDOSU	Dose Units	text	mg	CM.CMDOSU
ADCM	CMDOSFRQ	Dosing Frequency Per Interval	text	ONCE, PRN, QD, QID	CM.CMDOSFRQ
ADCM	CMROUTE	Route of Administration	text	ORAL	CM.CMROUTE
ADCM	CMSTDTC	Start Date/Time of Medication	date	ISO 8601	CM.CMSTDTC
ADCM	ASTDT	Analysis Start Date	integer	date9.	<Producer will insert derivation here>
ADCM	ASTDTF	Analysis Start Date Imputation Flag	text	D, M, Y	If start date is completely missing or missing the year then ASTDTF='Y' Else if start date has month missing then ASTDTF='M'

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADCM	CMENDTC	End Date/Time of Medication	date	ISO 8601	CM.CMENDTC
ADCM	AENDT	Analysis End Date	integer	date9.	<Producer will insert derivation here>
ADCM	AENDTF	Analysis End Date Imputation Flag	text	D, M, Y	If end date is completely missing or missing the year then AENDTF='Y' Else if end date has month missing then AENDTF='M'
ADCM	CMENRF	End Relative to Reference Period	text	ONGOING	CM.CMENRF
ADCM	ONTRTFL	On-Treatment Flag	text	Y	<Producer will insert derivation here>
ADCM	PREFL	Pre-treatment Flag	text	Y	<Producer will insert derivation here>
ADCM	SAFFL	Safety Population Flag	text	Y,N	ADSL.SAFFL
ADCM	TRTA	Actual Treatment	text	Drug A, Drug B	ADSL.TRT01A
ADCM	TRTAN	Actual Treatment (N)	integer	1, 2	ADSL.TRT01AN D r
ADCM	TRTSDT	Date of First Exposure to Treatment	integer	date9.	ADSL.TRTSDT
ADCM	TRTEDT	Date of Last Exposure to Treatment	integer	date9.	ADSL.TRTEDT
ADCM	AGE	Age	integer		ADSL.AGE
ADCM	AGEGR1	Pooled Age Group 1	text	<65, >=65	ADSL. AGEGR1
ADCM	SEX	Sex	text	M, F	ADSL.SEX

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADCM	RACE	Race	text	ASIAN	ADSL.RACE

9.3 Sample ADaM Data

Table 9.3.1 is an illustration of the concomitant medications analysis dataset (ADCM) defined above. The ADCM dataset illustrated in this example was designed to support some standard subsets and/or classifications of concomitant medications. The example describes some of the key variables and records that would be included in the dataset.
表 9.3.1 是对上述定义的合并用药分析数据集（ADCM）的一个举例说明。该示例中所阐释的 ADCM 数据集设计为支持某些标准的合并用药分组及分类。 该示例描述了数据集将包括的关键变量及记录。

Key points to note in the example are:
此示例中需注意的关键点：

1. The producer of the dataset chose to use the record level actual treatment variable (TRTA) populated with the same value across all rows in the dataset rather than the subject level treatment variable (TRT01A). For a parallel design either TRTA or TRT01A could be used as the actual treatment identifier. The producer interpreted TRTA as the treatment associated with the record for analysis display purposes and populated the baseline records with treatment even though subjects had not yet received treatment at that time.
   数据集的制作人选择使用由具有相同值的列填充的记录级别实际处理变量（TRTA），而不是受试者水平处理变量（TRT01A）。对于平行设计来说，TRTA 和 TRT01A 都可以用作实际处理标识符。制作人将 TRTA 作为与用于分析展示目的的记录联系在一起的治疗方法，并且在主体尚未接受治疗时，就根据该治疗方法填写了治疗前记录。

2. Variables such as CMSEQ, CMTRT, and CMSTDTC are copied in from SDTM CM domain to provide data point traceability.
   一些变量，例如 CMSEQ, CMTRT,和 CMSTDTC，都是从 SDTM CM 域复制得来，以提供数据点可追溯性。

3. Variables such as CMDECOD are copied in from the SDTM CM domain for analysis purposes.
   一些变量，例如 CMDECOD，都是从 SDTM CM 域复制得来，用于分析目的。

4. ASTDT and AENDT are the CM timing variables used for analysis. Other timing variables such as ASTDTF/AENDTF/ CMSTDTC/CMENDTC/TRTSDT/TRTEDT are supportive variables for metadata traceability.
   ASTDT 和 AENDT 为用于分析的 CM 时间变量。其他时间变量，如 ASTDTF/AENDTF / CMSTDTC/CMENDTC/TRTSDT/TRTEDT，为数据提供了元数据可追溯性。

5. The Occurrence Flags (AOCCFL, AOCCPFL, AOCC01FL, AOCC02FL, AOCC03FL) are permissible, and not required. The main purpose of these flags is to facilitate data point traceability between records in the dataset and unique counts in the summary displays. In addition if a Time to Event Analysis is built off of Concomitant Medications, the flags provide a crucial link between the summary records in the TTE BDS and the source of the records in ADCM.
   发生标帜（AOCC*FL, AOCCPFL, AOCC01FL, AOCC02FL, AOCC03FL）是许可变量，非必需变量。这些标帜的主要目的是便于数据集中的数据和分析汇总结果之间的数据点溯源性。另外，如果时间-时间（TTE）的分析是建立在不良反应的基础之上，这些标志就可以提供 TTE BDS 的汇总记录和 ADCM 的记录之间的重要连接。

6. The core variables of AGE, AGEGR1, SEX, and RACE are included in ADCM to facilitate subgroup analyses.
   AGE, AGEGR1, SEX, 和 RACE 的核心变量都包含在 ADCM 之中，以便于亚分组分析。

Table 9.3.1 Sample ADCM Data
表 9.3.1 示例 ADCM 数据

Row	STUDYID	USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	ATC1CD	ATC1	ATC2CD
1	ABC	ABC-001	1	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
2	ABC	ABC-001	2	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
3	ABC	ABC-001	3	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
4	ABC	ABC-001	4	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
5	ABC	ABC-001	5	CONTAC MS	CONTAC MS	CONTAC MS	N	NERVOUS SYSTEM	N02
6	ABC	ABC-001	6	FLONASE	FLONASE	FLUTICASONE PROPIONATE	R	RESPIRATORY SYSTEM	R01
7	ABC	ABC-002	1	ROBITUSSIN COUGH	ROBITUSSIN	NOVAHISTINE DMX	R	RESPIRATORY SYSTEM	R05
8	ABC	ABC-002	2	MOTRIN	MOTRIN	IBUPROFEN	M	MUSCULO-SKELETAL SYSTEM	M01
9	ABC	ABC-002	3	IBUPROFEN	IBUPROFEN	IBUPROFEN	M	MUSCULO-SKELETAL SYSTEM	M01
10	ABC	ABC-003	1	ZOLLOFT	ZOLOFT	SERTRALIN	N	NERVOUS SYSTEM	N06

Row	ATC2	ATC3CD	ATC3	AOCCFL	AOCCPFL
1 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS	Y	Y
2 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		
3 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		
4 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		
5 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		Y
6 (cont)	NASAL PREPARATIONS	R01A	DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOP		Y
7 (cont)	COUGH AND COLD PREPARATIONS	R05FA	COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS		Y
8 (cont)	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-S		Y
9 (cont)	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-S		
10 (cont)	PSYCHOANALEPTICS	N06A	ANTIDEPRESSANTS		Y

Row	AOCC01FL	AOCC02FL	AOCC03FL	CMINDC	CMDOSFRM	CMDOSE	CMDOSU	CMDOSFRQ	CMROUTE	CMSTDTC*	ASTDT*	CMENDTC*
1 (cont)	Y	Y	Y	HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-02	02Jan2011	2011-01-02
2 (cont)				HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-04	04Jan2011	2011-01-04
3 (cont)				HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-10	10Jan2011	2011-01-10
4 (cont)				HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-15	15Jan2011	2011-01-15
5 (cont)				COLD	TABLET	200	mg	ONCE	ORAL	2011-01-17	17Jan2011	2011-01-17
6 (cont)	Y	Y	Y	COUGH	TABLET	50	mg	QD	ORAL	2009-02-01	01Feb2009	
7 (cont)		Y	Y	INFECTION	SUSPENSION	500	mg	QID	ORAL	2011-03-01	01Mar2011	2011-03-15
8 (cont)	Y	Y	Y	LEG PAIN	TABLET	500	mg	PRN	ORAL	2011-05-14	14May2011	2011-06-01
9 (cont)				ARTHRITIS	TABLET	250	mg	QD	ORAL	2011-06-10	10Jun2011	
10 (cont)	Y	Y	Y	ANXIETY	TABLET	50	mg	QD	ORAL	2001-03		

** Variables ending in suffix DTC are character date/time fields in the ISO8601 format. Variables ending in DT are numeric dates, here shown using SAS date format date9. Other numeric date formats can be used, but care should be taken with newer date formats which might not be understood by all statistical packages.*
*以 DTC 为后缀的变量为 ISO8601 格式的字符型日期/时间字段。以 DT 为后缀的变量是数值型日期，这里使用 SAS 日期格式 date9 显示。可以使用其他数值型日期格式，但应注意新引进的日期格式，这些格式可能不是所有统计软件包都能识别。

Row	AENDT*	CMENRF	ONTRTFL	PREFL	SAFFL	TRTA	TRTAN	TRTSDT*	TRTEDT*	AGE	AGEGR1	SEX	RACE
1 (cont)	02Jan2011			Y	Y	Drug A	1	23JAN2011	15MAY2011	54	<65	M	ASIAN
2 (cont)	04Jan2011			Y	Y	Drug A	1	23JAN2011	15MAY2011	54	<65	M	ASIAN
3 (cont)	10Jan2011			Y	Y	Drug A	1	23JAN2011	15MAY2011	54	<65	M	ASIAN
4 (cont)	15Jan2011			Y	Y	Drug A	1	23JAN 2011	15MAY2011	54	<65	M	ASIAN

5 (cont)	17Jan2011			Y	Y	Drug A	1	23JAN2011	15MAY2011	54	<65	M	ASIAN
6 (cont)		ONGOING	Y	Y	Y	Drug A	1	23JAN2011	15MAY2011	54	<65	M	ASIAN
7 (cont)	15Mar2011			Y	Y	Drug B	2	10MAY2011	25NOV201	54	<65	M	ASIAN

Row	AENDT*	CMENRF	ONTRTFL	PREFL	SAFFL	TRTA	TRTAN	TRTSDT*	TRTEDT*	AGE	AGEGR1	SEX	RACE
8 (cont)	01Jun2011		Y		Y	Drug B	2	10MAY2011	25NOV2011	54	<65	M	ASIAN
9 (cont)		ONGOING	Y		Y	Drug B	2	10MAY2011	25NOV2011	54	<65	M	ASIAN
10 (cont)		ONGOING	Y	Y	Y	Drug A	1	16JUN2011	03JAN2012	54	<65	M	ASIAN

** Variables ending in DT are numeric dates, here shown using SAS date format date9. Other numeric date formats can be used, but care should be taken with newer date formats which might not be understood by all statistical packages.*

*以 DTC 为后缀的变量为 ISO8601 格式的特征日期/时间字段。以 DT 为后缀的变量为数值日期，这里显示的使用了 SAS 日期格式 date9。其他数字日期格式也可以使用，但必须小心使用，因为新引进的日期格式可能不会被所有统计软件包识别。

10 Example 7: Analysis of Medical History Mapped to MedDRA

10 示例 7:对应 MedDRA 的病史分析

The basic summary of medical history frequencies described in section 12.2.2 (and located in section 14.3.1) of ICH Guideline E3 [12] report should be used to display frequencies in treatment and control groups.
ICH 指导原则[12]E3 报告 12.2.2 节（位于 14.3.1 节）中所描述的基本的病史频数汇总应被用于展示治疗组及对照组中的频数。

This example displays a simple summary of all spontaneously reported medical history. The example is based on a two treatment parallel design study. The display summarizes (1) the number of subjects in each treatment group who had a given medical history event and (2) the rate of occurrence in each treatment group.
此示例展示了一份对全部的自主报告病史的简单汇总。该示例基于一项双治疗组平行设计试验。该展示汇总了（1）每个治疗组中具有某特定病史的受试者数目（2）每个治疗组中的发生率。

10.1 Analysis Display Example Layout

10.1 分析展示布局示例

Table 10.1.1 Example of Summary of Medical History*
表 10.1.1 病史汇总示例*

Summary of General Medical History Events
Safety Population

HISTORY CATEGORY Body System Event	Active Drug (N=4)	Placebo (N=5)	Total (N=9)
Any Medical History	3 (75.0%)	3 (60.0%)	6 (66.7%)
GASTROINTESTINAL	1 (25.0%)	0	1 (11.1%)
Gastrointestinal disorders	1 (25.0%)	0	1 (11.1%)
Abdominal pain	1 (25.0%)	0	1 (11.1%)
Gastroesophageal reflux disease	1 (25.0%)	0	1 (11.1%)
Nausea	1 (25.0%)	0	1 (11.1%)
HEMATOLOGICAL/LYMPHATIC	1 (25.0%)	0	1 (11.1%)
Blood and lymphatic system disorders	1 (25.0%)	0	1 (11.1%)
Anaemia	1 (25.0%)	0	1 (11.1%)
RESPIRATORY	3 (75.0%)	3 (60.0%)	6 (66.7%)
Immune system disorders	2 (50.0%)	3 (60.0%)	5 (55.6%)
Seasonal allergy	2 (50.0%)	3 (60.0%)	5 (55.6%)
Infections and infestations	1 (25.0%)	2 (40.0%)	3 (33.3%)
Upper respiratory tract infection	1 (25.0%)	2 (40.0%)	3 (33.3%)
Respiratory, thoracic and mediastinal disorders	1 (25.0%)	3 (60.0%)	4 (44.4%)
Asthma	1 (25.0%)	0	1 (11.1%)
Dyspnoea	0	3 (60.0%)	3 (33.3%)

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content not appearance.
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

The count and percent of unique subjects per classification group may be based on any of the classification variables. In this table, the count and percent of unique subjects is summarized by the variables MHSCAT, MHBODSYS, and MHDECOD. The table also summarizes the number of subjects who had any medical history event (e.g. the row 'Any Medical History'). The denominator counts (shown here in the (N=) in the column headings) are taken from the ADSL dataset and are based on the count of subjects in the population in the population of interest. Note that not all subjects in the population of interest will necessarily have data in the medical history file.
每一层级内非重复受试者的数目及百分比可基于任意分级变量。 该表中，非重复受试者的数目及百分比按照变量 MHSCAT, MHBODSYS 以及 MHDECOD 汇总。该表也汇总了具有任意病史事件的受试者数目（例如："任意病史"这一行）。分母数（此处显示于列标题（N=）之中）取自数据集 ADSL 且基于兴趣人群中的受试者数目。 需注意的是并非所有特定人群中的受试者都必须在病史文件中有数据。

This presentation is analogous to the logic typically used for Adverse Events summaries.
此分析展示与不良反应汇总所采用的经典逻辑相类似。

10.2 Sample ADaM Variable Metadata

10.2 示例 ADaM 变量元数据

This example describes an adverse events ADaM dataset named ADMH. ADMH is not a required dataset name.
此示例描述了一个命名为 ADMH 的不良反应 ADaM 数据集。ADMH 并非一个指定的数据集名称。

Table 10.2.1 Example of ADaM Variable Metadata
表 10.2.1 ADaM 变量元数据示例

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADCM	STUDYID	Study Identifier	text		MH.STUDYID
ADMH	USUBJID	Unique Subject Identifier	text		MH.USUBJID
ADMH	MHSEQ	Sequence Number	integer		MH.MHSEQ
ADMH	MHCAT	Category for Medical History	text		MH.MHCAT
ADMH	MHSCAT	Sub Category for Medical History	text		MH.MHSCAT
ADMH	MHDECOD	Dictionary-Derived Term	text		MH.MHDECOD
ADMH	MHBODSYS	Body System or Organ Class	text		MH.MHBODSYS
ADMH	MHTERM	Reported Term for the Medical History	text		MH.MHTERM
ADMH	MHSTDTC	Start Date/Time of Medication	datetime	ISO 8601	MH.MHSTDTC
ADMH	ASTDT	Analysis Start Date	integer		From MH.MHSTDTC, converted to SAS Date. Any derivations to derive partial start dates are applied here and listed in comments.
ADMH	ASTTM	Analysis Start Time	integer		From MH.MHSTDTC, converted to SAS Time.
ADMH	ASTDTM	Analysis Start Date/Time	integer		From MH.MHSTDTC, converted to SAS Datetime.
ADMH	MHENDTC	End Date/Time of Medication	datetime	ISO 8601	MH.MHENDTC
ADMH	AENDT	Analysis End Date	integer		From MH.MHENDTC, converted to SAS Date. Any derivations to derive partial start dates are applied here and listed in comments.
ADMH	AENTM	Analysis End Time	integer		From MH.MHENDTC, converted to SAS Time.
ADMH	AENDTM	Analysis End Date/Time	integer		From MH.MHENDTC, converter to SAS Datetime.
ADMH	MHENRF	End Relative to Reference Period	text		MH.MHENRF

10.3 Sample ADaM Data

10.3 示例 ADaM 数据

Table 10.3.1 is an illustration of the Medical History analysis dataset (ADMH) defined above. The ADMH dataset illustrated in this example was designed to support some standard subsets and/or classifications of Medical Histories. The example describes key variables and records that would be included in the dataset.
表 10.3.1 是对上述定义的病史分析数据集（ADMH）的一个举例说明。例中所示的 ADMH 数据集旨在支持一些病史的标准子集和/或分类。 该示例描述了数据集将包括的关键变量及记录。

The example data are assumed to be gathered on a case report form that contains a set of defined categories. A subject may or may not have had any significant medical history in any of the categories on the form. There is a record in the medical history file for each symptom or condition listed on the form; subjects with no recorded medical history may not appear in this file. The MHCAT variable indicates the type of CRF page the data were gathered on, and MHSCAT indicates the CRF category. MHTERM is the symptom term that was recorded; MHDECOD and MHBODSYS are taken from matching the text in MHTERM with a coding dictionary (in this case MedDRA). The date variables indicate the beginning and end timing of the medical history event.
假设收集该示例数据所用的一份病例报告表含有一系列明确的病史种类。 一位受试者可能有也可能没有该表含有的任意种类的病史。该病例报告表中所列的每条症状在病史数据文件中都有一条记录对应；无病史记录的受试者未必出现在此数据文件之中。变量 MHCAT 表明了收集数据的病例报告表单页的类型，而变量 MHSCAT 指明了该病例报告表的种类。变量 MHTERM 是所记录的症状术语；变量 MHDECOD 及 MHBODSYS 取自编码字典（此处为 MedDRA）中匹配变量 MHTERM 所含文本的术语。日期变量表明了病史事件的开始及结束时间。

Key points to note in the example are:
此示例中需注意的关键点：

1. Variables such as MHSTDTC and MHENDTC are copied in from SDTM MH domain to provide data point traceability.
   从 SDTM MH 域中复制变量诸如 MHSTDTC 及 MHENDTC 提供了数据的可追溯性。

2. Variables such as MHSCAT, MHDECOD, and MHBODSYS are copied in from the SDTM MH domain for analysis purposes.
   从 SDTM MH 域中复制变量诸如 MHSCAT, MHDECOD 及 MHBODSYS 则是为了分析的目的。

3. ASTDT and AENDT are the timing variables used for analysis. Another timing variable MHENRF is a supportive variable for metadata traceability.
   ASTDT 及 AENDT 是用于分析的时间变量。另一时间变量 MHENRF 则是为了支持元数据可追溯性。

4. This is a simple example to only illustrate variables that are relevant to ADMH. It does not include all variables that could be needed for analysis or all indicated in metadata in table 10.2.1. For example, it does not include variables like severity of the History event.
   这仅仅是一个阐释 ADMH 相关变量的简单示例。该示例并未包括分析所需或是表 10.2.1 中元数据指示的全部变量。例如，此处不包括病史事件严重性变量

5. For this analysis, the subject level treatment variable (TRT01A or TRT01P, not shown) would be appropriate. Record-level treatment variables would not be needed since the data are gathered prior to start of study treatment.
   受试者层面的治疗变量（TRT01A 或 TRT01P，此处未显示）适用于此次分析。由于数据收集于研究药物开始之前，记录层面的治疗变量则不需要。

6. The TRTEMFL (treatment emergent flag), ONTRTFL (on-treatment flag), FUPFL (follow-up flag) and PREFL (pre-treatment flag) are not included in this analysis file because this dataset will only be used for baseline summaries. (Note that these variables could be defined if there was an analysis purpose that called for them). Similarly, the Occurrence Flags are permissible but not required unless needed for a specific analysis purpose.
   由于该数据集将只用于基线信息汇总，变量 TRTEMFL（治疗期间标帜），ONTRTFL（治疗中标帜），FUPFL（随访标帜）及 PREFL（治疗前标帜）则未被包括在此分析数据文件中。（需注意的是若有需用到这些变量的分析需求则这些变量可被定义）。类似地，除非为了某特定分析目的的需求，不然发生事件标帜只是许可型变量而非必需型变量。

7. Core variables (such as AGE, RACE, and SEX) would typically be added to the dataset but are not shown in this example.
核心变量（诸如 AGE, RACE 及 SEX）虽未显示在该示例中但显然应被添加进该数据集。

Table 10.3.1 Sample Medical History Data for Spontaneously Reported Events
表 10.3.1 自主报告病史事件数据示例

Row	USUBJID	MHTERM	MHDECOD	MHBODSYS	MHCAT	MHSCAT	MHSTDTC*	ASTDT*	MHENDTC*	AENDT*	MHENRF
1	ABC-001	ANEMIA	Anaemia	Blood and lymphatic system disorders	MEDICAL HISTORY	HEMATOLOGICAL/ LYMPHATIC	2010-02-01	01FEB2010			ONGOING
2	ABC-001	GERD	Gastroesophageal reflux disease	Gastrointestinal disorders	MEDICAL HISTORY	GASTROINTESTINAL	2011-01-04	04JAN2011	2011-01-04	04JAN2011	
3	ABC-001	NAUSEA	Nausea	Gastrointestinal disorders	MEDICAL HISTORY	GASTROINTESTINAL	2011-01-10	10JAN2011	2011-01-10	10JAN2011	
4	ABC-001	SPLEEN PAIN	Abdominal pain	Gastrointestinal disorders	MEDICAL HISTORY	GASTROINTESTINAL	2011-01-15	15JAN2011	2011-01-15	15JAN2011	
5	ABC-001	ASTHMA	Asthma	Respiratory, thoracic and mediastinal disorders	MEDICAL HISTORY	RESPIRATORY	2011-01-17	17JAN2011	2011-01-17	17JAN2011	
6	ABC-002	SEASONAL ALLERGIES	Seasonal allergy	Immune system disorders	MEDICAL HISTORY	RESPIRATORY	2011-05-14	14MAY2011	2011-06-01	01JUN2011	

** Variables ending in suffix DTC are character date/time fields in the ISO8601 format. Variables ending in DT are numeric dates, here shown using SAS date format date9. Other numeric date formats can be used, but care should be taken with newer date formats which might not be understood by all statistical packages.*
*以 DTC 后缀结尾的变量是 ISO8601 格式的字符型日期/事件字段。以 DT 结尾的变量是数值型日期，此处以 SAS 日期格式 date9.显示。 其它的数值型日期格式亦可使用，但需小心，因为并非所有统计分析软件包均可识别新型的日期格式。

11 Example 8: Analysis of Medical History Pre-specified Events

11 示例 8：预先指定事件的病史分析

In the example data shown below, the data are gathered on a case report form that contains a pre-specified category (in this case diabetes history), including a checkbox to indicate whether or not the subject had this condition. Diabetes history is not coded.
如下示例所示，CRF 中收集的数据包含预先指定的分类（此示例为糖尿病史），包含一个复选框，以指示受试者是否具有此条件。糖尿病史没有编码。

Analysis of the number of subjects with and without pre-specified events is an option for medical history. This option does not have a counterpart in adverse events analysis, because the AE domain does not allow for the collection of pre-specified events with AEOCCUR of N.
对有或没有预先指定事件的受试者数量的分析是病史分析的一种选择。这个选项在不良事件分析中没有对应项，因为不良事件域不允许使用 AEOCCUR =N 来收集预先指定的事件。

11.1 Analysis Display Example Layout

11.1 分析展示布局示例

The data are analyzed here by counting the number of unique subjects per treatment group, MHCAT, MHTERM, and MHOCCUR. The values of MHOCCUR are formatted from Y and N to more readable values (e.g., 'Y=Reported History') for presentation. For the examples below, we assume that the ADMH file is merged with ADSL to ensure that all safety subjects are identified. However, there may be some safety subjects in ADSL who do not occur in ADMH. (This situation can occur due to missing CRF data).
病史数据通过治疗组，MHCAT，MHTERM 和 MHOCCUR 的分类统计相关受试者数量。MHOCCUR 的值从 Y 和 N 被格式化为更易读取的变量值（例如，Y= 'Y=Reported History'）以便展示。对于下面的例子中，我们假设 ADMH 合并了 ADSL 以确保所有安全集的受试者被标识。但是，可能有部分的 ADSL 中的安全性数据集中的受试者并不存在于 ADMH 中（其原因可能是 CRF 中根本没有数据）。

Table 11.1.1 Example of Summary of Medical History*
表 11.1.1 病史总结示例

Summary of Diabetes History Events Safety Population			
Diabetes History Category	**Active Drug (N=4)**	**Placebo (N=4)**	**Total (N=8)**
DIABETES HISTORY			
DIABETES MELLITUS[1]			
N=No History	3 (75.0%)	2 (100.0%)	5 (83.3%)
Y=Reported History	1 (25.0%)	0	1 (16.7%)
Diabetes History Not Available[1]	0	2	2
[1] Population counts in the column header include all subjects in the safety population. Percentages are based on the number of safety subjects in each treatment group for whom diabetes history data are available. The 'No Reported History' counts are based on subjects with the 'No' box checked on Medical History CRF page xxx.			

The choice of denominator will be based on statistical judgment and should be clearly described in the programming specifications. The choice of denominator should also be clearly identified somewhere on the report (for instance, in the title or footnotes).

分母的选择将基于统计判断，并应在编程文件中明确说明。分母的选择也应该在报告的某个地方清楚地标识出来(例如，在标题或脚注中)。
In the example above, we based the denominator on only the subjects in the population of interest who have records in ADMH with MHCAT = 'DIABETES HISTORY'.
上述示例中，确立的分母是基于在 ADMH 有记录且 MHCAT='DIABETESHISTORY'的特定受试者人群。

An alternative analysis would be to base the denominator on the number of subjects in the population (typically defined by the number of subjects with appropriate population flags in ADSL).
另一种分析方法是根据人群中的目标受试者人数(通常由 ADSL 中具有适当人群标识的受试者人数定义)来确定分母。

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content, not appearance.
*此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

Table 11.1.2 Alternate Example of Summary of Medical History*
表 11.1.2 病史总结的另一个例子*

Summary of Diabetes History Events
Safety Population

Diabetes History Category	Active Drug (N=4)	Placebo (N=4)	Total (N=8)
DIABETES HISTORY			
DIABETES MELLITUS			
N=No Reported History	3 (75.0%)	2 (50.0%)	5 (62.5%)
Y=Reported History	1 (25.0%)	0 (0.0%)	1 (12.5%)
Unknown[1]	0 (0.0%)	2 (50.0%)	2 (25.0%)

[1] Population counts in the column header include all subjects in the safety population. Percentages are based on the number of safety subjects in each treatment group, whether they had diabetes history data or not. The 'Unknown' counts are based on subjects who did not have a Medical History CRF page xxx.

11.2 Sample ADaM Variable Metadata

11.2 示例 ADaM 变量的元数据

This example describes an adverse events ADaM dataset named ADMH. ADMH is not a required dataset name.
这个例子描述了一个叫 ADMH 的关于不良事件的 ADaM 数据集。ADMH 不是一个必须的数据集名称。

Table 11.2.1 Sample ADaM Variable Metadata
表 11.2.1 示例 ADaM 数据

Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
STUDYID	Study Identifier	text		MH.STUDYID
USUBJID	Unique Subject Identifier	text		MH.USUBJID
MHSEQ	Sequence Number	integer		MH.MHSEQ
MHCAT	Category for Medical History	text		MH.MHCAT
MHTERM	Reported Term for the Medical History	text		MH.MHTERM
MHSTDTC	Start Date/Time of Medical History Event	datetime	ISO8601	MH.MHSTDTC
ASTDT	Analysis Start Date	integer		From MHSTDTC, converted to SAS Date. Any derivations to derive partial start dates are applied here and listed in comments.
ASTTM	Analysis Start Time	integer		From MH.MHSTDTC, converted to SAS Time.
ASTDTM	Analysis Start Date/Time	integer		From MH.MHSTDTC, converted to SAS Datetime.
MHENDTC	End Date/Time of Medical History Event	datetime	ISO8601	MH.MHENDTC
AENDT	Analysis End Date	integer		From MHENDTC, converted to SAS Date. Any derivations to derive partial start dates are applied here and listed in comments.
AENTM	Analysis End Time	integer		From MHENDTC, converted to SAS Time.
AENDTM	Analysis End Date/Time	integer		From MHENDTC, converted to SAS Datetime.
MHPRESP	Medical History Event Pre-Specified	text	N,Y	MH.MHPRESP Is Med Hx event from pre-specified CRF page
MHOCCUR	Medical History Occurrence	text	N,Y	MH.MHOCCUR Did subject have the event, Y or N
MHENRTPT	End Relative to Reference Time Point	text	ONGOING	MH.MHENRTPT
MHENTPT	End Reference Time Point	text	SCREENING	MH.MHENTPT

* The style of the display of the results of an analysis will be determined by the producer. The example is intended to illustrate content, not appearance.
* 此分析结果的展示方式是由其制作人来决定的。这个例子仅用来说明内容而不是表现形式。

11.3 Sample ADaM Data

11.3 示例 ADaM 数据

Table 11.3.1 is an illustration of the Medical History (Pre-Specified Events) analysis dataset (ADMH) defined above. The ADMH dataset illustrated in this example was designed to support some standard subsets and/or classifications of Medical Histories. The example describes key variables and records that would be included in the dataset.
表 11.3.1 是对上述定义的病史（预先指定）分析数据集（ADMH）的一个举例说明。例中所示的 ADMH 数据集旨在支持一些病史的标准子集和/或分类。 该示例描述了数据集将包括的关键变量及记录。
Key points to note in the example are:
此示例中需注意的关键点：

1. This is a simple example to only illustrate the ADMH Pre-Specified Events. It does not include all variables that could also be needed for analysis or all indicated in Metadata.
   这仅仅是一个阐释 ADMH 预先指定事件的简单示例。 该示例并未包括所有分析所需变量或所有标识的元数据。

2. The dataset is prepared to support analysis of pre-specified events by populating the variables MHCAT, MHTERM, MHPRESP, and MHOCCUR.
   通过准备诸如 MHSCAT, MHTERM, MHPRESP 及 MHOCCUR 等变量，来准备支持分析预先指定事件的数据集。

3. The MHCAT variable indicates the type of CRF page the data were gathered on, and MHPRESP is Y to indicate that the term is a pre-specified one. MHOCCUR is either Y or N to indicate whether the subject did or did not have the event.
   变量 MHCAT 表明 CRF 收集的预先指定事件类别，MHPRESP 是 Y 时，表明该术语是预设的，MHOCCUR 是 Y 或者 N 表明该受试者有或没有该事件。

4. MHTERM is the symptom term. Since the MHTERM variable for pre-specified events will have a known and finite set of values, these values are used here as a summarization category.
   MHTERM 是症状术语。由于预指定事件的 MHTERM 变量将具有一组已知的有限值，因此在这里将这些值用作总结的类别变量。

5. In this example, MHDECOD and MHBODSYS are not used. Instead MHCAT is used to categorize the data.
   此示例中，MHDECOD 和 MHBODSYS 没有使用。相反，MHCAT 用于对数据进行分类。

6. The date variables indicate the beginning and end timing of the medical history event (if any). It is null on records that do not indicate an event.
   日期变量表明了病史事件的开始及结束时间。没有发生的事件的记录为空。

Table 11.3.1 Sample Medical History Data for Pre-specified Events
表 11.3.1 预先指定病史事件数据示例

Row	USUBJID	MHSEQ	MHTERM	MHCAT	MHPRESP	MHOCCUR	MHSTDTC*	MHENDTC*	MHENRTPT	MHENTPT
1	ABC-001	6	DIABETES MELLITUS	DIABETES HISTORY	Y	N				
2	ABC-002	1	DIABETES MELLITUS	DIABETES HISTORY	Y	N				

Row	USUBJID	MHSEQ	MHTERM	MHCAT	MHPRESP	MHOCCUR	MHSTDTC*	MHENDTC*	MHENRTPT	MHENTPT
3	ABC-003	1	DIABETES MELLITUS	DIABETES HISTORY	Y	Y	2001-03		ONGOING	SCREENING
4	ABC-004	3	DIABETES MELLITUS	DIABETES HISTORY	Y	N				
5	ABC-005	4	DIABETES MELLITUS	DIABETES HISTORY	Y	N				
6	ABC-006	6	DIABETES MELLITUS	DIABETES HISTORY	Y	N				
7	ABC-007	5	DIABETES MELLITUS	DIABETES HISTORY	Y	N				
8	ABC-008	6	DIABETES MELLITUS	DIABETES HISTORY	Y	N				
9	ABC-009	1	DIABETES MELLITUS	DIABETES HISTORY	Y	N				

* Variables ending in suffix DTC are character date/time fields in the ISO8601 format.
*以 DTC 为后缀的变量为 ISO8601 格式的字符型日期/时间字段。

Appendices

Appendix A: References

1. Analysis Data Model (ADaM) version 2.1 http://www.cdisc.org/adam
2. Analysis Data Model (ADaM) Implementation Guide version 1.1 http://www.cdisc.org/adam
3. Study Data Tabulation Model Implementation Guide (SDTMIG) V3.2 and the SDTM document V1.4 http://www.cdisc.org/sdtm
4. Medical Dictionary for Regulatory Activities (MedDRA) http://www.meddramsso.com/
5. World Health Organization Adverse Reaction Terminology (WHO-ART) http://www.umc-products.com/DynPage.aspx?id=73589&mn1=1107&mn2=1664
6. International Classification of Diseases (ICD) http://www.who.int/classifications/icd/en/
7. Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) http://www.nlm.nih.gov/research/umls/sourcereleasedocs/current/CST/ Note: This coding system has been replaced by MedDRA at US FDA.
8. International Conference of Harmonization E2A "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting" http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2A/Step4/E2A_Guide line.pdf
9. International Conference of Harmonization E9 "Statistical Principles for Clinical Trials" http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E9/Step4/E9_Guideline .pdf
10. National Cancer Institute Common Toxicity (NCI CTC) version 4.03 http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14.xls
11. CDISC Define-XML Specification 2.0 http://www.cdisc.org/define-xml
12. International Conference of Harmonization E3 "Structure and Content of Clinical Study Reports" http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/Step4/E3_Guideline .pdf
13. Standardised MedDRA Queries (SMQs) http://www.meddramsso.com/subscriber_smq.asp
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15. The National Center for Biomedical Ontology Bioportal http://bioportal.bioontology.org/ontologies/MEDDRA?p=classes&conceptid=root

Appendix B: Revision History

This section lists all changes in the OCCDS document from Provisional version 1.0 to Final version 1.0.

Category/Section	Type	Description
Section 3.2.5 Indicator Variables	Update	Removed the word "Record" from the label of variable ANLzzFL to make it consistent with ADaMIG v1.1.

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