Analysis Data Model Implementation Guide

Version 1.1

Prepared by the
CDISC Analysis Data Model Team

Notes to Readers

This Implementation Guide is Version 1.1 and corresponds to Version 2.1 of the CDISC Analysis Data Model.

Revision History

Date	Version	Summary of Changes
2016-02-12	1.1 Final	Released version reflecting all changes and corrections identified during comment period.
2009-12-17	1.0 Final	

Note: Please 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

This document comprises the Clinical Data Interchange Standards Consortium (CDISC) Version 1.1 of the Analysis Data Model Implementation Guide (ADaMIG), which has been prepared by the Analysis Data Model (ADaM) Team of CDISC. The ADaMIG specifies ADaM standard dataset structures and variables, including naming conventions. It also specifies standard solutions to implementation issues.
本指南为临床数据交换标准协会 (CDISC) 分析数据模型执行指南 (ADaMIG) 版本 1.1，由 CDISC 分析数据模型 (ADaM) 小组进行起草。ADaMIG 阐述了 ADaM 标准数据集结构，变量及命名规则；同时还指出了对执行过程中的问题的标准解决方案。

The ADaMIG must be used in close concert with the current version of the document titled "Analysis Data Model (ADaM)" which is available for download at http://www.cdisc.org/adam. That document explains the purpose of the Analysis Data Model. It describes fundamental principles that apply to all analysis datasets, with the driving principle being that the design of ADaM datasets and associated metadata facilitate explicit communication of the content of, input to, and purpose of submitted ADaM datasets. The Analysis Data Model supports efficient generation, replication, and review of analysis results.
ADaMIG 必须与当前版本的《分析数据模型 (ADaM)》结合使用，该文档可在以下网址 http://www.cdisc.org/adam 进行下载。该文档解释了分析数据模型的目的，它描述了所有分析数据集需要遵守的基本原则，其驱动原则就是 ADaM 数据集及其相关 metadata 的设计目的是为了有助于清晰地阐明所递交的 ADaM 数据集的内容、数据来源和目的。分析数据模型能帮助高效的产生，重现和审阅分析结果。

Note that in the remainder of the ADaMIG, the document titled "Analysis Data Model (ADaM)" is referred to as the ADaM model document.
注意：在下文的 ADaMIG 中，《分析数据模型 (ADaM)》被简称为 ADaM 模型文档。

1.2 Background

1.2 背景

Readers of this implementation guide should be familiar with the CDISC Study Data Tabulation Model (SDTM) and the Study Data Tabulation Model Implementation Guide (SDTMIG), both of which are available at http://www.cdisc.org/sdtm, since SDTM is the source for ADaM data.
由于 SDTM 是 ADaM 数据的来源，本指南的读者需要非常熟悉 CDISC 研究数据列表模型 (SDTM) 和研究数据列表模型执行指南 (SDTMIG)，二者都可以在 http://www.cdisc.org/sdtm 进行下载。

Both the SDTM and ADaM standards were designed to support submission to a regulatory agency such as the United States Food and Drug Administration (FDA). Since inception, the CDISC ADaM Team has been encouraged and informed by FDA statistical and medical reviewers who participate in ADaM meetings as observers, and who have participated in CDISC-FDA pilots. The origin of the fundamental principles of ADaM is the need for transparency of communication with and scientifically valid review by regulatory agencies. The ADaM standard has been developed to meet the needs of the FDA and industry. ADaM is applicable to a wide range of drug development activities in addition to FDA regulatory submissions. It provides a standard for transferring datasets between sponsors and contract research organizations (CROs), development partners, and independent data monitoring committees. As adoption of the ADaM model becomes more widespread, the use of this common model will support more efficient data-sharing among pharmaceutical sponsors, contract research organizations, and any partners involved in in–licensing, out–licensing, or

mergers.
SDTM 和 ADaM 标准的设计宗旨都是为了帮助申办方向监管机构申报，如美国食品药品监督管理局 (FDA)。自成立以来，CDISC ADaM 小组得到了来自 FDA 统计及医学评审们的鼓励和影响，他们作为观察员参加了 ADaM 会议，还参与了 CDISC-FDA 试点项目。建立 ADaM 基本原则是源自与监管机构对数据进行沟通的透明性以及监管机构能够科学有效的审阅数据的需要。ADaM 标准的开发满足了 FDA 和行业的需求。ADaM 除了能用于向 FDA 监管申报外，还可广泛应用于药品研发活动。它提供了一个在申办方与合同研究组织 (CROs)、研发合作方，及独立数据监测委员会之间进行数据集交换的标准。随着 ADaM 模型的应用越来越广泛，这种通用模型的使用能促进制药行业申办方、合同研究组织以及参与使用许可、授权许可或许可合并的其它合作方之间更加有效的数据共享。

In addition, readers of the ADaMIG should be aware of information provided by the FDA. Specifically, the FDA website has a central location for the posting of FDA regulations and guidance documents that relate to data standards. The main page, entitled 'Study Data Standards Resources' contains links to important documents, both published and draft, for CDER, CBER, and CDRH (http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm). One such document is the Study Data Technical Conformance Guide, which is referred to in this implementation guide as the FDA TCG.
另外，ADaMIG 的读者必须注意 FDA 提供的信息。特别是 FDA 网站有个专门位置是用来发布 FDA 有关数据标准的监管和指南的文件。在主页上有个名为"研究数据标准资源"的链接可连到一些 CDER，CBER 和 CDRH 的重要文件，公开版和草案都有(http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm)。另一个类似的文档还有《研究数据技术一致性指南》，在本指南中被简称为 FDA TCG。

1.3 What Is Covered in the ADaMIG

1.3 ADaMIG 的使用范围

This document describes two ADaM standard data structures: the Subject-Level Analysis Dataset (ADSL) and the Basic Data Structure (BDS). The third ADaM standard data structure, the Occurrence Data Structure (OCCDS), is described in the document "ADaM Structure for Occurrence Data (OCCDS) v1.0".
本文说明了两种 ADaM 标准数据结构：受试者级别分析数据集（ADSL）和基本数据结构（BDS）。而第三种 ADaM 标准数据结构——事件类数据结构（OCCDS），则在《事件类数据（OCCDS）的 ADAM 结构 v1.0》中进行阐明。

The ADSL dataset contains one record per subject. It contains variables such as subject-level population flags, planned and actual treatment variables for each period, demographic information, stratification and subgrouping variables, important dates, etc. ADSL contains required variables (as specified in this document) plus other subject-level variables that are important in describing a subject's experience in the trial. ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial, even if no other ADaM datasets are submitted. Note that this ADaM requirement is also discussed in the FDA TCG v2.3.
在 ADSL 数据集中，每个受试者只有一条记录，包括受试者水平的人群标记、每个研究阶段计划/实际的治疗组信息、人口学特征信息、分层和亚组变量、重要的日期及其它信息。ADSL 除了包括必需的变量外（如本文规定的），还包括一些重要的在试验中用来描述受试者试验信息的受试者水平的变量。在基于 CDISC 的临床试验数据申报中，即使没有其他 ADaM 数据集需要递交，ADSL 和与其相关的元数据也必须递交。
注意：这些对 ADaM 的要求在 FDA TCG v2.3 中亦有提及。

A BDS dataset contains one or more records per subject, per analysis parameter, per analysis timepoint. Analysis timepoint is not required; it is dependent on the analysis. In situations where there is no analysis timepoint, the structure is one or more records per subject per analysis parameter. This structure contains a central set of variables that represent the actual data being analyzed. The BDS supports parametric and nonparametric analyses such as analysis of variance (ANOVA), analysis of covariance (ANCOVA), categorical analysis, logistic regression, Cochran-Mantel-Haenszel, Wilcoxon rank-sum, time-to-event analysis, etc.
在一个 BDS 数据集中，每个受试者的每个分析参数，在每个分析时间点都可以有一条或多条记录。分析时间点不是必需的，其有无取决于不同分析。在没有分析时间点的情况下，每个受试者的每个分析参数可包含一条或多条记录。BDS 结构是一组变量的中心集合，这些变量代表了要被分析的实际数据。BDS 数据结构支持参数和非参数分析如：方差分析 (ANOVA)、协方差分析 (ANCOVA)、定性数据分析、Logistic 回归、CMH 检

验、Wilconxon 秩和检验、时间事件分析等。

Though the BDS supports most statistical analyses, it does not support all statistical analyses. For example, it does not support simultaneous analysis of multiple dependent (response/outcome) variables or a correlation analysis across a range of response variables. BDS 虽然能支持大部分统计分析，但却不能涵盖所有的统计分析。例如：它不支持多个因变量（反应/结果）的同步分析或者对一系列反应变量的相关性分析。

The BDS was not designed to support analysis of incidence of adverse events or other occurrence data. Analysis of such data is supported in the OCCDS.
BDS 亦不能用于分析不良事件或其它事件类数据的发生率，分析事件类数据需使用 OCCDS。

This version of the implementation guide does not fully cover dose-escalation trials or integration of multiple studies.
本版执行指南亦不能完全适用于剂量递增试验或者是多个研究的整合研究。

1.3.1 Other ADaM-Related CDISC Documents

1.3.1 其它 ADaM 相关的 CDISC 文档

Other CDISC documents relevant to the ADaM standard have been produced by the ADaM Team, or by the ADaM Team in concert with other CDISC teams. The most current versions of these documents can be found on the CDISC website.
有关 ADaM 标准的其它 CDISC 文档已经由 ADaM 小组，以及与 ADaM 小组合作的其他 CDISC 团队所撰写。这些文档的最新版本都可以在 CDISC 的网站上找到。

Table 1.3.1.1 lists these documents and describes their applicability to ADaMIG versions 1.0 and 1.1.
表 1.3.1.1 列出了这些文档并说明了各自对 ADaMIG 版本 1.0 和 1.1 的适用性。

Table 1.3.1.1 Other CDISC Documents and their Applicability to ADaMIG Versions

Document	ADaMIG v1.0	ADaMIG v1.1
Analysis Data Model (ADaM) v2.1, December 2009	Foundation document for ADaMIG v1.0	Still applicable
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0, December 2011	Written for ADaMIG v1.0	Still applicable
The ADaM Basic Data Structure for Time-to-Event Analyses v1.0, May 2012	Written for ADaMIG v1.0	Still applicable
Update to the first CDISC SDTM/ADaM Pilot Project, January 2013	Written for ADaMIG v1.0	Still applicable
ADaM Data Structure for Adverse Event Analysis v1.0, May 2012	Written for ADaMIG v1.0	Superseded by OCCDS v1.0
ADaM Structure for Occurrence Data (OCCDS) v1.0, February, 2016	Not written for ADaMIG v1.0	Written for ADaMIG v1.1
CDISC ADaM Validation Checks v1.3, March 2015	Written for ADaMIG v1.0	Mostly applicable; v1.4 will be written for ADaMIG v1.1
Define-XML v2.0, March 2013	Applicable	Applicable
Analysis Results Metadata Specification for Define-XML Version 2 v1.0, January 2015	Applicable	Applicable

As shown in Table 1.3.1.1, for a particular version of the ADaMIG, documents with different release dates are often used together. If there are conflicts among the documents applicable to a particular version of the ADaMIG, the best practice is to use the content from the document with the latest date of final publication.

表 1.3.1.1 其它 CDISC 文档以及其对 ADaMIG 各版本的适用性

文档	ADaMIG v1.0	ADaMIG v1.1
分析数据模型（ADaM） v2.1，2009 年 12 月	ADaMIG v1.0 的基础文件	仍适用
通用统计分析方法的 ADaM 示例 v1.0，2011 年 12 月	基于 ADaMIG v1.0 编写	仍适用
时间事件分析的 ADaM 基本数据结构 v1.0，2012 年 5 月	基于 ADaMIG v1.0 编写	仍适用
对首个 CDISC SDTM/ADaM 试点项目的更新，2013 年 1 月	基于 ADaMIG v1.0 编写	仍适用
不良事件分析的 ADAM 数据结构 v1.0，2012 年 5 月	基于 ADaMIG v1.0 编写	被 OCCDS v1.0 取代
事件类数据（OCCDS）的 ADAM 结构 v1.0，2016 年 2 月	未基于 ADaMIG v1.0 编写	基于 ADaMIG v1.1 编写
CDISC ADaM 验证检查 v1.3，2015 年 3 月	基于 ADaMIG v1.0 编写	大部分适用；对于 ADaMIG v1.1，即将编写 v1.4
Define-XML v2.0，2013 年 3 月	适用	适用
基于 Define-XML 第 2 版的分析结果元数据规范 v1.0，2015 年 1 月	适用	适用

如上表 1.3.1.1 所示，对某一特定版本的 ADaMIG 而言，各个不同发行时间的文档通常可以同时参考。如果对适用于某一特定版本的 ADaMIG 的文档中存在矛盾，最佳方法是参考最新的最终版本。

The ADaM Team is currently working on additional ADaM standard documents addressing the following topics:

- Integration of multiple studies
- Pharmacokinetics
- Oncology
- Questionnaires, Ratings, and Scales

Some CDISC Therapeutic Area User Guides (TAUGs) are released in draft, provisional, or final versions that discuss analysis and propose approaches to ADaM implementation. These documents are useful to implementers of the ADaM standard, but do not officially comprise part of the ADaM standard until such time as the ADaM Team incorporates their recommendations in a release of the foundational standard.

ADaM 小组现正致力于开发中的附加 ADaM 标准文档涉及到以下的论题：

- 多个研究的整合
- 药物代谢动力学
- 肿瘤学
- 问卷、评分与量表

某些 CDISC 治疗领域用户指南 (TAUGs) 已发布了草案，临时版本或者最终版本用于讨论分析和探讨 ADaM 标准的执行。这些文档对 ADaM 标准的执行者非常有用，在 ADaM 小组建议将其纳入发布的基本标准前，尚未被正式纳入 ADaM 标准。

1.4 Organization of this Document

1.4 本文档的结构

This document is organized into the following sections:
本文档包括如下章节：

- Section 1, Introduction, provides an overall introduction to the importance of the ADaM standard and how it relates to other CDISC data standards.
- Section 2, Fundamentals of the ADaM Standard, provides a review of the fundamental principles that apply to all analysis datasets and introduces two standard structures that are flexible enough to represent the great majority of analysis situations.
- Section 3, Standard ADaM Variables, defines standard variables that commonly will be used in the ADaM standard data structures.
- Section 4, Implementation Issues, Standard Solutions, and Examples, presents standard solutions for implementation issues, illustrated with examples.
- Appendices provide additional background material and describe other supplemental material relevant to implementation.

- 第 1 节：介绍，此部分全面介绍了 ADaM 标准的重要性，以及和其它 CDISC 数据标准的关系。
- 第 2 节：ADaM 标准的基础知识。介绍了对所有分析数据集适用的基本原则，并介绍了两种足够灵活且能应用于大多数分析情况的标准结构。
- 第 3 节：标准 ADaM 变量。定义了可通用于 ADaM 标准数据结构的标准变量。
- 第 4 节：执行过程中的问题，标准解决方案及示例。通过图文示例的方式展示了执行过程中所遇问题的标准解决方案。
- 附录提供了附加的背景材料以及说明了其它有关执行的补充材料。

Throughout this document the terms “producer” and “consumer” are used to refer to the originator/sender/owner/sponsor of the data and the reviewer/user/recipient of the data, respectively. These terms are used to simplify the document and to avoid any implication that the statements made in the document only apply to ADaM datasets in the context of electronic submissions to regulatory agencies.
全文中的开发者 (producer) 及使用者 (consumer) 分别指代数据的组织者/发送方/所有人/申办方，以及数据的审阅人/用户/接收方。这些术语用来简化文档，并避免了一些误认为本文所作申明只适用于向监管机构递交 ADaM 数据集的歧义。

1.5Definitions

1.5 定义

1.5.1 General ADaM Definitions

1.5.1 ADaM 的一般定义

Analysis-enabling – Required for analysis. A column or row is analysis-enabling if it is required to perform the analysis. Examples: a hypertension category column added to the ADaM dataset to enable subgroup analysis; an age covariate added to enable the analysis to be age-adjusted; a center stratification factor in a multicenter study.
可分析性– 分析所必需的。当数据的一列或一行对执行分析来说是必需的，则称该行或列是可的。例如：某一高血压的分类被加入 ADaM 数据集用来执行亚组分析；协变量年龄被加入分析用来调整年龄的影响；一个多中心研究的中心分层因子。

Traceability – The property that enables the understanding of the data’s lineage and/or the relationship between an element and its predecessor(s). Traceability facilitates transparency, which is an essential component in building confidence in a result or conclusion. Ultimately, traceability in ADaM permits the understanding of the relationship between the analysis results, the ADaM datasets, the SDTM datasets, and the data collection instrument. Traceability is built by clearly establishing the path between an element and its immediate predecessor. The full path is traced by going from one element to its predecessors, then on to their predecessors, and so on, back to the SDTM datasets, and ultimately to the data collection instrument.
可追溯性 – 一种可以帮助理解某一元素和它的直接前身之间的数据的沿袭，或数据关系的特性。可追溯性提高了数据透明度，这是一个建立分析结果或结论的可信度的必要组成部分。ADaM 的可追溯性从根本上保证了对分析

结果，ADaM 数据集，SDTM 数据集和源数据采集端之间的关系是易于理解的。可追溯性是通过清晰地建立一个元素与它直接前身的关系而成立。通过完整的路径可从一个元素到追踪到它的前身，然后再到前身的前身，一直回溯到 SDTM 数据集，乃至源数据的采集端。

Supportive – A column or row is supportive if it is not required in order to perform an analysis but is included in order to facilitate traceability or review. Example: the LBSEQ and VISIT columns were carried over from SDTM in order to promote understanding of how the ADaM dataset rows relate to the study tabulation dataset.
辅助 – 当数据的列或行并不是执行分析的必需变量，却对数据追溯和审阅有帮助，则该行或列是辅助数据。例如：从 SDTM 继承而来的 LBSEQ 和 VISIT 列，用来帮助理解 ADaM 数据集的行与研究列表数据集的关系。

Record – A row in a dataset. A record is also referred to as an observation within this document.
记录 – 数据集中的行。在本文中，一条记录等同于一条观测。

Variable – A column in a dataset.
变量 – 数据集中的列。

1.5.2 Basic Data Structure Definitions

1.5.2 基本数据结构的定义

Analysis parameter – A row identifier used to uniquely characterize a group of values that share a common definition. Note that the ADaM analysis parameter contains all of the information needed to uniquely identify a group of related analysis values. In contrast, the SDTM --TEST column may need to be combined with qualifier columns such as --POS, --LOC, --SPEC, etc., in order to identify a group of related values. Example: The primary efficacy analysis parameter is "3-Minute Sitting Systolic Blood Pressure (mmHg)." In this document the word "parameter" is used as a synonym for "analysis parameter."
分析参数 – 一个行标识，用来唯一识别一组有共通定义的值的特征。注意：ADaM 分析参数包含了用来唯一识别一组相关的分析值所需要的所有信息。而相较之下，一个 SDTM 的--TEST 列可能需要和其它的限定符列，如--POS，--LOC，--SPEC 等相结合，才能用来识别一组相关的值。例如：主要有效性分析参数"3 分钟坐姿收缩压 (mmHg)"。下文中的"参数"一词用于指代"分析参数"。

Analysis timepoint – A row identifier used to classify values within an analysis parameter into temporal or conceptual groups used for analyses. These groupings may be observed, planned or derived. Example: The primary efficacy analysis was performed at the Week 2, Week 6, and Endpoint analysis timepoints.
分析时间点 – 一个行标识，用来区分一个分析参数的时间点或分析定义上的时间点的值。这些时间点也许是实际观测的、计划的或者推导的。例如：主要有效性分析在第 2 周，第 6 周和最终分析时间点执行。

Analysis value – (1) The numeric (AVAL) or character (AVALC) value described by the analysis parameter. The analysis value may be present in the input data, a categorization of an input data value, or derived. Example: The analysis value of the parameter "Average Heart Rate (bpm)" was derived as the average of the three heart rate values measured at each visit. (2) In addition, values of certain functions are considered to be analysis values. Examples: baseline value (BASE), change from baseline (CHG).
分析值 – (1) 由分析参数描述的数值型 (AVAL) 或字符型 (AVALC) 的值。分析值可来自输入数据、输入数据值的分类或其推导值。例如：参数"平均心率 (bpm)"的分析值是由每次访视测量的三次心率值的平均值计算的。(2) 另外，某些功能性的值也被认为是分析值。例如：基线值 (BASE)，相对基线变化值(CHG)。

Parameter-variant – A column that is derived as a function of AVAL (or AVALC) is parameter-variant if it is calculated differently for some parameters for which the variable is populated in a dataset.
参数可变性 –数据集中某些参数对应的值 AVAL(或者 AVALC)需要使用不同的方法计算，此被看为参数可变性。

Parameter-invariant – A column that is derived as a function of AVAL (or AVALC) is parameter-invariant if it is calculated the same way for all parameters for which the variable is populated in a dataset. Thus, a column is parameter-invariant if how it is derived does not depend on which parameter is on the row. The parameter-invariant derivation remains the same across all parameters, though it may be left null for parameters where it does not apply. For example, the derivation for the change from baseline variable is CHG=AVAL-BASE, an equation that is the same for

all parameters. CHG is therefore a parameter-invariant variable. The concept of parameter invariance is essential to the integrity of the BDS because it is an integral component in the rules defined in Section 4.2 that prohibit "horizontalization" (creation of new columns when the model dictates that a new row is required instead) by producers.
参数不变性 – 当对数据集中所有参数的值 AVAL（或 AVALC）的功能推导出的列是不变参数。所以，当如何推导值并不取决于该行记录是何参数时，该列为不变参数。不变参数的推导方式对所有参数保持不变，虽然当对某些参数不适用时，它可被置为空值。例如：相对基线变化值的衍生方式即是 CHG=AVAL-BASE，对所有参数来说都是一样的。因而 CHG 是一个不变参数。参数不变性的定义是 BDS 完整性的基础，因为禁止开发者"水平化"（当模型需要时一个新行时用生成的新列取代）是第 4.2 节中定义的基本规则的之一。

1.6 Analysis Datasets and ADaM Datasets

1.6 分析数据集与 ADaM 数据集

The section compares and contrasts analysis datasets in general versus ADaM datasets in particular.
本节对照了一般的分析数据集与特定的 ADaM 数据集的差异。

Analysis dataset – An analysis dataset is defined as a dataset used for analysis and reporting.
ADaM dataset – An ADaM dataset is a particular type of analysis dataset that either:

(1) is compliant with one of the ADaM defined structures and follows the ADaM fundamental principles; or
(2) follows the ADaM fundamental principles defined in the ADaM model document and adheres as closely as possible to the ADaMIG variable naming and other conventions.

Non-ADaM analysis dataset – A non-ADaM analysis dataset is an analysis dataset that is not an ADaM dataset. Examples of non-ADaM analysis datasets include:

- an analysis dataset created according to a legacy company standard
- an analysis dataset that does not follow the ADaM fundamental principles.

分析数据集——分析数据集定义为一个用于分析和报告的数据集。
ADaM 数据集——ADaM 数据集是分析数据集的一个特定类型，包括：

(1) 符合 ADaM 定义结构中的一种并采用 ADaM 基本原则，或者
(2) 采用 ADaM 模型文档定义的 ADaM 基本原则，且尽可能的遵守 ADaMIG 变量的命名规则和其它规则。

非 ADaM 分析数据集——非 ADaM 的分析数据集即为一个不为 ADaM 数据集的分析数据集。
非 ADaM 分析数据集的示例包括：

- 分析数据集参照了某个旧的公司标准
- 未采用 ADaM 基本原则的分析数据集。

It is important not to refer to non-ADaM analysis datasets as ADaM datasets.
重要的是，不可将非 ADaM 分析数据集误认为是 ADaM 数据集。

To prevent confusion, non-ADaM analysis dataset names should not start with the prefix AD. It is good practice to start the names of non-ADaM analysis datasets with the two-letter prefix "AX".
为防止混淆，非 ADaM 分析数据集的命名不应以字母 AD 开头。通常较好的方法是非 ADaM 分析数据集的命名以字母 AX 开头。

Currently ADaM has three structures: ADSL (Subject-Level Analysis Dataset), BDS (Basic Data Structure), and OCCDS (Occurrence Data Structure). These three structures correspond to the SUBJECT LEVEL ANALYSIS DATASET, BASIC DATA STRUCTURE, and OCCURRENCE DATA STRUCTURE classes of ADaM datasets. Analysis datasets that follow the ADaM fundamental principles and other ADaM conventions, but that do not follow one of the three defined structures (ADSL, BDS, OCCDS), are considered to be ADaM datasets with a class of ADAM OTHER. Controlled terminology for the class element of the analysis dataset metadata can be downloaded at http://www.cdisc.org/terminology.

目前 ADaM 有三种结构：ADSL（受试者水平分析数据集），BDS（基本数据结构）和 OCCDS（事件类数据结

构）。这三种数据结构对应 ADaM 数据集的三种类型：受试者级别分析数据集，基本数据结构和事件类数据结构。当某一分析数据集遵循 ADaM 的基本原则以及其它的 ADaM 规则，但不符合三种既定结构之一时（ADSL，BDS，OCCDS），其会被认为是 ADAM 其它类的 ADaM 数据集。分析数据集元数据的类别的受控术语集可以从 http://www.cdisc.org/terminology 下载到。

In the ADaM model, it is assumed that the original data sources for ADaM datasets are SDTM datasets, even when ADaM datasets are derived from other ADaM datasets. ADaM has features that enable traceability from analysis results to ADaM datasets and from ADaM datasets to SDTM datasets.

在 ADaM 模型中，假定原始数据源是从 SDTM 数据集到 ADaM 数据集，即便有时 ADaM 数据集是从其它 ADaM 数据集导出的。ADaM 具备能从分析结果追溯到 ADaM 数据集，以及从 ADaM 数据集追溯到 SDTM 数据集的特点。

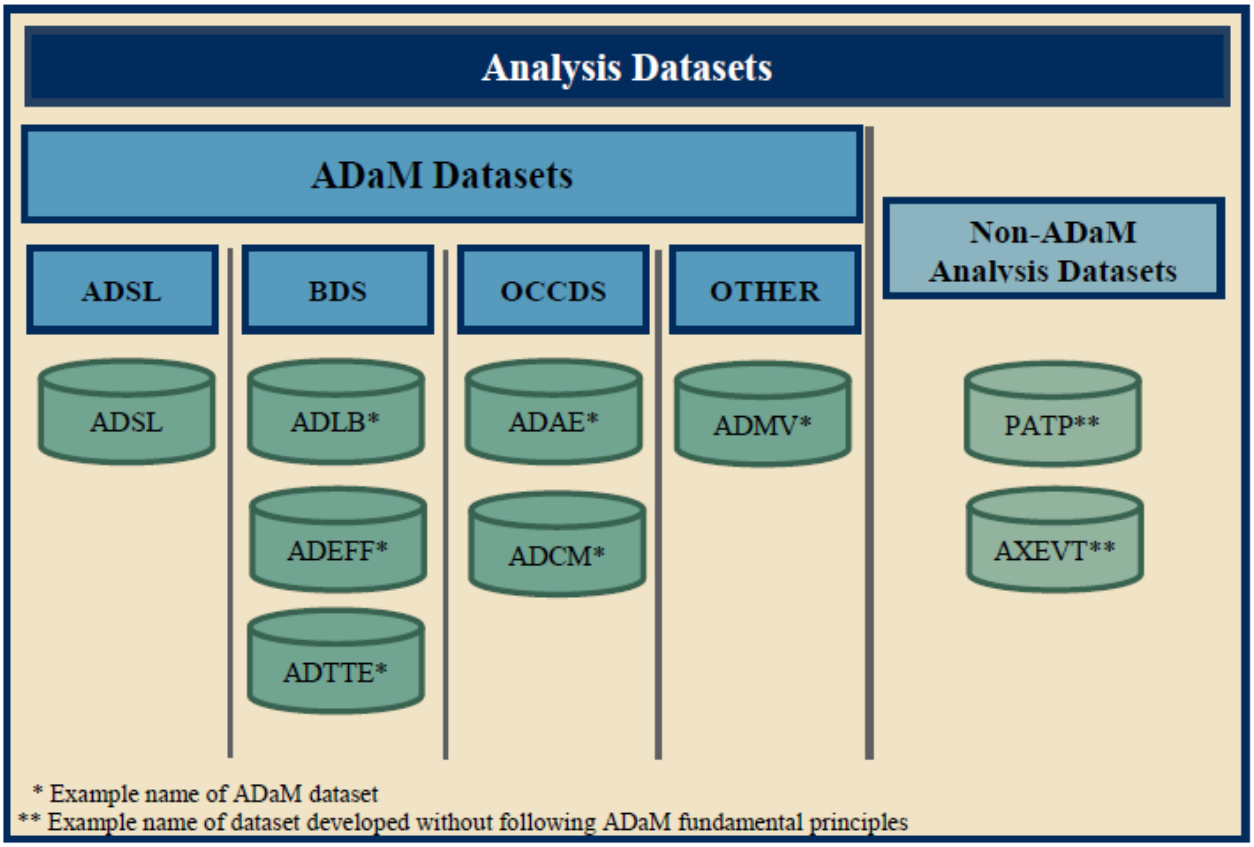

Figure 1.6.1 Categories of Analysis Datasets

Analysis Datasets within the eCTD Folder Structure

The specification for organizing datasets and their associated files in folders within a submission is summarized in the following figure, as noted in the FDA TCG v2.3. For ease of use with the define file and in the eCTD (electronic Common Technical Document) folder structure, all analysis datasets should be kept in one folder. If a set of analysis datasets includes an ADaM-compliant ADSL dataset (as required for a CDISC-conformant submission), then the whole set of analysis datasets should be placed into the adam folder. If not, the whole set of analysis datasets should be placed into the legacy folder.

eCTD 文件夹结构中的分析数据集

根据 FDA TCG v2.3 规定，在某一次申报的文件夹中，对整理数据集及其相关文件的规范如下图所示。为了便于在 eCTD（电子通用技术文档）文件夹结构中使用 define file（定义文件），所有分析数据集必须被储存在同一个文件夹内。如果一组分析数据集包含一个符合 ADaM 的 ADSL 数据集（对一次符合 CDISC 的申报是必须的），则整组分析数据集必须被置于 adam 文件夹。否则，整组分析数据集须被置于 legacy 文件夹。

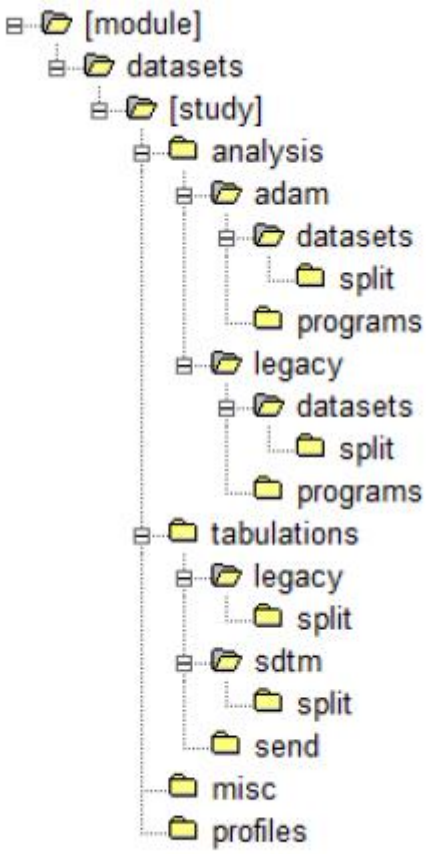

Figure 1.6.2 Analysis Data in the eCRT Structure

Figure 1.6.2 Analysis Data in the eCRT Structure
图 1.6.2 eCRT 结构中的分析数据

2 Fundamentals of the ADaM Standard

2 ADaM 标准的基础

2.1 Fundamental Principles

2.1 基本原则

ADaM datasets must adhere to certain fundamental principles as described in the ADaM model document:

(1) ADaM datasets and associated metadata must clearly and unambiguously communicate the content and source of the datasets supporting the statistical analyses performed in a clinical study.

(2) ADaM datasets and associated metadata must provide traceability to show the source or derivation of a value or a variable (i.e., the data's lineage or relationship between a value and its predecessor(s)). The metadata must identify when and how analysis data have been derived or imputed.

(3) ADaM datasets must be readily usable with commonly available software tools.

(4) ADaM datasets must be associated with metadata to facilitate clear and unambiguous communication. Ideally the metadata are machine-readable.

(5) ADaM datasets should have a structure and content that allow statistical analyses to be performed with minimal programming. Such datasets are described as "analysis-ready." ADaM datasets contain the data needed for the review and re-creation of specific statistical analyses. It is not necessary to collate data into "analysis-ready" datasets solely to support data listings or other non-analytical displays

Refer to the ADaM model document at http://www.cdisc.org/adam for more details.

ADaM 数据集必须遵循 ADaM 模型文档中所说明的特定的基本原则：

- ADaM 数据集及其相关的元数据必须清楚且无歧义地表明在该临床研究中用于支持统计分析执行的数据集的内容和来源。
- ADaM 数据集及其相关的元数据必须提供可追溯性，以展示一个值或一个变量的数据源或推导方式。（即，某一值和其前身之间的数据的沿袭或关系。）元数据必须指出分析数据是何时及如何被导出或被填补的。
- ADaM 数据集必须适用于常用软件工具。
- ADaM 数据集必须和元数据相关联，以利于清晰且无歧义地表达。理想的元数据是计算机可读取的。
- ADaM 数据集应该具有可通过最少的编程进行统计分析的结构和内容。这样的数据集被称作"分析就绪"的。ADaM 数据包含了用于审阅和重现特定分析所需的数据。如果仅仅为了输出列表或其它非分析用的结果，是没有必要将数据收集到"分析就绪"的数据集的。

更多细节可参考 http://www.cdisc.org/adam 网址中的 ADaM 模型文档。

2.2 Traceability

2.2 可追溯性

To assist review, ADaM datasets and metadata must clearly communicate how the ADaM datasets were created. The verification of derivations in an ADaM dataset

requires having at hand the input data used to create the ADaM dataset. A CDISC-conformant submission includes both SDTM and ADaM datasets; therefore, it follows that the relationship between SDTM and ADaM must be clear. This requirement highlights the importance of traceability between the analyzed data (ADaM) and its input data (SDTM).
为了帮助审阅，ADaM 数据集和其元数据必须清晰地表明 ADaM 数据集是如何生成的。对 ADaM 数据集中衍生数据的验证，需要产生这个 ADaM 数据集所用到的输入数据集。符合 CDISC 要求的递交材料包括 SDTM 和 ADaM 数据集；由此可见，SDTM 和 ADaM 之间的关系必须明确。这个要求使分析数据 (ADaM) 和其输入数据 (SDTM) 之间的可追溯性更为重要。

Traceability is built by clearly establishing the path between an element and its immediate predecessor. As described in Section 1.5.1, the full path is traced by going from one element to its predecessors, then on to their predecessors, and so on, back to the SDTM datasets, and ultimately to the data collection instrument.
可追溯性是通过清晰地建立元素和其直接前身之间的联系来建立的。如第 1.5.1 节所述。完整的相关关系可从一个元素追踪到它的前身，然后再到前身的前身，一直回溯到 SDTM 数据集，乃至源数据的采集端。

Note that the CDISC Clinical Data Acquisition Standards Harmonization (CDASH) standard is harmonized with SDTM, and therefore assists in assuring end-to-end traceability.
注意：临床数据采集标准 (CDASH)是和 SDTM 统一的，因此有助于确保数据采集端对递交端的可追溯性。

Traceability establishes across-dataset relationships as well as within-dataset relationships. For example, the metadata for supportive variables within the ADaM dataset facilitates the understanding of how (and perhaps why) derived records were created.
可追溯性建立了跨数据集之间的关系和数据集内部的关系。例如：在 ADaM 数据集中，用于支持变量的元数据有助于理解如何（或者为何）生成衍生记录。

There are two levels of traceability:

(1) Metadata traceability facilitates the understanding of the relationship of the analysis variable to its source dataset(s) and variable(s) and is required for ADaM compliance. This traceability is established by describing (via metadata) the algorithm used or steps taken to derive or populate an analysis variable from its immediate predecessor. Metadata traceability is also used to establish the relationship between an analysis result and ADaM dataset(s).
(2) Datapoint traceability points directly to the specific predecessor record(s) and should be implemented if practical and feasible. This level of traceability can be very helpful when trying to trace a complex data manipulation path. This traceability is established by providing clear links in the data (e.g., use of --SEQ variable) to the specific data values used as input for an analysis value. The BDS and OCCDS structures were designed to enable datapoint traceability back to predecessor data.

可追溯性有两种含义：

- 元数据的可追溯性有助于理解分析变量与其源数据集和变量之间的关系，且这是符合 ADaM 的要求所需的。这种可追溯性是通过说明从直接的前身数据推导或赋值分析数据时所使用的算法（基于元数据）或采取的步骤来建立的。元数据可追溯性还用于建立分析结果和 ADaM 数据集之间的关系。
- 如果通过数据点的追溯点直接指向特定的前身记录是切实可行的，应予以实施。当需要追踪复杂的数据操作时，这种可追溯性非常有用。这种追溯通过数据中提供明确的链接（如使用--SEQ 变量）来建立，这些链接指向用作分析值的特定的输入数据值。BDS 和 OCCDS 结构的设计目的就是使数据点能回溯到数据的前身。

It may not always be practical or feasible to provide datapoint traceability via record identifier variables from the source dataset(s). However metadata traceability must always clearly explain how an analysis variable was populated regardless of whether datapoint traceability is also provided.
虽然通过源数据集的记录标识符变量来提供追溯数据点并不总是切实可行的。但是，不管是否提供追溯数据点，元数据的追溯必须总是可以清楚地说明

分析变量是如何赋值的。

Very complex derivations may require the creation of intermediate analysis datasets. In these situations, traceability may be accomplished by submitting those intermediate analysis datasets along with their associated metadata.
Traceability would then involve several steps. The analysis results would be linked by appropriate metadata to the data which supports the analytical procedure; those data would be linked to the intermediate analysis data; the intermediate data would in turn be linked to the source SDTM data.
非常复杂的推导过程可能需要创建中间分析数据集。这种情况下，可追溯性可通过提交中间分析数据集及其相关的元数据来实现。这样的追溯会涉及多个步骤。分析结果会通过适当的元数据链接到支持分析过程的数据；这些数据将链接到中间分析数据；然后中间数据可依次链接到 SDTM 中的源数据。

When traceability is successfully implemented, it is possible to identify:
(1) Information that exists in the submitted SDTM data
(2) Information that is derived or imputed within the ADaM dataset
(3) The method used to create derived or imputed data
(4) Information used for analyses, in contrast to information that is not used for analyses yet is included to support traceability or future analysis
当成功的建立起数据间的可追溯性，就可以识别如下几点：

- 提交的 SDTM 研究表格数据中存在的信息
- 在 ADaM 分析数据集中衍生或填补的信息
- 用于创建衍生或填补数据的方法
- 用于分析的信息及那些不用来分析，但用来支持数据可溯源性或将来分析用的信息。

2.3 The ADaM Data Structures

2.3 ADaM 数据结构

A fundamental principle of ADaM datasets is clear communication. Given that ADaM datasets contain both source and derived data, a central issue becomes communicating how the variables and observations were derived and how observations are used to produce analysis results. The consumer of an ADaM dataset must be able to identify clearly the data inputs and the algorithms used to create the derived information. If this information is communicated in a predictable manner through the use of a standard data structure and metadata, the consumer of an ADaM dataset should be able to understand how to use the ADaM dataset to replicate results or to explore alternative analyses.
ADaM 数据集的基本原则就是清晰的信息表达。考虑到 ADaM 数据集包含源数据和衍生数据时，表达变量和观测是如何被衍生和表达如何用这些观测值来生成分析结果成为了一个主要的问题。ADaM 数据集的使用者必须能够清楚地辨认数据的输入来源和用于产生衍生信息的算法。如果通过使用标准数据结构和元数据以预先给定的方式表明这些信息，那么 ADaM 数据集的使用者就能够明白如何使用 ADaM 数据集来重现结果或探索其它的分析法。

Many types of statistical analyses do not require a specialized structure. In other words, the structure of an ADaM dataset does not necessarily limit the type of analysis that can be done, nor should it limit the communication about the dataset itself. Instead, if a predictable structure can be used for the majority of ADaM datasets, communication will be enhanced.
很多类型的统计分析不需要一个特殊的结构。也就是说，ADaM 数据集的结构不应该局限于可执行的分析类型，也不应该局限于数据集自身特定的信息表达。相应的，如果一个预先给定的结构可用于大多数 ADaM 数据集，则会增加信息表达量。

A predictable structure has other advantages in addition to supporting clear communication. First, a predictable structure eases the burden of the management of dataset metadata because there is less variability in the types of observations and variables that are included. Second, software tools can be developed to support metadata management and data review, including tools to restructure the data (e.g., transposing) based on known key variables. Finally, a predictable structure allows an ADaM dataset to be checked for conformance with ADaM standards, using a set of known conventions which can be verified.
除了帮助清晰的信息表达，预先给定的结构还具有其它的优势。首先，由于包含的观测和变量的类型变动较少，预先给定的结构可减轻管理数据集元数据的负担。其次，可以研发软件工具去帮助元数据的管理和数据的审阅，甚至可以研发基于已知的关键变量修改数据结构的工具（如数据转置）。最后，预先给定的结构使通用一组已知且可被验证的规则来检查 ADaM 数据集是否符合 ADaM 标准成为可能。

As described in Section 1, the ADaMIG describes two ADaM standard data structures: the subject-level analysis dataset (ADSL) and the Basic Data Structure (BDS). Standard ADaM variables are described in Section 3.
Implementation issues, solutions, and examples are presented in Section 4. Together, Sections 3 and 4 fully specify these standard data structures. A description of OCCDS (the third ADaM standard data structure) can be found in the document titled "ADaM Structure for Occurrence Data" as noted in Section 1.3.
如第 1 节所述，ADaMIG 说明了两种 ADaM 标准数据结构：受试者级别分析数据集 (ADSL) 和基本数据结构 (BDS)。其标准 ADaM 变量如第 3 节所述。执行问题，解决方案和示例则如第 4 节所示。也就是说，第 3 节和第 4 节完全地制定了有关的标准数据结构。OCCDS（第三种 ADaM 标准数据结构）的说明，如第 1.3 节提示的，可在《事件类数据（OCCDS）的 ADAM 结构》一文中找到。

2.3.1 The ADaM Subject-Level Analysis Dataset (ADSL)

2.3.1 ADaM 受试者级别分析数据集 (ADSL)

ADSL contains one record per subject, regardless of the type of clinical trial design. The label of the ADSL dataset is "Subject-Level Analysis Dataset".
无论临床试验的设计类型，ADSL 中每个受试者都只有一条记录。ADSL 数据集的标签是"受试者级别分析数据集"。

ADSL contains variables such as subject-level population flags, planned and actual treatment variables, demographic information, randomization factors, subgrouping variables, and important dates. ADSL contains required variables (as specified in Section 3.2) plus other subject-level variables that are important in describing a subject's experience in the trial. This structure allows merging with any other dataset, including ADaM and SDTM datasets. ADSL is a source for subject-level variables used in other ADaM datasets, such as population flags and treatment variables.
ADSL 包含如受试者级别的人群标帜，计划和实际治疗组变量，人口学信息，随机因子，亚组变量和重要日期等变量。ADSL 包括必需变量（如第 3.2 节指出的）以及其它记录着试验中重要的受试者经历的受试者级别变量。这个结构允许合并包括 ADaM 和 SDTM 在内的任何形式的数据集。在其它 ADaM 数据集中，ADSL 是受试者级别变量的来源，如人群标帜和治疗组变量。

It should be noted that though ADSL is a source for subject-level variables used in other datasets, there is no requirement that every ADSL variable be copied into a BDS dataset. However, at a minimum, all ADSL variables needed to enable analysis of the BDS dataset, such as statistical model covariates, population flags, subgrouping variables, etc., should be copied from ADSL into the BDS dataset. In addition, it is desirable to copy ADSL variables that are useful for traceability or supportive of review. Note that FDA TCG v2.3 requests that "core" subject-level variables be present in all analysis datasets. Refer to current regulatory agency requirements (see Section 1.2) and discuss with the reviewing agency.
值得注意的是，虽然 ADSL 是其它数据集中受试者级别变量的来源，但并不需要将所有 ADSL 变量复制到 BDS 数据集中。不过，至少需要将 BDS 数据集中所有实现分析所需的 ADSL 变量如统计模型协变量、人群标帜、亚组变量等，从 ADSL 复制到 BDS 数据集。另外，复制 ADSL 变量的可取之处在于有益于可追溯性或帮助审阅。注意：FDA TCG v2.3 要求所有"核心"的受试者级别的变量都需出现在所有的分析数据集。参见当前的监管机构要求（见

第 1.2 节）并咨询评审机构。

Although it would be technically feasible to take every single data value in a study and include them all as variables in a subject-level dataset, such as ADSL, that is not the intent or the purpose of ADSL. ADSL is used to provide key facts about the subject that are analysis-enabling or facilitate interpretation of analysis. ADSL is not the correct location for key endpoints and data that vary over time during the course of a study.
尽管将临床试验中的所有单个数据值全部通过变量的形式加入受试者级别的数据集如 ADSL 在技术上是可行的，但却并非 ADSL 的意图和主旨。ADSL 是用来提供关于受试者用于可分析性的或帮助解释分析的关键因子的。对于在研究过程中随时间变化的关键终点和数据，ADSL 并非一个正确的存储位置。

There is only one ADSL per study. ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other ADaM datasets are submitted.
每个研究只有一个 ADSL。在基于 CDISC 的临床试验数据申报中，即使没有其他 ADaM 数据集需要递交，ADSL 和与其相关的元数据也必须递交。

2.3.2 The ADaM Basic Data Structure (BDS)

2.3.2 ADaM 基本数据结构 (BDS)

A BDS dataset contains one or more records per subject, per analysis parameter, per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is one or more records per subject per analysis parameter. As defined in Section 1.5.2, analysis timepoint here represents one or more actual variables, such as Analysis Visit (AVISIT), Analysis Timepoint (ATPT), or other timing variables. In addition, other variables may be needed to describe more completely the structure of a given BDS dataset. For example, Baseline Type (BASETYPE) is needed when there is more than one definition of baseline for a given Analysis Parameter (PARAM) in the same dataset. This structure contains a central set of variables that represent the data being analyzed. These variables include the value being analyzed (e.g., AVAL) and the description of the value being analyzed (e.g., PARAM). Other variables in the dataset provide more information about the value being analyzed (e.g., the subject identification), describe and trace the derivation of it (e.g., DTYPE), or enable the analysis of it (e.g., treatment variables, covariates). It should be noted that though ADSL is a source for subject-level variables used in BDS datasets, this does not mean that every ADSL variable should be included in the BDS dataset.
BDS 数据集对每个受试者、每个分析参数的每个分析时间点包含了一条或以上的记录。分析时间点可根据分析需要有条件出现。在某些情况下可能会没有分析时间点，而结构会变成每个受试者每个分析参数有一条或多条记录。如第 1.5.2 节所述。分析时间点在此代表了一个或多个真实的变量，如分析访视 (AVISIT)、分析时间点 (ATPT)、或其它时间变量。另外，其它变量对给定的 BDS 数据集的结构可能需要更加完整的说明。例如：在同一数据集中，当某一给定分析参数有超过一个以上的基线定义时，基线类型 (BASETYPE) 是必需的。这样的结构包含了一组用来代表被分析数据的变量的中心组合。这些变量包括被分析的值（如 AVAL）和被分析的值的说明（如 PARAM）。而在数据集中的其它变量提供了有关这个被分析的值的更多信息（如受试者识别号），说明和追踪了其推导过程（如 DTYPE），或实现分析所用的变量（如治疗组变量、协变量）。值得注意得是，虽然 ADSL 是 BDS 数据集中受试者级别的变量的来源，但并不意味着所有 ADSL 变量需要被纳入 BDS 数据集中。

Readers are cautioned that ADaM dataset structures do not have counterparts in SDTM. Because the BDS tends toward a vertical design, some might perceive it as similar to the SDTM Findings class. However, BDS datasets may be derived from Findings, Events, Interventions and Special-Purpose SDTM domains, other ADaM datasets, or any combination thereof. Furthermore, in contrast to SDTM Findings class datasets, BDS datasets provide robust and flexible support for the performance and review of most statistical analyses.
读者需要注意的是，在 ADaM 数据集结构中并不包含 SDTM 的对应结构。因为 BDS 采用垂直设计，有人可能意识到了它和 SDTM 发现类的相似性。不过实际上，BDS 数据集可能是从发现类，事件类，干预类和特殊目的类 SDTM 域中、其它 ADaM 数据集中，或它们的任意组合中推导而出。此外，与

SDTM 发现类数据集相比，BDS 为大多数统计分析的执行和审阅提供了稳定和灵活的支持。

A record in an ADaM dataset can represent an observed, derived, or imputed value required for analysis. For example, it may be a time to an event, such as the time to when a score became greater than a threshold value or the time to discontinuation, or it may be a highly derived quantity such as a surrogate for tumor growth rate derived by fitting a regression model to laboratory data. A data value may be derived from any combination of SDTM and/or ADaM datasets.
在 ADaM 数据集中的一条记录代表一个由分析所需而观测到的、推导的、或填补的值。例如：它可能是一个到发生事件时间的记录，比如从开始到某一得分大于一临界值的时间，或从开始到终止治疗的时间，又或者是一个高度衍生的量，如通过对实验室数据的拟合回归模型推导出的肿瘤生长率的替代量。一个数据值可能是从任意 SDTM 及/或 ADaM 数据集的组合中推导出的。

The BDS is flexible in that additional rows and columns can be added to support the analyses and provide traceability, according to the rules described in Section 4.2. However, it should be stressed that in a study there is often more than one ADaM dataset that follows the BDS. The capability of adding rows and columns does not mean that everything should be forced into a single ADaM dataset. The optimum number of ADaM datasets should be designed for a study, as discussed in the ADaM model document.
根据第 4.2 节所述规则，BDS 可灵活地添加额外的行和列以帮助分析和提供可追溯性。不过应该强调的是，在一个研究中经常会有多个遵循 BDS 结构的 ADaM 数据集。。可以添加列和行并不代表需要把所有的数据都塞入某个单独的 ADaM 数据集中。正如 ADaM 模型文档所述，需要为研究设计 ADaM 数据集的最佳数量。

3 Standard ADaM Variables

3 标准 ADaM 变量

This section defines the required characteristics of standard variables (columns) that are frequently needed in ADaM datasets. The ADaM standard requires that these variable names be used when a variable that contains the content defined in Section 3 is included in an ADaM dataset. It requires these ADaM standard variables be used for the purposes indicated, even if the content of an ADaM variable is a copy of the content of an SDTM variable.
本节规定了 ADaM 数据集中常用的标准变量（列）的必备特征。ADaM 标准要求，当 ADaM 数据集中的变量包含了第 3 节中定义的内容时，必须使用相应的变量名称。而且指明这些 ADaM 标准变量必须用于指定的目的，尽管有时 ADaM 变量的内容是从 SDTM 变量中复制的。

This section also defines standard naming fragments (with position within the variable name included as the part of the definition in some instances) to be used in creating new variable names. In the variable name fragments below, a '*' is used to indicate that one or more letters can be added to create a producer-specific variable name. If a fragment is defined for a specific concept (Section 3.1.5, Variable Naming Fragments), it is best practice that any variable related to the concept contain the defined fragment in its name. Specific fragments, described in Table 3.1.5.1, are required to be used whenever the concept applies and are reserved to be used only for the corresponding concept. For example, the fragment "DTF" is defined as a suffix for date imputation flag variables; therefore, a variable that indicates whether or not a date has been imputed contains "DTF" as the last three characters in the variable name. In addition, Table 3.1.5.2 and Table 3.3.3.3 list fragments that can be used when naming variables in ADaM datasets. These lists of fragments are provided as a guide when naming variables in ADaM datasets, and are to be used in addition to the fragments defined in the SDTMIG. Section 3.1 defines ADaM Variable Conventions that apply to all ADaM variables, including the standard ADaM variables specified in Sections 3.2 and 3.3, as well as when defining new ADaM variables. Section 3.2 describes variables in ADSL. Section 3.3 describes variables in the BDS. Section 3.4 describes variables that are not specific to the ADSL or BDS structures.
本节还规定了标准命名构词法（在某些情况下，变量名称中的词缀的位置也作为定义的一部分）用来创建新的变量名称。在下文变量名称构词中，"*"用来表示将添加一个或以上开发者规定的字母作为特定的变量名称。如果一个词缀被定义为具有某一特殊的定义（第 3.1.5 节变量命名构词），则但凡变量涉及到相关定义的，最好在其名称中使用规定的词缀。无论相关定义是否应用，特殊词缀如表 3.1.5.1 所示都必须被使用，且只为相关的定义所保留。例如：词缀"DTF"定义为日期填补标记变量的后缀，因而，一个用以标记日期是否进行填补的变量，在变量名称中会有最后三个字符"DTF"。另外，表 3.1.5.2 和表 3.3.3.3 列出了 ADaM 数据集中变量命名所用的词缀列表。词缀列表为 ADaM 数据集中的变量命名提供了指导，也可另使用 SDTMIG 中定义的词缀。第 3.1 节规定了适用于所有 ADaM 变量的 ADaM 变量规则，包括第 3.2 节和第 3.3 节规定的标准 ADaM 变量和新定义的 ADaM 变量。第 3.2 节说明了在 ADSL 中的变量。第 3.3 节说明了 BDS 中的变量。第 3.4 节说明了一些不特定于 ADSL 或 BDS 结构的变量。

In this section, ADaM variables are described in tabular format. The two rightmost columns, "Core" and "CDISC Notes" provide information about the variables to assist producers in preparing their datasets. These columns are not meant to be metadata submitted in define.xml. The "Core" column describes whether a variable is required, conditionally required, or permissible. The "CDISC Notes" column provides more information about the variable. In addition, the "Type" column specifies whether the variable being described is character or numeric, though more specific datatype information will be provided in metadata (e.g., text, integer, float).
本节中，ADaM 变量以表格形式呈现。在最右侧的两列中，"核心"和"CDISC 注释"提供了有关开发者准备数据集时所用的变量信息。这些列并不意味着都需在 define.xml 中以元数据形式递交。"核心"列说明了变量是必需的,条件必需的或许可的。"CDISC 注释"列提供了更多关于变量的信息。另外，"类型"列定义了该变量是字符 (Char) 或数值 (Num)，而更进一步的数据类型信息会在元数据中提出（如文本型，整数型或小数型）。

Values of ADaM "Core" Attribute
Req = Required. The variable must be included in the dataset. **Cond** = Conditionally required. The variable must be included in the dataset in certain circumstances. **Perm** = Permissible. The variable may be included in the dataset, but is not required. Unless otherwise specified, all ADaM variables are populated as appropriate, meaning nulls are allowed.

ADaM 属性"核心"的值 **Req** =
需要。该变量必须在数据集中。 **Cond** = 条件需要。该变量在某些情况下必须在数据集中。 **Perm** = 适当添加。该变量可在数据集中但并非必须。 除非另有说明，所有 ADaM 变量应合理赋值，也就是说允许赋空值。

3.1 ADaM Variable Conventions

3.1 ADaM 变量规则

3.1.1 General Variable Conventions

3.1.1 一般变量规则

1. To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length, start with a letter (not underscore), and be comprised only of letters (A-Z), underscore (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.

   1. 为了符合 SAS 第 5 版的传输文件格式和 Oracle 的限制条件，所有的 ADaM 变量名称的长度不得超过 8 个字节，以字母（非下划线）开头，并且必须由英文字母（A-Z），下划线（_），和数字（0-9）组成。所有 ADaM 变量的标签的长度不得超过 40 个字节。所有 ADaM 字符型变量的长度不得超过 200 字节。

2. The lower case letters "*w*", "*xx*", "*y*", and "*zz*" that appear in a variable name or label in this document must be replaced in the actual variable name or label using the following conventions.
   a. The lower-case letter "*w*" in a variable name (e.g., PH*w*SDT, P*xx*S*w*SDT) is an index for the w^{th} variable where "*w*" is replaced with a single digit [1-9].
   b. The letters "*xx*" in a variable name (e.g., TRT*xx*P, AP*xx*SDT) refer to a specific period where "*xx*" is replaced with a zero-padded two-digit integer [01-99]. The use of '*xx*' within a variable name is restricted to the concept of a period.
   c. The lower-case letter "*y*" in a variable name (e.g., SITEGR*y*) refers to a grouping or other categorization scheme, an analysis criterion, or an

analysis range, and is replaced with an integer [1-99, not zero-padded]. Truncation of the original variable name may be necessary in rare situations when a two digit index is needed and causes the length of the variable name to exceed 8 characters. In these situations, it is recommended that the same truncation be used for both the character and numeric versions of the variables in a variable pair.

d. The lower-case letters "*zz*" in a variable name (e.g., ANL*zz*FL) are an index for the zz^{th} variable where "*zz*" is replaced with a zero-padded two-digit integer [01-99]. Note that the '*zz*' convention represents a simple counter, while the '*xx*' convention represents a specific period.

e. If an indexed variable is included in a dataset, there is no requirement that the preceding variable(s) in the sequence be included. For example, a dataset might include ANL02FL but not ANL01FL.

2. 在本文中，出现在变量名称或者变量标签中的小写字母"w"，"xx"，"y"，和"zz"必须根据如下规定替换成真正的变量名称或标签。

a. 变量名称中的小写字母"w"（如 PHwSDT，PxxSwSDT）是第 w 个变量的索引，其中"w"应被替换成一位数字[1-9]。

b. 变量名称中的字母"xx"（如 TRT*xx*P，AP*xx*SDT）是指一个特定的阶段，其中"xx"应被替换成两位补零整数[01-99]。在变量名称中使用"xx"需受限于该阶段的定义。

c. 变量名称中的小写字母"y"（如 SITEGR*y*）是指一个分组，或其它分类方案，或分析标准，或分析范围，应被一个整数替换[1-99，不补零]。在少数情况下需要使用两位索引，而由此导致变量名称的长度超过了 8 个字节时，缩短原变量名称或许是有必要的。在这种情形下，推荐对相对应的字符类型和数值类型的变量都作同样的缩短处理。

d. 变量名称中的小写字母"zz"（如 ANLzzFL）是指第 zz 个变量的索引，其中"zz"应被替换成两位补零整数[01-99]。注意："xx"代表的是一个指定的阶段，而"zz"只代表简单的计数。

e. 如果一个数据集包含了一个加了索引的变量，那么该变量顺序之前的变量不一定需要被纳入。例如：一个数据集有 ANL02FL 但不一定需要 ANL01FL。

3. Any variable in an ADaM dataset whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values." However, to optimize file size, it is permissible that the length of the variables differ (e.g., trailing blanks may be removed). In many cases it makes sense to copy over an SDTM variable. For example, the SDTM variable --SEQ may be useful for traceability. However, in other cases, it is also perfectly acceptable, and might be much better, to create an ADaM variable with a meaningful variable name and clear and unambiguous metadata. An SDTM variable may be somewhat meaningless when removed from its SDTM context. For example, the meaning of the SDTM variable DSDECOD may depend on other SDTM variables such as DSCAT and DSSCAT, and ultimately on how the data were collected and mapped to SDTM in a particular study; thus it may be better to create a clearly-defined ADaM variable. In any case, whenever values are modified in any way, it is mandatory to do so in an ADaM variable, and it is prohibited to do so in a variable whose name is that of an SDTM variable.

3. ADaM 数据集中的任何变量如果跟某一 SDTM 变量同名，那么该变量就必须是 SDTM 变量的复制，而它的标签，涵义和值都不能被改变。ADaM 遵循"相同名称，相同涵义，相同值"的统一原则。但是，有时候为了优化数据集的文件大小，变量长度的不一致是允许的（如：尾部空白会被移除）。在大多数情况下，从 SDTM 复制一个变量是非常合理的。例如：--SEQ 变量对可追溯性非常有用。但是在某些情况下，新建一个具备有意义的变量名称的 ADaM 变量，且规定相应的清楚且无歧义的元数据是完全可以接受的，甚至大有好处。有些 SDTM 变量可能从相应的 SDTM 背景中移除就没有意义了。例如：SDTM 变量 DSDECOD 的涵义也许会依赖其它变量如 DSCAT 和 DSSCAT，而根本上取决于特定研究中的数据是如何收集和映射到 SDTM 的。因此最好能建立一个定义清楚的 ADaM 变量。在任何情况下，无论值以何种方式被修改，都务必在 ADaM 变量中进行，而在 SDTM 变量同名的变量中进行修改是禁止的。

4. When an ADaM standard variable name has been defined for a specific concept, the ADaM standard variable name must be used, even if the

content of an ADaM variable is a direct copy of the content of an SDTM variable. For example, in the creation of ADLB, even if AVAL is just a copy of LBSTRESN the dataset must contain AVAL.

4. 当一个 ADaM 的标准变量名称已被赋于一个特定的含义，那就必须要使用这个变量名称，哪怕这个变量的内容是直接从 SDTM 变量的内容复制的。例如：在建立 ADLB 的过程中，哪怕 AVAL 只是 LBSTRESN 的复制，数据集也必须要包括 AVAL。

5. For variable pairs designated as having a one-to-one mapping within a specified scope (e.g., within a parameter, within a study), if both variables are present in the dataset and there exists a row in that scope on which both variables are populated, then there must be a one-to-one mapping between the two variables on all rows within the scope on which both variables are populated. The scopes noted in this document should be considered the minimum level for the mapping; it does not preclude the producer from using a broader level of scope. For example, if a one-to-one mapping is specified as within a PARAM, the producer may elect to use the same one-to-one mapping across all PARAMs within the dataset or study. In addition, note that "within a parameter" means "within a parameter within a dataset."

   5. 当一对变量被指定在特定的范围内一一对应（如在参数内，或在研究内），如果这两个变量同时出现数据集中，并且在存在范围内对该变量赋值的一行数据，那么这两个变量在范围内的所有行中都会被一一对应的赋值。本文所提到的范围指的是满足对应的最狭义级别；这不妨碍开发者使用更广义级别的范围。例如：如果规定了在参数内一一对应，那么开发者可以决定在研究或数据集中所有的参数都使用相同的一一对应。另外，注意"在参数内"是指"在数据集内且在参数内"。

6. In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (e.g., N for Numeric or C for Character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable, TRTP is character; but it is not named TRTPC. Similarly in the (APERIOD, APERIODC) pair, the primary variable, APERIOD, is numeric; but it is not named APERIODN. When the secondary variable is numeric, it can only be included if the primary variable is also present in the dataset. If both variables of a variable pair are present, there must be a one-to-one mapping between the values of the two variables, as described in Item 5 above.

   6. 在成对变量（如：TRTP, TRTPN）中，最主要或最通用的变量不包含后缀词或扩展词（例如，N 为数值型变量，或 C 为字符型变量）。一般只给在成对变量中次要的那个变量加上相应后缀。例如：在成对变量 (TRTP, TRTPN) 中，主要变量 TRTP 是字符型；但是它并没有被命名成 TRTPC。类似地，成对变量 (APERIOD, APERIODC)，主要变量 APERIOD 是数值型，但是它并没有被命名成 APERIODN。当次要变量是数值型时，只有当主要变量出现在数据集中才可以被纳入。当成对变量中的两个变量都出现时，变量的值必须是一对一对应的，如上文第 5 项所述。

7. In general, if SDTM character variables are converted to numeric variables in ADaM datasets, then they should be named as they are in the SDTM with an "N" suffix added. For example, the numeric version of the DM SEX variable is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. As stated previously, the secondary variable of the variable pair cannot be present in the dataset unless the primary variable is also present. Applying that to the variable pairs being described in this item, the numeric equivalent of the variable cannot be present in the dataset unless the character version is also present. If necessary to keep within the 8-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values map one-to-one to the values of the equivalent character variables. Note also that this convention does not apply to SDTM date/time ISO8601-formatted character variables converted to ADaM numeric *DT, *TM, and *DTM variables.

   7. 一般地，如果一个字符型的 SDTM 变量在 ADaM 数据集中被转成了数值型变量，那么变量名称就需要加 N 后缀。例如：在 ADaM 数据集中，DM SEX 变量转成数值型要变成 SEXN，RACE 转数值型变成 RACEN。如前文所述，成对变量中的次要变量不能单独出现在数据集中，除非主要变量同时出现。本条中的成对变量也适用这个规则，数值型的等价变量不能单独出现在数据集中，除非相应的字符型变量同时

出现。如果需要保证长度不超过 8 个字节的变量名称，可以在添加 N 后缀前去掉末位字符。注意：这种命名方案只适用于与等价的字符型变量一一对应的数值型变量。另外需要注意的是，这个规则不适用于 SDTM 时间/日期 ISO8601 格式的字符型变量转换成 ADaM 数值型*DT，*TM 和*DTM 变量的情况。

8. Variables whose names end in FL are character flag (or indicator) variables with at most two possible non-missing values, Y or N (i.e., yes or no). The name of the corresponding numeric flag (or indicator) variable ends in FN. If the flag is included in an ADaM dataset, the character version (*FL) is required but the corresponding numeric version (*FN) can also be included. If both versions of the flag are included, there must be a one-to-one mapping between the values of the two variables, as described in Section 3.1.4.

   8. 变量名称以 FL 结尾的字符型标记（或标志）变量，至少含有两种可能的非空值，Y 或 N（即，是或否）。相应的数值型标记（或标志）变量以 FN 结尾。如果标记被纳入了 ADaM 数据集，那么字符版本 (*FL) 是必须的，但是相应的数值版本 (*FN) 也是可以被纳入的，且两个变量之间必须一一对应，如第 3.1.4 节所述。

9. Variables whose names end in GR*y*, G*y*, or CAT*y* are grouping variables, where y refers to the grouping scheme or algorithm (not the category within the grouping). For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site-grouping algorithm; SITEGR3 does not mean the third group of sites. Within this document, CAT*y* is the suffix used for categorization of ADaM-specified analysis variables (e.g., CHGCAT*y* categorizes CHG).

   9. 变量名称以 GRy，Gy 或者 CATy 结尾的分组变量，其中 y 指的是分组方案或算法（不是指分组里的类别）。例如，SITEGR3 是包含中心分组（合并中心）名称的变量名称，其中分组是根据第三种中心分组的算法合并的；SITEGR3 并不意味着第三组中心。在本文中，后缀 CATy 被用作 ADaM 指定的分析变量的分类（如：CHGCATy 是 CHG 的分类）。

10. It is recommended that producer-defined grouping or categorization variables begin with the name of the variable being grouped and end in GR*y* (e.g., variable ABCGR*y* is a character description of a grouping or categorization of the values from the ABC variable for analysis purposes). If any grouping of values from an SDTM variable is done, the name of the derived ADaM character grouping variable should begin with the SDTM variable name and end in GR*y* (GR*y*N for the numeric equivalent) where y is an integer [1-99, not zero-padded] representing a grouping scheme. For example, if a character analysis variable is created to contain values of Caucasian and Non-Caucasian from the SDTM RACE variable, then it should be named RACEGR*y* and its numeric equivalent should be named RACEGR*y*N (e.g., RACEGR1, RACEGR1N). As described in Table 3.1.5.1, G*y* can be used as an abbreviated form of GR*y* when the use of GR*y* would create a variable name longer than 8 characters. Truncation of the original variable name may be necessary when appending suffix fragments GR*y*, GR*y*N, G*y*, or G*y*N.

    10. 对于开发者自定义的分组或者分类变量，建议以被分组的变量名称开头而以 GRy 结尾（如：变量 ABCGRy 是用于分析的，对变量 ABC 的值的分组或分类的字符描述）。如果一个分组变量来自已完成的 SDTM 变量，那么这个推导出的 ADaM 字符型分组变量应该以 SDTM 变量名称开头而以 GRy 结尾的（GRyN 用于等价的数值型），其中 y 是一个代表分组方案的整数[1-99，不补零]。例如：如果一个产生自 SDTM RACE 变量的字符型分析变量包含高加索人和非高加索人这两个值，那么这个变量应当被命名为 RACEGRy，而其等价的数值型应当被命名为 RACEGRyN（如：RACEGR1, RACEGR1N）。如表 3.1.5.1 所述，当以 GRy 建立的变量名称长度超过 8 个字节，Gy 可用来缩略 GRy。当添加后缀 GRy，GRyN，Gy，或 GyN 时，缩短原变量名称或许是有必要的。

3.1.2 Timing Variable Conventions

3.1.2 时间变量规则

1. Numeric dates, times and datetimes should be formatted, so as to be human-readable with no loss of precision.
2. Variables whose names end in DT are numeric dates.
3. Variables whose names end in DTM are numeric datetimes.
4. Variables whose names end in TM are numeric times.
5. If a *DTM and associated *TM variable exist, then the *TM value must match the time part of the *DTM value when the *DTM variable is populated. If a *DTM and associated *DT variable exist, then the *DT value must match the date part of the *DTM value when the *DTM variable is populated.
6. Names of timing start variables end with an S followed by the characters indicating the type of timing (i.e., SDT, STM, SDTM), unless otherwise specified elsewhere in Section 3.
7. Names of timing end variables end with an E followed by the characters indicating the type of timing (i.e., EDT, ETM, EDTM), unless otherwise specified elsewhere in Section 3.
8. Variables whose names end in DY are relative day variables. In ADaM as in the SDTM, there is no day 0. If there is a need to create a relative day variable that includes day 0, then its name must not end in DY.
9. ADaM relative day variables need not be anchored by SDTM RFSTDTC. The anchor (i.e., reference) date variable must be indicated in the variable-level metadata for the relative day variable. The anchor date variable should also be included in ADSL or the current ADaM dataset to facilitate traceability. Similarly, anchor time variables used to calculate values for ADaM relative time variables must be indicated in the variable-level metadata for the relative time variable, and must be included in ADSL or the current ADaM dataset. Note that it is possible to have different definitions for a relative day (or time) variable (e.g., ADY) in separate datasets, using different anchor dates (or times). For example, the derivation of ADY for efficacy datasets might be different from that for safety datasets.
10. Table 3.3.3.3 presents standard suffix naming conventions for producer-defined supportive variables containing numeric dates, times, datetimes, and relative days, as well as date and time imputation flags. These conventions are applicable to all ADaM datasets. The asterisk that appears in a variable name in the table must be replaced by a suitable character string, so that the actual variable name is meaningful and complies with the restrictions noted in Section 3.1.1.
11. The reader is cautioned that the root or prefix (represented by *) of such producer-specified supportive ADaM date, time and datetime variable names must be chosen with care, to prevent unintended conflicts among other such names and standard numeric versions of possible SDTM variable names. In particular, **potentially problematic values for producer-defined roots/prefixes (*) include:**
    a. One-letter prefixes.
    For an example of the problem, if * is Q, then a date *DT would be QDT; however, a starting date *SDT would be QSDT, which would potentially be confusing if the producer intended QSDT to be something other than the numeric date version of the SDTM variable QSDTC.
    b. Two-letter prefixes, except when intentionally chosen to refer explicitly to a specific SDTM domain and its --DTC, --STDTC, and/or --ENDTC variables.
    For an example of an appropriate intentional use of a two-letter prefix, if * is LB, then *DT is LBDT, the numeric date version of SDTM LBDTC.
    For an example of the problem, if * is QQ, then a date *DT would be QQDT, which would potentially be confusing if the producer intended QQDT to be something other than the numeric date version of a potential SDTM variable QQDTC.
    c. Three-letter prefixes ending in S or E.
    For an example of the problem, if * is QQS, then a date *DT would be QQSDT, which would potentially be confusing if the producer intended QQSDT to be something other than the numeric date version of a potential SDTM variable QQSTDTC.
12. In general, all three of *DT, *TM, *DTM are not required. Include only the *DT, *TM, and *DTM variables needed for analysis or review. However, when a *DTM variable exists, it is good practice to include a corresponding *DT variable.

For more information regarding date and time variable conventions, refer to Table 3.3.3.3.

1. 数值型日期，时间和日期时间有固定格式，以保证是人类可读且不损失精度的。
2. 变量名称以 DT 结尾的是数值型的日期变量。
3. 变量名称以 DTM 结尾的是数值型的日期时间变量。
4. 变量名称以 TM 结尾的是数值型的时间变量。
5. 如果*DTM 和相应的*TM 变量同时存在，那么*TM 的值必须与*DTM 变量所赋值的时间部分相吻合；如果*DTM 和相应*DT 变量同时存在，那么，*DT 的值必须与*DTM 变量所赋值的日期部分相吻合。
6. 时间开始变量的名称以字母 S 接上识别时间类型的字符组成（即，SDT，STM，SDTM），除非在第 3 节中另有说明。
7. 时间结束变量的名称以字母 E 接上识别时间类型的字符组成（即，EDT，ETM，EDTM），除非在第 3 节中另有说明。
8. 变量名称以 DY 结尾的是相对天数变量。在 ADaM 中和在 SDTM 中一样，没有第 0 天。除非需要产生一个包括第 0 天的变量，且其名称必须不以 DY 结尾。
9. ADaM 相对天数变量不需要以 SDTM RFSTDTC 为基准。基准（即参考）日期变量必须在变量级别的元数据的相对天数变量中被表明出来。基准日期变量也必须被纳入 ADSL 或当前 ADaM 数据集以增加可追溯性。同样的，用于计算 ADaM 相对时间变量的基准时间变量也必须在变量级别的元数据的相对时间变量中被表明出来，且相对时间变量必须被纳入 ADSL 或当前的 ADaM 数据集。注意：在不同的数据集中，对相对天数（或时间）变量（如 ADY）可能有不同的定义来使用不同的基准变量（或时间）。例如：对有效性数据集的推导方式或许与安全性数据集不同。
10. 表 3.3.3.3 展示了开发者自定义的辅助变量的标准后缀命名规则，包括数值型日期、时间、时间日期、和相对天数以及日期和时间的填补标记。这些规则对所有 ADaM 数据集都适用。表格中变量名称里出现的星号必须用适当的字符串替换，使得真正的变量名称具有意义并且符合第 3.1.1 节的限制条件。
11. 读者必须注意的是，对开发者自定义 ADaM 日期，时间，时间日期等辅助变量名称的词根或前缀，需谨慎选择，以防止不经意中对其它名称和有可能具有数值版本的 SDTM 变量名称发生冲突。开发者自定义的词根或前缀中，经常存在的潜在问题的自定义值如下：
    a. 单字母前缀
       问题示例：如果*为 Q 则*DT 日期会变成 QDT；然而，开始日期*SDT 会变成 QSDT，如果开发者意指 QSDT 是 SDTM 变量 QSDTC 的数值日期版本以外的日期，就会产生潜在的混淆。
    b. 双字母前缀，除了特意选择并明确引用到了 SDTM 域及其—DTC，--STDTC，和（或）--ENDTC 变量。
       双字母前缀合理选用示例：如果*为 LB 则*DT 日期会变成 LBDT——即 SDTM LBDTC 的数值日期版本。
       问题示例：如果*为 QQ 则*DT 日期会变成 QQDT，如果用户想用 QQDT 来代表 SDTM 变量 QQDTC 数值型日期版本之外的其它内容，则会导致潜在的混淆。。
    c. 三字母前缀且以 S 或 E 结尾。
       问题示例：如果*为 QQS 则*DT 日期会变成 QQSDT，如果用户想用 QQSDT 来代表 SDTM 变量 QQSTDTC 数值型日期版本之外的其它内容，则会导致潜在的混淆。。
12. 一般地，*DT，*TM，*DTM 不需要三个都出。只需纳入分析或审阅所需的*DT、*TM 和*DTM 变量。不过，当*DTM 变量存在时，最好能纳入相应的*DT 变量。

关于日期和时间规则的其它信息，可参考表 3.3.3.3。

3.1.3 Date and Time Imputation Flag Variables

3.1.3 日期和时间填补标记变量

When a date or time is imputed, it is required that the variable containing the imputed value be accompanied by a date or time imputation flag variable. The variable fragments to be used for these variables are DTF and TMF, as defined in Table 3.1.5.1. DF and TF can be used as abbreviated forms of DTF and TMF, respectively, when the use of DTF or TMF would create a variable name longer than 8 characters. These additional imputation flag variables are conditionally required. The root, identified by *, of the names of each pair of variables, *DT and *DTF (or *DF), should be identical. The same is true for the corresponding time and imputation flag variables *TM and *TMF (or *TF). Thus it is good practice to limit roots to 5 characters in length.
当一个日期或时间是填补的，必须相应的要有一个包含填补值的日期或时间填补标记变量。用于这些变量的词缀就是 DTF 和 TMF，根据表 3.1.5.1 规定的，当使用 DTF 或者 TMF 导致变量名称的长度超过 8 个字节，可以分别以 DF 和 TF 作为 DTF 或 TMF 的缩略形式。这些额外的填补标记变量在某些时候是必须的。成对变量*DT 和*DTF（或*DF）中以*识别的词根必须相同。对相应的时间和填补标记变量*TM 和*TMF（或*TF）也是如此。因此词根的长度以不超过 5 个字节为佳。

It should be noted that in many instances in Section 3, specific DTF and TMF flags are defined within sets of timing variables. However, imputation flags should be created for all date or time variables when imputation has been performed, even if there is not a specific variable mentioned in Section 3 (e.g., for EOSDT).
需要注意得是第 3 节提了的很多例子，在一系列时间变量中定义了特定的 DTF 和 TMF 标记。但是，对所有填补过的日期或时间变量都需要加上填补标记，尽管它在第 3 节中可能未被提及（如 EOSDT 的填补标记）。

1. As described in Table 3.1.5.1, variables whose names end in DTF are date imputation flags. *DTF variables represent the highest level of imputation of the *DT variable based on the source SDTM DTC variable. *DTF = Y if the year is imputed. *DTF = M if year is present and month is imputed. *DTF = D if only day is imputed. *DTF = null if *DT equals the SDTM DTC variable date part equivalent. If a date was imputed, *DTF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done. Note that the list of examples in Table 3.1.3.1 is not exhaustive.

1. 如表 3.1.5.1 所述，变量名称以 DTF 结尾的是日期填补标记变量。*DTF 代表了*DT 变量从 SDTM DTC 变量被填补的最高级别。当年被填补时，*DTF = Y。当年存在而月被填补时，*DTF = M。当只有日被填补时，*DTF = D。当*DT 与 SDTM DTC 变量的日期部分等价时，*DTF 为空。如果日期被填补了，*DTF 必须被赋值且必须存在。为了说明对填补的*DTM 的填补级别，*DTF 和*TMF 有可能都须存在。注意：表 3.1.3.1 中所列出的例子并未穷尽。

Table 3.1.3.1 Some Examples of Setting of Date Imputation Flag

Missing Elements	SDTM --DTC String	ADaM Date Value (*DT Variable)[1,2] (## indicates imputed portion)	Imputation flag (*DTF variable)
None	YYYY-MM-DD	YYYY-MM-DD	Blank
Day	YYYY-MM	YYYY-MM-##	D
Month	YYYY---DD	YYYY-##-DD	M
Month and Day	YYYY	YYYY-##-##	M
Year	--MM-DD	####-MM-DD	Y
Year and Month	----DD	####-##-DD	Y
Year and Month and Day		####-##-##	Y

[1] The ISO formats used in the ADaM Date Value column are for the purposes of illustration, and are not intended to imply any type of display standard or requirement. The DT variable is numeric and the producer will determine the appropriate display format.
[2] The indication of imputed values is not intended to imply an imputation rule or standard. For example, if the month is missing, imputation rules might specify that the collected day value be ignored so that both month and day are imputed.

表 3.1.3.1 日期填补标记设置的一些示例

缺失成分	SDTM --DTC 字符串	ADaM 日期值（*DT 变量）[1,2]（## 标志填补的部分）	填补标记（*DTF 变量）
无	YYYY-MM-DD	YYYY-MM-DD	空
日	YYYY-MM	YYYY-MM-##	D
月	YYYY---DD	YYYY-##-DD	M
月日	YYYY	YYYY-##-##	M
年	--MM-DD	####-MM-DD	Y
年月	----DD	####-##-DD	Y
年月日		####-##-##	Y

[1] ISO 格式应用于 ADaM 日期值一列只是为了图文示例目的，并不是用来暗示任何类型的显示标准或要求的。DT 变量为数值型，而开发者会负责决定合适的显示格式。
[2] 填补值的标志不是用来暗示某种填补规则或标准的。例如：如果月缺失了，填补规则可能会规定忽略收集到的日的值，结果月和日都被进行了填补。

2. As described in Table 3.1.5.1, variables whose names end in TMF are time imputation flags. *TMF variables represent the level of imputation of the *TM (and *DTM) variable based on the source SDTM DTC variable. *TMF = H if the entire time is imputed. *TMF = M if minutes and seconds are imputed. *TMF = S if only seconds are imputed. *TMF = null if *TM equals the SDTM DTC variable time part equivalent. For a given SDTM DTC variable, if only hours and minutes are ever collected, and seconds are imputed in *DTM as 00, then it is not necessary to set *TMF to "S". However if seconds are generally collected but are missing in a given value of the DTC variable and imputed as 00, or if a collected value of seconds is changed in the creation of *DTM, then *TMF should be set to "S". If a time was imputed *TMF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done.

   2. 如表 3.1.5.1 所述，变量名称以 TMF 结尾的是时间填补标记变量。*TMF 变量代表*TM（和*DTM）变量从 SDTM DTC 变量被填补的最高级别。当整个时间被填补时，*TMF = H。当分钟和秒被填补时，*TMF = M。当只有秒被填补时，*TMF = S。当*TM 与 SDTM DTC 变量的时间部分等价时，*TMF 为空。对一个给定的 SDTM DTC 变量，如果数据只收集小时和分钟，而秒在*DTM 内被填补为 00，则将*TMF 设为"S"是不必要的。不过，如果秒一般是被收集的，却在 DTC 变量中缺失了一个给定的值，并被填补为 00，又或者当收集到的秒的值在生成的*DTM 中被改变了，则*TMF 须被设为"S"。如果时间被填补了，*TMF 必须被赋值且必须存在。为了说明对填补的*DTM 的填补级别，*DTF 和*TMF 有可能都须存在。

Note that using SDTM --DTC variables for comparison purposes in analysis algorithms may be problematic in the presence of missing date or time elements. SDTM --DTC variables containing date, time, and datetime values are character strings that, in the presence of missing elements (year, month, day, hour, minute, or second), sort or compare in a manner that may be equivalent to imputation of missing elements with the lowest possible value. For example, if in a given --DTC variable in a dataset, dates are present on all records, but time is missing on some records, then within any given date, the records with missing time may sort or compare before the records that contain a value of time. Thus the --DTC variable would sort or compare in a manner that is equivalent to imputing midnight when time is missing. The sort or comparison may work mechanically, but imputing midnight may not be the most appropriate thing to do for statistical analysis. Furthermore, the effective imputation of midnight would be hidden and not made explicit. It is important to consider the implications of implicit or

explicit imputation whenever dates, times, or datetimes are compared or sorted.

注意：在分析算法中，使用 SDTM --DTC 变量进行比较，可能会在缺少日期或时间成分的情况下出现问题。包含日期、时间和日期时间值的 SDTM --DTC 变量是一组字符串，在缺少成分的情况下（如年、月、日、小时、分钟或秒），几乎是按等价于填补最小可能值的方法进行排序或比较的。例如：如果在数据集中给定的-- DTC 变量所有的记录都有日期，但是部分记录缺失了时间，对给定的日期来说，在排序和比较中，缺失时间的日期可能会排在有时间的记录前面。因此，当缺失时间时，--DTC 变量几乎是按等价于填补午夜 12 点的方法进行排序或比较的。在理论上，排序和比较可能会行得通，但是补全的午夜时间也许并不是最适合用来做统计分析的。再者，午夜时间的最佳填补有可能是隐藏和不显示。无论何时比较或排序日期、时间或日期时间，都必须考虑隐式或显式填补所代表的含义。

3.1.4 Flag Variable Conventions

3.1.4 标记变量规则

1. The terms “flag” and “indicator” are used interchangeably within this document, and “flag variables” are sometimes referred to simply as “flags.”
2. Population flags must be included in a dataset if the dataset is analyzed by the given population. At least one population flag is required for datasets used for analysis. A character indicator variable is required for every population that is defined in the statistical analysis plan. All applicable subject-level population flags must be present in ADSL.
3. Character and numeric subject-level population flag names end in FL and FN, respectively. Similarly, parameter-level population flag names end in PFL and PFN, and record-level population flag names end in RFL and RFN. Please also refer to Item 8 in Section 3.1.1.
4. For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed.
5. For subject-level numeric population flag variables: 0 = no (not included), 1 = yes (included). Null values are not allowed.
6. For parameter-level and record-level character population flag variables: Y = yes (included). Null values are allowed. Note that the controlled terminology is not the same for these population flag variables as for subject-level population flag variables. Depending on how validation checks are written, this difference could cause an issue for a producer-defined subject-level flag variable with a name that ends in “RFL” or “PFL” if it is copied into a BDS dataset.
7. For parameter-level and record-level numeric population flag variables: 1 = yes (included). Null values are allowed. Depending on how validation checks are written, this difference could cause an issue for a producer-defined subject-level flag variable with a name that ends in “RFN” or “PFN” if it is copied into a BDS dataset.
8. In addition to the population flag variables defined in Section 3, other population flag variables may be added to ADaM datasets as needed, and must comply with these conventions.
9. For character flags with variable names that end in FL and that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Table 3.3.4.2, and Table 3.3.8.1, some common character flags use the scheme Y/null. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and that are not population indicators.
10. Additional flags may be added if their names and values comply with these conventions.

1. 在本文中，术语“标记”和“标志”是可完全互换使用的，而“标记变量”有时候又会被称为“标记”。
2. 若数据集将以给定的人群进行分析，人群标记就必须被纳入数据集。对分析来说，分析集内至少应有一个以上的人群标记。字符型标志变量对每种统计分析计划定义的人群都是必需的。所有适用的受试者级别的人群标记都必须出现在 ADSL。
3. 字符型和数值型的受试者级别的人群标记名称分别以 FL 和 FN 结尾。同样地，参数级别的人群标记名称以 PFL 和 PFN 结尾，而记录级别的人群标记名称以 RFL 和 RFN 结尾。请参考第 3.1.1 节第 8 项。
4. 对受试者级别的字符型人群标记来说：N = 否（不纳入该人群），Y = 是（纳入）。空值是不被允许的。

5. 对受试者级别的数值型人群标记来说：0 = 否（不纳入该人群），1 = 是（纳入）。空值是不被允许的。
6. 对参数级别和记录级别的字符型人群标记来说：Y = 是（纳入）。空值是被允许的。注意：这些标记的受控术语和受试者级别的人群标记不一样。取决于如何编写验证检查，当一个开发者自定义的受试者级别的标记变量且名称以“RFL”或“PFL”结尾时，如果 BDS 数据集中也复制了它，这种差异就可能造成问题。
7. 对参数级别和记录级别的数值型人群标记来说：1 = 是（纳入）。空值是被允许的。注意：这些标记的受控术语和受试者级别的人群标记不一样。取决于如何编写验证检查，当一个开发者自定义的受试者级别的标记变量且名称以“RFN”或“PFN”结尾时，如果 BDS 数据集中也复制了它，这种差异就可能造成问题。
8. 除了在第 3 节中定义的人群标记变量外，在 ADaM 数据集中，其它人群标记可按需添加，但必须遵守这些规则。
9. 对字符型标记变量名称以 FL 结尾而不是人群标记的，Y/N/空或 Y/空的赋值方法可能是特定的。如表 3.3.4.2 和表 3.3.8.1 中就表明了一些通用字符型标记就使用了 Y/空的赋值方法。相应的 1/0/空和 1/空赋值方法也适用于数值型标记变量名称以 FN 结尾且并非人群标志的变量。
10. 如果标记的名称和值符合以上规则，则可额外添加该标记。

3.1.5 Variable Naming Fragments

3.1.5 变量命名构词法

Table 3.1.5.1 contains a list of standard suffix fragments (i.e., variable name fragments used as the last part of a variable name) that are required when naming variables in ADaM datasets, as defined in Section 3.1. For these fragments, it is a requirement that the appropriate fragment be used whenever the concept applies and that the fragment is reserved to be used only for the corresponding concept. For example, a variable whose name ends in DT must contain a numeric date, and a variable created to contain a numeric date must have a name ending in DT.
表 3.1.5.1 列举了当 ADaM 数据集里有变量命名时，根据第 3.1 节所规定必需的标准后缀（即，变量名称词缀用于变量名称的最后部分）。无论相关定义是否应用，适当的词缀必须被使用，且只为相关的定义所保留。例如：变量名称以 DT 结尾的，必定是数值型的日期变量，以及生成一个用于容纳数值型日期的变量，命名必须以 DT 为结尾。

Table 3.1.5.1 Required Suffix Fragments for Use in Naming ADaM Variables

Fragment	CDISC Notes
GRy	Suffix used in names of grouping variables, where y refers to the grouping scheme or algorithm (not the category within the grouping). Note that GRy can be abbreviated to Gy when necessary to comply with the variable name length limit of 8 characters. The corresponding numeric version of the variable will use the suffix GRyN (or GyN if the Gy abbreviation is used). For more information on grouping variables see Section 3.1.1. See Table 3.2.2 for examples of grouping variables.
FL	Suffix used in names of character flag variables, when the valid values of the variable are Y/Null or Y/N/Null. The corresponding numeric version of the variable will use the suffix FN. For more information on flag variables, see Section 3.1.1 and Section 3.1.4. See Table 3.2.3, Table 3.3.4.2, and Table 3.3.8.1 for examples of flag variables.
DT	Suffix used in names of numeric date variables. For more information on timing variables, see Section 3.1.2. See Section 3.3.3 for examples of timing variables.
TM	Suffix used in names of numeric time variables. For more information on timing variables, see Section 3.1.2. See Section 3.3.3 for examples of timing variables. Note that although ADaM variable ARELTM ends in TM, it is an exception, and is not a numeric time variable. In addition, the SDTM variables --ELTM are not numeric time variables.

Fragment	CDISC Notes
DTM	Suffix used in names of numeric datetime variables. For more information on timing variables, see Section 3.1.2. See Section 3.3.3 for examples of timing variables.
DTF	Suffix used in names of date imputation flag variables. Note that DTF can be abbreviated to DF to comply with the variable name length limit of 8 characters. For more information, see Section 3.1.3. See Section 3.3.3 for examples of timing imputation variables.
TMF	Suffix used in names of time imputation flag variables. Note that TMF can be abbreviated to TF to comply with the variable name length limit of 8 characters. For more information, see Section 3.1.3. See Section 3.3.3 for examples of timing imputation variables.
DY	Suffix used in names of relative day variables that do not include day 0. For more information on timing variables, see Section 3.1.2. See Section 3.3.3 for examples of timing variables.

表 3.1.5.1 用于 ADaM 变量命名的指定后缀词

词缀	CDISC 注释
GRy	用于分组变量名称的后缀，其中 y 指的是分组方案或算法（并非该分组中的分类）。注意：为了满足变量名称长度的 8 个字节限制，GRy 可被缩略为 Gy。相应的变量的数值型版本以 GRyN 为后缀（或当缩略为 Gy 时使用 GyN）。对分组变量的更多信息，见第 3.1.1。对分组变量的示例，见表 3.2.2。
FL	用于字符型标记变量名称的后缀，其中有效值可能是 Y/空，或 Y/N/空。相应的变量的数值型版本以 FN 为后缀。对标记变量的更多信息，见第 3.1.1 节和第 3.1.4 节。对标记变量的示例，见表 3.2.3，表 3.3.4.2， 和 表 3.3.8.1。
DT	用于数值型日期变量名称的后缀。对时间变量的更多信息，见第 3.1.2 节。对时间变量的示例，见第 3.3.3 节。
TM	用于数值型时间变量名称的后缀。对时间变量的更多信息，见第 3.1.2 节。对时间变量的示例，见第 3.3.3 节。注意：尽管 ADaM 变量 ARELTM 以 TM 结尾，但它是例外的，它不是一个数值型时间变量。除此以外，SDTM 变量–ELTM 都不是数值型时间变量。
DTM	用于数值型日期时间变量名称的后缀。对时间变量的更多信息，见第 3.1.2 节。对时间变量的示例，见第 3.3.3 节。
DTF	用于日期填补标记变量名称的后缀。注意：为了满足变量名称长度的 8 个字节限制，DTF 可被缩略为 DF。更多相关信息，见第 3.1.3 节。对时间填补变量的示例，见第 3.3.3 节。
TMF	用于时间填补标记变量名称的后缀。注意：为了满足变量名称长度的 8 个字符限制，TMF 可被缩略为 TF。更多相关信息，见第 3.1.3 节。对时间填补变量的示例，见第 3.3.3 节。
DY	用于相对天数，其中不包括第 0 天的变量名称的后缀。对时间变量的更多信息，见第 3.1.2 节。对时间变量的示例，见第 3.3.3 节。

Table 3.1.5.2 contains a list of additional standard reserved fragments to use as a guide when naming variables in ADaM datasets. This list should be used in addition to the list of timing fragments defined in Table 3.3.3.3 and to the fragments defined in the SDTMIG. It should be noted that some concepts have slightly different fragments in ADaM than in the SDTMIG; the ADaM fragment takes precedence when creating an ADaM variable. When using fragments, the general rule is to use the fragment(s) that best conveys the meaning of the variable within the 8-character limit. The list of fragments is provided as a guideline, not as a requirement.

表 3.1.5.2 包含了一个补充的标准保留词缀列表，用于在 ADaM 数据集中变量命名的指导。这个列表可以用作对表 3.3.3.3 规定的时间词缀列表和 SDTMIG 规定的词缀的补充。需要注意的是，与 SDTMIG 相比较，ADaM 对某些定义的词缀略有不同；当生成 ADaM 变量时使用 ADaM 词缀优先。在使用词缀时，一般规则是使用最能在 8 个字节限制内传达变量含义的词缀。词缀列表只提供一个指导，并非强制要求。

Table 3.1.5.2 Additional Fragments That May Be Used in Naming ADaM Variables

Fragment	CDISC Notes
BL	Baseline, position relative to type of variable. Not to be used to support more than one baseline definition for AVAL in BDS datasets. See note below.
CHG	Change, position relative to type of variable. Not to be used to support change from more than one baseline for AVAL in BDS datasets. See note below.
FU	Follow-up, position relative to type of variable.
OT	On treatment, position relative to type of variable.
RU	Run-in, position relative to type of variable.
SC	Screening, position relative to type of variable.

表 3.1.5.2 可能用于 ADaM 变量命名的补充后缀词

词缀	CDISC 注释
BL	基线，根据变量类型决定位置。不能用来支持在 BDS 数据集中对基线有一个以上定义的 AVAL。见下文注释。
CHG	差值，根据变量类型决定位置。不能用来支持在 BDS 数据集中有一个以上基线的相对基线变化值的 AVAL。见下文注释。
FU	随访期，根据变量类型决定位置。
OT	治疗期，根据变量类型决定位置。
RU	导入期，根据变量类型决定位置。
SC	筛选期，根据变量类型决定位置。

Fragment	CDISC Notes
TA	Taper, position relative to type of variable.
TI	Titer, position relative to type of variable.
U	Units, suffix To identify the units for a variable, a separate variable can be created, using the name of the original variable with a “U” suffix added. To keep within the 8-character variable name length limit, some truncation may be necessary prior to appending the U. In situations where the units do not vary within the ADaM dataset, it may be preferable to simply include the units in the variable’s label and metadata. The approach taken will be determined by the producer, based on the requirements of the analysis and review of the dataset. Note that there is no separate units variable for BDS variables PARAM or AVAL, since the units of AVAL will be included in the value of PARAM.
WA	Washout, position relative to type of variable.

词缀	CDISC 注释
TA	滴定期，根据变量类型决定位置。
TI	减量期，根据变量类型决定位置。
U	单位，后缀 为了识别变量的单位，可生成另一个变量，以原变量名称加上“U”后缀命名。为了保证变量名称长度不超过 8 个字节，加 U 之前变量名称可以做适当缩短。有时单位在 ADaM 数据集中没有变化，那么最好只在变量标签和元数据中直接纳入这些单位。所采取的方法将由开发者根据数据集的分析和审阅的要求确定。注意：BDS 变量 PARAM 或 AVAL 没有相应的另外的单位变量，是因为 AVAL 的单位会被纳入 PARAM 的值中。
WA	洗脱期，根据变量类型决定位置。

Note that in BDS datasets, there is only one baseline variable, BASE, and only one change from baseline variable, CHG. The BL and CHG fragments must not be used to create BDS variables containing alternative baselines and changes from baseline for AVAL. Additional definitions of baseline relevant to a given parameter must be accommodated by the addition of rows rather than addition of variables. See Section 3.3.4 and Section 4.2, Rule 6. However, if the baseline or change from baseline of a different parameter is needed in the analysis of a given parameter, for example, as a covariate in an analysis of covariance, that analysis-enabling variable may be added and its name should contain the fragment BL or CHG.
注意：在 BDS 数据集中，只有一个基线变量——BASE，只有一个相对基线变化值变量——CHG。BL 和 CHG 词缀不可以用来产生类似用以替代 AVAL 的基线和相对基线变化值的 BDS 变量。与指定参数相关的额外基线定义必须通过添加行而不是添加变量来进行调整。见第 3.3.4 节和第 4.2 节第 6 条。但是，如果在分析给定参数时需要不同参数的基线或相对基线变化值，例如：作为协方差分析中的协变量，则可添加该启动分析变量，其名称应包含缀词 BL 或 CHG。

There are two main categories of variable names relative to timepoints: content at a particular timepoint (e.g., weight at baseline) and timepoint timing (e.g., screening date). Assembly of these types of variable names using timing fragments defined in Table 3.1.5.2 is described below:
有两种主要的变量名称与时间点相关：某一特定时间点的事物（如：基线体重）和时间点上时间（如：筛选日期）。使用表 3.1.5.2 中规定的时间词缀组合这些类型的变量名称，如下所述：

Content at a timepoint: Because the timing of a variable qualifies the content of the variable, timing fragments are used as the variable name suffix. The complete variable naming convention is *(xx)FF, where * represents the content of the variable (up to 4 characters) and FF represents the timing fragment. For any timing fragments that are repeated for multiple periods, the period number (xx) should be placed before the suffix. If period numbers are not needed, the variable will be of the form *FF, with * representing the content of the variable (up to 6 characters)
时间点事物：因为变量中的时间限定了变量的内容，时间词缀将作为变量名称后缀。完整的变量命名规则为*(xx)FF，其中*代表变量的内容（最多 4 个字节），而 FF 代表时间词缀。如果时间词缀在多个阶段重复，阶段编号(xx)必须放在后缀前面。如果不需要阶段编号，变量名称就采用*FF 格式，*代表变量的内容（最多 6 个字节）。

Timepoint timing: If timepoint variables are needed that would use these timing fragments, the timing fragments will become the prefix of the variable name. For dates, then, the structure of the variable name is FF(xx)*, where * represents the date fragment (e.g., DT, SDT, EDTM, etc.) (up to 4 characters) and FF represents the timing fragment. This is consistent with ADSL timepoint variables such as RANDDT, TR01SDT, etc.
时间点时间：如果需要使用这些时间词缀的时间点变量，则时间词缀将成为变量名称的前缀。对日期来说，变量名称的结构是 FF(xx)*，其中*代表了日期词缀（如：DT，SDT，EDTM 等）（最多 4 个字节），而 FF 代表了时间词缀。这也与 ADSL 的时间点变量如 RANDDT，TR01SDT 等等是相一致的。

Some examples of variable names that follow these guidelines are:

- SBP01BL, SBP02BL – Period-level baseline variables for systolic blood pressure. Other abbreviations for systolic blood pressure are also acceptable.
- WEIGHTSC or WTSC – Screening weight. Other abbreviations of weight are also acceptable.
- RUSDT – Run-in start date, using the timing fragment as the prefix in a timing variable as defined in Table 3.3.3.3.
- WA01SDT, WA01EDT, WA02SDT and WA02EDT – Washout start and end dates for two periods, using the timing fragment as the prefix in a timing variable as defined in Table 3.3.3.3.

变量名称符合这些指导原则的示例：

- SBP01BL，SBP02BL – 收缩压各阶段别的基线变量。其它对于收缩压的缩略语也是被允许的。
- WEIGHTSC 或 WTSC – 筛选期体重。其它对于体重的缩略语也是被允许的。

- RUSDT – 导入期的开始日期，在表 3.3.3.3 规定的时间变量中采用时间词缀为前缀。
- WA01SDT，WA01EDT，WA02SDT 和 WA02EDT – 两个阶段洗脱期的开始和结束日期，在表 3.3.3.3 规定的时间变量中采用时间词缀为前缀。

3.1.6 Additional Information about Section 3

3.1.6 关于第 3 节的补充信息

In general, the variable labels specified in the tables in Section 3 are required. There are only two exceptions to this rule:
Descriptive text is allowed at the end of the labels of variables whose names contain indexes "y" or "zz"; and
Variable labels containing a word or phrase in brackets, e.g. {Time}, should be replaced by the producer with appropriate text that contains the bracketed word or phrase somewhere in the text (e.g., the label for a *TM variable is indicated as {Time} in this document) indicating any producer-defined label is permitted as long as the word Time is incorporated in it.
总体来说，变量标签必须符合第 3 节中的表格内的规定。只有两种情况除外：
名称中包含索引"y"或"zz"的变量标签的结尾，允许有描述性文字；以及
在括号中包含单词或短语的变量标签，如：{时间}，应由开发者用适当的文本替换进该文本中的某个位置中括号里的单词或短语（如：本文中*TM 变量中指示{时间}的位置），只要时间一词包含在其中，就表明此处允许使用任意开发商自定义的标签。

It is important to note that the standard variable labels by no means imply the use of standard derivation algorithms across studies and/or producers.
非常重要的是，标准变量标签绝不是暗示着在研究和/或开发者之间使用了某种标准推导算法。

It should be noted that when the CDISC Notes for a variable refer to another variable, it is understood that this means "on the same record or row". For example, the CDISC notes for TRTPN state "The numeric code for TRTP [on the same record]" where the text in brackets is understood.
应该注意的是，当 CDISC 注释某个变量引用另一个变量时，这意味着"在同一记录或行上"。例如：TRTPN 的 CDISC 注释说明为"TRTPN 的数值型编码[在同一记录上]"，其中括号中的文本被省略了。

Controlled terminology has been developed for the values of certain ADaM variables. The most current CDISC terminology sets can be accessed via the CDISC website (http://www.cdisc.org/terminology). In the tables in Section 3, the parenthesized external codelist name appears in the column labeled "Codelist/ Controlled Terms" where relevant. Where examples of controlled terms appear in this document, they should be considered examples only; the official source is the latest CDISC set available through the website.
受控术语是为特定的 ADaM 变量的值所开发的。最新的 CDISC 术语集可以通过 CDISC 网站（http://www.cdisc.org/terminology）访问。在第 3 节的表格中如有相关，带括号的外部编码列表名称会出现在标有"编码列表/ 受控术语"的列中。如果本文中出现受控术语的示例，则应仅将其视为示例；官方来源应是网站上提供的最新 CDISC 术语集。

Note that CDISC controlled terminology sets cannot represent null (absence of a value) in the list of valid terms since null isn't a term. However, unless specified in the definition for a specific variable below, null is allowed.
注意：CDISC 受控术语组不能在有效值列表中列出空值（缺失值）。因为空值并非一个术语。不过，除非下文中在特定变量的定义中指明，否则空值是允许的。

Additional variables not defined in Section 3 may be necessary to enable the analysis or to support traceability and may therefore be added to ADaM datasets, providing that they adhere to the ADaM naming conventions and rules as defined in this document.
第 3 节中未定义的其它变量可能是进行分析或支持可追溯性所必需的，因此可以添加到 ADaM 数据集，前提是它们遵守本文中所规定的 ADaM 命名规则和条例。

3.2 ADSL Variables

3.2 ADSL 变量

In the ADaM model document, it is noted that an ADaM-compliant ADSL dataset and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other ADaM datasets are submitted. The structure of ADSL is one record per subject, regardless of the type of clinical trial design.
在 ADaM 模型文档中提到：在基于 CDISC 的临床试验数据申报中，即使没有其它 ADaM 数据集需要递交，符合 ADaM 规范的 ADSL 和与其相关的元数据也是必需的。无论哪种临床试验设计类型，ADSL 的结构都是每个受试者一条记录。

This section lists standard ADSL variables. Section 2.3.1 describes the content of ADSL and addresses the kinds of variables that are and are not appropriate for inclusion in ADSL. Within a given study, USUBJID is the key variable that links ADSL to other datasets (both SDTM and ADaM).
本节列出了标准 ADSL 变量。第 2.3.1 节说明了 ADSL 的内容以及表明了适合纳入和不适合纳入 ADSL 的变量。对于一个给定的研究，USUBJID 是用来链接 ADSL 和其他数据集（包括 SDTM 和 ADaM）的关键变量。

For ADSL variables, the scope is "within the study." For example, the definition of SITEGR1 is consistent for all datasets within a study. It is acknowledged that the scope of USUBJID extends beyond the study, as defined in the SDTM Implementation Guide.
对于 ADSL 变量来说，它的范围是适用于"该研究内"。例如：SITEGR1 的含义在同一个研究中的所有数据集里保持一致。然而，公认的是 USUBJID 并不局限于一个研究，这与 SDTM 实施指南中的规定是一致的。

Table 3.2.1 ADSL Identifier Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	DM.USUBJID
SUBJID	Subject Identifier for the Study	Char		Req	DM.SUBJID. SUBJID is required in ADSL, but permissible in other datasets.
SITEID	Study Site Identifier	Char		Req	DM.SITEID. SITEID is required in ADSL, but permissible in other datasets.
SITEGRy	Pooled Site Group y	Char		Perm	Character description of a grouping or pooling of clinical sites for analysis purposes. For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site grouping algorithm, defined in variable metadata; SITEGR3 does not mean the third group of sites.
SITEGRyN	Pooled Site Group y (N)	Num		Perm	The numeric code for SITEGRy. One-to-one mapping to SITEGRy within a study.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
REGIONy	Geographic Region y	Char		Perm	Character description of geographical region. For example, REGION1 might have values of 'Asia', 'Europe', 'North America', 'Rest of World'; REGION2 might have values of 'United States', 'Rest of World'.
REGIONyN	Geographic Region y (N)	Num		Perm	The numeric code for REGIONy. Orders REGIONy for analysis and reporting. One-to-one mapping to REGIONy within a study.

表 3.2.1 ADSL 标识符变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
STUDYID	研究标识符	Char		Req	DM.STUDYID
USUBJID	受试者唯一标识符	Char		Req	DM.USUBJID
SUBJID	受试者标识符	Char		Req	DM.SUBJID.SUBJID 在 ADSL 中是必需的，但是在其它数据集里是可选的。
SITEID	研究中心标识符	Char		Req	DM.SITEID.SITEID 在 ADSL 中是必需的，但是在其它数据集里是可选的。
SITEGRy	研究中心分组 y	Char		Perm	以分析为目的对临床中心的分组或合并的特征描述。例如：SITEGR3 是包含中心分组（合并中心）名称的变量名称，根据变量元数据中定义，该分组是根据第三种中心分组的算法合并的。SITEGR3 并不意味着第三组中心。
SITEGRyN	研究中心分组 y(N)	Num		Perm	SITEGRy 的数值型编码。在研究中与 SITEGRy 一一对应。
REGIONy	地理区域 y	Char		Perm	地理区域的特征描述。例如：REGION1 分为"亚洲"，"欧洲"，"北美"，"其它地区"；REGION2 分为"美国"和"其它国家"。
REGIONyN	地理区域 y(N)	Num		Perm	REGIONy 的数值型编码。在分析和报告中为 REGIONy 排序。在研究中与 REGIONy 一一对应。

Table 3.2.2 ADSL Subject Demographics Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AGE	Age	Num		Req	DM.AGE. If analysis needs require a derived age that does not match DM.AGE, then AAGE must be added
AGEU	Age Units	Char	(AGEU)	Req	DM.AGEU
AGEGRy	Pooled Age Group y	Char		Perm	Character description of a grouping or pooling of the subject's age for analysis purposes. For example, AGEGR1 might have values of "<18", "18-65", and ">65"; AGEGR2 might have values of "Less than 35 y old" and "At least 35 y old".
AGEGRyN	Pooled Age Group y (N)	Num		Perm	The numeric code for AGEGRy. Orders the grouping or pooling of subject age for analysis and reporting. One-to-one mapping to AGEGRy within a study.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AAGE	Analysis Age	Num		Cond	Age used for analysis that is derived differently from DM.AGE. AAGE is required if age is calculated differently than in SDTM.
SEX	Sex	Char	(SEX)	Req	The sex of the subject is a required variable in ADSL; must be identical to DM.SEX.
RACE	Race	Char	(RACE)	Req	The race of the subject is a required variable in ADSL; must be identical to DM.RACE.
RACEGRy	Pooled Race Group y	Char		Perm	Character description of a grouping or pooling of the subject's race for analysis purposes.
RACEGRyN	Pooled Race Group y (N)	Num		Perm	The numeric code for RACEGRy. Orders the grouping or pooling of subject race for analysis and reporting. One-to-one mapping to RACEGRy within a study.

表 3.2.2 ADSL 受试者人口学变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
AGE	年龄	Num		Req	DM.AGE。如果分析需要一个与 DM.AGE 不一样的年龄变量，那么必须添加 AAGE 变量。
AGEU	年龄单位	Char	(AGEU)	Req	DM.AGEU
AGEGRy	年龄组 y	Char		Perm	以分析为目的对受试者年龄的分组或合并的特征描述。例如：AGEGR1 分为"<18"，"18-65"，和">65"；AGEGR2 分为"小于 35 岁"和"35 岁以上"。
AGEGRyN	年龄组 y(N)	Num		Perm	AGEGRy 的数值型编码。在分析和报告中为受试者年龄的分组或合并排序。在研究中与 AGEGRy 一一对应。
AAGE	年龄-分析用	Num		Cond	用于分析的年龄且推导方式与 DM.AGE 不同。如果年龄的计算有别于 SDTM 中，则 AAGE 是必需的。
SEX	性别	Char	(SEX)	Req	受试者的性别在 ADSL 中是必需的；必须和 DM.SEX 相同。
RACE	种族	Char	(RACE)	Req	受试者的种族在 ADSL 中是必需的；必须和 DM.RACE 相同。
RACEGRy	种族分组 y	Char		Perm	以分析为目的对受试者种族的分组或合并的特征描述。
RACEGRyN	种族分组 y(N)	Num		Perm	RACEGRy 的数值型编码。按受试者年龄分组或合并以进行分析和报告。在研究中与 RACEGRy 一一对应。

Population flags are required by ADaM. Table 3.2.3 describes ADaM population flags, though the list is not meant to be all-inclusive. See Section 3.5 for details on the differences between SDTM- and ADaM-defined population flags.
人群标帜是 ADaM 的必需变量。表 3.2.3 说明了 ADaM 的人群标帜，然而该列表并未包含所有人群定义。有关 SDTM 和 ADaM 所定义的人群标帜之间差异的详述见第 3.5 节。

Table 3.2.3 ADSL Population Indicator Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
FASFL	Full Analysis Set Population Flag	Char	Y, N	Cond	These flags identify whether or not the subject is included in the specified population. A minimum of one subject-level population flag variable is required in ADSL. Not all of the indicators listed here need to be included in ADSL. As stated in Section 3.1.4, Item 2, only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL. This list of flags is not meant to be all-inclusive. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included. Please also refer to Section 3.1.4.
SAFFL	Safety Population Flag	Char	Y, N	Cond	
ITTFL	Intent-To-Treat Population Flag	Char	Y, N	Cond	
PPROTFL	Per-Protocol Population Flag	Char	Y, N	Cond	
COMPLFL	Completers Population Flag	Char	Y, N	Cond	
RANDFL	Randomized Population Flag	Char	Y, N	Cond	
ENRLFL	Enrolled Population Flag	Char	Y, N	Cond	

表 3.2.3 ADSL 人群标志变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
FASFL	全分析集人群标帜	Char	Y, N	Cond	这些标记标明了受试者是否可纳入在指定的人群。ADSL 中至少需要一个受试者级别的人群标记变量。 并非此处列出的所有标志都需纳入 ADSL。如第 3.1.4 节第 2 项所述，只有那些与统计分析计划中定义的人群相对应的标记或用作分析基础的人群才需纳入 ADSL 中。 这个标记列表并不意味着包含了所有的人群标记。可添加额外的人群标记。 受试者级别的人群标记的值不能为空。如使用该标记，还可以使用人群标记相应的数字版本（*FN，其中 0=否和 1=是）。请另参阅第 3.1.4 节。
SAFFL	安全集人群标帜	Char	Y, N	Cond	
ITTFL	意向性治疗集人群标帜	Char	Y, N	Cond	
PPROTFL	符合方案集人群标	Char	Y, N	Cond	
COMPLFL	完成研究人群标帜	Char	Y, N	Cond	
RANDFL	随机化人群标帜	Char	Y, N	Cond	
ENRLFL	入组人群标帜	Char	Y, N	Cond	

Table 3.2.4 ADSL Treatment Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ARM	Description of Planned Arm	Char		Req	DM.ARM
ACTARM	Description of Actual Arm	Char		Perm	DM.ACTARM
TRTxxP	Planned Treatment for Period xx	Char		Req	Subject-level identifier that represents the planned treatment for period xx. In a one-period randomized trial, TRT01P would be the treatment to which the subject was randomized. TRTxxP might be derived from the SDTM DM variable ARM. At least TRT01P is required.
TRTxxPN	Planned Treatment for Period xx (N)	Num		Perm	The numeric code variable for TRTxxP. One-to-one mapping to TRTxxP within a study.
TRTxxA	Actual Treatment for Period xx	Char		Cond	Subject-level identifier that represents the actual treatment for the subject for period xx. Required when actual treatment does not match planned and there is an analysis of the data as treated.
TRTxxAN	Actual Treatment for Period xx (N)	Num		Perm	The numeric code variable for TRTxxA. One-to-one mapping to TRTxxA within a study.
TRTSEQP	Planned Sequence of Treatments	Char		Cond	Required when there is an analysis based on the sequence of treatments, for example in a crossover design. TRTSEQP is not necessarily equal to ARM, for example if ARM contains elements that are not relevant to analysis of treatments or ARM is not fully descriptive (e.g., "GROUP 1," "GROUP 2"). When analyzing based on the sequence of treatments, TRTSEQP is required even if identical to ARM.
TRTSEQPN	Planned Sequence of Treatments (N)	Num		Perm	Numeric version of TRTSEQP. One-to-one mapping to TRTSEQP within a study.
TRTSEQA	Actual Sequence of Treatments	Char		Cond	TRTSEQA is required if a situation occurred in the conduct of the trial where a subject received a sequence of treatments other than what was planned and there is an analysis based on the sequence of treatments.
TRTSEQAN	Actual Sequence of Treatments (N)	Num		Perm	Numeric version of TRTSEQA. One-to-one mapping to TRTSEQA within a study.
TRxxPGy	Planned Pooled Treatment y for Period xx	Char		Perm	Planned pooled treatment y for period xx. Useful when planned treatments (TRTxxP) in the specified period xx are pooled together for analysis according to pooling algorithm y. For example when in period 2 the first pooling algorithm dictates that all doses of Drug A (TR02PG1="All doses of Drug A") are pooled together for comparison to all doses of Drug B (TR02PG1="All doses of Drug B"). Each value of TRTxxP is pooled within at most one value of TRxxPGy.
TRxxPGyN	Planned Pooled Trt y for Period xx (N)	Num *		Perm	The numeric code for TRxxPGy. One-to-one mapping to TRxxPGy within a study.
TRxxAGy	Actual Pooled Treatment y for Period xx	Char		Cond	Actual pooled treatment y for period xx. Required when TRxxPGy is present and TRTxxA is present.
TRxxAGyN	Actual Pooled Trt y for Period xx (N)	Num *		Perm	The numeric code for TRxxAGy. One-to-one mapping to TRxxAGy within a study.
TSEQPGy	Planned Pooled Treatment Sequence y	Char		Perm	Planned pooled treatment sequence y. Useful when planned treatment sequences (TRTSEQP) are pooled together for analysis according to pooling algorithm y. For example, this might be used in an analysis of an extension study when the analysis is based on what the subject received in the parent study as well as in the extension study.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TSEQPGyN	Planned Pooled Treatment Sequence y (N)	Num		Perm	Numeric version of TSEQPGy. One-to-one mapping to TSEQPGy within a study.
TSEQAGy	Actual Pooled Treatment Sequence y	Char		Cond	Actual pooled treatment sequence y. Required when TSEQPGy is present and TRTSEQA is present.
TSEQAGyN	Actual Pooled Treatment Sequence y (N)	Num		Perm	Numeric version of TSEQAGy. One-to-one mapping to TSEQAGy within a study.
** TRxxPGyN and TRxxAGyN were mistakenly indicated as character variables in ADaMIG v1.0. The error is corrected above.*					

表 3.2.4 ADSL 治疗组变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
ARM	计划分组描述	Char		Req	DM.ARM
ACTARM	实际分组描述	Char		Perm	DM.ACTARM
TRTxxP	周期 xx 计划治疗	Char		Req	代表阶段 xx 的计划治疗的受试者级别的识别符。在一个单一阶段随机化的试验中，TRT01P 将会是受试者随机到的治疗组。TRTxxP 可能是从 SDTM DM 变量 ARM 中推导的。至少 TRT01P 是必需存在的。
TRTxxPN	周期 xx 计划治疗(N)	Num		Perm	TRTxxP 的数值型编码。在研究中与 TRTxxP 一一对应。
TRTxxA	周期 xx 实际治疗	Char		Cond	代表阶段 xx 的实际治疗的受试者级别的识别符。当实际治疗和计划治疗不同或要求按实际治疗进行分析时，该变量是必需的。。
TRTxxAN	周期 xx 实际治疗(N)	Num		Perm	TRTxxA 的数值型编码。在研究中与 TRTxxA 一一对应。
TRTSEQP	计划治疗序列	Char		Cond	当分析是基于一系列的治疗时必需存在。例如：在交叉设计中。TRTSEQP 没有必要和 ARM 相等。例如：ARM 包含与治疗的分析无关的成分或者 ARM 是被不完全描述的（如“组 1”，“组 2”）。基于一系列的治疗分析，不管是否和 ARM 相同，TRTSEQP 都是必需的。
TRTSEQPN	计划治疗序列(N)	Num		Perm	TRTSEQP 的数字版本。在研究中与 TRTSEQP 一一对应。
TRTSEQA	实际治疗序列	Char		Cond	在试验进行中，如果发生受试者接受的一系列治疗并不是计划的治疗的情况，且分析是基于一系列的实际治疗时，则 TRTSEQA 是必需的。
TRTSEQAN	实际治疗序列(N)	Num		Perm	TRTSEQA 的数字版本。在研究中与 TRTSEQA 一一对应。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
TRxxPGy	周期 xx 计划治疗合并分组 y	Char		Perm	阶段 xx 的计划合并治疗组 y。适用于当根据合并算法 y，在特定治疗阶段 xx 将计划治疗(TRTxxP)合并在一起分析时。。例如：当阶段 2 的第一个合并算法规定将药物 A 的所有剂量组（TR02PG1=“药物 A 的所有剂量”）都合并在一起用来比较药物 B 的所有剂量组（TR02PG1=“药物 B 的所有剂量”)。每个 TRTxxP 的值最多只能合并到 TRxxPGy 的一个值。
TRxxPGyN	周期 xx 计划治疗合并分组 y(N)	Num *		Perm	TRxxPGy 的数值型编码。在研究中与 TRxxPGy 一一对应。
TRxxAGy	周期 xx 实际治疗合并分组 y	Char		Cond	阶段 xx 的实际合并治疗 y。当 TRxxPGy 和 TRTxxA 存在时必需存在。
TRxxAGyN	周期 xx 实际治疗合并分组 y(N)	Num *		Perm	TRxxAGy 的数值型编码。在研究中与 TRxxAGy 一一对应。
TSEQPGy	计划治疗序列合并分组 y	Char		Perm	计划合并治疗序号 y。适用于当根据合并算法 y，将计划治疗序号(TRTSEQP)合并在一起分析时。例如：这可以应用于扩展研究的分析，若分析是基于受试者同时参与了原研究和扩展研究。
TSEQPGyN	计划治疗序列合并分组 y(N)	Num		Perm	TSEQPGy 的数字版本。在研究中与 TSEQPGy 一一对应。
TSEQAGy	实际治疗序列合并分组 y	Char		Cond	实际合并治疗序号 y。当 TSEQPGy 和 TRTSEQA 存在时必需存在。
TSEQAGyN	实际治疗序列合并分组 y(N)	Num		Perm	TSEQAGy 的数字版本。在研究中与 TSEQAGy 一一对应。
** TRxxPGyN 和 TRxxAGyN 在 ADaMIG v1.0 中被错误的标记为字符型变量。该错误在上文已被修正。.*					

Table 3.2.5 describes ADSL dose variables, which are used to describe dosage amount. These variables can only be used in addition to, not instead of, the ADSL treatment variables in Table 3.2.4. It is permitted to include dosing information in both the treatment variables and in the dosing variables.
表 3.2.5 说明了 ADSL 服药剂量变量，用于描述药物剂量。这些变量只能作为表 3.2.4 中 ADSL 治疗组变量的补充，却不能代替它们。允许在治疗变量和剂量变量中包含剂量信息

Table 3.2.5 ADSL Dose Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
DOSExxP	Planned Treatment Dose for Period xx	Num		Perm	Subject-level identifier that represents the planned treatment dosage for period xx.
DOSExxA	Actual Treatment Dose for Period xx	Num		Perm	Subject-level identifier that represents the actual treatment dosage for period xx.
DOSExxU	Units for Dose for Period xx	Char		Perm	The units for DOSExxP and DOSExxA. It is permissible to use suffixes such as “P” and “A” if needed, with labels modified accordingly.

表 3.2.5 ADSL 服药剂量变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
DOSExxP	周期 xx 计划治疗剂量	Num		Perm	代表阶段 xx 的计划治疗剂量的受试者级别的识别符。
DOSExxA	周期 xx 实际治疗剂量	Num		Perm	代表阶段 xx 的实际治疗剂量的受试者级别的识别符。
DOSExxU	周期 xx 剂量单位	Char		Perm	DOSExxP 和 DOSExxA 单位。可根据需要酌情添加后缀如“P”和“A”并修改标签。

Table 3.2.6 ADSL Treatment Timing Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRTSDT	Date of First Exposure to Treatment	Num		Cond	Date of first exposure to treatment for a subject in a study. TRTSDT and/or TRTSDTM are required if there is an investigational product. Note that TRTSDT is not required to have the same value as the SDTM DM variable RFXSTDTC. While both of these dates reflect the concept of first exposure, the ADaM date may be derived to support the analysis which may not necessarily be the very first date in the SDTM EX domain.
TRTSTM	Time of First Exposure to Treatment	Num		Perm	Time of first exposure to treatment for a subject in a study.
TRTSDTM	Datetime of First Exposure to Treatment	Num		Cond	Datetime of first exposure to treatment for a subject in a study. TRTSDT and/or TRTSDTM are required if there is an investigational product.
TRTSDTF	Date of First Exposure Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of first exposure to treatment. If TRTSDT (or the date part of TRTSDTM) was imputed, TRTSDTF must be populated and is required. See Section 3.1.3.
TRTSTMF	Time of First Exposure Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of first exposure to treatment. If TRTSTM (or the time part of TRTSDTM) was imputed, TRTSTMF must be populated and is required. See Section 3.1.3.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRTEDT	Date of Last Exposure to Treatment	Num		Cond	Date of last exposure to treatment for a subject in a study. TRTEDT and/or TRTEDTM are required if there is an investigational product. Note that TRTEDT is not required to have the same value as the SDTM DM variable RFXENDTC. While both of these dates reflect the concept of last exposure, the ADaM date may be derived to support the analysis which may not necessarily be the very last date in the SDTM EX domain.
TRTETM	Time of Last Exposure to Treatment	Num		Perm	Time of last exposure to treatment for a subject in a study.
TRTEDTM	Datetime of Last Exposure to Treatment	Num		Cond	Datetime of last exposure to treatment for a subject in a study. TRTEDT and/or TRTEDTM are required if there is an investigational product.
TRTEDTF	Date of Last Exposure Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of last exposure to treatment. If TRTEDT (or the date part of TRTEDTM) was imputed, TRTEDTF must be populated and is required. See Section 3.1.3.
TRTETMF	Time of Last Exposure Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of last exposure to treatment. If TRTETM (or the time part of TRTEDTM) was imputed, TRTETMF must be populated and is required. See Section 3.1.3.
TRxxSDT	Date of First Exposure in Period xx	Num		Cond	Date of first exposure to treatment in period xx. TRxxSDT and/or TRxxSDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, but are permissible for other trial designs. Also useful in designs where multiple periods exist for the same treatment (i.e., multiple cycles of the same study treatment).
TRxxSTM	Time of First Exposure in Period xx	Num		Cond	The starting time of exposure to treatment in period xx. TRxxSTM and/or TRxxSDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design (but are permissible for other trial designs), and time is important to the analysis.
TRxxSDTM	Datetime of First Exposure in Period xx	Num		Cond	Datetime of first exposure to treatment in period xx. TRxxSDT and/or TRxxSDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, but are permissible for other trial designs.
TRxxSDTF	Date 1st Exposure Period xx Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of first exposure to treatment in period xx. If TRxxSDT (or the date part of TRxxSDTM) was imputed, TRxxSDTF must be populated and is required. See Section 3.1.3.
TRxxSTMF	Time 1st Exposure Period xx Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of first exposure to treatment in period xx. If TRxxSTM (or the time part of TRxxSDTM) was imputed, TRxxSTMF must be populated and is required. See Section 3.1.3.
TRxxEDT	Date of Last Exposure in Period xx	Num		Cond	Date of last exposure to treatment in period xx. TRxxEDT and/or TRxxEDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, but are permissible for other trial designs.
TRxxETM	Time of Last Exposure in Period xx	Num		Cond	The ending time of exposure to treatment in period xx. TRxxETM and/or TRxxEDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, and ending time is important to the analysis, but are permissible for other trial designs.
TRxxEDTM	Datetime of Last Exposure in Period xx	Num		Cond	The datetime of last exposure to treatment in period xx. TRxxEDT and/or TRxxEDTM are only required in trial designs where multiple treatments are given to the same subject, such as a crossover design, but are permissible for other trial designs.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRxxEDTF	Date Last Exposure Period xx Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of last exposure to treatment in period xx. If TRxxEDT (or the date part of TRxxEDTM) was imputed, TRxxEDTF must be populated and is required. See Section 3.1.3.
TRxxETMF	Time Last Exposure Period xx Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of last exposure to treatment in period xx. If TRxxETM (or the time part of TRxxEDTM) was imputed, TRxxETMF must be populated and is required. See Section 3.1.3.

表 3.2.6 ADSL 治疗时间变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
TRTSDT	首次治疗日期	Num		Cond	研究中受试者的首次治疗暴露日期。研究涉及试验用药品时 TRTSDT 和（或）TRTSDTM 必需存在。注意：TRTSDT 并不需要和 SDTM DM 变量 RFXSTDTC 有相同的值。虽然二者都反映了对首次暴露的定义，但是为了帮助分析而推导出的 ADaM 日期未必刚好是 SDTM EX 域的第一个日期。
TRTSTM	首次治疗时间	Num		Perm	研究中受试者的首次治疗暴露时间。
TRTSDTM	首次治疗日期时间	Num		Cond	研究中受试者的首次治疗暴露日期和时间。研究涉及试验用药品时 TRTSDT 和（或）TRTSDTM 必需存在。
TRTSDTF	首次治疗日期填补标记	Char	(DATEFL)	Cond	对首次治疗暴露日期的填补水平。如果 TRTSDT（或者 TRTSDTM 的日期部分）填补了，TRTSDTF 必须赋值且必需存在。见第 3.1.3 节。
TRTSTMF	首次治疗时间填补标记	Char	(TIMEFL)	Cond	对首次治疗暴露时间的填补水平。如果 TRTSTM（或者 TRTSDTM 的时间部分）填补了，TRTSTMF 必须赋值且必需存在。见第 3.1.3 节。
TRTEDT	末次治疗日期	Num		Cond	研究中受试者的末次治疗暴露日期。研究涉及试验用药品时 TRTEDT 和（或）TRTEDTM 必需存在。注意：TRTEDT 并不需要和 SDTM DM 变量 RFXENDTC 有相同的值。虽然二者都反映了对末次暴露的定义，但是为了帮助分析而推导出的 ADaM 日期未必刚好是 SDTM EX 域的最后一个日期。
TRTETM	末次治疗时间	Num		Perm	研究中受试者的末次治疗暴露时间。
TRTEDTM	末次治疗日期时间	Num		Cond	研究中受试者的末次治疗暴露日期和时间。当研究试验用药品时 TRTEDT 和（或）TRTEDTM 必需存在。
TRTEDTF	末次治疗日期填补标记	Char	(DATEFL)	Cond	对末次治疗暴露日期的填补水平。如果 TRTEDT（或者 TRTEDTM 的日期部分）填补了，TRTEDTF 必须赋值且必需存在。见第 3.1.3 节。
TRTETMF	末次治疗时间填补标记	Char	(TIMEFL)	Cond	对末次治疗暴露时间的填补水平。如果 TRTETM（或者 TRTEDTM 的时间部分）填补了，TRTETMF 必须赋值且必需存在。见第 3.1.3 节。
TRxxSDT	周期 xx 首次治疗日期	Num		Cond	阶段 xx 的受试者的首次治疗暴露日期。TRxxSDT 和（或）TRxxSDTM 只在试验设计中会给与同一受试者多阶段治疗时才必需存在。例如：在交叉设计中，不过在其它试验设计中也可酌情使用。亦可适用于同一治疗中存在多阶段的（即同一研究治疗中的多个治疗周期）。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
TRxxSTM	周期 xx 首次治疗时间	Num		Cond	阶段 xx 的受试者的首次治疗暴露时间。TRxxSTM 和（或）TRxxSDTM 只在试验设计中会给与同一受试者多阶段治疗时才必需存在。例如：在交叉设计中（不过在其它试验设计中也可酌情使用），或对时间敏感的分析中。.
TRxxSDTM	周期 xx 首次治疗日期时间	Num		Cond	阶段 xx 的受试者的首次治疗暴露日期和时间。TRxxSDT 和（或）TRxxSDTM 只在试验设计中会给与同一受试者多阶段治疗时才必需存在。例如：在交叉设计中，不过在其它试验设计中也可酌情使用。
TRxxSDTF	周期 xx 首次治疗日期填补标记	Char	(DATEFL)	Cond	对阶段 xx 的首次治疗暴露日期的填补程度。如果 TRxxSDT（或者 TRxxSDTM 的日期部分）被填补了，TRxxSDTF 必须赋值且必需存在。见第 3.1.3 节。
TRxxSTMF	周期 xx 首次治疗时间填补标记	Char	(TIMEFL)	Cond	对阶段 xx 的首次治疗暴露时间的填补程度。如果 TRxxSTM（或者 TRxxSDTM 的时间部分）被填补了，TRxxSTMF 必须赋值且必需存在。见第 3.1.3 节。
TRxxEDT	周期 xx 末次治疗日期	Num		Cond	阶段 xx 的受试者的末次治疗暴露日期。TRxxEDT 和（或）TRxxEDTM 只在试验设计中会给与同一受试者多阶段治疗时才必需存在。例如：在交叉设计中，不过在其它试验设计中也可酌情使用。
TRxxETM	周期 xx 末次治疗时间	Num		Cond	阶段 xx 的受试者的末次治疗暴露时间。TRxxETM 和（或）TRxxEDTM 只在试验设计中会给与同一受试者多阶段治疗时才必需存在。例如：在交叉设计中，或对时间敏感的分析中。不过在其它试验设计中也可酌情使用。
TRxxEDTM	周期 xx 末次治疗日期时间	Num		Cond	阶段 xx 的受试者的末次治疗暴露日期和时间。TRxxEDT 和（或）TRxxEDTM 只在试验设计中会给与同一受试者多阶段治疗时才必需存在。例如：在交叉设计中，不过在其它试验设计中也可酌情使用。
TRxxEDTF	周期 xx 末次治疗日期填补标记	Char	(DATEFL)	Cond	对阶段 xx 的末次治疗暴露日期的填补程度。如果 TRxxEDT（或者 TRxxEDTM 的日期部分）被填补了，TRxxEDTF 必须赋值且必需存在。见第 3.1.3 节。
TRxxETMF	周期 xx 末次治疗时间填补标记	Char	(TIMEFL)	Cond	对阶段 xx 的末次治疗暴露时间的填补程度。如果 TRxxETM（或者 TRxxEDTM 的时间部分）被填补了，TRxxETMF 必须赋值且必需存在。见第 3.1.3 节。

Additional timing variables can be included for phase, period, and subperiod (APHASE, APERIOD, and ASPER are defined in Table 3.3.3.1). Table 3.2.7 provides the subject-level variables for these timing elements.
对分期、阶段和子阶段（APHASE、APERIOD 和 ASPER 的定义如表 3.3.3.1），额外的时间变量可被纳入数据集。。表 3.2.7 提供了时间元素的受试者级别的变量。

The following provisions apply to the inclusion or exclusion of sets of pairs of subject-level timing variables in ADSL (i.e., the pair of start and end variables for each of the timing elements in the study (e.g. APxxSDT and APxxEDT for each period in the study)). A set of timing variables for a specific timing element (i.e., phase, period, or subperiod) includes only those variables from Table 3.2.7 that are applicable to the study. For example, although the period start time is defined in the table below, it should be included in the set of period timing variables only if needed for the study.

- A set of timing variables can be included in ADSL only if the definitions for all of the variables in the set are fixed across the study (i.e., the definitions of the start and end of each timing element for a given subject do not change based on endpoint or data type).
- If any of the definitions of the variables in the set do vary, for example, when analysis period start and stop date definitions differ for safety and efficacy

analyses, then none of the variables in the set can be included in ADSL.

- If none of the variable definitions in the set vary, then the full set of variables can be included in ADSL (i.e., either the full set is included or none of the variables in the set are included).

以下规定适用于纳入或排除 ADSL 中成对的受试者级别的时间变量（即，研究中对每个时间元素成对的开始和结束变量（如研究中每个阶段的 APxxSDT 和 APxxEDT)）。仅须纳入表格 3.2.7 中研究适用的特定时间元素（即，分期，阶段，或子阶段）的一组时间变量，例如：尽管下表中定义了阶段开始时间，但只有研究需要相关阶段时间变量时才须纳入。

- 只有在整个研究中其所有的变量定义不变，这组时间变量才可被纳入 ADSL（即，对某一特定受试者的每个时间元素的开始和结束的定义是不随终点或数据类型而改变的)。
- 如果一组时间变量中任意一个变量的定义有差异，例如：安全性分析和有效性分析的阶段开始日期和结束日期的定义不同，则以上时间变量都将不被纳入到 ADSL 中。
- 如果一组时间变量所有变量的定义无差异，则整组变量将被纳入 ADSL（即，整组变量被纳入或者整组变量都不被纳入）。

Table 3.2.7 Subject-Level Period, Subperiod, and Phase Timing Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
APxxSDT	Period xx Start Date	Num		Perm	The starting date of period xx.
APxxSTM	Period xx Start Time	Num		Perm	The starting time of period xx.
APxxSDTM	Period xx Start Datetime	Num		Perm	The starting datetime of period xx.
APxxSDTF	Period xx Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period xx start date. See Section 3.1.3.
APxxSTMF	Period xx Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period xx start time. See Section 3.1.3.
APxxEDT	Period xx End Date	Num		Perm	The ending date of period xx.
APxxETM	Period xx End Time	Num		Perm	The ending time of period xx.
APxxEDTM	Period xx End Datetime	Num		Perm	The ending datetime of period xx.
APxxEDTF	Period xx End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period xx end date. See Section 3.1.3.
APxxETMF	Period xx End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period xx end time. See Section 3.1.3.
PxxSw	Description of Period xx Subperiod w	Char		Perm	Description of analysis subperiod w within period xx.
PxxSwSDT	Period xx Subperiod w Start Date	Num		Perm	The starting date of subperiod w within period xx.
PxxSwSTM	Period xx Subperiod w Start Time	Num		Perm	The starting time of subperiod w within period xx.
PxxSwSDM	Period xx Subperiod w Start Datetime	Num		Perm	The starting datetime of subperiod w within period xx.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
PxxSwSDF	Period xx Subper w Start Date Imput Flag	Char	(DATEFL)	Cond	The level of imputation of the start date for subperiod w within period xx. See Section 3.1.3.
PxxSwSTF	Period xx Subper w Start Time Imput Flag	Char	(TIMEFL)	Cond	The level of imputation of the start time for subperiod w within period xx. See Section 3.1.3.
PxxSwEDT	Period xx Subperiod w End Date	Num		Perm	The ending date of subperiod w within period xx.
PxxSwETM	Period xx Subperiod w End Time	Num		Perm	The ending time of subperiod w within period xx.
PxxSwEDM	Period xx Subperiod w End Datetime	Num		Perm	The ending datetime of subperiod w within period xx.
PxxSwEDF	Period xx Subper w End Date Imput Flag	Char	(DATEFL)	Cond	The level of imputation of the end date for subperiod w within period xx. See Section 3.1.3.
PxxSwETF	Period xx Subper w End Time Imput Flag	Char	(TIMEFL)	Cond	The level of imputation of the end time for subperiod w within period xx. See Section 3.1.3.
APHASEw	Description of Phase w	Char		Perm	Description of analysis phase w.
PHwSDT	Phase w Start Date	Num		Perm	The starting date of phase w.
PHwSTM	Phase w Start Time	Num		Perm	The starting time of phase w.
PHwSDTM	Phase w Start Datetime	Num		Perm	The starting datetime of phase w.
PHwSDTF	Phase w Start Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of the start date for phase w. See Section 3.1.3.
PHwSTMF	Phase w Start Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of the start time for phase w. See Section 3.1.3.
PHwEDT	Phase w End Date	Num		Perm	The ending date of phase w.
PHwETM	Phase w End Time	Num		Perm	The ending time of phase w.
PHwEDTM	Phase w End Datetime	Num		Perm	The ending datetime of phase w.
PHwEDTF	Phase w End Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of the end date for phase w. See Section 3.1.3.
PHwETMF	Phase w End Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of the end time for phase w. See Section 3.1.3.

表 3.2.7 受试者级别的阶段，子阶段，和分期时间变量

变量名称	变量标签	类型	编码列表/受控术语	核心	CDSIC 注释
APxxSDT	周期 xx 开始日期	Num		Perm	阶段 xx 的开始日期。
APxxSTM	周期 xx 开始时间	Num		Perm	阶段 xx 的开始时间。
APxxSDTM	周期 xx 开始日期时间	Num		Perm	阶段 xx 的开始日期和时间。
APxxSDTF	周期 xx 开始日期填补标记	Char	(DATEFL)	Cond	对阶段 xx 的开始日期的填补程度。见第 3.1.3 节。
APxxSTMF	周期 xx 开始时间填补标记	Char	(TIMEFL)	Cond	对阶段 xx 的开始时间的填补程度。见第 3.1.3 节。
APxxEDT	周期 xx 结束日期	Num		Perm	阶段 xx 的结束日期。
APxxETM	周期 xx 结束时间	Num		Perm	阶段 xx 的结束时间。
APxxEDTM	周期 xx 结束日期时间	Num		Perm	阶段 xx 的结束日期和时间。
APxxEDTF	周期 xx 结束日期填补标记	Char	(DATEFL)	Cond	对阶段 xx 的结束日期的填补程度。见第 3.1.3 节。
APxxETMF	周期 xx 结束时间填补标记	Char	(TIMEFL)	Cond	对阶段 xx 的结束时间的填补程度。见第 3.1.3 节。
PxxSw	子周期 xx-w 描述	Char		Perm	对阶段 xx 的分析子阶段 w 的描述。
PxxSwSDT	子周期 xx-w 开始日期	Num		Perm	阶段 xx 的子阶段 w 的开始日期。
PxxSwSTM	子周期 xx-w 开始时间	Num		Perm	阶段 xx 的子阶段 w 的开始时间。
PxxSwSDM	子周期 xx-w 开始日期时间	Num		Perm	阶段 xx 的子阶段 w 的开始日期和时间。
PxxSwSDF	子周期 xx-w 开始日期填补标记	Char	(DATEFL)	Cond	对阶段 xx 的子阶段 w 的开始日期的填补程度。见第 3.1.3 节。
PxxSwSTF	子周期 xx-w 开始时间填补标记	Char	(TIMEFL)	Cond	对阶段 xx 的子阶段 w 的开始时间的填补程度。见第 3.1.3 节。
PxxSwEDT	子周期 xx-w 结束日期	Num		Perm	阶段 xx 的子阶段 w 的结束日期。
PxxSwETM	子周期 xx-w 结束时间	Num		Perm	阶段 xx 的子阶段 w 的结束时间。
PxxSwEDM	子周期 xx-w 结束日期时间	Num		Perm	阶段 xx 的子阶段 w 的结束日期和时间。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDSIC 注释
PxxSwEDF	子周期 xx-w 结束日期填补标记	Char	(DATEFL)	Cond	对阶段 xx 的子阶段 w 的结束日期的填补程度。见第 3.1.3 节。
PxxSwETF	子周期 xx-w 结束时间填补标记	Char	(TIMEFL)	Cond	对阶段 xx 的子阶段 w 的结束时间的填补程度。见第 3.1.3 节。
APHASEw	分析期 w 描述	Char		Perm	对分析期 w 的描述。
PHwSDT	分析期 w 开始日期	Num		Perm	w 期的开始日期。
PHwSTM	分析期 w 开始时间	Num		Perm	w 期的开始时间。
PHwSDTM	分析期 w 开始日期时间	Num		Perm	w 期的开始日期和时间。
PHwSDTF	分析期 w 开始日期填补标记	Char	(DATEFL)	Cond	对 w 期的开始日期的填补程度。见第 3.1.3 节。
PHwSTMF	分析期 w 开始时间填补标记	Char	(TIMEFL)	Cond	对 w 期的开始时间的填补程度。见第 3.1.3 节。
PHwEDT	分析期 w 结束日期	Num		Perm	w 期的结束日期。
PHwETM	分析期 w 结束时间	Num		Perm	w 期的结束时间。
PHwEDTM	分析期 w 结束日期	Num		Perm	w 期的结束日期和时间。
PHwEDTF	分析期 w 结束日期填补标记	Char	(DATEFL)	Cond	对 w 期的结束日期的填补程度。见第 3.1.3 节。
PHwETMF	分析期 w 结束时间填补标记	Char	(TIMEFL)	Cond	对 w 期的结束时间的填补程度。见第 3.1.3 节。

Table 3.2.8 ADSL Subject-Level Trial Experience Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
EOSSTT	End of Study Status	Char		Perm	The subject's status as of the end of study or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.
EOSDT	End of Study Date	Num		Perm	Date subject ended the study – either date of completion or date of discontinuation or data cutoff date for interim analyses.
DCSREAS	Reason for Discontinuation from Study	Char		Perm	Reason for subject's discontinuation from study. The source would most likely be the SDTM DS dataset. Null for subjects who completed the study.
DCSREASP	Reason Spec for Discont from Study	Char		Perm	Additional detail regarding subject's discontinuation from study (e.g., description of "other").
EOTSTT	End of Treatment Status	Char		Perm	The subject's status as of the end of treatment or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
DCTREAS	Reason for Discontinuation of Treatment	Char		Perm	If a subject discontinued treatment in the study, then this variable indicates the reason for discontinuation. This is for discontinuation of treatment in the overall study and not to be used for discontinuation reason within individual treatment periods.
DCTREASP	Reason Specify for Discont of Treatment	Char		Perm	Additional detail regarding subject's discontinuation from treatment (e.g., description of "other").
EOTxxSTT	End of Treatment Status in Period xx	Char		Perm	The subject's treatment status as of the end of period xx, or data cutoff if within period xx. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCTxxRS	Reason for Discont of Treat in Period xx	Char		Perm	Reason for discontinuing treatment in period xx.
DCTxxRSP	Reason Spec for Disc of Trt in Period xx	Char		Perm	Additional detail regarding subject's discontinuation of treatment in period xx (e.g., description of "other").
EOPxxSTT	End of Period xx Status	Char		Perm	The subject's status as of the end of period xx, or data cutoff if within period xx. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCPxxRS	Reason for Discont from Period xx	Char		Perm	Reason for discontinuing analysis period xx.
DCPxxRSP	Reason Spec for Discont from Period xx	Char		Perm	Additional detail regarding subject's discontinuation from period xx (e.g., description of "other").
RFICDT	Date of Informed Consent	Num		Perm	Date subject gave informed consent. Generally equivalent to DM.RFICDTC.
ENRLDT	Date of Enrollment	Num		Perm	Date of subject's enrollment into trial.
RANDDT	Date of Randomization	Num		Cond	Required in randomized trials.
RFICyDT	Date of Informed Consent y	Num		Perm	This variable may be used in the case where there are multiple consent dates within a study. This date does not need to repeat the date in RFICDT. 'y' can start with 1 but it is not required to start with 1.
ENRLyDT	Date of Enrollment y	Num		Perm	This variable may be used in the case where there are multiple enrollment dates within a study. This date does not need to repeat the date in ENRLDT. 'y' can start with 1 but it is not required to start with 1.
RANDyDT	Date of Randomization y	Num		Perm	This variable may be used in the case where there are multiple randomization dates within a study. This date does not need to repeat the date in RANDDT. 'y' can start with 1 but it is not required to start with 1.
LSTALVDT	Date Last Known Alive	Num		Perm	If this variable is included in ADSL, the best practice is to populate it for everyone. If the derivation for subjects who died differs from the derivation for subjects who are not known to have died, the differences should be noted in metadata.
TRCMP	Treatment Compliance (%)	Num		Perm	Overall percent compliance with treatment in the trial. TRCMP may be useful for inclusion in ADSL for reasons such as defining subgroups and/or populations.
TRCMPGy	Treatment Compliance (%) Group y	Char		Perm	Grouping 'y' of TRCMP, treatment compliance percentage.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRCMPGyN	Treatment Compliance (%) Group y (N)	Num		Perm	Numeric version of treatment compliance (%) grouping 'y'. Must have a one-to-one mapping to TRCMPGy.
TRxxDURD	Treatment Duration in Period xx (Days)	Num		Perm	Treatment duration for period xx as measured in days. More than one of TRxxDURD, TRxxDURM, and TRxxDURY can be populated, but each represents the entire duration in its respective units.
TRxxDURM	Treatment Duration in Period xx (Months)	Num		Perm	Treatment duration for period xx, as measure in months. More than one of TRxxDURD, TRxxDURM, and TRxxDURY can be populated, but each represents the entire duration in its respective units.
TRxxDURY	Treatment Duration in Period xx (Years)	Num		Perm	Treatment duration for period xx, as measured in years. More than one of TRxxDURD, TRxxDURM, and TRxxDURY can be populated, but each represents the entire duration in its respective units.
TRTDURD	Total Treatment Duration (Days)	Num		Perm	Total treatment duration, as measured in days. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
TRTDURM	Total Treatment Duration (Months)	Num		Perm	Total treatment duration, as measured in months. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
TRTDURY	Total Treatment Duration (Years)	Num		Perm	Total treatment duration, as measured in years. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
DTHDT	Date of Death	Num		Perm	Date of subject's death. Derived from DM.DTHDTC.
DTHDTF	Date of Death Imputation Flag	Char		Cond	Imputation flag for date of subject's death. If DTHDT was imputed, DTHDTF must be populated and is required. See Section 3.1.3.
DTHCAUS	Cause of Death	Char		Perm	Cause of Death.
DTHCAUSN	Cause of Death (N)	Num		Perm	Numeric representation of cause of death. Must have a one-to-one mapping to DTHCAUS.
DTHCGRy	Cause of Death Group y	Char		Perm	Grouping 'y' of DTHCAUS, the subject's cause of death.
DTHCGRyN	Cause of Death Group y (N)	Num		Perm	Numeric version of grouping 'y' of the subject's cause of death. Must have a one-to-one mapping to DTHCGRy.

表 3.2.8 ADSL 受试者级别试验经历变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDSIC 注释
EOSSTT	研究结束状态	Char		Perm	研究结束时或数据截止时受试者的状态。例如：完成，终止，继续。
EOSDT	研究结束日期	Num		Perm	受试者结束研究的日期——可以是完成日期，或终止日期，或中期分析的数据截止日期。
DCSREAS	研究中止理由	Char		Perm	受试者终止研究的理由。来源基本上就是 SDTM DS 数据集。对于完成研究的受试者该变量为空值。
DCSREASP	研究中止理由详述	Char		Perm	对受试者终止研究的补充细节（例如：对结束理由"其它"的描述）。
EOTSTT	治疗结束状态	Char		Perm	治疗结束时或数据截止时受试者的状态。例如：完成，终止，继续。
DCTREAS	治疗中止理由	Char		Perm	当受试者在研究中终止治疗时，这个变量标志着终止的理由。这是对研究总体的终止理由，而非用于某一单阶段治疗的终止理由。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDSIC 注释
DCTREASP	治疗中止理由详述	Char		Perm	对受试者终止治疗的补充细节（例如：对结束理由“其它”的描述）。
EOTxxSTT	周期 xx 治疗结束状态	Char		Perm	受试者在阶段 xx 结束时，或阶段 xx 内数据截止时的治疗状态。例如：完成，终止，继续 。
DCTxxRS	周期 xx 中止治疗理由	Char		Perm	在阶段 xx 受试者终止治疗的理由。
DCTxxRSP	周期 xx 中止治疗理由详述	Char		Perm	对受试者在阶段 xx 终止治疗的补充细节（例如：对结束理由“其它”的描述）。
EOPxxSTT	周期 xx 结束状态	Char		Perm	受试者在阶段 xx 结束时，或阶段 xx 内数据截止时的状态。例如：完成，终止，继续 。.
DCPxxRS	周期 xx 中止理由	Char		Perm	阶段 xx 终止分析的理由。
DCPxxRSP	周期 xx 中止理由详述	Char		Perm	对受试者在阶段 xx 终止的补充细节（例如：对结束理由“其它”的描述）。
RFICDT	签署知情同意日期	Num		Perm	受试者签署知情同意的日期。一般等于 DM.RFICDTC。
ENRLDT	入组日期	Num		Perm	受试者研究入组的日期。
RANDDT	随机日期	Num		Cond	如果是随机试验，那么该变量是必需存在的。
RFICyDT	签署知情同意日期 y	Num		Perm	该变量可用于当研究中有多个知情同意日期时。该日期不需要重复 RFICDT。“y”可从 1 开始但并不要求必须从 1 开始。
ENRLyDT	入组日期 y	Num		Perm	该变量可用于当研究中有多个入组日期时。该日期不需要重复 ENRLDT。“y”可从 1 开始但并不要求必须从 1 开始。
RANDyDT	随机日期 y	Num		Perm	该变量可用于当研究中有多个随机日期时。该日期不需要重复 RANDDT。“y”可从 1 开始但并不要求必须从 1 开始。
LSTALVDT	已知最后生存日期	Num		Perm	如果该变量被纳入 ADSL，则最好对所有受试者都进行赋值。如果对死亡的受试者和对无法确定死亡的受试者的推导规则有差异，则应在元数据中加以注释。
TRCMP	治疗依从性(%)	Num		Perm	研究中治疗的总体依从性百分比。TRCMP 可能会按照定义在 ADSL 中作为纳入亚组和（或）人群的理由。
TRCMPGy	治疗依从性(%)分组 y	Char		Perm	治疗依从性百分比 TRCMP 的分组“y”。
TRCMPGyN	治疗依从性(%)分组 y(N)	Num		Perm	治疗依从性 (%) 分组“y”的数字版本。必须与 TRCMPGy 一一对应。
TRxxDURD	周期 xx 治疗持续时间(天)	Num		Perm	以天为度量单位的阶段 xx 治疗期间。TRxxDURD，TRxxDURM，和 TRxxDURY 这三个变量可出现一个以上，但每个变量都只代表各自单位的整个治疗期间。
TRxxDURM	周期 xx 治疗持续时间(月)	Num		Perm	以月为度量单位的阶段 xx 治疗期间。TRxxDURD，TRxxDURM，和 TRxxDURY 这三个变量可出现一个以上，但每个变量都只代表各自单位的整个治疗期间。
TRxxDURY	周期 xx 治疗持续时间(年)	Num		Perm	以年为度量单位的阶段 xx 治疗期间。TRxxDURD，TRxxDURM，和 TRxxDURY 这三个变量可出现一个以上，但每个变量都只代表各自单位的整个治疗期间。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDSIC 注释
TRTDURD	总治疗持续时间(天)	Num		Perm	以天为度量单位的总体治疗期间。TRTDURD，TRTDURM，和 TRTDURY 这三个变量可出现一个以上，但每个变量都只代表各自单位的整个治疗期间。
TRTDURM	总治疗持续时间(月)	Num		Perm	以月为度量单位的总体治疗期间。TRTDURD，TRTDURM，和 TRTDURY 这三个变量可出现一个以上，但每个变量都只代表各自单位的整个治疗期间。
TRTDURY	总治疗持续时间(年)	Num		Perm	以年为度量单位的总体治疗期间。TRTDURD，TRTDURM，和 TRTDURY 这三个变量可出现一个以上，但每个变量都只代表各自单位的整个治疗期间。
DTHDT	死亡日期	Num		Perm	受试者死亡日期。从 DM.DTHDTC 导出。
DTHDTF	死亡日期填补标记	Char		Cond	受试者死亡日期的填补标记。如果 DTHDT 填补了，DTHDTF 必须赋值且必需存在。见 3.1.3 节。
DTHCAUS	死亡原因	Char		Perm	死亡的原因。
DTHCAUSN	死亡原因(N)	Num		Perm	死亡的原因的数值表示法。必须与 DTHCAUS 一一对应。
DTHCGRy	死亡原因分组 y	Char		Perm	受试者的死亡原因 DTHCAUS 的分组“y”。
DTHCGRyN	死亡原因分组 y(N)	Num		Perm	受试者的死亡原因的分组“y”的数字版本。必须与 DTHCGRy 一一对应。

3.3 ADaM Basic Data Structure (BDS) Variables

3.3 ADaM 基本数据结构（BDS）变量

The ADaM model document introduces the ADaM Basic Data Structure. A BDS dataset contains one or more records per subject, per analysis parameter, per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is one or more records per subject per analysis parameter. Typically there are several BDS datasets in a study. This section of the ADaMIG defines the standard variables used in BDS datasets. See Section 3.2 for ADSL variables, any of which may be copied to BDS datasets to support traceability or enable analysis.
ADaM 文档介绍了 ADaM 基本数据结构，一个 BDS 数据集中，每个受试者在每个分析参数及每个分析时间点上可包含一条或多条记录。分析时间点信息在特定条件下是必需的，其取决于所作分析。在没有分析时间点信息的情况下，结构是每个受试者每个分析参数一条或多条记录。通常在一个研究中会创建多个 BDS 数据集，ADaMIG 在本节定义了用在 BDS 数据集中的标准变量。有关分析数据集 ADSL 中的标准变量，请参见本文档 3.2 章节，它们中的任何一个变量都可以复制到 BDS 分析数据集中，用于实现数据的溯源及实施相关分析。

Within Section 3.3, “within a given study, subject, and dataset” is implied, unless otherwise stated. For example, the description of ABLFL defines it as a variable that indicates baseline record for each parameter, or if there is more than one baseline definition, for each parameter and baseline type (BASETYPE). It should be understood that the baseline record is for the subject identified by USUBJID. In addition, note that “within a parameter” means “within a parameter within a dataset.”
在本文档 3.3 章节中，除非特别指出，“在某研究，某研究对象，和数据集中”为默认限定词语。比如，ABLFL 的定义为用来识别各参数水平基线记录的变量，或者用来识别在各参数和各基线类型（BASETYPE）水平中具有多个基线定义时基线记录的变量。在这个定义中是默指鉴于由 USUBJID 标识的每个研究对象的基线记录。此外，需要注意的是“在某个分析参数水平”指的是“在某个数据集中的某个分析参数水平”。

3.3.1 Identifier Variables for BDS Datasets

3.3.1 BDS 数据集的标识变量

Table 3.3.1.1 Identifier Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	DM.USUBJID
SUBJID	Subject Identifier for the Study	Char		Perm	DM.SUBJID. SUBJID is required in ADSL, but permissible in other datasets.
SITEID	Study Site Identifier	Char		Perm	DM.SITEID. SITEID is required in ADSL, but permissible in other datasets.
ASEQ	Analysis Sequence Number	Num		Perm	Sequence number given to ensure uniqueness of subject records within an ADaM dataset. As long as values are unique within a subject within the dataset, any valid number can be used for ASEQ.

表 3.3.1.1 BDS 数据集的标识变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
STUDYID	研究标识符	Char		Req	DM.STUDYID
USUBJID	受试者唯一标识符	Char		Req	DM.USUBJID
SUBJID	受试者标识符	Char		Perm	DM.SUBJID。在 ADSL 中必需，但是在其他数据集中是可允许存在的。
SITEID	研究中心标识符	Char		Perm	DM.SITEID。在 ADSL 中必需，但是在其他数据集中是可允许存在的。
ASEQ	序号-分析数据集	Num		Perm	用于确保 ADaM 数据集中每个研究对象的研究记录唯一可鉴别的序列号。只要在数据集水平及受试者水平中，任何有效值是唯一的，都可以作为 ASEQ。。ASEQ 可以在 ADaM 数据集的受试者水平用来索引特定研究记录。 当一个数据集输入到另外一个 ADaM 数据集时，ASEQ 对于溯源有帮助。为了查阅一条存在于先前的数据集中的记录，将先前的数据集的名字赋值给 SRCDOM，和将先前的数据集的 ASEQ 的值赋值给 SRCSEQ。

3.3.2 Record-Level Treatment and Dose Variables for BDS Datasets

3.3.2 BDS 数据集的研究记录水平的治疗变量和剂量变量

At least one treatment variable is required in a BDS dataset. This requirement is satisfied by any of the subject-level or record-level treatment variables (e.g. TRTxxP or TRTP). One is allowed to use any treatment variable in analysis of BDS. Any subject-level treatment variable may be copied into the BDS dataset from ADSL. In addition, record-level treatment variables, as defined in this section, may be used for analysis. See Section 4.1 for examples of treatment variables.
在 BDS 数据集中至少要有 1 个治疗变量。任何研究对象水平或者研究记录水平的治疗变量（如，TRTxxP 或 TRTP）都满足这需求。。在分析 BDS 时任一治疗变量都是可以使用的。任何研究对象水平的治疗变量可以从 ADSL 复制到 BDS 数据集中。此外，在此章节中定义的记录水平的治疗变量有可能会被用于分析。治疗变量的例子请参见本文档章节 4.1 。

All treatment variables defined in Table 3.3.2.1 are record-level. This means that the values contained in the variable may vary by record within a subject.
表 3.3.2.1 中所有治疗变量都是基于记录水平定义的。这意味着变量的值会因受试者的记录而不同。

Table 3.3.2.1 Record-Level Treatment Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRTP	Planned Treatment	Char		Cond	TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. Though there is no requirement that TRTP will correspond to the TRTxxP as defined by the record's value of APERIOD, if populated, TRTP must match at least one value of the character planned treatment variables in ADSL (e.g., TRTxxP, TRTSEQP, TRxxPGy). As noted previously, at least one treatment variable is required even in non-randomized trials. This requirement is satisfied by any subject-level or record-level treatment variables (e.g., TRTxxP, TRTP, TRTA). Even if not used for analysis, any ADSL treatment variable may be included in the BDS dataset.
TRTPN	Planned Treatment (N)	Num		Perm	The numeric code for TRTP. One-to-one mapping within a study to TRTP.
TRTA	Actual Treatment	Char		Cond	TRTA is a record-level identifier that represents the actual treatment attributed to a record for analysis purposes. TRTA indicates how treatment varies by record within a subject and enables analysis of crossover and other multi-period designs. Though there is no requirement that TRTA will correspond to the TRTxxA as defined by the record's value of APERIOD, TRTA must match at least one value of the character actual treatment variables in ADSL (e.g., TRTxxA, TRTSEQA, TRxxAGy). As noted previously, at least one treatment variable is required. This requirement is satisfied by any subject-level or record-level treatment variables (e.g., TRTxxP, TRTP, TRTA). Even if not used for analysis, any ADSL treatment variable may be included in the BDS dataset.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRTAN	Actual Treatment (N)	Num		Perm	The numeric code for TRTA. One-to-one mapping within a study to TRTA.
TRTPGy	Planned Pooled Treatment y	Char		Perm	TRTPGy is the planned pooled treatment y attributed to a record for analysis purposes. "y" represents an integer [1-99, not zero-padded] corresponding to a particular pooling scheme. Useful when planned treatments (TRTP) are pooled together for analysis, for example when all doses of Drug A (TRTPG1=All doses of Drug A) are compared to all doses of Drug B (TRTPG1=All doses of Drug B). Each value of TRTP is pooled within at most one value of TRTPGy.
TRTPGyN	Planned Pooled Treatment y (N)	Num		Perm	The numeric code for TRTPGy. One-to-one mapping within a study to TRTPGy.
TRTAGy	Actual Pooled Treatment y	Char		Cond	TRTAGy is the actual pooled treatment y attributed to a record for analysis purposes. "y" represents an integer [1-99, not zero-padded] corresponding to a particular pooling scheme. Required when TRTPGy is present and TRTA is present.
TRTAGyN	Actual Pooled Treatment y (N)	Num		Perm	The numeric code for TRTAGy. One-to-one mapping within a study to TRTAGy.

表 3.3.2.1 BDS 数据集中的研究记录水平的治疗变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
TRTP	计划治疗	Char		Cond	TRTP 是记录水平的标识符，是一条用于分析目的的计划治疗记录。TRTP 通过受试者的记录标明治疗是如何变化的，并且用于交叉设计和其他设计的分析。尽管 TRTP 不需要对应到用 APERIOD 的记录值所定义的 TRTxxP，但是如果一旦呈现此变量，TRTP 必须对应到 ADSL 中字符型计划治疗变量（如，TRTxxP,TRTSEQP,TRxxPGy）的至少其中一个值。如前文所示，即使在非随机研究中都需要至少一个治疗变量。如何一个研究对象水平或者研究记录水平的治疗变量（如，TRTxxP,TRTP,TRTA）都可以满足此要求。即使不用与分析，ADSL 中的治疗变量也可以被纳入 BDS 数据集。
TRTPN	计划治疗(N)	Num		Perm	TRTP 的数值型编码，在一项研究中与 TRTP 一一对应。
TRTA	实际治疗	Char		Cond	TRTA 是记录水平的标识符，这表示认为是一条用于分析目的的实际治疗记录。TRTA 用受试者的记录标明治疗是如何不一样的并且用于交叉设计和其他多阶段设计的分析。尽管 TRTA 不需要对应到用 APERIOD 的记录值所定义的 TRTxxA，但是如果一旦呈现此变量，TRTA 必须对应到 ADSL 中字符型实际治疗变量（如，TRTxxA,TRTSEQA,TRxxAGy）的至少其中一个值。如前文所示，需要至少一个治疗变量。如何一个研究对象水平或者研究记录水平的治疗变量（如，TRTxxP,TRTP,TRTA）都可以满足此要求。即使不用与分析，ADSL 中的治疗变量也可以被纳入 BDS 数据集。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
TRTAN	实际治疗(N)	Num		Perm	TRTA 的数值型编码，在一项研究中与 TRTA 一一对应。
TRTPGy	计划治疗合并分组 y	Char		Perm	TRTPGy 被认为是一条用于分析目的的合并计划治疗 y 组记录。 “y”代表一个整数[1-99,非零填充] 对应一个特定的合并治疗计划。当计划的治疗合并在一起进行分析时有用，例如当药 A 的所有剂量 (TRTPG1=药 A 的所有剂量)和药 B 的所有剂量(TRTPG1=药 B 的所有剂量)相比较，TRTP 的每个值最多合并到 TRTPGy 的一个值中。
TRTPGyN	计划治疗合并分组 y(N)	Num		Perm	TRTPGy 的数值型编码，与 TRTPGy 相对应。
TRTAGy	实际治疗合并分组 y	Char		Cond	TRTAGy 被认为是一条用于分析目的的合并实际治疗 y 组记录。“y”代表一个整数[1-99,非零填充] 对应一个特定的合并治疗计划。在 TRTPGy 和 TRTA 同时存在时必需呈现。
TRTAGyN	实际治疗合并分组 y(N)	Num		Perm	TRTAGy 的数值型编码，在一项研究中与 TRTAGy 一一对应。

All dose variables defined in Table 3.3.2.2 are record-level. This means that the values contained in the variable may vary by record within a subject. These record-level dose variables, plus subject-level dose variables copied from ADSL, can be used in addition to, but not instead of, treatment variables.
表 3.3.2.2 中所有关于剂量的变量都是基于记录水平。这表示同一个受试者的剂量变量的值可能会因记录而异。这些记录水平的剂量变量，及 ADSL 中的受试者水平的用药变量，可以作为治疗变量的补充，但无法取而代之。

Table 3.3.2.2 Record-Level Dose Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
DOSEP	Planned Treatment Dose	Num		Perm	DOSEP represents the planned treatment dosage associated with the record.
DOSCUMP	Cumulative Planned Treatment Dose	Num		Perm	Cumulative planned dosage of treatment for the subject at the point in time of the record (e.g., ADT).
DOSEA	Actual Treatment Dose	Num		Perm	DOSEA represents the actual treatment dosage associated with the record.
DOSCUMA	Cumulative Actual Treatment Dose	Num		Perm	Cumulative actual dosage of treatment for the subject at the point in time of the record (e.g., ADT).
DOSEU	Treatment Dose Units	Char		Perm	The units for DOSEP, DOSCUMP, DOSEA, and DOSCUMA. It is permissible to use suffixes such as “P” and “A” if needed, with labels modified accordingly.

表 3.3.2.2 BDS 数据集中的记录水平剂量变量

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
DOSEP	计划治疗剂量	Num		Perm	DOSEP 表示记录水平的计划治疗剂量。
DOSCUMP	累积计划治疗剂量	Num		Perm	受试者各时间点的累积计划治疗剂量(e.g., ADT).；
DOSEA	实际治疗剂量	Num		Perm	DOSEA 表示记录水平的实际治疗剂量。
DOSCUMA	累积实际治疗剂量	Num		Perm	受试者各时间点的累积实际治疗剂量(e.g., ADT).
DOSEU	治疗剂量单位	Char		Perm	DOSEP, DOSCUMP, DOSEA, 和 DOSCUMA 的单位.如需要，可以使用后缀如"P"和"A",同时标签做相应调整。

3.3.3 Timing Variables for BDS Datasets

3.3.3 BDS 数据集中的时间变量

Any SDTM timing variables (including, but not limited to, EPOCH, --DTC, --DY, VISITNUM, VISIT, and VISITDY) may be copied into ADaM datasets if they would help to support data traceability and/or show how ADaM timing variables contrast with the SDTM data.
如果有助于支持数据的可追溯性及/或显示 ADaM 时间变量与 SDTM 数据的对比，SDTM 中的时间变量（包括但是不限于 EPOCH, --DTC, --DY, VISITNUM, VISIT, 和 VISITDY）可以被复制引入到 ADaM 数据集中。

Table 3.3.3.1 defines analysis timing variables for BDS datasets. The timing variables whose names start with the letter "A" are the timing variables directly associated with the AVAL and AVALC variables in the ADaM dataset.
表 3.3.3.1 中定义 BDS 数据集的分析时间变量。名称以字母 A 开始的时间变量直接和 ADaM 数据集中的 AVAL 和 AVALC 变量相关联。

Timing variables (e.g., *DT) not directly characterizing AVAL should be prefixed by a character string instead of the placeholder asterisk shown in Table 3.3.3.1, so that their actual names comply with the variable naming conventions described in Section 3.1. In many cases, the prefix for these date and time variables would match that of an SDTM --DTC, --STDTC or --ENDTC variable name. For example, if a numeric date variable were created from --STDTC, then it would be named --SDT. However, if --DTC or --STDTC is the date that is associated with AVAL and AVALC, its numeric equivalent should be named ADT or ASTDT, as appropriate. The Timing Variable Conventions documented in Section 3.1.2 apply here as well.
不直接表示 AVAL 特征的时间变量（例如,*DT）应该以一个字符串作为前缀，而不是表 3.3.3.1 中呈现的占位符星号，这样一来它们实际的名称遵循在 3.1 节开始时描述的变量命名规则。在许多情形，这些日期时间变量的前缀和同一个 SDTM 中的--DTC, --STDTC 或者 –ENDTC 变量名称一样。例如，如果一个数值型日期变量是从 --STDTC 创建，它会被命名为 --SDT。但是，如果 --DTC 或--STDTC 是与 AVAL 和 AVALC 相关联的日期，它的数值型相应变量应该被适当地命名为 ADT 或 ASTDT。第 3.1.2 节中记录的时间变量的命名规则在这里也适用。

Table 3.3.3.1 Timing Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ADT	Analysis Date	Num		Perm	The date associated with AVAL and/or AVALC in numeric format.
ATM	Analysis Time	Num		Perm	The time associated with AVAL and/or AVALC in numeric format.
ADTM	Analysis Datetime	Num		Perm	The datetime associated with AVAL and/or AVALC in numeric format.
ADY	Analysis Relative Day	Num		Perm	The relative day of AVAL and/or AVALC. The number of days from an anchor date (not necessarily DM.RFSTDTC) to ADT. See Section 3.1.2.
ADTF	Analysis Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis date. If ADT (or the date part of ADTM) was imputed, ADTF must be populated and is required. See Section 3.1.3.
ATMF	Analysis Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis time. If ATM (or the time part of ADTM) was imputed, ATMF must be populated and is required. See Section 3.1.3.
ASTDT	Analysis Start Date	Num		Perm	The start date associated with AVAL and/or AVALC. ASTDT and AENDT may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration.
ASTTM	Analysis Start Time	Num		Perm	The start time associated with AVAL and/or AVALC. ASTTM and AENTM may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration.
ASTDTM	Analysis Start Datetime	Num		Perm	The start datetime associated with AVAL and/or AVALC. ASTDTM and AENDTM may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration.
ASTDY	Analysis Start Relative Day	Num		Perm	The number of days from an anchor date (not necessarily DM.RFSTDTC) to ASTDT. See Section 3.1.2.
ASTDTF	Analysis Start Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis start date. If ASTDT (or the date part of ASTDTM) was imputed, ASTDTF must be populated and is required. See Section 3.1.3.
ASTTMF	Analysis Start Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis start time. If ASTTM (or the time part of ASTDTM) was imputed, ASTTMF must be populated and is required. See Section 3.1.3.
AENDT	Analysis End Date	Num		Perm	The end date associated with AVAL and/or AVALC. See also ASTDT.
AENTM	Analysis End Time	Num		Perm	The end time associated with AVAL and/or AVALC. See also ASTTM.
AENDTM	Analysis End Datetime	Num		Perm	The end datetime associated with AVAL and/or AVALC. See also ASTDTM.
AENDY	Analysis End Relative Day	Num		Perm	The number of days from an anchor date (not necessarily DM.RFSTDTC) to AENDT. See Section 3.1.2.
AENDTF	Analysis End Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis end date. If AENDT (or the date part of AENDTM) was imputed, AENDTF must be populated and is required. See Section 3.1.3.
AENTMF	Analysis End Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis end time. If AENTM (or the time part of AENDTM) was imputed, AENTMF must be populated and is required. See Section 3.1.3.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AVISIT	Analysis Visit	Char		Cond	The analysis visit description; required if an analysis is done by nominal, assigned or analysis visit. AVISIT may contain the visit names as observed (i.e., from SDTM VISIT), derived visit names, time window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of any of these. AVISIT is a derived field and does not have to map to VISIT from the SDTM. AVISIT represents the analysis visit of the record, but it does not mean that the record was analyzed. There are often multiple records for the same subject and parameter that have the same value of AVISIT. ANLzzFL and other variables may be needed to identify the records selected for any given analysis. See Section 3.3.8 for information about flag variables. AVISIT should be unique for a given analysis visit window. In the event that a record does not fall within any predefined analysis timepoint window, AVISIT can be populated in any way that the producer chooses to indicate this fact (i.e., blank or "Not Windowed"). The way that AVISIT is calculated, including the variables used in its derivation, should be indicated in the variable metadata for AVISIT. The values and the rules for deriving AVISIT may be different for different parameters within the same dataset. Values of AVISIT are producer-defined, and are often directly usable in Clinical Study Report displays.
AVISITN	Analysis Visit (N)	Num		Perm	A numeric representation of AVISIT. Since study visits are usually defined by certain timepoints, defining AVISITN so that it represents the timepoint associated with the visit can facilitate plotting and interpretation of the values. Alternatively, AVISITN may be a protocol visit number, a cycle number, an analysis visit number, or any other number logically related to AVISIT or useful for sorting that is needed for analysis. Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT. (Best practice would dictate that the mapping would be one-to-one within a study, but that is not an ADaM requirement.) In the event that a record does not fall within any predefined analysis timepoint window, AVISITN can be populated in any way that the producer chooses to indicate this fact (e.g., may be null). Values of AVISITN are producer-defined.
ATPT	Analysis Timepoint	Char		Cond	The analysis timepoint description; required if an analysis is done by nominal, assigned or analysis timepoint (instead of or in addition to by-visit). Timepoints are relative to ATPTREF. ATPT may contain the timepoint names as observed (i.e., from SDTM --TPT), derived timepoint names, time window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of any of these. This variable is often used in conjunction with AVISIT. ATPT represents the analysis timepoint of the record. ATPT can be within an analysis visit (e.g., blood pressure assessments at 10 min, 20 min, and 30 min post-dose at AVISIT=Week 1) or can be unrelated to AVISIT (e.g., migraine symptoms 30 min, 60 min, and 120 min post-dose for attack 1). The way that ATPT is calculated, including the variables used in its derivation, should be indicated in the variable metadata for ATPT. The values and the rules for deriving ATPT may be different for different parameters within the same dataset. Values of ATPT are producer-defined, and are often directly usable in Clinical Study Report displays.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ATPTN	Analysis Timepoint (N)	Num		Perm	ATPTN provides a numeric representation of ATPT. Defining ATPTN so that its values represent the planned timepoints (e.g., minutes or hours after dosing) is not required but can facilitate plotting and interpretation of the values. Within the same parameter, there is a one-to-one mapping between ATPT and ATPTN. (Best practice would dictate that the mapping would be one-to-one within a study, but that is not an ADaM requirement.)
ATPTREF	Analysis Timepoint Reference	Char		Perm	Description of the fixed reference point referred to by ATPT/ATPTN (e.g., time of dose).
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.
APHASEN	Phase (N)	Num		Perm	APHASEN provides a numeric representation of APHASE. Within a study, there is a one-to-one mapping between APHASE and APHASEN.
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.
APERIODC	Period (C)	Char		Perm	Text characterizing to which analysis period the record belongs. One-to-one mapping within a dataset to APERIOD.
ASPER	Subperiod within Period	Num		Perm	The numeric value characterizing a sublevel within APERIOD to which the record belongs. Within each APERIOD, the first ASPER is 1 (i.e., it resets to 1 when the APERIOD value changes).
ASPERC	Subperiod within Period (C)	Char		Perm	Text characterizing to which subperiod the record belongs. One-to-one mapping within a period to ASPER.
ARELTM	Analysis Relative Time	Num		Perm	The time relative to an anchor time. The amount of time from an anchor time to ATM. When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM.
ARELTMU	Analysis Relative Time Unit	Char		Perm	The units of ARELTM. For example, “HOURS” or “MINUTES.” ARELTMU is required if ARELTM is present.

表 3.3.3.1 BDS 数据集中时间变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心	CDISC 注释
ADT	日期-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的数字型日期
ATM	时间-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的数字型时间。
ADTM	日期时间-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的数字型日期/时间。
ADY	日-分析用	Num		Perm	AVAL 及/或 AVALC 的相对天数，是从一个参考日期（不必是 DM.RFSTDTC）到 ADT 的天数。见 3.1.2。
ADTF	日期填补标记	Char	(DATEFL)	Cond	分析日期的填补级别。如 ADT（或 ADTM 的日期部分）是填补的，ADTF 必须要呈现。请参见章节 3.1.3。
ATMF	时间填补标记	Char	(TIMEFL)	Cond	分析时间的填补级别。如 ATM（或 ADTM 的时间部分）是填补的，ADTMF 必须要呈现。请参见章节 3.1.3。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
ASTDT	开始日期-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的开始日期。在 AVAL 总结的是一个时间区间内收集的数据或 AVAL 收集的是一个持续阶段时, ASTDT 和 AENDT 可能对追溯性有用。
ASTTM	开始时间-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的开始时间。在 AVAL 总结的是一个时间区间内收集的数据或 AVAL 是一个持续时间段时，ASTTM 和 AENTM 可能对追溯性有用。
ASTDTM	开始日期时间-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的开始日期/时间。在 AVAL 总结的是一个时间区间内收集的数据或 AVAL 收集的是一个持续阶段时, ASTDTM 和 AENDTM 可能对追溯性有用。
ASTDY	开始日-分析用	Num		Perm	从一个参考日期（不必是 DM.RFSTDTC）到 ASTDT 的的相对天数。见 3.1.2。
ASTDTF	开始日期填补标记	Char	(DATEFL)	Cond	分析开始日期的填补级别。如 ASTDT（或 ASTDTM 的日期部分）是填补的，则 ASTDTF 必须呈现。请参见章节 3.1.3。
ASTTMF	开始时间填补标记	Char	(TIMEFL)	Cond	分析开始时间的填补级别。如 ASTTM（或 ASTDTM 的时间部分）是填补的，则 ASTTMF 必须呈现。请参见章节 3.1.3。
AENDT	结束日期-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的结束日期。请参见 ASTDT。
AENTM	结束时间-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的结束时间。请参见 ASTTM。
AENDTM	结束日期时间-分析用	Num		Perm	与 AVAL 及/或 AVALC 相关联的结束日期/时间。请参见 ASTDTM.
AENDY	结束日-分析用	Num		Perm	从一个参考日期（不必是 DM.RFSTDTC）到 AENDT 的的相对天数。见 3.1.2。
AENDTF	结束日期填补标记	Char	(DATEFL)	Cond	分析结束日期的填补级别。如 AENDT（或 AENDTM 的日期部分）是填补的，则 AENDTF 必须呈现。请参见章节 3.1.3。
AENTMF	结束时间填补标记	Char	(TIMEFL)	Cond	分析结束时间的填补级别。如 AENTM（或 AENDTM 的时间部分）是填补的，则 AENTMF 必须呈现。请参见章节 3.1.3。
AVISIT	分析访视	Char		Cond	对分析访视的描述；如果分析基于方案既定的访视名称、指定的访视或者特定的分析访视则该变量必须存在。AVISIT 可以包含观察到的访视名称（如，来自 SDTM VISIT）、推断的访视名称、时间窗名称、概念描述（比如平均值、终点等等）或者这些的任意组合。AVISIT 是一个导出的字段，并且不是必须映射到 SDTM VISIT。AVISIT 表示记录的分析访视，但并不意味着该记录用于分析。经常一个受试者同一个参数下会有多条记录具有相同 AVISIT 值。ANLzzFL 和其他变量可能需要用于确认为任何给定分析而选择的记录。标志变量相关信息，请参见章节 3.3.8 。对于一个给定分析访视窗口，AVISIT 应该是唯一的。如果发生一个记录不落在任何事先定义的分析时间点时间窗内，AVISIT 可以用申办者选择来标示这个事实的任何方式填充（即，空或“不在时间窗内”）。AVISIT 计算的方法，包括用来推断它的变量，应该在 AVISIT 的元数据变量中指出。在同一数据集中，对于不同参数，AVISIT 的值以及用来推断 AVISIT 的规则有可能会有所不同。在同一数据集中可能会对不同的参数有所不同。AVISIT 是申办者定义的，且经常直接展示于临床研究报告。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
AVISITN	分析访视(N)	Num		Perm	AVISIT 的数值型编码。由于通常用确切的时间点来定义研究访视，因此 AVISITN 定义为与访视相关的时间点，也便于值的绘图和解释。或者 AVISITN 可能是一个方案访视号、一个周期号、一个分析访视号、或者任何其它的与 AVISIT 逻辑相关的号、或者有助于分析所需排序的号。 在一个参数中 AVISITN 和 AVISIT 之间的一对一映射的，所以 AVISIT 的每个不同值都对应着和它相应的 AVISITN 值。（最佳做法要求是同一个研究中是一一对应的映射，但不是 ADaM 必须的做法。）如果发生一个记录不落在任何提前定义的分析时间点视窗内，AVISITN 可以用申办方选择的任何填充方式来表明这种情况（例如，可以为空）。 AVISITN 的值是申办者定义的。
ATPT	分析时点	Char		Cond	分析时间点描述; 如果分析基于方案规定时间点，指定时间点或者分析时间点则该变量必须存在（替代访视或者访视之外的补充）。时间点是相对于 ATPTREF 的。ATPT 可以包含观察到的时间点名称（如，来自 SDTM --TPT）、推断的时间点名称、时间窗名称、概念描述（例如平均值、终点等等）或者这些的任意组合。ATPT 常和 AVISIT 一起连用。ATPT 呈现的是记录的分析时间点。ATPT 可以是在一个分析访视内（例如，血压评估在 AVISIT=Week1 用药后的 10 分钟、20 分钟、30 分钟）或者可以和 AVISIT 没有关系（例如，对于第一次头痛突发，用药后 30 分钟、60 分钟、和 120 分钟的偏头痛症状）。 ATPT 计算的方法，包括用来推断它的变量，应该在 ATPT 的元数据变量中指出。在同一数据集中，对于不同参数，ATPT 的值以及用来推断 ATPT 的规则有可能会有所不同。ATPT 是申办者定义的，且经常直接用于临床研究报告。
ATPTN	分析时点(N)	Num		Perm	ATPT 的数值型编码。定义 ATPTN 以便其值用于呈现计划时间点（比如，用药后的时间或小时数）是非必须的，但便于值的绘图和解释。在一个参数中 ATPT 和 ATPTN 之间的一对一映射的。（最佳做法要求是同一个研究中是一一对应的映射，但不是 ADaM 必须的做法。）
ATPTREF	分析时点参照	Char		Perm	由 ATPT/ATPTN 引用的固定参考点的描述（比如，用药时间）
APHASE	分析期	Char		Perm	APHASE 是一个研究中时间的分类，如同一个更高级别的 APERIOD 分类或一个分析时期。比如，APHASE 可以描述时间跨度为 SCREENING, ON TREATMENT, 及 FOLLOW-UP。
APHASEN	分析期(N)	Num		Perm	APHASEN 是 APHASE 的数值型编码. 在同一个研究中，APHASE 与 APHASEN 之间是一一对应的。
APERIOD	周期	Num		Perm	APERIOD 是记录水平的时间变量，用来呈现研究中与分析目的记录相关联的分析阶段 APERIOD（如果被填充） 的值必须与 ADSL TRTxxP 中的 xx 的其中一个值相一致。
APERIODC	周期(C)	Char		Perm	记录所属的分析阶段的文字描述。在同一数据集中与 APERIOD 是一对一映射的。
ASPER	子周期	Num		Perm	记录所属的 APERIOD 的次级的数值型编码。每个 APERIOD 中，ASPER 从 1 开始（即，当 APERIOD 值变化时，ASPER 的值重新赋值为 1）。

变量名称	变量标签	类型	编码列表/受控术语	核心	CDISC 注释
ASPERC	子周期(C)	Char		Perm	记录所属的次级阶段的文字描述. 在同一分析阶段中与 ASPER 是一对一映射的。
ARELTM	分析相对时间	Num		Perm	相对于锚点的时间。从锚点时间到 ATM 的用时。当 ARELTM 存在，锚点时间变量和 ARELTMU 也必须包括在数据集中，并且锚时间变量必须在 ARELTM 的元数据中标识。
ARELTMU	分析相对时间单位	Char		Perm	ARELTM 的单位。例如，“小时”或者“时间”。如果有 ARELTM 变量，则 ARELTMU 为必需。

Additional timing variables can be included for phase, period, and subperiod. Table 3.3.3.2 provides the record-level variables for these timing elements.
分析相，阶段，次阶段也可包含其他时间变量。表 3.3.3.2 为这些时间元素提供了记录水平的变量。

Table 3.3.3.2 Period, Subperiod, and Phase Start and End Timing Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
APERSDT	Period Start Date	Num		Perm	The starting date for the period defined by APERIOD.
APERSTM	Period Start Time	Num		Perm	The starting time for the period defined by APERIOD.
APERSDTM	Period Start Datetime	Num		Perm	The starting datetime for the period defined by APERIOD.
APERSDTF	Period Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period start date. If APERSDT (or the date part of APERSDTM) was imputed, APERSDTF must be populated and is required. See Section 3.1.3.
APERSTMF	Period Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period start time. If APERSTM (or the time part of APERSDTM) was imputed, APERSTMF must be populated and is required. See Section 3.1.3.
APEREDT	Period End Date	Num		Perm	The ending date for the period defined by APERIOD.
APERETM	Period End Time	Num		Perm	The ending time for the period defined by APERIOD.
APEREDTM	Period End Datetime	Num		Perm	The ending datetime for the period defined by APERIOD.
APEREDTF	Period End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period end date. If APEREDT (or the date part of APEREDTM) was imputed, APEREDTF must be populated and is required. See Section 3.1.3.
APERETMF	Period End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period end time. If APERETM (or the time part of APEREDTM) was imputed, APERETMF must be populated and is required. See Section 3.1.3.
ASPRSDT	Subperiod Start Date	Num		Perm	The starting date for the subperiod defined by ASPER.
ASPRSTM	Subperiod Start Time	Num		Perm	The starting time for the subperiod defined by ASPER.
ASPRSDTM	Subperiod Start Datetime	Num		Perm	The starting datetime for the subperiod defined by ASPER.
ASPRSDTF	Subperiod Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of subperiod start date. If ASPRSDT (or the date part of ASPRSDTM) was imputed, ASPRSDTF must be populated and is required. See Section 3.1.3.
ASPRSTMF	Subperiod Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of subperiod start time. If ASPRSTM (or the time part of ASPRSDTM) was imputed, ASPRSTMF must be populated and is required. See Section 3.1.3.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ASPREDT	Subperiod End Date	Num		Perm	The ending date for the subperiod defined by ASPER.
ASPRETM	Subperiod End Time	Num		Perm	The ending time for the subperiod defined by ASPER.
ASPREDTM	Subperiod End Datetime	Num		Perm	The ending datetime for the subperiod defined by ASPER.
ASPREDTF	Subperiod End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of subperiod end date. If ASPREDT (or the date part of ASPREDTM) was imputed, ASPREDTF must be populated and is required. See Section 3.1.3.
ASPRETMF	Subperiod End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of subperiod end time. If ASPRETM (or the time part of ASPREDTM) was imputed, ASPRETMF must be populated and is required. See Section 3.1.3.
PHSDT	Phase Start Date	Num		Perm	The starting date for the phase defined by APHASE.
PHSTM	Phase Start Time	Num		Perm	The starting time for the phase defined by APHASE.
PHSDTM	Phase Start Datetime	Num		Perm	The starting datetime for the phase defined by APHASE.
PHSDTF	Phase Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of phase start date. If PHSDT (or the date part of PHSDTM) was imputed, PHSDTF must be populated and is required. See Section 3.1.3.
PHSTMF	Phase Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of phase start time. If PHSTM (or the time part of PHSDTM) was imputed, PHSTMF must be populated and is required. See Section 3.1.3.
PHEDT	Phase End Date	Num		Perm	The ending date for the phase defined by APHASE.
PHETM	Phase End Time	Num		Perm	The ending time for the phase defined by APHASE.
PHEDTM	Phase End Datetime	Num		Perm	The ending datetime for the phase defined by APHASE.
PHEDTF	Phase End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of phase end date. If PHEDT (or the date part of PHEDTM) was imputed, PHEDTF must be populated and is required. See Section 3.1.3.
PHETMF	Phase End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of phase end time. If PHETM (or the time part of PHEDTM) was imputed, PHETMF must be populated and is required. See Section 3.1.3.

表 3.3.3.2 阶段，次阶段， 以及相开始和结束时间变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心性	CDISC 注释
APERSDT	周期开始日期	Num		Perm	由 APERIOD 定义的阶段的开始日期。
APERSTM	周期开始时间	Num		Perm	由 APERIOD 定义的阶段的开始时间。
APERSDTM	周期开始日期时间	Num		Perm	由 APERIOD 定义的阶段的开始日期与时间。
APERSDTF	周期开始日期填补标记	Char	(DATEFL)	Cond	阶段开始日期的填补程度。如果 APERSDT (或者 APERSDTM 的日期部分) 被填补，APERSDTF 必须有值且为必需。 参见章节 3.1.3.
APERSTMF	周期开始时间填补标记	Char	(TIMEFL)	Cond	阶段开始时间的填补程度。如果 APERSTM (或者 APERSDTM 的时间部分) 被填补，APERSTMF 必须有值且为必需。参见章节 3.1.3.
APEREDT	周期结束日期	Num		Perm	由 APERIOD 定义的阶段的结束日期。
APERETM	周期结束时间	Num		Perm	由 APERIOD 定义的阶段的结束时间。
APEREDTM	周期结束日期时间	Num		Perm	由 APERIOD 定义的阶段的结束日期与时间。
APEREDTF	周期结束日期填补标记	Char	(DATEFL)	Cond	阶段结束日期的填补程度。如果 APEREDT (或者 APEREDTM 的日期部分) 被填补，APEREDTF 必须有值且为必需。参见章节 3.1.3.

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
APERETMF	周期结束时间填补标记	Char	(TIMEFL)	Cond	阶段结束时间的填补程度。如果 APERETM (或者 APEREDTM 的时间部分) 被填补，APERETMF 必须有值且为必需。参见章节 3.1.3.
ASPRSDT	子周期开始日期	Num		Perm	由 ASPER 定义的次阶段的开始日期。
ASPRSTM	子周期开始时间	Num		Perm	由 ASPER 定义的次阶段的开始时间。
ASPRSDTM	子周期开始日期时间	Num		Perm	由 ASPER 定义的次阶段的开始日期与时间。
ASPRSDTF	子周期开始日期填补标记	Char	(DATEFL)	Cond	次阶段开始日期的填补程度。如果 ASPRSDT (或者 ASPRSDTM 的日期部分) 被填补，ASPRSDTF 必须有值且为必需。参见章节 3.1.3.
ASPRSTMF	子周期开始时间填补标记	Char	(TIMEFL)	Cond	次阶段开始时间的填补程度。如果 ASPRSTM (或者 ASPRSDTM 的时间部分) 被填补，ASPRSTMF 必须有值且为必需。参见章节 3.1.3.
ASPREDT	子周期结束日期	Num		Perm	由 ASPER 定义的次阶段的结束日期。
ASPRETM	子周期结束时间	Num		Perm	由 ASPER 定义的次阶段的结束时间。
ASPREDTM	子周期结束日期时间	Num		Perm	由 ASPER 定义的次阶段的结束日期与时间。
ASPREDTF	子周期结束日期填补标记	Char	(DATEFL)	Cond	次阶段结束日期的填补程度。如果 ASPREDT (或者 ASPREDTM 的日期部分) 被填补，ASPREDTF 必须有值且为必需。参见章节 3.1.3.
ASPRETMF	子周期结束时间填补标记	Char	(TIMEFL)	Cond	次阶段结束时间的填补程度。如果 ASPRETM (或者 ASPREDTM 的时间部分) 被填补，ASPRETMF 必须有值且为必需。 参见章节 3.1.3.
PHSDT	分析期开始日期	Num		Perm	由 APHASE 定义的相的开始日期。
PHSTM	分析期开始时间	Num		Perm	由 APHASE 定义的相的开始时间。
PHSDTM	分析期开始日期时间	Num		Perm	由 APHASE 定义的相的开始日期与时间。
PHSDTF	分析期开始日期填补标记	Char	(DATEFL)	Cond	相开始日期的填补程度。如果 PHSDT (或者 PHSDTM 的日期部分) 被填补，PHSDTF 必须有值且为必需。参见章节 3.1.3.
PHSTMF	分析期开始时间填补标记	Char	(TIMEFL)	Cond	相开始时间的填补程度。如果 PHSTM (或者 PHSDTM 的时间部分) 被填补，PHSTMF 必须有值且为必需。参见章节 3.1.3.
PHEDT	分析期结束日期	Num		Perm	由 APHASE 定义的相的结束日期。
PHETM	分析期结束时间	Num		Perm	由 APHASE 定义的相的结束时间。
PHEDTM	分析期结束日期时间	Num		Perm	由 APHASE 定义的相的结束日期与时间。
PHEDTF	分析期结束日期填补标记	Char	(DATEFL)	Cond	相结束日期的填补程度。如果 PHEDT (或者 PHEDTM 的日期部分) 被填补，PHEDTF 必须有值且为必需。参见章节 3.1.3.
PHETMF	分析期结束时间填补标记	Char	(TIMEFL)	Cond	相结束时间的填补程度。如果 PHETM (或者 PHEDTM 的时间部分) 被填补，PHETMF 必须有值且为必需。参见章节 3.1.3.

Table 3.3.3.3 lists suffixes that can be used for timing variables that are not directly descriptive of the analysis value (AVAL and/or AVALC) but may be included for support of review. There may be a number of "sets" of these variables as indicated by the "*" prefix. **See Timing Variable Conventions Item 11 for important cautions regarding the "*" prefix.** See Section 3.1.6 regarding labels for variables where bracketed words or phrases have been specified.
表 3.3.3.3 列出了可以用做时间变量名称的后缀，他们不直接描述分析值（AVAL 和/或 AVALC）但是可以被用来支持复审。正如前缀"*"所示这样的变量可能会有不止一套。**关于前缀"*"的重要注意事项请参见时间变量惯例条目** 11。对于注有带括号的词句的变量的标签请参考章节 3.1.6 。

Table 3.3.3.3 Suffixes for User-Defined Timing Variables in BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
*DT	{Date}	Num		Perm	Analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*TM	{Time}	Num		Perm	Analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*DTM	{Datetime}	Num		Perm	Analysis datetime not directly characterizing AVAL and/or AVALC in numeric format.
*ADY	{Relative Day}	Num		Perm	Analysis relative day not directly characterizing AVAL and/or AVALC.
*DTF	{Date Imputation Flag}	Char	(DATEFL)	Cond	The level of imputation of *DT. If *DT (or the date part of *DTM) was imputed, *DTF must be populated and is required. See Section 3.1.3.
*TMF	{Time Imputation Flag}	Char	(TIMEFL)	Cond	The level of imputation of *TM. If *TM (or the time part of *DTM) was imputed, *TMF must be populated and is required. See Section 3.1.3.
*SDT	{Start Date}	Num		Perm	Starting analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*STM	{Start Time}	Num		Perm	Starting analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*SDTM	{Start Datetime}	Num		Perm	Starting analysis datetime not directly characterizing AVAL and/or AVALC in numeric format.
*SDY	{Relative Start Day}	Num		Perm	Starting analysis relative day not directly characterizing AVAL and/or AVALC.
*SDTF	{Start Date Imputation Flag}	Char	(DATEFL)	Cond	The level of imputation of *SDT. If *SDT (or the date part of *SDTM) was imputed, *SDTF must be populated and is required. See Section 3.1.3.
*STMF	{Start Time Imputation Flag}	Char	(TIMEFL)	Cond	The level of imputation of *STM. If *STM (or the time part of *SDTM) was imputed, *STMF must be populated and is required. See Section 3.1.3.
*EDT	{End Date}	Num		Perm	Ending analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*ETM	{End Time}	Num		Perm	Ending analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*EDTM	{End Datetime}	Num		Perm	Ending analysis datetime not directly characterizing AVAL and/or AVALC in numeric format.
*EDY	{Relative End Day}	Num		Perm	Ending analysis relative day not directly characterizing AVAL and/or AVALC.
*EDTF	{End Date Imputation Flag}	Char	(DATEFL)	Cond	The level of imputation of *EDT. If *EDT (or the date part of *EDTM) was imputed, *EDTF must be populated and is required. See Section 3.1.3.
*ETMF	{End Time Imputation Flag}	Char	(TIMEFL)	Cond	The level of imputation of *ETM. If *ETM (or the time part of *EDTM) was imputed, *ETMF must be populated and is required. See Section 3.1.3.

表 3.3.3.3 BDS 数据里用户自定义的时间变量名称后缀

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
*DT	{日期}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型分析日期。
*TM	{时间}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型分析时间。
*DTM	{日期时间}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型分析日期与时间。
*ADY	{日-分析用}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关的相差天数。
*DTF	{日期填补标记}	Char	(DATEFL)	Cond	*DT 的填补程度。 如果*DT (或者*DTM 的日期部分) 被填补，*DTF 必须有值且为必需。参见章节 3.1.3.
*TMF	{时间填补标记}	Char	(TIMEFL)	Cond	*TM 的填补程度。如果*TM (或者*DTM 的时间部分) 被填补，*TMF 必须有值且为必需。参见章节 3.1.3.
*SDT	{开始日期}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型开始分析日期。
*STM	{开始时间}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型开始分析时间。
*SDTM	{开始日期时间}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型开始分析日期与时间。
*SDY	{开始日-分析用}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型开始分析相差天数。
*SDTF	{开始日期填补标记}	Char	(DATEFL)	Cond	*SDT 的填补程度。如果*SDT (或者*SDTM 的日期部分) 被填补，*SDTF 必须有值且为必需。参见章节 3.1.3.
*STMF	{开始时间填补标记}	Char	(TIMEFL)	Cond	*STM 的填补程度。如果*STM (或者*SDTM 的时间部分) 被填补，*STMF 必须有值且为必需。参见章节 3.1.3.
*EDT	{结束日期}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型结束分析日期。
*ETM	{结束时间}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型结束分析时间。
*EDTM	{结束日期时间}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型结束分析日期与时间。
*EDY	{结束日-分析用}	Num		Perm	与 AVAL 和/或 AVALC 非直接相关数值型结束分析相差天数。
*EDTF	{结束日期填补标记}	Char	(DATEFL)	Cond	*EDT 的填补程度。如果*EDT (或者*EDTM 的日期部分) 被填补，*EDTF 必须有值且为必需。参见章节 3.1.3.
*ETMF	{结束时间填补标记}	Char	(TIMEFL)	Cond	*ETM 的填补程度。如果*ETM (或者*EDTM 的时间部分) 被填补，*ETMF 必须有值且为必需。参见章节 3.1.3.

3.3.4 Analysis Parameter Variables for BDS Datasets

3.3.4 BDS 数据集分析参数变量

Table 3.3.4.1 Analysis Parameter Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
PARAM	Parameter	Char		Req	The description of the analysis parameter. Examples include: "Supine Systolic Blood Pressure (mm Hg)", "Log10 (Weight (kg))", "Time to First Hypertension Event (Days)", "Estimated Tumor Growth Rate", etc. PARAM should be sufficient to describe unambiguously the contents of AVAL and/or AVALC. PARAM must include all descriptive and qualifying information relevant to the analysis purpose of the parameter. Examples of qualifying information that might be relevant to analysis and therefore are candidates for inclusion in PARAM are units, specimen type, location, position, machine type, and transformation function. There is no need to include qualifiers that are not relevant to the analysis of PARAM. In contrast to SDTM --TEST, no additional variable is needed to further qualify PARAM. PARAM may be longer than 40 characters in length but is restricted to a maximum of 200 characters. PARAM is often directly usable in Clinical Study Report displays. Note that in the ADaMIG, "parameter" is a synonym of "analysis parameter."
PARAMCD	Parameter Code	Char		Req	The short name of the analysis parameter in PARAM. Values of PARAMCD should follow the SAS Version 5 transport file format and Oracle constraints as noted under General Variable Conventions in Section 3.1.1. There must be a one-to-one mapping to PARAM within a dataset.
PARAMN	Parameter (N)	Num		Perm	A numeric representation of PARAM. Useful for ordering and programmatic manipulation. There must be a one-to-one mapping to PARAM within a dataset.
PARAMTYP	Parameter Type	Char	(PARAMTYP)	Perm	Indicator of whether the parameter is derived as a function of one or more other parameters. This variable will be retired from the ADaMIG in the next version because it was confused with the concept of DTYPE and therefore was being misused. The variable metadata should be adequate to indicate when a parameter is wholly derived.
PARCATy	Parameter Category y	Char		Perm	A categorization of PARAM within a dataset. For example, values of PARCAT1 might group the parameters having to do with a particular questionnaire, lab specimen type, or area of investigation. Note that PARCATy is not a qualifier for PARAM. PARAM to PARCATy is a many-to-one mapping; any given PARAM may be associated with at most one level of PARCATy (e.g., one level of PARCAT1 and one level of PARCAT2).
PARCATyN	Parameter Category y (N)	Num		Perm	A numeric representation of PARCATy. This can be used for operations on PARCATy. There must be a one-to-one relationship within a dataset between PARCATy and PARCATyN.
AVAL	Analysis Value	Num		Cond	Numeric analysis value described by PARAM. On a given record, it is permissible for AVAL, AVALC, or both to be null. AVAL is required if AVALC is not present, since either AVAL or AVALC must be present in the dataset.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AVALC	Analysis Value (C)	Char		Cond	Character analysis value described by PARAM. AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one map between AVAL and AVALC within a given PARAM. AVALC should not be used to categorize the values of AVAL. Within a given parameter, if there exists a row on which both AVALC and AVAL are populated, then there must be a one-to-one mapping between AVALC and AVAL on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either AVAL or AVALC be included when determining whether the one-to-one mapping requirement is satisfied.) On a given record, it is permissible for AVAL, AVALC, or both to be null. AVALC is required if AVAL is not present, since either AVAL or AVALC must be present in the dataset.
AVALCATy	Analysis Value Category y	Char		Perm	A categorization of AVAL or AVALC within a parameter. Not necessarily a one-to-one mapping to AVAL and/or AVALC. For example, if PARAM is "Headache Severity" and AVAL has values 0, 1, 2, or 3, AVALCAT1 can categorize AVAL into "None or Mild" (for AVAL 0 or 1) and "Moderate or Severe" (for AVAL 2 or 3).
AVALCAyN	Analysis Value Category y (N)	Num		Perm	A numeric representation of AVALCATy. This can be used for ordering of values of AVALCATy or for other purposes. There must be a one-to-one relationship within a parameter between AVALCATy and AVALCAyN.
BASE	Baseline Value	Num		Cond	The subject's baseline analysis value for a parameter and baseline definition (i.e. BASETYPE) if present. BASE contains the value of AVAL copied from a record within the parameter on which ABLFL = "Y". Required if dataset supports analysis or review of numeric baseline value or functions of numeric baseline value. If BASE is populated for a parameter, and BASE is non-null for a subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter. Note that a baseline record may be derived (e.g., it may be an average) in which case DTYPE must be populated on the baseline record.
BASEC	Baseline Value (C)	Char		Perm	The subject's baseline value of AVALC for a parameter and baseline definition (i.e. BASETYPE) if present. May be needed when AVALC is of interest. BASEC contains the value of AVALC copied from a record within the parameter on which ABLFL = "Y". If both AVAL and AVALC are populated within a parameter, the baseline record for AVALC must be the same record as that for AVAL. Within a given parameter, if there exists a row on which both BASEC and BASE are populated, then there must be a one-to-one mapping between BASEC and BASE on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either BASE or BASEC be included when determining whether the one-to-one mapping requirement is satisfied.) On a given record, it is permissible for BASE, BASEC, or both to be null.
BASECATy	Baseline Category y	Char		Perm	A categorization of BASE or BASEC within a parameter. Not necessarily a one-to-one mapping to BASE or BASEC. For example, if PARAM is "Headache Severity" and AVAL has values 0, 1, 2, or 3, BASECAT1 can categorize BASE into "None or Mild" (for BASE 0 or 1) and "Moderate or Severe" (for BASE 2 or 3).
BASECAyN	Baseline Category y (N)	Num		Perm	A numeric representation of BASECATy. This can be used for ordering of values of BASECATy or for other purposes. There must be a one-to-one relationship within a parameter between BASECATy and BASECAyN.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
BASETYPE	Baseline Type	Char		Cond	Producer-defined text describing the definition of baseline relevant to the value of BASE on the current record. Required when there are multiple ways that baseline is defined. If used for any PARAM within a dataset, should be non-null for all records of that dataset. Refer to Section 4.2.1, Rule 6, for an example.
CHG	Change from Baseline	Num		Perm	Change from baseline analysis value. Equal to AVAL-BASE. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of CHG is left to producer choice.
CHGCATy	Change from Baseline Category y	Char		Perm	A categorization of CHG within a parameter. Not necessarily a one-to-one mapping to CHG. The definition of CHGCATy may vary by PARAM. For example, CHGCAT1 may be used to categorize CHG with respect to ranges of change in SYSBP; "-10 to -5 mm Hg", "-5 to 0 mm Hg" categories.
CHGCATyN	Change from Baseline Category y (N)	Num		Perm	A numeric representation of CHGCATy. This can be used for ordering of values of CHGCATy or for other purposes. There must be a one-to-one relationship within a parameter between CHGCATy and CHGCATyN.
PCHG	Percent Change from Baseline	Num		Perm	Percent change from baseline analysis value. Equal to ((AVAL-BASE)/BASE)*100. If used for a given PARAM, should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of PCHG is left to producer choice.
PCHGCATy	Percent Chg from Baseline Category y	Char		Perm	A categorization of PCHG within a parameter. Not necessarily a one-to-one mapping to PCHG. The definition of PCHGCATy may vary by PARAM. For example, PCHGCAT1 may be used to categorize PCHG with respect to ranges of change in SYSBP; ">5%", ">10%" categories.
PCHGCAyN	Percent Chg from Baseline Category y (N)	Num		Perm	A numeric representation of PCHGCATy. This can be used for ordering of values of PCHGCATy or for other purposes. There must be a one-to-one relationship within a parameter between PCHGCATy and PCHGCAyN.
R2BASE	Ratio to Baseline	Num		Perm	Ratio to the baseline value. Equal to AVAL / BASE. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of R2BASE is left to producer choice.
R2AyLO	Ratio to Analysis Range y Lower Limit	Num		Perm	Ratio to the lower limit of the analysis range y. Equal to AVAL / AyLO. AyLO must exist in the ADaM dataset. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of R2AyLO is left to producer choice.
R2AyHI	Ratio to Analysis Range y Upper Limit	Num		Perm	Ratio to the upper limit of the analysis range y. Equal to AVAL / AyHI. AyHI must exist in the ADaM dataset. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of R2AyHI is left to producer choice.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
SHIFTy	Shift y	Char		Perm	A shift in values depending on the defined pairing for group y. SHIFTy can be based on the change in value of any of the following pairs (BASECATy, AVALCATy), (BNRIND, ANRIND), (ByIND, AyIND), (BTOXGR, ATOXGR), (BASE, AVAL) or (BASEC, AVALC). Useful for shift tables. For example, "NORMAL to HIGH". If used for a given PARAM, should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate baseline and pre-baseline values of SHIFTy is left to producer choice.
SHIFTyN	Shift y (N)	Num		Perm	Numeric version of SHIFTy. SHIFTyN maps one-to-one to SHIFTy within a parameter. If used for a given PARAM, should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate baseline and pre-baseline values of SHIFTyN is left to producer choice.

表 3.3.4.1 BDS 数据集分析参数变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心性	CDISC 注释
PARAM	参数	Char		Req	对分析参数的描述。 例子："卧位收缩压(mmHg)"，"Log10 (体重 (kg))"， "距高血压首发时间间隔(天数)"，"肿瘤生长率估计值"。PARAM 描述应足够详细以便能够清晰的解释 AVAL 和/或 AVALC 的内容。PARAM 必须包括所有与参数分析目标相关的描述和限定的信息。 例如单位、样本类型、位置、姿势、器械类型和转换函数，这些与分析相关的限定信息可能被包含在 PARAM 里面。。与 PARAM 分析无关的限定词无需包括进来。与 SDTM–TEST 不同的是，无需用其他变量来进一步限定 PARAM。 PARAM 长度可以超过 40 个字符，但是最长不能超过 200 个字符。 PARAM 经常被直接引用到临床试验报告当中。请注意在 ADaMIG 中, "参数"与 "分析参数"同义。
PARAMCD	参数简称	Char		Req	分析参数 PARAM 的简称。PARAMCD 应当遵循 SAS 版本 5 传输文件格式 和 Oracle 约束条件，相关注释参见章节 3.1.1.里的通用变量惯例。在一个数据集里与 PARAM 是一对一映射的。
PARAMN	参数(N)	Num		Perm	PARAM 的数值型表示，被用来排序和做编程处理。在一个数据集里与 PARAM 是一对一映射的。
PARAMTYP	参数类型	Char	(PARAMTYP)	Perm	标明是否源于一个或多个其他参数的函数的指示符。此变量会从下一个版本的 ADaMIG 里剔除，原因是容易和 DTYPE 的概念混淆而被误用。如果参数是完全导出的变量的元数据应当充分说明此情况。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
PARCATy	参数类别	Char		Perm	在数据集里对 PARAM 的分类。例如 PARCAT1 的值可能组合了与某一问卷调查相关的特定参数，或是某一实验室样本，或者某一个领域的调查。请注意 PARCATy 不是 PARAM 的限定词。PARAM 与 PARCATy 是多对一的映射关系；任何给定 PARAM 只可能与最多一个层级的 PARCATy (例如一个层级的 PARCAT1 和一个层级的 PARCAT2)相关联。
PARCATyN	参数类别(N)	Num		Perm	PARCATy 的数值型表示，可以用来处理 PARCATy。 一个数据集里 PARCATy 和 PARCATyN 间必须存在一对一的对应关系。
AVAL	分析值	Num		Cond	由 PARAM 描述的数值型分析值。针对某一条给定记录，可以允许 AVAL， AVALC，或者两者都为空。如果 AVALC 不存在，AVAL 是必需的，因为 AVAL 和 AVALC 二者必有其一存在于数据集中。
AVALC	分析值(C)	Char		Cond	由 PARAM 描述的字符型分析值。AVALC 可以是映射到 AVAL 的字符串，但是如果是这样，针对给定 PARAM， AVAL 和 AVALC 间必须存在一对一的映射关系。 AVALC 不应该用来对 AVAL 的值进行分类。 在给定参数内，如果存在一行记录 AVAL 和 AVALC 都有值，那么对于所有 AVAL 和 AVALC 都有值的记录两者间必须存在一对一的映射关系。(换句话讲，AVAL 或 AVALC 为空的记录没有必要用来判断一对一映射关系是否被满足。) 针对某一给定记录，可以允许 AVAL，AVALC， 或者两者都为空。 如果 AVAL 不存在，AVALC 则是必需的，因为 AVAL 和 AVALC 二者必有其一存在于数据集中。
AVALCATy	分析值类别 y	Char		Perm	在某一个参数内对于 AVAL 和 AVALC 的分类，其与 AVAL 和/或 AVALC 不一定存在一对一映射关系。例如如果 PARAM 为 “头痛严重程度”，AVAL 取值 0， 1， 2 或 3，AVALCAT1 能够将 AVAL 归类为 “无或轻度” (当 AVAL 为 0 或 1) ，“中度或严重” (当 AVAL 为 2 或 3)。
AVALCAyN	分析值类别 y(N)	Num		Perm	AVALCATy 的数值型表示，可以被用来对 AVALCATy 的值进行排序或者用于其他目的。在某一参数内 AVALCATy 和 AVALCAyN 间必须存在一对一的映射关系。
BASE	基线值	Num		Cond	受试者的一个参数和基线定义（即 BASETYPE）的基线分析值。 BASE 包含了从参数内 ABLFL = “Y” 的记录复制过来的 AVAL 值。 如果数据集是用来支持数值型基线测量值或其函数的分析或检查，则此变量是必需的。如果 BASE 对于某一参数有值，而且 BASE 对于某一受试者的这个参数非空，那么对于这个受试者和这个参数，必有一条记录被 ABLFL 标注为基线。请注意基线记录可能是衍生的 (例如取平均值)，在这种情况下基线记录 DTYPE 必须有值。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
BASEC	基线值(C)	Char		Perm	受试者对于某一参数的 AVALC 基线分析值和基线定义(即 BASETYPE)，当 AVALC 是研究兴趣点时是需要的。 BASEC 包含了从参数内 ABLFL = “Y” 的记录复制过来的 AVALC 值。如果 AVAL 和 AVALC 在某个参数内有值， AVALC 与 AVAL 的基线记录必须是同一条。 在给定参数内，如果存在一行记录 BASEC 和 BASE 都有值，那么对于所有 BASEC 和 BASE 都有值的记录两者间必须存在一对一的映射关系。(换句话讲，BASE 或 BASEC 为空的记录没有必要用来判断一对一映射关系是否被满足。) 针对某一给定记录，可以允许 BASE，BASEC，或者两者都为空。
BASECATy	基线类别 y	Char		Perm	在某一个参数内对于 BASE 和 BASEC 的分类，其与 BASE 和/或 BASEC 不一定存在一对一映射关系。 例如如果 PARAM 为“头痛严重程度”，AVAL 取值 0， 1， 2 或 3，BASECAT1 能够将 BASE 归类为“无或轻度” (当 BASE 为 0 或 1) ，“中度或严重” (当 BASE 为 2 或 3)。
BASECAyN	基线类别 y(N)	Num		Perm	BASECATy 的数值型表示， 可被用来对 BASECATy 的值进行排序或者用于其他目的。在某一参数内 BASECATy 和 BASECAyN 间必须存在一对一的映射关系
BASETYPE	基线类型	Char		Cond	申办者定义的文字来描述当前记录与 BASE 值相关的基线定义，当存在多种方式来定义基线时是必需的。如果在数据集内使用于任何 PARAM， 对于数据集内所有记录都应非空。例子参见章节 4.2.1, 法则 6。
CHG	相对基线变化值	Num		Perm	相对基线变化分析值，等于 AVAL-BASE。 如果用于给定 PARAM，应该对此 PARAM 的所有基线后记录填充，不管这条记录是否被用作分析。 至于如何填充基线前和基线时的 CHG 值取决于申办者的选择。
CHGCATy	相对基线变化类别 y	Char		Perm	在某一参数内对 CHG 的分类，不一定存在一对一的映射到 CHG。CHGCATy 的定义可能随 PARAM 发生变化。 例如 CHGCAT1 可根据 SYSBP 的变化范围来分类 CHG； “-10 到 -5 mm Hg”, “-5 到 0 mm Hg”。
CHGCATyN	相对基线变化类别 y(N)	Num		Perm	CHGCATy 的数值型表示。可被用来对 CHGCATy 的值进行排序或者用于其他目的。在某一参数内 CHGCATy 和 CHGCATyN 间必须存在一对一的映射关系。
PCHG	相对基线变化百分比	Num		Perm	相对基线变化百分比分析值，等于 ((AVAL-BASE)/BASE)*100。如果用于给定 PARAM，应该对于此 PARAM 的所有基线后记录填充 (当可计算时) ，不管这条记录是否被用作分析。 至于如何填充基线前和基线时的 PCHG 值取决于申办者的选择。.
PCHGCATy	相对基线变化百分比类别 y	Char		Perm	在某一参数内对 PCHG 的分类， 不一定存在一对一的映射到 PCHG。PCHGCATy 的定义可能随 PARAM 发生变化。例如 PCHGCAT1 可根据 SYSBP 的变化范围来分类 PCHG; “>5%”, “>10%” 。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
PCHGCAyN	相对基线变化百分比类别 y(N)	Num		Perm	PCHGCATy 的数值型表示。 可被用来对 PCHGCATy 的值进行排序或者用于其他目的。在某一参数内 PCHGCATy 和 PCHGCAyN 间必须存在一对一的映射关系。
R2BASE	与基线的比值	Num		Perm	相对于基线值的比率， 等于 AVAL / BASE。如果用于给定 PARAM，应该对此 PARAM 的所有基线后记录填充 ，不管这条记录是否被用作分析。至于如何填充基线前和基线时的 R2BASE 值取决于申办者的选择。
R2AyLO	与分析范围 y 下限的比值	Num		Perm	相对于分析范围 y 的下限的比率，等于 AVAL / AyLO。AyLO 必须存在于 ADaM 数据集里。如果用于给定 PARAM，应该对此 PARAM 的所有基线后记录填充 ，不管这条记录是否被用作分析。至于如何填充基线前和基线时的 R2AyLO 值取决于申办者的选择。
R2AyHI	与分析范围 y 上限的比值	Num		Perm	相对于分析范围 y 的上限的比率，等于 AVAL / AyHI。AyHI 必须存在于 ADaM 数据集里。如果用于给定 PARAM，应该对此 PARAM 的所有基线后记录填充 ，不管这条记录是否被用作分析。至于如何填充基线前和基线时的 R2AyHI 值取决于申办者的选择。
SHIFTy	转变 y	Char		Perm	根据定义好的配对对于组别 y 发生的值的偏移。 SHIFTy 可基于下面任何配对的值的变化 (BASECATy, AVALCATy), (BNRIND, ANRIND), (ByIND, AyIND), (BTOXGR, ATOXGR), (BASE, AVAL) 或(BASEC, AVALC)，适用于相对基线变化表格。 例如“正常到高”。如果用于给定 PARAM，应该对于此 PARAM 的所有基线后记录填充 (当可计算时) ，不管这条记录是否被用作分析。 至于如何填充基线前和基线时的 SHIFTy 值取决于申办者的选择。
SHIFTyN	转变 y(N)	Num		Perm	SHIFTy 的数值型表示，在某一参数中 SHIFTyN 一对一映射到 SHIFTy。如果用于给定 PARAM，应该对于此 PARAM 的所有基线后记录填充 (当可计算时) ，不管这条记录是否被用作分析。 至于如何填充基线前和基线时的 SHIFTyN 值取决于申办者的选择。

Users may create additional variables that are parameter-invariant functions of AVAL and BASE on the same row. Refer to Section 4.2 for the rules governing when derivations are added as rows, and when they are added as columns.
用户还可以创建其他一些变量，这些变量是相对于参数恒定的基于同一行的 AVAL 和 BASE 的函数。关于规定什么时候这些导出作为行加入，以及何时作为列加入的规则请参靠章节 4.2 。

PARAM, AVAL, and AVALC
It is important to understand a key difference in approach between the SDTM Findings class variable --TEST and the ADaM BDS variable PARAM. SDTM --TEST is designed to work in conjunction with other variables called qualifiers, such as specimen type, machine type, body position, etc., in order to describe the collected result. In contrast, the ADaM BDS variable PARAM does not have any accompanying qualifier variables. PARAM is the only variable that describes AVAL or AVALC. Qualifiers are not allowed.
了解 SDTM 发现类变量--TEST 和 ADaM BDS 变量 PARAM 的关键区别很重要。SDTM 的--TEST 是与其他限定符变量，例如样本类型、机器类型、身体位置等，结合起来描述收集的结果。相反，ADaM BDS 中的变量 PARAM 是不需要任何附带的限定符变量。PARAM 是描述 AVAL 或 AVALC 的唯一变量。不允许使用任何限定符变量。

PARAM is created to meet an analysis need, not just because something was collected. PARAM may describe an analysis value that is highly derived from subject data from any combination of SDTM domains of any class or classes, and/or any ADaM dataset. PARAM describes what is in AVAL or AVALC.
创建 PARAM 是为了满足分析需求，而不仅仅是因为收集了一些信息。该值可能是由某一类或者某几类 SDTM 域和/或某个 ADaM 数据集的任意组合的受试者数据高度衍生出来的。PARAM 描述了 AVAL 或 AVALC 中的内容。

For most parameters, only AVAL or AVALC will be populated, not both. That both --STRESC and --STRESN are present and populated in SDTM Findings class domains does not imply that both AVAL and AVALC must be present and populated in BDS datasets. AVAL and AVALC have a different purpose than --STRESN and --STRESC. For example, for parameters corresponding to numeric tests in SDTM Findings class domains, it is not recommended to copy SDTM --STRESC into AVALC, because there is no analysis need for a character value. Furthermore, doing so may result in breaking the one-to-one mapping requirement in some cases. If it is desired for traceability or listing purposes to bring the value of --STRESC into the ADaM dataset, the variable --STRESC may be copied as is without renaming it.
对于大多数参数而言，只有 AVAL 或 AVALC 需要进行填充，而不是两者都填充。SDTM Findings 域中同时存在和填充了--STRESC 和 --STRESN 并不意味着在 BDS 数据集中 AVAL 和 AVALC 必须同时存在和填充。AVAL 和 AVALC 的用途不同于--STRESC 和 --STRESN。例如，对于与 SDTM Findings 域中的数值检测相对应的参数，不建议将其在 SDTM 中的变量—STRESC 的值复制到 AVALC 中，因为不需要对其字符性数值进行分析。此外，这样做可能会导致在某些情况下打破一对一的映射要求。如果出于可追溯或制表的目的需要将--STRESC 的值引入到 ADaM 数据集中，那么可以按原样复制变量--STRESC，而不必对其进行重命名。

AVAL and AVALC are both populated only when there is a one-to-one mapping that may be useful, for example:

- When PARAM describes the numeric score of an individual question from a questionnaire, AVAL contains the score, and AVALC can be populated with the question answer text. Populating AVALC with the question answer text is supportive of review, and may help the recipient understand the meaning of the numeric score that is the subject of the parameter. Within the parameter, there is a one-to-one relationship between AVAL and AVALC on the rows on which both are populated.
- When PARAM describes a character-valued response from a set of possible values, the result is contained in AVALC. If desired for ordering or other reasons, AVAL can be also be populated, as long as the result of populating both AVAL and AVALC for the parameter is that they are a one-to-one map on the rows on which both are populated.

只有当存在可能有用的一对一映射时，才需要同时填充 AVAL 和 AVALC，例如：

- 当 PARAM 描述问卷中单个问题的数值分数时，AVAL 包含分数，AVALC 可以用分数对应的文字描述来填充。在 AVALC 中填充分数对应的文字描述有助于审查，并有助于接收者理解作为受试者的这个参数的数值分数的含义。在该参数中，填充的 AVAL 和 AVALC 之间存在一对一的关系。
- 当 PARAM 描述来自一组可能值为字符型的响应时，将其字符型结果包含在 AVALC 中。如果出于排序或其他原因需要，也可以填充 AVAL，只要确保为相应参数填充的 AVAL 和 AVALC 在同一行上的一对一映射关系即可。

Table 3.3.4.2 Analysis Parameter Criteria Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
CRITy	Analysis Criterion y	Char		Perm	A text string identifying a pre-specified criterion within a parameter, for example SYSBP > 90. Required if CRITyFL exists. In some cases, the presence of the text string indicates that the criterion is satisfied on this record and CRITyFL is set to Y, while a null value indicates that the criterion is not satisfied or is not evaluable and is accompanied by a null value in CRITyFL. In other cases, the text string identifies the criterion being evaluated and is populated on every row for the parameter, but whether or not the criterion is satisfied is indicated by the value of the variable CRITyFL. See CRITyFL and CRITyFN. Refer to Section 4.7 for additional discussion of CRITy, CRITyFL and CRITyFN.
CRITyFL	Criterion y Evaluation Result Flag	Char	Y *or* Y, N	Cond	Character flag variable indicating whether the criterion defined in CRITy was met by the data on the record. See CRITy for more information regarding how to use CRITy and CRITyFL to indicate whether a criterion is met. Required if CRITy exists. Refer to Section 4.7 for additional discussion.
CRITyFN	Criterion y Evaluation Result Flag (N)	Num	1 *or* 1, 0	Perm	Numeric representation of CRITyFL. There is a one-to-one mapping between CRITyFL and CRITyFN. CRITyFN can be included only if CRITyFL is also included.
MCRITy	Analysis Multi-Response Criterion y	Char		Perm	A text string identifying a pre-specified criterion within a parameter, where the criterion can have multiple responses (as opposed to CRITy which has binary responses). Required if MCRITyML exists. For example, the grade of a lab analyte is compared to the baseline grade, with the possible conditions being 0 to 1, 0 to 2, etc. The text string identifies the criterion being evaluated (for example, "Grade increase") and is populated on every row for the parameter; which level of the criterion is satisfied is indicated by the value of the variable MCRITyML (for example "0 to 1", "0 to 2", etc.) See MCRITyML and MCRITyMN below, and refer to Section 4.7 for additional discussion of MCRITy, MCRITyML, and MCRITyMN.
MCRITyML	Multi-Response Criterion y Evaluation	Char		Cond	Character variable indicating which level of the criterion defined in MCRITy was met by the data on the record. See MCRITy for more information regarding how to use MCRITy and MCRITyML to indicate whether a criterion was met. Content is sponsor-defined. Required if MCRITy exists.
MCRITyMN	Multi-Response Criterion y Eval (N)	Num		Perm	Numeric representation of MCRITyML. There is a one-to-one mapping between MCRITyML and MCRITyMN. Content is sponsor-defined. MCRITyMN can be included only if MCRITyML is also included.

表 3.3.4.2 BDS 数据集的分析参数准则变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心性	CDISC 注释
CRITy	判断规则 y	Char		Perm	标识一个参数的预先制定准则的文本串，例如 SYSBP > 90。如果 CRITyFL 存在，则需要。在某些情况下，该文本串的存在表示此条记录满足该准则，并且将 CRITyFL 设置为 Y，而空值表示此条记录不满足准则或者无法用该准则对其进行评价，并且将 CRITyFL 设置为空值。在其他情况下，文本串标识正在评估的准则，并在参数的每一行上填充，但是否满足条件由变量 CRITyFL 的值指示。参见 CRITyFL 和 CRITyFN。有关 CRITy、CRITyFL 和 CRITyFN 的更多讨论，请参阅第 4.7 节。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
CRITyFL	判断规则 y 结果标帜	Char	是 或者 是，否	Cond	字符型指示变量，指出某条记录的某一特定参数值是否满足 CRITy 中定义的标准。有关如何使用 CRITy 和 CRITyFL,以及指示是否满足标准的详细信息，请参阅 CRITy。如果 CRITy 存在则该变量是必需的，详见 4.7 节中的讨论。
CRITyFN	判断规则 y 结果标帜(N)	Num	1 或1, 0	Perm	CRITyFL 的数值型。CRITyFL 和 CRITyFN 之间有一对一的映射。只有当 CRITyFL 存在的时候， CRITyFN 才能存在。
MCRITy	多分类判断规则 y	Char		Perm	标识一个具有多个响应的参数的预先制定准则的文本串（而不是只具有二元反应的 CRITy）。如果存在 MCRITyML，则需要。例如，将实验室分析物的等级与基线等级进行比较，可能的条件为 0 至 1、0 至 2 等。文本字符串标识正在评估的标准（例如，“等级增加”），并填充在参数的每一行；满足标准的哪一个等级由值表示变量 MCRITyML（例如“0 至 1”、“0 至 2”等）见下文中的 MCRITyML 和 MCRITyMN，有关 MCRITy、MCRITyML 和 MCRITyMN 其他讨论，请参阅第 4.7 节。
MCRITyML	多分类判断规则 y 结果	Char		Cond	字符变量，指示记录上的数据满足 MCRITy 中定义的标准的级别。有关如何使用 MCRITy 和 MCRITyML 来指示是否满足标准的更多信息，请参阅 MCRITy。内容由申办方定义。如果存在 MCRITy，则需要。
MCRITyMN	多分类判断规则 y 结果(N)	Num		Perm	MCRITyML 的数值型。在 MCRITyML 和 MCRITyMN 之间有一对一的映射。内容由申办方定义。只有在存在 MCRITyML 的情况下，才能存在 MCRITyMN。

3.3.5 Analysis Descriptor Variables for BDS Datasets

3.3.5 BDS 数据集的分析描述符变量

For a given parameter within a BDS dataset, it is important to 1) be able to distinguish analysis values that are special cases of AVAL/AVALC (those for which the value is determined differently than the other analysis values within the parameter), and 2) understand what method or algorithm was used to populate each

special case. The variable DTYPE (Table 3.3.5.1) is to be used to identify records within a given parameter that contain these special-case analysis values. The value of DTYPE indicates the method used for populating the analysis value; a null value of DTYPE indicates the analysis value was not a special case. The metadata for AVAL (or AVALC) will give further information about the details of any algorithm or statistical method used to derive or impute these values.
对于 BDS 数据集中的一个给定参数，重要的是 1）能够区分属于 AVAL/AVALC 特殊情况的分析值（这类值的确定与参数中的其他分析值不同）；2）了解用于填充每个特殊情况的方法或算法。变量 DTYPE（表 3.3.5.1）用于标识给定参数中包含这些特殊案例分析值的记录。DTYPE 的值表示用于填充分析值的方法；DTYPE 的空值表示分析值不是特殊情况。AVAL（或 AVALC）的元数据将提供有关用于推导或填充这些值的任何算法或统计方法的详细信息。

As an example, consider a situation where the analysis value for a parameter is populated by copying a value from an SDTM dataset, unless that value is missing. If the value is missing, then the analysis value is populated using a specific imputation method. It is helpful to be able to identify the “special case” instances when the analysis value is imputed rather than copied from SDTM, as well as knowing what imputation method was used.

例如，考虑这样一种情况，即通过从 SDTM 数据集中复制值来填充参数的分析值，除非该值丢失。如果缺少该值，则使用特定的插补方法填充分析值。对分析值进行插补而不是从 SDTM 中复制，这有助于能够识别“特殊情况”实例，以及了解使用了什么填补方法。

As another example, consider a situation where the analysis value for a parameter is populated based on the subject's corresponding value in another parameter or dataset, unless the value is outside a specified range. If the value is outside the range, then the analysis value will instead be populated with a pre-specified constant. It is helpful to be able to identify the "special case" instances where the analysis value was out of range and therefore replaced with a constant.
作为另一个示例，考虑这样一种情况，即一个参数的分析值是根据另一个参数或数据集中与主题的相对应的值填充的，除非该值超出指定的范围。如果该值超出范围，则将使用预先指定的常量填充分析值。能够识别分析值超出范围的“特殊情况”实例是很有用的，然后用常量替换来填充。

As yet another example, consider a situation where in addition to a subject's analysis value for each visit, an additional timepoint is to be identified called "POST-BASELINE" with the analysis value populated with an average of the analysis values from the subject's on-treatment visits. Though it is possible to identify the "special case" analysis values by looking at the value of AVISIT, DTYPE also facilitates the identification as well as providing information about the algorithm used.
另一个例子是，考虑这样一种情况，除了受试者每次访视的分析值之外，还需要确定一个额外的时间点，称为“基线后”，分析值由受试者治疗就诊时的分析值平均值填充。虽然可以通过查看 AVISIT 的值来识别“特殊情况”分析值，但 DTYPE 也有助于识别，并提供有关所用算法的信息。

See the CDISC Notes for DTYPE for a list of situations in which DTYPE should be populated. Examples of these instances are:

- A new record has been created within a parameter to facilitate a cross-timepoint derivation such as endpoint, minimum, maximum and average post-baseline, with the analysis value calculated according to the derivation algorithm (See Section 4.5.3);
- A new record is created within a parameter to represent a missing timepoint for a subject, with an imputed analysis value (see Section 4.5.1);
- The analysis value on an existing record is modified according to a pre-specified algorithm (e.g., setting AVAL to a pre-specified constant for results outside of a pre-specified range, replacing a missing AVAL based on a pre-specified algorithm).

有关填充数据类型的情况列表，请参阅 CDISC 注释中的数据类型。这些实例的示例包括：

- 在一个参数内创建了一个新的记录，以便于跨时间点推导，如端点、最小值、最大值和基线后平均值，根据推导算法计算分析值（见第 4.5.3 节）；
- 在一个参数内创建一个新的记录，用一个填补的分析值来表示一个主题缺失的时间点（见第 4.5.1 节）；
- 根据预先指定的算法修改现有记录的分析值（例如，为超出预先指定范围的结果将 AVAL 设置为预先指定的常量，根据预先指定的算法替换丢失的 AVAL）。

In short, when the analysis value on a record within a parameter has been imputed or modified, DTYPE will indicate the method used to populate the analysis value.
简而言之，当填补或修改了参数中记录的分析值时，DTYPE 将用于指示填充分析值的方法。

DTYPE would be used if there are special cases within the new parameter that should be identified. If a parameter is wholly derived, such as a Time-to-Event parameter, then it is a misapplication to populate DTYPE for all records in that parameter because, by definition, all records are derived using the same method.
如果新参数中有需要标识的特殊情况，则需使用 DTYPE。如果一个参数是完全派生的，例如 Time-to-Event 参数，那么为该参数中的所有记录填充 DTYPE 是一种误用，因为根据定义，所有记录都是使用相同的方法派生的。

Table 3.3.5.1 Analysis Descriptor Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
DTYPE	Derivation Type	Char	(DTYPE)	Cond	Analysis value derivation method. DTYPE is used to denote, and is required to be populated, when the value of AVAL or AVALC has been imputed or derived differently than the other analysis values within the parameter. DTYPE is required to be populated even if AVAL and AVALC are null on the derived record. Three common situations when DTYPE should be populated: (1)) a new row is added within a parameter with the analysis value populated based on other rows within the parameter, (2)) a new row is added within a parameter with the analysis value populated based on a constant value or data from other subjects, (3) an analysis value (AVAL or AVALC) on an existing record is being replaced with a value based on a pre-specified algorithm. DTYPE is used to denote analysis values that are "special cases" within a parameter. For each value of DTYPE, the precise derivation algorithm must be defined in analysis variable metadata, even for DTYPE values in the controlled terminology. The controlled terminology for DTYPE is extensible. See Section 4 for examples of the use of DTYPE. Examples of DTYPE values: LOCF = last observation carried forward. WOCF = worst observation carried forward. AVERAGE = average of values.

表 3.3.5.1 BDS 数据集的分析描述符变量

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
DTYPE	衍生类型	Char	(DTYPE)	Cond	分析值的推导方法。当推导的 AVAL 或 AVALC 值与参数中的其他分析值的填补或衍生方法不同时，则需要使用 DTYPE。表示并需要填充 AVAL 或 AVALC 的值。即使 AVAL 和 AVALC 在派生记录上为 null，也需要填充 DTYPE。 应该填充 DTYPE 的三种常见情况: (1) 根据参数中的其他行的分析值在参数中添加新行， (2) 在参数中添加新行，该行的分析值是根据常量值或来自其他受试者的数据填充， (3) 将现有记录上的分析值(AVAL 或 AVALC)替换为基于预先指定算法得到的值。 DTYPE 用于表示参数中属于"特殊情况"的分析值。对于 DTYPE 的每个值，必须在分析变量元数据中定义精确的派生算法，即使对于受控术语中的 DTYPE 值也是如此。DTYPE 的受控术语是可扩展的。有关使用 DTYPE 的示例，请参见第 4 节。 DTYPE的示例值： LOCF=末次观测值向前结转， WOCF=最差的观测值向前结转， AVERAGE=值的平均。

If analysis timepoints are defined by relative day or hour windows, then the variables in Table 3.3.5.2 may be used along with ADY or ARELTM to clarify how the record representing each analysis timepoint was chosen from among the possible candidates. The record chosen is indicated by the analyzed record flag ANLzzFL (see Table 3.3.8.1). Note that the variables in Table 3.3.5.2 may not be applicable in all situations and are presented as an option.
如果分析时间点是由相对的天或小时窗口定义的，那么表 3.3.5.2 中的变量可以与 ADY 或 ARELTM 一起使用，以阐明如何从可能的候选中选择代表每个分析时间点的记录。所选记录由分析的记录标志 ANLzzFL 表示(见表 3.3.8.1)。注意，表 3.3.5.2 中的变量可能并不适用于所有情况，只是作为一种选择。

Table 3.3.5.2 Analysis Visit Windowing Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AWRANGE	Analysis Window Valid Relative Range	Char		Perm	The range of values that are valid for a given analysis timepoint (a given value of AVISIT). For example, "5-9 DAYS".
AWTARGET	Analysis Window Target	Num		Perm	The target or most desired analysis relative day (ADY) value or analysis relative time (ARELTM) value for a given value of AVISIT.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AWTDIFF	Analysis Window Diff from Target	Num		Perm	Absolute difference between ADY or ARELTM and AWTARGET. It will be necessary to adjust for the fact that there is no day 0 in the event that ADY and AWTARGET are not of the same sign. If the sign of the difference is important, then AWTDIFF might have to be used in conjunction with ADY or ARELTM and possibly AWTARGET when choosing among records.
AWLO	Analysis Window Beginning Timepoint	Num		Perm	The value of the beginning timepoint (inclusive) needs to be used in conjunction to AWRANGE. For example, if AWRANGE is "5-9 DAYS", then AWLO is "5".
AWHI	Analysis Window Ending Timepoint	Num		Perm	The value of the ending timepoint (inclusive) needs to be used in conjunction to AWRANGE. For example, if AWRANGE is "5-9 DAYS", then AWHI is "9".
AWU	Analysis Window Unit	Char		Perm	Unit used for AWLO and AWHI. Examples: DAYS, HOURS.

表 3.3.5.2 BDS 数据集的分析访视窗变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心性	CDISC 注释
AWRANGE	时间窗范围	Char		Perm	对于一个给定的分析时间点的有效值的范围（AVISIT的一个给定值）。例如，"5-9天"。
AWTARGET	时间窗目标	Num		Perm	对于AVISIT一个给定值的目标，或者最期望的分析相对日（ADY）值，或者分析相对时间（ARELTM）值。
AWTDIFF	相对时间窗目标的偏差	Num		Perm	ADY或者ARELTM和AWTARGET之间的绝对差异。当出现ADY和AWTARGET是不同符号的时候，这个值有必要进行校正，因为这里是没有第0天的。 如果不同的符号是影响很大的，那么筛选记录时 AWTDIFF 可能不得不结合 ADY 或者 ARELTM 且可能与 AWTARGET 一起使用。
AWLO	时间窗下限	Num		Perm	开始时间点的值（包括所述的限度）需要结合 AWRANGE 一起使用，例如，如果 AWRANGE 是"5-9 天"，那么 AWLO 是"5"
AWHI	时间窗上限	Num		Perm	结束时间点的值（包括所述的限度）需要结合AWRANGE一起使用。例如，如果AWRANGE是"5-9天"，那么AWHI是"9"。
AWU	时间窗单位	Char		Perm	用于 AWLO 和 AWHI 的单位，例如：天、小时。

3.3.6 Time-to-Event Variables for BDS Datasets

3.3.6 BDS 数据集中的达到事件时间变量

Table 3.3.6.1 describes variables useful for time-to-event analysis. Please refer to the document titled "The ADaM Basic Data Structure for Time-to-Event Analyses" for discussion and examples of the use of these variables and other ADaM variables to support time-to-event analyses. For example, the document describes using AVAL for the length of time from the start of the at-risk period to the event of interest, ADT for the date of event or censoring, and AVISIT for the analysis visit where event or censoring occurred.
表 3.3.6.1 描述了用于时间到事件分析的变量。请参阅题为"时间到事件分析的 ADaM 基本数据结构"的文档，了解如何使用这些变量和其他 ADaM 变量来支持时间到事件分析。例如，该文件描述了使用 AVAL 记录从风险期开始到感兴趣事件发生的时间长度，ADT 表示事件或删失的日期，AVISIT 表示事件或删失发生的分析访视。

Table 3.3.6.1 Time-to-Event Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
STARTDT	Time-to-Event Origin Date for Subject	Num		Perm	The original date of risk for the time-to-event analysis. This is generally the time at which a subject is first at risk for the event of interest evaluation (as defined in the Protocol or Statistical Analysis Plan). For example, this may be the randomization date or the date of first study therapy exposure.
STARTDTM	Time-to-Event Origin Datetime	Num		Perm	The datetime associated with STARTDT in numeric format.
STARTDTF	Origin Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of the start date. See Section 3.1.3.
STARTTMF	Origin Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of the start time. See Section 3.1.3.
CNSR	Censor	Num		Cond	Defines whether the event was censored for the subject within the parameter (period of observation truncated prior to event being observed). It is strongly recommended to use 0 as an event indicator and positive integers as censoring indicators. It is also recommended that unique positive integers be used to indicate coded descriptions of censoring reasons. CNSR is required for time-to-event parameters.
EVNTDESC	Event or Censoring Description	Char		Perm	Description of the event of interest or censoring reason for the subject within the parameter.
CNSDTDSC	Censor Date Description	Char		Perm	Describes the circumstance represented by the censoring date if different from the event date that warrants censoring.

表 3.3.6.1 BDS 数据集中的达到事件时间变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心性	CDISC 注释
STARTDT	事件时间起点日期	Num		Perm	时间到事件分析的风险原始时间，这通常是受试者第一次处于感兴趣事件的风险时的时间（如在方案或统计分析计划中定义的），例如，这可能是随机化日期或者第一次研究治疗用药的日期。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
STARTDTM	事件时间起点日期时间	Num		Perm	以数字格式与 STARTDT 关联的日期时间。
STARTDTF	起点日期填补标记	Char	(DATEFL)	Cond	开始日期的插补水平。见第 3.1.3 节。
STARTTMF	起点日期时间填补标记	Char	(TIMEFL)	Cond	开始时间的插补水平。见第 3.1.3 节。
CNSR	删失	Num		Cond	定义某参数内受试者是否发生删失（在事件被观测到之前已停止继续观察）。强烈推荐使用 0 作为事件的指示，且用正整数作为删失的指示。也推荐使用唯一正整数作为删失原因的指示变量。也推荐使用唯一正整数作为删失原因的编码描述。对于时间到事件分析，CNSR 参数是必需的。
EVNTDESC	事件或者删失描述	Char		Perm	在受试者参数中感兴趣的事件或者删失原因的描述
CNSDTDSC	删失日期描述	Char		Perm	当实际删失日期与被视为删失的事件日期不同时，描述删失日期所代表的情况。

3.3.7 Toxicity and Range Variables for BDS Datasets

3.3.7 BDS 结构数据集的毒性和范围变量

Table 3.3.7.1 Toxicity and Range Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ATOXGR	Analysis Toxicity Grade	Char		Perm	Toxicity grade of AVAL or AVALC for analysis; may be based on SDTM --TOXGR or an imputed or assigned value.
BTOXGR	Baseline Toxicity Grade	Char		Perm	ATOXGR of the baseline record identified by ABLFL.
ANRIND	Analysis Reference Range Indicator	Char		Perm	Indicates where AVAL or AVALC falls with respect to the normal reference range for analysis; may be based on SDTM --NRIND or an imputed or assigned value.
BNRIND	Baseline Reference Range Indicator	Char		Perm	ANRIND of the baseline record identified by ABLFL.
ANRLO	Analysis Normal Range Lower Limit	Num *		Perm	Normal range lower limit for analysis; may be based on SDTM --NRLO or an imputed or assigned value.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ANRLOC	Analysis Normal Range Lower Limit (C)	Char		Perm	Character analysis normal range lower limit. ANRLOC can be a character string mapping to ANRLO, but if so there must be a one-to-one map between ANRLO and ANRLOC within a given PARAM. ANRLOC should not be used to categorize the values of ANRLO. Within a given parameter, if there exists a row on which both ANRLOC and ANRLO are populated, then there must be a one-to-one mapping between ANRLOC and ANRLO on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either ANRLO or ANRLOC be included when determining whether the one-to-one mapping requirement is satisfied.) On a given record, it is permissible for ANRLO, ANRLOC, or both to be null.
ANRHI	Analysis Normal Range Upper Limit	Num *		Perm	Normal range upper limit for analysis; may be based on SDTM --NRHI or an imputed or assigned value.
ANRHIC	Analysis Normal Range Upper Limit (C)	Char		Perm	Character analysis normal range upper limit. ANRHIC can be a character string mapping to ANRHI, but if so there must be a one-to-one map between ANRHI and ANRHIC within a given PARAM. ANRHIC should not be used to categorize the values of ANRHI. Within a given parameter, if there exists a row on which both ANRHIC and ANRHI are populated, then there must be a one-to-one mapping between ANRHIC and ANRHI on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either ANRHI or ANRHIC be included when determining whether the one-to-one mapping requirement is satisfied.) On a given record, it is permissible for ANRHI, ANRHIC, or both to be null.
AyLO	Analysis Range y Lower Limit	Num *		Cond	AyLO and/or AyHI are used for analysis ranges other than the normal range. AyLO and/or AyHI are created to capture the different levels of cutoff values used to determine whether an analysis is within a clinically acceptable value range or outside that value range. AyLO and/or AyHI are usually but not necessarily constants, parameter-specific constants, or subject-specific constants. AyLO must be included if R2AyLO is included in the dataset.
AyLOC	Analysis Range y Lower Limit (C)	Char		Perm	Character analysis range y lower limit. AyLOC can be a character string mapping to AyLO, but if so there must be a one-to-one map between AyLO and AyLOC within a given PARAM. AyLOC should not be used to categorize the values of AyLO. Within a given parameter, if there exists a row on which both AyLOC and AyLO are populated, then there must be a one-to-one mapping between AyLOC and AyLO on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either AyLO or AyLOC be included when determining whether the one-to-one mapping requirement is satisfied.) On a given record, it is permissible for AyLO, AyLOC, or both to be null.
AyHI	Analysis Range y Upper Limit	Num *		Cond	See AyLO. For example, if ECG QTc values are summarized based on values >450, values >480, and values >500, there is a need for 3 “hi value” range variables against which to compare values: A1HI=450, A2HI=480, A3HI=500. AyHI must be included if R2AyHI is included in the dataset.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AyHIC	Analysis Range y Upper Limit (C)	Char		Perm	Character analysis range y upper limit. AyHIC can be a character string mapping to AyHI, but if so there must be a one-to-one map between AyHI and AyHIC within a given PARAM. AyHIC should not be used to categorize the values of AyHI. Within a given parameter, if there exists a row on which both AyHIC and AyHI are populated, then there must be a one-to-one mapping between AyHIC and AyHI on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either AyHI or AyHIC be included when determining whether the one-to-one mapping requirement is satisfied.) On a given record, it is permissible for AyHI, AyHIC, or both to be null.
AyIND	Analysis Range y Indicator	Char		Perm	Indicates relationship of AVAL to the analysis range variables AyLO and/or AyHI, or the relationship of AVALC to the analysis range variables AyLOC and/or AyHIC.
ByIND	Baseline Analysis Range y Indicator	Char		Perm	AyIND of the baseline record identified by ABLFL.
** ANRLO, ANRHI, AyLO, and AyHI were mistakenly indicated as character variables in ADaMIG v1.0. The error is corrected above, and the character versions of the variables added.*					

表 3.3.7.1 BDS 结构数据集的毒性和范围变量

变量名称	变量标签	类型	编码列表/ 受控术语	核心性	CDISC 注释
ATOXGR	毒性分级-分析用	Char		Perm	分析值 AVAL/AVALC 的毒性等级，可以根据 SDTM 的-TOXGR 或者是一个估计/指定值。
BTOXGR	基线毒性分级	Char		Perm	ABLFL 标识的基线记录的 ATOXGR 值。
ANRIND	参考范围指示符-分析用	Char		Perm	分析值 AVAL/AVALC 落入关于正常范围的指示符，可以根据 SDTM 的—NRIND 或者是一个估计/指定值。
BNRIND	基线参考范围指示符	Char		Perm	ABLFL 标识的基线记录的 ANRIND 值。
ANRLO	正常值范围下限-分析用	Num *		Perm	分析的正常范围下限，可以根据 SDTM 的—NRLO 或者是一个估计/指定值。
ANRLOC	正常值范围下限(C)-分析用	Char		Perm	字符型分析正常范围下限。 ANRLOC 可以是一个映射到 ANRLO 的字符串，但是必须是在指定的参数内，ANRLOC 和 ANRLO 是一对一映射的。ANRLOC 不能用做 ANRLO 的分类变量。在给定的参数内，如果同一行的 ANRLOC 和 ANRLO 同时都有值，那么所有行的 ANRLOC 和 ANRLO 必须同时都一对一映射有值。换言之，没有要求说 ANRLO 或者 ANRLOC 其中一个为空值时，还需要满足 ANRLO 和 ANRLOC 是否需要一对一映射。对于一个给定的记录，ANRLO 和 ANRLOC 可以允许其中一个为空值，或者两个同时为空值。
ANRHI	正常值范围上限-分析用	Num *		Perm	分析正常范围上限，可以根据 SDTM 的—NRHI 或者是一个估计/指定值。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
ANRHIC	正常值范围上限(C)-分析用	Char		Perm	字符型分析正常范围上限。 ANRHIC 可以是一个映射到 ANRHI 的字符串，但是必须是在指定的参数内，ANRHIC 和 ANRHI 是一对一映射的。ANRHIC 不能用做 ANRHI 的分类变量。在给定的参数内，如果同一行的 ANRHIC 和 ANRHI 同时都有值，那么所有行的 ANRHIC 和 ANRHI 必须同时都一对一映射有值。换言之，没有要求说 ANRHI 或者 ANRHIC 其中一个为空值时，还需要满足 ANRHI 和 ANRHIC 是否需要一对一映射。对于一个给定的记录，ANRHI 和 ANRHIC 可以允许其中一个为空值，或者两个同时为空值。
AyLO	范围 y 下限-分析用	Num *		Cond	AyLO 和/或 AyHI 用来放分析范围而不是放正常范围。AyLO 和/或 AyHI 用来捕获不同水平上的决定临床上可接受或不可接受的范围值。AyLO 和/或 AyHI 很常见，但是通常是不需要的常量，参数特定常量或者受试者特定的常量。如果在一个数据集中 R2AyLO 存在则 AyLO 必须存在。
AyLOC	范围 y 下限(C)-分析用	Char		Perm	字符型分析正常范围 y 下限。 AyLOC 可以是一个映射到 AyLO 的字符串，但是必须是在指定的参数内，AyLOC 和 AyLO 是一对一映射的。AyLOC 不能用做 AyLO 的分类变量。在给定的参数内，如果同一行的 AyLOC 和 AyLO 同时都有值，那么所有行的 AyLOC 和 AyLO 必须同时都一对一映射有值。换言之，没有要求说 AyLO 或者 AyLOC 其中一个为空值时，还需要满足 AyLO 和 AyLOC 是否需要一对一映射。对于一个给定的记录，AyLO 和 AyLOC 可以允许其中一个为空值，或者两个同时为空值。
AyHI	范围 y 上限-分析用	Num *		Cond	参照 AyLO。 例如：如果心电图的 QTc 值依据.>450，>480, >500 这样有 3 个上限值变量来总结，则可以写为： A1HI=450, A2HI=480, A3HI=500. 如果在一个数据集中 R2AyHI 存在则 AyHI 必须存在。
AyHIC	范围 y 上限(C)-分析用	Char		Perm	字符型分析正常范围 y 上限。 AyHIC 可以是一个映射到 AyHI 的字符串，但是必须是在指定的参数内，AyHIC 和 AyHI 是一对一映射的。AyHIC 不能用做 AyHI 的分类变量。在给定的参数内，如果同一行的 AyHIC 和 AyHI 同时都有值，那么所有行的 AyHIC 和 AyHI 必须同时都一对一映射有值。换言之，没有要求说 AyHI 或者 AyHIC 其中一个为空值时，还需要满足 AyHI 和 AyHIC 是否需要一对一映射。对于一个给定的记录，AyHI 和 AyHIC 可以允许其中一个为空值，或者两个同时为空值。
AyIND	范围 y 指示符-分析用	Char		Perm	AVAL 和分析范围变量 AyLO 和/或 AyHI 关系指示符，或者是 AVALC 和分析范围变量 AyLOC 和/或 AyHIC 关系指示符。
ByIND	基线范围 y 指示符-分析用	Char		Perm	ABLFL 标识的基线记录的 AyIND 值。
** ANRLO, ANRHI, AyLO 和 AyHI 再 ADaM IG 1.0 版本中错误地指示为字符型变量。 这个错误已经在上面更正，并且增加了这些变量的字符型变量。*					

3.3.8 Indicator Variables for BDS Datasets

3.3.8 BDS 数据集中的标识变量

Refer to Section 3.1.4 for important points about the use of flag variables. See Section 3.5 for a discussion of the differences between ADaM population and baseline flags and the flags in the SDTMIG, and for a discussion of parameter-level and record-level population flags.
参照章节 3.1.4 中关于标识变量的重要部分，章节 3.5 中对 ADaM 人群和基线标识区别的讨论， 以及 SDTMIG 中的标识，参数水平和记录水平人群标识的讨论。

Table 3.3.8.1 Flag Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ABLFL	Baseline Record Flag	Char	Y	Cond	Character indicator to identify the baseline record for each subject, parameter, and baseline type (BASETYPE) combination. See BASETYPE in Table 3.3.4.1. ABLFL is required if BASE is present in the dataset. A baseline record may be derived (e.g., it may be an average), in which case DTYPE must also be populated. If BASE is populated for a parameter, and BASE is non-null for a subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter.
ABLFN	Baseline Record Flag (N)	Num	1	Perm	A numeric representation of ABLFL. ABLFN has a one-to-one mapping with ABLFL. As described in Section 3.1.1 Item 8, ABLFN can be included only if ABLFL is also included.
ANLzzFL	Analysis Flag zz	Char	Y	Cond	ANLzzFL is a conditionally required flag to be used in addition to other selection variables when the other selection variables in combination are insufficient to identify the exact set of records used for one or more analyses. Often one ANLzzFL will serve to support the accurate selection of records for more than one analysis. Note that it is allowable to add additional descriptive text to the label (see Section 3.1.6, Item 1). When one is defining the set of records used in a particular analysis or family of analyses, ANLzzFL is supplemental to, and is intended to be used in conjunction with, other selection variables, such as subject-level, parameter-level and record-level population flags, AVISIT, DTYPE, grouping variables such as SITEGRy, and others. The lower-case letter "zz" in the variable name is an index for the zzth record selection algorithm where "zz" is replaced with a zero-padded two-digit integer [01-99]. Every record selection algorithm "zz" (i.e., every algorithm for populating an ANLzzFL) must be defined in variable metadata. When the set of records that the algorithm "zz" operates on is pre-filtered by application of other criteria, such as a record-level population flag, then the selection algorithm definition in the metadata must so specify. Note that the ANLzzFL value of Y indicates that the record fulfilled the requirements of the algorithm, but does not necessarily imply that the record was actually used in one or more analyses, as whether or not a record is used also depends on the other selection variables applied. The ANLzzFL flag is useful in many circumstances; an example is when there is more than one record for an analysis timepoint within a subject and parameter, as it can be used to identify the record chosen to represent the timepoint for an analysis. "zz" is an index for a record selection algorithm, such as "record closest to target relative day for the AVISIT, with ties broken by the latest record, for each AVISIT within <list of AVISITS>." Note that it is not required that a specific ANLzzFL variable has the same definition across a project or even across datasets within a study. There is also no requirement that the ANLzzFL variables in a dataset or study be used in numerical order; e.g. ANL02FL might occur in a dataset or study without ANL01FL present in the same dataset or study.
ANLzzFN	Analysis Flag zz (N)	Num	1	Perm	Numeric version of ANLzzFL. There is a one-to-one mapping between ANLzzFL and ANLzzFN within a dataset. As described in Section 3.1.1 Item 8, ANLzzFN can be included only if ANLzzFL is also included.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ONTRTFL	On Treatment Record Flag	Char	Y	Perm	Character indicator of whether the observation occurred while the subject was on treatment. ONTRTFL is producer-defined, and its definition may vary across datasets in a study based on analysis needs.
ONTRTFN	On Treatment Record Flag (N)	Num	1	Perm	Numeric representation of ONTRTFL. There is a one-to-one mapping between ONTRTFL and ONTRTFN. As described in Section 3.1.1 Item 8, ONTRTFN can be included only if ONTRTFL is also included.
LVOTFL	Last Value On Treatment Record Flag	Char	Y	Perm	Character indicator of the subject's last non-missing value on treatment for each parameter.
LVOTFN	Last Value On Treatment Record Flag (N)	Num	1	Perm	Numeric representation of LVOTFL. There is a one-to-one mapping between LVOTFL and LVOTFN. As described in Section 3.1.1 Item 8, LVOTFN can be included only if LVOTFL is also included.

表 3.3.8.1 BDS 数据集中的标识变量

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
ABLFL	基线记录标帜	Char	Y	Cond	每个受试者，参数和基线类型（BASETYPE）组合下基线记录的字符型标识符。可参考表3.3.4.1的BASETYPE。如果在一个数据集中，BASE有值，则ABLFL必须存在。 基线记录可以是衍生的（比如它可以是均值），在此情况下，DTYPE 则必须被标记。如果一个参数的 BASE 被标记了，且受试者该参数的 BASE 为非空，则该受试者的该参数必定有一条记录被标记为 ABLFL。
ABLFN	基线记录标帜(N)	Num	1	Perm	ABLFL 的数值型表现。ABLFLN 和 ABLFL 是一对一映射的。在章节 3.1.1 的第 8 项中描述的，只有当 ABLFL 存在时，ABLFLN 才可以存在。
ANLzzFL	分析标帜 zz	Char	Y	Cond	当一个组合中的其他选择性变量不足以识别用于一个或多个分析的确切记录集时，ANLzzFL 是除了其他选择变量之外还要使用的有条件要求的标识。通常，一个 ANLzzFL 将用于支持准确选择多个分析的记录。它可以在标签中添加其他描述性文本（参照章节 3.1.6，第 1 项）。 当 ANLzzFL 在特定分析或者分析组中使用的记录集定义时，它是对其他选择变量的补充，并且旨在与其他选择变量一起使用，例如受试者水平，参数水平和记录水平人群标识，AVISIT, DTYPE, 分组变量，如 SITEGRy 等。变量名中的小写字母 zz 是第 zzth 个记录选择算法的索引，其中 xx 被替换为零填充的两位数[01-99]。每个记录选择算法 zz（如用于标记 ANLzzFL 的每个算法）必须定义在变量元数据中。当算法"zz"运行前，记录集预先被其他标准需求进行筛选，如记录水平的人群标帜，那么这种筛选算法的定义必须在元数据中指定 需注意的是，ANLzzFL的Y值表示记录满足算法的要求，但并不一定意味着记录实际用于一个或多个分析，因为是否使用记录也取决于其他选择变量的应用。ANLzzFL标识在许多情况下都很有用，例如：当一个受试者和参数的分析时间点有多个记录时，它可以用于辨认选择用于标识分析时间点的记录。zz是记录选择算法的索引，例如： 对于AVISIT最接近目标相对日的记录，AVISIT系列中的每一个AVISIT都被最新的一条记录打破。 还需注意，一个特定的 ANLzzFL 变量不需要在一个项目或者同一个研究的不同数据集中具有相同的定义，也不需要数据集中或者研究中 ANLzzFL 变量按数字顺序使用，例如 ANL02FL 可以存在于一个没有 ANL01FL 的数据集或研究中。
ANLzzFN	分析标帜 zz(N)	Num	1	Perm	ANLzzFL 的数值型表现。在一个数据集中，ANLzzFN 和 ANLzzFL 是一对一映射的。在章节 3.1.1 的第 8 项中描述的，只有当 ANLzzFL 存在时，ANLzzFN 才可以存在。

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
ONTRTFL	治疗中记录标帜	Char	Y	Perm	受试者发生在治疗中的观测的字符型标识符。ONTRTFL 是人为定义的，基于分析的需要，在一个研究的不同数据集中，其定义可以多变。
ONTRTFN	治疗中记录标帜(N)	Num	1	Perm	ONTRTFL 的数值型表现。ONTRTFL 和 ONTRTFN 是一对一映射的。在章节 3.1.1 的第 8 项中描述的，只有当 ONTRTFL 存在时，ONTRTFN 才可以存在。
LVOTFL	治疗中末次观测记录标帜	Char	Y	Perm	每个受试者，每个参数在治疗中的最后一个非缺失值字符型标识符。
LVOTFN	治疗中末次观测记录标帜(N)	Num	1	Perm	LOVTFL 的数值型表现。LOVTFN 和 LOVTFL 是一对一映射的。在章节 3.1.1 的第 8 项中描述的，只有当 LOVTFL 存在时，LOVTFN 才可以存在。

Table 3.3.8.2 BDS Population Indicators

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ITTRFL	Intent-To-Treat Record-Level Flag	Char	Y	Perm	These indicators identify whether or not the subject was in the specified analysis for the subject that do not satisfy requirements for the population. The valid values of these record-level population indicators are Y or Null. If a flag is used, the corresponding numeric version (*FN, where 1=yes) of the flag can also be included. As described in Section 3.1.1 Item 8, the *FN version of the variable can be included only if the corresponding *FL is also included. Additional indicators may also be used; refer to Section 3.1.4.
SAFRFL	Safety Analysis Record-Level Flag	Char	Y	Perm	
FASRFL	Full Analysis Set Record-Level Flag	Char	Y	Perm	
PPROTRFL	Per-Protocol Record-Level Flag	Char	Y	Perm	
COMPLRFL	Completers Record-Level Flag	Char	Y	Perm	
ITTPFL	Intent-To-Treat Parameter-Level Flag	Char	Y	Perm	These indicators identify whether or not the subject was in the specified analysis for the specific parameter. Useful when the subject is included in the subject-level population, but there are parameters for which the subject does not satisfy requirements for the population. The valid values of these parameter-level population indicators are Y or Null. If a flag is used, the corresponding numeric version (*FN, where 1=yes) of the flag can also be included. As described in Section 3.1.1 Item 8, the *FN version of the variable can be included only if the corresponding *FL is also included. Additional indicators may also be used; refer to Section 3.1.4, "Flag Variable Conventions."
SAFPFL	Safety Analysis Parameter-Level Flag	Char	Y	Perm	
FASPFL	Flag Full Analysis Set Parameter-Level Flag	Char	Y	Perm	
PPROTPFL	Flag Per-Protocol Parameter-Level Flag	Char	Y	Perm	
COMPLPFL	Flag Completers	Char	Y	Perm	

	Parameter-Level Flag				

表 3.3.8.2 BDS 人群标识

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC注释
ITTRFL	意向性治疗集记录水平标帜	Char	Y	Perm	这些标识符是用来鉴别受试者是否包含在特定记录的指定分析中。当受试者包含在受试者水平人群中，但该受试者有些记录不满足该人群要求时非常有用。这些记录水平的有效值人群标识符为Y或空值。如果一个标识被使用了，则其相应的数值型标识（*FN，可以是1=是）可以被使用。在章节3.1.1的第8项中描述的，只有当相应的*FL存在时，*FN才可以存在。参照章节3.1.4，额外的标识符也可能被使用。
SAFRFL	安全集记录水平标帜	Char	Y	Perm	
FASRFL	全分析集记录水平标帜	Char	Y	Perm	
PPROTRFL	符合方案集记录水平标帜	Char	Y	Perm	
COMPLRFL	完成研究记录水平标帜	Char	Y	Perm	
ITTPFL	意向性治疗集参数水平标帜	Char	Y	Perm	这些标识符用来鉴别受试者是否包含在特定参数的指定分析中。当受试者包含在受试者水平人群中，但该受试者有些参数不满足该人群要求时非常有用。这些参数水平的有效值人群标识符为Y或空值。如果一个标识符被使用了，则其相应的数值型标识（*FN，可以是1=是）可以被使用。在章节3.1.1的第8项中描述的，只有当相应的*FL存在时，*FN才可以存在。参照章节3.1.4，标识变量约定，额外的标识符也可能被使用。
SAFPFL	安全集参数水平标帜	Char	Y	Perm	
FASPFL	全分析集参数水平标帜	Char	Y	Perm	
PPROTPFL	符合方案集参数水平标帜	Char	Y	Perm	
COMPLPFL	完成研究参数水平标帜	Char	Y	Perm	

3.3.9 Datapoint Traceability Variables

3.3.9 数据点的可追溯性变量

Variables to support datapoint traceability should be included whenever practical. The dataset content that serves as primary candidates for datapoint traceability when used in conjunction with USUBJID are the dataset or domain name, the name of the source variable, and the relevant sequence number (SDTM domain--SEQ value or the ADaM ASEQ value). The ADaM ASEQ variable (Table 3.3.1.1) facilitates datapoint traceability by providing sequence numbers that are unique within a subject within an ADaM dataset, ensuring uniqueness of a record when used in combination with USUBJID.

用来支持数据点可追溯性的变量应该包含所有实用性的信息。当与 USUBJID 结合使用时，作为数据点可追溯性的主要候选者的数据集内容是数据集或域名，源变量名称以及相关的序列号（SDTM 域—SEQ 或者 ADaM ASEQ 值）。ADaM ASEQ 变量（表 3.3.1.1）通过提供 ADaM 数据集中受试者内唯一的序列号来促进进数据点的可追溯性，从而确保与 USUBJID 结合使用时记录的唯一性。

Table 3.3.9.1 defines additional variables useful in certain situations to facilitate datapoint traceability. They are useful in situations where a single ADaM dataset or multiple SDTM datasets and/or ADaM datasets were used to create one ADaM dataset. Section 4.4 contains an example of how to use these variables.
表 3.3.9.1 定义了额外的一些在某些特定情况下使数据点可追溯性更加容易的有用变量。当一个单独的 ADaM 数据集或者多个 SDTM 数据集和/或者 ADaM 数据集用来创建一个 ADaM 数据集的情况下用表 3.3.91 定义的变量非常有用。章节 4.4 包含一个如如何用这些变量的例子。

If the value of AVAL or AVALC in the ADaM dataset is taken from another ADaM dataset, SRCDOM, SRCVAR, and SRCSEQ will contain the name of the source ADaM dataset, the variable name and the ASEQ value of the row where the source datapoint is located, respectively.
如果一个 ADaM 数据集中的 AVAL 或者 AVALC 的值是从另外的 ADaM 数据集中获得时，SRCDOM, SRCVAR 和 SRCSEQ 将分别的包含源 ADaM 数据集的名字，变量名和源数据集坐落的行的 ASEQ 值。

If all values of AVAL or AVALC in the ADaM dataset are taken from a single SDTM domain, the SRC variables defined here can be used. However, all records in the ADaM dataset would have the same value for SRCDOM and SRCVAR. In this case, the producer may elect to simply include the --SEQ variable from the source SDTM domain since it would be sufficient to provide the needed traceability within a subject. In the event that the source SDTM dataset is a supplemental qualifier, the two-letter domain prefix of --SEQ in the ADaM dataset would be the related domain abbreviation (the value of RDOMAIN in SUPP-- or SUPPQUAL).
如果一个 ADaM 数据所有的 AVAL 或 AVALC 的值全部来自一个单独的 SDTM 域，此处定义的 SRC 变量可以使用。然而，ADaM 数据集中的所有记录将有相同的 SRCDOM 和 SRCVAR 值。在这种情况下，生产者可能简单地从源 SDTM 域中选取—SEQ 变量，因为—SEQ 已经足够的提供受试者的可追溯性。当源 SDTM 数据集是补充修饰语时，ADaM 数据集中的--SEQ 前缀上两个字母域可以关联域缩写（SUPP—或者 SUPPQUAL 中的 RDOMAIN 值）。

Variables used for datapoint traceability may also include any other variables that facilitate transparency and clarity of derivations and analysis.
用来追溯数据点的变量也可包含其他使衍生和分析更加透明和清楚的变量。

Table 3.3.9.1 Datapoint Traceability Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
SRCDOM	Source Data	Char		Perm	The SDTM domain name or ADaM dataset name that relates to the analysis value (e.g., AVAL or AVALC in a BDS dataset). If the source data is a supplemental qualifier in SDTM, this variable will contain the value of RDOMAIN in SUPP-- or SUPPQUAL.
SRCVAR	Source Variable	Char		Perm	The name of the column (in the domain or dataset identified by SRCDOM) that relates to the analysis value (e.g., AVAL or AVALC in a BDS dataset). In the event that SRCDOM is a SUPPQUAL, then SRCVAR will be populated with the value of the related QNAM.
SRCSEQ	Source Sequence Number	Num		Perm	The sequence number --SEQ or ASEQ of the row (in the domain or dataset identified by SRCDOM) that relates to the analysis value (e.g., AVAL or AVALC in a BDS dataset). In the event that SRCDOM is a SUPPQUAL, then this variable will contain the sequence number of the relevant related domain record.

表 3.3.9.1 数据点的可追溯性变量

变量名称	变量标签	类型	编码列表/受控术语	核心性	CDISC 注释
SRCDOM	源数据集	Char		Perm	与分析值有关的 SDTM 域名或者 ADaM 数据集名（如 BDS 数据集中的 AVAL, AVALC）。如果源数据是 SDTM 中的补充修饰语，这个变量将包含 SUPP--/SUPPQUAL 中的 RDOMAIN 值。
SRCVAR	源变量	Char		Perm	与分析值（如 BDS 数据集中的 AVAL 或者 AVALC）相关的列名（在域或者数据集中通过 SRCDOM 来辨别）。SRCDOM 是一个 SUPPQUAL，因此 SRCVAR 将根据其相关的 QNAM 来赋值。
SRCSEQ	源序号	Num		Perm	与分析值（如 BDS 数据集中的 AVAL 或者 AVALC）相关的行（在域或者数据集中通过 SRCDOM 来辨别）的序列号--SEQ 或者 ASEQ。SRCDOM 是一个 SUPPQUAL,因此该变量将包含域记录相关的序列号。

3.4 Analysis-Enabling Variables

3.4 可分析变量

There is a class of variables that enable one or more of the analyses that the dataset was designed to support. See the definition of analysis-enabling in Section 1.5.1. Often, these enabling variables would include the indicator variables and analysis descriptor variables described above, which are often needed to make the ADaM dataset one statistical procedure away from analysis results. Enabling variables may also include stratification and subgrouping variables, model covariates and any other variables required to be present in order to perform an analysis.

数据集设计就是为了支持这一类变量能够实现一种或多种分析，可参照章节 1.5.1 分析-授权的定义。通常，这些可行性变量将包含上述标识符变量和分析描述变量，这些标识符变量和分析描述变量通常需要使 ADaM 数据集中一个统计过程原理分析结果。可行性变量还可以包含分层和亚组变量，模型协变量和用来分析的任何其他变量。

3.5 Differences between SDTM and ADaM Population and Baseline Flags

3.5 SDTM 和 ADaM 人群和基线标识的区别

The SDTM Implementation Guide includes controlled terminology for some Supplemental Qualifier values for subject-level population flags. The conceptual mapping from those terms to ADaM indicator variables is presented in Table 3.5.1.
SDTM 实施指南中包含一些受试者水平人群标识补充限定语受控术语。表 3.5.1 中呈现了这些术语与 ADaM 指示变量的概念映射。

Table 3.5.1 ADaM Subject-Level Population Flags Corresponding to SDTM Supplemental Qualifiers

SDTM QNAM	SDTM QLABEL	ADaM Subject-Level Population Flags
COMPLT	Completers Population Flag	COMPLFL
FULLSET	Full Analysis Set Flag	FASFL
ITT	Intent to Treat Population Flag	ITTFL
PPROT	Per Protocol Set Flag	PPROTFL
SAFETY	Safety Population Flag	SAFFL

表 3.5.1 ADaM 受试者水平人群标识符与其对应的 SDTM 补充限定语

SDTM QNAM	SDTM QLABEL	ADaM 受试者水平人群标识
COMPLT	完成人群标识	COMPLFL
FULLSET	全分析集标识	FASFL
ITT	意向分析人群标识	ITTFL
PPROT	符合方案集标识	PPROTFL
SAFETY	安全人群标识	SAFFL

It is possible that the ADaM subject-level population flags might not match their conceptual counterparts in SDTM. For example, the SDTM ITT Supplemental Qualifier may not match the ADaM ITTFL indicator variable for a given subject. These population indicators may not match because of operational issues. It is entirely possible that a company could inherit a SDTM database that for various reasons cannot be changed. It is not incumbent on those creating ADaM datasets to go back and "fix" the SDTM population supplemental qualifiers and there may be good reason not to do so. The ADaM Team agrees that it would be best if the SDTM subject-level population Supplemental Qualifiers are in harmony with the ADaM population indicator variables, but it is important to recognize that there may be situations where they differ. There are additional ADaM subject-level population flags that do not have counterparts in SDTM. ADaM also supports parameter-level and record-level population flags, which do not exist in SDTM.
ADaM 受试者水平人群标识和 SDTM 中相对应的概念不匹配，例如，对一个给定的受试者，SDTM ITT 补充限定语可以与 ADaM ITT 指示符变量不匹配。这些人群标识符可能由于操作问题而不匹配。公司可以完全接手由于各种原因无法更改的 SDTM 数据库。创建 ADaM 数据集的人不应该返回并"修复"SDTM 人群补充限定语，并且可能有充分的理由不这样做。ADaM 团队一致认为，如果 SDTM 受试者水平的人群补充限定语和 ADaM 的人群标识变量一致是最好的，但最重要的是需认识到可以存在他们不相同的情况。还有其他 ADaM 受试者水平的人群标识符在 SDTM 中没有相对应。ADaM 还支持 SDTM 中不存在的参数水平和记录水平人群标识符。

Similarly, a baseline record identified in SDTM may not be the record identified in an ADaM dataset and there are many reasons why this may occur. There are ADaM parameters that are highly derived and do not have simple counterparts in a Findings domain. An ADaM parameter may be derived from SDTM data spanning multiple domains and classes. Such a parameter would not exist in the SDTM and so its baseline could only exist in the ADaM dataset. Also, it may be necessary to have separate baselines for different periods within the study, for example to support analyses of change from screening baseline, double-blind treatment baseline, and open-label extension baseline (see Section 4.2, Rule 6). When there is record-level population flagging, it may be necessary to have different baselines for two different analysis populations. Lastly, it may be desired to conduct analyses for different definitions of baseline. The ADaM baseline flag ABLFL, coupled with the BASE and BASETYPE columns, plus population flags, can handle all of these practical scenarios.
类似的，在 SDTM 中识别的基线记录可能不是 ADaM 数据集中识别的记录，并且可能出现这种情况的原因很多。ADaM 参数是高度衍生的，在发现域中没有简单的对应物。ADaM 参数可以从 SDTM 的跨越多个域和类数据导出，这样的参数不存在于 SDTM 中，因此其基线只存在于 ADaM 数据集中。此外，在一个研究中，可以有不同时期自己独立的基线，例如支持分析的相对筛选期变化的基线值，双盲治疗阶段的基线值，开放延伸期的基线值（可

参考章节 4.2 的第 6 条规则）。当存在记录水平的人群标识时，可以为两种不同分析人群设立不同的基线。最后，根据不同基线的定义进行分析。ADaM 基线标识 ABLFL，附加上 BASE 和 BASETYPE 两列， 人群标识，可以处理所有这些实际的情况。

For analysis purposes, the values of population and baseline flags used for analysis are found in the ADaM datasets. ADaM flags should be described in ADaM metadata.
就分析目的，用来分析的人群和基线标识的值须在 ADaM 数据集中存在。ADaM 标识需在 ADaM 元数据中描述。

4 Implementation Issues, Standard Solutions, and Examples

4 执行过程中的问题与解决方案及示例

The ADaM standard variables (columns) are described in Section 3. However, there is more to the ADaM model than just using the ADaM standard variables. The purpose of Section 4 is to provide additional guidance on how to implement ADaM standard datasets correctly.
在第三部分介绍了 ADaM 标准变量（列）。然而，ADaM 模型不仅仅是标准变量。第四部分将提供额外的介绍如何正确使用 ADaM 标准数据集。

Section 4.1 provides examples of treatment variables for common trial designs.
4.1，提供了常用实验设计的治疗变量的例子。

Sections 4.2-4.9 are concerned with the BDS. These sections provide standard solutions to BDS implementation issues, illustrated with examples. The focus of Sections 4.2-4.7 is the building of a BDS dataset. Section 4.2 focuses on assembling the rows and columns of the dataset. Sections 4.3 and 4.4 discuss issues around the inclusion/exclusion of rows not used in an analysis. Sections 4.5, 4.6, and 4.7 discuss issues around identification of rows for analysis. Section 4.8 contains an example of the use of the BDS variables for phase, period, and subperiod. Section 4.9 presents some comments on additional issues to consider in building ADaM datasets.
4.2-4.9 是与 BDS 结构相同。这几部分的例子提供了 BDS 结构中会遇到的一些问题的标准解决方案。4.2-4.7 重点介绍了如何建立 BDS 结构数据集。4.2 重点介绍了数据集当中的行与列。4.3 和 4.4 讨论了是否包含那些不需要用于分析的数据。4.5,4.6 和 4.7 如何找出那些需要分析的数据。4.8 包含一个 BDS 数据结构中，阶段，周期和次周期这些变量的例子。4.9 包含了一些在建立 ADaM 数据集时应当考虑的一些问题。

For examples of the OCCDS, refer to the separate document “ADaM Structure for Occurrence Data”.
关于 OCCDS 的例子，请参阅“ADaM Structure for Occurrence Data”文件。

For space reasons, the examples do not show complete datasets with all of the required and permissible variables. Rather, only those variables needed to illustrate the point being discussed are shown.
由于篇幅受限的因素，这些例子不会显示完整的数据集，而仅仅显示那些例子当中想要阐释的变量。

4.1 Examples of Treatment Variables for Common Trial Designs

4.1 常用实验设计治疗变量的例子

Examples 1-4 in this section illustrate the concepts related to treatment variables in ADSL for several different trial designs, including a parallel design, a crossover design, and an open-label extension of a parallel design study. Note that only selected variables are illustrated; these examples are not intended to imply that these are the only variables in ADSL. Examples 5 and 6 illustrate concepts related to treatment variables in BDS.
例子 1-4 阐释了 ADSL 里面的治疗变量在不同试验当中的用法，包括平行试验，交叉试验，和包含非盲扩展的平行设计。注意，例子当中只包含例子阐释的变量，并不代表 ADSL 只需要这些变量。例子 5 和 6 阐释了 BDS 结构中与治疗变量相关的概念。

Example 1

In the first example (Table 4.1.1), the treatment variables for three subjects in a parallel design study (one treatment period) are illustrated. Note that the third subject was randomized to active treatment yet received placebo instead. TR01SDT and TR01EDT are not required variables in trial designs that do not involve multiple treatment periods.

例 1

在第一个例子中（表 4.1.1），阐释了在平行试验中三个受试者的治疗变量。值得注意的是，第三个受试者被随机分配到了研究用药治疗组，然而实际接受的是对照组安慰剂治疗。在那些没有多个治疗阶段的试验中，TR01SDT 和 TR01EDT 并不是必须变量。

Table 4.1.1 Randomized Parallel Design

Row	USUBJID	ARM	ACTARM	TRT01P	TRT01A	TRTSDT	TRTEDT
1	1001	Drug X 5 mg	Drug X 5 mg	Drug X 5 mg	Drug X 5 mg	23OCT2007	17DEC2007
2	1002	Placebo	Placebo	Placebo	Placebo	19JUL2006	20SEP2007
3	1003	Drug X 5 mg	Placebo	Drug X 5 mg	Placebo	01NOV2007	20NOV2007

Example 2

The second example (Table 4.1.2) illustrates the treatment variables for three subjects in a two-period crossover design. It should be noted that TRTSDT and TRTEDT are not displayed, but TRTSDT=TR01SDT and TRTEDT is the maximum of TR01EDT and TR02EDT as some subjects may have discontinued before receiving TRT02P. Note that subjects 1002 and 1003 (in rows 2 and 3) were each exposed to placebo for both trial periods.

例 2

第二个例子（表 4.1.2），阐释了在两阶段交叉试验中三个受试者的治疗变量。需要注意的是，TRTSDT 和 TRTEDT 没有显示，但是 TRTSDT 等于 TR01SDT，TRTEDT 等于 TR01EDT 和 TR02EDT 当中最大的一个值。因为有一些受试者可能在接受第二阶段试验开始之前就退出了。受试者 1002 和 1003(第二行和第三行)，在第一阶段和第二阶段实际用药都是安慰剂。

Table 4.1.2 Two-Period Crossover Design

Row	USUBJID	TRTSEQP	TRT01P	TRT02P	TRTSEQA	TRT01A	TRT02A	TR01SDT	TR01EDT	TR02SDT	TR02EDT
1	1001	Placebo – Drug X	Placebo	Drug X	Placebo – Drug X	Placebo	Drug X	15FEB2006	03MAY2006	10MAY2006	15AUG2006
2	1002	Placebo – Drug X	Placebo	Drug X	Placebo – Placebo	Placebo	Placebo	01MAR2006	12JUN2006	20JUN2006	23SEP2006
3	1003	Drug X – Placebo	Drug X	Placebo	Placebo – Placebo	Placebo	Placebo	03FEB2006	25APR2006	01MAY2006	04AUG2006

Example 3

The third example (Table 4.1.3) illustrates the treatment variables for three subjects in a three-period crossover design. It should be noted that TRTSDT and TRTEDT are not displayed, but TRTSDT=TR01SDT and TRTEDT is the maximum of TR01EDT, TR02EDT, and TR03EDT as some subjects may have discontinued before receiving TRT03P. In this trial, all subjects received the planned treatment at each period so the TRTxxA variables are not needed.

例 3

第三个例子，阐释了三阶段交叉试验中三个受试者的治疗变量。需要注意的是，TRTSDT 和 TRTEDT 没有显示，但是 TRTSDT 等于 TR01SDT，TRTEDT 等于 TR01EDT，TR02EDT 和 TR03EDT 当中最大的一个值。因为有一些受试者可能在接受第三阶段试验开始之前就退出了。在这个试验当中，所有的受试者按计划接受了药物或者安慰剂，所以不需要 TRTxxA 这些变量。

Table 4.1.3 Three-Period Crossover Design

Row	USUBJID	TRTSEQP	TRT01P	TRT02P	TRT03P	TR01SDT	TR01EDT	TR02SDT	TR02EDT	TR03SDT	TR03EDT
1	1001	Placebo – Drug X – Drug Y	Placebo	Drug X	Drug Y	15FEB2006	03MAY2006	10MAY2006	15AUG2006	23AUG2006	14NOV2006

2	1002	Drug Y – Placebo – Drug X	Drug Y	Placebo	Drug X	01MAR2006	12JUN2006	20JUN2006	23SEP2006	01OCT2006	05DEC2006
3	1003	Drug X – Drug Y – Placebo	Drug X	Drug Y	Placebo	03FEB2006	25APR2006	01MAY2006	04AUG2006	12AUG2006	15OCT2006

Example 4

The fourth example (Table 4.1.4) illustrates the treatment variables for two subjects in an open-label extension from a parallel design study. For open-label studies, the variable TRT01P is used for the treatment to which the subject was randomized in the double-blinded trial. TRT02P is used for the open-label treatment.

例 4

第四个例子，阐释了包含非盲扩展的平行试验中两个受试者的治疗变量。对于非盲试验，变量 TRT01P 用于双盲随机化试验的治疗变量。TRT02P 被用于开放性阶段的治疗变量。

Table 4.1.4 Open-Label Extension of a Parallel Design – ADSL Dataset

Row	USUBJID	TRTSEQP	TRT01P	TRT02P	TR01SDT	TR01EDT	TR02SDT	TR02EDT
1	1001	Drug X 5 mg - Drug X 5 mg	Drug X 5 mg	Drug X 5 mg	14AUG2007	20SEP2007	21SEP2007	15MAR2008
2	1002	Placebo - Drug X 5 mg	Placebo	Drug X 5 mg	05JUL2007	15AUG2007	17AUG2007	04FEB2008

Examples 5 and 6 build on the ADSL dataset illustrated in Table 4.1.4.

第五个和第六个例子建立在表 4.1.4 中的 ADSL 数据集。

Example 5

As stated in Section 3.3.2, at least one treatment variable is required in a BDS dataset. This requirement is satisfied by any of the subject-level or record-level treatment variables, e.g. TRTxxP, TRTP. The following two examples illustrate some possible approaches for BDS treatment variables. These examples are not meant to imply a standard or best practice; they are for illustration purposes only. Please refer to Section 3.3.2 for important additional information.

例 5

像 3.3.2 部分阐释的，在 BDS 结构的数据集当中至少要有一个治疗变量。这个要求适用于任何受试者水平或者记录水平，例如 TRTxxP, TRTP。下面的两个例子阐释了 BDS 结构当中的治疗变量。这些例子并不意味着是标准的或者最好的做法，只是用于阐释而已。请参与 3.3.2 获取额外的重要信息。

In the first illustration of a BDS dataset (Table 4.1.5), the ADSL treatment variables have been copied into the BDS dataset. In addition, TRTP contains the treatment assigned at the time of the assessment (i.e., at ADT). This allows this dataset to support multiple analysis strategies. If the data are analyzed using therandomized treatment from the double-blinded trial, then TRT01P can be used as the treatment variable in the analysis. If the data are analyzed using the treatment assigned at the time of the assessment, then TRTP can be used as the treatment variable in the analysis. In this example, TRTP is blank for assessments that are not on-treatment.

在 BDS 数据集（表 4.1.5）中，ADSL 当中的治疗变量被复制到了 BDS 结构数据中。另外，在不同的评估时间点，TRTP 包含被指定的治疗信息。这种方法可以支持更多的数据分析。如果这个数据被用来分析随机双盲试验的阶段，TRT01P 是这个阶段的治疗变量。如果想要分析不同的评估时间点的数据，那么 TRTP 可以用来作为治疗变量。在这个例子当中，那些没有接受治疗阶段的记录的 TRTP 是空值。

Table 4.1.5 Open-Label Extension of a Parallel Design – BDS Dataset, Illustration 1

Row	USUBJID	APERIOD	ADT	TRTP	TRT01P	TRT02P
1	1001		10AUG2007		Drug X 5 mg	Drug X 5 mg
2	1001	1	14AUG2007	Drug X 5 mg	Drug X 5 mg	Drug X 5 mg
3	1001	2	21SEP2007	Drug X 5 mg	Drug X 5 mg	Drug X 5 mg
4	1002		01JUL2007		Placebo	Drug X 5 mg
5	1002	1	05JUL2007	Placebo	Placebo	Drug X 5 mg
6	1002	2	17AUG2007	Drug X 5 mg	Placebo	Drug X 5 mg

Example 6
A different approach is illustrated in the second illustration of a BDS dataset (Table 4.1.6), TRTP contains the treatment being used for the analysis of that record. Note that the assessment occurring prior to period 1 have TRTP populated, even though no treatment is actually administered on those dates, as seen by ADSL in Table 4.1.4.
例 6
在 BDS 数据结构中（表 4.1.6），显示了另一种阐释治疗变量的方法，TRTP 包含了每条记录的计划治疗信息。值得注意的是，在第一阶段开始前的数据，即使受试者还没有接受治疗，TRTP 也可以被赋值。

Table 4.1.6 Open-Label Extension of a Parallel Design – BDS Dataset, Illustration 2

Row	USUBJID	APERIOD	ADT	TRTP
1	1001		10AUG2007	Drug X 5 mg
2	1001	1	14AUG2007	Drug X 5 mg
3	1001	2	21SEP2007	Drug X 5 mg
4	1002		01JUL2007	Placebo
5	1002	1	05JUL2007	Placebo
6	1002	2	17AUG2007	Drug X 5 mg

4.2 Creation of Derived Columns versus Creation of Derived Rows

4.2 衍生列 VS 衍生行

This section provides specific rules to use in building a BDS dataset. These rules are essential, because they ensure the BDS dataset is analysis-focused, with all analysis-enabling variables and supportive variables included in a predictable structure, while preventing a "horizontalization" of the dataset.
这一部分提供了非常详细的建立 BDS 数据集的规则。这些规则非常重要，因为他们确保了 BDS 结构数据是注重分析的，在可预见的数据结构中包含了用于分析所需的变量和支持性变量，避免了数据的"扁平化"。。

The rows (i.e., records) in the ADaM BDS represent subject data for analysis parameters and timepoints (as applicable). There may be multiple rows within a given combination of subject, parameter and timepoint, depending on the number of observations collected or derived, baseline definition, etc.
在 ADaM BDS 数据集中的每一行，代表了受试者在某一时间（如果有）的分析参数的记录。一个受试者可能有许多条，这取决于观测值的收集，新衍生用于分析的记录和基线的定义。

The ADaM BDS structure contains a central set of columns (i.e., variables) that represent the data being analyzed. These variables include the value being analyzed (e.g., AVAL) and the description of the value being analyzed (e.g., PARAM). Other columns in the dataset provide more information about the value being analyzed (e.g., the subject identification) or describe and trace the derivation of it (e.g., DTYPE) or support the analysis of it (e.g., treatment variables, covariates). Standard columns exist for a variety of purposes, such as SDTM record identifiers for traceability, population and other record selection flags, analysis values, and some standard functions of analysis values. Permissible columns are not limited to those whose variable names are specified in Section 3,
and may include study-specific analysis model covariates, subgrouping variables, variables supportive of traceability, as well as other variables needed for analysis or useful for review. 在 ADaM BDS 结构中包含了一些被用于分析的主要列（变量）。这些变量包括用于分析变量（AVAL）和分析参数（PARAM）。其他列提供了更多的信息（例如，受试者编号）或者支持可溯源性的变量（例如 DTYPE）或者支持分析用的（例如治疗变量，协变量）。标准列的出现有很多目的，例如 SDTM 当中用于追溯每一条记录的变量，人群，其他记录的选择记录变量，分析数值和已经转化成标准的分析数值。允许的变量

不限于那些已经在第 3 部分当中列出的变量和可能包含试验特有的模型分析的协变量，亚组变量，用于支持追溯的变量，和其他分析需要用到的变量或者对于评审有用的变量。The BDS is flexible in that derived data can be added to the collected data as additional rows and columns that support the analyses and provide traceability. However, there are some constraints on how to incorporate derived data in the BDS dataset. Specifically, the subject of Section 4.2 is to address when derived data that are functions of analysis values should be added as additional columns, and when they should be added as additional rows instead.
BDS 数据结构很灵活，可以将衍生的数据添加到收集的数据中，以便支持分析和追溯。然而，在 BDS 结构中添加衍生的数据受到一些约束。特别是，在 4.2 部分阐释了哪些衍生的分析数据需要作为变量添加而哪些是作为记录进行添加。

The precise sequence of steps involved in creating a BDS ADaM dataset varies according to operational and study-specific needs. For the purposes of this discussion, it is useful to think of two fundamental steps.
下面简单的几步包含了根据不同的需求建立不同 ADaM BDS 数据集。基于本次讨论的目的，先讲讲两个基本步骤。

1. Create an initial dataset from the source datasets: The first step is to create a set of rows and columns more or less directly derived from or loaded from input datasets (primarily SDTM datasets and other ADaM datasets) into their appropriate places. This step will include creation and population of columns containing analysis parameters (PARAM etc.), analysis timepoint (AVISIT etc.) and analysis values (AVAL, AVALC, etc.). It would also include addition of columns containing identifiers (STUDYID, SITEID, USUBJID, SUBJID) and other SDTM variables for traceability (VISIT, --SEQ, etc.).
   1.从溯源数据集建立最初数据集：第一步从溯源数据集建立最初的数据集（主要是 SDTM 数据集和其他 ADaM 数据集）。这一步包含了分析参数（PARAM 等），分析时间点（AVISIT 等）和分析变量（AVAL,AVLC 等）。也要包含一些标识变量（STUDYID, SITEID, USUBJID, SUBJID）和其他 SDTM 可溯源性变量（VISIT, --SEQ 等）。

2. Add additional derived data as needed for the analysis: The second step consists of adding derived rows and columns based on the initial set of ADaM dataset records and columns. The rules that govern this step are:
   Rule 1: A parameter-invariant function of AVAL and BASE on the same row that does not involve a transform of BASE should be added as a new column.
   Rule 2: A transformation of AVAL that does not meet the conditions of Rule 1 should be added as a new parameter, and AVAL should contain the transformed value.
   Rule 3: A function of one or more rows within the same parameter for the purpose of creating an analysis timepoint should be added as a new row for the same parameter.
   Rule 4: A function of multiple rows within a parameter should be added as a new parameter.
   Rule 5: A function of more than one parameter should be added as a new parameter.
   Rule 6: When there is more than one definition of baseline, each additional definition of baseline requires the creation of its own set of rows.

2.增加额外需要衍生的数据用于分析：第二步是基第一步的数据集，衍生新的行和列。规则如下：

规则 1：在与参数无关的情况下，同一行的 AVAL 和 BASE 进行计算时，此时的 BASE 不需要任何转化的情况下，可以新增一个变量。
规则 2：对 AVAL 的变换，如不满足规则 1 的条件，则应该添加一个新的分析参数，而且 AVAL 应该包含所变换的值。
规则 3：对于同一个参数的情况下，一行或多行需要计算某一个分析时间点的时候，这时候需要新增一行，但是参数不变。
规则 4：对于同一个参数，需要多条记录计算的时候，应该建立一个新的参数。
规则 5：对于不同的参数，需要计算的时候，应该建立一个新的参数。
规则 6：当有多余一个基线定义的时候，每一个基线定义都要建立一组新的数据。

These rules are further described and illustrated in the remainder of this section.
这些规则会在下面的篇幅中进行阐释。

It is important to understand that the rules outlined here are specific to rows and columns that are created based on data already present in the ADaM dataset. The rules do not apply to data that are copied or derived directly from other datasets (either SDTM or ADaM or both). For example, how to include a transformation of AVAL within the same dataset is governed by the rules, but the inclusion of a covariate derived from another dataset (e.g., inclusion of a variable from ADSL) is not governed by these rules.
理解上述规则是针对具体的行和列是非常重要的，上面这些规则适用于已经是 ADaM 的数据集。这些规则不适用于数据直接从其他数据集拷贝或衍生而来（不论是 SDTM，还是 ADaM，或者是两者）。例如，AVAL 的转化需要按上述规则执行，但是从某些从其他数据集而来的协变量则不适用于这些规则（例如包含一些 ADSL 里面的变量）。

4.2.1 Rules for the Creation of Rows and Columns

4.2.1 新增数据集中行和列的规则。
To preserve the BDS, it is necessary to place constraints on when one is allowed to create derived columns. Rule 1 describes when derived data belongs in columns. Rules 2-6 describe situations in which one should derive data in new rows, whether as entire new parameters, or as additional rows in existing parameters. In the sections and examples below, there is some text that is bolded. The use of the bold font is to emphasize to the reader the importance of the concept or example that is being discussed.
为了保证 BDS 结构，新增列的限制是非常重要的。规则 1 描述了什么时候应该衍生列。规则 2-6 描述了什么时候应该衍生新的行，不论是新的分析参数还是参数不变。在这一部分，有些文字是粗体的。用粗体是想要让读者注意概念的重要性或者被讨论过的例子。

Rule 1. A parameter-invariant function of AVAL and BASE on the same row that does not involve a transform of BASE should be added as a new column.
规则 1. 在与参数无关的情况下，同一行的 AVAL 和 BASE 进行计算时，此时的 BASE 不需要任何转化的情况下，可以新增一个变量。

The three conditions of Rule 1 for when a function of AVAL and BASE should be added as a column (i.e., a function column) are:

1. The function is of AVAL and, optionally, BASE, on the same row; and
2. The function is parameter-invariant; and
3. The function does not involve a transform of BASE.

符合下面三个条件，对于 AVAL 和 BASE 需要计算时候，可以新衍生一列。
该函数是针对 AVAL 的， 也可以针对同一行的 BASE。
该函数与参数无关
该函数不涉及 BASE 的转换。

The remainder of the discussion of this rule is devoted to explaining these conditions.
下面来详细解释这些条件。

PARAM uniquely describes the contents of AVAL or AVALC. Often, AVAL itself is not the value that is needed for analysis. For example, in a change from baseline analysis, it is the change from baseline CHG that is analyzed. The change from baseline column CHG should be created according to Rule 1 because it satisfies the three conditions:
参数唯一性描述了 AVAL 或 AVALC 的内容。通常情况下，AVAL 本身的值本不是分析需要用的值。例如，在相对于基线的改变的分析中，CHG 是用来分析的变量。根据规则 1，CHG 需要被衍生出来，因为这个列符合了以下三个条件：

1. CHG is derived from AVAL and BASE on the same row;

CHG 是由同一行的 AVAL 和 BASE 的差值衍生而来。

2. The same calculation applies on all rows in the dataset on which CHG is populated (the function CHG=AVAL-BASE does not vary according to PARAM). This second condition is known as the property of "*parameter-invariance*"; **unless listed in Section 3**, a function of AVAL (and optionally BASE) may not be derived as a column if' it is parameter-variant (i.e., is calculated differently for different parameters) .
相同的计算规则可以适用于这个数据集中的所有行（方程 CHG=AVAL-BASE 不会因为不同的参数而不同）。第二个条件称为"参数的无关性"。除了在第三节所说的，针对 AVAL 的一个函数（或者也同时针对 BASE），如果它的目的是为了包含一组与参数相关的函数，不可以衍生一个新的列。

3. In the function CHG=AVAL-BASE, BASE is not transformed.
在函数 CHG=AVAL-BASE 中， BASE 不需要转化。

Table 4.2.1.1 illustrates the CHG column. Note that the producer elected not to populate CHG on the screening or run-in rows, as they are pre-baseline. The baseline flag column ABLFL identifies the row that was used to populate the BASE column.
表 4.2.1.1 阐释了 CHG 这列。需要注意的是，在筛查和导入期阶段的记录，CHG 不需要计算，是因为他们是基线前的数据。基线标记变量 ABLFL 标识了哪些行是用来衍生 BASE 这一列的。

Table 4.2.1.1 Illustration of Rule 1: Creation of a Column Containing a Same-Row Parameter-Invariant Function of AVAL and BASE

Row	PARAM	PARAMCD	AVISIT	ABLFL	AVAL	BASE	CHG
1	Weight (kg)	WEIGHT	Screening		99	100	**.**
2	Weight (kg)	WEIGHT	Run-In		101	100	**.**
3	Weight (kg)	WEIGHT	Baseline	Y	100	100	**0**
4	Weight (kg)	WEIGHT	Week 24		94	100	**-6**
5	Weight (kg)	WEIGHT	Week 48		92	100	**-8**
6	Weight (kg)	WEIGHT	Week 52		95	100	**-5**
7	Pulse Rate (bpm)	PULSE	Screening		63	62	**.**
8	Pulse Rate (bpm)	PULSE	Run-In		67	62	**.**
9	Pulse Rate (bpm)	PULSE	Baseline	Y	62	62	**0**
10	Pulse Rate (bpm)	PULSE	Week 24		66	62	**4**
11	Pulse Rate (bpm)	PULSE	Week 48		70	62	**8**
12	Pulse Rate (bpm)	PULSE	Week 52		64	62	**2**

Now consider the potential function column LOG10 = Log10(AVAL). This function satisfies all three conditions of Rule 1 and as such is allowed as a function column. However, LOG10BAS = Log10(BASE) and LOG10CHG = Log10(AVAL) – Log10(BASE) are not allowable columns as they involve a transform of BASE.

现在我们设想一下，如果我们需要计算函数列 LOG10=Log10（AVAL），这个函数满足规则 1 的所有条件，所以可以衍生一列。然而 LOG10BASE=Log10(BASE) 和 LOG10CHG=Log10(AVAL)-Log10(BASE)是不被允许新建一列的，因为他们都需要对 BASE 进行转换。
Therefore, if it is desired to perform change from baseline analysis in LOG10, columns for LOG10, baseline of LOG10 and change from baseline of LOG10 would be needed for analysis and review, then the Log10 transformation should instead be created as a new parameter, so that the usual columns AVAL, BASE and CHG can be used. This is because columns for baseline of LOG10 and change from baseline of LOG10 would not satisfy the conditions of Rule 1. Baseline of LOG10 violates the first condition, because it is not generally a function of AVAL on the same row (does not generally vary by AVAL), and instead is a function only of AVAL on the baseline row. "Change from baseline of LOG10" =LOG10(AVAL) - LOG10(BASE) violates the third condition, because it contains the Log10 transform of BASE.

因此，如果想要计算以对数 10 为底的参数值与基线差值，LOG10 列，以对数 10 为底的基线列，和以对数 10 为底的参数值与基线差值的列是分析所需要的，所以以对数 10 为底的转化需要一个新的参数，以便 AVAL, BASE 和 CHG 可以使用。这是因为对数 10 为底的基线列和以对数 10 为底的参数值与基线差值不满足规则 1 的条件。对数 10 为底的基线违反了第一个条件，并不是一个适用于所有行的方程，而是一个对于基线那一行的方程。以对数 10 为底的参数值与基线差值= LOG10(AVAL) - LOG10(BASE)违反了第三个条件，BASE 进行了以对数 10 为底的转换。

The intent is to use the standard columns as much as possible, to keep the structure as standard as possible, and avoid undue "horizontalization," while still permitting efficient use of function columns.
这样做的目的是尽可能使用标准变量，尽可能使结构标准化，避免过度的"扁平化"，同时允许函数列的高效使用。

Any function that satisfies the three conditions of Rule 1 is allowed as a column. If the function is listed in Section 3, then the ADaM standard column name must be used just as CHG is used in Table 4.2.1.1.
任何经满足规则 1 三个条件的函数，可以成为一列。如果该函数在第 3 部分中有列出，那么应使用 ADaM 标准列的名字，就像在表 4.2.1.1 里面 CHG 一样。

Rule 2. A transformation of AVAL that does not meet the conditions of Rule 1 should be added as a new parameter, and AVAL should contain the transformed value.
规则 2. 对 AVAL 的变换，如不满足规则 1 的条件，则应该添加一个新的分析参数，而且 AVAL 应该包含所变换的值。
If the intention is to redefine AVAL, BASE, CHG, etc. in terms of a transform of AVAL, then a new parameter must be added, in which PARAM describes the transform. **The creation of a new parameter results by definition in the creation of a new set of rows.**
如果想要重新定义 AVAL, BASE, CHG 等，需要对 AVAL 进行转化，那么需要新增一个参数，用这个参数来描述这个转化。

For example, as described in the discussion of Rule 1, in a change from baseline analysis of the logarithm of weight, AVAL should contain the log of weight, BASE should contain the baseline value of the log of weight, and CHG should contain the difference between the two. PARAM should contain a description of the transformed data contained in AVAL, e.g., "Log10 (Weight (kg))". In this way the ADaM standard accommodates an analysis of transformed data in the standard columns without creating a multiplicity of new special-purpose columns.
例如，就像规则 1 里面讨论的一样，在对体重的对数变换进行相对于基线变化的分析中，AVAL 的值应该是体重的对数，BASE 应该是体重基线数值的对数，CHG 应该是这两者的差值。PARAM 应该包含对 AVAL 进行转化的描述。例如，"Log(体重(千克))"。这样的话，ADaM 标准就可以适用于需要进行数据转化的分析，无需增加新的列。

In Table 4.2.1.2Table we see that the producer has chosen values of AVISITN that correspond to week number and which serve well for sorting and for plotting. VISITNUM is the SDTM visit number.
在表 4.2.1.2 中， 我们可以看到将 AVISITN 这一列的值设成了周数，可以很好的用于排序和画图。VISITNUM 是 SDTM 中访视编号。

Note that when SDTM variables, such as USUBJID, SUBJID, SITEID, VISIT, VISITNUM and --SEQ, are included in an ADaM dataset with their original SDTM variable names, their values must not be altered in any way.
注意，当 SDTM 变量，例如 USUBJID, SUBJID, SITEID, VISIT, VISITNUM 和--SEQ，需要包含在 ADaM 数据集中，它们的值必须保留原样，不能以任何方式被改变。

Table 4.2.1.2 Illustration of Rule 2: Creation of a New Parameter to Handle a Transformation

Row	PARAM	PARAMCD	VISIT	AVISIT	AVISITN	VISITNUM	ABLFL	AVAL	BASE	CHG
1	Weight (kg)	WEIGHT	Visit -1	Screening	-4	1		99	100	.
2	Weight (kg)	WEIGHT	Visit 0	Run-In	-2	2		101	100	.
3	Weight (kg)	WEIGHT	Visit 1	Baseline	0	3	Y	100	100	0

4	Weight (kg)	WEIGHT	Visit 12	Week 24	24	4		94	100	-6
5	Weight (kg)	WEIGHT	Visit 24	Week 48	48	5		92	100	-8
6	Weight (kg)	WEIGHT	Visit 26	Week 52	52	6		95	100	-5
7	Log10(Weight (kg))	L10WT	Visit -1	Screening	-4	1		1.9956	2	.
8	Log10(Weight (kg))	L10WT	Visit 0	Run-In	-2	2		2.0043	2	.
9	Log10(Weight (kg))	L10WT	Visit 1	Baseline	0	3	Y	2	2	0
10	Log10(Weight (kg))	L10WT	Visit 12	Week 24	24	4		1.9731	2	-0.0269

Row	PARAM	PARAMCD	VISIT	AVISIT	AVISITN	VISITNUM	ABLFL	AVAL	BASE	CHG
11	Log10(Weight (kg))	L10WT	Visit 24	Week 48	48	5		1.9638	2	-0.0362
12	Log10(Weight (kg))	L10WT	Visit 26	Week 52	52	6		1.9777	2	-0.0223

A related application of Rule 2 is in the case where it is necessary to support analysis and reporting in two different systems of units. In SDTM Findings domains such as LB, QS, EG, etc., the --STRESN column is the only numeric result column, and is also the only standardized numeric result column. The --ORRES column contains a character representation of the collected result, in the collected units specified in the --ORRESU column. The --ORRES column is not standardized. So for example, if data are typically collected in conventional units, SDTM cannot accommodate standardized data in both conventional units and the International System of Units (SI). In SDTM, for any given --TEST, a producer can standardize in one system of units but not two. If one wishes to be able to analyze standardized results in both conventional units and in SI units, a transform in an ADaM dataset is needed. In each such case, a new parameter must be created in order to accommodate standardized data in the other system of units.
规则 2 还可以用于在需要用两个不同系统单位做分析和报告的情况下。在 SDTM 测量域中，比如实验室数据，问卷数据，心电图数据等，--STRESN 列是唯一的一个数值型列，也是仅有的唯一的标准化数值列。--ORRES 列包含了字符型结果，--ORRESU 是收集的结果的单位。--ORRES 列不是标准化结果。例如，如果数据通常以传统单位收集的时候， SDTM 无法既包含传统单位的数据，又包含国际单位制（SI）标准化的数据。在 SDTM 中， 对于任何检验--TEST，我们只可以使用一种单位制，无法同时使用两种，如果想要分析一组数据， 既要有传统单位的数据，又要有国际单位变准化的数据，那么这个转化需要在 ADaM 中完成。在这种情况下，需要使用新的分析参数。

The description in the PARAM column must contain the units, as well as any other information such as location and specimen type that is needed to ensure that PARAM uniquely describes what is in AVAL, and differentiates between parameters as needed. PARAM cannot be the same for different units.
在 PARAM 的描述需要包含单位，以及任何其他信息，例如样本位置和样本类型，以确保这个 PARAM 唯一的描述了在 AVAL 值中到底是什么，对于不同的单位，PARAM 不能相同。

Table 4.2.1.3 shows an example of data supporting analyses of low-density lipoprotein (LDL) cholesterol in both conventional units (mg/dL) and SI units (mmol/L). In this study, SDTM cholesterol data were standardized in mg/dL. In the ADaM dataset, two records, one for each system of units, were generated from each original SDTM record. As described in Section 4.9.5, as a general rule, when a record is derived from a single record in the dataset, retain on the derived record any variable values from the original record that do not change and that make sense in the context of the new record (e.g., --SEQ, VISIT, VISITNUM, --TPT, covariates, etc.).
表 4.2.1.3 的数据为例，支持了低密度脂蛋白胆固醇在传统单位（mg/dL）和国际单位（mmol/L）的分析。在这个研究中， SDTM 低密度会蛋白数据以毫克/分升为单位标准化。在 ADaM 数据集中，从 SDTM 原始数据中，每一条初始 SDTM 数据，衍生了两条记录，一个单位一条。就像 4.9.5 部分描述的一般规则一样，当衍生一条记录时，需要保留原来数据当中那条记录的变量的值。（例如，--SEQ, VISIT, VISITNUM, --TPT, 协变量等）。

Table 4.2.1.3 Illustration of Rule 2: Creation of a New Parameter to Handle a Second System of Units

Row	PARAM	PARAMCD	AVISIT	AVISITN	VISITNUM	LBSEQ	ABLFL	AVAL	BASE	CHG	PCHG
1	LDL Cholesterol (mg/dL)	LDL	Screening	-2	1	2829		206.3	213.4		
2	LDL Cholesterol (mg/dL)	LDL	Run-In	-1	2	2830		202.1	213.4		

3	LDL Cholesterol (mg/dL)	LDL	Week 0	0	3	2831	Y	213.4	213.4	0.0	0.00
4	LDL Cholesterol (mg/dL)	LDL	Week 5	5	4	2832		107.4	213.4	-106.0	-49.67
5	LDL Cholesterol (mg/dL)	LDL	Week 11	11	5	2833		90.2	213.4	-123.2	-57.73
6	LDL Cholesterol (mg/dL)	LDL	Week 17	17	6	2834		96.8	213.4	-116.6	-54.64
7	LDL Cholesterol (mg/dL)	LDL	Week 23	23	7	2835		104.0	213.4	-109.4	-51.27
8	**LDL Cholesterol (mmol/L)**	**LDLT**	**Screening**	**-2**	**1**	**2829**		**5.3349**	**5.5185**		
9	**LDL Cholesterol (mmol/L)**	**LDLT**	**Run-In**	**-1**	**2**	**2830**		**5.2263**	**5.5185**		
10	**LDL Cholesterol (mmol/L)**	**LDLT**	**Week 0**	**0**	**3**	**2831**	**Y**	**5.5185**	**5.5185**	**0.0000**	**0.00**
11	**LDL Cholesterol (mmol/L)**	**LDLT**	**Week 5**	**5**	**4**	**2832**		**2.7773**	**5.5185**	**-2.7412**	**-49.67**
12	**LDL Cholesterol (mmol/L)**	**LDLT**	**Week 11**	**11**	**5**	**2833**		**2.3326**	**5.5185**	**-3.1859**	**-57.73**
13	**LDL Cholesterol (mmol/L)**	**LDLT**	**Week 17**	**17**	**6**	**2834**		**2.5032**	**5.5185**	**-3.0153**	**-54.64**
14	**LDL Cholesterol (mmol/L)**	**LDLT**	**Week 23**	**23**	**7**	**2835**		**2.6894**	**5.5185**	**-2.8291**	**-51.27**

Rule 3. A function of one or more rows within the same parameter for the purpose of creating an analysis timepoint should be added as a new row for the same parameter.

规则 3. 对于同一个参数的情况下，一行或多行需要计算某一个分析时间点的时候，这时候需要新增一行，但是参数不变。

For analysis purposes, there is often a need to impute missing data, or to create a derived conceptual timepoint. Such derivations should result in the creation of new derived records within the same parameter.

为了分析，经常会需要填补缺失数据，或者衍生概念的时间点。这样的衍生应该是相同参数内，创建新的衍生记录。

As described in Section 4.9.5, as a general rule, when a record is derived from a single record in the dataset, retain on the derived record any variable values from the original record that do not change and that make sense in the context of the new record (e.g., --SEQ, VISIT, VISITNUM, --TPT, covariates, etc.). When a record is derived from multiple records, then retain on the derived record all variable values that are constant across the original records, that do not change, and that make sense in the context of the new record. Note that there are situations when retention of values from an original record or records would make no sense on the derived record; in such cases, do not retain those values.

像 4.9.5 部分描述的那样，作为一个一般性规则，当一条记录是由数据集中一条单独记录衍生时，在衍生的记录当中保留任何来自初始记录里面没有改变的变量的值，和那些在新纪录当中有意义的变量值（例如，--SEQ, VISIT, VISITNUM, --TPT, 协变量等等）。但一条记录是从多条记录衍生时，在衍生的记录中保留那些和初始记录一致的没有改变的，且在新记录当中有意义的变量值。需要注意的是，在有些情况下，保留来自原始记录的值对于衍生的记录 没有任何意义，那么就无需保留那些值。

For example, suppose that the analysis endpoint value is defined as the average of the last two available post-baseline values. In this case, a new row should be added, with a corresponding description in AVISIT, and the DTYPE (derivation type) column should contain a description on that row such as "AVERAGE" to indicate both that the row was derived, and also the derivation method. The metadata associated with AVISIT=Endpoint should adequately describe which records are used in the definition of the average. Note that even though the set of records for the log transformation of weight are derived, DTYPE is not populated for every row. DTYPE should be used to indicate rows that are derived within a given value of PARAM and is not to be used as an indication of whether the record exists in SDTM.

例如，假设分析的终点值被定义为最后两条可用的基线后的观测值的平均值。在这种情况下，需要衍生一条新的记录，并在 AVISIT 当中进行相应的描述，并且这一行的 DTYPE（衍生类型）这一变量应该包含"平均"的描述，说明此行是衍生的，同时也指出了衍生方法。在 metadata 中，AVISIT=Endpoint 需要充分的描述衍生平均值需要用到的哪几条记录。需要注意的是，虽然体重的对数变换的一组记录是衍生的，但是 DTYPE 不需要每一行都填充.DTPYE 应该用来说明在一个给定的分析参数时衍生的行，而不是用来说明这条记录是否在原数据集 SDTM 中存在。

In Table 4.2.1.4, VISITNUM is not retained on the derived record because VISITNUM is not constant on the precursor records, and also makes no sense in the derived analysis timepoint, which is an average that in most cases will span multiple VISITs. Similarly VSSEQ is not constant across multiple original records, so

VSSEQ is not populated on the derived record. PARAM and BASE should be retained because they are constant on the precursor records and make sense in the context of the new record. For the new record, AVAL and change are recalculated, and AVISIT, AVISITN, and DTYPE are populated appropriately. Note that the metadata will specify the algorithm used for the calculation (in this example, the rows being averaged).
在表 4.2.1.4 中，VISITNUM 的值没有保留下来是因为用计算的那些记录的 VISITNUM 的值不相同，保留下来也没有意义，分析时间点是一个平均值，在大多视情况下跨越多个访视。同样的，VSSEQ 在多条原始记录中也不是一个常数，所以 VSSEQ 也无需在衍生记录中保留。分析参数和分析基数需要保留是因为他们原始记录中是一个不变的值，在新的衍生记录中有意义。对于新的记录，分析变量和与基数的差值被重新计算，且 AVISIT，AVISITN, 和 DTYPE 相应的被填充。需要注意的是，在 metadata 中需要说明计算的算法（此例此中，这一行是计算的平均值）

AVISIT and AVISITN are defined by the producer. AVISIT and AVISITN are not necessarily defined the same for the individual parameters within a dataset. The definition and derivation of the values of AVISIT, and any dependence on parameter, should be described in metadata. In this example, the producer decided to set AVISITN to 9999 on the derived AVISIT=Endpoint records.
AVISIT 和 AVISITN 由个人定义。AVISIT 和 AVISITN 在同一个数据集中，对于不同的分析参数，不要求定义一样。AVISIT 值的定义和衍生，及对于不同参数的定义，都需要在 metadata 当中描述清楚。在这个例子中， 当 AVISIT=Endpoint 时，定义 AVISITN=9999。

Table 4.2.1.4 Illustration of Rule 3: Creation of a New Row to Handle a Derived Analysis Timepoint

Row	PARAM	AVISIT	AVISITN	VISITNUM	VSSEQ	ABLFL	AVAL	BASE	CHG	DTYPE
1	Weight (kg)	Screening	-4	1	1164		99	100	.	
2	Weight (kg)	Run-In	-2	2	1165		101	100	.	
3	Weight (kg)	Baseline	0	3	1166	Y	100	100	0	
4	Weight (kg)	Week 24	24	4	1167		94	100	-6	
5	Weight (kg)	Week 48	48	5	1168		92	100	-8	
6	Weight (kg)	Week 52	52	6	1169		95	100	-5	
7	**Weight (kg)**	**Endpoint**	**9999**				**93.5**	**100**	**-6.5**	**AVERAGE**
8	Log10(Weight (kg))	Screening	-4	1	1164		1.9956	2	.	
9	Log10(Weight (kg))	Run-In	-2	2	1165		2.0043	2	.	
10	Log10(Weight (kg))	Baseline	0	3	1166	Y	2	2	0	
11	Log10(Weight (kg))	Week 24	24	4	1167		1.9731	2	-0.0269	
12	Log10(Weight (kg))	Week 48	48	5	1168		1.9638	2	-0.0362	
13	Log10(Weight (kg))	Week 52	52	6	1169		1.9777	2	-0.0223	
14	**Log10(Weight (kg))**	**Endpoint**	**9999**				**1.9708**	**2**	**-0.0292**	**AVERAGE**

An extension of Rule 3 is necessary in the case where there is value-level (record-level) population flagging. For example, assume the Statistical Analysis Plan states that if the subject is off drug for seven days prior to a visit, the measurement collected at that visit is not included in the per-protocol analysis. Then for some subjects, the last two available values may be different for Intent-to-Treat and for Per-Protocol analyses, so that the calculated endpoint averages would be different. For such subjects, two distinct derived endpoint rows would be needed, the appropriate row for each analysis indicated by the record-level population flags ITTRFL and PPROTRFL.
以防有【数】值层面（记录层面）的人群标记，规则 3 的拓展是很有必要的。举个例子，假设 SAP 强调了如果实验对象在一次访视前停药七天，那么这次访视的观测结果不会包括在完成治疗分析中。然而对于一些研究对象，最后两个有效值可能在意向性分析和完成治疗分析中不同，所以终点计算的平均值也会不同。对于这些研究对象，需要两条分别衍生的终点，ITTRFL 和 PPROTRFL 每种分析。

In Table 4.2.1.5, the analyzed endpoint value varies according to the population. For example, for PARAM=Weight (kg), the last two available ITT values are 92 and 95, whose average is 93.5; whereas the last two Per-Protocol values are 94 and 92, whose average is 93. That is why two derived Endpoint rows are required for

this subject. For other subjects, the ITT and Per-Protocol data that are input to the Endpoint average may be the same; in that case, only one Endpoint record would be needed, on which ITTRFL and PPROTRFL would both be set to Y. Values of AVISIT and AVISITN are producer-controlled. As in the example in Table 4.2.1.4, the producer decided to set AVISITN to 9999 on the derived AVISIT=Endpoint records. Note that the metadata will specify the algorithm used for the calculation (in this example, the rows being averaged).
在表格 4.2.1.5 中，根据人群的不同，终点分析值也会不同。比如参数=体重（kg），最后两条 ITT 的有效值是 92 和 95，平均值是 93.5；然而最后两条 PP 值则是 94 和 92，均值则是 93。这就是为什么这个研究对象必须要衍生出两条终点。对于其他对象来说，ITT 和 PP 的数据计算的终点均值可能是一样的；这种情况下，ITTRFL 和 PPROTRFL 都可以赋值为'Y'，且只需要一条终点记录。AVISIT 和 AVISITN 的值则是由申办者控制的，正如表格 4.2.1.4 里的例子，申办者在衍生 AVISIT=终点记录的时候决定把 AVISITN 设为 9999。这里说明一下元数据会指定计算的算法（这个例子里，这些行已经被平均了）。

Table 4.2.1.5 Illustration of Rule 3: Creation of New Rows to Handle a Derived Analysis Timepoint When There is Value-Level Population Flagging

Row	PARAM	AVISIT	AVISITN	VISITNUM	VSSEQ	ABLFL	AVAL	BASE	CHG	DTYPE	ITTRFL	PPROTRFL
1	Weight (kg)	Screening	-4	1	1164		99	100	.		Y	Y
2	Weight (kg)	Run-In	-2	2	1165		101	100	.		Y	Y
3	Weight (kg)	Baseline	0	3	1166	Y	100	100	0		Y	Y
4	Weight (kg)	Week 24	24	4	1167		94	100	-6		Y	Y
5	Weight (kg)	Week 48	48	5	1168		92	100	-8		Y	Y
6	Weight (kg)	Week 52	52	6	1169		95	100	-5		Y	
7	**Weight (kg)**	**Endpoint**	**9999**				**93.5**	**100**	**-6.5**	**AVERAGE**	**Y**	
8	**Weight (kg)**	**Endpoint**	**9999**				**93**	**100**	**-7**	**AVERAGE**		**Y**
9	Log10 (Weight (kg))	Screening	-4	1	1164		1.9956	2	.		Y	Y
10	Log10 (Weight (kg))	Run-In	-2	2	1165		2.0043	2	.		Y	Y
11	Log10 (Weight (kg))	Baseline	0	3	1166	Y	2	2	0		Y	Y
12	Log10 (Weight (kg))	Week 24	24	4	1167		1.9731	2	-0.0269		Y	Y
13	Log10 (Weight (kg))	Week 48	48	5	1168		1.9638	2	-0.0362		Y	Y
14	Log10 (Weight (kg))	Week 52	52	6	1169		1.9777	2	-0.0223		Y	
15	**Log10 (Weight (kg))**	**Endpoint**	**9999**				**1.9708**	**2**	**-0.0292**	**AVERAGE**	**Y**	
16	**Log10 (Weight (kg))**	**Endpoint**	**9999**				**1.9685**	**2**	**-0.0315**	**AVERAGE**		**Y**

In the example in Table 4.2.1.6, missing post-baseline values are imputed by last observation carried forward, and also by worst observation carried forward.
In this study, at Week 8, there is a scheduled visit (visit number 6). At that visit, blood pressure should be collected. However, for this subject, either there was no visit 6, or there was a visit 6, but no data on blood pressure were collected. The SAP says that missing post-baseline data should be imputed (derived) by two methods: LOCF (last observation carried forward), and WOCF (worst observation carried forward).
表格 4.2.1.6 举出的例子中，基线后缺失值由缺失前最后一条以及最差的一条观测来填补。在这个试验里，8 周的时候有个计划随访（随访号 6），在这次随访中会收集血压数据。然而，对于这个对象，要么就没有 6 号随访，要么就没有收集血压数据。SAP 写明用两种方法可以填充（衍生）缺失的基线后数据：LOCF(末次观测结转法)，和 WOCF（最差次观测结转法）。
For LOCF analysis, the missing Week 8 (VISITNUM 6) result is imputed by carrying forward the most recent prior available post-baseline value, which is the VISITNUM 5 value. That the Week 8 value is imputed is indicated by LOCF in the derivation type (DTYPE) column.
对于 LOCF 分析，第 8 周（随访 6）的结果由先前最近的一条有效值，也就是由随访 5 的值填充。被填充的第 8 周的值会由衍生类型列的 LOCF 来标明。

For WOCF analysis, even though the unscheduled VISITNUM 4.1 value was not chosen to represent the Week 2 analysis timepoint, it is used to impute the missing Week 8 timepoint because it was the worst post-baseline result up to that point.
对于 WOCF 分析，尽管计划外随访号 4.1 的值并没有被用来代替第 2 周的结果，但因为它是 8 周来最差的基线后结果，所以被用来填充第 8 周的结果。

The exact algorithms employed in the record derivation methods (LOCF and WOCF in this case) must be indicated in the metadata for DTYPE.
在记录中衍生方法（LOCF 和 WOCF）的计算必须在元数据中的 DTYPE 里被标注。

Traceability is enhanced by the addition of the SDTM VISITNUM and --SEQ columns. The combination of USUBJID and VSSEQ provides a link to the exact input record in the SDTM VS dataset. On the derived LOCF and WOCF rows, VISITNUM and VSSEQ provide clarity about where the value came from.
There are several other concepts presented in this example. Analysis relative day (ADY) in this protocol is defined relative to date of first dose. In many but not all protocols, ADY would equal the value of the SDTM --DY variable (or --STDY for some kinds of data). The data presented here illustrate that this particular subject did not take drug until two days after randomization, so the value of ADY is -2 at the randomization visit, Visit 3 (VISITNUM 3). As is the case for SDTM study day, there is no day 0 for ADY.
可追溯性会在 SDTM 随访号和各序号列中强调。USUBJID 和 VSSEQ 的结合可以提供 SDTM VS 数据集中精确录入记录的链接。在衍生的 LOCF 和 WOCF 中，通过随访号和 VS 序列号可以明确看出值是由何而来。这个例子里也展示了几个其他的概念。分析相关天数（ADY）在方案中被定义为第一次服药的相关日期。大部分但并不是所有方案中，ADY 应该是等于 SDTM --DY 变量（或者在一些别的数据中是 --STDY）。这里的例子说明了一些特定的受试者在随机化之后两天才开始服药，所以 ADY 的值在随机化当天是-2，第三次访视（VISITNUM 3）。 同样适用于 SDTM 的研究日，ADY 没有 0 天的值。

In this protocol, if there are multiple datapoints within an analysis time window, the value that is observed closest to a pre-specified target planned relative day is the value that is chosen to represent the analysis timepoint. For this study and parameter, AWTARGET = VISITDY (Planned Study Day) from SDTM, and ADY=VSDY. AWTDIFF is the absolute value of ADY - AWTARGET, adjusted for the fact that there is no day 0 (so that if ADY and AWTARGET have different signs, then AWTDIFF = |ADY - AWTARGET| - 1).
在这个方案中，如果在一个分析窗口中有多点记录，分析时间点的值则选取距离预先定义的相关日最近的一条记录。对于这个研究和参数，AWTARGET=SDTM 中的 VISITDY(计划研究日)，并且 ADY=VSDY。 AWTDIFF 自然是 ADY=AWTARGET， 会根据没有 0 天这个既定事实来调整（所以如果 ADY 和 AWTARGET 同为正负的话，那么 AWTDIFF=|ADY-AWTARGET|-1）.

For AVISIT=Week 2, there were two values observed, at study days 13 and 17 (rows 4 and 5). Day 13 is closer to the target, day 14. So the day 13 record (row is chosen for analysis, as denoted by the analysis flag ANL01FL = Y.
对于 AVISIT=2 周，如果有两条观测值，在研究第 13 日和第 17 日（第 4，5 行），第 13 日就里目标第 14 日较近，所以第 13 日的记录（第 4 行）就会被用来分析，并且要被打上分析标帜 ANL01FL=Y。

AVISIT by itself functions as a description of an analysis time window. AVISIT, DTYPE, and ANL01FL are all needed to identify the records to be used in a given analysis.
AVISIT 自己则被当作一个分析时间窗的描述。AVISIT,DTYPE,ANL01FL 都是需要判断记录是否被用在在特定分析中。

On the derived AVIST=Week 8 records, AWTARGET was set to the target for Week 8, and AWTDIFF was calculated accordingly. It did not make sense to retain the values of AWTARGET and AWTDIFF from the original records.
衍生的 AVISIT=8 周的记录中，AWTARGET 被设为第 8 周的目标值，相应计算出 AWTDIFF。保留 AWTARGET 和 AWDIFF 的原始值则不合理。

Table 4.2.1.6 Illustration of Rule 3: Creation of New Rows to Handle Imputation of Missing Values by Last Observation Carried Forward and Worst Observation Carried Forward

Row	PARAM	AVISIT	AVISITN	VISITNUM	VSSEQ	ABLFL	AVAL	BASE	CHG	DTYPE	ADY	AWTARGET	AWTDIFF	ANL01FL
1	Systolic BP (mm Hg)	Screening	-4	1	3821		120	114	.		-30	-28	2	Y
2	Systolic BP (mm Hg)	Run-In	-2	2	3822		116	114	.		-16	-14	2	Y
3	Systolic BP (mm Hg)	Week 0	0	3	3823	Y	114	114	0		-2	1	2	Y
4	Systolic BP (mm Hg)	Week 2	2	4	3824		118	114	4		13	14	1	Y
5	Systolic BP (mm Hg)	Week 2	2	4.1	3825		126	114	12		17	14	3	
6	Systolic BP (mm Hg)	Week 4	4	5	3826		122	114	8		23	28	5	Y
7	Systolic BP (mm Hg)	Week 8	8	5	3826		122	114	8	LOCF	23	56	33	Y
8	Systolic BP (mm Hg)	Week 8	8	4.1	3825		126	114	12	WOCF	17	56	39	Y
9	Systolic BP (mm Hg)	Week 12	12	7	3827		134	114	20		83	84	1	Y

Table 4.2.1.7 contains an example of data supporting change from baseline analyses of migraine pain. In this study, missing post-baseline data are imputed by the methods of Baseline Observation Carried Forward (BLOCF) and Last Observation Carried Forward (LOCF).
表 4.2.1.7 则是一个关于偏头痛的相关基线改变的分析，在这个研究中，基线后的缺失数据会根据 BLOCF 和 LOCF 方法来填充。

When a migraine headache occurs, subjects self-administer a single dose of blinded study treatment. Subjects assess migraine pain at planned timepoints Pre- Dose, 30 Minutes Post-Dose, 1 Hour Post-Dose, and 2 Hours Post-Dose. Collected data on migraine pain are tabulated in the SDTM Findings About domain.
当偏头痛发生时，受试者自主服用单剂量的盲态药物。受试者根据计划时间点对偏头痛进行评估，服药前，服药后 30 分钟，服药后 1 小时，服药后 2 小时。偏头痛的数据会被分配在 SDTM 相应的域中。

ATPT is the analysis timepoint description. ATPTN is the analysis timepoint number. FATPTNUM is the collected timepoint number from SDTM. AVALC contains the pain assessment, and AVAL contains the numeric coded value of the assessment. AVAL is a one-to-one map to AVALC.
ATPT 是相关时间点的描述。ATPTN 是相关时间点数。FATPTNUM 是 SDTM 中收集的时间点数。AVALC 包括疼痛评估，AVAL 则包含评估的数值编码值。AVAL 和 AVALC 之间是一一对应的。

Subject 000276 did not continue to provide data after 1 Hour Post-Dose. For this subject, the 2 Hours Post-Dose planned observation must be imputed. Therefore, subject 000276 is excluded from an observed case analysis of Migraine Pain at 2 Hours Post-Dose.
受试者 000276 没有继续提供服药后 1 小时的数据。对于这个受试者，计划服药后两小时的记录必须被填充。所以，受试者 000276 偏头痛服药后两小时的分析需要被剔除。

Subject 001863 had complete data, so no imputation was necessary.
受试者 001863 有完整的数据，不需要填充。

The data for both subjects are included in the BLOCF and LOCF analyses of Migraine Pain at 2 Hours Post-Dose.
两个受试者的数据都包括对于偏头痛服药后 2 小时 BLOCF 和 LOCF 分析中。

Table 4.2.1.7 Illustration of Rule 3: Creation of New Rows to Handle Imputation of Missing Values by Baseline Observation Carried Forward and Last Observation Carried Forward

Row	USUBJID	TRTP	PARAM	ATPT	ATPTN	FATPTNUM	FASEQ	ABLFL	AVAL	AVALC	BASE	CHG	DTYPE
1	000276	Placebo	Migraine Pain	Pre-Dose	0	1	14	Y	3	Severe Pain	3	0	
2	000276	Placebo	Migraine Pain	30 Minutes Post-Dose	0.5	2	22		2	Moderate Pain	3	-1	
3	000276	Placebo	Migraine Pain	1 Hour Post-Dose	1	3	27		1	Mild Pain	3	-2	
4	**000276**	Placebo	**Migraine Pain**	**2 Hours Post-Dose**	**2**	**1**	**14**		**3**	**Severe Pain**	**3**	**0**	**BLOCF**
5	**000276**	Placebo	**Migraine Pain**	**2 Hours Post-Dose**	**2**	**3**	**27**		**1**	**Mild Pain**	**3**	**-2**	**LOCF**
6	001863	Soma 30 mg	Migraine Pain	Pre-Dose	0	1	638	Y	3	Severe Pain	3	0	
7	001863	Soma 30 mg	Migraine Pain	30 Minutes Post-Dose	0.5	2	639		1	Mild Pain	1	-2	
8	001863	Soma 30 mg	Migraine Pain	1 Hour Post-Dose	1	3	640		1	Mild Pain	1	-2	
9	001863	Soma 30 mg	Migraine Pain	2 Hours Post-Dose	2	4	641		1	Mild Pain	1	-2	

Table 4.2.1.8 contains an example of some of the columns in a dataset supporting analysis of a 2-period crossover study.
表 4.2.1.8 是一个数据集中的部分列支持了一个 2 阶段交叉试验的分析的例子。

In a crossover trial design, all subjects are planned to receive all of the study treatments. The sequence of treatments is randomized. If in a study there are two treatments in a crossover design, two treatment periods are necessary.
在一个交叉实验设计中，所有受试者计划接受所有治疗。治疗的顺序是随机的。如果在一个试验中有两组治疗在同一个交叉设计里，那么就需要两个阶段。

In this example, the planned visits are 1 (Screening and beginning of placebo run-in period), 2 (Week -2, halfway through placebo run-in period), 3 (Week 0, end of placebo run-in and randomization), 4 (Week 4, the end of the first treatment period), and 5 (Week 8, the end of the second treatment period). Baseline is defined in the Statistical Analysis Plan as the average of the Week -2 (VISIT 2) and Week 0 (VISIT 3) measurements. This baseline is used for the analysis of both the first and the second crossover periods. USUBJID 0987_4252 has no VISIT 2 measurement, so the average is just the Week 0 (VISIT 3) measurement.
在这个例子里，计划访视是 1（筛选和安慰剂入组阶段），2（-2 周，安慰剂入组阶段中段），3（0 周，安慰剂入组结束和随机化），4（4 周，第一治疗阶段结束），5（8 周，第二治疗阶段结束）。基线在统计分析计划中被定义为-2 周（第 2 次访视）和 0 周（第 3 次访视）测量值的平均值。第一和第二交叉阶段的分析中都会用到这个基线。USUBJID 0987_4252 没有第 2 次访视的观测值，所以均值仅为 0 周（第 3 次访视）的观测值。

Within any post-baseline week window, the last observation is used to characterize that week. For example, for USUBJID 0987_3984, the VISIT 5 (row 7) value is used to characterize AVISIT=Week 8, as opposed to the earlier VISIT 4.1 value (row 6), which was also observed during the Week 8 time window. The variable ANL01FL is used in this study to identify the record selected for analysis when there are multiple records for a given AVISIT, and must be used in conjunction with other selection variables in order to identify the exact set of records used in a given analysis or summary.
在任何基线后的时间窗中，最后一条记录被用作描述这个时间。举个例子，USUBJID 0987_3984，VISIT 5（第 7 行）的值被用来代表 AVISIT=第 8 周，而不是早些的访视 4.1 的值（第 6 行），因为这个访视 4.1 的值也是在第 8 周的时间视窗里被观测到的。在这个研究中，变量 ANL01FL 被用来标记对于给定的 AVISIT 具有多条记录时为进行分析而选择的记录，并且为了标记用于一个给定分析或总结的更精确记录集合，必须和其它的选择变量一起使用。

APERIODC is the crossover period character description.
APERIODC 是交叉阶段特征描述。

Note that in general, APERIODC is not the same as EPOCH. For example, it is possible in some cases that boundaries of APERIODs would not align exactly with boundaries of EPOCHs. A simple example is a post-discontinuation record that is associated with the most recent treatment period for analysis.
注意一般来说 APERIODC 和 EPOCH 不同。比如在没有治疗可分析的基线前这样的时间阶段，不会定义 APERIOD/APERIODC。而且，在有些情形下，可能 APERIOD 的界限和 EPOCH 的界限不完全一致。举个简单的例子，比如要用于分析的最近治疗阶段与中止后记录相关联。

TRTSEQP, from ADSL, is the planned ordering of crossover treatments. TRTP is the treatment variable that will be used in the analysis of this dataset. The two endpoint records are derived only for the subjects who have data for both periods.
来自 ADSL 的 TRTSEQP 是交叉治疗的计划的顺序，TRTP 是一个给定阶段的被分析的计划的治疗，只有只在两个阶段都有数据的受试者，才需要衍生两个终点记录。

The conventions used in AVISITN are producer-defined. In this example, the producer has decided that AVISITN contains -8888 for the derived baseline records, 9999 for the derived endpoint records, and week number otherwise.
用在 AVISITN 的惯例是由申办者定义的。在这个例子在此例中，申办者已经决定对 AVISITN 变量，衍生的基线记录的值设为-8888，衍生的终点记录的值设为 9999，其它记录的值设为星期号。

It should be noted that in this example, the producer elected to define APERIOD only for the on-treatment visits, therefore leaving TRTP, APERIOD, and APERIODC empty on other records. This is not meant to imply a standard or best practice.
值得注意的是在这个例子中，申办者选取定义的 APERIOD 只针对在治疗中的访视，所以 TRTP,APERIOD,APERIODC 在别的记录都是空的。但并不代表这是一个标准或者最好的例子。

Table 4.2.1.8 Illustration of Rule 3: Creation of Endpoint Rows to Facilitate Analysis of a Crossover Design

Row	USUBJID	PARAMCD	AVISIT	AVISITN	VISITNUM	DTYPE	ANL01FL	TRTP	APERIOD	APERIODC	TRTSEQP	AVAL	ABLFL	BASE	CHG
1	0987_3984	ALT	Screening	-4	1		Y				Drug B, Drug A	16		17	.
2	0987_3984	ALT	Week -2	-2	2		Y				Drug B, Drug A	16		17	.
3	0987_3984	ALT	Week 0	0	3		Y				Drug B, Drug A	18		17	.
4	0987_3984	ALT	Baseline	-8888		**AVERAGE**	Y				Drug B, Drug A	17	Y	17	0
5	0987_3984	ALT	Week 4	4	4		Y	Drug B	1	Period 1	Drug B, Drug A	14		17	-3
6	0987_3984	ALT	Week 8	8	4.1			Drug A	2	Period 2	Drug B, Drug A	10		17	-7
7	0987_3984	ALT	Week 8	8	5		Y	Drug A	2	Period 2	Drug B, Drug A	12		17	-5
8	**0987_3984**	**ALT**	**Endpoint**	**9999**	**4**	**ENDPOINT**	**Y**	**Drug B**	**1**	**Period 1**	**Drug B, Drug A**	**14**		**17**	**-3**
9	**0987_3984**	**ALT**	**Endpoint**	**9999**	**5**	**ENDPOINT**	**Y**	**Drug A**	**2**	**Period 2**	**Drug B, Drug A**	**12**		**17**	**-5**
10	0987_4252	ALT	Screening	-4	1		Y				Drug A, Drug B	12		11	.
11	0987_4252	ALT	Week 0	0	3		Y				Drug A, Drug B	11		11	.
12	0987_4252	ALT	Baseline	-8888		**AVERAGE**	Y				Drug A, Drug B	11	Y	11	0
13	0987_4252	ALT	Week 4	4	4		Y	Drug A	1	Period 1	Drug A, Drug B	14		11	3
14	0987_4252	ALT	Week 8	8	5		Y	Drug B	2	Period 2	Drug A, Drug B	15		11	4
15	**0987_4252**	**ALT**	**Endpoint**	**9999**	**4**	**ENDPOINT**	**Y**	**Drug A**	**1**	**Period 1**	**Drug A, Drug B**	**14**		**11**	**3**
16	**0987_4252**	**ALT**	**Endpoint**	**9999**	**5**	**ENDPOINT**	**Y**	**Drug B**	**2**	**Period 2**	**Drug A, Drug B**	**15**		**11**	**4**

Rule 4. A function of multiple rows within a parameter should be added as a new parameter.
规则 4. 同一个参数内多个行的函数应该被添加为一个新参数
Rule 4 is a special case of Rule 2. The functions covered by this rule violate the second condition of Rule 1 (they are not same-row functions of AVAL), and may also violate the first and third conditions. 规则 4 是规则 2 的一个特例。这条规则包含的函数违反了规则 1 的第 2 个条件（它们不是 AVAL 的相同行函数），并

且也可能违反第 1 和第 3 个条件。

Table 4.2.1.9 shows an example of a clinical trial of a Human Immunodeficiency Virus (HIV) vaccine, where blood samples are drawn at each visit, and CD4 cell count is measured. To assess efficacy, it is important to look at the cumulative effect over time on CD4 cell count during follow-up after administration.
如表 4.2.1.9 中示例，在一个 HIV 疫苗的临床试验中，每次访视都要抽血样，并且要测量 CD4 的细胞数。为了评估有效性，给药之后的随访过程中，观察 CD4 细胞数随时间的累计效应就显得很重要。
Let AVAL(t) equal the value of CD4 cell count at post-baseline visit t, and let VISITDY(t) be the planned study day of visit t.
设 AVAL（t）等于在基线后访视 t 的 CD4 细胞数，并且设 VISITDY(t)为访视 t 的计划的研究天数。
CD4AUC (cumulative daily CD4 count over follow-up) is calculated at any given post-baseline visit as follows:

- CD4AUC at baseline visit is set to 0.
- CD4AUC(t) = CD4AUC(t-1) + [0.5 * AVAL(t-1) + 0.5 * AVAL(t)] * [VISITDY(t) - VISITDY(t-1)].

在任何给定的基线后访视以如下方式计算CD4AUC（随访中累计的每日CD4数）：

- ·将基线访视的CD4AUC设为0
- ·CD4AUC(t) = CD4AUC(t-1) + [0.5 * AVAL(t-1) + 0.5 * AVAL(t)] * [VISITDY(t) - VISITDY(t-1)]

CD4AUC is not a simple same-row function of BASE and AVAL. It is calculated based on data from multiple observations (rows) of CD4 data, so it should be added as a new parameter rather than as a new column. CD4AUC is not defined pre-baseline, which is why there is no Week -1 for this parameter.
CD4AUC 不是一个简单的 BASE 和 AVAL 的同行函数，它基于来自多个观察值（行）的 CD4 的数据的计算，所以它应该被添加为一个新的行，而不是新的列。CD4AUC 在基线前没有定义，所以这个参数没有第-1 周。

CD4AUCMB (cumulative average change from baseline in daily CD4 count over follow-up) is calculated as
CD4AUCMB(t) = CD4AUC(t) / [VISITDY(t) - 1] - baseline value of CD4 cell count.
CD4AUCMB（随访中 CD4 数相对于基线的累计平均变化）计算方法为：
CD4AUCMB(t) = CD4AUC(t) / [VISITDY(t) - 1] – CD4 细胞数的基线值 。

CD4AUCMB is a function of both CD4AUC and the baseline value of CD4, so it also must be its own parameter (see Rule 5 below). CD4AUCMB is not defined for pre-baseline and baseline records and therefore these records are not represented within this value of PARAM.
CD4AUCMB 是 CD4AUC 和 CD4 的基线值的函数，所以它也必须以它自己作参数（参见下面的规则 5）。CD4AUCMB 在基线前和基线记录没有定义，因此这些记录在 PARAM（参数）的这个值没有体现。

Table 4.2.1.9 Illustration of Rule 4: Creation of a New Parameter to Handle a Function of More Than One Row of a Parameter

Row	PARAM	PARAMCD	AVISIT	VISITDY	ABLFL	AVAL	BASE
1	CD4 (cells/mm3)	CD4	Week -1	-7		75	76
2	CD4 (cells/mm3)	CD4	Week 0	1	Y	76	76
3	CD4 (cells/mm3)	CD4	Week 2	15		128	76
4	CD4 (cells/mm3)	CD4	Week 4	29		125	76
5	CD4 (cells/mm3)	CD4	Week 8	57		191	76
6	CD4 (cells/mm3)	CD4	Week 12	85		167	76
7	CD4 (cells/mm3)	CD4	Week 16	113		136	76
8	**CD4 Cumulative AUC**	**CD4AUC**	**Week 0**	**1**	**Y**	**0**	**0**
9	**CD4 Cumulative AUC**	**CD4AUC**	**Week 2**	**15**		**1428**	**0**

10	**CD4 Cumulative AUC**	**CD4AUC**	**Week 4**	**29**		**3199**	**0**
11	**CD4 Cumulative AUC**	**CD4AUC**	**Week 8**	**57**		**7623**	**0**
12	**CD4 Cumulative AUC**	**CD4AUC**	**Week 12**	**85**		**12635**	**0**
13	**CD4 Cumulative AUC**	**CD4AUC**	**Week 16**	**113**		**16877**	**0**
14	**CD4 Cumulative AUCMB**	**CD4AUCMB**	**Week 2**	**15**		**26**	**.**
15	**CD4 Cumulative AUCMB**	**CD4AUCMB**	**Week 4**	**29**		**38.25**	**.**
16	**CD4 Cumulative AUCMB**	**CD4AUCMB**	**Week 8**	**57**		**60.125**	**.**
17	**CD4 Cumulative AUCMB**	**CD4AUCMB**	**Week 12**	**85**		**74.4167**	**.**
18	**CD4 Cumulative AUCMB**	**CD4AUCMB**	**Week 16**	**113**		**74.6875**	**.**

Rule 5. A function of more than one parameter should be added as a new parameter.
规则 5. 多于一个参数的一个函数应该被添加为一个新参数

There is often a need to derive for analysis a parameter that was not collected. Such parameters may be quite complex functions of data from multiple SDTM domains and domain classes. Rule 5 addresses the case where a parameter is derived from other parameters already present in the dataset.
为了进行分析，经常有需要衍生一个没有收集的参数。这样的参数可能是多个 SDTM 域和域类的数据的很复杂的函数。规则 5 处理的情况是一个参数是从数据集中已经存在的其它参数衍生。

For example, a questionnaire total domain score is calculated as a function of more than one observed question. The total domain score should be added as a new parameter, with its corresponding set of derived rows. For this derived parameter, the value of PARAM would be e.g., "Total Domain Score", and the value of the total domain score would be stored in the standard AVAL column, the baseline value would be stored in the standard BASE column, change from baseline would be stored in CHG, as usual.
例如，一个调查问卷所有域总分由多于一个观察到的问题的函数计算。所有域总分应该被添加为一个新函数，和它的相应的衍生行的集合。为了这个衍生的参数，PARAM 的值会是例如"所有域总分"，并且所有域总分的会被存储在标准的 AVAL 列，基线值会被存储在标准 BASE 列，相对于基线的变化会被存储在 CHG，像往常一样。

In the example in Table 4.2.1.10, blood samples are drawn at every visit, and laboratory test measurements of total cholesterol and high-density lipoprotein cholesterol are found in the SDTM LB dataset. The protocol calls for analysis of each individual lab analyte, and also for an analysis of the ratio of total cholesterol (C) to high-density lipoprotein (HDL) cholesterol. The ADaM dataset contains parameters for each of the two measured lab tests, as well as a new set of derived rows where the description in PARAM is "Total Cholesterol:HDL-C ratio", and AVAL contains the calculated ratio at each timepoint.
在表 4.2.1.10 的例子，在每次访视都会抽取血样，并且实验室检验测量总的胆固醇和高密度脂蛋白胆固醇可以在 SDTM LB 域中找到。方案需要每个单独实验室分析物的分析，也需要对于总的胆固醇（C）和高密度脂蛋白胆固醇（HDL）胆固醇比率的分析。分析数据集包含两个测量的实验室检验中每一个的参数，也包含一个新的衍生行的集合，在 PARAM 的描述是"总胆固醇：HDL-C 比率"，并且 AVAL 在每个时间点包含计算的比率。

The analysis of percent change from baseline (PCHG) is of interest for all three parameters and is therefore populated on all records. In general, however, if percent change is not analyzed for a particular value of PARAM, then it is not necessary to populate PCHG for those rows.
相对于基线变化的百分比对全部三个参数都很重要，因此对所有记录都需要填充。但是，一般来说，如果变化百分比对于 PARAM 的一个特殊值没有被分析，那么没有必要在那些行填充 PCHG。

Table 4.2.1.10 Illustration of Rule 5: Creation of New Parameter to Handle a Function of More Than One Parameter

Row	PARAM	PARAMCD	AVISIT	AVISITN	VISITNUM	LBSEQ	ABLFL	AVAL	BASE	CHG	PCHG
1	Total Cholesterol (mg/dL)	CHOL	Screening	-2	1	39394		265	266	.	.
2	Total Cholesterol (mg/dL)	CHOL	Run-In	-1	2	25593		278	266	.	.
3	Total Cholesterol (mg/dL)	CHOL	Week 0	0	3	23213	Y	266	266	0	0.000

4	Total Cholesterol (mg/dL)	CHOL	Week 2	2	4	32952		259	266	-7	-2.632
5	Total Cholesterol (mg/dL)	CHOL	Week 4	4	5	12768		235	266	-31	-11.654
6	Total Cholesterol (mg/dL)	CHOL	Week 8	8	6	18773		242	266	-24	-9.023
7	Total Cholesterol (mg/dL)	CHOL	Week 12	12	7	28829		217	266	-49	-18.421
8	High-Density Lipoprotein Chol (mg/dL)	HDL	Screening	-2	1	32437		44	42	.	.
9	High-Density Lipoprotein Chol (mg/dL)	HDL	Run-In	-1	2	26884		40	42	.	.
10	High-Density Lipoprotein Chol (mg/dL)	HDL	Week 0	0	3	52657	Y	42	42	0	0.000
11	High-Density Lipoprotein Chol (mg/dL)	HDL	Week 2	2	4	38469		43	42	1	2.381
12	High-Density Lipoprotein Chol (mg/dL)	HDL	Week 4	4	5	12650		47	42	5	11.905
13	High-Density Lipoprotein Chol (mg/dL)	HDL	Week 8	8	6	24345		46	42	4	9.524
14	High-Density Lipoprotein Chol (mg/dL)	HDL	Week 12	12	7	23484		47	42	5	11.905
15	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Screening**	**-2**	**1**			**6.023**	**6.333**	**.**	**.**
16	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Run-In**	**-1**	**2**			**6.950**	**6.333**	**.**	**.**
17	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Week 0**	**0**	**3**		**Y**	**6.333**	**6.333**	**0.000**	**0.000**
18	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Week 2**	**2**	**4**			**6.023**	**6.333**	**-0.310**	**-4.896**
19	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Week 4**	**4**	**5**			**5.000**	**6.333**	**-1.333**	**-21.053**
20	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Week 8**	**8**	**6**			**5.261**	**6.333**	**-1.072**	**-16.934**
21	**Total Cholesterol:HDL-C ratio**	**CHOLH**	**Week 12**	**12**	**7**			**4.617**	**6.333**	**-1.716**	**-27.100**

Rule 6. When there is more than one definition of baseline, each additional definition of baseline requires the creation of its own set of rows.
规则 6. 当有多个基线定义时，每个附加的基线定义都要求创建它自己的行集合

In case there is more than one definition of baseline in an ADaM dataset, new rows must be created for each additional alternative definition of baseline. There will therefore be multiple sets of rows, where each set of rows corresponds to a particular definition of baseline. Whenever there is more than one definition of baseline, the BASETYPE column is required. BASETYPE identifies the definition of baseline that corresponds to the value of BASE in each row. There is only one BASE column, and only one column for each qualifying function of AVAL and BASE.
在具有多于一个的基线定义的情况，必须为每一个另外附加的基线定义创建新的行。因此会有多组行，每组行相对于基线的一个特定的定义。无论何时具有多于一个的基线定义，BASETYPE 列都是必需的。BASETYPE 指定和每个行 BASE 的值对应的基线的定义。只有一个 BASE 列，并且对于每个具有资格的 AVAL 和 BASE 的函数只有一列。

The example in Table 4.2.1.11 presents a dataset supporting shift analysis from three different baselines. Accordingly, it makes use of the BASETYPE variable described above. The ANRIND, BNRIND, and SHIFTy variables are also illustrated. In this example, the three baselines of interest characterize different portions of the study: run-in, double-blind, and open-label. For any datapoint, it is desired to have the ability to analyze shift from the most recent baseline or any prior baseline. Rows 1-12 are the initial set of rows representing all of the collected data. They permit analysis of the shift in normal range indicator from the run-in baseline to any value in the run-in, double-blind, or open-label portions of the study. Additional sets of rows are added to support analysis of shift from the double-blind and open-label baselines: rows 13-19 permit analysis of the shift from the double-blind baseline normal range indicator for data in either the double-blind or open-label portions of the study; and rows 20-22 support analysis of shift from open-label baseline for data in the open-label portion of the study.
表 4.2.1.11 中的例子介绍了一个数据集，它支持相对于三个不同基线的交叉分析，相对应地，它使用上面描述的 BASETYPE 变量，也阐释了 ANRIND, BNRIND, 和 SHIFTy 变量。在这个例子中，三条基线分别在这个研究中有不同分量的占比：入组，双盲，或者开放试验。对于任何数据点，都很需要相对最近一次基线或者任何先于基线的交叉分析。1-12 行代表收集的数据的最初记录。在正常范围指标内允许分析在入组，双盲，开放试验的部分从基线入组到任何值的变化。额外添加的那些行是用来支持分析从双盲和开放基线的变化：13-19 行允许分析在双盲和开放试验部分从双盲基线正常范围指标的变化；20-22 行用来支持分析在开放实验部分中从开放基线的变化。

Note that only the rows needed for the analysis are included in the additional sets. For example, the set of rows for the shift from the double-blind baseline does not include the rows for EPOCH="RUN-IN" and EPOCH="STABILIZATION" as they are not analyzed using the double-blind baseline.
注意只有需要用来分析的行才会被额外添加。比如，从双盲基线开始的变化没有包括 EPOCH="RUN-IN" EPOCH="STABILIZATION"，因为分析中没有用到双盲基线。

For space reasons, the ANLzzFL variable is not shown, although it would be needed to identify which record is selected in cases of multiple observed records within an analysis timepoint, as is the case for AVISIT=WEEK 12 (DB) for this subject and parameter.
因为空间的缘故，没有显示 ANLzzFL 变量，虽然在一个分析时间点具有多个观察记录的情况需要确定选择哪个记录，对于这个受试者和参数，AVISIT=WEEK 12 (DB)就是这种情况。

Table 4.2.1.11 Illustration of Rule 6: Creation of New Rows to Handle Multiple Baseline Definitions - Supporting Comparisons to Any Prior Baseline

Row	BASETYPE	EPOCH	AVISIT	LBSEQ	AVAL	ANRLO	ANRHI	ANRIND	ABLFL	BASE	BNRIND	SHIFT1
1	RUN-IN	RUN-IN	BSLN (RUN-IN)	111	34.5	15.4	48.5	NORMAL	Y	34.5	NORMAL	
2	RUN-IN	RUN-IN	WK 8 (RUN-IN)	168	11.6	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
3	RUN-IN	RUN-IN	END POINT (RUN-IN)	168	11.6	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
4	RUN-IN	STABILIZATION	WK 14 (STAB.)	200	13.1	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
5	RUN-IN	STABILIZATION	END POINT (STAB.)	200	13.1	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
6	RUN-IN	DOUBLE-BLIND	BSLN (DB)	200	13.1	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
7	RUN-IN	DOUBLE-BLIND	WK 12 (DB)	295	13.7	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
8	RUN-IN	DOUBLE-BLIND	WK 12 (DB)	300	19.7	15.4	48.5	NORMAL		34.5	NORMAL	NORMAL to NORMAL
9	RUN-IN	DOUBLE-BLIND	END POINT (DB)	300	19.7	15.4	48.5	NORMAL		34.5	NORMAL	NORMAL to NORMAL
10	RUN-IN	OPEN-LABEL	BSLN (OPEN)	300	19.7	15.4	48.5	NORMAL		34.5	NORMAL	NORMAL to NORMAL
11	RUN-IN	OPEN-LABEL	WK 24 (OPEN)	350	28.1	15.4	48.5	NORMAL		34.5	NORMAL	NORMAL to NORMAL
12	RUN-IN	OPEN-LABEL	END POINT (OPEN)	350	28.1	15.4	48.5	NORMAL		34.5	NORMAL	NORMAL to NORMAL
13	DBL-BLIND	DOUBLE-BLIND	BSLN (DB)	200	13.1	15.4	48.5	LOW	Y	13.1	LOW	
14	DBL-BLIND	DOUBLE-BLIND	WK 12 (DB)	295	13.7	15.4	48.5	LOW		13.1	LOW	LOW to LOW
15	DBL-BLIND	DOUBLE-BLIND	WK 12 (DB)	300	19.7	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
16	DBL-BLIND	DOUBLE-BLIND	END POINT (DB)	300	19.7	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
17	DBL-BLIND	OPEN-LABEL	BSLN (OPEN)	300	19.7	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
18	DBL-BLIND	OPEN-LABEL	WK 24 (OPEN)	350	28.1	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
19	DBL-BLIND	OPEN-LABEL	END POINT (OPEN)	350	28.1	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
20	OPEN-LABEL	OPEN-LABEL	BSLN (OPEN)	300	19.7	15.4	48.5	NORMAL	Y	19.7	NORMAL	
21	OPEN-LABEL	OPEN-LABEL	WK 24 (OPEN)	350	28.1	15.4	48.5	NORMAL		19.7	NORMAL	NORMAL to NORMAL
22	OPEN-LABEL	OPEN-LABEL	END POINT (OPEN)	350	28.1	15.4	48.5	NORMAL		19.7	NORMAL	NORMAL to NORMAL

The example in Table 4.2.1.11 supports the ability to analyze shift from the most recent baseline or any prior baseline. In contrast, if it is needed only to have the ability to analyze shift from the most recent baseline, then the dataset does not need as many rows. Table 4.2.1.12 illustrates an arrangement supporting analysis from the most recent baseline only. Because there is more than one definition of baseline, the BASETYPE variable is still needed.
表 4.2.1.12 的例子支持了从基线或者先于基线的变化的分析。对比看来，如果只用分析从最近的一条基线的变化，那这个数据集就不需要那么多行。表 4.2.1.12 展示了只需要从最近的基线来分析的情况。因为基线不止一种定义，仍然需要 BASETYPE。

Table 4.2.1.12 Illustration of Rule 6: Creation of New Rows to Handle Multiple Baseline Definitions - Supporting Comparison to Most Recent Baseline

Row	BASETYPE	EPOCH	AVISIT	LBSEQ	AVAL	ANRLO	ANRHI	ANRIND	ABLFL	BASE	BNRIND	SHIFT1
1	RUN-IN	RUN-IN	BSLN (RUN-IN)	111	34.5	15.4	48.5	NORMAL	Y	34.5	NORMAL	
2	RUN-IN	RUN-IN	WK 8 (RUN-IN)	168	11.6	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
3	RUN-IN	RUN-IN	END POINT (RUN-IN)	168	11.6	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
4	RUN-IN	STABILIZATION	WK 14 (STAB.)	200	13.1	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
5	RUN-IN	STABILIZATION	END POINT (STAB.)	200	13.1	15.4	48.5	LOW		34.5	NORMAL	NORMAL to LOW
6	DBL-BLIND	DOUBLE-BLIND	BSLN (DB)	200	13.1	15.4	48.5	LOW	Y	13.1	LOW	
7	DBL-BLIND	DOUBLE-BLIND	WK 12 (DB)	295	13.7	15.4	48.5	LOW		13.1	LOW	LOW to LOW
8	DBL-BLIND	DOUBLE-BLIND	WK 12 (DB)	300	19.7	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
9	DBL-BLIND	DOUBLE-BLIND	END POINT (DB)	300	19.7	15.4	48.5	NORMAL		13.1	LOW	LOW to NORMAL
10	OPEN-LABEL	OPEN-LABEL	BSLN (OPEN)	300	19.7	15.4	48.5	NORMAL	Y	19.7	NORMAL	
11	OPEN-LABEL	OPEN-LABEL	WK 24 (OPEN)	350	28.1	15.4	48.5	NORMAL		19.7	NORMAL	NORMAL to NORMAL
12	OPEN-LABEL	OPEN-LABEL	END POINT (OPEN)	350	28.1	15.4	48.5	NORMAL		19.7	NORMAL	NORMAL to NORMAL

Table 4.2.1.11 and Table 4.2.1.12 illustrate example solutions in the case where different baselines are needed to characterize different portions of a study. In general, however, there might be other reasons that more than one definition of baseline might be needed. It could also be that there are multiple ways to construct a particular baseline value, e.g., last value prior to treatment, average value at the baseline visit, minimum value prior to treatment, etc.
表 4.2.1.11 和 4.2.1.12 示例了如果在试验不同部分需要的不同基线的解决办法。概括说来，然而，不止一个基线定义的其它原因有待说明。也许是由不同方法能构建一个特殊的基线值，比如，治疗前最后一条，基线访视的均值，治疗前的最小（低）值，等等。

For a given parameter, whenever there is more than one definition of baseline, BASETYPE is required and must be populated. For any given parameter and subject, whenever there is more than one definition of baseline, the number of records flagged with ABLFL=Y is equal to the number of values of BASETYPE.
对于一个特定的参数，不管是不是由多于一个的基线定义，BASETYPE 都是必须的而且必须被填充。对于任意特定参数和受试者，不管是不是基线的定义有多种，被标帜为 ABLFL=Y 的记录数必须和 BASETYPE 的值相同。

4.3 Inclusion of All Observed and Derived Records for a Parameter versus the Subset of Records Used for Analysis

4.3 参数中全部观测值与派生值纳入分析 VS 仅用记录值子集纳入分析

This section discusses whether the ADaM dataset should include all rows of an analysis parameter, or only the subset of rows that are used for analysis. A value of AVAL or AVALC for an analysis parameter at a specific timepoint may be observed (i.e., collected on the case report form or in an electronic diary at that timepoint), it may be imputed because it was missing, or it may be derived from a combination of other values.
本章节将讨论 ADaM 数据集是否应该包括一个参数的所有观测行或是仅仅这些行的子集用于分析。某个参数在特定时间点的值 AVAL 或 AVALC 可以是被观测的（例如在那个时间点收集的病例报告表的数据或者电子日记的数据），也可以是被填补的缺失值，还可以是综合其他几个值获得的。

To illustrate the issue being presented, assume that the total scores for Questionnaire A (administered at Visits 1, 2, and 3) are in the SDTM QS dataset as illustrated below. Any missing total scores are imputed by carrying the last post-baseline (post-Visit 1) total score forward. The total score for visit 3 will be analyzed.
为了说明存在的问题，假设问题 A（回答于访视 1，2，3）的总分存在于 SDTM 的 QS 数据集中，如下所示。任何缺失的总分都会用基线之后（访视 1 之后）的最近一次总分填补。将会用访视 3 的总分进行分析。

In the SDTM QS dataset data shown below, subject 0001 has data for visits 1, 2, and 3; subject 0002 will not be included in the analysis, as there are no post-baseline data for the subject; subject 0003 has data for visits 1 and 2, but is missing data for visit 3.
在如下所示的 SDTM QS 数据中，受试者 0001 在访视 1，2，3 都有数据；受试者 0002 因为没有基线之后的数据，所以不会被纳入分析；受试者 0003 在访视 1，2 有数据，但是在访视 3 的数据是缺失的。

Table 4.3.1 Illustration of Issue, Data as Found in SDTM QS Dataset

Row	DOMAIN	USUBJID	VISITNUM	QSSEQ	QSCAT	QSTESTCD	QSSTRESN
1	QS	0001	1	101	QUES-A	TOTSCORE	7
2	QS	0001	2	201	QUES-A	TOTSCORE	12
3	QS	0001	3	555	QUES-A	TOTSCORE	14
4	QS	0002	1	91	QUES-A	TOTSCORE	4
5	QS	0003	1	156	QUES-A	TOTSCORE	2
6	QS	0003	2	300	QUES-A	TOTSCORE	6

表 4.3.1 问题说明, SDTM QS 数据集所示数据

Row	DOMAIN	USUBJID	VISITNUM	QSSEQ	QSCAT	QSTESTCD	QSSTRESN
1	QS	0001	1	101	QUES-A	TOTSCORE	7
2	QS	0001	2	201	QUES-A	TOTSCORE	12
3	QS	0001	3	555	QUES-A	TOTSCORE	14
4	QS	0002	1	91	QUES-A	TOTSCORE	4
5	QS	0003	1	156	QUES-A	TOTSCORE	2
6	QS	0003	2	300	QUES-A	TOTSCORE	6

The questions that arise are whether or not the ADaM dataset should contain data for subject 0002 even though the subject is not included in the analysis and if the ADaM dataset should contain totals for visits 1 and 2 even though the data being analyzed are from visit 3.
所提出的问题是 ADaM 数据集是否应该包含受试者 0002 的数据，尽管该受试者没有被纳入分析；另外 ADaM 数据集是否应该包含访视 1 和访视 2 的总分，尽管所分析的是访视 3 的数据。

4.3.1 ADaM Methodology and Examples

4.3.1 ADaM 方法学和示例

The ADaM methodology is to include all observed and derived rows for a given analysis parameter. The inclusion of all the rows in the ADaM dataset, including those not used in the analysis, requires a way to identify the rows used in the specified analysis. The advantage to this approach is that the inclusion of all rows makes it easier to verify that the selection and derived timepoint processing was done correctly, thus providing useful traceability. In addition, the data are also then available to enable other analyses, including sensitivity analyses. However, this approach increases the size of the dataset, and introduces a risk that the appropriate selection criteria will not be incorporated and thereby generate incorrect analysis results.
ADaM 的方法学是：对于给定的参数，包含所有的观测值与派生值。在 ADaM 数据集中包含所有记录（即使那些不纳入分析的）需要一种方法来指明哪些记录将用于特定的分析。这种方法的优势是可以容易的确认所选择的记录和产生时间点的过程是否正确，从而提供有用的可溯源性。另外，这些数据可以用来进行包含敏感性分析的其他的分析。不过，这种方法会增大数据集的大小，并增加选择不合适的条件进而产生错误的分析结果的风险。

Regulatory reviewers prefer that the path followed in creating and/or selecting analysis rows be clearly delineated and traceable all the way back to the originating rows in the SDTM dataset, if possible and within reason. Simply including the algorithm in the metadata is often not sufficient, as any complicated data

manipulations may not be clearly identified (e.g., how missing pieces of the input data were handled). Retaining in one dataset all of the observed and derived rows for the analysis parameter provides the clearest traceability in the most flexible manner within the standard BDS. The resulting dataset also provides the most flexibility for testing the robustness of an analysis (e.g., using a different imputation method).
在可能且合理的情况下，监管层审阅者更希望在创建和/或选择分析行时遵循的路径能够被清晰描述，并且可以追溯到 SDTM 数据集中的原始数据行。仅仅在元数据中简单包含算法是不足的，因为一些复杂的数据整合很难被清楚的说明（例如输入数据里的缺失部分讨论了如何处理）。在标准 BDS 结构下，在一个数据集中保留所有观测值和分析参数的派生值提供了最清晰的可溯源性，同时也是一种最灵活的方式。结果数据集也提供了最大的灵活度来测试分析稳健性（例如使用不同的填补方法）。aq

Example 1
示例 1
In the example discussed above (Table 4.3.1), the ADaM dataset would contain the following rows (Table 4.3.1.1) for the total score parameter:
在上文讨论的示例中（表 4.3.1），对于总分这一参数，ADaM 数据集应该包含如下的行（表 4.3.1.1）。

Table 4.3.1.1 Example 1: ADaM Dataset
表 4.3.1.1 示例 1： ADaM 数据集

Row	PARAMCD	USUBJID	VISITNUM	AVISITN	AVISIT	AVAL	DTYPE	QSSEQ
1	TOTSCORE	0001	1	1	Visit 1	7		101
2	TOTSCORE	0001	2	2	Visit 2	12		201
3	TOTSCORE	0001	3	3	Visit 3	14		555
4	TOTSCORE	0002	1	1	Visit 1	4		91
5	TOTSCORE	0003	1	1	Visit 1	2		156
6	TOTSCORE	0003	2	2	Visit 2	6		300
7	TOTSCORE	0003	2	3	Visit 3	6	LOCF	300

For the analysis discussed above, the data to be analyzed are selected by specifying that AVISITN = 3 (or AVISIT=Visit 3).
对于上文讨论的分析，通过指定 AVISITN=3（或者 AVISIT=访视 3）来选择需要分析的数据。

It should be noted that this approach does not require the inclusion of all rows from the input dataset. For example, if the input dataset contains data for several different questionnaires, the extraneous data (e.g., for questionnaires other than the one being addressed) do not have to be included in the ADaM dataset.
需要注意的是这种方法不需要包括输入数据集中的所有行数。例如输入数据集包含了多个问题的的数据，多余的数据（例如未涉及的问题）不需要被纳入 ADaM 数据集。

Example 2
示例 2
In the following example (Table 4.3.1.2 and Table 4.3.1.3), the Q01 assessment is scheduled to be performed at visits 1, 3, 5, and 7, and results are to be summarized at those visits. Subject 1099 has data for the assessment at visits 1, 2, and 7. (Note that though the assessment was not scheduled to be performed at Visit 2, the data show the assessment was performed at that time for that subject.) Subject 2001 is not in the Full Analysis Set. Subject 3023 has two assessments at visit 5, and the study's analysis plan specifies that only the first occurrence within a visit will be analyzed; however, as this subject does not have a visit 7 row in the data, the later of the visit 5 rows is carried forward into visit 7. The SDTM dataset that is the basis for the ADaM dataset has the following rows:
在下面的示例中（表 4.3.1.2 和表 4.3.1.3），按照计划会在访视 1，3，5，7 进行 Q01 测量，并对这些访视的结果进行总结。受试者 1099 有访视 1，2，7 的测量值（请注意访视 2 并不在计划之内，但是数据显示该受试者在此时间点进行了测量）。受试者 2001 并不在全分析集中。受试者 3023 在访视 5 有 2 次测量，但试验的计划指明一次访视只有第一次测量会被分析；于此同时，该受试者的数据中并没有访视 7 的结果，访视 5 的较晚一次结果会被结转

进入访视 7。构成 ADaM 数据集的基础的 SDTM 数据集有如下的行：

Table 4.3.1.2 Example 2: Data as Found in SDTM QS Dataset
表 4.3.1.2 示例 2： SDTM QS 数据集所示数据

Row	QSTESTCD	USUBJID	QSSEQ	VISITNUM	VISIT	QSSTRESN	QSDTC
1	Q01	1099	111	1	BASELINE	25	2005-04-04
2	Q01	1099	121	2	VISIT 2	24	2005-05-02
3	Q01	1099	132	7	VISIT 7	15	2005-08-22
4	Q01	2001	150	1	BASELINE	27	2005-02-05
5	Q01	3023	117	1	BASELINE	31	2005-06-30
6	Q01	3023	123	3	VISIT 3	29	2005-07-25
7	Q01	3023	134	5	VISIT 5	28	2005-08-20
8	Q01	3023	135	5	VISIT 5	25	2005-08-21

The ADaM dataset contains rows corresponding to those found in SDTM as well as rows created by LOCF for the missing visit assessments, together with the flags and other columns needed to identify the rows to be included in a given analysis:
ADaM 数据集不仅包含了来自于 SDTM 的数据，也包含了通过 LOCF 方法产生的缺失访视的结果，同时也需要标记变量和其他列来指明哪些行会被纳入分析。

Table 4.3.1.3 Example 2: ADaM Dataset
表 4.3.1.3 示例 2： ADaM 数据集

Row	PARAMCD	USUBJID	VISITNUM	VISIT	AVISITN	AVISIT	AVAL	DTYPE	ANL01FL	FASFL	QSSEQ
1	Q01	1099	1	BASELINE	1	BASELINE	25		Y	Y	111
2	Q01	1099	2	VISIT 2			24			Y	121
3	Q01	1099	2	VISIT 2	3	VISIT 3	24	LOCF	Y	Y	121
4	Q01	1099	2	VISIT 2	5	VISIT 5	24	LOCF	Y	Y	121
5	Q01	1099	7	VISIT 7	7	VISIT 7	15		Y	Y	132
6	Q01	2001	1	BASELINE	1	BASELINE	27		Y	N	150
7	Q01	3023	1	BASELINE	1	BASELINE	31		Y	Y	117
8	Q01	3023	3	VISIT 3	3	VISIT 3	29		Y	Y	123
9	Q01	3023	5	VISIT 5	5	VISIT 5	28		Y	Y	134
10	Q01	3023	5	VISIT 5	5	VISIT 5	25			Y	135
11	Q01	3023	5	VISIT 5	7	VISIT 7	25	LOCF	Y	Y	135

Selection criteria applicable to this example include:

- DTYPE null identifies the data as found in the SDTM dataset.
- DTYPE="LOCF" specifies the method used to derive the added rows, and indicates that those rows were derived.
- FASFL="Y" (copied from ADSL) identifies the subjects who are members of the Full Analysis Set.
- ANL01FL="Y" identifies the rows chosen to represent each AVISIT. There were multiple observations for subject 3023 at AVISITN=5 and therefore in this example, rows with ANL01FL="Y" are the ones that have been chosen to represent their respective analysis timepoints.
- ANL01FL=null for subject 1099 for VISIT="VISIT 2" (row 2) because visit 2 is an unscheduled visit for this questionnaire and Visit 2 will not be presented in the analyses; AVISITN and AVISIT are also null because they do not map to visits used for analyses described in the study's analysis plan.
- The combination of "(ANL01FL="Y" and FASFL="Y" and AVISITN=5)" identifies the rows used in a FAS analysis of Visit 5 data.

本示例所使用的选择条件包含：

- DTYPE 为空表明数据同SDTM数据集
- DTYPE=“LOCF” 指定了用于产生派生行的方法，也同时指明了哪些行是派生的
- FASFL=“Y”（从ADSL复制而来）指明了哪些受试者在全分析集
- ANL01FL=“Y”指明了被选作代表各个访视的行。受试者3023的访视5有多次测量，因此在本示例中，ANL01FL=“Y”的行是被选作代表对应的分析时间点的行。
- 因为对于该问卷而言，访视2是一次计划外访视并且不会在分析中体现，所以对于受试者1099的VISIT=“访视2”(第2行) ANL01FL=空；AVISITN 与 AVISIT也都是空，因为根据试验分析计划，访视2不会用于分析。
- “(ANL01FL=“Y” and FASFL=“Y” and AVISITN=5)”的组合指明这些行将用于全分析集中访视5的数据。

Approaches Considered and Not Adopted
考虑到但未采用的方法

The other approach considered was to include in the ADaM dataset only the rows that are actually used in the analysis of the analysis parameter. In Example 1 above, only Visit 3 rows that were either observed or derived by LOCF would be included in the ADaM dataset. The main advantage of this approach would be to simplify the analysis, as no selection clause would need to be used to identify the appropriate rows for inclusion in the analysis. However, the primary disadvantages would be the loss of traceability and the loss of flexibility for testing the robustness of the analysis. Because of these disadvantages, this approach was not chosen.
另外一种考虑到的方法是在 ADaM 数据集中只包含实际用于该参数分析的行。在上面的示例 1 中，只有观测到的或者通过 LOCF 方法派生的访视 3 数据行会被纳入 ADaM 数据集。这种方法的主要优势的使分析简单化，因为不需要选择语句来判断哪些合适的行纳入于分析。不过，主要的缺点是会损失可溯源性与测试分析稳健度的灵活性。因为这些缺点，这种方法未被选择。

4.4 Inclusion of Input Data that are not Analyzed but that Support a Derivation in the ADaM Dataset

4.4 不会被分析但是辅助派生 ADaM 数据集的输入数据的纳入

Section 4.3 states that for a given analysis parameter, all observed and derived rows of that parameter should be included in the dataset, not just the rows that are used in the analysis. Section 4.3 is a simple case of a more general topic addressed here in Section 4.4.
章节 4.3 说明了对于给定的分析参数，所有的该参数观测到的和派生的行都会被纳入数据集，并不仅是纳入用于分析的行。章节 4.3 是该章节 4.4 讨论的更一般主题的一种简单情况。

This section addresses the broader issue of whether an ADaM dataset should contain the input data used in the derivation of the analysis data as well as the actual data being analyzed. This includes:

- Input data rows and columns to support traceability of the derivation of analyzed rows and columns, and
- Raw or derived predecessor parameters that are not analyzed themselves but are used to derive an analyzed parameter.

本章节讨论了 ADaM 数据集是否应该包含实际分析到的数据和用于产生派生值的输入数据的更广泛的问题。包括

- 输入数据行列，以支持用于分析的派生行列的可溯源性，与
- 原始或派生的中间参数（本身不用于分析但用于产生分析参数）。

The above input data rows and columns could come from one SDTM dataset or multiple datasets as necessary to derive the analysis data captured in AVAL or AVALC, as described by the analysis parameter.

根据生成的分析数据(在 AVAL 或 AVALC 体现)需求，按照分析参数的定义，上面的输入数据的行列可以来自于一个 SDTM 数据集中或多个数据集。

4.4.1 ADaM Methodology and Examples

4.4.1 ADaM 方法学与示例

ADaM datasets are developed to facilitate intended analyses. In the ADaM model, it is assumed that the original data sources for ADaM datasets are SDTM datasets, even when ADaM datasets are derived from other ADaM datasets. ADaM has features that enable traceability from analysis results to ADaM datasets and from ADaM datasets to SDTM datasets.
建立 ADaM 数据集以便于预期的分析。在 ADaM 模型中，假设 ADaM 数据集的原始数据来源是 SDTM 数据集，即使 ADaM 数据集是从其他 ADaM 数据集派生而来。ADaM 有一种特性-可以从分析结果溯源到 ADaM 数据集，进而从 ADaM 数据集溯源到 SDTM 数据集。

The ADaM methodology to achieve the expected traceability is to describe the derivation algorithms in the metadata and, if practical and feasible, to include supportive *rows* as appropriate for traceability. To include the input data as rows in the ADaM dataset, columns should be added where feasible to indicate the

source of the input data – domain, variable name, and sequence number. While this methodology increases both the size of the dataset and the complexity of selecting the appropriate rows for analysis, it also provides input data in an immediately accessible manner. In addition, intermediate values can be retained if appropriate flags are used to distinguish them.
为了实现这种期望的可溯源性，ADaM 的方法学是在元数据中描述这种派生算法，并且如果实际可行的话，纳入合适的辅助行来增加可溯源性。为了在 ADaM 数据集纳入这些输入数据作为行，应在合适的位置增加一些列来指明输入数据的来源-域，变量名和顺序号。虽然这种方法增加了数据的文件大小，并增加了选择用于分析的合适行的复杂性，但是它也提供了可以立即解读输入数据的模式。并且，如果有合适的标记变量来区分数据的话，中间数据值也可以保留。

In general, it is strongly recommended to include as much supporting data as is needed for traceability. However, there are situations in which it may not be practical. For example, if an analyzed parameter is a summary derived from a very large number of raw e-diary input records, it may be neither useful nor practical to include all of the raw e-diary records as rows in the ADaM dataset.
一般而言，强烈推荐增加尽可能多的可溯源性所需要的支持数据。但是，有些情况下可能不太实用。例如，一个分析的参数是从非常大量的原始电子日记输入记录中得到的一个总结，此时把所有的原始电子日记记录作为行纳入 ADaM 数据集既无用又不实际。

The remainder of this section addresses cases where the ADaM datasets contain not only the analysis data but also input data that are necessary to provide clearer traceability of the algorithms used to derive the analysis data. In addition to the actual values used in the analysis, the dataset may include rows not used in the analysis, rows containing input data, and rows containing intermediate values computed during the derivation of the analysis data. Flags or other columns are used to distinguish the various data types as well as to provide a traceable path from the input data to the value used in the analysis. The analysis results metadata specify how the appropriate rows are identified (by a specific selection clause). The identification of rows used in an analysis is addressed in Sections 4.5 and 4.6.
本章节剩余部分将讨论 ADaM 数据集既包含分析数据又包含了输入数据，用于产生清楚的可溯源性来跟踪派生这些分析数据的算法。数据集不仅包含用于分析的实际值，也包含了不用于分析的行和派生分析数据过程中计算的中间值的行。标记变量或者其他的列用于区分这些数据集的类型并提供从输入数据到分析数据的可追溯的路径。分析结果的元数据规定了如何识别对应的行(通过特定的选择语句)。这种识别用于分析的行将在章节 4.5 和 4.6 中讨论。

Unless the input data are already present as column(s) on the row (e.g., as covariate(s) or supportive variable(s)), the input data will be retained as rows in the ADaM

dataset. The analysis value column (AVAL and/or AVALC) on the retained input data row will contain a value for the analysis parameter. Not all columns from the input dataset are carried into the ADaM dataset; instead additional variables will be included indicating the source of the input data – domain, variable name, and sequence number. This approach will allow the inclusion of input data from multiple domains. If the input data are already included in columns on the analysis parameter row (e.g., as covariates or supportive information), there is no need to include additional rows for those input data. The decision on keeping the input data as rows or columns will therefore be dictated by the types of input data and whether they are used for other purposes in the ADaM dataset.
除非输入数据已经作为行的列变量（例如协变量或者支持变量），否则输入数据在 ADaM 数据集中依然为行变量。保留的输入数据行的分析值为列变量（AVAL 和/或 AVALC），该列变量包含分析参数的取值。输入数据集中并非所有变量都会纳入 ADaM 数据集中，取而代之的是会使用一些其他变量来指明输入数据的来源-域，变量名和顺序号。这种方法将允许输入数据来源于多个域。如果输入数据已经作为分析参数行的列变量纳入（例如协变量或者支持信息），则不需要纳入这些输入数据的其他行。将输入数据作为行或列保留取决于输入数据的类型和他们在 ADaM 数据集中是否用于其他目的。

Retaining in one dataset all data used in the determination of the analysis parameter value will provide the clearest traceability in the most flexible manner within the standard ADaM BDS. This large dataset also provides the most flexibility for testing the robustness of an analysis.
在标准的 ADaM BDS 模型下，把确定分析参数取值的所有必要数据保留在一个数据集中的方法将提供最清楚最灵活的可溯源性。较大的数据集也可以提供最大程度的灵活性来测试分析的稳健度。

If it is determined that this large dataset is too cumbersome, the producer can choose to provide two datasets, one that contains all rows and another that is a subset of the first, containing only the rows used in the specified analysis. To ensure traceability, the metadata for the subset ADaM dataset will refer back to the full ADaM dataset as the immediate predecessor. Though this approach provides the needed traceability as well as providing a dataset that can be used in an analysis without specifying a selection clause, the total file size is even larger. More importantly, the developer will need to ensure consistency is maintained between the two datasets and validation will need to be done for both datasets. There is also potential confusion about which dataset supported an analysis, if analysis results metadata is not provided for that analysis.
如果经过判断这个较大的数据集太难以处理，建立者可以选择生成 2 个数据集，其中一个包含所有的行，另外一个数据集则是第一个的子集，仅仅包含那些用于特定分析的行。为了确保可溯源性，这个子 ADaM 数据集的元数据将指代回包含全部行的 ADaM 数据集并将其作为中间数据集。尽管这种方法可以提供必需的可溯源性并且在不需要指明选择语句的情况下提供了分析所需的数据集，但是总的文件大小将会更大。更重要的是，建立者需要保证着两个数据集之前的一致性，也需要对这两个数据集都进行检验。另外对于该分析如果不提供分析结果元数据的话，也可能分不清哪个数据集是用作支持分析的。

Example 1
示例 1
An ADaM dataset is created to support time-to-event analysis of a hypertension event. The analysis parameter is the study day of a hypertension event, defined to be the earliest study day among those of the following events: hospital admission, diastolic blood pressure exceeded 90, and systolic blood pressure exceeded 140. If a subject does not experience any of these events, the subject will be analyzed as censored on the day he/she exited the study. 建立一个 ADaM 数据集来支持高血压事件的时间-事件分析。分析的参数是高血压事件发生的研究天数，定义为发生如下事件的最早研究天数：入院，舒张压超过 90 和收缩压超过 140。如果一个受试者没有发生以上事件，该受试者将作为删失处理，研究天数定义为从研究开始到他/她退出研究为止。

Table 4.4.1.1 Example 1: Data as Found in SDTM VS Dataset
表 4.4.1.1 示例 1：SDTM VS 数据集所示数据

Row	USUBJID	VISITNUM	VSSEQ	VSDTC	VSDY	VSTESTCD	VSSTRESN
1	2010	1	22	2004-08-05	1	SYSBP	115
2	2010	1	23	2004-08-05	1	DIABP	75
3	2010	2	101	2004-08-12	8	SYSBP	120
4	2010	2	102	2004-08-12	8	DIABP	90
5	2010	3	207	2004-08-19	15	SYSBP	135
6	2010	3	208	2004-08-19	15	DIABP	92
7	2010	4	238	2004-08-25	21	SYSBP	138
8	2010	4	239	2004-08-25	21	DIABP	95
9	3082	1	27	2004-09-08	1	SYSBP	120
10	3082	1	28	2004-09-08	1	DIABP	80
11	3082	2	119	2004-09-15	8	SYSBP	125
12	3082	2	120	2004-09-15	8	DIABP	84

Table 4.4.1.2 Example 1: Data as Found in SDTM DS Dataset
表 4.4.1.2 示例 1：SDTM DS 数据集所示数据

Row	USUBJID	DSSEQ	DSSTDTC	DSSTDY	DSDECOD	DSTERM
1	2010	25	2004-08-05	1	RANDOMIZED	Subject Randomized
2	2010	301	2004-08-26	22	COMPLETED	Subject Completed
3	3082	20	2004-09-08	1	RANDOMIZED	Subject Randomized
4	3082	130	2004-09-17	10	COMPLETED	Subject Completed

Table 4.4.1.3 Example 1: Data as Found in SDTM HO Dataset
表 4.4.1.3 示例 1：SDTM HO 数据集所示数据

Row	USUBJID	HOSEQ	HOTERM	HODECOD	HOSTDTC	HOENDTC	HOSTDY	HOENDY
1	2010	99	HOSPITAL	HOSPITAL	2004-08-13	2004-08-15	9	11
2	2010	199	HOSPITAL	HOSPITAL	2004-08-20	2004-08-22	16	18

The ADaM dataset contains the sub-event data used to derive the analysis parameter “HYPEREVT”.
ADaM 数据集包含用来派生分析参数“HYPEREVT”的子事件数据。

The ADaM methodology is illustrated in Table 4.4.1.4. Using this methodology, one would include all of the sub-events as analysis parameters (i.e., rows) and create the input domain, input variable, and input sequence columns (SRC* columns) to identify where the input rows came from. AVAL for PARAMCD=“HOSPADM” is the earliest relative day of hospitalization. AVAL for PARAMCD=“DBP” is the earliest relative day that diastolic blood pressure exceeded 90. AVAL for PARAMCD=“SBP” is the earliest relative day that systolic blood pressure exceeded 140. If a subject did not experience a particular sub-event, a row is still created for that sub-event indicating the subject was censored (CNSR=1) on the day the subject exited the study and the SRC* columns reference the DS dataset. AVAL for PARAMCD=“HYPEREVT” is derived as the earliest event of the three: HOSPADM, DBP, and SBP (the minimum AVAL of those three that have CNSR=0 will be the earliest relative day of the three types of events); a subject who meets one of these three conditions has CNSR=0 for PARAMCD=“HYPEREVT” to indicate the subject had an event. If a subject does not meet one of the three conditions (i.e., all three records have CNSR=1), then the subject is censored; that is, AVAL for PARAMCD=“HYPEREVT” is derived as the relative day that the subject exited the study and CNSR=1 is used to indicate the subject is censored. The analysis will focus on HYPEREVT, but HOSPADM, DBP and SBP are included to support traceability, and also to enable future analysis of the sub-events should it be desired. In this example, the SRC* variables were populated for the derived event (PARAMCD=“HYPEREVT”), as described

in Section 3.3.9.

将在表 4.4.1.4 中说明 ADaM 的方法学。应用这种方法，可以包含所有子事件作为分析参数（例如行）并建立输入域，输入变量和输入顺序号（SRC* 列）来说明这些输入行来自于何处。PARAMCD=“HOSPADM”的 AVAL 值是入院的最早相对日。PARAMCD=“DBP”的 AVAL 值是舒张压超过 90 的最早相对日。PARAMCD=“SBP”的 AVAL 值是收缩压超过 140 的最早相对日。如果一个受试者没有经历这些特定子事件，仍会对这些子事件建立对应的一行来说明该受试者删失（CNSR=1）于退出研究的那天,SRC 开头的列则来自于 DS 数据集。PARAMCD=“HYPEREVT”的 AVAL 值是根据以上三个事件 HOSPADM, DBP 和 SBP 的最早记录派生的（CNSR=0 的以上三个事件的最小 AVAL 值将会是三个事件的最早相对日）；一个受试者只要满足三个条件的任意一条并且对于 PARAMCD=“HYPEREVT”有 CNSR=0 的记录则说明该受试者经历一个事件。如果一个受试者全部不满足以上三个条件（例如所有的记录 CNSR=1）则该受试者是删失的，即 PARAMCD=“HYPEREVT”的 AVAL 值派生于该受试者退出研究的相对日，CNSR=1 说明该受试者删失。该分析以 HYPEREVT 为中心，但是 HOSPADM, DBP 和 SBP 也都会纳入来支持可溯源性，并且将来如果需要可以对子事件进行分析。在本例中，对于派生的事件（PARAMCD=“HYPEREVT”，）SRC 开头的变量是填充的，正如章节 3.3.9 中所描述的那样。

The main advantage of this structure is that it can handle sub-event input rows from many domains in only 3 standard supportive columns (i.e., SRCDOM, SRCVAR, and SRCSEQ). This approach is preferred because it is standardized, scalable, and supports analysis of sub-events.

这种结构主要的优势是它仅用三个标准支持变量（例如 SRCDOM, SRCVAR 和 SRCSEQ）就可以处理来自于多个域的子事件。这种方法之所以被推荐是因为它是标准的，可度量的，并支持分析子事件

Table 4.4.1.4 Example 1: ADaM Dataset
表 4.4.1.4 示例 1：ADaM 数据集

Row	USUBJID	PARAM	PARAMCD	AVAL	CNSR	EVNTDESC	SRCDOM	SRCVAR	SRCSEQ
1	2010	Time to First Hospital Admission (day)	HOSPADM	9	0	FIRST HOSPITAL ADMISSION	HO	HOSTDY	99
2	2010	Time to First DBP>90 (day)	DBP	15	0	FIRST DBP>90	VS	VSDY	208
3	2010	Time to First SBP>140 (day)	SBP	22	1	COMPLETED THE STUDY	DS	DSSTDY	301
4	2010	Time to Hypertension Event (day)	HYPEREVT	9	0	HYPERTEN. EVENT	DS	DSSTDY	99
5	3082	Time to First Hospital Admission (day)	HOSPADM	10	1	COMPLETED THE STUDY	DS	DSSTDY	130
6	3082	Time to First DBP>90 (day)	DBP	10	1	COMPLETED THE STUDY	DS	DSSTDY	130
7	3082	Time to First SBP>140 (day)	SBP	10	1	COMPLETED THE STUDY	DS	DSSTDY	130
8	3082	Time to Hypertension Event (day)	HYPEREVT	10	1	COMPLETED THE STUDY	DS	DSSTDY	130

Example 2

The analysis parameter is glomerular filtration rate (GFR) estimated from serum creatinine using the MDRD Equation (Modification of Diet in Renal Disease Study Group). The analysis value for this parameter is derived from plasma creatinine, BUN, and albumin values from the LB dataset, as well as age, race, and sex.

示例 2

该分析参数是肾小球滤过率（GFR）,根据 MDRD 方程(Modification of Diet in Renal Disease Study Group,肾脏疾病膳食改良研究组)基于血清肌酐估算而来。该参数的分析值派生于 LB 数据集的血浆肌酐，BUN 和白蛋白，也用到年龄，种族和性别。

Table 4.4.1.3 Example 2: Data as Found in SDTM LB Dataset
表 4.4.1.3 示例 2：SDTM LB 数据集所示数据

Row	USUBJID	VISITNUM	LBSEQ	LBTEST	LBTESTCD	LBSTRESN	LBSTRESU
1	3000	3	98	Creatinine	CREAT	78.2	micromol/L
2	3000	3	115	Blood Urea Nitrogen	BUN	9.1	mmol/L
3	3000	3	120	Albumin	ALB	40	g/L

Additional rows are not created for the input data age, race, and sex, as they are covariates in the ADaM dataset. The analysis records in Table 4.4.1.4 are identified

by PARAMCD=MDRD_GFR, the parameter code for PARAM = Glomerular Filtration Rate (GFR) (ml/min/1.73m**2). In this example, because all of the data come from a single source dataset (in this example, the LB dataset), the LBSEQ variable is retained for traceability, though it would also be valid to instead use the ADaM SRC variables.

因为输入数据的年龄，种族和性别是 ADaM 数据集中的协变量，所以不需要对它们产生另外的行。在表 4.4.1.4 中通过 PARAMCD=MDRD_GFR 来标记分析记录，对应的参数编码值 PARAM = Glomerular Filtration Rate (GFR) (ml/min/1.73m**2)。在本示例中，因为所有的数据都是来自于单一的源数据（在本例中是 LB 数据集），保留了 LBSEQ 变量来保持可溯源性，尽管也可以使用 ADaM 中的 SRC 变量来代替。

Table 4.4.1.4 Example 2: ADaM Dataset
表 4.4.1.4 示例 2：ADaM 数据集

Row	USUBJID	AGE	SEX	RACE	PARAM	PARAMCD	VISITNUM	AVAL	LBSEQ
1	3000	52	F	ASIAN	Creatinine	CREAT	3	78.2	98
2	3000	52	F	ASIAN	Blood Urea Nitrogen	BUN	3	9.1	115
3	3000	52	F	ASIAN	Albumin	ALB	3	40	120
4	3000	52	F	ASIAN	Glomerular Filtration Rate (GFR) (ml/min/1.73m**2)	MDRD_GFR	3	76.77	

Example 3

An ADaM dataset is created to contain the time to pain relief (ADTTPRLF), based on data in another ADaM dataset (ADPAIN). Pain relief is defined as a reduction in pain from moderate or severe at baseline (i.e., pain severity of at least 2) to mild or no pain (i.e., pain severity of no more than 1), with no use of rescue medication from baseline to that timepoint (i.e., RESCUEFL null at that timepoint and for the subject's records prior to that timepoint). Subjects who do not achieve pain relief are censored at their last pain severity assessment. Missing data are imputed in ADPAIN using LOCF. Because the source dataset is an ADaM dataset, the SRCDOM, SRCVAR, and SRCSEQ variables are used for datapoint traceability.

示例 3

建立一个包含疼痛缓解的 ADaM 数据集（ADTTPRLF）,该数据集是基于另外一个 ADaM 数据集（ADPAIN）。疼痛缓解定义为基线时的中等或严重疼痛（例如疼痛严重等级至少为 2）减少至轻度疼痛或无痛（例如疼痛严重等级不大于 1），并且从基线起至测量时未使用急救药物（例如受试者该时间点及之前的记录中 RESCUEFL 变量为空）。未达到疼痛缓解的受试者删失于该受试者的最后一次疼痛等级测量。运用 LOCF 方法填补 ADPAIN 数据集中的缺失值。因为源数据是 ADaM 数据集，所以应用 SRCDOM, SRCVAR 和 SRCSEQ 变量来保持数据点的可溯源性。

Table 4.4.1.5 Example 3: Data as Found in ADPAIN (Source ADaM Dataset)
表 4.4.1.4.5 示例 3：（源 ADaM 数据集）ADPAIN 所示数据

Row	USUBJID	ASEQ	PARAM	PARAMCD	ATPT	ATPTN	AVAL	AVALC	BASEC	CRIT1	CRIT1FL	DTYPE	RESCUEFL	QSSEQ
1	101-001	1	Pain Severity	SEVERITY	BSLN	0	3	Severe	Severe	Pain relief	N			100
2	101-001	2	Pain Severity	SEVERITY	30 MIN	30	2	Moderate	Severe	Pain relief	N			101
3	101-001	3	Pain Severity	SEVERITY	1 HR	60	1	Mild	Severe	Pain relief	Y			102
4	101-001	4	Pain Severity	SEVERITY	90 MIN	90	1	Mild	Severe	Pain relief	Y			103
5	101-001	5	Pain Severity	SEVERITY	2 HR	120	0	None	Severe	Pain relief	Y			104
6	101-002	1	Pain Severity	SEVERITY	BSLN	0	3	Severe	Severe	Pain relief	N			111
7	101-002	2	Pain Severity	SEVERITY	30 MIN	30	3	Severe	Severe	Pain relief	N			112
8	101-002	3	Pain Severity	SEVERITY	1 HR	60	2	Moderate	Severe	Pain relief	N		Y	113
9	101-002	4	Pain Severity	SEVERITY	90 MIN	90	2	Moderate	Severe	Pain relief	N		Y	114
10	101-002	5	Pain Severity	SEVERITY	2 HR	120	1	Mild	Severe	Pain relief	N		Y	115
11	101-003	1	Pain Severity	SEVERITY	BSLN	0	3	Severe	Severe	Pain relief	N			276
12	101-003	2	Pain Severity	SEVERITY	30 MIN	30	2	Moderate	Severe	Pain relief	N			277
13	101-003	3	Pain Severity	SEVERITY	1 HR	60	1	Mild	Severe	Pain relief	Y			278
14	101-003	4	Pain Severity	SEVERITY	90 MIN	90	1	Mild	Severe	Pain relief	Y	LOCF		278
15	101-003	5	Pain Severity	SEVERITY	2 HR	120	1	Mild	Severe	Pain relief	Y	LOCF		278

Table 4.4.1.6 Example 3: ADaM Dataset ADTTPRLF
表 4.4.1.6 示例 3：ADTTPRLF 数据集

Row	USUBJID	PARAM	PARAMCD	AVAL	CNSR	SRCDOM	SRCVAR	SRCSEQ
1	101-001	Time to First Pain Relief (minutes)	TTPRLF	60	0	ADPAIN	ATPTN	3
2	101-002	Time to First Pain Relief (minutes)	TTPRLF	120	1	ADPAIN	ATPTN	5
3	101-003	Time to First Pain Relief (minutes)	TTPRLF	60	0	ADPAIN	ATPTN	3

Approaches Considered and Not Adopted
考虑到但未采用的方法

A second approach that was considered was to describe the derivation algorithms in metadata and include the input data as columns in the ADaM dataset. Pointer columns would be added to indicate the source of the input data – variable name and sequence number. This option would allow all pertinent input data to be retained on the relevant analyzed row (i.e., all sub-events would be shown on the same row as a compound event), which might help simplify verification of the calculation of the analysis parameter. However, this approach would clearly increase the number of columns in the ADaM dataset and would require naming the variables in a clear and concise manner. The approach also assumes that the only data to be retained are the original input values. Another drawback of this approach is that if there were a need in the future to analyze the sub-events, sub-event parameters would have to be added to have an ADaM-conformant structure supporting the analysis of sub-events. For these reasons, this approach was not chosen.

考虑到的第二种方法是在元数据中描述派生算法并把输入数据作为列变量包含在 ADaM 数据集中。增加指示列来指明输入数据的来源-变量名和顺序号。这种选项将允许所有相关的输入数据保持在对应的分析行中（例如所有的子事件显示在同一行中作为一个复合事件），这种选项可以简单的验证该分析参数的计算过程是否正确。不过，这种方法明显的会增大 ADaM 数据集中的列数量，并需要一个清晰简明的变量命名方式。这种方法也假设唯一需要保留的数据就是原始输入数据。这种方法的另外一个缺点是如果将来需要分析子事件，我们需要在 ADaM 结构中增加子事件的参数来支持该分析。基于以上原因，这种方法未被选择。

A third approach that was considered was to describe the derivation algorithms in metadata and include no input data or identification of the input data in the ADaM dataset. The advantage to this approach would be simplification of the ADaM dataset. However, due to the simplified structure, there would be a loss of traceability between the data collected in the study (i.e., SDTM dataset) and the data analyzed (i.e., ADaM dataset). Unless the derivation algorithms described in the metadata

are straightforward, verification of the analysis data computation could be very challenging or even impossible. This approach should not be used.
第三种考虑到的方法是仅在元数据中描述派生算法，不在 ADaM 数据集中包含输入数据或指明输入数据。这种方法的优势是使 ADaM 数据集简单化。不过，因为这种简单的结构，试验中收集到的数据（例如 SDTM 数据集）与分析数据（例如 ADaM 数据集）之间的可溯源性会损失很多。除非元数据中描述的派生算法非常直接，否则对于分析数据计算的验证将会非常挑战甚至难以完成。所以这种方法未被采用。

4.5 Identification of Rows Used for Analysis

4.5 确定用于分析的数据行

This section addresses how to identify the rows of an ADaM dataset that are used for analysis. The four specific issues addressed include: 1) identification of the rows used in a last observation carried forward (LOCF) analysis; 2) identification of the row containing the baseline value; 3) identification of post-baseline conceptual timepoint rows, such as endpoint, minimum, maximum, or average; and 4) identification of specific rows used in an analysis.
本节描述了如何确定用于分析的 ADaM 数据集的数据行，所讨论的四个具体问题包括：1）确定用于 LOCF（末次观测值结转）分析的数据行； 2）确定包含基线值的数据行； 3）确定基线后的特定时间点数据行，比如终点，最小值，最大值，或平均值； 4）确定用于分析的特定数据行

4.5.1 Identification of Rows Used in a Timepoint Imputation Analysis

4.5.1 确定用于时间点插补分析的数据行

This section considers the issue of how to identify rows used in a timepoint-related imputation analysis as well as how to represent data imputed for missing timepoints in an ADaM dataset. Last observation carried forward (LOCF) is one of the most commonly used timepoint-related imputation analyses, and is therefore specifically mentioned. However, the methodology is general and is not restricted to LOCF analysis. Worst observation carried forward (WOCF) analysis is also mentioned to emphasize the generalizability.

本节描述了在 ADaM 数据集中，如何确定用于时间点相关的插补分析的数据行，以及如何呈现缺失时间点的插补数据。末次观测值结转（LOCF）是时间点相关的插补分析最常用方法之一，因此会特别提到。然而，该方法是通用的，并不局限于 LOCF 分析。为了体现了这种通用性也会提及最差观测值结转（WOCF）。

4.5.1.1 ADaM Methodology and Examples

4.5.1.1 ADaM 方法和例子

When an analysis timepoint is missing, the ADaM methodology is to create a new row in the ADaM dataset to represent the missing timepoint and identify these imputed rows by populating the derivation type variable DTYPE.
当分析时间点缺失时，ADaM 方法是在 ADaM 数据集中创建一个新数据行，以呈现缺失的时间点，并通过填充派生的类型变量 DTYPE 来识别这些新产生的数据行。

For example, when an LOCF/WOCF analysis is being performed, create LOCF/WOCF rows when the LOCF/WOCF analysis timepoints are missing, and identify these imputed rows by populating the derivation type variable DTYPE with values LOCF or WOCF. All of the original rows would have null values in DTYPE. It would be very simple to select the appropriate rows for analysis by selecting DTYPE = null for Data as Observed (DAO) analysis, DTYPE = null or LOCF for LOCF analysis, and DTYPE = null or WOCF for WOCF analysis. This approach would require understanding and communication that if the DTYPE flag were not referenced correctly, the analysis would default to using all rows, including the DAO rows, plus the rows derived by LOCF and WOCF. To perform a correct DAO analysis, one would need to explicitly select DTYPE = null.

例如，当用到 LOCF/WOCF 分析时，如果 LOCF/WOCF 分析时间点缺失时，创建 LOCF/WOCF 数据行，并且通过填充 LOCF 或 WOCF 到派生的类型变量 DTYPE，来识别这些新产生的数据行。所有原始数据 DTYPE 为空。通过筛选 DTYPE 为空的的数据行用于观测数据（DAO）分析，DTYPE 为空或 LOCF 的数据行用于 LOCF 分析，DTYPE 为空或 WOCF 的数据行用于 WOCF 分析，这样就很容易筛选出合适的数据行。这种方法需要理解和商榷的是，如果没有正确引用 DTYPE，将会默认使用所有记录，包括 DAO 记录，加上派生的 LOCF 和 WOCF 记录用于分析。要正确的执行 DAO 分析，需要明确地选择 DTYPE = null。

Example 1
示例 1
Identification of rows used in a LOCF analysis.
确定用于 LOCF 分析的数据行

In the example below (Table 4.5.1.1), some subjects have complete data and others have rows imputed by one method (LOCF). Subjects with no missing data have the observed number of rows with all DTYPE values blank. Subject 1001 has complete data. DTYPE is blank for all rows indicating they are not imputed. AVISIT matches VISIT (from SDTM) in this example. AVISIT does not always match VISIT from SDTM even in scenarios where there is no missing data.
Subject 1002 is missing the Week 2 assessment. Week 2 is imputed using the LOCF method. AVISIT=Week 2 but VISIT=Week 1 so one can see where the imputed value came from in the original data. Subject 1003 is missing Week 2 and 3 data. A Data as Observed (DAO) analysis can be performed by selecting only those rows where DTYPE is null. For a LOCF analysis, all rows (DTYPE=null or DTYPE="LOCF") should be used.

在下面示例（表 4.5.1.1）中，一些受试者有完整的数据，其他受试者有通过一种方法（LOCF）插补的数据行。没有缺失数据的受试者，所有观测到的记录的 DTYPE 值为空。受试者 1001 有完整的数据，其所有数据 DTYPE 为空，表示它们没有被插补。此例中，AVISIT 与 VISIT（来自 SDTM）一致。即使在没有数据缺失的情况下，AVISIT 不是总和 SDTM 的 VISIT 相一致。受试者 1002 缺失 Week 2 评估，Week 2 用 LOCF 方法插补，AVISIT=Week 2 但是 VISIT=Week 1，所以可以看出插补的数据从哪条原始数据来的。受试者 1003 缺失 Week 2 和 Week 3 数据。通过筛选 DTYPE 为空的数据行，进行观测数据（DAO）分析。对 LOCF 分析来说，所有的数据（包括 DTYPE 为空和 DTYPE="LOCF"）都该用于分析。

Table 4.5.1.1 Example 1: ADaM Dataset with Identification of Rows Used in a LOCF Analysis
表 4.5.1.1 示例 1: 具有用于 LOCF 分析的数据行的 ADaM 数据集

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE	VSSEQ
1	1001	Baseline	Baseline	-4	SUPINE SYSBP (mm Hg)	145		171
2	1001	Week 1	Week 1	3	SUPINE SYSBP (mm Hg)	130		191
3	1001	Week 2	Week 2	9	SUPINE SYSBP (mm Hg)	133		201
4	1001	Week 3	Week 3	20	SUPINE SYSBP (mm Hg)	125		211
5	1002	Baseline	Baseline	-1	SUPINE SYSBP (mm Hg)	145		50
6	1002	Week 1	Week 1	7	SUPINE SYSBP (mm Hg)	130		60
7	**1002**	**Week 1**	**Week 2**	**7**	**SUPINE SYSBP (mm Hg)**	**130**	**LOCF**	**60**
8	1002	Week 3	Week 3	22	SUPINE SYSBP (mm Hg)	135		70
9	1003	Baseline	Baseline	1	SUPINE SYSBP (mm Hg)	150		203
10	1003	Week 1	Week 1	8	SUPINE SYSBP (mm Hg)	140		213
11	**1003**	**Week 1**	**Week 2**	**8**	**SUPINE SYSBP (mm Hg)**	**140**	**LOCF**	**213**
12	**1003**	**Week 1**	**Week 3**	**8**	**SUPINE SYSBP (mm Hg)**	**140**	**LOCF**	**213**

Example 2
示例 2
Identification of rows used in both LOCF and WOCF analyses.
确定用于 LOCF 和 WOCF 分析的数据行

This set of rows (Table 4.5.1.2) shows a situation where there is more than one imputation method used. In this case, additional rows are generated for each type of imputation. A DAO analysis can be performed by selecting only those rows where DTYPE is null. For LOCF analysis, all rows with DTYPE=null or DTYPE="LOCF" should be used. For WOCF analysis, all rows with DTYPE=null or DTYPE="WOCF" should be used.
这组数据（表 4.5.1.2）展示了使用不止一种插补方法的情况。在此例中，将为各种类型的插补生成额外的数据行。通过只选择 DTYPE 为空的数据行，可以执行 DAO 分析。对于 LOCF 分析，应该使用所有 DTYPE=Null 或 DTYPE= LOCF 的数据行，对于 WOCF 分析，应该使用所有 DTYPE=Null 或 DTYPE= WOCF 的数据行。

Table 4.5.1.2 Example 2: ADaM Dataset with Identification of Rows Used in Both LOCF and WOCF Analyses
表 4.5.1.2 示例 2: 具有用于 LOCF 和 WOCF 分析的数据行的 ADaM 数据集

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE	VSSEQ
1	1002	Baseline	Baseline	-4	SUPINE SYSBP (mm Hg)	145		77
2	1002	Week 1	Week 1	3	SUPINE SYSBP (mm Hg)	130		78
3	1002	Week 2	Week 2	9	SUPINE SYSBP (mm Hg)	138		79
4	1002	Week 3	Week 3	18	SUPINE SYSBP (mm Hg)	135		80
5	**1002**	**Week 3**	**Week 4**	**18**	**SUPINE SYSBP (mm Hg)**	**135**	**LOCF**	**80**
6	**1002**	**Week 2**	**Week 4**	**9**	**SUPINE SYSBP (mm Hg)**	**138**	**WOCF**	**79**
7	1002	Week 5	Week 5	33	SUPINE SYSBP (mm Hg)	130		81
8	1003	Baseline	Baseline	-1	SUPINE SYSBP (mm Hg)	145		122
9	1003	Week 1	Week 1	7	SUPINE SYSBP (mm Hg)	140		123
10	1003	Week 2	Week 2	15	SUPINE SYSBP (mm Hg)	138		124
11	**1003**	**Week 2**	**Week 3**	**15**	**SUPINE SYSBP (mm Hg)**	**138**	**LOCF**	**124**
12	**1003**	**Week 2**	**Week 4**	**15**	**SUPINE SYSBP (mm Hg)**	**138**	**LOCF**	**124**
13	**1003**	**Week 2**	**Week 5**	**15**	**SUPINE SYSBP (mm Hg)**	**138**	**LOCF**	**124**

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE	VSSEQ
14	1003	Week 1	Week 3	7	SUPINE SYSBP (mm Hg)	140	WOCF	123
15	1003	Week 1	Week 4	7	SUPINE SYSBP (mm Hg)	140	WOCF	123
16	1003	Week 1	Week 5	7	SUPINE SYSBP (mm Hg)	140	WOCF	123

Approaches Considered and Not Adopted
考虑过但是没有采纳的方法

Another approach considered is to create a complete separate set of rows for each analysis type (or a separate dataset), indicating the various analysis types by assigning unique values of the analysis timepoint description AVISIT, e.g., "Week 4", "Week 4 (LOCF)" and "Week 4 (WOCF)". This approach would make it more foolproof to perform the DAO, LOCF, and WOCF analysis in one step by referencing only AVISIT. However, because so many rows would be duplicated, a very large dataset is one of the major disadvantages for this approach. In addition, this approach might be less tool-friendly, in that one might need to parse AVISIT searching for a key substring, e.g., "(LOCF)". This approach should not be used.
考虑的另一种方法是为每个分析类型创建一组完全独立的数据行（或独立的数据集），通过给分析时间点描述变量 AVISIT 赋特定值，来指示各种分析类型，例如，"Week 4"，"Week 4（LOCF）" and"Week 4（WOCF）"。 通过引用 AVISIT 这一个步骤，这种方法使 DAO, LOCF 和 WOCF 分析更加简单明了。然而，由于会有很多重复数据行，会产生一个非常大的数据集，这是主要缺点之一。此外，这种方法可能对工具不太友好，因为可能需要解析 AVISIT 搜索的一个关键子字符串，例如，"（LOCF）"，不应该使用这种方法。

A third approach considered is to create a flag (LOCFFL/LOCFFN) to indicate when a row is created by virtue of last observation carried forward; and similarly for WOCF. This is similar to the specified ADaM methodology, except that a separate flag is created for each derivation type, rather than indicating row derivation type in one column DTYPE. This approach might result in fewer rows than the recommended approach (for example if the WOCF row is the same as the LOCF row). In other respects, this approach shares the advantages and disadvantages of the recommended approach. This approach of creating separate flags for each derivation type is not recommended.
考虑的第三种方法是当一个数据行时通过 LOCF（末次观测值结转）产生时，创建一个标记变量（LOCFFL/LOCFFN）来指示； WOCF 亦然。除了为每个派生类型创建一个单独的标记变量，而不是在 DTYPE 这一列指示派生类型，这种方法与指定的 ADaM 方法类似。这种方法可能比推荐的方法产生更少的数据行（例如，如果 WOCF 行与 LOCF 行相同）。在其他方面，这种方法具有推荐方法相同的优点和缺点。不建议这种为每个派生类型创建单独标志变量的方法。

4.5.2 Identification of Baseline Rows

4.5.2 确定基线数据行

Many statistical analyses require the identification of a baseline value. This section describes how a record used as a baseline is identified.
许多统计分析需要确定基线值，本节描述如何确定用作基线的记录。

4.5.2.1 ADaM Methodology and Examples

4.5.2.1 ADaM 方法和例子

The ADaM methodology is to create a baseline flag column to indicate the row used as baseline (the row whose value of AVAL is used to populate the BASE variable). This method does not require duplication of rows in the event that the baseline row is not derived.

ADaM 方法是创建一个基线标记变量，以指示用作基线的数据行（其 AVAL 值用于填充基线值）。如果基线行不是派生产生的话，此方法不需要重复数据行。

Though a baseline row flag variable ABLFL is created and used to identify the row that is the baseline row, this does not prohibit also providing a row with a unique value of AVISIT, e.g., "Baseline", designating the baseline row used for analysis, even if redundant with another row. For more complicated baseline definitions (functions of multiple rows), a derived baseline row would have to be created as described in Rule 3. This methodology requires that clear metadata be provided for the baseline row variable so that the value can be reproduced accurately.
虽然创建了一个基线行标记变量 ABLFL 并用于标识基线数据行，但这并不禁止产生新的特定 AVISIT 值的数据行，即使与另一数据行重复，例如，'Baseline'，指定用于分析的基线行。对于更复杂的基线定义（多条数据行运行），必须按照规则 3 中描述的那样创建派生的基线数据行。这种方法要求为基线数据行变量提供清楚的元数据，以便能够准确的重复变量值。

Example 1
示例 1
Identification of baseline rows - using screening visit to impute a baseline row.
确定基线行 – 用 screening 访视来插补基线数据行

This example (Table 4.5.2.1) illustrates the use of a baseline flag variable ABLFL. It also illustrates the inclusion of an additional row for a baseline analysis timepoint (row 6). In this example, a unique value of AVISIT has been defined for the baseline record used for analysis. Subject 1001 had complete data. There was no record that qualified as a baseline value for Subject 1002 in the source data. A derived baseline record (AVISIT="Baseline") is added with DTYPE="LVPD" (Last Value Prior to Dosing) to indicate that the record is imputed to be used as baseline.
此例（4.5.2.1），阐释了基线标记变量 ABLFL 的使用。它还阐释了为基线分析时间点纳入额外的一行（第 6 行），在本例中，对用于分析的基线记录定义了特定的 AVISIT 值。受试者 1001 有完整的数据，受试者 1002 在原始数据中没有符合基线值的记录，添加一条派生的基线记录（AVISIT='Baseline'），其 DTYPE = 'LVPD'（给药前的最后一条观测值），表示该记录被插补为基线。

Table 4.5.2.1 Example 1: ADaM Dataset with Identification of Baseline Rows When Imputation is Used
表 4.5.2.1 示例 1， 使用插补时，确定 ADaM 数据集的基线数据行

Row	USUBJID	VISIT	AVISIT	ADY	ABLFL	PARAM	AVAL	BASE	DTYPE	VSSEQ
1	1001	Screening	Screening	-12		SUPINE SYSBP (mm Hg)	144			1
2	1001	Baseline	Baseline	1	Y	SUPINE SYSBP (mm Hg)	145			2
3	1001	Week 1	Week 1	6		SUPINE SYSBP (mm Hg)	130	145		3
4	1001	Week 2	Week 2	12		SUPINE SYSBP (mm Hg)	133	145		4
5	1002	Screening	Screening	-14		SUPINE SYSBP (mm Hg)	144			1
6	**1002**	**Screening**	**Baseline**	**-14**	**Y**	**SUPINE SYSBP (mm Hg)**	**144**		**LVPD**	**1**
7	1002	Week 1	Week 1	8		SUPINE SYSBP (mm Hg)	130	144		2
8	1002	Week 2	Week 2	14		SUPINE SYSBP (mm Hg)	133	144		3

Example 2
示例 2
Identification of baseline rows - using an average of multiple visits to derive a baseline row.
确定基线数据行 – 使用多次访视的平均值来派生基线数据行

This example (Table 4.5.2.2) illustrates the use of a baseline flag variable ABLFL to identify the record used as baseline for analysis in a scenario where the baseline

value is based on the average of the non-missing values collected prior to dosing. Row 3 is a derived "Baseline" record using the average of the values of row 1 and row 2. DTYPE = "AVERAGE" to indicate that row 3 is derived. The Baseline flag (ABLFL="Y") indicates that AVAL from row 3 is used to populate the BASE (Baseline) column. VISIT (from SDTM) is left blank on row 3 since AVAL on that record is not merely a copy of AVAL on another record.
这个例子 （表 4.5.2.2）说明了使用基线标记变量 ABLFL 来确定用于基线分析的记录，在这种情况下，基线值是基于吃药前收集的非缺失值的平均值，第 3 行是使用第 1 行和第 2 行的平均值，派生的一条"Baseline"记录，DTYPE = " AVERAGE "表示第 3 行是派生的。基线标记变量(ABLFL= " Y ")表示第 3 行的 AVAL 用于填充 BASE(Baseline)变量值。第 3 行的 VISIT 变量(来于 SDTM)保留为空值，因为该条记录的 AVAL 值不是仅从其他数据行复制而来的。

Table 4.5.2.2 Example 2: ADaM Dataset with Identification of Baseline Rows When Baseline is an Average
表 4.5.2.2 示例 2 当基线是平均值时，确定 ADaM 数据集的基线数据行

Row	USUBJID	VISIT	AVISIT	ADY	ABLFL	PARAM	AVAL	BASE	DTYPE
1	1001	Screening	Screening	-12		SUPINE SYSBP (mm Hg)	144	144.5	
2	1001	Baseline	Baseline	1		SUPINE SYSBP (mm Hg)	145	144.5	
3	1001		**Baseline**		**Y**	SUPINE SYSBP (mm Hg)	144.5	144.5	**AVERAGE**
4	1001	Week 1	Week 1	12		SUPINE SYSBP (mm Hg)	130	144.5	
5	1001	Week 2	Week 2	-14		SUPINE SYSBP (mm Hg)	133	144.5	

Example 3
示例 3
Identification of baseline rows - using an average of multiple visits to derive a baseline row.
确定基线数据行 - 使用多次访视平均值来派生基线数据行

This example (Table 4.5.2.3) is the same as Example 2 except that the analysis timepoint description "Screening/Baseline Combination" helps differentiate the derived average baseline record from an existing observed record whose timepoint description is "Baseline." This was helpful in analysis and reporting because it was desired to summarize all scheduled visits in addition to the average baseline visit. The analysis was straightforward using the distinct descriptions of AVISIT. The choice of AVISIT values is up to the producer.
此例(表 4.5.2.3)与示例 2 相同，除了分析时间点描述变量 AVISIT 为"Screening/Baseline Combination"，有助于将派生的平均基线记录与现有的观测记录区分开来，观测记录的时间点描述变量 AVISIT 是"Baseline"。这有助于分析和报告，因为除了平均基线访视外，还需要总结所有计划访视。分析因为使用不同描述的 AVISIT 值而直观化。AVISIT 值的选择取决于创建者。

Table 4.5.2.3 Example 3: ADaM Dataset with Identification of Baseline Rows, Including Description in Analysis Timepoint Variable
表 4.5.2.3 示例 3 确定 ADaM 数据集的基线数据行，包括分析时间点变量的描述

Row	USUBJID	VISIT	AVISIT	ADY	ABLFL	PARAM	AVAL	BASE	DTYPE
1	1001	Screening	Screening	-12		SUPINE SYSBP (mm Hg)	144	144.5	
2	1001	Baseline	Baseline	1		SUPINE SYSBP (mm Hg)	145	144.5	
3	1001		**Screening/Baseline Combination**		**Y**	SUPINE SYSBP (mm Hg)	144.5	144.5	**AVERAGE**
4	1001	Week 1	Week 1	12		SUPINE SYSBP (mm Hg)	130	144.5	
5	1001	Week 2	Week 2	-14		SUPINE SYSBP (mm Hg)	133	144.5	

4.5.3 Identification of Post-Baseline Conceptual Timepoint Rows

4.5.3 确定基线后时间点数据行

When analysis involves cross-timepoint derivations such as endpoint, minimum, maximum and average post-baseline, questions such as "Should distinct rows with unique value of AVISIT always be created even if redundant with an observed value record, or should these rows just be flagged?" should be considered. There are two approaches presented in this section.
当分析涉及到交叉时间点的派生，例如终点、最小值、最大值和基线后平均值等，"应该总是创建具有特定 AVISIT 值的不同数据行，即使观测值的记录是重复的，还是应该仅仅标记这些数据行?" 诸如此类的问题需要加以考虑。本节介绍了两种方法。

4.5.3.1 ADaM Methodology and Examples

4.5.3.1 ADaM 方法与实例

The ADaM methodology is to create a new row with a unique value of AVISIT in cases where analysis is based on AVISIT. The advantage of this approach is that it is simple and analysis friendly. It is recognized that such new rows might be redundant with observed rows for some kinds of conceptual timepoint definitions.
ADaM 的方法，是在基于 AVISIT 的分析中，创建具有特定 AVISIT 值的新数据行。这种方法的优点是简单且易于分析。已经认识到的是，从某些概念时间点定义，这些新的数据行与观测到的记录可能是冗余的。
Always creating a row with a unique value of AVISIT designating the row used for analysis (e.g., "Endpoint", "Post-Baseline Minimum", "Post-Baseline Maximum") has the advantage that once the AVISIT values are understood, producers, consumers, and software can rely on these values of AVISIT. This approach represents the general case since any such cross-timepoint derivation can be represented in a new row with a unique AVISIT description. The disadvantage is that the dataset would contain more rows, and conventions would have to be communicated and understood.
总是创建指定用于分析的、有特定 AVISIT 值的新数据行 (例如，"Endpoint", "Post-Baseline Minimum", "Post-Baseline Maximum")，具有这样的优势: 一旦理解了 AVISIT 值，创建者、用户和软件就可以依赖这些 AVISIT 值。这种方法代表了通用情况，因为任何这样的交叉时间点派生都可以用特定的 AVISIT 描述在新数据行中显示。缺点是数据集将包含更多的数据行，按照惯例会需要沟通和理解。

In cases where analysis is not based on AVISIT, then either solution is valid. It is recognized that in cases where the AVISIT values are not defined in the analysis documentation, then adding a flag may be more appropriate. Which methodology is appropriate for situations where an "analysis visit" value is not defined can be driven by how the analysis will be performed. In cases where only a subset of data is analyzed (i.e., only on treatment minimum values), then flagging the values that qualify for analysis might be a better choice than creating an additional row to contain the minimum value. However, where the subset of data is analyzed within the context of a greater pool of data, then creating an additional row to contain the minimum value would help facilitate analysis-ready usage and review.
在不基于 AVISIT 分析的情况下，任何一种解决方案都是有效的。在分析文档中没有定义 AVISIT 值的情况下，添加标记变量可能更合适。在没有定义 "analysis visit"值的情况下，由如何分析来确定适合的方法。在只分析数据子集的情况下(例如，只有治疗的最小值)，然后标记符合分析条件的值， 可能是比创建包含最小值的额外数据行更好的选择。但是，如果数据子集是在更大的数据池中进行分析的，那么创建一个包含最小值的额外数据行将有助于方便分析和检查。

Example 1
示例 1
Identification of endpoint rows.
确定终点数据行

This example (Table 4.5.3.1) shows the creation of an added row with a unique value of AVISIT designating the Endpoint record used for analysis. Subject 1001 discontinued at Week 2, and a derived Endpoint record (AVISIT="Endpoint") is added using the Week 2 visit. DTYPE="LOV" (Last Observed Value) indicates how the AVISIT="Endpoint" record is populated. Subject 1002 did not have any post-baseline visits, and therefore has no Endpoint record.
此例(表 4.5.3.1)，展示了为用于分析的终点记录，创建额外的有特定 AVISIT 值的数据行。受试者 1001 在 Week 2 退出，使用 Week 2 访视，新加派生的终点记录(AVISIT= " Endpoint ")。DTYPE= " LOV "(最后观测到的值)表明 AVISIT= " Endpoint "记录是如何填充的。受试者 1002 没有任何基线后的随访，因此没有终点记录。

Table 4.5.3.1 Example 1: ADaM Dataset with Identification of Endpoint Rows
表 4.5.3.1 示例 1 确定 ADaM 数据集的终点数据行

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE
1	1001	Screening	Screening	-12	SUPINE SYSBP (mm Hg)	144	
2	1001	Baseline	Baseline	1	SUPINE SYSBP (mm Hg)	145	
3	1001	Week 1	Week 1	6	SUPINE SYSBP (mm Hg)	130	
4	1001	Week 2	Week 2	12	SUPINE SYSBP (mm Hg)	133	
5	**1001**	**Week 2**	**Endpoint**	**12**	**SUPINE SYSBP (mm Hg)**	**133**	**LOV**
6	1002	Screening	Screening	-14	SUPINE SYSBP (mm Hg)	144	
7	1002	Baseline	Baseline	-1	SUPINE SYSBP (mm Hg)	144	

Example 2
示例 2
Identification of endpoint and post-baseline minimum, maximum, and average rows.
确定终点和基线后最小值、最大值和平均值的数据行。

This example (Table 4.5.3.2) shows the creation of rows with unique values of AVISIT designating the Endpoint record, and the Post-Baseline Minimum, Maximum, and Average rows. Subject 1001 had minimum post-baseline result at Week 1, maximum post-baseline result at Week 2, and the average post-baseline result was based on the average of Week 1 and Week 2. This subject discontinued at Week 2. A derived Endpoint record (AVISIT="Endpoint") is added using the Week 2 visit. DTYPE="LOV" (last observed value) indicates that the AVISIT="Endpoint" record is a derived record. Subject 1002 did not have any post-baseline visit. Therefore, the Post-Baseline Minimum, Post-Baseline Maximum, Post-Baseline Average, and Endpoint rows could not be derived for that subject.
此例(表 4.5.3.2)，展示了使用特定 AVISIT 值表示终点记录的数据行，以及基线后最小值、最大值和平均值的数据行的创建。受试者 1001 在 Week1 有基线后最小值，在 Week 2 有基线后最大值，基于 Week 1 和 Week 2 的基线后平均值。这个受试者在 Week 2 退出。使用 Week2 访视添加派生的终点记录(AVISIT= " Endpoint ")。DTYPE="LOV"(最后观测到的值)表示 AVISIT="Endpoint"记录是一条派生记录。受试者 1002 没有任何基线后的访问。因此，不能为该受试者派生出基线后最小值、基线后最大值、基线后平均值和终点数据行。

Table 4.5.3.2 Example 2: ADaM Dataset with Identification of Endpoint and Post-Baseline Minimum, Maximum, and Average Rows
表 4.5.3.2 示例 2 确定 ADaM 数据集的终点数据行，基线后最小值，最大值和平均值

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE	VSSEQ
1	1001	Screening	Screening	-12	SUPINE SYSBP (mm Hg)	144		1
2	1001	Baseline	Baseline	1	SUPINE SYSBP (mm Hg)	145		2
3	1001	Week 1	Week 1	6	SUPINE SYSBP (mm Hg)	130		3
4	1001	Week 2	Week 2	12	SUPINE SYSBP (mm Hg)	133		4
5	**1001**	**Week 1**	**Post-Baseline Minimum**	**6**	**SUPINE SYSBP (mm Hg)**	**130**	**Minimum**	**3**
6	**1001**	**Week 2**	**Post-Baseline Maximum**	**12**	**SUPINE SYSBP (mm Hg)**	**133**	**Maximum**	**4**
7	**1001**		**Post-Baseline Average**		**SUPINE SYSBP (mm Hg)**	**131.5**	**Average**	
8	**1001**	**Week 2**	**Endpoint**	**12**	**SUPINE SYSBP (mm Hg)**	**133**	**LOV**	**4**
9	1002	Screening	Screening	-14	SUPINE SYSBP (mm Hg)	144		22
10	1002	Baseline	Baseline	-1	SUPINE SYSBP (mm Hg)	144		23

Example 3
示例 3
Identification of post-baseline minimum and maximum rows.
确定基线后最小值和最大值的数据行

This example (Table 4.5.3.3) shows the identification of the Post-Baseline Minimum and Maximum rows. Subject 1001 had minimum post-baseline result at Week 1 (identified with ANL01FL=Y) and maximum post-baseline result at Week 2 (identified with ANL02FL=Y). Subject 1002 did not have any post-baseline visit. Therefore, the Post-Baseline Minimum and Post-Baseline Maximum could not be identified for that subject.
此例 (表 4.5.3.3)，显示了基线后最小值和最大值数据行的确定。受试者 1001 在 Week 1 有基线后最小值 (标志为 ANL01FL=Y)，在 Week 2 有基线后最大值(标志为 ANL02FL=Y)。受试者 1002 没有任何基线后的访视。因此，无法确定该受试者的基线后最小值和基线后最大值。

Table 4.5.3.3 Example 3: ADaM Dataset with Identification of Post-Baseline Minimum and Maximum Rows
表 4.5.3.3 示例 3 确定 ADaM 数据集的基线后最小值，最大值

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	ANL01FL	ANL02FL
1	1001	Screening	Screening	-12	SUPINE SYSBP (mm Hg)	144		
2	1001	Baseline	Baseline	1	SUPINE SYSBP (mm Hg)	145		
3	1001	Week 1	Week 1	6	SUPINE SYSBP (mm Hg)	130	Y	
4	1001	Week 2	Week 2	12	SUPINE SYSBP (mm Hg)	133		Y
9	1002	Screening	Screening	-14	SUPINE SYSBP (mm Hg)	144		
10	1002	Baseline	Baseline	-1	SUPINE SYSBP (mm Hg)	144		

4.5.4 Identification of Rows Used for Analysis – General Case

4.5.4 确定用于分析的数据行 - 一般情况

It is important to identify the rows used in or excluded from analysis. Should rows used in the analysis be identified via flags or by unique values of analysis timepoint window description AVISIT?
确定分析中使用或排除的数据行是很重要的。是否应该通过标记变量，或者分析时间窗描述的特定 AVISIT 值， 确定分析中使用的数据行?

4.5.4.1 ADaM Methodology and Examples

4.5.4.1 ADaM 方法和例子

The ADaM methodology is to use an analysis flag (ANLzzFL) to indicate the rows that fulfill specific requirements for one or more analyses. For example, ANLzzFL=Y indicates rows meeting the requirements for analysis and is blank (null) in other rows such as a duplicate row that was not the one selected for analysis, or pre-specified post-study timepoints not included in the analysis. This allows multiple rows within a parameter with the same value of AVISIT. However, it also requires flags to be added to the dataset to be used in selecting appropriate rows for analysis. Understanding of the flags is required for correct analysis results to be generated. In addition to ANLzzFL, additional flags might also be required, such as row-based population flags, e.g., ITTRFL and PPROTRFL.
ADaM 的方法是使用一个分析标记变量(ANLzzFL)，来表示满足一个或多个分析的特定需求的数据行。例如，ANLzzFL=Y 表示满足分析需求的数据行，并且在其他数据行中为空(null)，例如没有被选择用于分析的重复数据行，或者在分析中没有包含的预先指定的研究后时间点。这允许在一个参数中有多个相同 AVISIT 值的数据行。但是，它还需要将标记变量加到数据集中，以便为分析选择合适的数据行。为了生成正确的分析结果，需要了解标记变量。除了 ANLzzFL 之外，可能还需要额外的标记变量，例如基于数据行的人口标记变量，如 ITTRFL 和 PPROTRFL。

Please note that there can be multiple ANLzzFL variables. In this case it will be imperative to have clear and robust metadata to indicate the basis for creation and populating of each ANLzzFL variable.
请注意可以有多个 ANLzzFL 变量。在这种情况下，必须有清晰和稳定的元数据来指定创建和填充每个 ANLzzFL 变量的基本原则。

Example 1
示例 1
Identification of rows used for analysis – multiple visits that fall within a visit window.
确定用于分析的数据行-访视窗口内的多次访视。

This example (Table 4.5.4.1) illustrates the use of the analysis flag variable ANLzzFL to indicate the rows that were chosen for analysis from among the multiple visits that fall within the analysis timepoint windows of “Baseline” and “Week 2”. Subject 1001 had two observed Baseline and Week 2 analysis timepoints according to analysis window definitions. The one that is used in analysis is flagged with ANL01FL=Y. This approach is used because all original visits (rows) are included in the dataset, and those selected for analysis must be identified. For traceability reasons, the AWTARGET and AWTDIFF columns are included in order to indicate more clearly how the analyzed rows were selected from among the candidate rows within each analysis window. In this example, the record that falls closest to the scheduled visit day is the one that will be analyzed.
此例(表 4.5.4.1)，阐明了使用用于分析的标记变量 ANLzzFL，来呈现如何从“Baseline”与“Week 2”分析时间窗的多次访视中，选择用于分析的数据行。根据分析窗口的定义，受试者 1001 有 Baseline 和 Week 2 两个观测到的分析时间点。分析中使用的标记为 ANL01FL=Y。之所以使用这种方法，是因为所有原始访视(数据行)都包含在数据集中，并且需要标记被选中用于分析的数据行。为了可追溯性，也包括了 AWTARGET 和 AWTDIFF 列，以便更清楚地说明如何从每个分析窗口中的候选数据行中选择用于分析的记录。在本例中，离计划访视日期最近的记录将被分析。

Table 4.5.4.1 Example 1: ADaM Dataset with Identification of Rows Used for Analysis When Multiple Visits Fall Within a Visit Window
表 4.5.4.1 示例 1：当多次访视落于一个访视窗口时，确定 ADaM 数据集的用于分析的数据行

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE	ANL01FL	AWTARGET	AWTDIFF
1	1001	Screening	Baseline	-5	SUPINE SYSBP (mm Hg)	144			1	5
2	1001	Baseline	Baseline	1	SUPINE SYSBP (mm Hg)	145		Y	1	0
3	1001	Week 1	Week 1	7	SUPINE SYSBP (mm Hg)	130		Y	7	0
4	1001	Week 2	**Week 2**	12	SUPINE SYSBP (mm Hg)	133		Y	14	2
5	1001	Week 3	**Week 2**	17	SUPINE SYSBP (mm Hg)	125			14	3
6	1001	Week 4	Week 4	30	SUPINE SYSBP (mm Hg)	128		Y	28	2

Example 2
示例 2
Identification of rows used for analysis – visit falls outside of a target window.
确定用于分析的数据行 -落于目标窗口外的访视。

In this example (Table 4.5.4.2), the Week 3 visit for subject 1001 was outside the day window of analysis Week 3, so "Post-Study" was assigned to AVISIT. This visit as well as the first baseline visit were excluded from the analysis per the Statistical Analysis Plan. The "Worst Post-Baseline" analysis timepoint (Row was imputed by worst observed case (DTYPE=WOC). The "Endpoint" row was derived using the "Week 2" visit, since it was the last available eligible observation based on the Statistical Analysis Plan. Both of the derived rows are flagged with ANL01FL=Y since they were rows selected for analysis.
在本例(表 4.5.4.2)中，受试者 1001 的 Week 3 访视时间在分析 Week 3 的时间窗之外，因此将" Post-Study"赋值给 AVISIT。根据统计分析计划，这次访视以及第一次基线访视被排除在分析之外。"Worst Post-Baseline"分析时间点(第 6 行)由最坏观测记录(DTYPE=WOC)派生。"Endpoint"数据行是使用"Week 2"访视得出的，因为基于统计分析计划它是最后一个可用的合格观测。两条派生数据行都被标记为 ANL01FL=Y，因为它们被选择用于分析。

Table 4.5.4.2 Example 2: ADaM Dataset with Identification of Rows Used for Analysis When Visit Falls Outside of a Target Window
表 4.5.4.2 示例 2：当访视落于目标访视窗口之外时，确定 ADaM 数据集的用于分析的数据行

Row	USUBJID	VISIT	AVISIT	ADY	VISITDY	PARAM	AVAL	DTYPE	ANL01FL
1	1001	Screening	Baseline	-5	1	SUPINE SYSBP (mm Hg)	144		
2	1001	Baseline	Baseline	1	1	SUPINE SYSBP (mm Hg)	145		Y
3	1001	Week 1	Week 1	7	7	SUPINE SYSBP (mm Hg)	150		Y
4	1001	Week 2	Week 2	12	14	SUPINE SYSBP (mm Hg)	133		Y
5	1001	Week 3	**Post-Study**	**40**	**21**	SUPINE SYSBP (mm Hg)	140		
6	**1001**	**Week 1**	**Worst Post-Baseline**	**7**	**7**	**SUPINE SYSBP (mm Hg)**	**150**	**WOC**	**Y**
7	**1001**	**Week 2**	**Endpoint**	**12**	**14**	**SUPINE SYSBP (mm Hg)**	**133**	**LOV**	**Y**

Example 3
示例 3
Identification of rows used for analysis – a visit not flagged for the analysis is used to create imputed LOCF rows.
确定用于分析的数据行-用没有分析标记的访视创建插补的 LOCF 数据行

This example (Table 4.5.4.3) illustrates a scenario where two visits occur within a window (Week 2). The first record (on row 4) is analyzed as is (it is the record chosen to represent analysis timepoint Week 2 based on an algorithm defined in the SAP and referred to in the metadata of ANL01FL). The second Week 2 timepoint record (on row 5) is the basis for the LOCF derivation of analysis timepoints Week 3, 4 and 5 (rows 6, 7, and 8). In the LOCF analysis, Week 2 is based on the observed data on row 4, and Weeks 3, 4, and 5 are imputed using the last available observation on row 5.
这个例子(表 4.5.4.3)，阐释了两次访视发生在同一时间窗(Week 2)的情形。第一条记录(第 4 行)是按原样进行分析(根据 SAP 中定义的算法，并在元数据的

ANL01FL 中提及) 。第二条 Week 2 (第 5 行)记录是派生 Week 3，Week 4，和 WeeK 5 (第 6、7 和 8 行) LOCF 分析时间点的基础。在 LOCF 分析中, Week 2 是基于第 4 行的观测记录，Week 3， Week 4， Week 5 是使用第 5 行的最后一条可观测的记录派生来的。

Table 4.5.4.3 Example 3: ADaM Dataset with a Value that is Carried Forward but Not Included in the Analysis
表 4.5.4.3 示例 3：ADaM 数据集存在插补而来但不用于分析的记录值

Row	USUBJID	VISIT	AVISIT	ADY	PARAM	AVAL	DTYPE	ANL01FL
1	1001	Screening	Baseline	-5	SUPINE SYSBP (mm Hg)	144		
2	1001	Baseline	Baseline	1	SUPINE SYSBP (mm Hg)	145		Y
3	1001	Week 1	Week 1	7	SUPINE SYSBP (mm Hg)	130		Y
4	**1001**	**Week 2**	**Week 2**	**12**	**SUPINE SYSBP (mm Hg)**	**133**		**Y**
5	**1001**	**Week 3**	**Week 2**	**17**	**SUPINE SYSBP (mm Hg)**	**125**		
6	1001	Week 3	Week 3	17	SUPINE SYSBP (mm Hg)	125	LOCF	Y
7	1001	Week 3	Week 4	17	SUPINE SYSBP (mm Hg)	125	LOCF	Y
8	1001	Week 3	Week 5	17	SUPINE SYSBP (mm Hg)	125	LOCF	Y

Approaches Considered and Not Adopted
考虑过但没有采纳的方法

Another option considered was to create unique values of the timepoint window description AVISIT. For example, add an asterisk to the end of AVISIT such as "Week 2 *" if not analyzed. This approach might be less confusing because one would not need to be aware of a flag. The disadvantage is that one would need to have a convention for AVISIT values, and tools would need to parse values of AVISIT for correct results to be generated. For these reasons, this approach was not chosen.

考虑的另一个选项是创建特定的时间点窗口描述 AVISIT 值。例如，如果没有用于分析，在 AVISIT 后面添加星号，例如"Week 2 *"。这种方法可能不那么令人困惑，因为不需要知道标记。缺点是需要约定 AVISIT 值，工具需要解析 AVISIT 值以生成正确的结果。由于这些原因，没有选择这种方法。

4.6 Identification of Population-Specific Analyzed Rows

4.6 特定人群分析行的标识

It is not uncommon in the statistical analysis of clinical trials to conduct analyses based on multiple populations of interest. The population of interest can be defined either at the subject level, the row (measurement) level, or both. For example, when defining an analysis population, a subject may be included in one analysis population such as Intent-to-Treat but may be excluded from another analysis population such as Per-Protocol. Analysis populations may also be defined using characteristics of individual measurements. For example, a measurement that was assessed outside of a pre-specified time window for a particular visit may not be included in a per-protocol visit-level population. In this section, it is assumed that the definition of a row-level analysis population is dependent on the definition of the subject-level population. In other words, if a subject is excluded from the subject-level Per-Protocol population, then none of that subject's rows would be candidates for inclusion within the row-level Per-Protocol population. Given the variety of possible population definitions, the same row in an analysis dataset could be included in one analysis and excluded from another, depending on characteristics of the subject as a whole and the characteristics of the individual measurement. Therefore, the issue becomes how best to select rows for each analysis.

在临床试验的统计分析中常常对多个感兴趣的人群进行分析。感兴趣的人群可以在受试者水平定义，也可以在行（测量）水平定义，或者同时在这两个水平上定义。例如，当定义一个分析人群时，一个受试者可能包含在一个分析人群中，比如意向性治疗人群，但是可能被排除在另一个分析人群比如符合方案人群外。分析人群也可以用单个测量的特征来定。例如一个在事先指定的时间窗之外的特定访视的测量可能不被包括在访视水平的符合方案人群中。在本节中假定行水平分析人群的定义取决于受试者水平人群的定义，换句话说，如果一个受试者被排除在受试者水平的符合方案人群之外，那么这个受试者的所有行都不会被包含在行水平的符合方案人群的分析中。考虑到人群定义的多样性，一个分析数据集中的同一行可能包含在一个分析中但是在另一个分析中被排除，这取决于受试者作为一个整体的特征以及单个测量的特征。因此，这个问题演变为如何最好地为每一种分析选择行。

4.6.1 ADaM Methodology and Examples

4.6.1 ADaM 方法和实例

The ADaM methodology for this analysis issue is to create one ADaM dataset that can be used to perform multiple analyses using population flag variables to identify rows that are used for each type of analysis. An advantage of this approach is that the one ADaM dataset can be used for multiple analyses. Flag variables obviate the need to replicate rows for each type of analysis. This approach promotes efficiency in the operational aspects of electronic submissions, clarity of analyses, and ease in comparing selected values for each population. This approach does, however, require that clear metadata be provided for the flag variables so that each specific analysis can be reproduced accurately. Below are several examples of the use of population flag variables to identify rows used for different analyses.

对于这个分析问题的 ADaM 方法是创建一个可以进行多种分析的分析数据集，用特定人群的指示变量来标识每种分析所用的行。这种做法的好处是只要一个分析数据集就可以进行多种分析，而标志变量的使用不必为每种不同的分析复制相同的行。这提高了电子提交的操作效率，也使得分析很清晰，并且便于 FDA 审阅者对不同人群所选定的值进行比较。但是这个方法也要求为指示变量提供清晰的元数据，才能使每个具体的分析都能精确地再现。下面是使用特定人群指示变量来标识不同分析行的几个例子。

Example 1
例 1：

Use of subject-level flag variables (ITTFL and PPROTFL) and row-level flag variables (ANL01FL and PPROTRFL).
使用受试者水平指示变量（ITTFL 和 PPROTFL）和行（测量）水平指示变量（ANL01FL 和 PPROTRFL）

In some statistical analyses, even if a subject is included in the Per-Protocol population, some or all data for that subject in a particular dataset may not be appropriate for a per-protocol analysis. Consider a situation in HIV studies where a Per-Protocol analysis excludes all data after permanent discontinuation of study medication or addition of other antiretroviral therapy. An example of an ADaM dataset to support this type of analysis is illustrated in Table 4.6.1.1. This ADaM dataset (Table 4.6.1.1) can be used to repeat analyses based on multiple populations of interest either at the subject level or at the row (measurement) level.
在一些统计分析中，即使一个受试者被包括在符合方案人群中，在一个特定数据集中那个受试者的一些或全部数据可能并不适合做符合方案分析。考虑 HIV 研究中的一种情况，其中一个符合方案分析排除了永久中止研究药物或添加其他抗逆转录病毒治疗之后的所有数据。表 4.6.1.1 是支持这种分析的一个 ADaM 数据集的例子。这个 ADaM 数据集（表 4.6.1.1）能对多个感兴趣人群进行重复分析，分析可以在受试者水平进行，也可以在行（测量）水平进行。

ITTFL and PPROTFL are subject-level analysis population flags. If a subject is in the Intent-to-Treat population, then the column ITTFL will have the value of "Y" ("N" if not). In Table 4.6.1.1, subjects 1001, 1002, and 1003 are in the Intent-to-Treat population. Similarly, if a subject is in the Per-Protocol population, the column PPROTFL will have the value of "Y" ("N" if not). Subjects 1001 and 1003 in Table 4.6.1.1 are in the Per-Protocol population while subject 1002 with PPROTFL=N is excluded from any Per-Protocol analysis. These indicator variables are used to identify individual subjects that belong to each subject-level population.
ITTFL 和 PPROTFL 是受试者水平的分析人群标志。如果一个受试者属于意向性治疗人群，那么 ITTFL 列值将为"是"（如果不是则为"否"）。在表 4.6.1.1 中，受试者 1001，1002 和 1003 属于意向性治疗人群。与此相似，如果一个受试者属于符合方案人群，则 PPROTFL 列值将为"是"（如果不是则为"否"）。在表 4.6.1.1 受试者 1001 和 1003 属于符合方案集，而 PPROTFL=否的受试者 1002 被排除在任何符合方案分析之外。这些指示变量用来标识每个受试者属于哪个受试者水平的人群。

In contrast to the subject-level population flags, the column PPROTRFL is the per-protocol analysis flag at the row level. As illustrated in Table 4.6.1.1, if a row is a candidate for the Per-Protocol analysis, the variable PPROTRFL is set to "Y", it is null if the row does not fulfill the criteria for this analysis. In the example, subjects 1001 and 1002 continue with study medication after Week 2; the last dose of study medication for subject 1003 is at Week 1. In Table 4.6.1.1, all three rows for subject 1002 and two of four rows for subject 1003 are not row-level Per-Protocol data and would not be selected for a Per-Protocol analysis when we apply the subset condition: PPROTRFL="Y". PPROTRFL is null on the last two rows for subject 1003 and will be excluded from any row-level Per-Protocol data analysis as they occur after the subject discontinued study medication.
与受试者水平的人群标志相比，列 PPROTRFL 是行水平的符合方案分析标志。如表 4.6.1.1 所示，如果一行适合作符合方案分析，变量 PPROTRFL 值被设为"是"，如果不满足此分析的条件，变量 PPROTRFL 值为空（null）。在这个例子中,受试者 1001 和 1002 在第 2 周后继续研究药物给药；受试者 1003 的最后一次研究药物给药在第 1 周。在表 4.6.1.1 中，受试者 1002 的全部三条记录以及受试者 1003 四条记录中的两条不是行水平的符合方案数据，当我们应用子集条件：PPROTRFL="是"时这些记录不会被选中。对于受试者 1003 的最后两条记录，PPROTRFL 为空，由于这些记录发生在受试者中止研究用药之后其会被排除在任何行水平的符合方案数据分析之外。

Not all rows in Table 4.6.1.1 are included for analysis purposes. In this example, the analysis flag ANL01FL is null for one row (USUBJID=1003, VISIT=Week 1, AVISIT=Week 1, AVAL=999) because its value was replaced by the retest result in the next row (USUBJID=1003, VISIT=Retest, AVISIT=Week 1, AVAL=49). The analysis flag for the Retest record is Y.

不是表 4.6.1.1 的所有行都用于分析。此例中，分析行标志 ANL01FL 有一行为空（USUBJID=1003, VISIT=第 1 周, AVISIT=第 1 周，AVAL=999），因为它的值被下一行的重新检测结果代替（USUBJID=1003, VISIT=重新检测, AVISIT=第 1 周, AVAL=49）， 重新检查记录的分析标志为“是”。

Table 4.6.1.1 Example 1: ADaM Dataset with Subject-Level and Row-Level Indicator Variables

Row	USUBJID	ITTFL	PPROTFL	VISIT	AVISIT	PARAMCD	AVAL	ANL01FL	PPROTRFL
1	1001	Y	Y	Week 0	Week 0	TEST1	500	Y	Y
2	1001	Y	Y	Week 1	Week 1	TEST1	400	Y	Y
3	1001	Y	Y	Week 2	Week 2	TEST1	600	Y	Y
4	1002	Y	N	Week 0	Week 0	TEST1	500	Y	
5	1002	Y	N	Week 2	Week 1	TEST1	48	Y	
6	1002	Y	N	Week 2	Week 2	TEST1	46	Y	
7	1003	Y	Y	Week 0	Week 0	TEST1	999	Y	Y
8	1003	Y	Y	Week 1	Week 1	TEST1	999		Y
9	1003	Y	Y	Retest	Week 1	TEST1	49	Y	
10	1003	Y	Y	Week 2	Week 2	TEST1	499	Y	

表 4.6.1.1 例 1: 具有受试者水平和行水平指示变量的分析数据集

行	USUBJID	ITTFL	PPROTFL	VISIT	AVISIT	PARAMCD	AVAL	ANL01FL	PPROTRFL
1	1001	是	是	第 0 周	第 0 周	检测 1	500	是	是
2	1001	是	是	第 1 周	第 1 周	检测 1	400	是	是
3	1001	是	是	第 2 周	第 2 周	检测 1	600	是	是
4	1002	是	否	第 0 周	第 0 周	检测 1	500	是	
5	1002	是	否	第 2 周	第 1 周	检测 1	48	是	
6	1002	是	否	第 2 周	第 2 周	检测 1	46	是	
7	1003	是	是	第 0 周	第 0 周	检测 1	999	是	是
8	1003	是	是	第 1 周	第 1 周	检测 1	999		是
9	1003	是	是	重新检测	第 1 周	检测 1	49	是	
10	1003	是	是	第 2 周	第 2 周	检测 1	499	是	

To identify rows used for an Intent-to-Treat analysis for parameter code “TEST1” at Week 1 requires the following selection specification:

AVISIT=“Week 1” & PARAMCD=“TEST1” & ANL01FL=“Y” & ITTFL=“Y”

Similarly, to identify rows used for a Per-Protocol analysis of values of for parameter code “TEST1” at Week 1 requires the following selection specification:

AVISIT=“Week 1” & PARAMCD=“TEST1” & ANL01FL=“Y” & PPROTRFL="Y"

Since an error in the specification of the selection for either of the above conditions will yield incorrect results, it is important that the metadata be clear for each indicator variable. In addition, ADaM analysis results metadata will specify the selection criteria to provide clear documentation of how the indicator variables were used to select analyzed rows for identified analyses.

要标识第 1 周时参数编码为“检测 1”的意向性治疗分析的那些行，只需要如下的选择条件：

AVISIT=“第 1 周” & PARAMCD=“检测 1” & ANL01FL=“是” & ITTFL=“是”

相似地，为了标识第 1 周时参数编码为“检测 1”的符合方案分析的值的那些行，只需要如下的选择条件：

AVISIT=“第 1 周” & PARAMCD=“检测 1” & ANL01FL=“是” & PPROTRFL =“是”

因为上述两种情况下只要选择条件一出错，都将会产生不正确的结果，所以对每个指示变量来说，其元数据要很清楚。另外，ADaM 分析结果元数据中会指定选择条件，以对某分析是如何用指示变量来选择分析所用的行提供清楚的文档说明。

Example 2
例 2：
Use of subject-level indicator variables and parameter-level indicator variables.
使用受试者水平指示变量和参数水平指示变量。

For the purposes of this example, it is assumed that the producer's statistical analysis plan included a definition of an efficacy analysis population, defining it as consisting of subjects with a baseline efficacy assessment and at least one post-baseline efficacy assessment, without restriction to a specific assessment. In this example, there are two efficacy parameters (Test 1 and Test 2), and three visits (Week -1, Baseline, and Week 2). Subjects have results for the assessments as noted in Table 4.6.1.2.
对于这个例子，假定申办者的统计分析计划包括疗效分析人群的定义,将它定义为由有基线疗效评估和至少一个基线后疗效评估的受试者组成,没有限制到一个特定的评估。在这个例子中,有两个疗效参数(检测 1 和检测 2),和三个访视(第 1 周、基线和第 2 周)。受试者的评估结果见表 4.6.1.2。

Table 4.6.1.2 Example 2: Data available for each subject in illustration

Subject	Does Subject have a Baseline TEST 1 Assessment?	Does Subject have a Post-Baseline TEST 1 Assessment?	EFFPFL for TEST1	Does Subject have a Baseline TEST 2 Assessment?	Does Subject have a Post-Baseline TEST 2 Assessment?	EFFPFL for TEST2	EFFFL
1001	Y	Y	Y	Y	Y	Y	Y
1002	Y	Y	Y	N	N		Y
1003	Y	N		Y	Y	Y	Y
1004	Y	N		Y	N		N

表 4.6.1.2 例 2:受试者数据说明

受试者	受试者有基线检测 1 评估吗？	受试者有基线后检测 1 评估吗？	关于检测 1 的 EFFPFL	受试者有基线检测 2 评估吗？	受试者有基线后检测 2 评估吗？	关于检测 2 的 EFFPFL	EFFFL
1001	是	是	是	是	是	是	是
1002	是	是	是	否	否		是
1003	是	否		是	是	是	是
1004	是	否		是	否		否

In contrast to subject-level population flags, the column EFFPFL is a parameter-level population flag. A subject is included in the efficacy analysis population for a specific parameter if the subject has a baseline efficacy assessment and at least one post-baseline efficacy assessment for that parameter. If a subject is eligible for the efficacy analysis for the specific parameter, the variable EFFPFL is set to "Y" for the subject's records within the parameter; it is null if the subject is not a candidate for the analysis of the parameter. In Table 4.6.1.3, the efficacy analysis population for TEST1 includes subjects 1001 and 1002; the efficacy analysis population for TEST2 includes subjects 1001 and 1003.
与受试者水平的人群标志相比，列 EFFPFL 是参数水平人群标志。如果一名受试者对于某个参数有基线疗效评估和至少一个基线后疗效评估，这名受试者就会被包含在这一参数的疗效分析人群。如果一名受试者符合特定参数疗效分析的条件，那么对于该受试者此参数对应的记录变量 EFFPFL 值被设为

“是”，如果不满足这一参数的分析条件，变量 EFFPFL 值为空（null）。在表 4.6.1.3 中，受试者 1001 和 1002 属于检测 1 的疗效分析人群；受试者 1001 和 1003 属于检测 2 的疗效分析人群。

Table 4.6.1.3 Example 2: ADaM Dataset with Subject-Level and Parameter-Level Indicator Variables

Row	USUBJID	EFFFL	AVISIT	PARAMCD	AVAL	EFFPFL
1	1001	Y	Wk -1	TEST1	500	Y
2	1001	Y	Bsln	TEST1	500	Y
3	1001	Y	Wk 2	TEST1	600	Y
4	1001	Y	Wk -1	TEST2	10	Y
5	1001	Y	Bsln	TEST2	10	Y
6	1001	Y	Wk 2	TEST2	12	Y
7	1002	Y	Wk -1	TEST1	500	Y
8	1002	Y	Bsln	TEST1	500	Y
9	1002	Y	Wk 2	TEST1	46	Y
10	1002	Y	Wk -1	TEST2	11	
11	1003	Y	Wk -1	TEST1	780	
12	1003	Y	Bsln	TEST1	799	
13	1003	Y	Wk -1	TEST2	28	Y
14	1003	Y	Bsln	TEST2	30	Y
15	1003	Y	Wk 2	TEST2	32	Y
16	1004	N	Wk -1	TEST1	250	
17	1004	N	Bsln	TEST1	300	
18	1004	N	Wk -1	TEST2	15	
19	1004	N	Bsln	TEST2	15	

表 4.6.1.3 例 2:具有受试者水平和参数水平指示变量的 ADaM 数据集

行	USUBJID	EFFFL	AVISIT	PARAMCD	AVAL	EFFPFL
1	1001	是	第 1 周	检测 1	500	是
2	1001	是	基线	检测 1	500	是
3	1001	是	第 2 周	检测 1	600	是
4	1001	是	第 1 周	检测 2	10	是
5	1001	是	基线	检测 2	10	是
6	1001	是	第 2 周	检测 2	12	是
7	1002	是	第 1 周	检测 1	500	是
8	1002	是	基线	检测 1	500	是
9	1002	是	第 2 周	检测 1	46	是
10	1002	是	第 1 周	检测 2	11	
11	1003	是	第 1 周	检测 1	780	
12	1003	是	基线	检测 1	799	
13	1003	是	第 1 周	检测 2	28	是
14	1003	是	基线	检测 2	30	是
15	1003	是	第 2 周	检测 2	32	是

行	USUBJID	EFFFL	AVISIT	PARAMCD	AVAL	EFFPFL
16	1004	否	第 1 周	检测 1	250	
17	1004	否	基线	检测 1	300	
18	1004	否	第 1 周	检测 2	15	
19	1004	否	基线	检测 2	15	

4.7 Identification of Rows Which Satisfy a Predefined Criterion for Analysis Purposes

4.7 标识符合预定分析标准的行

For analysis purposes, criteria are often defined to group results based on the collected value's relationship to one or more algorithmic conditions. For example, subjects who had a result greater than five times the upper limit of the normal range or subjects who had a systolic blood pressure value > 160 mmHg with at least a 25 point increase from the BASE value. In addition to creating subgroups of subjects, the categorization of the presence or absence of a criterion is often used in listings, tabular displays or statistical modeling (as a covariate or a response variable).
为了达到分析目的，通常会预先定义一些判断条件或标准，然后根据这些条件将所收集的结果值进行分组。例如， 受试者的测量值超过正常值范围上限的 5 倍或者受试者的收缩压超过 160 mmHg 且与基线值相比增长 25 mmHg 以上。除了用于分组，是否满足某一条件还将用在分析列表和表格的创建上以及统计模型里（作为协变量或者应变量）。

4.7.1 ADaM Methodology and Examples When the Criterion Has Binary Responses

4.7.1 针对判断条件是二分类结果的 ADaM 方法和实例

ADaM methodology provides an analysis criterion variable, CRITy, paired with a criterion evaluation result flag, CRITyFL, to identify whether a criterion is met. These variables are defined in Section 3.3.4. The variables MCRITy and MCRITyML are defined in Section 3.3.4 for use in situations where the criterion can have multiple responses (as opposed to CRITy which has binary responses).
ADaM 方法提供了一个条件变量 CRITy 和一个条件判断结果标记变量 CRITyFL, 来共同识别是否满足某一条件。这两个变量的具体定义在 3.3.4 节。当判断条件有多重应答时，则使用变量 MCRITy 和变量 MCRITyML（不同于 CRITy 只有两类结果），其具体定义在 3.3.4 节。

CRITy is populated with a text description defining the conditions necessary to satisfy the presence of the criterion. The definition of CRITy can use any variable(s) located on the row, and the definition must stay constant across all rows within the same value of PARAM. A complex criterion which draws from multiple rows (different parameters or multiple rows for a single parameter) will require a new PARAM be created (see Example 3 Table 4.7.1.3).
CRITy 包含一段文字描述，用于定义判断条件。CRITy 的定义可以使用同一条记录的任何变量，并且其定义必须在具有相同 PARAM 值的所有行内保持一致。基于多条记录得出的判断条件，需要新增一条带有不同 PARAM 值的记录（见例 3 表 4.7.1.3）。

CRITyFL, "Criterion Evaluation Result Flag", is the character indicator of whether the criterion described in CRITy was met. Variable CRITyFL must be present on the dataset if variable CRITy is present. CRITyFN is permitted if a numeric result flag is needed.

CRITyFL，条件判断结果标记变量，是用于识别 CRITy 定义的条件是否被满足的字符型标记变量。变量 CRITyFL 必须与变量 CRITy 同时存在于数据集中。如果需要数值型的标记变量，允许添加变量 CRITyFN。

ADaM methodology allows the option of only populating CRITy on a row if the CRITy criterion is met for that row (see Example 1 Table 4.7.1.1). In that case, CRITyFL is set to "Y" only if CRITy is populated and is null otherwise. If this option is not used and CRITy is populated on all rows within the parameter (see Example 2 Table 4.7.1.2), then CRITyFL is set to "Y" or "N" or null. The choice of populating CRITy on only the rows where the criteria is met versus on all rows is dependent on the analysis need, as shown in the examples that follow.
ADaM 允许仅在 CRITy 定义的条件被满足的时候才赋值给 CRITy（见例 1 表 4.7.1.1）。在这种情况下，当 CRITy 被赋值时将 CRITyFL 赋值为"Y"，否则 CRITyFL 留空。另一种方式是，无论 CRITy 定义的条件是否被满足，同一参数（PARAM）内所有记录的 CRITy 均被赋值，此时 CRITyFL 可以被赋值为"Y"，"N"或者留空。具体采用哪一种方式，正如后面例子所示，取决于你的分析需求。

CRITy and CRITyFL facilitate subgroup analyses. ADaM methodology does not preclude the addition of rows (in contrast to the addition of multiple CRITy and CRITyFL columns) to the BDS for the criterion CRITy. However, CRITy must be kept constant (if populated) across all rows within the same value of PARAM. CRITy, CRITyFL and CRITyFN are not parameter-invariant in that CRITy can vary across parameters within a dataset, as can the controlled terminology used for the corresponding CRITyFL and CRITyFN. In other words, CRITy for one parameter can be different than CRITy for a different parameter in the same dataset. (See Example 8: Categorical Analysis of Subjects Meeting Hy's Law Criteria in the document "ADaM Examples in Commonly Used Statistical Analysis Methods.")
CRITy 以及 CRITyFL 有助于亚组分析。除了在 BDS 数据集里增加多对 CRITy 和 CRITyFL 变量，ADaM 并不排除为不同的 CRITy 增加新的行。但是 CRITy 的赋值必须在具有相同 PARAM 值的所有行内保持一致。CRITy，CRITyFL 和 CRITyFN 在不同参数间并不是保持恒定不变，同一数据集内不同参数间的 CRITy 可以不同，用于 CRITyFL 和 CRITyFN 的统一术语也是如此。换句话说，针对某一个参数的 CRITy 可以不同于针对另一个参数的 CRITy。（见例 8）

Example 1
例 1：
CRITy populated only when criterion met.
CRITy 仅在满足条件是被赋值。

Using this approach, when a criterion is defined for a PARAM but conditions are not met on a specific row, both CRITy and CRITyFL are set to null. CRITy and CRITyFL are also set to null if one or more missing data inputs to a criterion result in an unevaluable criterion (unevaluability is producer-defined, and is not necessarily triggered by missing data inputs).
采用这种方法时，当对一个 PARAM 定义判断条件时，如果在某一行上条件不满足，CRITy 和 CRITyFL 都留空。如果对某条件有一个或多个输入数据缺失而导致条件无法进行判断时（是否无法判断是申办者定义的， 并不一定由输入数据缺失引起），CRITy 和 CRITyFL 也都被留空。

One purpose of this option is to facilitate subsetting within a parameter when the interest is in the subgroup of subjects who fulfilled the criterion. It is also relevant when simple counts of criteria are desired. The following conditions must be true when this option is used:

1. Variables CRITy and CRITyFL are present on the dataset;
2. Analysis Variable Metadata defines CRITy relative to the specific parameter;
3. CRITy and CRITyFL are set to null for rows within the parameter where the criterion is not met or is unevaluable.

这样做的目的是当对满足某一条件的亚人群感兴趣时，根据某个参数进行亚分组分析很方便。当需要得到符合条件的简单计数时，这种方法也是有用的。采用这种方法时下面的条件必须成立:

1.变量 CRITy 和 CRITyFL 都同时存在于数据集中。
2.分析变量元数据根据特定的参数来定义 CRITy。
3.当条件不满足或不可评估时，CRITy 和 CRITyFL 被设为空值。

Table 4.7.1.1 illustrates ADaM methodology option "CRITy populated only when criterion met". The presence of a value in CRIT1 indicates Subject 1001 satisfied the criterion. With this option, CRIT1 facilitates subsetting when the interest is in the subgroup of subjects who fulfilled the criterion. The null value in CRIT1 is because Subject 1002 did not satisfy the criterion. The null value in CRIT1 is because the criterion is unevaluable due to missing inputs for Subject 1003.
表 4.7.1.1 举例说明了这种方法 "只在条件满足时赋值 CRITy"。CRIT1 被赋值表明受试者 1001 满足该条件。当对满足条件的受试者亚组感兴趣时，采用这种方法便于利用变量 CRIT1 进行分组。因为受试者 1002 不满足这个条件，所以 CRIT1 的值为空。对于受试者 1003 来说，CRIT1 的值为空是因为缺少输入数据而使条件无法评估。

Table 4.7.1.1 Example 1: ADaM Dataset with CRITy Populated Only When Criterion Met

Row	USUBJID	PARAM	AVAL	BASE	CHG	CRIT1	CRIT1FL
1	1001	Systolic Blood Pressure (mm Hg)	163	148	15	Systolic Pressure >160	Y
2	1002	Systolic Blood Pressure (mm Hg)	140	148	-8		
3	1003	Systolic Blood Pressure (mm Hg)		120			

表 4.7.1.1 例 1: 仅当条件满足时 CRITy 被赋值的分析数据集

Row	USUBJID	PARAM	AVAL	BASE	CHG	CRIT1	CRIT1FL
1	1001	收缩压（毫米汞柱）	163	148	15	收缩压>160	是
2	1002	收缩压（毫米汞柱）	140	148	-8		
3	1003	收缩压（毫米汞柱）		120			

Example 2
例 2：
CRITy populated on all rows within a parameter.
对于同一参数的所有记录 CRITy 均赋值。

Using this approach, CRITy is populated on all rows within the parameter and CRITyFL is set to "Y" or "N" or null. The purpose of this option is to facilitate analyses where the criterion is used in tabular displays and/or statistical modeling for the parameter.
使用该方法时，同一参数内所有记录的 CRITy 均赋值，此时 CRITyFL 可以被赋值为"Y"，"N"或者留空。采用该方法的目的是当要列表显示和/或要在统计模式中使用该参数时，可以便于分析的进行。

Table 4.7.1.2 illustrates ADaM methodology option "CRITy populated on all rows within a parameter". Since this criterion is used for modeling or analysis in this example, it is necessary to populate the rows which fail to satisfy the criterion. CRIT1FL indicates whether or not the subject meets the criterion. CRIT1FL is set to null for Subject 1005 because the criterion is unevaluable due to missing input(s).
表 4.7.1.2 举例说明了这种方法"对于同一参数的所有记录 CRITy 均赋值"。因为在本例中这个条件要用于设计模型或者进行分析，有必要赋值给所有的记录无论其是否满足条件。CRIT1FL 指明受试者是否满足预定的条件。本例中因为输入数据的缺失导致条件不可评估，所以受试者 1005 的 CRIT1FL 被设为空。

Table 4.7.1.2 Example 2: ADaM Dataset with CRITy Populated on All Rows within a Parameter

Row	USUBJID	PARAM	AVAL	BASE	CHG	CRIT1	CRIT1FL
1	1001	Systolic Blood Pressure (mm Hg)	163	148	15	Systolic Pressure >160 and Change from Baseline in Systolic Pressure>10	Y
2	1002	Systolic Blood Pressure (mm Hg)	140	148	-8	Systolic Pressure >160 and Change from Baseline in Systolic Pressure>10	N
3	1005	Systolic Blood Pressure (mm Hg)	120			Systolic Pressure >160 and Change from Baseline in Systolic Pressure>10	

表 4.7.1.2 例 2: 对于同一参数的所有记录 CRITy 均赋值的分析数据集

Row	USUBJID	PARAM	AVAL	BASE	CHG	CRIT1	CRIT1FL
1	1001	收缩压（毫米汞柱）	163	148	15	收缩压>160 且相对于基线的收缩压变化>10	是
2	1002	收缩压（毫米汞柱）	140	148	-8	收缩压>160 且相对于基线的收缩压变化>10	否
3	1005	收缩压（毫米汞柱）	120			收缩压>160 且相对于基线的收缩压变化>10	

Example 3
例 3：
Compound criteria.
复合条件。

If the definition of a criterion uses values located on multiple rows (different parameters or multiple rows for a single parameter), then a new row must be added with the value of PARAM being the textual description of the criterion (see Section 4.2.1, Rule 4 and Rule 5). The text of PARAM and CRITy are producer-defined and can be as long or as short as needed to be meaningful, within the 200-character limitation for the columns.
对于基于多条记录（来自不同参数的记录或者来自同一参数的多条记录）得出的判断条件，必须新增一条记录，其对应的 PARAM 的值是对判断条件的文字描述（参见 4.2.1 节，规则 4 和 5）。PARAM 以及 CRITy 由申办者定义，长短自定，但需 200 字以内且意义明确。对于采用复合条件的记录，

For compound criterion rows, AVALC must always be populated with Y/N/null. If an analysis also requires a numeric indicator variable, either of the following two options may be chosen:

1. CRITy may be set to the same criterion text as PARAM, CRITyFL set to the same Y/N/null value as AVALC, and CRITyFN set to 1/0/null.
2. AVAL may be set to a numeric 1/0/null indicator value.

AVALC 总是被赋值成 Y/N 或者缺失。如果分析需要数值型的指示变量，可以采用以下两种方法:

1.可以给 CRITy 赋相同 PARAM 的值，CRITyFL 则被赋予同 ACALC 相同的值 Y/N/或者为空，而 CRITyFN 则是 1/0 或者缺失。

2.AVAL 可以赋值成 1/0 或者缺失。

If an analysis requires only simple subsetting of the "hits" on a particular compound criterion, it is acceptable to add only the "compound criterion met" (AVALC="Y") rows to the dataset. If this option is chosen, rows are not added where the assessment of a compound criterion in PARAM would result in AVALC="N" or null.
如果一个分析只要求简单的划分是否满足某复合条件，也可以只在数据集里添加"复合条件满足（AVALC="Y"）"行。如果采用此方法，当复合条件的判断结果是 AVALC="N" 或者缺失时，相应的行不需添加。

Note that if a compound criterion is defined, then its components do not have to exist on their own in the dataset unless these components are themselves used for subsetting, display, or modeling purposes, or are needed for traceability.
需要注意的是，如果定义了复合条件，该条件涉及到的记录或者变量不一定需要保留在数据集中，除非他们也需要用于划分子集，输出显示，分析模型，或者是为了保持可追溯性。

Table 4.7.1.3 illustrates a compound criterion (row 3) included in the same dataset with non-compound criteria (rows 1 and 2).
表 4.7.1.3 举例说明了复合条件（第 3 行）和非复合条件（第 1 行和第 2 行）同时包含在同一个数据集的情况。

Table 4.7.1.3 Example 3: ADaM Dataset with Both Compound and Non-compound Criteria

Row	USUBJID	PARAM	AVAL	AVALC	BASE	CHG	CRIT1	CRIT1FL	CRIT1FN	CRIT2	CRIT2FL	CRIT2FN
1	1001	Systolic Blood Pressure (mm Hg)	163		148	15	Systolic Pressure > 160	Y	1	Change from Baseline in Systolic Pressure > 10	Y	1
2	1001	Diastolic Blood Pressure (mm Hg)	96		87	9	Diastolic Pressure > 95	Y	1			
3	1001	Systolic Pressure >160 and Diastolic Pressure > 95		Y								

Row	USUBJID	PARAM	AVAL	AVALC	BASE	CHG	CRIT1	CRIT1FL	CRIT1FN	CRIT2	CRIT2FL	CRIT2FN
1	1001	收缩压（毫米汞柱）	163		148	15	收缩压>160	是	1	收缩压相对于基线的变化>10	是	1
2	1001	舒张压（毫米汞柱）	96		87	9	舒张压>95	是	1			
3	1001	收缩压>160 且舒张压>95		Y								

Note that criterion "Diastolic Pressure >95" (Row 2) can coexist in the same CRIT1 column with "Systolic Pressure >160" (Row 1). Each of these criteria is specific to its own subset of PARAM rows.
需要注意的是，条件"舒张压>95"（第 2 行）可以跟 "收缩压>160" （第 1 行）同时存在于同一列 CRIT1 内。每个条件都分别对应于相应的 PARAM 子集.

4.7.2 ADaM Methodology and Examples When the Criterion Has Multiple Responses

4.7.2 针对判断条件是有多重应答的 ADaM 方法和实例

ADaM methodology provides an analysis criterion variable, MCRITy, paired with a criterion evaluation result flag, MCRITyML, to identify which level of a multiple response criterion is met. These variables are defined in Section 3.3.4.
ADaM 提供了一个条件变量 MCRITy 和一个条件判断结果标记变量 MCRITyML, 来共同识别满足哪个等级的条件。其具体定义见 3.3.4 节。
MCRITy is populated with a text description identifying the criterion being evaluated. The definition of MCRITy can use any variable(s) located on the row and the definition must stay constant across all rows within the same value of PARAM. A complex criterion which draws from multiple rows (different parameters or multiple rows for a single parameter) will require a new PARAM be created.
MCRITy 包含一段文字描述，用于定义判断条件。MCRITy 的定义可以使用同一条记录的任何变量，并且其定义必须在具有相同 PARAM 值的所有行内保持一致。基于多条记录得出的复合判断条件，需要新增一条记录且赋予不同 PARAM 值（见例 3 表 4.7.1.3）。

MCRITyML, “Multi-Response Criterion y Evaluation”, is the character flag variable that indicates which level of the criterion defined in MCRITy was met. Variable MCRITyML must be present on the dataset if variable MCRITy is present. MCRITyMN is permitted if a numeric result flag is needed.
MCRITyML，
多重判断结果标记变量，是用于识别满足于 MCRITy 定义的哪一个条件标准的字符型标记变量。变量 MCRITyML 必须与变量 MCRITy 同时存在于数据集中。如果需要数值型的标记变量，允许添加变量 MCRITyMN。

MCRITy and MCRITyML facilitate subgroup analyses. ADaM methodology does not preclude the addition of rows (in contrast to the addition of multiple MCRITy and MCRITyML columns) to the BDS for the criterion MCRITy. However, MCRITy must be kept constant (if populated) across all rows within the same value of PARAM.
MCRITy 以及 MCRITyML 有助于亚组分析。除了在 BDS 数据集里增加多对 MCRITy 和 MCRITyML 变量，ADaM 并不排除为不同的 MCRITy 增加新的行。但是 MCRITy 的赋值必须在具有相同 PARAM 值的所有行内保持一致。

MCRITy, MCRITyML and MCRITyMN are not parameter-invariant in that MCRITy can vary across parameters within a dataset, as can the controlled terminology used for the corresponding MCRITyML and MCRITyMN. In other words, MCRITy for one parameter can be different than MCRITy for a different parameter in the same dataset.
MCRITy，MCRITyML 和 MCRITyMN 在不同参数间并不是保持恒定不变，同一数据集内不同参数间的 MCRITy 可以不同，用于 MCRITyML 和 MCRITyMN 的统一术语也是如此。换句话说，针对某一个参数的 MCRITy 可以不同于针对另一个参数的 MCRITy。

Example 1
例 1
Table 4.7.2.1 illustrates partial laboratory data for Alanine Aminotransferase (IU/L). As with other examples, some of the necessary columns for analysis and traceability (e.g., CHG, PCHG, AWTARGET, AWTDIFF, LBSEQ) have been excluded from the illustration. In this example, ALT values are evaluated for changes in toxicity grade. (Laboratory Grading in this example is based on CTCAE Version 4 so Grade 1 is >ULN - 3.0 x ULN, Grade 2 is >3.0 - 5.0 x ULN,
表 4.7.2.1 展示了丙氨酸转氨酶的部分实验室数据。同其他例子一样，一些用于分析和追溯的必要变量（比如 CHG,PCHG,AWTARGET,LBSEQ）被排除在此表中。该例子评估了 ALT 的毒性等级变化（此例中的实验室分级是基于第四版的 CTCAE，所以等级 1 : >上限-上限的 3 倍，等级 2:>上限的 3 倍-5 倍。
Grade 3 is >5.0 - 20.0 x ULN, and Grade 4 >20.0 x ULN.) In a typical analysis situation, it is of interest to know the shift in the number of toxicity grades from

baseline. Generally, an increase from a Grade 1 at baseline to a Grade 3 at a post baseline visit is treated the same as an increase from Grade 2 to Grade 4; that is, both of these are considered an increase in 2 Grades. 等级 3：>上限的 5 倍-20 倍，等级 4：>上限的 20 倍）。一个典型的分析是想知道毒性等级从基线开始的变化。一般来说，毒性等级从基线的等级 1 上升到基线后的等级 3 等同于从等级 2 上升到等级 4。这是因为这两种情况均是上升了两个等级。

Note that for some laboratory analytes, only increases in toxicity grades are of interest. For other analytes, the interest is only in decreases in toxicity grades. Finally, for a few analytes, the change in toxicity in both directions (increases and decreases) is of interest.
需要注意的是，对于一些实验室分析物，我们只对毒性等级的增加程度感兴趣。对于另一些实验室分析物来说，我们只对毒性等级的减少程度感兴趣。对于另外一些分析物来说，我们可能对毒性等级的增加和减少都感兴趣。

In this example, it is increases in toxicity grades that are of interest. Within the analysis dataset, MCRIT1 identifies the criterion being evaluated and MCRIT1ML contains the level of criterion met, and MCRIT1MN contains a numeric version of the response. In contrast, CRIT1 assesses whether or not the value of ALT exceeded 8 times ULN.
在下面的例子中，我们只关心毒性等级的增加。在分析数据集内，MCRITy 描述了被评估的条件，MCRITyML 包含被满足的水平信息，MCRITyMN 则用数值反应达到的水平。相反的是，CRIT1 只评估 ALT 的值是否超过了上限的八倍。

Note that in this example, the producer has elected to not populate the values of MCRIT1ML on the screening and baseline records. Values of MCRIT1ML represent the number of grade increases from baseline. Note that for visits where there is either no increase in toxicity grade OR where the grade decreases, MCRIT1ML is given a value of 'No Grade Increase'. This approach is suitable for analytes where only grade increases is of interest. Should decreases also be of interest, then a second set of MCRIT variables would be added to contain the observed number of toxicity grade decreases.
需要注意的是，本例中对于筛选和基线记录申办者选择不赋值给 MCRIT1ML。MCRIT1ML 的值反映的是相较于基线增加的毒性等级数。如果在某个访视，毒性等级没有增加或者有下降时，MACRIT1ML 被赋值为"等级没有增加"。这种方法适用于当只对毒性等级增加程度感兴趣时。如果对毒性等级下降程度也感兴趣时，需要增加另外一套 MCRIT 变量来包含等级下降数。

This example also illustrates other BDS variables, notably SHIFT1 and SHIFT2. SHIFT1 is defined as the shift between BNRIND and ANRIND while SHIFT2 is defined as the shift between BTOXGR and ATOXGR. These shifts of normal ranges and CTCAE toxicity grades are often of interest for analysis.
下面的例子同时也展示了其他 BDS 变量，尤其是 SHIFT1 和 SHIFT2。SHIFT1 被定义为 BNRIND 于 ANRIND 之间的变化，而 SHIFT2 则定义为 BTOXGR 和 ATOXGR 之间的变化。这些正常范围值以及 CTCAE 毒性等级间的变化常常是分析感兴趣的。

Table 4.7.2.1 ADaM Dataset with a Criterion that Has Multiple Responses

Row	USUBJID	PARAMCD	AVISIT	VISIT	ADY	AVAL	ANRLO	ANRHI	ANRIND	ATOXGR	ABLFL	ANL01FL	BASE	BNRIND	BTOXGR
1	ABC-0001	ALT	Baseline	SCREENING	-14	30	0	35	Normal	0	Y	Y	30	Normal	0
2	ABC-0001	ALT	Week 1	WEEK 1	2	31	0	35	Normal	0		Y	30	Normal	0
3	ABC-0001	ALT	Week 3	WEEK 3	22	45	0	35	High	1		Y	30	Normal	0
4	ABC-0001	ALT	Week 5	WEEK 5	34	81	0	35	High	1		Y	30	Normal	0
5	ABC-0001	ALT	Week 7	WEEK 7	51	110	0	35	High	2		Y	30	Normal	0
6	ABC-0001	ALT	Week 9	WEEK 9	65	554	0	35	High	3		Y	30	Normal	0
7	ABC-0001	ALT	Month 3	MONTH 3	92	1077	0	35	High	4		Y	30	Normal	0
8	ABC-0002	ALT	Screening	SCREENING	-14	30	0	31	Normal	0			32	High	1
9	ABC-0002	ALT	Baseline	WEEK 1	1	32	0	31	High	1	Y	Y	32	High	1
10	ABC-0002	ALT	Week 3	WEEK 3	21	23	0	31	Normal	0		Y	32	High	1
11	ABC-0002	ALT	Week 3	UNSCHEDULED	25	25	0	31	Normal	0			32	High	1
12	ABC-0002	ALT	Week 5	WEEK 5	39	33	0	31	High	1		Y	32	High	1
13	ABC-0002	ALT	Week 7	WEEK 7	53	100	0	31	High	2		Y	32	High	1
14	ABC-0002	ALT	Week 9	WEEK 9	64	27	0	31	Normal	0		Y	32	High	1
15	ABC-0002	ALT	Month 3	MONTH 3	89	22	0	31	Normal	0		Y	32	High	1
16	**ABC-0002**	**ALT**	**Month 6**	**MONTH 6**	**181**	**20**	**0**	**31**	**Normal**	**0**		**Y**	**32**	**High**	**1**

Row	USUBJID	PARAMCD	AVISIT	VISIT	ADY	AVAL	ANRL0	ANRHI	ANRIND	ATOXGR	ABLFL	ANL01FL	BASE	BNRIND	BTOXGR
1	ABC-0001	ALT	基线	基线	-14	30	0	35	正常	0	Y	Y	30	正常	0
2	ABC-0001	ALT	1 周	1 周	2	31	0	35	正常	0		Y	30	正常	0
3	ABC-0001	ALT	3 周	3 周	22	45	0	35	高	1		Y	30	正常	0
4	ABC-0001	ALT	5 周	5 周	34	81	0	35	高	1		Y	30	正常	0
5	ABC-0001	ALT	7 周	7 周	51	110	0	35	高	2		Y	30	正常	0
6	ABC-0001	ALT	9 周	9 周	65	554	0	35	高	3		Y	30	正常	0
7	ABC-0001	ALT	3 月	3 月	92	1077	0	35	高	4		Y	30	正常	0
8	ABC-0002	ALT	筛选	筛选	-14	30	0	31	正常	0		Y	32	高	1
9	ABC-0002	ALT	基线	基线	1	32	0	31	高	1	Y	Y	32	高	1
10	ABC-0002	ALT	3 周	3 周	21	23	0	31	正常	0		Y	32	高	1
11	ABC-0002	ALT	5 周	5 周	25	25	0	31	正常	0		Y	32	高	1
12	ABC-0002	ALT	7 周	7 周	39	33	0	31	高	1		Y	32	高	1
13	ABC-0002	ALT	9 周	9 周	53	100	0	31	高	2		Y	32	高	1
14	ABC-0002	ALT	3 周	3 周	64	27	0	31	正常	0		Y	32	高	1
15	ABC-0002	ALT	3 月	3 月	89	22	0	31	正常	0		Y	32	高	1
16	ABC-0002	ALT	6 月	6 月	181	20	0	31	正常	0		Y	32	高	1

Row	SHIFT1	SHIFT2	MCRIT1	MCRIT1ML	MCRIT1MN	CRIT1	CRIT1FL
1 (cont)			ALT Grade Increase			ALT > 8*ULN	N
2 (cont)	Normal to Normal	0 to 0	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N
3 (cont)	Normal to High	0 to 1	ALT Grade Increase	Increase of 1 Grade	1	ALT > 8*ULN	N
4 (cont)	Normal to High	0 to 1	ALT Grade Increase	Increase of 1 Grade	1	ALT > 8*ULN	N
5 (cont)	Normal to High	0 to 2	ALT Grade Increase	Increase of 2 Grades	2	ALT > 8*ULN	N
6 (cont)	Normal to High	0 to 3	ALT Grade Increase	Increase of 3 Grades	3	ALT > 8*ULN	Y
7 (cont)	Normal to High	0 to 4	ALT Grade Increase	Increase of 4 Grades	4	ALT > 8*ULN	Y
8 (cont)			ALT Grade Increase			ALT > 8*ULN	N
9 (cont)			ALT Grade Increase			ALT > 8*ULN	N
10 (cont)	High to Normal	1 to 0	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N

Row	SHIFT1	SHIFT2	MCRIT1	MCRIT1ML	MCRIT1MN	CRIT1	CRIT1FL
11 (cont)	High to Normal	1 to 0	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N
12 (cont)	High to High	1 to 1	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N
13 (cont)	High to High	1 to 2	ALT Grade Increase	Increase of 1 Grade	1	ALT > 8*ULN	N
14 (cont)	High to Normal	1 to 0	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N
15 (cont)	High to Normal	1 to 0	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N
16 (cont)	High to Normal	1 to 0	ALT Grade Increase	No Grade Increase	0	ALT > 8*ULN	N

Row	SHIFT1	SHIFT2	MCRIT1	MCRIT1ML	MCRIT1MN	CRTT1	CRIT1FL
1(conj)			ALT 等级增加程度			ALT > 8*上限	N
2(conj)	正常到正常	0 to 0	ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N
3(conj)	正常到高	0 to 1	ALT 等级增加程度	增加 1 级	1	ALT > 8*上限	N
4(conj)	正常到高	0 to 1	ALT 等级增加程度	增加 1 级	1	ALT > 8*上限	N
5(conj)	正常到高	0 to 2	ALT 等级增加程度	增加 2 级	2	ALT > 8*上限	N
6(conj)	正常到高	0 to 3	ALT 等级增加程度	增加 3 级	3	ALT > 8*上限	Y
7(conj)	正常到高	0 to 4	ALT 等级增加程度	增加 4 级	4	ALT > 8*上限	Y
8(conj)			ALT 等级增加程度			ALT > 8*上限	N
9(conj)			ALT 等级增加程度			ALT > 8*上限	N
10(conj)	高到正常		ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N
11(conj)	正常到高		ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N
12(conj)	高到高		ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N
13(conj)	高到高		ALT 等级增加程度	增加 2 级	1	ALT > 8*上限	N
14(conj)	高到正常		ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N
15(conj)	高到正常		ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N
16(conj)	高到正常		ALT 等级增加程度	等级没有增加	0	ALT > 8*上限	N

4.8 Examples of Timing Variables

4.8 时间变量例子

4.8.1 Example of Phase, Period and Subperiod Variables

4.8.1 有关阶段变量，周期变量以及次周期变量的例子

Table 4.8.1.1 provides a schematic example of the use of the BDS variables for phase, period, and subperiod. The example is of a study in which there are three analysis phases: Screening, Treatment, and Follow-up. The treatment phase consists of a two-period crossover design. In each period of the treatment phase, there are distinct subperiods in which the dose of the corresponding therapy is escalated, then maintained, and then de-escalated.
表 4.8.1.1 展示了如何使用 BDS 变量来描述阶段，周期和次周期的例子。例子中的研究有 3 个分析阶段：筛选，治疗和随访。其中治疗阶段由一个两阶段的交叉设计构成。在治疗阶段的每一个周期内，又包含不同的次周期，相对应治疗方案的升级，保持和降级。

Table 4.8.1.1 Example of Phase, Period and Subperiod Variables

Variable	Variable Values							
APHASE	Screening	Treatment						Follow-up
APHASEN	1	2						3
APERIOD		1			2			
APERIODC		Crossover Period 1			Crossover Period 2			
ASPER		1	2	3	1	2	3	
ASPERC		Escalation	Maintenance	De-escalation	Escalation	Maintenance	De-escalation	

变量	变量值							
APHASE	筛选	治疗						随访
APHASEN	1	1			2			3
APERIOD		交叉阶段 1			交叉阶段 2			
APERIODC								
ASPER		1	2	3	1	2	3	
ASPERC		升级	保持	降级	升级	保持	降级	

Note that, in general, there is no requirement to use all three of APHASE, APERIOD and ASPER when only one or two suffice. Also note that, in general, there is no requirement that the number and nature of subperiods, if any, be the same in each period. If ASPER is used, APERIOD must also be present.
需要注意是，当一个或两个时间变量已经足够时，没有要求一定要使用这三个变量。同时，一般不要求每个周期内的次周期的数量和性质必须相同。如果使用 ASPER，APERIOD 必须同时使用。

4.9 Other Issues to Consider

4.9 其它要考虑的问题

The issues presented in the previous sections represent analysis decisions that commonly occur when creating ADaM datasets. However, the ADaM Team recognizes that those are not an exhaustive list. This section provides comment on some additional issues that may arise.
在前述章节提出的一些问题中包括了在创建分析数据集时经常会碰到的一些分析决策。但是 ADaM 小组认识到那并不全面，在本节里继续对其它可能出现的问题提供一些看法。

4.9.1 Adding Records to Create a Full Complement of Analysis Timepoints for Every Subject

4.9.1 添加记录，为每个受试者创建所有分析时间点

It is not unusual for a given subject to have missing data for a specified analysis timepoint. For example, suppose an analysis is to be performed for the data obtained at each of 4 visits and that no imputation is to be performed. For subjects who did not attend all 4 visits, it would be possible to create records in the ADaM dataset for these missed assessments, with AVAL and AVALC missing (null) and appropriate variable(s) set to indicate these added records. For example, DTYPE could contain a producer-defined value such as "PHANTOM." There are some advantages of having an ADaM dataset contain the same number of observations for each subject. For example, programming is facilitated by having the same data dimensions for all subjects, and by explicitly representing missing data rather than implicitly representing it by the absence of a record. This also allows ADaM datasets to support listing creation, especially for data that is not present in SDTM (e.g., added analysis parameters). For some categorical analyses, the denominators can be obtained directly from the ADaM dataset rather than from another input such as ADSL. The disadvantage of this approach is that it may require additional metadata to explain the use of these derived blank records and would require in some cases that subsetting statements be used to exclude the rows on which AVAL is missing. In general, the ADaM Team neither advocates nor discourages this practice for BDS datasets.
某个受试者在某个分析时间点没有数据并不罕见，例如假定要对一个具有 4 次访视的数据按访视进行分析，对缺失数据不进行填补。对于没有参加所有四个访视的受试者，可以在分析数据集中为那些缺失的评估创建记录，其 AVAL 和 AVALC 为缺失（空 null），并用合适的变量来指明这些添加的记录。例如 DTYPE 可能包含一个申办者定义的值比如"PHANTOM"。每个受试者在分析数据集中具有相同数目观测值具有一些好处，例如所有的受试者都具有相同数据维数使得编程更加便利，编程时可以明确地表示缺失数据，而不是通过缺失整条记录来"暗示"。这也允许 ADaM 数据集支持清单的创建，特别是在 SDTM 中没有的数据（例如添加的分析参数）的清单创建。对于一些分类数据的分析，分母可以直接通过分析数据集获得，而不是另一个输入数据集如 ADSL 获得。这个方法的不便之处在于它可能需要另外的元数据来解释如何使用这些推导出的空白记录，且在一些情况下，要用选择语句来排除那些 AVAL 缺失的行。在一般情况下，对于 BDS 数据集 ADaM 小组既不提倡也不阻止这种做法。

4.9.2 Creating Multiple Datasets to Support Analysis of the Same Type of Data

4.9.2 创建多个数据集，支持相同类型数据的分析

The statistical analysis plan often specifies that an analysis will be performed using slightly different methodologies. For example, the primary efficacy analysis may be performed using two different imputation algorithms for missing values. The producer must decide whether to include both sets of the imputed observations in one ADaM dataset or create two ADaM datasets, each representing just one of the imputation algorithms. ADaM provides variables that can be used to identify records that are used for different purposes. However, this does not imply that the producer should not or cannot submit multiple ADaM datasets of similar content, each designed for a specific analysis.
统计分析计划通常会规定一个分析将要用稍微不同的方法进行。例如，主要疗效分析可能会对缺失值使用两种不同的填补算法进行。申办者必须决定是将两组填补观测值包括在一个分析数据集里还是创建两个分析数据集，每个数据集只包含一种填补算法。ADaM 提供的变量能用来标识用于不同分析目的的记录。但是，这不意味着申办者不该或不能提交具有相似内容的多个分析数据集，每个数据集是为一个特定的分析而设计。

4.9.3 Size of ADaM Datasets

4.9.3 ADaM 数据集的大小

It is important to consider the size of ADaM datasets, because large datasets can pose problems for transferring between parties, loading into data warehouses, or software processing. The maximum size of a dataset and how to handle large datasets should be discussed with the recipient of the data and clearly documented. Refer to the FDA website (see Section 1.2) for recommendations concerning sizes of submitted datasets.
考虑 ADaM 数据集的大小是重要的，因为大数据集会造成各方之间传递、加载到数据仓库或软件处理的问题。应该与数据接收者讨论一个数据集的最大大小及如何处理大数据集并且清晰地记录下来。参考 FDA 网站（见 1.2 节）有关提交数据集大小的建议。

4.9.4 Traceability When the Multiple Imputation Method is Used

4.9.4 使用多种填补方法时的可追溯性

There has been increased attention in the analysis of clinical trial data to address problems associated with missing data and with this increased attention has come new ways to deal with this problem. In the past, simple methods such as 'last observation carried forward' or 'baseline observation carried forward' were routinely used to replace missing values. Such 'single point imputation' methods have been shown to underestimate the standard error of the estimates of various statistics computed from the data. A more sophisticated method, termed 'multiple imputation' was introduced in 1987 and is now fully supported by frequently used software packages. In brief, this methodology deals with the uncertainty of the missing data by employing a three step process. The first step is the creation of multiple datasets in which plausible values for each missing data value are imputed. The second step is to analyze each of these datasets with the desired statistical procedure and capture the resulting statistical estimates. The third and final step is to use these estimates to generate a combined (pooled) estimate. It is these estimates which are based on the pooling of the estimates from the multiple imputation datasets that are used to evaluate statistical significance.
在临床试验的数据分析中，人们越来越关注与缺失数据相关问题的解决，并且随着关注的增加有了新方法来处理这个问题。在过去,简单的方法如"最后

观测结转”或“基线观测结转”经常用来替换缺失值。这样的‘单点填补’方法已被证明会低估从数据中计算出的各种统计量的估计的标准误差。一种更复杂的方法,被称为“多重填补”，在 1987 年被提出，现在常用的软件包完全支持这种方法。简而言之，这种方法处理缺失数据的不确定性的过程分为三个步骤。第一步是创建多个数据集，这些数据集为每一个缺失的数据值填补了合理的估算值。第二步是用所需的统计过程逐一分析这些数据集从而得到统计估计结果。第三和最后一步是用这些估计来生成一个合并的(综合的)的估计。这些估计是基于来自多重填补数据集的综合估计，用于评估统计学意义。

Using the SAS software as an example, the above three step process is achieved using PROC MI to create the multiple datasets (Step 1). Step 2 would utilize the procedure associated with the desired statistical model, such as PROC LOGISTIC. Step 3 would use PROC MIANALYZE to create the combined pooled estimates.
以 SAS 软件作为一个例子,上面的三个步骤是通过 PROC MI 创建多个数据集来实现的(步骤 1)。第二步会利用所需的统计模型的过程步,如 PROC LOGISTIC.。第三步会使用 PROC MIANALYZE 来创建合并后的综合估计。

In ADaM, the documentation of derived variables via variable level metadata, and statistical results via analysis results metadata, is paramount to achieving the concept of traceability. However, documenting the traceability of estimates created via multiple imputation cannot be achieved with these current metadata methods. Additionally, it would not be practical to include all datasets that are created from the PROC MI process as part of a submission. To address traceability, the recommendation from ADaM is to provide the program statements from the three procedures mentioned above as a part of the analysis results metadata. This would allow the reviewer to re-create the analysis as desired. Of primary importance is to ensure that the options used in PROC MI, specifically the value of the seed, the number of iterations, and the method used for imputation are clearly denoted.
在 ADaM 中，衍生变量的文档记录在变量水平元数据，统计结果记录在分析结果元数据，因此实现这两者的可追溯性是至关重要的。然而，用现在的元数据方法来记录由多重填补产生的估计的可追溯性还无法实现。此外，将所有由 PROC MI 过程创建的数据集作为提交的一部分并不实用,。要想解决可追溯性,ADaM 的建议是提供上述三个过程的程序语句作为分析结果元数据的一部分。这将允许审阅者重新生成所需的分析。最重要的是要确保用于 PROC MI 的选项，特别是种子值，迭代次数和填补方法被清楚地指明。

4.9.5 Copying Values onto a New Record

4.9.5 复制值到一条新记录

As a general rule, when a new record is derived from a single record in the dataset, retain on the derived record any variable values from the original record that do not change and that make sense in the context of the new record (e.g., --SEQ, VISIT, VISITNUM, --TPT, covariates, etc.). When a record is derived from multiple records, then retain on the derived record all variable values that are constant across the original records, do not change, and that make sense in the context of the new record. Note that there are situations when retention of values from an original record or records would make no sense on the derived record; in such cases, do not retain those values. Refer to Table 4.2.1.3 and Table 4.2.1.4 for two examples.
作为一般规则，当一条新记录衍生于数据集中的单条记录，对任何来自原始记录值不变的变量以及对新记录理解有意义的变量，保持衍生的记录中这些变量值不变 (如--SEQ,VISIT、VISITNUM、TPT,协变量等等)。当衍生记录来自多条记录,如果变量在原始记录中值一样并且对新记录的理解有意义，保持衍生的记录中这些变量值不变。需要注意的是，某些情况下,当保留原始记录值对衍生记录无意义时;在这些情况下,不用保留那些值。参见表 4.2.1.3 和表 4.2.1.4 这两个例子。

Appendices

Appendix A: Abbreviations and Acronyms

附录 A：缩略语表

The following is a list of abbreviations and acronyms used multiple times in this document. Not included here are explanations of the various SDTM domains (e.g., QS, DM). Also not included is a description of the variables referenced.
下表是在本文档中多次用到的缩略语。不包括各个 SDTM 域的解释（如：QS,DM）。也不包括引用变量的描述。

ADaM	CDISC Analysis Data Model	CDISC 分析数据模型
ADaM model document	The document entitled “Analysis Data Model (ADaM)”	名为“分析数据模型(ADaM)”的文件
ADaMIG	Analysis Data Model Implementation Guide	分析数据模型实施指南
ADSL	ADaM Subject-Level Analysis Dataset	ADaM 受试者水平分析数据集
BDS	ADaM Basic Data Structure	ADaM 基本数据结构
BLOCF	Baseline Observation Carried Forward	基线末次观察推进法
CDASH	Clinical Data Acquisition Standards Harmonization	临床数据采集标准协调
CDISC	Clinical Data Interchange Standards Consortium	临床数据交换标准协会
DAO	Data as Observed	观测到的数据
eCTD	electronic Common Technical Document	电子通用技术文档
FDA	United States Food and Drug Administration	美国食品和药物管理局
ITT	Intent-to-Treat	意向治疗
LOCF	Last Observation Carried Forward	末次观察推进法
LOV	Last Observed Value	末次观测值
LVPD	Last Value Prior to Dosing	给药前末次值
OCCDS	ADaM Occurrence Data Structure	ADaM 事件数据结构
SAP	Statistical Analysis Plan	统计分析计划
SDS	Submission Data Standards	提交数据标准
SDTM	Study Data Tabulation Model	研究数据制表模型
SDTMIG	Study Data Tabulation Model Implementation Guide	研究数据制表模型实施指南
TAUG	Therapeutic Area User Guide	治疗领域用户指南
FDA TCG	FDA Study Data Technical Conformance Guide	FDA 研究数据技术一致性指南
WOC	Worst Observed Case	最差观测情况
WOCF	Worst Observation Carried Forward	最差观测结转
XML	Extensible Markup Language	可扩展标记语言

Appendix B: Revision History

This section lists changes in the ADaMIG from version 1.0 to version 1.1.

Category/Section	Type	Description
General	Clarification	Made changes throughout the document to increase clarity.
General	Clarification	Clarified scope (i.e., within a variable, within a parameter, within a dataset, or within a study) throughout the document.
General	Update	Changed wording from "analysis datasets" to "ADaM datasets" where applicable.
General	Clarification	Changed wording from "analysis variable" to "analysis value" where applicable.
General	Clarification	Changed wording from originator/sender/owner/sponsor of the data to "producer" where appropriate. Changed wording from reviewer/user/recipient of the data to "consumer" where appropriate.
General	Clarification	Increased precision and consistency of text referring to date, time and datetime variables. For example, used "datetime" instead of variants such as "date/time" when describing ADaM numeric datetime variables.
Section 1.1 Purpose	Clarification	Updated Section 1.1, "Purpose", to provide more detail.
Section 1.2 Background	Clarification	Updated Section 1.2, "Background", to provide more detail, and to refer readers to the FDA website for additional information.
Section 1.3 What is Covered in the ADaMIG	Addition	Added reference to the external document that describes the OCCDS data structure.
Section 1.3.1 Other ADaM-related CDISC Documents	Addition	Added section 1.3.1, "Other ADaM-related CDISC Documents".
Section 1.4 Organization of the Document	Addition	Noted changes in wording from the terms originator/sender/owner/sponsor to "producer", and from the terms reviewer/user/recipient to "consumer".
Section 1.5.1 General ADaM Definitions	Update	Updated definition of "record" to include "observation" in addition to "row" in a dataset.
Section 1.5.2 Basic Data Structure Definitions	Clarification	Added clarity to the definition of parameter-invariant. Added definition for term parameter-variant.
Section 1.6 Analysis Datasets and ADaM Datasets	Addition	Added section 1.6, "Analysis Datasets and ADaM Datasets", to clarify the distinctions among "analysis datasets", "ADaM Datasets", and "non-ADaM analysis datasets".
Section 2.1 Fundamental Principles	Clarification	Minor modifications to text to clarify concepts.
Section 2.2 Traceability	Addition	Added a cross-reference to section 1.5.1. Added mention of the BDS and OCCDS structures.
Section 2.3 The ADaM Data Structures	Clarification	Minor modifications to text to clarify concepts.
Section 2.3.1 The ADaM Subject-Level Analysis Dataset (ADSL)	Update	Significant updates to the text to clarify the contents of ADSL and to add tips on how ADSL variables should be carried forward to BDS datasets.
Section 2.3.2 The ADaM Basic Data Structure (BDS)	Update	Clarified analysis timepoints and included a reference to section 1.5.2. Clarified the description of the structure of the BDS.
Section 3 Standard ADaM Variables	Clarification	Expanded and added clarity to the first three paragraphs, including to the concept of standard naming fragments.

Category/Section	Type	Description
Section 3 Standard ADaM Variables	Format	Consolidated and updated existing content into new section 3.1, "ADaM Variable Conventions". Numbering of all following subsections of section 3 updated accordingly.
Section 3.1.1 General Variable Conventions	Format	Moved general variable naming conventions into new section 3.1.1. Reordered that content.
Section 3.1.1 General Variable Conventions	Clarification	Clarified that there is no requirement that digits be consecutive when replacing w, xx, y, zz in variable names.
Section 3.1.1 General Variable Conventions, Item 2a	Addition	Added "w" reference in variable name as an index to the w^{th} variable
Section 3.1.1 General Variable Conventions, Item 2c	Update	Updated reference to "y" variables to allow non-left-zero-padded indices in variable names to go from 1-99 now.
Section 3.1.1 General Variable Conventions, Item 3	Update	Added statement that variable length of SDTM variables can differ between SDTM and ADaM in order to optimize file size.
Section 3.1.1 General Variable Conventions, Item 4	Addition	Added requirement that if an ADaM standard variable name has been defined for a specific concept, then the ADaM standard variable name must be used.
Section 3.1.1 General Variable Conventions, Items 5 and 6	Clarification	Clarified paired variables and one-to-one mapping.
Section 3.1.1 General Variable Conventions, Item 8	Clarification	Clarified the instructions for FL variables.
Section 3.1.1, General Variable Conventions, Item 9	Update	Added Gy and CATy variables to the discussion about GRy variables.
Section 3.1.2 Timing Variable Conventions	Format	Moved timing variable conventions into new section 3.1.2. Reordered that content.
Section 3.1.2 Timing Variable Conventions, Item 9	Clarification	Clarified the concept of anchor dates and times. Stated that relevant anchor date and time variables should be specified in metadata and included in ADSL or current dataset.
Section 3.1.3 Date and Time Imputation Flag Variables	Addition	Moved date and time imputation flag variable conventions into new section 3.1.3.
Section 3.1.4 Flag Variable Conventions	Format	Moved flag variable conventions into new section 3.1.4. Reordered that content.
Section 3.1.4 Flag Variable Conventions	Clarification	Added details to Items 1, 3, 6, 7, 8 and 9.
Section 3.1.5 Variable Naming Fragments	Addition	Added Section 3.1.5, "Variable Naming Fragments".
Section 3.1.6 Additional Information about Section 3	Update	Moved text following "Additional Information about Section 3" to new section 3.1.6, and expanded.
Section 3.1.6 Additional Information about Section 3	Update	Clarified when and how variable labels may be modified.
Sections 3.2 and 3.3	Clarification	Clarified and added text in this section, including in the CDISC Notes of many variables.
Section 3.2 ADSL Variables	Format	Divided previous Table 3.1.1 into different tables (3.2.x) to separate ADSL variables into logical groups.
Section 3.2 ADSL Variables	Clarification	Clarified that an "ADaM compliant" ADSL is required in a CDISC submission.
Table 3.2.1 ADSL Identifier Variables	Clarification	Revised text to specify that SUBJID and SITEID are required in ADSL but permissible in other datasets.
Table 3.2.1 ADSL Identifier Variables	Addition	Added geographical region variables REGIONy and REGIONyN.

Category/Section	Type	Description
Table 3.2.2 ADSL Subject Demographics Variables	Addition	Added age grouping variables AGEGRy, AGEGRyN, and analysis age variable AAGE.
Table 3.2.2 ADSL Subject Demographics Variables	Clarification	Clarified CDISC notes for AGE and AGEU.
Table 3.2.4 ADSL Treatment Variables	Addition	Added SDTM variable ACTARM.
Table 3.2.4 ADSL Treatment Variables	Update	Corrected the Type of TRxxPGyN and TRxxAGyN from Char to Num.
Table 3.2.4 ADSL Treatment Variables	Addition	Added pooled treatment sequence variables TSEQPGy, TSEQPGyN, TSEQAGy, and TSEQAGyN.
Table 3.2.5 ADSL Dose Variables	Addition	Added dosing variables DOSExxP, DOSExxA, and DOSExxU.
General	Clarification	Changed occurrences of the terms "date-time" and "date/time" to "datetime" when referring to ADaM variables.
Table 3.2.7 Subject-Level Period, Subperiod, and Phase Timing Variables	Addition	Added new variables PxxSw, PxxSwSDT, PxxSwSTM, PxxSwSDM, PxxSwSDF, PxxSwSTF, PxxSwEDT, PxxSwETM, PxxSwEDM, PxxSwEDF, PxxSwETF, APHASEw, PHwSDT, PHwSTM, PHwSDTM, PHwSDTF, PHwSTMF, PHwEDT, PHwETM, PHwEDTM, PHwEDTF, and PHwETMF.
Table 3.2.8 ADSL Subject-Level Trial Experience Variables	Addition	Added new variables EOSSTT, EOSDT, DCSREAS, DCSREASP, EOTSTT, DCTREAS, DCTREASP, EOTxxSTT, DCTxxRS, DCTxxRSP, EOPxxSTT, DCPxxRS, DCPxxRSP, RFICDT, ENRLDT, RFICyDT, ENRLyDT, RANDyDT, LSTALVDT, TRCMP, TRCMPGy, TRCMPGyN, TRxxDURD, TRxxDURM, TRxxDURY, TRTDURD, TRTDURM, TRTDURY, DTHDT, DTHDTF, DTHCAUS, DTHCAUSN, DTHCGRy, and DTHCGRyN.
Table 3.3.1.1 Identifier Variables for BDS Datasets	Addition	Added variable ASEQ.
Section 3.3.2 Record-Level Treatment and Dose Variables for BDS Datasets	Addition	Added record-level dose variables DOSEP, DOSCUMP, DOSEA, DOSCUMA, and DOSEU.
Section 3.3.2 Record-Level Treatment Variables for BDS Datasets	Update	Updated section 3.3.2, including the CDISC Notes for TRTP, to state that at least one treatment variable is required, which may be a subject-level or record-level variable. Changed Core value from Required to Conditional for TRTP.
Table 3.3.3.1 Timing Variables for BDS Datasets	Clarification	Changed "reference date" to "anchor date" in CDISC Notes for ADY, ASTDY, AENDY. Changed "reference time" to "anchor time" in the CDISC Notes for ARELTM.
Table 3.3.3.1 Timing Variables for BDS Datasets	Update	Changed Core value from Conditional to Permissible for ARELTMU.
Table 3.3.3.1 Timing Variables for BDS Datasets	Addition	Added variables APHASEN, ASPER, ASPERC.
Table 3.3.3.2 Period, Sub-period, and Phase Start and End Timing Variables	Addition	Added variables APERSDT, APERSTM, APERSDTM, APERSDTF, APERSTMF, APEREDT, APERETM, APEREDTM, APEREDTF, APERETMF, ASPRSDT, ASPRSTM, ASPRSDTM, ASPRSDTF, ASPRSTMF, ASPREDT, ASPRETM, ASPREDTM, ASPREDTF, ASPRETMF, PHSDT, PHSTM, PHSDTM, PHSDTF, PHSTMF, PHEDT, PHETM, PHEDTM, PHEDTF, and PHETMF.
Section 3.3.4 Analysis Parameter Variables for BDS Datasets	Addition	Added text to clarify the purpose and relationships of PARAM, AVAL and AVALC, in contrast to SDTM Findings Class variables --TEST, --STRESN, and --STRESC.

Category/Section	Type	Description
Table 3.3.4.1 Analysis Parameter Variables for BDS Datasets	Update	Removed requirement that PARAMN must be integer.
Table 3.3.4.1 Analysis Parameter Variables for BDS Datasets	Update	Added note that PARAMTYP will be retired in the next version.
Table 3.3.4.1 Analysis Parameter Variables for BDS Datasets	Update	Specified Core separately for AVAL and AVALC. Changed Core value from Required to Conditional for AVAL and AVALC, but specified that at least one of the two is required.
Table 3.3.4.1 Analysis Parameter Variables for BDS Datasets	Addition	Added variables AVALCAyN, BASECAyN, CHGCATyN, and PCHGCAyN.
Table 3.3.4.2 Analysis Parameter Criteria Variables for BDS Datasets	Addition	Added multi-response criterion evaluation variables MCRITy, MCRITyML, and MCRITyMN.
Section 3.3.5 Analysis Descriptor Variables for BDS Datasets	Clarification	Added text to clarify DTYPE and visit windowing variables.
Section 3.3.6 Time-to-Event Variables for BDS Datasets	Update	Moved Time-to-Event Variables to new section 3.3.6, and aligned with the document titled "The ADaM Basic Data Structure for Time-to-Event Analyses", v1.0, including addition of variables STARTDTM, STARTDTF, STARTTMF, and CNSDTDSC.
Table 3.3.7 Toxicity and Range Variables for BDS Datasets	Update	Generalized the toxicity and range variables previously found in table 3.2.5.4, "Lab Related Analysis Variables for BDS Datasets", to be applicable to non-laboratory-test data. These variables are now in their own section 3.3.7, "Toxicity and Range Variables for BDS Datasets".
Table 3.3.7 Toxicity and Range Variables for BDS Datasets	Update	Corrected the Type of AyLO and AyHI from Char to Num.
Table 3.3.7 Toxicity and Range Variables for BDS Datasets	Addition	Added variables ANRLOC, ANRHIC, AyLOC, AyHIC, AyIND, and ByIND.
Table 3.3.8.2 BDS Population Indicator(s) Variables	Update	Corrected the Variable Name of variable COMPRFL to COMPLRFL, and corrected the Variable Name of COMPPFL to COMPLPFL, to make consistent with the subject-level population flag variable COMPLFL.
Table 3.3.8.2 BDS Population Indicator(s) Variables	Update	Changed the Core of parameter-level and record-level population flags from Cond to Perm.
Table 3.3.8.2 BDS Population Indicator(s) Variables	Update	Removed numeric versions of parameter-level and record-level population flag variables ITTRFN, SAFRFN, FASRFN, PPROTRFN, COMPLRFN, ITTPFN, SAFPFN, FASPFN, PPROTPFN, and COMPLPFN.
Section 3.3.9 Datapoint Traceability Variables	Update	Created new section about variables useful for datapoint traceability, including and expanding upon relevant content that was in the previous section 3.2.8, "Other Variables".
Section 3.4 Analysis-Enabling Variables	Format	Moved discussion of analysis-enabling variables from previous section 3.2.8, "Other Variables" to new section 3.4.
Section 3.5, Differences between SDTM and ADaM Population and Baseline Flags	Update	Corrected mention of ADaM variable name COMPFL to COMPLFL.
Example 1 in Section 4.1 Examples of Treatment Variables for Common Trial Designs	Clarification	Added ACTARM, TRTSDT, and TRTEDT to the parallel group design example. Removed TRT01SDT and TRT01EDT from the example because they are not required in a one-period treatment study. Clarification added to text.
Example 5 in Section 4.1 Examples of Treatment Variables for Common Trial Designs	Addition	Added new example showing TRTP representing treatment at time of actual visit within a BDS structure, along with TRT01P and TRT02P (from ADSL).

Category/Section	Type	Description
Example 6 in Section 4.1 Examples of Treatment Variables for Common Trial Designs	Addition	Added another example showing TRTP representing treatment used for analysis within a BDS structure in an alternative to Example 5 in the same section.
Section 4.2 Creation of Derived Columns versus Creation of Derived Rows	Addition	Added list of rules that are each covered in separate subsections of section 4.2.1.
Section 4.2.1 Rules for the Creation of Rows and Columns	Added	Added explanation of bolding in the examples in section 4.2.1.
Rule 1 in Section 4.2.1 Rules for the Creation of Rows and Columns	Clarification	Clarified text regarding parameter invariance.
Rule 2 in Section 4.2.1 Rules for the Creation of Rows and Columns	Clarification	Added VISIT to Table 4.2.1.2 for comparison with AVISIT. Added clarification about what variables and values to retain when deriving a record from an individual existing record.
Rule 3 in Section 4.2.1 Rules for the Creation of Rows and Columns	Update	Deleted mention of PARAMTYP from 3rd paragraph and deleted PARAMTYP from Table 4.2.1.4. Changed the SDTM source domain for the migraine data in table 4.2.1.7 from Clinical Findings (CF) to Findings About (FA). Added text to clarify crossover example shown in Table 4.2.1.8.
Rule 6 in Section 4.2.1 Rules for the Creation of Rows and Columns	Addition	Expanded description of original example shown in Table 4.2.1.11. Added Table 4.2.1.12 to show a solution for the case where only the most recent baseline is needed for change from baseline analysis. Added text regarding relationship among definitions of baseline, ABLFL, and BASETYPE.
Section 4.3.1 ADaM Methodology and Examples	Addition	Added QSSEQ to Tables 4.3.1.1 and 4.3.1.3.
Table 4.3.1.3	Addition	Added PARAMCD to table.
Section 4.4.1 ADaM Methodology and Examples	Clarification	Clarified wording about ADaM data sources in the first paragraph.
Section 4.4.1 ADaM Methodology and Examples	Update	Changed the SDTM source domain for the hospitalization data from Disposition (DS) to Hospitalization (HO), inserting table 4.4.1.3.
Example 2 in Section 4.4.1 ADaM Methodology	Update	Replaced SRC* variables with LBSEQ in Table 4.4.1.5, because all data came from a single source dataset. Clarified that SRC* variables are valid as well. Added PARAM to table. Removed eGFR equation footnote.
Example 3 Section 4.4.1 ADaM Methodology	Addition	Added new example 3 using SRC* variables pointing to predecessor ADaM dataset.
Example 1 in Section 4.5.1.1 ADaM Methodology and Examples	Update	Added VSSEQ to Table 4.5.1.1 to document traceability methodology.
Example 2 in Section 4.5.1.1 ADaM Methodology and Examples	Update	Added VSSEQ to Table 4.5.1.2 to document traceability methodology.
Example 1 in Section 4.5.2.1 ADaM Methodology and Examples	Update	Added VSSEQ to Table 4.5.2.1 to document traceability methodology.
All Examples in Section 4.5.2.1 ADaM Methodology and Examples	Update	Added BASE to all tables to demonstrate which value is used as baseline,
Example 1 in Section 4.5.4.1 ADaM Methodology and Examples	Update	Added AWTARGET and AWTDIFF to table and discussed in text in order to indicate more clearly how the analyzed rows were selected from the candidate rows.
Example 3 in Section 4.5.4.1 ADaM Methodology and Examples	Clarification	Added reference to windowing method defined in SAP.
Example 2 Section 4.5.4.2	Update	Changed values of DTYPE in example.

Category/Section	Type	Description
Example 1 in Section 4.6.1 ADaM Methodology and Examples/ Example 1	Clarification	Added text to explain the overall concept that subject-level and row-level flag variables allow analyses on multiple populations of interest within the same dataset.
Example 2 in Section 4.6.1 ADaM Methodology and Examples/ Example 2	Addition	Added new example 2 using subject-level and parameter-level population indicator (flag) variables.
Section 4.7.1 ADaM Methodology and Examples When the Criterion Has Binary Responses	Addition	Added mention of MCRIT* variables. Added text to clarify that the alternative methods for populating CRITy and CRITyFL support different analysis needs.
Example 3 of Section 4.7.1 ADaM Methodology and Examples When the Criterion Has Binary Responses	Deletion	Removed mention of PARAMTYP.
4.7.2 ADaM Methodology and Examples When the Criterion Has Multiple Responses	Addition	Added section 4.7.2 to provide examples of the new variables MCRITy, MCRITyML and MCRITyMN.
Section 4.8 Examples of Timing Variables, with 4.8.1 Example of Phase, Period and Subperiod Variables.	Addition	Inserted new section 4.8, containing new subsection 4.8.1, in order to provide an example of the relationship among phase, period and subperiod variables.
Section 4.9 Other Issues to Consider	Format	Moved previous section 4.8 to Section 4.9.
Section 4.9.3 Size of ADaM Datasets	Addition	Added new section 4.9.3.
Section 4.9.4 Traceability When the Multiple Imputation Method is Used	Addition	Added new section 4.9.4.
Section 4.9.5 Copying Values onto a New Record	Addition	Added new section 4.9.5.
Appendix B	Addition	Inserted Appendix B, “Change History”.

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