Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG)

研究数据列表模型–元数据递交指南（SDTM-MSG）

Prepared by the CDISC SDS Metadata Team

由CDISC SDS 元数据团队（SDS Metadata Team）开发

Notes to Readers

This is Version 1.0 of the Metadata Submissions Guidelines created by the CDISC Submission Data Standards Metadata subteam.

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1 Introduction 简介

1.1 Purpose 目的

The purpose of the Study Data Tabulation Model - Metadata Submission Guidelines (SDTM-MSG) is to provide guidance for compiling the eCTD module 5 "sdtm" folder. This document and the associated sample submission illustrate the components recommended for electronic submission of SDTM data. The sample submission components include an annotated CRF, submission datasets compliant with the SDTMIG 3.1.2 in SAS version 5 transport format, a define.xml file describing the structure and content of the submitted datasets, a style sheet (define2-0-0.xsl) for visualizing the define.xml in a user-friendly way, and an optional Reviewers' Guide.

研究数据列表模型—元数据递交指南(SDTM-MSG) 的目是为完成 eCTD 模块 5 的"sdtm"文件夹提供指导。本文档和相关的递交示例说明了电子递交 SDTM 数据所推荐的组件内容。递交示例文档中包括：一个注释 CRF， 符合 SDTMIG 3.1.2 中以 SAS 5 Xport 格式的递交数据集，一个用于描述递交数据集结构和内容的 define.xml 文件，一个方便用户可视化呈现的样式表(define2-0-0. xsl) ，以及一个（可选的）审评者指南。

The SDTM-MSG will enable users to become familiar with the SDTM submission components. This entire package is intended to illustrate acceptable practices and formats that sponsors should incorporate into their submissions, but is not intended to dictate the only acceptable practice. The scope of this document and associated study-related files is the SDTM portion of a submission.

SDTM-MSG 意在让用户熟悉 SDTM 递交的组件内容。整个文档的目的是为了描述申办方递交时应纳入的已认可的实践和格式，但这并不是唯一认可的实践。本文档的范畴和研究相关的文件是递交中的 SDTM 部分。

In order to view the sample submission, the ZIP file should be downloaded from the CDISC website (www.cdisc.org). Extracted files should be stored in the same folder to preserve the inter-component linking. This document encompasses the latest FDA recommendations; however, sponsors are encouraged to work with their review division when compiling their submissions.

其递交示例可以从 CDISC 官网(www.cdisc.org) 下载相应 ZIP 文件来查看。所提取的文件应该存放在相同的文件夹中，以保持组件之间的可连接性。本文档包含最新的 FDA 建议，同时，也鼓励申办方在递交过程中与其审查部门沟通合作。

1.2 References and Abbreviations 参考和缩写

The current versions of the documents referenced in the SDTM-MSG may be accessed via the links provided below.

SDTM-MSG 参考的当前版本文件可通过以下链接获取：

- CDISC website
  http://www.cdisc.org/
- SDTMIG- CDISC SDTM Implementation Guide Version 3.1.2
  http://www.cdisc.org/extranet/index.php?a=1209
- SDTM - Study Data Tabulation Model (SDTM) Final Version 1.2
  http://www.cdisc.org/extranet/index.php?a=1209
- CRT-DDS-Case Report Tabulation Data Definition Specification (define.xml) Version 1.0
  http://www.cdisc.org/models/def/v1.0/index.html
- FDA eCTD Guidance - Electronic Common Technical Document)
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm
- FDA Study Data Specifications (Version 1.6)
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm
- Controlled Terminology
  http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc
- CDER Common Data Standards Issues Document (Version 1.0/May 2011)
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm

1.3 Organization of this Document 文档结构

This document is organized into the following sections to facilitate review and understanding of the submission components.

为了便于审阅和理解递交的组成内容，该文档由以下章节组成：

- Section 1, INTRODUCTION, outlines the organization of this document.
  第 1 节，简介，概括该文档的结构
- Section 2, GENERAL SPECIFICATIONS FOR SUBMITTING SDTM, describes the components of an eCTD module 5 sdtm folder.
  第 2 节，SDTM 递交的一般规定，描述 eCTD 模块 5： stdm 文件夹的组成
- Section 3, DEFINE.XML, explains the definition portion of the submission datasets. Descriptions of the various components including tables, table content, and hyperlinks between components are included. This section describes the organization of the define.xml and is not a technical guide to the define.xml. The technical information can be found in the CRT-DDS.
  第 3 节，DEFINE.XML，解释了递交数据集的定义部分。对各种不同组件作了描述，

包括各种表格、表格内容、以及各组件之间的超链接。该章节描述了 define.xml 的结构，但并非 define.xml 的技术指南。具体的技术信息可以从 CRT-DDS 中找到。

- Section 4, GUIDELINES FOR ANNOTATING and BOOKMARKING CRFs, provides guidelines for annotating CRFs according to the SDTM specifications.

第 4 节，CRF 注释和标签指南，根据 SDTM 要求对注释 CRF 提供指导参考。

- Section 5, SUBMISSION DATASETS, explains the SDTM domains and datasets contained in the sample submission.

第 5 节，递交数据集，用递交示例解释了 SDTM 域和数据集。

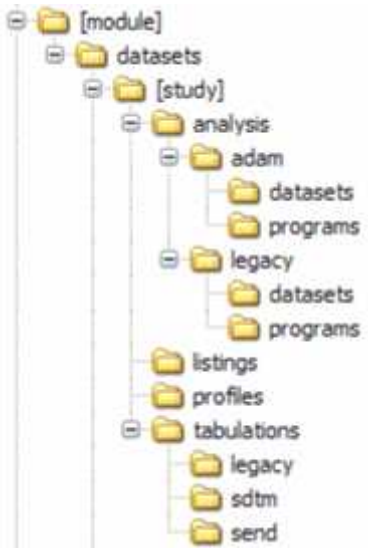
2 General Specifications for Submitting SDTM

SDTM 递交的一般规定

2.1 Submission Structure 递交结构

The FDA Study Data Specifications recommends the following folder structure for the data portion of the eCTD. The image below is the structure at the time of this publication, but the sponsor should check the current specification for the latest update. The Study Data Tabulation Model (SDTM) datasets (in SAS version 5 transport file format), define.xml, annotated CRF, and any additional documentation are located in the "sdtm" folder. Refer to the FDA Study Data Specifications for the intended contents of the other folders. The naming conventions used for files within the sdtm folder must comply with the FDA eCTD Guidance.

FDA 研究数据规范为 eCTD 数据部分建议如下文件夹结构。下图是本文发表时的 eCTD 文件夹结构，申办方应该查到并获取最新的文件夹结构。研究数据列表模型(SDTM)数据集(SAS 5 的 Xport 格式) 、define.xml、注释 CRF 和任何额外的文档都放在"sdtm"文件夹中。其他文件夹的内容可参考 FDA 研究数据规范。sdtm 文件夹内的文件命名规则必须符合 FDA 的 eCTD 指南。



2.2 Define.xml

The define.xml is the metadata describing the structure and content of the submitted datasets. The define.xml placed in the sdtm folder along with the submission datasets. See Section 3of this document and the FDA Study Data Specifications for additional details. A printable (PDF) version of the define.xml was also added to the sample submission based on the CDER Common Data Standards Issues Document. The PDF was created through a separate process, and the method of creation and the format is sponsor defined.

define.xml 是用于描述递交数据集的结构和内容的元数据。define.xml 和递交数据集一起放置在 sdtm 文件夹中。本文档的第 3 节和 FDA 研究数据规范对此提供了更多细节。根据 CDER 常见数据标准问题的文件，一个可打印(PDF)的 define.xml 文件也可添加到递交示例中。PDF 文件可单独产生，其创建方法和格式由申办方来定义。

2.3 Annotated CRF 注释 CRF

The bookmarked and annotated CRF from the study should be saved in a PDF named blank crf.pdf and stored in the "sdtm" folder. All unique CRF pages or forms should be annotated to match the SDTM datasets and variables. See Section 4for additional details.

有书签和注释的研究 CRF 应当以 PDF 格式保存，并命名为 blankcrf.pdf， 存放在"sdtm"文件夹中。所有独一的 CRF 页面或表单应注释，并与 SDTM 数据集和变量相匹配。更多细节请见*第四节*。

2.4 Tabulation Datasets 表格型数据集

The "sdtm" folder within the tabulations folder is reserved for datasets, in SAS Version 5 transport format, conforming to the CDISC SDTM standard. See Section 5for additional details.

表格文件夹中的"sdtm"文件夹用于存放符合 CDISC SDTM 标准的、SAS 5 Xport 格

式的数据集。更多细节见*第五节*。

2.5 Reviewers' Guide 审评者指南

A Reviewers' Guide provides additional information for the reviewers about the submitted data. The inclusion of a Reviewers' Guide and its content are at the discretion of the sponsor. When the SDTM data are validated, errors and/or warnings may occur. All structural errors, those that are related to dataset and variable attributes, are generally within the sponsor's control and should be corrected. Any errors in structure or content that cannot be resolved may be explained in a Reviewers' Guide. A sample Reviewers' Guide is included in the "sdtm" folder of the sample submission which contains instructional text and reviewer information.

"审评者指南"为审评者提供了关于递交数据的一些额外信息。"审评者指南"的内容由申办方自由裁定。在 SDTM 数据验证时可能发生一些错误或警告信息。所有与数据集和变量属性相关的结构性错误通常由申办方来控制，并应予以纠正。任何无法解决的结构或内容方面的错误可以在"审评者指南"作以解释。递交示例的"sdtm"文件夹所包含的"审评者指南"，涵盖说明文本和审评者信息。

A number of approaches can be taken for validating the SDTM data. Third-party tools may be used and these tools may have their own interpretation of the requirements for properly formed SDTM datasets. Sponsors should understand and evaluate these interpretations. Validation issues related to an interpretation of a requirement should be noted in the Reviewers' Guide.

许多方法可用以验证 SDTM 数据。可以使用第三方工具，这些工具对于如何正确形成 SDTM 数据集可能有其自己的说明要求。申办方应该理解和评估这些说明。与这些说明要求相关的验证问题应该备注在审评者指南中。

3 Define.xml

3.1 Introduction 简介

The define.xml document specifies the standard for providing Case Report Tabulation Data Definitions in an XML format for submission to regulatory authorities (e.g. FDA). Basically, the define.xml is the metadata describing the format and content of the submitted datasets. The metadata, and the stylesheet used to display the metadata, are described within this section.

define.xml 文件对以 XML 格式标准向监管机构（如 FDA）递交病例报告列表的数据定义作了明确规定。define.xml 基本上是一种元数据，用以描述各递交数据集的格式和内容。本节将详细介绍元数据以及用于展示元数据的样式表。

- Dataset-level metadata, often referred to as the Table of Contents, in Section 3.2.
- 数据集级别的元数据，通常被称为目录表，请见*3.2*。
- Variable-level metadata, often referred to as the Data Definition Tables,

in Section 3.3.

- 变量级别的元数据，通常被称为数据定义表，请见*3.3*
- Value-level metadata in Section 3.4.
- 值级别的元数据，请见*3.4*。
- Controlled Terminology, referred to as Codelists, in Section 3.5.
- 用于编码的受控术语，请见*3.5*。
- Stylesheets used to display the xml in Section 3.6.
- 用于显示 XML 的样式表，请见 *3.6*。
- Define.xml schema validation in Section 3.7.
- Define.xml schema的验证，请见*3.7*。

3.2 Dataset-Level Metadata 数据集级别的元数据

Dataset-level metadata provide basic information about each of the datasets included in the "sdtm" folder. The format of the metadata is predefined by the define.xml specification. An "ItemGroupDef" element is provided for each SDTM dataset in the submission. Each "ItemGroupDef" element contains a set of "ItemRef" elements corresponding to the variables in the SDTM dataset. The SDTM variable-level metadata are described in "ItemDef" elements. Refer to the **CRT-DDS** for further details.

数据集级别的元数据对每个列入"SDTM"文件夹中的数据集提供基本信息描述。元数据的格式已预定义在define.xml说明中。递交资料中每个SDTM数据集都会对应一个"ItemGroupDef"元素。每一个"ItemGroupDef"元素都含有一组"ItemRef"元素，它们分别与SDTM数据集中各个变量一一对应。SDTM变量级别的元数据由"ItemDef"元素来描述。更多细节请参阅*CRT-DDS*。

In the event that no records are present in a dataset (e.g., a small study where no subjects took concomitant medications), the empty dataset should not be submitted or described in the define.xml. Please refer to Section 4.1.1 for information regarding the annotations of such a dataset.

如果一个数据集中没有任何记录（例如没有受试者合并用药的小型临床研究），这个空数据集就不应该被递交或纳入define.xml中描述。有关此类数据集的信息请参见第*4.1.1*。

3.2.1 Organization 结构

All tabulation datasets, CDISC and sponsor-defined, must be included in the dataset-level metadata and they should be organized by their SDTM class**.** Datasets should be listed in alphabetical order by name attribute within each class in the define.xml file. In the case of split domains, this may not be sufficient and other attributes may be used as demonstrated in the sample define.xml.

数据集级别的元数据需包含所有CDISC及申办方定义的表格数据集，并按照其所属的SDTM类别进行组织。define.xml文件中，每个类别内的数据集应根据其英文命名按字

母顺序排列。在分割域的情况下，这种排序可能不完善，可以使用其它属性，如在define.xml案例中所示那样。

The recommended order for the classes is:

对类别的排序建议如下：

- Trial Design Datasets
- 试验设计数据集
- Special-purpose Domains
- 特殊目的域
- Interventions Domains
- 干预类域
- Events Domains
- 事件类域
- Findings Domains
- 发现类域
- Relationship Datasets
- 关系数据集

3.2.2 Content 内容

The structure of the dataset-level metadata is predefined by the define.xml schema and specification. The presentation format is defined through the associated stylesheet chosen by the sponsor. In the absence of published guidance, the sponsor should determine which metadata attributes to display.

数据集级别元数据的结构已预定义在define.xml schema及其说明中。其展现形式定义在申办方选择的相关样式表中。若指南中无明确定义，申办方应确定要显示哪些元数据属性。

Table 3.2.2.1: Dataset-Level Metadata

XML Attribute	Stylesheet Display	Notes
ItemGroupDef Attributes		
OID		The unique ID of the domain
Name	Dataset	The name of the dataset (e.g., "DM", "AE").
Repeating		Valid values are "Yes" or "No". "Yes" is for datasets with the potential of having more than one record per subject. "No" is for domains restricted to 1 record per subject. Repeating should be populated "No" for the Trial Design domains.
IsReferenceData		Valid values are "Yes" or "No". "Yes" is for datasets that contain reference data only (e.g., Trial Design datasets). "No" indicates subject data. Absence of this attribute indicates subject data.
Purpose	Purpose	The purpose for the dataset. The purpose of all SDTM datasets is "Tabulation".
def:Label	Description	A short description of the type of information contained within the dataset (e.g. "Demographics", "Adverse Events") that matches the SDTMIG domain description, or the sponsor-defined domain description in the case of custom domains. A hyperlink should be defined by the stylesheet from the def:Label attribute to the variable-level metadata for the dataset.
def:Structure	Structure	The level of detail represented by individual records in the dataset (e.g., "One record per subject", "One record per subject per visit", "One record per subject per event").
def:DomainKeys	Keys	The domain level keys are a series of variables whose primary purpose is to uniquely identify a record in the dataset.
def:Class	Class	The general class of the observations within the domain as defined in the SDTM model (e.g., "Trial Design", "Special Purpose", "Interventions", "Events", "Findings", or "Relationship")
def:ArchiveLocationID	Location	This contains a reference to a def:leaf element containing the transport file filename and path. A hyperlink to the transport file should be provided by the stylesheet.

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328 表 3.2.2.1 数据集级别元数据

XML 属性	样式表显示	备注
ItemGroupDef 属性		
OID		域的唯一ID
Name	Dataset	数据集名称 (如, "DM", "AE").
Repeating		有效值为"是"或"否"。"是"指每个受试者在数据集中可能有多条记录。"否"指域限定了每个受试者仅有1条记录。在试验设计域中，"Repeating"的值应为"否"。
IsReferenceData		有效值为"是"或"否"。"是"指该数据集仅包含用于参考的数据（例如，试验设计数据集）。"否"表示受试者数据。该属性缺失时默认为受试者数据。
Purpose	Purpose	数据集的目的。所有SDTM数据集的目的都是"tabulation（制表）"。
def:Label	Description	对数据集信息的简短描述，与SDTMIG对域的描述一致，（如，人口统计学，不良事件），或者在自定义域的情况下，使用申办方定义的域名描述。样式表应在 def: Label 属性设定一个超链接至该数据集对应的变

		量级别元数据。
def:Structure	Structure	数据集中单个记录的详细程度（如"每个受试者一条记录"，"每次访视一条记录"，"每个受试者的每次事件一条记录"）。
def:DomainKeys	Keys	域级别的关键字由一系列变量构成，其主要目的是用于特异识别数据集中的记录。
def:Class	Class	域的通用观测数据类别，与SDTM模型中定义一样（例如，"试验设计"，"特定目的"，"干预"，"事件"，"发现"或"关系"）。
def:ArchiveLocationID	Location	包含一个对def: leaf元素的引用，该元素包含传输文件的文件名和路径。样式表应提供一个关联至传输文件的超链接。

def:Class

The domain Class implies a predefined set of variables and can aid in the review, as well as the validation, of the data.

域的类别意味着数据集已预定义一组变量，这些信息有助于数据的审阅以及验证。

def:Structure

The description of structure should match the dataset, and may be different from the description of the structure in the SDTMIG. The LB entry in the define.xml of the sample submission is an example of a structure description that is less detailed than that in the SDTMIG. This example is not intended to recommend a structure description different than in the SDTMIG, but to illustrate the fact that a different description is possible.

结构的描述应和数据集匹配，但可能与SDTMIG描述的结构不同。例如，递交示例define.xml中LB条目就是对结构描述的一个例子，它比SDTMIG中的详细程度要低。这个例子并不是为了建议大家对结构描述与SDTMIG不同，而是为了说明可以有不同的描述。

def:DomainKeys

As stated in Table 3.2.2.1, the primary purpose of the keys is to uniquely identify a record within a dataset. The keys serve as an aide to reviewers in understanding the dataset structure and potentially defining a sort order. However, the keys do not necessarily have to reflect the sort order of the submission dataset.

如表3.2.2.1所述，使用关键字的主要目的是用于特异识别数据集的某条记录。这些关键词可以帮助审阅者了解数据集的结构和潜在的排序方式。然而，关键词并不一定非要反映递交数据集的排序方式。

The keys shown in the dataset-level metadata of the sample submission (See Sample define.xml) are only examples and sponsors should organize

their dataset keys according to their preferences and data requirements. For subject-related data, the first 2 keys are always STUDYID and USUBJID. These keys are often followed by topic and timing variables, which may be a term or treatment and date for the Events and Interventions class domains, and a test code and visit number and/or time point for Findings class domains.
递交示例里的数据集级别元数据中显示的关键字（见define.xml示例）仅仅是例子，申办方应根据自己的偏好和数据的要求来组织其数据集的关键字。受试者相关的数据，前2个关键字总是STUDYID和USUBJID，其后通常是主题和时间变量，可能是用于事件类和干预类域的术语或治疗和日期；还有，用于发现类域的一个实验代码、访视编号和/或时间点。

3.3 Variable-Level Metadata 变量级别的元数据

The variable-level metadata contain the attributes for each variable within each dataset. In the define.xml, each variable is represented by an "ItemDef" element describing the metadata for that variable. Refer to the **CRT-DDS** for further details.
变量级别的元数据包含每个数据集内的每个变量的属性。在define.xml，每个变量由"ItemDef"元素来描述该变量的元数据。具体细节请进一步参阅*CRT-DDS*。

Normalized datasets, such as those in the Findings General Observation Class and Supplemental Qualifiers, are further described by value-level metadata. See Section 3.4 for additional information.
纵向（标准化）数据集，如那些用于通用观测数据发现类和补充修饰语，由值级别的元数据来进一步描述。请参阅*3.4*节获得更多信息。

3.3.1 Organization 结构

Every dataset listed in the dataset-level metadata (define.xml "ItemGroupDef") will have associated variable-level metadata (define.xml "ItemDef"). The stylesheet should provide a hyperlink from the "Description" column in the display of the dataset-level metadata to the variable-level metadata table for each of the datasets.
列入数据集级别元数据（define.xml "ItemGroupDef"）的每一个数据集都有与之相关的变量级别的元数据（define.xml "ItemDef"）。每一个数据集应在样式表中提供一个超链接，将数据集级别元数据中"Description"列所显示的内容链接到其变量级别的元数据上。

In the display generated by the stylesheet, the variable-level tables should be listed in the same order as the datasets in the dataset-level metadata table. In the stylesheet this is taken care of by nested loops over "ItemGroupDef" and the containing "ItemRef". See the comments in the stylesheet (define2-0-0.xsl) for technical details about how this is accomplished.

由样式表生成的显示结果中，变量级别表格的排列顺序应与数据集在数据集级别元数据表格中的排序一致。在样式表中，需注意"ItemGroupDef"和"itemref"的嵌套循环。请参阅样式表（define2-0-0.xsl）里的注解来了解如何实现的技术细节。

The variables within each dataset ("ItemRef" within "ItemGroupDef" in the define.xml) must be ordered according to the sequence specified in the SDTMIG, Section 4.1.1.4. The stylesheet should ensure that this order is maintained in the display. In addition, the order of the variables in the define.xml and the order of the variables within the dataset must be identical.

每个数据集中的变量（define.xml中"ItemGroupDef"内的"ItemRef"）必须根据在SDTMIG 第4.1.1.4章节规定的顺序进行排序。样式表应确保该排序正确显示。此外，变量在define.xml中的顺序和在数据集内的顺序也必须相同。

3.3.2 Content 内容

The content of the variable-level metadata is predefined in the define.xml schema and specification. The associated stylesheet provides the presentation formatting.

变量级别元数据的内容已经预定义在define.xml schema及其说明中。由与之相关的样式表来提供其展现形式。

In the define.xml specification, ItemRef and ItemDef describe variable-level metadata. ItemRef lists the variables used in a dataset and, within that dataset, the order of variables, their role, and whether they are mandatory. ItemDef describes variable attributes such as label, data type, length, and origin independently of the dataset(s) where the variables are used. This structure enables common variables such as STUDYID and USUBJID to be defined once but used in all applicable datasets.

在define.xml说明中，ItemRef和ItemDef用于描述变量级别的元数据。ItemRef列出了一个数据集中所使用的变量，并描述变量在此数据集中的顺序、角色、以及是否强制要求使用。 ItemDef独立于其被使用的数据集来描述变量的属性，如标签、数据类型、数据长度、及其来源。这种结构使的公共变量（如STUDYID和USUBJID）只需被定义一次，便可适用于所有数据集。

Variable-level metadata include the following items:

变量级别的元数据包括以下内容：

Table 3.3.2.1: Variable-Level Metadata

XML Field	Stylesheet Display	Notes
ItemRef Attribute		
ItemOID		Reference to the corresponding ItemDef.
OrderNumber		Indicates the order of the variable within the dataset.

<table>
<tr><td>Mandatory</td><td></td><td>SDTM Core required variables should have a value of “Yes” while expected and permissible should have a value of “No”.</td></tr>
<tr><td>Role</td><td>Role</td><td>Information on how a variable is used within the dataset (e.g., "IDENTIFIER", "TOPIC", "TIMING", "SYNONYM QUALIFIER", “GROUPING QUALIFIER”, “VARIABLE QUALIFIER”, “RECORD QUALIFIER”, “RESULT QUALIFIER”, “RULE”).</td></tr>
<tr><td>RoleCodeListOID</td><td></td><td>The OID of the corresponding Role Code List. Role and RoleCodeListOid are a pair, if one is provided, then the other needs to be provided also.</td></tr>
<tr><td>ItemDef Attribute</td><td></td><td></td></tr>
<tr><td>OID</td><td></td><td>Unique identifier for the ItemDef. Usually the variable name is used with a prefix containing the domain code when the variable is specific to a domain. For example: DM.AGE, STUDYID.</td></tr>
<tr><td>Name</td><td>Variable</td><td>The name of the variable should match the variable name in the dataset.</td></tr>
<tr><td>DataType</td><td>Type</td><td>The permissible XML variable type ("text", "float", "integer", "date", "datetime", "time") as defined in the define.xml specification Section 2.1.2.4. The value reported in the define.xml maps to the SAS transport data type as indicated in the table below:
<table>
<tr><th>Define.xml Data Type</th><th>SAS Data Type</th></tr>
<tr><td>text</td><td>Char</td></tr>
<tr><td>integer</td><td>Num</td></tr>
<tr><td>float</td><td>Num</td></tr>
<tr><td>datetime**</td><td>Char**</td></tr>
<tr><td>date**</td><td>Char **</td></tr>
<tr><td>time**</td><td>Char**</td></tr>
</table>
** For ISO-8601 formatted date/time variables, the format reported in DataType is either "date", "datetime", or "time". If date and time are collected then “datetime” should be used, even if no time values are actually collected. If date values only, and not time values, are collected then “date” should be used.</td></tr>
<tr><td>Length</td><td></td><td>Length is required for text, integer and float type variables.</td></tr>
<tr><td>SignificantDigits</td><td></td><td>When the float data type is used, the number of digits after the decimal point is required. For float</td></tr>
</table>

		type variables the length does not include the decimal point. e.g. if length=4 and significant digits=2 then the maximum value would be 99.99
Origin	Origin	Indicator of the origin of the variable. Examples could include "CRF Page #", "Derived", "eDT", "Assigned", or "Protocol." Refer to SDTMIG section 4.1.1.8.1. The stylesheet should ensure that hyperlinks are provided in the display to specific pages or sections of the annotated CRF.
Comment	Comment	Other information regarding the variable definition if needed.
def:Label	Label	Labels should match the variable labels in the datasets. See SDTMIG 2.6 and SDTMIG 3.2.2 for additional guidance.
def:DisplayFormat		Display format for numeric variables (e.g., 8.2, 7.3). It is anticipated that this attribute will be deprecated in future versions of the CRT-DDS.
def:ComputationMethodOID	Hyperlink in Comment	The identifier of the computational algorithm used to derive or impute the variable values. When def:ComputationMethodOID is present, the stylesheet should add the text "See Computational Method:" to the rendered "Comment" column and provide a hyperlink to the table containing Computational Algorithms (representing all define.xml "def:ComputationMethod" elements). Refer to value level metadata for EG testcodes of QTCB and QTCF. Alternatively, the stylesheet may generate an additional column that provides a hyperlink to the computational method or displays the computational algorithm. Refer to Section 6.3 for information on the sample stylesheet included in the submission that displays these columns.
ItemDef Child Elements		
CodeListRef	Controlled Terms or Format	A reference to the codelist of possible values for that variable or external dictionary. This is used for variables with a code/decode. The stylesheet should provide a hyperlink to the table "Controlled Terminology" containing a list of all

		define.xml "CodeList" metadata.
def:ValueListRef	Hyperlink on variable name	If applicable, a reference to a value list associated with the variable. If a value list exists, the stylesheet should provide a hyperlink in the display to the associated value list. See Section 3.3.3 for additional information.

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436 表 3.3.2.1: 变量级别的元数据

XML 属性	样式表显示	备注
ItemRef 属性		
ItemOID		相应ItemDef的参考。
OrderNumber		该变量在数据集里的顺序。
Mandatory		当该变量的SDTM核心类别为必需时，其值应该为"是"；反之若为预期和许可，则为"否"。
Role	Role	该变量在数据集中被使用的信息(如., "IDENTIFIER（标识符）", "TOPIC（主题）", "TIMING（时间）", "SYNONYM QUALIFIER（同义修饰符）", "GROUPING QUALIFIER（群组修饰符）", "VARIABLE QUALIFIER（变量修饰符）", "RECORD QUALIFIER（记录修饰符）", "RESULT QUALIFIER（结果修饰符）", "RULE（规则）").
RoleCodeListOID		相应（Role Code List）角色代码表的OID。角色(Role)和RoleCodeListOID是成对出现，如果提供了一个，则必须同时提供的另一个。
ItemDef 属性		
OID		ItemDef的唯一标识符。通常变量名的前缀含有域代码表明该变量是从属于该域。例如：DM，AGE，STUDYID。
Name	Variable	变量的名称应该与数据集中的变量名相匹配。
DataType	Type	XML允许的变量类型（"文本"，"浮点"，"整数"，"日期"，"日期时间"，"时间"），如同在define.xml说明2.1.2.4节中的定义。从define.xml报告的值映射到SAS传输数据类型的值如下表所示： **Define.xml Data Type** / **SAS Data Type** text / Char integer / Num float / Num datetime** / Char** date** / Char ** time** / Char** **对于ISO-8601格式的日期/时间变量，报告数据类型的格式是"日期"，"日期时间"或"时间"。如果日期和时间同时被采集，即使没有实际采集时间，应使用"日期时

		间”。如果仅要求采集日期值，而不是时间值，则应选择“日期”。
Length		对文本、浮点、整数变量需明确值的长度
SignificantDigits		当为浮点数据类型时，需要明确有效位数。计算浮点类型变量的长度不需要包括小数点。例如，如果长度=4和有效位数= 2，那么最大值是99.99
Origin	Origin	变量结果的数据来源，如CRF第#页、衍生、eDT、指定或方案规定。请参阅SDTMIG 第4.1.1.8.1节。样式表应确保通过超链接来显示注释CRF的特定页面或章节。
Comment	Comment	其它关于变量定义的信息(若适用)。
def:Label	Label	标签应与数据集中的变量标签相符。见SDTM IG 2.6和SDTMIG 3.2.2来获得更多的指导。
def:DisplayFormat		数值型变量的显示格式（例如，8.2，7.3）。据预测，此属性将在CRT-DDS的未来版本中被弃用。
def:ComputationMethodOID	Hyperlink in Comment	用于衍生或推导变量值的计算方法的标识符。当def:ComputationMethodOID存在时，样式表应该在“Comment”一栏中添加文字“参看计算方法：”，并提供超链接连接到包含算法的表格（define.xml中代表“def:ComputationMethod”的所有元素）。请参见：值级别的元数据QTcB值和QTcF间的EG检测代码。 此外，样式表可能会产生额外的列来显示算法或提供一个超链接至计算方法。参见6.3节中用于递交的样式表示例信息来了解如何显示这些列。
ItemDef 子元素		
CodeListRef	Controlled Terms or Format	这是变量可能的值或外部字典的编码列表的参考。这个变量用于编码/解码。样式表应该提供一个超链接表到“受控术语”表，该表含所有define.xml“代码表”元数据的列表。
def:ValueListRef	Hyperlink on variable name	如适用，这是与变量关联的值列表的参考。如果值列表存在，样式表应该提供一个超链接来显示相应的值列表。请参见3.3.3节获得更多信息。

Type 类型

Type is the data type of the submitted variable. Eventually data will be submitted to the FDA through XML and Type will reflect the XML data type; however, currently data are contained in SAS transport files. The mapping between define.xml types and SAS data types is indicated in Table 3.3.2.1 above. For numeric variables which may contain a mix of integer and float data types (--STRESN) data type “float” should be specified with a length and significant digits large enough to accommodate all results.

Type是递交变量的数据类型。最终数据将通过XML递交给FDA，Type将反映XML的数据类型；然而，目前数据是包含在SAS传输文件中。 define.xml类型和SAS数据类型之间的映射关系参见上表3.3.2.1。对于可能混合包含整数和浮点的数据类型（--STRESN），应明确"浮点"数据类型其容纳所有结果的最大长度和有效位数。

Controlled Terms or Formats 受控术语或格式

Controlled terms must be specified in the codelist section of the define.xml. In the rendered define the controlled terms column links to the table of terms. Since controlled terminology associated with a variable is defined through a codelist, it is not expected that format catalogs would be included as part of the submission. Therefore, external SAS formats should not be applied to variables in SDTM. Note that variables linked to a value list (e.g., VSTESTCD, QNAM) would normally not be associated with a codelist since the full list of possible values is described by the value list.

受控术语必须在define.xml的编码列表部分中说明。在呈现受控术语列定义时需与表格中的术语相连接。由于与变量相关的受控术语已定义在编码列表中，其格式目录可以不必作为递交的一部分。因此，SDTM变量不适合应用外部SAS格式。需注意，链接到值列表的变量（例如，VSTESTCD，QNAM）通常不会与编码列表相关联，因为该变量所有的可能结果已描述在值列表中。

If the controlled terminology is based on an external dictionary (e.g., MedDRA, WHODRUG,), a link to the External Dictionaries section of the define should be provided.

如果受控术语是基于外部词典（例如，MedDRA，WHODRUG），应当提供链接到定义的外部字典的相应章节。

Origin 来源

The SDTMIG defines multiple values for origin. If the origin is designated as "Derived", then either the derivation definition should be specified in the Comments field, or a reference to either the computational method (def:ComputationMethod) or supplemental data definitions document (def:SupplementalDoc) should be provided.

SDTMIG定义了多种数据来源。如果数据来源为"衍生"，要么在注释（Comments）字段中明确其衍生定义，要么就提供计算方法（Def:ComputationMethod）或补充数据定义文件（def:SupplementalDoc）的引用。

If the origin is a page number in the annotated CRF (blankcrf.pdf), then the stylesheet should ensure that a hyperlink to the corresponding page within the annotated CRF is provided in the Origin column of the display. If there are multiple occurrences of a form only the first occurrence is listed in the Origin field. The subsequent pages should not be listed. If a collected variable or pre-printed information is annotated on the CRF, the origin must be CRF.

如果数据来源为注释CRF（blankcrf.pdf）的页码，样式表应确保在显示Origin列时提供超链接至注释CRF相应页码。如果一个表单多次出现，则只需要在第一次出现时列在Origin列。随后的页面就不需要列出。如果采集的变量或预打印信息注释在CRF中，则数据来源一定是CRF。

Comments 注释

Comments are primarily used for defining data derivations. If the derivation is of a reasonable size, it can be placed directly in the Comments field. For longer derivations, or if the sponsor prefers, an alternative is to describe the derivation method in the define.xml "def:ComputationMethod" element, and to reference it from the define.xml "ItemDef" describing the SDTM variable (define.xml "def:ComputationMethodOID"). The stylesheet should ensure that a hyperlink from the "Comments" column to the "Computational Algorithms" section is generated in the display. More than one variable can link to the same computational method.

Comments（注释）主要用于定义数据的推导。如果衍生定义的长度合适，它可以直接放置在注释字段中。对于较长的衍生定义，或者根据申办方偏好，另一种方式是在define.xml 里 "def：ComputationMethod" 的元素中描述衍生方法，并在define.xml 里 "ItemDef" 引用SDTM变量（define.xml "def: ComputationMethodOID"）。样式表应确保从"Comments"列到"Computational Algorithms（计算方法）"能够产生显示一个超链接。多个变量可以链接到相同的计算方法。

If the derivations for certain variables within a domain are large and involve complex logic or diagrams, the rendered Comments column may be used to provide a link to a "note" within a separate PDF file. This can be accomplished by having the stylesheet search for text such as "See Note xx" in the Comments field and produce a hyperlink to a named destination in the PDF file(s) listed as "SupplementalDoc" in the define.xml. If more than one external derivation is needed in supplemental data definitions, then the sponsor may choose to add these to the same or different external documents, or possibly included as part of the reviewers' guide. These additional PDFs should be located in the current "sdtm" folder or where determined by your regulatory department.

如果一个域内的某些变量的衍生定义较长且涉及到复杂的逻辑或图示，呈现Comments列时，应提供一个链接到一个单独的PDF文件中的 "备注（note）"事项。这可以通过在样式表中搜索文本，如在注释字段"见备注事项 xx"并产生一个超链接到define.xml "SupplementalDoc"中某个PDF文件。如果在定义数据时有必要补充一个以上的外部衍生，那么申办方可以选择将这些内容添加到相同或不同的外部文件，或作为 "评审者指南" 的一部分。这些额外的PDF文件应位于当前"sdtm"文件夹或由您的注册管理部门确定。

3.4 Value-Level Metadata

The normalized data structure of the SDTM Findings Class and Supplemental Qualifiers (SUPP--) datasets provide an efficient standardized structure for the exchange of data. Since different types of observations may be presented in the same structure, there is a need to provide additional metadata to describe the nature of the data included in the dataset. For example, if heart rate, weight, and frame size are collected for a vital signs dataset, heart rate is typically collected as a numeric integer value, weight is often collected with fractional numeric values (data type = float), and frame size may be collected as a coded character field (SMALL, MEDIUM, LARGE). This variability is not evident when looking at the variable metadata for the VS dataset. For these types of normalized datasets, all test codes (--TESTCD values) should be provided as well as the attributes of the results for each test code. In some cases a complete list may be accessible by a link on –TESTCD (e.g. VSTESTCD), in other cases a hierarchical categorization of --TESTCD values is used (e.g. LB). See further discussion below. Likewise, for Supplemental Qualifiers datasets, a list of variables (QNAM values) and their attributes should be provided. This information is "value-level" metadata since it varies based on the value of a particular variable (--TESTCD and QNAM values). Value-level metadata are required for Findings Class and Supplemental Qualifiers. Although not required, a sponsor may find it useful to use value-lists for variables within Events and Interventions.

SDTM发现类及补充修饰语(SUPP--)数据集的纵向数据结构为数据交换提供了一个高效的标准化结构。因为不同类型的观测结果可以用相同的结构来记录，为此有必要提供额外的元数据来描述数据集的数据的性质。例如，如果心率、体重和胸廓大小的数据搜集在生命体征数据集里，心率的值通常是整数，而体重通常是小数数值（数据类型=浮点型），胸廓大小是编码字符字段（小，中，大）。从变量级别元数据来看，这种差异在VS数据集里并不明显。对于这些纵向（标准化）数据集，应提供所有检测代码（ -TESTCD值）及每个检测结果的属性。在某些情况下可以通过在-TESTCD的链接（如VSTESTCD）获得一个完整的列表，而在其他情况下应使用分层分类的 - TESTCD值（如LB），详见下文。同样地，对于补充修饰语数据集，应提供变量（QNAM值）以及各自属性的列表。这个信息是"值级别"的元数据，因为它基于特定变量的值（ -TESTCD和QNAM值）而变化。发现类及补充修饰语需要设定值级别的元数据。虽然不是必需的，但在事件和干预中对变量使用值列表可能会对申办方非常有用。

In the define.xml, def:ValueListDef, ItemRef and ItemDef are used to describe value-level metadata (See Table 3.3.2.1). The use of ItemRef and ItemDef is the same as for variable level metadata (see section 3.3.2). This structure allows values to be defined once and used in multiple datasets. For example, the value list for IETESTCD, describing protocol inclusion and

exclusion criteria, could be defined once and used in both the IE and TI datasets.
在define.xml中，def：ValueListDef，ItemRef和ItemDef 被用于描述值级别的元数据（见表3.3.2.1）。ItemRef和ItemDef的使用类似于变量级别元数据的使用（参见3.3.2节）。这种结构则允许值只需定义一次，便可被多个数据集使用。例如，对于IETESTCD的值列表，只需定义一次试验方案入选和排除标准的描述，便可同时在IE和TI数据集里使用。

Value-level metadata are described using the same attributes as variable-level metadata. The Name and Label attributes list all possible values and corresponding labels for the variable. For example, in a Findings Class dataset such as VS, a row for each possible value of VSTESTCD would be described with labels matching the corresponding VSTEST values. For Supplemental Qualifiers datasets, all possible values of QNAM would be described with corresponding labels matching QLABEL.
描述值级别的元数据所使用的属性与变量级别的相同。通过Name（名称）和Label(标签)属性来列举该变量所有可能值和对应标签。例如，在一个发现类数据集如VS，每一排描述了一个可能的VSTESTCD值，及与VSTEST值相匹配的标签。而对补充修饰语数据集，QNAM所有可能的值都会由其相匹配的QLABEL标签值来描述。

The remaining attributes (DataType, CodeListRef, Origin, Comment, etc.) describe the result. For Supplemental Qualifiers datasets, these attributes describe QVAL. For Findings Class datasets that include both original and standardized results, define.xml is limited in that it has a mechanism to describe only one result. The metadata should describe the original result when there is one. If necessary, a comment or computational method may be included to describe the derivation of the standardized result.
其余的属性（DataType, CodeListRef, Origin, Comment等）用来描述结果。对于补充修饰语数据集，这些属性用来描述QVAL。对发现类数据集，它可能同时包含原始结果和标准化结果，但define.xml被限制的只能描述一个结果。当只能选一个时，元数据应说明原始结果。若必要，应加入注释或计算方法来描述标准化结果的衍生。

For an illustration of these concepts refer to the VS dataset in the define.xml. In the display, in the variable-level table, a hyperlink is associated with variable VSTESTCD. This hyperlink is created by the stylesheet when finding a def:ValueListRef element child element of the variable-level ItemDef. Follow this link to view the value-level metadata for VSTESTCD. Note the following:
在define.xml中，VS数据集阐明了这些概念。变量级别表格中会显示：有一个超链接会关联到变量VSTESTCD上。此超链接是样式表在变量级别ItemDef查找def:ValueListRef的子元素时创建的。点击此链接可以查看VSTESTCD对应的值级别的元数据。请注意以下几点：

- In the value-level metadata table, all possible values for VSTESTCD for this study are shown as well as their corresponding labels. The test code values and labels shown in the define.xml metadata match those found in the VS dataset in variables VSTESTCD and VSTEST.
- 在值级别的元数据表中，应显示本研究所有可能的VSTESTCD值都以及其相应的标签。VSTESTCD和VSTEST变量在define.xml元数据显示的检测代码值和标签应与VS数据集里的值相匹配。

- Data type reflects the way the original result (VSORRES) was collected for each test code. The data type (text, integer, float), length, and number of significant digits varies based on the value of the test code.
- Data type反映了每个检测代码原始结果（VSORRES）的采集方式。不同的检测代码，其数据类型（文本，整数，浮点数）、长度和小数位数不同。

- Origin describes where each value originated. In this example, all vital signs test results were collected using a CRF page, but it would be possible for tests to appear on different pages or a mix of sources such as CRF and eDT (electronic data transfer).
- Origin描述每个值的来源。在这个例子中，所有的生命体征检测结果是通过CRF页来采集，但它有可能是来源于CRF不同页面的检测项目，或诸如CRF和eDT（电子数据传输）的混合来源。

- A link to the codelist associated with FRMSIZE is displayed in the rendered Controlled Terms or Format column. This codelist provides a discrete list of possible values for VSORRES when the test code is FRMSIZE. Note that in the variable-level metadata, a codelist is not associated with VSORRES since the codelist is not applicable to all records within the dataset.
- 与FRMSIZE相关的编码表链接是在受控术语或格式列中显示。当检测代码是FRMSIZE，这个编码表提供了VSORRES所有可能的离散值列表。另外在变量级别元数据中，编码表不与VSORRES关联，因为编码表并不适用于数据集内的所有记录。

In some circumstances, it may be necessary to "nest" value-level metadata in order to group topic variables because the topic variable alone is not specific enough to represent the attributes. For example, if multiple questionnaires are collected and included in a single QS dataset, the data might best be described by first providing a value list reference for QSCAT. This value list would describe each questionnaire collected. Then a value list could be associated with each QSCAT value. Each "secondary" value list would describe the test codes and result attributes particular to each questionnaire. Likewise, when using the CDISC standard laboratory test code dictionary, it may be necessary to nest on lab specimen, method, etc. in order to provide appropriate descriptions of different types of results that share the same test code. For example, serum glucose, quantitative urine

glucose, and qualitative urine glucose (dipstick) all share the same LBTESTCD value (GLUC), but may have different data types, origin, length, etc.
在某些情况下，有可能通过嵌套值级别的元数据来对主题变量分组，因为独立的主题变量不能够充分地代表观测结果的属性。例如，多个问卷被采集，但被包含在一个QS数据集中，这些数据最好首先通过QSCAT的参考值列表来描述。此值列表会描述每一个用于采集的问卷，然后该值列表可以与QSCAT的每个值相关联。每一个"次要"值列表将描述针对每一个问卷调查的检测代码和结果属性。同样，采用CDISC标准的实验室检测代码字典的时候，可能有必要嵌套实验室的标本、方法等，从而对那些不同类型而又享有相同检测代码的结果提供适当的描述。例如，血糖，定量尿糖，和定性尿糖（试纸）都有着相同的LBTESTCD值（GLUC），但可能有不同的数据类型，如来源、长度等。

The sponsor should decide when multiple levels are required in order to properly describe the attributes of a test. In the sample submission define.xml, –CAT was nested for QS, LB, and IE. Again this is only an example and the sponsor should customize the define.xml and stylesheet to display their data in a logical manner.
申办者应决定何时需要多层次结构才能正确描述检测的属性。在define.xml案例中，-CAT嵌套了QS、LB和IE。再次声明，这仅仅是一个例子，申办方应当对define.xml和样式表进行自定义，以合理的方式展示他们的数据。

The above concepts are illustrated in the define.xml of the sample submission. Further explanation of the implementation can be found in Section 6.3.
上述概念在递交示例的define.xml中有所说明。进一步的解释可以在第6.3节中找到。

In the questionnaire datasets the following are noted:
在问卷数据集里，需注意以下几点：

- In the variable-level table, a link is associated with variable QSCAT. The value-level metadata for QSCAT can be seen when the link is opened.
- 在变量级别表中，QSCAT变量与一个链接相关联。打开链接可以看到QSCAT的值级别元数据。
- In the value-level metadata table, the values of QSCAT describe the questionnaires included in the QS dataset. Each questionnaire value is a link (this is the "nesting" described above). The link should lead to a view of the test codes (questions) associated with each questionnaire.
- 在值级别元数据表中，QSCAT值描述了QS数据集里包含的问卷。每个问卷值是一个链接（如上述的"嵌套"）。这个链接应连接到每个问卷的检测代码（问题）的视图上。

In the laboratory dataset, the following are noted:
在实验室检测数据集里，需注意以下几点：

- In the variable-level table, a link is associated with variable LBCAT. The value-level metadata for LBCAT can be seen when the link is opened.
- 在变量级别表中，LBCAT变量与一个链接相关联。打开时链接可以看到LBCAT的值级别元数据。
- In the display of the value-level metadata table, the values of LBCAT describe the test categories (CHEMISTRY, HEMATOLOGY, and URINALYSIS). Each category has a link (this is the "nesting" described above) to Specimen (LBSPEC) since the specimen further defines the uniqueness of a LBTESTCD. This distinction is necessary since the same LBTESTCD is used within multiple LBCATs.
- 在显示值级别元数据表时，LBCAT的值描述了检测类别（化学、血液学和尿分析）。每个检测类别都有一个链接（如上述的"嵌套"）到样本变量（LBSPEC），由此进一步确定LBTESTCD值的唯一性。这种区分是必要的，因为同一LBTESTCD会被多个检测类别（LBCAT）使用。
- LBCAT="URINALYSIS" uses the same LBTESTCD (GLUC) and the same LBSPEC (URINE) and needs further categorization by method (LBMETHOD=DIPSTICK OR QUANT) to ensure the uniqueness of the test. The sample submission define.xml and stylesheet have been modified to demonstrate this categorization.
- LBCAT="尿分析"使用相同的LBTESTCD（GLUC）和相同的LBSPEC（尿液），需要进一步根据检测方法（LBMETHOD=试纸或定量）来分类从而保证检测的唯一性。递交示例的define.xml和样式表已被修改来展示这种分类。

3.5 Controlled Terminology 受控术语

The Controlled Terminology used in a study, whether it is Sponsor defined, CDISC defined, or extracted from an external dictionary, must be included in the SDTM metadata. All possible values for the variable within the trial should be included in the define.xml, except in the case of external dictionaries. The values for a variable in the SDTM datasets must match the list of controlled terminology in the define.xml, including case sensitivity. If a value of "MULTIPLE" was a potential value for a variable associated with a codelist, "MULTIPLE" should be included in the codelist. This recommendation pertains to both sponsor-defined and CDISC-defined codelists, including those designated as non-extensible. See the DM.RACE variable in the sample submission for an example. Values that are represented as value-level metadata (e.g. --TESTCD,--TEST) need not be repeated in the controlled terminology/code list section of the define.xml. It is important to note that, at the value-level, the codelist is associated with the --ORRES variable as opposed to either the --STRESC or the –STRESN variables.

在一个研究中使用的受控术语，无论是申办方定义的，CDISC定义的，或从外部词典提取的，都必须被包括在SDTM元数据。除了在使用外部词典的情况下，变量在试验中的所有可能的值应该被包括在define.xml。SDTM数据集里变量的值必须与

define.xml的受控术语列表相匹配，包括大小写。如果"MULTIPLE"是与编码表关联的变量的可能值，那么"MULTIPLE"应包含在编码表。该建议适用于申办方定义和CDISC定义的编码表，包括那些指定为不可扩展的编码表。参看递交示例中DM.RACE的变量示例。代表值级别元数据的那些值（-- TESTCD， --TEST）不需要在define.xml的受控术语/代码列表中重复。需注意的是，在值级别中，编码表与--ORRES变量相关联，而不是与-- STRESC或--STRESN变量。

3.5.1 Define.xml

Table 3.5.1.1 - Controlled Terminology Metadata

XML Field	Stylesheet Display*	Description
CodeList attributes		
OID		Identifier for the codelist
Name*	Controlled Terms or Format	Name of codelist
DataType		Type of code. SDTM data uses a value of "text" in most cases.
CodeList Child Elements*		
CodeListItem	Controlled Terms or Format	An entry in the CodeList. Either a CodeList or ExternalCodeList element is required
ExternalCodeList	Controlled Terms or Format	Details of an external CodeList Either a CodeList or ExternalCodeList element is required.
CodeListItem attributes[1]		
CodedValue*	Code Value	The value of the code
def:Rank		Can be used for ordering of values e.g. Codelist for VSTESTCD = FRMSIZE: 1 = SMALL, 2 = MEDIUM, 3 = LARGE
CodeListItem Child Elements[1]		
Decode*	Code Text	If the CodedValue is self explanatory this may be an exact copy. If the CodedValue is an abbreviation the decode is the full description.
Decode Child Elements		
TranslatedText*	Code Text	The translated "text" of the code associated with the Decode element.
ExternalCodeList attributes		If an external code list is used the following attributes can be specified
Dictionary[2]	External Dictionary	Name of dictionary.
Version[2]	Dictionary Version	Dictionary version.

Table 3.5.1.1 – 受控术语元数据

XML 属性	样式表显示	备注
CodeList 属性		
OID		编码表的识别符

Name*	Controlled Terms or Format	编码表的名称
DataType		编码的数据类型。SDTM数据在大多数情况下是"text"。
CodeList 子元素*		
CodeListItem	Controlled Terms or Format	在代码表中的条目。CodeList或ExternalCodeList必选其中一项
ExternalCodeList	Controlled Terms or Format	外部编码表的细节。CodeList或ExternalCodeList必选其中一项
CodeListItem 属性[1]		
CodedValue*	Code Value	编码的值
def:Rank		可以对值进行排序，如编码表中，当VSTESTCD = FRMSIZE: 1 = SMALL, 2 = MEDIUM, 3 = LARGE
CodeListItem 子元素[1]		
Decode*	Code Text	如果CodedValue能自解释，那这里仅是相同的复制。如果CodedValue是缩写，则这里是全称。
Decode 子元素		
TranslatedText*	Code Text	与Decode元素相关的代码翻译成的"文字"。
ExternalCodeList 属性		如果使用一个外部代码列表，则通过以下属性来指定
Dictionary[2]	External Dictionary	字典名称
Version[2]	Dictionary Version	字典版本

* Attributes recommended to be displayed. However attributes actually displayed are determined by the sponsor in the stylesheet.

*推荐显示的属性。但最终显示的属性由申办方的样式表决定。

[1] Paired variables, containing the same data in different ways, can be represented using CodedValue and Decode. Examples of this may include the pair ARMCD and ARM.

[1] 配对变量，以不同的方式涵盖相同的数据，可以使用CodedValue和Decode来表示，。例如ARMCD和ARM。

[2] Dictionary and version are used for the ExternalCodeList attributes. They are used to specify the external coding dictionary and the version that was used for coding (e.g. MedDRA 9.0). In the sample define.xml, an external codelist (with OID "AEDICT_F") was included for the SDTM variable "AEDECOD". Similarly, an external codelist (with OID "DRUGDICT_F") was included for the SDTM variable "CMDECOD".

[2] 字典和版本用于ExternalCodeList属性。它们被用来指定外部编码字典和用于编码的版本（例如MedDRA的9.0）。在示例define.xml，外部编码表（OID为"AEDICT_F"）

被列入了SDTM变量"AEDECOD"。同样，外部编码表（用OID"DRUGDICT_F"）被列入了SDTM变量"CMDECOD"。

3.5.2 CDISC Controlled Terminology CDISC 受控术语

CDISC **Controlled Terminology** is constantly being updated. Currently there is a phased approach for developing controlled terminology. It is recommended that the sponsor uses the controlled terminology defined by CDISC, which may require a planned transition. If the sponsor decides to map their existing data to CDISC terminology when creating the SDTM datasets, an explanation of the mapping should be provided. In simple cases this mapping can be done through CRF annotations (see MHENRF in the annotated CRF). In other cases the use of the define.xml comments field can specify that mapping took place. If the mapping from sponsor data to SDTM controlled terminology is ambiguous, a further explanation of the mapping can be provided in either the comments or the supplemental data definition.

CDISC 受控术语一直在更新．目前在分阶段开发受控术语。建议申办方使用由CDISC定义的受控术语，但这可能需要一个过渡计划。如果申办方在创建SDTM数据集时决定将其现有的数据映射到CDISC术语，则应提供映射的解释。在简单的情况下，这种映射可以通过CRF的注释来完成（见注释CRF的MHENRF）。其他情况下可以使用define.xml注解栏来说明映射过程。如果从申办方的数据映射到SDTM受控术语是模糊不清的，需提供注释或补充数据定义来进一步解释其映射过程。

3.6 Stylesheets for the Define.xml Define.xml 的样式表

A stylesheet is a tool to transform an XML file to a different format. One use of a stylesheet is to dynamically transform XML to HTML, so that the XML document can be displayed in a user-friendly way within a browser. While the XML is designed to house the data, the stylesheet is designed to display the data. Stylesheets are required when submitting define.xml files to the FDA.

样式表是一种将XML文件转换为不同格式的工具。样式表的其中用途是使动态地将XML转换为HTML，以便XML文档以用户友好的方式显示在浏览器中。XML被设计用于储存数据，其样式表则被设计用来显示数据。当define.xml文件递交到FDA时，必需包含样式表。

There is a basic stylesheet available for download at the CDISC website or sponsors may use the stylesheet included in the sample submission. CDISC does plan to develop stylesheets in the future. For now, sponsors have the option of developing their own stylesheet or modifying the sample provided. The sample submission stylesheet takes care of displaying the minimal amount of information to the reviewer, but also includes functionality such as bookmarking and links to simplify navigation.

CDISC网站现有一个基本样式表可供下载，或者申办方也可使用包含在递交示例中的

样式表。 CDISC计划在未来开发更多样式表。现在，申办方可以定制自己的样式表或对CDISC提供的示例进行修改。递交示例中的样式表根据评审员的需要尽可能少地显示信息，但同时也包括一些功能，例如书签和链接，以方便导航。

3.7 Define.xml Schema Validation Define.xml Schema 验证

The define.xml schema needs to be validated prior to submission. A useful reference is the XML Schema Validation white paper found on the CDISC website:
define.xml schema需要在递交之前进行验证。CDISC网站中的XML Schema验证白皮书提供了一个有用的参考供下载：
http://www.cdisc.org/stuff/contentmgr/files/0/464923b10ea16b477151fcaa9f465166/misc/definereport_v1_0.pdf
A number of approaches can be taken in validating the define.xml against the XML-schema and against the define.xml specification, including the use of third-party tools. These tools each have their own interpretation of the requirements for valid XML as per the ODM and define.xml standard, and it is incumbent on the sponsor to understand and evaluate these interpretations. If validation issues are found relating to an interpretation of a requirement, this should be noted in the Reviewers' Guide
可以采取许多方法对照XML schema和define.xml说明来验证define.xml，包括使用第三方工具。按照ODM及define.xml标准来验证XML，每个工具对该要求都可有自己的解释，申办方有义不容辞的责任来了解和评价这些解释。如果在对有关的要求进行解释时发现了验证问题，应该记录在“评审者指南”中。

4 Guidelines for Annotating and Bookmarking CRFs 注释和标记 CRF 指南

4.1 Basic Principles for Annotations 注释的基本原则

Sponsors may choose any available tool for creating annotations. Irrespective of the tool used, the annotations should be searchable, (i.e. text-based), to enhance the review process. Since the blankcrf.pdf supports the review process, the annotations should reflect the data that are expected to be submitted within the SDTM. In the event that data were intended to be collected for a variable, but none actually was, the annotated CRF will represent the data that would have been submitted had data been

received. It is not necessary to re-annotate the blankcrf.pdf to indicate that data were not collected. Sponsors may choose to add this information to their Reviewers' Guide. Annotations of the operational data, while normally needed by the sponsor for data management, should not be included on the blankcrf.pdf that is used for submission of the SDTM data.

申办者可以选择任何可用的工具创建注释。不论使用什么工具，注释都应该是可搜索的，（例如：基于文本的），以提高审阅过程。由于blankcrf.pdf支持审阅过程，注释要能反应出在SDTM中预期的递交数据。如果某个变量本来是要采集数据的，而实际情况却没有采集，在注释CRF表中依然要标明这样的变量，因为如果有采集到数据的话，这些变量本会被递交的。没有必要为了表示数据没有被采集而重新注释blankcrf.pdf。申办者可以选择把这些信息添加到他们的审阅指南中。操作目的的数据注释通常是申办者用于管理数据的，不应包含在用于递交SDTM数据的blankcrf.pdf中。

4.1.1 Annotating Unique CRF Pages 唯一 CRF 页的注释

Currently some sponsors include the entire casebook in the blankcrf.pdf while others include unique forms. Conventions that have traditionally been used for annotating a PDF rendition of paper CRFs may not translate to best practices when annotating eCRFs. For example, when a Vital Signs form is used at 10 visits, 10 physical copies of the form exist in a paper case book. In an eCRF there is one electronic Vital Signs form which is presented 10 different times, once for each data collection instance.

目前一些申办者在 blankcrf.pdf 中包含了病例报告表的所有页，其他的申办者只包含了那些唯一表单。那些对纸质 CRF 的 PDF 格式进行注释的传统实践，在注释电子 CRF 时不一定是最佳的。例如，在 10 次访视中都有同一个生命体征表单时，如果使用纸质的 CRF 就需要对这个表单进行十份物理拷贝。而在电子 CRF 中只有一张生命体征表，这张表会出现在 10 个不同的时间，每次采集数据时出现一次。

The purpose of the blankcrf is to represent the data collected in the study and where it resides within the SDTM. The recommended dual bookmarking (See Section 4.2) and TOC will provide the reviewer with an overview of the data collection flow for the study. Based on this premise the following annotation guidelines are provided:

blankcrf 的目的是要说明在研究中采集的数据及这些数据在 SDTM 中存在的位置。推荐使用双书签（参见章节 4.2）和 TOC（目录），可以为审阅者提供这个研究的数据采集流程的概述。基于这个目的，还有如下注释指南：

- Include and annotate unique forms only. Bookmarking will present the form as many times as needed to reflect how the data were collected at the investigational site. For example, even though "Vital Signs" would be bookmarked in visits 1, 3, and 5, all three bookmarks would link to the unique vital signs page.
- 只包含和注释唯一表单。为了体现数据在研究中心是如何被采集的，可以根据需要对一个表单书签为多次。例如，虽然生命体征在第 1、3、5 次访视中都有做书签，但所有这三个书签都会链接到唯一的生命体征页。

- If the sponsor chooses to submit the entire CRF rather than unique forms, the sponsor should annotate the first occurrence only. Subsequent pages would not be annotated or linked back to the first annotated occurrence. Dual bookmarks described in Section 4.2 would be used to locate subsequent occurrences. Just as in the scenario in the previous bullet, the bookmarks for vital signs at visits 1, 3 and 5 would appear just as they would if only unique pages were submitted.The difference is that, in this case, the bookmarks would all link to the appropriate PDF page, with only the first occurrence being annotated.
- 假如申办者选择递交整个 CRF 而不是唯一表单，申办者应当只注释第一次出现的表单。之后的页面不注释，也不链接返回到第一次注释出现的页面。章节 4.2 中描述的双书签是用于定位后续的出现。前一种情况所述，生命体征在第 1、3、5 次访视都会做书签，但只有唯一页面被递交。而这种情况的区别是，所有书签都将链接到合适的 PDF 页面，但只有首次出现的页面会被注释。

When viewed through a web browser, the define.xml Origin column should have a link to the page where the annotated variable appears. This is illustrated in the sample submission.

通过浏览器查看时，define.xml 的 Origin 列应当有一个链接指向注释变量出现的页面。递交示例中有举例说明。

The metadata team recommends that when data are recorded on the CRF but are not submitted in SDTM, the CRF be annotated with the text "NOT SUBMITTED". For example, data which were used for operational purposes only, such as the question "Did subject take any concomitant medications?", will be annotated “NOT SUBMITTED” and the data will not be included in the datasets. Brackets are placed around the annotation text in the submission example ("[NOT SUBMITTED]"). The brackets are not required but do help to distinguish the submitted versus not submitted items. In the event that a dataset is not submitted because it is empty, the annotated CRF will show the annotations for the data that would have been submitted had data been received; it is not necessary to return to the CRF post data collection and change the annotation to indicate that no records were collected.

当数据虽录入到 CRF 中但未在 SDTM 递交时，元数据小组建议 CRF 注释应为“未递交”。例如，只为操作目的使用的数据，比如问题“受试者是否服用了任何伴随药物？”，这样的数据将被注释为“未递交”并且不会包含在数据集中。在递交示例中使用了方括号（”[未递交]”），方括号不是必须的，但的确有助于区分递交和未递交的条目。对于数据集是空的而未递交的情形，那么注释 CRF 将对那些采集到的才会递交的数据进行注释；没有必要在事后返回到 CRF 更改注释以说明数据未采集。

Note: The FDA recommends the phrase “Not entered in database”; however, the metadata team recommends the phrase “NOT SUBMITTED”, since items may be in the sponsor’s operational database but not appropriate for SDTM

submission (e.g. "Were there any adverse events?").
备注：FDA推荐用语"未录入数据库"；然而，因为这个条目可能出现在申办者的操作性数据库中，但不适合SDTM递交（例如，"是否出现了不良事件？"），因此元数据小组推荐用语为"未递交"。

4.1.2 Appearance of Annotations 注释的展现

The annotated CRF should be prepared in compliance with FDA Study Data Specifications. In addition, all text in the annotations that represent variable and domain names should be capitalized. If possible, the annotations should not obstruct any text on the CRF page. A sponsor may choose to resize the domain annotation based on the CRF layout.
注释的CRF应该遵守FDA研究数据规范。此外，所有描述变量和域名的文本应该大写。所有注释应尽可能不要遮盖CRF页面上的文本。申办者可以根据CRF的布局自行调整注释的大小范围。

Each domain that is represented on a CRF page should have its own annotation on the left side of the CRF page with the 2 letter domain code and domain name (e.g. IE = Inclusion/Exclusion). Note that domain names rather than dataset names are annotated. SUPPQUAL dataset names do not need to be annotated since SUPPQUAL variables are annotated as part of the main domain. The same is true for split domains where domain names are annotated rather than dataset names.
CRF页面上的每个域都应该在页面左侧附上包含2个字母的域代码和域名的注释（例如，IE=入组/排除标准）。注意是注释域名而不是数据集名。因为SUPPQUAL变量已作为主域的一部分被注释，因此SUPPQUAL数据集名没有必要重新注释。分割域也是这样的，只注释域名，而非数据集名。

The following are optional recommendations that may be helpful for a reviewer when distinguishing between domains and variables within domains.
为了帮助审阅者区分是域还是域中变量注释，有如下可选推荐。

- To distinguish the domain level annotations from the variable annotations a slightly larger font can be used for the domain annotations.
- 为了区分域注释和变量注释，可以对域注释使用稍大些的字体。
- If more than one domain exists on a page as each domain annotation, and all of its variables, should be color-coded. For an example, refer to the Demographics CRF. It is not necessary to continue the color scheme for a domain across CRF pages. A standard default color scheme can be used across all CRF pages, but if two or more domains exist on a single page then they should use different color schemes. If a CRF page has a large number of SDTM domains then the color difference might become less distinct, but in most cases, this will add a great amount of clarity to

the annotations.

- 如果一个页面上存在不止一个域，那么每个域注释以及它们的所有变量，应该标记不同的颜色。以人口学CRF为例，没有必要在CRF所有页面中为每个域使用一个配色方案。所有CRF页面可以使用一个标准默认的配色方案，但当两个及以上的域同时存在一页时，它们应使用不同的配色方案。如果一页CRF有大量的SDTM域，颜色将难以区分。但多数情况下，这样的注释会更清晰。

4.1.3 Annotating Findings Domains 发现类域的注释

Because of the vertical nature of the SDTM findings domains, it may be necessary to include the value of ” --TESTCD" in the annotations. For example, annotating a field as simply VSORRES or VSORRESU is not sufficient; .it is necessary to indicate the VSTESTCD to which the result or units applies. When annotating “Systolic Blood Pressure” the recommended format would be "VSORRES/VSORRESU when VSTESTCD =SYSBP". For specific annotation examples refer to the blankcrf.pdf in the sample submission.

由于SDTM发现类域的垂直属性，注释中可能需要包含“--TESTCD”的值。例如，只是简单的注释成VSORRES或者VSORRESU是不够的，需要指明VSTESTCD与哪个结果或单位关联。注释“收缩压”的推荐格式是：“当VSTESTCD =SYSBP时，VSORRES/VSORRESU”。详细的注释例参照递交示例的blankcrf.pdf。

4.1.4 Annotating Supplemental Qualifier Variables 补充修饰语变量的注释

When annotating SUPPQUAL variables, annotate the QNAM value and the SUPPQUAL dataset, for example,“RACEOTH in SUPPDM”. The rationale for this approach is that the review tools join the supplemental values with the correct data row(s) from the parent domain and the reviewer needs to know only the variable name and that it originated in the supplemental dataset.

注释SUPPQUAL变量时，要注释QNAM值和SUPPQUAL数据集，例如“SUPPDM中的RACEOTH”。这个方法的原理是，审阅工具将补充变量值和父域里的数据行正确连接起来，审阅者不仅需要知道变量名，还要知道该变量在补充修饰语数据集中的位置。

4.1.5 Annotating RELREC Records 关联记录的注释

Relationship data collected on CRF pages and documented in RELREC should be annotated. In the sample submission, adverse events are collected on the Adverse Events CRF as numbered running records and the AE number is mapped to AESPID. If a subject discontinues due to an AE, the relationship is established by entering the associated AE number (AESPID) on the Termination CRF. A RELREC record is created to link the discontinuation due to an adverse event record in DS to the related adverse event record in AE

via AESPID. This relationship is documented on the Termination CRF by the annotation "Linked to related AE record via RELREC." It is important to note that the RELREC annotation is made on the Termination CRF, not on the originating Adverse Event CRF.
在CRF页面采集的和在RELREC中记录的关联数据应该被注释。在递交示例中，不良事件以连续编号记录的形式采集在CRF不良事件页中，这个不良事件编号被映射到了AESPID。如果受试者因为不良事件终止了试验，在终止CRF页中录入其关联的不良事件编号（AESPID），那么这个关联就建立了。RELREC记录就是将DS域中因不良事件而终止的记录与其相关的不良事件记录通过AESPID关联起来。在终止CRF页中，这种关系被注释为"通过RELREC与相关不良事件关联"。需要特别注意的是，只有终止CRF页中有RELREC注释，原始的不良事件CRF页中没有此注释。

4.2 Bookmarking CRFs/eCRFs　　CRF/eCRF 书签

Annotated CRFs included in the eCTD should be bookmarked 2 ways (dual bookmarking): bookmarks by timepoints, often analogous to planned visits in the study, and bookmarks by CRF topics or forms. SDTM domains do not necessarily have a 1-to-1 relationship with CRF topics or forms, nor is the reverse true. For example, in the annotated CRF, both DM and SC are collected on the Demography panel, while SC data are collected from the Enrollment Form and the Demography pages. The purpose of the dual bookmarking is to enhance the reviewers' ability to navigate through the unique CRFs either by timepoint or by CRF topic. There may not be a one-to-one relationship between CRF topics and SDTM domains.
包含在eCTD中的注释CRF应以两种方式做书签（即，双书签）：根据时间点做书签，类似于研究中的访视计划；根据CRF主题或表单做书签。SDTM的域不一定与CRF主题或表单是一对一的关系，反之亦然。例如，在注释CRF中，DM和SC都可以在人口学资料模块中采集，但SC数据可以从入组表单和人口学页面中被采集。双书签的作用是通过时间点或CRF主题来帮助审阅者更容易地找到唯一的CRF表。CRF主题和SDTM域之间可能没有一对一的关系。

- Bookmarks by timepoints should be ordered chronologically according to the study Time and Events Schedule (T&E) with study-level bookmarks (e.g., Adverse Events) presented last. Within each timepoint,topic bookmarks should appear in the order that they appear in the annotated CRF.
- 根据时间点做的书签，应该根据研究的时间与事件计划（T&E）按时间顺序排列，研究水平的书签（例如，不良事件）排在最后。在每个时间点中，主题书签应该以它们在注释CRF中出现的顺序展现。
- Bookmarks by topics should be ordered alphabetically. Within each topic all applicable timepoints should be ordered chronologically according to the T&E schedule.
- 根据主题做的书签，应根据字母顺序排列。在每个主题中，所有可用的时间点应该

根据T&E计划按时间顺序排列。

4.3 Table of Contents for the Annotated CRF 注释 CRF 目录

The bookmarks act as Table of Contents (TOC) for the reviewers. Although it is not required, a printable TOC may be included at the beginning of the annotated CRF. This is intended to facilitate the review when the reviewer is using a printed version of the CRF, and serves the same purpose as the bookmarks for the electronic version.
对于审阅者来说，书签就类似于目录。虽然不是必需的，但注释CRF的开头应包含可打印的目录。这是为了使审阅者在使用打印版的CRF时更方便审阅，同样也方便作为书签存在于电子版中。

There are several commercially available PDF tools available which will create a TOC based on the bookmarks. However; it is possible to create a TOC using word processing software, as was done in the sample submission. Additionally, the TOC should be hyperlinked to the appropriate page.
有很多商业PDF工具可以用来基于标记生成目录，然而，就像递交示例那样，使用文字处理软件来创建目录也是可行的。此外，目录应该链接到相应的页面。

5 Submission Data Sets 递交数据集

The purpose of this section is to highlight noteworthy aspects of domains in the sample submission that accompanies this document. Since these are examples, the subsections that follow may describe an implementation choice made by the SDS Metadata Team. The order of the domains in this section follows the order of the domains as they appear in the define.xml document.
本章节的目的是为了强调递交示例中的域模型值得注意的地方，递交示例附带在本文档中。因为这些只是示例，接下来的内容可能只是SDS元数据团队的一个执行选择。本章节中域的编排顺序和它们在define.xml的顺序保持一致。

5.1 Trial Design 试验设计

5.1.1 General Considerations 一般注意事项

The Trial Design domains describe the overall characteristics of the study. Presently, five Trial Design domains are defined.

试验设计域描述的是试验总的特征。目前定义了5个试验设计域。

5.1.2 Trial Arms (TA) 试验分组(TA)

ARMCD can be up to 20 characters in length with no special character restrictions. The arm name (ARM) variable length must not exceed 200 characters due to SAS version 5 transport requirements.
ARMCD的长度不能超过20个字符，没有特殊字符限制。由于SAS 版本5的传输要求，分组名（ARM）不能超过200个字符。

5.1.3 Trial Inclusion/Exclusion Criteria (TI) 试验入/排标准(TI)

The full inclusion/exclusion criteria text should be stored in IETEST and corresponding metadata. When inclusion/exclusion text is greater than 200 characters one of the following options could be considered.
完整的入选/排除标准应该存储在IETEST和相应的元数据里。当入选/排除标准文本长度超过200字符时，可以考虑下面的方法。

- If the annotated CRF contains the inclusion/exclusion criteria, insert either the first 200 characters or the text of the criteria abbreviated to 200 characters in TI. In the rendered define.xml Origin column for IETESTCD provides a link to the annotated CRF page that contains the full inclusion/exclusion text.
- 如果注释CRF包含了入选/排除标准，要么取前200个字符，要么将文本缩短到200个字符以内，然后放到TI中。在define.xml中，IETESTCD的Origin列提供一个链接，指向包含有完整入选/排除标准的注释CRF页面。
- If the annotated CRF does not specify the full inclusion/exclusion text, it is recommended that a PDF be created to store the full inclusion/exclusion criteria text. Through the stylesheet, provide a link to the PDF containing the full inclusion/exclusion criteria text in the comments column of the IETESTCD variable. Store the PDF in the SDTM submission folder.
- 如果注释CRF没有详细说明完整的入选/排除标准，建议创建一个PDF文件来存储完整的入选/排除标准。通过样式表，在IETESTCD的comments列提供一个链接，指向包含有完整入选/排除标准的PDF文件，并将该PDF文件存储在SDTM递交文件夹中。

5.2 Special-Purpose Domains 特殊目的的域模型

5.2.1 Demographics (DM) 人口学(DM)

The CDISC SDTM-defined Demographics (DM) domain has one record for

each subject who was randomized, was a screen failure, or passed the inclusion criteria but was never assigned to an ARM.
在CDISC SDTM定义的人口学（DM）域中，每个受试者只有一条记录，要么被随机分组，或者筛选失败，或者通过了入选标准但是从未被分组。

5.2.1.1 General Considerations 一般注意事项

Reference start date/time (RFSTDTC) and reference end date/time (RFENDTC) are sponsor-defined items and the sample submission uses the Comments field in the define.xml to define the logic used to populate the values. RFSTDTC and RFENDTC are null for screen failures.
基准开始时间（RFSTDTC）和基准结束时间（RFENDTC）是申办者定义的条目。递交示例在define.xml的Comments里面定义赋值的逻辑。筛选失败时RFSTDTC和RFENDTC为空值。

A subject who was a screen failure is included in the sample submission and identified according to the recommendation in the SDTMIG (ARM = "Screen Failure" and ARMCD="SCRNFAIL").
筛选失败的受试者也包含着递交示例中，可以根据SDTMIG的建议识别出来(ARM = "Screen Failure"和ARMCD="SCRNFAIL")。

Subjects with a RACE value of OTHER or MULTIPLE in the sample submission have additional data regarding race in the SUPPDM dataset.
递交示例中，当受试者的RACE是OTHER或者MULTIPLE时，有关于种族的补充数据被记录在SUPPDM数据集。

5.2.1.2 Define.xml Considerations Define.xml 注意事项

In the sample submission DM has collected and derived supplemental qualifiers. There are two ways to view the data definition of the Supplemental Qualifier dataset using the define.xml stylesheet. One way is a link to the SUPPDM dataset from the dataset-level table. A second way is a link within the stylesheet, at the end of the DM domain, to the value-level metadata for the supplemental dataset. For convenience, an additional link is included at the end of the value-level metadata for the SUPP datasets to return the viewer to the parent DM domain.
在递交示例中，DM采集并衍生了补充修饰语。使用define.xml样式表，有两种方法可以看到对补充修饰语的数据定义。第一种方法，从数据集水平的表单中的SUPPDM直接就能链接过去。第二种方法是，在DM域的下面有一个链接指向补充数据集的值水平元数据。为了方便，在SUPP数据集的值水平元数据最后也有一个链接，可以返回到父域DM。

The variable QNAM within SUPPDM has an associated value-level metadata list. The link on QNAM displays the value-level metadata list and associated attributes of the supplemental items. If the QNAM variable has an origin of

CRF, there is a link to the annotation in the rendered Origin column. If the origin is specified as derived, the derivation, or a link to that derivation, must always be in the Comments field.
SUPPDM中的QNAM变量有一个相关的值水平元数据列表，QNAM的链接显示为值水平的元数据列表和补充条目的相关属性。如果QNAM变量来源于CRF，在Origin列需要有一个链接指向CRF上相应的注释处；如果是衍生而来的，Comments里必须有衍生的方法，或者是指向衍生方法的链接。

5.2.1.3 Additional or Related Data, Supplemental Qualifiers 额外数据或相关数据，补充修饰语

The population flags used within the SDTM submission are stored as supplemental qualifiers and defined in SUPPDM. In the sample submission a population flag (SAFETY) and a randomization flag (RAND) are stored in SUPPDM.
在SDTM递交里用到的人群标帜作为补充修饰语被存储和定义在SUPPDM里。在递交示例中，人群标帜（SAFETY）和随机化标帜（RAND）被存储在SUPPDM里。

Data collected regarding 'Race, Other' or multiple races are in the SUPPDM dataset. In the sample submission, QNAM values of RACEOTH, RACE1, RACE2, and RACE3 contain 'Race Other' and multiple collected races.
关于"其他种族"和多种族的数据记录在SUPPDM里。在递交示例中，QNAM中RACEOTH, RACE1, RACE2和RACE3这些值包含了"其他种族"和多种族的信息。

In the sample submission, randomization number and randomization flag are annotated on the CRF and defined as supplemental qualifiers for Demographics. These randomization variables are not required and, in many cases, may be coming from an IVRS or a source other than the CRF.
在递交示例中，随机编号和随机化的标帜在CRF上有被注释出来，并定义为人口学补充修饰语。这些随机变量并非必须的，在许多情况下，可能出自于IVRS或者CRF之外的来源。

5.2.2 Subject Visits (SV) 受试者访视 (SV)

The Subject Visits (SV) domain relates to the Trial Visits (TV) domain as demonstrated in the sample submission. The SV domain records the visits, including the visit start dates, end dates, and planned visit day in relation to the reference start date. The visit number, description and planned visit day for planned visits are identical to the corresponding items in the TV domain.
正如递交示例所显示的一样，受试者访视（SV）域与试验访视（TV）域相关。SV域记录了访视，包括访视的开始时间，结束时间和相对于基准开始时间（RFSTDTC）的计划访视日。其中访视编号，访视名称和计划访视日和TV域里对应的条目完全一样。

5.3 Interventions 干预类

5.3.1 General Considerations 一般注意事项

Treatments within the Interventions domains are often coded using an external dictionary. The Dictionary reference and version must be specified in the define.xml using the define.xml ExternalCodeList element, and Dictionary and Version attributes. The dictionary and version should not be specified in the Comments field as recommended prior to version 3.1.2 of the SDTMIG.

通常会使用外部词典来编码干预措施域里的治疗，参考词典和版本必须在define.xml中使用ExternalCodeList元素，Dictionary和Version属性详细说明，不应如SDTMIG 3.1.2之前的版本所建议的，在Comments里说明参考词典和版本。

5.3.2 Concomitant Medications (CM) 伴随用药(CM)

The Concomitant Medications (CM) dataset in the sample submission contains data from the Concomitant Medication and Psychotropic Drug Treatment History forms. The Concomitant Medication Category (CMCAT) variable is used to identify the type of medication and has values of either "CONCOMITANT MEDICATIONS" or "PSYCHOTROPHIC DRUG TREATMENT HISTORY."

递交示例中的伴随用药（CM）数据集包含合并用药及精神类药物治疗史这两个表格的数据。伴随用药分类（CMCAT）变量用于区分药物类型，有"合并用药"和"精神类药物治疗史"这两种值。

In the sample submission, modification of CMTRT was necessary to facilitate coding. Hence, CMMODIFY was included and contains the modified text.

在递交示例中，为了便于编码，需要对CMTRT作出修改。因此，CMMODIFY被列入，它包含了修改后的文本。

The medication dose was collected as character in the sample submission. Hence, the dose on the Concomitant Medications CRF is annotated using the CMDOSTXT variable instead of CMDOSE, which is numeric.

在递交示例中药物剂量作为字符型被采集，因此，合并用药CRF上的剂量被注释为CMDOSTXT，而不是数字型变量CMDOSE。

For the route of administration, the sponsor mapped the CRF data to CDISC controlled terminology. Only the subset of the CDISC controlled terminology appropriate for the study was used to map the data.

对于给药途径，申办者将CRF数据映射成CDISC受控术语。只有适合试验的那部分CDISC受控术语才被用于映射CRF数据。

5.3.3 Exposure (EX) 暴露(EX)

In the sample submission the value in EXDOSE is the amount of each administration which was taken. The number of tablets taken per administration is recorded on the CRF. The dose, EXDOSE, was derived by multiplying the number of tablets taken, (SUPPEX.QNAM=SMNO), by the dose contained in each tablet. The placebo doses within the submission were represented by zero doses.

在递交示例中，EXDOSE的值是每次的给药总剂量。每次给药片数记录于CRF。总剂量EXDOSE是服用的药片数（SUPPEX.QNAM=SMNO）和每片所含药量的相乘。在递交示例中，安慰剂的剂量用0来表示。

5.4 Events 事件类

5.4.1 General Considerations 一般注意事项

Terms within the Events domains are often coded using an external dictionary. The Dictionary reference and version must be specified in the define.xml using the define.xml ExternalCodeList element, and Dictionary and Version attributes. The dictionary and version should not be specified in the define.xml Comments field as recommended prior to version 3.1.2 of the SDTMIG.

通常使用外部词典来编码事件域里的词。参考词典和版本必须在define.xml中使用ExternalCodeList元素，Dictionary和Version属性详细说明，不应如SDTMIG 3.1.2之前的版本所建议的，在Comments里说明参考词典和版本。

5.4.2 Adverse Events (AE) 不良事件(AE)

In the sample submission, the sponsor's instructions for the "Ongoing" checkbox confirm that the adverse event was ongoing at the point of last contact. The AEENRF value defines the status of the adverse event in relationship to the reference period.

在递交示例中，申办者对"正在进行"复选框的勾选确认为不良事件在最后联系时仍在进行。AEENRF的值定义了不良事件相对于参考期的状态。

5.4.3 Disposition (DS) 处置(DS)

It may be necessary to rename, reformat and/or translate the data that were collected on the CRF in order to create appropriately formatted Disposition (DS) records. For example in the sample submission, a "Yes" response to the Termination CRF question "Did the subject complete the study?" was mapped as DSTERM "COMPLETED" and DSDECOD as "COMPLETED."
为了创建格式合理的处置（DS）记录，可能有必要重命名、重格式化和/或翻译CRF上采集来的数据。例如，在递交示例中，终止CRF上的问题"受试者是否完成试验？"回答"是"，于是，DSTERM = "COMPLETED" 并且DSDECOD = "COMPLETED"。

The reasons for discontinuation collected on the termination CRF do not comply with CDISC controlled terminology. The DS domain variable DSTERM contains the original termination reason from the CRF or a free text specification. The DS domain variable DSDECOD was mapped from the CRF values to match CDISC controlled terminology.
终止CRF上采集的退出原因与CDISC受控术语并不一致。DS域变量DSTERM记录的是CRF上采集的原始退出原因或者自由文本说明，DSDECOD记录的是从CRF值映射到CDISC受控术语的值。

For simplicity and in order to not clutter the page unnecessarily, the annotations on the study termination page show one instance where DSDECOD is preprinted and DSTERM is entered, and one instance where they are both preprinted. Additional annotations of DSTERM and DSDECOD would not convey any additional information and are not necessary.
为简单起见，不引起CRF页面不必要的杂乱，试验终止页面的注释展示了一个DSDECOD被预印刷、DSTERM被录入的例子，以及一个二者都被预印刷的例子。额外的DSTERM和DSDECOD注释不表达其他任何信息，也是不必要的。

5.4.4 Medical History (MH) 既往病史(MH)

In the sample submission two CRFs - Medical and Surgical History and Psychiatric History are used to capture history data. MHCAT is used to categorize the 2 event types. For the Psychiatric History form, we chose to have our sample dataset include a record for each listed term, MHPRESP indicates that MH events were prespecified, and MHOCCUR is set to 'Y' when a date is present and 'N' when a date is not present. Other approaches would also be reasonable such as submitting records only where a date was collected and omitting the MHOCCUR variable.
在递交示例中，医学手术史，及精神病史这两页CRF用于采集历史数据。MHCAT用来

将这两种事件分类。对于精神病史表格，在示例数据集中，每条记录只采集一条术语。MHPRESP表示MH事件是预先设定的，如果提供了日期，则MHOCCUR="Y"，如果没有提供日期，则MHOCCUR="N"。其他方法也可行，比如，只递交采集了日期的记录，忽略MHOCCUR变量。

On the Medical and Surgical History page, whether the event is resolved or ongoing is collected for each event, both of which are mapped to the MHENRF. If the event is marked as resolved, then we know that the event ended before the study (since this is collected at screening), and this is mapped to BEFORE in MHENRF. If the event is marked as ongoing, then we are not sure exactly when it does end, so this is mapped to DURING/AFTER in MHENRF.

在医学手术史页面，每个事件是否已解决或者仍在继续被记录下来，并被映射到MHENRF。如果事件标记为已解决，于是我们便知道事件在试验开始前就已经结束（因为事件是在筛选期采集的），因此MHENRF="BEFORE"。如果事件被标记为仍在继续，于是我们不确定它什么时候能结束，因此MHENRF="DURING/AFTER"。

5.5 Findings 发现类

5.5.1 General Considerations 一般注意事项

The test codes (--TESTCD) and the test codes descriptions (--TEST) in the Drug Accountability (DA), ECG (EG), Laboratory Tests (LB), Subject Characteristics (SC), and Vital Signs (VS) domains are based on CDISC Controlled Terminology or SDTMIG recommended terminology when available. For the other findings domains the test codes are purely examples and should not be interpreted as CDISC controlled terminology.

药物分发与回收记录（DA），心电图检查结果（EG），实验室检查结果（LB），受试者特征(SC)和生命体征(VS)域模型里的参数编码(--TESTCD)和参数名称(--TEST)是基于CDISC受控术语或者可用的SDTMIG建议术语。对于其他的发现类域模型，参数编码仅仅只是例子，不能被理解为CDISC受控术语。

5.5.1.1 Define.xml Considerations Define.xml的注意事项

Since the number of decimal digits in a floating point variable pertaining to the values of the variables --STRESC, --STRESN, and --ORRES depend on the test, one value of significant digits may not correctly represent all tests in the dataset. If this is the case, the maximum number of significant digits across tests should be used in the define.xml at the variable level. For example, at the variable level LBSTRESN has SignificantDigits set to 2 to accommodate the Lymphocytes test, even though other tests, pH for example, do not need use decimal places.

浮点型变量—STRESC, --STRESN和—ORRES值的小数位取决于具体的检查项目，因

此只用一种有效的小数位数可能不能正确代表数据集里所有的检查项目。如果是这样的话，在define.xml里的变量水平应该用所有检查项目的最大有效数字位数。例如，在变量水平，LBSTRESN的SignificantDigits被设定为2，以适应淋巴细胞检查，尽管其他检查项目不需要使用小数位，比如PH值。

5.5.1.2 CRF Annotations for Findings 发现类的CRF注释

The --TEST variable is annotated on the CRF, but in some cases the value of --TEST may paraphrase the preprinted text on the CRF. For example, DATEST has the values of 'Dispensed Amount' and 'Returned Amount', although the CRF page has 'Number of Tablets Dispensed' and 'Number of Tablets Returned'. This convention is acceptable as long as the conceptual meaning is equivalent to the --TEST value and the annotation is clear to the reviewer. The --TESTCD is assigned based on the test description (--TEST) and may be referenced as part of the annotation to link --TEST and the result (--ORRES), as on the Inclusion Criteria page where the annotation reads 'IEORRES when IETESTCD = INCL01.'

--TEST变量被注释在CRF上，但有时--TEST的值可能以另一种方式预印在CRF上。比如，尽管CRF页面上是"分发片数"和"返还片数"，但是DATEST的值为"分发量"和"返还量"。只要本义和--TEST的值相同，并且对审阅者来说注释很清楚，这种做法是可以接受的。--TESTCD是根据--TEST的描述来指定的，并且可能作为注释一部分，被用来关联--TEST和--ORRES。例如，在入选标准页面可以注释成"IEORRES when IETESTCD = INCL01"。

5.5.1.3 Split Domains 分割域

Split domains are not specific to Findings however Findings domains may lend themselves to being split because they can become quite large. The rules associated with splitting domains are in the SDTMIG Section 4.1.1.7. In the sample submission the domain was split into 3 datasets according to the questionnaire name that is in QSCAT. The QS domain has been split for illustrative purposes only. The intention is to show how to split domains, and does not speak to the rationale for splitting domains. The domain variable value for all split domains is QS; however, the dataset names are unique and prefixed with QS. The annotated CRF refers to the domain name (QS) as opposed to the dataset name (QSCG, QSCS, or QSMM).

分割域并非仅仅针对发现类域模型，但是因为发现域往往相当巨大，所以更适合分割。分割域的相关原则详见SDTMIG 第4.1.1.7章节。在递交示例中，QS域模型根据问卷名（存放在QSCAT）被分割成3个数据集。QS域模型被分割仅仅是一个例证，目的是为了展示如何分割域，并未涉及到分割域的原因。所有分割域的domain变量的值均是QS，但是，数据集名是唯一的，且前缀是QS。但是注释CRF指向的是域名（QS）而不是数据集名（QSCG, QSCS或者QSMM）。

If the decision had been made to split a submission dataset, it is recommended that the sponsor communicate with their review division

regarding exactly what needs to be included in the submission, i.e. the split datasets or both the split datasets and the unsplit datasets.
如果决定分割一个递交数据集，建议申办者与其对应的审阅部门关于递交的内容进行沟通，是只递交分割数据集，还是分割数据集和未分割数据集都递交。

5.5.2 ECG Test Results (EG) 心电图检查结果(EG)

5.5.2.1 General Considerations 一般注意事项

In the sample submission the sponsor defined two derived ECG results, QTCF (*Fridericia's Correction Formula*) and QTCB (*Bazett's Correction Formula*). In the EG dataset, the value of the derived flag EGDRVFL was set to Y for each occurrence of an EGTESTCD equal to QTCB or QTCF. For the two derived tests, QTCB and QTCF, the original result and the original unit variables (EGORRES/EGORRESU) were set to null.
在递交示例中，申办者定义了两个衍生的心电图结果，QTCF (*Fridericia校正方法*) 和QTCB (*Bazett校正方法*)。在心电图数据集中，当EGTESTCD等于QTCB或者QTCF时，衍生标帜EGDRVFL的值被设定为Y，这两个衍生的参数（QTCB和QTCF）原始结果和单位变量（EGORRES/EGORRESU）都被设定为空值。

5.5.2.2 Define.xml Considerations Define.xml注意事项

In the value-level metadata table, the origin for the EGTEST value is CRF for all but two of the ECG parameters. QTC Fridericia and QTC Bazett are derived variables with an origin of "Derived". Links to the derivations of QTCB and QTCF in the Computational Methods Section may be found in the rendered Comments column. Within the computation method, the derived parameter is specified under the Reference Name field and the derivation formula is in the Computation Method field.
在值水平的元数据表中，除了QTCB和QTCF这两个参数外，所有EGTEST值的来源都是CRF。QTC Fridericia和QTC Bazett是衍生来的变量，因此来源应该写"衍生"。在Comments列提供一个链接，指向Computational Methods里QTCB和QTCF的衍生方法。在Computational Methods部分，衍生参数在Reference Name下指出，计算方法在Computation Method下面说明。

5.5.3 Inclusion/Exclusion Criteria Not Met (IE) 未符合入选/排除标准(IE)

In the define.xml for the sample submission, the IE and TI domains share the value list IECAT.
在递交示例的define.xml中，IE和TI域模型公用IECAT的值列表。

5.5.4 Laboratory Test Results (LB) 实验室检查结果(LB)

5.5.4.1 General Considerations 一般注意事项

In the sample submission the data are received via an electronic data transfer thus having an origin of eDT.

在递交示例中，该数据是通过电子数据传输接收的，因此，来源是"eDT"。

5.5.4.2 Define.xml Considerations Define.xml注意事项

The define.xml and stylesheet for the LB domain illustrate sub-setting on several levels: LBCAT, LBSPEC, and LBMETHOD. This is necessary to distinguish the value-level metadata for LBTESTCD since some tests with the same value of LBTESTCD are not unique across LBCAT, LBSPEC, and in some cases LBMETHOD. This was described further in Section 3.4 Value-Level Metadata and is portrayed in the accompanying sample submission.

LB域模型在define.xml和样式表中以几个层次来说明子集：LBCAT, LBSPEC和LBMETHOD。因为有些LBTESTCD值相同的记录，通过LBCAT，LBSPEC并不能唯一确定，因此有必要区分LBTESTCD的值水平元数据。在3.4部分的值水平元数据里有进一步的解释，在递交示例中也有描述。

5.5.5 Physical Examination (PE) 体格检查(PE)

The Physical Examination eCRF has an annotation for PESTAT. However, PESTAT is not included within the PE domain in the sample submission. Since all assessments in this sample were completed and all values for the PESTAT variable were null, PESTAT was removed from the define.xml and the domain. As stated in the SDTMIG 2.5, "As long as no data was collected for Permissible variables, a sponsor is free to drop them and the corresponding descriptions from the define.xml".

体格检查的电子CRF上有注释PESTAT，但是在递交示例的PE域模型中并没有包含PESTAT。因为所有的评估都完成，PESTAT全为空值，因此，PESTAT在define.xml和domain中被移除了。正如SDTMIG 2.5所说，"只要许可变量没有采集数据，申办者可以将其从define.xml中拿掉。"

5.5.6 Questionnaire (QS) 调查量表(QS)

In the sample submission, the QS domain contains the data from the "Clinical Global Impressions (CGI-I)", "Cornell Scale for Depression in Dementia (CSDD)", and "Mini Mental State Examination (MMSE)" questionnaires. The questionnaire is indicated within the QSCAT variable. The best practice for representation of QS data and metadata are under

discussion by CDISC. Controlled terminology for questionnaires is currently in development and may differ from these examples. In the sample submission for the CGI and CSDD questionnaires the original text is stored in the QSORRES variable and the numeric equivalent is stored in the QSSTRESC and QSSTRESN variables. In the define.xml controlled terminology, the numeric value from the questionnaire is included in the Code Value field which is the value in QSSTRESC and QSSTRESN. The original text in the Code Text field is the value for QSORRES.
在递交示例中，QS域模型包含了来自"临床总体印象量表(CGI-I)"，"康奈尔痴呆抑郁量表(CSDD)"和"简易精神状态评价量表(MMSE)"调查表的数据，QSCAT用于标示不同的调查表。CDISC正在讨论表现QS数据和元数据的最佳方法，调查量表的受控术语正在开发当中，可能和现在这些例子不太一样。在递交示例中，CGI和CSDD调查表的原始文本存储在QSORRES变量中，对应的数字型存储在QSSTRESC和QSTRESN变量中。在define.xml受控术语中，调查量表的QSSTRESC和QSSTRESN数字型值在Code Value下，原始文本QSORRES的值在Code Text下。

5.5.7 Vital Signs (VS) 生命体征(VS)

In the sample submission, because the investigator was allowed to collect height and weight in different units, all data values that were collected in units other than the standard were converted to metric in the VSSTRESC and VSSTRESN variables with the metric units going into VSSTRESU.
在递交示例中，因为允许研究者以不同单位采集身高和体重，用非标准单位采集的数据被转换标准的并存放在VSSTRESC和VSSTRESN中，度量单位存放在VSSTRESU。

5.6 Relationship Datasets 关联数据集

5.6.1 Define.xml Considerations Define.xml 注意事项

The SUPP-- datasets have been ordered after all the subject-related domains in the define.xml Table of Contents. They appear alphabetically by dataset.
在define.xml的目录表中，SUPP--数据集排在所有受试者相关的域后面，并按照字母顺序排列。

The variable QNAM within each SUPP-- dataset has an associated value list. The link on QNAM displays the value list and associated attributes of the supplemental items. If the QNAM variable has an origin of CRF, the link to the annotation will be in the rendered Origin column. If the Origin is specified as derived, the derivation definition will be displayed in the rendered Comments column, or a link will be provided to the associated computational method.

在每个SUPP--数据集中，变量QNAM都有一个相关的值列表。QNAM上的链接指向值列表和补充条目的相关属性。如果QNAM变量来源于CRF，则在Origin列会有一个链接指向CRF上相应的注释处。如果是衍生来的，则在Comments列会提供衍生的方法，或者提供链接指向相关的计算方法（computational method）。

It is recommended that the stylesheet provides a link between all parent domains and their associated Supplemental Qualifier datasets. In the sample submission, there is a link to SUPPAE dataset at the bottom of the AE domain, and there is a return link to the parent AE domain at the bottom of the SUPPAE dataset. These links are available for all the domains with associated supplemental qualifiers datasets.

建议样式表提供父域和相关补充修饰语数据集的链接。在递交示例中，在AE域的下方有一个链接指向SUPPAE数据集，并且在SUPPAE数据集的下方也有链接可以返回到AE父域。这样的链接适用于所有具有相关补充修饰语数据集的域模型。

5.6.2 RELREC 相关记录数据集

One purpose of the RELREC dataset is to define a relationship between records in separate domains. An example of a relationship that could be defined would be when a subject terminates a study due to an adverse event. It is possible, by using a RELREC dataset to link the adverse event causing the termination to the termination record within the Disposition (DS) domain. An example using RELREC has been included within the sample submission and it resembles the following.

RELREC数据集的一个目的是为了定义记录在不同域之间的关系。比方说，受试者由于某个不良事件终止试验，这个时候就可以定义关系了，可能是通过RELREC数据集来联系导致试验终止的不良事件和处置（DS）域里相应的终止记录。递交示例中提供了RELREC应用的例子，和下面很类似。

AE Domain subset　AE域的部分数据

STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AEDECOD	AEACN
CDISCC1	AE	CDISCC1.20000[illegible]		1	Anxiety	DOSE NOT CHANGED
CDISCC1	AE	CDISCC1.200001	2	2	Nausea	DOSE NOT CHANGED
CDISCC1	AE	CDISCC1.200001	3	3	Constipation	DOSE NOT CHANGED
CDISCC1	AE	CDISCC1.200001	4	4	Fatigue	DOSE NOT CHANGED
CDISCC1	AE	CDISCC1.200001	5	5	Arthralgia	DRUG WITHDRAWN

DS Domain subset　DS域的部分数据

STUDYID	DOMAIN	USUBJID	DSSEQ	DSDECOD
CDISCC1	DS	CDISCC1 200001	1	INFORMED CONSENT
CDISCC1	DS	CDISCC1 200001	2	RANDOMIZED
CDISCC1	DS	CDISCC1 200001	3	ADVERSE EVENT

RELREC Domain　RELREC域

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
[illegible]	AE	[illegible]	AESPID	5		1
[illegible]	DS	[illegible]	DSSEQ	3		1

Some things to note about the tables above:

关于上面的表格需要注意的地方有：

- The highlighted row in the AE table indicates that the action taken with study drug for that AE was to withdraw the drug.
- AE表中突出显示的行表明为这个不良事件采取的措施是终止用药
- The highlighted row in the DS table indicates that the subject withdrew due to an AE.
- DS表中突出显示的是受试者由于AE终止用药
- The first five columns of the RELREC domain are for relating back to the parent domain. RDOMAIN, IDVAR, and IDVARVAL function just as they do in the SUPPQUAL domains.
- RELREC域的前五列可用来回溯到各自的父域，RDOMAIN, IDVAR和IDVARVAL和它们在SUPPQUAL域里的功能是一样的。
- Identical RELID (within the same subject) values indicate that these records are related.
- RELID相同（在同一受试者内）则表示这些记录是相关联的。
- As a whole, the RELREC indicates that in study CDISC01, for subject CDISC01.200001, any rows in AE where AESPID=5 are related to any rows in DS where DSSEQ=3.
- 从整体上来讲，RELREC表示，在CDISC01这个试验里，对于受试者CDISC01.200001来说，AESPID=5的任意AE记录都和DS里DSSEQ=3的任意记录相关联。

Please refer to Section 4.1.5 for information regarding annotating RELREC variables.

关于RELREC变量注释信息请参阅*4.1.5*部分。

6 Appendices 附录

6.1 CDISC SDS Metadata Team CDISC SDS 元数据团队

角色	姓名	公司
联席团队领导	Carolyn Wilson	Forest Research Institute
联席团队领导	Richard Lewis	Octagon Research Solutions
	Gail Stoner	Johnson and Johnson
	Madhavi Vemuri	Johnson and Johnson

	Gary Walker	Quintiles
	Susan Hamilton	Eli Lilly
	Carol Vaughn	Sanofi-Aventis
	Tang Li	
	Carlo Radovsky	Etera Solutions
	Vineet Sharma	
	Jozef Aerts	XML4Pharma

6.2 Sample Submission Software Issues 递交示例中软件问题

6.2.1 Adobe 7 Links to blankcrf.pdf 用 Adobe 7 点击到 blankcrf.pdf 的链接时

There is a known problem with Adobe Acrobat 7 when trying to link to a specific page in a PDF from an HTML document, in this case an XML file rendered in a web browser. In the submission example, the links within the define.xml are defined to point to a specific page number within the blankcrf.pdf. If a version of Acrobat other than version 7 is used, the links should work perfectly. However, if Acrobat 7 is used, the links will always point to the first page within the blankcrf.pdf.

从 HTML 文档链接到 PDF 的一个指定页面的时候，使用 Acrobat 7 有一个已知的问题，这时候 XML 文件是用网页浏览器打开的。在递交示例中，define.xml 里面的链接指向的是 blankcrf.pdf 的一个特定页面。如果使用的 Acrobat 不是版本 7，这些链接工作正常。但是，如果使用的是 Acrobat 7，这些链接总是指向 blankcrf.pdf 的首页。

The issue described above may be found using the following link:

上面描述的问题可以通过下面这个链接找到：

http://www.adobe.com/cfusion/knowledgebase/index.cfm?id=326332

Using named-destinations in the hyperlink, instead of using CRF page numbers in the hyperlink, should resolve this issue.

在超链接中指向名称而不是指向CRF页码，就可以解决这个问题。

6.2.2 Back Arrows within the Define.xml Define.xml 中的返回箭头

In some cases the back arrows do not work when maneuvering within the define.xml. It is believed that this functionality is associated with the

browser and version used.
在某些情况下，define.xml中的返回箭头会出现不工作的情况。据说这与使用的浏览器和版本有关。

6.2.3 Browser Display/Functionality Issues 浏览器显示/功能的问题

Depending on your Adobe version and your browser and its settings, you may experience bookmark functionality issues or observe display and functionality issues in the rendered XML. Adjusting your browser settings can rectify this, but due to so many combinations it is not possible for this document to describe them all.
由于你的 Adobe 版本和你使用的浏览器及浏览器的设置，可能会遇到标签功能问题或者 xml 显示和功能的问题。调整你的浏览器设置可以解决这些问题，但由于有太多种原因，本文档不可能把所有的情况都列出来。

6.3 VALUELISTS 值列表

This appendix to the MSG has been included to explain ValueLists in more technical detail. Included in the "alternative sample tabulations" folder of the Metadata package is a stylesheet (define2-0-0_extended.xsl) that displays more detailed information about each of the value-level and variable-level metadata. There is also a copy of the define.xml (define_no_stylesheet.xml) that does not reference a stylesheet, displaying only the XML when viewed through a web browser. These additional files are not considered to be submission components, but are rather included for illustrative purposes. Modifications might be necessary for these files to be used as alternatives. The necessary documentation is included in the README file in the same folder.
MSG 的这个附录包含了对值列表更多技术细节上的解释。在元数据包的”alternative sample tabulations”目录中有一个样式表（define2-0-0_extended.xsl），显示了每一个参数值水平和变量水平元数据的更多的细节信息。还有一个 define.xml 的副本（define_no_stylesheet.xml），这个文件没有引用样式表，通过浏览器查看的时候仅仅显示 XML。这些附加的文件不是必须的递交组件，但是为了说明的目的，还是应该尽量包含在递交文件中。作为替代方案对这些文件的修改是必须的。必要的文档信息包含在同一个目录中的 README 文件中。

In the define.xml, variable-level metadata are described by ItemRef elements (within ItemGroupDef elements) and ItemDef elements. The former describe which variables are a part of each domain; whereas, the latter describe the metadata details (data type, length, controlled

terminology) of each of the variables. See Section 2.1.4 of the CRTDDS for additional details.

在 define.xml 中，变量水平的元数据由 ItemRef 元素（包含在 ItemGroupDef 元素中）和 ItemDef 元素描述。前者描述每个域都应该包含哪些变量，后者描述每个变量的元数据详细信息（数据类型、长度、受控术语）。更多详细信息见 CRTDDS 的 2.1.4 节。

The value-level metadata in the define.xml are described by def:ValueListDef and ItemRef elements, referenced from the ItemDef of the SDTM Variable through a ValueListRef. For example, the ValueList for VSTESTCD in the sample submission is defined using:

define.xml 中参数值水平的元数据由 def:ValueListDef 和 ItemRef 元素描述，通过 ValueListRef 来引用 ItemDef 定义的 SDTM 变量。例如，在递交示例中 VSTESTCD 的值列表使用以下定义：

```
<ItemDef OID="VS.VSTESTCD" Name="VSTESTCD" DataType="text" Length="20"
  Origin="Assigned" Comment="" def:Label="Vital Signs Test Short Name">
  <def:ValueListRef ValueListOID="ValueList.VS.VSTESTCD" />
</ItemDef>
```

and the possible values for VSTESTCD are described by:

VSTESTCD 可能的取值描述为：

```
- <def:ValueListDef OID="ValueList.VS.VSTESTCD">
    <ItemRef ItemOID="VS.VSTESTCD.DIABP" OrderNumber="22" Mandatory="No" />
    <ItemRef ItemOID="VS.VSTESTCD.FRMSIZE" OrderNumber="23" Mandatory="No" />
    <ItemRef ItemOID="VS.VSTESTCD.HEIGHT" OrderNumber="24" Mandatory="No" />
    <ItemRef ItemOID="VS.VSTESTCD.PULSE" OrderNumber="25" Mandatory="No" />
    <ItemRef ItemOID="VS.VSTESTCD.SYSBP" OrderNumber="26" Mandatory="No" />
    <ItemRef ItemOID="VS.VSTESTCD.WEIGHT" OrderNumber="27" Mandatory="No" />
  </def:ValueListDef>
```

Just as for variable-level metadata, the details of each of the value-level test codes are further defined by an ItemDef element. The possible values for test codes are defined by the "Name" attribute. The details for the value-level test codes DIABP, FRMSIZE, HEIGHT, PULSE, SYSBP and WEIGHT are defined by:

这只作为变量水平的元数据，每个参数值水平的元数据测试编码由 ItemDef 元素进一步定义。测试编码的可能值由"Name"属性定义。参数值水平测试编码 DIABP, FRMSIZE, HEIGHT, PULSE, SYSBP 和 WEIGHT 的详细信息定义为：

```
<ItemDef OID="VS.VSTESTCD.DIABP" Name="DIABP" DataType="integer" Length="2" Origin="CRF Page 11"
  def:Label="Diastolic Blood Pressure" />
<ItemDef OID="VS.VSTESTCD.FRMSIZE" Name="FRMSIZE" DataType="text" Length="6" Origin="CRF Page 11"
  def:Label="Body Frame Size">
  <CodeListRef CodeListOID="SIZE" />
</ItemDef>
<ItemDef OID="VS.VSTESTCD.HEIGHT" Name="HEIGHT" DataType="float" SignificantDigits="1" Length="5"
  Origin="CRF Page 11" def:Label="Height" />
<ItemDef OID="VS.VSTESTCD.PULSE" Name="PULSE" DataType="integer" Length="2" Origin="CRF Page 11"
  def:Label="Pulse Rate" />
<ItemDef OID="VS.VSTESTCD.SYSBP" Name="SYSBP" DataType="integer" Length="3" Origin="CRF Page 11"
  def:Label="Systolic Blood Pressure" />
<ItemDef OID="VS.VSTESTCD.WEIGHT" Name="WEIGHT" DataType="float" SignificantDigits="1" Length="4"
  Origin="CRF Page 11" def:Label="Weight" />
```

So this set of metadata defines that ”DIABP” has a data type of integer, a maximum length of 2, a label “Diastolic Blood Pressure”, and can be found on page 11 of the CRF.

这样 “DIBAP”的元数据定义集有数值型的数据类型，最大长度是 2，标签是“舒张压”，并且在 CRF 的第 11 页可以找到。

Value-level metadata is also needed to describe QNAM in the SUPPAE dataset.

在 SUPPAE 数据集中参数值水平的元数据还需要描述 QNAM。

suppae.xpt

	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	CDISC01	AE	CDISC01.100008	AESEQ	1	AETRTEM	Treatment Emergent Flag	Y	DERIVED
2	CDISC01	AE	CDISC01.100008	AESEQ	1	HLGT	Higher Level Group Term	Anxiety disorders and symptoms	DERIVED
3	CDISC01	AE	CDISC01.100008	AESEQ	1	HLT	Higher Level Term	Anxiety symptoms	DERIVED
4	CDISC01	AE	CDISC01.100008	AESEQ	1	LLT	Lowest Level Term	Agitation	DERIVED
5	CDISC01	AE	CDISC01.100008	AESEQ	2	AETRTEM	Treatment Emergent Flag	Y	DERIVED
6	CDISC01	AE	CDISC01.100008	AESEQ	2	HLGT	Higher Level Group Term	Anxiety disorders and symptoms	DERIVED
7	CDISC01	AE	CDISC01.100008	AESEQ	2	HLT	Higher Level Term	Anxiety symptoms	DERIVED
8	CDISC01	AE	CDISC01.100008	AESEQ	2	LLT	Lowest Level Term	Anxiety	DERIVED
9	CDISC01	AE	CDISC01.100008	AESEQ	3	AETRTEM	Treatment Emergent Flag	Y	DERIVED
10	CDISC01	AE	CDISC01.100008	AESEQ	3	HLGT	Higher Level Group Term	Appetite and general nutritional disorder	DERIVED
11	CDISC01	AE	CDISC01.100008	AESEQ	3	HLT	Higher Level Term	Appetite disorders	DERIVED
12	CDISC01	AE	CDISC01.100008	AESEQ	3	LLT	Lowest Level Term	Decreased appetite	DERIVED
13	CDISC01	AE	CDISC01.100014	AESEQ	1	AETRTEM	Treatment Emergent Flag	Y	DERIVED
14	CDISC01	AE	CDISC01.100014	AESEQ	1	HLGT	Higher Level Group Term	Gastrointestinal motility and defaecation	DERIVED
15	CDISC01	AE	CDISC01.100014	AESEQ	1	HLT	Higher Level Term	Diarrhoea (excl infective)	DERIVED
16	CDISC01	AE	CDISC01.100014	AESEQ	1	LLT	Lowest Level Term	Diarrhoea	DERIVED
17	CDISC01	AE	CDISC01.100014	AESEQ	2	AETRTEM	Treatment Emergent Flag	Y	DERIVED
18	CDISC01	AE	CDISC01.100014	AESEQ	2	HLGT	Higher Level Group Term	Gastrointestinal vascular conditions	DERIVED
19	CDISC01	AE	CDISC01.100014	AESEQ	2	HLT	Higher Level Term	Haemorrhoids and gastrointestinal varices	DERIVED
20	CDISC01	AE	CDISC01.100014	AESEQ	2	LLT	Lowest Level Term	Haemorrhoids	DERIVED

For the supplemental qualifiers for dataset AE using:

作为数据集 AE 的补充修饰符使用：

```
<ItemDef OID="SUPPAE.QNAM" Name="QNAM" DataType="text" Length="7" Origin="Assigned"
  def:Label="Qualifier Variable Name">
  <def:ValueListRef ValueListOID="ValueList.SUPPAE.QNAM" />
</ItemDef>
```

And the possible values for QNAM are then given by:

并且 QNAM 可能的值有：

```
<def:ValueListDef OID="ValueList.SUPPAE.QNAM">
  <ItemRef ItemOID="SUPPAE.QNAM.AETRTEM" OrderNumber="1" Mandatory="No" />
  <ItemRef ItemOID="SUPPAE.QNAM.HLGT" OrderNumber="2" Mandatory="No" />
  <ItemRef ItemOID="SUPPAE.QNAM.HLT" OrderNumber="3" Mandatory="No" />
  <ItemRef ItemOID="SUPPAE.QNAM.LLT" OrderNumber="4" Mandatory="No" />
</def:ValueListDef>
```

defining that QNAM in SUPPAE has the values “AETRTEM”, “HLGT”, “HLT” or “LLT”.

在 SUPPAE 中 QNAM 定义的值有“AETRTEM”, “HLGT”, “HLT” or “LLT”。

The details of each of the value-level QNAMs are defined by the corresponding “ItemDef” elements:

每个参数值水平的 QNAM 的详细信息由相应的”ItemDef”元素定义：

```
<ItemDef OID="SUPPAE.QNAM.AETRTEM" Name="AETRTEM" DataType="text" Length="1" Origin="Derived" Comment="If it
  was not present prior to the RFSTDTC, or it was present prior to the RFSTDTC but increased in severity during the
  treatment period then equal Y.." def:Label="Treatment Emergent Flag">
  <CodeListRef CodeListOID="NY" />
</ItemDef>
<ItemDef OID="SUPPAE.QNAM.HLGT" Name="HLGT" DataType="text" Length="52" Origin="Assigned" def:Label="High Level
  Group Term">
  <CodeListRef CodeListOID="AEDICT_F" />
</ItemDef>
<ItemDef OID="SUPPAE.QNAM.HLT" Name="HLT" DataType="text" Length="60" Origin="Assigned" def:Label="High Level
  Term">
  <CodeListRef CodeListOID="AEDICT_F" />
</ItemDef>
<ItemDef OID="SUPPAE.QNAM.LLT" Name="LLT" DataType="text" Length="18" Origin="Assigned" def:Label="Lowest Level
  Term">
  <CodeListRef CodeListOID="AEDICT_F" />
</ItemDef>
```

Each of the value-level QNAMs (defined by the "Name" attribute) has a different length, a label, and associated controlled terminology (CodeLists).
每个参数值水平的 QNAM（由"Name"属性定义）有不同的长度，一个标签，和相关的受控术语（代码表）。

The details of each value-level QNAM are applicable to the result fields in the SUPPAE dataset, i.e. on "QVAL".So the above metadata shows that the maximum character length for the result in QVAL for the case where QNAM=AETRTEM is 1, and that only the values defined in the codelist "NY" (N/Y) are possible.
每个参数值水平 QNAM 的详细信息同样适用于 SUPPAE 数据集的结果值，例如，"QVAL"的值。所以从上面的元数据定义可以看出，在 QNAM=AETRTEM 时 QVAL 的值的最大字符长度是 1，并且值只可能是代码表"NY"中定义的（N 或 Y）。

Similarly, it shows that the maximum character length for the result in QNAM for the case where QNAM=HLGT is 52, and that the allowed values come from the (external) codelist "AEDICT_F" (MedDRA v.8.0).
同样的，可以表明在 QNAM=HLGT 的情况下，QVAL 值的字符最大长度为 52，允许的值来自（扩展）代码表"AEDICT_F"（MedDRA V.8.0）。

The stylesheet in the sample submission allows one to inspect the value-level metadata in a much more user-friendly way than the source XML. If an SDTM variable has a valuelist, then a hyperlink is provided in the column "Variable", which when clicked, jumps to a table containing the associated valuelist.
在递交示例中有一个样式表，可以把参数值水平的元素据使用用户友好的方式来呈现，而不是 XML 源码的方式。如果一个 SDTM 变量有一个值列表，然后在列"变量"中设置了一个超链接，那么在点击的时候，会跳转到包含相关值列表的表格中。

The latter lists the source variable (e.g. VSTESTCD), the value-level variable (e.g. "DIABP"), the label (e.g. "Diastolic Blood Pressure"), the datatype (e.g. integer), whether controlled terminology is applicable (and if so a link to the associated codelist), and the origin (e.g. "CRF Page 11"). Also columns for

the "Role" and "Comments" are provided. The stylesheet provides a limited amount of information: the maximum length for example is not displayed.
以下列出了源变量（如：VSTESTCD），参数值水平变量（如："DIABP"），标签（如："舒张压"），数据类型（如：整数），是否使用受控术语（如果使用，会有一个到相关编码表的链接），来源（如："CRF 的第 11 页"）。还列出了"Role"和"Comments"。但是样式表只提供了有限的信息：例如最大长度信息没有显示。

Value Level Metadata (ValueList.VS.VSTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Comment
VSTESTCD	DIABP	Diastolic Blood Pressure	integer		CRF Page 11	
VSTESTCD	FRMSIZE	Body Frame Size	text	SIZE	CRF Page 11	
VSTESTCD	HEIGHT	Height	float		CRF Page 11	
VSTESTCD	PULSE	Pulse Rate	integer		CRF Page 11	
VSTESTCD	SYSBP	Systolic Blood Pressure	integer		CRF Page 11	
VSTESTCD	WEIGHT	Weight	float		CRF Page 11	

As mentioned at the beginning of this appendix, a second stylesheet (define2-0-0_extended.xsl) is found in the 'additional samples' folder, allowing for display of considerably more detailed information about each of the value-level and variable-level metadata.
正如本附录开头提到的，在'附加示例'文件夹中有第二个样式表（define2-0-0_extended.xls），用来显示每个参数值水平和变量水平的元数据的更多详细信息。

For the SUPPAE dataset, the stylesheet provides a hyperlink from the "QNAM" variable to a table containing a valuelist with all possible values for "QNAM" in the SUPPAE dataset. This valuelist table then displays further details for each of the allowed values of QNAM: source variable ("QNAM"), variable value (e.g. "AETRTEM"),the label (e.g. "Treatment Emergent Flag"), the data type, whether controlled terminology is applicable (and if so a link to the associated codelist), the origin, and when present, a comment.
对于 SUPPAE 数据集，样式表提供了一个从"QNAM"变量到一个表格的超链接，这个表格包含 SUPPAE 数据集中"QNAM"变量所有可能值的一个值列表。这个值列表显示了 QNAM 每个允许值的更多详细信息：来源变量("QNAM")，变量值（如："AETRTEM"），标签（如："治疗中出现的标帜"），数据类型，是否使用受控术语（如果使用，会有一个到相关编码表的链接），来源，有时候会有一个注释。

The stylesheets also provide backlinks from the supplemental data tables to the table for the originating dataset.Notice that this backlink relies on the value of def:Label being composed of: "Supplemental Qualifiers for " + dataset name.

样式表也提供了从补充数据表格到原始数据集表格的反向链接。请注意，反向链接依赖于 def:Label 的值，这个值由“补充修饰符(Supplemental Qualifiers for)”+数据集名称组成。

Value Level Metadata (ValueList.SUPPAE.QNAM)						
Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Comment
QNAM	AETRTEM	Treatment Emergent Flag	text	NY	Derived	If it was not present prior to the RFSTDTC, or it was present prior to the RFSTDTC but increased in severity during the treatment period then equal Y.
QNAM	HLGT	High Level Group Term	text	AEDICT_F	Assigned	
QNAM	HLT	High Level Term	text	AEDICT_F	Assigned	
QNAM	LLT	Lowest Level Term	text	AEDICT_F	Assigned	
Dataset (AE)						

In some circumstances, it may be necessary to "nest" value-level metadata in order to group topic variables because the topic variable alone is not specific enough to represent the attributes. For example, if multiple questionnaires are collected and included in a single QS dataset, the data might best be described by first providing a value list reference for QSCAT. This value list would describe each questionnaire collected. Then a value list could be associated with QSCAT. Each "secondary" value list would describe the test codes and result attributes particular to each questionnaire.

在一些情况下，由于单独的主题变量不足以表示这些属性，有必要用参数值水平的元数据“嵌套”来对主题变量进行分组。例如，如果在一个QS数据集中有多个调查问卷，那么最好首先提供一个QSCAT值列表来对数据进行说明。这个值列表描述每个采集到的问卷。然后再给QSCAT关联一个值列表。每个“二级”值列表来描述每个特定问卷的测试编码和结果属性。

An alternative approach is to provide a single dataset for each questionnaire, as was done in the sample submission.

另一种方式是为每一个调查问卷创建一个独立的数据集，就像示例递交中做的一样。

Likewise, when using the CDISC standard laboratory test code dictionary, it may be necessary to nest on lab specimen and method in order to provide appropriate descriptions of different types of results that share the same test code. For example, serum glucose, qualitative urine glucose, and quantitative 24-hour urine glucose all share the same LBTESTCD value (GLUC), but have different attributes.

同样，在使用CDISC标准的实验室测试编码字典时，也需要通过实验室标本和测试方法嵌套来描述同一个测试编码的不同类型和结果。例如，血糖、尿糖定性分析和24小时尿

糖定量分析都有相同的测试编码（LBTESTCD）（值为GLUC），但是有不同的属性。

In the sample submission, a valuelist is provided for LBCAT. For each possible value of LBCAT ("CHEMISTRY", "HEMATOLOGY", "URINALYSIS"), a new valuelist is defined based on the possible values of LBSPEC. For example, for "CHEMISTRY", the allowed values for LBSPEC are "BLOOD" and "SERUM", whereas the only possible values for LBSPEC in "HEMATOLOGY" is "BLOOD". For "URINALYSIS", the only possible value for LBSPEC is "URINE".
在递交示例中，为LBCAT提供了一个值列表。对于LBCAT的每个可能值（"化学"，"血液学"，"尿液分析"），都会为LBSPEC提供不同的值列表。例如，对于"化学"，LBSPEC的可选值是"血液"和"血清"，但是对于"血液学"来说LBSPEC的可选值只有"血液"。对于"尿液分析"，LBSPEC的可选值只有"尿液"。

```
<def:ValueListDef OID="ValueList.LB.LBCAT">
      <ItemRef ItemOID="LB.LBCAT.CHEMISTRY" OrderNumber="1" Mandatory="No"/>
      <ItemRef ItemOID="LB.LBCAT.HEMATOLOGY" OrderNumber="2" Mandatory="No"/>
      <ItemRef ItemOID="LB.LBCAT.URINALYSIS" OrderNumber="3" Mandatory="No"/>
</def:ValueListDef>
```

```
<ItemDef OID="LB.LBCAT.URINALYSIS" Name="URINALYSIS" DataType="text" Length="10" Origin="eDT"
      Comment="" def:Label="URINALYSIS">
      <def:ValueListRef ValueListOID="ValueList.LB.LBCAT.URINALYSIS.LBSPEC"/>
</ItemDef>
```

```
<def:ValueListDef OID="ValueList.LB.LBCAT.URINALYSIS.LBSPEC">
      <ItemRef
            ItemOID="LB.LBCAT.URINALYSIS.LBSPEC.URINE" OrderNumber="4" Mandatory="No"/>
</def:ValueListDef>
```

The latter is then further differentiated by method: the possible values are "DIPSTICK", "QUANT" (quantitative) and "NOMETHOD".
下面通过检测方法进行进一步的细化：可选的值有"浸量尺",”QUANT"（定量的）和"没有方法"。

```
<ItemDef OID="LB.LBCAT.URINALYSIS.LBSPEC.URINE" Name="URINE" DataType="text" Length="5"
      Origin="eDT" Comment="" def:Label="URINE">
      <def:ValueListRef ValueListOID="ValueList.LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD"/>
</ItemDef>
```

```
<def:ValueListDef OID="ValueList.LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD">
      <ItemRef ItemOID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD.DIPSTICK" OrderNumber="1"
            Mandatory="No"/>
      <ItemRef ItemOID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD.QUANT" OrderNumber="2"
            Mandatory="No"/>
      <ItemRef ItemOID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD.NOMETHOD" OrderNumber="3"
            Mandatory="No"/>
</def:ValueListDef>
```

```
<ItemDef OID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD.NOMETHOD" Name="(no method)"
      DataType="text" Length="5" Origin="eDT" Comment="" def:Label="NO METHOD">
      <def:ValueListRef
            ValueListOID="ValueList.LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD.NOMETHOD.LBTESTCD"/>
</ItemDef>
```

```
<def:ValueListDef
      OID="ValueList.LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBMETHOD.NOMETHOD.LBTESTCD">
      <ItemRef ItemOID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBTESTCD.OCCBLD" OrderNumber="9"
       Mandatory="No"/>
      <ItemRef ItemOID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBTESTCD.PH" OrderNumber="10"
       Mandatory="No"/>
</def:ValueListDef>
```

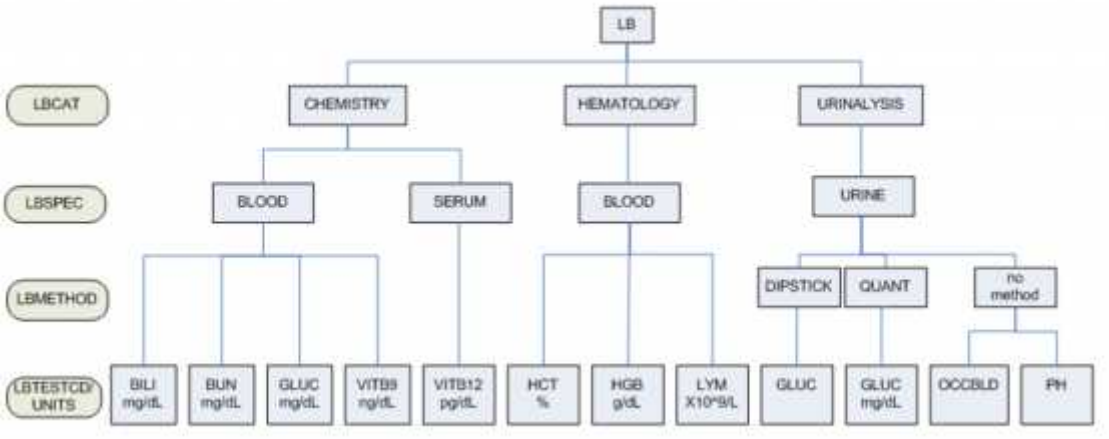
For the category "NOMETHOD" a further differentiation is made by lab test code: the possible values are "OCCBLD" (occult blood), and "PH".

在"没有方法"分类中又可以通过实验室检查编码进一步细化，可能的值有"OCCBLD"（潜血）和"PH值测定"。

```
<ItemDef OID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBTESTCD.OCCBLD" Name="OCCBLD"
  DataType="text" Length="8" Origin="eDT" Comment="" def:Label="Occult Blood"/>
<ItemDef OID="LB.LBCAT.URINALYSIS.LBSPEC.URINE.LBTESTCD.PH" Name="PH"
  DataType="float" SignificantDigits="1" Length="3" Origin="eDT" Comment="" def:Label="pH"/>
```

Differentiation is also made for the other laboratory test categories. A further differentiation is made. For example,in case LBCAT=CHEMISTRY and LBSPEC=BLOOD, the allowed values for LBTESTCD are "BILI" (Bilirubin), "BUN" (Blood Urea Nitrogen), "GLUC" (Glucose), and "VITB9" (Folic Acid; Vitamin B9). Each of these nested test codes has its own datatype, label, units etc.The full scheme of the nested valuelists for the LB domain is depicted below:

其他的实验室检查类别也会有进一步的细化。一个进一步细化的例子，在LBCAT=CHEMISTRY(化学)并且LBSPEC=BLOOD(血液)中，LBTESTCD允许的值有"BILI"（胆红素），"BUN"（血尿素氮），"GLUC"（葡萄糖）和"VITB9"（叶酸；维生素B9）。每个嵌套的测试编码都有自己的数据类型，标签，单位等。LB域中对所有嵌套的值列表定义描述如下：



The sponsor should decide when multiple levels are required in order to properly describe the attributes of a test. In the sample submission define.xml, --CAT was nested for QS, LB, and IE. Again this is only an example and the sponsor should customize the define.xml and stylesheet to

1815 display their data in a logical manner.
1816 由申办者决定什么时候需要用多层嵌套才能正确描述测试的属性。在递交示例
1817 define.xml中，--CAT在QS，LB，IE域中是嵌套的。再次声明这只是一个示例，申办者
1818 应该定制define.xml和样式表以便用合理的方式显示数据。