



Therapeutic Area Data Standards User Guide for Asthma

Version 1.0

Prepared by the
CFAST Asthma Team



Notes to Readers

- This is the provisional version 1.0 of the Therapeutic Area Data Standards User Guide for Asthma.
- This document corresponds to the SDTM v1.3 and SDTMIG v3.1.3, but incorporates new domains developed after v3.1.3 was released.
- This document also corresponds to the CDASH Standard v1.1.
- The TAUG-Asthma v1.0 package includes a user guide (this document), two draft domains, and seven workbooks of somewhat simplified, prototype metadata as they may be represented in the CDISC SHARE repository.

Revision History

Date	Version	Summary of Changes
2013-11-26	1.0	Provisional
2013-09-13	1.0 Draft	Draft for Public Review

See [Appendix H](#) for Representations and Warranties, Limitations of Liability, and Disclaimers

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1 Introduction

This Therapeutic Area Data Standards User Guide for Asthma (TAUG-Asthma) was developed under the Coalition for Accelerating Standards and Therapies (CFAST) initiative.

CFAST, a joint initiative of CDISC and the Critical Path Institute (C-Path), was launched to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health. CFAST partners include TransCelerate BioPharma Inc. (TCB), the U.S. Food and Drug Administration (FDA), and the National Cancer Institute Enterprise Vocabulary Services (NCI-EVS), with participation and input from many other organizations. See [Appendix B](#) for a description of CFAST participating organizations.

CDISC has developed industry-wide data standards enabling the harmonization of clinical data and streamlining research processes from protocol (study plan) through analysis and reporting, including the use of electronic health records to facilitate study recruitment, study conduct and the collection of high quality research data. CDISC standards, implementations and innovations can improve the time/cost/quality ratio of medical research, to speed the development of safer and more effective medical products and enable a learning healthcare system.

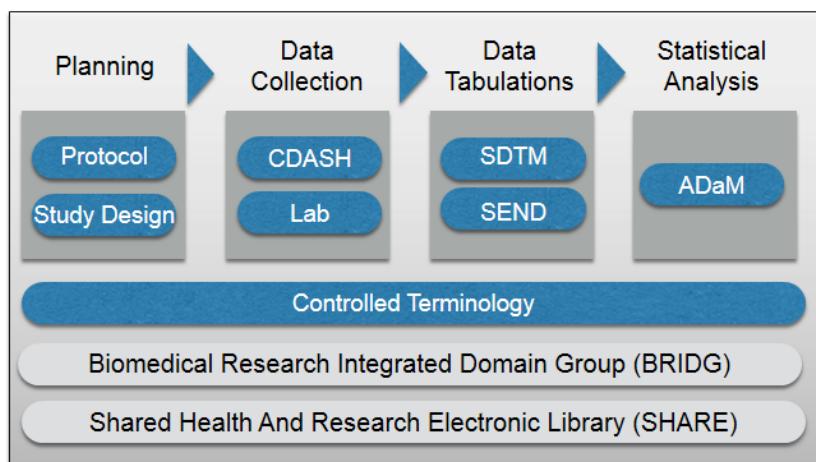


Figure 1: CDISC Industry Wide Data Standards

The goal of the CFAST initiative is to identify a core set of clinical therapeutic area concepts and endpoints for targeted therapeutic areas and translate them into CDISC standards to improve semantic understanding, support data sharing and facilitate global regulatory submission.

1.1 Purpose

The focus of this Version 1.0 (v1.0) of the TAUG-Asthma is on clinical trials of drugs to treat asthma in an *adult* population. Guidelines for handling data specific to pediatric and device development studies are not addressed in this version. See [Appendix A](#) for the project proposal that was approved by the CFAST Steering Committee.

This TAUG-Asthma v1.0 describes the most common data needed for asthma studies, so that those handling the data (e.g., data managers, statisticians, programmers) understand the data and can apply standards appropriately. Descriptions addressed in this TAUG-Asthma v1.0 include the clinical situations from which the data arise, and the reasons these data are relevant for asthma. The overall goal is to provide the metadata needed to assist in the move toward closer semantic interoperability between health care and clinical trials.

The TAUG-Asthma v1.0 also strives to define research concepts unambiguously, so that consistent terminology can be used in asthma studies to enable aggregation and comparison of data across studies and drug programs.

Further, this standard includes prototype metadata for the research concepts, including the properties of the data items that are parts of the concepts, controlled terminology for those data items, and the ways in which the concepts relate to each other. These metadata, useful in their current form to create define files, are described further in [Appendix F](#). They will be further developed and included in the CDISC SHARE metadata repository (<http://www.cdisc.org/cdisc-share>).

And finally, the TAUG-Asthma v1.0 describes how to use CDISC standards to represent data:

- For the Study Data Tabulation Model (SDTM) and the SDTM Implementation Guide for Human Clinical Trials (SDTMIG), these instructions include guidance on which domains and other datasets data should be stored in, how variables should be used, and example datasets.
- For Clinical Data Acquisition Standards Harmonization (CDASH), the guidance includes examples of CDASH-conformant forms for data collection where they exist. Conformance rules are specified in the CDASH UG v1.1. If no CDASH domain tables have been established, the examples provided are consistent with the CDASH Best Practice Recommendations described in CDASH v1.1.
- For the Analysis Data Model (ADaM), the form of guidance has not yet been established, but will be in future iterations of this document.

These CDISC standards are freely available at www.cdisc.org. It is recommended that implementers consult the Study Data Tabulation Model (SDTM) and the CDASH standard prior to implementing these asthma clinical data standards.

It is important to note that *the inclusion of concepts in this user guide should not be construed as a requirement to collect data on these concepts in any particular study in asthma*. The examples included are intended to show how data of particular kinds can be represented using CDISC standards. In some areas, there is no consensus on an approach in assessing a specific aspect of disease (e.g., the definition of an asthma exacerbation). In those areas, this user guide emphasizes that *examples given are for guidance only and should not be over-interpreted*. The collection of certain data items, especially those that are related to safety (e.g., hospitalizations, exacerbations) and other standard items such as demography, medical history, and concomitant medications should also be collected to meet the established standards for these endpoints.

1.2 Asthma Regulatory and Clinical Guidelines

Research concepts, in the context of this document, are defined as the data, organization, resources, rules, and processes involved in protocol-driven research. The authors of this user guide considered the recommendations from the Asthma Outcomes Workshop* held by several National Institutes of Health, focusing on the core (data that the report recommends be required in future asthma clinical trials) and supplemental (data whose inclusion would be optional) outcome measures. The outcome domains described in the Asthma Outcomes Workshop Report are consistent with the statements made by the American Thoracic Society and European Respiratory Society on standardizing endpoints for clinical asthma trials and clinical practice¹.

The Asthma Outcomes Workshop Report categorizes outcomes in the following seven areas: biomarkers, asthma control, exacerbations, healthcare utilization and costs, pulmonary physiology, quality of life, and symptoms². Of these areas, this user guide focuses primarily on pulmonary physiology, exacerbations, and biomarkers, with less discussion of symptoms, quality of life, asthma control, and healthcare utilization. This document also covers allergen skin tests, since people with asthma often also suffer common aeroallergies, as well as a subject's history of asthma and some elements of routinely collected data (e.g., medical history, adverse events, concomitant medications) that might be of particular interest to asthma studies.

* Available at: http://www.jacionline.org/issues?issue_key=S0091-6749%2812%29X0003-4.

1.3 Organization of this Document

The organization of this TAUG-Asthma v1.0 differs from that of prior CDISC therapeutic area user guides, which mirrored the general structure of the SDTMIG by describing interventions, events, and findings in that order. Instead, the Asthma user guide has a more clinically oriented organization.

- [Section 1, Introduction](#), provides an overall introduction to the purpose and goals of the Asthma project.
- [Section 2, Subject and Disease Characteristics](#), covers data that are usually collected once at the beginning of a study.
- [Section 3, Disease Assessments](#), covers data that are used to evaluate disease severity, control, or progression. These are usually collected repeatedly during a study, and may be used as efficacy endpoints.
- [Section 4, Routine Data](#), covers background data that are collected in most studies. Only aspects of these data that arise in asthma studies and that are not covered by existing standards are discussed.
- [Appendices](#) provide additional background material and describe other supplemental material relevant to asthma.

A list of domains used in the examples in this document, and the sections in which these examples appear, is given below:

Domains from SDTMIG	Section
Interventions	
AG – Procedure Agents*	3.1.6
CM – Concomitant Medications	3.1.6 , 4.2.2
Events	
AE – Adverse Events	4.1.1
HO – Healthcare Encounters†	4.3.1
MH – Medical History	2.2.1
Findings	
LB – Laboratory Test Results	3.3.3
RE – Respiratory System Findings*	3.1.6
Findings About Interventions and Events	
FA – Findings About	2.1.1 (for MH), 4.1.1 (for AE), 4.3.1 (for HO)
SR – Skin Response†	2.3.1

* Domain was not published in SDTMIG v3.1.3 and is not final.

† Domain is new in SDTMIG v3.2

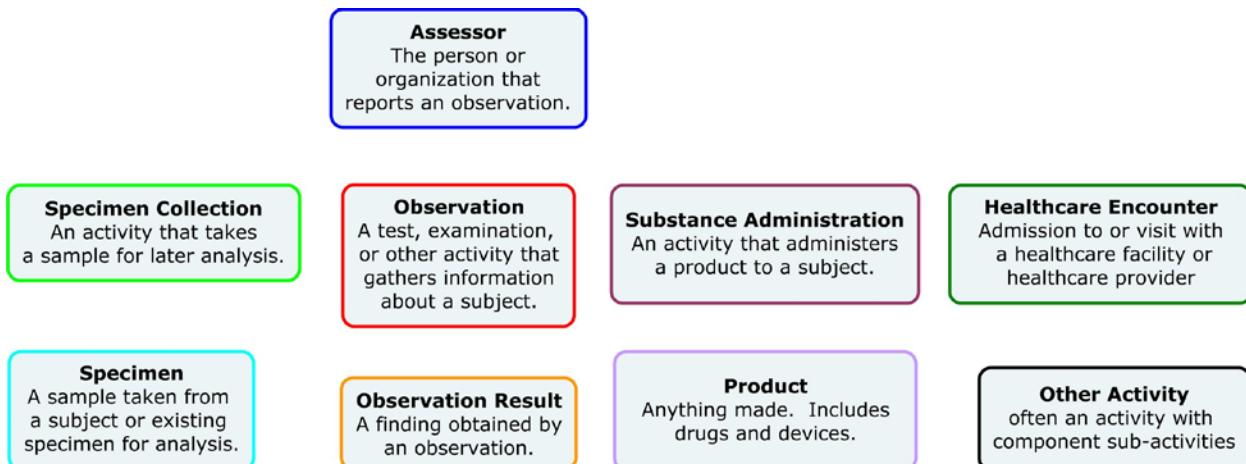
Domains from SDTMIG-MD	Section
DI – Device Identifier	3.1.6
DU – Device-in-Use	3.1.6

Note that in this version of the TAUG-Asthma, devices domains are used for ancillary devices only.

1.4 Concept Maps

This document uses concept maps to explain clinical processes and research concepts. Concept maps, also sometimes called mind maps, are diagrams which include “bubbles” representing concepts/ideas/things and labeled arrows that represent the relationships between the concepts/ideas/things. They are generally easier to draw and more accessible than more formal modeling diagrams, such as Unified Modeling Language (UML) diagrams.

The diagrams in this document use the following color-coding. The classification of things represented by these colors is based on classes in the BRIDG model. These colors have been used to highlight kinds of things that occur commonly in clinical data and therefore give rise to common patterns of data.



1.5 Controlled Terminology

CDISC Controlled Terminology is a set of standard value lists that are used throughout the clinical research process, from data collection through analysis and submission. Terminology applicable to CDASH and/or SDTM data collection fields is either in production or under development by the CDISC Terminology Team at the time of publication of this document. Production terminology is published by the National Cancer Institute’s Enterprise Vocabulary Services (NCI EVS) and is available at:

<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>.

CDISC Controlled Terminology is updated quarterly. Because this document is a static publication, it refers readers to the NCI EVS page for CDISC terminology (at the link given above). For the same reason, this document cannot claim to use controlled terminology in either the lists of laboratory tests or in the examples provided; users should not refer to these as the ultimate authority on what terms to use or to not use.

Heretofore, domain specification tables have listed any codelists that are associated with a particular variable. In the future, it is envisioned that the CDISC SHARE metadata repository (which is not static) will provide not only the codelist associated with a particular variable, but also a list of values from the codelist applicable to a particular concept. For more on prototype SHARE metadata, see [Appendix F](#).

1.6 Relationships to Other Standards

This section describes the relationship of this document to other standards, whether CDISC or external. This document does not replace the foundational CDISC standards or their implementation guides. The user should read those standards and implementation guides before applying the advice in this user guide.

The following kinds of data have existing CDASH and SDTM standards which can be used in asthma studies without additional development or customization:

- Demography
- Clinical laboratory tests (including pregnancy tests)
- Physical exams
- ECG
- Substance use (smoking, alcohol, substance abuse)

Representations of the research concepts used in this document, in an expanded format consistent with the CDISC SHARE metadata repository, will be developed separately. A set of somewhat simplified, prototype concept metadata displays as they may be represented in SHARE is attached as part of the TAUG-Asthma v1.0 package. The metadata displays are listed in [Appendix F](#).

This document uses domains and assumptions which are not final at the time of publication and therefore are subject to change or deletion without formal notice. Please check the most recent version of SDTM and SDTMIG to ascertain their current status.

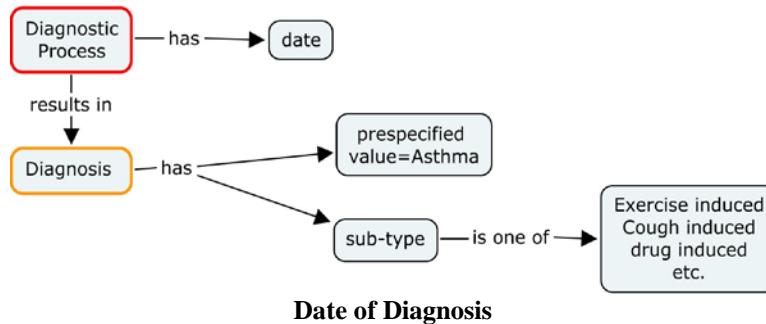
- The Respiratory System Findings (RE) domain is still a work in progress (i.e. a “draft” domain), which has not appeared prior to this TAUG-Asthma package.
- The Procedure Agents (AG) domain, like the RE domain, is a draft domain that has not previously appeared.
- The Skin Response (SR) domain has been through public review and is expected to be released with SDTM v1.4 and SDTMIG v3.2.
- The Healthcare Encounters (HO) domain has been through public review and is expected to be released with SDTM v1.4 and SDTMIG v3.2.
- The assumptions for the Concomitant Medications (CM) domain given in this document are draft assumptions. They will be considered for inclusion in a future version of the SDTMIG.

In some cases when a definitive SDTM modeling approach does not exist, a suggested approach is offered but may be subject to change over time.

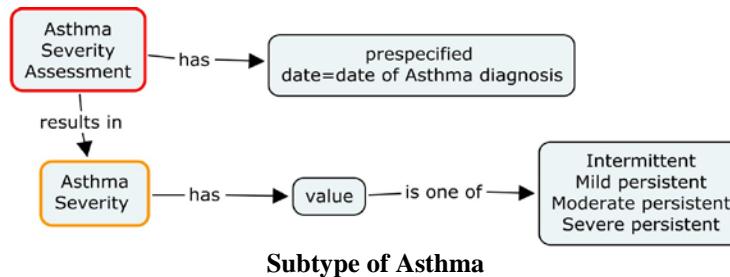
2 Subject and Disease Characteristics

2.1 Asthma History

Asthma studies usually collect data on the diagnosis of the asthma, including the date of diagnosis (which may be defined as the patient-reported date, the date based on medical records, or other definition), age at onset, and the sub-type of asthma (e.g., exercise induced, cough induced, occupational, nocturnal, aspirin exacerbated, eosinophilic, drug or allergy induced).



The result of the severity assessment at the time of diagnosis may be collected as part of asthma history. The assessment of severity in newly diagnosed, untreated subjects is somewhat different from the assessment of severity in asthma subjects under treatment. At initial diagnosis, the severity of asthma is based primarily on level of symptoms, airflow limitation, and lung function variability³. Once treatment has been initiated, asthma severity is classified on the basis of the intensity of treatment required to achieve good asthma control⁴.



Data on asthma history usually also includes information about recent events associated with asthma severity. For example, data on hospitalizations, emergency room visits, or exacerbations within a pre-study time period (e.g., within the year before study start) are often collected. These data may be collected to determine

eligibility, or as baseline covariates. Allergy history (e.g. allergic rhinitis, eczema, atopic dermatitis, history of anaphylaxis) and history of positive methacholine/histamine challenge may also be collected.

See [Section 3.2](#) and [Section 4.3](#) for more information.

2.1.1 Examples for Asthma History

Example 1

Date of diagnosis of asthma and sub-type of asthma are collected. Because asthma is part of the inclusion criteria for the study, there may or may not be a medical history record with MHTERM = Asthma. Even if there is an MH record for asthma, the variable MHSTDTC is vaguely defined, and might refer to date of diagnosis or to some other notion of “start” of asthma. In order to show the date that is specifically the date of diagnosis, this date is captured as the result of a test in the Findings About Interventions and Events (FA) domain. This approach, although it has been shown in other CDISC therapeutic area user guides, is controversial, as it involves treating a date as a result, which is generally to be avoided. The CDISC SDS team is working to provide definitive implementation advice on this issue.

The asthma sub-type has also been handled as a finding about asthma, although this is also somewhat controversial, since there are several MedDRA codes for specific types of asthma, and this data could have been treated as a series of observations about pre-specified medical history conditions.

Asthma History

Date of diagnosis: DD-MMM-YYYY

What type of asthma does the subject have?

Exercise induced	Drug induced	Occupational
Cough induced	Allergy induced	Nocturnal

Row 1: The subject was diagnosed with Asthma in 1992.

Row2: The subject has exercise-induced asthma.

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Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
1	ABC123	FA	456	1	DIAGDTC	Date of Diagnosis	Asthma	Asthma History	1992	1992	2013-05-24
2	ABC123	FA	456	2	SUBTYPE	Subtype	Asthma	Asthma History	Exercise induced	Exercise induced	2013-05-24

Example 2

Data are collected about the severity of the subject’s asthma at the time of diagnosis.

Data collection such as severity at time of diagnosis presents a dilemma for the population of timing variables in an SDTM findings domain. In most findings domains, the --DTC variable and the visit and timepoint variables describe the time when the collected data apply to the subject. For historical data such as this, one could argue that the date of diagnosis should be used to populate the --DTC value. However, Demography and in Events and Interventions domains, the --DTC variable is routinely used to represent the date when the data was recorded for the study, and so it could be argued that the date of collection should be used to populate the --DTC value. There are similar issues with the --TPT variable, which is generally used to describe a testing time planned within the study,

but which has been used in some other therapeutic area user guides to describe a particular time before the study. Discussions are ongoing within the SDS team to provide definitive implementation advice on the use of timing variables for pre-study findings.

This finding has been handled as a finding about asthma, since this is a type of severity assessment that is generally used only at time of diagnosis, rather than for repeated assessments.

Asthma History

Date of assessment: DD-MMM-YYYY

At the time of diagnosis, what was the severity of the subject's asthma?

Intermittent Mild persistent Moderate persistent Severe persistent

Row 1: At the time the subject was diagnosed with asthma, the severity of the subject's disease was judged to be "moderate persistent." FATPT has been populated with the description "Diagnosis" to indicate that this is the time at which the assessment of severity was made. FADTC has been populated with the date on which this information was collected. Note that these uses of --TPT and --DTC are problematic, as described above.

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Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESC	FATPT	FADTC
1	ABC123	FA	456	1	SEV	Severity	Asthma	Asthma History	MODERATE PERSISTENT	MODERATE PERSISTENT	Diagnosis	2013-05-24

2.2 Medical History of Special Interest

Diagnosing asthma includes the collection of medical history. A physician not only records the symptoms of the disease but also studies the medical history, family history, co-morbidities, and physical characteristics of the subject. The medical history helps to confirm the diagnosis, rule out other confounding factors, identify the underlying triggers, identify hereditary patterns, etc. Data collected for diagnosis of asthma or treatment of ongoing asthma includes symptoms, pattern of symptoms (e.g., perennial, seasonal, continual, episodic, diurnal variation, precipitating or aggravating factors), age of onset, history of exacerbations, social history, smoking history, and impact of asthma on the subject's life (health care utilization, limitation of activity, etc.)⁵. Typically, asthma clinical trials may exclude subjects with a smoking history greater than a threshold (e.g. > 5 pack years of cigarette use, where 1 pack year is 20 cigarettes per day for 1 year), however it is also known that a substantial proportion of people with asthma are smokers or ex-smokers, so smoking history should be documented. This version of the TAUG-Asthma does not address all the possible aspects of medical history described above. It is limited to the following items, considered to be of special interest for asthma: sinusitis, atopic dermatitis, eczema, nasal polyposis, ASA sensitivity, seasonal allergic rhinitis, and allergic conjunctivitis.

The most frequently reported asthma comorbidities are rhinitis, sinusitis, gastroesophageal reflux disease, obstructive sleep apnea, and other manifestations of atopic disease. These conditions may share a common pathophysiological mechanism with asthma, and may influence asthma control and response to treatment. For example, it is estimated that from 20% to 70% of asthmatic adults have coexisting sinus disease. Conversely, 15% to 56% of those with allergic rhinitis (hay fever) or sinusitis have evidence of asthma. Thus, the existence and treatment of these comorbidities should be documented to understand their impact on the subject's asthma.

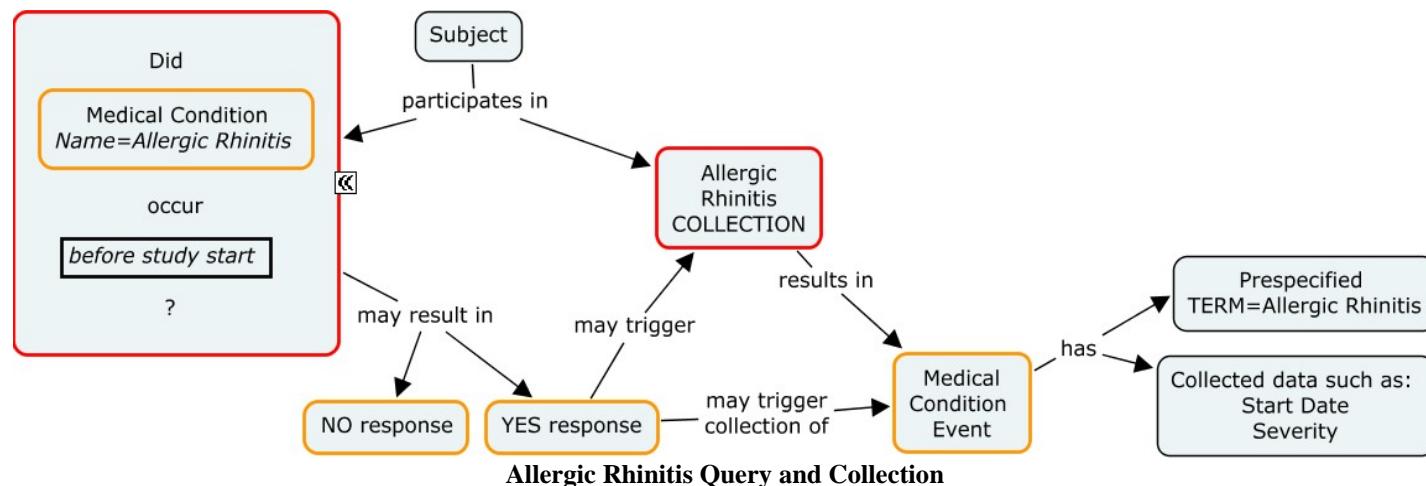
Data collected for Medical History of Special Interest can include:

- Whether or not a subject had any of the Special Interest Medical History conditions followed by a specific question about the occurrence of each pre-specified condition with a Y/N response.

- Additional details such as start date, end date, severity etc., may be collected for each Medical History of Special Interest condition that the subject had.

Example: Allergic Rhinitis Query

The concept map below shows a query about the occurrence of allergic rhinitis during a time period. The kind of event the question is asking about (in this case, allergic rhinitis) is called the focal context of the question. The time period the query is asking about is called the focal time period. If the answer to the query is “Yes,” then additional information about allergic rhinitis such as start date, end date, and severity may be collected.



This diagram includes two questions (the red boxes).

Allergic Rhinitis Query:

The relevant data include its focus (the kind of event and the time period) and its response. In this example, the focus of the query is allergic rhinitis. It is part of the question, and is “hard coded” in the final data. In this example, the time period over which the question is focused is the subject’s lifetime up until their start in the study. The data to be collected for this kind of research concept includes data about the question and the response:

- Pre-specified question properties:
 - The pre-specified (focal) event
 - The focal time period
 - Possibly, the fact that this question was nested in a category, such as “Asthma Related History”
- Collected question properties:
 - The subject of the question (the subject)
 - When the question was asked (date/time and relative study timing)
 - Possibly, that the question was not asked, and why not
- Collected response properties:
 - The response to the question

- Possibly, that although the question was asked, an answer was not recorded, and why not

Allergic Rhinitis Collection:

The relevant data include the question, including its focus, and the response. A response to this question is only collected if an event of the pre-specified type occurred during the focal time period. The data to be collected for this kind of research concept includes data about the question and the response:

- Pre-specified question properties:
 - The fact that the focal event was pre-specified
 - The focal time period
 - Possibly, the fact that this question was nested in a category, such as “Asthma Related History”
- Collected question properties:
 - The subject of the question (the subject)
 - When the question was asked (date/time and relative study timing)
- Pre-specified response properties:
 - The name of the event
 - Probably, the MedDRA term for the event
- Collected response properties:
 - Possibly, when the event occurred (start date/time, end date/time or that the event is ongoing at the time the question was asked)
 - Possibly, severity

Details of the mappings of these questions and answers to the BRIDG Model and to SDTM, along with controlled terminology to be used for them are presented in the spreadsheet, “Medical History Metadata Display,” which is part of the “Asthma Metadata Displays” package of spreadsheets that accompanies this user’s guide.

2.2.1 Examples for Medical History of Special Interest

Example 1

Data are collected only about occurrence of specific asthma-related conditions. The data was collected in the following CDASH-compliant form:

Asthma-Related History

Has the subject had sinusitis?	Yes	No
Has the subject had atopic dermatitis?	Yes	No
Has the subject had eczema?	Yes	No
Has the subject had seasonal allergic rhinitis?	Yes	No
Has the subject had allergic conjunctivitis?	Yes	No

Row 1: The subject had a history of sinusitis. In this and following rows, the variable MHEVINTX is populated with “Time before query” to make the evaluation interval for the occurrence question explicit. Since the time before the query is the usual implicit evaluation interval for questions about occurrence for which an evaluation interval is not specified, the inclusion of MHEVINTX is not required.

Rows 2-3: The subject did not have a history of atopic dermatitis or eczema.

Row 4: The subject had a history of seasonal allergic rhinitis.

Row 5: The subject did not have a history of allergic conjunctivitis.

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Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHPRESP	MHOCCUR	MHDTC	MHEVINTX
1	ABC123	MH	456	1	Sinusitis	Sinusitis	Asthma Related	Y	Y	2013-05-24	Time before query
2	ABC123	MH	456	2	Atopic dermatitis	Dermatitis, atopic	Asthma Related	Y	N	2013-05-24	Time before query
3	ABC123	MH	456	3	Eczema	Eczema	Asthma Related	Y	N	2013-05-24	Time before query
4	ABC123	MH	456	4	Seasonal allergic rhinitis	Rhinitis, seasonal	Asthma Related	Y	Y	2013-05-24	Time before query
5	ABC123	MH	456	5	Allergic conjunctivitis	Conjunctivitis, allergic	Asthma Related	Y	N	2013-05-24	Time before query

Example 2

Data are collected about the occurrence of specific asthma-related conditions. If the event occurred, a start date is collected. The data was collected in the following CDASH-compliant form:

Asthma-Related History

- Has the subject had sinusitis? Yes No If yes, start date: _____
- Has the subject had atopic dermatitis? Yes No If yes, start date: _____
- Has the subject had eczema? Yes No If yes, start date: _____
- Has the subject had seasonal allergic rhinitis? Yes No If yes, start date: _____
- Has the subject had allergic conjunctivitis? Yes No If yes, start date: _____

Row 1: The subject had a history of sinusitis.

Rows 2-3: The subject did not have a history of atopic dermatitis or eczema.

Row 4: The subject had a history of seasonal allergic rhinitis.

Row 5: The subject did not have a history of allergic conjunctivitis.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHPRESP	MHOCCUR	MHDTC	MHSTDTC	MHEVINTX
1	ABC123	MH	456	1	Sinusitis	Sinusitis	Asthma Related	Y	Y	2013-05-24	2009	Time before query
2	ABC123	MH	456	1	Atopic dermatitis	Dermatitis, atopic	Asthma Related	Y	N	2013-05-24		Time before query
3	ABC123	MH	456	1	Eczema	Eczema	Asthma Related	Y	N	2013-05-24		Time before query
4	ABC123	MH	456	1	Seasonal allergic rhinitis	Rhinitis, seasonal	Asthma Related	Y	Y	2013-05-24	1999	Time before query
5	ABC123	MH	456	1	Allergic conjunctivitis	Conjunctivitis, allergic	Asthma Related	Y	N	2013-05-24		Time before query

2.3 Allergen Skin Tests

Allergen skin tests are conducted as a standard procedure to determine the allergens to which the subject shows an allergic reaction. They are generally conducted in conjunction with a physical examination and a discussion about past and current symptoms as a part of asthma diagnosis. It may be useful to document for a given clinical study how the atopic or allergic status was assessed (e.g. by skin testing, allergen-specific IgE levels, a combination of methods). Allergen skin tests involve the application of an allergen subcutaneously or topically. After a waiting period, the skin's reaction to the allergen is evaluated. There are three main types of allergy skin tests: the Skin Prick Test, the Intraepidermal Skin Test, and the Patch Test.

Skin prick test:

A small amount of substance is placed on the skin, most often on the forearm, upper arm, or back. Then, the skin is pricked so that allergen goes under the skin's surface. The health care provider closely watches the skin for swelling and redness or other signs of an allergic reaction. If the test is positive, the skin becomes itchy within a few minutes and then becomes red and swollen with a "wheal" in the center. The wheal has a raised edge, which slowly expands to reach its maximum size in about 15-20 minutes, clearing for most people within an hour. Two control samples are included to make sure that the test has worked. One of the controls will cause a reaction in all people (positive control), and the other should not cause a reaction in anyone (negative control). Using the Skin Prick Test, several allergens can be tested at the same time.

Data collected about skin prick test can include:

- Date/time of allergen test conducted
- Location of the test
- Tested allergen (or substance), including positive/negative control
- Any of the following types of result:
 - Size of the wheal
 - Semi-quantitative assessment of wheal size (e.g., 0 to 4+)
 - Flare (redness, swelling of the skin) to each allergen, usually as a semi-quantitative result (e.g., 0 to 4+)
 - Classification of the result as negative or positive based on a threshold wheal size
 - Semi-quantitative result (e.g., 0 to 4+) based on a combination of flare and wheal size
 - Skin index (SI) result based on the allergen wheal size divided by the size of histamine wheal size⁶

Intraepidermal skin test:

A small amount of allergen is injected into the skin. Then the health care provider watches for a reaction at the site. Whereas skin prick tests are often used for testing a battery of allergens, this test is more likely to be used to test for a specific allergic reaction, such as bee venom or penicillin. The skin reaction is characterized by a round raised area called a wheal, and a larger reddened area called a flare.

Data collected from the intraepidermal skin test can include:

- Date/time of allergen test conducted
- Location of the test
- Tested allergen (or substance), including positive/negative control

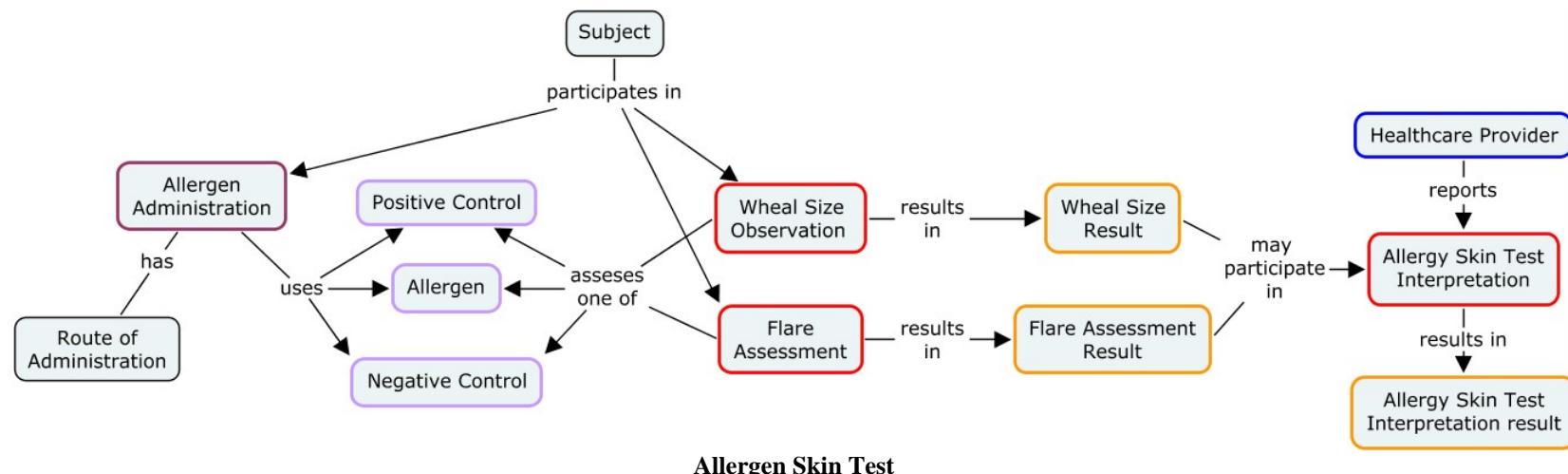
- Any of the following types of result:
 - Wheal diameter
 - Flare diameter
 - Semi-quantitative assessment of wheal size (e.g., 0 to 4+)
 - Flare (redness, swelling of the skin) to each allergen, usually as a semi-quantitative result (e.g., 0 to 4+)
 - Classification of the result as negative or positive based on a threshold wheal size
 - Semi-quantitative result (e.g., 0 to 4+) based on a combination of flare and wheal size

Patch test:

Patch testing is a method to diagnose the cause of skin reactions that occur after the substance is applied to the skin. Possible allergens are taped to the skin for 48 hours. Then, the patches are removed and the health care provider will examine the area in 72 - 96 hours to determine whether any red inflamed areas ("wheals") have appeared.

Data collected from the patch test can include:

- Date/Time of allergen test conducted
- Location of the test
- Tested allergen (or substance), including positive control
- Any of the following types of result:
 - Size of the wheel
 - Flare to each allergen
 - Interpretation result



This diagram displays the administration of three test substances: an allergen, a positive control, and a negative control (lavender boxes) to sites on the skin. The reactions at these sites are observed via a measurement and an assessment, which an assessor then evaluates to reach an interpretation.

Wheal size observation:

Data can include:

- Pre-specified question properties:
 - Name of the test
 - Location of the test (the substance administration site)
 - Object of the test (the substance/allergen test, i.e., allergen, positive control, negative control)
- Collected question properties:
 - The subject of the question (the study subject)
 - Time of the question
 - Possibly, that the question was not asked, and why not
- Collected response properties:
 - The response to the question, e.g., size of the wheal, semi-quantitative assessment of wheal size (e.g., 0 to 4+)
 - Possibly, that although the question was asked, an answer was not recorded, and why not

Flare assessment:

Data can include:

- Pre-specified question properties:
 - Name of the test
 - Location of the test (the substance administration site)
 - Object of the test (the substance/allergen test, i.e., allergen, positive control, negative control)
- Collected question properties:
 - The subject of the question (the study subject)
 - Time of the question
 - Possibly, that the question was not asked, and why not
- Collected response properties:
 - The response to the question, e.g., the flare (redness, swelling of the skin) to each allergen, usually as a semi-quantitative
 - Possibly, that although the question was asked, an answer was not recorded, and why not

Allergen skin test interpretation:

Data can include:

- Pre-specified assessment properties:
 - Name of the interpretation
 - Object of the interpretation (the substance/allergen test, i.e., allergen, positive control, negative control)
- Collected assessment properties:
 - The subject of the assessment (the study subject)
 - Time of assessment
 - Possibly, that the assessment was not made, and why not

- Collected response properties:
 - The interpretation result, e.g., classification of the result as negative or positive based on a threshold wheal size, semi-quantitative result (e.g., 0 to 4+) based on a combination of flare and wheal size
 - Possibly, that although the assessment was made, an answer was not recorded, and why not

2.3.1 Examples for Allergen Skin Tests

These examples use the Skin Response (SR) domain, which is not final at the time of publication of this document.

Example 1

In this example, the subject is dosed with a positive (histamine) control, negative control, and allergens at screening, which the sponsor has designated “VISIT 1”. This case differs from the example shown in the diagram above: both wheal and flare were measured, and no interpretation of combined wheal and flare was performed.

Row 1-6: Show wheal diameter responses associated with the administration of a histamine (positive control), negative control, and specific allergens.

Rows 7-12: Show testing for wheal flare response.

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU	SRLOC	VISITNUM	VISIT
1	ABC-001	SR	ABC-001-1234	1	WHEALDIA	Wheal Diameter	Histamine Control	10	mm	10	10	mm	FOREARM	1	VISIT 1
2	ABC-001	SR	ABC-001-1234	2	WHEALDIA	Wheal Diameter	Negative Control	0	mm	0	0	mm	FOREARM	1	VISIT 1
3	ABC-001	SR	ABC-001-1234	3	WHEALDIA	Wheal Diameter	Grass Mix	5	mm	5	5	mm	FOREARM	1	VISIT 1
4	ABC-001	SR	ABC-001-1234	4	WHEALDIA	Wheal Diameter	Cat Dander	5	mm	5	5	mm	FOREARM	1	VISIT 1
5	ABC-001	SR	ABC-001-1234	5	WHEALDIA	Wheal Diameter	Cockroach	6	mm	6	6	mm	FOREARM	1	VISIT 1
6	ABC-001	SR	ABC-001-1234	6	WHEALDIA	Wheal Diameter	Dust Mite	8	mm	8	8	mm	FOREARM	1	VISIT 1
7	ABC-001	SR	ABC-001-1234	7	WHEALFL	Wheal Flare	Histamine Control	25	mm	25	25	mm	FOREARM	1	VISIT 1
8	ABC-001	SR	ABC-001-1234	8	WHEALFL	Wheal Flare	Negative Control	3	mm	24	24	mm	FOREARM	1	VISIT 1
9	ABC-001	SR	ABC-001-1234	9	WHEALFL	Wheal Flare	Grass Mix	25	mm	25	25	mm	FOREARM	1	VISIT 1
10	ABC-001	SR	ABC-001-1234	10	WHEALFL	Wheal Flare	Cat Dander	25	mm	25	25	mm	FOREARM	1	VISIT 1
11	ABC-001	SR	ABC-001-1234	11	WHEALFL	Wheal Flare	Cockroach	20	mm	20	20	mm	FOREARM	1	VISIT 1
12	ABC-001	SR	ABC-001-1234	12	WHEALFL	Wheal Flare	Dust Mite	21	mm	21	21	mm	FOREARM	1	VISIT 1

Example 2

In this example, the wheal diameter for each allergen was assessed as a positive or negative response for each allergen tested.

Row 1-6: Show the classification of the wheal diameter responses for specific allergens.

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU	VISITNUM	VISIT
1	ABC-001	SR	ABC-001-1234	1	WHEALRSP	Wheal Response	CAT DANDER	POSITIVE		POSITIVE			1	VISIT 1
2	ABC-001	SR	ABC-001-1234	2	WHEALRSP	Wheal Response	COCKROACH	POSITIVE		POSITIVE			1	VISIT 1
3	ABC-001	SR	ABC-001-1234	3	WHEALRSP	Wheal Response	DUST MITE	NEGATIVE		NEGATIVE			1	VISIT 1
4	ABC-001	SR	ABC-001-1234	4	WHEALRSP	Wheal Response	GRASS MIX	POSITIVE		POSITIVE			1	VISIT 1
5	ABC-001	SR	ABC-001-1234	5	WHEALRSP	Wheal Response	MOLD	NEGATIVE		NEGATIVE			1	VISIT 1
6	ABC-001	SR	ABC-001-1234	6	WHEALRSP	Wheal Response	TREE MIX	NEGATIVE		NEGATIVE			1	VISIT 1

3 Disease Assessments

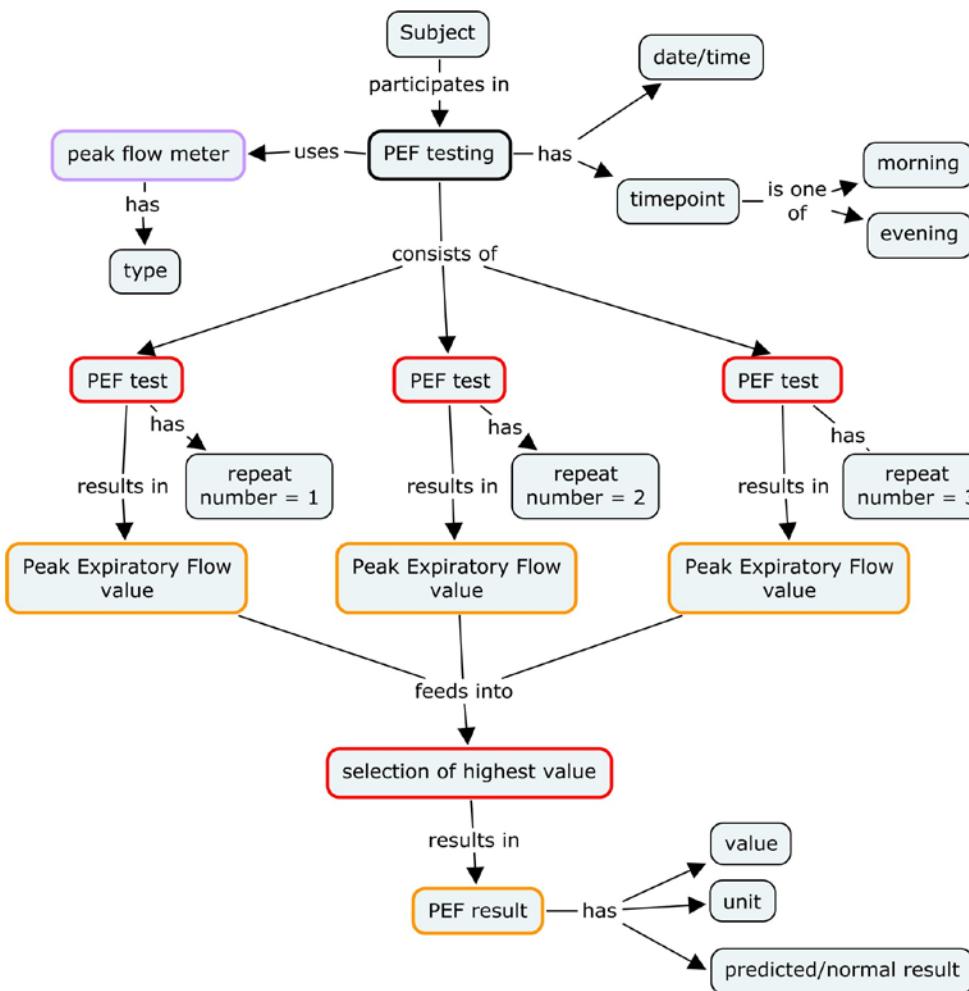
3.1 Pulmonary Physiology

Pulmonary function tests (PFTs) are objective measures of lung function. PFTs may be used to support a diagnosis of lung disease and/or to quantitate the impairment in patients with known lung disease. Some PFTs can be performed at home, such as with a peak flow meter (see [Section 3.1.1](#)). However, they are not as accurate as PFTs performed in the clinic with specialized equipment and coaching of the patient by a trained PFT technician, such as spirometry (see [Section 3.1.2](#)). Neither peak flow meters nor spiroometers can measure the volume of air that remains in the lungs after a full exhalation and cannot provide measures of gas exchange. For these and other pulmonary physiology measures not covered by peak flow measurements or spirometry, see [Section 3.1.3](#).

3.1.1 Peak Flow Measurements

Peak expiratory flow (PEF) is a measure of maximum expiratory flow rate and is used as an indicator of the degree of airway bronchial obstruction in asthma⁷. PEF is considered a supplemental outcome in clinical asthma research. PEF can be measured with a simple device called a peak flow meter, which is often used for at-home measurements. This device is easier to use than a spirorometer and provides a measure of airflow rate through the large airways. It is used primarily for daily home monitoring of lung function, usually in the morning and in the evening. Subjects should be instructed to take peak flow measurements before taking their bronchodilator medication to reduce variability among measurements. To measure PEF, the subject is required to inhale deeply and then exhale through the mouthpiece of the peak flow meter as hard and as fast as possible.

PEF values obtained by peak flow meter should be analyzed separately from values obtained from spirometry. Some devices can also measure the forced expiratory volume at 1 second (FEV1), but these values are less reliable than those obtained by clinic spirometry since the effort is not being coached. For FEV1 as measured by a spirometer, see [Section 3.1.2](#).



Measurement of Peak Flow

This diagram includes three repeated tests (the red boxes) accompanied with their results (the orange boxes).

PEF test (for each effort):

The relevant data includes the topic (the name of the test) and its response.

- Pre-specified test properties:
 - The device type used to perform the test
- Collected test properties:

- The subject of the test (the study subject)
- When the test was performed (date/time and relative study timing)
- A sequence number to distinguish between efforts
- Possibly that the test was not performed, and why not
- Possibly, properties of the device used in testing
- Collected result properties:
 - The result of the test
 - The units associated with the result of the test
 - Possibly, that although the test was performed, the result was not recorded, and why not

Selection of highest value:

The relevant data includes the topic (the name of the test) and its response.

- Pre-specified test properties:
 - The device type used to perform the test
- Collected test properties:
 - The subject of the test (the study subject)
 - When the test was performed (date/time and relative study timing)
 - Possibly, that the test was not performed, and why not
 - Possibly, properties of the device used in testing
- Collected result properties:
 - The result of the test
 - The units associated with the result of the test
 - Possibly, that although the test was performed, the result was not recorded, and why not

3.1.1.1 Sample Peak Flow Meter Report

Peak flow can be measured to monitor patient lung functions between clinic visits and data from the peak flow meter may be integrated with an e-diary device, allowing for data transmission for centralized reporting of both PEF and e-diary data as shown in the report below.

Visit Number:	V2	Date of Visit:	31OCT2012	Site #:	123456	SYS#:	800018-021384-000003																						
Am Serial number:	010290	Patient Number:	4410003	Date of Birth:	03MAR1980	Height:	181 cm																						
Age:	32 years	Gender:	Male	Race:	Caucasian																								
ALERT: >= 12 puffs/day of rescue medication on > 2 consecutive days																													
Patient did not complete >= 80% AM3 sessions.																													
No PEF deterioration alert since last Download.																													
Compliance with use of AM3: 43%																													
Randomisation Compliance with use of AM3 at Visit 2: 41%				Study Medication Compliance: n.a																									
Mean morning PEF: 467.7[L/min]																													
PEF Stability Limit: 327.4[L/min]																													
	Morning Measurements								Evening Measurements																				
Date	Time	MQ1	MQ2	MQ3	MQ4	AL1	Time	PEF1	PEF2	PEF3	FEV1	FEV2	FEV3	AL1	AL2	Time	EQ1	EQ2	EQ3	AL1	Time	PEF1	PEF2	PEF3	FEV1	FEV2	FEV3	AL1	AL2
19Oct2012																													
20Oct2012	06:10	1	6	1			06:10	439	406	444	3.964	2.93	3.04			18:13	6	1			18:13	529	430	470	4.20	2.79	3.31		
21Oct2012	06:13	1	12	1			06:13	388	418	439	2.844	2.89	3.01																
22Oct2012	06:14	1	12	1	X		06:14	384	418	529	2.745	2.66	3.86																
23Oct2012	06:16	1	4	1			06:16	350	406	422	2.77	2.74	3.05																
24Oct2012	06:17	1	4	1			06:17	516	464	418	3.894	3.34	2.80																
25Oct2012	06:19	1	3	1			06:19	444	426	410	3.175	3.06	2.74																
26Oct2012	06:19	1	4	1			06:19	430	480	347	2.697	3.87	2.48																
27Oct2012	06:20	1	4	1			06:20	510	470	464	3.725	3.25	3.17																
28Oct2012	06:20	1	4	1			06:20	426	392	486	3.174	2.81	3.34																
29Oct2012	06:20	1	3	1			06:20	505	458	464	4.199	3.11	3.44																
30Oct2012	06:20	1	3	1			06:20	368	448	564	2.864	2.99	4.56																
31Oct2012																													

Legend:

- MQ1 Did you wake up during the night due to your asthma? (1=Did not wake up, 2=Woke up once, 3=Woke up 2-5 times, 4=Woke up more than 5 times, 5=Was awake all night)
- MQ2 How many puffs of rescue medication did you use during the last 12 hours?
- MQ3 Did you take your inhaled corticosteroid medication yesterday evening? (1=Yes, 0=No)
- MQ4 Did you take your study medication yesterday evening from the EVENING inhaler? (1=Yes, 0=No)
- EQ1 How many puffs of rescue medication did you use during the last 12 hours?
- EQ2 Did you take your inhaled corticosteroid medication this morning? (1=Yes, 0=No)
- EQ3 Did you take your study medication this morning from the MORNING inhaler? (1=Yes, 0=No)
- V Data time stamped with 'V' acquired in 'Vacation mode'
- Alert PEF deterioration: marked if PEF falls below PEF Stability Limit for 2 or more days
- Alert RM (Rescue Medication): marked if 12 or more inhalations of rescue medication per day for more than 2 consecutive days.

Figure 3.1.1.1: Sample Peak Flow Meter Report*

* Report courtesy ERT (eResearchTechnology, Inc.).

3.1.2 Spirometry

Spirometry is the most important type of PFT for asthma clinical trials because it measures the flow rates and volumes of both exhaled and inhaled air, which are considered to be core pulmonary physiological outcomes for describing a population with asthma and assessing response to treatment. The spirometer, which can be relatively small and portable, displays numerical results for the relevant volumes and flow rates and may also produce detailed graphical displays of each maneuver. Each device will have slightly different specifications and the displays can be customized for each clinical trial. Sponsors may choose to provide spirometers to the sites to support standardization of the spirometry assessments, or sites may use their own spirometers if the equipment conforms to standards (e.g., the ATS standards). Spirometry measures are highly repeatable within a single testing session. To minimize intersession variability, spirometers should be calibrated each day before use, using a certified calibration syringe, and it is recommended that the same spirometer be used for all measurements for an individual patient. Serial measurements should be done around the same time of day (± 2 hours) due to the diurnal variability in lung function. In addition, in many asthma studies, it is specified that bronchodilators should be withheld for a specified time period prior to testing (e.g., inhaled long-acting β -agonist (LABA) and anticholinergic medications for 6-24 hours, inhaled short-acting β -agonist (SABA) for 4-6 hours⁷). The actual time when bronchodilators were taken before spirometry testing may be recorded, or simply confirmation recorded that bronchodilators were withheld for the prespecified time period. Spirometers may include software that can "lock" the device if prespecified washout criteria have not been met. These may be "hard locks", where spirometry measurements cannot be made, or "soft locks" where the warning can be overridden.

The spirometry measurements relevant to asthma clinical trials are obtained during a forceful exhalation. It is important to note that spirometry requires effort. This is an effort-dependent test that requires not only significant effort by the patient but also high-quality coaching by the study coordinator or PFT technician to obtain consistent results. Following the ATS/ERS guidelines on standardization of lung function testing⁸, criteria have been established for acceptability and repeatability of efforts (see Steps 7 and 8 below).

Normal values for spirometry results vary from person to person according to gender, age, height, and race. The patient's result is reported as a percent predicted of the expected value generated from a reference equation that incorporates age, gender, and height. Race has been included in some equations. Reference equations are generated from large data sets of representative healthy subjects, and the preferred reference equations vary globally, with the NHANES equations being one of the most commonly used. The clinical trial PFT manual should specify which reference equation will be used, and the study spirometer is set up to calculate the percent predicted values based on the reference equation selected.

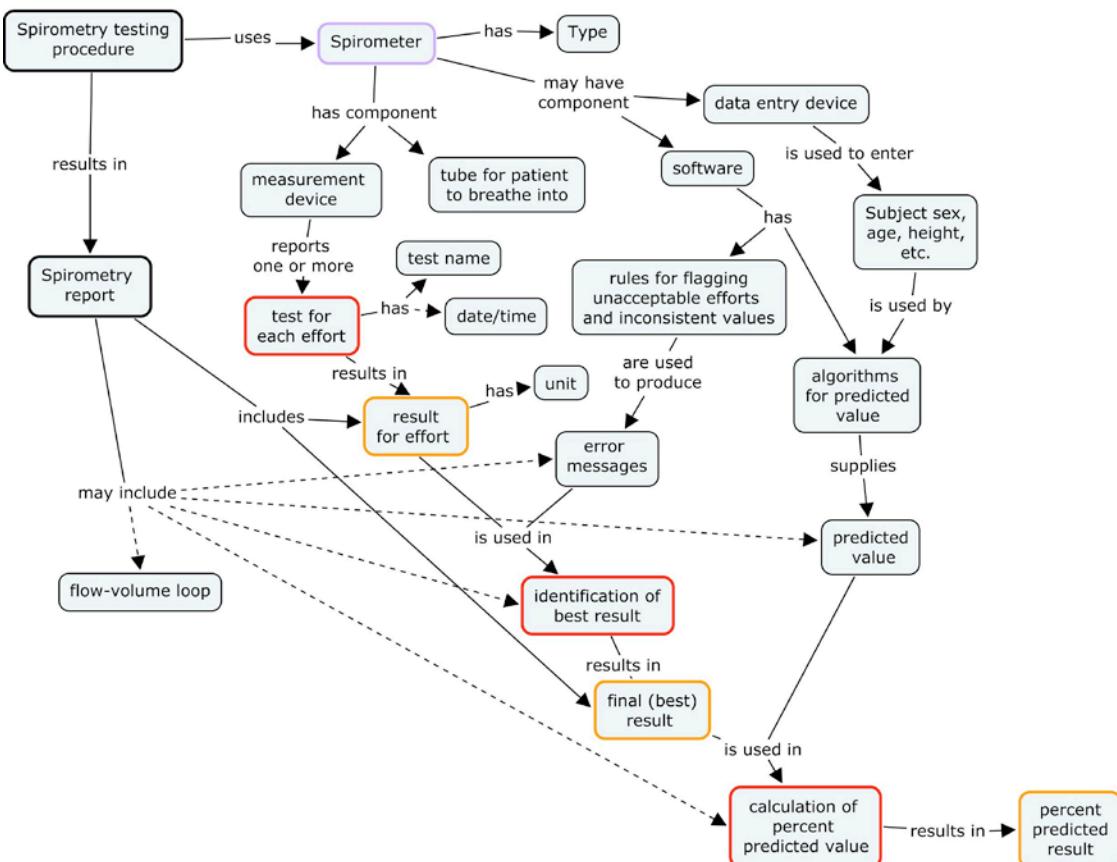
Spirometry procedure:

0. The study coordinator records the patient's age, sex, race (if required), and height at the first visit. These values are needed to calculate predicted values and are usually "frozen" at study entry.
 1. The patient is instructed to sit upright and may optionally apply a nose clip to prevent breathing through the nose.
 2. The patient places the mouthpiece in the mouth with lips closed tightly around the mouthpiece.
 3. The patient breathes normally for a short time.
 4. Forced Vital Capacity Maneuver (Effort):
 - a. The patient inhales as deeply as possible then exhales as fast and forcefully as possible through the mouthpiece and continues to exhale for as long as possible. (This maneuver is for measurement of FVC, *Forced Vital Capacity*, FEV1, *Forced expiratory volume in 1 sec* and PEF, *Peak expiratory flow*.)
 - b. The exhalation is then followed by a full inhalation.
 5. The patient then rests and breaths normally off the mouthpiece.
 6. Repeat Steps 2-5 up to 8 times to achieve repeatability.

7. The study coordinator checks each effort for acceptability. An acceptable effort is one with a good start, a satisfactory duration of exhalation, and without artifacts such as coughs or technical problems.
8. The study coordinator checks maneuver efforts for repeatability. The two largest FVC values must be within 150 ml of each other, and the two largest FEV1 values must be within 150 ml of each other⁹. For patients with a FVC value of < 1.0L, the values must be within 100 ml of each other. If results are not consistent, repeat Steps 2-5 again, but do not exceed eight forced spirometry efforts.
9. The highest value from an acceptable effort that meets the repeatability criteria is taken as the test result for each parameter. The highest value for each parameter may be taken from a different effort i.e. the best FEV1 value could come from one effort and the best FVC value from another effort, as long as the efforts meet the acceptability and repeatability criteria.

The spirometry report will include:

- Test results from individual efforts, from Step 4 above
- Graphical depictions called flow-volume loop diagrams for each effort in Step 4
- Results from the “best” effort, from Step 9
- Predicted values for each test, based on the subject’s age, sex, height, and sometimes race
- Percent predicted values for each test, defined as $(\text{result}/\text{predicted value}) \times 100$



Process behind a Spirometry Report

Measurements are repeated for at least three efforts, and the highest result from the repetitions is chosen as the “best” value. If a repetition is flagged as unacceptable, it is not considered in choosing the best result. If repetitions do not meet criteria for repeatability, results are reported with an error flag.

This diagram includes three tests (the red boxes) relating to a single research concept and the associated results (the orange boxes). Multiple research concepts may be investigated during a spirometry testing procedure.

Test for each effort:

The relevant data includes the topic (the name of the test) and its response. In this example, the topic could be Forced Expiratory Volume in One Second (FEV1). The data to be collected for this type of research concept includes data about the test and the result.

- Pre-specified test properties:
 - The method used to perform the test (device type)
- Collected test properties:
 - The subject of the test (the study subject)
 - When the test was performed (date/time and relative study timing)
 - A sequence number to distinguish between efforts
 - Possibly that the test was not performed, and why not
 - Possibly properties of the device used in testing
 - Possibly timing of test relative to last bronchodilator use
- Collected result properties:
 - The result of the test
 - The units associated with the result of the test
 - An indicator that the result should be considered as a baseline value
 - Possibly, that although the test was performed, the result was not acceptable, and why not
 - Possibly, that although the test was performed, the result was not recorded, and why not
- Reference results:
 - The predicted value of the test
 - The algorithm used in calculating the predicted value

Identification of best result:

The relevant data includes the topic (the name of the test) and its response as well as a reference result value. In this example, the topic could be Forced Expiratory Volume in One Second (FEV1). The data to be collected for this type of research concept includes data about the test and the result.

- Pre-specified test properties:
 - The method used to perform the test
- Collected test properties:
 - The subject of the test (the study subject)
 - When the test was performed (date/time and relative study timing)
 - Possibly, that the test was not performed, and why not
 - Possibly, properties of the device functioning as the assessor
- Collected result properties:
 - The result of the test
 - The units associated with the result of the test
 - An indicator that the result should be considered as a baseline value
 - Possibly, that although the test was performed, the individual results were not consistent, and why not
 - Possibly, that although the test was performed, the result was not recorded, and why not

- Reference results:
 - The predicted value of the test
 - The algorithm used in calculating the predicted value

Calculation of percent predicted value:

The data to be collected for this type of research concept includes data about the test and the result.

- Pre-specified test properties:
 - The method used to perform the test
 - An algorithm describing how the test results are to be derived, i.e., as the ratio of the test value to the predicted value, expressed either as a proportion or as a percent
 - Possibly, properties of the device functioning as the assessor
- Collected test properties:
 - The subject of the test (the subject)
 - When the test was performed (date/time and relative study timing)
 - Possibly, that the test was not performed, and why not
- Collected result properties:
 - The result of the test
 - The units associated with the result of the test
 - An indicator that the result should be considered as a baseline value
 - Possibly, that although the test was performed, the result was not recorded, and why not

3.1.2.1 Spirometry Test Results

Spirometry test results are used to assess disease state, with interpretation of the results depending on a subject's age, sex, height, and sometimes race. For this reason, predicted normal values for combinations of these factors have been established for spirometry tests, and results are routinely normalized by dividing by the subject's predicted normal value¹⁰. The result is a percent predicted value of the absolute value.

The most commonly measured spirometry parameters measured in asthma studies are described in the diagram and table below. The diagram shows a flow-volume loop and a volume-time curve, both annotated to show spirometry results derived from them. In the flow-volume loop, volume is shown on the x-axis, so volume measurements such as FVC are measured horizontally. Flow is shown on the y-axis, with negative values during inspiration and positive values during expiration, so peak expiratory flow is measured vertically at the highest point of the loop. FEV₁ is derived from the volume-time curve.

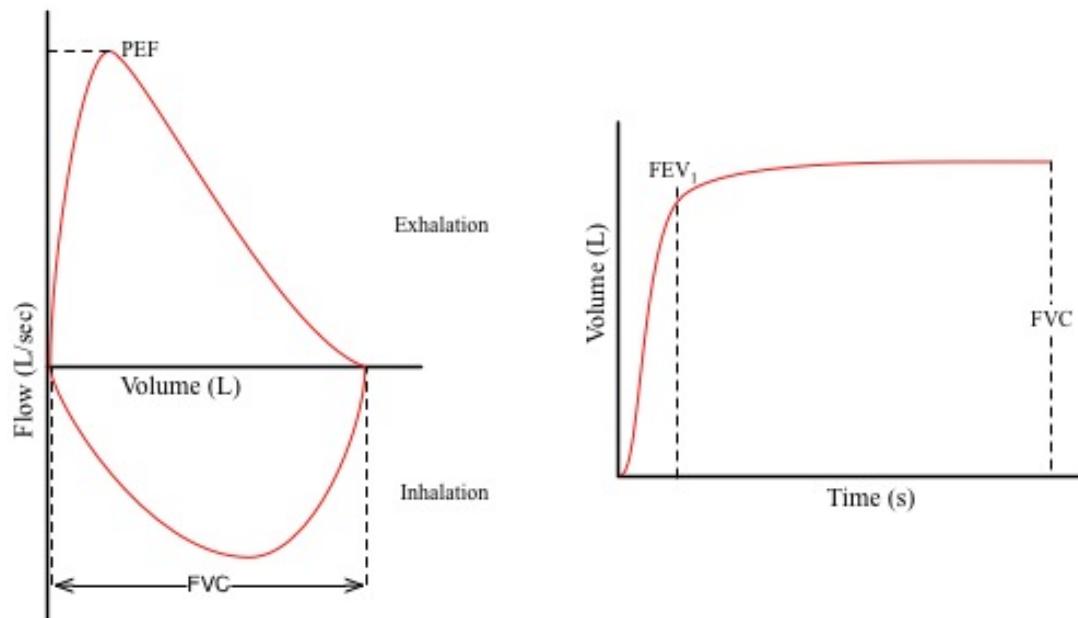


Figure 3.1.2.1-1: Flow-Volume Loop and Volume-Time Curve

Note that the abbreviations and test names given in the two tables in this section are those commonly used in clinical practice. (“Percent predicted” tests do not have such commonly used abbreviations.) These abbreviations are not necessarily the TESTCD and TEST values in CDISC Controlled Terminology. Similarly, the definitions describe these tests in the context of asthma, and are not the Controlled Terminology definitions. When constructing standard datasets, construct the current version of CDISC Controlled Terminology (available at: <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>) for values of TEST and TESTCD.

Common Test Abbreviation	Test Name	Definition	Units
FVC	Forced vital capacity	The volume of air expired over the course of a forced, maximal exhalation after a full inhalation. The maximum amount of air a person can expel forcibly from the lungs after a maximum inhalation. It is equal to the sum of inspiratory reserve volume, tidal volume, and expiratory reserve volume.	L, mL
	Percent predicted FVC	(FVC value divided by the subject's predicted normal value)*100	
FEV1	Forced expiratory volume in 1 second	The volume of air that is exhaled in the first second of a forced spirometry test (coached for maximum effort)	L, mL
	Percent predicted FEV1	(FEV1 value divided by the subject's predicted normal value)*100	
FEV1/FVC	FEV1/FVC ratio or percentage	The value provides a measure of the proportion of total FVC that is expelled during the first second of a forced exhalation. This ratio is a good index of airflow obstruction in asthma and COPD	Ratio, %
	FEF25-75	Forced expiratory flow at 25%-75% of vital capacity, also called maximal mid expiratory flow	
	Percent predicted FEF25-75	(FEF25-75 value divided by the subject's predicted normal value)*100	
PEF	Peak expiratory flow	The maximal flow rate achieved during a maximally forced exhalation	L/sec L/min
	Percent predicted PEF	(PEF value divided by the subject's predicted normal value)*100	

The spirometry values used for data analysis are the values selected from the best effort from each spirometry test session, as described in [Section 3.1.2](#). Selecting the best spirometry value requires an experienced study coordinator or PFT technician, even if the criteria are clearly outlined in the clinical trial PFT manual. To ensure collection of reliable data, many asthma clinical trials choose to perform over-reading of the spirometer sessions. Over-readers are PFT experts (usually at a centralized location) who review and interpret spirometry sessions for the study. Results are usually communicated to the sponsor and the sites. The site may be informed that the best effort has been changed, or may be given the option to accept or reject the change, with appropriate documentation of any changes. For studies with over-reading, two “best” results may be available for each test session for each variable (i.e. if the site has the option to reject the change, there would be a site-selected “best” FEV1 and an over-reader-selected “best” FEV1).

For data analysis, the over-reader “best” values are usually preferred but all results should be available for review. Implementers should consult with their reviewing division whether to submit individual results or just the “best” values.

The following parameters may also be measured by spirometry, and may be measured in COPD studies, but are less commonly measured in asthma studies.

Common Test Abbreviation	Test Name	Definition	Units
FEV6	Forced expiratory volume in 6 sec	Volume of air that a subject with fully inflated lungs can forcibly breathe out in the first six seconds (coached for maximum effort). This is a surrogate for FVC.	L, mL
FIV1	Forced inspiratory volume in 1 sec	Volume of air that a subject can breathe in during the first second (coached for maximum effort) after a complete exhalation.	L, mL
FIFx	Forced Inspiratory Flow	Forced inspiratory flow at a point or for a portion of the FVC curve, where x describes the point or the portion of FVC e.g. FIF50 (where 50 is the percentage remaining of the FVC) or FIFmax.	L/sec

Common Test Abbreviation	Test Name	Definition	Units
TV	Tidal volume	The volume of air moved into and out of the lungs during quiet breathing.	L, mL
IC	Inspiratory capacity	The sum of IRV and TV – the volume that can be inhaled from the end of tidal exhalation.	L, mL
ERV	Expiratory reserve volume	The maximal volume of air that can be exhaled from the lungs from the end-expiratory position.	L, mL
IRV	Inspiratory reserve volume	The maximal volume of air that can be inhaled from the tidal end-inspiratory position.	L, mL
SVC	Slow vital capacity	The maximal volume of air that can be exhaled slowly after slow maximal inspiration.	L, mL

Several of these parameters are described in the diagram below. Tidal volume (TV) is measured during quiet breathing at rest, while expiratory reserve volume (ERV) and inspiratory reserved volume (IRV) are measured during a forced maneuver. Since residual volume (RV) is the volume of the lung after maximal exhalation, its measurement requires the use of a whole-body plethysmograph, rather than an external spirometer (see [Section 3.1.3](#)).

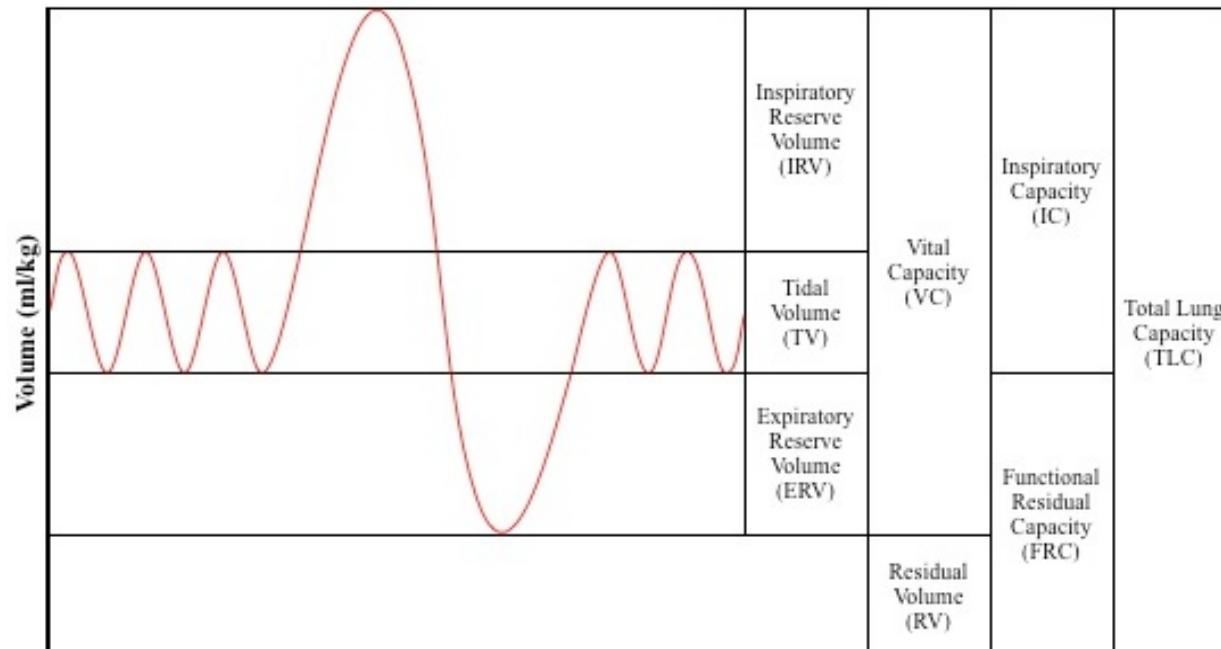


Figure 3.1.2.1-2: Lung Volumes

3.1.2.2 Sample Spirometry Reports

This section shows two sample spirometry reports, with somewhat different formats.

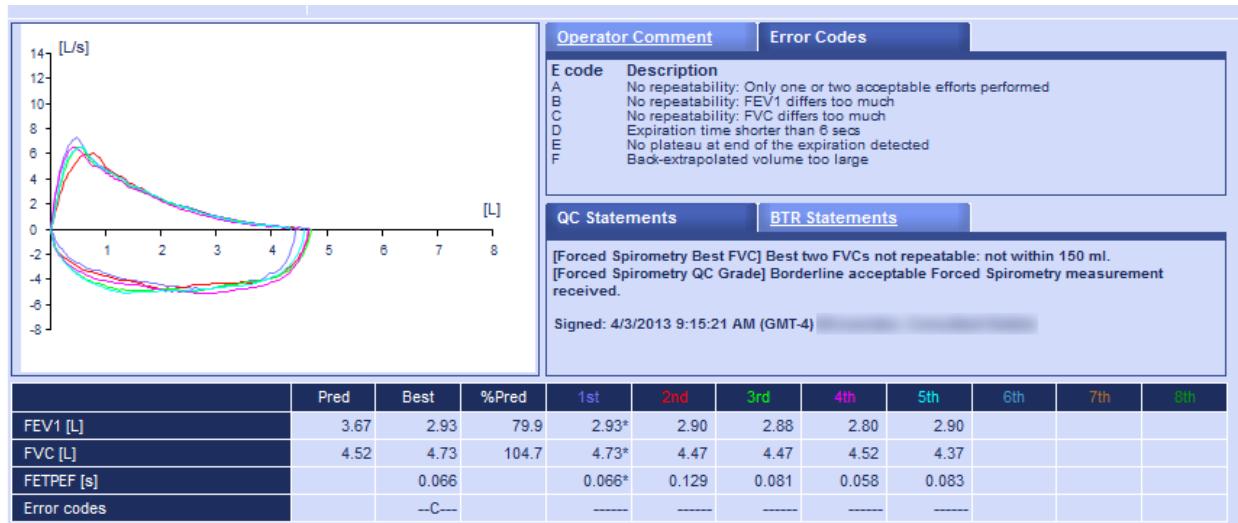


Figure 3.1.2.2-1: Sample Spirometry Report 1[†]

This output includes:

- The *flow-volume loop*, in the upper left of the sample above, graphically depicts the flow rate on the Y-axis and the total volume inspired or expired on the X-axis. Results are derived from measurements of the loop as depicted in the table.
- The area above the X-axis displays the exhalation and the area below the X-axis displays the inhalation
- Columns labeled ‘1st’, ‘2nd’, ‘3rd’, etc., display absolute results (liters, liters per second, %) for each spirometry effort. Efforts should be repeated until three acceptable readings are obtained for each test; however, testing should not exceed eight efforts (see detailed description of the spirometry process in [Section 3.1.2](#)).
- The column labeled ‘Best’ displays the best result for the measured efforts. Best results for different tests may be derived from different efforts.
- The column labeled ‘Pred’ displays the predicted result for patient based on the reference equation selected for the study
- The column labeled ‘%Pred’ displays the best result as a percentage of the predicted result
- Error codes (key in the top right corner) are automatically produced based on quality criteria for a ‘good effort’ to flag unusable results. In this example, individual efforts are acceptable, but there are issues with consistency between efforts, as indicated by the code in the “Best” column. The “QC Statements” give more detail on the consistency criteria not met.

[†] Screenshot provided by ERT (eResearchTechnology, Inc.).

Site #: 123456		Date of Visit: 27FEB2013		Date of Printing: 08MAR2013 16:36:53	
SYS#	800018-022059-000001	Patient Number	T4411001	Gender	Female
Height	178 cm	Date of Birth	06JUN1956	Race	Caucasian
Age	56 years				

Post FEV1 measurement is missing.

Result not available.

Pre FEV1 must be between >= 60% and <= 90% of the predicted value.

Medication Washout Compliance: Yes

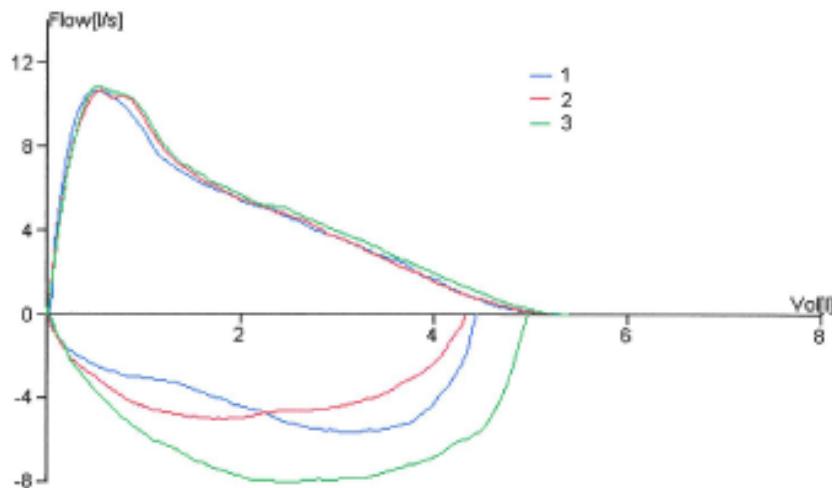
Pre PFT 27FEB2013 16:58:31 - Best FEV1 at 17:03:25

Operator: KOA

Parameter	Pred	1st	2nd	3rd	4th	5th	6th	7th	8th	*Best	%Pred
FEV1 [L]	3.03	4.23	4.22	*4.36						4.36	144
FVC [L]	3.54	5.30	5.34	*5.39						5.39	152
FEV1/FVC [%]		80	79	*81						81	
PEF [L/min]	420	640	643	*649						649	155

E code

Pre PFT 27FEB2013 16:58:31 - Best FEV1 at 17:03:25



Ambient data: 27FEB2013 16:53:46, 23 °C, 999 hPa, 45% Calibration: 27FEB2013 16:54:31, KIN 0.98, KEX 0.99

E code Description:

- A No repeatability, Less than 3 accepted forced measurements
- B FEV1 repeatability is unacceptable
- C FVC repeatability is unacceptable
- D Expiration time was too short(< 6 sec)
- E No plateau was detected at the end of the expiration
- F Back extrapolation volume was too large
- G PEF repeatability is unacceptable
- H Late peak flow detected
- I Coughing was detected in the first part of the expiration

Figure 3.1.2.2-2: Sample Spirometry Report 2*

* Printout provided by ERT (eResearchTechnology, Inc.).

This output includes additional information including the following:

- Subject and characteristics relevant for identifying predicted normal values
- Study context, including:
 - Subject identifier
 - Confirmation that the patient adhered to medication washout requirements
 - Timing relative to other things such as a 'challenge' or bronchodilator use can be critical information)
- Other information that may be relevant to the interpretation of the results, including:
 - Time of day of the measurements
 - Ambient data
 - Calibration of the instrument
 - Operator initials

3.1.2.3 Interpretation of Spirometry Results

The interpretation of spirometry results is usually based on percent predicted results, since these have been normalized to take into account the subject's age, sex, height, and other relevant characteristics. It is important to note that a decline in FEV1 can also occur in restrictive disease. The FEV1/FVC ratio and the shape of the flow volume loop should be reviewed to determine if the decline is obstructive or restrictive.

3.1.3 Other Pulmonary Physiology Measures

Other pulmonary physiology measures may be collected during asthma clinical trials, such as lung volumes and other parameters measured by whole-body plethysmography (e.g., residual volume, total lung capacity, functional residual capacity, vital capacity, specific airway resistance, and conductance). Guidelines on the standardization of lung function testing have been published⁹. Gas exchange can be measured by the diffusing capacity for carbon dioxide (DLCO) test, which measures the integrity and surface area of the alveolar-capillary membrane of the lung. Guidelines for measuring DLCO have been published¹¹. These tests are considered in the Asthma Outcomes report to be supplemental for characterizing study populations and as endpoints in asthma clinical trials⁷ and are not described further in this user guide.

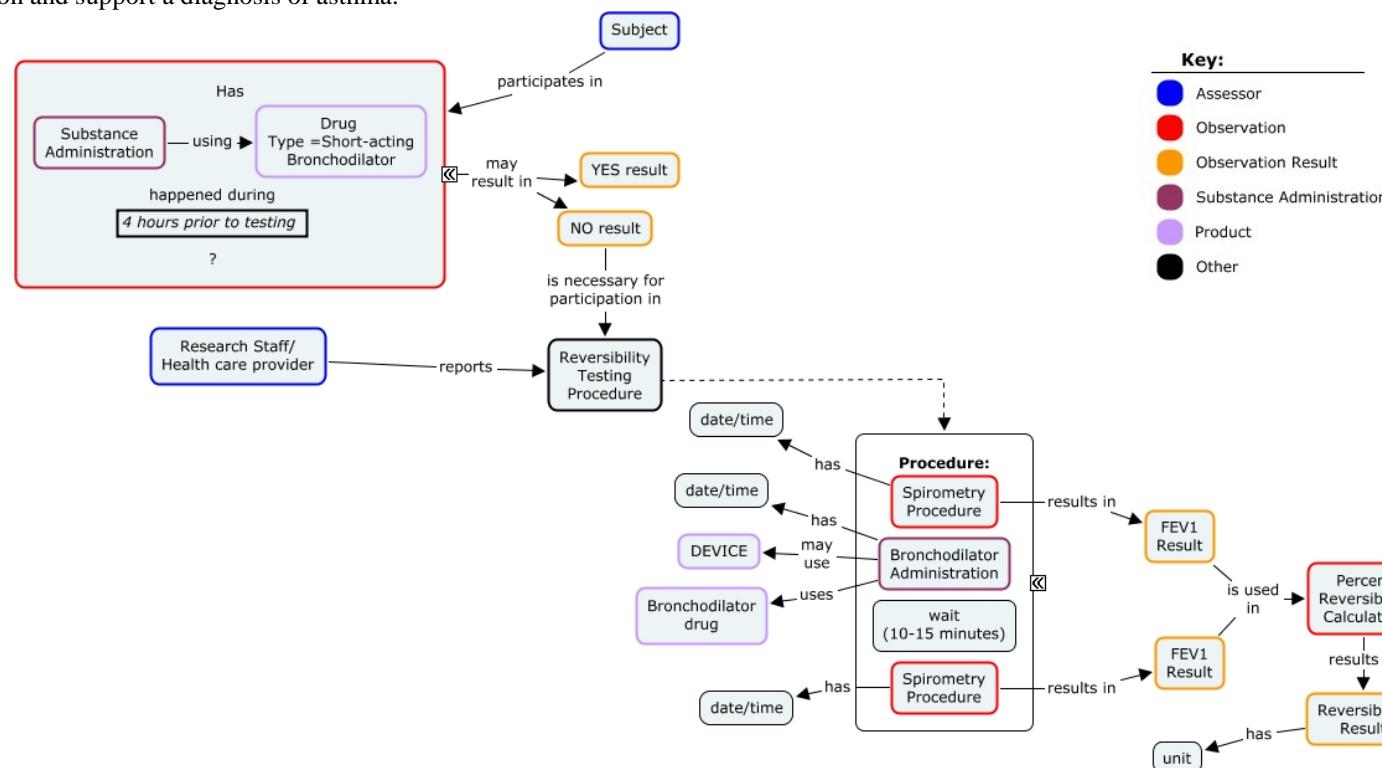
3.1.4 Reversibility (Bronchodilator Response)

Bronchodilator reversibility testing is undertaken to determine whether a patient shows evidence of reversible airflow limitation, and is a measure of the magnitude of airway smooth-muscle relaxation⁷. It is considered a core measure for describing an asthma population prior to entering a clinical trial. Since asthma is characterized as being a reversible obstructive airways disease, reversibility testing is an important part of the initial diagnosis of the disease. Obstructive lung diseases include conditions that involve increased resistance and obstruction of the airways (e.g., asthma and COPD), especially during expiration. Restrictive lung diseases are characterized by reduced total lung volumes, either due to lung diseases or due to factors external to the lungs (e.g. chest wall abnormalities or neuromuscular weakness) Since bronchodilator reversibility is diminished in patients with well-controlled asthma, as well as those with predominant inflammatory narrowing or remodeling of the airways, bronchodilator reversibility is not used to define asthma severity. Reversibility testing may also be used for assessing response to treatment.

Reversibility is assessed by performing spirometry (usually measuring FEV1), then dosing with a short-acting bronchodilator, following standard guidelines such as the GINA guidelines, waiting a specified period (usually 10-30 minutes), then repeating the pulmonary function test⁹.

1. Confirm subject has withheld bronchodilators for an appropriate period (inhaled long-acting β -agonist (LABA) and anticholinergic medications for 6-24 hours, inhaled short-acting β -agonist (SABA) for 4-6 hours) Perform standard spirometry and record values from the best effort as described in section 3.1.2.1.
2. Administer bronchodilator (note – the number of puffs of bronchodilator is usually specified in the study protocol and should be recorded. The same number of puffs is typically used for subsequent reversibility tests).
3. Repeat standard spirometry 10-30 minutes after bronchodilator administration and record values from the best effort. Timing varies with type of bronchodilator used.
4. Calculate percentage bronchodilator reversibility: Percentage reversibility = (Post-bronchodilator FEV1 – pre-bronchodilator FEV1)/pre-bronchodilator FEV1*100.

The Asthma Outcomes Workshop Report proposes that reversibility $\geq 12\%$ and an absolute change of ≥ 200 mL are considered to represent clinically significant bronchodilation and support a diagnosis of asthma.



Reversibility Testing Process for a Short-Acting Bronchodilator

The time the subject must withhold their bronchodilator before reversibility testing is longer for a long-acting bronchodilator.

This diagram includes a question, two tests, a calculation (the red boxes), and the associated results (the orange boxes), as well as the administration of a bronchodilator drug.

Short-Acting Bronchodilator Occurrence Query: Questions about whether bronchodilators were withheld are concomitant medication queries. Concepts of this kind are discussed in [Section 4.2](#).

Spirometry Testing Procedure: The data collected in spirometry testing is described in [Section 3.1.2](#).

Bronchodilator Administration:

When bronchodilators are administered with the intent of relieving symptoms, the administration is recorded as concomitant medications, as described in [Section 4.2](#). When they are administered as part of a testing procedure, they are recorded as procedure agents (see the attached AG domain and [Section 3.1.6](#)). In either case, the relevant data includes information about the medication and its administration:

- Pre-specified medication properties:
 - The name of the medication
 - The class of the medication
 - Its dosage form
- Pre-specified administration properties:
 - Probably, the dose of the intervention
- Collected administration properties:
 - When the intervention occurred (date/time)
 - Possibly, the dose of the intervention

Percent Reversibility Calculation:

The relevant data includes the topic (the name of the test) and its response. The data to be collected for this type of research concept includes data about the test and the result.

- Pre-specified test properties
 - The algorithm used to calculate the test (post-bronchodilator value – pre-bronchodilator value as a proportion of pre-bronchodilator value)
 - When the test was planned to be performed (relative study timing in relation to the bronchodilator administration)
- Collected test properties
 - The subject of the test (the subject)
 - When the test was performed (date/time and relative study timing)
 - Possibly, that the test was not performed, and why not
 - Possibly properties of the device functioning as the assessor
- Collected result properties
 - The result of the test
 - The units associated with the result of the test
 - Possibly, an indicator that the result should be considered as a baseline value

3.1.5 Airway Responsiveness

Airway responsiveness (also known as airway hyperresponsiveness or reactivity) is a measure of sensitivity to bronchoconstriction with provocative agents, such as methacholine, histamine, mannitol, or other allergen (e.g., cat dander, house dust mite, grass pollen), exercise, cold air, or isocapnic hyperventilation with airway responsiveness being considered in the Asthma Outcomes Report as a supplemental test in asthma research³. Methacholine and histamine are commonly used agents to test airway responsiveness in asthma clinical trials. The procedure to test airway responsiveness is similar to reversibility testing, except that a provocative agent that causes bronchoconstriction, rather than a bronchodilator, is administered.

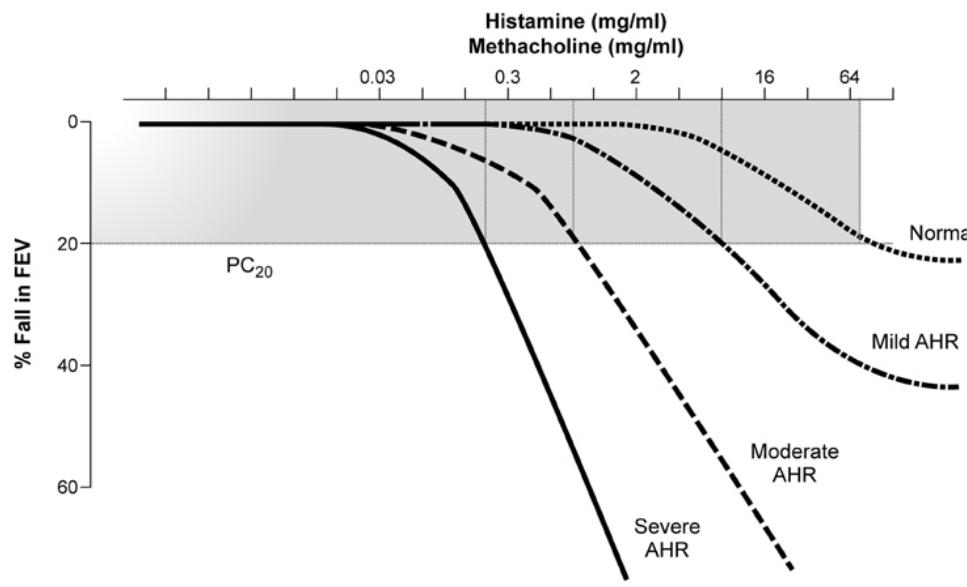
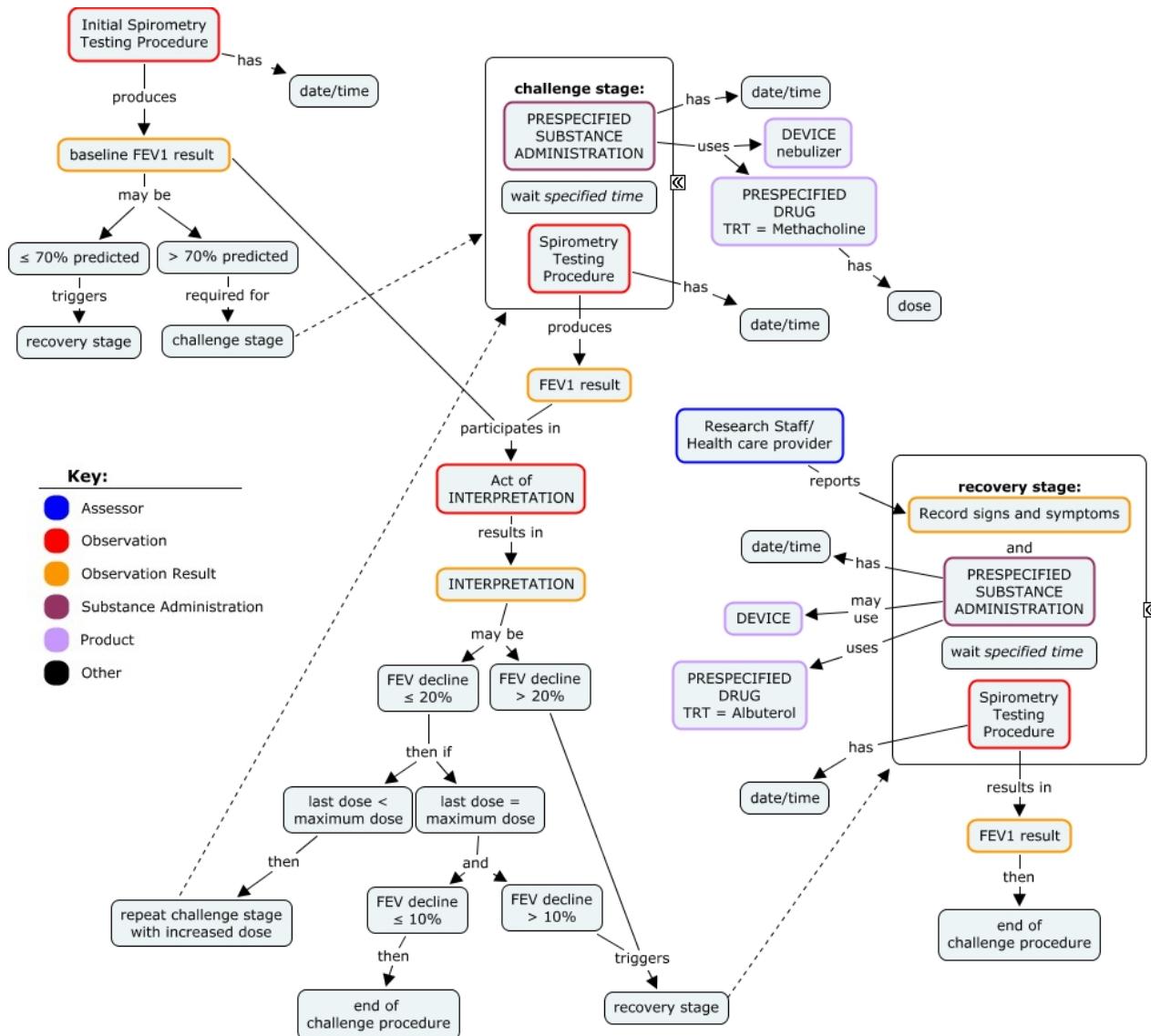


Figure 3.1.5: Measuring Airway Responsiveness*

Bronchoprovocation challenge tests are contraindicated in patients with severe airway obstruction due to the safety issue of worsening the obstruction in the airways, but may be useful when asthma is suspected in a patient with a normal or near-normal result on pulmonary function testing.

In the methacholine or histamine challenge tests⁷, the patient is administered increasing doses of methacholine or histamine to provoke a defined level of bronchoconstriction measured by spirometry (typically a decrease in FEV1 of 20% i.e. PC₂₀). The concentration of methacholine or histamine required to cause this degree of bronchoconstriction is inversely related to the degree of airway hyper-responsiveness. Guidelines for methacholine and histamine challenge testing have been published¹². The concept map below describes the process for methacholine challenge. Histamine challenge follows the same process. This example shows 70% of predicted FEV1 as a cut-off for performing the challenge test, but the level at which testing is contraindicated is controversial, with cut-off points varying between 60% and 80%. The concentration of challenge agent (methacholine concentration in mg/mL in example below) that causes the defined percentage drop in FEV1 is calculated by interpolation or extrapolation methods at the clinic.

* Image courtesy *Global Strategy for Asthma Management and Prevention*



Airway challenge testing will result in several kinds of data.

- Questions about whether bronchodilators were withheld are concomitant medication queries. Concepts of this kind are discussed in [Section 4.2](#).
- The data collected in spirometry testing is described in [Section 3.1.2](#).
- Data on challenge agent dosing is standard dosing data. [Section 3.1.6](#) has examples for the draft Procedure Agents domain in which this dosing is stored.
- Symptom data collection is described in [Section 3.4](#).
- The administration of albuterol at the end of the testing procedure is a concomitant medication administration which would be recorded in the standard way.

3.1.6 Examples for Pulmonary Physiology

Example 1

This example shows results from several spirometry tests using either a spirometer or a peak flow meter where only the best result is available. The Device Identifiers (DI) domain contains the total set of characteristics necessary for device identification, and the Device In-Use (DI) domain contains information important for submission but that are not part of the device identifier.

Because the original and standardized units of measure are identical in this example, RESTRESC, RESTRESN, RESTRESU, and RESTREFN are not shown. Instead, an ellipsis marks their place in the dataset.

- Rows 1-2:** Show the data in original units of measure in REORRES for the best result for spirometry tests with the predicted values in REORREF.
- Rows 3-4:** Show the data in original units of measure in REORRES of percent predicted tests as output by the spirometer device. REORREF is null as there are no reference results for percent predicted tests.
- Row 5:** Shows the data in original units of measure in REORRES for the peak flow test with the predicted values in REORREF.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF	...	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	2.73	L	3.37	...	2	VISIT 2	2013-06-30
2	XYZ	RE	XYZ-001-001	ABC001	2	FVC	Forced Vital Capacity	3.91	L	3.86	...	2	VISIT 2	2013-06-30
3	XYZ	RE	XYZ-001-001	ABC001	3	PPFEV1	Percent Predicted FEV1	81	%	2	VISIT 2	2013-06-30
4	XYZ	RE	XYZ-001-001	ABC001	4	PPFVC	Percent Predicted FVC	101.3	%	2	VISIT 2	2013-06-30
5	XYZ	RE	XYZ-001-001	DEF999	5	PEF	Peak Expiratory Flow	6.11	L/s	7.33	...	4	VISIT 4	2013-07-17

- Rows 1-2:** Show the device type that was used to perform for the pulmonary function tests

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER
2	XYZ	DI	DEF999	1	TYPE	Device Type	PEAK FLOW METER

- Row 1:** Displays the record the reference equation used by the spirometer device.
Row 2: Displays the record the reference equation used by the peak flow meter device.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	XYZ	DU		ABC001	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III
2	XYZ	DU		DEF999	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III

Example 2

This example shows results from several spirometry tests using a spirometer where both the best result and individual results are available. The best result has been flagged using a supplemental qualifier.

Because the original and standardized units of measure are identical in this example, RESTRESC, RESTRESN, and RESTRESU are not shown. Instead, an ellipsis marks their place in the dataset.

Rows 1-3: Show the data in original and standardized units of individual test results for FEV1 as measured by spirometry. The absence of a flag in REIRESFL indicates that the data were adequate.

Row 4: Shows the data in original and standardized units of an individual test result for FEV1 as measured by spirometry. The presence of a flag in REIRESFL indicates that the data were inadequate. SUPPRE.xpt contains two reasons why this was the case.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REIRESFL	VISITNUM	VISIT	REDT	
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	1.94	L	...	2	VISIT 2	2013-04-23	
2	XYZ	RE	XYZ-001-001	ABC001	2	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	...	2	VISIT 2	2013-04-23	
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	...	2	VISIT 2	2013-04-23	
4	XYZ	RE	XYZ-001-001	ABC001	4	FEV1	Forced Expiratory Volume in 1 Second	1.57	L	...	Y	2	VISIT 2	2013-04-23

Row 1: Shows that the record in the RE dataset with RESEQ value of 1 has a supplemental qualifier indicating that this is the best result.

Rows 2-3: Show that the record in the RE dataset with RESEQ value of 4 has supplemental qualifier records providing the reasons the result collected was inadequate. Those reasons were that coughing was detected and that the repeatability was unacceptable.

suppre.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	XYZ	RE	XYZ-001-001	RESEQ	1	REBRESFL	Best Result Flag	Y	CRF	
2	XYZ	RE	XYZ-001-001	RESEQ	4	REIRREA1	Inadequate Result Reason 1	COUGHING WAS DETECTED IN THE FIRST PART OF THE EXPIRATION	CRF	
3	XYZ	RE	XYZ-001-001	RESEQ	4	REIRREA2	Inadequate Result Reason 2	FEV1 REPEATABILITY IS UNACCEPTABLE	CRF	

Row 1: Shows the device type that was used to perform for the pulmonary function tests.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER

Row 1: Displays the record the reference equation used by the spirometer device.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	XYZ	DU	XYZ-001-001	ABC001	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III

Example 3

This example shows the administration of a procedure agent (AG domain) administered as part of a reversibility assessment with the associated spirometer results, as well as the spirometry measurements (RE domain) obtained before and after agent administration. Depending on the study design, the route of bronchodilator administration (via meter dose inhaler (MDI) or nebulizer) and dose per actuation (puff) or nebulé may also be collected.

Reversibility Assessment

Date of assessment: DD-MMM-YYYY

Was the subject administered a short-acting bronchodilator in the previous 4 hours? Yes No

Pre-Bronchodilator Spirometry (5 Minutes before Albuterol Dosing)

Time of Assessment: HH:MM

Forced Expiratory Volume in 1 Second (FEV1) Result: _____ L

Albuterol Administration

Was the subject administered Albuterol? Yes No

Time of Administration: HH:MM

Number of Puffs administered: _____

Post-Bronchodilator Spirometry (20 Minutes after Albuterol Dosing)

Time of Assessment: HH:MM

Forced Expiratory Volume in 1 Second (FEV1) Result: _____ L

Percentage Reversibility: _____ %

Row 1: Shows the administration data of an agent (Albuterol) which was pre-specified on the CRF as part of the reversibility procedure.

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRESP	AGOCCUR	AGDOSE	AGDOSU	AGDOSFRM	AGDOSFRQ	AGROUTE	VISIT	AGSTDTC
1	XYZ	AG	XYZ-001-001	1	ALBUTEROL	Y	Y	2	PUFF	AEROSOL	ONCE	RESPIRATORY (INHALATION)	VISIT 2	2013-06-18T10:05

Row 1: Shows the record with the question as to whether a short-acting bronchodilator was administered in the 4 hours prior to the reversibility assessment. A short-acting bronchodilator administered prior to the reversibility test is used with therapeutic intent so is tabulated in the CM domain. Note that CMTRT has been populated with a description of a kind of medication rather than a single medication. See Section 4.2.1 [Example 1](#) for an alternative approach.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMPRESP	CMOCCUR	CMEVLINT
1	XYZ	CM	XYZ-001-001	1	SHORT-ACTING BRONCHODILATOR	Y	N	-PT4H

- Row 1:** Shows the data in original and standardized units of measure in REORRES, RESTRESC and RESTRESN for FEV1 of a pre-bronchodilator-administration spirometry test performed as part of a reversibility assessment with the associated timing reference variables RETPT, RETPTNUM, REELTM, RETPTREF, and RERFTDTC. This test was performed 5 minutes before the bronchodilator challenge.
- Row 2:** Shows the data in original and standardized units of measure in REORRES, RESTRESC and RESTRESN for FEV1 of a post-bronchodilator administration spirometry test performed as part of a reversibility assessment with the associated timing reference variables RETPT, RETPTNUM, REELTM, RETPTREF, and RERFTDTC. This test was performed 20 minutes after the bronchodilator challenge.
- Row 3:** Shows the data in original and standardized units of measure in REORRES, RESTRESC and RESTRESN for the percentage reversibility where this is collected.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	REGRPID	RETESTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN
1	XYZ	RE	XYZ-001-001	ABC001	1	1	FEV1	Forced Expiratory Volume in 1 Second	2.43	L	2.43	2.43
2	XYZ	RE	XYZ-001-001	ABC001	2	1	FEV1	Forced Expiratory Volume in 1 Second	2.77	L	2.77	2.77
3	XYZ	RE	XYZ-001-001	ABC001	3	1	PCTREV	Percentage Reversibility	13.99	%	13.99	13.99

Row	RESTRESU	VISIT	REDTA	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC
1 (cont)	L	VISIT 2	2013-06-18T10:00	PRE-BRONCHODILATOR ADMINISTRATION	1	-PT5M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
2 (cont)	L	VISIT 2	2013-06-18T10:25	POST-BRONCHODILATOR ADMINISTRATION	2	PT20M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
3 (cont)	%	VISIT 2	2013-06-18T10:25				BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05

- Row 1:** Shows the device type that was used for the pulmonary function tests as part of the reversibility procedure.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER

- Rows 1-3:** Show the relationship of the test agent to the spirometry measurements obtained before and after its administration and to the prior occurrence of short acting bronchodilator administration.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	XYZ	AG	XYZ-001-001	AGSEQ	1		1
2	XYZ	RE	XYZ-001-001	REGRPID	1		1
3	XYZ	CM	XYZ-001-001	CMSEQ	1		1

Example 4

This example captures data about the allergen used by the subject as part of a bronchial allergen challenge (BAC) test. Initially, the subject had a skin prick allergen test (see [Section 2.3](#)) to help identify the allergen to be used for the BAC test. The allergens tested were cat dander, house dust mite, and grass. For this subject, grass provided the largest skin test reaction and was the allergen chosen to be used in the BAC test. A predetermined set of ascending doses of the

chosen allergen are used in the screening BAC test. The results of the screening BAC are used to choose the allergen dose that will be used in subsequent BAC tests (not shown).

Allergen Used?	Inhalation End Time	Allergen Concentration SQ-u/mL	Time of FEV1 FEV1 (L)	
			FEV1	FEV1 (L)
<input type="checkbox"/> Cat Dander	____:____	Saline=0	0	____:____ .____
<input type="checkbox"/> House Dust Mites	____:____	Dose1	250	____:____ .____
<input type="checkbox"/> Grass	____:____	Dose2	1000	____:____ .____
	____:____	Dose3	2000	____:____ .____

Rows 1-3: Correspond to the first part of the CRF. The skin response results corresponding to these allergen administrations were used to choose grass as the allergen for the BAC.

Rows 4: The first dose given in the BAC was saline.

Rows 5-6: Three successively higher doses of grass allergen were given.

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRESP	AGOCCUR	AGDOSE	AGDOSU	AGROUTE	VISIT	AGENDTC
1	XYZ	AG	XYZ-001-001	1	CAT DANDER	Y	N			INTRAEPIDERMAL	SCREENING	2010-10-31
2	XYZ	AG	XYZ-001-001	1	HOUSE MITE DUST	Y	N			INTRAEPIDERMAL	SCREENING	2010-10-31
2	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y			INTRAEPIDERMAL	SCREENING	2010-10-31
3	XYZ	AG	XYZ-001-001	1	SALINE	Y	Y	0	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T10:56:00
4	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y	250	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T11:19:00
5	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y	1000	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T11:43:00
6	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y	2000	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T12:06:00

Example 5

For reversibility testing on a spirometry CRF page, data were collected to confirm that no dose of short acting bronchodilator was taken within 8 hours prior to spirometry and that no dose of long acting bronchodilator was taken within 48 hours prior to spirometry. The data were collected in the following manner:

Confirmation of Withheld Bronchodilators

Date of assessment: DD-MMM-YYYY

Time of assessment: HH:MM

Was a short-acting bronchodilator taken in the 8 hours prior to spirometry? No Yes

Was a long-acting bronchodilator taken in 48 hours prior to spirometry? No Yes

If either answer is yes, reschedule spirometry.

Rows 1-2: Show that no short-acting bronchodilator was taken in the 8 hours prior to spirometry, but a long-acting bronchodilator was taken in the 48 hours prior to spirometry. Though it does not say so specifically in the dataset, it could be concluded that the spirometry was therefore rescheduled.

Row 3-4: Show that no short-acting bronchodilator was taken in the 8 hours prior to spirometry, and no long-acting bronchodilator was taken in the 48 hours prior to spirometry.

cm.xpt

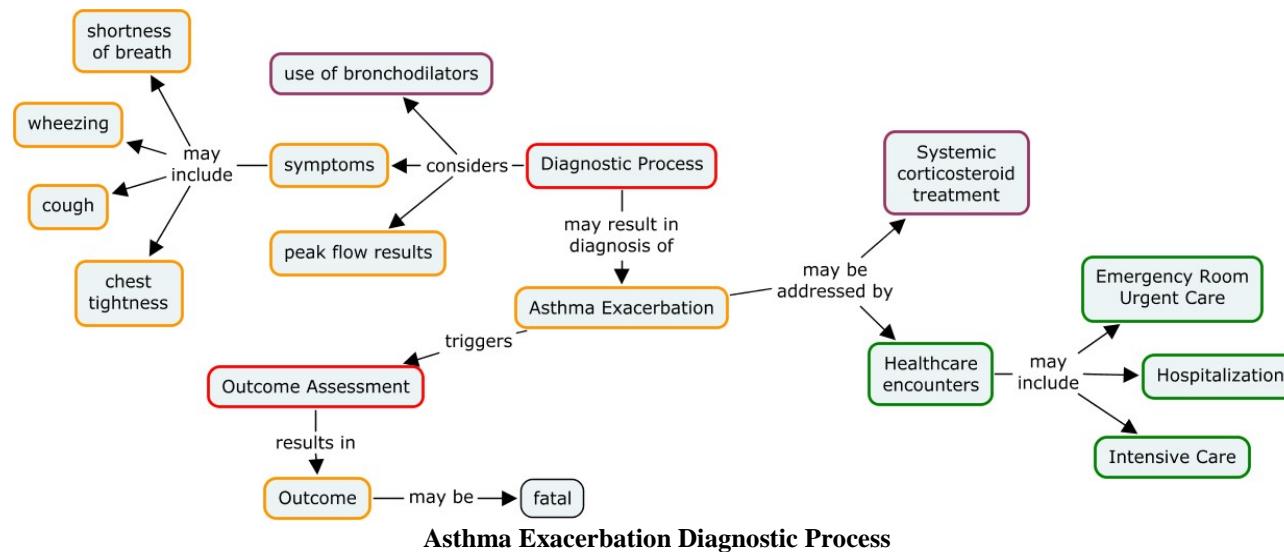
Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMPRESP	CMOCCUR	VISITNUM	CMDTC	CMEVLINT
1	DEF-001	CM	DEF-001-1234	1	SHORT-ACTING BRONCHODILATOR	Y	N	1	2010-10-28T12:01	-PT8H
2	DEF-001	CM	DEF-001-1234	2	LONG-ACTING BRONCHODILATOR	Y	Y	1	2010-10-28T12:01	-PT48H
3	DEF-001	CM	DEF-001-1234	3	SHORT-ACTING BRONCHODILATOR	Y	N	2	2010-11-05T09:28	-PT8H
4	DEF-001	CM	DEF-001-1234	4	LONG-ACTING BRONCHODILATOR	Y	N	2	2010-11-05T09:28	-PT48H

3.2 Exacerbations of Asthma

Asthma exacerbations are acute or sub-acute episodes of progressively worsening of shortness of breath (dyspnea), cough, wheezing, and chest tightness, or some combination of these symptoms. Exacerbations are characterized by decreases in expiratory flow, increasing symptoms, and increased use of bronchodilators. Data collected to characterize exacerbations typically include measures in these three areas. In clinical studies, definitions of exacerbations and their severity differ depending on the asthma population under study. The Asthma Outcomes Workshop Report proposes the following definition: an exacerbation is a worsening of asthma requiring the use of systemic corticosteroids (or for patients on a stable maintenance dose, an increase in the use of systemic corticosteroids) to prevent a serious outcome¹³. The report considers exacerbations as a core outcome which should be reported in all asthma clinical trials. Since the above definition does not include detailed aspects of an asthma exacerbation that describe levels of severity, characterize the nature of the exacerbation, or relate to its outcome, the Asthma Outcomes Workshop Report recommends that, at minimum, the following information should be collected to allow for more in-depth analysis and for better comparisons between studies:

1. All worsening asthma events in which systemic corticosteroids were initiated or increased to prevent a serious outcome, including use of systemic corticosteroids in association with any form of healthcare provider encounter;
2. All asthma-specific Emergency Room (ER) or Urgent Care (UC) visits that involved treatment with systemic corticosteroids;
3. All asthma-specific hospitalizations that involved treatment with systemic corticosteroids
4. All asthma-specific Intensive Care Unit (ICU) admissions or intubations; and
5. All asthma-related deaths

The ATS/ERS guidelines¹ provide similar recommendations, focusing on severe exacerbations defined as including at least one of the following: use of systemic corticosteroids, or increase from a stable maintenance dose for at least 3 days, or a hospitalization or ER visit because of asthma requiring treatment with systemic corticosteroids.



The recommended definition of an asthma exacerbation based on the medication used to treat the symptoms (e.g., an event that requires the use (or increase in dose) of systemic corticosteroids for a specific time period (usually a minimum of 3 days)) permits analyses of data across trials. Additionally, asthma exacerbations may also be defined based on increased symptoms (e.g., increased nighttime awakenings) or as a hospitalization or an emergency room visit due to worsening asthma symptoms. **Regardless of what definition is used in any specific study, it is necessary that the minimum data described above be collected in a uniform manner so that analyses using the recommended definition can be performed.** Using this standard definition, the start and stop dates for exacerbations can be determined, and the following analyses can be performed:

- Overall rate (number of events requiring systemic corticosteroids /time interval specified by study)
- Weighted mean rate (total exacerbations in the study group/total person time in the group)
- Time to first exacerbation
- Percentage of study group with an exacerbation
- Total corticosteroid dose (mg/patient/unit of time and duration of treatment)

Data for the parameters used for the recommended asthma exacerbation definition (i.e., medication used to treat the symptoms) is collected primarily from the concomitant medication eCRF, with additional information collected from the adverse event/serious adverse event, hospitalization, and symptom eCRFs. For the recommended definition of severe exacerbation, the start and stop dates are taken from those of the change of systemic corticosteroid dose. Bronchodilator use usually needs to be collected separately (e.g., by daily diary card or e-diary) since concomitant medication eCRFs do not collect these data with sufficient granularity (number of puffs or number of occasions of use per 12- or 24-hour period), particularly when change in rescue medication use is being collected as an efficacy parameter. Details for the collection of events and therapies can be found in the sections of the SDTMIG dealing with Events and Interventions, and in [Section 4.1](#) and [Section 4.2](#) of this document. Details for the collection of the questionnaire data can be found in [Section 3.5](#).

For data analysis purposes, it is important also to define when events should be considered as separate or combined as an ongoing event. For example, symptoms treated by courses of corticosteroids separated by less than seven days may be treated as a single exacerbation event. This definition of an exacerbation event would be documented in the ADaM analysis metadata.

3.3 Biomarkers

Biomarkers can be measured as surrogates of clinical relevance (sensitivity and specificity for the disease) and can be responsive to treatment effects. Many biomarkers studied in asthma are measures of inflammation. In some drug trials, biomarkers may measure some aspect of the mechanism of action of the drug.

The figure to the right shows the cascade of responses when an allergen comes in contact with bronchial tissues¹⁴. Drugs that interfere with step(s) in this cascade have the potential to offer therapeutic benefit. The measurement of changes in these biomarkers can provide proof of mechanism for the drug under study, and can potentially act as surrogate efficacy endpoints.

3.3.1 Specimen Collection

Biomarkers for asthma patients are measured mainly from the specimens of the following types:

- Blood, blood serum, or blood plasma
- Samples from sites in the respiratory tract such as sputum, bronchoalveolar lavage (BAL) fluid¹⁵, or bronchial biopsy samples
- Exhaled breath
- Urine, in particular urine from a 24-hour collection

Examples of specimen collection procedures are listed below. Blood collection and processing is routine, but sputum collection is a more challenging procedure for obtaining reproducible results. Bronchoalveolar lavage and bronchial biopsy are significant medical procedures that require sedation of the subject. Capture and analysis of exhaled breath, although easy, requires expensive specialized equipment.

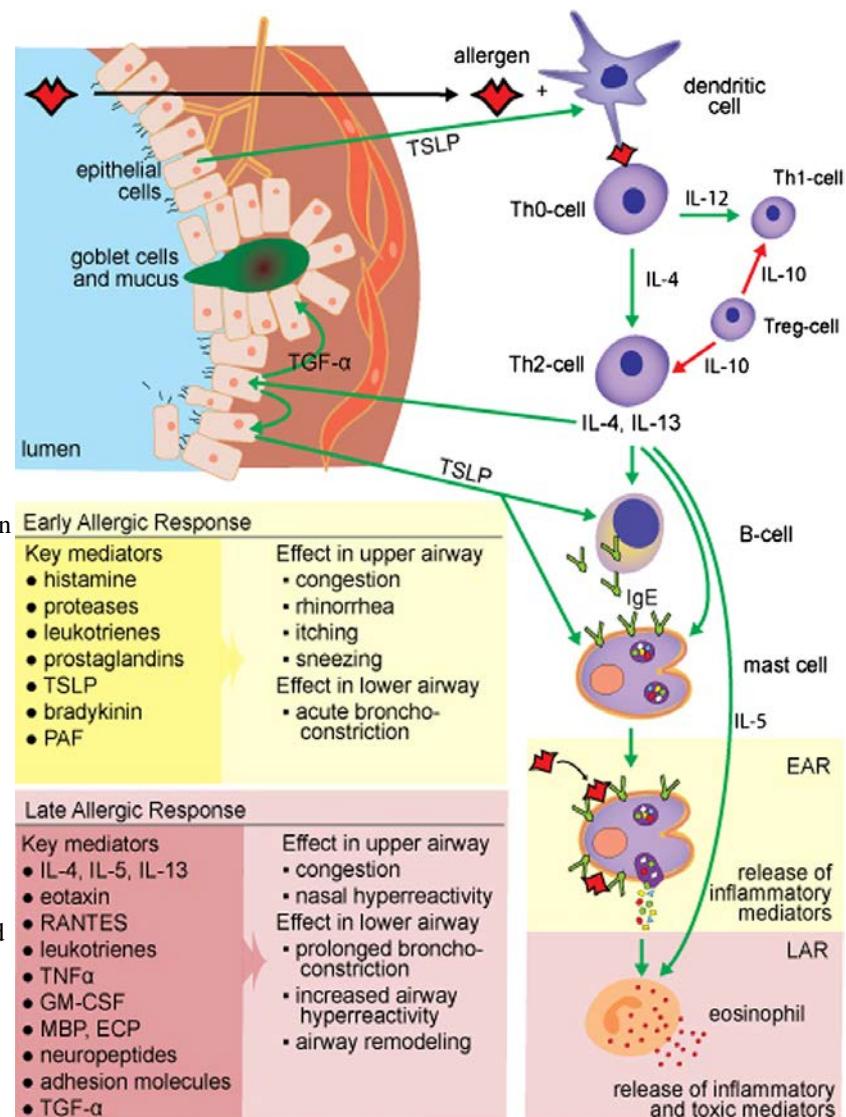


Figure 3.3: Allergic Airway Response[†]

[†] Originally published in *Pulm Pharmacol Ther.* 2010;23(6):468-81. Reproduced with permission.

Specimen collection	Description of process	Resulting specimen type
Blood collection	Blood is taken from a subject's vein	Blood (whole blood)
Plasma extraction	Blood plasma is blood from which cells are removed from a blood sample. This is usually achieved by spinning anti-coagulated blood in a centrifuge until the cells fall to the bottom.	Plasma
Serum extraction	Blood serum is blood from which cells and clotting proteins have been removed.	Serum
Urine collection	A urine sample is collected from the patient.	Urine
Sputum collection	Sputum is the mucus produced by the respiratory system that is expelled by coughing. Sputum collection thus involves the subject coughing up sputum.	Sputum
Induced sputum collection	If the subject is unable to produce a sputum specimen, a salt solution may be inhaled to facilitate coughing and production of a specimen.	Sputum (induced sputum)
Bronchial sampling (BAL, biopsies, and brushings)	In these procedures, a bronchoscope is passed through the nose or mouth into the lungs, and samples are collected or fluid is instilled into a small part of the lungs, and then recollected.	Tissue or cell samples, bronchoalveolar lavage fluid
Online exhaled breath sampling	The subject exhales directly into a device that analyzes the exhaled breath.	Exhaled breath
Offline exhaled breath sampling	The subject exhales into a reservoir (such as a mylar balloon) which is analyzed later.	Exhaled breath

The specimen types listed in the table above are not from CDISC controlled terminology. See

<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc> for accepted values for the --SPEC variable.

3.3.2 Measures of Inflammation

In clinical practice, biomarkers can provide information on presence and severity of disease or inflammation. In clinical trials, biomarkers are also used for predicting or monitoring treatment response.

3.3.2.1 Laboratory Tests

This section includes tests performed on samples other than exhaled breath, which is treated separately because it is not routinely handled by clinical laboratories. Data collected for clinical laboratory tests is described in the CDASH standard and in the SDTMIG.

The Asthma Outcomes Workshop Report states that atopic status is an important phenotype and should be documented in clinical research studies. The presence of allergen-specific immunoglobulin E (IgE) is a biomarker for atopic status, and can be measured by a serological multiallergen screen (e.g. the Phadiatop assay). This is considered a core biomarker to permit characterization of atopic status¹⁶.

Other supplemental outcomes have been identified, which may be relevant, depending the mechanism of action of the drug being tested. These include the following: sputum eosinophils, blood eosinophils (usually as part of a complete blood count (CBC)), total IgE, allergen-specific IgE, and urinary Leukotriene E4 (LTE4). The following two tables list these core and supplemental biomarkers and several less commonly measured biomarkers that may be of interest in asthma clinical trials.

Note that the abbreviations and test names given in the two tables in this section are those commonly used in clinical practice. These abbreviations are not necessarily the TESTCD and TEST values in CDISC Controlled Terminology. Similarly, the definitions describe these tests in the context of asthma, and are not

the Controlled Terminology definitions. When constructing standard datasets, consult the current version of CDISC Controlled Terminology (available at: <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>) for values of TEST and TESTCD.

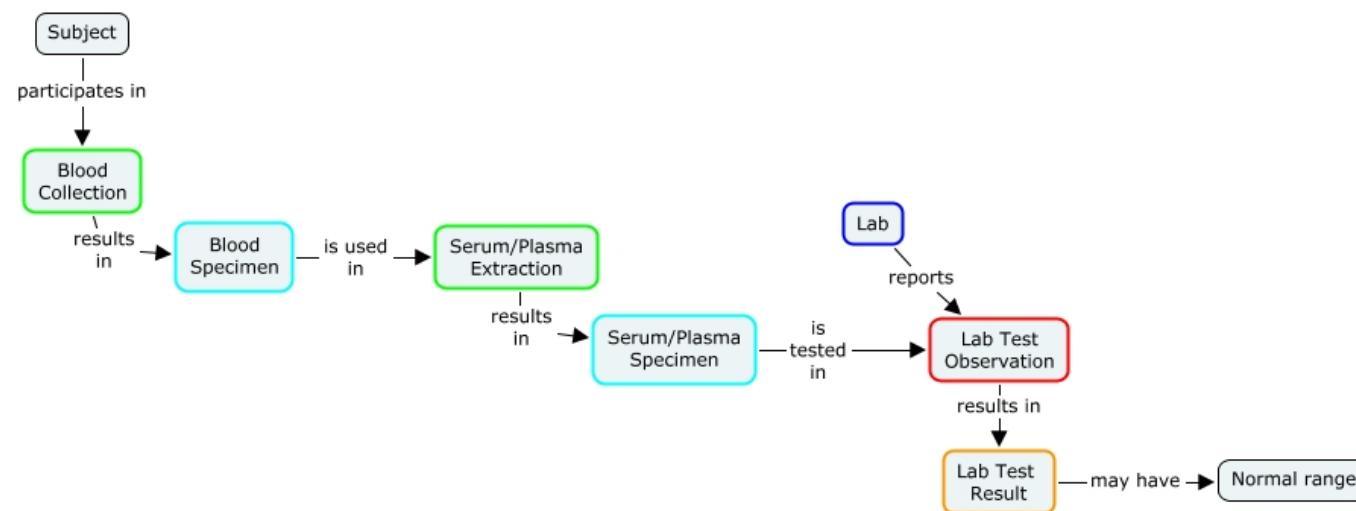
Core and Supplemental Biomarkers

Common Test Abbreviation	Test Name	Description	Specimen(s)
Multiallergen screen	Serological multiallergen screen (IgE) to define atopic status	The Phadiatop test simultaneously detects specific IgE antibodies to any of 10 aeroallergens, generating both a positive/negative result for atopy and a semi-quantitative estimate of relative positivity, with a 0.35 kUa/L positive cut point criterion to define the presence of atopy.	Serum
LTE4	Leukotriene E4	Cysteinyl leukotrienes are produced by a variety of cells associated with allergic inflammation. The end metabolite of cysteinyl leukotrienes, LTE4, can be measured in random urine samples. Urinary LTE4 increases with asthma exacerbations, aspirin and allergen challenge, and possibly at night with nocturnal asthma.	Urine
IgE/allergen-specific IgE	Immunoglobulin E	Total blood IgE levels are elevated in some but not all asthmatics, and correlate with asthma severity ¹⁷ . Allergen-specific IgE tests are used to confirm a suspicion of allergy and to determine the offending allergen, or to rule out allergens for which test results are negative. Results can also be helpful in monitoring the IgE levels of antibodies over time.	Plasma/Serum
Eosinophils	Eosinophils	The key cell type studied in asthmatic sputum and blood. Eosinophilia (an abnormally high number of eosinophils) is seen in up to 80% of steroid-naïve asthmatics. Eosinophils and eosinophil cationic protein (ECP) in sputum from asthmatic patients are significantly elevated compared with healthy control subjects. Sputum eosinophil numbers correlate with asthma severity, airway hyper-reactivity (AHR), peak flow variability, and daily asthma symptom scores ¹⁷ .	Sputum/Blood

Additional Asthma-Associated Biomarkers

Common Test Abbreviation	Test Name	Description	Specimen(s)
IL-4	Interleukin 4	One of the inflammatory cytokines, an IL-4 level is increased in asthma patients.	Plasma/Serum/Sputum
IL-5	Interleukin -5	One of the inflammatory cytokines, an IL-5 level is increased in asthma patients.	Plasma/Serum/Sputum
IL-13	Interleukin-13	One of the inflammatory cytokines, an IL-13 level is increased in asthma patients.	Plasma/Serum/Sputum
IL-8	Interleukin-8 (CxCL8)	Increased levels of IL-8 have been demonstrated during asthma exacerbations and in more severe disease.	Plasma/Serum/Sputum
IP-10	Interferon gamma-induced protein 10; C-X-C motif chemokine 10 (CxCL10)	IP-10 is involved in mast cell migration to airway smooth muscle bundles. It is a marker for rhinoviral infections in asthma patients ¹⁸ .	Plasma/Serum
TARC (CCL17)	Thymus and activation-regulated chemokine	It is known that blood/BAL TARC levels are increased in asthma patients.	Plasma/Serum/BAL

Common Test Abbreviation	Test Name	Description	Specimen(s)
Eotaxin (CCL11)	Chemokine (C-C motif) ligand 11	Eotaxin is a marker of neutrophilic and eosinophilic inflammation, and blood/BAL eotaxin level is increased in asthma patients.	Plasma/Serum/BAL
Eotaxin -2 (CCL24)	Chemokine (C-C motif) ligand 24	Eotaxin-2 is reported to have important role in eosinophil chemotaxis and activation, and is increased in asthma patients ¹⁹ .	Plasma/Serum
Eotaxin -3 (CCL26)	Chemokine (C-C motif) ligand 26	Eotaxin-3 is reported to have important role in eosinophil chemotaxis and activation and is increased in asthma patients ¹⁹ .	Plasma/Serum
SP-D	Surfactant Protein-D	SP-D is an immune molecule that has been shown to be crucial in protecting against lung infection and allergens. It is also effective in alleviating bronchial hyperresponsiveness.	Plasma/Serum/BAL
CCL18	Chemokine (C-C motif) ligand 18	CCL18 is a chemokine preferentially expressed in the lung, and it is known that CCL18 may be involved in allergic asthma ²⁰ .	Plasma/Serum
hsCRP	C-reactive protein; CRP; High-sensitive C-reactive Protein; hsCRP	CRP level has been shown to be raised in the blood of stable COPD patients. It is used to predict prognosis in terms of hazard ratios for hospitalization and death from COPD ¹⁷ . It is known that CRP is a useful biomarker to indicate inflammation associated with asthma	Plasma/Serum/Sputum
	Fibrinogen	Fibrinogen level is increased during exacerbations of COPD. It is also known that fibrinogen level is high in asthma patients.	Plasma/Serum/Sputum
	Periostin	Periostin is known as a biomarker of eosinophilic airway inflammation in asthma patients. It is also known that the level of periostin is increased in asthma patients ²¹ .	Plasma/Serum/Sputum



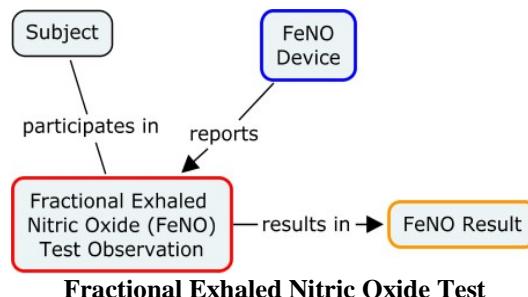
Concept map does not show all the data collected. Data collection is standard. Refer to the Laboratory Test Results (LB) domain and the current version of the SDTMIG for further information.

3.3.2.2 Exhaled Breath

It is increasingly recognized that the measurement of exhaled mediators in general, and nitric oxide in particular, constitutes a novel way to monitor separate aspects of diseases, such as asthma. In asthma, it has been proposed to use fractional exhaled nitric oxide (FeNO) to diagnose asthma, to monitor the response to anti-inflammatory medications, to verify adherence to therapy, and to predict upcoming asthma exacerbations. It is also proposed that adjusting anti-inflammatory medications guided by the monitoring of noninvasive markers such as FeNO could improve overall asthma control ²².

Recommendations have been published detailing standardized procedures for both online and offline measurements of FeNO ²². Online measurement is more commonly used in clinical trials, using standardized equipment. A number of factors can impact the measurement of FeNO (e.g. time since last bronchodilator use, spirometry measurement, food or beverage consumption, strenuous exercise, and smoking) ²² and should be standardized as much as possible. FeNO should be performed prior to spirometry.

Test Abbreviation	Test Name	Description
FeNO	Fractional Exhaled Nitric Oxide	Used to diagnose asthma, to monitor the response to anti-inflammatory medications, to verify adherence to therapy, and to predict upcoming asthma exacerbations.



This diagram shows a FeNO test performed on a subject.

Fractional exhaled nitric oxide (FeNO) Test Observation:

The data to be collected for this kind of research concept includes data about the test and result:

- Pre-specified question properties:
 - The name of the test (i.e., FeNO)
 - The lab category
 - Units
- Collected test properties:
 - The subject of the question (the subject)
 - When the test was collected (date/time and relative study timing)
 - The test method (offline or online measurement) including exhalation flow rate
 - Possibly, timing relative to a substance administration
 - Possibly, that the test was not collected, and why not

- Collected response properties:
 - The result from the test
 - Possibly, if no result, that an answer was not recorded and why not
- The normal range

3.3.3 Examples for Biomarkers

Example 1

In this example, the subject is tested for a couple of biomarkers.

Row 1: Eosinophils were measured in a blood sample taken during Visit 1.

Row 2: C Reactive Protein was measured in serum from a sample collected during Visit 1.

Row 3: Eosinophil numbers were measured in a sputum sample collected during Visit 2, one hour after a methacholine challenge test was performed.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSPEC	LBORRES	LBORRESU	LBORNLO	LBORNHI	LBSTRESC
1	ABC-001	LB	ABC-001-1234	1	EOS	Eosinophils	HEMATOLOGY	BLOOD	0.08	10 ⁹ /L	0.03	0.44	0.08
2	ABC-001	LB	ABC-001-1234	2	CRP	C Reactive Protein	CHEMISTRY	SERUM	0.47	mg/L	0	5	0.47
3	ABC-001	LB	ABC-001-1234	3	EOSLE	Eosinophils	IMMUNOLOGY	SPUTUM	5	%			5

Row	LBSTRESN	LBSTRESU	VISITNUM	VISIT	LBDTC	LBTPPT	LBTPPTNUM	LBELOTM	LBTPPTREF
1 (cont)	0.08	10 ⁹ /L	1	VISIT 1	2011-01-11T11:31:00				
2 (cont)	0.47	mg/L	1	VISIT 1	2011-01-11T11:31:00				
3 (cont)	5	%	2	VISIT 2	2011-01-18T13:31:00	1 HOUR	1	PT1H	METHACHOLINE CHALLENGE

Example 2

In this example, the subject is tested for an online FeNO test as well as allergen-specific IgE tests.

Row 1-9: Allergen-specific IgE tests are performed on a serum sample from a subject.

Rows 10-11: An online FeNO test was performed before and after BAC.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU
1	ABC001	LB	ABC001-1234	1	IEMIX	IgE Mixed Allergens	IMMUNOLOGY	33.0	kU/L	33.0	33.0	kU/L
2	ABC001	LB	ABC001-1234	2	IECATD	IgE Cat Dander	IMMUNOLOGY	29.6	kU/L	29.6	29.6	kU/L
3	ABC001	LB	ABC001-1234	3	IEDOG	IgE Dog Dander	IMMUNOLOGY	3.87	kU/L	3.87	3.87	kU/L
4	ABC001	LB	ABC001-1234	4	IEDFAR	IgE D. farinae	IMMUNOLOGY	<0.35	kU/L	<0.35	.	kU/L
5	ABC001	LB	ABC001-1234	5	IEDPTER	IgE D. Pteronyssinus	IMMUNOLOGY	<0.35	kU/L	<0.35	.	kU/L
6	ABC001	LB	ABC001-1234	6	IEAMNCK	IgE American Cockroach	IMMUNOLOGY	0.41	kU/L	0.41	0.41	kU/L
7	ABC001	LB	ABC001-1234	7	IEAFUMIG	IgE A. fumigatus	IMMUNOLOGY	<0.35	kU/L	<0.35	.	kU/L

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU
8	ABC001	LB	ABC001-1234	8	IEPEN	IgE Penicillium notatum	IMMUNOLOGY	<0.35	kU/L	<0.35	.	kU/L
9	ABC001	LB	ABC001-1234	9	IEATEN	IgE A. tenuis alternata	IMMUNOLOGY	<0.35	kU/L	<0.35	.	kU/L
10	ABC001	LB	ABC001-1234	10	FENO	Fractional Exhaled Nitric Oxide	IMMUNOLOGY	43	ppb	43	43	ppb
11	ABC001	LB	ABC001-1234	11	FENO	Fractional Exhaled Nitric Oxide	IMMUNOLOGY	35	ppb	35	35	ppb

Row	LBSPEC	VISITNUM	VISIT	LBDTC	LBTPT	LBTPTNUM	LBELTM	LBTPTREF
1 (cont)	SERUM	1	SCREENING	2010-10-01				
2 (cont)	SERUM	1	SCREENING	2010-10-01				
3 (cont)	SERUM	1	SCREENING	2010-10-01				
4 (cont)	SERUM	1	SCREENING	2010-10-01				
5 (cont)	SERUM	1	SCREENING	2010-10-01				
6 (cont)	SERUM	1	SCREENING	2010-10-01				
7 (cont)	SERUM	1	SCREENING	2010-10-01				
8 (cont)	SERUM	1	SCREENING	2010-10-01				
9 (cont)	SERUM	1	SCREENING	2010-10-01				
10 (cont)	EXPIRED AIR	1	SCREENING	2010-10-01T10:30:00	PRE-BAC	0		BAC
11 (cont)	EXPIRED AIR	1	SCREENING	2010-10-01T22:41:00	11 HOURS	11	PT11H	BAC

3.4 Symptom Assessment

The most common symptoms of asthma are wheezing, cough, breathlessness, chest tightness, and nighttime awakenings. These symptoms are often assessed using validated instruments as described in [Section 3.5](#). They may also be described using sponsor-defined Likert scales or visual analog scales. Data typically collected for asthma symptoms include the focal time period and the subject's rating of symptom severity or symptom impact. Occurrence is sometimes combined with severity or impact by including a value of "None" or "Absent" in the set of severity or impact responses.

Subjects may record their symptoms in a diary (paper or electronic), which is completed first thing in the morning and last thing at night. The focal time period for symptoms assessment is thus often "during the day" or "during the night"; in other words, the time period since the last diary completion.

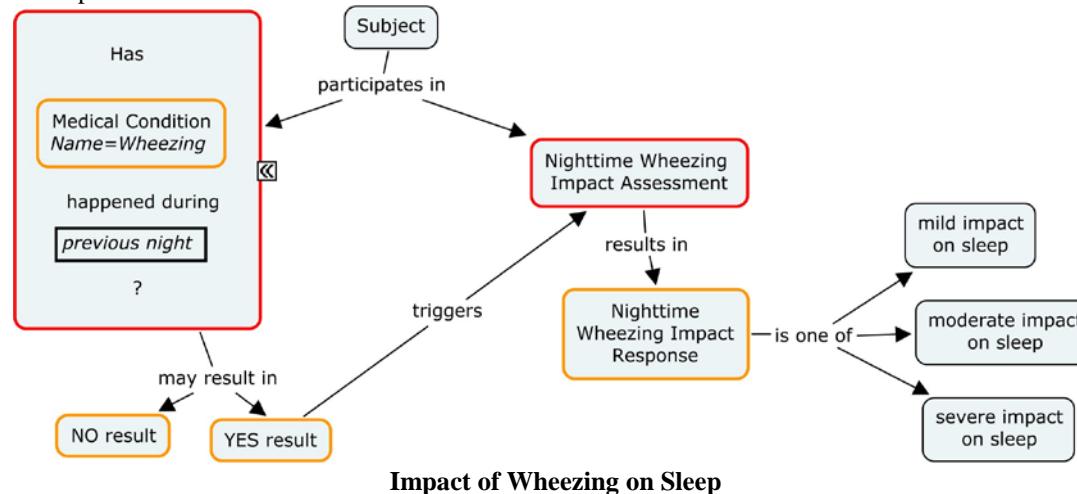
Symptoms are often assessed by the impact of a particular symptom or asthma symptoms collectively on a subject's daily activities or sleep at night. Typical questions during the "daytime" focal period include how the symptom affected the subject's ability to work or go to school. "Nighttime" impact of symptoms is often measured by number of awakenings.

Asthma symptoms are often assessed by a validated questionnaire. Several validated instruments used in asthma studies are listed in [Appendix E](#) of this document. However, sponsor specific questions are often used. These can be of several types.

- A Likert scale presents a statement with a set of responses indicating the degree to which the subject agrees with the statement. The subject chooses one response.
- A visual analog scale presents a line with labels at the ends describing the extremes of possible responses. The subject makes a mark on the line indicating their position between these extremes.
- Many scales present the subject with an ordered set of responses, from which the subject selects one response. Sometimes such scales are loosely called "visual analog scales" but a true visual analog scale yields a continuous, rather than a discrete, response.

Example: Scale to assess nighttime impact of wheezing

In this example, the occurrence of wheezing and the severity of its impact are recorded as separate test results. The sponsor would define what is meant by mild, moderate, and severe impact on sleep.



The questions asked about symptom severity or impact tend to be sponsor defined scales. The CDISC Pain Therapeutic Area User Guide²³ for SDTM implementation describes how to handle data from several kinds of scales used to measure severity or impact of pain, and that advice can be applied to asthma symptoms.

3.4.1 Examples for Asthma Symptom Assessments

Example

Data are collected about occurrence of specific asthma-related symptoms. The data was collected in the following way:

Asthma Symptoms					
Focal time: Over the past 12 hour nighttime period	Questions	Wheezing	Cough	Breathlessness	Chest tightness
Did you experience the symptom?	Did you experience the symptom?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Did it impact your sleep?	Did it impact your sleep?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
How would you rate the severity of the impact on your sleep?	How would you rate the severity of the impact on your sleep?	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe			

An episode of one of these symptoms could be recorded as an event in the CE domain, with a start and end and a severity. However, in this case the data collected are all answers to questions about a particular kind of symptom during a particular time period. For this reason, the data have been represented as findings about clinical events. The kind of symptom is represented in FAOBJ. The time at which this data was collected is represented by the combination of FADTC and the timepoint, for which TPT = MORNING and TPTNUM = 1. The time period that is the focus of the question is represented by the combination of the date and timepoint of collection and FAEVINTX = NIGHTTIME. (Asthma diary data are usually collected morning and evening. The symptom data collected at the EVENING timepoint would collect the occurrence question, a query about impact on daily activities, and an assessment of the severity of that impact.)

Rows 1-3: The subject experienced wheezing which impacted their sleep. The severity of the impact was severe.

Rows 4-6: The subject experienced cough which impacted their sleep. The severity of the impact was moderate.

Row 7: The subject did not experience breathlessness. The value given in FAOBJ is "Dyspnoea" because this is a MedDRA term to which breathlessness codes.

Rows 8-9: The subject experienced chest tightness, but this did not impact their sleep.

face.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FATPT	FATPTNUM	FADTC	FAEVINTX
1	ABC123	FA	456	1	OCCUR	Occurrence	Wheezing	Asthma Related	Y	Y	MORNING	1	2012-04-05	NIGHTTIME
2	ABC123	FA	456	2	IMPSLP	Impact on Sleep	Wheezing	Asthma Related	Y	Y	MORNING	1	2012-04-05	NIGHTTIME
3	ABC123	FA	456	3	IMPSLPSV	Severity of Impact on Sleep	Wheezing	Asthma Related	Severe	Severe	MORNING	1	2012-04-05	NIGHTTIME
4	ABC123	FA	456	4	OCCUR	Occurrence	Cough	Asthma Related	Y	Y	MORNING	1	2012-04-05	NIGHTTIME
5	ABC123	FA	456	5	IMPSLP	Impact on Sleep	Cough	Asthma Related	Y	Y	MORNING	1	2012-04-05	NIGHTTIME
6	ABC123	FA	456	6	IMPSLPSV	Severity of Impact on Sleep	Cough	Asthma Related	Moderate	Moderate	MORNING	1	2012-04-05	NIGHTTIME
7	ABC123	FA	456	7	OCCUR	Occurrence	Dyspnoea	Asthma Related	N	N	MORNING	1	2012-04-05	NIGHTTIME
8	ABC123	FA	456	8	OCCUR	Occurrence	Chest discomfort	Asthma Related	Y	Y	MORNING	1	2012-04-05	NIGHTTIME
9	ABC123	FA	456	9	IMPSLP	Impact on Sleep	Chest discomfort	Asthma Related	N	N	MORNING	1	2012-04-05	NIGHTTIME

3.5 Questionnaires and Diaries

The selection of an instrument for a clinical study depends on the domains of interest and the characteristics most relevant to the study. Several commonly-used patient-reported outcome (PRO) measures are listed in [Appendix E](#). These PROs cover a wide range of potential types of measurements that are reported by the patient. The responses to the questions are either gathered via interviews in the clinic, or recorded directly by the patient (either in the clinic or at home). The methods for recording patient responses may include paper diaries or questionnaires (with the answers transcribed to CRFs/eCRFs) or electronic patient diaries or devices.

In addition to responses to asthma symptom-assessment questions, diaries may be used to collect:

- Spirometry measurements (usually PEF measurements taken once or twice daily by peak flow meter)
- Investigational product intake (occurrence, date/time)
- Maintenance treatment intake (occurrence, date/time)
- Rescue medication intake (occurrence, number of occasions/inhalations)

A diary is usually not a formally validated instrument, so such diary data are not stored in the SDTM Questionnaires domain, but would be split into appropriate SDTM domains (e.g., EX for study treatments, CM for rescue medications, CE and/or FA for symptoms).

Asthma-related questionnaires have been designed to focus on either a range of impairments or on a specific impairment, and may be used to assess:

- Symptoms (impairments) and other aspects of well-being
- Functioning (disability)
- Health status
- General health perceptions
- Quality of Life (QoL)
- Health related quality of life (HRQoL)
- Reports and ratings of health care.

A partial list of validated instruments relevant to asthma is available in [Appendix E](#).

Of the kinds of data that may be collected via questionnaires and/or diaries, the Asthma Outcomes Workshop Report marks quality of life and control of asthma as especially significant.

3.5.1 Quality of Life Measures

Quality of life (QoL) is an important dimension of asthma outcomes, distinct from other outcome measures of clinical signs and symptoms. Asthma-related QoL as an outcome measure refers to the perceived impact that asthma has on the patient's quality of life²⁴. Many current instruments measure impairment, which can include symptoms or functional status, as well as QoL. In general, higher symptom levels and poorer functional status are associated with poorer QoL. However, a patient's perspective on disease impact can vary greatly depending on priorities, expectations, and lifestyle. No particular QoL instrument is recommended as core in the Asthma Outcomes Report.

While many questionnaires focus on a patient's impairments and limitations, some QoL instruments also assess the patient's ability to fulfill their needs and their emotional response to their restrictions.

3.5.2 Asthma Severity and Control

As described in the NAEPP Expert Panel Report 3 (2007), asthma severity can be defined as the intrinsic intensity of the disease process and asthma control can be defined as the degree to which the manifestations of asthma (symptoms, functional impairments, and risks of untoward events) are minimized and the goals of therapy are met. Both severity and control include the domains of current impairment and future risk. Classifying severity is emphasized for initiating therapy,

whereas assessing control is emphasized for monitoring and adjusting therapy. Since asthma control is a major goal of asthma therapy, asthma control composite score instruments are considered as a core measure in the Asthma Workshop Report, and have been developed as single questionnaires (with or without physiologic measures such as FEV1 or PEF) to measure the multidimensional construct of asthma control (which is more than just asthma symptoms and frequency of SABA use)²⁵. Examples of these are the ACQ and ACT, listed in [Appendix E](#), which are recommended as appropriate asthma control composite score instruments.

4 Routine Data

4.1 Adverse Events of Special Interest

Adverse Events (AEs) of Special Interest are those events that are associated with the investigational compound or disease under study. Events of Special Interest are identified and developed by the project team in conjunction with the experts in the therapeutic area in which the drug is being developed.

This TAUG-Asthma does not cover all the adverse events that may be of interest for a particular study. It deals with the following adverse events that are commonly considered to be of special interest for asthma: upper respiratory tract infections, sinusitis, bronchitis, pneumonia, anaphylaxis, and nasopharyngitis. The examples provided below can serve as examples of how to handle other adverse events of interest for a particular study.

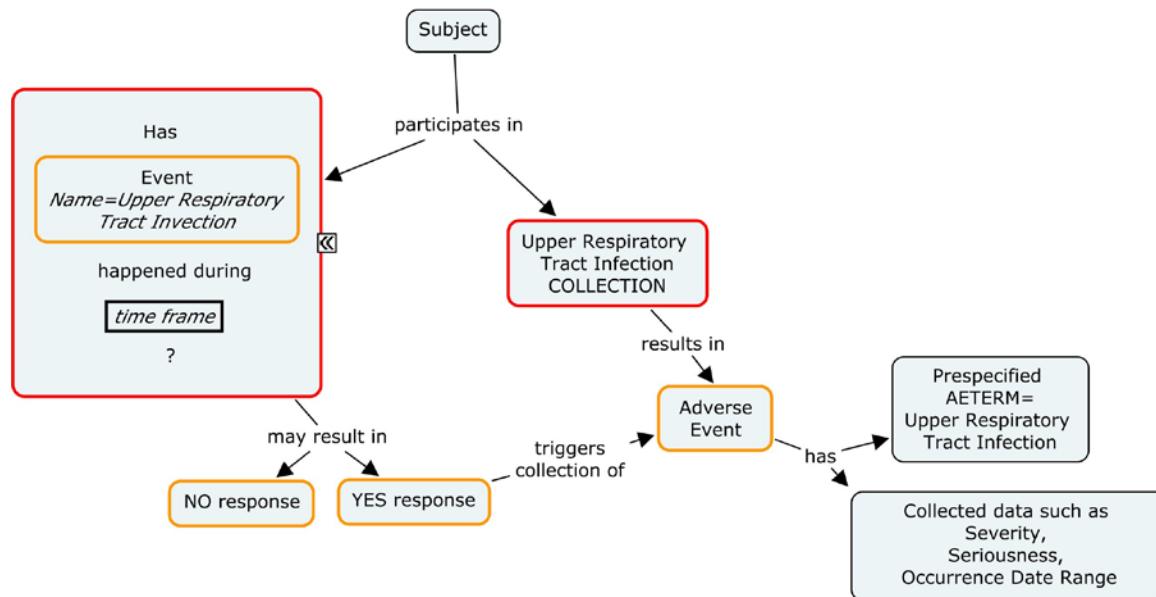
These adverse events of special interest are often associated with the occurrence of asthma exacerbations. Upper respiratory tract infections (URIs), particularly those of viral origin, can cause inflammation of the lung and airway narrowing, which can trigger an acute asthma exacerbation, leading to changes in medication and additional healthcare utilization. In a similar manner as how asthma causes inflammation in the lining of the airways, sinusitis causes inflammation in the mucous membranes that line the sinuses. When the sinuses get inflamed, the airways respond similarly in many people with asthma. Prevention and prompt treatment of a sinus infection is often necessary to help relieve asthma symptoms.

Data collected for AEs of Special Interest can include

- Whether a subject had any of the Special Interest Adverse Events followed by a specific question about the occurrence of each pre-specified event with Y/N response.
- Additional details such as severity, seriousness, start date etc., may be collected for each Special Interest AE.

Example: Upper Respiratory Tract Infections (URI) Query

The concept map below shows a query about the occurrence of URI during a time period. The kind of event the question is asking about (in this case, URI) is called the focal context of the question. The time period the query is asking about is called the focal time period. If the answer to the query is “Yes,” then additional information about the URI, such as severity, seriousness, and start and end dates may be collected.



4.1.1 Examples for Adverse Events of Special Interest

Example 1

Data are collected about the occurrence of specific asthma-related adverse events. Because the AE domain does not include the --OCCUR variable, the SDTMIG recommends that, if it is important to know which adverse events from a pre-specified list were not reported as well as those that were, then these data should be submitted in the FA domain (see *SDTMIG 3.2, Section 6.2, AE Domain, Assumption 4b*). If the event occurred, then a complete AE record is collected on the AE form. The data was collected in the following CDASH-compliant form:

Asthma-Related Adverse Events

Date of assessment: DD-MMM-YYYY

Has the subject had upper respiratory tract infection?	Yes	No
Has the subject had sinusitis?	Yes	No
Has the subject had bronchitis?	Yes	No
Has the subject had pneumonia?	Yes	No
Has the subject had nasopharyngitis?	Yes	No

If any of the above events occurred, then enter a complete record on the AE form.

FACAT is populated with “Asthma Related AE” to indicate the reason for collecting this data.

- Row 1:** The subject had an adverse event of upper respiratory tract infection.
- Rows 2-3:** The subject did not have an adverse event of sinusitis or bronchitis.
- Row 4:** The subject had an adverse event of pneumonia.
- Row 5:** The subject did not have an adverse event of nasopharyngitis.

faae.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
1	ABC123	FA	456	1	OCCUR	Occurrence	Upper respiratory tract infection	Asthma Related AE	Y	Y	2013-05-24
2	ABC123	FA	456	2	OCCUR	Occurrence	Sinusitis	Asthma Related AE	N	N	2013-05-24
3	ABC123	FA	456	3	OCCUR	Occurrence	Bronchitis	Asthma Related AE	N	N	2013-05-24
4	ABC123	FA	456	4	OCCUR	Occurrence	Pneumonia	Asthma Related AE	Y	Y	2013-05-24
5	ABC123	FA	456	5	OCCUR	Occurrence	Nasopharyngitis	Asthma Related AE	N	N	2013-05-24

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AECAT	AEPRESP	AELOC	AELAT	AESEV	AEACN	AESTDTC	AEENDTC
1	ABC123	AE	456	1	Upper respiratory tract infection	Upper respiratory tract infection	Asthma Related	Y			MILD	NONE	2013-05-20	2013-05-31
2	ABC123	AE	456	1	Pneumonia	Pneumonia	Asthma Related	Y	LUNG	LEFT	SEVERE	NONE	2013-05-22	2013-06-08

4.2 Concomitant Medications of Special Interest

Medications are given for asthma to relieve immediate symptoms or to achieve long-term prevention and control of symptoms. There are several kinds of medications used for long-term control of symptoms. These have different risks, so physicians seek to find the least risky combination of medications that will achieve symptom control for a particular subject. This means that control of symptoms is monitored, and treatments are adjusted, as needed, to achieve and maintain control. One of the factors considered in assessing control of asthma is the subject's need to use short-acting bronchodilators for immediate relief of symptoms.

Severity of asthma for subjects under treatment can be judged by the kinds of medication necessary for control.

Medications of interest for asthma include:

- Short-acting medications for relief of symptoms (rescue medications) that increase air flow in the lungs. The bronchodilators most frequently used in asthma are beta-2 agonists.
- Long-acting medications for prevention and control of symptoms (controller medications). These include the following:
 - Corticosteroids (may be administered by inhalation or systemically, with oral corticosteroids used for very severe asthma)
 - Long-acting beta-2 agonists (LABA): The use of LABA as monotherapy is contraindicated due to concerns raised by data suggesting the treatment with LABA alone may increase the risk of death and hospitalization in asthmatic patients. However, inhaled corticosteroids in combination with LABA are very commonly used in the treatment of asthma.
 - Leukotriene modifiers
 - Anti-IgE therapy
 - Anticholinergics
 - Theophylline compounds

Data collected about short-acting bronchodilators can include the following:

- Whether a subject is using any of these drugs.
- Whether a drug is used to treat asthma symptoms
- Which of these drugs the subject is using, with dates of use. Dosing data may be minimal, as these drugs are used as needed.
- Data collected on a daily or twice-daily basis about number of times or amount used; and, since short-acting bronchodilators are taken on an as-needed basis, detailed records of change in use. Bronchodilator use usually needs to be collected separately (e.g. by daily dairy card or e-diary) since concomitant medication eCRFs do not collect these data with sufficient granularity (number of puffs or number of occasions of use per 12- or 24-hour period), particularly when change in medication use is being collected as an efficacy parameter.
- Data collected on drug and amount used in the course of reversibility testing.

Data collected about long-acting medications can include the following:

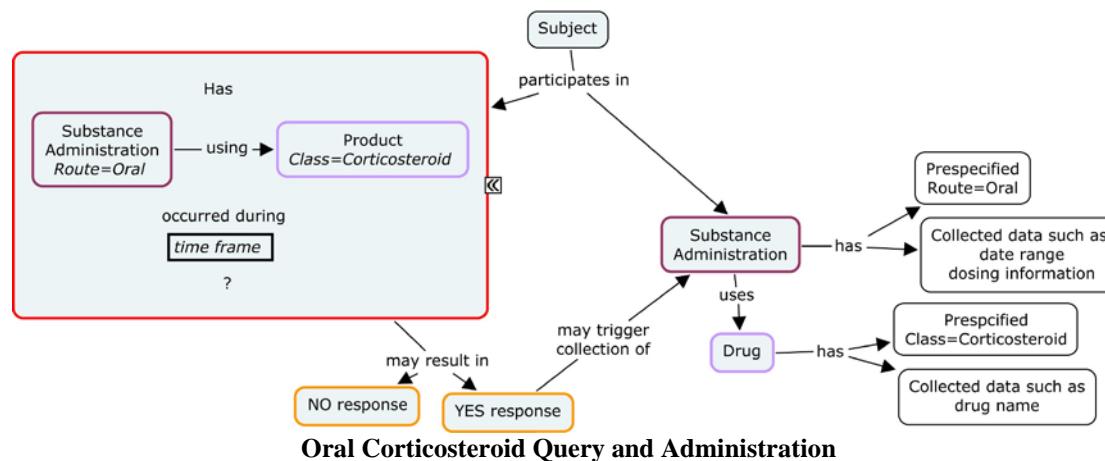
- Whether a subject has used or is using any of a certain kind of drug.
- Whether drug is used to treat asthma symptoms
- Which drugs of a certain kind the subject is using, with drug name, dates of use, and dosing information, including route of administration (e.g., inhaled, oral, or other route).

Past history may include only medications taken at study entry, or may be collected for a specified period prior to study entry to confirm eligibility criteria.

The following examples show queries about specific kinds of medication use which may be included in an asthma study. Whether or not such specific queries are included, standard data on concomitant medications taken during the study would be collected.

Example: Oral Corticosteroids Query and Administration

The concept map below shows a query about oral corticosteroids during a time period. If the answer to the query is “Yes,” then additional information about the oral corticosteroid administration, such as its timing, dosing details, and the drug name, may be collected.



The diagram includes a question (the red box).

Oral corticosteroid query:

The relevant data includes the kind of intervention (oral corticosteroids) and the time period within the query and the response to the query. The kind of intervention and the time period within the question are "hard coded" in the final data. The time period within the question is not specified in the concept map, but could be (1) the subject's lifetime up until their start in the study or (2) the subject's start in the study until their discontinuation from the study. The data to be collected for this kind of research concept includes data about the question and the response:

- Pre-specified question properties:
 - The pre-specified (focal) intervention (in this case, drug class = 'Corticosteroid' and route of administration = 'Oral' is pre-specified.)
 - The focal time period
 - The fact that this question was nested in a category, such as "Asthma Medications", etc.
- Collected question properties:
 - The subject of the question (the subject)
 - When the question was asked (date/time and relative study timing)
 - Possibly, that the question was not asked, and why not
- Collected response properties:
 - The response to the question to the Oral Corticosteroid Query (in this case: Yes, No)
 - Possibly, that although the question was asked, an answer was not recorded, and why not.

Substance administration:

If the question is answered 'Yes', details surrounding subject administration (dark purple box) as well as properties of the drug (light purple box) are collected.

- Pre-specified administration properties:
 - In this case, the route of administration
- Collected administration properties:
 - When the substance was administered (start date/time, end date/time)
 - Possibly, that the administration is ongoing at the time the question was asked
- Pre-specified drug properties:
 - In this case, name of the drug class (corticosteroids)
- Collected drug properties:
 - The drug name
 - Possibly, the WHO Drug term for the substance administered

4.2.1 Additional Assumptions for Concomitant Medications

The SDTMIG provides limited advice for collection of data about concomitant medications. The following draft assumptions were used to populate the examples in this document. These assumptions will be considered for inclusion in a future version of the SDTMIG.

1. Concomitant medication data collection always focuses on a combination of kind of concomitant medication to be recorded and time period for which concomitant medications are to be recorded. The kind of concomitant medication that is the focus of data collection can range from all concomitant medications to a specific named concomitant medication.

2. Collection of data concomitant medications can take one of three forms:
 - a. Collection of details of dosing and timing of medication administrations within the focus of collection.
 - b. The answer to a question asking whether concomitant medication administrations within the focus of collection occurred.
 - c. A combination of the above, i.e., the answer to a question asking whether concomitant medication administrations within the focus of the collection occurred, followed, if the answer is yes, by the recording of details of dosing and timing of medication administrations within the focus of collection. A yes answer could trigger the creation of multiple concomitant medications. For example, if a subject took antibiotics twice a day for 10 days on two separate occasions, there would be two records.
3. Scope of concomitant medications collected
 - a. If collection includes all concomitant medications, then CMCAT is null and PRESP is null.
 - b. If collection focuses on a particular group of medications, then CMCAT is populated with a description of the group of medications. If one group of medications is nested within another group of medications, then both CMCAT and CMSCAT will be populated.
 - i. If the data collection includes an explicit question asking whether any drugs in the group were taken, then the answer to the query is represented by a record where CMTRT is populated with the same description of the group of medications that appears in CMCAT or CMSCAT, whichever is appropriate, and OCCUR is populated with Y or N.
 - ii. If the occurrence question is followed by collection of details of medications in the group that were administered, then each record recording administration a medication in the group has the name of the drug in TRT and OCCUR = Y
 - iii. If the data collection does not include an explicit question asking whether any drugs in the group were taken, then any record of administration of a medication in the group has the name of the drug in TRT and OCCUR = null.
 - c. If collection focuses on a particular named medication, then TRT is populated with the name of the medication and PRESP = Y.
 - i. If collection focused on a particular named medication is nested within a module which focuses on a particular group of medications, then CMCAT is also populated
 - ii. If the data collection includes an explicit question asking whether this medication was taken, then the answer to the query is represented by either a record with OCCUR=N or one or more records with OCCUR=Y.
4. Focal time period of concomitant medication collection
 - a. If collection is focused on concomitant medications taken “during the study” then neither CMEVLINT nor CMEVINTX need be populated. CMDTC also need not be populated
 - i. This is “standard” concomitant medication collection. Collection is usually via a log form, so there is no one date of data collection, which is why CMDTC is not populated.
 - b. For any other focal time period, either EVLINT or EVINTX must be populated.
 - i. If the focal time period is described with EVLINT, then CMDTC must be collected, since EVLINT alone does not specify a focal time period and does not specify a particular focal time period.
 - ii. If the focal time period is described by EVINTX, then whether CMDTC must be populated depends on the value of EVINTX. A value such as “since the last visit” requires the date of this visit to fully describe the time period. A value such as “the first year after diagnosis of Disease X” is independent of the date of data collection.

4.2.2 Examples for Concomitant Medications of Special Interest

Example 1

Data are collected about the use of specific asthma-related prior medications. If a medication was taken, the duration of its use and the stop date are collected. The data were collected in the following CDASH-compliant form:

Prior Medications for Asthma*If yes, please provide:*

Has the subject taken systemic corticosteroids?	No	Yes	Duration _____	End date: DD-MMM-YYYY
Has the subject taken inhaled corticosteroids (ICS)?	No	Yes	Duration _____	End date: DD-MMM-YYYY
Has the subject taken long-acting beta-agonists (LABA)?	No	Yes	Duration _____	End date: DD-MMM-YYYY
Has the subject taken short-acting beta-agonists?	No	Yes	Duration _____	End date: DD-MMM-YYYY
Has the subject taken omalizumab?	No	Yes	Duration _____	End date: DD-MMM-YYYY
Has the subject taken zafirlukast?	No	Yes	Duration _____	End date: DD-MMM-YYYY

Since this CRF module focuses on medications for asthma, SDTM records of data from this CRF module populate CMCAT with ASTHMA MEDICATIONS. The groups of medications described in the first four rows of the CRF are used to populate CMSCAT. The fact that these are prior medications is captured in the data through the use of CMEVINTX=PRIOR, meaning prior to the date of data collection in CMDTC. Note that CMEVINTX indicates the period of time (the period prior to CMDTC) covered by the “occur” question, and is populated even if OCCUR=N. This is different from the CDASH variable CMPRIOR, used to indicate whether a given drug was taken before the study.

- Row 1:** The subject has not taken systemic corticosteroids prior to the start of the trial.
Row 2: The subject has taken inhaled corticosteroids prior to the start of the trial.
Row 3-4: The subject has not taken short or long-acting beta-agonists prior to the start of the trial.
Row 5-6: The subject has taken zafirlukast prior to the start of the trial.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMSCAT
1	ABC-001	CM	ABC-001-1234	1	SYSTEMIC CORTICOSTEROIDS	ASTHMA MEDICATIONS	SYSTEMIC CORTICOSTEROIDS
2	ABC-001	CM	ABC-001-1234	2	INHALED CORTICOSTEROIDS (ICS)	ASTHMA MEDICATIONS	INHALED CORTICOSTEROIDS (ICS)
3	ABC-001	CM	ABC-001-1234	3	LONG-ACTING BETA-AGONISTS (LABA)	ASTHMA MEDICATIONS	LONG-ACTING BETA-AGONISTS (LABA)
4	ABC-001	CM	ABC-001-1234	4	SHORT-ACTING BETA-AGONISTS	ASTHMA MEDICATIONS	SHORT-ACTING BETA-AGONISTS
5	ABC-001	CM	ABC-001-1234	5	OMALIZUMAB	ASTHMA MEDICATIONS	
6	ABC-001	CM	ABC-001-1234	6	ZAFIRLUKAST	ASTHMA MEDICATIONS	

Row	CMPRESP	CMOCCUR	CMDTC	CMENDTC	CMDUR	CMEVINTX
1 (cont)	Y	N	2010-09-15			PRIOR
2 (cont)	Y	Y	2010-09-15	2008	P2M	PRIOR
3 (cont)	Y	N	2010-09-15			PRIOR
4 (cont)	Y	N	2010-09-15			PRIOR
5 (cont)	Y	Y	2010-09-15	2005-09-15	P2Y	PRIOR
6 (cont)	Y	Y	2010-09-15	2009-03	P10M	PRIOR

Example 2

In this example the subject is directed to use albuterol as a rescue medication if needed. Diary data are collected on a twice-daily basis in the morning and the evening. A question is asked in the evening about the amount of medication taken during the day. A question is asked in the morning about the amount of medication taken during the previous night.

Diary collection of short-acting bronchodilator (rescue medication)

EVENING

Did the subject take albuterol during the daytime?

Y N

Total dose during the daytime _____ puffs

MORNING

Did the subject take albuterol during the nighttime?

Y N

Total dose during the nighttime _____ puffs

The two occasions each day on which the diary is completed are represented by the TPT values MORNING and EVENING and the TPTNUM values 1 and 2. The fact that albuterol is a rescue medication is indicated in the dataset by CMCAT=RESCUE MEDICATION. Since there is a specific question about albuterol use, CMPRESP=Y and CMOCCUR is populated. This data collection focuses on evaluation intervals which are described by the combination of the date in CMDTC and an EVINTX value of either DAYTIME or NIGHTTIME. The format in which dosing information is collected, as the total dose during the evaluation interval, is not one which can be expressed with standard SDTM interventions class variables, so the total dose during the evaluation interval has been represented using a supplemental qualifier, TDSEVI. The standard variable CMDOSU can be associated with CMDOSE, CMTOTDOS, or CMDOSTXT, and is used here to hold the unit for the supplemental qualifier. The SDS team is considering the addition of additional dosing variables, so there may be a standard variable for this dosing data reported in this format in the future. DOSU is used to represent the pre-specified unit, PUFFS.

- Row 1:** Shows that the evening query about albuterol use in the daytime was answered with “No”.
- Row 2:** Shows that the morning query about albuterol use in the nighttime was answered with “Yes”. Therefore, the cumulative amount of albuterol taken during the nighttime period was also collected (see suppccm.xpt row 1).
- Row 3:** Shows that the evening query about albuterol use in the daytime was answered with “Yes”. Therefore, the cumulative amount of albuterol taken during the daytime period was also collected (see suppccm.xpt row 2).
- Row 4:** Medication use solicited in diary but was not collected.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMPRESP	CMOCCUR	CMSTAT	CMDOSU	CMDOSFRQ	CMDTC
1	DEF-001	CM	DEF-001-1234	1	ALBUTEROL	RESCUE MEDICATION	Y	N				2010-10-28
2	DEF-001	CM	DEF-001-1234	2	ALBUTEROL	RESCUE MEDICATION	Y	Y		PUFFS	PRN	2010-10-29
3	DEF-001	CM	DEF-001-1234	3	ALBUTEROL	RESCUE MEDICATION	Y	Y		PUFFS	PRN	2010-10-29
4	DEF-001	CM	DEF-001-1234	4	ALBUTEROL	RESCUE MEDICATION	Y		NOT DONE			2010-10-30

Row	CMTPT	CMTPTNUM	CMEVINTX
1 (cont)	EVENING	2	DAYTIME
2 (cont)	MORNING	1	NIGHTTIME
3 (cont)	EVENING	2	DAYTIME
4 (cont)	MORNING	1	NIGHTTIME

suppccm.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	DEF-001	CM	DEF-001-1234	CMSEQ	1	CMTDSEVI	Total Dose in Evaluation Interval	3	CRF	
2	DEF-001	CM	DEF-001-1234	CMSEQ	2	CMTDSEVI	Total Dose in Evaluation Interval	5	CRF	

Example 3

This example is exactly the same as Example 2, except that the data are collected about the number of administrations in the evaluation interval, rather than as the total dose during the evaluation interval.

Diary collection of short-acting bronchodilator (rescue medication)**EVENING**

Did the subject take albuterol during the daytime? Y N
Number of times taken during the daytime _____

MORNING

Did the subject take albuterol during the nighttime? Y N
Number of times taken during the nighttime _____

The dataset for this example is the same as that for Example 2 except that there is supplemental qualifier used to store the number of administrations in the evaluation interval and there are no dose units.

Row 1: Shows that the evening query about albuterol use in the daytime was answered with “No”.

Row 2: Shows that the morning query about albuterol use in the nighttime was answered with “Yes”. Therefore, the cumulative amount of albuterol taken during the nighttime period was also collected (see suppccm.xpt row 1).

Row 3: Shows that the evening query about albuterol use in the daytime was answered with “Yes”. Therefore, the cumulative amount of albuterol taken during the daytime period was also collected (see suppccm.xpt row 2).

Row 4: Medication use solicited in diary but was not collected.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMPRESP	CMOCCUR	CMSTAT	CMDOSFRQ	CMDTC
1	DEF-001	CM	DEF-001-1234	1	ALBUTEROL	RESCUE MEDICATION	Y	N			2010-10-28
2	DEF-001	CM	DEF-001-1234	2	ALBUTEROL	RESCUE MEDICATION	Y	Y		PRN	2010-10-29
3	DEF-001	CM	DEF-001-1234	3	ALBUTEROL	RESCUE MEDICATION	Y	Y		PRN	2010-10-29
4	DEF-001	CM	DEF-001-1234	4	ALBUTEROL	RESCUE MEDICATION	Y		NOT DONE		2010-10-30

Row	CMTPT	CMTPTNUM	CMEVINTX
1 (cont)	EVENING	2	DAYTIME
2 (cont)	MORNING	1	NIGHTTIME
3 (cont)	EVENING	2	DAYTIME
4 (cont)	MORNING	1	NIGHTTIME

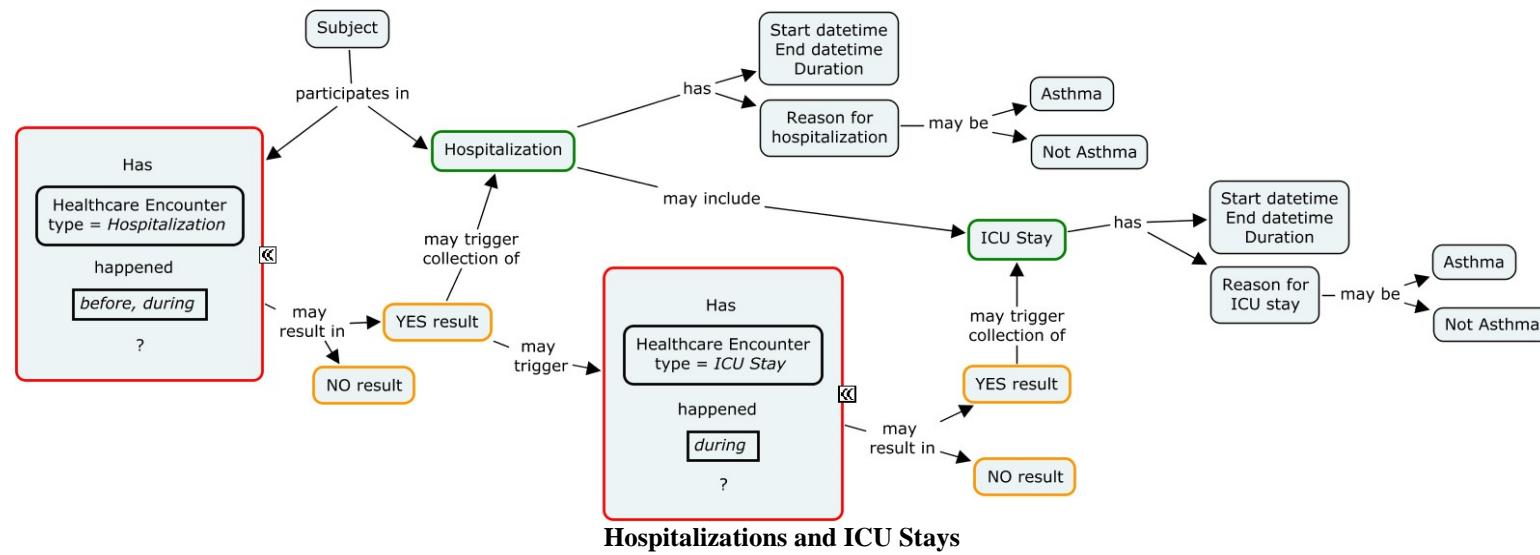
suppccm.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	DEF-001	CM	DEF-001-1234	CMSEQ	1	CMNADEVI	Number of Administration in Evaluation Interval	3	CRF	
2	DEF-001	CM	DEF-001-1234	CMSEQ	2	CMNADEVI	Number of Administration in Evaluation Interval	5	CRF	

4.3 Healthcare Encounters of Special Interest

Asthma studies collect data on healthcare utilization such as hospitalizations and emergency room (ER) visits because these events are a clinically relevant endpoint that are of interest to patients, clinicians, and payers. The frequency and duration of hospitalizations and ER visits can indicate severity of asthma, and are used to identify and assess the severity of asthma exacerbations. Data may also be collected on unscheduled doctor visits for asthma. Data on hospitalizations and ER visits can be complex, but this version of the asthma guide will deal only with the following kinds of observations:

- Whether hospitalizations/ER visits occurred in a focal time period such as the year before study start or during the study.
- The number of hospitalizations/ER visits that occurred in a focal time period such as the year before study start.
- Data about individual hospitalizations/ER visits, including the dates of hospitalization, the duration of time in an ICU, need for intubation, and the reason for hospitalization. The reason for hospitalization/ER visit may be treated simply as Asthma/Not asthma.
- It is also useful to establish guidelines as to when an ER visit should be considered as a hospital stay (e.g. ER visits lasting ≥ 24 hours).



4.3.1 Examples for Healthcare Encounters of Special Interest

These examples use the Healthcare Encounters (HO) domain, which is not final at the time of publication of this document.

Example 1

Data are collected about the occurrence of hospitalizations during the study. If hospitalization occurred, then additional information on the dates, duration in ICU, and whether it is related to asthma are collected. However, no attempt is made to collect potential relationships between HO and AE records. The reason for hospitalization (ASTHMA or NOT ASTHMA) has been represented using a supplemental qualifier, although a proposal to add a standard variable SDTM to collect the reason for an event that is not a medical condition (e.g., not in the AE, MH, or CE domains) is being considered. The data was collected in the following manner:

Hospitalization during the study

Date of assessment: DD-MMM-YYYY

Has the subject been hospitalized? Yes No

If yes, please provide the following:

Date of admission: DD-MMM-YYYY

Date of discharged: DD-MMM-YYYY

Was the hospitalization for asthma? Yes No

Was the subject admitted to the ICU? Yes No

If yes, please provide the following:

Date of admission to ICU: DD-MMM-YYYY

Date of discharge from ICU: DD-MMM-YYYY

Row 1: The subject was not hospitalized.

Rows 2-3: The subject was hospitalized from 2013-04-10 to 2013-04-17 and was in ICU from 2013-04-11 to 2013-04-13. It was not for asthma.

Rows 4-5: The subject was hospitalized but did not spend any time in ICU. This hospitalization was for asthma.

ho.xpt

Row	STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOPRESP	HOOCUR	HOCAT	HOEVLINT	HODTC	HOSTDTC	HOENDTC
1	ABC123	HO	456	1	HOSPITALIZATION	Y	N			2013-05-24		
2	ABC123	HO	789	1	HOSPITALIZATION	Y	Y			2013-05-24	2013-04-10	2013-04-17
3	ABC123	HO	789	2	INTENSIVE CARE UNIT	Y	Y			2013-05-24	2013-04-11	2013-04-13
4	ABC123	HO	345	1	HOSPITALIZATION	Y	Y			2013-05-27	2013-05-01	2013-05-05
5	ABC123	HO	345	2	INTENSIVE CARE UNIT	Y	N			2013-05-27		

suppho.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAME	QLABEL	QVAL	QORIG	QEVAL
1	ABC123	HO	789	HOSEQ	1	HOREAS	Reason for Healthcare Encounter	NOT ASTHMA	CRF	
2	ABC123	HO	345	HOSEQ	1	HOREAS	Reason for Healthcare Encounter	ASTHMA	CRF	

Example 2

Data are collected only about the occurrence of hospitalizations due to asthma in the year prior to participation in the study. Since no data about individual healthcare encounter events is collected, these data are handled as findings about healthcare events, rather than in the HO domain. The data was collected in the following manner:

Asthma-Related Hospitalizations

Date of assessment: DD-MMM-YYYY

Has the subject had any asthma-related hospitalizations in the past year? Yes No

If yes, how many times? _____

Row 1: Subject 456 had no hospitalizations in the prior year.

Row 2: Subject 789 did have hospitalizations in the prior year.

Row 3: Subject 789 had 3 asthma-related hospitalizations in the prior year.

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Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST		FAOBJ	FACAT	FAORRES	FAORRESC	FASTRESN	FADTC	FAEVLINT
1	ABC123	FA	456	1	OCCUR	Occurrence	Hospitalization	ASTHMA-RELATED	N	N		2013-05-24	-P1Y	
2	ABC123	FA	789	2	OCCUR	Occurrence	Hospitalization	ASTHMA-RELATED	Y	Y		2013-05-24	-P1Y	
3	ABC123	FA	789	2	NUMBER	Number of episodes	Hospitalization	ASTHMA-RELATED	3	3	3	2013-05-24	-P1Y	

Appendices

Appendix A: Project Proposal

CFAST is proposing development of v1.0 of the CDISC Asthma therapeutic area data standard. This standard will build on the existing SDTM and related CDASH standards to facilitate the collection and use of data relevant to Asthma clinical trials.

The workgroup proposes developing a CDISC therapeutic area user guide, including concept maps, metadata, examples, and controlled terminology. The standardization effort is expected to focus on the following areas of specific interest to Asthma: efficacy measurements such as pulmonary physiology, biomarkers and Quality of Life questionnaires, asthma symptom assessment, asthma and other medical history, exacerbations including hospitalizations, and concomitant medications and adverse events typical with asthma patients.

The project is planned to begin in Q4 2012, with target completion of the Asthma therapeutic area data standard user guide in Q4 2013.

For more information on Asthma, see: <http://www.who.int/mediacentre/factsheets/fs307/en/>.

Appendix B: CFAST Organizations

Member Organizations:

CDISC

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website.

C-Path

An independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA), C-Path's mission is to improve human health and well-being by developing new technologies and methods to accelerate the development and review of medical products. An international leader in forming collaborations, C-Path has established global, public-private partnerships that currently include 1,000+ scientists from government regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies.

Major Collaborators:

U.S. Food and Drug Administration

The FDA is an agency of the United States Department of Health and Human Services. FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

TransCelerate Biopharma, Inc.

Launched in September 2012, TransCelerate Biopharma Inc. aims to simplify and accelerate the delivery of innovative medicines to patients. With so much progress and so much future opportunity, we have continued to refine our focus. The new statements below reflect our organization's continued commitment:

National Cancer Institute Enterprise Vocabulary Services

Since 1997, NCI Enterprise Vocabulary Services (EVS) has provided terminology content, tools, and services to accurately code, analyze and share cancer and biomedical research, clinical and public health information. EVS works with many partners to develop, license and publish terminology, jointly develop software tools, and support harmonization and shared standards. EVS provides the foundational layer for NCI's informatics infrastructure, and plays an important role in federal and international standards efforts.

Appendix C: Workgroup

Name	Institution/Organization
Rhonda Facile, Team Leader	CDISC
Sharon Broderick	Boehringer Ingelheim
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Chris Price	Roche
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Pam Rinaldi	Boehringer Ingelheim
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Rosemary Watt	Johnson & Johnson
Brittny Weather	Johnson & Johnson
Diane Wold	Glaxo Smith Kline
Ron Fitzmartin	FDA Liaison
Xu Wang	FDA
Feng Zhou, M.D.	FDA

Appendix D: Glossary and Abbreviations

ADaM	Analysis Data Model
ATS/ERS	American Thoracic Society/European Respiratory Society
BRIDG	Biomedical Research Integrated Domain Group
BAC	Bronchial Allergen Challenge
BAL	Bronchoalveolar Lavage
CDASH	Clinical Data Acquisition Standards Harmonization Project. The name for the project that delivers basic data collection fields.
CDISC	Clinical Data Interchange Standards Consortium, a Collaborative Group Member
CFAST	Coalition for Accelerating Standards and Therapies
Collected	“Collected” refers to information that is recorded and/or transmitted to the sponsor. This includes data entered by the site on CRFs/eCRFs as well as vendor data such as core lab data. This term is a synonym for “captured”.
Controlled Terminology	A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. A codelist is one type of controlled terminology.
CRF	Case Report Form (sometimes called a Case Record Form). A printed, optical, or electronic document designed to record all required information to be reported to the sponsor for each trial subject.
Domain	A collection of observations with a topic-specific commonality about a subject.
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
ER	Emergency Room. Also called an Emergency Department (ED).
FeNO	Fractional Exhaled Nitric Oxide. The formal abbreviation is FE_{NO} .
FEV1	Forced Expiratory Volume in first second. The formal abbreviation is FEV_1 .
Foundational Standards	“Foundational standards” is the term used to refer to the suite of CDISC standards that describe the clinical study protocol (Protocol), design (Study Design), data collection (CDASH), laboratory work (Lab), analysis (ADaM), and data tabulation (SDTM and SEND). See http://www.cdisc.org/ for more information on each of these clinical data standards.
FVC	Full Volume Capacity
ICU	Intensive Care Unit
IgE	Immunoglobulin E
LABA	Long acting β agonist
MedDRA	Medical Dictionary for Regulatory Activities. New global standard medical terminology designed to supersede other terminologies (such as COSTART and ICD9) used in the medical product development process.
NCI EVS	National Cancer Institute (NCI) Enterprise Vocabulary Services
NIH	National Institutes of Health
Patient	A recipient of medical attention.
PEF	Peak Expiratory Flow
PFT	Pulmonary Function Test
PRO	Patient Reported Outcome
QoL	Quality of Life
SDS	Submission Data Standards. Also the name of the team that created the SDTM and SDTMIG
SDTM	Study Data Tabulation Model
SDTMIG	SDTM Implementation Guide (for Human Clinical Trials)
SABA	Short acting β agonist
SHARE	CDISC’s metadata repository that is currently under development.
Subject	A participant in a study.
UC	Urgent Care
UG	User Guide
UML	Unified Modeling Language

Appendix E: Questionnaires

The following questionnaires have been determined to be of interest to asthma.

Full Name and Abbreviation	Status of Permission to develop controlled terminology	Status of controlled terminology
Asthma Control Questionnaire ACQ	Permission denied	Terminology will not be developed.
Asthma Control Test ACT	Under discussion	
Asthma Quality of Life Questionnaire AQLQ	Permission denied	Terminology will not be developed.
Airway Questionnaire 20 AQ20	Permission received	Terminology will be developed.
Baseline and Transition Dyspnea Indexes BDI / TDI	Permission received	Terminology in Package 14 (release date 28Jun2013)
Borg Scale of Peak Dyspnea Borg CR-10 Scale Questionnaire BORG-CR-10	Permission requested	
Modified Medical Research Council Dyspnea Questionnaire MMRC	Public Domain	Terminology in Package 14 (release date 28Jun2013)
Short Form -36 SF-36	Under discussion	
St. George's Respiratory Questionnaire SGRQ	Permission received	Terminology will be developed.
Work productivity and activity impairment - Asthma version WPAI - Asthma	Public Domain	Terminology will be developed.

Further information on CDISC supplements and controlled terminology for questionnaires can be found at <http://www.cdisc.org/content2909>.

Appendix F: Prototype SHARE Metadata

SHARE metadata are will be a new CDISC deliverable once the SHARE metadata repository, currently in development, is released for full production use. In this first version of the Asthma user guide, examples of prototype metadata are represented in spreadsheets as supplemental information since the SHARE metadata repository is still in development is not yet available. These metadata are a sample subset of the metadata to be ultimately provided by SHARE. In their current form, they provide metadata needed to construct define files, including value-level metadata. This is a first step toward producing more robust and complete metadata study specifications via SHARE. A study specification initiated at the time of protocol writing will enable automation of processes such as eCRF development, database specification, and analysis dataset creation.

The prototype SHARE metadata for a concept provides:

- Representation of the properties of the concept in terms of BRIDG class, class attribute, the complex datatype of the class attribute, and a component of the complex datatype.
- For properties which use controlled terminology, a list of relevant controlled terminology values, e.g., units relevant for representing the test result value.
- Representation of the properties of the concept in SDTM. This includes the SDTM variable(s) in which a concept property is stored, the domain, and, where relevant, TEST and TESTCD values.
- Other concepts which may or must be associated with the concept, e.g., specimen(s) on which a test may be performed or device(s) which may be used to perform the test.

Each workbook includes two introductory sheets which describe the contents of the workbook and the layout of the individual spreadsheets. One spreadsheet, labeled “Template” includes all the BRIDG-based concept properties used in the rest of the workbook. The remaining spreadsheets hold metadata for one concept or type of concept.

The spreadsheets in the Pulmonary Function Test workbook all represent specific concepts (individual tests). However, many of the spreadsheets in other workbooks represent a type of concept. For example, in the Symptom Assessment workbook, the Symptom OCCUR spreadsheet is a generic concept, which would be tailored for use in a study by substituting a particular symptom where the spreadsheet has the value “<pre-specified>”. The same workbook also contains an even more generic worksheet, which shows the general structure for a finding about a symptom which has a coded response. This structure would be used for a test such as the example in the UG which assesses the impact of wheezing on the subject’s sleep.

The prototype metadata provided in the spreadsheets associated with this UG do not represent the full range of metadata that will be available in the SHARE metadata repository. Metadata are not provided for all concepts described in the UG. SHARE metadata for laboratory data are being developed by the Controlled Terminology Lab sub-team. SHARE metadata for questionnaires is dependent on the development of controlled terminology, which in turn is dependent on permission to develop the terminology.

Metadata Display Workbook	Worksheet	Concept Description
Medical History	OCCUR MH TERM	Pre-specified medical history query
Medical History	PRESP MH TERM	Pre-specified medical history collection
Medical History	MH LOG	Collection of details of medical history
Allergen Skin Tests	Wheal Diam	Diameter of wheal formed in response to administration of allergen to the skin
Allergen Skin Tests	Wheal SQ	Semi-quantitative diameter of wheal formed in response to administration of allergen to the skin
Allergen Skin Tests	Skin Index	The ratio of allergen weal diameter divided by the histamine wheal size
Allergen Skin Tests	Flare SQ	Semi-quantitative assessment of extent of flare in response to administration of allergen to the skin
Allergen Skin Tests	Wheal POSNEG	Classification of the result as negative or positive based on a threshold wheal size

Metadata Display Workbook	Worksheet	Concept Description
Allergen Skin Tests	Wheal-Flare SQ	Semi-quantitative interpretation based a combination of the wheal diameter and flare
Pulmonary Function Tests	FVC	Forced Vital Capacity
Pulmonary Function Tests	PPFVC	Percent Predicted Forced Vital Capacity
Pulmonary Function Tests	FEV1	Forced Expiratory Volume in first second
Pulmonary Function Tests	PPFEV1	Percent Predicted Forced Expiratory Volume in first second
Pulmonary Function Tests	FEV1_FVC	Ratio of FEV1 to FVC
Pulmonary Function Tests	FEF25_75	Forced Expiratory Flow at 25% - 75% of Vital Capacity
Pulmonary Function Tests	PPFEF	Percent Predicted Forced Expiratory Flow at 25% - 75% of Vital Capacity
Pulmonary Function Tests	PEF	Peak Expiratory Flow
Pulmonary Function Tests	PPPEF	Percent Predicted Peak Expiratory Flow
Symptom Assessment	Symptom OCCUR	Did <pre-specified symptom> occur in evaluation interval?
Symptom Assessment	PRESP Symptom	Collect details of <pre-specified symptom>
Symptom Assessment	FA Symptom	Findings about <pre-specified symptom>
Adverse Events	AE OCCUR	Did <pre-specified> adverse event occur?
Adverse Events	PRESP AE	Collection of details of <pre-specified> adverse event
Adverse Events	LOG AE	Collection of details of adverse events
Concomitant Medications	OCCUR CM TRT	Did administration of <pre-specified medication> occur in evaluation interval?
Concomitant Medications	PRESP CM TRT	Details of administrations of <pre-specified medication> in evaluation interval
Concomitant Medications	OCCUR CM Group	Did <administrations of pre-specified type> occur in evaluation interval?
Concomitant Medications	PRESP CM Group	Details of <administrations of pre-specified type> in evaluation interval
Concomitant Medications	CM LOG	Collection of details of concomitant medications
Healthcare Encounters	HO OCCUR	Did <pre-specified> healthcare encounter occur?
Healthcare Encounters	HO NUMBER	How many <pre-specified type of healthcare encounter> occurred in <evaluation interval>?
Healthcare Encounters	PRESP HO	Collection of details of <pre-specified> healthcare encounter
Healthcare Encounters	LOG HO	Collection of details of healthcare encounters

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Appendix G2: Figures

The following figures have been reproduced, with permission:

<u>Figure 3.1.1.1</u>	eResearchTechnology, Inc.
Sample Peak Flow Meter Report	http://www.ert.com
<u>Figure 3.1.2.2-1</u>	eResearchTechnology, Inc. (email, April 4, 2013)
Sample Spirometry Report 1	http://www.ert.com
<u>Figure 3.1.2.2-2</u>	eResearchTechnology, Inc. (email, March 21, 2013)
Sample Spirometry Report 2	http://www.ert.com
<u>Figure 3.1.5</u>	GINA (email, June 28, 2013)
Measuring Airway Responsiveness	Global Initiative for Asthma (GINA). <i>Global Strategy for Asthma Management and Prevention</i> . 2012. Available at: http://www.ginasthma.org/documents/4
<u>Figure 3.3</u>	Zuzana Diamant (email, July 1, 2013)
Allergic Airway Response	Diamant Z, Boot JD, Mantzouranis E, Flohr R, Sterk PJ, Gerth van wijk R. Biomarkers in asthma and allergic rhinitis. <i>Pulm Pharmacol Ther.</i> 2010;23(6):468-81. doi: 10.1016/j.pupt.2010.06.006

Appendix G3: Further Reading

The following works are of interest to this document, but not actively referenced within it.

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Appendix H: Representations and Warranties, Limitations of Liability, and Disclaimers

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6 Domain Models Based on the General Observation Classes

6.1 Interventions

AG – Procedure Agents

Some tests involve administration of substances, and it has been unclear what domain these should be stored in. The Concomitant Medications domain seemed particularly inappropriate when the substance was one that would never been given as a medication. Even substances that are medications are not being used as such when they are given as part of a testing procedure. The Exposure domain also seemed inappropriate, since although the testing procedure might be part of the study plan, these data would not be used or analyzed in the same way as data about study treatments. The Procedure Agents domain was created to fill this gap. The Procedure Agents domain has advantages over the draft Procedures domain for this purpose. It allows recording of multiple substance administrations for a single testing procedure. It also separates data about substance administrations from data about procedures which do not involve substance administration.

AG – Description/Overview for Procedure Agents Domain Model

The Procedure Agents domain is a draft domain at the time of this publication. No CDISC controlled terminology definition exists for the domain yet.

Both the provisional Procedures domain and this draft Procedure Agents domain allow collection of doses administered during a procedure, and discussions are ongoing to provide guidance on deciding what data should be stored in which domain. The draft Procedure Agents domain can be used to provide data on several substance administrations within the same procedure, as shown in Example 2 below.

AG – Specification for Procedure Agents Domain Model

ag.xpt, Procedure Agents — Interventions, Version 3.x.x. One record per recorded intervention occurrence per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	AG	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
AGSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
AGGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm

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AGSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.	Perm
AGTRT	Reported Agent Name	Char		Topic	Verbatim medication name that is either pre-printed or collected on a CRF.	Req
AGMODIFY	Modified Reported Name	Char		Synonym Qualifier	If AGTRT is modified to facilitate coding, then AGMODIFY will contain the modified text.	Perm
AGDECOD	Standardized Agent Name	Char	*	Synonym Qualifier	Standardized or dictionary-derived text description of AGTRT or AGMODIFY. Equivalent to the generic medication name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes. If an intervention term does not have a decode value in the dictionary then AGDECOD will be left blank.	Perm
AGCAT	Category for Agent	Char	*	Grouping Qualifier	Used to define a category of agent. Examples: CHALLENGE AGENT, or PET TRACER.	Perm
AGSCAT	Subcategory for Agent	Char	*	Grouping Qualifier	Further categorization of agent.	Perm
AGPRESP	AG Pre-Specified	Char	(NY)	Record Qualifier	Used to indicate whether (Y/null) information about the use of a specific agent was solicited on the CRF.	Perm
AGOCCUR	AG Occurrence	Char	(NY)	Record Qualifier	When the use of specific agent is solicited, AGOCCUR is used to indicate whether or not (Y/N) use of the agent occurred. Values are null for agents not specifically solicited.	Perm
AGSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question about a pre-specified agent was not answered. Should be null or have a value of NOT DONE.	Perm
AGREASND	Reason Test Not Performed	Char		Record Qualifier	Describes the reason procedure agent was not collected. Used in conjunction with AGSTAT when value is NOT DONE.	Perm
AGCLAS	Agent Class	Char	*	Variable Qualifier	Drug class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow assumption 4.1.2.8.3 or omit AGCLAS.	Perm
AGCLASCD	Agent Class Code	Char	*	Variable Qualifier	Class code corresponding to AGCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then follow assumption 4.1.2.8.3 or omit AGCLASCD.	Perm
AGDOSE	Dose per Administration	Num		Record Qualifier	Amount of AGTRT taken.	Perm
AGDOSTXT	Dose Description	Char		Record Qualifier	Dosing amounts or a range of dosing information collected in text form. Units may be stored in AGDOSU. Example: 200-400, 15-20.	Perm
AGDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for AGDOSE and AGDOSTXT. Examples: ng, mg, or mg/kg.	Perm
AGDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for AGTRT. Examples: TABLET, AREOSOL.	Perm
AGDOSFRQ	Doing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of AGDOSE within a specific time period. Example: ONCE	Perm
AGROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for AGTRT. Examples: ORAL.	Perm

SDTMIG Draft Domain: Procedure Agents (AG)

VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
AGSTDTC	Start Date/Time of Agent	Char	ISO 8601	Timing		Perm
AGENDTC	End Date/Time of Agent	Char	ISO 8601	Timing		Perm
AGSTDY	Study Day of Start of Agent	Num		Timing	Study day of start of agent relative to the sponsor-defined RFSTDTC.	Perm
AGENDY	Study Day of End of Agent	Num		Timing	Study day of end of agent relative to the sponsor-defined RFSTDTC.	Perm
AGDUR	Duration of Agent	Char	ISO 8601	Timing	Collected duration for an agent episode. Used only if collected on the CRF and not derived from start and end date/times.	Perm
AGSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the agent relative to sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into AGSTRF.	Perm
AGENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the agent relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into AGENRF.	Perm
AGSTRPT	Start Relative to Reference Time Point	Char	BEFORE, COINCIDENT, AFTER, U	Timing	Identifies the start of the agent as being before or after the reference time point defined by variable AGSTTPT.	Perm
AGSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by AGSTRPT. Examples: "2003-12-15" or "VISIT 1".	Perm
AGENRPT	End Relative to Reference Time Point	Char	BEFORE, COINCIDENT, AFTER, ONGOING, U	Timing	Identifies the end of the agent as being before or after the reference time point defined by variable AGENTPT.	Perm
AGENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by AGENRPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

AG – Assumptions for Procedure Agents Domain Model

1. AG Definition and Structure
 - a. CRF data that captures the agents administered to the subject as part of a procedure or assessment as opposed to drugs, medications and therapies administered with therapeutic intent. An example is a short-acting bronchodilator administered as part of a reversibility assessment. Other examples of substance administrations that could be submitted in this domain include contrast agents and radio labeled substances used in imaging studies. Discussions are ongoing on the handling of radiation (e.g., x-rays or visible light) in SDTM interventions domains.

SDTMIG Draft Domain: Procedure Agents (AG)

- b. The structure of the AG domain is one record per agent intervention episode, or pre-specified agent assessment per subject. It is the sponsor's responsibility to define an intervention episode. This definition may vary based on the sponsor's requirements for review and analysis.
2. Procedure Agent Description and Coding
 - a. AGTRT captures the name of the agent and it is the topic variable. It is a required variable and must have a value. AGTRT should include only the agent name, and should not include dosage, formulation, or other qualifying information. For example, ALBUTEROL 2 PUFF is not a valid value for AGTRT. This example should be expressed as AGTRT = ALBUTEROL, AGDOSE = 2, AGDOSU = PUFF, and AGDOSFRM = AEROSOL
 - b. AGMODIFY should be included if the sponsor's procedure permits modification of a verbatim term for coding.
 - c. AGDECOD is the standardized agent term derived by the sponsor from the coding dictionary. It is possible that the reported term (AGTRT) or the modified term (AGMODIFY) can be coded using a standard dictionary. In this instance the sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.
3. Pre-specified Terms; Presence or Absence of Procedure Agents
 - a. AGPRESP is used to indicate whether an agent was pre-specified.
 - b. AGOCCUR is used to indicate whether a pre-specified agent was used. A value of Y indicates that the agent was used and N indicates that it was not.
 - c. If an agent was not pre-specified the value of AGOCCUR should be null. AGPRESP and AGOCCUR are permissible fields and may be omitted from the dataset if all agents were collected as free text. Values of AGOCCUR may also be null for pre-specified agents if no Y/N response was collected; in this case, AGSTAT = NOT DONE, and AGREASND could be used to describe the reason the answer was missing.
4. Additional Permissible Interventions Qualifiers
 - a. The variables --INDC, --DOSTOT, and --DOSRGM from the Interventions general observation class would not generally be used in the AG domain because AG should only contain agents used as part of a procedure or an assessment.
 - b. Other additional Qualifiers from the SDTM Interventions Class may be added to this domain.

AG – Examples for Procedure Agents Domain Model

Example 1

This example shows the administration of a procedure agent administered as part of a reversibility assessment with the associated spirometer results, as well as the spirometry measurements (RE domain) obtained before and after agent administration. Depending on the study design, the route of bronchodilator administration (via meter dose inhaler (MDI) or nebulizer) and dose per actuation (puff) or nebulule may also be collected.

Reversibility Assessment

Date of assessment: DD-MMM-YYYY

Was the subject administered a short-acting bronchodilator in the previous 4 hours? Yes No

Pre-Bronchodilator Spirometry (5 Minutes before Albuterol Dosing)

Time of Assessment: HH:MM

Forced Expiratory Volume in 1 Second (FEV1) Result: _____ L

Albuterol Administration

Was the subject administered Albuterol? Yes No

Time of Assessment: HH:MM

Number of Puffs administered: _____

SDTMIG Draft Domain: Procedure Agents (AG)

Post-Bronchodilator Spirometry (20 Minutes after Albuterol Dosing)

Time of Assessment: HH:MM

Forced Expiratory Volume in 1 Second (FEV1) Result: _____ L

Percentage Reversibility: _____ %

Row 1: Shows the administration data of an agent (Albuterol) which was pre-specified on the CRF as part of the reversibility procedure.

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRESP	AGOCUR	AGDOSE	AGDOSU	AGDOSFRM	AGDOSFRQ	AGRROUTE	VISIT	AGSTDTC
1	XYZ	AG	XYZ-001-001	1	ALBUTEROL	Y	Y	2	PUFF	AEROSOL	ONCE	ORAL	VISIT 2	2013-06-18T10:05

Row 1: Shows the record where the question as to whether a short-acting bronchodilator was administered in the 4 hours prior to the reversibility assessment. A short-acting bronchodilator administered prior to the reversibility test, is used with therapeutic intent so is tabulated in the CM domain. Note that AGTRT has been populated with a description of a kind of medication rather than a single medication.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMPRESP	CMOCCUR	CMEVLINT
1	XYZ	CM	XYZ-001-001	1	SHORT-ACTING BRONCHODILATOR	Y	N	-PT4H

Row 1: Shows the data in original and standardized units of measure in REORRES, RESTRESC and RESTRESN for FEV1 of a pre-bronchodilator-administration spirometry test performed as part of a reversibility assessment with the associated timing reference variables RETPT, RETPTNUM, REELTM, RETPTREF, and RERFTDTC. This test was performed 5 minutes before the bronchodilator challenge.

Row 2: Shows the data in original and standardized units of measure in REORRES, RESTRESC and RESTRESN for FEV1 of a post-bronchodilator-administration spirometry test performed as part of a reversibility assessment with the associated timing reference variables RETPT, RETPTNUM, REELTM, RETPTREF, and RERFTDTC. This test was performed 20 minutes after the bronchodilator challenge.

Row 3: Shows the data in original and standardized units of measure in REORRES, RESTRESC and RESTRESN for the percentage reversibility where this is collected.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	REGRPID	RETESTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN
1	XYZ	RE	XYZ-001-001	ABC001	1	1	FEV1	Forced Expiratory Volume in 1 Second	2.43	L	2.43	2.43
2	XYZ	RE	XYZ-001-001	ABC001	2	1	FEV1	Forced Expiratory Volume in 1 Second	2.77	L	2.77	2.77
3	XYZ	RE	XYZ-001-001	ABC001	3	1	PCTREV	Percentage Reversibility	13.99	%	13.99	13.99

Row	RESTRESU	VISIT	REDTCT	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC
1 (cont)	L	VISIT 2	2013-06-18T10:00	PRE-BRONCHODILATOR ADMINISTRATION	1	-PT5M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
2 (cont)	L	VISIT 2	2013-06-18T10:25	POST-BRONCHODILATOR ADMINISTRATION	2	PT20M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
3 (cont)	%	VISIT 2	2013-06-18T10:25				BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05

SDTMIG Draft Domain: Procedure Agents (AG)

Row 1: Shows the device type that was used for the pulmonary function tests as part of the reversibility procedure.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER

Rows 1-3: Shows the relationship of the test agent to the spirometry measurements obtained before and after its administration and to the prior occurrence of short acting bronchodilator administration.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYP	RELID
1	XYZ	AG	XYZ-001-001	AGSEQ	1		1
2	XYZ	RE	XYZ-001-001	REGRPID	1		1
3	XYZ	CM	XYZ-001-001	CMSEQ	1		1

Example 2

This example captures data about the allergen used by the subject as part of a bronchial allergen challenge (BAC) test. Initially, the subject had a skin prick allergen test to help identify the allergen to be used for the BAC test. The allergens tested were cat dander, house dust mite, and grass. For this subject, grass provided the largest skin test reaction and was the allergen chosen to be used in the BAC test. A predetermined set of ascending doses of the chosen allergen are used in the screening BAC test. The results of the screening BAC are used to choose the allergen dose that will be used in subsequent BAC tests (not shown).

Allergen Used?	Inhalation End Time	Allergen Concentration	Time of	
			FEV1	FEV1 (L)
<input type="checkbox"/> Cat Dander	____:____	Saline=0	0	____:____
<input type="checkbox"/> House Dust Mites	____:____	Dose1	250	____:____
<input type="checkbox"/> Grass	____:____	Dose2	1000	____:____
	____:____	Dose3	2000	____:____

Rows 1-3: Correspond to the first part of the CRF. The skin response results corresponding to these allergen administrations were used to choose grass as the allergen for the BAC.

Rows 4: The first dose given in the BAC was saline.

Rows 5-6: Three successively higher doses of grass allergen were given.

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRESP	AGOCCUR	AGDOSE	AGDOSU	AGROUTE	VISIT	AGENDTC
1	XYZ	AG	XYZ-001-001	1	CAT DANDER	Y	N			INTRAEPIDERMAL	SCREENING	2010-10-31
2	XYZ	AG	XYZ-001-001	1	HOUSE MITE DUST	Y	N			INTRAEPIDERMAL	SCREENING	2010-10-31
2	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y			INTRAEPIDERMAL	SCREENING	2010-10-31
3	XYZ	AG	XYZ-001-001	1	SALINE	Y	Y	0	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T10:56:00
4	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y	250	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T11:19:00
5	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y	1000	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T11:43:00
6	XYZ	AG	XYZ-001-001	1	GRASS	Y	Y	2000	SQ-u/mL	RESPIRATORY (INHALATION)	SCREENING	2010-11-07T12:06:00

6 Domain Models Based on the General Observation Classes

6.3 Findings

RE – Respiratory System Findings

RE – Description/Overview for Respiratory System Findings Domain Model

A domain for physiological findings related to the respiratory system, including the organs that are involved in breathing such as the nose, throat, larynx, trachea, bronchi and lungs.

The Respiratory System Findings domain is a draft domain at the time of this publication. Note also that REORREF, RESTREFN, and REIRESFL are new variables. REORREF and RESTREFN are needed because pulmonary function test results are compared to a single predicted normal value rather than to a normal range. The idea of a single reference result was introduced in the Virology User Guide. REIRESFL indicates that the result may be problematic. A flag indicating the presence of such problems rather than a variable with a value describing the problem was chosen because a test with a questionable result often has multiple problems.

RE – Specification for Respiratory System Findings Domain Model

re.xpt, Respiratory Physiology — Findings, Version 3.x.x, One record per finding or result per time point per visit per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	RE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for a device	Perm
RESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
REGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
REREFID	Reference ID	Char		Identifier	Internal or external procedure identifier.	Perm

SDTMIG Draft Domain: Respiratory System Findings (RE)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.	Perm
RETESTCD	Test or Examination Short Name	Char	(RETESTCD)	Topic	Short name of the measurement, test, or examination described in RETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in RETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). RETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: FEV1, FVC	Req
RETEST	Test or Examination Name	Char	(RETEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in RETEST cannot be longer than 40 characters. Examples: Forced Expiratory Volume in 1 Second, Forced Vital Capacity	Req
RECAT	Category for Test	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
RESCAT	Subcategory for Test	Char	*	Grouping Qualifier	A further categorization.	Perm
REPOS	Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm
REORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the procedure measurement or finding as originally received or collected.	Exp
REORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for REORRES and REORREF.	Perm
REORREF	Reference Result in Original Units	Char		Variable Qualifier	Reference result for continuous measurements in original units. Should be populated only for continuous results.	Perm
RESTRESC	Character Result/Finding in Std Format	Char	*	Result Qualifier	Contains the result value for all findings, copied or derived from REORRES in a standard format or standard units. RESTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in RESTRESN.	Exp
RESTRESN	Numeric Result/Finding in Std Format	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from RESTRESC. RESTRESN should store all numeric test results or findings.	Perm
RESTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for RESTRESC, RESTRESN and RESTREFN.	Perm
RESTREFN	Reference Result in Standard Units	Num		Variable Qualifier	Reference result for continuous measurements in standard units. Should be populated only for continuous results.	Perm
RESTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in REORRES.	Perm
REREASND	Reason Test Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with RESTAT when value is NOT DONE.	Perm

SDTMIG Draft Domain: Respiratory System Findings (RE)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RELOC	Location Used for Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement. Example: 'LUNG', 'BRONCHUS'	Perm
RELAT	Laterality	Char	(LAT)	Record Qualifier	Side of the body used to collect measurement. Examples: RIGHT, LEFT, BILATERAL, UNILATERAL	Perm
REDIR	Directionality	Char	(DIR)	Record Qualifier	Directionality to indicate where on the body the collection was taken. Examples: PROXIMAL, DISTAL, ANTERIOR	Perm
REMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method used to create the result.	Perm
REBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
REDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records, or that do not come from the CRF, or are not as originally collected or received are examples of records that would be derived for the submission datasets. If REDRVFL=Y, then REORRES could be null, with RESTRESC, and (if numeric) RESTRESN having the derived value.	Perm
REEVAL	Evaluator	Char	*	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE.	Perm
REIRESFL	Inadequate Results Flag	Char	(NY)	Record Qualifier	Used to indicate that a result is not considered acceptable/adequate according to the assessment protocol. The value should be Y or null. If additional qualification of the result is collected then this could be recorded in a Supplemental Qualifier variable.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
REDTA	Date/Time of Test	Char		Timing	Date/Time of procedure or test.	Exp
REDY	Study Day of Test	Num	ISO 8601	Timing	1. Study day of the procedure or test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
RETPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See RETPTNUM and RETPTREF. Examples: Start, 5 min post.	Perm
RETPTNUM	Planned Time Point Number	Num		Timing	Numerical version of RETPT to aid in sorting.	Perm
REELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (RETPTREF). Not a clock time or a date time variable. Represented as an ISO	Perm

SDTMIG Draft Domain: Respiratory System Findings (RE)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by RETPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by RETPTREF.	
RETPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by REELTM, RETPTNUM, and RETPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
RERFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, RETPTREF.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

RE – Assumptions for Respiratory System Findings Domain Model

1. RE Definition: This domain has been designed to store data on respiratory physiological findings that include information relating to the lungs and airways, including the nose, throat, larynx, trachea, and bronchi, such as forced expiratory volume in one second (FEV1) and forced vital capacity (FVC).
2. This domain holds the results/findings of a respiratory diagnostic procedure. Information about the conduct of the procedure(s), if collected, should be submitted in the Procedures (PR) domain. Data describing structural measurements or assessments of the lungs should be reported in the Morphology (MO) domain.
3. SPDEVID provides a consistent variable for linking data across Device domains, independent of the level of granularity by which a device might be identified by a sponsor in a study. SPDEVID is a mechanism for aggregating any number of identifiers into one, allowing for a consistent structure for identifying all devices. SPDEVID is a surrogate identifier that represents all the characteristics of a device in the Study Device Identifier (DI) domain, and is also a simple, short identifier that can appear in each dataset.

RE – Examples for Respiratory System Findings Domain Model

Example 1

This example shows results from several spirometry tests using either a spirometer or a peak flow meter where only the best result is available.

The Device Identifiers (DI) domain contains the total set of characteristics necessary for device identification, and the Device Properties (DO) domain contains information important for submission but that are not part of the device identifier.

Because the original and standardized units of measure are identical in this example, RESTRESC, RESTRESN, RESTRESU, and RESTREFN are not shown. Instead, an ellipsis marks their place in the dataset.

- Rows 1-2:** Show the data in original units of measure in REORRES for the best result for spirometry tests with the predicted values in REORREF.
- Rows 3-4:** Show the data in original units of measure in REORRES of percent predicted tests as output by the spirometer device. REORREF is null as there are no reference results for percent predicted tests.
- Row 5:** Shows the data in original units of measure in REORRES for the peak flow test with the predicted values in REORREF.

SDTMIG Draft Domain: Respiratory System Findings (RE)

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF	...	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	2.73	L	3.37	...	2	VISIT 2	2013-06-30
2	XYZ	RE	XYZ-001-001	ABC001	2	FVC	Forced Vital Capacity	3.91	L	3.86	...	2	VISIT 2	2013-06-30
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1PP	Percent Predicted FEV1	81	%	2	VISIT 2	2013-06-30
4	XYZ	RE	XYZ-001-001	ABC001	4	FVCPP	Percent Predicted FVC	101.3	%	2	VISIT 2	2013-06-30
5	XYZ	RE	XYZ-001-001	DEF999	5	PEF	Peak Expiratory Flow	6.11	L/s	7.33	...	4	VISIT 4	2013-07-17

Rows 1-2: Show the device type that was used to perform for the pulmonary function tests

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER
2	XYZ	DI	DEF999	1	TYPE	Device Type	PEAK FLOW METER

Row 1: Displays the record the reference equation used by the spirometer device.

Row 2: Displays the record the reference equation used by the peak flow meter device.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	XYZ	DU		ABC001	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III
2	XYZ	DU		DEF999	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III

Example 2

This example shows results from several spirometry tests using a spirometer where both the best result and individual results are available. The best result has been flagged using a supplemental qualifier.

Because the original and standardized units of measure are identical in this example, RESTRESC, RESTRESN, and RESTRESU are not shown. Instead, an ellipsis marks their place in the dataset.

- Rows 1-3:** Show the data in original and standardized units of individual test results for FEV1 as measured by spirometry. The absence of a flag in REIRESFL indicates that the data were adequate.
- Row 4:** Shows the data in original and standardized units of an individual test result for FEV1 as measured by spirometry. The presence of a flag in REIRESFL indicates that the data were inadequate. SUPPRE.xpt contains two reasons why this was the case.
- Row 5:** Shows the data in original and standardized units of the best test result for FEV1 as measured by spirometry.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REIRESFL	VISITNUM	VISIT	REDTC	
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	1.94	L	...	2	VISIT 2	2013-04-23	
2	XYZ	RE	XYZ-001-001	ABC001	2	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	...	2	VISIT 2	2013-04-23	
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	...	2	VISIT 2	2013-04-23	
4	XYZ	RE	XYZ-001-001	ABC001	4	FEV1	Forced Expiratory Volume in 1 Second	1.57	L	...	Y	2	VISIT 2	2013-04-23

SDTMIG Draft Domain: Respiratory System Findings (RE)

- Row 1:** Shows that the record in the RE dataset with RESEQ value of 1 has a supplemental qualifier indicating that this is the best result.
- Rows 2-3:** Show that the record in the RE dataset with RESEQ value of 4 has supplemental qualifier records providing the reasons the result collected was inadequate. Those reasons were that coughing was detected and that the repeatability was unacceptable.

suppre.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	XYZ	RE	XYZ-001-001	RESEQ	1	REBRESFL	Best Result Flag	Y	CRF	
2	XYZ	RE	XYZ-001-001	RESEQ	4	REIRREA1	Inadequate Result Reason 1	COUGHING WAS DETECTED IN THE FIRST PART OF THE EXPIRATION	CRF	
3	XYZ	RE	XYZ-001-001	RESEQ	4	REIRREA2	Inadequate Result Reason 2	FEV1 REPEATABILITY IS UNACCEPTABLE	CRF	

- Row 1:** Shows the device type that was used to perform for the pulmonary function tests

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER

- Row 1:** Displays the record the reference equation used by the spirometer device.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	XYZ	DU		ABC001	1	SPIREFEQ	Spirometric Reference Equation	NATIONAL HEALTH NUTRITION EXAMINATION SURVEY (NHANES) III

Development of Concepts and Prototype Metadata

The TAUG-Asthma piloted a new approach to standards development. The steps in this process are described below. For some groups of data, all the products described below are not present, either because they are redundant with material available elsewhere (e.g., data collection and datasets are adequately described in the CDASH and SDTM standards) or because they are still under development (e.g., controlled terminology and supplements for questionnaires).

This process will be modified in future to extend the TAUGs to cover implementation of standards for study design and analysis.

- 1) The meaning and role of data in the therapeutic area and where the data come from in the clinical processes were researched with input from clinical experts. Text to explain this was written, and included references and figures as necessary.
- 2) Concept maps were constructed to illustrate processes and the inherent structure of the data. This process used “modules” based on BRIDG classes. The color code in Section 1.4 explains the kinds of things (instances of modules) that were used in the concept maps. Concept maps also include data items associated with these things, generally in “bubbles” with thin black outlines. Concept maps usually do not show all data items, since doing so would often make the concept maps cluttered and less clear.
- 3) The “concepts” in the concept map were identified. In general a “concept” corresponds to a module or a pair of modules. The most common kind of concept is an observation/response pair.
- 4) A “template” for creating prototype metadata for a group of related concepts was devised. This template is included in the metadata workbook for the group of concepts. (Note that templates created for the TAUG-Asthma may be re-used for other therapeutic areas, so this step will not always be needed.)
 - a) The template was constructed by selecting, from among the attributes of the BRIDG classes corresponding to the modules involved, those most important for the concepts being modeled. The template includes “concept variables” which represent individual data items, each of which is derived from BRIDG and named with BRIDG class, class attribute, complex datatype, and datatype component(s). Periods (.) separate the parts of the concept variable name. Complex datatypes often have multiple levels within them, so the number of levels of datatype specification for a concept variable varies.
 - b) For each concept variable either a description of a simple datatype (e.g., decimal or free text) or information on the controlled terminology was associated with the concept variable. Sometimes the controlled terminology was specified completely at the template level, sometimes only a codelist was identified; in some cases it was possible only to specify that controlled terminology would be needed at the concept level.
 - c) An “attribute description” was added to each group of closely related concept variables (usually at the class attribute level).
 - d) SDTM variable mappings were added where possible. In some cases SDTM did not have a variable for a concept variable (e.g., SDTM generally does not include codes, only decodes) and sometimes the mapping between concept variables and SDTM variables was not direct.
- 5) For each concept identified, the template was copied to create a sheet in the metadata workbook.
 - a) Concept level metadata (Definition, TEST and TESTCD if applicable, value of PRESP if applicable) was provided.
 - b) Any concept variables not relevant for this particular concept were removed.
 - c) Controlled terminology was further specified, where necessary and possible.
 - d) SDTM mappings were further specified, as needed.
 - e) Information about other concepts that may or must be linked to the concept was added. Sometimes properties of a related concept were mapped to SDTM variables, since they would appear in the same SDTM record. (E.g., the device for a spirometry test is a separate concept from the test/result, but its identifier is included in the SDTM record for the spirometry test.)
- 6) For each concept, a bulleted list of data items to be included in the TAUG was created. The list of data items is a simplified, natural language version of the information in the metadata.
- 7) Examples for inclusion in the TAUG were created.
 - a) A description of the situation that produced the example data was written.
 - b) A CRF mock-up was created where relevant.
 - c) SDTM dataset example(s) with row captions were created.

Introduction Red bold text in the upper left hand corner of each page is the page name.

SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata.

The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based:
 - Where applicable, the controlled terminology to be used for the item
 - Other research concepts to which the research concept may or must be connected
 - The SDTM domain in which the research concept is assigned
 - Where the data item is represented in SDTM

The **Key to Layout** worksheet explains the metadata and how it is organized.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the the superset of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains three concepts.

The first two concepts are themselves "templates" in the sense that they involve a pre-specified adverse event.

When used in a study, a particular adverse event would be specified.

- **AE OCCUR** is a query about the occurrence of a particular kind of adverse event. It is handled in SDTM in the Findings About structure.
- **PRESP AE** collects details (start and end dates, severity, etc.) of a particular pre-specified kind of adverse event.
- **LOG AE** collects details (start and end dates, severity, etc.) of adverse events. This is the usual, general form of adverse event collection.

Key to Layout

Concept: Did <pre-specified > AE occur?

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain: FA
FATEST=Occurrence
FATESTCD=OCCUR

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
AECRIT.DefinedAdverseEvent.categoryCode.CD.code	<i>from sponsor-defined code system</i>	Pre-specified category	FACAT
AECRIT.DefinedAdverseEvent.categoryCode.CD.displayName.value	<pre-specified>		
AECRIT.DefinedAdverseEvent.categoryCode.CD.originalText.value	<pre-specified>		
AECRIT.DefinedAdverseEvent. <i>value</i> .CD.code	<i>from MedDRA</i>		
AECRIT.DefinedAdverseEvent. <i>value</i> .CD.displayName.value	<pre-specified>	Pre-specified term	FAOBJ
AECRIT.DefinedAdverseEvent. <i>value</i> .CD.originalText.value	<pre-specified>		
AEQUERY_O.DefinedObservation. <i>value</i> .decimal	<i>decimal (in SDTM, ISO8601 duration)</i>	Focal time period as a period of defined length	FAEVLINT
AEQUERY_O.DefinedObservation. <i>value</i> .code			
AEQUERY_O.DefinedObservation. <i>value</i> .displayName.value			
AEQUERY_O.DefinedObservation. <i>value</i> .TS>.	<i>text describing start of focal time period</i>	Focal time period as a textual description	FAEVINTX
AEQUERY_O.DefinedObservation. <i>value</i> .TS>.	<i>text describing end of focal time period</i>		
AEQUERY_O.PerformedObservation. <i>value</i> .low.value	<i>datetime</i>	Observation Date	FADTC
AEQUERY_O.PerformedObservation. <i>value</i> .<INT>.low.value	<i>integer</i>	Observation Study Day	FADY
AEQUERY_O.PerformedObservation.negationReason.DSET<SC>.item.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	FASTAT
AEQUERY_O.PerformedObservation.negationIndicator.BL.value	<i>free text</i>	Negation Reason	FAREASND
AEQUERY_R.PerformedObservationResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Reason	FAREASND
AEQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487	<i>Shaded cells represent paired values.</i>	
AEQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N		FAORRES, FAORRES, FASTDES

Possible associated concepts

Obs	<i>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</i>	"Yes" response	Pre-specified adverse event collection (PRESP AE)	
		<i>The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.</i>	<i>The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).</i>	<i>The third column describes an "attribute" of the test. There may be several BRIDG-based data items for a single attribute.</i>

CDISC Therapeutic Area Data Standards: User Guide for Asthma (Version 1.0)

Template

Concept:

Domain: *AE or FA*

AETERM:

AEPRESP:

FATEST=Occurrence

FATESTCD=OCCUR

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable		
AECRIT.DefinedAdverseEvent.categoryCode.CD.code	<i>from sponsor-defined code system</i>	Pre-specified category	AECAT	Criterion Block used when AE is pre-specified	
AECRIT.DefinedAdverseEvent.categoryCode.CD.displayName.value	<pre-specified>				
AECRIT.DefinedAdverseEvent.categoryCode.CD.originalText.value	<pre-specified>				
AECRIT.DefinedAdverseEvent.value.CD.code	<i>from MedDRA</i>		AETERM		
AECRIT.DefinedAdverseEvent.value.CD.displayName.value	<pre-specified>				
AECRIT.DefinedAdverseEvent.value.CD.originalText.value	<pre-specified>				
AEQUERY_O.DefinedObservation.focalDuration.PQ.value	<i>decimal (in SDTM, ISO8601 duration)</i>	Focal time period as a period of defined length	AEEVLINT	Defined observation block for a question about a pre-specified AE	
AEQUERY_O.DefinedObservation.focalDuration.PQ.unit.code					
AEQUERY_O.DefinedObservation.focalDuration.PQ.unit.displayName.value					
AEQUERY_O.DefinedObservation.focalDateRange.IVL<TS>.low.originalText.value	<i>text describing start of focal time period</i>	Focal time period as a textual description	AEEVINTX		
AEQUERY_O.DefinedObservation.focalDateRange.IVL<TS>.high.originalText.value	<i>text describing end of focal time period</i>				
AEQUERY_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Observation Date	AEDTC	Performed observation block for a question about a pre-specified AE	
AEQUERY_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Observation Study Day	AEDY		
AEQUERY_O.PerformedObservation.negationReason.DSET<SC>.item.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	STAT		
AEQUERY_O.PerformedObservation.negationIndicator.BL.value	<i>free text</i>	Negation Reason	REASND		
AEQUERY_R.PerformedObservationResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	REASND	Result block for a question about a pre-specified AE	
AEQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result	FAOCCUR		
AEQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N				
AECOLL_O.DefinedObservation.focalDuration.PQ.value	<i>decimal (in SDTM, ISO8601 duration)</i>	Focal time period as a period of defined length	AEEVLINT	Defined observation block for gathering details about a pre-specified AE (or all AEs)	
AECOLL_O.DefinedObservation.focalDuration.PQ.unit.code					
AECOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value					
AECOLL_O.DefinedObservation.focalDateRange.IVL<TS>.low.originalText.value	<i>text describing start of focal time period</i>	Focal time period as a textual description	AEEVINTX		
AECOLL_O.DefinedObservation.focalDateRange.IVL<TS>.high.originalText.value	<i>text describing end of focal time period</i>				
AECOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Observation date	AEDTC	Performed observation block for gathering details about a pre-specified AE (or all AEs)	
AECOLL_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Observation study day	AEDY		

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AECOLL_R.Performed.AdverseEvent.value.CD.originalText.value	free text	Adverse event name	AETERM	Result block for gathering details about a pre-specified AE (or all AEs)
AECOLL_R.Performed.AdverseEvent.valueCodeModifiedText.ST.value	free text		AEMODIFY	
AECOLL_R.Performed.AdverseEvent.value.CD.code	from MedDRA		AEPTCD	
AECOLL_R.Performed.AdverseEvent.value.CD.displayName.value	from MedDRA		AEDECOD	
AECOLL_R.Performed.AdverseEvent.bodySystemCode.CD.code			AEBODSYS	
AECOLL_R.Performed.AdverseEvent.bodySystemCode.CD.displayName.value		Adverse event occurrence date range	AESTDTC	
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.low.value	datetime		AEENDTC	
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.value	datetime		uncertain start datetime uses AESTRF or AESTTPT & AESTRTPT	
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative infinity			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.low.uncertainRange.low.value	datetime		uncertain end datetime uses AEENRF or AEENTPT & AEENRTPT	
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.low.uncertainRange.high.value	datetime			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative infinity			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.uncertainRange.low.value	datetime			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive infinity			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.high.uncertainRange.high.value	datetime			
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.width.value	decimal (in SDTM, ISO8601 duration)	AEDUR		
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.width.unit.code				
AECOLL_R.Performed.AdverseEvent.ocurrenceDateRange.IVL<TS>.width.unit.displayName.value				
AECOLL_R.Performed.AdverseEvent.gradeCode.CD.code		Toxicity grade	AETOXGR	
AECOLL_R.Performed.AdverseEvent.gradeCode.CD.displayName.value				
AECOLL_R.Performed.AdverseEvent.severityCode.CD.code	C41338, C41339, C41340	Severity	AESEV	
AECOLL_R.Performed.AdverseEvent.severityCode.CD.displayName.value	MILD, MODERATE, SEVE			
AECOLL_R.Performed.AdverseEvent.categoryCode.CD.code	from sponsor-defined code s	Category	AECAT	
AECOLL_R.Performed.AdverseEvent.categoryCode.CD.displayName.value	from sponsor-defined code s			
AECOLL_R.Performed.AdverseEvent.ocurrencePatternCode.CD.code		Occurrence pattern	AEPATT	
AECOLL_R.Performed.AdverseEvent.ocurrencePatternCode.CD.displayName.value				

AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.code		Adverse event anatomic site	AELOC	Result block for gathering details about a pre-specified AE (or all AEs)	
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.displayName.value					
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.originalText.value					
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteLateralityCode.CD.code		Adverse event anatomic site laterality	AELAT		
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteLateralityCode.CD. displayName.value					

Possible associated concepts

<i>nature of relationship of associated concept to this concept</i>	<i>name of associated concept</i>		

AE OCCUR

Concept: Did <pre-specified > AE occur?

Domain: FA
 FATEST=Occurrence
 FATESTCD=OCCUR

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
AECRIT.DefinedAdverseEvent.categoryCode.CD.code	<i>from sponsor-defined code system</i>	Pre-specified category	FACAT
AECRIT.DefinedAdverseEvent.categoryCode.CD.displayName.value	<pre-specified>		
AECRIT.DefinedAdverseEvent.categoryCode.CD.originalText.value	<pre-specified>		
AECRIT.DefinedAdverseEvent.value.CD.code	<i>from MedDRA</i>	Pre-specified term	FAOBJ
AECRIT.DefinedAdverseEvent.value.CD.displayName.value	<pre-specified>		
AECRIT.DefinedAdverseEvent.value.CD.originalText.value	<pre-specified>		
AEQUERY_O.DefinedObservation.focalDuration.PQ.value	<i>decimal</i> (in SDTM, ISO8601 duration)	Focal time period as a period of defined length	FAEVLINT
AEQUERY_O.DefinedObservation.focalDuration.PQ.unit.code			
AEQUERY_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
AEQUERY_O.DefinedObservation.focalDateRange.IVL<TS>.low.originalText.value	<i>text describing start of focal time period</i>	Focal time period as a textual description	FAEVINTX
AEQUERY_O.DefinedObservation.focalDateRange.IVL<TS>.high.originalText.value	<i>text describing end of focal time period</i>		
AEQUERY_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Observation Date	FADTC
AEQUERY_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Observation Study Day	FADY
AEQUERY_O.PerformedObservation.negationReason.DSET<SC>.item.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	FASTAT
AEQUERY_O.PerformedObservation.negationIndicator.BL.value	<i>free text</i>	Negation Reason	FAREASND
AEQUERY_R.PerformedObservationResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	FAREASND
AEQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result	FAORRES, FAORRESC, FASTRES
AEQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Possible associated concepts

Observation triggered by "Yes" response	Pre-specified adverse event collection (PRESP AE)	
---	---	--

PRESp AE

Concept: Collection of details of <pre-specified> adverse event

Domain: AE
 ATERM =
 <pre-specified>
 AEPRESP = Y

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
AECRIT.DefinedAdverseEvent.categoryCode.CD.code	<i>from sponsor-defined code system</i>	Pre-specified category	AECAT
AECRIT.DefinedAdverseEvent.categoryCode.CD.displayName.value	<pre-specified>		
AECRIT.DefinedAdverseEvent.categoryCode.CD.originalText.value	<pre-specified>		
AECRIT.DefinedAdverseEvent.value.CD.code	<i>from MedDRA</i>	Pre-specified term	AEPTCD
AECRIT.DefinedAdverseEvent.value.CD.displayName.value	<pre-specified>		AETERM
AECRIT.DefinedAdverseEvent.value.CD.originalText.value	<pre-specified>		
AECOLL_O.DefinedObservation.focalDuration.PQ.value	<i>decimal (in SDTM, ISO8601 duration)</i>	Focal time period as a period of defined length	AEEVLINT
AECOLL_O.DefinedObservation.focalDuration.PQ.unit.code			
AECOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
AECOLL_O.DefinedObservation.focalDateRange.IVL<TS>.low.originalText.value	<i>text describing start of focal time period</i>	Focal time period as a textual description	AEEVINTX
AECOLL_O.DefinedObservation.focalDateRange.IVL<TS>.high.originalText.value	<i>text describing end of focal time period</i>		
AECOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date of collection	AEDTC
AECOLL_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>		AEDY
AECOLL_R.Performed.AdverseEvent.value.CD.originalText.value	<i>free text</i>		AETERM
AECOLL_R.Performed.AdverseEvent.valueCodeModifiedText.ST.value	<i>free text</i>	Adverse event name	AEMODIFY
AECOLL_R.Performed.AdverseEvent.value.CD.code	<i>from MedDRA</i>		AEPTCD
AECOLL_R.Performed.AdverseEvent.value.CD.displayName.value	<i>from MedDRA</i>		AEDECOD
AECOLL_R.Performed.AdverseEvent.bodySystemCode.CD.code			AEBODSYS
AECOLL_R.Performed.AdverseEvent.bodySystemCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.low.value	<i>datetime</i>		AESTDC
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.value	<i>datetime</i>	Adverse event occurrence date range	AEENDTC
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	<i>NINF</i>		uncertain start datetime uses AESTRF or AESTTPT & AESTRTPT
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	<i>Negative infinity</i>		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.value	<i>datetime</i>		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.low.uncertainRange.high.value	<i>datetime</i>		...
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	<i>NINF</i>		

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AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative infinity	Adverse event occurrence date range	uncertain end datetime uses AEENRF or AEENTPT & AEENRTPT
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.value	<i>datetime</i>		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive infinity		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.width.value	<i>decimal</i> (in SDTM, ISO8601 duration)		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.width.unit.code		AEDUR	
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.width.unit.displayName.value			
AECOLL_R.Performed.AdverseEvent.gradeCode.CD.code		Toxicity grade	AETOXGR
AECOLL_R.Performed.AdverseEvent.gradeCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.severityCode.CD.code	C41338, C41339, C41340	Severity	AESEV
AECOLL_R.Performed.AdverseEvent.severityCode.CD.displayName.value	MILD, MODERATE, SEVERE		
AECOLL_R.Performed.AdverseEvent.categoryCode.CD.code	<i>from sponsor-defined code system</i>	Category	AECAT
AECOLL_R.Performed.AdverseEvent.categoryCode.CD.displayName.value	<i>from sponsor-defined code system</i>		
AECOLL_R.Performed.AdverseEvent.occurrencePatternCode.CD.code		Occurrence pattern	AEPATT
AECOLL_R.Performed.AdverseEvent.occurrencePatternCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.code		Adverse event anatomic site	AELOC
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.originalText.value			
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteLateralityCode.CD.code		Adverse event anatomic site laterality	AELAT
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteLateralityCode.CD.displayName.value			

Possible associated concepts

Triggering observation response	Pre-specified adverse event query (AE OCCUR)		
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LOG AE

Concept: Collection of details of adverse events

Domain: AE
 AETERM: collected
 AEPRESP=null

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
AECOLL_O.DefinedObservation.focalDuration.PQ.value	<i>decimal</i> (in SDTM, ISO8601 duration)	Focal time period as a period of defined length	AEEVLINT
AECOLL_O.DefinedObservation.focalDuration.PQ.unit.code			
AECOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
AECOLL_O.DefinedObservation.focalDateRange.IVL<TS>.low.originalText.value	<i>text describing start of focal time period</i>	Focal time period as a textual description	AEEVINTX
AECOLL_O.DefinedObservation.focalDateRange.IVL<TS>.high.originalText.value	<i>text describing end of focal time period</i>		
AECOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date of collection	AEDTC
AECOLL_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>		AEDY
AECOLL_R.Performed.AdverseEvent.value.CD.originalText.value	<i>free text</i>	Adverse event name	AETERM
AECOLL_R.Performed.AdverseEvent.valueCodeModifiedText.ST.value	<i>free text</i>		AEMODIFY
AECOLL_R.Performed.AdverseEvent.value.CD.code	from MedDRA		AEPTCD
AECOLL_R.Performed.AdverseEvent.value.CD.displayName.value	from MedDRA		AEDECOD
AECOLL_R.Performed.AdverseEvent.bodySystemCode.CD.code			AEBODSYS
AECOLL_R.Performed.AdverseEvent.bodySystemCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.low.value	<i>datetime</i>	Adverse event occurrence date range	AESTDTC
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.high.value	<i>datetime</i>		AEENDTC
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.low不确定Range.low.nullFlavor.code	NINF		uncertain start datetime uses AESTRF or AESTTPT & AESTRTPT
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.low不确定Range.low.nullFlavor.displayName.value	Negative infinity		
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.low不确定Range.low.value	<i>datetime</i>		
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.low不确定Range.high.value	<i>datetime</i>		uncertain end datetime uses AEENRF or AEENTPT & AENRPTP
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.high不确定Range.low.nullFlavor.code	NINF		
AECOLL_R.Performed.AdverseEvent occurrenceDateRange.IVL<TS>.high不确定Range.low.nullFlavor.displayName.value	Negative infinity		

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AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.value	<i>datetime</i>	Adverse event occurrence date range	uncertain end datetime uses AEENRF or AEENTPT & AEENRPT
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive infinity		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>		
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.width.value	<i>decimal</i> (in SDTM, ISO8601 duration)	AEDUR	
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.width.unit.code			
AECOLL_R.Performed.AdverseEvent.occurrenceDateRange.IVL<TS>.width.unit.displayName.value			
AECOLL_R.Performed.AdverseEvent.gradeCode.CD.code		Toxicity grade	AETOXGR
AECOLL_R.Performed.AdverseEvent.gradeCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.severityCode.CD.code	C41338, C41339, C41340	Severity	AESEV
AECOLL_R.Performed.AdverseEvent.severityCode.CD.displayName.value	MILD, MODERATE, SEVERE		
AECOLL_R.Performed.AdverseEvent.categoryCode.CD.code	<i>from sponsor-defined code system</i>	Category	AECAT
AECOLL_R.Performed.AdverseEvent.categoryCode.CD.displayName.value	<i>from sponsor-defined code system</i>		
AECOLL_R.Performed.AdverseEvent.occurrencePatternCode.CD.code		Occurrence pattern	AEPATT
AECOLL_R.Performed.AdverseEvent.occurrencePatternCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.code		Adverse event anatomic site	AELOC
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.displayName.value			
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteCode.CD.originalText.value			
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteLateralityCode.CD.Code		Adverse event anatomic site laterality	AELAT
AECOLL_R.Performed.AdverseEvent.targetAnatomicSiteLateralityCode.CD.displayName.value			

Possible associated concepts

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Introduction Red bold text in the upper left hand corner of each page is the page name.

SHARE Metadata Displays

These workbooks contain somewhat simplified versions of SHARE metadata.

The metadata held in the SHARE metadata repository will include information on research concepts, including

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains how the metadata is organized on the page.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the superset of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbo contains metadata for nine allergen skin tests, including measurements and semi-quantitative assessments of allergic skin responses.

Also included is the Allergic Skin Response Index, which compares skin response of an allergen to skin response of a positive control.

- **WHLDIAM**, Wheal Longest Diameter (measurement)
- **WHMDIAM**, Wheal Mean Diameter (measurement)
- **WHEALSZ**, Wheal Size (semi-quantitative)
- **ASRINDEX**, Allergic Skin Response Index (ratio of longest wheal diameter for an allergen to longest wheal diameter for a positive control)
- **FLLDIAM**, Flare Longest Diameter (measurement)
- **FLMDIAM**, Flare Mean Diameter (measurement)
- **FLARESZ**, Flare Size (semi-quantitative)
- **WHEALRSP**, An assessment of the diameter of a wheal on the skin as positive or negative based on a threshold diameter.
- **ASRINT**, Allergic Skin Response Intensity (semi-quantitative, based on wheal and flare combined)

The semi-quantitative assessments can use a variety of response scales, and controlled terminology for these responses has not been developed.

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At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Key to Layout

Concept: The average diameter of the area of redness that forms around the site of an antigenic challenge to the skin.

Domain: SR

TEST: Flare Mean Diameter

TESTCD: FLMDIAM

Blue text indicates terminology that has not yet been approved.

BRIDG "variable"	value(s)	Attribute	SDTM variable
FLMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062		
FLMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK	Location	SRLOC
FLMDIAM_TES.originalText.value	getAnatomicSiteCode.CD. <i>The main body of the sheet contains the data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class attribute, controlled terminology (if applicable) and where the data item is represented in SDTM.</i>	free text	
FLMDIAM_TES.item.value	dateRange.IVL<TS>.low.value	datetime	SRDT
FLMDIAM_TES.low.value	studyDayRange.IVL<INT>.	integer	SRDY
FLMDIAM_TES.item.value	negationReason.DSET<SC>.	free text	SRREASND
FLMDIAM_TES.item.value	negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	SRSTAT
FLMDIAM_RES.value.PQ.value	decimal	Result Value	SRORRES, SRSTRESC, SRSTRESN
FLMDIAM_RES.value.PQ.unit.code	C28251, C49668	<i>Shaded cells represent paired values.</i>	
FLMDIAM_RESN.PerformedClinicalResult.value.PQ.unit.displayName.value	mm, cm		SRORRESU, SRSTRESU
FLMDIAM_RESN.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Null Result Reason	SRREASND

Nature of the association

<i>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</i>	in response to the administration of an allergen or a role	Substance administration	SROBJ
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The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.

The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).

The third column describes an “attribute” of the test. There may be several BRIDG-based data items for a single attribute.

The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.

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Template

Concept: Measurement of the raised part of a wheal that is the response to the administration of an allergen to the skin

Domain: SR
TEST:
TESTCD:

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)		
SR_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC	Block for collected properties of test	
SR_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK				
SR_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	free text				
SR_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	datetime		SRDT		
SR_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer		SRDY		
SR_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	free text		SRREASND		
SR_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT	Block for pre-specified properties of result	
SR_RES.DefinedObservationResult.derivationExpression.ST.value	formula for test result				
SR_RES.PerformedClinicalResult.value.PQ.value	decimal	Result Value (numeric)	SRORRES, SRSTRESC, SRSTRESN		
SR_RES.PerformedClinicalResult.value.PQ.unit.code	C28251, C49668	Result Value (numeric) Unit	SRORRESU, SRSTRESU		
SR_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	mm, cm				
SR_RES.PerformedClinicalResult.value.CO.originalText.value	free text	Result Value (semi-quantitative)	SRORRES, SRSTRESC	Block for collected properties of response	
SR_RES.PerformedClinicalResult.value.CO.value	integer				
SR_RES.PerformedClinicalResult.value.CO.code.code	from code system				
SR_RES.PerformedClinicalResult.value.CO.code.displayName.value	from code system				
SR_RES.PerformedClinicalResult.value.CD.originalText.value		Result Value (coded)	SRORRES, SRSTRESC		
SR_RES.PerformedClinicalResult.value.CD.code	C38758, C38757				
SR_RES.PerformedClinicalResult.value.CD.displayName.value	POSITIVE, NEGATIVE				
SR_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Null Result Reason	SRREASND		

Nature of the association

Possible associated concepts

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WHLDIAM

Concept: The longest diameter of the flat, circular, slightly raised area that forms around the site of an antigenic challenge to the skin.

Domain: SR

TEST: Wheal Longest Diameter

TESTCD: WHLDIAM

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
WHLDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
WHLDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
WHLDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
WHLDIAM_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
WHLDIAM_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
WHLDIAM_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Negation Reason	SRREASND
WHLDIAM_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
WHLDIAM_RESN.PerformedClinicalResult.value.PQ.value	<i>decimal</i>	Result Value	SRORRES, SRSTRESC, SRSTRESN
WHLDIAM_RESN.PerformedClinicalResult.value.PQ.unit.code	C28251, C49668	Result Unit	SRORRESU, SRSTRESU
WHLDIAM_RESN.PerformedClinicalResult.value.PQ.unit.displayName.value	mm, cm		
WHLDIAM_RESN.PerformedClinicalResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen or a positive or negative control	Substance administration		SROBJ
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WHMDIAM

Concept: The average diameter of the flat, circular, slightly raised area that forms around the site of an antigenic challenge to the skin.

Domain: SR

TEST: Wheal Mean Diameter

TESTCD: WHMDIAM

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
WHMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
WHMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
WHMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
WHMDIAM_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
WHMDIAM_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
WHMDIAM_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Negation Reason	SRREASND
WHMDIAM_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
WHLDIAM_RESN.PerformedClinicalResult.value.PQ.value	<i>decimal</i>	Result Value	SRORRES, SRSTREC, SRSTRESN
WHLDIAM_RESN.PerformedClinicalResult.value.PQ.unit.code	C28251, C49668	Result Unit	SRORRESU, SRSTRESU
WHLDIAM_RESN.PerformedClinicalResult.value.PQ.unit.displayName.value	mm, cm		
WHMDIAM_RESN.PerformedClinicalResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen or a positive or negative control	Substance administration		SROBJ
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WHEALSZ

Concept: A semi-quantitative size assessment of the flat, circular, slightly raised area that forms around the site of an antigenic challenge to the skin.

Domain: SR
TEST: Wheal Size
TESTCD: WHEALSZ

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
WHEALSZ_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
WHEALSZ_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
WHEALSZ_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
WHEALSZ_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
WHEALSZ_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
WHEALSZ_TEST.PerformedObservation.negotiationReason.DSET<SC>.item.value	<i>free text</i>	Negotiation Reason	SRREASND
WHEALSZ_TEST.PerformedObservation.negotiationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negotiation Indicator	SRSTAT
WHEALSZ_RESC.PerformedClinicalResult.value.CO.originalText.value	<i>free text</i>	Result value	RORRES, SRSTRES
WHEALSZ_RESC.PerformedClinicalResult.value.CO.value	<i>integer</i>		
WHEALSZ_RESC.PerformedClinicalResult.value.CO.code.code	<i>from code system</i>		
WHEALSZ_RESC.PerformedClinicalResult.value.CO.code.displayName.value	<i>from code system</i>		
WHEALSZ_RESC.PerformedClinicalResult.value.NullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association	Possible associated concepts		
This concept assesses skin response to the administration of an allergen or a positive or negative control	Substance administration		SROBJ

ASRINDEX

Concept: The ratio measurement of the allergen longest wheal diameter to the positive control longest wheal diameter in an allergen skin test.

Domain: SR

TEST: Skin Response Index

TESTCD: ASRINDEX

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
ASRINDEX_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
ASRINDEX_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
ASRINDEX_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	free text		
ASRINDEX_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	SRDT
ASRINDEX_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	SRDY
ASRINDEX_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	SRREASND
ASRINDEX_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
ASRINDEX_RESN.DefinedObservationResult.derivationExpression.ST.value	allergen wheal longest diameter positive control wheal longest diameter		
ASRINDEX_RESN.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	SRORRES, SRSTRESC, SRSTPESN
ASRINDEX_RESN.PerformedClinicalResult.value.PQ.value	decimal		
ASRINDEX_RESN.PerformedClinicalResult.value.PQ.unit.code		Result Unit	SRORRESU, SRSTRESU
ASRINDEX_RESN.PerformedClinicalResult.value.PQ.unit.displayName.value	%, RATIO		
ASRINDEX_RESN.PerformedClinicalResult.value.NullFlavorReason.ST.value	free text	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen compared to the response to a positive control	Allergen administration		SROBJ
The concept uses the skin response to administration of histamine as a basis for comparison for the skin response to administration of an allergen	Histamine administration		
When associated with allergen administration, the numerator of this derived concept. When associated with histamine administration, the denominator of this derived concept.	Longest wheal diameter		

FLLDIAM

Concept: The longest diameter of the area of redness that forms around the site of an antigenic challenge to the skin.

Domain: SR

TEST: Flare Longest Diameter

TESTCD: FLLDIAM

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
FLLDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
FLLDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
FLLDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	free text		
FLLDIAM_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	SRDT
FLLDIAM_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	SRDY
FLLDIAM_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	SRREASND
FLLDIAM_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
FLLDIAM_RESN.PerformedClinicalResult.value.PQ.value	decimal	Result Value	SRORRES, SRSTRESC, SRSTRESN
FLLDIAM_RESN.PerformedClinicalResult.value.PQ.unit.code	C28251, C49668	Result Unit	SRORRESU, SRSTRESU
FLLDIAM_RESN.PerformedClinicalResult.value.PQ.unit.displayName.value	mm, cm		
FLLDIAM_RESN.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen or a positive or negative control	Substance administration		SROBJ
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FLARESZ

Concept: A semi-quantitative size assessment of the area of redness that forms around the site of an antigenic challenge to the skin.

Domain: SR
 TEST: Flare Size
 TESTCD: FLARESZ

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
FLARESZ_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
FLARESZ_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
FLARESZ_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
FLARESZ_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
FLARESZ_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
FLARESZ_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Negation Reason	SRREASND
FLARESZ_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
FLARESZ_RESC.PerformedClinicalResult.value.CO.originalText.value	<i>free text</i>	Result value	SRORRES, SRSTRESC
FLARESZ_RESC.PerformedClinicalResult.value.CO.value	<i>integer</i>		
FLARESZ_RESC.PerformedClinicalResult.value.CO.code.code	<i>from code system</i>		
FLARESZ_RESC.PerformedClinicalResult.value.CO.code.displayName.value	<i>from code system</i>		
FLARESZ_RESC.PerformedClinicalResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen or a positive or negative control	Substance administration		SROBJ
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FLMDIAM

Concept: The average diameter of the area of redness that forms around the site of an antigenic challenge to the skin.

Domain: SR
TEST: Flare Mean
TESTCD: FLMDIAM

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
FLMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
FLMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
FLMDIAM_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
FLMDIAM_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
FLMDIAM_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
FLMDIAM_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Negation Reason	SRREASND
FLMDIAM_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
FLMDIAM_RESN.PerformedClinicalResult.value.PQ.value	<i>decimal</i>	Result Value	SRORRES, SRSTRESC, SRSTRESN
FLMDIAM_RESN.PerformedClinicalResult.value.PQ.unit.code	C28251, C49668	Result Unit	SRORRESU, SRSTRESU
FLMDIAM_RESN.PerformedClinicalResult.value.PQ.unit.displayName.value	mm, cm		
FLMDIAM_RESN.PerformedClinicalResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association	Possible associated concepts
This concept assesses skin response to the administration of an allergen or a positive or negative control	Substance administration SROBJ

WHEALRSP

Concept: Classification of the wheal formed in response to an administration of a substance to the skin as positive or negative based on a threshold wheal size.

Domain: SR
TEST: Wheal Positiv
TESTCD: WHEALR

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
WHEALRSP_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
WHEALRSP_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
WHEALRSP_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
WHEALRSP_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
WHEALRSP_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
WHEALRSP_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Negation Reason	SRREASND
WHEALRSP_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
WHEALRSP_RESN.PerformedClinicalResult.value.CD.originalText.value		Result value	SRORRES, SRSTRESC
WHEALRSP_RESN.PerformedClinicalResult.value.CD.code	C38758, C38757		
WHEALRSP_RESN.PerformedClinicalResult.value.CD.displayName.value	POSITIVE, NEGATIVE		
WHEALRSP_RESN.PerformedClinicalResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen	Substance administration		SROBJ
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e-Negative

SP

ASRINT

Concept: A semi-quantitative assessment of the intensity of the wheal and flare reaction.

Domain: SR

TEST: Allergic Skin Resp Intensity

TESTCD: ASRINT

BRIDG "variable"	value(s)	Attribute	SDTM variable(s)
ASRINT_TEST.PerformedObservation.targetAnatomicSiteCode.CD.code	C32141, C13062	Location	SRLOC
ASRINT_TEST.PerformedObservation.targetAnatomicSiteCode.CD.displayName.value	ARM, BACK		
ASRINT_TEST.PerformedObservation.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
ASRINT_TEST.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Range	SRDT
ASRINT_TEST.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Study Day Range	SRDY
ASRINT_TEST.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Negation Reason	SRREASND
ASRINT_TEST.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	SRSTAT
ASRINT_RESC.PerformedClinicalResult.value.CO.originalText.value		Result value	SRORRES, SRSTRESC
ASRINT_RESC.PerformedClinicalResult.value.CO.value	<i>integer</i>		SRORRES, SRSTRESC
ASRINT_RESC.PerformedClinicalResult.value.CO.code.code	<i>from code system</i>		SRORRES, SRSTRESC
ASRINT_RESC.PerformedClinicalResult.value.CO.code.displayName.value	<i>from code system</i>		SRORRES, SRSTRESC
ASRINT_RESC.PerformedClinicalResult.valueNullFlavorReason.ST.value	<i>free text</i>	Null Result Reason	SRREASND

Nature of the association**Possible associated concepts**

This concept assesses skin response to the administration of an allergen	Substance administration	SROBJ
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Introduction Red bold text in the upper left hand corner of each page is the page name.

SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata.

The metadata held in the SHARE metadata repository will include information on research concepts, including

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains the metadata and how it is organized.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the set of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains metadata for five concepts. The first four are "templates" in the sense that they deal with information about pre-specified concomitant medications or groups of concomitant medications. When used in a study, the particular kind of concomitant medication administrations would be specified.

- **OCCUR CM TRT**, a query about administrations of a particular medication during an evaluation interval.
- **PRESP CM TRT**, recording of details of administrations of a particular medication during an evaluation interval.
- **OCCUR CM Group**, a query about a particular type of administration of concomitant medication during an evaluation interval.
- **PRESP CM Group**, recording of details of a particular type of administration of a concomitant medication during an evaluation interval.
- **LOG CM**, collection of concomitant medications that are not pre-specified. This is standard concomitant medication collection with an implicit evaluation interval of "during the study."

OCCUR CM TRT

Concept: Query whether <pre-specified concomitant medication> was taken during an evaluation interval

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain:

TRT: <pre-specified>

PRESP=Y

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
MEDCRIT.Defined.Drug.code.CD.code	from drug dictionary	Pre-specifieddrug	CMTRT
MEDCRIT.Defined.Drug.code	from drug dictionary		
MEDCRIT.Defined.Drug.code	free text		
CMQ_O.DefinedObservation.f	SDTM uses ISO8601 duration format	Focal time period	CMEVLINT
CMQ_O.DefinedObservation.f			
CMQ_O.DefinedObservation.f			
CMQ_O.DefinedObservation.f	originalText.value	free text	CMEVLTXT
CMQ_O.PerformedObservatio	value	datetime	CMDTC
CMQ_O.PerformedObservatio	>.low.value	integer	CMDY
CMQ_O.PerformedObservatio	e	TRUE, FALSE (SDTM NOT DONE, null)	CMSTAT
CMQ_O.PerformedObservatio	>.item.value	free text	CMREASND
CMQ_O.PerformedObservatio	>.item.code.code	sponsor codelist	
CMQ_O.PerformedObservatio	>.item.code.displayName.value	sponsor codelist	
CMQ_R.PerformedObservatio	C49488, C49487	Result value	CMOCCUR
CMQ_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Possible associated concepts

<i>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</i>	<i>Trig e to this concept</i>	Collection of details of pre-specified CM administration (PRESP CM TRT)	
	<i>The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.</i>	<i>The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).</i>	<i>The third column describes an “attribute” of the test. There may be several BRIDG-based data items for a single attribute.</i>

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Template

Concept:

Domain:

TRT: or TEST:

PRESP= or TESTCD:

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable		
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.code	from drug dictionary	Pre-specified class	in CMCAT	Block for pre-specified properties of kind of medication on which question or data collection is focused	
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.displayName.value	from drug dictionary				
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.originalText.value	free text				
MEDCRIT.Defined.Drug.code.CD.code	from drug dictionary		CMTRT		
MEDCRIT.Defined.Drug.code.CD.displayName.value	from drug dictionary				
MEDCRIT.Defined.Drug.code.CD.originalText.value	free text	Pre-specified dose form	in CMCAT		
MEDCRIT.Defined.Drug.formCode.CD.code	from codelist C66726				
MEDCRIT.Defined.Drug.formCode.CD.displayName.value	from codelist C66726				
MEDCRIT.Defined.Drug.formCode.CD.originalText.value	free text	Pre-specified description	in CMCAT		
MEDCRIT.Defined.Drug.description.ST.value	free text				
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code	from codelist C66729	Pre-specified route of administration	in CMCAT	Block for pre-specified properties of kind of medication administration on which question or data collection is focused	
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	from codelist C66729	Pre-specified target site	in CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code	from codelist C74456				
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value	from codelist C74456				
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value	free text	Pre-specified site of administration	in CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code	from codelist C74456				
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	from codelist C74456				
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	free text	in CMCAT	in CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229				
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT	Pre-specified indication	in CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.code	sponsor codelist				
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	sponsor codelist				
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	free text				
CMQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format	Focal time period	CMEVLINT	Block for pre-specified properties of question	
CMQ_O.DefinedObservation.focalDuration.PQ.unit.code					
CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			CMEVLTXT		
CMQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	free text	Question datetime	CMDTC	Block for collected properties of question	
CMQ_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime				
CMQ_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer				
CMQ_O.PerformedObservation.negativeIndicator.BL.value	TRUE, FALSE (SDTM NOT DONE, null)	Question not asked	CMSTAT		

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CMQ_O.PerformedObservation.negationReason.DSET<SC>.item.value	<i>free text</i>	Reason question not asked	CMREASND	Block for collected properties of question	
CMQ_O.PerformedObservation.negationReason.DSET<SC>.item.code.code	<i>sponsor codelist</i>				
CMQ_O.PerformedObservation.negationReason.DSET<SC>.item.code.displayName.value	<i>sponsor codelist</i>				
CMQ_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result value	CMOCCUR (if occurrence question)	Block for collected properties of response to question	
CMQ_R.PerformedObservationResult.value.CD.displayName.value	YES, NO				
MEDCOLL.Performed.Drug.codeModifiedText.ST.value	<i>free text</i>	Medication administered	CMMODIFY	Block for collected properties of medication administration	
MEDCOLL.Performed.Drug.code.CD.code	<i>from drug dictionary</i>				
MEDCOLL.Performed.Drug.code.CD.displayName.value	<i>from drug dictionary</i>		CMDECOD		
MEDCOLL.Performed.Drug.code.CD.originalText.value	<i>free text</i>		CMTRT		
MEDCOLL.Performed.Drug.formCode.CD.code	<i>from codelist C66726</i>	Doseform of administered medication	CMDOSFRM		
MEDCOLL.Performed.Drug.formCode.CD.displayName.value	<i>from codelist C66726</i>				
MEDCOLL.Performed.Drug.formCode.CD.originalText.value	<i>free text</i>				
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code	<i>from codelist C66729</i>	Route of administration of administered medication	CMROUTE	Block for collected properties of medication administered	
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	<i>from codelist C66729</i>				
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value	<i>free text</i>				
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value	<i>free text</i>	Amount of product administered	CMDOSE		
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value	<i>decimal</i>		CMDOSU		
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code	<i>from codelist C71620</i>				
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value	<i>from codelist C71620</i>	Amount of active ingredient administered	CMDOSE	Block for collected properties of medication administered	
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value	<i>free text</i>		CMDOSU		
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value	<i>decimal</i>				
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code	<i>from codelist C71620</i>				
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value	<i>from codelist C71620</i>	Total amount of product administered in period	CMDOSTOT (if period is a day)	CMDOSU	
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value	<i>free text</i>		CMDOSU		
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.value	<i>decimal</i>				
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code	<i>from codelist C71620</i>	Total amount of active ingredient administered in period	CMDOSTOT (if period is a day)	CMDOSU	
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value	<i>from codelist C71620</i>		CMDOSU		
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.originalText.value	<i>free text</i>				
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.value	<i>decimal</i>	CMDOSU	CMDOSU		
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code	<i>from codelist C71620</i>				
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.displayName.value	<i>from codelist C71620</i>	CMDOSU	CMDOSU		

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ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code	C25301, C29844, C29846	Period for total amount administered			
ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value	DAY, WEEK, MONTH				
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code	from codelist C71113	Frequency of medication administration	CMDOSFRQ		
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value	from codelist C71113				
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value	free text				
ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value	decimal	Reason for dose change	CMADJ		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code	from codelist C74456	Site of medication administration	CMLOC		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	from codelist C74456				
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	free text				
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229	RIGHT, LEFT	CMLAT		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.value	datetime	Start datetime of medication administration	CMSTDTC	Block for collected properties of medication administered	
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.originalText.value	free text				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.nullFlavor.code	NINF				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.nullFlavor.displayName.value	Negative Infinity				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.value	datetime				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.lowClosed	TRUE, FALSE				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.high.value	datetime				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.highClosed	TRUE, FALSE				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.value	datetime		End datetime of medication administration		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.originalText.value	free text				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.nullFlavor.code	NINF				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.nullFlavor.displayName.value	Negative Infinity				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.value	datetime				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.lowClosed	TRUE, FALSE				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.high.nullFlavor.code	PINF				

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ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive Infinity	Uncertain end datetime of medication administration	CMENRF or CMENRTPT & CMENTPT	Block for collected properties of medication administered	
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>				
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.highClosed	TRUE, FALSE				
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Start study date of med admin	CMSTDY		
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.high.value	<i>integer</i>	End study day of med admin	CMENDY		
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.code	<i>sponsor codelist?</i> <i>MedDRA?</i>	Indication for medication administration	CMINDC		
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	<i>sponsor codelist?</i> <i>MedDRA?</i>				
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>				

Possible associated concepts

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OCCUR CM TRT

Concept: Query whether <pre-specified concomitant medication> was taken during an evaluation interval

Domain:

TRT: <pre-specified>

PRESP=Y

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
MEDCRIT.Defined.Drug.code.CD.code	from drug dictionary	Pre-specifieddrug	CMTRT
MEDCRIT.Defined.Drug.code.CD.displayName.value	from drug dictionary		
MEDCRIT.Defined.Drug.code.CD.originalText.value	free text		
CMQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format	Focal time period	CMEVLINT
CMQ_O.DefinedObservation.focalDuration.PQ.unit.code			
CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
CMQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	free text	Question datetime	CMDTC
CMQ_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime		
CMQ_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer		
CMQ_O.PerformedObservation.negotiationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Question not asked	CMSTAT
CMQ_O.PerformedObservation.negotiationReason.DSET<SC>.item.value	free text	Reason question not asked	CMREASND
CMQ_O.PerformedObservation.negotiationReason.DSET<SC>.item.code.code	sponsor codelist		
CMQ_O.PerformedObservation.negotiationReason.DSET<SC>.item.code.displayName.value	sponsor codelist		
CMQ_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result value	CMOCCUR
CMQ_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Possible associated concepts

Triggered by Yes response to this concept	Collection of details of pre-specified CM administration (PRESP CM TRT)	
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PRESp CM TRT

Concept: Collection of details of administrations of <pre-specified concomitant medication> during an evaluation interval

Domain: CM

TRT: <pre-specified>

PRESp=Y

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
MEDCRIT.Defined.Drug.code.CD.code	from drug dictionary	Pre-specifieddrug	CMTRT
MEDCRIT.Defined.Drug.code.CD.displayName.value	from drug dictionary		
MEDCRIT.Defined.Drug.code.CD.originalText.value	free text		
MEDCOLL.Performed.Drug.codeModifiedText.ST.value	free text	Medication administered	CMMODIFY
MEDCOLL.Performed.Drug.code.CD.code	from drug dictionary		
MEDCOLL.Performed.Drug.code.CD.displayName.value	from drug dictionary		CMDECOD
MEDCOLL.Performed.Drug.code.CD.originalText.value	free text		CMTRT
MEDCOLL.Performed.Drug.formCode.CD.code	from codelist C66726	Doseform of administered medication	CMDOSFRM
MEDCOLL.Performed.Drug.formCode.CD.displayName.value	from codelist C66726		
MEDCOLL.Performed.Drug.formCode.CD.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code	from codelist C66729	Route of administration of administered medication	CMROUTE
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	from codelist C66729		
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value	free text	Amount of product administered	CMDOSE
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value	decimal		CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code	from codelist C71620		
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value	from codelist C71620	Amount of active ingredient administered	CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value	decimal		
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code	from codelist C71620	Total amount of product administered in period	CMDOSTOT (if period is a day)
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.value	decimal	Total amount of active ingredient administered in period	CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code	from codelist C71620		
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.originalText.value	free text	Total amount of active ingredient administered in period	CMDOSTOT (if period is a day)
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.value	decimal		CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code	from codelist C71620		
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code	C25301, C29844, C29846	Period for total	

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ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value	DAY, WEEK, MONTH	amount administered	
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code	from codelist C71113	Frequency of medication administration	CMDOSFRQ
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value	from codelist C71113		
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value	decimal	Reason for dose change	CMADJ
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code	from codelist C74456	Site of medication administration	CMLOC
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	from codelist C74456		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229		CMLAT
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.value	datetime	Start datetime of medication administration	CMSTDTC
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.nullFlavor.or.code	NINF	Uncertain start datetime of medication administration	CMENRF or CMSTRPT & CMSTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.nullFlavor.or.displayName.value	Negative Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.lowClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.high.value	datetime	End datetime of medication administration	CMENDTC
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.highClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.value	datetime	Uncertain end datetime of medication administration	CMENRF or CMENRPT & CMENTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.nullFlavor.code	NINF		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.nullFlavor.displayName.value	Negative Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.lowClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.high.nullFlavor.code	PINF		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.high.nullFlavor.displayName.value	Positive Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.high.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.highClosed	TRUE, FALSE		

ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Start study date of med admin	CMSTDY
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.high.value	<i>integer</i>	End study day of med admin	CMENDY
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.code	<i>sponsor codelist? MedDRA?</i>	Indication for medication administration	CMINDC
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	<i>sponsor codelist? MedDRA?</i>		
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>		

Possible associated concepts

May trigger this concept	Query whether <pre-specified concomitant medication> was taken during an evaluation interval (OCCUR CM TRT)	
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OCCUR Group

Concept: Query about occurrence of any of <group of pre-specified concomitant medication administrations> in an evaluation interval

Domain: CM
TRT: <pre-specified group>
PRESP=Y

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable		
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.code	<i>from drug dictionary</i>	Pre-specified class	in CMTRT and CMCAT		
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.displayName.value	<i>from drug dictionary</i>				
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.originalText.value	<i>free text</i>				
MEDCRIT.Defined.Drug.formCode.CD.code	<i>from codelist C66726</i>	Pre-specified dose form	in CMTRT and CMCAT		
MEDCRIT.Defined.Drug.formCode.CD.displayName.value	<i>from codelist C66726</i>				
MEDCRIT.Defined.Drug.formCode.CD.originalText.value	<i>free text</i>				
MEDCRIT.Defined.Drug.description.ST.value	<i>free text</i>	Pre-specified description	in CMTRT and CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code	<i>from codelist C66729</i>	Pre-specified route of administration	in CMTRT and CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	<i>from codelist C66729</i>				
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code	<i>from codelist C74456</i>	Pre-specified target site	in CMTRT and CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value	<i>from codelist C74456</i>				
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value	<i>free text</i>				
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code	<i>from codelist C74456</i>	Pre-specified site of administration	in CMTRT and CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	<i>from codelist C74456</i>				
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	<i>free text</i>				
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229	Pre-specified indication	in CMTRT and CMCAT		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT				
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.code	<i>sponsor codelist</i>				
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	<i>sponsor codelist</i>	Focal time period	CMEVLINT		
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>				
CMQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format				
CMQ_O.DefinedObservation.focalDuration.PQ.unit.code					
CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value					
CMQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	<i>free text</i>		CMEVLTXT		

CMQ_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Question datetime	CMDTC
CMQ_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Question study day	CMDY
CMQ_O.PerformedObservation.negativeIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Question not asked	CMSTAT
CMQ_O.PerformedObservation.negativeReason.DSET<SC>.item.value	<i>free text</i>	Reason question not asked	CMREASND
CMQ_O.PerformedObservation.negativeReason.DSET<SC>.item.code.code	<i>sponsor codelist</i>		
CMQ_O.PerformedObservation.negativeReason.DSET<SC>.item.code.displayName.value	<i>sponsor codelist</i>		
CMQ_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result value	CMOCCUR
CMQ_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Possible associated concepts

Triggered by Yes response to this concept	Collection of details of pre-specified group of CM administrations (PRESP CM Group)	
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PRESP CM Group

Concept: Collection of details of administrations of <pre-specified group of concomitant medication> during an evaluation interval

Domain:

TRT: <pre-specified group>

PRESP= Y

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.code	from drug dictionary	Pre-specified class	in CMCAT
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.displayName.value	from drug dictionary		
MEDCRIT.Defined.Drug.classCode.DSET<CD>.item.originalText.value	free text		
MEDCRIT.Defined.Drug.formCode.CD.code	from codelist C66726	Pre-specified dose form	in CMCAT
MEDCRIT.Defined.Drug.formCode.CD.displayName.value	from codelist C66726		
MEDCRIT.Defined.Drug.formCode.CD.originalText.value	free text		
MEDCRIT.Defined.Drug.description.ST.value	free text	Pre-specified description	in CMCAT
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code	from codelist C66729	Pre-specified route of administration	in CMCAT
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	from codelist C66729		
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code	from codelist C74456	Pre-specified target site	in CMCAT
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value	from codelist C74456		
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value	free text		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code	from codelist C74456	Pre-specified site of administration	in CMCAT
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	from codelist C74456		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	free text		
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229		in CMCAT
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT		
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.code	sponsor codelist	Pre-specified indication	in CMCAT
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	sponsor codelist		
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	free text		
CMQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format	Focal time period	CMEVLINT
CMQ_O.DefinedObservation.focalDuration.PQ.unit.code			
CMQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
CMQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	free text	Medication administered	CMEVLTXT
MEDCOLL.Performed.Drug.codeModifiedText.ST.value	free text		CMMODIFY
MEDCOLL.Performed.Drug.code.CD.code	from drug dictionary		CMDECOD
MEDCOLL.Performed.Drug.code.CD.displayName.value	from drug dictionary		CMTRT
MEDCOLL.Performed.Drug.code.CD.originalText.value	free text		

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MEDCOLLPerformedDrug.formCode.CD.code	from codelist C66726	Doseform of administered medication	CMDOSFRM
MEDCOLLPerformedDrug.formCode.CD.displayName.value	from codelist C66726		
MEDCOLLPerformedDrug.formCode.CD.originalText.value	free text		
ADMINCOLLPerformedSubstanceAdministration.routeOfAdministrationCode.CD.code	from codelist C66729	Route of administration of administered medication	CMROUTE
ADMINCOLLPerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	from codelist C66729		
ADMINCOLLPerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value	free text		
ADMINCOLLPerformedSubstanceAdministration.productDose.PQ.originalText.value	free text	Amount of product administered	CMDOSE
ADMINCOLLPerformedSubstanceAdministration.productDose.PQ.value	decimal		CMDOSU
ADMINCOLLPerformedSubstanceAdministration.productDose.PQ.unit.code	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.productDose.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value	free text	Amount of active ingredient administered	CMDOSE
ADMINCOLLPerformedSubstanceAdministration.activeIngredientDose.PQ.value	decimal		CMDOSU
ADMINCOLLPerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value	free text	Total amount of product administered in period	CMDOSTOT (if period is a day)
ADMINCOLLPerformedSubstanceAdministration.periodProductDoseTotal.PQ.value	decimal		CMDOSU
ADMINCOLLPerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.originalText.value	free text	Total amount of active ingredient administered in period	CMDOSTOT (if period is a day)
ADMINCOLLPerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.value	decimal		CMDOSU
ADMINCOLLPerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.displayName.value	from codelist C71620		
ADMINCOLLPerformedSubstanceAdministration.dosePeriodCode.CD.code	C25301, C29844, C29846	Period for total amount administered	
ADMINCOLLPerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value	DAY, WEEK, MONTH		

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ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code	<i>from codelist C71113</i>	Frequency of medication administration	CMDOSFRQ
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value	<i>from codelist C71113</i>		
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value	<i>decimal</i>	Reason for dose change	CMADJ
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code	<i>from codelist C74456</i>	Site of medication administration	CMLOC
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	<i>from codelist C74456</i>		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229	RIGHT, LEFT	CMLAT
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value			
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.value	<i>datetime</i>	Start datetime of medication administration	CMSTDTC
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.nullFlavor.code	NINF		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.nullFlavor.displayName.value	Negative Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.low.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.lowClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.high.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low不确定Range.highClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.originalText.value	<i>free text</i>	End datetime of medication administration	CMENDTC
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.nullFlavor.code	NINF		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.nullFlavor.displayName.value	Negative Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.low.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high不确定Range.lowClosed	TRUE, FALSE		

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ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange. high.nullFlavor.code	PINF	Uncertain end datetime of medication administration	CMENRF or CMENRTPT & CMENTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange. high.nullFlavor.displayName.value	Positive Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange. high.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange. highClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Start study date of med admin	CMSTDY
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.high.value	<i>integer</i>	End study day of med admin	CMENDY
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.code	<i>sponsor codelist?</i> <i>MedDRA?</i>	Indication for medication administration	CMINDC
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item. displayName.value	<i>sponsor codelist?</i> <i>MedDRA?</i>		
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item. originalText.value	<i>free text</i>		

Possible associated concepts

May trigger this concept	Query whether any of <pre-specified group> of concomitant medication administrations occurred during an evaluation interval (OCCUR CM Group)	
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LOG CM

Concept: Collection concomitant medication details

Domain: CM

PRESP= null

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable
MEDCOLL.Performed.Drug.codeModifiedText.ST.value	<i>free text</i>	Medication administered	CMMODIFY
MEDCOLL.Performed.Drug.code.CD.code	<i>from drug dictionary</i>		
MEDCOLL.Performed.Drug.code.CD.displayName.value	<i>from drug dictionary</i>		CMDECOD
MEDCOLL.Performed.Drug.code.CD.originalText.value	<i>free text</i>		CMTRT
MEDCOLL.Performed.Drug.formCode.CD.code	<i>from codelist C66726</i>	Doseform of administered medication	CMDOSFRM
MEDCOLL.Performed.Drug.formCode.CD.displayName.value	<i>from codelist C66726</i>		
MEDCOLL.Performed.Drug.formCode.CD.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.code	<i>from codelist C66729</i>	Route of administration of administered medication	CMROUTE
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	<i>from codelist C66729</i>		
ADMINCOLL.PerformedSubstanceAdministration.routeOfAdministrationCode.CD.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.originalText.value	<i>free text</i>	Amount of product administered	CMDOSE
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.value	<i>decimal</i>		CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.code	<i>from codelist C71620</i>		
ADMINCOLL.PerformedSubstanceAdministration.productDose.PQ.unit.displayName.value	<i>from codelist C71620</i>	Amount of active ingredient administered	CMDOSE
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.originalText.value	<i>free text</i>		CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.value	<i>decimal</i>		
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.code	<i>from codelist C71620</i>		CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.activeIngredientDose.PQ.unit.displayName.value	<i>from codelist C71620</i>	Total amount of product administered in period	CMDOSTOT (if period is a day)
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.value	<i>decimal</i>		
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.code	<i>from codelist C71620</i>	Total amount of active ingredient administered in period	CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.periodProductDoseTotal.PQ.unit.displayName.value	<i>from codelist C71620</i>		CMDOSTOT (if period is a day)
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.originalText.value	<i>free text</i>		
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.value	<i>decimal</i>	CMDOSU	CMDOSU
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.code	<i>from codelist C71620</i>		
ADMINCOLL.PerformedSubstanceAdministration.periodActiveIngredientDoseTotal.PQ.unit.displayName.value	<i>from codelist C71620</i>		

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ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.code	C25301, C29844, C29846	Period for total amount administered	
ADMINCOLL.PerformedSubstanceAdministration.dosePeriodCode.CD.displayName.value	DAY, WEEK, MONTH		
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.code	from codelist C71113	Frequency of medication administration	CMDOSFRQ
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.displayName.value	from codelist C71113		
ADMINCOLL.PerformedSubstanceAdministration.doseFrequencyCode.CD.originalText.value	free text	Reason for dose change	CMADJ
ADMINCOLL.PerformedSubstanceAdministration.changeReason.ST.value	decimal		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD.code	from codelist C74456	Site of medication administration	CMLOC
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD. displayName.value	from codelist C74456		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteCode.CD. originalText.value	free text	CMLAT	
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229		
ADMINCOLL.PerformedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD. displayName.value	RIGHT, LEFT	Start datetime of medication administration	CMSTDTC
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.originalText.value	free text	Uncertain start datetime of medication administration	CMENRF or CMSTRPT & CMSTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.uncertainRange. low.nullFlavor.code	NINF		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.uncertainRange. low.nullFlavor.displayName.value	Negative Infinity	End datetime of medicaiton adminstration	CMENDTC
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.uncertainRange. low.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.uncertainRange. lowClosed	TRUE, FALSE	Uncertain end datetime of medication administration	CMENRF or CMENRTPT & CMENTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.uncertainRange. high.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.low.uncertainRange. highClosed	TRUE, FALSE	Uncertain end datetime of medication administration	CMENRF or CMENRTPT & CMENTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.value	datetime		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.originalText.value	free text		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange. low.nullFlavor.code	NINF	Uncertain end datetime of medication administration	CMENRF or CMENRTPT & CMENTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange. low.nullFlavor.displayName.value	Negative Infinity		

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ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.low.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.lowClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF	Uncertain end datetime of medication administration	CMENRF or CMENRTPT & CMENTPT
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive Infinity		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>		
ADMINCOLL.PerformedSubstanceAdministration.dateRange.IVL<TS>.high.uncertainRange.highClosed	TRUE, FALSE		
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.low.value	<i>integer</i>	Start study date of medication administration	CMSTDY
ADMINCOLL.PerformedSubstanceAdministration.studyDayRange.IVL<INT>.high.value	<i>integer</i>	End study day of medication administration	CMENDY
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.code	<i>sponsor codelist?</i> <i>MedDRA?</i>	Indication for medication administration	CMINDC
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	<i>sponsor codelist?</i> <i>MedDRA?</i>		
ADMINCOLL.PerformedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>		

Possible associated concepts

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Introduction

SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata.

The metadata held in the SHARE metadata repository will include information on research concepts, including

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains how the metadata is organized on the page.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the superset of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains four concepts, three of which collect data about a pre-specified type of healthcare encounter.

These three concepts are "templates" themselves in the sense that a particular kind of healthcare encounter is specified when the concept is used in a particular study.

- **HO NUMBER**, a query about the number of healthcare encounters of a pre-specified type during a particular evaluation interval.
The SDTM variables show the handling of this data in a Findings About structure.
- **HO OCCUR**, a query about occurrence of a healthcare encounter. The SDTM variables show the handling of this data in a Findings About structure.
- **PRESp HO**, details (e.g., start and end time) collected about healthcare encounters of a pre-specified type.
- **LOG HO**, details collected about healthcare encounters. This represents general collection of healthcare encounters.

Key to Layout

Concept: How many <pre-specified type of healthcare encounter> occurred in <evaluation interval>?

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain: FA

FATEST=Number of encounters

FATESTCD=NUMBER

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
HCE_CRIT.DefinedActivity.nameCode.CD.code			
HCE_CRIT.DefinedActivity.nameCode.CD.displayName	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT	Name (type)	FAOBJ
HCE_CRIT.DefinedActivity.nameCode.CD.value	Text.value	free text	
HCEQ_O.DefinedObservedObject	it.code	SDTM uses ISO8601 duration format	FAE
HCEQ_O.DefinedObservedObject	it.displayName.value		
HCEQ_O.DefinedObservedObject	<TS>.originalText.value	free text	FAEVINTX
HCEQ_O.PerformedObservation	S>.low.value	datetime	FADTC
HCEQ_O.PerformedObservation	/L<INT>.low.value	integer	FADY
HCEQ_O.PerformedObservation	BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	FASTAT
HCEQ_O.PerformedObservation	SET<SC>.item.value	free text	FAREASND
HCEQ_O.PerformedObservation	SET<SC>.item.code.code	sponsor codelist	
HCEQ_O.PerformedObservation	SET<SC>.item.code.displayName.value	sponsor codelist	
HCEQ_R.PerformedObservationResult.valueNullFlavorReason.ST.value	datetime	Reason Null Result	FAREASND
HCEQ_R.PerformedObservationResult.value.PQ.value	integer	Result value	FAORRES

Possible associated concepts

<i>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</i>	Trig the sponse	Pre-specified healthcare encounter query (See HO OCCUR spreadsheet)	

The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.

The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).

The third column describes an “attribute” of the test. There may be several BRIDG-based data items for a single

The fourth column shows where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.

Template

Concept:

Domain: HO

TERM:

PRESP:

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)		
HCE_CRIT.DefinedActivity.nameCode.CD.code				Block for pre-specified kind of healthcare encounter	
HCE_CRIT.DefinedActivity.nameCode.CD.displayName.value	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT	Name (type)	HOTERM		
HCE_CRIT.DefinedActivity.nameCode.CD.originalText.value	free text				
HCEQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format	Focal time period	HOEVLINT	Block for question about healthcare encounters	
HCEQ_O.DefinedObservation.focalDuration.PQ.unit.code					
HCEQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			HOEVINTX		
HCEQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	free text				
HCEQ_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Question datetime	HODTC		
HCEQ_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Question study day	HODY		
HCEQ_O.PerformedObservation.negotiationIndicator.BL.value	TRUE, FALSE (SDTM NOT DONE, null)	Question not asked	HOSTAT		
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Reason question not asked	HOREASND		
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.code.code	sponsor codelist				
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.code.displayName.value	sponsor codelist				
HCEQ_R.PerformedObservationResult.valueNullFlavorReason.ST.value	free text	Reason Null Result	HOREASND	Block for response to question about healthcare encounters	
HCEQ_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result value	HOOCCUR (if occurrence question)		
HCEQ_R.PerformedObservationResult.value.CD.displayName.value	Y,N				
HCECOLL.DefinedActivity.nameCode.CD.code		Name (type)	HOTERM		
HCECOLL.DefinedActivity.nameCode.CD.displayName.value					
HCECOLL.DefinedActivity.nameCode.CD.originalText.value	free text				
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.value	datetime	Start occurrence datetime	HOSTDTC	Block for recording details of healthcare encounter	
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF	Uncertain start datetime of healthcare encounter	HOSTRF or HOSTRTPT & HOSTTPT		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative Infinity				
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.value	datetime				
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.lowClosed	TRUE, FALSE				
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.high.value	datetime	End occurrence datetime	HOENDTC		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.highClosed	TRUE, FALSE				
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.value	datetime				

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HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF	Uncertain end datetime of healthcare encounter	HOENRF or HOENRTPT & HOENTPT	Block for recording details of healthcare encounter	
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative Infinity				
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.value	<i>datetime</i>				
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.lowClosed	TRUE, FALSE				
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF				
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive Infinity				
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>				
HCECOLLPerformedActivity.dateRange.IVL<TS>.high.uncertainRange.highClosed	TRUE, FALSE				
HCEPerformedActivity.duration.PQ.value	decimal (SDTM uses ISO8601 duration)	Duration	HODUR		
HCEPerformedActivity.duration.PQ.unit.code					
HCEPerformedActivity.duration.PQ.unit.displayName.value		Reason for healthcare encounter	QNAM=HOREAS		
HCEPerformedActivity.reasonCode.DSET<CD>.item.code	<i>from sponsor-defined code system</i>				
HCEPerformedActivity.reasonCode.DSET<CD>.item.displayName.value	<i>from sponsor-defined code system</i>				
HCEPerformedActivity.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>				

Possible associated concepts

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HO OCCUR

Concept: Did <pre-specified> healthcare encounter occur?

Domain: FA

FATEST= Number of

FATESTCD= NUMBER

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
HCE_CRIT.DefinedActivity.nameCode.CD.code			
HCE_CRIT.DefinedActivity.nameCode.CD.displayName.value	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT	Name (type)	FAOBJ
HCE_CRIT.DefinedActivity.nameCode.CD.originalText.value	free text		
HCEQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format	Focal time period	FAEVLINT
HCEQ_O.DefinedObservation.focalDuration.PQ.unit.code			
HCEQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
HCEQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	free text		FAEVINTX
HCEQ_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Question datetime	FADTC
HCEQ_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Question study day	FADY
HCEQ_O.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Question not asked	FASTAT
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Reason question not asked	FAREASND
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.code.code	sponsor codelist		
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.code. displayName.value	sponsor codelist		
HCEQ_R.PerformedObservationResult.valueNullFlavorReason.ST.value	free text	Reason Null Result	FAREASND
HCEQ_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result value	FAORRES, FAORRESC
HCEQ_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Possible associated concepts

Observation triggered by "Yes" response	Pre-specified healthcare encounter collection (see PRESP HO spreadsheet)	
Observation triggered by "Yes" response	Number of healthcare encounters (see HO NUMBER spreadsheet)	

HO NUMBER

Concept: How many <pre-specified type of healthcare encounter> occurred in <evaluation interval>?

Domain: FA

FATEST=Number of encounters

FATESTCD=NUMBER

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
HCE_CRIT.DefinedActivity.nameCode.CD.code			
HCE_CRIT.DefinedActivity.nameCode.CD.displayName.value	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT	Name (type)	FAOBJ
HCE_CRIT.DefinedActivity.nameCode.CD.originalText.value	free text		
HCEQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601 duration format	Focal time period	FAEVLINT
HCEQ_O.DefinedObservation.focalDuration.PQ.unit.code			
HCEQ_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
HCEQ_O.DefinedObservation.focalDateRange.IVL<TS>.originalText.value	free text		FAEVINTX
HCEQ_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Question datetime	FADTC
HCEQ_O.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Question study day	FADY
HCEQ_O.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Question not asked	FASTAT
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Reason question not asked	FAREASND
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.code.code	sponsor codelist		
HCEQ_O.PerformedObservation.negationReason.DSET<SC>.item.code. displayName.value	sponsor codelist		
HCEQ_R.PerformedObservationResult.valueNullFlavorReason.ST.value	datetime	Reason Null Result	FAREASND
HCEQ_R.PerformedObservationResult.value.PQ.value	integer	Result value	FAORRES

Possible associated concepts

Triggering observation response	Pre-specified healthcare encounter query (See HO OCCUR spreadsheet)	
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PRESp HO

Concept: Collection of details of <pre-specified> healthcare encounter

Domain: HO

HOTERM = <pre-specified>

HOPRESP = Y

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
HCECOLL.DefinedActivity.nameCode.CD.code		Name (type)	HOTERM
HCECOLL.DefinedActivity.nameCode.CD.displayName.value	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT		
HCECOLL.DefinedActivity.nameCode.CD.originalText.value	<pre-specified>		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.value	datetime	Start occurrence datetime	HOSTDTC
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF	Uncertain start datetime of healthcare encounter	HOSTRF or HOSTRTPT & HOSTTPT
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative Infinity		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.lowClosed	TRUE, FALSE		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.high.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.highClosed	TRUE, FALSE	End occurrence datetime	HOENDTC
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative Infinity	Uncertain end datetime of healthcare encounter	HOENRF or HOENRTPT & HOENTPT
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.lowClosed	TRUE, FALSE		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive Infinity		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.value	datetime	Duration	HODUR
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.highClosed	TRUE, FALSE		
HCE.PerformedActivity.duration.PQ.value	decimal (SDTM uses ISO8601 duration)		
HCE.PerformedActivity.duration.PQ.unit.code		Duration	HODUR
HCE.PerformedActivity.duration.PQ.unit.displayName.value			

HCE.PerformedActivity.reasonCode.DSET<CD>.item.code	<i>from sponsor-defined code system</i>	Reason for healthcare encounter	QNAM=HOREAS
HCE.PerformedActivity.reasonCode.DSET<CD>.item.displayName.value	<i>from sponsor-defined code system</i>		
HCE.PerformedActivity.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>		

Possible associated concepts

Triggering observation response	Pre-specified healthcare encounter query (See HO OCCUR spreadsheet)	
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LOG HO

Concept: Collection of details of healthcare encounters

Domain: HO
 TERM: collected
 PRESP=N

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
HCECOLL.DefinedActivity.nameCode.CD.code		Name (type)	HOTERM
HCECOLL.DefinedActivity.nameCode.CD.displayName.value	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT		
HCECOLL.DefinedActivity.nameCode.CD.originalText.value	free text		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.value	datetime	Start occurrence datetime	HOSTDTC
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF	Uncertain start datetime of healthcare encounter	HOSTRF or HOSTRTPT & HOSTTPT
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative Infinity		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.low.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.lowClosed	TRUE, FALSE		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.high.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.low.uncertainRange.highClosed	TRUE, FALSE		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.value	datetime	End occurrence datetime	HOENDTC
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF	Uncertain end datetime of healthcare encounter	HOENRF or HOENRTPT & HOENTPT
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative Infinity		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.low.value	datetime		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.lowClosed	TRUE, FALSE		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive Infinity		
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.high.value	datetime	Duration	HODUR
HCECOLL.PerformedActivity.dateRange.IVL<TS>.high.uncertainRange.highClosed	TRUE, FALSE		
HCE.PerformedActivity.duration.PQ.value	decimal (SDTM uses ISO8601 duration)	Duration	HODUR
HCE.PerformedActivity.duration.PQ.unit.code			

HCE.PerformedActivity.duration.PQ.unit.displayName.value	HOSPITALIZATION, INTENSIVE CARE UNIT STAY, EMERGENCY DEPARTMENT VISIT	Duration	HODUR
HCE.PerformedActivity.reasonCode.DSET<CD>.item.code	<i>from sponsor-defined code system</i>	Reason for healthcare encounter	
HCE.PerformedActivity.reasonCode.DSET<CD>.item.displayName.value	<i>from sponsor-defined code system</i>		QNAM=HOREAS
HCE.PerformedActivity.reasonCode.DSET<CD>.item.originalText.value	<i>free text</i>		

Possible associated concepts

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Introduction

SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata. The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains how the metadata is organized on the page.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the superset of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook include metadata describing three concepts.

specified.

- **OCCUR MH TERM**, a query about the occurrence of a pre-specified medical condition during an evaluation interval.
The SDTM variables given handle the observation and its response in the MH domain using the PRESP and OCCUR variables.
- **PRESP MH TERM**, collection of details (e.g., start and end) of a pre-specified medical condition that occurred during an evaluation interval.
- **LOG MH**, collection information about medical conditions that are not pre-specified.
This is the concept used in standard Medical History data collection; the evaluation interval is usually not populated but is implicitly the time before the date of data collection.

Key to Layout

Concept: Pre-specified medical history query

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain: MH
TERM: <pre-specified>
MHPRESP = Y

BRIDG-based concept variable	value(s)	Attribute	SDTM variable
MHCRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA		
MHCRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>	Pre-specified term	MHTERM
MHCRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
<i>The main body of the sheet contains the data items (variables) that make up the concept, described in terms of the BRIDG class and attributes on which they are based, along with a component of the complex datatype for the class attribute, controlled terminology (if applicable) and where the data item is represented in SDTM.</i>	decimal (in SDTM, ISO8601 duration)	Focal time period	MHEVLINT
MHQQUER.calDuration.PQ.value			
MHQQUER.calDuration.PQ.unit.code			
MHQQUER.calDuration.PQ.unit.displayName.value			
MHQQUER.calDateRange.IVL<EXPR<TS>>.low.expressi	text describing start of focal time period		
MHQQUER.calDateRange.IVL<EXPR<TS>>.high.exress	text describing end of focal time period		
MHQQUER.dateRange.IVL<TS>.low.value	datetime		
MHQQUER.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)		
MHQQUER.negationReason.DSET<SC>.item.value	free text		
MHQQUERY_R.PerformedObservationResult.valueNullFlavorReason.ST.value	free text		
MHQQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487	Shaded cells represent paired values.	MHOCUR
MHQQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Blue text indicates terminology that has not yet been approved.

Possible associated concepts

<i>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</i>	"Yes" response in this concept	Pre-specified medical history collection (PRESPMH TERM)		
	<i>The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.</i>	<i>The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).</i>	<i>The third column describes an "attribute" of the test. There may be several BRIDG-based data items for a single attribute.</i>	<i>The fourth column shows where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.</i>

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Template

Concept:

Domain: MH
MHTERM:
MHPRESP:

BRIDG-based concept variable	value(s)	Attribute	SDTM variable	
MHCRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA	Pre-specified term	MHTERM	Criterion Block used when MH is pre-specified
MHCRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>			
MHCRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>			
MHQRY_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO860	Focal time period	MHEVLINT	Block for properties of a question about MH events
MHQRY_O.DefinedObservation.focalDuration.PQ.unit.code				
MHQRY_O.DefinedObservation.focalDuration.PQ.unit.displayName.value				
MHQRY_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>.low.exression.ED.value	<i>text describing start of focal time period</i>	DateRange	MHDTC	Block for collected properties of a question about MH events
MHQRY_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>.high.exression.ED.value	<i>text describing end of focal time period</i>			
MHQRES_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	NegationIndicator	MHSTAT	Block for response to question about MH events
MHQRES_O.PerformedObservation.negativeIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)			
MHQRES_O.PerformedObservation.negativeReason.DSET<SC>.item.value	free text			
MHQRES_R.PerformedObservationResult.valueNullFlavorReason.ST.value	free text	Reason Null Result	MHREASND	Block for collected properties of an observation collecting details of MH events
MHQRES_R.Result.PerformedObservationResult.value.CD.code	C49488, C49487			
MHQRES_R.PerformedObservationResult.value.CD.displayName.value	Y, N			
MHCOLL_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO860	Focal time period	MHEVLINT	Block for collected properties of an observation collecting details of MH events
MHCOLL_O.DefinedObservation.focalDuration.PQ.unit.code				
MHCOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value				
MHCOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>.low.exression.ED.value	<i>text describing start of focal time period</i>	DateRange	MHDTC	Block for collected properties of an observation collecting details of MH events
MHCOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>.high.exression.ED.value	<i>text describing end of focal time period</i>			
MHCOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Occurrence date range	MHSTDTC	Block for collected properties of an MH event
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.value	datetime			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.value	datetime			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF	uncertain start datetime uses MHSTRF or MHSTTPT & MHSTRTP	MHENDTC	Block for collected properties of an MH event
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative infinity			

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MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.value	<i>datetime</i>	Occurrence date range	uncertain start datetime uses MHSTRF or MHSTTPT & MHSTRTPPT	Block for collected properties of an MH event
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.high.value	<i>datetime</i>		uncertain end datetime uses MHENRF or MHENTPT & MHENRTPT	
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative infinity			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.value	<i>datetime</i>			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive infinity			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.value	<i>decimal</i> (in SDTM, ISO8601 duration)			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.unit.code			MHDUR	
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.unit.displayName.value				
MHCOLL_R.PerformedMedicalConditionResult.value.CD.code	<i>from MedDRA</i>	Pre-specified result	MHTERM	
MHCOLL_R.PerformedMedicalConditionResult.value.CD.displayName.value	<pre-specified>			
MHCOLL_R.PerformedMedicalConditionResult.value.CD.originalText.value	<pre-specified>			
MHCOLL_R.PerformedMedicalConditionResult.severityCode.CD.code	C41338, C41339, C41340	Severity	MHSEV	
MHCOLL_R.PerformedMedicalConditionResult.severityCode.CD.displayName.value	MILD, MODERATE, SEVERE			

Possible associated concepts

<i>nature of relationship of associated concept to this concept</i>	<i>name of associated concept</i>		
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OCCUR MH TERM

Concept: Pre-specified medical history query

Domain: MH
 TERM: <pre-specified>
 MHPRESP = Y

BRIDG-based concept variable	value(s)	Attribute	SDTM variable
MHCRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA	Pre-specified term	MHTERM
MHCRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>		
MHCRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
MHQUERY_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO8601 duration)	Focal time period	MHEVLINT
MHQUERY_O.DefinedObservation.focalDuration.PQ.unit.code			
MHQUERY_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
MHQUERY_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>, low.exression.ED.value	<i>text describing start of focal time period</i>		MHEVINTX
MHQUERY_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>, high.exression.ED.value	<i>text describing end of focal time period</i>		
MHQUERY_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date of query	MHDTC
MHQUERY_O.PerformedObservation.negativeIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation indicator	MHSTAT
MHQUERY_O.PerformedObservation.negativeReason.DSET<SC>.item.value	free text	Negation reason	MHREASND
MHQUERY_R.PerformedObservationResult.valueNullFlavorReason.ST.value	free text	Reason Null Result	MHREASND
MHQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487	Result value	MHOCCUR
MHQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N		

Possible associated concepts

Observation triggered by "Yes" response in this concept	Pre-specified medical history collection (PRESPMH TERM)	
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PRESPH MH TERM

Concept: Pre-specified medical history collection

Domain: MH

TERM: <pre-specified>

MHPRESP = Y

BRIDG-based concept variable	value(s)	Attribute	SDTM variable
MHCRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA	Pre-specified term	MHTERM
MHCRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>		
MHCRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
MHCOLL_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO8601 duration)	Focal time period	MHEVLINT
MHCOLL_O.DefinedObservation.focalDuration.PQ.unit.code			
MHCOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
MHCOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>low.exression.ED.value	<i>text describing start of focal time period</i>	Date of collection	MHEVINTX
MHCOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>high.exression.ED.value	<i>text describing end of focal time period</i>		
MHCOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime		
MHCOLL_R.PerformedMedicalConditionResult.occurrenceDateRange.IVL<TS>.low.value	datetime	Occurrence date range	uncertain start datetime uses MHSTRF or MHSTTPT & MHSTRTPPT
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.value	datetime		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative infinity		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.value	datetime		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.high.value	datetime		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative infinity		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.value	datetime		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive infinity		

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MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>	Occurrence date range	uncertain end datetime ... MHDUR
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.value	<i>decimal</i> (in SDTM, ISO8601 duration)		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.unit.code			
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.unit.displayName.value			
MHCOLL_R.PerformedMedicalConditionResult.severityCode.CD.code	C41338, C41339, C41340	Severity	MHSEV
MHCOLL_R.PerformedMedicalConditionResult.severityCode.CD.displayName.value	MILD, MODERATE, SEVERE		

Possible associated concepts

Yes response may trigger this concept	Pre-specified medical history query (See OCCUR MH TERM spreadsheet)	
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MH LOG

Concept: Collection of concomitant medication administrations.

Domain: MH
 MHTERM: collected
 MHPRESP=null

BRIDG-based concept variable	value(s)	Attribute	SDTM variable
MHCOLL_O.DefinedObservation.focalDuration.PQ.value	<i>decimal</i> (in SDTM, ISO8601 duration)	Focal time period	MHEVLINT
MHCOLL_O.DefinedObservation.focalDuration.PQ.unit.code			
MHCOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			MHEVINTX
MHCOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>low.exression.ED.value	<i>text describing start of focal time period</i>		
MHCOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>high.exression.ED.value	<i>text describing end of focal time period</i>		
MHCOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>		MHDTC
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.value	<i>datetime</i>		MHSTDTC
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.value	<i>datetime</i>		MHENDTDC
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.code	NINF		uncertain start datetime uses MHSTRF or MHSTTPT & MHSTRTPPT
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.nullFlavor.displayName.value	Negative infinity		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.low.value	<i>datetime</i>		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.low.uncertainRange.high.value	<i>datetime</i>		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.code	NINF		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.nullFlavor.displayName.value	Negative infinity		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.low.value	<i>datetime</i>		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.code	PINF		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.nullFlavor.displayName.value	Positive infinity		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.high.uncertainRange.high.value	<i>datetime</i>		
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.value	<i>decimal</i> (in SDTM, ISO8601 duration)		MHDUR

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MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.unit.code		Occurrence date range	MHDUR
MHCOLL_R.Performed.MedicalConditionResult.occurrenceDateRange.IVL<TS>.width.unit.displayName.value			
MHCOLL_R.PerformedMedicalConditionResult.value.CD.code	<i>from MedDRA</i>		
MHCOLL_R.PerformedMedicalConditionResult.value.CD.displayName.value	<pre-specified>	Pre-specified result	MHTERM
MHCOLL_R.PerformedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
MHCOLL_R.PerformedMedicalConditionResult.severityCode.CD.code	C41338, C41339, C41340		
MHCOLL_R.PerformedMedicalConditionResult.severityCode.CD.displayName.value	MILD, MODERATE, SEVERE	Severity	MHSEV

Possible associated concepts

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Introduction Red bold text in the upper left hand corner of each page is the page name.

SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata.

The metadata held in the SHARE metadata repository will include information on research concepts, including

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain to which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains how the metadata is organized on the page.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the superset of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains metadata for nine pulmonary function tests.

SHARE metadata has been developed only for those pulmonary function tests most commonly used measured in asthma studies.

- **FVC**, Forced Vital Capacity
- **PPFVC**, Percent Predicted FVC
- **FEV1**, Forced Expiratory Volume in 1 second
- **PPFEV1**, Percent Predicted FEV1
- **FEV1/FVC**, Ratio of FEV1 to FVC
- **FEF25-75**, Forced Expiratory Flow at 25% - 75% of Vital Capacity
- **PPFEF25-75**, Percent Predicted FEF25-75
- **PEF**, Peak Expiratory Flow
- **PPPEF**, Percent Predicted PEF

Key to Layout

Concept: Percent Predicted FVC

Definition: Forced vital capacity (FVC) as a proportion of the predicted normal FVC for a person of the same height, weight, and demographic characteristics.

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

Domain: RE

TEST: Percent

Predicted FVC

TESTCD: PPFVC

Blue text indicates terminology that has not yet been approved. via DOMAIN=RE

BRIDG-based concept variable	value(s)	Attribute	
PPFVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	
PPFVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
PPFVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
PPFVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
PPFVC_OBS.DefinedObservation.CD.code	SPIROMETRY		
PPFVC_OBS.DefinedObservation.displayName.value	<i>from codelist C85492</i>	Pre-specified method	REMETHOD
PPFVC_OBS.OriginalText.value	<i>free text</i>		
PPFVC_OBS.PerformedClinicalResult.L<TS>.low.value	<i>datetime</i>	Date Range	REDTCT
PPFVC_OBS.PerformedClinicalResult.IVL<INT>.low.value	<i>integer</i>	Study Day Range	REDY
PPFVC_OBS.PerformedClinicalResult.Negator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
PPFVC_OBS.PerformedClinicalResult.NonDSET<SC>.item.value	<i>free text</i>	Negation Reason	REREASND
PPFVC_RES.DefinedObservation.Expression.ST.value	FVC result value/FVC reference result value	Derivation Expression	
PPFVC_RES.PerformedClinicalResult.NegatorReason.ST.value	<i>free text</i>	Value NullFlavor Reason	REREASND
PPFVC_RES.PerformedClinicalResult.NegatorOriginalText.value	<i>free text</i>		REORRES, RESTRESC, RESTRESN
PPFVC_RES.PerformedClinicalResult.value.PQ.value	<i>decimal</i>	Result value	
PPFVC_RES.PerformedClinicalResult.value.PQ.unit.code	C25613, C44256	<i>Shaded cells represent paired values.</i>	REORRESU, RESTRESU
PPFVC_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	%, RATIO	Unit	
PPFVC_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL

Possible associated concepts

At the bottom of the sheet are other research concepts to which the research concept may or must be connected.

Normalized value is

The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.

Spirometer

The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).

The third column describes an “attribute” of the test. There may be several BRIDG-based data items for a single attribute.

SPDEVID

The fourth column shows the where the attribute is stored in SDTM. The mapping from data item to SDTM variable is not necessarily 1:1. Some data items are not stored in SDTM, and some are transformed.

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Template

Concept:

Domain: RE

Definition:

TEST:

TESTCD:

BRIDG-based concept variable	value(s)	Attribute	SDTM variable	
PFT_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via	Block for pre-specified properties of the test
PFT_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		DOMAIN=RE	
PFT_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421		RELOC	
PFT_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY			
PFT_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY			
PFT_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		REMETHOD	
PFT_OBS.DefinedObservation.methodCode.CD.originalText.value	free text	Prespecified method		
PFT_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime		REDTC	Block for collected properties of the test
PFT_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer		REDY	
PFT_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT	
PFT_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND	
PFT_RES.DefinedObservationResult.derivationExpression.ST.value	formula for percent of predicted normal value	Derivation Expression		Block for pre-specified properties of the result
PFT_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND	
PFT_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN	
PFT_RES.PerformedClinicalResult.value.PQ.value	decimal			
PFT_RES.PerformedClinicalResult.value.PQ.unit.code	from codelist C71620		REORRESU, RESTRESU	
PFT_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	from codelist C71620	Result unit		Block for collected properties of the result
PFT_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)		REBLFL	
PFT_RES.ReferenceResult.value.PQ.expression.value	formula for predicted normal value	Reference result value	REORREFR, RESTREFR	Block for properties of the reference result
PFT_RES.ReferenceResult.value.PQ.value	decimal			
PFT_RES.ReferenceResult.value.PQ.unit.code	from codelist C71620	Reference result unit	see	
PFT_RES.ReferenceResult.value.PQ.unit.displayName.value	from codelist C71620		Result unit	

Possible associated concepts

nature of relationship of associated concept to this concept	name of associated concept		
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FVC

Concept: Forced Vital Capacity

Definition: The maximum volume of air that can be exhaled after forced maximum inhalation.

Domain: RE
 TEST: Forced Vital Capacity
 TESTCD: FVC

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
FVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
FVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
FVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
FVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
FVC_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY	Prespecified method	REMETHOD
FVC_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		
FVC_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
FVC_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTA
FVC_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
FVC_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
FVC_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
FVC_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
FVC_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN
FVC_RES.PerformedClinicalResult.value.PQ.value	decimal		
FVC_RES.PerformedClinicalResult.value.PQ.unit.code	C28254, C48505	Result unit	REORRESU, RESTRESU
FVC_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	mL, L		
FVC_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL
FVC_RES.ReferenceResult.value.PQ.expression.value	formula for predicted normal value	Reference result value	REORREFR, RESTREFR
FVC_RES.ReferenceResult.value.PQ.value	decimal		
FVC_RES.ReferenceResult.value.PQ.unit.code	C28254, C48505	Reference result unit	see Result unit
FVC_RES.ReferenceResult.value.PQ.unit.displayName.value	mL, L		

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Normalized value derived from this result	Percent Predicted FVC		

PPFVC

Concept: Percent Predicted FVC

Definition: Forced vital capacity (FVC) as a proportion of the predicted normal FVC for a person of the same height, weight, and demographic characteristics.

Domain: RE

TEST: Percent

Predicted FVC

TESTCD: PPFVC

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
PPFVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
PPFVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
PPFVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
PPFVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
PPFVC_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY	Pre-specified method	REMETHOD
PPFVC_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		
PPFVC_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
PPFVC_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTCT
PPFVC_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
PPFVC_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
PPFVC_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
PPFVC_RES.DefinedObservationResult.derivationExpression.ST.value	FVC result value/FVC reference result value	Derivation Expression	
PPFVC_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
PPFVC_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN
PPFVC_RES.PerformedClinicalResult.value.PQ.value	decimal		
PPFVC_RES.PerformedClinicalResult.value.PQ.unit.code	C25613, C44256	Result unit	REORRESU, RESTRESU
PPFVC_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	%, RATIO		
PPFVC_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Result from which this normalized value is derived	FVC		

FEV1

Concept: Forced Expiratory Volume in first second

Definition: The volume of air that a subject can breathe out during the first second of exhalation after maximum inhalation.

Domain: RE

TEST: Forced Expiratory
Volume in 1 Second

TESTCD: FEV1

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
FEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468		
FEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG	Pre-specified target site	via DOMAIN=RE
FEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421		
FEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY	Pre-specified site of administration	RELOC
FEV1_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY		
FEV1_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492	Method	REMETHOD
FEV1_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
FEV1_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTC
FEV1_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
FEV1_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
FEV1_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
FEV1_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
FEV1_RES.PerformedClinicalResult.value.PQ.originalText.value	free text		REORRES, RESTRESC, RESTRESN
FEV1_RES.PerformedClinicalResult.value.PQ.value	decimal		
FEV1_RES.PerformedClinicalResult.value.PQ.unit.code	C28254, C48505		REORRESU, RESTRESU
FEV1_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	mL, L		
FEV1_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL
FEV1_RES.ReferenceResult.value.PQ.expression.value	formula for predicted normal value		REORREFR, RESTREFR
FEV1_RES.ReferenceResult.value.PQ.value	decimal		
FEV1_RES.ReferenceResult.value.PQ.unit.code	C28254, C48505		see
FEV1_RES.ReferenceResult.value.PQ.unit.displayName.value	mL, L	Reference result unit	Result unit

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Normalized value derived from this result	Percent Predicted FEV1		

PPFEV1

Concept: Percent Predicted FEV1

Definition: Forced expiratory volume during the first second of exhalation (FEV1) as a proportion of the predicted normal FEV1 for a person of the same height, weight, and demographic characteristics.

Domain: RE

TEST: Percent

Predicted FEV1

TESTCD: PPFEV1

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
PPFEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
PPFEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
PPFEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
PPFEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
PPFEV1_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY	Pre-specified method	REMETHOD
PPFEV1_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		
PPFEV1_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
PPFEV1_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTC
PPFEV1_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
PPFEV1_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
PPFEV1_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
PPFEV1_RES.DefinedObservationResult.derivationExpression.ST.value	FEV1 result value/ FEV1 reference result value	Derivation Expression	
PPFEV1_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
PPFEV1_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN
PPFEV1_RES.PerformedClinicalResult.value.PQ.value	decimal		
PPFEV1_RES.PerformedClinicalResult.value.PQ.unit.code	C25613, C44256	Result unit	REORRESU, RESTRESU
PPFEV1_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	%, RATIO		
PPFEV1_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Result from which this normalized value is derived	FEV1		

FEV1/FVC

Concept: Ratio of FEV1 to FVC

Definition: The proportion of total forced vital capacity that is expelled during the first second of a forced exhalation.

Domain: RE
 TEST: FEV1/FVC
 TESTCD: FEV1FVC

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
FEV1FVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
FEV1FVC_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
FEV1FVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
FEV1FVC_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
FEV1FVC_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY	Method	REMETHOD
FEV1FVC_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		
FEV1FVC_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
FEV1FVC_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTC
FEV1FVC_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
FEV1FVC_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
FEV1FVC_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
FEV1FVC_RES.DefinedObservationResult.derivationExpression.ST.value	FEV1 result value/FVC result value		
FEV1FVC_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
FEV1FVC_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN
FEV1FVC_RES.PerformedClinicalResult.value.PQ.value	decimal		
FEV1FVC_RES.PerformedClinicalResult.value.PQ.unit.code	C25613, C44256	Result unit	REORRESU, RESTRESU
FEV1FVC_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	%, RATIO		
FEV1FVC_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Numerator of this derived value	FEV1		
Denominator of this derived value	FVC		

FEF25-75Concept: **Forced Expiratory Flow at 25% - 75% of Vital Capacity**Definition: **In a maximal exhalation, the mean flow during the period between 25% and 75% of forced vital capacity.**

Domain: RE

TEST: **Forced Expiratory****Flow 25-75% Capacity**TESTCD: **FEF25_75**

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
FEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
FEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
FEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
FEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
FEV1_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY	Pre-specified method	REMETHOD
FEV1_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		
FEV1_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
FEV1_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTC
FEV1_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
FEV1_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
FEV1_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
FEV1_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
FEV1_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN
FEV1_RES.PerformedClinicalResult.value.PQ.value	decimal		
FEV1_RES.PerformedClinicalResult.value.PQ.unit.code	C64777, C67388, C67390, C69073	Result unit	REORRESU, RESTRESU
FEV1_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	mL/s, mL/min, L/s, L/min		
FEV1_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL
FEV1_RES.ReferenceResult.value.PQ.expression.value	formula for predicted normal value	Reference result value	REORREFR, RESTREFR
FEV1_RES.ReferenceResult.value.PQ.value	decimal		
FEV1_RES.ReferenceResult.value.PQ.unit.code	C64777, C67388, C67390, C69073	Reference result unit	see Result unit
FEV1_RES.ReferenceResult.value.PQ.unit.displayName.value	mL/s, mL/min, L/s, L/min		

Possible associated concepts

Device used in testing	Spirometer	SPDEVID
Normalized value derived from this result	Percent Predicted FEF25_75	

PPFEF25-75

Concept: Percent Predicted FEF 25-75

Definition: Forced Expiratory Flow at 25% - 75% of Vital Capacity (FVE25-75) as a proportion of the predicted normal FVE25-75 for a person of the same height, weight, and demographic characteristics.

Domain: RE
 TEST : PERCENT
 Predicted FEF 25-75
 TESTCD: PPFEF

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
PPFEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
PPFEV1_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
PPFEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
PPFEV1_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
PPFEV1_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY		
PPFEV1_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492	Pre-specified method	REMETHOD
PPFEV1_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
PPFEV1_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTC
PPFEV1_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
PPFEV1_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
PPFEV1_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
PPFEV1_RES.DefinedObservationResult.derivationExpression.ST.value	FEF 25-75 result value/ FEF 25-75 reference result value	Derivation Expression	
PPFEV1_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
PPFEV1_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	RESTRESC, RESTPESNL
PPFEV1_RES.PerformedClinicalResult.value.PQ.value	decimal		
PPFEV1_RES.PerformedClinicalResult.value.PQ.unit.code	C25613, C44256	Result unit	REORRESU, RESTRESU
PPFEV1_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	% , RATIO		
PPFEV1_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Result from which this normalized value is derived	FEF25_75		

PEF

Concept: Peak Expiratory Flow

Definition: The maximal flow achieved during the maximally forced expiration initiated at maximum inhalation.

Domain: RE

TEST: Peak

Expiratory Flow

TESTCD: PEF

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
PEF_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468		
PEF_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG	Pre-specified target site	via DOMAIN=RE
PEF_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421		
PEF_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY	Pre-specified site of administration	RELOC
PEF_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY		
PEF_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492	Pre-specified method	REMETHOD
PEF_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
PEF_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTA
PEF_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
PEF_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
PEF_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
PEF_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
PEF_RES.PerformedClinicalResult.value.PQ.originalText.value	free text		REUNRES, RESTPRESN
PEF_RES.PerformedClinicalResult.value.PQ.value	decimal	Result value	RESTRESC, RESTPRESN
PEF_RES.PerformedClinicalResult.value.PQ.unit.code	C64777, C67388, C67390, C69073		REORRESU, RESTRESU
PEF_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	mL/s, mL/min, L/s, L/min	Result unit	RESTRESU
PEF_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL
PEF_RES.ReferenceResult.value.PQ.expression.value	formula for predicted normal value		REORREFR,
PEF_RES.ReferenceResult.value.PQ.value	decimal	Reference result value	RESTREFR
PEF_RES.ReferenceResult.value.PQ.unit.code	C64777, C67388, C67390, C69073		see
PEF_RES.ReferenceResult.value.PQ.unit.displayName.value	mL/s, mL/min, L/s, L/min	Reference result unit	Result unit

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Device used in testing	Peak Flow Meter		SPDEVID
Normalized value derived from this result	Percent Predicted PEF		

PPPEF

Concept: Percent Predicted PEF

Definition: Peak Expiratory Flow (PEF) as a proportion of the predicted normal PEF for a person of the same height, weight, and demographic characteristics.

Domain: RE

TEST: Percent

Predicted PEF

TESTCD: PPPEF

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
PPPEF_OBS.DefinedObservation.targetAnatomicSiteCode.CD.code	C12468	Pre-specified target site	via DOMAIN=RE
PPPEF_OBS.DefinedObservation.targetAnatomicSiteCode.CD.displayName.value	LUNG		
PPPEF_OBS.DefinedObservation.approachAnatomicSiteCode.CD.code	C12421	Pre-specified site of administration	RELOC
PPPEF_OBS.DefinedObservation.approachAnatomicSiteCode.CD.displayName.value	ORAL CAVITY		
PPPEF_OBS.DefinedObservation.methodCode.CD.code	SPIROMETRY	Method	REMETHOD
PPPEF_OBS.DefinedObservation.methodCode.CD.displayName.value	from codelist C85492		
PPPEF_OBS.DefinedObservation.methodCode.CD.originalText.value	free text		
PPPEF_OBS.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	REDTC
PPPEF_OBS.PerformedObservation.studyDayRange.IVL<INT>.low.value	integer	Study Day Range	REDY
PPPEF_OBS.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	RESTAT
PPPEF_OBS.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	REREASND
PPPEF_RES.DefinedObservationResult.derivationExpression.ST.value	PEF result value/ PEF reference result value	Derivation Expression	
PPPEF_RES.PerformedClinicalResult.valueNullFlavorReason.ST.value	free text	Value NullFlavor Reason	REREASND
PPPEF_RES.PerformedClinicalResult.value.PQ.originalText.value	free text	Result value	REORRES, RESTRESC, RESTRESN
PPPEF_RES.PerformedClinicalResult.value.PQ.value	decimal		
PPPEF_RES.PerformedClinicalResult.value.PQ.unit.code	C25613, C44256	Result unit	REORRESU, RESTRESU
PPPEF_RES.PerformedClinicalResult.value.PQ.unit.displayName.value	%, RATIO		
PPPEF_RES.PerformedClinicalResult.baselineIndicator.BL.value	TRUE, FALSE (SDTM: Y, null)	Baseline Indicator	REBLFL

Possible associated concepts

Device used in testing	Spirometer		SPDEVID
Device used in testing	Peak Flow Meter		SPDEVID
Result from which this normalized value is derived	PEF		

Introduction

SHARE Metadata Displays

The Excel workbooks contain somewhat simplified versions of SHARE metadata. The metadata held in the SHARE metadata repository will include information on research concepts, including:

- The name and definition of the concept
- The data items (variables) that make up the concept, each described in terms of the BRIDG class and attribute and complex datatype component on which it is based
- Where applicable, the controlled terminology to be used for the item
- Other research concepts to which the research concept may or must be connected
- The SDTM domain in which the research concept is assigned
- Where the data item is represented in SDTM

The **Key to Layout** worksheet explains how the metadata is organized on the page.

Also included are explanations of the formats of contents of the table.

The **Template** worksheet shows the superset of BRIDG-based components from which the metadata for individual concepts were drawn.

The rightmost column describes the blocks of data items which are separated by bold lines. This column does not appear in tables for individual concepts.

This workbook contains three concepts. The first two are "templates" in the sense that they involve a pre-specified symptom. When used in a study, the particular symptom would be specified. When used in a study, the particular test about the symptom would be specified, as well as the particular symptom.

- **Symptom OCCUR**, a query whether a pre-specified symptom occurred during an evaluation interval.
The SDTM variables show this query handled as a Finding About.
- **PRESP Symptom**, collection of data (e.g., start and end) for a pre-specified symptom. The SDTM variables show the symptom handled as a clinical event.
- **FA Symptom**, a finding about a pre-specified symptom that has a coded response.

Key to Layout

Concept: Pre-specified symptom assessment query

At the top of the sheet are the concept name and the SDTM domain to which it is assigned. For tests, the TEST and TESTCD are also held here.

DOMAIN: FA

TEST=Occurrence

TESTCD=OCCUR

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
CECRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA		
CECRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>	Pre-specified term	FAOBJ
CECRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
CEQUERY_O.Definition.PQ.value	decimal (in SDTM, ISO8601 duration)		
CEQUERY_O.Definition.PQ.unit.code			FAEVLINT
CEQUERY_O.Definition.PQ.unit.displayName.value			
CEQUERY_O.Definition.RANGE.IVL<EXPR<TS>>low.expression.ED.value	text describing start of focal time period		
CEQUERY_O.Definition.RANGE.IVL<EXPR<TS>>high.expression.ED.value	text describing end of focal time period		FAEVINTX
CEQUERY_O.PerformedObservation.time.IVL<TS>.low.value	datetime	Date of collection	FADTC
CEQUERY_O.PerformedObservation.negationReason.DSET<SC>.item.value	TRUE, FALSE (SDTM NOT DONE, null)	Negation indicator	FASTAT
CEQUERY_O.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation reason	FAREASND
CEQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487	Shaded cells represent paired values.	FAORRES,
CEQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N		FASTRESC

Possible associated concepts

<i>At the bottom of the sheet are other research concepts to which the research concept may or must be connected.</i>	Yes" response	Pre-specified clinical event collection (PRESP Symptom)	
	<i>The first column shows the BRIDG-based data items. The names in this column are comprised of a short name for the concept, and the names of a BRIDG class, a BRIDG class attribute, and the (possibly multi-layered) name of a component of a complex datatype.</i>	<i>The second column shows either code values associated with the data item or a description of the data format (e.g., ISO8601 datetime or free text or integer).</i>	<i>The third column describes an "attribute" of the test. There may be several BRIDG-based data items for a single attribute.</i>

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Template

Concept:

DOMAIN:

TERM: or TEST:

PRESP= or TESTCD:

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)	
CECRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA		CETERM	Block for pre-specified asthma symptom event
CECRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>	Pre-specified term		
CECRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>			
CEQUERY_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO8601 duration)		CEEVLINT	
CEQUERY_O.DefinedObservation.focalDuration.PQ.unit.code		Focal time period		
CEQUERY_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			CEEVLTXT	
CEQUERY_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>low.exression.ED.value	<i>text describing start of focal time period</i>			Block for question about asthma symptom events
CEQUERY_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>high.exression.ED.value	<i>text describing end of focal time period</i>			
CEQUERY_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date of question	CEDTC	
CEQUERY_O.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	CESTAT	
CEQUERY_O.PerformedObservation.negationReason.DSET<SC>.item.value	free text	Negation Reason	CEREASND	
CEQUERY_R.PerformedObservationResult.value.CD.code	C49488, C49487		CEOCCUR	Block for response to question about asthma symptom event
CEQUERY_R.PerformedObservationResult.value.CD.displayName.value	Y, N	Result Value		
CECOLL_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO8601 duration)		CEEVLINT	
CECOLL_O.DefinedObservation.focalDuration.PQ.unit.code		focal time period		
CECOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			CEEVLTXT	
CECOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>low.exression.ED.value	<i>text describing start of focal time period</i>			Block for recording details of the asthma symptom event
CECOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>high.exression.ED.value	<i>text describing end of focal time period</i>			
CECOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date Range	CEDTC	
CECOLL_R.PerformedMedicalConditionResult.occurrenceDateRange.IVL<TS>.low.value	datetime	Ocurrence date range	CESTDTC	
CECOLL_R.PerformedMedicalConditionResult.occurrenceDateRange.IVL<TS>.high.value	datetime		CEENDTC	
CECOLL_R.PerformedMedicalConditionResult.value.CD.code	from MedDRA		CETERM	
CECOLL_R.PerformedMedicalConditionResult.value.CD.displayName.value	<pre-specified>	pre-specified result		
CECOLL_R.PerformedMedicalConditionResult.value.CD.originalText.value	<pre-specified>			

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CEFA_O.DefinedObservation.nameCode.CD.code	< <i>sponsor-defined</i> >	Test	FATESTCD, FATEST	Block for observation about symptom event	
CEFA_O.DefinedObservation.nameCode.CD.displayName.value	< <i>sponsor-defined</i> >				
CEFA_O..DefinedObservation.description.ST.value					
<PrespecifiedClinicalEvent>DefinedMedicalConditionResult.value.CD.code	<i>from MedDRA?</i>	Clinical Term	FAOBJ		
<PrespecifiedClinicalEvent>DefinedMedicalConditionResult.value.CD.displayName.value	< <i>pre-specified</i> >				
<PrespecifiedClinicalEvent>DefinedMedicalConditionResult.value.CD.originalText.value	< <i>pre-specified</i> >				
CEFA_O.PerformedObservation.dateRange.IVL<TS>.low.value	<i>datetime</i>	Date Collected	FADTC		
CEFA_O.PerformedObservation.negationIndicator.BL.value	TRUE, FALSE (SDTM: NOT DONE, null)	Negation Indicator	FASTAT		
CEFA_O.PerformedObservation.negationReason.DSET<SC>	<i>free text</i>	Negation Reason	FAREASND		
CEFA_R.PerformedObservationResult.value.ANY	<i>free text</i>	Result	FAORRES	Block for result of observation about symptom event	
CEFA_R.PerformedObservationResult.valueCodeModifiedText	C66742	Result	FASTRESC		

PRESP Symptom

Concept: Pre-specified symptom assessment collection

DOMAIN: CE
 TERM: <pre-specified>
 CEPRESP = Y

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
CECRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA?	Pre-specified term	CETERM
CECRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>		
CECRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
CECOLL_O.DefinedObservation.focalDuration.PQ.value	decimal (in SDTM, ISO8601 duration)	Focal time period	CEEVLINT
CECOLL_O.DefinedObservation.focalDuration.PQ.unit.code			
CECOLL_O.DefinedObservation.focalDuration.PQ.unit.displayName.value			
CECOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>low.exression.ED.value	<i>text describing start of focal time period</i>		CEEVLTXT
CECOLL_O.DefinedObservation.focalDateRange.IVL<EXPR<TS>>high.exression.ED.value	<i>text describing end of focal time period</i>		
CECOLL_O.PerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date of question	CEDTC
CECOLL_R.PerformedMedicalConditionResult.occurrenceDateRange.IVL<TS>.low.value	datetime	Occurrence date range	CESTDTC
CECOLL_R.PerformedMedicalConditionResult.occurrenceDateRange.IVL<TS>.high.value	datetime		

Possible associated concepts

Triggering observation response	Pre-specified clinical event query	
Triggered by the occurrence of the event	Query about defined medical condition collection (Symptom OCCUR)	

FA Symptom

Concept: Finding about a symptom event with coded response

DOMAIN: FA

TEST: <Sponsor-defined>

TESTCD: <Sponsor-defined>

BRIDG-based concept variable	value(s)	Attribute	SDTM variable(s)
CEFA_O.DefinedObservation.nameCode.CD.code	<sponsor defined>	Test	FATESTCD, FATEST
CEFA_O.DefinedObservation.nameCode.CD.displayName.value	<sponsor defined>		
CEFA_O.DefinedObservation.description.ST.value			
CECRIT.DefinedMedicalConditionResult.value.CD.code	from MedDRA?	Clinical event term	FAOBJ
CECRIT.DefinedMedicalConditionResult.value.CD.displayName.value	<pre-specified>		
CECRIT.DefinedMedicalConditionResult.value.CD.originalText.value	<pre-specified>		
CEFA_OPerformedObservation.dateRange.IVL<TS>.low.value	datetime	Date collected	FADTC
CEFA_OPerformedObservation.negativeIndicator.BL.value	code list C66789	Negative indicator	FASTAT
CEFA_OPerformedObservation.negativeReason.DSET<SC>	free text	Negative reason	FAREASND
CEFA_R.PerformedObservationResult.value.CD.code	from response codelist	result	FAORRES, FAORRESC
CEFA_R.PerformedObservationResult.valueCD.displayName.value	from response codelist		

Possible associated concepts

Triggering findings about defined medical condition collection	Pre-specified clinical event collection (PRESP Symptom)	
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