[\*](#Core" \o "Element classified as Core)Date Medical History Taken: (mm/dd/yyyy)

Does the participant/subject have a history of any medical problems/conditions in the following body systems? [ ]  No (leave rest of form blank) [ ]  Yes

Enter all significant medical history items, including surgeries, EXCEPT the problem/condition that is the focus of this study. Use only one line per description.

\*Use BODY SYSTEM categories for medical history:

Constitutional symptoms (e.g., fever, weight loss)

Eyes

Ears, Nose, Mouth, Throat

Cardiovascular

Respiratory

Gastrointestinal

Genitourinary

Hepatobiliary

Musculoskeletal

Integumentary (skin and/or breast)

Neurological

Psychiatric

Endocrine

Hematologic/Lymphatic

Allergic/Immunologic

Medical History Data Table

| \*Body System | \*Medical History Term(one item per line) | Start Date(mm/dd/yyyy) | Ongoing? | End Date(mm/dd/yyyy) |
| --- | --- | --- | --- | --- |
| Cardiovascular | Example: Hypertension | 03**/**99**/**2009 | [ ] Yes[ ] No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |
| Data to be entered by site | Data to be entered by site | (mm/dd/yyyy) | [ ]  Yes[ ]  No | (mm/dd/yyyy) |

1. Gestational age at birth: ( ) weeks
2. Birth weight:

The following interview questions can be use to help make sure a complete medical history is documented:

Has a doctor or other medical professional ever told you that you have or have had the following? (If yes, provide year diagnosed

1. Any stroke: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Transient ischemic attack (TIA): [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Migraine(s): [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Epilepsy/ Seizure disorder: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Central nervous system infection: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Dementia: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Depressive disorder diagnosis: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Anxiety disorder diagnosis: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Bipolar disorder diagnosis: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Psychotic disorder: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown (y y y y)

If YES, specify type(s): (choose all that apply)

[ ]  Schizophrenia

[ ]  Depression w/ psychotic features

[ ]  Bipolar disorder

[ ]  Dementia with psychotic ideation

[ ]  Other, specify:

1. Cardiac arrhythmia: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

1. Coronary artery disease: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

1. Valvular heart disease: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Congestive heart failure: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Peripheral arterial disease: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Hypertension: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Diabetes mellitus: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

[ ]  Type I (Juvenile Onset) [ ]  Type II (adult onset or related to obesity)

Has a doctor or other medical professional ever told you that you have or have had the following? (If yes, provide year diagnosed)

1. High blood cholesterol / Hypercholesterolemia: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Cancer: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

(choose all that apply)

[ ]  Brain

[ ]  Breast

[ ]  Colorectal

[ ]  Endometrial

[ ]  Esophagus

[ ]  Lung

[ ]  Prostate

[ ]  Renal (kidney)

[ ]  Skin

[ ]  Hematologic

[ ]  Other, specify:

1. Connective tissue disease: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

1. Inflammatory bowel disease: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Thyroid disease (except cancer): [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

1. Glaucoma: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Cataracts: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Macular edema: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Sleep apnea: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Renal (kidney) failure: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Chronic liver failure: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Irritable bowel syndrome: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Fibromyalgia: [ ]  Yes (y y y y)

[ ]  No [ ]  Unknown

1. Arthritis: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

1. ADHD: [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

1. Autism Spectrum Disorder: : [ ]  Yes (y y y y) If YES, specify type:

[ ]  No [ ]  Unknown

## General Instructions

Medical History data are collected to verify the inclusion and exclusion criteria (e.g., no history of cognitive disabilities) and to describe the study population. Typically, the Medical History Form captures conditions that EVER occurred at some point in time within a protocol-defined period (e.g., the last 12 months).

The form should focus on significant medical history of all problems or conditions other than those related to the focus of the study and are presented in the order typically used during a patient visit. If the participant/ subject reports more than one medical condition per system, record each condition on a separate line.

All elements on this CRF are classified as Supplemental unless otherwise indicated by an asterisk (\*) and should be collected if the research team considers them appropriate for their study.

\*This element is classified as Core.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date Medical History Taken – Record the date (and time) the medical history was taken. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Does this participant/subject have…? – Choose one. If this question is answered NO then the rest of the form is blank. If the question is answered YES then the medical history for at least one body system should be recorded.
* Body System – Record the appropriate body system for each line of medical history.
* Condition/Disease - Record one Medical History term per line. See the data dictionary for additional information on coding the condition using SNOMED CT.
* Start Date – Record the date the medical condition/disease started. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Ongoing? – Check Yes or No to indicate if the medical condition/disease is still present.
* End Date – If the condition is not ongoing, record the date (and time) the medical condition/disease stopped. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Gestational Age – Record the gestational age of the participant/subject in weeks and days. This element is intended for pediatric clinical studies.
* Birth Weight – Record the birth weight of the participant/ subject in kilograms (Kg). This element is intended for pediatric clinical studies.