1. **[\*](#Core" \o "Element classified as Core)**Date Medical History Taken: **//** (yyyy-mm-dd)
2. [**\***](#Core)Does the participant/subject have a history of any medical problems/conditions in the following body systems?

Yes  No (leave rest of form blank)

1. 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

Musculoskeletal

Integumentary (skin and/or breast)

Neurological

Psychiatric

Endocrine

Hematologic/Lymphatic

Allergic/Immunologic

Example of Medical history data collection grid

| \*Body System | \*Medical History Term (one item per line) | \*Start Date (month/day/year) | \*Ongoing? | \*End Date (month/day/year) |
| --- | --- | --- | --- | --- |
| Cardiovascular | Example: Hypertension | 03**/**31**/**2009 | YesNo | // |

Medical history data grid

| \*Body System | \*Medical History Term (one item per line) | \*Start Date (month/day/year) | \*Ongoing? | \*End Date (month/day/year) |
| --- | --- | --- | --- | --- |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | YesNo | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | YesNo | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | YesNo | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | YesNo | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | YesNo | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | YesNo | Data to be entered by site |

\*Element is classified as Core

## 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 General Medical History CRF captures conditions that occurred at some point in time within a protocol defined period as opposed to the Medical History of Neuromuscular Diseases CRF which captures conditions specifically related to NMD.

## Specific Instructions

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

The majority of the data elements on the CRF have the following instructions:

When asking participant/ subject use the following: Has a doctor or other medical professional ever told you that you have/ have had a(n)? History can also be obtained from a family member, friend, or chart/ medical record. If the informant is unable to answer the question or is deemed unreliable (e.g., the participant/ subject has dementia) the history should be obtained from the medical record.

* Date Medical History Taken - Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ([International Standard Organization 8601](http://www.iso.org/iso/iso8601)). 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.).
* Does this participant/subject have…? - If this question is answered NO then the rest of the form is blank. If the question is answered YES then fill out the chart with all relevant medical history.
* 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 (and time) 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 – Record the date (and time) 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.