Did the participant/subject take any medications (Insert number of days here) days before or during the study?\*  Yes  No (Leave rest of form blank)

Table Prior and Concomitant Medications

| Medication Name  (Trade or generic name) | Indication  (If given for AE, enter exact term from AE CRF) | Dose | Units | Freq. | Route[[1]](#footnote-1) | Start Date  (yyyy-mm-dd) | End Date  (yyyy-mm-dd) | Ongoing? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No |

## General Instructions

Collecting medications taken prior to the study in a defined time window (e.g., 30 days) is important when there may be potential interactions with the study intervention. Study exclusion criteria may identify drugs that cannot be taken during the study and so prior medications are identified to determine whether an individual may be eligible for the study.

Collecting concomitant medications taken during a study is also important for safety reasons. Some drugs may interact with the study intervention and must not be taken during the study. Additionally, there may be some drugs that are not known to interact with the study intervention and may be identified through an adverse event. It may be helpful to ask study participants/subjects or their caregivers to bring prescription and over-the-counter medications to follow-up visits so that the medications can be more easily and accurately recorded on the CRF

Important note:

For ALS: None of the data elements included on this CRF Module are classified as Core (i.e., required for all studies to collect).

For FSHD: All data elements are classified as Supplemental- Highly Recommended (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

For CMD: One data element is considered Core.

The Prior and Concomitant Medications form should be filled out at the baseline visit and every study visit/time point thereafter.

Studies that plan to submit their data to regulatory authorities are recommended to code their medication data using a standard terminology such as the WHO Drug dictionary.

## Specific Instructions

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

* Any Medications? – Choose one. If this question is answered YES then at least one prior/concomitant medication record needs to be recorded. Do NOT record study medications taken (if study has a drug intervention) on this form. Refer to the Study Drug Dosing form to record study medications.
* Medication Name – Record the verbatim name (generic or trade name) of the medication the participant/subject reports taking. See the data dictionary for additional information on coding the medication name using RXNorm.
* Indication – Record the reason the participant/subject gives for taking the medication. If given for an AE, enter exact term from Adverse Event CRF.
* Dose – Record the strength and units of the medication the participant/subject is taking.
* Dose Units - Record the units of the medication the participant/subject is taking. See the data dictionary for additional information on coding the dosage unit of measure using Unified Code for Units of Measure (UCUM).
* Frequency - Record how often the medication is being taken. See the data dictionary for additional information on coding the frequency using CDISC SDTM Frequency Terminology.
* Route – Record the route of administration. Acceptable responses for Route are shown below the medication table.
* Start Date and Time – Record the date (and time if applicable to the study) the participant/subject started taking the medication. 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. Start Date can be used to distinguish between prior medications and concomitant medications. Studies that need to collect Start Time will need to add fields for time to the form template.
* End Date and Time – Record the date (and time if applicable to the study) the participant/subject stopped taking the medication. 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. End Date should be recorded if Continuing Medication is answered NO. Conversely, End Date should remain blank if Continuing Medication is answered YES. Studies that need to collect End Time will need to add fields for time to the form template.
* Ongoing? – Choose one. Answer YES if the participant/subject is still taking the medication or NO if the participant/subject has stopped taking the medication.

\* Element is classified as Core for CMD.

1. Select from the following for medication route: Buccal, Inhaled, Intramuscular, Intravenous, Nasal, Oral, Rectal, By ear, Topical, Subcutaneous, Sublingual, Transdermal, Unknown, Other specify [↑](#footnote-ref-1)