Prior and Current Treatments Table

| Treatment Type | Dose Units | Dose Frequency |
| --- | --- | --- |
| A = Acetylcholinesterase inhibitor  B = Corticosteroids  C = Immunosuppressant, specify  D = Immunomodulating agent, specify  E = IVIg  F = PLEX  G = Other, specify | g = gram  mcg = microgram  mcL = microliter  mg = milligram  mL = milliliter  oz = ounce  OTH = other, specify  UNK = unknown  NA = Not applicable | BID = twice daily  TID = three times a day  QID = four times a day  q2h = every 2 hours  q4h = every 4 hours  q6h = every 6 hours  q8h = every 8 hours  QAM = one dose in morning  QPM = one dose in evening  QD = once daily  AD = alternating day (every other day)  HS = at bedtime  PRN = as needed  OTH = other  UNK = unknown  NA = Not applicable |

Treatment Type Table

| \*Treatment Type | \*Treatment Name | \*Total (or average) Daily Dose | \*Dose Units | \*Dose Frequency | Start Date (mm/dd/yyyy) | End Date (mm/dd/yyyy) | \*Ongoing? | \*Side effect or complication? | \*Response |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Yes  No | Yes  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | Yes  No | Yes  No | Data to be entered by site |

\*Element is classified as Core

## 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. Thus, a potential participant/subject may need to stop a medication prior to starting the study intervention (washout period). Furthermore, the 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.

The Prior and Current Treatment 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 RXNorm.

## 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.
* Treatment type - Record one treatment per row. For each treatment record the treatment type - choose one. If Immunosuppressant, Immunomodulating agent, or Other are answered for Treatment Type, specify agent used
* 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.
* 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.
* 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.
* Side effect or complication – Record for each treatment.
* Prior or concominant response – Record the response to each treatment. If no response, record more.