1. Has the participant/subject ever taken steroids for the treatment of Duchenne or Becker Muscular Dystrophy?

[ ]  Yes Complete Table #1 - add additional lines as needed. Use a separate line when the dose or frequency of a treatment has changed.)

[ ]  No (Do not complete Table #1, Skip to Question #2)

Table Steroids Taken Abbreviations Table

| Dose Units | Dose Frequency | Route |
| --- | --- | --- |
| mg = milligramOTH = other, specifyUNK = unknown | BID = twice dailyBIW = 2 days per week QAM = one dose in morning ys on/ 10 days off QPM = one dose in evening QD = once daily AD = alternating day (every other day) | PO – oralOTH – other, specify UNK=unknown |

Table #1:

Table 2 Steroids Taken Table

| Treatment Name (Trade or generic name) | Dose | Dose Units | Frequency | Route | Start Date(mm/dd/yyyy)ORAge (to the nearest ½ year) | Stop Date(mm/dd/yyyy)ORAge (to the nearest ½ year) | Reason(s) Stopped/Changed | Ongoing? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  PO  (Oral) [ ] Other, specify**:** | (mm/dd/yyyy)Age: | (mm/dd/yyyy)Age: | [ ] Hypertension[ ]  Excessive [ ]  Weight Gain[ ] Adjustment for growth [ ] Loss of ambulation [ ] Fractures [ ]  Behavior [ ]  Disorder[ ]  Growth Failure[ ]  Delayed Puberty | Data to be entered by site |

1. Has the participant/ subject ever taken physician prescribed medications, investigational medications, or supplements?

[ ]  Yes Complete Table #2 - add additional lines as needed. Use a separate line when the dose or frequency of a medication has changed.)

[ ]  No (Stop Completing Form)

Table 3 Prescribed Medications Taken Abbreviations Table

| Dose Units | Dose Frequency | Route |
| --- | --- | --- |
| g = gram mcg = microgram mcL = microliter mg = milligram mL = milliliteroz = ounce OTH = other, specify UNK = unknown NA = Not applicable | BID = twice dailyTID = three times a day QID = four times a dayq2h = every 2 hours q4h = every 4 hours q6h = every 6 hoursq8h = every 8 hours QAM = one dose in morning QPM = one dose in evening QD = once dailyAD = alternating day (every other day)HS = at bedtimePRN = as neededOTH = other UNK = unknown NA = Not applicable | IM – intramuscular IN - intranasal INH – inhaled IT – intrathecally IV – intravenousPO – oral SC – subcutaneous TOP – topical OTIC – by ear OTH – other, specify |

Table #2

Table 4 Prescribed Medications Taken Table

| Medication/ Supplement Name (Trade or generic name) | Indication(If given for AE, enter exact  term from AE CRF) | Dose | Dose Units | Frequency | Route | Start Date(mm/dd/yyyy) OR Age (to the nearest ½  year) | Stop Date(mm/dd/yyyy) OR  Age (to the nearest ½ year) | Ongoing? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 | (mm/dd/yyyy)Age: | (mm/dd/yyyy)Age: | [ ]  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. 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 current 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 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 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 YESthen at least one prior/current

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 above 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.

* Stop 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.