Did the patient/participant take any medications: XX days before or during the study?  Yes  No(If “No”, leave rest of form blank)

Table 1 Concomitant Medications

| Medication Name  (Trade or generic name) | Indication  (If given for AE, enter exact term from AE CRF) | Dose | Dose Units | Frequency | Route[[1]](#footnote-1) | Start Date | End Date | Ongoing? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| TBD | TBD | TBD | TBD | TBD | TBD | TBD | TBD | Yes  No |

Add more rows as needed

For specific medication questions related to the neurological, genitourinary, gastrointestinal or cardiovascular system, please see the Exploratory list of questions below, which may be applicable.

## Additional Exploratory Elements (as applicable):

1. Any steroids administered\*\*\*:

Methylprednisone/Corticosteriods:

NASCIS II (Methylprednisolone or Solumedrol run as an infusion x 23 or 24 hrs)

NASCIS III (Methylprednisolone or solumedrol run as an infusion x 47 or 48 hrs)

Other, specify

None

Unknown

Date and time administered\*\*\*:

1. Any vasopressor use\*\*\*

No

Yes

Unknown

Date and time administered\*\*\*:

Date medication history taken:

1. Any drugs for the urinary tract within the last year\*\*\*1:

No

Yes

Unknown

If Yes, indicate type of drugs for the urinary tract used within the last year:

Bladder relaxant drugs (anticholinergics, tricyclic antidepressants, etc.)

Sphincter/bladder neck relaxant drugs (alpha adrenergic blockers, etc.)

Antibiotics/antiseptics:

For treatment of urinary tract infection

For prophylactic reasons

Other, specify

1. Medication affecting bowel function / constipating agents (within the last four weeks)\*\*\*2:

No

Yes

Unknown

If Yes, specify medication affecting bowel function/constipating agents:

Anticholinergics

Narcotics

Other, specify:

1. Oral laxatives (within the last four weeks)\*\*\*2:

No

Yes

Unknown

If Yes, indicate which type of medication:

Osmotic laxatives (drops)

Osmotic or bulking laxatives (tablets or granulates)

Irritant laxatives (drops)

Irritant laxatives (tablets)

Prokinetics

Other, specify:

1. Any medication affecting cardiovascular function on the day of examination\*\*\*3:

No

Yes

Unknown

If Yes, indicate type of medication affecting cardiovascular function:

Anticholinergics

Antihypertensives (beta-blocker, ACE etc.)

Antihypotensives

Cardiac (digitalis, anti-arrhythmics, etc.)

Other, specify

1. Any treatment for spasticity/spasms within the last four weeks\*\*\*4:

No

Yes

Unknown

### **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 patient/participant 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 patients/participants 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 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 RXNorm.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are Supplemental (or Exploratory where indicated) and should be collected on clinical trials and only if the research team considers them appropriate for their study.

### **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 TimeRecord: 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.
* Special Note: The ISCoS International SCI Data Sets have been included in the exploratory data elements on this template CRF:

[1 International SCI Lower Urinary Tract Function Basic Data Set](http://www.iscos.org.uk/international-sci-lower-urinary-tract-function-data-sets) (Version 1.0)

[2 International SCI Bowel Function Basic Data Set](http://www.iscos.org.uk/international-sci-bowel-data-sets) (Version 1.0)

[3 International SCI Cardiovascular Function Basic Data Set](http://www.iscos.org.uk/international-sci-cardiovascular-function-data-sets) (Version 1.1)

[4 International SCI Musculoskeletal Basic Data Set](http://www.iscos.org.uk/international-sci-musculoskeletal-data-sets) (Version 1.0)

\*\*\*Element is classified as Exploratory

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)