1. (Based on chart abstraction) Did participant take hydroxyurea since last assessment?

Yes  No

1. Last dose
   * 1. Value
     2. Units
     3. Frequency
     4. Route
2. Start date/End date (Length of time)

**The following to include history of narcotics/pain killers including dose and frequency**

Did the participant/subject take any other medications (please specify) days before or during the study?  Yes  No (Leave rest of form blank)

Table to Record Medications Taken by Participant/Subject

| 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  (m m/dd/yyyy) | End Date  (m m/dd/yyyy) | 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 | //20 | //20 | 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 | //20 | //20 | 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 | //20 | //20 | 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 | //20 | //20 | 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 | //20 | //20 | Yes  No |

The following interview questions can be used to help make sure a complete record of all prior and concomitant medications is documented.

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

Folic acid  Yes  No  Unknown

Prophylactic PCN  Yes  No  Unknown

1. Antiplatelets:

Yes  No  Unknown

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Aspirin (ASA)

Clopidogrel (Plavix)

Cilostazol (Pletal)

ASA/Dypiridamole (in separate formulations or as Aggrenox)

Ticlopidine (Ticlid)

Ticagrelor (Brilinta)

Pentoxiphylline (Trental)

Prasugrel (Effient)

Other, specify:

1. Anticoagulants:

Yes  No  Unknown

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Unfractionated heparin IV

Warfarin (Coumadin)

Full dose LMW heparin (Enoxaparin, Others)

Fondaparinux (Arixtra)

Other, specify:

1. Cholesterol-reducing/ controlling medications:

Yes  No  Unknown

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Statin  Fibrate  Other, specify:

1. Diabetic medications:

Yes  No  Unknown

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Insulin

Metformin

Acarbose

1st generation sulfonylurea (chlorpropramide)

2nd generations sulfonylurea (glyburide, glipizide)

Rosiglitazone, piolitazone and other "glitazones"

Repaglinide/ Nateglinide

Other, specify:

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

##### Antihypertensive medications:

Yes  No (Skip to Question 6)  Unknown (Skip to Question 6)

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Diuretic *(*Answer 5B)

Beta-blocker (Answer 5C)

Angiotensin receptor blocker (Answer 5D)

Calcium-channel blocker (Answer 5E)

Ace inhibitor (Answer 5F)

Potassium supplement

Other (Answer 5G)

1. If diuretic history, indicate medication(s) the patient took within the past week: (choose all that apply)

Thiazides (HCTZ, chlorthalidone)

Furosemide/ loop diuretic

Potassium sparing

Other, specify:

1. If beta-blocker history, indicate medication(s) the patient took within the past week: (choose all that apply)

Propranolol

Atenolol

Metoprolol

Carvedilol

Other, specify:

1. If angiotensin receptor blocker history, indicate medication(s) the patient took within the past week: (choose all that apply)

Candestartan  Losartan  Other, specify:

1. If calcium-channel blocker history, indicate medication(s) the patient took within the past week: (choose all that apply)

Verapamil–ER

Felodipine

Amlopidine

Other, specify:

1. If ace inhibitor history, indicate medication(s) the patient took within the past week: (choose all that apply)

Enalapril

Lisinopril

Fosinopril

Ramapril

Other, specify:

1. If other medication history, indicate medication(s) the patient took within the past week: (choose all that apply)

Central alpha agonists (clonidine)

Alpha-blockers (prazosin, terazosin)

Vasodilator: minoxidil

Vasodilator: hydralazine

Other antihypertensive, specify:

##### Hormonal replacement medications:

Yes  No  Unknown

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Estrogen  Progesterone Combination of Estrogen and Progesterone Other, specify:

1. If YES, indicate the route of hormonal replacement therapy:

Oral  Topical  Transdermal  Other, specify: Unknown

1. Oralcontraceptives

Yes  No  Unknown

1. Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?
2. Implanted, estrogen-containing contraceptives

Yes  No  Unknown

1. Any other medicationsnot already listed:

Yes  No  Unknown

1. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

Digoxin/cardiac glycosides

Antiarrhythmic drugs (quinidine, amiodarone)

Thyroid preparations

Benzodiazepines (Valium, Librium, Ativan, Xanax)

Non-aspirin salicylates (salsa late)

Other nonsteroidal anti-inflammatory drugs

Gingko derivatives/other herbals

Vitamin E (more than multivitamins)

Nitrates

SSRIs and new-generation antidepressants

Tricyclic antidepressants (amitriptyline, imipramine, doxepin)

H2 blocker (e.g. cimetidine) or proton pump inhibitor (e.g. omeprazole)

Donazepril and related meds

Analgesics (acetaminophen, codeine)–daily

Cox 2 inhibitors (rofecoxib, celecoxib, valdecoxib) (e.g. ibuprofen, naproxen)

Multivitamin

Other, specify:

## Additional Pediatric-specific Elements

These elements are recommended for pediatric stroke studies.

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

1. Attention Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) medications:

Yes  No  Unknown

1. Cold preparations/ medications:

Yes  No  Unknown

1. L-asparaginase

Yes  No  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 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 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.

## 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.

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)