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

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 |

Select from the following for medication route: Buccal, Inhaled, Intramuscular, Intravenous, Nasal, Oral, Rectal, By ear, Topical, Subcutaneous, Sublingual, Transdermal, Unknown, Other specify

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?

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/Dipyridamole (in separate formulations or as Aggrenox)

Ticlopidine (Ticlid)

Ticagrelor (Brilinta)

Pentoxifylline (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)

Phenprocoumon

Acenocoumarol

Dabigatran (Pradaxa)

Apixaban (Eliquis)

Rivaroxaban (Xarelto)

Edoxaban (Savaysa)

Betrixaban (Bevyxxa)

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 Ezetimibe Other, specify:

* 1. If YES, was patient taking PCSK9 inhibitors within past three months (alirocumab, evolocumab)

Yes No Unknown

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 (chlorpropamide)

2nd generation sulfonylurea (glyburide, glipizide, glimepiride)

Thiazolidinedione (rosiglitazone, pioglitazone)

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 (ARB) history, indicate medication(s) the patient took within the past week: (choose all that apply)

Candesartan Losartan Other, specify:

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

Verapamil

Felodipine

Amlodipine

Diltiazem

Other, specify:

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

Enalapril

Lisinopril

Fosinopril

Ramipril (Altace)

Captopril

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 Testosterone Other, specify:

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

Oral Topical Transdermal Other, specify: Unknown

1. Oralcontraceptives

Yes No Unknown

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

1. Implanted, estrogen-containing contraceptives

Yes No Unknown

1. Stimulants

Amphetamine derivatives

Caffeine (Xanthine derivative)

Modafinil

Phentermine

Theophylline (Xanthine derivative)

Other, specify:

Duration of use (months):

Age when use started (years):

Age when use ended (years):

1. \*\*\*Potency-enhancing drugs:

Sildenafil (Viagra)

Avanafil (Stendra)

Tadalafil (Cialis)

Vardenafil (Levitra)

Duration of use (months):

Age when use started (years):

Age when use ended (years):

1. \*\*\*Immunosuppressants:

Corticosteroids, systemic

Corticosteroids, local

Others, specify:

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)

Anti-Parkinsonian meds (including selegiline)

Non-aspirin salicylates (salsalate)

Other nonsteroidal anti-inflammatory drugs

Ginkgo 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)

Donepezil and related meds

Analgesics (acetaminophen, codeine)–daily

COX inhibitors (e.g., ibuprofen, naproxen)

COX 2 inhibitors (e.g., celecoxib)

Multivitamin

Other, specify:

1. Cocaine: Exposure to cocaine within one year of clinical presentation of UIA:

Yes

No

If yes:

Duration of use (months):

Age when use started (years):

\*\*\*Age when use ended (years):

1. \*\*\*Taking supplements?

Yes

No

Unknown

\*\*\*If YES, type(s) of supplements (Choose all that apply):

Beta Carotene

Calcium

Dehydroepiandrosterone (DHEA)

Echinacea

Flax Seed Oil

Folic Acid

Ginkgo

Ginseng

Saw Palmetto

Soy Protein Powder

Soy Supplements

St. John's Wort

Vitamin A

Vitamin C

Vitamin E

Weight Loss Supplements

Wheat Germ

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.

Important note: Some data elements included on this CRF Module are considered Exploratory as specified by asterisks below:

\*\*\*Element is classified as Exploratory

The remaining data elements are Supplemental and should only be collected 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 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.
* Cocaine use: Exposure of cocaine within one year of clinical presentation of UIA.

1. [↑](#footnote-ref-1)