For some studies (e.g., clinical trials) it may be important to record the details of each medication administered during the study on a Prior and Concomitant Medications form. The General CDEs include a [Prior and Concomitant Medications template form.](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/General/F0020_Prior_and_Concomitant_Medications.docx)

## In-Hospital Medications

1. \*\*Did the participant/ subject receive anticoagulant agents?  Yes  No

\*\*IF YES, type(s) of anticoagulant agents received: (choose all that apply)

Unfractionated heparin IV

Full dose LMW heparin (Enoxaparin, Others)

Warfarin (Coumadin)

Direct thrombin inhibitor (Lepirudin, Desirudin, Bivalirudin, Argatroban, Dabigatran)

Factor Xa inhibitor (Apixaban, Betrixaban, Edoxaban, Rivaroxaban, Fondaparinux)

Other, specify:

1. \*\*Did the participant/ subject receive antiplatelet agents?  Yes  No

\*\*IF YES, type(s) of antiplatelet agents received: (choose all that apply)

Aspirin

Aspirin/Dipyridamole (in separate formulations or as Aggrenox)

Clopidogrel (Plavix)

Cilostazol

Other, specify:

1. Was the participant/ subject diagnosed with VTE?  Yes  No (Skip to 4)

(VTE = extracranial venous thromboembolism)

1. IF YES, diagnosed with which type(s): (choose all that apply)

Deep venous thrombosis (DVT)

Pulmonary embolism

Other, specify:

1. IF YES, type(s) of VTE prophylaxis used: (choose all that apply)

Low dose unfractionated heparin (LDUH)

Low molecular weight heparin (LMWH)

Intermittent pneumatic compression devices (IPC) e.g. venous foot pump

Direct thrombin inhibitor (Lepirudin, Desirudin, Bivalirudin, Argatroban, Dabigatran)

Factor Xa inhibitor (Apixaban, Betrixaban, Edoxaban, Rivaroxaban, Fondaparinux)

Other, specify:

## Discharge Medications

1. Specify discharging location:

Acute hospital

Intensive Inpatient rehabilitation facility (IRF) including distinct rehabilitation units of a hospital: three hours or greater of therapy per day

Skilled nursing facility (SNF)/ subacute rehab: less than two hours a day of therapy

Medicare certified long-term care hospital (LTCH)

Hospice- home or medical facility providing hospice level of care

Other not defined above:

1. \*\*Which class(es) of medications was the participant/ subject prescribed at discharge? (choose all that apply)

Anticoagulant agents (Answer 5A and Skip 6)

Antiplatelet agents (Answer 5B and Skip 6)

Antihypertensive agents (Answer 5C and Skip 6)

Anti-diabetic agents (Answer 5D and Skip 6)

Lipid lowering agents (Answer 5E and Skip 6)

1. \*\*IF anticoagulant agents prescribed, specify type(s): (choose all that apply)

Low molecular weight heparin (LMWH) (Enoxaparin, others)

Warfarin (Coumadin)

Direct thrombin inhibitor (Lepirudin, Desirudin, Bivalirudin, Argatroban, Dabigatran)

Factor Xa inhibitor (Apixaban, Betrixaban, Edoxaban, Rivaroxaban, Fondaparinux)

Other, specify:

1. \*\*IF antiplatelet agents prescribed, specify type(s): (choose all that apply)

Aspirin

Aspirin/Dipyridamole (in separate formulations or as Aggrenox)

Clopidogrel (Plavix)

Cilostazol

Other, specify:

1. \*\*IF antihypertensive agents prescribed, specify type(s): (choose all that apply)

Beta-blocker (atenolol, metoprolol, propranolol, others)

Calcium channel blocker (amlodipine, diltiazem, nifedipine, verapamil, others)

Diuretic (chlorothiazide, hydrochlorothiazide, chlorthalidone, others)

ACE-inhibitor (enalaopril, lisinopril, ramipril, others)

Angiotensin II receptor blocker (candesartan, losartan, valsartan, others)

Alpha blocker (doxazosin, prazosin, terazosin)

Combined alpha and beta-blocker (carvedilol, labetalol)

Central agonist (alpha methyldopa, clonidine, others)

Other, specify:

1. \*\*IF anti-diabetic agents prescribed, specify type(s): (choose all that apply)

Insulin

Amylin analogs (Pramlintide)

Sulfonylureas (glimepiride, glipizide, glyburide, others)

Meglitinides (nateglinide, repaglinide)

Biguanides (metformin)

Thiazolidinediones (pioglitazone, rosiglitazone)

Alpha-glucosidase inhibitors (acarbose, miglitol)

Dipeptidyl peptidase inhibitors (alogliptin, linagliptin, others)

Sodium-glucose co-transporter 2 inhibitors (canagliflozin, dapagliflozin, others)

Oral combination drugs

Other, specify:

1. \*\*IF lipid lowering agents prescribed, specify type(s) (choose all that apply)

Statin (atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)

PCSK9 inhibitors (alirocumab, evolocumab)

Selective cholesterol absorption inhibitors (ezetimibe)

Bile acid sequestrants (cholestyramine, colestipol, colesevelam)

Fibrates (gemfibrozil, fenofibrate, clofibrate)

Niacin

Omega-3 fatty acid ethyl esters (Lovaza, Vascepa)

Marine-derived omega-3 polyunsaturated fatty acids

Other, specify:

1. Reason(s) antithrombotic therapy (i.e., anticoagulant or antiplatelet agents) was not prescribed at discharge: (choose all that apply)

Allergy to aspirin, clopidogrel, dipyridamole, cilostazol, warfarin, direct thrombin inhibitor, factor Xa inhibitor or heparin (history or current)

Patient/Family refused

Risk for bleeding

Discontinued due to bleeding

Serious side effect to medication, specify:

Terminal illness/Comfort measures only

Other, specify:

## General Instructions

This case report form (CRF) contains data elements related to antithrombotics and other medications the participant/ subject is treated with while in the hospital for the stroke event or is prescribed upon discharge. Several of the elements were taken from are taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental – Highly Recommended based on study type, disease stage and disease type as indicated by asterisks below. Please refer to Start-Up document for details.

\*\*Element is classified as Supplemental – Highly Recommended

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.

The CRF includes most of the instructions available for the data elements at this time. One element has some additional instructions not included on the CRF:

* Reason(s) for no antithrombotic therapy– If reasons are not mentioned in the context of antithrombotics, do not make inferences (e.g., do not assume that antithrombotics are not being prescribed because of a bleeding disorder unless documentation explicitly states so).

## References

Barnes GD, Ageno W, Ansell J, Kaatz S; Subcommittee on the Control of Anticoagulation of the International Society on Thrombosis and Haemostasis. Recommendation on the nomenclature for oral anticoagulants: communication from the SSC of the ISTH [published correction appears in J Thromb Haemost. 2015;13(8):1539]. J Thromb Haemost. 2015;13(6):1154–1156.

Kim BJ, Kwon SU, Park JH, Kim YJ, Hong KS, Wong LKS, Yu S, Hwang YH, Lee JS, Lee J, Rha JH, Heo SH, Ahn SH, Seo WK, Park JM, Lee JH, Kwon JH, Sohn SI, Jung JM, Navarro JC, Kim HY, Kim EG, Kim S, Cha JK, Park MS, Nam HS, Kang DW; PICASSO Investigators. Cilostazol Versus Aspirin in Ischemic Stroke Patients With High-Risk Cerebral Hemorrhage: Subgroup Analysis of the PICASSO Trial. Stroke. 2020 Mar;51(3):931-937.