# CAPTIVA 12 MONTH & END OF STUDY VISIT CHECKLIST

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| **CONDUCT 12 MONTH ASSESSMENTS & RECORD ALL DATA** | |
| | **At the time of the 12 Month visit**, complete & submit the Visit Summary **F308 CRF** to release all the required CRFs for completion in the Subject CRF Binder. **DO NOT** complete **F308 CRF** before the visit is conducted. |
| | Obtain Vital Signs **F117 CRF**<br>• Weight<br>• 3 separate BP & heart rate measurements, at least one minute apart, with the study-provided device<br>• 1 standing BP measurement with the study-provided device **IF**:<br>○ Subject reports orthostatic symptoms (lightheadedness upon standing)<br>○ Systolic blood pressure dropped >15 mm Hg from sitting to standing at the prior visit |
| | Conduct Neurological Exam (PI or Sub-I only) \| **No CRF; documentation in study files required** |
| | **Optional**: Conduct NIH Stroke Scale **F143 CRF** \| NIHSS Test in the WebDCU Toolbox |
| | Conduct modified Rankin scale (mRS) **F144 CRF** \| mRS Test in the WebDCU Toolbox |
| | Conduct Montreal Cognitive Assessment (MoCA) **F167 CRF** \| MoCA Instructions and MoCA Test in the WebDCU Toolbox |
| | Document PACE-Physical Activity **F507 CRF** & PACE-Smoking Status **F508 CRF** |
| | **If instructed by the CAPTIVA Team**, collect a Repeat Genotype Sample (store locally for up to 2 weeks) & update **F181 CRF Q13 to "Yes"** \| *Mouthwash Sample Collection Instructions* in the WebDCU Toolbox |
| | Collect & record 12 Month LDL & HgA1c, if diabetic \| **F105 CRF** |
| | Review & Document all Medications & update Q06-QK with the last assessment date **F288 CRF** |
| | Review previous Adverse Events (AEs) & update their status, if needed. Only report **new** AEs that meet the criteria noted on the top of **F104 CRF**. |
| | Conduct pill counts & record study drug adherence in **Section D** on the **MONTH 8 F512 Study Drug CRF**. Under **Section C, Q21/Q23**, **DO NOT** select **"Yes"** unless the subject **prematurely** stopped study drugs.<br>• Use of the app, "Pilleye" can assist with pill counts |
| | Remaining AM Bottle Pills: |
| | Remaining PM Bottle Pills: |
| | Remaining Aspirin Bottle Pills: |
| | If applicable, collect and upload follow-up neuroimaging to Ambra Health **F510 CRF** |
| | If applicable, Log & Ship the genotype sample by selecting [Study Material Tracking] then [Specimen Shipping] in WebDCU. Select your sample record by clicking the **blue hyperlink**. In the record form, enter the shipment details in lines 8-11 and [Save Record]. Access the pre-filled *Specimen Packing Slip* by clicking the **green arrow** on line 12. Only ship Mondays-Wednesdays and not prior to a holiday. |
| **CONDUCT END OF STUDY ASSESSMENTS & RECORD ALL DATA** | |
| | In the Subject CRF Binder, click [Add New Visit] and select 'End of Study' to release all the required CRFs for completion |
| | Complete Treatment Blinding Assessments: |
| | Subject \| **F501 CRF** |
| | Study Coordinator \| **F502 CRF** |
| | Principal Investigator \| **F503 CRF** |
| | End subject's participation in CAPTIVA \| **F126 CRF** |
| | Send the *Letter to PCP – Final Visit* (see WebDCU Toolbox) |
| | Ensure continuity of care:<br>• Schedule clinical follow-up<br>• Prescribe open-label antithrombotic therapy; choice of medication(s) is at PI discretion<br>• Continue risk factor management medications(s) & arrange prescriptions, especially if transitioning from Walgreen's-provided medications<br>• Collect updated contact information |
| | Subject and Family Phone Number(s): |
| | Subject Email: |