Process Step Table v1.0

Strategy/Protocol Design

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Notify COA Scientist of Intended Clinical Trial	• Sponsor/CRO Study Team will notify COA Scientist of the new study design/concept and inform them of goals for data collection	*Sponsor/CRO:* Development Team (R) COA Scientist (I)	8+ months prior to FPFV
Develop COA Strategy as Part of Study Concept	• Review study objectives and recommend COA measures and collection methods (determine frequency and appropriate mode of data collection and/or administration)	*Sponsor/CRO:* COA Scientist (R)	8+ months prior to FPFV
Review/Approve Study Concept	• Review/approve the study concept as developed by the Study Team including COA strategy and finalize the necessary information to begin protocol development including countries and languages	*Sponsor/CRO:* Protocol Review Committee (R)	7+ months prior to FPFV
Develop Sponsor Study Resource Request	• Ensure that eCOA deployment has the appropriate resources and budget allocations based on COA strategy	*Sponsor/CRO:* Project Manager (R) Contracts Manager (C)	6+ months prior to FPFV
Develop, Review, and Finalize Protocol	• Study team drafts protocol including required eCOA components, who is completing eCOA (e.g., participant, clinician), and whether measures are completed at home or at site	*Sponsor/CRO:* Study Team- Other (R) COA Scientist (R) Protocol Review Committee (R)	6+ months prior to FPFV

Study Start-Up/Study Build

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
Licensing and Translations			
Initiate COA Licensing	• Licensing Specialist (LS) requests license and translations for all COAs from copyright holder(s) / licensing agent(s), providing estimates for number of uses, based on number of participants, number of administrations, countries/languages, etc. • Copyright holder / licensing agent provides a quote and license agreement • LS arranges signatures and payment for license • Copyright holder / licensing agent provides licensed measure(s) and available requested languages • LS confirms any electronic use guidelines (including exact copyright statement language to be visualized on eCOAs) • LS confirms which copyright holders / licensing agents will require review/approval of screenshots • LS distributes to all relevant parties • If any needed COA translations do not exist, then a COA translation provider is selected, depending on copyright holder / licensing agent or other requirements	*Sponsor/CRO or eCOA Provider:* Licensing Specialist (R) Project Manager (I) *eCOA Provider:* Project Manager (I) *Other:* Copyright Holder / Licensing Agent (C)	After Stable Draft Protocol (If done by eCOA Provider/ translation provider - after provider contracted)

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Conduct Translation Provider and eCOA Provider Kick-Off Meeting - (Sponsor/CRO can be involved)	• Present overview on needed translations and linguistic validation based on protocol • Confirm languages already available, if any, and discuss needed languages • Review translation Scope of Work (SOW) • Present preliminary timelines • Present translation plan • Include discussion of IRB submission materials and dates	*eCOA Provider:* Project Manager (R) eCOA System Designer (C) *Sponsor/CRO (if desired):* Contracts Manager (I) COA Scientist (I) Project Manager (I) Data Manager (I) Study Team –– Other (I) *Other:* Translation provider (R)	After Final Protocol and *Conduct Kick-Off Meeting*
Initiate New Translation and Linguistic Validation of COAs	• Translation Specialist (TS) requests quote from translation provider(s) • TS arranges signatures and payment for translations • Translation provider provides COA translations according to agreed-upon methodology after coordinating with copyright holder (if required) ○ **Note:** If full linguistic validation (with cognitive interviews) is required, timelines need to be extended • TS distributes COA translations to all relevant parties	*Sponsor/CRO or eCOA Provider:* Translations Specialist (R) *eCOA Provider:* Project Manager (I) Translation Coordinator (I) *Other:* Translation Provider (R) Copyright holder/distributer (C)	After *Initiate COA Licensing* (and country selection) Translations may start prior to the Translation Provider and eCOA Provider Kick-Off Meeting, dependent on timeline needs. A translation kick off with the translation provider would happen separately in this instance.

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Complete New Translation and Linguistic Validation of COAs	• Translation Specialist (TS) requests quote from translation provider(s) • TS arranges signatures and payment for translations • Translation provider provides COA translations according to agreed upon methodology after coordinating with copyright holder / licensing agent (if required) • TS distributes COA translations to all relevant parties	*Sponsor/CRO or eCOA Provider:* Translation Specialist (R) *eCOA Provider:* Project Manager (I) Translation Coordinator (I) *Other:* Translation Provider (R) Copyright Holder / Licensing Agent (C)	After *Initiate COA Licensing* (and country selection) If Sponsor/CRO is
Migrate Translations	• eCOA Provider sends final technical files • Migrate existing translations from paper into technical files • Develop any new translations not previously developed (e.g., reminders, task titles)	*eCOA Provider:* Translation Coordinator (R) Project Manager (R) *Other:* Translation Provider (R)	After *Approve Go Live of System*
Review and Approve Translated Screenshots	• Translation provider completes local language screenshot review rounds with linguists and QC until final non-COA text is complete • Translation provider or eCOA Provider sends screenshots for copyright holder / licensing agent review and approval (if required) • If requested, Sponsor/CRO may review prior to finalization • Translation provider issues final screenshots and certificate of translation to eCOA Provider and eCOA Provider provides to Sponsor/CRO	*eCOA Provider:* Translation Coordinator (R) Project Manager (R) *Sponsor/CRO* (if review is requested): Project Manager (C) Study Team - Other (C) *Other:* Translation Provider (R) Copyright Holder / Licensing Agent (R)	After *Migrate Translations (*on rolling basis)

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
Submit Translated Screenshots (if required)	• If required, Sponsor/CRO collects final screenshots and certificates of translation and submits to local EC/IRBs for approval	*Sponsor/CRO:* Project Manager (R) Study Team – Other (C)	After *Review and Approve Translated Screenshots* (before EC/IRB submission)
Initiation of eCOA Contract			
Select eCOA Provider	• Sponsor/CRO drafts request for proposal (RFP) and submits to eCOA Providers • eCOA Provider receives and responds to RFP • Sponsor/CRO reviews proposal and holds bid defenses (as needed) with eCOA Provider • Sponsor/CRO selects eCOA Provider • eCOA Provider develops a SOW and a contract • eCOA Provider and Sponsor/CRO execute contract	*Sponsor/CRO:* Contracts Manager (R) Project Manager (C) COA Scientist (C) *eCOA Provider:* Account Director (C) Project Team – Other (C)	After *Develop Study Resource Request*
Align on Strategy - Sponsor/CRO Pre-Kick-Off Meeting	• Align on open items for implementation of eCOA system to prepare for eCOA Provider/Sponsor kick-off meeting, e.g., timing and order of measures, user base to complete measure (e.g., age range dependent, caregiver vs participant), timelines, countries/languages • ***Note:*** when a CRO is involved, discuss a communication plan to define who will be responsible for making decisions on what and who will be signing the documents	*Sponsor/CRO:* COA Scientist (C) Project Manager (R) Data Manager (C) Study Team - Other (C)	After Stable Draft Protocol and *Select eCOA Provider*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
eCOA Provider Internal Sales to Service Handover	• Review SOW • Discuss License/Translation aspects • Discuss lessons learned from previous studies/ similar studies with Sponsor and from implementation of measures used in previous trials • Identify efficiencies with other trials run with the same Sponsor or with the same measures (e.g., translations of same measure used in other studies) • Discuss timelines to ensure system and all training materials are ready prior to FSIV and FPFV	*eCOA Provider:* Project Manager (R) eCOA System Designer (C) Translation Coordinator (C) Licensing Specialist (R) Data Manager (C) Project Team - Other (C)	After *Select eCOA Provider*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
Conduct Kick-Off Meeting (KOM) (Sponsor/CRO and eCOA Provider)	eCOA Provider leads KOM: ● Present system design overview based on protocol ● Discuss design open items ● Review SOW ● Present eCOA migration strategy ● Present preliminary timelines ● Present overview on needed translations and linguistic validation based on protocol ● Confirm languages already available, if any, and discuss needed languages ● Discuss licensing status ● Review training plan ● Present logistics plan/constraints ● Include discussion of EC/IRB submission materials and dates ● Ensure Sponsor/CRO/eCOA Provider align with their understandings of what is provided with each deliverable.	*Sponsor/CRO:* Contracts Manager (C) COA Scientist (C) Project Manager (C) Data Manager (C) Study Team - Other (C) *eCOA Provider:* Project Manager (R) eCOA System Designer (C) Translation Coordinator (C) Licensing Specialist (R) Training Specialist (C) Project Team - Other (C) COA Scientist (C)	After *eCOA Provider Internal Sales to Service Handover* and *Align on Strategy - Sponsor/CRO Pre-Kick-Off Meeting*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Design			
Draft Design Requirements and Screens	• eCOA Provider writes design requirements document • eCOA Provider and Sponsor/CRO review base language COA screens/screenshots and design requirements	*Sponsor/CRO:* COA Scientist (C) Project Manager (C) Data Manager (C) Study Team - Other (C) *eCOA Provider:* eCOA System Designer (R) Project Manager (R)	After *Conduct Kick-Off Meeting (KOM) (Sponsor/CRO and eCOA Provider)*
Finalize Requirements Document and Review Screens	• eCOA Provider and Sponsor/CRO sign off requirements and screenshots in base language • Copyright holder / licensing agent approves base language screens (if required)	*Sponsor/CRO:* COA Scientist (C) Project Manager (R) Data Manager (C) Study Team - Other (C) *eCOA Provider:* eCOA System Designer (R) Project Manager (R) *Other:* Copyright Holder / Licensing Agent (C)	After *Draft Design Requirements and Screens*
Finalize Build and Test Study-Specific Software	• eCOA Provider finalizes build/configuration to align with approved requirements • eCOA Provider QCs/validates study build against requirements and source measures	*eCOA Provider:* eCOA System Designer (R) Project Manager (R) Project Team - Other (R)	After *Finalize Requirements Document and Review Screens*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
Create System Integration Specifications (with Other Systems/Devices if applicable)	• If any integrations are needed with other systems (e.g., IxRS), devices (e.g., wearables) and other devices (e.g., peak expiratory flow meter, sleep tracker) • Define between involved providers which data should be transferred • Define the format and frequency of the data transfer • All stakeholders review and approve specifications	*Sponsor/CRO:* Project Manager (C) Data Manager (C) Study Team – Other (C) *eCOA Provider:* Project Manager (R) eCOA System Designer (R) Data Manager (R) *Other:* Provider in scope for integration (C) (e.g., IxRS)	After *Draft Design Requirements and Screens*
Generate Data Transfer Specifications	• Sponsor/CRO to define data and format of data to be transferred and delivery method/location if not covered in eCOA requirements • Development or confirmation of existing CDISC format or variables • eCOA Provider to review/create specifications • All stakeholders review and approve specifications	*Sponsor/CRO:* Data Manager (C) COA Scientist (C) Study Team - Other (C) *eCOA Provider:* Data Manager (R) Project Manager (R)	After *Draft Design Requirements and Screens*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
UAT			
Conduct eCOA UAT Kick-Off	• Align team on process to be used for UAT • Define involved roles for UAT • Define timelines for different UAT steps • Discuss communication pathways and issues tracking and resolution process • Plan for shipment and set up of UAT devices	*Sponsor/CRO:* COA Scientist (C) Data Manager (C) Project Manager (C) Study Team – Other (C) *eCOA Provider:* Project Manager (R) eCOA System Designer (C)	After *Draft Requirements and Screens.* (2 weeks prior to UAT Start)
Create eCOA UAT Plan	• Define scenarios to be tested and create scripts to cover these • Perform risk assessment on which areas to test • Define roles of testers	*Sponsor/CRO:* Project Manager (R) Data Manager (R) Study Team – Other (C) *eCOA Provider:* Project Manager (C) Project Team – Other (C)	After *Conduct eCOA UAT Kick-Off*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Conduct eCOA Device UAT	• Perform UAT according to UAT Plan and scripts • Document any findings in issue log • eCOA Provider to correct findings and validate/ retest • Sponsor/CRO retest updates • Approval of UAT summary	*Sponsor/CRO:* COA Scientist (C) Project Manager (R) Data Manager (R) Study Team – Other (C) *eCOA Provider:* Project Manager (C) eCOA System Designer (C) Project Team – Other (R)	After *Create eCOA UAT Plan* and *Finalize Build and Test Study-Specific Software* (Allow for at least two 2-week cycles)
Approve Go Live of System	• After UAT has been completed, sign off on final requirements and specifications • Approve Go Live of system	*Sponsor/CRO:* Project Manager (R) COA Scientist (C) Study Team - Other (C) *eCOA Provider:* eCOA System Designer (C) Project Manager (C)	After *Conduct eCOA Device UAT*
Conduct Data Transfer UAT	• eCOA Provider sends data in agreed upon format to agreed-upon location • Sponsor/CRO to review received data for completeness, correctness, and correct format • Document any findings in issue log • eCOA Provider to correct findings and validate/ retest • Sponsor/CRO retest updates • Approval of UAT summary	*Sponsor/CRO:* Project Manager (R) Data Manager (R) Study Team - Other (C) *eCOA Provider:* Data Manager (R) Project Manager (R) Project Team – Other (R)	After *Conduct eCOA Device UAT* and *Generate Data Transfer Specifications*

Study Launch

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
eCOA Software Moved into Production			
Set Up Sites and User Accounts in Production	• Sponsor/CRO collects Site and User details. Information may include site level info, user level info, and initial shipment quantities • Site and User accounts are created	*Sponsor/CRO:* Project Manager (R) *eCOA Provider:* Project Manager (R)	After *Conduct Kick-Off Meeting (KOM) (Sponsor/CRO and eCOA Provider)* (1-2 weeks prior to scheduled Go Live then throughout start up for each country
Move Software to Production	• eCOA Provider receives completed UAT approval form from Sponsor/CRO • eCOA Provider moves software into Production • eCOA Provider verifies system is functioning in Production as approved	*eCOA Provider:* Project Manager (R) Project Team- Other (R)	After *Approve Go Live of System* (2 to 4 days prior to Go Live)
Release Countries/Languages/ Sites (as approved)	• Sponsor/CRO provides confirmation to eCOA Provider for release • eCOA Provider activates country/language and site as each one is ready • eCOA Provider confirms release completed to study team	*Sponsor/CRO:* Project Manager (R) *eCOA Provider:* Project Manager (R)	After *Move Software to Production* and *Review and Approve Translated Screenshots*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
Device Deployment Strategy and Implementation			
Identify Country Shipping Requirements	• Confirm all countries participating in the study • Review shipping requirements for each country	*Sponsor/CRO:* Project Manager (R) Logistics Manager (R) *eCOA Provider:* Project Manager (R) Logistics Manager (R)	After *Conduct Kick-Off Meeting (KOM) (Sponsor/CRO and eCOA Provider)*
Obtain Import Licenses	• Identify country-specific requirements • Confirm import license is received for each participating country	*Sponsor/CRO:* Logistics Manager (R) Project Manager (C) *eCOA Provider:* Logistics Manager (R) Project Manager (C)	After *Identify Country Shipping Requirements*
Ship Production Devices to Initial Sites	• Confirm number of devices for shipment, ship devices, maintain log of asset tags and associated sites	*eCOA Provider:* Logistics Manager (R)	After *Obtain Import Licenses*, *Set Up Sites and User Accounts in Production* and 2-4 weeks before FPFV

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Ship Production Devices to Other Sites and/or Country Depot	• Sponsor/CRO confirms site contract is executed and details device provisioning and management • Confirm number of devices for shipment, ship devices, maintain log of asset tags and associated sites	*Sponsor/CRO:* Study Start-up Manager (C) Project Manager (C) *eCOA Provider:* Logistics Manager (R)	After *Release Countries/ Languages/ Sites (as approved)* (based on estimated country shipping times and individual sites FPFV)
eCOA Training			
Define Mandatory eCOA Training	• Working with eCOA Provider, determine which applicable training will be developed for each level: participant, site, and study. Training materials may be integrated into broader materials for the clinical trial	*Sponsor/CRO:* Project Manager (C) *eCOA Provider:* Project Manager (R)	After *Conduct Kick-Off Meeting (KOM) (Sponsor/CRO and eCOA Provider)*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***

Create and Approve Training Plan; Identify and Develop Training Materials	• Define training plan for both sites and participants
	• Define if any custom training is needed and what should be included and mode of delivery to be used
	• Customize training according to study needs
	• Review and approve final training material
	• Determine which materials need to be translated
	• At a minimum, develop:
	  ○ eCOA Site User guide
	  ○ eCOA Device User guide
	• May also include Supplementary Participant Trial Guide
		Sponsor/CRO:
		COA Scientist (C)
		Project Manager (C)
		Site Monitor (C)
		Study Team - Other (C)
		eCOA Provider:
		Training Specialist (R)
		Project Manager (R)
		eCOA System Designer (C)
			After *Define Mandatory eCOA Training* and *Draft Design Requirements and Screens* but prior to *Approve Go Live of System*

Train and Launch Help Desk/Support Team	• Identify help desk and support team resources • Ensure custom system functionality is documented • Train/re-train resources • Document training records	*eCOA Provider:* Help Desk (I) Project Manager (R)	1 week prior to UAT Start
Prepare Materials for Investigator Meeting(s)	• Define content and format • Presentation (e.g., PowerPoint) • Device demonstration	*Sponsor/CRO:* Project Manager (C) COA Scientist (C) *eCOA Provider:* Project Manager (R) Training Specialist (R)	After *Conduct eCOA Device UAT*

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ ***Step Dependencies***
Provide and Complete Site- and User-Specific Training	• Mandatory for sites and participants • Should be built into eCOA device or readily accessible elsewhere • Sites and participants perform their basic introductory training • Detailed step by step documentation on how to refresh a device at either the site or participant level as provided by the eCOA Provider	*Site:* Study Coordinator (R) Principal Investigator (R) *eCOA Provider:* Project Manager (R) Training Specialist (C)	After *Identify and Develop Training Materials* and starts no later than 1 week prior to FPFV

Study Conduct/Monitoring

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Re-supply Devices (as needed)	• Re-supply requested by site/eCOA Provider/CRO or Sponsor/CRO • Review of re-supply request • Confirm re-supply request as adequate • Initiate shipment of replacement device • eCOA Provider sends return airway bill to site • Site ships defective device back to eCOA Provider	*Sponsor/CRO:* Project Manager (C) *eCOA Provider:* Project Manager (R) Logistics Manager (R) *Other:* Study Coordinator (I)	As Needed Through Study Conduct/ Monitoring phase
Resolve Post-Release System Issues	• System issues not identified during UAT discovered throughout conduct of study • eCOA Provider provides scope and timelines for resolution and then resolves issues • Sponsor/CRO PM and sites (as applicable) notified of issue resolution	*Sponsor/CRO:* Project Manager (R) Project Team – Other (C) *eCOA Provider:* Project Manager (R)	As Needed Through Study Conduct/ Monitoring phase

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Update Systems for Protocol Amendments	• eCOA Provider initiates system change request • eCOA Provider assesses system impact, provides cost and timelines • Sponsor/CRO approves cost • Sponsor/CRO updates, reviews, and approves requirements • eCOA Provider updates system (build, test, regression test) • Sponsor/CRO performs UAT of changes • If required, eCOA Provider provides updated participant-facing screenshots and site training • Sponsor/CRO obtains IRB/EC approval of updates • eCOA Provider deploys updates to production • Sponsor/CRO communicates release to sites	*Sponsor/CRO:* Project Manager (C) Data Manager (C) Contracts Manager (C) Study Team - Other (C) *eCOA Provider:* Project Manager (R) eCOA System Designer (R) Data Manager (R) Account Director (R) Project Team – Other (C)	As Needed Through Study Conduct/ Monitoring phase

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Clean Data and Monitor Data Quality	• Sponsor/CRO create eCOA trial monitoring plan (including compliance expectations, participant recruitment levels, data change policies, data clarification/change request [DCR] handling processes, etc.) • Sponsor/CRO query systems per trial monitoring plan • Sponsor/CRO review data from each data transfer • eCOA Provider investigates issues and raises DCRs, as needed • Study Coordinator/Principal Investigator approves DCRs • Sponsor/CRO track protocol deviations	*Sponsor/CRO:* Project Manager (C) Data Manager (R) *eCOA Provider:* Project Manager (C) Data Manager (C) *Other:* Study Coordinator (C) Principal Investigator (C)	Continuously After FPFV
Process DCRs	• eCOA Provider processes DCRs per agreed upon processes which may be documented in SOPs, Project Management Plan, Data Management Plan, Monitoring Plan, etc. • Steps may include notifying the Sponsor of DCRs initiated by the sites for critical data	*eCOA Provider:* Data Manager (R) *Sponsor/CRO:* Project Manager (I) Data Manager (I)	As Needed Through Study Conduct/ Monitoring phase
Monitor Compliance	• Site Monitor reviews site and participant compliance according to Data Monitoring Plan • Site Monitor performs site retraining as needed • Study Coordinator performs participant retraining when compliance issues are identified	*Sponsor/CRO:* Project Manager (C) Data Manager (C) Site Monitor (R) *Other:* Study Coordinator (R)	Continuously After FPFV

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Manage Issues	• eCOA Provider PM reviews help desk trends at periodic meetings • Identifier communicates issue to other party • eCOA Provider identifies root cause • eCOA Provider informs site of workaround (if applicable) • eCOA Provider communicates issue to impacted sites • eCOA Provider communicates issue to other Sponsor/CROs, if system-wide issue • eCOA Provider resolves issue via corrective action • eCOA Provider documents, reviews, finalizes, and approves CAPAs (if applicable) • eCOA Provider implements preventative action	*Sponsor/CRO:* Project Manager (C) *eCOA Provider:* Project Manager (R) Help Desk (R) Project Team - Other (C)	As Needed Through Study Conduct/ Monitoring phase

Study Close-Out and Archiving

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Create Decommissioning Plan	• Creation of plan for all close-out activities, including returning devices, final compliance reporting, final data reconciliation, final data transfer, and archiving of data	*Sponsor/CRO:* Project Manager (C) Data Manager (R) *eCOA Provider:* Project Manager (C) Data Manager (C)	After FPFV

Plan for Database Lock and Close-Out	• Create timelines for all close-out, database lock, and archiving activities, including:
	  ○ closing out of sites based on LPLV
	  ○ implementation of an LDA item in timeline
	  ○ data cleaning and resolution
	• eCOA Provider reports on status of data, devices, and compliance
		Sponsor/CRO:
		Project Manager (C)
		Data Manager (R)
		eCOA Provider:
		Project Manager (C)
		Data Manager (C)
			3 months before Study Last Patient Last Visit (LPLV)

Return Devices to eCOA Provider	• eCOA Provider provides return instructions and airway bill to site • Site does a final data upload and then returns all devices • eCOA Provider checks each device for stored data and uploads any stored data to server • eCOA Provider resets device and returns to inventory • Final reconciliation of inventory occurs, documenting any lost/stolen devices	*Sponsor/CRO:* Project Manager (C) Data Manager (C) Site Monitor (C) *eCOA Provider:* Project Manager (R) Data Manager (C) *Other:* Study Coordinator (R)	Starts After First Site LPLV

Process Step	Tasks/Definition	Roles Responsible (R) Consulted (C) Informed (I)	Milestones/ *Step Dependencies*
Complete Final Data Reconciliation	• Data Management tasks include the completion of ongoing reconciliation of written DCRs and reconciliation trackers as per Data Management Plan • Financial/Operational tasks include resolving CAPAs, finalizing budget/invoicing including change orders	*Sponsor/CRO:* Project Manager (R) Data Manager (R) Site Monitor (C) *eCOA Provider:* Project Manager (R) Data Manager (R) *Other:* Study Coordinator (C)	After LDA
Complete Final Data Transfer	• eCOA Provider sends pre-lock final data to Sponsor/CRO for review and approval • Sponsor/CRO requests eCOA Provider to lock database • eCOA Provider locks database • eCOA Provider sends post-lock final data to Sponsor/CRO for review and approval	*Sponsor/CRO:* Project Manager (R) Data Manager (R) *eCOA Provider:* Project Manager (R) Data Manager (R)	After *Complete Final Data Reconciliation*
Provide Archive to Sponsor and Sites	• Data and study documentation are delivered from eCOA Provider to Sponsor/CRO in a final archive format (e.g., DVD, USB) • Transfer directly back to site (via encrypted USB drives, servers, DVDs) • eCOA Provider confirms receipt by site and acknowledgment that site can read files	*Sponsor/CRO:* Project Manager (C) Data Manager (C) *eCOA Provider:* Project Manager (C) Data Manager (R) *Other:* Study Coordinator (C)	After *Complete Final Data Transfer*