Roles Table v1.0

This document lays out the roles involved in the eCOA system development and implementation process and their responsibilities. The roles are intended to be company-agnostic because different positions/titles in a company may handle multiple roles (e.g., project manager may also be the training specialist or logistics manager).

Role Name/Abbreviation	Organization	Role Responsibilities
Account Director (AD)	eCOA Provider	Develops initial proposal and negotiates statement of work with Sponsor/CRO (contract research organization)
COA Scientist	Sponsor/CRO	Designs and implements COA strategy in protocol; expert in use and development of COAs; usually advises on translation methodology and training
Contracts Manager	Sponsor/CRO	Defines scope of work with eCOA Provider / translation vendor together with clinical operations; sets up contracts with eCOA Provider / translation vendor
Copyright Holder / Licensing Agent	Other	Provides copyrighted materials that have been licensed for use in the study; includes communication regarding use of their measure and requirements for electronic implementation and translations, and provides final contract for Sponsor review/signature
Data Manager	Sponsor/CRO	Provides input on data standards and receives and reviews data transfers to ensure that there are no anomalies.
Data Manager	eCOA Provider	Oversees data change request and data flow from eCOA database into sponsor/CRO database, ensures that the data are transferred as agreed upon; responsible for eCOA database lock, archiving, and updating specifications for mid-study changes affecting data transfer
Development Team	Sponsor/CRO	Oversees new study designs and protocol initiations

Role Name/Abbreviation	Organization	Role Responsibilities
eCOA System Designer	eCOA Provider	Designs and builds the eCOA system; assesses the scope of work and budget impact associated with system design; gathers requirements and writes specifications; produces the study-specific software; elicits feedback and makes updates to the system and documentation
Help Desk	eCOA Provider	Supports sites and participants for the duration of the study and assists them with any device-specific or study software-specific issues that they may encounter
Licensing Specialist (LS)	eCOA Provider or Sponsor/CRO	Researches copyright/licensing requirements for measures in scope; drafts a license agreement with the copyright holder / licensing agent; follows up with copyright holder / licensing agent and delivers a contract for review to the Sponsor signatory
Logistics Manager	Sponsor/CRO	Provides timing and addresses for site delivery of eCOA devices and related study material; manages device storage depot/warehouse for devices coming in/out where necessary
Logistics Manager	eCOA Provider	Manages process for shipment of eCOA devices and related study material from the eCOA Provider; coordinates customs documentation
Principal Investigator	Other	Provides oversight and responsible for all research and clinical trial activities that occur at a site
Project Manager (PM)	Sponsor/CRO	Oversees study management-related tasks: 1. Decisions related to budget 2. Point of contact for local study teams 3. Tracking of IRB submission timings and requirements 4. Inventory planning 5. Study planning - including timelines 6. Monitoring and escalation of poor compliance 7. Training strategy planning and materials review
Project Manager (PM)	eCOA Provider	Manages the design and implementation aspect of the eCOA build project, including project timelines, specifically in relation to the eCOA technology being deployed.
Project Team - Other	eCOA Provider	Other members can include the Subject Matter Experts (Scientific), Project Analyst, Testers, Developers, Account Leadership, etc., per the organizational structure and processes specific to that eCOA Provider.

Role Name/Abbreviation	Organization	Role Responsibilities
Protocol Review Committee	Sponsor/CRO	A sponsor cross-functional peer review committee tasked with a full scientific review of proposed protocols, assessing general feasibility, annual accrual expectations, and competing studies. Monitoring to assure that clinical trials and projects are scientifically sound and that approved studies maintain adequate participant accrual and scientific relevance and progress.
Site Monitor	Sponsor/CRO	Reviews participant compliance at specified sites, retrains site staff on eCOA device, system, and/or technology, monitors other study-related activities at sites
Study Coordinator	Other	Coordinates operational activities at site including enrolling participants, training participants on use of eCOA technology, as well as on protocol-specific expectations.
Study Start-up Manager	Sponsor/CRO	Oversees country feasibility, site identification, and site contracts at the Sponsor or CRO.
Study Team - Other	Sponsor/CRO	Other members can include implementation specialists, statistician, clinical leads, medical monitor, etc. This group collectively may provide input to the eCOA design and set-up.
Training Specialist	eCOA Provider	Drafts site and participant training, including reference guides, online training videos, and investigator meeting presentations; attends and demonstrates at investigator meetings.
Translation Coordinator	eCOA Provider	Schedules and scopes translation projects; coordinates with translation vendors and/or copyright holder / licensing agent to deliver work per schedule requirements and defined scope; tracks status and progress of projects.
Translation Specialist (TS)	Sponsor/CRO eCOA Provider	Coordinates new translations and linguistic validation of licensed COAs if not provided by the copyright holder / licensing agent.
Translation Vendor	Other	Translates COA and non-COA text, migrates into the electronic code, and reviews/approves screenshots containing the translated text.