

GBTI_Roles_Table_v1



eCOA: Getting Better Together Initiative



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 personalities in a company may handle multiple roles (e.g., project manager may also be the training specialist or logistics manager).

Role Name/Representation	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	Owns 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 real-time changes affecting data transfer
Development Team	Sponsor/CRO	Oversees the study design and protocol initiation