

Project Scoping and RACI

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Developed as part of the *eCOA Translations and Licensing Management* project, a collaboration between Critical Path Institute and ISOQOL

The purpose of this document is to provide an overview of what each institutional stakeholder is responsible, accountable, consulted, and informed for as it relates to eCOA Licensing, Translation, and eCOA migration, as well as to provide a detailed description of standard process steps for these activities. The document may be linked to the **Stakeholders and Responsibilities** document, as necessary.

SUB-TEAM TITLE

Translation & Licensing Education & Communications
Consolidated Group

OBJECTIVE

Due to the complex nature of COA/eCOA licensing and translation processes, and the many stakeholders from different industries, a common understanding of process steps and responsibilities is currently lacking. Building on the Stakeholders and Responsibilities Document, the Project Scoping and RACI document lists all steps of the COA/eCOA licensing and translation processes and identifies which stakeholders are responsible, accountable, consulted, and informed for each.

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Project Scoping and RACI

Key	Definition
R - Responsible	Performs the work needed to complete the task
A - Accountable	Accountable for overall task completion and success, reports status updates and ensures task is completed
C - Consulted	Subject matter experts or team members whose input may be considered before the work is signed off
I - Informed	Notified about status and completion of task

Project Task or Activity	Sponsor	COA Developer	Copyright Holder	Licensor	Licensee	Contract Research Organizations (CRO) (Where applicable)	eCOA Provider	Language Service Provider (LSP)	Risks
Identification of COAs required for the study	R/A		C			(C)	I	I	Sponsors may select COAs that are not well suited to the trial's objectives
Identification of country/language allocations for the study	R/A		C			(C)	I	I	Incorrect selection of languages/ dialects for study sites may lead to participants being unable to read, accurately understand items, or complete the COA
Contacting Licensor/Copyright Holder to obtain licensing requirements, translation requirements, and license template	I	I	I	I	R/A	(I)			This process may be lengthy if the Licensor is difficult to contact or requires extensive legal review
Legal review of licensing agreements	A		R	R	R	(C)			
Facilitating execution of licensing agreements	I	I	I	R	R/A	(I)			This process may be lengthy if the Licensor is difficult to contact
Obtaining existing translations and certifications	I	I	I	C	R/A	(I)	I	I	

Project Task or Activity	Sponsor	COA Developer	Copyright Holder	Licensor	Licensee	Contract Research Organizations (CRO) (Where applicable)	eCOA Provider	Language Service Provider (LSP)	Risks
Translation and Linguistic Validation of COAs, following developer's methodological requirements	C	I/A	I			(I)	I	R	Some developer-specific methodological requirements may significantly add to project timelines
Review and approval of translations	I	I	R/A	R		(I)	I	R	
Certificates of translation created and submitted to sponsor/CH	I	I	C/I	C/I	I	I	I	R/A	
Completed/approved translations (paper format deliverable) are returned to the CH	I	I	I	I	I	I	I	R/A	
Completion of eCOA build for all COAs in scope	C	I				(I)	R/A	I	eCOA builds must match developer requirements, or they may be rejected for use
Modification of COA translations, as necessary, for eCOA implementation (e.g., "circle" to "select")			C	C			I	R/A	This process may be lengthy if the Licensor is difficult to contact
Development and distribution of eCOA Handoff Package, containing technical files and source language screenshots for all COAs	I					(I)	R/A	C	
Migration of eCOA translations into technical file	I					(I)	I	R/A*	Migration output must be carefully QC'd to avoid eCOA screenshot errors
Proofreading and certification of translated eCOA screenshots	I		C			I		R/A	Proofreading of eCOA screenshots must be done thoroughly and carefully to avoid eCOA screenshot errors

* Although the Language Service Provider (LSP) is frequently responsible for the migration of eCOA translations into technical files, other stakeholders may also support this process.