

Stakeholders and Responsibilities

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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 for as it relates to eCOA Licensing and Translation. The document may be linked to the **Project Scoping and RACI** document, as necessary. After an assessment of the GBTI Roles Table v1.0, relevant aspects have been added to this file to ensure consistency. These passages appear in blue font.

SUB-TEAM TITLE

Translation & Licensing Education & Communications Consolidated Group

OBJECTIVE

As COA processes such as Licensing and eCOA migration can be done by a variety of different stakeholders, a common resource to define stakeholders and their responsibilities is needed. The table will provide clarity regarding definitions and responsibilities of all parties, using the definitions provided in Lexicon v3 as a guide.

MEMBERS

Caroline Anfray (IQVIA); **Anita Bradley Gilbride**, PhD, (Health Psychology Research Ltd); **Barbara Brandt**, MA, (C Path); **Alexandra Crane** (TransPerfect); **Scottie Kern** (C Path); **Marlene Knupfer** (Fortrea); **Jeremy Lambert**, PhD, (UCB); **Glenda Leung**, PhD, (RWS Group); **Shawn McKown**, MA, (IQVIA); **Andrea Murison** (Kayentis); **Emily Parks Vernizzi**, MBA, (FACITtrans); **Elinor Rees** (IQVIA); **Louise Simpson Jones** (Roche Products, Ltd.)

Stakeholder	Definition	Responsibilities
Sponsors	Definition from Lexicon v3 (May 2023): In the conduct of a clinical study, a sponsor is an individual, company, institution, or organization that takes responsibility for initiation, management, and/or financing of a clinical trial, but may not actually conduct the investigation.	• Design and implementation of COA strategy in protocol; includes an expert in use and development of COAs; usually advises on translation methodology and training when there are no prior requirements from the copyright holder. • Defines scope of work (e.g., instruments, countries/languages, timelines, whether there is eCOA implementation) with eCOA Provider / Language Service Provider (LSP); sets up contracts with eCOA Provider / LSP. [May outsource some or all functions to a CRO.] • Oversight of study management-related tasks, ensures the following are obtained: ▪ The appropriate COA licenses (and requirements are understood and must be disseminated to all stakeholders using the COA). ▪ List of country-specific languages where translations are required. ▪ Timelines from all contracted services. ▪ Status and progress of project in collaboration with LSP and eCOA Provider. ▪ Notification to relevant stakeholders that trial is complete with report of usage as applicable to study. • Researches copyright/licensing requirements for measures in scope; drafts/updates a license agreement with the copyright holder / licensor; follows up with copyright holder / licensor, and delivers a contract for review to the Sponsor signatory. [In certain circumstances this may be performed by a Licensing Department of an LSP, eCOA provider, Sponsor, or CRO.] • Coordinates new translations and linguistic validation of licensed COAs if not provided/ managed by the copyright holder / licensing agent. • When contracting with the LSP, the sponsor ensures final translations and certificates are received from the LSP and disseminated to the eCOA provider.
Contract Research Organizations (CROs)	Lexicon V3 (May 2023) uses the ICH glossary definition: A person or an organization (commercial, academic, or other) contracted by the Sponsor to perform one or more of a sponsor's trial-related duties and functions	• The CRO holds to the same responsibilities as the Sponsor when handling licensing on their behalf. • Manages eCOA implementation responsibilities (e.g., contracting and/or development), as applicable.

Stakeholder	Definition	Responsibilities
Instrument developer / measure developer / author	Definition from Lexicon v3 (May 2023): <i>(At the time of this document's creation an official definition for COA developer has not been released. COA developer refers to Instrument developer / measure developer / author.)</i> The person(s) or organization that develops and publishes an instrument/measure for use in research, ensuring that it is a valid and reliable measure of a specific concept of interest. Note: May be distinct from copyright holder.	• Develops and publishes COA version changes. • Communicates the rationale for any changes to original versions [Can be delegated to the copyright holder/licensor]. • Develops and publishes COA scoring guidelines. • Approves all translations developed by LSPs and any revisions thereof (may depend on Developer's interest, capacity and availability) [Can be delegated to the copyright holder/licensor]. • Reviews/approves concept definitions created by LSPs. • When possible and depending on the requirements of measure, develops and publishes guidelines for eCOA migration/implementation.
Copyright holder	Lexicon V3 (May 2023): The person, organization, or company that owns the copyright to a work and has exclusive rights* to do and to authorize specific actions to the copyrighted work including the licensing of the clinical outcome assessment. *Defined in Section 106 of the United States Copyright Act.	• Establishes the terms for the Licensor to distribute the measure. • Facilitates communications between Developers and Licensors regarding COA's target population (treatment, or conditions, etc.), COA versions, translations availability, and needs. • Authorizes copyright material usage to interested parties. Can include permissions for modification of previous agreements and denial of usage [Can also be the COA developer, licensor, or in some cases the Sponsor]. • When possible and depending on the requirements of measure, develops and publishes guidelines for eCOA migration/implementation.
Licensor (License holder)	Lexicon V3 (May 2023) defines License holder as: The person, organization, or company that licenses a copyrighted instrument/measure and executes a license agreement granting permission to third parties to use the instrument/measure. This may be the copyright holder or someone working on behalf of the copyright holder.	• Ensure the rights of the copyright holder are communicated clearly, monitored, and upheld. • Make standardized contracts available to facilitate legal operations. • Provide customer support that is consistent, readily available for users and copyright holders. • Track updates of COA versions, terminology or language revisions, etc. • Maintain latest versions of each COA available, history, and content of version changes (when applicable/necessary). • May maintain library and notification of languages available for use. Included in the available library are publications, manuscripts, and data analysis procedures (e.g., scoring manuals, user guidance) to ensure assessment is administered accurately and the measure's integrity respected. • May track contracts with pricing, timelines, and approval / limitations of use in particular studies, and any revisions thereafter. • Provide client support, e.g., troubleshooting with clients on any issue related to the COA licensed in the relevant study.

Stakeholder	Definition	Responsibilities
		- Each Licensor delineates what is and what is not within scope of customer support. - Provide clear consistent guidelines to LSPs and Licensees about required translation methodology and preferred providers. - Draft amendments to licenses when items change in a trial and circulates to relevant stakeholders, e.g., Licensee. - Ensure licenses are paid for and adhere to licensing terms. Deals with copyright violations as agreed to with copyright holder.
Licensee	The person, organization, or company that obtains the COA license for use in the study	- Ensures requested new translations are provided to the Licensor/Copyright Holder and are in accordance with the license agreement. - Facilitates communication with Licensor/Copyright Holder on behalf of Sponsor to request information / initiate any third-party provider agreements. - Liaises with Licensor/Copyright Holder to receive approval for eCOA screens. - May establish Copyright Holder information repository to expedite initial licensing communication. - Drafts amendments to licenses when items change in a trial and circulates to relevant stakeholders, e.g., Licensor.
eCOA Provider <i>Ensure consistent usage of "eCOA Provider" vs. "eCOA vendor" across deliverables. We recommend "eCOA Provider." Recommend adding "eCOA Provider" to next version of Lexicon.</i>	eCOA Providers develop electronic platforms for COA data collection (i.e., data entry onto computers, laptops, tablets, smartphones, etc.). Supports Sponsor, sites, patients' study needs throughout a clinical trial	- Develops initial proposal and negotiates statement of work with Sponsor/CRO (contract research organization). - 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. - Configures electronic COAs according to copyright holder requirements, ensuring content matches paper version. - Works and/or contracts with LSP to receive translations for migration into eCOA software. - Implements any necessary electronic modifications to content, such as 'circle' > 'select.' - Where an instrument library exists, maintains technology to easily reuse approved configurations/screens. - As required by Licensor, enters into vendor agreement on study basis. - Establishes good relationships/master service agreements with copyright holders to expedite screen reviews on individual studies.

Stakeholder	Definition	Responsibilities
Language Service Providers (LSPs) <i>GBTI Roles Table uses "Translation Vendor." TCA-SIG endorses Language Service Provider (LSP) and LSP has been adopted in the other TLM materials, e.g., RACI, etc. No definition exists in Lexicon. We recommend that LSP be added to the Lexicon in the context of this TLM initiative.</i>	Language Service Providers (LSPs) are companies providing translation and linguistic validation services to the life science industry for clinical trial documentation. This section discusses the translation and linguistic validation of COA measures, although other clinical trial documents may be relevant.	- Adheres to translation methodology appropriate to the COA Copyright holder's requirements, the disease, treatment and condition-specific needs of the COA. - Language/country requiring translation and/or linguistic validation with patients, cognitive interviewing, harmonization, timeline, and pricing. - Provides methodologically trained staff to manage projects from kick-off to completion. - Works with linguists/translators to conduct translation work. - Drafts and provides Translation Certifications of each language in relevant study. - As necessary per contract terms, drafts and delivers regulatory-submission-ready reports comprised of executive summary, translation methodology, translation and pilot testing documentation, test versions of the documents, and the final versions of the documents. - Maintains timely communication with other stakeholders related to translation delays, errors in translations tied to root cause analysis, and solutions derived thereof. - Works with eCOA provider to enter translations into software and obtain relevant documentation (e.g., screen reports) to proofread or linguistically validate the translations. Translation migration to technical files may be handled by either the LSP or eCOA provider. - Some sponsors or developers intend for the measure to be administered electronically, and linguistically validating the translations in the context of a screen report (i.e., after the eCOA migration process) further validates the measure's appropriateness for electronic use in every language. Additionally, some EMA and FDA submissions require screens of the software platform to be provided rather than paper versions. Approaches may vary across eCOA providers and LSPs, what follows are steps that may be used to ensure translations are properly uploaded into software: - eCOA Migration and Proofreading [<i>when validated translations are available</i>]: - LSP populates technical files [e.g., Excel JSON or similar] to send to eCOA provider for screen report creation. - eCOA Provider sends LSP screen reports with translations. - LSP conducts screen report proofreading with one (or more) proofreader, native speaker of the target language. - LSP and eCOA provider reconcile proofreading comments. - eCOA Translation and Proofreading [<i>when translations do not yet exist</i>]: - If translations are not available, LSP translates the eCOA items according to industry-standard methodology. - Migration and proofreading may be incorporated into the translation methodology, typically at the formatting and proofreading stages, though this approach may vary depending on timelines and parties involved.