LICENSING ROADMAP

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

SUB-TEAM TITLE

TLM Licensing Communications Sub-team

OBJECTIVE

This flowchart guides users on essential steps required for the licensing of electronic formats of COAs for use in clinical trials.

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ROADMAP – FLOWCHART

STEP 1

The responsible party* gathers full scope of licensing requirements incl. final protocol (if available). Sponsor signatory and qualified person is established.

STEP 2

Responsible party begins researching availability, correct version of COA, copyright requirements, feasibility, cost, and timelines for all languages/ countries.

Additional Step: Can be streamlined by establishing information repository.

STEP 3

Responsible party begins licensing activities by contacting Licensors.

STEP 4

Licensing agreements and third-party vendor agreements drafted and signed by Sponsor/responsible party/third party vendor where applicable.

STEP 5

Fully executed agreement received. Payment sent to Licensor.

STEP 6

Responsible party receives source COA measure for all available languages.

STEP 7

Responsible party works with Licensor to identify requirements for Linguistic Validation (LV). Activities for any translations not yet available to be initiated (with Language Service Provider (LSP), Licensor, other party).

STEP 8 eCOA provider drafts source screenshots.

STEP 9 Source screenshots reviewed by Sponsor, Copyright Holder (CH), and/or Licensor, if applicable. Any edits implemented accordingly.

STEP 10 Source screenshots submitted to the relevant authority such as Ethics Committee (EC) and/or Institutional Review Board (IRB), if required.

STEP 11 Linguistically Validated instruments received and submitted to relevant authority in paper format (it may be possible to submit draft versions).

STEP 12 Documents distributed to relevant eCOA migration partners (eCOA vendor and/or LSP). Migration activities initiated by eCOA vendor in collaboration with LSP* for all target languages.

STEP 13 Translated SRs drafted by eCOA Team in coordination with Translation Vendor/ CH.

STEP 14 Translated SRs reviewed by LSP and CH (where required). Any edits implemented accordingly.

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*__ASSUMPTIONS__

1. ‘Responsible party’ is defined as the party who will be ultimately responsible for executing licensing activities.
2. Sponsor has final or late-stage draft Protocol with all instruments, study schedule, and expected study population listed.
3. Due diligence should be performed at the start of this process, at the time of choosing the appropriate COA, e.g., feasibility of including this COA for the study, available translations, required methodology etc.

__RISKS__

1. Instruments and versions must be established at licensing Kick Off or delays will occur.
2. eCOA vendor cannot act as signatory on every agreement. Qualified person or Sponsor signatory must be identified in order to avoid delays.