

LICENSING ROADMAP

Publication Date: TBD

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.

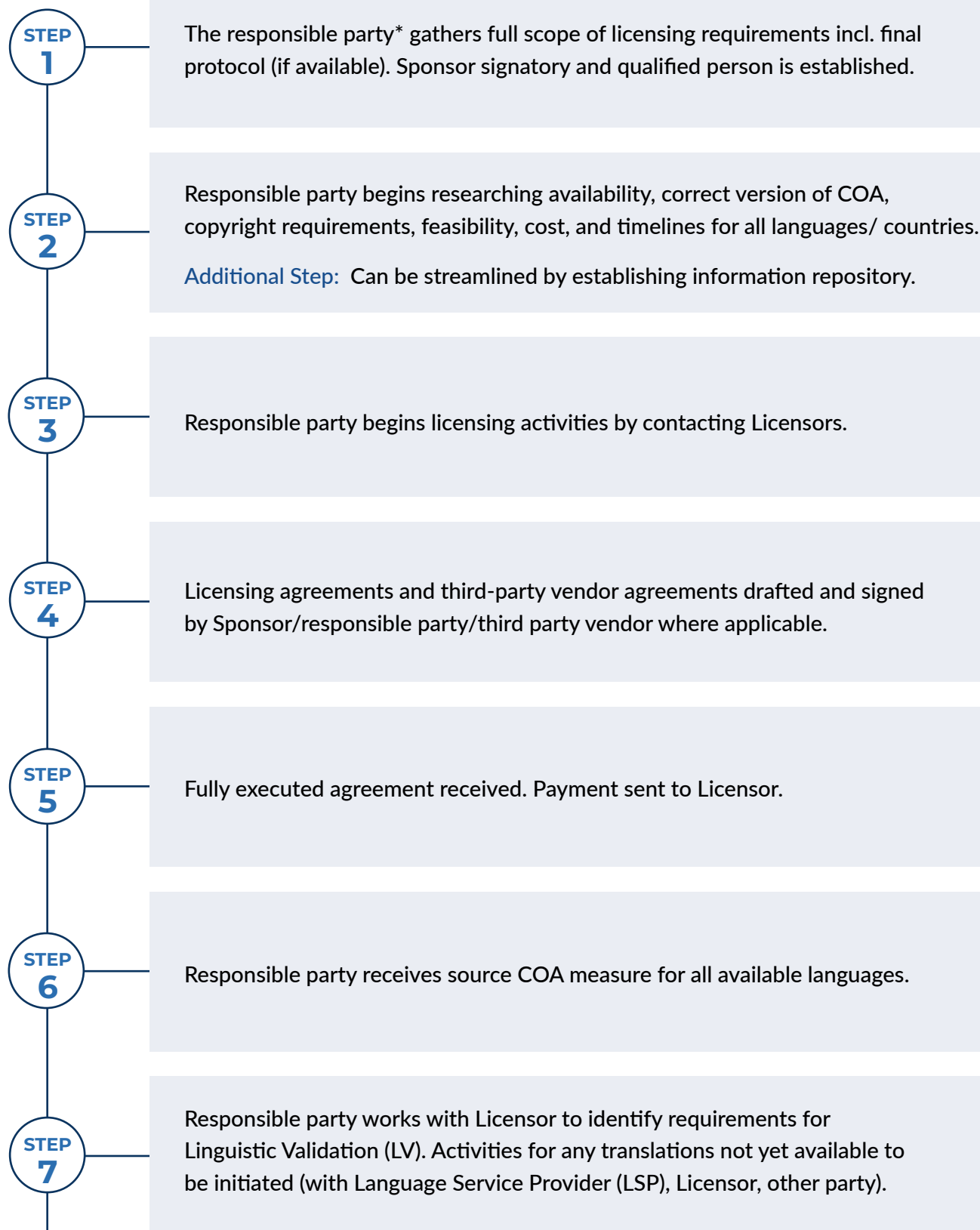
MEMBERS

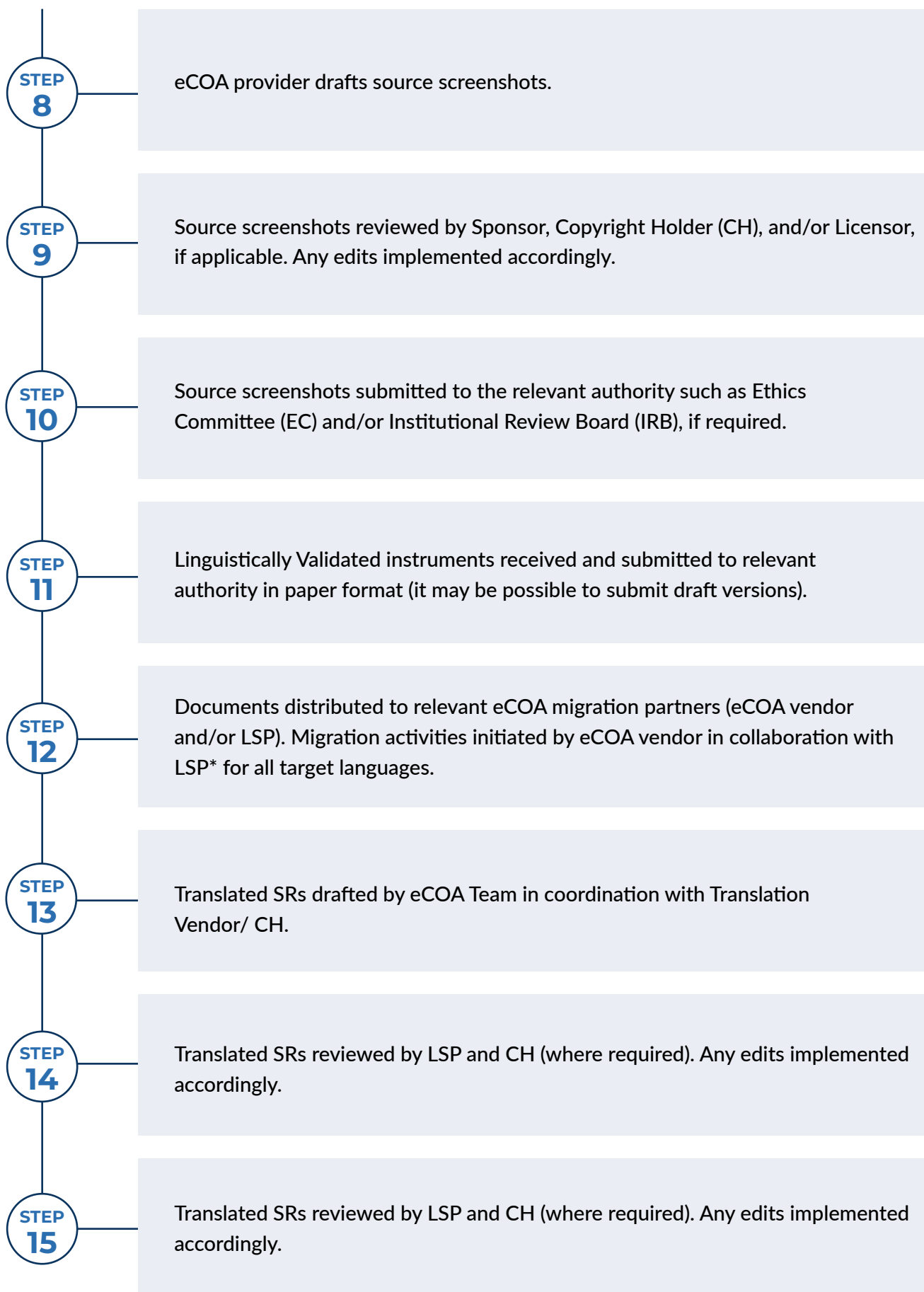
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ROADMAP – FLOWCHART





***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.