

CLINICAL OUTCOME ASSESSMENT TRANSLATION REQUIREMENTS

This form is designed to facilitate the accurate and efficient collection of requirements related to the translation of clinical outcome assessments (COAs). It serves as a standardized tool for:

- > Communicating essential translation process details; and
- > Gathering, documenting, and clarifying translation requirements.

By capturing key information in a consistent format, the form supports alignment among stakeholders, ensures compliance with licensing expectations, and promotes high-quality translations of COAs.

This form can be used by any party working with COAs, including sponsors, eCOA providers, copyright holders, distributors, and LSPs. Information can be gathered from publications, websites, databases, previous translation projects, or, preferably, from the copyright holders/distributors.

INSTRUCTIONS

For each row, the right box allows for free text or selection from a drop down. For fields with “Choose an item”, please click on the text to see a dropdown list of options.

Measure Details	
Name and acronym: list all measures to which these requirements apply	
Licensing	
Is a license required? If yes, describe requirements below	
Details of licensing contact	
Additional licensing information	
New language version	
Who is responsible for producing a new translation?	
Name of required Language Service Provider (if applicable)	
Is universal or country-specific translation required? <i>For example: universal French for all French-speaking countries in Europe vs separate country-specific versions for France, for Belgium, and for Switzerland</i> Click here to add further details, if required.	
Translation initiation	
Standard time to launch translation following execution of license agreement: number of business days needed to launch	

Documents provided at launch (for example, source files, concept definitions)	
Forward Translation	
Number of forward translations needed	
Reconciliation	
How should reconciliation be conducted?	
Back Translation	
Number of back translations (BT) needed	
Back translation requirements (if more than one BT required)	
Reviews	
Developer review of BT and/or the draft translation required?	
Standard time to review: number of business days to complete	
Linguist review of BT and/or the draft translation required?	
Number of linguists to review BT and/or the draft translation	
Clinician review of the draft translation required?	
Sponsor local affiliate review of the draft translation required?	
Other reviews of BT and/or the draft translation required?	

Is proofreading required? If yes, click to describe the requirements.	
How many rounds of proofreading are required?	
How many proofreaders are required?	
Drafts available for EC/IRB?	
Does developer allow a draft translation (before cognitive interviews) to be provided for EC/IRB submissions?	
Cognitive Interviewing	
How many participants are required for cognitive interviewing?	
Which population(s) are required?	
Alternatives if there are challenges in recruitment	
Developer review of cognitive interviewing results required?	
Other reviews required?	
Is proofreading required? If yes, click to describe the requirements.	
How many rounds of proofreading are required?	
How many proofreaders are required?	
Finalisation Steps	
Description of any finalisation steps	

Is the certificate provided by developer or language service provider?	
Is a final report required?	
eCOA Requirements	
Approval of modifications to the wording of the measure's instructions required (source language)?	
Is screenshot review required (source language)?	
Contact details of screenshot reviewer(s)	
Standard time to review screenshots (per round): Number of business days to review screens	
Approval of translations of modifications to the wording of the measure's instructions required?	
Is screenshot review required (target languages)?	
Contact details of translated screenshot reviewer(s)	
Standard time to review translated screenshots (per round): number of business days to review translated screens	
Other Resources	
Additional information can be found at the following location:	