

WORKING WITH COA LICENSE HOLDERS AND AUTHORS

Once you have selected the COA measures you'd like to use, it's important to ensure you have the right permissions to use them in your clinical trial. Many COA instrument owners require a license agreement and a fee to use their intellectual property and impose processes and requirements on the users of their measures to ensure their correct and consistent use. Here are our recommendations for navigating these processes effectively.



01 IDENTIFY THE LICENSE HOLDER

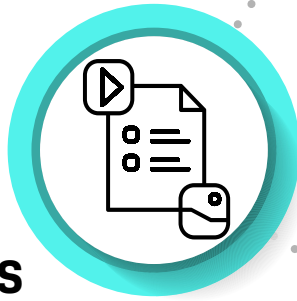
First identify the instrument author or license holder for each COA measure. Some authors contract the license management of their measures to a third-party organization, or license holder. A good place to start is the online database ePROVIDE, maintained by the Mapi Research Trust (Lyon, France), which contains details for many common COA measures.

[VISIT THE ePROVIDE WEBSITE →](#)



02 IDENTIFY THE REQUIRED VERSION, FORMAT AND LANGUAGES

Many COA measures exist in multiple versions and have many validated language versions. It's important to know which version is required, and which languages are needed, to avoid delays later. For example, the SF-36 v2 quality-of-life measure has over 190 translated versions. Remember that some countries may require multiple language versions, and some measures may have different translations for the same language used in different cultures (e.g., US English and UK English).



03 IDENTIFY SUPPLEMENTARY MATERIALS

Some COA measures require the production and provision of supplemental materials. For example, the ADAS-Cog uses a testing kit containing standardized apparatus such as printed word cards for use in some of the assessments.



04 UNDERSTAND THE LICENSE HOLDER'S SPECIFIC REQUIREMENTS

Each license holder may have different requirements, which may include some of the following:

- Sponsor licensing agreement
- Fee structure/payment model
- eCOA vendor undertaking agreement
- Required electronic implementation standards
- Screen review process to verify compliant implementation
- Required language translation process and/or vendor (new languages)
- IP ownership of newly translated materials

Take time to understand the specific requirements for each COA measure you plan to use.



05 COORDINATE LICENSE SIGNATORIES ACROSS ALL PARTIES

Ensure there is time for legal approval of licensing agreements, that the agreement refers to the correct version of the measure, and the correct format (e.g., paper or electronic), and that all required parties in addition to the sponsor are able to sign their agreements.



06 PLAN FOR TRANSLATIONS AND CULTURAL ADAPTATION

Where new languages are required, the license holder may sometimes specify a translation process and vendor that they require for valid translation of their measure. If not, a best practice approach should be followed which should include a number of steps including forward and backward translations, cognitive interview, and certification.

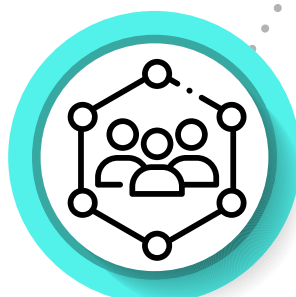
CULTURAL ADAPTATION

Valid translation of COA measures must account for cultural differences to ensure the instrument is measuring the same concept of interest across different countries and cultures. This will include, for example, ensuring that specific terms used are relevant and understood in each culture (e.g., "walking the length of a football pitch", "lifting a gallon of milk" or "climbing stairs"). Translation vendors must account for this carefully in producing valid new language translations of existing measures.

07 USE VENDOR SCALE MANAGEMENT TEAMS

Some eCOA vendors and CROs have in-house specialists that manage scale licensing and translations. **Engage with Signant's scale management team to take the uncertainty out of the process.**

[EXPLORE SIGNANT'S SCALE MANAGEMENT SOLUTIONS →](#)



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