# Kayentis

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## Key #5 for successful ePRO selection in your ophthalmology clinical trial: Anticipate cultural differences in multi country clinical trials

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Before selecting a PRO for use in a large global trial, it is important to anticipate that responses to questionnaires may vary based on the country or cultural differences.

Ensuring that the phrasing or choice of examples used in the questionnaire makes sense for each country or culture is key. In developing a Japan specific NEI-VFQ-25, authors included different choices for the near-vision and distant vision subscales, where items from the original version were endorsed by very few participants. For example, in the 'Distance vision' subscale, replacing 'going out to movies/plays' with 'seeing television program' reduced the rates of missing data and therefore increased the measurement precision.

Occasionally, the structure of questionnaires or even an entire question may be difficult to apply to certain populations. These situations require thoughtful customization work to avoid generating data inconsistencies and statistical comparability risks.

In the same Japan example, the 'Driving' subscale had a high rate of missing data since most participants did not drive, so the driving question was excluded. Additionally, the participants did not find an expression equivalent to 'not applicable.' Re-structuring of the questionnaire to include additional conditional questions was necessary to generate similar responses. Participants had to be asked whether they participated in an activity first, before asking if they had difficulty doing that activity or if they did not do the activity due to vision problems.

Good preparation and planning can help with finding a balance between maintaining

cultural relevance and data quality. It can be challenging, especially in cases where question exclusion or restructuring may be desired for specific countries, to ensure data collection and analysis are standardized.

The ISPOR task force developed a 10-step process to translate and adapt PRO instruments to cultural differences. This is a good resource to refer to when planning for a multi-country study.

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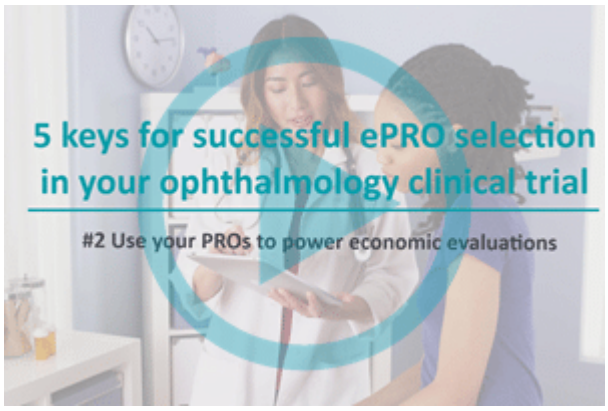


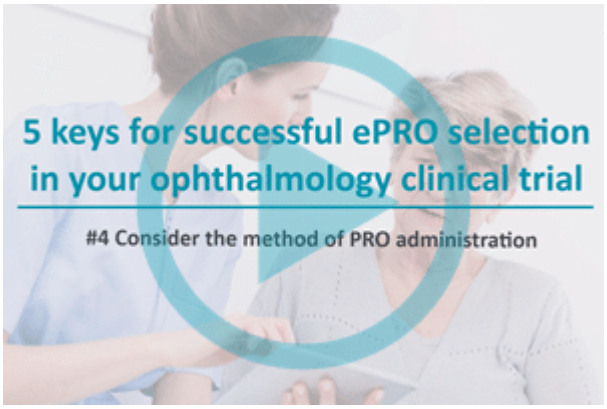


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