SPECIAL POPULATION CONSIDERATIONS IN eCOA STUDY DESIGN

The success of ePRO implementation begins with a thorough understanding of your patient population and how they will engage with your ePRO solution.

Recommended considerations include:

01 UNDERSTAND YOUR TRIAL POPULATION

Special considerations may be particularly important when a population contains one or more of the following characteristics:

- Cognitive or developmental challenges (e.g., pediatric patients, patients with dementia)
- Dexterity challenges (e.g., patients with rheumatoid arthritis or Parkinson's disease)
- Visual acuity challenges (e.g., partially sighted patients)
- Technology-literacy challenges (e.g., technology-naïve patients)
- Significant disease and/or treatment burden

02 PEDIATRIC POPULATION CONSIDERATIONS

Choose between observer-reported measures in young children, to self-report in older children and adolescents by considering the age at which patients can understand for themselves the questions and response scales used. Explore whether age-appropriate versions of patient-reported outcome measures (PROMs) are available, or whether further validation work might be required. For self-completion, consider the number of questions required and the willingness of the patient to cooperate in regular completion.

READ MORE IN THIS ARTICLE →

A USEFUL STARTING POINT TO CONSIDER SELF-COMPLETION AGES IN PEDIATRIC TRIALS

AGE RANGE	RECOMMENDATION
< 5 YEARS OLD	No clear evidence of reliability or validity for self-report
5-7 YEARS OLD	Self-report is possible, but reliability and validity are often questionable
8-11 YEARS OLD	Improved reliability and validity of self-report
12-18 YEARS OLD	Self-report is typically preferred

Based on: ISPOR Good Research Practices Task Force for the assessment of children and adolescents

03 ELDERLY PATIENT CONSIDERATIONS

Age isn't necessarily a special consideration when we consider ePRO. We often see amongst the highest ePRO completion rates in older patients.

However, factors associated with age can be important, such as cognitive abilities and dexterity challenges.

Some older users, may be less confident using technology and this can be addressed with hands-on training.

Pooled ePRO completion compliance is **84.1%**

but it's highest in older users **88.0%**

and caregivers of infants **93.2%**

OVERCOMING TECHNOLOGY ANXIETY IN OLDER PATIENTS

Some older patients are less likely to familiarize with an ePRO solution through experimentation, for fear of "doing something wrong". This performance anxiety can be overcome by:

- Providing a hands-on training system that must be used before starting the study
- Allowing older users time to run through the training system, supervised at site, more than once to build confidence and familiarity.

READ MORE IN OUR RESEARCH PAPER →

04 DESIGN FOR DEXTERITY CHALLENGES

Adapting the ePRO interface to enhance usability for patients with dexterity challenges is vitally important. The use of larger control buttons with larger hit-spots, for example, helps patients with Parkinson's disease to operate ePRO screens using knuckle-taps when experiencing tremor.

Find a vendor with flexible design capabilities who can provide these design adaptations as needed.

05 ACCESSIBILITY CONSIDERATIONS

Consider font size, line spacing, control button sizes, screen brightness and contrast settings to ensure good usability in the target patient population. Extended session timeouts and flexible completion windows may help accommodate patients who need longer completion times. Signant's experienced implementation specialists and flexible design capabilities have this covered.

Consider using the patients' own mobile devices (BYOD), as they typically self-select hardware sizes and features that ensure good individual usability.

06 CAREGIVER COMPLETION

In some patient populations, there may be times when patients need help filling in their PROMs. This could be due to fatigue, motor disturbances, or feeling too unwell. In this case, caregivers can complete the entries as directed by the patient. Design your ePRO to include caregiver completion options with a separate caregiver logon and transparent data attributability built in.

07 COMPLETION BURDEN CONSIDERATIONS

Limiting missing data is essential to derive reliable inferences. Carefully consider how many PROMs are needed, whether multiple PROMs are measuring the same concepts, and how long and how frequently PROM completion will be required. Consider whether the completion times and frequencies required are realistic, especially for patients with debilitating diseases and/or treatments.

08 ENGAGE COA SCIENTISTS

When considering special populations, engage early with our medical and scientific experts who can help you to expertly navigate these challenges.

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