HOW TO DESIGN AND VALIDATE A CUSTOM ELECTRONIC PATIENT DIARY

Patient diaries facilitate collection of valuable experience data in clinical trials, helping assess patient health status and treatment. When developing a new eDiary there are important considerations to ensure custom diaries are considered valid and suitable for use and can support regulatory decision making.

01 WHAT NEEDS TO BE MEASURED?

The concepts of interest of the study protocol will drive what your eDiary needs to measure. Patient diaries are often implemented to record disease-related symptoms/ episodes, treatment tolerability, and study and rescue medication usage. When assessing symptoms, it's important that these reflect the full set of symptoms that are meaningful to patients with respect to the concept of interest. It will be important to provide evidence to support this content validity.

CONTENT VALIDITY

Content validity is the extent to which a measure represents all facets of a given construct. Evidence of eDiary content validity can be obtained from qualitative research in patients (see point 7 below) but may also be found through existing published research and other sources such as regulatory guidance documents.

02 EVENT-DRIVEN AND SCHEDULED DIARIES

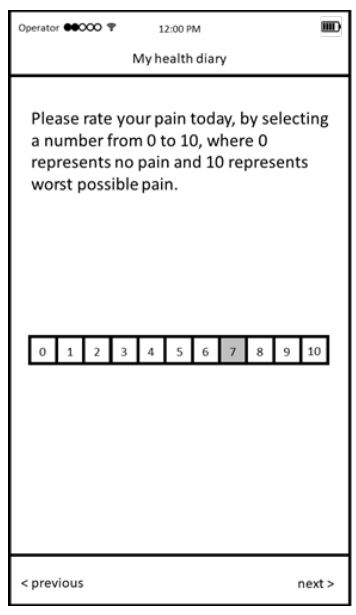
Depending on the concept of interest, you may consider event-driven or scheduled diary options. Event-driven diaries record aspects of specific events that may occur episodically – such as epilepsy seizures, urinary incontinence episodes, and hemophilia bleeding episodes. Scheduled diaries measure symptoms over a period of time such as a day or a week – for example overall chronic pain, asthma symptoms etc.

03 ITEM DEVELOPMENT

The wording of questions to assess each symptom or piece of information needs to be carefully considered. Use established measurement scales (e.g., verbal response and numeric response scales). Questions and response options should be easy to understand by the patient population, be shown to be understood exactly in the way intended (see cognitive debrief, below), and facilitate translation into other languages and cultures.

VERBAL RESPONSE SCALE

NUMERIC RESPONSE SCALE



Figures from Byrom and Muehlhausen, Electronic Patient-reported Outcomes Measures: An Implementation handbook For Clinical Research, Second Edition. 2023. https://a.co/d/6qhQAE9

COGNITIVE DEBRIEF

Cognitive debrief can be useful in assessing whether diary questions and response options are fully understood in the way intended – to ensure the diary produces reliable data. Cognitive debrief is a qualitative research method that involves analysis of narrative data from patient interviews (see point 7 below).

04 FREQUENCY OF USE AND RECALL PERIOD

Diary questions should clearly identify the associated recall period – for example, "now", "today", or "over the past week." Choice of recall period depends on the aspect being measured, and the ability of patients to accurately recall over the selected time interval. The frequency of assessment should be considered in relation to practicality and feasibility in the patient population, carefully considering respondent burden.

05 COMPLETION WINDOWS AND RETROSPECTIVE ENTRY RULES

Limiting missing data is important to derive reliable inferences. In some cases, daily eDiaries may allow patients to enter data for previous missing days as well as completing the current day. How far back to allow retrospective entries should be driven by careful consideration of the ability of patients to accurately recall over the timeframe permitted.

06 BEST PRACTICE FORMAT AND DESIGN

Keep your eDiary simple, and design it following industry best practices for ePRO implementation. These are well documented in the industry textbook by Bill Byrom and Willie Muehlhausen. Involve Signant early – our experienced science team will drive optimal diary design.

EXAMPLE

Signant Scientists developed a new epilepsy seizure diary in collaboration with The Epilepsy Study Consortium (TESC). TESC chose Signant because of our considerable experience developing complex eDiaries and conducting epilepsy trials.

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07 COMPILE SUPPORTING EVIDENCE

Compile evidence to support the content validity of your eDiary, and that its questions and response options are understood correctly by patients. This can be done with prospective qualitative interview studies in patients, or if there isn't time, you might consider in-trial interviews. Speak to Signant to help determine the best, practical approach to collect the supporting evidence you need.

08 COLLABORATE WITH eCOA SCIENTISTS

When considering developing and using a custom eDiary, engage early with Signant's medical and scientific experts who can help you to expertly navigate these challenges.