Strategies for Electronic Instrument Development: Incorporating Technology from Day One

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Until recently, new instrument development for clinical outcome assessments (COA), such as patient-, clinician-, and observer-reported outcome instruments, has been conducted with the assumption that the instrument would be administered using paper and pen. Electronic administration has been, at best, a consideration and, at worst, an afterthought that requires migration from the paper version to the electronic platform; additional cognitive interviews and usability testing, and in some cases, equivalence testing if the modifications during migration are considered moderate. This sequential approach to instrument development results in delays to the finalization of the instrument for clinical trial use, and in some cases, the migration equivalence studies are conducted at risk because of the need to maintain clinical trial starting dates. Recognizing the many benefits of electronic COA data collection, sponsors have a growing interest in better strategies to accomplish electronic implementation of new instruments in development.

The purpose of this article is to offer recommendations for incorporating electronic modes of data collection from Day One of the COA planning and instrument development process. Use of technology at early stages of instrument development has the potential to revolutionize how instrument development is conducted; to shape the final instruments to be better suited to electronic modes, and even to take advantage of their capabilities that surpass those of paper. Another benefit of the Day One approach to incorporating electronic modes at early stages of development is to streamline the instrument development process and increase efficiency, thereby reducing time and cost and enabling sponsors to meet their clinical trial start dates and seamlessly incorporate the electronic version of the instrument in their clinical trials.

Incorporating Discussion of Electronic Administration During Concept Elicitation

The concept elicitation phase of instrument development involves identifying the concepts that are most important and relevant to patients with regard to the condition of interest. This phase involves exploration of how frequently symptoms may occur and the appropriate recall period to use. It also provides the opportunity to begin exploring the potential for electronic administration and determining the suitability of different modes to a particular patient population. This information will be extremely useful during the process of mode selection for the instrument itself in following phases.

Incorporating Technology During Instrument Construction

Between the concept elicitation and cognitive interview phases, the draft instrument is constructed based on the conceptual framework and information regarding appropriate recall period and response options generated during concept elicitation. Many decisions are made at this stage regarding instrument structure and format, and these can have a major impact on future implementation in electronic platforms. Translatability assessments are often conducted during this phase to ensure that the wording of the instrument is amenable to translation and, more recently, “migratability assessments” are also being incorporated to assess the suitability of the instrument for future migration. It is during this phase that selection of the appropriate mode of data collection for the instrument takes place.

With advances in technology tools that streamline the screen design process, it is now possible for sample screens to be developed during this phase of instrument construction to simulate the appearance of the instrument in a prospective electronic platform. This capability helps to ensure that the wording of the new instrument is suitable for the electronic platform and that it will fit the space appropriately. Early development of screens also provides the opportunity to identify potential issues with future translations if the text or responses run very long in English, and to make appropriate revisions so that the future translations will also fit in the electronic format.

If interactive voice response (IVR) is the preferred technology for the instrument, this stage would be the appropriate place to develop the IVR script language for how the instrument would
be administered in an IVR setting. The IVR script would be read aloud during the interview to simulate the IVR system, but no actual programming or technology is needed to conduct the cognitive interviews with the script. Therefore, incorporating an IVR instrument into cognitive interviews can be done without additional technology costs or time for programming.

With the Day One approach, instrument construction becomes a comprehensive process that involves thinking about the content and method of data collection simultaneously and focuses on design, function, and presentation.

Incorporating Technology During Cognitive Interviews
There are several options for incorporating technology during the cognitive interview phase of instrument development, during which the content validity of the new instrument is confirmed with the target patient population. In most cases, several rounds of cognitive interviews are conducted to refine the concepts and wording of the items and responses. For earlier rounds of interviews, a “mock screen” paper format may be used, which would simulate the electronic version. For example, if the instrument is a daily diary to be administered on a smartphone device, the “mock” version presents the questions one at a time to simulate the electronic presentation. Once item and response wording are refined, the instrument can be programmed into a demo device that could be used during cognitive interview to assess both the content validity and the usability of the instrument in the electronic format.

For daily diaries, cognitive interviews may also involve conducting a longer usability testing process in which the instrument is programmed into a device, along with reminders and completion windows, and the patient takes the device home to respond to the diary over the course of several days to a week. When the patient returns at the end of the period, an interview is conducted to assess the content of the instrument now that the patient has become more familiar with it, and to assess the usability of the device after experienced patient use. This approach is more time consuming but may provide greater insight into how successfully the patient uses the device at home and any issues that may cause problems with compliance in future clinical trials.

With the Day One approach, the electronic version of the instrument is included in cognitive interviews automatically as an essential component of the instrument development process, with the added benefit of usability testing while the instrument is still in development.

Transitioning from Cognitive Interviews to Clinical Trial Use
Once the cognitive interview phase is complete in the Day One approach, no further migration studies need to be conducted. The instrument can be finalized and stored in an electronic instrument library, where it can be accessed for future implementation in clinical trials. Having an electronic version of the instrument available in a library potentially reduces the time required to gather study requirements and design the instrument during the implementation and start-up phase of the clinical trial. Early planning with the ePRO vendor is critical during the start-up phase in order to provide the vendor with the questionnaire and ensure there will be no complications with configuration on the selected hardware. In the Day One approach, the time between completion of the cognitive interview phase and start of the validation study or clinical trials is greatly reduced and allows the sponsor to move forward quickly with the new instrument and future use.

The Day One approach, early planning and collaboration with ePRO vendors to integrate technology into all phases of COA development enables sponsors to measure critical clinical trial end points more effectively using electronic instruments that are developed in an efficient and cost-effective way.

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References