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CLINPAL

ePRO poised to get more user friendly as eClinicalHealth develops validation for BYOD

By Suz Redfearn

Sponsors and CROs are enthusiastic about the usefulness of handheld devices in clinical trials, which allow study subjects to input information in real time, rather than having all patient info stuffed into the patient's meeting at the study site. Naturally, many companies are now in a race to make electronic patient-reported outcomes (ePRO) more user friendly. **eClinicalHealth** of Stirling, Scotland, has just pulled ahead.

eClinicalHealth, in conjunction with Icon, recently released a device-independent methodology to validate and standardize patient questionnaires on handheld devices, allowing patients to download an app to track the info needed for the clinical trial they are enrolled in.

ePRO has faced some big obstacles. Namely cost, as providing dedicated devices to patients is expensive and hard to manage, but validation is also a problem. If a patient is using their own device—referred to as Bring Your Own Device (BYOD)—the device must be validated in order to meet **FDA** guidelines, and validating hundreds or thousands of phones for a study can be a tall order.

A key feature—it can work across different data capture tools.

Kai Langel, eClinicalHealth's director of Patient Solutions, explained the company is developing and validating a "migration standard" so that PRO instruments can convert from paper formats to electronic formats, allowing patients to use their own devices.

"Through collaboration with device makers and patient observation, key elements—such as minimum screen size and placement of instructions—are identified that the standard must address to ensure data captured electronically is of equivalent or better quality than the original paper design," said Langel. "The final, device-independent standard undergoes testing using the industry's standard testing practices."

Unlike the current standard practice, this methodology is not specific to any vendor or device, Langel said, adding that once it is developed, any vendor can follow the same standard and it can be used with most devices.

Regarding cost, Langel said, in the mid- to long-term, the methodology is less costly than the current process, because the standard need only be developed once for each instrument.

"The migration standard should be owned by the PRO instrument copyright holder, which ideally makes it freely available to all sponsors and vendors," he explained. "If such a standard does not already exist, the process for developing one is not much more expensive than what is currently done. The investment to develop the standard almost certainly will be recouped in the second study in which the instrument in question is used."

Those in the industry believe this is the next step for ePRO and welcome it.

"Such solutions are needed if we are to move forward as an industry," said David Stein, independent eClinical consultant with D. Bartley Consulting. "At present, there is too much uncertainty associated with BYOD and it is hindering the potential benefits. Evidence shows that patients are more compliant over time when using their own devices rather than having to carry and maintain a separate device. We need practical solutions that will reduce the validation burden without compromising quality, and this approach can help achieve that."

He said by establishing minimal requirements, such as screen size and resolution, and ensuring that best practices for electronic clinical outcome assessments (eCOA) design are followed, a methodology like this could eliminate the onerous validation problem the field now faces.

But as exciting as this is to those working on clinical trials, Stein warns that all systems on it must be a go for there to be significant upside. One must ensure that best design practices are followed, he said, that the instrument is not changed across modalities, and that if someone attempts to use a device that does not meet the minimal requirements, the instrument will not load.

Elements of the technology may have been there all along, but readiness for the sea of change wasn't. Now it is.

"This represents less of a technology evolution and more of a clinical trial mindset evolution," said Drew Schiller, CEO and co-founder at **Validic**, an IT company that connects data from wearable and medical devices to companies across the healthcare ecosystem. "This enables studies to be conducted more efficiently and at lower cost given that additional smart devices will not need to be provisioned and subjects may be more adherent if they are able to use a device that is already in their pocket."

eClinicalHealth had help from Icon to develop the methodology. Said Langel, Icon was involved in writing the guides for the interviews and study protocol used to test the methodology. The company also analyzed the results and reviewed the final standard.

"Our collaboration with eClinicalHealth proves that new concepts to validate instruments can be developed to support successful bring-your-own-device models," said Willie Muehlhausen, Icon's head of Innovation, in a release.

Langel said being able to have patients use their own devices just makes sense.

"There are several benefits, such as cost and time savings for the sponsor, as well as added convenience for sites and patients when extra logistics, hardware maintenance and training can be eliminated," he said. "For example, some sponsors have identified gaps in their data over weekends and holiday periods when patients are asked to use provisioned, study-specific devices. This is not surprising as patients are less likely to carry an extra device during these times. However, patients will almost always have their own personal device with them."

Moving away from providing devices to patients "would be a giant step forward to improve clinical trial efficiency," Langel said.

Since 2000, Kai has been a pioneer in patient-facing systems for clinical trials. Through his involvement in technical, operational and scientific roles, he has gained an in-depth understanding of all aspects of the patient journey in clinical trials from recruitment and engagement through data capture. An innovator for electronic patient reported outcomes, Kai has been involved in new instrument development, instrument migration projects and industry consortiums developing best practices. Kai is a respected leader in the industry and frequently speaks at industry conferences. He has authored several articles targeting eClinical working practices and lessons learned.