Philips Offers Best Practices for Inclusion of Digital Health Technologies in Trials, Leading to Better-Prepared Sites and Improved Data Outcomes

Philips Applies CTTI’s Digital Health Technology Recommendations

SUMMARY

Digital technology is changing the healthcare landscape every day, but many sponsors are still unsure of exactly how to integrate these technologies into trials in a way that ensures quality data and good compliance. In fact, survey results published recently by DT Consulting showed that up to 43 percent of clinical trial sites are not utilizing digital devices in research, and the sites that are using these tools are using them only for patient recruitment. Complexity of regulations around digital technologies and identification of the right technologies are among the top-rated challenges cited by trialists. Fortunately, CTTI’s Digital Health Technologies (DHT) recommendations offer tools and tactics for bringing technology into the clinical trial fold successfully. Here is how Philips North America uses the recommendations to bring sponsors and sites into alignment.

GOAL(S)

Clinical trials that use digital health technologies have many unique considerations with respect to site infrastructure requirements. The Philips Motion BioSensors Group is tasked with regular interactions with sponsors explaining these considerations, including how to appropriately use Philips’ actigraphy motion biosensors in clinical trials. Used correctly, Philips’ actigraphy tools can offer rich data and streamline processes, but without full alignment across a clinical trial, even small errors like forgetting to charge a device’s batteries at the site can cause headaches for trialists and poor data quality.

CHALLENGES

Over time, the Motion BioSensors Group has noticed gaps in communication between Philips, the customer, and the trial sites, mostly in situations when a contract research organization, or CRO, is brought in to support a trial. The guidance provided to the sponsor was not getting transferred to the CRO or the sites in a consistent manner. Additionally, the sponsor or CROs were not appropriately vetting the sites for the necessary technical capabilities, so the enrolled sites had significant limitations with the technology. Philips needed resources that could guide sponsors and sites on how to use Philips’ digital health technology in clinical trials to close these gaps in communication. With no formal regulatory guidance in place, finding a vetted and trusted resource was a challenge.

SOLUTION(S)

Philips began referencing CTTI’s DHT recommendations to help sponsors design and run successful, fit-for-purpose digital health trials that meet their research goals. From selecting the right technology to planning trial logistics and study communications, CTTI’s DHT recommendations and resources offer a one-stop-shop for the best use of digital health technology in clinical research.

TAKING ACTION

Philips relied heavily on two CTTI resources to address its challenge. The first was CTTI’s Checklist for Sponsors: Considerations in Selecting and Equipping Sites for Clinical Trials with Mobile Technologies. The checklist identifies factors specifically related to the use of digital health technologies that sponsors may wish to consider during the site identification process. The second resource Philips used was CTTI’s Advancing the Use of Mobile Technology for Data Capture and Improved Clinical Trials, which offers a comprehensive guide to the many considerations that accompany the decision to use a digital health technology for data capture. CTTI brought together regulatory, technical, clinical, operational, and patient experts to create the resource, which supports both newcomers and seasoned pros using digital health technologies. Rather than a transitory conversation, Philips began sharing these documents as a way to offer concrete and consistent guidance sponsors and sites could reference throughout the trial process.

IMPACT

Since implementation of CTTI’s resources to support the use of digital health technology in research, the organization is seeing relatively better-prepared sites, consistency, and alignment of sponsors and sites. The CTTI resources have been critical to bring all parties onto the same page and bring out the best of Philips’ actigraphy tools in clinical trials.

ADVICE

The Philips Motion BioSensors Group recommends holding cross-functional meetings prior to the trial launch to bring together all functions and reinforce the criticality of following CTTI’s guidance and using digital health technology appropriately. Early engagement brings all the teams into alignment and offers an opportunity for sharing best practices and lessons learned related to digital health trials. If more lessons could be shared broadly, the industry would be better adept at using digital health technologies in trials and harnessing the rich benefits digital health technology can offer.

ORGANIZATION

Philips Sleep and Respiratory Care

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ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2019
TOPIC
Digital Health Technologies

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