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Considerations For The Use Of Wearables In Clinical Trials

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With wearables, we now have the means to innovate the "where" and the "how" of patient data capture, creating a 24-hour digital map of physical behaviors. The recent Sanofi-sponsored VERKKO trial (a fully remote trial), for example, highlights the possibility of creating patient-centric virtual studies, eliminating the need for the subject to travel long distances to sites. Thus, wearables could become an integral component of this place-shifting strategy.

However, integrating wearables into a trial is more complex than simply giving the patient a smartwatch and generating clinically relevant data. Wearables are already subject to negative commentary; critics say the huge quantities of data generated by them add to the complexity of trials.

Before integrating wearables into a trial, you should first make sure their inclusion fits with the clinical hypothesis. Will adding them add value? Will their inclusion offer data not available from other sources? Wearables can generate primary, secondary, and exploratory endpoints. They have value in screening and compliance (e.g., inclusion/exclusion criteria require patients to have specific activity and sleep patterns).

Of course, patient acceptance is critical; if the device is not worn, there is no data. Design, ease of battery-recharging, and water-resistance all impact compliance. The more a patient removes the device, the greater the risk of their not wearing it in the future. To further improve a wearable's acceptability, its materials need to be hypoallergenic to avoid any skin irritation or burns.

ENSURING GREATER COMPLIANCE, ACCEPTANCE

The selection of a device class depends on the intended use, labelling claims, and supporting scientific evidence. It's more common to use medical devices for the generation of clinically significant primary and secondary endpoints and wellness or investigational devices for less-critical data generation. Here again, patient acceptance is crucial. In the past, medical devices tended to be uncomfortable to wear and designed based on functional engineering principles rather than the user experience. In contrast, wellness devices tend to be more design-focused, although bulky, targeting mostly men and not always suitable for the elderly or children.

A number of companies that are members of the Consumer Technology Association (CTA) Health & Fitness Technology Division are developing industry standards that address the issue of data and device quality. In addition, companies such as Withings, iHealth, and Philips are creating devices that meet consumer demands and are medical devices. This new development could ensure greater compliance and acceptance.

THE CHALLENGE OF DATA TRANSMISSION

One of the challenges associated with wearables is data transmission. Each method of data transmission (e.g., apps, hubs) has cost and regulatory implications that need to be mapped and risk assessed. Data management processes need to be in place to manage the flow of data into a validated clinical data management system, to perform data quality control, and to map to data standards when required.

Regulators are struggling to keep pace with the digital explosion. The FDA recently added a page to its website dedicated to digital health and sought input from stakeholders regarding the use of digital technology in clinical trials. The agency also issued a number of guidance documents on the subject.

But just focusing on technology and sandwiching it into a trial is not a best practice. Wearables need to be viewed as a component of an overall patient-centric strategy rather than a solution in themselves. When creating a remote trial, sponsors shouldn't be simply shifting the burden to patients, requiring them to carry out an unsustainable number of tasks in an unsupported, uncontrolled environment.

Via wearables, we now have the capability of capturing real-life, continuous data streams that could unlock new insights into therapeutic responses, which are also meaningful to the patient, thereby creating a true patient-centric clinical trial. L

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