

Report from the eDigital Expert Group

How to reduce the burden of wearables implementation in clinical trials

The 4 major questions all clinical data managers must answer prior to the addition of a new source of data to their studies.

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Wearable technology is now a hot topic in the clinical trial industry, offering new and exciting possibilities to collect data and promising easy and accessible ways of adding it to a study. The industry is filled with excitement but lacking knowledge and best practices on how to utilize this technology in a way that provides value without adding more problems for the Clinical Data Managers.

With the goal of removing some of these problems before they start, we discussed with experts in the field to gather their recommendations and best practices and share with the ACDM community in an effort to encourage the informed use of wearable technologies and answer some of the most frequent questions.



1. WHAT IS THE SCOPE?

The first decision that must be made when considering using a wearable source for collecting data regards the scope of the data.

- **What endpoint are we going to measure, how is it relevant to the study?**

It is easy to get carried away with the vast opportunities in using wearables. The first question you must ask yourself is how does this help the overall objective of the study and even all the way through to the NDA and Summary of Product Characteristics (SPC). Are there traditional methods being used that you need to validate this new wearable technology against? Or should you use the traditional methods as they are more accepted?

- **What problem are we solving with this device?**

Wearables have the opportunity to bring new and insightful data into the clinical trial setting, however as data managers we need to be conscious of whether the device is actually helping us to solve a problem especially since the addition can often add more complexity to our study. We must start the process by determining if the data is relevant to the clinical trial and whether it appropriately addresses the effect of the treatment on the patient and the outcome can be measured in a way that current data collection options are failing or being less effective.

- **What data do I want to collect via wearable technology?**

Another consideration is to decide if we are looking at primary, secondary or even tertiary endpoints and to assess if, in the context of our study, this data will enhance the outcome.

- **How does this additional data blend with my study type and goal?**

The study type will highly influence the parameters set up around the wearable device ranging from wear time, target population or passive or reactive data collection set-up. Wearable devices are not a fit-all type of solution and the selection must be determined by the study objectives.

2. WHY ARE YOU CONSIDERING WEARABLES?

After deciding on the scope, we should verify that this solution can add value to the study in an efficient way.

- **Is the data relevant to the overall trial endpoints?**

Our initial analysis should also verify how the wearable data connects to the remaining endpoints gathered through traditional EDC or eCOA systems. Careful consideration should be applied when evaluating potential duplication of data or actual methods for the wearable data to complement the remaining data.

- **Could these endpoints be collected through any of the traditional options with the same efficiency and quality?**

By staying within traditional methods, we can simplify operational aspects of the trial.

- **Do we have the knowledge to analyse this data?**

Before jumping to the adoption of this new data collection devices we must assess if we understand the data, the results and how it interacts with remaining endpoints. Factors such as raw data format or integration capabilities are questions that should be answered prior to making decisions.

- **How are we validating the device and the data?**

Computerized system validation should be performed to include usage, training and education processes for target groups. Hardware and software validation are major factors that directly impact the success of the trial and pose questions that should be asked very early in the process. Data Managers must evaluate if inhouse validation tests are required or if the components are already sufficiently validated by providers.

3. HOW DO YOU HANDLE THE LOGISTICS?

If the analysis proves that there is value in collecting these endpoints via wearable technology, then logistical items must be considered next.

- **How much data do I want to collect?**

The volume of data will increase exponentially and a collection of a few samples per second will soon lead to huge amounts of data. When evaluating analysis and storage capabilities we should consider whether minute-level, hourly or daily summary data would better fit our purpose as well as the frequency of receiving this data.

- **Can we standardise the way the device is used in the real world?**

Real life applicability for the device is a factor that can significantly impact the ability to collect the endpoints and risk assessments should be performed to help guide the proposed solution. The impact the device has on the subject and their normal routine might directly affect your ability to collect data. For example, you may get better compliance if the subject is required to wear a device for 24 hours a day, 7 days a week for 2 weeks to limit the risk of them forgetting to put the device back on.

- **What are the operational requirements for using the wearables?**

Part of the risk assessment should include common device issues such as battery life or device malfunction. Contingency plans must be put in place to assure minimal data loss when such issue occur. Additional technology such as Bluetooth or communication gateway devices might be required and should be evaluated for potential impact on usage.

- **How will we incorporate change management to the data?**

One significant benefit for wearable data is of course the quality of the data through the minimum interaction required. But even when the interaction with data is limited, we should still consider and be prepared for situations where data changes might be required. Data collection via wearables differs from the standard means used in clinical studies and for common occurrences such as missing data, querying the patient might not be an option.

4. WHERE DOES THIS FIT BEST?

Now that the initial questions are answered, we have a rough understanding of the undertaking and we must decide how this element fits into the overall plan for the clinical trial.

- **When should I start considering the wearable implementation?**

When speaking to wearable providers, one main challenge they highlighted was timing and the importance of planning the introduction of the device in advance. Even if the device is not intended to be used for the full duration of the study or from the start, the process should be analysed prior to study launch to assure minimum impact to the lifecycle and results of the trial.

- **What are the vendor requirements to implement this solution?**

As we mentioned earlier, wearables are not a fit-all solution and vendor capabilities are a major factor in how the device will be used. The vendor you select will dictate a consistent part of the implementation through their timelines, recommendations, challenges and overall experience in similar applications.

- **How do I engage my patients to assure compliance?**

In order to ensure compliance is high, patient engagement tactics are essential however your tactics may change depending on the target population. In some instances, the use of reminders or gamification may improve patient compliance in terms of wear time or milestone achievement.

- **Would I like to reuse the data in the future?**

The more value we obtain through this data, the more likely it becomes that we would like to reuse it in the future. Best practices would be to prepare in advance by including this action in informed consent processes and in storage considerations.

FINAL COMMENTS

This addresses many of the common questions across a broad application for wearables in clinical trials, however there may be additional questions depending on your therapeutic area or type of wearable you are considering, and each study design will contribute to the overall complexity of the process.

The main take away from our discussions with the ACDM community as well as with the experts from the wearables industry is that this technology requires careful consideration and when executed well there is the potential to offer new insights. In this era of big data, as data managers we must carefully consider whether this volume of data is a meaningful step towards our objectives or a distraction.

If you have any questions, please feel free to contact ACDM on admin@acdmglobal.org.

About the **ACDM eDigital Team**: We are a data management expert group focusing on driving thought leadership discussions on how current innovative digital technologies are changing and enhancing the resources available to data managers. The group meets on a monthly basis to develop advisory material to the wider ACDM community by utilising our collective experience and by inviting topic experts to provide additional background to enhance our understanding.