What do data managers need to know when considering wearables for their data collection?

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How much data is required?

For example, 32 samples per second will lead to terabytes of data. Is your system able to do this or would you rather consider minute-level, hourly or day summary data?

Is the data relevant to the trial endpoints?

This is of course important for GCP purposes. For example, does the compound have an effect on body's ability to move, the subject's behaviour or sleep patterns? If yes, then there could be a benefit to using an accelerometer

Does the data add value to the trial?

Or is this a nice to have?

What format does the raw data come in?

Is this binary, decimal or hexadecimal, integer or floating point, text or numeric? How is it converted and added to the eCRF?

How is the data being analysed?

Is this the sponsor or has this been delegated to a CRO, eCRF vendor or the wearable vendor? What algorithms are being used and how have they been validated?

How valid is the data?

Do you need to run validation tests inhouse before beginning the clinical trial?

Can you standardise the way the device is used in the real world?

What measures will you put in place? Will you ask the subject 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?

For example, what is the battery life? What are your contingency plans if the wearable fails?

Who is responsible for the contract with your wearables provider?

Is this through your legal team or a different department?

Who owns the data?

The subject or the sponsor or the wearable vendor?

How will you manage change management to the data?

For example, what if the incorrect date has been entered due to device malfunction or operating error?

Would you like to reuse the data in the future?

If yes, how will you go about informed consent?

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