Digital Health: Implementation Challenges to Best Laid Plans

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How tech savvy is your study population?

Younger patient population

- Familiarity with user interfaces of digital devices
- More “buy in” with new technology
- For BYOD studies, may already have compatible devices
How tech savvy is your study population?

- Many don’t have email addresses
- Steeper learning curve with digital device interfaces
- Physical challenges
Integrating mHealth with EDC

**Integration of mHealth solution with EDC**
- mHealth data is automatically uploaded to EDC in real-time, or when device syncs.

**Batch uploading of mHealth data into EDC**
- mHealth data is incorporated with clinical data via batch upload into EDC, like lab data.
- Not real-time, may require manual push.
Should (or could) I integrate with EDC?

**Protocol considerations**
- Eligibility assessments
- Edit checks across mHealth data points
- Timeliness of data availability

**Technical considerations**
- Open API
- Implementation team
  - Internal or vendor support
- EDC page requirements for integration
  - EDC page design limitations
  - Timing of build
Integrating the data with EDC

- mHealth data is needed to make real-time decisions (eligibility, randomization, dose escalation, etc.)
- mHealth data is key for primary endpoint evaluation
- Data management review of mHealth data in the context of other data in EDC is required
- Data is discrete and manageable (answers to questionnaires, dosing information, number of night awakenings, etc.)
Keeping the data separate

- Data is not needed for decision-making during study
- Data is not needed for primary endpoint and integration effort compromises study timeline and cost milestones
- Data management and cleaning is already being performed by the mHealth vendor outside of the EDC
- Data is continuous and therefore, voluminous
Big data – Is more data always better?

Wearable devices can collect millions of data points per subject per day

Can the DMP and SAP cover what to do with all that data

True data signals can be dampened with the noise from that kind of volume

Integration may be more than the EDC can handle
Creative solutions

- mHealth vendors may pre-process the data for visualization and analytics instead of integrating the raw data into EDC
- Design EDC to capture only certain intervals of data or data points
- Outsource the handling of the data completely to pros at the mHealth vendor
  - Separate DM team for cleaning and verifying mHealth data
  - Separate biostats team for data analysis