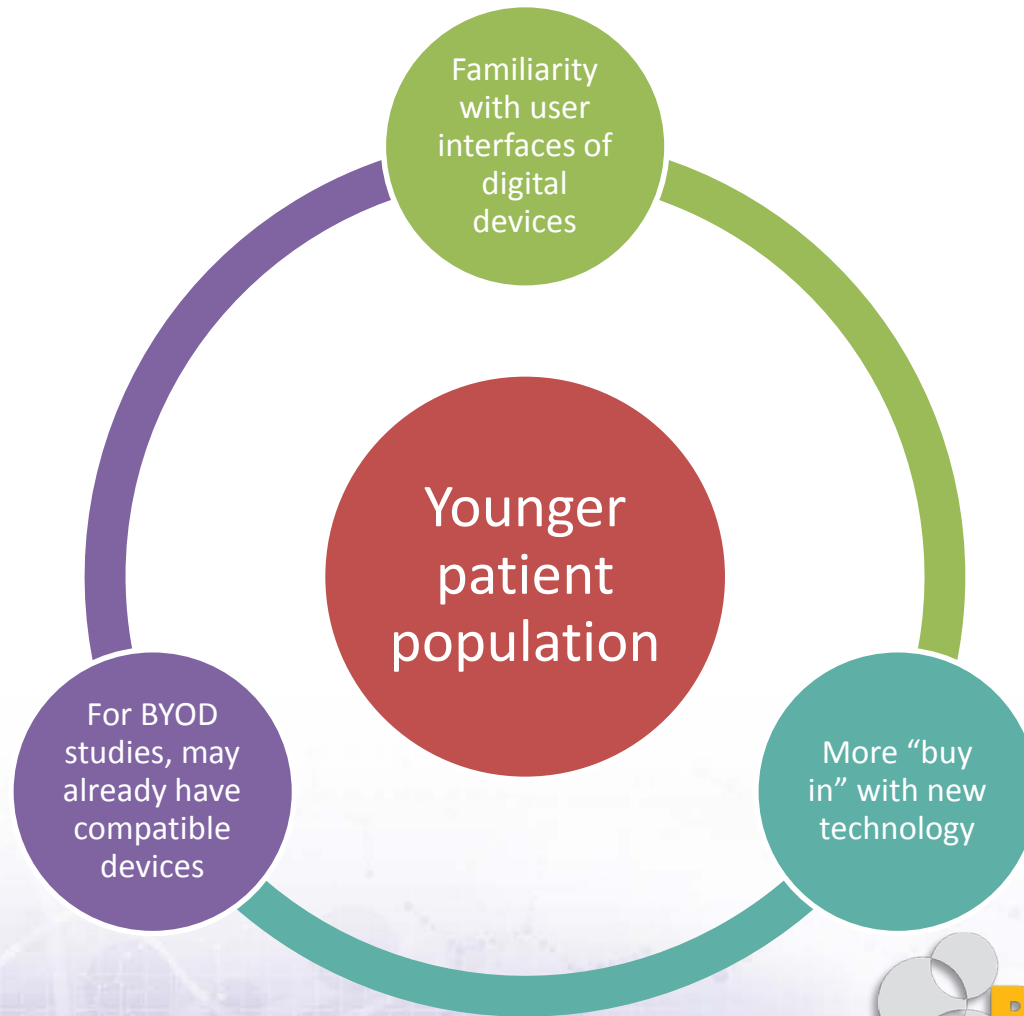




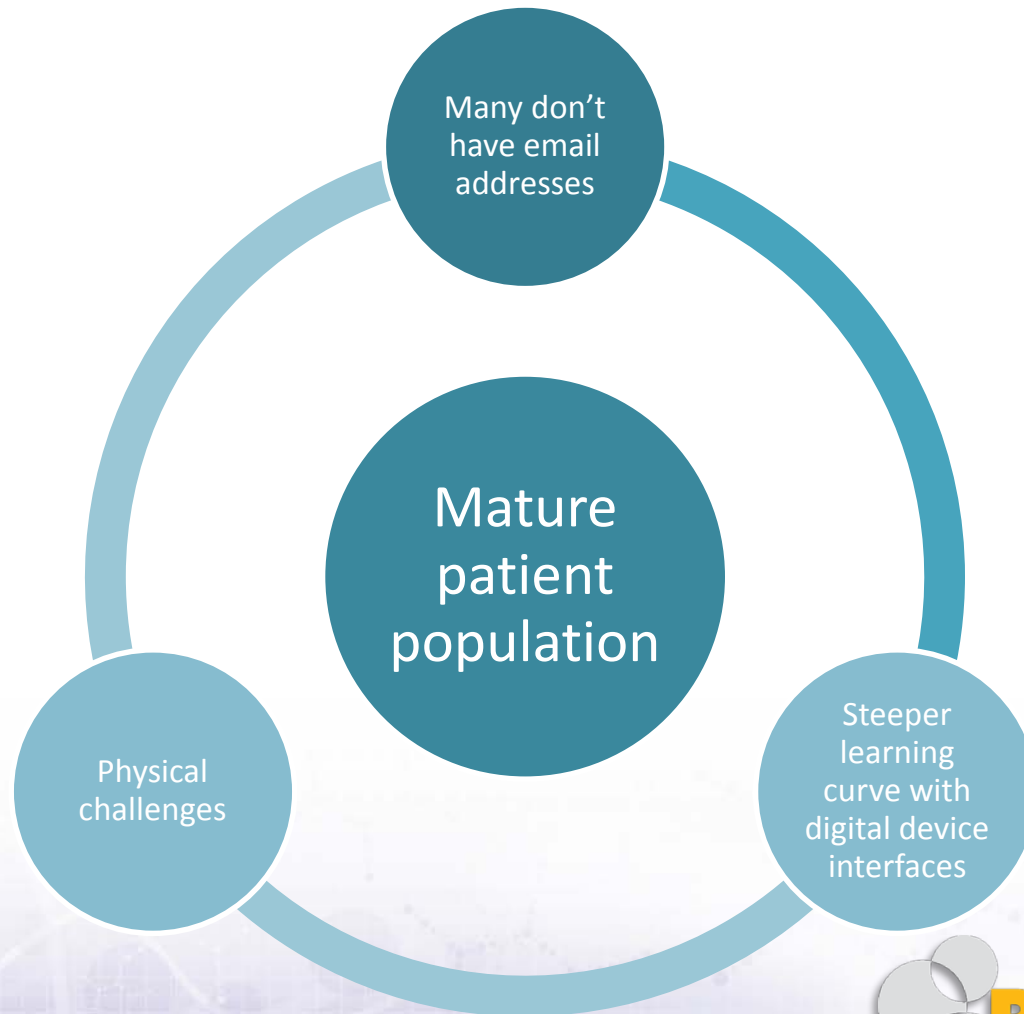
Digital Health: Implementation Challenges to Best Laid Plans

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How tech savvy is your study population?



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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