

Using Patients' Phones to Collect Clinical Data: Challenges (and solutions) from a Sponsor's Perspective

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BYOD: the new kid on the block

Bring Your Own Device (to clinical trials)



How do you do it?



Agenda/Steps

- When BYOD, and when NOT
- Technology and Design
- Regulatory
- Timelines and Costs
- Vendors and New Market Trends
- Help and Resources



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- Studies which already pose a heavy burden on site logistics (i.e., site manages other study equipment)



...and when NOT

- Short/small studies (both time-wise and patient-wise)
- Studies run in countries where smartphone penetration is (currently) weak (but new markets are opening up quickly)
- Studies run with elderly target population

Please note all of the above apply to provisioned phones as well, and sponsors often still resort to paper diaries in such instances



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Design and technical considerations

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Weblinks:

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Apps:

- Faster than weblinks
- More secure
- Can collect data offline
- Expensive



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- Installation should be quick and effortless (no more than 5-10 min)
 - differences in process between IOS and Android



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- 4) Ensure data security*



1) Ensure no bias in patient selection

If a subject does not own a smartphone or do not want to use her own for the study, a “provisioned model” solution should always be available at site

This provisioned device should have the standard study app already loaded and ready to be used – follow standard eCOA model

Regulatory

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Run an equivalence study

- *Extra (hidden) time (1 to 2 extra months)*
- *Extra (hidden) costs (50k-80K)*
- *Considerations on design:*

smallest vs largest device?

Within vs Between subjects?

3) Ensure patient privacy

- *The app should not communicate with any other app on the phone*
- *The vendor needs to collect phone number and OS type for installation*
- *The subject will receive study specific in-app reminders and/or alerts which should not be disabled by the subject*

Make this explicit in Informed Consent

4) *Ensure data security*

- *The app should be pin protected*
- *Data should be encrypted to the latest standards*
- *Device should store no data locally after data-sending*
- *App cannot be remotely deleted, but data sending/receiving can be disabled remotely at trial termination*
- *In case of lost or stolen phone, data sending/receiving should also be disabled*

Timelines and costs

- *BYOD development timelines are longer than provisioned eCOA model*
- *Development costs are not necessarily lower*
- *Additional cost:*
 - *Patient reimbursement for data plan usage*
 - *Should not cover for the monthly plan (data usage is minimal)*
 - *Should cover for unplanned roaming costs, if needed*



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- *Additional issue:*
 - *If patient runs out of credit, loses phone, wants to stop using own phone: a provisioned device should be ready at site*



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- *Most EDC systems can now also offer BYOD capabilities, but with many limitations (no app but weblink, limited support, no provisioned backup)*



Help and Resources

- *ePRO Consortium: leading body in the field*
- *International meetings (SCDM, ISPOR)*
- *Webminars (usually vendors' sponsored)*
- *Users groups*
- *Data will slowly come in – publications and reports*



Good luck!

