Session 8:
Bring Your Own Device (BYOD) - Application in Clinical Trials

FIFTH ANNUAL
PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP

April 29 - 30, 2014 ■ Silver Spring, MD

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Session Participants

Moderator

- *J. Jason Lundy, PhD* – Director, ePRO Consortium, Critical Path Institute

Presenters and Panelists

- *Hannah O'Gorman, BSc* – ePRO Specialist, Exco InTouch
- *Tara Symonds, PhD* – Senior Director, Global Head PRO Center of Excellence, Pfizer
- *Jonathan Helfgott, MS* – Associate Director for Risk Science (Acting), Office of Scientific Investigations, CDER, FDA
- *Willie Muehlhausen, DVM* – Vice President, eCOA and Innovation, ICON

Background

- BYOD White Paper
  - Draft being reviewed by ePRO Consortium members
  - Available June 2014 at

    www.c-path.org/programs/epro/

- A series of ePRO webinars are being planned
  - Starting in June/July 2014
  - Up to six sessions, approximately 6 weeks apart
  - Will be recorded and posted on the website

Bring Your Own Device – PROs, CONs, and Challenges for Consideration

Hannah O'Gorman
Exco InTouch

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Agenda

- Introduction to BYOD
- Equivalence across platforms
- Access to a suitable device
- Getting software on all phones/devices
- Ownership and distractions
- Who pays for data
- Regulatory issues
- Security - physical and electronic
- Privacy and boundaries of acceptable data capture
- Summary

Introduction to BYOD

- Broadest definition:
  - allows participants in a clinical trial to use their own computer devices to access and respond to study related questionnaires.
- Arguments for BYOD for clinical trials:
  - Reduced costs for Sponsors
  - Reduced burden on patients
  - Reduced burden on study sites
  - Enables patient centric studies with limited site involvement

Equivalence across platforms

- A key issue against BYOD in clinical trials:
  - Equivalence of validated instruments across different platforms, in particular when they are being used to support of labelling claims.
  - Migration to a new platform counts as modification
    - needs to demonstrate that the instruments are capturing equivalent data. (FDA expects one to demonstrate that a “fit for purpose” instrument)

Equivalence across platforms

- Currently using mixed modes in a clinical study requires a qualitative equivalence study.
- This approach becomes impractical in the BYOD model.
- However, the only significant difference would potentially be screen size.

Access to a suitable device

- Make ownership of an appropriate device part of the inclusion criteria.
- Creates a bias sample ?
- Provide participants who do not have appropriate devices with stand-alone hardware.

Getting software on all phones/devices

- Accessing questionnaires
  - With web-enabled devices such as smart phone subjects could access the questionnaires on their web browser.
  - Use of an App
- Web-system or App needs to be compatible with operating systems and web browsers available.
  - Overcome by creating on the most widely used operating systems such as Android, iOS and Windows, and the most widely used Web-browsers such as Internet Explorer, Firefox, Safari and Chrome, so as to ensure greater access and compatibility.

Ownership and distractions

- Sponsor does not have control of the device:
- A multi-purpose device may have benefits as well.
- Storage becomes an issue with devices that are not under your control.
- Subject can delete the app at any time, even with captured and un-submitted data, at any time.
- Sponsors can’t force the subject to have notifications turned on.

Who pays for data

- Traditional eCOA studies where subjects are provided hardware by the sponsor:
  - Data sending costs is automatically covered by the sponsor with the included SIM on the device.
- BYOD model
  - Expectation is that the subject is using their own device and thus entail all the data sending costs on their contract.
  - Reasonable expectation to reimburse subject for these costs
  - Should be made clear in any stipend provided to the subject.

Regulatory issues

- Limiting factor in using the consumer grade devices may come from regulators.
- A question to be considered is - when does the app on a smartphone or tablet become a medical device?

Security - physical and electronic

- How secure is data on a device owned by the subject as opposed to a device that is provisioned?
  - Data storage
  - Data transfer
  - Subject's privacy

Privacy and boundaries of acceptable data capture

- Personal smartphones and tablets could also offer unique ways to feed information back to subjects. A number of questions arise:
  - How much data can (and should) be accessed when making clinical decisions?
  - Can data collected outside the trial be useful?
  - Who is responsible for the shared data?
  - If permission to view the data is revoked by the subject at some point, how does that affect the trial endpoints?
  - If permission is revoked, does the provider still have rights to the data from when it was shared?
  - Does more data equate to better care?

Summary

- There are a number of challenges that need to be considered with using BYOD in clinical trials.
- Hopefully this presentation has given the information that is required when weighing the pros and cons of a BYOD model for clinical trials.

Bring Your Own Device: An Industry Perspective

Tara Symonds
Pfizer Ltd

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Overview

- Why should we go BYOD?
- What are the risks?
- A proposal

Why should go BYOD?

- Increasing pressure to run cost-efficient clinical trials
  - Device costs are lowered
  - Study can be conducted more expeditiously
- Embracing ePRO data capture has been slow in some areas due to poor experiences when e-devices have been used:
  - Data connectivity
  - Patient training issues
  - Devices being embargoed

What are the risks of BYOD?

- Hard enough getting a PRO claim without increasing likelihood of failure by using multiple modalities?
- Equivalence testing across electronic devices will be necessary but for reasons other than appearance because we have sufficient evidence that generally modality doesn't matter?
  - Compliance when there are many other potential distractions on a device
  - Ability to build in alerts
- Other risks:
  - Recruitment bias
  - Some using BYOD, others using dedicated device
  - Reimbursement of patients
  - Security of the data

Proposal

- ePRO Consortium takes on responsibility for running pilot studies to look at the impact of some of these potential risks
  - Industry/e-vendors to sponsor
  - Work collaboratively with FDA
- Single sponsor studies – start piloting in your own companies?
  - Please present/publish so we all learn from the experience!

FDA CDER Perspective on Bring Your Own Device Models

Jonathan S. Helfgott
Associate Director for Risk Science (Acting)
Office of Scientific Investigations, CDER, FDA

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(Additional FDA) Disclaimer

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Overview

- Preparing for an FDA Inspection
- Emerging Trends
- Considerations when Using Mobile Applications to Support FDA Regulated Clinical Research

Preparing for an FDA Inspection

- All relevant records must be made available during an FDA site inspection
  - Ability to *reconstruct* clinical study from data at sites
    - What is the *process* for capturing Source/"Raw" Data?
  - Training/User Guides
  - UAT results at Sponsor/CRO sites (i.e.-print-screen shots)
- See BIMO Sponsor/CRO Compliance Program Guidance Manual (CPGM)
  - Part III Inspectional, Section M, Electronic Records & Electronic Signatures

Emerging Trends

- Increasing Use of Automation in Clinical Trials
  - EDC
  - ePRO
  - EHRs
  - CTMS/RTMS
  - Cameras
  - Motion Sensors

Considerations when Using Mobile Applications to Support FDA Regulated Clinical Investigations

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- BYOD vs. Custom Instruments
  - Demonstrating “Equivalence” Across Multiple Modalities
- “Fit For Purpose”
- Data Life Cycle
- Clinical Investigator Access to Data
- Role of Vendors & TTPs
- User Authentication
- Medical Devices
- Failure Modes
- Clinical Monitoring Considerations

References

- BIMO CPGM:
  - http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133777.htm
- Guidance on Electronic Source Data in Clinical Investigations:
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf
- Guidance on Computerized Systems Used in Clinical Investigations:
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf
- *Specific Concerns When Using Electronic Patient Reported Outcomes (ePRO)*:
  - *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071975.pdf*
- Guidance on Mobile Medical Applications:
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

Panel Discussion Topics

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- Is BYOD really more cost efficient? Where do the savings come from? Just device cost?
- How do we support patients when using their own device and they have issues with the app or website?
- How do we support sites when checking if the patient device is sufficiently equipped?
- How will we reimburse patients for their data cost?
- How will we address the measurement equivalence issue?

Questions?

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