



Bring Your Own Device (BYOD)

Moderated by: Cindy Howry

Presented by: Paul O'Donohoe and Jennifer Crager

Presenter Biographies

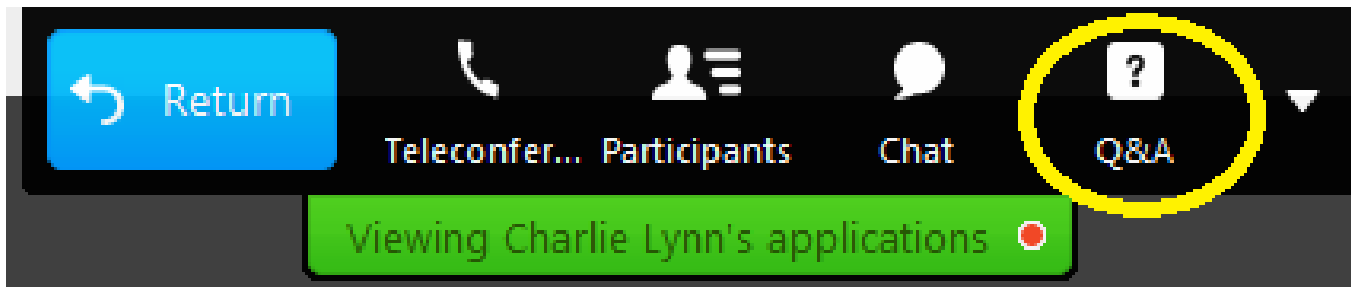


Paul O'Donohoe is Director of Health Outcomes at CRF Health and is based in their London office. He is responsible for developing the company's internal health outcomes expertise and supporting clients across the range of scientific issues that can arise during the course of a clinical trial. He is passionate about developing the field of eCOA through research and active involvement in industry consortia. Previously, Paul worked as a research psychologist at a child and adolescent mental health clinic based in Dublin, Ireland. He moved into the health consulting field with United BioSource Corporation where he worked across the health outcomes, health economics and health data capture groups. He has a MSc in Cognitive and Clinical Neuroscience.

Jennifer Crager has worked in the eCOA industry for over 13 years, in both the disease management and the clinical trial space. She has been a leader in eCOA and BYOD by working closely with clinical trial sponsors to implement this approach to data collection. She has a passion for creating systems that provide a robust experience for the end user resulting in high quality data. Her experience also includes oversight over customer support, quality assurance, training, and project management departments. She has created processes and training materials for each of these departments with a focus on continuous improvement. She has also been involved in the Baldrige Performance Excellence Framework through a successful program application as well as by contributing to the program's development as a reviewer.

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- When asking questions, be sure to select “All Panelists”

Critical Path Institute (C-Path)



- Established in 2005 by the University of Arizona and the FDA's Center for Drug Evaluation and Research (CDER)
- An independent, non-profit organization
- Dedicated to implementing FDA's *Critical Path Initiative* - a strategy for transforming the way FDA-regulated products are developed, evaluated, manufactured, and used
- Provides a neutral, pre-competitive venue for collaboration aimed at accelerated development of safe and effective medical products

ePRO Consortium



- The Critical Path Institute established the ePRO Consortium on April 1, 2011.

Mission:

“The mission of the ePRO Consortium is to advance the science of clinical trial endpoint assessment by collaboratively supporting and conducting research, designing and delivering educational opportunities, and developing and disseminating best practice recommendations for electronic collection of clinical outcome data.”

ePRO Consortium Members



Agenda

- The increasing significance of electronic collection of patient-reported outcome data
- The growing interest in Bring Your Own Device
- The different manifestations of BYOD
- The unique challenges of BYOD in clinical trials
- The path forward

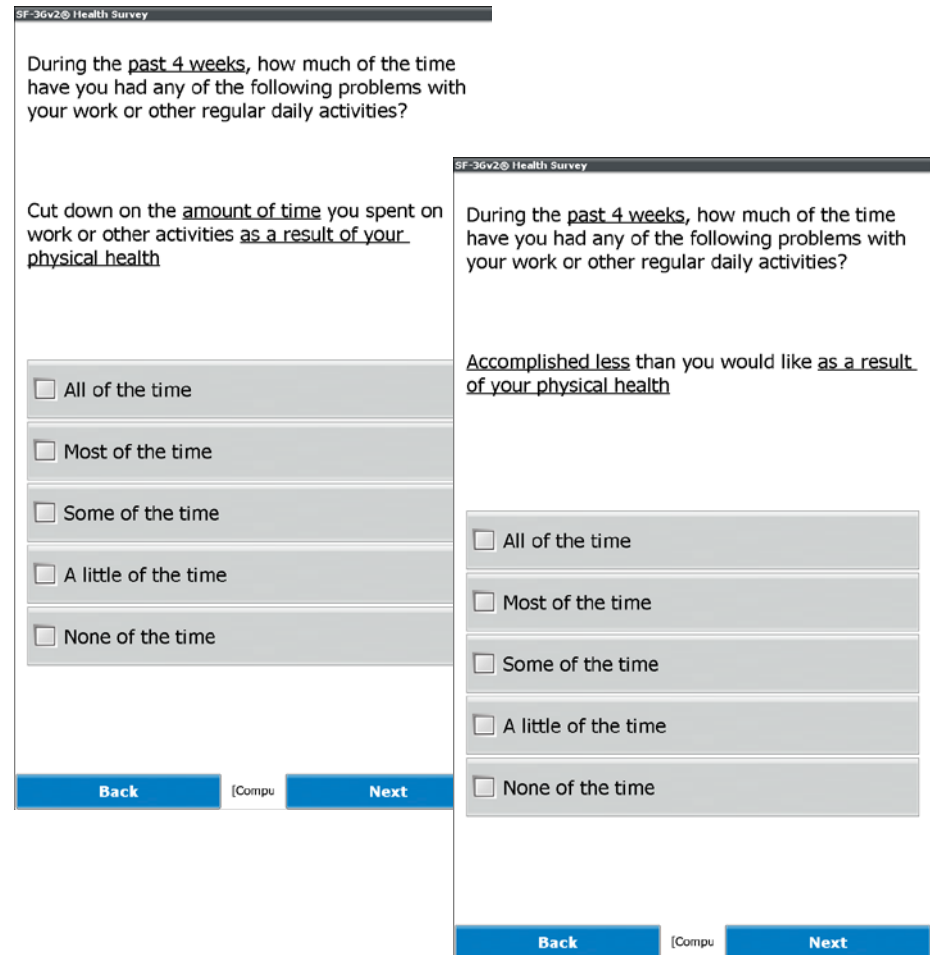
Electronic Clinical Outcome Assessments (eCOAs)

- eCOAs administer the traditionally paper-based COAs on an electronic platform



Electronic Patient-Reported Outcomes (ePROs)

- A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.
- FDA PRO Guidance



SF-36v2 Health Survey

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities?

Cut down on the amount of time you spent on work or other activities as a result of your physical health

All of the time

Most of the time

Some of the time

A little of the time

None of the time

Back [Compu] Next

SF-36v2 Health Survey

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities?

Accomplished less than you would like as a result of your physical health

All of the time

Most of the time

Some of the time

A little of the time

None of the time

Back [Compu] Next

Why is ePRO becoming more mainstream?



- More accurate and complete data
- Improved protocol compliance
- Avoidance of secondary data entry errors
- Easier implementation of skip patterns
- Less administrative burden
- High respondent acceptance
- Reduced sample size requirements and potential cost savings

Bring Your Own Device (BYOD)



- Rather than provisioning hardware to participants in a clinical trial, we take advantage of their own Internet-connected device
- The current industry focus is implementation of PRO measures on smartphones

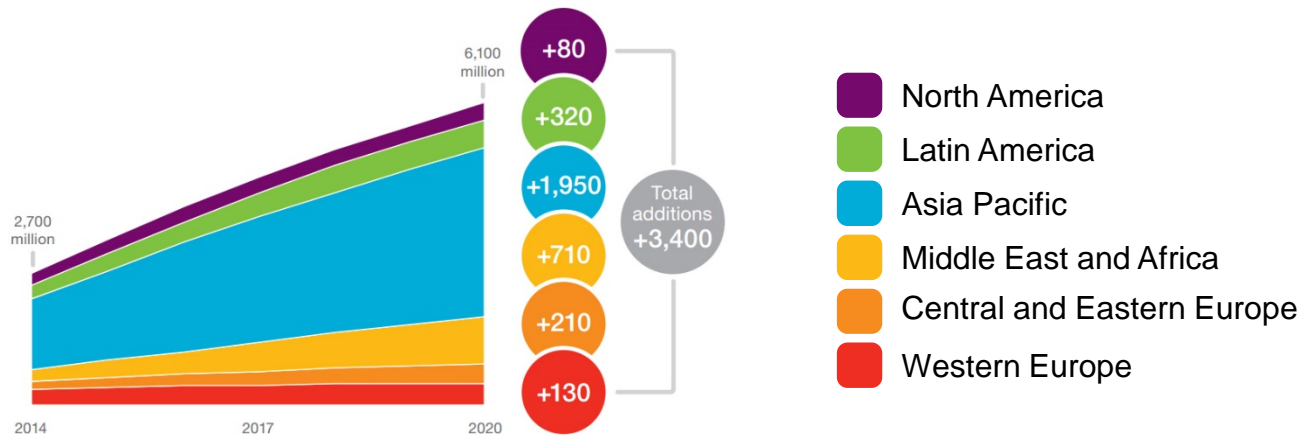
Interest in BYOD driven by...

- Perceived reduced hardware cost
 - Hardware typically makes up 25% of the cost of an eCOA study
- Perceived reduction in patient burden
 - Using the device they interact with daily
 - Participant more likely to “keep up” with personal smartphone
- Perceived reduction in burden on clinical staff, if appropriate support documents are in place.

But largely down to smartphone saturation

- By 2020...
 - More than 6 billion smartphone subscriptions
 - 90% of all broadband subscriptions will be for mobile broadband

Smartphone subscriptions per region 2014–2020



Smartphones Saturation

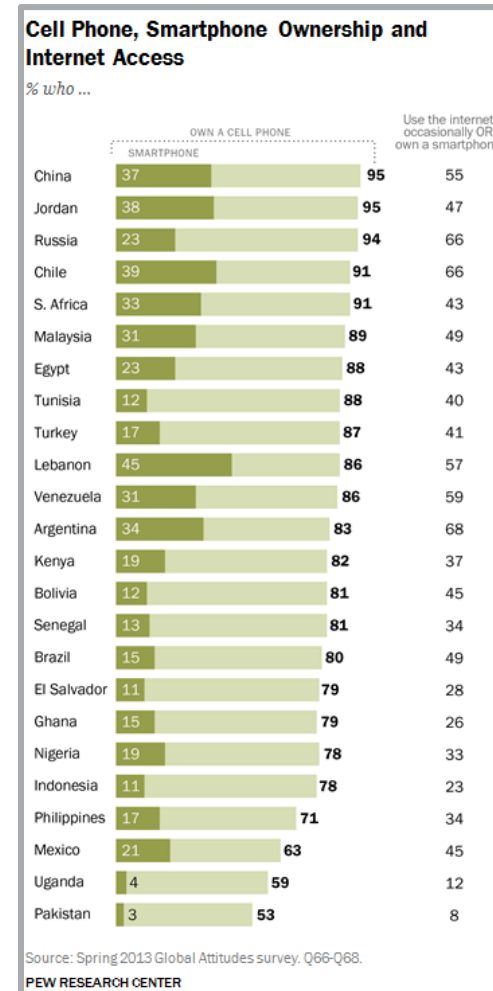
Smartphone Ownership Highest Among Young Adults, Those With High Income/Education Levels

% of U.S. adults in each group who own a smartphone

All adults	64%
Male	66
Female	63
18-29	85
30-49	79
50-64	54
65+	27
White, non-Hispanic	61
Black, non-Hispanic	70
Hispanic	71
HS grad or less	52
Some college	69
College+	78
Less than \$30,000/yr	50
\$30,000-\$49,999	71
\$50,000-\$74,999	72
\$75,000 or more	84
Urban	68
Suburban	66
Rural	52

Combined analysis of Pew Research Center surveys conducted December 4-7 and 18-21, 2014.

PEW RESEARCH CENTER



Types of BYOD

- **Two types of applications:**

Native: an application specifically designed to run on a device's operating system. It typically needs to be adapted/adjusted for different devices.

Web: an application in which all or some parts of the software are downloaded from the Web each time it is run. It can usually be accessed from all Web-capable mobile devices.

Native App

- Users download app from online app store or app marketplace like iTunes Store or Google Play Store
- Data can be entered without having Internet access
- Have a direct line to the OS and hardware so they can run faster and more secure but they have to run on their targeted platforms (e.g. iOS, Android or Windows phone)
- **Example:** App to record exercise where all data can be entered without Internet

Web App

- Internet-enabled app accessible by mobile device Web browser
- Does not need to be downloaded
- Internet access needed to enter data
- HTML5 apps are cross-platform mobile applications, written using the standard HTML5, JavaScript and CSS
- They run on multiple devices since they mostly run in Web browsers
- **Example:** Web app to complete exercise survey. When the website is accessed from mobile device, the app adjusts in size and design for the device.

Hybrid App

- Users download app from online app store or app marketplace
- Some functions within the app require Internet access
- Some functions do not require Internet access for use
- **Example:** Downloadable app to record exercise with function that requires Internet access to retrieve past exercise records

App Features

Feature	Native	Web	Hybrid
Download from App Store	Yes	No	Yes
Data entry without Internet	Yes	No	Some
System limited to target platform	Yes	No	Yes
Accessed through Web browser	No	Yes	Some
Runs on multiple devices	Yes	Yes	Yes

App Technologies

What requirements/features are necessary in App?	Native	Web
Offline Access	Yes	No
Update/Change App without new download	No	Yes
Familiarity	High	Low
Distribution	App Store	Web
Camera	Yes	No
Notifications	Yes	Yes
Provisioned Devices	Yes	Yes

However...

- No widespread uptake in Phase II, III and IV clinical trials.
Why?
- **Main reasons:**
 - Measurement equivalence
 - Logistical concerns
 - Patient privacy and security
 - Technologies, skills, and processes required to build and deploy apps
 - Support of deployed apps
 - Reimbursement of personal device use

Measurement Equivalence

- Best practice has dictated that, in certain situations, one should demonstrate equivalence between paper and electronic versions of patient-reported outcome measures

Table I PRO to ePRO measurement equivalence: instrument modification and supporting evidence

Level of modification	Rationale	Examples	Level of evidence
Minor	The modification can be justified on the basis of logic and/or existing literature. No change in content or meaning.	<ol style="list-style-type: none"> 1) Nonsubstantive changes in instructions (e.g., from circling the response to touching the response on a screen). 2) Minor changes in format (e.g., one item per screen rather than multiple items on a page). 	Cognitive debriefing Usability testing
Moderate	Based on the current empirical literature, the modification cannot be justified as minor. May change content or meaning.	<ol style="list-style-type: none"> 1) Changes in item wording or more significant changes in presentation that might alter interpretability. 2) Change in mode of administration involving different cognitive processes (e.g., paper [visual] to IVR [aural]). 	Equivalence testing Usability testing
Substantial	There is no existing empirical support for the equivalence of the modification and the modification clearly changes content or meaning	<ol style="list-style-type: none"> 1) Substantial changes in item response options 2) Substantial changes in item wording 	Full psychometric testing Usability testing

Adapted from Shields et al. [62].

Equivalence complicated in BYOD

- Facing a situation with possibly tens if not hundreds of different devices in a single study
- We can't test all possible devices or screen sizes

Equivalence testing to date?

Abstract

OBJECTIVE:

To conduct a systematic review and meta-analysis of the equivalence between electronic and paper administration of patient reported outcome measures (PROMs) in studies conducted subsequent to those included in Gwaltney et al's 2008 review.

METHODS:

A systematic literature review of PROM equivalence studies conducted between 2007 and 2013 identified 1,997 records from which 72 studies met pre-defined inclusion/exclusion criteria. PRO data from each study were extracted, in terms of both correlation coefficients (ICCs, Spearman and Pearson correlations, Kappa statistics) and mean differences (standardized by the standard deviation, SD, and the response scale range). Pooled estimates of correlation and mean difference were estimated. The modifying effects of mode of administration, year of publication, study design, time interval between administrations, mean age of participants and publication type were examined.

RESULTS:

Four hundred thirty-five individual correlations were extracted, these correlations being highly variable ($I^2 = 93.8$) but showing generally good equivalence, with ICCs ranging from 0.65 to 0.99 and the pooled correlation coefficient being 0.88 (95% CI 0.87 to 0.88). Standardised mean differences for 307 studies were small and less variable ($I^2 = 33.5$) with a pooled standardised mean difference of 0.037 (95% CI 0.031 to 0.042). Average administration mode/platform-specific correlations from 56 studies (61 estimates) had a pooled estimate of 0.88 (95% CI 0.86 to 0.90) and were still highly variable ($I^2 = 92.1$). Similarly, average platform-specific ICCs from 39 studies (42 estimates) had a pooled estimate of 0.90 (95% CI 0.88 to 0.92) with an I^2 of 91.5. After excluding 20 studies with outlying correlation coefficients ($\geq 3SD$ from the mean), the I^2 was 54.4, with the equivalence still high, the overall pooled correlation coefficient being 0.88 (95% CI 0.87 to 0.88). Agreement was found to be greater in more recent studies ($p < 0.001$), in randomized studies compared with non-randomised studies ($p < 0.001$), in studies with a shorter interval (< 1 day) ($p < 0.001$), and in respondents of mean age 28 to 55 compared with those either younger or older ($p < 0.001$). In terms of mode/platform, paper vs Interactive Voice Response System (IVRS) comparisons had the lowest pooled agreement and paper vs tablet/touch screen the highest ($p < 0.001$).

Explore a range of screen sizes?



Logistical Concerns

- Cannot exclude a patient from a clinical trial because they do not own an expensive piece of hardware
 - Distractions when participants use personal phones
 - Patients can silence notifications and/or move to another page/screen
 - Devices are not locked down; therefore, can accidentally delete app
 - Compliance
 - Assumption is compliance will increase
 - Already at 90%, not much room to improve

Patient Privacy and Security

- To download an app or receive notifications via email or text, patients must provide their personal contact information (such as email/phone number)

Technologies, skills, and processes required to build and deploy apps



- To build and deploy mobile apps, eCOA vendors must have the development skill set to build a mobile app
- If a native app is deployed it must reside in an app store which requires set up
 - Time needed to develop, submit and get accepted

Support

- Patients using their own devices may run into many support issues where vendor's support team must be able to assist
 - Updating app
 - App impacts on other functionality on phone
 - Moving to a new phone

Reimbursement

- If patients are using their own devices, their device's data plan may be affected where fees are incurred each month.

The Path Forward

Challenges/Consideration



- **Measurement Equivalence:**
 - Explored as part of a clinical trial?
 - C-Path exploring potential study
- **Logistical Concerns:**
 - Provision smartphones for those without, will depend on country and demographics
 - Create checklist for study site to verify appropriate smartphone
- **Patient Privacy and Security**
 - Add to Informed Consent form acknowledgement of release of email/telephone number for access to app store, messaging, and alerts

The Path Forward

Challenges/Consideration



- **Technologies, skills, and processes:**
 - Choose the appropriate application type (native or web) for the study
 - Use more widely accepted OS like Android and iOS (Blackberry and Windows Mobile are not recommended)
 - Development and validation teams to include skill set for mobile development and testing
- **Customer support**
 - Customer support agents to have many devices available for knowledge and availability when users require help
 - Customer support agents to have familiarity with IT support for web app
- **Reimbursement:**
 - Add stipend for use of personal phone

Wrap-up

- Bring your own device is an important part of the future of ePRO, and eCOA more generally
- While unique challenges exist for BYOD in the clinical trial space, none are insurmountable
- Driving the wide-spread acceptance of BYOD will be a community effort
- Can't lose sight of what's best for the patient

Useful References

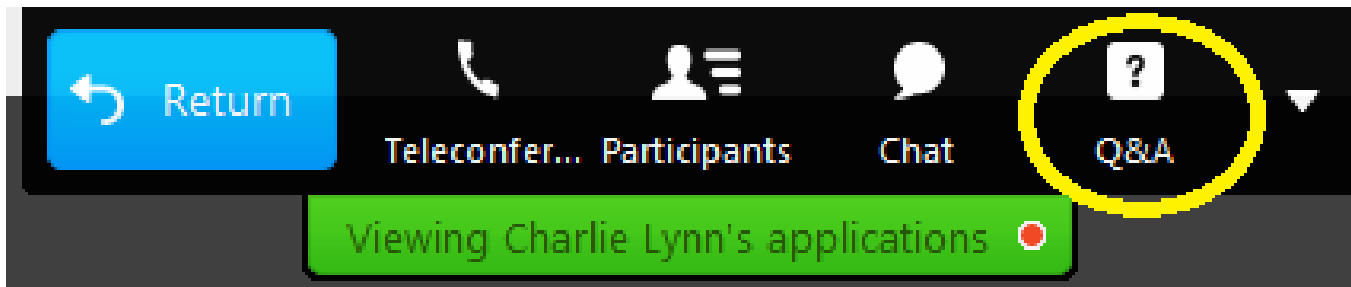
- Gwaltney C, Coons SJ, O'Donohoe P, O'Gorman H, Denomey M, Howry C, Ross J. "Bring Your Own Device" (BYOD): The Future of Field-Based Patient-Reported Outcome Data Collection in Clinical Trials? *Therapeutic Innovation & Regulatory Science*. 2015;49:783-791.
- Muehlhausen W, Doll H, Quadri N, Fordham B, O'Donohoe P, Dogar N, Wild D. Equivalence of electronic and paper administration of patient-reported outcome measures: a systematic review and meta-analysis of studies conducted between 2007 and 2013. *Health and Quality of Life Outcomes*. 2015;13:167.

Questions?

<http://c-path.org/programs/epro>

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**Thank you for attending this
ePRO Consortium Webinar
BYOD**