Bring Your Own Device (BYOD) Approaches To The Collection Of Electronic Patient – Reported Outcome Data

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Apple Health

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“Talking Progress” for Major Depressive Disorder

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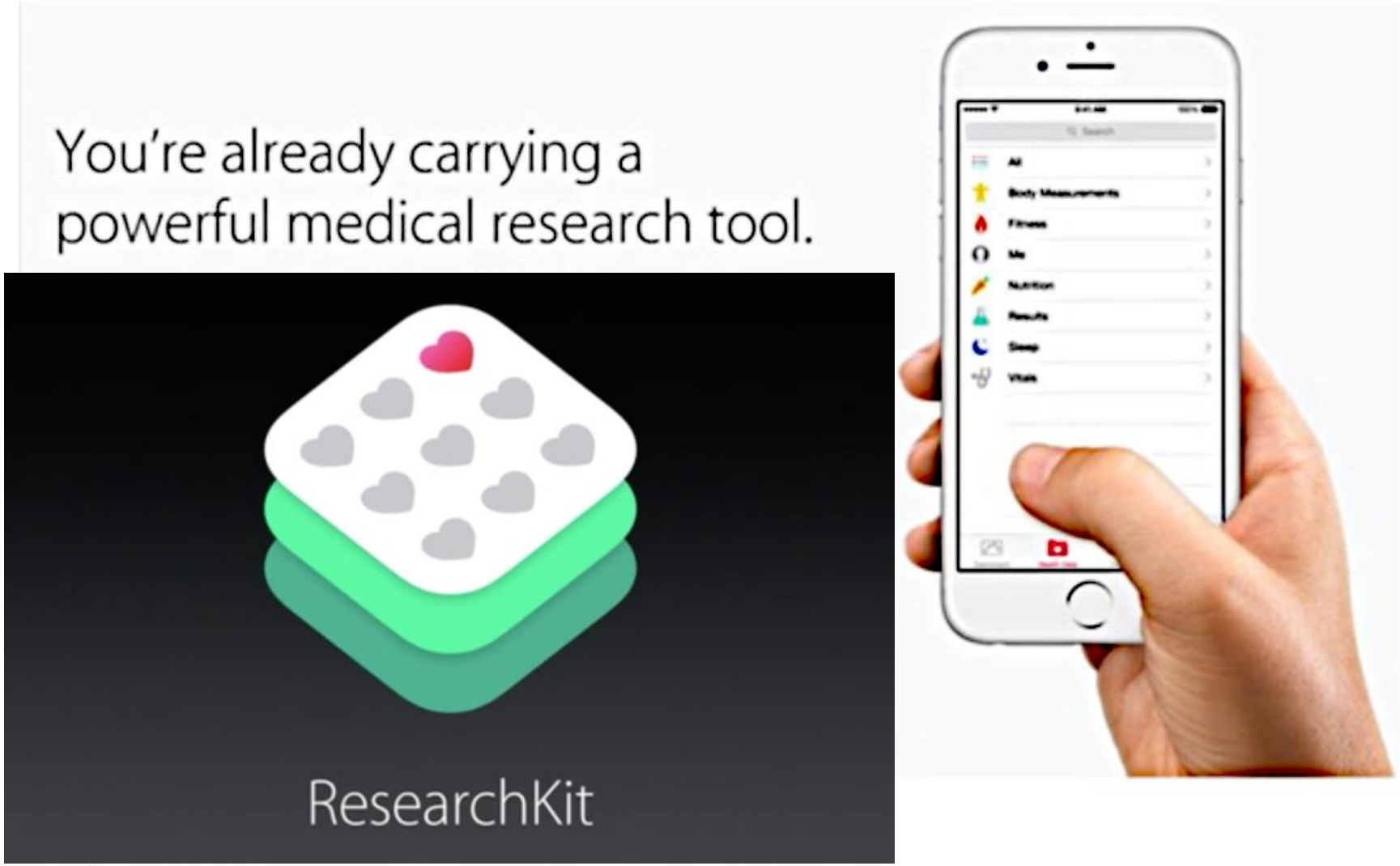
Apple ResearchKit



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What Defines a BYOD Approach

- Dedicated device model
  - Patients use devices provisioned by sponsors and sites
- BYOD model
  - Patients' use their own computers/telecommunications devices
- ePRO assessments are delivered through web-based or app-based program
- Patients can access the assessments on different types of platforms
  - Different categories of devices (e.g., smartphones, tablets) and different models within a single category (e.g., Apple, Android)

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Objectives for Today's Session

- Discuss the current state and future directions of BYOD in clinical research
- Strengths of BYOD Approaches
  - Chris Watson, Exco InTouch
- Challenges Associated with BYOD Approaches
  - Karl McEvoy, CRF Health
- Open Scientific, Regulatory, and Operational Questions Regarding BYOD
  - Stephen Joel Coons, Ph.D., PRO Consortium, Critical Path Institute
- Interactive discussion/Q&A

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Strengths Of BYOD Approaches

Christopher D Watson, PhD
Product Manager
Exco InTouch Ltd

exco intouch

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Bring Your Own Device (BYOD) in Clinical Trials

- Allows clinical trial participants to use their own computer devices to access and respond to study related questionnaires
- Benefits of ePRO but on a patients own device
- What is covered by BYOD?
  - Mobile phones
    - Feature Phone
    - Smartphone
  - Tablet PC
  - Computer
  - Other connected devices

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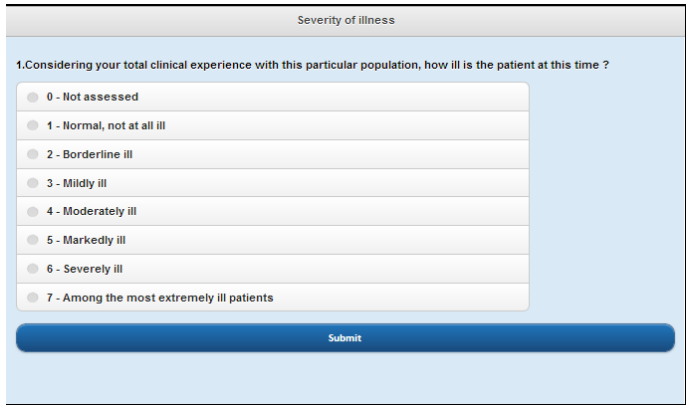
How Should BYOD be Implemented?

- BYOD and the Provisioned model use the same eCOA app

NATIVE APP

WEB



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How Should BYOD be Implemented?

NATIVE APP

- Enhances user familiarity
- Enables device integration

BUT

- Develop for each operating system
- Identify which OS in use

WEB

- Simple questionnaires
- Broad populations
- Just code once

BUT

- Test across browsers
- Can’t integrate devices
- Becoming outdated

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Benefits of BYOD Approach

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Patient Engagement

How Does BYOD Support Engagement?

- Web Diaries can be completed on any web enabled device
- As patients use their own devices, which are often carried around with them, and checked regularly, sponsors are able to provide information and motivation alongside data capture to help keep patients engaged
- eCOA data entry is still protected and confirmed by PIN
- Patient Choice - Potential for eCOA collection on multiple patient devices
- Can configure the data uploads to use WIFI as a primary preference to reduce patient costs
- Develop reminder functionality from within the eCOA app

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Familiarity

How Does BYOD affect The End User?

- 2.7bn Smartphone devices (2014)
- Patients use their own device(s) meaning they understand their devices and interface
  - BYOD uses the OS they are most familiar with
  - Enables the use of Native controls
- Build eCOA services to be equivalent across OS

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Cost Effectiveness

What is the Cost of BYOD?

- Removes cost of provisioning devices
  - Full provisioning can equate to 33% of total eCOA budget
- Logistics of device management
  - No need to send devices to patients
    - no need to manage import/export regulations
    - removes burden of provisioning and device management

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Maintenance

What Impact Does BYOD Have On Maintenance?

- BYOD device issue rates are similar to those of provisioned services (<1%)
- Patients use their devices for other activities so keep them charged and in serviceable condition
- Can easily maintain App and data integrity
  - set up a eCOA App recovery and disablement functionality
- Can enable user to upgrade their device

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Site Burden

- How Does BYOD Reduced Burden On Study Sites?

  - Facilitates Patient Focussed studies with limited site involvement
  - BYOD does not have to be an Inclusion Criteria
  - Can have a Partial provisioning model for eCOA devices
    - Provisioned devices need account for around 20% of total eCOA devices
  - BYOD can impact Patient Support levels:
    - Range of devices that can be used changes the support levels
    - Recommend setting up online patient support tools
    - Vendors Should extend 24*7 support desks to handle potential BYOD issues

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Challenges and Potential Limitations of a BYOD Approach

Karl J. McEvoy PhD

Manager, Health Outcomes

CRF Health

C R F SM HEALTH
REAL PATIENT DATA 24/7

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Bring Your Own Device

- Traditional studies utilising electronic Clinical Outcome Assessments (eCOA) provides patients with the hardware they need to input study data.

- “Bring Your Own Device” means allowing participants in a clinical trial to use their own computer devices to access and respond to study related questionnaires
  - Smart phone
  - Laptop
  - Desktop PC
  - Internet enabled TV etc…

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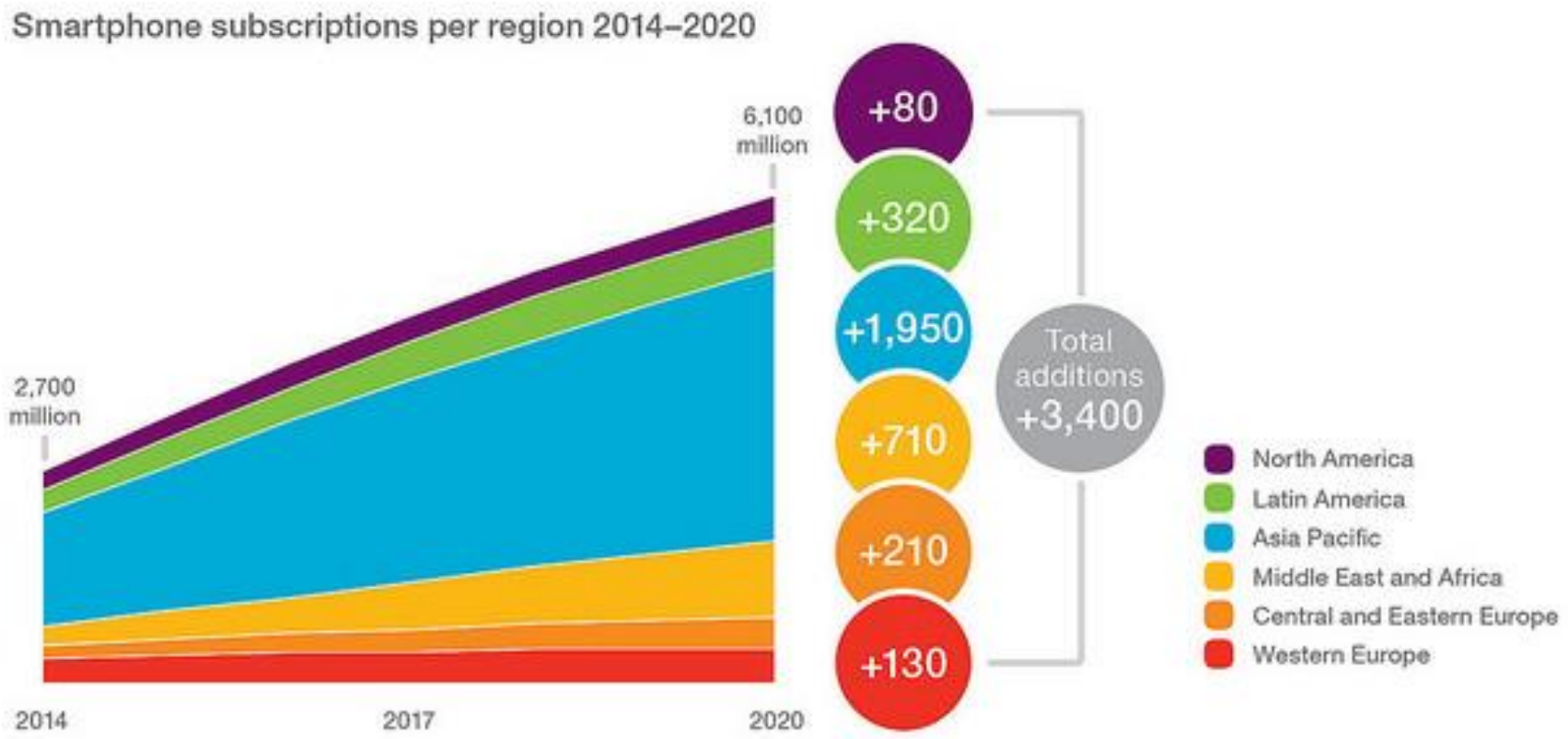
Growth in access

By **2020…**

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



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BYOD – All the benefits of eCOA, PLUS

- Reduced costs for Sponsors as study specific hardware does not need to be provided and distributed.
- Reduced burden on patients as they can use the hardware they are most familiar with and have access to in their normal day to day.
- Reduced burden on study sites as they do not need to manage devices.
- Streamlined, patient centric process for giving access to questionnaires.

Clinical Trials: Solved!??

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Challenges

Does the population have access to smart phones?

Adequate specifications?

Variation within populations?

Age

Wealth

Access to suitable device

Limitations

How to avoid bias?

Provisioning of devices – how much?

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Challenges

WiFi/Cellular connection at site

Easy and Intuitive installation

How to troubleshoot multiple device types?

Smartphone specifications

Getting software on all devices

Limitations

Sites with connectivity problems

No staff to guide patient

OR
staff expected to be familiar with huge range of devices?

Is personal data private?

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REAL PATIENT DATA 24/7

Challenges

Providing replacement device with minimal data loss

Both devices sent data...but it was different

What do we provision?

Android?

Apple?

Windows?

Blackberry?

Lost/duplicated devices?

Limitations

Loss of devices?

Providing replacement without data loss

What if a patient is in a contract?

Device constantly online?

Do we take back the device after?

Sim card size?

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Challenges

Patient has low data allowance

Tied to a contract

Traveling? Roaming charges?

Under paid?

Over paid?

Who pays for data?

Limitations

Can't alter the terms

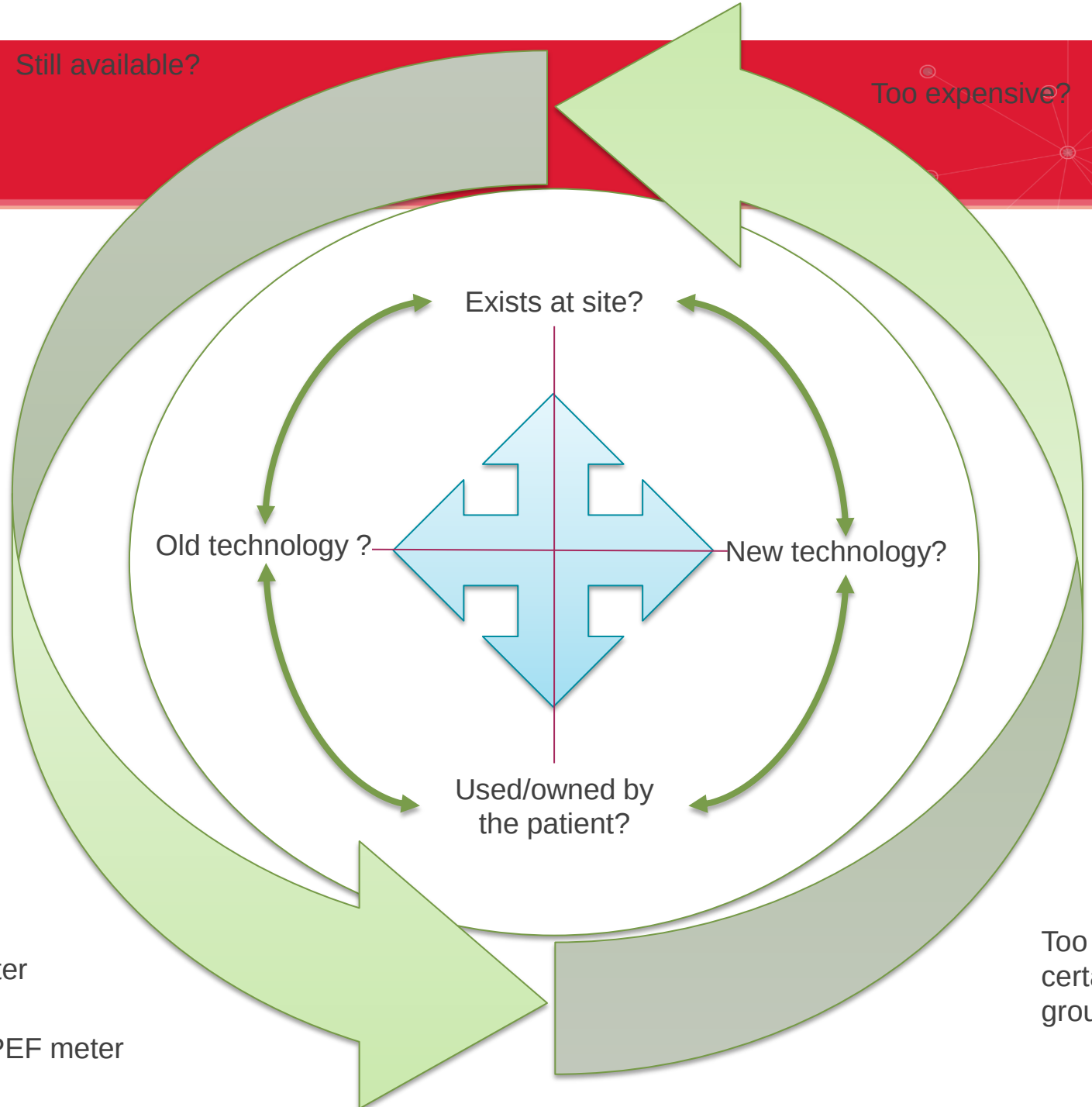
Tied to a contract

Network doesn't allow!

Traveling? Roaming charges?

DIA C-R-F HEALTH REAL PATIENT DATA 24/7

Integration with other devices and data sources


Still available?
Too old to integrate?
Too expensive?
Tried and tested? -Regulators?
Secure?
Will it last?
Compatibility?
Exists at site?
Old technology ?
New technology?
Used/owned by the patient?
Are all devices equal? (Calibration)
Early adopter?
Too trendy for certain patient groups?
Glucose meter
PEF meter

Challenges

Regulators?

Sponsors?

Instrument authors?

Equivalence of questionnaires across platforms and devices

Limitations

Regulators?

Sponsors?

Instrument authors?

Open Scientific, Regulatory, and Operational Questions Regarding BYOD

Stephen Joel Coons, PhD
Executive Director
Patient-Reported Outcome Consortium
Critical Path Institute

PRO CONSORTIUM
CRITICAL PATH INSTITUTE

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Scientific Issues

- **Is there potential selection bias?**
  - Will a hybrid approach (BYOD plus provisioned devices) assure appropriate representativeness?
- **How will data quality be impacted?**
  - Will subjects be at least as compliant with data entry protocols as with a fully provisioned trials?
- **Can the difference in screen size introduce response bias?**

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Regulatory Issues

- **Is the risk of data breaches higher with BYOD than a provisioned ePRO device model?**
- **In the hybrid model, will the endpoint data be poolable from subjects that use a provisioned device and subjects that use their own device?**
- **Will compliance with requirements for electronic records (e.g., electronic signatures, data access, data reporting, data retention for audit and inspection) be impacted in any way?**

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Operational Issues

- **What proportion of subjects participating in trials will have suitable/acceptable devices?**
- **How does study duration impact the decision to include BYOD as an option?**
- **Should subjects be able to download the app to multiple devices (e.g., smartphone and tablet)?**
  - If so, what are the implications?

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Operational Issues (continued)

- **How will the costs associated with data transmission be managed and reimbursed?**
- **What level of helpdesk support will be needed due to the multiple device types and operating systems that may be used by subjects?**

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Conclusions

Although there are issues that remain unresolved, the promise of BYOD opens a new and exciting chapter in the evolution of ePRO data collection.

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