Optimizing Technology Selection for Remote Outcomes Data Capture

Aaron Coleman, Fitabase
John Hubbard, Genstar Capital
Barry Peterson, Independent Consultant
Linda Ricci, FDA, CDRH
Drew Schiller, Validic
Jeremy Wyatt, ActiGraph
Session I Relevant Materials

- Watch Session I – Device Selection from the Mobile Technologies Event
- Technology Selection handout
- CTTI recommendations and resources:
  - Recommendations
  - Related Resources
    - Mobile Technology Selection Framework
  - Related Case Studies
    - Verification & Validation Processes in Practice
    - Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture

Glossary: Definition Technical & Regulatory Terms
Overview

Mobile technology offers a powerful tool to improve the quality and efficiency of clinical trials.

Potential benefits include:

- Capturing previously unavailable, objective, “real world” data from patients during their daily lives – “patients in the wild”
- Reduced barriers to participation, supports virtual trials, and
- Potentially, lowers the costs associated with conducting clinical trials.

However, there are critical considerations that must be considered when mobile technologies are incorporated in clinical trials....
Considerations and Important Questions on the Selection of Mobile Technologies

- Start with the end in mind: What type of data do I need to collect and what are my primary and secondary endpoints?

- How will mobile technologies improve the data collection strategy, regulatory requirements and quality?

- Potential pitfalls:
  - Making a selection where you can’t access the data you need, or selecting a technology that doesn’t actually capture the data you need.

- Technology selection should come only after you know what you want to measure - Never start with a technology and make it a hammer in search of a nail.
This Session will…

- Simulate a process whereby a project team evaluates the need for mobile technology to support their data collection for a new Phase II clinical trial in COPD.

- The team members are multidisciplinary and I will serve as the Clinical Lead (moderator) for the program.

Team, I called you together today to…
The “Vital Meter”

**Measures:**
- Activity
- Steps
- Heart rate
- Systemic blood pressure
- Respiratory rate
- Calorie expenditure
- Sleep time
- Sleep stage
- Depression
- Body temperature
- Arterial oxygenation
- Anxiety level

- Provides all data to a mobile phone
- Battery life depends on number of endpoints selected
- Recharges in 4 hours
- FDA 510K cleared

*This device will do half the work of your clinical trial!*
Will this technology work for us?

Can we begin with the end in mind and consider what we’re actually trying to measure?

Mobile technology selection should be driven by the:

- Technical performance specifications and functional characteristics needed to measure the outcome assessment of interest,
- Study needs (i.e., constraints and nuances of the central scientific question), and
- Needs and preferences of study participants.

This is a multi-factorial decision that should be tailored to each trial.

Collaboration is key—sponsors should engage both technology manufacturers and patients as partners.
How will we even know what to ask the technology manufacturers?

CTTI has developed a framework of specifications for sponsors to consider:

- Technical Performance Specifications
- Data Management Specifications
- Safety Specifications
- Human Factors Specifications
- Operational Specifications
- Non-Performance Specifications
- Measurement Performance
- Mobile Technology Communication & Data Transfer
- Data Access

All of the specifications should be considered together, with their importance weighted relative to the data they are collecting, the patient population and the risk profile of the sponsor.
What about the regulatory status of the technology?

*This device will do half the work of your clinical trial!*

FDA 510K cleared
Verification and Validation

Verification – an engineering assessment
- Assessment of the basic sensors of the devices with respect to:
  - Accuracy
  - Precision
  - Consistency across time, devices and environmental conditions
  - Lack of errors in firmware that processes the sensor data
- Usually compared to a physical “bench” standard
- Variances in sensor measurements are usually very small (<1%)
- Verification data should be provided by device manufacturer/vendor

Validation – a biological assessment
- Assessment of the accuracy and precision of the biological endpoints derived from the sensor data
  - —usually against an independent measurement standard.
- Variances in endpoint measurements may be large (5-15%) but may still be useful (statistical question)
- Validation data can be provided by:
  - device manufacturer
  - from an independent study by a user, or
  - from a new study for a specific patient population
Examples of “V and V” for the “Vital Meter”

Table 1: Verification and Validation

<table>
<thead>
<tr>
<th>Description</th>
<th>VERIFICATION</th>
<th>VALIDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Data</td>
<td>Processed Data</td>
<td>Outcome Assessment</td>
</tr>
<tr>
<td>Output from physical sensor</td>
<td>→ Output from mobile technology firmware</td>
<td>→ Output from analysis algorithm</td>
</tr>
<tr>
<td>Example: Accelerometry</td>
<td>Acceleration (m/s²)</td>
<td>→ Activity counts (n)</td>
</tr>
<tr>
<td>Example: ECG</td>
<td>Electrical potential (mv)</td>
<td>→ Heart rate (beats/min)</td>
</tr>
</tbody>
</table>

The pNN50 statistic is a time domain measure of heart rate variability (HRV).
Summary

Verification

Did I make the device “right” (properly)?
- *i.e. Is the physical device doing what it was designed to do?*

Validation

Did I make the right device?
- *i.e. Are the outputs/endpoints of the device useful for my study objectives and does it have sufficient accuracy/precision in my study population?*
A Los Angeles hospital is using Fitbits to help patients go home sooner.
Feasibility

1. Device & System Setup
2. Charging
3. Syncing
4. Patient Wear & Comfort
5. Patient Use & Understanding
6. Data Access
7. Data Portability Across Systems
8. Data Availability for Analysis
9. System Use by Nurses / Physicians
10. Patient Mobility Troubleshooting
Recommendations in Summary

- Know what you want to measure before selecting the mobile technology.
- Mobile technology selection should be specification-driven and collaborative.
- CTTI recommends that a technology’s regulatory status not be the sole driver in sponsors’ decisions about which mobile technology to use.
- The appropriateness of the selected mobile technology should be justified through verification and validation processes.
- Feasibility studies conducted before full implementation in a large study reduce risk.
Supporting Resources

- Mobile technology selection framework
- Two case studies:
  1. Verification and Validation Processes in Practice
  2. Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture
- Glossary defining key terms, including verification and validation
THANK YOU.

Barry Peterson  barry.t.peterson@gmail.com
Drew Schiller   drew.schiller@validic.com
Linda Ricci     Linda.Ricci@fda.hhs.gov
John Hubbard    JHx2SNOWY@aol.com
Jeremy Wyatt    jeremy.wyatt@actigraphcorp.com
Aaron Coleman   aaron@fitabase.com

https://www.ctti-clinicaltrials.org/projects/mobile-technologies