Mobile in Clinical Trials: Developing Novel Endpoints for use in Clinical Trials

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To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

Public-Private Partnership
Co-Founded by FDA and Duke
involving all stakeholders
70+ members
CTTI Membership

*Version: September 26, 2016*
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Mobile Clinical Trials (MCT) Program

PURPOSE:
Develop evidence-based recommendations that affect the widespread adoption and use of mobile technology in clinical trials

ANTICIPATED IMPACT:
Increase the number of clinical trials appropriately leveraging mobile technology

4 PROJECTS

- Legal & Regulatory Issues
- Novel Endpoints
- Mobile Devices
- Stakeholder Perceptions

*Scope: FDA-regulated clinical trials after the time of initial research volunteer consent
Developing Novel Endpoints Generated by Mobile Technology for Use in Clinical Trials

**Purpose:**
- This project aims to issue recommendations that clarify the pathway for developing novel endpoints*, generated using mobile technology, for use in clinical trials.

**Objective:**
- Describe best practices for developing novel endpoints, generated using mobile technology, for use in clinical trials.

* We have defined novel endpoints as either 1) new endpoints that are not currently used, or 2) existing endpoints that can now be measured in new and possibly better ways using mobile technology.
## Project Team

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<th>Team Leaders</th>
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<th>CTTI Project Manager</th>
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<tr>
<td>Lauren Bataille, MJFF</td>
<td>Stephen Friend, Apple&lt;br&gt;Ashish Naryan, Northwell&lt;br&gt;Elektra Papodopoulous, FDA</td>
<td>Jen Goldsack, CTTI</td>
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<td>Rob DiCicco, GSK</td>
<td>Theresa Strong, FPWR&lt;br&gt;Komathi Stem, ReThynk Consulting&lt;br&gt;Ken Skodacek, FDA</td>
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<td>Cheryl Grandinetti, FDA</td>
<td>Nirav 'Rav' Sheth, MC10&lt;br&gt;Andrew Trister, Sage Bionetworks&lt;br&gt;Marc Walton, Janssen</td>
<td>CTTI Executive Committee Champion</td>
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<td>Will Herrington, Oxford</td>
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<td>John Alexander, Duke</td>
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Our Approach

Determine Information Needed from Existing Case Studies (Extraction Tool)

Determine Search Terms for Identifying Case Studies

Create a "long list" of possible novel endpoints that we could write use cases for

Determine criteria and weightings to use to select endpoints for use cases

"Quick Search" of case studies to identify which novel endpoints have already been studied to some degree

Systematic Review of Existing Case Studies

Publication of Systematic Review

Use Case Selection (using Pugh Matrix tool)

Publication of conceptual framework for selecting novel endpoints for inclusion in clinical studies

Use Case #1

Use Case #2

Use Case #3

Use Case #4

Recommendations

Publication(s) of Use Cases

USE CASES:
1. Physical activity and gait / Parkinson’s disease / accelerometer
2. Physical activity / heart failure / accelerometer
3. Blood sugar level / diabetes / CGM
4. Physical activity / muscular dystrophy / accelerometer
Meeting Objectives

Identify how to develop novel endpoints for use in clinical trials by writing the following use cases:

- Physical activity level and gait, measured using an accelerometer, as an endpoint for Parkinson's disease
- Physical activity level, measured using an accelerometer, as an endpoint for heart failure
- Blood sugar level, measured using a wearable continuous glucose monitor, as an endpoint for diabetes
- Physical activity level, measured using an accelerometer, as an endpoint for muscular dystrophy
Thank you.

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