Mobile in Clinical Trials: Potential Research Participant Perspectives
Agenda

Brief Background and Methods

Presentation of Survey Data (brief Q&A to follow each)
- Willingness to Participate in Mobile Trials (Angie Botto-van Bemden)
- Attributes of Mobile Devices (Les Jordan)
- Data Privacy & Access, Communications Preferences (Cindy Geoghegan)

Open Discussion
The MCT Stakeholder Perceptions Project Team

- Cindy Geoghegan, Patient and Partners
- Steve Morin, FDA
- Virginia Nido, Genentech
- William Wood, UNC-Chapel Hill
- Maria Ali, The George Institute
- Annick Anderson, CISCORP*
- Ricky Bloomfield, Duke*
- David Borasky, WIRB-Copernicus Group IRB
- Angie Botto-van Bemden, Arthritis Foundation
- David Brennan, MedStar Health Research Institute*
- Kara Dennis, Medidata Solutions
- Sue Dubman, Individual Patient
- Guy Eakin, Arthritis Foundation*
- Terri Hinkley, ACRP*
- Les Jordan, Target Health
- Hassan Kadhim, Boehringer Ingelheim
- Kristine Nelson, EMMES*
- Amanda Niskar, Individual Patient
- Petros Okubagzi, MedStar Health Research Institute
- Ido Paz-Priel, Genentech
- Ken Skodacek, FDA
- Junyang Wang, FDA
- Immo Zadazensky, FDA*
- Amy Corneli, CTTI Social Science Lead
- Brian Perry, CTTI Associate Social Scientist
- Zachary Hallinan, CTTI Project Manager

*Former Team Leader
Survey of Potential Research Participants

**Purpose:** To understand patients’ interest in, preferences for, and concerns with using mobile technology in clinical research

**Methods:**
- Recruitment via ResearchMatch (a secure online tool that connects volunteers with research studies)
- Purposeful, non-probability sampling focused on gathering expert perspectives of patients
- Not focused on making inferential, generalizable statements about a larger study population

**Sample size:** 193 respondents
- Arthritis=99 respondents
- Diabetes=63 respondents
- Parkinson’s disease=18 respondents
- Cardiovascular disease=13 respondents
Respondent Characteristics

<table>
<thead>
<tr>
<th>Age</th>
<th>Average 60 years old (range 23-83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>62% female, 38% male</td>
</tr>
<tr>
<td>Education</td>
<td>95% had some college or higher</td>
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<tr>
<td>Race/Ethnicity</td>
<td>88% White / Not Hispanic or Latino</td>
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<tr>
<td></td>
<td>5% Black or African American / Not Hispanic or Latino</td>
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<tr>
<td></td>
<td>3% White / Hispanic or Latino</td>
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<tr>
<td></td>
<td>4% Other</td>
</tr>
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</table>

Health

- 73% reported being diagnosed 5+ years ago by a medical doctor
- 63% reported good to very good overall health
- 42% visit doctor 2-3 times per year

Trial and Technology Experience

- 72% have never participated in a trial
- 56% have never used fitness monitor
- 87% use smartphone daily
Willingness to Participate in Mobile Trials

Angie Botto-van Bemden
### Mobile vs. Traditional Trial Scenarios

- Participants heard information about two versions of the same trial
- Same overall description (e.g., purpose, risk, benefits), but procedures were adjusted to reflect differences in mobile vs. traditional trials:

<table>
<thead>
<tr>
<th>Traditional Trial</th>
<th>Mobile Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ 13 site visits over 1 year</td>
<td>➢ 3 site visits over 1 year</td>
</tr>
<tr>
<td>➢ Patient diary completed at home</td>
<td>➢ Most data collection at home</td>
</tr>
<tr>
<td>➢ Most data collection at site</td>
<td>• Daily use of wrist-worn health monitor and smartphone app</td>
</tr>
<tr>
<td>• Movement tests</td>
<td>• Weekly home use of blood pressure cuff and bodyweight scale</td>
</tr>
<tr>
<td>• Physical exam / vital signs</td>
<td>• Requirement to connect smartphone to wireless network daily to upload data</td>
</tr>
<tr>
<td>• QoL questionnaire</td>
<td></td>
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</tbody>
</table>

CTTI
We are doing a clinical trial to learn more about an experimental drug for people who have diabetes. This drug is not approved by the Food and Drug Administration for use in treating the symptoms of diabetes. We are doing the trial to find out if this new drug works for this purpose.
Scenario Pathway for Survey Respondents

Scenario 1
- 48.7% (n=94) randomized to view traditional trial first
- 51.3% (n=99) randomized to view mobile trial first

Scenario 2 (opposite of scenario 1)

“Would you take part in the trial?”

“Would you take part in the trial?”

Confirmation Question

Additional Devices
Most Participants Preferred the Mobile Trial

“If you had the option to take part in either of these trials (traditional or mobile), which would you be more likely to join?” (Confirmation question)

- **76% preferred the mobile trial**
- **12% would join either**
- **7% preferred the traditional trial**
- **4% would not join either trial**
## Willingness to Participate by Respondent Characteristics

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Respondents Who Were MORE WILLING To Join</th>
</tr>
</thead>
</table>
| **Traditional Trial Scenario** | • Men (55% vs 49% of women; p=0.05)  
  • Participants whose health condition had a greater impact on how they feel day-to-day compared to those who did not (p=0.05)  
  • Participants who visited their doctor more often than those who do not (p=0.03)                                                                                     |
| **Mobile Trial Scenario**     | • Participants who had greater prior use of smartphones compared to those who did not (p=0.02)  
  • Participants who had greater prior use and comfort with mobile health applications (prior use: p=0.003; comfort: p=0.01)  
  • Participants who visited their doctor more often than those who do not (p=0.02)                                                                                     |
Participants who preferred the Mobile Trial scenario said:

- Involves less time and effort:
  - Fewer visits to the clinic
  - Better daily compliance with study-related procedures
- Allows for more accurate data collection
- Allows patients to track their health
- Allows patients to use an interesting technology
- Provides more responsive safety monitoring

Participants who preferred the Traditional Trial scenario said:

- Use of mobile technology would be too burdensome:
  - Daily record keeping
  - Uncomfortable with or inability to wear the device 24/7
  - Maintenance of the device
- Traditional trial allowed for more direct interaction with the doctor

It requires less of me on a daily basis and fewer clinic visits. I am not good about daily recording in a diary.

I would wear a monitor for a month, or for 1 week each month for a year, but not 24/7 for a whole year. It's just too long. Too uncomfortable. And I don't like the idea of monitoring my vitals every minute.
“How does the use of a health monitor worn on your wrist affect your willingness to take part [in the mobile scenario]?”

- 49% said “more likely to take part” because mobile technology used
  - 42% said no direct impact on their decision
  - 8% said less likely to take part

- No significant associations between participant demographics and impact of mobile technology use on willingness to participate

<table>
<thead>
<tr>
<th>Demographics</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.46</td>
</tr>
<tr>
<td>Gender</td>
<td>0.77</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>0.37</td>
</tr>
<tr>
<td>Education</td>
<td>0.62</td>
</tr>
<tr>
<td>Marital status</td>
<td>0.07</td>
</tr>
<tr>
<td>Time since diagnosis</td>
<td>0.77</td>
</tr>
<tr>
<td>Frequency of doctor visits</td>
<td>0.95</td>
</tr>
<tr>
<td>Disease impact of how they feel day to day</td>
<td>0.47</td>
</tr>
<tr>
<td>Overall health</td>
<td>0.49</td>
</tr>
</tbody>
</table>

i P-values are based on Mantel-Haenszel chi-square rank based group means score statistics
BYOD vs Provisioned Health Monitors

Preference for BYOD* or Provisioned Device (n=181)
- 55% Provisioned
- 32% BYOD
- 13% Doesn't matter

* Assuming they own the same device that would be provided as part of the trial

If Trial Requires Provisioned Device (n=186)
- 75% Wear only provisioned device
- 21% Wear both BYOD and provisioned device
- 4% Not participate in trial*

* Each also reported that they would either prefer the traditional trial and/or would be less likely to take part in the mobile trial because of the use of mobile technology (Q45)

Most (86%) thought that it was important that the mobile technology used in the trial does not use personal data minutes that they would pay for when sharing information with trial staff.
Willingness to use additional mobile technology

- **Arthritis**: Multiple task-based mobility monitors (wearable accelerometer)
- **Heart disease**: Holter monitor
- **Diabetes**: Continuous Glucose Monitor
- **Parkinson’s Disease**: Task-based mobility monitor (wearable accelerometer)
Willingness to use **additional** mobile technology
(among those willing to participate in mobile scenario)

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Less likely to take part</th>
<th>Equally likely to take part</th>
<th>More likely to take part</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple task-based mobility monitors (Arthritis, n=89)</td>
<td>19.1%</td>
<td>56.2%</td>
<td>23.6%</td>
</tr>
<tr>
<td>Continuous glucose monitor (Diabetes, n=56)</td>
<td>28.6%</td>
<td>55.4%</td>
<td>16.1%</td>
</tr>
<tr>
<td>Task-based mobility monitor (Parkinson's, n=18)</td>
<td>22.2%</td>
<td>66.7%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Holter monitor (Heart disease, n=12)</td>
<td>16.7%</td>
<td>50.0%</td>
<td>33.3%</td>
</tr>
</tbody>
</table>
Key Takeaways

- Most (but not all) participants preferred the mobile trial scenario.

- The use of mobile technology per se made the mobile scenario more appealing to many (but less appealing to some).

- Among those willing to join the mobile scenario, most (but not all) were willing to use more than one device/technology.
Questions / Comments?
Attributes of Mobile Devices

Les Jordan
“If you were asked to join a trial, would you be willing to use…”

- Wrist-worn device
- Smartphone or tablet app
- Patch
- Bodily-fluid diagnostic device
- Ingestible

[Bar chart showing willingness to use different devices]
Most said they would use a wearable monitor daily for one year or as long as the trial lasts.
Important Attributes Of Wearable Monitors*

All or nearly all reported:
- Easy to learn (100%)
- Convenient to use (100%)
- Physical comfort (99%)
- Availability of tech support (99%)

Many reported:
- Password protection (78%)
- Not easily noticed or seen (68%)
- Fun to use (64%)

Fewer reported:
- Attractiveness (37%)

*Similar patterns observed for Patch and Bodily-Fluid Diagnostic Device
Important Attributes of Ingestible Sensors

- Nearly 90% reported that each of the relevant attributes were important.
- Everyone reported that an ingestible sensor should be **physically comfortable** to swallow.

Displaying data from the sensor to a smartphone, tablet or computer (89%) was less frequently reported than other important attributes.
“How important or not important is it to you that your [spouse / friends / doctor] are okay with you using a wearable monitor?”

- **Doctors are important**: 70% felt doctor acceptance/approval was important
- **Spouses/Partners less important**: Roughly half felt spouse or partner acceptance/approval was important
- **Friends not important**: Between 10% and 15% felt friend acceptance/approval was important
Key Points

- Respondents expressed willingness to use a variety of devices—and most say they are willing to wear devices daily for a year or as long as the trial lasts.

- Almost all reported ease of use and comfort as important.
  - While attractiveness was less important, about two thirds of respondents said the device should not be easily noticed.

- Respondents also noted they wanted to see their data.
  - But they wanted the device to collect the data on its own.

- Doctors’ opinions mattered more to respondents than others in social networks (spouses, friends).
Questions / Comments?
Data Privacy & Access, Communications Preferences

Cindy Geoghegan
Confidentiality Important But Majority Appear Not to be Concerned

- 49% ($n=91$) reported they would not take part in a mobile trial if they were uncertain their information would remain confidential.

But...

- Over half (55%, $n=103$) reported that they were not worried that others, besides the research team, would be able to see their data collected by the technology.

- Over half (62%, $n=116$) reported that they were comfortable or very comfortable using mobile technology that tracked their location in a clinical trial.

Willingness to Participate if Confidentiality of Data Uncertain

- YES (definitely / probably) 28%
- Not Sure 23%
- NO (definitely / probably) 49%
Few Concerns About Data Storage

- Overall, few were uncomfortable with any of these options.
- More participants were uncomfortable with data being stored on the manufacturers’ server than other options.

![Bar Chart showing discomfort levels]
Only 2% said it is ‘not important’ to see info collected about them by mobile technology.

“How important or not important is it that you are shown the information collected about you by the mobile technology?”

- Very Important: 48%
- Important: 32%
- Somewhat Important: 18%
- Not Important: 2%

**Preferred Frequency of Feedback**
- Instantly = 16%
- Every Day = 25%
- Every Week = 26%
- 2-3 Times Per Month = 7%
- Monthly or Less = 15%
- After Trial Over = 11%

**Preferred Methods**
- Webpage (67%)
- On the Device (52%)
- Meet with Trial Staff (30%)
- Printout (24%)
- Another Way (4%)
Data Feedback Preferences by Respondent Characteristics

- Women were significantly more likely than men to want printouts (p=0.04)
- Participants whose health condition had a greater impact on how they feel day-to-day (than those who did not) had a greater preference for one-on-one meetings with trial staff (p=0.03)

<table>
<thead>
<tr>
<th>Demographics</th>
<th>P-value (^1)</th>
<th>P-value (^1)</th>
<th>P-value (^1)</th>
<th>P-value (^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.08</td>
<td>0.55</td>
<td>0.21</td>
<td>0.07</td>
</tr>
<tr>
<td>Gender</td>
<td>1.00</td>
<td>0.85</td>
<td>0.04*</td>
<td>0.43</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>0.95</td>
<td>0.11</td>
<td>0.93</td>
<td>0.17</td>
</tr>
<tr>
<td>Education</td>
<td>0.31</td>
<td>0.63</td>
<td>0.94</td>
<td>0.67</td>
</tr>
<tr>
<td>Disease impact of how they feel day to day</td>
<td>0.60</td>
<td>0.64</td>
<td>0.18</td>
<td>0.03*</td>
</tr>
<tr>
<td>Overall health</td>
<td>0.56</td>
<td>0.12</td>
<td>0.63</td>
<td>0.93</td>
</tr>
</tbody>
</table>

\(^1\) P-values are based on Pearson chi-square test for all categorical row variables.

\(^*\) P-value is based on Cochran-Mantel-Haenszel statistics to test row mean scores difference
Clinic Visit and Communication Preferences

“How often would you prefer to see the trial doctor if you took part in a clinical trial that used a mobile technology?”

- Numerous times during trial: 16%
- Start and end of trial: 47%
- Never: 5%
- Doesn't matter: 31%

- 90% of respondents willing to use alternate forms of communication with trial doctor (other than in-person visits)

- Among those willing to use other forms of communication (n=148):
  - Email (85%)
  - Telephone (80%)
  - Online live chat (72%)
  - Video conferencing (68%)
  - Text message (62%)
Participants age 60+ had a significantly greater preference for in-person training than younger participants (p=0.02).
Preference for Site Involvement in Troubleshooting Device

“Who would you most want to contact to fix the mobile technology if it stopped working?”

- Trial staff: 79%
- The company who made the mobile technology: 16%
- Someone else: 5%
- No one. I would stop using it if it stopped working: 1%
Key Takeaways

- Privacy concerns could reduce willingness to participate, but few respondents appeared to have concerns.

- When using mobile technology in a trial, almost all respondents say they would want to see the information collected:
  - Many would want the information either instantly (16%), daily (25%), or weekly (26%)
  - Only 11% willing to wait for results at the end of the trial
  - Preferred access is via a website or on the device itself

- Site interactions remain important (and the preferred resource for device training and troubleshooting), but many of those interactions may not have to be in person.
Questions / Comments?
Summary Findings

Mobile clinical trials were preferred by most (but not all) over traditional clinical trials.

Provisioned wearables were generally preferred over BYOD.

Participants were willing to use many kinds of mobile devices, as well as multiple devices in the same trial.

A variety of device attributes were important, including comfort and ease of use.

Participants’ doctor’s opinions on the use of mobile devices matter.

Data privacy and confidentiality are important, though majority did not express having concerns.

Data feedback is important; although frequency of feedback varies, many want instant or daily access.

Many (but not all) open to fewer visits with study doctor, potentially via remote communication.

Sites were a preferred resource for device training and troubleshooting.

About half of respondents also expressed interest in having written instructions and/or short training videos on how to use new mobile devices.
Discussion

1. What new opportunities are created by mobile technology to meaningfully engage patients in their clinical trial? What new barriers are created?

2. What are the most important takeaways that could form the basis of recommendations for the research enterprise?
THANK YOU.

www.ctti-clinicaltrials.org