Presentation of Evidence on Scientific and Technological Issues

Aiden Doherty, University of Oxford
Brian Perry, Duke University
Barry Peterson, Philips
Ashish Narayan, Northwell Health
Kaveeta Vasisht, FDA
Day 2 Data bundles

- Device Management, Device Reuse, Device Training and Device Failure
- Device Selection, Device Validation and Device Calibration
- Sharing Data with Patients in Real-Time
- Real Time Safety Signals
- Scientific and Technological Challenges
  - Lessons Learned
  - Interviewees’ Recommendations
Phase I Interviewees: Sponsors (15)

Focus of research:
- All involved in drug development
- Almost all were involved in biologics

Use of devices:
- All used movement sensors
- 73% had used smartphone apps
- Some had used biosensors, pressure sensors, video cameras, audio sensors, global positioning systems (GPS), adherence monitors, and electronic patient-reported outcome devices
Phase I Interviewees: Investigators (8)

- All worked in an academic institution or academic health system that has research and education responsibilities

- Role in current trials:
  - PI=7
  - Sub-I/co-PI=1

- Focus of research:
  - 75% involved in medical devices
  - 50% involved in drug trials

- Use of devices:
  - All used movement sensors
  - All used smartphone apps
  - Some used biosensors, pressure sensors, video cameras, audio sensors, and GPS
Phase II Interviewees: Subject matter experts

- 20 experts interviewed:
  - Device manufacturers (n=10)
  - Data management experts (n=2)
  - Biostatisticians (n=4)
  - Data security experts (n=4)

- Device manufacturers included software and hardware developers of:
  - Inertial sensor devices (n=5)
  - Glucose monitors (n=2)
  - Mobile data hubs (n=1)
  - Wearable cardiac and respiratory monitors (n=1)
  - Mobile health applications (n=1)

- One commercial device company was represented among manufacturers
Device Management, Device Reuse, Device Training and Device Failure
Aiden Doherty, University of Oxford
Brian Perry, Duke University
Our Working Definition of Device Management

Device management is the process of managing the implementation, operation, and maintenance of mobile devices, as defined for this project.
Some said sponsors are responsible for device management

- Have in-house team responsible for routine device management (e.g., shipping, logistical, and technical details)
- Handle upgrades through managed software on the device (when provided by the study)
- Stay current with the latest versions of software (when using BYODs)
- Lock down devices or minimize the amount of technology used
We are provisioning [the devices]. So, as part of our agreement with our technical vendor, they are procuring the devices from Apple. And so they will configure the phone for the study. You go to a site; the subject doesn’t want to use their phone or doesn’t have an iPhone that’s compatible, then they would be provided an iPhone. The iPhone has limited functionality. Basically, you turn the phone on and you’ll see the app and that’s basically it. You can’t make calls. You can’t search the internet, can’t send text messages and so forth. —Sponsor
I know in the past we've allowed them to upgrade or we'd just advise to not upgrade when the upgrade has come out. But our first few attempts of sending tablets out to sites to view those things we didn't have it like locked down at all. I think we've learned that it would be best if we could prevent those types of upgrades. I didn't even know that today's master data management software can actually prevent the end user from upgrading to iOS. —Sponsor
Investigators’ and Sponsors’ Comments on Device Management

Several said the device or app manufacturer, vendor, or external company were responsible

- Particularly for proprietary technology or technology that is being developed
- Management tasks vary
- FDA-cleared devices are typically managed by companies who offer full-service support
  - Should work with vendors with a proven track record
    - Ensures logistics, device management, and troubleshooting are properly handled
- 510k cleared devices are rarely updated
Investigators’ and Sponsors’ Comments on Device Management

- BYOD trials
  - Sponsors provide technical support, generic guidance to different kinds of users and situations
  - Patients responsible for routine device maintenance
Working Definition of Device Reuse

Our project team’s interest in device reuse is limited to conventional reuse, where the device is used again for capturing data in a clinical trial, perhaps with another participant.
Investigators’ and sponsors’ comments on device reuse

Several believed a good approach

Concerns:
- Security of data
- Recalibration of devices prior to reuse

Provisioned devices:
- Internal IT staff would clear returned devices
- Reassess calibration

Rented devices:
- Return device and vendor would clear
- Vendor redistributed device to the same or another study
Device training describes approaches taken to prepare users, including study coordinators and trial participants, to correctly use the device for activities such as data collection, data transfer and charging.
Investigators’ and Sponsors’ Comments on Device Training

- Sponsors provided role-based training to implementing partners, particularly for study coordinators.
- Implementing partners were responsible for providing training to study participants, which was limited to simple and straightforward instructions.
- Some sponsors created materials and videos on using the devices.
- Some apps associated with the device had embedded instructions about how to use the app.
Investigators’ and Sponsors’ Comments on Device Training

Case example—one sponsor’s innovation lab:

- Simulated patients’ and study staff’s experience in using the device
  - Incorporated lessons learned from the simulation into patient and staff training
- Conducted hands-on training with investigators and site staff at two sites as part of study start up
  - Staff used the device in the presence of a trainer, identified the issues they had in using the device, and had their questions answered
  - Lessons learned were applied to the overall training materials to be used with the next sites in line for training
Working Definition of Device Failure

**Device failure** refers to any event in which a mobile device, as defined for this project, cannot accomplish its intended purpose or task. This may be because the mobile device stopped working, is not performing as desired, or is not meeting target expectations due to defects.
Investigators’ and Sponsors’ Comments on Device Failure

How to identify when remote technology fails during the trial:

- Create an algorithm for automating failure detection (based on trends) with built-in alerts
- Develop a predictive model to determine when batteries will likely stop working
- Establish a patient call center for problem solving device issues
- Rely on the device vendor to monitor patient data, with notifications to sites if device malfunction is suspected
How to manage technology failure during trial:

- Rely on a third party (e.g., vendor, manufacturer, developer) to replace or fix devices and provide support if technology malfunctions during a trial.
- Have a dedicated manager/coordinator manage all technical and logistical issues and provide patient support.
Investigators’ and Sponsors’ Comments on Device Failure

How to minimize the impact of device failure or loss:

- Have extra devices that the sponsor can promptly ship to sites if patient’s device fails
- Provide sites with extra replacement devices to have on hand if patient’s device fails
How to minimize the likelihood of technology malfunction:

- Test devices in advance to ensure all are working properly
- Conduct feasibility studies
- Download and evaluate data to detect internal device failure error messages
Investigators’ and Sponsors’ Comments on Approaches for Dealing with Device Failure

- Device battery problems and/or device failure
  - Retrain participants about charging batteries
  - Document device failure and provide feedback to manufacturers
- Participants are out of wireless range and unable to upload data
  - Upload data when back in wireless range (although this can be a problem in areas with limited cell phone coverage)
- Managing failure of BYOD
  - Have patients be responsible for fixing their own devices
Manufacturers’ and Data Managers’ Comments on Device Failure

- Loss of data or diminished precision in measurement as result of reduced battery life
- Diminished memory or storage capacity
- Lack of wireless connectivity
- Variations in temperature or environmental conditions
- Lost or destroyed devices
Manufacturers’ and Data Managers’ Comments on Device Failure

**Challenge:** Diminished battery

- A reduction in the device’s battery power does not impact the precision of its measurement → but, when the device is no longer on because the battery dies, the device can no longer capture or send data

**Solutions**—design devices where:

- Previously-collected data (before the battery died) remains stored on device in an internal hard drive
- A low-battery alert is sent to the user
Manufacturers’ and Data Managers’ Comments on Device Failure

**Challenge:** Diminished memory or storage capacity
- While diminished memory or storage is a concern, data collected during research studies will not likely meet the memory capacity of devices

**Solutions:**
- Use technologies that free up memory once they are synced remotely
- Include a software alert warning the user when reaching storage capacity
Manufacturers’ and Data Managers’ Comments on Device Failure

**Challenge:** Limited or variable wireless connectivity

**Solutions:**

- Devices that store data on the device itself can continue to collect data while out of wireless range
  - Data will be uploaded once the user reconnects
- If the study requires feedback to user via the device, algorithms can be programmed directly into the device, wireless not needed
- When collecting continuous data (but expect spotty wireless), one manufacturer said they collect data in real-time and retrospectively each week; impute data not collected real-time when unable to sync
Manufacturers’ and Data Managers’ Comments on Device Failure

**Challenges:** Changes in temperature and environment

**Solutions:**

- Because tested under multiple temperatures and environmental conditions, manufacturers are aware of the types of corrections to make the device’s programming or to data analysis to account for differing environmental conditions.
- Select technology and sensors that are less prone to offset.
Manufacturers’ and Data Managers’ Comments on Device Failure

**Challenge:** Always a risk of device loss or destruction

**Solutions:**
- Sync data remotely from the device as often as possible
Device Management, Device Reuse, Device Training and Device Failure

Brief questions and comments
Device Selection, Device Validation and Device Calibration

Barry Peterson, Phillips

Brian Perry, Duke University
Our Working Definition of Device Selection

Device selection should occur only after clinician experts in a therapeutic area, in partnership with patients, have determined that a mobile based outcome assessment would be valuable.* Device selection is the process of identifying the optimal mobile device to capture data required to inform this assessment.

* See CTTI MCT Novel Endpoints recommendations for more information about optimizing the timing of device selection
Investigators’ and Sponsors Approach to Device selection

- Define the clinical need
- Define how to measure their desired outcome

**Novel endpoints project**

- Review potential device options that can measure the desired outcome(s)
  - Vet implementing partners and explore vendor offers and capabilities
  - Consider whether the study or patients should provide the devices to be used in the trial
  - Conduct internal assessments of proposed devices
  - Conduct user acceptability and feasibility testing
Device Selection: Defining Clinical Need

Define clinical need:

- First identify need
- Then determine whether inclusion of a mobile device is appropriate to meet that need

“…I think rather than starting with the technology—like: ‘We have all these devices; how do we use it?’—it really needs to start with: ‘What are the things that are of interest to measure?’”

—Sponsor
Device Selection – Investigators and Sponsors Report Evaluating Potential Device Options that can Measure the Desired Outcome

- Balance clinical and regulatory needs:
  - FDA-510K-cleared technologies –
    - Were favored
    - But limited technology options because they may not meet study-related needs

- Patient acceptability was key:
  - Favored technology –
    - Familiar to patients
    - Easy to use

- Proven track-record also important
Device Selection: BYOD?
Investigators’ and Sponsors’ views

**PROS**
- Patients’ familiarity
- Some patients say makes it easier to participate
- Can lead to a more geographically diverse study population
- Less burdensome

**CONS**
- Inter-operability of technology platforms
- Management and troubleshooting technical problems
- Potential unwillingness of trial participants to use their personal technology
- Limiting the number of patients who can enroll (because they must already have the specific device)
- More upfront costs for staff training and technological infrastructure development
- Lack of standardization
Device Selection: Study-provided?
Investigators’ and Sponsors’ views

**PROS**
- Greater control of the devices
- Can “lock down” the device
  - Remove any features not directly study-related
  - Ensure devices will not automatically update
- Improved tacit knowledge of device and software
- Better technical support offered by staff
- Increased access to trial participation

**CONS**
- Possible increased study cost
Device selection: Hybrid?

Some investigators and sponsors are using a hybrid model of device provision

- Pre-select (limited) device options can be trial-provided or BYOD
- Patients can use their own device, if they have it
- If not, trial provides device

“Based on the meetings we have with different patient focus groups we've seen a split. People want to provision the device and others want to use their own device, and so from that perspective we want to make it as convenient as possible.”—Sponsor
Device selection: *Additional Considerations Reported by Investigators and Sponsors*

Sponsors and investigators suggest vetting vendors for appropriate mobile clinical trial experience and capabilities

- Have regulatory experience, know how to measure data that would be accepted by regulators
- Can innovate
Device selection: *Additional Considerations Reported by Investigators and Sponsors*

- Conduct internal assessments, with varying experts
  - Clinical and diagnostic
  - Legal and regulatory experts
  - Technological and analytics
  - Some had established internal teams whose mission is to identify innovative approaches to clinical trial data collection

- Conduct small-scale, user acceptability and feasibility studies to ensure that the selected technologies were acceptable to patients and were feasible to use
Our Working Definition of Device Validation

Device validation shows that the device is able to collect the requested data and that this captured data does not vary among like devices or in time.

Note: the BEST Glossary defines analytical validation as the process of establishing that the performance characteristics of a test, tool, or instrument are acceptable in terms of its sensitivity, specificity, accuracy, precision, and other relevant performance characteristics using a specified technical protocol.
Almost all interviewees said they had concerns about determining the accuracy of mobile devices.

*We [often] assume that everything collected by a device is perfect. But, we have to prove it before using it in a clinical trial, because we want to prove the efficacy of the drug. And if our outcome measure has not been validated, we cannot prove anything.*—Investigator
Two frequently-mentioned approaches to validation were:

- Comparing traditionally-measured data (e.g., patient reported) to the data collected by the mobile device
- Relying on the manufacturer to ensure that devices are validated, although a few did not trust this approach and therefore did their own validation

Most commented that device validation is still in its beginning stages and that data derived from devices are not yet ready to replace data collected via traditional methods

510k cleared devices were mentioned as an advantage
Our Working Definition of Device Calibration

**Calibration** is the setting or correcting of a measuring device, usually by adjusting it to match or conform to a dependably known and unvarying measure.
Investigators’ and Sponsors’ Comments on Device Calibration

All believed sponsors were ultimately responsible for ensuring that mobile devices were calibrated

- However, many relied on the device manufacturer or app developer to ensure the technology is calibrated initially
- Often asked vendors for proof of calibration during the vetting process

Calibrations are routinely manufacturers' responsibility, and that's an expensive charge.—Investigator
Investigators’ and Sponsors’ Comments on Device Calibration

After devices are given to patients, implementing partners are responsible for calibration

- Or to at least monitor for irregular data which may indicate device calibration errors
- If calibration errors are identified, sponsors contact manufacturer/vendor and ask to recalibrate the device, if sponsors can’t perform the recalibration in-house
Our Working Definitions of Verification & Validation Testing

- **Verification testing**: an internal process for ensuring that software is programmed correctly and meet a set of design specifications.

- **Validation testing**: the process for ensuring that the technology fulfilled its intended use.
  - Occurs both internally (within the company) and externally (with clients and company partners).
Device Manufacturers’ Comments on Verification and Analytical Validation

Findings grouped into six steps

- Determine design specifications in partnership with subject matter experts (e.g., the sponsor)
- Identify the appropriate form of technology to use to capture data the most robust measurement of the observation in the target population
- Calibrate sensor technology according to a reliable gold standard or absolute measures and test sensor reliability under varying conditions
- Develop and verify algorithms that convert raw data into clinical outcomes and correct for any environmental off-setting
- Conduct internal validation studies with healthy controls and/or patients with the target conditions
- Conduct independent validation testing in controlled and free-living conditions
Device Manufacturers’ Comments on Calibrating Sensor Technology

Two procedures described where the manufacturer...

- Compares the raw data from the device to known absolute or gold standards to ensure the sensors are calibrated and functioning consistently
- Tests the sensor’s precision under various environmental and user conditions, such as with different skin pigments and temperatures, depending on the intended use of the technology
Device Manufacturers’ Comments on Calibrating Sensor Technology

- Depending on the type of sensor, a variety of bench tests are used.

- Manufacturers record all aspects of the controlled bench testing, including the:
  - Ambient temperature in which the tests were run
  - Degree of error when compared with the absolute or gold standard measurement
Device Manufacturers’ Comments on Developing and Verifying Algorithms

Based on the findings of tests just described, manufacturers may:

- Develop compensation algorithms that will calculate the device’s raw data differently depending on the known variations in error in the test results (e.g., variations due to changes in ambient temperature)
- Develop appropriate filters to remove noise caused by environmental factors, e.g., vibrations the device records while the user is riding in a vehicle
- Conduct small clinical studies under controlled conditions to develop, test and/or further refine the algorithms
Device Manufacturers’ Comments on Conducting Internal Validation Studies

“Ground truthing”: The newly-developed algorithm is then tested in other internally-run clinical studies where the measure produced by the mobile device is compared to gold standard measurement.

Must consider: The current gold standard can be imperfect, and that the mobile technology-acquired measurement may in fact be a more objective measurement than the gold standard.
Conduct Internal Validation Studies

In our case, and this is a really big stumbling block for us…The gold standard is a clinician like me saying, "You've got [condition], and that form of movement is worse than that one," so that's very difficult to quantify against. So…there is no knockout validation test…we're just as good and bad as the old clinical scale, and people didn't like the clinical scale…We don't want to be an accurate reproduction of what was a flawed measurement. —Device Manufacturer

Depending on what we're measuring, sometimes we're kind of given a gold standard of measure. They can be quite crude, but very often you're working with kind of, what I sometimes jokingly refer to as "last century's biomarkers." Effectively, you might have a really crude measure, and then you're using that to basically show that you can significantly move.—Device Manufacturer
Conduct Internal Validation Studies

Does it actually measure drugs we know that work? Can it capture that improvement? And you go through a series of things like that to say that it does what it says it does. —Device Manufacturer
Device Manufacturers’ Comments on Conducting Independent Validation Tests

- Human factor testing: Once the above is done, external researchers often conduct independent, external validation tests of the device.

- Researchers examine how human factors, such as how patients use the device, may impact the quality of the measurement.

- Challenges of validation testing in free-living conditions:
  - Sometimes unable to compare to the gold standard.
    - Thus, assume valid based on how device was calibrated.
  - Some manufacturers monitor publications to ensure device is performing as expected and was used correctly.
Device Manufacturers’ Comments on Providing Proof of Validation

Manufacturers noted that some companies may be reluctant to provide the algorithms used for converting raw data into specific measurements because the code may be considered intellectual property.
- Although the process for developing the algorithms may be made available.

Manufacturers said clients rarely asked for documentation of the verification and validation process.
- Although this information can be provided upon request or is already publically available.
- Currently available in journals, FDA Summary of Safety and Effectiveness reports, 510K clearance documents, and manufacturer-published User Guides.
Device Manufacturers’ Comments on Providing Proof of Validation

Information provided to clients include:

- The manufacturer’s SOPs on device data management
- Information on the limitations of the technology
- Record of design specifications and software/hardware changes
- Variance and variability of data, so sponsors calculate effect size as well as monitor device calibration
- Information about their manufacturing processes so the client can be assured that the technology is developed according to industry-approved standards
Device Manufacturers’ Comments on Providing Proof of Validation

In addition, some manufacturers –

- Provide sponsors with guidance and suggestions for using their technology within a research context
- Assist clients with interpreting results and answering questions from the FDA during review
Device Selection, Device Validation and Device Calibration

Brief questions and comments
Sharing Data with Patients in Real-Time
Real Time Safety Signals
Ashish Narayan, Northwell Health
Our Working Definition of Real Time Data

Real-time data is information that is delivered and presented as it is acquired, with no delay in the timeliness of the information provided.
Investigators’ and Sponsors’ Comments on Sharing Data in Real Time

- Overall concerns related to providing patients real-time feedback:
  - Timing of when to provide feedback
  - Scientific and ethical concerns about providing feedback
  - Type and extent of feedback to provide

- Approaches to the timing of providing feedback ranged from –
  - Providing it in real time
  - Providing it at the end of the study

- Several said that they didn’t provide any feedback
Investigators’ and Sponsors’ Comments on Sharing Data in Real Time

- Some who provided feedback said the point of their studies was to provide real-time feedback to participants.
- Some said they provided feedback to patients because the data belong to patients and feedback helps to drive patient engagement and/or retention and empowers patients to manage their own symptoms.
- Feedback included information directly on the app as well as staff-initiated feedback.
- Several who waited until the end or who didn’t provide feedback were concerned about bias.
Our Working Definition of Real-Time Safety Signals

Real time safety signals describe the issue that new patient safety signals, those not previously captured using traditional protocol design and monitoring, may be captured as a result of using mobile devices. Examples: someone wearing an EKG all the time you might detect arrhythmias that you would have never been captured before; someone wearing an accelerometer may fall and you know about that immediately rather than at the next study visit.
Sponsors’ and Investigators’ Primary Concerns Regarding Real-Time Safety Signals

- How to identify safety signals
- How patients should report safety signals
- What to do with safety signals once identified
Investigators’ and Sponsors’ Comments on Real-Time Safety Signals

Identifying safety signals
- One sponsor said that researchers should take the same approach as in non-device trials: identify what you plan to measure in the protocol and if it is out of bounds of safety parameters, report it following GCP guidelines
- Some said trend detection can be used

Patients reporting safety signals
- Following SOP guidelines for reporting AEs
- Reporting AEs on an app with an algorithm that provides patient guidance, assesses severity, and advises about next steps
- Having an algorithm in app that notified the site when patients reported they were at risk of hurting themselves or others and suggested that the patient immediately contact a help hotline
Investigators’ and Sponsors’ Comments on Handling Safety Signals Identified by a Mobile Device

- Determine if the safety signals are actionable—for example, contacting the site, the PI, or study physician about potential safety signals that may need to be followed up on
- Use a patient guide to assess the significance and course of action for patients
We spent a lot of time defining what you know what would be considered a serious criteria on some of these measures. Like we can get a blip in your heart rate, but it wouldn't be something actionable. We are working with our advisory board... [to determine when (text removed for confidentiality reasons)] you would actually medically intervene and we're able to get around to an answer on that and setup the system. Then we were able to simulate that happening and then simulate our navigator reaching out to the patient to ensure their wellbeing. — Sponsor
Sharing Data with Patients in Real-Time
Real Time Safety Signals

Brief questions and comments
Scientific and Technological Challenges
- Lessons Learned
- Interviewees’ Recommendations

Kaveeta Vasisht, FDA
Brian Perry, Duke University
What would sponsors and investigators do differently in future studies using mobile devices for data capture?

Specifically related to device challenges:

- Use the endpoints to drive device selection rather than selecting a device first and building the trial around it
- Integrate multiple functionalities to be integrated into a single device
- Encourage adoption of BYOD
- Evaluate device specs and limitations before selecting the device
- Incorporate pre-trial user testing of devices into the study timeline
- Validate device up front
What questions do sponsors and investigators recommend asking device manufacturers during device selection?

- Whether the device is reliable and valid: does it measure what it purports to measure? What kind of validation was done?
- Is the device validated in clinical settings that matches how it will be used in the study?
- Is the device fixed or can it be customized to meet the study’s needs?
- Can the device be viewed in person to determine if its physical characteristics are relevant for the study population?
What questions do sponsors and investigators recommend asking device manufacturers during device selection?

- What’s the vendor’s experience with using this device in clinical settings?
- How is the vendor compliant with federal regulations?
- How do you manage privacy issues?
- How can the study team access study data?
- How often do data transfers occur?
- What are your quality control procedures?
Sponsors & Investigator Recommendations

- Focus on the endpoint first and work backwards from there to select a device, rather than getting excited about a certain technology first and then trying to find a clinical application to fit it.
- Take time to validate device or select one that is both valid and reliable.
- Determine if the type and frequency of data output generated by the device appropriately meets the trial’s needs.
- Understand the form in which data are generated and how often they will be sent to investigators.
Sponsor & Investigator Recommendations

- Use a medical-grade, not consumer-grade, device if their ultimate goal is a labeling claim.
- Consider the device platform, e.g., Apple vs. Android, to determine which is a better fit for the study population.
- Be wary of inconsistencies across different technologies, which may eliminate the ability to do cross-patient analyses.
- Obtain coordinator feedback about whether device is patient-friendly (i.e., don’t rely only on vendor reports).
Sponsor & Investigator Recommendations

- Closely monitor patients and verify that they are following trial instructions
- Keep both the device and the analysis as simple as possible
- Do not focus too much on device aspects but instead think about how sensors might be positioned differently on the body, in accordance with different symptoms
Sponsor & Investigator Recommendations

- Vendors improve their communication with study teams
  - Vendors should be more transparent about their devices’ capabilities, as well as about how particular devices could benefit a trial or patient population
- Choose an experienced and credible vendor
- Recognize that vendors may be overly enthusiastic about their devices, so the technology may not work as well as the vendor says it will
- Vendors should partner with research teams to create better quality devices for the long term
Device Manufacturer Recommendations

- Sponsors should expect general transparency from manufacturers regarding methods used to verify and validate measurements recorded by their device.

- Vendors should be able to provide sponsors with detailed information showing how—
  - Validation was performed
  - How algorithms are established without providing propriety information
  - How and whether devices of different model years compare
  - Usability features that may impact trial conduct or patient compliance
Device Manufacturer Recommendations

The questions to ask are basically transparency, unbelievable transparency, that everything that's being done with the data should be available to the sponsor, every single detail, how the things are calculated, how the data is collected, especially in cases of the device. Also the uniformity of the device. Have confidence that they are indeed interchangeable not only across devices but also in time. —Device Manufacturer
Device Manufacturer Recommendations

**Establishing standards:** Establish and adhere to standards for recording raw data and making it available in order to advance the field

- Similar devices ought to adhere to similar standards for calibration
- All devices ought to be able to produce raw data
- Methods for summarizing/interpreting raw data should be done “away from the device” on accompanying apps

**Outcomes/scientific considerations:** Allow for validation studies to be performed by third parties
Scientific and Technological Challenges
- Lessons Learned
- Interviewees’ Recommendations

Brief questions and comments
THANK YOU.