The Future of Clinical Trials: How Will New Technologies Affect The Lives Of Participants?

CSW Workshop
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Agenda

- Introduction to *The Playbook*
- A Vision for the Future
TOUR OF DUTY: Driving adoption

The Playbook: Digital Clinical Measures

Introducing the essential guide for successful remote monitoring across clinical research, clinical care, and public health.
A heart-beat is a heart-beat.
Sleep is sleep.

Digital clinical measures should:

- measure what matters most to patients, participants, professionals, and people.
- improve decision-making and make a difference.
- be defined and deployed similarly across clinical research, clinical care, and public health.

Source: Playbook team analysis
Benefits of digital clinical measures span research, care, and public health

To accelerate
clinical research

- Accelerate timelines and decrease cost (e.g., improve enrollment; increase study power; reduce sample sizes; speed time to determine intervention effects)
- Increase applicability of research results to broader populations
- Better inform go/no-go, regulatory, and reimbursement decisions
- Create more accessible, patient-centric research

To enhance
clinical care

- Improve the quality of information available to clinicians
- Improve care efficiency by moving from a 9-5 to a 24/7 model of care
- Create more accessible, patient-centric care

To power
public health

- Identify risk behaviors and risk factors
- Deliver timely interventions towards improved prevention
- Provide surveillance tools to recognize trends that influence health outcomes
- Better inform public health decision-making

Source: Playbook team analysis
Measuring health using digital sensing products offers a more holistic view of a person’s lived experience.

**Visible Data Points** (episodic)
- Data collected from traditional visits to hospitals, clinics, and sites

**Invisible Data Points** (continuous)
- Data collected during everyday life

Source: “Visible vs. Invisible Data” chart designed by Evidation Health, re-worked by Elektra Labs, Playbook team analysis
Build the foundation for digital clinical measures

**Measures**
What do you want to measure? Why?

**Technologies**
What are the right tools for the job?

**Operations**
What’s needed to deploy remotely and at scale?

Then customize by context of use...

...to accelerate *Clinical Research*.

...to enhance *Clinical Care*.

...to power *Public Health*.

Source: Playbook team analysis
Following **The Playbook** flow, you’ll avoid order related pain points

### OPTIMAL FLOW

**Measures**
"Parkinson’s patients tell us that being able to walk independently is important, so we’re interested in measuring activity"

**Technologies**
"Using a smartwatch with accelerometer"

**Operations**
"Deploying 250 smartwatches across 15 countries"

### COMMON ISSUE #1

**Technologies**
"I saw a cool Apple watch at a Conference"

**Operations**
"I ordered 250 of them! Shipping to our patients."

**Measures**
"2 years later reviewing results: ‘Discard data. No clinically relevant signals yet in Parkinson’s’"

### COMMON ISSUE #2

**Operations**
"We’re deploying 250 smartwatches across 15 countries"

**Technologies**
"Patients are having Bluetooth connection issues; security incident. Compliance is down"

**Measures**
"We weren’t able to gather any usable data to construct a measure"

Source: Playbook team analysis
The Playbook builds a shared foundation for developing and deploying digital clinical measures using a step-wise approach:

**Measures**
1. Determine the **meaningful aspect of health** (MAH)
2. Identify the **concept of interest** (COI)
3. Define the **digital measure** (e.g., outcome/endpoint)

**Technologies**
Evaluate the **risk/benefit** to ensure safety and efficacy (e.g., validation (V3), utility & usability, security, data rights)

**Operations**
Plan for the **jobs to be done** during deployment (e.g., purchasing, distribution, monitoring, data analysis)

Opportunities for **collaboration across industry** include:
- Promoting a culture of **ethics** to ensure equity and justice
- Setting and developing **standards** for digital measures
- Developing **benchmarks** to compare digital measures (e.g., algorithms)
- Participating in the **policy and regulatory** process (e.g., public comments)

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Source: Playbook team analysis
Begin by using the V3 framework to evaluate whether a digital measurement product is fit-for-purpose

**Verification** evaluates sample-level sensor outputs

**Analytical validation** evaluates the performance of an algorithm to convert sensor outputs into physiological metrics using a defined data capture protocol in a specific subject population

**Clinical validation** evaluates whether the physiological metric acceptably identifies, measures, or predicts a meaningful clinical, biological, physical, functional state, or experience, in the stated context of use and specified population

Source: [https://www.nature.com/articles/s41746-020-0260-4](https://www.nature.com/articles/s41746-020-0260-4), Playbook team analysis
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Source: Playbook team analysis
An evaluation framework for *fit-for-purpose* digital measurement products

**V3: Verification, Analytical Validation and Clinical Validation**
Does the tool measure what it claims to measure? Is the measurement appropriate for the target population?

**Security**
Does the manufacturer build safety by design? Is there a Disclosure Policy? Software Bill of Materials?

**Data Rights, Privacy, & Governance**
Who has access to the data and when? Is the privacy policy publicly accessible?

**Utility and Usability**
How is the tool worn? Battery life? Available technical support?

**Economic Feasibility**
What's the net benefit versus price? Is cost a one-time or subscription model?

Source: [https://www.nature.com/articles/s41746-020-0237-3](https://www.nature.com/articles/s41746-020-0237-3), Playbook team analysis
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Source: Playbook team analysis
Four stages of operational considerations when deploying remote monitoring

1. **Procure digital measurement products**
   - Acquire access to the needed technologies

2. **Prepare product-level ecosystem**
   - Authenticate, configure, and provision the tech
   - Integrate tech into broader platform
   - Prepare User Acceptance testing (UAT)
   - Train the staff

3. **Post Go-Live**
   - Monitor and serve the population
   - Provide alerts, software updates, maintenance
   - Tech support as needed

4. **Close Out**
   - ‘Close out’ processes look different across research, care and public health, though exist across all contexts

Source: Playbook team analysis
Digital measurement products are, by definition, connected to the internet. They are a type of *internet of (medical) things (IoMT)* product.

**With IoMT, you almost never deploy and forget.** These deployments are not static. Lessons from the world of traditional IoT can inform healthcare deployments.

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Source: Playbook team analysis
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A vision for the Future

The power of efficient, effective, & person-centered trials

- **Mary and David**
  - How stronger primary care relationships create a positive feedback loop of care outcomes.
- **Sarah**
  - How decentralized trials enable a broader group of individuals to participate.
- **Tim**
  - How connected sensors and real world data collection make it possible to run trials for rare diseases.

Mary and David

Cancer in the Latinx community

2021

- Trials are mostly done on white men
- Primary Care Providers don’t know about relevant trials
- Data is scattered and often not helpful

2030

- Trials are done across all populations
- Primary Care Providers are a central part of the clinical trial process
- Data is easily shared but controlled by the patient
Sarah
A BRCA2 “previvor”

<table>
<thead>
<tr>
<th>2021</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Most trials happen in a handful of major metros</td>
<td>● Trials can recruit from all over the world</td>
</tr>
<tr>
<td>● Data collection is done in a clinic or trial site</td>
<td>● Data is collected at home or via connected sensors</td>
</tr>
<tr>
<td>● Travel keeps many from participating in trials</td>
<td>● No travel means more participants in trials</td>
</tr>
</tbody>
</table>
Clinical trials for a rare kidney disease

2021

- Rare diseases are hard and not economically feasible to study
- Control arms can lead to unnecessary suffering
- Only large companies can absorb the cost

2030

- Anyone with a rare disease can participate in trials with remote sensors
- Synthetic control arms decrease the risk
- Smaller pharma companies can run trials