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*.

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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

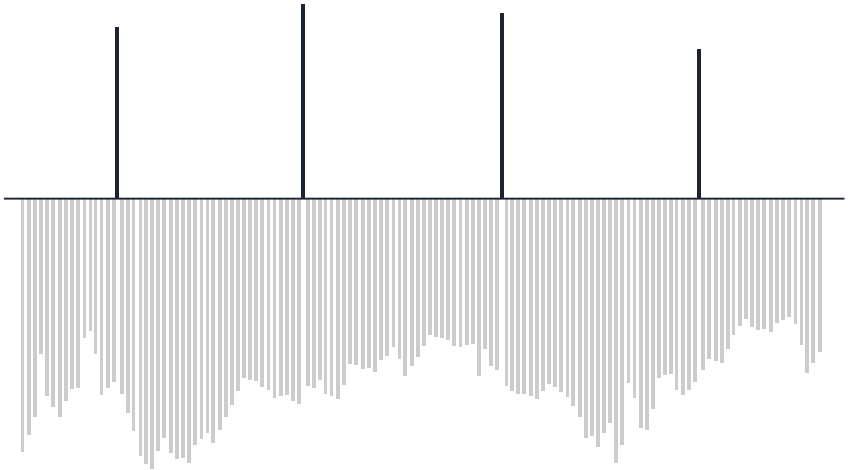
To power *public health*

- **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)



Invisible Data Points
(continuous)

Data collected from **traditional** visits to hospitals, clinics, and sites

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

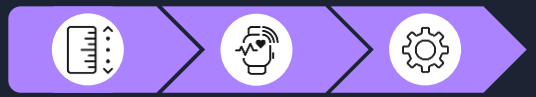
What's needed to deploy remotely and at scale?

Source: Playbook team analysis

Then customize by context of use...

...to accelerate *Clinical Research.*

...to enhance *Clinical Care.*



...to power *Public Health.*

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)

Source: Playbook team analysis

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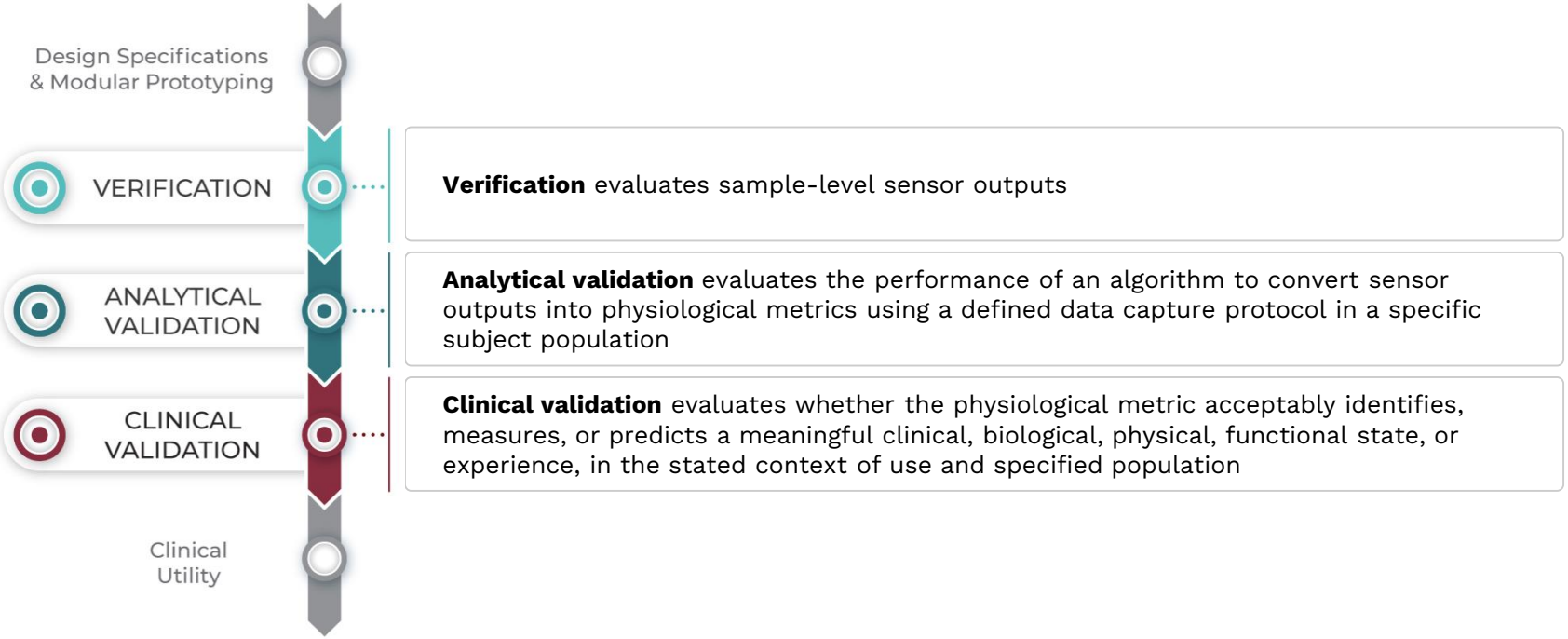
Source: Playbook team analysis

Begin by using the V3 framework to evaluate whether a digital measurement product is fit-for-purpose



Source: 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, Playbook team analysis

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Source: Playbook team analysis

Four stages of operational considerations when deploying remote monitoring

Go Live

Patients start using digital measurement products

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

PRO TIP

Operational considerations pull from **internet of (medical) things (IoMT)** concepts

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.

Source:https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/medtech-internet-of-medical-things.html, https://www.avnet.com/wps/portal/us/resources/article/3-steps-to-iot-deployment/, Playbook team analysis

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Source: Playbook team analysis

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Source: Creative Commons, Playbook team analysis

A vision for the Future

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

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

- **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.

SOURCE: https://www.healthaffairs.org/do/10.1377/hblog20210505.673654/full/

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”

2021

- Most trials happen in a handful of major metros
- Data collection is done in a clinic or trial site
- Travel keeps many from participating in trials

2030

- Trials can recruit from all over the world
- Data is collected at home or via connected sensors
- No travel means more participants in trials

Tim

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