The Playbook in action: Case Study Library

The Playbook
Driving Adoption

a DiME Project

playbook.dimesociety.org

See how organizations are using *The Playbook* resources to solve real-world problems within their organizations.
(Alphabetical by organization name)
(Last update October 4, 2021)

Want to include your case study? Submit details here.

ActiGraph provides sensors, services, and software for the use of digital endpoints in clinical research and trials.

> *The Playbook is a great "toolbox" when working with a diverse team. It allows for a clear level set on current situations, understand client needs, expand on education, and use technology successfully in a clinical trial.*

The Problem

We often start with determining how a problem/situation should be described, how it's resolved, and how to better understand the benefit of digital measures for specific roles using the correct methods. Improving the dialogue between technology providers and pharma companies is paramount to supporting more digital trials.

The Impact

✓ Project success, Greater patient centricity ✓ Clear communication internally - execs ✓ Clear communication - external partners ✓ Operational efficiencies and/or faster decision making ✓ Refined / Improved strategy

The Resources

The Business Developers and Operations use tools such as the "Dossiers" to scope their client conversations to address the biggest needs for their role.

- "Glossary" is also used by all departments as terms such as "digital endpoints", "wearables", "measures", "digital biomarkers", etc. are often misused by groups in industry.
- Masterclasses are often distributed by our BD and Scientific team to outlined the best practices in Digital Endpoint Development, Key Considerations for remote monitoring, and general domain knowledge building for clients.
- Micro-Playbooks (specifically, "Do we need a 510(k)") are great to reference during a client education to explain that certain regulations are required for use in clinical, but help outline some of the known issues with using consumer devices.
- Specific slides are often utilized to provide visual context to the correct order of events in novel endpoint development (like slide 27). The idea of identification of Measures beneficial to the patient leading to Tech validation and then actual deployment is largely misunderstood in industry.

Bayer is a Life Science company with a more than 150-year history and core competencies in the areas of healthcare and agriculture. With our innovative products, we are contributing to finding solutions to some of the major challenges of our time.

> *"The Playbook provided a comprehensive and well-structured information resource that helps our organization to build a common language and establish a common knowledge baseline for different functions to be able to engage in a more constructive and streamlined fashion."*

The Challenge

Several cross-functional working groups have been established within Bayer to establish processes and share knowledge about the use and development of novel digital measures and DCT components in our clinical development programs. We were trying to address several challenges:

- Promoting the right sequence of steps within cross-functional teams
- Understanding of validation requirements and how validation evidence is generated for novel digital measures
- Awareness of operational and data processing challenges that need to be factored into technology selection criteria
- Promoting patient- and science-focused approaches.

The Resource

The Playbook in its entirety provided a comprehensive and well-structured information resource that helps us to build a common vocabulary and establish a common knowledge baseline for different functions to be able to engage in a more constructive and streamlined fashion. Several functions are able to find valuable information in *The Playbook* slides and either dive deep into aspects directly related to their work or to get a general understanding of aspects related to the work of other functions.

The Impact

✓ Operational efficiency ✓ Clear communication with internal and external stakeholders ✓ Team education & cohesion ✓ Better alignment ✓ Greater patient-centricity ✓ Resulting in enhanced strategy

HumanFirst

HumanFirst serves those pioneering decentralized clinical trials and virtual care. Twenty-two of the top 25 pharmaceutical companies use HumanFirst's workflow and infrastructure solutions to evaluate and deploy connected sensor technologies.

> *"The Playbook is driving the industry towards a consistent language and framework for remote monitoring that leads to more productive conversations and empowered decision making."*

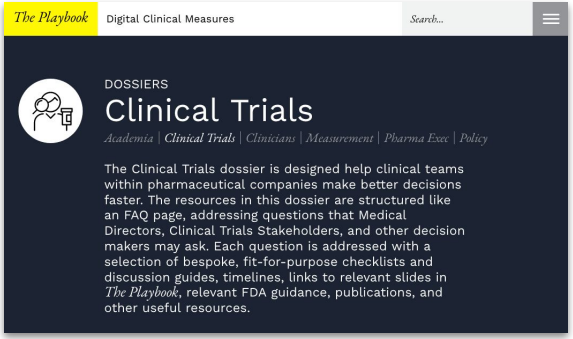
The Problem

All too often, organizations want to jump immediately into the technology selection and want HumanFirst to recommend, "XZY is the best heart rate monitor."

However, we found that selecting technology too soon results in circular conversations and there is no "best heart rate monitor" - it depends on the use case.

The Resource

The Playbook concretely distills language for WHY jumping into technology too soon creates problems. Citing *The Playbook* as an industry standard gives credibility to the process of starting with meaningful measurement and provides a framework for technology evaluations that a customer can adopt and adjust for their unique needs.



The Impact

✓ Operational efficiency ✓ Clear communication with pharma partners ✓ Team education & cohesion

koneksa
The Digital Biomarker Company

Koneksa is a leading patient-centric digital biomarker company for the pharmaceutical and biotechnology industries that develops end-to-end solutions for remotely collected clinical data. Koneksa supports agile decision-making in drug development and market strategy. By delivering integrated solutions for efficient trial designs that produce more meaningful data, Koneksa aims to revolutionize effect detection in clinical research.

> *"We are extremely proud of our involvement in the development of The Playbook, and wanted to promote The Playbook while demonstrating how our work exemplifies the principles it sets out."*

The Problem

At Koneksa, we are constantly seeking new and better ways to educate trial sponsors - our current clients, our potential clients, and the industry at large - on the potential benefits that digital clinical trials hold for them.

The Resource

Koneksa have developed our "Playbook Digest", a series of short whitepapers in which we summarize a relevant portion of *The Playbook* and relate it to an illustrative example of our recent work (see recent examples on oncology and pulse oximetry).

We used series to help increase awareness and understanding in the industry. It's great to have documentation of the collective wisdom of all of the thought leaders in this space.

The Impact

- ✓ Advance adoption of *The Playbook*
- ✓ Enable clear communication with external partners
- ✓ Advocate for increased patient centricity

Medable

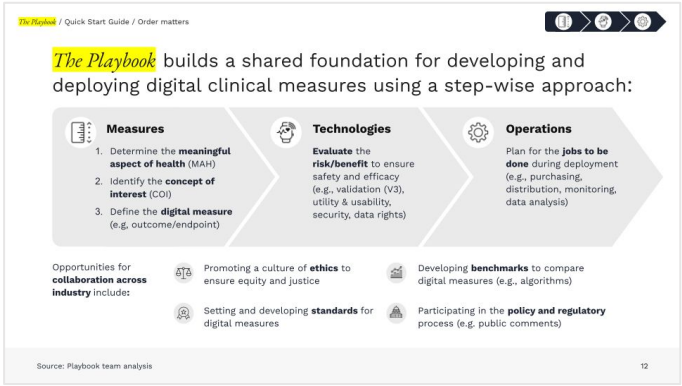
Medable is solving many of the longest standing challenges in healthcare: cost, time, and access to clinical trials. This mission is realized through a decentralized clinical trial platform that's proven to shorten trial timelines, capture efficiencies in research, and expand clinical trial access to every body and every biology.

> *"If we truly aim to be patient-centered, we must take a measured & patient-first approach to sensors.*
>
> *The technology will follow."*

The Resource

We have used *The Playbook* to educate both internally and externally about how we need to reshape and reorder our thinking as it relates to connected sensors and wearables. As a technology company with an enthusiasm for exploring innovative and interesting technology workflows, if we truly aim to be patient-centered, we must take a measured & patient-first approach to sensors. The technology will follow.

"Start with the measures" has been an incredibly powerful and simple idea to realign our approach and to have more effective conversations with sponsors considering remote measures via connected sensors.



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> *"The Playbook will become a well trusted reference for academics and commercial entities alike."*

The Resource

The Playbook has been a wonderful additional tool to point to for our customers. It helps align their understanding and expectations and supports the internal perspective we have built over the past several years as part of our NIH funded work.

As scientific expertise in this area grows and programs are built around digital measures that matter to patients and have clinical impact, the playbook will become a well trusted reference for academics and commercial entities alike.

MERCK

For more than 130 years, Merck (known as MSD outside of the U.S. and Canada) has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives.

> *"The Playbook provides a practical 'how to' guide for trial teams on coordinating the multi-functional efforts involved in implementation of digital measures in clinical trials"*

The Problem

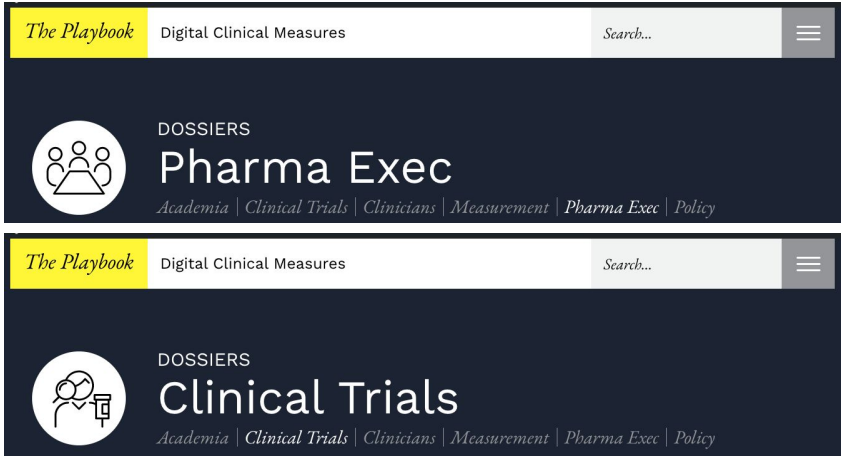
Highly cross-functional efforts are needed to enable successful implementation of digital health technologies (DHTs) and use of digital clinical measures in clinical trials.

We sought to develop resources for our multidisciplinary clinical trial teams to document best practices and considerations throughout the technology selection, trial planning, and execution processes and enable smooth coordination across functions.

The Resource

We are leveraging *The Playbook* and the following dossiers in building internal resources for clinical trial teams

- Pharma Exec Dossier
- Clinical Trial Operations Team Dossier



The Impact

✓ Operational efficiency ✓ Clear communication with Internal team ✓ Team education & cohesion

Takeda is a patient-focused, values-based, R&D-driven global biopharmaceutical company committed to bringing Better Health and a Brighter Future to people worldwide. Our passion and pursuit of potentially life-changing treatments for patients are deeply rooted in over 230 years of distinguished history in Japan.

> *"The Playbook(s) provided a useful reference and a single place where we could find the answers to many questions as well as credibility to our work."*

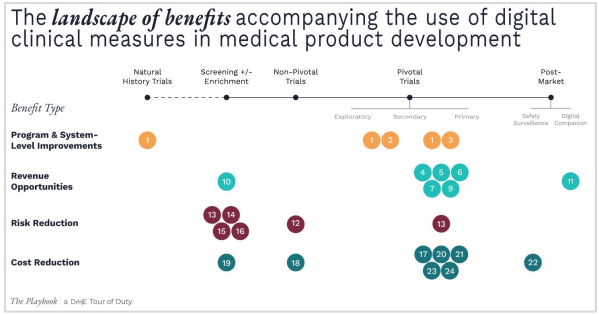
The Problem

We had to create internal educational materials for colleagues and leadership, to enable decentralized clinical trials and to get buy-in and support for our projects.

The Resources

We used *The Playbook* in its entirety as a reference guide as well as the micro playbooks on "Pharma Execs" and "510(k) need for devices" to refine our internal strategy

And, we used the suite of Playbook resources as a backbone for our own Playbook on Decentralized Clinical Trials and to support a dozen or so trials in 2021, leveraging digital devices for remote monitoring, biomarkers, at-home data collection, etc.



The Impact

✓ Project success ✓ Greater patient centricity ✓ Clear communication internally - team ✓ Clear communication internally - execs ✓ Operational efficiencies / faster decision making ✓ Team education and cohesion ✓ Refined / Improved strategy

VivoSense

VivoSense is an agile end-to-end scientific solutions company developing novel digital endpoints from wearable sensor data. We are focused on healthcare research & delivery, clinical trials and patient wellness. Our hypothesis-driven framework provides analytical and clinical validation leading to FDA approval.

> *"Having a common language from which to operate regardless of background or expertise has helped improve efficiency and project outcomes both internally and externally."*

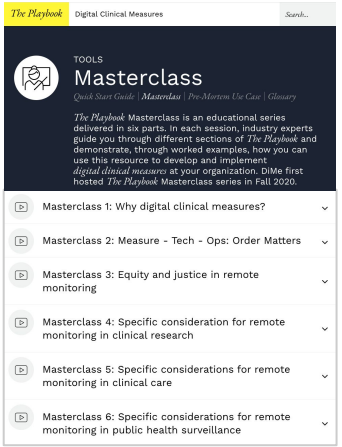
The Problem

Successful development and implementation of digital clinical measures requires experts that span a spectrum of disciplines including, data science, hardware and software engineering, regulatory, clinical research and medicine.

Effective communication across multidisciplinary teams cannot be taken for granted. It is important for us to enter conversations with clients and collaborators using a shared language.

The Resources

To help improve communication we have implemented the Masterclass Series for all new (and old) hires and refer often to the Glossary on *The Playbook* website. Having a common language from which to operate regardless of background or expertise has helped improve efficiency and project outcomes both internally and externally.



The Impact

✓ Operational efficiency ✓ Clear communication with pharma partners ✓ Team education & cohesion

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> *"The fact that these tools were collaboratively developed by a diverse group of experts with various stakes has made it an invaluable resource that we can confidently reference."*

The Problem

Pharmaceutical clients frequently approach us with a specific use case - they want to use a specific sensor in a specific clinical population to measure a specific endpoint.

Prior to the Measurement Dossier and the V3 framework published by DiMe, the large majority of these conversations were uphill battles, with clients not fully understanding why or when additional validation is required.

The Impact

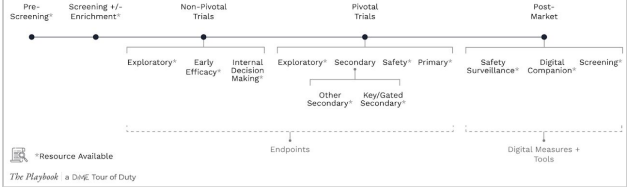
- ✓ Operational efficiency
- ✓ Clear communication with pharma clients

The Resource

We use the Measurement Dossier to help guide internal R&D decisions and recommendations to external clients. Part of our job at VivoSense is to evaluate the state of existing analytical and clinical validity evidence relevant for the specific use case, identify any missing pieces and make recommendations on how to most effectively move forward with the project or conduct additional validation activities.

The Measurement Dossier directly and concisely outlines the level of evidentiary requirements needed for digital clinical measures throughout the drug development process.

The landscape of resources for ***evidence requirements for digital clinical measures*** at various stages of drug development



WINTERLIGHT

Winterlight Labs has developed an automated speech analysis platform to monitor neurodegenerative and psychiatric conditions. Our tools are objective, sensitive, and easy-to-use, and are used by 5 of the top 10 Life Sciences companies to monitor disease progression and response to treatment.

> *"Patient-centricity is critical to novel biomarker development. The Playbook establishes best practices for patient engagement, including a practical how-to for the industry to follow."*

The Problem

Patient engagement, early and often, is critical to developing novel digital measures. Being patient-focused means developing measures derived from patient feedback, including a clear understanding of the aspects of health matter to patients.

We have the opportunity to re-define clinical measurement of speech and language by building novel measures that capture health concepts that are meaningful to patients.

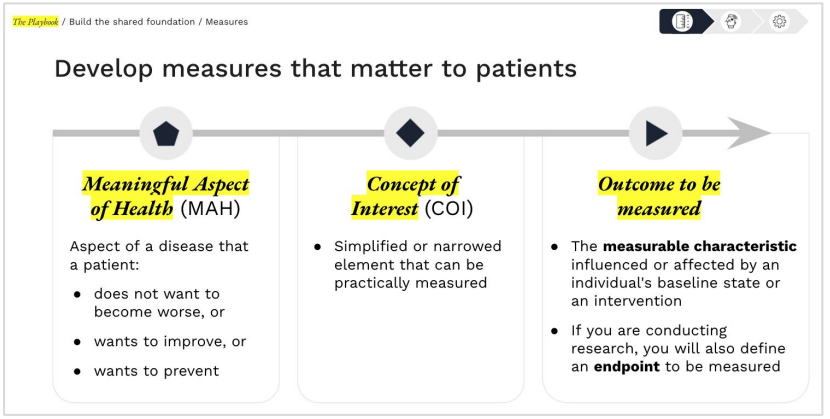
The Impact

✓ Clear communication with internal team ✓ Team education & cohesion ✓ Greater patient-centricity ✓ Operational efficiencies and/or faster decision making

The Resource

The Playbook presents a framework, including questions to ask patients at each step, that walks users through how to gather patient feedback with the aim of developing meaningful measures. The example questions and step-by-step guide from "Meaningful aspect of heath" to "Outcome to be measured" establishes best practice in patient engagement for the field to follow.

When developing new speech-based digital tools, we use the "measures that matter to patients" framework from *The Playbook* to guide patient interviews and to ensure we're building high quality, patient-centric measures of health.



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> *"The measurement checklists provide a framework for best practices in developing and validating novel digital measures. These will help bring consistency and scientific rigour to the field!"*

The Problem

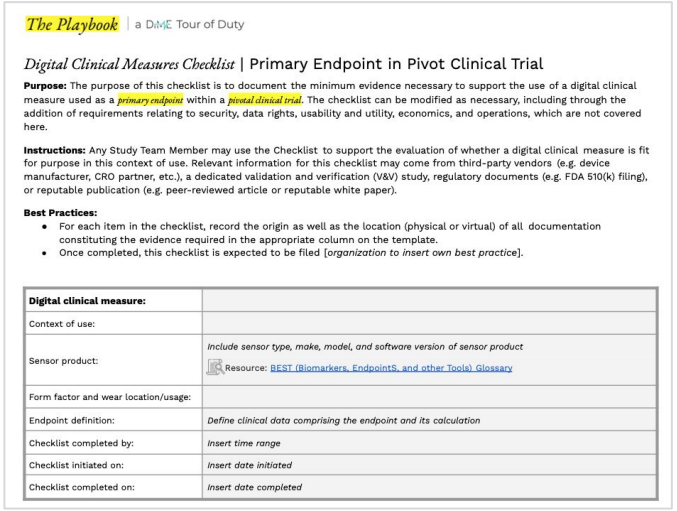
Winterlight's technology is currently used as an exploratory endpoint in a number of clinical trials in neurodegenerative disorders. As we collect data in more indications and further develop our technology, we want to work toward being validated as a secondary or primary endpoint.

The Impact

- ✓ Clear communication with internal team
- ✓ Clear communication with external partners
- ✓ Team education & cohesion
- ✓ Greater patient-centricity

The Resource

The Measurement Checklists on *The Playbook* website provide useful summaries of the types of evidence and clinical data required for different contexts of use. These checklists have helped inform our validation strategy and guide our research program into how speech is affected in various disease and disorders. We can use these frameworks to organize our existing data, know what to communicate to our partners, and define our next steps for research and validation.



The Playbook | a DiME Tour of Duty

Digital Clinical Measures Checklist | Primary Endpoint in Pivot Clinical Trial

Purpose: The purpose of this checklist is to document the minimum evidence necessary to support the use of a digital clinical measure used as a *primary endpoint* within a *pivotal clinical trial*. The checklist can be modified as necessary, including through the addition of requirements relating to security, data rights, usability and utility, economics, and operations, which are not covered here.

Instructions: Any Study Team Member may use the Checklist to support the evaluation of whether a digital clinical measure is fit for purpose in this context of use. Relevant information for this checklist may come from third-party vendors (e.g. device manufacturer, CRO partner, etc.), a dedicated validation and verification (V&V) study, regulatory documents (e.g. FDA 510(k) filing), or reputable publication (e.g. peer-reviewed article or reputable white paper).

Best Practices:

- For each item in the checklist, record the origin as well as the location (physical or virtual) of all documentation constituting the evidence required in the appropriate column on the template.
- Once completed, this checklist is expected to be filed [*organization to insert own best practice*].

Digital clinical measure:	
Context of use:	
Sensor product:	*Include sensor type, make, model, and software version of sensor product* Resource: BEST (Biomarkers, EndpointS, and other Tools) Glossary
Form factor and wear location/usage:	
Endpoint definition:	*Define clinical data comprising the endpoint and its calculation*
Checklist completed by:	*Insert time range*
Checklist initiated on:	*Insert date initiated*
Checklist completed on:	*Insert date completed*

WKD.SMRT

WKD.SMRT enables clinical trials to be faster, easier, lower cost, and lower risk by providing more powerful in-home real-life data. Using the power and reach of technology the WKD.SMRT system provides access to clinical trial participants in their own home, no matter where they live, with superior retention and adherence.

> *"If you're interested in learning more about #remotemonitoring across #clinical research, clinical care, and #publichealth - with a specific focus on connected #sensor products - DiMe Playbook is your one stop shop."*

The Problem

As a startup in the DCT space, we are accelerating innovation using more connected digital infrastructure which can capture RWD for participants in clinical trials who need to be continuous ambient monitoring. For this we needed to build processes that would help us:

- Benchmark; the current standard of care lacks sensitive or objective measures, and benchmarking a score across multiple independent data sets builds confidence that what we are measuring is a clinically meaningful benefit to patients and/or caregivers >>>
- Better understand how digital biomarkers can help set criteria for inclusion/exclusion, treatment allocation and evaluate treatment response, in particular because our platform will complement current standard of clinical trial processes. >>>
- Consider ethical and privacy concerns after reading the *The Playbook*, which allowed us to revise our vision and make it patient-first in this data-first digital era. >>>

The Resource

We used the following pages from *The Playbook* to address these challenges directly:

- Page 216: Benchmarking can identify the best measure when there are multiple approaches to measuring the same concept
- Page 259: Should I use an eCOA or a digital biomarker as my endpoint?
- Page 188: Fundamentals for clinicians / Redefining patient safety / Ethics: Ethical considerations in technology selection

The Impact

✓ Project success ✓ Greater patient centricity ✓ Operational efficiencies and/or faster decision making
✓ Team education and cohesion ✓ Refined/improved strategy ✓ Area knowledge/subject matter

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