VETERANS HEALTH ADMINISTRATION

Office of Health Equity

Madison Coffey, MPP(c)

Graduate Health Equity Fellow

Email: madison.coffey@va.gov

OFFICE OF HEALTH EQUITY

Created in 2012

Vision: To ensure that VHA provides appropriate individualized health care to each Veteran in a way that-

- Eliminates disparate health outcomes and
- Assures health equity

OFFICE OF HEALTH EQUITY GOALS

- 1. Leadership: Strengthen VA leadership to address health inequalities and reduce health disparities.
- 2. Awareness: Increase awareness of health inequalities and disparities.
- 3. Health Outcomes: Improve outcomes for Veterans experiencing health disparities.
- **4. Workforce Diversity:** Improve cultural and linguistic competency and diversity of the VHA workforce.
- **5. Data, Research and Evaluation:** Improve data and diffusion of research to achieve health equity.

OFFICE OF HEALTH EQUITY POPULATIONS

Veterans who experience greater obstacles to health related to:

- Race or ethnicity
- Gender
- Age
- Geographic location
- Religion
- Socio-economic status

- Sexual orientation
- Mental health
- Military era
- Cognitive /sensory / physical disability

OFFICE OF HEALTH EQUITY WEBSITE

https://www.va.gov/healthequity



TODAY'S CYBERSEMINAR

Advancing Health Equity through Inclusive Digital Health Measurement Product Development and Deployment



Madison Coffey, MPP(c)
Graduate Health Equity Fellow
Email: madison.coffey@va.gov



Yashoda Sharma, PhD

Program Director

Digital Medicine Society (DiMe)

Email: yashoda@dimesociety.org



Amanda Lienau Purnell, PhD

Director, Data and Analytics Innovation

Counseling Psychologist

VHA Office of Healthcare Innovation and Learning

Email: <u>Amanda.Purnell@va.gov</u>





Yashoda Sharma, PhD Program Director

Digital Medicine Society (DiMe)

Advancing Health Equity Through Inclusive Digital Health Measurement Product Development And Deployment

Veterans Health Administration - Office of Health Equity's Cyberseminar

Nov. 9, 2022 | Virtual



Our purpose

To advance the **ethical**, **effective**, **equitable**, **and safe** use of digital medicine to redefine healthcare and improve lives.



We launched in May 2019...







Strategic Advisory & Scientific Leadership Boards



















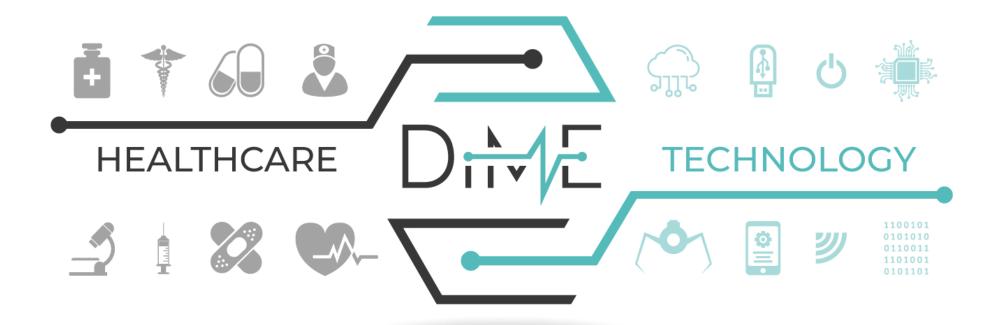
We deliver clinical quality work on a tech timeline

New knowledge & capabilities in the field spark new collaboration opportunities **Communication & education** Community Resources & publications generated by DiMe members, partners, & experts from DiMe & thought leaders in the field are across tech & healthcare unite to exchanged between various stakeholders & collaborate & identify ways to overcome across the many disciplines in the field. barriers to success. Greatest challenges & Actionable, evidenceopportunities to advancing based resources the field Research

Experts from across all disciplines address shared challenges through deep inquiry & data generation, creating actionable, evidence-based resources.



Interdisciplinary, multi-stakeholder collaborations





Starting with a new digital tool - digital health measurement



How do we ensure that we use digital measures to improve individuals' care, not violate their privacy?



How do we ensure that we can take a data-driven approach to public health without facilitating harmful surveillance?



How do we use digital health measures to improve access to care & health equity, not exacerbate these challenges along the digital divide?



FDA prioritized pre-competitive collaborations

Collaborative communities are pre-competitive collaborations of diverse stakeholders in the medical device ecosystem that are dedicated to improving outcomes and solving challenges in a specific health area. The FDA's Center for Devices and Radiological Health (CDRH) has designated participation in collaborative communities as a strategic priority.





The <u>Digital Health Measurement</u>
Collaborative Community (<u>DATAcc</u>),
advancing digital medicine to optimize human health.

Source: https://datacc.dimesociety.org



Expertise from across the healthcare ecosystem

- Fostering a diverse and inclusive community of experts in pursuit of our mission
- Establishing global best practices for successfully developing and deploying digital health measurement
- Supporting the advancement of regulatory science and commercial practices that foster success in the real world at scale
- Optimizing the person-centered use of digital health measurement across contexts of use and wherever it can do the most good for all people



Source: https://datacc.dimesociety.org



Ensure that those who need access, have access

Priority: Digital Inclusion

To ensure that diverse voices are included in all stages of the product development lifecycle so that diverse populations can utilize and benefit from digital health measurement, when the products are deployed

Inclusion Vectors

- Age
- Annual Household
 Income
- Cultural Practices
- Digital Technology
 Access
- Digital TechnologyLiteracy
- Disability

- Educational
 Attainment
- Gender Identity
- Geography
- Language
- Race and Ethnicity
- Sex Identified at Birth
- Sexual Orientation

Source: https://datacc.dimesociety.org



Inclusive digital health product development



DATAcc Toolkit for Inclusive Development

This toolkit helps digital measurement product developers to take an inclusive approach to product development.



Market Opportunity Calculator

Estimate the increase in market size and value by including new target populations



Library of Evidence

Access 100+ resources providing evidence of the benefits of inclusive product design



The Digital Health Measurement Product Development Process

Use this process lifecycle as the foundation of your product development

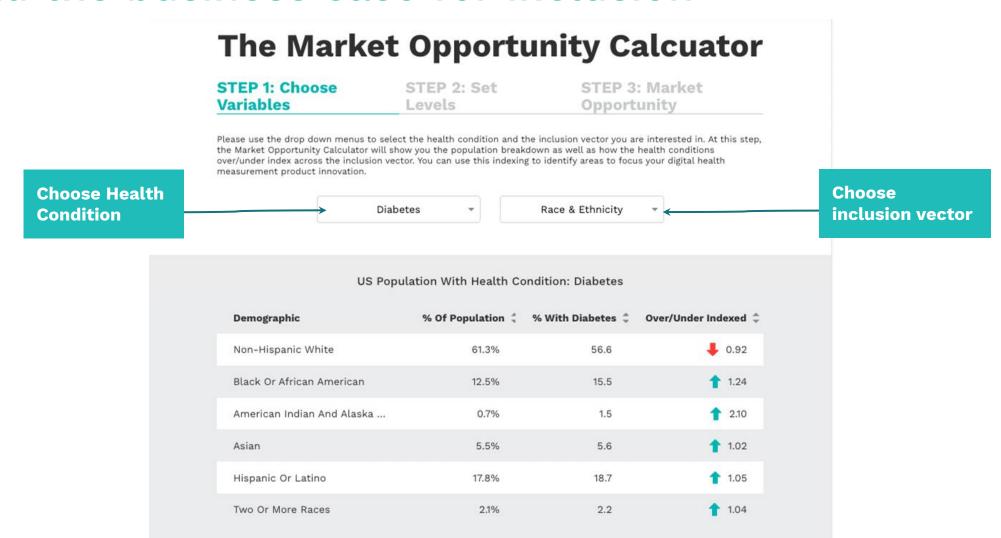


Framework for Inclusive Development

Utilize this step-by-step guide to drive inclusive approaches at each step of your product lifecycle



Build the business case for inclusion



Source: The Market Opportunity Calculator



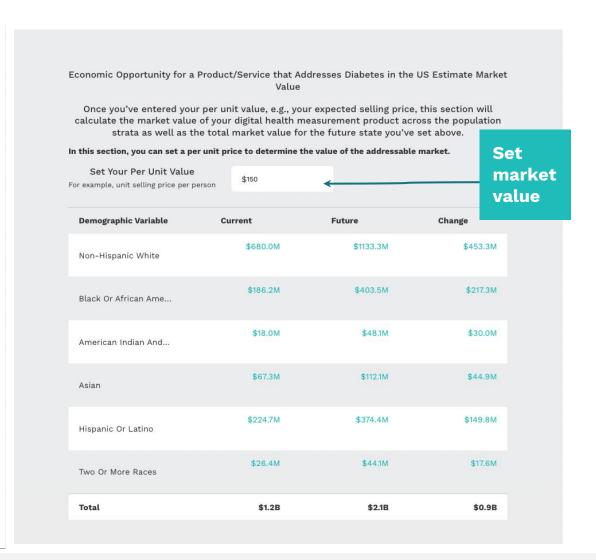
Build the business case for inclusion

STEP 1: Choose STEP 2: Set STEP 3: Market **Variables** Levels Opportunity Estimate Addressable Market Size and Set Levels for Current and Future State At this step, you will provide your estimates of current and future state. An example is level of engagement. First, you set levels around current engagement. Then, you set levels of engagement that your new product will achieve. You'll see the size of the population affected at your chosen threshold levels. The overall change in addressable population is automatically generated in the final column. Current Future Change 30% 50% **1** 20 Non-Hispanic white Population: 3,022,215 Population: 4,533,323 Population: 7,555,538 30% 65% **1** 35 Black or African American Population: 1,448,367 Population: 2,689,825 Population: 1,241,458 **1** 50 30% 80% American Indian and Alaska Native Population: 200,235 Population: 120,141 Population: 320,376 30% 50% 1 20 Asian Population: 299,018 Population: 448,527 Population: 747,544 30% 50% **1** 20 Hispanic or Latino Population: 998,506 Population: 1,497,759 Population: 2,496,264 **1** 20 50% 30% Two or more races

Population: 293,678

Population: 176,207

Population: 117,471



Set current

and future

market size



Build the business case for inclusion

Change in populations and value read out



Source: The Market Opportunity Calculator



Evidence for the benefits of an inclusive approach



The Library of Evidence Supporting Inclusive Design

This document contains links to over 100 publicly available resources that demonstrate quantified benefits, i.e, real numbers, in various aspects of inclusive design. They are sorted by the categories indicated.

Type of Benefit Inclusion Vector Digital Gender/sexual **Ameliorate** Better Broader Competitive Cognitive Digital/tech Language/ technology Age existing biases outcomes usage advantage impairment literacy orientation literacy access 44 50 49 Corporate Risk Strategic Organizational Physical Residential Socioeconomic Race/ethnicity Religion responsibility reduction disability setting imperative diversity Status **DATACC** Inclusivity | Toolkit for Digital Health Measurement Product Development

Source: The Library of Evidence



Evidence for the benefits of an inclusive approach

DATAcc Inclusivity | The Library of Evidence Supporting Inclusive Design

TYPE OF BENEFIT: Ameliorate Existing Biases

- 17. Do Professional Interpreters Improve Clinical Care for Patients with Limited English Proficiency? A Systematic Review of the Literature &
- Adherence to Cardiovascular Disease Medications: Does Patient-Provider Race/Ethnicity and Language Concordance Matter?
- Association of Patient-Physician Language Concordance and Glycemic Control for Limited-English Proficiency Latinos With Type 2 Diabetes &
- Lack of Diversity in Genetic Datasets is Risky for Treating Disease &
- The "inconvenient truth" about AI in healthcare &
- If Technology is to Improve Health Equity, It Won't Happen By Accident &
- The Economics of Inclusion: A Broader Customer Base Is the Bottom Line &

- Closing the Digital Divide in Healthcare & Equitable Telehealth Access
- Closing the Digital Divide: Ensuring Patients Have Access to Healthcare Technology Is a Priority of
- Characteristics of telehealth users in NYC for
- COVID-related care during the coron How Diversity, Equity, and Inclusion of
- Healthcare & What Is Disability Inclusion & Healtho
- That Promote It & Diversity and Inclusion Best Practice:
- We Must Bridge the Digital Divide in I
- Advancing Health Equity Through Tec
- Digital Healthcare Solutions: A Strate 32.

DATAcc Inclusivity | The Library of Evidence Supporting Inclusive Design

INCLUSION VECTOR: Race/Ethnicity

- 1. 36 Eye-Opening Inclusive Marketing Statistics That Prove Its Power for 2022 8
- 2. Inclusive Design: Bridging the digital divide and increasing ROI &
- Despite 25 Years Of Ad Growth, Diversity Remains A Challenge &
- Characteristics of telehealth users in NYC for COVID-related care during the coronavirus pandemic &
- Digital healthcare platforms must focus on inclusion of
- How Diversity, Equity, and Inclusion can Influence Healthcare &
- Diversity and Inclusion Best Practices in Healthcare &
- We Must Bridge the Digital Divide in Health Care &
- How to Narrow the Digital Divide in U.S. Health Care 2
- The diversity and inclusion revolution: Eight powerful truths &

- 11. Racial Bias in Pulse Oximetry Measurement 🔗
- The Cost of Connectivity 2020 8
- The Business Case for Product Inclusion Design Practices
- Fact Sheet: Health Disparities by Race and Ethnicity 🔗
- Inclusive ads are affecting consumer behavior, according to new research 2
- Medical Algorithms Are Failing Communities Of Color 🔗
 - Real-World Evidence: Research Reveals a Lack of Racial Diversity in Clinical Trials for Cancer Drugs
- Algorithmic Bias in Health Care Exacerbates Social Inequities — How to Prevent It &
- Ensuring that biomedical AI benefits diverse populations 19.
- Dissecting racial bias in an algorithm used to manage the health of populations.
- How Diverse Leadership Teams Boost Innovation &
- Why digital inclusion matters to health and social care
- Amplifying Black voices. What health care organizations can do to advance diversity, equity, and inclusion in the workforce &

DATACC

Inclusivity | Toolkit for Digital Health Measurement Development

DATACC Inclusivity | Toolkit for Digital Health Measurement Development

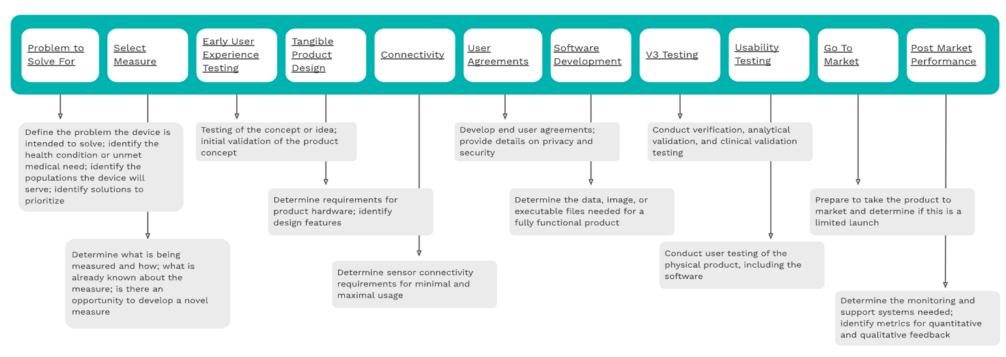
Source: The Library of Evidence 25



Key steps in the development lifecycle



Digital Health Measurement Product **Development Process**



NOTE: This development process was designed by DATAcc Subject Matter Experts, following the FDA Device Development Process.

DATAcc Inclusivity | Toolkit for Digital Health Measurement Product Development





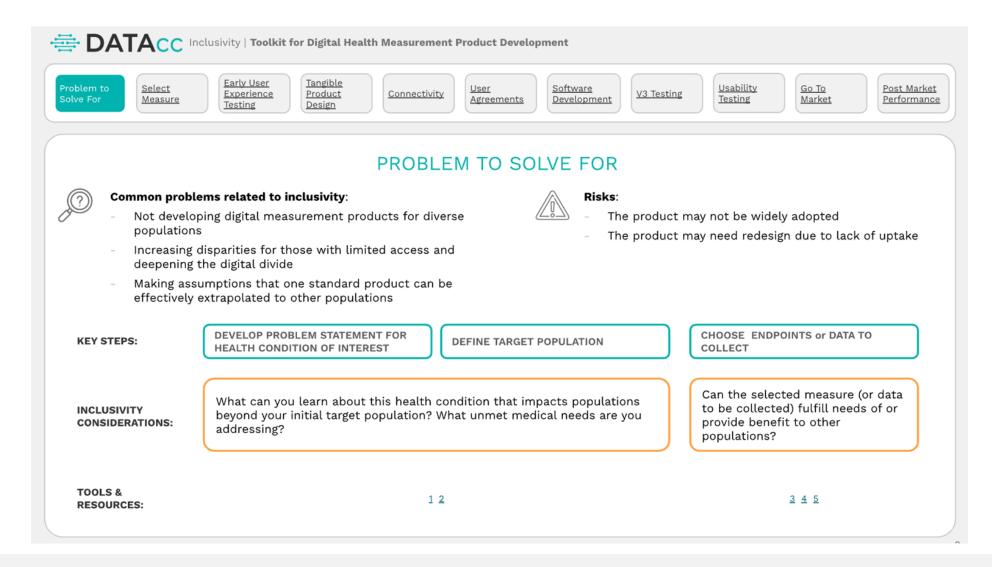
The **Framework** for Inclusive Development

Inclusivity Considerations throughout the

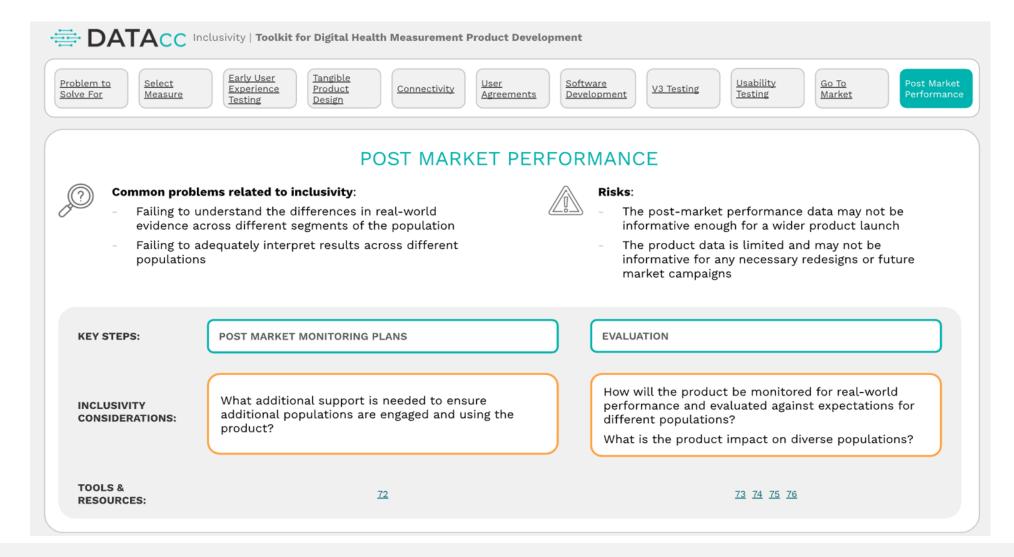
Digital Health Measurement Product Development Process

Early User <u>Tangible</u> <u>Usability</u> Problem to Select Software Go To Post Market User Experience Product Connectivity V3 Testing <u>Performance</u> <u>Development</u> <u>Testing</u> <u>Market</u> Solve For <u>Measure</u> **Agreements** <u>Testing</u> <u>Design</u>

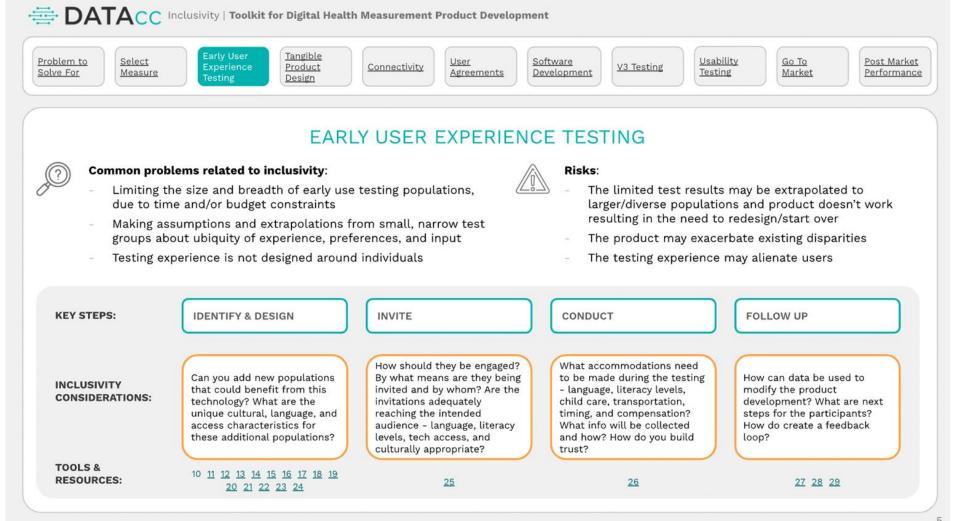












)



Appendix. Tools & Resources

Problem to Solve For

- 1 Designing for All: Consumer Response to Inclusive Design
- 2 DATACC Digital Inclusion Framework DRAFT
- 3 Personal Tech and the Pandemic: Older Adults Are Upgrading for a Better Online Experience
- 4 How digital health apps are empowering patients
- 5 7 facts about Americans with disabilities

Select Measure

- 6 Lack of Diversity in Genetic Datasets is Risky for Treating Disease
- 7 Benefits of using digital clinical measures in medical product development
- 8 <u>Digital Measures That Matter to Patients; A Framework to Guide the Selection and Development of Digital Measures of Health</u>
- 9 Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Early User Experience Testing

- 10 DATAcc Digital Inclusion Framework
- 11 Inclusive Public Engagement Plan
- 12 Six Essential Strategies for Inclusive Community Engagement
- 13 Inclusive Design: Building Products for Wide Spectrum of Users
- 14 Health Literacy Data Map
- 15 Visualizing the U.S. Population by Race
- 16 US Census Bureau OuickFacts
- 17 Worldometer Demographics
- 18 CDC Chronic Diseases in America
- 19 Chronic disease morbidity

20 Nielsen's 10th-Year African American Consumer Report Explores The Power Of The Black Community From Moment To Movement

₩ DATACC

- 21 2020 Profile of Older Americans
- 22 NHE Fact Sheet
- 23 The Economic Costs of Pain in the United States
- 24 7 facts about Americans with disabilities
- 25 You Need to Ask Patients
- 26 PCORI Engagement Rubric
- 27 90% of Patients Say Loyalty Relies on Patient Financial Experience
- 28 America's Health Rankings 2021
- 29 1 in 5 Patients Find Wearables Hard to Use

Tangible Product Design

- 30 An Open Approach
- 31 Accessible Design vs. Inclusive Design
- 32 Designing for inclusivity: How and why to get started
- 33 What is a Modular Design? Everything You Want to Know in 8 Easy Answers!
- 34 Top 10 UX Design Fundamentals That Developers Should Know

Connectivity

- 35 Connect 2 Health FCC
- 36 Mobile IoT Deployment Map
- 37 Internet/Broadband Fact Sheet
- 38 Focus on the United States
- 39 How might internet connectivity affect health care access?
- 40 IoT Empowers People with Chronic Diseases to Achieve Quality of Life



Resources in action



A Member of the Roche Group

Genentech is a large biotech company with digital focus areas in Oncology, Neuroscience, Inflammation, and Respiratory diseases.

There is great value in having DATAcc as an easily accessible resource that can quickly surface data on one aspect of value that inclusivity brings to the business.

- Celine Marquez, MD, Global Medical Director, Digital Health,



> We needed a foundational resource to point our study teams to when designing a digital trial



We provided our study teams with the <u>DATAcc Inclusivity Toolkit for</u> Development to increase inclusive and diverse patient representation in



- ✓ Greater patient centricity.
- ✓ Clear communication with internal teams and executives,
- Team education and cohesion.
- ✓ Refined/improved strategy.
- ✓ Operational efficiencies.
- / More buy-in.
- ✓ Meeting strategic imperative regarding inclusivity.

Strategic Planning



a D™E Project



BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care.

Just educating during the roll out of a product is not enough; we need to make sure that the data input that informs products are also enabling inclusivity early in the data collection phase in order to minimize unintentional exclusion.

- Kalvin Yu, MD VP, Medical Affairs, US Region, BD

TOOLKIT TOOLKIT FOR DEVELOPMENT



access to healthcare are disproportionately affected by COVID. Analytics related to COVID outcomes are largely based on electronic records that are notorious for being less accurate in designating race and ethnicity. As the pandemic has shown, better documentation of such can improve the analytic outputs that examine infectious disease outcomes by demographics.

>> Populations who traditionally have poorer



The Impact

We expect:

✓ Greater patient centricity, ✓ Clear communication internally and externally, 🗸 Refined / Improved strategy, ✓ More buy-in, ✓ Meeting strategic imperative regarding



The Resources

- » BD has partnered with the CDC in creating a COVID dashboard that gives them insight to end organ inflammation, ICU care, length of stay and other outcomes that may inform public health policy:
- >> The DATAcc Toolkits for Inclusivity touched upon known bottlenecks in accurately collecting race and ethnicity data from core inputs. The Toolkits may be helpful in sharing with relevant stakeholders in an education campaign to highlight the downstream analytic importance of having more accurate race and ethnicity data to help strengthen the insights regarding outcomes in demographics that might have poorer access to healthcare.

Identify Gaps

Knowledge.

AliveCor®

company producing ECG hardware and software for consumer mobile devices. The company is the first to receive FDA-clearance for a medical-device accessory to the Apple Watch.

> These tools helped us flip the 80/20 rule on its head and prioritize edge cases which result in designs that work for more people and have higher adoption, engagement, and retention.

- Justin W Ranton. Director, UX, AliveCor



The Problem

>> The challenge is always showing the return on investment (ROI) of design in different ways. In this case, it's helping to communicate the ROI of being inclusive in how we approach product design specifically around folks with disabilities through accessible design.



The Resources

> We have been able to use the DATAcc Inclusivity Toolkit for Development to influence our UX strategy and focus on one of our core design values of delivering inclusive experiences. The Market

Opportunity Calculator helps us communicate and prioritize inclusivity for different market segments by assigning a dollar value to the effort, helping us better communicate the ROI of inclusivity as a part of our design process.



The Impact

- ✓ Greater patient centricity
- ✓ Clear communication both internally and externally
- ✓ Operational efficiencies and/or faster decision making
- ✓ Team education and cohesion
- ✓ Refined/improved strategy
- ✓ More buy-in
- ✓ Meeting strategic imperative regarding incl

DATACC Inclusivity | Toolkit for Development



verily

Verily is an Alphabet company combining a data-driven. people-first approach to bring the promise of precision health to everyone, every day,

> Wearable devices offer an incredible opportunity to increase diversity in clinical studies, but they need to be accessible to a broader set of users to make this vision true.

- Kristin Size.

Head of Study Devices, Verily

The Problem

» Digital health technologies, such as wearable devices, can allow for remote data collection, allowing studies to be run in a decentralized manner and capturing data in free living situations. However, to do this, a wearable device must be designed to perform across demographically and medically diverse populations in real-world settings.



The Impact

- ✓ Greater patient centricity
- ✓ Clear communication ✓ Team education and



>> The DATAcc Framework for Inclusive Development provides targeted questions and checkpoints at each point in the development process that help ensure that inclusion stays a focus. The team used it to think about common problems associated with inclusion in wearable devices such as: skin tone, connectivity, body size, and age-related

Sensor performance:

>> PPG technology has an innate challenges due to green light absorption varying across different skin tones. Using the Framework for Inclusive Development we focused on endpoints that would allow us to evaluate performance. In addition, we prioritized including participants with darker skin, varying hair density, and wrist size in our early technical feasibility studies to optimize the sensor design.

Access & accessibility:

>> We also completed usability testing for items like setup, wearing and care for the device, and completing ePROs.

TOOLkit for Development

a DIME Project

Source: DiMe Resources In Action Hub - DATAcc



Inclusive digital health product deployment



DATAcc Toolkit for Inclusive Deployment

This toolkit is designed for teams in charge of deploying digital health measurement products to people, patients and communities to operationalize inclusivity.



Patients, Participants and Communities

Your tools for supporting understanding and trust in communities of end users



Implementing Inclusive Deployment

Your tools for implementing inclusive approaches when you deploy digital health measurement products in healthcare and research



Resources for Inclusive Deployment

A library of over 90 publicly available resources related to inclusivity that you can use in your deployment plan



Plan for effective community partnerships



Digital Health Measurement Collaborative Community

Guide for Developing Community Partnerships

Key Considerations to Support Inclusive Deployment

Purpose of this resource

- Provide an overview of the value of community partnerships for inclusive deployment
- Provide a list of key considerations
- Provide select references for more in-depth instruction and best practices for reaching out to community partners

Intended users | Clinicians, researchers, or other parties wanting to deploy a digital health measurement product.

Using the tool | When identifying the:

- 1. Scope of a healthcare program or research study, and/or
- 2. Key populations or segments of populations of interest that will be included.

Inclusivity lens | Community organizations can give health systems some insights into who, how, and why specific population groups defined by geography, age, race, ethnicity, culture, health condition, could benefit from a digital medicine technology. Authentic partnerships will seek strategies that benefit both types of organizations.

Essential Components

- Community Partnerships can Improve Long-Term Outcomes
- Key Steps for Developing Community Partnerships (Detailed instructions)
- Principles of Partnerships American Hospital Association
 Lessons Learned

Source: Patients, Participants, Communities



35

Design an inclusive engagement plan



Digital Health Measurement Collaborative Community

Guide for Inclusive Engagement

Purpose of this resource

- Describe the value of inclusive engagement for recruiting diverse populations and encouraging robust engagement with technology
- Provide a tool to help clinicians and researchers develop inclusive engagement
- Provide references for more in-depth information, best practices, and templates

Intended users | Clinicians, researchers, and other parties planning deployment of a digital health measurement product to the end user (patient or participant).

When this tool can be used | Early in the design/planning process, in conjunction with the Guide for Developing Community Partnerships.

Inclusivity lens | Inclusive engagement planning considers best practices such as multimedia training materials, comprehension level, spoken languages, transparency, access to information, and digital literacy and access. These elements will be instrumental for recruitment and retention for product use and overall program success

Essential Components

- Benefits of Inclusive Engagement
- Levels of Engagement Spectrum:
 Notify > Solicit > Integrate >
 Support
- Considerations for Inclusive Engagement Plan
- Resources for Designing Inclusive Engagement

Source: Patients, Participants, Communities



Quick start guides

Quick Start Guide for Community Partnerships

Quick Start Guide for Community Relationships

What To Do	How To Do It	Additional Tools
Define the purpose, goals, and intended outcomes of deploying this digital health product	Use the answers to these questions to formulate the purpose of your work: What are the goals for the individual and for the population? How does this product/program/study affect individuals and groups (potential benefits and/or risks)? Who are the intended user populations from whom digital measures will be collected? What digital measures will be collected? How will the digital measures or data collected be used? What are the goals for advancing the field?	Guide for Community Partnerships
Identify community needs, learn why you need help engaging the populations you want to reach	Determine how the perceived benefits of your product fit with the priorities of population groups you want to engage. Determine whether issues reflect distrust by that population of the health system, or if barriers are logistic and economic. Ensure your team attains cultural competency so that they can address rather than exacerbate underlying trust issues.	
Draft a deployment plan	Use the questions above and information about the community to draft a deployment plan and highlight	Inclusive Deployment Plan Worksheet



Quick Start Guide: Inclusive Engagement Plan

Quick Start Guide to Designing an Inclusive Engagement Plan:

What To Do	How To Do It	Additional Tools
Identify purpose and goals for the engagement plan	This should be based on information learned from the community partner	Use the <u>Inclusive</u> <u>Deployment Plan</u> <u>Worksheet</u>
Start with a diverse team	The team should reflect or include people who understand the lived experience of the population groups they seek to include (e.g. by race/ethnicity, age, sexual and gender identify, or language preference)	
Determine specific goals for engagement and identify key strategies	Review institutional data to determine who would benefit from the technology Set goals for recruiting specific populations and monitor recruitment and engagement	
Identify strategies for getting input from people with different types of barriers to technology adoption and use	Develop a communication plan with messages that reflect the value of the technology to different types of users • Go out into the community • Develop materials that are culturally respectful • Design materials to reflect health literacy best practices (i.e. at different reading levels) • Design materials for different visual preferences (i.e. graphics, videos) • Translate materials into multiple languages	See DATAcc Inclusivity Workbook: Inclusive Deployment

Source: Patients, Participants, Communities 36



Provide ongoing support for patients

WORKBOOK:

Prepping End Users

This workbook contains **sample** documents to support patients, participants, or communities to better understand the different aspects of a digital health measurement products. These tools should be used to supplement conversations between the clinician/researcher and end user.

- I. Sample End User License Agreement
- II. FAQs for End User Privacy & Security
- III. Questions to Ask Patient/Participant Perspective
- IV. FAQ Digital Health Measurement Product
- V. End User Bill of Rights
- VI. Learning About Context of Daily Life

Inclusivity Considerations through Deployment:

Inclusive deployment considers best practices such as multimedia training materials, comprehension level, preferred languages, transparency, access to information, and tech literacy and access.

The primary objectives for inclusivity are to increase accessibility, comprehension, and communication to foster trust for successful use of digital health measurement products.

□ DATACC

Inclusivity | Toolkit for Digital Health Measurement Product Deployment

Source: Patients, Participants, Communities 37



38

Empowering patients

Tools for Patients, Participants, and Communities | Workbook for Prepping End Users

Sample End User License Agreement

A sample end-user license agreement (EULA) with descriptions and plain language explanation of each clause

Inclusivity Impact | Explain digital product end-user agreements to **support transparency** and contribute to building **trust** that can result in long-term product use and **successful outcomes**.

Purpose of this resource | Provide definitions and examples of terms typically found in user agreements to help people understand the legal conditions associated with product use.

Note: This is a simplified example for training purposes. The "digital health. measurement product" in this case is a mobile phone application.

Intended users | Patients, research study participants, other users of a digital health measurement product. Clinicians/researchers and others planning for training their staff. This tool can also be used by patient advocates and community groups to train their staff or to distribute it to their community members.

When this tool can be used \mid Share with users when the product is first introduced and prior to them agreeing to use it. Use it to train and prepare staff for fielding questions from users.

Tools for Patients, Participants, and Communities | Workbook for Prepping End Users

FAQs for End User Privacy & Security

A list of frequently asked questions (FAQs) and answers explaining privacy and security elements end users should be aware of before agreeing to use a digital product

Inclusivity Impact | Explain key points from the informed consent, earlier, to **support transparency** and contribute to building **trust** that can result in long-term product use and **successful outcomes**.

Purpose of this resource | A handout for patients/digital product end users on privacy and security in general to reach a meaningful level of comprehension.

Intended users | Patients, research study participants, other users of a digital health product. This tool can also be used by patient advocates, community groups, and program leads with training their staff or they can distribute it to their community members.

When this tool can be used | Provided to users when the product is first introduced and prior to them agreeing to use it. It can also be used by clinicians/researchers to prepare their staff to discuss the product with the end users.

Tools for Patients, Participants, and Communities | Workbook for Prepping End Users

End User Bill of Rights

Similar to a patient's bill of rights, these are key elements users should be aware of when asked to use a digital health product

Inclusivity Impact | Explain requirements for digital health measurement product use to **support transparency** and contribute to building **trust** that can result in long-term product use and **successful outcomes**.

Purpose of this resource | A handout to help guide end users when deciding to use a digital health measurement product.

Intended users | Patients, research study participants, other users of a digital health product. Patient advocates, community groups, and program leads can distribute it to their community members.

When this tool can be used \mid Shared with end users prior to them beginning use of the product.

Source: Patients, Participants, Communities

Empowering patients

Tools for Patients, Participants, and Communities | Workbook for Prepping End Users

FAQ - Digital Health Measurement Product

A list of questions and answers that end users may have for the digital health product

Inclusivity Impact | Inclusive engagement planning considers best practices such as multimedia training materials, comprehension level, spoken languages, transparency, access to information, and tech literacy and access. This tool will provide support to ease users' concerns about the product.

Purpose of this resource | To ensure that the end user understands what the digital health measurement product does, how to use it, and why it's important.

Intended users | Patients or study participants. This tool can be customized to be fit-for-use by research teams or care teams to help train and prepare staff to field questions from end users.

When this tool can be used | The tool should be customized by the clinical/research team as soon as possible and shared with the user when they are introduced to the product.

Tools for Patients, Participants, and Communities | Workbook for Prepping End Users

Questions to Ask -Patient/Participant Perspective

This tool suggests questions that end users should ask the clinical or research team when they are first asked to use a digital health product

Inclusivity Impact | Explain the process and requirements for digital health measurement product use to support transparency and contribute to building trust that can result in long-term product use and successful outcomes.

Purpose of this resource | Provide patients with a list of questions that they sho ask related to the digital health measurement product, its operation, and how it relates to their health.

Intended users | Patients, research study participants, other users of a digital health product. This tool can also be used by patient advocates, community groups, and program leads with training their staff or they can distribute it to thar are inviting patients or participants to use a digital health community members.

When this tool can be used | Provided to users when the product is first introdu and prior to them agreeing to use it. It can also be used by clinicians/researcher to prepare their staff to discuss the product with the end users.

Tools for Patients, Participants, and Communities | Workbook for Prepping End Users

Learning About Context of Daily Life

This at-a-glance tool highlights information that would be valuable to care providers and researchers at the moment they measurement product

Inclusivity Impact | Notify patients and participants of **information to** share with clinic/research team so the team can better support users for long-term product use and successful outcomes.

Purpose of this resource | To give the product deployer a short checklist of pertinent information for the end user to share with the product deployer to better understand in context of the daily life in which the product will be

Intended users | Patients, research study participants, other users of a digital health product. This tool can also be used by patient advocates, community groups, and program leads with training their staff or they can distribute it to their community members.

When this tool can be used | As early as possible when establishing the relationship with the patient/end user.

Source: Patients, Participants, Communities

39



WORKBOOK:

Inclusive Deployment

This workbook contains **recommendations and best practices** to support clinicians and researchers when planning and implementing a protocol to deploy a digital health measurement product. These tools are intended to add a level of consideration that will allow for more inclusivity with the product use.

- I. Inclusive Deployment Plan Worksheet
- II. Inclusive Deployment Checklist
- III. Considerations When Deploying a Digital Health Measurement Product
- IV. Inclusive Communications Guide
- V. Digital Readiness Workflow
- VI. Digital Health Literacy Resources
- VII. End User Onboarding Checklist
- VIII. Informed Consent Considerations for Inclusivity

A Clear and Comprehensive Plan is Important to Ensure Inclusive Deployment of Digital Health Measurement Products

Your inclusive product deployment plan should begin by following the standard workflows and protocols used for deploying any product in clinical care or research. This includes adhering to standards required by your organization and Federal regulations.

The tools provided in this workbook are intended to supplement the tools currently used and will augment your process for inclusive deployment of a digital health measurement products

DATACC

Inclusivity | Toolkit for Digital Health Measurement Product Deployment

Source: Implementing Inclusive Deployment



This workbook contains tools to support deployment teams with onboarding users to a digital health measurement product, in an inclusive manner that can enhance transparency and build trust.

Inclusive Deployment Plan Worksheet

This tool can be used to draft an inclusive deployment plan and should be used with the rest of the toolkit.

Inclusivity Impact: Demonstrating process efficiency, which can build trust and result in long term product use and successful outcomes.

Inclusive Deployment Checklist

This tool serves as a check to ensure steps necessary for inclusive product deployment were followed.

Inclusivity Impact: An additional check to ensure the elements necessary to be more inclusive are included.

Considerations When Deploying a Digital Health Measurement Product

This tool serves as a final check to ensure steps and considerations necessary for inclusive product deployment were followed.

Inclusivity Impact: Additional checks to ensure that attention has been paid to the elements necessary for appropriate and full use of the digital health measurement product.

End User Onboarding Checklist

This tool serves as a final check to ensure steps and considerations necessary for inclusive product deployment were followed.

Inclusivity Impact: An additional checkpoint to ensure inclusive elements were followed.



Digital Readiness Workflow

This tool can be used to evaluate the end user's ability to receive the digital health measurement product and informs deployers of opportunities to be more inclusive.

Inclusivity Impact: An assessment to evaluate end user's digital readiness, within the context of what is needed to use the product.

Digital Health Literacy Resources

A list of digital literacy training modules ready for you to use that can be used as-is.

Inclusivity Impact: Provide additional support to users and communities, at any time, to build trust and result in long term product use and successful outcomes.

Inclusive Communications Guide

This tool provides guidelines for developing clear communications to ensure inclusivity.

Inclusivity Impact: Recommendations on making communications more inclusive and accessible to wider audiences of what is needed to use the product.

Informed Consent - Considerations for Inclusivity

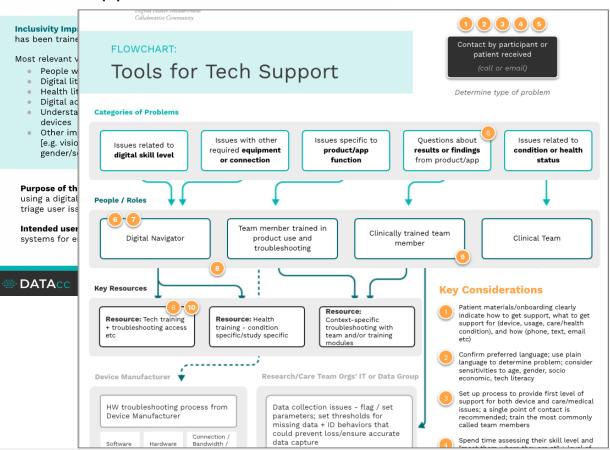
This tool lists additional concerns for inclusivity with a digital health measurement product that should be added to standard informed consent documents.

Inclusivity Impact: A list of key elements that will allow for better informed users.



Implementing Inclusive Deployment | Workbook of Inclusive for Support of End Users

Flowchart of Calls for User Support



Implementing Inclusive Deployment | Workbook of Resources for Support for End Users

Guide for In-Person Site Visits

Key points they come

Inclusivity In contribute to product use

Purpose of t check in with correctly.

Intended use

When this to



- 1. At the initial visit, schedule a follow up visit.
- Ask users to bring the digital health measurement product and any supporting components (e.g. chargers).
- Ensure that you have adequate resources to support the onsite visit (e.g. bilingual staff, and people who can help patients use accessibility features of the product or their mobile device).
- Use the **teach back method** and ask the user to explain how they are using the product.
- If available, review the data that reflects their usage of the product with them, noting any patterns for which troubleshooting could help.
- Use curiosity questions to learn and understand how the product is being used and the end user's level of comfort with the product.
- 7. Allow time for the end user to ask their own questions.
- Find out if there are any changes in the user's daily life, i.e. change in work schedule or home environment, that could interfere with using the product, fully or as needed.
- Determine if any adjustments need to be made to allow the user to continue to
 use the product, e.g., does their work schedule impact their ability to track or
 sync up data as required by the care/research team.
- Confirm that the end user understands how to use the product, has everything needed to use the product effectively, and knows how to get additional help if needed.



Source: Implementing Inclusive Deployment

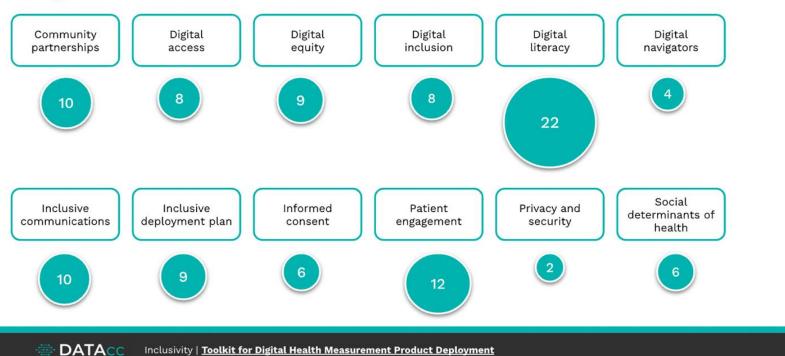




The Resource Library: Inclusive Deployment

This document contains links to publicly available resources that support inclusivity throughout the deployment process. They are sorted by the where they can provide information relevant to the toolkits; some may serve multiple purposes.

Categories of resources



Source: The Resource Library: Inclusive Deployment



Digital Access

- 1. Digitunity
- 2. EveryoneOn
- 3. Human-I-T
- 4. Literacy Minnesota
- 5. Mobile Citizen
- 6. National Digital Equity Center
- 7. National Digital Inclusion Alliance
- 8. PCs for People

Digital Equity

- 1. Digital Inclusion in Health and Care
- 2. Digital Inclusion For Health And Social Care
- 3. Leveraging Healthcare for Digital Inclusion
- 4. <u>How Healthcare Can Support Digital Health</u> <u>Equity</u>
- 5. MANA, a National Latina Organization
- 6. Toolkit for Digital Health Equity
- 7. <u>Digital Equity Playbook</u>
- Informative Technologies; Center for Digital Equity
- 9. Digital Inclusion Coalition Guidebook

➡ DATACC

Inclusivity | Toolkit for Digital Health Measurement Product Deployment

Resources in action





Public Health Innovators, LLC provider consulting services to support development and adoption of digital health tools to benefit individuals and population groups that have been historically excluded from the opportunity to use the internet to transform their lives and their communities

The DiMe toolkits have been invaluable for my work helping health systems and technology companies ensure that digital health products mitigate, rather than exacerbate health inequities. The synergistic power of the digital health and the digital inclusion ecosystems can now be leveraged at scale."

-Amy R Sheon, PhD, President, Public Health Innovators



The Problem

- Digital health tools have been optimized for the digitally privileged, and health systems are struggling to reach patients that lack access to the internet, devices and skills needed for digital medicine.
- > The health and technology sectors have limited awareness of digital inclusion organizations and methods, and digital inclusion experts have limited experience applying their methods to health applications and settings.



he Resources

- Public Health Innovators is using the <u>DATAcc</u> Toolkits for Inclusive Development and Deployment of Digital Health Technology to adapt the National Digital Inclusion Alliance's (NDIA) Digital Navigator model for health care.
- Currently, public health organizations in Northeast Ohio are disseminating the DATAcc Toolkits to those accessing their Digital Access Indicators Dashboard
- One health system is incorporating tools such as the <u>Guide for</u> Developing Community Partnerships and the Digital Readiness Workflow as they prepare to test a model to screen and refer patients lacking digital health readiness to community resources. The health system is also incorporating the Inclusive Communications Guide and the End User Onboarding Checklist as they prepare providers and patients for an impending transition to a new electronic health record
- The Flowchart of Calls for User Support within the Workbook for Inclusive Support is intended to ensure that tech support can help patients with basic digital skill and device barriers.



- > By adapting digital inclusion best practices for health care, health systems can deliver digital solutions to all patients. Groups that have been historically marginalized can begin to leverage digital tools to improve their health and communities. Collectively, the DATAcc Toolkits enabled Public Health Innovators to help
- √ Greater patient centricity
- √ Clearer communication and team cohesion
- ✓ Operational efficiencies and faster decision making
- √ Improved health outcomes and reduced health disparities



a DimE Project



Healthy Northeast Ohio is a public online resource for data on health and social determinants of health in Northeast Ohio. Healthy Northeast Ohio's mission is to improve and support community health across a 9-county region by providing stakeholders with access to vetted population health data and resources. The website offers users access to more than 300 health and quality of life indicators, other indices, dashboards, and other resources to support local health improvement activities



- Healthy Northeast Ohio



The Problem

- > Internet access and adoption are now recognized as social determinants of health
- > Resources are urgently needed to ensure that digital health strategies, made ubiquitous by the pandemic, benefit all populations.



The Resources

- » Digital Access Indicators, which highlight disparities in ownership of computers, smartphones and subscriptions to broadband internet service for households in the region, are collected in one of several dashboards on healthyneo.org.
- >> Health Northeast Ohio has started to direct its partners and website visitors to the DATACC Toolkits for Inclusive Development and Deployment of Digital Health Measurement Products to support digital equity and inclusion in the Northeast Ohio region.
- > The Workbook for Inclusive Deployment is helping Healthy Northeast Ohio partners and website visitors to plan for incorporating digital health technology in public health and health care.
- > The Workbook for Prepping End Users is helping to ensure that people understand the security and privacy issues involved with digital health tools.



Adding the DATAcc resources to Healthy Northeast Ohio's website is helping its partners:

- ✓ Drive greater awareness of the range of digital health products available for health care, public
- ✓ Learn about the potential for digital health to improve individual and population health.
- ✓ Leverage strategies to mitigate the risk of digital health worsening health disparities.
- Decrease digital access disparities and increase health equity.



a D₩E Project



Demonstrating DATAcc in Action With ... IeHE

THE BACKGROUND

» Underserved communities are disproportionately impacted by chronic disease; with tools and care models deployed using new technology, there are growing concerns that innovations will lead to an

exacerbation of disparities.

- » Many digital health products are created and introduced, to the market lacking cultural competency, impacting usage rates in diverse groups.
- » Tackling barriers to improved health outcomes requires stakeholder collaboration across the healthcare

THE ORGANIZATION

- » Institute for eHealth Equity is a social impact consulting firm that works to improve health equity and reduce health disparities.
- » Through the creation of culturally appropriate, collaborative online spaces. the Institute works with faith and community-based organizations to promote the benefits of leveraging technology to improve health outcomes
- » The Institute is working with digital innovators to ensure technology is developed in a culturally aware manner. It is also fostering a relationship between digital innovators and community stakeholders - An important piece of this being: getting de-identified and aggregated data back to community leaders to understand the impact of their work.

WHY IT MATTERS

"Digital health tools have not yet shown substantial adoption or impact among underserved populations and this may lead to greater disparities in health outcomes. Our work, along with our DATAcc partners, is specifically designed to change paradigms, and deliver culturally appropriate solutions that shorten the distance between health technology developers, the tools they create, and the underserved community members that benefit from greater inclusivity" - Silas Buchanan, Founder and CEO, Institute for eHealth Equity

The DATAcc Resource to Use

The DATAcc Toolkits for Inclusive Development and **Deployment** offer product development resources and guide for developing community partnerships.



a D™E Project

Source: DiMe Resources In Action Hub - DATAcc



Resources in action



health-care provider in the state of Connecticut, offers primary medical, dental and mental health services to low-income, uninsured and underinsured patients using innovative service delivery models and state of the art technology. CHC is one of seven FQHCs enrolling for the All

Engaging with people who have historically been underrepresented in biomedical research was a cornerstone to our mission. The toolkit allowed us to design our outreach strategy in a participant-centric and inclusive way.

- Amy Taylor, Vice President, CHC



CHC needed tools to

engagement of the

inform their outreach and



The Resources

- >> The CHC team leveraged DATACC resources, specifically the Guide for Community Partnerships looking to expand the eligibility for inclusion to and Guide for Inclusive Engagement, to help plan non-patients for a AoURP. engagement with community-based organizations.
 - > CHC incorporated guidance from the Inclusive Deployment Checklist to ensure they were thinking of the needs of members of the community and not just their organization's needs.



non-patient populations. The Impact

- > CHC achieved greater patient-centricity by using DATAcc resources, Although the community members are not patients, they will be participants in the research study, and it is necessary to understand what matters to them most and how to engage in a participant-centric way.
- As CHC expands its outreach for inclusion in its research, it wants to reach historically underrepresented populations in biomedical research. DATAcc helped them understand the community's needs and how to build trusting, long-term partnerships.





An inclusive communications strategy is foundational to our work in our national research program. Using this tool kit allowed us to align our team members to one strategy with

> Katrina Yamazaki. Principal Investigator and Senior Scientist, CHC

clear and accessible expectations.

Commun*ty Health Center, Inc.

Connecticut, offers primary medical, dental

and mental health services to low-income.

uninsured and underinsured patients using

of the art technology.

innovative service delivery models and state



The Problem

> The CHC team wanted to ensure that its communication strategy for engagement with potential and existing participants is transparent, appropriate, and inclusive.



The Resources

- » The CHC leveraged several <u>DATACC</u> resources including the <u>Workbook for Inclusive</u> Deployment, Inclusive Deployment Plan Worksheet, Inclusive Communications Guide, and Digital Readiness Workflow to help inform CHC's communications strategy.
- >> The organization leveraged the key elements of the tool's recommendations, including utilizing a clear, concise message; having the appropriate reading level, including visual aids; and avoiding jargon to be more effective in its outreach, engagement, and retention work with participants and community members.



- > The area of greatest impact was the team training utilizing this guide helped the CHC team have clear direction on how to engage with participants at every stage and provided CHC managers with very clear training guidelines for their team members, with a focus on inclusivity and participant-centered design.
- > The tool was also impactful because it is accessible and can be put into use immediately.



DATACC Inclusivity | Toolkit for Deployment



TACC Inclusivity | Toolkit for Deployment

a DIME Project



Community Health Center, Inc. (CHC), a leading health-care provider in the state of Connecticut, offers primary medical, dental and mental health services to low-income, uninsured and underinsured patients using innovative service delivery models and state of the art technology.

The engagement tool provides for a highly accessible, actionable plan to help organizations more effectively partner with key stakeholders to produce greater benefits for all.

- Amy Taylor, Vice President, CHC



The Problem

The CHC team that focused on community-based COVID-19 vaccination efforts in vulnerable communities wanted to understand best practices for outreach and population.



The Resources

- > The CHC team leveraged DATACC resources, specifically the inity Partnerships and Guide for Inclusive
- >> The guides helped CHC:
 - Understand partners' key needs better
- Create long-term plans for engagement, rather than single transactional moments
- Engage in trust building with key stakeholders
- Remain consistent with follow throughs



The Impact

- >> DATAcc helped shifted CHC's focus from short-term wins to long-term engagement and helped the organization develop an enduring strategy, despite the challenges of the pandemic.
- The engagement tools helped CHC better engage its typical partners (such as local health departments and community-based organizations) and broaden its reach to new partners.
- > New partners including those most skeptical and reluctant to receive a vaccine were successfully engaged by partnering with trusted community members (such as park workers,



a D™E Project



leading health-care provider in the state of Connecticut, offers primary medical, dental and mental health services to low-income, uninsured and underinsured patients using innovative service delivery models and state of the art technology.

The informed consent is critical to the success of participant engagement in any project. The DATAcc toolkit helps to ensure we are considering the critical points of the process.

 Katrina Yamazaki. Principal Investigator and Senior Scientist, CHC



>> The CHC team wanted to ensure that its informed consent was appropriately geared towards the intended population.



The Resources

- » The CHC leveraged several <u>DATAcc</u> resources including the <u>Workbook for Inclusive</u> Deployment, Inclusive Deployment Plan Worksheet, Digital Readiness Workflow, and Informed Consent - Considerations for Inclusivity
- >> The Informed Consent resource provided CHC with a guide to ensure that the informed consent it received from its national partner was appropriate for the intended population.
- >> The tools also helped CHC consider how to support the participant's engagement with the informed consent through the recommendation to include other family members (when and where appropriate) and to provide a clear way for participants to get in touch if any issues arise in the future.



The Impact

>> These tools greatly impacted the team's training and understanding of the appropriate way to present and share the informed consent with participants, encouraging appropriate family engagement and re-contact information



a DME Project



Inclusivity as the foundation



Start with developing digital health products that can serve the people who can benefit from it the most.

Be specific and deliberate throughout the product development lifecycle.



Patients, participants and the communities have to be the primary focus.

Build trust by understanding the needs of the people your clinical trials will serve.



Implementation of clinical trials and the use of digital health products needs to be intentional and focused on inclusivity.

Set the clinical trials team up for success with the appropriate approaches for inclusivity

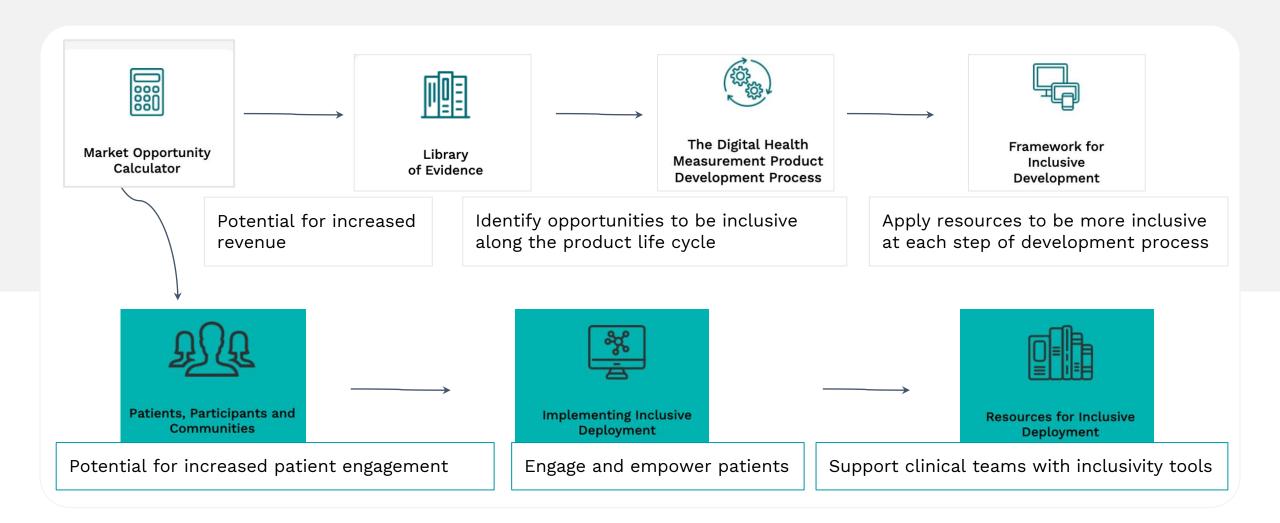


None of this work can be done in isolation, innovation for improved health outcomes and health equity needs all stakeholders, working together.

Decentralized and digitized clinical trials are complex, partnerships across the industry are critical.



Start with the business case



Source: https://datacc.dimesociety.org
49



Advancing best practices for digital health measurement

- Welcome new members
- New opportunities
 - o to build a more **robust community**
 - to address challenges inhibiting the advancement of digital health measurement products
 - o to **drive adoption and implementation** to ensure
 inclusion is foundational to digital
 health measurement



Source: https://datacc.dimesociety.org



Join us in advancing health outcomes and equity

Resource in Action



How are you advancing digital medicine?

Tell us how you're using DiMe resources & we'll feature your story in our new Resources in Action Hub!





THANK YOU

Yashoda Sharma, PhD | <u>yashoda@dimesociety.org</u>





Discussant

Dr. Amanda Purnell

Audience Q&A

Thank you!