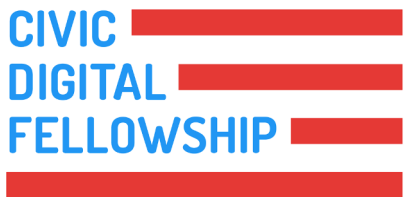


# DIGITAL HEALTH AT THE NIH: TRENDS, CHALLENGES, AND OPPORTUNITIES

Division of Blood Diseases and Resources, NHLBI  
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Columbia University

# WHAT IS DIGITAL HEALTH?

## **FDA Digital Health Center of Excellence, September 2020:**

The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

### Digital health is...

- Rapidly growing and diversifying
- Gaining attention across federal agencies
- Amplifying changes in biomedical and clinical research process

### Emerging challenges

- Difficult to track and define
- Unclear processes for validation and regulation

## DIGITAL HEALTH: A BRIEF TIMELINE

- 2009: Health IT for Economic and Clinical Health (HITECH) Act
- 2016: 21<sup>st</sup> Century Cures Act
- 2019: FDA Technology Modernization Action Plan
- Mar. 2020: FDA Digital Health Innovation Action Plan
- 2020: CMS and FDA promote telehealth and digital health therapeutics during COVID-19 public health emergency
- Sept. 2020: FDA Digital Health Center of Excellence established

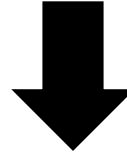
### Ongoing

- Office of the National Coordinator for Health IT (ONC) — Global Digital Health Partnership
- Agency for Healthcare Research and Quality (AHRQ) — Digital Health Research Program

## DIGITAL HEALTH AT NIH

- 2018: NIH Strategic Plan for Data Science
  - 2019: Notice on Fast Healthcare Interoperability Resources (FHIR) Standards
- 2020: Interagency Smart and Connected Health Initiative (w/ NSF)
- 2022: Notice of Special Interest on Digital Health and AI Validation
- Ongoing
  - ODSS implements FHIR Initiatives
  - Office of Science Policy initiatives
  - Digital Health Programs within NHLBI, NIBIB, NIA, and other I/Cs
  - Internal trans-agency and interagency working groups

Literature Review  
Federal government resources and webinars  
Conversations with NIH Employees



**Problem Statements:**  
What are the big picture trends in digital health at the NIH?  
What are the broader implications of this emerging field?

# Part I. Report on Trends in Digital Health

# DIGITAL HEALTH ACROSS FEDERAL AGENCIES

FDA Digital Health Criteria (Mar. 2018)	NIH RCDC Terms (FY 2022)
Advanced Analytics	Data Science (FY 2019 – present)
Artificial Intelligence	Machine Learning and Artificial Intelligence (FY 2019 – present)
Software as a Medical Device (SaMD)	Networking and Information Technology Research and Development (NITRD)
Cloud	
Cybersecurity	
Interoperability	
Medical Data Device System (MDDS)	
Mobile Medical App (MMA)	
Novel Digital Health	
Wireless	Telehealth (FY 2021 – present)

# METHODOLOGY

## Search Criteria:


- Activity Code: R01 and SBIR/STTR
- Award Type: New (Type 1)
- Fiscal Years 2013-2022

## Step 1. RCDC Terms

- NITRD
- Machine Learning and Artificial Intelligence
- Telehealth

## Step 2. Manual Search

- 10 FDA Categories
- Novel Digital Health
- Blood-disease-related projects



### Search Results

637 Projects

Search Criteria

Fiscal Year: 2022, 2021, 2020, 2019, 2018, 2017, 2016, 2015, 2014, 2013

Award Type: New

Activity Code: R01, SBIR/STTR

Exclude Subprojects: Yes

Text Search: "mobile health" OR "mHealth" OR "mobile application" OR "mobile medical application" (advanced)

Limit to: Project Title, Project Terms, Project Abstracts

Results are sorted by **Relevance**

Projects

Publications

Patents

Clinical Studies




News & More

List

Charts

Map

Filters

T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
<b>Promoting Effective Self-Management of Chronic Pain with mHealth Neurofeedback</b>									
1	R01NR019788	-01A1	 <a href="#">ELBOGEN, ERIC B.</a>	DUKE UNIVERSITY	2022	NINR	NINR	\$402,500	<a href="#">View &gt;</a>
<b>Clinic-level implementation of mHealth to improve HIV viral suppression for patients with substance use disorders</b>									
1	R01DA055527	-01A1	 <a href="#">WESTERGAARD, RYAN PATRICK</a> <a href="#">QUANBECK, ANDREW</a>	UNIVERSITY OF WISCONSIN-MADISON	2022	NIDA	NIDA	\$741,799	<a href="#">View &gt;</a>
<b>REDES: a peer network and mobile health (mHealth) enhanced CHW model to maximize COVID-19 vaccination among low income Latinos</b>									
1	R01MD017364	-01	 <a href="#">PAGE, KATHLEEN R</a> <a href="#">YANG, CUI</a>	JOHNS HOPKINS UNIVERSITY	2022	NIMHD	NIMHD OD	\$536,844 \$200,000	<a href="#">View &gt;</a>
<b>Home-based cardiac rehabilitation using a novel mobile health exercise regimen following transcatheter heart valve interventions (HOME RUN HITTER)</b>									



# 1. RCDC CATEGORIES

## NITRD:

- Funding stagnates around \$500M from 2010-2015
- Funding doubles from \$1B to \$2B from 2015-2021

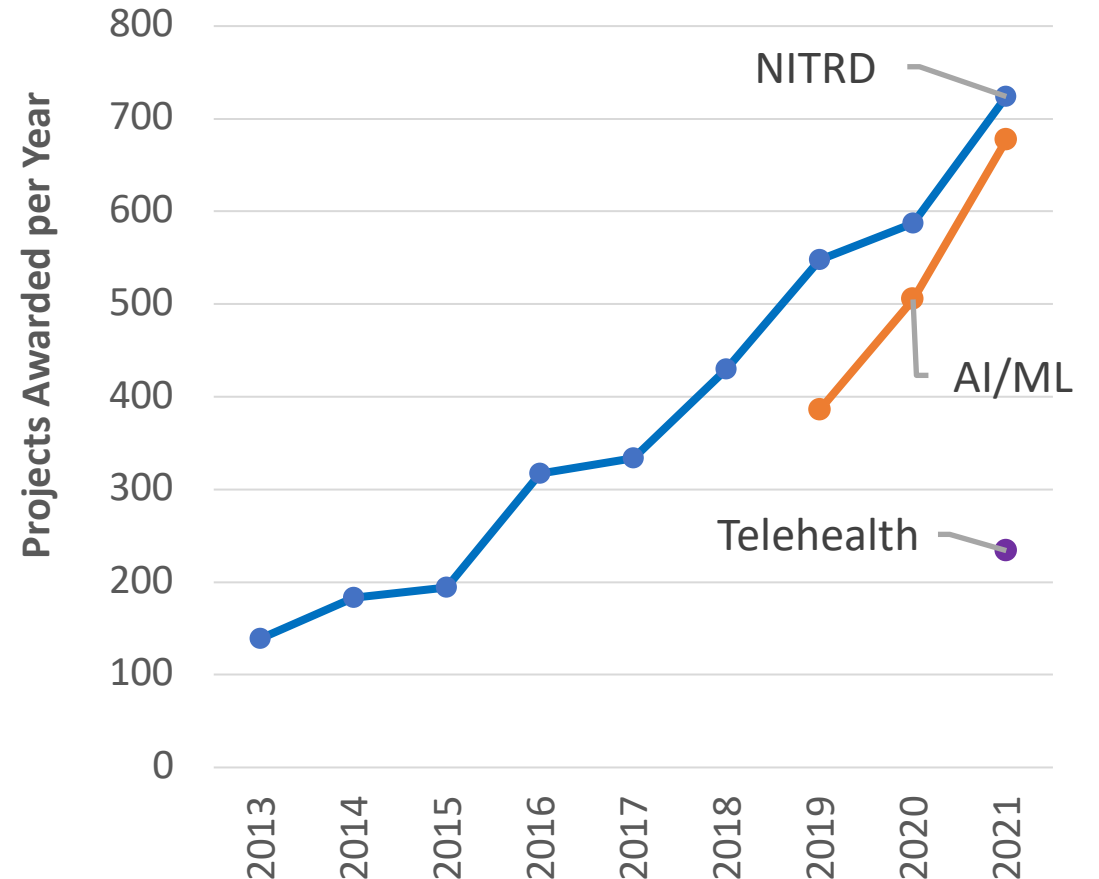
## Machine Learning and AI:

- RCDC established in 2019 (alongside Data Science)
- Funding doubles from \$585M to \$1.14B from 2019-2021

## Telehealth

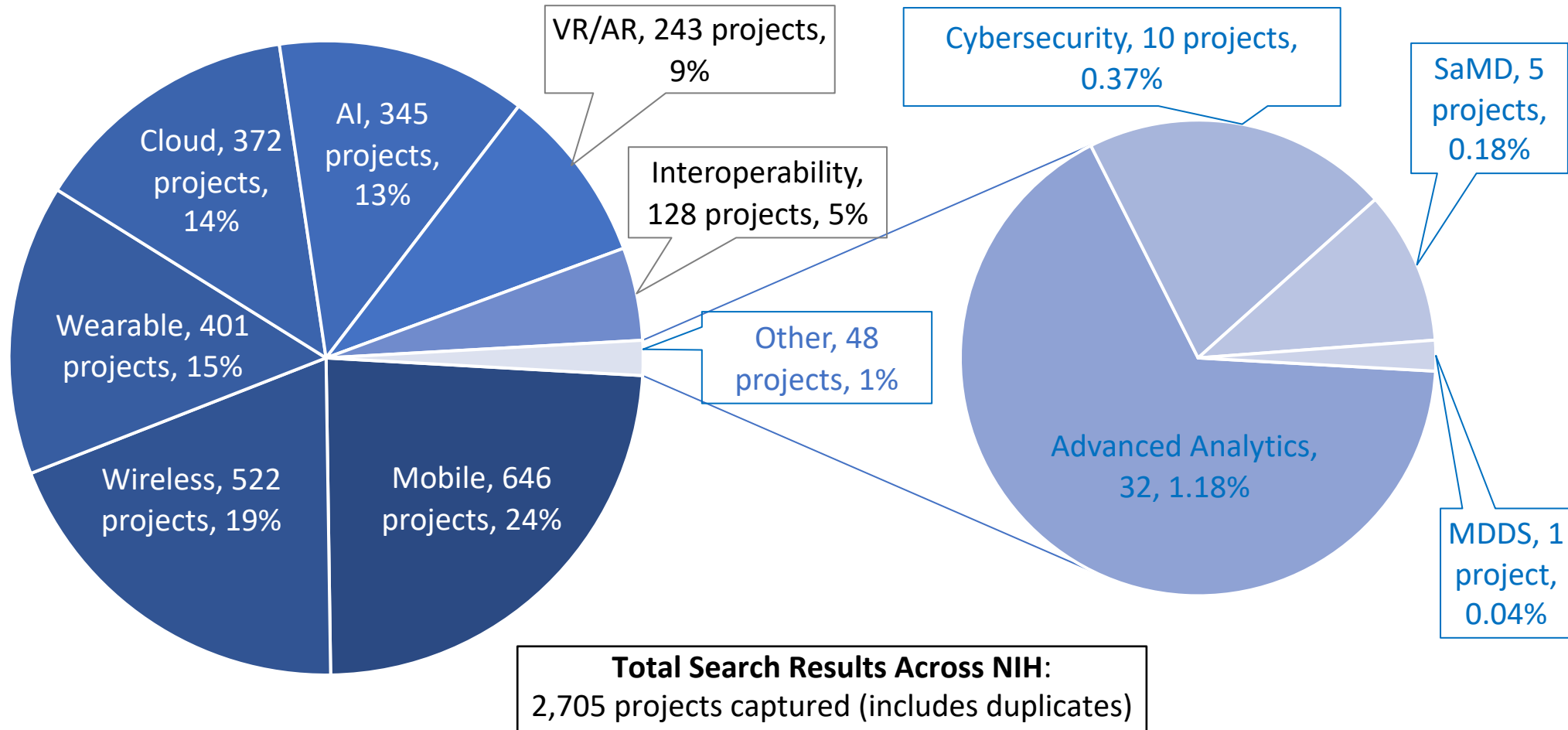
- \$379M of funding in 2021

**Fig 1. RCDC Categories, FY 2013-21**

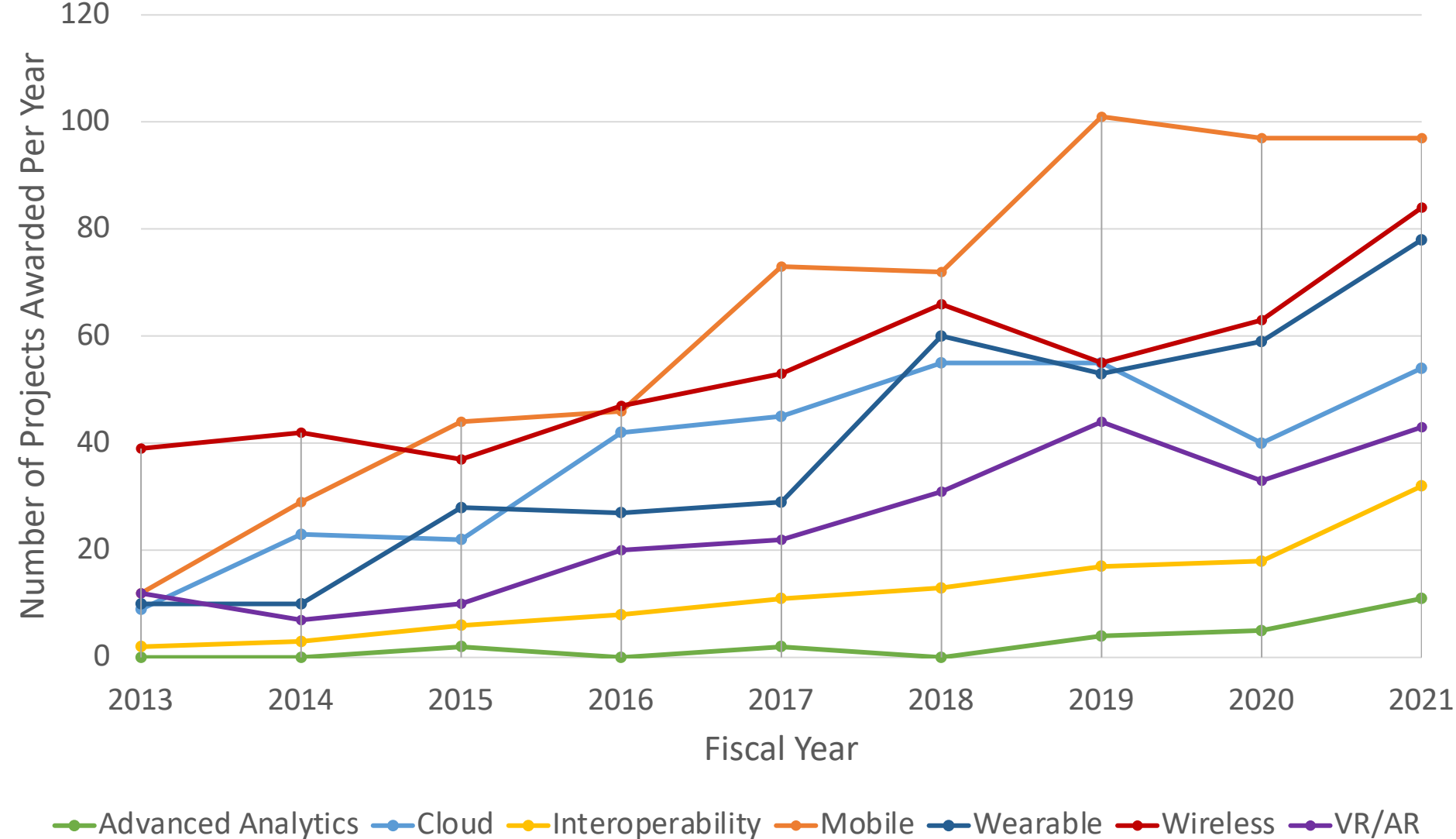


## 2. MANUAL SEARCH ACROSS NIH

**Fig 2. NIH-Wide Projects by FDA Criteria Keywords, FY 2013-2022**



**Fig 3. NIH-Wide Projects by Keyword Search: Trend over Time\***



\* Results from 2022 omitted, still being updated in database

### 3. DIGITAL HEALTH AT NHLBI

**Fig 4. NHLBI-Administered Projects by Search Keyword, FY 2013-2022**

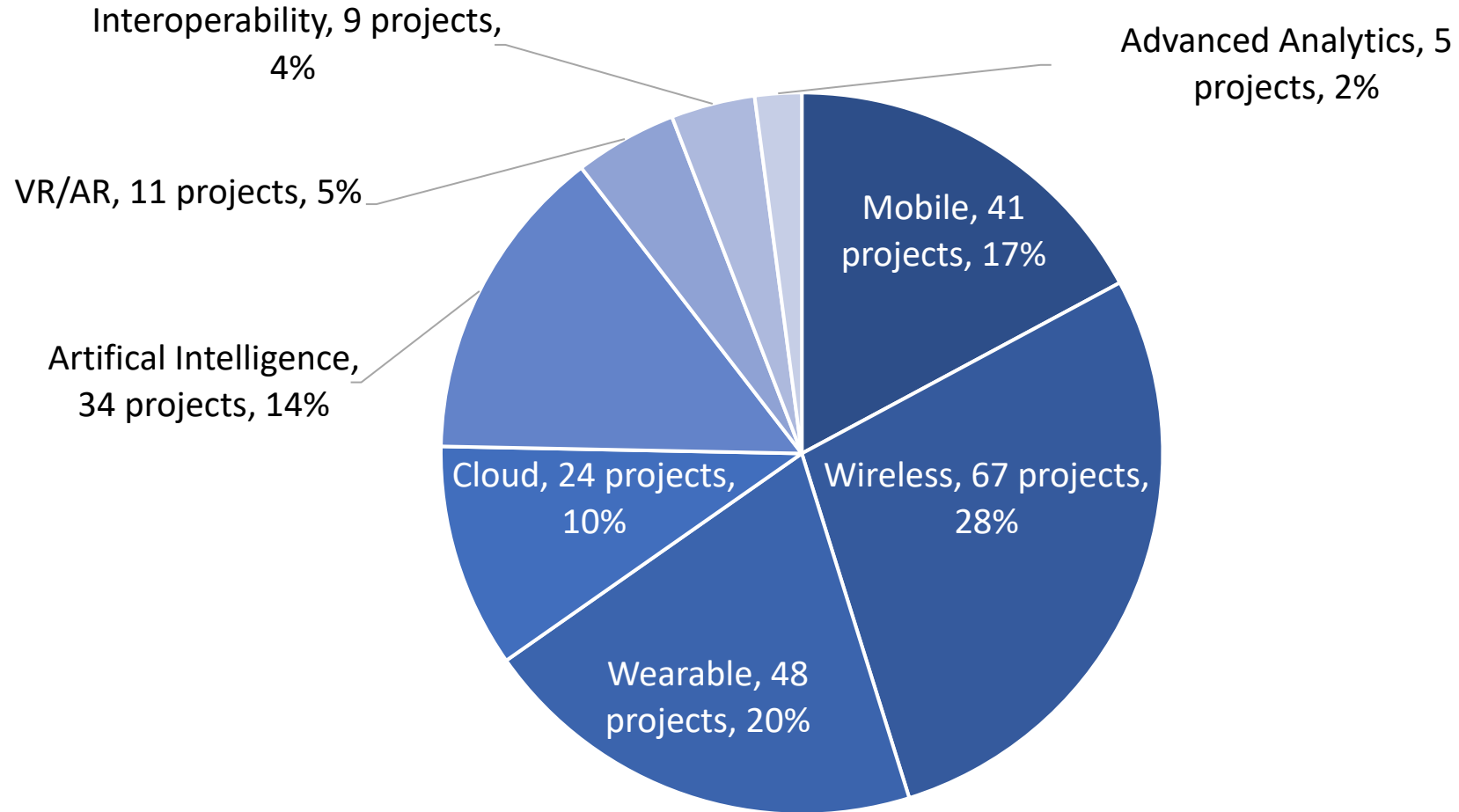
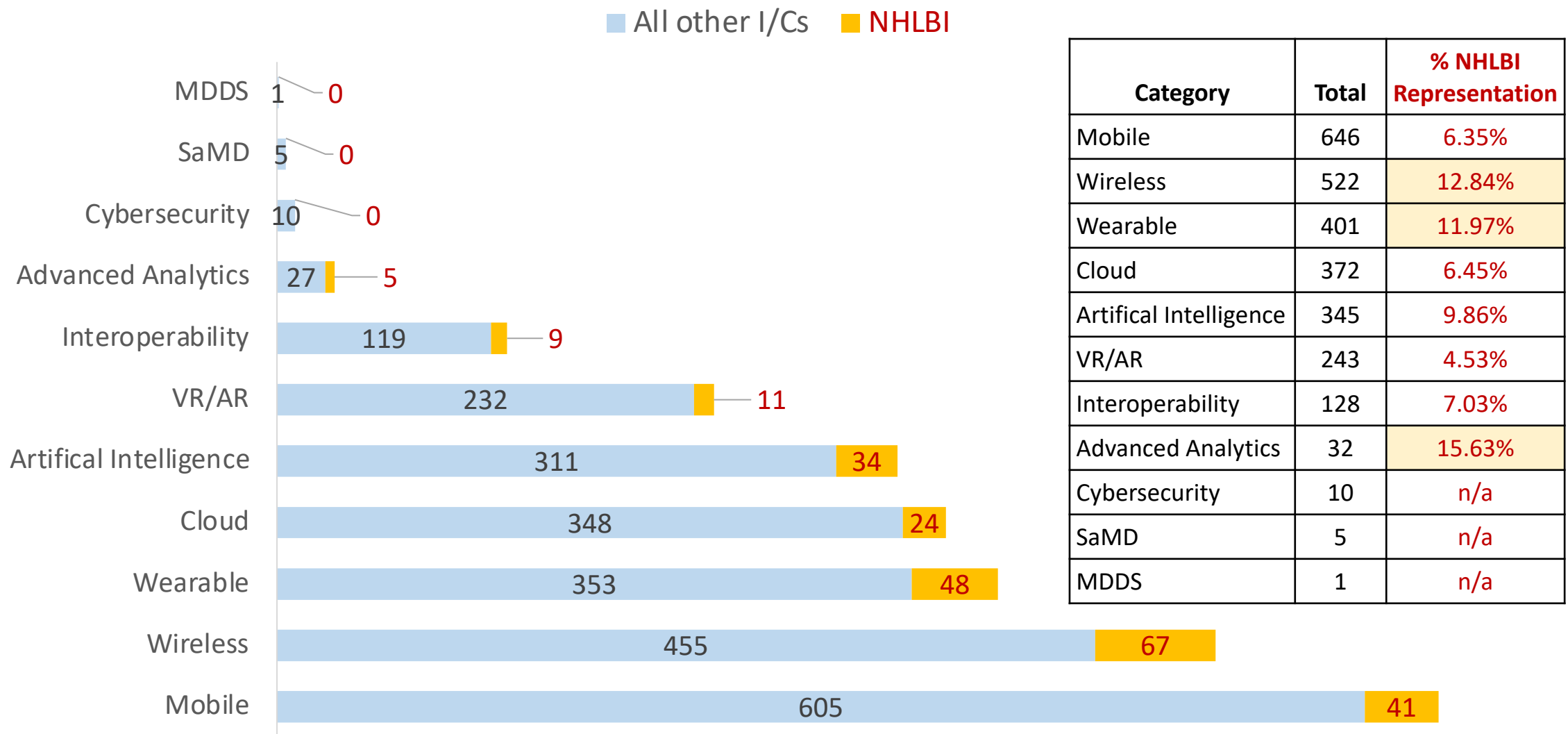


Fig 5. NHLBI versus NIH Search Comparison, FY 2013-2022



## 4. DIGITAL HEALTH IN BLOOD DISEASES AND RESEARCH

FDA Category		Project Titles in RePORTER
Artificial Intelligence		<ul style="list-style-type: none"> <li><u>Leveraging Artificial Intelligence Solutions to Develop Digital Biomarkers for Precision Trauma Resuscitation</u></li> </ul>
Cloud		<ul style="list-style-type: none"> <li><u>Chronic thrombus ablation with histotripsy and thrombolytics</u></li> </ul>
Mobile Health		<ul style="list-style-type: none"> <li><u>An mHealth Strategy to Improve Medication Adherence in Adolescents with Sickle Cell Disease</u></li> </ul>
Wireless		<ul style="list-style-type: none"> <li><u>Momitor: Wearable Technology for Early Detection of Postpartum Hemorrhage</u></li> </ul>
Novel Digital Health	Wearable	<ul style="list-style-type: none"> <li><u>Wearable technology to reduce risk of DVT and increase patient compliance</u></li> <li><u>Wearable muscle fiber excitation system for preventing blood clot</u></li> </ul>
	Virtual Reality	<p>Example from NINR:</p> <ul style="list-style-type: none"> <li><u>Home-Based Self-Management of Chronic Pain in Adults with Sickle Cell Disease: Applying a Biopsychosocial and Technological Approach</u></li> </ul>
	Gaming	<p>Example from NIMHD:</p> <ul style="list-style-type: none"> <li><u>PINPOINT: Gaming technology to engage adolescent sickle cell patients in precision pain management</u></li> </ul>

# KEY TAKEAWAYS AND LEARNINGS

## Report Takeaways

- Varying amounts of public-facing engagement on digital health across agencies
- Digital health categories vary from organization to organization
- Overall trends in research and investment is upwards
- Opportunities for investment in novel digital health technologies

## Personal Learnings

- NIH funding and grant mechanisms
- Interagency collaborations

## REPORT LIMITATIONS

- Limited search results obtained
  - Omitted R01 equivalents (U01, R21)
  - Only looked at Type 1 projects
- Does not include projects funded through supplements, other transactions, etc.
- Does not separate RCDC subcategories
- Digital health categories used are overlapping




# Part II. ELSI + Digital Health Equity Blog Post

# DIGITAL HEALTH STAKEHOLDERS

- Healthcare Providers
  - Clinical researchers
  - Medical technology industry
  - Government agencies
  - Patients
  - Caregivers
  - Technology industry
  - Private investors
  - Startup companies
  - Data providers
- 
- Increased Participation
- Increased Relevance

# DIGITAL HEALTH AND ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI)

## 1. Real World Evidence



The screenshot shows the top portion of the FDA's Real-World Evidence (RWE) program page. At the top is a dark blue header with the FDA logo on the left, a search bar with a magnifying glass icon and the word "Search", and a menu button with a hamburger icon and the word "Menu". Below the header, the text "IN THIS SECTION" is followed by a downward-pointing chevron. A breadcrumb trail shows a left arrow followed by the text "Science and Research Special Topics". The main heading "Real-World Evidence" is centered. Below it are three social media sharing buttons: "Share" with a Facebook icon, "Tweet" with a Twitter icon, and "Email" with an envelope icon. The main content area begins with a bold statement: "Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions." This is followed by a bulleted list of three points.

FDA

Search Menu

IN THIS SECTION

← [Science and Research Special Topics](#)

### Real-World Evidence

Share Tweet Email

**Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions.**

- FDA uses RWD and RWE to monitor postmarket safety and adverse events and to make regulatory decisions.
- The health care community is using these data to support coverage decisions and to develop guidelines and decision support tools for use in clinical practice.
- Medical product developers are using RWD and RWE to support clinical trial designs (e.g., large simple trials, pragmatic clinical trials) and observational studies to generate innovative, new treatment approaches.

# DIGITAL HEALTH AND ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI)

1. Real World Evidence
2. Decentralized Clinical Trials

## Facilitating and Encouraging Innovation

*e.g., Digital Health Tools (DHTs)*



A digital health technology (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for healthcare and related uses

### Potential benefits:

- Ability to study diseases in new ways
- Improved recruitment of patients (e.g., those with limited mobility)
- Data capture outside of health care setting
- Continuous data rather than snapshots
- Objective measurements
- Reduced missing data
- Capturing rare events



**FDA Will Issue a Guidance on  
Digital Health Technologies for  
Remote Data Acquisition in Clinical  
Investigations**

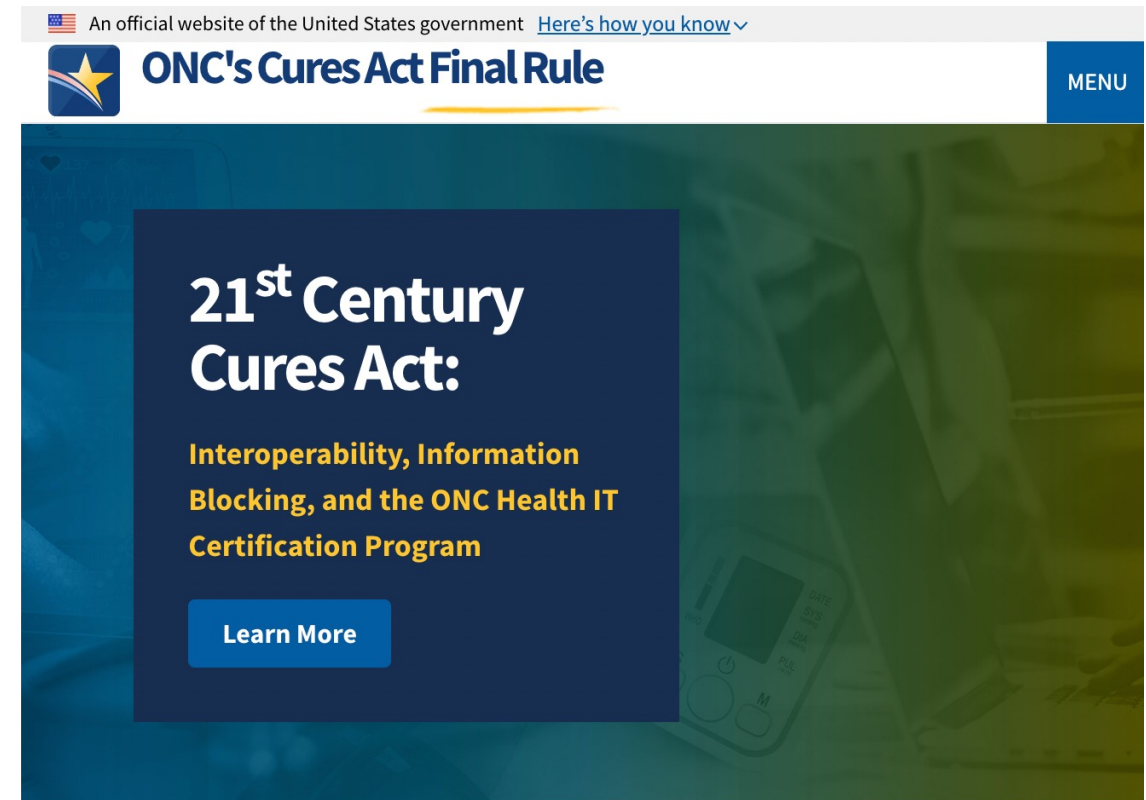


[www.fda.gov](http://www.fda.gov)

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# DIGITAL HEALTH AND ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI)

1. Real World Evidence
2. Decentralized Clinical Trials
3. Data Sharing



# DIGITAL HEALTH AND ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI)

1. Real World Evidence
2. Decentralized Clinical Trials
3. Data Sharing
4. Privacy and Cybersecurity



≡ MAIN MENU

≡ EXPLORE BY TAG

[> Defense Advanced Research Projects Agency](#) [> Our Research](#) [> Guaranteeing AI Robustness Against Deception](#)

## Guaranteeing AI Robustness Against Deception (GARD)

[Dr. Bruce Draper](#)

The growing sophistication and ubiquity of machine learning (ML) components in advanced systems dramatically expands capabilities, but also increases the potential for new vulnerabilities. Current research on adversarial AI focuses on approaches where imperceptible perturbations to ML inputs could deceive an ML classifier, altering its response. Such results have initiated a rapidly proliferating field of research characterized by ever more complex attacks that require progressively less knowledge about the ML system being attacked, while proving increasingly strong against defensive countermeasures. Although the field of adversarial AI is relatively young, dozens of attacks and defenses have already been proposed, and at present a comprehensive theoretical understanding of ML vulnerabilities is lacking.

GARD seeks to establish theoretical ML system foundations to identify system vulnerabilities, characterize properties that will enhance system robustness, and encourage the creation of effective defenses. Currently, ML defenses tend to be highly specific and are effective only against particular attacks. GARD seeks to

# DIGITAL HEALTH AND ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI)

1. Real World Evidence
2. Decentralized Clinical Trials
3. Data Sharing
4. Privacy and Cybersecurity
5. Patient-centered design
  - (Mis)trust
  - Usability
  - Community engagement





# DIGITAL HEALTH EQUITY BLOG POST

## Digital Healthcare Research

Informing Improvement in Care Quality, Safety, and Efficiency



MENU



Home > Funded Projects > [Use of Mobile Technology To Improve Acute Care Utilization in Sickle Cell Disease](#)

## Use of Mobile Technology To Improve Acute Care Utilization in Sickle Cell Disease

The screenshot shows the NIH RePORTER interface. At the top, there's a navigation bar with 'NIH RePORTER', 'FAQs', 'API', 'EXPORTER', and a 'Sign In' button. Below this, the 'Search Results' and 'Project Details' tabs are visible. The project title is 'RE-aiming at Hydroxyurea Adherence for Sickle cell with mHealth (RE-HASH)'. A sidebar on the left lists various categories: Description, Details, Sub-Projects, Publications, Patents, Outcomes, and Clinical Studies. The main content area shows the project number (5U01HL133996-06), the contact PI/Project Leader (HANKINS, JANE SILVA), and the awardee organization (ST. JUDE CHILDREN'S RESEARCH HOSPITAL). Below this, the 'Description' section is expanded, showing the 'Abstract Text' which discusses the use of hydroxyurea in sickle cell disease.

Project Number	Contact PI/Project Leader	Awardee Organization
5U01HL133996-06	HANKINS, JANE SILVA	ST. JUDE CHILDREN'S RESEARCH HOSPITAL

**Description**

**Abstract Text**

PROJECT SUMMARY Hydroxyurea is a once-a-day oral medication that reduces hospitalizations, transfusions, and medical care costs among patients with sickle cell disease (SCD). Despite these positive benefits, hydroxyurea is not widely used, which reduces the clinical benefits of the drug. The

## INVESTMENT IN DIGITAL HEALTH EQUITY REQUIRES A BALANCED TAKE ON INNOVATION

By Cindy Xie, ODSS-NHLBI Summer 2022 Civic Digital Fellow

Over the past few years, the wide-ranging landscape of digital health technology continues to grow exponentially diversify, and federal funding opportunities and programs have followed.<sup>1,2,3,4,5</sup> At the same time, the mainstream attention brought to long-standing racial and socioeconomic inequities in healthcare during the COVID-19 pandemic spurred nationwide conversations across academic journals, healthcare organizations, and government agencies. Can digital technologies bolster existing efforts towards health equity, ensuring that all individuals and communities have the opportunity to be healthy as possible?<sup>6</sup> Yes—but it requires a balanced view of both the opportunities and difficulties at hand.

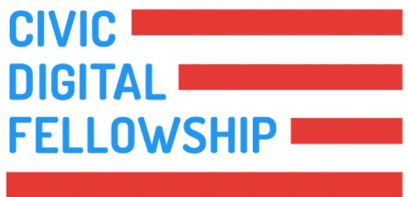
For example, in Sickle Cell Disease (SCD), the genetic condition almost exclusively affects people of color in the United States, with the majority of cases diagnosed at birth occurring among African Americans.<sup>7</sup> Meanwhile, SCD patients struggle from a lack of treatment options as well as from the skepticism of healthcare providers who sometimes undermine their experiences of chronic pain.<sup>8</sup> Advocates argue that greater awareness and educational opportunities are needed in clinical research and the medical field at large.<sup>9</sup>

Federally-funded research on digital health interventions seek to address this gap at various pain points. For example, a 2019 project funded by the Agency for Healthcare



# THANK YOU!

**Disclaimer:** The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the National Institutes of Health (NIH). No official endorsement by the National Heart, Lung, and Blood Institute (NHLBI)/NIH is intended or should be inferred.



CINDY XIE

ODSS-NHLBI Civic Digital Fellow