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

Division of Blood Diseases and Resources, NHLBI

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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

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DIGITAL HEALTH: A BRIEF TIMELINE

- 2009: Health IT for Economic and Clinical Health (HITECH) Act
- 2016: 21st 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

<u>Ongoing</u>

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

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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

<u>Ongoing</u>

- 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

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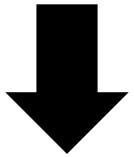
Literature Review
Federal government resources and webinars
Conversations with NIH Employees



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

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Part I. Report on Trends in Digital Health

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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)

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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

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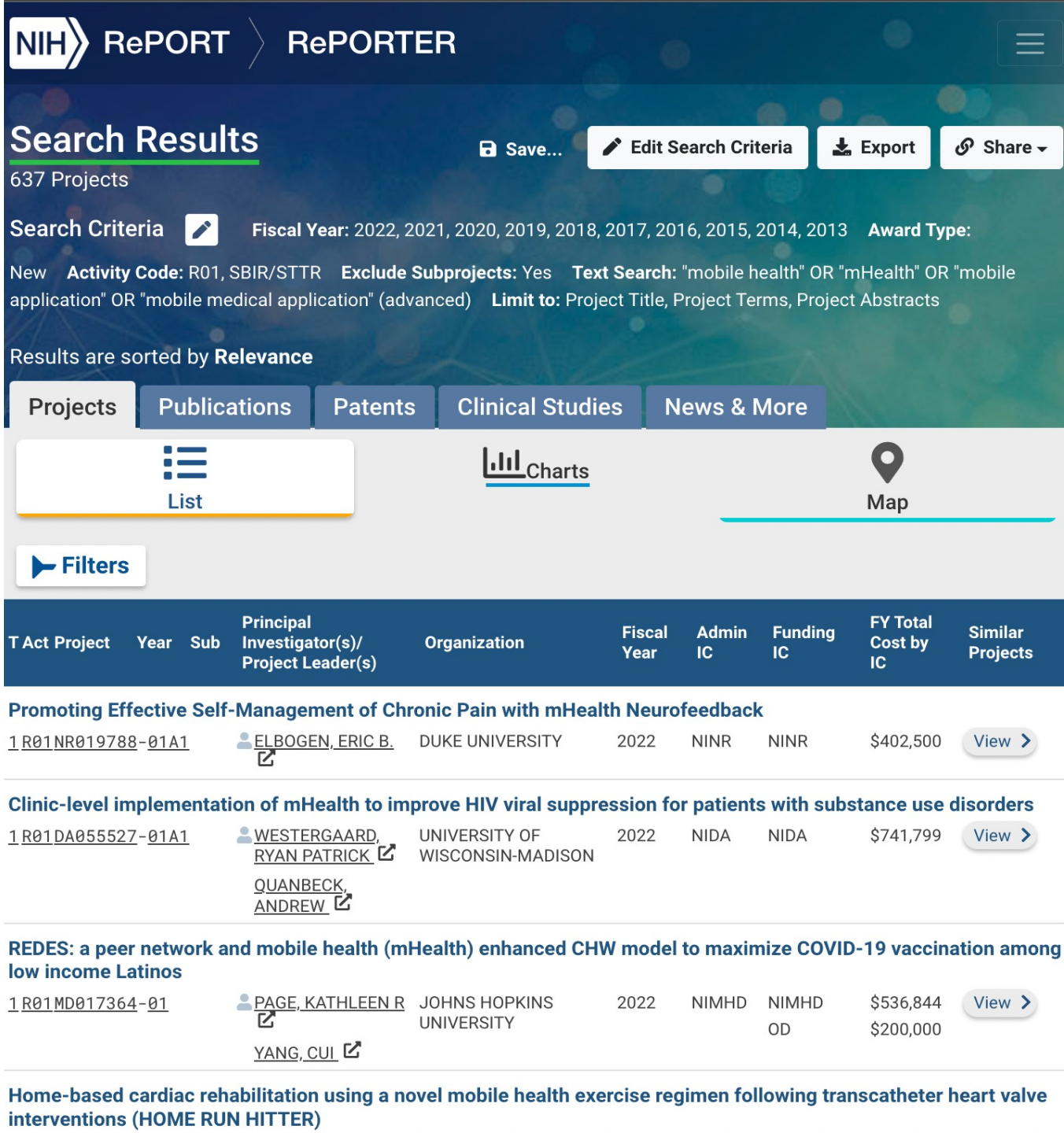


1. RCDC CATEGORIES

NITRD:

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

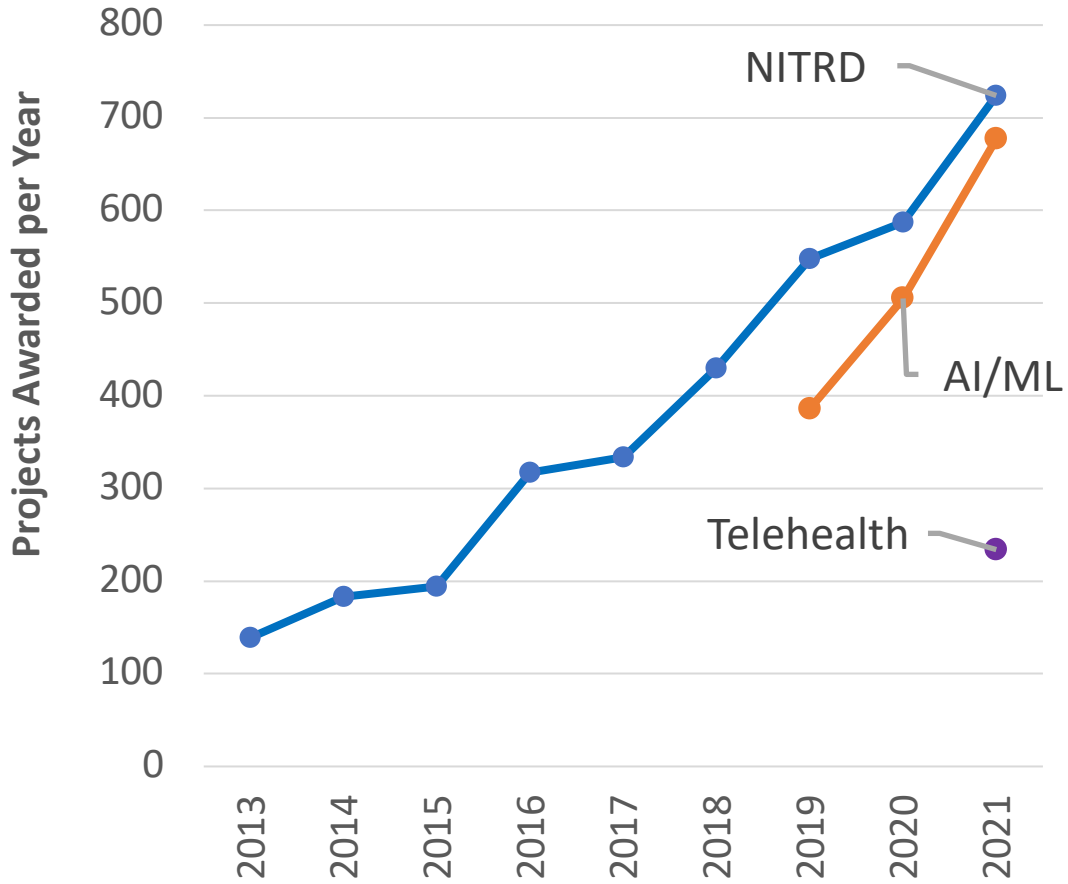
Machine Learning and AI:

- 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



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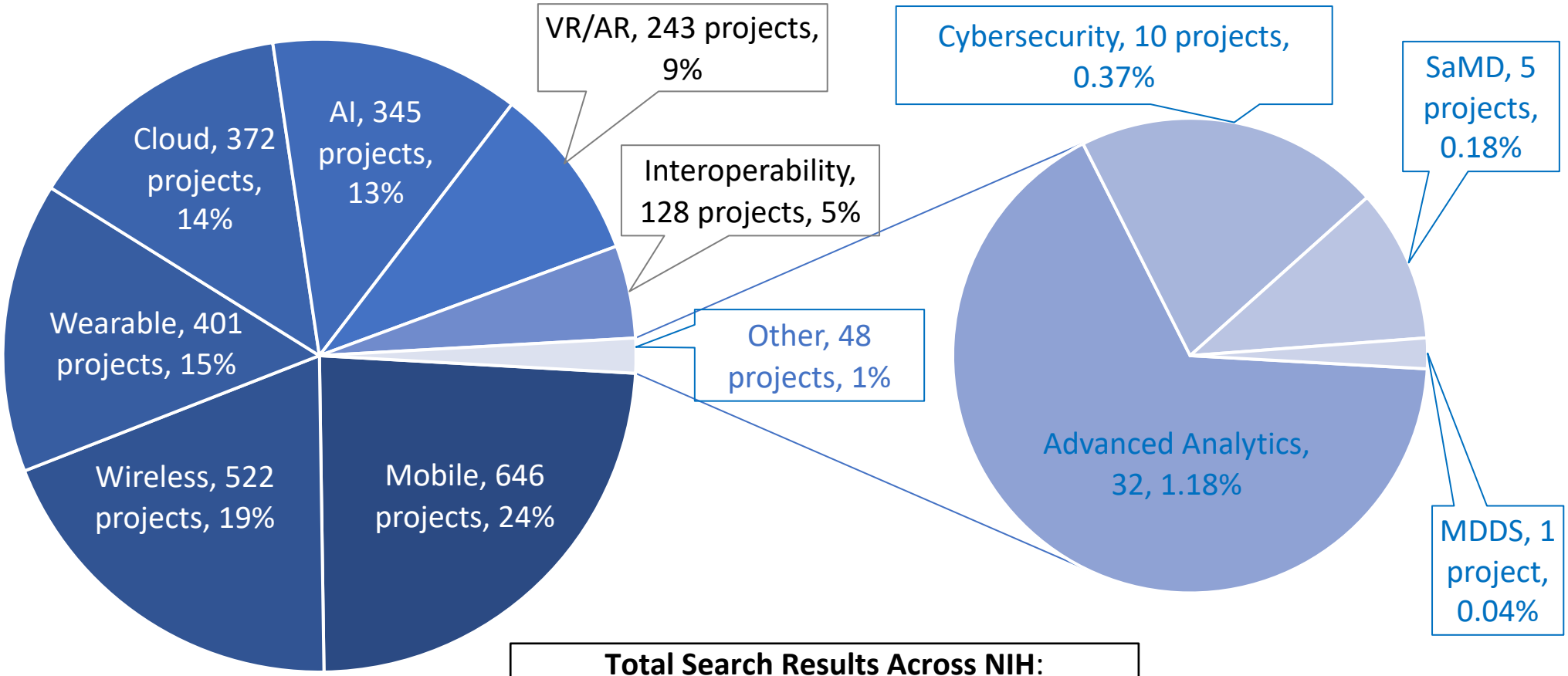
2. MANUAL SEARCH ACROSS NIH

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



Total Search Results Across NIH:
2,705 projects captured (includes duplicates)

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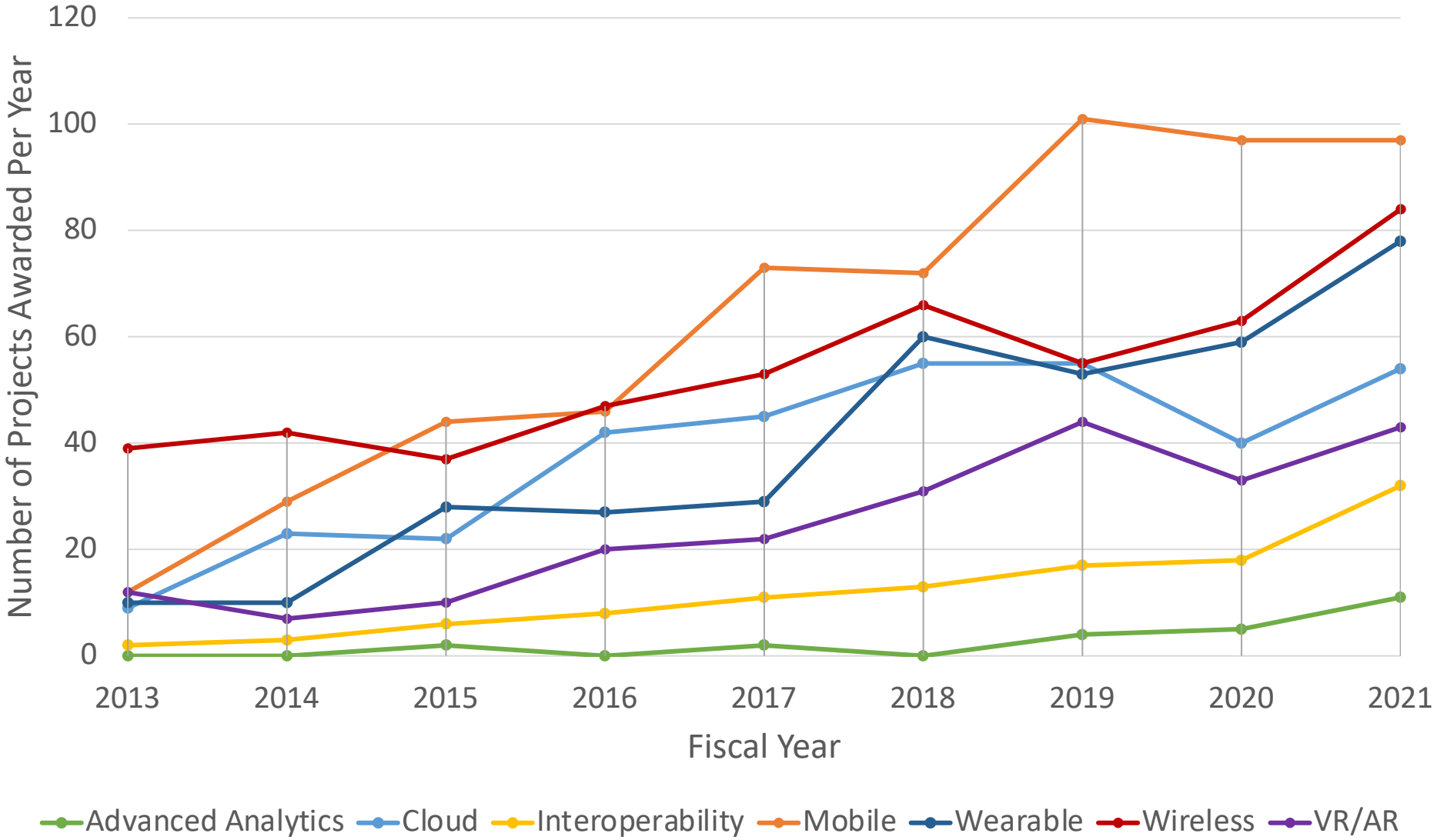
Fig 3. NIH-Wide Projects by Keyword Search: Trend over Time*



* Results from 2022 omitted, still being updated in database

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3. DIGITAL HEALTH AT NHLBI

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

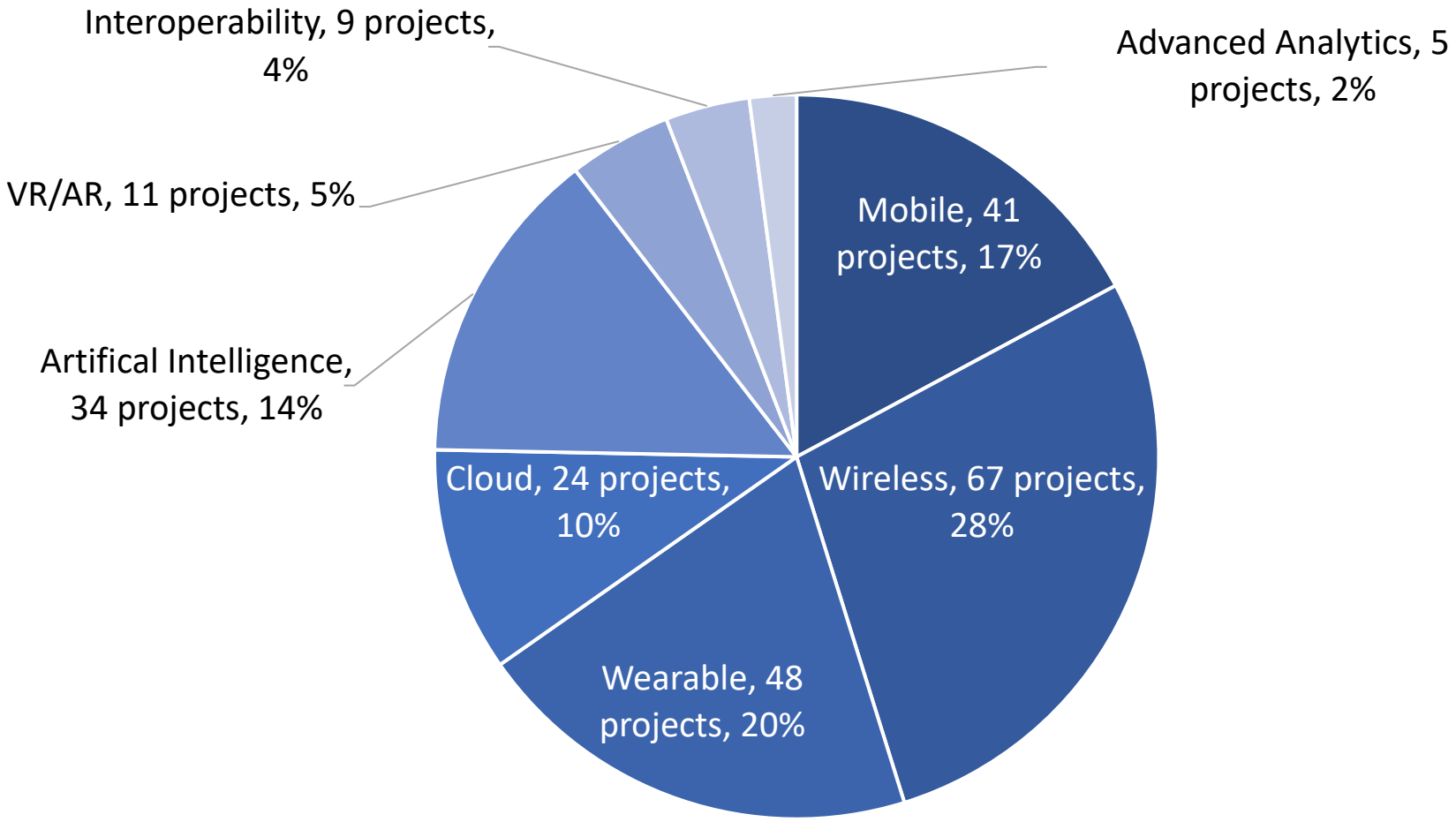

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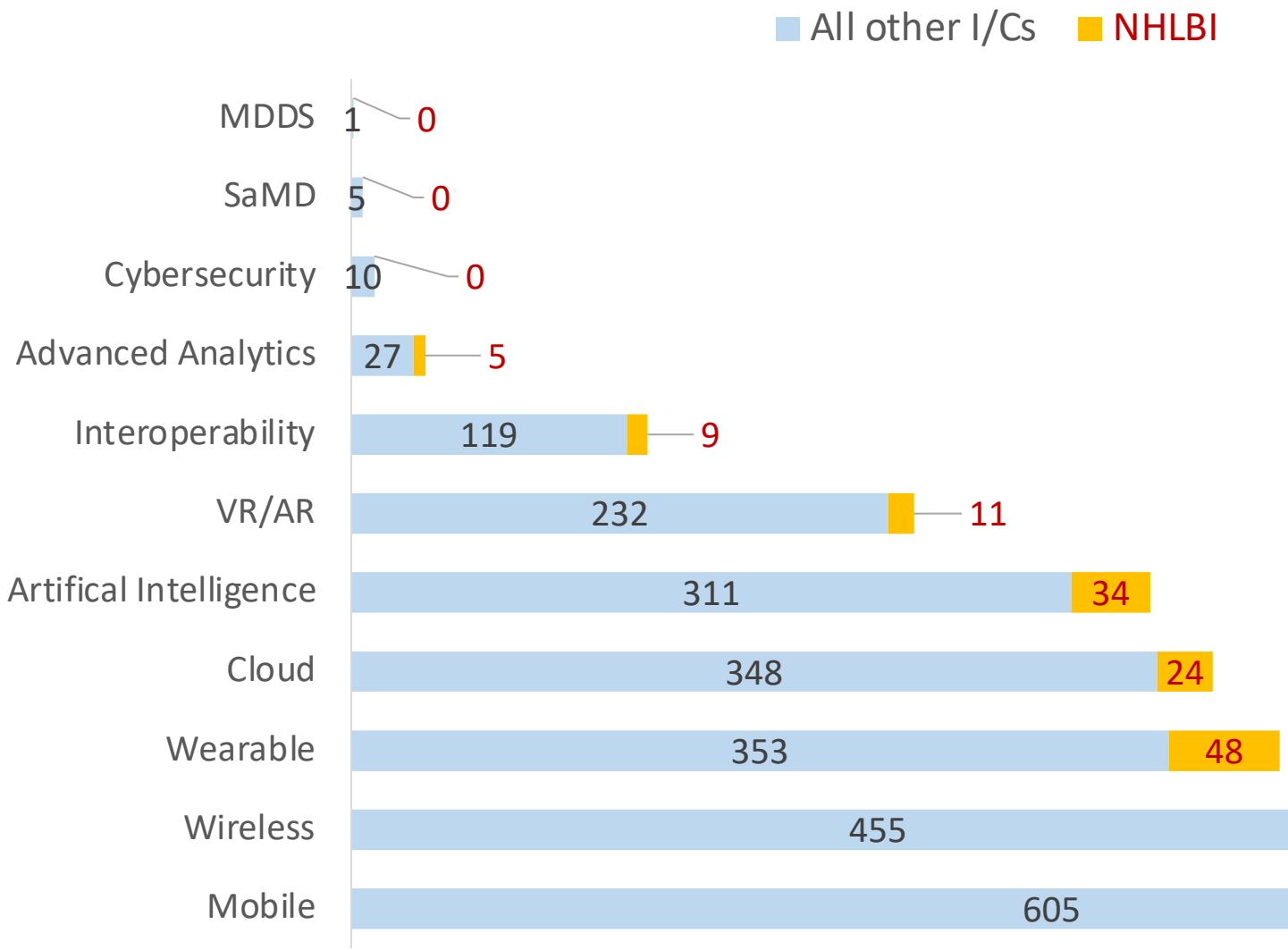
Fig 5. NHLBI versus NIH Search Comparison, FY 2013-2022



Category	Total	% NHLBI Representation
Mobile	646	6.35%
Wireless	522	12.84%
Wearable	401	11.97%
Cloud	372	6.45%
Artifical Intelligence	345	9.86%
VR/AR	243	4.53%
Interoperability	128	7.03%
Advanced Analytics	32	15.63%
Cybersecurity	10	n/a
SaMD	5	n/a
MDDS	1	n/a

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4. DIGITAL HEALTH IN BLOOD DISEASES AND RESEARCH

FDA Category		Project Titles in RePORTER
Artificial Intelligence		• Leveraging Artificial Intelligence Solutions to Develop Digital Biomarkers for Precision Trauma Resuscitation
Cloud		• Chronic thrombus ablation with histotripsy and thrombolytics
Mobile Health		• An mHealth Strategy to Improve Medication Adherence in Adolescents with Sickle Cell Disease
Wireless		• Momitor: Wearable Technology for Early Detection of Postpartum Hemorrhage
Novel Digital Health	Wearable	• Wearable technology to reduce risk of DVT and increase patient compliance • Wearable muscle fiber excitation system for preventing blood clot
	Virtual Reality	Example from NINR: • Home-Based Self-Management of Chronic Pain in Adults with Sickle Cell Disease: Applying a Biopsychosocial and Technological Approach
	Gaming	Example from NIMHD: • PINPOINT: Gaming technology to engage adolescent sickle cell patients in precision pain management

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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

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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

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Part II. ELSI + Digital Health Equity Blog Post

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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

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

1. Real World Evidence

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*FDA Website, “Real-World Evidence Program"

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

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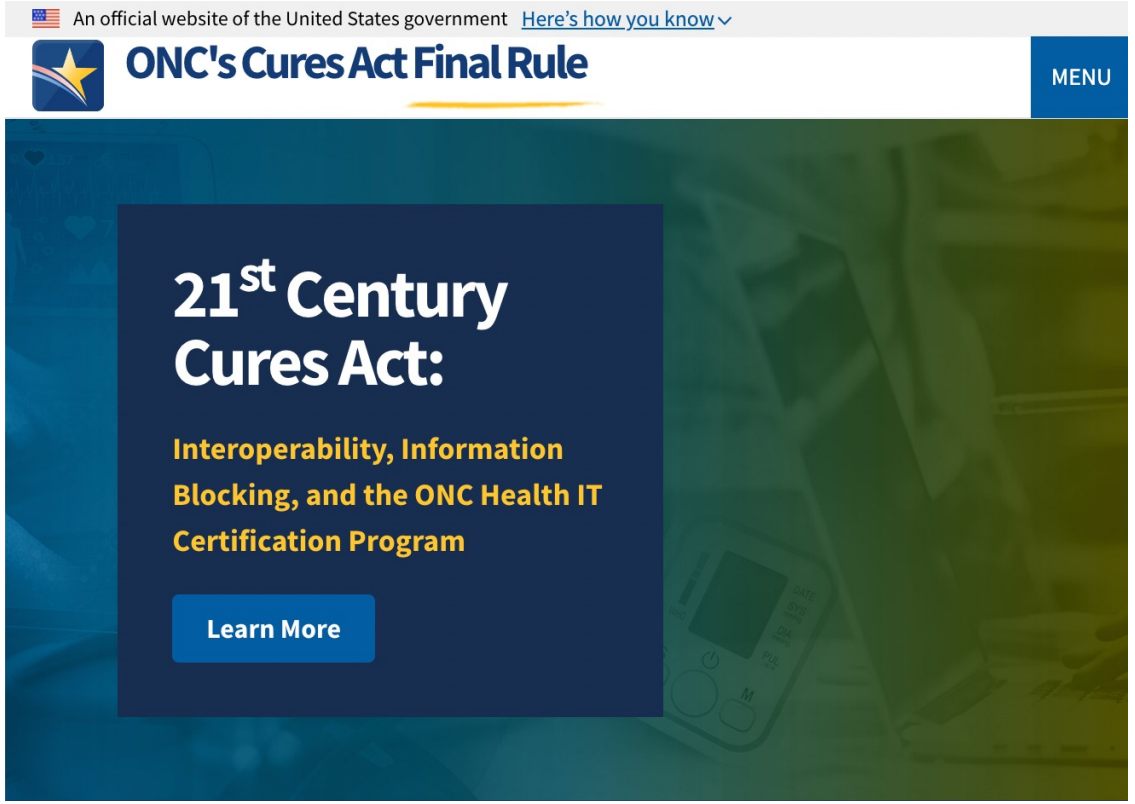
*FDA, “Advancing Efficient and Inclusive Clinical Trials Meeting of the Directors of the NCI-designated Cancer Centers,” 2021.

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

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



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*ONC Website, "ONC's Cures Act Final Rule"

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

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

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*DARPA Website, “Guaranteeing AI Robustness Against Deception”

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

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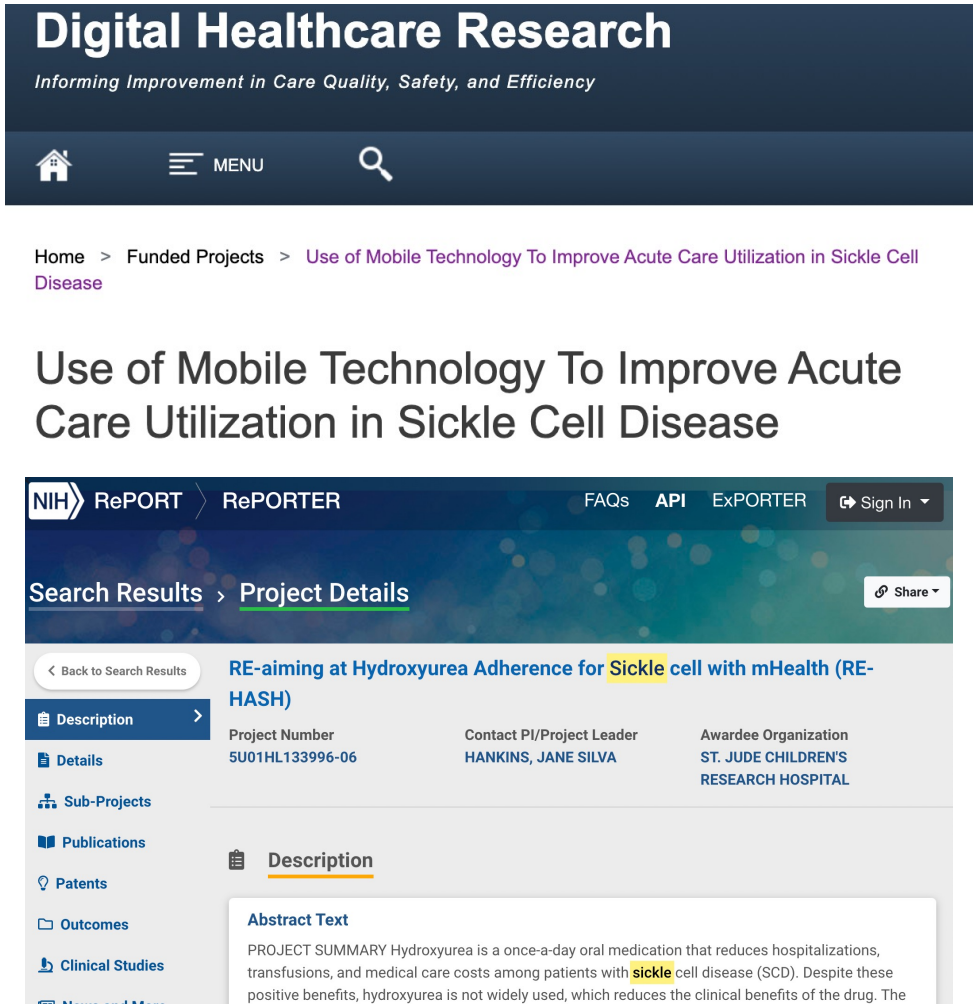
*Top: Science Magazine, 2010; Bottom: Patient Centered Outcomes Research Institute, “The PCORI Strategic Plan”

DIGITAL HEALTH EQUITY BLOG POST



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.[1,2,3,4,5] 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?[6] 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.[7] 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.[8] Advocates argue that greater awareness and educational opportunities are needed in clinical research and the medical field at large.[9]

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

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THANK YOU!

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