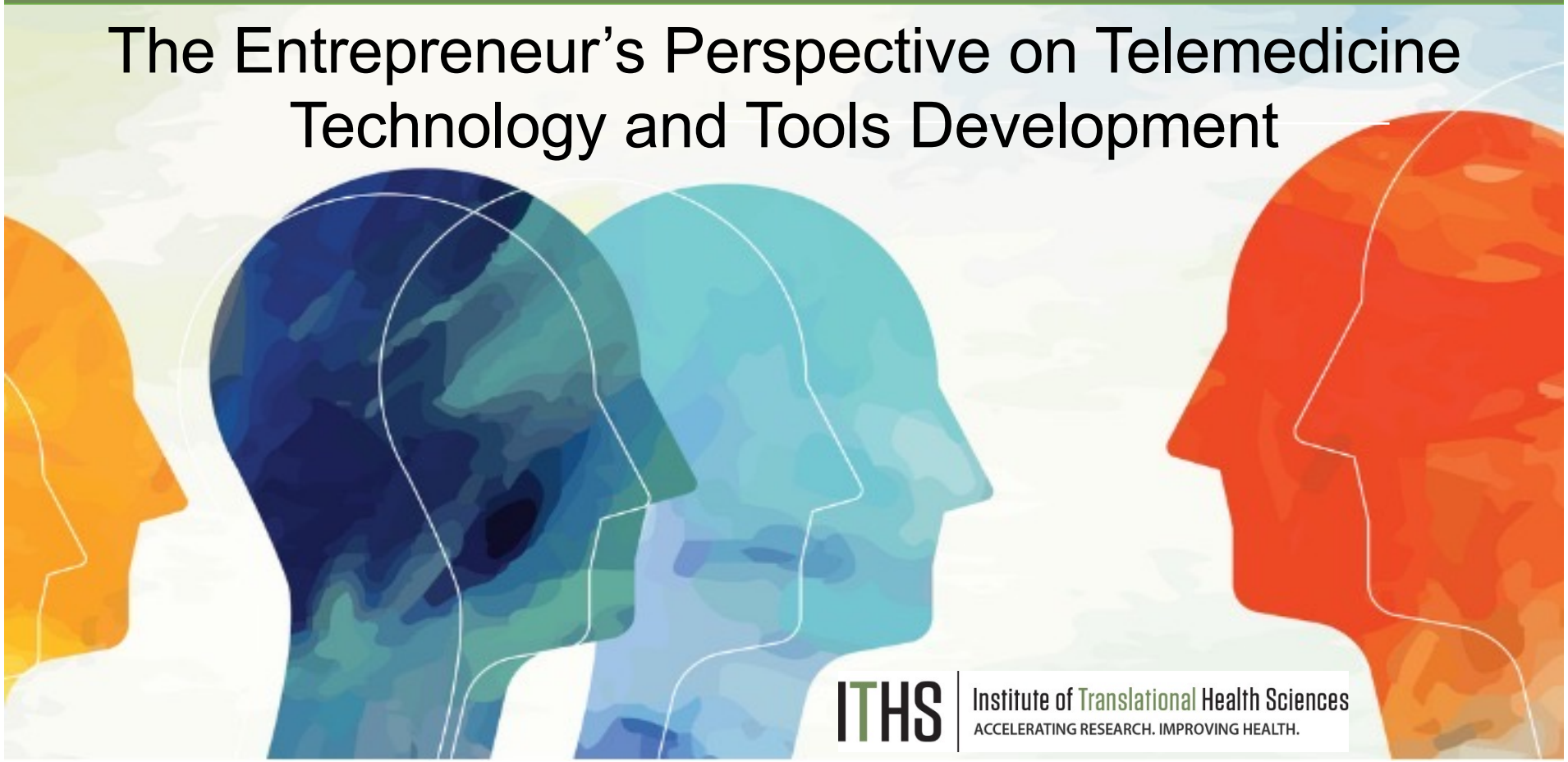
Career Development Series 2024

# The Entrepreneur's Perspective on Telemedicine Technology and Tools Development



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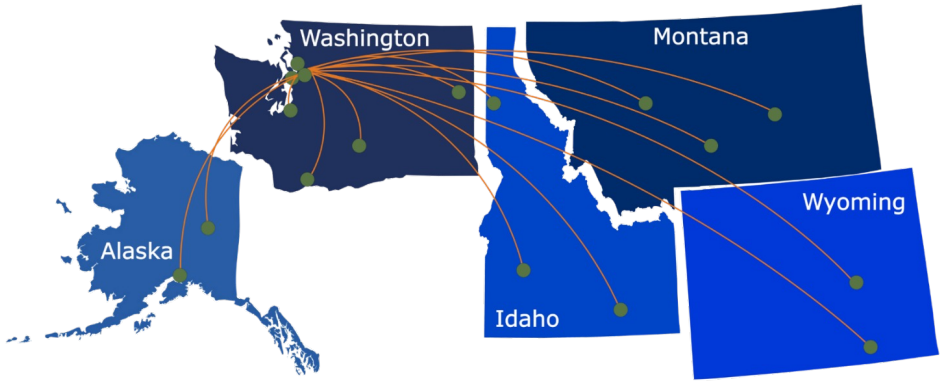


# What We Offer:

1. **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

2. **Community Engagement:** Members can connect with regional and community based practice networks

3. **Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

4. **Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

# Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Career Development Series 2024

# The Entrepreneur's Perspective on Telemedicine Technology and Tools Development

Telemedicine 2.0 Series: Session 5

*Presented by:*


**Cindy Lin, MD, FACSM, FAAPMR**

**Terri Butler, PhD**

**Teddy Johnson, PE, MBA**


ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

## *Disclosures*

Teddy Johnson has a financial relationship with Oncodisc, Inc. presented in the following slides.

Dr. Lin is a medical advisor for OpenEvidence.

# Telemedicine 2.0 Series

| Date | Session | Title |
|---|---|---|
| | Session 1 | Telemedicine 2.0: How Is It Relevant to Me? *(Pre-recorded video available)* |
| Sept. 25, 2024 | Session 2 | Telehealth Then and Now |
| Oct. 1, 2024 | Session 3 | Telemedicine Regulatory Issues: Licensing, Standards of Practice, Billing, and Reimbursement |
| Oct. 8, 2024 | Session 4 | Protecting Privacy and Maintaining Security in Telemedicine |
| Oct. 15, 2024 | Session 5 | The Entrepreneur's Perspective on Telemedicine Technology and Tools Development |
| Oct. 24, 2024 | Session 6 | Digital Inclusion and Access to Care by Telemedicine |

More details at: https://www.iths.org/event/telemedicine-then-and-now/?instance_id=1372

# Learning Objectives

**At the end of the session, participants will be able to:**

1. Identify new product needs from patient and provider experiences

2. Appreciate the health care capabilities of sensor integration into consumer products and medical devices

3. Understand how integrated systems are used in telehealth applications

Career Development Series 2024

# Overview

*Terri Butler, PhD*

*ITHS*

# Digital Health Drivers

***Big bucks are at stake →***

Improve financial processes in healthcare.

***Long wait times to see clinicians →***

Improve efficiency and experience.

***Underinsured and remote locations →***

Increase access to care.

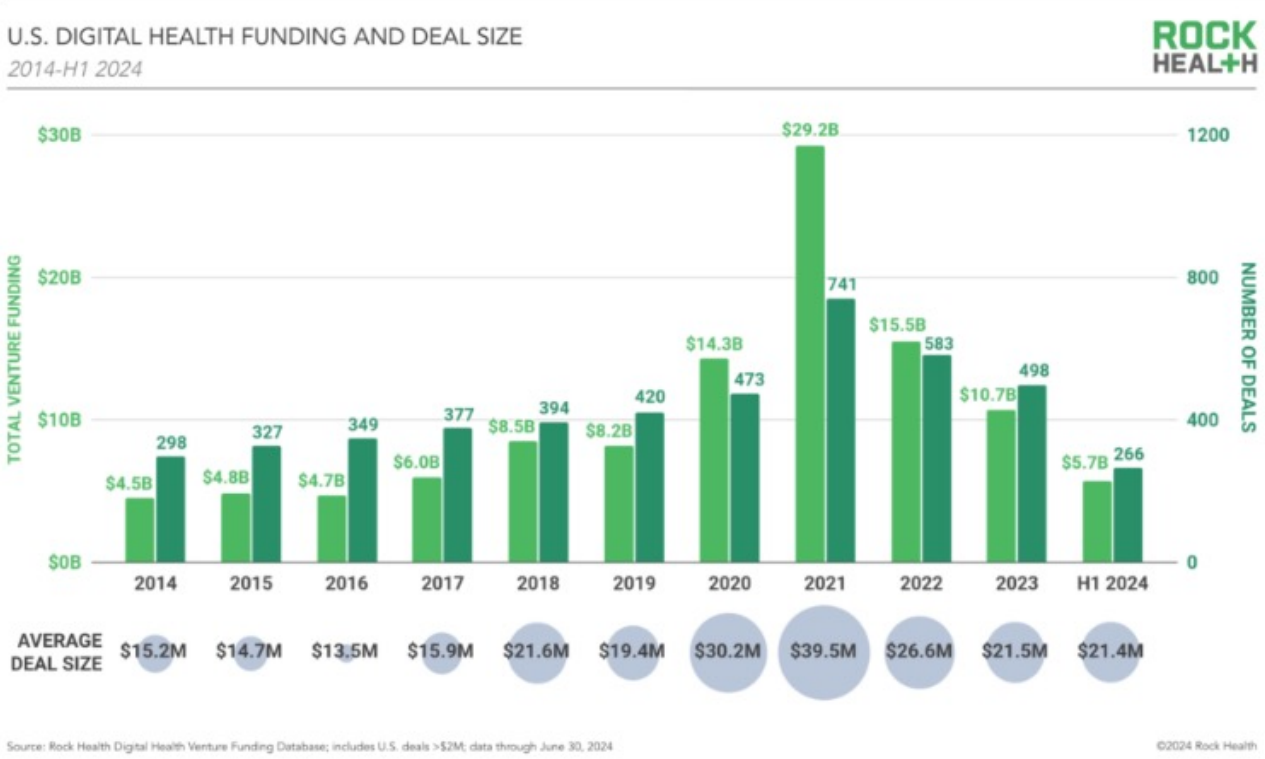
***Tools to assist clinicians →***

Better care, avoiding errors.

***Patient self-care →***

Chronic disease management, wellness.

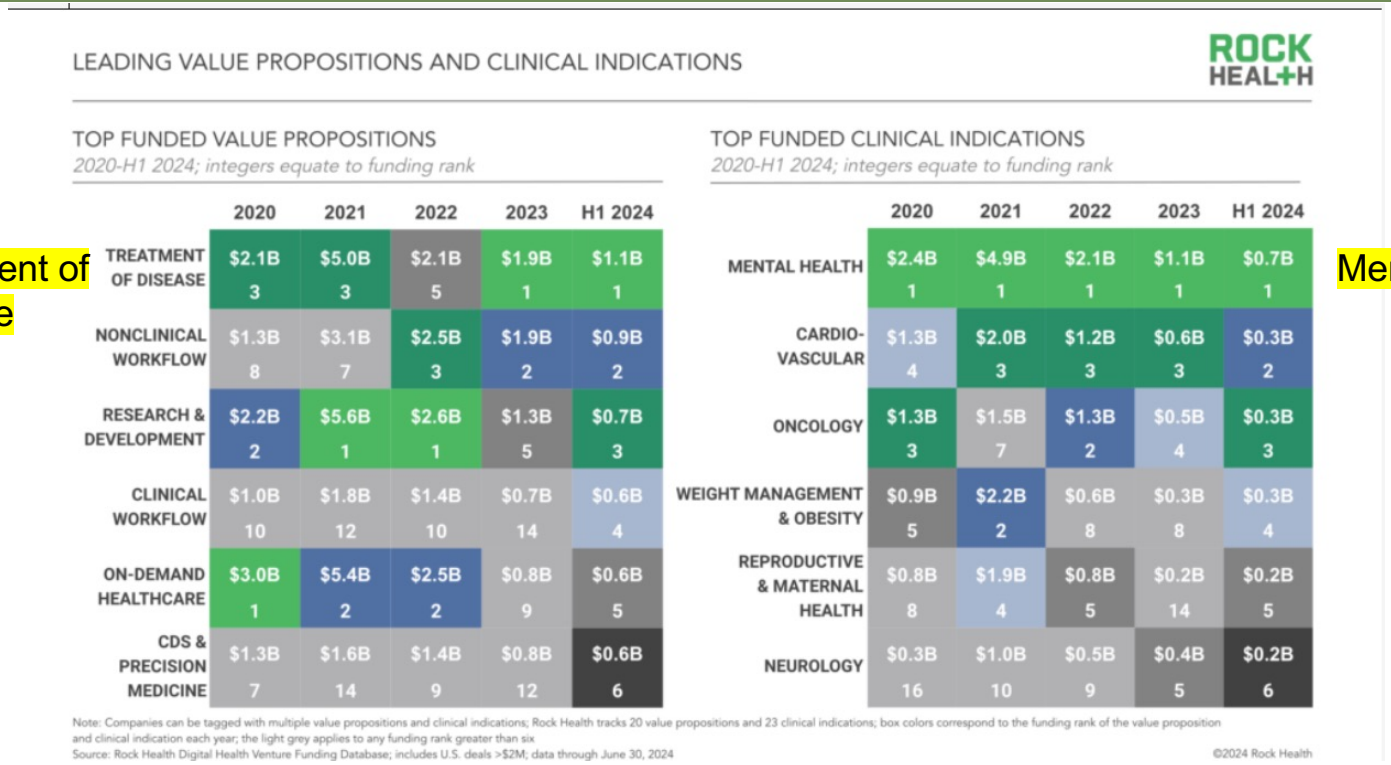
# Digital Health Funding (as of mid-year 2024)






Rock Health https://rockhealth.com/insights/h1-2024-digital-health-funding-resilience-leads-to-brilliance/

# Top Value Propositions and Clinical Indications



LEADING VALUE PROPOSITIONS AND CLINICAL INDICATIONS

ROCK HEALTH

TOP FUNDED VALUE PROPOSITIONS

*2020-H1 2024; integers equate to funding rank*

| | 2020 | 2021 | 2022 | 2023 | H1 2024 |
|---|---|---|---|---|---|
| TREATMENT OF DISEASE | $2.1B 3 | $5.0B 3 | $2.1B 5 | $1.9B 1 | $1.1B 1 |
| NONCLINICAL WORKFLOW | $1.3B 8 | $3.1B 7 | $2.5B 3 | $1.9B 2 | $0.9B 2 |
| RESEARCH & DEVELOPMENT | $2.2B 2 | $5.6B 1 | $2.6B 1 | $1.3B 5 | $0.7B 3 |
| CLINICAL WORKFLOW | $1.0B 10 | $1.8B 12 | $1.4B 10 | $0.7B 14 | $0.6B 4 |
| ON-DEMAND HEALTHCARE | $3.0B 1 | $5.4B 2 | $2.5B 2 | $0.8B 9 | $0.6B 5 |
| CDS & PRECISION MEDICINE | $1.3B 7 | $1.6B 14 | $1.4B 9 | $0.8B 12 | $0.6B 6 |

TOP FUNDED CLINICAL INDICATIONS

*2020-H1 2024; integers equate to funding rank*

| | 2020 | 2021 | 2022 | 2023 | H1 2024 |
|---|---|---|---|---|---|
| MENTAL HEALTH | $2.4B 1 | $4.9B 1 | $2.1B 1 | $1.1B 1 | $0.7B 1 |
| CARDIO-VASCULAR | $1.3B 4 | $2.0B 3 | $1.2B 3 | $0.6B 3 | $0.3B 2 |
| ONCOLOGY | $1.3B 3 | $1.5B 7 | $1.3B 2 | $0.5B 4 | $0.3B 3 |
| WEIGHT MANAGEMENT & OBESITY | $0.9B 5 | $2.2B 2 | $0.6B 8 | $0.3B 8 | $0.3B 4 |
| REPRODUCTIVE & MATERNAL HEALTH | $0.8B 8 | $1.9B 4 | $0.8B 5 | $0.2B 14 | $0.2B 5 |
| NEUROLOGY | $0.3B 16 | $1.0B 10 | $0.5B 9 | $0.4B 5 | $0.2B 6 |

Note: Companies can be tagged with multiple value propositions and clinical indications; Rock Health tracks 20 value propositions and 23 clinical indications; box colors correspond to the funding rank of the value proposition and clinical indication each year; the light grey applies to any funding rank greater than six

Source: Rock Health Digital Health Venture Funding Database; includes U.S. deals >$2M; data through June 30, 2024



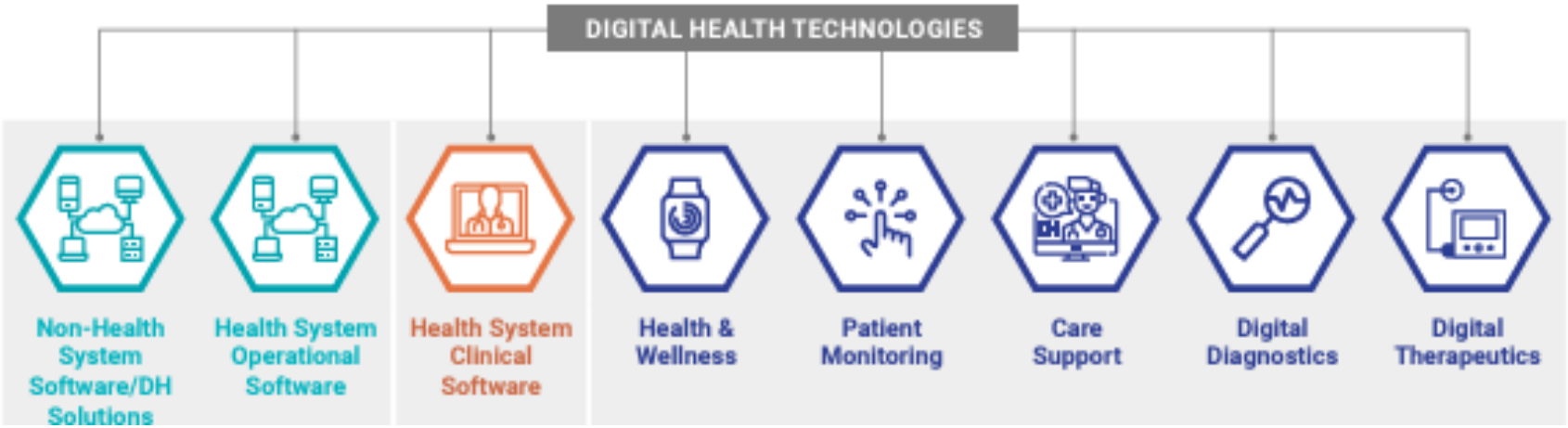
Treatment of Disease

Mental Health



Rock Health https://rockhealth.com/insights/h1-2024-digital-health-funding-resilience-leads-to-brilliance/

# Digital Health Categories




**Noom** person diet tracking

**CodaMetrix** automated medical coding

**Abridge** automating medical records

**Maven** digital services for underserved women & families

**Omada** diabetes monitoring

**Summer Health** pediatrics connections

**AliveCor** heart monitor

**Akili** EndeavorRx ADHD



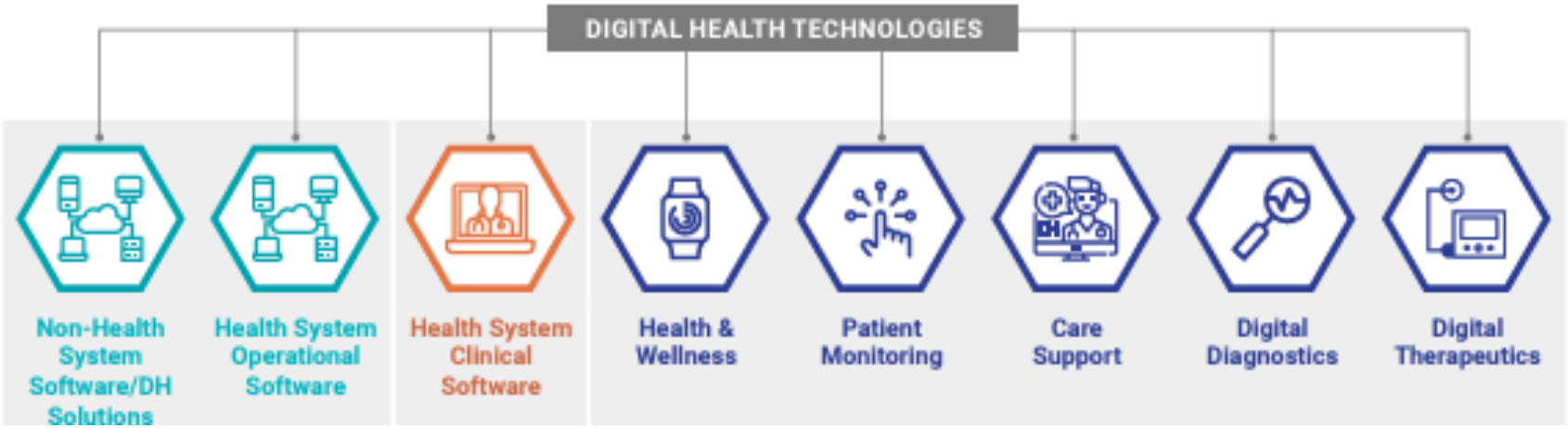
*https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference*

# Examples of Companies

- **Zephyr AI** - $111M
  - Data platform for clinical development, biomarkers identify patients for precision medicine.
- **Allez Health** - $60M
  - Glucose monitoring, biometric sensor platform, multiple health applications.
- **Fabric Healthcare** - $60M
  - AI-powered care enablement company, digital front door, intake, triage, virtual care, for health systems, ambulatory clinics.
- **Foodsmart** - $1.1B total
  - Food as medicine for chronic condition care like cholesterol, diabetes, hypertension, weight loss, telehealth with dietitians, digital meal planning and grocery delivery. Customers are individuals and organizations like employers and health plans, Medicare and Medicaid.

*Rock Health* *https://rockhealth.com/insights/h1-2024-digital-health-funding-resilience-leads-to-brilliance/*

# Digital Health Categories




**FDA Regulatory Requirements**



*https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference*

# FDA Digital Health Center of Excellence



- https://www.fda.gov/medical-devices/digital-health-center-excellence
- https://www.ftc.gov/business-guidance/resources/mobile-health-apps-interactive-tool

*Computing* platforms, connectivity, software, and sensors [used] for health care and related uses.

FDA is committed to supporting digital health technology.

- Guidance for development
- Connecting stakeholders
- Advancing regulatory approaches

**Other government agency's rules may apply:**

- Federal Trade Commission
- Office of the National Health Information Coordinator
- Office for Civil Rights

# FDA Umbrella

FDA's focus on digital health is on uses defined as "medical devices."

- **A medical device** is an instrument, machine, or other tool used to prevent, diagnose, or treat disease or other conditions. Medical devices can also be used to detect, measure, restore, correct, or modify the structure or function of the body. https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device

  - **Software as a Medical Device (SaMD)**
  - **Artificial Intelligence and Machine Learning in Software as a Medical Device**
  - **Cybersecurity**
  - **Device Software Functions including Mobile Medical Applications**
  - **Health IT**
  - **Medical Device Data Systems**
  - **Medical Device Interoperability**
  - **Telemedicine**
  - **Wireless Medical Devices**

  - *https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device*
  - *https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health#focus*

# Digital Therapeutics

## Digital Therapeutics (DTx) are

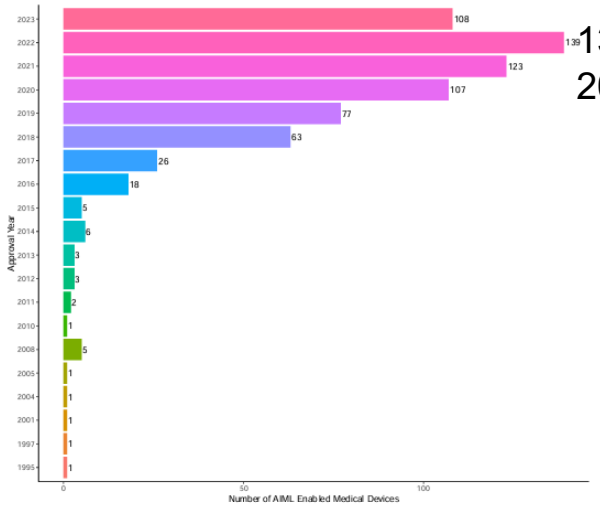
- **health software**
- **intended to treat or alleviate a disease, disorder, condition, or injury**
- **by generating and delivering a medical intervention**
- **that has a demonstrable positive therapeutic impact on a patient's health.**

*Digital Therapeutics Alliance, https://dtxalliance.org/*

# FDA AI/ML Clearance Trends

FDA-Approved Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices: An Updated Landscape

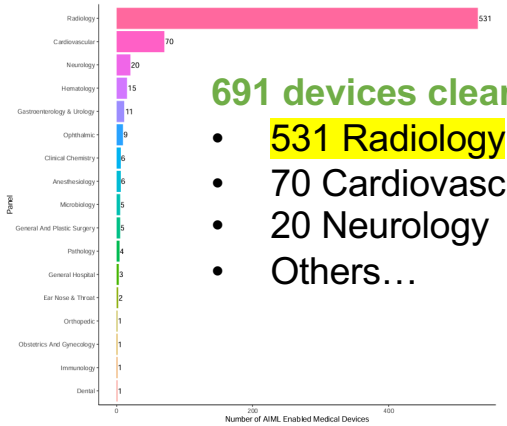
2023




139 cleared in 2022

1995

**Figure 2.** Graphical representation of the annual trends in FDA approval for AI/ML-enabled medical devices showcasing the surge in technological integration in healthcare.



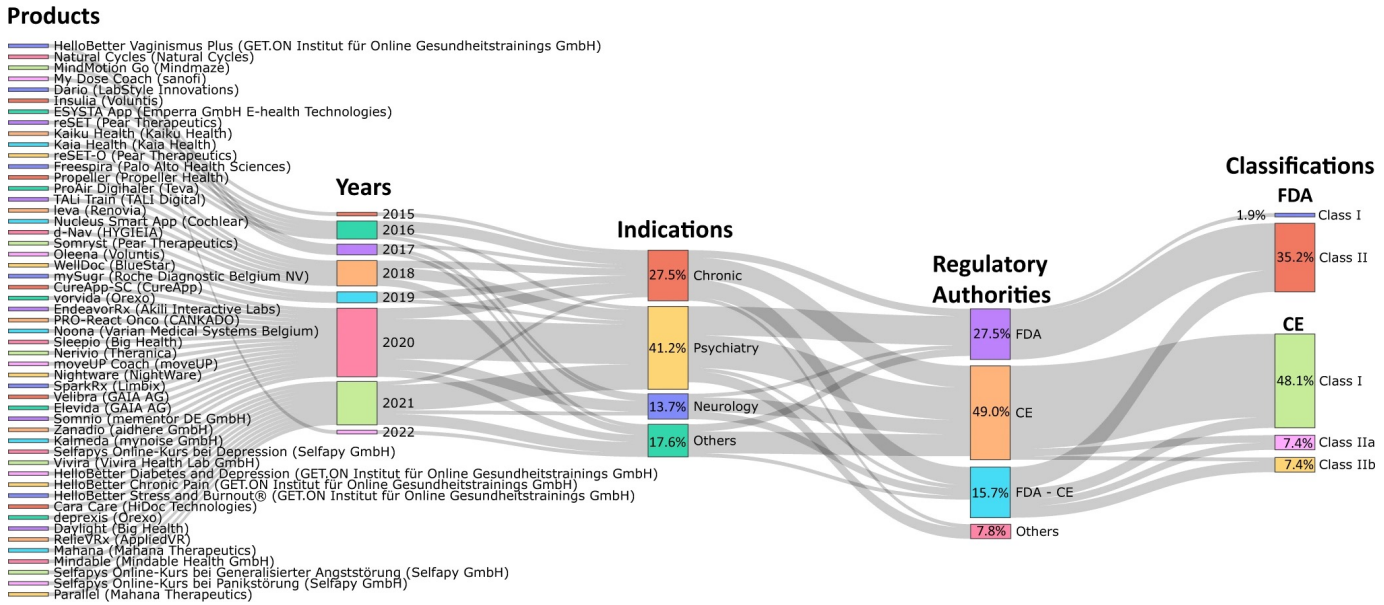

**691 devices cleared as of Oct 2023**

- 531 Radiology
- 70 Cardiovascular
- 20 Neurology
- Others…

*Joshi, G. et. al. Electronics 2024, 13, 498. https://doi.org/10.3390/electronics13030498*

# Digital Therapeutics Clearance Trends

## Digital Therapeutics from Bench to Bedside




*Wang, C., Lee, C. & Shin, H. Digital therapeutics from bench to bedside. npj Digit. Med.* ***6****, 38 (2023). https://doi.org/10.1038/s41746-023-00777-z*

# Digital Therapeutics Clinical Trials

**ClinicalTrials.gov**

- **80 studies underway** (search “digital therapeutics”)
- 79%  are randomized controlled trials
- Most are smartphone or web-based, some include games and virtual reality
- Different countries → different regulations

**Disease Indications:**

- Chronic disease management, e.g. diabetes, asthma, chronic pain, heart disease
- Drug abuse prevention, alcoholism, smoking cessation
- Sleep management, insomnia
- Psychological or psychiatric disease management, e.g. anxiety, depression, schizophrenia, PTSD, ADHD
- Clinical applications such as tumors, cranial nerve, obstetrics, urinary system, digestive system, orthopedic applications, respiratory system, immune system, multiple sclerosis.


- *Wang, C., Lee, C. & Shin, H. Digital therapeutics from bench to bedside. npj Digit. Med.* ***6****, 38 (2023).* *https://doi.org/10.1038/s41746-023-00777-z*
- *https://clinicaltrials.gov/search?term=%22digital%20therapeutics%22&viewType=Table*

# ADDITIONAL QUESTIONS?

- Digital Health tools are playing a significant role in healthcare transformation.
- Regulatory authorities are supportive of new technologies and are providing efficacy and safety study guidance and stakeholder connections.
- Investors continue to support new companies that have business models that fit health system operations and patient needs.

# The Entrepreneur's Perspective on Telemedicine Technology and Tools Development

**Cindy Lin, MD, FAAPMR, FACSM**
Clinical Professor, Sports & Spine Medicine,
University of Washington Medical Center
Endowed Professorship in Sports and Exercise Medicine
Director of Clinical Innovation, The Sports Institute

October 15th, 2024

EXERXC

# Lecture Objectives

ExerciseRx as a case example:

1. Patient and provider experiences with identifying needs gaps through UI/UX research
2. Integrating new digital health tools to patient care flow in clinical setting, challenges and opportunities
3. Assessing patient and provider satisfaction with new digital health tools

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# Physical Activity is Mostly left out of Healthcare

**80% of Americans** do not meet U.S. National Physical Activity Guidelines. **More than 50%** of Americans have a preventable chronic disease; many associated with lifestyle factors

Patient physical activity is largely **self-reported**, which can be inaccurate and difficult to interpret in the healthcare setting

Despite the **increase in wearables and digital health**, they are not being used as a routine part of clinical practice

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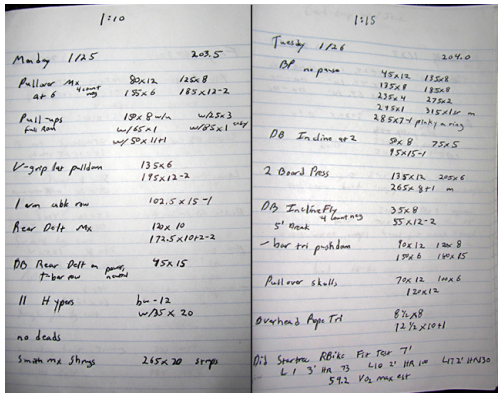
# CURRENT STATE: How Patients Share Physical Activity Data with Healthcare Providers

## Paper-Based Logs



## Self-Report


## Wearables, Smartphone Activity Metrics

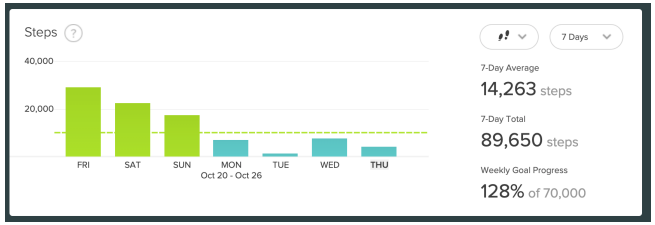



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Image Credit: Powerful Reasons to Use a Workout Log (t-nation.com), Solved: Monthly data - Fitbit Community

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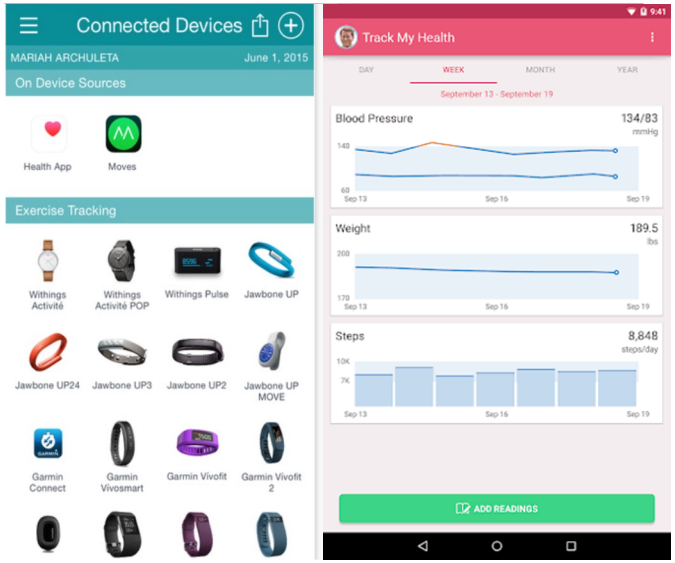
TECH

# Doctors say most metrics provided by your Apple Watch, Fitbit aren't helpful to them

**Dalvin Brown** USA TODAY

Published 5:04 a.m. ET Aug. 14, 2019 | **Updated 2:17 p.m. ET Aug. 14, 2019**

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## Challenges Digital Health Data in Clinical Practice

- Electronic health records data overload & provider burnout
- Reimbursement challenges and limited support for care teams to interpret and act on data
- Uncertainty about what data means, accuracy & liability concerns

www.imedicalapps.com/2015/11/app-wearables-electronic-health-record/

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# Current State: Electronic Health Records Inbasket Overload

*Adding a digital health metric introduces another inbasket to check on top of 10+ inbaskets to review daily*

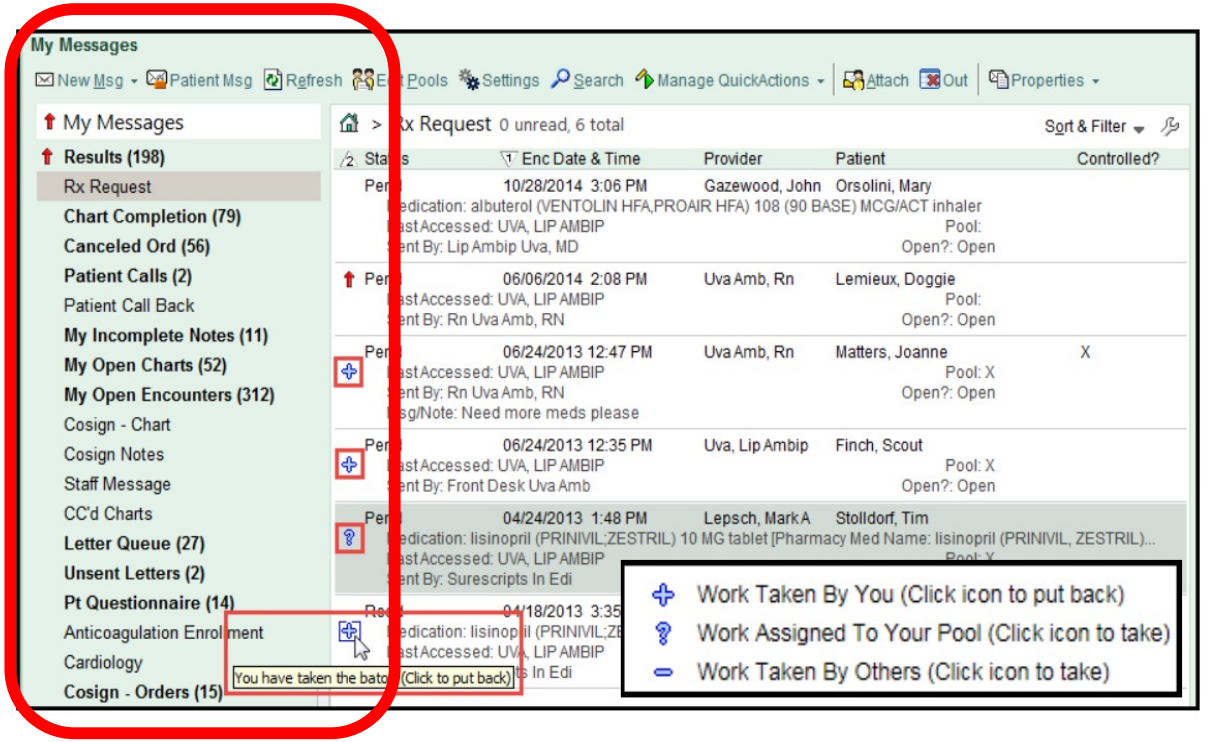


Image credit: 2015 amb general updates (virginia.edu)

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# ExerciseRx Team

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ubicomplab

HUMAN CENTERED DESIGN & ENGINEERING
UNIVERSITY of WASHINGTON

## Samuel R. Browd, MD, PhD
Director

- Professor of Neurological Surgery, UW
- Pediatric Neurosurgeon, Seattle Children's Hospital

## Karla Landis, MS
Associate Director

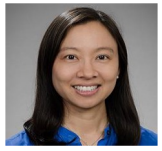
- Chief strategist and head of operations
- Capacity building

## Otari Ioseliani, MS
Software Engineer

- Paul G. Allen School of Computer Science & Engineering, Electrical & Computer Engineering, Ubiquitous Computing Lab

## Richard Li, MS
Engineer

- PhD Candidate, Paul G. Allen School of Computer Science & Engineering, Electrical & Computer Engineering, Ubiquitous Computing Lab



## Cindy Lin, MD
Director of Clinical Innovation

- Clinical Professor of Sports & Spine Medicine
- Endowed Professorship Sports and Exercise Medicine

## Shwetak Patel, PhD
Endowed Professor

- Washington Research Foundation Endowed Professor
- Paul G. Allen School of Computer Science & Engineering

## Sean A. Munson, PhD
Associate Professor

- Human Centered Design & Engineering
- HCDE PhD program director

## Kristen Gustafson
Engineering Student Assistant

- Computer Science & Engineering Major

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# Barriers to Physical Activity Support for Patients in Healthcare Setting

Lack of pragmatic solutions for patients who cannot afford gyms, personal trainers, wearables



Patients want personalized guidance on what exercises are safe and effective for their medical conditions



Clinicians are unable to provide personalized, ongoing support due to time, knowledge, and resource constraints

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# UI/UX Research: Patient Voices

50+ patients from diverse backgrounds and medical conditions participated in UI/UX interviews as part of IRB approved research and HCDE Capstone project:

**Key takeaways**

- Personalized activity goal
- Meaningful connection to provider

> *Anything **coming from my provider means more to me**; it feels personal.*

> *If I was doing the exercises and doing them right and doing a good job, I would appreciate Dr. XX reviewing them and being aware.*

> *"When go to a PT appointment, you're given a piece of paper, and you have to rely on their stick drawings for what it looks like."*

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# UI/UX Research: Healthcare Providers

## 30+ healthcare providers participated in interviews:

- Primary Care
- Family Medicine
- Cardiology
- Diabetes Specialists
- Oncologists
- Orthopedic Surgeons
- Weight management
- Rehabilitation medicine
- Integrative Medicine
- Pain Medicine
- Sports Medicine
- Adult & Pediatric Physical Therapists
- Registered Dieticians

***I would absolutely prescribe this to patients**. I would especially use it to assess how they've done in the interim. It would be helpful for that conversation during their next visit, and about discussing the barriers to improve.*
*- Physician, Pain Medicine*

***This could be helpful in changing patient behavior.** Whatever is measured tends to improve and having external motivation – like somebody helping to track that – can be helpful.*
*- Physician, Multiple Sclerosis Center*

**Key factors for adoption**
- EHR integration
- Light touch for providers

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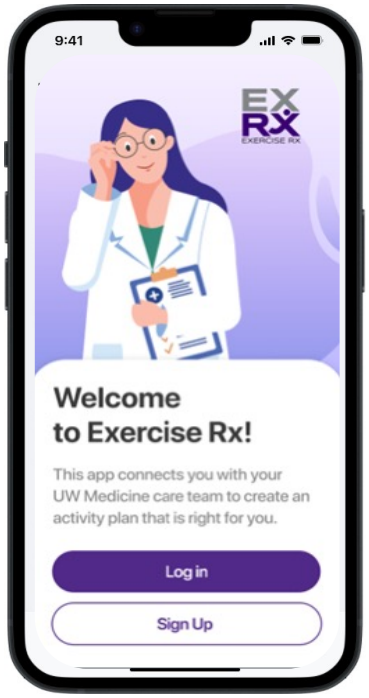
# Version 1 Patient App: Started Out Simple Wellness Support




**Only +1,000 steps/day**

Associated with 28% decrease in all-cause mortality in older adults[1]; reduces frailty[2]; lowers heart disease & mortality[3]


1. Nystoriak MA, Bhatnagar A. Cardiovascular Effects and Benefits of Exercise. *Front Cardiovasc Med*. 2018;5:135. Published 2018 Sep 28. doi:10.3389/fcvm.2018.00135
2. Chaudhry UAR, Wahlich C, Fortescue R, Cook DG, Knightly R, Harris T. The effects of step-count monitoring interventions on physical activity: systematic review and meta-analysis of community-based randomised controlled trials in adults. *Int J Behav Nutr Phys Act*. 2020;17(1):129. Published 2020 Oct 9. doi:10.1186/s12966-020-01020-8
3. Shcherbina A, Hershman SG, Lazzeroni L, et al. The effect of digital physical activity interventions on daily step count: a randomised controlled crossover substudy of the MyHeart Counts Cardiovascular Health Study. *Lancet Digit Health*. 2019;1(7):e344-e352. doi:10.1016/S2589-7500(19)30129-3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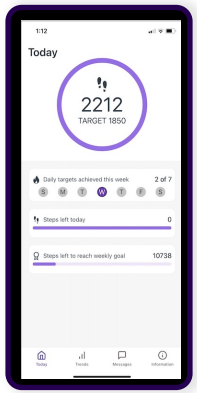
# ExerciseRx Version 2.0

## Patient App

Physical Activity Data Capture


Home Exercise Sensing




## Provider Dashboard

Epic

Clinically Relevant PA Data Integration

Triage and support

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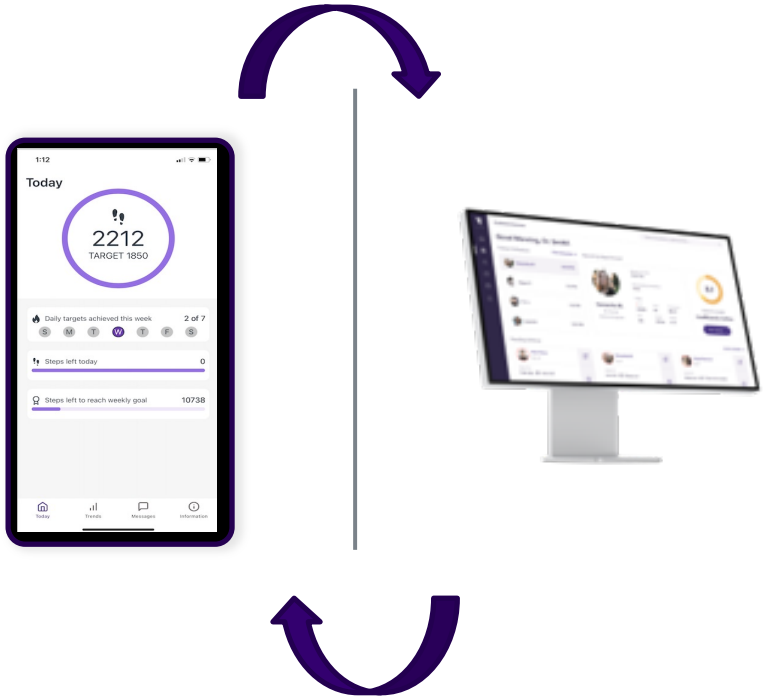
# ExerciseRX Supports Physical Activity without Burdening Providers

Activity progression based on behavior change research that emphasizes incremental change and building on successes




Physical activity profile for each patient

Seamless integration with providers' workflow

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# ExerciseRx Clinical Pilot Study Findings

## 25+ Patients

**Demographics**

- Mean age 46 ± 12 years, 64% female
- 53% White/Caucasian, 23.5% Hispanic/Latino, 18% Asian American, 6% African American/Black.
- 65% overweight/obese

**Inclusion Criteria**

- Insufficiently active
- Smartphone with iOS13+ or an Android 4.1+.
- Walk without fall risk

## Study Protocol

**Primary Objective**

Assess the effectiveness of the Exercise Rx platform in supporting inactive patients in improving their mean daily step counts

**Secondary Objectives**

Evaluate app usability and associations between patient-provider engagement and step count changes.

## Preliminary Findings

**Pilot Data**

70% of study participants had an increase in step count. Average step count change was approx. 1K steps overall.

Exit interviews to understand patient and provider voices

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# Patient Feedback

"I was literally walking around in my apartment trying to meet the goal. So, it really ***helped set me up to start walking a little bit more. It got to my head that there was this thing I had to do for my health.***

"I like that it gave me a goal to reach with ***someone looking over my shoulder*** to make sure I reached it – that definitely **was a motivating factor.**

"I feel more active – that I'm able to do it. ***Reaching that goal every week made me feel better about myself.*** I can actually do this. That's how it really helped me and is still helping me.

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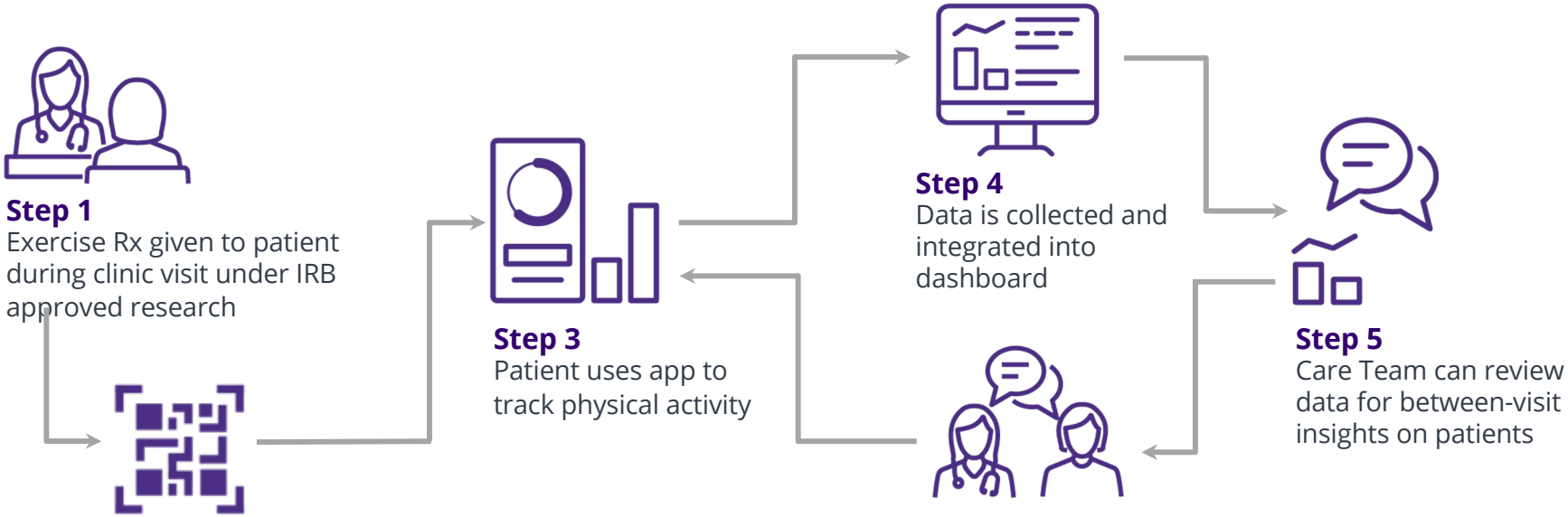
# ExerciseRx Clinical Flow



**Step 1**
Exercise Rx given to patient during clinic visit under IRB approved research

**Step 2**
Download app

**Step 3**
Patient uses app to track physical activity

**Step 4**
Data is collected and integrated into dashboard

**Step 5**
Care Team can review data for between-visit insights on patients

**Step 6**
Patient sees Care Team and reviews plan

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# ExerciseRx Project Support to Date

UW CoMotion Innovation Gap Fund - $50k

Washington Research Foundation Technology Commercialization - $50k

Seattle Children's Hospital Cerebral Palsy Research Grant - $250k

Bladder Cancer Advocacy Network Translational Research Grant - $1.1m

National Multiple Sclerosis Society Research Grant - $725k

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# Lessons Learned, Discussion, and Future Work

## Learnings

Development centered on patients and providers voices and needs

Start out simple

Diverse team members, build better ideas & solutions. Be humble, willing to learn from each other & change course when needed

Balancing research and  implementation

## Future Work

Continue to grow collaborations with clinical champions

Integration of clinically relevant metrics

Expanding accessibility to providers and patients

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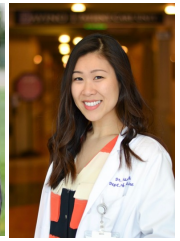
Sarah Psutka MD


Cindy Lin MD


Hanna Hunter MD

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Bladder Cancer Advocacy Network

THE SPORTS INSTITUTE®
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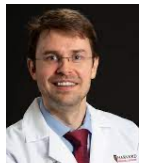
Florian Fintelmann MD


**The University of Washington/ Fred Hutch Cancer Center Bladder Cancer Team**

*Thank you to our patients and their families!*

Department of Urology
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UW Medicine

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# Thank you!





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Career Development Series 2024

# Case Study:

# **Developing a Smart Implantable Device**

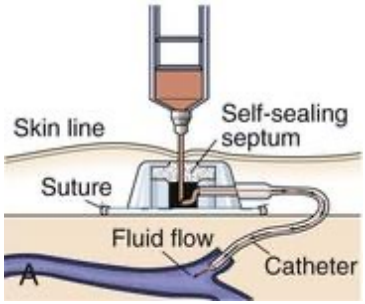
Teddy Johnson, ITHS

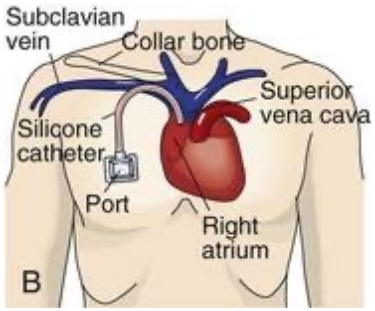
# Problem 1: Covid Prevented Early Cancer Diagnosis

| COVID-19 Pandemic | Prevention & Early Detection | Diagnosis | Treatment |
|---|---|---|---|
| **Reduced Access to Care**<br>• Shutdowns & social distancing<br>• Fear of infection<br>• Reallocation of health care resources<br>• Unemployment leading to financial insecurity & loss of insurance | **Delayed Routine Care**<br>• Preventive visits<br>• Screening<br>• Symptom follow-up<br>• Abnormal test follow-up | **Later-stage Diagnosis**<br>• Fewer treatment options<br>• More intensive treatment<br>• Lower probability of survival | **Delayed/Modified Treatment**<br>• Postponed surgery, radiation, and chemotherapy<br>• Less intense chemotherapy |

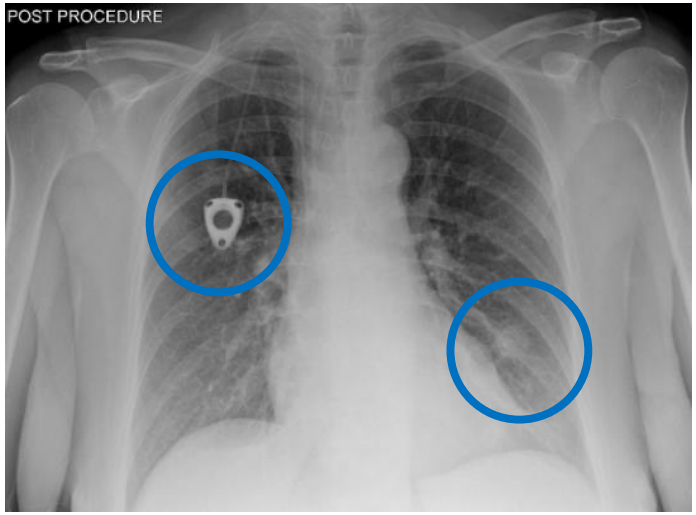
# Finding and Treating a Metastasis with Chemotherapy…

… and a commoditized vascular access port




## X-Ray




Right IJV chest port with tip at the cavo-atrial junction. No pneumothorax. Left mid/lower zone pulmonary nodule projects over posterior left 9th rib.

## CT

CT confirms the pulmonary nodule on chest x-ray is a solid soft-tissue density nodule.

# Problem 2: Sepsis Is Identified Too Late

# New Trend in Reimbursement: Value-Based Care

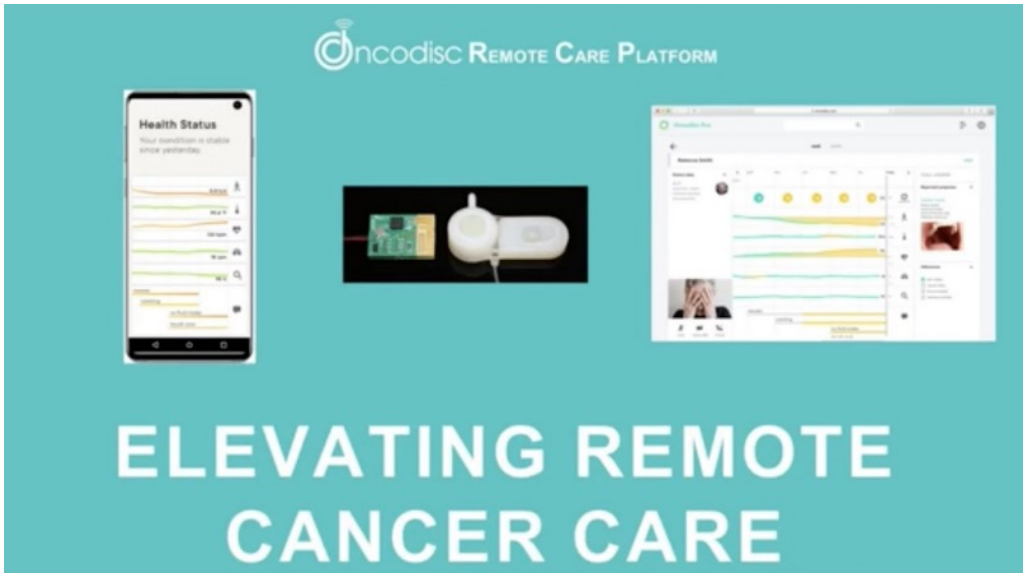
CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Oncology Care Model

## Oncology Care Model (OCM)

- The Innovation Center's Oncology Care Model (OCM) focuses on an episode of cancer care, specifically a chemotherapy episode of care
- The goals of OCM are to utilize appropriately aligned financial incentives to improve:
    1) Care coordination
    2) Appropriateness of care
    3) Access for beneficiaries undergoing chemotherapy
- Financial incentives encourage participating practices to work collaboratively to comprehensively address the complex care needs of beneficiaries receiving chemotherapy treatment, and encourage the use of services that improve health outcomes.

# Oncodisc: Mitigating Risks of Sending Chemo Patients Home




**Physician Comments Driving Design and Regulatory Path:**

- I don't want the device to make a diagnosis. I just want readouts.
- I want to be able to assess each patient in <15 seconds.
- How many alerts will I get?
- If I don't respond to a notification, am I at risk of negligence?

# What Will the Device Do?

Temperature for fever indication of infection

Heart Rate & Blood Pressure for indication of sepsis

Motion for “performance status”, fall prevention / detection

Bluetooth communication with smartphone to communicate with care team

Futures:
Blood testing?

# Building the Team to Deliver the System Features

**Features and Functions Driving Team Formation:**

- Implantable vascular access port device
- Hardware sensors
- Firmware to drive and read sensors
- Software to control and set device
- UI/UX design to optimize interfaces and dashboards
- Quality system covering market needs assessment through fabrication, sales, clinical experience
- Intellectual property to create investible assets
- Manufacturing via contract, then in-house
- Regulatory strategy
- Clinical study

# Stretching a Penny in Intellectual Property

The most important thing for founders to do is to prepare for delays in fundraising. To mitigate financial risk, founders should use fixed price services whenever possible.

From patent landscape and “freedom-to-operate” analyses to patent filing and prosecution, IP costs may vary wildly.

Seek IP attorneys with early startup client experience and sensitivity to startup costs. Fixed price patent work is preferable.

# Thank You!

Open for Questions

# Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.