But first, housekeeping

- Please note: **today's session is being recorded**
  - Slides and recording will be available on DiMe's webinar page after the session
- To ask a question for discussion during live Q&A, please either:
  - **'Raise your hand'** in the Reactions and the moderator will unmute you to ask your question live, or
  - **Type your question** into the chat box

Note: Transcription of the webinar is not permitted during this webinar; violators might be removed from the session.

Agenda

- Welcome and housekeeping (2mins)

- A Pulse of Digital Health in 2024 (3mins)

- Introductions (5mins)

- Short presentation from Jacqueline (8-10mins)

- Short presentation from Ben (8-10mins)

- Panel discussion (30 mins)

- Next steps

A Pulse of Digital Health in 2024

Great (reset in) expectations: Innovators are clipping along in a smaller funding market

DiME

- **$2.7B** in funding in Q1
- Across **133 digital health deals**
- High value deals are back – **higher deal volume** at **lower check sizes**
- **Avg deal size - $20.6M**
- **Lowest first quarter** investment by sector funding since 2019
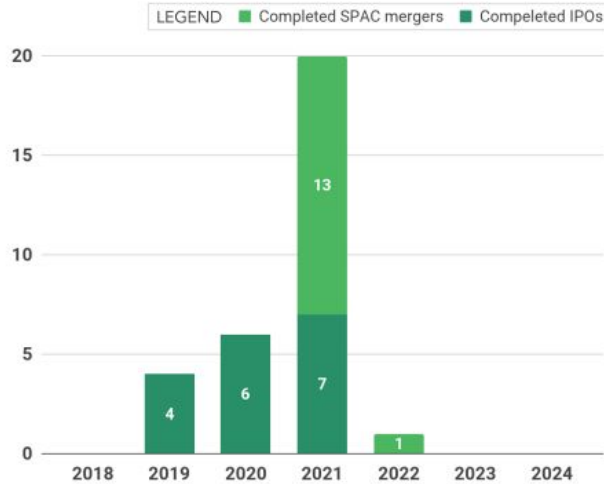- **480 partnerships** were announced in Q1 2024.

U.S. DIGITAL HEALTH FUNDING AND DEAL SIZE
2014-Q1 2024

ROCK HEAL+H

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Q1 2024
Total venture funding	$4.5B	$4.8B	$4.7B	$6.0B	$8.5B	$8.1B	$14.3B	$29.2B	$15.4B	$10.7B	$2.7B
Number of deals	298	327	349	376	395	416	476	738	579	496	133
AVERAGE DEAL SIZE	$15.2M	$14.7M	$13.5M	$15.8M	$21.6M	$19.5M	$30.1M	$39.6M	$26.5M	$21.6M	$20.6M

Where is market heading and what more will be seen for the digital health market?

- Real conversations about outcomes **(big focus on ROI)**
- **Growth in AI investment** trends upward
- Resets in public cohorts and **exit mindsets** with predominant **M&As**
- Continued creative fundraising

EXITS ONTO NASDAQ OR NYSE
2018-Q1 2024; by exit pathway

LEGEND ■ Completed SPAC mergers ■ Completed IPOs

DELISTINGS FROM NASDAQ OR NYSE
2022-Q1 2024

DECLARED BANKRUPTCY
babylon   Better⁺   PEAR THERAPEUTICS   UPHealth

ACQUIRED
Benefitfocus   Castlight   Science37
signifyhealth   TabulaRasa HealthCare⁺

TAKEN PRIVATE¹
nextgen
SOC Telemed™

CHANGED EXCHANGE
veradigm OTC

¹This category includes companies that were acquired by investment firms or private equity firms, or were taken private through alternative pathways
Note: Rock Health's Public Company Index tracks companies that meet our definition of digital health and trade on the NASDAQ or NYSE.
Source: Rock Health Public Companies Index; data through March 31, 2024

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Trend of US hospitals moving more acute care delivery to the home setting

- CMS allowed certain **Medicare-certified hospitals to treat patients with inpatient-level care at home** using Section 1135 waivers of the Social Security Act. CMS waived specific hospital Conditions of Participation that require 24-hour onsite nursing for patients.
- As of March 1, **315 hospitals across 131 systems in 37 states have been approved to participate in the Acute Hospital Care at Home program**. However, that CMS waiver is set to expire at the end of this year.
- U.S. lawmakers have drafted legislation to expand the CMS waiver for hospital-at-home programs through 2027
- House legislation that would **extend loosened pandemic rules for telehealth and hospital care at home won unanimous approval** in the Ways and Means Committee. In the Senate, Marco Rubio (R-Fla.) and Tom Carper (D-Del.) have a bill that would extend the rules permitting government reimbursement of care at home.

POLITICO

HEALTH CARE

Hospitals' new message for patients: Stay home

Health systems are trying to move more of the work they do to your house.

New codes from the AMA could mean more RPM reimbursement by 2025

- **If the CPT Editorial Panel approves new changes and Medicare and private payers follow suit,** providers that expand their remote patient monitoring programs to fit the new codes will gain the most benefits for their patients and clinics.
- Today, **most remote patient monitoring services are billed under four CPT codes**. These codes can be split into two categories to help understand their uses. There are **two RPM device monitoring codes – 99453 and 99454** – and **two timed RPM management service codes – 99457 and 99458**.
- Medicare was the first to cover RPM. Currently, it also is [covered in some form by about 32 state Medicaid programs](). Numerous commercial payers also cover RPM, sometimes within their telehealth coverage policies.

Q. Please summarize the proposed changes to RPM coding for the May CPT Editorial Panel meeting convened by the American Medical Association.

A. The first – and this would be a very big deal – is the addition of a code that would cover two to 15 calendar days of collected and transmitted data. CPT 99454, the only current general RPM device supply CPT code, can only be used when a provider has received and recorded 16 or more days of patient data within a 30-day period.

The addition of a new code would enable providers to code for those 30-day periods where fewer than 16 but at least two readings are captured.

The second noteworthy change under consideration is a revision of CPT 99457 to include 11-20 minutes of RPM care management time. 99457 currently requires at least 20 minutes of recorded care management time.

Revising 99457 would decrease the amount of time a provider's clinical staff needs to provide RPM monitoring and care management time for a patient during the month to report the code.

The third is a revision of CPT 99458 to cover each additional 10 minutes of interactive communication. 99458 currently requires at least an additional 20 minutes of interactive communication. Revising 99458 would reduce the amount of additional time clinical staff must spend to report the code.

Ray of sunshine for breakthrough devices this summer (don't expect sunny days yet)

DiME

Dora Hughes, center director at CMS, shares at the Medical Device Manufacturers' Association conference that the agency wanted to take the time to meaningfully address feedback sent during the comment period, which closed in August. She also noted the **organization's goal of releasing the final rule with a slate of other policies,** including a **rule <u>clarifying the agency's thinking on what kind of evidence would be needed</u>** to convince the agency that a given device is both reasonable and necessary.

But CMS estimated it would accept only five devices a year into the program; a rather small number given the <u>almost 1,000 breakthrough-designated devices likely to seek reimbursement</u>. Hughes said on Thursday the agency wanted to be conservative with its device estimate given budget constraints.

HEALTH TECH

STAT+

Medicare official says breakthrough device reimbursement rule coming in early summer

By <u>Lizzy Lawrence</u> 🐦 April 19, 2024

<u>Reprints</u>

MEDICARE HEALTH INSURANCE

Name/Nombre

A federal rule that could make Medicare reimbursement for breakthrough devices easier is slated for early summer.
ADOBE

With tightening digital health funding and escalating expectations, how can innovators efficiently construct evidence for their products?
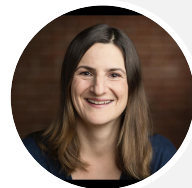
![DiME Digital Medicine Society logo]

Tuesday, May 21, 2024

11:00 a.m. ET

Steve Seuntjens
Partner - PHS Capital

Jacqueline Lutz
Digital Health & Clinical Science Consultant
LUJA Consulting LLC

Benjamin Vandendriessche
VP, Science
Digital Medicine Society (DiMe)

Smit Patel
Associate Program Director
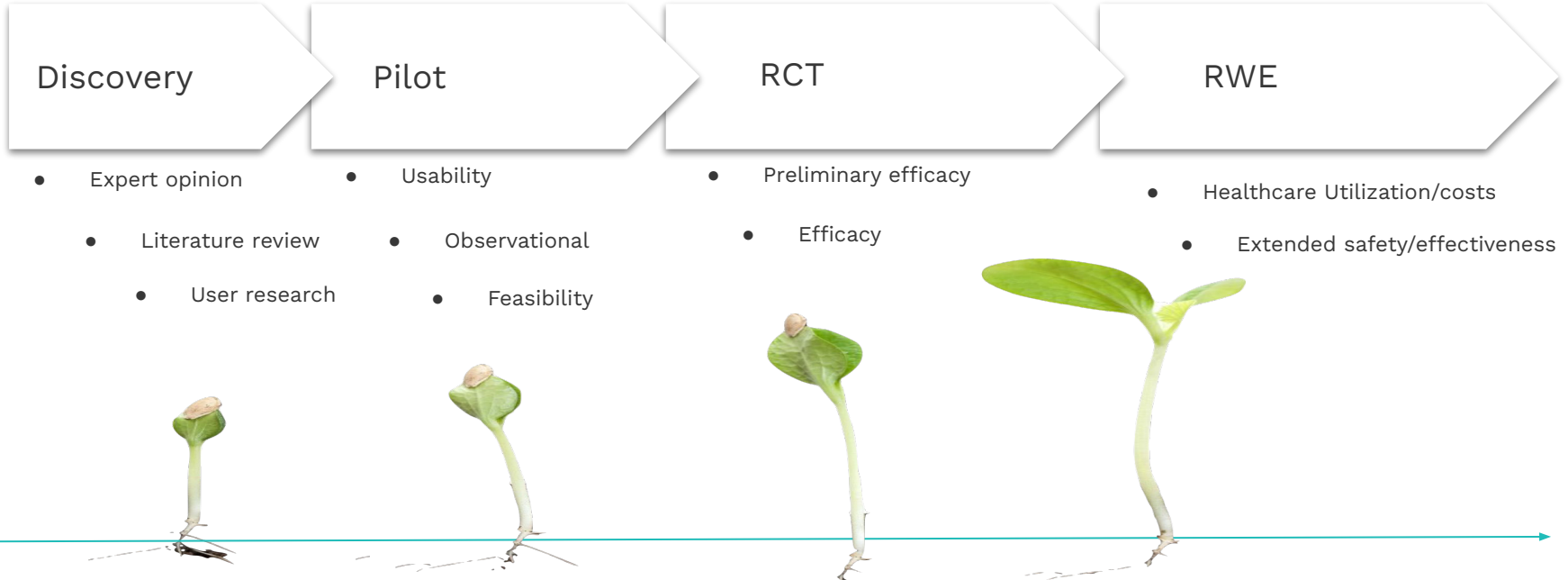Digital Medicine Society (DiMe)

Innovator Scientist Presentation

Innovation + research journey

Meditation

Plattform R+D

Digital patient solution / companion
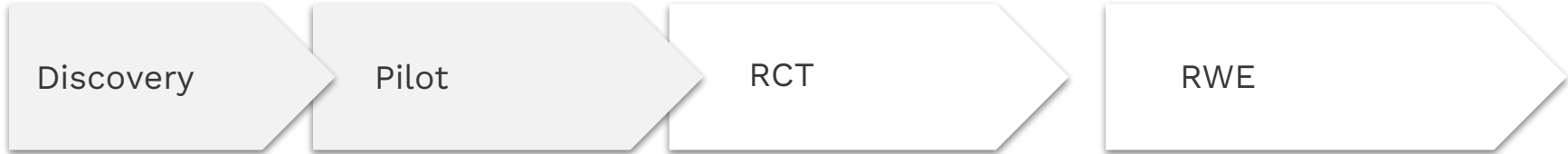
DTx Product Evidence Strategy

EMA + Brainimaging

Pilot

Stimulus validation

Pilot

Real-world evidence

Anxiety

MS

Marketing study

User research

Observational

Feasibility

MDD

SZ

MCI

Label extension

Expert interviews

ADHD

Employee study

Chronic pain

Growing evidence

Discovery	Pilot	RCT	RWE

Discovery
- Expert opinion
- Literature review
- User research

Pilot
- Usability
- Observational
- Feasibility

RCT
- Preliminary efficacy
- Efficacy

RWE
- Healthcare Utilization/costs
- Extended safety/effectiveness

Increasing evidence strength / Increasing time + costs for evidence generation

Early evidence

| Discovery | Pilot | RCT | RWE |

- Evidence on the evidence needed: Type and strength for key stakeholders
- Existing evidence
- Stakeholder-based evidence plan + prioritization - Trade-offs
- Signals along the way to steer product/evidence
- Creative period for out-of-the box approaches
- Plan ahead, including dissemination:
  "This is not research" "Can we publish this?"

Later stages

Discovery   Pilot   RCT   RWE
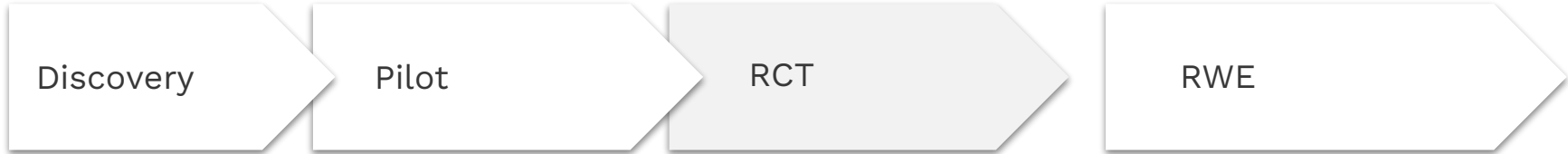
- Clinical trial operations
- Superpowers
    - Marketers turn trial recruiters
    - Technology in clinical trials
    - Designers turn poster wizards

With a little help

Scientists

Academics

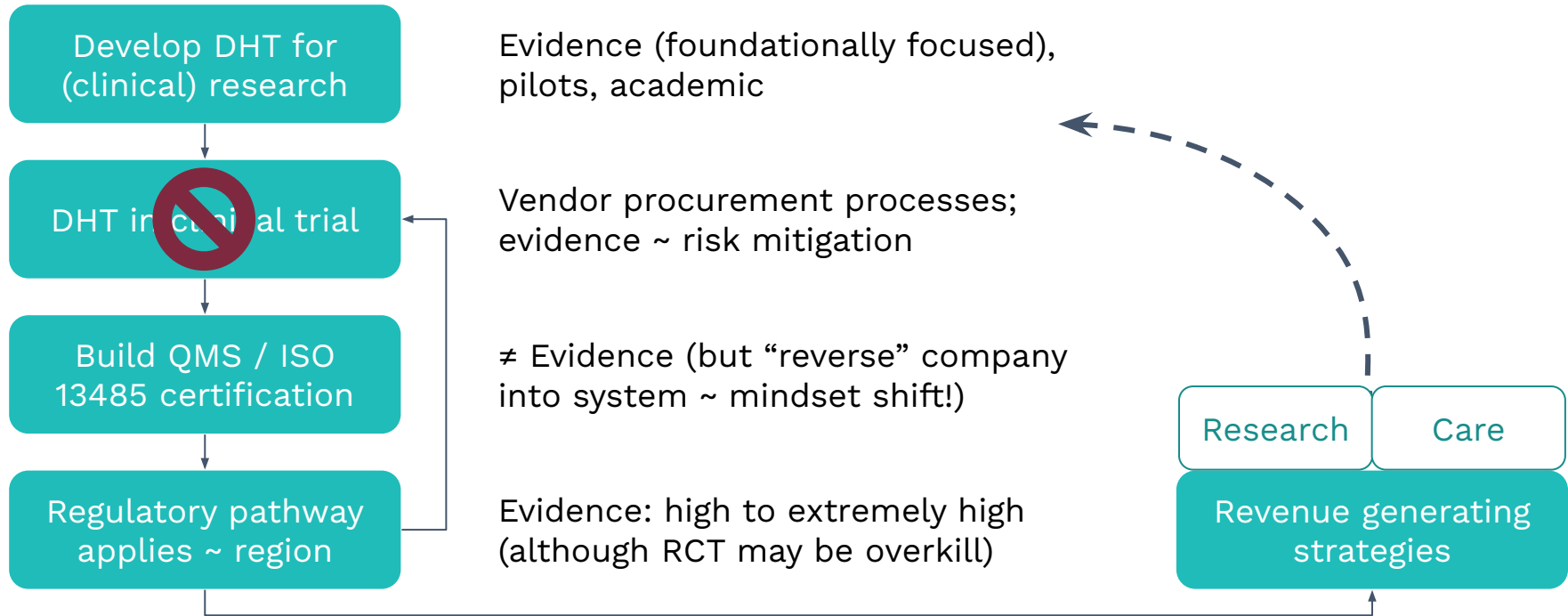Digital friendly HCP/sites

Early adopters

Industry outside the box thinkers

DiMe

Evidence Generation is a Continuum
(but there are "seismic" shifts)

An example of the forces that "pull" a company in a certain evidence direction

Develop DHT for (clinical) research

Evidence (foundationally focused), pilots, academic

DHT in clinical trial

Vendor procurement processes; evidence ~ risk mitigation

Build QMS / ISO 13485 certification

≠ Evidence (but "reverse" company into system ~ mindset shift!)

Regulatory pathway applies ~ region

Evidence: high to extremely high (although RCT may be overkill)

Research | **Care**

Revenue generating strategies

The many DiMe resources that are leveling the playing field

A WEBINAR SERIES BY

DATAcc
Digital Health Measurement Collaborative Community

DEEP
DIGITAL EVIDENCE ECOSYSTEM & PROTOCOLS

by

DME
DIGITAL MEDICINE SOCIETY

Digital Measurement Of Nocturnal Scratch:
New developments

June 4, 11 a.m. ET
Recent Regulatory Feedback

June 11, 11 a.m. ET
Updates from R&D of Algorithms and Tools

June 18, 11 a.m. ET
Processes, Validation, and Adoption

Public Workshop

Using Patient Generated Health Data in Medical Device Development: Case Examples of Implementation Throughout the Total Product Lifecycle

FDA

DiME
DIGITAL MEDICINE SOCIETY

June 26, 2024 | 11am - 3pm ET

June 27, 2024 | 11am - 3pm ET

Thank you

https://dimesociety.org/

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