

# Digital Health Strategy Monitor Edition 07

Coverage period 28 April 2026 – 31 May 2026

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## Introduction

This briefing provides a curated overview of notable developments in digital health between April 28 and May 31, 2026, based solely on publicly available sources. It is not a comprehensive transaction or policy database, but a selection of signals that are particularly relevant for stakeholders in the US and Europe (including DACH).

## 1. Executive Summary

The five-week window closing Q2 2026 confirmed three structural shifts that have defined digital health this year: **capital is concentrating in fewer, larger AI-native rounds; strategic consolidation is accelerating** as scaled platforms acquire complementary point solutions; and the new **CMS–FDA RAPID pathway** is rewriting how breakthrough digital devices reach Medicare coverage. Mental health, metabolic care, and clinical-AI infrastructure dominated both funding and deal flow, while wearables and AI imaging captured the most regulatory wins.

## 2. Venture Capital & Growth Investments

May 2026 was one of the strongest funding months of the year, with capital concentrated in late-stage AI plays and metabolic / virtual specialty care.

Date	Company	Round / Amount	Category	Lead / Notes
29 May	H1	\$40M	AI provider-directory	Led by CVS Health Ventures <a href="#">MobiHealthNews</a>
27 May	Signos	\$20M	CGM-based weight management	Dexcom, GV, BCBS Alabama <a href="#">MobiHealthNews</a>
27 May	Rosarium Health	\$6M	Senior in-home care marketplace	<a href="#">MobiHealthNews</a>
21 May	The Path (Tony Robbins)	\$14.3M	AI mental health	Co-founded by ex-Calm leadership <a href="#">MobiHealthNews</a>
20 May	Neurosoft Bioelectronics	\$7.5M	Brain-computer interface	<a href="#">MobiHealthNews</a>
19 May	Commure	\$70M	Clinical AI / workflow	Post-money valuation \$7B; total raised \$750M <a href="#">MobiHealthNews</a>
19 May	Nourish	\$100M	Virtual nutrition / metabolic	Expands AI tooling & clinical network <a href="#">MobiHealthNews</a>
19 May	Century Health	\$5M seed	RWE / life sciences data	Oversubscribed <a href="#">MobiHealthNews</a>
15 May	9amHealth	\$26M	Virtual specialty care	<a href="#">MobiHealthNews</a>

14 May	Anomaly	\$17M	AI payer-intelligence	Claims analytics & reimbursement <a href="#">MobiHealthNews</a>
7 May	Dandelion Health	\$14M	Precision medicine platform	<a href="#">MobiHealthNews</a>

**Read-through:** Mega-rounds remained scarce after the Q1 surge (Whoop \$575M, OpenEvidence \$250M, Verily \$300M, Talkiatry \$210M), but the May cohort shows healthy mid-stage activity. Strategic corporates (CVS, Dexcom, BCBS) led several rounds — a continued sign that payers and device incumbents are anchoring digital health balance sheets [DHI](#).

### 3. Mergers & Acquisitions

Strategic consolidation continued into the reporting window, with the **Infosys–Optimum Healthcare IT** close as the headline transaction.

- **Infosys completes acquisition of Optimum Healthcare IT (5 May 2026)** — Closes the digital-transformation services deal announced earlier in the year, expanding Infosys' US provider-side EHR and AI advisory footprint. [Infosys](#)

Carry-over context from earlier 2026 deals that remained referenced in May market commentary [Xtalks](#):

- **Hims & Hers – Eucalyptus** (up to \$1.15B) — international telehealth expansion (AU, JP, UK, DE, CA).
- **UHS – Talkspace** (~\$835M) — payer-grade behavioral health acquisition.
- **Sword Health – Kaia Health** (\$285M) — strengthens MSK position and unlocks Germany's DiGA channel.
- **OpenAI – Torch** (~\$100M acqui-hire) — consolidates AI-EHR talent into ChatGPT Health.
- **Oura – Galen AI** — wearables + clinical AI convergence.

**Read-through:** The dominant pattern is platform-buys-feature: scaled telehealth, MSK and wearable platforms absorbing clinical-AI and data-integration teams to defend moats as foundation-model players (OpenAI, Google) enter health workflows.

## 4. Market Access & Regulatory

### 4.1 The RAPID Pathway — biggest structural news of the period

**CMS and FDA jointly launched the RAPID (Regulatory Alignment for Predictable and Immediate Device) pathway** in May 2026. The mechanism aligns FDA clinical-evidence review with Medicare coverage determinations so that breakthrough device evidence can

simultaneously support both clearance and reimbursement. For digital health and AI/ML SaMD vendors, RAPID materially compresses the time from clearance to revenue — historically the longest single bottleneck in the US market-access journey. [NanoApps Medical](#)

## 4.2 Notable FDA clearances in May 2026

Date	Company	Product	Pathway / Note
26 May	Spectral AI	DeepView System (burn-wound healing prediction)	De Novo; AI on multispectral imaging; BARDA-backed <a href="#">GlobeNewswire</a>
May	Abbott	Ultreon 3.0 coronary imaging software	510(k) + CE Mark; AI-automated insights <a href="#">Today's Medical Developments</a>
May	Siemens Healthineers	Six Artis interventional imaging systems with Optiq AI chain	510(k) <a href="#">Today's Medical Developments</a>
May	RIVANNA	Accuro XV diagnostic ultrasound (MSK)	510(k); AI add-ons BoneEnhance & CAdex in clinical study <a href="#">Today's Medical Developments</a>

## 4.3 FDA digital-health framework

The **2026 FDA guidance update** continued to take effect during the window, expanding the general-wellness enforcement-discretion zone for low-risk wearables (sleep, activity, HRV, stress) and clarifying the CDS-software boundary. Combined with RAPID and the **TEMPO pilot**, the US is signaling a more bifurcated regime: lighter for wellness, faster for breakthrough. [Berkley Lifesciences](#)

## 4.4 EU / NL context

No new DiGA listings or NL-specific reimbursement decisions surfaced in this window with high enough signal to report; Sword-Kaia (Q1) remains the most impactful EU access move of 2026. Worth monitoring for June: ATA's late-May 2026 commentary to FDA on **digital health technologies in drug clinical investigations** signals trans-Atlantic alignment on DCT/DHT evidence standards. [ATA Action](#)

## 5. Notable Clinical Studies

The reporting window was relatively light on landmark digital health RCT readouts, but several signals are worth flagging:

- **ATA Nexus 2026 (Orlando, 12–15 May)** — the largest US telehealth congress of the year served as the venue for multiple real-world evidence presentations on AI-augmented stethoscopy (Eko Health) and virtual-care outcomes. [Eko Health](#)
- **Spectral AI DeepView** — De Novo clearance was supported by a clinically validated dataset of >340 billion pixels of burn-wound imagery, one of the largest training corpora cited in a recent dermatology-adjacent AI clearance. [GlobeNewswire](#)

- **Mayo Clinic wearables-in-COPD study** (published earlier 2026, referenced widely in May) — sleep data from consumer wearables predicted engagement in remote pulmonary rehabilitation, reinforcing the wearable-as-adherence-signal thesis. [Mayo Clinic](#)
- **ASCO 2026 (29 May – 2 June)** — early sessions emphasized AI-driven RWE in GI oncology, including Verana–COTA's combined oncology data platform (post-merger). [ASCO Educational Book](#)

## 6. Utilization & Adoption Signals

- **OpenEvidence** — referenced again in May commentary as used daily by **>40% of US physicians**, with \$100M ARR. The clearest "category-defining utilization" datapoint of the year. [DHI](#)
- **Whoop** — running at **~\$1.1B revenue run-rate** at the time of its \$575M Series G, ahead of a reported IPO path.
- **Grow Therapy** — **~\$1B revenue on ~7M annual visits**, validating the virtual-mental-health-marketplace model at scale.
- **Talkiatry** — **1,745% revenue growth 2021→2024**, now the largest private psychiatrist employer in the US.
- **CMMI ACCESS Model** — applications to participate "exceeded expectations" per CMS, drawing nearly every major payer into a common value-based payment framework — a structural utilization tailwind for digital health vendors aligned to outcome-based contracts. [DHI](#)

## 7. Outlook into June 2026

1. **RAPID's first pilot devices** — the first vendors entering RAPID will set precedent for digital-health reimbursement timelines; expect announcements in June.
2. **ASCO 2026 readouts** — watch for AI-CDS and digital biomarker studies; the GI-oncology track is densest.
3. **Continued telehealth M&A** — fragmented behavioral and metabolic care platforms remain the most likely targets following the UHS–Talkspace and Hims–Eucalyptus templates.
4. **NL / EU angle** — DiGA renewals and the EU AI Act's medical-device interplay become operational mid-year; Dutch providers should track Sword–Kaia integration as a benchmark.

