

Digital Health News Report

Reporting period: 1 September 2026 – 30 September 2026

Prepared by Woesthuis MedTech Consultancy

Focus: VC & growth investments · M&A · Market access · Clinical evidence · Adoption & utilization · Urology deep-dive

Executive summary

September was the strongest month of 2026 for digital health dealmaking, and the clearest confirmation that the market has turned. US digital health funding reached \$7.4B across 244 deals in H1 2026, up from \$6.4B a year earlier, with the pace accelerating rather than slowing: roughly \$1.85B across nine disclosed rounds in the last 30 days of September alone. Median deal size rose from \$12M to \$14M. Meanwhile M&A captured 97.6% of digital health exits, and healthcare IT deal volume grew 23% year-over-year to 179 deals by September, on track to beat 2025's record 348.

The clearest strategic pattern: capital is concentrating in AI that removes real operational burden — clinical documentation, workflow automation, benefits administration — rather than consumer-facing apps. And in urology, September delivered the month's single most consequential European regulatory milestone: FemPulse's CE Mark for a non-invasive overactive bladder therapy.

1. Venture capital and growth investments

EliseAI raised \$350M at a \$4B valuation (29 September) to expand healthcare AI automation, workforce and North American footprint.

Heidi Health raised \$340M at a \$900M valuation (22 September) for its AI clinical scribe.

Precision Neuroscience raised \$250M Series D (24 September), bringing total capital to \$430M, as it expands its clinical program and prepares for commercialization in brain-computer interfaces.

Angle Health closed a \$600M Series C (18 September) in SMB health benefits.

Rightway raised \$155M Series E (24 September), led by Francisco Partners, for pharmacy benefits technology. Forus raised \$150M Series C at a \$3B valuation (8 September) for AI-powered medication access. Thatch raised \$108M Series C at a \$1B valuation (15 September).

Tandem Health (Sweden) raised \$100M Series B (14 September), led by the Scaleup Europe Fund managed by EQT, to scale clinical workflow and administrative AI across European healthcare networks — the standout European round of the month, backed by the EU's €5B tech startup initiative.

Other notable rounds: Inspiren \$70M (AI senior care), Implicity \$40M (AI cardiac monitoring; 250+ medical centres, 120,000+ patients monitored daily across the US, France and Germany), PatientIQ \$30M Series C, Teal Health \$22M (at-home cervical cancer screening), Corridor \$25M seed, Onalabs €9.3M Series A (Spain, non-invasive sweat-monitoring wearable), Holifya €2M (Italy, AI-assisted metabolic clinic and GLP-1 adherence), Penelope Health €87M (London, payer rules and revenue-cycle automation).

Read-through: a new SMB health-benefits cluster has formed (Angle Health, Thatch, Corridor). European capital is concentrating on clinical workflow AI and diagnostics infrastructure rather than standalone wellness apps.

2. Mergers and acquisitions

Hinge Health acquired Cylinder Health for \$105 million, expanding from musculoskeletal and migraine care into digestive health — the month's most strategically significant deal, and a clear signal that Hinge is building a multi-condition chronic care platform.

DexCare acquired Mila Health (30 September), adding care coordination to patient navigation. Medallion acquired Andros, an NCQA-certified credentials verification organization. Hello Patient acquired Converse Health, extending AI agents across the full patient conversation.

Medtronic invested \$700M in Cornerstone Robotics (1 September), distributing the Sentire surgical system alongside its Hugo platform in select non-US markets. Manulife Canada partnered with Sword to expand physiotherapy access.

3. Market access and regulatory

DeepHealth received FDA 510(k) clearance for Chest XRay (16 September) — a chest X-ray computer-aided detection solution built on a foundation model, detecting nodules, consolidation, and mediastinal and hilar findings. Its CE-marked version is already in European use, analysing more than 2.8 million examinations annually. Notable precedent: a foundation model translated into a cleared clinical capability, with EU deployment preceding US clearance.

FDA released draft guidance for robotic surgical devices — directly relevant to surgical robotics and AI-assisted procedural systems.

a2z Radiology AI received FDA clearance for a2z-Abdo-Triage (21 September), covering 10 findings on abdomen-pelvis CT.

In Europe, the parallel application of the EU AI Act and MDR/IVDR still adds 18–24 months to certification timelines for software above Class IIa.

4. Clinical studies and evidence

September was lighter on landmark RCTs than on infrastructure news. The most substantive evidence signals came from imaging AI at scale (DeepHealth's 2.8 million annual examinations in Europe) and cardiac monitoring at scale (Implicity's 120,000 patients daily across three countries).

A theme worth noting for market-positioning work: reporting from EBSCO flagged that the health systems least likely to catch errors in AI models often serve the patients most likely to be affected — AI governance is becoming a procurement criterion.

5. Market adoption and utilization

Implicity — 250+ medical centers, 120,000+ patients monitored daily across the US, France and Germany.

DeepHealth Chest XRay — 2.8M+ examinations analyzed annually in Europe.

Amazon Health Benefits Connector — expanded partnerships connecting users to virtual care benefits including nutrition therapy and sleep care.

Manulife Canada–Sword — physiotherapy access expanded at payer scale.

6. Urology focus

September was a landmark month for urology digital health, and the milestone was European.

FemPulse secured CE Mark certification under EU MDR for the FemPulse Ring (announced 17 September from Vienna and San Francisco), a non-implanted, patient-managed vaginal neuromodulation device for overactive bladder (OAB) in women. The device is now listed in EUDAMED, opening distribution across EU member states. The CE marking was supported by positive safety and efficacy data from four clinical studies. The mechanism is a first-line alternative to pharmaceutical medication: mild electrical nerve stimulation, inserted vaginally and worn by the patient — explicitly positioned against implanted neurostimulators, which the company describes as expensive, invasive and requiring specialists. OAB affects one in five women worldwide, with over 50 million women in Europe. The device remains investigational in the US.

Why this matters commercially: OAB is large, chronically underserved, and has historically been addressed through pharmacotherapy with poor adherence or through invasive implanted neuromodulation. FemPulse clears the world's hardest regulatory bar with a non-invasive, self-administered alternative and now has EU-wide market access in hand. For anyone advising urology companies on European market access and reimbursement strategy, FemPulse is now the reference case. Clinical data will be presented at ICS on 9 October 2026 — the next datapoint to watch.

Supporting urology developments in the period:

- SpaceOAR Flex Hydrogel received FDA 510(k) clearance for prostate radiotherapy (25 September) — spacer technology that reduces rectal dose during prostate radiation, relevant to the quality-of-life side of prostate cancer treatment.
- PACE-A phase 3 trial: SBRT and prostatectomy showed similar 8-year disease control in localized prostate cancer, with lower rates of urinary incontinence after SBRT (reported 28 September). Clinically significant for treatment-choice conversations and for the digital tools supporting shared decision-making.
- Enrolment goal met in a phase 3 study of 68Ga-PSMA-PET in the pre-biopsy setting (2 September) — relevant to the diagnostic pathway that feeds AI-based risk stratification.
- FDA approved belzutifan plus lenvatinib (LITESPARK-011) for advanced kidney cancer (24 September) — the renal cell carcinoma side of the uro-oncology portfolio.
- Leica Biosystems received multiple FDA 510(k) clearances for digital pathology products (August, sustaining into September) — the infrastructure layer that AI prostate and bladder diagnostics depend on.
- Prostate Cancer Awareness Month prompted sector-wide discussion of the shift from one-size-fits-all screening to individualized, risk-adapted strategies (3 September).

Read-through for urology: value creation in urology digital health continues to sit in precision diagnostics, imaging support, digital pathology and bioelectronic intervention — not consumer telehealth. FemPulse's CE Mark establishes overactive bladder as a credible commercial target for non-invasive neuromodulation in Europe, and it is the clearest example this year of a urology digital health company converting clinical evidence into European market access.

7. Outlook

Dealmaking momentum is carrying into Q4: at September's pace, healthcare IT transaction volume will exceed 2025's record. Categories to watch: AI workflow automation at scale, SMB benefits administration, and clinical AI in Europe backed by the Scaleup Europe Fund. For urology, the next milestones are **FemPulse's ICS data presentation on 9 October**, US regulatory progress for overactive bladder bioelectronics, and continued FDA movement in AI prostate and bladder diagnostics.