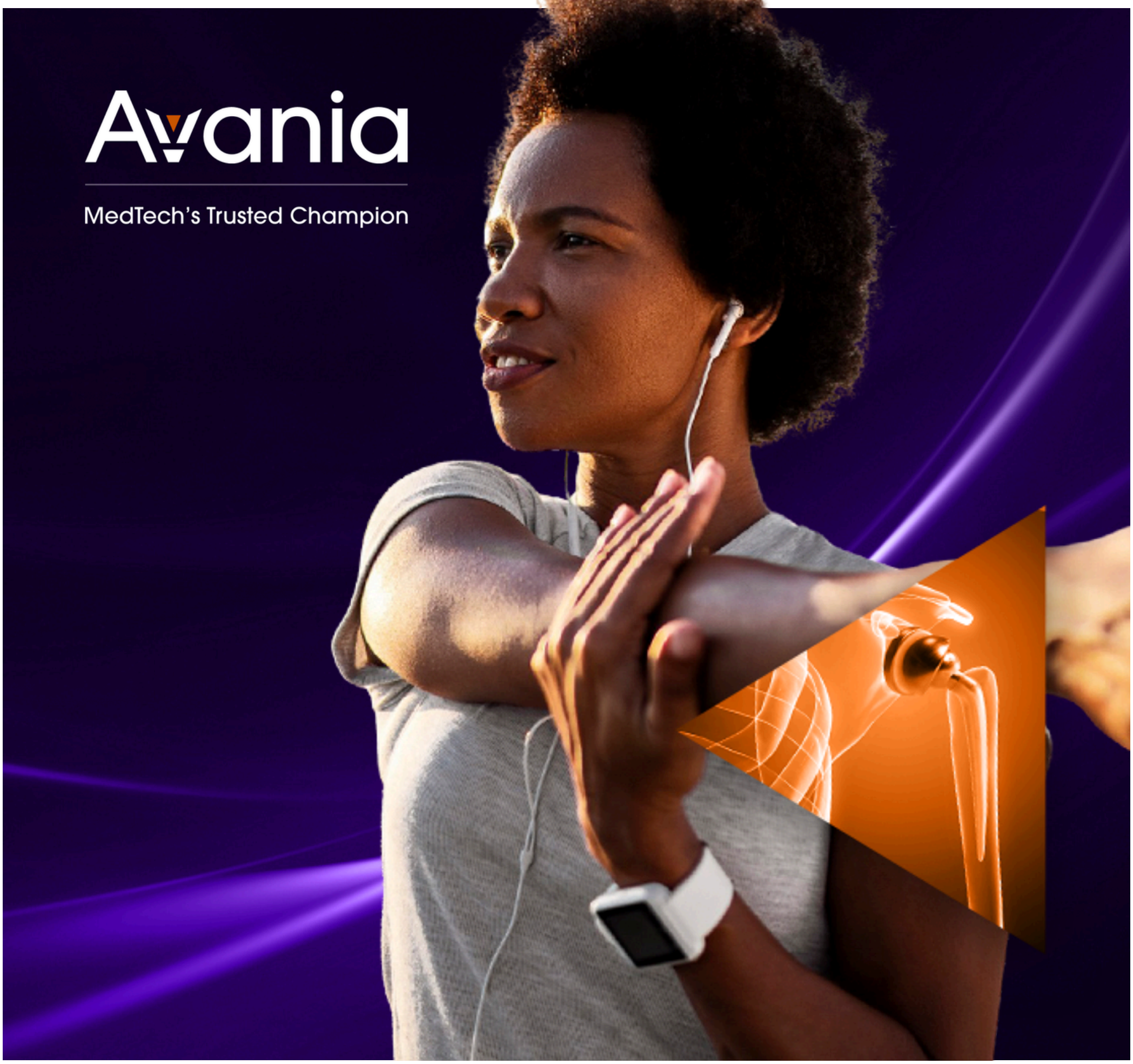
Avania

MedTech's Trusted Champion



MedTech Industry Pulse

May 2026

May ‘26 Summary

- **Kyle Diamantas, J.D. named Acting Commissioner of the FDA**
- **84 MedTech Clinical Trial starts in May – a 17% decrease from April (100)**
  - YTD Cardiovascular represents 25% of all starts
- **MiRus received a $1.5B investment from Boston Scientific**
- **AI enters FDA inspections (May 6)**
- **7 key acquisition announcements:**
  - Roche acquired Path AI
  - Medtronic acquired SPR Therapeutics
  - ResMed acquired Noctrix Health
  - Olympus acquired Bioprotect
  - Artivion acquired Endospan
  - Endologix acquired Pounce Thrombectomy
  - Johnson & Johnson acquired Atraverse
- **5 PMA Approvals & 4 De Novo Approvals**
- **Mobia Medical completed a $150M IPO raise**

Avania

May ‘26 Funding Successes

Company	Country	Funding Stage	Amount	Focus
MiRus	United States	Strategic Investment	$1.50B	TAVR (investment from Boston Scientific)
Pulnovo Medical	China	Strategic financing	$100M	Interventional therapies for pulmonary hypertension
UroMems	France	Strategic financing	$60.0M	Smart implantable artificial urinary sphincter
ClearNote Health	United States	Series D	$52M	Early cancer detection platform focused on pancreatic & ovarian cancer
BlueWind Medical	Israel	Equity + debt financing	$47.8M	Neuromodulation for urinary incontinence
Median Technologies	France	Capital raise	€40M–50M	Oncology imaging and AI-driven lung cancer screening platform
Sonomind	France	Series A	€20M (~$23M)	Non-invasive ultrasound neuromodulation tech for treatment-resistant depression
Triomics	United States	Series B	$22M	AI platform helping cancer centers manage oncology clinical & research workflows
Butterfly Medical	United States	Series C	$21.0M	Implantable treatment for BPH
Signos	United States	Funding round	$20.0M	AI-powered metabolic health platform
Rivermark Medical	United States	Series D	$20.0M	Prostatic stent technology
Lucis	France	Series A	$20.0M	Develop AI health companion, longitudinal monitoring & clinical safety tools
Vortex Imaging	United States	Financing round	$12.0M	Computational ultrasound imaging
Lungpacer Medical	United States	Convertible Notes	$12.0M	Medical device for ventilation and ICU lung support
Centese	United States	Financing round	$15.0M	Cardiothoracic post-operative surgical monitoring equipment
Urologic Health	United States	Seed	$11.0M	Bladder function monitoring
Adenocyte	Israel	Series A	$10.0M	Pioneering early detection of pancreatic cancer & its precancerous precursors
iFAST Diagnostics	UK	Funding Round	£5.0M	Antimicrobial Susceptibility Testing (AST)
Nanochon	United States	Seed Prime II	$4.1M	Orthopedic implant for treatment of articular cartilage defects in the knee.

May ‘26 Initial Public Offerings (IPO)

MOBIA

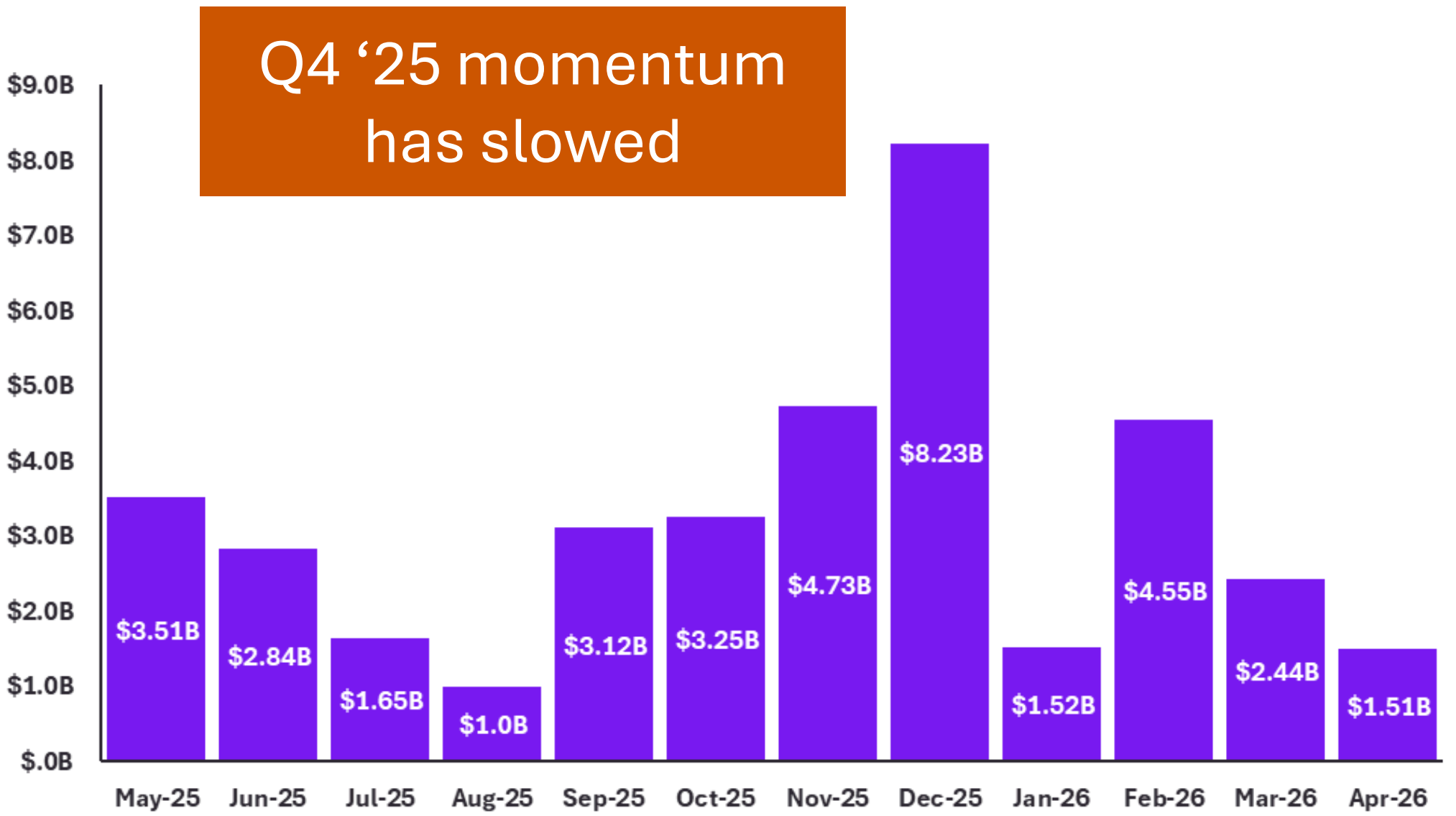
$150M Raised

A commercial-stage medical device company specializing in neurological rehabilitation.

Recognized for developing the Vivistim® Paired VNS™ System, which is the first & only FDA-approved implantable neurostimulation therapy clinically validated to improve upper limb motor function in chronic ischemic stroke survivors.

Avania

BioWorld MedTech Financings



- **Transaction Types:** IPOs, follow-ons, private placements, venture capital rounds, and loans.
- **Sector Coverage:** Companies developing medical devices, diagnostics, and other technologies for medical use.
- **Exclusions:** Grants and money received through corporate acquisitions, partnerships, or licensing deals.

Avania

Announced M&A

Roche

$1.05B Acquisition

PathAI

Medtronic

$650M Acquisition

SPR Therapeutics

Resmed

$340M Acquisition

NOCTRIX HEALTH

OLYMPUS

$270M Acquisition

BIOPROTECT

Avania

Announced M&A

ARTIVION

$175M + milestones Acquisition

ENDOSPAN

Endologix

Not disclosed

Pounce Thrombectomy

Johnson&Johnson

$340M Acquisition

ATRAVERSE

Avania

INSIGHTS
REGULATORY & MARKET ACCESS

Regulatory & Market Access May ‘26

Trends top Watch in the Market Access and Regulatory Landscapes to position for Q2 ‘26

Market Access

Coverage and HTA rules in flux

- **NTAP repeal comment window closes (Jun 9).** Proposal to end the Breakthrough Device add-on payment pathway takes effect FY 2028, raising the evidence bar.
- **FY2027 inpatient rule under review.** CMS proposes device NTAP approvals and a first UDI-for-implants reporting measure for hospitals.
- **EU device HTA launches (June).** First EU Joint Clinical Assessments cover high-risk devices and Class D IVDs.

Regulatory & Compliance

AI oversight tightens as EU deadlines land

- **AI enters FDA inspections (May 6).** FDA began one-day AI-informed assessments of lower-risk facilities, shifting resources toward higher-risk sites.
- **EU AI Act deal keeps medtech in scope (May 7).** Device AI obligations deferred to Aug 2028, high-risk status confirmed.
- **EUDAMED mandatory (May 28).** EU device transparency and supply-chain visibility push intensifies.

Avania

INSIGHTS
REGULATORY & MARKET ACCESS

Regulatory & Market Access May ‘26

Reliance pathways multiply as transparency and AI deadlines arrive worldwide

United States

LEADERSHIP CHANGES AND AI-DRIVEN OVERSIGHT

- **FDA Commissioner change.** Makary resigned May 12; Kyle Diamantas, the food chief and a lawyer, is acting commissioner pending a Senate-confirmed pick.
- **AI moves into inspections (May 6).** FDA launched a one-day inspectional assessment pilot using AI to flag lower-risk facilities; 46 completed by late April, mostly No Action Indicated.
- **Human Factors guidance finalized (May 28).** New content expectations for HF information in 510(k), De Novo, PMA, and HDE submissions.
- **Breakthrough coverage reshaped**. RAPID pathway live; comments on the NTAP alternative-pathway repeal close Jun 9.

EU / EAA

EUDAMED MANDATORY AND AI ACT ANSWER LANDS

- **EUDAMED mandatory (May 28).** New MDR and IVDR devices must be registered in the UDI/Device module before market placement; all economic operators need an SRN.
- **AI Act Digital Omnibus deal (May 7).** Medical devices stay subject to high-risk AI requirements; industrial AI won an exemption, medtech did not. Device obligations deferred to Aug 2028.
- **Classification guidance refreshed.** MDCG 2021-24 Rev 1 and a new post-market surveillance guidance shape how device records map into EUDAMED.

United Kingdom

BIGGEST DEVICE REFORM SINCE BREXIT GOES TO DRAFT

- **Draft Medical Devices Regulations published (May 8).** Notified to the WTO; closer alignment with EU MDR and IVDR, plus mandatory UDI and implant cards.
- **International reliance route proposed.** Streamlined GB access for devices already approved in the US, Canada, or Australia.
- **PCCP pathway for software.** Pre-defined SaMD changes without full re-certification. Impact survey open until Jun 19; adoption expected Dec 2026.

Canada

LIFECYCLE OVERSIGHT NOW IN FORCE

- **Terms and Conditions powers active.** Health Canada can now impose or amend license conditions at any point in a device's lifecycle.
- **REP mandatory and IMDRF-aligned.** The Regulatory Enrolment Process replaced email filings for Class II to IV; submissions now use the IMDRF Table of Contents.
- **Tighter significant-change and AI rules.** Lower threshold for software, cybersecurity, and compatibility changes; clinical evidence assessed across the full lifecycle.

China

NEW BIOMEDICAL & EXPORT RULES LIVE MAY 1

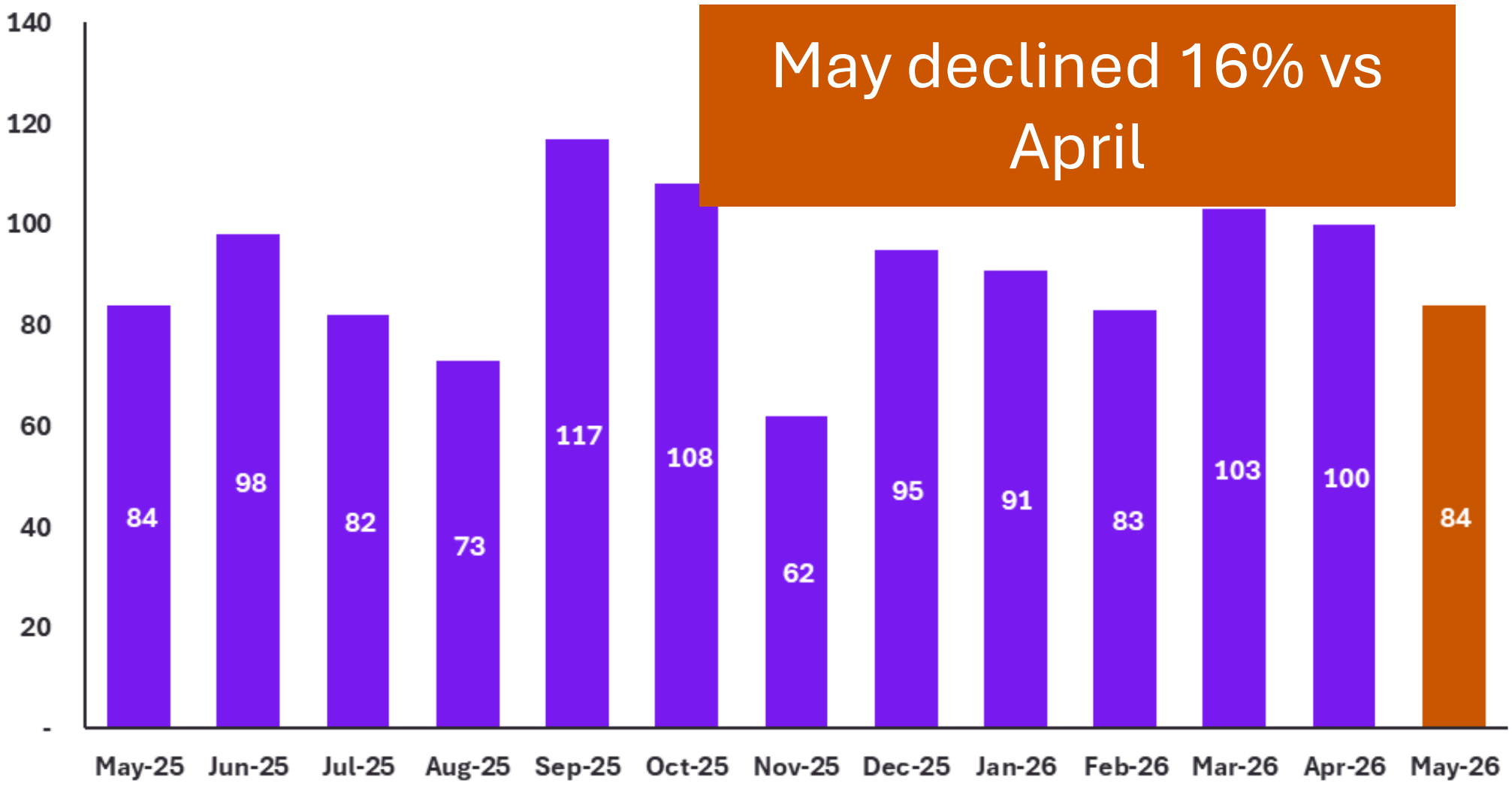
- **Biomedical technologies rule live (May 1).** Unified framework for stem cells and gene editing, applicable to foreign-invested institutions.
- **Export certificate reform live (May 1).** Two-tier system: Type I for China-registered devices, Type II for unregistered devices meeting GMP.
- **Standards harmonization continues.** NMPA's 2026 plan adds 80-plus new and revised standards, deepening ISO alignment and AI oversight.

Asia-Pacific (Japan, Australia, New Zealand, ASEAN)

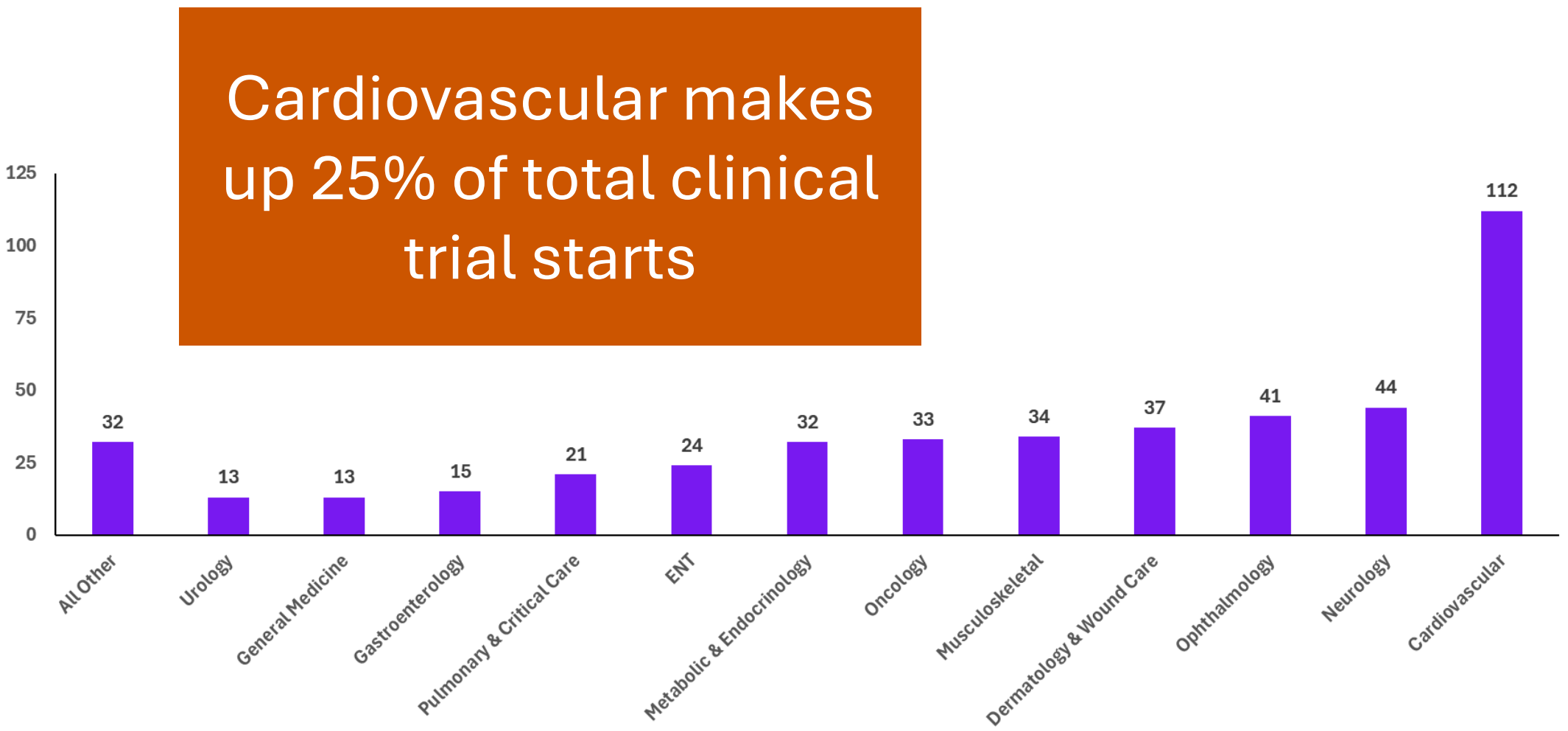
RELIANCE PATHWAYS SWITCH ON

- **Japan recognizes FDA as equivalent authority (May 1).** US-registered devices with a Japanese predicate gain priority review; conditional approval pathways expanded.
- **Australia opens supply-resilience reliance (May 1).** TGA may authorize devices cleared in the EU/US/UK/Canada/Japan to address shortages; UDI starts Jul 1.
- **ASEAN reliance continues to expand.** Regional reliance programs broaden across Class B-D devices; New Zealand maintains its TGA-aligned approach.

Clinical Trial Starts (Interventional, Industry Funded)



May YTD Trial Starts by Therapeutic Area



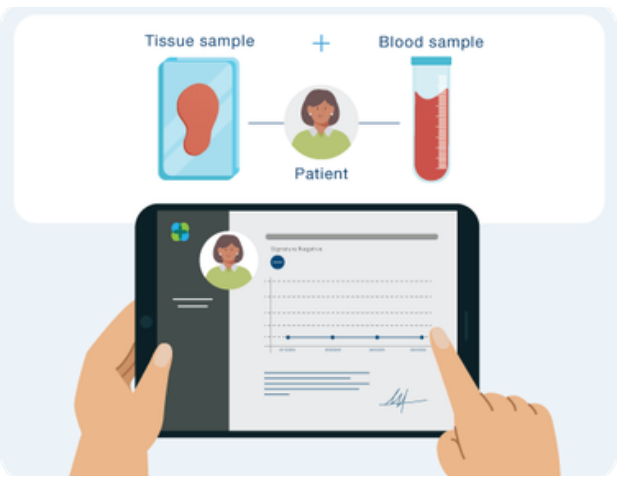
Avania

May ‘26 PMA Approvals

- **Belotero Volume (+) Lidocaine** (Merz)
- Approval for deep (subcutaneous and/or supraperiosteal) injection to improve volume deficit in the mid-face or to correct mid-face contour deficiencies in adults 22 years or older

- **Guardant360® Liquid CDx** (Guardant Health, Inc.)
- Blood-based liquid biopsy panel for advanced cancer patients that analyzes circulating tumor DNA & epigenomic markers to identify genetic alterations and support targeted therapy selection without tissue biopsy.

- **Signatera™ CDx** (Natera, Inc.)
- Personalized blood test that detects circulating tumor DNA (ctDNA) to identify molecular residual disease
- Allows oncologists to monitor for cancer recurrence early and guide treatment decisions



Avania

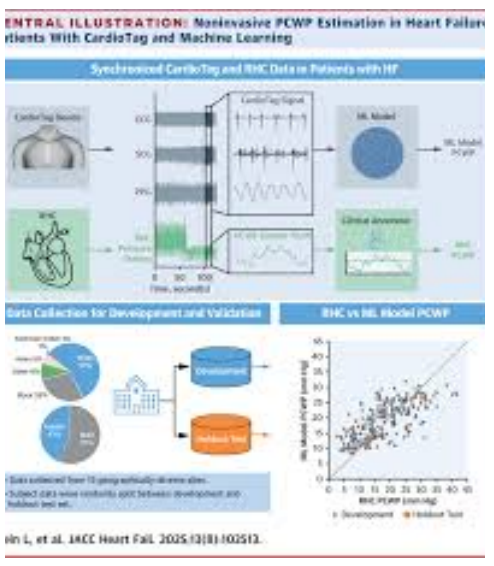
May ‘26 PMA Approvals

- **Atellica IM free PSA II (fPSAII)** (Siemens Healthcare Diagnostics, Inc.)
- Designed for the Atellica Solution, it quantitatively measures free (non-complexed) prostate-specific antigen in human blood serum and plasma to help distinguish between prostate cancer and benign prostatic conditions.

- **LIAISON Biotrin Parvovirus B19 IgM Plus** (DiaSorin, Inc.)
- Automated, chemiluminescent immunoassay (CLIA) used to qualitatively detect IgM antibodies to human Parvovirus B19 in human serum or plasma

Avania

May ‘26 De Novo Approvals



- **PCWP Analysis Software** (Cardiosense, Inc)
- AI-powered system that noninvasively estimates Pulmonary Capillary Wedge Pressure. It pairs with their wearable CardioTag sensor to evaluate cardiac filling pressures, allowing clinicians to detect fluid buildup in heart failure patients without invasive catheters.

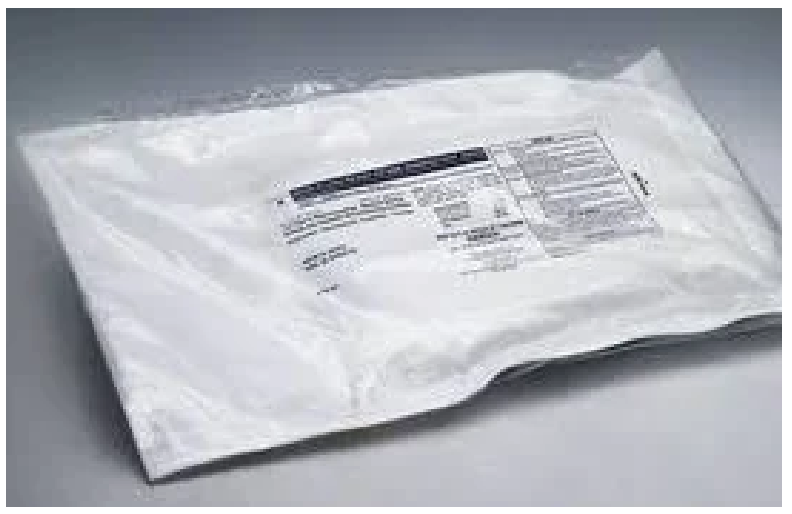
- **DeepView AI® System** (Spectralmd, inc.)
- A diagnostic platform that uses multispectral imaging & deep learning to predict burn wound healing potential.
- Provides clinicians with a rapid, objective assessment of enabling earlier and more precise treatment decisions.

Avania

May ‘26 De Novo Approvals

- **Modius Spero** (Neurovalens Limited)
- At-home, non-invasive neuromodulation device for treating symptoms of Post-Traumatic Stress Disorder
- The wearable headset delivers low-level electrical pulses to stimulate the vestibular nerve behind the ears, which targets deep areas of the brain associated with PTSD.

- **Prolystica Pass Thru Disinfectant Wipes** (Steris)
- Ready-to-use, one-step cleaners and intermediate-level disinfectants. They are used in healthcare facilities to clean and disinfect hard, non-porous medical devices but are strictly prohibited for use on flexible endoscopes.



Avania

Ready to Advance Your MedTech Innovation?

Partner with Avania And experience the difference of the MedTech-only CRO: trusted expertise, collaborative engagement, and proven results.

Email us at info@avaniaclinical.com