Artificial Intelligence Stakes a Claim on Medtech

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By Christian Johnson, Jennifer McCaney, Mahruq Siddiqui, Gunnar Trommer, Erik Adams, Meghna Eichelberger, and Peter Lawyer

BCG + UCLA Biodesign Program

Contents

Introduction

From their origins as hard-coded, embedded software in medical devices and equipment, artificial intelligence and machine learning (AI/ML) now lay claim to over 1,000 US clearances and approvals. After **our first collaboration on medtech innovation and regulatory evolution** in 2022 documented the rise of AI/ML solutions in medtech, UCLA Biodesign and BCG set out to understand how the technology is evolving within the sector. Our team examined which specialties are most heavily penetrated, how much time is required to bring products to market, where innovative technology hotbeds are located, and how regulatory regimes are managing the load of new applications. We also sought to understand how much has been spent, what sources are funding the great upsurge in innovation, and how these sources of investment are evolving as AI/ML goes mainstream in medtech.

AI/ML appears to be well on its way to achieving mainstream acceptance. In the past seven years alone, AI/ML-enabled device authorizations from the US Food and Drug Administration (FDA) soared from the single digits to 223 in 2023 alone. Radiology continues to dominate the AI/ML race, but other medical specialties such as cardiology are making great strides as well. Software defines success for today's AI/ML tools—and not just the hard-coded variety that has powered devices and equipment for decades. Today, such products account for about 24% of authorizations, while three-quarters of today's approved products consist of standalone software and algorithms. At the same time, distinct geographic hotspots for AI/ML-enabled device development are visible in the San Francisco Bay Area, Tel Aviv, Seoul, Paris, and Shanghai.

The FDA has invested heavily in expertise and capacity to keep the innovation machine humming. Still, the median time to clearance for AI/ML is 25% longer than for non-AI/ML, leaving considerable room for improvement. Judicious use by the FDA of third-party reviewers is helping, but the rate of improvement for AI/ML clearance time pales in comparison to that for non-AI/ML products. One area that has not seen a notable rise is AI/ML-based products that feature adaptive algorithms. To date, we have uncovered just three adaptive-logic product authorizations with an FDA-authorized "Predetermined Change Control Plan."[1]

Some $14 billion in venture capital (VC) has paced the development of AI/ML-enabled devices from 2010 through Q3 2024, with 3,057 investors backing 387 companies that have collectively produced about half of the 1,016 AI/ML products cleared by the FDA. Private capital represents about two-thirds of activity in the space, with public companies responsible for just over one-third of AI/ML products. Venture funding has shifted from seed and early stage to Series C and Series D rounds since 2020, with 16 deals netting over $100 million each. The sector has seen nearly 60 exits since 2010, including corporate mergers and acquisitions (M&A), initial public offerings (IPOs), and leveraged buyouts (LBOs) with deal sizes ranging from the single millions to multiple billions.

Our work underscores how AI/ML software has come of age in the medtech sector. We are excited to provide this analysis to executives of both startup and well-established medtech companies, as well as to regulators, VC professionals, and academics. We believe that this report represents the most comprehensive compendium of global AI/ML-based product authorizations available to date and provides a solid tally of product funding by source. **(See "Methodology.")** We realize that there will inevitably be blind spots in and omissions from our list, but we hope that the insights gleaned from this work will more than make up for any limitations.

1. **https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles**.

Key Findings

The period from 2015 through Q3 2024 saw growth of more than 35X in AI/ML-enabled devices, with 1,016 products authorized by the FDA to date.

Just three AI/ML-enabled devices authorized to date contain adaptive logic with an FDA-approved change control program, and no GenAI-enabled devices have received authorization.

Radiology remains the leading application, as image processing and triage software accounts for three-quarters of all authorizations, but penetration of other specialties is growing.

Two-thirds of AI/ML products were sponsored by private companies at the time of authorization.

Software-as-a-medical-device (SaMD) sets the standard, accounting for 71% of all AI/ML authorizations.

Half of AI/ML authorized devices came from VC-backed companies, which have cumulatively invested $14 billion in AI/ML-enabled devices since 2010.

Coding hotspots in the US are responsible for about half of AI/ML authorizations, with Israel, France, China, South Korea, and Japan adding another 27%.

A total of 16 VC megadeals (deals exceeding $100 million) for AI/ML companies were completed between 2020 and Q3 2024, versus a total of just 8 in the prior five-year period.

The median time to approval for AI/ML-enabled devices took 25% longer (about four weeks more) than for non-AI/ML products, despite considerable focus and investment by the FDA to improve capacity and bolster expertise.

Exit activity has increased since 2020, with 41 total exits (31 acquisitions, 5 IPOs, and 5 LBO/buyouts) from 2020 through Q3 2024, with a combined value of approximately $11 billion, versus 17 exits in the prior decade from 2010 to 2019.

Third-party reviewers offer a marginal advantage for AI/ML-enabled devices, providing a two-week improvement in time-to-clearance in AI/ML versus a three-month improvement for non-AI/ML products.

Innovation

Medtech AI/ML Is Soaring

The age of AI/ML in the medtech industry has arrived, with annual authorizations ballooning from single digits in the early part of the past decade to a cumulative 1,016 by Q3 2024, the latest reported data. **(See Exhibit 1.)** Although they still account for just a small fraction of annual 510(k) clearances, AI/ML-enabled devices are carving out an important niche in the sector. Since September 2023, a dozen De Novo AI/ML-enabled devices have received FDA approval—versus only 20 during the entire prior decade. **(See Exhibit 2.)** The message to the medtech industry is clear: the march toward AI/ML-enabled devices is accelerating and changing the game in this innovation-based market.

Radiology Paces the Field

Nowhere is this movement more evident than in the field of radiology, which accounts for 75% of all AI/ML authorizations since 2010. The unique attributes of imaging come into play in this field, where computerized algorithms outperform the human eye in looking for patterns in pixels. This holds true across x-ray, computed tomography (CT), ultrasound, endoscopy, and 1,012 other authorizations, all of which involve some form of image processing or clinical prioritization and triage.[2]

The cardiovascular field holds a distant second place, with 70 authorizations in the past five years. Given the similarities between imaging modalities in the cardiac catheterization lab and in radiology suites, the same factors that are driving radiology toward AI/ML solutions come into play in the cardiovascular space. Nonimaging AI/ML technology—such as algorithms from multiple companies that detect patterns in heart rhythms—have bolstered the cardiovascular numbers. Other specialties, including neurology, hematology, gastroenterology and urology, and ophthalmology have also gained AI/ML approvals. One senior regulatory official commented, “There is similar capability and opportunity in other clinical settings. However, cardiology already has a large number of devices in their space, an organized hospital structure around it, and an urgency to time to treatment…”

2. Total number of authorizations = 1,016; technology review excludes four PMA approvals.

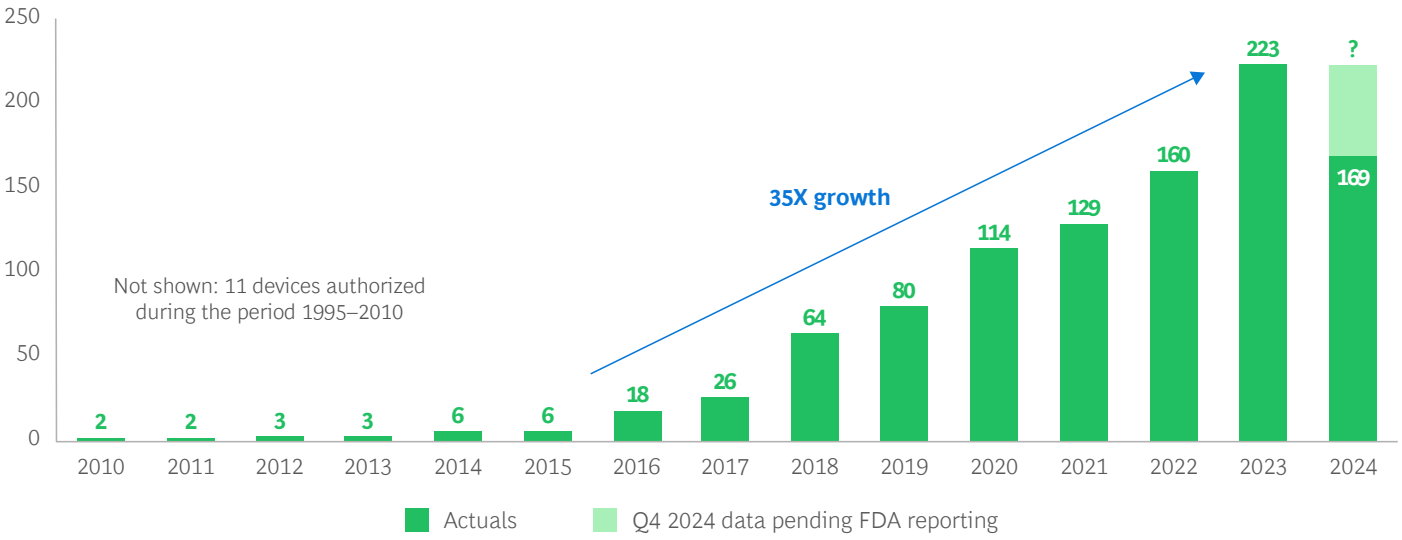
EXHIBIT 1

The Rise of AI

More than 35X increase in AI/ML devices since 2015

Exponential increase in AI/ML approvals, 2010–2024

Number of AI-enabled medical devices authorized by the FDA



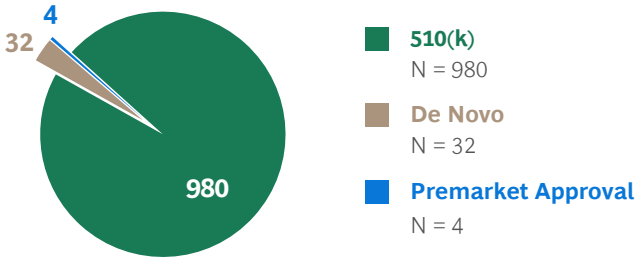
Source: US Food and Drug Administration.

EXHIBIT 2

Regulatory Pathways and FDA Review Times for AI/ML Medtech Devices

Most approved AI/ML devices obtain 510(k) clearance within 5 months of FDA submission

Which regulatory pathways?



FDA review times

	510(k)	De Novo	Premarket Approval
Median	4.4 months	10 months	12 months
Average	5 months	12 months	11 months

Sources: US Food and Drug Administration data; analysis performed by BCG and UCLA Biodesign.

The Emerging Roadmap for AI/ML Devices

Over the past five years, companies commercializing AI/ML technologies in these specialties appear to be following similar principles. They prioritize software over hardware, integrate the software into existing imaging, monitoring, or surgical planning systems and diagnostic platforms, and use AI to integrate multimodal data across various inputs (such as electrical activity sensors, physical sensors, images, and specimens).

The AI/ML logic typically performs one or more functions:

- Automating high-labor tasks that predict or detect acute events
- Providing surgical planning or real-time procedural guidance
- Serving as a decision-support tools for diagnostic aids

Categorized by purpose, AI/ML-enabled devices fall into six main classes. **(See Exhibit 3.)**

EXHIBIT 3

Emerging Classes of AI/ML Devices in Medtech

Device purpose	Opportunity	Data or input	Role of the AI	Integration	Specialties	AI/ML-enabled device examples
Automated image analysis	Speed up review; improve early detection	Digital images (e.g., fundus, OCT, slides)	Detection; segmentation; classification	Software add-on with imaging systems	Radiology; pathology; GI; dental	GI Genius; IDx-DR; Paige Prostate; Dental Monitoring
Signal or event detection	Automate time-series review	Sensor data (EEG, PSG, respiratory, acoustics)	Pattern detection; alerts	Embedded software in monitors	Cardiology; neurology; sleep; anesthesiology	encevis; autoscore; EnsoSleep, Tyto Insights
Real-time navigation	Enhance procedural precision	Live imaging and tracking	Registration; AR overlays (multimodal)	Software integrated with surgical tools	Neurosurgery; orthopedics; dental	ClearPoint System; X-Guide; Precision AI Planning
Risk prediction	Forecast risk progression	Multimodal clinical data	Risk scoring; tracking and prediction	Standalone software/EHR modules	Cardiology; neurology; hospital; labs	BrainSee; Sepsis ImmunoScore; KidneyIntelX; Acumen HPI
Personalized procedure planning	Tailor interventions to patient specifics	Pre-op imaging; 3D scans	Simulation; panning	Interfaces with CAD/CAM and robotics	Orthopedics; dental; neurosurgery	Precision AI Surgical Planning System; United Orthopedic Knee Patient Specific Instrumentation
Adjunctive decentralized diagnostics	Perform rapid screening in decentralized settings (point of need)	Images; sensors; manual input; specimen	Adaptive classification	Portable home devices; smartphone apps	Ophthalmology; anesthesiology; labs	Notal Home OCT; DreaMed Advisor; TytoCare Crackle Detection; Healthy.io

Source: BCG and UCLA Biodesign.
Note: AR = augmented reality; CAD/CAM = computer-aided design/computer-aided manufacturing; EEG = electroencephalography; EHR = electronic health record; Gi = gastrointestinal; OCT = optical coherence tomography; PSG = polysomnography.

Software Is the New Device

When it comes to the types of AI/ML-enabled devices currently receiving FDA clearance, we see another profound skew—this time toward standalone software, more commonly referred to as *software as a medical device* (SaMD). SaMD represented 699 of the 980 510k clearances and 22 of the 32 De Novo AI/ML clearances that occurred in the past five years. Whether software qualifies as SaMD depends on whether it satisfies two criteria:

- The software provides a patient benefit, and a malfunction of the technology would present a risk to patients.
- The software can operate independently of other machinery and equipment.

If both conditions hold, the product is considered SaMD. If it does not meet the second condition, the technology is considered software in a medical device (SiMD), and the device itself (rather than the software) must receive FDA authorization.[3]

Much of the remainder of AI/ML clearances and approvals (27%) combine software and hardware, often in the form of precoded software loaded onto a dedicated platform. Some of the earliest AI/ML successes have involved capital equipment, frequently leveraging a machine's memory cache with intelligent software to interpret new data and assist with diagnosis and treatment. Examples range from ultraportable imaging solutions to real-time invasive imaging to procedural guidance capital equipment systems with recent devices. Hyperfine's The Swoop ultra-low field magnetic resonance portable bedside MRI system, for instance, expands access to high-quality brain imaging across multiple settings of care, and Medtronic's GI Genius is the first intelligent computer-aided endoscopy system that can detect polyps in real-time to accelerate time to detection, reduce diagnostic variability, and improve accuracy of diagnosing colorectal cancer.

AI/ML Is Still Embryonic in In Vitro Diagnostics

Though only 22 AI/ML clearances and approvals in our sample came from the in vitro diagnostics (IVD) space, these products share two unique traits:

- They can miniaturize lab-scale diagnostics.
- They deliver lab-quality results at the point of care or need.

AI has transformed large, high-throughput lab platforms across hematology, immunology, and microbiology into portable benchtop devices, thereby enabling immediate, affordable, accurate tests for cancer, chronic diseases, and infections, even as over-the-counter options.

This shift spans the diagnostic chain for IVD from lab to hospital to home. For example, traditional players such as CellaVision have adapted their digital platforms (for example, the CellaVision DC-1 analyzer) for use in small, independent labs and distributed networks. More recently, startups such as Israel's Healthy.io have leveraged smartphone cameras and colorimetric detection to perform at-home tests for conditions such as urinary tract infections, renal health, and wound care, allowing patients to report results via telemedicine and receive prescriptions without visiting a centralized lab or waiting a week for mail-in lab results.

Medtech AI/ML Coding Hotspots Are Popping Up

Given the prominence of software in AI/ML-enabled devices, innovation tends to cluster in recognized coding hotspots around the world. **(See Exhibit 4.)** California spikes as the most prominent development center, accounting for 13% of the global total, and the San Francisco Bay Area has contributed 95 of the Golden State's 127 AI/ML successes. Across the country, other areas that have achieved a strong showing for AI/ML clearances tend to be global or regional headquarters and R&D center locations for major players in the diagnostic imaging field such as GE in Wisconsin, Siemens in Pennsylvania, Philips in Tennessee, and Canon in California.

Outside the US, five nations—Israel, France, China, South Korea, and Japan—account for about 27% of all AI/ML clearances and approvals. Israel's contribution is especially notable, with Tel Aviv–based Aidoc and Zebra Medical Vision combining for 34 of the country's 81 US AI/ML authorizations. An Israeli medtech AI leader explained why his country was able to punch above its weight: "Young adults get brought into the military and are trained as data scientists. You get a great cohort of people who were trained … before even starting at university. Also, a lot of people are passionate about health care. You want to connect to a higher purpose and [be] doing something meaningful. This mindset is ingrained in us."

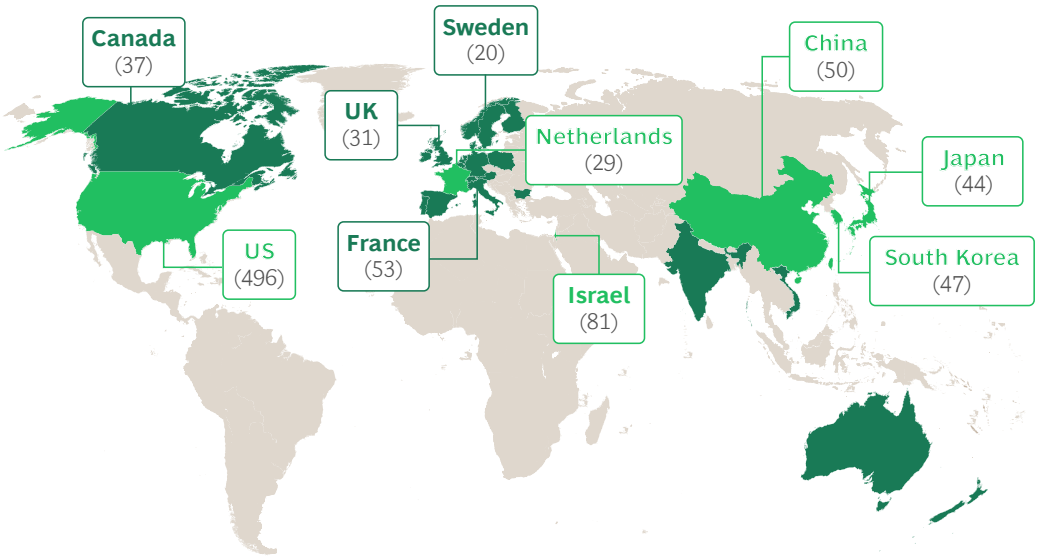
Some cities outside the US have a diverse collection of companies that produce AI/ML devices (Seoul, for example, hosts 14 companies that are responsible for 29 devices); others tend to center on the overseas headquarters of global medical device companies, including United-Imaging in Shanghai, China; Canon Medical Systems in Japan; and Samsung in South Korea.

3. Bernhard Knappe et al., "Software as a Medical Device (SaMD): What It Is and Why it Matters," *Orthogonal*, October 8, 2024.

EXHIBIT 4

Global AI Hotspots

The US leads in number of AI devices (49% all time); Israel leads outside the US; South Korea has entered the top 5



Top 10 AI/ML hubs (as of September 2024)

	Number of AI/ML devices	Percentage of total (%)
US	**496**	**49**
Israel	**81**	**8**
France	**53**	**5**
China	**50**	**5**
South Korea	**47**	**5**
Japan	**44**	**4**
Canada	**37**	**4**
UK	**31**	**3**
Netherlands	**29**	**3**
Sweden	**20**	**2**
Rest of the world	**128**	**13**

Insights

- 1,016 AI/ML developed worldwide
- 49% (496) originated in the US [10% (127) originated in California]
- Israel leads outside the US with 81 AI/ML (8%)
- South Korea knocked Japan out of the top 5 producers of AI/ML as of 2023
- Germany ranks 12th (18 total) but skyrocketed with 10 in 2023 alone

Sources: US Food and Drug Administration data; BCG and UCLA Biodesign.

Regulation

FDA Road Signs Are Becoming Clearer

Medtech's digital age began just before the new millennium, with the confluence of three events: the FDA issued its first quality guidelines for software; the agency created the De Novo approval pathway for Class I and Class II devices with no predicate; and the first AI/ML-enabled device received clearance. The product that ushered in the AI/ML era was a device called PAPNET Testing System, which in 1995 received Premarket Approval (PMA) to detect abnormalities and lesions missed during manual microscopic examination of pap smears.[4] Over the next decade, regulators from around the world came together to hash out SaMD guidelines and definitions, and the FDA created the Breakthrough Device program.

By 2017, some 50 standalone AI software products had received FDA authorization, setting the stage for the agency to promulgate a regulatory framework for updates and modifications of cleared AI/ML products. In the fall of 2024, the FDA convened a Digital Health Advisory Committee to explore regulatory measures for AI/ML-based SaMD and generative AI (GenAI) development—the goal being a protocol that "outlines a holistic approach to total product life cycle oversight to further the enormous potential that these technologies have to improve patient care while delivering safe and effective software functionality that improves the quality of care that patients receive."[5]

4. **www.accessdata.fda.gov/cdrh_docs/pdf/p940029.pdf**.
5. US Food & Drug Administration, Center for Device and Radiological Health. *Artificial Intelligence/Machine Learning [AI/ML]-Based Software as a Medical Device [SaMD] Action Plan*. January 2021.

Medtech Executives Are Optimistic, but Wary of Roadblocks

With the total number of AI/ML-based devices now exceeding 1,000, the FDA continues to update its guidelines for total life cycle management of AI/ML-enabled devices. Medtech companies navigating this space approach the topic with understandable caution. A UCLA Biodesign/BCG survey of 52 medtech executives and directors showed that eight out of ten respondents rated FDA regulatory requirements as a critical challenge complicating efforts to bring their innovations to market. **(See Exhibit 5.)** At the top of their list for AI/ML was the issue of ensuring data privacy and security. As one R&D leader summed it up, "Data privacy and security becomes murky with some AI devices, and it's a huge barrier."

The FDA's efforts to establish a predictable regulatory environment that prioritizes upholding patient safety while allowing innovation to flourish are numerous and noteworthy. AI/ML is one of 20 ongoing regulatory research programs at the agency whose goal is to create the least burdensome comprehensive evaluation of safety and effectiveness of these products. Currently, the program focuses on methods and metrics for training algorithms and testing data; minimizing bias; establishing standards for gauging the performance, safety, and effectiveness of continuously learning algorithms; assessing emerging clinical applications; and monitoring postmarket effects. In addition to addressing its immediate regulatory challenges, the FDA must also grapple with harmonizing its system with international regulatory regimes.[6]

Radar Gun: Clocking Submission-to-Authorization Time for AI/ML

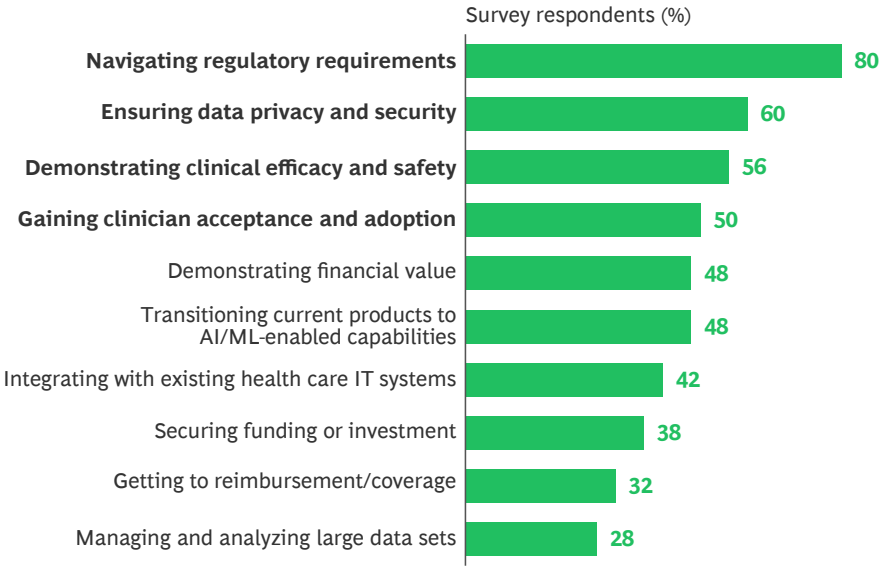
The UCLA Biodesign/BCG team evaluated 1,016 successful AI/ML FDA authorizations received by 387 companies through Q3 2024. The team noted the approval type and number of products (980 510(k) clearances, 32 De Novo, and 4 PMA), time to first approval, and time to subsequent approvals. From this group, the team generated a comparative sample of 659 510(k) cleared AI/ML-enabled devices as well as a matching control group of 6,347 standard (that is, not AI/ML) 510(k) cleared devices, basing the matches on products sharing the same product code classification (for example, product code LLZ = System, Image Processing, Radiological). The team compared the times from FDA submission to authorization for AI/ML-enabled devices and for standard devices through 2023 (the last complete year of reported authorizations).

EXHIBIT 5

Challenges That Medtech Companies Face

Regulations, data privacy, clinical efficacy, and adoption are the biggest challenges for AI/ML devices

Q. What are some of the **main challenges you face** in bringing AI/ML-enabled medical devices to market?



> "There is frustration about the standards, but it's understandable. FDA experts are smart, and they want to collaborate on AI devices, but they realized they must bring in more AI and ML expert reviewers and now **there are more stakeholders that you must satisfy to get approval.**
>
> *—CTO at an international medtech company*

> "**Data privacy and security becomes murky** with some AI devices, and it's a huge barrier. FDA gets very nervous if your device retains the data for any reason such as self-learning.
>
> *—R&D lead and director at an international medtech company*

> "Customer adoption is a major challenge because every user will do their own personal verification. They won't just get excited if we say it's AI-enabled—that era has passed. In the end, **clinicians only look at the outcomes and assess if the device actually makes their job easier.**
>
> *—President and CEO at an international medtech company*

Source: BCG and UCLA Biodesign.

6. Christian Johnson et al., Interstates and Autobahns: Global Medtech Innovation in the Digital Age. Boston: Boston Consulting Group and UCLA Biodesign Center, March 2022.

Despite the difficulties outlined above, AI/ML-enabled devices do not appear to suffer an undue regulatory penalty in the US. **(See Exhibit 6.)** Median clearance time for AI/ML-enabled devices ran about 25%—approximately four weeks—longer than standard devices. Foreign applicants for AI/ML product authorization fared slightly better than their domestic counterparts, with median clearance times of 129 days for foreign applicants and 135 days for US applicants. In contrast, US applicants for standard devices received authorization roughly two weeks sooner than foreign companies did.

Company and Regulatory Experience Affect Authorization Timing…

Not surprisingly, median clearance time for AI/ML-enabled versus standard medical devices runs longer for first-time approvals than for subsequent successes. **(See Exhibit 7.)** Median first-time AI/ML clearances took about five weeks longer than median first-time clearances for standard products, but the delay for subsequent authorization dropped to just 22 days. The learning curve for companies submitting applications and for the regulators reviewing their submissions most likely accounts for the speedier timeline on subsequent applications.

The most significant regulatory gap occurred in the performance of third-party reviewers. In principle, third-party reviewers bring subject matter expertise and much-needed capacity to the task of helping the FDA manage its regulatory workload. The relative performance, as measured by time to authorization, is quite stark for non-AI/ML approvals. Third-party reviewers authorize standard products in a median time of just 29 days versus 114 for their FDA staff counterparts. However, the performance differential drops sharply for AI/ML-enabled products, where median time to authorization required 115 days for third-party reviewers versus 134 days for FDA staff.

These findings raise an obvious question: can industry expect median clearance time to improve significantly as more third-party reviewers come on board and gain familiarity with AI/ML regulatory frameworks? The chief technology officer of one international medtech company expressed his hope for exactly that outcome as aggregate experience grows, saying, “There is frustration about the standards, but it’s understandable. FDA … realized that they must bring in more AI and ML expert reviewers, and now there are more stakeholders that you must satisfy to get approval.”

…But Specific Product Type Does Not Matter as Much

The type of AI/ML product under review plays only a minor role in median approval time. **(See Exhibit 8.)** The median time to clearance for AI/ML products in the sample was 133 days versus 106 for standard products. Interestingly, Pulsed Doppler Ultrasound applicants—both AI/ML and standard—significantly outperformed these benchmarks at 98 and 67 days, respectively. Median AI/ML clearance time across five other categories ranged from 112 to 140 days versus non-AI/ML performance of 91 to 129 days. The remainder of our sample clocked in at a median of 146 days for AI/ML versus 117 days for their standard product comparators.

EXHIBIT 6

Statistical Analysis: 510(k) Clearance Timelines by Geography

	AI/ML clearances			Non-AI/ML clearances			
510(k)	**N**	**Mean** (standard deviation)	**Median** (IQR)	**N**	**Mean** (standard deviation)	**Median** (IQR)	**p-value[1]**
Overall	659	152.9 (94.6)	133.0 (87.0–209.0)	6,347	136.2 (112.4)	106.0 (56.0–186.0)	<0.0001
US	318	151.8 (89.7)	135.5 (89.0–202.0)	3,558	129.2 (106.3)	100.0 (55.0–171.0)	<0.0001
Non-US	341	153.9 (99.1)	129.0 (86.0–210.0)	2,789	145.2 (119.2)	115.0 (57.0–204.0)	0.0014

Overall summary: AI/ML devices
~4 weeks (27 days) longer for approval of AI/ML devices than non-AI/ML devices

Geographic (US vs. non-US)
~5 weeks longer in the US for approval of AI/ML devices than non-AI/ML devices

~6 days longer for approval of non-US AI/ML devices than of US AI/ML devices

Source: UCLA Biodesign.
Note: IQR = interquartile range.
[1]A p-value of less than 0.05 is considered statistically significant.

EXHIBIT 7

Statistical Analysis: 510(k) Clearance Timelines by Experience

	AI/ML clearances			Non-AI/ML clearances			
510(k)	**N**	**Mean** (standard deviation)	**Median** (IQR)	**N**	**Mean** (standard deviation)	**Median** (IQR)	**p-value[1]**
First approvals	146	189.7 (93.4)	186.5 (120.0–252.0)	1,083	179.5 (126.4)	152.0 (86.0–254.0)	0.0202
Subsequent approvals	513	142.4 (92.4)	121.0 (79.0–191.0)	5,264	127.3 (107.2)	99.0 (52.0–168.0)	<0.0001
Third-party reviewer	56	129.3 (106.1)	115.5 (47.5–165.0)	481	49.4 (52.7)	29.0 (21.0–56.0)	<0.0001
No third-party reviewer	603	155.0 (93.3)	134.0 (87.0–212.0)	5,866	143.3 (113.1)	114.0 (61.0–195.0)	<0.0001

First approvals: AI/ML devices
~5 weeks longer than non-AI/ML devices

Subsequent approvals: AI/ML devices
~2.5 weeks longer than non-AIML devices

Third-party review: AI/ML devices
~ 2.5 weeks longer with no third-party reviewer within AI/ML group

~5 months longer (144 days) than non-AIML devices with third-party reviewer

~3 weeks longer with no third-party reviewer than non-AIML devices

Source: UCLA Biodesign.
Note: IQR = interquartile range.
[1]A p-value of less than 0.05 is considered statistically significant.

EXHIBIT 8

Statistical Analysis: 510(k) Clearance Timelines by Product Type

510(k)		AI/ML clearances			Non-AI/ML clearances			
Product type	**Product code**	**N**	**Mean** (standard deviation)	**Median** (IQR)	**N**	**Mean** (standard deviation)	**Median** (IQR)	**p-value[1]**
Pulsed Doppler, ultrasound	IYN	39	106.6 (48.2)	98.0 (84.0–139.0)	656	87.1 (73.3)	67.5 (32.5–113.0)	0.0016
X-ray, CT	JAK	57	147.7 (85.1)	140.0 (81.0–227.0)	280	144.8 (96.4)	129.0 (77.5–189.0)	0.5901
Image processing, radiology	LLZ	125	141.3 (101.6)	118.0 (71.0–190.0)	1,000	124.8 (104.4)	91.0 (50.0–170.0)	0.0073
Nuclear MRI	LNH	34	140.7 (89.5)	131.5 (60.0–188.0)	280	113.2 (87.6)	91.0 (57.0–141.0)	0.0431
Computer-assisted triage notification software	QAS	40	122.7 (83.0)	111.5 (74.5–160.0)	10	96.5 (41.3)	97.0 (72.0–119.0)	0.5390
Computer-assisted prioritization software for lesions	QFM	27	159.3 (85.6)	137.0 (92.0–214.0)	3	223.7 (95.1)	198.0 (144.0–329.0)	–
Automated image processing, radiology	QIH	79	171.4 (114.0)	140.0 (101.0–231.0)	13	154.6 (82.4)	123.0 (92.0–254.0)	0.8756
Other	Other	258	166.5 (91.7)	146.0 (96.0–232.0)	4,105	147.8 (119.4)	117.0 (60.0–205.0)	<0.0001

Product code

IYN took the shortest time compared to other product codes for both AI/ML and non-AI/ML devices

~11 days more for JAK AI/ML device clearance than non-AI/ML device clearance

2–4 weeks more for all other product codes compared to non-AI/ML devices

Source: UCLA Biodesign.
Note: CT = computed tomography; IQR = interquartile range; MRI = magnetic resonance imaging.
[1]A p-value of less than 0.05 is considered statistically significant.

Adaptive Logic Is Off to a Slow Start

Although the march of AI/ML-enabled devices continues unabated, one technology has been slow to progress: adaptive logic. The caution is understandable. Before authorizing adaptive algorithms, regulators must be convinced not only that today's offering is safe and efficacious, but that this dynamic product will continue to operate within prescribed guardrails as it logically evolves. Such assurance requires a full predetermined change control plan (PCCP) that sets those boundaries, as well as a postmarket surveillance system to ensure compliance. The exact number of applications for adaptive logic that have been submitted is not a matter of public record, but only 3 of the 1,016 AI/ML-enabled device authorizations to date include a PCCP. As a senior regulatory executive said, "No one has cracked the code on how to control the unknown."

Medtech Leaders Are Confident About AI/ML Technology

Increasing regulatory comfort and familiarity with AI/ML-enabled devices has boosted confidence among industry participants. A UCLA Biodesign/BCG survey of 52 medtech executives and directors indicates exceptionally strong faith among respondents in their likelihood of obtaining US regulatory approval, given the FDA's evident interest in investing in the technology. The chief technology officer of one medtech respondent commented, "FDA is very interested in learning and partnering. The collaboration has been great since they want to improve care as well, and [they] are willing to work with you in the process."

Although their degree of conviction varies, half of medtech respondents were confident to very confident in their ability to commercialize their products once approved. **(See Exhibit 9.)** This finding stands in stark contrast to an earlier UCLA Biodesign/BCG collaboration on the broader set of digitally enabled medtech products, which indicated that only 8% of those surveyed were optimistic about their ability to commercialize their approved products, due to concerns over reimbursement.[7]

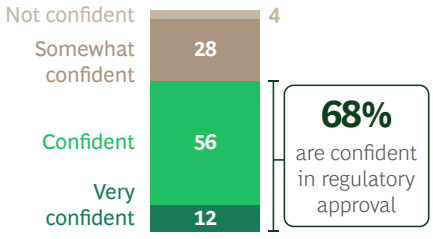
This is a critical issue. Because VC funding provides the main source of capital for digital medtech product innovation, a clear line of sight to revenue generation becomes the critical go/no-go issue for those putting up investment capital. To quote one medtech CEO, "Customer adoption is a major challenge because every user will do their own personal verification. They won't get excited if we say it's AI-enabled—that era has passed. In the end, clinicians only look at the outcomes and assess if the device actually makes their job easier."

EXHIBIT 9

Outlook for AI in Medical Devices

Medtech companies are largely confident in obtaining regulatory approval…

Q. How confident are you in **obtaining regulatory approval** for AI/ML-enabled devices? (%)

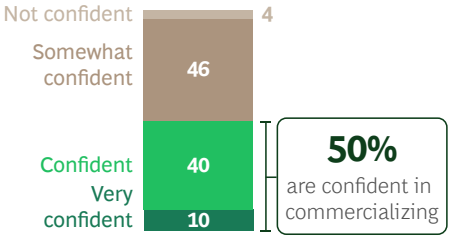


Getting approval might take longer than you like, **but there's nothing that stops you** if you know your data and product.

—CTO at a medtech company

…But not as confident in commercializing the approved devices…

Q. How confident are you in **commercializing** AI/ML-enabled devices after approval? (%)

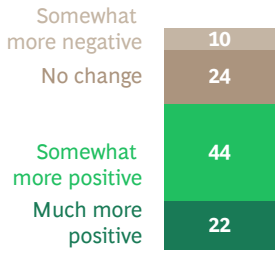


It starts with making sure that you **solve a problem that is valuable for customers**, with an interoperable solution. That's 90% of the work.

—R&D lead at a medtech company

…Yet confidence is growing as both awareness of and comfort with AI devices increase

Q. How has your **sentiment** toward AI/ML-enabled devices changed in the past 12 months? (%)



My confidence has grown because of the awareness in the market. I was startled at how quickly the industry adopted AI devices.

—President and CEO at a medtech company

Source: BCG and UCLA Biodesign.

7. Christian Johnson et al., Interstates and Autobahns: Global Medtech Innovation in the Digital Age. Boston: Boston Consulting Group and UCLA Biodesign Center, March 2022.

Investment

Are AI/ML Products on the Road to Riches?

Private capital occupies center stage in the unfolding story of FDA regulated AI/ML medtech. Since 2010, VC firms have invested $14 billion in AI/ML medtech products. **(See Exhibit 10.)** During this time, 3,057 investors backed 387 companies seeking AI/ML-based product clearances. Most deal medians were in the low to middle single digits during the prepandemic era, shifting to double digits postpandemic, with larger deal sizes occurring in the past several years. From 2020 onward, investors have exhibited more confidence in AI/ML medtech postclearance, with double-digit deal sizes to support product commercialization and growth. Total VC funding peaked during the pandemic, including 16 megadeals valued at over $100 million apiece since 2020. VC funding for FDA-regulated AI/ML-enabled device deals remained steady at around $2 billion per year for 343 deals during the 2020–2022 COVID-19 period.

The Role of Venture Capital Is Evolving

Since 2017, angel investors and VC companies backed 50% of the total, and nearly 40% of funding for FDA-regulated products came from public companies. **(See Exhibit 11.)** Capital from grants and nonventure interests provided the balance of funding for cleared products.

In our sample, 10% of AI/ML medtech companies with first cleared devices were backed by preventure funds (accelerators, angel, and preseed investors), 66% from VC, and 8% from grants. **(See Exhibit 12.)** Postpandemic, public funding increased—including IPOs and acquisitions of private AI/ML medtech companies by the likes of Philips, Enovis, Olympus, and Paragon 28. The largest VC megadeal, however, occurred in 2017. **(See "Investment in Chinese Medtech: A Megadeal Profile.")**

Investment in Chinese Medtech: A Megadeal Profile

The largest VC deal—$506 million (RMB 3.3 billion) with a $5 billion valuation—was raised by United-Imaging in 2017. Founded in 2011 and headquartered in Shanghai, United-Imaging is a Chinese medical-imaging company that develops AI/ML-based products such as MRIs, PET/CT, mobile x-ray units, and digital radiology technology. United-Imaging currently holds 25 AI/ML clearances, including 14 for capital equipment and 11 for SAMD. It received its first four AI/ML clearances in 2020. The $506 million deal was forged by nine investors, including national and privately subsidized investment firms. After an undisclosed VC round, United-Imaging had an IPO of $1.62 billion (RMB 10.99 billion), emerging with a valuation of $13.4 billion.

EXHIBIT 10

VC Funding Trends for FDA Authorized AI/ML Medtech

2020–2022 were the highest funding years, with the highest average deal size as well, followed by postpandemic stabilization

387/1,016
Companies/devices

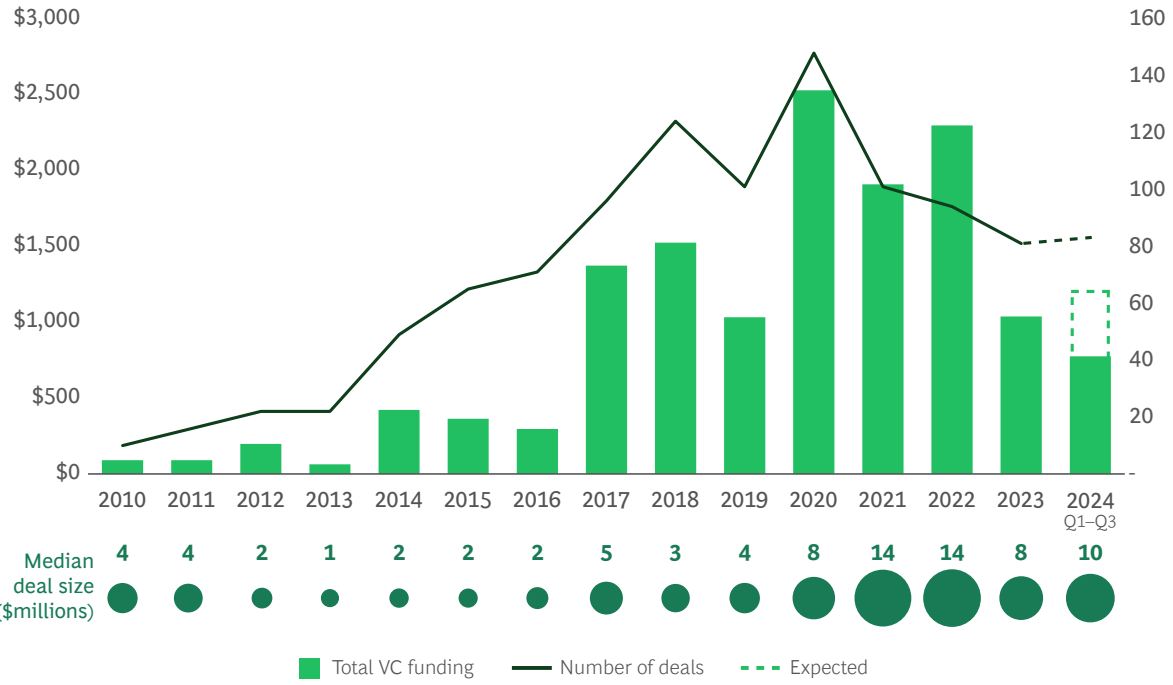
1,064/1,369
Dilutive deals/ dilutive + grants

3,057
Number of investors

$14 billion
Capital invested

58
Exits

$506 million
Largest VC deal



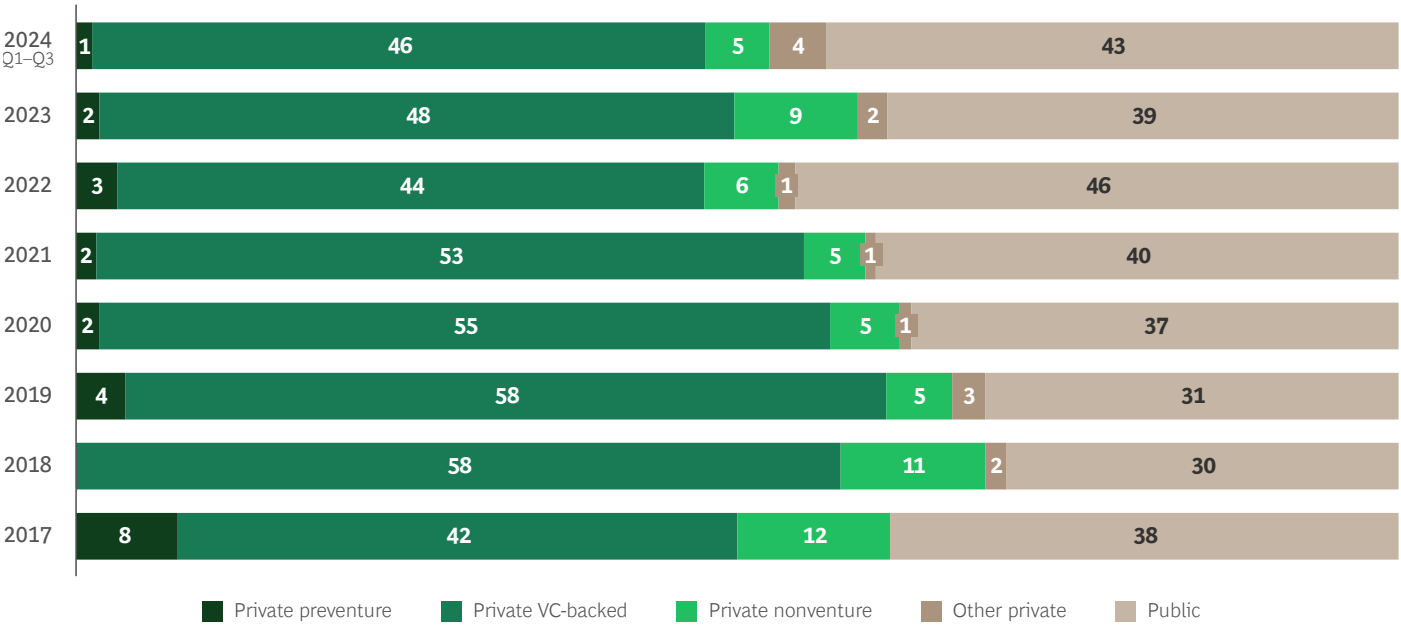
Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
Note: The clearances listed occurred during or after 2010. Dotted lines indicate estimated number of Q4 deals, based on trends from FDA and non-FDA AI/ML medtech device deals. VC = venture capital.

EXHIBIT 11

Capital Backing in Medtech Companies for All FDA-Cleared AI/ML Devices

50% VC and 39% public investment (M&A, IPO, or other public)

Investment source (%)

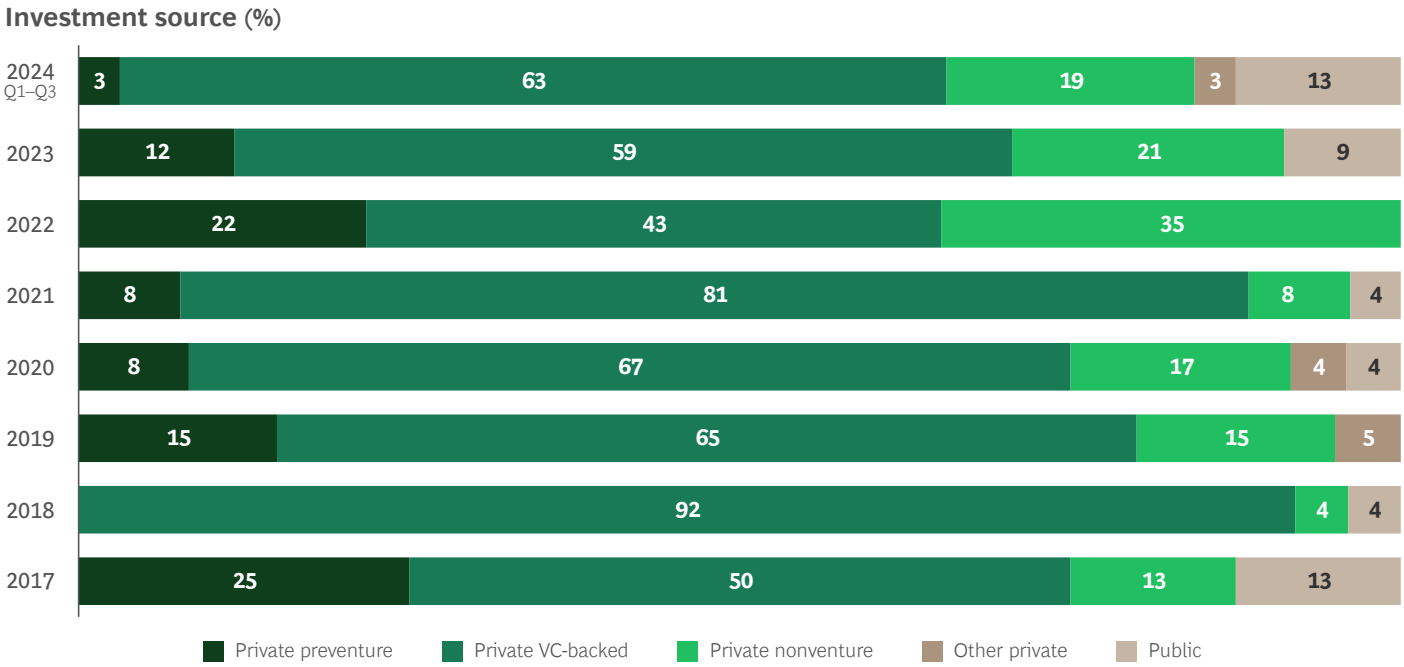


Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
Note: Data is for all FDA-regulated AI/ML medtech; N = 966. M&A = mergers and acquisitions; IPO = initial public offering, VC = venture capital. Because of rounding, not all bar segment totals add up to 100%.

EXHIBIT 12

Capital Backing in Medtech Companies for First FDA-Cleared AI/ML Devices

65% VC and 6% public investment (M&A, IPO, or other public)



Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
Note: Data is for first FDA-cleared AI/ML medtech; N = 192. M&A = mergers and acquisitions; IPO = initial public offering, VC = venture capital. Because of rounding, not all bar segment totals add up to 100%.

Returning Investors and Later-Stage Capital for Medtech AI/ML

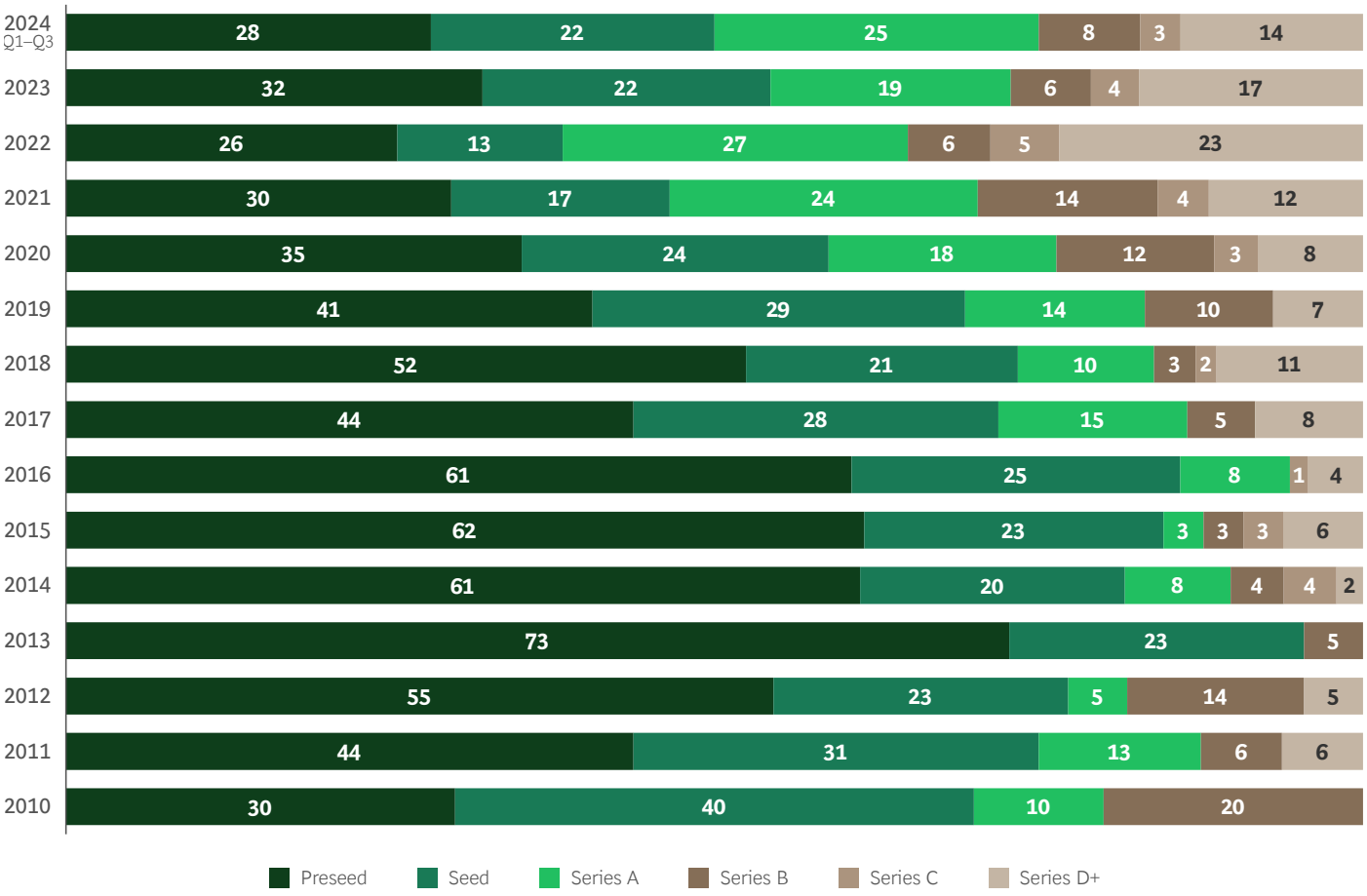
From 2010 to 2015, most VC deals funding medtech companies took the form of preseed and seed capital (75%), plus some Series A (10%) and Series B+ funding (13%). By 2023, Series A deals had doubled to 20%, while Series B, Series C, and Series D funding accounted for just under a third (28%) of the deals for private companies. **(See Exhibit 13.)** Meanwhile, preseed and seed rounds dropped to about 50% of total VC transactions.

The pandemic years brought in the highest number of investors in FDA-regulated AI/ML medtech, with a peak in 2020. **(See Exhibit 14.)** From 2017 to 2019, the ratio of new investors to return investors was 4.2:1. That ratio fell to 2.5:1 in the ensuing years, suggesting increased investor confidence in sustained demand for AI/ML-enabled products.

EXHIBIT 13

Distribution of Deals by Funding Stage

Funding stage (%)



2017–2019
Majority were preseed and early-stage funding

2020–2022
1.5X increase in late-stage funding for growth-scale startups

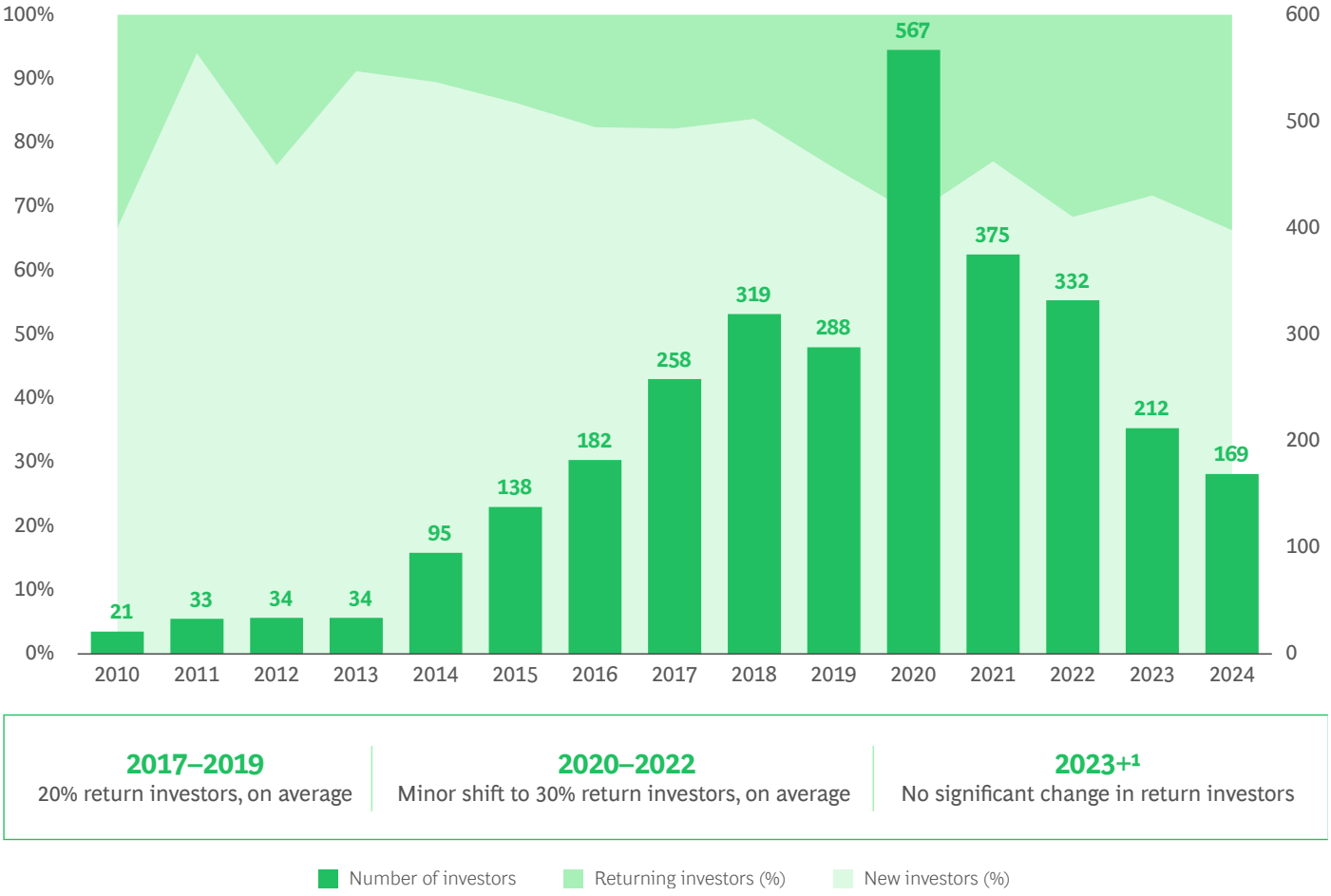
2023+
Stabilization: continued distribution of funding to early- and late-stage startups

Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.

EXHIBIT 14

New vs. Returning Investors

The number of investors peaked during the pandemic, with a minor shift to return investors during and after the pandemic



Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
[1]Funding data for 2023 onward is incomplete.

Investors Are Shifting Gears to Focus on Authorized Devices

From 2017 to 2019, medtech companies landed 158 deals to support their first FDA-regulated AI/ML product authorizations, raising more than $600 million in VC funds compared to just 54 deals for postapproval products that attracted $551 million. **(See Exhibit 15.)**

The pandemic years had fewer preapproval deals than in prior years, but similar total funding. However, the number of post-FDA-approval deals during the pandemic jumped to 142, with total VC funding at $3.3 billion, and median deal sizes were two to three times higher than during the previous three years. Along the way, medtech AI/ML products gave rise to some spectacular valuations. **(See "A Parade of Unicorns.")**

EXHIBIT 15

VC Funding Trends for FDA-Authorized AI/ML Medtech

Funding for first FDA-cleared device by preclearance and postclearance

196/196
Companies/devices

414/298
Dilutive deals
(preclearance/postclearance)

955/997
Number of investors
(preclearance/postclearance)

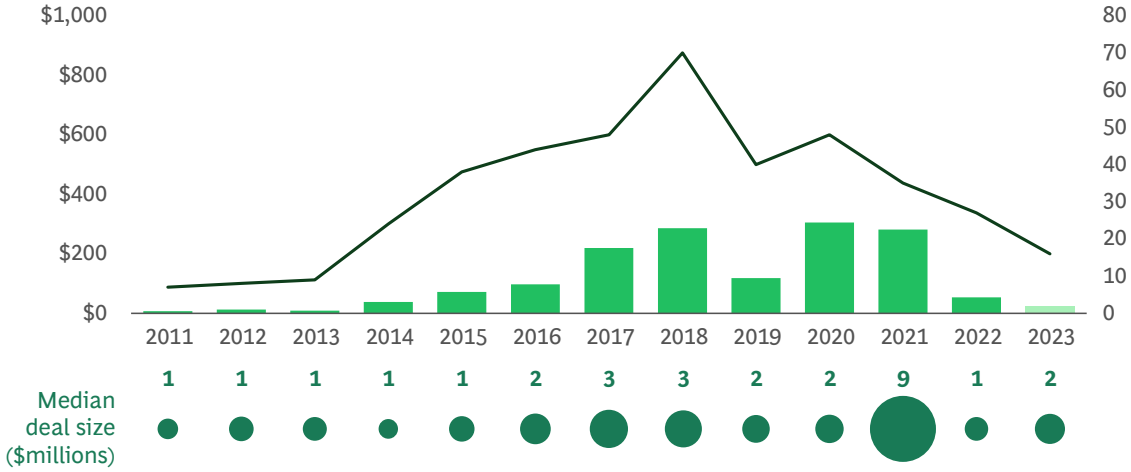
Preclearance

High VC confidence in funding precleared devices before and during the pandemic

Highest average deal size during the pandemic

Deal size stabilized after the pandemic

2017–2019: 158 deals; raised $623 million
2020–2022: 110 deals; raised $639 million
2023+[1]: 16 deals; raised $23 million



$1.5B/$4.9B
Capital invested
(preclearance/postclearance)

1/21
Exits
(preclearance/postclearance)

$65M/$320M
Largest deal
(preclearance/postclearance)

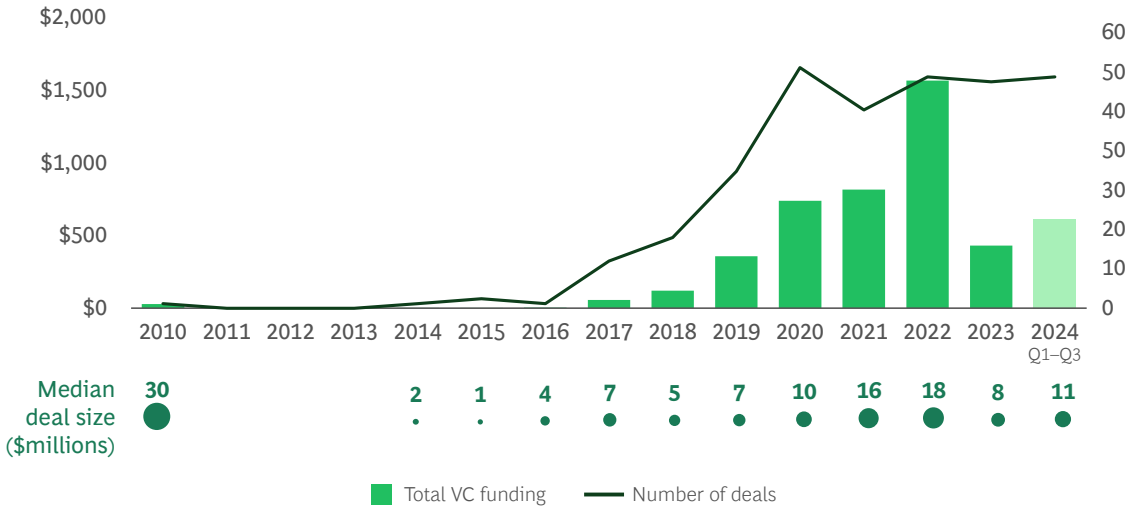
Postclearance

High VC confidence in funding cleared devices during and after the pandemic

3X number of deals and 6X capital raised during the pandemic, with the highest VC funding and largest deal size in 2022

Funding and number of deals stabilized after the pandemic

2017–2019: 54 deals; raised $551 million
2020–2022: 142 deals; raised $3.2 billion
2023+[2]: 97 deals; raised $1.07 billion



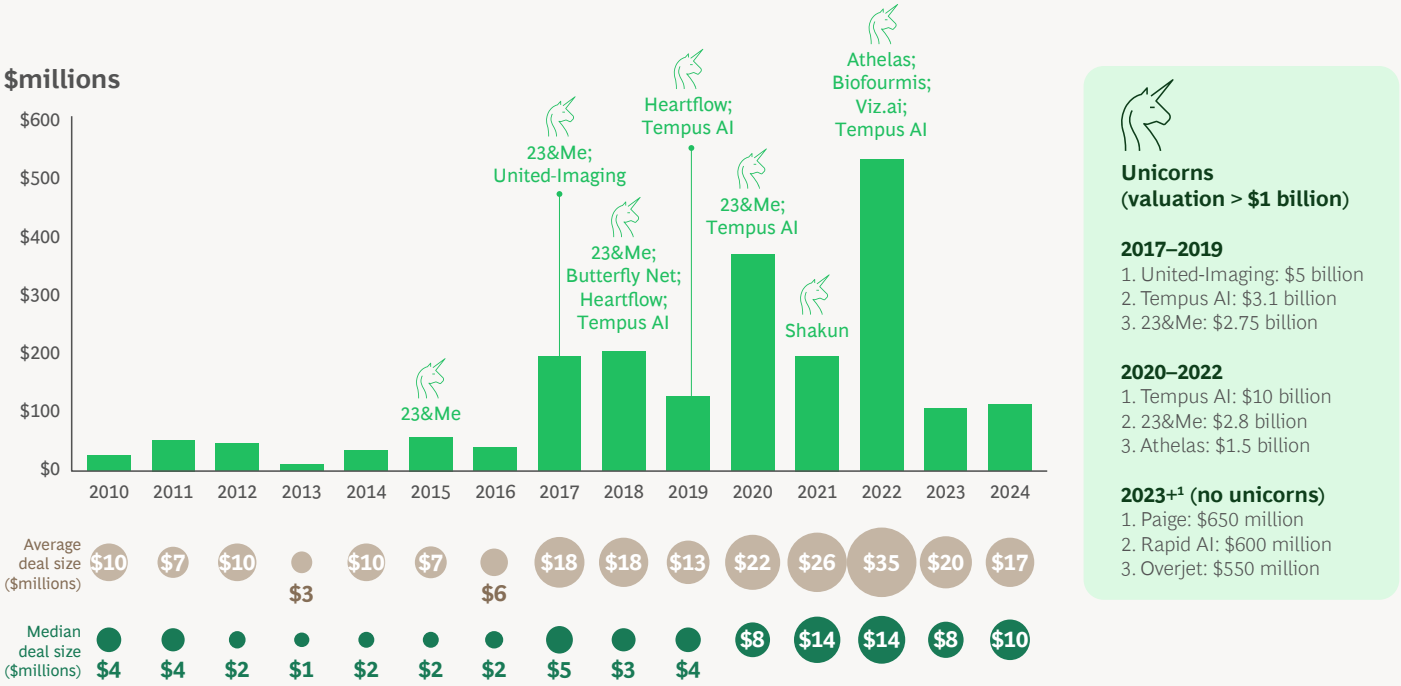
Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
Note: Data is for clearances that occurred during or after 2010. VC = venture capital.
[1]Funding data is incomplete for devices not yet submitted for FDA clearance.
[2]Funding data is incomplete for 2024 and later.

A Parade of Unicorns

With United-Imaging, Tempus AI, and 23&Me setting the pace in the prepandemic era, the 2020s brought valuations to new heights. **(See the exhibit.)** Tempus AI and 23&Me, already tipped as unicorns, were back again, this time with valuations of a staggering $10 billion and an impressive $2.3 billion, respectively. Shakun, Athelas, Biofourmis, and Viz AI were the other new unicorns born during the pandemic, although some lofty valuations (such as those for 23&Me and Biofourmis) have subsequently plummeted. From 2023 to Q3 2024, average and median deal sizes returned to prepandemic levels, and no new unicorns debuted.

Average Postdeal Valuation vs. Deal Size

The highest postdeal valuations and largest deal sizes occurred during the pandemic



Unicorns (valuation > $1 billion)

2017–2019
1. United-Imaging: $5 billion
2. Tempus AI: $3.1 billion
3. 23&Me: $2.75 billion

2020–2022
1. Tempus AI: $10 billion
2. 23&Me: $2.8 billion
3. Athelas: $1.5 billion

2023+[1] (no unicorns)
1. Paige: $650 million
2. Rapid AI: $600 million
3. Overjet: $550 million

Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
Note: 23&Me first reached unicorn status in 2015; Butterfly Net, Heartflow, and Tempus AI first reached unicorn status in 2018.
[1]Valuation data incomplete for 2023 and later is incomplete for devices not yet submitted for FDA clearance.

More VC Investors Are Heading to the Exit Ramp

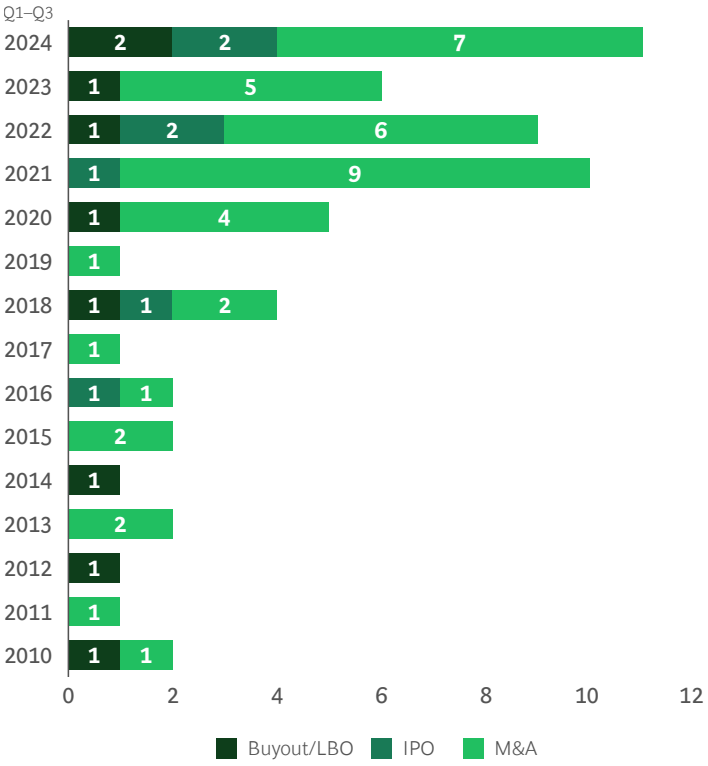
For VC investors, the ultimate indicator of success is a great exit. From 2010 to 2023, Pitchbook tallied 58 medtech AI/ML exits representing paydays for VC investors. **(See Exhibit 16.)** Large public companies such as GE Healthcare, Philips, Medtronic, Stryker, Boston Scientific, and Hill-Rom accounted for the outright majority of buyers, but the largest individual deal was the $6 billion takeover of Athelas by Commune in October 2023. In addition to M&A, VC players chalked up exits with seven LBOs and four IPOs involving companies with new AI/ML-enabled devices.

Strong exit activity for AI/ML-related products suggests sustained confidence in the technology's transformative potential—a sentiment underscored by the recent UCLA Biodesign/BCG survey of 50 medtech executives and board directors. Two-thirds of respondents said they were somewhat more or much more positive about the outlook for AI/ML-enabled devices than they had been just 12 months prior. None claimed to be much more negative, and just 10% indicated that their outlook for the technology was slightly more pessimistic. As the president and CEO of one medtech company put it, "My confidence has grown because of the awareness in the market. I was startled at how quickly the industry adopted AI devices."

EXHIBIT 16

Exit Activity

M&A activity was strong during the pandemic and has remained strong afterward



After 2017, a rising wave of exits accompanied the surge in AI/ML medical devices cleared by the FDA

Type	Year	Company	Amount	Acquirer
IPO	2017–2019	PrediLife	$4.08 million	
	2020–2022	Spectral AI	$15.6 million	
		Lunit	$28 million	
		United Imaging	$1.6 billion	
	2023+	Ceribell	$180 million	
Buyout/LBO	2017–2019	The Esaote Group	$354 million	Multiple
	2020–2022	Therenva	–	Ziehm Imaging
		ScanMed	$20 million	DirectMed Imaging
	2023+	RadFormation	$6.9 million	BVP Forge
		Limbus AI	–	RadFormation
		Sonio	$92 million	Samsung Medison
	2017–2019	Behold.ai	–	Simon Raslingham
		Withings	–	Mr. Eric Carreel
		Quantitative Insights	–	Qlarity Imaging
M&A	2020–2022 (21 total)	Excel Medical	$19.2 million	Hill Rom Holdings
		Preventice	$936 million	Boston Scientific
		7D Surgical	$120 million	Sea Spine
		Gauss	$160 million	Stryker
		Zebra Medical Vision	$110 million	Nanox
		BK Medical Holding	$1.4 billion	GE Healthcare
		Cathworks	$585 million	Medtronic
	2023+ (12 total)	Caption Care	$150 million	GE Healthcare
		DIA Imaging Analysis	$100 million	Philips
		Athela	$6 billion	Commune
		Volpara Health	$292 million	Lunit

Sources: BCG and UCLA Biodesign; FDA; Pitchbook, January 2025.
Note: IPO = initial public offering, LBO = leveraged buyout; M&A = mergers and acquisitions.

Travelogue

The Road Ahead

You Are Now Arriving at the Future of AI/ML

As a technology, AI is still in its infancy, as ongoing development and breakthroughs are announced daily. With just over 1,000 devices authorized for the US market cumulatively, AI/ML-enabled products are a tiny fraction of the 3,000 or so products that the FDA clears each year across 510k, De Novo, PMA, and other pathways. As experience with AI/ML grows, so will the backlog of marketed devices. How these products perform will determine whether early promises of greater efficiency, clinical improvement, and patient satisfaction come to fruition—along with the attendant financial rewards for the companies that bring these products to market.

Road Hazards: Data Privacy and Ownership Rights

AI/ML technology requires access to underlying patient and clinical data, raising thorny issues about what patients, clinics, and companies can claim as their own. There is an obvious need for de-identified patient data with clear usage rights established, but there is as yet no straightforward way to ensure its provenance. The problem compounds as more AI/ML-enabled devices hit the market because so many of them generate their own data stream. Companies developing AI/ML-enabled devices need to be able to define where their data came from, how they obtained it, and how they used it. Otherwise, they may face downstream legal battle if their inventions are challenged in court.

Road Construction: A New Bill

A Senate bill proposed by Democratic Senator Matt Heinrich of New Mexico and Republican Senator Marsha Blackburn of Tennessee would offer a reimbursement pathway for health care services provided by AI/ML-enabled devices.[8] The senators hope to promote widespread adoption of AI devices in the clinic, resulting in better patient outcomes and greater efficiency. Current Centers for Medicare and Medicaid Services (CMS) guidelines do not stipulate standard or consistent billing procedures for providers using AI/ML algorithms. The proposed bill would create an Ambulatory Payment Classification (APC) for a period of five years, allowing CMS to determine whether to assign a permanent code. The bill comes during a period of tremendous upheaval and uncertainty in the federal government, however, and whether it will gain traction remains to be seen.

International Road Signs Are Hazy

International regulatory harmonization is always a challenge, with different schools of thought on how to regulate AI on display across the US, the EU, and China. As described by Anu Bradford in *Foreign Affairs*, the US can be characterized as taking a pro-business approach, versus a privacy-first paradigm in the EU and more reliance on government control of content in China.[9] These differences will be difficult to resolve, especially for smaller, VC-backed companies, resulting in delays or outright forfeiture of overseas markets. Time will tell whether local variation will suffice or whether independent new product development processes will be required to access different markets.

Adaptive Logic and GenAI: From Side Trip to Main Route

The potential for adaptive logic to power broad clinical improvements and individualized patient therapy is a lofty goal worth pursuing. The technological hill to climb is steep, but regulatory issues are even more forbidding. With proper guidelines (for example, clean training data, clear boundaries, and fail-safes) to prevent AI hallucination, greater experience with PCCPs, and a fit-for-purpose postmarketing surveillance process, we anticipate that AI/ML-enabled devices with adaptive logic will provide the next phase of growth for this exciting technology. As for GenAI, the hill it has to climb is even steeper, but one avenue that appears quite promising is the use of synthetic data to train large language models.

8. Health Tech Investment Act. S. Bill, 119th Congress, 2025.
9. Anu Bradford, "The Race to Artificial Intelligence" *Foreign Affairs*, June 27, 2023.

Summary

Although the first FDA-recognized device was launched in 1995, AI/ML-enabled devices did not become commonplace until the early 2020s. Claiming 1,016 authorized products by Q3 2024, AI/ML devices are carving out an increasing share of the medtech landscape. More importantly, this technology is changing how innovation occurs, how regulatory bodies operate, and how funding flows into the medtech sector.

Innovation remains heavily concentrated in the radiology sector, where image processing technology has been a boon to clinicians in interpreting patterns in microscopic data. Other specialties are gaining headway, too, especially cardiology, given its heavy reliance on image, neurological, and acoustic processing. Occupying center stage in all AI/ML innovation is software. SaMD accounts for 71% of authorizations to date, with software/hardware combinations responsible for the balance. For this reason, the innovators behind AI/ML-enabled devices tend to be heavily concentrated in coding hotspots in the US, Israel, France, China, and South Korea.

The FDA has continuously invested and adapted to accommodate the rapid influx of new AI/ML-enabled devices. Throughout the past decade, the agency has brought on staff and engaged third-party reviewers with deep software expertise—and as recently as January 2025, the FDA issued additional guidance for total life cycle management of AI/ML-enabled devices. As a result, AI/ML-enabled products now experience only a four-week penalty in median time to authorization versus standard products (133 days versus 106 days). US applicants lag slightly behind foreign players in median time to approval (135.5 days versus 129 days). The use of third-party reviewers, which collapses median time to authorization for standard products from 114 to 29 days, has less impact on AI/ML-enabled devices, which experience a decrease of just 26 days (155 days versus 129 days).

Another area where regulation is progressing slowly is adaptive learning. To date, just 3 of the 1,016 authorized AI/ML-enabled devices contain self-learning algorithms. Still, medtech executives are excited about the prospects for their AI/ML-enabled devices, and 96% describe themselves as at least somewhat confident about their likelihood of receiving FDA approval and achieving successful commercialization.

Their confidence is echoed by the trajectory of AI/ML-enabled device funding, which has skyrocketed since 2010. VC leads the way with $14 billion raised across 3,057 unique investors in 387 companies. Early-stage investments in the single millions characterized the early 2010s, but more recently VC has funded a string of megadeals exceeding $100 million—the largest of which attracted $506 million. Although the absolute number of VC deals has fallen from a high point in 2022, absolute investment remains close to prepandemic numbers. Public corporations account for 40% of the AI/ML-enabled devices on the market, with large imaging companies setting the pace for the entire industry. Meanwhile, strong exits continue to power interest in the space, as the five largest deals (M&A and IPO) netted a collective $10.6 billion for their creators.

We believe that this report includes the most comprehensive and current information on approval and funding trends for AI/ML-enabled devices. In such a fast-moving space, there will undoubtedly be errors and omissions in our data set. Nonetheless, we hope that our work will guide medtech innovators, regulators, and investors as they chart their course in the AI/ML-enabled device landscape. We will continue to monitor progress in this dynamic field, which has already changed the face of the medtech industry and promises to make an even deeper impact in the years to come.

Methodology

In this first-of-a-kind study, we examined the AI/ML-enabled medical device landscape in the US from 1995 to 2024. Our team compared successful authorizations for AI/ML-enabled devices and comparable products to understand overall growth and penetration trends, time from submission to authorization, and potential drivers of variance. In addition, we identified aggregate investment levels for AI/ML-enabled medical technologies, classified investor types, and examined IPO, M&A, and merger activity for companies developing AI/ML-enabled devices.

Analytical Methods

1. **Creation of Database for FDA-Authorized AI/ML-Enabled Devices.** The UCLA Biodesign team and the UCLA Biostatistics department developed, cleaned, and analyzed a novel proprietary database that merges and integrates product and regulatory data from the FDA's Medical Device database, the FDA's Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices list, Pitchbook's data set on public and private company and capital data, and a multitude of other publicly available and private medical device data sets to curate a total data set covering 1,016 AI/ML-enabled medical devices (including 980 510(k) clearances, 32 De Novo clearances, and 4 PMA clearances) from 387 companies during the time period from 1995 to Q3 2024—when the FDA last released AI/ML data.

2. **Comparative Analysis of Time to Authorization for AI/ML-Enabled and Standard Devices.** UCLA Biodesign started with the recent data set of 1,016 AI/ML-enabled medical devices from 387 companies that it released in Q3 2024. We analyzed this list to uncover overall trends and establish benchmarks for insights including annual FDA market authorizations for 510(k), De Novo, and PMA pathways, average and median times in FDA review for various pathways and medical specialties, and segmentation and characterization of AI/ML-enabled devices by geography, product code, technology type (a categorization established by UCLA Biodesign), medical specialty, and other segments. Then, to compare time to authorization between AI/ML-enabled medical devices and standard (that is, non-AI/ML-enabled) devices within the same product code classification (for example, product code LLZ = System, Image Processing, Radiological), we distilled and matched a study group of 659 AI/ML-enabled medical devices that obtained 510(k) clearance from 2010 to 2023 to that for a control group (N = 6,347) of standard (that is, non-AI/ML-enabled) 510(k) cleared medical devices within the same product code classifications and time period.

3. **Aggregate Venture Capital Funding for AI/ML-Enabled Devices and Exit Activity.** We filtered and distilled the integrated database to isolate study and control group companies whose funding activity was recorded by Pitchbook from 2010 to Q3 2024. The team tabulated capital raised by 133 new ventures from time of incorporation to time of positive FDA decision (510(k) clearance, De Novo granting, or Premarket Approval (PMA)). Where available, the team captured funding rounds, the size of each deal, pre- and post-valuations, and other funding variables. We used a subset of this group, consisting of 107 companies that recorded their first AI/ML-enabled device authorization, to assess how much capital is required to develop, test, validate, and obtain FDA market authorization for a medical device. In addition, the team compiled available data on VC exit activity, capturing deal size for IPOs, mergers, LBOs, and acquisitions by investor type.

4. **Medtech Executive Survey.** UCLA Biodesign and BCG prepared and conducted a four-question online survey of 52 C-suite- or vice-president-level executives with experience in AI/ML-enabled medical device development, regulation, and commercialization. The survey sought to understand these leaders' experiences, sentiments, perceived needs and gaps, and recommendations for the advancement of AI/ML-enabled devices. We conducted the survey in November 2024 and supplemented it with a series of in-depth interviews to provide additional context for the team's findings.

Limitations of the Study

Although we believe our approach and analysis provides many useful insights, readers should be aware of some important limitations of the study, including the following:

- **Incomplete Record of AI/ML-Enabled Devices.** The FDA updates and publishes information on AI/ML-enabled devices on a quarterly or semiannual basis, sometimes reclassifying authorized products in arrears. As a result, our database may not include all AI/ML-enabled devices in the US market since 1995.

- **Incomplete Record of Venture Capital Investment.** Our analysis of VC funding relies on published totals from Pitchbook, which may or may not be complete. We have explicitly omitted insights on 2024 VC investment when examining year-on-year trends because the FDA-authorized AI/ML-enabled device list has not yet been updated for Q4 2024.

- **Imperfect Classification of Devices.** We based our segmentation of technologies on the review of device descriptions and technical descriptions in the 510(k), De Novo, and PMA submissions and summary letters on FDA's website, for which general categorizations may or may not be accurate.

- **Limited Geographic Analysis.** We based our regional distribution of companies on the location of each company at time of regulatory submission, whether it was a private venture, a global headquarters of a multinational company, or a subsidiary or joint venture of a company. We did not present a geographic distribution based on the parent company's global headquarters.

- **Management of Outliers.** We used interquartile range to manage outliers, and we applied a Wilcoxon two-tailed test to compare approval times between the AI/ML and control data sets. Although we obtained averages as part of the study, we calculated and cited medians throughout the discussion to minimize skew and reduce the impact of outliers.

Areas for Future Study

This work sheds light on the speed of innovation, regulatory timeframes, and aggregate VC funding levels for AI/ML-enabled devices. However, other intriguing questions would bear further investigation:

- **Device Success Rates.** The study did not tabulate total submissions for AI/ML-enabled devices and their comparators and, therefore, provides no guidance on relative success rates.

- **Aggregate Investment in AI/ML-Enabled Devices.** This study compiled only private investment from VC, plus capital provided by grants, foundations, downstream mergers, acquisitions, and IPOs. Specifically missing is the cost of developing AI/ML-enabled devices in-house for publicly traded companies and how that cost compares with the cost of developing standard devices.

- **Adaptive AI-Enabled and GenAI-Enabled Device Experience.** To date, only 3 of the 1,016 FDA-authorized AI/ML-enabled devices include adaptive (self-learning) devices and none include generative (self-creating) AI software. As the industry evolves along these vectors, future studies could document the innovation process, regulatory experience, and cost to bring such technology to market.

About the Authors

Christian Johnson is founder and CEO of ScoutMedix, a strategy and advisory consulting firm focused on the medtech industry, and a frequent collaborator with UCLA Biodesign. You may contact him by email at **christian@scoutmedix.com**.

Jennifer McCaney is chief innovation officer at UCLA Health, executive director of UCLA Biodesign, and an adjunct associate professor at the UCLA David Geffen School of Medicine and Anderson School of Management. You may contact her by email at **jmccaney@anderson.ucla.edu**.

Mahruq Siddiqui is a principal at M3S Labs, advising medtech and life sciences companies on digital technology strategy and implementation. She is currently collaborating with UCLA Biodesign on an AI/ML medtech research study. You may contact her by email at **mahruq@m3slabs.com**.

Gunnar Trommer is a managing director and partner in the Manhattan Beach office of Boston Consulting Group. He serves as health care leader for BCG X in North America and as global medtech leader for BCG X. You may contact him by email at **trommer.gunnar@bcg.com**.

Erik Adams is a managing director and partner in BCG's San Diego office. You may contact him by email at **adams.erik@bcg.com**.

Meghna Eichelberger is a partner and associate director for medical technologies in BCG's Boston office. She is topic leader for clinical, market access, and regulatory issues for BCG's medtech sector. You may contact her by email at **eichelberger.meghna@bcg.com**.

Peter Lawyer is a senior advisor to BCG, a former senior partner and managing director with the firm, and the founder of its medtech sector. You may contact him by email at **lawyer.peter@advisor.bcg.com**.

For Further Contact

If you would like to discuss this report, please contact the authors.

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