Global Insights | Wellness

Smart Thinking on AI in Healthcare: Part 2 – Medical Devices

AI is increasingly disrupting radiology

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Executive Summary

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This is our second report on *Smart Thinking on AI in Healthcare.* Seven years ago there were almost no AI-enabled devices being approved by the FDA but they've grown roughly in a straight line, and now ~40% of all radiology devices being approved are AI enabled. Sales of AI-enabled diagnostic equipment are likely to grow at 33% CAGR over the next five years, according to independent forecasters. In some areas AI is now just a cost of doing business; in others it's possible to provide AI as a service, particularly when serving BioPharma. The path won't be completely smooth, however, because many doctors are reluctant to embrace AI-enabled devices. The FDA has tried to encourage innovation, however, and as a result AI-driven devices are typically launched in the U.S., rather than in Europe. Companies say the main barrier to innovation is now the lack of clarity around reimbursement.

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The Transformation of Health

The second report in a five-part series

This is the second report in our series *Smart Thinking on AI in Health.* We're focusing on medical devices because they're one part of health care where AI is clearly already having an impact, in particular on medical imaging.

Seven years ago there were almost no AI-enabled devices being approved but they've grown roughly in a straight line, and now about 40% of all radiology devices being approved are AI enabled, as Figure 1 shows. As a result sales of AI diagnostic devices are likely to grow rapidly – the consensus forecast is for 33% compound growth over the next five years.[1]

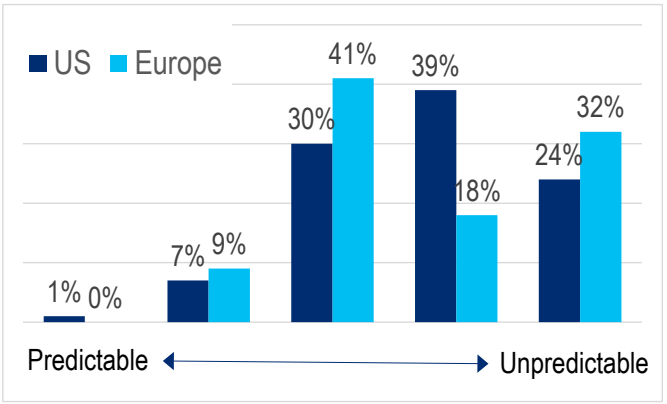
Roughly 40% of all radiology devices being approved currently are AI enabled

This means there's a big opportunity, both for start-ups and established players. In some areas, AI has now become a necessary cost of doing business; in others it is possible to carve out a niche providing AI as a service particularly when serving the BioPharma industry.

Figure 1. AI-enabled devices as a % of all radiology devices approved by the FDA

Source: FDA

Figure 2. Predictability of Reimbursement for Digital Devices



Source: BCG and UCLA Biobank

The path won't be completely smooth, however, because many doctors are reluctant to embrace AI-enabled devices, as we discuss on pages 16-18.

The FDA has tried to encourage innovation, and as a result AI-driven devices are now typically launched in the U.S. By contrast the EU's new safety-first approach has made it much harder to introduce products there. Many companies now say they will delay their European launches, if they do so at all.

[1] Consensus of forecasts from Nova 12 Advisor, GVR, BCC, Verified Market, and Precedence Research.

In the U.S. the most important barrier to the use of new types of medical devices now revolves around "reimbursement" rather than "approval". The FDA, or its equivalents overseas, may approve an AI-enabled device, but health providers will buy it only if they believe payers will reimburse its use. Unfortunately, Figure 2 shows companies find it extremely hard to predict whether there will be reimbursement for new digital medical devices, both in the U.S. and in Europe.

Despite these issues, however, AI-enabled medical devices are growing rapidly – which means MedTech is likely to be the first area within health where AI will have a significant impact.

Figure 3. Reports planned in the Smart Thinking on AI in Healthcare series

1	**Overview**	AI will progressively transform the health system
2	**Medical Devices**	AI devices are already becoming more common, especially in radiology
3	**Health Administration**	AI will help automate a lot of admin, taking over mundane tasks and saving time and cost
4	**BioPharma**	BioPharma will be deeply affected as transformers analyze large molecules
5	**Role of Doctors**	Gradually AI will automate diagnosis and prescription, letting doctors focus on higher tasks

Source: Citi Global Insights

Which companies are using AI in medical devices?

Please contact the Citi Global Data Insights team for screens of companies exposed to the themes in this report

Our colleagues in Citi Global Data Insights are able to generate screens of companies exposed to the themes in this report, based on a quantitative analysis both of patents filed and of newsflow.

These screens cover quoted and unquoted companies. They can be ranked in many ways. For example it is possible to rank by the number of patents obtained related to AI in medical devices, or the quality of those patents, or the percentage of a company's patents that fall in this area.

Please do reach out to Helen Krause (helen.krause@citi.com), for more information.

AI will gradually change more and more of the health system

The first report in our series on AI and healthcare laid out our overall thesis, which is that AI will gradually but profoundly change the healthcare industry:

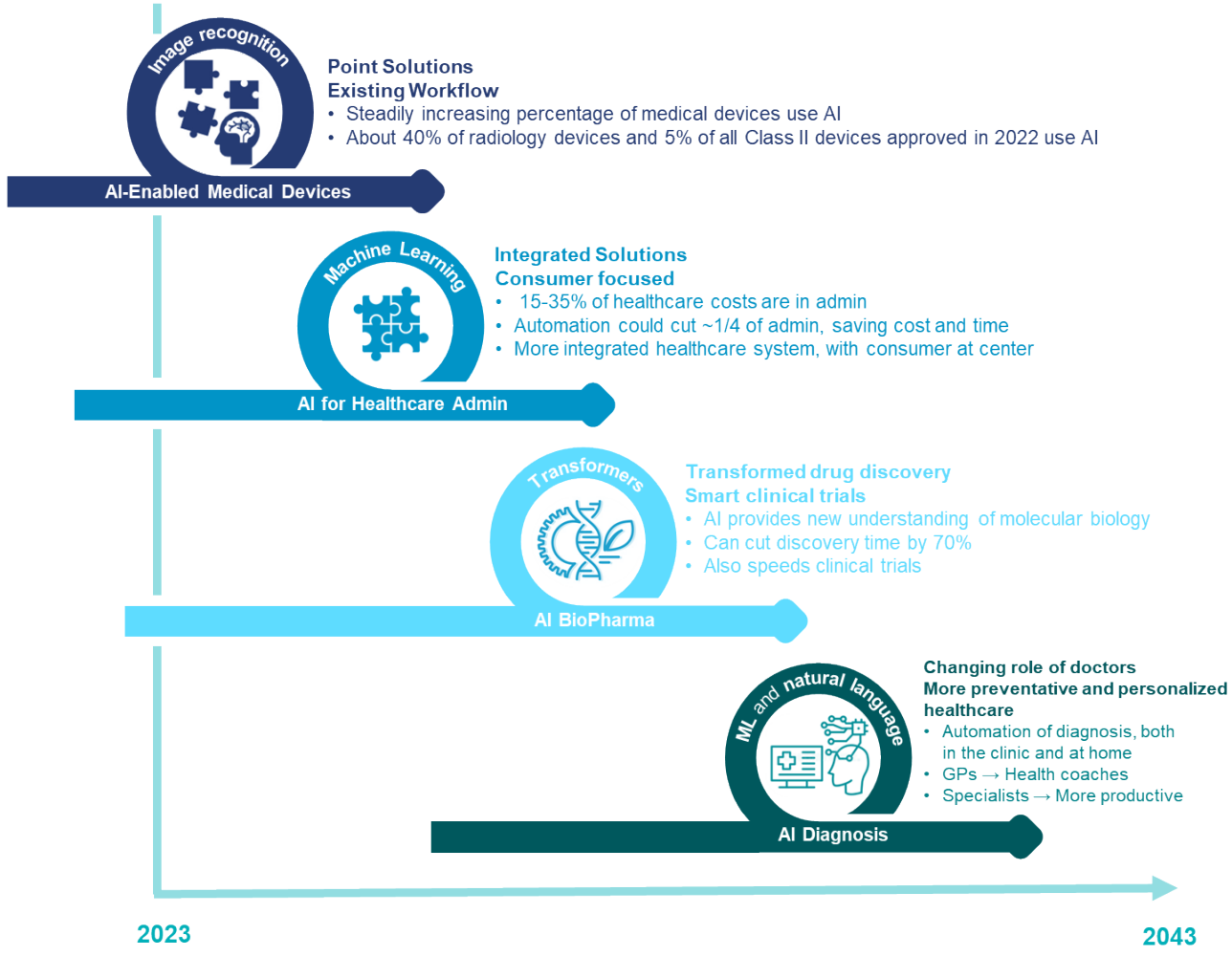
- **So far** AI's impact on healthcare has been relatively modest, with some interesting developments in radiology, BioPharma and in a handful of health-specific admin systems. *These products are mostly point solutions that address the needs of the pre-existing players in their pre-existing workflows.*
- **In the next few years** AI is likely to automate a good deal of health admin, relieving workers of mundane tasks, saving both money and time, and thereby improving clinical outcomes. *This sort of AI will integrate the different parts of the system, for example the payers and providers, much more tightly*.

- **We also expect AI to profoundly affect the BioPharma industry.** The transformer technology that can understand ordinary languages (like English), and which is driving innovations like ChatGPT, can also be used to analyze large molecules like DNA and proteins.

- **In the long term** we believe AI will fundamentally change the relationship between clinicians and patients. We believe diagnosis will become increasingly automated. We expect that family doctors will become more like health coaches and hospital specialists will become more productive, attempting more personalized and ambitious procedures. *We therefore think AI will trigger a significant change in the way healthcare is delivered.*

Mike Guarino is the global head of health technology at Citi's investment bank, and he believes AI will be a central driver in the future of health. "AI is going to be a critical component of healthcare moving forward," he says.

Figure 4. AI in Healthcare



Source: Citi Global Insights

What kind of AI?

AI comes in many forms, as we discussed in AI Time - 10 Ways AI is Getting Real. So far, the main types of AI that have impacted health have revolved around image recognition – which is why there has been such a big impact on radiology – and machine learning, which is vital for diagnosis and health administration.

AI is particularly suited to radiology because (1) medical images contain a huge amounts of data,[2] and (2) AI started outperforming humans in image recognition about eight years ago.

One of the two most important breakthroughs in AI came back in 2012, with the ImageNet competition.[3] ImageNet was (and still is) a database that contains lots of hand-labeled images – about 1.3 million at the time; about 16 million now. The breakthrough came when a program with a new type of neural network[4] won the competition to identify them accurately, and by 2015, neural networks were outperforming humans. Since then, image recognition has gotten more and more accurate, and as a result, AI is now exceptionally well suited to categorizing images, which is the core of diagnostic radiology.

A good example of AI beating humans in radiology occurred last year in a blinded study at Cedar-Sinai and the Smidt Heart Institute that focused on echocardiograms.[5] In the study, consultant radiologists evaluated almost 3,500 ECGs that had previously been assessed either by ultrasound technicians or by AI. (The ECGs showed left ventricular ejection fraction, which is the main way of assessing cardiac function.) It turned out the consultants had to correct 27% of the technicians' initial assessments, but only 17% of the AI system's.

Providing advice vs. final diagnosis

In radiology, it's possible to think of the use of AI as part of a progressive series of steps, as we lay out in Figure 5. First there was the move away from analog images to digital. Then the digital images were analyzed off-site. Now, we're moving to AI interpretation, but even that has a series of steps. Most AI solutions in place at the moment highlight issues on the images to human radiologists, or they make recommendations for triage. In other words they're steps 3 or 4 in Figure 5.

We think moving to step 5, which is whether the AI suggests a preliminary diagnosis, would be a big jump. Moving to step 6 – where AI decides on a diagnosis – would be even bigger. We expect it will be several decades before society is willing to let AI make the final judgement on a diagnosis.

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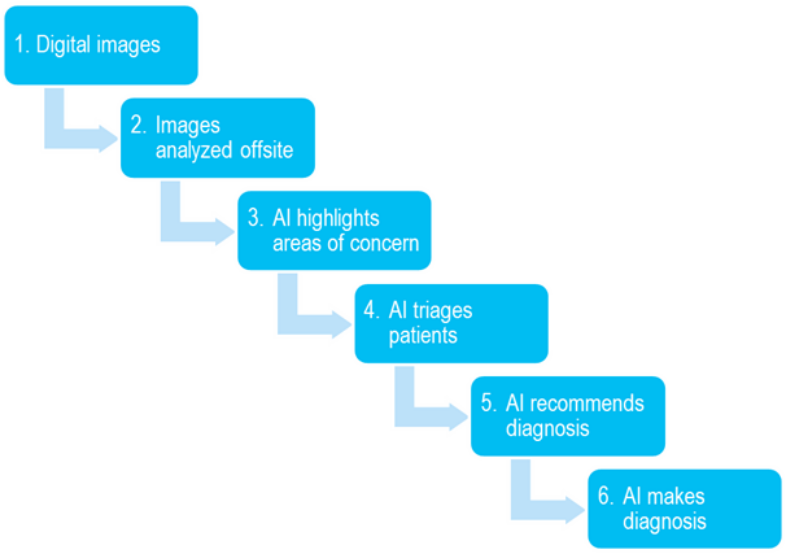
[2] In 2015, IBM researchers said 90% of data in healthcare comes from imaging. Forbes 2015: IBM promises to read your x-rays

[3] The other really important breakthrough was the creation of transformers in 2017.

[4] A neural network is program that mimics elements of the biological networks in the human brain. The winning entry was called AlexNet, and it used what's known as "convoluted neural network."

[5] Cedars-Sinai.Org 2022: AI More Accurate Than Technicians

Figure 5. Stages of automation in radiology



Source: Citi Global Insights

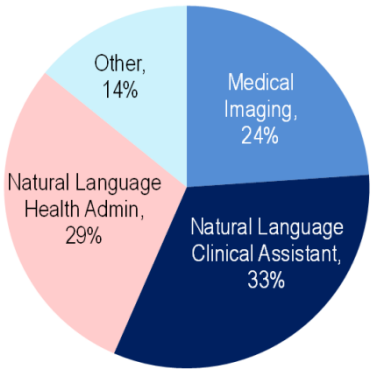
Natural language and medical devices

As we discussed in the first report in this series, we have examined the companies with patents relating to natural language processing and health, and the results are shown in Figure 6.

It's not a surprise that many of the companies are focused on what we call natural language clinical assistants – in other words tools that collect data (via natural language inputs) and provide medical advice either to clinicians or consumers. A further group aim is to provide administrative support for health care professionals.

In our survey, about a quarter of small companies with patents in "natural language" and "health" were focused on medical imaging

Figure 6. Breakdown of small companies filing patents that referred to "natural language" and "health" or "healthcare"



See Appendix on page 25 of the first report in the series for a detailed description of this chart.

Source: Citi Global Insights

What is significant (or at least intriguing) for this report, however, is that for 24% of companies with these sort of patents, the prime focus is medical imaging. It is possible that some of these imaging companies are considering whether to branch into other fields, like natural language clinical assistants; but it is also possible that some are hoping to use natural language processing to make their products more user friendly.

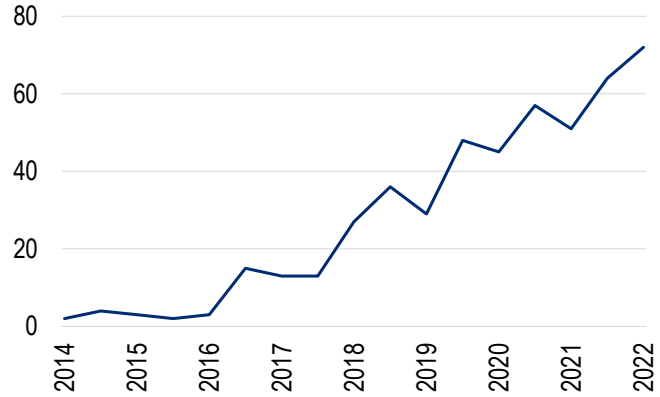
Medical AI products are growing steadily, mainly in radiology

The number of AI-enabled medical devices is growing steadily

The number of AI-enabled medical devices approved by the FDA has grown steadily, as Figure 7 shows, from close to zero before 2015 to 72 in 2H21 (the last six-month period we have full data for).

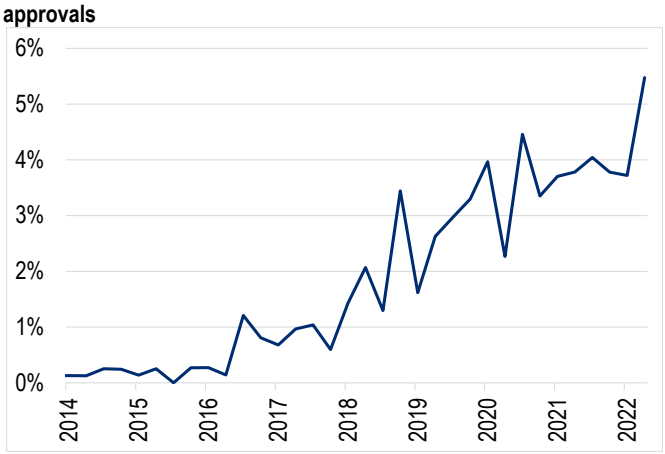
The growth is impressive, and there is no sign that the rate increase will slow down. However it's important to put it in context: Figure 8 shows that AI-enabled devices still represent only about 5% of all Class II medical devices being approved.[6]

Figure 7. Number of AI devices approved by FDA (# per 6-month period)



Source: FDA

Figure 8. AI-enabled device approvals as a % of all FDA Class II approvals



Source: FDA

About ¾ of AI-enabled devices are used for radiology

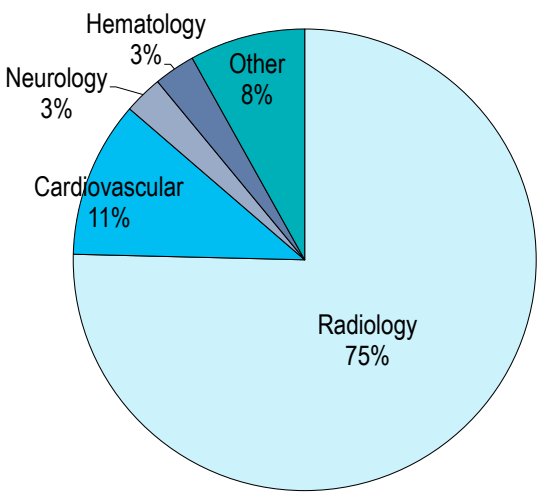
About three quarters of all the AI products that have been approved are in radiology, in other words in medical imaging, with cardiovascular devices a distant second.[7]

Figure 10 shows that almost 90% of those radiology devices are for diagnosis and that the main techniques in the field – CT, Ultrasound, MRI, X-Ray – are all well represented. The dark blue slice shows that only 11% of AI-enabled radiology devices are dedicated to the therapeutic side of radiology – which typically involves using radiation to kill cancer cells, often in the earlier stages of cancer.

[6] Class III medical devices are the potentially most dangerous if they go wrong – often items inserted into the body, like pacemakers. Class I have very low risk, for example, an elastic bandage. Class II devices require an intermediate level of regulatory scrutiny, and include things like catheters and MRI scanners.

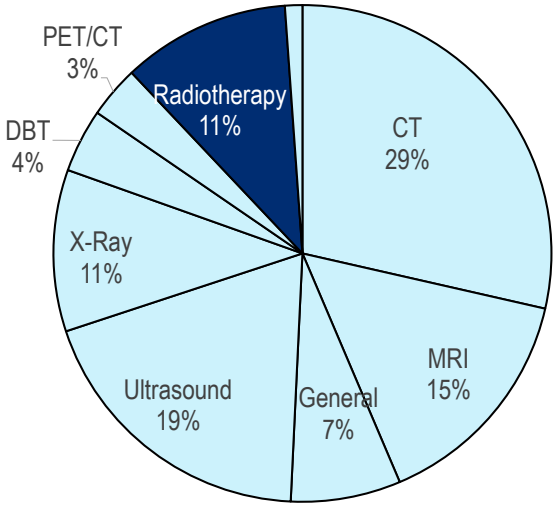
[7] Cardiovascular = Related to the heart and blood vessels.

Figure 9. AI-enabled devices -- Branch of Medicine Served



Source: FDA

Figure 10. AI-enabled radiology devices by imaging technology



DBT = what. PET/CT = PET

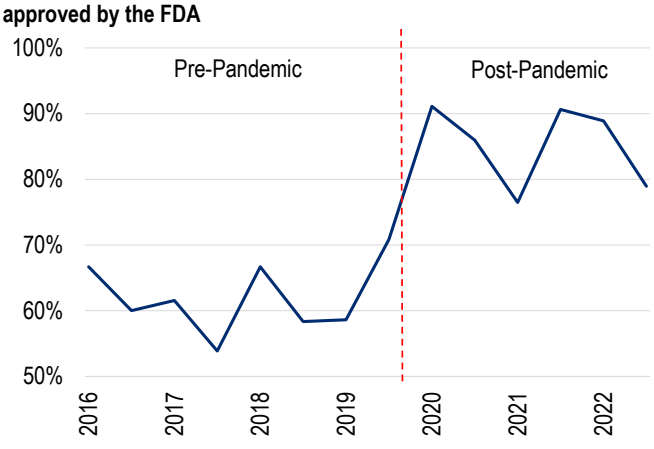
Source: FDA

AI is becoming more and more important within radiology

Radiology still accounts for 80%-90% of all AI enabled devices approved by the FDA

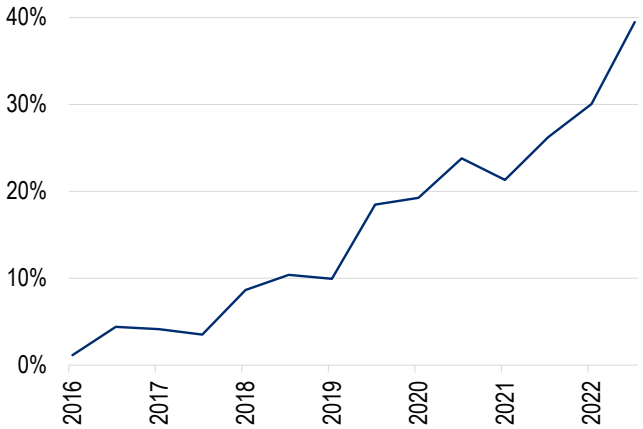
As the number of AI-enabled radiology devices being approved grows, they are becoming more and more important within the discipline. Figure 12 shows that now about 40% of all devices approved by the FDA for radiology are driven by AI, and this percentage has risen roughly in a straight line, from around zero six or seven years ago. We fully expect the percentage to go on increasing.

Figure 11. Radiology devices as a % of all AI-enabled devices approved by the FDA



Source: FDA

Figure 12. AI-enabled devices as a % of all radiology devices approved by the FDA



Source: FDA

Of course AI has moved on to other areas in the years since image recognition was the main focus. However, it's important to note that in the past couple of years radiology still accounts for 80%-90% of all AI enabled devices approved by the FDA, as Figure 11 shows.

Examples of AI radiology products

Two products that illustrate how AI can be used in radiology are **Cleerly** – which helps prevent heart attacks – and **Viz.ai** – which helps treat strokes more effectively.

Cleerly uses AI radiology to help predict heart disease

Cleerly uses AI to interpret what are called CCTA scans[8] to predict which people are at risk of heart disease, allowing doctors and patients to develop plans to help prevent them.

It's important medically because heart disease is the No1 cause of death worldwide. About 1 in 2 men and 1 in 3 women will develop severe heart disease after the age of 40.[9]

The traditional method of diagnosing heart disease uses CT scans to detect when the build-up of fatty deposits (called plaque) in the arteries restricts the blood supply to the heart muscle. But by that point a heart attack is already likely.

However, a landmark study published in 2020 showed that the best way of predicting heart attacks in patients without chest pain is by looking at the build-up of low-density plaque: Patients with >4% low-density plaque are nearly five times more likely to have a heart attack.[10]

As a result, the focus is now on finding ways to quantify the build-up of plaque. The AI used by Cleery has been trained with over 10 million CCTA images from over 40,000 patients. As a result it can rapidly interpret CCTAs, providing quantified plaque readings and highlighting risk features. It also reduces the number of cases where it's necessary to perform an invasive angiogram.[11]

"Clinical trials have validated Cleerly as one of the most accurate approaches for identification, quantification and characterization of CAD [coronary artery disease]." Cleerly says: "These trials show that Cleerly has superior accuracy against every current, clinical gold standard."[12]

In short, Cleery's AI can inform clinicians and patients of the risks of heart disease, enabling them to take personalized action to address the issue.

Viz.ai speeds the treatment of strokes

Whereas Cleerly uses AI for preventative medicine, Viz.ai technology is all about speeding emergency care in areas where every minute counts – like strokes,

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[8] CCTA scans: coronary computed tomography angiography scans.

[9] https://pubmed.ncbi.nlm.nih.gov/27500157/

[10] https://www.ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.119.044720

[11] Invasive angiograms involve inserting a catheter through a patient's blood vessels into the heart. In one clinical trial, Cleerly reduced the number of invasive angiograms by 86%. See Yukim Kim et al. In Submission. ESC Imaging 2022.

[12] Company website

cerebral aneurysms and pulmonary embolisms[13]. The aim is to improve patient outcomes, and hence save money.

Again this a really important area: stroke is the second cause of death globally,[14] after heart disease. It's responsible for over 6 million, or 1 in 10, deaths worldwide each year.

Viz.ai analyzes neurovascular and vascular images (including CTs, MRIs, and ECGs) to triage patients, and also send alerts to clinicians. It provides a system – which it calls Intelligent Care Coordination – that allows clinicians to look at 3D images and data on their mobile phones, wherever they are, and also communicate rapidly across teams. The AI identifies suspected problems, and sends alerts to get quick responses.

Figure 13. Example of a Viz alert

Note: An LVO is a type of stroke where a large artery in the brain is blocked.
Source: Viz.AI

Figure 14. Viz allows mobile users to inspect images dynamically

Note: This is a still from an animated video of a brain scan
Source: Viz.AI

[13] Strokes occur when blood stops flowing properly in the brain, rapidly destroying brain cells. Cerebral aneurysms occur when there is a bulge a blood vessel in the brain Pulmonary embolisms occur when a blood clot gets stuck in an artery in the lung, blocking blood flow to part of the lung.

[14] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

All this is aimed at saving time between imaging and care delivery. Viz.ai's stroke module has achieved 96% sensitivity[15] and 94% specificity[16] in CT images from about 2,500 consecutive patients in 140 hospitals, the company says, leading to 66 minutes (39%) saved. This in turn has led to a 37% improvement on discharge, 3½ fewer days in ICU and 2½ fewer days in hospital.[17]

In other clinical areas, AI devices are mostly diagnostic tools

The bulk of the non-radiology AI-enabled devices are also diagnostic tools, designed for use in hospitals, but a third are for consumer worn devices, which supports our view that wearables will become increasingly more effective at collecting and analyzing biometrics. (See Consumer- and clinical-grade wearables and The Transformation of Health.)

Figure 15 lists all 17 of the non-radiology AI-enabled devices that the FDA approved during the 12 months to July 2022 – which is the most recent data available. About 70% are designed to help doctors gather data and diagnose particular conditions in clinical settings; the rest are destined for use at home. The biggest field is cardiovascular, which fits in with Figure 9.

[15] Sensitivity = true positive rate = true positive / actual positive

[16] Specificity = true negative rate = true negative / actual negative

[17] https://www.viz.ai/intelligent-care-coordination

Figure 15. All AI enabled devices approved by FDA Jan-July 2022

Device	Description	Company	Field	Target	Consumer Operated?
DeepRhythmAI	Analyses all the heart beats in a processed ECG signal to classify them as correct or arrhythmic	Medicalgorithmics	Cardiovascular	Arrythmia	
Study Watch with Irregular Pulse Monitor	Designed for clinical studies	Verily Life Sciences	Cardiovascular	Irrelgular pulse	Yes
Zio Watch	The Zio system is a consumer wearable to detect and diagnose irregular heart rhythms	iRhythm Technologies	Cardiovascular	Irrelgular pulse	Yes
Minuteful - kidney test	Urine testing system and app	Healthy.io	Clinical Chemistry	Chronic Kidney Disease	Yes
Eko Murmur Analysis Software	Platform to help screen for cardiac conditions using a digital stethoscope	Eko Devices	Cardiovascular	Murmurs and Afib	
IDx-DR v2.3	Autonomously diagnosis based on images from a specialized camera	Digital Diagnostics	Ophthalmic	Diabetic Retinopathy and Macular Edema	
EarliPoint System	Uses eye-tracking technology to help diagnose ASD	EarliTec Diagnostics	Neurology	Austism SD	
Atrial Fibrillation History Feature	Helps track your AFib history, as captured on an Apple Watch	Apple	Cardiovascular	AFib	Yes
eMurmur Heart AI	Platform analyzing sounds from stethoscope. Telehealth-enabled.	CSD Labs GmbH	Cardiovascular	Heart & Lung Health	
X100HT with Full Field PBS Application	Display and analyzes images of blood cells	Scopio Labs	Hematology	Blood cell analysis	
AliveCor QT Service	6-lead ECG to monitor cardiovascular side effects that can come with particular drugs	AliveCor	Cardiovascular	QT Duration	
DEEPVESSEL FFR	Non-invasive physiological functional assessment of narrowing of heart blood vessels	KeyaMed	Cardiovascular	Coronary Stenosis	
EndoScreener	Notes every polyp detected during colonoscopy	Chengdu Wision Medical Device	Gastroenterology Urology	Polyps	
IM007	Uses implanted cardiac device	Implicity	Cardiovascular	Arrythmia	
IRNF App	Tells Apple Watch users if there pulse is irregular	Apple Inc.	Cardiovascular	Irrelgular pulse	Yes
Paige Prostate	Helps pathologists diagnose prostate issues	Paige.AI	Pathology	Prostate	
Feops HEARTguide	Helps surgeons plan operations for a particular device to help cut stroke risk	Feops	Cardiovascular	Heart operation planning	

Source: FDA and CGI

Dollar sales are currently small, but expected to grow fast

As we've said, AI-enabled devices have grown to 40% of all radiology devices approved by the FDA from nearly zero seven years ago and that percentage is likely to grow further. But that does not mean that 40% of devices *in use* are AI-enabled, although it does suggest rapid growth in the future.

We looked at five independent estimates[18] for total sales – in dollar terms – for AI diagnostic devices, combining hardware, software and services, and these points were reflected in their assessments.

[18] The forecasts are from Nova 12 Advisor, GVR, BCC, Verified Market, and Precedence Research.

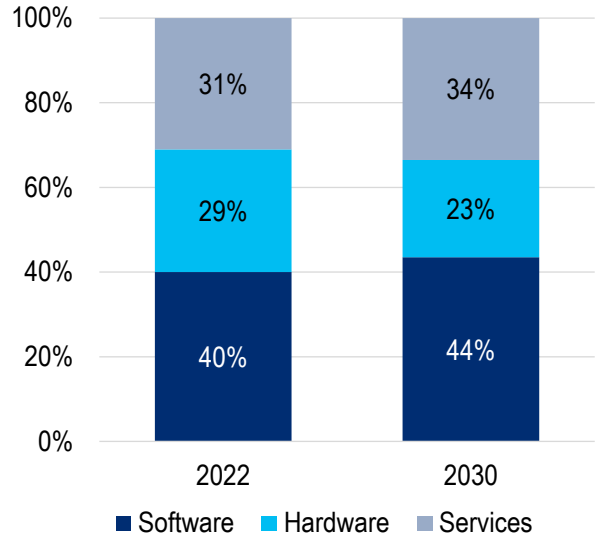
- **Currently the market for AI diagnostic devices is quite small**: the average estimate for global sales for 2022 was under $1 billion.
- **But it is expected to grow rapidly**: The average forecast for sales in 2027 is $4 billion, implying a 33% five-year CAGR.

The hardware is the smallest part of the market for AI-based diagnostic devices – software and services are both bigger, and growing faster

That 33% estimated CAGR *is* fast. Last year we collated market forecasts for 100 different growth areas in our Mapping Innovations report: the 33% expected growth rate predicted for AI diagnostics would put it in the fastest growing 10% of the areas we studied.

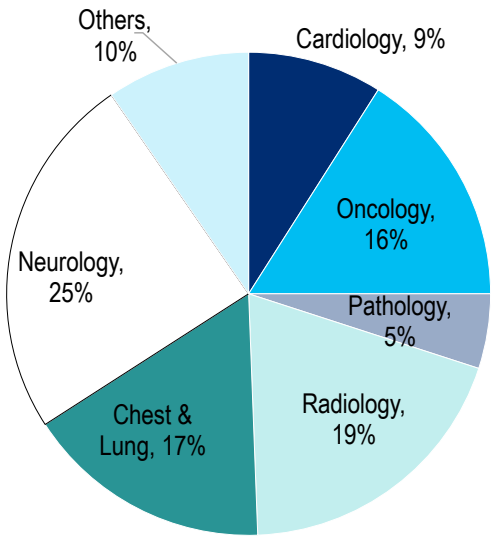
About 40% of sales currently come from software, according to Figure 16. In terms of treatment area, the biggest area is neurology (brain imaging). Cardiology is also growing fast.

Figure 16. Global AI diagnostic market by component



Source: Grand View Research

Figure 17. U.S. AI diagnostic market by area, 2022



Source: Grand View Research

The U.S. is by far the most important market by geography, although Asia Pacific, especially China, is catching up. According to Grand View Research, the U.S. AI diagnostics market accounts for 51% of the global market.[19] China accounted for 10% of the market last year, but it's expected to increase to 17% by 2027.[20]

[19] https://www.grandviewresearch.com/industry-analysis/artificial-intelligence-diagnostics-market

[20] The expected growth rate in China is 40%, vs. 25% in the U.S. (Source: https://www.giiresearch.com/report/kbv1155119-asia-pacific-artificial-intelligence-medical.html)

How is AI being monetized?

In some areas, AI has now become a necessary cost of doing business; but in others companies are carving out a niche providing AI as a service. We look at a few examples in the section below.

Pranjal Gambhir, is a managing director in Citi Investment Bank's Healthcare team, focused on Medical Technology, and he says it depends in large part on what part of the market the companies serve. "There are certainly examples of firms provide AI as a service, for example where they're selling to the BioPharma sector, because they may be analyzing many hundreds of images in a week and need AI to simplify the workflow and create efficiency," he says. "But in regular diagnosis, having a good AI system is just a cost of doing business now."

Serving the biopharma industry

An example of this is **Vida**, which provides AI-driven insights from medical images to biopharma clients, to help accelerate the creation of life-saving treatments.

"Many companies have data and AI, the challenge is in leveraging those assets to solve the most impactful problems and monetize the value of AI," Susan Wood, the CEO, told us. "The use of AI resonates with biopharma companies because they operate in a high stakes environment of expensive clinical trials with high failure rates. They need the increased quality of information and efficiency that AI provides."

Vida says that its systems help make clinical trials more efficient in several ways.

1. **By finding subjects.** Trials are expensive for many reasons, and one of them is finding an appropriate (and diverse) cohort of participants, especially if the therapy is aimed at highly specific type of patient. If a person has a routine clinical scan, for example, Vida's AI can automatically analyze the image and identify individuals who meet enrolment criteria. This analysis allows the attending clinician to match that the person with a suitable trial. Vida has a network of more than 1,000 sites, allowing trial sponsors to quickly reach populations in many geographies.

2. **By leveraging digital biomarkers.** By analyzing high resolution images deeply, Vida's AI can precisely measure changes in structure and function over time, often well before these changes will become apparent in conventional clinical tests (for example pulmonary function tests).

3. **By enabling better imaging data workflows**, Thanks to its cloud-based platform, which automates tasks for participating sites, leverages AI for quality control, and simplifies the operations of an imaging-based trial.

"Clinical trials have traditionally been slow and inefficient, which is why they're so expensive," Dr Wood says. "If we can make them more efficient – by finding the right patients and sites quickly and measuring treatment response more precisely – that creates significant value for sponsors and naturally we're able to monetize that."

Helping companies developing therapies for Parkinson's

Rune Labs is an example of a software and data analytics company that works in neurology, in particular on Parkinson's. Its StrivePD app runs on an Apple Watch and gathers data on a patient's movements and combines this with self-reported symptom information and clinical information, for example brain imaging and genetic data. The aim is to empower people with Parkinson, provide better data to their physicians, and help companies develop new products that can help to treat the disease.

Nonetheless the largest source of revenue comes from providing AI-driven insights to companies developing therapies – both medical device companies and BioPharma. "That's the high margin bit," Brian Pepin, the founder and CEO, told us. "And that's what will really drive Rune forward."

Providing precise, personalized healthcare

GE Healthcare operates on a different scale to companies like Vida or Rune, given it is one of the Big Three medical imaging companies.[21] It hopes to monetarize AI in a completely different way.

A core part of its strategy is to use AI to knit together health data, both from its devices and third party sources, to provide highly individualized care. The aim is to use integrate data both from its devices and third party sources, using AI, to find precise insights about the individual patient. This, GE hopes, will both improve clinical outcomes, and to improve productivity, thereby helping the both the patient and the provider.

"This is a critical enabler over the next 3 to 5 years," the CEO, Pete Arduini, said at an investor day in December. "We think this can be a transformative engine for us to grow."

[21] The other two are Philips and Siemens Healthineers

Some clinicians dislike AI

In the previous chapters we showed how AI-enabled medical devices are growing fast and how companies are planning to monetarize AI. It's important to realize however, that the path won't be completely smooth. Not all doctors welcome AI-enabled devices with open arms.

Uncertainties around legal liability

One issue revolves around legal liability, just as it does with self-driving cars. Who is liable if an AI product advises on a certain cause of action, the doctors follow that advice, and it all turns out badly?

"Trouble is, it's not clear who'd be held liable if the recommendation isn't accurate – the AI, the data scientists, or the physician," says Morgann Carlon, a Health AI leader at Deloitte. "Plenty of hospitals are not implementing all the AI they could be, because their legal teams are worried."

Case Study: AI could help triage dermatology patients in Britain . . .

We see quite a lot of evidence that many clinicians don't warm to AI.

Dr Clare Gerada is President of the Royal College of General Practitioners, the professional body for primary care doctors in the UK,[22] and she says clinicians are often the issue.

"Many doctors, fuelled by media reports, are reluctant to embrace digital solutions," she told us. "They're harking back to an idealized past where doctors were supposed to be ever-present and to provide hands-on care. . . . . The only way we're going address our future health care is by using technologies such as digital consultations, AI and wearables."

Dr Wood of Vida agrees. She told us that even in imaging, many radiologists still want to work in the way they're gotten used to. "To really optimize the value of AI you must disrupt the workflows and drive higher quality and efficiencies," she says. "But physicians, in general, are slow to change."

One example of this can be seen in practice in dermatology in the National Health Service in England. As in many countries, the health system there is currently under severe stress. This author of this report is writing from Canary Wharf in London, where the nearest hospital says the waiting time for a dermatology appointment is "up to 45 weeks for 9/10 patients", except where cancer is suspected.

[22] In Commonwealth countries, primary care doctors are known as General Practitioners (or GPs). The RCGP, which has 55,000 members, sets the training, professional standards and the postgraduate licencing exam that newly qualified GPs must pass.

A start-up called **Skin Analytics** has created an AI-driven device, called Derm, which analyzes photos of the skin, recognizing the most common malignant, pre-malignant, and benign skin lesions. The aim is to instantly triage patients, save doctors' time and send patients to the right place within the health system. Derm won an NHS award for "AI in Health and Care" in 2021 and has received regulatory approval.

. . . but the professional body is discouraging

One therefore might expect Derm to have been rolled out rapidly around the various providers that make up the NHS.

However, the relevant professional body -- the British Association of Dermatologists (or BAD) -- is anything but supportive. Its position paper on AI says: "[T]he current evidence-base for effectiveness of AI interventions in dermatology is weak. It does not improve patient care by enhancing the patient experience without compromising safety." [23]

Figure 18. Skin Analytics uses AI applied to photographs of the skin

Source: Skin Analytics

BAD has stated that if Derm suggests a patient should be discharged, that decision should be reviewed by a consultant. BAD goes on to say: "Any doctor knowingly diagnosing and treating these skin cancer patients **must** be employed by their NHS hospital and be a core member of the skin MDT."[24] From their point of view, Skin Analytics points out that they pay for these extra consultants, and that in practice they overturn about a third of the AI discharges, but in the last six months none of these has led to a diagnosis of cancer.

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[23] Source: https://www.bad.org.uk/clinical-services/artificial-intelligence/

[24] https://www.bad.org.uk/clarification-on-the-challenge-to-the-bad-2ww-letter-and-use-of-ai/. The word **must** is in bold in the in the original. MDT = multi-disciplinary team.

Against a backdrop of the current UK crisis in dermatology treatment[25] this is an example of the difficulties that AI technologies can still face in changing the views and practices of established authorities.

Skin Analytics' CEO is Neil Daly: "We're committed to helping patients navigate the dermatology outpatient crisis in the UK," he told us. "We are supported by the NHS but unfortunately we're being held up by old institutions that have proven time and again that they want to resist innovation."

Despite this, he is optimistic about the future: "There is momentum building, so I'm confident that you'll see services like ours becoming mainstream very soon."

[25] https://www.independent.co.uk/independentpremium/long-reads/dermatology-skin-rash-diganosis-doctors-b1835080.html

MedTech companies now prefer to launch innovative products in the U.S. than Europe

Survey results (e.g. from BCG/ UCL) and feedback from the medical device companies we've spoken suggest an overwhelming preference to launch products in the U.S., rather than the EU.

This is a complete turnaround from the early 2000s, however. Back then MedTech companies generally launched their products in Europe several years before they launched in the U.S., because it was easier to get regulatory approval there. In 2010 a Stanford University study concluded that "unpredictable, inefficient, and expensive regulatory processes put the U.S. at risk of losing its global leadership position in medtech innovation."[26]

It appears that in the U.S., the most important barrier to the use of new types of medical devices now revolves around "reimbursement" rather than "approval".

Substantial reforms have made the FDA much more innovation-friendly

Since then, however, there have been a series of reforms in the U.S. – set out in Figure 19 – that have made it much easier to obtain approval for innovative products, especially digital products.

Figure 19. Selected FDA actions to encourage innovation in devices

2007	Medical Device User Fee Act enabled the FDA to **allocate more staff to regulating medical devices**
2012	FDA Safety and Innovation Act let the FDA launch **a risk-based regulatory framework for software and mobile apps**
2015	The FDA created **Breakthrough Device** pathway to quicken approvals for devices likely to provide significantly better care
2016	21st Century Cures Act clarified the definition and rules around ***Software as a Medical Device***
2017	The FDA launched **its Digital Health Innovation plan**.
2020	The FDA opened the **Digital Health Center of Excellence** to focus on regulating digital health products.

Source: FDA

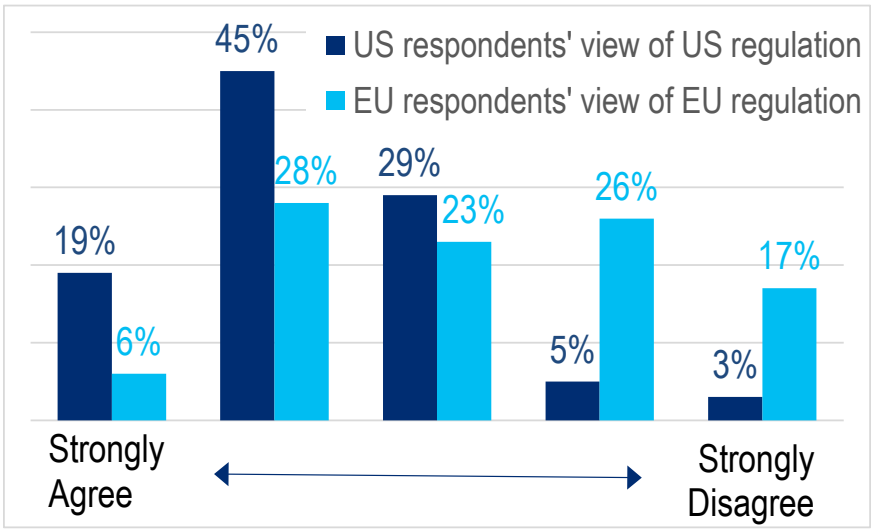
In the EU, by contrast to the U.S., regulation has got a lot more restrictive as a results of the new Medical Device Regulation (or MDR). This is four times as long as the rulebook it replaced. Furthermore, the EU now requires more extensive clinical trials for more products. As a result few MedTech companies want to launch innovative products there.

Figure 20 shows that 64% of U.S. respondents to a BCG/ UCL survey agree that the FDA has responded well to the growth of digital medical devices, whereas only 34% of European respondents would say the same about the EU. Almost a quarter of firms that already have EU approvals for products say that in future they will launch in China or Japan before they launch in Europe.

[26] FDA impact on US medtech innovation

64% of U.S. respondents agree that the FDA has responded well to the growth of digital medical devices, whereas only 34% of EU respondents would say the same about the European regulatory authorities.

Figure 20. Assessment of whether US and EU regulators have responded well to digital technology

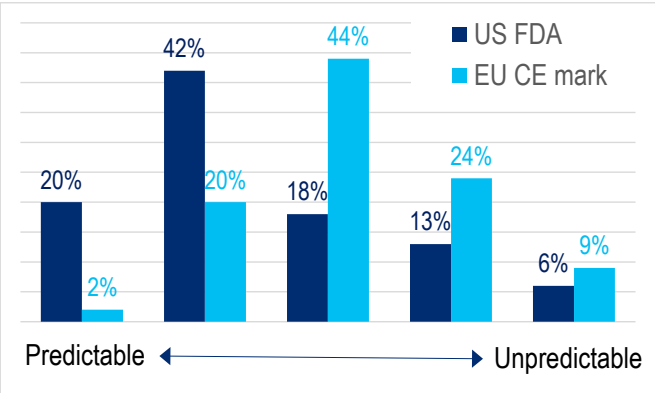


Source: BCG and UCLA Biodesign

Now MedTech companies "overwhelmingly view [the] new MDR rules as complex and unpredictable, making it less appealing to develop and launch novel products in Europe," according to the UCLA/ BCG report. "Nearly half the products in our survey had been launched in EU markets; but 89% of companies sponsoring these products say they will prioritize US regulatory approval going forward. In fact, 23% of respondents with successful CE mark products say [that in future] they will pursue Japanese and Chinese registration prior to EU clearance."

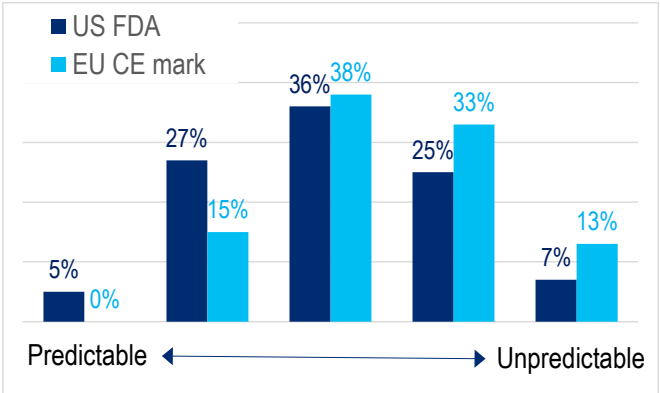
Figure 21 shows how the MedTech companies now prefer FDA to EU regulation for traditional devices, with 62% of respondents saying U.S. regulation is either very or quite predictable, vs only 22% saying the same for the new EU regulation.

Figure 21. Predictability of U.S. and EU regulatory pathways - traditional medical devices



Source: BCG and UCLA Biodesign

Figure 22. Predictability of U.S. and EU regulatory pathways - software devices



Source: BCG and UCLA Biodesign

When it comes to software products, however, even the U.S. isn't considered that good – with only 32% of respondents saying FDA regulation is very or quite predictable. This is still better than the EU though: only 15% of respondents say the same about the CE mark.

And the limiting factor has become reimbursement

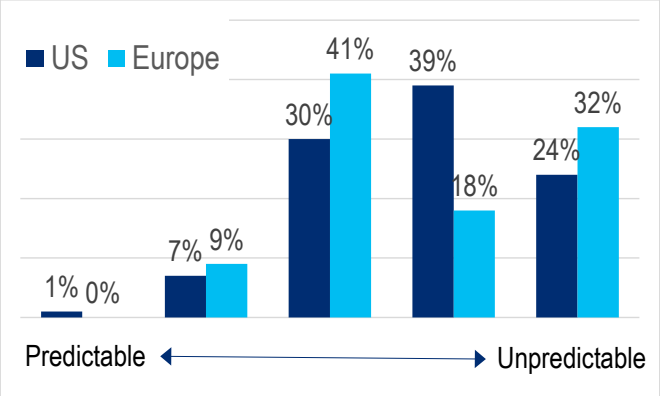
One of the most important factors limiting innovation of AI-driven devices – if not *the* most important factor – is now around reimbursement.

The FDA and its equivalent overseas may approve an AI-enabled device, but hospitals will buy it only if they believe payers – most importantly the CMS – will reimburse its use. And companies find it extremely hard to predict in advance whether hospitals will get reimbursed for using new digital medical devices, both in the U.S. and in Europe, as Figure 23 shows.

Companies find it very hard to predict whether a digital product will be reimbursed, and this is limiting the development of novel medical devices

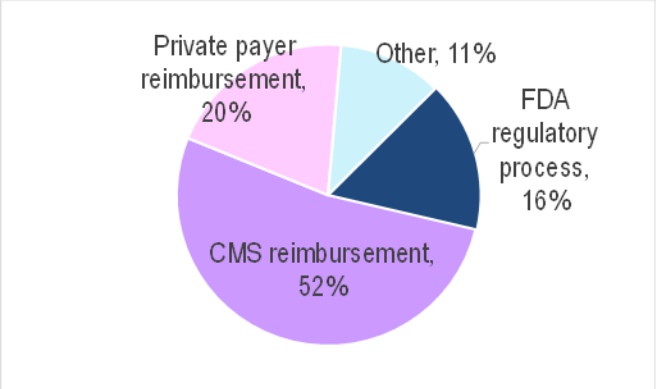
In the U.S., reimbursement rather than approval appears to have become the most important barrier to the use of new types of medical devices. Figure 24 shows that 72% of the respondents to the survey said the primary barrier is now reimbursement; only 16% said it is FDA regulation.

Figure 23. Predictability of Reimbursement for Digital Devices



Source: BCG and UCLA Biobank

Figure 24. Barriers preventing patients accessing novel medical devices in the U.S.



Source: BCG and UCLA Biobank

The obvious solution would be for greater coordination between the regulatory approval and reimbursement agencies. The UK has said it is exploring this idea, but it doesn't appear to be on the agenda elsewhere.

The FDA would like to implement a radical change to regulating software . . .

Interestingly, the FDA has said it wants to go much further to help regulate new types of digital devices, especially algorithms that change over time, by introducing a completely new sort of regulatory pathway.

Although the 21st Century Cures Act helped cement the idea of *Software as a Medical Device,* the law wasn't written with modern AI in mind. It states that if the software or algorithms in a medical device change significantly, it requires a new approval. The FDA *has* been able to approve products where the algorithm is

locked, under the 21st Century Cures Act, because a locked algorithm applies a fixed set of rules to data, and therefore a regulator can assess it.

By contrast an adaptive algorithm changes the rules that the device follows in the light of new evidence, which means a regulator needs to find a way of working out in advance whether the changed product will remain safe and effective.

The FDA's Digital Health Innovation plan – which came out a year after the 21st Century Cures Act -- included a section on regulating adaptive algorithms. Specifically the *Software Pre-Certification (Pre-Cert) Pilot Program* contained a totally new approach to regulating software, and in particular changing algorithms: It examines how software is developed, rather than the particular instance of it. The FDA calls this a Total Product Life Cycle (or TPLC) approach, and it explained it as follows:

> In the Pre-Cert TPLC approach, [the] FDA [would] assess the culture of quality and organizational excellence of a particular company and have reasonable assurance of the high quality of their software development, testing, and performance monitoring of their products. This approach would provide reasonable assurance of safety and effectiveness throughout the lifecycle of the organization and products so that patients, caregivers, healthcare professionals, and other users have assurance of the safety and quality of those products.[27]

. . . but it won't be implemented unless the underlying law changes

However, the FDA concluded in September last year that this new TPLC approach "is not practical to implement under our current statutory and regulatory authorities."[28]

It therefore appears that the FDA won't go ahead with the TPLC approach, unless Congress changes the law around Software as a Medical Device. "Appropriate new legislative authority would be necessary to support the development and implementation of a new regulatory paradigm," the FDA concluded.

In simple terms this means that under the law as it stands today, the FDA will be able to go on approving locked algorithms, but not many adaptive ones.

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[27] FDA 2021: Proposed Regulatory Framework for Modifications to AI SaMD - Discussion paper

[28] FDA 2022: Pre Pilot Program -- TPLC approaches and key findings

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