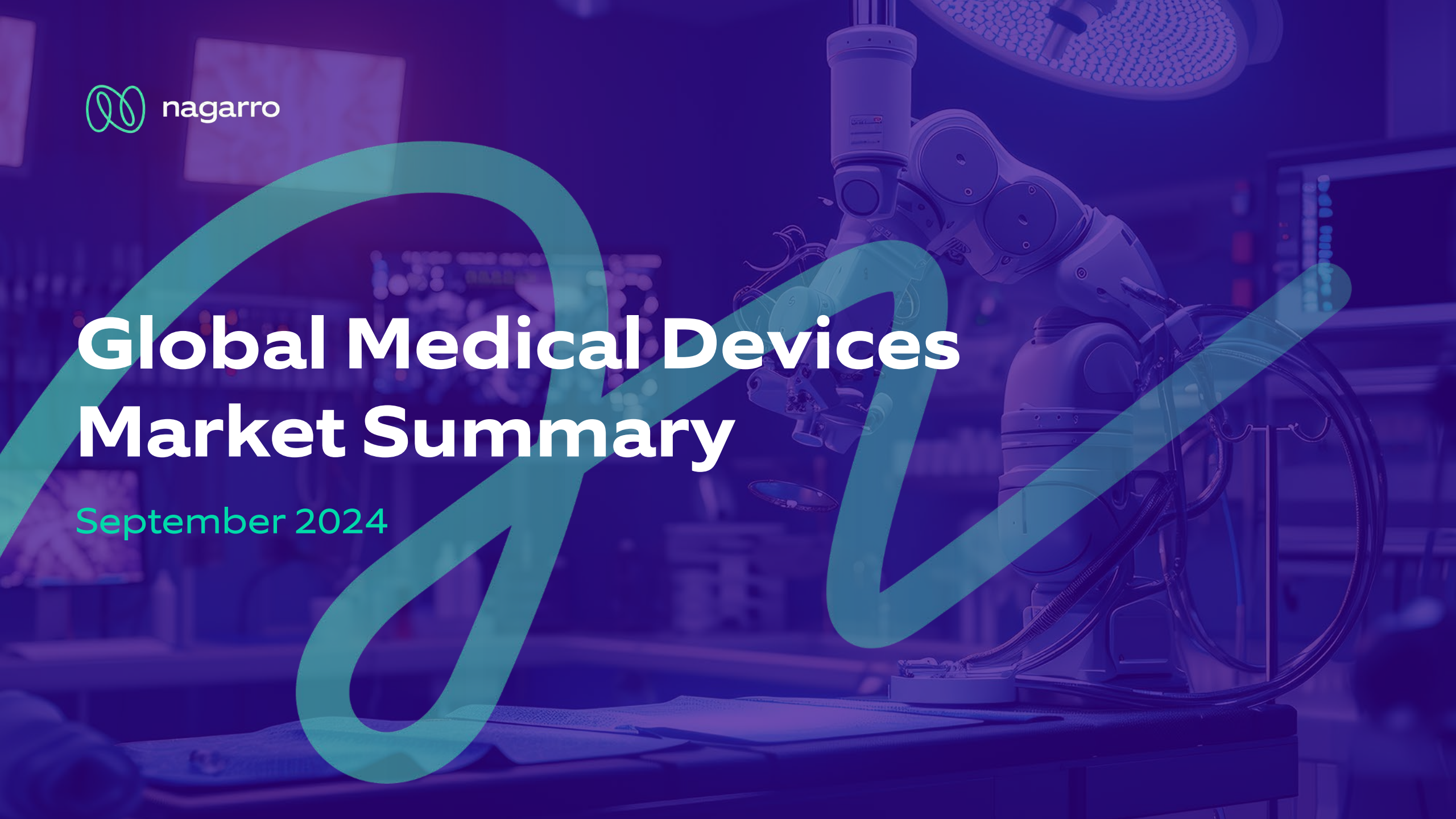


nagarro

Global Medical Devices Market Summary

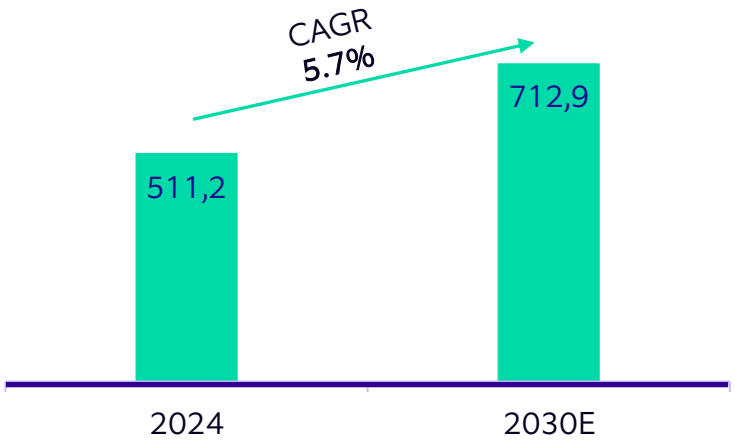
September 2024

Table of contents

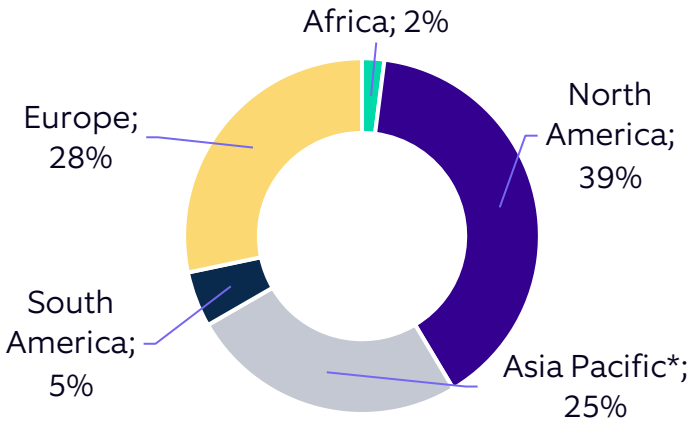
1. Market overview

Summary: Global medical devices market is expected to reach $712.9 bn by 2030

Global medical device market[4] ($ bn)



Regional market share[1] (2024)



Key industry insights

- Patients are increasingly demanding convenience, accuracy, and an overall smoother experience from the healthcare system;[2]
- Medical devices are becoming smarter, more AI-driven and more interconnected, enabling earlier diagnosis and enhancing communication between doctor and patient;[1]
- Medical device companies are prioritizing protection against cyber-attacks, security backups and sustainability initiatives to improve general community safety;[2]
- Popularity of digital therapeutics (software-based medical devices) skyrocketed during the pandemic and shows no signs of slowing down.[3]

Market drivers[2,5]

Technological advancements

Rise in geriatric population

Increased R&D investment by MedTech companies

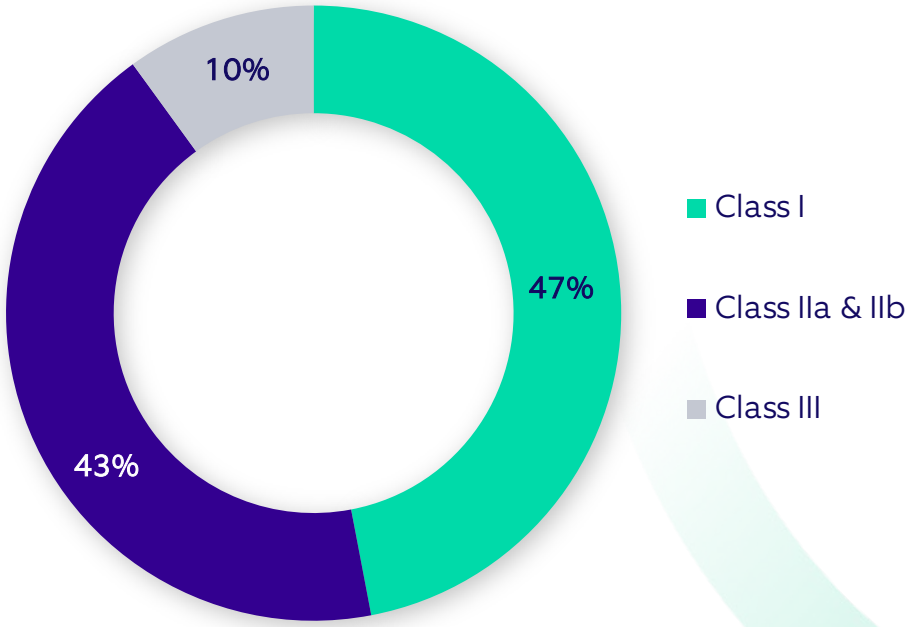
Market restraints[1]

Regulatory approvals & stringent barriers

* Middle East countries are included in Asia Pacific

Summary: Class I medical devices accounts for majority of the market share

% of device presence in the US[2] (as classified by the FDA)



In-vitro diagnostics (IVD) is the largest segment in 2024, with 19.3% share of the global market[5].

In-vitro diagnostics market is valued at $98.97 bn in 2024, and is expected to grow at a CAGR of 2.72%[5].

In-vitro diagnostics market is set to grow rapidly with the rise of remote patient monitoring systems enabling diagnosis outside traditional healthcare[4].

Neurology is expected to be the fastest-growing device specialty[1].

Increasing prevalence of cardiovascular diseases has boosted the use of medical devices in hospitals and clinics worldwide[4].

1.1 Driver: Technological advancements are driving the medical devices industry

Connected health solutions[2]

Technological advancements in medical devices are enabling real-time monitoring, data collection, and analysis, allowing healthcare professionals to make informed decisions promptly.

Personalized healthcare[2]

Devices can now gather patient-specific data to customize treatment approaches, leading to improved outcomes and patient satisfaction.

Minimally invasive innovations[2]

Robotic-assisted surgeries, micro-scale implants, and advanced imaging techniques are enhancing precision and reducing patient recovery times.

AI & ML integration[4]

AI and ML are being applied in medical devices to improve diagnostic accuracy, enhance patient outcomes, and streamline clinical workflows.

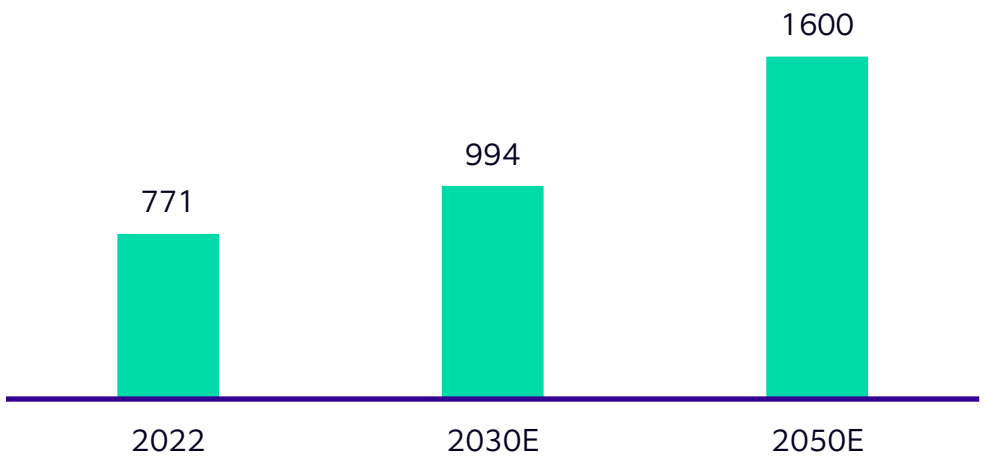
IoMT adoption: 43% of MedTech businesses use data to inform business choices[1].

AI adoption: 69% of healthcare organizations are testing or adopting AI[1].

Technological advancements are driving innovation and growth in the medical device industry, leading to improved patient outcomes, enhanced healthcare delivery, and increased efficiency in medical device development and manufacturing[2,3].

1.2 Driver: Rising geriatric population is a key driving factor for the growth of the medical devices market

Persons aged 65 or over[1] (mn)



As per UN World Population Prospects Report 2022, the geriatric population is expected to reach **1.6 bn by 2050**, which can be around **16%** of the total world population[1].

Key benefits[2,3]

There is a positive association between elderly individuals and an increase in the incidence of disorders such as cardiovascular, neurological, and orthopedic conditions.

Aging population represents a crucial market for the medical devices industry, driven by the increasing need for advanced home care solutions tailored to the elderly.

Significant investments by market players in improving elderly care devices are expected to bolster market growth. These investments are channeled into innovative startups dedicated to enhancing care for the elderly.

Advancements in medical device technology have resulted in a significant increase in the number of conditions that can be managed in a home care setting, providing opportunities for market expansion.

Aging population worldwide is leading to an increased demand for healthcare services and medical devices, particularly for chronic disease management[2].

1.3 Restraint: Regulatory barriers and stringent approval processes pose significant challenges in the market

Medical devices are subject to various regulatory standards from multiple entities and agencies such as:

- **FDA Regulations**: FDA now requires a comprehensive software bill of materials (SBOM) and minimum cybersecurity standards for connected medical devices[1];
- **EU Regulations**: EU's new legislation for medical and in-vitro diagnostic devices includes stricter safety requirements and a longer recertification process[2].

Medical device companies must navigate multiple regulatory bodies and jurisdictions, which can be complex and time-consuming[4].

Pre-Market Approval[1] (PMA)

Devices classified as Class III, which pose a high risk to patients, require a more involved and costly approval process, involving rigorous testing and review.

Manufacturing[1]

Manufacturers must demonstrate substantial equivalence to an already cleared or approved device, which can be a lengthy and costly process.

Clinical trial[1]

Devices requiring clinical trials must obtain an investigational device exemption (IDE) and conduct trials to demonstrate safety and effectiveness.

Development process[2]

Manufacturers must follow formal development processes, documenting user needs, design inputs & validation to ensure device safety & effectiveness.

Post-market surveillance[2,4]

Devices must be monitored for post - market cybersecurity threats and comply with regulatory requirements for ongoing maintenance and updates.

2. Industry challenges

Summary: Challenges faced by the global medical devices industry

1

Regulatory hurdles

Stringent regulations that differ from country to country, also includes IPR and counterfeiting issues.

2

Pricing and distribution

Complex factors lead to difficulties in pricing and further add uncertainty for distributor agreements regarding margins.

3

Supply disruptions

Essential electronic components and specific materials are highly vulnerable to supply side shocks.

4

Changing customer needs

Consumers ask for more personalized and customized medical devices on an on-demand basis.

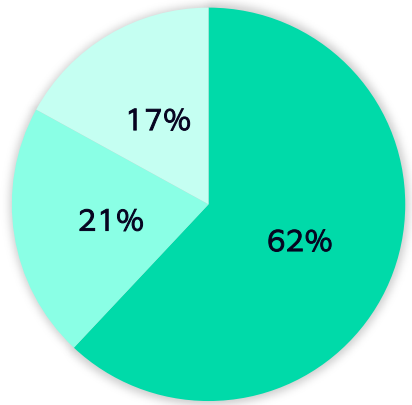
5

Competition in industry

Big players in the industry often look to expand their market share in diverse geographies, making entry difficult.

2.1 Differing regulatory compliances across geographies present a big hurdle to manufacturers and distributors

Existence of National Regulatory Authorities (NRA)



Regulatory frameworks across the world

% of countries with a legal framework for medical devices is **highest in the European region (91%)** and **lowest in the African region (32%).**

EU and **FDA** have different **risk classifications** for devices, which **increases approval times** and **compliance costs**, especially for **global players** looking to diversify into new countries.

Countries having no legal framework for medical devices often pose **risky markets for big players** due to **no assistance from local governments** against any possible compliance issues.

Counterfeiting remains a big problem in lower-income countries where local-made (often inferior) devices are sold off under a brand name for a premium price.

e.g. In India, counterfeit oximeters were being sold in Kolkata by a local manufacturer due to poor implementation of Medical Devices Rules 2019 and IPR regime.

- Low-income countries are not attractive markets due to a lack of regulatory frameworks, substantially **lower purchasing power,** and **counterfeiting** of devices;
- High-income countries continue to be high-revenue geographies with the **EU and North America** dominating the global revenue share for devices;
- **IPRs** and **enforcement** for medical devices are stringent in the developed world which makes them safer markets for patented devices.

2.2 Downward pricing pressure on players coupled with rising costs presents a difficult scenario

Demand for cost effective solutions

Hospitals and healthcare facilities want lower-priced solutions due to patients' concerns about rising out-of-pocket expenditures.

High manufacturer costs

Steadily climbing costs to producers due to R&D, commitment to advanced technology, quality assurance, and regulatory compliance costs.

Reimbursement prices[2]

Downward pricing pressures due to the reduction in reimbursement prices, which decrease willingness to pay.

Negotiating power of providers

Group Purchasing Organizations (GPOs) and purchase price consultation services have led to reduced prices in market.

Price in the market faces downward pressures while costs to manufacturers have increased in the past decade

Margin squeeze trap[1]

(Difficulties setting appropriate margins with distributors)

2.3 Supply chains tend to be vulnerable to many shocks with large impacts due to larger interdependencies

Material supply

Critical raw materials (e.g. titanium) have become scarce due to **energy crises**, **geopolitical volatility**, and **overdependence** on specific locations for supply. Semiconductor chip shortages still pose a big threat.

Labor trends

A large challenge of high demand and **low supply of skilled technicians.** The industry also struggles to keep **hybrid working opportunities** available which are demanded by the workforce.

Inventory systems

Systems like **JIT, Lean, and Six Sigma** have been overleveraged by the industry to such an extent that there are increased risks of **stockouts** and **disruptions** due to the inability to absorb a risk event.

Trade and transport

Government-imposed **trade restrictions** and **logistical challenges**, compounded by natural disasters or geopolitical events hinder the timely movement within the **upstream** and **downstream** supply chains.

Supplier issues

The inorganic growth of companies has led to a **narrower supplier base** due to companies trying to leverage their spending, while new suppliers take a long time to enter the equation due to **high qualifying regulations**.

High degree of global interdependencies

Complexities within the supply chain

Greater risks and larger impact of supply shocks

2.4 Rapidly changing consumer needs necessitates innovation in products and processes by the players

Changing consumer trends

- **User-friendly devices:** More and more consumers especially patients with chronic diseases are demanding ease-of-use monitoring devices to avoid visiting the physician as much as possible.
- **Proactive users:** Patients are actively involved with healthcare providers in decision-making and tend to ask for the latest device/technology for treatment.
- **Digital integration:** A common digital platform for integrating many devices is a recurring demand, especially after the trend of wearable monitoring devices (smartwatches).

Evolving physician needs

Interoperability

Physicians want most of their devices to seamlessly integrate together to avoid data transfer issues.

Digitalization

Use of Digital platforms and records to support day to day works of clinicians.

Reliability

More accurate and consistent diagnosis using emerging applications of AI and cloud diagnosis.

Data security

Increased risks of cyber attacks and liabilities arising due to technology-related medical errors.

More specialized and personalized medical devices lead to greater demand for low-volume production, which has inspired a shift toward on-demand production. This can lead to greater inefficiencies for manufacturers.

2.5 Presence of established players in the global markets presents to be a significant barrier to entry

Major players in the industry

Medtronic, Siemens Healthineers, Philips Healthcare, GE HealthCare, CardinalHealth, Johnson&Johnson MedTech, Medline, Stryker, Baxter, Abbott

High barriers to entry for new firms due to regulatory compliance requirements and medical efficacy standards.

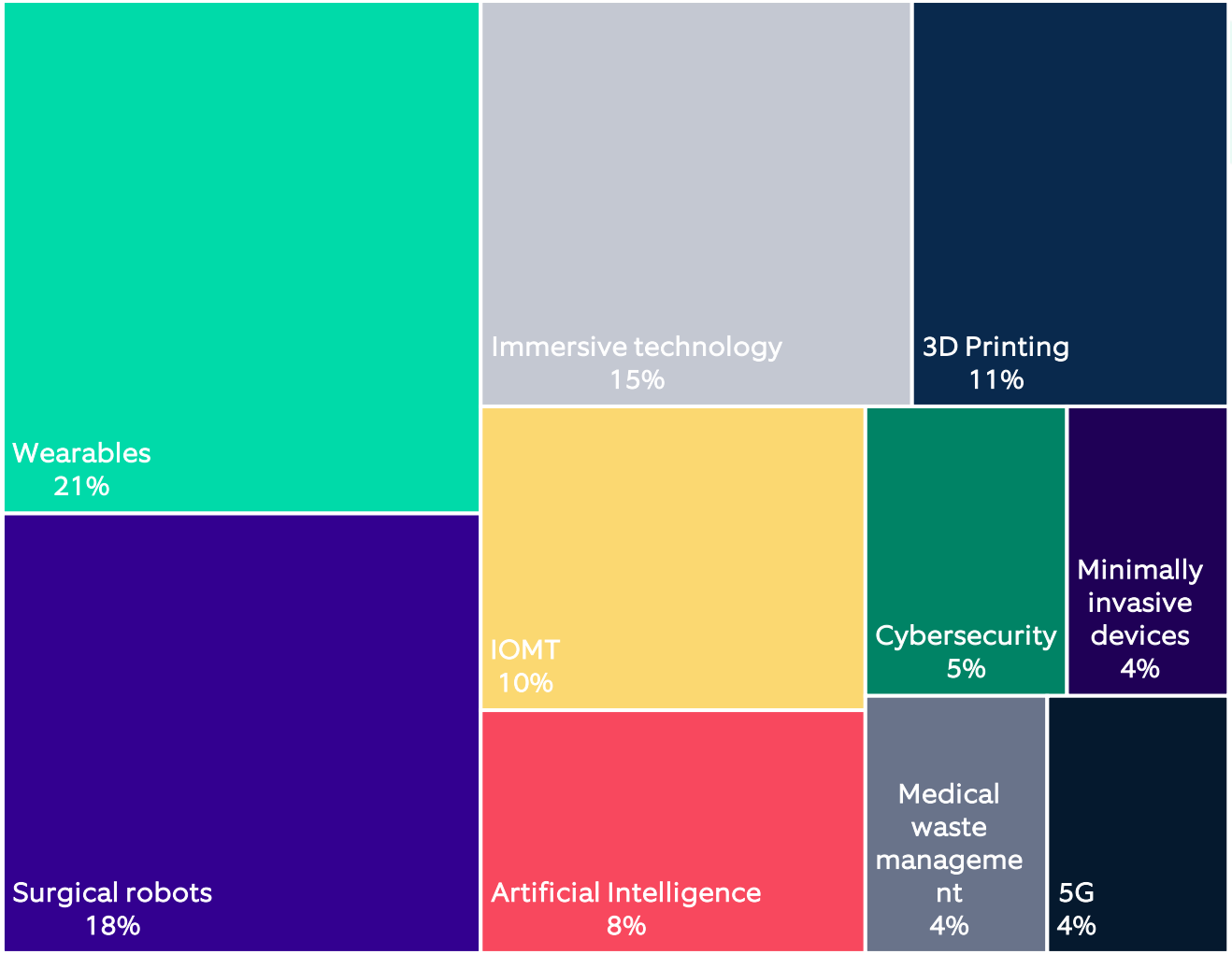
Longer life devices are already established in renowned facilities, thus curbing demand for new devices.

Major hospitals may have long term contracts with the big players, thus decreasing incentive to switch providers.

Large players operate in high-revenue **established markets** in the EU and North America and control a high market share. They also look for **opportunities in emerging markets** due to higher growth trends.

3. Industry trends

Summary: Innovation trends transforming the global medical devices industry



Wearables and surgical robotics are driving the innovation trends followed by other trends.

Technological innovations, such as robotic-assisted surgery and minimally invasive techniques, enhance surgical precision, shorten recovery times, and improve patient outcomes.

Wearable medical devices, such as smart watches and wearable sensors, are empowering individuals to proactively manage their health by continuously monitoring vital signs and health parameters outside clinical settings.

3.1 Wearable technologies are growing due to chronic diseases, aging population, home healthcare, and remote monitoring

$40.7 Market size in 2023

11.2% Poised to be CAGR

Factors affecting wearables market

Ease of use and convenience: These are user-friendly, enabling patients to monitor their health at home, reducing hospital visits, and improving patient outcomes.

Real-time data & increased awareness: They offer real-time data, helping healthcare professionals track patient health and make decisions. They promote continuous vital sign monitoring, increasing the adoption.

Growing demand for RPM & focus on preventive care: Adoption of wearable devices for remote patient monitoring has increased, offering a convenient, effective way to track health and play a key role in preventive care and chronic disease management.

Medtronic + BioIntelliSense	Partnered to monitor US hospitals for 30-day post-acute hospital-to-home distribution rights of the BioButton multi-parameter wearable for continuous monitoring.
Abbott	Announced the development of a new consumer bio wearable, Lingo, designed to detect critical body signals like ketones, glucose, and lactate, helping people better understand their general health and take necessary action.
Medtronic + fitbit	Fitbit partnered with Medtronic to develop a wearable device that tracks vital signs and can detect irregular heart rhythms.
+ Google	Apple and Google collaborated to innovate healthcare by integrating medical devices with tech products, digitizing the system, and incorporating wearable health monitors.

There has been substantial growth in the home healthcare market, driven primarily by the expanding geriatric population, a growing incidence of chronic diseases, and the accessibility of advanced medical devices, including wearable medical devices.

3.2 Surgical robotics transforming minimally invasive surgeries and enhancing precision in medical devices

$18 bn
market size and estimated to grow $83 bn by 2032

78%
of the surgeons in the U.S. are interested in surgical robotics

4.8 mn
estimated laparoscopic procedures will be performed globally using robots by 2032

56%
of all laparoscopic procedures in the U.S. will be robot-assisted by 2032

Key advantages

- Enhanced surgical precision;
- 3-D images aid visualization;
- Minimally invasive surgeries improve outcomes;
- Long-term benefits like tissue preservation;
- Robotic systems enable novel techniques.

Top players

INTUITIVE, stryker, ZIMMER BIOMET, Medtronic, SmithNephew, Johnson&Johnson, THINK SURGICAL

Recent approvals

Mar, 2024 Intuitive gains FDA clearance for 5th generation of da Vinci Robotic System, da Vinci 5 introduces numerous enhancements aimed at improving surgical precision, workflow efficiency, and overall user experience.

Feb, 2024 Virtual Incision gains the de novo clearance from the FDA for its MIRA surgical robot, in the development of miniaturized robotic-assisted surgery (miniRAS) devices.

Feb, 2024 Zimmer Biomet gets FDA clearance for ROSA Shoulder system, marking it as the world's first robotic-assisted surgery system for shoulder replacement.

Aug, 2023 Levita Magnetics gained FDA clearance for its MARS platform aimed at abdominal surgery, a first-of-its-kind minimally invasive surgical platform that combines magnets and machines.

Driven by the advantages of robotic minimally invasive surgery, including greater accuracy, repeatability, and efficiency, the surgical device market looks promising in the future outlook of the medical device industry.

3.3 Immersive technologies are revolutionizing the medical devices industry

Applications

Medical education and training

MASSACHUSETTS GENERAL HOSPITAL

MGH's Department of Orthopedic Surgery uses a system called PrecisionOS to train medical students and allows them to develop the essential motor skills they'll need in the operating room through safe, simulated practice.

AR surgical navigation

Johnson & Johnson

Johnson & Johnson has developed an AR-based surgical navigation system that uses an optical see-through head-mounted display (HMD) to provide real-time guidance and visualization to surgeons during procedures.

Pain management

St. Jude Children's Research Hospital

St. Jude Research Hospital implemented EaseVRx, a VR platform, to help patients manage chronic pain without opioids. solution offers immersive games, relaxing environments, and educational tools. After six months, pain scores were reduced by 50%.

Overcoming mental health disorders

XRHealth

XRHealth developed a virtual clinic for mental health treatment. Patients receive treatment at home through VR headsets. Solution helps with stress reduction, psychosis, depression, helps in effective drug-free therapy.

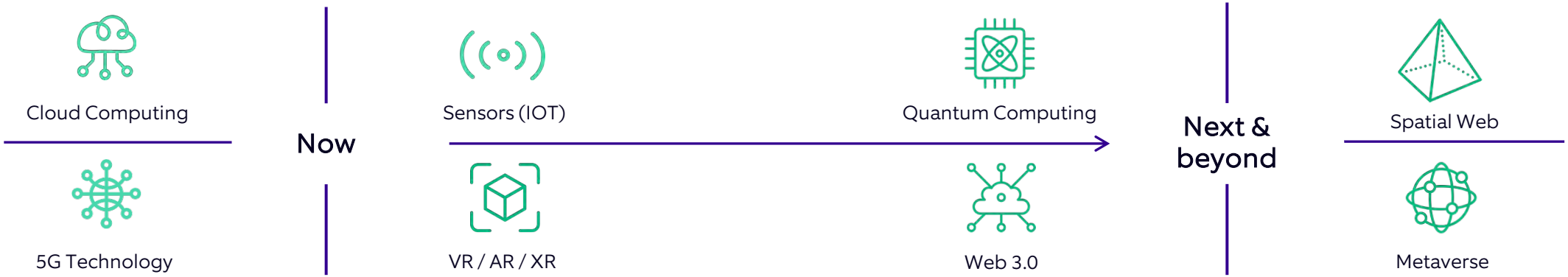
3D body mapping

Spencer Hospital
Healthier Together.

Iowa Spencer Hospital implemented an AR solution using SLAM technology. By directing a smartphone at the patient's body, doctors could virtually map organs and tumors. This approach increased biopsy success rates by 50%.

AR and VR have the potential to revolutionize the healthcare industry by providing immersive and realistic experiences to deliver new types of treatments and diagnostics.

3.4 Intelligent health ecosystem



PHILIPS

Philips' Capsule Medical Device Information Platform connects medical devices and EMRs in hospitals through a vendor-neutral system. It enables easy device integration, vital signs monitoring, and clinical surveillance, allowing caregivers to access patient data and respond to high-risk events more quickly.

Honeywell

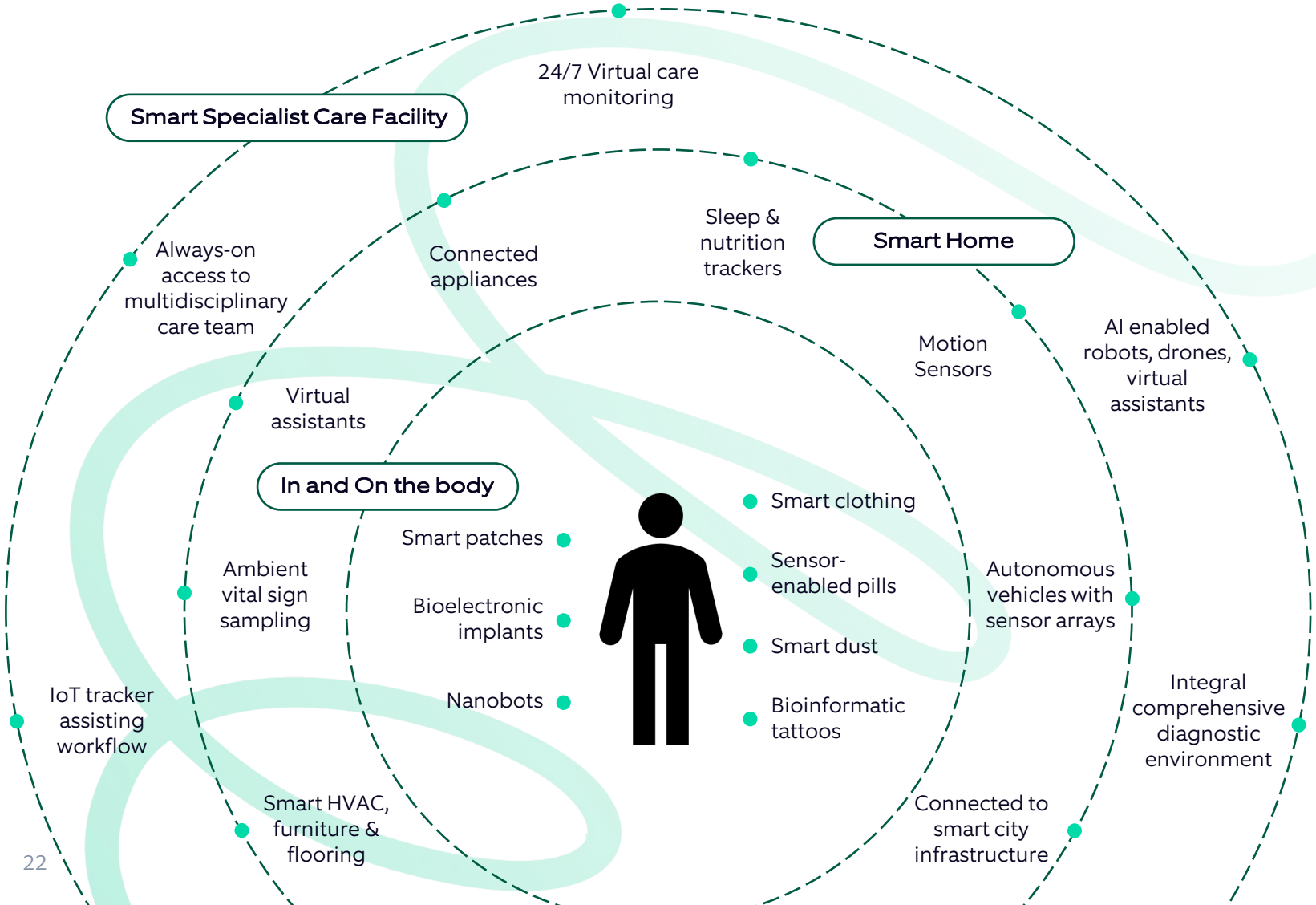
Honeywell's Genesis Touch connects patients with remote care providers via a dashboard that receives biometric data. It supports video visits, allows multiple providers to access vital statistics, and integrates with an oximeter, blood pressure monitor, and precision health scale.

aeris

Offers a platform for manufacturers and healthcare providers to monitor patients' compliance with medical advice. Sensor-based monitoring allows patients to stay at home, reducing travel time and hospital costs. For healthcare providers, it enables frequent assessments, timely treatments, and transparent compliance, aiding insurance reimbursements.

Smart health system uses different digital health tools that can work together. It also uses big data and artificial intelligence to collect and analyze information. This helps in providing better support and care for people's health.

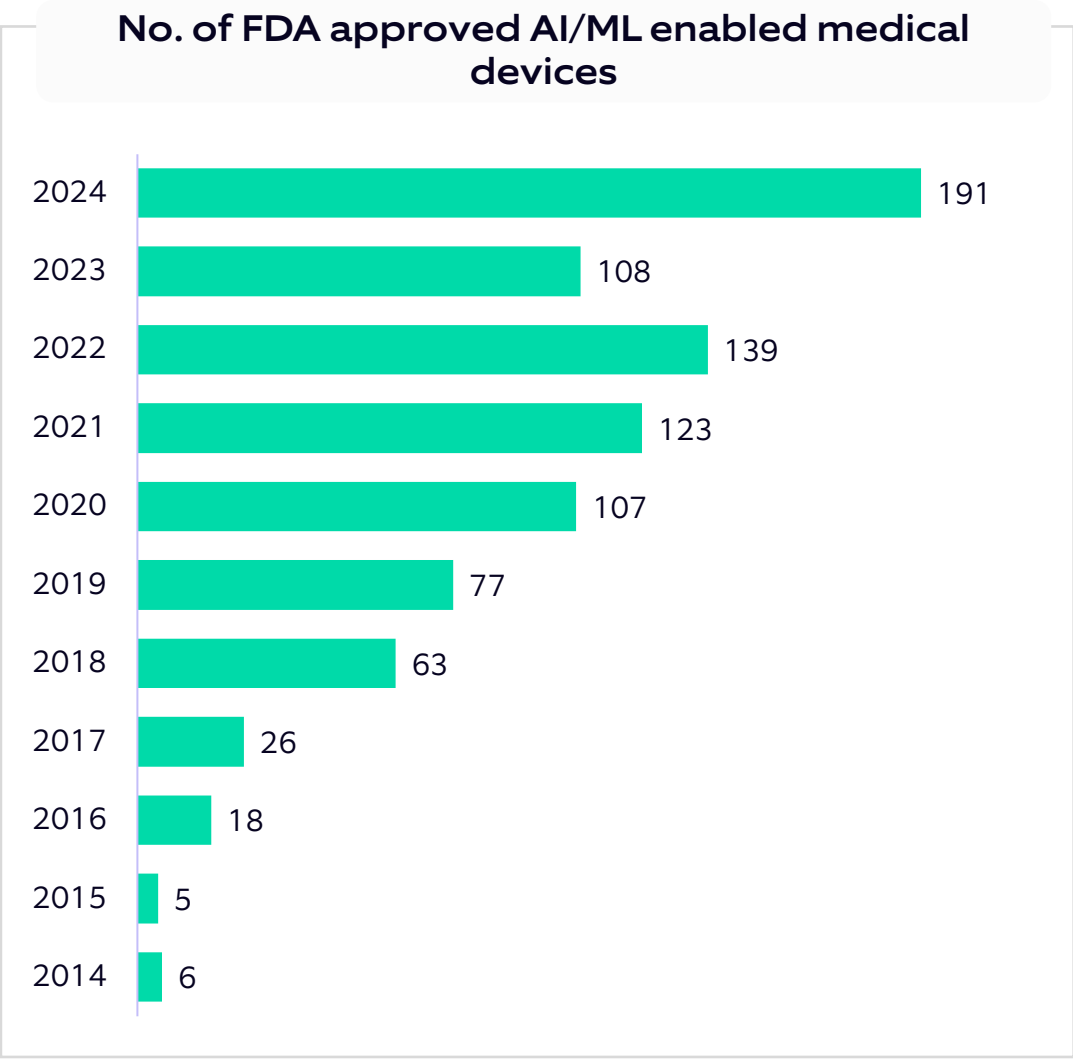
3.4 Advancements are creating a new Internet of Medical Things (IoMT) “inside” and “on” humans, resulting in IOMT “everywhere”



Benefits

- Enabling real-time data acquisition;
- Wireless data transmission to healthcare professionals;
- Personalized tracking and feedback;
- Remote monitoring reduces hospital visits, lowers costs, and provides timely interventions;
- Intelligent algorithms and data analytics enhance diagnostic accuracy;
- Improved communication between patients and service providers.

3.5 Rise of AI/ML enabled solutions



882

FDA approved AI/ML medical devices (as of May, 2024)

280%

Increase of FDA approved AI medical devices since 2018

76%

FDA-approved AI/ML-enabled medical devices belong to the radiology subspeciality

3.5 AI/ML enabled new innovations and M&A activity in the market

Although the broader MedTech sector M&A activity has declined since 2021, strategics continue to adopt & invest in AI-related healthcare technology.

LARSEN & TOUBRO

L&T Technology Services revealed a new partnership with chip maker NVIDIA to create software-defined architectures. Leveraging NVIDIA's Holoscan and IGX Orin platforms, the solution offers low-latency data transfer, superior image processing & scalability.

Smith+Nephe

Smith+Nephew announced a forthcoming new feature for its CORI◊ Surgical System, this exclusive image-agnostic robotic-assisted surgical solution is designed to help personalize surgery, advance efficiencies & optimize performance.

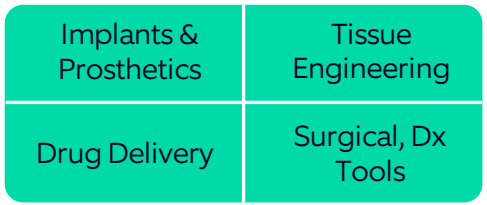
GE HealthCare

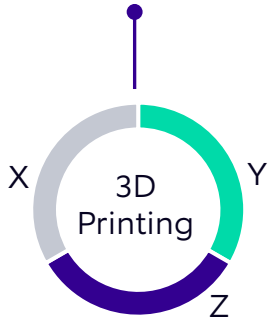
Precision DL, an innovative deep learning-based image processing software that is engineered to provide increased small, low-contrast lesion detectability compared to the conventional Time-of-Flight PET/CT scanner.

Target	Acquirer	Deal Value	Date	Deal Type
ScienceIO	Veradigm	$140 Mn	Feb, 2024	Acquisition
Volpara Health Technologies	Lunit	$194 Mn	Dec, 2023	Acquisition
Spectral AI; Spectral MD	-	$170 Mn	Apr, 2023	Merger
Envoy Medical	-	$150 Mn	Apr, 2023	Merger
Globus Medical; NuVasive	-	$3752 Mn	Feb, 2023	Merger

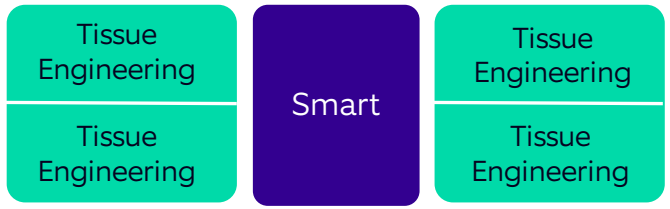
3.6 3D & 4D printing in medical devices industry

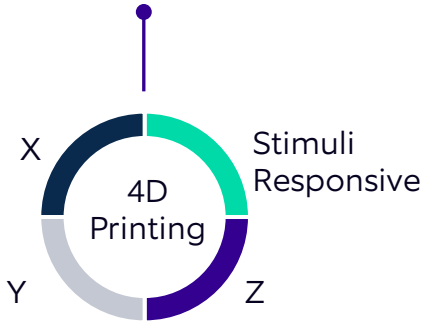
- 3D printing builds physical medical devices from digital designs;
- 4D printing goes a step further. It creates objects that can change shape or properties over time.





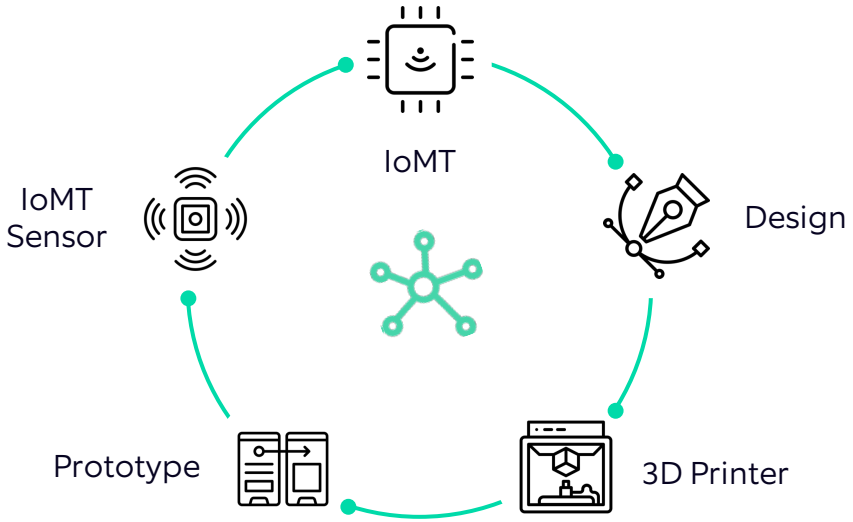
- Cost-effective;
- Design flexibility;
- Reduced waste;
- Rapid prototyping;
- Better functionality.





- High personalization;
- Self-morphing capacities;
- Incorporates stimuli-responsive materials, such as shape-memory polymers, hydrogels, and bio-inks;
- Less error-prone.

IoMT AND 3D printing interaction



Key benefits

- Improved patient outcomes through customized devices tailored to individual anatomy;
- Reduced costs and increased efficiency in the manufacturing process;
- Ability to create smart medical devices that can adapt to patient movements and provide better functionality;
- Potential for targeted drug delivery and improved bioavailability;
- Potential for tissue engineering and regenerative medicine applications.

3.7 Software-laden medical devices raise the cybersecurity and data breach vulnerability

Healthcare reported the highest costs for the 13th year in a row.	Healthcare data breach cost amounted to $10.93 mn in 2023.	Over the past three years, the average cost of a data breach in healthcare has grown by 53.3%.	Report from HIPAA Journal that 24 data breaches of 10,000 or more healthcare records were reported in January 2024.

Endpoint security and education: A centralized management portal for a comprehensive endpoint security solution is essential for reinforcing enterprise security.

Multi-factor authentication: Adopting multi-factor authentication enhances data sharing and protects patient data from unauthorized access and tampering.

Real-time analytics: Real-time analytics in medical devices is limited but can effectively prevent outsider attacks and detect internal threats.

Strategic partnerships: Medical device companies are partnering with tech firms to enhance offerings and protect against cyberattacks.

Cybersecurity regulations: Hacking risks for connected medical devices like infusion pumps & pacemakers have increased pressure for cybersecurity regulations.

March 13, 2024: FDA issued the draft guidance **Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act**, which proposes updated recommendations to the industry on cybersecurity considerations for cyber devices and provides recommendations for documentation in device premarket submissions.

November 15, 2023: FDA contracted with MITRE to develop the report, **Next Steps Toward Managing Legacy Medical Device Cybersecurity Risks,** the publication outlines practical approaches and recommendations that build on previous work and can further drive sector-wide legacy device cyber risk management efforts.

3.7 Partnerships in cybersecurity in medical devices industry

To ensure patient safety, the FDA demands robust cybersecurity in medical devices. Manufacturers must prioritize cybersecurity throughout development and lifecycle management to gain approval.

Tuttnauer + CHECK POINT

Check Point collaborated with Tuttnauer's T-Connect software, utilized in medical and laboratory sterilization devices, integrates Check Point Quantum IoT Nano Agent for embedded protection, safeguarding against evolving cyber threats and end-to-end security for patient data and device integrity.

CloudWave + FDA

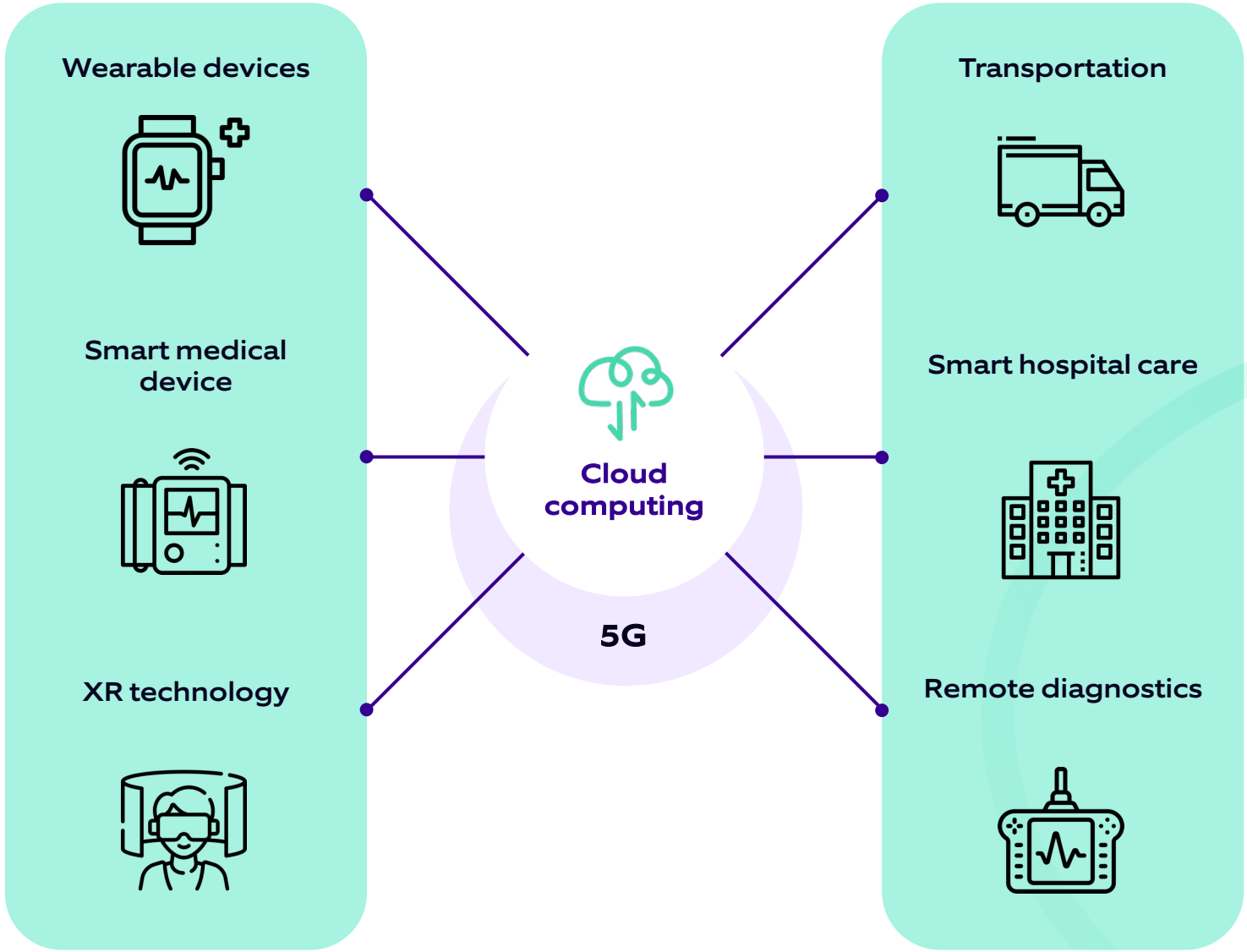
CloudWave, announced the renewal of its MOU with the United States Food and Drug Administration (FDA), to share critical threat intelligence in the case of nationwide suspected threats to medical device security and the integrity and security of the surrounding healthcare IT infrastructure.

medcrypt + STRATIGOS SECURITY

MedCrypt, Inc. announced its partnership with Stratigos Security to offer a suite of third-party assessment and advisory services, with specialized penetration tests for medical device makers to assure the safety and effectiveness of their devices.

New tech brings benefits, but also risks. Considering safety, security, and ethics when using AI, robotics, and wearables in medical devices has become significant.

3.8 5G is changing the medical devices landscape



Patient health monitoring using 5G

Management of preventing infectious diseases using 5G

Robotic surgery using 5G

5G in wearable technology

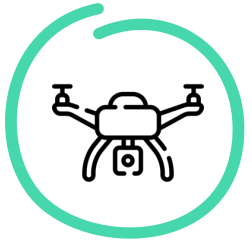
3.8 5G is at the forefront of this transformation, and its use cases in healthcare are already promising

Connected ambulances

Mobile tech (broadband & 5G) lets ambulances transmit real-time patient data. 5G slicing creates dedicated networks for ambulances on existing infrastructure.

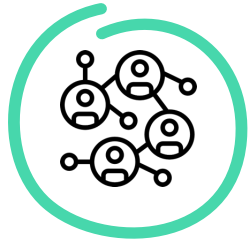
Remote collaborations

5G-enabled AR/VR headsets would let specialists directly guide remote procedures, ensuring patient data privacy with high-speed, private connections.



5G-Connected drones

They can be steered by a remote pilot, offering a swift and safe alternative. 5G-connected drones have the potential to transform the medical device industry by improving efficiency, safety, and access to care.



5G Private networks

Private 5G networks offer healthcare providers a secure and dedicated solution, meeting cybersecurity needs and ensuring reliable connectivity through network slicing.

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vodafone

In Milan, Italy, Vodafone has set up 5G-connected ambulances to facilitate real-time communication between paramedics, ambulance operators, trauma center coordinators, and hospital staff.

RODS & CONES

Rodes & Cones solution, the mirrOR KIT, allows medical device reps to attend surgeries remotely and provide technical support to surgeons.

WINGCOPTER

Wingcopter partnered with Vodafone, NUIG, Skytango, Survey Drones Ireland and Novo Nordisk to evaluate the first diabetes medication delivery via drone.

celona

Celona's private 5G network provides reliable connectivity for clinical communications and monitoring applications.

4. Business model transformation

Summary: Four potential business model transformations that can be implemented

1	Pricing and payment innovations	• Pricing models that can share risks and benefits with buyers • Strategic innovative pricing • Alternative forms of financing
2	Localization of model in LIMICS	• Frugal innovation • Deskilling • Simplified services
3	Expansion into new indications	• Multipurpose devices • Widespread indication coverage • Lower cost ancillary equipment for additional use cases
4	Diversify partnerships	• Knowledge based partnerships with academic institutions • NGOs can act as accelerators, incubators or funders • Private companies for various business contracts and agreements

4.1 Pricing and payment innovations

Innovative pricing

Shared savings contracts: Supply devices at a low price in exchange for a % of revenue from the device.

Risk-sharing services contracts: Hospitals pay an annual fee to the service provider for all device needs.

- ✓ Aligned incentives on both the buyer and seller side;
- ✓ Lower barrier to new technology adoption.

- x Revenue is dependent on performance.

GE HealthCare

GE is responsible to optimize TUHS's radiology services and receives part of the shared savings based on goals.

Leasing of devices

Direct leasing: Customized contracts with flexible terms based on length, installments, depreciation, etc.

Leasing through distributors: Distributors purchase devices upfront and lease them to hospitals.

- ✓ Long-term revenue streams for manufacturer;
- ✓ Revenue from buyers who can't afford lump-sum payment.

- x Long time to recover investment costs and the burden of contract.

SIEMENS Healthineers

In China, Siemens cooperated with distributors that specialize in diagnostic imaging centers.

Risk sharing model

Outcome guarantee: Manufacturers give large discounts/rebates if certain outcomes are not met.

Gain sharing: Provide products at low prices with an agreement to share revenues/cost savings.

- ✓ Protection from price erosion and stickier relationship with customers;
- ✓ Increased use of non-reimbursable products.

- x Resistance from insurers or government payers.

Medtronic

Medtronic reimburses hospitals if its Tyrx antibacterial sleeve can't prevent infections in cardiac implant patients.

4.2 Localization of model in low- and middle-income countries (LMICs)

Current status in LMICs

50%

of medical equipment is broken, unused or unfit in LMICs

- x No access to spare parts;
- x No properly trained maintenance personnel;
- x No access to proprietary device maintenance documents.

Solutions LMICs

Frugal innovation

Focus on cost reduction and addressing local needs while maintaining performance. Maximize value-to-resource ratio for solutions tailored to resource-constrained environments.

GE made Vscan, which was **85% cheaper** than ultrasound units used in **China.**

Deskilling

Simplification of manufacturing processes for lesser-skilled or resource-limited personnel. This may help expand medical services by empowering individuals with limited training.

Cervical Cancer Prevention Project simplified **Pap smear** technique in **Vietnam.**

Simplified services

Simplifying an existing premium product for a mid- or low-tier market and still generate profit, by lowering operating costs. Centralizing operations with smaller supply chains to decrease operational costs and increase output.

GE developed a low-cost battery powered **portable ECG** machine for **rural India.**

There is no “one size fits all” framework to successfully invent and implement devices due the complexities of regulatory and business operating environment, expensive market readiness costs, and extensive safety testing of the device.

4.3 Expansion into new indications

Process flow for expansion into new indications

Existing device in clinics	Expensive and large medical devices with expensive applications are the most suited for expansion, especially within the same medical subcategory (e.g. oncology).
New use/indication discovered	Physicians and clinicians are legally allowed to use devices in additional ways that they deem safe and effective for patients' specific needs.
Ancillary equipment (if required)	Additional applications and multiple purposes for the devices need significant acceptance in the field before they can be legally considered as a "labeled" indication. These may require additional equipment from the manufacturer.
Device used in new indications	Once established as a new indication and widely accepted, the manufacturer can reap the revenue benefits through ancillary equipment sales and consumers gain additional benefits without substantial capital expenditure.

Examples

- **Cancer radiotherapy** devices have expanded to be able to treat various types of cancer-like lung, pancreas, liver, etc.;
- Redesigning a **surgical robot** to have additional robotic arms with different precision levels suited for different parts of the body;
- **J&J ThermoCool SmartTouch catheter** for cardiac ablation was granted FDA label extension to treat atrial fibrillation.

Manufacturers can help make a device more attractive to buyers under budget pressure looking to recoup up-front procurement costs as quickly as possible. Manufacturers will need to plan life cycle strategies starting early in development to access the full potential of their products.

4.4 Diversify partnerships

Academic institutions

Universities, research organizations, medical colleges

Strengthening local **human capacity**, training for **staff** in the medical field researching **efficacies** of medical devices, and innovating newer devices.

- ✓ Partnerships with academic institutions can lead to powerful new health technologies;
- ✓ Increases acceptance of new devices at the institutional level.

Life Science Outsourcing

LSO partners with many universities in the USA to support research projects dealing with medical devices.

NGOs

Accelerators, incubators, funders (social sector improvement NGOs)

Identify **promising innovators** and provide a **network of resources** such as financial investment, expertise, and access to development opportunities.

- ✓ Promote innovation at all stages and enhance access to other stakeholders;
- ✓ Incorporate government support into product development.

BILL & MELINDA GATES foundation

Gates Foundation invests in promising innovators and provides extensive support throughout the device life.

Local stakeholders

Medical providers, biomedical engineers, patients, government

Contextual expertise is essential, as they are best suited to analyze the needs of their patients and the country's **health systems capabilities.**

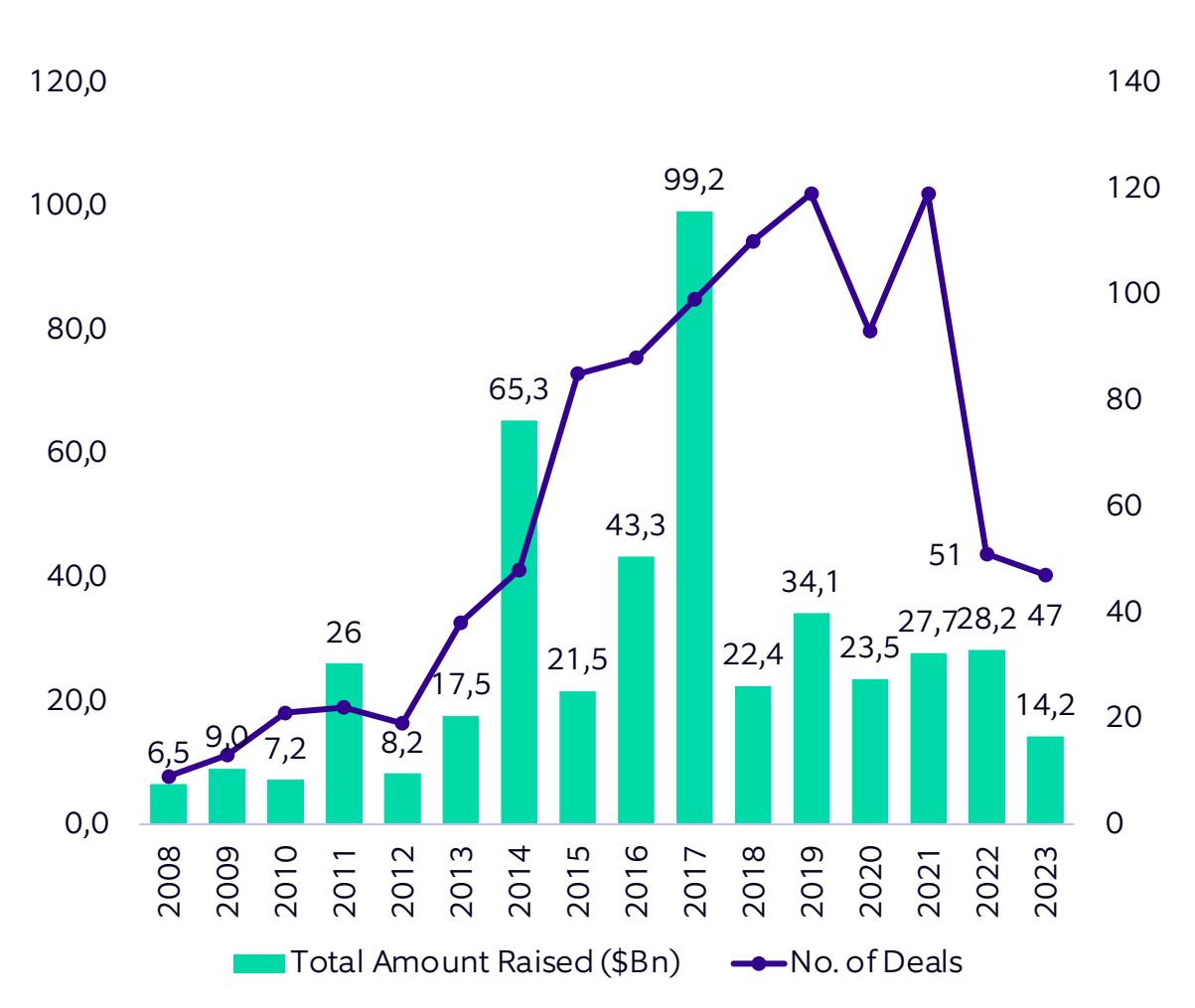
- ✓ In-country manufacturers and distributors have existing supply chains;
- ✓ Physicians can serve as product champions.

GE HealthCare

GE and Sinopharm are in a joint venture to expand access to CT and ultrasound imaging in China.

5. M&A trends

M&A – MedTech, devices, digital health and wearables



Insights

- In 2023, there were 47 M&A deals in MedTech, compared to 51 in 2022, indicating a slight reduction in the number of mergers and acquisitions.
- Total upfront cash and equity for M&A deals in 2023 amounted to $12.72 Bn, with a total deal value of $14.21 Bn, which is significantly lower than 2022, which had $24.60 Bn in upfront cash and equity and a total deal value of $28.26 Bn.
- Most MedTech deals in 2023 were tuck-in acquisitions of products or services that fit within the existing pipelines of the acquiring companies, rather than novel acquisitions that could have brought them into new areas.
- The pandemic has forced medical device companies to adapt to new challenges and opportunities, leading to a shift in M&A strategies toward strategic acquisitions, regulatory expertise, and digital capabilities.

Top M&A by value in MedTech industry

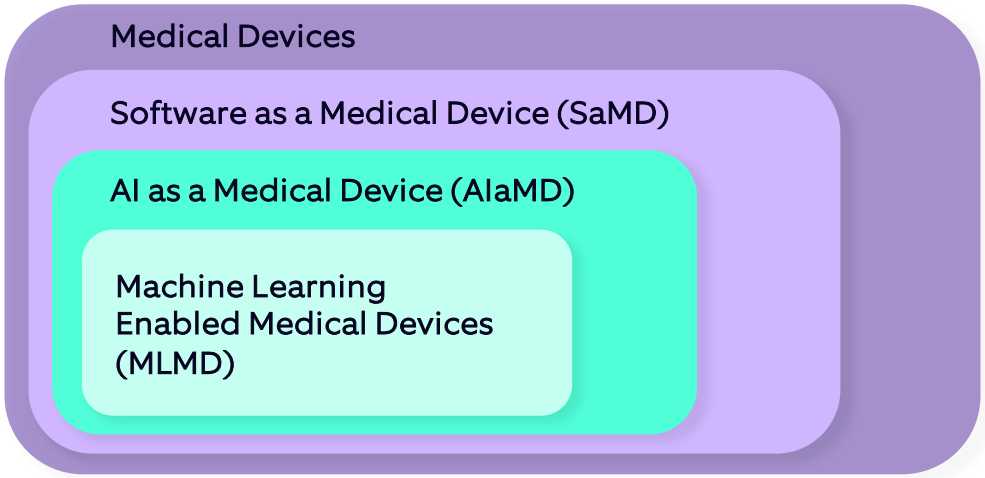
Type	Target	Acquirer	Size	Date	Description
Acquisition	ILC DOVER	Ingersoll Rand	$2.3 bn	Mar 2024	Ingersoll Rand bought ILC Dover to grow in life sciences, ILC Dover brings established market positions and brands in the biopharmaceutical, pharmaceutical, and medical device markets.
Acquisition	SHOCKWAVE MEDICAL	Johnson & Johnson	$13.1 bn	Apr 2024	To expand J&J's cardiovascular portfolio into two high-growth segments: coronary artery disease (CAD) and peripheral artery disease (PAD) with Shockwave's intravascular lithotripsy (IVL) enhancing J&J's offerings in cardiovascular care.
Acquisition	Axonics	Boston Scientific	$3.7 bn	Jan 2024	Deal focuses on Boston Scientific's expanding its urology portfolio with differentiated technologies and enhancing its presence in the sacral neuromodulation market.
Acquisition	Olink	Thermo Fisher SCIENTIFIC	$3.1 bn	Oct 2023	To expand Thermo Fisher's capabilities in the proteomics market, as Olink's technology provides high-throughput analysis for quantitative PCR and next-generation sequencing systems used by biopharma companies and academic researchers.
Acquisition	SPECTRUM PLASTICS GROUP	DUPONT	$1.7 bn	May 2023	Spectrum's expertise in advanced manufacturing and customer relationships with major medical device OEMs complements DuPont's existing healthcare offerings, including Liveo silicone solutions and Tyvek medical packaging.
Merger	NUVASIVE GLOBUS MEDICAL	-	$3.7 bn	Feb 2023	To create the world's leading musculoskeletal technology company by combining their portfolios and operational strengths.
Acquisition	Baxter	WARBURG PINCUS	$4.2 bn	May 2023	Warburg Pincus and Advent International to acquire Baxter to form Simtra. Simtra will be a fully independent, end-to-end contract development and manufacturing organization (CDMO) offering services from clinical development to commercial fill/finish.

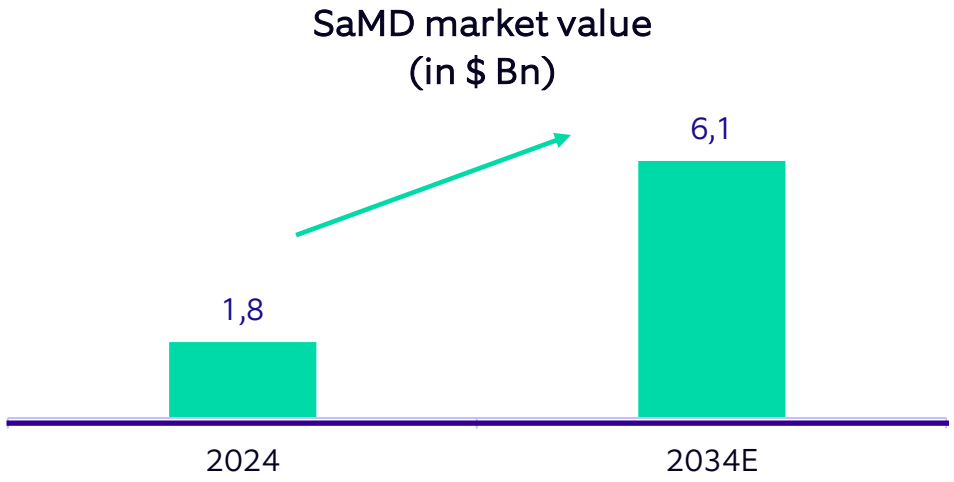
Key trends driving the medical devices M&A, investment markets

1	**Outsourced regulatory support**	Outsourced providers with regulatory expertise are in high demand due to increasingly complex approval processes and higher R&D spending. Continued development of complex medical products and devices is driving increased demand for full-service CMOs that can provide solutions from front-end design and development work through high-volume productions.
2	**Shift to 510(k) pathway**	Investors now prefer funding devices that utilize a quicker 510(k) pathway, making a shift from recent years when they preferred devices requiring Premarket Approval (PMA).
3	**Increased digital transformation**	Industry is undergoing significant digital transformation, with companies investing heavily in digital technologies such as artificial intelligence, blockchain, and the Internet of Things (IoT).
4	**Orthopedic & cardiac markets**	The orthopedic market is expected to grow significantly due to backlogged procedures, particularly joint replacements, driven by factors such as the COVID-19 pandemic and demographic shifts. Emerging cardiac markets, with companies actively engaging in deals to capitalize on growth opportunities presented by advancements in cardiac technologies and treatments.
5	**Strategic shifts**	Companies are shifting their focus from large acquisitions to organic growth and smaller, strategic tuck-in deals to manage risks better and integrate new capabilities more efficiently.

6.
Software and AI as a Medical Device

Software and AI as a Medical Device making significant advances in medical industry





Software as a Medical Device (SaMD)

- SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device;
- Software used to drive or control the infusion pump or an implantable pacemaker;
- These types of software are referred to as embedded software, firmware, or micro-code.

AI as a Medical Device (AIaMD)

- AI approaches are being incorporated into SaMD, and these may be described as AIaMD;
- Just like traditional medical devices, AIaMDs are designed to assist healthcare professionals and improve patient outcomes;
- AIaMD leverages extensive datasets and intricate statistical methodologies to unveil novel connections among inputs, actions, and outcomes.

Key market insights (SaMD)

- The g lobal SaMD market is calculated to reach $6.1 Bn by the end of 2034;
- The m arket is projected to grow at a CAGR of 13% during the forecast period of 2024-2034;
- Cutting-edge innovations drive growth in the market size.

Trends impacting the SaMD and AIaMD industry

Personalized healthcare and remote monitoring

AI-powered SaMD solutions and remote monitoring tools are personalizing healthcare by analyzing data, predicting risks, and enabling early intervention.

Data analytics and integration

AI adoption in healthcare fuels SaMD growth, but robust data security and user trust are paramount to overcome privacy concerns and achieve widespread use.

Government initiatives and competitive landscape

Several regional governments are actively promoting digital healthcare and investing in SaMD, creating a supportive environment for market expansion.

Regulatory framework and documentation

Evolving SaMD/AIaMD regulations emphasize post-market monitoring, AI-specific challenges, and efficient delivery, while robust documentation with SBOMs is key for compliance and safety.

Cybersecurity risks and integration

High cybersecurity concerns, requiring robust safeguards for safe devices, and integration with existing healthcare systems demand careful documentation & compliance for smooth operation.

Mobile health boom and technological advancements

High mobile penetration in Asia-Pacific fuels SaMD/AIaMD adoption, while AI, machine learning, and cloud advancements drive innovation for more effective healthcare solutions.

SaMD and AIaMD are changing the industry by improving outcomes, reducing costs and enhancing the quality of care

SaMD

Remote patient monitoring

Surgical planning

Computer-aided detection (CAD) software

Telemedicine

AIaMD

AI-powered diagnostic tools & medical imaging

Predictive analytics

Personalized medicine

Robotics & automation

Medical device maintenance & repair

Major players in the industry

DIGITAL DIAGNOSTICS

ARTERYS

iz.ai

IMAGEN

Medtronic

PHILIPS

SIEMENS Healthineers

Roche

CorticoMetrics

ENLITIC

NVIDIA

amazon

3M

Atomwise

Benevolent AI

CYCLICA

Regulatory scenario of AIaMD in UK

Regulatory body	Medicines and Healthcare products Regulatory Agency (MHRA) is the independent regulator of medicines, medical devices, and blood components for transfusion in the UK.

Regulation of medical devices in the UK is in a transition phase. Currently medical devices on the UK market (including SaMD and AIaMD) are regulated under the UK's Medical Devices Regulations 2002 (as amended).

In September 2021,MHRA announced the Software and AI as a Medical Device Change Programme, a programme of work to ensure regulatory requirements for software and AI are clear and patients are protected.

MHRA's Software Group has responsibility for all SaMD and AIaMD placed in the UK market. goal is to ensure safety and performance while enabling rapid innovation.

Pre-market requirements	Post-market requirements
A regulatory 'airlock' will be introduced to help devices intended to meet an unaddressed clinical need to generate the necessary pre-market phase evidence.	MHRA currently uses the Yellow Card Scheme for the reporting of medical device adverse events and this system will be integrated into the Change Programme, clarifying reporting obligations and next steps.

UK regulatory framework for AIaMD is evolving, with a focus on balancing innovation and safety

- UK Medical Devices Regulations 2002 are being reformed, with new regulations expected to be introduced in 2025;
- MHRA has launched a pilot regulatory sandbox, AI Airlock, in spring 2024, to identify and address the unique challenges posed by AIaMD from a regulatory perspective;
- MHRA is exploring the use of AI to enhance its regulatory decisions, including leveraging AI to improve the timeliness of access to medical products;
- MHRA is developing a data strategy that prioritizes applying advanced analytics and AI within the regulator safely and responsibly, aiming to improve the quality of applications for medicines licenses and enhance regulatory services.

Regulatory scenario of AIaMD in US

FDA reviews medical devices through an appropriate premarket pathway, such as premarket clearance (510(k)), De Novo classification, or premarket approval.

Apr, 2019 — FDA published, "Proposed Regulatory Framework for Modifications to (AI/ML)-Based (SaMD)", which describes a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications.

Jan, 2021 — In January 2021, the FDA published the "AI/ML SaMD Action Plan".

Oct, 2021 — Proposed "Good Machine Learning Practice for Medical Device Development: Guiding Principles".

Apr, 2023 — Draft Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for (AI/ML)-Enabled Device Software Functions.

Oct, 2023 — Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles.

Mar, 2024 — FDA published the "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together," which represents the FDA's coordinated approach to AI.

Approach to total product lifecycle for AI/ML medical devices:

- **Quality Management Systems (QMSs):**
  FDA expects QMSs to be adapted to the specifics of developing AI/ML Medical Devices.
- **Initial premarket assurance:**
  FDA requires data on the Valid Clinical Association, Analytical Validation, and Clinical Validation of AI/ML Medical Devices to ensure ethical AI and accurately address bias.
- **"Predetermined Change Control Plans" system:**
  Mechanism of the FDA pre-approving changes to medical devices that include AI components where careful justification and evidence exist to support allowing these changes.
- **Transparency and post-market surveillance:**
  FDA wants to ensure AI/ML medical devices are performing well over time and that developers are being transparent when changes in performance occur.

7. Orphan medical devices

Orphan medical devices are used to treat rare diseases which present various challenges

Rare diseases by numbers

~300Mn
people worldwide live with a rare disease

50%
affected by rare diseases are children

6000+
different identified rare diseases

72%
rare diseases are genetic

Diagnostic odyssey

- Time for correct diagnosis: **5 to 7 years**
- Physicians consulted: **up to 8**
- Misdiagnoses**: 2 to 3**

Genomics can improve these indicators, but it is expensive

Challenges identified

- No universal definition
- Delayed diagnosis
- Misdiagnosis
- Limited treatment options
- Financial burden
- Social burden

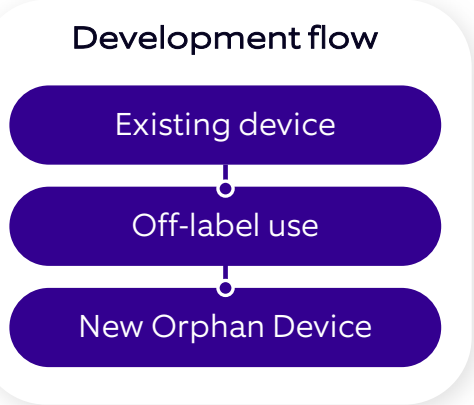
Orphan Medical Devices need to cater to a **broad diversity** of symptoms and disorders that **vary for patients** suffering the **same disease**.
Rare diseases have a big impact on patients' quality of life, thus making it imperative for orphan devices to be **effective** and **affordable** for **chronic management of disease.**

Significant shortage of orphan medical devices globally due to complex landscape of application

Causes for unmet needs

Over **90%** of medical specialists in a US Survey indicated the need for **more** and **specific** orphan medical devices

- **64%** clinicians are dissatisfied with existing orphan medical devices;
- FDA has an approval rate of around **1 out of 20 designations** for rare disease applications;
- **37%** clinicians repurpose an existing medical device for rare disease applications;
- Only **2** countries – USA(FDA) and Japan(PMDA) have orphan **device authorizations.**



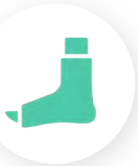
Devices required especially by children

Special focus area - children

Lack of orphan devices affects children more, because of **smaller body parts** and even **rarer diseases** than adults;

- **Prosthetics:** Used after rare cancer surgery in children which will grow as the child grows;
- **Implantable pacemakers:** For children with rare heart conditions, which can be replaced over time;
- **Smartphone apps:** Support parents with their child's nutrition and drug regimen;
- **Alarming device:** for small and big seizures in rare epilepsy conditions.

Some examples of orphan medical devices and their manufacturers



Brace for clubfoot in newborns

Congenital talipes equinovarus (CTEV) is a birth defect where one or both feet are rotated inward and downward.

Treatment involves initial casting for 6 weeks, followed by surgery and **continued casting** for several weeks, then **brace support** will lead to a total cure.

D-Bar Enterprises

Massons healthcare

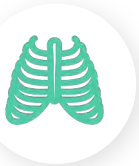
Nebulizers for cystic fibrosis

Cystic fibrosis is a genetic condition that affects cells that produce mucus, sweat and digestive juices.

Treatment involves **controlling symptoms** through nebulizer therapy with drugs like albuterol, pulmozyme, and inhaled antibiotics (Tobi and Tobramycin), varying from patient to patient.

OMRON

PHILIPS Healthcare



Vertical expandable prosthetic titanium rib (VEPTR)

Thoracic insufficiency syndrome is a chest wall deformity that interferes with lung function and development.

Treatment involves implanting the rib into infants and **expanding the device** through **outpatient surgery** every 6 months. The device **stays in place** and adjustments can be made **till skeletal maturity**.

SYNTHES®

8. Software and data initiatives by big players

Patient support programs (PSPs) and education initiatives are driven by data management and software applications (1/2)

Companies	Therapy Areas	Descriptions
Abbott	Cardiology, neurology, women's health, digestive health, respiratory health	• **a:care app and website:** Personalized treatment schedules and behavioral analysis of patients through **gamification.** Patients can **stay informed** through the news on disease management, nutrition, and lifestyle support.
Medtronic	Cardiology, diabetes, neurology, invasive therapies	• **Medtronic patient services:** General educational information about all medical devices offered, along with contact lines for support for **doctors** and **patients.** Separate procedures and channels for communication regarding returns and **replacements**.
Johnson&Johnson MedTech	Orthopedics, surgery, interventional solutions, vision	• **JnJInstitute:** Offers healthcare professionals access to a robust collection of educational content, available online through a website; • **Support resources and information:** Specific details for each product and support contact lines.
SIEMENS Healthineers	Cardiology, hepatology, radiology, neurology, oncology, women's health	• **eHealth solutions:** Care collaboration, **patient engagement**, and **information exchange platforms** to assist doctors to collaborate and deliver the best care possible; • Education and Coaching are provided for staff upskilling in hospitals through an online portal.
FRESENIUS MEDICAL CARE	Hepatology, patient care, mental health	• **Support possibilities platform:** Educational content on **complete treatment pathways** and relevant information about all aspects of kidney disease. Portal for connections with **other patients** for insights and personal experiences.
BD	Critical care, surgery, diagnostics, urology	• **New care settings** and **patient self-care management** are priority areas under innovation through technology; • The webinar series for Critical Care on the website is conducted every month.

Patient support programs (PSPs) and education initiatives are driven by data management and software applications (2/2)

Companies	Therapy areas	Descriptions
GE HealthCare	Surgery, observation, critical care	• **Large patient care solution portfolio:** Data driven solutions to **physician needs** like access to data, knowledge base and especially tracking of monitoring data for better care and quicker result for patients. **Indirect benefits** to patients through improving capabilities of clinicians.
stryker	Orthopedics, ENT, chronic back pain	• **Patient education:** Informative sites on various therapy areas for patient aid relating to **lifestyle improvements** and **overall wellbeing** to foster their return to an active life. **Orthopedic surgeons** can be located and found for patients based on their requirements.
PHILIPS Healthcare	Respiratory, imaging, monitoring, oncology, diagnostics	• **RespirTech:** Payment obligations for patients needing **financial help** for **inCourage Airway Clearance Therapy** are covered by the online application; • Education resources for Imaging, Monitoring, Oncology, and Diagnostics for support staff.
CardinalHealth™	Patient care, oncology, ophthalmology, neurology	• **Patient access and support insights:** Patient care products designed for home care, which can ease patient access, eliminate cost concerns; • Educational resources on the website for healthcare professionals and other stakeholders.

3/10

Companies offer dedicated PSP platforms/portals

4/10

Companies offer patient education initiatives

Medical Device companies still seem to be lagging in terms of PSPs and education initiatives (especially for patients), as only a few of them have a dedicated platform or portal for the same.

Data related partnerships of industry players revolve around cloud computing and IoT

BD

Improve business agility, consolidate operations, support connected health products

- Azure — Data storage, sharing and analysis for connected devices
- SAP — On-premise cloud platform
- Vormetric, A Thales company — Data security platform

Roche

Accelerating device research and development, securely sharing data externally with regulators

- Azure — Develop early cancer detection software solutions
- aws — Personalized healthcare through Apollo platform
- snowflake — Created a data mesh for decentralized ownership of data

Johnson&Johnson MedTech

Enhancing overall customer experience, improving patient and economic outcomes

- Azure — Connect and manage IoT enabled devices and platform to collect and process data from records
- aws — Hybrid cloud strategy in 2014 to switch computing workloads to the cloud for J&J (parent)

Medical Device companies have already adopted the cloud computing trend and now largely look forward to expansion into AI&ML and IoT driven partnerships.

The Big Four tech companies show increasing interest in the healthcare industry

Google

Precision medicine

AI can create a new paradigm for the detection, diagnosis, and treatment of disease

- Algorithm that can **diagnose diabetic retinopathy** in high-quality images;
- **Project baseline:** study that aims to establish a baseline of **good health** and understand risk factors for disease;
- If AI can better detect and manage disease, **turn to the insurance business** that can help patients manage risk.

Clinical research

CEO's goal is to build Apple Health as a big contributor to mankind

- Certified by **FDA** for a **faster approval track** for innovations;
- Partnered with **Stanford Medicine** for the Apple Heart Study based on watches;
- **HealthKit:** health information database on iPhones;
- **ResearchKit:** enables users to enroll in medical tests for their condition.

amazon

Pharmacy & virtual care

Seeks to leverage existing presence as an eCommerce giant to expand into healthcare

- **PillPack:** online pharmacy that works with insurance plans;
- Software that **mines patient medical records** to be used to improve treatments;
- **Echo and Alexa:** medication management for the elderly, blood pressure management, programs and tips for a healthier lifestyle.

Microsoft

Cloud market

Transform care by combining research, health product development and partnerships

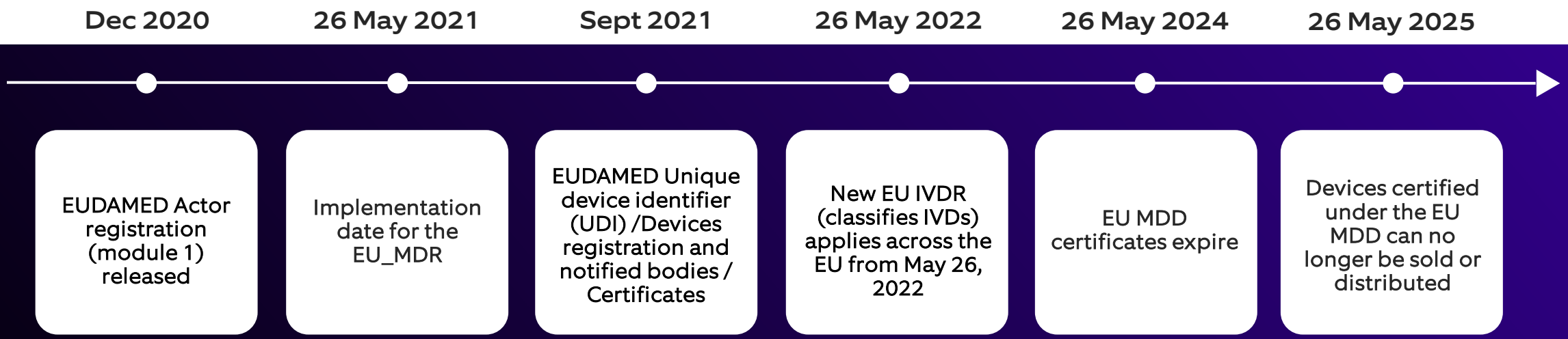
- **Upsell** current healthcare clients and forge new collaborations;
- Significant number of **patents** filed for AI and Telehealth;
- **Healthcare NExT:** AI-driven initiative for the future of health;
- Over **14,000 partnerships** with hospitals and healthcare institutions worldwide.

Consumer demands for fast healthcare services have led to the healthcare industry moving towards digital tech, and big tech companies are lending their expertise to become partners for the job.

9. Recent regulatory insights

European Union reformed its existing medical device regulations

Council of EU adopted new medical device regulations (MDR) to reform existing medical device & in-vitro diagnostics regulations. Under the new guidelines, all medical devices will need to undergo safety & performance assessment before they can be marketed in Europe.



- EU MDR, which came into effect in 2017, has a transition period ending on 31 December 2027 or 31 December 2028, as applicable;
- Commission implementing regulation as of 5 December 2023 designates European Union reference laboratories (EURLs) in the field of in vitro diagnostic medical devices;
- On 15 March 2023, Regulation (EU) 2023/607 was formalized, providing medical device manufacturers more time to certify medical devices to mitigate potential shortages.

Impact of EU MDR on Medical Device Manufacturers (1/2)

Reclassification or up-classification of devices

- Under the MDR and IVDR, changes will made to the way medical devices are classified;
- Requirements will be scrutinized based on risk to the patients;
- E.g., certain devices that meet the spinal cord will move up from class II to class III
- Reclassification will require a costly certification process for new & existing products.

Elevated clinical testing requirements

- For medical devices, the new regulations require reassessment of clinical data for devices already on the market;
- If the data do not meet the new requirements, devices will be required to undergo additional testing to be recertified, increasing the expense of maintaining legacy devices;
- Due to the reclassification of IVDs, device makers that have not previously been required to perform clinical testing will have to develop the ability to do so.

Focus on post-market surveillance

- Under the new IVDR and MDR, there will be an increased emphasis on post-market surveillance;
- This includes proactively monitoring device performance for recertification, rapid reporting of safety incidents, and annual safety updates for higher-risk class devices.

Impact of EU MDR on Medical Device Manufacturers (2/2)

Separate regulatory framework

- With the MDR 2020 coming into effect in April 2020 providing an all-inclusive and comprehensive definition of medical devices, until then unregulated sector has been given a due and separate regulatory framework from that of drugs and medicines;
- From April 2020, all medical device manufacturers have been mandated to register themselves with a government-designated portal to carry out any manufacturing, distribution, sale, and importing of a medical device.

Risk based classification

- For medical devices, the new regulations require reassessment of clinical data for devices already on the market;
- If the data do not meet the new requirements, devices will be required to undergo additional testing to be recertified, increasing the expense of maintaining legacy devices;
- Due to the reclassification of IVDs, device makers that have not previously been required to perform clinical testing will have to develop the ability to do so.

Robust verification regime

- Under the new IVDR and MDR, there will be an increased emphasis on post-market surveillance;
- This includes proactively monitoring device performance for recertification, rapid reporting of safety incidents, and annual safety updates for higher-risk class devices.

Recent key regulatory highlights in the US medical devices market

Sept 2023

Modernizing the 510(k) programme

FDA released guidance to improve the 510(k) program's predictability and transparency, especially for implants. This aims to enhance review processes and device safety.

Sept 2023

Revamped guidance document: cybersecurity in Medical Devices

Due to increased cyberattacks, the FDA released updated cybersecurity guidance for medical devices. It includes recommendations for risk assessments and premarket documentation.

June 2023

List of Medical Device shortages gets shorter

FDA updated its list of medical device shortages, removing several categories. CDRH will invest $11.6 Mn in the Resilient Supply Chain Program by September 2024.

May 2023

Transitioning COVID-19 EUA Medical Devices

FDA's CDRH issued guidance to transition COVID-19 devices from EUAs to traditional marketing. This aims to normalize operations after over 4,000 devices received EUAs.

April 2023

New rules on AI and ML-based Medical Devices

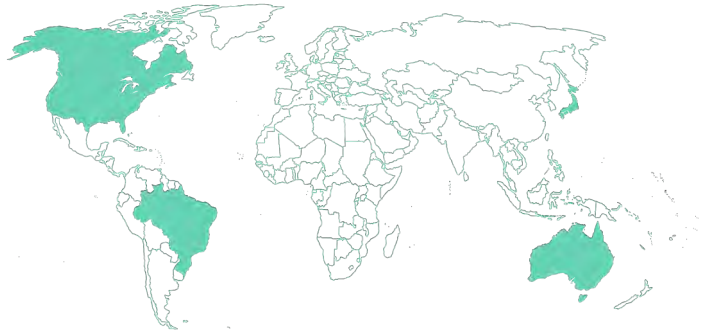
FDA issued guidance for AI/ML-enabled devices, supporting their improvement while ensuring safety. It outlines requirements for a Predetermined Change Control Plan in marketing submissions.

Recent regulatory scenario in other parts of the world

In India, Medical device trade margins is set to be capped at **30%** Cardiac stents, drug-eluting stents, and intra-uterine devices are included in the National List of Essential Medicines and are, therefore, subject to notified price caps. Stents and knee implants were the latest to be brought under the price control.

China's Center for Medical Device Evaluation recently released new procedures for device registration in 2020. This includes increased standardization of the filling review process and new withdrawal and re-submission procedures for up-classified devices.

Recently, **South Korea's Ministry of Food and Drug Safety (MFDS)** released a draft revision to the Regulation on Medical Device Codes & Classification. Amendments include a new category in the product classification system for SaMD, a new category for medical respirators, and minor adjustments to existing medical device product classification codes.



A global harmonization effort among the **US, Canada, Brazil, Japan, and Australia**, which became operational on January 1, 2017. Additional markets and organizations, including the World Health Organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Singapore's Health Science Authority (HAS), and European Union (EU), are official observers of the **Medical Device Single Audit Program (MDSAP)**.

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