nagarro

Analysis of the global Medical Device market

July 2021

Thinking Breakthroughs

Global medical device market is expected to grow to ~$797 bn by 2025

Global Medical Device Market Size ($ bn)

$796,9

$605,7

CAGR: 5.6%

2020   2025 F

North America holds the largest share; US remains the major market, valued at **$176.7 billion** in 2020
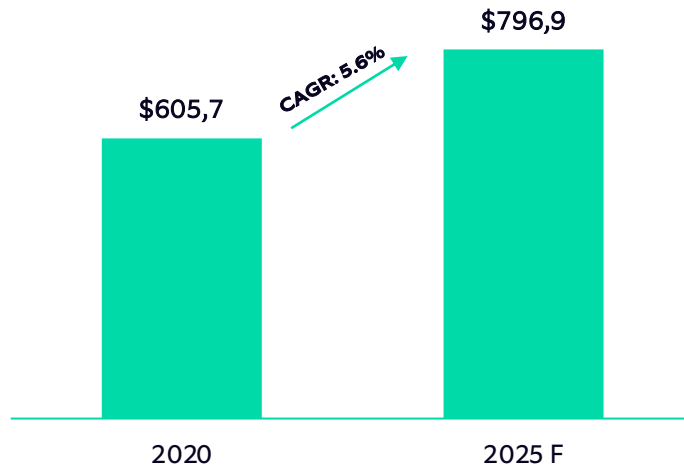
Key insights

- Significant growth opportunities in emerging geographies, stagnating growth in established markets
- Convergence of technologies – IoMT, AI/ML, wearable technology, 3D printing, Blockchain, enhanced cybersecurity, and others
- Growing complex regulatory environment; increasing cost pressure from payers & providers

Drivers of Growth

Rapid integration of advanced technologies

Shift in consumer demand

Growing burden of chronic diseases
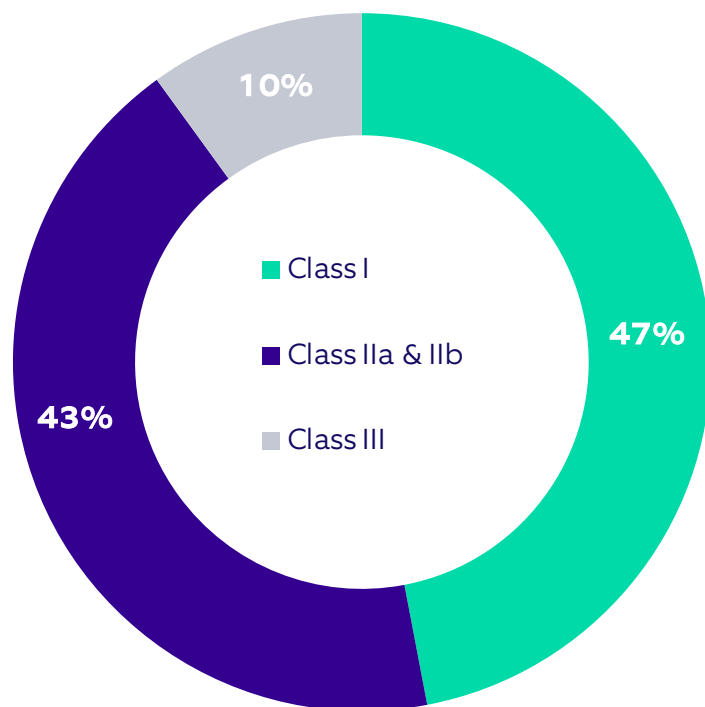
Increasing healthcare spending

Diversified funding support base

Emerging global markets

In-vitro diagnostics emerged as the largest segment in the year 2020

Percentage (%) of device presence in the US (as classified by US FDA)

- Class I
- Class IIa & IIb
- Class III

47%

43%

10%

In-vitro diagnostics was the largest segment in 2020 with a share of **13.8%** of the global market

In-vitro diagnostics market was valued at **$83.4 billion** in 2020, and is expected to grow at a **CAGR of 4.5%** (2021-2027)

Increasing number of testing due to pandemic, growing number of new product launches, and development of automated IVD systems fuel its market growth

Sources: evidera.com, gradviewresearch.com

COVID-19 impact on US MedTech during H1 2020

Aggregate revenue decline is **5%**

2/3 of medtechs report revenue drop in H1 2020

7 of the top **10** companies by revenues report H1 2020 downturns vs. H1 2019

8 companies, primarily focused on elective procedures, saw revenues **fall by 15%**, but diagnostic companies surged, accounting for

4 of the 6 biggest revenue increases

Sources: jdsupra.com, siteselection.com

MedTech's role in the COVID-19 response

448
COVID-19 related diagnostics launched in market or in development (as of Aug. 2020)

232
Viral in-vitro diagnostics

148
Antibody in-vitro diagnostics

56
Medical device partnerships (digital, diagnostic testing, scaling manufacturing, telemedicine and virtual care)

Key industry challenges

The challenges impeding the growth of the Medical Device market

Growing Pricing Pressure	1	Pressure to reduce medical device prices is a key concern for the industry
Changing consumer demands	2	Medtech consumer requirements are continuously changing; driving the need for innovation
Non-traditional entrants	3	Growing interest of technology giants in medical devices may hamper the market share of existing players
Increasing no. of start-ups	4	Increasing number of start-ups are imposing continuous innovation pressure on MedTech companies
Less regulated geographies	5	Less complex regulations are supporting growth of local innovators; evolving as a competitor for larger players
Need for evidence	6	Regulatory bodies and providers are demanding "evidence" to ensure safety and effectiveness of devices
Cybersecurity risks	7	Cybersecurity risk is a major concern for the industry

1. Pricing pressure on medical device manufacturers continues to increase

Uncertain regulatory scenario

- Continuously changing on medical devices resulted into relentless downward pressure on pricing

- Further uncertainty lies ahead, with the new EU device regulation in 2020 & price capping imposed by Indian government on essential medical devices

Increasing negotiating power

- In the US, group purchasing organizations (GPOs) are consolidating their power

- Negotiating power of hospital systems is growing, and they increasingly contract below GPO prices

Shift to Value Based Care

- Shift in focus from devices to more outcome or value-based measures

- Demand is to pay less for medical devices and see proof of greater value in terms of better patient outcomes

Reimbursement pressure

- Reimbursement pressure are growing in both US & Europe, disrupting the established players and creating significant decrease in prices

Low visibility to OEMs

- MedTech companies generally have only limited visibility into pricing performance. In some cases, even lack the tools to generate vital tracking and reporting analysis

2. MedTech consumers/physicians are becoming more demanding

Evolving behavior of MedTech consumers

- Patients/consumers are becoming more proactive; they are actively involved with their healthcare providers in decision making and are very accustomed to asking for the latest device
- Rising consumerism leads to preferences for devices or diagnostics that are more "user-friendly," reliable and built to last
- More consumers are using technology for health monitoring and are willing to share their data

Physicians* needs

Interoperability	Optimized Workflow	Intelligent Augmentation	Data Security & Integrity
83% expected that patient-generated data will be integrated into care delivery in the next 5–10 years	**61%** highlighted their greatest need for today which is improving routine processes in the clinical practice	**64%** anticipated that AI will help in predicting & diagnosing diseases as well as prevent acute events	**47%** wondered about cyberattacks. **69%** wanted to know the liability if a technology related medical error occur

*N = 680 physicians

3. Non-traditional players are invading the medical device market; prompting OEMs to re-evaluate their strategies

amazon

Amazon partnered with Arcadia, a consultancy group, to launch Choice, an exclusive brand of consumer-use medical devices for diabetes and hypertension management

SAMSUNG

Tech giants including Apple and Samsung have recently received FDA clearance for their smartwatches with ECG monitoring app

Top growth areas

- Improved Access to Care

- Healthcare Efficiency Improvements

- Outcomes Improvement
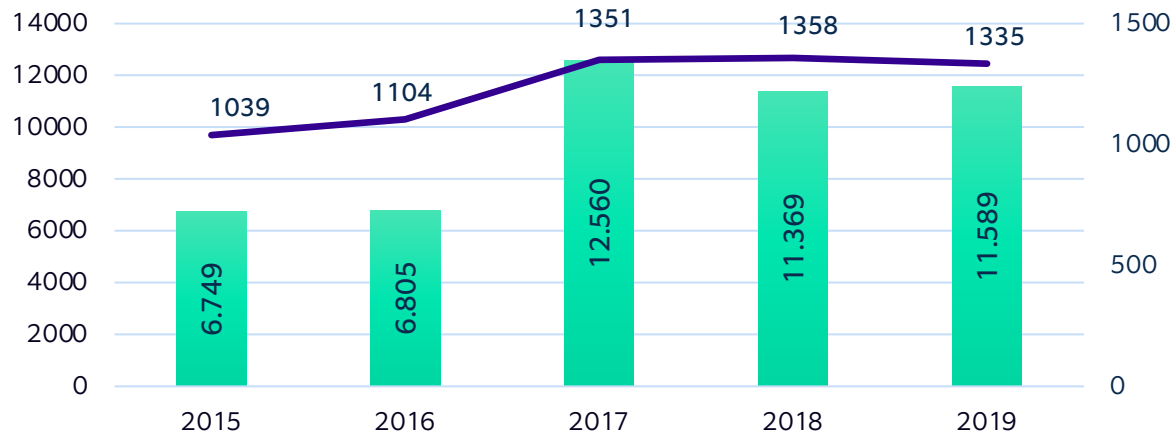
- Preventive Disease Management

Key implications

- Driven by the need for continuous innovation and quality care, the medical device sector is likely to see continued entry of non-traditional players over the coming decade
- It is expected that these new entrants will overcome the regulatory barrier & move upward to higher end products
- Some of these are partnering with Life Sciences & Genomics and hiring their own healthcare experts, signaling their intent to create new value propositions for patients

4. Industry competition is becoming fierce due to the growing number of start-ups

No. of equity deals and amount of funding raised ($ Million) by MedTech startups, 2015-2019

Year	2015	2016	2017	2018	2019
Funding	6.749	6.805	12.560	11.369	11.589
Deals	1039	1104	1351	1358	1335

Major MedTech start-ups that raised the most money in 2020

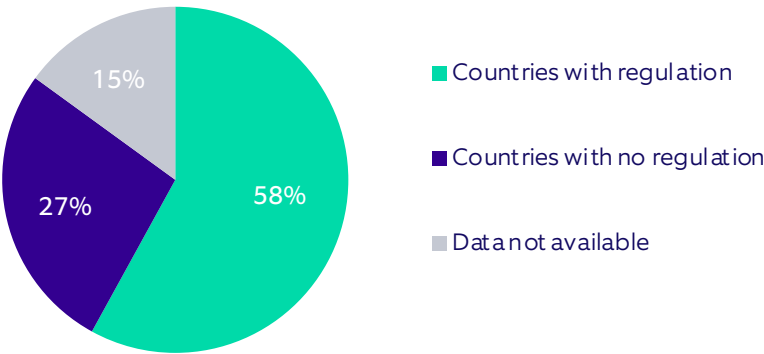| S.No.	Company name	Total funding ($M)
1.	Tempus	**620**
2.	Freenome	**507.6**
3.	Recursion	**465.4**
4.	CMR Surgical	**384.8**
5.	AbCellera Biologics	**296.2**

Key implications

- Medical Device start-ups have raised $10 bn+ for 3 years in a row
- As venture capitalists continue to invest heavily in medical technology, the pressure to innovate is increasing
- Increased competition is leading to the consolidation of more startup companies with the ability to drive MedTech innovations
- Fierce competition from start-ups, new regulatory requirements, and rapidly emerging technologies are creating new complexities and challenges for those operating in this sector

Sources: cbinsights, greelight.com

5. Growing competition from players located in countries with less complex regulations

Current global status of medical device regulations (N=113)

- Countries with regulation
- Countries with no regulation
- Data not available

58%
27%
15%

Basic elements regulated in countries with legal framework for medical devices (N=113)

Element	Value
Definition	93
Risk Classes	73
Essential Principles	69
Listing of Medical Devices	86
Registration of Establishments	78
Import Controls	65
Adverse Event Reporting	69

Asia-Pacific countries including Vietnam, Malaysia, Thailand, Sri Lanka, and to some extent India, offer less stringent regulations as compared to US & EU. Governments in these countries are incentivizing domestic production and supporting growth of innovative start-ups.

Latin American countries including Chile, Peru, Colombia, and Mexico have friendly regulatory climate. Peru and Colombia take around 30-90 days review time based on device risk. It involves a reasonable set of requirements and straightforward approval process.

Middle eastern countries such as UAE and Israel are witnessing significant growth in number of health technology start-ups. These start-ups are leveraging their less developed & business friendly regulated environment to foster innovation.

Source: who.int

6. The growing need for evidence in medical devices from regulators

Medical device manufacturers are facing extreme pressure by regulatory bodies as well as hospitals to provide evidence to product claims and value propositions – evidence the manufacturers often do not have.

Under the new EU medical device regulations, the amount of clinical data required will be increased significantly, and notified bodies will enforce this need for clinical data.

The European MDR demands that "confirmation of conformity with relevant general safety and performance requirements under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk-ratio, shall be based on clinical data providing sufficient clinical evidence.

Impact

Post-market surveillance: Clinical evidence on safety and efficacy is required for products to retain existing products in market while demonstrating safety and efficacy to improve competitive position and grow market share

Market access: Demonstrate comparative value for existing products and label modification (e.g. safety warnings)

R&D: Required new process changes due to clinical evidence requirements

7. Medical Device cybersecurity vulnerabilities may disrupt future innovation

FDA recently informed about potential cybersecurity vulnerabilities "URGENT/11" for connected medical devices.
It is estimated that 97% of OT devices impacted by URGENT/11 have not been patched.

Software issues is emerging as the top reason for medical devices recalls

Company	Product type	Units recalled	Reasons for recall
Fresenius Kabi	Infusion pump	9,461	Alarms & multiple software errors
Hamilton Medical	Ventilators	4,338	Potential sporadic message
Brainlab	Surgical navigation software	60	Inaccurate display during brain surgery
Medtronic	Surgical navigation software	5,487	Inaccuracies displayed
Medtronic	Insulin pump	~4,000	Cybersecurity vulnerabilities

25% of cyberattacks in healthcare delivery organizations will involve the IoMT

67% probability of a medical device likely to be attacked within next 12 months

80% of MedTech manufacturers believe that medical devices are difficult to secured

53% of device makers believe there is a lack of QA & Testing procedures that lead to vulnerabilities

23% of recalls were caused by software failures, including software anomalies and false results

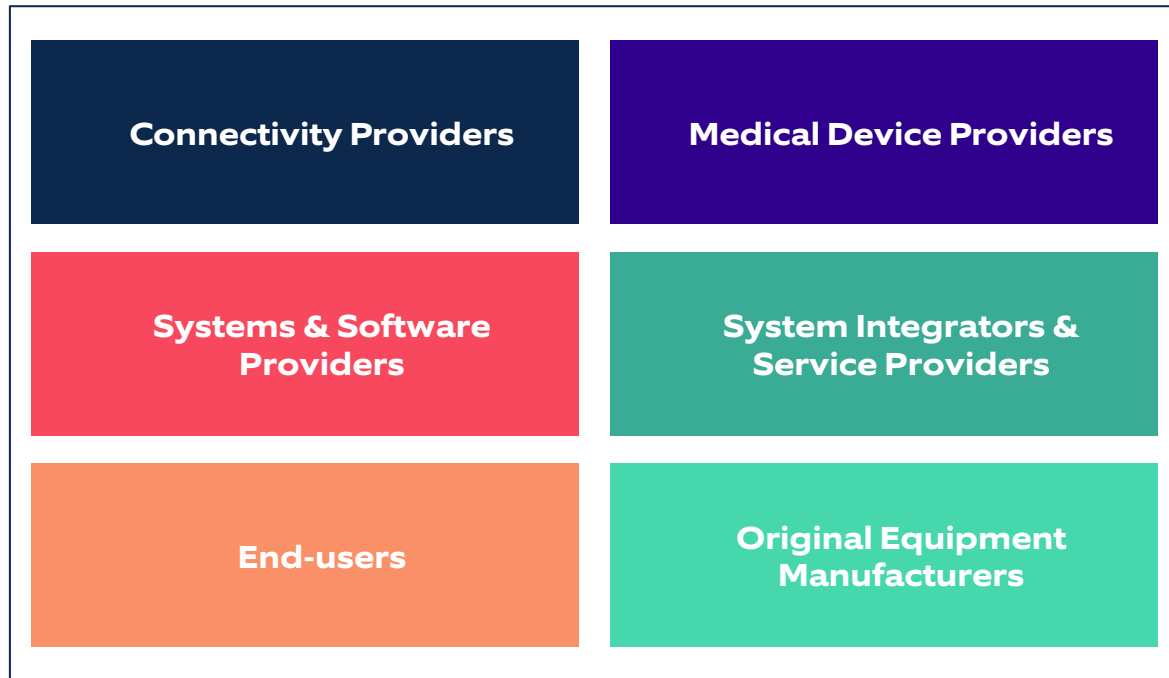Sources: FDA.gov, herjavecgroup.com, securitymagazine.com

Key industry trends

Analysis of the global medical device market, July 2021

The seven challenges impeding the growth of the Medical Device market

Internet of Medical Things (IoMT)	IoMT is bringing together people, processes, enablers, and data to improve patient outcomes efficiency
Convergence of Medical Devices	Integration of medical device with patients EMR, wearables, smartphones, and telehealth platforms is delivering key insights for better clinical and operational decision making
Blockchain	Blockchain is improving the privacy of data sharing across large network of device users and gaining traction across medical device value chain
Robotics	Robotic surgeries are gaining a lot of momentum in the recent years with multiple new device launches and approvals
3D/Additive Manufacturing	Significantly reducing the costs of medical implants and surgical tools, and addressing the challenges of recent pandemic

IoMT is helping Medical Device companies move from product suppliers to insightful partners in healthcare

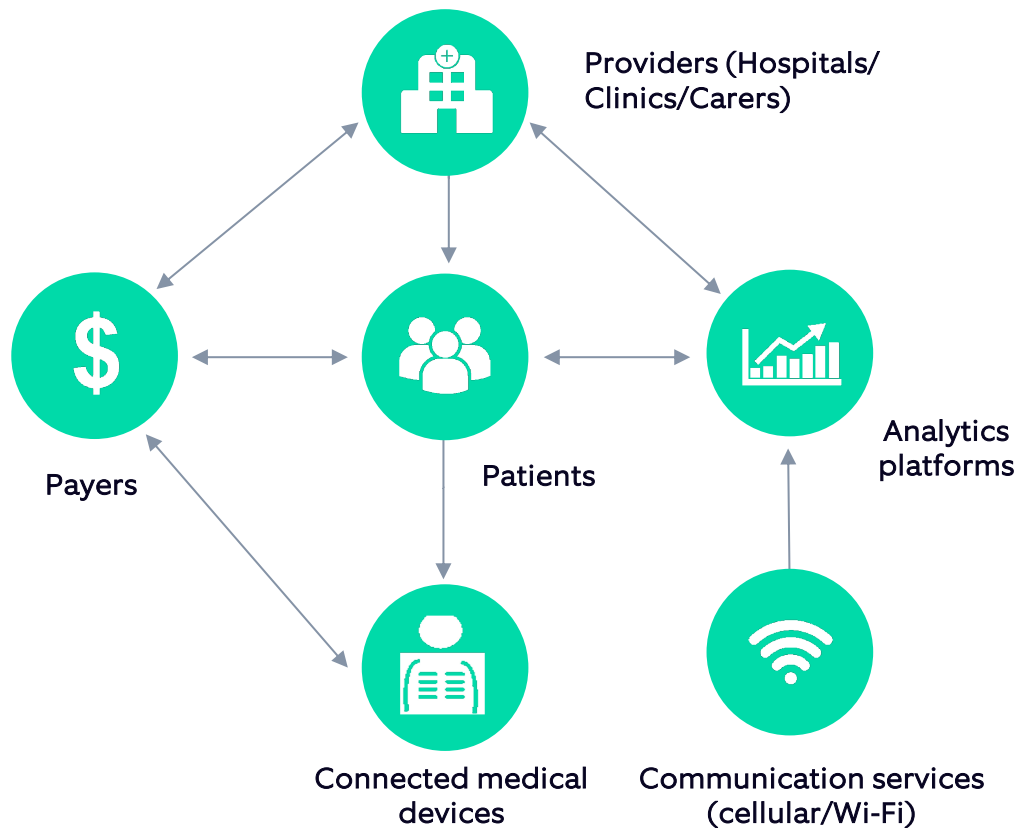| Connectivity Providers	Medical Device Providers
Systems & Software Providers	System Integrators & Service Providers
End-users	Original Equipment Manufacturers

IoMT Ecosystem

- Improved patient outcomes
- Improved diagnostic & treatment
- Decreased costs
- Remote monitoring of chronic diseases
- Improved disease management
- Enhanced patient experience

The convergence of medical devices with health information technologies is transforming patient health

Connected medical device collaborations

Providers (Hospitals/Clinics/Carers)

Payers

Patients

Analytics platforms

Connected medical devices

Communication services (cellular/Wi-Fi)

Key enablers driving connected medical device success

- Collaboration between healthcare providers and MedTech is key to the effective deployment of the connected ecosystem

- Adding connectivity to device allows data to be generated on patient's condition. This will allow medical device companies to understand the exact requirements and provide solutions that deliver value to all stakeholders

- These connected ecosystems act as a common platform to share, aggregate, and view data to drive both clinical and operational value

- Applying advanced analytics to the data generated from this connected environment will help in delivering critical insights and better decision making

Source: Deloitte.com

Applicability of blockchain is spreading across medical device value chain

Clinical	Regulatory approval	Manufacturing	Distribution	Marketing
• Patient enrolment • E-consent • Trial documentation • Data sharing	• Data sharing & tracking • Smart contracts • Records management • IP registration and exchange • Proof of existence for patents filing	• Smart contracts with CROs, CMOs • Manufacturing process control • Payment transactions across supply chain • Regulatory compliance requirements	• Digital track and traceability • Counterfeit protection • Inventory management systems • Targeted recalls • Payment transactions	• Smart patient health profile • Connected ecosystem • Secure medical device data • Preventive device maintenance • Health coin and health insurance

PHILIPS / **Gem**

Philips partnered with Blockchain specialist Gem and launched Gem Health a network for developing applications & shared infrastructure for a patient-centric approach to healthcare.

KSW / **KSB** / **UNIVERSITÄTS-KINDERSPITAL ZÜRICH** / **Spitalregion Fürstenland Toggenburg**

Recently, in January 2020, four Swiss hospitals along with two two medical device suppliers Anandic System Medical AG and ITRIS Medical AG announced successful processing on a trial of medical device orders via the Blockchain.

Surgical Robotic market is witnessing multiple new launches; expected to grow to $11 bn in size by 2025

December 2019	Medtronic received FDA clearance for its cranial robotic platform
July 2020	Smith+Nephew launched its new generation handheld robotics platform - the CORI Surgical System. The device has received FDA clearance for sale in the US.
November 2020	Ganymed Robotics announced the successful completion of functional prototype tests of its surgical robotic assistant for total knee arthroplasty
December 2020	Sysmex Corporation announced the launch of hinotori Surgical Robot System, a surgical robot unit for medical institutions in Japan
January 2021	DePuy Synthes received 510(k) FDA clearance for VELYS Robotic-Assisted Solution designed for use with the ATTUNE Total Knee System

# 3D-Printing is providing solutions for the challenges posed by COVID-19
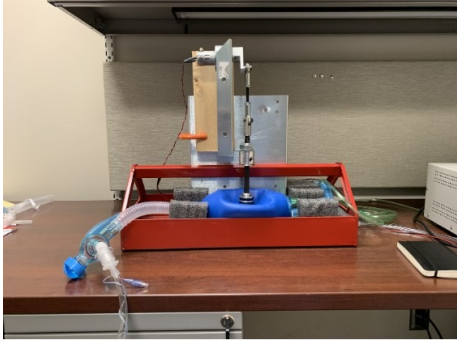
Protolab has worked with a team at the University of Minnesota to develop, a low-cost ventilator.

The ventilator relies on a motor to pump manual "Ambu" bags so that hospitals could produce their own in the event of life-or-death shortages.

Isinnova, a Brescia based engineering company met the shortage of respiratory valves

3D printing was used to connect the COVID-19 patients to the machines to save their lives.
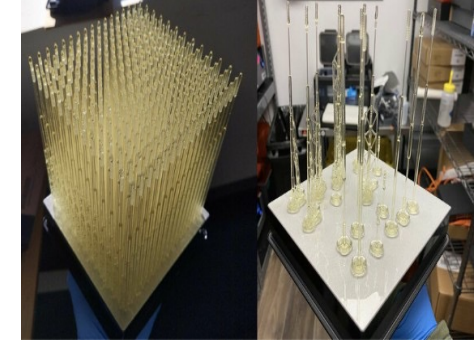
Formlabs, a 3D-printer maker, worked with medical experts at USF Health in Tampa and Northwell Health to rapidly develop and test nasal swabs.

Source: greyb.com

Technology-driven transformation

Medical Devices as a Data & Analytics Partners

Mining, managing and analyzing a vast array of data from medical grade wearables, connected imaging devices and monitoring devices is a key part of deriving value from the IoMT.

Clinical Decision Making	Risk Prediction/Patient Identification	Operational Efficiency	Measure Device Performance

Recent highlights

- In April 2019, **GE Healthcare** integrated its Edison AI platform with American College of Radiology's AI-LABTM, providing ACR members and other radiology professionals with connectivity to valuable Edison AI services
- Edison is a tool that tracks the source and usage of data in AI development and simplifies radiologists' ability to create, validate and deploy compliant algorithms with partner institutions

- In Dec. 2020, **Philips** acquired BioTelemetry
- BioTelemetry deals in remote cardiac diagnostics and monitoring with portfolios in AI based analytics & services and wearable heart monitors
- This helped the company in strengthening its AI capabilities

Medical Devices as a Service Provider

Medical device manufacturers are delivering optimized care through holistic solutions, including hardware, software, and services.

Healthcare providers are increasingly facing margin and growth pressures; increasingly seeking solutions that deliver better and more consistent outcomes at reduced costs

Medical device manufacturers are playing significant roles in collaborating with hospitals to deliver better patient care

Key services

Clinical Decision-Support Tools

Cath-lab Outsourcing

Population Health Management

Treatment Planning Tools

Workflow Management/ Consulting Services

Positioning relative to core product or portfolio offering
Some solutions are linked or adjacent to core product or portfolio offerings (e.g., clinical-support tools, Cath-lab outsourcing).

Others are agnostic to the core offer and have the potential to be stand-alone solutions (e.g., management and consulting services).

Primary stakeholder for solutions
Few solutions (e.g., treatment planning tools) are primarily targeted towards existing stakeholders including surgeons and providers.

Others (e.g., population health management & work-flow solutions) are primarily targeted towards new stakeholders including patients, payers, & broader health-system executives.

Medical Devices as a Data & Analytics Partners

There is an increase in medical devices being used for self-management and reporting pushed into home with the intended benefits of patient convenience and low healthcare cost .

Medtech manufacturers are increasingly focusing on designing devices that drives patient self-monitoring and treatment

Recent highlights

TANDEM®
DIABETES CARE

BOSE®

Tandem's **new interoperable insulin pump** can be used with different components that makes up diabetes therapy systems, allowing patients to **customize their diabetes management** to individual device preferences

Bose hearing aids – the first FDA approved hearing aids are known as the **self-fitting air-conduction hearing aid**. No preprogramming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional

Ensuring connected device "safety" will improve innovation

Mining, managing and analyzing a vast array of data from medical grade wearables, connected imaging devices and monitoring devices is a key part of deriving value from the IoMT.

| Industry-wide standards & cybersecurity by design | Improved awareness, education & training | Investments in cybersecurity incident response processes | Defining all the security requirements of the product |

Recent highlights

- In Feb 2020, GE launched new medical device cybersecurity offering, Skeye to protect connected medical devices at health systems
- It utilizes AI-enabled tools together with the security operations center to analyze, monitor and help manage cybersecurity vulnerabilities

- In Nov. 2020, Philips partnered with CyberMDX, a leader in connected medical device security, and introduce Philips Cybersecurity Services to protect connected medical systems and devices
- The services will initially be deployed in the U.S., with expansion to other geographies planned for 2021

Sources: www.mpo-mag.com, philips.com, ge.com

3D printing is addressing the Medical Device costs challenges

Cost savings	• Over **90%** of the top medical device companies uses 3D printing to develop accurate prototypes of medical devices, as well as fixtures and jigs to simplify testing • One of the medical device manufacture reported cost reduction of up to **70%**. Another medical research institute estimated that if they uses 3D printed models in **10-15%** of cases, it could save up to **$1,750,000 a year**
Affordable prosthetics	• Custom-fit prosthetics are **often expensive** and only accessible to patients with insurance in developed countries • Prosthetics are increasingly taking advantage of 3D printing's **flexible design** to mitigate these financial barriers
Surgical instruments	• Using 3D printing to produce surgical instruments is an **accurate and cost-effective** way to quickly manufacture highly-demanded medical supplies • It is easy to modify designs for surgical needs, even for complex instruments

Surgical robotics market is flourishing with multiple competitors adopting differentiation strategy

- Intuitive Surgical's minimal access surgery (MAS) robot **da Vinci** rule the market ever since its launched. A **32%** increase is reported in Intuitive Surgical's global procedures from 2017 to 2018
- However, now, over two decades after it first entered the market, da Vinci's **patents are expiring**. This expire is opening market to multiple new competitors

|	
CMR SURGICAL	- CMR Surgical is considered as a **key challenger** to Intuitive Surgical's market dominance - It raised **over 236 million** to finance the global commercialization of its MAS Versius robotic system - Its **modular design and competitive cost** are factors that should help CMR gain a larger market share in the coming years
ZIMMER BIOMET	- Zimmer Biomet is competing with like Stryker in robot assisted knee surgery through its **Rosa platform** - As of August 2020, the company had **150** Rosa knee systems placed around the world - The company acquired the initial Rosa technology through its roughly **$132 million** purchase of Medtech in 2016
TransEnterix	- The company has made a push into **automated intelligence** - TransEnterix's Senhance System boasts **haptic feedback**, surgeon camera control via **eye sensing** and improved ergonomics - The company received both **CE & US FDA** clearance for marketing

Blockchain has the ability to ensure data privacy across connected medical ecosystem

Doctor

Prescription

Heart Monitor

MRI

Bio Sensors

Blood Pressure

Lab Results
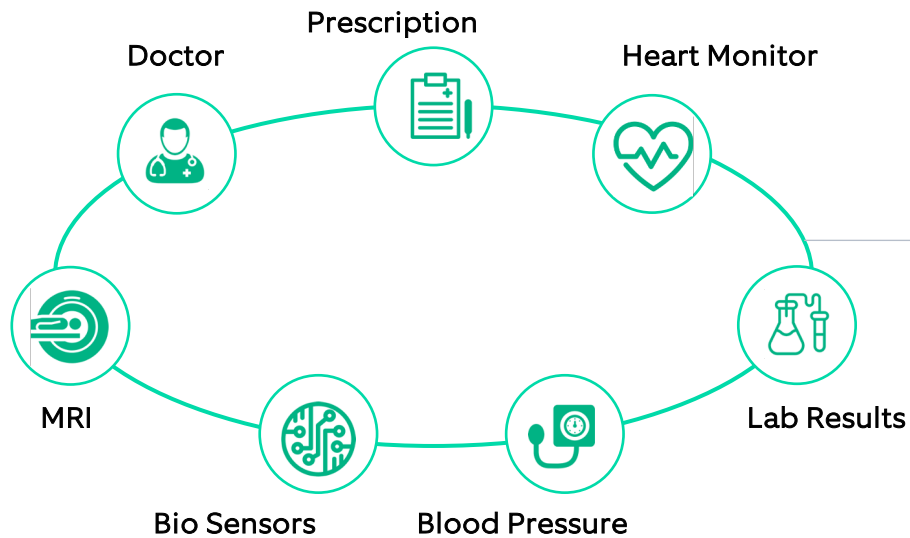
Health Blockchain

List of all health records and data collected throughout patient's life. Type & location of data is includes

Data Lake

All health data is stored in the data lake. Each blockchain transaction stores the location of health data it refers

Interoperability

Falsifying data becomes impossible, and health information, medical test dates and results, billing & payments are immutably and automatically recorded, preventing fraudulent activity

Optimized workflow

Improved data sharing process can be achieved through smooth coordination between multiple care providers, streamlined verification processes and automated claims adjudication based on immutable, complete records
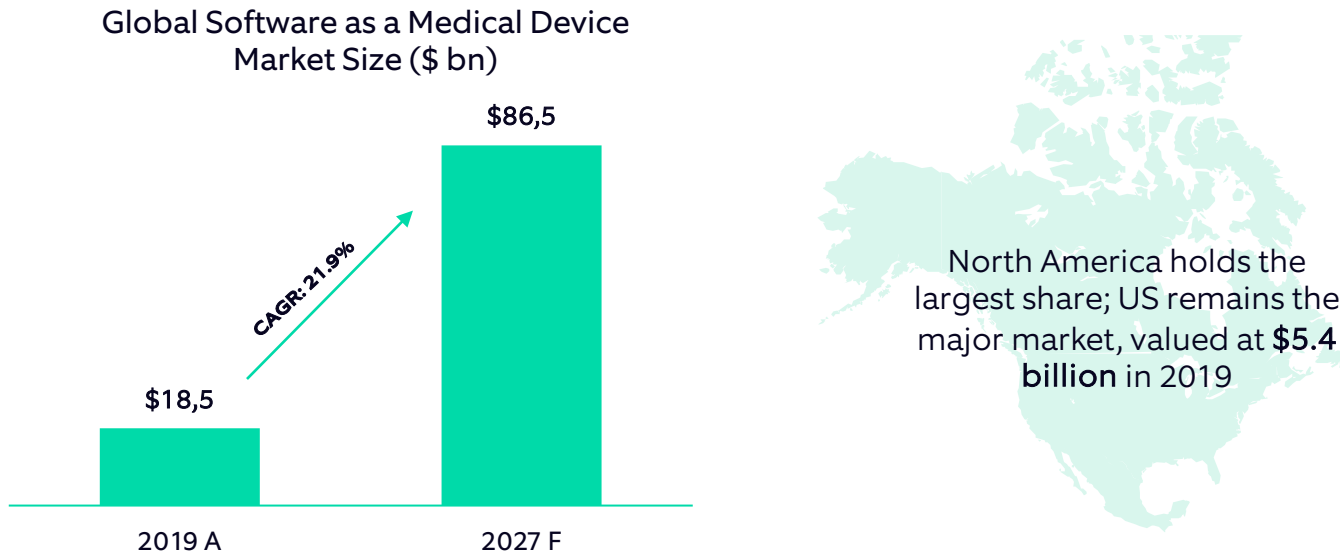
Intelligent augmentation

Blockchain technology guarantees data prevalence in healthcare and allows trust without the need for third parties. A high degree of privacy and safety is obtained by authenticating and securely storing data

Software as Medical Device (SaMD) market overview

Global Software as a Medical Device market is expected to grow to ~$86.5 bn by 2027

Global Software as a Medical Device Market Size ($ bn)

$86,5

$18,5

CAGR: 21.9%

2019 A

2027 F

North America holds the largest share; US remains the major market, valued at **$5.4 billion** in 2019

Key insights

- The software as a medical device (SaMD) market is projected to grow at a CAGR of 21.9% during the forecast period of 2019-2027
- The market is anticipated to gain ~$ 68 billion by the end of 2027 end
- This trend is driven by product differentiation being increasingly in software as well as the introduction of cloud-based and holistic solutions

Sources: FDA, Knowledge Sourcing

Types of Medical Device Software

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
- Referred to as embedded software, firmware, or micro-code

Software that are not SaMD

- If the software is part of a hardware medical device, it does not meet the definition of SaMD
- Software as a Medical Device ranges from software that allows a smartphone to view images obtained from an MRI for diagnostic purposes to CAD software

Software as a Medical Device technology is empowering patients; providing more control over their own health

Portability & affordability	KARIUS — clarity at speed	CMR SURGICAL
	freenome	SONENDO
	GenapSys	SaMD is helping revolutionize the medical device industry and the healthcare industry. The technology makes medical devices smaller, more portable, and more affordable.

Treatment ownership	ELEMENT⁺ SCIENCE	
	.Outset	The technology gives patients more access to medical devices, thus giving patients more ownership over their treatment and overall health
	vayyar	

Real-time analysis	INSIGHTEC	
	anandic MEDICAL SYSTEMS	The technology helps medical professionals get vital health information in real-time instead of only at visits
	Imperative CARE	

Sources: McKinsey, Analytics Insights, Knowledge Sourcing, boundarysys

Trends impacting the SaMD market

SaMP trends	Description	Impact on software in MedTech
Integrated solutions	Integrated medical ecosystems with shared information across medical devices and electronic health record (EHR) systems to allow for continuous care and remote management	Interoperability, software quality and cyber security become a major concern as connected medical devices are vulnerable to integration issues as well as cyber security and hacking concerns
Regulations	Regulatory bodies continue to implement stricter guidelines for medical device software, development processes, design control, and quality standards required prior to release	Developers must adopt modular architectures that allow for faster validation, collaborative development, easier integration and improved quality
Smarter devices	Multifunctional devices, combining multiple sensors, processing capabilities with customizable setup and preferences and a personalized user interface	Software is becoming the differentiator for medical device manufacturers, with increased focus on quality as products become more complex with inter-related features and new functions
Real-time analytics	Software systems that perform real-time, predictive analytics and machine learning to determine trends and risks, and to enable immediate and personalized medicine	Increased product complexity that requires new and different skill sets such as advanced analytics and algorithms, patient care operations, cloud, etc.

Recent regulatory insights

Analysis of the global medical device market, July 2021

Medical Devices as a Data & Analytics Partners

In March 2017, the EU Council adopted new medical device regulations (MDR) in order to reform existing medical device and 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.

May 2021	May 2022	May 2024	May 2025
MDR date of application	EC certificates of conformity issued before May 27, 2017 expire	Required for all EC certificates issued 5 years from the issue/renewal date or 4 years from the MDR date of application	Devices certified under the MDD can no longer be sold or distributed

From January 2021, UK adopted new medical device registration process and will not be be adopting the EU MDR

- Starting from Jan 1, 2021, a new mark was introduced in the UK – the UKCA (K Conformity Assessed) and it will be required on all devices placed on the Great Britain market from July 1, 2023
- EU will no longer recognize UK Notified Bodies, and they will not be able to issue CE certificates
- New UK regulations requires all medical devices available on the UK market to be registered with the MHRA
- Class I medical devices, custom-made devices and IVDs are required to register immediately, with other devices awarded a grace period until either May 1 or September 1, 2021

Impact of EU MDR on Medical Device Manufacturers

Reclassification or up-classification of devices

Under the MDR and IVDR, changes will made to the way the medical devices are classified.

Requirements will be scrutinized based on risk to the patients, for e.g., certain devices that come into contact with the spinal cord will move up from class II to class III.

Reclassification will require 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 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.

Key regulatory highlights of 2020

The US

• In January 2021, US FDA released "Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan" in response to stakeholder feedback on its April 2020 discussion paper

• It outlines a multi-pronged approach to advance the Agency's oversight of AI/ML-based medical software

• In September 2020, US FDA launched Digital Health Center of Excellence within the Center for Devices and Radiological Health (CDRH)

• This was intended to increase agency's efforts towards advancements in digital health technology, including mobile health devices, SaMD, wearables when used as a medical device, and technologies used to study medical products

• US FDA issued Emergency Use Authorizations (EUA) for medical device including IVD test kits for COVID-19 testing and PPE such as filtering facepiece respirators

• In addition, FDA released final guidance on ventilator devices that facilitates EUA designations for these products to treat COVID-19 patients

Sources: www.fda.gov, fdapressrelease, www.emergobyul.com, aseanbriefingcompanies.com, emergobyul.com, economictimes.com, lexology.com, emergobyul.com, emergobyul.com

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 control.

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

In **Brazil,** a new ordinance was published by **INMETRO** which requires additional registration prerequisite for most electro-medical devices subject to IEC 60601, along with some other device types such as hypodermic needles, breast implants, surgical gloves & syringes

In 2019, **Australia's Therapeutic Goods Administration** released a three-pronged proposal aimed at boosting the country's oversight of medical devices, more tightly regulating how medical devices enter the AU market, strengthening post-market monitoring and publishing more information on how decisions are made for higher risk devices.

Get in touch!

We're happy to help with any questions

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Imagine what we can do together.

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