

White Paper

THE RISE OF GLOBAL MEDICAL TECHNOLOGY

An overview of the market and trends

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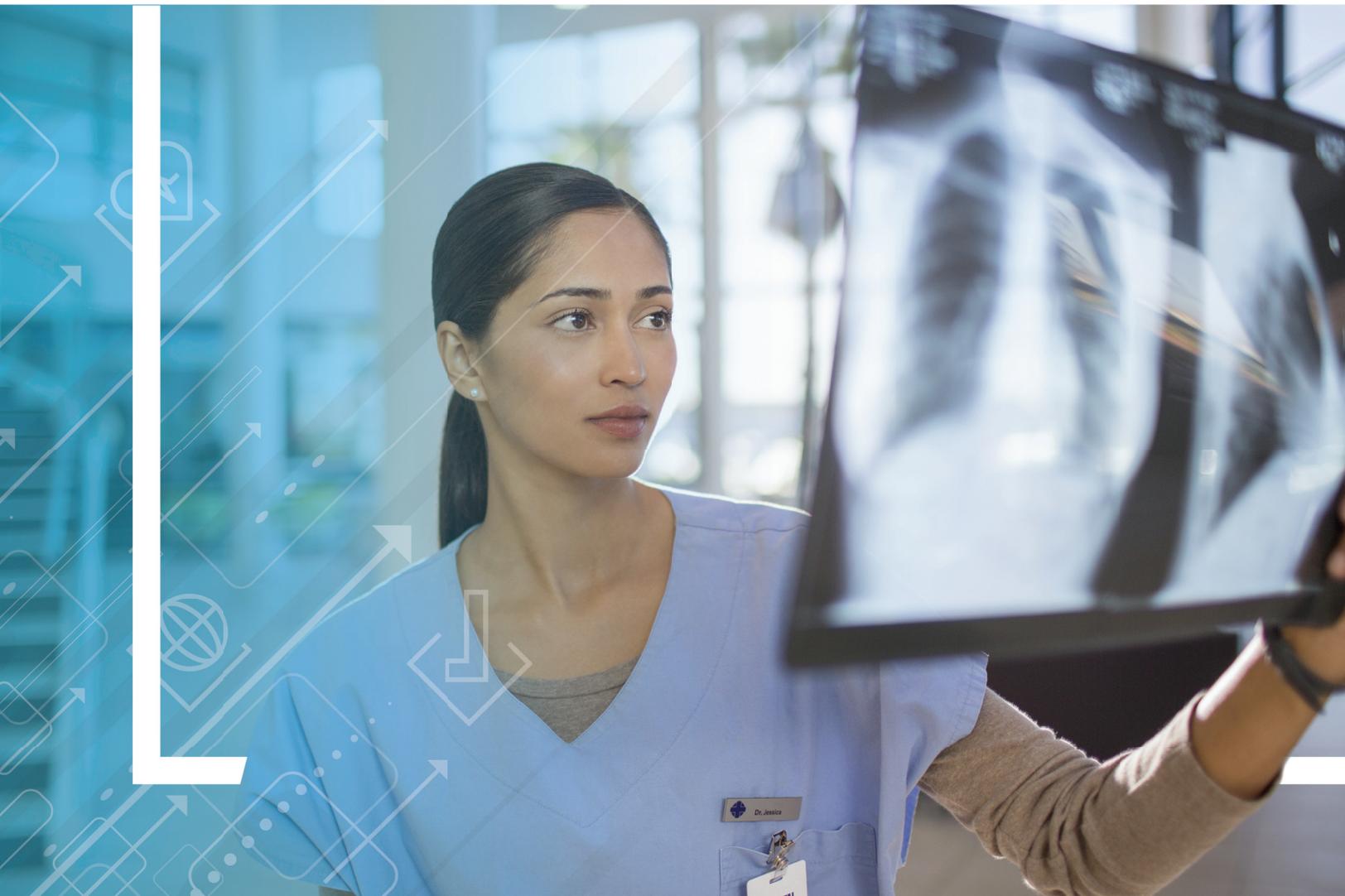


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EXECUTIVE SUMMARY

Over the past few years, the MedTech industry has witnessed significant growth and development. An aging population, rising burden of chronic diseases and increased trust in medical devices by clinicians and consumers have resulted in greater alliances between pharmaceutical companies and the MedTech sector. However, the MedTech industry is also facing increasing challenges, such as an ever-changing regulatory environment, reimbursement cuts, high cost of advanced medical technologies and safety pressures.

Despite these challenges, the global MedTech market revenue for 2017 was at \$438 billion USD. With a compound annual growth rate (CAGR) of 6%,¹ by 2022, global revenue is poised to reach an estimated \$585 billion USD.¹

The U.S. and EU are two of the largest MedTech markets, with an estimated revenue of \$162 billion USD and \$134 billion USD, respectively. Despite their market strength, developed regions are facing numerous market drivers and barriers that are restricting opportunities for growth. In order to navigate these challenges, leading MedTech companies are targeting emerging markets as potential areas for growth and development. In fact, companies like Johnson & Johnson (J&J), Abbott and Medtronic have set up manufacturing, and research and development (R&D) centers in Brazil, China and India, where markets are growing three-to-four times faster than in developed countries.

In 2017, in vitro diagnostics (IVD) held the top position among all therapeutic segments of medical technology products, followed by cardiology, with market sizes of around \$62 billion USD and \$50 billion USD, respectively. Increased incidence of chronic disease, expansion of insurance coverage and increasing affordability of MedTech products have propelled growth of these medical device segments. Neurology is predicted to be the fastest-growing segment, with a forecast growth of 9% between 2017 and 2022.

There are three main areas which have significant influence on a MedTech company's success: successfully managing the R&D process, compliance with the evolving regulatory requirements and navigating the ever-changing commercial trends such as:



Impact of Brexit



Proposed new trade tariffs in the U.S.



Investment in advanced digital technologies



Growth potential of emerging countries



Rise in mergers and acquisitions (M&A)



Adoption of a value-based reimbursement model



Increase in aging population

One of the biggest market trends has been the rise of artificial intelligence (AI). MedTech companies are investing heavily in the R&D of AI-based technologies, such as cloud-based software and healthcare applications. These technologies have the potential to change the face of the MedTech market, aiding clinical decision-making and early diagnosis of disease. AI-based technologies enable self-testing by patients and point-of-care (POC) diagnosis, resulting in fewer visits to hospitals and individualized treatment. It's not without its challenges, however, as cybersecurity issues have negatively impacted progress of AI development.²

Even though there are challenges, the global MedTech industry will continue to expand due to the rising burden of disease, aging population and greater awareness of healthcare. To navigate these challenges successfully, companies need to strengthen their position in high-growth (emerging) markets, stay in front of the evolving regulatory environments, and utilize investments in R&D and M&A activity to expand and strengthen their product offerings.

INTRODUCTION

Over the past decade, the MedTech industry has seen significant growth and has become an increasingly important partner in healthcare. Technology now plays a key role in every aspect of our daily lives, and innovative developments in MedTech have become crucial for sustaining health.

In their many forms, MedTech companies offer advanced medical devices and diagnostics used in the prevention, diagnosis and treatment of disease, such as:



Total body scanners



Blood glucose monitoring devices



Ultrasound imaging



Life-supporting machines



Implantable devices



Neuro-stimulators and prosthetics

There are now more than 500,000 types of devices available for improving, extending and transforming people's lives.³ Nowadays, both physicians and patients prefer advanced medical devices due to their targeted approach and ease of use, leading to shorter diagnosis time and quicker recovery with better outcomes.

Despite changing and increasingly complex reimbursement and regulatory processes, the global MedTech market is expected to grow at a CAGR of 6% during the forecast period.

This increased growth is mainly driven by M&A, increase in R&D expenditure, development of AI-based technologies and rising demand for MedTech products in emerging geographies such as Latin America (LATAM), Asia Pacific (APAC) and Middle East and Africa (MEA), as well as pre-established markets such as North America, Europe and Japan.

Using its in-depth industry knowledge and an extensive literature review, IQVIA™ has developed this white paper to provide an overview of:

- the global MedTech industry, including forecasts by region and therapeutic area until the year 2022
- market trends, drivers and barriers, including the impact of a changing regulatory environment
- key participants of the MedTech industry
- future outlook

The paper will also provide insight into the most critical opportunities and risks that device firms should consider when bringing new technologies to the market.

GLOBAL MEDTECH MARKET OUTLOOK

In 2017, the global MedTech market generated \$438 billion USD, and is expected to deliver a CAGR of 6%¹ resulting in an estimated \$585 billion USD¹ by 2022. North America is the leading MedTech market, followed by Europe, with estimated revenues of \$162 billion USD and \$134 billion USD, respectively.

NORTH AMERICA

- Valued as at 2017: \$162 billion USD
- Expected value 2022: \$207 billion USD
- CAGR: 5%

Canada

- Valued as at 2017: \$7 billion USD
- Expected value 2022: \$9 billion USD

United States

- Valued as at 2017: \$155 billion USD
- Expected value 2022: \$198 billion USD

Mexico

- Valued as at 2017: \$6 billion USD
- Expected value 2022: \$7 billion USD

LATAM

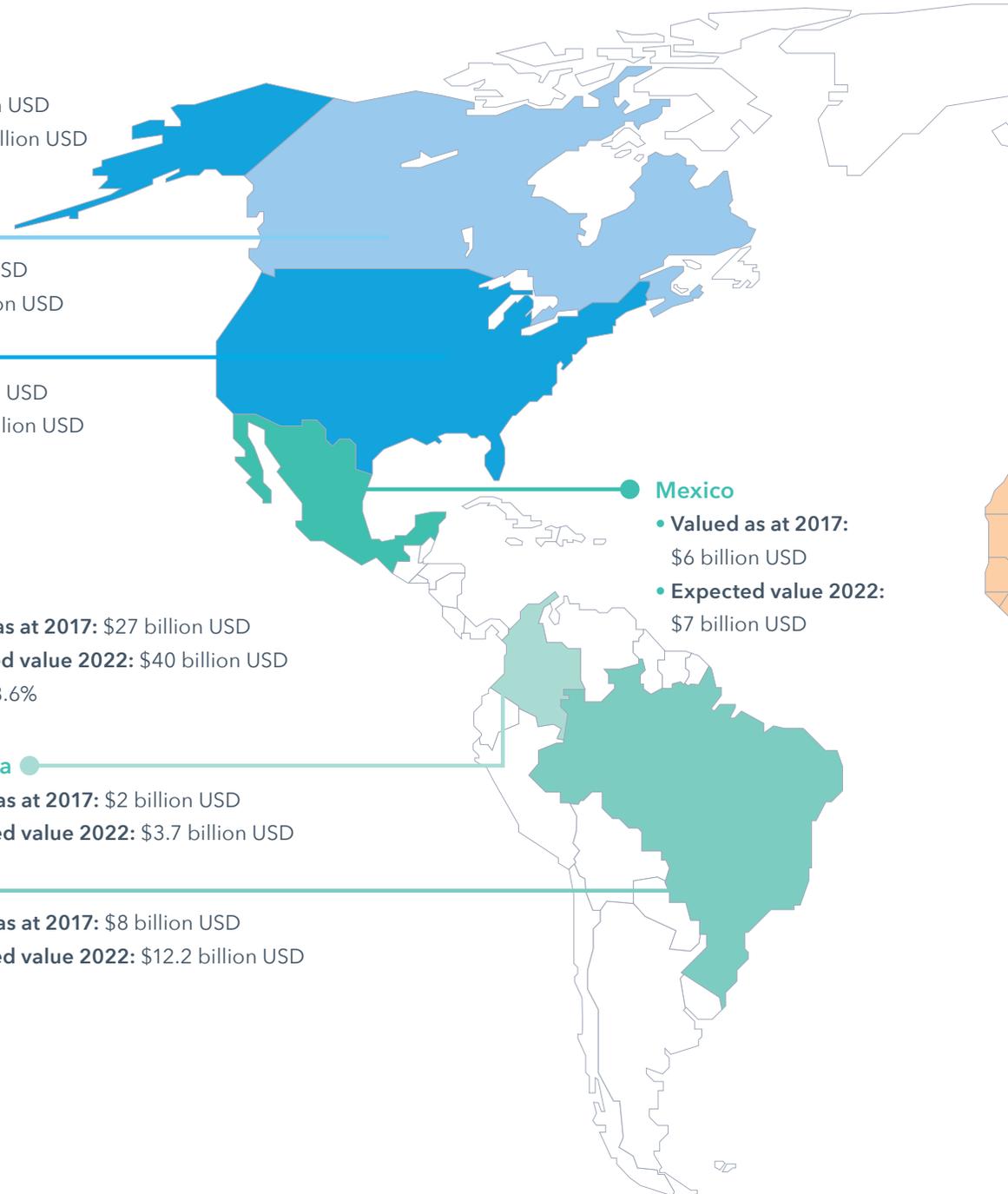
- Valued as at 2017: \$27 billion USD
- Expected value 2022: \$40 billion USD
- CAGR: 8.6%

Colombia

- Valued as at 2017: \$2 billion USD
- Expected value 2022: \$3.7 billion USD

Brazil

- Valued as at 2017: \$8 billion USD
- Expected value 2022: \$12.2 billion USD



EUROPE

- Valued as at 2017: \$134 billion USD
- Expected value 2022: \$163 billion USD
- CAGR: 4%

France

- Valued as at 2017: \$20 billion USD
- Expected value 2022: \$25 billion USD

U.K.

- Valued as at 2017: \$15 billion USD
- Expected value 2022: \$19 billion USD

Germany

- Valued as at 2017: \$36 billion USD
- Expected value 2022: \$44 billion USD

Italy

- Valued as at 2017: \$13 billion USD
- Expected value 2022: \$14 billion USD

Spain

- Valued as at 2017: \$6 billion USD
- Expected value 2022: \$7 billion USD

Turkey, Saudi Arabia and the United Arab Emirates

- Valued as at 2017: \$7 billion USD
- Expected value 2022: \$10 billion USD

Africa

- Valued as at 2017: \$7 billion USD
- Expected value 2022: \$8 billion USD

MIDDLE EAST AND AFRICA (MEA)

- Valued as at 2017: \$13 billion USD
- Expected value 2022: \$18 billion USD
- CAGR: 7.3%

APAC

- Valued as at 2017: \$103 billion USD
- Expected value 2022: \$157 billion USD
- CAGR: 8.8%

Japan

- Valued as at 2017: \$29 billion USD
- Expected value 2022: \$33.7 billion USD

China

- Valued as at 2017: \$20.4 billion USD
- Expected value 2022: \$30.6 billion USD

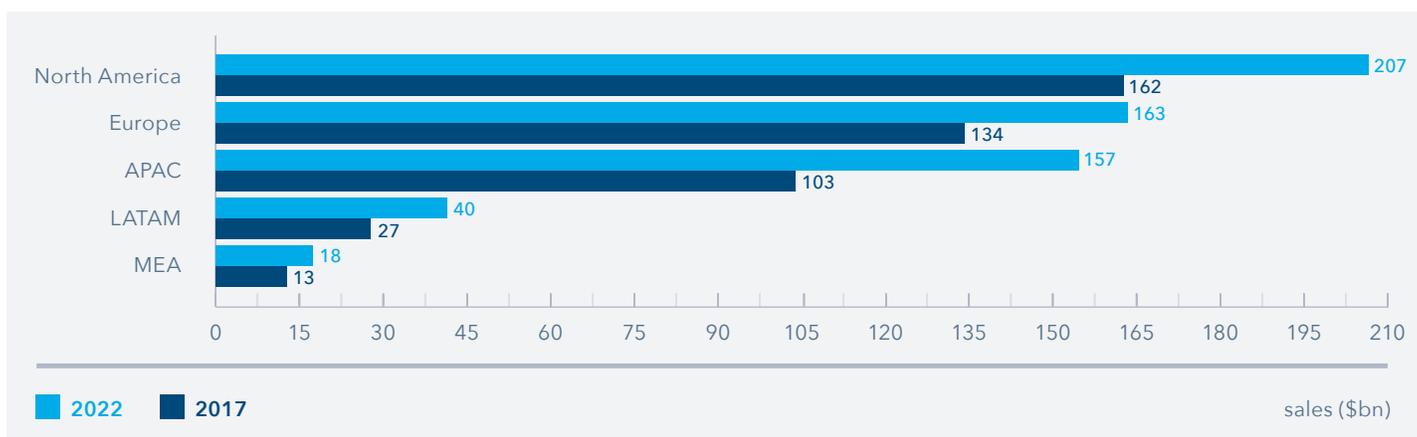
India

- Valued as at 2017: \$4.9 billion USD
- Expected value 2022: \$8.4 billion USD

GLOBAL MEDTECH OVERVIEW BY REGIONS

For the purpose of this analysis, the global MedTech market has been divided into five regions: North America, Europe, APAC, LATAM and MEA (Figure 1). Although North America and Europe currently hold 68% of the global MedTech market share, MedTech companies are shifting their focus to emerging regions of APAC, LATAM and MEA for R&D of new medical devices to facilitate increased growth and revenue (Figure 1; Table 1).

Figure 1: Global Market Share By Region



NORTH AMERICA

U.S.

The U.S. medical device industry was valued at \$155 billion USD in 2017 and is expected to reach \$198 billion USD by 2022, with an expected CAGR of 5%.¹

The U.S. Food and Drug Administration (FDA) provided premarket approval (PMA) to 46 medical devices in 2017, compared with 39 PMA approvals in 2016.⁴ It is evident that MedTech companies are adapting to higher regulatory and reimbursement thresholds, and are investing in clinical studies to prove the safety and efficacy of their medical devices.

Looking ahead, the U.S. market's performance is likely to be challenged by rapid growth in venture capital (VC) investment in China, Brazil and India, along with increasing local investor interest in emerging economies. Furthermore, poor reimbursement processes, implications of the Medical Device Excise Tax (MDET), and extra fees for classification of novel medical devices by FDA's De Novo pathway, are likely to make companies think twice before entering this market.⁵

CANADA

The Canadian medical device market generated revenue of \$7 billion USD in 2017 and is expected to reach \$9 billion USD by 2022, with a CAGR of 5.1%.¹ The Canadian market is sophisticated and mature, with a strong demand for premium quality and advanced medical technologies. In the coming years, Canada's robust manufacturing and health industries, together with initiatives in the development of advanced digital technologies, will likely boost MedTech growth in this country.

Currently, 80% of the Canadian medical device market is comprised of imported goods, which include diagnostic, orthopedic, prosthetic and dental equipment. This trend offers significant opportunities for foreign manufacturers;¹ however, companies from outside North America would face tough competition from U.S. companies, which cover more than 50% of the Canadian MedTech market. Geographic proximity and similar safety and quality standards make this relationship difficult to penetrate.⁶

EUROPE

In 2017, the European MedTech market generated revenue of \$134 billion USD, and is expected to reach \$163 billion USD by 2022.^{1,7} During the forecast period, the European market is expected to grow at a modest rate of 4% due to potential implications of the new EU Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). Nevertheless, the continued development of advanced technologies offer the potential for continued, if not moderate growth.

EU5 (France, Germany, Italy, Spain and U.K.)

In 2017, the EU5 generated around \$90 billion USD in revenue, capturing 67% of the European MedTech market share. Among the EU5 countries, the German MedTech market is the largest, with revenue of \$36 billion USD in 2017 that is expected to reach \$44 billion USD by 2022.¹ The German market is driven by a strong innovative technological environment, with the most promising MedTech areas including digital health, biomedical devices and diagnostic and imaging technologies.

France is the second highest contributor to the European MedTech industry, generating \$20 billion USD in 2017 and predicted to reach \$25 billion USD by 2022.¹ The French MedTech market is growing at a rate of 4.5%, driven mainly by an increasing elderly population, universal healthcare insurance coverage and development of advanced medical technologies such as telemedicine.

The U.K. MedTech market generated revenue of \$15 billion USD, and is expected to reach \$19 billion by 2022.¹ The predicted growth of the U.K. market is mainly driven by the development of advanced technologies and increased funding in the National Health Service (NHS) over the next five years. But the U.K. has had a slower adoption of expensive medical devices due to the conservative and lengthy process of the NHS's reimbursement system. In addition, the U.K. MedTech market is also likely to be negatively impacted by the outcomes of Brexit.

In 2017, the Italian MedTech market generated revenue of \$13 billion USD, and is forecasted to reach \$14 billion USD by 2022, at a conservative growth rate of 1.3%.¹ The slow growth is due to the economic crisis and late payment by the public sector to the medical device industry.

Although Italy has a substantial medical device manufacturing market, it is highly dependent on imports.⁸ The Italian MedTech market is a strong advocate of advanced technologies; as such, the Italian government is likely to invest in the development of AI-based technologies in the coming years.

Among the EU5, the Spanish MedTech market generated the lowest revenue of \$6 billion USD in 2017; it is expected to reach \$7 billion USD by 2022, with a sluggish growth rate of 1.3%.¹ Hampered by the economic crisis and late payment by the public sector, market growth in Spain will also be limited by budgetary pressures and cost-containment measures in the National Health System (SNS - Sistema Nacional de Salud). Additionally, irregular health investments will result in regional inequalities, decreased usage of advanced medical devices and increased taxation on devices.

REST OF EUROPE

For the rest of Europe, regulatory guidelines have been restructured to attract foreign investment in their MedTech markets to overcome the eurozone crisis. The burden imposed by new regulatory guidelines in Western Europe has ultimately driven MedTech companies to invest in the Eastern European sector.

In comparison with other markets, Eastern European countries have simpler regulatory processes and a low cost, skilled workforce – factors that have attracted investments from Western European manufacturers. In addition, the emergence of private healthcare facilities has created a fresh revenue stream for the medical device market. As a result of increasing competition among medical device manufacturers and changing policies that have served to complicate the decision-making process, strategic planning and detailed analysis of the device environment and therapeutic segments has become a critical requirement for success in Eastern Europe.

Impact of MDR and IVDR on the European MedTech Industry

In May 2017, the EU released final versions of both the MDR and IVDR, which will be implemented by 2020 and 2022 respectively.^{9,10} These regulations will completely reframe the regulatory processes for MedTech companies.

According to the new regulations, MedTech companies would have to more rigorously monitor clinical performance and collect clinical evidence following product launch. Additionally, in line with the new IVDR, 80% of IVD products will require CE approval, compared to 20% of products required by previous regulations. In order to be compliant with these new regulations, companies will now have to conduct clinical trials to prove clinical efficacy and safety of medical devices, which will further increase the cost of the products.

The European MedTech market is predominantly comprised of small MedTech companies that will be significantly impacted by the MDR and IVDR and will find it challenging to comply with the new regulations. Also, VCs that support the development of innovative medical devices are beginning to ask if MedTech companies can develop and market their products in line with the new regulations while maintaining required financial returns in light of the new MDR and IVDR requirements.

While the MDR and IVDR will make it more difficult to bring products to market, there is nonetheless a positive aspect to the new regulations. By identifying risks associated with marketed products, the regulations will serve to enhance the safety of medical devices and, in doing so, strengthen the trust of patients, doctors and regulatory bodies in their use.

APAC

In 2017, the APAC region generated revenue of \$103 billion USD and is estimated to reach \$157 billion USD by 2022. The projected growth of 8.8% is mainly driven by factors such as:

- an aging population
- increased incidence of chronic diseases
- establishment of R&D centers by major MedTech companies
- collaboration between foreign and local companies
- generous reimbursement structures and increased government focus on the development of healthcare infrastructure

APAC is a mix of individual markets, with trends differing from country to country.

JAPAN

In Japan, robust reimbursement structures, a favorable environment for the development of innovative technologies, and initiatives taken by the government to promote the healthcare industry, have enabled Japan to hold a 6.6% share of the global MedTech market.¹ On the other hand, internal competition and absence of direct approval of the CE mark and FDA-approved products in Japan are limiting growth to a moderate 3%.

CHINA

Recently, major MedTech companies have focused on China's MedTech market, which is growing at a rate of 8.5%.¹ Currently 80% of advanced technologies are imported, which makes China an attractive market for long-term investments. However, the government's "Made in China 2025" initiative has conveyed that China is keen on keeping the cost of MedTech products low, encouraging local companies to manufacture advanced medical devices instead of importing them.

As a further incentive, the Innovative Medical Device Assessment office (part of the Chinese Food and Drug Administration [CFDA]) provides grants and loans to local companies to support R&D in segments such as diagnostic imaging, cardiovascular implants and IVD. These initiatives, along with reimbursement and tendering process reforms, have strengthened the competitiveness of local companies.

INDIA

India is among the top 20 MedTech markets in the world, with revenue of \$4.9 billion USD in 2017.¹ Future growth will be driven by the rapid expansion of R&D investment, economic expansion of the middle-class population, and multiple government initiatives such as Ayushman Bharat (health insurance scheme), "Startup India" (support for startup businesses) and "Make in India".

As part of these newly introduced regulations, device registration fees have been reduced to facilitate the

availability of high-end medical devices in the country. Furthermore, these regulations include a shift from four to two-phase clinical trials, making it easier for manufacturers to increase their footprint in the market. From January 2018, the newly drafted regulations have been implemented in accordance with the Global Harmonization Task Force (GHTF) framework, resulting in the adoption of global best practices.¹¹

LATAM

Together, LATAM countries including Brazil, Mexico, Colombia, Chile, Argentina and others comprise the fourth largest economy in the world,¹² with healthcare expenditure comparable to that of China and India. In 2017, the LATAM MedTech market had generated revenue of \$27 billion USD, with a substantial growth rate of 8.6%.¹

Brazil has the largest MedTech market in the LATAM region¹² with a forecasted market size of \$8 billion USD, followed by Mexico and Colombia, which have market sizes of \$6 billion USD and \$2 billion USD, respectively. The increased incidence of chronic diseases, rise in the economic status of the middle-class population, and the availability of skilled labor are the key driving factors for growth in the LATAM MedTech market. However, in order to meet the standards of the FDA and European notified bodies, regulatory guidelines in LATAM countries are rapidly changing, which has increased the complexity of approvals for foreign registrations. Despite the changing regulatory environment, some LATAM countries offer expedited approval routes for devices that are already FDA-approved or CE-marked.

MIDDLE EAST AND AFRICA (MEA)

In 2017, the MEA region generated revenue of \$13 billion USD, and is expected to reach \$18 billion USD by 2022, with an expected CAGR of 7.3%.¹ Despite tremendous

differences in the financial status among the countries of the Middle East, the majority of MedTech markets are growing at a considerable rate. This growth is mainly influenced by factors such as increased population size, improved economic status of the middle-class, insurance coverage, improved healthcare indicators and an increasing incidence and burden of lifestyle-related diseases such as type 2 diabetes, obesity and cardiovascular disease.¹³

TURKEY, SAUDI ARABIA AND THE UNITED ARAB EMIRATES

Turkey, Saudi Arabia and the United Arab Emirates were the three largest Middle Eastern MedTech markets in 2017. This is largely attributed to individual government initiatives to drive healthcare markets, creating new opportunities for businesses.

With respect to medical device regulations, most Middle Eastern countries have their own monitoring and approval systems, which has made approval processes in these countries extremely difficult. In the last few years, efforts have been made to standardize the regulations against global guidelines. The International Medical Devices Regulators Forum (IMDRF), which builds on the strong foundational work of the GHTF, is working towards the harmonization of regulatory requirements between Middle Eastern countries and international medical device companies.^{11,14}

Reimbursement processes have been a challenge for MedTech companies due to the multi-factorial processes involved, but acceptance of CE and FDA-approved products in Turkey and approval of MedTech products from Saudi Food and Drug Authority (SFDA) have paved the way for foreign companies to enter the Middle Eastern market.

Although North America and Europe currently hold 68% of the global MedTech market share, MedTech companies are shifting their focus to emerging regions of APAC, LATAM and MEA for R&D of new medical devices to facilitate increased growth and revenue

AFRICA

In Africa, the MedTech market is mainly driven by the development of stronger, biocompatible materials, as well as growth of healthcare mobile applications and cloud integration. Conversely, a number of key factors are restraining growth of the MedTech market in Africa, including:

- economic burden
- poor internet connectivity
- high cost of imported medical devices
- high sales tariffs

- dynamic regulatory framework
- low penetration of medical devices

Africa is extremely dependent on medical device imports, which account for approximately 90% of the total market and are predominantly from Chinese medical device suppliers. Africa, South Africa and Egypt account for 40% of the MEA MedTech market. Collaboration with global companies and technical transfer will remain the key strategy for developing the African market.

Table 1: Global Medtech Market Revenue By Regions

Region	Sales (\$bn)		CAGR	Factors Influencing the MedTech Market Growth Rate				
	2017	2022	% Growth	Impact of Regulatory Authorities	Reimbursement Process	R&D Expenditure	M&A	Development of Advanced Technologies
North America	162	207	5%	++++	+++	++	+++	++++
Europe	134	163	4%	++++	++++	++	+++	++++
APAC	103	157	8.8%	+++	+++	+++	++	+++
LATAM	27	40	8.6%	++++	++++	+++	++	++
MEA	13	18	7.3%	++++	++	++	++	++
				+ Positive Impact			+ Negative Impact	

GLOBAL MEDTECH OVERVIEW BY SEGMENTS

While MedTech is largely an aggregation of a number of individual segments, the top seven represent almost 60% of the total market (Table 2). With annual sales in 2022 forecasted to be \$77.6 billion USD, IVD is the largest segment and is well ahead of the second-placed cardiology segment. Neurology is predicted to be the fastest-growing segment, with an estimated yearly market growth of 9% between 2017 and 2022.¹

Table 2: Worldwide Medtech Sales By Segments: Top 15 Segments (2017 & 2022)

Segment	WW Sales (\$bn)		CAGR	Market Share		Chg. (+/-)
	2017	2022	% Growth	2017	2022	
 IVD	62.2	77.6	+4.5%	14.2	13.2	-0.9
 Cardiology	50.1	69.9	+6.9%	11.4	11.9	+0.5
 Diagnostic Imaging	43.1	53.9	+4.6%	9.8	9.2	-0.6
 Orthopedics	38.7	49.8	+5.2%	8.8	8.5	-0.3
 Ophthalmology	29.1	39.7	+6.5%	6.6	6.8	+0.2
 General & Plastic Surgery	22.8	31.2	+6.5%	5.2	5.3	+0.1
 Endoscopy	20.1	28.8	+7.5%	4.6	4.9	+0.3
 Drug Delivery	20.7	27.6	+5.9%	4.7	4.7	0-0
 Dental	14.4	20.0	+6.8%	3.3	3.4	+0.1
 Wound Management	14.4	19.0	+5.6%	3.3	3.2	-0.1
 Diabetic Care	12.5	18.2	+7.9%	2.8	3.1	+0.3
 Nephrology	12.3	16.4	+5.8%	2.8	2.8	0-0
 General Hospital and Healthcare Supply	12.0	14.4	+3.7%	2.7	2.5	-0.3
 Neurology	8.5	13.0	+9%	1.9	2.2	+0.3
 ENT	9.0	12.5	+6.8%	2.0	2.1	+0.1
 Others (Wound care management, Healthcare IT, etc).	68.6	93.5	+6.4%	15.7	16	+0.3
Total	438.2	585.4	6%			

IVD

In 2017, the IVD segment generated a revenue of \$62.2 billion USD and is expected to reach \$77.6 billion USD by 2022, with a CAGR of 4.5% (Table 2). IVD is comprised of sub-segments, each featuring varying technology, as well as regional and competitor trends. At a high level, the IVD industry can be segmented into laboratory, diabetes, POC, molecular and histochemistry, which together comprises 98% of global revenue. Growth of the global IVD market is mainly driven through an increased awareness of wellness testing, together with a rise in non-communicable, lifestyle-related diseases, such as cardiovascular disease and type 2 diabetes. Increasing adoption of automated platforms, personalized medicine, expansion of universal healthcare and primary care models in select regions of APAC and LATAM will increase the need for IVD solutions. Conversely, pricing pressure due to increased budgetary constraints and reimbursement cuts, introduction of the Patient Protection and the Affordable Care Act (PPACA) in the U.S., and changes in regulatory guidelines in Europe are predicted to lead to a decline in market share of the IVD market by 0.9% during the forecast period.

For more detailed information on IVD, please refer to IQVIA's White Paper on "Global Outlook on the In Vitro Diagnostics Industry" (available at: iqvia.com/library/white-papers/global-outlook-on-the-in-vitro-diagnostics-industry).

CARDIOLOGY

Cardiology is the second largest MedTech segment, with global annual sales of \$50.1 billion USD in 2017, which are projected to reach \$69.9 billion USD at an expected CAGR of 6.9% by 2022 (Table 2).

The cardiac medical device market includes pumps and heart-lung machines, diagnostics, defibrillators, implants and surgical equipment. Growth of the cardiology market is mainly driven by technological advancements such as the introduction of magnetic resonance imaging (MRI), pacemakers, subcutaneous implantable cardioverter-defibrillators (ICDs) and home-automated external defibrillators (AEDs).¹⁶ Other contributory factors in the expansion of the cardiac medical device market include:

- advanced infrastructure
- arrival of new professional skills in emerging markets

- wider availability of medical insurance
- acceptance of reimbursements for different types of cardiovascular diseases

DIAGNOSTIC IMAGING

In 2017, diagnostic imaging generated a global revenue of \$43.1 billion USD and is expected to reach \$53.9 billion USD by 2022, with a modest growth rate of 4.6% (Table 2). The high cost of diagnostic imaging technologies has restrained the growth rate of this segment by forcing developed MedTech markets, such as the U.S. and Europe, to pursue technologies that are considered efficient and affordable for hospitals and healthcare providers. Additionally, the radiological side effects of imaging and shortage of trained users have further limited growth of the diagnostic imaging segment. It is anticipated, however, that medical imaging will see a growth in the coming years due to an aging population, increasing cancer rates, increased investments and government grants, adoption of cloud-based technologies, as well as an increasing preference for minimally invasive treatments.¹⁵

ORTHOPEDICS

The global orthopedics devices market was valued at \$38.7 billion USD in 2017, and is expected to reach \$49.8 billion USD by the end of 2022, with a CAGR of 5.2% (Table 2). The emergence of advanced technologies such as robotic surgeries, ortho-biologics, smart sensor-enabled devices, implants and 3D printing techniques, in parallel with a predicted increased incidence of orthopedic disorders such as osteoporosis, arthritis and sports injuries will be significant contributors to increased market growth.¹⁶

Despite positive market drivers, challenging market conditions such as high cost of implants, reimbursement constraints, biocompatibility issues, strict regulatory approval procedures, lack of skilled labor, and strong competition in the orthopedics device market will hamper market growth.

OPHTHALMOLOGY

The global ophthalmic devices market accounted for \$29.1 billion USD in 2017 and is anticipated to reach \$39.7 billion USD by 2022, with an expected CAGR of 6.5% (Table 2). An increased prevalence of eye diseases, such as glaucoma, cataracts, macular degeneration and diabetic retinopathy will be primary growth factors in the ophthalmic market.

Additionally, the increased use of technologically advanced, minimally invasive surgeries such as laser-assisted in situ keratomileusis (LASIK) surgery, multi-wavelength diabetic retinopathy treatment, ultrasound phacoemulsification and femtosecond laser surgery will further increase the revenue and market share of the ophthalmic device segment. On the other hand, lack of patient awareness about eye-related diseases may lower the growth rate of the market during the forecast period.

ENDOSCOPY

The endoscopy MedTech market is estimated to reach \$28.8 billion USD by 2022, increasing from \$20.1 billion USD in 2017, at an expected CAGR of 7.5% (Table 2). An increase in the prevalence of cancer, gastrointestinal diseases and other chronic diseases will be key drivers for market growth, in addition to increasing numbers of hospitals and increased investment in endoscopy facilities.¹ Technological advancements in visualization, diagnosis, surgical endoscopic treatment and an increased awareness among healthcare professionals and patients regarding the benefits of endoscopic technologies are stimulating the demand for endoscopic devices and boosting market growth. However, the high cost of endoscopy procedures, equipment and reimbursement restrictions are likely to limit market growth.

DIABETIC CARE

The diabetes MedTech segment was valued at \$12.5 billion USD in 2017 and is forecast to reach \$18.2 billion USD by 2022, with a significant growth rate of 7.9% (Table 2). Principal growth factors will be the increased prevalence

of obesity and cardiovascular diseases due to sedentary lifestyles, as well as the development of advanced technologies. Moreover, advancements in the monitoring and delivery of insulin have provided significant opportunities to large MedTech companies; however, high costs of treatment and reimbursement challenges have stifled market growth.

NEUROLOGY

Although neurology does not currently command a high market share, it is forecast to be the fastest growing medical device segment, with a significant growth rate of 9% and predicted global revenue of \$13 billion USD by 2022 (Table 2). Key growth factors will be the predicted increased incidence of neurological disorders such as Alzheimer's disease, ischemic stroke, multiple sclerosis, brain cancer and other neurologic traumas. Additionally, a global aging population will generate an increased demand for neurological medical devices. Moreover, patients are indicating a preference for treatment with medical devices versus pharmacological therapies due to greater efficacy and fewer side effects.¹⁷

The neurology medical device industry is forecasted to be the fastest-growing segment, with a significant growth rate of 9%, expected to generate a revenue of \$13 billion USD, by 2022

KEY MARKET TRENDS

The future trends of the medical device industry are reflective of the swift pace of development of innovative medical technologies observed over the past few years. As MedTech companies realize the benefits of analytics, AI and new digital technologies, the MedTech industry will see a new wave of opportunities for increased growth and market share. Conversely, new regulatory guidelines and reimbursement models will likely impede development of new products. In this section, we discuss some of the most salient commercial, regulatory, compliance and R&D trends that are currently impacting the growth of the MedTech market and consider the impact of these factors on future growth.

COMMERCIAL TRENDS

Impact of Brexit on the Medical Devices Sector

The planned exit of the U.K. from the EU on March 29, 2019 has led to ongoing discussions on future trade and regulatory obligations between the EU and U.K. Although many anticipate that a mutually beneficial withdrawal deal will emerge, the European Commission issued a Notice to U.K. economic stakeholders (including manufacturers, importers, distributors and authorized representatives) on January 10, 2018, emphasizing the legal and practical implications of a potential “No Deal” scenario on medical devices, active implants and in vitro medical devices.

Irrespective of the outcome, it is certain that Brexit will have far-reaching impacts on the MedTech industry. Potential consequences are discussed below.

Impact of Brexit on U.K. Manufacturers, Importers and Distributors

Currently, countries located outside of the EU are considered “third countries.” Economic operators who place products on the European medical device market from a third country are considered importers and must comply with specific union legislation (Directive 85/374/EEC) that differs from legislation applied to products sourced from within the EU. The Directive will apply to the U.K. following its formal withdrawal from the EU and distributors will become liable for their product.

Establishment of Authorized Representatives

Manufacturers located outside of the EU must appoint authorized representatives to ensure compliance with the relevant EU product legislation and conformity assessment procedures. Representatives located in the U.K. are no longer recognized as authorized representatives; the European Commission Notice directs that all U.K. manufacturers must take steps to ensure that they have an authorized representative settled in the EU before March 29, 2019 in order to continue marketing their products within Europe.

Impact on CE Certification

According to current EU product legislation, MedTech companies must appoint notified bodies to conduct conformity assessment procedures to certify that the product complies with EU standards and requirements. Compliance is verified by a CE certificate and CE marking of products.

Post March 29, 2019, U.K. notified bodies will no longer be recognized and will be removed from the EU’s New Approach Notified and Designated Organizations (NANDO) information system. As such, U.K. notified bodies will no longer be able to perform conformity assessments and CE certificates issued prior to Brexit may be canceled. Instead, U.K. MedTech companies who wish to continue marketing their devices in the EU will have to apply for a new CE certificate issued by the EU notified bodies. They may also temporarily transfer

the CE certificate of their products to the EU notified body; however, transfer will most likely be expensive, adding to the manufacturing cost of devices, making them more costly for consumers.

Impact of Trade Tariffs on the MedTech Market

In April 2018, U.S. President Donald Trump announced that the U.S. government would impose a 25% tariff on Chinese imports. The U.S. administration has also threatened to impose an additional \$100 billion USD in tariffs on top of the original \$50 billion USD, after China announced it would impose \$50 billion USD in tariffs on U.S. products, triggering a global trade war.

On April 3, 2018, the U.S. Trade Representative (USTR) released a list of products that would be subject to 25% tariffs. The list includes medical devices and would affect MRI scanners, orthopedic devices, defibrillators, X-ray equipment, sports medicine, patient monitoring systems and respiration devices.

If implemented, the tariffs will impose an increased cost burden on major MedTech firms such as Zimmer Biomet, Medtronic and GE Healthcare, all of whom import devices from China at a lower price. Conversely, the medical device industry in countries like Japan, China and Korea is likely to benefit from lower prices of medical devices, as Asian MedTech companies are encouraged to manufacture devices at a lower cost.

Development of Advanced Technologies

Advances in digital technologies, such as robotic surgery units, 3D printing, portable and handheld ultrasound and digital tomosynthesis, have led to an increased interest and uptake of digital devices among key stakeholders, including patients, providers, payers and regulators. This has been coupled with increasing clinical evidence for the benefits of digital applications in chronic diseases such as diabetes, depression and anxiety.¹⁸

The global market share of emerging markets is expected to increase to one-third of the total MedTech market by 2022

In 2017, major MedTech companies began collaborating with startup digital device manufacturers and global technological companies such as Google, Apple and IBM. For example, Medtronic has collaborated with IBM Watson, Qualcomm and Glooko to create an integrated diabetes management program that allows patients to track their blood sugar levels and receive appropriate therapeutic doses of insulin.^{19,20,21} This innovative tool has resulted in fewer visits to hospitals and a reduction in treatment costs.

Despite the threat of cybersecurity issues related to digital technologies, investment by healthcare organizations in digital health technology continues to grow. Indeed, in the next ten years, use of digital health technology is likely to become a standard-of-care for many healthcare providers.

Long-Term Investment in Emerging Markets

Emerging markets are likely to see a significant increased usage of medical devices in the coming years, due to government-led healthcare initiatives, increased prevalence of chronic diseases, as well as increased insurance coverage and affordability. The growth of the economy and growing medical awareness in these countries have ensured that they are viewed as good investment opportunities. The global market share of emerging markets is expected to increase to one-third of the total MedTech market by 2022, which will further encourage key market players to make long-term investments.

Further compounding the shift, new regulatory guidelines and complex reimbursement processes in developed regions such as the U.S. and Europe have shifted the focus of major MedTech companies to emerging countries such as China, India and Brazil.

Table 3: Top M&A of 2017

Acquiring Company	Acquired Company	Deal Value (\$bn)
Becton Dickinson	C.R. Bard	24
Cardinal Health	Medtronic (medical supplies)	6.1
Johnson & Johnson	Abbott (Abbott Medical Optics)	4.3
Svenska Cellulosa Aktiebolaget	BSN medical	3.0
Allergan	Acelity (LifeCell)	2.9
Hologic	Cynosure	1.7
Integra LifeSciences	Johnson & Johnson (Codman Neurosurgery)	1.0
Teleflex	Vascular Solutions	1.0
Stryker	Novadaq Technologies	0.7

Increase in M&A and Strategic Partnerships

In recent years, M&A has become a driving force of MedTech industry growth (Table 3). Indeed, this has been the biggest recent trend in the MedTech industry. The total value of MedTech M&A rose by a massive 178% in the first half of 2017, and MedTech companies have invested considerably in M&A in order to maximize the number of therapeutic segments in which they operate. M&A is widely focused on the development of innovative medical devices, expansion into different geographies and increase in market share, along with accelerated revenue growth.

It is interesting to note that companies are not only acquiring or merging, but also divesting in order to focus on their core portfolios. For example, Medtronic sold its monitoring and recovery business to Cardinal Health for \$6.1 billion USD cash. As part of this deal, Medtronic handed over its patient care,

deep vein thrombosis and nutritional insufficiency divisions to Cardinal, who is well known for its expertise in these areas.²²

Additionally, in order to provide clinical evidence for approval of medical devices, MedTech companies are increasingly collaborating with pharmaceutical companies to undertake clinical trials.

Moving Towards a Value-based Reimbursement Model

In the past, major MedTech companies have not been concerned about the impact of insurance reimbursement models. In 2015, however, the U.S. Department of Health and Human Services (DHHS) and Medicare Access and CHIP Reauthorization Act (MACRA) set a goal to link traditional payments to a value-based reimbursement model by end of 2018.^{23,24} The value-based reimbursement model is likely to replace the fee-for-service model completely, suggesting that doctors will receive their payments based on the outcomes of the treatment for patients. Thus, in order to increase their value-based payments, companies are investing money in developing medical devices that offer superior therapeutic results.

Increase in Aging Population

According to a recent report funded by the National Institutes of Health (NIH) and developed by the U.S. Census Bureau, currently 8.5% of the global population, equating to approximately 617 million people, are aged 65 and above.²⁴ This number is expected to more than double by 2050 to 1.6 billion.^{24,25} An aging population is increasing the need for medical devices, especially those used in the diagnosis and treatment of orthopedic, cardiovascular and eye disorders. In addition, the increase in diabetes, obesity and cardiovascular disorders in elderly patients has accelerated the development of advanced digital technologies such as healthcare apps and wearable devices that enable patients to self-monitor glucose, heart rate and blood pressure.

R&D TRENDS

Continuous growth and a competitive environment in the MedTech industry have resulted in companies developing innovative medical technologies, rather than investing in the existing ones. In 2017, worldwide R&D expenditure by MedTech companies was \$27.8 billion USD; this is expected to reach \$33.5 billion USD in 2022, with a growth rate of 4.7%. Key R&D trends are discussed opposite.

Rise of Artificial Intelligence

AI has extensive applications in the fields of drug discovery and medical imaging, being capable of performing tasks that require human-like qualities of judgment and perception.²⁶

Currently, the majority of AI-based technologies are developed by start-up companies. For example, Sense.ly developed the first virtual nurse, Molly, to help people monitor and treat their conditions between doctor's visits.²⁷

Major companies such as IBM, Google and Apple are also involved in the development of AI-based technologies, such as the IBM program, Medical Sieve, which has been designed to assist in clinical decision-making in radiology and cardiology.²⁷

AI applications for medical devices generally fall into three main categories:²⁸

- **Management of chronic disease:** Machine learning is used to monitor patients in order to automate the delivery of treatment using connected mobile apps (e.g., diabetes and automated insulin delivery)
- **Medical imaging:** AI technologies present multiple opportunities to detect subtle signs of a disease in medical images more accurately than humans. Companies are incorporating AI-driven platforms in medical scanning devices to improve image clarity and clinical outcomes by reducing exposure to radiation and detecting early signs of disease (e.g., GE Healthcare CT scans for liver and kidney lesions; Enlitic and Picture Archiving and Communications [PAC] deep learning algorithm for detecting signs of disease from MRI, CT scans, ultrasound and X-ray²⁹)
- **AI and Internet of Things:** Companies are integrating AI and Internet of Things to better monitor patient adherence to treatment protocols and to improve clinical outcomes

Despite its potential for transforming the healthcare industry, AI technology development is currently hindered by:

- cybersecurity issues
- challenges of high-volume data storage
- training of medical personnel
- high cost
- lack of satisfactory software for rare medical conditions

- reluctance by patients to adopt new technologies in their treatment plan

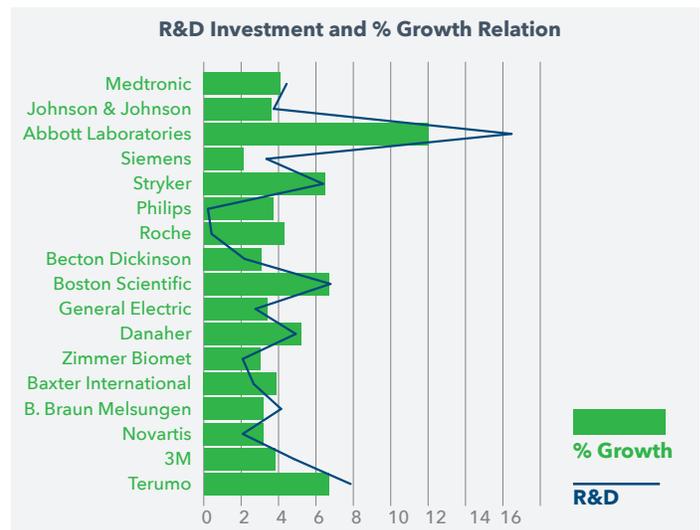
Despite such barriers, investments by MedTech companies in the development of AI-based technologies are likely to increase, with AI becoming a standard-of-care for many healthcare providers.

Increasing R&D spend

Technological advancements such as in robotic surgery and 3D printers have encouraged firms to invest heavily in R&D, serving to increase product portfolio and financial outlook.

Figure 2 provides an overview of R&D spending and impact on growth of some of the leading firms in the MedTech industry.

Figure 2: Impact of R&D Expenditure on Growth Rate of Top 15 Medtech Companies



REGULATORY AND COMPLIANCE TRENDS

Changing Regulatory Environment and Government Initiatives

Over the past few years, increasingly stringent regulatory guidelines and continually changing regulatory environments have become one of the biggest barriers to growth of the MedTech market in developed regions (Table 4). Conversely, government initiatives in emerging markets such as China, India and Brazil have incentivized investments from large MedTech companies (Table 4).

Reimbursement Scenarios for the MedTech Market

Similarly, reimbursement processes for medical devices across different geographies have also impacted the growth rate of the MedTech industry (Table 5). In developed regions, complex reimbursement processes and an increasing inclination towards Health Technology Assessments (HTA) have impacted the commercial model of many MedTech products. On the contrary, government-led initiatives have increased the growth rate of the global MedTech market in developing countries.

Table 4: Changing Regulatory Environment and Government Initiatives

Geographies	Changing Regulatory Environment and Government Initiatives
North America (U.S. and Canada)	<ul style="list-style-type: none"> • Risk-based approach for approval of medical devices will slow down the development of new medical devices • Benefit-risk framework to facilitate patient participation: benefit-risk assessments are done in advance, customized to the patient's needs, to enable earlier access to useful new devices that meet patients' needs³⁰ • Reliance on De Novo pathway will further increase the cost burden on MedTech companies • The Health Canada initiative in establishing Therapeutic Products Directorate's Medical Devices Bureau will allow targeted pre-market review of digital health technologies³¹ • Health Canada has been actively engaging with the medical device industry to support its transition to the new Medical Device Single Audit Program (MDSAP) by January 1, 2019 in order to reduce audit time for small enterprises³² • Health Canada has conveyed that all manufacturers of class II, III, and IV medical devices holding licenses or applying for new, or amending licenses must complete the transition to ISO 13485:2016 by March 1, 2019
Europe	<ul style="list-style-type: none"> • Implementation of Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) will further increase the cost of medical devices, as any payments made to the notified bodies for consulting services have to be covered by the manufacturers • Difficulty in obtaining CE marking due to new regulations will decrease the market growth rate • Increased business challenges for Notified Bodies has made entry difficult for companies looking to enter the European market
APAC	<ul style="list-style-type: none"> • Absence of direct approval of the CE mark and FDA-approved products in Japan has restricted the growth rate of MedTech market • "Made in China, 2025" will offer additional benefits to local manufacturers and slow down foreign investors • In India, the National Pharmaceutical Pricing Authority (NPPA) slashed coronary stent prices by as much as 85% and imposed price ceilings for all drug-eluting stents and bio-absorbable stents • Central Drugs Standard Control Organization (CDSCO), the national regulatory body for Indian pharmaceuticals and medical devices will facilitate single window clearance for medical device and diagnostics industry, through "Sugam portal"
LATAM	<ul style="list-style-type: none"> • Continuously changing regulatory environment in order to meet the requirements of FDA and European Notified Bodies, resulted in declining market growth • Some LATAM countries offer expedited approval routes for devices already FDA-approved or CE-marked
MEA	<ul style="list-style-type: none"> • Significant development in terms of standardizing the regulations, aligned with global guidelines • The International Medical Devices Regulators Forum (IMDRF) is working towards the harmonization of device regulation, to simplify the regulatory relationship between Middle Eastern countries and stakeholders from international medical device companies

Implications of Unique Device Identification (UDI)

The FDA is implementing a phased UDI system to adequately identify medical devices through distribution (logistics providers) to end-users (patients). The identifier label (human and machine readable forms) provides detailed information on the medical device including batch number, serial number, expiration date, manufacturing date and product version. Cellular and tissue-based products have an additional identification code. Additionally, barcode, enterprise resource planning (ERP), electronic data interchange (EDI), electronic health record (EHR) and radio-frequency identification (RFID) technologies are increasingly used to facilitate UDI. Although the aim of the UDI system is to improve patient safety, modernize device post-market surveillance, and facilitate medical device innovation, the introduction of these additional regulatory requirements may increase the time and cost required for devices to enter the market.

Table 5: Reimbursement Scenarios For The Medtech Market

Geographies	Reimbursement Scenarios for the MedTech Market by Region
<p>North America (U.S. and Canada)</p>	<ul style="list-style-type: none"> • The U.S. market performance will be challenged by reimbursement cuts arising from the Protecting Access to Medicare Act (PAMA), rolled out in January 2018 • Additionally, the Affordable Care Act (Obamacare), Medicaid and other federal healthcare funding systems have impacted companies' reimbursement strategies and contributed to overall uncertainty in terms of U.S. FDA compliance • Canadian Agency for Drugs and Technologies in Health (CADTH), has begun structuring technology assessments for medical device reimbursements³³ • Diversity in reimbursement requirements and processes from individual provinces are making the Canadian MedTech market increasingly attractive for MedTech companies
<p>Europe</p>	<ul style="list-style-type: none"> • The frequent changes in budgeting and reimbursement decisions from country to country in Europe, have restricted to an extent, the growth of medical device companies in the region⁸ • Medical device companies in Europe are currently partnering with various payers, to set up a platform for funding and reimbursement⁸ • Increasing demand of clinical evidence along with economic studies for insurance coverage further add to the overall cost of product
<p>APAC</p>	<ul style="list-style-type: none"> • All the medical devices sold in Japan are paid for by its National Health Insurance (NHI) system • Tendering systems in China have made the reimbursement process more difficult for foreign investors • Reimbursement for devices in China is adequate for locally made products but not sufficient for imported products • In India, the government has rolled out healthcare insurance programs like "Start-up India" and "Ayushman Bharat" resulting in better affordability and accessibility of medical devices • In other APAC countries, the government reimbursement policies depend upon the type of medical device used in the diagnosis and treatment of disease
<p>LATAM</p>	<ul style="list-style-type: none"> • In LATAM, coverage policies are defined for procedures, rather than a particular medical device • There will be a fixed reimbursement amount for procedures based on global averages, which will put financial constraints around the procedures, further decreasing the demand of these procedures • Public financing and private insurance have been trending upward, while self-paying insurance has been decreasing in LATAM • The changing regulatory environment in LATAM countries is making reimbursement processes more complex for foreign manufacturers
<p>MEA</p>	<ul style="list-style-type: none"> • Supportive reimbursement processes have been implemented by the Middle Eastern countries, to ensure quality healthcare provisions for every citizen • The increasing interest of government in rolling out national health insurance programs in the Middle Eastern countries is expected to drive the market growth rate

MARKET DRIVERS AND BARRIERS

The global MedTech market is predicted to continue to grow at an appreciable pace; however, this growth will be dependent on key drivers and barriers detailed in Table 6 below.

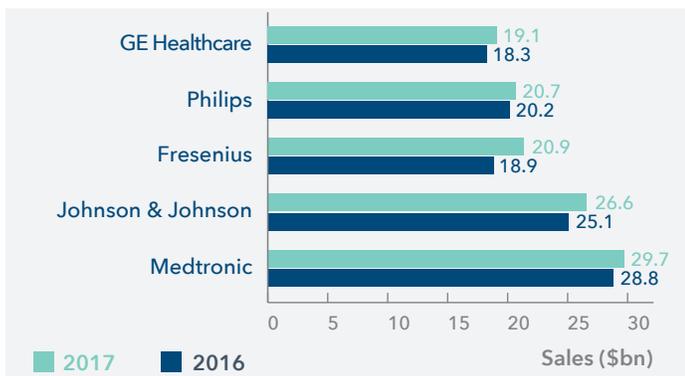
Table 6: Market Drivers and Barriers

Geographies	Market Drivers	Barriers
North America (U.S. and Canada)	<ul style="list-style-type: none"> Investment in development of advanced technologies Aging population High prevalence rate of chronic diseases 	<ul style="list-style-type: none"> Stringent regulatory norms Investment by local investors in emerging markets Poor reimbursement of costly medical devices
Europe	<ul style="list-style-type: none"> Rise in mergers and acquisitions New European regulations will allow companies to show clinical evidence of their products and earn the trust of patients and physicians Inclination of MedTech companies towards development of AI based technologies 	<ul style="list-style-type: none"> Changing regulatory environment Fragmentation in reimbursement scenarios Stringent and frequent screening by notified bodies making it difficult for companies to enter the European market High cost of development of advanced technologies
APAC	<ul style="list-style-type: none"> Expansion in insurance coverage Economic expansion of middle-class population Initiatives taken by government to improve healthcare infrastructure and reimbursement process Aging population and increased incidence of diseases 	<ul style="list-style-type: none"> Stringent regulatory guidelines for the approval of medical devices Fragmentation in reimbursement scenarios High cost of advanced technologies Lack of development of advanced technologies Poor accessibility of medical device in rural areas
LATAM	<ul style="list-style-type: none"> Availability of cheap and skilled labor Rise in the economic status of middle-class population Enhanced patient awareness 	<ul style="list-style-type: none"> Changing regulatory environment resulting in an increase in the complexity of approval process Poor reimbursement process High cost of advanced technologies
MEA	<ul style="list-style-type: none"> Increased burden of lifestyle-related disorders such as diabetes and cardiovascular diseases Expanded insurance coverage Economic expansion of middle-class population Increase in healthcare expenditure 	<ul style="list-style-type: none"> Extremely challenging regulatory processes Instability and non-transparent regional political environment has been the biggest hurdle for foreign companies to enter into the MEA countries Availability of regulatory documents in only the local language makes documentation more difficult

KEY MARKET PARTICIPANTS

Top 5 manufacturers in the global MedTech market include Medtronic, Johnson & Johnson, Fresenius, Philips and GE Healthcare, collectively representing more than 20% of global sales.

Figure 3: Global Medtech Sales - Top 5 Companies



Medtronic is the largest manufacturer in the MedTech industry, having generated \$29.7 billion USD in revenue during 2017, and is projected to have a CAGR of approximately 5% (Figure 3). Medtronic's primary products include those used for:³²

- cardiac rhythm disorders
- cardiovascular disease
- advanced and general surgical care
- respiratory and monitoring solutions
- neurological disorders, spinal conditions and musculoskeletal trauma
- urological and digestive disorders
- ear, nose and throat disorders
- diabetes

Johnson and Johnson holds second place in terms of revenue, with sales of \$26.6 billion USD during 2017, representing an increase of 5.9% (Figure 3). Growth was driven mainly by the strong performance of electrophysiology products in the cardiovascular segment, endo-cutters and bio-surgical products in the advanced surgery segment; Acuvue® contact lenses in the vision care sector, wound closure products in the general surgery sector, and partially offset by declines in the diabetes care business and spine products in the orthopedics sector.³²

Fresenius is placed third in terms of revenue with sales of \$20.9 billion USD in 2017³² and is probably best known for its dialysis machines and services for patients with kidney failure. Its key segments are dialysis services, healthcare products and care coordination.

Philips and GE Healthcare hold the fourth and fifth positions, generating revenues of \$20.7 billion USD and \$19.1 billion USD in 2017,³² respectively (Figure 3). The growth of both companies has been attributed to increased sales of interventional imaging systems, smart catheters, planning and navigation software, and healthcare services.

Other companies have demonstrated potential for substantial growth due to recent approval of advanced medical technologies including Siemens (Biograph Vision), Abbott Laboratories (continuous flash glucose monitoring system called Libre®), Abiomed (Impella RP®), Arterys (Cardio DL® a cloud-based platform), Butterfly (Butterfly iQ®, a chip-based imaging system) and Hologics (Affirm®).

In the coming years, major and new players will continue to utilize R&D investments and M&A activity, and form partnerships to expand and strengthen their product offerings, while looking towards global expansion initiatives in developed and emerging regions.

FUTURE OUTLOOK OF THE GLOBAL MEDTECH INDUSTRY

The medical device industry has the potential to exert a paradigm shift in patient care, bringing forth new technologies, value-based treatments and diagnostic tools. While opportunity for growth exists, many challenges remain. Regulatory hurdles, reimbursement pressure, local competition and lower-cost providers represent significant barriers for growth. In this final section, we contemplate how the MedTech landscape might look in the near future.

Adoption of New Technologies in Medical Devices:

A new wave of innovative MedTech companies such as Intuitive Surgical, Auris and Verb are developing new device solutions by marrying AI and robotic technology. This trend is expected to flourish, as big players such as Johnson and Johnson, Medtronic and Philips line up their own portfolio of AI and robotic solutions. Development of advanced AI-based technologies, such as portable and handheld ultrasound, digital tomosynthesis used in breast imaging and digital chest tomosynthesis (DCT) for detecting lung nodules, are expected to spur market growth in the next 2-3 years. In addition, MedTech companies are collaborating with IT service providers to develop cloud-based software, biosensors, wearable devices and healthcare apps that will offer patients a range of benefits, including accurate POC testing and personalized care. Advancement in technologies such as robotic surgery units and 3D printers are also likely to boost growth of the medical device industry in the coming years.

Increased Focus on End-of-Life and Palliative Care

Shifting demographics and advances in medicine and healthcare over the past few decades is driving a significant increase in the percentage of the world's population over the age of 65. MedTech companies focusing on or offering end-of-life palliative care products will see a growth in market opportunities.

Changing Regulatory Guidelines

The ever-changing regulatory environment is dramatically impacting what is required to bring a new MedTech product to market in both mature and emerging markets. Future commercial success will require manufacturers to not only understand the existent landscape, but also establish processes and internal mechanisms that allow them to

pro-actively work with local regulators to understand this evolving landscape.

Reimbursement and Pricing

Continued cost pressures are forcing both public and private payors to re-examine their reimbursement and pricing practices. We have already seen the introduction of price ceilings on certain devices, the growing utilization of HTAs and the shift from a fee-for-service to a value-based pricing model. MedTech companies are certain to face continued pricing and reimbursement challenges in the coming years. Moving forward, manufacturers must ensure products contain sufficient "value" early in the R&D process, before the product comes to market. Furthermore, go-to-market models will begin to focus on better communication of the product's value in terms of both cost effectiveness and product usefulness.

Focus on Developing Markets

With the growth of developed markets slowing down due to stringent regulatory guidelines and reimbursement challenges, MedTech companies will need to aggressively target emerging markets such as APAC and LATAM in order to drive growth.

Cybersecurity and Digitalization

With increasing penetration of digital technologies in the MedTech market, a number of digital-enabled solutions are expected to be launched in the near future that should lead to greater responsiveness and, ultimately, better care.

Inherent security issues of digital technologies are a continuing cause for concern for both patients and regulators. As the FDA makes headway in the regulation of digital health, navigating these regulations and leveraging the resulting data will become critical for success.

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APPENDIX

Definition

The definition of MedTech/medical device used in this paper is based on WHO guidelines which defines a medical device as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease/diagnosis, monitoring, treatment for an injury
- Investigation, replacement, modification or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Providing information by means of in vitro examination of specimens derived from the human body

Market Sizing Methodology

In this report, markets are valued based on secondary sources. This report does not use any single approach, but uses multiple verification stages and research sources to determine MedTech market size.

The MedTech market of each region is valued-based on historical data available from the below mentioned secondary sources, which were further used for building log-linear/exponential forecasting models to derive market estimates.

Numbers were adjusted to best fit our market definition.

While deriving market size, we have also considered all the important factors such as implication of new regulatory guidelines, changes in reimbursement policies, initiatives taken by government towards MedTech industry etc., which will impact the growth rate of the MedTech market in that particular region.

Region	List of Sources Used for Calculating MedTech Market Size
Historical North America \$ market	Select U.S.: U.S. Department of Commerce's business-investment facilitator, Intelligent Product Solutions, Emergo group Health Canada: 2016 Canada: Overview of medical device industry and healthcare statistics - 2015
Historical Europe \$ Market	The European Medical Technology industry in figures: 2018 Verdict medical devices: Optimism on the rise for Russian healthcare markets - March 2017
Europe and U.S. Trends	EY-Pulse of the industry: Medical technology report 2017
Historical LATAM \$ Market	GHI analysis: The 5 biggest healthcare growth Mecomed: MENA MedTech market markets in Latin America - 2015 and 2016
Historical MEA \$ Market	The South African medical device industry: Facts Mecomed: MENA MedTech market
Historical APAC \$ Market	Asia Pacific medical technology association
Worldwide MedTech Market Segments and Trends	Evaluate MedTech World Preview 2017, Outlook to 2022 International trade administration: 2016 Top Markets Report Medical Devices Global medical device market: EPSICOM 2015

Limitations

The key caveats to the approach are:

- Limited secondary data at an aggregated level lead to certain assumptions in order to estimate MedTech market size
- Usage of various secondary data sources could potentially lead to a slight overlap of market size of some countries and therapeutic segments

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Pravindra has over 15 years' of experience in healthcare, Life Sciences and in-vitro medical devices, specifically in cardiology and oncology therapy areas, Pravindra has extensive knowledge surrounding market sizing, patient research, customer segment identification and targeting.

He also specializes in strategic solutioning and developing commercial models. His other areas of expertise include, geographic exposure in the U.S., EU5, India and emerging markets, geographic expansion, new market-entry strategies, epidemiological assessment/forecasting, and qualitative and quantitative research.

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John has over 19 years' of experience working with the life sciences industry throughout all stages of the Commercial and Strategy Development processes. Throughout his career John has built and managed multiple local and global information offerings and has lead various consulting and services teams. In his current role, he is responsible for IQVIA's commercial solutions, specifically relating to our Medical Technology segment. This includes long-term strategy development, global product development initiatives, data acquisition strategies and overall product commercialization. Holding an Economics degree from Villanova University and an MBA from the Villanova School of Business, John also has a J.D. from the Villanova School of Law.

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