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2nd Global Medtech Industry Report:

Accelerating Transformation for Success

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While this report is intended to provide an overview of the Medtech sector and its opportunities with a global perspective at the time of print, each individual Medtech manufacturer, supplier or other company may have to conduct their own analysis to get a better understanding of the possibilities and opportunities available to them. The reader is encouraged to explore and develop his/ her opportunities based on additional research and in-depth analysis tailored to your own specific situation.

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Introduction letter from the authors

Since publishing our first Global Medtech Industry Report, the healthcare environment has continued its rapid pace of change. The changing environment continues to hit the bottom-line of Medtech companies. Medtech executives have to cope with a multi-strategy world. Some are stretching their organizations to craft and execute radically different visions of the future. Partnering is becoming a key success factor, required to be able to implement new business models. Brazil, China and other fast-growing markets are emerging beyond recognition, with novel opportunities and threats. Although not yet seen as the most important lever to achieve top-line growth, there is a need to change the Medtech commercial model to remain competitive, particularly in developed markets, such as the US. Medtech corporate headquarters will play a vital role in accelerating the ongoing transformation and keeping-up the pace of change for companies to remain successful in the future.

The Medtech experts who participated in the 2nd World Medtech Forum Lucerne (WMTF) from September 17th to 19th, 2013 prioritized topics and challenges. They flagged the most important changes in 2013 compared to the year before, provided their views on the next two years until 2015, and anticipated the most important trends for the next five years, and beyond.

This report builds on their thought-provoking contributions and the highly interactive discussions held during the 2013 WMTF. The large number of Medtech experts on stage was challenged by the experienced audience who contributed their opinions through electronic voting on 15 different questions using PowerVote on the Executive Day, the North America Day and South America Day. The quantitative PowerVote survey and qualitative insights were sifted into a set of hypotheses that were then discussed one on one with 21 Medtech executives and experts. The interviews provide a rich insight into the future of the Medtech sector and were further distilled into quotes as a concluding food for thought in the last chapter, such as:

- “Smart and holistic solutions outweigh traditional product-only offerings”
- “Pressure across the health care value chains is squeezing-out intermediaries”
- “ICT players will digitize healthcare driving customer/ patient data business models”

In this report, we complement the Medtech insights with remarkable case studies from outside the Medtech sector, highlighting the impact and speed of radical innovations. The rate of change often accelerated faster than anticipated and overwhelmed established and well-known industry leaders. Once the tipping point was reached, the incumbents could no longer react adequately to correct the situation. With that in mind, there is a strategic imperative to shape future Medtech markets proactively before it might be too late for a company.

Based on the insights from the WMTF 2012 & 2013 and our reports, we have developed the “Medtech Transformation Tracker”. It is a tool to enable executives to visualize strategic vision and highlight initiatives needed to get there successfully. Three key questions can be addressed with the tool:

- Which strategic levers are being pulled (including ongoing initiatives)?
- What is the strategic vision across the levers over the next 5 years?
- How will transformation be accelerated over the next 2 years?

We want to thank all speakers and attendees who participated in the PowerVote survey at the WMTF 2013, as well as the Medtech experts who took the time to provide us with their perspectives during personal discussions. We hope that this report builds on your collective wisdom and provides you with further food for thought, enabling both you and your Medtech colleagues to identify and capture the many opportunities that the ongoing tectonic shifts in healthcare provide.

Beatus Hofrichter | Aleksandar Ruzicic | Dr. Patrick Dümmler

1. Hitting the bottom-line

Tectonic globalization and demographic shifts are underway in global healthcare that will sooner rather than later have a dramatic effect on the bottom line of Medtech companies. An unprecedented growth in demand for healthcare service is about to hit Western and Emerging Markets, a growth curve that is expected to last well beyond 2030. These demographic and wealth-related lifestyle changes are behind an almost epidemic sized increase in related diseases globally. Diabetes alone is expected to increase healthcare spending to almost half a trillion US dollars by 2030, consuming between ten to fifteen percent of healthcare budgets. For further reading, see International Diabetes Federation, 2012 Diabetes Atlas, sixth edition.

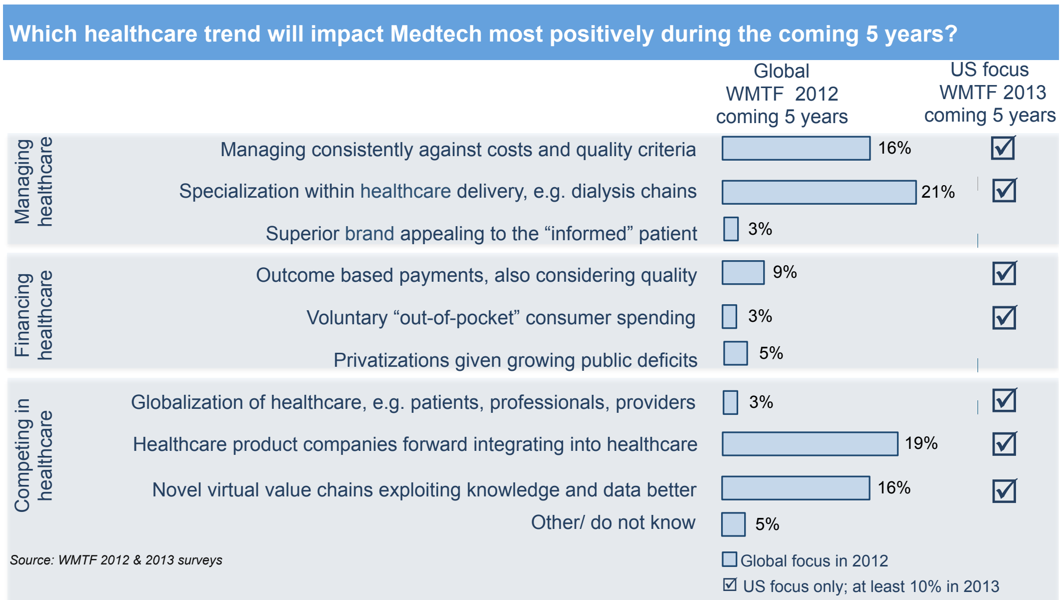
Demand is increasing in mature markets but many are facing shrinking population growth, which means a much tighter labor pool for healthcare segments. Even a fast-developing country like China is getting old before its population is getting rich, a delayed effect of the one-child policy implemented decades ago.

Medtech companies are seeking novel solutions, particularly in countries with tight national immigration policies, which exacerbate the demographic problems. In Japan, for example, pilots of healthcare robots are underway, while Sweden tests elderly care facilities in Thailand due to constraint budgets.

Other newer trends, such as international pricing pressure and market consolidation, continue to affect the way that healthcare companies are managed, financed and how they compete. It makes for a pretty challenging business environment with all healthcare players exposed to changes in industry economics. Pressure is exerted all the way down the value-chain from payers and providers, cascading down to Medtech companies and their suppliers being highly vulnerable to any further tightening of prices.

Last year's Global Medtech Industry Report identified several trends and their impact on Medtech. In the meantime, Medtech companies have turned threatening trends into business and growth opportunities, as illustrated in Figure 1.1 "Which healthcare trend will impact Medtech most positively during the coming 5 years", comparing survey results from 2012 and 2013.

Figure 1.1



Payers and providers are attempting to put the brakes on spending. The healthcare systems in Denmark (See Case Study 3), Sweden, UK, Ireland, Scotland, Australia, New Zealand, and Turkey are on the forefront of reining in costs by using outcome and quality evaluations.

Some industry players are anticipating these healthcare trends and have started to invest significantly to support them by using advanced ICT to tap real-world evidence. Others are capitalizing on lessons learned from emerging and frontier markets where innovative business models were put in place to meet the needs of a low-income environment. For example, to overcome the sales hurdle of a high up-front and out of pocket expense, hearing aids are being sold in Brazil via hearing aid subscription plans. A model like this becomes increasingly relevant in mature markets facing high price-pressure and changes in reimbursement schemes. Such tactics can and will be transferred, particularly for high-value premium branded products, such as hearing aids.

Privatization is a trend that threatens existing business models and relationships. Mature markets see increasing privatization of providers, with consolidation of ownership of hospitals and clinics. For example, in Germany Fresenius-owned Helios acquired a significant part of the Rhön-Kliniken network to become the largest European hospital network with over EUR 5 billion in revenues annually. But the trend is not limited to mature markets, developing markets are also seeing growth amongst private providers, such as Medi-Clinic in South Africa and the integrated payer/ provider Fortis Healthcare in India, or Brazil's Amil integrating with United Healthcare, a US-based company. When this kind of thing happens, Medtech CEOs have to be prepared to implement new strategies to avoid being cut out of the market, if, for example, one of these emerging giants decides to take a preferred-supplier approach.

Globalization has increased competition and shrunk margins. In the healthcare value chain certain intermediaries are being cut out, leaving only the largest and most powerful laboratories and distributors/ wholesalers in place. Medtech executives are responding to a more hostile competitive environment with forward integration and novel (virtual) value chains to go directly to end-users/ patients. Some are positioning themselves to become the favored healthcare "insider" winning over the supplying "outsiders". One early Medtech mover is Medtronic, which recently started to acquire and run cardiac catheter labs. It is positioning itself in Italy to become a preferred supplier within a value chain that it will partially own through a stake in an Italian outsourcing-oriented catheter lab network. (See TCB Magazine's report here).

Overcoming Negative Trends

With buyers reining in healthcare spending, price pressure and single-digit revenue growth is the single most worrying trend in developed markets. The leading players serving those markets are affected. Many Medtech experts interviewed for this report are expecting even faster consolidation within and beyond the Medtech sector, "leaving no stone unturned".

Figure 1.2

Which Medtech trend is impacting the sector most negatively?

		Global WMTF 2012 coming 5 years	Global WMTF 2013 Δ to 2012	US focus WMTF 2013 Most unique
Competitive dynamics	Price pressure from healthcare buyers and/ or competitors	1	1	1
	Consolidation of medtech players (both within and across segment)			
	Novel players (outside Medtech) and/ or novel products			3
Increasing barriers	Limited access to healthcare stakeholders, e.g. KOLs			
	Increasing requirements for product registrations	2	2	
	Increasing requirements for reimbursement/ listing	3	3	
Other challenges	Shortage in human talent, e.g. regulatory, management			2
	Acceleration of innovations cycles			
	Others/ Do not know			

Source: WMTF 2012 & 2013 surveys

Consolidation is a response to the single digit revenue growth. It is driven typically by four goals: desire to improve global presence (same products sold into more markets), access new market segments (obtaining new/ complementary products/ technologies), dominating at the product portfolio level and increasing market share. Four recent examples are Johnson & Johnson's acquisition of Synthes, Microport's acquisition of Wright Medical, Zimmer's acquisition of Biomet, and Baxter's acquisition of Gambro for hemodialysis.

Cross-sector consolidation is also evident, often driven by value chain integration to improve "margin share". An example of convergence between pharma and Medtech is Valeant's purchase of Bausch & Lomb, while value chain (forward) integration is very evident in the M&A activity exhibited by the as-yet-unrivalled-first-mover Fresenius.

The second most significant trend attracting Medtech executive attention is the soaring requirements for product registrations (See Figure 1.2). It was already a trend in the US, but now the European Union has tightened the process in the aftermath of the PIP scandal. This regulatory development will lead to prolonged and more costly approvals. At the same time requirements for reimbursement/ listing are also increasing, particularly in developing markets, such as South America. This could lead to a "re-nationalization", counter to the current globalization trend in pharmaceuticals. For example, Russia has put in place policies favoring local manufacturers.

Executives are almost equally concerned about talent management in emerging markets. Fast growing developing markets, such as South America, pose the challenge of talent shortage to be able to tap growth opportunities. The issue is not unique to South America.

As a result, Medtech executives are turning their sights on digitization. The potential to increase digitization in the healthcare value chain is causing the same kind of investment in technologies undertaken by media, music and film industries. It is revolutionizing healthcare models by integrating customer/ patient-centric data and creating opportunities, for example, remote monitoring of patients.

Case Study 1: Eighteen months that changed the music industry ….

In August 1991 the web had gone live. Around 1995, the global music industry was still dominated by the "Big 6" (EMI, Warner, Sony Music, Philips, BMG, Virgin), which controlled approximately 90% of the market share. Music formats were dominated by higher priced CDs; vinyl and tapes were rapidly fading out. The common personal music device was the Sony Walkman. New technology in 1995 employed formats such as CD-now, CD+ and CD-ROM to connect the listening and web experiences to the then standard product platform of CDs, but all flopped shortly after release. Strategic thinking at the time was "wait and see" and "this is no threat to us, yet" with the thinking that the new web media was too slow, did not provide any sensational appeal to consumers, and had no bandwidth for downloads.

In 1999, Napster, the first commercial media player based on their MP3 format, was launched on the web and gained fast attention in the consumer world. Within two years Napster had amassed 80 million users. In a reactionary move, the industry defended their stakes in a lawsuit and forced the shutdown in 2001 but by this time consumers had become used to the MP3 format, which was not yet supported by the industry itself. Suddenly, a new player arrived out of nowhere - Apple.

The Apple iPod was released in 2001 (a technology they acquired from SoundJam which was a Mac OS compatible MP3 format). After optimizing the user interface and adding the ability to burn CDs, iTunes was born. The industry was taken by surprise. Market share immediately began to erode. Today, the iTunes Store is the leading media web platform for music, movies and TV downloads and purchases, and it now competes with Amazon's audiobook sales.

Evidently, not only healthcare companies see a giant-sized opportunity in healthcare value chains; major players from the ICT world do too. They are developing integrated product/ software solutions. Even Google is active, undertaking early stage R&D on glucose monitoring contact lenses, for example. It may be hard to imagine today how Google, Apple, Samsung and other ICT leaders could affect healthcare in the future. However, we do know that ICT companies have a track record in creative destructing of established industries and business models. They can indeed be very disruptive and thus pose a threat. A recent example from the music industry shows what can happen. (See Case Study 1)

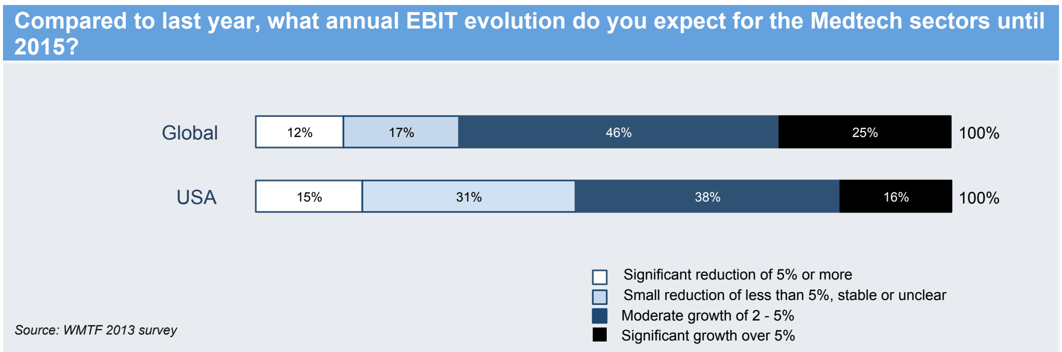
Healthcare and Medtech trends affect profitability, at least in the short-term

Medtech experts are skeptical about EBIT growth in the coming two years due to price pressures, with a large proportion targeting moderate growth at home and abroad (See Figure 1.3). This view is particularly acute for EBIT margins in the US, with a sizeable number expecting stagnation, or even a slight decrease until 2015.

Industry insiders are more upbeat on net growth in emerging markets where EBIT gains of 5%-10% are anticipated, but they worry about rising inflation and/ or currency adjustments in these markets. Such developments would potentially erode the anticipated gains.

Longer term, the Medtech segment leaders are optimistic. They believe that EBIT evolution will be significantly stronger in the medium-term, and will indeed return to the double-digit percentages they are used to from the past.

Figure 1.3



2. A multi-strategy world

While being faced with accelerating change and operational turmoil to maintain profitability, it is difficult to manage the current business and simultaneously find appropriate strategic answers to fast increasing challenges. Many Medtech executives see their oceans turning red and they are hard pressed to do anything beyond continuing to compete using traditional and tactical approaches.

It will be increasingly difficult to defend high-margin products in mature markets while trying to capture a significant enough proportion of volume growth in developing countries. Future-oriented market leaders have already crafted their vision on "Where to play" and "How to win" in, also preparing for taking advantage of tectonic shifts in healthcare through significant investments.

Strategic Levers "Where to play"

Our research has captured how leading Medtech executives are thinking about "Where to play" (See Figure 2.1). They expect the greatest impact on top-line growth coming from expanding the "geographic footprint". Since the first WMTF in 2012, this expectation has remained remarkably consistent, justifying a chapter on its own in this report (See "Emerging beyond recognition"). Companies have become highly selective in their geographic investment strategies - "We do not invest in shrinking markets, but we are not blindly investing in emerging markets per se either".

Figure 2.1

Which strategic levers do Medtech companies pull most with regards to top-line growth?

		Global WMTF 2012 coming 5 years	Global WMTF 2013 Current	Emerging Markets WMTF 2013 Current
Where to play	Medtech model		3	
	Life Science model			
	Forward integration into healthcare	1	2	
	Geographic footprint	1	1	1
How to win	Technical capabilities			
	Operational excellence		3	1
	Value chain	3		1
	Commercial model			

Source: WMTF 2012 & 2013 surveys

Forward integration has moved from a top position in 2012 to second ranked in 2013. When pursued strategically, it almost always results in a radical business transformation, creating novel revenue mechanisms, typically moving beyond product pricing to treatment costs for a specific period, such as for dialysis patients. Not surprisingly, paying consumers/ patients are a desirable target market. Sonova's Phonak has been quick to tap the niche with its "invisible" hearing aid Lyric, using a subscription-based business model in mature and developing markets.

Traditional Medtech business models seem no longer able to generate significant top-line growth. Whereas in the past the right combination of premium and commodity dental care products was a reliable model, now there has to be more value added. In orthopedics the trend has been to offer a greater range of complementary services driving customer loyalty and/ or improving outcomes. The cost of instruments and technical support in orthopedics has created additional costs for implant manufacturers and it is starting to erode margins. Truly innovative technology companies have been able to protect their revenue stream by innovating on products that improve outcomes, such as Sorin which has established a niche in high-end, high-value cardiovascular disease products, driven by constant innovation.

Some life science players integrate a variety of products and services into “smart” solutions applying integrated Electronic Health Record (EHR) data and ICT technology capabilities into their offerings, targeting needs more holistically, such as in renal care, diabetes and cardiovascular risk management. While many diversification strategies resemble life sciences models, very few truly integrate Medtech and pharma products. The historically rather different business models remain entrenched. However, early and successful life science model transformations do seem to suggest there is opportunity in managing complex (chronic) diseases, with a continuous access to patients, and significant room to improve outcomes. Chronic diseases lend themselves particularly to “smart” solutions, both early on to maintain health through better education and prevention, for example through better diagnostics and patient adherence, and later on, post-intervention, to provide lower cost after-care, for example through remote monitoring at home.

Larger Medtech players are able to create “new” winning truly holistic approaches quickly into cross regional models by collaborating across business units and value chain partners. Several companies are improving diabetes care outcomes by optimized mining of historical patient EHR data as J&J Medical Devices & Diagnostics (MD&D) alongside J&J Pharma and multiple insurers have done. Medtronic and Aetna are taking a similar approach. (See Medtronic article here.)

Strategic Levers “How to win”

The previous section describes where the opportunities for growth lie. This section describes internal processes or “how to win”. Medtech executives expect operational excellence to provide top-line growth, by freeing-up resources and redeploying these optimally into revenue-generating activities. Developing markets, such as South America, are no different. In fact, they seem to require even more attention on continuous improvements in operations as a result of strong global and local competition, reflecting the current growth stage of the market. Interestingly, Medtech executives do not expect to increase their revenues much by adapting their commercial models, it is seen more as a basic necessity in order to remain commercially competitive.

Medtech companies are continuing to modify their value chain strategically for success in developing markets, such as engineering/ development and manufacturing of (local) products. Many established players appear to be adapting a platform strategy as a more reliable method of achieving margins, where component sourcing and assembly are now key success factors with a clear division in responsibility, such as between Roche Diagnostics and Hitachi.

Large Medtech firms are not hesitating to acquire novel technology through acquisitions. There were around 20 transactions in 2013 in the orthopedic and cardiovascular segments alone (Source: In Vivo, Medtech 2013, *Devices companies go where the growth is*, page 30). The ability of developing in-house technical capacity, such as engineering and development, once seen as key to growth, is now no longer enough. It is not a top strategy to defend and develop lucrative niche products, as in the past. A number of companies continue to bet on highest quality innovation and production successfully, e.g. Sorin, Mathys, Medartis, Biotronik, Medela Healthcare.

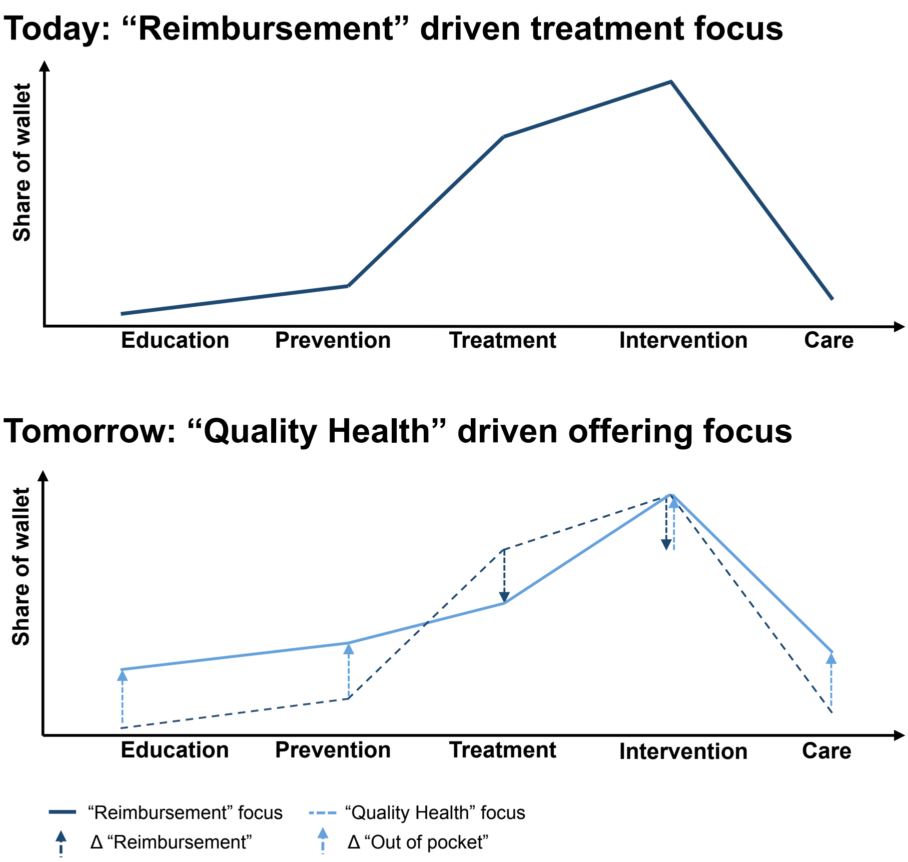
A compass for navigating towards less competitive blue oceans in the future

The completion of the human genome project in 2001 was expected to be the beginning of a new era, in which individual patient information would enable optimal healthcare decisions. David Ewing Duncan, an award-winning, best-selling author, published his attempts to perform all diagnostic tests, such as those now offered by 23andme, in his book The Experimental Man in 2009. The highly regulated healthcare market will take much more time to put the information into the hands of customers/ patients, as evidenced by the FDA's actions against the US personalized medicine startup 23andme over the past four years (See relevant article in Venturebeat.)

Many more businesses are seeking to use modern ICT to empower consumer/ patients, such as PatientsLikeMe, a global patient network founded by Jamie Heywood in 2004. Interview partners say they believe that better informed patients will one day be able to make choices to increase their health quality and delay the onset or prevent diseases to which they are genetically pre-disposed (See Figure 2.2).

ICT leaders have set their sails and are navigating rapidly towards vast "blue oceans". For example, Google founded CALICO along with Arthur D. Levinson, Chairman of Apple and Genentech. Other ICT leaders, such as Samsung, Sony and Nintendo, are also actively pursuing consumer/ patient centric business models, shaping healthcare for all players, including Medtech. It is clear that leaders from healthcare, ICT and other industries will drive their offerings to target well-defined "spending pools", such as consumers/ patients willing to pay "out-of-pocket" and reimbursed healthcare services. They observe consumers' willingness to pay "out-of-pocket" for both traditional products and services, such as Weight Watchers, but also those that provide medical technical progress, such as 23andme.

Figure 2.2



Better patient education and prevention offered by well-positioned players such as dacadoo, Polar, Garmin, Suunto and Healthways, should delay and/ or reduce costly interventions which will still be responsible for a large share of spending, as observed for cardiovascular diseases. The early stages of consumer/ patient education and prevention will command an increasing share of spending. It may also provide for life-long interactions that are likely to lead to new entry barriers. However, offerings beyond the protected and regulated healthcare environment raise the level of competitive uncertainty. It opens up opportunities for newcomers who might master the new environment more easily. A stronger focus on patients and the quality of their health will lead to an increase in spending for late stage care, for example by staying longer at home and decreasing nursing intensity.

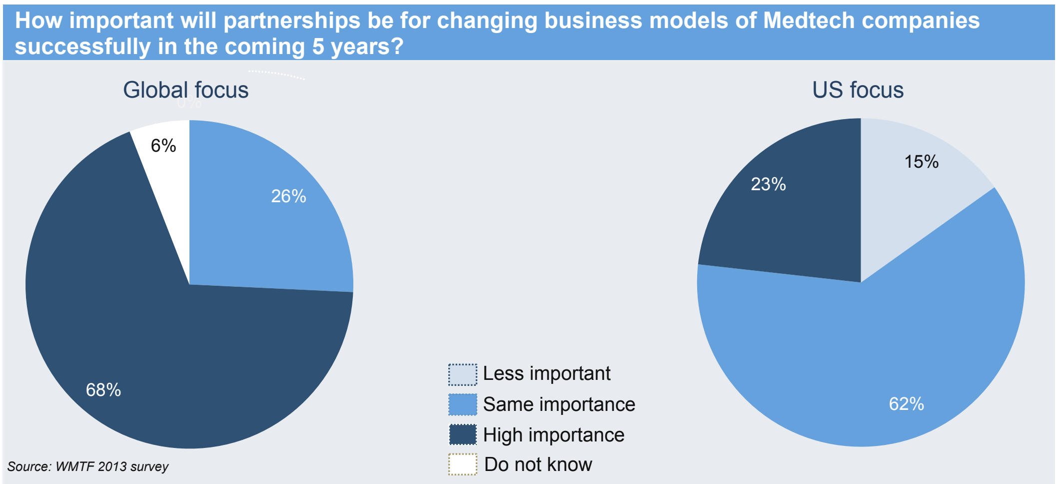
Healthcare payers continue to invest into treatments and care that reduce and/ or delay future healthcare costs, for example by reducing length of hospitalizations and lowering care costs. As a result, reimbursement focused offerings will continue to play a major role in the future, requiring stronger attention to consumers/ patients to unlock incremental out-of-pocket spending.

A holistic approach to individual citizens, consumers/ patients across their life will lead to better understanding of conditions/ diseases, resulting ultimately in truly personalized healthcare. By that stage, the future leaders will have developed strong relationships with their (consumer/ patient) customers, similar to the personal advisors in financial services. Quality health players will combine their own solutions with traditional healthcare services and life science products, such as medical devices and drugs, into holistic offerings across stages. Any non-differentiated products and services across the education, prevention, treatment, intervention and care stages will be commoditized if not competing on quality health.

3. Partnering for new business models

Partnerships are entrenched as a key strategy, particularly amongst CEOs when establishing their "Where to Play" and "How to win" strategies and changing their business models. Partnerships are expected to become more important to enable changing Medtech business models. Looking at the situation on a global basis, more than two thirds of Medtech experts predict that partnerships will increase in importance in the coming 5 years, compared to today. This is also true at the regional level. In North America, for example, partnerships are expected to continue to have the same or a higher importance to change Medtech business models compared to today for more than 85% of experts. Only 15% say partnerships will decrease in importance. (See Figure 3.1)

Figure 3.1



Medtech companies have traditionally been open to accessing product innovation externally through partnerships, with some of them undertaking M&A of innovative smaller players. With healthcare models undergoing a massive transformation, leading Medtech players are anticipating future trends by integrating value-chain data pools, convergence across life sciences, and positioning themselves to exploit or capture the power of real-world patient data. For example, Medtronic acquired healthcare equipment and supplies companies over the last 12 months, including two that prove the trend discussed here. It acquired Cardiocom (a population health management telehealth company with heart failure, hypertension and diabetes focus), and TYRX, for its AigisRx Antibacterial Envelop, a drug-device combination product, as reported by Medcitynews and Xconomy.

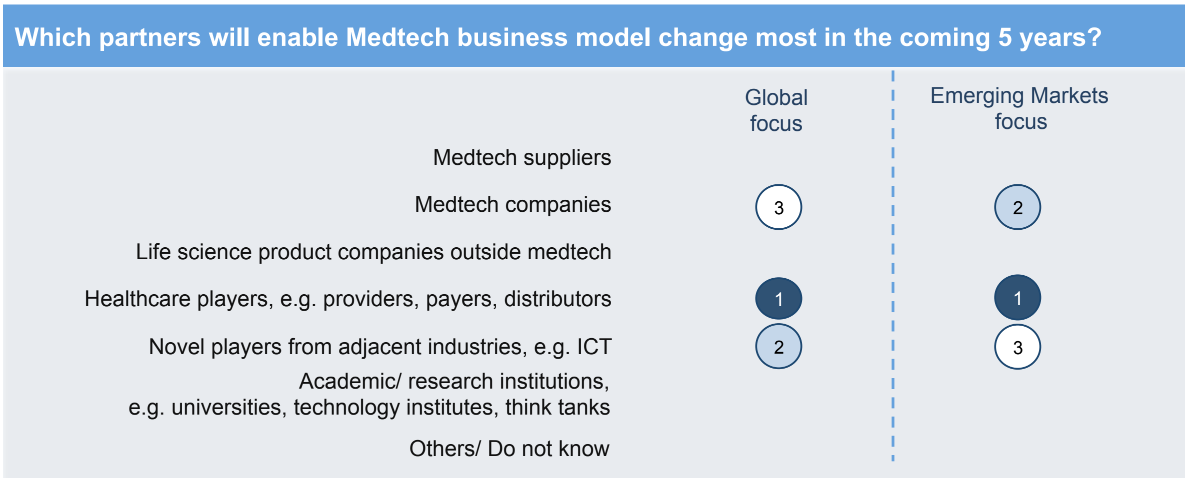
Beyond M&A activity, the larger Medtech companies continue to strike innovative partnerships with other healthcare companies to provide them with complementary patient access, services and capabilities. For example, Medtronic announced in a press release a collaboration with health insurer Aetna to provide insulin pumps and educational support for diabetes patients. The pilot project with Aetna may become part of an innovative new way to reach the market, cut costs for insurers, and improve patient outcomes.

Another strategy used by leading Medtech players is to undertake new licensing and distribution deals to expand their geographic footprint. This is an approach more typical in the pharma/ biotech world. A good example is Straumann's publicly announced cooperation with Biodenta. Straumann is the leading company in dental implants, and Biodenta is a younger fast-growing total solution provider for digital dentistry. The deal is meant to enable each company access to China, India, Russia/ Ukraine, Turkey, Middle East, as well as the USA, Switzerland and Taiwan, according to a Biodenta announcement.

With the emerging “Quality Health” market, we expect even more partnerships across the value chain. The sweet spots we note are education/ prevention (for example, health/ sports monitoring, fitness/ sports centers, and genetic testing solutions) and care (for example, rehab centers, home care, mobility solutions). Partnering and collaboration agreements have long-term implications. Today’s management decisions will have far reaching effects on businesses and their value chain partners.

In emerging markets, such as Latin America, partnerships are seen as key enablers of access to end user markets. The sentiment is that success is only possible with good local distribution/ licensing partners and their networks (See Figure 3.2). Clearly, the Medtech experts expect that a variety of different partnerships will be necessary, depending on their current positions and their employers’ strategic needs. The kinds of partners sought to address the changing Medtech business models were analyzed based on survey results. Healthcare players, such as providers, payers and distributors appear to be the most important to enable Medtech business model changes in the coming 5 years, both globally as well as in emerging markets, such as Latin America.

Figure 3.2



Source: WMTF 2013 survey

Novel players from adjacent industries, such as ICT, score particularly high at the global level. They are perceived to enable technical leapfrogging in emerging markets. Two examples stand out in telemedicine services, national leaders (such as the Danish e-Health portal sundhed.dk and privately-owned MedicallHome in Mexico) and globally operating companies (such as Global TeleMed presenting its activities in South America, Asia and beyond at the WMTF 2013).

Emerging markets, such as Latin America, require specific Medtech-related partnerships to obtain access to the market by providing “local” products and distribution networks, according to the survey results. An example of this strategy already underway is Straumann’s strategic investment in Neodent, a transaction that will deliver two benefits. It will provide access to Brazil’s market, and give Straumann a second lower price dental implant product line for use in other markets.

While other types of partners did not make it into the experts ranking of the top 3 types, groups such as academic/ research institutions are still seen as important in innovation and addressing specific strategic needs. As in the past, technology players outside the industry will continue to drive novel breakthrough solutions in ways that Medtech companies are not able to achieve with their current manufacturing capabilities. For example, Organovo is developing 3D printing to deliver human tissues on demand for medical research.

There are a growing number of examples of partnerships for proven and novel technologies or services. The characteristics of these partnerships are that they are based on long term contracts, clear division of responsibility, sustainability and the equality of mindset. It is expected that Medtech companies will foster more of this kind of collaboration with 3rd parties. One example is a partnership between Roche Diagnostics and Hitachi that is slated to run over 25 years for platform equipment manufacturing.

In the past, companies in the Medtech and pharma branches operated separately, enabling Medtech to get closer to customers and patients because they had continuous exposure and interactions along the treatment cycle. Medtech's proximity to customers can be a springboard to develop a pharmaceutical and drug discovery business on top of the original business model. Fresenius Medical Care is a frontrunner, showing exactly how Medtech can successfully expand into other aspects of healthcare.

Three approaches are underway. 1) It has completed multiple transactions since acquiring National Medical Care in 1996, acquiring pharmaceutical products via acquisitions of companies such as PhosLo from Nabi Biopharmaceuticals. 2) It formed partnerships with likes of Amgen and Vifor. 3) It also provides services to pharma/ Medtech companies, under its recently announced clinical development service re-branded as Frenova. Frenova claims to be the only Phase I-IV drug and device clinical development services provider dedicated exclusively to renal research.

At the same time pharmaceutical companies are adopting the "Own the Disease" model, which spans both pharma and Medtech products to be able to compete successfully beyond pills and drugs. Sanofi is an example of this in diabetes. (See Case Study 2). The window of opportunity for healthcare products companies is still open in most diseases, and the jury still out on who will win the race to "Own the Disease". Will it be a leading player from Medtech, pharma or other adjacent sectors, such as ICT?

Case Study 2: "Own the Disease" model spanning across healthcare segments

In recent years, strong product and service portfolio concentration and build-up is evident in Medtech. The highest profile, and for a long time the only example, is Fresenius Medical Care which aims to provide full renal care. Here, a major success factor is the company's ability to forward integrate into healthcare service, leveraging its existing medical device/ technology-driven business model.

Similarly in pharmaceuticals, for decades Novo Nordisk could be said to "Own the Disease' in diabetes care. In the meantime, Sanofi has emerged to contest it with assertive communications around its products, particularly its flagship insulin Lantus. Sanofi has since widened its remit to occupy similar ground to Novo Nordisk in terms of disease ownership, forming a dedicated diabetes business unit in 2010 with the express aim of becoming a 360 degree solutions provider.

The window of opportunity for healthcare products companies is still open in most diseases, despite an acceleration and rapid growth of specialized healthcare service provider chains. To make an impact in the market place, close collaborations with payers are sought in order to cater to more integrated healthcare service needs and to insure best cost-effective outcomes.

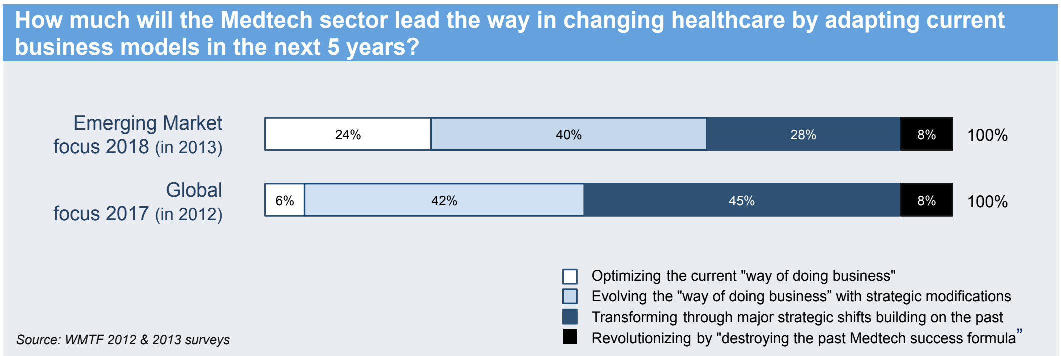
	Fresenius Medical Care	*Sanofi Diabetes*
Indication	End-stage renal disease	Diabetes
Primary revenues	Dialysis services (>75%)	Drugs (>85% Lantus)
Pharma products	Renal Pharma (own products and JVs, e.g. Vifor Pharma)	Lantus, Apidra and others (rich R&D portfolio with partners)
Medtech products	Comprehensive dialysis treatment modalities, e.g. hemodialysis	BGStar and iBGStar blood glucose monitoring (with AgaMatrix)
Healthcare services	More than 3,200 dialysis centers globally	Patient programs and other (free) services
Outcomes management	Continuous quality monitoring and improvement (EuCliD)	Diabetes Manager with (iPhone) interface (for patients and HCPs)
Perceived competitors	DaVita, Baxter/ Gambro, Amgen	Novo Nordisk, Eli Lilly

4. Emerging beyond recognition

A substantial share of tomorrow's growth is expected to come from developing markets, such as Brazil, Russia, and China (BRIC), South Korea, Mexico and Turkey, as well as so-called Frontier Markets, such as Vietnam, South Africa and the Gulf region. Rising affluence and a fast growing middle-class make these countries attractive. They represent new markets with large volume/ sales growth potential. And they also have the potential to provide local capacity for doing business across the value chain, most notably manufacturing resources, which in turn can be used to serve global markets. As a result, Medtech companies need to adapt and transform business models in order to meet local needs, taking advantage of the opportunity to "lead the way in changing healthcare" in emerging markets. (See Figure 4.1)

On the whole, Medtech experts feel that the industry is still able to shape healthcare in emerging markets over the next 5 years. It will mean changing business models, however. More than a third of Medtech executives believe that they need to transform or "revolutionize by destroying" their current business models in order to lead the way in changing healthcare in emerging markets. It also means improving "brand value", according to executives who support the idea of "evolving the way of doing business". They expressed the need to elevate "brand value" onto a global level as "existing products do not hold automatically the same value in emerging markets". Without investment in brand value local favorites will tend to often outperform Western players, is how they see it.

Figure 4.1



There are several evolving opportunities in emerging markets, some of which are not obvious. Medtech companies have typically accessed demand in emerging markets using a standard approach. They initially target it as an export market, served via local distributors, until the company can build up its own marketing affiliates. Typically this happens in the most important countries, such as Brazil and China. The strategy is still valid; however Medtech companies need to make strategic decisions about which BRIC and "Next 11" markets[1] to address next, understanding how they will focus their energies in order to unlock significant volume and sales growth. It requires a step-wise, sequential approach aligned with currently available resources.

[1] The Next Eleven (known also by the numeronym N-11) are the following eleven countries – Bangladesh, Egypt, Indonesia, Iran, Mexico, Nigeria, Pakistan, the Philippines, Turkey, South Korea, and Vietnam – identified by Goldman Sachs investment bank and economist Jim O'Neill (Source: Wikipedia)

Which markets?

Most Medtech experts strongly agree with the statement that ***"China is a must win"*** market in order to increase a company's future competitiveness. The opinion is based on the growth rate and sheer market size. The value of the Chinese market is expected to double by 2020 to reach $53 billion per annum, according to RnR Market Research cited in Healthcare Finance News. The Chinese market is a challenging mix of "high-tech" premium, secondary local brands, and mature commodity segments. But even commoditized segments, such as pens and needle systems, can find a market as premium products, particularly products manufactured to high international standards. A case in point is Owen Mumford (OM), a leading provider of medical devices for diabetes and other diseases. In 2012 it was able to enter the Chinese diabetes market through a successful distribution agreement with DKSH Healthcare, according to DKSH. After eight months of collaboration with DKSH, OM's revenue in China had "expanded dramatically" and market share had risen "significantly".

To be successful over the long-term, companies have to consider the optimal product portfolio for the Chinese market. Historically, Medtech companies have leveraged low-cost labor for off-shoring specific manufacturing activities, particularly the labor-intensive processes, such as assembly of hearing aids, infusion kits and many other Medtech products. Winning Medtech companies are targeting high-population growth markets, particularly China and India, by developing value chain activities locally. With local engineering, clinical trials, manufacturing in these markets, access will improve. And if done well, the returns on such investments can be significantly greater than in developed or Western markets.

As key emerging markets mature and the "Next 11" markets progress, a diversity of novel business and commercial models will surface. Addressing these white space opportunities will push the boundaries beyond today's approaches. Western players can learn from these frontier markets and apply the lessons learned in other countries. Turkey is pushing ahead to become a regional stronghold and an essential hub for the EMEA markets to many manufacturers. The growth is supported by a regulatory environment and a government-backed healthcare initiative. (See Reuters report.) Taiwan, Vietnam, South Africa and also the Saudi Arabia/ Arabic Emirates are tipped to be among the winners of the "Next 11" in the years to come. Most markets have a common set of influencing factors requiring them to change commercial models driven by demographic changes, soaring need healthcare professional education, and to deliver better access in rural areas.

The challenge is to execute an effective and timely launch with coordinated regulatory compliance. Timing is important in order to be able to achieve market share before competition from local suppliers becomes fixed. "Underserving the initial demand often causes disruption and drastic loss of future sales potential, as local competitors fill any gaps extremely fast," observes one Medtech executive interviewed for this report. Indeed, emerging market Medtech companies are confident about their ability to compete in a global market, as evident in the latest survey of the medical device industry by Emergo Group. (See Figure 4.2)

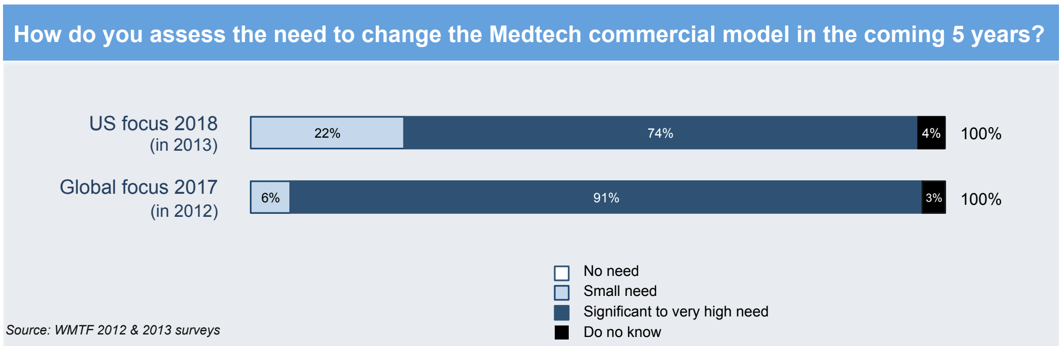
Figure 4.2

The source of the greatest competition over the longer-term is believed to be China. Chinese companies ranked highest by survey participants based on their potential to become significant rivals to established Western companies by 2025. It is clear that Chinese companies have global ambitions, and are willing to do M&A in order to gain strength, as evidenced by MicroPort Scientific Corporation's recent acquisition of Wright Medical's OrthoRecon unit, a hip and knee implant business. South Korean companies are also seen as high-potential rivals. Korean ventures are expected to gain in momentum over the next few years, driven by strong government support, which includes initiatives to stimulate growth of the local medical device industry. The goal is a fivefold increase in revenues and a position as a significant research and manufacturing hub, as reported in a recent Fierce Medical Devices article.

5. Remaining commercially competitive

Medtech executives have always concentrated on adapting their company's commercial approaches to achieve top-line and bottom-line growth, particularly through tactical adaptations. However, with increasing global competition and the entry of local players, their focus is shifting to improving commercial operation across all available channels. A striking majority of executives consulted for this report indicate a significant need to change Medtech commercial models globally, as well as in the US, in the coming 5 years in order to anticipate more fierce competition. (See Figure 5.1)

Figure 5.1



At the same time, market leaders are working on commercial excellence to address both industry consolidation and competition from developing markets. They are not complacent and invest in developing profitable services and solutions. One executive sums it up well when he said: **"**Future winners possess the abilities to serve entire healthcare value chains in part or holistically***."***

Key drivers propelling future commercial models

Just what is meant by the phrase "entire healthcare value chain" is evident in ideas like "own the disease", or "own the department/ center" (See "Global Medtech Report 2012: Visions in Times of Change", page 20). In practice, it means focusing on an integrated "brand value" that includes important stakeholders. It means developing commercial models that include stakeholders beyond healthcare professionals, adding new managerial roles or departments in the organization to target payers, for example. Market leaders have also identified consumers/ patients as decision-makers, acknowledging this group's influence in treatment choices. A specific approach is "Quality Health". Another is the introduction of innovative purchasing schemes (to capture out-of-pocket spending for premium products). Phonak's Lyric subscription targeted at patients, is an example.

Furthermore, Medtech leaders are investing in proprietary distribution channels in both developed and emerging markets. This approach serves to erect entry barriers and improve access to customers. It is evident in dental, hearing aids, and ophthalmology markets. Leaders are also addressing e-Health as an opportunity to integrate directly into the healthcare value chain through web-based solutions. Both healthcare and life sciences players can have a direct interface to customers. Two models, EHR and "big data", within e-Health show promise when it comes to making better decisions for patients at the point-of-care. For example, the Danish national healthcare system (see Case Study 3) was early to adopt this technological and regulatory evolution in a way that is attractive to both government and ICT leaders.

First movers in e-Health exploit technology to differentiate their products and services. There is potential in Smartphone apps to engage consumers in what is dubbed the “quantified self”. For example, diagnostics apps, behavior change tracking apps, and remote monitoring. Another technology trend to exploit is “Gamification”, or applying insights gaming/ software to Medtech products. A market leader already doing that is Hocoma with its body-movement tracking device and associated software “Valedo”.

A third way for Medtech leaders break out from the crowd is to learn from consumer goods’ strategic marketing and superior branding methods. It is an approach already used by global nutritional leader, Nestle Health Science.

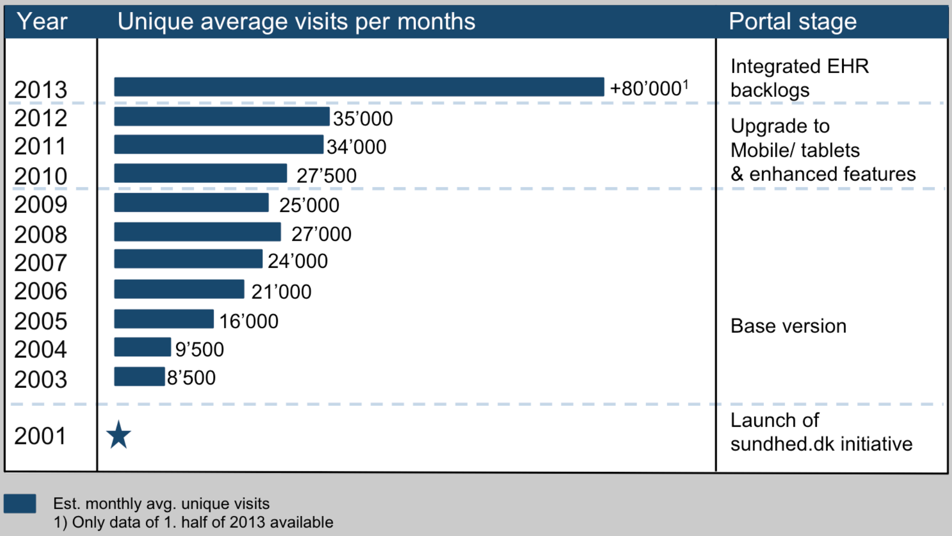
Case Study 3: "Sundhed.dk - a leading national healthcare portal"

The Danish healthcare portal sundhed.dk was founded in 2003 as part of a national quality improvement initiative. A core objective is to support the national healthcare service goals by aligning and integrating all relevant patient-centric communications into one portal. It unites patients and providers via an affordable investment in infrastructure and a shared system for all healthcare services at municipal and regional level, enabling more hospitals to use a common e-Health system. It leads all other OECD countries in this respect.

Uptake by patients was initially moderate. However, an ICT overhaul in 2010 led to higher user acceptance and usage soared in 2013, with a twofold increase compared to the year before. Today, activities are not only focused downstream (e.g. patients/ relatives, citizens, providers) but also integrated upstream too (e.g. providers, payers, governmental agencies). Patients in need are directed via sundhed.dk directly to the nearest available GP/ specialist. All entitled parties have access to the electronic health record (EHR) at any time. Any prescription and treatment data is instantly logged centrally, enabling seamless referrals and high visibility on treatment quality and outcome. In the background, centralized procurement bodies fulfill product replenishments automatically based on publicly issued tenders. Recently, sundhed.dk added patient EHRs comprehensively dating back to 1970's in order to provide a holistic and complete data set.

Based on a wide acceptance, sundhed.dk is now leapfrogging into a vast array of state of the art applications. For example, embedded telemedicine, self-booking based on provider availability, patient data authorizations/ referrals to next in kin, sharing of medication records, optimizing data mining for research, development and clinical/ intensive care usage and more advanced chronic disease management modules, such as diabetes care. It is anticipated that by 2015, 80% of all referrals, reporting, formal letters and other written communication between individual citizens and the healthcare services will be digital.

User acceptance since launch of sundhed.dk



Source: www.sundhed.dk & WMTF 2013 presentation

6. Headquarter-driven transformation

We've observed over the past few years several accelerating healthcare and Medtech trends that drive corporations to transform strategies, business and commercial models. One strategy was expressed in an interview when an executive said: "HQ activities must become as lean as possible to optimize bottom-line contributions". Other executives say they anticipate headquarters' functions to add value beyond the obvious strategy setting. They identified three distinct topics to be prioritized. (See Figure 6.1)

Figure 6.1

How can global Medtech headquarters add the most value currently?

	US focus 2013	Emerging Markets focus 2013
Formulating strategy/ plans		3
Changing business and/ or commercial models	1	
Scouting/ committing new partnerships	3	1
Streamlining processes/ interactions, e.g. shared services	2	2
Advancing product innovation, Meeting financial targets, and/ or Promoting talent management,		
Others/ Do not know		

Source: WMTF 2013 survey

The top priorities for headquarters are strongly linked to themes discussed in previous chapters. In established markets, such as North America, headquarters' focus is primarily on commercial models, whereas in emerging markets, e.g. Latin America, the number one priority is scouting and committing to new partnerships. All agree that continuous streamlining of processes/ interactions is the second highest priority, followed by the development of shared service capacity. Taking advantage of near- and off-shoring is something that Medtech has lagged other industries in undertaking, but it is now a higher priority, particularly amongst medium and large sized Medtech players, as an article in MDDI Online makes clear.

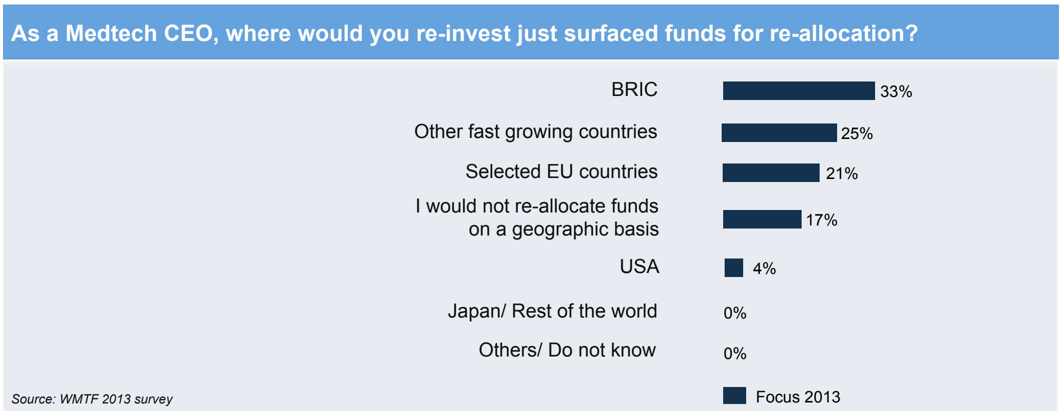
Due to increasing M&A, more Medtech executives are also prioritizing "simplifying within and across business units" in order to successfully integrate acquisitions. Additional trends affecting headquarters' priorities emerged in interviews with Medtech executives. One large manufacturer sees the need to re-focus on innovation rather than improving existing technologies, and neglecting investment in innovation. If done correctly, innovation is a way to leverage the overall portfolio. Another priority, particularly for niche-focused "high quality product" players, is investment in global functions, such as R&D/ technical capabilities.

Clearly, another trend affecting talent management is related to emerging market companies establishing their overseas' headquarters in Western markets. The trend makes the "war for talent" fiercer, and may cause talent shortages over time, particularly in large lucrative markets, such as the US. Several Chinese Medtech market leaders described in an article in CFO Innovation exhibit the trend.

As the future unfolds, the responsibilities of HQ are increasing. The winning formula for success is believed to be based on a lean organization structure and new management skills. This is particularly true for responses to questions about “Where to play” and “How to win”, and understanding how to cater to local markets. Talent and know-how contribute strongly to the transformation of Medtech companies. Experts interviewed for this report believe that visionary managers will be a key competitive advantage. Visionary managers are able to lead innovation efforts, integrating all internal stakeholders and external partners. And they may form novel intra-sector partnerships. An example of that is Dental Campus, a learning platform for dental implant global providers/ specialists. Rotating talent between headquarters and emerging/ rising markets is also a strategy from winning companies. The tactic enhances cultural values and delivers managerial leadership and skills to local markets. Furthermore, future industry leaders need a new type of management skill, one based on a holistic end-to-end interdisciplinary understanding and perspective if they hope to integrate multiple stakeholders and partners across the healthcare value chain.

Many Medtech executives are re-investing bottom-line gains in new markets. When asked which region is the target for re-invested funds, the majority of executives said that they seek to reallocate funds to BRIC countries and other fast growing countries, followed by selected EU countries. More than 15% of executives say they would not re-allocate such funds to any region/ country. (See Figure 6.2)

Figure 6.2



7. Concluding food for thought

As with our first Global Medtech Industry Report, we are sharing the collective wisdom obtained in recent interviews with over 20 Medtech experts, combined with the PowerVote survey results of the WMTF 2013. The industry experts conveyed views that were supportive, controversial and insightful. The authors have selected quotes, grouped into categories that correspond with earlier chapters, and added a brief commentary as “food for thought”:

Supportive quotes   Controversial quotes   Insightful quotes

The Medtech experts confirmed the PowerVote survey identifying near-term trends in managing, financing and competing in healthcare, the trends expected to affect Medtech significantly in the years to come. They spoke about the need to systematically question traditional approaches.

“The US healthcare reform ‘Affordable Care Act’ increased uncertainty with its many open issues, and the implication of as yet unclear rulings.”

“Price pressure in Western markets will open doors for novel competitors, not only with medical products but also with healthcare solutions.”

“Diseases have no borders - we as an industry have to collaborate with healthcare authorities to cater for their local needs.”

Managers seek multiple avenues to achieve top- and bottom-line growth globally. They leverage M&A and alliances systematically both within and across the healthcare value chains to broaden their “Where to play” space. Furthermore, integrated healthcare solutions providers, often non-traditional players, are emerging.

“Consolidation affects healthcare today since players are grabbing market shares, also beyond the traditional Medtech space.”

“Some of the largest Chinese hospitals with more than 5,000 beds are already leveraging ‘big data’ solutions to manage their operations.”

“Medtech leaders can learn from dominant ICT players and past IT revolutions leading to transformation in other industries.”

Establishing external partnerships across the healthcare value chain is becoming more important. Medtech leaders are making decisions now on a new set of ‘partners of choice’ to fast-track their intended business model changes, particularly with healthcare players and beyond. Medtech, pharma and adjacent sectors are converging through M&A and alliances that focus on a specific disease.

“More demanding healthcare customers and well-educated patients value an integrated offering, driving the need for collaboration.”

“Firms cannot wait 5 years and have to act now to avoid being run over and/ or being acquired sooner, rather than later.”

“We collaborate with international insurers and/ or large provider chains to align margins with outcomes, leveraging ‘big data’ insights.”

The Medtech sector will benefit from substantial growth in developing and frontier markets over the years to come. Today's leaders are offering "high-tech" premium products, secondary/ local value brands, and even mature commodities, in some cases. Launch, regulatory excellence and marketing/ distribution capabilities are seen as essential to win against already strong local competition.

"We are not investing blindly in emerging markets per se, but focus on Tier II market segments taking the lion's share in the future."

"The patient-rich and high-volume markets are the global battlefield with cutthroat pricing spilling-over to Western markets, as well."

"After China and Brazil, the next emerging and frontier markets are being propelled by spending on 'quality health' products and solutions."

In today's world, Medtech executives drive changes in their commercial models proactively at the global level. Expansion into proprietary distribution channels can secure unique market access, particularly in emerging markets. Ultimately, the growing e-Health infrastructure will shape future commercial degrees of freedom.

"The commercial model must alter significantly as clinical evidence and outcomes are the dominant arguments in procurement negotiations."

"Traditionally complementary services represent a large commercial burden which is difficult to maintain under current price pressure."

"Medtech companies try to consolidate the direct interface to clients/ patients, taking-out the middle men with a narrow portfolio."

When being hit on the bottom-line, Medtech executives prune their headquarters to focus on the most value-added activities. Lean organizational structures and processes free-up country managers and their teams on serving customers better. Any cost savings and other funds available for re-allocation are being invested into fast-growing emerging and frontier markets.

"Headquarters should strive for constant simplifications within and across business units and value chain processes."

"To overcome 'infant industry protection', Medtech multinationals cannot shy away from investing into global functions in high-growth markets."

"Future winners will focus on more rotation of internal talent between the headquarter and their most important emerging/ frontier markets."

These excerpts reveal that Medtech executives are doing their utmost to accelerate the necessary transformation that is required to be successful in the long-term. They have to anticipate the impact of healthcare and Medtech trends to identify their own winning strategies. In order to plot and reach their strategic vision, Medtech leaders can exploit the "Medtech Transformation Tracker" to highlight the current situation, and identify mid-term gaps that could delay or even block being able to achieve the long-term vision (See Appendix 3). The proposed tool can be used to capture and communicate throughout the organization "Where to play" and "How to win" levers to facilitate strong buy-in, uncover compelling initiatives and enable flawless execution.

Appendix: Methodology & acknowledgements

'*The Global Medtech Industry: Accelerating Transformation for Success*' report is jointly published by ConCeplus GmbH and Executive Insight AG. The report builds on the presentations, panel discussions and electronic voting from September 17th - 19th, 2013 at the second WMTF Lucerne. It was written in close collaboration with Medtech executives and experts who provided their insights in over 20 interviews.

The quantitative PowerVote survey was conducted through real-time electronic voting at the WMTF 2013, similar to the WMTF 2012 a year earlier. Three sets of 15 questions were asked on September 17th, 18th and 19th using PowerVote, a user-friendly audience response system. The Medtech experts and moderators participating in the WMTF 2013 panel debates, as well as the Medtech experienced audience, answered each question which resulted in up to 44 answers per question on the Executive Day and up to 27 answers per question on the North American and South American Day each. The authors want to thank all the 2013 WMTF Lucerne attendees and, particularly, the presenters and panel members for their thought provoking contributions.

The quantitative PowerVote survey and qualitative insights were summarized in a set of hypotheses and synthesized in a 20-page discussion document. 21 Medtech executives and experts answered around 15 pre-formulated questions in personal interviews lasting up to 1½ hours. The authors want to thank all the Medtech executives and experts for taking the time from their busy schedules to participate in these interviews (Medtech companies and associations listed in alphabetical order):

B. Braun	Biodenta	Biomet[2]	Biotronik
Cochlear	DePuySynthes/ J&J	Forteq	GE Healthcare
HBM Healthcare Investments	Hocoma	Holution	LifeScan/ J&J
Mathys	Philips Healthcare	Roche Diagnostics	Schiller
Smith&Nephew	Sonova	Straumann	Viveve
Zimmer[2]			

Last but not least, the authors want to thank all those who contributed to the writing of 'The Global Medtech Industry: Accelerating Transformation for Success' report, particularly Sarah Moyle and Valerie Thompson.

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[2] The interviews with senior management at Zimmer Europe and Biomet Europe were conducted inQ1 2014 independently. The merger of both companies was executed in April 2014.

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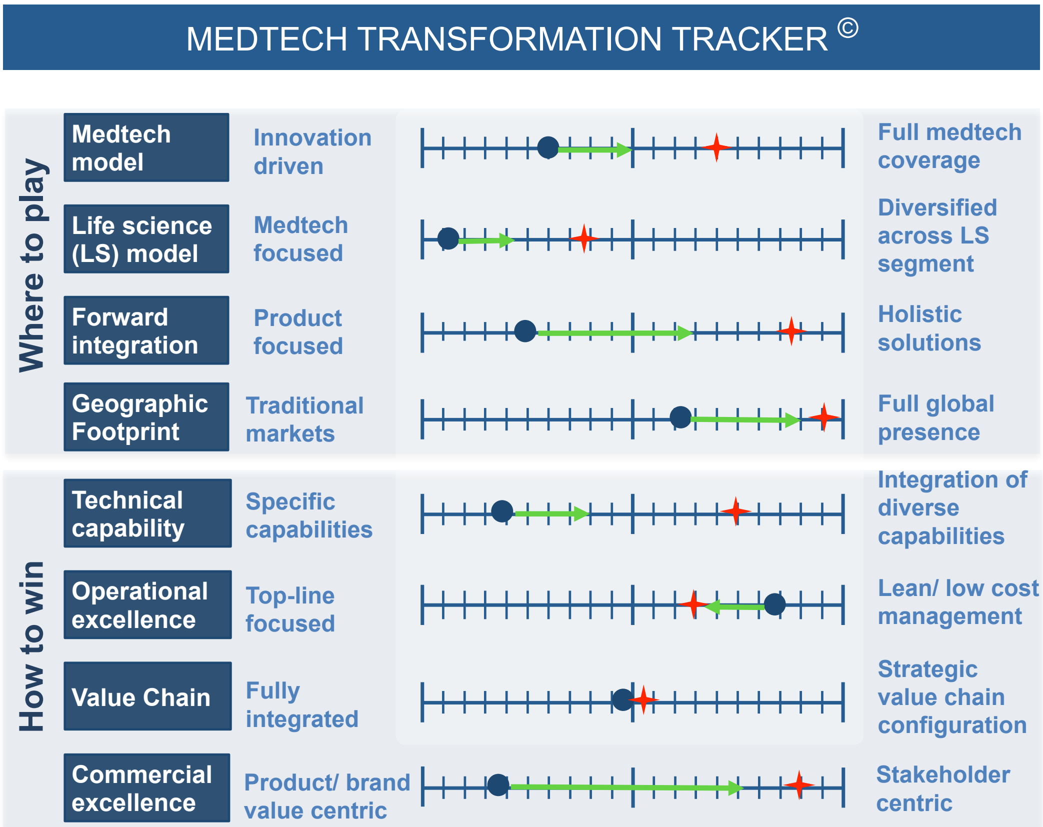
Appendix: "Medtech Transformation Tracker"

Based on the insights from the WMTF 2012 and 2013 and our related reports, we have developed the "Medtech Transformation Tracker" to enable executives to plot their strategic vision and see how to reach it successfully. The proposed tool can be used to both identify and communicate "Where to play" and "How to win" levers.

Four steps to define your "Medtech Transformation Tracker"

- Assess your starting point ● for each strategic lever already pulled currently (considering the impact of prior initiatives that are already launched)
- Formulate the vision for each "Where to play" and "How to win" strategic lever (highlighting the key competitive differentiators)
- Position the anticipated target point ✦ for each strategic lever after 5 years (reflects the magnitude of the transformation required compared to today)
- Scale the incremental transformation vector ⟶ for the coming 2 years (showing the required acceleration in an increasingly dynamic market)



You can review and challenge the self-assessment periodically to adjust the necessary speed to achieve the anticipated transformation, and unlock much-desired growth in a dynamic market.