Software Design for Medical Devices Investment Activity

Investment Activity Market Commentary

The Medical Device Technologies Market is forecasted to undergo exponential growth from 2015 up to 2021. (5)

Forecasted global market value for emerging medical device technologies by 2021: **£90.8bn**
This is from 2016's valuation of $55.9 billion . (4)

The growth of this market is underpinned by the rise of segments in cardiovascular, orthopedic, diabetes care, in vitro diagnostics, neurology, ophthalmology, drug delivery/pain management as well as patient monitoring. Other driving factors include looking at the rising prevalence of chronic diseases, digital advancements in medical devices and the aging population.(4)

Forecasted market value of medical device connectivity by 2021 (6) **US$ 1,344.1m**

2015 saw the services segment take the largest share of this market which is connected to the increased use of EHRs and healthcare information exchange systems. (6) North America stood as both the largest and fastest growing regional market, followed by Europe, Asia-Pacific and the RoW.

Software design for medical devices requires a dedication to continuous improvement. In a recent article published by Healthcare Informatics, Heather Landi maintains that, although challenging, it is important to host a central repository of up to date and accessible information tracking the software versions that are active in a healthcare facility in order to successfully manage required updates. A lack of visibility of these notifications can impact patient safety and care through downtime or degrading the performance of the devices or their connections.1 Software gaps can expose devices and patient data in regards to potential cyber attacks, Heather adds that data can be lost, stolen or remain inaccessible.
Despite this urgency, spending on med device cyber security is still too low.

Also, it is important that device manufacturers select and invest within the software designers that have developed established risk management systems and meet today's standards.

In a recent report, Pharma IQ discovered a selection of investment behaviours regarding medical device software design. This year, we ask a selection of experts to provide their analysis on those findings and their projections on how the industry will behave in the years ahead.

Expert Panel

**Orna Nesher,** Manager, Software Design QA Medtronic

Brian Shoemaker, Ph.D, Principal Consultant, ShoeBar Associates

Adrian Gerhaeusser, Head of R&D at Siemens Digital Factory, Siemens and former Program Manager for Software Platforms within Siemens Healthineer.

NOTE: The opinions expressed by experts in this piece do not necessarily represent those of the companies they are associated with.

2015 Research Base

WHAT CATEGORY DOES YOUR COMPANY FALL IN TO?

- TECHNOLOGY 12.5%
- BIOTECHNOLOGY 6.3%
- SOFTWARE DESIGN 9.4%
- PHARMACEUTICAL 21.9%
- MEDICAL DEVICE 50%
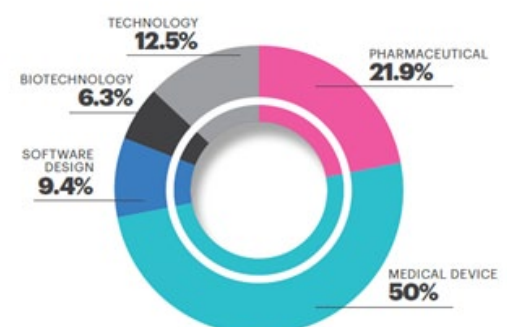
Investment Trends – A year in review

In this section we asked our base whether there had been a change in investment levels in certain primary areas. On average, over the 12 months prior respondents had witnessed a substantial increase in investment levels. Agile development solution providers appear to be the region which saw the least movement in investment.

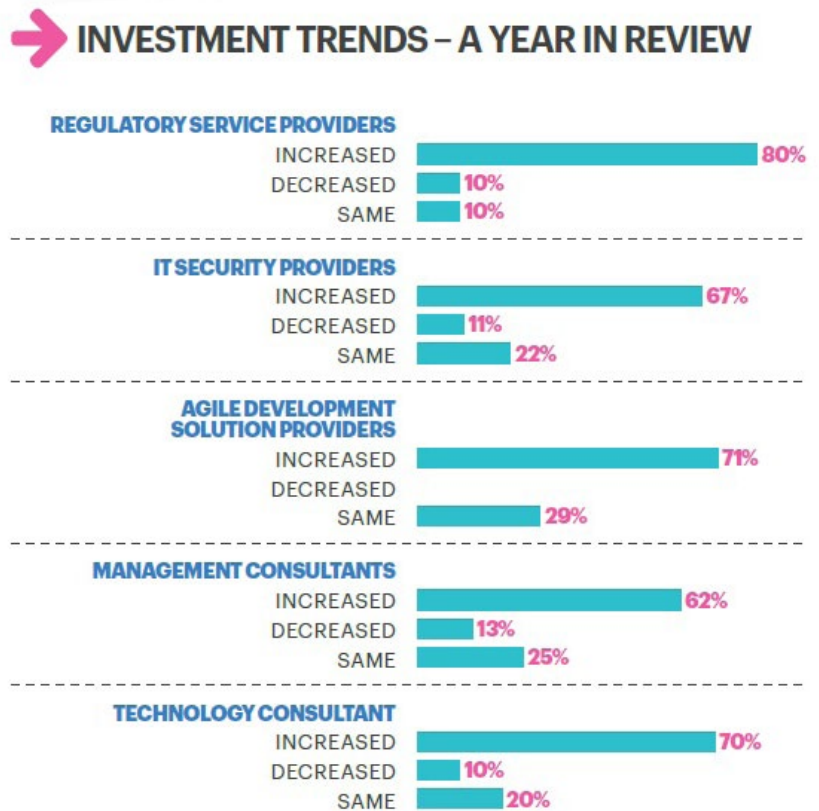*NOTE: RESPONDANTS COULD SELECT MORE THAN ONE ANSWER*

Analysis

Orna: "These results aren't surprising to me, because our company is working actually according to the [majorities in this] result. "Each of these categories actually explain where the companies want to be in a couple of years." She added that spend on technology consultants is logical in regards to incorporating the development of new technologies and cyber security methods to remain competitive. However, these levels are likely to change especially as companies master the Agile process spending in understanding this area will lower.

Brian: "It's quite significant to me that there has been a considerable increase in the investment in agile development solution providers, because, personally I happen to believe that an agile approach is what the industry needs in order to maintain competitiveness, especially here in the US. Nobody [has indicated] that there was a decrease because most people are starting from zero."

Brian adds that in a few years time there may be a drop in spend on management consultants but a rise in spend on agile solution providers and IT security providers.

Adrian: "The first surprise is that everything is growing because budgets are always restricted, so I think investment is more spread.

"What I can clearly see is getting more attention than in the past is IT security. The FDA, DOD and the other Federal

INVESTMENT TRENDS – A YEAR IN REVIEW

REGULATORY SERVICE PROVIDERS	
INCREASED	80%
DECREASED	10%
SAME	10%

IT SECURITY PROVIDERS	
INCREASED	67%
DECREASED	11%
SAME	22%

AGILE DEVELOPMENT SOLUTION PROVIDERS	
INCREASED	71%
DECREASED	
SAME	29%

MANAGEMENT CONSULTANTS	
INCREASED	62%
DECREASED	13%
SAME	25%

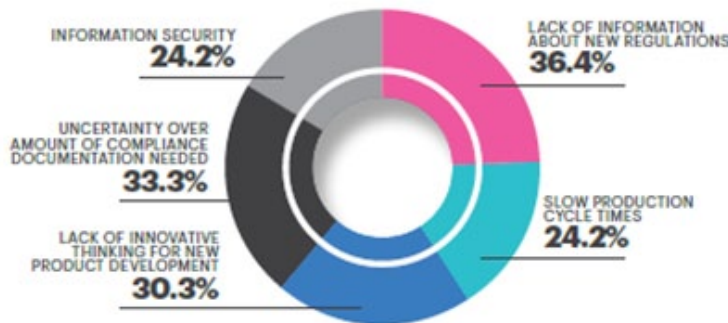| TECHNOLOGY CONSULTANT	
INCREASED	70%
DECREASED	10%
SAME	20%

agencies are [focusing on this topic] more and more. So, here I would completely concur that there is more spend coming. It is a bit surprising that there is still a steep increase on the regulatory service providers side, as I would have assumed that these aspects are more standard. We didn't invest too much last year in increasing the budget as indicated in these results.

"Technology consultations will also be on a high level over the next [few] years because of new data analysts' roles or gaining basic knowledge from the big IT companies. A lot of the healthcare companies which are mainly still hardware driven, at least from what I have experienced, lack in knowledge and capacity."

Investment Trends - Obstacles

WHAT ARE THE MAIN CHALLENGES YOU ARE CURRENTLY FACING?

- INFORMATION SECURITY 24.2%
- LACK OF INFORMATION ABOUT NEW REGULATIONS 36.4%
- UNCERTAINTY OVER AMOUNT OF COMPLIANCE DOCUMENTATION NEEDED 33.3%
- SLOW PRODUCTION CYCLE TIMES 24.2%
- LACK OF INNOVATIVE THINKING FOR NEW PRODUCT DEVELOPMENT 30.3%

Here we asked to hear about the main challenges faced by our participants in regards to software design for medical devices. Compliance related considerations are of clear prominence here, with a lack of information on new regulations and uncertainty of needed compliance documentation being the dominant challenges encountered by respondents.

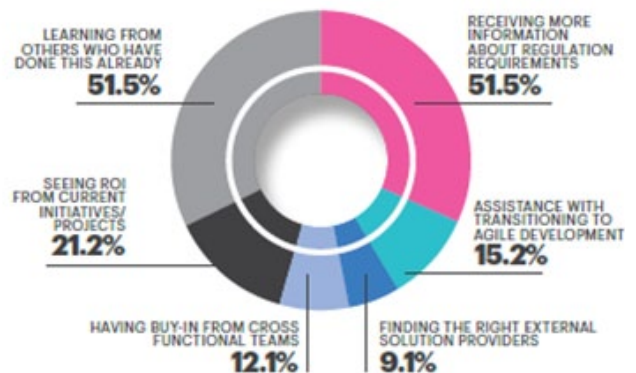*NOTE: RESPONDANTS COULD SELECT MORE THAN ONE ANSWER*

Analysis

Brian: "I am surprised about the lack of innovative thinking, because at least where I'm located, here in the Boston area, there are numerous small start-ups, which have very innovative ideas. It may very well be that this is an industry that has a strong, highly pyramidal structure - with a few people at the very top, holding the vast amount of the production and money. This makes it very difficult to get innovative thinking through in a high found organisation."

Adrian can understand the responses in regards to the lack of information about new regulations in particular with the FDA or the CFDA. As these authorities are adopting multiple new aspects with more standards and possible regulations on med device security for instance. So, there's an uncertainty as to how fast the basic regulative bodies will move.

Cloud based DevOps approaches are labelled as game changers for improving speed and cycle times, going against the standard deployment structure of new software releases. He notes that a lot of partnerships are appearing between healthcare and IT companies. Strategic moves to learn from others and welcome new knowledge that may be exterior to the healthcare domain. Acquisitions of this nature are data led with a view to pre-empt the market's approaching challenges.

He adds that it is not perhaps a lack of innovative thinking

WHAT WOULD HELP YOU OVERCOME THESE CHALLENGES?

- LEARNING FROM OTHERS WHO HAVE DONE THIS ALREADY 51.5%
- RECEIVING MORE INFORMATION ABOUT REGULATION REQUIREMENTS 51.5%
- SEEING ROI FROM CURRENT INITIATIVES/PROJECTS 21.2%
- ASSISTANCE WITH TRANSITIONING TO AGILE DEVELOPMENT 15.2%
- HAVING BUY-IN FROM CROSS FUNCTIONAL TEAMS 12.1%
- FINDING THE RIGHT EXTERNAL SOLUTION PROVIDERS 9.1%

but more a lack of capability to grow in a domain which is not typically medical but more IT led. Although, Adrian feels that medical device software providers will have to be open to collaborate with other competitors in order to make a difference in the future.

He hasn't noticed that regulatory documentation stands as a substantial challenge in the industry in comparison to the IT considerations with security.

Adrian notes that focus is also shifting to the low end equipment providers – which produce simpler devices to satisfy developing countries on a mass scale. This is a useful offering when considering that healthcare budgets are reducing. Europe has a big demand for this segment - the big vendors are struggling to give very compelling offers towards this low price market segment.

Here the report requests insight into annual budgets for the development of medical device software and indication where exactly this investment is being targeted. Despite noting regulatory matters as the main obstacles to address in the industry, respondents collectively indicated that technology consultants are gaining the largest chunk of investments. Regulatory service providers and agile solution providers receive the second largest amount of investments.

INVESTMENT TRENDS – TODAY

WHAT IS YOUR COMPANY'S ANNUAL BUDGET FOR THE DEVELOPMENT OF SOFTWARE DESIGN FOR MEDICAL DEVICES?

UP TO £10,000PA	25%
UP TO £100,000PA	43.8%
UP TO £1,000,000PA	18.8%
MORE THAN £1,000,000PA	12.5%

Analysis

Brian: "Well, an obvious reason for the annual budget figures is the fact that more devices are smart devices and software is essential to making things work. I have worked with diabetes systems, where they want to link information being gathered at an artificial pancreas system so it automatically gets loaded back into a doctor's database - to monitor the patient remotely. This set up just will not happen without software and communication capabilities.

Orna would have expected spending in terms of the annual budget on software development to be higher with the necessity of software development with today's hardware.

WHERE IS YOUR COMPANY CURRENTLY FOCUSING MOST OF ITS INVESTMENT?

REGULATORY SERVICE PROVIDERS	24.2%
IT SECURITY PROVIDERS	21.2%
AGILE DEVELOPMENT SOLUTION PROVIDERS	24.2%
MANAGEMENT CONSULTANTS	15.2%
TECHNOLOGY CONSULTANTS	30.3%

Analysis

Brian: "As far as the focusing of investment, I'm extremely interested in those figures. There is always going to be a place for technology consultants, because not every company can have its own people on [site] to be able to do development.

Adrian "From these results it can be seen that technologies are a trend in regards to merging, acquisition and partnering in regards to expanding towards innovative product development.

Adrian concurs with the results on technology, but with IT security however he is a little astonished that it stands as lower than other areas.

WHAT IS THE MOST IMPORTANT FACTOR WHEN CONSIDERING AN EXTERNAL SOLUTION PROVIDER?

COST	53.3%
ACCESSIBILITY	53.3%
LOCALITY	33.3%
REPUTATION	46.7%
CUSTOMER SERVICE	40.0%

Analysis

Adrian "Here it depends - if you are looking for solution providers which are more standard like a third-party review for filing, then I would say, yes, it's mainly the cost but also the long-term relationships you have typically with the solution provider. If you do bring in new solution providers, you have to invest first quite a bit to bring them up to speed on knowing you and your products.

"If you go for a new aspect and are unsure on how to navigate the area and you would prefer to have providers who are knowledgeable and can bring value to you. Here I would be surprised that cost of accessibility is the most driving factor, I would have expected to see competence and reputation as quite high.

"But it might be also a big company speaking. You typically have a lot of existing expertise in a big company but in smaller companies you might not. Then you presumably would have a standard consultant available to teach the basics for a cheaper price."

Investment Trends – The Future

In the final section of the report respondents were invited to pinpoint where they predicted the future of spend is likely to fall in the industry. As well as the main challenges blocking their progression in the industry.

Analysis

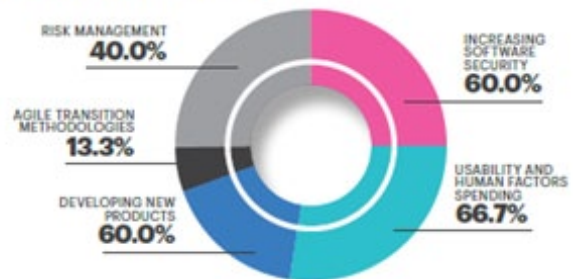**Brian:** "Risk management, software security and human factors are elements that I think should already be well in hand. However, the increase of investment in those areas means that people are waking up and saying, 'Yes, we need to have those well in hand'. The agile transition methodologies, I can only see the level of that growing, because its contribution to competitiveness is only going to increase in recognition, and the ability to change rapidly and refocus, as competitive information changes.

"The development of new products - that is a consistent, solid need. New products are absolute lifeblood of the industry. "On that one last circle graph, cost is an unfortunate impediment for a lot of companies because a large number of the companies are small in this space. Cost is a considerable issue in moving forward because so many companies are small and struggling."

Adrian: "I think I would concur with nearly everything.

INVESTMENT TRENDS – TOMORROW

WHERE DO YOU SEE THE FUTURE OF SOFTWARE DESIGN FOR MEDICAL DEVICES SPEND?

- RISK MANAGEMENT 40.0%
- INCREASING SOFTWARE SECURITY 60.0%
- AGILE TRANSITION METHODOLOGIES 13.3%
- USABILITY AND HUMAN FACTORS SPENDING 66.7%
- DEVELOPING NEW PRODUCTS 60.0%

The only thing which I was a little surprised at is the level regarding risk management, because safety or product risks at least for the established companies is a very basic topic. Clearly the information security is something which is coming and creating.

"New product development is a strategic trend we are currently seeing. I think a lot of firms will be focusing on the upcoming fairs, such as RSNA end of November, new offerings
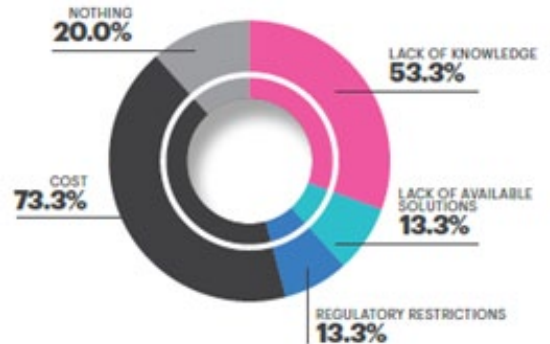
Analysis

regarding big data and combining the data with the product portfolio to improve machine capacities and so on.

"I would also here completely agree with the lack of knowledge segment. I think firms are going into new areas where they do not yet have the expertise.

WHAT IS STOPPING YOU FROM MOVING FORWARD IN THIS SPACE?

- NOTHING 20.0%
- LACK OF KNOWLEDGE 53.3%
- COST 73.3%
- LACK OF AVAILABLE SOLUTIONS 13.3%
- REGULATORY RESTRICTIONS 13.3%

Final Remarks

Unsurprisingly cost is seen as the main inhibitor to progression in this space. Although, despite this the majority of respondents pinpointed an increase in investment levels across the board. Technology consultants seem to be attracting the dominant portion of funds with the report participants forecasting that spend is likely to gravitate towards usability and human factors in software design for medical devices alongside the consideration of newer products. Cyber security is likely to experience an exponential increase in spend with the rising regulatory focus on the area.

Take Action And Attend:

SD MD Software Design for Medical Devices Europe™

21st - 22nd February 2017 | London,

Ground-breaking innovations, cutting-edge ideas and out-of-the-box development techniques are making the medical device marketplace more competitive every day. At the same time, increasingly rigorous standards and regulations are making regulatory compliance more difficult than ever before.

New for 2017

- Innovative Thinking and Pioneering Mind SetShifts: Medtronic's Software Verification and Validation Processes - *Orna Nesher, Manager, Software Design QA, Medtronic*

- Documentation for Agile Development - Shared Understanding, Vacation Photos, and Compliance - *Brian Shoemaker, Principal Consultant, Shoebar Associates*

- Large Scale Agile Transition With Off-Shore Partner Sites and Global Team Considerations *Adrian Gerhaeusser, Department Head Release Management, Digital Factory Division, Factory Automation, Siemens*

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Resources
1.	http://www.healthcare-informatics.com/news-item/cybersecurity/infusion-errors-poor-software-management-among-top-10-health-technology
2.	https://www.abiresearch.com/press/cybersecurity-spending-connected-medical-devices-s/
3.	http://www.archer-soft.com/en/blog/medical-devices-development-trends-2016
4.	http://www.prnewswire.com/news-releases/global-markets-for-emerging-medical-device-technologies-300344763.html
5.	http://www.medgadget.com/2016/10/medical-device-technologies-market-set-to-grow-exponentially-during-the-forecast-2015-2021.html
6.	http://www.marketwatch.com/story/medical-device-connectivity-market-worth-13441-million-usd-by-2021-2016-10-20-112033055