

# APACMed Digital Health Survey: Results and Recommendations

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**MARCH 5**

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**APACMed Digital Health Committee  
Pre-read for Board meeting**

## Purpose

*The purpose of this document is to provide our board members with a high-level overview of the results from our Digital Health survey done with members January 2020, as preparation for the upcoming Board Meeting on 11 February, 2020.*

*It results from the initial work carried out by the APACMed Digital Health Committee, after it was launched in November 2019. Methods of analysis included open interviews and in-depth discussions with members, experts and desk research (articles, reports, websites, etc.).*

***The findings confirm how strategic digital health is for our member companies and the APAC MedTech Industry, crucially underling the existence of several common needs and focus areas. This input has been used to define our Committee Charter and deliverables for 2020.***

*Lastly, included in the document is a brief overview of the following:*

- *Overview of the Digital Health Ecosystem*
- *Key digital health technologies*
- *Regional developments in the field of regulatory and reimbursement*
- *Finally, examples of ‘digital’ initiatives driven by APACMed members are included in the appendix.*

# 1. APACMed Digital Health Survey

As input for our new Digital Health Committee, APACMed conducted face to face interviews with 24 member companies – 16 corporates and 8 SMEs / startups – to assess the following:

- level of activity in the field of digital health;
- key stakeholders with whom they interact;
- views on the major challenges in the region.

We focused on a few key topics: regulatory, data governance, market access, technical, legal, ethics, and compliance

## Key Insights from the survey:

- 76% of participants mentioned **Big data & Cloud computing** as the most relevant digital health solution, followed by **Clinical Decision Support Software**, mentioned by 53% of respondents;
- **Cybersecurity** is the most relevant macro-level regulatory topic for 82% of the participants, followed by **Patient privacy** (70%). As for the regulations specific to digital health solutions, Data quality and Software as Medical Device (SAMd) are the most critical topics for 41% and 35% of the participants, respectively;
- **Accuracy of Data** is the most relevant data governance topic for 59% of participants, followed by **Electronic Medical Records**, for 47%;
- The top market access topics are **Clinical Decision Support Software** and **Value-based payment**, both for 65% of the participants;
- 76% of participants mentioned **Data ownership** and 64% mentioned **Standards** as the most relevant technical and legal topics;
- The participants consider international organisations (such as WHO), healthcare providers, KOLs and patients are the most relevant stakeholders that APACMed should prioritise in advocacy;
- They would like APACMed to partner with IT players (mainly Google and Microsoft) and imaging companies (mainly GE, but also Philips, Siemens and United Imaging).

## Key Recommendations from the survey:

- A common need is the creation of a diverse and robust **digital health ecosystem** across the APAC region, allowing stakeholders to collaborate more effectively. This network should enable medtech players to share knowledge; leverage each other's expertise; discuss and structure policy requirements, all while being supported and coordinated by a regional, neutral organisation such as APACMed.
- **Interoperability** is clearly a major issue in APAC for all medtech companies. On the one hand, digital devices from different vendors should be compatible so as to share data and "talk to each other". On the other, the interoperability of connected medical devices and other digital health solutions should be made possible across multiple settings (hospital to home for example) and across geographies. Messaging interfaces are currently being used to exchange information across healthcare information systems. Health Level 7 (HL7) is, to date, the most widely implemented interface standard in the industry. However, being HL7 compliant does not necessarily mean direct interoperability between healthcare systems; a unique set of international standards should therefore be put in place.
- **Cybersecurity** is also a big challenge in the medtech space, and cyber risks are ever increasing as medical devices become more connected. Today, a universal cybersecurity policy framework does not exist; due to a lack of harmonization between regulations, healthcare industry spends valuable time to comply to the standards of different regulators. Electronic health records have been misused to create fake identities, purchase medical equipment and medications, or even file false insurance claims. It is estimated that data breaches will cost the global healthcare sector US\$300 billion over the next five years. In Singapore, a recent data breach within one of the public hospital clusters exposed the Prime Minister's health records. Cyber threats are thus very real, and healthcare providers, technology manufacturers and vendors, need to have robust plans in place to mitigate for such risks.
- Most of the **regulations** in place today do not apply to digital health solutions, and instead target traditional medical technologies. In addition, approaches across the region differ greatly, with some markets seeking to boost innovation by de-regulating digital health (i.e. South Korea), whilst others have turned to stricter regulation (i.e. China with AI). To bolster digital health innovation and

harness the full potential of new technologies and solutions, a regional, agile, harmonised regulatory framework is required.

- The **reimbursement** of digital health solutions and the notion of value-based care are also key. However, respondents perceive this question as very complex: digital health includes highly diverse solutions and health systems differ greatly from country to country.

Based on the insights and recommendations of its members, APACMed developed a Charter outlining clear strategic areas of focus and key deliverables.

## 2. The Digital Health Committee Charter

In this challenging and opportunity-rich context, APACMed has been asked to support its members to build a digital health ecosystem and advocate for adequate policy frameworks that enable digital health innovation and implementation. The Digital Health Committee is headed by Elisabeth Staudinger, of Siemens Healthineers and involves both MNCs, SMEs, start-ups, knowledge partners and regional associations. To date, we have identified four key areas, around which we will build dedicated working groups. Each working group will meet once a month and report out every quarter to the board. The strategic areas of focus and key deliverables are as follows:

1. The development of **internationally harmonised standards to allow interoperability** among connected medical devices and digital solutions in various settings and across borders. The working group plans to focus on the identification and promotion of international standards to allow interoperability and will publish a position paper to share the outcomes.
2. The **implementation of policy frameworks for data privacy and cybersecurity**, in order to regulate the use of health data for the benefit of global health. The output will be a paper advising policy makers on the creation of a regional framework for cybersecurity in digital health.

3. The **development of regulatory measures** that support digital health innovation. The working group will identify best practices, translate them to the local health system context and share them with regulators.
  
4. The establishment of **optimal reimbursement schemes** for digital health solutions in APAC. This working group will be formed during Q4.

Digital Health Committee	
<b>Mandate</b>	Increase the readiness of APACMed members in digital health by facilitating knowledge sharing Promote digital health for the benefit of patients and healthcare systems by advocating for policies that ease digital health innovation: data security, privacy, governance, harmonized standards, regulatory and value-based reimbursement
<b>Board Sponsor</b>	Elisabeth Staudinger (Siemens Healthineers)
<b>Core Team</b>	Roberta Sarno
<b>No. of Individual Members</b>	30+
<b>Working Groups</b>	Interoperability, Cybersecurity, Regulatory, Reimbursement
<b>Meeting frequency</b>	Monthly
<b>External partnerships</b>	AdvaMed, MedTech Europe, COCIR, DITTA

**Table 1**  
Digital Health Committee overview

Objectives	Deliverables	Timeline
<b>Build the team</b>	<ul style="list-style-type: none"> <li>Recruit multi-disciplinary experts from multiple membership categories: Corporate, SME &amp; Start-ups, and Associations</li> <li>Leadership team nomination and appointment</li> </ul>	By Q1 of 2020
<b>Map the ecosystem</b>	<ul style="list-style-type: none"> <li>Launch a Survey among the members in order to:               <ul style="list-style-type: none"> <li>Identify key stakeholders</li> <li>Identify key challenges and needs</li> </ul> </li> <li>Make a repository of key digital health solutions</li> </ul>	By Q1 of 2020
<b>Define areas of work</b>	<ul style="list-style-type: none"> <li>Starting from members' key challenges and needs, determine and prioritize areas of work and build dedicated Centres of Excellence (CoE)</li> <li>For each area of work, identify key stakeholders and partners to collaborate with</li> </ul>	By Q1 of 2020
<b>Thought leadership in building an interoperable and sustainable ecosystem for digital health</b>	<ul style="list-style-type: none"> <li>Publish a position paper on raising awareness for internationally harmonized standards to allow interoperability among connected medical devices and digital solutions in various settings and across the borders</li> <li>Organise an event with experts to share knowledge</li> <li>Organise an event to promote the paper</li> </ul>	By Q2 of 2020
<b>Advise for the implementation of regional policy framework for cybersecurity</b>	<ul style="list-style-type: none"> <li>Research on ecosystem readiness (industry, govt, providers, patients) towards cybersecurity to better advise the government in designing the policy framework</li> <li>Publish a paper to advise the policy makers about the creation of a regional framework for cybersecurity in digital health.</li> <li>Organise an event to promote the paper</li> </ul>	By Q3 of 2020
<b>Advocate for an agile regulatory framework specific to digital health</b>	<ul style="list-style-type: none"> <li>Research on best practices in regulatory measures for enabling digital innovations, and share findings with regulators in key markets</li> <li>Publish position paper on the need of regulatory framework</li> <li>Organise a webinar with expert to share knowledge</li> <li>Organise an event to promote the paper</li> </ul>	By Q4 of 2020
<b>Advocate for the establishment of optimal reimbursement schemes for digital health solutions</b>	Publish a position paper on digital health reimbursement based on patient outcome assessment/Value-based healthcare (such as on remote monitoring) <i>TBD at the end of 2020</i>	Q4 of 2020 - 2021

**Table 2**  
Digital Health Committee 2020 deliverables and timeline

## 3. Landscape of Digital Health

Valued at \$144.2billion USD in 2018 and predicted to grow to \$206 billion USD by the end of 2020, the global digital health market is growing at a CAGR of 27.7%.

First introduced in 2000 by Seth Frank, digital health two decades ago largely encompassed internet-focused applications and media to improve medical content, commerce, and connectivity [1]. The term digital health has now expanded to encompass a much broader set of scientific concepts and technologies, including genomics, big data, artificial intelligence, 3D printing, SaMD (Software as a Medical Device), virtual and augmented reality, robotic surgery, analytics<sup>1</sup>, wearables, bio-sensors, digital therapeutics (i.e. smart pills), mobile health, companion diagnostics, mobile applications, and telemedicine.

### Key Technologies

Examples of technology applications in digital health:

- **Augmented reality** for diagnosis and health education
- **Artificial Intelligence** in medical decision support
- **Portable connected medical devices** to enable healthcare professionals to diagnose and treat patients outside of the hospital setting
- **Genomic analysis** to customise treatments
- **Health sensor** to enable patients/consumers to monitor their health: wearables, digital tattoos, smart clothes
- **3D-printed** tissues, skin, blood vessels, bones and organs
- **Robotic** nurse assistants
- **Telemedicine**
- **Big data and AI** to drive precision medicine and identify the best treatments for patients based on genetics, environment and lifestyle

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<sup>1</sup> Analytics is the discovery, interpretation, and communication of meaningful patterns in data. It also entails applying data patterns towards effective decision making. In other words, analytics can be understood as the connective tissue between data and effective decision making.

## Key stakeholders

The digital health ecosystem is diverse and brings together different stakeholders, from traditional healthcare players to new entrants in the field:

- **Pharmaceutical companies, MedTech companies** and **start-ups** are driving smart healthcare to improve patient outcomes and reduce the cost of healthcare delivery.
- **New players** have entered the field – tech giants and car manufacturers are an example
- **Healthcare professionals** are changing the way they manage patients thanks to technology
- **Hospitals** are integrating digital technologies
- **Patients** are empowered by technology and are becoming more active in managing their own health and treatment when they are ill
- **Governments** are working on regulatory and reimbursement policies to help bring digital health applications and products to patients

## The Digital Patient

The convergence of technology and healthcare is not only improving healthcare, but is reshaping it at all levels, from ecosystem stakeholders and dynamics, to the role played by patients and their experience across the care continuum.

The **increasing demand for healthcare across APAC** in both developed and emerging markets, is driven mainly by population growth – with many emerging markets about to reach their “peak” population – and an ageing population[2]. In addition to this, the lifestyle of a rising middle class has led to a **surge in chronic diseases**. Digital solutions that are data driven, innovative and affordable, ones that re-imagine care and cost and focus on the patient will drive this digital transformation. However more work needs to be done on mapping patient pathways in Asia. Below is an example of patient journey, which illustrates how digital technologies are already transforming the patient journey: from **diagnosis to treatment; clinical decision support; care management, and care delivery**.

In summary, digital technologies have the potential to greatly improve care delivery, create operational efficiencies and enhance patient and staff experience. By collecting data through devices, viewing patient information and providing diagnosis in real time, real outcomes can be measured.

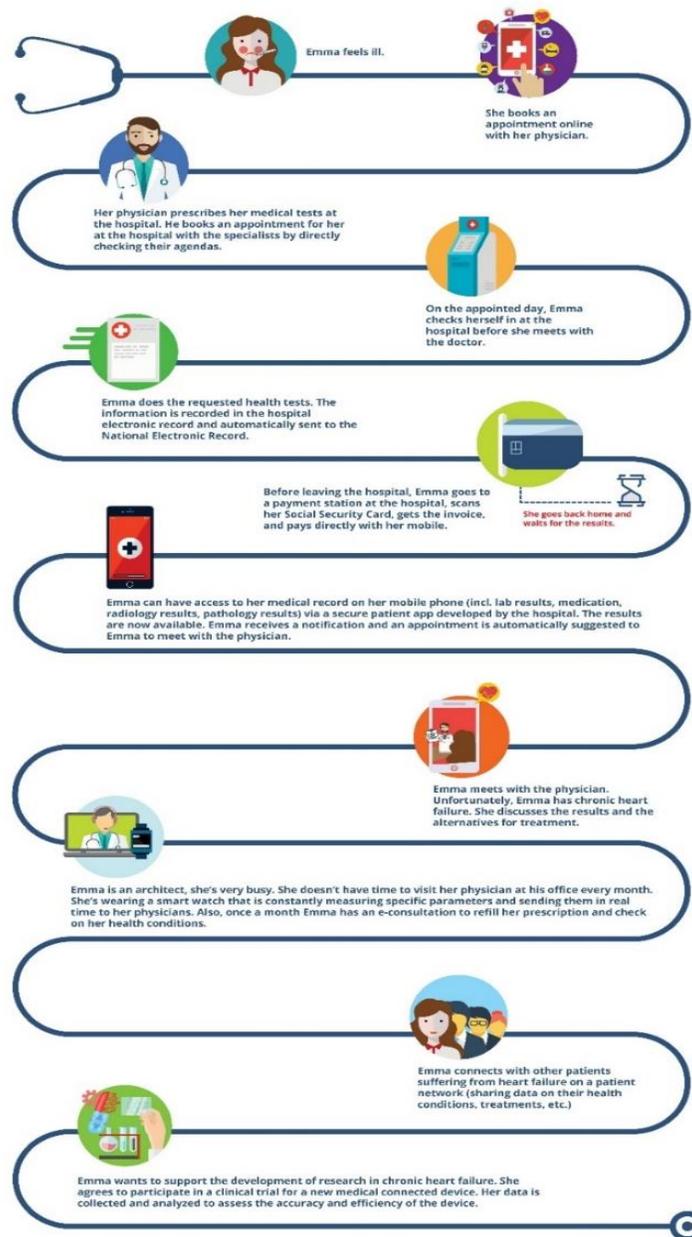


Figure 1

Emma's journey towards smart health [3]

## Opportunities and Challenges

A widespread adoption of digital health solutions provides the opportunity to address the increasing demand in care, whilst containing ever increasing costs. Digital health solutions can also help solve region specific challenges such as the shortage of healthcare professionals; limited access to hospitals and specialists in rural areas, whilst suiting the changing needs of better-informed patients, who have increasingly higher expectations of high quality, yet affordable healthcare.

That said, some serious challenges need to be addressed in order to deliver on the vision of personalised care at a lower cost:

- Interoperability
- Patient privacy
- Cybersecurity
- Regulatory framework
- Reimbursement pathways

## Regulatory and reimbursement in APAC

Two key challenges in the region are the lack of fit for purpose regulatory and reimbursement frameworks for digital health solutions.

The regulatory landscape in APAC is highly heterogeneous and far broader than digital health and. Existing frameworks target medical devices rather than digital health solutions, even though some regulators are creating special regulatory pathways to accelerate innovation - sometimes with digital health-specific measures. Moreover, a harmonised framework is lacking, and products are regulated differently across different markets, as national legislation is implemented to address country-specific needs. Key regulatory measures in place in Australia, China, Japan and Korea are outlined below.

The reimbursement of digital health solutions is very recent in most markets across the region. Asia Pacific reimbursement policies for digital health products are limited and fragmented, differing from country to country. Based on an initial assessment, some reimbursement frameworks exist in mature markets like Australia, Japan and South

Korea. Major developments in the regulatory and reimbursement space are summarised in table 3.

	Regulatory	Reimbursement
<b>AU</b>	<p>Australian Therapeutic Goods Act regulates digital health solutions under the existing medical device framework and is not planning to build a separate regulatory scheme for digital health[6].</p> <p>TGA regulates software as a medical device, that include many types of software such as apps that calculate insulin doses based on a patient's blood glucose levels, X-ray image-processing software, software that uses information about a patient to make a diagnosis, etc. Particularly, there are regulatory frameworks about SaMD's risk categorization, SaMD's clinical evaluation and application of quality management system in software.</p> <p>Medical device software standards and requirements for software safety also exist; they are IEC standards, elaborated by the International Electrotechnical Commission. TGA regulates cybersecurity of medical devices through a guidance for industry – including pre-market and post-market guidance, compliance and risk monitoring[7].</p>	<p>Australia has a private insurance reimbursement scheme for telehealth and remote monitoring solutions. Some telehealth and remote monitoring solutions are included in private health insurance schemes in Australia. Some private health insurers, such as Medibank Private, have telehealth solutions included in some of their insurance products, e.g. Telephonic and Webchat Nurse Triage services. Some remote monitoring solutions are also included in the prostheses list.</p>
<b>CN</b>	<p>In China, the government has been reforming the regulatory framework since 2015. China Food and Drug Administration (CFDA) released guiding principles for MD software, mobile apps, deep learning, AI, monitoring software, standalone software and PACS (Picture Archiving and Communication System). These principles cover the definition, type and general requirements for registration of the mentioned digital health solutions.</p> <p>Guiding principles also exist for cybersecurity in medical devices. They apply to the registration of Type II and Type III medical devices that can be connected to networks (i.e. fixed line and mobile networks) to conduct electronic data exchanges or remote control, as well as Type II and Type III medical devices that use storage media to conduct data exchanges. Applicants who intend to file registrations for such medical devices now have clearer guidance on managing cybersecurity aspects.</p>	<p>As part of a pilot program launched in the Guizhou Province in 2016, qualified telemedicine services were trialed for reimbursement under the Chinese social insurance program. The pilot program lasted for one year.</p>
<b>JP</b>	<p>The Pharmaceuticals and Medical Devices Agency (PMDA) of Japan recognises that strict premarket evaluation often delays patients from gaining access to some innovative products[8]. To shorten the premarket evaluation, the Sakigake fast-track development and review system and “Conditional Early Approval System for Innovative Medical Device Products”, have been initiated. They apply to innovative health solutions including AI.</p>	<p>The Japanese government reimburses some remote monitoring solutions (i.e. blood pressure monitoring), some remote examinations, and continuous glucose monitoring.</p>
<b>KR</b>	<p>The South Korean government has identified the country's strict data regulations as a key stumbling block for innovation within digital healthcare and announced it will invest up to GBP 678mn towards the expansion and deregulation of the local data market – a prerequisite for the digital healthcare industry to flourish.</p> <p>A draft guideline was published in 2019 to regulate pre-market review and approval for medical device cybersecurity and on how to apply cybersecurity on medical devices, with practical cases.</p> <p>Guidelines also exist on Review &amp; Approval for Big Data &amp; AI-applied Medical Devices, on Clinical Evaluation of Validity for AI medical devices, on Clinical trial protocols of AI-based MDs (draft), on 3D Printing personalised medical devices according to manufacturing process and on Bio-informatics Approaches for NGS. A proposal of GMP-related International Standards was drafted in 2019 for 3D printed medical devices.</p> <p>Guidelines regulate approval, review and re-market submission for VR- and AR-based medical devices, as well as review and approval for rehabilitation robots.</p>	<p>South Korea currently has partial reimbursement for Continuous Glucose Monitoring, which will likely increase to full coverage this year.</p>

**Table 3**

Major regulatory and reimbursement developments in APAC

# Appendix

## 1. Digital Health initiatives driven by MedTechs.

There are a considerable number of initiatives driven by both medtechs and pharmaceutical companies in the field of digital health. The table below aims to capture some of the most recent initiatives implemented by APACMed members.

<b>Abbott</b>	<b>In October 2019, Abbott and Omada Health announced they are partnering to integrate Abbott's FreeStyle Libre system, a continuous glucose monitoring technology, with Omada Health's pioneering digital care program, aiming to create a new paradigm for people with Type 2 diabetes. Collaboration combines Abbott's world-leading glucose sensing technology with Omada Health's best-in-class, proprietary digital coaching platform to provide personalized, on-the-go care.</b>
<b>Abbott</b>	In March 2019, Abbott launched the app A:Care in emerging markets such as Mexico, India, the Philippines, Vietnam, Russia and Brazil. For physicians, the platform offers scientific information and virtual learning tools from international experts. Although the platform is neutral, it will focus on treatments for diabetes, thyroid and osteoarthritis. These are Abbott's fastest-growing businesses in India, especially the diabetes portfolio.
<b>Alcon</b>	SMART Suite by Alcon will drive innovation in ophthalmology delivering personalised and seamless end-to-end care for cataract patients. The SMART Suite by Alcon will connect multiple diagnostic and surgical devices through a digital, open cloud-based infrastructure that seamlessly integrates with practices' existing cataract diagnostic equipment, electronic medical record systems, and technologies in the Alcon Cataract Refractive Suite. As envisioned, eye care professionals will have easy access to patients' vital diagnostic data throughout the cataract procedure, providing a simplified clinical process, consistency and greater efficiency. The cloud-based data will help eye care professionals analyze and optimize procedures with increased precision, driving improved patient outcomes.
<b>Align technology</b>	In March 2019, Align Technology announced its partnership with digital smile design (DSD), a pioneer in holistic, digital and emotional dentistry solutions. The collaboration aims to advance multi-disciplinary dentistry by building a streamlined end-to-end digital workflow as well as best-in-class clinical education.
<b>Align technology</b>	In 2019, Align Technology, announced commercial availability of the iTero Element 2 scanner in China. The launch exemplifies Align's continued innovation and investment to advance digital dentistry in China. The iTero Element 2 scanner is the digital gateway for a broad range of dental, restorative and orthodontic procedures.
<b>Baxter</b>	In February 2019, the Patient Safety Movement Foundation (PSMF) announced that Baxter has signed the PSMF's Open Data Pledge as the 89th company to demonstrate the importance of data sharing to improving patient safety. Companies that have signed the PSMF's Open Data Pledge are committed to allowing access to the data generated by their medical devices to anyone, including researchers, software engineers and entrepreneurs, that seeks to improve patient safety.

Baxter	Baxter and Ayogo launched CKD&Me in November 2019. CKD&Me supplements the education programs provided by nephrologists and their teams. The digital tool provides pre-dialysis education to help patients feel empowered to confidently engage in their kidney care and participate in shared decision making about their therapy options. It also provides nephrologists insights into patients' level of engagement in the education process, their values, lifestyle needs and confidence in therapy selection.
Baxter	In February 2019, NantHealth, a leader in connected care solutions, and Baxter announced that a NantHealth digital health solution was available to connect Baxter's Prismaflex system to a hospital electronic medical record. Prismaflex is used in the intensive care unit to treat patients with acute kidney injury and certain blood and autoimmune conditions, which can be life-threatening. NantHealth has built a device driver allowing integration of its DeviceConX platform with the Prismaflex system. NantHealth's DeviceConX works with various electronic medical record systems and enables straightforward integration of information from the device to the EMR.
<b>Boston Scientific</b>	In April 2019, Wellframe partnered with Boston Scientific to deliver digital heart health management solution. By delivering a digital heart health management solution, the organisations aim to help cardiology teams improve quality and outcomes, extend the reach of staff to engage more patients, and strengthen their brand to differentiate from competitors.
<b>Cardinal Health</b>	In October 2019, University of Texas, Cardinal Health, Amazon Web Services partnered on AI medical research
<b>Dräger</b>	In February 2019, Dräger announced the adoption of SDC New Interoperability Standard for Hospitals. Before, hospitals have had their own protocols for electronic data traffic, depending on the medical device and manufacturer. Because proprietary transmission methods limit the availability of data, not all important data is available where it is needed. In addition, the administrative effort to integrate different systems and the risk of incorrect data transmission increase. As a protocol with a standardized nomenclature and self-explanatory data structures, SDC will overcome these limits in the future. Collected data can be shared with other devices and displayed on different screens. Other possibilities of this technology include secure remote control of other medical devices and partial automation of clinical processes to support clinical users. In addition to the seamless networking of the devices, SDC also bridges the gap to hospital communication standards HL7 and FHIR (Fast Healthcare Interoperability Resources). These are mainly used for real-time data processing from the Hospital Information System (HIS) and other data infrastructures such as PACS (Picture Archiving and Communication System) and LIS (Laboratory Information System).
<b>Dräger</b>	In August 2019, Dräger launched the DrugCheck app, to make using the DrugCheck 3000 even simpler. With the app, users can scan, evaluate, document, and archive test results in just a handful of steps.
<b>Fresenius</b>	In March 2019, Fresenius Medical Care North America has launched its new connected health platform called TheHub. The platform is comprised of three integrated applications - PatientHub, CareTeamHub and ProviderHub - that enable patients, care teams, and providers to better collaborate and monitor patient treatments. Research by FMCNA indicates that patients who actively use these connected health solutions have a 20 percent lower risk of hospitalization, higher transplantation rates, and stay on the modality longer.
<b>Hill-Rom</b>	Hill-Rom announced in January 2019 a collaboration with Microsoft to bring advanced, actionable point-of-care data and solutions to caregivers and healthcare provider organizations. The combined offerings, using Microsoft Azure, are intended to

	dynamically analyze real-time sensing data from medical devices and historical medical record information, and communicate potential patient risk and hospital protocol actions directly to caregivers at the point of care. The Hill-Rom® digital solution offerings will be available to hospitals beginning later in 2019.
<b>Hologic</b>	In 2019, Hologic introduced 3DQuorum imaging technology powered by Genius AI, and Unifi Workspace. 3DQuorum technology works in tandem with Hologic’s Clarity HD high resolution imaging technology to reduce tomosynthesis image volume for radiologists by 66 percent. Unifi Workspace is a comprehensive breast diagnostic reading solution designed to enable more informed decision making and improve workflow efficiencies for radiologists.
<b>J&amp;J</b>	Johnson & Johnson announced in Feb 2019 it would buy robotic surgery firm Auris Health for \$3.4 billion in cash. The company is creating a “connected digital ecosystem” that uses data and robotic technology to guide surgeon through procedures and improve patient treatment.
<b>J&amp;J</b>	In June 2019, J&J leads \$7M round for German digital health company Cara Care. Cara Care, a digital health startup focused on digestive diseases, offers its app in German and English to patients with diseases such as irritable bowel syndrome, inflammatory bowel disease and gastrointestinal reflux disease. The company developed the app to bridge a gap in care for patients with these diseases and help them manage their medications and tweak their diets to improve their health.
<b>Medtronic</b>	In December 2019, Medtronic has acquired Klue, a US-based digital health startup, focused on behavior tracking and change. The startup uses gesture sensing and other behavioral health metrics to determine when a user is eating a meal, providing real-time insights into eating habits. Medtronic plans to integrate Klue’s technology into its Personalized Closed Loop (PCL) insulin pump system.
<b>Medtronic / Philips</b>	In May 2019, Philips and Medtronic partnered on image-guided AF treatment. Philips’ KODEX-EPD dielectric imaging and navigation system, dielectric imaging sensors, clinical software and services will be leveraged to support cryoablation procedures performed using the Medtronic Arctic Front Advance cryoablation technology.
<b>Medtronic</b>	In June 2019, Medtronic announced a collaboration with Tidepool to develop Tidepool Loop. Medtronic will be developing a new, Bluetooth-enabled MiniMed™ pump that will be a fully supported delivery device for Tidepool Loop once both are approved. Tidepool and Medtronic will also collaborate on regulatory and software processes for interoperability.
<b>Olympus</b>	In October 2019, Olympus and Inhealthcare launched of a brand-new digital education service which will cut the number of wasted appointments. Working in partnership to digitalize the endoscopy patient pathway, Olympus and Inhealthcare will collaborate with NHS trusts to deliver a full process review to transform the entire patient journey, from referral through to post procedure, at a time when demand for endoscopy services is ever increasing.
<b>Siemens Healthineers</b>	In March 2019, Siemens Healthineers signed a memorandum of understanding with Tencent Medical, Deepwise, Infervision and ZHU to promote the development of a digital healthcare ecosystem in China. This initiative will continuously provide innovative digital healthcare solutions, aiming further to build up a digital healthcare ecosystem and fulfill its corporate commitment of digitalising healthcare.
<b>Siemens Healthineers</b>	icometrix, the world leader in software solutions using artificial intelligence to extract clinically meaningful data from brain scans, has announced in February 2019 its partnership with Siemens Healthineers. This alliance allows radiologists to get access

	to the best-in-class icobrain artificial intelligence technology for MRI through the Siemens Healthineers digital marketplace.
<b>Smith &amp; Nephew</b>	In March 2019, Smith & Nephew announced the development of NAVIO 7.0, the next version of Smith & Nephew’s handheld robotic surgical system. NAVIO 7.0 is being designed to improve the surgeon experience through a new intuitive interface, expanded surgical preferences, and streamlined workflow which may reduce surgery time over the previous version.
<b>Stryker</b>	In July 2019, Stryker announced the opening of its Digital Platform Services Centre of Excellence in Dublin, Ireland, and a strategic collaboration with RCSI (Royal College of Surgeons in Ireland) to develop digital health solutions for use in emergency and specialist care settings to provide more seamless care coordination for patients suffering from time critical medical emergencies.
<b>Varian</b>	In September 2019, Philadelphia-based Oncora has developed an analytics platform in collaboration with MD Anderson oncologists that collects data on cancer patients, their treatments and clinical outcomes. The information is then used to model outcomes for treatments devised for new patients. Varian and Oncora plan to apply Oncora’s predictive models to help plan treatments that minimize the risk of toxicity to patients and improve the chances for a cure, The data set they developed includes radiation treatment plans, imaging, chemotherapy administration data, patient medical information such as cancer history and past disease history, and treatment outcomes data, including side effects.

## 2. Benchmarking the work of AdvaMed and MedTech Europe in the field of Digital Health

Both the US and European MedTech Trade Associations have established Digital health programs.

AdvaMed’s Center for digital health works on four main areas: (i) Data Privacy, (ii) Software, (ii) Digital Technologies Payment and (v) Cybersecurity. The main initiatives include guidance on clinical decision support software and premarket submission, FDA initiatives on AI/ML regulation, influence regulators about cybersecurity, publish white papers on barriers to digital technologies’ reimbursement, etc.

MedTech Europe’s Digital Health Committee includes three working groups: (i) Reimbursement, (ii) Interoperability and (iii) Artificial Intelligence. The key initiatives include position papers on interoperability and AI, consultations on ethical guidelines for AI and WHO strategy on digital health, proposed guiding principles for reimbursement of digital health solutions, etc.



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