APACMed Digital Health Committee

Examples and learnings from digital health reimbursement and monetization in APAC

27 July 2020

Agenda

- **Project overview**
- Executive summary
- Key research findings
- Digital health profiles

APACMed has set up a Digital Health Functional Committee that aims to facilitate knowledge sharing and advocate policies to ease digital health innovation

Arms	Cybersecurity	Interoperability	Regulatory	Reimbursement
Key objectives	To **develop a universal cybersecurity policy framework**	To **develop a unique set of standards** for **interoperability** among different devices, products, technologies or systems, to be used by all vendors in all countries	To **better support digital health innovation** and **adoption** in APAC, through developing a better harmonized and agile regulatory mechanism	To **support policymakers in the establishment of optimal reimbursement schemes** for digital health solutions across APAC

L.E.K. is pleased to have collaborated with APACMed once more to provide support on the 'Reimbursement' initiative

This report represents L.E.K.'s work in supporting APACMed with the profiling of successful digital health examples in APAC and a summary of best practices

Reimbursement

To **support policymakers in the establishments of optimal reimbursement schemes** for digital health solutions across APAC

Focus of this document

Key outputs identified by APACMed

1) Digital health reimbursement database APAC
2) Webinar on digital health reimbursement policy landscape
3) Webinar on multi-stakeholder point of view on digital health value and reimbursement
4) **Collection of successful use cases of digital health reimbursement and monetization[1] in APAC**
5) Position paper with guiding principles for reimbursement and monetization of digital health solutions in APAC

Note: 1) Monetization refers to the commercial models that companies have adopted to earn revenue from their products

Over a period of 8 weeks in May-Jun 2020, L.E.K. built detailed profiles of digital health examples and generated insights on the best practices demonstrated

L.E.K. project approach

	1 Collection of use cases and / or examples to profile	2 Prioritization of successful digital health examples for detailed profiling	3 Detailed profiling of digital health examples	4 Synthesis of best practices
Key outputs	• Initial view of digital health use cases and examples of interest / relevance to APAC and APACMed members to profile in more detail	• Set of 15 prioritized digital health examples to further analyze	• Detailed profiles of successful digital health examples of reimbursement and monetization in APAC	• Key success factors in demonstrating value and identifying the right payer to pay for the solution • Implications for APACMed members

We kept the definition of digital health broad and encompassing a variety of technologies and solutions in order to include a wide range of examples

Diagnosis, treatment, coaching and monitoring at a distance

American Well
中国人民解放军总医院 CHINESE PLA GENERAL HOSPITAL
TELADOC
云南省第一人民医院 The First People's Hospital of Yunnan Province 昆明理工大学附属医院
Doctrin
babylon
medgate

Decision making support and personalized medicine

verily
maxQ Artificial Intelligence
iz.ai
Lunit

Patient engagement and self-care

amazon
Welltok
WellDoc
jameda
happify HEALTH
ada

Tools to improve efficiency, safety and quality

Neusoft
Epic
HC3i.cn 中国数字医疗网
ALLOCATE
Google DeepMind
amazon
OPENeP
Datix Software for Patient Safety
ish med

Data exchange and personal health records

腾爱糖大夫
ORION HEALTH
My Health Record
ORIEN
Vivy
IBM
docman

Population health & health management

Lightbeam Health Solutions
丁香园 WWW.DXY.CN
PHILIPS
i2i
HEALTHEC HEALTHCARE ENHANCED CONNECTIVITY
SPH analytics
众安保险

Source: L.E.K. analysis

In order to identify the right digital health examples to profile, various dimensions were considered, with three of them set as high priority

High priority considerations	
Purpose / functionality	• Only considered products that are for clinical purposes, rather than administrative purposes
Complementary to MedTech/ clinically-validated product	• Included products that are complementary to core Medtech products • For purely digital products, included those that are clinically validated[1]
Customer / payer	• Ensured research coverage cuts across all major customer / payer types (e.g., public payers, hospital service providers / physicians, patients, etc.)

Other deprioritized considerations	
End users	• Coverage across different customer / payer types was deemed more relevant to extract monetization best practices
Product type	• Digital solutions in different product forms[2] (e.g., wearable, app, platform solution) were all deemed relevant
Indication	• Digital solutions for different indications, patient types, or conditions were all deemed relevant
Product owners	• Digital solutions commercialized by different company types (MNCs, SMEs or start-ups) were all deemed relevant
Regulatory landscape	• As regulations for digital health in APAC are still developing and relative levels of scrutiny on products are yet to be defined, this was not used as a filter

Note: 1) Clinically validated: Implies that expected results / outcomes of the products or applications have been validated through clinical studies or publications, or by recognized international organizations and bodies; 2) The scope of digital health solutions in this study includes genomics, big data, artificial intelligence, 3D printing, SaMD (Software as a Medical Device), virtual and augmented reality, robotic surgery, analytics , wearables, bio-sensors, digital therapeutics (i.e. smart pills), mobile health, companion diagnostics, mobile applications, and telemedicine

L.E.K.

L.E.K. and the APACMed Working Group then collectively prioritized the following 15 digital health examples for profiling

#	Product	Manufacturer	Use case	Digital health component	Customer / Payer type	Geographical origin	Commercial availability in APAC[1]	APAC countries reimbursed
1	**HeartFlow Analysis**	**HeartFlow**	AI imaging – cardiology	Software	Hospitals / Public payer	US	JP	JP
2	**da Vinci Robotic**	**Intuitive Surgical**	Robotic surgery	Coupled with medical device		US	Across APAC	JP, KR
3	**FreeStyle Libre**	**Abbott**	Glucose monitoring system		Patients / Public payer	US	Across APAC	JP, KR, AU[4]
4	**Space Pump**	**B Braun**	Smart treatment		Hospitals / Public payer	DE	Across APAC	KR, TH, CN (specific provinces)
5	**Merlin@Home transmitter**	**Abbott**	Remote home monitoring		Patients / Public payer / Private insurers	US	Across APAC	AU[4]
6	**VNS Therapy System**	**Liva Nova**	Treatment – Neuromodulation			UK	Across APAC	JP, AU, TW, KR
7	**Propeller sensor**	**Propeller Health**	Smart treatment			US	Across APAC[2]	Not publicly reimbursed[5]
8	**Welwalk Robotic System**	**Toyota and Fujita Health Uni. Hospital**	Robotic system		Hospital service providers	JP	JP	
9	**Selena+**	**EyRIS**	AI imaging – ophthalmology	Software		SG	SG, MY	
10	**iBreastExam**	**UE Lifesciences**	Breast cancer diagnostics	Coupled with medical device		US	Across APAC	
11	**Ultrasound iQ**	**Butterfly Network**	Smart imaging			US	ANZ	
12	**InferRead solutions**	**Infervision**	AI imaging – multiple diseases	Software		CN	CN	
13	**Avellan OPM Technology**	**Avellan**	BP and heart rate monitoring	Coupled with medical device	Hospitals / Patients / Private insurers	UK	Across APAC[3]	
14	**Neurotrack cognitive assessment**	**Neurotrack**	Digital therapeutics	Software	Patients / Private insurers	US	JP	
15	**Kardia Mobile**	**Kardia**	ECG Monitoring	Coupled with medical device	Patients	US	Across APAC	

Note: 1) Based on publicly available information and interviews with company representatives for selected companies, products commercialized across APAC are likely to be found in the key markets like CN, KR, JP, IN, TW, ANZ, and SEA; 2) Expected to be commercialized in APAC in 2020; 3) Avellan OPM technology is currently progressing FDA / CE registration; commercialization plans are still being developed; 4) Private reimbursement; 5) Not publicly reimbursed, and paid for by other customer types such as hospitals, physicians, or patients;

Detailed profiles were built leveraging interviews with the Working Group and external parties, internal L.E.K. experience and extensive secondary research

Primary research

We have conducted interviews with representatives from the following companies and L.E.K. internal experts to gather insights around the examples selected

B BRAUN SHARING EXPERTISE

LivaNova Health innovation that matters

Abbott

Avellan

Propeller

- Representatives include company founders and market access regional and country leads

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- L.E.K. internal experts with prior experience on digital health examples

Secondary research

In addition, we have also leveraged various secondary sources to derive insights for the prioritized digital health profiles

Source type	Sources
Digital Health / Start-up databases	• CB Insights, Crunchbase, Mobi Health News, Galen Growth Healthtech, TechInAsia
Regulatory / Reimbursement documentation	• Medicare Benefits Schedule, Prostheses List, MHLW (Japan), HIRA (Korea), CDE (Taiwan), HSA (Singapore)
Annual reports / Company websites / Analyst reports	• Abbott AR 2019 • Intuitive Surgical AR 2019
News articles	• Forbes, Pharma Boardroom, Bloomberg, Korea Biomed, Korea Times, Japan Times, Financial Times
Publications / Journal articles / Industry White Papers	• Evolving HTA for Medical Device and Diagnostics in APAC • Other clinical studies published in databases like PubMed, or published by industry associations

Summary insights were generated by extracting best practices demonstrated by the 15 prioritized digital health examples that were profiled in detail

What L.E.K. did

- Conducted extensive research to profile the 15 prioritized digital health examples, with a focus on reimbursement and monetization approaches
- Aggregated best practices demonstrated by the 15 digital health examples specifically profiled as a part of this study

What L.E.K. did not do

- Conduct a broader assessment of the digital health market in APAC and relative opportunity attractiveness based on market size, growth, therapeutic area focus, technology type, competitive landscape, etc
- Seek to identify or assess any inter-regional differences in regulation or approach (e.g. with US or EU)
- Seek to assess the impact of planned or possible regulatory and market changes

Using this report

- The best practices highlighted in this document represent key considerations for industry players in evaluating opportunities for the reimbursement and monetization of digital health products in APAC
- A more detailed, market- and product-specific assessment will be essential for industry players to customize their strategy in pursuing reimbursement and monetization for a digital health solution in APAC

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Best practices identified around digital health reimbursement and monetization in APAC were categorized into two broad types

Best practices to be followed similar to gaining reimbursement for medical devices, allowing industry to draw on existing capabilities

Best practices to be considered that are tailored specifically to digital health

Most cases of reimbursed digital health solutions appear in Japan, Korea, Australia, Taiwan and selected provinces in China, suggesting greater likelihood of success in pursuing reimbursement in these geographies

Source: L.E.K. analysis

Overall, there are nine best practices that we have identified, some that draw on existing MedTech capabilities

1 D		Develop a thorough understanding of local reimbursement requirements, including additional practical considerations
2 I		Invest in initiating HTA and cost-effectiveness studies for key markets early to justify product pricing
3 G		Generate superior clinical evidence against the existing standard of care
4 I		Invest in market creation and market acceptance of digital health products
5 T		Target existing reimbursement codes first and concurrently assess feasibility of gaining new reimbursement codes
6 A		Attain advocacy through known digital champions
7 L		Land partnerships that offer access to valuable datasets
8 L		Look for alternative funding paths for digital health products
9 E		Embrace a monetization model that considers the unique nature of the digital health product

Best practices similar to medical devices

Best practices tailored to digital health

Source: L.E.K. analysis

L.E.K.

A clear understanding of reimbursement requirements and investing in HTA / cost-effectiveness studies to justify product pricing

Best practices observed	Findings from digital health profiles		
1 D **Develop a thorough understanding of local reimbursement requirements, including additional practical considerations**	Abbott - FreeStyle Libre ensured that the high requirements for clinical evidence were met in Australia; while not mentioned as an official rule, there has to be a Randomized Clinical Trial conducted for the service to be listed on the MBS		**Across profiles** - In some markets (e.g. China), solutions typically need to be on the market and used for a few years before they will be considered for reimbursement
2 I **Invest in initiating HTA and cost-effectiveness studies for key markets early to justify product pricing**	INTUITIVE SURGICAL - Intuitive Surgical conducted cost-effectiveness studies in Japan to demonstrate that total cost to treat per patient episode has been lowered, through shorter duration of hospital stays	HeartFlow - HeartFlow demonstrated cost prevention from using HeartFlow Analysis of up to USD 4k in the US and USD 260 in the UK per process	Abbott - FreeStyle Libre showed long-term reduction in cost[1], such as reducing the likelihood of debilitating co-morbidities - Merlin@Home demonstrated cost reduction opportunities[2] in studies of ICDs and pacemakers with remote monitoring in the US

Note: 1) All-cause health system resource use (hospital admissions, emergency room visits and ambulance use) was lower for people using flash monitoring compared with those using routine SMBG, especially in the REPLACE trial; 2) Through various clinical studies, including the EVOLVO study presented at the Heart Rhythm Society, and the CONNECT trial published by the Journal of the American College of Cardiology

Source: Company websites; news articles; L.E.K. interview and analysis

Generation of superior clinical evidence against the existing standard of care and investing in market creation for digital health can enable success

Best practices observed	Findings from digital health profiles		
3 G **<u>Generate</u> superior clinical evidence against existing standard of care**	Abbott - FreeStyle Libre presented real-world use data to the reimbursement bodies in Japan and UK, showing that users could scan their glucose levels more frequently and lead to improved glucose control	HeartFlow - HeartFlow Analysis demonstrated that results from non-invasive analysis can provide a more accurate determination of arterial blockages associated with coronary ischemia, compared to invasive coronary angiography[1]	AliveCor - AliveCor demonstrated in a RCT that ECGs taken with KardiaMobile after discharge allowed doctors to diagnose more patients within a shorter time period, compared to those who received the standard care
4 I **<u>Invest</u> in market creation and market acceptance of digital health products**	INTUITIVE SURGICAL - Intuitive Surgical made continuous investments in Japan market shaping and generation of evidence through clinical studies, which led to reimbursement of selected procedures after 10 years	LivaNova Health innovation that matters - For the VNS Therapy System, in Australia, Liva Nova had to commit resources to provide 2 years of health economics and clinical data, and this has been recognized as a rigorous and costly process	Propeller - Propeller Health was prepared to commit resources for 2 – 3 years to obtain successful reimbursement in the US for its Propeller sensors

Note: 1) HeartFlow's press release - 2013
Source: Company websites; news articles; L.E.K. interview and analysis

Some companies have relied on existing reimbursement codes while negotiating for new ones; additionally, advocacy through known digital champions is valuable

Best practices observed	Findings from digital health profiles		
5 T **Target existing reimbursement codes first and concurrently assess feasibility of gaining new reimbursement codes**	B|BRAUN - In Korea and Thailand, B. Braun's space pumps are currently reimbursed at the same rate as the conventional pumps, with no distinction made; concurrently working with HIRA and MOHW in Korea to get separate reimbursement codes	INTUITIVE SURGICAL® - Intuitive Surgical was able to bypass some of the difficulties in securing new reimbursement codes, by working with existing procedural codes for laparoscopic procedures	Propeller - Propeller sensor devices were able to achieve US reimbursement under the existing remote monitoring code
6 A **Attain advocacy through known digital champions**	Abbott - Patient and professional advocacy organizations, such as Diabetes Australia, helped to drive reimbursement coverage in Australia for FreeStyle Libre - Patient advocacy, supported by Korean Diabetes Association and Korean Pediatric Diabetes Association, led to changes in nation-wide policies related to reimbursement of medical devices, including CGM devices	HeartFlow® - Organizations such as Evidence Street[1], NICE, American College of Cardiology, American Heart Association helped to support reimbursement for HeartFlow Analysis - In Japan, HeartFlow gathered support from professors and KOLs in teaching universities and associations such as Japan Association of Cardiovascular Intervention and Therapeutics	UE LifeSciences - For iBreastExam device, UE LifeSciences collaborated closely with Indian public health agencies to facilitate large-scale implementation and gather advocacy in India

Note. 1) Conducts healthcare technology evaluation for Blue Cross Blue Shield Association
Source: Company websites; news articles; L.E.K. interview and analysis

Developing partnerships with hospitals and channel partners is also key for digital health products; companies should also look out for alternative funding paths

Best practices observed	Findings from digital health profiles
7 L **Land partnerships that offer access to valuable datasets**	**inferVISION** - Infervision partnered with some of the largest 3A hospitals in China, resulting in access to the largest medical training database in the world - In Japan, they partnered with teaching hospitals (e.g., Keio University Hospital, Kindai University Hospital, Tokyo Women's Medical University Hospital, etc.) **EyRIS** - In Singapore, for Selena+, EyRIS partnered with Singapore Optometric Association to provide wider access to primary eye care leveraging AI support, through its network of 23 optometric practices
8 L **Look for alternative funding paths for digital health products**	**neurotrack** - In Japan, Neurotrack partnered with large private insurers, Dai-ichi Life and Sompo Himawari, to roll out its digital Neurotrack Cognitive Assessments **INTUITIVE SURGICAL** - In Japan, Tokyo Medical University helped to apply for Robot-assisted laparoscopic radical prostatectomy to be considered an advanced treatment, and the MHLW approved and covered cost for the treatment in 2008 **Across profiles** - Companies should assess if there are opportunities to commercialize digital health products through other budgets - In Australia, there are disease-specific funds like Diabetes Australia that provides subsidized products to diabetic patients - In selected APAC markets, there may be hospital tenders specifically for home-based products, which may cover some digital health products

Source: Company websites; news articles; L.E.K. interview and analysis

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Digital health companies should evaluate the pros and cons of each monetization model, and arrive at the most appropriate model(s) over the product lifecycle

Best practices observed

9 E

Embrace a monetization model that considers the unique nature of the digital health product

Findings from digital health profiles

- The choice of monetization model depends on the nature of the digital product, e.g.,
  - Who are the targeted end users? What is their affordability level?
  - Who is expected to pay for the product?
  - What is the current level of competitive intensity within the market?
  - Is the product purely digital / involve a medical device / large capital equipment?
  - What is the level of maintenance / servicing required for the product?
  - What is the expected volume and frequency of usage?
  - How regularly does software need to be updated?

- Additionally, companies should also monitor market conditions and adapt the monetization model over the product life cycle as necessary:

INTUITIVE SURGICAL®

- Intuitive Surgical moved towards a leasing model and usage-based model for da Vinci robotic surgery systems, which will allow Intuitive to place more of its systems in the market before competitors like Medtronic's Hugo and CMR Surgical's Versius enter the market

TOYOTA

- Toyota revised the monetization model for its Welwalk robotic system; while the first version of the robotic system was monetized on a leasing basis, the second version was made available for purchase, with monthly maintenance fees lowered from JPY 350k to JPY 50k

Butterfly™ Network

- For the Ultrasound iQ device, Butterfly Network introduced their Enterprise business model, in addition to the original Pro Individual and Pro Team model, in order to provide greater integration capabilities and support to customers

Source: Company websites; news articles; L.E.K. interview and analysis

L.E.K.

As an example of best practices adoption, HeartFlow undertook a multi-step approach in Japan to successfully gain reimbursement

x **Best practice demonstrated**

Key actions		Key findings
Worked with regulatory body in Japan to obtain regulatory approval	**Nov 2016**	• HeartFlow Analysis was approved for use in Japan by the **Japanese Pharmaceuticals and Medical Devices Agency (PMDA)** in Nov 2016 • First non-invasive technology to deliver insights on both the extent of a coronary blockage and the impact of blockage on the blood flow to the heart
4 I 6 A 7 L **Collaborated with university hospitals and associations to promote treatment pathway**	***Across 2 years***	• Piloted the software in teaching hospitals such as **Wakayama Medical University**, which helped to gather support from KOLs in Japan • Gathered advocacy from cardiovascular associations such as **Japan Association of Cardiovascular Intervention and Therapeutics, American College of Cardiology, American Heart Association**
2 I 3 G **Conducted clinical studies in key markets to support case for reimbursement**		• **Clinical evidence:** Demonstrated that results from non-invasive test can match existing invasive tests and improve patient outcome; supported by 300+ peer-reviewed articles and 200+ patients and decades of clinical research • **Cost-effectiveness:** Demonstrated that a HeartFlow-guided strategy would result in fewer invasive coronary angiograms, hence reducing the cost of diagnosis and treatment; cost prevention of up to USD 4k in the US and USD 260 in UK per process
Gained support from medical council who successfully recommended product for reimbursement	**Nov 2018**	• **After ~2 years of market shaping and promotional efforts, Central Social Insurance Medical Council (Chuikyo)** recommended to provide reimbursement for HeartFlow analysis • **Japanese Ministry of Health, Labour and Welfare (MHLW)** finally approved the recommendation in Nov 2018

Source: Corporate website; news articles; L.E.K. analysis

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On the path to reimbursement, we have observed different stakeholders to be involved, some playing a greater role in enabling reimbursement approval

Key stakeholders for digital health reimbursement

Key Stakeholders	Potential role in digital health reimbursement process
Regulatory bodies	**Shape regulatory approval pathway** and **determine requirements** for digital health solution approval
Reimbursement bodies	**Shape reimbursement pathway** for digital health solutions, including the requirements for HTAs, evidence generation and cost-effectiveness studies
Clinical associations / KOLs	**Advocate for the adoption of new technology**, especially for new digital health solutions that require re-shaping of the existing treatment paradigm
Hospitals / providers	**Provide access to valuable datasets** for training algorithms and **promote wide-scale adoption** for digital health solutions
Patient advocacy groups	**Provide feedback** on the use of digital health solutions to support reimbursement
Private insurers	**Co-pay** and **promote adoption** of digital health solutions
Pharma	**Identify opportunities** where digital health solutions can be leveraged to improve treatment outcome, and support reimbursement of these solutions
Technology firms	**Leverage existing core capabilities** to support reimbursement through improving functionality of digital health solutions
Other partners	Other partners such as **distributors** and **communications companies** can help to **promote and widen access and build experience for digital health solutions** and support reimbursement efforts

Policymakers

Partners to build advocacy and collect evidence

Other partners

To summarize, some best practices identified apply to digital health products as they would to medical devices; medtechs can draw on existing capabilities

Best practices observed	Summary of key findings	Key stakeholders
Develop a thorough understanding of local reimbursement requirements, including additional practical considerations	Reimbursement pathway for digital health products typically follows that of medical devices, and it is important for companies to understand any "unspoken rules" for reimbursement	• Reimbursement bodies
Invest in initiating HTA and cost-effectiveness studies for key markets early to justify product pricing	Similar to medical devices, HTA should be performed for digital health products to evaluate cost effectiveness and justify product pricing to payers Evaluation process for digital health products is likely to be the same as that of medical devices; no special or additional requirements are noted for digital health	• Hospitals • KOLs • Patient advocacy groups
Generate superior clinical evidence against the existing standard of care	Similar to medical devices, digital health products need to demonstrate superiority in treatment outcome when compared to the standard of care Evaluation process for digital health products is likely to be the same as that of medical devices; no special or additional requirements are noted for digital health	• Hospitals • KOLs • Patient advocacy groups • Pharma

Source: L.E.K. analysis

Additionally, tactics specific to digital health can be pursued to target reimbursement in APAC

Best practices observed	Summary of key findings	Key stakeholders
Invest in market creation and market acceptance of digital health products	Commit resources and investment over multiple years to drive adoption of digital health, potentially through additional cost-effectiveness studies and ongoing evidence generation	• Hospitals • Patient advocacy groups • Pharma • Clinical associations • KOLs
Target existing reimbursement codes first and concurrently assess feasibility of gaining new reimbursement codes	Work with existing reimbursement codes to speed up time to market; concurrently seek separate codes for digital health and higher reimbursement amounts	• Reimbursement bodies
Attain advocacy through known digital champions	Identify and work with KOLs and clinical societies that have demonstrated greater propensity to champion adoption of new technology in the past	• Hospitals • Clinical associations • KOLs • Patient advocacy groups
Land partnerships that offer access to valuable datasets	Build relationships with credible providers and channel partners who can provide access to substantial datasets for training algorithms and to help promote wide-scale adoption for digital health solutions	• Hospitals • Private insurers • Pharma • Technology firms
Look for alternative funding paths for digital health products	Scout for alternative means for payers to recognize the value of the digital health solutions, tap into alternative public budgets or target private payers supportive of digital health solutions	• Private insurers • Hospitals
Embrace a monetization model that considers the unique nature of the digital health product	Consider various dimensions for the monetization model; additionally, monitor market conditions and adapt monetization model over the product life cycle	• Hospitals • Patients • Distributors

Source: L.E.K. analysis

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- Digital health profiles

In the next few slides, we have detailed our findings related to regulation, reimbursement and monetization of digital health products in APAC

Digital Health Regulation, Reimbursement and Monetization: Key questions addressed

1. How does the **regulatory process** for a digital health product differ from that of a medical device?
2. Among the list of prioritized digital health examples, which are **currently reimbursed in APAC**?
3. What **commercial scale is required** to engage in reimbursement discussions?
4. Who **initiates reimbursement discussions**?
5. What is the **timeline** required for reimbursement?
6. Are there **HTA requirements** for reimbursement?
7. What are **alternative pathways** to reimbursement for digital health?
8. Is it possible to obtain regulatory approval and reimbursement for **standalone digital products**?
9. How does digital health **access change after reimbursement**?
10. Which **countries are more attractive to launch** first for digital health?
11. Which **therapeutic areas** are digital health products commonly targeted at?
12. What are the **types of monetization models** we have observed?
13. Are there certain **monetization models** that work better for a **specific type of product**?
14. Have companies **switched their monetization model** over time?

Across APAC, digital health products are typically reviewed under medical device guidelines (1/2)

1 How does the regulatory process for a digital health product differ from that of a medical device?

- **Global:**
  - Regulation for digital health products typically follows that of medical devices; however, changes are currently underway
  - **US**: Piloted the digital health pre-certification program in 2019
  - **EU**: The EU Medical Devices Regulation, applicable from 26 May 2020, specifically addresses software as medical device and specifies the classification and regulatory requirements for digital health, depending on its classification as medical device and risk level

- **In Korea:**
  - For smart infusion pumps: While MFDS has a set of criteria for assessing software as a medical device, both the software and hardware components of the smart infusion pump are evaluated as a single application by the MFDS
  - For Medical AI[1]: As of Dec 2019, 6 AI solutions have been approved by the Korean MFDS; first AI software regulation was issued in Dec 2017
    - If a new digital solution is classified as an existing technology, no additional fees apply; to date, all medical AI solutions for which applications have been made have been classified as existing technologies

Note: 1) Current status and Future direction of digital health in Korea
Source: Regulatory websites, news articles, primary interviews

Across APAC, digital health products are typically reviewed under medical device guidelines (2/2)

1 How does the regulatory process for a digital health product differ from that of a medical device?

- **In Australia[1], regulation of software follows that of medical device, which adopts a risk-based approach**
  - Medical software embedded within a medical device is considered part of the device, and not regulated separately; a mobile app linked to a glucose meter is regulated as part of the glucose meter device

- **The situation in Singapore is the same as Australia, with guidelines published by Health Sciences Authority[2] (HSA):**
  - Software and standalone digital health products generally follow the same regulatory approval process as a medical device
  - Clinical evidence generation: literature reviews, post market experience, clinical studies, depending on the intended use of the app
  - For AI as a medical device, there are specific considerations (in addition to regulation as medical device) given to continuous training capabilities, level of human intervention, training and re-training of models; for all registered AI-MDs locally, companies are required to monitor the real-world performance post deployment and submit periodic post-market reports to HSA

- Overall, digital health products are likely to continue to be regulated as part of medical devices in APAC; adoption of regulatory frameworks for digital health in APAC has been slow

Note: 1) Therapeutic Goods Administration; 2) Medical Device Guidelines published in Dec 2019 by HSA
Source: Regulatory websites, news articles, primary interviews

Among the digital health examples profiled, 6 are reimbursed in select APAC markets

2 Among the list of prioritized digital health examples, which are currently reimbursed in APAC?

	Product	Manufacturer	Use case	APAC countries reimbursed
1	**HeartFlow Analysis**	**HeartFlow**	AI imaging – cardiology	Japan
2	**da Vinci Robotic Surgery**	**Intuitive Surgical**	Robotic surgery	Japan, Korea
3	**FreeStyle Libre**	**Abbott**	Glucose monitoring system	Japan, Korea, Australia
4	**Space Pump**	**B. Braun**	Smart infusion pump	Korea, Thailand, China (specific provinces)
5	**Merlin@Home**	**Abbott**	Remote home monitoring	Australia[1]
6	**VNS Therapy System**	**Liva Nova**	Treatment – Neuromodulation	Japan, Australia[1], Taiwan, Korea
7	**Propeller sensor**	**Propeller Health**	Smart treatment	Not publicly reimbursed[2]
8	**Welwalk Robotic System**	**Toyota and Fujita Health University Hospital**	Robotic system	
9	**Selena+**	**EyRIS**	AI imaging – ophthalmology	
10	**iBreastExam**	**UE Lifesciences**	Breast cancer diagnostics	
11	**Ultrasound iQ**	**Butterfly Network**	Smart imaging	
12	**InferRead solutions**	**Infervision**	AI imaging – multiple diseases	
13	**Avellan OPM Technology**	**Avellan**	BP and heart rate monitoring	
14	**Neurotrack cognitive assessment**	**Neurotrack**	Digital therapeutics	
15	**Kardia Mobile**	**Kardia**	ECG Monitoring	

Note: 1) Private reimbursement; 2) Not publicly reimbursed, and paid for by other customer types such as hospitals, physicians, or patients
Source: Company websites; news articles

Reimbursed examples

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In terms of requirements for reimbursement, having a large commercial scale is likely to help generate the clinical evidence required to support reimbursement

3 What commercial scale is required to engage in reimbursement discussions?

- In most markets, commercial scale is not stated as a key consideration for reimbursement, unlike considerations like cost effectiveness and clinical outcomes
  - **In Australia**, application for reimbursement can happen in parallel with regulatory approval

"… An application to MSAC[1] can be lodged before relevant therapeutic goods are included on the ARTG[2] provided that the applicant has evidence that the relevant sponsor has commenced the TGA process. Confirmation of inclusion on the ARTG is required before MSAC can finalize its own appraisal of the corresponding medical service…"
Medical Services Advisory Committee guidelines

  - **In Japan,** it is stated that upon receipt of regulatory approval, reimbursement request dossier can be submitted to the Ministry of Health, Labour and Welfare; however, in practice, the negotiations for reimbursement can also happen in parallel to regulatory application
  - **In Korea**, reimbursement request has to be submitted within 30 days after KFDA approval; fast-track review option is available for selected items[3], offering near-parallel review by KFDA[4] and HIRA[5]

- Overall, having a larger scale of commercialization is likely able to help generate the clinical evidence required to support reimbursement applications (e.g. in China, solutions typically need to be on the market and used for a few years before they will be considered for reimbursement)

Note. 1) Medical Services Advisory Committee; 2) Australian Register of Therapeutic Goods; 3) similar items on the reimbursement list; 4) Korean Food & Drug Administration; 5) Health Insurance Review and Assessment Service
Source: Regulatory websites, news articles

The reimbursement approval timeline is unlikely to be affected by the type of stakeholder initiating reimbursement discussions

4 Who initiates reimbursement discussions?

- **Korea:** Reimbursement may be initiated by manufacturers, medical institutions or medical societies
- **Australia:** Applications can be made by the medical profession, medical industry and others with an interest in seeking Australian Government funding for a medical service or technology
- **Japan:** Reimbursement applications are to be submitted by manufacturers
- **Overall, we have not observed a difference in reimbursement approval / timeline based on applications by different stakeholders**

Source: Regulatory websites, news articles

In terms of timeline, reimbursement for newer technologies is likely to take a longer time, due to requirements for more comprehensive reviews (1/2)

5 What is the timeline required for reimbursement?

Public reimbursement

- **In Japan, the reimbursement timeline will be dependent on the reimbursement category submitted for the medical device**
  - A C1 device may take 7 months while a C2 may take up to 1 year
- **In Australia and Korea, it is dependent on the classification as a new or existing procedure**
  - **Australia:** For new procedures, the process of approval can take ~2 years (with very high evidence requirements for HTA), while for existing procedures, it may take a few months to a year
  - **Korea:** The official duration is ~100 days for reimbursement approval after application; however, in reality, the process can take between 1 to 3 years, especially if devices require new HTA approval
- **Overall, across the different markets, reimbursement for newer technologies is likely to require a more comprehensive review, and will take a longer time to be reimbursed**

Source: Regulatory websites, news articles, primary interviews

In terms of timeline, reimbursement for newer technologies is likely to take a longer time, due to requirements for more comprehensive reviews (2/2)

5 What is the timeline required for reimbursement?

Private insurance in Australia

- The prostheses list is the list of surgically implanted prostheses, human tissue items and other medical devices that private health insurers must pay benefits for; listing on the prostheses list is key for medical device manufacturers in Australia
- In order for products to be listed on the prostheses list, there has to be an accompanying MBS code; if the product already has an existing MBS code, it could take ~4 - 8 months to be listed on the prostheses list
- If a new MBS code is required, process to list on the prosthesis list could take 2 – 3 years

Source: Regulatory websites, news articles, primary interviews

Across APAC, there are different levels of HTA requirements; in most markets, some form of HTA is required by the various evaluation committees

Country	6 Are there HTA requirements for reimbursement?
Australia	• For new medical technologies that do not have an existing MBS item describing the medical service, MSAC requires a comprehensive HTA review process, which includes the submission of extensive clinical and economic evidence; this process can take around 2 years • No option for accelerated review available currently; local HTA is preferred
Korea	• New HTA program for medical technologies was introduced in 2007, which considers the evidence for safety, efficacy, and effectiveness and proposes a recommendation to a 20-member committee • Localized data preferred for evidence generation, while cost data must be local[1]
Taiwan	• HTA division was set up in 2008, which performs clinical effectiveness and economic assessment of new medical device to assist NHI in reimbursement and pricing decisions; Only new medical devices with new medical functions or better clinical effectiveness, or medical device with budget > TWD 30 Mn, need to undergo HTA • Local HTA required if reference market differs from Taiwan in terms of demographics or epidemiologic characteristics, treatment pattern, financial incentives and pricing[2]; price premium of 10% may be offered if data from local pharmacoeconomic study is used
Japan	• Formal HTA was launched in April 2019, after a 3-yr pilot study • HTA is used to retrospectively assess whether the premium pricing is justified
China	• Increasingly integrating HTA into the healthcare system • However, it is still not fully embedded as a mandatory component

Across these markets, evidence like CE analysis, Systematic Literature Reviews, Meta-analysis, Randomized controlled trials, and Real-world Evidence are considered

Note: 1) IPSOR; 2) Taiwan: 10 years of the Center for Drug Evaluation Health Technology Assessment Division
Source: White paper – The Evolving Health Technology Assessment for Medical Devices and Diagnostics in the Asia Pacific Region and Key Considerations for Value Assessment Framework (IQVIA and APACMed)

In Japan, an alternative pathway to reimbursement is available; private insurance and alternative funds may also offer coverage for digital health products

7 What are alternative pathways to reimbursement for digital health?

- In Japan, to ensure patient's early access, hospitals / medical institutions can request the government to apply as "Advanced Medicine" (through the Advanced Medical Treatment Expert Meeting), when 1) the technology has regulatory approval but is not reimbursed or 2) technologies are not regulatory approved yet
  - **For da Vinci:** Tokyo Medical University applied for Robot-assisted laparoscopic radical prostatectomy to be considered an advanced treatment, and the MHLW **approved and provided coverage for the treatment in 2008**; the procedure was covered by NHI in 2012

- Private insurance providers can also offer coverage for digital health products
  - In Japan, **Neurotrack partnered with large private insurers**, Dai-ichi Life and Sompo Himawari, to roll out its digital Neurotrack Cognitive Assessments
  - Insurance providers such as **Bupa have specific programs** (Bupa Telehealth) to offer their members with hospital cover on a range of telehealth coaching services to help support them on various aspects of their health journey

- In selected APAC markets, there may be **hospital tenders specifically for home-based products**, which may be relevant for some digital health products
  - In Japan[1], durable medical equipment for home use are covered by Statutory Health Insurance System, while in China, selected items or devices for home use come from a separate budget with a specific set of regulations

Note: 1) Commonwealth Fund Publication
Source: Publications, news articles

Selected standalone digital products, such as AI Medical Imaging software, have been approved and reimbursed in selected countries

8 Is it possible to obtain regulatory approval and reimbursement for standalone digital products?

- From the research, we have observed the following standalone digital products that have obtained regulatory approvals:
  - **Approved and reimbursed**
    - **HeartFlow Analysis in Japan:** HeartFlow Analysis uses advanced algorithms to build a personalized, digital model of patients' coronary arteries from a CT scan image; test performed using the algorithm is reimbursed in Japan
  - **Approved and not reimbursed**
    - **InferRead solution in China:** Infervision's InferRead solution suite is a comprehensive medical imaging solution series
    - **Selena+ solution in Singapore:** An intelligent deep learning system (DLS) designed to perform automated image analysis for diabetic eye diseases, such as diabetes retinopathy, glaucoma and age-related macular degeneration
    - **VunoMed Bone Age in Korea:** First AI-based medical product approved in Korea in May 2018 to help diagnose growth and development of a child through analyzing a child's bone images; received CE Mark in Jan 2019
    - **Pear Therapeutics in Singapore:** HSA has authorized reSET for the treatment of adults with substance use disorder on 18th June 2020, making it the first digital therapeutic with medical claims to be authorized; reSET was also the first software to receive a label to treat any human disease from FDA

Source: Company website, regulatory websites, news articles

Post reimbursement, while the overall usage is expected to increase, the rate of adoption will be dependent on other factors, including the treatment paradigm

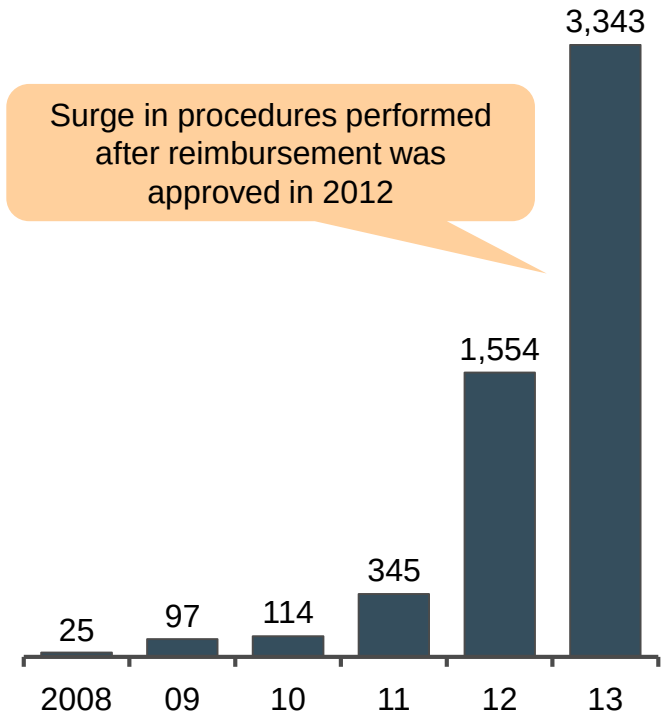
9 How does digital health access change post reimbursement?

- Reimbursement will likely lead to an overall increase in usage – example provided in the chart
- However, the rate of adoption post-reimbursement will depend on various factors, including the existing treatment paradigm
  - E.g. For the successful reimbursement of 12 additional procedures for da Vinci in Jan 2018, the adoption ramp was expected to be slower compared to when da Vinci was first reimbursed for the prostatectomy procedure

"… Unlike the markets for prostatectomy and nephrectomy, which saw Intuitive convert from open to laparoscopic surgeries, many of the newer approvals are for procedures that are already being done laparoscopically …"

Richard Newitter and Jaime Morgan, Analysts at Leerink Partners

Robotic-assisted laparoscopic radical prostatectomy procedures performed in Japan[1]



Note: 1) Japan Society for Endoscopic Surgery
Source: Company website, news articles

Launch sequence is usually dependent on individual company's internal assessment of market readiness, need and broader commercial considerations

10 Which countries are more attractive to launch first for digital health?

- Reimbursement considerations alone rarely drive launch sequencing; market readiness, need and broader consideration of commercial opportunities are the key factors
  - Healthcare infrastructure: Readiness of hospital infrastructure to adopt proposed technology
    - **B Braun:** Hospital infrastructure across APAC markets were found to be very different, resulting in very different levels of readiness for new technology like smart infusion pumps
  - Physician readiness: Readiness of physicians / surgeons to adopt advanced treatment methods
    - **HeartFlow**: Assessed that the existing diagnostic pathway in Japan favored the use of HeartFlow Analysis, as there was already strong support among the medical community for CT to be the initial diagnostics for suspected CAD cases, which feeds directly into the data source for HeartFlow Analysis
    - **Intuitive Surgical:** Assessed the culture of surgeons and clinical societies in Japan and Korea to be more innovative and accepting of new technologies, and hence invested to build innovation centers in these markets to facilitate training

- In terms of commercialization sequence across countries, regulatory applications are often submitted across APAC around the same time, and the subsequent launch sequences and promotional efforts are modified based on regulatory approval timing

- Most cases of reimbursed digital health solutions appear in Japan, Korea, Australia, Taiwan and selected provinces in China, suggesting greater likelihood of success in pursuing reimbursement in these geographies

Source: Company website, news articles, primary interviews

Digital health products have been observed to target therapeutic areas such as Diabetes, Neurology, Cardiovascular and Radiology

11 Which therapeutic areas are digital health products commonly targeted at?

- Globally, digital health products appear to target therapeutic areas such as Diabetes, Neurology, Cardiovascular and Radiology
  - **Diabetes (management):** A number of continuous glucose monitoring (CGM) devices have been commercialized for diabetes management; examples include Abbott's FreeStyle Libre, Medtronic's Guardian Sensor, DexCom's G6 CGM system
    - Other trends include the partnerships between CGM device manufacturers and connected insulin pen providers, to facilitate integration of data for diabetes management
  - **Neurology (prevention):** In terms of disease prevention, neurologic conditions represent the most targeted for digital health; an example in APAC is Neurotrack's cognitive assessment
  - **Cardiovascular (detection):** A number of wearables and digital health solutions have also been approved for the detection of cardiovascular diseases
    - Kardia Mobile: FDA-cleared device that can detect the three most common arrhythmias, by enabling patients to capture a medical-grade ECG in 30s
    - Other technologies that have been recognized include Ambulatory Blood Pressure Monitoring
  - **Radiology (diagnostic support):** AI imaging solutions, which are used to support clinicians in diagnosis, have been widely studied and applied in the healthcare setting
    - Examples in APAC include the InferRead solutions from Infervision, Selena+ from EyRIS, HeartFlow Analysis from HeartFlow

Source: A digital health industry cohort across the health continuum published by Nature on May 2020; L.E.K. analysis

L.E.K.

We have observed different types of monetization models adopted by companies so far

12 What are the types of monetization models we have observed?

- **Pay per use:**
  - HeartFlow charges **hospitals** a fee of USD 1,500 / GBP 700 for every test analysis performed *(Reimbursed in selected markets)*
- **Upfront + Maintenance / Rental Fees**: Adopted for systems / devices that require regular maintenance
  - **da Vinci robotic surgery system**: Intuitive Surgical charges **hospitals** an upfront fee of USD 1 Mn – 2.3 Mn, depending on the specific model and geography, and annual maintenance fee of USD 100k – 180k
  - **Welwalk WW1000 robotic system**: Toyota charges **hospitals** an upfront fee of ~USD 9,000 and monthly maintenance fee of ~USD 3,200 to hospitals for rental
- **Device + consumables:** Adopted for devices that come with consumables which have to be replaced on a regular basis
  - **FreeStyle Libre:** Abbott charges **patients** a fee of USD 69 for the device (reader) and USD 120 for a pair of 14-day sensors *(Reimbursed in selected markets)*
- **Upfront + subscription**: Adopted for systems that require additional software support or premium software features such as unlimited image storage
  - **Ultrasound iQ:** Butterfly Network charges **hospitals** USD 1,999 for initial purchase of the device, and subscription fee of USD 420 annually for one user or USD 1,200 for a group rate of up to 10 users

Source: Company website, news articles

The choice of monetization model will be dependent on the nature of the product, considering factors such as the targeted end users and targeted customers

13 Are there certain types of monetization models that work better for a specific type of product?

- **The choice of monetization model is dependent on the nature of the product. Listed below are some of the key considerations:**
  - Who are the targeted end users?
  - What is the affordability level of the targeted end users?
  - Who is expected to pay for the product?
  - What is the current level of competitive intensity within the market?
  - Is the product a purely digital offering, or does it involve a medical device or large capital equipment requiring regular maintenance? (E.g. da Vinci, Welwalk robotic system)
  - What is the level of maintenance / servicing required for the product?
  - What is the expected volume and frequency of usage?
  - How regularly does software need to be updated?
  - What kind of differentiated software offerings can there be?

Source: Company website, news articles

We have also observed that companies have switched their monetization model over time, due to changes in competition in the market or customer demands

14 Have companies switched their monetization model over time?

- **Monetization models have been observed to change, as companies continue to optimize commercialization of their products**
  - **da Vinci:**
    - Moving towards a **leasing model and usage-based model**, which will allow Intuitive to **place more of its systems in the market before competitors** (Medtronic's Hugo, CMR Surgical's Versius) enter the market
    - Of the 275 systems shipped globally during the 3rd quarter in 2019, 1/3 were under operating lease and usage-based arrangements, instead of the previous model of upfront payment
  - **Welwalk WW1000**
    - While the first version of the robotic system was monetized on a leasing basis, the second version was made available for purchase, due to "requests from healthcare institutions"; monthly maintenance fees were lowered from JPY 350k to JPY 50k

Source: Company website, news articles

Going forward, APAC would benefit from establishing regulatory and reimbursement frameworks that are specific to digital health solutions

Regulatory and reimbursement frameworks for digital health solutions in APAC are still nascent

- **Digital health solutions are typically reviewed as classical medical devices**
  - In Australia and Singapore, the respective regulatory authorities have published guidelines which dictate that software are to be regulated as medical devices
- **Reimbursement pathway for digital health solutions also follows that of medical devices**
  - Some of the profiled examples have achieved reimbursement in Japan, Korea, Australia, Taiwan and selected China provinces

There is value in having specific regulatory and reimbursement frameworks for digital health

- **To ensure that different stakeholders can access digital health solutions** with proven clinical outcomes and cost-effective benefits
- **To ensure that public payers can evaluate** innovative digital health solutions with a **well-defined and objective set of criteria**
- **To ensure that digital health providers can follow a clear and transparent pathway** to commercialize their solutions

Source: L.E.K. analysis

L.E.K.

Agenda

- Project overview
- Executive summary
- Key research findings
- **Digital health profiles**

Digital health profiles

- **HeartFlow Analysis**
- da Vinci Robotic Surgery
- FreeStyle Libre
- B. Braun Space Pump
- Merlin@Home Transmitter
- VNS Therapy
- Propeller Sensor
- Welwalk WW-1000
- Selena+
- iBreastExam
- Ultrasound iQ
- InferRead Solutions
- Avellan OPM Technology
- Neurotrack Cognitive Assessment
- KardiaMobile

HeartFlow Analysis

Company overview

- US-based medical technology company founded in 2007 by Stanford University scientists Charles Taylor and Chris Zarins
- Recently valued at USD 1.5 Bn in a Series E financing round; key investors include Wellington Management, GE Ventures, BlueCross BlueShield ventures

Current commercialization status

Countries / collaborations

- Currently approved for use in US, Canada, Europe and Japan
- Global collaboration with Philips who will help to promote use of HeartFlow Analysis for patients with suspected CAD[1]
- Global collaboration with Siemens Healthineers to pair CT scanners with HeartFlow analysis

Scale

- Product has been used in >30,000 patients globally, across 200 institutions

Product overview

Key product functionality

- HeartFlow Analysis uses advanced algorithms to build a personalized, digital model of patients' coronary arteries from a CT scan image, and apply computational fluid dynamics to compute the blood flow and FFR[2] at each point
- Complete analysis is a colour-coded digital 3D model of the heart, reflecting the impact that blockages have on blood flow
- CE-marked (2011) and FDA approved (2014)

Targeted end users

- Intended to provide support to qualified clinicians on the evaluation and assessment of coronary arteries

Value propositions

HCP / Physician

- Accurate and timely results: Data demonstrated 86% accuracy against the gold standard of invasive FFR[2]
- Convenience of integration: > 50% analysis completed and returned within 5 hrs or less, which allows the analysis to fit into existing clinical pathway

Patients

- Lowered risk and faster diagnosis: Reduction in the need for unnecessary invasive coronary angiograms

Public payer

- Lowered cost: Studies demonstrated cost prevention of up to USD 4k in the US and USD 260 in the UK per process

Note. 1) CAD: Coronary Artery Disease; 2) Fractional Flow Reserve
Source: Corporate website, News articles

HeartFlow Analysis

Reimbursement progress

- **US:** Approved for use in 2014; reimbursed by Medicare from 1 Jan 2018; reimbursement rate at USD 1,450 per test

  "… CMS decision to assign a New Technology APC for FFRct technology for Medicare recipients is a recognition of the value of this technology, and its demonstrated ability to reduce the no. of invasive diagnostic coronary angiography procedures and help medical centers reduce cost …"

  Professor for Research, Duke University

- **UK:** Approved for use in 2011, and reimbursed through the ITP[1] from Apr 2018 to 31 Mar 2020
- ITP designation follows guidance issued by NICE in Feb 2017

  "… The case for adoption is supported by the evidence. The technology is non-invasive and safe, and has a high level of diagnostic accuracy …"

  Final guidance issued by NICE

- **JP:** Approved for use in 2016 and reimbursement from Dec 18

  "… In clinical studies, we were able to see firsthand how the HeartFlow Analysis can help to improve patient management and avoid invasive procedures in some patients. The reimbursement approval will enable more physicians and patients to obtain benefits…"

  Takeshi Akasaka, Professor of Medicine, Wakayama Medical University

Monetization model

- HeartFlow charges a fee of USD 1,500[2] / GBP 700[3] for every test analysis performed using HeartFlow Analysis
  - For most patients, this will be covered by public reimbursement or private insurance (> 235 Mn Americans have insurance plans that reimburse the technology)

Key Success Factors for reimbursement

1. **Strong clinical evidence**: Demonstrated that results from non-invasive test can match existing invasive test and improve patient outcome; Supported by > 300+ peer reviewed articles, 200+ patents and decades of clinical research
2. **Strong evidence for cost-savings:** Study was conducted to show that a HeartFlow-guided strategy would result in fewer invasive coronary angiograms, hence reducing the cost of diagnosis and treatment
3. **Strong advocacy by reputable organizations**: Supported by organizations such as Evidence Street[4], NICE, American College of Cardiology, American Heart Association
4. **Partnership with private insurers before public reimbursement:** A growing number of commercial payers and organizations have already recognized the value of HeartFlow prior reimbursement: Anthem, Aetna, BlueCross Blue Shield have collectively provided health insurance coverage for approximately 80 Mn people

Note. 1) ITP Program was launched to help hospitals adopt innovation faster and more systematically; 2) In the US; 3) In the UK; 4) Conducts healthcare technology evaluations for Blue Cross Blue Shield Association

Source: Corporate website, News articles

HeartFlow Analysis

Key findings for Japan

1

Tapped local market diagnostic preferences

- Japan was selected as a suitable expansion market for HeartFlow, as there was already strong support among the medical community for CT to be the initial diagnostics for suspected CAD cases, which feeds directly into the data source for HeartFlow analysis; this reduced the need for HeartFlow to alter the existing diagnostic pathway
- In other markets like the US, there was a need to shape the diagnostic pathway for CAD, as CT scans was not commonly used at the initial stages

2

Fulfilled existing unmet needs, leading to strong advocacy by physicians

- Physicians in Japan were keen to more effectively diagnose patients and reduce the need for unnecessary tests, and HeartFlow was able to offer the solution

"… *When a patient presents with symptoms suggesting CAD, we want to be able to quickly and effectively diagnose patients while reducing the need for unnecessary tests or invasive procedures. In clinical studies, we were able to see firsthand how the HeartFlow analysis can help to improve patient management and avoid invasive procedures…*"

Takashi Akasaka, Professor of Medicine, Cardiovascular, Wakayama Medical University

"… Adding the HeartFlow Analysis to the anatomical information provided by a coronary CT angiogram enables us to better detect and treat CAD. With the broader availability of the HeartFlow Analysis, physicians in Japan will be able to more efficiently diagnose CAD while minimizing unnecessary tests or delaying care for patients…"

Hiroyoshi Yokoi, Vice Chairman, Japan Association of Cardiovascular Intervention and Therapeutics

3

Focused on increasing accessibility through reimbursement

- Rapid adoption is likely to be driven by the approval for the reimbursement of HeartFlow Analysis

"… As we launch in Japan, our general strategy is to make the HeartFlow Analysis available to as many physicians and patients with suspected coronary artery disease as possible …"

John Stevens, HeartFlow CEO

Source: Corporate website, News articles

Digital health profiles

- HeartFlow Analysis
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- Welwalk WW-1000
- Selena+
- iBreastExam
- Ultrasound iQ
- InferRead Solutions
- Avellan OPM Technology
- Neurotrack Cognitive Assessment
- KardiaMobile

da Vinci Robotic Surgery

Company overview

- Intuitive Surgical is a US-based company that focuses on the development, manufacturing and marketing of the da Vinci surgical system
- Listed on NASDAQ

Product overview

Key product functionality

- da Vinci System consists of an ergonomic surgeon console(s), a patient-side cart with interactive arm(s), a high performance vision system, and other instruments and accessories
  - **Surgeon console:** Serves as the control for surgeons
  - **Patient-side cart:** Holds the camera and surgical instruments, which are controlled through the console
  - **Vision cart**: Facilitates communications between components and supports the vision system

Targeted end users

- Enables surgeons to perform minimally invasive procedures; widely used in urology and gynecology procedures

Current commercialization status

Scale

- Installed base of 5,582 da Vinci systems globally, with 780 in Asia;
- Total of > 6 million procedures performed globally till date, accompanied by ~16,000 peer-reviewed clinical journal articles

Value propositions

HCP / Physician

- **Increased range of motion:** Provides greater range of motion and dexterity for the surgeon, compared to fixed, non-rotating laparoscopic instruments used in conventional surgeries
- **Increased precision:** Facilitates increased precision of surgery
- **Enhanced visualization**: Highly magnified, 3D high-definition views of the surgical areas allows surgeons to work on areas that may not be seen by the naked eye

Patients

- **Improved patient experience**: Lesser blood loss, risk of infection, pain and shorter recovery time
- **Smaller incisional scars**: Patients are also left with smaller surgery scars post operation

Public payer

- **Lowered cost:** In studies conducted globally and in Japan to compare the cost effectiveness of da Vinci, total cost to treat per patient episode has been found to be lowered, through shorter duration of hospital stays

Source: Corporate website, News articles

da Vinci Robotic Surgery

INTUITIVE SURGICAL®

Commercialization progress in APAC

2005
- Entered **Korea** in 2005, with the first robotic-assisted surgery performed by Yonsei University Severance Hospital
- 51 systems installed as of Sep 17

2014
- **Japan:** First introduced in Keio University for clinical studies in March 2000
- Systems were distributed by Adachi Co before Jun 2014, helping to establish ~150 customers in the country
- **Intuitive Surgical commenced direct operations in Japan from Jun 2014**; offering employment to selected Adachi employees experienced in da Vinci business

2016
- **China:** Intuitive's products have been distributed by Fosun's subsidiary Chindex Medical since 2011
- Sep 2016: **Established a JV with Fosun Pharma** to research and market new robotic-assisted, catheter-based medical devices
- 102 systems installed across 84 hospitals, as of Nov 19

2017
- **Korea:** Opened a new surgical innovation and training center in South Korea, located at the Sangam DMC High-Tech Industry Center
- The innovation center is the 4th in the world, with two in the US and 1 in Japan

2018
- **Commenced direct operations in India in May 2018**, following seven years of doing business in India through distributor Vattikuti Technologies, with > 65 systems in use
- > 60 former Vattikuti employees became part of Intuitive's business

- **Taiwan: Commenced direct operations in Dec 2018**, after working with a distributor Unison Surgicals since 2009

Source: Corporate website, News articles

L.E.K.

da Vinci Robotic Surgery

INTUITIVE SURGICAL®

Commercialization: Key findings

1

Adopted "Distributor first" strategy to develop local market understanding

- In most of the key APAC markets, Intuitive has engaged local distributors to help shape the market
- When sufficient sales volume is established, the next step has been to commercialize da Vinci products directly, simultaneously offering opportunities to distributor's employees who are familiar with the products
- Comprehensive training and technical support were always emphasized and provided through distributors

2

Adapted strategy to local surgical culture and readiness, to develop relationship and market understanding

- da Vinci tailors its strategy based on assessment of the surgical culture and readiness of surgeons to adopt advanced technology
- Robot training centers were established in Japan and Korea, where anyone can learn how da Vinci works, and offers a place for surgeons to gather and have meaningful discussions
  - In Japan, surgical societies and surgeons were observed to be thoughtful, always seeking clinical improvements
  - In Korea, surgeons were deemed to have a higher culture of innovation, and a drive to continuously innovate to create better options for patients globally

3

Made continued investments over time to build trust

"… For India, the idea is it will take some time to build our capabilities in India but we also think it's an economy that's been growing, there's a strength in the surgical community in India, both there and globally. And so it's an important long-term market for us. And the point of illustrating some of the Japanese example is that building a real presence and building the organization and the trust within the healthcare community in those markets takes time …"

Gary S Guthart, Intuitive Surgical CEO and President

4

Collaborated with clinical societies and organizations to gather advocacy

- In Japan, sale team engaged with surgical societies to discuss on the training pathways, education and courseware, as well as fellowship programs

Source: Corporate website, News articles

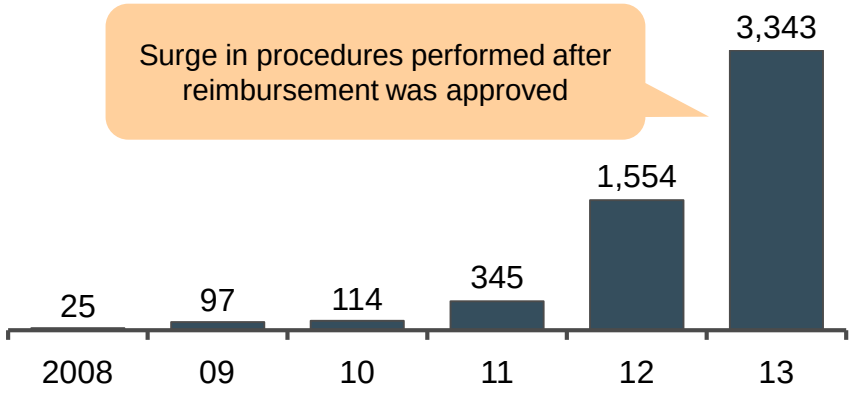
L.E.K.

da Vinci Robotic Surgery

Reimbursement progress

- **Japan:** Regulatory approval in Nov 2009; as of Aug 2019, estimated 400 systems installed
- Reimbursement started only for prostatectomy (USD 5,420) in 2012 and nephrectomy (USD 3,485) in 2016
- In 2018, additional 12 procedures were approved for reimbursement: colorectal, gynecological and thoracic surgeries, plus gastrectomy, bladder cystectomies, esophagostomies and mitral valvuloplast
- **Korea:** Only robotic-assisted cardiac surgery and arthroplasty procedures are reimbursed

Number of robotic-assisted laparoscopic radical prostatectomy procedures performed in Japan[2]



Reimbursement: Key findings

Demonstrated clinical superiority over laparoscopy

- Across the different indications, robot-assisted surgeries are often compared to existing laparoscopic surgeries, in terms of clinical outcomes
- Reimbursement was initially provided for prostatectomy as it was a procedure that was challenging to perform laparoscopically, and da Vinci was able to fill the gap

Gained strong advocacy by institutions and surgeons

- Reimbursement for prostatectomy was initiated by the Tokyo Medical University, who applied for it to be considered an advanced medical treatment[1] and MHLW approved it in 2008

Continued investments to shape the treatment pathway

- Took close to a decade for the additional procedures to be reimbursed in Japan

> *"… We have been investing in Japan for over 10 years and we are now seeing the fruits of that investment in terms of a 12-procedure reimbursement …"*
>
> *Marshall Mohr, CFO Intuitive Surgical*

Worked with existing reimbursed procedure code (in markets where an alternative reimbursement code exists)

- By working with existing procedural codes (for laparoscopic procedures), Intuitive Surgical was able to bypass some of the difficulties other device manufacturers have encountered in securing reimbursement codes

Note. 1) This allowed the cost of the robotic procedure to be covered by public health insurance; 2) Japan Society for Endoscopic Surgery
Source: Corporate website, News articles

da Vinci Robotic Surgery

Monetization model

Upfront fee + annual operating fee

- Upfront purchase price for the machine ranges from USD 1 Mn to USD 2.3 Mn, depending on the specific system and geography
- Ongoing annual operating costs can reach USD 340k; annual service contract between a hospital and Intuitive can cost between USD 100k and 180k

Leasing model and usage-based model

- In the past 1 – 2 years, Intuitive has been moving towards a new monetization model which will place more of its systems in the market before competitors enter the market[1]

- To drive adoption, the procedural volume within a hospital has to be sufficiently high to cover the equipment's amortization, operating costs and generate a positive ROI
  - As an estimate, investment experts have estimated that in order to make the purchase of a da Vinci Surgical System feasible, hospitals must perform anywhere from 150 to 310 procedures within six years to offset upfront and ongoing costs

Other trends and development

Pending approval of da Vinci for telesurgery

- On 28 Jun 2019, a MHLW expert panel in Japan approved a draft amendment to the guidelines for online medical treatment, lifting the ban on robotic telesurgery
- Under the scheme, telesurgeries will be performed using the da Vinci Surgical System
- Doctors of the Japan Surgical Society and others had demanded the government lift the ban on using da Vinci for telesurgery, saying that current high-speed communication networks allow for stable procedures.

Note: 1) Of the 275 systems shipping during the 3rd quarter in 2019, 1/3 were under operating lease and usage-based arranged
Source: Corporate website, News articles

Digital health profiles

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- B. Braun Space Pump
- Merlin@Home Transmitter
- VNS Therapy
- Propeller Sensor
- Welwalk WW-1000
- Selena+
- iBreastExam
- Ultrasound iQ
- InferRead Solutions
- Avellan OPM Technology
- Neurotrack Cognitive Assessment
- KardiaMobile

FreeStyle Libre

Company overview

- FreeStyle Libre is a product of Abbott, and is considered one of the frontrunners of the digital diabetes market

Product overview

Key product functionality

- The FreeStyle Libre system consists of a FreeStyle Libre reader which displays glucose data with every scan in a meaningful and user-friendly way, and a FreeStyle Libre sensor to be worn on the back of the upper arm
- Linked with a mobile app that can provide an ambulatory glucose profile (snapshot of patient's glucose level over a day)
- Received the Prix Galien award – the highest honour for biomedical innovation

Targeted end users

- Indicated for replacement of blood glucose testing and detection of trends and tracking patterns in the detection of hyperglycemia and hypoglycemia episodes

Current commercialization status

Scale

- As of 2019, FreeStyle Libre has approximately 2 million users worldwide, increasing organic sales by 70% over the previous year

Value propositions

HCP / Physician

- **Facilitates better treatment decision:** Provides doctors with deeper insights through the data gathered

Patients

- **Convenient**: Painless to apply and easy to use; water resistant; "liberates from the hassles of routine finger pricking", with no need for calibration
- **Discreet:** Glucose readings can be derived with a painless one-second scan, even through clothing
- **Disease management:** Through the app, patients can discover glucose patterns and trends to help in diabetes management

Public payer

- **Long-term reduction in cost**[1], such as reducing the likelihood of debilitating co-morbidities such as eye damage, limb amputation, kidney diseases or heart failure

Note: 1) All-cause health system resource use (hospital admissions, emergency room visits and ambulance use) was lower for people using flash monitoring compared with those using routine SMBG, especially in the REPLACE trial
Source: Corporate website, News articles

FreeStyle Libre

Commercialization model

- **In most markets, FreeStyle Libre has been launched through the major pharmacies, with the following objectives:**

Patients

Increased convenience

"… Many patients with diabetes use the pharmacy as a primary source for obtaining testing supplies today, and we wanted to enable patients to be able to continue to access their CGM supplies in the channel they find most convenient…"

Abbott

Payer

Ease of tracking

- Use of the pharmacy channel offers significant cost savings, the ability to easily track utilization and offers payers' members a simple and convenient place to get their products

Monetization model

- **Adopts a fixed fee for device and separate fee for sensors (consumables)**
  - One-off device cost: USD 69 for the reader
  - Consumables: USD 120 for a pair of 14-day sensors

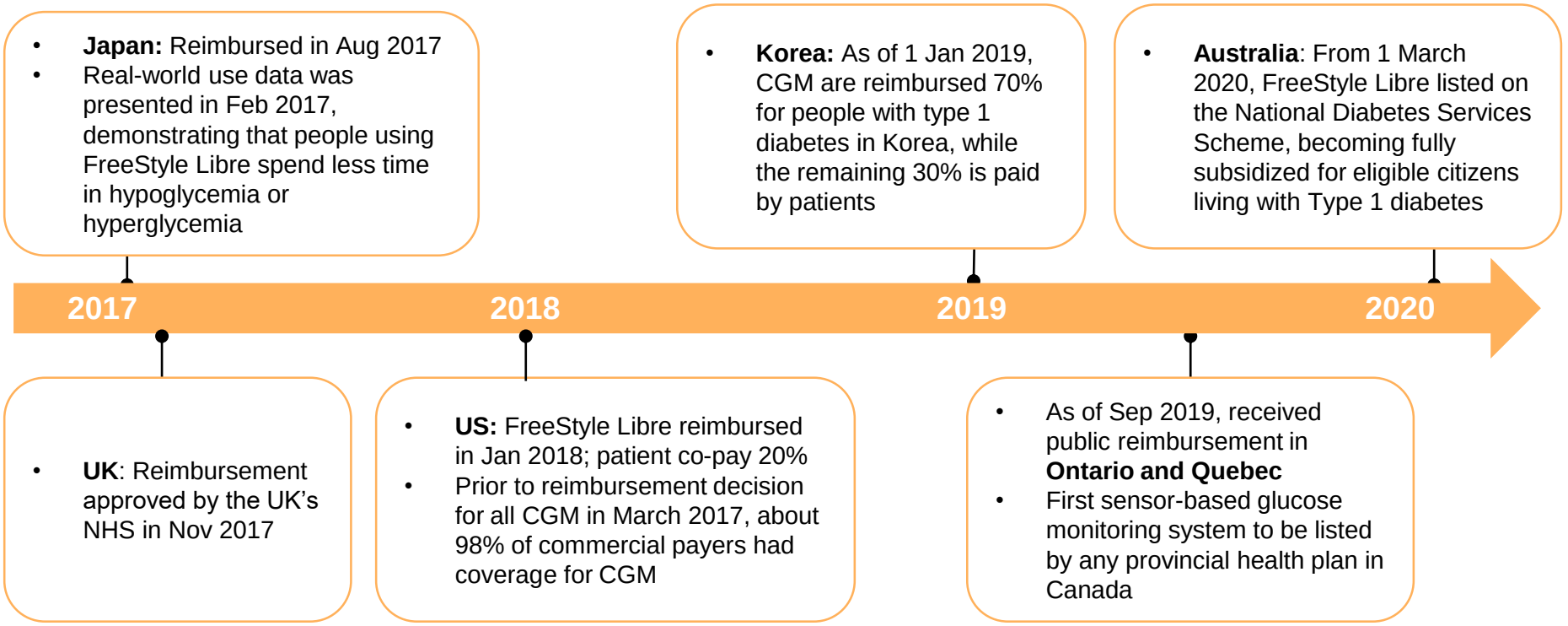
Other collaborations with insulin delivery providers

- **Sep 19:** Non-exclusive partnership with Sanofi to digitally connect FreeStyle Libre with Sanofi's connected insulin pens and software
- **Feb 19:** Non-exclusive partnership with Novo Nordisk to integrate insulin dose data from Novo's connected pens with digital health tools compatible with Abbott's FreeStyle Libre
- **Jul 17:** Abbott and Bigfoot Biomedical have entered into an agreement to develop and commercialize diabetes management systems, integrating Abbott's glucose sensing technology with Bigfoot's insulin delivery systems

Source: Corporate website, News articles

FreeStyle Libre

Reimbursement Progress



Source: Corporate website, News articles

FreeStyle Libre

Reimbursement: Key findings

1

Gained strong advocacy by clinical societies and patient groups

- **In Australia**, the expanded reimbursement coverage decision for CGM devices has been driven by efforts of patient and professional advocacy organizations, such as Diabetes Australia
- **In Korea**, patient advocacy, supported by organizations like Korean Diabetes Association, Korean Pediatric Diabetes Association led to changes in nation-wide policies related to reimbursement of medical devices (including CGM)

2

Demonstrated strong clinical evidence with positive outcome

- In Japan and the UK, real-world use data was presented, demonstrating that people using FreeStyle Libre were able to scan their glucose levels more frequently and spend less time in hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar), hence able to achieve improved glucose control overall

  "… "For people living with diabetes frequent glucose measurement is key to effective diabetes management. It is often challenging for my patients to comply with glucose testing because of the pain, inconvenience and stigma of using finger sticks…"

  Dr Yoshihito Atsumi, Director of Diabetes Center, Eiju General Hospital

3

Collaborated with private insurers

- Prior to reimbursement by Medicare in the US, ~98% of commercial insurers already recognized the value of FreeStyle Libre and provided coverage for policyholders

Source: Corporate website, News articles

Digital health profiles

- HeartFlow Analysis
- da Vinci Robotic Surgery
- FreeStyle Libre
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- Merlin@Home Transmitter
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- Ultrasound iQ
- InferRead Solutions
- Avellan OPM Technology
- Neurotrack Cognitive Assessment
- KardiaMobile

B Braun Space Pump

Company overview

- The Infusomat® Space pump is a product of B. Braun, medical and pharmaceutical company based in Germany

Product overview

Key product function-ality

- The Infusomat® Space pump is the volumetric infusion pump solution to configure customized, tailor-made solutions as individual pumps, small therapy units, or a complex infusion system
- Across all therapies, Space pump provides HCPs with a secure, digitally-enhanced solution that can help to monitor dosage and use of medicine, as a safety proposition

Targeted end users

- Intended for use on adults or pediatrics for the intermittent or continuous delivery of parenteral fluids, medications, blood and blood products through clinically accepted routes of administration

Value propositions

Biomedical engineers

- **Mechanical safety:** Space pump is designed with safety mechanisms such as Anti Free-flow mechanisms in place, protecting against free flow of therapy

Nurses / Physician

- **Ease of use:** The interface of the system is designed to be user-friendly
- **Streamlined workflow:** All parameters can be easily pre-defined within the drug library, which can store up to 1,200 drug names; Space system can be easily connected to Patient Data monitoring system and store all infusion therapy data
- **Optimized effectiveness and safety**: The pump database is able to work out the right dosage for each drug to be administered

Hospitals

- **Reduced workload for nurses:** Facilitates more efficient allocation of resources, especially driven by the COVID-19 situation, which has drained medical resources

Patients

- **Enhanced safety:** A complete customizable drug library also allows personalized settings and limits for individuals, helping to ensure a safer stay in hospitals

Source: Corporate website; news articles; primary interview

B Braun Space Pump

Commercialization model

Geographical market

- B Braun does not adopt a specific elected market approach for the commercialization of the Space pumps
- Time schedule for launch is dependent on the regulatory approval process for each market
- However, need to assess the different states of readiness for each market; in markets like India and Vietnam, hospitals may not be ready to adopt more advanced pumps
  - In these cases, B Braun may choose to work with local organization to understand how best to market and position the product, and to educate the relevant stakeholders

Channel strategy

- Within each market, the **teaching hospitals and private hospitals** will be identified first and targeted; these are the settings where the KOLs will usually be situated in
- **The ICUs within hospitals are also targeted,** due to the high volume of pumps used in this setting; this group is also a key existing customer group for B Braun

Reimbursement model

Current situation

- **In Korea,** the Space pumps are currently being reimbursed at the same rate as the conventional pumps (KRW 2,060 per day), with no distinctions made
  - There was no difficulty in getting the smart pumps reimbursed using the reimbursement code for the conventional pumps
- **In Thailand,** reimbursed at the same rate as the conventional pumps (THB 180 per day)
- **Across the rest of APAC**, reimbursement for smart infusion pumps remains limited / non-existent

Current strategy

- **Industry associations:** Working with the relevant authorities (HIRA, MOHW) to help distinguish smart pumps from the conventional ones, with the aim to get a separate reimbursement code
- **Hospitals:** Positioning the smart infusion pump as key to prevention of medication errors (using the Drug Library), and working towards integration with other systems such as the EMR systems within hospitals

Source: Corporate website; news articles; primary interview

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- KardiaMobile

Merlin@Home transmitter

Company overview

- Merlin@Home transmitter was a product of St Jude Medical, which was subsequently acquired by Abbott in 2017

Product overview

Key product function-ality

- The Merlin@Home transmitter allows efficient remote care management of patients with implanted cardiac devices through scheduled transmissions and daily alert monitoring
- Upon reading of the data, information is transmitted to the **Merlin.net Patient Care Network**, where physicians can view uploaded data for monitoring disease status and manage remote follow-ups

Value propositions

HCP / Physician

- **Increased efficiency:** Transmitter is designed to streamline workflow and support informed clinical decision, by facilitating easy and efficient remote care patient management
- **Detection of anomalies and early notifications:** DirectAlert notifications alert physician if the remote follow-up or remote monitoring reveals an episode or event that requires further attention
- **Increased follow-up compliance**: Higher follow-up compliance achieved through automatic uploading of data with RF devices and transmitters

Patients

- **Increased convenience**: Reduced need for travelling for in-office consultations, which can be replaced with remote consultations

Public payer

- **Cost effective**: Studies of ICDs and pacemakers with remote monitoring in the US have demonstrated cost reduction opportunities[1]

Note. 1) Through various clinical studies, including the EVOLVO study presented at the Heart Rhythm Society, and the CONNECT trial published by the Journal of the American College of Cardiology
Source: Corporate website; news articles; primary interview

Merlin@Home transmitter

Reimbursement

Current situation in AUS

- In Australia currently, both the Merlin@Home transmitter (device) and the process to implant ICDs / pacemaker (procedure) are reimbursed
  - **Medicare Benefits Schedule (MBS):**
    - Procedure to insert ICD / pacemaker
    - Process to review implanted pacemaker via remote consultation
  - **Prostheses list:**
    - Merlin@Home transmitter: Reimbursed at A$1,450 under billing code SJ369 / SJ370
- **In the private setting:** Patients who are covered by private insurance do not pay OOP for the transmitter or the procedure fees
- **In the public setting:** Hospitals that prescribe the transmitter have to absorb the cost from the hospital budget; hence, uptake in public setting has been very low compared to private

Situation in APAC

- Currently, Merlin@Home transmitter is not reimbursed in China, Taiwan, Korea or Japan[2]

Other key findings

- **Procedure must be listed on MBS**
  - In order for medical device to list on the prostheses list, the procedure must first be listed on the MBS
  - For application of new MBS code, **process could take 2 to 3 years of evaluation by MSAC[1]**, with requirements of HTA
- **Listing on prostheses list can happen in parallel**
  - Application for prostheses list can take place in parallel to MBS listing
  - If a medical device already has a MBS code, the evaluation process can take **~1 - 2 reimbursement cycles (~4 - 8 months)**
- **Evidence generation is key**
  - In Australia, the requirements for clinical evidence for both the applications are very high; comparative evidence against the Standard of Care / existing comparators is required
  - While not mentioned as an official rule, **there has to be a Randomized Clinical Trial conducted for the service** to be listed on the MBS

Note: 1) Medical Services Advisory Committee; 2) In Japan, remote monitoring fee may be paid to hospitals; however, remote monitoring transmitter is not reimbursed
Source: Corporate website; news articles; primary interview

Merlin@Home transmitter

Other key findings

- **Software reimbursement**
  - In Australia, the Merlin.net software is not seen as a separate item from the medical device, and will be regulated together as an entire system
  - For other mobile applications not linked to any medical device, there are currently no platform for reimbursement

- **Choice of private insurance policy**
  - The type of healthcare policies with private insurers will determine the amount of coverage one gets for different diseases
  - There may be certain amount of OOP component, depending on the extent of insurance coverage
  - However, the maximum amount that will be reimbursed, across all policies with appropriate coverage, will be the prices listed on the prostheses list

Monetization

- In Australia, monetization essentially begins only with prostheses listing; while companies can sell in the public setting, uptake is likely to remain limited
- For the transmitters, Abbott adopts a fixed fee payment model, where hospitals purchases each transmitter at a cost of A$1,450
- While there could be variances across hospitals due to different commercial agreement, the prices listed on the prosthesis list will usually serve as the reference points

Additional efforts after prostheses listing

- Need to provide technical and educational support during implantation process, while pairing device with transmitter
- Need to provide significant support to hospitals and physicians to facilitate the remote monitoring process for patients, including:
  - **Ongoing technical and clinical support** to hospitals and clinicians
  - **Maintenance of IT infrastructure** for the technology

Source: Corporate website; news articles; primary interview

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- KardiaMobile

VNS Therapy

LivaNova
Health innovation that matters

Company overview

- The VNS Therapy System was pioneered by Liva Nova (previously by Cyberonics), a global medical technology company built on decades of experience, and a world leader in cardiovascular and neuromodulation solutions

Product overview

Key product function-ality

- The VNS Therapy System is considered the #1 implantable device for drug-resistant epilepsy
- VNS prevents seizures by sending regular pulses of electrical energy to the brain via the vagus nerve; it consists of a device implanted under the skin, an electrode or wire attached to the generator device and wound around the vagus nerve
- Device is programmed in the outpatient clinic to deliver pulses and stimulation; the amount of stimulation has to be adjusted over time (Optimal frequency, amplitude, and pulse width)
- Product is FDA-approved in 2005 and CE-marked in 2001; till date, VNS Therapy System has been used in more than 100,000 patients around the world

Value proposition

Patients

- **Lowered risk:** From an observational study[1], it was found that SUDEP (Sudden Unexplained Death in Epilepsy) risk significantly decreases during long-term follow-up of patients with refractory epilepsy receiving VNS therapy
- **Reduction in seizures overall**: After VNS, seizure frequency was found to reduce by an average of 45%[2]
- **Improved Quality of Life[3]:** In an analysis using the VNS Therapy Patient Outcome Registry, 7 metrics related to QOL after VNS for epilepsy in >5,000 patients were examined, and found that VNS led to an improvement in various QOL metrics
- **Increased convenience**: With the improvement in the programmer device used for VNS, the need to physically visit a physician to adjust the level of stimulation is gradually reduced

Hospitals

- **Lowered ED and ICU admission:** Proven to result in lowered admission to Emergency Department and ICU[4]

Note. 1) Long-term Surveillance of SUDEP in drug-resistant epilepsy patients treated with VNS therapy; 2) VNS for epilepsy: Meta-analysis of efficacy and predictors of response; 3) Quality of Life Metrics with VNS for Epilepsy from Provider survey data; 4) In a comparative study, VNS surgery was found to have lower rate of complications and reoperations and is associated with reduced incidence of seizure-related ED visits and hospital admissions in the first 2 post-operative years

Source: Corporate website; news articles; primary interview

L.E.K.

VNS Therapy

LivaNova
Health innovation that matters

Reimbursement

Current situation in Australia

- **In Australia currently,** both the VNS generator (device) and the process to implant it are reimbursed
  - **Medicare Benefits Schedule:**
    - Insertion / replacement of VNS generator
    - Placement of leads to connect generator to vagus nerve
    - Follow-up visits to physicians for programming
  - **Prostheses list:**
    - **VNS Therapy Demipulse Generator**: Reimbursed at A$11,435 under billing code SA185
    - **VNS Therapy Lead**: Reimbursed at A$3,069 under SA187

Other APAC Markets

- **In Taiwan and Japan,** VNS therapy is also reimbursed (for both procedures and device)
- **In Korea**, reimbursement rate is 80% for the device
- **In China,** device is currently not reimbursed

Other key findings

- **In Australia,** companies need to understand that they need to be able to provide 2 years of health economics and clinical data, and this is a rigorous and costly process
- **Across all markets**, it is also essential to get the right stakeholders on board (surgeons, epilepsy clinical societies) to support the application

Trends and development

- **Moving forward,** Liva Nova will continue to develop its programmer device, so that the optimal dosage of stimulation can be programmed with reduced need to visit the physician physically

Source: Corporate website; news articles; primary interview

L.E.K.

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Propeller Sensor

Company overview

- Founded in 2010, Propeller Health is a leading digital health company dedicated to the management of chronic respiratory disease; Company was acquired by Resmed in Dec 2018 for USD 225 Mn

Product overview

Key product function-ality

- Propeller sensor is attached to an inhaler, and medication can be used as prescribed;
- **Connected to a digital app,** Propeller also helps patients to understand causes of symptoms and gain further insights for disease management

Current approvals

- Propeller sensor is approved for use with inhalers made from Boehringer Ingelheim, GlaxoSmithKline, Novartis, Orion and other generic drugmakers; In May 2020, Propeller also received FDA approval for use with AstraZeneca's Symbicort inhaler

Value proposition

Patients

- **Ease of integration with existing medication:** Propeller works with over 90% of inhaled medications available in the U.S.
- **Reduced frequency of asthma attacks:** Based on an analysis of patients using the Propeller system**,** up to 79% of patients experienced fewer asthma attacks
- **Increased medication adherence**: Up to 50% more doses taken on schedule; Propeller programs show average medication adherence of 46.6%, with many programs showing consistent adherence > 55%, compared to US average of 22.1%
- **Improvement in asthma control**: On average, over 50% of patients with uncontrolled asthma achieve controlled status within one year of starting on Propeller, as demonstrated in randomized clinical studies and commercial programs

Health systems

- **Cost savings to healthcare systems**: Based on a study conduced by Zeiger (N=96,631), costs savings for controlled asthma (compared to uncontrolled asthma) amounted to ~USD 2,100 per year

Source: Corporate website; news articles, primary interview

Propeller Sensor

Monetization

Key consider-ations

- The priority in terms of monetization was not adding extra costs to the system; Propeller wanted to be the solution to eliminating existing costs in the system through better management of respiratory diseases
- Monetization considerations need to account for the different groups of patients that Propeller serves:
  - COPD[1] patients: Tend to be older with co-morbidities
  - Asthma patients: Often younger patients; **per patient cost of exacerbation** tend to be lesser than that of COPD patients

Monetiz-ation model

- Cost for propeller health sensor are paid on a **per patient per time period basis**
  - This includes payment for both the sensor and the application
  - Cost are usually covered by private insurers or public payers
  - Due to the COVID-19 situation, **Propeller sensors are increasingly being reimbursed under the remote monitoring code**

Reimbursement best practices

- **Start to collect evidence early** to support reimbursement
- **Gather support early** from professional societies and KOLs
- **Identify potentially relevant reimbursement codes**
  - Even if there is an existing reimbursement code, there is still the need to raise awareness, educate the physicians and work closely with payers
- **Allocate resources and prepare to commit** for 2 – 3 years for successful reimbursement

Note: 1) COPD: Chronic Obstructive Pulmonary Disease
Source: Corporate website; news articles, primary interview

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Welwalk WW-1000

TOYOTA

藤田保健衛生大学
FUJITA HEALTH UNIVERSITY

Company overview

- Toyota has been developing rehabilitation assist robots in collaboration with Fujita Health University, since the end of 2007
- Pilot testing has been conducted since 2011, and the robots have been installed in 23 medical facilities throughout Japan between 2011 and 2014 for clinical research

Product overview

Targeted end users

- The Welwalk WW-1000 is designed to aid in the rehabilitation of individuals with lower limb paralysis as a result of stroke and other causes

Key product functionality

- System comes with a main unit (the robotic training system) and a robotic leg
- It comes with a range of rehabilitation support functions based on motor learning theory, including the ability to adjust the difficulty level to suit the patient, and feedback about the patient's gait characteristics

Development progress

- **2007:** Start of joint research with Fujita Health University
- **2011**: Commencement of pilot testing
- **Between 2011 and 2014**, robots have been installed across **23 medical facilities** for clinical research
- **Nov 2016**: Approved as a Medical Device
- **2017:** Start of rental service
- **As of Nov 2019**, the Welwalk WW-1000 has been used at **~80 medical institutions** in Japan

Source: Corporate website; news articles

L.E.K.

Welwalk WW-1000

TOYOTA

藤田保健衛生大学
FUJITA HEALTH UNIVERSITY

Key features of the system

System also provides **appropriate support** to the patient with **high level of adjustability offered**

Monitor for therapists to **study the pressure and body weight distribution** on affected leg

Monitor for patients with mirror and side view to **monitor and correct posture in real-time**

Value propositions

Patients

- Collectively, this system provides a **feedback function** to the patient as it monitors the **different indicators and posture** of the patient, to facilitate faster recovery
- System is also designed to offer support and freedom of movement, which is not possible for a therapist to provide; this also helps to speed up the recovery rate

HCP / Physician

- Helps to analyze patient's recovery process
- Ease of set up of the system and design of the system facilitate practical integration into the clinical environment

Source: Corporate website; news articles

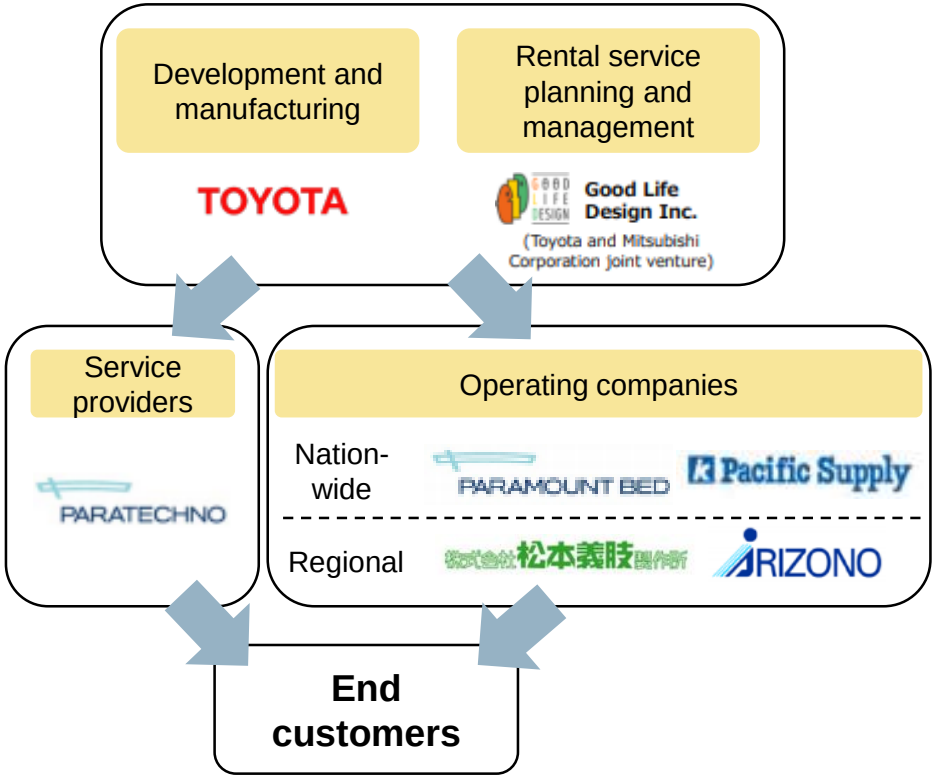
L.E.K.

Welwalk WW-1000

TOYOTA

藤田保健衛生大学 FUJITA HEALTH UNIVERSITY

Commercialization model



- Toyota has chosen to tie up with other operating companies and service providers with vast experience in healthcare, to commercialize the Welwalk WW-1000 system

Monetization model

Welwalk WW-1000

Rental model is adopted:

- Upfront fee of JPY 1,000,000
- Monthly fee of JPY 350,000

Welwalk WW-2000

- Due to requests from healthcare institutions, Welwalk WW-2000 will **be made available for purchase** with the **aim of improving overall quality of service, and to "provide the joy of walking to more patients"**
- Cost to the hospitals have been listed as such:
  - Hardware: JPY 23.5 Mn
  - Maintenance agreement: JPY 50,000 per month for 5 years (starting in the 2nd year)

- The newer version of the robot, Welwalk WW-2000, which was expected to be delivered in Feb 2020, provides the following upgraded features:
  - Functions that display assistance settings in real time to improve abnormal gait and a game function to help maintain motivation

Source: Corporate website; news articles

L.E.K.

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Selena+

Company overview

- Selena+ (Singapore Eye Lesion Analyzer Plus), was jointly developed by Singapore Eye Research Institute (Seri) and the NUS School of Computing, and the license is held by SingHealth, one of the public healthcare clusters in Singapore
- Selena+ is licensed to local start-up EyRIS

Current commercialization status

- System was approved by the Health Sciences Authority in Singapore in Oct 2019; currently in use in the SNEC Ocular Reading Centre and Tan Tock Seng Hospital
- CE-marked in March 2020, to help facilitate its acceptance in overseas market
- Distributed by Nova MSC in Malaysia (Nov 19)

Product overview

What is it?

- **An intelligent deep learning system (DLS)** designed to perform **automated image analysis** for diabetic eye diseases, such as diabetes retinopathy, glaucoma and age-related macular degeneration
- Excellent image processing capabilities was developed and originally trained on anonymized retinal images acquired from diabetic patients who attended the Singapore Integrated Diabetic Retinopathy Programme (SIDRP) over 10 years
- Subsequently, a multi-centre global collaborative effort involving more than 10 centres such as Mexico, United Kingdom, New Zealand, Australia, United States, China and Thailand was conducted to validate the program

How does it work?

- SELENA+ diagnose by scanning the photographs for signs of three diabetic eye diseases:
  - **Diabetic retinopathy**: Yellow and red lesions in the retina
  - **Glaucoma:** Abnormal cup-to-disc ratio
  - **Age-related macular degradation**: Yellow lesions in the macular

Source: Corporate website; news articles

Selena+

Value proposition

Hospitals / Physicians

- **Fast diagnosis:** The tool developed requires less than two minutes to determine if a person has major eye problems; down from 1 hour previously
- **High accuracy:** Tool can tell from a photograph if a person has diabetic retinopathy, glaucoma, or age-related macular degeneration with an accuracy > 90%;
- **Efficiency of resources**: Selena+ is expected to replace the role of existing primary graders
    - The SNEC Ocular Reading Center receives ~4,000 images a day, which are then processed by 8 to 10 staff; these images go through 3 levels of checks, and ~50% of the images turn out to have no abnormalities

"… With the AI system, it can potentially reduce 80% of the workload of graders and optometrists, freeing up their time for treatment …"

Prof Wong Tien Yin, Chairman of Seri

Payer

- **Reduction of economic burden:** Offers early detection and evaluation of diabetes-related eye diseases to prevent blindness
- **Increased access for primary eye care:** Offers increased access for countries where there is a lack of centers specializing in fundus image grading

Other development

- **Expansion of use across local facilities**: MoU was signed with the Singapore Optometric Association in March 2020, to provide wider access to primary eye care for Singaporeans
- This is done through a network of 23 optometric practices, with the aim to be deployed nationwide by 2022

- **Indication expansion**: To be developed for use in other disease areas such as cardiovascular

"… The development of Selena+ does not end here. More research is taking place to turn it into a tool that can predict the risk of cardiovascular disease …"

Singapore Health Minister Gan Kim Yong

- **Geographic expansion**: To be developed for use in other countries, such as Middle East, Africa, and Australia

Source: Corporate website; news articles

Selena+

	Challenges faced	Key considerations
AI approaches requires a large number of images	• While data sharing from different centers is an obvious approach to increase the number of input data for network training, increasing the number of data elements does not necessarily enhance the performance of a network (e.g. adding more data from healthy subject will not improve disease classification) • In addition, the large number of images need to be well-phenotyped for different diseases; performance of the network will depend on the quality of those images and how representative the data is for the entire spectrum of disease	**Need for optimal number of cases for training and quality control on the images**
Regulation and state privacy laws	• Regulations on data privacy differ across countries • Implementation of the necessary solutions (data storage, management, and analysis) is time consuming and costly	**Continued collaboration across the different stakeholders (regulators, researchers)**
Integrating AI into existing workflow	• Implementing AI solutions into the existing workflow is challenging and requires sufficient connectivity	**Concerted effort from all relevant stakeholders is required**

Source: Corporate website; news articles

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iBreastExam

UE LifeSciences

Company overview

- UE LifeSciences is a med-tech startup headquartered in Philadelphia, with satellite offices in India and Malaysia
- As of Oct 2019, it has accumulated USD 1.5 Mn of grants and USD 4.2 Mn in revenue
- Investors include Kiran Mazumdar-Shar, Dr Ranjan Pai and Unitus Seed Fund

Product overview

Key product function-ality

- iBreastExam (iBE) is the world's first hand-held painless and radiation free mobile health solution for breast lesions detection using patented piezoelectric ceramic sensor technology
- Through its patented tactile sensor technology, the algorithm in the device is able to accurately assess and identify tissue elasticity differences between hard and stiff breast tumors and normal tissues
- The iBE software is an interface where the data and analysis are stored, and includes a data tracker which serves as a cancer registry
- FDA-cleared in 2015; CE-marked

Commercialization

Scale

- Till date, 300,000 women have been examined across 12 countries
- In India, over 50 healthcare providers including Manipal, Aster, Narayana Health Hospitals and Apollo Telehealth are using the device

Commercial model

<u>Distributor-driven approach</u>

- In 2017, partnership with GE has led to the devices being distributed to 25 countries in South Asia, Southeast Asia, and Africa

<u>Manufacturing</u>

- While the Head office is in the US, manufacturing facilities was established in India

Collabora-tions

- Close collaboration with public health agencies to introduce large-scale implementation in India:
  - Enrolled 74,500 women at 16 medical colleges in Maharashtra
  - Entered into tie-ups with state govts of Maharashtra, J&K, and Rajasthan

"… We work closely with HCPs, hospitals, primary health centers, diagnostics clinics, as well as NGOs and government hospitals, in India to market and promote the need for early detection of breast cancer …"

Mihir Shah, Founder

Source: Corporate website; news articles

L.E.K.

iBreastExam

UE LifeSciences

Value propositions

HCP / Physician

- **Ease of use:** iBreastExam is designed such that a nurse, lab technician or community health worker can be trained to operate the device
- **Ease of results interpretation:** Results do not require a doctor's interpretation
- **Speed of diagnosis:** iBreastExam results take 7 to 10 minutes for a bilateral breast screening, compared to 15 minutes for a mammogram, and 20 – 30 minutes for ultrasound

Patients

- **Clinically proven**: Offers a painless and radiation method to detect non-palpable lesions at an early stage and improve efficacy of clinical breast exams, with 84% sensitivity and 94% specificity
- **Removal of mental barriers:** Helps to remove the stigma and shyness towards breast cancer check ups, which may serve as barriers for check-ups

Payer

- **Increased access:** Facilitates early treatment of breast cancer, especially in countries lacking medical screening solutions
  - Device can be kept in any primary setting as a point of care device with no requirements of medical professional to deliver the test

Monetization

- While one device is available in the market for a cost between USD 8,000 and USD 10,000, the company has targeted programs with high volumes (especially for the govt, NGOs and CSR initiatives), which results in scans being as low as USD 1 per scan
- In India, it costs ~USD 6 for screening in the private hospitals, but only ~USD 1 in government hospitals

Other developments

- Explore potential to use the platform to develop scans for other cancer types

  "… There has never been a mobile, connected tool like iBreastExam that can not only help detect the disease early, but also work as a mobile breast cancer registry. We can help healthcare providers and decision makers understand where breast cancer is emanating from regionally as a heat map, parse through the data to develop deep understanding of the disease and make better healthcare decisions …"

  Mihir Shah, Founder

Source: Corporate website; news articles

L.E.K.

Digital health profiles

- HeartFlow Analysis
- da Vinci Robotic Surgery
- FreeStyle Libre
- B. Braun Space Pump
- Merlin@Home Transmitter
- VNS Therapy
- Propeller Sensor
- Welwalk WW-1000
- Selena+
- iBreastExam
- **Ultrasound iQ**
- InferRead Solutions
- Avellan OPM Technology
- Neurotrack Cognitive Assessment
- KardiaMobile

Ultrasound IQ

Company overview

- Butterfly Network was founded by Jonathan Rothberg, a serial biotechnology entrepreneur who has previously led two companies
- He was presented with the National Medal of Technology and Innovation for his pioneering inventions and commercialization of next-generation DNA sequencing technologies
- Raised USD 350 Mn from investors such as Fidelity, Fosun Pharma and Gates Foundation

Product overview

Key product function-ality

- Butterfly iQ facilitates point-of-care ultrasound testing by combining a probe to an iPhone installed with a Butterfly App
- It translated the traditional ultrasound technology (which uses piezoelectric crystal), onto a tiny silicone chip, which contains 9,000 tiny drum-like mechanisms that can receive and emit sounds

Current scale / accredita-tion

- Since its introduction in 2018, the Butterfly iQ device has been adopted by >15,000 HCPs globally, and is available across 20 markets
- FDA-approved in Oct 2017; CE-marked in Apr 2019

Monetization model

1 **Pro Individual Model**

- One-time fee of USD 1,999 for medical device and USD 420 per year for membership

2 **Pro Team**

- One-time fee of USD 1,999 for medical device and USD 1,200 per year for membership
- Catered for team of clinicians (5 licenses included)
- Offers real-time collaboration tools and worksheets for documentation and billing working integration, in addition to the individual subscription model

3 **Enterprise**

- Provides a suite of quality assurance tools, customizable worksheets, EMR integration and 3rd party device support
- Unlimited licenses for hospital teams and departments
- Price available only upon request

Source: Corporate website; news articles

Ultrasound IQ

Value propositions

HCP / Physician

- **Single probe can be used for different scenarios:** Butterfly's iQ 2D array of micro-machined sensors can emulate any type of transducers – linear, curved or phased
- **Portable and affordable:** With a single probe, ultrasound for the whole body can be performed, starting under USD 2,000

  "… I've been able to carry it around in my pocket on call and it's now become part of my ward round. Rather than listen to children's chests, I'm actually looking at them with ultrasound …"
  Dr Michael Griksaitis, Consultant pediatric intensivist and clinical lead at Southhamptom Children's Hospital
- **Ease of use:** Butterfly's app also features 19 presets and different modes, facilitating ease of use; the user simply selects the type of scan being performed on the Butterfly app
- **Secure and safe**: Data is AES 256-bit encrypted in the Butterfly Cloud and in the iQ app; SOC II certification also ensure secure access to data

Collaborations

- **With charity organizations:** Butterfly iQ devices have been donated to medical charities in 13 low-income countries, with 7 in Africa; accessibility to ultrasound scanners or X-ray machines and CT scanners remains very low in these countries
- These scanners are used to check for pneumonia in rural villages, which is a major cause of death for children in poor countries and is frequently misdiagnosed

- **Collaboration with Atrium healthcare:** Atrium Health became the first major health system in the nation to put into wide practice a new point of care ultrasound device – Butterfly iQ
- Large fleet of devices have already been deployed to perform thousands of scans under an agreement with Butterfly Network, placed in high-priority locations such as COVID-19 testing centers, ICUs, emergency departments

  "… The value of the Butterfly iQ extends well beyond this particular pandemic. Its ability to streamline workflow and provide clinicians important tools they need to help patients, right at their fingertips, is changing the future of medical imaging forever …"
  Dr John Martin, Butterfly's CMO

Source: Corporate website; news articles

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- **InferRead Solutions**
- Avellan OPM Technology
- Neurotrack Cognitive Assessment
- KardiaMobile

InferRead Solutions

Company overview

- Infervision is a leading global high-tech enterprise in medical artificial intelligence, using A.I. and deep learning technologies to develop multiple platforms, including an A.I. applications management platform, an A.I. data-mining research platform, and several A.I. clinical application platforms
- Company was founded in Jan 2015, and has raised ~RMB 482 Mn till date

Commercial footprint

- As of March 2020, Infervision has expanded the global strategic layout to North America, Asia-Pacific and Europe, with presence in 10 countries worldwide, and has processed over a total of 16 Mn cases

Product overview

Key product function-ality

- Infervision's InferRead solution suite is a comprehensive medical imaging solution series that is designed to integrate into the clinical workflow, providing imaging assisted-diagnosis for multiple body areas including, but not limited to, brain, lung, skeleton, and bone
- Core Product is InferRead CT Lung

Value proposition

HCP / Physician

- **Increased efficiency:**
  - Helps doctor to identify tiny nodules and complete the same task 3x faster[1]
- **Automated analysis and diagnosis:**
  - Auto-analysis based on historical images to compare for nodule changes and evaluate treatment outcome[1]
  - Diagnosis reports can be automatically generated in accordance with professional guidelines, with recommendations for follow-up
- **Increased accuracy and reduced misdiagnosis:**
  - Demonstrated sensitivity > 96.6% and specificity > 86.2% in a study in the Third People's Hospital of Shenzhen[2]
  - In the diagnosis of Black Lungs, Medical Weekly reported that doctors with less than 5 years of experience only diagnosed correctly 44% of the time, while research from Zhejiang university found that the clinical misdiagnosis rate averaged 46%; InferRead solutions are expected to improve the accuracy rate by 20%
- **Ease of integration into existing systems**
  - InferRead solutions can be integrated into PACS, SR or VNA

Note: 1) For InferRead CT Lung; 2) InferRead Tuberculosis
Source: Corporate website; news articles

InferRead Solutions

Monetization

- Different monetization models are adopted by Infervision:
  - **One-time fee for software**: Charges RMB 0.5 Mn to 1 Mn per software directly to hospitals
  - **Sales through CT machines suppliers**: Provides ~40% discount to suppliers
- Payment for these services usually come from the hospital's budget or in some cases, hospital's allocation towards research funding

Existing collaborations

- **In China:** Partnered with some of the largest 3A hospitals, with access to the largest medical training database in the world

- Imaging Clinic (CVIC) is one of Infervision's partners **in Japan**
- With InferRead CT Lung, the time taken to write a diagnosis report has been shortened from 4 – 7 days to 2 to 3 days
- Other key hospitals in Japan include Keio University Hospital, Kindai University Hospital, Nihon University Hospital, and Tokyo Women's Medical University Hospital

Use in diagnosis of COVID-19

- COVID-19 screening solution was launched on Jan 31, and by Mar 12, Infervision was used to analyze >80,000 chest CT scans to identify >6,000 patients, with accuracy rate of ~98%
- By April 7, >190,000 cases had been diagnosed in China and overseas

- **Japan:** In early march, Infervision starting working with Doctor Net, a Japanese enterprise with the largest team of certified radiology specialists
- While Japan has the highest number of CT machines in the world, there are only 6,000 registered radiologists
- Infervision was able to solve the shortage issue by deploying its AI-screening solutions in the Japanese hospitals

- Infervision has also deployed its solutions in the US and Italy:
  - **In the US**, within a week of being contacted by Thomas Jefferson University Hospital, the AI-screening system was set up and used for testing and monitoring
  - **In Italy,** the InferRead system was also set up upon urgent request in the Unicampus Bio-medicine Rome Hospital

Source: Corporate website; news articles

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Avellan OPM technology

Avellan

Company overview

- The Avellan OPM technology was developed by Tarilian Laser Technologies (TLT), which was acquired by Huma in Dec 2019
- TLT is now known as Avellan, the MedTech subsidiary of Huma Ltd

Product overview

Key product function-ality

- Avellan's technology makes use of a **proprietary optoelectronic method** instead of the **oscillatory method** for **ambulatory blood pressure monitoring (ABPM), in a non-invasive manner**
- This **enables clear, real-time beat-to-beat measurement and continuous display of BP** in digital format throughout the day, **without the need for calibration**
- Data from the readings can then be plotted on the Arteriogram, and analyzed through Avellan's proprietary algorithms to identify other potential problems of the heart and blood vessels
- Avellan is progressing FDA and CE marking, and preparing for registration across APAC

Value proposition

Patients

- **Ease of use:** Patients simply wear the wearable around their wrist, and continuous BP readings will be taken in a non-invasive and unobtrusive manner, throughout the day
- **Clear display of results:** When connected to an app, the readings can also be displayed in real-time
- **Early detection of diseases:** With the beat-to-beat readings, the technology also has the potential to identify other problems of the heart and blood vessels

Physicians

- **Analysis of data:** Updated data collected over time allows physicians to make more informed treatment decisions; **Cutting-edge AI and ML techniques** are applied to **develop novel digital biomarkers and precision medicine insights**

Payers

- **Cost-effective:** Various studies have been published to demonstrate that use of ABPM could result in cost savings, as compared to conventional clinical blood pressure or Home BP Monitoring[1]

Note: 1) Cost Effectiveness of Ambulatory Blood Pressure by Lawrence R Krakoff, Modelling study conducted by Hadi Beyhagni and Anthony J. Viera, Cost-effectiveness of ABPM in the follow-up of hypertension
Source: Corporate website; news articles, primary interview

Avellan OPM technology

Avellan

Monetization

- Two different revenue sources have been identified and may be adopted by Avellan:
  - **One-time fee for device and the software**
  - **Generation of insights that can be sold to consumers, HCPs, or medical device companies**

Current status of ABPM in APAC

Current situation

- Across APAC, the recognition and adoption of ABPM varies[1]:
  - While some markets have specific guidelines for the use of ABPM (Korea, Japan), others rely on international guidelines
  - ABPM is used almost exclusively in referral centers, and not in primary care clinics
  - ABPM is currently largely indicated for diagnosis of hypertension, including white-coat hypertension or masked hypertension

Current status of ABPM outside APAC

- **UK:** In 2011, the **National Institute for Health and Care Excellence (NICE)** recommended that ABPM be performed on all patients with suspected hypertension to confirm the diagnosis and reduce unnecessary treatment in people who do not have true hypertension[2]
- **US:**
  - In 2015, the US Preventative Services Task Force[3] recommended Ambulatory Blood Pressure Monitoring (ABPM) as the “best method” for measuring blood pressure, endorsing its use both for confirming the diagnosis of hypertension and for excluding ‘white coat’ hypertension[2]
  - ABPM is also endorsed by the **American College of Cardiology / American Heart Association Task Force**, as a reasonable screening tool to detect white coat and / or masked hypertension; findings of superiority of ABPM compared with clinic and home blood pressure assessment in terms of cost-effectiveness and prognostic value[4]
  - In 2019, the CMS expanded reimbursement coverage for ABPM, after the American Heart Association and American Medical Association issued a joint request to expand the coverage of ABPM[5]

Note: 1) Current status of ambulatory blood pressure monitoring in Asian countries: A report from HOPE Asia Network; 2) Insights in Public Health: Ambulatory Blood Pressure Monitoring; 3) Independent, voluntary panel of experts in disease prevention and evidence-based medicine; 4) Revisions of Medicare Reimbursement policy for ABPM and the role of qualitative analysis, published by Wiley; 5) Cardiovascular Business Article, Medscape article

Source: Corporate website; news articles, primary interview

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- Avellan OPM Technology
- **Neurotrack Cognitive Assessment**
- KardiaMobile

Neurotrack Cognitive Assessment

Company overview

- Neurotrack is building the cognitive health platform of the future, giving people direct access to tools and technology to assess, strengthen, and monitor their cognitive health
- Co-founded in 2012 by Elli Kaplan, and leading neuroscientists and researchers Stuart Zola, Ph.D., Elizabeth Buffalo, Ph.D., and Cecelia Manzanares

Funding raised

- As of Jun 2019, company has raised more than USD 50 Mn, including USD 6.8 Mn in grants from the National Institute of Health and National Institute of Aging
- Investors include Khosla Ventures, Sozo Ventures, Dai-ichi Life, SOMPO Holdings and AME Cloud Partners

Product overview

What is it?

- **Neurotrack** is the only digital platform that combines scientifically-validated cognitive assessments with a personalized intervention program
- **Cognitive Assessments:** Utilize groundbreaking eye-tracking technology and measure multiple cognitive domains, providing individuals with a report of their current cognitive health; designed to be taken regularly so that progress can be tracked
- **Intervention program**: Empowers individuals to make life-changing improvements in their cognition, through nutrition, exercise, sleep, stress management, cognitive training, and social engagement

How does it work?

- Technology uses the groundbreaking research of renowned neuroscientist and Neurotrack's co-founder, Dr. Stuart Zola, whose breakthrough clinical study on Alzheimer's Disease showed that eye movements, tracked through a camera, reveal important data about the state of our cognitive health and its potential for decline
- Assessment measures multiple cognitive domains, including processing speed, recognition memory, implicit learning, associative learning, associative memory, and spatial working memory

Source: Corporate website; news articles

Neurotrack Cognitive Assessment

Value proposition

Patients

- **Reduced risk of cognitive decline:**
  - Modelled after the multi-domain intervention that was proven to be effective in the FINGER[1] study;
  - A year-long Phase 1 trial on the Neurotrack Cognitive Health Program demonstrated **improvements in cognitive function, relief from depression**, and **a reduction in anxiety among older adults** who were at-risk of cognitive impairment
- **Continuous monitoring and early detection of cognitive impairment:**
  - The company claims it has the **first fully integrated, clinically validated platform** that can assess a person's cognition through its cognitive assessment — which can predict conversion from healthy to mild cognitive impairment (MCI) or MCI to Alzheimer's disease within three years at 89% accuracy, and within six years at 100% accuracy

Monetization model

- **Partnered with Dai-ichi Life, second largest life insurance in Japan, in Nov 2018**
  - **Plans to sell a dementia insurance product** that will allow each of the policyholders to take the 5-minute Imprint Memory Assessment test via a program that tracks eye movement

  "… We are excited about the partnership between Neurotrack and Dai-ichi Life, and our joint continued dedication to lowering the growth rate of dementia in Japan. We believe in the power of Neurotrack's products which is why we are a customer and now an investor …"

  Yasumasa Iwai, Executive Officer in charge of InsurTech at Dai-ichi Life
- **Partnered with Sompo Himawari Life, who started to provide Neurotrack service on 30 Jan 2020**
  - Sompo introduced InsurHealth, a new initiative which combines the primary function of insurance with health support functions; service also provides a suite of cognitive assessments delivered by Neurotrack's mobile app

Note: 1) The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability: A multi-year study of 1,200 adults at risk for cognitive decline. People who engaged in a multi-domain lifestyle intervention, including diet, exercise, and cognitive training, demonstrated improved cognitive performance

Source: Corporate website; news articles

Digital health profiles

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- **KardiaMobile**

KardiaMobile

AliveCor®

Company overview

- KardiaMobile was developed by AliveCor, a medical device and AI company that was recognized by Fast Company as one of 2017's most innovative companies
- AliveCor is based in California; key investors include Omron, Mayo Clinic, Khosla Ventures, Bold Capital Partners

Product overview

Key product function-ality

- KardiaMobile device is a FDA-cleared, clinical grade personal EKG monitor, which can capture a medical-grade EKG in 30 seconds "anywhere and anytime"
- Helps to detect Atrial Fibrillation, Bradycardia, Tachycardia or Normal heart rhythm, and is used by the world's leading cardiac care medical professionals and patients
- KardiaPro, the associated digital platform, also facilitates the sharing of medical data between physicians and patients
- It is the only FDA-cleared device that can detect the three most common arrhythmias[2]; till date, more than 60 Million EKGs have been recorded globally

Value proposition

Physicians

- **Allows physicians to manage patients remotely:**
  - With KardiaPro, data can be stored and retrieved in a HIPAA compliant manner for secure ECG and blood pressure review

  "… Utilization of the Kardia device with the KardiaPro monitoring service has proven to be a remarkable improvement in the management of patients with AFib. Managing non-Kardia AFib patients feels like navigating a forest with a blindfold …"

  Dr Anthony Pearson, Author of the Skeptical Cardiologist

- **Sensitive and accurate results:** Based on a study in 2013, Kardia demonstrated 98% sensitivity and 97% specificity in the detection of Atrial Fibrillation[1]

Patients

- **Ease of use:** Patients simply place fingers on the sensors, with no wires, patches or gels required
- **Data can be shared with doctors remotely:** Data can be tracked over time and sent to doctor for review, with reduced need for face-to-face consultations

Note: 1) Lau JK, Lowres N, Neubeck L, Brieger DB, Sy RW, Galloway CD, et al. Int J Cardiol. 2013;165(1):193-4; 2) Atrial Fibrillation, Bradycardia, and Tachycardia
Source: Corporate website; news articles

L.E.K.

KardiaMobile

AliveCor®

Reading can be seen on the app after 30s; notification will be provided for patients with abnormal readings or detection of possible atrial Fibrillation

User simply places fingers on the pads

Monetization

- **Fixed fee for device:** Every purchase of KardiaMobile includes the basic service free of charge, which includes unlimited EKG recordings with instant analysis, blood pressure and weight tracking, and storage of recorded EKGs on your phone
  - KardiaMobile: USD 99
  - KardiaMobile 6L: USD 149
- **Optional premium protection plan:** For a monthly price, additional services can be provided – device replacement, cloud storage and security, personalized heart health report, and medication tracking

Commercialization status

- **Device is available in the following markets through the following resellers:**
  - Australia: Alive Technologies
  - New Zealand: U-Health
  - Hong Kong / Macau: Mellica
  - India: LeapVault / Amazon India
  - Thailand: Medical Solutions
  - Malaysia: BioD Medica

Source: Corporate website; news articles

L.E.K.

Glossary of acronyms

Acronym	Definition
ABPM	Ambulatory Blood Pressure Monitoring
ARTG	Australian Register of Therapeutic Goods
CAD	Coronary Artery Disease
CGM	Continuous Glucose Monitoring
COPD	Chronic Obstructive Pulmonary Disease
HCP	Healthcare Professionals
HIRA	Health Insurance Review and Assessment Service
HSA	Health Sciences Authority
HTA	Health Technology Assessment
KFDA	Korean Food & Drug Administration
KOL	Key Opinion Leaders
MBS	Medical Benefits Schedule
MCI	Mild Cognitive Impairment
MFDS	Ministry of Food and Drug Safety
MHLW	Ministry of Health, Labour and Welfare

Acronym	Definition
MSAC	Medical Services Advisory Committee
NICE	National Institute for Health and Care Excellence
OOP	Out-of-Pocket
PACS	Picture Archiving and Communication System
QOL	Quality of Life
ROI	Return on Investment
TGA	Therapeutic Goods Administration

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