Time to refresh!

Spring cleaning is a practice found in many cultures, but it is a great way to “reset” and prepare for the next step. Are you ready? Find information to stay up-to-date with Access-2-Healthcare’s MedTech Gateway for April 2022.

MALAYSIA

MDA are making changes to the Change Notification guidance (MDA/GD/0020) and the draft document is open for comment and feedback. Industry stakeholders are welcome to provide inputs before Apr 20, 2022.

Draft Medical Device Guidance on Change Notification for Registered Medical Device

Learn More

UNITED STATES

US FDA sets Performance Goals for Medical Device Reviews

Learn More

US FDA aims to promote more timely access to effective and safe medical devices hence has proposed a reduction in the total time taken to reach a decision goal for 510k submissions. From 128 days for FY 2023, it may be reduced to 112 days by 2027.

TAIWAN

On January 21, 2022, the Taiwan Food and Drug Administration (TFDA) launched a new online pre-market application platform for medical devices, the TFDA Medical Device Premarket E-submission System. The system aims to provide manufacturers with an alternative way to submit pre-market application documents, so as to improve the convenience of pre-market applications for medical devices, and to comply with the trend of paperless, which can save the resources required to prepare paper documents. TFDA encourages but does not compel manufacturers to submit pre-market applications for class II and III medical devices through this new system

Taiwan FDA launches a new online Medical Device Electronic Pre-market Application Platform：TFDA Medical Device Premarket E-Submission System

Learn More

AUSTRALIA

Medical device application processing times

Learn More

The TGA processing times for conformity assessment applications and applications for inclusion on the ARTG are calculated using the TGA Half-yearly Performance Snapshot 2 July to 31 December 2021.

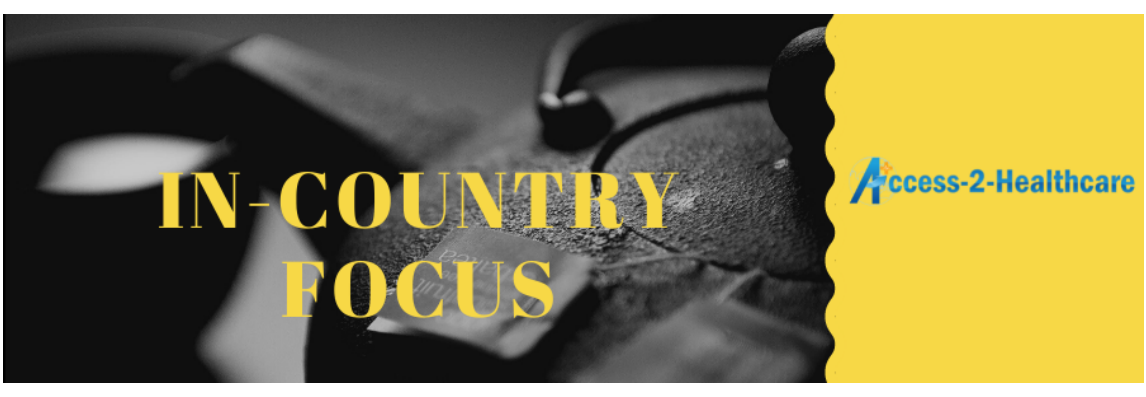
Designated NBs

1. **3EC International (Slovakia) – 2265** (MDR scope)
2. **BSI (Netherlands) – 2797** (MDR scope & IVDR scope)
3. **CE Certiso (Hungary) – 2409** (MDR scope)
4. **CERTIQUALITY S.r.l. – 0546** (MDR scope)
5. **DEKRA Certification (Germany) – 0124** (MDR scope & IVDR scope)
6. **DEKRA Certification (Netherlands) – 0344** (MDR scope & IVDR scope)
7. **DNV Product Assurance AS (Norway) – 2460** (MDR scope)
8. **DQS Medizinprodukte (Germany) – 0297** (MDR scope)
9. **Eurofins Expert Services Oy (Finland) – 0537** (MDR scope)
10. **Eurofins Product Testing Italy S.r.l. (Italy) – 0477** (MDR scope)
11. **GMED SAS (France) – 0459** (MDR scope & IVDR scope)
12. **IMQ (Italy) – 0051** (MDR scope)
13. **Intertek Medical Notified Body AB (Sweden) – 2862** (MDR scope)
14. **Istituto Superiore Di Sanita’ (Italy) – 0373** (MDR scope)
15. **ITALCERT SRL (Italy) – 0426** (MDR scope)
16. **KIWA CERMET ITALIA S.P.A (Italy) – 0476 (**MDR scope)
17. **Kiwa Dare B.V (Netherlands) – 1912 (**MDR scope)
18. **MDC Medical Device Certification (Germany) – 0483** (MDR scope)
19. **MEDCERT (Germany) – 0482** (MDR scope)
20. **NSAI (Ireland) – 0050** (MDR scope)
21. **SGS Belgium NV (Belgium) – 1639** (MDR scope)
22. **SGS FIMKO OY (Finland) – 0598** (MDR scope)
23. Slovenian Institute of Quality and Metrology – SIQ (Slovenia) – 1304 (MDR scope)
24. **TÜV NORD CERT GmbH (Germany) – 0044** (MDR scope)
25. **TÜV Rheinland Italia SRL (Italy) – 1936** (MDR scope)

26. **TÜV Rheinland LGA (Germany) – 0197** (MDR scope & IVDR scope)
27. **TÜV SÜD (Germany) – 0123** (MDR scope & IVDR scope)
28. **UDEM Adriatic d.o.o. (Croatia) – 2696 (**MDR scope)

Withdrawals

1. **BSI Assurance (UK) – 0086**
2. **DQS Polska (Poland) – 2282**
3. **ECM (Germany) – 0481**
4. **GMED SAS (France) – 0459**
5. **Presafe (Denmark) – 0543**
6. **SGS United Kingdom Limited (UK) – 0120**



US

Health Resources and Services Administration Announces Availability of New Funding to Support Community-Based Doulas

Today, the U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced the availability of $4.5 million for hiring, training, certifying, and compensating community-based doulas in areas with high rates of adverse maternal and infant health outcomes. This announcement builds on the Biden-Harris Administration's commitment to reduce maternal mortality and morbidity and address the nation's Black maternal health crisis. "Every person deserves to have the best support and care during pregnancy," said HHS Secretary Xavier Becerra. "Today's announcement represents another important investment by the Biden-Harris Administration to improve maternal health and equity in communities most in need. We will continue to fund programs and efforts that will lead to healthier pregnancies and help save lives."

Learn More

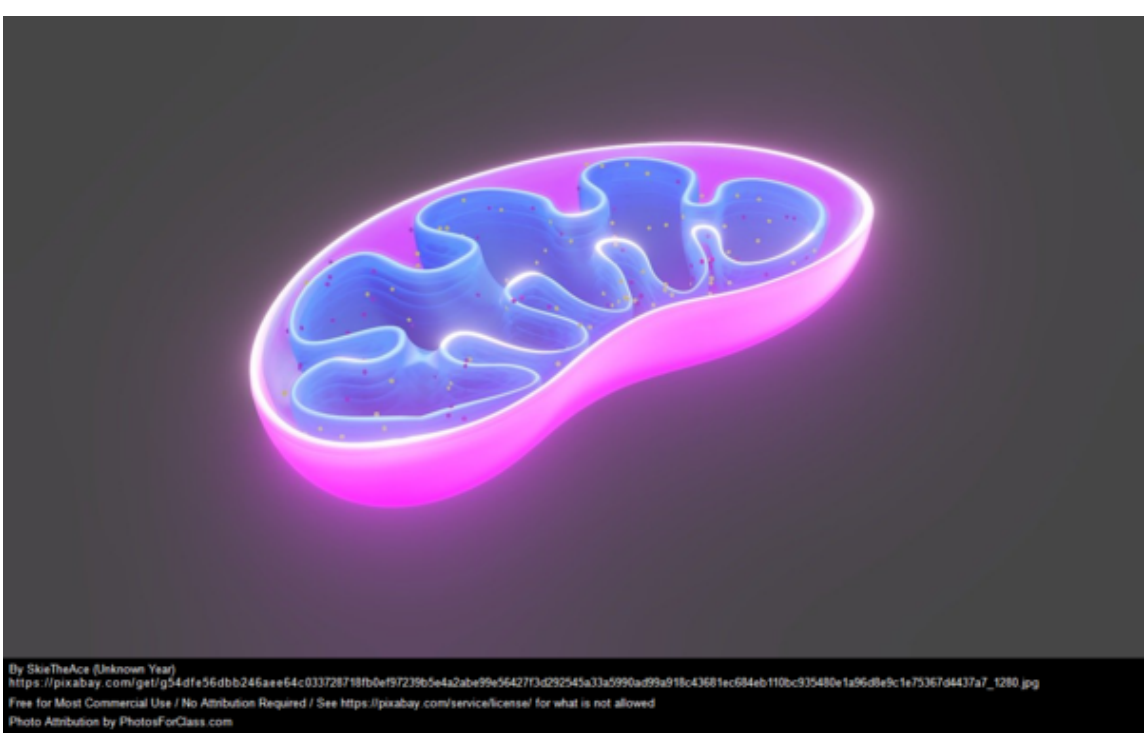
UK

Infants, Children and Families to Benefit from Boost in Support

Thousands of babies, children and families will benefit from a multi-million-pound package which will improve access to support, advice and services from birth through to adulthood. Ensuring every child is properly supported throughout their life is vital for helping them thrive in future. The government is today (Saturday 2 April) announcing wide-ranging support across its flagship family programmes for those who need extra help to fulfil their potential, levelling up opportunities for children across the country.

Learn More

AUSTRALIA



Australian research to support children with Mitochondrial disease

Leading Australian researchers will receive $15 million from the Australian Government to determine the safety, efficacy and feasibility of implementing mitochondrial donation reproductive technology following the passing of Maeve's Law

Learn More

KOREA

“Doctor Heli” takes flight over Jeju Island, a World Natural Heritage Site

The Ministry of Health and Welfare announced that Jeju Special Self-Governing Province was selected for deployment of emergency medical helicopter (‘Doctor Heli’). Doctor Heli is a helicopter dedicated to rapid air transport or first-aid treatment in rural areas with vulnerabilities in emergency medical services such as islands or mountainous areas on the basis of the Emergency Medical Service Act.

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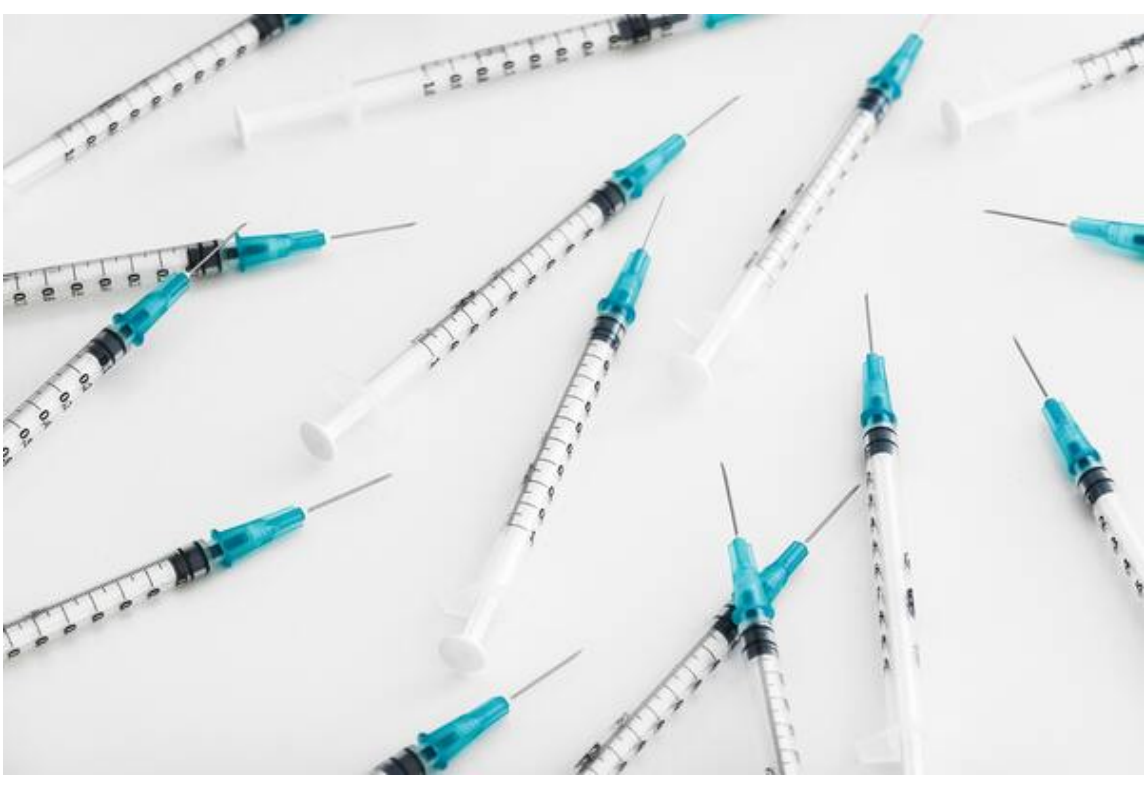
UNITED KINGDOM



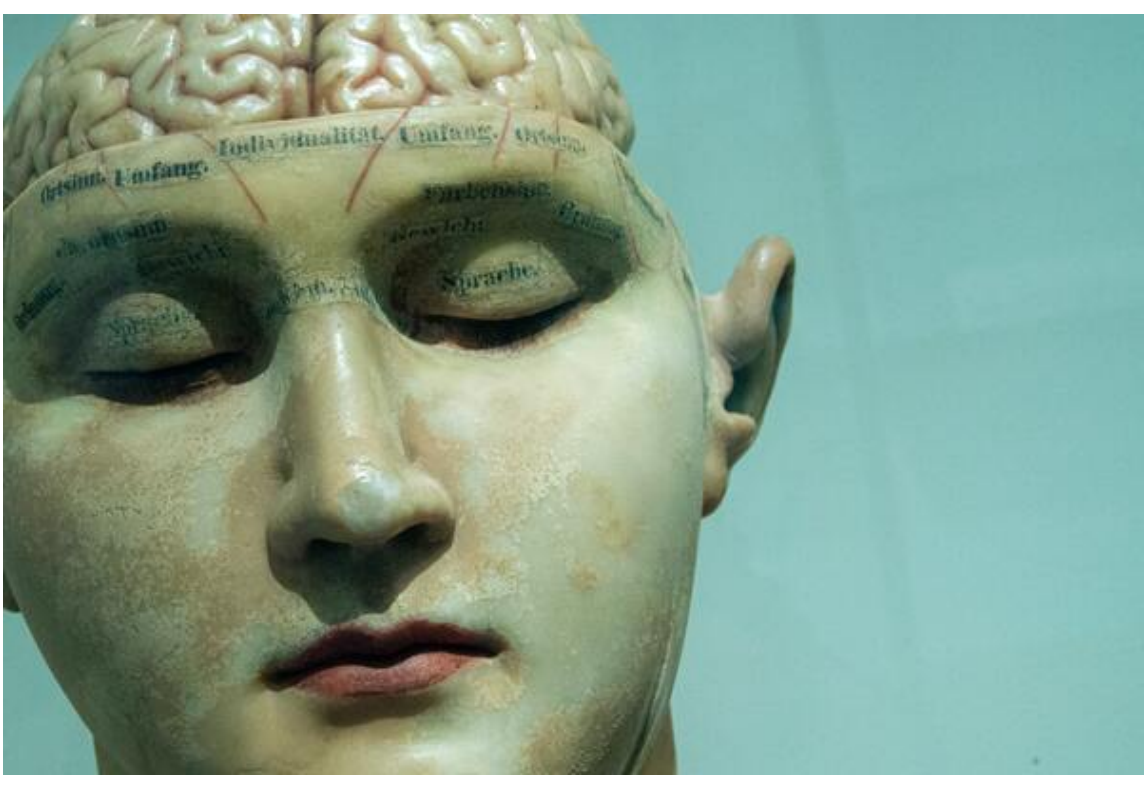
NeedleSmart Helps NHS Carbon Reduction Strategy Reduce Carbon Emissions by 95%

Needlesmart clinical waste boxes to save the nhs more than £120 million in government plastic tax technology to prevent 100,000 needlestick injuries to clinical staff, saving the nhs £127 million each year

British smart MedTech company NeedleSmart is at the forefront of helping the NHS radically reduce CO2 emissions in its clinical waste disposal by a staggering 95% as part of its Carbon Reduction Strategy, saving £10s of millions in clinical waste destruction. NeedleSmart is collaborating with the NHS, facilitated through the NHS Supply Chain innovation route, to drive a campaign forward to minimise single-use plastics and associated packaging. As of 1st April, and as part of the Government’s recycling policies, all plastic packaging must contain 30% recycled material or be subject to a levy of £200 per tonne.

Learn More

UNITED STATES

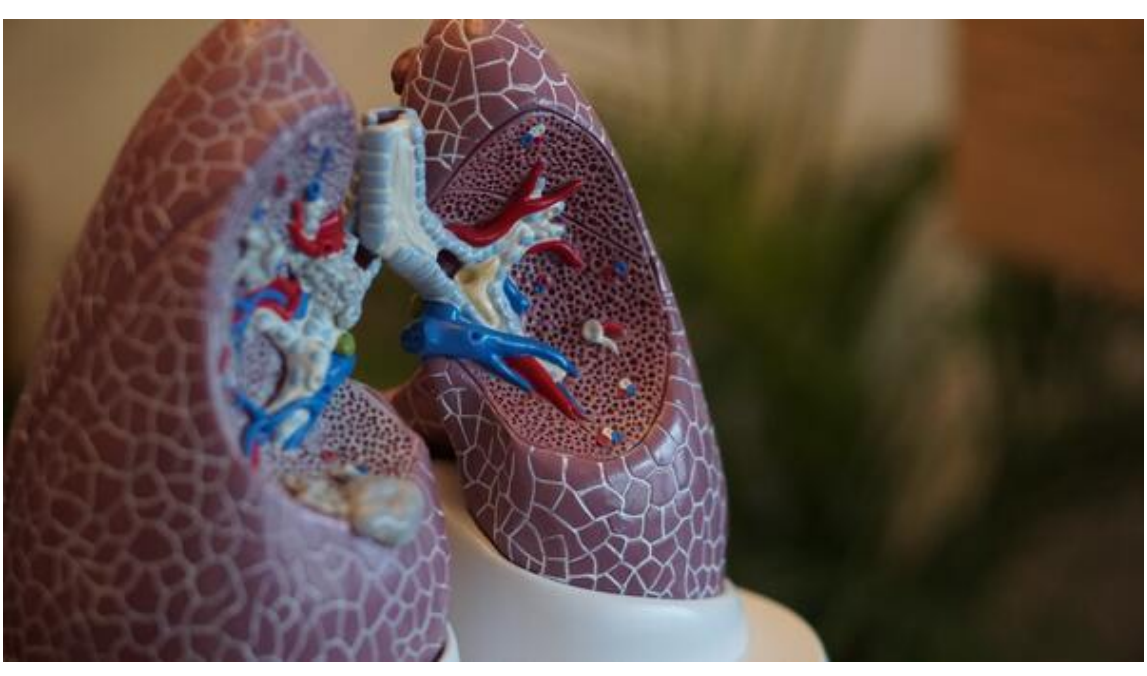


Quanterix’ Simoa® Technology Powers Large, International Comprehensive Reference Range Study Utilizing Serum Neurofilament Light (SNfL) to Assess Disease Activity in Multiple Sclerosis (MS) Patients

Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis with the goal of advancing the science of precision health, today announced its Simoa® technology supported a large international and comprehensive study to establish reference ranges of sNfL to assess disease activity and drug response in MS patients at the individual level, according to a recent study published in The Lancet Neurology. Researchers from the University Hospital Basel and University of Basel, led by Professor Jens Kuhle, leveraged Simoa’s ability to precisely detect the sNfL protein at ultra-low levels, enabling a large-scale international study in which sNfL could be reliably measured across a spectrum of normal healthy individuals.

Learn More

AUSTRALIA



World’s First Lung Scanner to Change Millions of Lives

Australians with lung conditions will be able to access the world’s first and only dedicated lung scanner, which was developed and built in Australia, at the Prince of Wales Hospital, Sydney. Funded through the Morrison Government’s landmark Medical Research Future Fund (MRFF), the XV Scanner uses an automated scanning process to produce detailed lung function information in real time.

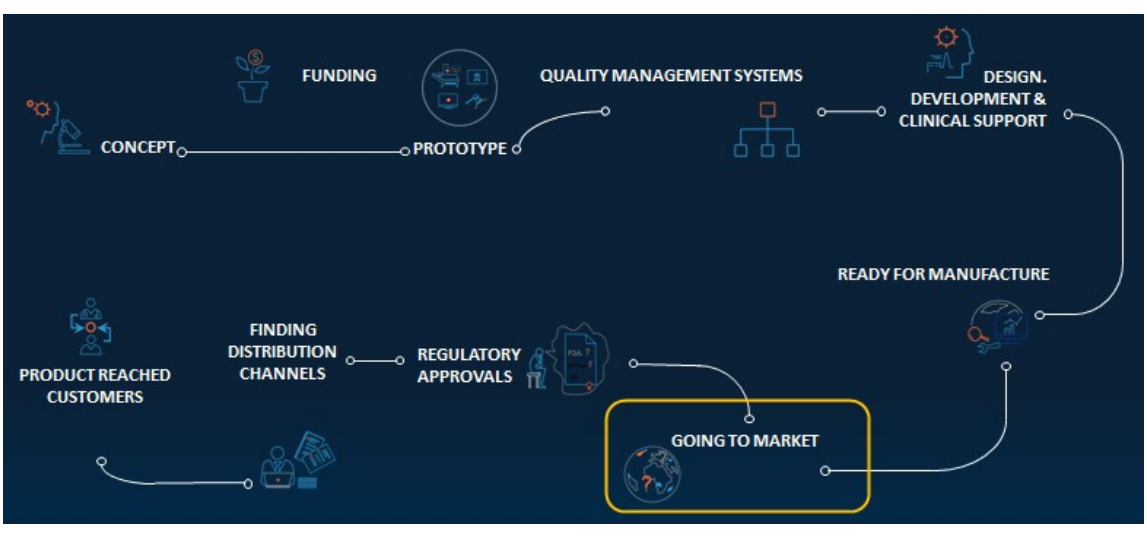
Learn More

KOREA

MolecuLight i:X® Receives Regulatory Clearance and Reimbursement in South Korea

MolecuLight Inc., the leader in point-of-care fluorescence imaging for real-time detection of wounds containing elevated bacterial loads, and KOVE Inc., announce that the MolecuLight i:X® device has successfully received regulatory clearance and is now commercially available to the wound care market in South Korea. In addition, the MolecuLight device has also received reimbursement in Korea from the Ministry of Health and Welfare enabling clinician reimbursement for performing the medically necessary MolecuLight procedure. Reimbursement for the MolecuLight procedure was granted by the Ministry of Health and Welfare of Korea, as per the notification number 259-858. This was announced based on Reimbursement data from the Korea New Medical Technology – Stability and Effectiveness Evaluation.

Learn More



Go to Market Strategy

Thinking out of the box

Recently, another prospective client sent yet another request for distributor contacts.

In most cases, there's not a lot wrong with this approach. Why?

Access to sales channels, warehousing, logistics, regulatory. Share some margin, no upfront investment, and perhaps something can be done.

Oftentimes with innovative medical devices, distributors don't work that well. It is precisely BECAUSE it is innovative, that's why established distributors don't know how to position the device to the existing channels.

1. Thoroughly understand your clinical workflow

This might seem obvious, however, what we often still see is a lack of understanding the details of the clinical workflow. Many factors from various perspectives determine if the device will fly or sink. One of the key areas is to understand stakeholder motivations (what is in it for them?) With that, it may lead to further product development, changing the form factor. Sometimes customers can help you refine the clinical workflow or even advise on your business model.

Ultimately, the person who understands the clinical workflow the most is the product owner, not the distributor, and it is critical for the product owner to share the methods after learning about the local situation from the distributor.

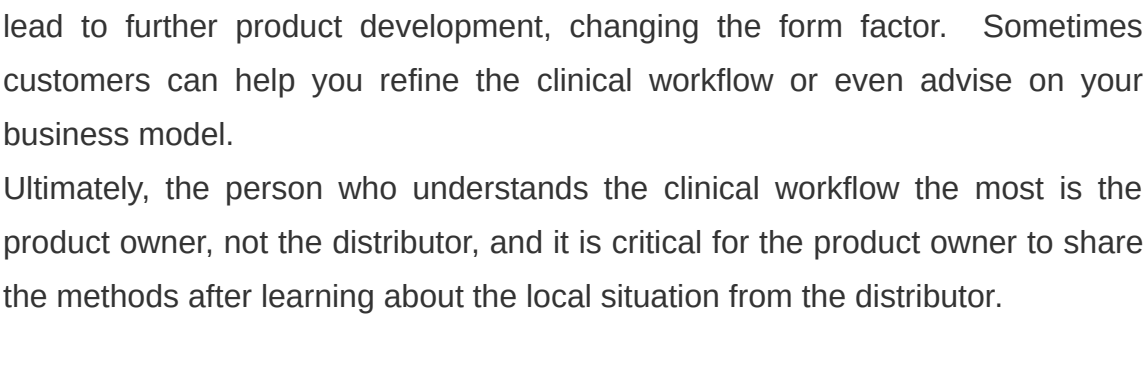
2. Understanding who is willing to pay who is actually paying

The top-level determination is reimbursed/non-reimbursed (including private insurance coverage) market. Public vs private healthcare facilities. Hospitals vs clinics vs home or workplaces. A better understanding will lead to the right way of charging the customer, and your distributor (if you are still keen).

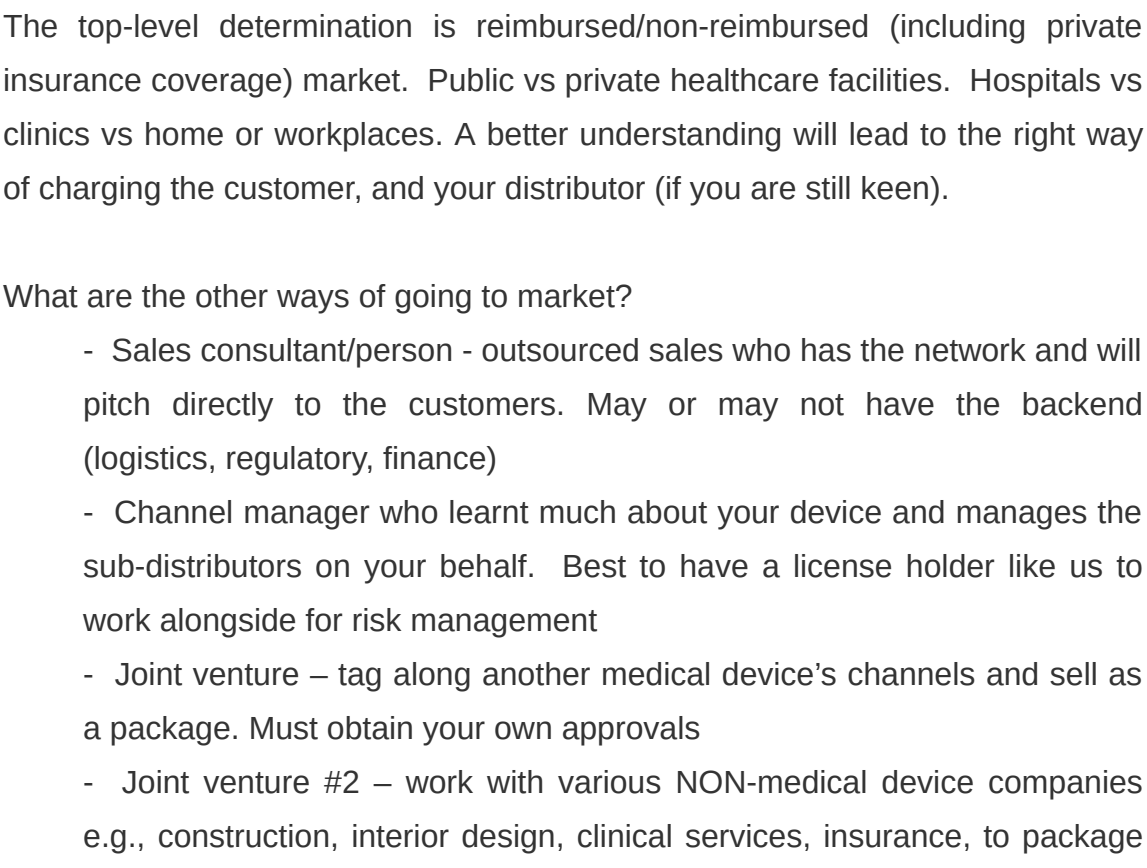
What are the other ways of going to market?

- Sales consultant/person - outsourced sales who has the network and will pitch directly to the customers. May or may not have the backend (logistics, regulatory, finance)
- Channel manager who learnt much about your device and manages the sub-distributors on your behalf. Best to have a license holder like us to work alongside for risk management
- Joint venture – tag along another medical device's channels and sell as a package. Must obtain your own approvals
- Joint venture #2 – work with various NON-medical device companies e.g., construction, interior design, clinical services, insurance, to package as an integrated solution

The selection of the most appropriate go-to-market strategy will depend on the depth of understanding of the 2 factors, then selecting one of the pathways to explore. Good Luck!



Face-2-Face with the Future



Access-2-Healthcare's Group Executive Director Ee Bin Liew was invited to give a seminar at the Medical Innovations Development Center (MIND Center) in Mahidol University (Thailand) on April 4, 2002. Access-2-Healthcare has a clinical collaboration with the Faculty of Medicine Ramathibodi Hospital, which runs the MIND Center together with the Faculty of Engineering and the Faculty of Science, Mahidol University. Talking about "Creating MedTech for the Healthcare Market: From the Clinicians' Dreams to Reality," he had an

opportunity to inspire the next generation of clinicians in Thailand. Check out Ee Bin's LinkedIn post to read about his account of this encounter.

Learn More

May 2022

April starts with April Fool's Day, but you would be a fool not to attend some of the exciting events that are on this month. Here's a list of some events to try.

2022 Design of Medical Devices
Conference
Apr 11-14, 2022
Minneapolis, MN
http://www.dmd.umn.edu/

MD&M West
April 12-14,2022
Anaheim, CA
https://www.mdmwest.com/en/home.html

Medtec Japan Tokyo
April 20-22,2022
Virtual
http://www.medtecjapan.com/en

Medical Device Software: Complying with the MDR & FDA Regulations
April 25-28, 2022
Online course
https://management-forum.co.uk/product/details/2149/medical-device-software-complying-with-the-eu-mdr-eu-ivdr-fda-regulations

2022 Annual Device Research & Regulatory Conference
April 28-29, 2022
Savannah, GA
https://www.socra.org/conferences-and-education/training-conferences-workshops-courses/device-conference/program-information/

DesignCon 2022
April 5-7, 2022
Santa Clara, CA
https://www.designcon.com/en/home.html

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