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Existing Pathways for Innovative Devices

Erin Cutts
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Sep 25, 2023

European Commission

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The U.S. FDA's Breakthrough Devices Program

Breakthrough Devices Program

- Intended to provide patients and health care providers with timely access to devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- Expedites the development, assessment, and review of certain devices that meet the program eligibility criteria

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

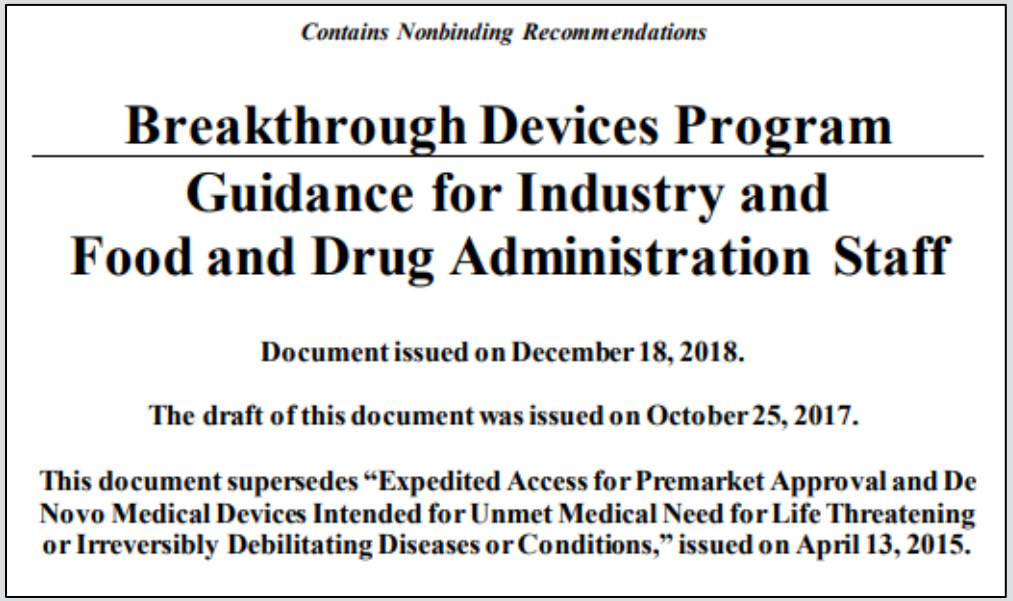
Principles and Benefits

- Interactive and timely communication
- Prioritized review of marketing application
- Enhanced opportunity for pre/post-market balance
- Efficient and flexible clinical study design
- Expedited review of preapproval manufacturing and quality systems compliance
- Preserves the statutory standards for marketing authorization

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Regulatory Context

- Program is statutorily mandated under Section 515B of the FD&C Act
- Guidance describes implementation
- Participation is voluntary for sponsors



Contains Nonbinding Recommendations

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

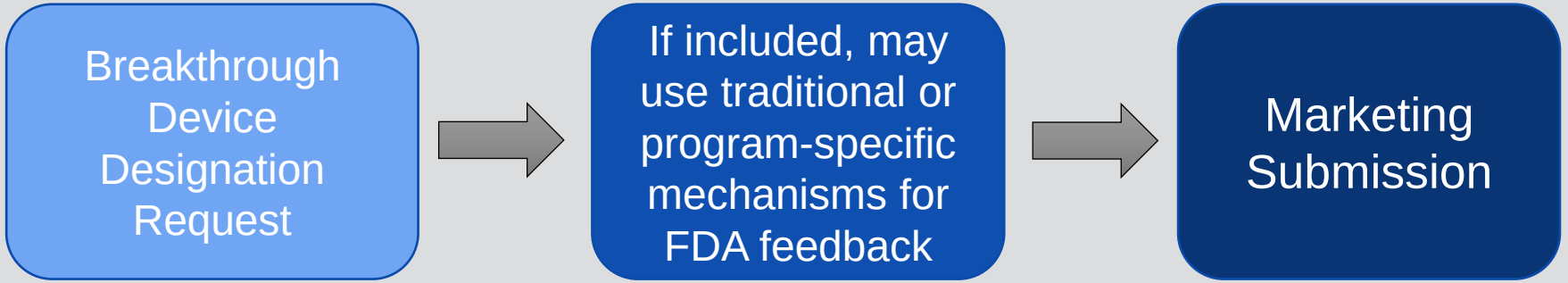
Document issued on December 18, 2018.

The draft of this document was issued on October 25, 2017.

This document supersedes "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," issued on April 13, 2015.

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Program Overview



For devices granted Breakthrough Device designation:

- Designation tracks with the device for subsequent submissions
- Prioritized review and other benefits

Breakthrough Devices Designation Criteria

Eligibility Considerations

- Medical devices and device-led combination products
- Subject to future marketing authorization via Premarket Approval (PMA), De Novo, or 510(k)
- Meets the Breakthrough criteria specified in Section 515B(b) of the FD&C Act
  - Must fully meet Breakthrough Device Criterion 1 AND one of the sub-parts of Breakthrough Device Criterion 2

Breakthrough Device Criterion #1

Criterion 1: provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions

Reference: Section 515B(b)(1) of Food, Drug and Cosmetic Act

Considerations for “more effective”

- Sponsor should demonstrate a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use
  - Technical success: the device could function as intended
  - Clinical Success: a functioning device could more effectively treat or diagnose the identified disease or condition
- Mechanisms for demonstrating a reasonable expectation of technical and clinical success could include literature or preliminary data (bench, animal, or clinical)

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Considerations for disease/condition

- Life-threatening: a disease or condition for which the likelihood of death is high unless the course of the disease is interrupted in a population or subpopulation
  - Examples: acute stroke, myocardial infarction, cancer

- Irreversibly Debilitating: impact on such factors as survival, day-to-day functioning, and the likelihood that the disease or condition, if left untreated, will progress to a more serious disease or condition
  - Examples: amyotrophic lateral sclerosis (ALS)

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

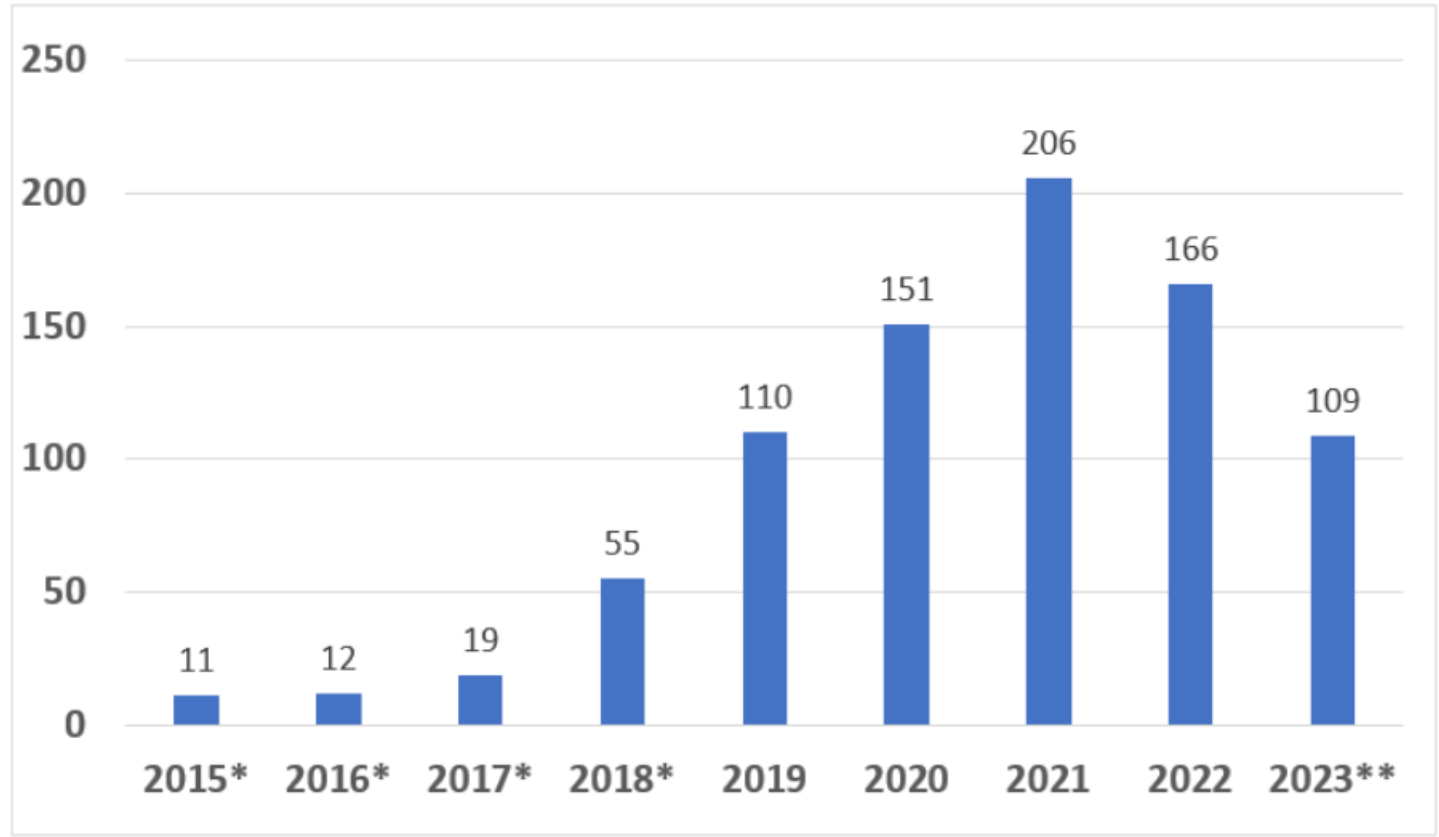
Breakthrough Device Criterion #2

Meets one of the following sub-parts in Criterion 2:

- 2A: that represent breakthrough technologies; or
- 2B: for which no approved or cleared alternatives exist; or
- 2C: that offer significant advantages over existing approved or cleared alternatives; or
- 2D: the availability of which is in the best interest of patients.

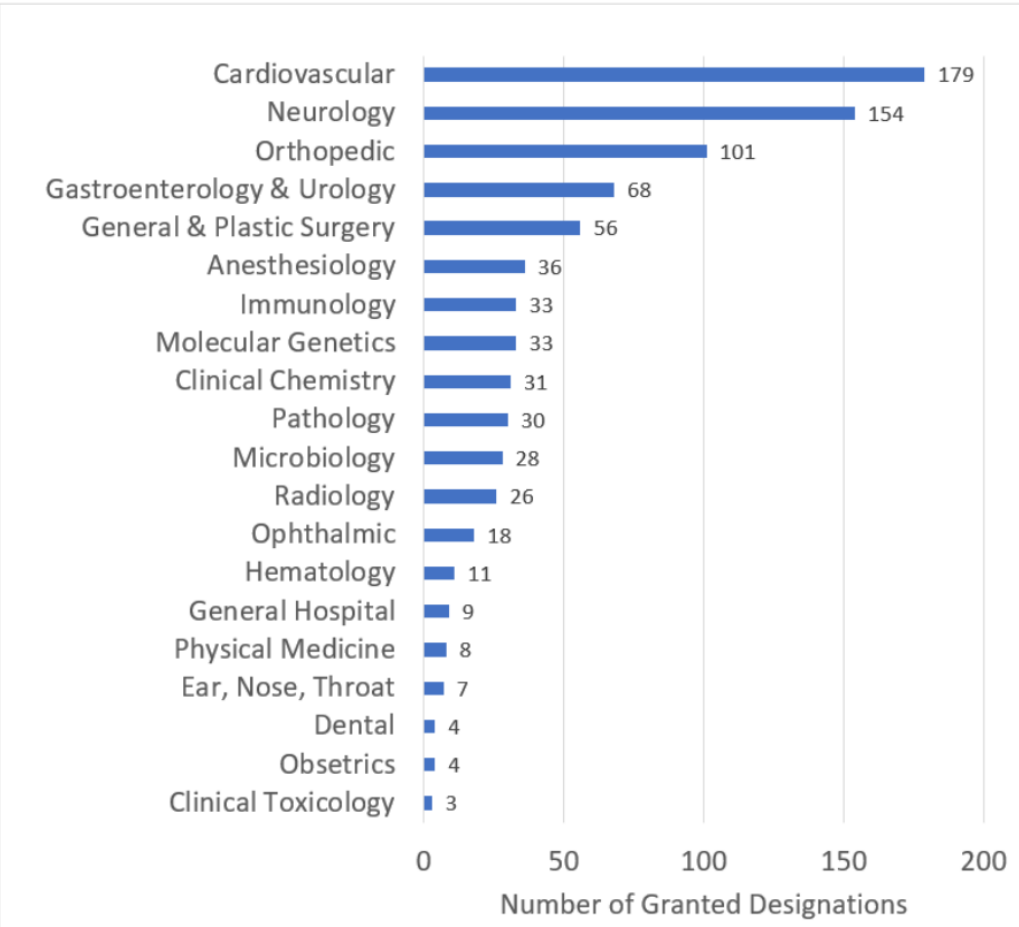
Reference: Section 515B (b)(2) of Food, Drug and Cosmetic Act

Number of Granted Breakthrough Designation Requests by Fiscal Year (**through June 30, 2023)



See [Breakthrough Devices Program | FDA]

Number of Granted Breakthrough Designation Requests by Clinical Panel (**through June 30, 2023)



See [Breakthrough Devices Program | FDA]

Breakthrough Devices Program Features

Breakthrough Devices Program Features

- Data Development Plan
  - Optional map of development process from entry into program until marketing submission & post-market activities as necessary
- Sprint Discussion
  - Highly interactive process to facilitate reaching rapid agreement on a single development issue
- Clinical Protocol Agreement
  - Binding agreement on clinical study design/protocol
- Traditional Pre-submission
- Regular Status Updates
  - In between submissions, no feedback expectations
  - Useful for planning purposes

Marketing Submission

- For devices seeking Breakthrough Device designation, a request must be requested prior to marketing submission
- Program principles and benefits applied to marketing submission
  - Interactive and timely communication
  - Priority review
  - Senior management engagement
  - Pre/post-market balance when appropriate
- Statutory standard for marketing does not change

As of June 30, 2023, 81 Breakthrough Devices have received marketing authorization.

- 77 in CDRH, 4 in CBER
- List of all devices available here: Breakthrough Devices Program | FDA

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
RENALYTIX AI, INC.	KIDNEYINTELX.DKD	DEN200052	06/29/2023
ABBOTT MEDICAL	AVEIR DR LEADLESS SYSTEM	P150035/S003	06/29/2023
AVITA MEDICAL AMERICAS, LLC.	RECELL AUTOLOGOUS CELL HARVESTING DEVICE	BP220799	06/16/2023
PREMIA SPINE, LTD.	TOPS SYSTEM	P220002	06/15/2023
AVITA MEDICAL AMERICAS, LLC	RECELL AUTOLOGOUS CELL HARVESTING DEVICE	BP170122/S502	06/07/2023
ENDOLOGIX, LLC.	DETOUR SYSTEM	P220021	06/07/2023
CERIBELL, INC.	CERIBELL STATUS EPILEPTICUS MONITOR	K223504	05/23/2023
BRAHMS GMBH, PART OF THERMO FISHER SCIENTIFIC	B·R·A·H·M·S SFLT-1/ PLGF KRYPTOR TEST SYSTEM	DEN220027	05/18/2023
SWING THERAPEUTICS, INC.	STANZA	DEN220083	05/09/2023
W. L. GORE & ASSOCIATES, INC.	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	P210032/S007	05/02/2023
NOCTRIX HEALTH, INC.	NTX100 TONIC MOTOR ACTIVATION (NTX100 TOMAC) SYSTEM	DEN220059	04/17/2023
MOXIMED, INC.	MISHA KNEE SYSTEM	DEN220033	04/10/2023
MASIMO CORPORATION	MASIMO SAFETYNET OPIOID SYSTEM	DEN200011	03/31/2023
BIORETEC, LTD.	REMEOS SCREW LAG SOLID	DEN220030	03/29/2023
REWALK ROBOTICS, LTD.	REWALK P6.0	K221696	03/02/2023
ABBOTT LABORATORIES	TBI	K223602	03/02/2023
REFLEXION MEDICAL, INC.	REFLEXION MEDICAL RADIOTHERAPY SYSTEM (RMRS)	DEN220014	02/01/2023

Summary

- The Breakthrough Devices Program is intended to provide patients and health care providers with timely access to breakthrough devices.
- Devices are designated by meeting the statutory criteria.
- Designated Breakthrough Devices can benefit from program features intended to expedite the development, assessment, and review of these devices.

THANK YOU / QUESTIONS

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EXISTING PATHWAYS FOR INNOVATIVE MEDICAL DEVICES

Sally Prawdzik
A/Director, Bureau of Policy and International Programs
Medical Devices Directorate, Health Canada

September 25, 2023

European Commission

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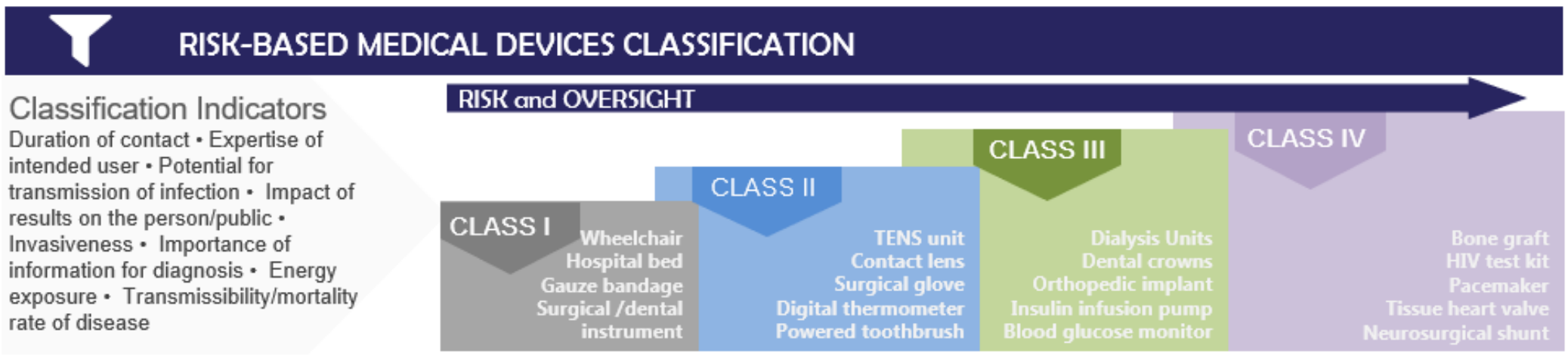
OVERVIEW

Regulation of medical devices in Canada

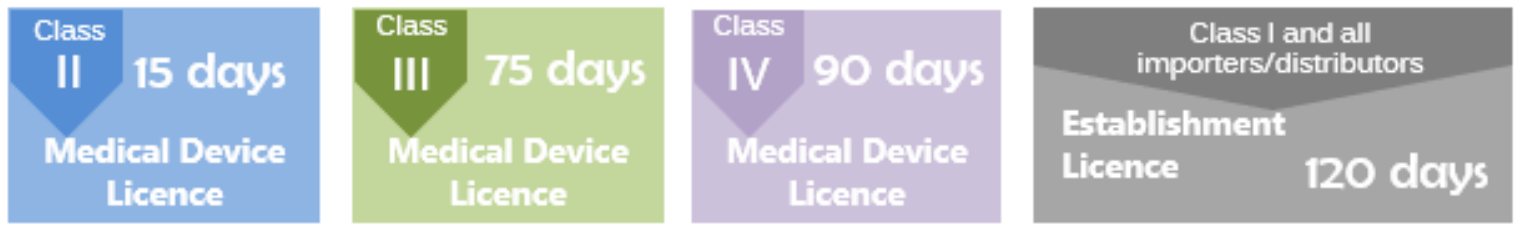
Tools to support innovative medical devices

Enabling Advanced Therapeutic Products

REGULATION OF MEDICAL DEVICES IN CANADA



SERVICE STANDARDS & LICENCE TYPES



TOOLS TO SUPPORT INNOVATIVE MEDICAL DEVICES

INNOVATION MEETINGS

Opportunity to engage with manufacturers of innovative devices well in advance of the application process (investigational testing or licensing)

PRE-CLINICAL MEETINGS

Opportunity to discuss concerns and issues regarding the clinical protocol or device development strategy

PRE-SUBMISSION MEETINGS

Opportunity to present relevant data and discuss the information and evidence manufacturers intend to use to support a medical device licence application

PRIORITY REVIEW

Can be granted for certain Class III and IV medical devices intended for diagnosis or treatment of a serious disease or condition (with supporting clinical evidence)

AGILE LICENSING

Proposal to expand the scope of Terms & Conditions to support the life cycle approach for regulating medical devices

DEVICE LICENCING INQUIRIES

devicelicensing-homologationinstruments@hc-sc.gc.ca

ENABLING ADVANCED THERAPEUTIC PRODUCTS

Advanced Therapeutic Products (ATPs) are drugs and/or devices that are so unique, complex and/or distinct that existing regulatory frameworks and enforcement tools are not equipped to handle them.

- Some innovative products, developed at a rapid pace in the health and biosciences sector, are anticipated to challenge Health Canada's current regulatory frameworks
- Changes to the Food and Drugs Act enabled Health Canada to create a new legislative pathway to authorize Advanced Therapeutic Products (ATPs)
- If a drug or device cannot fit within existing regulatory frameworks, the ATP Framework could be leveraged
- Tailored requirements, as part of an ATP Pathway, would be developed to address a product's specific characteristics, while maintaining Health Canada's high standards for patient safety

THANK YOU / QUESTIONS

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Existing pathways for innovative medical devices

Wong Woei Jiuang, Health Sciences Authority

25 September 2023

European Commission

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Pre-Market Consultation (PMC) Scheme

1 Medical Device Development Consultation

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

2 Medical Device Pre-submission Consultation

Channel for stakeholders to **seek feedback on their device dossier, prior to pre-market submission** in terms of completeness and appropriateness of supporting documents.

Pre-Market Development Consultation

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

1 Medical Device Development Consultation

SCOPE: Clarification on regulatory requirements applicable to the device in development, which may include

Regulatory strategy

Regulatory requirements

- Device claims
- Safety / Performance studies
- Sterility
- Biocompatibility
- Risk management
- Clinical trials

Medical Device Pre-Submission Consultation

SCOPE: Seek feedback on the device dossier, in accordance to prescribed Common Submission Dossier Template (CSDT) guidance template, which may include

Risk Classification

Registration Route

Grouping

Technical & administrative documents

2 Medical Device Pre-submission Consultation

Channel for stakeholders to **seek feedback on their device dossier, prior to pre-market submission** in terms of completeness and appropriateness of supporting documents.

Process & Timeline

5 Months before	≥ 30 Days before	●●●	Appointment Date
1. Appointment booking Slots are available for booking on the online Appointment Booking System **5 months before** the appointment date. *E.g. on 1 August 2017, applicants will be able to book appointments till 31 December 2017.*	**2. Document Submission** **ALL** required documents **30 days** before appointment date. **Failure to submit** required documents by the due date may result in **rescheduling** or **cancellation** of the appointment.	**Request for Information** Upon submission, HSA will review the documents and may **request for further information or clarification** via email before the appointment, where necessary. **Failure to respond** or address deficiencies **by the stipulated period** may result in **rescheduling** or **cancellation** of the appointment.	

No extension of due date is permitted.
Only **ONE** rescheduling is allowed per booking reference.
Fees paid are non-refundable.

Priority Review Scheme

Qualification criteria

Medical devices* to be registered via FULL Evaluation Route

1

Falls under 1 of the 5 healthcare focus area

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases

+

2

Designed & validated to meet unmet clinical needs

Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis

OR

Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

Supporting Innovation

The developer of a gastric cancer test based on miRNA approached HSA as early as 2015 during the early phase of development of the test. HSA provided scientific and regulatory advice throughout the development of this test from 2015 to 2018

- Scientific advice on the design of the test kit
- Designing the analytical validation studies for the test
- Clinical study design and protocols
- Regulatory advice on the appropriate intended purpose and developing the instructions for use for the test including precautions, contraindications etc.

In Jan 2019, the GASTROClear test was submitted for evaluation and registration by MirXes under Priority Review.

- Registered in May 2019

Supporting Digital Health Product Innovation

1. Immediate Registration Pathway for Standalone Software and Mobile Applications

This pathway was implemented in 2018 by leveraging the regulatory review and approval from our reference regulatory agencies in Australia, Canada, the European Union, Japan and the United States. This pathway allows immediate market access upon successful submission of a product registration application, while we perform a backend review to verify the qualification criteria are met and that these devices are safe and effective for use on our patients. More information on the various product registration pathways can be accessed in our Guidance on medical device product registration. [Click here]

2. Regulatory Guidelines for Telehealth Product

To help manufacturers, developers or importers of a digital health device to (i) determine if their device, software or app are regulated medical devices under HSA and (ii) understand the relevant regulatory requirements. [Click here]

3. Device Development Consultation Scheme

The purpose of the consultation is to provide medical device developers and/ or researchers with a platform to seek regulatory advice during various stages of the medical device development (e.g. device validation, clinical trial), in preparation for regulatory submission. [Click here]

4. Regulatory Guidelines for Software Medical Devices

This serves as a one stop reference on the regulatory requirements for management of software in medical devices throughout its entire life cycle. [Click here]

5. Artificial Intelligence (AI) in Healthcare Guidelines

Co-developed by MOH, HAS and Synapxe (previously known as IHiS) to provide a set of recommendations to encourage the safe development and implementation of AI-Medical Devices. [Click here]

Pandemic Special Access Route (PSAR)

Key features

- Designation of an emergency therapeutic product (ETP) or emergency medical device (EMD) by Minister contingent on the following criteria:
  - The need for the ETP or EMD to be used for the treatment, prevention or diagnosis of any potentially serious or life-threatening medical condition resulting from a civil defence emergency or infectious disease outbreak; and
  - HSA's (scientific) determination that the benefits of using the ETP or EMD outweigh the risks, both at the outset and on an ongoing basis. There is continued exercise of regulatory oversight through ongoing iterative review of safety and efficacy data which are made available over time

"civil defence emergency" means any fire, explosion, earthquake, oil spill, eruption, flood, storm, hazardous materials incident or other happening (whether or not attributable to an attack by an enemy or to any warlike act) that causes or may cause destruction of or damage to property or loss of life or injury or distress to persons or that in any way endangers the safety of the public in Singapore or in any part thereof;

THANK YOU / QUESTIONS

Contact information

Email: wong_woei_jiuang@hsa.gov.sg

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Existing Pathways for Innovative Medical Devices

João Martins - Abbott

25 September 2023

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Innovating for a brighter tomorrow

João Martins

Abbott

25 September 2023

OVERVIEW

General Objectives and Device Scope 4

Pathways 5

Messages 6

General Objectives and Device Scope

- Provide patients and health care providers with timely access to medical devices.
- Provide innovators and manufacturers with a support service that brings new products to patients sooner.
- Device eligibility for innovative pathways depends on a serious of criteria:
  - Provides treatment or diagnostic of Life-threatening or seriously debilitating disease/condition
  - Unmet need/significant improvement to existing alternatives
  - Breakthrough Technology

Pathways for Innovative Medical Devices

Country/Jurisdiction	Program/Pathway name	Responsible entity	Details
Australia	Priority Review designation	TGA	Priority application guidelines and application forms are available.
Canada	Pathway for advanced therapeutic products	Health Canada	Consultation period closed on March, 2023. Innovation information meetings take place.
China	Innovation Green Pathway	NMPA	Applicant's ownership of legal patent rights of the product's core technology in China.
European Union (EU)	Expert Panels	Experts appointed by the European Commission	Several opinions have been provided and are available here.
Japan	Fast Track Review Process	PMDA	Fast-track review and conditional fast-track review pathways.
United Kingdom (UK)	Innovative Devices Access Pathway (IDAP)	MHRA, NICE and other partners	Launched September 2023.
United States of America (USA)	Breakthrough Devices Program	U.S. FDA	As of June 30, 2023, 81 Breakthrough Devices received marketing authorization.

Messages

- Stakeholders' collaboration is key to ensure safe and effective medical devices reach patients in need in a timely manner.

- “The future of medical products regulation is in convergence/harmonization, collaborating, and networking based on **reliance** and trust”

THANK YOU / QUESTIONS

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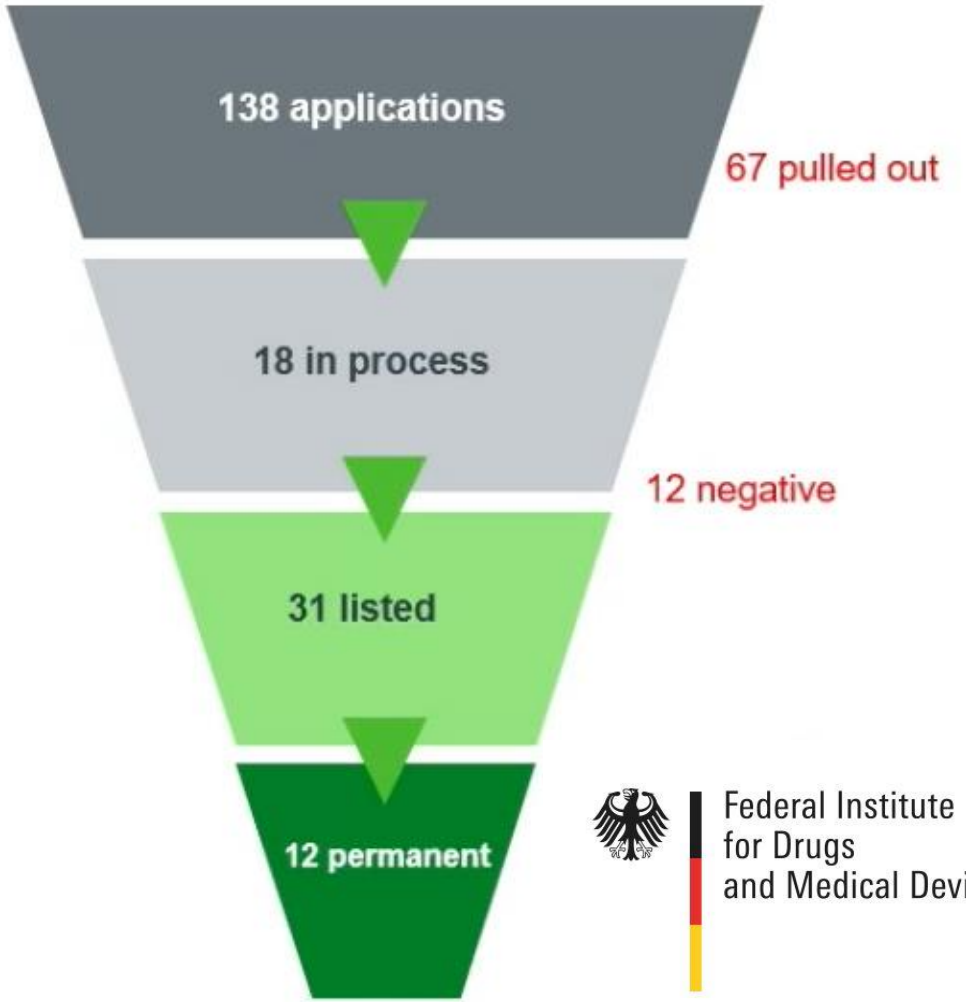
Korea Regulatory Achievements and Future of Digital Therapeutics : Industry Perspective

Yujin Lee, MD, WELT corp

The German market is opening for digital therapies

31 apps are now listed as DiGA (as of 22nd June)



Source: BfArM

Federal Institute for Drugs and Medical Devices

Depression: deprexis, Selfapy	Diabetes: ESYSTA, vitadio, HelloBetter Diabetes	Anxiety, phobias, panic disorders: Novego, Invirto, velibra, deprexis, VORVIDA	Nichtraucher Helden.de
Tinnitus: kalmeda, Meine TinnitusApp	Migraine: M-Sense	Onc. diagnosis: Cankado, Mika	Stroke rehabilitation: Rehappy
Multiple Sclerosis: elevida	Insomnia: Somnio	Adipositas: zanadio	Back, knee, hip pain and arthrosis: MAWENDO, ViRA, Companion Patella
Speech disorders: neolexon	Gut health: CaraCare	Impotence: Kranus Edera	

France to enable rapid market access for digital therapeutics

Emmanuel Macron announced plans to replicate Germany's DiGA Fast Track process.

By **Tammy Lovell** | October 20, 2021 | 06:45 AM

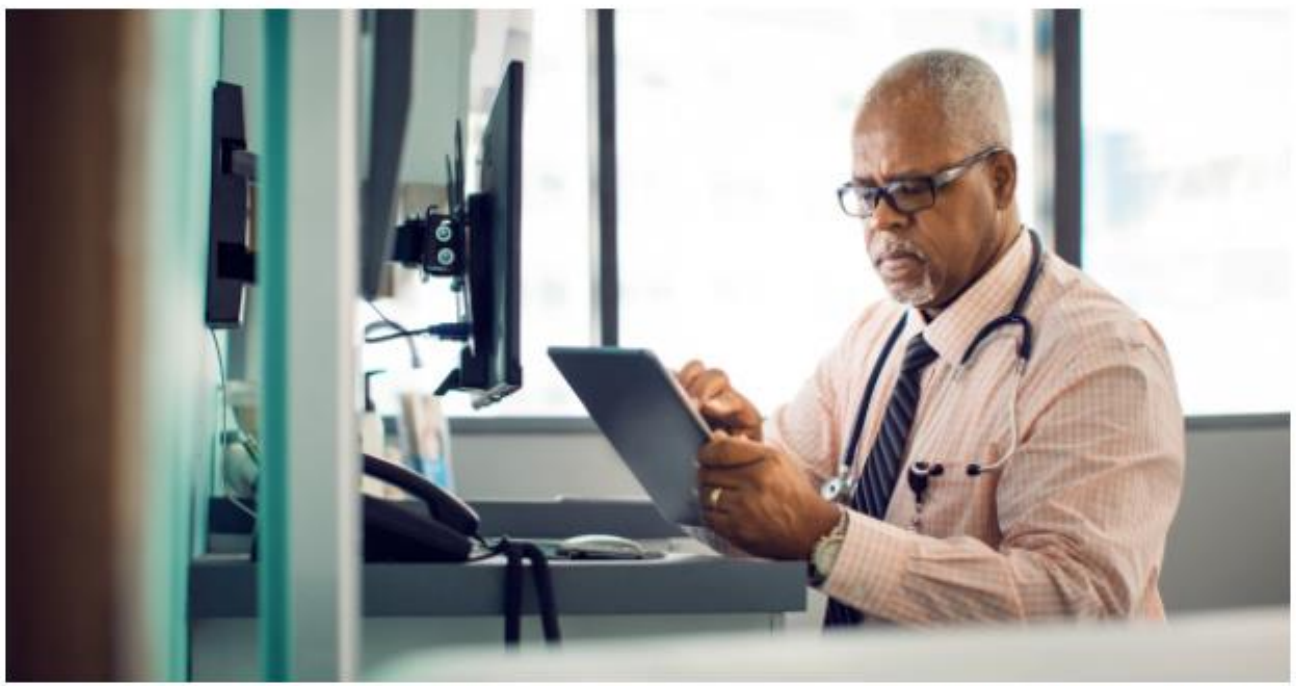
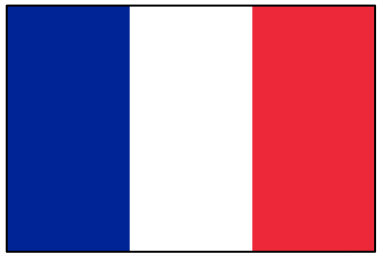


Photo: John Fedele/Getty



Country	Reimbursement
Germany	●
Belgium	●
France	◔
UK	◑
Netherlands	◑
Sweden	◑
Norway	◑
Denmark	◑
Spain	◑
Austria	◑
Switzerland	◑
Italy	◑
Ireland	◑
Portugal	◑

Korea Regulatory achievements for DTx

FDA

21st Century Cures Act (2016)
Enactment of legislation for technological innovation and advancement aimed at improving patient access and efficiency of medical care

Digital Health Innovation Action Plan (2017)
FDA policies and procedures for active adoption of digital health

Digital Health Pre-Cert Program (pilot: 2017-2020)
Development of a concise and efficient regulatory model for software as medical devices (SaMD)

MFDS of Korean government

2020. 02. 21
Revision of safety management guidelines for mobile medical apps
디지털 치료제를 의료기기로 분류하여 포함

2020. 03. 06
Expert Council for Digital Therapeutics Guideline

보건복지부 Ministry of Health and Welfare / 식품의약품안전처

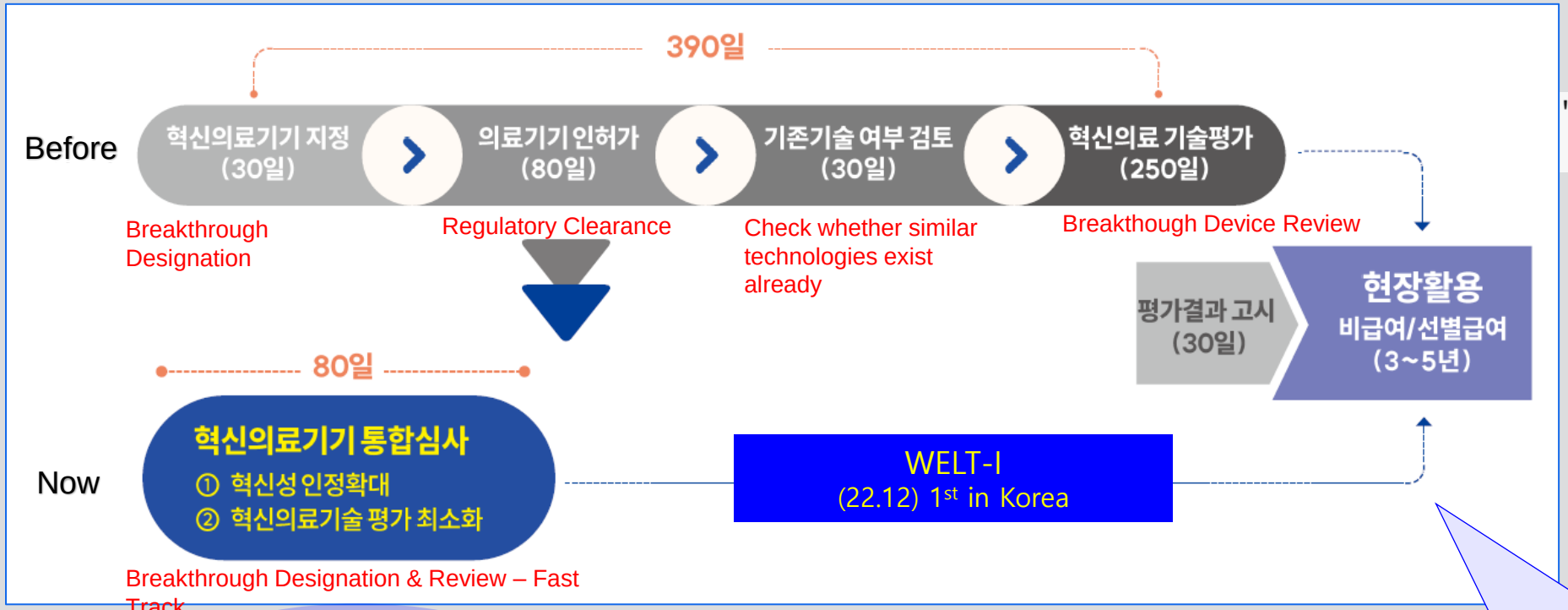
WELT corp
Participate as committee

2020.08.27
Disclosure of digital therapeutics approval guidelines
제조·수입 허가·인증, 기술문서 등 심사, 임상시험계승인 등

식품의약품안전처 식품의약품안전평가원 의료기기심사부 / WELT

WELT product used as Guideline example

'Fast Track Case #1'



"국내 AI 의료기기, 130개 허가 품목 중 보험등재 두 건뿐"

Only 2 out of 130 approved AI medical devices are covered under insurance

Faster Market Entry & Reimbursement

건강보험심사평가원 HEALTH INSURANCE REVIEW & ASSESSMENT SERVICE

식품의약품안전처 NECA 한국보건의료연구원

WELT-I ver 1.0


오늘
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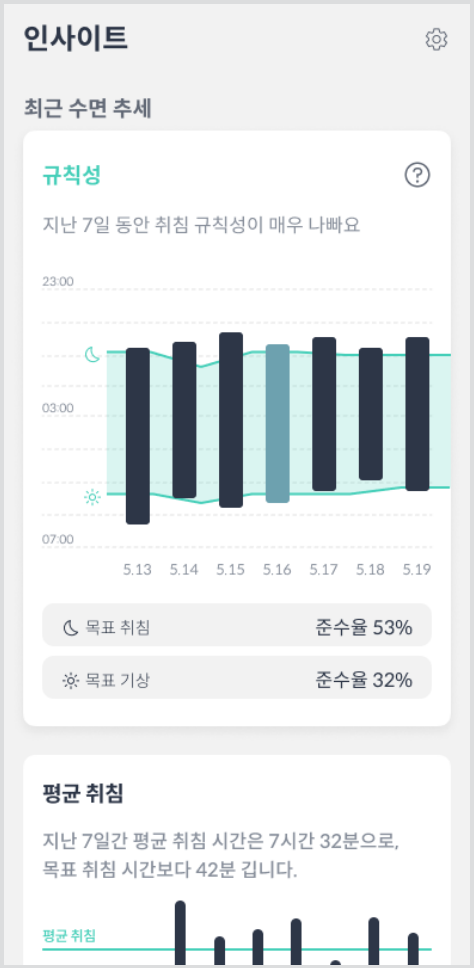
취침 목표
6시간 30분
취침
기상
01 : 00
07 : 30
취침 목표가 업데이트 되었어요!
데일리 미션 1
수면기록
수면 기록
리뷰하기
오늘
인사이트
프로그램


인사이트
최근 수면 추세
규칙성
지난 7일 동안 취침 규칙성이 매우 나빠요
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준수율 32%
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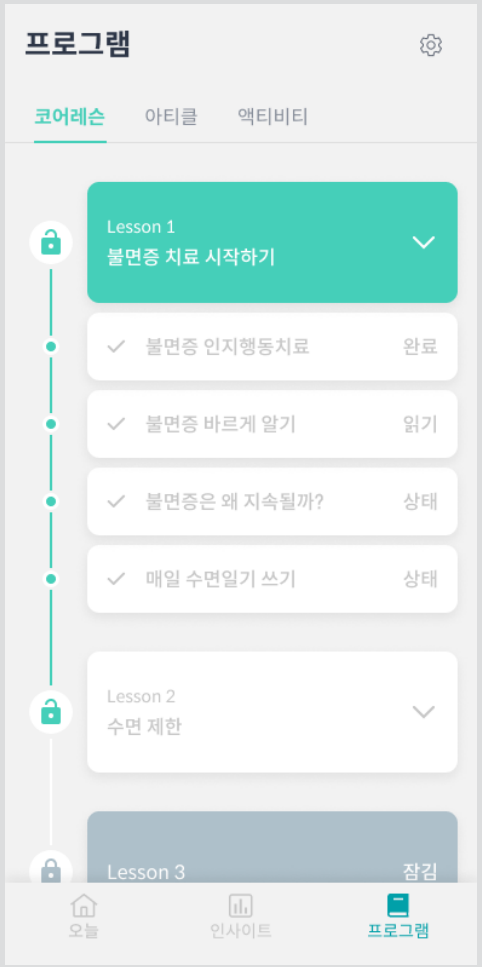
목표 취침 시간보다 42분 깁니다.
평균 취침


프로그램
코어레슨
아티클
액티비티
Lesson 1
불면증 치료 시작하기
불면증 인지행동치료
완료
불면증 바르게 알기
읽기
불면증은 왜 지속될까?
상태
매일 수면일기 쓰기
상태
Lesson 2
수면 제한
Lesson 3
잠김
오늘
인사이트
프로그램


프로그램
코어레슨
아티클
액티비티
필로우봇
머릿속을 복잡하게 하는 생각과 고민을
필로우봇과 함께 해결해 보세요.
이완호흡
긴장을 풀어주는 호흡법으로
몸과 마음을 편안하게 만들어요
바디스캔
신체 구석구석을 살피는 바디스캔을
통해 온몸의 근육을 이완해 보세요
노을빛 해변
오늘
인사이트
프로그램

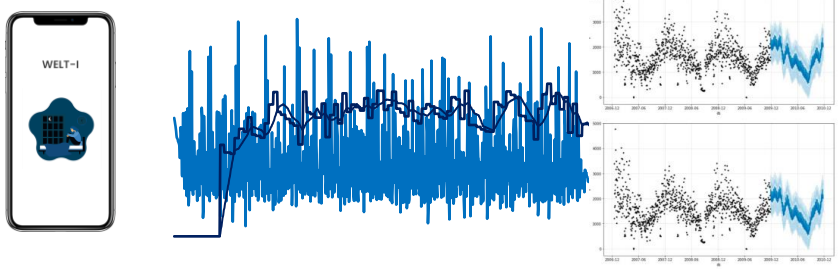

프로그램
코어레슨
아티클
액티비티
인지행동치료와 불면증
인지행동치료가
뭘까?
치료 중
경험할 수 있는
부작용
잠에 대한 상식과 정보
낮잠으로 부족한
잠을 보충하면
되지 않을까?
점심만 먹으면
졸음이
쏟아지는걸
읽음
수면제한치료가 걱정된다면
1. 이미 잠이
너무 부족한 걸
2. 너무 졸려서
버티기 힘들지
않을까?
오늘
인사이트
프로그램

WELT-I ver 2.0

AI-powered symptom monitoring

Phase 1 (~2022)

Biomarkers from the Smartphone
(IND Approved by the KFDA)



Digital phenotyping and Prediction of Sleep Patterns

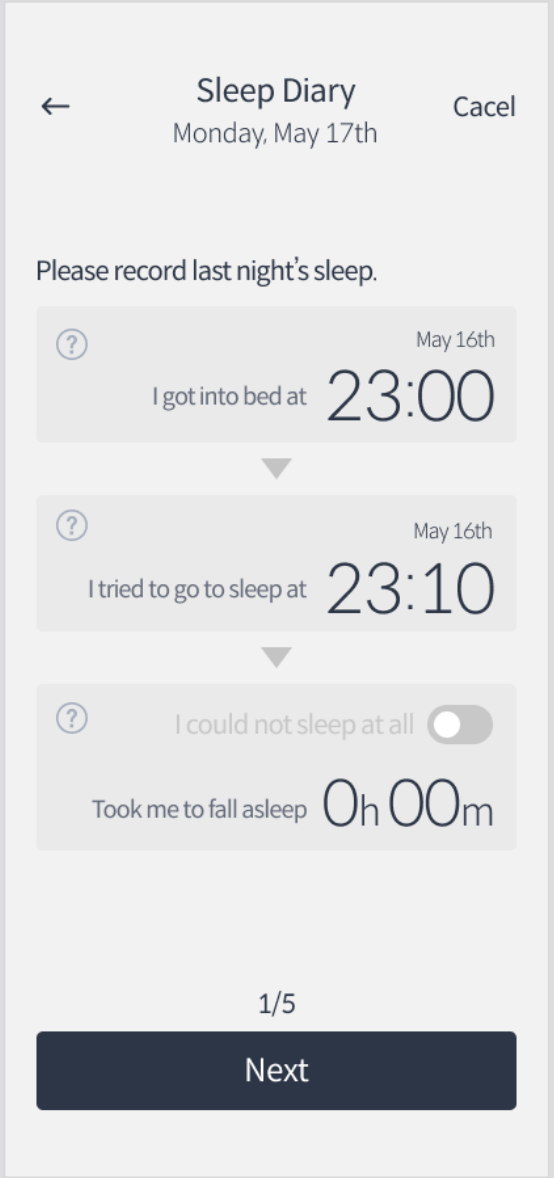
Phase 2 (~2024)

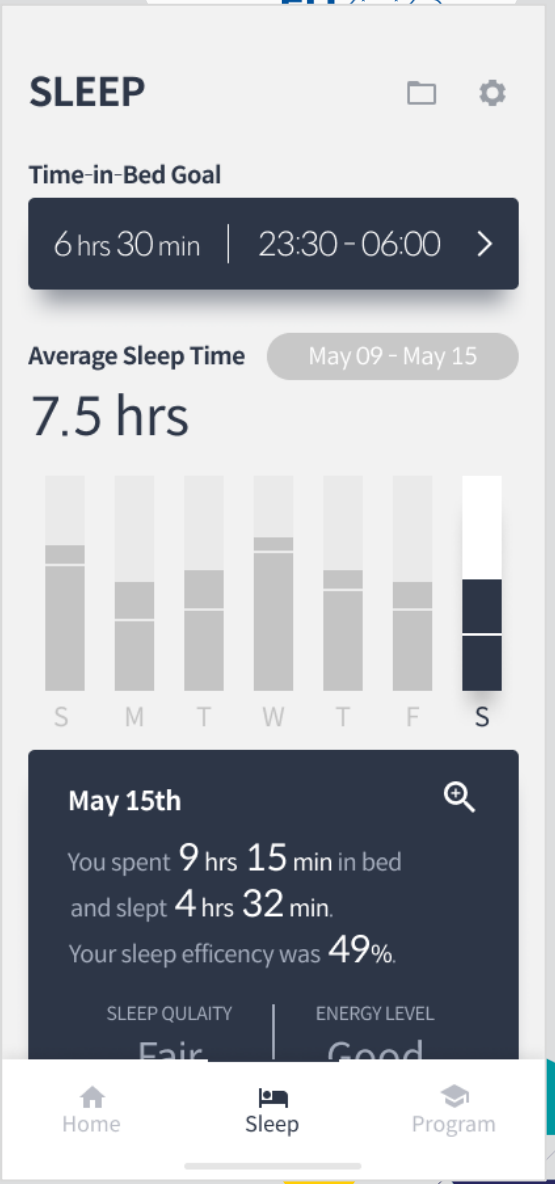
Biomarkers from 3rd Party wearables
(Partnered with SAMSUNG)

Privileged SDK authorized for WELT

- Sleep Onset Latency
- MOTN
- Wake-Up Time

Biosignal Algorithm





WELT-I ver 3.0

Safety

Efficacy

Decentralized Clinical Trial (DCT= RWE = eQMS)

Digital Biomarker as Secondary endpoint

Galaxy S

<Smart Phone>

Galaxy watch

<Wearables>

1. **Experimental** vs **Control**
2. **Pre** vs **Post**
3. vs **Gold standard**

Korea = Best place for evolution

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보다나은 정부

청렴한 세상

의료기기의 실사용증거(RWE) 적용에 대한 가(민원인

2019.

식품의약품안
식품의약

의료기기심사부

Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Surveillance and Biometrics (OSB) at 301-796-5997 or CDRHClinicalEvidence@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

의료기기 소프트웨어 경미한 변경사항 관련 주요 질의응답 사례

2023.

식품의약
의 료 기

Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

This document supersedes *Deciding When to Submit a 510(k) for a Change to an Existing Device*, dated January 10, 1997.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Staff at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Future of Digital Therapeutics

Precision and predictive medicine

Safety

Efficacy

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Existing Pathways for Innovative Medical Devices

Nataliya Deych – Edwards Lifesciences

25 September 2023

European Commission

Funded by the European Union

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What Does it Take to Innovate?
High Risk Cardiovascular Implants

Nataliya Deych

Edwards Lifesciences

25 September 2023

OVERVIEW

Cardiovascular Implants 4

Stages of innovation development
case of SAPIEN 3 Ultra heart valve 5

Why interactive approach is a key? 6

Summary message 7

Cardiovascular Implants

Cardiovascular Diseases (CVDs) are the leading cause of death in many GEOs and an important factor in the number of chronic conditions and disabilities. Only in EU CVDs costed 282BN€ in 2021

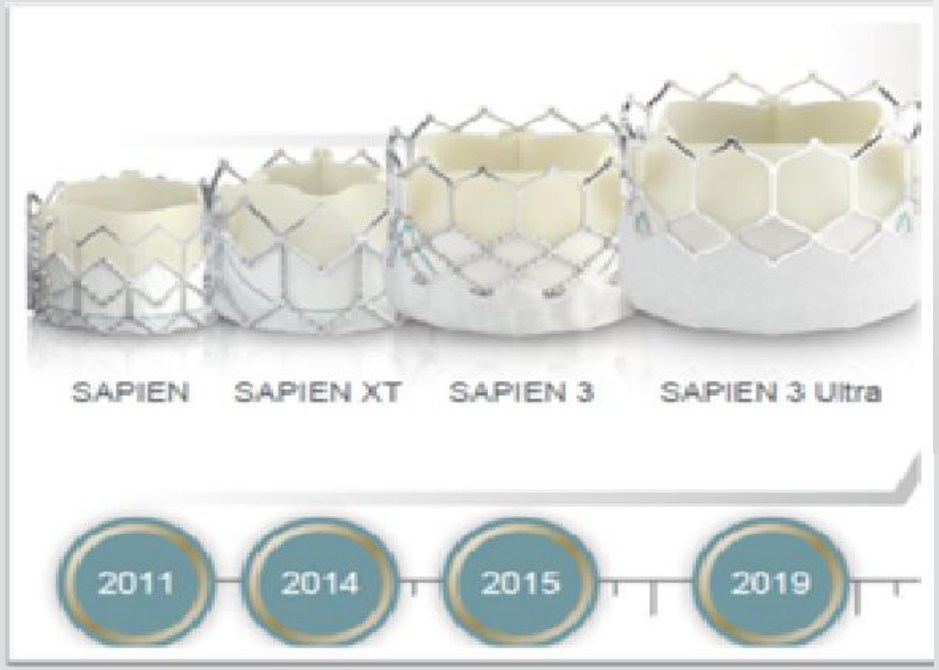
Complex high risk cardiovascular implants are a small part of medical device portfolio with significant contribution to advancing health.

- FDA: ~ 10% of medical devices are Class III devices
- ESC: “More than 50% of high-risk implantable medical devices in Europe are used in cardiology and orthopaedics – such as heart valves and hip replacements”
- Cardiovascular treatments become highly specialized (sub- specialties)

Innovation starts preceding regulations – Lets collaborate on innovation pathways

Stages of innovation development – SAPIEN 3 Ultra

- 100+ cross-functional team members
- **~4 yrs. developing and gathering evidence**
- >100's of tests
- >1000's components utilized

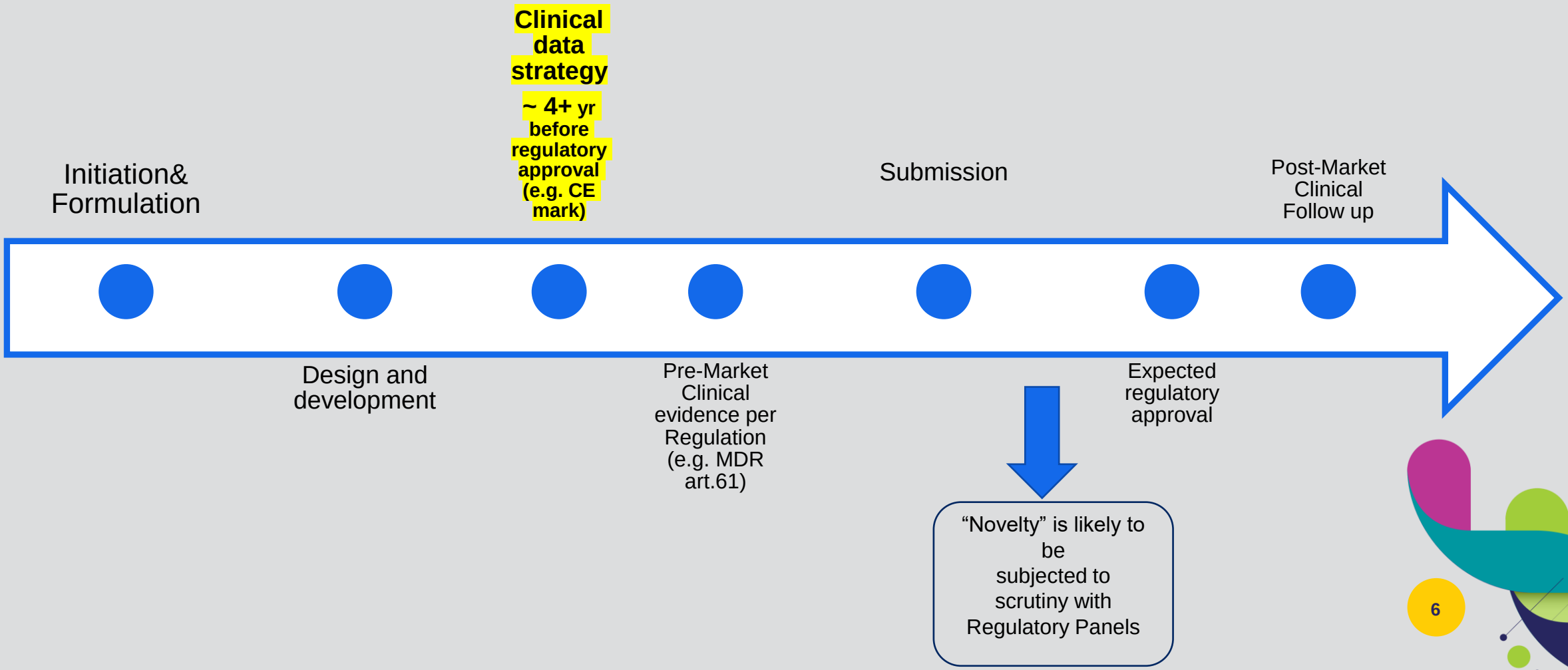


Build on proven design of SAPIEN 3

- Outerskirt increased by 40%
- Same biocompatible outerskirt material
- ~50% additional skirt to anatomy contact area

Committed and accountable for patient lives

Why Interactive Approach is Important?



Incentives that help attracting innovation

- Secure predictable regulatory environment to attracts investment
- Innovator and Regulators interaction should start from early clinical development
- Interactive scientific discussion and timely communications throughout the regulatory process
- Incentives that improve ROI, such as: harmonised EFS, priority review, grants for e.g. early clinical development

THANK YOU / QUESTIONS

Nataliya Deych

Nataliya_Deych@edwards.com

Edwards Lifesciences

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Innovative medical devices

Existing pathways for innovative medical devices

Erbe Elektromedizin | Dr Helmut Scherer, CTO

Day 1 | September 25, 2023 | 11:40–13:20

European Commission

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Technologies

- ELECTROSURGERY
- PLASMASURGERY
- THERMOFUSION
- HYDROSURGERY
- CRYOSURGERY
- IMAGING

HYBRID TECHNOLOGIES

Medical specialties

- PULMONOLOGY
- GASTROENTEROLOGY
- GENERAL/VISCERAL SURGERY
- GYNECOLOGY
- UROLOGY

More then products:

erbe+ academy
erbe+ service
erbe+ finance

Solutions.

Revenue 2022:
381 Mio €

Active in 110 country markets, Including 16 SSU, 4 SPU and 1 MSU

> 1.700 Employees worldwide
2023-08

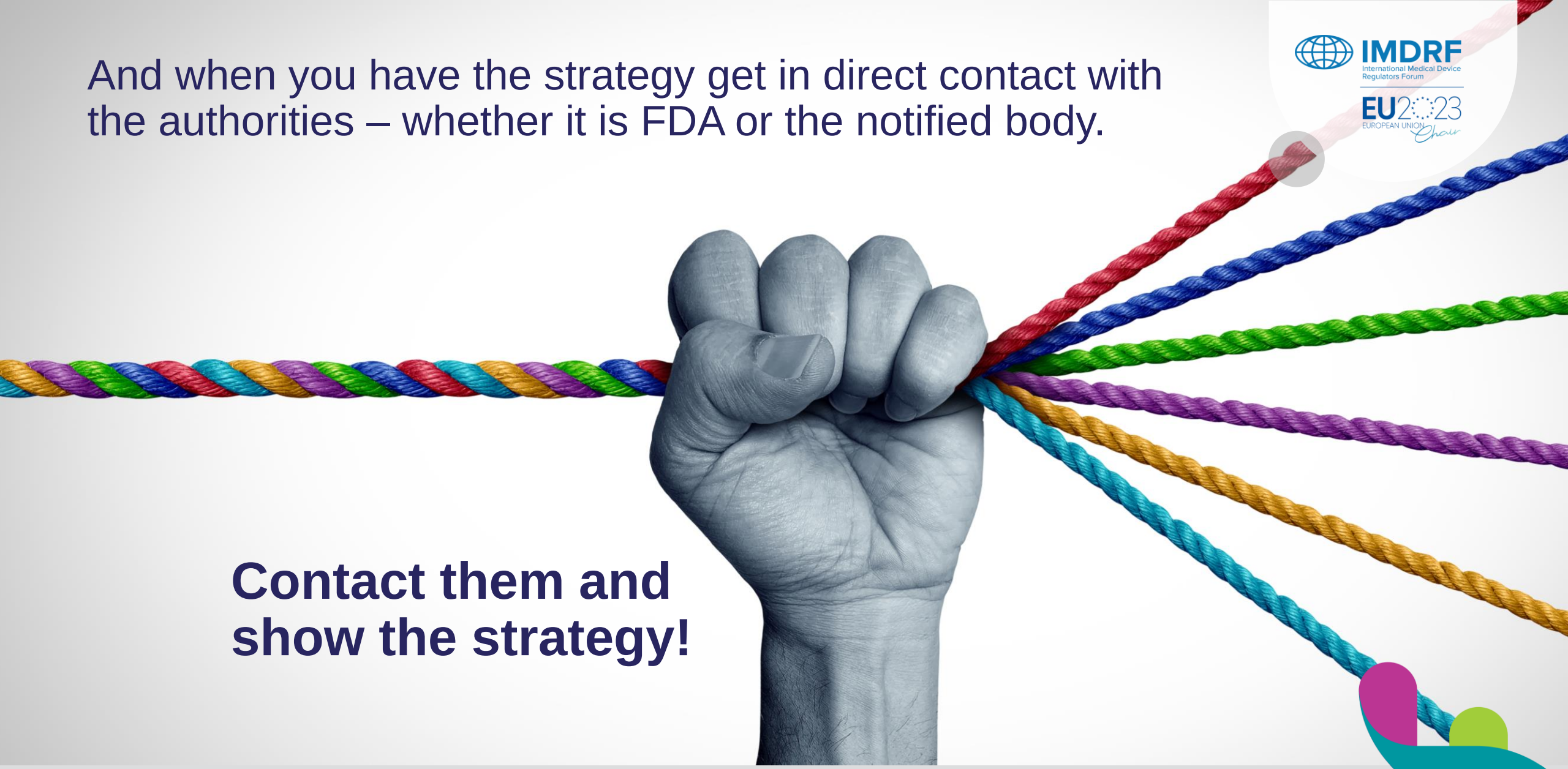
Family-owned and managed company in the 5th generation

Erbe Elektromedizin GmbH - a strong and innovative group of companies since 1851

You need to have a registration and approval strategy ideally at the start of a development project.

And if you don‘t have it, create one!

And when you have the strategy get in direct contact with the authorities – whether it is FDA or the notified body.



Contact them and show the strategy!

Registration strategies

Analyze the intended use of your new product very detailed and compare with your existing products AND competition!

Analyze your existing technologies also in parts and try to create synergies between them and your new product

Analyze the literature in detail (again also include parts of the technology from competitors)

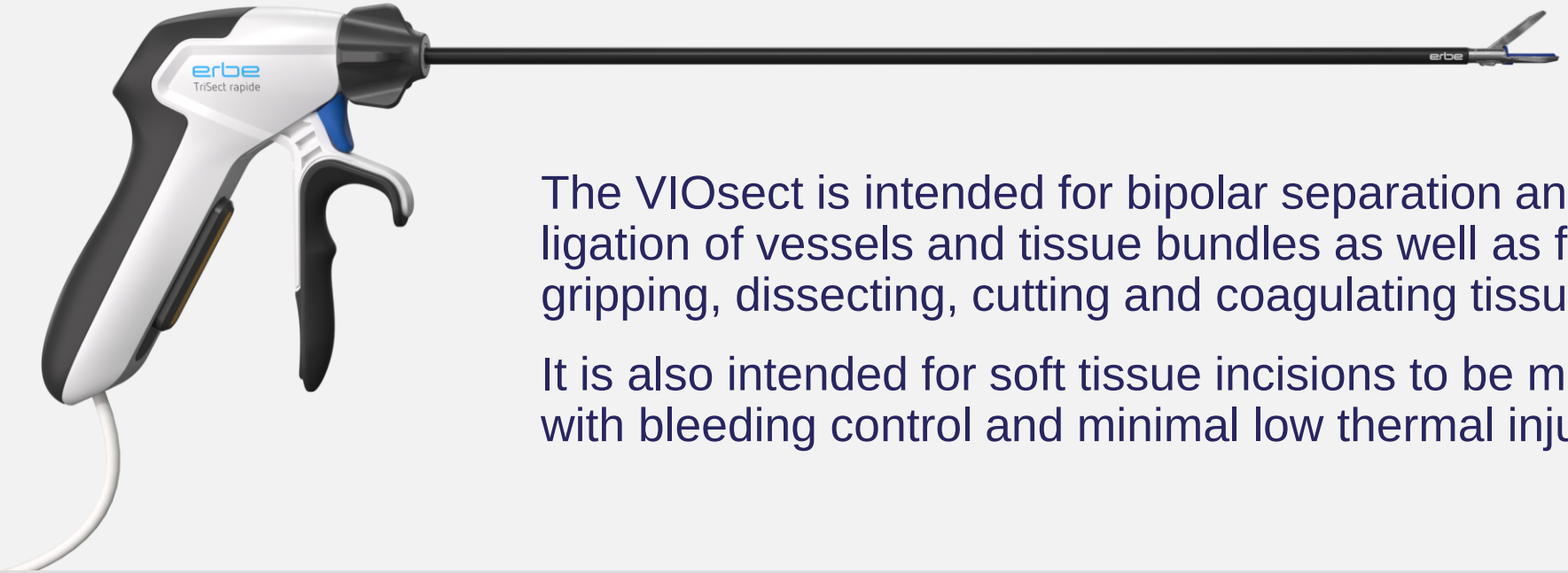
Performance Route:

Show the outcome with numbers to your authority (separated by region but show all)

Show a summary of the risk analysis with the remaining risks

Create a PMS plan – in most cases a PMCF plan where you really collect data that you need anyway to improve your product.

Intended use



The VIOsect is intended for bipolar separation and ligation of vessels and tissue bundles as well as for gripping, dissecting, cutting and coagulating tissue.

It is also intended for soft tissue incisions to be made with bleeding control and minimal low thermal injury.

Technology Experience

Year of introduction of technology for sealing of vessel larger than 3 mm / cutting	Brand name	Manufacturer	Technology
1998 (US patent US005827271A, "Energy Delivery System for Vessel Sealing") 1998 (US: FDA Zulassung, 510(k) K981916)	LigaSure	Covidien (today: Medtronic)	Bipolar coagulation/sealing
2005 (CE)	**BiClamp**	**Erbe Elektromedizin GmbH**	**Bipolar coagulation/sealing**
2007 (US: FDA Zulassung, 510(k) K070165)	Enseal	SurgRx, Inc. (today: Johnson & Johnson, Ethicon)	Bipolar coagulation/sealing, Mechanical cutting
2008 (US: FDA Zulassung, 510(k) K024286)	Trisector (today: PKS Omni)	Gyrus ACMI (today: Olympus)	Bipolar coagulation/sealing, Bipolar cutting
2011 (CE)	**BiCision**	**Erbe Elektromedizin GmbH**	**Bipolar coagulation/sealing, Mechanical cutting**
2011 (CE)	**BiSect**	**Erbe Elektromedizin GmbH**	**Bipolar cutting**
2012 (US: FDA Zulassung, 510(k) K111202)	Thunderbeat	Olympus	Bipolar coagulation/sealing Ultrasonic cutting
2012 (US: FDA Zulassung, 510(k) K121550)	Harmonic	Johnson & Johnson, Ethicon	Ultrasonic coagulation/sealing Ultrasonic cutting

Evidence

Performance

Laboratory tests (30 tests in 2018/2019) prove the efficiency.

- To date: burst pressure, function and stability, tissue
- Planned: Live animal, further burst pressure, 21-day survivor animal test.

Safety

- Usability tests (65 surgeons, some of them interviewed several times) were conducted and prove safe use
- Standard tests prove the technical safety of the prototypes

Benefits

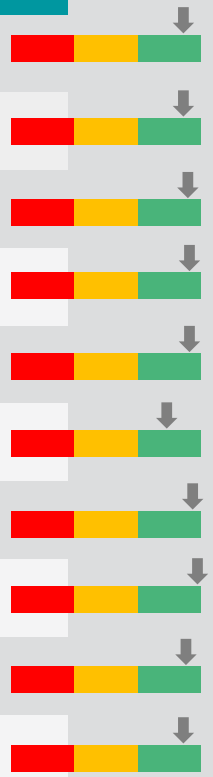
Reference data demonstrates less frequent and less significant complications compared to conventional technologies; in addition:

- Handling
- Reduced instrument changes

Results usability test

Formative usability test with functional 3D printing samples (52 users)

Function	Evaluation mark	Mean value at maximum response 5 (number of responses)
In general	Safety after use	4,6 ± 0,6 (37)
	Suitability	4,6 ± 0,6 (39)
Preperation	Safety	4,8 ± 0,3 (29)
	Suitability, Simplicity	4,8 ± 0,3 (29)
	Ergonomics	4,8 ± 0,3 (29)
Dissection	Safety	4,5 ± 0,8 (33)
	Suitability, Simplicity	4,9 ± 0,2 (30)
Coagulation	Safety	5,0 ± 0,0 (29)
	Suitability, Simplicity	4,7 ± 0,5 (30)
	Ergonomics	4,9 ± 0,3 (27)



Performed standard tests

Applied Standards

- EN 60601-1 Third Edition from October 2006 + A1 October 2013 (General Requ.)
- IEC 60601-2-2 Ed. 6.0 from March 2017 (HF Equipment)
- EN 60601-1-2 Fourth Edition from September 2015 (EM Disturbances)
- EN 60601-1-6 Edition from April 2010 + A1 May 2015 (Usability)
- EN ISO 14971 Edition from July 2012 (Risk Management)
- EN 62366-1 April 2015 + AC December 2015 (Usability)
- EN 556-1 Edition from October 2001 + AC November 2016 (Sterilization)
- EN ISO 11135 Edition from July 2014 (Sterilization EO)
- EN ISO 11607-1 Edition from July 2017 (Packaging, Materials)
- EN ISO 11607-1 Edition from July 2017 (Packaging, Validation)
- EN ISO 11737-1 Edition from April 2006 + AC from April 2009 (Packaging, Microbiology)
- EN ISO 11737-2 Edition from November 2009 (Packaging, Microbiological Tests)
- EN ISO 10993-1 Edition from October 2009 + AC June 2010 (Biololgical Evaluation)
- EN 1041 Edition from August 2008 + A1:2013 (supplied Information)
- EN ISO 15223-1 Edition from November 2016 (Symbols)

Basic research

From 1991 literature sources 592 were identified & analyzed

Livivo and PubMed query for the following search terms (any time until 04.06.2018 (date of search)):

- BiClamp: PubMed 37 hits, Livivo 61 hits
- BiCision: PubMed 4 hits, Livivo 28 hits
- BiSect: PubMed 2 hits, Livivo 15 hits
- bipolar vessel sealing: PubMed 260 hits, Livivo 349 hits
- thermofusion: PubMed 22 hits, Livivo 495 hits
- laparoscopic, bipolar, tissue dissection: PubMed 124 hits, Livivo 51 hits
- laparoscopic scissors: PubMed 367 hits, Livivo 393 hits
- Vessel sealing, injury: PubMed 52 hits, Livivo 47 hits
- ENSEAL: PubMed 35 hits, Livivo 39 hits
- LigaSure: PubMed 606 hits, Livivo 782 hits
- Harmonic ACE: PubMed 73 hits, Livivo 88 hits
- Thunderbeat: PubMed 22 hits, Livivo 21 hits
- Sonicision, Medtronic: PubMed 8 hits, Livivo 0 hits

Evaluation

**The use of thermofusion instruments is known in the market, safe and effective.
All mentioned risks have been balanced in with risk analysis.**

Vigilance data

Instrument name	Year	Reclamation rate	Number of approved incidents	Number of approved complaints	Number of sales
BiCision	2014-2018	**0.3 %**	5	77	25458
BiClamp	2014-2018	**1.6 %**	22	756	47284
BiClamp MF-2	2018	**1.25 %**	0	3	240
BiSect	2014-2018	**0.51 %**	0	34	6650

Vigilance data

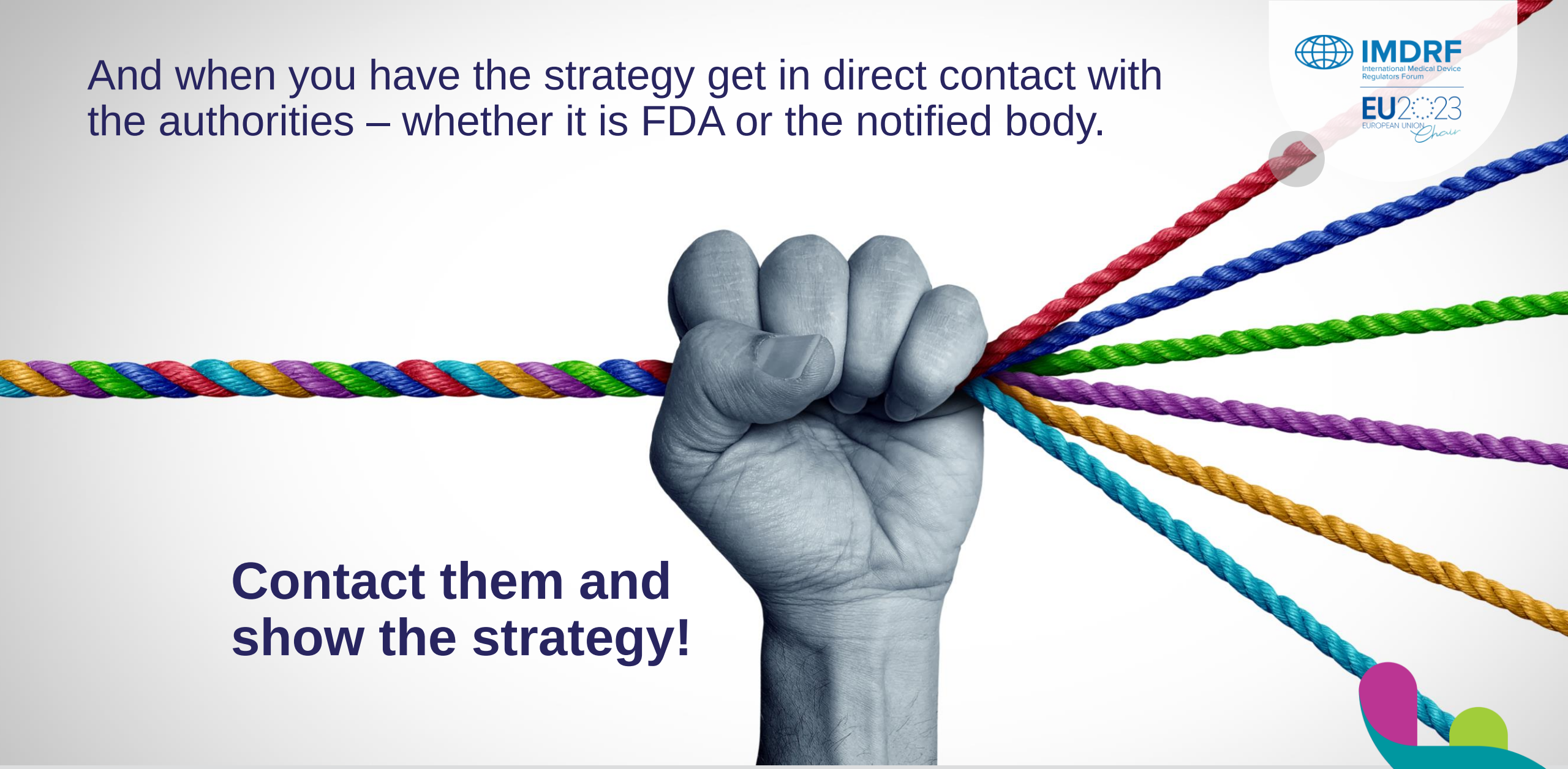
Competitors and own products

Review	Search terms	Action
A review of adverse events for “advanced” bipolar thermofusion devices was performed within the data bases of BfArM and MAUDE	• time range from 2014/01/31 to 2019/01/31 • BiCision, BiClamp, BiSect, EnSeal, Ligasure, Harmonic • Death, injury, malfunction • Because of >500 number of entries, the search terms for “injury” and “malfunction” for the brand name “Ligasure” was narrowed to the devices “Ligasure Maryland” and “Ligasure Blunt” • Because of >500 number of entries, the search terms for “malfunction” for the brand name “Enseal” was narrowed to “Enseal G2” • Because of >500 number of entries, the search terms for “malfunction” for the brand name “Harmonic” was narrowed to “HAR36” and “HAR23”, respectively.	Vigilance data across some thermofusion products, have been incorporated and assessed in the risk analysis.

You need to have a registration and approval strategy ideally at the start of a development project.

And if you don‘t have it, create one!

And when you have the strategy get in direct contact with the authorities – whether it is FDA or the notified body.



Contact them and show the strategy!


We’ll see you in the future.
erbe
power your performance.

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THANK YOU / QUESTIONS

helmut.scherer@erbe-med.com
erbe-med.com

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Innovative medical devices
Opportunities for convergence and reliance

Augusto Geyer – ANVISA

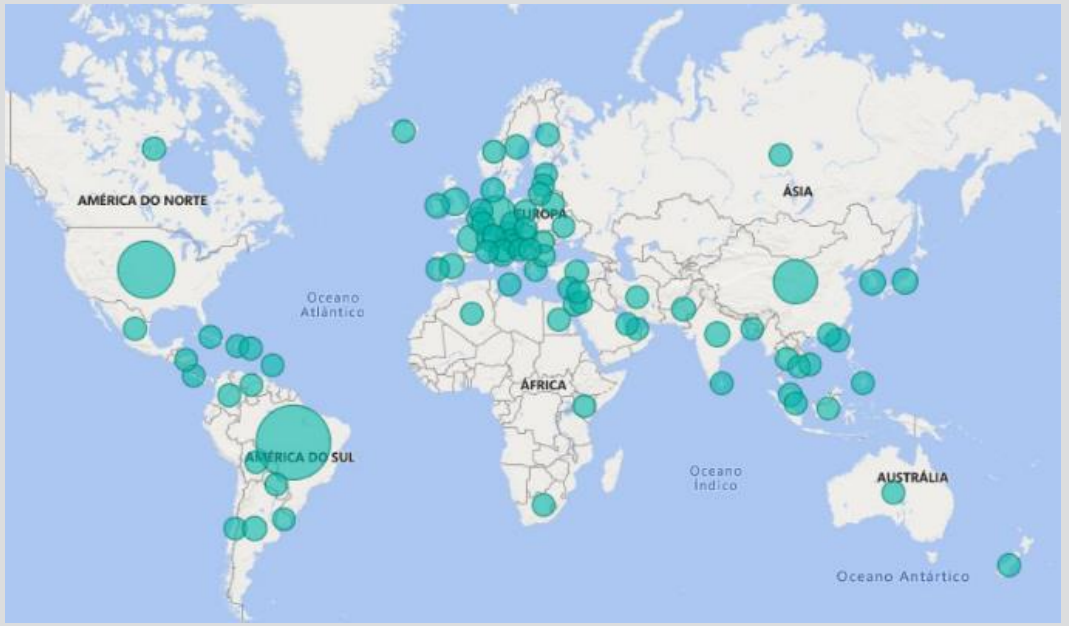
25 September 2023

European Commission

Funded by the European Union

ORIGIN OF LICENSED MD IN BRAZIL

Position	Country	Authorizations	Percentage
0	Brazil	26546	30,11%
1	USA	15613	18,40%
2	China	12462	13,99%
3	Germany	8484	10,02%
4	Italy	2284	2,64%
5	France	2197	2,60%
6	UK	1605	2,40%
7	Switzerland	1588	1,91%
8	South Korea	1433	1,75%
9	Japan	1384	1,53%
10	India	1282	1,49%
11	Spain	1030	1,16%
12	Argentina	809	0,96%
13	Ireland	710	0,85%
14	Taiwan	706	0,79%
15	Pakistan	672	0,79%
16	Sweden	612	0,73%
17	Denmark	576	0,68%
18	Israel	483	0,56%
19	Turkey	478	0,55%
20	Malaysia	474	0,55%

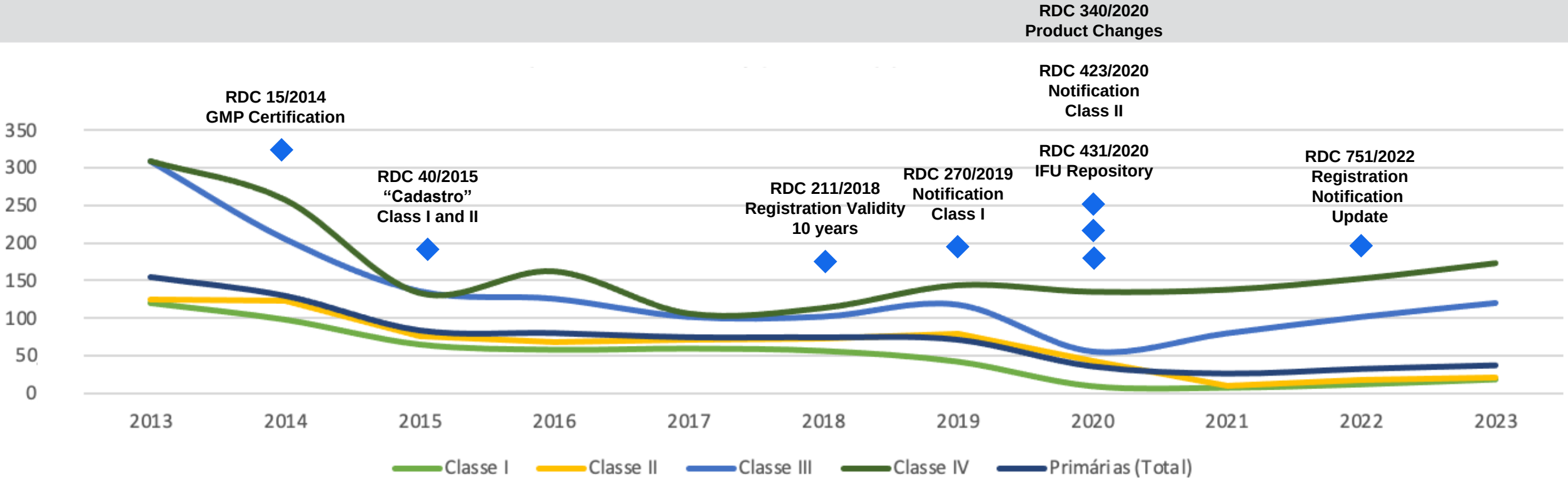


National **31,6%**

Imported **68,4%**

(Mar 2023)

MEDICAL DEVICE MARKET AUTHORIZATION



Average Time to Final Decision from ANVISA per Risk Class (days)

ANVISA
Agência Nacional de Vigilância Sanitária

REGULATORY CONVERGENCE

Key Factors and Motivations

- Complexity of the MD sector
- Predictability
- Capacity and confidence building
- Avoid duplication of efforts for Regulators and Industry
- Globalization of supply chains
- Accelerate patient access to new technologies
- Patient safety and public health

IMDRF

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

MERCOSUL

ISO IEC

Bilateral agreements

World Health Organization

RELIANCE MECHANISMS FOR PRE-MARKET AUTHORIZATIONS

reliance. *The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.* ***The relying authority remains independent, responsible, and accountable for the decisions taken****, even when it relies on the decisions, assessments, and information of others.*

(WHO Global Model Regulatory Framework)

RELIANCE MECHANISMS FOR PRE-MARKET AUTHORIZATIONS

abridged pathways. *Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or widely based on the application of reliance. This usually involves some degree of work by the relying agency.*

(WHO Global Model Regulatory Framework)

RELIANCE MECHANISMS FOR PRE-MARKET AUTHORIZATIONS

Structured regulation on reliance – RDC 741/2022

Pathway for abridged review process

Normative Instruction for MD and IVD MD under public consultation

- Public Consultation 1200/2023
- http://antigo.anvisa.gov.br/consultas-publicas#/visualizar/509352
- Open for contributions until 25 October 2023

Product registration certificates from Equivalent Foreign Regulatory Authorities will be used as a trigger for expedited review

- Initially from the same founding members authorities of MDSAP

RELIANCE MECHANISMS FOR PRE-MARKET AUTHORIZATIONS

Conditions that will apply

Agreement on the exchange of confidential information with the Foreign Equivalent Regulatory Authorities

Classes III and IV – Registration submissions

Product should be essentially the same

- Same intended use (and indications for use)
- Same manufacturing sites and legal manufacturer
- Same “regulatory version”

RELIANCE MECHANISMS FOR PRE-MARKET AUTHORIZATIONS

Conditions that will apply

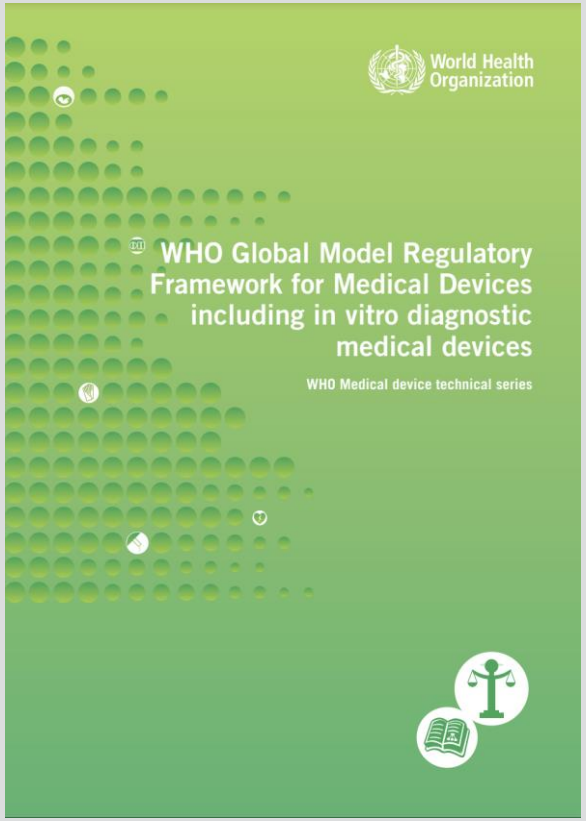
Brazilian labelling and specific certification requirements must be fulfilled

Anvisa may choose to perform the full assessment of the Technical Dossier

Anvisa may request clarification regarding the documents submitted for review

RELIANCE MECHANISMS FOR PRE-MARKET AUTHORIZATIONS

Implementation of Reliance as a Measure of Regulatory Maturity



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Augusto Geyer – Medical Devices Office – ANVISA

augusto.geyer@anvisa.gov.br

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Opportunites for Reliance & Convergence

- an APAC Snapshot

Yasha Huang, Head Regulatory Policy APAC, Roche Diagnostics/APACMed RA Committee Vice Chair

25 September 2023

European Commission

Funded by the European Union

The Interplay between Convergence and Reliance

Convergence

A voluntary process whereby the regulatory requirements in different countries or regions become more similar or “aligned” over time. Convergence results from gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.

Reliance

The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Source: *Annex 11 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021*

How does the interplay work

- Reliance represents a “smarter” form of regulatory oversight, based on constructive regional and international collaboration, that will facilitate and promote convergence and the use of common international standards and guidelines, resulting in more predictable, faster approval to improve access to quality-assured medical products for patients worldwide.
- Convergence and harmonization of requirements, standards and guidelines are important enablers of regulatory cooperation and reliance.
- However, differences in standards and practices, do not prevent one authority from relying on another, particularly when the relying authority has limited capacity and expertise.

Source: *Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021*

Reliance in a glance for APAC

(Data source: Roche internal analysis of 14 markets for IVD products only)

	Formal reliance existing (based on current effective regulations)	**Informal or no reliance existing** (based on current effective regulations)
Markets (in alphabetical order)		

Notes:

- Even for markets with formal reliance models, there is still huge potential for further improvement on efficiency and/or expansion to the total product lifecycle.
- Markets were categorized as informal reliance due to different reasons; markets with no official regulation in place will be categorized as no reliance existing.

WHO recommends, “the concept of reliance for regulation of medical products should be applied throughout the life cycle of medical products and in all regulatory functions.”

(Data source: Roche internal analysis for IVD products only)

	Markets with formal reliance mechanism
Pre-market registration	AU, IN, MY, SG, TH, VN
QMS	AU, IN, JP, MY, SG, TH, VN
Clinical	AU, IN, JP, MY, SG, TH, VN
Post-approval changes	AU
Vigilance	

- *In APAC, reliance is mostly practiced in the QMS, clinical and pre-market registration, indicating big potential for future expansion into other phases (post-approval changes & vigilance).*
- *Most of these markets rely on **GHTF countries**.*

Opportunities for Convergence

There is better convergence among markets with formal reliance mechanism

Convergence status

Yes	Partial	No

Formal reliance existing

A set of good practices	Country A	Country B	Country C	Country D	Country E	Country F	Country G
Adoption of IMDRF best practices (e.g. risk classification)							
Common dossier template (e.g. AMDD CSDT, IMDRF RPS)							
Acceptance of overseas clinical evidence							
No in-country lot testing							
No country-specific labeling requirements							
No prior approval required in country of origin and/or country of manufacturer							
No re-registration requirements							
No redundant inspections							
Leverage Real World Evidence (RWE)							

No formal reliance

A set of good practices	Country H	Country I	Country J	Country K	Country L	Country M	Country N
Adoption of IMDRF best practices (e.g. risk classification)				N/A			
Common dossier template (e.g. IMDRF RPS, AMDD CSDT)				N/A			
Acceptance of overseas clinical evidence				N/A			
No in-country lot testing				N/A			
No country-specific labeling requirements				N/A			
No prior approval required in country of origin and/or country of manufacturer				N/A			
No re-registration requirements				N/A			
No redundant inspections				N/A			
Leverage Real World Evidence (RWE)				N/A			

Data source: Roche internal analysis of 14 markets for IVD products. Country K is N/A because there is no enforced regulation for MD/IVD yet.

Benefits of implementing global convergence and reliance

- Conserve and optimize the use of limited regulatory resources, elevate regulation to one high standard and accelerate access to safe, high-quality, effective, and innovative medical technologies to benefit patients, caregivers, and healthcare providers.
- Facilitate an environment conducive to the growth of the medical technology sector, enhancing innovation and providing knowledge-based jobs.
- Enhance global health equity through the acceleration of global access to safe, effective and innovative medical technologies.

"The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on reliance and trust."

Source: *GMTA paper on The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology. Dr. Samvel Azatyan, RCN/REG/RPQ, World Health Organizaton. WHO Activities: focus on reliance. 10th Asia Regulatory Conference.*

THANK YOU

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Pre- and Post-Market Clinical Evidence Strategies for Innovative Medical Devices
Opportunities for Convergence and Reliance

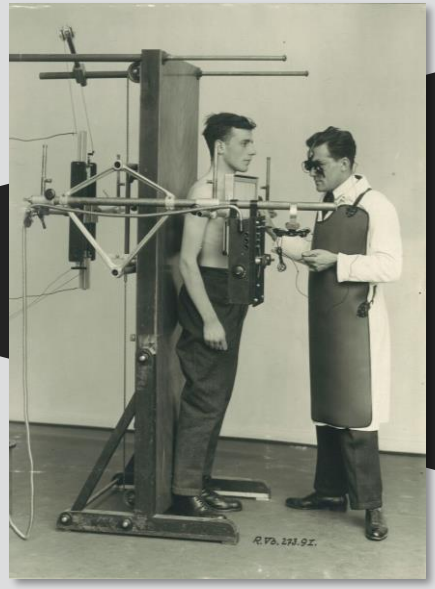
Latifa Lakehal, Philips / Dr. Johanna Sorsa, Siemens Healthineers

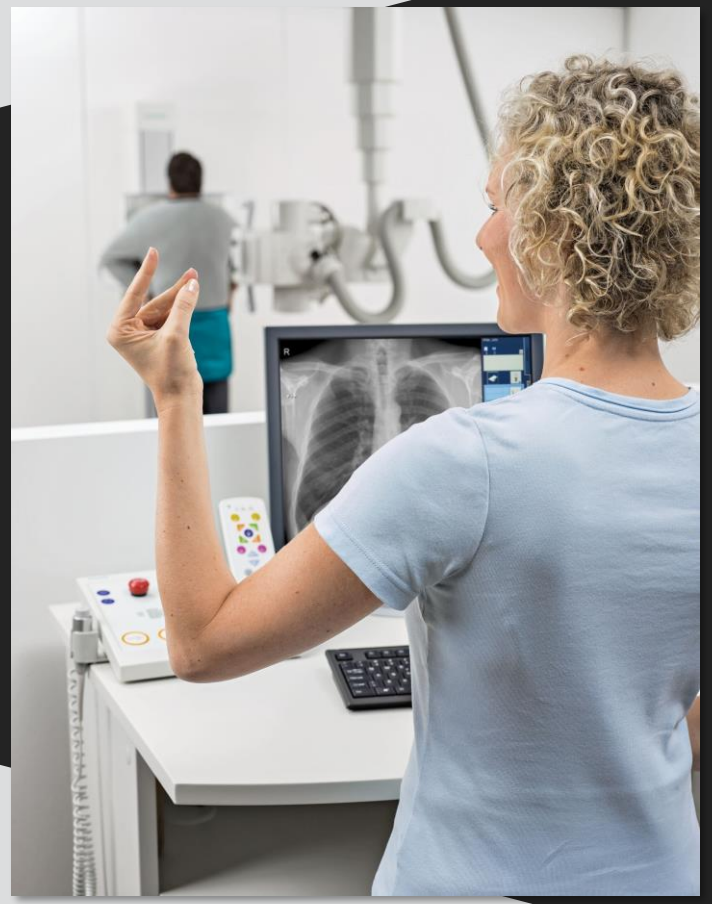
September 25, 2023

European Commission

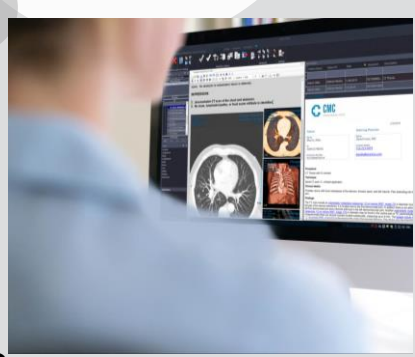
Funded by the European Union

THE INNOVATION AS DRIVER





BALANCE BETWEEN INNOVATION AND REGULATORY CONTROLS



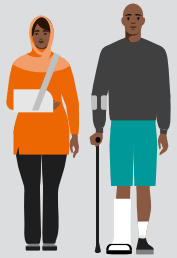
Patient populations are evolving

The importance of patient experience is growing

Qualified clinical staff are in short supply

The cost of providing care is rising overall

Opportunities and challenges of digitalization



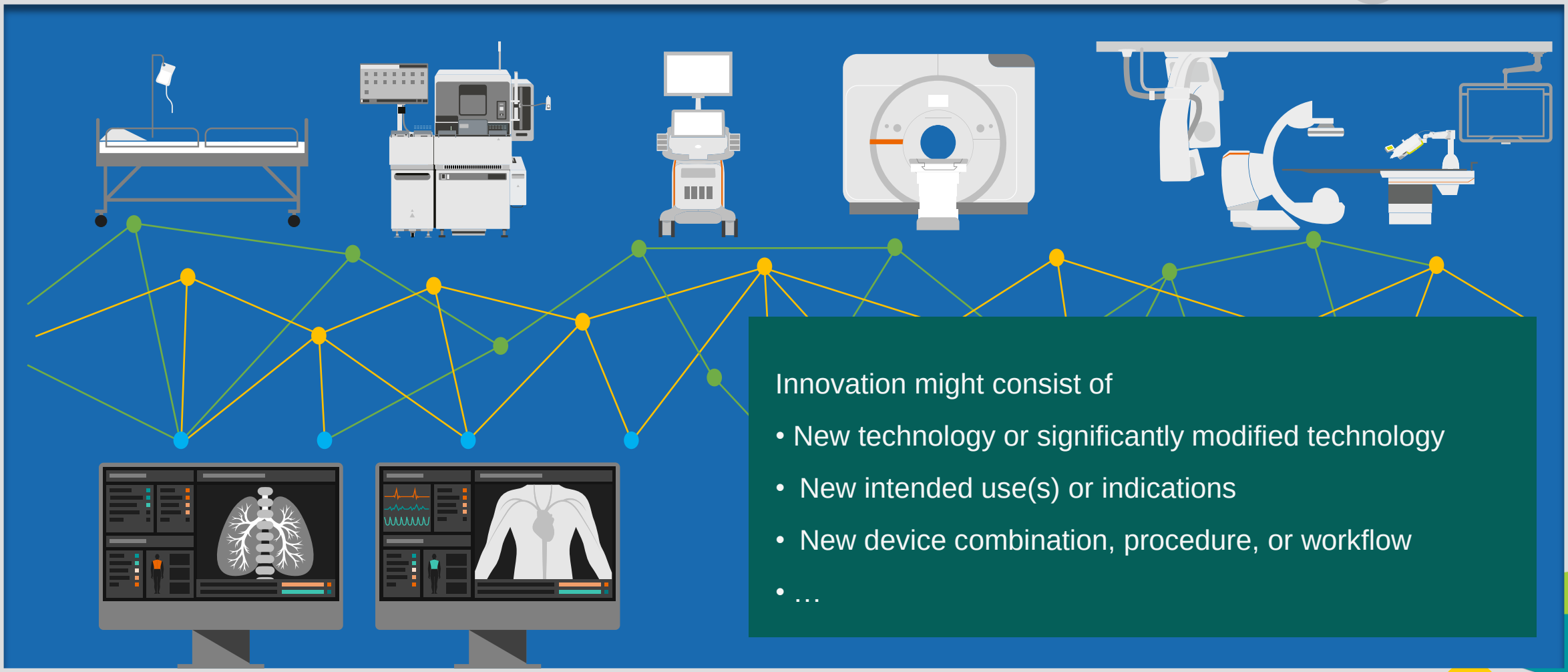
REGULATORY CONVERGENCE FOR THE BENEFIT OF THE PATIENT

"Regulatory convergence," on the other hand, represents a process whereby the regulatory requirements across countries or regions become more similar or "aligned" over time as a result of the ***gradual adoption of internationally recognized technical guidance documents, standards and scientific principles, common or similar practices and procedures****, or adoption of regulatory mechanisms that might be specific to a local legal context but that align with* ***shared principles to achieve a common public health goal****. It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation.*

Source: U.S. FDA Regulatory Harmonization and Convergence, 08/07/2019

THE HEART OF THE REGULATORY FRAMEWORK IS THE PATIENT – UNDER TWO MAIN PILLARS: SAFETY AND INNOVATION

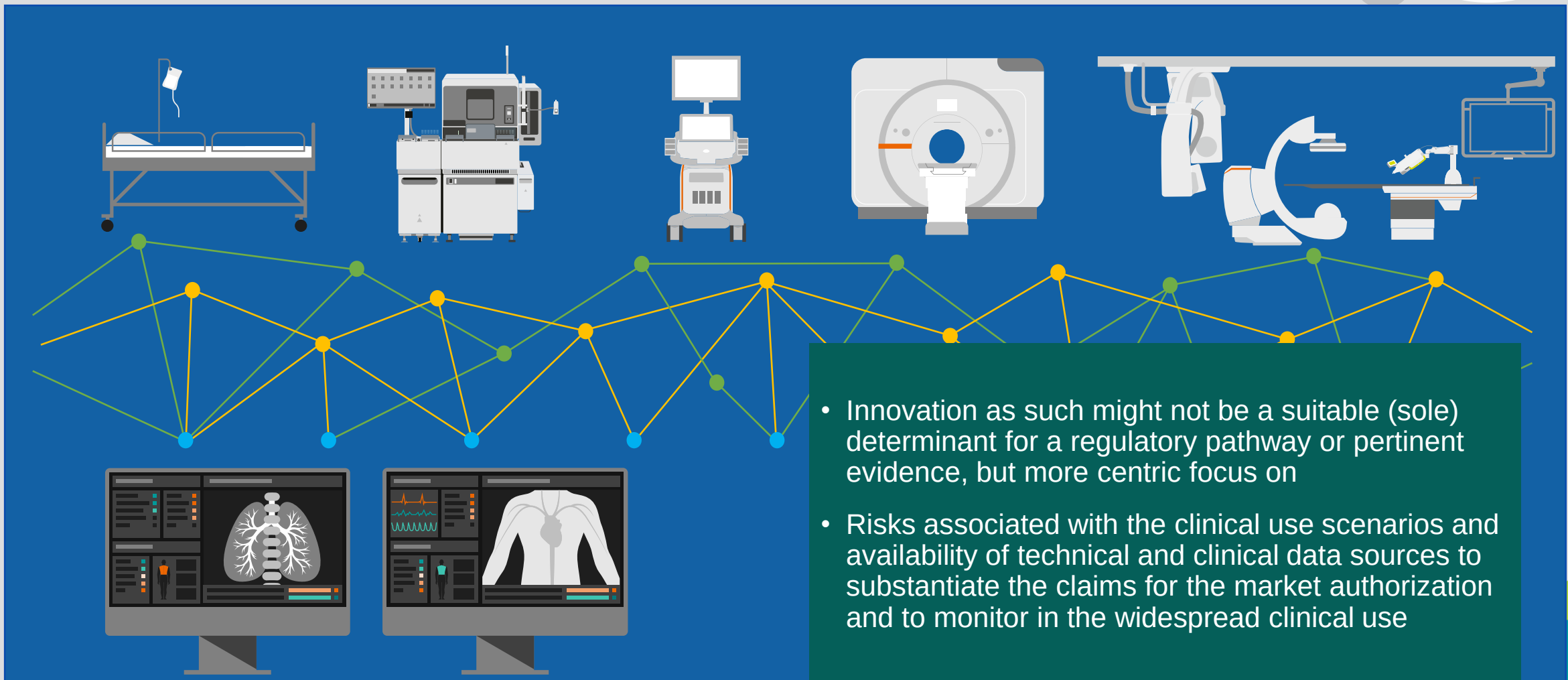
INNOVATION IN MEDICAL TECHNOLOGIES



Innovation might consist of

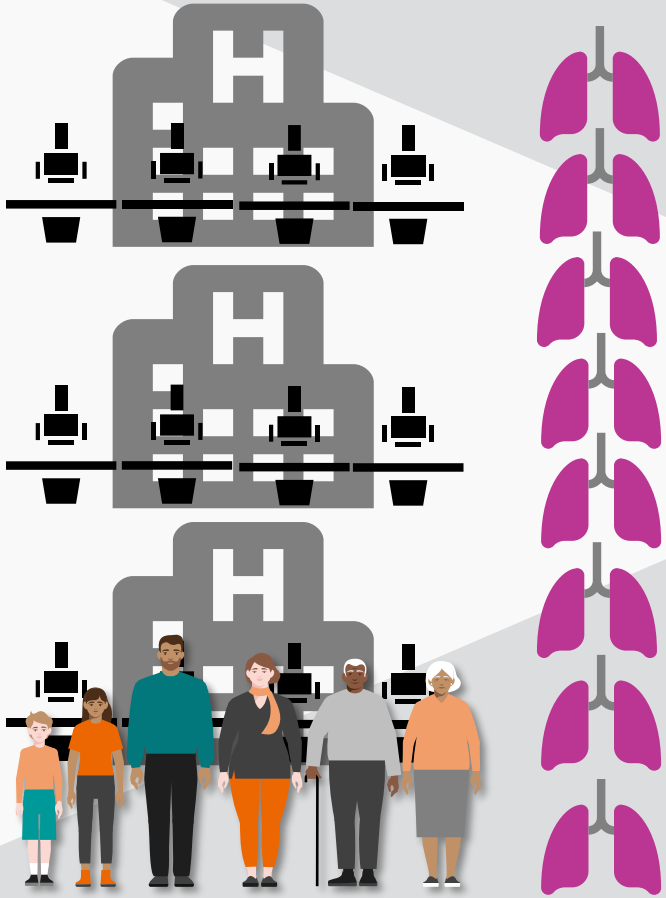
- New technology or significantly modified technology
- New intended use(s) or indications
- New device combination, procedure, or workflow
- …

INNOVATION IN MEDICAL TECHNOLOGIES

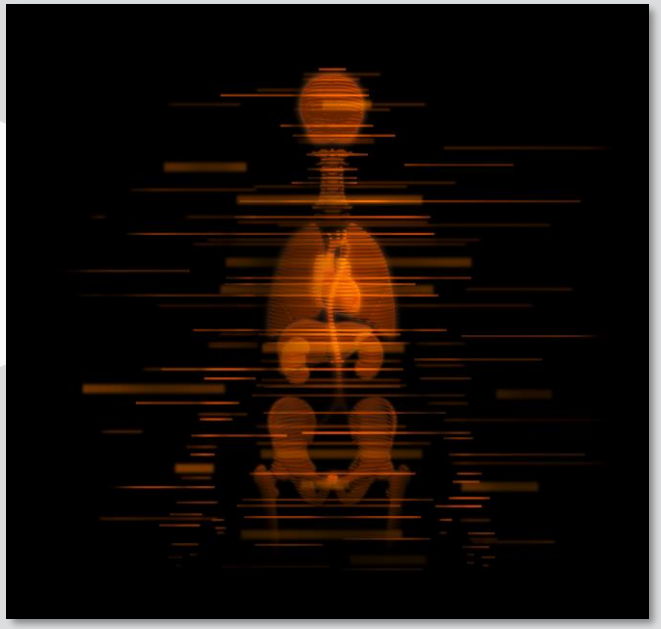


- Innovation as such might not be a suitable (sole) determinant for a regulatory pathway or pertinent evidence, but more centric focus on
- Risks associated with the clinical use scenarios and availability of technical and clinical data sources to substantiate the claims for the market authorization and to monitor in the widespread clinical use

DATA - DRIVEN DEVELOPMENT



Training



Clinical validation

Real-world evidence generation

VARIABLE REAL-LIFE USE SCENARIOS

Pre-market assessment:

- technical testing scenarios
- clinical use scenarios, including prospective and retrospective studies
- state-of-the-art
- risk management
- …..

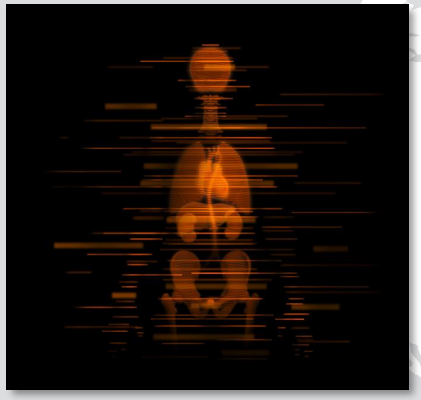
Simulating and predicting real-life use in a controlled environment

Variations in the **real-life use** scenarios:

- patient populations
- clinical routine procedures
- user interfaces and workflows
- use environments
- staff knowledge levels
- …..

Unexpected is expected

HOLISTIC CLINICAL LIFECYCLE MANAGEMENT SYSTEM



Design and development

Clinical evaluation

Technical performance
Clinical performance

Confirmation and monitoring

Generalisability
Usability

Post-market surveillance: complaint handling and trending, field (safety) actions, vigilance data

Post-market clinical follow-up (PMCF)/Real-World-Evidence (RWE): prospective studies, retrospective data analysis, reference site follow-up, automated customer input modules, installed base and stationary use analytics, published data screening….

Product risk management: assessment of new and known clinical risks, right assignment of the intended purpose and correctness of the information provided to the user

CLINICAL EVALUATION: STANDARD FRAMEWORK

Target:

- **Global** guiding principles on the scientific assessment of the device's clinical performance, benefits, and safety
- Do not contradict the regulatory frameworks of the **major legislations** (EU, GHTF, USA, Japan, China)
- **Minimal consensus** on the clinical evaluation independently of the device type, risk classification, clinical application, and maturity of the technology
- **Cross-process alignment** and harmonization with the other applicable ISO standards to the medical devices and manufacturers (esp. ISO 14971, ISO 13485)

Basis framework:

- IMDRF/SaMD WG/N41FINAL:2017 Software as a Medical Device (SaMD): Clinical Evaluation
- IMDRF MDCE WG/N56FINAL:2019 (formerly GHTF/SG5/N2R8:2007) Clinical evaluation
- EU Medical Device Regulations 2017/745 (MDR)
- European Commission guidelines on clinical evaluation (MDCG 2020-1, -5, -6, -7, -8, -13, MEDDEV 2.7/1 rev. 4)
- National Medical Device Authority (NMPA) of P.R. China Technical Guidelines of Clinical Evaluation of Medical Devices
- Therapeutic Goods Administration (TGA) of Australia Clinical evidence guidelines for medical devices
- Health Canada Guidance on clinical evidence requirements for medical devices: Overview
- ISO 14971 Medical devices - Application of risk management to medical devices
- ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes
- IEC 62366-1 Medical devices — Part 1: Application of usability engineering to medical devices
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process
- Etc.

Normative global consensus

[main document]

Clinical evaluation

Legislation -dependent adaptations

[normative/informative annexes]

- Plan and report template
- Literature search and appraisal
- Demonstration of equivalency
- Clinical evaluation in the post-market phase
- Pre-clinical evaluation /Early phase clinical evaluation
- Etc.

[horizontal standard]

Clinical evaluation

Product –specific requirements

[vertical/particular standards]

- Software as a medical device
- Clinical evaluation based on the performance data
- Active implantable devices
- Low-risk devices
- Diagnostic imaging
- Etc.

CLINICAL EVALUATION: GLOBAL MINIMAL CONSENSUS

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Purpose

Management responsibility for process, conduct, and provision of qualitied resources

Objectives and planning

Minimal requirements for a scientifically valid, systematic, and methodologically sound procedure appropriate for the device

When required under the respective jurisdiction: processing of the output, implementation of an ongoing process and post-market monitoring system throughout the device's lifecycle

KEY TAKE AWAYS

- Medical device technologies and applications are highly variable and rapidly evolving field driven by data
- Innovation may not be the purposeful determinant for a regulatory pathway, but the strategy must be adapted on case-to-case basis in alignment with the regulatory bodies
- Pre-market assessment of the expected clinical performance and safety is essential, but the variables in the long-term clinical use can only be anticipated
- Post-market monitoring system is necessary to assure patient and user safety among real-life conditions, but it can also effectively be utilized to collect factual evidence on the efficiency in the clinical use
- Regulatory convergence can be achieved by aligning on the minimal consensus on the global clinical evidence strategy and existing standard framework applicable for the medical device manufacturers

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THANK YOU / QUESTIONS

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Regulatory Convergence & Reliance

Diane Wurzburger, GE HealthCare for GMTA

September 25, 2023

European Commission

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What we can agree on

- ✓ Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical technologies
- ✓ Small differences in regulations, standards, and guidance can result in major differences in the regulatory path for the same medical device (e.g., MD/IVD classification)
- ✓ These differences are amplified during a pandemic
- ✓ The rapid advancement of medical device innovations is challenging traditional regulatory frameworks

Global Medical Technology Alliance

Innovating for a Healthier World

*Foundational Principles**

- Implement convergent regulatory frameworks based on internationally recognized best practices and standards.
- Implement regulatory reliance, including recognition
- Implement core tenets of medical device regulations

**The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology*, May 2023
http://www.globalmedicaltechnologyalliance.org/papers.html

Core Tenets

- Ensure predictability and adequate resources
- Support innovation and apply equal regulation to both domestic and international companies
- Adopt Good Regulatory Practices (GRP)
- Avoid requirements that lack a patient safety benefit
- Accept global clinical trial data and leverage Real World Evidence

Core Tenets

- Implement a risk-based approach to product changes
- Avoid unnecessary barriers to access based on product country of origin
- Implement a single dossier
- Adopt electronic instructions for use
- Accept digital labels

Opportunity for convergence & reliance*

- Predictability of decision-making
- Transparency
- Capacity building
- Decrease in workload, duplicative efforts
- Strategic use of resources
- Increased efficiencies
- Collaboration & trust
- Increase timely patient access to innovation
- Increase health system preparedness & response during PHE

*National Regulatory Authority retains independence, sovereignty and accountability for decision-making

Thank you & Questions

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