MEDCON
CONFERENCE
Columbus, OH • April 24-27, 2023
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Global Regulatory Convergence and Shaping Innovation

Fatemeh Razjouyan

Director of Regulatory Policy, International and Global Harmonization

Medtronic

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

What is Convergence?

The International Medical Device Regulators Forum (IMDRF) defines convergence as a voluntary process whereby regulatory requirements and approaches across countries and regions become more similar or aligned to internationally recognized best practices [1]

1 IMDRF (2018), IMDRF Terms of Reference

Why are we talking about Convergence?

- Globally convergent regulation brings us closer to one transparent, predictable, and trusted standard, no matter the jurisdiction, thereby **expediting patient access** to safe, effective, and quality-assured medical devices

- Avoids unnecessary duplication of regulatory processes and **reduces time and costs** associated with gaining access to multiple markets

Picture from inc.com

Speakers will present on:

- Global Regulatory Convergence and Shaping Innovation – an Update from US FDA
- Regulatory Convergence and Key Updates of the Brazilian Regulatory Framework for Medical Devices
- Industry Perspectives on Convergence

MEDCON CONFERENCE
COLUMBUS, OH • APRIL 24-27, 2023

Session speakers

Erin Cutts
Senior International Policy Analyst
FDA OCD - CDRH

Augusto Bencke Geyer
Deputy General Manager of the Medical Devices Office
ANVISA

Tammy Steuerwald
Global Head Regulatory Policy, Foundational Principles & Supranational Organizations
Roche

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

Global Regulatory Convergence and Shaping Innovation - an Update from US FDA

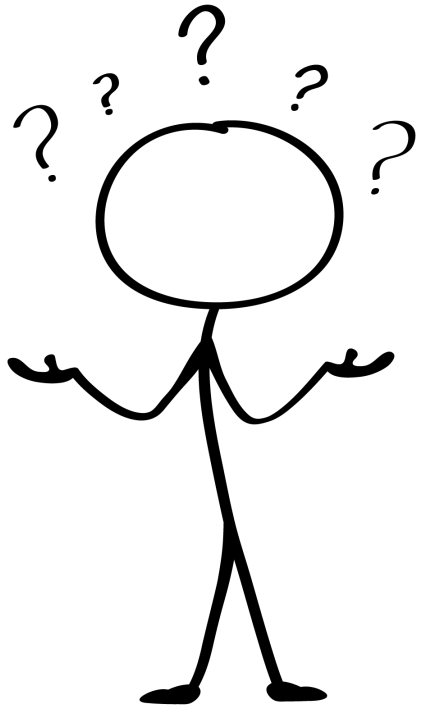
Erin Cutts
Senior International Policy Analyst
Office of the Center Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration


Assoc. Director
Melissa Torres
Erin Cutts
Davina Marano
CDR Neil Mafnas
Michelle Noonan
Stephanie Shedd
CDRHInternational@fda.hhs.gov

Why a global approach?

- The medical device sector has become increasingly globalized and complex.
- Each economy may develop and implement its own regulatory requirements and its own path to market products, especially as emerging and innovative technologies are considered.
- This means regulatory authorities must administer, and industry must navigate adherence to, numerous and sometimes redundant regulatory requirements.
- Reducing these inefficiencies through harmonization, convergence, and reliance on the work of others promotes a more effective regulatory model for medical devices.
- Ultimately, a more efficient and effective model means patients (in the US and globally) have better access to safe, effective, and high-quality medical devices.

What is “convergence”? (Poll Question)

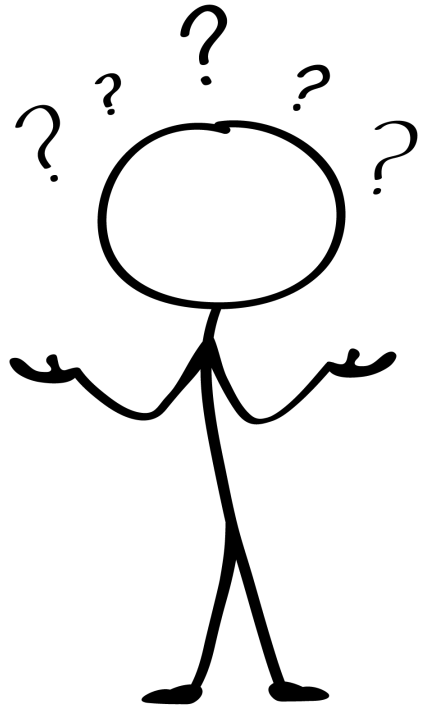


a) The process whereby technical guidelines are developed in order to be uniform across participating regulatory authorities in multiple countries

b) A voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time

c) The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another or trusted institution, or to any other authoritative information in reaching its own decision

What is “convergence”? (Poll Question)



a) The process whereby technical guidelines are developed in order to be uniform across participating regulatory authorities in multiple countries

b) A voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time

c) The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another or trusted institution, or to any other authoritative information in reaching its own decision

What is “convergence”?

- A voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.

Source: IMDRF’s Terms of Reference (IMDRF/MC/N1 FINAL:2023)

IMDRF’s role in global convergence

IMDRF is a key leader in medical device global convergence work.

Official Observers

World Health Organization

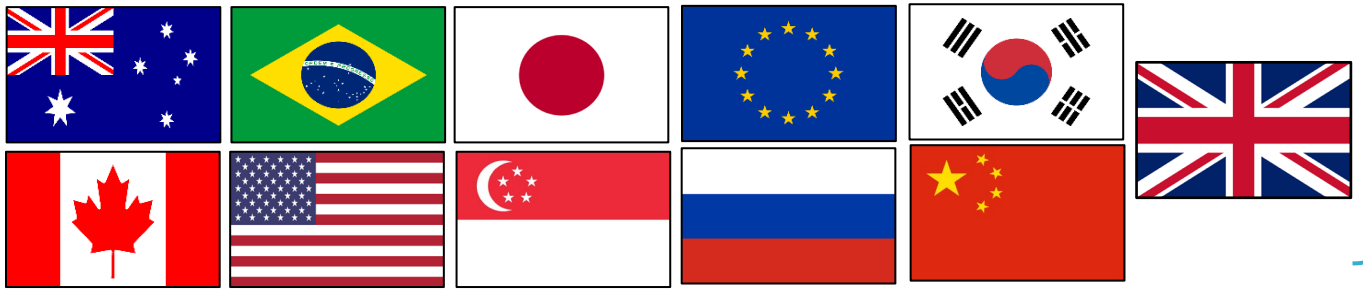
Regional Harmonization Initiatives

APEC
Asia-Pacific Economic Cooperation

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Pan American Health Organization

Management Committee (MC) Members



IMDRF
International Medical Device Regulators Forum

www.imdrf.org

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What is IMDRF's role in medical device global convergence?

- "Convergence" is directly in IMDRF's mission:
  - The mission of the International Medical Device Regulators Forum (IMDRF) is to **strategically accelerate** international medical device **regulatory convergence** to promote an **efficient** and **effective regulatory model** for medical devices that is responsive to **emerging challenges** in the sector while **protecting** and maximizing **public health and safety**.
- IMDRF brings regulators from across the world together to discuss policy and best practices for a variety of medical device topics.
- The Management Committee forms working groups with a specific focus. These working groups draft guidance documents that are then reviewed and, if agreed upon by all members of the Management Committee, published.

IMDRF
International Medical Device Regulators Forum

Current Working Groups

FDA

Good Regulatory Review Practices

- Chairs: US and Singapore

Regulated Product Submission

- Chairs: US and Canada

Cybersecurity

- Chairs: US and Canada

Software as a Medical Device

- Chair: US and Canada

Adverse Event Terminology

- Chairs: US and Germany

Artificial Intelligence/Machine-Learning

- Chair: US and UK

Personalized Medical Devices

- Chair: Australia

Quality Management Systems

- Chair: US and Europe

At least 2 representatives from CDRH are on each of the IMDRF working groups
Some working groups include industry representatives
Harmonized documents are created by each WG within 12-18 months

IMDRF
International Medical Device Regulators Forum

Closed Working Groups

FDA

- Medical Device Single Audit Program (MDSAP)
- Standards
- Unique Device Identification (UDI)
- National Competent Authority Report (NCAR)
- Patient Registries
- Clinical Evaluation
- Principles of In Vitro Diagnostic Medical Device Classification

IMDRF
International Medical Device Regulators Forum

Most Recent Documents

FDA

- Final:
  - IMDRF/CYBER WG/N73: Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity (published April 13, 2023)
  - IMDRF/NCAR WG/N14: Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form (published April 11, 2023)
  - IMDRF/CYBER WG/N70: Principles and Practices for the Cybersecurity of Legacy Medical Devices (published April 11, 2023)
  - IMDRF/PMD WG/N74: Personalized Medical Devices – Production Verification and Validation (published April 11, 2023)
  - IMDRF/GRRP WG/N71: Medical Device Regulatory Review Report: Guidance Regarding Information to be Included (published Feb 7, 2023)
- Consultations:
  - IMDRF/RPS WG/N9: Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC) (consultation closed May 30, 2023)
  - IMDRF/RPS WG/N13: In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC) (consultation closed May 30, 2023)

IMDRF Membership Application Form

Applications must be submitted at least two (2) months before an IMDRF Management Committee meeting, which are usually held two times each year (for example, March and September (variable each year)).

If the application is for a Regional Harmonization Initiative, the application must be submitted by the Chair of the RHI. Any questions should be directed to the Chair of the IMDRF Management Committee which is listed on the IMDRF website.

Type of Membership

Select type of membership

- Select type of membership
- Membership Committee
- Official Observer
- Affiliate Member
- Regional Health Initiative
- Other

Contact Person(s):

Title:

Address:

Phone:

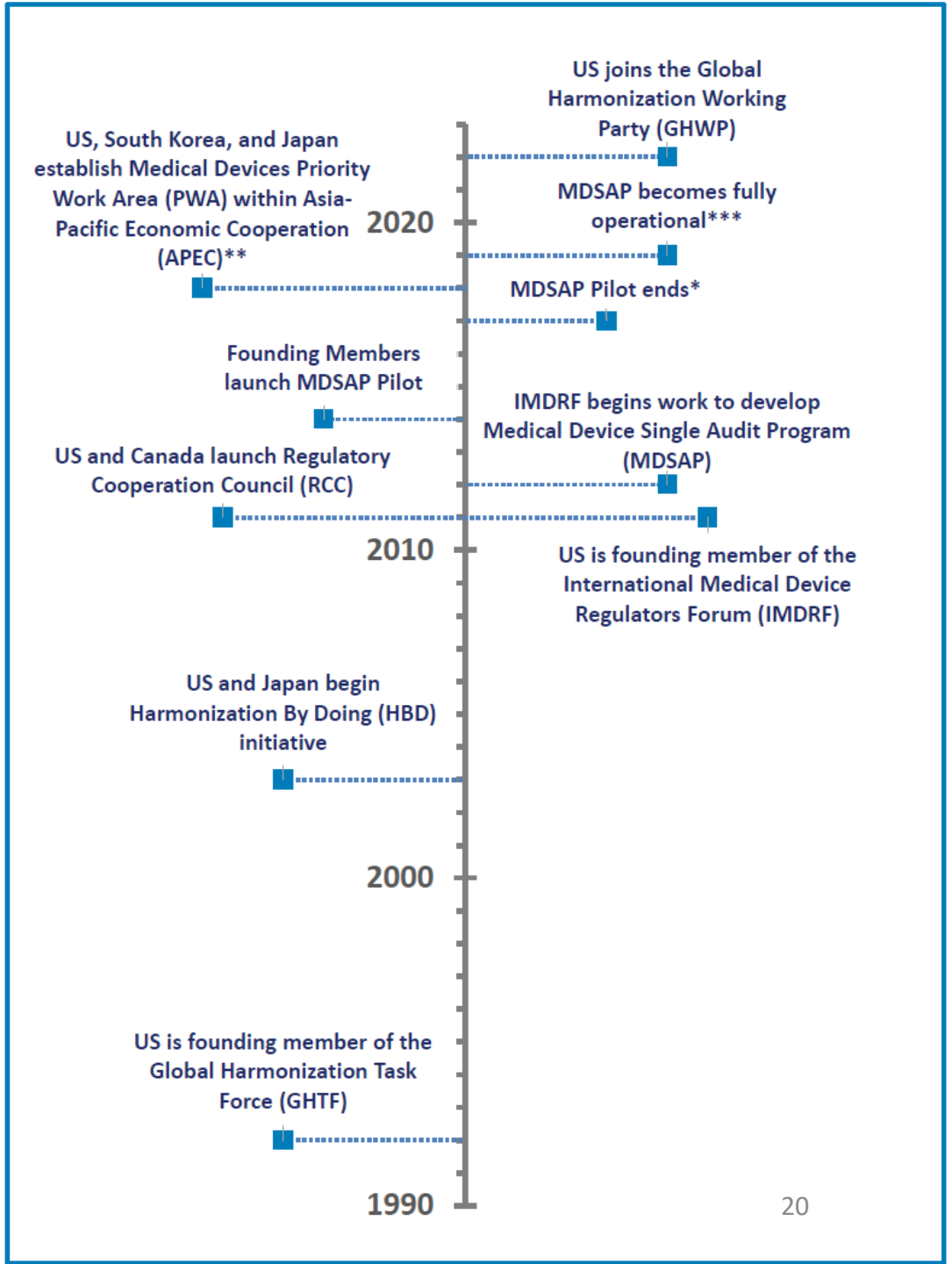
Email:

In Dec 2022, IMDRF added a new membership type ("Affiliate Member").

- Role:
  - Attend the "open" IMDRF MC meetings
  - May participate in open Working Groups.
  - Do not participate in the decision-making process of IMDRF
  - Provide annual updates on implementation status of IMDRF documents
- Criteria:
  - Must be a regulatory authority
  - Recognized commitment to the objectives of IMDRF demonstrated by implementation or a plan for implementation of IMDRF documents

FDA's role in global convergence

CDRH has been working on global convergence for 30+ years.



MDUFA International Harmonization Commitments

1. **Expand engagement in international harmonization and convergence efforts** through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.
2. **Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners** with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies and practices, as needed and consistent with applicable disclosure law and policy.
3. Commencing in FY 2023, **assess the extent of CDRH implementation of International Medical Device Regulators Forum (IMDRF) technical documents** and make this information publicly available to enhance clarity and transparency.
4. **Support the creation of a forum to engage with relevant stakeholders**, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision making.
5. **Participate in outreach activities to other regulatory authorities** that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.
6. By the end of FY 2023, **issue for public comment a draft strategic plan** with additional details and timelines associated with achieving the international harmonization objectives described above.
7. Commencing with FY 2024, **publish an annual assessment of the international harmonization activities** described the strategic plan above, including the progress assessment described in subparagraph 3 above.

In January 2023, FDA and Health Canada started a joint pilot to test the use of a single eSTAR submitted to both regulators.

IMDRF/RPS WG/N9(Edition 3) FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices Version 0.7 (XXXX-XX-XX)

STATUS: eSTAR INCOMPLETE This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and not reviewed. You will be notified by a standard eCopy Hold email.

Introduction

This template is intended for use in both constructing a non-in vitro diagnostic medical device premarket application/ submission, and in being a resource of non-in vitro medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A Red Bar indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions and/or feedback?
A: Questions and feedback regarding this template can be sent to eSubFbk@fda.hhs.gov.

Q: What if I have several devices in one submission?
A: When a question asks about a device, consider the question as it applies to any device within the submission.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices, and therefore should be ignored.

Q: Is eSTAR compatible with Mac computers?
A: Yes. However, Mac computers will add hidden dot files (e.g., ".Trashes") to thumb drives by default. These dot

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.

Version History

0.7 (XXXX-XX-XX): Added Safety and Performance information to the Predicates and Substantial Equivalence

Application/Submission Type

Application Jurisdiction: ○ US FDA ○ Health Canada

Thank you!

- CDRHInternational@fda.hhs.gov
- CDRH International Programs | FDA
- Office of Global Policy and Strategy | FDA


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Regulatory Convergence and Key Updates of the Brazilian Regulatory Framework for Medical Devices

MedCon Conference 2023

Augusto Geyer

MEDICAL DEVICES OFFICE

Brazilian Health Regulatory Agency

Agência Nacional de Vigilância Sanitária – ANVISA

26 April 2023

Medical Devices Office

Head count:

Pre-market authorization: 48

Inspection, enforcement and MDSAP: 32

Post-market surveillance: 7

- Review of submissions for registration, notification, renewal, changes and cancellation of MD
- Issuance of Medical Devices registration requirements and guidance’s
- Provide information regarding the status of regulated products
- Support to GMP inspections for enforcement and certification processes
- **PROMOTE REGULATORY CONVERGENCE**

Origin of Licensed Medical Devices in the Brazilian Market

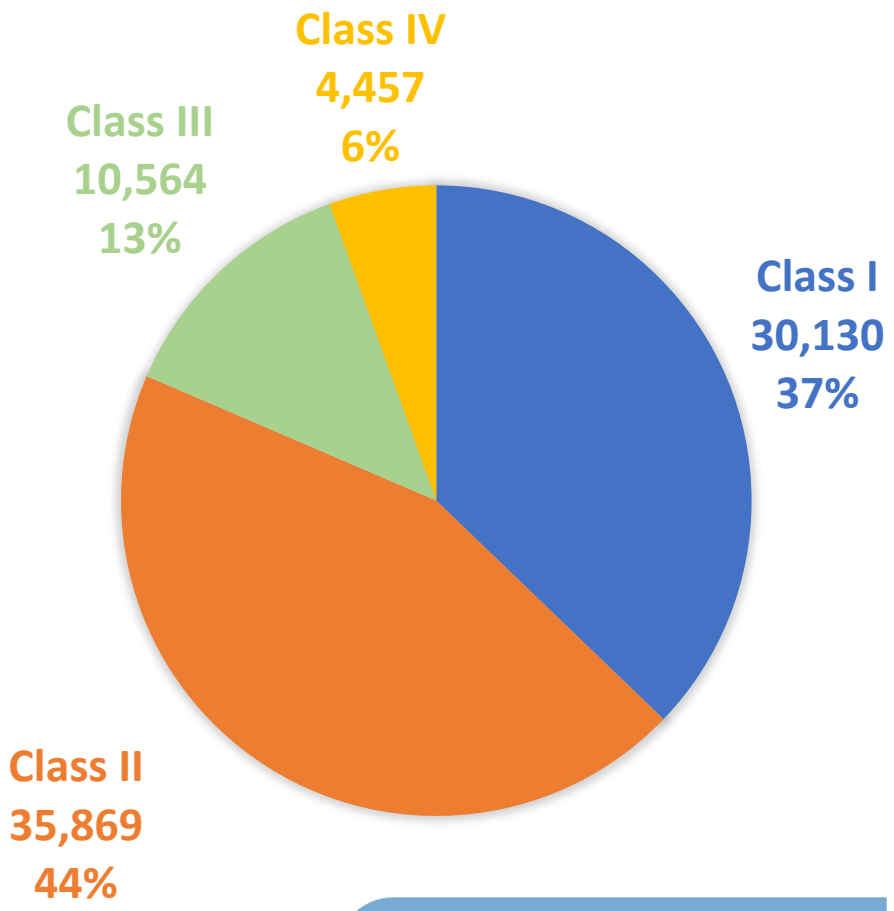
(Jan 2023)

Position	Country	# of licenses	%
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	United Kingdom	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%

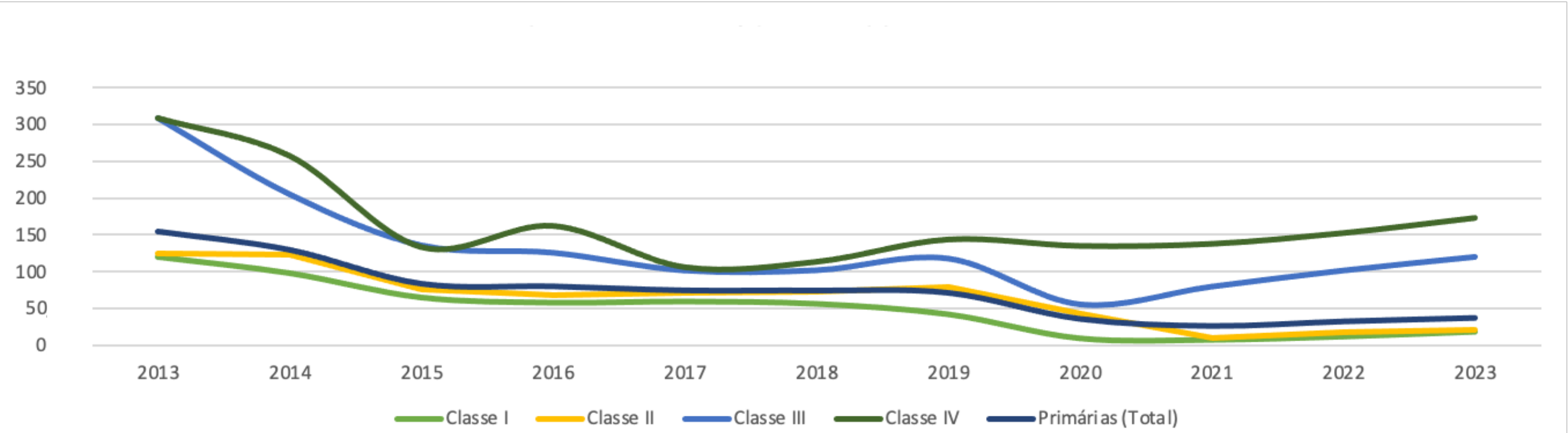
Imported – 68.4%

Licensed Medical Devices per Risk Class



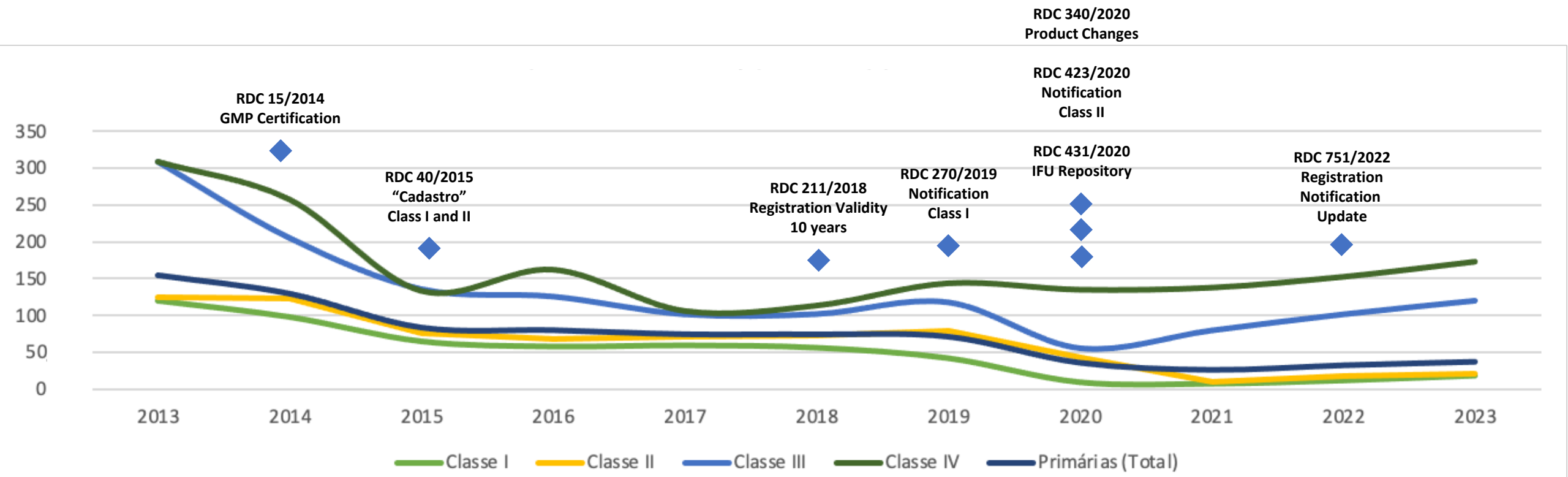
Total
81.020
Authorized
Medical Devices
(Jan 2022)

Medical Device Market Authorization



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

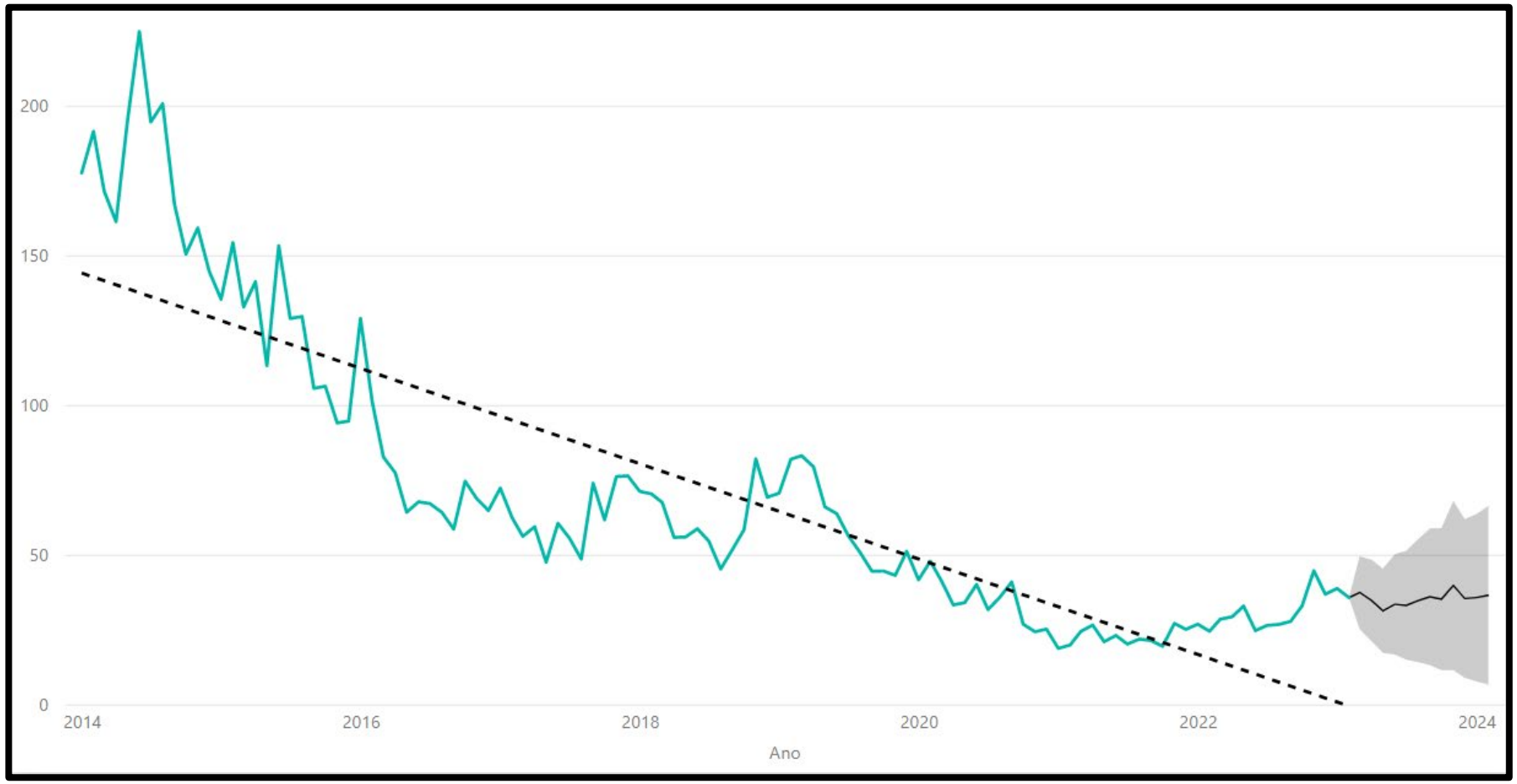
Medical Device Market Authorization



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

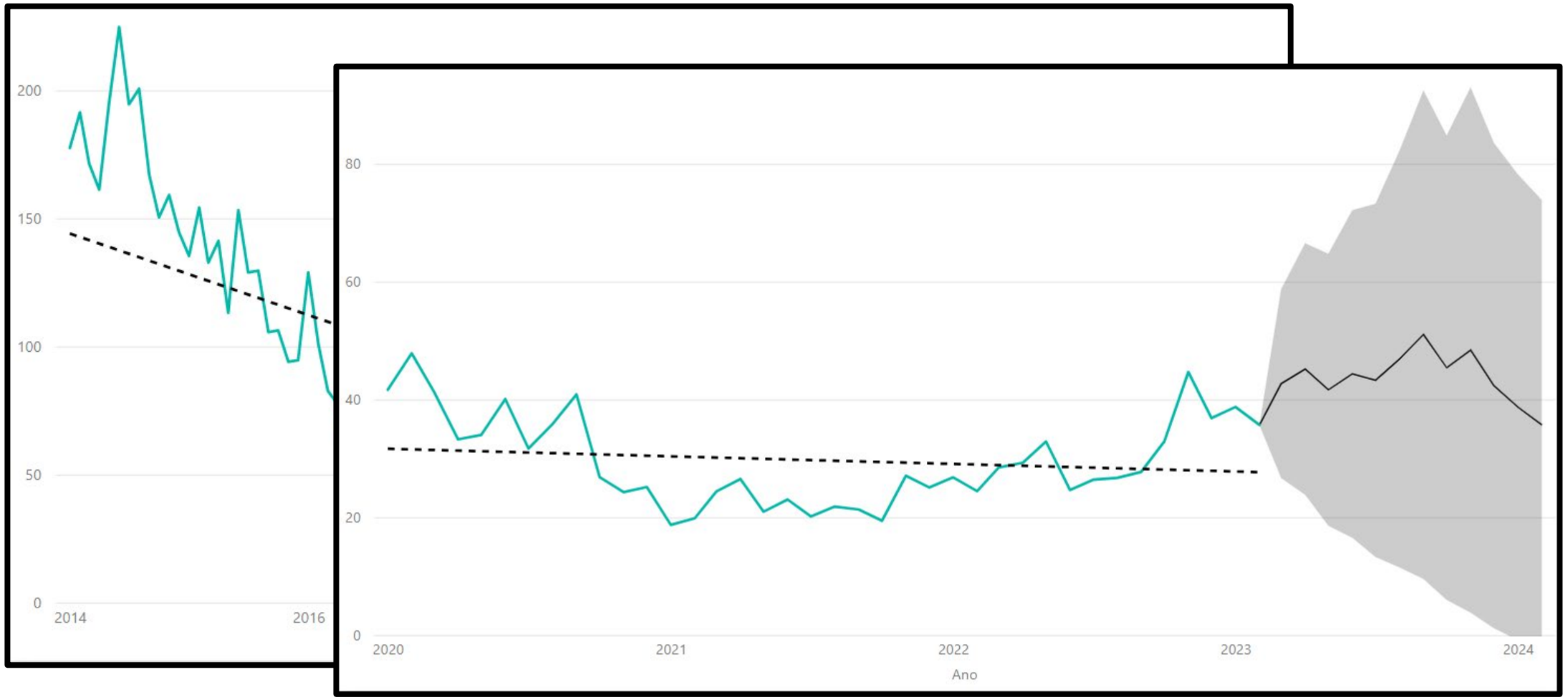
Medical Device Market Authorization

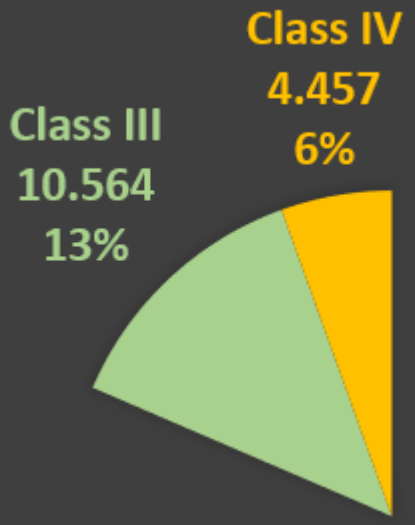
Average Time to Final Decision from ANVISA – All Risk Classes (days)



Medical Device Market Authorization

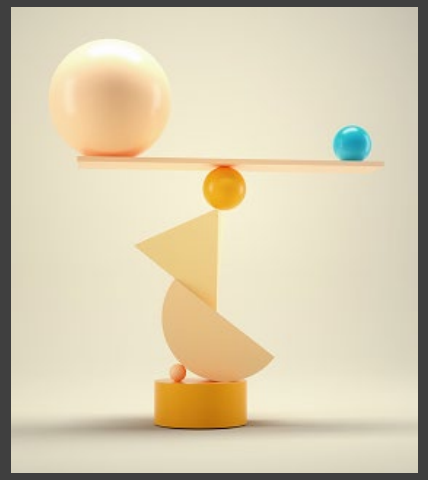
Average Time to Final Decision from ANVISA – All Risk Classes (days)





Small portion of the universe of medical devices

BUT



Heaviest part of the regulatory pre-market effort

Simplification of work processes for lower risk products

AND

Better use of the workforce

Licensing of Medical Devices

RDC 751/2022

- Definitions and classification rules updated considering new technologies
  - Software as Medical Device – linked to RDC 657/2022
  - Nanomaterials
  - Manufacturers (legal manufacturer and manufacturing sites)
  - Notification (low risk products)
  - Regulatory assessment revision
- Consolidation with other regulations – MD changes; e-IFU
- Simplification of required administrative documents
- Good Regulatory Practices and Regulatory Convergence
- Effective since 1st of March, 2023

Licensing of IVD MD

New RDC soon (Revision of RDC 36/2015)

- Completion of the consolidation of contributions from the public consultation
- Submission of the final text for deliberation by the Collegiate Board of Anvisa
- Definitions and classification rules updated according to IMDRF/IVD WG/N64 FINAL:2021 – Principles of IVD MD Classification
- Consolidation with other regulations – MD changes; e-IFU
- Simplification of required administrative documents
- Good Regulatory Practices and Regulatory Convergence
- Expect to publish the RDC in the 1st semester 2023
- Effective date will be 180 days after publication

Regulatory Convergence

IMDRF International Medical Device Regulators Forum

MERCOSUL

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

World Health Organization

Bilateral agreements

ISO

IEC

Implementation of IMDRF Documents

- **Unique Device Identification**
  RDC 591/2021 (Long-term project)
- **Update of the Essential Requirements of Safety and Performance**
  Consolidation of contributions to public consultation
  Mercosur harmonization
  (IMDRF/GRRP WG/N47FINAL:2018)
- **Update of Medical Devices Risk Classification Rules**
  GHTF/IMDRF basis – RDC 751/2022
- **Adoption of the IMDRF ToC as an option of submission format**
  Regulated Product Submission (RPS)

Implementation of IMDRF Documents

- **Regulation for Software as Medical Device**
  RDC 657/2022
- **Regulation for Personalized Medical Devices**
  RDC 305/2019
- **Clinical Investigation, Clinical Evidences and Clinical Evaluation**
  Guidances 29/2019; 30/2019; and 31/2021
- **MD Cybersecurity Guide**
  Guidance 38/2020
- **Medical Device Single Review Program (MDSRP)**
  First steps

WHO Global Model Regulatory Framework for Medical Devices including IVDs

World Health Organization

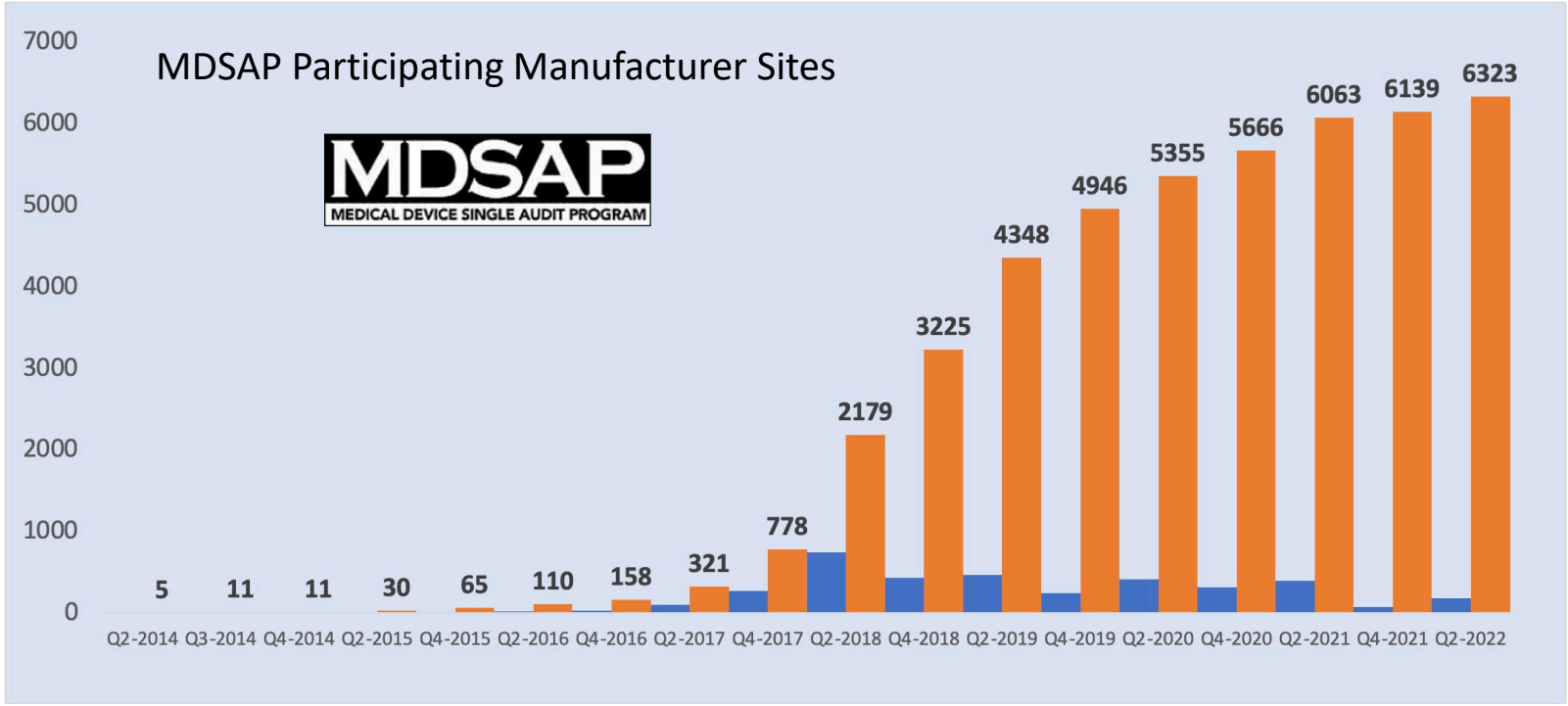
- **Use of GMRF recommendations to improve regulatory processes**
  - The second version of the GMRF is expected to be published in May 2023
- **Anvisa carried out a comprehensive exercise with Global Benchmarking Tool (GBT+) to diagnose the actions and areas that must be improved**
  - Not including the entire universe of medical devices
- **Expectation to perform an internal exercise with GBT+MD in the future (Fact Sheets)**
  - National Regulatory System
  - Registration and Marketing Authorization
  - Vigilance
  - Market Surveillance and Control
  - Licensing Establishments
  - Regulatory Inspection
  - Laboratory Testing
  - Clinical Trials Oversight
  - Glossary and Definitions

Medical Device Single Audit Program

MDSAP Members

MDSAP Official Observers

MDSAP Affiliate Members



GMP certificate is required for registration of classes III and IV medical devices

GMP rules are provided on RDC 665/2022 (update from RDC 16/2013) – “Mercosur” harmonization

Medical Device Single Audit Program

Number of GMP Certificates Issued Based on MDSAP Reports by ANVISA per Year

Year	# GMP Certificates Issued Based on MDSAP Reports (% of total)
2017	38 (4.7%)
2018	107 (19,3%)
2019	374 (48,7%)
2020	544 (49,1%)
2021	529 (51,4%)
2022	621 (59,7%)
2023	103 (69,1%)

Until 28 February

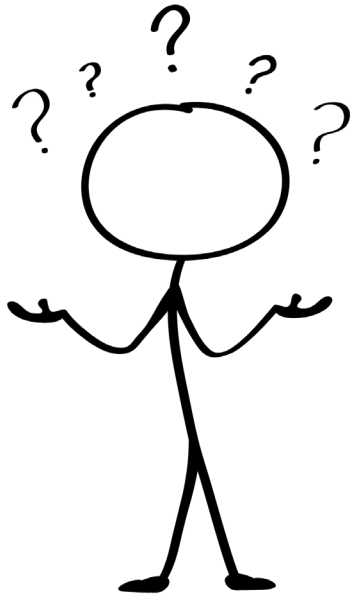
What is the definition of regulatory reliance according to the World Health Organization (WHO)? (Poll Question)

a) 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

b) The process of one regulatory authority relying on the work of another regulatory authority for the purposes of regulatory decision-making

c) The process of regulatory authorities delegating their regulatory functions to non-governmental organizations

d) The process of regulatory authorities collaborating with industry stakeholders to develop new regulatory policies



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

<u>Structured regulation on reliance – RDC 741/2022</u>

Pathway for abridged review process

Normative Instruction for MD and IVD MD under development

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

Reliance Mechanisms for Pre-Market Authorizations

<u>Conditions that will apply</u>

Agreement on the exchange of confidential information with the relied NRA

Classes III and IV – Registration processes

Product should be essentially the same

- Same indications for use
- Same mfg. 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


Access
Time
Safety

THANK YOU!

OBRIGADO!

MEDICAL DEVICES OFFICE

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área especial 57 - Lote 200
CEP: 71205-050
Brasília – DF
Brasil

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Industry Perspectives on Convergence

Tammy Steuerwald

Global Head Regulatory Policy, Foundational Principles & Supranational Organizations

Roche

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

RAPS

Convergence and Reliance are foundational to:

- Build a **Sustainable and Efficient** Regulatory Framework
- **Accelerate** access
- Ensure **Global Health**

Time to Diagnosis and Treatment Matters

More than 9 of every 10 cases of cervical cancer are caused by HPV and can be **prevented**[1] with early detection

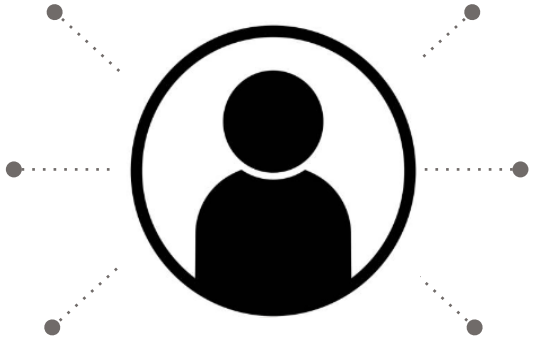
HPV

Breast Cancer

Early detection and [breast cancer] treatment has proven successful in high-income countries and should be applied in countries with limited resources where some of the standard tools are available[4]

The spread of TB is **preventable** when diagnosed early and, in most cases, treatable[2]

TB



Heart Disease

Early detection of cardiovascular disease can **be the difference between life and death**[5]

Earlier diagnosis **improves Covid-19 prognosis**[3]

Covid

Alzheimer's

An **early diagnosis can improve the quality of care and quality of life** and may reduce the financial and emotional impact of the disease[6]

1. https://www.cdc.gov/hpv/parents/cancer.html. Accessed March 27, 2023.
2. https://www.cdc.gov/niosh/topics/tb/default.html#:~:text=TB%20is%20preventable%20and%2C%20in,by%20available%20anti%2DTB%20drugs. Accessed March 27, 2023.
3. Earlier diagnosis improves COVID-19 prognosis: a nationwide retrospective cohort analysis, June 9, 2021
4. https://www.who.int/news-room/fact-sheets/detail/breast-cancer. Accessed April 2023.
5. https://www.cardiophoenix.com/news/the-importance-of-the-early-detection-of-cardiovascular-disease. Accessed April 2023.
6. https://www.alz.org/professionals/public-health/public-health-topics/early-detection-diagnosis,. Accessed April 2023.

Jurisdiction Specific Requirements Can Delay Patient Access

- Product classification
- Clinical trial/evidence
- Local standards
- In country lot testing
- Unique dossier formats
- Unique labeling requirements
- Country specific inspections
- Country specific post market reporting

How Do we Accelerate Access?

Converge to One High International Best Practice

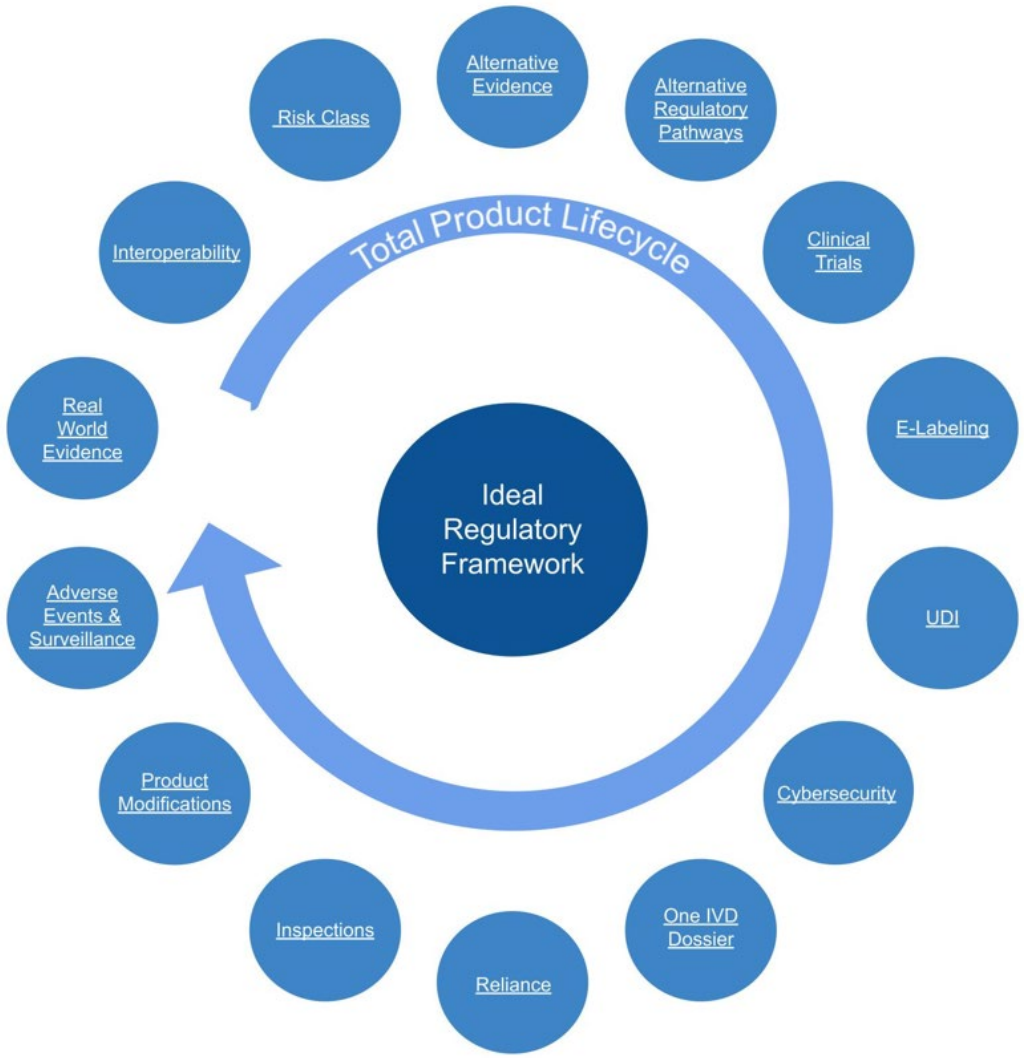
Accelerate Access and Improve Health Outcomes

Divergent Regulation

Convergent Regulation

International Medical Device Regulators Forum (IMDRF)

Apply Convergence to the Total Product Lifecycle

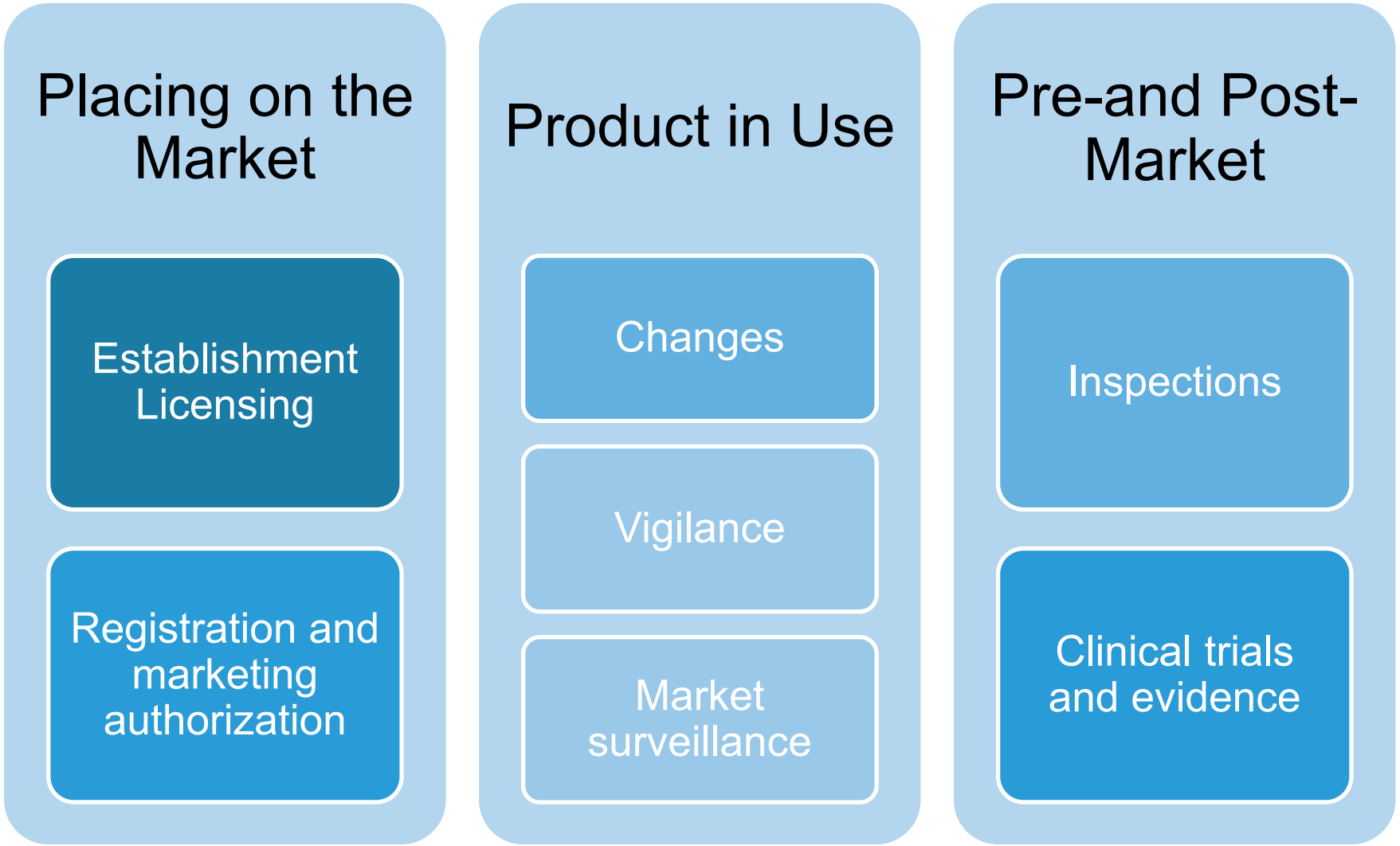


Drive to one high standard no matter the jurisdiction

- MD/IVD **classifications** drive downstream requirements
  - IMDRF MD Classification
  - IMDRF IVD Classification
  - SaMD Classification
- Implement **expedited pathways** for innovative products and **emergency use authorization**
- Align to IMDRF **Essential Principles** Guidance to drive evidence requirements
- Leverage **global clinical data** to avoid unnecessary country specific clinical trials
- Adopt **e-labeling** to facilitate quicker availability of product information
- Implement IMDRF **SaMD, UDI and cybersecurity** guidance's
- Adopt a risk-based approach for **product modifications**
- Allow the use of **RWE**
- Drive **digitization** of the regulatory process
- Embrace and **implement Reliance throughout the TPLC**
  - Market authorization
  - Pre and post inspections
  - Product Changes

Implement Reliance throughout the TPLC

The WHO Requires Implementation of Reliance as a Measure of Regulatory Maturity (GBT+)[1]



1. WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF), WHO/BS/2022.2425, June 2022, draft. Final anticipated May 2023.

Keep the Patient at the Center of Collaboration

Patients Need Supranational Organizations to Work Together

At the center of global convergence is IMDRF.

- Longest history of establishing international best practice (1992 as GHTF).

- WHO working to establish GBT+ and GMRF.
- Making great strides in aligning to IMDRF.
- **Encourage WHO to align with IMDRF to avoid confusion and promote convergence to one high standard.**

- Newest entity focused on international best practice (Previously AHWP)
- Encourage GHWP to:
  - Adopt established IMDRF best practices.
  - Avoid redundant work items and outputs.
  - Focus on international best practice.

IMDRF is the Leading Supranational Organization for International Best Practice for regulation of MD/IVDs

Success Factors:

- **Longest history** of establishing international best practice (1992 as GHTF)
- Comprised of Regulators who **actively engage** in collaboration and work items
- Appropriate **balance** between Regulators and industry

The IMDRF Management Committee recently announced a new membership category - **IMDRF Affiliate Member**

- As an IMDRF Affiliate Member, the Regulator may attend IMDRF Management Committee open meetings and participate in open working groups.

Recommendation:

- **Industry to encourage Affiliate membership and Regulators are encouraged to learn more.**
- Affiliate membership can further facilitate global convergence.
- Several Regulators have already shown interest or been accepted.
  - Egypt, Israel, Saudi Arabia, S. Africa, Swiss Medic, Kenya, and the African Medicines Forum
- Official Observers include Argentina and the WHO.

IMDRF International Medical Device Regulators Forum

IMDRF Membership Application Form (Cover Page)

Applications must be submitted at least two (2) months before an IMDRF Management Committee meeting, which are usually held two (2) times each year (for example, March and September (variable each year)).

If the application is for a Regional Harmonization Initiative, the application must be submitted by the Chair of the RHI. Any questions should be directed to the Chair of the IMDRF Management Committee which is listed on the IMDRF website.

Contact Details for Applicant:

Name of Applicant Organization:	
Contact Person(s):	
Title:	
Address:	

To accelerate patient access:

- Implement international **best practice**
- Implement regulatory **reliance** across the TPLC
- Strive for **harmony** between supranational organizations

Doing so will:

- Build **strong sustainable** and efficient regulatory frameworks
- **Accelerate** patient access
- Help ensure **Global Health**

Thank you!!

Tammy Steuerwald, JD, Global Head of Regulatory Policy, Foundational Principles and Supranational Orgs
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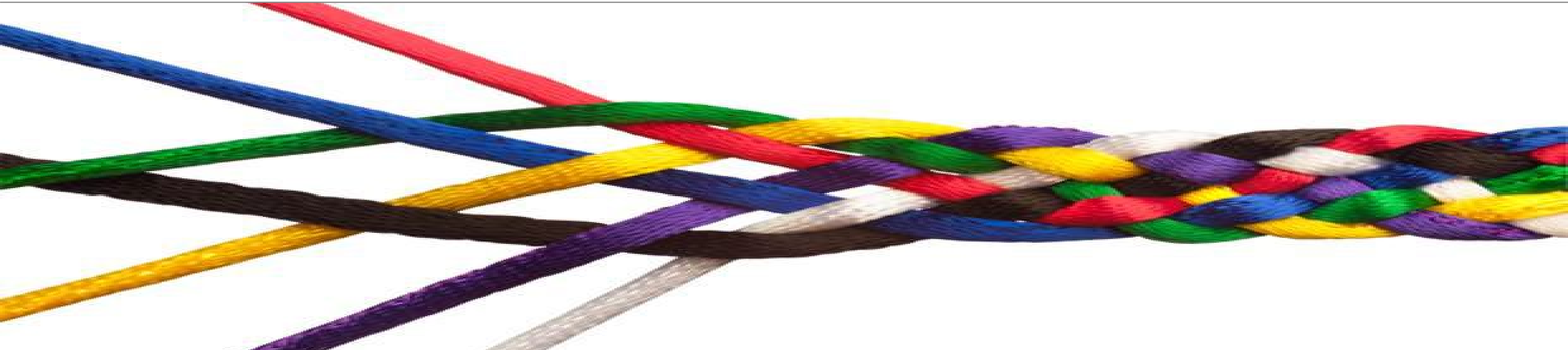

MEDCON CONFERENCE
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Session speakers

Erin Cutts
Senior International Policy Analyst
FDA OCD - CDRH

Augusto Bencke Geyer
Deputy General Manager of the Medical Devices Office
ANVISA

Tammy Steuerwald
Global Head Regulatory Policy, Foundational Principles & Supranational Organizations
Roche

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