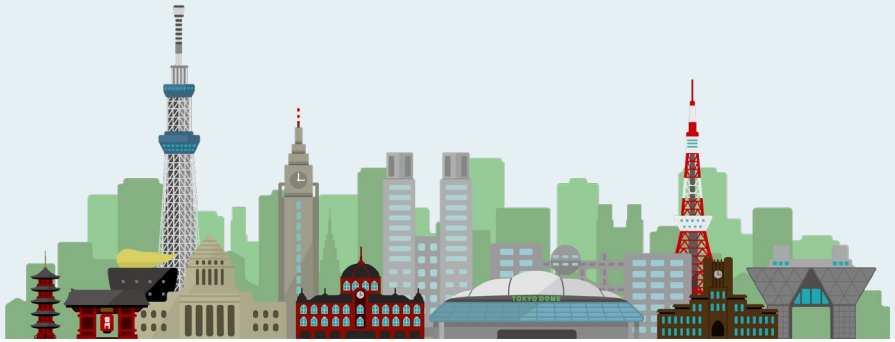
IMDRF International Medical Device Regulators Forum



Reliance in Practice – Examples and Opportunities for Expansion

Brad Spring, Global Head of Regulatory Policy & Intelligence
Roche Diagnostics

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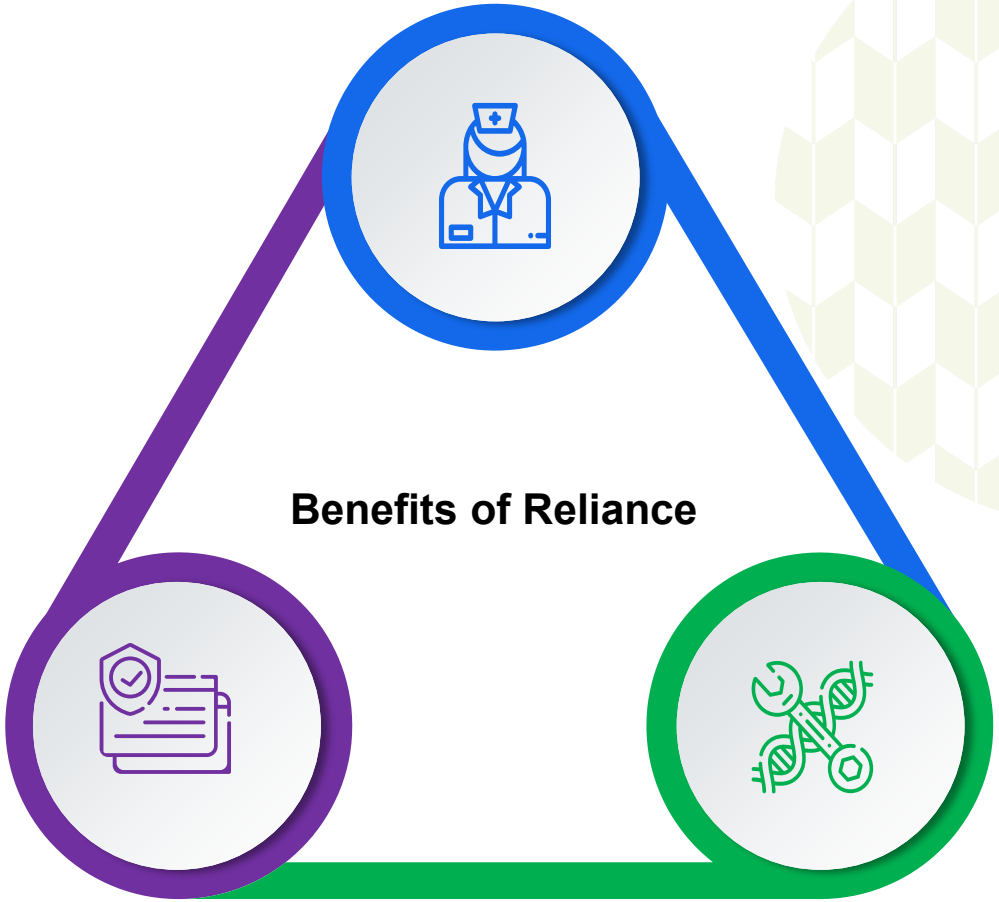
Multiple Advantages

Patients and Providers

Timely access to safe & effective devices



Regulatory Authorities

Efficient utilization of resources by avoiding duplication of work, providing opportunities to strengthen systems. Maintaining sovereignty over decision making.

Device Industry

Avoidance of duplicative work. Streamlining submissions and global supply systems with predictable and timely approvals.

Derived from Innovative Approaches to Regulatory Reliance FIFARMA-IFPMA Joint Webinar, May 8, 2024, Janis Bernat IFPMA

Types of Reliance Pathways Across the Product Lifecycle

Total Product Lifecycle	Abridged Pathway	Work Sharing	Regional Reliance	Unilateral Recognition	Mutual Recognition
Pre-Market Registration	A procedure that allows an NRA of one country to use another country's assessment to make its own decision on product approvals, data sharing, inspections, etc.	NRAs of two or more jurisdictions share activities to accomplish specific regulatory tasks	These pathways usually encompass broad industries that would include medical products. The European Union is an example of Regional Reliance	When one country recognizes the approval or other information from another country with no reciprocity	When two or more countries agree to recognize each others approvals or other information.
QMS/Inspection					
Clinical Evidence/Analytical Data					
Post Approval Changes					
Post Market Surveillance (including Vigilance Reporting)					

Example 1: Paraguay - Pre Market IVD Submissions

Product	Classification	Reference Country*	Registration (working) days – Simplified Process	Registration (working) days – Regular Process
Roche Elecsys® TSH Roche Elecsys® T3 Roche Elecsys® T4 Roche Elecsys® FT3 III Roche Elecsys® FT4	II	Germany (IVDR CE mark and Certificate of Free Sale)	20	134 (average working days)

*Reference country can be:

- PAHO/WHO Reference Regulatory Authorities
- IMDRF Management Committee member countries
- Countries with bilateral agreements with DINIVISA
- Must also obtain a Certificate of Free Sale from the reference country
- The product must be marketed in any of the countries listed above

Examples of some of the items to be submitted:

- Certificate of conformity to ISO 13485
- Product stability study for those that require cold chain
- All labeling and packaging artwork
- Proof of company registration in Paraguay
- Certificate of Free Sale from reference country

Example 2: Brazil - Pre Market IVD Submissions

Product	Classification	Reference Country	Registration Time – Reliance Pathway (Calendar Days#)	Registration Time – Regular Pathway (Calendar Days#)
ONLINE TDM Methotrexate	III	Canada	122	150- 180 (average)

#Includes time in queue. Actual review times will be shorter

Background

- Normative instruction for MD and MD-IVD approved on April 2024 and became effective June 2024
- Reference Agency/Country are initially, the official members of MDSAP (Australia, Canada, Japan and the United States)
- Product registration certificates from Equivalent Foreign Regulatory Authorities may be used as a trigger for abridged reviews and market authorization

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Opportunities for Expansion

	Communication	Harmonization	Convergence
Pre -Market	Increased transparency and sharing across NRAs. Leverage mfrs for learning	Increase standardization of data to improve sharing of data and ease submissions	Agree on the adoption of internationally recognized standards
Clinical/Analytical	Share trial and testing designs to build confidence in the robustness of data	Align on the classification of SW and the type of information to be submitted	Agree on global evidentiary standards for each type of device.
Change Mgt	NRAs share what types of changes require submission and why	Harmonize classification systems and apply PCCP approach to changes	A universal definition of a “significant change”
Post-Market	Capacity building for new inspectors globally.	Expand MDSAP globally	Adopt ISO 13485 globally

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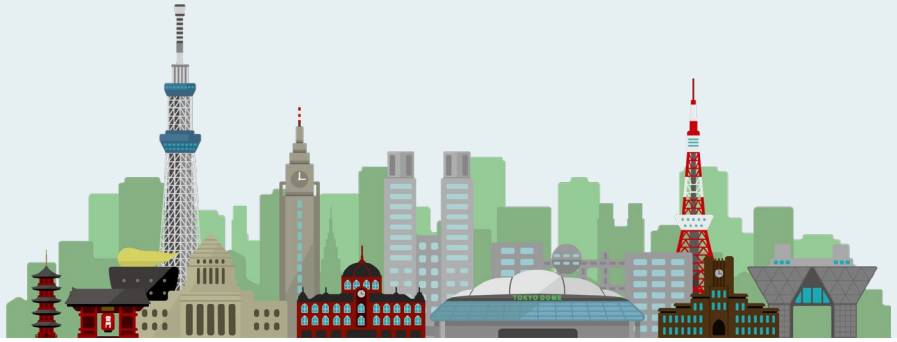

Thank you / Questions?

Acknowledgements:

Juan Diaz Guerrero – Technical Director, Quality, Regulatory, Medical and Scientific Affairs, **Paraguay**

Giovanna Oliveira – Regulatory Affairs Specialist, **Brasil**