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Jornada Regulatória

Maio/2026

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Reliance Regulatória na América Latina: Impactos para o Acesso e a Conformidade de Dispositivos Médicos

Maio/2026

Reliance Global Efforts

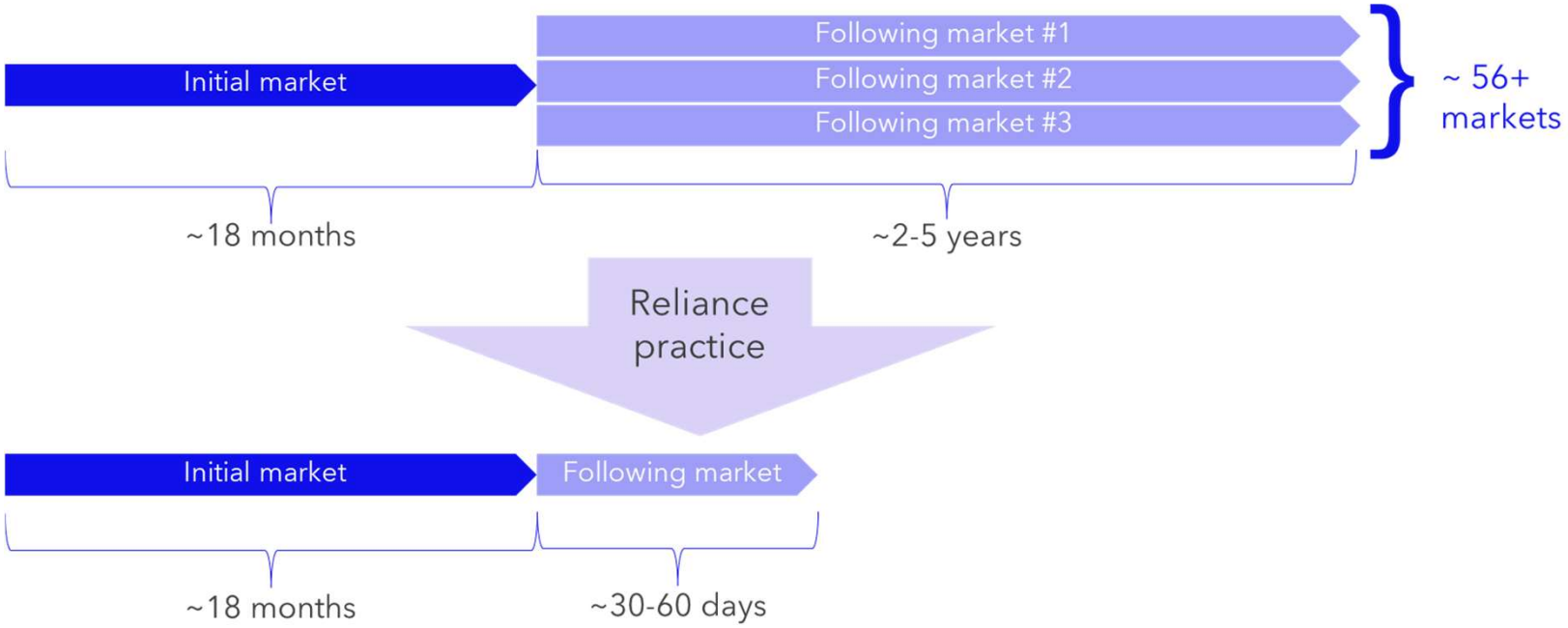
IMDRF Reliance Playbook: The answer to a global question

- An **international methodology** written by regulators for regulators with all levels of maturity.
- Designed specifically for **MD/IVDs** ensuring it is jurisdiction-appropriate & supports sovereignty.
- Provides a **trusted method** with case studies to implement & evolve a globally convergent reliance program.
- Delivers **tangible patient benefits** through innovation and collaboration.

Principles & Objectives of the Reliance Playbook

- **Retain** sovereign decision-making and accountability
- **Apply** reliance in a risk-based, proportionate manner
- **Build** trust through clarity, communication & confidentiality
- **Increase** efficiency and predictability without lowering rigor
- **Enable** lifecycle use (premarket + postmarket)
- **Engage** stakeholders across the reliance lifecycle

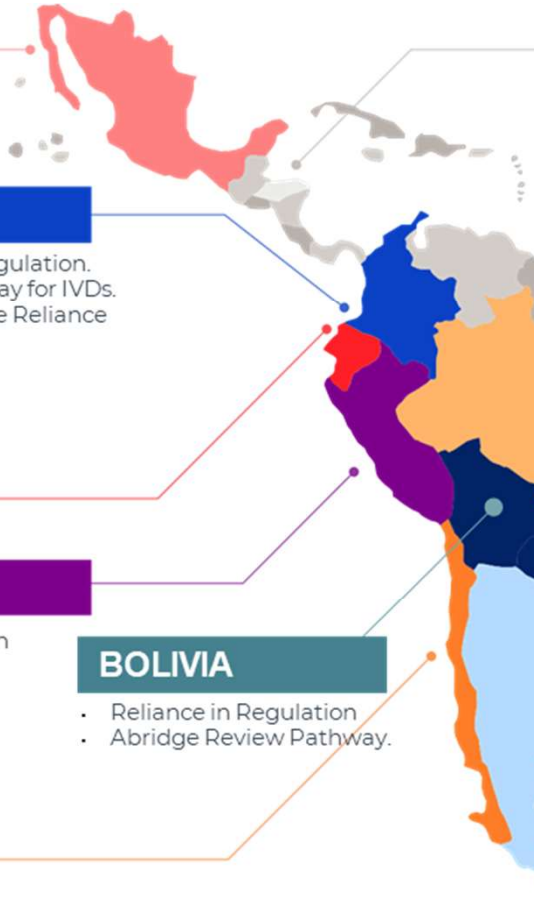
Global Data: The future of medical product regulation is in convergence, harmonization, trust, and reliance[1]



1 "The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on reliance and trust." Azatyan, S., MD, PhD (2020, November 3). WHO Activities: focus on reliance [Conference Presentation], 10th Asia Regulatory Conference. https://arc.ifpma.org/wp-content/uploads/2016/05/ARC_2020_S.Azatyan-WHO-01-11-2020.pdf, page 16.

Reliance
Current status in LATAM

LATAM Reliance Map[1]



MEXICO
- Reliance in Regulation.
- Abridge Review Pathway.
- MDSAP recognition.

COLOMBIA
- Reliance partially in Regulation.
- Abridge Review Pathway for IVDs.
- Draft regulation include Reliance

ECUADOR
- Reliance in Regulation
- Simplied Registration Route.
- MDSAP Recognition.

PERU
- No Reliance Pathway in Regulation.
- MDSAP Recognition.

CHILE
- No Reliance Pathway in Regulation.
- MDSAP Recognition.

BOLIVIA
- Reliance in Regulation
- Abridge Review Pathway.

BRAZIL
- Reliance in regulation.
- Abridge Review Pathway.
- MDSAP recognition.

ARGENTINA
- Reliance in Regulation.
- Recognition Pathway (Low-risk devices)*.
- MDSAP recognition.

CENTRAL AMERICA

Cuba, El Salvador
- Reliance in Regulation.
- Abridge Review Pathway
- MDSAP Recognition.

Dominican Republic & Panama
- No Reliance Pathway.
- Draft regulations include Reliance.

Costa Rica
- No Reliance Pathway in Regulation.

PARAGUAY
- Reliance in regulation.
- Abridge Review Pathway.
- MDSAP recognition.

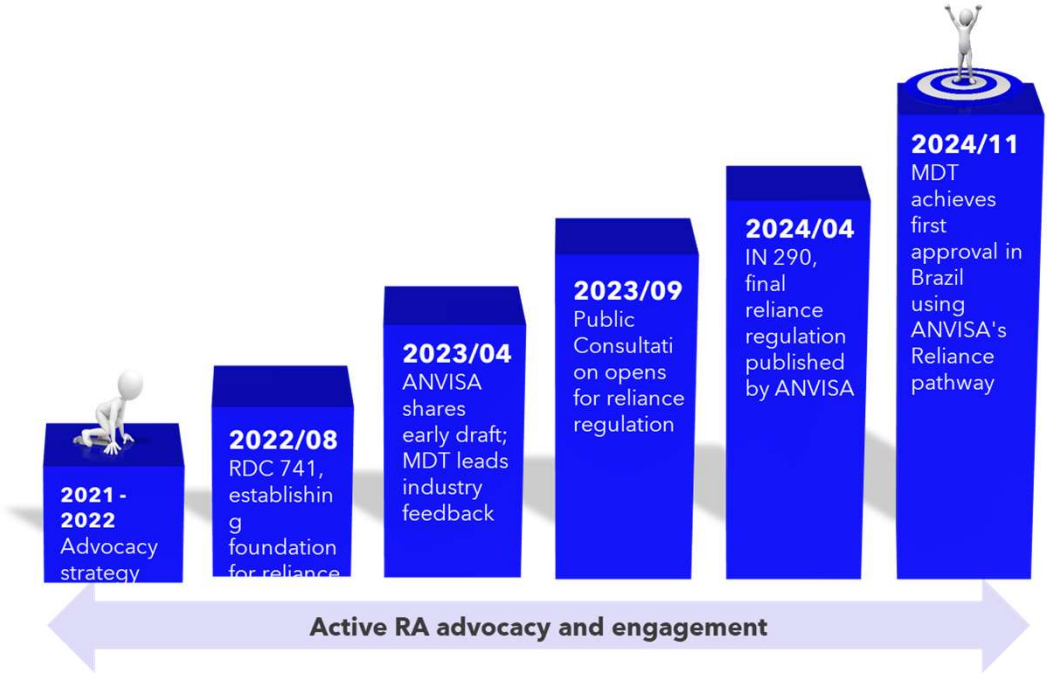
URUGUAY
- No Reliance Pathway in Regulation.

[1]The Reliance Map is based on existing regulatory frameworks and drafts regulations published for public consultations. Does not reflect effectiveness in adoption of reliance and/or operationalization in practice.

Impact in Brazil (cases and results)

Brazil reliance milestone: from advocacy to accelerated approvals

Advocacy strategy and engagement with Brazil's reliance regulation resulted in accelerated approvals



	PRODUTO A (2026/03)	PRODUTO B (2025/06)	PRODUTO C (2024/11)
Typical approval timeline	5 – 7 months (Classe IV)	6 – 9 months (Class IV)	12+ months (Class IV)
Approval timeline under reliance	2 months and 25 dd	< 3 months	< 9 months total (5-day technical review)
Time saved	**~ 43,3%**	**~50-67%**	**~25% overall**
Reference approval used	TGA	US FDA 510(k) clearance	Health Canada medical device license

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Obrigado!

Thank You!