IMDRF Reliance Playbook Implementation

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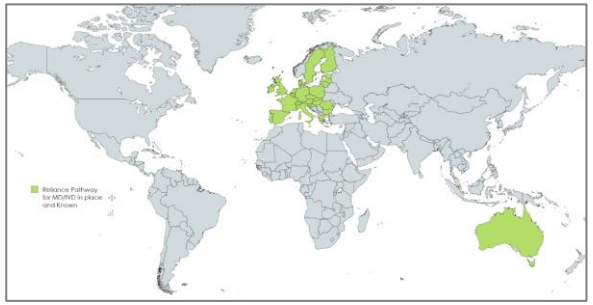
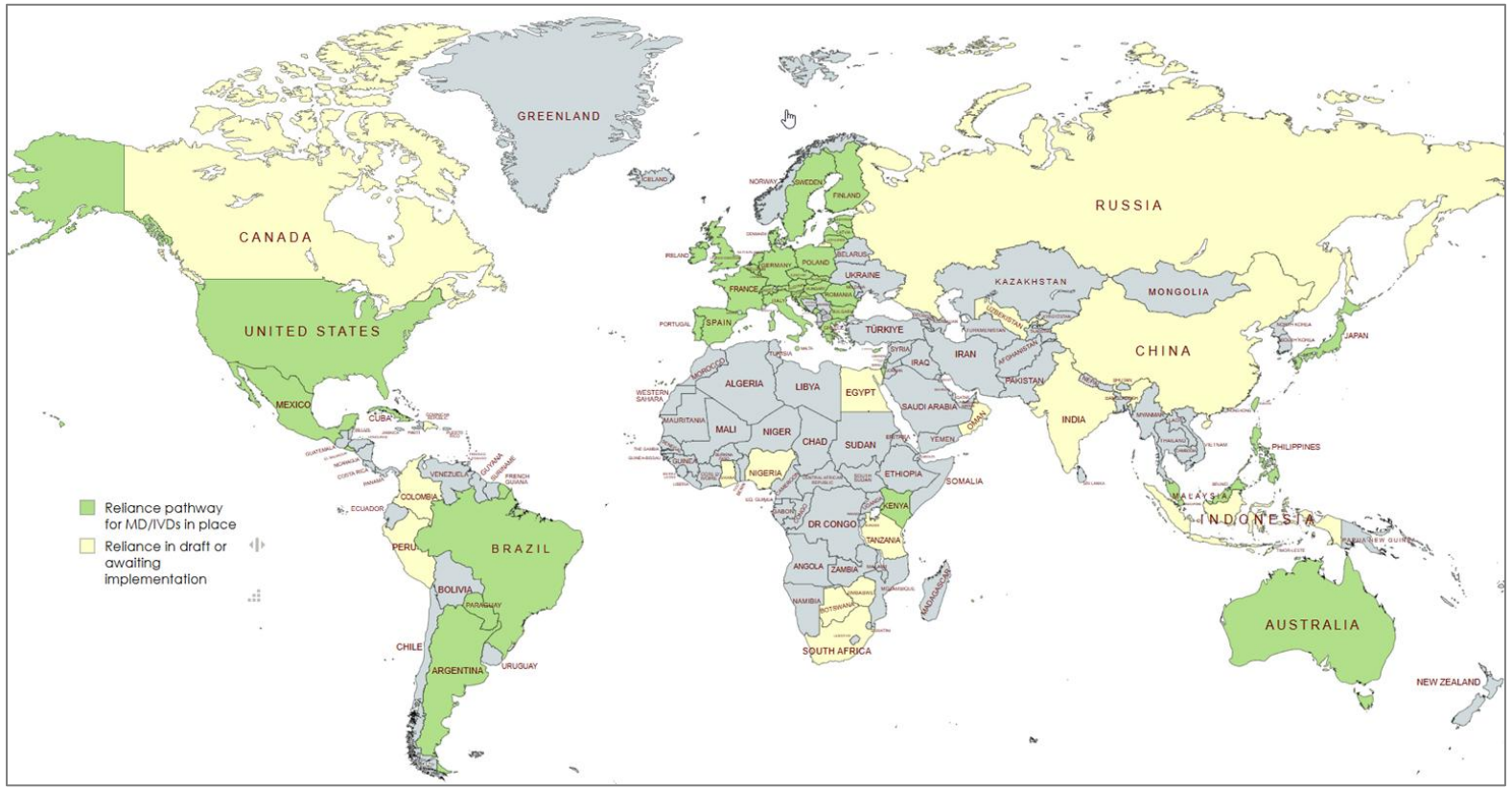
Reliance Practice Growth from 2020 to 2026

IMDRF Members Only



2020 reliance practices in IMDRF jurisdiction



January 2026 reliance practices in IMDRF jurisdictions

Note: there are many ways to interpret whether reliance pathways exist and if they are effective. If you have a question about a particular IMDRF jurisdiction, please let us know and we will do our best to explain our rational. We do our best to get this data as accurate as possible and we are learning together.

Example 1: Australia - Premarket Submission

IMDRF March 2024

Product	Product Description	Time to authorize (working days)	Expected Registration (working days)
Elecsys PIVKA II –New Registration -Class 3	Immunoassay for the quantitative measurement of protein induced by vitamin K absence or antagonist-II (PIVKA-II) in human serum and plasma. The assay is **used as an aid in the diagnosis of hepatocellular carcinoma (HCC).**	5	90
Elecsys HSV-1 and Elecsys HSV-2 – Change Registration–Class 3	Immunoassay for the **qualitative determination of IgG-antibodies to Herpes Simplex Virus type 1, 2**.	43	90
cobas HPV on cobas 5800 (addition of cobas 5800)Change Registration –Class 3	Qualitative in vitro test for the **detection of Human Papillomavirus in clinician-collected cervical specimens**	9	90
DPX-Parvo B19 & Hep A –New Registration –Class 4	In vitro test for the direct **quantitation of parvovirus B19 genotypes 1, 2, and 3 DNA and the direct qualitative detection of Hepatitis A virus (HAV) genotypes I, II, and III RNA in human plasma.**This test is intended for use as an in-process test to quantify parvovirus B19 DNA alone or to simultaneously quantify parvovirus B19 DNA and detect HAV RNA in plasma intended for further manufacture collected from donors of whole blood, blood components, or plasma.	**20**	255

*Based on TGA conformity assessment)

Example 2: Paraguay - Premarket Submission

IMDRF March 2025

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 3: Brazil - Premarket Submissions

IMDRF March 2025

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, Japan, Canada, and the United States)
- Product registration certificates from Equivalent Foreign Regulatory Authorities may be used as a trigger for abridged reviews and market authorization

While Reliance Pathways have greatly increased, clear operationalized pathways that work for MD/IVDs are still limited

Growing Global Momentum

Even though reliance pathways have significantly increased over the last 5 years, much work remains to be done.

Operational Barriers

Significant barriers to operationalize reliance still prevail, hindering clear and efficient implementation.

Regulatory Misalignment for MD/IVDs

- Reliance for MD/IVD is often retrofitted to drug and vaccine regulation.
- Pathway criteria are frequently written based on drug/vaccine characteristics rather than device-specific needs.
- Lack of transparency and stakeholder engagement.
- Lack of following the established process consistently prevents manufacturers from being able to depend on a predictable, repeatable process.

Operationalizing Reliance: Success Criteria, Practical Steps & Sustainability

Design Smart:

- Prioritize publicly available regulatory information over CFG/CFS
- Leverage trusted work products
- Align to IMDRF international best practices & TOC

Engage Early & Often:

- Engage cross-functionally within government & external stakeholders
- Establish a dialogue to support mutual understanding & trust
- Have clear criteria & timelines

Start Small & Scale:

- Start with pilots: define scope, learn fast
- Measure performance + stakeholder feedback
- Refine & mature program

Per the WHO implement Performance Tracking: Use performance-based indicators to track reliance progress and report to the public and legislature

Thank you!!
Gracias!!