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From Concept To Practice: Advancing Regulatory Reliance For Medical Devices

Workshop Outcomes Paper

This paper reflects key insights and practical outcomes drawn from the closed-door Global Regulatory Reliance Workshop which took place on December 5th, 2025, in Bangkok, Thailand. It does not represent a consensus position of IMDRF, GHWP or their members, nor does it replace or duplicate existing guidance.

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Executive Summary

Regulatory reliance has moved from concept to necessity in medical device regulation. Faced with increasing product complexity, constrained regulatory resources, and growing expectations for timely patient access, regulators worldwide are exploring reliance to strengthen regulatory systems. Global guidance documents developed by the World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF) have established clear principles to support this approach*.

Despite this progress, many authorities continue to face challenges translating reliance principles into day-to-day regulatory practice. Recognising this gap, a group of regulators, led by Singapore HSA, Malaysia MDA, Thailand FDA, supported by the World Health Organization (WHO) and APACMed, convened a closed-door **global regulatory reliance workshop** to enable candid exchange on the practical implementation of regulatory reliance. The discussions brought together authorities from multiple jurisdictions and stages of reliance maturity, alongside industry and clinician perspectives, and focused on how reliance can be operationalised responsibly within diverse legal frameworks, regulatory maturity, institutional capacities and public health priorities. The real-world experiences, implementation challenges and emerging practices shared during these exchanges form the basis for the insights and forward-looking considerations consolidated in this paper.

The approach taken recognises that regulatory reliance must be context-specific, risk-based, and legally grounded, rather than anchored in a single model. Practical application across pre-market review, quality management system oversight, and post-approval change is examined, while reaffirming national decision-making authority and accountability. Emphasis is placed on implementation, including defining "sameness," managing acceptable variation, calibrating review depth based on risk. A key outcome from this workshop is alignment on key success metrics, ensuring reliance impact is being measured by outcome-focused indicators in order to achieve improved patient outcomes and efficiency throughout the entire healthcare ecosystem.

Intended for regulators, policymakers, and stakeholders involved in medical device oversight, this white paper consolidates practical lessons and proposes a common foundation for progress, supporting authorities at different stages of maturity in strengthening regulatory systems through reliance, and ultimately contributing to more efficient regulation, stronger oversight, and improved patient access to safe and effective medical devices worldwide.

* At the time of the workshop, the IMDRF playbook was in draft form. The final version was officially published during the editing period of this report and has been reviewed to ensure full alignment.

1. Why this paper: moving beyond principles to practice

Regulatory reliance is increasingly recognised as a necessary tool to address growing regulatory complexity, constrained resources and expectations for timely patient access to medical devices. Global guidance from the WHO and the IMDRF has established clear principles for reliance, and its legitimacy is no longer in question.

However, experience shared across jurisdictions shows that implementation remains uneven and cautious, with reliance often applied selectively, during public health emergencies, or through limited pilot initiatives with no legislative support, or only limited to certain regulatory activities instead of across the entire product lifecycle, or in a restricted way that offers no actual benefits comparing to traditional pathway. A persistent gap remains between global principles and day-to-day regulatory practice, in order to fully harness the benefits of reliance.

Discussions during the workshop highlighted four recurring barriers that continue to hinder broader adoption, expansion and optimisation of reliance pathways:

- **Trust and confidence between regulatory authorities**, including challenges related to transparency, consistency of regulatory decisions, and confidence in the quality of reference authority assessments.
- Concerns related to **regulatory capacity and capability**, including potential deskilling among reviewers, where reliance may be perceived as reducing scientific capability, judgement or professional development, rather than reallocating effort towards higher-risk or value-added activities.
- **Government and policy-level concerns around sovereignty**, including fears that reliance may dilute national decision-making authority, despite reliance frameworks explicitly preserving final regulatory responsibility.
- The **absence of clearly defined success metrics**, with reliance programmes sometimes measured through "vanity metrics" (e.g. number of agreements or pathways) rather than meaningful indicators such as time saved for patient access, accelerated innovation, regulatory authority internal resource optimisation, and institutional strengthening.

In parallel, regulators reported practical challenges that are insufficiently addressed in existing guidance, including WHO Good Regulatory Practices (GRP), Good Reliance Practices (GRelP), and IMDRF playbooks. These include internal change management, strengthening inter-agency trust, access to assessment data, and alignment across pre-market and post-market functions.

The workshop responded to these realities by shifting the discussion from whether reliance should be used to how it can be implemented responsibly and sustainably. It builds on WHO Good Regulatory Practices and Good Reliance Practices, and aligns with IMDRF concepts and playbooks, without redefining established principles. Instead, it translates them into implementation-focused insights grounded in real regulatory experience.

> ***"Effective reliance is essential for strengthening health systems and improving patient access."***
>
> ***— Dr Muralitharan Paramasua, MDA Malaysia***

By bringing together regulators, industry and clinician's perspectives, the workshop—and this paper—aim to demystify reliance, surface true regulatory journeys, clarify what success should look like for patients, regulators and industry, and support the development of a more informed, trusted and collaborative reliance ecosystem.

2. Reliance in Practice: What Actually Worked?

2.1 Reliance across the medical device lifecycle

Discussions revealed that regulatory reliance is most effective when applied deliberately, transparently, and across the medical device lifecycle rather than limited to initial market authorisation. While legal frameworks and maturity levels vary, regulators consistently highlighted common practices that have delivered tangible value in real-world implementation.

Pre-market authorisation

Authorities noted that **pre-market reliance is often the initial and most familiar application of reliance**, particularly where trusted assessment reports or conformity assessment outputs are available. However, discussions consistently highlighted that limiting reliance to initial authorisation alone delivers only partial benefits and creates downstream bottlenecks if not extended across the product lifecycle.

In practice, regulators described selective use of pre-market reliance through:

- Assessment reports and scientific summaries from trusted reference authorities
- Clinical or performance evaluation outputs aligned with international standards
- Conformity assessment and audit reports, including MDSAP where applicable

Risk-based scoping was identified as essential, with reliance more readily applied to well-established technologies and clearly defined product configurations. Regulators emphasised that pre-market reliance does not remove oversight, but rather leverage the great work being done by other competent authorities or organisations which enables reallocation of effort toward activities that must remain local, including market-specific requirements and post-market responsibilities.

Quality Management Systems (QMS)

During the workshop, regulators recognised QMS oversight as a practical area where reliance can deliver efficiency gains, particularly through the use of internationally recognised audits. Reliance on MDSAP audits and ISO-based inspections conducted by trusted bodies was discussed as a means to reduce duplication while maintaining confidence in manufacturer compliance.

Authorities noted that, where appropriately implemented, QMS reliance can free up regulatory resources to focus on higher-risk activities, such as complex technologies, emerging safety signals or post-market oversight. Effective use of this approach depends on confidence in audit quality, clear oversight of auditing organisations, and timely access to audit findings and corrective action outcomes.

Post-market oversight and post-approval change management

Discussions across regulators converged on post-market oversight and post-approval change management as the most critical, and currently least mature, area for regulatory reliance. While reliance is increasingly applied at the point of initial market authorisation, authorities noted that limiting reliance to first approval alone constrains its long-term value and creates downstream inefficiencies as medical devices evolve.

Drawing on practical experience, Australia TGA highlighted that reliance already plays an important role beyond initial approval, including the use of comparable overseas evidence, MDSAP audit reports, and structured information sharing between regulators to support earlier identification of safety issues. As noted during the workshop, this approach allows regulators to "focus on the things that we need to focus on from an Australian perspective," while retaining full sovereign decision-making and accountability.

Singapore HSA emphasised that reliance must be understood as a dynamic, lifecycle-based approach rather than a static regulatory fast track. Reflecting on its own journey, HSA noted that "reliance is not static – it doesn't stop at the moment we implement something," and that confidence built through experience has enabled the authority to progressively adjust review depth, rebalance pre- and post-market resources, and expand reliance pathways over time. Importantly, HSA shared that early internal concerns around potential "deskilling" required deliberate mindset shifts, reinforcing that reliance enhances, rather than replaces, regulatory capability.

From both regulatory and industry perspectives, participants highlighted that the absence of structured reliance approaches for post-approval changes leads to duplicated reviews, and delayed implementation of incremental improvements. This fragmentation was associated with delays in implementing incremental improvements and safety enhancements, increased regulatory workload without commensurate risk reduction, and reduced willingness to introduce updates in smaller or reliance-based markets.

Breakout discussions provided more granular insight into why post-approval changes remain a persistent pressure point for reliance. Participants emphasised that reliance for changes cannot function without clear communication mechanisms anchored in the initial reliance decision, and that maintaining sameness over time is essential starting with "apple and apple" at registration and avoiding divergence into "apple and banana" products across markets as changes are introduced. Discussions highlighted that effective post-approval change reliance depends on early agreement on how changes will be communicated and assessed, clear roles for manufacturers and regulators, and the ability to accommodate limited national requirements without undermining the basis of reliance. Existing models, such as the WHO Collaborative Registration Procedure (CRP), were cited as useful reference points for structured information flow following initial authorisation, beyond emergency or donor-funded contexts.

To operationalise post-approval change reliance, participants identified a small set of practical design elements:

- **Define scope upfront** by specifying which categories of post-approval changes are eligible for reliance and which require local assessment
- **Anchor decisions in risk-based principles**, calibrating review depth based on device risk, change type, and available reference evidence
- **Establish clear communication pathways** at the outset to ensure changes affecting sameness are visible to relying authorities in a timely manner
- **Leverage existing reliance tools across the lifecycle**, including assessment reports, audit outcomes (e.g. MDSAP), and post-market data, to avoid duplicative reviews

2.2 Trust, transparency, and sovereignty: lessons from regulators

This section reflects regulatory experience and lessons shared during the workshop on how reliance functions in practice, beyond formal definitions and frameworks.

Trust as the Primary Enabler

Trust was consistently identified as the single most important condition for effective reliance.

Several authorities stressed that trust is earned incrementally, through repeated interaction, shared problem-solving, and exposure to real regulatory decisions.

Singapore HSA illustrated this clearly. HSA described how its reliance journey began with limited, clearly scoped use of assessment outputs from established GHTF founding members, combined with bridged reviews that preserved reviewer engagement with the underlying rationale. By continuing to review selected elements, HSA enabled its staff to learn from international assessments while retaining ownership of the final decision. As experience accumulated, review depth was deliberately recalibrated, reliance pathways expanded, and resources progressively shifted toward other priority areas. This measured progression ultimately positioned HSA not only as a relying authority, but as one that others now reference.

Thailand FDA described a similarly deliberate approach. Reliance was first introduced through narrowly defined pilots covering a small number of products, allowing reviewers and leadership to observe how reliance functioned in practice before expanding its scope. Over time, Thailand moved from product-specific pilots to broader, class-based reliance pathways, and more recently to reliance arrangements with Singapore HSA that include post-market elements. This sequencing—pilot, expand, then extend across the lifecycle—was described as critical in building confidence within an organisation experiencing frequent leadership turnover.

Across discussions, regulators reinforced that trust is not static. It requires ongoing engagement, data-driven reassurance, and continuous demonstration that reliance delivers better use of limited regulatory resources without compromising control.

Transparency Builds Confidence

Transparency in regulatory decision-making was repeatedly highlighted as essential for reliance to function. Authorities stressed that trust cannot be sustained without visibility into how decisions are made.

> ***"Regulators need to be more open about how decisions are made if they want others to rely on them."***
>
> ***— Dr Agnes Sitta Kijo, WHO***

Discussions made clear that transparency is not limited to publishing final decisions. Authorities emphasised the importance of making visible how assessments are conducted in practice, including the structure of reviews, the role of expert input, and the points at which regulatory judgement is applied. Understanding how conclusions are reached was seen as just as important as knowing what the conclusion is.

Equally important was clarity on which standards and evidence are considered sufficient, and how international standards, guidance documents, and conformity assessment outputs are interpreted within a national framework. Regulators noted that uncertainty around evidentiary expectations, rather than disagreement on science, often prevents effective reliance.

Participants also highlighted transparency around risk management across the product lifecycle as critical. This includes how risk classification influences review depth, how post-market data is monitored and acted upon, and how emerging risks trigger regulatory intervention. Visibility into these processes reassures relying authorities that oversight continues beyond initial approval.

Australia TGA provided a tangible example of transparency supporting reliance. TGA described how publicly available guidance clearly sets out when overseas certificates may be accepted, how applications are triaged for additional review, and what factors trigger deeper scrutiny. This approach was described as enabling reliance without ambiguity, allowing manufacturers to understand expectations upfront, and giving other regulators confidence that reliance is applied selectively, consistently, and in a risk-based manner rather than as an automatic fast track.

Across discussions, regulators consistently observed that lack of transparency, particularly around review logic and risk controls, was a more significant barrier to reliance than scientific or technical differences between jurisdictions.

Sovereignty Is Retained, Not Relinquished

A recurring concern raised, particularly by regulators at earlier stages of reliance, was the fear of losing control. Workshop discussions addressed this directly. Regulators consistently emphasised that reliance does not mean outsourcing responsibility.

> ***"Reliance does not weaken regulatory authority — it actually strengthens it."***
> ***— Dr Agnes Sitta Kijo, WHO***

Both Australia TGA and Singapore HSA underscored that reliance frameworks explicitly preserve national decision-making authority. In practice, this includes the ability to:

- Request additional information where needed,
- Adjust review depth based on local context and risk, and
- Impose post-market obligations or controls

Australia TGA illustrated this with concrete case examples shared during the workshop, where reliance on overseas certification was combined with local actions such as narrowing intended use and imposing long-term post-market data collection requirements. Singapore HSA similarly highlighted that reliance has enabled it to reallocate effort, shifting resources from duplicated pre-market review to post-market surveillance, compliance audits, and lifecycle oversight, without relinquishing accountability. It is worth noting that both TGA and HSA started their medical device regulation journey by incorporating reliance at the starting point. Their success confirms that reliance doesn't weaken an NRA; it provides a pathway to stronger technical capacity. This reassurance was seen as particularly important for internal stakeholders and policymakers, where resistance to reliance often stems from perception rather than technical risk.

Regulators also emphasised that accountability under reliance is distributed across the regulatory ecosystem, encompassing manufacturers, regulators, healthcare professionals, and health systems.

3. Translating Global Principles into Operational Pathways

Building on these practical lessons, this section outlines how regulators have translated reliance principles into structured, operational pathways, drawing on real-world experience shared during the workshop. Rather than proposing a single model, it highlights common sequencing and decision points observed across authorities at different stages of reliance maturity.

3.1 Choosing reliance partners

Regulators emphasised that trust is built in regulatory systems and processes—not in labels of size, maturity, or geography.

> ***"We should rely on systems, not on the size of an authority."***
> ***— Dr Madoka Murakami, PMDA Japan***

In practice, selecting a reliance partner starts with understanding how another regulator works, rather than who they are. This includes **examining assessment methodologies, use of international standards, decision-making logic, and approaches to lifecycle oversight** before considering any formal reliance arrangement.

Early engagement typically begins in a limited and exploratory manner, for example by **reviewing publicly available guidance, assessment templates**, or **decision criteria**, and by **examining real regulatory outputs** such as assessment summaries, audit reports, or case examples. This allows a regulator to assess whether review depth, risk tolerance, and evidentiary expectations can be understood, explained, and defended within its own legal and policy framework.

Several authorities highlighted that confidence is built fastest through more focused, use-case-driven interaction in the beginning. This may involve focusing initially on a specific device class, a defined risk category, or a single regulatory function such as quality management system audits or clinical evaluation. Such limited exposure allows reliance to be tested at a smaller scale while trust is being built.

Alignment with international standards (including IMDRF guidance and ISO standards) was repeatedly referenced during discussions as a practical anchor, particularly for regulators that must justify reliance internally or to policymakers. **Strength in post-market surveillance and vigilance** was also identified as critical, as confidence in lifecycle oversight underpins any willingness to rely beyond initial authorisation.

While geographical and cultural proximity and existing collaboration platforms/agreements were recognised as useful facilitators, speakers cautioned that these should support, rather than replace, objective evaluation of regulatory systems. Formal mechanisms, such as memoranda of understanding, confidentiality agreements, or structured information-sharing arrangements, were described as tools that consolidate reliance after confidence has been established, rather than prerequisites for the partnership. Ultimately, it would depend on the specific model of reliance and agreements among the two or more partnering authorities.

Overall, partner selection was characterised as an iterative process. The following elements are not an exhaustive list, but reflect common entry points identified during discussions for regulators beginning to assess potential reliance partners:

- Review publicly available guidance, assessment frameworks, and decision criteria
- Examine real regulatory outputs (e.g. assessment summaries, audit reports, case examples)
- Assess alignment with international standards (e.g. IMDRF guidance, ISO standards)
- Understand review depth, risk tolerance, and how local considerations are applied
- Examine how lifecycle oversight is handled, particularly post-market surveillance and vigilance
- Ask a simple test question: Could we justify and defend our own decision, based on this regulator's assessment, within our legal and policy framework?

3.2 Defining scope: what can realistically be relied upon

Defining the scope of reliance is a foundational design step for any reliance pathway. Scope-setting clarifies which regulatory elements can be leveraged, which remain subject to local assessment, and where national discretion is explicitly retained, providing a practical bridge between global principles and day-to-day regulatory decision-making.

Singapore HSA illustrated this clearly by describing reliance as a progressive and adjustable mechanism rather than a fixed rule, noting that "reliance is not static – it doesn't stop at the moment we implement something." This perspective underscored that scope must evolve with experience, confidence, and regulatory maturity, rather than being defined once at the outset.

In practice, participants described scope-setting as a risk-based and context-specific exercise, commonly informed by:

- Device risk and maturity, including classification, novelty, and intended use
- National legal authority and regulatory capacity, determining what can be relied upon in law and in practice
- Quality, completeness, and accessibility of reference information, including assessment outputs and audit evidence
- Clarity on division of effort, specifying which elements are relied upon versus locally reviewed
- Explicit retention of national decision points, ensuring accountability and explainability
- Ability to extend scope over time, particularly beyond initial authorisation to post-approval changes and post-market activities

3.3 Designing fit-for-purpose reliance pathways

Throughout discussions, participants noted that reliance pathways evolve in practice and are shaped by legal constraints, experience, capacity, and confidence over time.

This paper distils a set of practical considerations that can help regulators think through which type of reliance pathway may be appropriate at different stages of implementation, reflecting common themes raised during the workshop.

For regulators initiating or expanding reliance, pathway design can be informed by asking:

- **Legal feasibility**: Does the existing legal or policy framework allow reliance without a formal agreement, or only on specific regulatory outputs (e.g. audit reports, assessment summaries)?
- **Nature of the relationship**: Is reliance being considered with an authority where interaction has been limited, or where regular technical exchange and information-sharing already exist?
- **Regulatory capacity and experience**: What level of internal review capability is available to interpret and act on relied-upon information, and where would reliance most effectively relieve pressure?
- **Operational urgency**: Is reliance being considered to address immediate public health needs or workload constraints, or to support a more routine, long-term regulatory pathway?
- **Retention of national decision-making**: How will final regulatory decisions, escalation points, and national discretion be preserved within the chosen approach?

Discussions suggested that regulators often start conservatively, applying reliance in limited, clearly defined ways, and adjust the depth or form of reliance as experience accumulates. Unilateral, output-focused reliance was frequently referenced as a practical entry point, while more structured or collaborative approaches were described as becoming feasible only once confidence, trust, and legal clarity increase. There are ongoing efforts and discussions around multi-lateral work-sharing reliance pathways among more than three authorities at various platforms (e.g. AMDC, GHWP, IMDRF), among which MDSAP is the most successful and most cited example of such model.

4. Defining the Essentials

4.1 Minimum information requirements to enable reliance

Effective reliance depends on identifying a minimum, decision-relevant information set, rather than replicating a full local dossier. Across discussions, participants converged on a limited core set of information that is typically sufficient to support reliance decisions:

- Device description and intended purpose, including high-level technical and performance information
- Labelling and IFU applicable to the local market, enabling comparison with the reference jurisdiction
- Evidence of conformity with international standards, including justification where alternatives are used
- Manufacturer and QMS certification, with acceptance of recognised schemes such as ISO 13485 or MDSAP
- Post-market experience, where available, to support lifecycle oversight

A recurring theme was the importance of distinguishing between "must-have" information, which directly informs the reliance decision—and "nice-to-have" information, which may provide comfort but does not change regulatory outcomes. "Nice-to-have information" remain important, but can be held by the manufacturer, requested post-market if concerns arise, and used to support investigations, compliance actions, or post-approval changes.

> ***"Over-requesting documentation undermines reliance by increasing burden without improving safety or performance."***
>
> ***— Eng Faiza Alzadjali, Oman MOH***

Minimum information requirements were also described as dependent on the reliance model applied. Abridged reviews may justify additional targeted information, while unilateral recognition relies more heavily on reference authority outputs.

Minimum information requirements were described as dynamic rather than fixed. Abridged reviews may justify additional targeted information to support local decision-making, while unilateral recognition relies more heavily on trusted reference authority outputs. Beyond the reliance pathway itself, several practical factors influence minimum information requirements, including:

- Risk and novelty of the device
- Maturity and transparency of the reference authority, including confidence in its assessment depth and lifecycle oversight
- Availability and quality of relied-upon outputs, such as assessment reports, audit outcomes, or post-market data
- Ability to manage gaps post-authorisation, through surveillance, vigilance, and enforcement tools

4.2 Defining “sameness” and acceptable variation

“The deal breaker is when differences touch safety, quality, or effectiveness.”

— Eng Faiza Alzadjali, Oman MOH

Reliance is only defensible where the relied-upon decision remains valid for the product placed on the local market. Differences are therefore assessed based on whether they undermine the basis of the original regulatory decision.

Assessing sameness is not a binary exercise, but a risk-based judgment, influenced by:

- **Type of reliance model applied** (greater verification under abridged review than unilateral recognition)
- **Authority’s risk tolerance and regulatory maturity**

Sameness must be maintained over time, not only at initial authorisation. Where reliance is applied, post-approval changes that affect the basis of sameness require visibility and, where necessary, reassessment, reinforcing the link between sameness, change management, and post-market oversight.

In practice, regulators described applying a simple decision test when assessing sameness:
Does this difference change the basis on which the reference authority reached its decision?

- If yes, local assessment is required.
- If no, reliance can be maintained, with appropriate post-market controls.

According to the WHO Good Reliance Practice, sameness of product means that two products have identical essential characteristics (i.e. the product being submitted to the relying authority and the product approved by the reference regulatory authority should be essentially the same). All relevant aspects of drugs, medical devices and in vitro diagnostics, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar [...]. Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same. The impact of potential, justified differences should be assessed by the manufacturer and the relying NRA in determining the possibility of using foreign regulatory assessments or decisions. Due to the evolving nature of medical devices, products are frequently updated to reflect technological advances and clinical needs. Global manufacturers often launch products in different markets at different times, and national registration timelines vary significantly.

As a result, version differences across jurisdictions are often inevitable, even where the underlying product remains fundamentally the same. To preserve “sameness” in practice, reliance must extend beyond initial registration to defined categories of post-approval changes. Without lifecycle reliance, products may gradually diverge across markets, undermining the basis of the original reliance decision and risking disruption to supply and patient access.

5. How Can Regulators Champion Reliance with Policymakers?

Several authorities highlighted that legal or policy language is often the limiting factor, even where technical readiness exists. Explicit enabling language, whether in legislation, regulation, or policy guidance, was described as giving regulators the confidence to act and defend reliance decisions politically.

> ***"As much as regulators may be ready, outdated legal provisions often prevent implementation."***
>
> ***— Dr Agnes Sitta Kijo, WHO***

Implementing reliance is as much a policy and governance exercise as it is a technical one. Regulators emphasised that progress depends on their ability to clearly explain why reliance matters, what it changes, and what it does not change.

Concerns around loss of sovereignty and accountability were identified as the most persistent political barrier. Regulators stressed that these concerns should be addressed proactively, rather than defensively. Messages that regulators found effective with policymakers focused on three core clarifications:

- Final regulatory decisions remain national and independent
- Reliance changes how decisions are informed, not who makes them
- Accountability and legal responsibility remain fully with the national authority

Participants noted that policymakers respond most strongly to demonstrated outcomes, rather than technical arguments alone. Evidence showing improved patient access, more efficient use of regulatory resources, and strengthened post-market oversight was described as particularly persuasive. These success metrics, and how they can be applied in practice, are explored in the next section.

6. Measuring What Matters: Defining Success

Demonstrating real-world impact is essential to sustaining political, institutional, and organisational support for reliance beyond initial pilots. Traditional process indicators alone, such as the number of approvals, agreements, or pathways established, do not adequately reflect the value of reliance and are more vulnerable to political challenge and internal resistance. These were described as "vanity metrics" that may signal activity, but not impact. Instead, success should be measured and communicated around outcome-based indicators, aligned with public health and system performance.

Indicators most frequently highlighted included:

- Faster and more predictable patient access to safe and effective medical devices (e.g. review time saved and approval timeline consistency)
- Regulatory capacity gains, measured by staff hours saved or reallocated to higher-risk activities, international collaboration, or capability building on regulatory science and emerging technologies, or establishment of innovative regulatory pathways or approaches. Reduced duplication of regulatory effort across jurisdictions, without lowering standards or oversight
- Stronger post-market performance, including earlier detection of safety issues and more coordinated corrective actions

"Success should ultimately be measured by whether patients get faster access to safe medical devices, and whether regulators can redirect effort to where risk really lies."

— Dr Muralitharan Paramasua, MDA Malaysia

7. Key Takeaways and the Path Forward

The workshop confirmed that regulatory reliance is no longer theoretical, but a practical necessity. Reliance is most effective when treated as a system-level approach, grounded in trust, transparency, and strong post-market oversight, rather than as an isolated regulatory accelerated pathway.

First, moving from principle to practice requires operational clarity. Regulators highlighted the importance of clearly defining what can be relied upon, what minimum information is needed, and how local review is calibrated based on risk. Reliance works best when focused on assessment outputs, applied proportionately, and embedded across the product lifecycle.

Second, legal clarity and institutional trust are critical enablers. Where legal frameworks are restrictive or ambiguous, reliance may face challenges such as hesitation in initial adoption (even if the legal framework does not explicitly preclude it), barriers to scope expansion, or inefficient implementation. Regulators therefore play a key role in engaging policymakers early, framing reliance as a tool that strengthens oversight and accountability rather than diminishes sovereignty.

Finally, sustaining reliance depends on demonstrating outcomes. Participants emphasised the need to move beyond process or "vanity" metrics and focus on tangible impact, including faster patient access, more efficient use of regulatory resources, reduced duplication, and stronger lifecycle oversight.

Taken together, these discussions point to a clear path forward: embed reliance into routine regulatory systems, ground it in clear legal and organisational foundations, and consistently demonstrate its value.

"Reliance is not simply a regulatory tool, it is a strategic pathway to stronger oversight, smarter resource allocation, and better patient outcome."

— Dr Agnes Sitta Kijo, WHO

8. Resources

WHO Good Reliance Practice https://www.who.int/publications/m/item/annex-10-trs-1033
IMDRF Reliance Playbook* https://www.imdrf.org/documents/playbook-medical-device-regulatory-reliance-programs
GMTA Regulatory Reliance Paper https://www.globalmedicaltechnologyalliance.org/papers/GMTA%20Global%20Harmonization%20of%20Medical%20Technology%20Regulations.pdf

9. Acknowledgement Workshop Co-Organizers and Participants

We would like to express our sincere appreciation to the organising committee — Singapore HSA, Malaysia MDA, and Thailand FDA — for their partnership and commitment in delivering this workshop. We extend particular thanks to Woei Jiuang from HSA for her leadership and coordination in shaping the programme, and to Dr Agnes from WHO for her valuable guidance and contributions throughout its development.

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* At the time of the workshop, the IMDRF playbook was in draft form. The final version was officially published during the editing period of this report and has been reviewed to ensure full alignment.

About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**