



Building Trust: HSA Medical Device Regulatory Reliance

Accelerating patient access to medical innovation through global collaboration and rigorous oversight

Redundant Reviews Block Tech

Patients wait for cardiac monitors safe in the US, Europe, and Australia, stalled by local duplication



Volume Overload

Health systems manage thousands of device types, overwhelming traditional review capacities



Systemic Fracture

National reviews create redundant global efforts, causing wait-time gaps where technology is out of reach

Reliance is a smart approach to existing clinical evidence

Regulatory reliance is defined as an authority giving weight to trusted institutions

Core Definition

An authority gives significant weight to assessments performed by trusted reference institutions while reaching its own decision

Independent Accountability

This is not an outsourcing responsibility; the relying authority remains fully independent and accountable for the final market authorisation

Regulatory Analogy

It is like a senior colleague reviewing a peer's rigorous analysis rather than starting the research from zero

Strategic Benefit

By giving credit to the work of others, regulators can move with both intelligence and speed, focusing their unique expertise where it is most needed

Three pillars drive the case for regulatory reliance

The move towards reliance is underpinned by 3 strategic benefits that serve regulators, industry, and the public

Efficiency

Reduces work duplication, enabling faster processing of standard applications

01

Industry Support

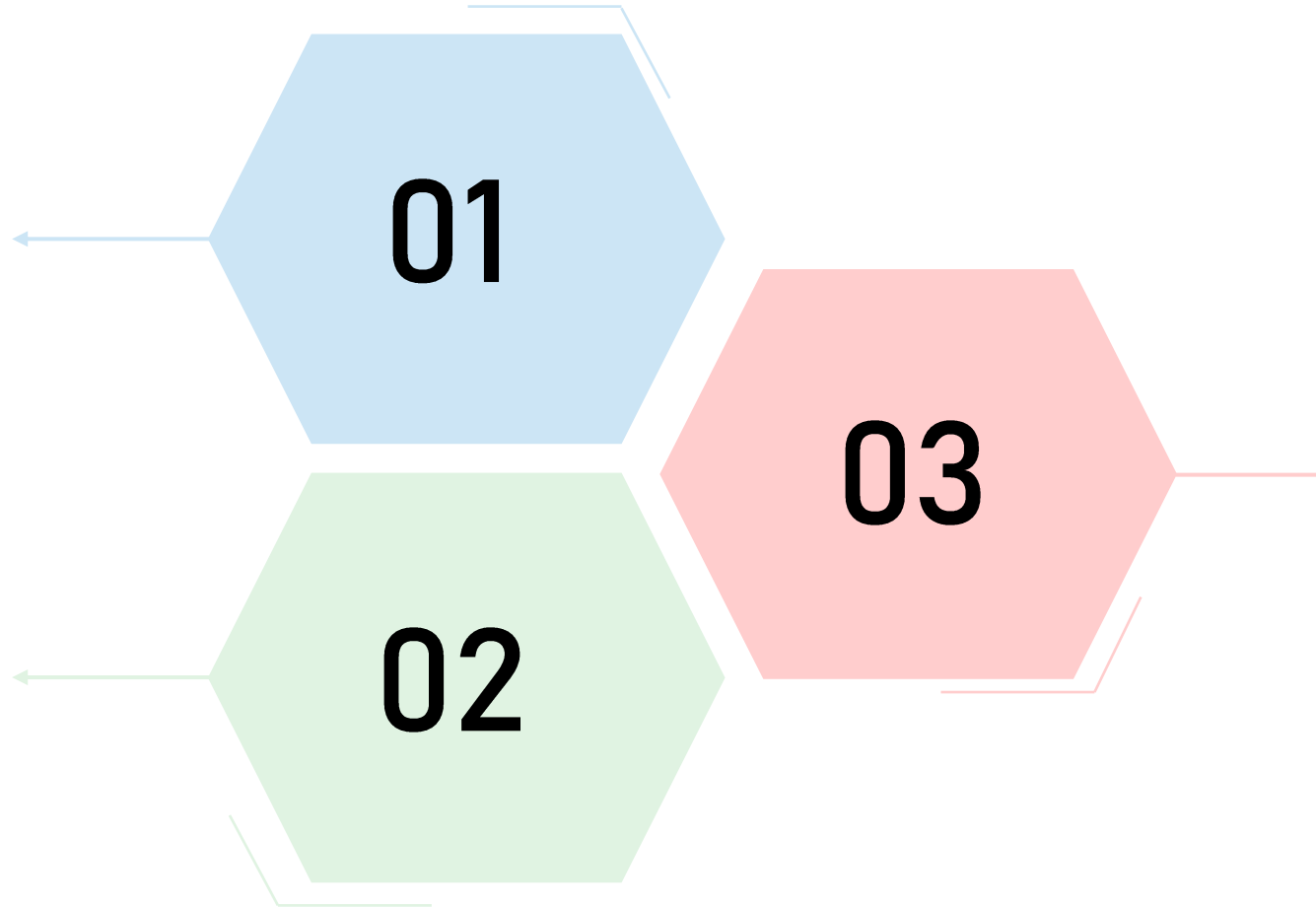
Lower barriers for SMEs to enter multiple markets by aligning requirements

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Resource Optimisation

Frees reviewers to focus on high-risk technologies and post-market surveillance



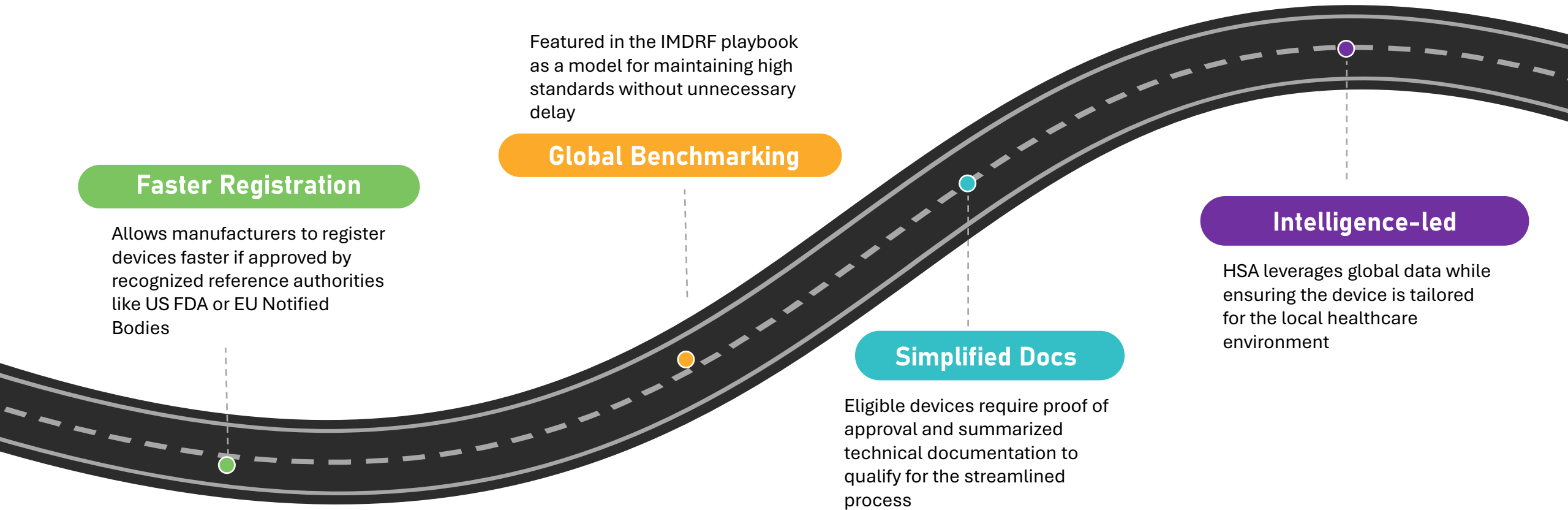
Choosing the right path across the reliance spectrum

The IMDRF playbook identifies three distinct models of reliance that authorities can adopt based on local legal/ technical needs

Model	Description	Primary Example
Work-sharing	Multiple authorities collaborate to jointly perform regulatory tasks	MDSAP (Medical Device Single Audit Program)
Abridged Pathway	A partial review relying on a trusted partner's comprehensive assessment	Singapore HSA Abridged Pathway
Recognition	Direct acceptance of another authority's decision with minimal review	EU CE Marking / Australia-UK MRA

The HSA Reliance Pathway

HSA's pathway allows manufacturers to register devices faster if they have already been approved by recognized reference authorities



Maintaining integrity through the “sameness” criteria

Identical Intended Use

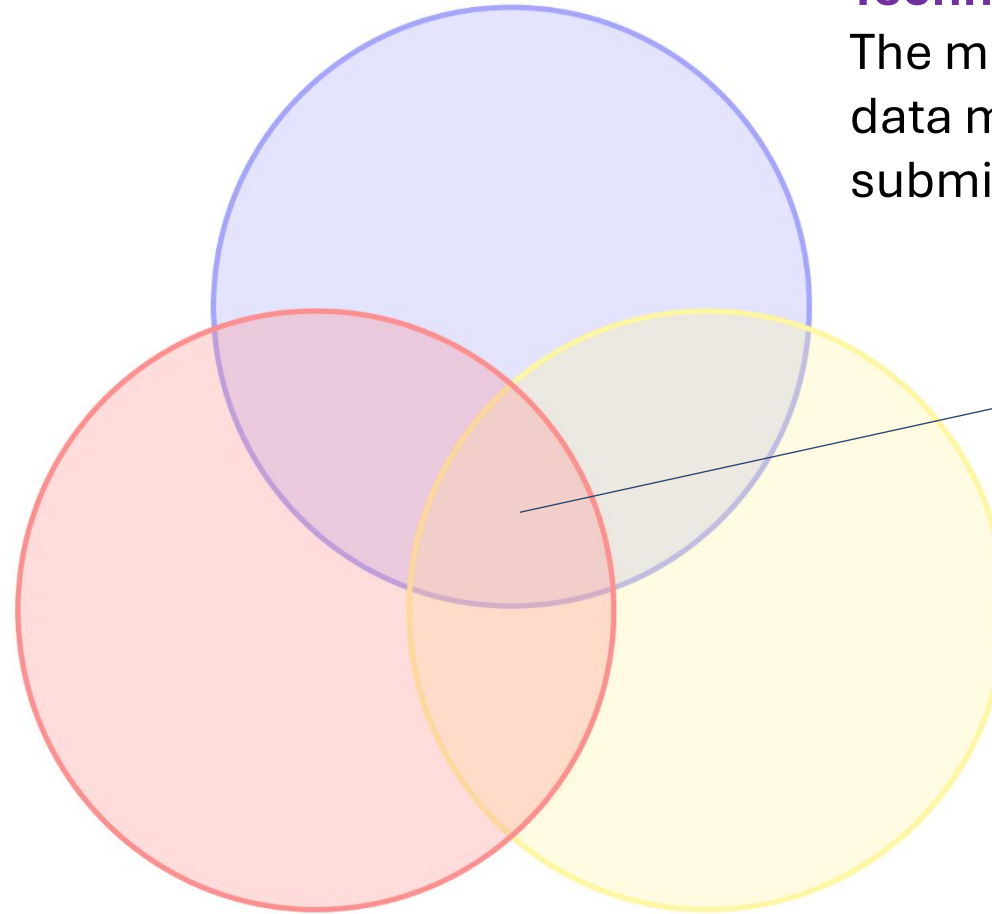
There must be no essential differences in how the device is meant to be used

Technical Equivalence

The manufacturing and clinical data must match approved submission

Integrity Check

If a device is materially different, the reliance rationale breaks down



Sameness criteria

HSA: Reliance & Authority

HSA retains the absolute right to request additional information or clarification at any stage

Reliance

Leveraging international regulatory assessments as foundational input for efficiency

Local Authority

Retaining absolute right to verify, request additional info, and prioritise regional clinical needs

Health outcome for patients

Faster market access is more than a commercial victory; it is a direct improvement in patient welfare and survival rates

Time saved

Reliance allows devices to reach clinics faster than traditional full-review timelines

Safety safeguards

Independent final decisions ensure that speed never compromises patient safety

Access to Innovation

Singapore patients get access to advanced cardiac, diagnostic, and AI tools

Lessons for a durable reliance program

Based on the HSA experience and the IMDRF playbook, successful reliance requires a mature 5-step strategic approach



The IMDRF Playbook establishes a global reliance framework.

The IMDRF codified practices in the Playbook for Medical Device Regulatory Reliance Programs, a guide enabling authorities like Singapore's HSA to build trust