



# A Step-Wise Approach to Regulating Medical Devices:

## Reliance and Recognition

---

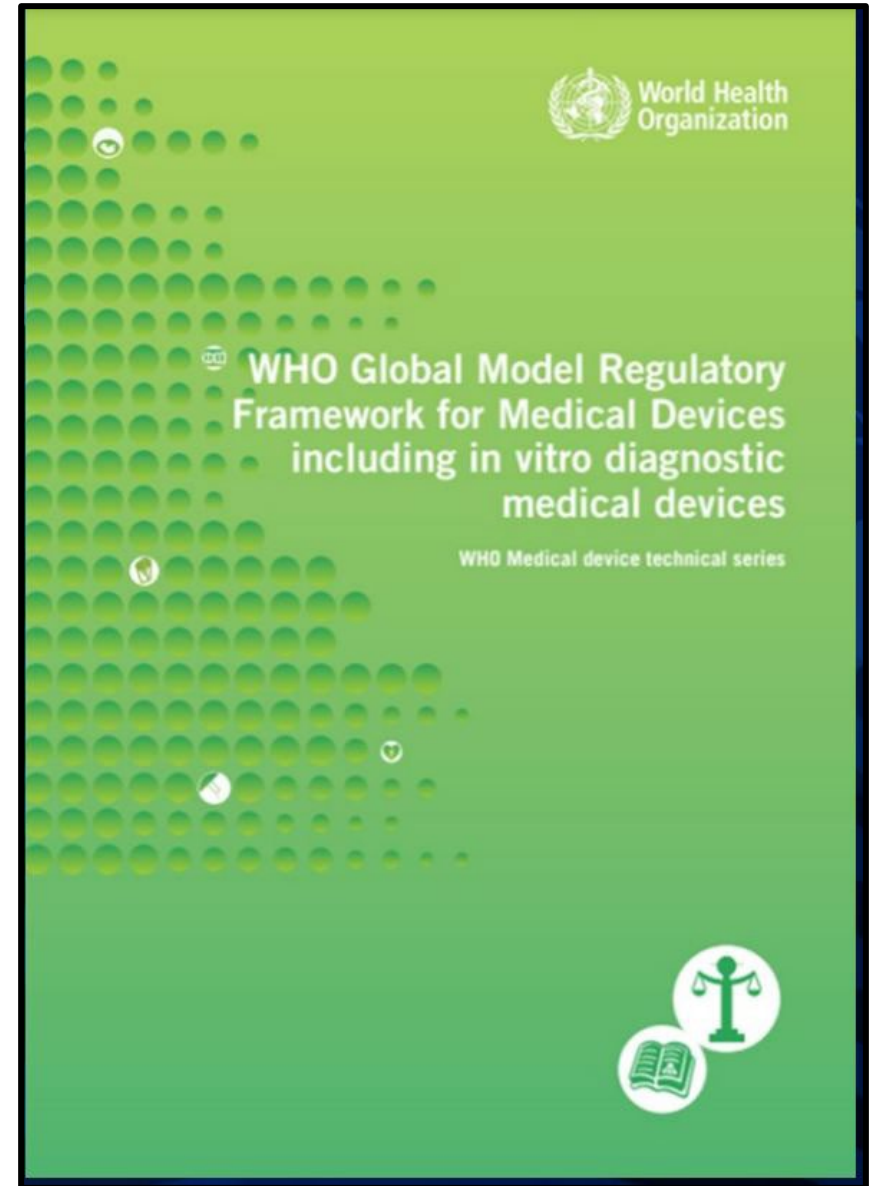
Diane Wurzburger  
VP RAQA & Global Policy  
GE HealthCare



Reliance: A Shared Goal for Timely Patient Access to Medical Technology

# ***WHO Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices***

- ✓ Roadmap to build an effective and efficient regulatory framework
- ✓ Aligns with IMDRF foundational guidance
- ✓ Based on foundational principles & reliance



# Building Blocks for Reliance

Trust and collaboration

Transparency

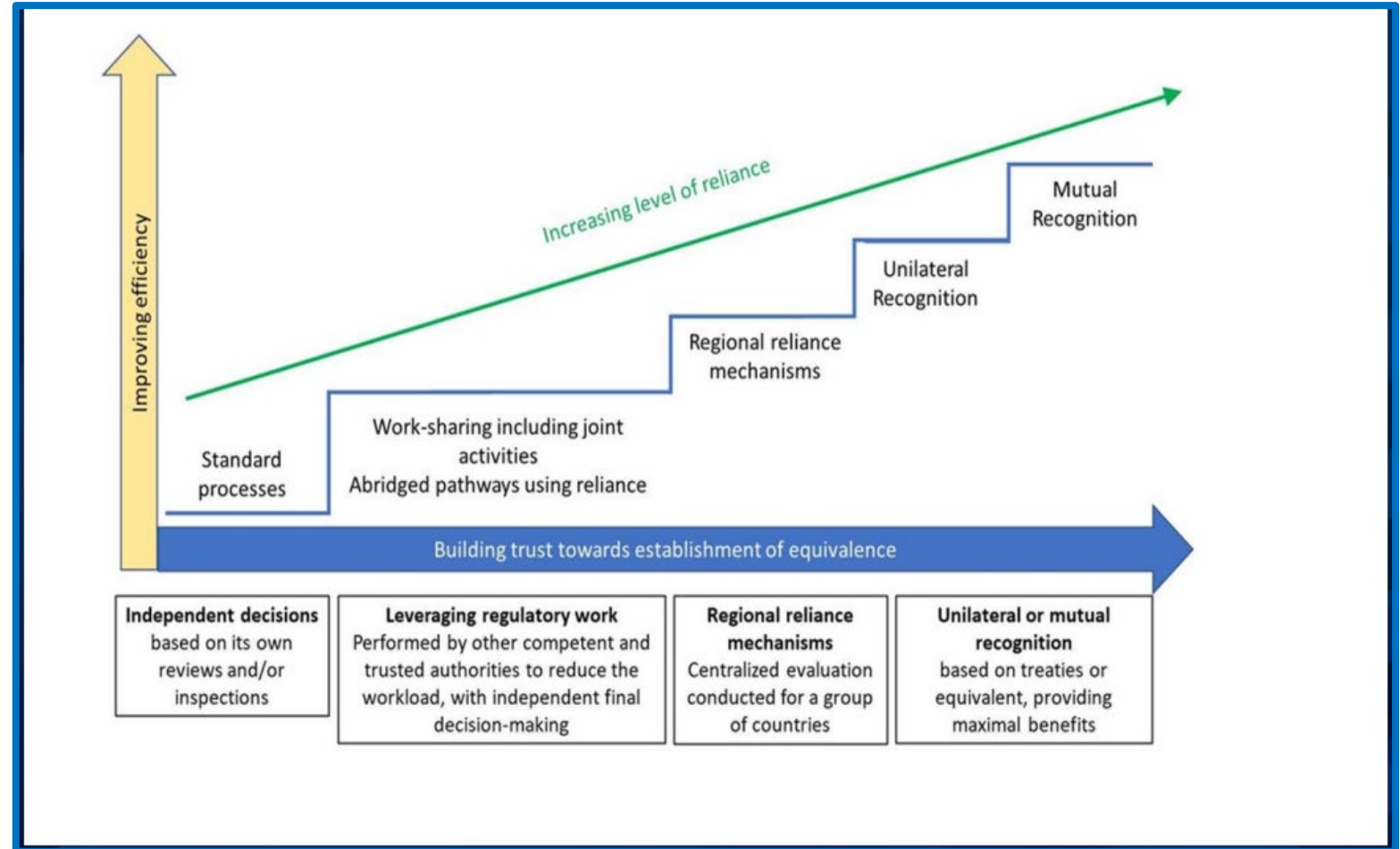
Independent decisions

Applied across the TPLC

Incremental

Not “one size fits all”

IMDRF Reliance Playbook



Source: WHO- Good Reliance Practices in the Regulation of Medical Products: High Level Principles & Considerations, October 2021

# Strategic Importance of Reliance



Capacity building



Enhanced efficiency



Strategic use of resources



Predictability of decision-making



Accelerate Review and Decision Time



Increase timely patient access to innovation



**Reliance** is not about lowering standards—it's about ***strategic collaboration*** to ensure safe and timely access to medical technology innovation.



*Thank you*



Global Medical  
Technology Alliance  
*Innovating for a Healthier World*



**DITTA**  
GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT &  
RADIATION THERAPY  
TRADE ASSOCIATION