GMTA/DITTA Workshop on Reliance

- **Scene Setting:** What is reliance and why is it important?
- **Session 1:** Reliance in a premarket setting
- **Session 2:** Reliance in a post market setting
- **Next Steps**

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

GMTA
Global Medical Technology Alliance
Innovating for a Healthier World

Status of Reliance

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IMDRF International Medical Device Regulators Forum

What is Reliance?

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.

The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Annex 10, WHO Technical Report Series, No.1033, 2021:

Good reliance practices in the regulation of medical products: high level principles and considerations

Where we are today

…Product Registration…Postmarket…MDSAP…Clinical…Standards…

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What we can agree on

- ✓ **Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical technologies**
- ✓ **The rapid advancement of medical device innovations is challenging traditional regulatory frameworks**
- ✓ **Small differences in regulations, standards, and guidance can result in major differences in the regulatory path for the same medical device (e.g., MD/IVD classification) →need for regulatory convergence**

Foundational Principles*

- **Implement convergent regulatory frameworks based on internationally recognized best practices and standards.**
- **Implement core tenets of medical device regulations**
- **Implement regulatory reliance, including recognition**

*GMTA White Paper: *The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology,* May 2023

Core Tenets

- **Adopt Good Regulatory Practices (GRP)**
- **Avoid requirements that lack a patient safety benefit**
- **Support innovation and apply equal regulation to both domestic and international companies**
- **Avoid unnecessary barriers to access based on product country of origin**

Core Tenets

- Implement a risk-based approach to product changes
- Implement a single dossier
- Accept global clinical trial data & leverage Real World Evidence
- Adopt electronic instructions for use
- Accept digital labels
- Ensure predictability and adequate resources

Why reliance is needed

- Increase timely patient access to innovation
- Transparency
- Predictability of decision-making
- Capacity building

- Increased efficiencies
- Decrease in workload, duplicative efforts
- Strategic use of resources
- Increase health system preparedness & response during PHE

Collaboration & Trust

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