



Global Medical  
Technology Alliance  
*Innovating for a Healthier World*

# **Advancing Global Regulatory Convergence during a Global Pandemic**

IMDRF Stakeholders Session  
September 23, 2020



# Presentation Outline

- GMTA membership
- Regulatory Convergence principles
- Ensuring rapid access to needed medical technology
- Recommendations



Global Medical  
Technology Alliance  
*Innovating for a Healthier World*

# GMTA Membership

- **Open to medical technology associations (not companies):**
  - willing to accept GMTA governance rules
  - with functioning code of ethical business practices
  
- **30 associations in the following:**  
**Argentina, Asia-Pacific, Australia, Brazil, Canada, Chile, China, Colombia, Ecuador, Europe, Japan, Korea, Mexico, Middle East, New Zealand, Russia, South Africa, Turkey, Ukraine, United States**



# Regulatory Convergence Principles

- Least Burdensome approach
- Transparency, Efficiency and Predictability
- Consistent training on GHTF/IMDRF documents
- Adoption of international consensus standards
- Reliance on regulatory decisions



# Ensuring Rapid Access to Needed Medical Technology

- Harmonized GHTF/IMDRF guidance documents contemplated regulatory flexibility to meet patient needs
- IMDRF regulators used “rapid access” mechanisms to meet specific needs during COVID -19 pandemic
- Access to COVID diagnostic tests, personal protective equipment, ventilators in high demand
- Reliance principles on regulatory decisions from other regulators plays an important role



# Recommendations

- Ensure that current IMDRF documents acknowledge the need to ensure rapid access
- Utilize reliance mechanisms to promote rapid access
- Consider the development of specific IMDRF guidance to promote the use of rapid access mechanisms during a global pandemic
- Ensure adequate training and communication for regulators