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
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