GMTA

- Getting innovative medical technologies to patients –
- How IMDRF matters -
Who Are We?

1990s  Origins date as informal network
2010  Formally established
2013  Became legally constituted in Switzerland as an “association”
2015  WHO approved as official NGO
• Governed by Articles of Association, Governance Rules, Elected Board of Directors
◆ Membership open to medical technology associations (not companies)
  - willing to accept GMTA governance rules
  - with functioning code of ethical business practices
Countries Represented by GMTA
IMDRF Strategic Plan

“The mission of the IMDRF is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.”

the Management Committee (MC) intends to put particular focus on the objective, “Support innovation and timely access to safe and effective medical devices”
MedTech Innovation to Patients

- Novel concept
- Investment
- Development
- Regulatory approval
- Financing / purchasing
- Patient
MedTech Innovation to Patients

IMDRF!
Regulatory Challenge?

When do regulatory systems risk becoming a barrier to supporting health systems having access to safe and effective medical devices?
Beyond IMDRF and in the news...
Zika outbreak & IMDRF members

Vector Present:
- Australia
- Brazil
- China
- EU
- Japan
- Russia
- USA

Vector Free:
- Canada
What we hear about Zika?

Mosquito control
Vaccine Development
Health Policy
But... Medical Technologies are critical

- Diagnosis
- Treatment Guillain-Barré
- Safety of Blood supply
- Monitoring of Pregnancy
- Care of Vulnerable Neonates
- Personal Protection
Are they all available?

### Novel
Investment in new technologies
- Very strong investment in new technologies
- Focused on a single jurisdiction (sometimes even a single hospital)

### Existing
Critical technologies exist but...
- Not all are available around the world – regulatory approval a concern

### Emergency
Diverging issues
- Emergency approvals are very different
- Hard to see how to get an emergency approval in all relevant jurisdictions
Conclusion

IMDRF has a pivotal role in the access pathway for innovative technologies

GMTA Actively supports the IMDRF 2020 Strategic Plan

Access to innovative medical technologies remains a challenge

When dealing with a global health crisis innovation in Medical technologies is essential
Muito obrigado!
Thank you for your time!