GMTA

- Getting innovative medical technologies to patients –
- View on Work Items -
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
Select Work items

• NCAR
• SAMD
• MDSAP
• MD Adverse Event Terminology
• Registries
• RPS / UDI
View on NCAR

Look forward to end of pilot

Extension of NCAR welcomed

Expect to see impact
Considerations on NCAR

- Notification to Manufacturers
- NCAR Beyond IMDRF?
- Outreach Industry
View on SAMD

There is an APP for THAT!
Considerations SAMD

- Regulatory impact of changes to SAMD
- Fuzzy logic – when is an APP a MD?
- Very welcomed key to harmonization
  Software distribution can be truly global
View on MDSAP

I give you two thumbs up.
Considerations MDSAP

- Question of Capacity – Are there enough AUDITORS?
- Extending MDSAP – more members on board?
- Reassuring Industry – accepting MDSAP audit reports
Adverse Event Terminology

Welcome codification of reporting

Development of terminology – where will it be used?

Looking forward to consultations
View Registries
Considerations registries

1. Generate lots and lots of data
2. Who (and how) accesses the data?
3. Confidentiality questions
Considerations RPS

Welcome the ToC

Represents a major investment

Concerns about deployment
UDI

Original IMDRF/GHTF idea: to develop a global UDI system

More realistic conclusion: Deployment of a small number of regional UDI databases

The future: Manufacturers’ UDI will be feeding into regional databases which will ideally talk to each other
Essential Principles – Global UDI

• UDI gives each product a unique number, which would enable full traceability if used by all stakeholders. The same UDI must be present on the label around the world.

• Products need to be tracked through the supply chain using the same Identifier from point of production to point of care – if a different UDI is used, traceability is lost. This includes hospitals using UDI to trace the devices used on patients (all the way to the electronic health record).

• Databases should be built with interoperability in mind – core elements in particular should be compatible to enable the effective sharing of information.
Recapitulation...

Pre Market
- RPS/UDI

Post Market
- NCAR
- MDAET
- MDSAP
- SAMD
- Regist.
Recapitulation...

Communication
- RPS/UDI
- NCAR
- MDAET

Information
- MDSAP
- SAMD
- Regist.
Conclusion

IMDRF has a strong focus on the key challenges facing the MedTech Sector

GMTA Actively supports and engages with IMDRF

IMDRF can enable access innovative medical technologies

Communication and Information management are important regulatory trends
Muito obrigado!
Thank you for your time!