

GMTA COLLABORATION WITH IMDRF: Third Anniversary



About GMTA

>Who are we?

➤ What do we do?

> How do we work with IMDRF?



Who Are We?

- ➤ Origins date to 1990s as informal network
- > Formally established in 2010
- Secretariat and website in Geneva
- ➤ Became legally constituted in Switzerland as an "association" in 2013
- > WHO approved recognition as official NGO in 2015
- Governed by Articles of Association, Governance Rules, elected Board of Directors

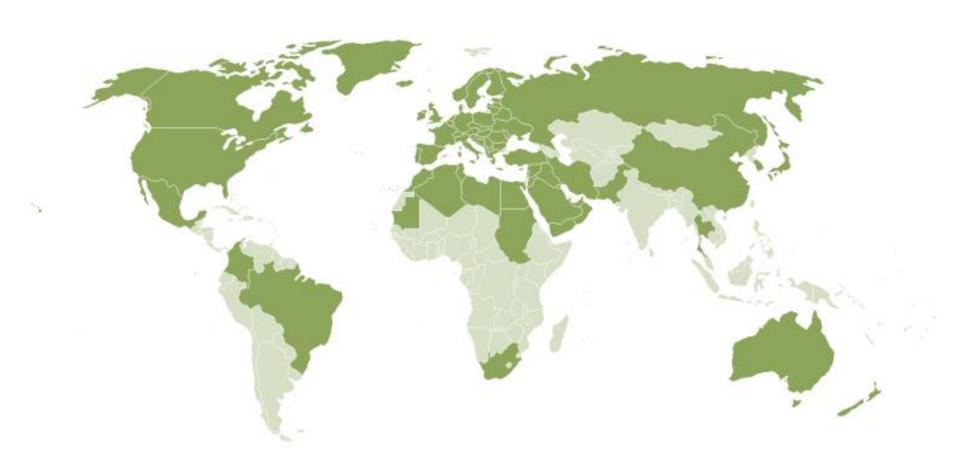


Who Are We?

- Membership open to medical technology associations (not companies):
 - willing to accept GMTA governance rules
 - with functioning code of ethical business practices
- 24 associations in: Australia, Brazil, Canada, China, Colombia, Europe, Japan, Korea, Mexico, Middle East, New Zealand, Turkey, Russia, South Africa, United States



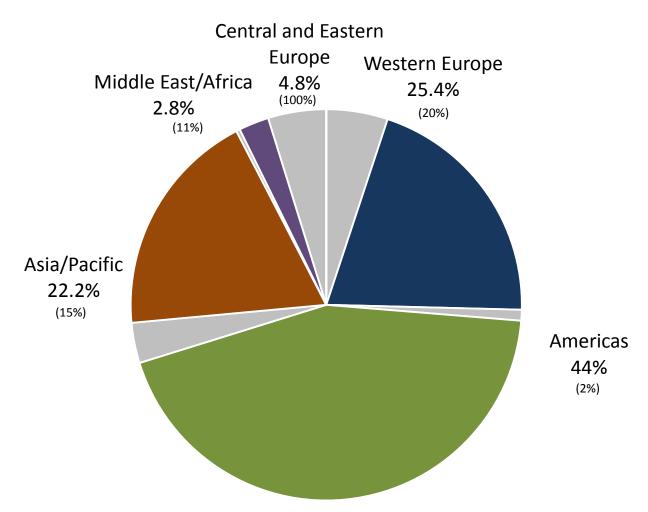
Countries Represented by GMTA





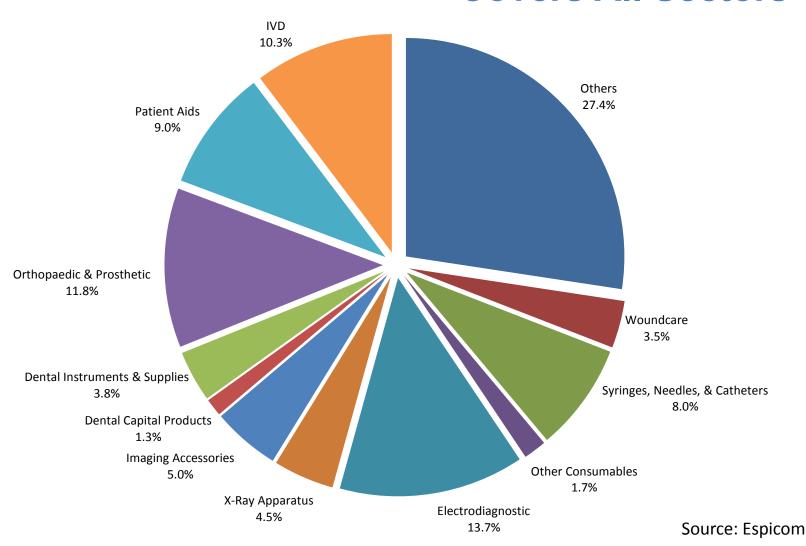
Covers Almost All Markets*

Source: Espicom





Covers All Sectors





What do we do?

Our Mission

The mission of GMTA is to support the objectives of providing safe, effective and innovative medical technology that saves and enhances lives, benefiting people and society.



What do we do?

- Provides a forum in which Members exchange information and jointly develop and advocate policies that encourage innovation in medical technology to address patients' healthcare needs on a global basis.
- > Examples include:
 - Health Technology Assessment best practices
 - WHO injection safety conferences
 - WHO pre-qualification tendering policy/program
 - UNGA NCD conference recommendations
 - WHO Global Medical Device fora (2010, 2013)
- General Assembly and Board meet twice yearly



GMTA-IMDRF Work

- > Subcommittee on IMDRF Regulatory Policies
- > Participate in IMDRF Management Committee
- Provide expertise and company representatives to IMDRF working groups (UDI, RPS, Software)
- > Appreciate outreach to industry on MDSAP pilot



GMTA-IMDRF Work

- > Support IMDRF goal of regulatory harmonization
- > Support transparency as guiding principle
- > Support capacity considerations for new projects
- > Proposals to IMDRF include:
 - promote global acceptance of UDI systems
 - ability to comment on proposed NCAR changes
 - convergence in use of major standards



THANK YOU!