Global Medical Technology Alliance
Innovating for a Healthier World

Update and Overview of GMTA Principles and Position Papers

Zach Rothstein
GMTA

IMDRF Open Stakeholder Day
Wednesday, March 21, 2018
Shanghai, China

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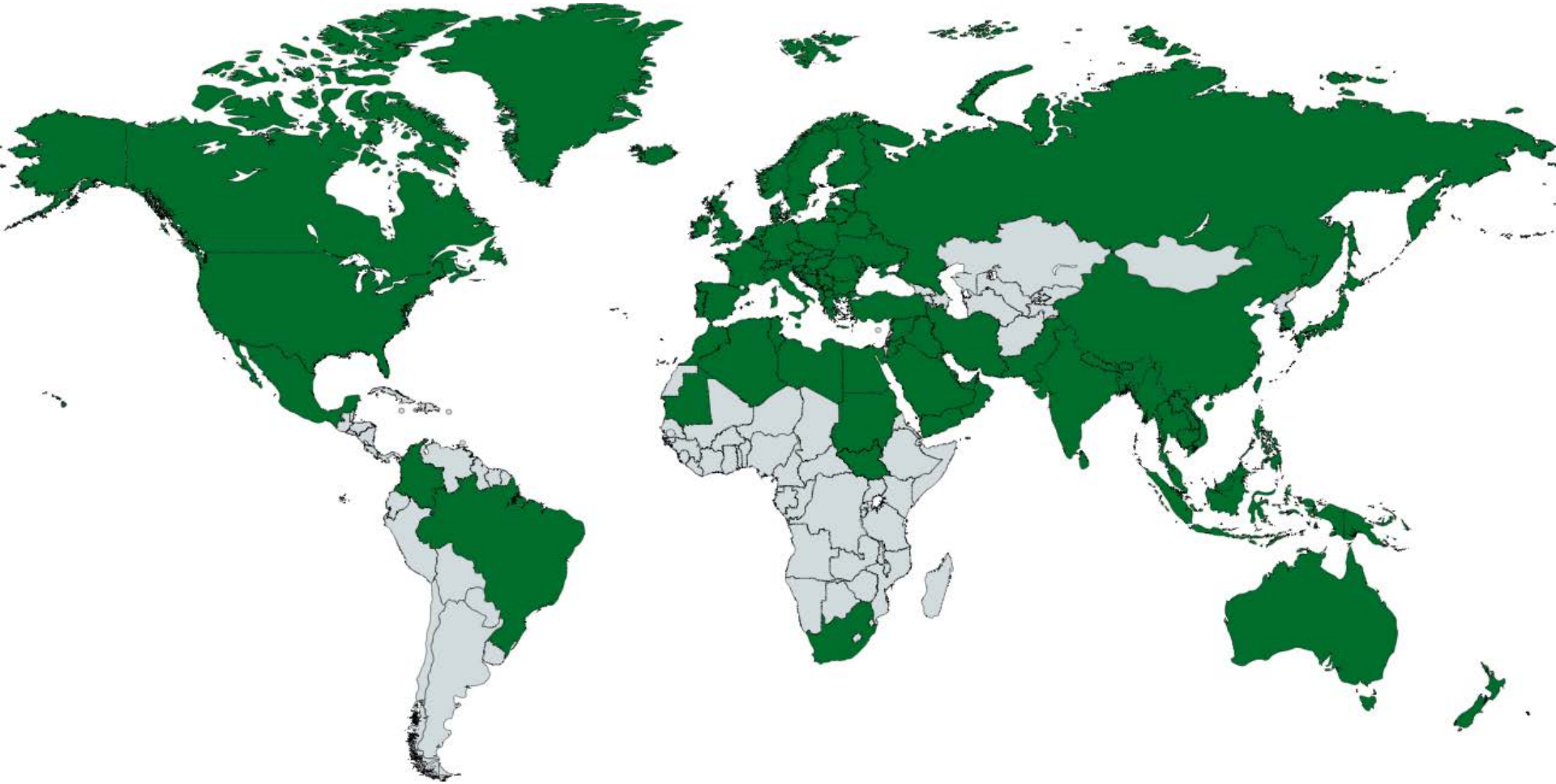
Who Are We?

- Origins date to 1990s as informal network
- Formally established in 2010 with Secretariat and website in Geneva; legally constituted in Switzerland as an "association" in 2013; WHO recognized NGO in 2015
- Membership open to medical technology associations (not companies):
  - Willing to accept GMTA governance rules
  - With functioning code of ethical business practices

With 25 member associations, here are the countries represented by GMTA…



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GMTA Principles and Position Papers

- UDI
- Cybersecurity
- Registries
- Real World Evidence

Available at GMTA's website: globalmedicaltechnologyalliance.org

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GMTA UDI White Paper

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UDI Principles

1. Rules should be phased-in and based on risk
   - Initial implementation timeline should be two years or more
2. Rely on standards and globally accredited issuing agencies
   - Manufacturers already work with existing globally accredited issuing agencies (e.g. GS1, HIBCC, ICCBBA, GMDN)

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UDI Principles

3. Regulators should provide on-going assistance to industry
   - Help desk, training, and public communications
4. Include a mechanism to request exception, exemptions, alternatives, and extensions of time
   - Enables manufactures to address implementation challenges in a positive and constructive manner

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UDI Principles

5. Date of manufacture should not be a required element of the production identifier unless no other production identifier is available
   - Including DOM in PI presents many technical challenges
6. UDI rules should not apply to devices manufactured or labeled prior to the rule's compliance dates
   - Locating, removing, storing, and/or reworking devices after the compliance date to either re-label or destroy is unproductive and could lead to product shortage

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UDI Principles

7. Triggers for a new device identifier should be limited to the rules of the UDI issuing entities
   - Not all product changes should require a new DI
   - Reflected in CFDA's UDI Rule

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GMTA Cybersecurity Principles

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Cybersecurity Principles

- Objective
  - Provide principles for use by the medical technology industry to establish effective cybersecurity for its medical devices
  - Demonstrate the device industry's commitment to patients and health care practitioners to provide secure medical device
- Application
  - Applies to connected devices only (for example, devices that connect via internet, hospital networks, or directly to another medical device)

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Cybersecurity Principles

1. Medical device development and security risk management
   - Cybersecurity risk management program that incorporates both premarket and postmarket phases
2. System level security
   - Shared responsibility for security incidents to be investigated collaboratively

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Cybersecurity Principles

3. Coordinated disclosure
   - Establishment of coordinated disclosure process for researchers to submit findings
4. Consensus standards, regulatory requirements, and education
   - Cooperative effort among regulators, manufacturers and security experts to develop standards and regulations

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GMTA Registry Principles

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Registry Principles

- Objectives for a registry
- Threshold questions
- Data governance
- Policies for use and publication of data

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Registry Principles

- Objectives for a registry
  - Improve patient care and outcomes
  - Improve patient access to new therapies
  - Evaluate safety and/or effectiveness of product
  - Meet regulatory requirements for postmarket surveillance

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Registry Principles

- Threshold questions
  - Do objectives warrant the level of investment required to develop and maintain a registry?
  - Is registry the least-burdensome means to collect the necessary data to achieve the scientific objectives?
  - Are there reliable data collection instruments available to collect the data?
  - Will the registry have a stable and diverse source of funding to promote long-term sustainability?

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Registry Principles

- Data Governance
  - Rules governing access to data
  - Process for data request review
  - Controlled process for data release
  - Process for device safety data reporting

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Registry Principles

- Policies for use and publication
  - Company access to own data and aggregate data
  - Safety signals reported to company for further investigation
  - Regulatory bodies seek input from company before taking regulatory action based on registry data
  - Protect against unauthorized use of data and ensure appropriate transparency

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GMTA Real World Evidence Principles

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Real World Evidence Principles

- Real world evidence includes data collected from a variety of sources, such as:
  - Registries
  - Public and private health plans
  - Manufacturers
  - Electronic health records (EHR)
  - Regulators

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Real World Evidence Principles

- Potential benefits of real world evidence include:
  - Improve patient care and outcomes
  - Improve patient access by expanded use and indications
  - Support streamlined device modifications
  - Enhance postmarket data collection

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Real World Evidence Principles

1. System has clear purpose, objective, and participation requirements
   - Data must be of appropriate quality for intended use; data integrity and security must be maintained
2. System overseen by data governance committee
   - Inclusive of manufacturers, the committee should set criteria for data ownership, access, and use

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Real World Evidence Principles

3. Regulators have clear policies for use of RWE
   - Information shared with manufacturers prior to taking action
4. Data access
   - Qualified scientific, medical and economic researchers to benefit health or patient care
   - Manufacturers' permitted full and timely access to data on their products

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Real World Evidence Principles

5. Compliance with applicable laws and regulatory requirements
   - Protection of patient privacy; informed consent obtained
   - Protection of all confidential, proprietary information from release