

# Global Medical Technology Alliance

GMTA Update

**Diana Kanecka, GMTA**



# Who are we?

- GMTA is the Global Medical Technology Alliance
- Origins date to 1990s initially as informal network, formally established in 2010 in Switzerland
- WHO recognized NGO since 2015, official stakeholder to the IMDRF since 2012 and **liaison member of GHWP since 2022**
- With more than 30 member associations, GMTA represents innovative medtech companies that develop and manufacture 85 percent of the world's medical devices, diagnostics and digital health solutions
- Some GMTA members also represent a significant number of distributors, particularly in countries that have little or no local manufacturers of medical technology





# GMTA paper on regulatory reliance

- Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices
- Small differences in standards, guidance and regulations can cause major differences in the regulatory path (e.g., MD/IVD classification)
- These differences are amplified during a pandemic as seen in countless emergency use pathways





# Foundational principles

- Implement convergent regulatory frameworks based on internationally recognized best practices and standards
- Implement regulatory reliance, including recognition
- Implement core tenets of medical device regulations





# Core tenets

- Ensure predictability and adequate resources
- Support innovation and apply equal regulation to both domestic and international companies
- Adopt Good Regulatory Practices (GRP)
- Avoid requirements that lack a patient safety benefit
- Accept global clinical trial data and leverage Real World Evidence





# Core tenets

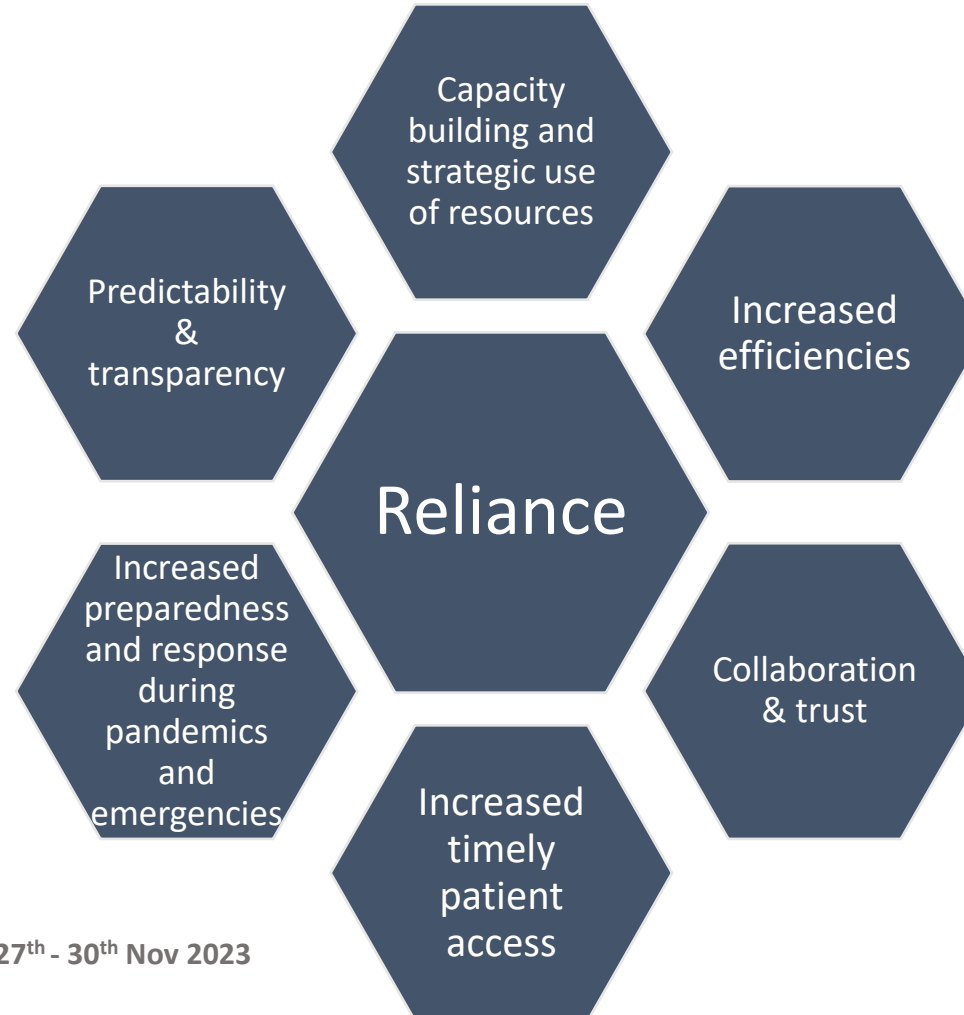
- Implement a risk-based approach to product changes
- Avoid unnecessary barriers to access based on product country of origin
- Implement a single dossier
- Adopt electronic instructions for use
- Accept digital labels

➤ Access the full document [here](#)





# Benefits and opportunities



# Thank you!

Diana Kanecka  
[d.Kanecka@medtecheurope.org](mailto:d.Kanecka@medtecheurope.org)