Global Medical Technology Alliance
Innovating for a Healthier World

IMDRF - DITTA and GMTA Joint Workshop Agenda

The life cycle of medical devices: The importance of post-market-related activities

Lifecycle approach to medical devices (scene setter)

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Device Life cycle

Post Market Surveillance System

Support for product risk classification, risk management process, benefit risk determination, PMS planning

Source of Human Clinical Data, Literature Search, Post Market Quality Data, size and other characteristics of the population using the device

CAPA, Field Safety Corrective Action, Field Safety Notice

Complaints, Adverse Events, Serious Incidents (MIR, PSR), PMCF, undesirable side-effects; feedback from users, distributors and importers

Quality and safety signals, threshold updates

Complaint Trending, Trend Report, medical or technical literature, databases and/or registers, PMCF Report, sales data

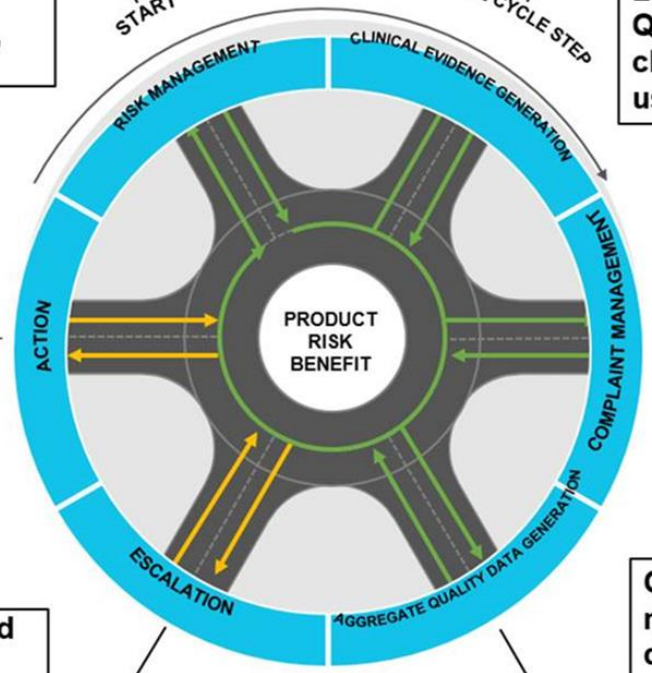

Image 1: Data source feeds to be used for the generation of the Reports

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New Technologies
SAMD- AI

- Challenges posed by Software- Artificial intelligence
  - Rapid innovation iteration . communication vs FSCA
  - New data feed to be defined . eg Consumers , focus groups ; Real World Evidence ……
- Need harmonization , pooling data
  - Reliance on IMDRF Adverse Event Terminology

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GMTA's message

*"The future of medical products regulation is in convergence/harmonization, collaboration, and networking based on **reliance** and trust."*