Personalized Medical Devices
Working Group Update

Working Group Chair: Dr Elizabeth McGrath
Therapeutic Goods Administration
Department of Health, Australia
NWIE Purpose

• The goal of this project is to develop an IMDRF Technical Document that will provide recommendations to support a harmonized approach to regulating medical devices that are manufactured for individual patients.

Rationale

• Technology has progressed to where it is now possible to ‘mass produce’ individualized medical devices:
  – e.g. 3D printing of devices based on patient CT Scan data.

• Original GHTF documentation does not adequately address these types of devices.
Benefits

- Addresses an emerging trend towards personalized treatments in the medical devices sector.
- Ensures an appropriate level of regulatory oversight is undertaken.
- Leads to harmonisation of requirements for safety, performance and manufacturing of these products.
- Provides a basis for consistent and transparent requirements across multiple jurisdictions.
- Aligns with IMDRF Strategic Priorities.
Progress

- Published N49 – Definitions for Personalized Medical Devices – Nov 2018

- Maintained Working Group membership from definitions work – all member jurisdictions represented, also one Affiliate Organization member.

- Built on concepts developed in the definitions document.

- Developed draft document proposing regulatory pathways for the different categories of personalized medical devices.
Features of the Draft Document
Personalized Medical Device Decision Tree
Proposed Regulatory Pathways

Custom-made Medical Devices
- Highest level of detail
- Recognizes unique pathway for custom-made devices

Patient-matched Medical Devices
- Reliance on usual regulatory requirements, according to the device risk classification
- Focus on validation of design envelope

Adaptable Medical Devices
- Reliance on usual regulatory requirements, according to the device risk classification
- Focus on validated instructions for the adaptable features
Proposed Annexes

Annex 1 Considerations for Additive Manufacturing
• Focus on status of raw materials for additive manufacture

Annex 2 Considerations for Point of Care Manufacture
• Introduces concept of medical device production system (MDPS)
  – collection of goods for producing a particular medical device
• MDPS regulation similar concept to regulation of adaptable medical device
  – Based on the device it is intended to produce
  – Reliance on validated instructions for using the specified system
Next Steps

April/May 2019
Public Consultation

June 2019
Face to Face Meeting to Incorporate Public Comments (Location TBD)

July/August 2019
Teleconferences to Finalize Document

Sept 2019
MC Consideration of Final Document
Thank You