



IMDRF

International Medical
Device Regulators Forum

Personalized Medical Devices Working Group Update

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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.





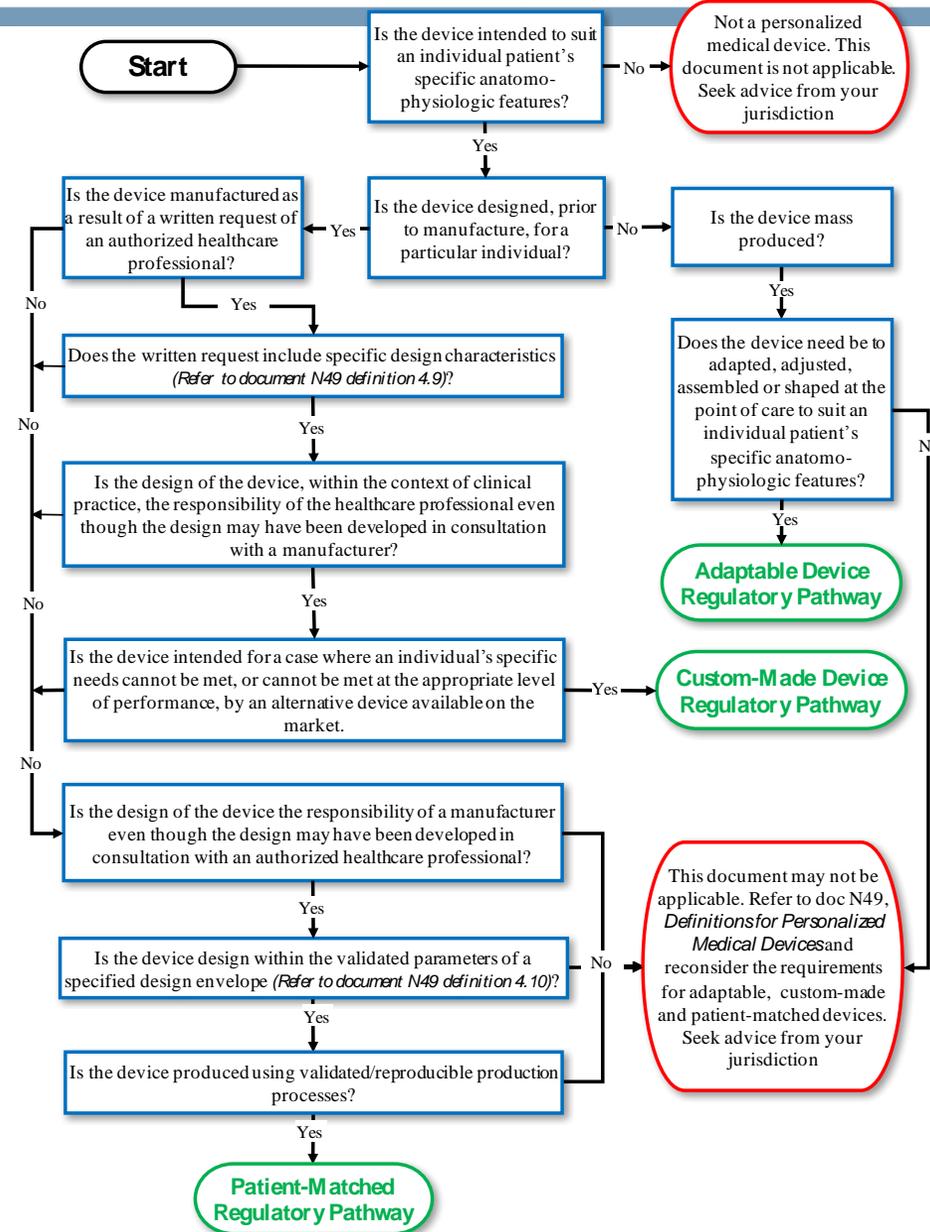
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Features of the Draft Document



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

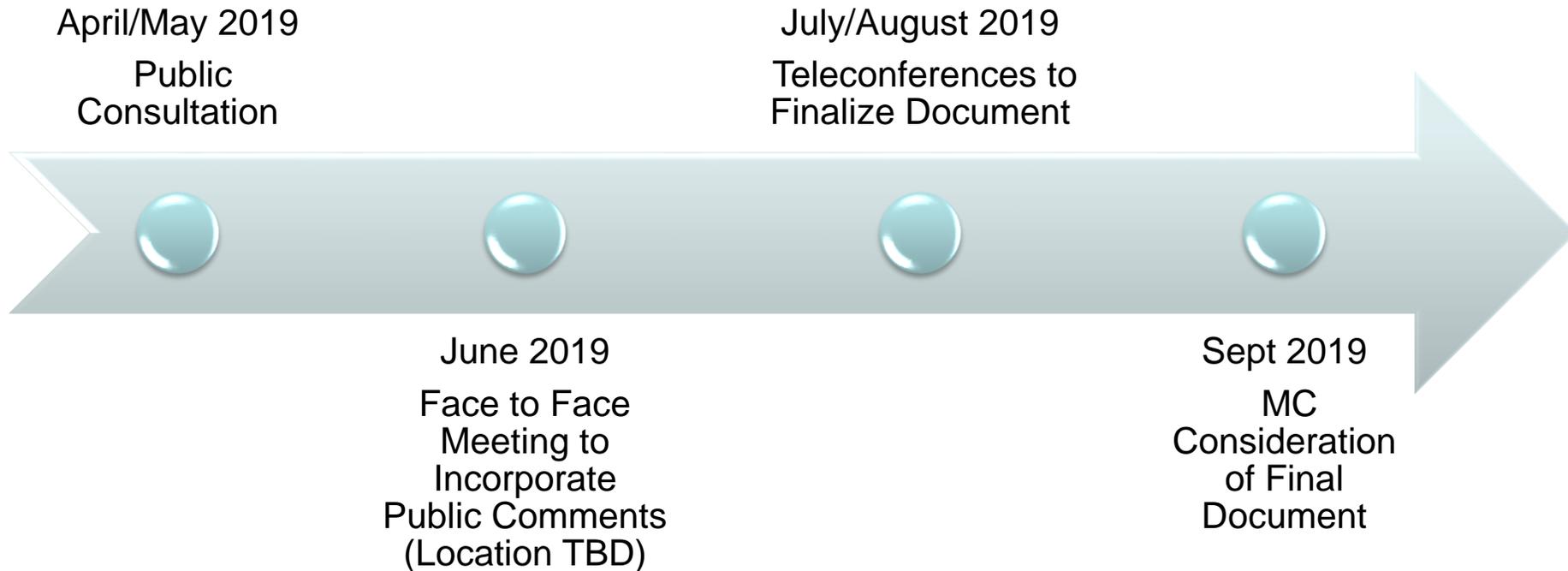
- Focus on status of raw materials for additive manufacture

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





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**Thank
You**