

## **IMDRF Status Update**

Dec 1, 2021

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## **Table of Contents**

- **01 IMDRF Management Committee Meetings in 2021**
- **02 IMDRF-DITTA Joint Workshop**
- 03 Stakeholder Forum Special Session : COVID-19
- **04** Decisions by the IMDRF MC



## **IMDRF Management Committee Meetings in 2021**

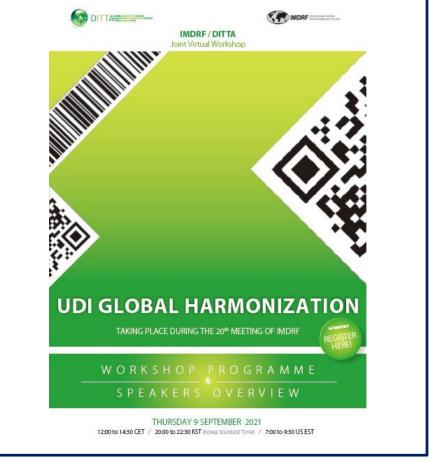
		March	September	
		16 <sup>th</sup> – 25 <sup>th</sup> March	9 <sup>th</sup> – 16 <sup>th</sup> September	
	Date	IMDRF-DITTA Joint Workshop Open Session of MC Meeting Open Stakeholder Forum Closed Session of MC Meeting		
	Dortioinanta	<ul> <li>Management Committee         <ul> <li>Australia, Brazil, Canada, China, EU,</li> <li>Japan, Russia, Singapore, South Korea, USA</li> </ul> </li> </ul>		
	Participants	Official Observers WHO, UK	Official Observers WHO, UK, Argentina	3



## **IMDRF-DITTA Joint Workshop**

# March IMDRF / DITTA WHAT TO LEARN FROM COVID-19? TAKING PLACE DURING THE 19th MEETING OF IMDRI WORKSHOP PROGRAMME TUESDAY 16 MARCH 2021 12:00 to 14:30 CET / 20:00 to 22:30 KST (Korea Standard Time) / 7:00 to 09:30 EST

### September



## Stakeholder Forum – Special Session: COVID-19 (September, 2021)



#### [ Update on the WHO EUL for IVDs ]

- WHO experience with EUL reviews
- Challenges: product dossier, QMS



#### [ Recommendation ]

- Promote rapid review and approval mechanisms
- Ensure adequate training and communication for regulators
- Leverage regulatory agility beyond pandemic

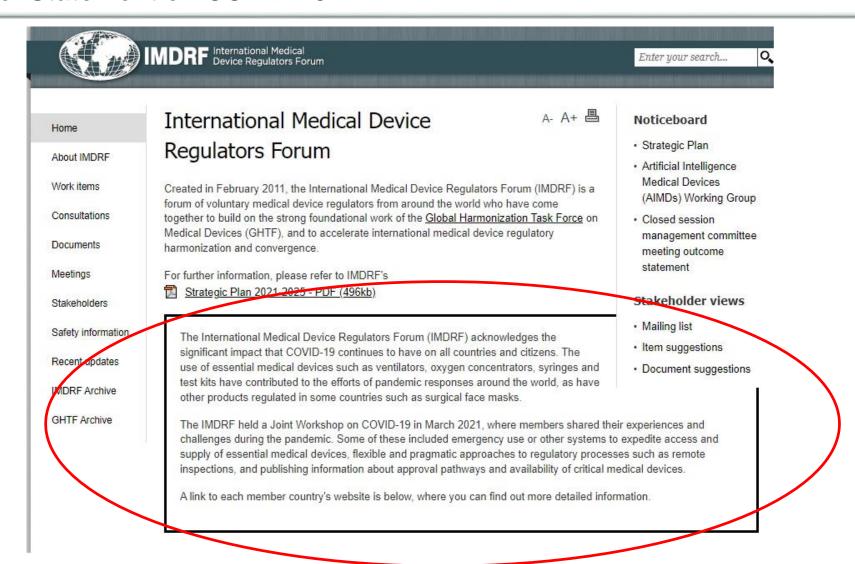


#### [ Update on MFDS's Lessons ]

- Regulatory Support(review & QMS) for Market authorization of IVDs and Medical equipment
- Establishment of the Act on medical products to respond to crisis on public health
- Improvement of Information Sharing (e.g. IMDRF)



#### **Brief Statement on COVID-19**



## **Decisions by the IMDRF MC**

## Working Groups

- AIMD : Public consultation on proposed document
- MDSAP: Revision of N4, N6 and N11 document
- MDCE & IVD : Working Groups Closed
- NWIP: Revision and Update of the GHTF clinical evidence documents for IVD

#### **IMDRF Secretariat**

## **IMDRF Secretariat 2022**

- > Australia will be the IMDRF Secretariat in 2022
  - A team is being assembled to support the Chair next year



## Thank you