The first day morning will be open to the public.

Time	Day 1	Day 2	Day 3
Morning	Registration	Registration	Registration

	Introduction of Workshop
	• Keynote speech
	  ◦ Role of standards in conformity assessment (GHTF/SG1/N44)
	  ◦ Role of standards in the assessment of medical devices (AHWP/WG2-WG8/F002:2014)
	• Introduction on Roadmap and Core-Curriculum of Medical Device PWA
	• Introduction of CoE pilot workshop
		Standards Recognition Process
		• Breakout group discussion
		• Group presentations
			• Case study: How to use the standards in conformity assessment
			• Group presentations
			• Panel discussion (Q&A)

	Coffee Break	Coffee Break	Coffee Break

	Special Section
	• Introduction of medical device registration in each economy
	• Panel discussion (Q&A)
		<u>Topic 2: Identify the Challenges in Standards for Regulatory Purposes</u>
		• Keynote speech
		  ◦ List of international standards recognized by IMDRF management committee members
		  ◦ Improving the quality of international standards for regulatory use
		  ◦ Optimizing standard for regulatory use (IMDRF/Standards WG/N51 FINAL:2018)
			Expectations from the Workshop and Next Steps
			• Stakeholder presentations
			• Certificate award ceremony

Noon	Lunch	Lunch	Lunch
Afternoon	**<u>Topic 1: Understand the Importance of the Use of Standards in the Assessment of Medical Devices</u>** • Basic scheme of conformity assessment procedure and classification (GHTF/SG1/N77&N78) • Summary of essential principles (IMDRF/GRRP WG/N47)	Common Challenges with Registration of Medical Devices • Breakout group discussion • Group presentations	Manufacturing Site Visit
	Coffee Break	Coffee Break	
	• Conformity assessment based on the standards • Standards recognition process in Japan • ISO/IEC standards recognition process • EU standard harmonization process • Panel discussion (Q&A)	**<u>Topic 3: Optimizing Standards for Regulatory Use</u>** • Keynote speech: How Standards are improved by following IMDRF guidance • Case Study: 3rd Party Review based on EP and Standards	
Evening	Welcome Reception		