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&

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Global Efforts for Harmonization

IMDRF GHWP Meeting
February 2023

JEEWON JOUNG, PhD
APEC Harmonization Center

Introduction of AHC

AHC
APEC Harmonization Center

The **APEC Harmonization Center (AHC)** was established in 2009 as an Specialized APEC Center to **promote regulatory reform and harmonization** in APEC with support of Government of Korea

Background

2008.08

Proposed establishment of Harmonization Center by APEC LSIF

2009.06

Establishment of AHC at the MFDS, Korea

2008.11

Declared & Endorsed ROK's establishment of the AHC at the Ministerial Joint Statement & Leader's Meeting

Mission

- Facilitate regulatory convergence in the region
- Enhance Quality, Safety and Efficacy of medical products
- Promote Collaboration and Information Sharing
- Support access to Best Practices and Int'l Guidelines

Introduction of AHC

VISION

Advancing APEC's trade facilitation & regional economic integration by **promoting convergence on regulatory approval procedure** for medical products

Strategic Approaches

01 Capacity Building

→ **Workshops** & In-person training

→ **Online training** via AHC website & e-Learning Center

02 Research

→ Survey on regulatory gap & training needs

→ **Publication** of drug regulatory systems

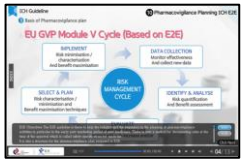
03 Collaboration

→ **Joint Projects** with Int'l organizations & APEC fora (ex. APEC KPI, AHC-ICH training module)

Overview on AHC's activities & achievements

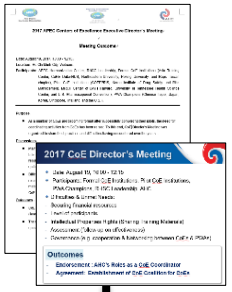
Numbers at a Glance
(As of Dec. 2022)

- Total of **58 workshops**, **12,353 participants**, **408 Trainees**
- **AHC e-Learning Center,** total of **2,327 users** from **97 countries**
- **Drug Approval System Reports : 21 APEC economies & 18 beyond APEC**



2015-2016
Collaborate with ICH in developing **online training module**

2015-2022
Report on Drug Approval Systems for APEC & beyond



2017-2018
Organizing **CoE Director's Meeting** to share challenges & experiences

2018-2021
Survey & Analysis of **APEC Key Performance Indicator (KPI)** & **PWA PI**

2019
APEC LSIF **Policy Dialogue** to envision next strategic framework

2019 & 2021
APEC Press Release & Journal on APEC's progress toward regulatory convergence (KPI)

2021-2022
Roundtable Dialogue on **Post-Pandemic** Regulatory Innovation & Convergence

AHC's effort for Medical Device

Capacity Building

01 Workshop

Annual workshop on Medical Device **since 2010** including co-hosted workshops with Regulatory authorities & AHWP

Topic Areas	Medical Device Regulations & Vigilance, Clinical Evidence, GHTF document implementation, etc.

02 CoE Pilot Training

Upbringing regulatory experts via **hands-on small group training** by APEC CoE Pilot program training

MD CoE Pilot	(2018) Medical Device Vigilance (co-host: NIDS) (2020) Medical Device Total Life Cycle (co-host: SCH Univ.)

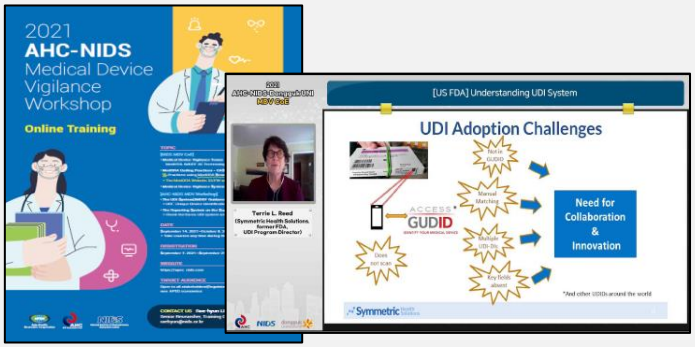
AHC's efforts for Medical Device

1) Topics of High Interest

Co-host: NIDS

Medical Device Vigilance Workshop

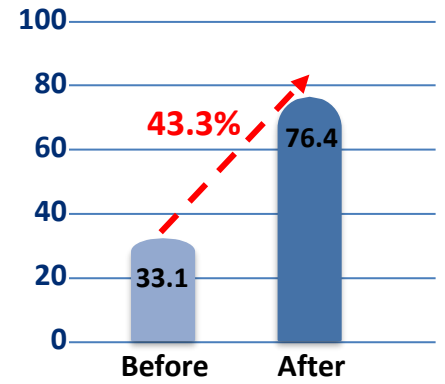
Sept. 14 – 15, 2021 | Online



⇒ **50 participants** from **6 economies** joined

⇒ Foster deeper understanding on

1) **Standardized Medical Device UDI system** with IMDRF UDI guidance and case studies (US, Korea)
2) **UDI Labeling** by comparing existing global standards (GS1, HICDD, ICCBBA)



Improvement in Understanding

Survey Results

Overall Satisfaction

Participant Feedback

Most Useful Session

- Understanding of IMDRF UDI guidance
- UDI & Reporting System on the Supply of Medical Devices

Future Training Suggestion

- Software as Medical Device (SaMD)

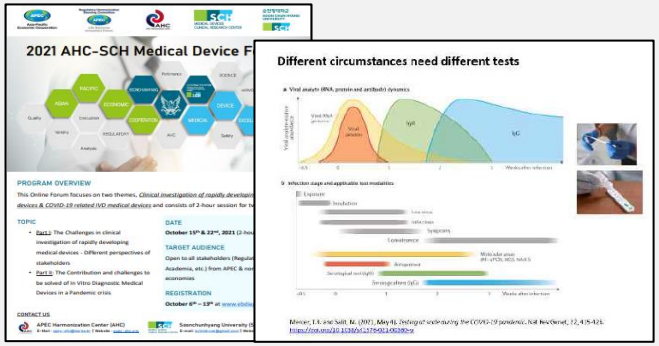
AHC's efforts for Medical Device

1) Topics of High Interest

Co-host: SCH Univ.

Medical Device Forum

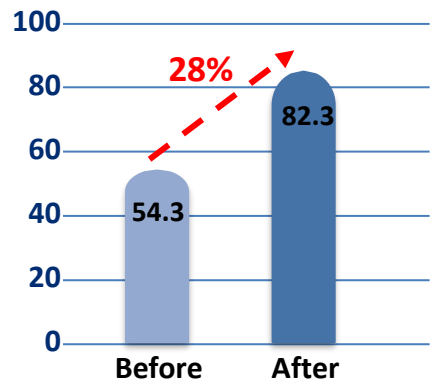
Oct. 15 & 22, 2021 | Online



⇒ **127 participants** from **22 economies** joined

⇒ Focused on discussing barriers, challenges & opportunities in **clinical investigation of innovated devices** & **IVD experiences** during COVID-19 pandemic

⇒ Recognized **need of global harmonization** for future pandemic preparedness



Improvement in Understanding

Survey Results

Overall Satisfaction

Participant Feedback

Most Useful Session

- Medical Device Innovation: Development of Digital Therapies

Future Training Suggestion

- Medical Device Regulation beyond APEC
- Software as Medical Device (SaMD)

AHC's efforts for Medical Device

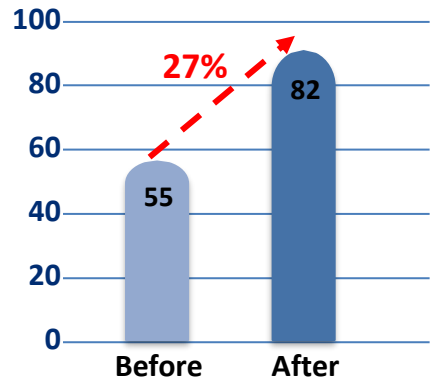
2) Supporting Regulatory Best Practices & Innovation

Co-host: AdvaMed

1st Post-Pandemic Regulatory Innovation & Convergence

Nov. 4 - 5, 2021 | Online

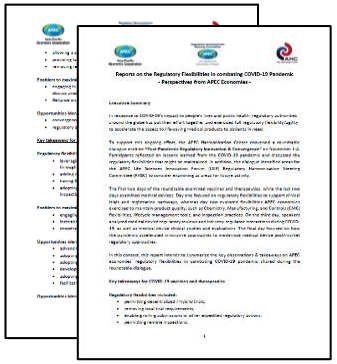
- ⇒ **109 participants** from **16 economies** joined
- ⇒ Shared **best practices & lessons learned** for regulatory review, clinical and post-market approaches during COVID-19
- ⇒ Discussed **opportunities for continued cooperation** including use of real-world evidence and reliance practices



Improvement in Understanding

Survey Results

Overall Satisfaction



Reports on **Key Takeaways & Recommendation**

Topic Suggestion

- Clinical Studies & Evaluation
- Artificial Intelligence (AI)
- Software as Medical Device (SaMD)

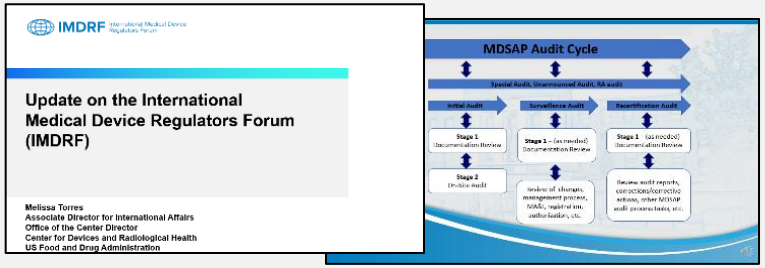
AHC's efforts for Medical Device

2) Supporting Regulatory Best Practices & Innovation

Co-host: AdvaMed

2nd Post-Pandemic Regulatory Innovation & Convergence

Nov. 8 - 9, 2022 | Hybrid

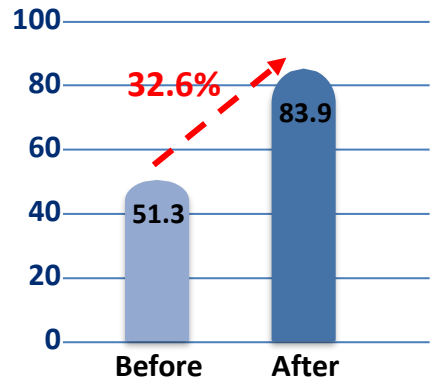


⇒ **66 participants** from **17 economies** joined

⇒ Shared **Global guidance and its application** (WHO, IMDRF), **Reliance pilot experience** that enables recommendations from the 1st Roundtable Dialogue

⇒ Addressed **additional opportunities** for regulatory convergence and innovation

Survey Results



Improvement in Understanding

Overall Satisfaction

Reports on **Key Takeaways & Future Opportunities**

Topic Suggestion

- International Guidance (ISO, IMDRF, WHO)
- In-Vitro Diagnostics (IVD)

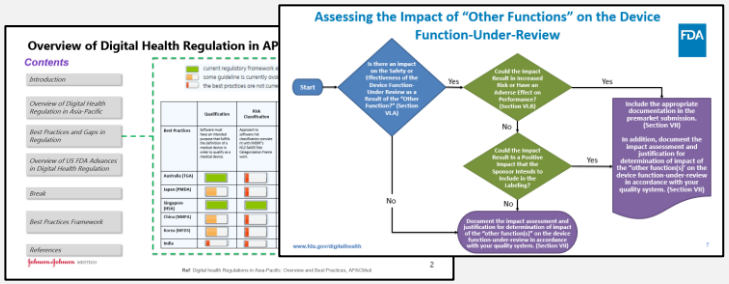
AHC's efforts for Medical Device

2) Supporting Regulatory Best Practices & Innovation

Co-host: IDHC

Accelerating Digital Health Regulatory Convergence

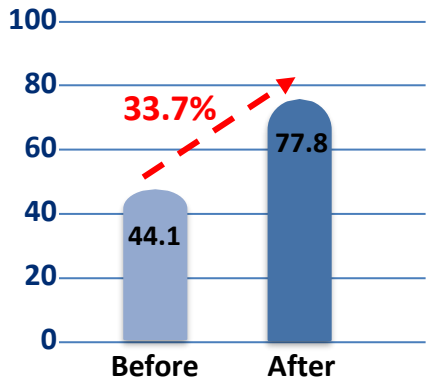
Nov. 9 - 10, 2022 | Hybrid



⇒ **61 participants** from **15 economies** joined

⇒ Introduced **overview on Digital Health regulation** including SaMD Qualification, Risk Classification and Unique Consideration for AI

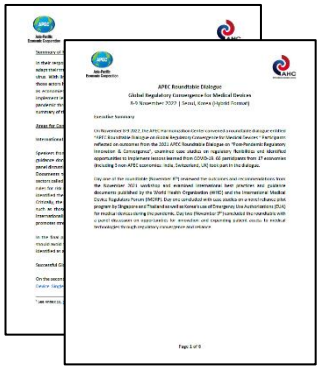
⇒ Foster understanding on **key applicable IMDRF documents** & opportunities for regulatory convergence & innovation



Improvement in Understanding

Survey Results

Overall Satisfaction



Reports on **Key Takeaways & Recommendation**

Topic Suggestion

- Applicable Standards for AI/SaMD
- ML and AS

AHC's efforts for Medical Device

Collaboration : PWA PI Project

Measuring Progress of Regulatory Convergence in RHSC MD Roadmap

Objective

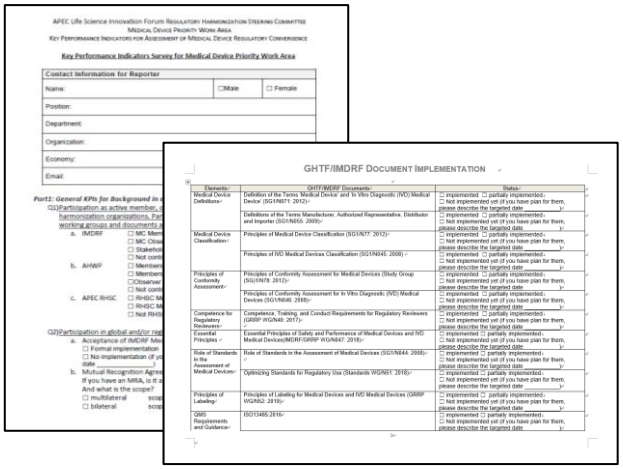
To **examine current regulatory status** of APEC member economies and develop **future strategic approaches & direction** for achieving regulatory convergence

Key Questionnaires

01 Participation in **global & regional harmonization activities**

02 Adoption of **harmonized regulatory models**

03 **Implementation of GHTF/IMDRF Document**



Current Status

Developing standardized survey template & process with RHSC leadership and Roadmap lead to ensure **accuracy** of the data and **efficiency** in its process

Future Plans

2023 AHC Workshop & Training Plan

No.	Topic	Date	Method
1	**Post Approval Change Management Protocols (PACMP)** * Introduce the concept of PACMP and applicability within the APEC region by equipping participants with practical tools & regulatory best practices	**July (TBD)**	**Online** OR **Hybrid**
2	**Post-Pandemic Roundtable Dialogue : Clinical Trials** * Discuss regulatory flexibilities & current trends in digital technology, and identify recommendations for post-pandemic regulatory innovation in clinical trials	**Sept (TBD)**	
3	**Medical Device Regulatory Convergence** * Promote regulatory best practices & experience sharing among stakeholders to facilitate implementation of international guidance and reliance practices	**Nov (TBD)**	

AHC is open for suggestions on **training needs & collaboration opportunities** with other international harmonization organization.

If interest, please contact AHC at apec-ahc@korea.kr

Asia-Pacific Economic Cooperation

APEC Harmonization Center

Thank you!