WG5 – "Clinical Evidence for Performance and Safety"

Chair: Yuwadee Patanawong

Co-Chair: Sumati Randeo

Secretary: Gaurav Verma

TC Meeting, Cebu Philippines

Nov '2016

WG5 Membership & Meeting Updates

- Total number of WG members: 27 (TBC)
  - Regulators: 7, Industry: 20
- Advisors: 2
  - Martin Devitt (Medical Devices)
  - Shelly Tang (IVDs)
- Steering Committee Members: 7
  - Yuwadee Patanawong, Sumati Randeo, Greg LeBlanc, Benny ONS, Gaurav Verma, Asma Zuberi, Mie Ohama
  - *Members of the WG who would like to actively engage in drafting and finalizing the guidance documents can apply for the membership of the steering committee to the Chair and Co-Chair, with their respective areas of interest.*
- 2016 WG5 meetings
  - *April 2016 – Face to Face meeting and through teleconference on April 27th Seoul, South Korea*
  - *Teleconference organized*
    1st Qtr --- Mar 31st 2016
    4th Qtr --- Nov 17th 2016

Proposed Work Plan 2016

Work Plan 2016 Status Update

Work Item 1 (Framework)	Output	Target & Status Update
Initiate SWOT Analysis of WG 5 Framework *Annual exercise & analysis*	Report to be submitted to TC	Report finalized Nov 17th 2016

Work Item 2 (Regulatory Updates)	Output	Target & Status Update
Regular review of Global clinical regulatory updates	Presentation at WG 5 meeting	APAC updates shared in March meeting  Adobe Acrobat Document Further updates will be shared in WG5 workshop organized in Cebu on Nov 22nd

Work Item 3 (Collaboration & Liaison with TC & Global Forums)	Output	Target & Status Update
Developing a guidance document on **"General Principles of Clinical Investigation Audit & Inspection"**	Achieve convergence on key concepts, definitions and essential principles	Report and first draft circulated for members input Nov 17th 2016.
IMDRF	Monitor IMDRF activities and evaluate the guidance documents	Provide periodic updates to the WG  Microsoft PowerPoint Presentat

Work Plan 2016 Status Update

Work Item 4 (Develop & Draft Guidance Documents)	Output	Target & Status Update
1. Clinical investigations 2. Post-Market Clinical Follow-up Studies	Draft guidance document	Documents reviewed it was suggested by WG members to compare and do gap assessment with ISO 13485:2016 and ISO 14155. Assessment to completed by Dec 2016 and report / comments consolidation by Feb 2017. Endorsement plan to be discussed in the TC meeting in Mar 2017
3. IVDs -- ISO 20916: In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects – Good study practices	Monitor the progress of draft standard	WG3 of ISO TC 212 will review the comments in a meeting in June 2017 with the aim to produce a DIS version during the next annual ISO TC 212 meeting in Nov 2017. For the moment project is still on track to have a final standard in Nov 2018, three years after the work started.

Work Plan 2016 Status Update

Work Item 5 (Standards & Best Practices)	Output	Target & Status Update
• AHWP WG 5 will propose a new WI for 2016 regarding developing a guidance document on **"General Principles of Clinical Investigation Audit & Inspection"**. • WG 5 seeks collaboration with ISO 14155 TC to support the development of the Guidance Document	WG 5 chair to facilitate approval from AHWP TC and AHWP chair for collaboration with ISO 14155 at AHWP Annual TC Meeting 2015	Approval received and consensus built March 2016 Report finalized draft shared with WG members Nov 17th for comments and further circulation during the annual meeting in Cebu Philippines Nov 2016

Proposed Work Plan 2016

Work Item 6 (Training)	Output	Target & Status update
Work Group documents	Clinical Evaluation	AHWP Annual Meeting

Training for WG 5 and AHWP members :

WG5 organizing workshop during AHWP annual meeting in Cebu Philippines on Nov 22nd

Topics covered:

- Comparative overview of Global Clinical Investigation Regulations
- Clinical Evaluation for IVD Medical Devices
- Clinical Evaluation & Investigation for General Medical Devices
- Overview of ISO 14155 Clinical Investigation Requirements.

Thanks