WG5 – "Clinical Evidence for Performance and Safety"

Chair: Yuwadee Patanawong

Co-Chair: Sumati Randeo

Secretary: Gaurav Verma

TC Meeting, New Delhi
December '2017

WG5 Membership & Meeting Updates

- Total number of WG members: 32
  - Regulators: 8, Industry: 24
- Advisors: 2
  - Shelly Tang , Martin Devitt
- 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.*
- 2017 WG5 meetings
  - *There were **"Two"** face to face meetings organized as follows:*
  - *March in Hong Kong, 7-8 June in Sydney*

WG5 accomplishments in 2017

- To ensure that WG5 members were up-to-date with global regulatory environment and to increase awareness of regional new and changing regulations, the WG5 meeting took place in June 2017 in Sydney. The following updates were shared and accomplished.
  - Updates on IMDRF WG, India MDR, EU MDR IVDR,
  - Regulatory Environment in Australia: TGA Device Regulations & Planned MMDR Reforms, Introduction to the New TGA Clinical Evidence Guideline and national clinical landscape in Australia
- Collaboration with Global forums with regards to developing new guidance documents was achieved.
  - Gap analysis between following GHTF documents, the latest ISO 13485:2016 and updates from ISO 14155.
    - Clinical Investigations
    - Post - Market Clinical Follow Up Studies
  - Engaged in review of updated ISO 14155
  - Understanding on development of ISO 20196
- While WG5 developed a draft guidance document, 'General Principles of Clinical Investigation Audit & Inspection' per approval from AHWP TC and ISO 14155TC, the WG5 SC concluded that the guidance document will not be released in 2017 (see the next slide).

Summary of AHWP WG5 SC discussion on 'General Principles of Clinical Investigation Audit & Inspection'

- Background:
  - Development of 'General Principles of Clinical Investigation Audit & Inspection' was added as a working item for AHWP WG5 during the TC meeting in 2015 since audits & external inspections on clinical investigations are not in the scope of AHWP WG6 (Quality Management System: Audit & Assessment) and this working item doesn't fit to other working groups.
  - During the AHWP WG5 meeting in June 2017 in Sydney, the Steering Committee deliberated on the inclusion of this guidance as part of "Clinical Evidence" document before the ISO 14155 standard revision. It was decided that the rationale will be prepared both with the merits and demerits of including this document and based on the rationale developed decision will be deferred to TC chair for adoption or denial of this guidance.

- Merits vs. Demerits

Merits	Demerits
○ Development of 'General Principles of Clinical Investigation Audit & Inspection' per the 2017 AHWP WG5 working plan. ○ AHWP guidance covers	○ Current AHWP working draft is based on Annex J of ISO TC194 working documents. The final Annex J document will not be available until 2019. If AHWP WG5 release a guidance document this year, there might be inconsistencies between AHWP WG5 document and the final ISO 14155 document which will require additional update for the AHWP WG5 document.

- Conclusion:
  - To reassess if it makes sense for AHWP WG5 to develop a guidance on General Principles of Clinical Investigation Audit & Inspection after ISO 14155 Annex J is release in 2019.

Work Plan 2017

WG 5 Work Plan 2017- Status Update

Work Item 1 (Framework)	Target Output	Status Update
Annual review SWOT Analysis of WG 5 Framework ***Annual exercise & analysis***	Report to be submitted to TC	On track

Work Item 2 (Regulatory Updates)	Target Output	Status Update
Regular review of Global clinical regulatory updates	To share and update the WG 5 members of constantly changing regulatory landscape with respect to Clinical Investigation regulations and guidance.	COMPLETED Workshop held on June 7th 2017 in Sydney Australia on the following topics: • TGA Regulatory and planned MMDR reforms • New TGA Clinical Evidence Guidance Pre and Post- Market. • Overview of New India MDR 2017 • New EU MDR IVDR updates

WG 5 Work Plan 2017- Status Update

Work Item 3 (Collaboration & Liaison with TC & Global Forums)	Target Output	Status Update
IMDRF	Monitor IMDRF activities and share the updates	COMPLETED IMDRF March 2017 meeting updates presented during June 7th 2017 meeting in Sydney.
ISO 14155	Monitor the progress of updated standard and share the updates	COMPLETED Updates presented on the following during the WG 5 steering committee workshop in Sydney June 8th 2017 • Current revision of ISO 14155:2011 • Comparative analysis presented of ISO 14155:2011 with that of ISO 13485:2016 and New India MDR 2017 requirements.
IVDs -- ISO 20916: In vitro diagnostic medical devices	Monitor the progress of draft standard and share the updates	COMPLETED Updates presented on the development of the structure of the standard and expected timelines for publication in DIS during the WG 5 steering committee workshop in Sydney June 8th 2017

WG 5 Work Plan 2017- Status Update

Work Item 4 (Develop & Draft Guidance Documents)	Target Output	Status Update
1. Clinical investigations 2. Post-Market Clinical Follow-up Studies	Finalize guidance document for endorsement in Annual Meeting in Dec 2017	COMPLETED

Work Item 4 (Develop & Draft Guidance Documents)	Target Output	Status Update
Guidance on clinical investigation audits Reference Annexure J of the draft under revision of ISO 14155	Rationale for inclusion it as a section in the Clinical Investigation Guidance document	COMPLETED During the steering committee meeting on June 9th 2017 it was decided to defer the decision to AHWP TC Chair.

WG 5 Work Plan 2017- Status Update

Work Item 5 (Standards & Best Practices)	Target Output	Status Update
Collaboration with ISO 14155 TC on the development of documents	Support revision of the standard by actively contributing to the sub groups of the standard committee	COMPLETD All three recommendations made to the revision of the standard by WG 5 steering committee have been accepted and incorporated in the draft.

Proposed Work Plan 2018

Proposed Work Plan 2018

Work Item 1 (Framework)	Output	Target & Status Update
Annual review SWOT Analysis of WG 5 Framework ***Annual exercise & analysis***	Report to be submitted to TC	To be completed by Nov 2018
Work Item 2 (Regulatory Updates)	**Output**	**Target & Status Update**
Regular review of Global clinical regulatory updates	Presentation at WG 5 meeting	Periodic updates to be shared with the WG members
Work Item 3 (Collaboration & Liaison with TC & Global Forums)	**Output**	**Target & Status Update**
IMDRF	Monitor IMDRF activities a	Periodic updates to be shared with the WG members
ISO 14155	Monitor the progress of updated standard	Periodic updates to be shared with the WG members
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	Periodic updates to be shared with the WG members For the moment project is still on track to have a final standard in Nov 2018, three years after the work started.

Proposed Work Plan 2018

Work Item 4 (Develop & Draft Guidance Documents)	Output	Target & Status Update
1. General Principles of Clinical Investigation Audit & Inspection 2. Identify areas of focus for AHWP WG 5 guidance document for 2018	Finalize guidance document	Continue to monitor a working draft of ISO 14155 and Target endorsement in Q4 2019 New area of focus will be determined in Q1 2018
Work Item 5 (Standards & Best Practices)	**Output**	**Target & Status Update**
Collaboration with ISO 14155 TC on the development of documents	Mutual input into documents	Ongoing
Work Item 6 (Training)		
For training for WG 5 and AHWP members, WG5 could organize a workshop during AHWP annual meeting in 2018..		

Thanks