



# WG5 – “Clinical Evidence for Performance and Safety”

**Chair:** Yuwadee Patanawong

**Co-Chair:** Sumati Randeo

**Secretary:** Gaurav Verma

AHWP 19<sup>th</sup> TC Meeting  
5 Nov 2015, Bangkok

# WG5 Membership & Meeting Updates

- Total number of WG members: 27
  - Regulators: 7, Industry: 20
- Advisors: 2
  - Shelly Tang , Martin Devitt (TBC)
- 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.*
- 2015 WG5 meetings
  - There were **“Three”** face to face meetings organized as follows:
  - *March in Singapore, 26-28 May in Bangkok and 2-5 November in Bangkok*
  - *Four Teleconference organized on Quarterly basis*

# Proposed Work Plan 2015 - 17

# Proposed Work Plan 2015 -17

Work Item 1 ( Framework )	Output	Target
<ol style="list-style-type: none"> <li>1. Re-name WG 5 from “Clinical Performance &amp; Safety” to “<b>Clinical Evidence for Performance and Safety</b>”</li> <li>2. Nomination of Advisor for the term 2015-17</li> <li>3. Reconstitution of the WG 5 Structure</li> </ol>	<p>Consensus amongst WG5 members and TC</p>	<p>2015 -17</p>
Work Item 2 (Regulatory Updates)	Output	Target
<p>Regular review of Global clinical regulatory updates</p>	<p>Presentation at WG 5 meeting</p>	<p>Minimum Quarterly calls and Face – Face meeting as and when decided.</p>
<p>Consolidated annual update</p>	<p>Presentation at annual meeting</p>	<p>AHWP annual meeting</p>

# Proposed Work Plan 2015 -17

Work Item 3 (Collaboration & Liaison with TC, WGs & Global Forums )	Output	Target
• Closely co-ordinate and liaise with AHWP different WGs and TC	Achieve convergence on key concepts, definitions and essential principles	TC meetings
• IMDRF	Monitor IMDRF activities and evaluate the guidance documents	Provide periodic updates to the WG

# Proposed Work Plan 2015 -17

<b>Work Item 4 (Develop &amp; Draft Guidance Documents )</b>	<b>Output</b>	<b>Target</b>
Identify and draft minimum two AHWP WG 5 guidance document annually.	Seek inputs and build consensus amongst WG5 members	Finalize draft by WG third quarter meeting .
	Seek inputs and build consensus amongst AHWP TC members	Target Endorsement at AHWP annual meeting
	Seek approval from TC	


# Proposed Work Plan 2015 - 17

<b>Work Item 5 (Liaise with ISO 14155 TC )</b>	<b>Output</b>	<b>Target</b>
Provide comments on the ISO Revisions as and when amendments are subjected through the ISO 14155 TC	Review the draft and prepare recommendations	As per the deadlines provided
Participate in the ISO 14155 TC annual meetings (June 2015)	Present WG 5 recommendations to ISO 14155 TC	ISO 14155 TC annual meetings
Present ISO 14155 TC updates	AHWPWG 5 meetings	Qtr Meetings

# Proposed Work Plan 2015 -17

Work Item 6 (Training)	Output	Target
Global documents	Identify minimum one Global guidance document annually for training	Annual Trainings dates will be determined during meetings
Work Group documents	Training to be conducted on the endorsed documents	





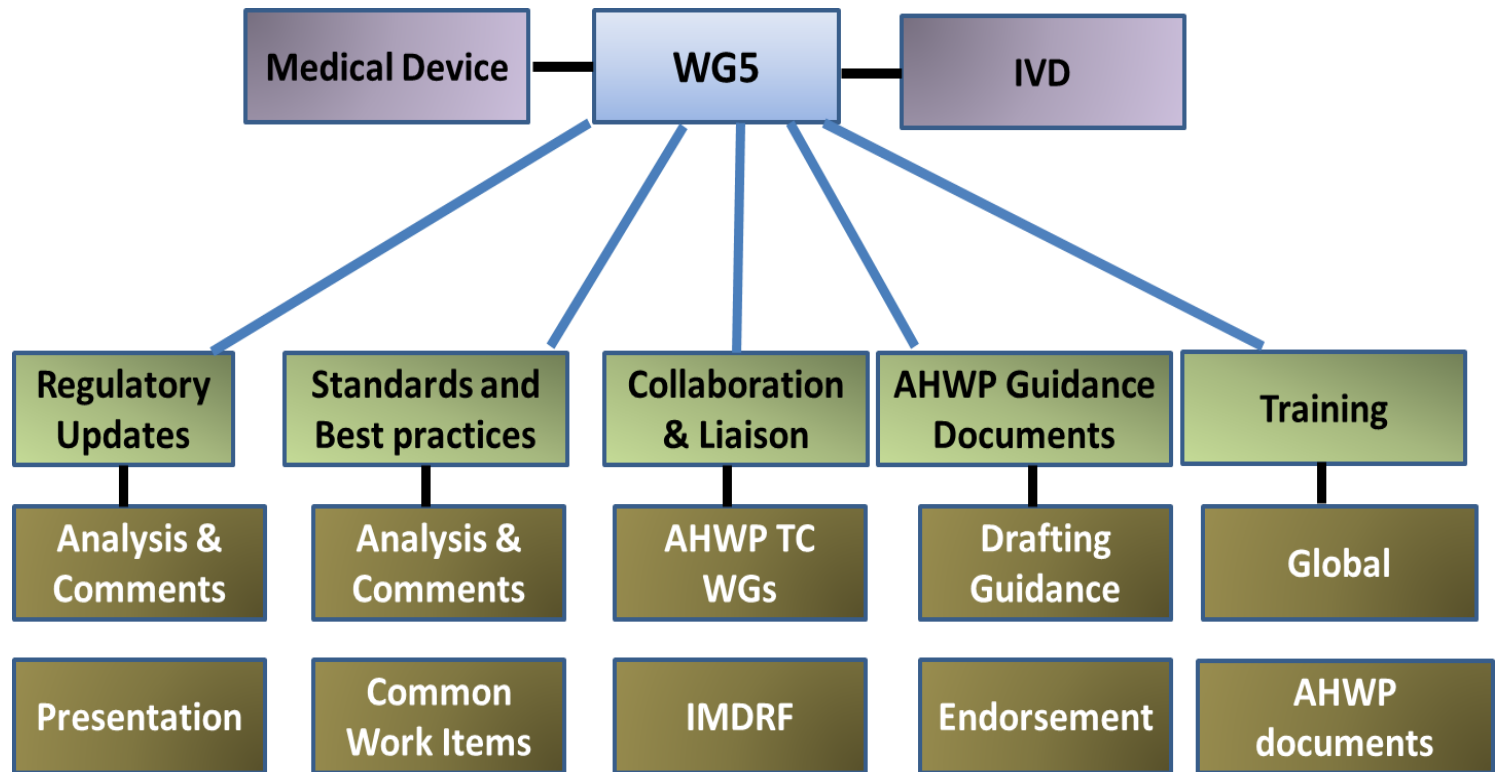
# Work Plan 2015

## Updates & Progress Report

# Work Plan 2015 - Updates

Work Item 1 (Reconstitution of the WG 5)	Output	Target & Status
<ul style="list-style-type: none"> <li>Proposed name <b>“Clinical Evidence for Performance and Safety”</b></li> <li>WG5 restructured as follows:               <div data-bbox="241 628 1120 1085" data-label="Diagram"> <pre> graph TD     MD[Medical Device] --- WG5[WG5]     IVD[IVD] --- WG5     WG5 --- RU[Regulatory Updates]     WG5 --- SBP[Standards and Best practices]     WG5 --- CL[Collaboration &amp; Liaison]     WG5 --- AGD[AHWP Guidance Documents]     WG5 --- TR[Training]     RU --- RUC[Analysis &amp; Comments]     RU --- RP[Presentation]     SBP --- SBPC[Analysis &amp; Comments]     SBP --- SBPW[Common Work Items]     CL --- CLTC[AHWP TC WGs]     CL --- CLIM[IMDRF]     AGD --- AGDG[Drafting Guidance]     AGD --- AGDE[Endorsement]     TR --- TRG[Global]     TR --- TRAD[AHWP documents]           </pre> </div> </li> <li>Two Advisors nominated are               <ol style="list-style-type: none"> <li>Shelly Tang – IVD Confirmed</li> <li>Martin Devitt – MD (TBC)</li> </ol> </li> </ul>	<p>New name and WG 5 restructuring endorsed by WG and TC chair</p> <p>Constituted WG5 Steering Committee</p> <p>Framed the “Ground Rules” to enhance WG working</p>	<p><b>Achieved</b></p>

# WG5 restructured



- **Two Advisors nominated are**
  1. Shelly Tang – IVD Confirmed
  2. Martin Devitt – MD (TBC)

# Work Plan 2015 - updates

Work Item 2 (Regulatory Updates)	Output	Target & Status
<ul style="list-style-type: none"><li>Present India regulatory updates and Review of the documents on Accreditation of Ethics Committee, Investigators &amp; Clinical Sites</li></ul>	Seek inputs and comments from WG members	Achieved shared the update with the group in March WG call
<ul style="list-style-type: none"><li>Country Updates on Revised Regulations</li></ul>	Presentation at the WG 5 meeting in Bangkok	Achieved Updates were presented for India , Pakistan and China at May 2015 Bangkok meeting.

# Work Plan 2015 - Updates

Work Item 3 (Collaboration & Liaison with TC & Global Forums )	Output	Target & Status
<ul style="list-style-type: none"><li>Closely co-ordinate and liaise with AHWP different WGs and TC</li></ul>	Initiated discussion with AHWP Co Chair & TC chair and Sectary. Consensus was build to develop the glossary of Key concepts and definitions TBD in next TC meeting	Initiated discussion on Nov 2 <sup>nd</sup> 2015
<ul style="list-style-type: none"><li>IMDRF</li></ul>	Monitor IMDRF activities and evaluate the guidance documents	Provided updates during WG meeting on Nov 2 <sup>nd</sup> 2015

# Work Plan 2015 - Updates

## Work Item 4 (Develop & Draft Guidance Documents )

## Output

## Target

- Steering Committee of WG 5 deliberated on the documents coming out of GHTF, it was determined that the GHTF guidance documents were suitable to serve as foundation and will be the key reference for the AHWP WG5 Guidance Documents
- Same was held for the analogous IVD documents.

Current work plan was revised to reflect these changes and WI 4 segregated as follows:

1. Clinical Evidence Definition & Key Concepts MD
2. Clinical Evidence Definition & Key Concepts IVD
3. Clinical Evaluation MD
4. Clinical Evidence - Scientific Validity Determination and Performance evaluation- IVD

## Achieved

**Listed 4 documents** Draft Documents sent for comments which were deliberated by Steering Committee. These were mapped with GHTF & ISO 14155 documents

**The documents are proposed for endorsement**

**Conditionally** as decided by Steering Committee and TC chair that **the references, definitions and common concepts** need to be converged and aligned with other Working Groups.



# 2015 Targets & Steps for Document Endorsement

- Bangkok Draft scrubbed and shared with SC – June 15<sup>th</sup>
- SC meets through Conference call & finalizes draft – June 24<sup>th</sup>
- WG 5 Members Comment deadline – July 20<sup>th</sup>
- Comments Consolidated from WG 5 Members – July 22<sup>nd</sup>
- SC Scrubs the draft – July 24<sup>th</sup>
- SC team meets through conference call – July 30<sup>th</sup>
- Draft finalized by WG 5 to be posted for public comments – Aug 14<sup>th</sup>
- Public Comments Deadline – Sept 15<sup>th</sup>
- Public Comments review by SC & volunteers from WG 5 – Sept 21<sup>st</sup>
- SC team meets through conference call – Sept 25<sup>th</sup>
- Scrub the draft to be released to TC – Oct 7<sup>th</sup>
- TC approves for endorsement before annual meeting- Oct 15<sup>th</sup>



# Work Plan 2015 - Updates

Work Item 5 (Liaise with ISO 14155 TC)	Output	Target
Provide comments on the ISO Revisions as and when amendments are subjected through the ISO 14155 TC	Reviewed three proposed drafts of ISO 14155 and recommendations submitted	Achieved
Participate in the ISO 14155 TC annual meetings	Present WG 5 recommendations	Achieved Attended meeting in June 2015 at Lund Sweden
Present ISO 14155 TC updates	<ul style="list-style-type: none"><li>AHWPWG 5 meetings</li></ul>	Achieved Updates provided during May 28 <sup>th</sup> and Nov 2 <sup>nd</sup> meetings

# Work Plan 2015 - Updates

Work Item 6 (Training)	Output	Target & Status
Global documents	Organize a panel discussion on Clinical Evaluation	Achieved Panel discussion organized at Annual AHWP Meeting Bangkok
<p>It was decided to organize a session on Clinical during the annual AHWP Meeting workshop on 3<sup>rd</sup> Nov 2015.</p>		
<p>The panelists shared their experiences from established regulatory systems and emerging regulatory systems, examples: Health Canada, Australia TGA , EU (Germany), India and Thailand</p>		
<p><b>PROPOSAL</b> : Online training for WG members who are not able to attend face to face.</p>		

# Proposed Work Plan 2016

# Proposed Work Plan 2016

Work Item 1 ( Framework )	Output	Target
Initiate SWOT Analysis of WG 5 Framework	Report to be submitted to TC	End of term 205-2017
Work Item 2 (Regulatory Updates)	Output	Target
Regular review of Global clinical regulatory updates	Presentation at WG 5 meeting	Quarterly calls
Work Item 3 (Collaboration & Liaison with TC & Global Forums )	Output	Target
<ul style="list-style-type: none"> <li>Proposal for a new Work Instruction for 2016 regarding developing a guidance document on <b>“General Principles of Clinical Investigation Audit &amp; Inspection”</b></li> </ul>	Achieve convergence on key concepts, definitions and essential principles	TBD at TC meetings
<ul style="list-style-type: none"> <li>IMDRF</li> </ul>	Monitor IMDRF activities and evaluate the guidance documents	Provide periodic updates to the WG

# Proposed Work Plan 2016

## Work Item 4 (Develop & Draft Guidance Documents )

## Output

## Target

- |   |             |                            |
|---|-------------|----------------------------|
| 1. Clinical investigations                | TBD and TBC | TBD and TBC at TC meetings |
| 2. Post-Market Clinical Follow-up Studies |             |                            |

# Proposed Work Plan 2016

Work Item 5 (Standards & Best Practices)	Output	Target Date
<ul style="list-style-type: none"><li>AHWP WG 5 will propose a new WI for 2016 regarding developing a guidance document on <b>“General Principles of Clinical Investigation Audit &amp; Inspection”</b>.</li><li>WG 5 seeks collaboration with ISO 14155 TC to support the development of the Guidance Document</li></ul>	WG 5 chair to facilitate approval from AHWP TC and AHWP chair for collaboration with ISO 14155 at AHWP Annual TC Meeting 2015	TBD

# Proposed Work Plan 2016

Work Item 6 (Training)	Output	Target
Work Group documents	TBD	TBC in next face to face WG meeting
Training for WG members on *		
1. GHTF Clinical Investigation----- Greg		
2. GHTF Clinical Performance Studies --- Benny / Shelly (TBC)		
3. ISO 14155 wrt Clinical Investigation ---- Ohama Mie		
* Subject to approval of the Evidence documents prepared by WG in case not approved then the training will be on Clinical Evidence .		

Thanks