Work Group 5
Clinical Safety/Performance

AHWP TC Meeting,
Bangkok
26th Feb' 2013

Work Group V - Overview

Chair: **Ms. Yuwadee PATANAWONG**
Food and Drug Administration (Thai FDA) **Thail**

Co-chair: **Ms. SUMATI Randeo**
Abbott Laboratories, India

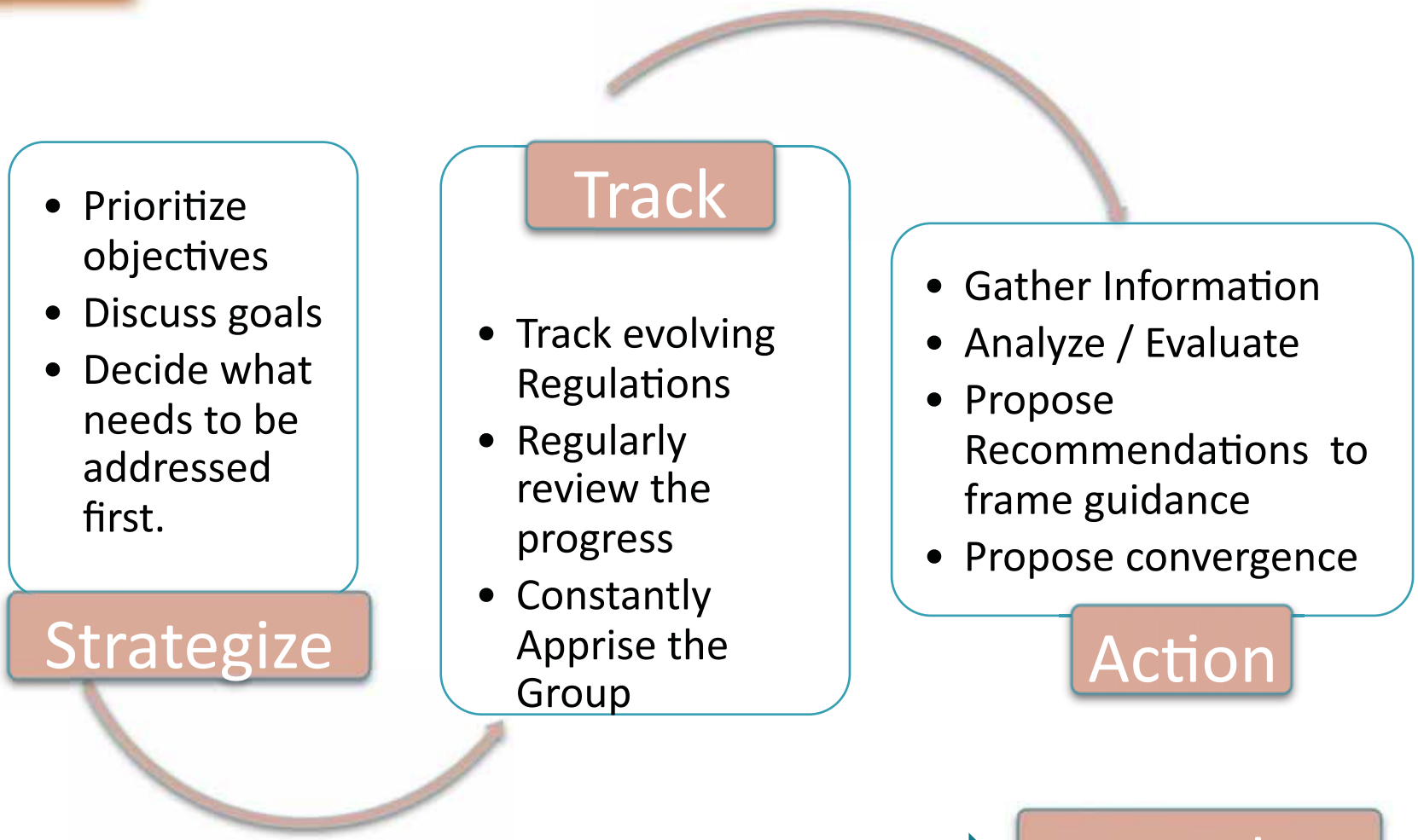
Number of members: **21 (including secretary by Feb 2013)**

Extend Covers 7 member economies i.e. India, China, Saudi Arabia, Malaysia, Thailand, Singapore and also a member from USA.

Three Sub Groups

- **Comparative Study**
- **Document Review & Adoption**
- **Trainings**

WG V – STAR Vision



FASTER CONVERGENCE → Result

TC Recommendations

- Keep track of new and emerging regulations in member economies
- Evaluate and update the group so that we can foster the conversions faster.
- To evaluate and understand IMDRF objectives regarding
  - Harmonized Standards
  - Guidance on how to determine Risk / Benefit Analysis both in Pre and Post Market Scenario
  - Clinical & Non Clinical Evaluation of Nano - particles

Proposed Plan 2012 - 2014

W 1	• Establish annual & long term work plan for WG 5 by April 2012
W 2	• To build consensus within the WG to continue framing the guidance document based on GHTF SG 5, ISO 14155 and ICH GCP
W 3	• Review SG5 & other relevant guidance documents • Make recommendations to AHWP member economies on the feasibility of adoption
W 4	• Comparative study of regulations & related guidance on Clinical Trial in AHWP member economics
W 5	• Training on Clinical Evaluation & Investigational Plans
W 6	• Partner with other TC Work Groups' initiatives to provide expertise & input relating to clinical safety/performance

Deliverables & Status 2012

WI Priority	Deliverables	Action Plan	Target	Status
W1	Consensus on framing the guidance	Survey to conducted & take inputs from Member Economies	June 2012	Initiated
W2	Advisor: Possibility of having clinician as advisors	Collaborate with TC chair and other WG chairs , co chairs	June 2012	To be discussed with TC chair
W3	Mapping with SG5 GN and latest version of ISO 14155	Comparison to be done between the two ISO versions	Oct 2012	Completed

Deliverables & Status 2012

WI Priority	Deliverables	Action Plan	Target	Status
W4	Comparative study of regulations & related guidance on Clinical Trial Requirements	Keep tracking the emerging regulations regarding Clinical Investigations in the member economies	Present the updates in the TC meetings	Completed
W5	IMDRF initiatives with respect to their WG on Risk / Benefit Analysis	Keep track of the developments at IMDRF and apprise TC at annual Meeting	Nov 2012	Ongoing

Deliverables & Status 2012

WI Priority	Deliverables	Action Plan	Target	Status
W6	Partner with other TC Work Groups' initiatives to provide expertise & input relating to clinical safety/ performance	Provided the consolidated comments on New GHTF Guidance documents SG5 (PD)/N06R3 –"Clinical Evidence for IVD Key concepts & Definitions" SG5(PD)/N07R4 – –"Clinical Evidence for IVD Scientific Validity Determination & Performance Evaluation" to AHWP WG1 a for further evaluation	Nov '12	Completed

WG5 Training Needs Identified

Priority	Work Item	Deliverables	Action Plan	Target
1	W3	Training on GHTF SG5 GN and latest version of ISO 14155	Conduct the workshop for WG 5 and facilitate it with the help of WGVI.	Completed Inputs provided to WG 6 on 4th June'2012
2	W4	Training on Clinical Evaluation & Investigation plan like 1.Monitoring 2.Site Audits 3.Data Evaluation	Conduct the workshop for WG 5 and facilitate it with the help of WGVI.	

AHWP Plan 2013

WI Priority	Deliverables	Action Plan	Target
W1	Consensus on framing the guidance	Survey: On the regulation and implementation of Clinical Investigation including clinical trial requirements	Roll the survey by Q2 2013 Inputs to be collated by Nov 13
W2	Advisor: Possibility of having clinician as advisors	Inputs to be taken from TC advisors & TC chair	Q1 2013 (31st Mar2013)
W3	Mapping with ICH GCP, SG5 GN and latest version of ISO 14155	Provide inputs to the next ISO/TC 194/WG 4 "Clinical investigations of medical devices in humans"	Q2 2013 (25th & 26th April 2013)

Plan 2013

WI Priority	Deliverables	Action Plan	Target
W4	Comparative study of regulations & related guidance on Clinical Trial Requirements	Keep tracking the emerging regulations regarding Clinical Investigations in the member economies	Present the updates in the TC meetings & Annual Meeting
W5	IMDRF initiatives with respect to their WG on Risk / Benefit Analysis	Keep track of the developments at IMDRF and apprise TC at annual Meeting	

Plan 2013

WI Priority	Deliverables	Action Plan	Target
W6	Partner with other TC Work Groups' initiatives to provide expertise & input relating to clinical safety/performance		On going

Training Plan 2013

Priority	Work Item	Deliverables	Action Plan	Target
1	W3	Training on ICH GCP, GHTF SG5 GN and latest version of ISO 14155	Conduct the workshop for WG 5 and facilitate it with the help of WGVI.	
2	W4	Training on Clinical Evaluation & Investigation plan like 1.Monitoring 2.Site Audits 3.Data Evaluation	Conduct the workshop for WG 5 and facilitate it with the help of WGVI.	

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Working Towards Medical Device Harmonization in Asia