Work Group 5
Clinical Safety/Performance

AHWP TC Meeting, Singapore

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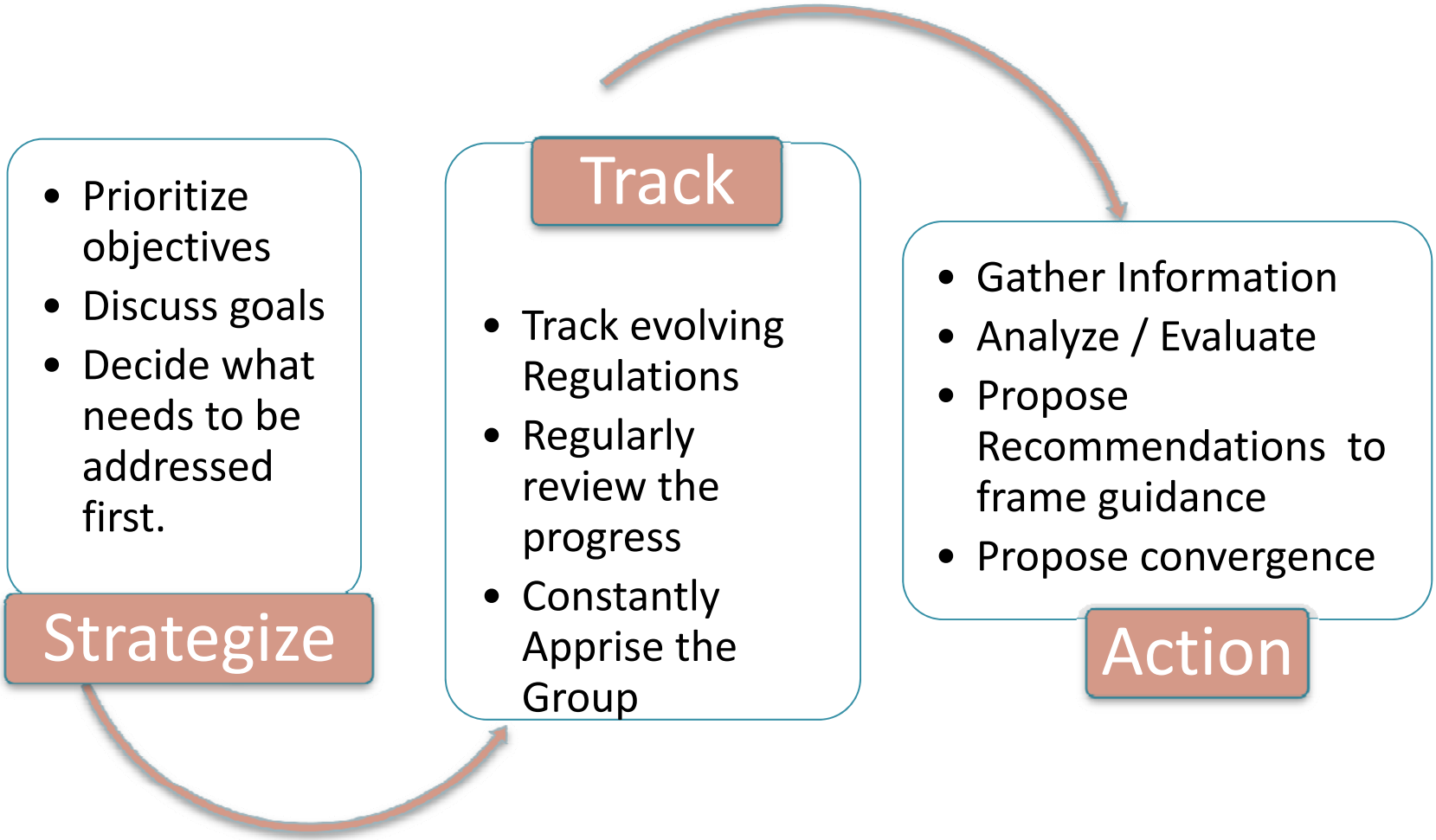
1st- 2nd Mar'2012

WG V Proposed Plan



Proposed Plan 2012 - 2014

W 1	• Establish annual & long term work plan by April 2012
W 2	• To build consensus within the WG to continue framing the guidance document based on GHTF SG 5 and ISO 14155
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

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

Future Opportunities

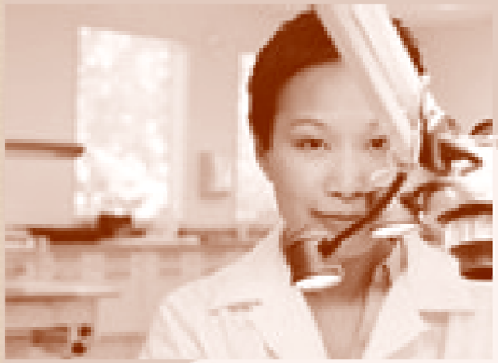
- Support Member Economies in the development of clinical trial regulations
- Seek advice from the Expert (GHTF SG5)
  - Foster convergence for clinical trials regulations development in emerging member economies
  - Develop applicable AHWP GN
  - Training modules on regulatory aspects of clinical safety/performance through e-learning platform
- Collaborate with IMDRF to understand the progress made by them with regards to GHTF SG5.
- Partner with other TC work groups' initiatives to provide expertise & input relating to clinical safety/performance
- Possibility of AHWP to liaison for GHTF legacy and training with IMDRF

AHWP Deliverables with Target for 2012

WI Priority	Deliverables	Action Plan	Target
W1	Consensus on framing the guidance	Survey to conducted & take inputs from Member Economies	June 2012
W2	Advisor: Possibility of having clinician as advisors	Collaborate with TC chair and other WG chairs , co chairs	June 2012
W3	Mapping with SG5 GN and latest version of ISO 14155	Evaluate and analyze various regulatory models and provide the comparative study	Oct 2012
W4	Requirement of Registration with respect to Clinical Data requirement	Focus on the Must to have and good to have and provide consolidated inputs	Oct 2012
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

AHWP

THANK YOU !



Working Towards
Medical Device
Harmonization
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