

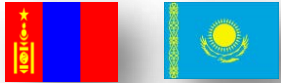
AHWP Update

September, 2017



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Expansion of AHWP Member Economies



2 new countries
joined in 2015



4 new countries
joined in 2016



1 new application
received in 2017

**Total of 30 member economies
as of Sept, 2017**

AHWP Meetings

2015

20th AHWP Annual Meeting

Nov 2-6th in Bangkok

- 241 participants, 28 countries
- 11 main themes and 6 panel discussions with 36 speakers
- 2 new member economies



TC Leaders Meeting

Mar 19-20th in Singapore



2016

21st AHWP Annual Meeting

Nov 21-25th in Cebu

- 300 participants, 40 countries
- 12 main themes and 5 panel discussions with 66 speakers
- 4 new member economies
- 1 new liaison



TC Leaders Meeting

April 27-29th in Seoul

2017

TC Leaders Meeting

March 2-3rd in Hong Kong

- Development of guidance documents with AHWP leaders, advisors and WG members
- International conference



Upcoming Events

22nd AHWP Annual Meeting

will be held
in Dec 4-8th in New Delhi, India

20th Anniversary of AHWP

Celebration Ceremony

Certificate of appreciation for all of 30 member economies & 3 liaisons



AHWP Website Renewal

work in progress to launch a new official website for easier access and better communication

AHWP Capacity Building Program

CBP Overview

- Kick-off in Nov 6th, 2015 in Thailand
- Overall budget is \$50,000 USD



In-Country Training in Indonesia

- July 28-29th, 2016
- 50 Indonesia regulators
- 20 experts from industry
- **Topics: AHWP's essential principles of safety and performance and clinical studies**



Capacity Building Workshop in Philippines

- November 21-22nd, 2016
- 150 international regulators & industrial members
- Topics: cybersecurity, GMDN, product dossier for pre-market registration submission, post-market report and review



In-Country Training in Vietnam

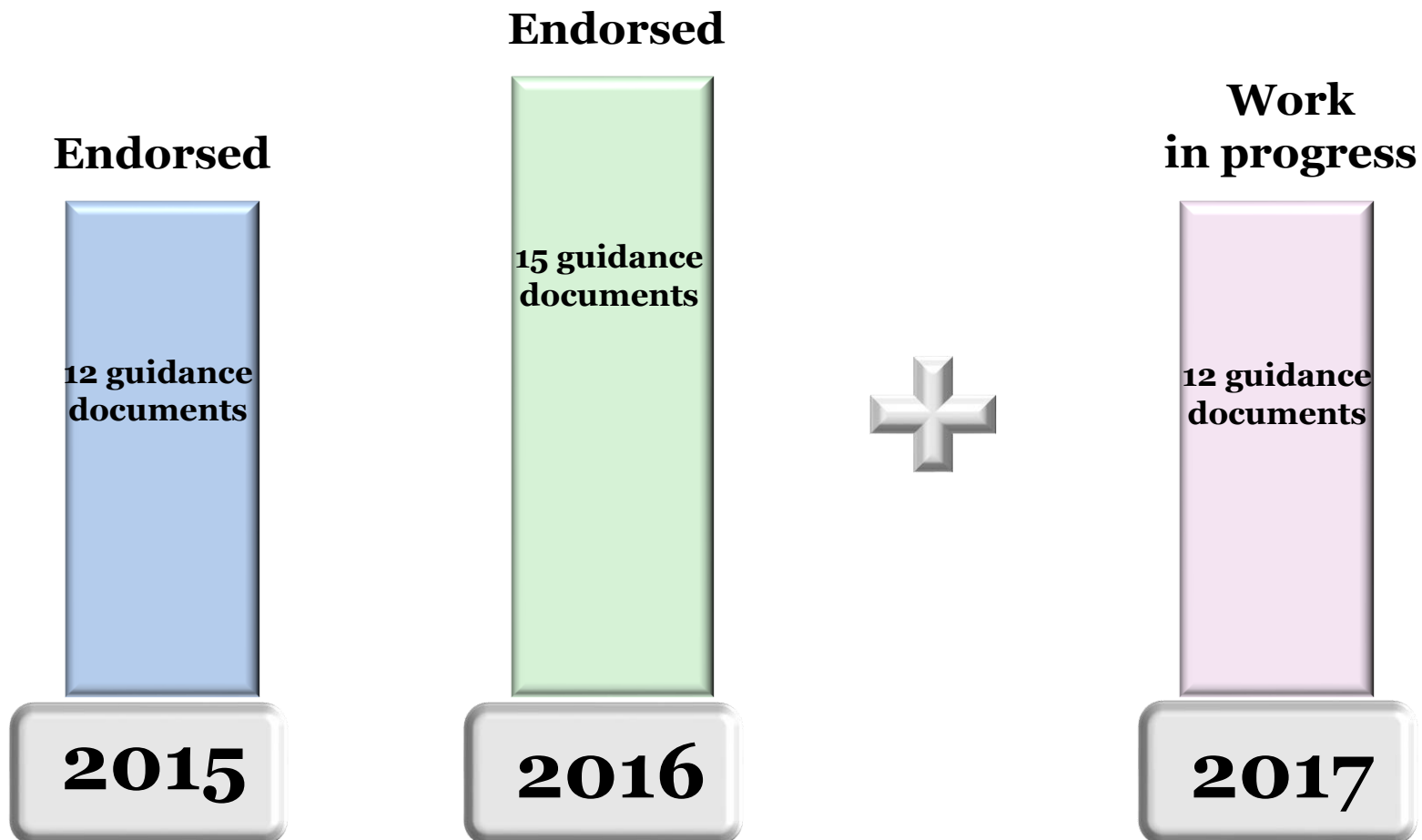
- August 25-26th, 2016
- 50 Vietnam regulators & experts from industry
- Topics: classification of medical devices & IVDs, pre-market approval, post-market surveillance



In-Country Training in Malaysia

- August 10th, 2017
- 200 international regulators & experts from industry
- Topics: software, information technology, post-market considerations

AHWP Guidance Documents



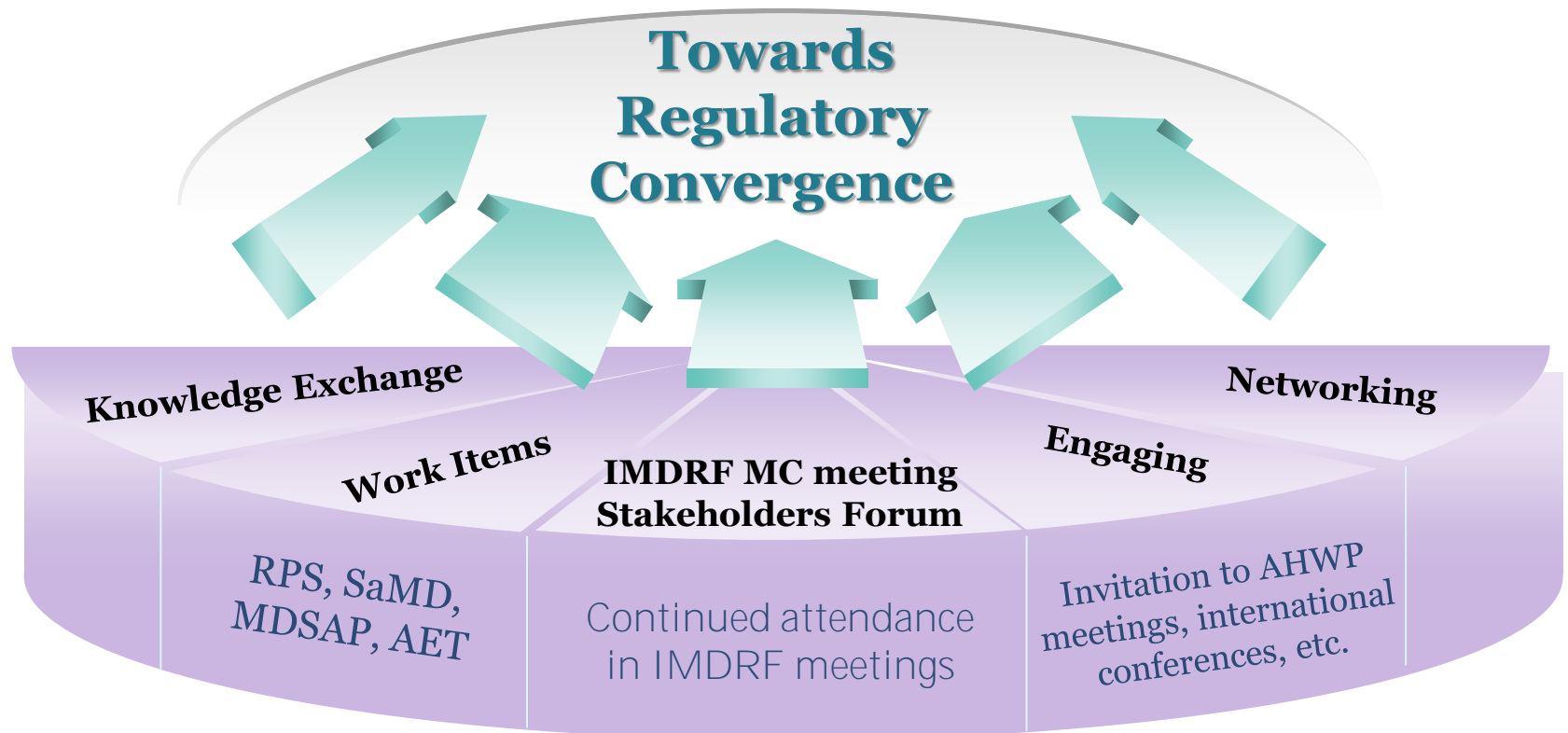
Collaboration with IMDRF



IMDRF



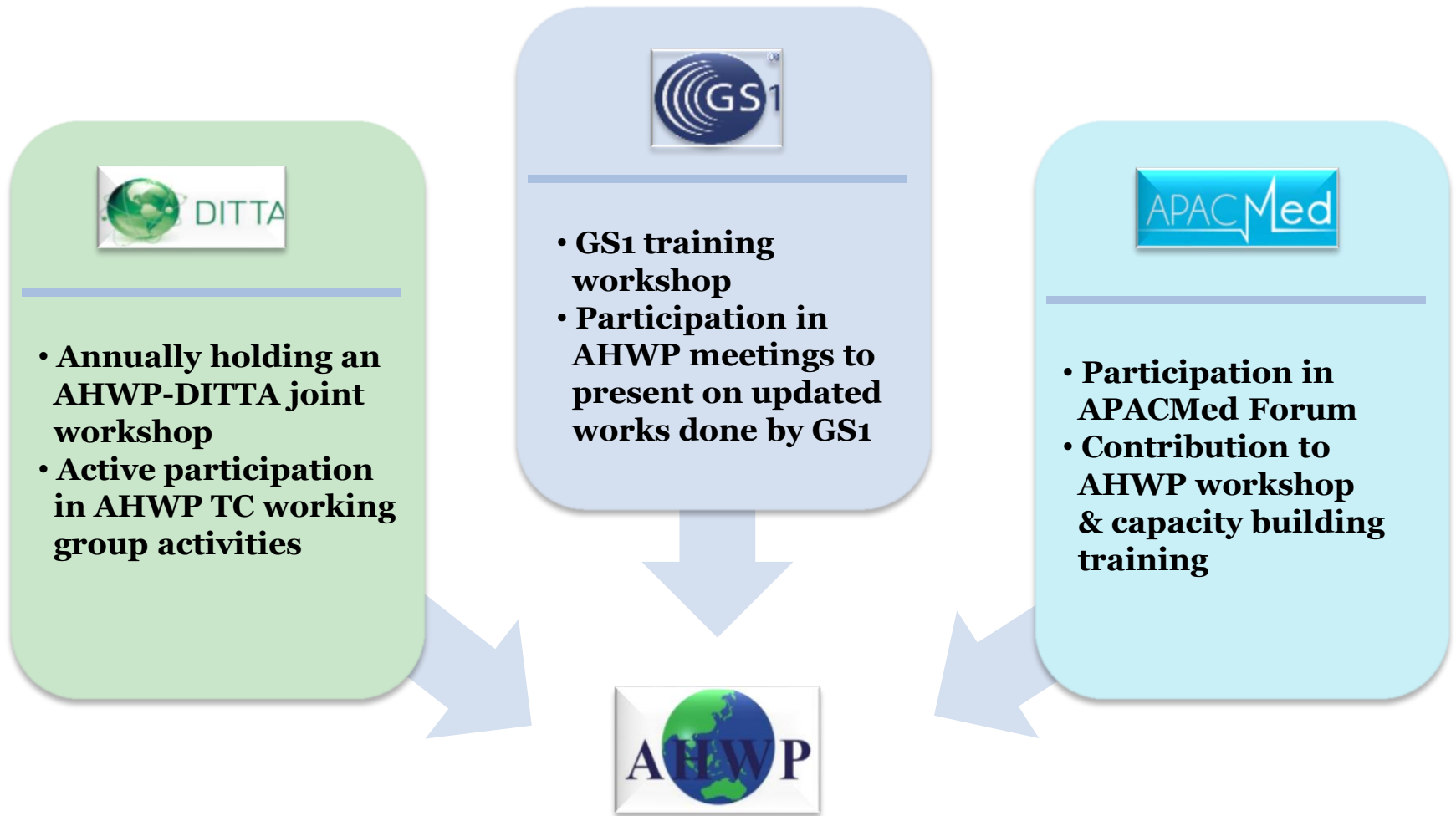
AHWP



AHWP Global Partnership



AHWP Activities with Liaisons



22nd AHWP Annual Meeting



- Date: Dec 4th- 8th, 2017
- Venue: the Grand New Delhi, India
- Program: AHWP annual meeting, AHWP Technical Committee (TC) meeting, Capacity building workshops, Joint workshops with liaisons, Updates of IMDRF and other international organizations, election

Thank you



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA