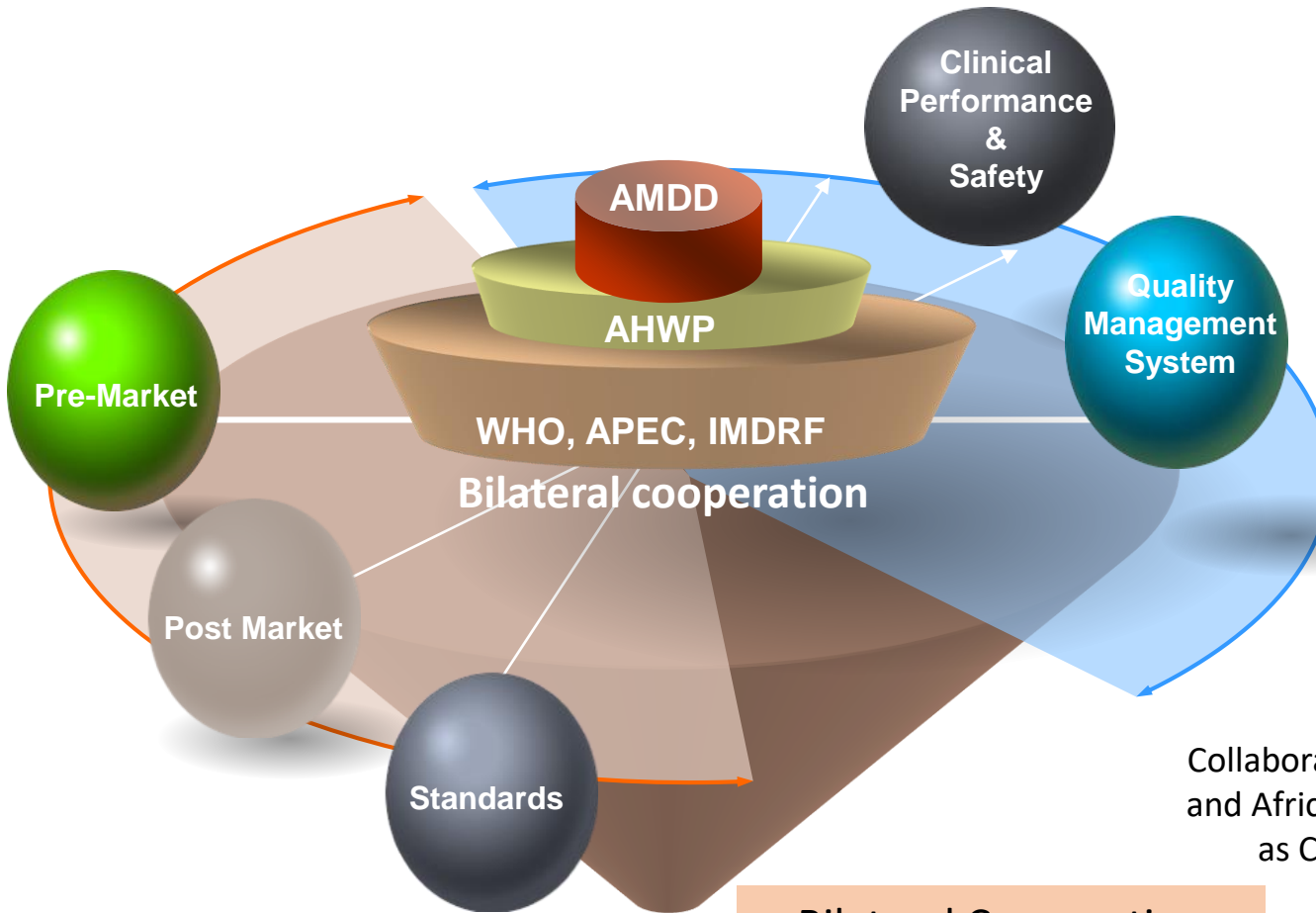
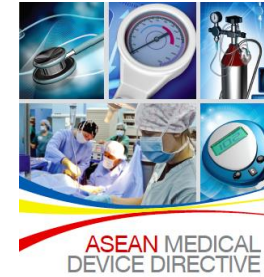


INDONESIA MEDICAL DEVICE REGULATION BASED ON REGIONAL AND GLOBAL PRACTICES



Regional and multilateral cooperation



Indonesia has ratified ASEAN MEDICAL DEVICE DIRECTIVE (AMDD). 10 ASEAN Member states has harmonized their MD regulation.



Asia-Pacific Economic Cooperation

Priority Working Area: Medical Devices meliputi Pre-Market, Post-Market dan QMS



Indonesia as Chair of ASEAN Medical Device Technical Committee



Collaboration with Asia, Middle East and Africa through AHWP. Indonesia as Chair of WG clinical trial



World Health Organization

Collaboration with South East Asia countries for medical products with one of Working Group is Medical Device and IVD
Indonesia as Chair of WG Medical Device

Bilateral Cooperation

- | | | | |
|---------------------|---------------|---------------|-------------------------|
| • USA | • India | • Laos | • China |
| • Australia | • Iran | • PNG | • Turkey |
| • Netherland | • Colombia | • Qatar | • Vietnam |
| • Brunei Darussalam | • South Korea | • Singapore | • Etc (MoU on progress) |
| • Denmark | • Cuba | • Timor Leste | |

Conducting and explore the market access opportunities through joint venture cooperation and Health Business Forum