

# **STG (U&N)**

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**AHWP 19<sup>th</sup> TC Meeting**  
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**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

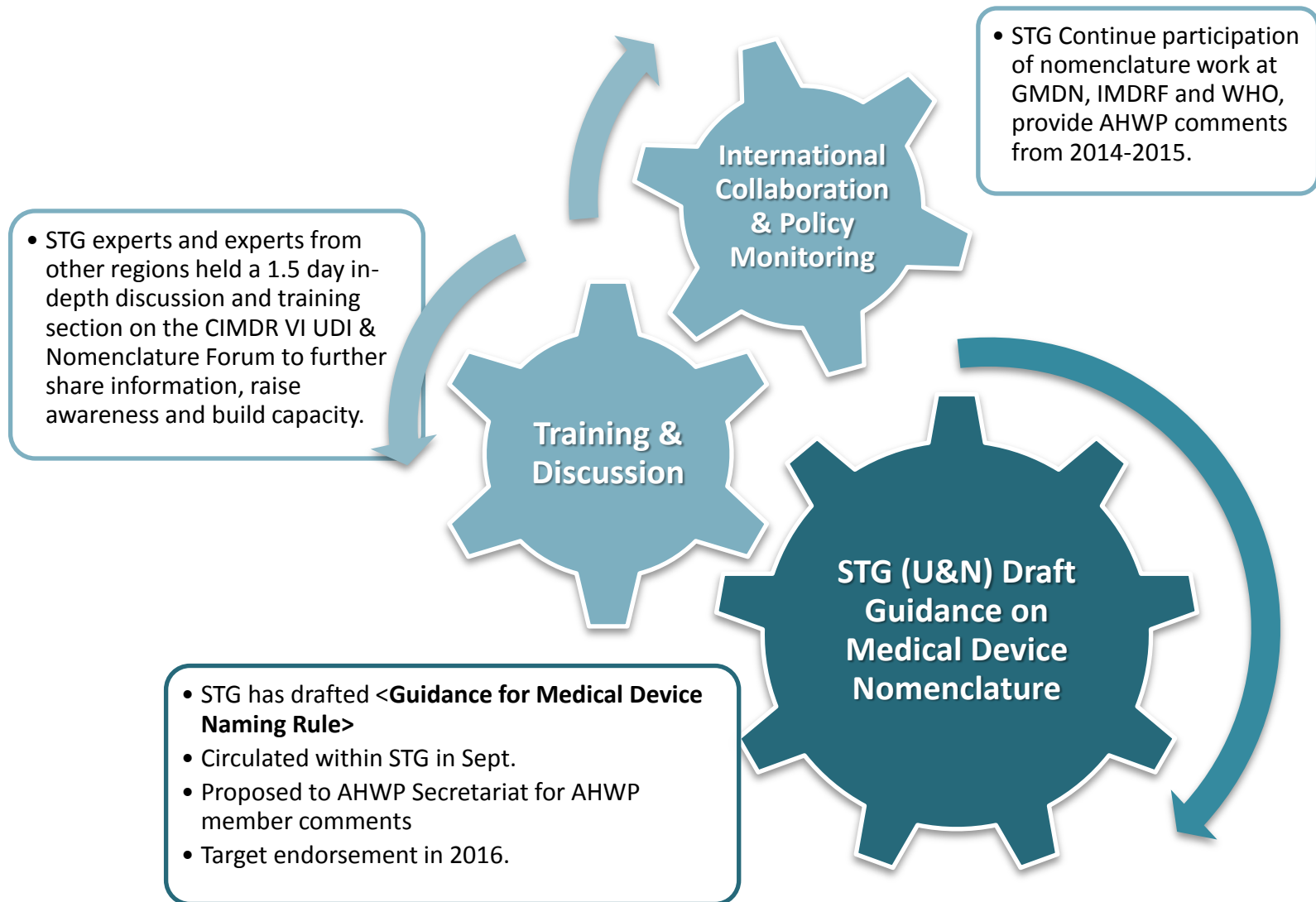
# Membership

- Review and valid active members
  - Regulator: 9
  - Industry: 17

- Member Economies:

China, Chinese Taipei, HongKong, Saudi Arabia,  
Singapore, Southeast Asia, South Korea, Thailand,  
U.S.A

# Status of WG Items - Nomenclature



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<b>Work in Progress</b>	
1.	STG is monitoring device nomenclature update via different platforms/occasions, such as information exchange platform with IMDRF, US FDA and DG GROW, etc.
2.	China as a key member of STG will continuously work on Medical Device Naming Catalogue and Naming Guidance, share experience learn from these initiative to STG members.
<b>Future Action Plan</b>	
1.	STG will continuously involve in the harmonization work in device nomenclature.
2.	STG sees the efforts GMDN put on the medical device information exchange, and will continuously look into the use GMDN term/code and implementation experience.
3.	STG will further promote the establishment of a unified device nomenclature system to successfully set-up a device fast identification and accurate tracking system within member economies.

# Status of WG Items - UDI

## Discussion & Training

- 1.5 day in-depth discussion and training section on the CIMDR VI UDI & Nomenclature Forum - further share information, raise awareness and build capacity.

## STG provide support on development of UDI.

- CFDA's "UDI Leadership Working Group" established in 2014 continuously lead both the regulator and industry effort.

# Status of WG Items – UDI - Work in Progress

- ❑ STG is **monitoring** device UDI and UDID update via different platforms/occasions, such as information exchange platform with IMDRF, US FDA and DG GROW , etc.
- ❑ STG continuously follow member economies on UDI implementation status, and **provide support** as necessary to ensure the alignment with IMDRF global model.
- ❑ STG is continuing UDI **pilot research** in China with start of feasibility study for selected product types in 2015.

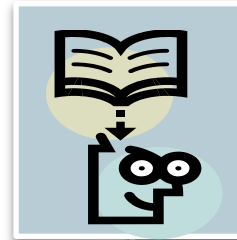
# Status of WG Items – UDI

## - Future Work plan



### **POLICY MONITOR & HARMONIZATION**

- STG provides continuous guidance to the AHWP member economies on the harmonized approach of the UDI system.



### **FUTURE SURVEY IN STG MEMBER ECONOMIES**

- Motivation/Intent of Regulation
- Timing of Regulation
- Devices subject to Regulation
- Responsible Party
- Regulatory Agency
- Data Requirements
- Data Exchange / Methodology
- Labeling Requirements
- Direct Part Marking
- Additional Policy Statements Required?



**Thank you**