

ICH update

January 15th 2016

Chair, JPMA ICH Committee

VP, New Drug Regulatory Affairs Dep. DST

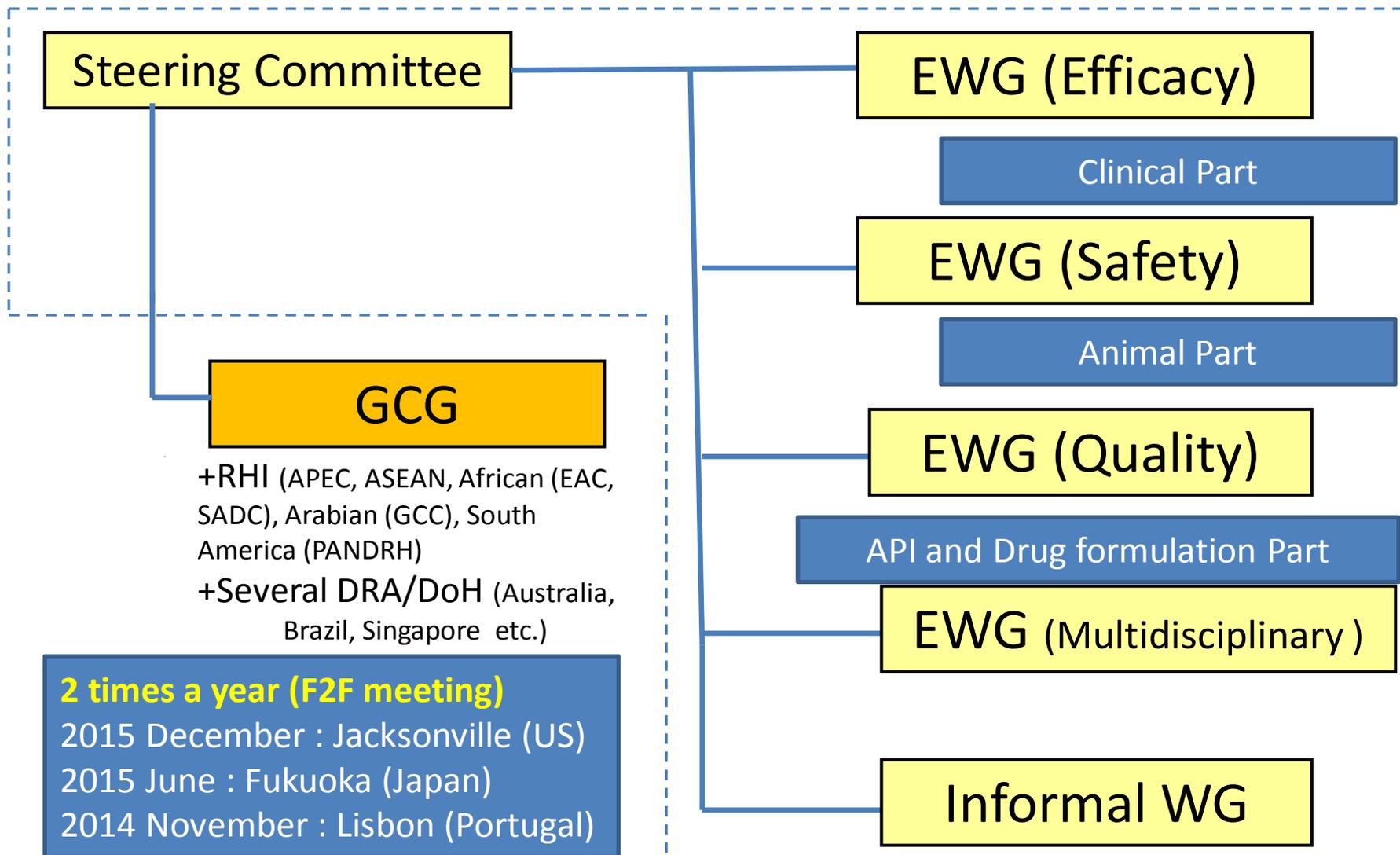
Hironobu Saito

ICH Structure

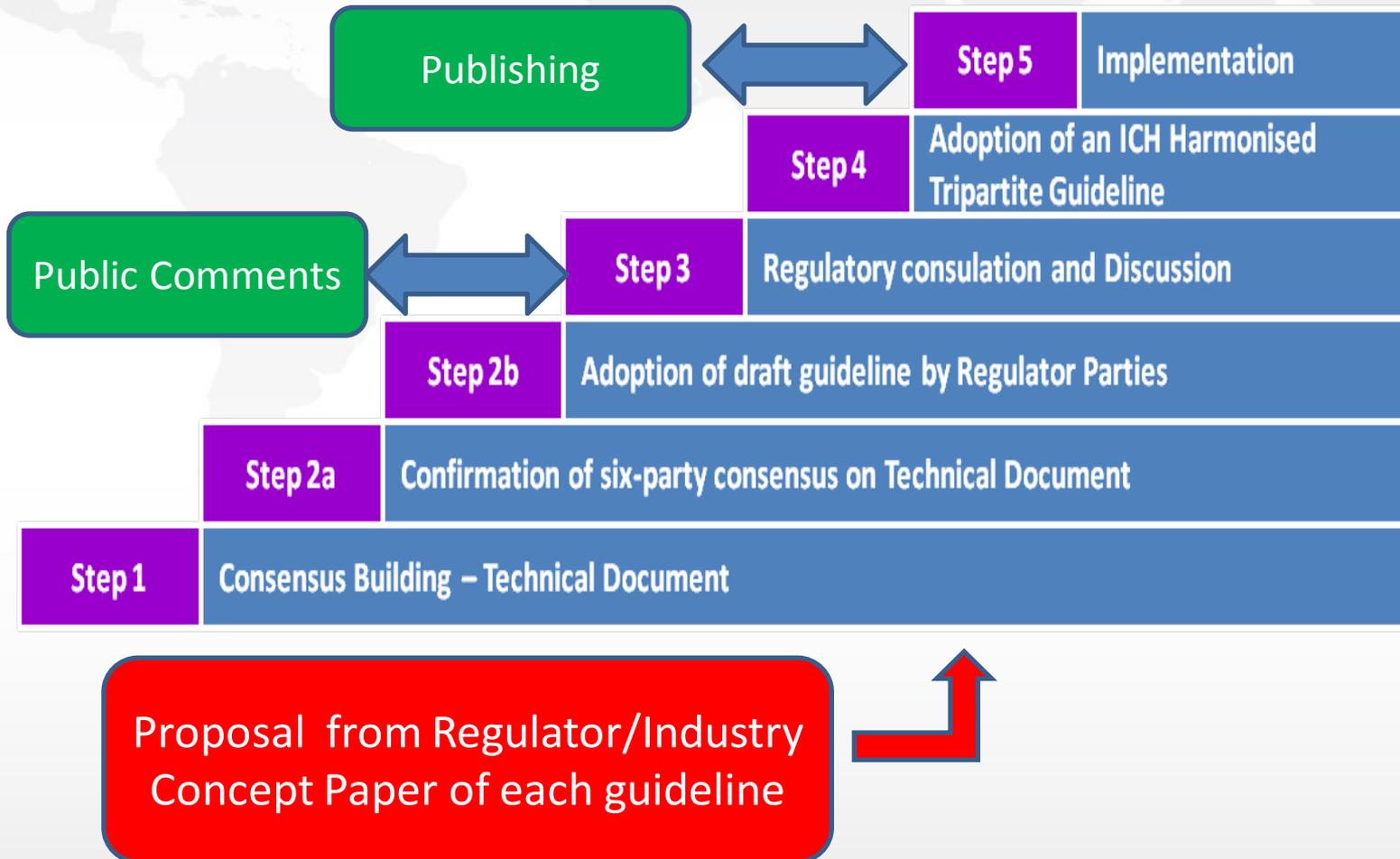
Member: JP: MHLW/PMDA+JPMA Europe: EC/EMA+EFPIA USA: FDA+PhRMA

Observer: Health Canada, EFTA(Switzerland), WHO

Secretariat: IFPMA



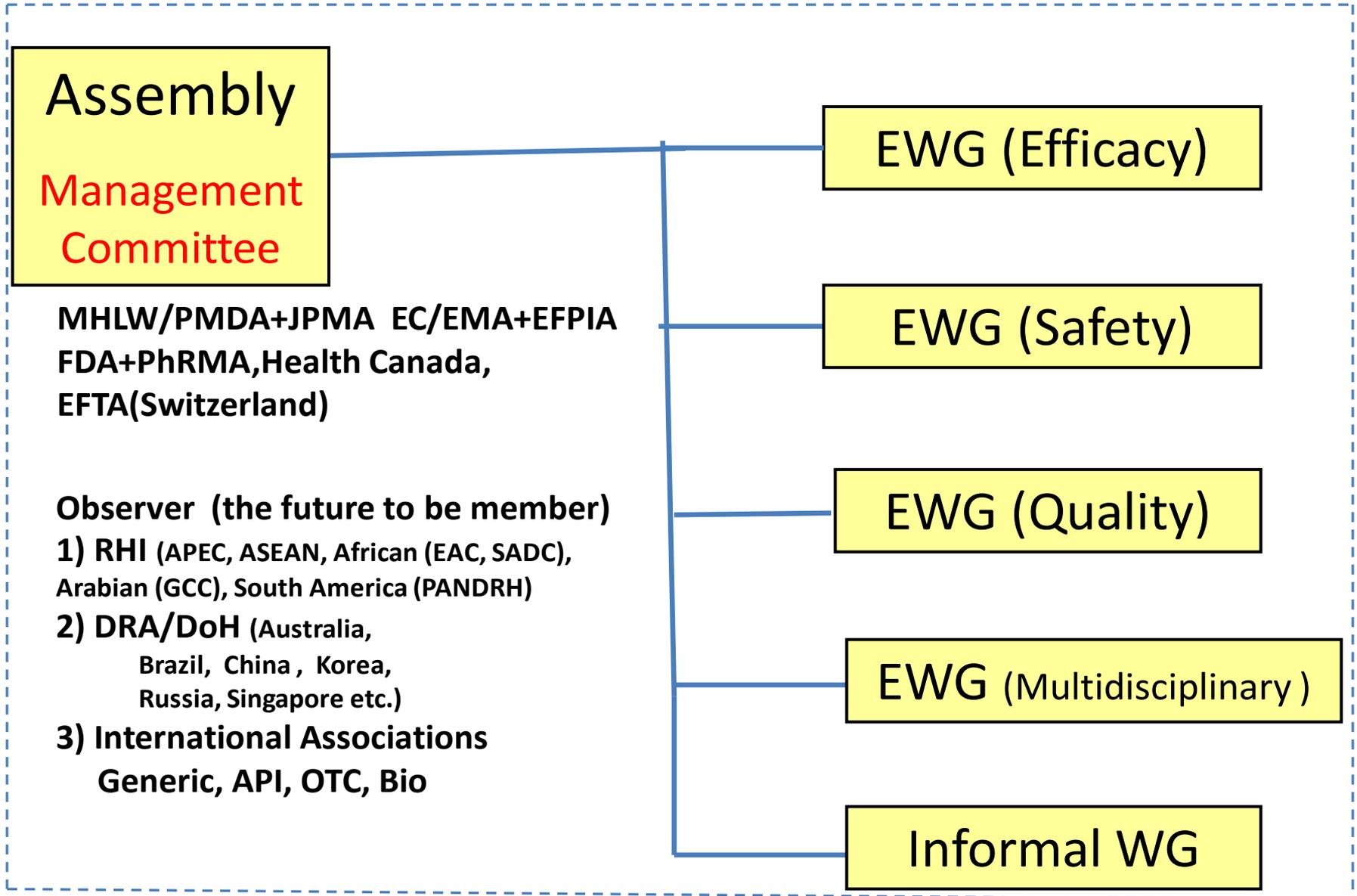
ICH Process for new guideline



Enhancing the Steering Committee activities

- Activities of the ICH Steering Committee
In addition to approval of the guidelines,
1) organizational restructuring , 2) newly projects, and 3) education support have been considered.
- Specific actions taken
 - Establishment of Assembly (facilitating participation of countries other than Japan, the United States and Europe)
 - Proposal of new guidelines
 - Acceleration of revision of guidelines
 - Promoting education to each country

ICH Organization (From 2015 December)



Sub-Committee Activity in Managing Committee

- Financial Sub-committee (cascade down)
- Membership Sub-committee
 - Evaluation process
- Communication Sub-committee
 - 2016 Communication strategy
 - Transparency strategy
- Training Sub-committee (New)
- New Topic Sub-group (New)

ICH activity for Global Patients

