Update on APEC Regulatory Harmonization

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Asia-Pacific Economic Cooperation

Regulatory Harmonization Steering Committee

Life Sciences Innovation Forum

APEC

- Asia-Pacific Economic Cooperation (APEC) created in 1989
- Currently comprised of 21 member economies (US, Canada, China, Russia, and etc.)
- Goals: Promote trade, sustainable economic growth and prosperity of member economies through policy alignment and economic and **technical cooperation**
- APEC agenda and annual work plan developed around SOMs culminating in Leaders declaration
- APEC Chair rotates annually – host economy (China, 2014, Philippine, 2015)

APEC Regulatory Harmonization

- **LSIF (Life Science Innovation Forum):**
  - Created following endorsement by APEC Leaders in 2002
  - Recognized importance of *life sciences innovation* in promoting public and economic health
  - From outset, **harmonization seen as prerequisite to fostering innovation**, important development in Seoul, 2009
    - Inauguration of the APEC Harmonization Center (AHC)
    - Creation of a Regulatory Harmonization Steering Committee (RHSC)
  - Unique tripartite group: regulators, industry and academia

RHSC

- Formed in June 2009 to promote access to safe medical products, innovation and trade within the APEC region through regulatory convergence and cooperation
- Marshals resources of regulatory authorities, industry coalitions and academia, guided by a strategic framework and roadmaps
- Operates under the auspices of the LSIF and in cooperation with the AHC

Mandate

To promote a more ***strategic***, ***effective*** and ***sustainable*** approach to harmonization by:

- Proactively identifying and prioritizing projects seen to be of greatest value
- Strengthening linkages with harmonization initiatives, training organizations and other key players to promote ***complementary*** actions and most effective use of resources
- Ensuring sustained efforts
- Products of interest: medical products

Members

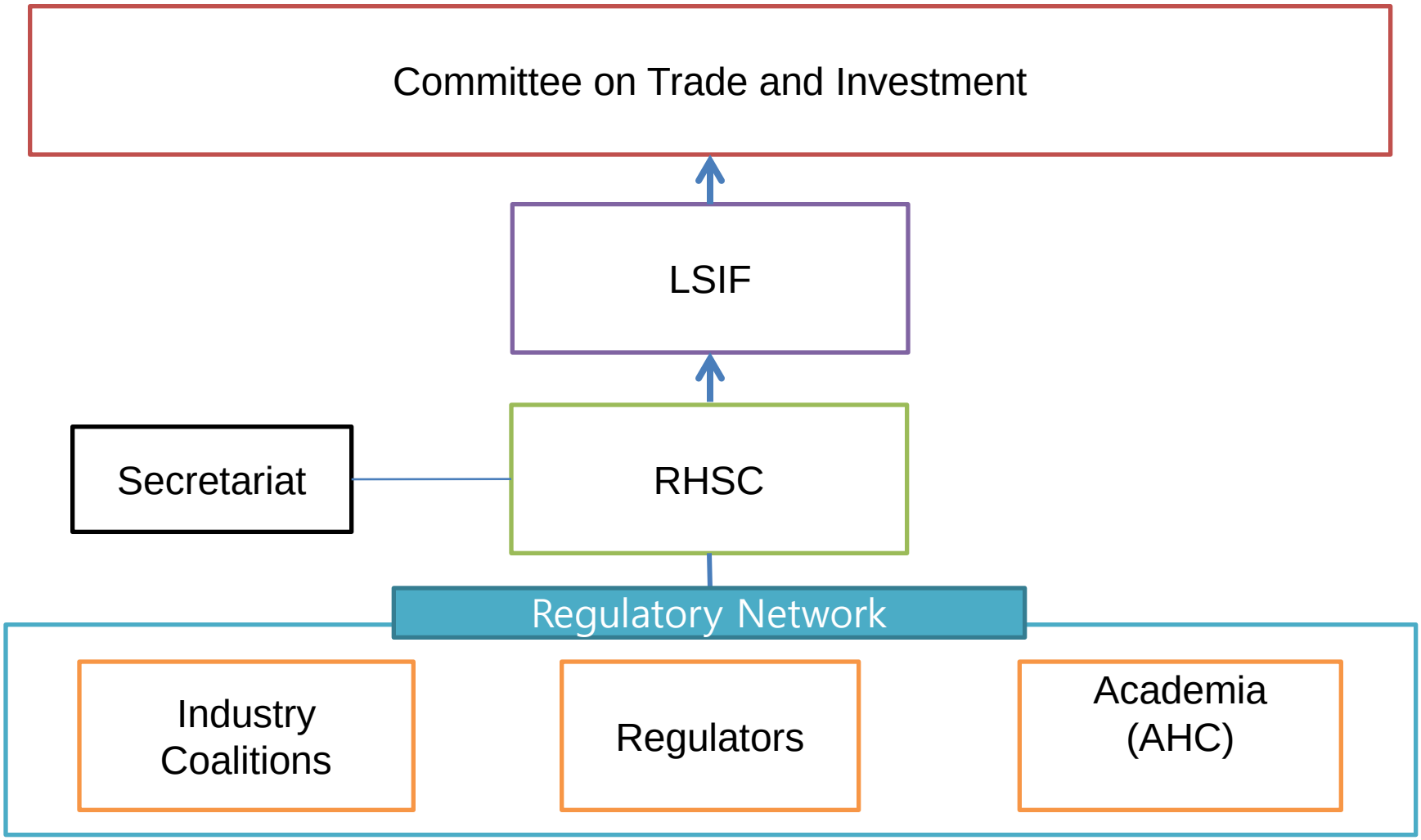
- Regulators from 15 APEC Economies:
  - Canada, Brunei Darussalam, Chile, China, Chinese Taipei, Indonesia, Japan, Korea, Malaysia, Mexico, Philippines, Peru, Singapore, Thailand, US (new)
- Industry coalitions:
  - Research based pharmaceutical sector
  - Medical Devices sector
  - Generic pharmaceutical sector
  - Biotechnological products sector
- Secretariat: KHIDI
- Chair (Canada) and Vice-Chair (US)

Linkages

- Establishment of official liaisons with international harmonization initiatives and organizations

- Reflects position that APEC should act as a catalyst for international action on issues that demand a global approach

Governance



Strategic Linkages to Regional/International Bodies

Strategic Framework

- Framework outlines strategic multi-year approach for achieving greater regulatory convergence by 2020
- Describes guiding principles and general multi-step approach:

  Gap analysis -> Addressing Gaps ->Evaluation
- Voluntary action: each economy proceeds at own pace
- Includes definition of regulatory convergence
- Endorsed by APEC Ministers in November 2011

Regulatory Convergence

Regulatory Convergence represents the process whereby regulatory requirements, approaches and systems become more similar or aligned over time as a result of the adoption of internationally recognized technical guidances, standards and best practices

Strategic Framework

Coordinated approach
to promote regulatory convergence

Priority Work Areas

Champion and roadmap for each PWA

Project Project Project

Priority Work Areas

PWAs and Champion Economies:

- MRCTs (Japan)
- Supply chain integrity (US)
- Good Review Practices and Combination Products (Chinese Taipei)
- Biotherapeutic Products and Pharmacovigilance (Korea)
- GCP Inspection (Thailand)
- Cellular and Tissue Therapies (Singapore)
- Good Submission Practices (New: CT)

Some Highlights to Date

- Pilot program for establishing Centre of Excellence for Multi-regional Clinical Trials to promote global drug development
- Gap Analysis, workshops and development of toolkits under Supply Chain Integrity roadmap (with aid of $0.5 M USD in APEC funds)
- Develop paper and elements of training curriculum on Good Review Practices: lays foundation for WHO guideline

Center of Excellence (COE) for Multi-regional Clinical Trials (MRCT)

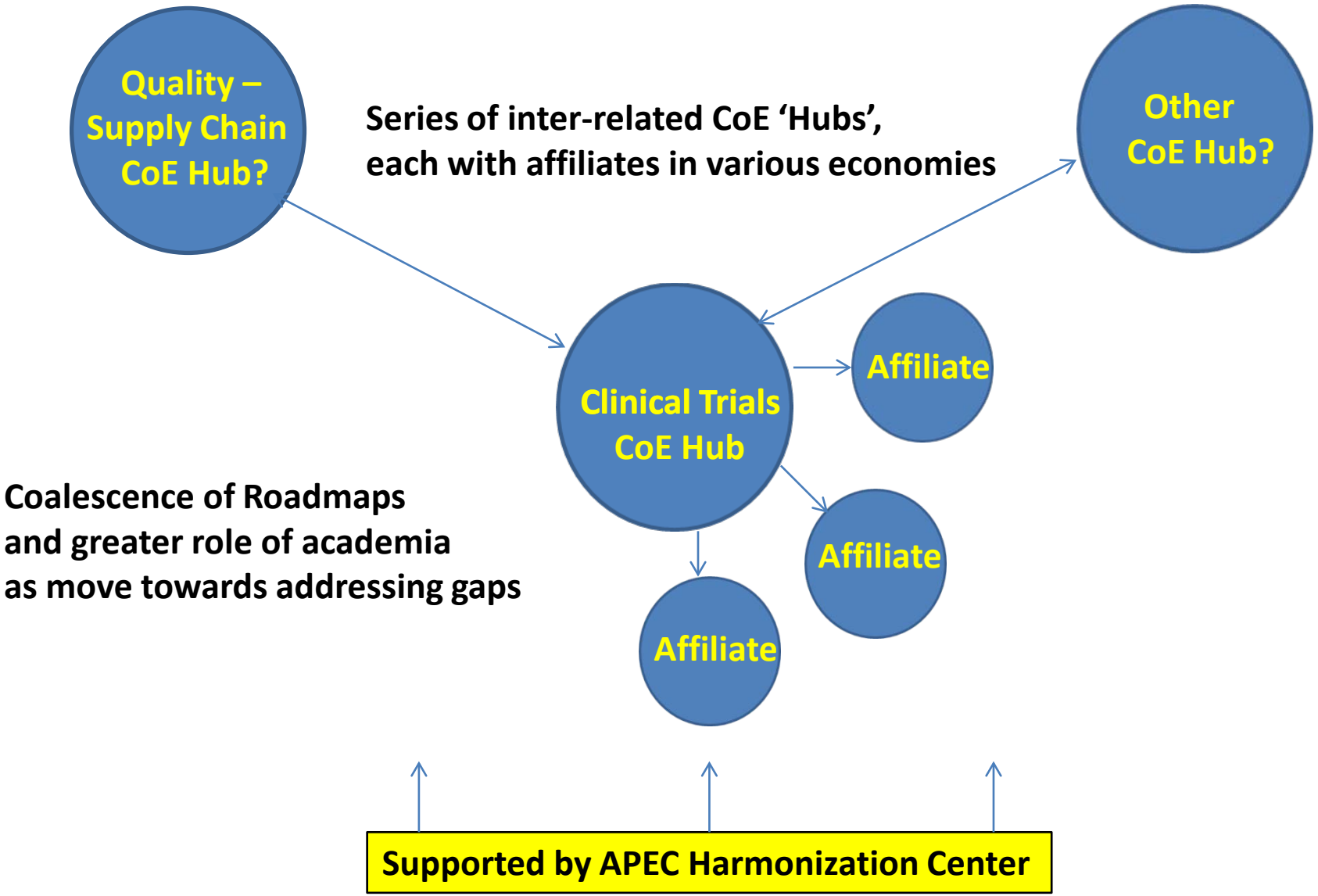
COE objectives :

- Enhance understanding of requirements for acceptance of MRCT results for review by regulators
- Facilitate training in internationally recognized technical guidance (e.g. ICH)
- Promote science-based review and evaluation of MRCTs

Accomplishments/Deliverables for 2014

- Workshops on Biotherapeutics, Cell and Tissue Therapies, MRCT-GCP Inspection and Supply Chain
- Successful pilot of MRCT COE in March 2014 in cooperation with Duke-NUS and AHC
- Endorsement of *Good Review Practices* guideline and hand over to WHO. WHO expert committee endorsed the APEC developed GRevP document. This now goes to the WHO EB for final endorsement.
- Conduct pilot with ABAC on track and trace to demonstrate value of global standards – part of Supply Chain roadmap
- Consider new PWA on Good Submission Practices
- Develop strategy on promoting targeted engagement of academia
- Establish and implement a model for sustained, coordinated actions through network of COEs.

A Model for Driving and Sustaining Change



Thank You!