APEC MRCT Roadmap: Regulatory authorities’ efforts to promote multi-regional clinical trials (MRCTs)

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APEC, LSIF, and RHSC

APEC Member Economies

- Leaders Meeting
- Ministerial Meeting
- Senior Officials Meeting
- Committee on Trade and Investment

LSIF (Life Science Innovation Forum)

Regulatory Harmonization Steering Committee (RHSC)

Member: Canada, China, Japan, Korea, Peru, Taiwan, Thailand, USA
APEC Vision 2020
Regulatory Convergence For Medical Products

Pharmaceuticals
- Multi Regional Clinical Trials
- Good Review Practices
- Product Quality
- Pharmacovigilance

Medical Devices
- Post-Marketing Surveillance
- Clinical Evidence
- Good Review Practices
- Quality Management System

Projects to support overall strategy and components of Roadmaps

Proposals for Projects

24th Annual EuroMeeting Copenhagen 2012
**Strategic Framework**
Coordinated approach to promote regulatory convergence

**Priority Work Areas**
Needs assessment from diagnostic workshops and a roadmap for promoting best practices

Individual projects are part of strategy & contribute to goals

Move away from Ad Hoc/Individual Proposals
Roadmaps
APEC MRCT Roadmap
The accumulated number of industry sponsored trial sites both globally and for the US alone registered with ClinicalTrials.gov from 2000 onwards, before and after the implementation of the US FDA act concerning life-threatening diseases (FDA ACT) and the ICMJE policy (IMJCE), respectively.

Source: Clinical Trial Magnifier Vol.1:3 Mar 2008
www.ClinicalTrialMagnifier.com
Increase in MRCT (2)

The number of industry sponsored clinical trial sites in the most active countries/regions in Asia, by local and multi-national type of trials.

Goal: To facilitate MRCTs and acceptance of MRCT results for drug review by regulatory authorities in APEC region.

Assessment of Status Quo (2011, 2012)


Interim assessment of the achievement Recommendation to improve MRCT (2016)

Training/workshop geared to reach the goal Recommendation for regulatory harmonization (2017-2020)
What has been done to implement MRCT Roadmap
APEC Multi-Regional Clinical Trial Workshop
(Sep. 13-15, 2010, Seoul, Korea)
Recommendations from Seoul WS

1. Overall
   - MRCTWS should be continued on MRCT Roadmap
   - China-Japan-Korea Cooperation: valuable effort for entire APEC Region

2. Study Design (statistical point of view)
   - In order to reduce variance of data, involvement of the region in question in early stage is important.

3. Operational Aspects
   - Trainings for CRCs, principal investigators and support staff are urgently needed
APEC Multi-Regional Clinical Trial Workshop
(Nov. 1-2, 2011, Tokyo Japan)
Findings & Recommendations from Tokyo WS

Development Strategy (1)

- East Asia is expected to produce more pivotal studies in the form of MRCT.
- The ethnic differences among the participating Asian populations should be examined in the early phases.
- Each participating country’s strength should be exploited to form a strategic regional alignment.
Drug development strategy should be flexibly made by mixing single-country clinical trial, regional (e.g. East Asian) trials, and world-wide trials.

Regulatory harmonization among Asian regulatory agencies is highly expected.

The regulatory agencies and the industry should collaborate more in various aspects.
Findings & Recommendations from Tokyo WS

Statistical study Design

- When there exists large variability among regions, the sample size for each region has a strong impact on ethnic differences.
- It is very important to reduce variability among regions. Employment of hard endpoints in the early phase of drug development and a clear definition of regions must be considered.
Findings & Recommendations from Tokyo WS

Oncology Case Study

- Importance of North East Asia (China, Japan, Korea, and Taiwan) is mounting.
- The emerging strategy in East Asia is to participate at the discovery phase.
- Oncology trials in East Asia have the following (potential) advantages; good quality, fast approval by ethics committees and regulatory agencies, unique cancer population, fast accrual, low cost, friendly C.T. environment.
Activities from 2012 onward

1. Expansion in Area
   • Possibly to Southeast Asia

2. Practice-Oriented
   • Tokyo WS placed emphasis on Strategy
   • More on practical aspects of conducting MRCT

3. Training
   • From 2013 Training of investigators, etc. is planned. 2012 should see Draft Curriculum.
Thank you!

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