



APEC LSIF Update

by

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Topic

- **Background**
- **The Strategic Plan**
- **Year 2005**
- **Key projects –*Research Group***
- **Harmonization –*Development Group***
- **Proposal to the GCG/ICH**

Background



Background (1)

- **Beginning**

- *October 27, 2002 in APEC Economic Meeting*

- *mandate “to develop a Strategic Plan for LSI in the region”*

- *priority*

- **risk detection & prevention**

- **treatment & cure of communicable-lifestyle diseases**

Background (2)

• The Meetings

→ *APEC-LSIF meeting*

- LSIF I (Aug. 2003 in Phuket, Thailand)

- LSIF II (Sep. 2004 in Penang, Malaysia)

→ *Expert Working Group meeting*

- 1st meeting (Feb.04 in Khon Khan, Thailand)

- 2nd meeting (Jun.04 in Washington DC, USA)

→ *APEC LSI Planning Group meetings*

Background (3)

- **Task Forces**

- *Ad Hoc Planning Group*

- *Expert Working Group*

- **Intention**

- *recognize the existing APEC-ongoing activities*

- *not intend to duplicate the work, but would support to meet the LSIF's Goal*

Background (4)

- **Outcome**

- *TOR (Feb.03)*

- *Framework for the Strategic Plan (Aug.03)*

- *Readiness assessment template*

- *The endorsed Strategic Plan*

The Strategic Plan

The Strategic Plan (1)

Set of Best Practices guidelines

- *to promote Life Sciences Innovation*
- *addressing*,
 - challenges of Risk detection & prevention
 - treatment & cure of the Communicable & Life-style diseases
- *structured to*,
 - allow determination on supportive Regulatory+Policy environment
 - allow decision on how 4 areas of LSI be most developed & aligned

The Strategic Plan (2)

- *Development*

- based on Common themes & principle
- covers 4 key areas (research, dev., m & m, health service)
- identified Principles & Best Practice in each key area
- bench-marked the Principle & Best Practice against International best practice
- aiming to a better/optimal Policy approach (to support Innovation & health of the region)



The Strategic Plan (3)

- *Developed from*

- work products of the 1st & 2nd LSIF meeting
- Expert Working group
- APEC LSI Planning group

- *Endorsement*

- reviewed by the Forum, and APEC Senior Officials
- endorsed by APEC Leaders (Nov.2004)

Year 2005

Year 2005 (1)

- **finalize and Utilize the LS-RA Template** (completion of the Assessment by July 05)
- **outreach to other APEC groups**
- **The Ad Hoc Technical Working Group meeting**
- **The Ministerial-level meeting**
- **attend Pacific Health Summit** (June 05, USA)
- **Completion of “1st Draft Ways of Implement Collective actions, Recommendation, and Priority areas”**(for presentation to Ministers)

Year 2005 (2)

- **finalize Economy specific and collective milestones for implementation (Jul.05, by Economies)**
- **submission of Statements of Intent & Capacity Building Needs (Aug.05)**
- **The APEC-LSIF III meeting (Sep.05, Korea)**
- **Progress report to Ministers/Leader (Nov.05)**

Key Projects *Research Group*

Key Projects of *Research Group*

Chair of LSIF *Research gr.* – Dr. Lee Hartwell

- **International Biomarker Discovery**
- **Global Cohort study**
- **Improved Infrastructure for Clinical Trial**

Harmonization *Development Group*

Harmonization- *Development Group (1)*

Chair of LSIF *Development gr.* – Mr. Mike Ward(?)

The Goal:

- *effective Regulatory Framework & Infrastructure*
- *partnership → Harmonizing Regulatory Practices & Policies*
- *improved Scientific & Technical Infrastructure*
- *effective Mechanism that promotes access to innovation*

Harmonization- *Development Group (2)*

Selected Area for Best Practice Approach :

→ *Clinical Trials area*



development of Roadmap

to expand Capacity, Competence, Expertise

in Conducting Clinical Trials
throughout 21 economies

Proposal to the GCG/ICH

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Suggestion and Support

→ developing a *Strong Infrastructure for Clinical trial*
(research gr.)

→ the work in *Clinical Trial Areas* (development gr.)



Thank You

