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
  - benchmarked 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 1\textsuperscript{st} & 2\textsuperscript{nd} 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
Proposal to the GCG/ICH

Suggestion and Support

- developing a Strong Infrastructure for Clinical trail (research gr.)
- the work in Clinical Trial Areas (development gr.)
Thank You