



Regulatory Capacity Development and Regulatory Convergence: Perspectives from the Centre of Regulatory Excellence

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Scope

- Overview of Centre of Regulatory Excellence (CoRE)
- Enhancing regulatory capacity to facilitate convergence
- Facilitating engagement of regulatory stakeholders
- Enabling regulatory cooperation and convergence



Challenges faced by regulators and industry today

Insufficient regulatory knowledge and capacity

Fragmented regulatory requirements across Asia

Lack of suitable platforms for regulatory science and policy innovation in Asia



CoRE provides a neutral academic platform for networking of health products regulatory stakeholders in Asia, with a special focus on South-East Asia, to promote capacity development and innovation



Centre of Regulatory Excellence



“We are now looking beyond the immediate value-chain activities, to develop leadership in developing regulatory standards and to prototype new business models: In November 2014, a new Centre of Regulatory Excellence (CoRE) was set up at the Duke-NUS Graduate Medical School Singapore ... It will promote regulatory leadership and policy innovation in regulatory science. The centre will bring together industry players and regulators, as well as build a pipeline of regulatory talent to support Asia's rapidly-growing healthcare sector.”

**Singapore Deputy Prime Minister
Tharman Shanmugaratnam
11 March 2015**



Centre of Regulatory Excellence

- Supported by the Singapore Ministry of Health and Economic Development Board
- MOU with the Health Sciences Authority





CoRE's Vision and Mission

Vision

To be a leading Centre enhancing regulatory capability and scientific excellence for health related products in Asia

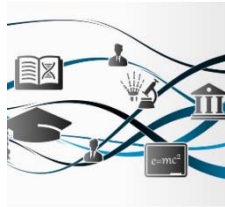
Mission

To establish regional platforms and networks to grow competencies, enhance collaboration and promote thought leadership in innovative regulatory science and policy



CoRE's Purpose and Strategic Goals

To ensure patients in Asia have timely access to safe, effective and high quality therapeutic products through excellent regulation



Strengthen Regulatory Leadership

Customise training to advance competencies and standards for Asian regulatory professional leaders



Policy and Systems Innovation

Promote intellectual capital in regulatory sciences and policy innovation in Asia



Regulatory Networks

Establish regional platforms and networks to foster closer collaboration in regulatory science and policy best practice



CoRE Advisory Board

Chair
CoRE Advisory Board

Prof Sir Alasdair Breckenridge
Former Chair
UK Medicines & Healthcare
products Regulatory Agency



Special Advisor
CoRE Advisory Board

Dr Margaret Hamburg
Foreign Secretary
National Academy of Medicine &
Immediate Past Commissioner
US FDA



Advisor
CoRE Advisory Board

Mr Jean Luc-Butel
President
K8 Global



Asst Prof Bruce Burnett
Director, Regulatory Affairs
Duke Translational Medicine
Institute
Duke University



Dr Mimi Choong
Chief Executive Officer
Health Sciences Authority
Singapore



Dr Tatsuya Kondo
Chief Executive
Pharmaceuticals and
Medical Devices Agency
Japan



Dr Joseph Scheeren
Senior Vice President &
Head Global Regulatory
Affairs
Bayer Healthcare



Dr Paul Huckle
Chief Regulatory Officer
& Senior Vice President
GlaxoSmithKline



Mr Michael Gropp
Chair
RAPS
Global Advisory Council





Scope of CoRE Activities

Seminars

Symposiums

Workshops & Customised Training

Focus Groups & Roundtables

Research



Participation in CoRE Events

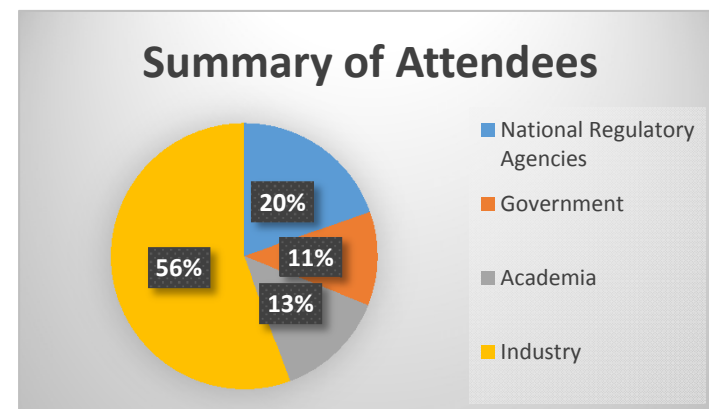
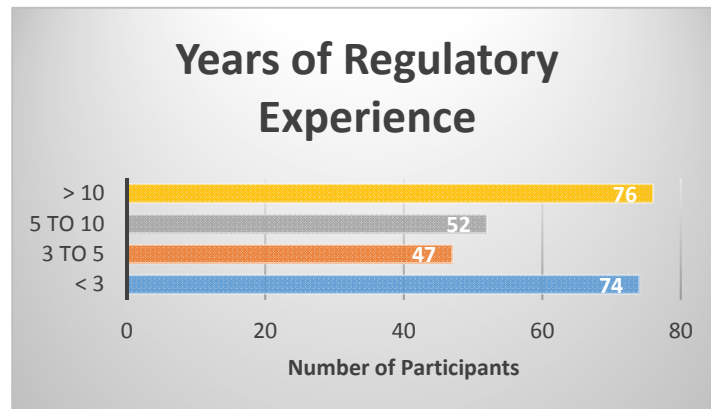
- Provide a neutral platform for sharing innovation, best practices and open dialogue amongst regulatory stakeholders (regulators, industry and academics)
- Promote regulatory convergence and thought leadership
- Collaborate with global networks

Who attended (2014-16):

- Average attendance >100
- Attendees with diverse regulatory experience

What people are saying:

- Great Networking
- Engaging Speakers
- Relevant Topics





CoRE Inaugural Scientific Conference 2015



Dr Margaret Hamburg, former US FDA Commissioner delivered the inaugural CoRE Lecture. She said: "Having Singapore as the home of this conference makes a lot of sense as Singapore has a demonstrated commitment to supporting biomedical research, innovation, and also sits at the gateway to the Asian region." She said that she had attended many meetings but this gathering had been of exceptional quality.



CoRE Scientific Conference 2016



2016 CoRE Lecture

Guido Rasi
Executive Director
European Medicines Agency

Speakers and Session Chair

Akira Kawahara, Japan Pharmaceutical Manufacturer Association
Alasdair Breckenridge, Former Chair, UK Medicines & Healthcare Products Regulatory Agency
Emer Cooke, European Medicines Agency
Jean-Luc Butel, Economic Development Board
John Lim, Centre of Regulatory Excellence
Larry Kelly, Therapeutics Goods Administration
Michael Gropp, World Health Organisation
Mike Ward, World Health Organisation
Murray Lumpkin, Gates Foundation
Tatsuya Kondo, Pharmaceutical and Medical Devices Agency
Silke Vogel, Centre of Regulatory Excellence
Yangfeng Wu, Peking University
Zamane Abdul Rahman, Ministry of Health, Malaysia



Enhancing regulatory capacity to facilitate convergence



Trends Supporting Convergence

1. Advances in regulatory approaches

- **Good Cooperation Practice**
 - Reliance on and Referencing of other agencies' decisions
 - Collaboration instead of transaction
- **Effective regulatory systems**
 - Enhancing efficiency across entire Regulatory System instead of regulatory functions in silos
- **Communication amongst regulatory stakeholders**
 - Open dialogue and discussion
 - Neutral platforms for interaction





Trends Supporting Convergence

2. Strengthening of regulatory practice

- Facilitate effective adoption of best practices into current processes
- Minimise country-specific requirements to enhance regional regulatory efficiency
- Strengthen regulatory systems for robust decision-making



Good Review Practice
for Regulators



Good
Registration
Management



Good Submission Practice
for Industry



Trends Supporting Convergence

3. Regulatory professional development

- **Skills upgrading and career progression**
 - Technical competencies to understand and appropriately apply good regulatory practices
 - Updating of knowledge and standards of practice
 - Growing the regulatory talent pool
- **Enhance regulatory leadership**
 - Developing strategic thinking and executive leadership skills



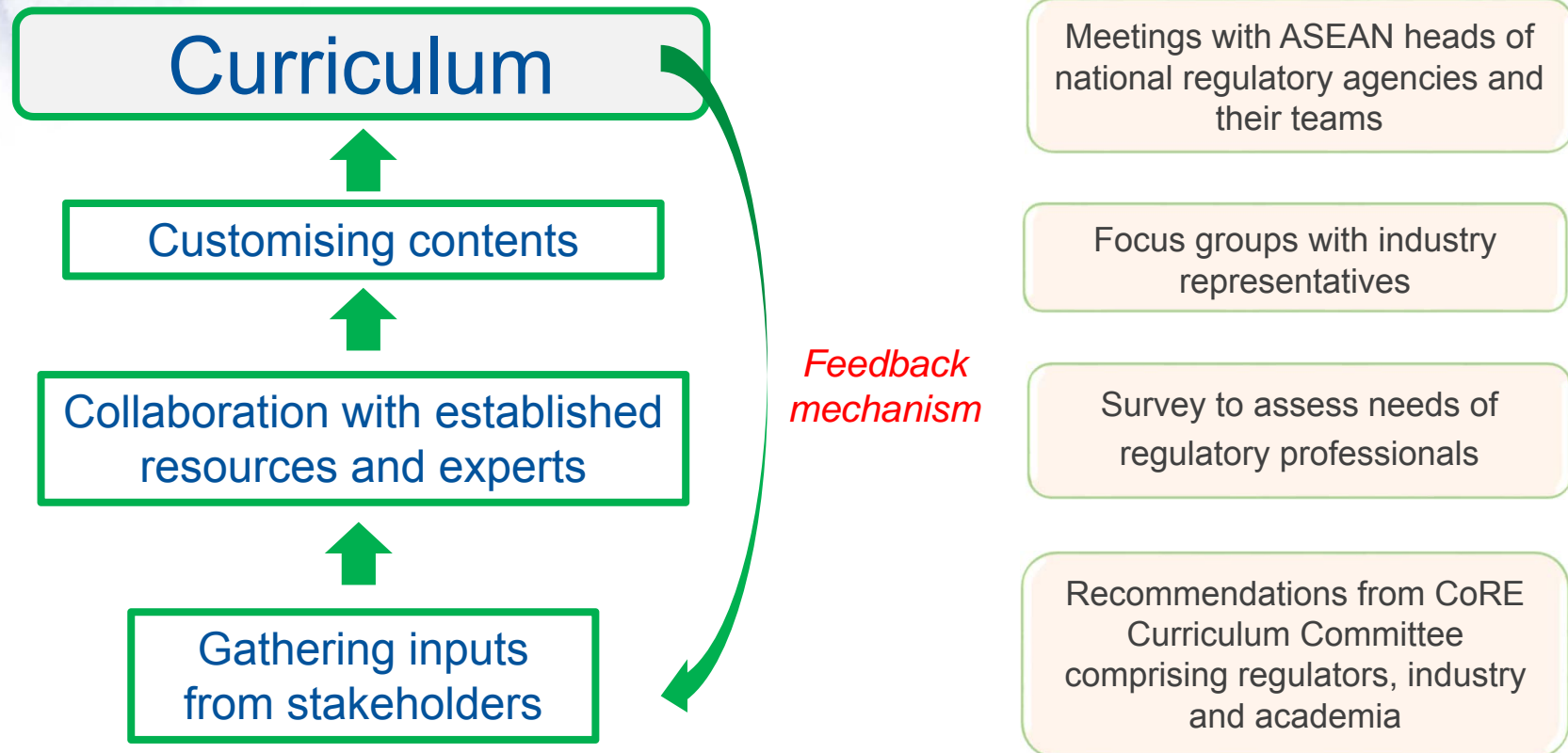


Enhancing Regulatory Capacity

Challenges to Regulatory Performance in Asia	CoRE's Approaches To Promote Regulatory Excellence
<input type="checkbox"/> Insufficient regulatory knowledge and capacity	<input type="checkbox"/> Develop curriculum to build capability and enhance professional development, spanning technical competencies to leadership skills <input type="checkbox"/> Ongoing research to maintain practical value and relevance of curriculum to stakeholders
<input type="checkbox"/> Fragmented regulatory requirements	<input type="checkbox"/> Develop initiatives supporting global guidelines and practices to facilitate convergence <input type="checkbox"/> Emphasise importance of efficient regulatory processes and systems <input type="checkbox"/> Facilitate implementation of good practices
<input type="checkbox"/> Limited platforms for networking to promote innovation in regulatory science	<input type="checkbox"/> Provide neutral academic environment to facilitate interaction among regulators, industry and health professionals <input type="checkbox"/> Encourage collaboration and innovation in regulatory processes

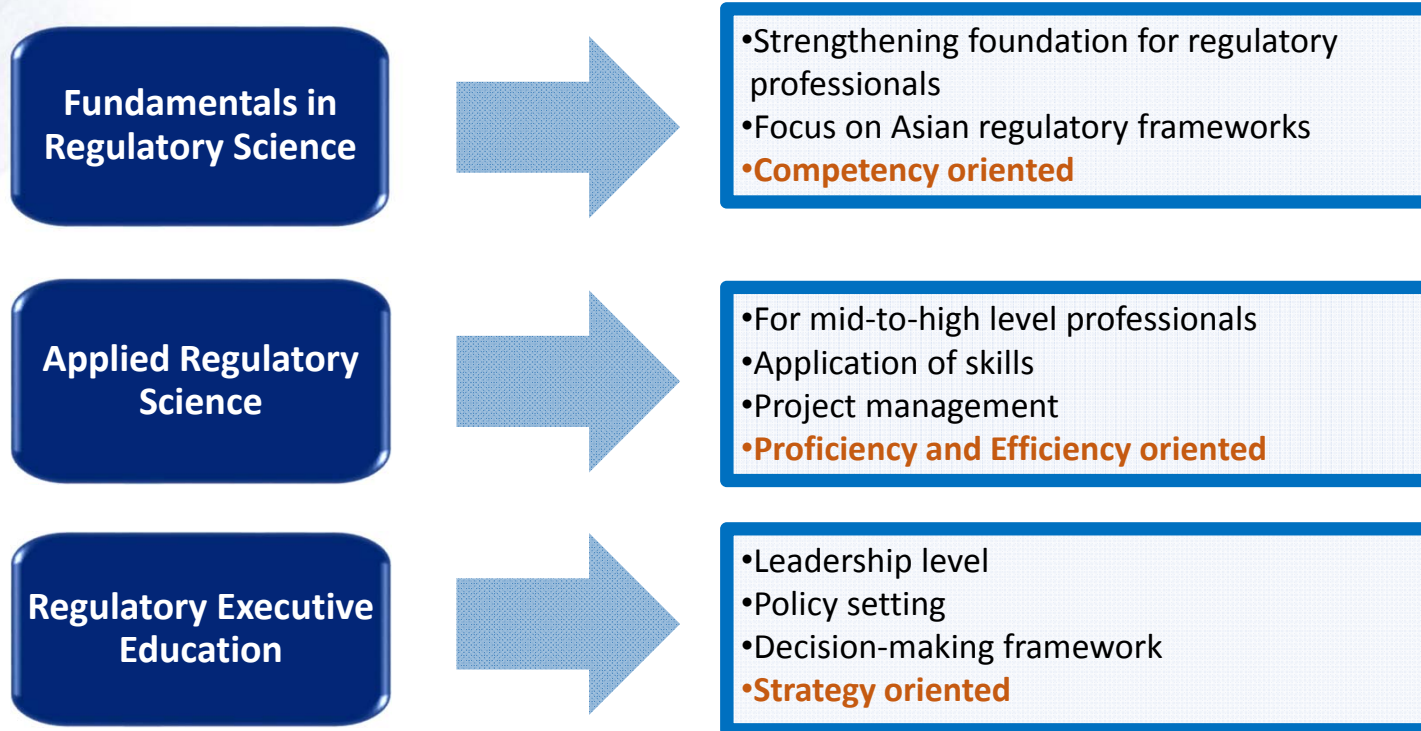


Developing CoRE's Curriculum





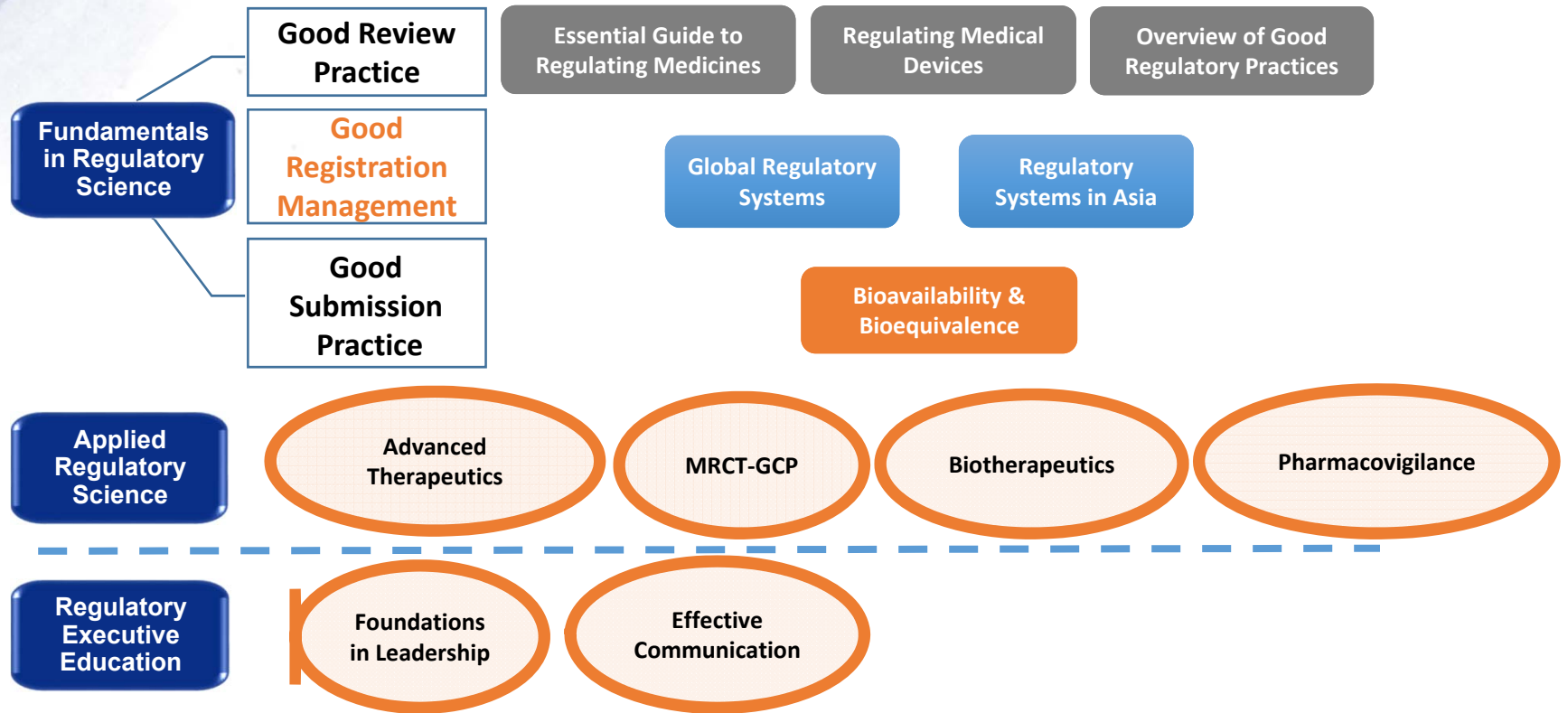
CoRE Curriculum Tiers



Blended Learning Approach for Working Professionals comprising On-Line Modules and TeamLead Interactions



Examples of CoRE Education Activities





Impact on Regulatory Capability

A. For regulatory systems

1. Minimise capacity gaps

- National agencies enabled to address key gaps in capacity and capability
- Alignment on understanding and application of international guidelines and best practices

2. Better manage cutting edge therapeutic products

- Strengthen regulatory systems to better accommodate innovation around new technology and approaches



Impact on Regulatory Capability

B. For Industry

- Increased regulatory workforce with
 - enhanced technical competencies
 - improved project management and leadership skills
- Networking platform

C. For Regulatory Professionals

- Training opportunities for career development
- Asia-centric and accessible materials
- Enabling professionals across different career stages
- Networking platform with regulatory leaders and professionals



Facilitating engagement of regulatory stakeholders



Convening Regulatory Experts

Neutral academic platform to collate inputs from regulatory leaders and experts for developing robust initiatives supporting regulatory excellence and convergence



Advisory Roundtables

26-27 March, 2015, Singapore

Day 1: *Regulatory Landscape Analysis*

Day 2: *Referencing in Asia*

Attendees: Heads/Former Heads of Regional Agencies, WHO, Academia and Industry members



Advanced Therapeutics Roundtable

15 January, 2016, Singapore

Enhancing the Regulation of Advanced Therapeutics in Asia



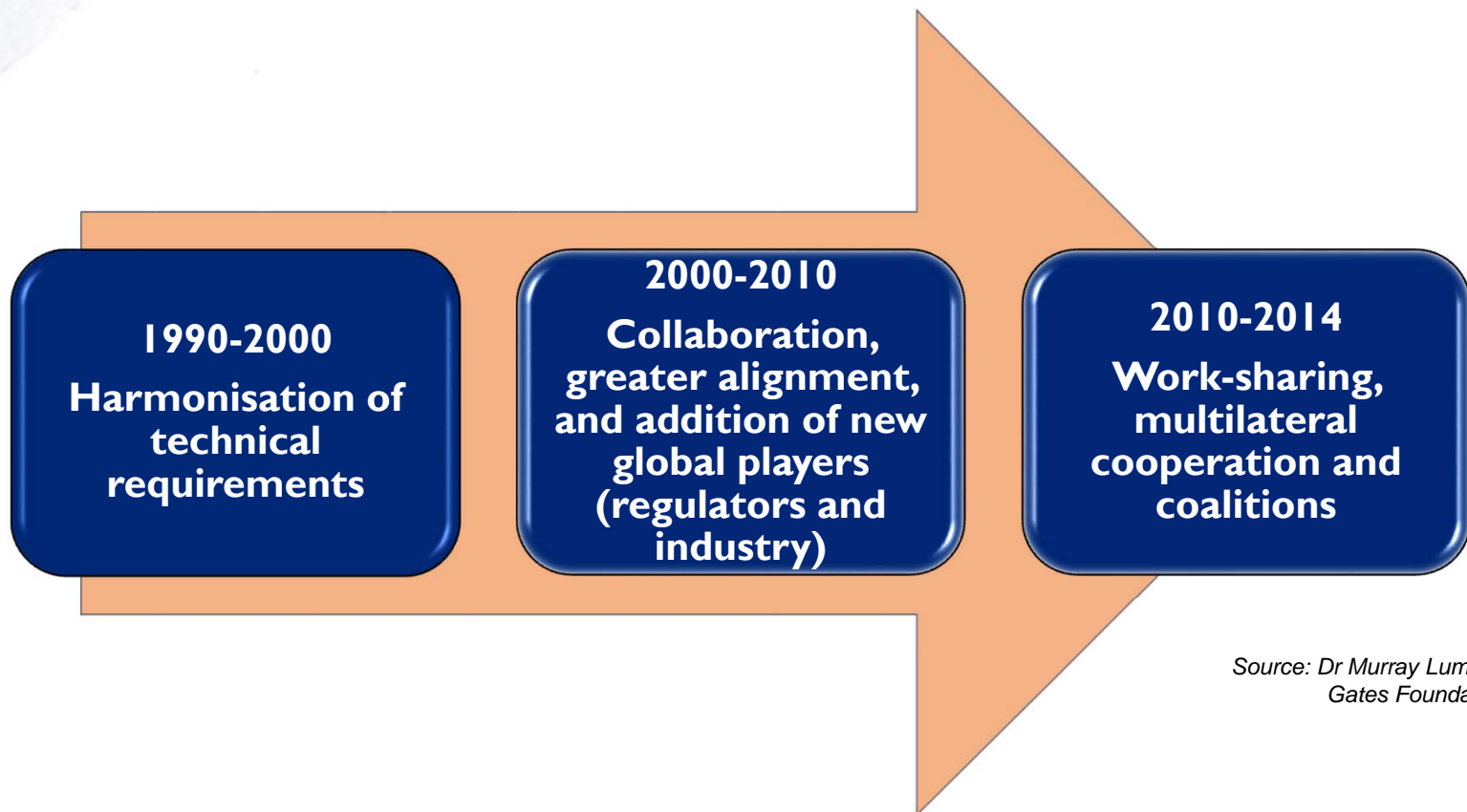


Enabling regulatory cooperation and convergence



International Regulatory Cooperation

Phases in international cooperation and collaboration



*Source: Dr Murray Lumpkin
Gates Foundation*

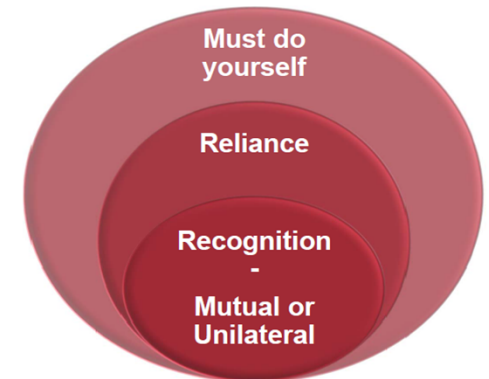


International Regulatory Cooperation

WHO is promoting Good Cooperation Practice through regulatory agency cooperation and reliance

Benefits of agency work-sharing and risk-based reliance:

- Reduces review work by leveraging on reports available from reference agencies, addressing resource and expertise issues
- Aims to reduce approval timelines and provide timely access to health products
- Enables decision-making based on local context and maintains sovereignty in decision-making



*Source: Dr Murray Lumpkin
Gates Foundation*

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- **Opportunity for Asia Pacific to develop its own models for cooperation and reliance**
 - **Possibilities for greater intra- or sub-regional referencing and work-sharing**



Regulatory Capacity and Convergence

CoRE promotes regulatory convergence through strengthening of regulatory capacity



Regulatory Curriculum

Enhancing capacity and competency for best practices

Neutral, academic platform

Convening experts and facilitating collaborative partnerships

Innovation in regulatory science

Promoting new approaches for effective and efficient regulatory systems



Improving Lives

To ensure **patients** in Asia have **timely access** to safe, effective and high quality therapeutic products through **excellent regulation**

Strengthening Regulatory Leadership

CoRE will **enable** regulatory professionals, talent development, capability building, applied learning, leadership, sharing best practices, and building intellectual capital

Policy and Systems Innovation

CoRE will strive to be a **thought leader** and driver of policy innovation

Regulatory Networks

CoRE will serve as a **neutral academic platform**, bridging industry, regulatory agencies, and other like-minded organizations to promote excellence in regulatory science in Asia

Enabling
Regulatory
Excellence

Improving
People's
Lives