

International Conference on Phase 1 and Early Phase Clinical Trials

April 26, 2013, Hong Kong



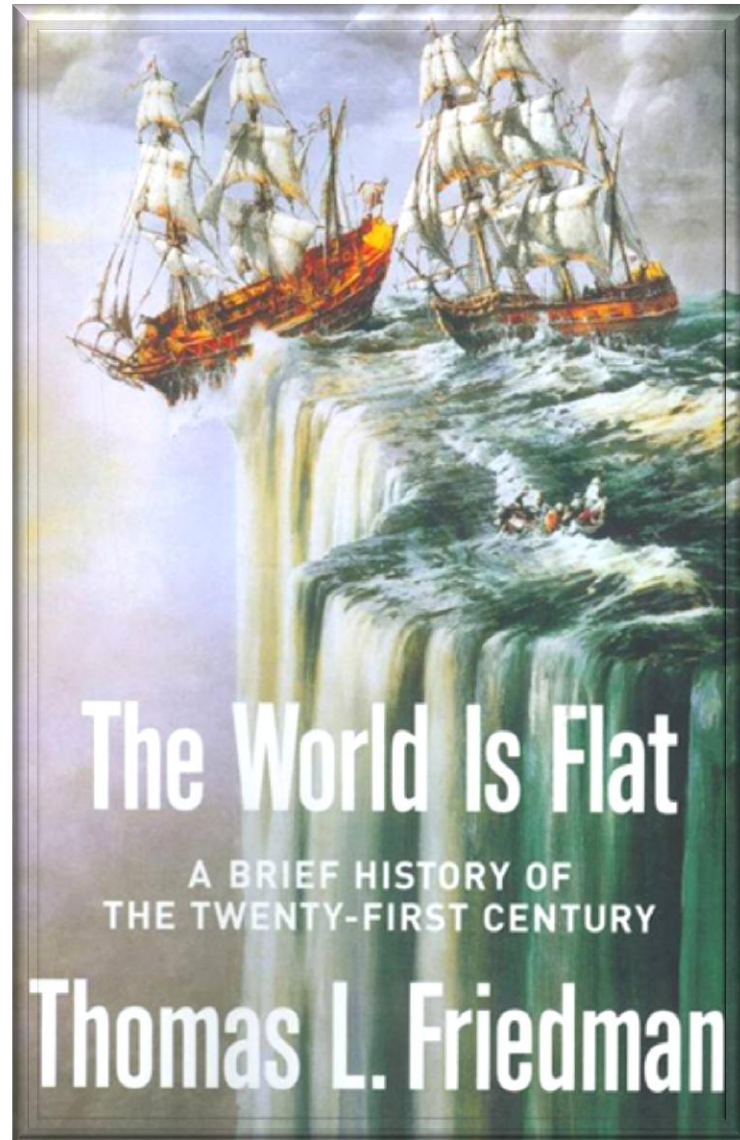
Establishment of the HKU Phase 1 Clinical Trials Centre

Henry Yau

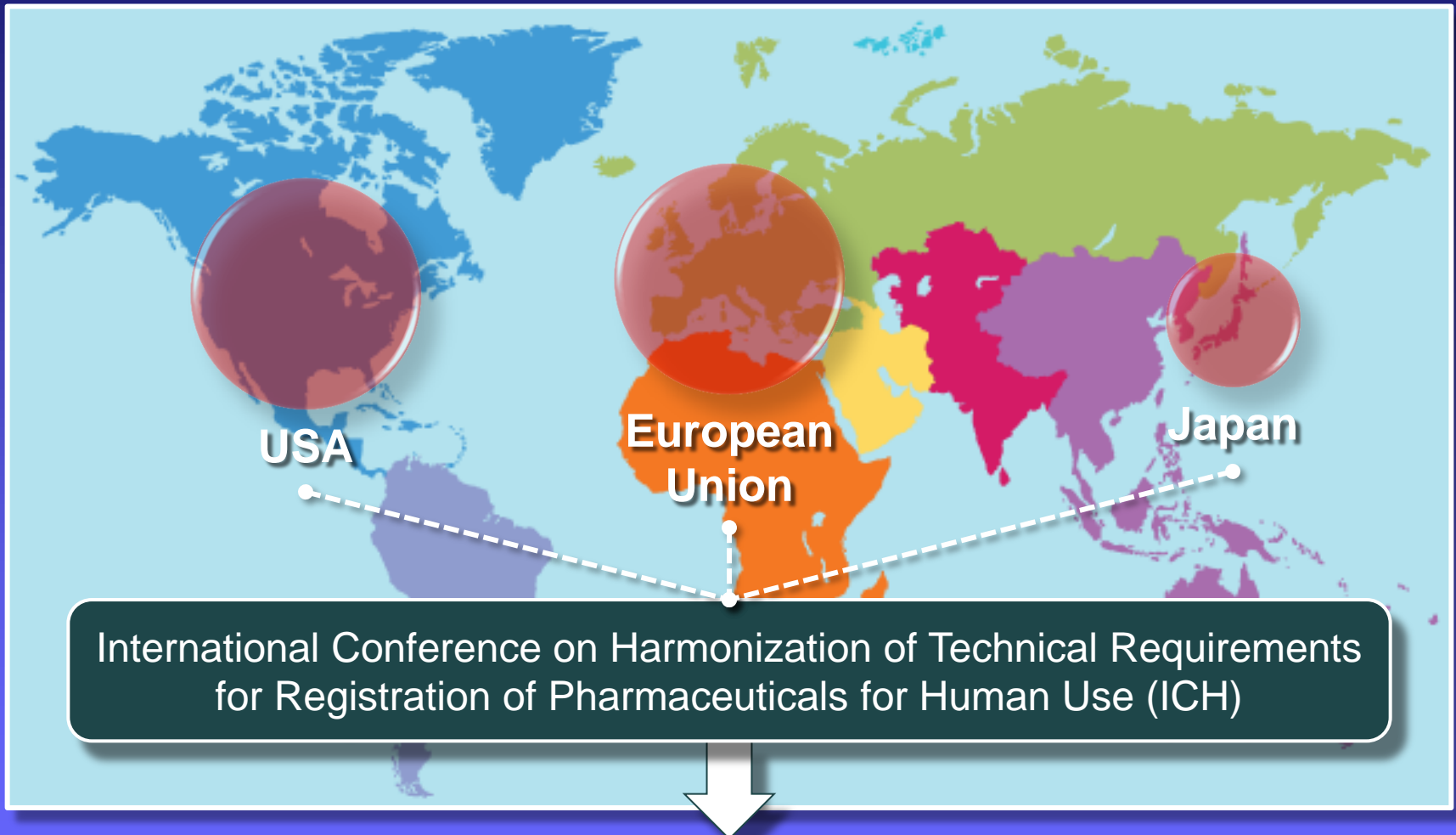
Managing Director, Clinical Trials Centre, The University of Hong Kong



The World of Clinical Trials is Flat !

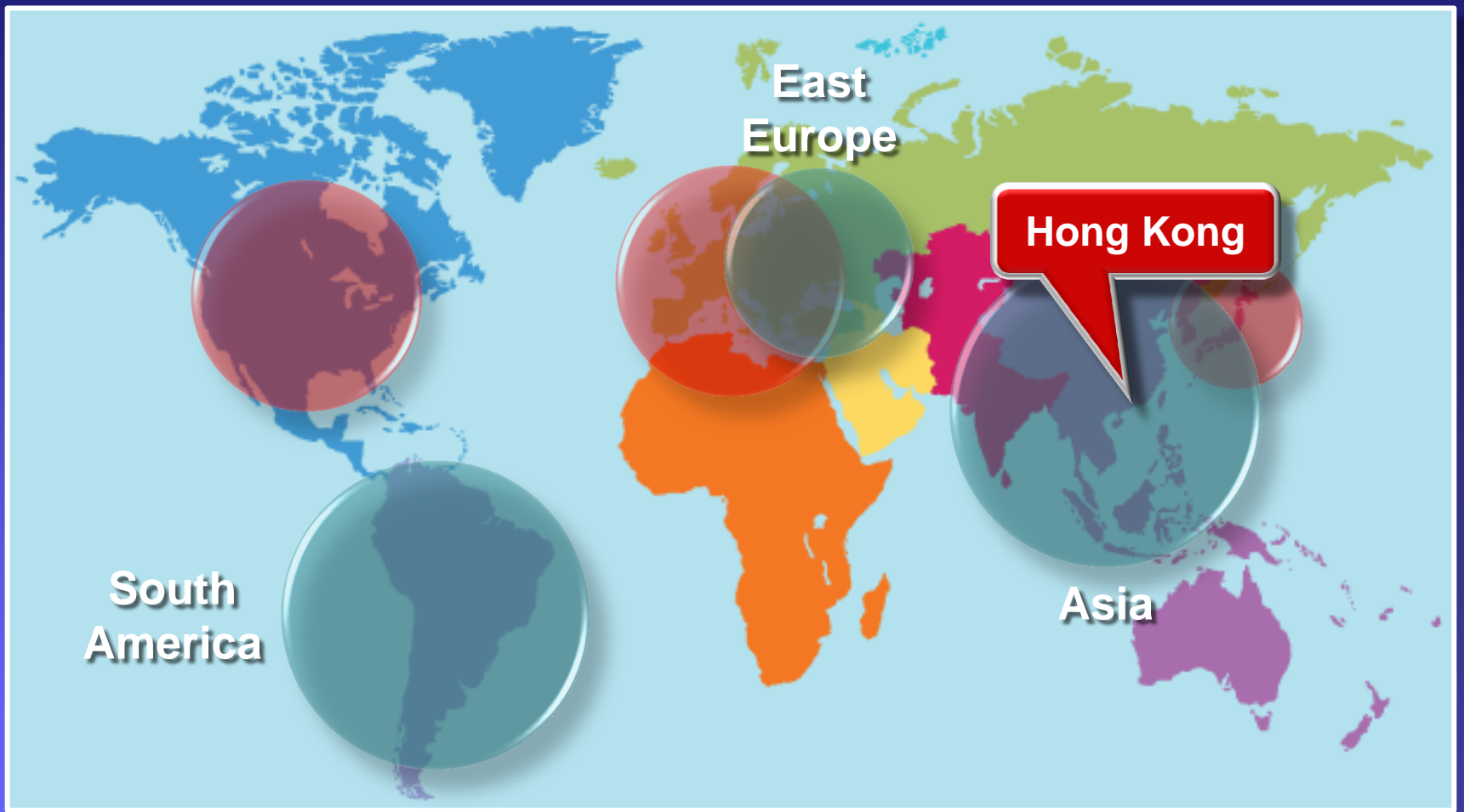


Globalization of Clinical Trials



Year 1996: ICH Good Clinical Practice (ICH GCP)

Globalization of Clinical Trials



HKU Clinical Trials Centre

Founded: **Year 1998**

Mission: To enhance human healthcare by attracting and facilitating clinical trials and safeguarding the core principles of subject protection, science and data integrity.



Track Records of HKU CTC

15 years' history

148 sponsors worldwide

704 sponsored studies contracted

215 studies ongoing

57 studies under preparation

By Apr 2013



Clinical Trials Centre
臨床試驗中心

Clinical & Scientific Expertise of HKU/QMH

Since 1887



HKU Medical Faculty

Since 1937



Queen Mary Hospital

HKU Medical Faculty

- Oldest medical college in Hong Kong (126 years since 1887)
- Pioneer in medical research and education

Queen Mary Hospital

- Regional acute care hospital with about 1,700 beds
- Accredited by the Australian Council on Healthcare Standards (ACHS) since 2010
- Clinical laboratories accredited by the College of American Pathologists (CAP) since 2002
- 24 hours emergency / ICU support

Clinical & Scientific Expertise of HKU/QMH

Since 1887



HKU Medical Faculty

Since 1937



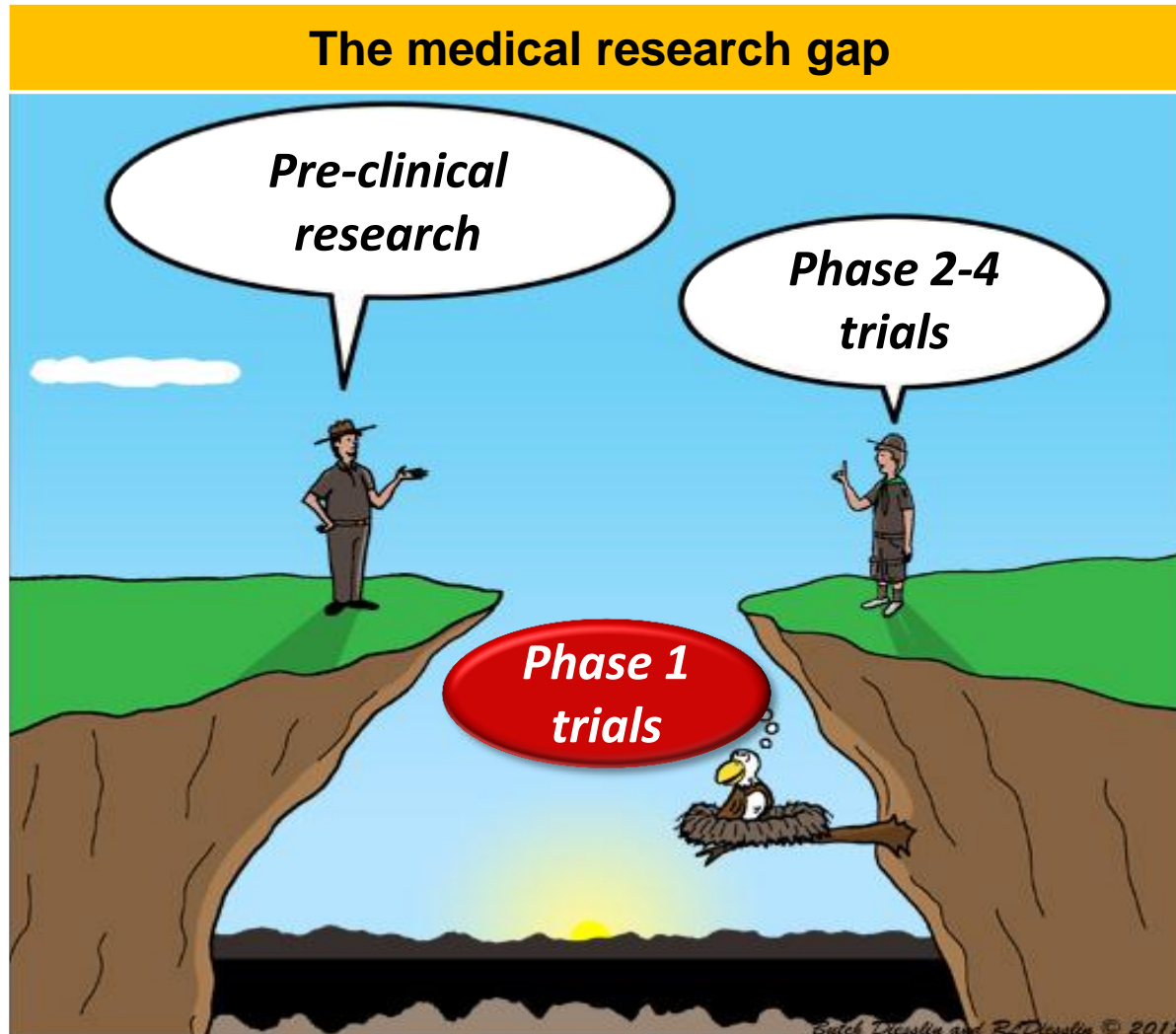
Queen Mary Hospital

Clinical Research Expertise

- Over 100 clinical investigators
- 7 clinical specialties accredited by the China FDA since 2006
- Inspected by regulatory authorities from Mainland China, Hong Kong, US and Japan:

Year	US FDA	Japan MHLW	HK DOH	China FDA
1998	✓			
2002	✓	✓		
2004	✓			
2006				✓
2008	✓			
2009	✓			✓
2012			✓	✓

Phase 1 Trials: Bridging the Gap of Medical R&D



The Good News !

Budget Speech 2011

106. *Hong Kong is well-placed to develop into an international clinical trial centre and a translational research centre. To advance the development of the pharmaceutical and biopharmaceutical industries, the Hospital Authority (HA) will set up **Phase I clinical trial centres in Queen Mary** and Prince of Wales Hospitals to conduct preliminary clinical trials for new drugs..... We will also map out our way forward for different phases of clinical trials for drugs, and strengthen the organisation, management and planning for clinical trials to promote development in this area.*

Value of Phase 1 Clinical Trials to Hong Kong

Local Healthcare:

- Early access to new medicines
- Safeguarding the quality of generic drugs

Medical Education:

- Supporting education in pharmaceutical medicine
- Training opportunities for medical professionals

Phase 1 Clinical Trials

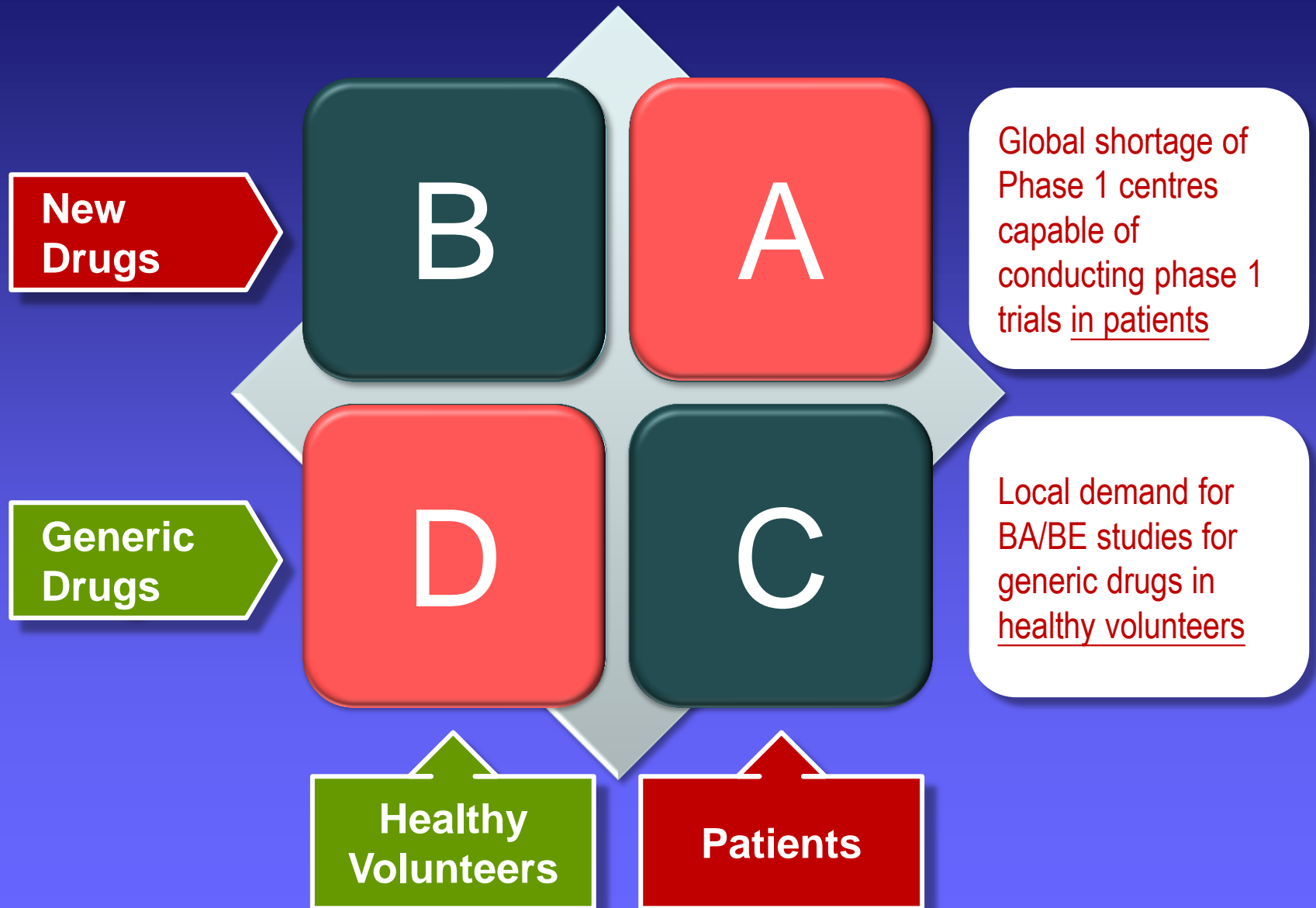
Hong Kong Economy:

- Supporting the development of local pharmaceutical / life sciences industry

Mainland-HK Integration:

- Overseas companies → HK → Mainland
- Mainland companies → HK → Overseas

Research Focuses

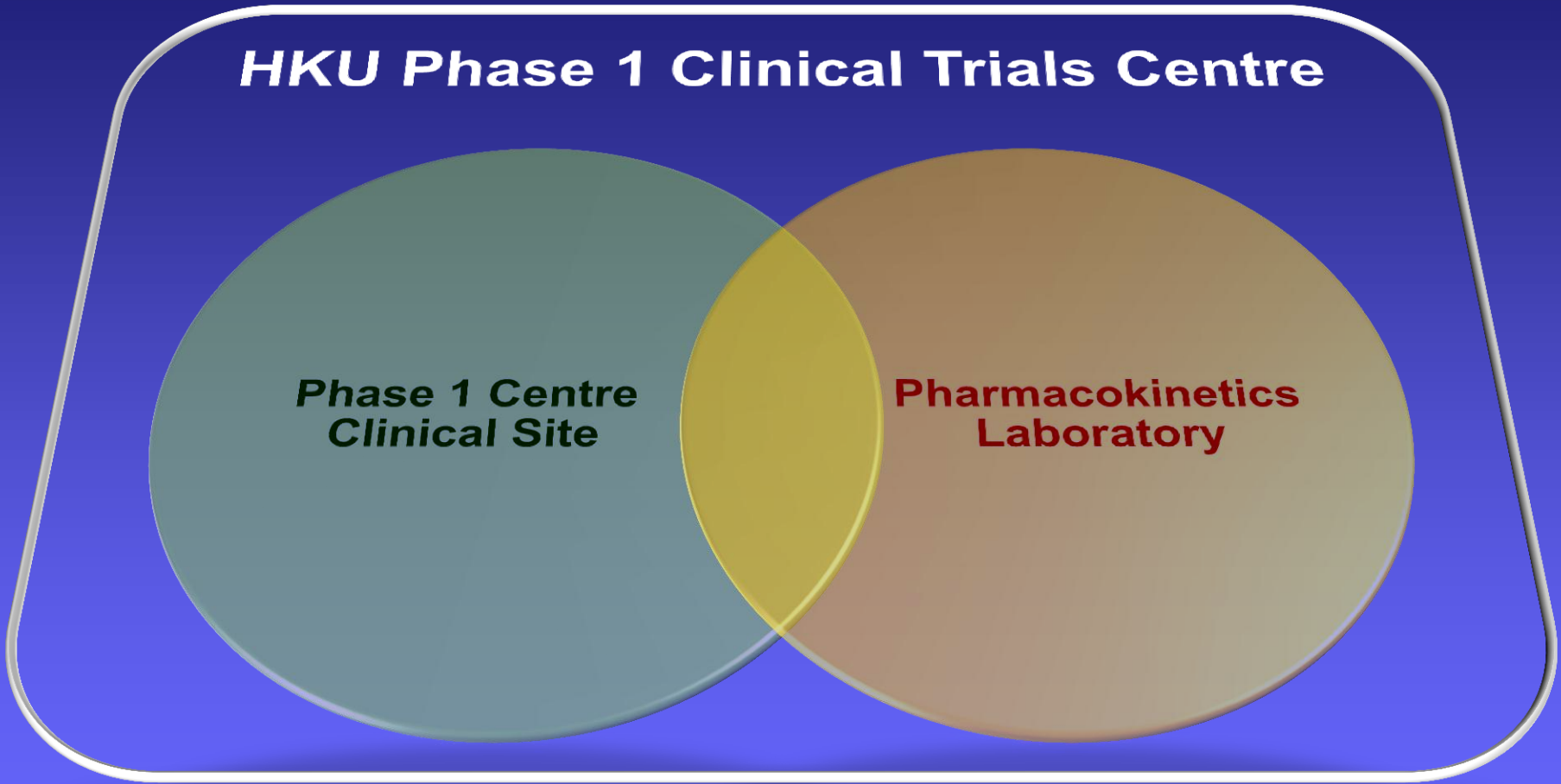


HKU Phase 1 Facilities

HKU Phase 1 Clinical Trials Centre

**Phase 1 Centre
Clinical Site**

**Pharmacokinetics
Laboratory**



HKU Phase 1 Centre: Clinical Site

Location



2/F Block K
Queen Mary Hospital
Pokfulam, Hong Kong

Main Facilities

- 24 beds
- Safety Monitoring System
- Drug Storage & Processing Facilities
- Specimen Storage & Processing Facilities
- Resuscitation Facilities
- Dining & Leisure Area
- Access & Security Control

Nurse Station



Dining & Leisure Area



Beds Area



Physiological Monitors



Resuscitation Room



Drug Processing Room



Drug Storage Room



Specimen Processing Room



Specimen Storage Room



HKU Phase 1 Centre: Pharmacokinetics Lab

Location

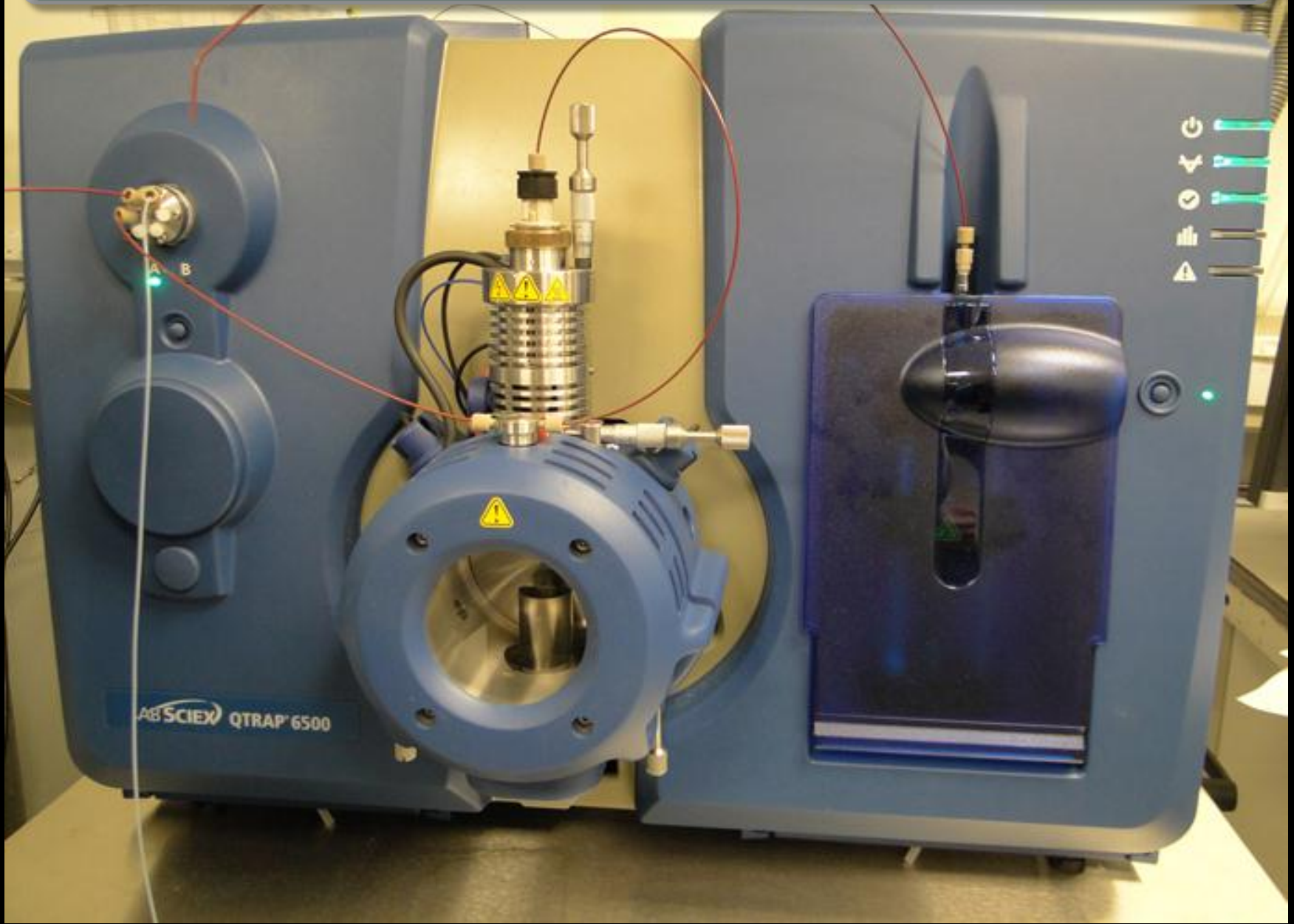


6/F Laboratory Block
Li Ka Shing Faculty of Medicine
The University of Hong Kong

Main Equipment

- AB SCIEX QTRAP 6500 AMCR
- AB SCIEX TripleTOF 5600 AMCR
- Beckman P/ACE MDQ System
- Waters Acquity UPLC System
- Dionex 2D-NanoLC

AB SCIEX QTRAP 6500



AB SCIEX TripleTOF 5600



Waters Acquity UPLC System



Beckman P/ACE MDQ CE System



3-tier Governance Structure



Management Structure

Current Structure of HKU CTC

Chief Director
(Prof. YL Lau)

Managing Director
(Mr. Henry Yau)

Corporate Services & Administration Team

Project Management & Contract Services Team

Business & Project Acceleration Team

- Human Resources Management
- Corporate Finance Management
- Information Technology Management
- Facilities Management
- General Administration

- Protocol Development
- Regulatory Affairs
- Project Management
- Study Monitoring
- Data Management
- Medical Statistics

- Business Development
- Feasibility Assessment
- Project Coordination
- Ethics Affairs
- Budget & Payment Management
- Contract Management & Legal Affairs
- Study Drug Management
- Specimen Management
- Clinical Research Coordinator Support

New Structure for Phase 1 Centre

Medical Director
(Prof. Bernard Cheung)

Director of Drug Metabolism & Pharmacokinetics
(Prof CW Lam)

Scientific & Clinical Leadership

Scientific & Operational Leadership

Quality Assurance Team

Phase 1 Centre Operations Team

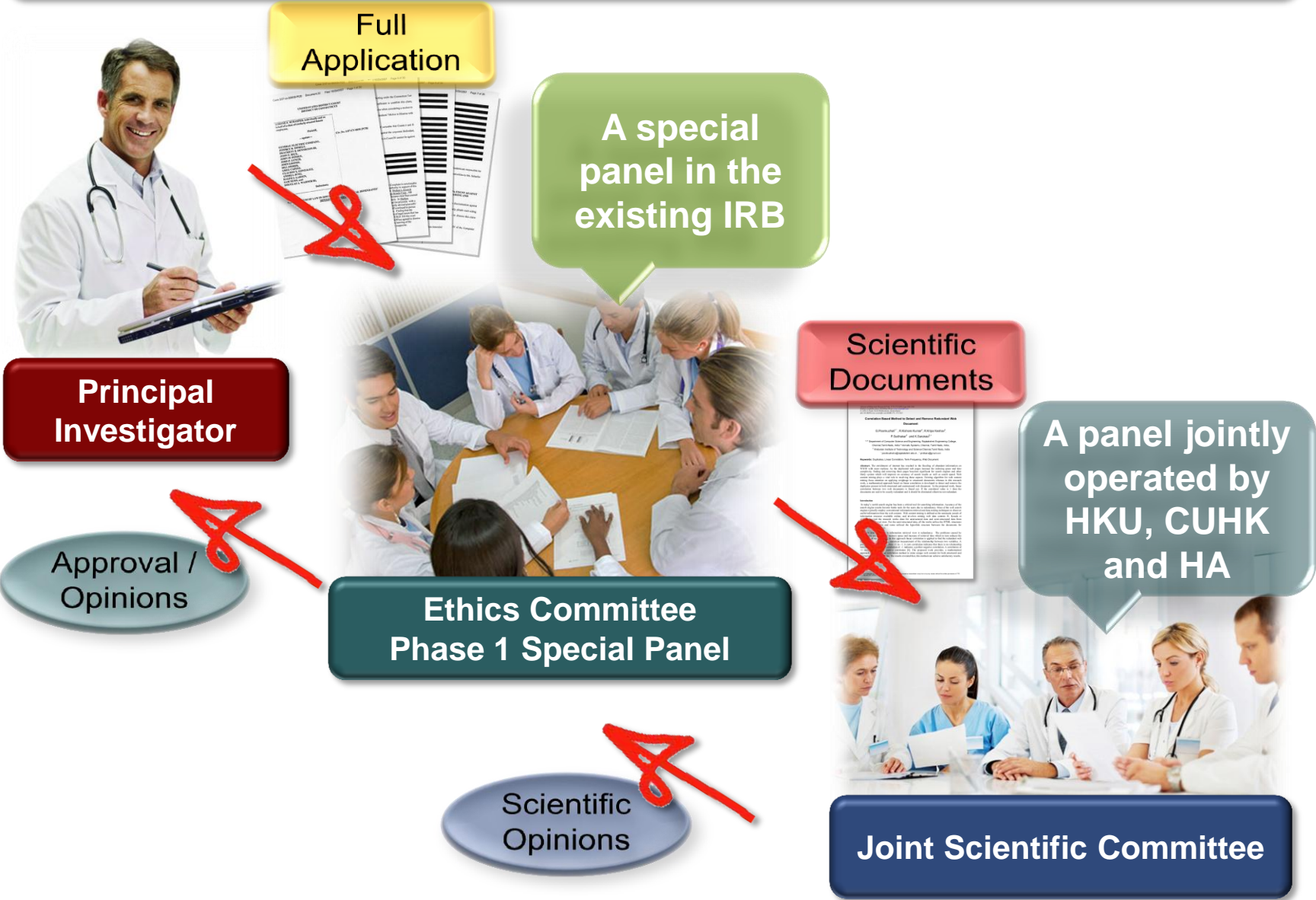
Pharmacokinetics Laboratory Team

- SOPs Management
- Internal Audit Coordination
- External Audit and Inspection Facilitation
- Accreditation Management and Coordination

- Phase 1 Trial Subjects Recruitment
- Phase 1 Trial Operations
- Phase 1 Centre Facilities Management

- Scientific Consultation on Pharmacokinetics and Drug Analysis
- Pharmacokinetics Laboratory Operations
- Pharmacokinetics Laboratory Facilities Management

Ethics & Scientific Oversight



Ethics & Scientific Oversight



The University of Hong Kong



Hospital Authority



The Chinese University of Hong Kong

Standard Operating Procedure of the Joint Scientific Committee for Phase 1 Clinical Trials

Document Particulars	
Document Type	<input checked="" type="checkbox"/> SOP ^(a) <input type="checkbox"/> Guideline ^(b) <input type="checkbox"/> Working Manual ^(c)
Document Reference No.	CHAIR/SOP/JSC/001
Initial Issue Date	<DATE>
Version No.	1
Issue Date	<DATE>
Effective Date	<DATE>
Author(s)	Group authors including representatives from the relevant institutions

Approval		
_____	_____	_____
<NAME>	<NAME>	<NAME>
<TITLE>	<TITLE>	<TITLE>
The University of Hong Kong	Hospital Authority	The Chinese University of Hong Kong
Date: _____	Date: _____	Date: _____

- (a) A Standard Operating Procedure (SOP) is an official document outlining the necessary procedures for executing a specified task, which shall be approved by the authorized representative(s) of the organization(s) and complied with by the relevant operating unit(s) and personnel.
- (b) A Guideline is a guidance document for elaborating and facilitating compliance with the relevant SOP(s) or requirement(s), which could be approved by the authorized quality assurance specialist(s) and/or the authorized representative(s) of the organization(s).
- (c) A Working Manual is a document providing more details about execution of the required procedures under the relevant SOP(s), which could be approved by the authorized representative(s) of the operating unit(s) responsible for the task concerned and followed by the relevant operational personnel.



The University of Hong Kong



Hospital Authority



The Chinese University of Hong Kong

Guideline on Ethics Oversight and Scientific Evaluation of Phase 1 Clinical Trials

Document Particulars	
Document Type	<input type="checkbox"/> SOP ^(a) <input checked="" type="checkbox"/> Guideline ^(b) <input type="checkbox"/> Working Manual ^(c)
Document Reference No.	CHAIR/GL/PH1/001
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Accreditation by China FDA

Target: Phase 1 Clinical Trials

Anaesthesiology

Cardiology

Endocrinology & Metabolism

Haematology & Bone Marrow Transplantation

Hepatobiliary/Pancreatic Surgery & Liver Transplantation

Obstetrics & Gynaecology

Respiratory Medicine

Acknowledgement

**Food and Health Bureau
Department of Health
Hospital Authority
Queen Mary Hospital**

Acknowledgement

Peking Union Medical Centre Hospital

Peking University First Hospital

Dong-A University Hospital

Inje University Busan-Paik Hospital

Pfizer Clinical Research Unit

Zenith Technology

Acknowledgement

Bayer

Boehringer Ingelheim

Bristol-Myers Squibb

Novartis

PAREXEL

Quintiles

Acknowledgement

Hong Kong Association of the Pharmaceutical Industry
Hong Kong Science & Technology Parks



• Thank You •