

From Founding to Flourishing: What a One-stop CTC means to a Biomedical R&D Ecosystem





ANNIVERSARY

Since 1998



**HKU
Med**

LKS Faculty of Medicine
Clinical Trials Centre
香港大學臨床試驗中心

Formula 1 Racing - for 25 years !!





Administration Office



Site Management Organization



Contract Research Organization



Phase 1 Centre



Pharmacokinetics Laboratory



Professional Training

One-stop clinical research platform

1998

2023

 **Clinical Trials Centre**
The University of Hong Kong

4

>1,800

clinical studies of all sorts

Phase I Phase II Phase III Phase IV

>100



Administration Office



Site Management Organization



Contract Research Organization



Phase 1 Centre



Pharmacokinetics Laboratory



Professional Training

One-stop clinical research platform

1998

2023



International connections



1

2



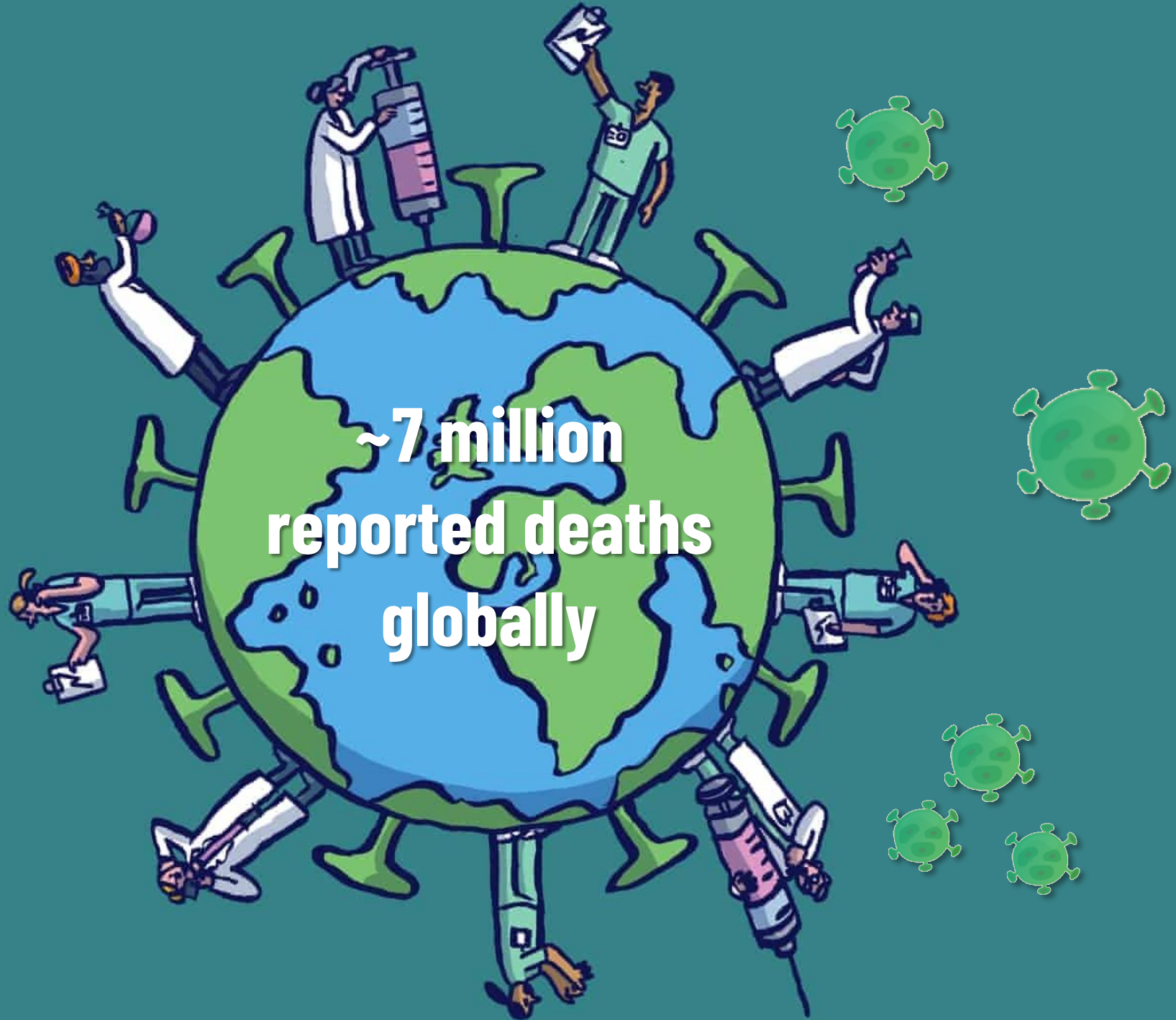
Public Health

**SOCIAL
VALUE
CREATION**

Biomedical
R&D
Industry

Value ①

**Tackling
Public
Health
Challenges**



**~7 million
reported deaths
globally**

- **WHO World Health Assembly Resolution WHA75.8 (2022):**

Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research **quality** and **coordination**

- **WHO Guidance for Best Practices for Clinical Trials (2023):**

... every country should work to establish at least one **well-functioning clinical research institution** ...

... include a focus on **conduct and governance** of clinical trials and that they can **work with or develop additional clinical research sites** within relevant communities to respond to public health needs ...

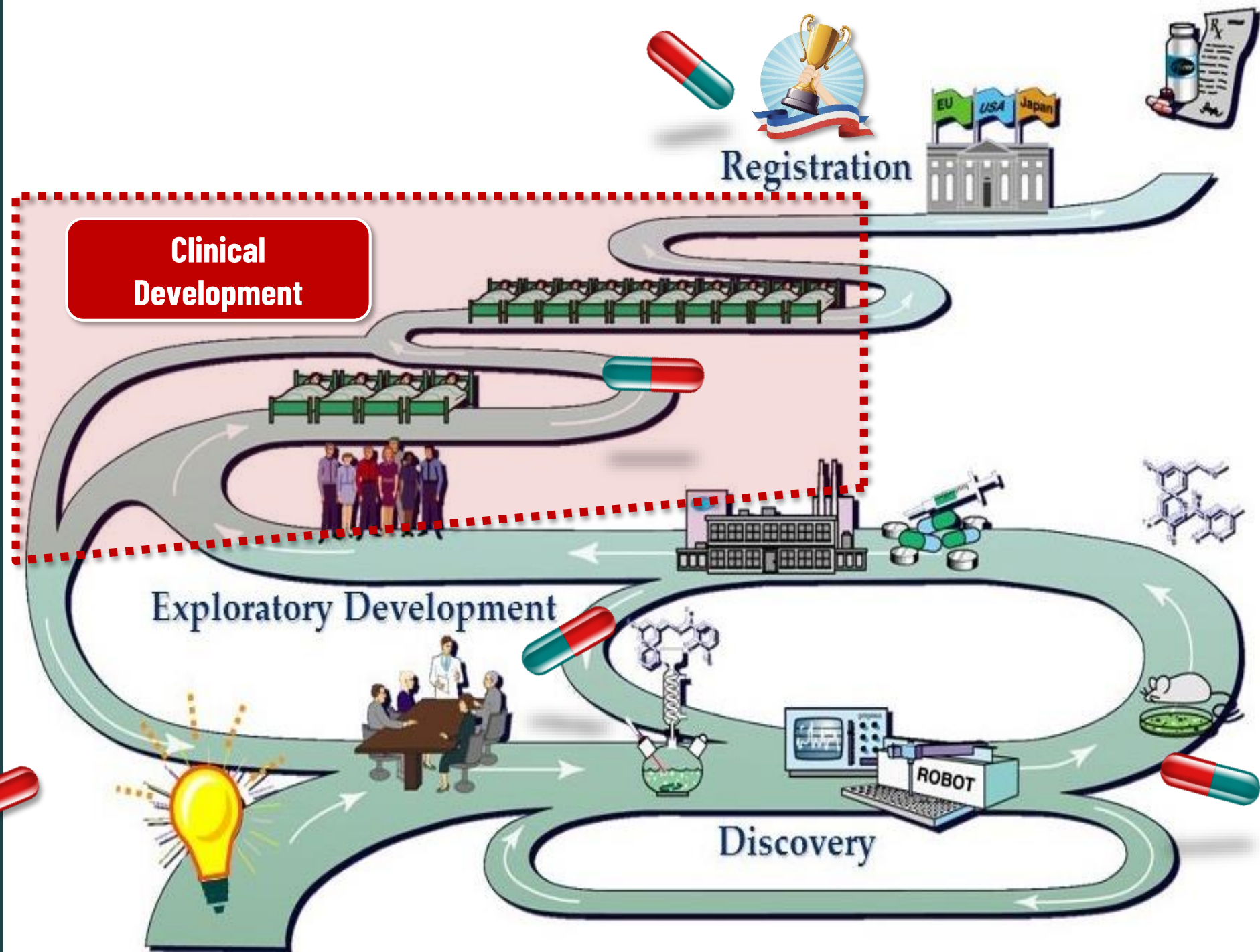




World Health Organization

Value ②

Supporting Biomedical R&D





BASIC RESEARCH



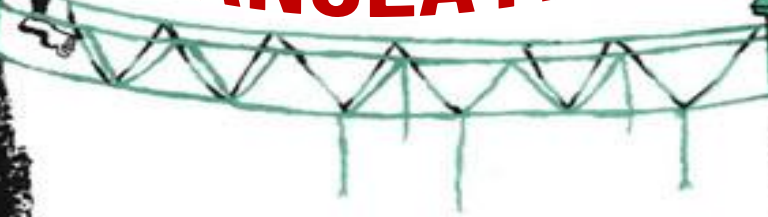
**CLINICAL
TRANSLATION**



CLINICAL APPLICATION

ACADEMIA / STARTUP

BIOMEDICAL INDUSTRY



CROSSING THE VALLEY OF DEATH



Basic, Clinical & Data Sciences



SMO 法規申報及法務事務
Regulatory Submissions & Affairs

- 法規許可申請及後續法規申報
Application for regulatory approval & subsequent regulatory submissions
- 研究藥物進口申請
Application for study drug import licenses

SMO 財務預算及財務管理
Budgeting & Financial Management

- 研究中心及合同研究服務財務預算
Budgeting for study sites & CRO services
- 研究追蹤、開帳發票及收帳管理
Study tracking, invoicing & payments management

SMO 合同管理
Contracts Management

- 合同洽商及行政
Contract negotiation & administration
- 合同責任監察
Contract responsibilities monitoring

SMO 在公眾臨床試驗登記冊登記
Registration with Public Clinical Trial Registries

- 在公眾臨床試驗登記冊登記
Registration on public clinical trial registries
- 更新登記冊內的研究資料
Updating of study information on registries

NOT only about operations



SMO 生物樣本管理及實驗室統籌
Biop specimen Management & Laboratories Coordination

- 生物樣本管理系統開發
Development of biop specimen management system
- 生物樣本管理、包裝、運送及儲存/管理
Processing, packaging, shipment & storage/archiving of biop specimens
- 與本地及海外實驗室
Coordination with local/overseas laboratories

SMO 藥代動力學/藥效動力學
Pharmacokinetics (PK)/ Pharmacodynamics (PD)

- 分析方法開發及驗證
Analytical methods development & validation
- 生物樣本採集
Biop specimen sampling
- 生物樣本分析
Biop specimen analysis
- 藥代動力學/藥效動力學數據分析
PK/PD data analysis

SMO 統籌研究中心外判服務
Coordination of Outsourced Site Services

- 供應商評估
Vendor assessment
- 統籌與溝通、註冊者及研究中心
Coordination with vendors, sponsors & study sites

SMO 研究數據收集、記錄及保存
Study Data Collection, Documentation & Retention

- 數據收集指南撰寫
Development of data collection guides
- 源數據記錄
Source data recording
- 源報告書填寫
Case report forms completion
- 必要研究文件存檔
Archiving of essential study documents

Ethics, Regulatory, Quality & Risk Management



SMO 策略性項目諮詢
Strategic Project Consultation

- 臨床開發策略性規劃
Clinical development strategy planning
- 項目策略性規劃
Project strategy planning
- 研究可行性評估
Study feasibility assessment

SMO 研究設計及方案制定
Study Design & Protocol Development

- 研究設計
Study design
- 研究方案撰寫
Study protocol development

SMO 項目策劃及管理
Project Planning & Management

- 研究者及研究中心遴選
Investigator & study sites identification
- 項目團隊建立及管理
Project team building & management
- 項目時間排期及進度追蹤
Time planning & milestones tracking
- 資源規劃及管理
Resources planning & management
- 應變管理
Contingency management

SMO 倫理申報及倫理事務
Ethics Submissions & Affairs

- 首次倫理申報及後續申報
Initial ethics submission & continuing submissions
- 與倫理委員會持續溝通
Ongoing communication with ethics committees

Strategy, Business & Finance Management



SMO 參加者招募、聯繫及溝通
Participants Recruitment, Relation & Communication

- 病人/健康志願者招募
Recruitment of patients/healthy volunteers
- 與參加者持續保持溝通
Continuing communication with participants
- 收集及分析參加者反饋
Collecting & evaluating feedback from participants

SMO 研究程序統籌及執行
Study Procedure Coordination & Performance

- 研究營運規劃
Study operations planning
- 統籌及執行研究程序
Coordination & performance of study procedures

SMO 安全管理及藥物管職
Safety Management & Pharmacovigilance

- 設立獨立數據及安全監察委員會
Setting up independent data & safety monitoring committees
- 持續進行安全監量及安全數據收集和評估
Ongoing safety monitoring & safety data collection & evaluation
- 向研究者、倫理委員會及監管單位報告安全事件
Reporting of safety events to sponsors, ethics committees & regulatory authorities

SMO 研究藥物管理
Study Drug Management

- 藥物手冊撰寫
Development of pharmacy manual
- 研究藥物接收、儲存、處理、分發及棄置
Study drugs receipt, storage, handling, dispensing & disposal
- 研究藥物清點
Study drugs accountability

Clinical, Pharmacy & Laboratory Operations



SMO 內部質量管理
Internal Quality Control

- 內部質量管理規劃
Internal quality control planning
- 持續執行內部質量管理
Ongoing internal quality control

SMO 監察
Monitoring

- 監察計劃撰寫
Development of monitoring plans
- 持續執行監察
Ongoing monitoring

SMO 數據管理、生物統計學及結果報告
Data Management, Biostatistics & Results Reporting

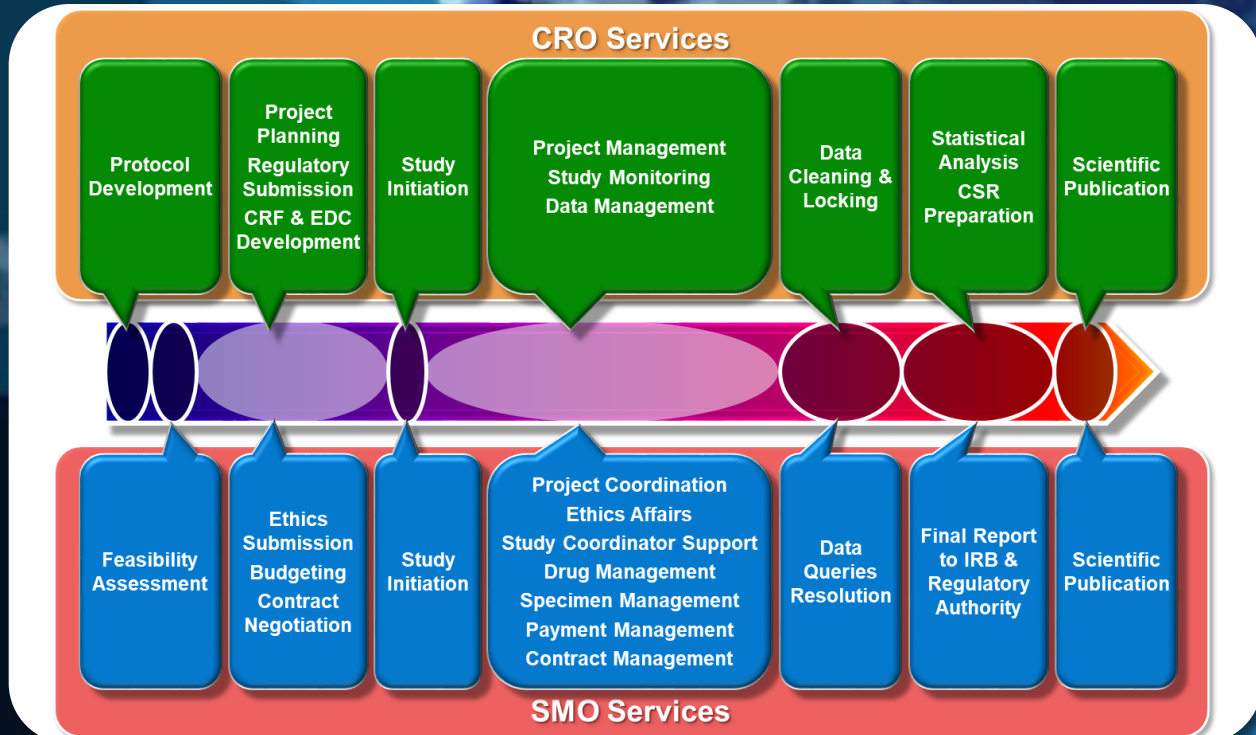
- 數據管理及統計分析計劃開發
Development of data management & statistical analysis plans
- 設立數據管理系統及電子數據交換表
Setting up & validation of study database & electronic data transfer forms
- 持續執行數據管理、檢查及驗證
Ongoing data management, checking & validation
- 進行數據分析及撰寫統計分析報告
Performing data analysis & development of statistical analysis reports
- 最終臨床研究報告撰寫
Development of final clinical study reports

SMO 結果披露及科學發表
Results Disclosure & Scientific Publication

- 於科學期刊發表
Publication in scientific journals
- 於科學會議披露
Disclosure in scientific meetings
- 向公眾發布結果
Dissemination of results to the public

Case 1: Investigator-initiated Clinical Trial

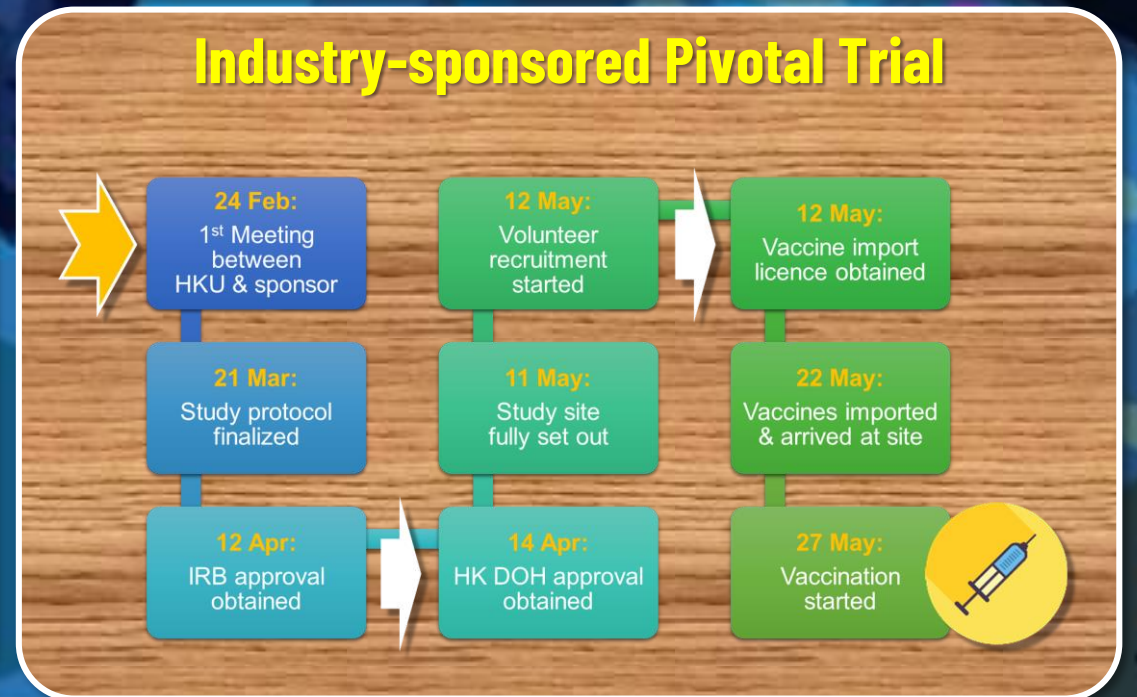
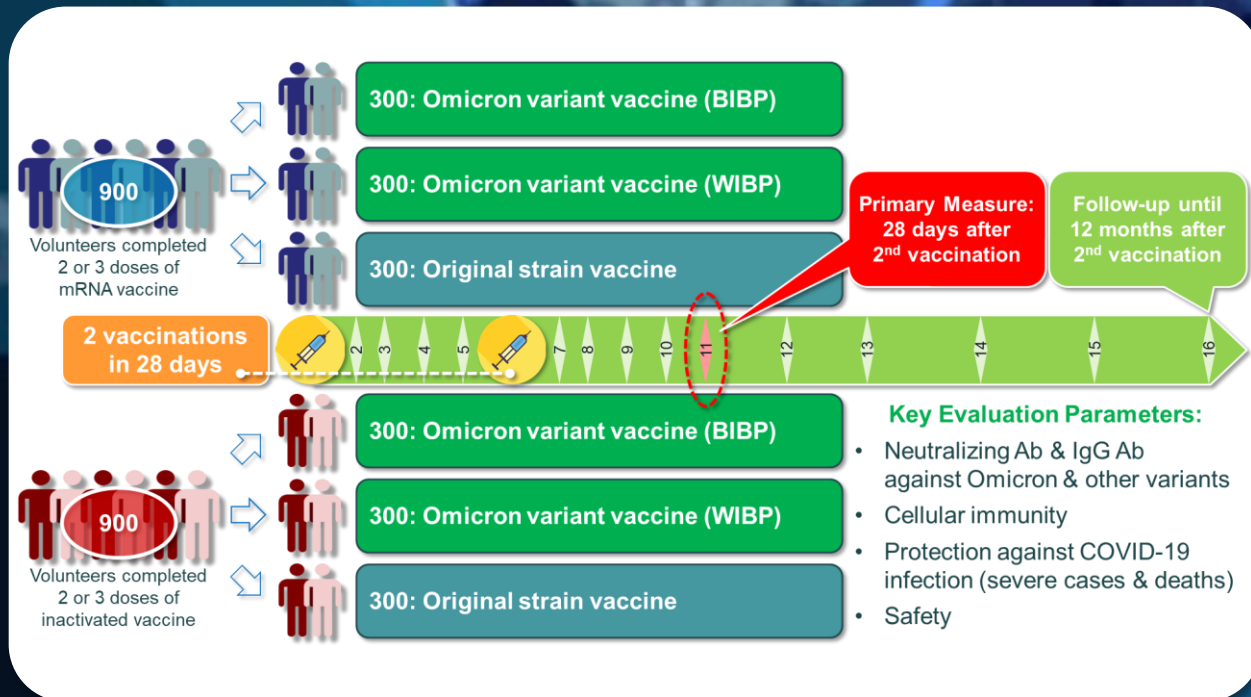
COVID-19 Pandemic



Case 2: Industry-sponsored Clinical Trial

COVID-19 Pandemic

Omicron Inactivated Vaccine



Management Digitalization

EN



Digital Cloud Platform for Clinical Trials Institution Management

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Central Project Registry



Quality Management



Approval Portal



User Management



Finance Management



Bio Specimen Management



Drug Management



Setting





Project Details

Project



eNPF

1

Summary

My Projects

Info Setting

Report

Analytics

Contact



Master Access Control

Project | 2475 | HKU1 | Study Status: | Under Preparation | IRB | Not yet submitted | Budget | Not yet submitted | CTA | N/A | **SAVE**

Last updated by Philip Li on 14-Nov-2023 09:58:14.

Study Information

Study Title

Protocol Number	Project Type Sponsored	Study Phase / Type I	IRB Reference Number
Disease Area Abdominal Aortic Ane...	Therapeutic Area Cardiovascularology	CT Cert Number	International / Local Study International
NMPA Filed Yes	CT Cert (Issue) Date dd-----yyyy	CT Cert (Expiry) Date dd-----yyyy	Phase 1 Center Involvement Full
ATP Under Cap 138 Yes	LOA Date dd-----yyyy	Global / Local Sample Size 100 / 10	Satellite / Referral Site [Select]
Financial Closure Date dd-----yyyy	Internal Archiving Status [Select]	ArchiveEasy Status [Select]	

Remark

Contacts

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Working Folders

Name	Date Modified
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📁 Budget	11/24/2023 18:04
📁 ICF	11/24/2023 18:04
📁 IRB	11/24/2023 18:04
📁 Protocol	11/24/2023 18:04

项目详情

项目

项目 | 2475 | HKU1 | 研究状态: 准备中 | 研究伦理委员会 | Not yet submitted | 财务预算 | Not yet submitted | CTA | N/A

储存

Last updated by Philip Li on 14-Nov-2023 09:58:14.

研究资讯

研究标题

协议编号	项目类别 有赞助	研究阶段 / 类型 I	IRB 参考编号
疾病领域 Abdominal Aortic Ane...	治疗领域 Cardiovascularology	CT 证书编号	国际 / 本地研究 国际
NMPA 归档 是	CT 证书(发出)日期 dd----yyyy	CT 证书(过期)日期 dd----yyyy	一期临床研究中心参与 全部
ATP Under Cap 138 是	授权书日期 dd----yyyy	全球 / 本地样本量 100 / 10	Satellite / Referral 地点 [选择]
财务截止日期 dd----yyyy	内部存档状态 [选择]	ArchiveEasy 状态 [选择]	

备注

通讯簿

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工作目录

名称	修改日期
没有母目录	
Budget	11/24/2023 18:07
ICF	11/24/2023 18:07
IRB	11/24/2023 18:07
Protocol	11/24/2023 18:07



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A dark blue cloud-shaped graphic containing the eSMO+ logo and a white login form. The form has fields for "Username" and "Password" and a "Login" button. A small link for help is at the bottom.



multi-centre utilization

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**cross-border
utilization**

Greater Bay Area

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SMO+ International Clinical Trial Institutions Management Network

Greater Bay Area
Collaboration



瑪麗醫院 (香港)
Queen Mary Hospital (Hong Kong)



港怡醫院 (香港)
Gleneagles Hospital Hong Kong (Hong Kong)

Public-Private
Collaboration



希愈腫瘤中心 (香港)
HEAL Oncology (Hong Kong)



香港大學深圳醫院 (深圳)
The University of Hong Kong -
Shenzhen Hospital (Shenzhen)



澳門科技大學及其科大醫院 (澳門)
Macau University of Science and Technology
and its University Hospital (Macao)



Policy Address

Policy Measures

Highlights

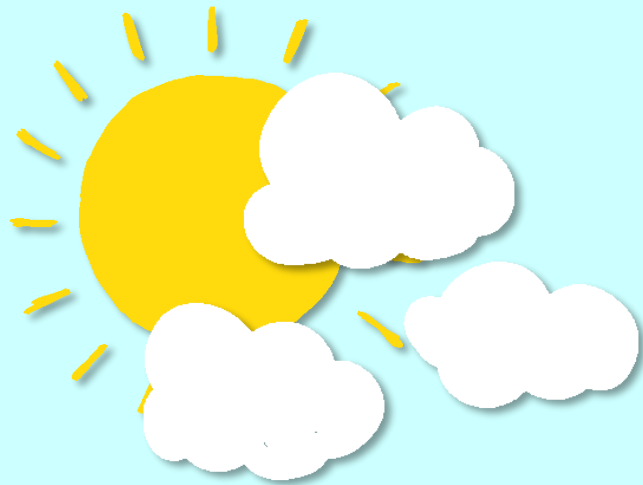
Webcast

Press Releases and Speeches

Multimedia

Policy Address

- (iii) establish the Greater Bay Area International Clinical Trial Institute. We will establish the Greater Bay Area International Clinical Trial Institute in the Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone next year to provide a one-stop clinical trial support platform for medical research institutions. The Institute will co-ordinate clinical trial resources in the public and private healthcare sectors in Hong Kong, including researchers, supporting services, data banks, sample banks, laboratories, etc. We will discuss with the Shenzhen Municipal Government regarding a cooperation framework, with a view to achieving coordinated development of the Hong Kong and Shenzhen Parks. We will also explore cooperation with the clinical trial networks in the Mainland, in particular the GBA, through the Institute, and co-ordinate clinical trial work between the two places to comply with national and international standards;



**GBA Collaboration
& Harmonization**

**Management
Digitalization**

**Global
Connections**



**Advancing
Professional
Capabilities & Capacity**



HKU Med LKS Faculty of Medicine
Clinical Trials Centre
香港大學臨床試驗中心



港大臨床試驗(中國)
HKU Clinical Trials (China)





Clinical research for people . Clinical research for tomorrow .



**HKU
Med**

LKS Faculty of Medicine
Clinical Trials Centre
香港大學臨床試驗中心

in celebration of the 25th anniversary