

A photograph of the Peking University Third Hospital building, a large, modern multi-story structure with a prominent glass facade and a red-tinted section. The building is set against a blue sky with scattered white clouds. The text is overlaid on a semi-transparent red band across the middle of the image.

# Improve clinical research ability after joining ICH

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# Join ICH and integrate into global R & D



国家食品药品监督管理总局成为国际人用药品注册技术协调会成员



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**ICH**  
harmonisation for better health

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**ICH Guidelines** / Work Products /

The ICH topics are divided into four categories and ICH topic codes are assigned according to these categories.

- Q Quality Guidelines**  
Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.
- S Safety Guidelines**  
ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.
- E Efficacy Guidelines**  
The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.
- M Multidisciplinary Guidelines**  
These are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

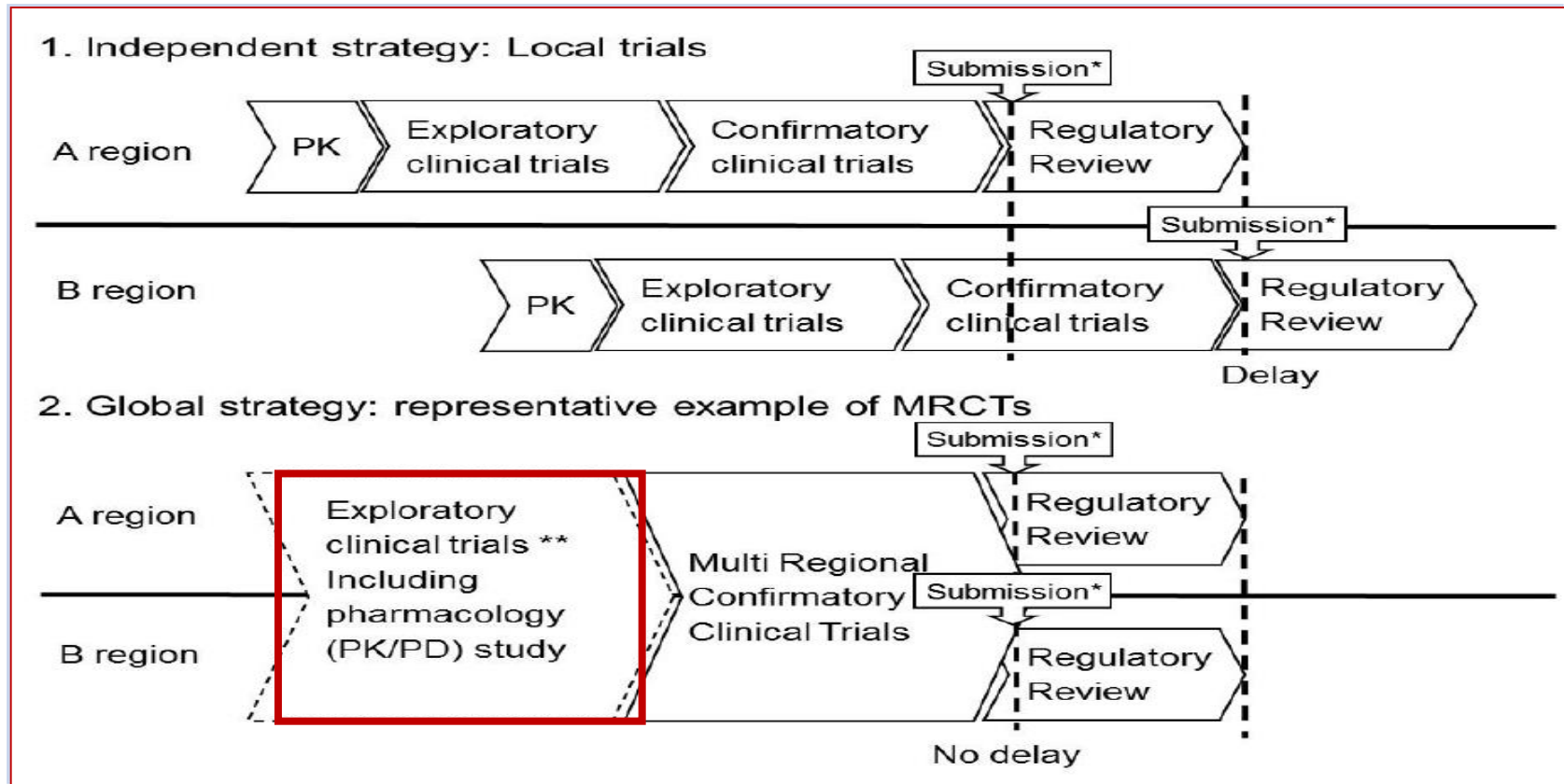
## Hospitals have established the innovation system to meet the needs of R & D

- **Strategy**- GCP center has become an important research platform of hospital
- **Professional experts**-Training and education
- **Quality** improvement (ICH E6)



团结/奉献/求实/创新

# ICH E17 (MRCT) - Early joining global R & D strategy



# Establishment of Medical Innovation Research Institute (2019-5)

## 推动转化研究和临床研究落地



基础医学研究中心

省部级重点实验室  
中心实验室  
生物样本库  
代谢组学中心

临床医学研究中心

国家临床医学研究中心  
临床流行病学研究中心  
药物临床试验机构  
临床干细胞研究中心

创新转化中心

科技成果转化办公室  
政府、企业、准入  
市场、临床

探索发现

临床前研究

临床研究

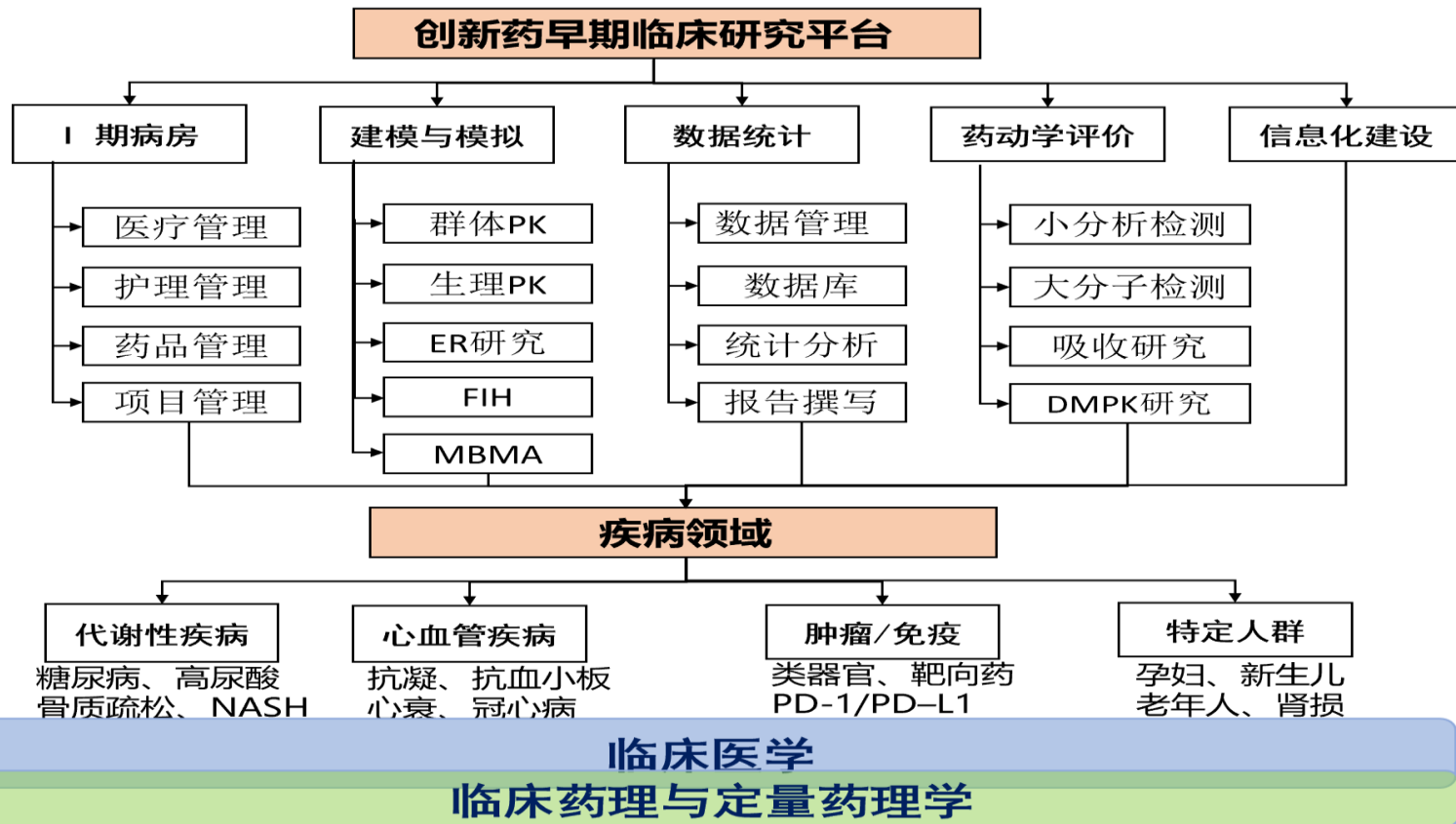
评估评价

培训推广



团结/奉献/求实/创新

# Early clinical development platform of innovative drug



# Explore the early development acceleration strategy of innovative drugs guided by MIDD



↓  
C-QT 研究 (ICH E14)





**Thank you very  
much for your  
attention !**

