Deepening the Drug Innovation Ecosystem Reform–
A Plan to Design and Build China’s Clinical Research System

推动临床研究体系设计与实施，
深化医药创新生态系统构建

R&D-based Pharmaceutical Association Committee (RDPAC)
Committee of Drug Clinical Evaluation and Research, Chinese Pharmaceutical Association
Peking University Asia Pacific Economic Cooperation Regulatory Sciences Center of Excellence (PKU APEC Regulatory Sciences CoE)
Peking University Clinical Research Institute (PUCRI)
China Pharmaceutical Enterprises Association (CPEA)
China Pharmaceutical Industry Association (CPIA)
China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

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Health is the common aspiration of all mankind, and a healthy China constitutes an integral part of the “China Dream”. As President Xi Jinping’s report at the 19th CPC National Congress points out, a healthy population is a key mark of a prosperous nation and a strong country. The *Healthy China 2030 Plan* depicts the blueprint and action plans for building a healthy China, and clinical research is the cornerstone towards better healthcare services, improved livelihood of the population, and stronger innovation capabilities.

Clinical research facilitates drug innovation and creates an innovative pharmaceutical industry, which in turn allows for continuous improvements for the health of the general population. In recent years, basic medical needs are better met after rapid improvement in healthcare services. Moving forward, the priority of the supply-side reform in the healthcare sector will be improving disease diagnosis and treatment and meeting unmet clinical needs, all of which require support from clinical research. Clinical research is an indispensable part and the very step that consumes most of the time and resources committed in drug innovation. Therefore, it represents the most crucial part of the whole drug innovation ecosystem.

The speed of clinical research capability building determines whether China can leverage the hard-won “window of opportunity” for its drug innovation industry. Continuous capital investment from public and private sectors has laid a solid foundation for China’s drug innovation sector to take off. In the past two years, China’s State Council and CFDA have rolled out a series of reform measures in drug review and approval. The objectives of those measures are to: 1) incentivize the R&D of new drugs; 2) accelerate clinical trials initiation and the review and approval of new drugs; and 3) encourage harmonization of clinical research globally.

Regulatory review and approval are no longer the major bottleneck for drug innovation. More innovative compounds are entering the pipeline in China. At the same time, as China moves forward with its healthcare reform, we are seeing the initial benefit of the “tiered healthcare system”: physicians from Class IIIA hospitals who are capable of and passionate about clinical research will gradually have more time and energy for clinical research; and they will have a more supportive environment to do so.

In the second half of 2017, ministries & commissions of the State Council released a series of policies to further encourage drug innovation and clinical research capability building. In July, MoST (Ministry of Science and Technology), NHFPC (National Health and Family Planning Commission), Logistical Support Department of CMC (Central Military Commission), and CFDA jointly published three documents that chart the course for the top-down design of the clinical research system: 1) *Five-year Plan (2017-2021) for National Research Centers of Clinical Medicine*, 2) *Administrative Measures for National Research Centers of Clinical Medicine (2017 Version)*, and 3) *Operational Performance Review Plan for National Research Centers of Clinical Medicine (Trial version)*. These policies assessed the status quo of development of National Research Centers of Clinical Medicine in China, and laid out the short-term goals and implementation measures for the next five years, symbolizing key progress in the top-down design of the national-level clinical research system. On October 8th, the General Office of the Central Committee of CPC (The Communist Party of China) and the General Office of State Council published *Opinions on Deepening the Reform of Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices*, which proposes several major reforms in clinical trial management, review and approval acceleration, and the facilitation of drug innovation and generic drug development. On October 23th, CFDA released *Drug Registration Regulation (Revised Edition)*. On October 26th, the General Office of MoST issued *Notice on Improving Review and Approval Procedures for Human Genetic Resources*.
Administration. The document laid out an improved approval process that uses China’s human genetic resources in international clinical trial cooperation to obtain market authorization for relevant drugs and medical devices.

In this context, seven associations and institutions initiated this study to facilitate the development of China’s clinical research system and to provide suggestions for the next-level design and implementation of relevant policies. This study aims to analyze the current status and issues of China’s clinical research system, identify possible solutions, and summarize such findings in the form of a research report. The project received strong support and kind advice from more than 40 experts in the advisory committee, to whom we convey our heartfelt appreciation for their valuable insights.

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SUMMARY

Significance of upgrading China's clinical research capabilities

- **Clinical research is the driving force for modern medicine, as well as the fundamental support to meet healthcare demands of the general population.** Clinical research and clinical practice are inextricably linked. Clinical research originates from everyday clinical practices, yet it also explores the frontier of disease diagnosis and treatment, translating new medical discoveries into clinical practices. *Healthy China 2030* clearly articulates the goal to “Eradicate the threat of a number of critical diseases”. Better diagnosis and treatment solutions for many critical illnesses and chronic diseases would require scientific data from Chinese population as references for evidence-based medicine. There is very limited innovation worldwide for the treatment of critical diseases with high prevalence in China (e.g. liver cancer, gastric cancer, esophagus cancer and hepatitis B). The responsibility therefore lies upon Chinese practitioners to explore new solutions through clinical research.

- **Clinical research provides the foundation to improve healthcare delivery and standardization.** Clinical research capability building is a critical way to enhance standardized operation in diagnosis and treatment. However, due to historical reasons such as imbalanced economic development, flawed treatment guidelines and clinical pathways, there are huge differences in clinical practices among geographic regions. Clinicians can better understand standard clinical pathways, treatment methods and cutting-edge technologies by engaging in clinical research and trials. By doing so, they can accumulate guideline-based treatment experiences and enhance the standardization of disease diagnosis and treatment procedures. Furthermore, every leading healthcare system must be backed by leading academic medical centers, and healthcare delivery, education and research are the three pillars of those academic centers. For China’s Class IIIA hospitals, further development in clinical research capabilities is very important to their goal of becoming leading academic medical centers in China and globally.

- **Clinical research is a key link in drug innovation. It is critical to the development of a sustainable and globally competitive drug innovation ecosystem.** The ultimate beneficiary of any innovation in healthcare is the human body, rendering clinical research an indispensable step. Clinical trial is the only way to test the safety and efficacy of drugs used in human body. It is also the step that needs the heaviest investment in both capital and time. Based on global experiences, the whole life cycle of clinical trial for a new drug usually takes 4-6 years with an average cost of 1 billion RMB. The time and capital committed to clinical trial account for ~70% of the overall drug development process. The importance of clinical research in R&D is indisputable. As *Healthy China 2030* points out, “China aspires to rank among the global leaders in health technology innovations” and to realize this aspiration, China needs to build a drug innovation ecosystem at the national level, enhance innovation capabilities in sectors such as patented drugs, and nurture a number of globally competitive companies and products with intellectual property. In all of these efforts, clinical research holds the key to translating innovation into application.
Urgency of upgrading China’s clinical research system

Development of clinical research already lags behind other parts of the drug innovation value chain. If efficiency and capability issues in clinical research remain unresolved, China’s drug innovation is estimated to be set back by 5-10 years.

- Development of clinical research lags behind other parts of the drug innovation value chain such as basic research and drug discovery. To illustrate this point, the number of peer-reviewed articles published in Cell, Nature and Science by Chinese researchers, representing the capabilities and commitment in basic research, reached a total of 140 articles in 2014-16. In contrast, the number of articles published in Lancet, NEJM and JAMA by Chinese researchers, representing the capabilities and commitment in clinical research, only reached a total of 29 articles in the same period. Due to the lack of mindset, attention, and resources given to clinical research, there is still a long way to go before clinical research can catch up to basic research.

- To further demonstrate this point, we also see strong growth momentum in pharmaceutical R&D, driven by the reform in drug evaluation and review policies, stronger talent, and capital support. For instance, the number of Chemical new Class 1 and Biologics Class 1 molecules approved for clinical trials in the first 10 months of 2017 is 2 times higher than that of 2014. By contrast, we do not see a significant increase in the number of clinical trial sites with GCP certification in China between 2014 and 2016. Moreover, the 168 sites accredited in 2017 are likely not ready for clinical trials of innovative drugs yet. To our delight, on October 8th, 2017, the General Office of the Central Committee of CPC and the General Office of State Council published Opinions on Deepening the Reform of Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices. According to the documents, the government will adopt a filing system for the clinical trial sites and encourage private investment in establishing these sites. These new policies will give birth to more eligible clinical trial sites and bring in more clinical resources. However, it remains unknown whether those new clinical trial sites will be ready for the early development trials of innovative drugs or multi-region clinical trials (MRCT). Even for existing clinical trial sites, there are significant capability gaps. Some are with limited experience in joining clinical trials for drug registration and approval, or MRCT. As drug innovation grows rapidly, these issues urgently require our attention and effort to determine the appropriate solutions.

Emerging technologies are promoting innovations in clinical research. Emerging concepts and technologies such as precision medicine and immuno-oncology are giving birth to a series of innovative treatments for cancer and other critical diseases; the increasing availability of healthcare big data can potentially transform the way we traditionally conduct clinical research and trials; the development of tele-medicine and artificial intelligence can disrupt how doctors interact with patients in the traditional experience-based clinical settings. However, none of these technological trends can bypass clinical research. These new technologies not only challenge and complement traditional medicine, but also bring opportunities for major innovations and transformations. As emerging technological trends constantly drive innovations of clinical research, China’s clinical research needs to leverage these trends and become the leader in drug innovation.
An objective assessment of China’s clinical research capabilities in a global context

The overall assessment was based on four indicators: number of interventional clinical trials, number of phase I clinical trials, number of Phase II/III MRCT, and number of papers published in leading clinical research journals between 2014 and 2016. We compared China with 11 other global leading drug innovation countries. Analysis shows China currently ranks No. 9 amongst leading drug innovation countries in terms of clinical research capabilities, behind Japan and Korea in Asia (Exhibit 1). Among key drivers of clinical research capabilities, inefficient clinical trial initiation and limited clinical research skillsets are the major constraints for China’s clinical research development.

Exhibit 1
China currently ranks No. 9 amongst leading drug innovation countries in terms of clinical research capabilities

In each dimension, the country with the highest value (No.1 country) is indexed as 100; others countries’ scores = value of that country / value of No 1 country*100

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1 Excluding trials for generics such as bioequivalence trials

SOURCE: ClinicalTrials.gov; ANZCTR database; Asuno Shinyaku database; CTRI database; DKRS database; Health Canada’s Clinical Trials database; EU Clinical Trials Register; UK Clinical Trial Gateway; South Korea’s CRIS database; Web of Science database; GBI Metrix database

Underlying challenges faced by China’s clinical research system

Core components of clinical research system can be categorized at three levels: top-down design, trial design and execution, and supporting mechanisms (Exhibit 2). Top-down design determines national-level development strategy and system design for clinical research, which is led by the central government and implemented through cross-ministerial collaboration. Investigator teams and sponsors hold the key to successful trial design and implementation. A trial needs upfront approval from regulators. Stakeholders participating in a trial are also subject to regulators’ supervision and inspection. Third-party service agencies provide investigator teams and sponsors with various supports through outsourcing, helping to ensure the efficiency
and data quality of clinical trials. Supporting mechanisms lay the foundation for the long-term, sustainable development of the clinical research system and quality assurance of clinical trials. A sound talent development and education system will constantly expand the pool of talent, nurturing more competent researchers. As an indispensable part of clinical research system, a well-established trial subject education system can enhance subjects’ understanding of clinical research, by informing and giving guidance.

The underlying challenges faced by China’s clinical research system now include:

- **Top-down design is missing in clinical research.** The planning for the clinical research system has been progressing slowly for a long period of time. Over the past 15-20 years, due to unclear targets and lack of policy support, funding in medical science has been to “prioritize basic research over clinical research”. For example, national scientific research fund did not provide sufficient support for clinical research, especially interventional clinical trials initiated by the investigators; and the evaluation methods did not give full consideration to the characteristics of clinical research.

  Challenges posed from weak top-down design are mainly three-fold: the network of clinical research centers, incentive mechanism, and clinical research capability building. The current system of clinical research centers is poorly designed and managed, with fragmented resources that lack integration, with unbalanced structure and non-streamlined coordination among centers. No effective incentive mechanism for hospitals and doctors to support clinical trials in China. The medical education systems and national talent plans fail to put enough emphasis on clinical research. All those issues have led to the shortage of top talents in the field of clinical research, low participation and lack of interests from doctors.

- **Clinical research regulation involves bodies and entities such as CFDA, Institutional Review Boards (IRB, or ethics committee) and Human Genetic Resource Administration of China under the Ministry of Science and Technology (HGRAC), Key challenges are as follows:**
— Low efficiency in regulatory review and approval. The time required to initiate clinical trials in China is significantly longer than that in other leading countries such as the US and South Korea. There are several main reasons behind this phenomenon: the review and approval process requires that every step be sequential to each other; multi-regional ethical review lacks efficiency and collaborative review or central IRB review has not been fully adopted; HGRAC review, while having undergone optimization, still lacks consistency and transparency as well as practical evaluation criteria.

— Clinical trial inspection system needs improvement. Since July 22, 2015, clinical trial inspection (GCP inspection) has played a well-recognized role in driving drug evaluation and review, and changed the mindset of pharmaceutical companies. After the “inspection storm”, there is still room to build and improve a sustainable mechanism for data inspection, including adopting a risk-based regulatory mindset, improving inspection-related rules and regulation policies, deficiency tiering, right & responsibility definition, and inspection team building.

— IRB is generally inefficient when conducting ethical reviews for multi-region clinical trials (MRCT), with significant variance in the review capability.

- Challenges in trial design and execution lie in the mindset, capabilities and management mechanisms of all stakeholders (including sponsors, hospitals, GCP sites, investigator teams, and 3rd-party providers). The sponsors need to improve both mindset and capability, i.e., shifting perception about their own responsibilities and mindset to work together with the investigators, improving design capability for the trial plans and clinical research management system. In terms of the relationship among hospitals, GCP sites, and investigator teams, there are no clear definitions of the roles, functionality and staffing; no sound clinical trial management and supporting system is yet established in most clinical trial sites; clinical trial fee allocation lacks a well-defined and transparent process, which only dampens the interests of the investigator team; internal management quality of GCP needs further improvement, such as contract communication and signing efficiency. In the context of fast growing clinical demand, 3rd-party providers are faced with several main challenges: high turnover rate of employees, large capability gaps and lack of industry-wide norms and standards.

- Weak supporting mechanisms for the clinical research system, including education and training for medical talents, and trial subject education and protection. Current medical talent education and training system with “5+3” at the core puts little emphasis on clinical research, resulting in shortage of clinical research talents and professional research team. As an indispensable part of clinical research, the subject is not fully aware of the value and purpose of the clinical trial and his or her own rights, resulting in either lack of interest or ill-informed participation. In the process of recruiting, it is also found that the subject faces challenges such as limited access to accurate trial information or support of healthcare professionals when making decisions.

Key recommendations on driving clinical research design and implementation

Recently, ministries and commissions of the State Council released a range of policies to further encourage innovation and clinical research capability building. In July, MoST, NHFPC, Logistical Support Department of CMC, and CFDA jointly published three documents that
chart the course for China’s clinical research system and represent the key achievements made thus far on top-down design of clinical research: Five-year Plan (2017-2021) for National Research Centers of Clinical Medicine, Administrative Measures for National Research Centers of Clinical Medicine (2017 Version), and Operational Performance Review Plan for National Research Centers of Clinical Medicine (Trial version). These policies assessed the status quo of development of National Research Centers of Clinical Medicine in China, and laid out the short-term goals and implementation measures for the next five years, symbolizing key progress in the top-down design of the national-level clinical research system.

On October 8th, the General Office of CPC Central Committee and the General Office of State Council published Opinions on Deepening the Reform of Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices, which proposes major reform measures in clinical trial management, review and approval acceleration, and the facilitation of drug innovation and generic drug development. CFDA revised the Measures for the Administration of Drug Registration and drafted and issued the Measures for the Administration of Drug Registration (Revised Draft) on October 23, 2017, and solicited public comments for the Draft. On October 26th, the General Office of MoST issued Notice on Improving Review and Approval Procedures for Human Genetic Resources Administration. The document put forward an improved approval process of relevant drugs and medical devices by using China’s human genetic resources in international clinical trial cooperation.

Taking into full considerations the guiding principles of these documents, as well as current clinical research capabilities in China and challenges ahead, we propose the following priorities for each phase of clinical research development:

Short term (2018-2020): refine top-down design and create momentum for clinical research in China:

- **Look far and aim high:** make clinical research one of the national strategies and make clinical research capability building a key target for science and technology innovation capability building and medical reforms.

- **Activate resources:** build a multilevel hospital clinical trial center (CTC) system; improve trial handling capacity of existing CTCs; pilot 3rd-party CTCs that are operated independently.

- **Incentivize doctors:** optimize professional evaluation and performance assessment mechanisms; create opportunities for hospitals and researcher teams to pursue research interests.

- **Optimize supporting mechanisms:** solve efficiency bottlenecks; accelerate trial initiation; refine regulatory & inspection systems.

Mid-long term (2021-2030): holistically upgrade research capabilities and build a world-class clinical innovation system:

- **Build centers of excellence:** develop a clinical research center system with distinctive layers; establish a number of national-level clinical research centers with cutting-edge innovative capabilities.

- **Establish safeguard mechanisms:** build highly competent regulation teams and standardized mechanism for GCP inspection; build effective and high-standard ethical review mechanisms.

- **Reinforce foundation:** reform medical education system; encourage organizations in the
industry to facilitate capability improvement for professionals; boost education for the public; establish protection system for trial subjects and medical institutions.

1. Top-down design

- Develop clinical research development strategy at the national level; attribute greater importance and resources to clinical development; define clinical research capability improvement as one of the key objectives of medical reform; set short-term and long-term goals for clinical research development. In October 2016, NHFPC and four other ministries and commissions jointly issued the Guiding Opinions on Promoting Scientific and Technological Innovation of Sanitation and Health in an All-round Way (The Opinions). The Opinions proposed “to comprehensively strengthen clinical research” and “to build innovation bases including clinical research centers, strive to build innovative clinical research team, and increase and sustain efforts in clinical research. Proactively establish science and technology programs and projects exclusively for clinical research, explore indigenous innovation in clinical research and support basic clinical research”. Based on these guiding principles, we recommend next steps to be establishing detailed incentive plans, implementation guidelines and timelines, as well as allocating specialized national fund for clinical research to effectively drive the development of clinical research system and proprietary clinical research projects.

- Establish cross-ministerial collaboration mechanism at the State Council level and ensure policy consistency. Facilitate development of clinical research capability through collaboration; implement the Five-year Plan (2017-2021) of National Research Center of Clinical Medicine; accelerate the implementation of Opinions on Deepening the Reform of Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices.

- Design and establish a diversified clinical research center system with clear positioning; facilitate the development of National Research Center of Clinical Medicine and Academic Research Organization (ARO); improve clinical research capabilities of research hospitals so that they can become pioneers in China’s clinical research capability upgrade.

- Reform rating and performance evaluation criteria for hospitals and departments; reform professional title appraisal and performance evaluation process for doctors; include clinical research related indicators into the evaluation process and increase the weighted importance of these indicators; structure and evaluate clinical research staff separately from clinical staff and allocate separate bed quota for research to ensure sufficient, dedicated research resources.

- Strengthen the holistic supporting mechanisms for clinical research, including talent development and training, clinical trial subject education and protection.

2. Regulatory systems

- Accelerate the process of trial initiation by improving the efficiency in review and approval. — Request parallel review and approval of CTA, IRB and HGRAC; — Improve the IRB review mechanism (such that the leader IRB review is recognized by other IRBs in the same MRCT) and improve the efficiency and quality of MRCT review; — Explore regional, central IRB, or collaborative IRB review mechanisms and provide guidance for the ethical review of clinical trial agencies; — Change the function of HGRAC from review and approval to record-filing and clearly
define the scope of review.

- Establish long-term mechanism for clinical trial GCP inspection.
  - Improve the legal framework of GCP inspection, policies and guidelines, adopt a risk-based inspection mindset, integrate inspection criteria with ICH-GCP;
  - Build a qualified inspection talent pool, improve inspection capabilities, and standardize inspection behaviors.

- Improve ethical review and subject protection mechanism.
  - Build a sound training and certification system for IRB members; encourage IRBs to participate in a well-recognized IRB certification system;
  - Explore and build an IRB system with diverse types;
  - Put in place a sound regulatory system, such as a filing and recording system, blacklist system.

- Accelerate issuance of draft policies at the national level that encourage healthcare innovation, such as filing system for GCP trial sites, specific and detailed guidelines on adopting foreign data for domestic registration.

3. Trial design & implementation

- Improve CTC (clinical trial center) management.
  - Clearly define CTC roles & responsibilities, drive the establishment of clinical research platform, improve service and capabilities of CTC by promoting the adoption of an investigator accountability system;
  - Allow different models of clinical trial centers (including those affiliated to hospitals and 3rd party clinical trial centers);
  - Encourage increased CTC autonomy within the hospital, improve CTC management and trial initiation efficiency.

- Improve CTC staff management.
  - Define CTC FTE staffing requirements;
  - Outline a clear career path for CTC staff;
  - Establish staffing requirements for research nurses, which is separated from clinical nurses;
  - Develop a separate set of evaluation criteria for research nurses.

4. Supporting mechanisms

- Introduce systematic courses related to clinical research into current medical education, and integrate content related to clinical research into residency trainings to facilitate talent building for clinical research.

- Improve trial subject education, with the government playing a guiding role and all other stakeholders contributing, to help foster a positive and accurate portrayal of clinical trials.

- Improve clinical research related insurance mechanism and provide effective risk management for all stakeholders, including clinical trial institutions, doctors, nurses, and pharmacists participating in clinical research as well as IRB members.
前言

健康是全人类的共同诉求，健康梦是中国梦的重要部分。十九大报告中深刻指出了“人民健康是民族昌盛和国家富强的重要标志”。《健康中国2030》规划纲要提出了健康中国建设的宏伟蓝图和行动纲领，而临床研究是提高健康医疗水平、加强民生保障、增强创新实力的核心方式之一。

临床研究为人民健康生活的持续改善提供长期支持，同时也是发展医药创新产业的关键能力。近年来医疗水平迅速提升，人民群众的基本医疗需求得到进一步满足。未来医疗供给侧改革的重点之一，是进一步提升诊疗水平、满足未被满足的临床需求，这需要坚实的临床研究能力作为支撑。而纵观医药创新产业链，临床研究是无法替代的一步，也是投入时间和资源最多的阶段，是整个医药创新生态系统最为重要的环节。

能否迅速提升临床研究能力，决定了中国是否能够把握住医药创新产业所处的来之不易的发展“机会窗”。政府和社会资本在生物医药研发领域的持续投入，为未来中国创新药产业腾飞奠定了良好基础。近两年，国务院和国家食药监总局出台一系列药品审评审批改革措施，鼓励新药研发，加快临床试验和上市的审评审批，鼓励全球同步临床研发。既往审评审批环节的挑战将不再是医药创新生态系统的主要瓶颈，未来将有更多的在研创新药进入临床研究阶段。与此同时，随着医改的逐渐深化，分级诊疗效果初显，三甲医院有科研能力和热情的医生的时间精力有望得到逐步释放，具备了更好地开展临床研究的条件。

2017年下半年国家各部委出台了一系列政策，进一步鼓励创新，推动临床研究能力提升。2017年7月，科技部、卫计委、军委后勤保障部和食药监总局印发了《国家临床医学研究中心五年（2017-2021年）发展规划》、《国家临床医学研究中心管理办法（2017年修订）》和《国家临床医学研究中心运行绩效评估方案（试行）》三份文件，是临床研究体系顶层设计的重要成果。2017年10月8日，中共中央办公厅和国务院办公厅发布《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》，在改革临床试验管理、加快上市审评审批、促进药品创新等方面，提出了若干项重大改革举措。食药监总局于2017年10月23日发布了《药品注册管理办法（修订稿）》。2017年10月26日，科技部办公厅发布了《关于优化人类遗传资源行政审批流程的通知》，提出了针对为获得相关药品和医疗器械在中国上市许可、利用中国人类遗传资源开展国际合作临床试验的优化审批流程。
在这样的历史背景下，为了进一步推动中国临床研究体系的发展并为各项政策细化与落地实施提供参考，七家协会和机构发起了专题研究，着力分析中国临床研究体系的现状和问题，探讨解决方案和路径，并形成专题调研报告。本项目也得到了四十余位顾问委员会专家的悉心指导，对于各位专家给予本项目的宝贵建议，在此表示衷心的感谢。

中国外商投资企业协会药品研制和开发行业委员会
中国药学会药物临床评价研究专业委员会
北京大学亚太经合组织监管科学卓越中心
北京大学临床研究所
中国医药企业管理协会
中国化学制药工业协会
中国医药保健品进出口商会
顾问委员会（按姓氏笔画排序）

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王睿         解放军总医院医学伦理委员会副主任
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概要

提升中国临床研究水平的重要性

临床研究是现代医学进步的推动力，是满足人民群众对医疗健康新需求的根本民生保障。临床研究与临床医学实践高度统一，密不可分。实践出真知，临床研究源自临床医学，同时又不断探索疾病前沿，源源不断地把新技术、新的医疗解决方案转化为临床医学实践。

《健康中国2030》明确提出要“消除一批重大疾病危害”。对于许多重病、慢性病的诊疗方案，需要通过临床研究收集中国人群的科学数据，作为循证医学的参考，从而不断提高中国的诊疗水平。而对于许多中国高发的严重疾病（如肝癌、胃癌、食道癌和乙肝），在世界范围内缺少创新，更加需要通过中国医学工作者借助临床研究手段去探索解决方案。

临床研究为医疗水平提升和规范化提供能力支撑。临床研究是提升医生诊疗规范化水平的重要手段。由于经济发展不平衡、诊疗指南和临床路径不完善等历史原因，不同地区的临床诊疗实践存在较大差异。通过开展临床研究、参与临床试验，临床医生可更好地了解标准临床路径、诊疗方法以及最前沿的治疗手段，增加依从指南的治疗经验，从而提高整体诊疗规范化水平。此外，在任何一个全球领先的医疗卫生体系中，都有一流的学术医学中心，而教育和研究是学术医学中心的三大支柱。对于中国的三甲医院而言，要实现成为一流的学术医学中心的目标，不断提高临床研究能力十分关键。

临床研究是医药创新产业的关键环节，对打造可持续发展的、具备国际竞争力的医药创新生态系统至关重要。临床试验是验证药物在人体内安全性和有效性的唯一方法，也是新药研发过程中资金和时间投入最多的环节。从全球经验来看，单个药物临床试验从启动到完成一般需要4-6年，平均成本超过10亿元人民币，时间与资金投入在整个新药研发中约占70%。要实现《健康中国2030》里提出的“健康科技创新整体实力位居世界前列”的目标，需要建设国家医药创新生态系统，而临床研究是创新成果转化应用的必经之路。

提升中国临床研究水平的紧迫性

临床研究的发展已经落后于医药创新产业链其它环节，临床研究的能力和资源问题若得不到及时解决，将至少延缓中国医药创新产业发展进程五到十年。

临床研究环节的发展水平已经滞后于基础研究、药物发现等环节。在基础研究领域，在2014-16年间，中国研究者作为通讯作者在《细胞》、《自然》及《科学》杂志上发表的生物医药学科文章达到140篇；而在临床研究领域，在2014-16年间，中国研究者作为通讯作者发表于《新英格兰医学杂志》、《柳叶刀》及《美国医学会杂志》的文章仅有29篇。

对临床研究的需求与临床研究资源之间的不平衡加剧。2017年1-10月获批临床的化药1.1类和生物1类分子数是2014年的3倍。相比之下，中国获得GCP（临床试验质量管理规范）认证的机构数量在2014年到2016年间却没有显著变化，而2017年新增的168家机构也基本尚未具备规模开展创新药临床试验的能力。值得欣喜的是，在2017年10月8日两办发布的《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》中提出临床试验机构资格认定实行备案管理，并鼓励社会力量投资设立临床试验机构。
机构。这些新的政策将有效拓展临床试验机构的数量，缓解临床资源数量不足的矛盾。但在短期内，新增临床试验机构的能力是否能够迅速满足药物研发，尤其是创新药早期研发和国际多中心合作研发的要求，还存有疑问；同时现有临床试验机构能力参差不齐，部分临床试验机构在参与注册上市临床研究或多中心临床研究的经验欠缺，在未来医药创新快速发展的环境下，这都是亟需正视和解决的问题。

全球新兴技术趋势不断推动临床研究创新，中国需要把握机会窗。近几年来，随着科学技术的全面进步，临床医学也面临着潜在的重大变革。精准医学、肿瘤免疫等新兴治疗理念和治疗，正在推动针对癌症等重症顽症的全新治疗方式；医疗大数据的逐步可及，有可能改变我们传统临床试验的研究方法；而远程医疗、人工智能的兴起，则有可能彻底改变传统医疗模式。所有这些技术趋势，都离不开临床研究这个金标准。这些新技术既是对传统医学的挑战和补充，也是重大创新变革的机会。中国临床研究需要能够及时把握住这些技术趋势，实现弯道超车，成为医药创新领先国家。

全球背景下对中国临床研究水平的客观评估

基于四项临床研究水平评价指标，即干预性临床试验总数、一期临床试验数量、国际多中心临床试验总数和顶尖临床研究论文数量，我们依据2014-2016年数据对比了中国和另外11个全球主要医药创新国家现阶段的临床研究水平。分析显示中国当前的临床研究总体水平在世界创新领先国家中排名第九，在亚洲位列日本和韩国之后（图1）。在临床研究水平的驱动因素中，临床试验的启动效率偏低、临床研究能力和资源不足是制约中国临床研究水平提升的主要因素。

<table>
<thead>
<tr>
<th>临床试验总数</th>
<th>一期临床试验数量1</th>
<th>国际多中心临床试验（MRCT）数量</th>
<th>高水平临床研究文章</th>
</tr>
</thead>
<tbody>
<tr>
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<td>第2名</td>
<td>第3名</td>
<td>第4名</td>
</tr>
<tr>
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</tr>
<tr>
<td>100</td>
<td>38</td>
<td>7</td>
<td>10</td>
</tr>
</tbody>
</table>

1 不包含生物等效性试验等用于仿制药研发的试验

数据来源：ClinicalTrials.gov；ANZCTR数据库；Asuno Shinyaku数据库；CTRI数据库；DKRS数据库；Health Canada's Clinical Trials Database；EU Clinical Trials Register；UK Clinical Trial Gateway；韩国CRIS数据库；Web of Science数据库；GBI Metrix数据库

图1 全球主要医药创新国家临床研究水平总体评估
临床研究体系面临的深层次挑战

临床研究体系的核心组成要素可分为顶层设计、试验设计与执行和支撑机制三大层面（图2）。顶层设计决定国家层面的临床研究发展战略和体系设计，由政府主导制定，需要各部委协作共同推进。研究者团队和申办方是设计与执行阶段的核心，负责方案设计并开展临床试验。试验开始前需经监管机构批准；试验进行过程中参与各方还需接受各监管机构的监督和核查。第三方服务机构以外包形式为研究者团队和申办方提供一系列试验支持服务，确保试验高效顺利进行，保证试验数据质量。支撑机制是临床研究体系长期可持续发展、保证临床试验质量的基础。其中，人才教育与培养体系确保为临床研究提供源源不断的高素质人才，持续提升研究者水平。完善的受试者教育体系通过宣传和引导增加受试者对临床研究的了解，也是临床研究体系不可或缺的一环。

当前中国临床研究体系面临的深层次挑战主要体现在：

- 临床研究的顶层设计欠缺。长期以来临床研究体系发展战略规划进展缓慢。由于没有明确的目标和政策支持，在过去15-20年对医学科学领域的资金支持“重基础、轻临床”。国家级科研基金对临床研究，尤其是研究者发起的干预性临床试验的支持力度显著不足，科研基金的管理和考核方式对临床研究的特点考虑不足，不符合临床研究的客观规律。顶层设计的不足的挑战还体现在临床研究中心网络体系、激励机制以及临床研究能力培养方面。现阶段中国的临床研究中心体系建设滞后，资源高度分散，组成单一且中心之间协作不顺畅。此外，中国尚未建立起有效的医院和医生激励机制来支持研究者开展临床研究。医疗人才教育培养体系和国家人才计划也对临床研究重视不足。这些问题导致了临床研究的高水平人才匮乏，医生总体参与程度和积极性不高。

- 临床研究监管涉及食药监总局、伦理委员会、科技部人类遗传资源管理办公室（以下简称“遗传办”）等机构和部门，所面临的主要挑战包括：

  - 监管审批效率低。对比领先国家，中国临床试验启动所需时间显著长于美国、韩国等国家。主要原因包括：审批流程不合理，各环节以“串联”方式依次进行；多中心伦理

1 Contract Research Organization，合同研究组织
2 Site Management Organization，现场管理组织
审查效率较低，协作审查和中心审查模式尚未被广泛采用；遗传办审批流程虽然已经优化，但仍缺乏统一透明、操作性强的评判标准。

—— 临床试验核查体系有待完善。自“7.22”以来，临床试验数据核查在推动药品审评审批制度改革中发挥的作用有目共睹，短时间内净化了医药研发的生态环境，也促进了企业的理念转变。核查风暴之后，数据核查的长效机制依然有待建立和完善，包括贯彻基于风险的监管理念，完善核查相关的法律法规、缺陷分级和职责划分，以及加强核查队伍建设。

—— 伦理委员会开展多中心临床研究伦理审查的效率普遍较低，而审查能力参差不齐。试验设计与执行的多重挑战体现在参与各方（申办方、医院、研究者团队、第三方服务机构）的理念、能力和管理机制。申办方临床研究的理念和能力有待提升，其中包括转变对于自身责任的认识和与研究者合作的理念，试验方案设计能力以及临床研究管理体系。对于医院、机构和研究者团队，目前机构办公室的定位、职能和人员编制等设置缺乏明确规定，多数机构尚未建立起完善的临床试验管理和支持体系；临床试验服务费分配缺乏明确的标准和透明高效的流程，影响了研究者团队的积极性；药物临床试验机构（GCP机构）内部管理水平也有待提升，例如合同沟通和签订的效率有待提高。而在临床需求高速增长的背景下，第三方服务机构面临的最主要挑战在于从业人员流动性高、能力参差不齐以及缺乏行业规范和标准等方面。

—— 临床研究体系的支撑机制薄弱，包括医疗人才教育培训，以及受试者教育与保护。中国现有的“5+3”为主体的医疗人才培养体系对临床研究重视不足，导致了临床研究人才和专业化研究团队匮乏。而作为临床研究必不可少的参与方的受试者群体，目前对于临床试验的价值和意义、受试者权益等问题仍缺乏正确认识，导致参与临床研究的积极性不高或者盲目要求参加临床试验。在招募过程中，受试者还面临着获取准确的试验信息的渠道、在决策过程中缺少专业人士相关支持等挑战。

推动临床研究体系设计与实施的主要建议

近期，国家各部委出台了一系列政策，进一步鼓励创新，推动临床研究能力提升。2017年7月，科技部、卫计委、军委后勤保障部和食药监总局制定并印发了《国家临床医学研究中心五年(2017-2021年)发展规划》、《国家临床医学研究中心管理办法(2017年修订)》和《国家临床医学研究中心运行绩效评估方案(试行)》三份文件，提出了未来五年建设发展的短期目标和实施路径，是临床研究体系顶层设计的重要成果。

2017年10月8日，两办发布《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》，在改革临床试验管理、加快上市审评审批、促进药品创新和仿制药发展等方面，提出了若干项重大改革举措。食药监总局组织对《药品注册管理办法》进行了修订，并于2017年10月23日起草发布了《药品注册管理办法(修订稿)》，并向社会公开征求意见。2017年10月26日，科技部办公厅发布了《关于优化人类遗传资源行政审批流程的通知》，提出了针对为获得相关药品和医疗器械在中国上市许可，利用中国人类遗传资源开展国际合作临床试验的优化审批流程。

在此历史背景下，并考虑到中国临床研究能力现状和需解决的深层次挑战，我们对中国临床研究体系发展和建设的阶段性重点提出以下建议：
短期 (2018-2020): 完善顶层设计, 释放中国临床研究活力:

- **高瞻远瞩**, 把临床研究放在国家战略的高度, 把提升临床研究能力作为科技创新能力建设和医改的重要目标。
- **盘活资源**, 建立多级医院临床试验中心体系, 提高现有机构试验承接能力, 允许试点独立运营的第三方临床试验中心。
- **激励医生**, 优化医院和医生等级职称评定和绩效考核机制, 释放医院和研究者团队开展临床研究的热情。
- **完善配套**, 解决效率瓶颈, 提升试验启动速度, 完善监管核查体系。

中长期 (2021-2030): 全面提升能力, 构建世界一流临床创新体系:

- **卓越中心**, 形成层次分明的临床研究中心体系, 建立一批具备前沿创新能力的国家级临床研究中心。
- **机制保障**, 建立高素质的核查队伍及数据核查长效机制, 建立高效率高质量的伦理审查机制。
- **夯实支撑**, 改革医学生教育体系, 鼓励行业组织推动从业人员能力提升, 推动公众教育, 建立受试者和医疗机构保障体系。

1. 顶层设计

- 制定国家层面的临床研究发展战略, 提高重视程度, 将提升临床研究能力作为医改目标之一, 明确临床研究发展短期和长期目标。2016年10月, 国家卫计委与其它四部委共同发布了《关于全面推进卫生与健康科技创新的指导意见》, 其中提出 “全面加强临床医学研究”, “结合临床医学研究中心等创新基地建设, 努力打造临床研究创新团队, 加大稳定支持临床研究投入力度。积极争取设立专门面向临床研究的科研计划和项目, 探索设立自主创新的临床研究项目, 积极支持临床研究基础性工作” 等意见。我们建议, 未来能够出台更细化的鼓励措施、实施细则和实施时限要求, 设立针对临床研究的国家级基金项目, 有效推动临床研究体系建设, 有的放矢地资助临床研究项目。
- 在国务院层面建立跨部委协作机制, 确保政策一致性, 协同推进临床研究水平发展, 落实《国家临床医学研究中心五年 (2017-2021年) 发展规划》; 加速推动《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》的落地实施。
- 设计并建立定位清晰、分工明确的多样化的临床研究中心体系, 推动建设国家临床医学研究中心和学术性临床研究组织 (ARO), 推动研究型医院临床研究水平提升, 从而起到引领带头作用。
- 改革医院和专科等级评定和绩效考核方法, 改革医生职称评定和绩效考核方法, 增加临床研究相关指标和比重, 单独设置并考核临床研究相关人员和床位编制, 提供充足资源保障。
- 推动加强支撑机制, 包括临床研究人才培养与教育, 受试者教育和保护机制。
2. 监管体系

- 加快试验启动速度，提高审批效率。
  - 要求临床试验申请审查、伦理审查和遗传办审批平行进行。
  - 完善组长单位伦理认可制度，提高多中心临床试验审查效率和质量。
  - 探索区域或中心伦理协作审查制度，指导临床试验机构伦理审查工作。
  - 人类遗传资源管理审批改为备案制，明确审查的范围，即针对遗传资源相关的临床试验进行审查。建立临床试验数据核查长效机制。
  - 完善GCP核查法律框架，政策及指南体系，尽快实施基于评审需要和风险的核查理念，核查标准与ICH-GCP要求接轨。
  - 建立合理的核查人员梯队，提升核查人员能力，规范核查行为。

- 完善伦理审查和受试者保护机制。
  - 建立健全伦理委员会成员培训和认证体系，鼓励各伦理委员会参与行业公认的认证。
  - 探索多样化的伦理委员会制度。
  - 建立完善的监管机制，如备案登记制度、黑名单制度等。

- 尽快落实国家出台的鼓励医药创新的政策草案，例如机构备案制、国外数据用于国内注册的具体指南等。

3. 试验设计与执行

- 优化临床试验中心管理。
  - 明确临床试验中心的职责定位，推动建立临床研究平台，在鼓励推行研究者负责制的基础上，加强临床试验中心的服务意识和能力。
  - 允许设立多种模式的临床试验中心（医院内临床试验中心和医院外第三方临床试验中心）。
  - 鼓励医院内临床试验中心提高自主权，优化临床试验中心管理流程，提高试验启动效率。

- 优化临床试验中心专职人员管理。
  - 明确临床试验中心的专职人员配置要求。
  - 明确临床试验中心专职人员的职业发展路径。
  - 单独设置研究护士的编制要求，与临床护士分开计算。
  - 设置单独的研究护士职称评定标准。

4. 支撑机制

- 在现有医学教育体系中增加系统的临床研究相关课程，在住院医师规范化培训中加入临床研究相关内容，推进建立临床研究人才梯队。
- 由政府主导，联合社会各界力量共同推进中国的受试者教育，引导建立对临床试验的正确认识。
- 完善临床研究相关保障机制，为临床研究参与各方，如临床试验机构、参加临床研究的医生、护士和药师等人员以及伦理委员会成员提供有效的风险管控措施。