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Full length article

Innovative practices and reflections on the development of hospital-led co-constructed state key laboratories

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ABSTRACT

Focusing on the development of the State Key Laboratory for Complex, Severe, and Rare Diseases since its restructuring, this paper explores its practices in fully integrating the advantages of multi-party resources, constructing a medical engineering integrated scientific research system, and innovating management mechanisms. Since the restructuring, the laboratory has focused on three core research directions (complex diseases, severe diseases, and rare diseases), and achieved remarkable results in research projects, academic papers, patent authorizations, and achievement transformation. Its recent representative achievements cover state strategic medical research fields such as pancreatic cancer mechanism research, therapeutic strategies for immunodeficiency-related sepsis, and large models for rare diseases. In the future, the laboratory will continue to benchmark against international advanced standards, strengthen open cooperation and talent echelon construction, accelerate the clinical transformation of scientific research achievements, and help enhance the hospital's original innovation capability and international influence in the field of Complex, Severe, and Rare Diseases.

As a core component of state strategic sci-tech forces and a key carrier of the scientific and technological innovation system, state key laboratories play an irreplaceable strategic role in promoting breakthroughs in original innovation, tackling key core technologies, seizing opportunities in the new round of scientific and technological revolution, and advancing high-level sci-tech self-reliance and self-strengthening as well as Chinese-style modernization.[1,2] Since the launch of restructuring work in 2021, the state key laboratories have undergone exploration and practice, and basically completed the restructuring in 2024. Currently, the reorganized state key laboratories are in a critical stage of construction and operation. Major issues to be addressed and studied urgently include: how to align with state strategic needs to enhance basic research capabilities and key core technology innovation capabilities; how to carry out organized scientific research in a systematic manner; how to optimize management and operation mechanisms; and how to improve the efficiency of scientific and technological achievement transformation and the level of industry-academia-research integration.[3–5].

At present, there are still relatively few hospital-led co-constructed state key laboratories in the medical field in China. This model breaks the traditional pattern of medical scientific research dominated by universities and research institutes, marking a key step in hospitals' in-depth participation and innovative leadership in the field of medical scientific research. The unique positioning of hospital-led laboratories enables them to give full play to the advantages of rich clinical resources, promote the in-depth integration of clinical practice and scientific research, and provide new ideas and paths for solving complex medical problems, thus holding irreplaceable significance in the medical scientific research system. Taking the "State Key Laboratory of Complex, Severe, and Rare Diseases" reorganized under the leadership of Peking Union Medical College Hospital as an example, this paper systematically sorts out its restructuring background, summarizes its practical

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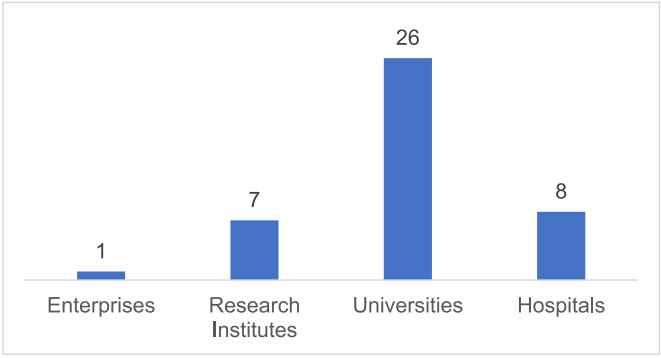


Fig. 1. Distribution of state key laboratories in the medical field.

experience and development reflections in innovating management mechanisms and transforming scientific research achievements, aiming to provide useful references for similar medical institutions in promoting the construction of state key laboratories and scientific research platforms.

1. Current development status of state key laboratories in the medical field

1.1. Distribution of State Key Laboratories in the medical field

According to incomplete public data statistics, there are 42 state key laboratories related to the medical field in China (excluding pharmacy-related ones), covering key directions such as basic medicine, clinical medicine, and infectious disease prevention and control. Among these 42 laboratories, 26 are led by universities, 7 by research institutes, 8 by hospitals, and 1 by enterprises—indicating that the current medical scientific research pattern is still dominated by universities, while hospital-led laboratories are relatively few (See Fig. 1).

Currently, there are 8 hospital-led co-constructed state key laboratories in China (Table 1), with research directions covering digestive health, cardiovascular diseases, hematological diseases, cancer treatment, and complex, severe and rare Diseases. Such laboratories generally adopt a co-construction model involving hospitals, universities, research institutes, or enterprises, and the leading hospitals are all Class A tertiary hospitals with strong scientific research capabilities and rich clinical resources.

1.2. Advantages, disadvantages, and development dilemmas of hospital-led Co-constructed state key laboratories

Compared with university-led state key laboratories, hospital-led ones excel in clinical-oriented transformation and application research, while their shortcomings lie in the depth of basic theories and the breadth of interdisciplinary integration.

1.2.1. Core advantages

(1) **Monopoly of clinical resources**: Direct access to hospital patient groups enables the acquisition of massive, high-quality clinical samples (e.g., tumor tissues, blood samples) and real-world data (e.g., case follow-up records, efficacy of diagnosis and treatment protocols).
(2) **Strong practicality of research topics**: Research topics are mostly derived from clinical pain points, such as bottlenecks in the treatment of Complex, severe and rare Diseases and optimization of diagnosis and treatment for rare diseases. Research results can quickly solve practical medical problems (e.g., optimizing surgical procedures, improving chronic disease management), leading to faster realization of social benefits.

Table 1
Overview of hospital-led Co-constructed state key laboratories.

No.	Name of State Key Laboratory	Supporting, Participating, and Co-Constructing Entities	Main Research Directions
1	Diagnosis and Treatment of Severe Zoonotic Infectious Diseases	Tongji Hospital, Huazhong University of Science and Technology, Jilin University	Pathogenic mechanisms, factors leading to severe disease, and inhibitory targets; Pathogen diagnosis and clinical intelligent diagnostics; Innovative solutions and technologies for critical care treatment.
2	Biotherapy	West China Hospital of Sichuan University, West China School of Clinical Medicine	Biological therapy research for major diseases such as tumors and infectious diseases; Functional genomics and proteomics research; Stem cell and tissue engineering research, etc.
3	Digestive Health	Beijing Friendship Hospital Affiliated to Capital Medical University, Institute of Materia Medica of Chinese Academy of Medical Sciences, Suzhou Guoke Medical Technology Development (Group) Co., Ltd	Precision molecular diagnosis and new drug development; Breakthroughs in key diagnostic and therapeutic technologies and equipment R&D; Innovation in integrated diagnostic and treatment strategies.
4	Heart Disease	Dongfang Hospital Affiliated to Tongji University, Zhongshan Hospital Affiliated to Fudan University, Tongji University	Fundamental theories addressing the root causes of heart disease; Translational medicine research to accelerate clinical application of research findings; Development of technologies and products to reduce cardiovascular disease incidence and mortality.
5	Blood and Health	Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, PLA General Hospital, Tianjin Medical University	Focus on the pathogenesis, treatment technologies, and health intervention strategies for hematological diseases (e.g., leukemia, lymphoma).
6	Female Fertility Promotion	Peking University Third Hospital, Peking University	Exploring key molecules in fertility formation from the perspective of genetic and epigenetic inheritance and causes of birth defects; Revealing molecular regulatory networks for fertility maintenance from ovarian and uterine physiological and pathological mechanisms; Targeting key regulators of fertility to develop new technologies for fertility restoration and establish new systems for birth defect prevention and treatment.
7	Molecular Oncology	Cancer Hospital of Chinese Academy of Medical Sciences, Tsinghua University, Peking University	Tumor molecular etiology and molecular epidemiology; Cellular and molecular mechanisms of tumorigenesis and progression; Tumor systems biology, etc.
8	Complex, severe and rare Diseases	Peking Union Medical College Hospital, Tsinghua University, Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences	Discovery of clinically valuable biomarkers and novel drug targets; Development of original drugs/devices with independent intellectual property rights; Proposal of new diagnostic and therapeutic strategies and prevention plans.

(3) **High transformation efficiency**: Research directions are highly aligned with clinical needs, ensuring efficient implementation of achievements. For example, newly developed diagnostic reagents by the laboratory can be directly verified in the hospital's clinical laboratory, and new treatment protocols can quickly initiate in-hospital clinical trials.

1.2.2. Main shortcomings

(1) **Insufficient depth of basic research**: More resources and efforts are invested in applied research, while less investment is made in 0-to-1 basic theoretical exploration (e.g., disease molecular mechanisms, drug action targets), making it difficult to produce top-tier basic research achievements like those from universities.
(2) **Limited breadth of interdisciplinary integration**: The core disciplines of hospitals are concentrated in the medical field (e.g., internal medicine, surgery, pharmacy), lacking the interdisciplinary ecosystem of "science-engineering-medicine" integration that universities possess. For instance, when conducting "AI + Medical Imaging" research, hospitals may need to rely on computer teams from external universities, while universities can directly mobilize internal research resources.

1.2.3. Development dilemmas

Although such laboratories generally adopt a co-construction model involving hospitals, universities, or research institutes, there is still room for improvement in giving full play to the complementary advantages of supporting entities and enhancing the synergy of scientific research. The main problems are as follows:

(1) **Disputes over fund sharing ratio and usage rules due to multi-party involvement**: To avoid disputes, the two parties may choose "independent fund usage"—hospitals use funds for clinically led research, while universities use funds for university-led basic research. This reduces the co-constructed laboratory to "two names but separate operations," making it impossible to achieve in-depth integration of "clinical samples + basic technologies."
(2) **Inconsistent standards for professional title promotion and performance evaluation among supporting entities**: Dual-appointment personnel or cross-institutional cooperative researchers may be caught in a dilemma of meeting requirements from both sides, making it difficult for them to focus on scientific research or achieve efficient collaboration.
(3) **Barriers to resource sharing**: There are significant differences in management standards between hospitals' clinical samples, electronic medical record data, and universities' scientific research equipment and platforms. Resource sharing requires multi-level approval, and data formats are incompatible, leading to the isolation of samples and technologies and failure to achieve resource complementarity.

Therefore, hospital-led co-constructed state key laboratories should avoid "formal collaboration but de facto separation"—that is, the failure to integrate hospitals' clinical advantages with universities/research institutes' basic research advantages through efficient collaboration mechanisms, which ultimately leads to a "$1 + 1 < 2$" situation and deviates from the original purpose of co-construction.

2. Innovative practices and development reflections of the State Key Laboratory of Complex, severe, and rare diseases

2.1. Innovation in restructuring mechanism

In February 2022, the General Office of the Ministry of Science and Technology issued the Notice on Implementing the Plan for Restructuring the State Key Laboratory System, which put forward the Standards for the Construction of state key laboratories (Trial) and the Five Questions for the Construction of State Key Laboratories, and further issued the Notice on Organizing the Recommendation of state key laboratories in the Fields of Medicine, Energy, and Engineering.[6] Against this background, Peking Union Medical College Hospital, relying on its profound historical heritage, outstanding medical technology, and rich clinical experience, actively responded to the State call, restructured on the basis of the State Key Laboratory of Complex, Severe, and Rare Diseases, and specifically introduced Tsinghua University as a co-construction entity. This restructuring plan will give full play to the respective advantages of the three supporting entities, achieve synergistic breakthroughs, clarify the mechanisms of more Complex, severe and rare Diseases, provide important scientific basis for new methods, strategies, and technologies for disease prevention, diagnosis, treatment, and rehabilitation, and form a synergistic effect of "$1 + 1+1 > 3$":

(1) **Support for basic research**: The Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences has accumulated profound research achievements in cell biology, molecular biology, genetics, etc., providing a solid theoretical foundation for exploring the mechanisms of Complex, severe and rare Diseases.
(2) **Technological empowerment for innovation**: Relying on its advantages in engineering and talent cultivation, Tsinghua University injects cutting-edge technologies into the laboratory in the fields of bioinformatics, biomedical engineering, and artificial intelligence, supporting the analysis of disease mechanisms and the development of diagnosis and treatment methods.
(3) **Driving force from clinical resources**: As the leading entity, Peking Union Medical College Hospital gives full play to its rich clinical resources and diagnosis and treatment experience, providing real cases and samples for the laboratory and ensuring that scientific research achievements have high clinical transformation value.

2.2. Innovation in management mechanism

(1) **Exploring a new paradigm of "medical-engineering integration" to enhance scientific research synergy**: The laboratory fully leverages the support of 33,000 square meters of core space, and opens and shares the 80,000 square meters of translational medicine complex building of Peking Union Medical College Hospital, as well as various scientific research platforms and instruments of Tsinghua University and the Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences. At the same time, it standardizes the storage and sharing of clinical resource banks and biomedical databases. Through mechanisms such as joint meetings, joint research projects, mutual appointment and recognition of professors, and joint talent cultivation, the three supporting entities break disciplinary barriers, achieve resource sharing and advantage complementarity, construct an in-depth medical-engineering integrated scientific research system of "clinical medicine-basic research-engineering technology," and create a new scientific research paradigm led by hospitals and integrated with multiple parties.
(2) **Building a three-dimensional scientific research system of "research direction-research group PI-technical platform"** (See Fig. 2): The laboratory implements a director responsibility system under the supervision of supporting entities. A full-time management office is set up, which is directly responsible to the laboratory director, realizing relatively independent management of personnel, funds, and materials. At the lower level, it adopts the "PI responsibility system for research groups" for operation and management. Among them, leading talents in the field of Complex, severe and rare Diseases are gathered through

existing talent pools, dual appointments, and global recruitment to form PI teams. The research teams cover three disease directions: complex diseases, severe diseases, and rare diseases, with each direction composed of several PI teams. The supporting entities organize annual assessments of PI teams, with a three-year evaluation cycle. The evaluation comprehensively assesses the overall operation of PI teams, covering indicators such as research level and contribution, team building and talent cultivation, and open communication and operation management.

In addition, the laboratory is equipped with a variety of public technical platforms, implementing a platform leader responsibility system under the leadership of the laboratory director. The laboratory director, PIs, and public platform leaders plan, construct, and manage the laboratory's daily operations at various levels within their respective responsibilities. With the specific coordination and support of the management office, they organize scientific research, talent cultivation, and academic exchanges in their respective fields.

(3) **Improving the talent evaluation mechanism to break the "four-dimensional constraints"**: A talent utilization mechanism and a classified talent evaluation system oriented to innovation value, capability, and contribution are established. The laboratory fully utilizes the State "decentralization, management, and service" policies, and leverages the policy dividends of high-level hospitals and achievement transformation pilot units to build itself into a State strategic sci-tech force.

2.3. *Showcase of representative achievements in recent years*

Based on the above innovative management practices, the laboratory has given full play to the resource advantages and scientific research synergy of the three supporting entities since its restructuring nearly two years ago, and achieved significant representative achievements in the directions of complex diseases, severe diseases, and rare diseases. Taking 2024 as an example:

2.3.1. *Complex disease direction*

The team led by Academician Zhao Yupei published a study in *Gastroenterology*.[7] Using single-cell RNA sequencing, spatial transcriptome sequencing, and multiplex immunohistochemistry, the study revealed changes in the transcriptomic characteristics of pancreatic endocrine cells during pancreatic ductal adenocarcinoma (PDAC) progression. Mouse models (including KrasLSL-G12D Pdx1-Cre, KrasLSL-G12D p53LoxP Pdx1-CreER, etc.) were used to further explore the relationship between pancreatic cancer development and endocrine cell changes.

The team led by Wang Xiaoshuang published a paper in *Development Cell*.[8] Through studying the characteristics of lymphoid development during early embryonic development, the team discovered the dynamics of hematopoietic stem cell (HSC)-independent lymphoid hematopoiesis in human embryos before the emergence of HSCs. This work identified a population of innate lymphoid-biased progenitors in the human yolk sac before the appearance of HSCs, described the origin and developmental dynamics of these cells, and provided a theoretical basis for the regenerative acquisition of lymphoid progenitors.

2.3.2. *Severe disease direction*

The team led by Du Bin published a study in *Critical Care Medicine*,[9] finding that earlier transition from non-invasive positive pressure ventilation (NIV) to invasive mechanical ventilation (IMV) improves survival rates in patients with sepsis. This State study involving more than 36,000 immunocompromised sepsis patients showed the potential harm of prolonged NIV dependence before delayed IMV transition. The team identified a dose–response relationship: compared with early IMV, a longer duration of IMV after initial NIV was associated with a gradual increase in mortality. This suggests that prolonged initial NIV trials in immunocompromised sepsis patients may be associated with increased mortality in patients who eventually require intubation.

2.3.3. *Rare disease direction*

The team led by Zhang Shuyang launched the "Xiehe Taichu" large model for rare diseases, supporting the early identification and detection of rare diseases.[10] The team led by Zhu Lan published a study in *Nature*

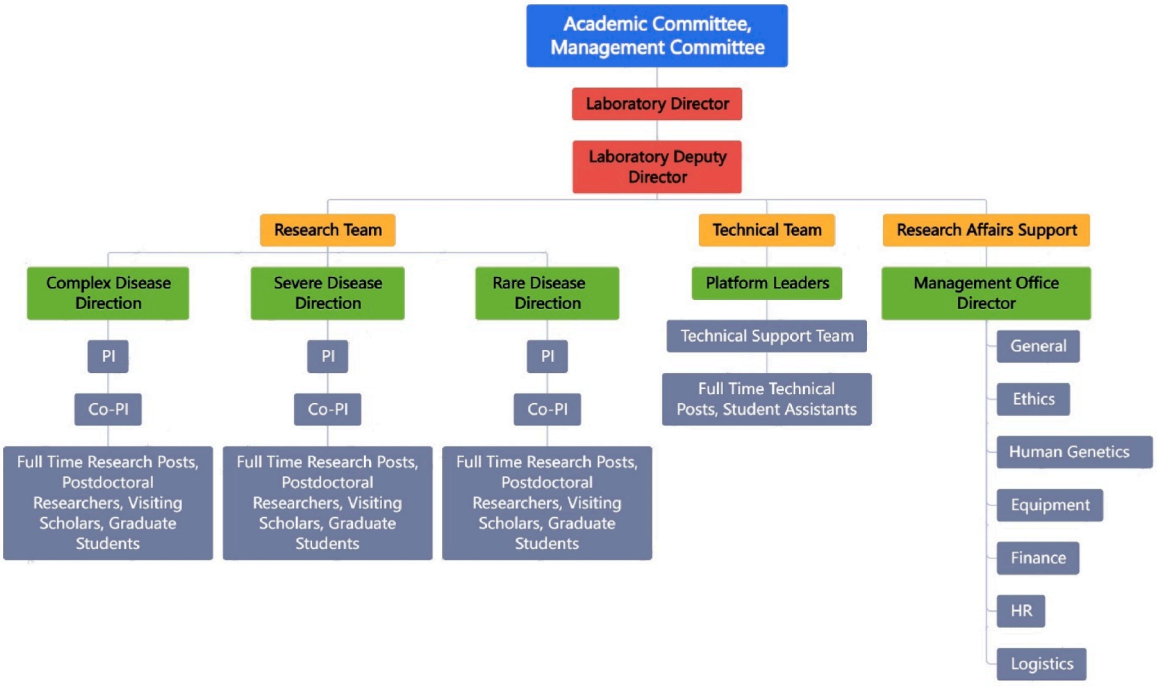


Fig. 2. Innovative organizational management model.

Communications,[11] showing that the neovagina is a blank niche during initial construction, and the microbiota in adjacent areas (e.g., vaginal fossa and anus) is similar to the "seed bank" of the neovagina. Under the combined influence of the "seed bank" and environmental selection, the vaginal microbiota undergoes continuous changes. This study is the first to discover the evolution law of the neovaginal microbiota in patients with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome, providing a theoretical basis for research in this field. The team led by Academician Qiu Guixing and Wu Zhihong published a study in *Nature Communications*,[12] conducting a gene-based ultra-rare variant burden test using exome or whole-genome sequencing data from 873 patients with congenital vertebral malformations and 3794 healthy controls. This study identified multiple high-effect risk genes, including ITPR2, TBX6, TPOH6PD, and SEC24B.

2.4. Shortcomings and development reflections of the laboratory

2.4.1. Benchmarking against international advanced standards and moving forward with clear goals

The laboratory has always paid close attention to global frontier trends in disciplines and actively benchmarked against international-lead medical centers and scientific research institutions, such as Mayo Clinic, Johns Hopkins Hospital, Massachusetts General Hospital, and the State Institutes of Health (NIH) Clinical Center. Although it has initially established a scale in strategic layout and resource integration, compared with the above international leading institutions, there is still much room for improvement in the output of original achievements in basic research and the transformation and application of clinical research results. In terms of exploring new mechanisms and developing new diagnosis and treatment technologies, the laboratory as a whole is still in the stage of "running alongside" or "following behind," with relatively limited original breakthroughs. To achieve leapfrog development from "running alongside" to "leading the way," the laboratory continues to carry out organized scientific research through collaboration with Tsinghua University and the Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences, focusing on key scientific issues and striving for substantive breakthroughs in relevant advantageous disciplines.

2.4.2. Strengthening open cooperation and pooling scientific research synergy

Although the laboratory has achieved certain scientific research results, there is still room for improvement in giving full play to the resource advantages of the three supporting entities and enhancing scientific research synergy. The laboratory strives to build a State-level scientific research platform featuring open sharing and win–win cooperation, and needs to further incorporate the open cooperation development strategy into its development plan, such as establishing open research project funds, expanding cooperation with external enterprises and scientific research institutions, and opening up and sharing laboratory infrastructure. In 2025, the laboratory has planned an application mechanism for independent research projects and open projects, initially realizing joint application by PIs from the three entities, promoting medical-engineering interdisciplinary integration and substantive cooperation, and further enhancing the scientific research synergy and resource integration capabilities among supporting entities.

2.4.3. Strengthening talent introduction and cultivation to build an academic echelon

A high-level talent team is the foundation for the sustainable development of the laboratory. In terms of talent cultivation, more efforts should be made to cultivate and attract outstanding scientific research talents and build an internationally competitive scientific research team. Currently, the number of PIs in the laboratory is not sufficient to meet the needs of future research layout and development, and talent reserves need to be strengthened urgently. To this end, the laboratory continues to promote PI selection within supporting entities and the introduction of high-level talents, while increasing social recruitment efforts to support the rapid formation of newly introduced PI teams. It strives to build a structurally reasonable, echeloned, and internationally competitive academic talent echelon, providing a solid guarantee for improving the laboratory's original innovation capability.

2.4.4. Focusing on achievement transformation to benefit patients

The transformation of clinical scientific research achievements is an important mission of the laboratory to serve society. Currently, the laboratory's capability in transforming scientific research achievements into clinical applications is still insufficient: basic research is relatively in-depth, but the development of new diagnosis and treatment technologies and their practical application in clinical practice are limited. It is necessary to further improve the mechanism for transforming clinical research achievements and strengthen the bridge construction from basic research to clinical application. The laboratory should further utilize existing laboratory technology platforms to solve problems in clinical work more quickly and conveniently, organically integrate scientific research with clinical work, truly realize "scientific research originating from clinical practice and serving clinical practice," promote more innovative diagnosis and treatment technologies and achievements to benefit patients, and effectively improve the health and well-being of the people.

3. Conclusions and prospects

Since its restructuring, the State Key Laboratory of Complex, Severe, and Rare Diseases has carried out innovative explorations in medical-engineering interdisciplinary integration and laboratory management mechanisms, and achieved remarkable achievements in research projects, scientific and technological innovation, achievement transformation, talent cultivation, and academic influence. In the next 5–10 years, the laboratory will continue to focus on complex, severe and rare Diseases to carry out a series of original research, build a state-level scientific research platform featuring open sharing and win–win cooperation, and strive to become a pioneering model of hospital-led co-constructed state ley laboratories.

Looking forward, hospital-led co-constructed state key laboratories have broad development prospects, as well as opportunities and challenges. The laboratories should keep pace with the times, focus on the frontiers of medicine and clinical needs, continuously strengthen scientific research innovation capabilities, carry out high-level basic research and applied research, provide more theoretical support and technical means for overcoming major diseases, and make greater contributions to promoting the progress of China's medical science and technology and improving the state health level.

CRediT authorship contribution statement

Hu Jin: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Bai Hua:** Writing – review & editing. **Wang Chengcheng:** Writing – review & editing. **Huang Hui:** Writing – review & editing. **Song Yimin:** Writing – review & editing, Validation.

Data availability

The data used in the research related to the National Key Laboratory for Complex, Severe and Rare Diseases are primarily derived from Peking Union Medical College Hospital.

For specific data access, researchers may contact the corresponding author (Prof. Song Yimin, E-mail: songyimin@vip.sina.com) or the Management Office of the National Key Laboratory for Complex, Severe and Rare Diseases, and submit a formal data access application including a research plan, ethical compliance statement, and commitment to data security.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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