附件1 中英文资助领域描述

**针对疫苗管理和监管科学的优先领域研究**

**主 题：**

促进我国疫苗研制和创新，助推疫苗产业高质量发展，保证疫苗的质量和供应，研究和开发新的监管科学体系、工具和方法，应用于疫苗的研制、注册、生产、预防接种和上市后管理的优先领域。

**1.目标**

1. 探索适应新发展阶段疫苗管理的政策体系和体制机制，研究提高疫苗治理效能和改革疫苗管理体系的路径，发展疫苗监管科学的决策方法，为全面优化疫苗管理和加速创新疫苗研发提供理论、方法和目标战略。
2. 借鉴国际创新疫苗全生命周期管理的经验，解决制约新型技术路线和多联多价疫苗管理中的关键问题，创新疫苗管理中的监管科学新体系、新工具、新方法，最终形成可以支持监管治理决策的新模式和方法论。
3. 借鉴疫苗上市后主动药物警戒的国际经验，研究、开发和验证与前瞻性药物警戒系统和主动药物警戒活动相关的标准程序和机制，加速中国疫苗国家监管体系成熟度的再提升。

**2.需要解决的科学问题**

科技进步、产业发展和国际化给中国疫苗监管带来新的机遇和挑战。目前，我国疫苗管理，研发、注册和上市后安全性监测的监管标准与国际规范尚存在差距。为了促进新技术路径疫苗的研发创新和多联多价疫苗的升级叠代，加速中国疫苗国家监管体系成熟度的再提升，本项目支持通过定性和定量方法完善中国疫苗管理体系，识别疫苗全生命周期影响监管治理效能的关键问题和优先领域，制定研究策略和方案，创建和验证用于支持疫苗监管决策的新模式和方法论，明确使用场景，最终整合到中国的药品监管法律、法规和政策实践当中，为加快创新疫苗研发、上市评价和上市后主动药物警戒活动及前瞻性监测提供高效、可行的路径。

**3.研究支持的领域**

项目申请人聚焦以下领域提交具有前瞻性、创新性、科学性和可行性的课题申请书。我们鼓励项目申请人组建公共政策、法学、药学等多学科交叉整合的研究团队开展研究，将确认优先领域的具体问题、探索研究解决问题的方案、开发和验证用于支持疫苗监管决策的新模式、新工具和新方法，以及政策建议整合在一项研究中。

课题申请书在描述科研活动的同时，应包含在项目执行期内至少每年一次的项目交流会，与国家自然科学基金委员会、盖茨基金会、国家药品监督管理局和国内外同行汇报和探讨项目的进展、发现、研究结果和政策建议等。

1. **提高疫苗治理效能的政策和路径研究：**围绕人民高品质生活和疫苗产业高质量发展的目标，以及疫苗产品的战略性和公益性，研究我国疫苗治理效能的主要评价维度和指标体系；研究影响疫苗治理效能的主要因素和分析框架；研究疫苗治理中行政资源、监管能力、效能产出之间的逻辑机理；研究主要发达国家创新疫苗全生命周期管理的经验；研究促进疫苗研制和创新的总体思路和具体方法。
2. **疫苗管理体制改革和机制优化研究：**针对我国疫苗管理多元主体、多重目标、动态交互等特征，以及公众健康与商业利益交织的特点，研究疫苗管理体制改革的动力机制和疫苗全生命周期管理；研究疫苗研制创新、规模化生产、生产工艺过程变更、预防接种异常反应等领域的体制性障碍及其内在逻辑；研究主要发达国家和典型发展中国家疫苗管理的可行经验；研究疫苗管理中产品、产业、健康目标协同发展和治理的机制和方法；研究现代化新征程中疫苗管理体制改革的战略性对策。
3. **评价疫苗效力、安全性和生产质量的新监管科学工具和新方法研究：**为加快新型技术路线和多联多价疫苗的研发，促进中外同步开展国际多中心临床试验进行疫苗研发和注册，满足公共卫生（包括老人、孕妇等特殊人群）需求和应对新发和突发传染病，本领域支持监管新工具和临床试验创新方法学研究。开展测量疫苗效力和安全性的测量工具、决策支持工具和应用场景研究，建立研发和审评知识库；开展疫苗创新性的临床试验设计（如适应性设计）、对照组的选择和临床终点（替代终点）的选择、统计分析的创新理论和方法研究，推动疫苗临床试验技术在我国的革新和应用。
4. **疫苗上市后主动药物警戒的创新研究：**世界卫生组织疫苗国家监管体系成熟度4级要求国家监管机构具备开展主动药物警戒的能力，即“制定和实施主动药物警戒活动及前瞻性监测方案”。本领域支持加快我国疫苗安全性主动监测能力建设的新模式研究，包括但不限于研究符合我国国情的开展主动药物警戒活动的工作模式、技术方案、能力要求和经费需求等。在技术实现方面，鼓励研究利用区域性健康医疗大数据等多种数据源开展疫苗安全性主动监测，在数据治理、信号发现、信号验证和信号处置等环节开发策略、技术、工具和管理模式，建立多种方式实现的前瞻性主动警戒的标准程序和机制，并通过搭建疫苗主动警戒平台进行试点和验证。最终形成适合我国国情的《与前瞻性药物警戒系统相关的标准程序和机制》和《与主动药物警戒活动相关的标准程序和机制》的政策建议和最佳实践案例，加速中国疫苗国家监管体系成熟度的再提升。

 **Research on Priority Areas for Vaccine Management and Regulatory Science**

**Themes:**

Advancing vaccine development and innovation in China to further drive high-quality development of vaccine industry and ensure safety and supply of vaccines; and developing new regulatory science systems, tools, and methodologies applicable to priority areas of vaccine development, registration, manufacturing, vaccination, and post-marketing management.

**1. Objectives**

1. To explore policy and institutional mechanisms for vaccine management adaptable to new development stages; identify pathways to more effective vaccine regulation and management; develop more effective standard decision-making procedures and processes for vaccine regulation; and contribute theories, methodologies, and targeted strategies for accelerating novel vaccine R&D and comprehensive optimization of vaccine regulatory management.
2. To draw on international experience in the whole lifecycle management of novel vaccines; address key barriers and constraints on the management of new technologies and multiplexed polyvalent vaccines; develop innovative systems, tools, and methodologies for vaccine regulation; and ultimately create new models and methodologies in support of regulatory governance decision making.
3. To draw on international experience in active post-marketing pharmacovigilance for vaccines; develop and validate standard procedures and protocols related to prospective pharmacovigilance systems and active pharmacovigilance activities; and accelerate the maturation of China’s national vaccine regulatory system.

**2. Scientific challenges to be addressed**

Technological advances, industrial development, and internationalization have brought about new opportunities and challenges to vaccine regulation in China. At present, gaps remain between Chinese and international standards in vaccine regulation, R&D, registration, and post-marketing safety surveillance. This collaborative research program is aimed to promote vaccine R&D innovations with new technological pathways, upgrade and iterate multiplexed polyvalent vaccines, and accelerate the maturation of China’s national vaccine regulatory system. The program is designed to support continuing improvement of China’s vaccine regulatory management system through developing qualitative and quantitative methods, identifying key challenges and priority areas with an impact on regulatory effectiveness throughout vaccine lifecycles, developing research strategies and protocols, developing and validating new models and methodologies in support of vaccine regulatory decision making, identifying and compiling use cases that will ultimately be integrated into China’s drug laws, regulations, and policy practices, and developing efficient and feasible pathways to accelerate innovative vaccine development, marketing evaluation, manufacturing quality, and active post-marketing pharmacovigilance activities and prospective surveillance.

**3. Areas of Support**

Program applicants shall submit forward-looking, innovative, scientifically robust, and feasible proposal focusing on the areas described below. Applicants are encouraged to form a multidisciplinary research team including expertise in areas such as public health, public policy, law, clinical research, and pharmacology, to conduct research on a set of specific problems identified in a priority area, analyze, develop, and validate potential solutions such as new models, tools, and methodologies in support of vaccine regulatory decision making, and provide policy recommendations.

While describing research activities, the proposal should include, at least, an annual briefing session during the study period to report and discuss progress and findings of the project, and potential policy implications and recommendations with the National Natural Science Foundation of China (NSFC), Bill & Melinda Gates Foundation (BMGF), National Medical Products Administration (NMPA), and Chinese and international peers.

1. **Research on policies and pathways to improve effectiveness of vaccine regulation**: With the goal of improving people’s living standards and seeking high-quality development of vaccine industry, and recognizing the strategic importance of vaccine products as a public good, this area of research should focus on major evaluation dimensions and indicators of the vaccine regulatory system’s effectiveness in China; the main factors affecting vaccine regulatory effectiveness and analytical framework; the causal relationships among administrative resources, regulatory capacity, and efficiency gains in vaccine regulation; the experiences of major developed markets in the whole lifecycle management of innovative vaccines; and general approaches and specific methodologies to promote vaccine development and innovation.
2. **Research on vaccine regulatory system reform and process optimization**: In light of the diverse players, multiple objectives, and dynamic interactions in vaccine life-cycle regulation (including efficacy, safety, and manufacturing quality during clinical trials, initial authorization, and post-authorization changes) in China, as well as the interwoven public health and commercial interests, this area of research focuses on the dynamics of vaccine life-cycle regulatory system reform; institutional barriers to vaccine development and innovation, mass production, production process changes over time, and Adverse Event Following Immunization (AEFI) systems, and their inherent drivers; replicable experiences of vaccine regulation in major developed countries and typical developing countries; mechanisms and methods of synergistic development and management of products, industries, and health objectives in vaccine regulation; and strategic recommendations for vaccine regulatory system reform on the new journey to modernization.
3. **Research on new regulatory science tools and new approaches to evaluating vaccine efficacy, safety, and manufacturing quality (including technology transfer implications)**: In order to accelerate the development of novel technological routes and multiplex polyvalent vaccines, drive simultaneous multicenter clinical trials for vaccine development and registration in China and internationally, meet public health needs (including those of special groups such as the elderly and pregnant women), and to respond to emerging infectious diseases, this area of research supports new tools for regulation of and innovative methodologies for clinical trials. Research should be conducted on measurement tools, decision support tools, use cases for measuring vaccine efficacy and safety, and the creation of a knowledge bank for R&D and review, as well as novel theories and methods for innovative clinical trial design (e.g., adaptive design), selection of control groups and clinical endpoints (e.g., surrogate endpoints), and statistical analyses of vaccines to drive innovation and the application of such vaccine clinical trial advances in China.
4. **Innovative research on active post-marketing pharmacovigilance for vaccines**: The WHO Vaccine National Regulatory System operating at maturity level 4 requires national regulatory authorities (NRAs) to have the capacity for active pharmacovigilance, i.e., “develop and implement active pharmacovigilance activities and prospective surveillance programs”. This area of research supports new models for accelerating capacity building for active vaccine safety surveillance in China, including, but not limited to, working models, technical solutions, capacity requirements, and funding needs for active pharmacovigilance activities in line with China’s national conditions. In terms of technical implementation, we encourage research on the use of multiple data sources (such as regional healthcare big data) to carry out active surveillance of vaccine safety; the development of strategies, technologies, tools, and management models in data governance; the development of signal discovery, signal verification, and signal disposal to establish standard procedures and mechanisms for prospective active vigilance enabled in multiple ways; and the application of pilots and validation by building an active vaccine pharmacovigilance platform. Ultimately, the goal is to formulate policy recommendations and best practice cases of the Standard Procedures and Mechanisms Related to Prospective Pharmacovigilance Systems and Standard Procedures and Mechanisms Related to Active Pharmacovigilance Activities commensurate with China’s national conditions, which will help accelerate the maturation of China’s national vaccine regulatory system.