# **BMGF-NSFC Joint Project on Regulatory Science**

**Full Proposal**

*We appreciate your interest in submitting a proposal to the Bill & Melinda Gates Foundation.*

* This is a proposal shaping document and not a commitment by the foundation to fund the work.
* the proposal must be submitted in English, one and only application is accepted from one principal investigator (lead investigator).
* The softcopy (e.g. saved to a disk or USB device) of the this proposal alone with one printed copy must be submitted via physical mail by China Postal EMS (post-marketed date) to the Gates Foundation’s contractor the China S&T Exchange Center （打印版和存储版英文申请书需要通过中国邮政EMS快递在规定日期前寄至：中国科学技术交流中心美大处李宁， 北京市三里河路54号 邮编：100045） by the application deadline specified in the joint BMGF-NSFC Call for Proposal in Chinese. Applications post-marketed after the deadline date will not be accepted.
* Applications must be submitted following the word limits as instructed and following all instructions in the BMGF-NSFC Call for Proposal. Applications which fail to comply with any of the guidance supplied will be rejected.
* Applicants must fill in all sections of the Proposal.
* Applications must be submitted as a word document.

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| **SECTION A – INVESTMENT Essential Information (Chinese Investigator to Complete)** |

**GENERAL INFORMATION**

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| **Chinese Investigators** (please delete or add more rows as needed) |
| **Role:** (PI, CoI, etc.) | **Name:** | **Organization:** | **Division/Department:** | **Hours per week on project:** |
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| **Project title** [no more than 30 words]: |  |

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| **Executive summary** (please describe research objectives, problem(s) to be solved, the technical route/approach, innovations) [no more than 2000 words] |
| Research objective(s):Problem(s) to be solved:Technical approach:Innovations: |

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| ***Focus areas******(please indicate which the focus area(s) are covered in your proposal)*** |
| *(1) Research on policies and pathways to improve effectiveness of vaccine regulation* | ***[ ]***  |
| *(2) Research on vaccine regulatory system reform and process optimization* | *[ ]*  |
| *(3) Research on new regulatory science tools and new approaches to evaluating vaccine efficacy, safety, and manufacturing quality (including technology transfer implications)* | *[ ]*  |
| *(4) Innovative research on active post-marketing pharmacovigilance for vaccines* | *[ ]*  |

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| **Duration of grant in months**(36 months) |  |

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| **Project Partners** One international collaborator (at the individual or institutional level) is required; One or two domestic partners (two maximum) are allowed (. Please delete or Add more rows as needed) |
| **Name:** | **Organization:** | **Input into project (funds, advice, facilities, etc.) and whether proposed or secured:** |
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| **Composition, expertise and experience of your project team, including any previous collaborations** [no more than 500 words] |
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| **Annual work plan, including approaches, activities, milestones, and how your work plan can address the research objective (s) of the project** [no more than 1000 words] |
| Year 1Year 2Year 3 |

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| **Collaboration plan** **with project partners** [no more than 1000 words] |
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| **Expected outcome and impact, including translational pathways and feasibility for use in low- and middle-income countries** [no more than 500 words] |
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| **Risks and mitigation** (please describe potential risks/challenges to the success of the project and the plan to address them, including any external factors or critical relationships with other partners/projects that may influence the success of the project) [no more than 200 words] |
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**RESOURCES**

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| **Estimated resources requested** |
| BMGF resources RMB |  |
| China resources RMB |  |

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| **BMGF (RMB)** | **China (RMB)** |
| 1st year |  | 1st year |  |
| 2nd year |  | 2nd year |  |
| 3rd year |  | 3rd year |  |
| Total |  | Total |  |

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| **SECTION B – INVESTMENT DETAILS** |
| **General Information - Chinese Investigator to Complete** |

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| **Estimated Start Date** |  | **End Date** |  |
| **Requested Amount (RMB Yuan ￥)** |  | **Total Project Cost (RMB Yuan ￥)** |  |
| **Organization Legal Name1** |  |
| **Mailing Address** |  | **Primary Contact Name** |  |
|  Street Address 1 |  | **Primary Contact Title** |  |
|  City |  |  |  |
|  State / Province |  |  |  |
| **Website** (if applicable) |  |  |  |

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| **Project Overview – Chinese Investigator to Complete** |

**Please provide or expand upon the information provided in the narrative space below:**

* **What is the primary outcome(s) or result(s) this investment will achieve or significantly contribute to? How will You know when that result(s) has been achieved (how will the result be measured)? If sustainability is a component of proposed outcomes, please describe the vision of long-term sustainability of this Project. Consider the economic/financial, organizational or behavioral factors to sustain outcomes beyond this project’s time frame and funding.**
* **Describe the approach You will take to achieve the intended results of this Project: a) Overall Scope of Work b) Timing and/or phases, and c) Narrative of resource needs to support the budget (ex: people, capabilities, technical expertise, experience, specific assets, including any external collaborators/contributors to the Project).**
* **Describe potential risks/challenges to the success of this Project and how You plan to address them. Include any external factors or critical relationships with other partners/projects that may influence the success of this project (including any anticipated agreements to be entered into for purposes of the Project).**
* **Describe any changes or improvements You plan to make to Your organization's capacity to undertake or achieve the outcomes of the proposed investment.**

The foundation requires that funded projects are conducted and managed in a manner that will ensure a positive, sustainable impact on the foundation’s intended beneficiaries.  Please provide a response to each question in the bullets below, highlighting how Your management of the project described in this Investment Document (the “Project”) and the intended outcomes align with the Strategic Fit, Charitable Purpose, and the foundation’s Global Access requirements.

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| **Primary Outcomes:****Project Approaches:****Potential risks/challenges:****Capacity of your research team and organization:** |

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| **Investment Results- Chinese Investigator to Collaborate**  |

**Provide specific details on the outcomes this investment will achieve (including those that define what success is for the investment), and the key outputs that signal whether the investment is on track.** Add more rows, as needed.

**“Outcome”** is the ultimate or overall change(s) in-systems, populations or behaviors the investment seeks to achieve within the context of the investment time frame; tells us what success looks like for the investment. Add more rows as needed.

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| **Outcome****Number** | **Outcome Description** | **Target** **Completion Date** | **Actual** **Completion Date** | **Payment** **Contingency** |
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 **“Output**” or “**Funded Development**” means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). Note: You will be required to disclose and update Intellectual Property (IP) and include any links to applications, filings, or registrations, as applicable, in future progress report(s). Add more rows as needed.

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| **Output/Funded Development Number** | **Output/Funded Development****Description** | **Target** **Completion Date** | **Actual** **Completion Date** | **Payment** **Contingency** | **Third-Party agreement required?** If yes, by when? | **Will any IP rights be filed/generated?** |
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| **Global Access/Impact for Foundation’s Beneficiaries – Chinese Investigator to Complete** |

**To ensure a positive impact on the foundation’s intended beneficiaries, the foundation requires that all Projects and outputs be managed to ensure Global Access. You will be requested to update the responses below, as may be applicable, in future progress reports.**

**“Global Access”** is a foundation policy requiring that: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

**“Funded Developments”** means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology).

**“Background Technology”** means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project.

1. **How will You disseminate the knowledge and information arising from the Project? (For peer-reviewed publications see our** [**Open Access policy.)**](https://www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy)

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1. **How will You ensure affordable and meaningful access to the Funded Developments arising from the Project (and Background Technology, if any)?**

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1. **Do You foresee any obstacles to achieving Global Access (e.g., third-party rights, restrictions on Background Technology, time frame, affordability)?**

**No\_\_\_**

**Yes\_\_\_\_ (please explain and describe the specific steps that You will take to address them).**

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1. **Please confirm that You will make available for Global Access purposes the Funded Developments and any Background Technology that is (i) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (ii) either incorporated into a Funded Development or reasonably required to use the Funded Development.** See the Global Access terms located in the foundation’s [grant terms and conditions.](https://docs.gatesfoundation.org/Documents/Sample-Terms-and-Conditions.pdf)

**Confirmed \_\_**

**Not confirmed \_\_\_\_ (please explain)**

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| **SECTION C – BUDGET INFORMATION** |

*The purpose of the budget narrative is to supplement the information provided in the Excel-based budget template by justifying how the budget cost elements are necessary to implement Project activities and accomplish target outcomes. The budget information section is used to help foundation staff fully understand the budgetary needs of the Project and is an opportunity to provide descriptive information about the key costs and risks that can’t be easily communicated in the budget template. Together, this budget narrative and Excel budget should provide a complete quantitative and qualitative description that supports the proposed budget. The description provided in the budget template should be very brief. Please use this budget narrative to provide a thorough description of Your budget and only complete questions that are relevant to Your proposal.*

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| **Budget Summary - Chinese Investigator to Complete**  |

**Please explain the major cost drivers and how costs relate to planned activities and target outcomes. Also explain any potential risks in spending as budgeted and any plans to mitigate those risks.**

**If budgeting by outcomes, or additional dimension, please explain the major cost drivers per outcome or other relevant dimension.**

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| **Detailed Budget Information - Chinese Investigator to Complete**  |

**Personnel and Benefits: Provide a brief explanation of personnel budgeted, including responsibilities as they relate to the grant. Also include assumptions made for any staff budgeted which are to-be-hired, including salary estimates for these personnel. Describe the components of the benefits (column R of the “Budget Details” sheet) included with the salary costs. For example: pension, health insurance, expatriate costs, etc.**

**Travel: Provide rationale for the travel budgeted and assumptions used to determine appropriate number of trips and personnel required. Also include a brief rationale for how travel costs were estimated.**

**Consultants: Provide a brief description of the work to be performed by consultants in support of the overall Project and describe any expenses that have been included.**

**Capital Equipment: Provide a brief justification and description of any items required for the Project with a unit cost of greater than ￥35,000 (RMB) and a useful life of more than one year.**

**Other Direct Costs: Provide a brief description and rationale for other direct costs required, including cost assumptions used to develop the budget for these costs.** Add more rows as needed.

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| Items | Cost | Item description |
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| Total |  |  |

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| **Indirect Cost Rate – Chinese Investigator to Complete** |

**Briefly explain the indirect cost rate being charged on this project and the rationale and assumptions behind it.**

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| **Other Sources of Support for this Project - Chinese Investigator to Complete** |

**If You are requesting funding from the foundation for only a portion of this Project and will depend on funds from other sources, please describe Your contingency plans if full Project funding does not become available. If You have applied for funding from other sources which overlap with the funding requested in this proposal, please indicate the nature and timing of that potential funding. Any expected in-kind contributions (e.g. drug donations, personnel time) should be included in the description.**

NOTE: Names of the other sources and their expected dollar (RMB) contributions should be included on the ‘Financial Summary & Reporting’ sheet of the budget in the Funding Plan table.

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| **Geography Served- Chinese Investigator to Complete** |

**List all countries and sub-regions/states that would benefit from this work and associated RMB Yuan amounts. If areas to be served include the United States, indicate city and state.** Add more rows as needed. More information about Geographic Areas to Be Served can be found [here](https://docs.gatesfoundation.org/documents/geography-frequently-asked-questions.pdf). Add more rows as needed.

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| **Location** | **Foundation Funding (RMB)** |
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| **Location of Work - Chinese Investigator to Complete**  |

**List all countries and sub-regions/states where this work would be performed and associated RMB Yuan amounts. If location of work includes the United States, indicate city and state.** Add more rows as needed. More information about Geographic Location of Work can be found [here](https://docs.gatesfoundation.org/documents/geography-frequently-asked-questions.pdf).

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| **Location** | **Foundation Funding (RMB)** |
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Many countries, including India, Vietnam and Bangladesh, require organizations conducting activities funded with foreign funds to comply with local registrations or other requirements. These restrictions may apply to funds you subgrant under this project. Please confirm that your organization will ensure compliance with any such requirements.

Confirmed \_\_

Not applicable \_\_\_\_ (please explain)

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| **SECTION D – ROLES & RESPONSIBILITIES**  |

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| **Conduct and Control of the Project - Chinese Investigator to Complete** |

*In answering the questions in this section, please consider all Project activities, such as those involving: confidential or protected information (including personally identifiable information or protected health information); the inclusion of children or vulnerable populations; research involving human subjects; clinical trials; post-approval studies; field trials; experimental medicine; provision of medical services (diagnostic, prophylactic or treatment); product development; use of genetically modified organisms, human tissue, animals, radioactive isotopes, pathogenic organisms, recombinant nucleic acids, select agents or toxins (*[*www.selectagents.gov*](http://www.selectagents.gov/)*), dual-use technology (*[*http://export.gov/regulation/eg\_main\_018229.asp*](http://export.gov/regulation/eg_main_018229.asp)*), or any substance, organism, or material that is toxic or hazardous; use of aircraft, unmanned vehicle systems, drones or satellites; and the import, export, transfer, approvals, consents, records, data, specimens, images, and materials related to any of the forgoing.*

1. **Please confirm that Your organization:**
2. **will maintain the expertise necessary to conduct, control, manage, and monitor all aspects of the Project in compliance with all applicable ethical, legal, regulatory, and safety requirements including applicable international, national, state, local, and institutional, school district or school network standards and policies and is responsible for determining and complying with these requirements and standards;**
3. **will not disclose any confidential or protected information to the Foundation without obtaining prior written approval from the foundation and all necessary consents to disclose such information;**
4. **acknowledges that any activities by the Foundation in reviewing documents, providing input or funding does not modify Your organization’s responsibility for determining and complying with all applicable ethical, legal, regulatory, and safety requirements for the Project in all places;**
5. **is a government agency, public institution or multilateral organization or will otherwise maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally-accepted standards and as required by law (for instance, general, professional, clinical trial, product liability, medical malpractice, workers' compensation, or otherwise);**
6. **will not transfer any biological materials, chemicals, reagents, hazardous materials or the like to the Foundation.**

**Confirmed \_\_\_\_**

**Not confirmed \_\_\_\_ (please explain)**

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| N/A | **\_\_** Yes **\_\_** No  | **\_**Yes **\_**No  |  |  |
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| **SECTION D – PROJECT-SPECIFIC QUESTIONS** |

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| **Measurement and Evaluation - Chinese Investigator to Complete** |

**Describe your plan for monitoring and evaluation of the outputs and outcomes identified in the narrative above.** Specifically address:

1. The learning/evaluation questions for this investment and how You plan to answer them through monitoring and/or evaluation;
2. The resources (financial, technical, human) You need to ensure high quality monitoring and/or evaluation data; and
3. If You are planning a formal evaluation, describe when it will be conducted during the grant, who will conduct it (external/third party or not), the methodology You will consider, and how the main evaluation audiences will use the findings.

See the foundation’s [evaluation policy](http://www.gatesfoundation.org/How-We-Work/General-Information/Evaluation-Policy) for reference.

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| **Data Access - Chinese Investigator to Complete** |

**We anticipate this investment, if funded, would generate datasets that may be of interest to the foundation and/or to the field if made publicly available. Please describe any datasets that will be generated as part of this investment. Specifically address when and how the datasets would be made available to the foundation and/or to the public, in what form or format, and any anticipated costs to your organization.** Additional information about Data Access can be found [here](https://docs.gatesfoundation.org/documents/FAQs%20for%20Grantees%20and%20Partners.docx).

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Appendix:

**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.