Notice of the Ministry of Science and Technology on
Issuing the National Key R&D Programme 2020 Application Guide for
International Cooperation Projects in response to COVID-19

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Relevant units,

In line with the overall arrangement of the Reform of the National S&T Funding Programmes of the State Council (Guo Fa [2014] No. 64), according to the relevant requirements of the National Key R&D Programme (NKP), the 2020 Application Guide for International Cooperation Projects in response to COVID-19 is hereby published. Specific details are the following:

1. Project requirements

1) The organisation and implementation of the project should be oriented to respond to the needs under the COVID-19 epidemic, be oriented towards practical applications, make full use of the existing R&D foundation, efficiently allocate and comprehensively integrate the scientific and technological innovation resources of both parties of cooperation, mobilise their strength, step up scientific and technological research and development breakthroughs, highlight the urgent need for prevention and control, and effectively resolve the difficult problems in clinical application, so as to make due innovation contributions for all mankind to win the battle of prevention and control against the epidemic.

2) Project research that involves human bodies should pass ethical reviews and sign informed consent letter according to relevant rules. Collection, storage, utilisation and provisions of human genetic resources should be carried out in compliance with relevant rules of the Regulations of the People’s Republic of China on the Management of Human Genetic Resources. Transportation, mail or carrying human genetic resources out of China must be reported for approval in strict accordance with the relevant regulations of the Human Genetic Resources Management Regulations of the People’s Republic of China. Experimental animals and animal tests should observe the national laws, regulations, technical standards and rules on laboratory animals by using qualified laboratory animals to conduct animal tests in qualified devices, to ensure that the experiment process is legal, the test results are authentic and effective, and pass the experimental animal welfare and ethical reviews. At the same time, relevant research activities should comply with biosafety-related regulations such as Regulations for the Biosafety of Pathogenic Microbiology Laboratories and Guidelines for Biosafety of New Coronavirus Laboratories (Second Edition).

3) The content and method of project cooperation shall comply with the relevant laws and regulations of China and the countries (regions, international organisations) where the cooperation institutions are located. Those conducting clinical research on drugs, vaccines, etc. overseas should obtain clinical approvals from the local drug regulatory authorities for the indications of new coronavirus pneumonia, and have a comprehensive understanding of the specific provisions of local laws and regulations and ethical review requirements, as

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1 https://service.most.gov.cn/kjh_tzg_all/20200706/3414.html
well as relevant key items such as medical behaviours and commercial insurance, to avoid violating local laws or causing disputes.

4) The scientific data generated by the projects should be submitted unconditionally and timely to the platform designated by the Ministry of Science and Technology, and be open for sharing by all scientists and the general public.

2. Recommendation organisations

1) S&T departments and bureaus of relevant administrations of the State Council;
2) S&T administrations of provinces, autonomous regions, municipalities and cities;
3) Industrial associations transformed from former industrial administrations;
4) Strategic industrial technology innovation alliances of A type listed as pilots by the Ministry of Science and Technology, and pilots of S&T service alliances listed by the Ministry of Science and Technology and the Ministry of Finance.

Recommendation organisations should recommend proposals within their responsibility and business scopes and should be responsible for the authenticity of the recommended projects. Relevant administrations of the State Council will recommend those entities of their affiliates. Industrial associations, strategic industrial technology innovation alliances and pilot alliances of S&T services will recommend their members. Provincial S&T administrations recommend entities within their administrative scope. The list of recommendation organisations is published at the National S&T Information System Public Service Platform.

3. Procedures of project application

1) Applicants will submit proposals in the form of projects in line with the research content provided in the Guide. No tasks (or topics) will be set up under projects. Proposals should be submitted as a whole to cover all the research content and fulfil the corresponding research indicators provided in the Guide. Project application organisations should nominate one researcher as Principal Investigator (PI).

2) Evaluation of proposals will be conducted as the following:

- In line with relevant requirements provided in the Guide, applicants shall fill up and submit the project application forms via the portal of National S&T Information System.

- Project lead applicants sign cooperation research agreements with foreign partners and joint application agreement with all participants with indications of the time for signature. Project lead applicants and PIs should sign commitment letters of integrity. Project lead applicants and all participating organisations should fulfil the requirements set forth in the Several Opinions on Further Strengthening Scientific Research Integrity, reinforce checks on application documentations, and eliminate exaggerations, inaccuracies and falsifications.

- Recommendation organisations should strengthen checks on the project applications to be recommended and submit projects at their recommendation timely via the portal of National S&T Information System.
- After receipt of project applications, China S&T Exchange Centre (CSTEC) will organise administrative checks and evaluations. Projects will be selected on merits based on the results of expert reviews.

4. Application eligibility requirements

1) Project lead applicants and participating entities should be research institutes, universities and enterprises registered in Chinese mainland with independent legal person status before 31 May 2019, with competent R&D capacities and conditions and sound operational management. Government agencies cannot lead or participate in applications.

   Project lead applicants, participating entities and project team members should have good integrity status, and have no records of severe research dishonesty in disciplinary enforcement nor relevant social credit "black list" records.

   A proposal should include one (or more) foreign participant(s). Foreign participants should be research institutes, universities and enterprises registered outside Chinese mainland for above three years with independent legal person status. They should be organisations that have related advantageous resources in this field and strong R&D capabilities and conditions, and have long-term and stable cooperation basis with the Chinese project applicants (former cooperation results such as cooperation patents of Chinese and foreign partners, collaborative papers, major cooperative projects with significant impact etc. should be provided in annex) and sound operational management.

2) Principal investigators should hold senior professional titles or PhD degrees, born after 1 January 1960, with at least 6 months of working time dedicated to the proposed projects.

3) Principal investigators should in principle be the proposers of the main research ideas of the proposed projects and the scientists who lead practical research activities. Public service staff (including those undertaking S&T programme administration functions) in central and local government agencies cannot apply.

4) Principal Investigators can only apply for one project. Principal Investigators of ongoing projects (including tasks or topics) under the National Major S&T Projects, National Key R&D Programmes and STI 2030 Major Projects cannot lead project applications. Principal Investigators of ongoing projects (excluding leaders for tasks or topics) under the National Key R&D Programmes and STI 2030 Major Projects cannot participate in project applications either.

   The total numbers of projects applied for and ongoing projects undertaken by Principal Investigators and key project team members under the National Major S&T Projects, National Key R&D Programmes, or STI 2030 Major Projects should not exceed two. Principal Investigators of ongoing projects (including tasks or topics) under the National Major S&T Projects, National Key R&D Programmes or STI 2030 Major Projects, should not withdraw from projects (including tasks or topics) currently undertaken due to applications for projects under the National Key R&D Programmes. In principle, during the project implementation, after withdrawal from the project team, principal investigators and key members of ongoing projects (including tasks or topics) of the National Major S&T Projects, National Key R&D Programmes, and STI 2030 Major Projects, cannot lead or participate in the applications for new projects under the National Key R&D Programmes.
Ongoing projects (including tasks or topics) with implementation durations (including those extended) until 31 December 2020, and projects with allocated national budget of less than RMB 4 million under the Inter-governmental STI Cooperation Special Programme are not covered by the project number limit.

5) Experts that participated in the formulation of the application guide of the current year cannot apply for projects under this Guide.

6) Scientists of foreign nationalities recruited by Chinese mainland entities and scientists from Hong Kong, Macao and Taiwan can be Principal Investigators. Employees under full recruitment conditions should provide valid full recruitment documentations issued by the Chinese mainland employers, while employees under part-time recruitment conditions should provide valid recruitment documentations issued by both employers, which should be submitted together with the proposals.

7) Foreign participants in a project should designate one foreign leader. The foreign leader shall work at least 6 months per year in the foreign institution and shall hold senior R&D positions (equivalent to positions above deputy senior professional technical positions in China, or in charge of technology and product R&D), or PhD degrees, with high international academic reputation and scientific research level. The project foreign leader should participate in the project based on his/her host institution and should provide relevant proof documentations issued by the institution (proof of employment, cooperation agreement or intentional agreement, memorandum of understanding, certificate letter or clear indication of the job title of the foreign leader in the cooperation agreement should be provided in annex).

8) In principle, once project proposals are received, applicant entities and principal investigators cannot be changed.

9) The cooperation parties should have a clear agreement or intentional agreement on the future attribution of intellectual property rights (IPRs) and the attribution of achievement conversion benefits, in compliance with the relevant provisions of the laws and regulations of China on the attribution of IPRs and the achievement of conversion benefits. (agreements or intentional agreements on IPRs, memorandum of understanding, certificate letter or relevant provisions on IPRs in cooperation agreements should be provided in annex)

10) Please refer the application guide for detailed application requirements.

5. Submission of proposals

Online submission: Paperless application. Applicant entities are kindly requested to strictly follow the national and local epidemic prevention and control requirements, innovate working methods, make full use of video conferences and online office platforms to form R&D teams, reduce gatherings, and submit online proposals via the National S&T Information System (http://service.most.gov.cn). CSTEC will organise administrative checks and project evaluations based on the proposals submitted online. Annexes requested in the submissions should be scanned and uploaded. If unable to do so due to the epidemic, applicants should provide and upload scans of explanatory notes. CSTEC shall notify the applicants to provide later taking into consideration of the situation.
The online submission will be open from 8 July 2020 08:00 to 31 August 2020 16:00.

Recommendation organisations are requested to confirm the recommended projects and upload scans of the recommendation letters with official stamps via the National S&T Information System before 7 September 2020 16:00.

Technical inquiries:
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I. Overall objectives

Public health security is a common challenge faced by mankind and requires all countries to work together. At present, COVID-19 has appeared in many countries. To strengthen international cooperation in scientific research on the epidemic prevention and control, international cooperation projects are to be arranged, with the objectives of enhancing scientific research cooperation on drugs, vaccines, testing, and Chinese medicines with relevant countries, in particular those with high number of outbreaks, as well as international organisations, and sharing research data and information, so as to jointly resolve the key difficult scientific issues in epidemic prevention and control and contribute to building of a human community with a shared future.

II. Directions and requirements

In 2020, 11 research tasks will be deployed in four directions targeted at drugs, vaccines, testing reagents and Chinese medicines in fighting against COVID-19. The total number of projects to be supported will not exceed 37, with planned national budget of RMB 100 million. The project duration shall not exceed two years.

Projects shall be implemented in line with the research directions provided in level-2 headings (e.g. 1.1) of this guide. No tasks (or topics) will be set up under projects. Research content and implementation cycle of the proposed project should correspond to the relevant content in the cooperation research agreement signed with the foreign partner. The research content of the proposed project should cover all the research content and fulfil corresponding indicators provided in the guide. The total number of Chinese participants in each project shall not exceed 10. Details are the following.

1. R&D for anti-COVID-19 drugs

Drug type: joint R&D on anti-viral drugs, immunotherapy drugs, and antibody drugs

1.1 International multi-centre clinical study on COVID-19 drugs

Research content: Through international multi-centre clinical studies, safety and effectiveness of candidate drugs will be verified, aiming for registration for market.

Number of projects to be supported: not exceeding 5 projects

Related instructions:

1) Clinical studies aiming for market registration should be led by enterprises. Clinical studies initiated by research institutions could be led by research institutions or enterprises.
2) The fund for projects led by enterprises shall mainly come from enterprises, to be supplemented by the national allocated budget. The national allocated budget applied for cannot be more than 25% of the total project budget.

3) When the proposal is submitted, the candidate drug to be tested should have obtained the clinical approval for the COVID-19 indications from the drug regulatory authority of at least one country (China or partner country). Clinical research carried out in newly added countries during the implementation of the project must be approved by the State drug administration of the country where the clinical research is located. If it involves international multi-centre clinical study of COVID-19 combined medicine, the combined medicine scheme should meet the relevant requirements of China and partner countries on clinical research.

1.2 Preclinical International Cooperative Research on anti-COVID-19 drugs

Research content: Through preclinical research, anti-COVID-19 drugs will be filtered and selected. When a proposal is submitted, the anti-virus drugs and antibody drugs should have been screened in vitro and animal experiments and have demonstrated good anti-COVID-19 activities.

Assessment indicators: According to drug registration requirements, complete pre-clinical research and submit applications for drug clinical trials to the drug regulatory authorities of China or partner countries.

Number of projects to be supported: not exceeding four projects.

2. Vaccine R&D

2.1 COVID-19 vaccine international multi-centre clinical studies

Research content: Where conditions are available for clinical studies (laboratory research and pilot studies have been completed, quality control methods have been initially established, basic data are available on animal safety and effectiveness evaluation), carry out international multi-centre clinical studies for COVID-19 vaccines, aiming for registration for market. Support COVID-19 vaccine Phase I, Phase II and Phase III international multi-centre clinical studies. Priorities will be given to vaccines that have completed Phase I and Phase II clinical studies to carry out international multi-centre clinical studies and new drug registration as well as WHO PQ certification.

Number of projects to be supported: not exceeding eight projects

Related instructions:

1) Clinical studies that aim for registration for market should be led by enterprises. Clinical studies initiated by researchers could be led by research institutions or enterprises.

2) The fund for projects led by enterprises shall mainly come from enterprises, to be supplemented by the national allocated budget. The national allocated budget applied for cannot be more than 25% of the total project budget.
3) When the proposal is submitted, the candidate vaccine for test should have obtained clinical approval or been filed in record (applicable only for record filing countries) by the drug administration of at least one country (China or partner countries). Clinical research carried out in newly added countries during the implementation of the project must be approved by the State drug administration of the country where the clinical research is located.

2.2 International cooperation study on key technologies for COVID-19 vaccine international quality evaluation

Research content: Carry out research on evaluation technologies for key quality indicators of COVID-19 vaccine R&D, and establish scientific, normative and standardized international standards for antigens, antibodies and vaccines and corresponding quality standards. Jointly conduct research on evaluation method of the effectiveness of COVID-19 vaccines with WHO and other international organisations.

Number of projects to be supported: not exceeding two projects

Related instructions: In principle, only one project will be supported. If the evaluation results of the first two proposals are similar, and the technical routes are obviously different, the two projects will both be supported.

2.3 New adjuvants-based vaccine R&D and international cooperation

Research content: Carry out international cooperation research on COVID-19 vaccines using new adjuvant. Establish international quality evaluation methods and quality standards for new adjuvants. Establish evaluation methods and standards for adjuvant vaccines.

Number of projects to be supported: not exceeding two projects

Related explanations: In principle, only one project will be supported. If the evaluation results of the first two proposals are similar, and the technical routes are obviously different, the two projects will both be supported.

2.4 International cooperation in basic research related to vaccine R&D

Research content: To include one or more items of the following: immunopathological mechanism, animal model, antibody-dependent enhancement (ADE) etc.

Number of projects to be supported: not exceeding three projects

3. Test reagents

3.1 International cooperation research on new technologies and new methods for COVID-19 detection
Research content: International joint R&D on fast, accurate and automated testing technologies and methods, including one or more items of the following: performance improvement of key raw materials (e.g. more efficient enzymes, antibodies, etc.), core component development (e.g. sensors, microfluidic chips etc.), new detection principles and methods, etc.

Number of projects to be supported: not exceeding four

3.2 International joint R&D on reagents and equipment for rapid on-site automated nucleic acid detection

Research content: Through international cooperation and joint R&D, break through the limitations of existing nucleic acid detection technology on personnel/places, improve the sensitivity of nucleic acid detection, shorten the detection time, improve the convenience, and realize rapid on-site automated nucleic acid detection

Assessment indicators: Detection scenario: on-site, rapid, accurate, portable, high-throughput. Inspection process safety: convenient sampling and no risk of pollution leakage. Detection time: the entire process does not exceed 30 minutes. Detection accuracy: detection sensitivity reaches below 300 copies/ml. Detection reagent: can be promoted on a large scale and has a complete supply chain. Time to obtain registration certificate: within 3 months after project establishment. Degree of automation: Integration, high level of automation, and can realise "sample in, result out". Technology maturity: the principle prototype has been completed.

Number of projects to be supported: not exceeding two projects

Related instructions:

1) The project should be led by an enterprise with a good pre-research basis and strong industrialization capabilities. The proposal should be jointly submitted with clinical institutions that can provide samples. Cooperation between industries, universities, research, medical and inspection institutions is encouraged.

2) When the proposal is submitted, test results of real COVID-19-infected pneumonia clinical specimens should be provided.

3) In principle, only one project will be supported. If the evaluation results of the first two proposals are similar, and the technical routes are obviously different, the two projects will both be supported.

3.3 International cooperation research on high-sensitivity, high-throughput integrated solution for COVID-19 detection

Research content: International cooperation research on scaled, standardised, informational and automated testing platforms for COVID-19, form a complete and integrated solution for pathogen detection, realize virus screening with high sensitivity and high throughput.

Assessment indicators: can realize batch testing of samples, average daily detection flux is not less than 10,000 cases, detection sensitivity reaches below 200 copies/ml. The test
platform construction cycle does not exceed 2 weeks. Comprehensive solutions can be quickly replicated and extensively promoted. The test conditions meet the relevant requirements of biosafety management and hospital infection management. Strictly distinguish between clean areas, semi-contaminated areas, and contaminated areas, complete with biological safety facilities, and areas for medical waste disposal and storage.

Number of projects to be supported: not exceeding two projects

Related instructions:

1) The project should be led by an enterprise with a good pre-research basis and strong industrialization capabilities.

2) In principle, only one project will be supported. If the evaluation results of the first two proposals are similar, and the technical routes are obviously different, the two projects will both be supported.

4. Chinese medicine

4.1 International cooperation research on the mechanism of the effect of Chinese Medicine in treating pneumonia caused by COVID-19

Research content: cooperate with high-level foreign research institutions on selected prescriptions or proprietary Chinese medicines with clinical evidence for the treatment of COVID-19 pneumonia, reveal the mechanism of the effect of traditional Chinese medicine in the treatment of COVID-19 pneumonia, consolidate the scientific basis of traditional Chinese medicine application, and promote global recognition of traditional Chinese medicine.

Number of projects to be supported: not exceeding three projects

4.2 International cooperation research on the treatment of COVID-19 pneumonia with Chinese medicine

Research content: Focusing on the prescriptions or proprietary Chinese medicines that have been included in China's diagnosis and treatment guidelines, cooperate with foreign high-level scientific research institutions on clinical studies on the treatment of COVID-19 pneumonia. Through international multi-centre clinical research, evaluate the effectiveness and safety of drugs, form high-level evidence-based proofs, clarify the key links affecting clinical efficacy, form an optimized clinical treatment plan that can be promoted and applied, and make efforts to achieve product registration and marketing. Focus on clinical research for the treatment of light and ordinary patients.

Number of projects to be supported: not exceeding two projects

Related instructions:

1) Clinical studies aiming for registration for marketing should be led by enterprises. Clinical studies initiated by researchers can be led by research institutions or enterprises.
2) The budget for projects led by enterprises should mainly come from enterprises, to be supplemented by national allocated budget. The national allocated fund applied for should not exceed 25% of the total project cost.

3) When the proposal is submitted, the experiment Chinese medicine should have submitted the clinical research application for the COVID-19 pneumonia indication to the national drug regulatory administration where the clinical research is located. The clinical research carried out during the implementation of the project must be approved by the national drug regulatory authority of the partner country.

4) For drugs containing toxic plant ingredients, the dosage should be readjusted in accordance with the provisions of the Pharmacopoeia of the People's Republic of China and meet the requirements of the drug regulatory regulations of the partner countries.
2020 Application Guide for International Cooperation
Projects in response to COVID-19

Administrative check requirements

Project proposals should meet the following administrative check requirements.

1. Requirements on filling up the application form

1) The content in the project proposal should comply with the directions provided in the Guide.

2) The project proposals and annexes should be filled up in complete as requested in the templates.

2. Eligibility conditions of applicants

1) Principal investigators should be born after 1 January 1960 and should hold senior professional titles or PhD degrees.

2) Scientists of foreign nationalities recruited by Chinese mainland entities and scientists from Hong Kong, Macao and Taiwan can be Principal Investigators. Employees under full recruitment conditions should provide valid full recruitment documentations issued by Chinese mainland employers, while employees under part-time recruitment conditions should provide valid recruitment documentations issued by both employers, which should be submitted together with the project proposals.

3) Principal Investigators can only submit for one project. Principal Investigators of ongoing projects (including tasks or topics) under the National Major S&T Projects, National Key R&D Programmes and STI 2030 Major Projects cannot lead project applications. Principal Investigators of ongoing projects (excluding leaders of tasks or topics) under the National Key R&D Programmes and STI 2030 Major Projects cannot participate in project applications either.

Experts that participated in the formulation of this Guide cannot apply for projects under this Guide.

4) Good integrity status, no records of severe research dishonesty in disciplinary enforcement nor relevant social credit "black list" records.

5) Public service staff (including those undertaking S&T programme administration functions) in central and local government agencies cannot apply.

3. Eligibility conditions of applicant entities

1) Legal person entities such as research institutes, universities and enterprises registered in Chinese mainland. Government agencies cannot lead or participate in applications.

2) The time of registration should be prior to 31 May 2019.
3) Good integrity status, no records of severe research dishonesty in disciplinary enforcement nor relevant social credit "black list" records.

4. Please refer to the specific instructions on other administrative check requirements defined in this Guide.

Persons in charge of administrative checks: Yun Tao, Li Shanshan
## List of Experts for Guide Formulation

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