

Request for Applications (RFA):

Establishment on an International Technology Platform for Influenza Vaccines

In line with national government efforts and the WHO Global Action Plan related to pandemic influenza preparedness and planning, the World Health Organization (WHO) intends to facilitate acquisition of capacity by developing country manufacturers for the domestic production of human H5N1 influenza vaccines (or other vaccines derived from influenza strains of pandemic potential). The long-term objective of this project is to mitigate the anticipated global shortage of influenza vaccines in the event of an influenza pandemic. In order to enable developing country manufacturers to access the appropriate know-how, WHO proposes to establish a technology platform which will allow transfer to developing country manufacturers of a single robust production process as well as of all relevant documentation including Standard Operating Procedures (SOP), Batch Process Records, validation procedures, analytical methods and release criteria. The production process is to be for the production of inactivated whole-cell vaccine on eggs. Funding is available initially for a one year grant to put together a package of technology which could be subsequently transferred to interested developing country manufacturers. It is envisaged that further funding will become available in the future to continue this project with preclinical and clinical development.

Applicants are invited to submit letters of intent to the WHO indicating their interest in, and plans for, establishing a robust transferable process for the manufacturing of egg-based whole-cell inactivated vaccine candidates. Letters of Intent will be reviewed by an expert committee which will prepare recommendations to the WHO secretariat. Applicants whose proposals are assessed as meeting all requirements of this RFA will be invited to submit a full proposal. Successful candidates for the full grant will receive up to a maximum of US\$ 2,500,000 for activities for a one year project.

ELIGIBILITY INFORMATION

This funding opportunity is open to public or private entities, if they meet the following eligibility requirements:

- Have an acceptable virus handling facility in compliance with WHO biosafety guidelines for the production of human pandemic-influenza vaccine and National Regulatory Authority guidelines on current Good Manufacturing Practices (cGMP) for vaccine manufacturing;
- Have capacity to work with genetically modified organisms;
- Have a documented experience in transferring vaccine production technology to a developing-country manufacturer;
- Preference will be given to candidates who
 - provide evidence of strong manufacturing related quality assurance capacity;

- demonstrate convincingly how the project would be sustainable and how the institution would be able to engage into technology transfer for at least 5 to 10 years in the absence of funding by the WHO;
- are currently engaged into production of influenza vaccines or have in-house industrial knowledge of influenza vaccine production processes.

Investments allowed under the proposed grant agreements:

The grants provided to selected institutions will be used to develop capacity at pilot-plant level (10,000-100,000 eggs pilot-plant capacity) for pandemic influenza vaccine development and will cover the following activities:

- Modification of virus-propagation facilities to enable pilot plant scale production
- Equipment of the facilities with relevant specific equipment;
- Salaries, reagents and equipment to undertake pandemic influenza vaccine process development, to develop and validate Quality Control tests (QC), to write relevant SOP and develop validation procedures for essential equipment;
- Preclinical GLP immunogenicity, efficacy and toxicology studies of vaccine produced using the process developed by the institution;
- Conduct of QC and stability studies on the vaccine;
- Hiring of experts to assist in influenza vaccine production technology-transfer process.

The influenza vaccine production technology that is eligible for funding under the proposed award consists of egg-based killed whole virus influenza vaccine.

Proposal details

Letters of intent should include the following elements (maximum four pages length for all the following items):

- Identification of the institution and responsible persons with full contact information.
- Evidence of prior experience in transferring vaccine production technology to another manufacturer;
- Existing human vaccine production capacities and proof of approval by national regulatory agency.
- Evidence of prior experience with influenza vaccine manufacturing.
- Evidence of ability to handle pathogenic organisms according to internationally acceptable biosafety guidelines.
- Evidence of capacity to handle genetically modified organisms for vaccine production according to WHO guidelines.
- An outline of the institution's interest in engaging over the medium-long term into technology transfer activities with developing country vaccine manufacturers for the production of pandemic influenza vaccine, and a preliminary identification of potential additional funding sources to ensure sustainability of this goal.

The full grant proposals submitted by successful candidates in response to their LOI will be evaluated based on the following criteria :

- Project Plan
- Staffing and Management Plan
- Performance Measures
- Understanding of Operational Tasks.

Interested institutions are invited to submit their Letter of Intent to WHO by 15 August 2007 at the latest, addressed by electronic mail only at the following E-mail address:

palkonyayl@who.int

WHO reserves the right to freely decide on the selection of those applicants who will be invited to select a full proposal and on the selection of the successful project, in WHO's sole discretion, and without having to provide any justification to applicants who will not be so invited. WHO will advise only those applicants who have been selected, and the selection process will not be subject to any claims or appeal.

Additional information may be requested from:

Initiative for Vaccine Research
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(1) " Developing Country" means any country other than Andorra, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Monaco, the Netherlands, New Zealand, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, the United Kingdom, and the United States of America. For the purpose of this Request for Proposals the status of any republic, previously included in the former Union of the Soviet Socialist Republics and the former Federal Socialist Republic of Yugoslavia, as well as Albania, Bulgaria, the Czech Republic, Hungary, Poland, Romania, and the Slovak Republic, shall be determined by the first document emanating from the United Nations system classifying or listing it as either a developed, a developing, or least developed country. Republics classified or listed in such document as a developing or least developed country shall be deemed as a Developing Country under this Request for Proposals.