HIV/AIDS Vaccine: Indian Council of Medical Research

This HIV/AIDS initiative is a collaborative venture between the Indian Council of Medical Research (ICMR), New Delhi, the International AIDS Vaccine Initiative (IAVI), New York, National AIDS Control Organization (NACO/Indian Ministry of Health), New Delhi and Therion Biologics, Cambridge, Mass. The project aims to develop a safe and effective HIV/AIDS vaccine—such development has been mandated by the Indian government—for India and other developing countries. The vaccine has now been developed by ICMR in collaboration with Therion and is undergoing clinical trials.

Under the terms of this public-private partnership (PPP), ICMR will provide technical expertise, obtain all necessary permissions and permits, conduct R&D to develop the vaccine in collaboration with Therion, prepare the community (in India) for clinical trials, and conduct the trials. ICMR will select an Indian partner for the manufacture of vaccine and has overall responsibility for ensuring that the project is executed according to its objectives. NACO will facilitate the execution of the project. IAVI will support the project, facilitate development of an appropriate vaccine through transfer of technology from Therion, engage in capacity building and advocacy, and facilitate technology transfer for the local manufacture of the vaccine. Therion will assist ICMR with the vaccine development and help transfer technology to the selected Indian manufacturer.

The project involved an overall agreement between ICMR and IAVI, a patent and technology transfer agreement between ICMR and IAVI, and an IP (intellectual property) rights and confidentiality agreement between ICMR and Therion Biologics. A project management committee was set up, comprising representatives from ICMR and IAVI, to coordinate and monitor all activities and assessments of the R&D programs. The committee is also responsible for strategic IP management.

All new intellectual property generated will be jointly held by IAVI and ICMR, and the Indian government shall have the exclusive right to use all patent and other new IP rights to inventions arising out of the program to benefit India and its neighboring countries. The ICMR will grant nonexclusive royalty-free and sublicensable licenses to all new intellectual property arising out of the project to selected third parties in order to make, use, sell, and import the HIV/AIDS vaccine in countries other than those indicated in the agreement (to the extent ICMR has the right to permit this use). The IAVI shall have IP rights for rest of the world.

Initially, the program was to be implemented only in India, but the Government of India, realizing that the program could benefit other developing countries as well, asked for licensing rights. In arriving at this realization, policymakers (bureaucrats) of the government needed to be educated about intellectual property and its role in technology transfer. This case has highlighted the importance of keeping government officials involved in order for an international PPP to be successful.

Although no patents were filed in India, a significant amount of clinical trial data was generated. From an IP perspective, it was crucial to recognize private sector interests. Therion has global rights for the technology needed for the vaccine construct, but India

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will have rights to improvements made to the vaccine. Therion's stringent IP regulations meant confidentiality agreements were imposed on collaborating scientists, which the Government of India appreciated.

The recruitment process for the vaccine trials envisages serious ethical concerns as well as potential liability issues, as the vaccine is for HIV/AIDS. It was recognized that clinical trials must be conducted in a fair and transparent manner and the interests of participants protected through informed consent as per the ICMR's Ethical Guidelines and that all necessary safeguards to protect subjects of the study had to be built into the system.

The case study recognizes (1) the role of "honest broker" that international nongovernmental organizations like IAVI can play in a PPP, providing funding and access to high technology from a private company; (2) the need to educate policymakers (bureaucrats) from the beginning of a project to ensure smooth progress; and (3) the equally crucial need to involve policymakers, lawmakers, politicians, women's associations, and other civil society organizations in the execution of such projects that envisage clinical trials. This project is offered as an example of productive North–South collaboration and broad capacity building and a partnership in which the strengths of the partners complement each other.

TYPES OF AGREEMENTS

As part of the HIV/AIDS project, ICMR entered into the following types of agreements:

- an overall agreement between the ICMR and the IAVI for the entire project including provisions for development, upscaling, manufacture, and distribution of the vaccine in India, neighboring countries, and the rest of the world
- a separate technology transfer and manufacturing agreement between Therion and the manufacturer identified jointly by IAVI, the Government of India, and Therion

IP RIGHTS DECISIONS AND IP MANAGEMENT

The project has resulted in the following arrangements with respect to IP rights and strategic IP management issues:

- IAVI and the Government of India-ICMR will jointly hold the new intellectual property generated during the project.
- The Government of India-ICMR shall have exclusive rights to use all patent and other new IP rights to inventions arising out of the program in India and neighboring (SAARC) countries.
- ICMR grants IAVI a nonexclusive, worldwide, royalty-free sublicensable license to all new patents and other intellectual property arising out of the program that would permit IAVI or third parties selected by IAVI to make, use, sell, offer for sale, and import HIV/AIDS vaccines in countries other than those indicated in the agreement (to the extent ICMR has the right to permit the use of the same).
- Intellectual property is jointly managed by the ICMR and IAVI through the project management committee.

POLICY IMPLEMENTATION

Policy is implemented through a project management committee comprising representatives from the IAVI, ICMR and NACO, and jointly chaired by members appointed by ICMR and IAVI. The committee is responsible for the coordination and monitoring of all activities, periodic assessments and updates, and refinements and revisions of the R&D program.

EXTERNAL FACTORS THAT AFFECTED DECISION MAKING

A number of external considerations influenced ICMR's strategies and decision making. These include:

- the potential use of the vaccine(s) in India's neighboring countries
- the need to provide an effective and affordable vaccine to the people

KEY LESSONS LEARNED AND HEALTH-ACCESS ISSUES

The following items represent key lessons from ICMR's HIV/AIDS vaccine project, which may be applicable to other entities that aim to utilize intellectual property:

- Only through strategic public-private partnerships can such ventures succeed.
- Private sector's interests need to be considered.
- The role of an international nongovernmental agency such as IAVI is important and vital for the success of such a project.
- There is a need to educate government officials on issues relating to IP rights and technology transfer, as the government's role is crucial in the clearance and approval of projects of national interest.
- The importance of (1) ethics in carrying out clinical trials and (2) the need to involve policymakers, women's associations, and other civil society groups in the execution of the project cannot be overstated. ■

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