11 Public- and Private-Sector Biotechnology Research and the Role of International Collaboration

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Abstract

International collaboration plays an essential role in building capacity in developing countries for making research, management, and policy decisions for biotechnology. This chapter analyzes the design and implementation of an international initiative in biotechnology undertaken by a bilateral development agency. It describes the project's origins, how priorities were set, innovative mechanisms for supporting commercial research, and the way in which final proposals were solicited and selected. It highlights the associated managerial, oversight, and funding issues faced by the agency during this process with regard to stimulating public-private sector partnerships.

Introduction

A major challenge for international development agencies is determining effective means to link the needs of farmers and other beneficiaries with an increasing array of applications in agricultural biotechnology. Assessing new projects raises questions of organizational and departmental priorities as well as agency strategies and funding limitations. More recently development agencies have also reviewed their role in enhancing efficiencies between public and private research organizations. Agencies supporting biotechnology need to consider internal capabilities such as the capacity to provide significant technical, managerial, and regulatory oversight for relevant projects, and the commitment of financial resources once such research projects are approved.

This chapter examines the design and implementation of a collaborative project in biotechnology, undertaken by the United States Agency for International Development (USAID) through its Office of Agriculture. The objective of this paper is to analyze the decision-making process that was used to develop this bilateral initiative in biotechnology. It highlights the following critical steps taken during the process:

- securing USAID's commitment and financing for a priority setting exercise that tapped developing-country and international expertise, and making recommendations from the exercise available for peer review, with final results published for wider dissemination and transparency

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- developing opportunities for funding public and commercial research partnerships with national and private-sector organizations in developing countries
- enhancing USAID's internal capability to manage and provide oversight for a new initiative in plant biotechnology
- integrating the technical dimensions of biotechnology with respective policy considerations regarding biosafety, intellectual property rights (IPR), and internships for training in these areas.

Project development – lessons learned from project evaluation

The Tissue Culture for Crops Project

Developing the new biotechnology project began with a review of USAID's first major initiative in plant biotechnology: the Tissue Culture for Crops Project (TCCP). Beginning in 1984 and implemented from Colorado State University, the TCCP sought to (1) develop methodologies for improved stress-tolerant germplasm in several cereal and legume crops, (2) train scientists from developing countries in the project's methodologies, and (3) form an international network of scientists working on plant biotechnology.

The main research methodology applied in the TCCP project involved the in vitro selection of cells tolerant to various stresses (insects, salinity, acid soils, and drought) in rice, wheat, and sorghum. Regenerated lines were tested under both field and greenhouse environments to verify stress tolerance and to determine efficiency of in vitro selection. Teams of scientists from US universities, research centers of the Consultative Group on International Agricultural Research (CGIAR), and developing-country collaborators conducted this research.

A 1998 external review and evaluation of the TCCP project concluded that with the methodology applied and the institutions involved, the ability to successfully derive germplasm tolerant to the selected complex range of abiotic stresses was limited. A few notable exceptions occurred, including the registration and release of sorghum germplasm with improved tolerance to fall armyworm and to acid/aluminum soil conditions. These successes, however, were not on the scale expected, nor did they verify the methodologies being employed. The evaluation further identified management issues as follows:

> "There has been some ambiguity and resultant confusion regarding the purpose of the TCCP, the research hypothesis to be tested, and the methodology to be employed in validating it. This has contributed to some of the management and communication problems that are now being resolved by the concerted efforts of both parties. Less than adequate management performance has been manifested by poor and late reporting to [USAID]; static and untimely work planning; insufficient emphasis on producing outputs; inefficient use of outside advisory expertise; and missed opportunities to involve [USAID] and Colorado State University in joint, substantive decision- making." (USAID 1991).

Other problems with the project's design also became apparent. The project was based on tissue culture methodologies from which agronomic variation was expected. However, the bulk of the financial and human resources in the project focused on laboratory procedures, leaving few resources for field-testing and confirmation of agronomic fitness. Also, the project as conceived relied exclusively on in vitro technologies and did not account for advances in genetic engineering. Finally, difficulties existed in moving from model

systems in the lab to germplasm with agronomic importance to developing-country farmers. In summary, the evaluation of the TCCP project highlighted the need for an integrated research initiative, with resources equally distributed between in vitro and conventional agricultural research, emphasizing the need to confirm agronomic performance.

Considering the context

The evaluation of TCCP was the starting point for developing the new project. However, three trends affecting agricultural research and biotechnology emerged after TCCP had begun. These were incorporated into the context analysis for the new project:

1. **Increased importance of IPR and commercial opportunities in agricultural research.** As project development began, public and private research collaboration in the USA was increasing, responding to national laws regarding availability of patents from federally sponsored research. Universities began filing for patents to effect technology transfer through private-sector product development. Previously, publication of nonpatented information critical for product development and commercialization could result in the loss of (foreign) patent rights and additional revenues. Patents became one tool used to protect university-based research, secure industrial support for university research, and raise awareness of the usefulness of university findings (Nelson 1998).
2. **Need for biosafety review and regulation in developing countries.** The production of transgenic crops called attention to the need for biosafety protocols and regulation in developing countries. As international collaboration increased, enhanced national capabilities in biosafety helped ensure that these countries participated in and benefited from technology exchanges. Special efforts were needed from the international research community to develop this capability and to ensure appropriate regulatory review.
3. **Increased emphasis on sustainable agriculture in USAID projects**[1]**.** USAID began designing a new project in sustainable agriculture at the same time as it considered biotechnology. The increased emphasis on sustainability, which became more apparent after the 1992 United Nations Conference on the Environment and Development, affected USAID's perceptions for projects using biotechnology. Sustainability discussions raised questions as to whether new technologies contribute to broader views of the agricultural system, such as natural resource management.

Preparatory steps

After analyzing these trends, USAID sought to benefit from experiences gained from developing projects within and outside the agency. At this point, it had four options:

1. extend the agreement with Colorado State University for another three to five years to address issues coming out of the evaluation, with the project left under prior management

[1] Sustainable agriculture, as used here, defines a system that meets rising demands for food at economic, environmental, and other social costs consistent with rising welfare of the people served by the system.

2. undertake a thorough review of the need for alternatives in plant biotechnology, which might lead to advertising for and awarding a new project
3. undertake biotechnology in a more limited manner through ongoing projects, which would mean that an additional project was not justified
4. drop biotechnology in favor of other pressing needs confronting the USAID.

After internal consultation, USAID decided to pursue option 2, raising the first key management challenge. This required securing commitment and financing for a formal priority-setting exercise that would provide for peer review, involvement of international and developing-country expertise regarding plant biotechnology, and the publication of results.

Setting priorities: consulting with public, commercial, and developing-country representatives

Prior to designing an international biotechnology program, an assessment of the needs, constraints, and priorities and the potential impact of biotechnology on the agricultural system should be conducted. There are many ways of doing this, as shown in chapters 4 and 5 of this book and in other volumes (Cohen and Komen 1994; Toenniessen and Herdt 1989; CTA/FAO 1990). Setting priorities helped ensure that eventual research programs would address relevant productivity constraints in developing countries.

It was suggested that USAID use a more rigorous analysis for setting priorities and determining constraints than it had done in the past. It was also agreed that a panel of experts would undertake an external consultation. Convened by the National Research Council (NRC) and funded by USAID, the panel would analyze innovations in biotechnology expected in the coming three to five years that could benefit developing-country agriculture. The panel included members from national agricultural research organizations in developing countries, private industry, universities, CGIAR centers, the United States Department of Agriculture (USDA), and the Rockefeller Foundation. At its first meeting in September 1989, the panel identified priority areas in biotechnology that are sufficiently advanced to support collaborative initiatives between US and developing-country scientists.

As an initial step in the priority-setting process, panel members received background materials, including summaries of priorities made by some of the panelists, recommendations from two prior meetings on agricultural biotechnology, and a number of related reports. The chairman collected potential research activities on an individual basis, each activity addressing how it would "improve agriculture significantly in developing countries." These were ranked using a modified scoring technique (NRC 1990). The number of initial suggestions was reduced to eight by eliminating duplicates, combining closely related ideas, and disregarding projects that were likely to exceed the three- to five-year target and those that did not fit within USAID's mandate. The final grouping was circulated to panelists unable to attend the meeting and to outside experts who had peer-reviewed the report.

The panel's report (NRC 1990) found a distinct need for a collaborative biotechnology program encouraging developing-country researchers to focus on critical problems of local importance. Institutional priorities that were identified included the following:

- **Biosafety.** USAID should assist developing countries in implementing and monitoring appropriate biosafety regulations.
- **IPR.** USAID should participate in developing policies to promote cooperation in IPR.
- **Human resource development and networking.** USAID should enhance biotechnology capabilities through doctoral and postdoctoral fellowships.

The scientific recommendations for biotechnology were divided into three categories representing the most promising near-term applications of biotechnology to agriculture:

- **Tissue culture, micropropagation, and transformation.** The panel recommended that USAID support the building of developing-country capacity in plant tissue culture technologies, including micropropagation, cell selection, embryo rescue, and haploid techniques to augment conventional plant improvement programs. They also advocated improved ability to use micropropagation for production of virus-free planting material. USAID was also urged to support the development of transformation and regeneration technologies.
- **Plant disease and pest control.** (1) *Bacillus thuringiensis* strain identification to assist developing countries in identifying and cloning *Bacillus thuringiensis* strains effective against insect pests of importance in tropical areas. These bacteria produce a protein crystal that is selectively lethal to foliage-feeding lepidopterous insects but not to others or to animals and humans. (2) Antiviral strategies: support development of antiviral technologies for plant viruses that attack beans, cassava, sweet potatoes, groundnuts, and tropical fruits and vegetables. (3) Pathogen diagnostics and probes: support research to develop DNA probes, as well as antisera and monoclonal antibody probes for plant bacteria, fungi, and viruses that attack crops of importance in the developing world.
- **Genetic mapping of tropical crops.** This category summarized interest in developing specific genetic maps for major crop plants. It included guidance that USAID should assist CGIAR-center and developing-country crop breeders to acquire the capacity to use restriction fragment generated maps in their plant breeding programs.

Consultations to confirm priorities

USAID favorably reviewed the NRC report and sought broader agreement for the proposed technical objectives and project modalities from national agricultural research organizations in developing countries, in-country USAID offices, and CGIAR centers. Restrictions on available funds eliminated the diagnostic research and genome mapping. The agency agreed on the following:

Mutual benefit

The project would seek to derive mutual benefits from research and commercialization programs for both US and developing-country public- and private-sector participants. This would be achieved by encouraging partnerships that allow institutions to disseminate products of research through either the public sector or the commercial sector.

Proven research, integrated programs, and sustainability

Project proposals were reviewed with a preference to proven applied research integrated with conventional and sustainable agricultural programs that provide for human resource development. The project would *not* provide funds to create new biotechnology centers or move scientific capability out of ongoing agricultural research programs. The limited funds were not to be used for constructing buildings and laboratories or making renovations that required extensive recurrent funding but that had no proven source of revenue. Support was given to research connecting agronomic research at the cell or molecular level with product development.

Integrating biotechnology with sustainable agriculture was regarded as a priority. Biotechnology research results derived from new cultivars would allow farmers to control weeds, insects, and diseases more effectively and with less dependence on chemicals. Research should strengthen biotechnology capabilities in developing countries through postdoctoral fellowships while supporting appropriate training in biosafety and IPR.

Finally, building an integrated approach maximized efforts to relate the field-testing of genetically modified plants with regulatory needs and conditions. This approach would bring together the technical and policy dimensions of biotechnology, providing a learning opportunity for scientists and policymakers in the participating countries.

Multiple partnership mechanisms for germplasm development, including the commercial sector

The project would provide alternative mechanisms for building research partnerships, including public-public, public-private, and private-private (see chapter 22 of this volume). These partnerships provided alternative routes for disseminating improved germplasm, using public-sector institutions such as the national agricultural research system (NARS), university cultivar release programs, international release of germplasm through the CGIAR, and commercial cultivar development. Providing these options increased the means by which products arising from research could reach targeted end users and beneficiaries.

Project design and management implications

One of the recommendations of the NRC report was that proposed project should address a number of significant technical issues. To achieve effective oversight for such a project required the USAID to increase its internal competency in this area. A science and diplomacy fellow was recruited through the American Association for the Advancement of Science. With this additional expertise, USAID was better able to communicate technical matters to its field missions and stakeholders in the international agricultural research community.

The starting point for conceptualizing the project would be to address perceived technical and institutional inadequacies that affect the application of biotechnology in developing-country agriculture. Less developed countries often lack the technical capability, scientific infrastructure, and financial support to apply biotechnology to constraints affecting agricultural production. Privatization of the technology in developed countries, with applications favoring crops of obvious commercial interest, compounds the problem, limiting the ability to access needed technologies and products.

Increasing technical capability alone does not ensure the sustained participation of developing-country scientists in local and global biotechnology research. Another essential component of the project therefore would be a coordinated and integrated effort to strengthen institutional capacity in the management of science. Additional efforts were required to ensure that the technological capability of the institutions, which may be enhanced through the research and technology transfer component of the project, is fully employed. The project document outlined complementary efforts designed to strengthen capabilities in formulating and implementing regulatory policy, intellectual property protection, and, where possible, downstream product development and commercialization of laboratory research results.

These developments led to another managerial challenge for USAID: it did not have necessary expertise in-house to provide regulatory oversight for issues associated with the development of transgenic crops and the policy and management issues identified for the project. It therefore appointed a Standing Committee on Biotechnology to serve as an "institutional biosafety committee," securing appropriate linkages with official US government regulatory bodies and developing mechanisms to ensure that appropriate regulatory review and approval was undertaken in and by the relevant developing countries (Cohen and Chambers 1990). The committee was a novel development, the importance of which has since been recognized by other development organizations, such as the Department for International Development (DfID) in the UK (DFID 1999).

Options for research: public and private

The project put equal weight on designing mechanisms that facilitated the participation of the commercial sector and that allowed federal funding of public- and private-sector research addressing productivity constraints in developing countries. USAID had already had a number of discussions, both internally and with the private sector, on possible collaboration with the private sector, but few developing-country-oriented projects actually stimulated private-sector research. It was hoped that providing adequate funding and management mechanisms would stimulate the interest and resources of private-sector research organizations. To encourage the private-sector organizations to participate, they were made equal partners in project implementation from the start and were able to propose activities in agreement with their particular expertise.

Financial commitments from public and private sources would be needed to support this involvement. It was argued that part of the financial burden must be provided from USAID's development budget, and that the commercial sector should be eligible to compete for funding. Getting the private sector to join in research is one means of gaining access to the expertise and resources of commercial agriculture and applying it to the needs of developing countries. Specific activities were then considered that would enhance capabilities in managing biotechnology research and support the transition of basic laboratory results into products. These activities, which were considered innovations at the time, included the following:

1. establish links with the commercial sector for appropriate technologies developed in the project between US companies and universities and developing-country institutions
2. use internships to raise awareness about the protection of IPR and the development of science-based regulatory policy

3. provide consultants for intellectual property agreements, economic impact analyses, and marketing analyses
4. enable developing countries to participate and network in biotechnology trade associations, such as the Association of Biotechnology Companies
5. coordinate with other USAID projects in plant biotechnology and field missions
6. sponsor three industry-based management seminars
7. provide comprehensive environmental and field analysis of proposed larger-scale field tests in both host countries and the USA

The unique design of the project at the time called for a full-time project manager, a position that was eventually advertised as managing director. The position was to be based at the institution that would be awarded the project. In addition to the managing director, other positions were envisioned to address many of the items above, either separately or in a coordinated training function.

Including the above activities in the project required careful budgeting and ensuring that the budget would not be entirely allocated to support ongoing research. This raised some controversy, as some argued that more of the project's budget be attributed purely to research. However, in the final budget the seven points above were supported through separate line items in the budget, with some only becoming available as research neared the product development phase. Thus, it was ensured that researchers could move towards field-testing and product development as rapidly as possible.

Soliciting and evaluating proposals

The final design of the project was based on the objectives and modalities presented above. Existing international biotechnology programs were analyzed to ensure the current project would be unique and complementary. Once it was established that the proposed initiative would not duplicate other efforts, USAID approved the Agricultural Biotechnology for Sustainable Productivity (ABSP) project. USAID was authorized to provide funding for proposals received from both public and commercial institutions addressing identified constraints on sustainable productivity at the local level in developing countries. Following external peer review of proposals, the project's managing director would coordinate the research.

USAID's call for project proposals had to provide a mechanism supporting alternative routes for technology transfer and delivery of benefits. It was decided to first solicit proposals from public and private nonprofit institutions to address pest- and disease-related productivity constraints and to handle the management and network functions of the project. Following this first round of proposals, commercial institutions were solicited to submit proposals addressing constraints regarding the production of disease-free planting material or the development of germplasm with improved disease or pest resistance, to be distributed through commercial production. After the peer review, USAID would enter into a single cooperative agreement with the institution that submitted the "best" proposal in the first round. USAID would then designate a second award to the commercial sector, to be issued in a subagreement in the following year.

Monitoring and evaluation functions

The institution selected to implement ABSP would also be tasked with establishing a technical advisory group. This group would advise on technical matters and evaluate progress in meeting the objectives and expected outputs. Specifically, it would assist in the following:

- reviewing annual workplans and quarterly and annual reports, as well as recommending additions to or modification and deletion of project components
- consulting with USAID and the ABSP managing director on the management implications of the technical advisory group's recommendations
- arranging the annual review and in-depth evaluation of each component of the cooperative agreement
- securing appropriate persons and resources, in conjunction with the project's managing director, including a financial audit of project expenditures

Establishing the technical advisory group was of fundamental importance because of the managerial complexities expected for the project, the need to monitor regulatory matters, confidentiality and financing implications arising from working with the commercial sector, and having external evaluators available to provide continuity over time. This group would oversee construction of public and private partnerships and evaluate progress on the technical and policy dimensions regarding the project's research.

Project budget: Separating public- and commercial-sector research

Once budget categories are established and the budget is approved, USAID's financial procedures prohibit the movement of moneys between items without formally modifying the agreement. To ensure opportunities for public-private-sector collaboration (indicated as the innovative activities of the project), funding was divided between activities before the project began. The second award for research was to address a different productivity constraint, undertaken by a private-sector or commercial organization.

Agreeing to such segmentation in the budget indicated that USAID was able to provide public moneys for collaborative research with the private sector, as well as for subsequent needs for commercialization. It could also contribute to the equitable protection of IPR by providing funds for legal assistance while developing collaborative research agreements. This also meant that total funding available in the cooperative agreement would be divided between the public and private sectors, with innovative funding available depending on research progress and on the needs associated with structuring public-private agreements.

Award of cooperative agreement

Applications to implement the project were received from public institutions, CGIAR centers, and the private sector. NRC commissioned a number of independent, external consultants to peer-review the proposals and to rate them in terms of technical and managerial merit. The prioritized list of proposals was submitted to USAID, which analyzed the budgets and institutional matching costs. Based on the peer reviews and following agreement from USAID missions and relevant bureaus, the first cooperative agreement for the ABSP project (see figure 11.1) was awarded in September 1991 to

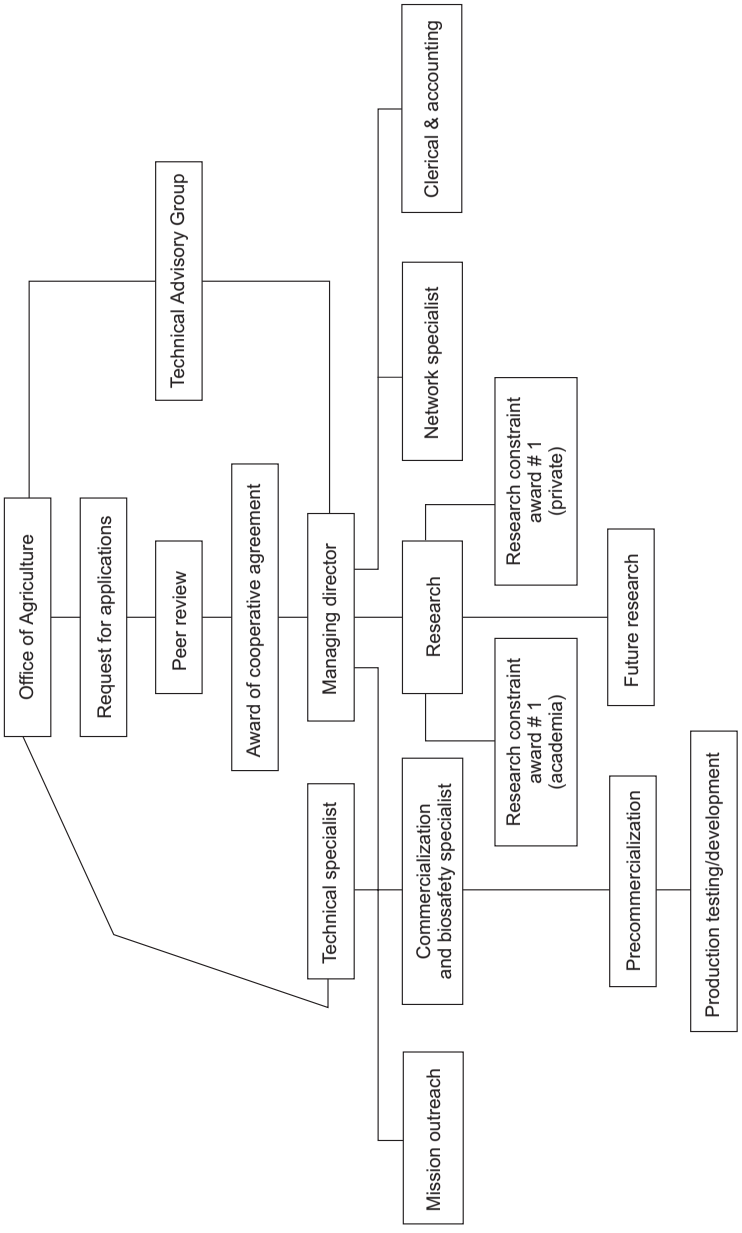

Figure 11.1. Design scheme for the ABSP Project

Michigan State University in collaboration with Kenya, Egypt, Indonesia and Costa Rica. The second cooperative agreement, issued at a later date for the commercial sector, went to DNA Plant Technology, Inc in collaboration with Fitotek of Indonesia and Agrobiotechnologia de Costa Rica.

Conclusions

One of the most important managerial decisions taken was to increase transparency and disseminate USAID's priorities among stakeholders. NRC's review of the panel's report and its publication helped raise awareness and understanding of and reach consensus for the research that the project would undertake. It also laid the foundation for the research to be integrated with relevant policy and managerial capacity building. The time and money invested by USAID for this preliminary work helped build support for the project and its implementation.

The priority-setting process also stimulated discussion on how the project should be awarded. It reinforced the need for consensus and facilitated dissemination of results to developing-country scientists. Its formal publication by the NRC added legitimacy to the project development exercise. It provided confidence in the process to key decision makers, and it provided potential stakeholders from the public and commercial sector with a solid understanding of the proposed objectives.

While developing the project, USAID had to make fundamental choices with regard to its human resources. Managing a long-term biotechnology project implied that it had to enhance its technical expertise in this area. USAID accomplished this by recruiting a senior professional within the Office of Agriculture and using external fellowship programs and interagency exchanges. These individuals helped ensure internal understanding of biotechnology developments within USAID and provide a framework for biosafety and licensing of technology that met with federal guidance.

The project's focus on innovative planning and budget mechanisms helped secure and fund public- and private-sector research partnerships. The mechanisms for including commercial agricultural research institutes have provided many learning experiences, including licensing and IPR agreements (see also chapter 22 of this volume). Public and commercial partnerships allowing for distribution of products to end users were made possible. Both mechanisms are functioning in the current project. Providing such options overcame a major flaw of the previous project: inadequate mechanisms for improved germplasm dissemination. Also, TCCP research was based exclusively at the university and the CGIAR centers, whereas ABSP enriched the supply of available and new technologies by involving the private sector. The project was also designed to ensure that capabilities for biosafety and IPR were developed within the public and private collaborating institutions through a series of internships with regulatory, legal, and university offices.

Applications for project implementation had to be submitted for external peer review. Many private-sector companies, however, are reluctant to share research results with an external review committee. By establishing a long-standing technical advisory committee, thus eliminating the need for one-time or ad hoc reviews by outsiders, USAID helped instill the necessary confidence in companies that research results would be treated confidentially. In this way, external review and guidance could be provided for both public and commercial research activities.

Confidence was also gained with regard to project management, with resources committed to an expanded management and oversight function within USAID, as well as recognition of the need for an overall managing director for the project. Close attention to internal and external management was essential for integrating developments regarding the technical research base of the project with the policy and managerial dimensions posed by such collaborative biotechnology projects. This integration also ensured that related policy matters were not addressed in the abstract, but rather came directly from specific elements of the projects' public and private research partnerships.

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