

Strategic Priorities for Biotechnology Program





Kingdom of Saudi Arabia

King Abdulaziz City for Science and Technology

Ministry of Economy and Planning



Strategic Priorities for Biotechnology Program

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Executive Summary

The National Policy for Science and Technology was approved by the Council of Ministers on 1423 H (2002 G). This national policy defined 11 programs for the development and transfer of strategic technologies that are essential for the Kingdom's future development. The biotechnology program is one of these programs. This strategic plan outlines a direction for the biotechnology program to ensure that it will contribute to the future

development of the Kingdom.

The development of the biotechnology plan is driven by the desire to increase growth in the Saudi Arabian economy and to provide a safe place to live for all members of society. These goals can be achieved through a focused effort on developing and transferring biotechnology research within the Kingdom of Saudi Arabia.

While King Abdulaziz City for Science and Technology (KACST) is in charge of supervising the implementation of the National Policy for Science and Technology, the Natural Resources and Environment Research Institute (NRERI) is in charge of developing and implementing a strategic plan for biotechnology. This plan is to cover the next five years (2008 – 2012) and is to include all applications of biotechnology. This plan was developed after carefully studying the state of biotechnology research and development in the Kingdom. NRERI has prepared this plan with the assistance of biotechnology experts from academic institutions, governmental agencies, and private companies. The involvement of these stakeholders was important to the successful development of this plan. The development of this plan was also supervised by the Center of Strategic Planning at KACST.

Program Vision

After discussions with stakeholders, the following vision was chosen by NRERI for the biotechnology program: "to be pioneers in biotechnology for best life."

Executive Summary



Strategic Objectives

The strategic objectives that the biotechnology program hopes to achieve are:

- Transfer and develop the cutting edge biotechnologies.
- Provide an environment that encourages creativity and investment in the field of biotechnology.
- Direct the applications of biotechnology to achieve health and food safety.
- Use biotechnology to achieve food and health security.
- Protect the environmental resources of KSA through the development of appropriate biotechnology applications and products.
- Strengthen the relationship between the biotechnology program and society.

The priority technology areas that have been identified to be important to KSA are:

- Medical research:
- Chronic diseases.
- Growth and aging diseases.
- Infectious diseases.
- Cancer.
- Cardiovascular diseases.
- Diabetes and its complications.
- Agricultural research:
- Plant breeding.
- Animal breeding.
- Bioproduct production.
- Plant protection.
- Environmental research:
- Microbial biodiversity
- Bioremediation.
- Microbial enhancement.
- Biopolymers.
- Biosensors.
- Fermentation and bioreactors.
- Biorecycling.

Background

Operating under its authority, KACST proposed in 1986 a national policy to develop science and technology and to create the necessary strategies and plans for this purpose. Subsequently, KACST began an inclusive effort in cooperation with the Ministry of Economy and Planning (MOEP) to develop a long-term national policy for science and technology. In July 2002 the Council of Ministers

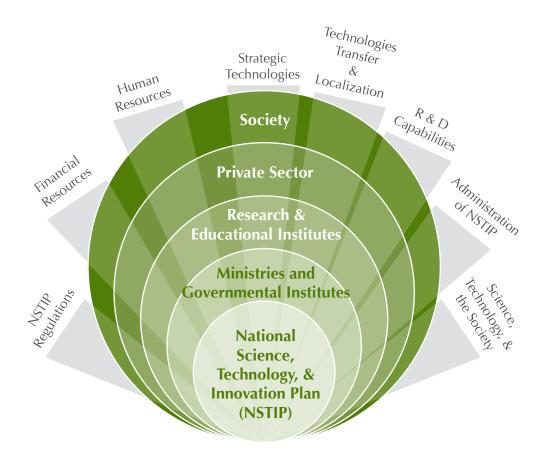
validated the national policy for science and technology under the name of "The Comprehensive Long-Term National Policy for Science and Technology".

KACST and MOEP, in collaboration with relevant stakeholders, developed the national plan for science, technology and innovation (STI) under the framework of the Comprehensive Long-Term National Policy for Science and Technology. The plan outlined the focus and future direction of science, technology and innovation in the Kingdom, with special consideration of the role of KACST, universities, government, industry and the society at large.

The plan encompasses eight major programs, depicted in figure 1, as follows:

- 1. Strategic and advanced technologies.
- 2. Scientific research and technical development capabilities.
- 3. Transfer, development and localizing technology.
- 4. Science, technology and society.
- 5. Scientific and technical human resources.
- 6. Diversifying financial support resources.
- 7. Science, technology and innovation system.
- 8. Institutional structures for science, technology and innovation.

Figure 1: Science and Technology Programs



In the "Strategic Technologies" area, KACST is responsible for 5-year strategic and implementation plans for 11 technologies:

- 1. Water.
- 2. Oil & Gas.
- 3. Petrochemicals.
- 4. Nanotechnology.
- 5. Biotechnology.
- 6. Information Technology.
- 7. Electronics, Communication, & Photonics.
- 8. Space and Aeronautics.
- 9. Energy.
- 10. Environment.
- 11. Advanced Materials.

Each plan establishes a mission and vision, identifies stakeholders and users, and determines the highest priority technical areas for the Kingdom.

Scope

This plan outlines a strategy for biotechnology R&D in the KSA over the next five years (2008-2012). Biotechnology is defined as the technical use of living creatures on the cellular or molecular level to obtain beneficial results. This plan focuses on three major biotechnology applications: medical, agricultural, and environmental. The plan includes only technologies and applications that will ensure that the goals of the Kingdom's national strategic plan are achieved. This plan specifies strategic objectives and defines the role of KACST and other stakeholders in



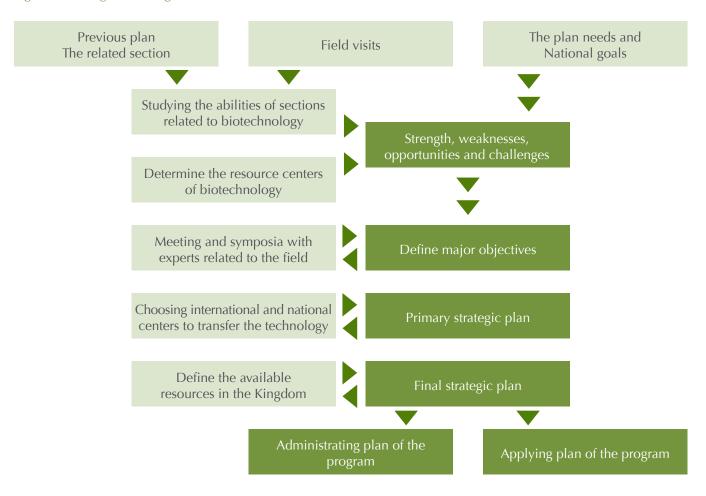
achieving these objectives. The plan also discusses project organization and cooperation with international centers specializing in biotechnology.

The plan is consistent with the goals of the national policy for science and technology. The plan was prepared in cooperation with the Administration of Strategic Planning, which was recently establish within KACST to direct the national science and technology strategy, as well as cooperation from stakeholders in industries, universities, and government agencies involved in strengthening biotechnology R&D in KSA.

Plan Development Process

The development of this strategic plan was guided by a process that was informed by the national policy for science and technology in light of scientific possibilities and current research capabilities. The process helped to identify the biotechnology applications that are the focus of this plan. The process is summarized in figure 2.

Figure 2: Strategic Planning Process



The process outlined above was used to create a plan that was consistent with the vision of the program and with the realities of biotechnology research and development. The development of the plan was aided by a consensus among stakeholders on the components of the plan.

With the growth of biotechnology research around the world, it is important that the Kingdom adopts an effective strategy to take advantage of the latest developments. This strategy includes a mechanism for developing and transferring technologies that serve all of the sectors in the Kingdom, including government, universities, and private corporations. The strategy also aims to position the Kingdom as a leader in biotechnology among

Arab countries. The strategy focuses on three major applications of biotechnology:

- Medical applications of biotechnology (Red)
- Agricultural applications of biotechnology (Green)
- Environmental applications of biotechnology (White)

The major biotechnology needs of the Kingdom were specified through workshops that included experts in biotechnology-related subject areas. There are currently nearly 27 million people living in KSA. The average population growth rate is the highest in the world at 2.9 percent. This growth creates significant challenges that biotechnology products can address.

The biotechnology industry in the Kingdom faces significant challenges due to the increased demand for products in the medical, agricultural and environmental fields. A very important product area within the medical field is the development of therapeutics. The Kingdom also needs to improve the quantity and quality of its agricultural production. Biotechnologies will aid in the development of agricultural land and with the reclamation of new lands to fulfill the need for increased agricultural production due to high population growth. Biotechnology will also play an important role in protecting the environment, which will become increasingly important as the population and economy of KSA grow.



Capabilities in the Kingdom

Current Status of Biotechnology Research in Saudi Arabia

With the rapid growth of industries in Saudi Arabia, the use of biotechnology in the fields of food and agriculture, medicine, and environment has become inevitable. In Saudi Arabia, biotechnology is being used both for research and commercial applications. The biotechnology market in the kingdom is still in its infancy but is indeed a challenging and growing one. The market, however, is dominated by medical products like Insulin, Vaccines, Interferon, and Heparins from multinational companies. Locally, there are now efforts in the direction of developing biotech products. For example, a "Bio City" is planned in Jeddah city to serve this purpose. This is just the beginning and the destination remains far. We are confident that strategic plans for biotechnology program like this will pave the way for rapid growth in the biotechnology field.

In the Kingdom, many ministries, scientific research institutes, and hospitals are involved in biotechnology research and its application. KACST, King Saud University, King Abdulaziz University, King Khalid Hospital, Ministry of Agriculture and King Fahad Medical City are a few of the many to mention. These have grown rapidly in recent years and in the future a huge growth of new centers with better facilities is expected.

Saudi Arabia has recently planned to set up a biotechnology incubator to help start-up biotech companies for commercial and technological success. KACST will soon establish the biotech incubator in cooperation with King Fahad Medical City, to be followed by a series of incubators to be set up in different disciplines.

King Abdullah University and a biotechnology park in Jeddah have also been established the biotechnology park in Jeddah is meant to be the largest scientific, medical, manufacturing, and economic centre in the Middle East. Projects include biogenetics, pre-clinical and clinical research facilities, manufacture of insulin & blood products, and others.

Biotechnology Fields and Scope in Saudi Arabia

Medicine

In medicine, research centers have started research to diagnose local commonly inherited diseases. Other centers have started to use biotechnology in gene therapy and the early diagnosis of diseases. Stem cells technology has attracted many Saudi scientists to find new treatments for diseases that have been long thought to be untreatable. This technology is now being practiced and has shown promising results. Furthermore, the use of genomic tools will enable scientists to track down the genes responsible for different diseases. Many research centers in Saudi Arabia have already started investigating common diseases in the population. On the other hand, forensic departments are using DNA fingerprints in their crime investigations using modern methods and instruments. Some pharmaceutical research centers have now initiated technology transfer to produce certain bioproducts using biotechnology methods. Other companies are also support this biotechnology movement by producing the required oligonucleotides and enzymes. Since biotechnology in the country is in its early stages, researchers are trying to apply the latest techniques and methods such as biosensors, surface plasmon resonance and transgenic methods.

Food and Agriculture

In food and agriculture, biotechnology is a good tool to solve the threats of plant and animal diseases and environmental stresses. The cash crops of Saudi Arabia, such as date palms, wheat and vegetables are facing many problems related to productivity and quality. For example, insects such as the red weevil "Rhynchophorus ferrugineus" destroy thousands of date palms, especially in the Eastern Province. The production includes more than 400 cultivars including 50-60 commercially important cultivars. Most plant tissue culture activities

are geared towards date palms in the Kingdom. Tissue culture research was first started in 1982 at King Faisal University Date Palm Research Center. Since then, public and private labs and research activities have increased to reach more than 6 public labs and 5 private labs authorized by the Ministry of Agriculture and funded by Saudi Arabian Agricultural Bank. Other than just micropropagation, some labs are developing cultivars for salt tolerance also. Some other crops are also being given attention for in vitro research. As an example at King Saud University, Riyadh, applied research was funded by KACST to study potato diseases and production of pathogen-free potato clones via tissue culture. KACST also has funded many research projects related to biotechnological applications. The first activity of plant biotechnology research and its application started with micropropagation of date palm trees in 1982 in King Faisal University - Al-Hofuf. In 1986 the Date Palm Research Center developed a protocol for somatic embryogenesis and in 1995 an organogenesis protocol was established. The later is highly recommended to eliminate mutants in date palms. The plant biotechnology in KACST started with the establishment of tissue culture lab in 1996. The Tissue Culture Lab Program includes in vitro culture of important cultivars of date palm and their DNA fingerprinting. Both embryogenesis and organogenesis methodology has been adopted. DNA fingerprinting of date palm cultivars is also in progress. Fingerprints have been used successfully for the identification and assessment of genetic diversity among the different cultivars of date palm. This assessment can be used as a data base for further research on date palm identification.

Stakeholder's Roles

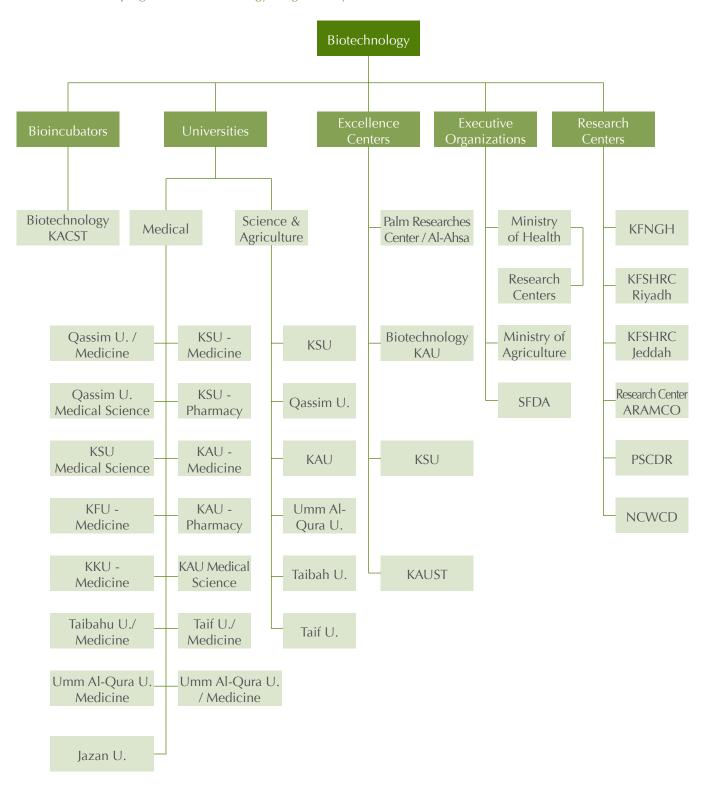
The stakeholders for the Biotechnology Program which include KACST, KSA universities, various independent or specialized research institutes, other governmental

agencies, and private companies, can be grouped as shown in flowchart 1. Table 1 shows the roles of these stakeholders in the program.

Table 1: Stakeholders and their roles

Stakeholder	Role		
	Plan, coordinate and manage the program.		
	 Conduct applied research, technology transfer and prototype applications development. 		
	Manage and participate in national projects.		
KACST	Provide support for university and industrial participation in national projects.		
	 Provide and manage national research facilities with advanced instrumentation. 		
	■ Provide advice and services to government on science and technology.		
	Create new basic and applied scientific knowledge.		
Universities	■ Train students in biotechnology.		
Offiversities	 Host and participate in Technology Innovation Centers. 		
	Participate in collaborative projects.		
	 Create new applied scientific knowledge. 		
Independent or Government Specialized Research Centers	Participate in collaborative projects.		
	■ Train students.		
	■ Provide input to program on government R&D needs.		
Ministries and Government Agencies	Reduce regulatory and procedural barriers to R&D and innovation.		
	■ Support R&D in universities and industry.		
	 Develop and commercialize products & processes resulting from the program. 		
Private Sector	■ Communicate company needs to program.		
	 Support and participate in collaborative R&D projects. 		
	■ Support and participate in the Technology Innovation Centers.		

Flowchart 1: Grouping of the Biotechnology Program Players.



Analysis of Comparable Environmental Technology R&D Institutes

As part of the background work for this plan, the planning team reviewed several other biotechnology research laboratories around the world, selected to include a mix of government supported laboratories with functions similar to that of KACST's biotechnology program in diverse countries. They included:

■ The Commonwealth Scientific and Industrial Research Organization (CSIRO) Biotechnology, Australia.

- The Biotechnology Research Institute (BRI), Canada.
- The Hong Kong Institute of Biotechnology Limited (HKIB), Hong Kong.
- The Kluyver Center for Genomics of Industrial Fermentation, Netherlands.
- The Biomedical Research Council (BMRC), Singapore.

These institutes are working in a range of technical areas similar to those considered for this plan, as shown in table 2.

Table 2: Research Institute Core Capabilities

Institute	Human biotech	Plant biotech	Industrial biotech	Bioinfor- matics
Commonwealth Scientific and Industrial Research Organization (CSIRO) Biotechnology	√	✓	✓	✓
Biotechnology Research Institute (BRI)	✓		✓	✓
Hong Kong Institute of Biotechnology Limited (HKIB)	✓			
The Kluyver Center for Genomics of Industrial Fermentation			✓	√
Biomedical Research Council (BMRC)	✓			✓

A full description of these laboratories' programs can be found in a separate document.¹

Analysis of Biotechnology Publications and Patents

In this section, publication and patent data are used to provide measures of science and technology output, impact, and collaboration in fields related to the KSA interests in biotechnology. Numbers of publication and patent activity are widely used as indicators of research and invention output.² In addition, the frequency with which publications and patents are cited by others (forward citations) is commonly used as a measure of the impact of the publications or patents. Co-authoring relationships are used as an indicator of scientific collaboration. Although there is general agreement that these are useful indicators, it is important to recognize that they are not by themselves complete indicators of R&D output or quality.³

The overall field, "biotechnology," as well as subtopics, were defined in close consultation with KACST researchers and other KSA stakeholders. KACST researchers identified three sub-topics relevant to KSA strategic priorities (medical research, agricultural research, and environmental research) and provided detailed lists of keyword terms that were used to develop

search queries for publication and patent databases.⁴ Biotechnology R&D is a multidisciplinary field that spans many research areas, such as biochemistry, plant science, genetics, and microbiology. Due to the fast-moving nature of the biotechnology field, the scope of this study was restricted to only recent publication (2006-2007) and patent (2002-2006) activity in the three KACST defined sub-topics.

Global Biotechnology Publication Activity

Between 2006 and 2007, there were 37,842 articles published worldwide in journals related to KSA biotechnology priorities in environmental research, agricultural research, and medical research.⁵ (Figure 3) The United States was the world's largest producer of related articles, generating 13,882 articles over this time period. The People's Republic of China was a distant second, producing 3,417 articles followed by Germany and Japan with 3,256 and 3,196 articles, respectively. Saudi Arabia was tied for the 62nd largest producer of publications, producing only 23 articles in ISI-indexed journals. Figure 4 shows the number of publications produced by selected countries over this time period.⁶

² Seminal research in the use of publications as a measure of scientific productivity includes A.J. Lotka, "The frequency distribution of scientific productivity," Journal of the Washington Academy of Sciences, vol 16 (1926); D. Price, Little Science, Big Science, (New York: Columbia university Press, 1963); J.R. Cole and S Cole, Social Stratification in Science, (Chicago: The University of Chicago Press, 1973); J. Gaston, The reward system in British and American science, (New York: John Wiley (1978); and M.F. Fox, "Publication productivity among scientists: a critical review," Social Studies of Science, vol 13, 1983.

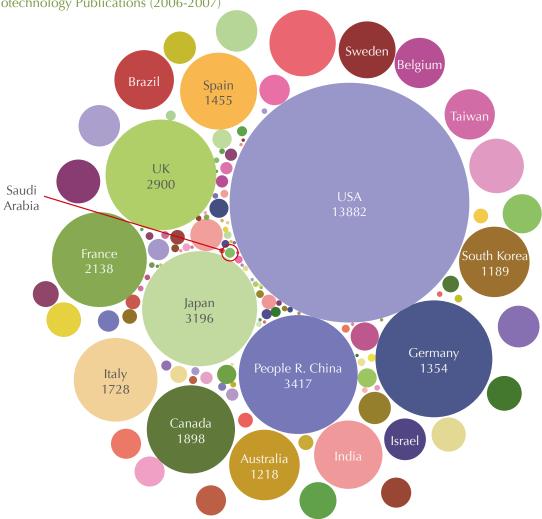
³ For example, they do not cover research results that are presented on conferences, technical reports, or new technology that is protected by copyrights rather than patents.

⁴ ISI Web of Science and Delphion were queried for scientific publication and U.S. patent application data, respectively. The ISI Web of Science is a database of peer-reviewed articles in major scientific journals from around the world. Delphion is a searchable database of global patent activity, including the U.S. Patent and Trademark Office (USPTO). The USPTO is one of the world's major granters of patents and it has been argued that the U.S. market is so large that most important inventions from around the world are patented there.

⁵ Throughout this section, "biotechnology" refers only to the subset of biotechnology defined by the KSA biotechnology program.

⁶ A publication is assigned to a country if any of the publication's author's affiliations are located in that country. Because publications often have multiple authors, a single publication may be assigned to multiple countries. Aggregate figures, such as total global publication output, count each publication only once, but adding up sub-totals may yield a result larger than the reported total due to multiple counting.





As shown in table 3, environmental research accounts for the largest number of biotechnology related publications, followed by agricultural research, and medical research. These subtopics were defined using keywords provided by KACST biotechnology program staff. The KACST definition of "medical research" is tightly focused on KSA priorities, such as diabetes, which accounts for the relatively small number of medical research publications in this database.

Table 3: Biotechnology Sub-Topics

Sub-Topic	Publications
Environmental Research	17759
Agricultural Research	13970
Medical research	7521

Benchmark Country Publication Impact

Average publication impact is calculated as the number of citations of articles from a particular country divided by the total number of articles published by authors from that country. For instance, a country that published 50 articles that were cited 100 times would have an average publication impact of two. Between 2006 and 2007, the

Netherlands had the highest average publication impact of all countries at 3.34 followed by the US (3.14), the UK (2.95), and Germany (2.83). The average publication impact for Saudi Arabia was 0.43 with 10 citations of 23 articles. Table 4 presents publication and citation counts for the benchmark countries.⁷

Table 4: Biotechnology Publication Impact (2006-2007)

Country	Publications	Total Citations	Average Publication Impact
Netherlands	1078	3597	3.34
United States	13882	43536	3.14
United Kingdom	2900	8554	2.95
Germany	3256	9214	2.83
France	2138	5412	2.53
Canada	1898	4751	2.50
Sweden	812	2017	2.48
Australia	1218	2981	2.45
Italy	1728	3885	2.25
Spain	1455	3065	2.11
Saudi Arabia	23	10	0.43

Biotechnology Research Organizations

Biotechnology R&D publications are produced at thousands of research institutions in nearly 150 countries. As shown in table 5, the three institutions producing the largest number of publications related to biotechnology R&D in the KSA subfields are the University of Texas (751), the United States Department of Agriculture

(666), and the Chinese Academy of Sciences (627). The Chinese Academy of Sciences is the number one producer in environmental research, while the USDA is the number one producer in agricultural research and the University of Texas is the number one producer in medical research.

⁷ Benchmark countries include global leaders in terms of total biotechnology output in addition to a list of specific countries provided by KACST.

Table 5: Global Biotechnology R&D Organizations (2006-2007)

Institution	Total Publications	Average Impact	Medical Research	Agricultural Research	Environmental Research
Univ Texas	751	4.16	502	207	63
USDA	666	1.74	96	506	117
Chinese Acad Sci	627	1.69	125	349	170
Harvard Univ	545	6.30	444	80	31
Univ Washington	462	4.50	325	106	45
INRA	378	2.37	73	256	62
Univ Florida	362	2.28	155	173	49
Univ Tokyo	344	2.46	163	168	24
CSIC	337	2.15	66	141	137
Cornell Univ	327	3.67	129	174	39
Univ Calif Davis	289	2.88	91	166	45
Univ Wisconsin	271	3.55	111	130	39
Univ Calif Los Angeles	263	4.28	202	50	20
Univ Paris	258	2.65	145	63	53
Johns Hopkins University	254	5.97	214	21	22

International Collaboration and Publication Impact

For countries with a similar level of publication activity, those countries with a high level of international collaboration also tend to produce publications with a high level of impact. In this study, international collaboration is calculated as the average number of countries represented per publication, based on authors'

addresses. Figure 4 plots a country's level of international collaboration (horizontal axis) against the average impact of its publications (vertical axis). Countries such as the Netherlands and the United Kingdom, which show significant international collaborative activity, also produce papers with a higher average impact.

3.5 USA Netherlands • Peoples R. China USA 3 Germany UK Germany Japan France • UK Canada 2.5 Average Impact Sweden Australia France Canada Spain Japan 2 Italy Spain South Korea 1.5 Australia Peoples R. China South Korea India Netherlands Brazil 0.5 Sweden Saudi Arabia • Saudi Arabia 0 2 0.5 1.5 2.5 Average Level of International Collaboration

Figure 4: Biotechnology Collaboration and Publication Impact (2006-2007)

KSA Collaboration Activity

As shown in table 6, KSA-affiliated authors collaborated on more than one article with authors from Germany, the United Kingdom, France, Sweden, and the United States. KSA-affiliated authors collaborated on single publications with authors from Australia, Austria, Bahrain, Belgium, Cuba, Egypt, Finland, Pakistan, and China.

Table 6: KSA Publication Collaborators (2006-2007)

Country	Number of Publications
Germany	5
UK	3
France	2
Sweden	2
USA	2

Biotechnology Journals

The table 7 presents journals with a significant level of publication activity related to KSA biotechnology sub-fields from 2006-2007.

Table 7: Biotechnology Journals (2006-2007)

	Journal	Publications
	JOURNAL OF BIOLOGICAL CHEMISTRY	320
	CANCER RESEARCH	318
	VACCINE	315
Medical Biotech	PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA	277
al Bio	JOURNAL OF VIROLOGY	271
edic	CLINICAL CANCER RESEARCH	210
Σ	JOURNAL OF IMMUNOLOGY	196
	BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS	191
	INFECTION AND IMMUNITY	164
	INTERNATIONAL JOURNAL OF CANCER	136
	APPLIED AND ENVIRONMENTAL MICROBIOLOGY	222
	SOIL BIOLOGY & BIOCHEMISTRY	217
ch	BIOSENSORS & BIOELECTRONICS	184
3iote	ENVIRONMENTAL MICROBIOLOGY	115
Environmental Biotech	CHEMOSPHERE	111
nmel	ENVIRONMENTAL SCIENCE & TECHNOLOGY	108
wiro	FEMS MICROBIOLOGY ECOLOGY	108
Ъ	MICROBIAL ECOLOGY	92
	ANALYTICAL CHEMISTRY	86
	SENSORS AND ACTUATORS B-CHEMICAL	85

	Journal	Publications
	PLANT PHYSIOLOGY	352
	PLANT JOURNAL	274
S	PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA	210
Biotech	JOURNAL OF BIOLOGICAL CHEMISTRY	192
	PLANT CELL	190
Agricultural	PLANT MOLECULAR BIOLOGY	169
Agr	PLANTA	167
	JOURNAL OF EXPERIMENTAL BOTANY	155
	PLANT SCIENCE	152
	PLANT CELL REPORTS	148

Biotechnology Patent Activity

Between 2002 and 2006, there were 2095 biotechnology related patent applications filed with the United States Patent Office (USPTO). As shown in table 8, the majority

of these (1426) listed at least one inventor from the United States. Other countries with a significant number of inventors include: Canada (144 applications), Japan (133 applications), and Germany (128 applications).

Table 8: Biotechnology Patents (2002-2006)

Rank	Country	Medical Research	Agricultural Research	Environmental Research	Total
1	United States	723	318	424	1426
2	Canada	45	42	59	144
3	Japan	55	31	50	133
4	Germany	47	31	56	128
5	United Kingdom	45	24	26	90
6	France	38	20	8	64
7	Australia	19	14	4	35
8	Netherlands	16	8	11	30
10	Sweden	16	1	9	26
15	South Korea	6	1	11	18

Rank	Country	Medical Research	Agricultural Research	Environmental Research	Total
16	India	5	11	1	16
17	China	7	7	2	15
18	Italy	2	1	12	14
19	Spain	4	7	2	12
20	Brazil	3	5	0	8
-	Saudi Arabia	0	0	0	0

As shown in table 9, the majority of biotechnology related patent applications are defined as individually owned patent applications (1422 applications) by the United States Patent Office. However, some institutions are designated as the patent assignee on a significant number of applications. These institutions, which have records as inventors in areas related to KSA biotechnology priorities,

could be future targets for collaboration. Genentech Inc. is listed as the patent assignee on 35 biotechnology related applications followed by Human Genome Sciences Inc. (33 applications), Millennium Pharmaceuticals Inc. (13 applications), Pioneer Hi-Bred International Inc (3 applications), and the Universities of California and Texas (11 and 10 applications respectively).

Table 9: Leading Biotechnology Patent Assignees (2002-2006)

USTPO Assignee	No. of Patents Apps.
Individually Owned Patents	1422
Genentech Inc.	35
Human Genome Sciences Inc.	33
Millennium Pharmaceuticals Inc.	13
Pioneer Hi-Bred International Inc	11
University of California	11
University of Texas	10

Summary of SWOT Analysis for Biotechnology R&D in KSA

This section contains information on the strengths, weaknesses, opportunities, and threats related to biotechnology R&D in the Kingdom. Strengths and weaknesses are internal to the organization while opportunities and threats are defined as external to the organization. For the purpose of this analysis, the "organization" is the Saudi Biotechnology Program, including KACST, universities, other government agencies, and companies.

Strengths

- Adequate financial resources.
- Strong desire among researchers to perform applied research.
- Starting the biotechnology business incubator facilities.
- Opening of many universities and research centers in the field of biotechnology.
- Availability of labs and infrastructure, and the new biotechnology building.
- Access to databases.
- Modern communication technologies.
- Existence of governmental graduate scholarship programs.

Weaknesses

- Lack of diversity in scientific specialties. Biotechnology requires collaboration between researchers from many different scientific specialties.
- Lack of robust transportation, purchasing mechanisms, and customs licenses consistent with the nature of biotechnology products. The majority of biotechnology samples require rapid and environmentally controlled transport.
- Difficulty of employing technical personnel in

the Kingdom due to the government policies and procedures.

- Difficulty attracting international experts.
- Lack of private sector grants for researches.
- Failure to adopt an efficient research management plan, which will lead to projects that waste time and money.
- Researchers' incentives to monopolize important information and not participate with others in research due to the regulations regarding academic promotions.
- Lack of group work and collaboration.
- Poor coordination and cooperation between research centers.
- Lack of rapid adaptation to global requirements.
- Asymmetry between incentives and strategic goals.
- Lack of a fair evaluation system for scholars.
- Governmental policies and procedures (mainly purchasing regulations) interrupt the accomplishment of efficient research.
- Changing research priorities, visions, and directions due to high turnover in executive departments.

Opportunities

Opportunities in Biotechnology

- Existence of germ plasma from plants, microbial, and marine genetic resources in the Kingdom. The Kingdom should develop and transfer technologies to handle germ plasma (maintenance, well behaved usage, environmental impact, and the production of pharmaceutics and diagnosis medicinal and diagnostic production...etc.).
- Presence of genetic diseases among inhabitants of the Kingdom necessitates developing and transferring new technologies for early diagnosis and treatment.
- Expected financial return from biotechnology is relatively high.
- Existence of Saudi-based institutions interested in biotechnology research.

Move towards a knowledge-based economy (technology production, investment in technology, establishment of scientific incubators, new industrial, knowledge cities (and the biozone).

Opportunities in the Strategy

- Approval for the national policy for science and technology which includes technical strategic programs to support research, development and technology transfer.
- Possibility of attracting foreign investment in biotechnology, and the strong position of Saudi investment organizations in the Kingdom to attract investment in biotechnology.
- Possibility of attracting external human resources through naturalization and residence systems.
- Incentives to develop lower cost technologies (government support through donation of land and facilities, availability of workers and primary substances, and tax breaks).
- Need to treat local genetic diseases in both humans and animals.
- Provision of scientific certificates for studies or training in biotechnology fields.
- The private sector has slowly increased their interest to finance research and development projects at national research institutes with the help of government's promotions.
- Increased interest by private sector (especially in industry) to establish national centers for research and development.

Threats

- Biotechnology inputs and technical workers are both very expensive.
- Difficulty of transferring some technologies or research due to security, economic and political restrictions.

- Lack of sufficient educational programs to produce qualified workers in technical fields to work in both industry and government.
- Lack of initial funding.
- Biotechnology field is not considered a priority in the private sector.
- Joining the global economy leads to an influx of cheap products that limit incentives for research and development.
- International competition for qualified experts in biotechnology.
- Retention of qualified workers in private sector research by offering competitive salaries.
- Lack of motivation to perform research in the Kingdom.
- Some of the government's policies and procedures are inconsistent with the needs of scientific researchers.
- Lack of specialized institutions that are capable of performing some of the important requirements for biotechnology, especially drug testing.
- Inability of producing high quality products throughout the development cycle.
- Time needed to develop biotechnology products is long.

Program Strategy

The biotechnology strategic planning team specified a vision and outlined priorities and procedures that will lead to a successful biotechnology research and development program in the Kingdom. The vision, mission, and strategic objectives will guide the development of this program keeping in mind the best interests of the inhabitants of Saudi Arabia. This strategic plan also ensures that the country will develop a biotechnology R&D program that

is consistent with the values of the Kingdom while at the same time providing strong incentives for innovation.

The development of the vision, mission, and strategic objectives was aided by the cooperation of a large number of stakeholders, including many biotechnology experts in the Kingdom.

Vision

To be pioneers in biotechnology for best life.

Mission

Excellence and creativity in innovating and developing biotechnology applications to accomplish scientific and economic benefits.

Values

- Consideration for the Islamic religion, the Arabic language, and the societal knowledge.
- Adhering to the principles of justice, honesty, sincerity and transparency.
- Safety and security.
- Consideration of ethical issues.
- Strong and sustained ambition.

Program Strategy



Strategic Goals

- Transfer and develop the newest medical, agricultural, and environmental biotechnologies.
- Provide settings that encourage creativity and investment in the field of biotechnology.
- Direct the applications of biotechnology to achieve health and food safety.
- Use biotechnologies to achieve food and health security.
- Protect the biodiversity resources of the Kingdom through the development of appropriate biotechnology applications.
- Strengthen the relationship between the biotechnology programs and society.
- Use biotechnology to prevent, diagnose, and cure common problems in Saudi Arabia.

Biotechnology

Like many other countries, KSA has a myriad of diseases spanning infections, cancer, diseases of growth and aging, diabetes ...etc. KSA has unique aspects in some of these diseases (e.g. medical aspects of Hajj season, prevalence of consanguinity resulting inherited diseases, diseases related to urbanization). As such, biotechnology can have a major impact on prevention, early

detection and treatment of these diseases.

Due to modernization, environmental pollution is also a significant medical concern for nearly every country around the world. This is reflected by increasing cancer rates. As these diseases spread, many treatments will come from the field of biotechnology. This provides a significant opportunity for the Kingdom to develop and transfer biotechnologies to diagnose and cure these spreading diseases.

The diseases that would benefit the most from the biotechnology research and development are:

- Chronic diseases, such as kidney disease, respiratory disease, obesity, and related diseases of the digestive system, and anemia.
- Growth and old-age diseases, such as paralysis and hormonal disorders that affect growth, genetic diseases, Parkinson's disease, and diseases of aging such as Alzheimer's.
- Infectious diseases, such as bacteria, fungi, viruses, and parasites.
- Cancers, such as breast, blood, thyroid, prostate, and lymphatic cancer.
- Cardiovascular and vascular diseases, such as angina, chest congestion, blood clots, and high blood pressure.
- Diabetes and its complications.



Agricultural Applications of Biotechnology

Environmental constraints limit the growth of agriculture in the Kingdom. A lack of water for irrigation, high temperatures, and high levels of salt in the water and sand are major challenges facing agricultural expansion. Biotechnology can help address some of these challenges.

The very young and rapidly growing population of the Kingdom requires the development of biotechnologies to help overcome the barriers limiting agricultural growth. Biotechnology will aid the production of new agricultural products that fulfill the increasing food needs of the Kingdom.

Gene transfer and cellular fusion techniques were considered as a breakthrough in biotechnology and helped scientists develop plants possessing nitrogen fixation properties. In addition, biotechnology can be used to develop and produce new vegetables that are resistant to diseases and able to survive in the harsh Saudi Arabian environment. Biotechnology developments will also decrease the use of the chemical fertilizers that cause environmental pollution in the Kingdom.

Since the Kingdom has a large coastline, it also is possible to use biotechnology to develop the aquatic resources of the Kingdom such as mosses and fisheries. These can also be an important resource for the food industry in the Kingdom.

The agricultural areas that would benefit the most from the biotechnology research and development are:

- Plant breeding:
- Genetic engineering to produce crops resistant to drought or salinity.
- Enhance quality of local crops using molecular biotechnology.
- Study of the genetic diversity sources of main crops.
- Examination of the genetic or molecular structure of local plants.
- Animal breeding:
- Study of the genetic diversity of domestic animal breeds.
- Molecular diagnosis of animal diseases.
- Diagnostic studies of common diseases among humans and animals.
- Genetic manipulation to improve agricultural productivity of animals.

- Bioproduct production:
- Application of technical doubling to separate vital vegetation materials for diagnostic and therapeutic purposes.
- Identify active substances in plants to be used in medicines.
- Plant protection:
- Genetic improvement of agricultural crops to make them resistant to nematodes diseases.
- Diagnosis and definition of causes of plant infections using molecular methods.
- Monitoring of genetically modified food for safety.
- Diagnostics for diseases transferred to food.
- Purification of molecular food components to eliminate unwanted components from food.

Environmental Applications of Biotechnology

Even though that the Kingdom is considered one of the richest countries in the world in terms of oil and natural gas resources, there have been very few applications of biotechnology to increase production of oil or to minimize the resulting pollution. Protecting the environment is becoming more and more important and will be crucial to the future of the oil industry.

The rapid population growth and the expansion of industry in the Kingdom create challenges for keeping a clean and healthy environment. Biotechnology will play a key role in finding innovative ways to deal with garbage and in developing fermentation and biological reactive technologies. Using biotechnology, agricultural, industrial, and oil byproducts can be transformed to produce substances capable of decomposition (biological polymers) and other high value materials. It is also important to develop and transfer technologies that can detect biological contaminants.

The environmental areas that would benefit the most from the biotechnology research and development are:

- Microbial biodiversity:
- Study and preserve microbes in the soil, water, and air and deploy them in critical application areas such as gene transfer.
- Develop methods for detection and analysis of microbes and their physiological properties.

■ Bioremediation:

- Use of microbes and genetically engineered microbes in the field or in the laboratory for the decontamination of chemical fertilizers and petroleum contaminated land and water.
- Treatment of critical components such as chemical contaminants and radioactive heavy water in the earth.
- Studies of environmental conditions appropriate for successful bioremediation.

Microbial Enhanced Production:

- Detecting and developing microbes with capacity to improve oil production in oil wells, pipelines, and/or refineries
- Employing microbes for oil desulphurization.
- Modifying microbes to endure difficult conditions in oil wells and pipelines.
- Producing of improved biomaterials to enhance the production of oil.

■ Biopolymers:

- Discovery of microbes with the capacity to form polymers, analyze the required environmental conditions, and improve the ability of these microbes to increase production.
- Study environmental conditions and methods of commercial production.
- Improve characteristics of polymers using nanotechnology techniques.



- Biosensors:
- Developing and using microbes to monitor environmental contaminators.
- Employing modify microbes to monitor oil spill.
- Studying safety and security of biosensors.
- Fermentation and bioreactors:
- Developing biofilms and bioreactors.
- Employing biofilms and bioreactors for biomaterials production.
- Studying optimization conditions of fermentation processes.
- Biorecycling:
- Studying the biosafety of biorecycling condition of industrial, agricultural and medical wastes.
- Determining the benefits of biorecycling wastes.
- Identifying and modifying microbes for biorecycling.
- Studying optimization conditions for biorecycling processes.

Program Management

KACST will establish the Strategic Planning Administration to manage the activities and progress of the Kingdom's strategic plan. A large technical personnel with knowledge of biotechnology will work in this administration. In addition, many specialized courses will be given to members of this administration to aid in the success of this strategic plan. The Strategic Planning Administration will be responsible for all projects. It will also coordinate collaboration

among experts and organizations within the Kingdom. The Strategic Planning Administration will be given sufficient legal authority to enter cooperative agreements with specialized international centers.

The manager of the Strategic Planning Administration will be responsible for managing the administration and preparing official reports about the progress of the program every six months. These reports will be presented to supervisory committee in KACST.

A stakeholder coordinating committee will also be established that includes experts in biotechnology related fields to study the growth of biotechnology. At the same time, this committee will study the progress of the biotechnology initiatives within the Kingdom that are outlined in the strategic plan. This committee will meet periodically under the leadership of the manager of the Strategic Planning Administration.

The execution of the plan involves many stakeholders, plus the fact that biotechnology has three areas:

- 1- Medical.
- 2- Agricultural.
- 3- Environmental.

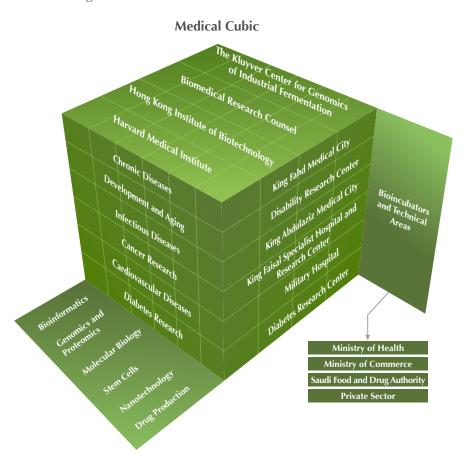
Each of these areas has several techniques involved with different applications, and each technique has a number of branches. A relational cubic has been devised to aid in the program management by linking all different routes with the role for each stakeholder.

Cubic design

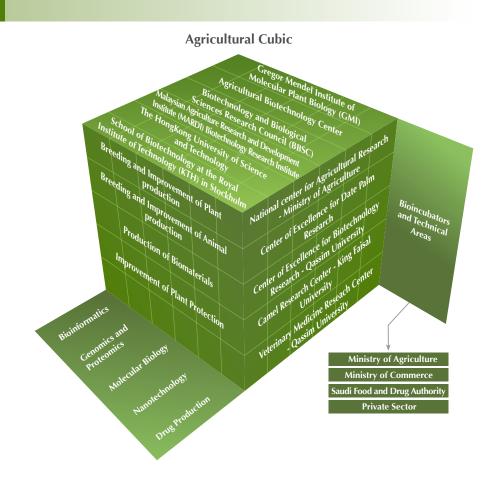
A cubic was designed for each area independently. Each area uses several techniques, each technique includes a number of technical applications, and each technique is associated with a central center as an internal incubator for such

technology. The product of the research is associated to the relevant agencies and the private sector.

The following are illustrative forms of the cubic:



Program Management



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Operational plans include a portfolio management plan, a technology transfer plan, a quality management plan, a human resources plan, a communications plan, and a risk management plan.

Portfolio Management

The Biotechnology Program will include a variety of projects with different goals and objectives. The program will aim to achieve a balance across multiple objectives. Some factors to be considered in program balance include:

- The balance between projects to achieve an immediate objective versus building long-term capacity (especially human resources) for the program.
- The balance between meeting the needs of existing companies versus establishing new technology-based industries in the Kingdom.
- The balance between low-risk incremental projects and high risk/high return projects.
- The balance among different national needs and major stakeholders (government agencies, biotechnology companies, industrial users of biotechnology companies, universities).

The program manager and advisory committee will review the program to ensure that it maintains an appropriate balance among these factors.

Technology Transfer Plan

The Biotechnology Program will follow internationally recognized best practices in technology transfer. Key elements of the program that are designed to facilitate technology transfer are:

- Involvement of users in the program design: this occurs through user participation in planning workshops and user involvement in the Biotechnology advisory committee. It is well recognized that user involvement in the research design leads to research and outcomes that are more likely to meet the needs of users, and thus, are more likely to lead to successful innovation.
- National programs focused on the development of advanced pilot application projects: the projects involve universities as well as companies, and knowledge is transferred to the companies in the course of the project. This is a proven method for developing technologies that serve a need and can be transferred readily to government or commercial users.
- The use of university/industry centers as a major research mechanism throughout the plan: industry involvement in these centers (providing advice and funding) will encourage university research to be focused on user needs, increasing the likelihood of technology transfer. These centers will also transfer knowledge to industry though the training and graduation of students (who have been trained on problems of interest to industry), who then take jobs in companies or form their own companies.
- The linkage between the Biotechnology Program and technology business incubators and other programs to aid the start-up of new biotechnology companies.

Quality Management Plan

The Biotechnology Program will follow international best practice quality management processes for science and technology programs. Elements of the quality management plan include:

- Advisory committee review of the overall program design and budget.
- Competitive, peer-reviewed selection processes for university-based research centers and projects.
- Annual reviews of technology development projects to ensure that milestones are being met.
- Periodic (every 5 years) subprogram evaluations conducted by a review committee supported by an experienced evaluator.

Procedures will be developed for disclosing and managing potential conflicts

of interest among reviewers. In many cases, some international experts will be used on review panels to reduce possible conflicts of interest and to provide an independent external assessment.

Human Resources Plan

As noted in the SWOT analysis, human resources are a critical barrier for the success of the Biotechnology Program. The availability of skilled people, including both researchers and technical managers and leaders, is likely to limit the growth and success of KSA biotech programs. The plan will require substantial numbers of biotechnology professionals, including additional researchers, technical managers, and technical leaders at KACST, at universities and at companies. A central task of the program management function will be to address this issue.

To achieve the goals of the program, KACST will need to hire or develop additional program managers with the skills to lead national programs. To do this, KACST will need additional flexibility with respect to compensation packages, speed of hiring, and ability to hire international staff.

Universities and companies will need additional researchers and software engineers with the skills to develop innovative technologies. This will require broader changes, some of which are outside of the scope of this plan. As part of the activities in this plan, the Biotechnology Program will:

- Analyze biotechnology human resource issues and advocate changes to improve the quality of math and science education in primary and secondary education
- Work with the other agencies to improve the quality of undergraduate education in biotechnology-related fields, especially at regional universities

- Work with new universities to develop research and education programs that especially match the Kingdom's biotechnology needs.
- Work to expand the contribution of women to biotechnology.
- Work to change policies to allow more international hiring, to bring specialized expertise to the Kingdom
- Support training for researchers to become R&D managers and leaders.

At the undergraduate and especially graduate level, this plan is designed to help increase the numbers of biotechnology researchers through its emphasis on university-industry centers. These centers are designed to train new students with research and innovation skills needed by research organizations and industry.

Communications Management Plan

The purpose of the communications management plan is to provide appropriate information to the program participants and stakeholders. One element of the communications plan is to improve communication throughout the KSA biotechnology community and to expand collaboration among members of the community. Aspects of this include:

- There will be a public website with information on program goals, accomplishments, funding opportunities, and other news.
- Periodic workshops will be held with users and stakeholders to define future program needs.
- Requests for proposals (for university centers, grants, and pilot application development programs) will be announced to the public.
- The program advisory board will review and comment on the program, and advisory board reports will be made public on the website.
- The program will sponsor workshops, conferences, and professional society activities to expand communication

and networking throughout the community.

 Presentations on the program will be made at national and international conferences.

Another element of the plan is to define appropriate communications within the management structure of the plan. It is especially important for information about risks or difficulties in the program, such as delays, lack of resources, or non-attainment of goals to be rapidly communicated to higher levels of management. A general principle is that management should never be surprised by bad news.

Risk Management Plan

The program presented here is an ambitious program that will challenge the capabilities of the Kingdom. There are several types of risks that could prevent attainment of program goals, including technical risks, market risks, and financial risk.

One source of technical risk - risk to attainment of technical goals – is, as described above, the lack of adequate human resources to implement the program. Approaches to managing this risk are:

- Changing policies to attract people with the needed skills. This may involve raising salaries and recruiting internationally.
- Delaying or phasing in some program elements if people are cannot be hired.
- Expanding the pool of people with needed skills through education and training programs, such as university biotechnology research centers (see human resources plan).

Another cause of technical risk is overly ambitious goals. The way to address this risk is to have an independent review of technical goals to ensure they are feasible, and to adjust technical goals if milestones are not being met.

Market risk is the risk that projects, while technically successful, do not lead to successful products because of poorly understood or changing market conditions, such as the development of other technical approaches. A way to address this risk is through:

- Designing programs based on carefully considered market needs.
- Monitoring international technology and market developments.
- Continual readjustment of plans in responses to changes in the environment.

Financial risk is the risk of funding shortfalls or cost overruns. The way to address risks in this area is through careful program planning and monitoring, and early identification of possible cost overruns. Another financial risk is due to changes in the plan or funding due to political or policy changes. It will be important for the plan management to maintain communication with policy leaders to ensure they are aware of the accomplishments of the program and to get early warning of any policy changes that may affect the program.

Key Performance Indicators

Stakeholders helped the biotechnology program to specify performance indicators. Each indicator is a metric related to a strategic objective. The key performance indicators are:

- Percentage of human resource requirements available.
- Assessment of return on investment achieved by the program.
- Average achievement of strategic objectives across projects.
- Knowledge obtained by use of cutting-edge technologies in research activity.
- Average of strategic objectives achievement across selected technologies.
- The rate of active strategic partnerships.
- Number of basic research discoveries that lead to new applications in biotechnology.
- The proportion of applied research leading to production of new business models or practical solutions.
- Percentage of research institutions that lead to new production lines or solutions.
- The proportion of enterprises that led to production lines or technical solutions.
- Percentage of applied research that leads to production of technologies locally.
- Percentage of research institutions which are established and produce production lines or technical solutions.
- Percentage of available technology that is transferred and developed in the Kingdom measuring the productivity of the new technologies in our research strategic plan.

Key Performance Indicators

- Percentage of available technologies that create production lines or technical solutions.
- Percentage of new work methods that are adopted by bioincubators.
- Percentage of new work methods that are adopted and developed at centers for biotechnology research.

The process of developing this plan included several stakeholders' workshops, which focused on biotechnology needs in the Kingdom and on defining programs to meet those needs. The following lists the participants in the plan. While this document includes input from many individuals, the views expressed in this document do not necessarily reflect the views of every individual consultant or participant.

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