



## Hot Team Business Plan Template

### KANSAS INSTITUTE FOR HUMAN AND ANIMAL HEALTH

I. **Describe the initiative(s):** 5-8 specific sentences on intent, prioritization, overarching outcome for the region

We propose the creation of the Kansas Institute for Human and Animal Health (KIHAN), a therapeutic and diagnostic agent research and development funding agency under the Kansas Bioscience Authority (KBA). The mission of the Institute will be the financial support of research and development on medical product discovery, product development and clinical trials including new, improved or individualized therapies and diagnostics for both human and animal health. In particular, the Institute would award grants/contracts to aid in the discovery of new medicines, diagnostics or other therapeutic modalities; the preclinical development of such new products; and, the beginning of clinical trials of these new products. As described below, funding from the Institute will require collaboration between basic and clinical scientists on targeted, medically important projects as well as collaboration between academia and industry for the commercial development of new products. Whenever possible, development contracts will specifically target companies and universities in Kansas for completion of the preclinical and clinical research. Developmental R&D includes drug candidates from sources outside of the state of Kansas, as for example, an orphan drug discovered, but not developed by a large pharmaceutical company. Funding for clinical trials work will require extensive partnering with private sector companies. In addition, this proposal includes the creation or expansion of research resource centers in genomics, gene expression, proteomics, and bioinformatics at both Kansas State University and the University of Kansas.

II. **Describe the long-term goal:** global (hub/node) vs. national-regional (hub/node)

The purpose of the Institute is to give Kansas a competitive edge in the discovery and development of medical therapeutics and diagnostics for both humans and animals. This funding program will: 1) expand biomedical research capacity by supporting core facilities in genomics, proteomics, and bioinformatics at the state's two largest research universities; 2) stimulate collaboration between basic research scientists and clinical research scientists from Kansas's universities and bioscience businesses; 3) Give Kansas companies and entrepreneurs a competitive edge in the race to develop new therapies and diagnostics, by partially subsidizing both the discovery and development processes for products developed in Kansas. The availability of funds for both discovery and development research will help make Kansas an attractive site for new and emerging bioscience businesses. This new funding program, coupled with the

proximity of the Stowers Institute, has the potential to make Kansas a national hub for discovery, and in particular, for development of new drugs, diagnostics and other therapeutic approaches.

- a. *Why this is important?* Nearly every state is making some sort of economic development effort in bioscience because it is clear that medicine and bioscience will be growth industries for the coming decades. Although the National Institutes of Health are unparalleled in supporting basic biomedical research, development of promising leads is largely left to the private sector. However, the private sector tends to view many of the discoveries coming from academia as too risky or insufficiently developed to justify use of their funds to advance the potential product. This creates a gap between discovery and development. The proposed funding mechanism creates programs to bridge the gaps between discovery, development and implementation.
- b. *On what current assets?* At the University of Kansas in Lawrence, strong programs exist in drug discovery, drug delivery, drug analysis and vaccines, especially related to neurological diseases and cancer. Much of this activity is located in the School of Pharmacy which in 2004 was ranked third nationally in NIH funding for schools of pharmacy. In addition, the KTEC supported Higuchi Biosciences Center focuses on drug product developmental research and has an excellent track record in commercialization of products. At Kansas State University, the College of Veterinary Medicine has over 65 faculty members conducting research ranging from rapid diagnostic techniques to neurosciences to surgery. KSU has recently added an impressive new Food Safety and Security Facility with multiple BSL 3 and BSL 2 laboratories for animal research. At the KU School of Medicine in Kansas City there are many major research centers such as the Masonic Cancer Center, the Hognlund Brain Imaging Center and the Gerontology Center. Combined, these three institutions garnered in excess of \$130 million in federal science and engineering research funds in 2002 (most recent year for which data are available).

Additional attention should be drawn to the existence of such State of Kansas programs as the Kansas Technology Enterprise Corporation which has invested heavily in technology commercialization through its centers of excellence and its innovation and commercialization centers. Recent efforts by the state have led to substantial new research buildings at KU, KSU and KUMC. Finally, the groundbreaking legislation that led to the creation of the Kansas Bioscience Authority will serve as a driver of Kansas bioscience commercial development, and also as a model to other states.

A bioinformatics infrastructure and capability is being strengthened within the state. The K-INBRE funded through the National Institutes of Health Center for Research Resources supports bioinformatics efforts throughout the State of Kansas. The new Center for Bioinformatics at the University of Kansas carries out fundamental research in life sciences, develops computer modeling tools, fosters community-wide activities in bioinformatics, and provides education for the new generation of researchers. A new Bioinformatics center at KU will focus on research in the area of modeling of protein interactions. The Bioinformatics and Computational Life-Sciences Laboratory of the University of Kansas Information and Telecommunications Technology Center is composed of new bioinformatics focused computer science faculty that are working on knowledge discovery, data mining, and analysis as it relates to the life sciences. They are focused on advancing bioinformatics methods and tools for genomics and proteomics data analysis

and other life-sciences-related problems. Kansas State University has a Bioinformatics research center and a Bioinformatics undergraduate minor as well as a Bioinformatics combined BS/MS are in the approval process. Within this research umbrella, more than 20 different departments conduct interdisciplinary genomics and bioinformatics research.

- c. *On what future assets required for success?* The major needs for this program to succeed are 1) dedicated research and development funds of roughly \$6 million per year; 2) core support funds of \$2 million per year for biomedical research core laboratories such as genomics, proteomics, lipidomics, and bioinformatics; 2) additional high-quality research faculty at the state's major research universities; 3) additional state-of-the-art laboratory space. This proposal only addresses the first and second needs.

III. **Describe impact on the four phases of the innovation lifecycle (conception-formation-growth-maturity):** Will the initiative(s) catalyze positive churn around the four quadrants?

- a. *Conception.* The greatest impact of the Institute will be on this phase of the innovation lifecycle. Collaborative research grants will result in potential new products or services, invention disclosures, patents, federal research dollars and accumulation of expertise in selected research areas. Product development contracts to fund preclinical drug development in Kansas increase the alliance between Kansas researchers and Kansas development firms. Furthermore, these contracts should increase the number of licensable products emerging from the state's efforts and help establish the state as a national node for early stage medicinal product development. Creation or enhancement of biomedical research core facilities will provide strong support to the drug discovery process and will enhance the ability of the state's universities to attract both federal funding and high caliber faculty.
- b. *Formation.* Assistance provided to Kansas start-up companies to bring products to early stage clinical trials will directly enable the formation of new companies dedicated to providing therapeutic and diagnostic solutions to current health care issues. Doing this work in Kansas with Kansas companies and universities will add to the status of the state as a place to perform clinical trials. Bringing a potential product from the discovery stage to the IND stage adds substantial valuation. More clinical trial work will also enhance the area's reputation as a good site for clinical trials.
- c. *Growth.* Successful completion of Phase I clinical trials, which would be partially funded by the Institute, would logically lead to growth and development of the sponsoring company as the treatment candidate progresses to Phase II trials and beyond. A recent McKinsey report (*The McKinsey Quarterly*, 2002, Number 4) suggests that on average pharmaceutical licensing deals are worth \$2M up front, \$15 million in milestone payments and a 7 percent royalty for drugs licensed in to pharmaceutical companies at the preclinical stage. For Phase I deals, the corresponding numbers jump to \$5M up front, \$25M milestone, and a 10% royalty. For Phase II deals the numbers go up again to \$10M, \$35M and 20% royalty.
- d. *Maturity.* The Institute is likely to generate new products that will be of value to existing Kansas companies as a means of enhancing product pipeline. By focusing efforts on those drug candidates that are not likely to be selected for further development by large pharmaceutical companies, yet still present market

opportunities in the >\$50 million per year range, Kansas has an opportunity to accumulate a significant number of products and companies to add to an emerging drug development capability. A secondary benefit will be increased collaboration between mature and forming companies as the funding mechanism envisioned draws companies and university scientists together.

**IV. Describe impact on the innovation attributes (intellectual capital, human capital, financial capital, role of proximity, and social capital):** Will the initiative(s) resolve a gap or “increase our supply” of one or more of the attributes?

The Kansas Bioscience and Innovation roadmap identifies drug discovery, delivery, and pharmacogenomics as a potential area for innovative development. Enhancing the State’s competitive profile in these areas would significantly impact several innovation attributes. The State currently has high quality relevant programs and capabilities such as the Higuchi Biosciences Center, the Kansas Masonic Cancer Center, the Hoglund Brain Imaging Center, the National Agricultural Biosecurity Center, highly ranked schools of pharmacy, medicine and veterinary medicine, the Information and Telecommunications Technology Center and several Centers of Biomedical Research Excellence (COBRE) and Biochemical Research Infrastructure awards. Typically, these activities and programs are largely unlinked, scattered across various academic, industrial, and business entities and poorly integrated. The critical mass gained through collaborative or associated expertise, facilities, sponsorship, and the shared leadership necessary to be competitive with other emerging or established centers of bioscience across the country is lacking. Achieving critical mass through a combination of alignment or re-alignment, interaction, innovation, attraction, and coordinated leadership would position Kansas to better attract and retain scientists, create and enhance technical infrastructure, create and/or attract bioscience-related businesses, and ultimately generate revenues for participating partners and the State. This Institute will go far to addressing these shortcomings in the state’s dispersed infrastructure.

Core support for bioinformatics capabilities at KSU and KU, if made available to bioscience businesses at reasonable costs, will allow even small business entities to address projects and problems that are usually limited to well financed start-up companies on the east and west coast, or to major international corporations with vast resources. By participating in the risk for early stage drug development, the Institute will make Kansas a very attractive location for small drug, therapeutic and diagnostic businesses to start or grow their enterprise. The State of Kansas can see the return on this investment in the form of new businesses, more and higher paying jobs and new sources of tax revenue.

**V. Describe the implementation strategy including the implementation champion(s) and the organizational “home” for implementation**

The Institute would be a new creation of the Kansas Bioscience Authority. The most logical “home” for the Institute would be either the KBA or the Kansas Technology Enterprise Corporation (KTEC), with the latter more likely to have the required administrative infrastructure. A director of this program would be hired and would be the champion to implement the program. The director would be housed at KTEC but would be an employee of

the KBA. It is anticipated that KTEC staff (expanded and partially supported with Institute funds) would be sufficient to assist the director.

VI. **Describe the resource requirements:** what will it take in terms of:

- a. **Leadership.** Leadership to organize the funding program and to encourage and steer collaborations so as to reach the expected critical mass of academic and industrial researchers that this program envisions will most likely come from a dedicated full or part-time director to coordinate outreach activities that promote collaboration. Ideally, this individual will have a strong scientific background and significant leadership experience. It will be necessary to have a full-time administrative assistant to help the director. Equally important is the creation of an appropriate review committee for selection of projects. This committee should consist of more industrial than academic members, preferably with the majority of the members coming from out of state. The director would be charged with recruiting and coordinating this committee
- b. **Infrastructure – both physical and virtual** Almost no additional physical infrastructure is needed for the Institute. An office within the KTEC suite would be needed for the Director and the administrative assistant. It is assumed that existing research infrastructure at the state's universities and businesses is adequate to accommodate the increased research and development effort envisioned in this plan. The virtual infrastructure on the other hand will be large and ideally should encompass all academic and industrial scientists in the state who are active in research and development of therapeutic and diagnostic agents. A portion of this virtual infrastructure already exists within KTEC which is another reason to place the Director of the Institute in KTEC's offices. Additional infrastructure will be needed at both KSU and KU for the bioinformatics effort. This would consist of appropriate technical directors, laboratory space and research equipment. Support by the Institute should be planned for a ten year period with the expectation that after that time the individual institutions would assume permanent support and be supplemented by user fees.
- c. **Capital – public, investor, federal, philanthropic, other.** Both private and public investments will be required. Discovery efforts will be built upon observations made largely on federal research grants but supplemented with targeted research using KIHAAH funds. An annual total of \$7.1 million will allow funding for up to 30 discovery grants at a maximum of \$100,000 per grant; up to four product development contracts at a maximum of \$500,000 per contract; and two to three clinical trials assistance grants at a maximum of \$250,000 per year; salary support of approximately \$800,000 - \$900,000 (plus escalations, total for both programs) per year, depending on which programs are adopted at each institution, for up to four technical directors of bioinformatics component labs at each of the state's two largest research universities. Additionally, the Institute will need a one time expenditure of up to \$2 million to renovate and equip these core labs. In order to cover the cost of reviewers' time/travel, director and administrative assistant salaries and necessary operational costs, an additional \$450,000 will be needed. Private funds would be needed to cover the complete cost of the product development and phase I clinical trials categories and would come in the form of corporate cash matches. For product

development contracts, the sponsoring entity would be expected to provide fifty cents for each dollar provided by public funds. For clinical trials assistance grants, the sponsoring entity would have to provide a dollar for dollar match with the public money. In addition, investor funds would be required for the start-up companies that would be the beneficiaries of most of the development work.

- d. Regional communications and domestic/global branding-marketing. It will be necessary to educate all the educational and private sector resources in Kansas about each other and of the existence of this funding program so that they can look to partner with groups within the state. Global branding will be of importance to the extent that the existence of the Institute is a business recruitment tool. This is best accomplished by partnering with existing marketing activities directed to this end such as the Department of Commerce and area Chambers of Commerce.

**VII. Describe how the initiative will be sustained (through an existing mechanism, new mechanism, collaborative partnership, federal center of excellence, etc.)?**

This is a new initiative that should be funded through the KBA and administered through KTEC. Progress would be reviewed annually by the KBA for continued funding. Funding beyond the ten year anticipated lifetime of the Kansas Economic Growth Act will be determined by state leadership after a track record has been established for the Institute. Funding for the bioinformatics core laboratories would have to be assumed by the host institutions after a ten year period.

**VIII. Describe 6–8 specific performance metrics that the initiative will influence and impact and how:**

- a. Increase leveraged public, private and direct foreign investment? Appropriate metrics would include SBIR/STTR or similar funding generated as a result of discovery grants; increased capital investment in the corporate entity that advances the commercialization of the technology; licensing and royalty revenue resulting from value added to the product from the pre-clinical and clinical work performed under this program.
- b. Increase high-skilled, high paying jobs? Although it can be anticipated that high paying jobs will be added through the growth of businesses commercializing products anticipated from this initiative, this is always a difficult quantity to measure and is unreliable as an assessment tool. For start-up companies, a direct correlation between research or product development advances and employee growth is marginally possible, however, for larger companies (i.e., greater than 20 employees) the impact of an entire new product line may not change the employment picture, but simply allow the retention of jobs that would have been lost. Global measures of bioscience-based jobs relative to a current benchmark can be used to describe the overall health of the bioscience business base, but cannot be attributable to single effectors.
- c. Facilitate new company start-ups from university spinouts, corporate spinouts, entrepreneurial founding? Discovery of new treatments and diagnostics for human and animal diseases will increase the number of potential technologies emanating from Kansas's universities upon which to create new companies. Product development awards will assist spinout companies from universities or industry to

overcome the early demands for development data that consume capital and inhibit company growth.

- d. Assist existing or new companies relocating to or expanding in the region? This should be a prime outcome for this program. The availability of research and development grants to assist companies in the affected industries should be a prime recruiting tool. To assess the impact, the Institute will need to work closely with chambers of commerce and other agencies usually involved in corporate recruitment.
- e. Increase 'brain gain' of scientists, managers, entrepreneurs, faculty, students? This is unlikely to be a valuable metric for this program
- f. Increase internships for high school and college students? This is unlikely to be a valuable metric for this program
- g. Enhance university-industry relationships through increased contract research dollars, endowed chairs, royalty and licensing fees? Monitoring university-industry relationships will be done initially by counting the number of proposals that with university and industry partners submitted to the Institute. Tracking of follow-on contract research dollars will require excellent communication between Institute personnel, university grants management personnel and principal investigators. This will not be straightforward. Increases in royalties or licensing fees directly attributable to Institute funding will require excellent communication between Institute personnel, university technology transfer officers and principal investigators on Institute grants and contracts.
- h. Increase federal-national research dollars to the region through SBIR or ATP funding increases, federally-funded research center, or line-item appropriations? This is an anticipated outcome for the Institute, however, monitoring of this metric will be difficult as it will depend upon follow through by university or industry principal investigators who often have little motivation to keep track of long chains of funding histories.
- i. Increase the amount of venture capital investments and/or the creation of new funds in the region? The Institute should increase the amount of quality technologies in the state having strong commercial potential—stronger deal flow means more opportunities to attract venture capital and recruit personnel at all levels, especially seasoned managers. The Institute will help develop more mature technologies than most of those currently developed in the state by funding pre-clinical and Phase I clinical studies—the closer drugs are to the market the more likely investors will provide capital.
- j. Create new global partnerships and global image through increased exports, direct foreign investment, international conferences and forums? Although one anticipated outcome of the Institute will be increased partnerships between Kansas companies and the major pharmaceutical and diagnostic companies likely to be the final commercializing entity of the products of this effort, it will be exceedingly difficult to track the results in a meaningful fashion. For therapeutics, the time line for product development is extremely long making it more difficult to keep track of the thread of connectivity to initial Institute funding.
- k. Increase new vendor-supplier networks within the region? This is unlikely to be a valuable metric for this program