



# Developments

## Biotechnology Innovation and Optimization Center

*A KTEC Center of Excellence*

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### *BIO Center Formed to Aid Centralization of Development Efforts*

The Kansas Technology Enterprise Corporation (KTEC) and the Kansas University Center for Research (KUCR) have announced the establishment of the Biotechnology Innovation and Optimization Center (BIO Center) at the University of Kansas. The establishment of the BIO Center is part of ongoing efforts to centralize the focus for advancing University technologies into the private sector. These technologies result from pharmaceutical and biomedical research efforts on both the Lawrence and Medical Center campuses. The centralization efforts include the Office of Therapeutics, Discovery, and Development (OTDD), the Office of Technology Transfer and Intellectual Property, and the Office of Business Relations and Development. The BIO Center is a KTEC Center of Excellence.

*"The overall mission and vision will remain the same, to develop life enhancing pharmaceutical and biomedical technologies . . . and successfully manage the commercialization of these technologies to become a regional economic development engine,"*

*- Dr. Richard Lariviere.*

Center, the KTEC funds were administered by the Higuchi Biosciences Center, which pursued the dual missions of enabling multi-investigator basic research grants and technology development and commercialization. The BIO Center has now assumed the development and commercialization mission. "On behalf of KTEC, we are pleased to continue our support of these outstanding bioscience research, development and commercialization efforts at the University of Kansas," said Tracy Taylor, President and CEO of KTEC. The HBC continues with a singular mission of fostering and enabling multi-investigator research grants.

"The overall mission and vision will remain the same, to develop life enhancing pharmaceutical and biomedical technologies through applied physical and chemical based research, and successfully manage the commercialization of these technologies to become a regional economic development engine," said University of Kansas Provost and Executive Vice Chancellor Dr. Richard Lariviere about the KTEC funding moving from HBC to the BIO Center. By working closely with the OTDD and the Office of Technology Transfer, the BIO Center will support development of technologies originating from the Medical Center campus also, thereby increasing the leverage of KTEC funds. BIO Center funding will support four general areas which are: core development resources (laboratory personnel, equipment and supplies), technology transfer, seed funding and grant administration.

"The establishment of the BIO Center speaks to the foresight of Provost Richard Lariviere, Associate Vice-Provost George Wilson, and HBC Director Eli Michaelis to centralize drug development efforts within the University," said Dr. Rajewski. "These centralization efforts will lead to a decrease in redundancies and increased strategic impacts on cross-campus development projects. The Bio Center will continue to build on the history of economic development efforts of Prof. Valentino Stella and others as it enters this new era."

KTEC is a private/public partnership established by the state of Kansas to promote technology based economic development. The KTEC Centers of Excellence are charged with the mission of converting university-based technological discoveries into products, services, jobs, and companies to further research as it pertains to economic development in Kansas. ▼

The BIO Center will be under the direction of Dr. Roger Rajewski and consist primarily of personnel and other resources previously associated with the Product Development Core (PDC) within the Higuchi Biosciences Center (HBC). Dr. Rajewski served as associate director of the PDC and acting director of the Center for Drug Delivery Research.

KTEC has funded bioscience research at The University of Kansas since 1989. Prior to the establishment of the BIO

### **Director's Corner**

*Welcome to the first edition of 'Developments.' This newsletter will be published three times a year to keep KU researchers and our off-campus colleagues current on biotechnology development and commercialization efforts and capabilities at KU.*

*Over the life of the KTEC grant to the University, the focus of the University and the Center for Research on drug development has been continually refined. Nowhere is this focus more apparent than in the function of the Office of Therapeutics, Discovery and Development (OTDD). The OTDD spans both the Lawrence and Medical Center campuses and brings industry best practices and project management to our collective efforts. A summary of the OTDD led KU Drug Discovery and Development Program is featured in this newsletter.*

*Support for the continued growth of a self-sustaining biotechnology and biomedical industry cluster in Kansas is at an all-time high. The BIO Center is committed to our KTEC supported mission to aid in this growth. It's not just what we do, it's who we are and what we believe in.*

*- Roger Rajewski*

## KU Drug Discovery and Development – A Primer

In early fall 2006, a team of University researchers and administrators were given the task to define the drug discovery process at KU, and provide a business plan to direct its implementation. Led by Dr. Scott Weir, Director of the Office of Therapeutics, Discovery and Development (OTDD), the plan was finalized and received the approval of KU administration from the Lawrence and Medical School campuses in December 2006.

The vision of the KU Drug Discovery and Development Program (KUDDDP) is for KU to become the premier institution in pharmaceutical research, pharmaceutical education, and commercialization of the resulting intellectual property. The objectives are to advance and improve health care through the

*The KUDDDP approach is based on the successful model used in the pharmaceutical industry. Multi-disciplinary project teams, . . . are empowered to define overall project objectives, key decision points, and detailed project plans.*

discovery of promising pharmaceutical agents for the treatment and prevention of disease, grow research funding, create unique educational opportunities for students, and create commercial opportunities.

In managing the KUDDDP, the OTDD ensures that researchers, clinicians, cores, centers, industry partners, regulatory and technology transfer resources work

together in a highly integrated, organized, collaborative fashion to support creation and advancement of drug projects. Project Directors organize and manage multifaceted project teams whose members represent the above-mentioned parties.

The OTDD functions much like a virtual biotechnology company within a university setting. It is staffed with senior, highly experienced staff from the pharmaceutical industry. The Director, Scott J. Weir, Pharm.D., Ph.D., has over 21 years drug development experience. The Deputy Director, Sitta N. Sittampalam, Ph.D., has 23 years drug discovery experience in large pharma. Melinda Broward, B.Sc., M.Sc., Project Director, has 19 years experience in drug discovery and preclinical development. Michael Hughes, B.Sc., M.B.A., Project Director, has 13 years industry expertise with a strong background in pharmaceutical sciences.

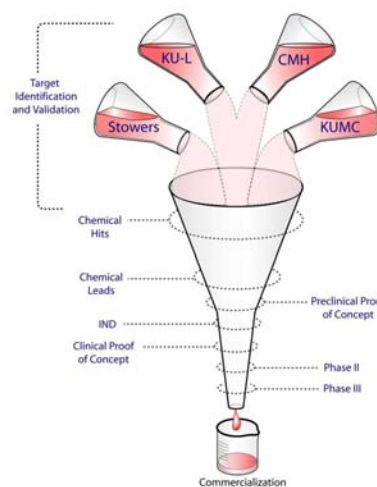
Projects are brought to the KUDDDP by individual investigators, center directors, departmental chairs, school deans, the technology transfer officer, and numerous other routes. The KUDDDP approach is based on the successful model used in the pharmaceutical industry. Multi-disciplinary project teams, composed of tenure-track faculty, staff researchers, and experts from other academic institutions and the pharmaceutical industry are empowered to define overall project objectives, key decision points, and detailed project plans. Regularly scheduled team meetings (with preset agendas and formal minutes) are held to raise and resolve issues and make decisions.

Project team members inexperienced in drug discovery and development are aided by "Pharmaceutical Development Guidelines," an internal document adapted from proven pharmaceutical industry practices. The guidelines define typical key decision points from drug target identification and validation through clinical proof of concept (see Figure 1).

Furthermore, they identify key data typically required to support each of the decision points as well as the key experiments or studies required to generate the decision-making data. The guidelines also provide structure to the profiling or characterization of pharmaceutical intellectual property—in

effect, characterizing new chemical entities and drug products, very similar to the approach taken by many pharmaceutical companies. As a result, KU pharmaceutical intellectual property is well characterized and in a strong position to be licensed to private industry, who has the resources to advance new chemical entities and drug products to late stage development and commercialization.

The Biotechnology Innovation and Optimization Center (BIO Center) works closely with the OTDD and the Technology Transfer Office in the identification, selection, and support of projects in the KUDDDP. The BIO Center provides preclinical and pharmaceutical sciences resources to KUDDDP projects. When appropriate, the BIO Center solicits the approval of its Industrial Advisory Board to use KTEC resources to support these preclinical studies.



**Figure 1. Translational Research Flow**

The current KUDDDP drug pipeline contains approximately 40 drug projects. Projects are categorized as a function of their current stage of drug discovery and development. Strategically, the drug pipeline strives to achieve a balance between novel, drug discovery or new chemical entity compounds and drug delivery projects. Although a major focus of the program is cancer and neuroscience, this program supports researchers working in all therapeutic areas. The KUDDDP also supports drug discovery and development projects originating from collaborating partners (e.g., Stowers Institute for Medical Research, Children's Mercy Hospital, University of Missouri Kansas City) as well as other regional and national institutions including Kansas State University, Scripps Institute in San Diego, and the Cancer Prevention Program within the Mayo Clinic Comprehensive Cancer Center.

Additional information may be found at:  
<http://cancer.kumc.edu/ddoverview.html>

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