Center of Excellence for Vaccine Development

LEQSF (2007-12)-ENH-PKSFI-PRS-02

Year 2 Annual Report
6/30/2009

INTRODUCTION

The Center of Excellence for Vaccine Development (Louisiana Vaccine Center) encompasses three major Louisiana university campuses, LSUHSC-New Orleans, Tulane University Health Sciences Center and Xavier University of Louisiana, and was created in order to focus existing interdisciplinary strengths in the basic and translational science of microbial pathogenesis, host immunity and vaccine research to foster development of novel approaches to vaccination against infectious disease. The goal is to establish a tower of strength in Louisiana with a research and development infrastructure to support its future growth and expansion. Vaccine research and development is currently a field of great current prominence worldwide.

The Center's goal is to establish a framework for research and development in infectious disease and vaccines that will in turn provide a focus for retention of established researchers and promising junior scientists. Through this work, the Center will foster new collaborations between scientific institutions in Louisiana and strengthen our capacity to compete for large-scale research and development grants and contracts. Through our educational programming, we are stimulating the interest of high school and college students in vaccine-related research and their future participation in higher education in related fields. Our commercialization initiatives are working towards the development of intellectual property in the form of patents and/or licenses. The Center will therefore play a critical role in the development of the local infrastructure necessary for the development of novel vaccines for infectious disease.

The primary focus of the Center in Year 2 has been to build upon the foundation established in Year 1 and continue to foster the growth of our research, education and commercialization programs. The details of these initiatives are explained in detail in the Activities and Findings section of the Report below. Some of the Center highlights of Year 2 against our established Performance Measures include:

- Three meetings of the Center Steering Committee (CSC) were held to facilitate the organization and conduct of scientific matters, Core laboratories, and administrative matters pertaining to the Project. In addition, the first on-site meeting of the External Advisory Committee (EAC) was held in conjunction with the Center's Annual Meeting and Research Fair on September 24th and 25th, 2008 (see Section 2 a.v).

- The Center completed planning for and held a discipline-based, day-long research symposium entitled, *"Symposium on Mycobacteria, Tuberculosis and Host Defense"* on November 21st, 2008 at LSUHSC-NO campus, the first of our "theme-based" initiatives designed to foster new collaborative ventures leading to the growth of towers of strengths in different areas and the development of new federal funding submissions (see Section 2 a.vi).

- The Center held a workshop on intellectual property for Project participants. The Center is also currently holding planning meetings for the development of a Research and Development Series that will focus on IP as well as other areas such as IRB and IACUC for investigators (see Section 2 a.iii).

- The Center has identified and awarded ten 2-year Collaborative Pilot Research Project Awards in Year 2 and each awardee PI has recently submitted a summary report of their progress (see Section 2 a.iii).

- The Center has supported the appointment of five new postdoctoral fellows to projects in vaccine-related research programs as a direct result of Center pilot grant funding: Ratish Gambhira Ph.D., Miriam Mancuso, Ph.D., Raman Agrawal, Ph.D., Maria Lewis, MD and Miao Luo, Ph.D.

- The Center has held a high-profile seminar program featuring Project faculty, Project research trainees, and distinguished visiting speakers. The Center's *Infection, Immunity and Vaccine Seminar Program* featured seven high-profile national speakers, along with a number of local presenters (see Section 2 c.iv). In addition, Access Grid technology has allowed the Center to transmit these seminars to the LSU School of Veterinary Medicine (Baton Rouge, LA) and the Tulane University National Primate Center (Covington, LA).

- Center investigators have submitted over $43 million in new external grant submissions, primarily to the NIH. These include two large, programmatic grants: a Developmental Center for AIDS Research (D-CFAR) application for over $4.5M over 5 years (a LSUHSC/Tulane/Xavier collaboration) and a P01 application on Vaccines and Therapies for HIV-related pulmonary infection for $9M over 5 years, both applications focusing on Center investigators areas of strength and expertise (see Section 2 a.iv).

- A total of twenty student interns have now been recruited into the LVC Summer Internship Program during the summers of 2008 and 2009 (see Section c.i). The students that participated in the summer 2008 Program created and presented posters based on the work they conducted over the term of their internship (see Section 2 c.i). Students completed evaluation of summer student experience using Goal Attainment Scaling as formative assessment, with overall satisfaction survey as summative assessment (see Section 2 c.ii). Two of the participants in the summer 2008 Internship Program, Timothy Tate and Sharon George, both minority students, were recruited for a 1-year research placement in a Center research laboratory during Year 2 (see Section 2 c.iii).

1. PERSONNEL

Key personnel in the Center in Year 2 include:

Alistair Ramsay PhD (Professor of Medicine and Director of the Gene Therapy Program at LSU Health Sciences Center). He is Principal Investigator, Center Director, and a member of the Center Steering Committee. Dr. Ramsay has been centrally involved in all Center activities in Year 2. He has attended meetings with members of the Center Steering Committee during this period at which progress reports were presented by research, education and commercialization coordinators and development strategies were discussed and appropriate actions were initiated. In particular, these initiatives included the continued development and enhancement through support of Center Research Cores, the second year of support of the Summer Internship Education Program, the continued development and enhancement of a first class seminar program with a number of high-profile visiting speakers continuing to visit the Center, and the continued support and development of a Pilot Research Grant Program that currently funds 10 pilot awards. He also chaired the Center's Mycobacterium Symposium, the Annual Meeting and Research Fair and also attended the External Advisory Committee meeting. He is an integral part in the implementation of the Center's commercialization initiatives. He has also attended two high profile vaccine meetings on the Center's behalf. He is Director of the BSL-3 Bio-Containment Core Facility.

John Clements PhD (Professor and Chairman of Microbiology & Immunology at Tulane University HSC). He is co-PI and a member of the Center Steering Committee. He has regularly attended meetings with members of the Center Steering Committee during this period at which progress reports were presented by research, education and commercialization coordinators and development strategies were discussed and appropriate actions were initiated. He is an integral part in the implementation of the Center's commercialization initiatives. He is Director of the Protein Core Facility.

Seth Pincus MD (Nelson Ordway Professor of Pediatrics at LSU Health Sciences Center and Director of the Research Institute for Children in New Orleans). He is co-PI and a member of the Center Steering Committee. He has regularly attended meetings with members of the Center Steering Committee during this period at which progress reports were presented by research, education and commercialization coordinators and development strategies were discussed and appropriate actions were initiated. He attended the Center's Annual Meeting and Research Fair and the External Advisory Committee meeting. He is the Director of the Molecular Interaction Core Facility.

Tarun Mandal PhD (He is McCaffrey Norwood Professor of Pharmacology at Xavier University of Louisiana). He is co-PI and a member of the Center Steering Committee. He has participated in the development and implementation of research, education and commercialization strategies. He attended the Center's Annual Meeting and Research Fair and the External Advisory Committee meeting. He is also Director of the Nanotechnology Core Facility.

Paula Gregory PhD (Associate Professor of Genetics at LSUHSC) is Education Program coordinator and Fern Tsien PhD (Instructor of Genetics at LSUHSC) is Assistant Education Program coordinator. They attended and presented at the Center's Annual Meeting and Research Fair. Together, they have developed and implemented the Center Education Program that focuses initially on summer research internships for college and undergraduate students.

Thomas Lallier PhD (Associate Professor of Anatomy and Cell Biology at LSUHSC) is Research Program facilitator. He has attended meetings with members of the Center Steering Committee during this period at which research initiatives were discussed and appropriate actions were initiated. He attended and was a presenter at the Center's Annual Meeting and Research Fair and the External Advisory Committee meeting. He has played a key role in integrating and coordinating the development of the Center Research Core Facilities and, now that the cores have been established, continues to coordinate and facilitate their use by Center investigators.

Steven Ceulemans MS is the Commercialization Facilitator. He has regularly attended meetings with members of the Center Steering Committee during this period at which commercialization development strategies were discussed and appropriate actions were initiated. He attended and was a presenter at the Center's Annual Meeting and Research Fair and the External Advisory Committee meeting. He has now implemented a commercialization strategy for the Center, beginning with a full inventory of grants and intellectual property held by Center members as well as the introduction of the LVC Faculty Interview Program to identify potential commercial opportunities. He has also attended two high profile vaccine meetings on the Center's behalf. His activities are overseen by Aaron Miscenich (Director of the New Orleans BioInnovation Center), in partnership with the Vaccine Center Steering Committee.

Patricia D'Arensbourg is the Administrative Coordinator. She assisted the Director and the Steering Committee with all administrative functions in the Center.

Lesley LeBlanc BS is the Associate for Research and Development. She has attended meetings with members of the Center Steering Committee during this period at which progress reports were presented by research, education and commercialization coordinators and development strategies were discussed and appropriate actions were initiated. She helps to coordinate the development and implementation of research, education and commercialization strategies. She has attended two annual vaccine meetings and an international biotechnology convention on the Center's behalf. She has played a key role in integrating and coordinating awareness of the Center Research Core Facilities in order to facilitate their use by Center investigators. She has also played a key role in the implementation of the Center's Faculty Interview process within the commercialization program.

2. ACTIVITIES AND FINDINGS

Central to the continued development of the Center are **(a) RESEARCH:** The growth of essential research and development infrastructure and development and support of vaccine-related research and development projects, **(b) COMMERCIALIZATION:** The implementation of a commercialization strategy that identifies novel ideas among Center investigators, facilitates the technology transfer process and provides the link to establishing partnerships with outside collaborators and **(c) EDUCATION:** The education and training in vaccine-related research and development. The primary focus of the Center in Year 2 continues to be in these key areas.

(a) Research- The continued growth of essential research and development infrastructure is critical to the Center during Year 2. The plan for Core growth and development was designed specifically to aid the flow of vaccine-related research from discovery to vaccine preparation and delivery and through pre-clinical testing and analysis towards the development and conducting of clinical trials.

i. Core Enhancements: Each of these Cores is at a different stage of development with regard to its Center-related research support activities, as outlined below. Enhancement of these facilities will continue in Year 3.

1) Genomics Core
2) Proteomics Core
3) Protein Core
4) Nanotechnology Core
5) Vector Development Core
6) Immunology Core
7) Molecular Interaction Core
8) Imaging Core
9) BSL3 Containment Lab Core

The following is a full summary of progress to date in the development of each of these facilities:

1). Genomics Core

Core Directors: Doan Nguyen PhD and Jovanny Zabaleta PhD

Location: LSUHSC-CSRB

The mission of the Genomics Core is to provide comprehensive genomics, microarray and bioinformatics support to Center investigators through state-of-the-art analytical equipment and data analysis capabilities. Services include assistance in microarray experimental design and data analysis, protein and nucleotide sequence analysis, functional analysis of high-throughput data,

data mining, data organization and repository, whole microbial and mammalian genome mapping, and database development.

2). Proteomics Core

Core Director: Chau-Wen Chou PhD

Location: LSUHSC – CSRB

The Proteomics Core was established at LSUHSC through institutional and State funding. As a result, extensive equipment is available for 2D Gel Electrophoresis analyses, fluorescent tags and special purposed stains (phosphorylation, glycosylation), high performance liquid chromatography, mass spectrometry and a Global Proteome Server Explorer workstation for fast protein identification in quantization and biomarker discovery.

3). Protein Core

Core Directors: John Clements PhD and Anders Frisk PhD

Location: Tulane School of Medicine

The Protein Core is located at Tulane HSC and its major goal is to provide Center researchers with purified protein antigen for use in vaccine research. Personnel dedicated to Center projects assist researchers in the selection of optimal recombinant expression systems (prokaryotic and eukaryotic), will sub-clone genes of interest into expression vectors, and will optimize protein expression and purification. The core also assists in generating site-directed mutants of proteins of interest and in scaling up of recombinant protein production. Emphasis is placed on purity, with removal of bacterial endotoxin and contaminating immunogens from protein preparations, while minimizing degradation. In Year 2, the Protein Core made an $8000 upgrade of its chromatography equipment to enhance its efficiency and provide a greater level of service to Center investigators.

4). Nanotechnology Core

Core Director: Tarun Mandal PhD

Location: Xavier University of Louisiana

The major goal of this Core is to maintain a state-of-the-art innovative polymeric vaccine delivery research facility in order to support inter-disciplinary research within the Vaccine Center. Core personnel will provide leadership in planning, designing, and implementing innovative nanotechnology and will also assist investigators in conducting pre-formulation and formulation studies of any potential novel vaccine delivery system for preclinical and NDA studies (New Drug Application following USFDA guidelines). Nano-delivery technology is

being developed and/or adapted, in collaboration with Center researchers, to address the special requirements of either systemic or mucosal (i.e. intranasal, pulmonary, oral, or intra-vaginal) particle-mediated delivery of peptides, proteins and/or recombinant DNA vaccines in preclinical and, ultimately, clinical studies. Targeted particle- or lipid-mediated delivery either of proteins via novel routes (e.g. transcutaneous) or of alternative recombinant vaccine vectors is already under development in the Core and this technology will also be made available to other Center investigators. Currently, the NIH-funded nanotechnology research laboratory is equipped with R&D-scale pharmaceutical formulation equipment, with research staff that has developed unique skills in micro-encapsulation for controlled release. A Water Acquity SQD LC/MS System was funded by the Center and operating within the Core to help to more readily identify successful synthesis and product deformulation.

5). Vector Development Core

Core Director: Robert Kutner

Location: LSUHSC – MEB

This Core greatly facilitates co-operative Center research through the design, engineering, preparation and purification of new recombinant vaccine vectors and novel vector technology in a variety of new vaccine vector systems. The Core is already equipped for manufacture of lentvirus, poxvirus, adenovirus and adeno-associated virus vector systems for Center investigators through LSUHSC, Gene Therapy Consortium and NIH funding. To date in Year 1, Center investigators from LSUHSC and the Research Institute for Children have received a total of 12 vaccine-based vector preparations generated in the Core, while another researcher was aided in HPLC purification of an antibody of interest. The Vector Core has also been investigating newer vaccine technologies to expand its portfolio to better suit infectious disease-related research. Newer technologies include implementing double-stranded AAV production, large-scale batch-fed endotoxin-free plasmid production, and development of a fowl pox-producing helper cell line. With demand for vaccine-based vectors increasing, the addition of modern production techniques already implemented, and the future addition of newer technologies, the Core is now well situated to cater for Center researcher's needs. New Developments, Equipment and Technologies in Year 2 include:

For enhanced adenovirus vector production, we modified our viral propagation protocol by using Hyper flasks. This increased the yield and quality of adenovirus due to the added number of cells per unit volume of media-culture and the reduced number of sample handling steps. Incorporating this new cell culture system in tandem with our Mustang Q (PALL Corporation) anion exchange chromatography purification protocol facilitated transition towards tangential flow production.

Generation of endotoxin-free plasmid DNA vaccine vector production was established. Initially, plasmid DNA was generated by traditional commercial kits but pilot studies aimed to increase the plasmid yield were explored. Through these studies bench-side scalable processes were developed where improved bacterial culture conditions and methods for chromatographic capture of plasmid were implemented. The amount of bacteria able to be grown was greatly increased by acquiring a New Brunswick BIOFLO 310 bio-reactor for scalable fermentation processes. Subsequent large-scale plasmid purification is now accomplished with Mustang Q chromatography and the use of a surfactant with an affinity for endotoxins is used to prevent chromatographic capture of endotoxins during binding thereby maintaining endotoxins-free plasmids products.

Modified vaccine Ankara production was established. MVA virus and insertion plasmids were obtained from Dr. Bernard Moss LVD, NIAID, NIH and used to develop the MVA production. With minor modifications in the previously established poxvirus protocol to generate primary chicken skin cells we were able to generate large-scale stocks of MVA. Concentration and purification of large-scale MVA via ultracentrifugation through a sucrose-cushion was subsequently established.

6). Immunology Core

Core Director: Ping Zhang MD, PhD

Location: LSUHSC – CSRB

The Immunology Core serves Center investigators in the measurement of immune responses in vaccine-related studies and data analysis. State-of–the–art Flow Cytometry and Immunoassay equipment has been purchased by LSUHSC and NIH funds, while the Core is directed by and has a fully qualified FACS operator (Constance Porretta MS). Full FACS acquisition services and immune assay development support are provided to Center researchers. The Core also continues to train investigators, medical students, graduate students and research assistants to perform analyses using equipment and procedures. An experienced Vaccine Center-funded research technician, Olha Nicholls MS, is employed in the Core to assist with all aspects of Center investigator's research. In 2009, LVC Immunology Core acquired a new BD FACSCanto II system using the funding of LVC and other resources. This new flow cytometer is equipped with 3 lasers and measures 8 color/10 parameters. With addition of this new system, the Core has further increased its capacity of FACS analysis which will strengthen the analytical support of the Core for ongoing investigations of LVC.

7). Molecular Interaction Core

Core Directors: Seth Pincus MD and Miriam Corti PhD

Location: Research Institute for Children, Children's Hospital

This new Core utilizes Biacore technology to study intermolecular interactions in real time and is extremely useful in determining affinities of monoclonal antibodies and polyclonal antisera, activities important for many of the Center investigator's research projects. Because antibody affinity is often a correlate of protective activity, this presents a method for analyzing the quality of the antibody response elicited by experimental vaccines.

New personnel as of June 2008: Miriam Corti, Ph.D.

Training: Biacore Basics by GE Healthcare, San Diego, June 2008, Kinetics by GE Healthcare, Baltimore, MD, September 2008, Surface Plasmon Resonance literature review: on-going

Facility: Set up working laboratory and stocked commonly used reagents and supplies

Center Clients: Li Shen, Ping Zhang, Ashok Aiyar, Christopher Summa, Seth Pincus, Clorinda Johnson, T. Cooper Woods

Recent Operating Changes: Over the last year, all experiments were performed by Miriam Corti under advisement of the principal investigators and the core director, Dr. Seth Pincus. In the future, investigators interested in the technology will be trained on the usage of the machine so that they may perform their own experiments and personally decide the direction of their research. In addition to training and being available for technical assistance, we will serve as advisors on experimental design and data analysis.

8). Imaging Core

Core Director: Luis Marrero

Location: LSUHSC – CSRB

The Gene Therapy Morphology and Imaging Core (MIC) in the LSUHSC-NO campus is a comprehensive histopathology and specialized imaging center for use by the Louisiana Vaccine Center and partners. The MIC facilitates technical expertise in the fields of histology; immunological and chemical detection of gene expression; and imaging of cellular targets at the molecular level; underpinned by scientific input, advice in experimental design and interpretation of results. The MIC clientele services over 25 Center investigators.

During the past year, the MIC staff has been involved in designing and executing a vast array of experimental protocols including but not limited to investigations requiring phenotyping of inflammatory responses and organism burden in models of tuberculosis; characterization of Chlamydia trachomatis persistence in aging endocervix through deconvolution microscopy; visualization of Pseudomonas aeruginosa ocular infection by routine histological stains; detection of lymphocyte death in lungs afflicted with Pneumocystis Carinii infection using triple immunofluorescence labels of apoptosis; and descriptive analysis of cellular uptake of biotoxins such as ricin during time-lapse imaging. High-resolution photomicrographs include details to the order of a single chromosome and are often complemented with quantitative analyses.

The MIC has recently implemented new state-of-the-art technologies for use by the LVC including a laser micro-dissection system to allow for functional and molecular analysis of cells dissected and isolated from precise regions of tissue sections; and two real-time imaging chambers to non-invasively monitor and record cellular and genetic activity within a living organism. In addition, an infrared illumination based, multi-photon microscope has been recently incorporated to allow high resolution imaging of fluorescently labeled serum, microorganisms, cells, and tissues in fixed or live samples, with minimal sample degradation, and at 200 times greater depth than conventional microscopes.

9). BSL-3 Bio-Containment Core

Core Director: Alistair Ramsay PhD

Location: LSUHSC-CSRB

This facility that is critical for work with pathogens that require bio-containment was originally established through LSUHSC and LEQSF Enhancement Funds. Vaccine Center enhancements in Year 2 have enhanced the utility of this facility for Center Investigators through the purchase of two Microvent Hepa-filtered Animal Racks for the Core that will help to facilitate animal studies ongoing in the laboratory in three distinct Tb vaccine projects.

ii. **Core Awareness Slide Presentations:** In an effort to enhance the exposure and capabilities of the Cores during Year 2 and as recommended by the External Advisory Committee during the Annual Meeting, the Center launched a series entitled, "Core Awareness Slides" that run prior to the seminar in *Infection, Immunity and Vaccine Seminar Program*. These rolling PowerPoint presentations are 5-7 slides in length and highlight the objectives, equipment and services of a particular core. These presentations allow the Center to inform investigators about the access they have to state-of-the-art equipment as well as the wealth of knowledge and expertise of core facility personnel, all in an effort to aid them in their vaccine-related research projects. The Center has highlighted a total of five Core facilities thus far: Vector Development, Molecular Interaction, Imaging, Protein and Nanotechnology (see **APPENDIX A**).

iii. **Pilot Grant Recipients:** A major initiative undertaken by the Center in Year 2 was the development and support of vaccine-related research and development projects via a Cooperative Pilot Research Grant Fund in partnership with the RC/EEP-funded South Louisiana Institute for Infectious Disease Research (SLIIDR). This initiative is intended to foster the development of novel local multidisciplinary and collaborative research projects in the fields of infectious disease, immunity and/or vaccine development. This addresses our goals that include the generation of new project and collaborative program applications funded extramurally, and discoveries with potential for clinical application and/or commercial development. Applications from new investigators and those from established investigators that propose new research directions were encouraged. A Request for Proposals was circulated to all Faculty working in relevant Departments and Centers at LSUHSC, Tulane HSC and Xavier in April 2008. Following peer reviews, ten of these grant applications were awarded in July 2008, Year 2. Successful projects will be funded up to $75K/year for 2 years. (See **APPENDIX B** for notice of award letter and for a list of recipients.) These awards will foster the development of collaborative projects by new investigators and will also allow established investigators to explore new research directions.

It is critical to the success of this program that the Center maintain regular contact with each of the pilot grant recipients in order to stay informed about their research project. These periodic meetings have been successful in gauging the strengths of the program as well as areas for improvement. As a direct result of these meetings and recipient feedback, the Center is creating a Research and Development Series that will launch in fall 2009 (Year 3). This monthly series will cater to investigators and cover such topics as grants, clinical trials, IRB, IACUC, etc. and the requirements needed to process them. Personnel experienced in these areas will be invited to present. Currently, the Center has held a number of planning meetings in preparation for this series. (See **APPENDIX C** for tentative topics.)

iv. **External Grant Funding Submissions:** In Year 2, Center Investigators have submitted new funding applications for over $43 million, primarily to the NIH. Particular highlights include a LSUHSC/Tulane/Xavier Developmental Center for AIDS Research (D-CFAR) application to NIH ($4.5M), and a NIH P01 application to look at vaccines and therapies for HIV-related pulmonary infections ($9M). Both arose directly from interactions facilitated by the Vaccine Center. In addition, multiple R01 and RC1 "Challenge" grant applications were submitted. This highlights the growing strength of infectious disease and vaccine-related research interactions within the Center. Submissions are tabulated below.

Table of External Funding Submissions by Vaccine Center Investigators in Year 2

Agency	Type of Award	Name of Project	PI
NIH	Developmental Center for AIDS Research (D-CFAR)	The LSU-Tulane Joint D-CFAR	Marx/Molina
NIH	P01	Host Defense Against HIV-Related Pulmonary Infections	Shellito/ Ramsay/Kolls
NIH-NIAAA	R01	Alcohol Use and Shedding of HIV-1 in the Female Genital Tract	Amedee
NIH-NCRR	P20	Mentoring Oral Health Researchers in Louisiana (administrative supplement)	Fidel
NIH	RC1 Challenge	GRITS (Girls Raised in the South Do Science)	Gregory
NIH	RC1 Challenge	Rebuilding Science Education in New Orleans	Gregory
NIH	R01	Multilevel Communication Effects on HPV Outcomes	Hagensee
NIH-NCI	R01	Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ Women (administrative supplement)	Hagensee
NIH	R01	Detection of EBV in Residual Pap Smear Fluid to Enhance Cervical Cancer Screening	Hagensee
NIH-NCI	R01	Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ Women (competing supplement)	Hagensee
NIH-NIAAA	K08	Alcohol, Pulmonary Cytokines, and Host Defense (administrative supplement)	Happel
NIH-NIAID	R01	CLP Proteolysis in M.Tb	Kaushal
NCRR	R21	Macaques Model for Tb-AIDS Co-Infection	Kaushal
NIH-NHRBI	RC1 Challenge	Discovery of Biomarker for Coincidental Tb and AIDS	Kaushal
NIH-NIAAA	R01	Alcohol, ROS, and Macrophage Epigenetics	Kolls
NIH-NHLBI	R01	IL-23/IL-17 and Lung Host Defense (administrative supplement for summer research)	Kolls
NIH-NHLBI	R01	CD8 Cells and Host Defense Against P. Carinii (administrative supplement for summer research)	Kolls
NIH-NHLBI	R01	CD8 Cells and Host Defense Against P. Carinii (administrative supplement)	Kolls
NIH-NHLBI	R01	IL-23/IL-17 and Lung Host Defense (administrative supplement)	Kolls
NIH-NIAAA	R01	Alcohol, ROS, and Macrophage Epigenetics (administrative supplement)	Kolls
NIH-NIAAA	R01	Alcohol, ROS, and Macrophage Epigenetics (administrative supplement for summer research)	Kolls
NIH-NIAAA	R01	Non-CD4 Host Defense Against P. Carinii Pneumonia	Kolls
NIH-NHLBI	R01	Th 17 Cytokines and Lung Immunity	Kolls

Agency	Type of Award	Name of Project	PI
NIH-NIAID	R01	Nasal DNA/Protein Vaccine for Anti-HIV antibody and CTL (supplement)	Kozlowski
Gates Foundation	Grant Challenges Explorations, Phase I	Adjuvant and PLGA-DOTAP Hybrid Nanocarriers for Vaginal Administration of HIV Vaccines	Kozlowski
NIH	R01	"HIV ENV Epitope Engineering"	Landry
Gates Foundation	Grant Challenges Explorations, Phase I	"Engineering Antigen Processing for Improved Immunity"	Landry
Gates Foundation	Grant Challenges Explorations, Phase I	New Use of Hybrid Nanoparticles for Delivery of a Defective Particle HIV DNA Vaccine	Luftig
NIH	RC1 Challenge	New receiving environments and risk networks of Latino migrant men	Martin
NIH-NIAID	P20	Sexually Transmitted Infections Cooperative Research Centers (administrative supplement)	Martin
NIH-NIAAA	R01	TB and Tregs	Mason
NIH-NIAAA	R01	Alcohol and Reactivation TB (Economic Stimulus Supplement)	Mason
NIH-NIAAA	R01	Alcohol and Reactivation TB (administrative supplement)	Mason
Gates Foundation	Grant Challenges Explorations, Phase I	Double Strike Against TB	Mason/Ramsay
NIH	RC1 Challenge	Two Strikes and TB is Out	Mason/Ramsay
NIH	R01	"Immunogenicity and Protective Efficacy of Novel Burkholderia psueudomallei Subunit Vaccines"	Morici
NIH-NIAAA	P30	Alcohol, HIV Infection, and Host Defense (Competing Renewal)	Nelson
NIH-NIAID	R01	Chlamydial Growth Patterns in Human Female Genital Tract	Quayle
NIH-NIAID	R01	Mucosal Innate Effectors in HIV Transmission	Quayle
NIH	RC1 Challenge	Chlamydia trachomatis-specific immunity in human female genital mucosa	Quayle
NIH	R01	Vaccination strategies against pulmonary tuberculosis (administrative supplement)	Ramsay
NIH-NIAID	R01	Analyses of Sigma Factor 28 of C. Trachomatis (Renewal)	Shen
NIH-NIAID	R01	Signaling complexes and the 14-3-3 protein in Candida (administrative supplement)	Sturtevant
NIH-NIAID	R01	Signaling Complexes and the 14-3-3 Protein in Candida (administrative supplement for summer research)	Sturtevant

v. Annual Meeting and Research Fair including the External Advisory Committee Meeting: The Center's First Annual Meeting, Research Fair and EAC Meeting were conducted on September 24 th and 25th, 2008 on the Tulane University Health Sciences Center and LSU-NO Health Sciences Center campuses in coordination with the South Louisiana Institute for Infectious Disease Research (SLIIDR). This two day event allowed Center management, administration and core directors to give updates to the attendees on the progress of the Center thus far and provided opportunities for meeting on future planning. The Research Fair was held on Wednesday, September 24th and focused on having researchers think beyond the lab and realize other opportunities for growth. Additionally, each of the Center Cores created posters and gave presentations about the services they provide. The Annual Meeting was held on September 25th. (See **APPENDIX D** for agenda and poster.) The Center Director and Coordinators gave presentations on the progress of the research, education and commercialization initiatives of the Center during Year 1. Additionally, the newly awarded pilot grant recipients presented the early stages of their work to meeting attendees. Following these presentations was the latest installment of the "Infection, Immunity, and Vaccine Seminar Program" with Arturo Casadevall, MD, PhD of the Albert Einstein College of Medicine, Bronx, NY as the featured speaker. This was followed by a feedback meeting with the External Advisory Committee (EAC). The members of the Center's EAC include:

Lawrence R. Stanberry, M.D., Ph.D. (EAC Chairman)
Reuben S. Carpentier Professor and Chairman
Department of Pediatrics
College of Physicians and Surgeons, Columbia University, New York, NY

Roger G. Rank, Ph.D.
Professor
Chlamydia Research Group
Arkansas Children's Hospital Research Institute
Little Rock, Arkansas

The first EAC meeting was of a general advising nature and the EAC complimented the Center on excellent progress and establishing a solid foundation for growth. Beginning with the 2nd Annual EAC meeting (scheduled for September 29th, 2009) a formal report of EAC recommendations and responses/outcomes will be included in the annual reports of the Center.

vi. Mycobacterium Symposium: A major goal of the Center is to foster the development of key areas of strength towards new collaborations and grant submissions. To this end, we will organize a series of symposiums to bring investigators together. First up, the Center held a day-long symposium entitled, "Symposium on Mycobacteria, Tuberculosis and Host Defense" on November 21st, 2008. Invited to present at this seminar were faculty, post-doctoral fellows and graduate students currently working in TB-related research at LSUHSC-NO, Tulane University Primate Research Center and LSU-Baton Rouge. Approximately twenty participants attended 12

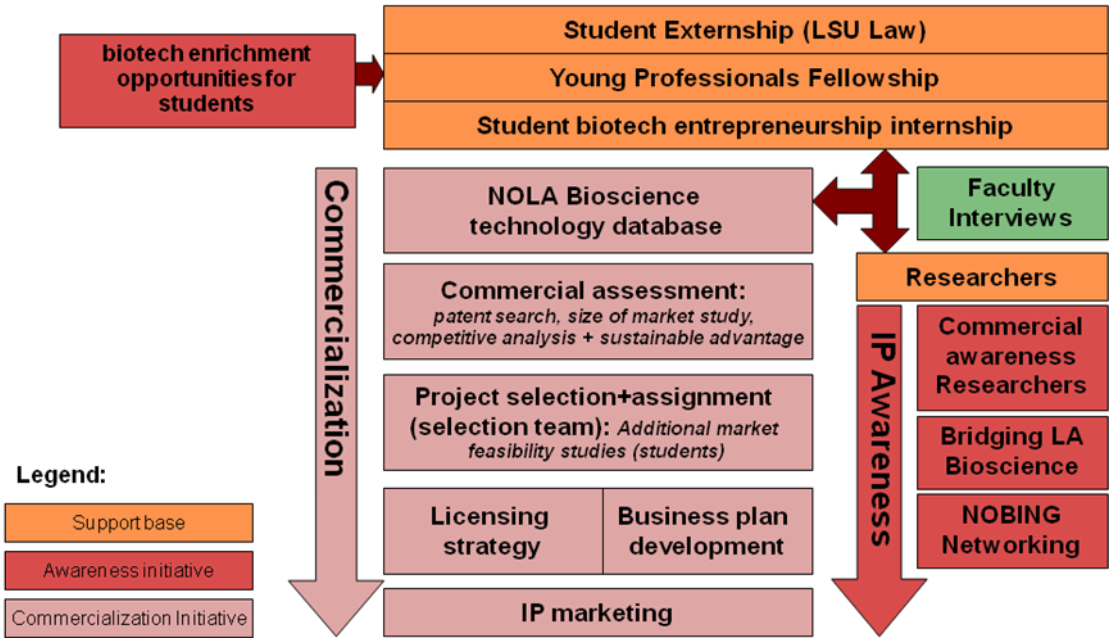
presentations covering a wide of array of ongoing projects in Mycobacterium tuberculosis (Mtb), tuberculosis and vaccine development. (See **APPENDIX E** for Symposium Program and for photos from the Symposium.) Follow up plans include a regular journal club/discussion group and a further symposium.

vii. **Grant Seekers:** The Center realizes that one of the critical pieces of its success is the generation of new funding for researchers in areas of infectious disease and vaccine development. The Grant Seekers meetings, held in coordination with SLIIDR, are designed to advise researchers, through a constructive process as to the best approach to prepare or modify their proposal so as to increase its chances of funding. All SLIIDR and LVC members are invited to join and contribute to this process. These meetings have also drawn attendance by junior faculty. Future reports will provide ongoing analyses of the success rate of grant applicants after undergoing the Grant Seeker process. (See **APPENDIX F** for Grant Seekers meeting schedule.)

viii. **Website Development:** The Center launched its website, www.louisianavc.org, in the spring of 2009. By doing so, it furthers the goals and objectives of the Center by informing Center investigators and other visitors to the site, about our mission, ongoing research projects, membership, Core facilities, as well as news and events. The website will aid the Center in establishing a profile both within our local bioscience community and also the larger bioscience community. (See **APPENDIX G** for homepage.)

ix. **Publications:** Center investigators have published 122 new original papers in Years 1 and 2 of Center activity. Many of these have resulted from new collaborations directly facilitated by the Center. These publications will help to raise the profile of the Center and form the basis of new grant applications and future clinical and commercial developments. (NOTE: See publications uploaded as a separate document as required for PKSFI reporting.)

(b.) Commercialization- One of the aims of the Louisiana Vaccine Center is to promote the development of our research with the aim of clinical translation and commercialization. A schematic overview of the commercial strategy as it is currently pursued is provided below:



Several elements of this commercial strategy have been implemented over the past year. These "Commercial Building Blocks" include student training in bioscience entrepreneurship through internships, externships, and a "young professional" fellowship; faculty interviews to raise commercial awareness and to actively facilitate research commercialization; a commercialization track including technology, IP and market assessment and development of commercial outcomes to ongoing academic research; and finally an IP awareness track focusing on networking and education of faculty, students and entrepreneurs on bioscience commercialization. Each of these building blocks is discussed below.

i. **Student Training:** One of the initiatives of the Vaccine Center's commercialization strategy is to expose business and law students to biotechnology through internships. Ideally, these students will have a background in science with an interest in areas such as biotech business development, entrepreneurship and patent law. This foundation allows them to guide Center faculty with any potential novel invention, model or method through the technology transfer process at their affiliated university. Over the past year, a total of 12 interns and 1 extern were engaged with the various commercial initiatives of the Center. There were a total of three interview teams, each composed of one law student and one business student, which conducted Faculty Interviews (see below). In addition, there were six additional interns and one extern that supported critical tasks involving the commercial aspect of the Center's initiatives.

All internships are a continuation and expansion of efforts started in Year 1. The externship has been instituted over the past year and entails collaboration with the LSU Law School in Baton Rouge. Externs, typically senior level law students with a science background and interest in health/patent law, complete up to 200 hours of activities in their area of interest, for which they are supervised by their law school mentor and obtain course credit. Recent externs have been involved primarily with invention disclosure assistance, patent/prior-art searches and (provisional) patent writing.

Interview Teams

Team 1

Ashton Prat is currently pursuing a MBA from the A.B. Freeman School of Business, Tulane University and specializes in market analyses and business development; **Justin Levy** is a recent graduate of Tulane University School of Law and specializes in legal research, intellectual property law and patent prosecution.

Team 2

Derek Little is pursuing a Masters of Finance from the A.B. Freeman School of Business, Tulane University and specializes in market analyses and business development; **Jenna Matheny** is a recent graduate of Tulane University School of Law and specializes in legal research, intellectual property law and patent prosecution.

Team 3

Michael Saunders is a recent graduate of Tulane University School of Law and specializes in legal research, intellectual property law and patent prosecution; **Ishaneka Williams** is currently pursuing a MBA from the A.B. Freeman School of Business, Tulane University and specializes in market analyses and business development.

Ancillary Team

Anjali Borhade is currently pursuing a Masters in Public Health from the Tulane School of Public Health. She works as the Programming Coordinator and is responsible for alliance building, commercial awareness and networking programs; **Damon Bowe** works as an extern, specializing in patent drafting. Damon has a Ph.D. in Pharmacology and Toxicology from the University of Alabama at Birmingham. He is currently pursuing his Juris Doctorate and Bachelor of Civil Law at Louisiana State University, Paul M. Hebert Law Center; Justin **Peno** specializes in the strategic development and market research of intellectual property held by universities in the New Orleans area. He is a recent graduate of the A.B. Freeman School of Business at Tulane University; **Page Young** specializes in market research and business plan writing related to select biotechnologies currently under development. Page recently graduated with a degree in genetics from Georgia

State University; **Shreya Biswas:** Shreya is a Tulane law student with a background in chemical engineering. As an intern, Shreya contributed to an inventory of inventions from LSU, Tulane University, University of New Orleans and Xavier University; **Azfar Butt:** Azfar is pursuing a computer science degree at UNO. His internship work includes starting the development of a skills and capabilities database aimed at providing a single view of bioscience resources in New Orleans; **Kris Ryals:** Kris is currently working on the website design and database administration for NOBIC, SLIIDR, LVC and CTRECP. He is currently pursuing his Masters of Science degree in computer science from UNO.

ii. **Faculty Interviews:** A recent initiative begun during the past year and supported by student interns is the faculty interviews. The purpose of these interviews is to consult with LVC research investigators to learn more about their current, ongoing research projects. In this effort, we hope to nurture existing and foster new research partnerships and if they exist, explore and facilitate potential commercial opportunities. The development of research towards commercialization is a multi-step process and clearly, not all research is aimed in this direction. However, it is important that researchers are aware of the commercial and translational potential of their work, including any funding and other opportunities that are available and might assist in this process. Examples of this include, identifying potentially novel inventions that have not been disclosed and possible sponsored research agreements, SBIR and STTR opportunities.

In addition, we are looking to use the information compiled during this interview process to complete and verify information for the Skills and Capabilities Database. This database will provide a consolidated view of available biotechnology resources in the area. It will provide insight into faculty members' areas of expertise and key lab equipment, as well as ongoing research projects and related intellectual property. Furthermore, it will map all available core lab resources, testing capabilities and clinical resources and expertise to establish avenues for the local bioscience and academic communities to take optimal advantage of them. All of these activities are being coordinated through the Institutional Technology Transfer offices with their full support.

The Faculty Interview process is being overseen by the Center's Commercialization Coordinator, **Steven Ceulemans** and Associate for Research and Development, **Lesley LeBlanc**. The interviews are prepared and conducted by law and business school student interns with scientific backgrounds. Having an understanding of the science and business of an investigator's research provides the interns with a foundation to conduct these interviews effectively. Since its inception in the spring of 2009, we had a total of nine interns and one extern involved with various aspects of the faculty interview process, working primarily at the New Orleans BioInnovation Center (NOBIC).

The interview process is multi-step and organized as follows:

*****The pre-interview step includes updating an Excel template with all current researcher specific database information. Faculty members are provided with an updated spreadsheet compiled using information from their Curriculum Vitae and/or biosketch. Each faculty member is asked to review the spreadsheet content and alert the interns to any changes or corrections. This is done in order to verify the information for the Skills and Capabilities Database as well as in-house record keeping. Also, the interns compile background folders on each researcher prior to the interview to better understand their work before meeting with them.

*****The interview itself is approximately one hour in duration and focuses on ongoing research and commercial plans and ambitions. The interview team has a set of questions they work from in order to give the interview some structure and direction. These questions cover the general areas of research, commercialization and core facility topics and are intended for use during the interview as a guide. The faculty member is also provided these questions prior to the interview. For the interview Steve, Lesley and one of the student intern teams visit with faculty in their offices. At this time, we also reiterate the intellectual property policies of each institution and discuss disclosures of new intellectual property.

*****The post-interview process focuses on future support related to topics identified through the interviews. These areas may include assisting faculty to assess potential commercial viability of their discoveries and fully exploring commercialization options (e.g. assistance with SBIR applications, invention disclosures, etc). In addition, each team completes a summary of the interview to document discussed items and to determine plans, if any, for follow up.

Through the initial and follow-up interviews with faculty, it is possible to obtain a substantial understanding of the research areas, ongoing projects and potentially novel inventions in Center labs. To obtain interview feedback, as well as metrics on researcher need for commercial support and education, a post-interview questionnaire is used to obtain feedback on the perceived value of the interview, and to pole for topics of interest for future commercial education events and seminars (See **APPENDIX H** for interview guide and post-interview questionnaire). All questionnaires are conducted in an anonymous fashion and are discussed in this report.

A graphical overview of the interview flow is provided below:

Of the approximately 70 Center faculty, a group of 25 were targeted as the initial group of investigators to be interviewed. This interview process is ongoing; to date several interviews have led to promising follow-ups with commercial relevance. Currently, there are approximately five potential novel inventions, models or methods that are being explored further. To date, 3 novel inventions have been disclosed as a direct result of the faculty interviews.

Overall, the faculty interview process has been well received by Center researchers, as well as affiliated university administration and the technology transfer offices. A majority of the faculty has been more than accommodating and willing to participate. Those interviewed seemed to enjoy the interview process and what they got out of it. Many gained knowledge regarding the patent process that they were not previously aware of. The interns were highly productive and have added much to the interviews and follow-up.

Remaining Center faculty will all eventually be interviewed and, in the future, faculty interviews will be repeated on a yearly basis.

iii. **Research Commercialization:** One of the underlying goals of the faculty interviews is to establish an inventory of Vaccine Center research projects with potential for commercialization. Through the interview process, interns explain the intellectual property policies of each institution encourage disclosures of new intellectual property, help faculty understand the potential commercial viability of their discoveries, and fully explore the commercialization options. This commercial exploration includes patent searches, preliminary size of market studies, competitive analyses and assessments of potential sustainable competitive advantages.

While not all potential intellectual property identified provides the strategic and enabling features to support creation of a new business endeavor, the initial technical and commercial due diligence allows for a more market conscious approach to technology commercialization, thereby improving the odds of resulting commercial success.

Faculty interviews and commercial leads generated over the past year have led to the commercial exploration of a number of projects currently under development. These projects currently include a joint-venture between a European CRO company and the Tulane Primate Center; an academic hybrid GMP facility, and a novel ELISA-based HPV test.

iv. Awareness and Outreach: To serve the educational goal of raising awareness of research translation and commercialization as a potential outcome for academic research among Center researchers, four separate initiatives were conceived that aim to bring the local universities, business community, and economic development professionals together:

The first seminar series termed "Commercial Awareness for Researchers" aimed to bring academic researchers and clinicians from all New Orleans health science institutions together to attend two speaker sessions organized to date and presented by an experienced bio-entrepreneur, a bioscience venture capitalist, and a local group of angel investors. Forty attendants participated in the November 2008 event, 60 people attended the most recent June 2009 event.

The second event termed "Bridging Louisiana Bioscience" is aimed at existing Louisiana biotech companies and presented two programs that could enhance business-academic interaction and could leverage research dollars. Dr. Gene D'Amour from Xavier University presented information about a program that places life science interns in the workplace free of charge to the company. The second presenter, Roy Keller, presented information about a statewide program hosted by the Statewide Technology Small Business Development Center that provides funding and guidance to help companies apply for federal SBIR and STTR grants. Fifteen attendees from 7 local companies participated in this event.

In concert with one of the Commercial Awareness for Researchers and Bridging Louisiana Bioscience events, biotech networking social termed "Biotech Connect" was organized at the Columns Hotel in New Orleans. This social event was aimed at bringing together local scientists, entrepreneurs, business facilitators, lawyers and investors, who do not usually mix. This event attracted over 100 people from local universities, government, and the private sector.

The most recent event organized for late June of 2009 will include a 2-day workshop on Innovation and Technology Leadership. Topics discussed in this workshop will include

an insight into the dynamics of technology acquisition, and how the integration process is managed. The workshop also provides tools on how to structure successful deals and manage the relationships of integrating external technology sourcing into business processes. (See **APPENDIX I** for all event announcements and speaker bios.)

Outreach

The Center was a participant at two major National/International vaccine conferences (the 9th Annual World Vaccine Congress in Washington, D.C. and the 12th Annual Conference on Vaccine Research in Baltimore, MD) and also at the 2009 International Bio convention in Atlanta, as a featured exhibitor. This helped to build 'brand awareness' of the Center and to facilitate interactions with leading academic and industry vaccine R&D houses on the Center's R&D ambitions with focus on collaborative development. This goal was achieved by exposing close to 1,000 top-tier vaccine executives and scientists to the Vaccine Center and its research, education and commercialization objectives and its key attributes.

Concept

The cornerstone of the LVC's conference presence was an exhibition booth consisting of a number of exhibition panels specifically designed to highlight the center's collaborative ambitions, specific areas of research expertise and core facility resources in a comprehensive format. Panel content was developed by Dr. Alistair Ramsay, Lesley LeBlanc and Steven Ceulemans and provides an overview of the Center's mission, areas of expertise and core facilities.

In addition to the panels, a LVC flyer was developed. This provides a synopsis of the Center's commercial ambitions by highlighting its areas of strength in research and development and listing the principle offerings of the core facilities. (See **APPENDIX J** for the Center flyer.)

World Vaccine Congress
9th edition
20 Apr 2009 to 23 Apr 2009
Westfields Marriott Washington Dulles,
Washington DC, United States
(See **APPENDIX K** for WVC Post Event Report)

Exhibition

The Louisiana Vaccine Center was a first time exhibitor and delegate attendee at the **9th Annual World Vaccine Congress in Washington**. The Congress is considered "*North America's most progressive vaccine industry event*" which gathers vaccine science and business leaders to discuss philosophy, policy and advances in the field. As one of twenty-six sponsors and exhibitors at the World Vaccine Congress, LVC displayed the expertise and facilities it has to offer alongside the following companies: Accelovance, Beardsworth®, BD Medical-Pharmaceutical Systems, Catalent, CRF Health, CSL Biotherapies, Covance®, Crucell, Millipore™, Pall® Life Sciences, ProImmune, Quintiles, Radiant Research, Research Across America, SAFC Pharma™, Schreiner MediPharm, SNBL Clinical Pharmacology Center, Sterigenics, SynCo BioPartners, University Clinical Research (UCR) and Vince & Associates Clinical Research.

The Louisiana Vaccine Center partnered with the New Orleans BioInnovation Center at this meeting to promote vaccine-related biotech development in the Greater New Orleans area. By doing so, this gave an opportunity to display local efforts in vaccine research and development and the ability to network with Biotech companies for potential commercialization opportunities. Dr. Alistair Ramsay, LVC Director, Steve Ceulemans, LVC Commercialization Coordinator, and Lesley LeBlanc, LVC Associate for Research and Development attended the Congress.

With approximately eight hours of access per day, and as a venue for meals, inter-session breaks and speed-networking sessions, the exhibition hall provided an excellent opportunity for sponsors, delegates and other exhibitors to come by and visit the exhibit and learn more about the Center throughout the three days of the Congress. As a first time exhibitor at the Congress, the LVC generated much interest around the following themes:

* What is the Louisiana Vaccine Center and what does it do?
* What are the Center's affiliations?
* What are the Center's specific areas of expertise?
* What is the Center's funding source?
* What types of partnerships is the Center looking to foster?

These questions provided a good platform to start a dialog and identify joint areas of interest with conference participants. In the course of the Center exhibiting at the World Vaccine Congress, several companies looking to explore possible partnerships and collaborations approached us. A sampling of these representatives along with their affiliated company/organization included:

*Senior Program Officer**, Global Health Discovery, Bill and Melinda Gates Foundation***: interested in Center researchers with expertise in the fields of HIV pathogenesis and immunity for possible participation in a panel during a program currently under development;

*VP of Business Development**, Cobra Bio***: inquired if any of the Center's current research would be in need of their areas of expertise;

*Program Director-Vaccines and Emerging Biotech, **Millipore***: looking to facilitate partnerships with investigators with expertise in influenza, meningitis, and streptococcus pneumonia;

*Project Manager**, Innovation Bridge, Bill and Melinda Gates Foundation***: looking to foster collaborations between university and vaccine manufacturers in developing countries;

BD Medical-Pharmaceutical Systems: possible collaboration involving TB vaccine inhalation delivery: pulmonary diseases.

Sessions and Panel Discussions

The World Vaccine Congress also had a robust offering of (scientific) sessions and panel discussions. The presentation and panel sessions offered a good mix of public health, safety, technology and manufacturing/distribution related topics for vaccines. Unlike many scientific conferences, this conference allowed executives and other industry leaders to present on aspects of these topics.

Annual Conference of Vaccine Research
12th edition
April 27 – 29, 2009
Baltimore Marriott Waterfront
Baltimore, MD, United States

Exhibition

The Louisiana Vaccine Center was also a first time exhibitor and attendee at the **Twelfth Annual Conference on Vaccine Research** sponsored by the National Foundation for Infectious Diseases in collaboration with the CDC, Center for Biologics Evaluation and Research-FDA, Center for Vaccine Development, University of Maryland, Emory

Vaccine Center, Foundation Mérieux, International Association of Biologicals, International Society of Vaccines, International Vaccine Institute, NIAID, NVI-Netherlands Vaccine Institute, Albert B. Sabin Vaccine Institute and the USDA. The ACVR is the "*largest scientific meeting devoted exclusively to research on vaccines and associated technologies for disease prevention and treatment."* The conference focuses on the areas of basic science, product development and clinical/field studies.

As one of sixteen exhibitors at the Twelfth Annual Conference on Vaccine Research, the Center was able to display the expertise and facilities it has to offer alongside the following companies: Advanced Bioscience Laboratories, Inc., Bridge Laboratories, Clinical Research Advantage, Clinical Research Management, Congressionally Directed Medical Research Programs (CDMRP), Covance Research Products, Inc., DynPort Vaccine Company LLC, FDA/Center for Biologics Evaluation and Research, IIT Research Institute, Immune Epitope Database and Analysis Resource (IEDP), JPT Peptide Technologies GmBH, National Institute of Allergy and Infectious Diseases, Protein Sciences Corporation, sanofi Pasteur and Spring Valley Laboratories, Inc.

The main objective of attending the *Annual Conference of Vaccine Research* was to promote the Louisiana Vaccine Center to facilitate new partnerships and collaborations. The meeting attendees were mostly academics and federally funded agencies, resulting in a number of recognizable opportunities for partnering. The Center was well received at the *Twelfth Annual Conference on Vaccine Research* and several of the contacts that were made during the showing can be built upon for the future.

Bio International Convention
May 18 - 21, 2009
Atlanta, GA, United States

The Louisiana Vaccine Center attended the 2009 BIO International Convention-The Global Event for Biotechnology - held at the Georgia World Congress Center in Atlanta, Georgia from May 18th -21st, 2009. This event is recognized as the "world's largest gathering of the biotechnology industry." This year's theme was "Heal, Fuel, Feed the World." The Center had three members attend as full convention attendees: Dr. Alistair Ramsay, Center Director, Steve Ceulemans, Commercialization Coordinator and Lesley LeBlanc, Associate for Research and Development. In addition, the Center participated as a member of the Louisiana Pavilion on the BIO 2009 exhibit floor in coordination with the South Louisiana Institute of Infectious Disease, the Clinical and Translational Research, Education and Commercialization Program and the New Orleans BioInnovation Center.

BIO Business Forum, Partnering for Growth: The business partnering forum is a system that allows participants from academia, industry and the public sector to setup specific meetings with parties that can be identified in anticipation of the event using background profiles on topics of interest. These topics typically include licensing, partnering, joint-ventures or sponsored research. Steven Ceulemans met with 20 organizations of interest to the Center, mostly related to potential licensing of vaccine and other technologies developed at LSUHSC and Tulane University.

BIO Exhibition: The large exhibit floor allowed the opportunity to encounter over 2,000 companies from all over the world in order to network and mingle. The Louisiana Vaccine Center exhibited in the Louisiana Pavilion that was sponsored in part by the Louisiana Department of Economic Development. This gave the opportunity for the state of Louisiana to promote all aspects of the biotechnology industry across the entire state as well as the incentives in place to attract more biotech businesses. There were over twenty-five participants in the Louisiana Pavilion and included: ALBEMARLE CORPORATION, BIOMEDICAL RESEARCH FOUNDATION OF NW LOUISIANA, BODY EVOLUTION TECHNOLOGIES, CALOSYN PHARMA, EMBERA NEUROTHERAPEUTICS INC., ESPERANCE PHARMACEUTICALS, INTERTECH SCIENCE PARK, LOUISIANA FUND ONE, LOUISIANA GENE THERAPY RESEARCH CONSORTIUM, LOUISIANA VACCINE CENTER, LSU BUSINESS & TECHNOLOGY CENTER, LSU SYSTEM RESEARCH & TECHNOLOGY FOUNDATION, LOUISIANA EMERGING TECHNOLOGY CENTER, LOUISIANA VENTURES LP, MAYOR'S OFFICE, CITY OF SHREVEPORT, NEW ORLEANS BIOINNOVATION CENTER, NORTHWEST LOUISIANA ECONOMIC DEVELOPMENT FOUNDATION, NUPOTENTIAL, PENNINGTON BIOMEDICAL RESEARCH CENTER, SCALARSCOPES, SOUTH LOUISIANA INSTITUTE FOR INFECTIOUS DISEASE RESEARCH, SOUTHERN ISOTOPES LLC, TEMPEST BIOTECH, THERAVASC, LLC, TRANSGENRX, TULANE UNIVERSITY CGMP SERVICES and VCE CAPITAL.

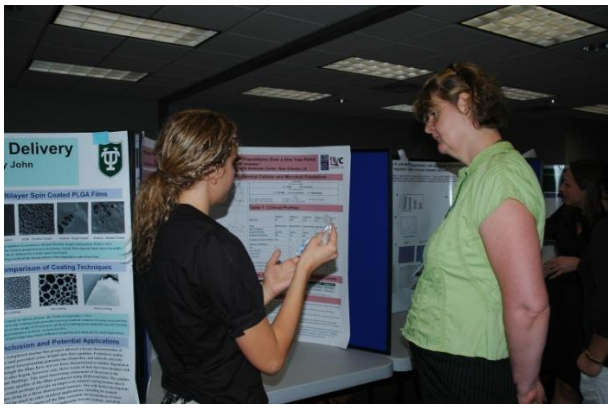
The Center displayed panels in a coordinated effort with the South Louisiana Institute for Infectious Disease Research (SLIIDR) and the Clinical and Translational Research, Education and Commercialization Project (CTRECP) projects realizing the opportunity to discuss possible partnerships with several groups and organizations on the exhibit floor.

These "Commercial Building Blocks" have been critical in moving forward the commercial initiatives for the Center in Year 2. Through student training in bioscience entrepreneurship through internships, externships, and a "young professional" fellowship, we are exposing our local talent and future leaders to the industries of research and biotechnology. The faculty interviews raise the commercial awareness of our researchers and actively facilitate research commercialization through technology, IP, market assessment and development of sharp-end commercial outcomes to ongoing academic research. Through the educational seminars and

programming, the goal is to encourage networking between and education of faculty, students and entrepreneurs on bioscience commercialization. Furthermore, our attendance at national and international conferences showcases the growth of commercial contacts made at these meetings will be vigorously pursued as relevant developments occur within the Center.

(c.) Education- During Year 2, there have been many enhancements to the Educational Program. In the summer of 2008, ten students from local high schools and colleges all over the country participated in the Summer Internship Program. Through this program, they were afforded the opportunity to work alongside many of our researchers. Additionally, the *Infection, Immunity and Vaccine Seminar Program* continues to be a highly successful event with several high-profile outside speakers as well as presenters from Center partner institutions.

i. **Summer Internship Program- Education and Training in vaccine-related research:** The summer internship program provides Louisiana students with an intensive research experience in the areas of immunology and vaccines. The program exposes students to cutting edge research and provides an introduction to graduate school as well as preparing them for careers in basic and translational research. Students learn about the scientific process, learn how to design experiments and to analyze and interpret data; furthermore, they gain valuable hands on bench experience.



The summer program is modeled after the NIH Summer Internship Program and has three main components. Students work directly with faculty and graduate students on a research project. They learn by doing. The second component of the program encompasses didactic learning through seminars, journal clubs and lab meetings. The program hosts a seminar series that covers a variety of topics related to vaccine research. Special seminars cover the responsible conduct of research and presentation skills. The third part of the program is the Summer Research Poster Session. At the end of the summer, the students present their research results at a poster session that is attended by students from other labs and the mentors and the other members of their labs. Students are taught how to put a poster together and how to effectively present their data (see image above).

The Table below summarizes the student population that is supported with Center funds in Year 2. There are four undergrads and five medical students, all but one of these students are eligible to do a year-long research project (see below). Forty percent of the students are female and 10% are minority. We continue to target undergraduate students from local universities (Tulane,

SLU, UNO and Xavier) in order to have a competitive pool of applicants to continue working on their research projects.

2009 Summer Internship Student Participants

Student	Mentor	Academic Level	School
Xinyue Guo	Joe Lasky Tulane University	High School	Grace King High School
Phillip Calmes	Ping Wang- Children's Hospital	undergrad	Southeastern Louisiana University
Jasmine Harris	Shen Li- LSUHC-MIP	undergrad	UNO
Anisha Ravichandran	Vishua Dixit Pennington Biomed Res.	undergrad	LSU
Yuanyue Sun	Deborah Fox Children's Hosp	undergrad	U. of Southern California
Phillip Calmes	Pin Wang Children's Hosp	undergrad	Southeastern Louisiana University
David Becnel	Stephania Cormier LSUHSC-Pharm	LSU Med student	LSUHSC
Daniel Johnson	Bonnie Dickinson Children's Hosp	LSU Med student	LSUHSC
Jerry Miller III	Ashok Aiyar LSUHSC-MIP	LSU med student	LSUHSC
Whitney Nichols	Michael Hagensee LSUHSC-Internal Med	LSU med student	LSUHSC
Xu Teng	Greg Bagby LSUHSC-Phys	LSU med student	LSUHSC

ii. Post-Internship Evaluation: Student interns were given a Post-Internship Evaluation form to complete as well as a Goal Attainment Scaling Survey (GAS). Forty percent of the students ranked their mentor and/or the post doc they worked with providing them with a "very good" research experience and 50% ranked them as "great". All of the students presented their research results at the Summer Poster Session and 50% plan to apply for other research fellowships in the future. When asked about the impact of the program on their career goals, 30% of students reported that the program reinforced their prior goals for a career in research, while 40% said the

program influenced them to consider including research in their career. Seventy percent of the students ranked having personal interactions with a faculty member as a "very important" benefit of the program. Seventy percent of the students reported that preparing and presenting their poster was "very important".

Students also completed the Post-Internship Goal Attainment Scaling survey. This validated measurement tool is flexible enough to provide formative evaluation of how much the students felt they had achieved. Goal Attainment Scaling is an outcome-oriented method of program evaluation that has been used to evaluate other summer internship programs (1). Students ranked their goal attainment in eight dimensions ranked into five different outcome levels, 1 – 5 with 5 being the "Best Anticipated Success". The overall Goal Attainment score for the student group was 29.7. The Table below summarizes the scores by dimension.

Post-program mean dimension scores for the student interns

Dimension	Mean Score
1. Understanding of Project	3.7
2. Interest in Project	2.3
3. Conducting Independent Research	4.3
4. Knowledge of Research	3.4
5. Clarification of Career Plans	3.3
6. Personal Growth	4.5
7. Satisfaction with Program	4.5
8. Completion of Reporting Requirements	3.0

Based on these results, we will work to strengthen the interest the students have in their projects. The other dimensions are within the range of those found in the published study.

1. *The Use of Goal Attainment Scaling to evaluate a cancer research training program for high school and college students*. Cookfair DL, Zevon MA, Mirand EA, Cancer Education. Vol1 (4), pp255-263, 1986.

iii. LVC Year-Long Research Experience: In 2008, two undergraduate students were nominated by their mentors and chosen by the Center to be supported throughout the year to continue work on their projects. Because the summer is such a short period of time, this support is essential for students who are interested in continuing their research. It is an excellent way to introduce the students to what graduate school will be like. The students chosen were both undergraduates at Tulane University. Tim Tate was a freshman and Sharon George was a senior. One student worked with a mentor at Tulane and one worked with a LSU mentor.

The students' mentors were very happy with their efforts and much was accomplished by the students. Their projects are summarized below.

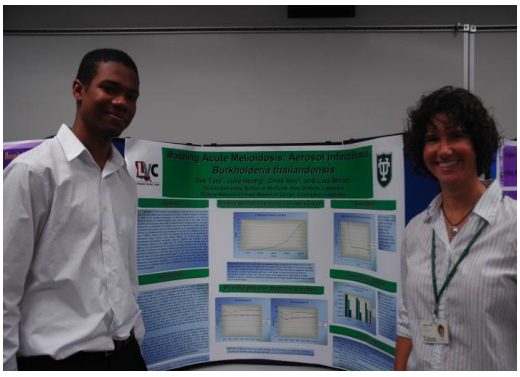
Timothy Tate and Drs. Morici and John

Timothy Tate is a New Orleans native. He graduated with honors from Brother Martin High School in 2008, receiving a full academic scholarship to Tulane University where he is a cell -biology major, starting his sophomore year. While in high school, he worked as a summer intern in Dr. Kyle Happel's laboratory in the LSUHSC Department of Medicine in the summers of 2006 and 2007. His project was entitled "Ethanol intoxication and CXC chemokine response to *S. aureus* pneumonia". In 2008, he participated in the summer internship program funded by the Louisiana Vaccine Center with Dr. Lisa Morici in the Department of Microbiology and Immunology at Tulane University Health Sciences Center. Tim's research with Dr. Morici focused on vaccine discovery and development against aerosol bacterial agents. His summer project was titled "Acute melioidosis and aeorosol infections with *Burkholderia thailandensis*".

After the summer, he began work in Dr. Vijay John's lab, where he worked on developing an infection-resistant, biodegradable, controlled delivery method for antibiotics. He learned how to engineer porous bio-films containing various concentrations of polylactic-co-glycolic acid (PLGA), polyethylene glycol, or a combination of both using the breath figure method. He also learned how to perform degradation studies on these bio-films as well as use a SEM to analyze and capture images of the extent of the degradation over an 8 week period. Tim's research in Dr. John's lab will be presented at the 2009 AIChE Annual Meeting in Nashville, Tennessee. The title of this project is "Breath Figure Thin Films of Biodegradable Polymers for Controlled Antibiotic Release".

In Dr. Lisa Morici's lab, Tim's work has paid off in many ways. They are submitting a manuscript in June 2009 to *Microbial Pathogenesis* titled "Differential susceptibility of inbred mouse strains to Burkholderia thailandensis aerosol infection" and Tim is a co-author. They also presented a poster at the American Society for Microbiology 109th General Meeting in May titled "Modeling acute melioidosis: aerosol infection with B. thailandensis" and Tim was listed as a co-author. Dr. Morici is also submitting a grant proposal this month to the Western Regional Center for Excellence in Biodefense and Emerging Infectious Diseases and using part of Tim's work in the preliminary data section.

Timothy Tate and Dr. Lisa Morici



Sharon George and Dr. Cutler

Sharon George is a New Orleans native and recent graduate of Tulane University, where she majored in Neuroscience and Spanish. She entered the summer internship program in 2008 with no laboratory experience, but plenty of enthusiasm for vaccine research. She had previously done extensive community service work in under-privileged communities where she initially became interested in immunology and vaccine studies.

Sharon worked with Dr. James Cutler during the summer of 2008 and remained in his lab, continuing her research project throughout the year. The focus of her work was to investigate established and novel adjuvant systems that could be useful in humans for initiation of clinical trials for our vaccine against candidiasis. The results of her work are important to us, as she was able to rule-out the use of some adjuvants, but she also found at least one adjuvant system that is showing some potential. If the results continue to be encouraging in up-coming experiments, she will be one of the co-authors on a manuscript to be submitted for publication in a rigorously peer-reviewed scientific journal.

Sharon presented some of her findings at the Southwest Medical Mycology Meetings held in New Orleans last November. The two-day annual event was well-attended by about 50 scientists from Texas, Oklahoma and Louisiana. Sharon's work was received with interest and enthusiasm.

Dr. Cutler recently submitted a grant application to the National Center for Research Resources of the NIH for a COBRE (Centers of Biomedical Research Excellence). In that application, five junior faculty members were selected who will receive research project support if the COBRE is funded. One of the junior faculty is Dr. Hong Xin, who served as co-mentor for Sharon and who is a member of my laboratory. The results of Sharon's project prompted us to include her work in the Preliminary Data section of Dr. Xin's project and the essence of Sharon's efforts have been incorporated into one of the specific aims of Hong's project.

Dr. Cutler, Dr. Xin and Sharon George

iv. **Infection, Immunity and Vaccine Seminar Program:** The second major focus of our Education activities has been the continued development and enhancement of a first-rate seminar program in Infection, Immunity and Vaccines, in partnership with SLIIDR. During Year 2, the seminar program featured seven high-profile national speakers (from University of Arkansas, Children's Hospital of Pittsburgh, University of Pennsylvania, Arkansas Children's Hospital Research Institute, University of Washington School of Medicine, New York University Medical Center and the Rocky Mountain Laboratories National Institutes of Health) and seven prominent local speakers from all partner institutions. These sessions have proven to be an outstanding success, and have sustained attendance of over 100 attendees per session. The program has exposed large numbers of Center post-doctorates and graduate students to high-profile national and local research, often with follow-up meetings with the visiting speakers. Importantly, the series also serves to raise the profile of the Vaccine Center and of research activity in general in Louisiana, through exposure of eminent visitors to our work (See **APPENDIX L** for Seminar Program). During Year 2, the access of outside groups to our seminars has been greatly improved by the implementation of Access Grid technology. This technology allows our seminars to be beamed out to off-site locations, providing greater potential for collaboration. To date, several seminars have been beamed to the Tulane University Health Sciences Center in New Orleans, the Tulane University National Primate Center in Covington, and the LSU in Baton Rouge. There are plans to further expand this access in order for us to reach more scientific groups in the region as possible, one of the main outreach objectives of the Center.

Problems encountered in Year 2: No significant problems were encountered in Year 2.

3. CONTRIBUTIONS

In Year 2, our focus has been to build upon the successes in Year 1 on the continued growth and development of the research, commercialization and education initiatives of the Center. The goal is to aid the flow of vaccine-related research from discovery to vaccine preparation and delivery and through pre-clinical testing and analysis towards the development and conduct of clinical trials and research commercialization.

- In Year 2, Center Investigators have submitted new funding applications for over $43 million, primarily to the NIH. Particular highlights include a collaborative LSUHSC/Tulane/Xavier Developmental Center for AIDS Research (D-CFAR) application to NIH ($4.5M), and a NIH P01 application to look at vaccines and therapies for HIV-related pulmonary infections ($9M). Both arose directly from interactions facilitated by the Vaccine Center. In addition, multiple R01 and RC1 "Challenge" grant applications were submitted. This highlights the growing strength of infectious disease and vaccine-related research interactions within the Center.

- Through the Grant Seekers Program and the ongoing development of our Research and Development Series, the Center is playing an important role in advising and educating our junior and mid-level investigators about processes involved in submitting NIH research grants (including R01s and SBIRs), as well as key, related Institutional documents, thereby setting the stage for a continuation of our stream of external funding applications, such as those outlined above, into the future.

- Center investigators have published 122 new original papers in Years 1 and 2 to date. Many of these have resulted from new collaborations directly facilitated by the Center. These publications will help to raise the profile of the Center and form the basis of new grant applications and future clinical and commercial developments.

- The Center completed planning for and held a discipline-based, day-long research symposium entitled, *"Symposium on Mycobacteria, Tuberculosis and Host Defense"* on November 21st, 2008 at LSUHSC-NO campus, the first of our "theme-based" initiatives designed to foster new collaborative ventures leading to the growth of towers of strengths in different areas and the development of new federal funding submissions.

- The Center held a workshop on intellectual property for Center participants and the local research community in general.

- The Center awarded ten 2-year Collaborative Pilot Research Project Awards in Year 2, with an emphasis on applications exhibiting potential for the innovative new collaborations with clinical and/or biotech potential - in this way we hope to seed new R01, P01 and SBIR (commercialization) federal grant applications leading to clinical trials and research commercialization.

- The Center has supported the appointment of five new postdoctoral fellows to projects in vaccine-related research programs as a direct result of Center pilot grant funding.

- The Center held a high-profile seminar program featuring Project faculty, Project research trainees, and distinguished visiting speakers. The Center's *Infection, Immunity and Vaccine Seminar Program* featured seven high-profile national speakers, along with a number of local presenters.

- The Center initiated Access Grid technology to transmit its *Infection, Immunity and Vaccine Seminar Program* to the LSU School of Veterinary Medicine (Baton Rouge, LA) and the Tulane University National Primate Center (Covington, LA).

- The Center has now recruited twenty student interns into the LVC Summer Internship Program during the summers of 2008 and 2009. The students that participated in the summer 2008 Program created and presented posters based on the work they conducted over the term of their internship. Students completed evaluation of summer student experience using Goal Attainment Scaling as formative assessment, with overall satisfaction survey as summative assessment.

- The Center has recruited two of the participants in its summer 2008 Internship Program, Timothy Tate and Sharon George, both minority students, for a 1-year research placement in a Center research laboratory during Year 2.

- To serve the educational goal of raising awareness of research translation and commercialization as a potential outcome for academic research among Center researchers, the Center has played a key role in the development of four separate initiatives aimed at bringing local universities, the local business community, and economic development professionals together to facilitate education and interaction in research commercialization - these include seminars/workshops entitled: *Commercial Awareness for Researchers*, *Bridging Louisiana Bioscience*, *Biotech Connect*, and *Innovation and Technology Leadership*.

- The Center was a participant at three major National/International vaccine conferences and/or biotech meetings. These included the 9th Annual World Vaccine Congress in Washington, D.C., the 12th Annual Conference on Vaccine Research in Baltimore, MD and the 2009 International BIO Convention in Atlanta, as a featured exhibitor. This helped to build 'brand awareness' of the Center and to facilitate interactions with leading academic and industry vaccine R&D houses on the Center's R&D ambitions with focus on collaborative development. This goal was achieved by exposing close to 1,000 top-tier vaccine executives and scientists to the Vaccine Center and its research, education and commercialization objectives and its key attributes.

- The Center exposed 13 local business and law students to biotechnology through internships, training them to guide Center faculty through commercialization-related aspects of potential novel inventions, models or methods through the technology transfer process at their affiliated university.

- A number of Center faculty (25 to date), have been interviewed by trained teams of local business and law student interns - promising follow-ups to date include disclosure of three potential novel inventions as a direct result of these faculty interviews.

4. PROJECT REVISION

Project revisions concerning the development of BSL-3 and Molecular Interaction Core facilities and also to support Project Development proposals within the Center were approved by the Board of Regents on 6/30/2008. There have been no further project revisions in Year 2.

Center of Excellence for Vaccine Development

LEQSF (2007-12)-ENH-PKSFI-PRS-02

Year 2 Annual Report
6/30/2009

APPENDIX

APPENDIX A: LVC Core Awareness Slide Presentations

APPENDIX B: Cooperative Pilot Research Grant Fund

APPENDIX C: Tentative Topics for the LVC Research and Development Series

APPENDIX D: Annual Meeting and Research Fair

APPENDIX E: Mycobacterium Symposium Announcement, Program and Photos

APPENDIX F: LVC Grant Seekers Meeting Schedule

APPENDIX G: LVC Website Homepage (www.louisianavc.org)

APPENDIX H: Interview Guide and Post-Interview Questionnaire

APPENDIX I: LVC Commercialization Event Announcements

APPENDIX J: LVC Flyer

APPENDIX K: World Vaccine Congress Post-Event Report

APPENDIX L: LVC Infection, Immunity and Vaccine Seminar Program Schedule

APPENDIX A: LVC Core Awareness Slide Presentations

A1. Vector Development Core

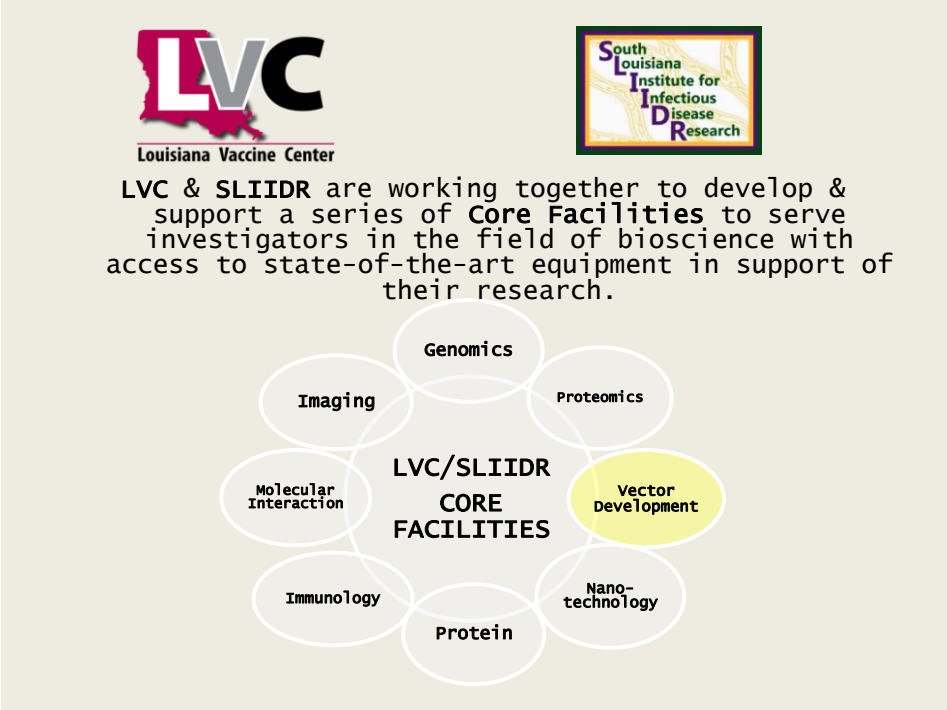
A2. Molecular Interaction Core

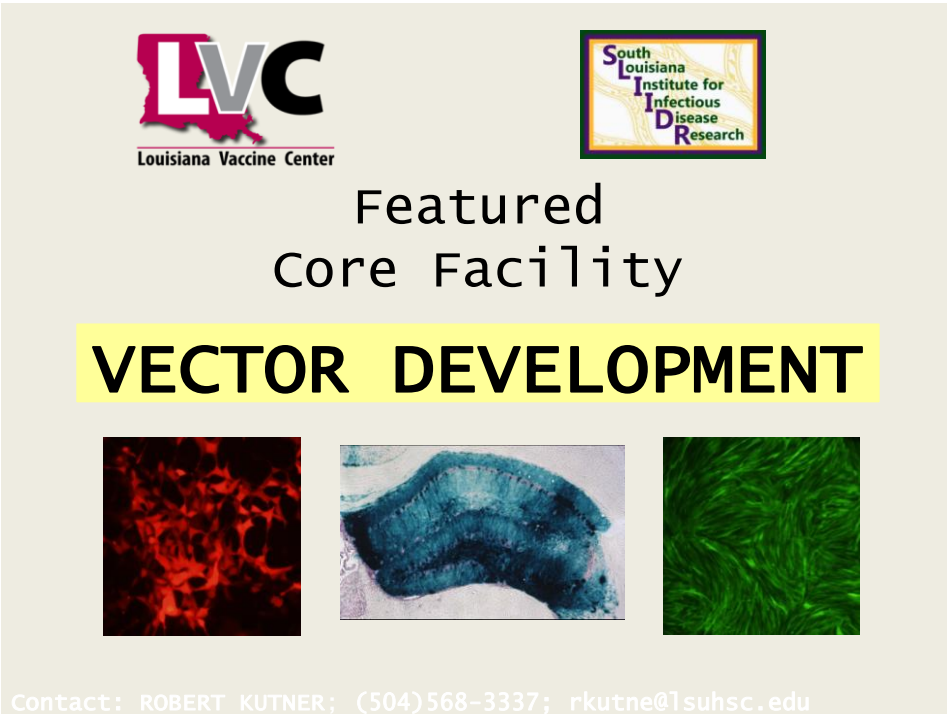
A3. Imaging Core

A4. Protein Core

A5. Nanotechnology Core

A1. Vector Development Core





Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

VECTOR DEVELOPMENT CORE

Objective

- To provide investigators access to new recombinant vaccine vectors and novel technology for basic research applications and other preclinical studies

Services

- Consultation
- Vector Construction
- Vector Production
- Molecular Assays
- Biological Assays
- Chromatography

Contact: ROBERT KUTNER; (504)568-3337; rkutne@lsuhsc.edu

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

VECTOR DEVELOPMENT CORE

VECTOR SYSTEMS AVAILABLE

ADENOVIRUS

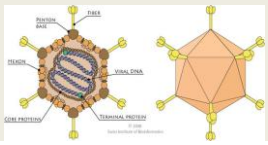
- Efficient high titer viral vectors for gene delivery
- Broad range for in vivo and in vitro uses

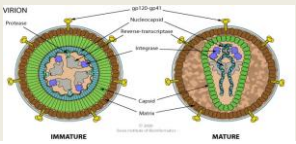
LENTIVIRUS

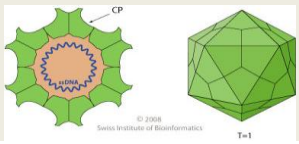
- Provides long-term stable gene expression
- Modifiable tissue tropism

ADENO-ASSOCIATED VIRUS

- Wide range host of the virus due to serotypes available
- Low immunogenicity







Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

VECTOR DEVELOPMENT CORE

REPORTER TRANSGENES

Ideal for microscopy:

- ***ZsGreen*** → brighter, more stable version of *EGFP*
- ***TurboRFP*** → brighter, more stable version of *DsRed express*
- ***LacZ(co)*** → Codon optimized β-galactosidase which reports more robust expression than traditional *LacZ*

Ideal for animal studies:

- ***Katushka*** → protein of choice for visualization within animals; well suited for bioimaging
- ***Luc2***→ brighter more stable version of *Luciferase*
- ***LacZ(co)*** → Codon optimized β-galactosidase which reports more robust expression than traditional *LacZ*

Contact: ROBERT KUTNER; (504)568-3337; rkutne@lsuhsc.edu

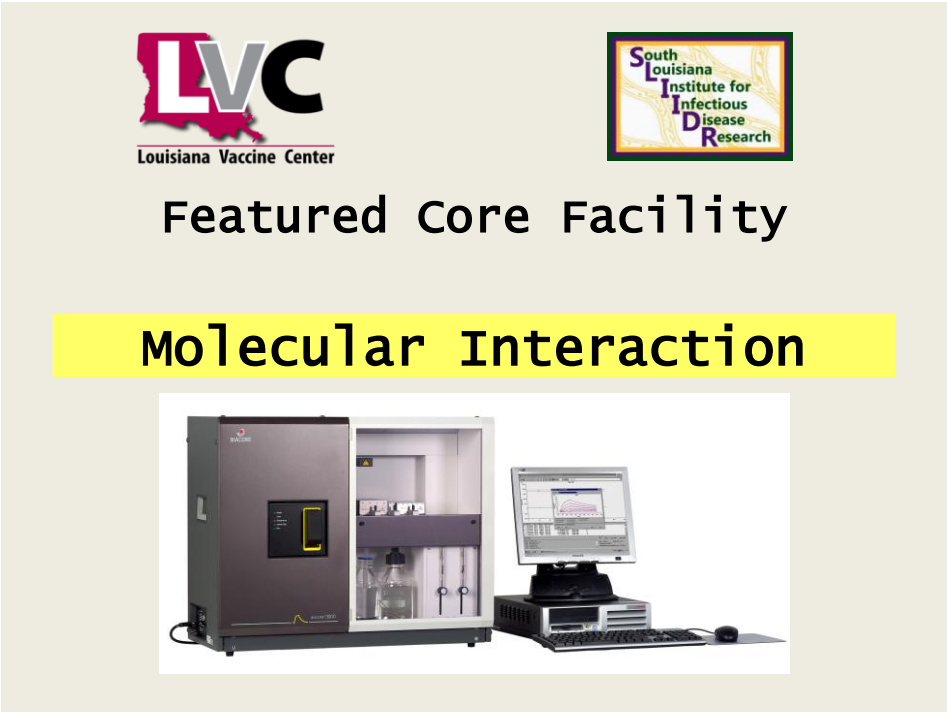
Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

VECTOR DEVELOPMENT CORE

For more information, please contact:
ROBERT KUTNER
(504)568-3337
rkutne@lsuhsc.edu

A2. Molecular Interaction Core



Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Molecular Interaction Core

Objective

- To visualize and analyze label-free molecular interactions in real time using surface plasmon resonance technology

Services

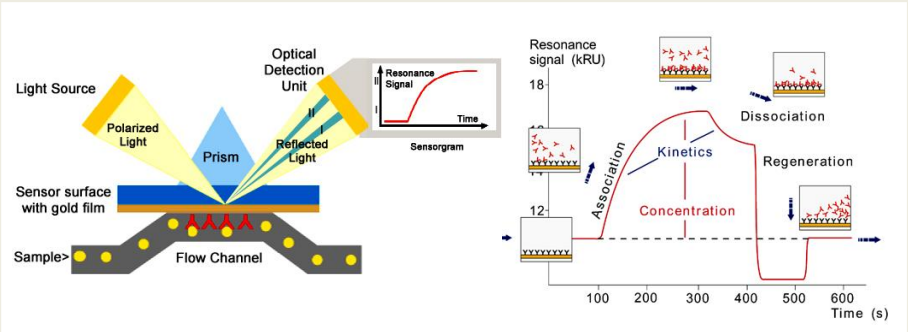
- Sensor surface preparation.
- Optimization of experimental conditions and sensor surface regeneration conditions.
- Generation of ligand-analyte interaction curves.
- Analysis of data.

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Molecular Interaction Core

Surface Plasmon Resonance



Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Molecular Interaction Core

How can the surface plasmon resonance technology be applied to biomedical research?

- Binding specificity.
- Interaction kinetics.
- Concentration in complex samples.
- Monoclonal antibody screening.
- Antibody-antigen affinity.
- Epitope mapping.
- Receptor ligand interactions.
- Multiple complex formation.
- Ligand fishing for MS analysis.

- Proteins
- Carbohydrates
- Nucleic acids
- Lipid bilayers
- Intact cell membranes
- Cell/tissue lysates
- Serum/plasma
- Viruses
- Whole cells

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Molecular Interaction Core

Sensor Surface Chips

Chip	Dextran	Modification	Application
CM5	100 nm	100% carboxylation	General (amine, thiol, aldehyde, maleamide coupling)
CM4	100 nm	30% carboxylation	Cell extracts / serum samples (decreased charge)
CM3	30 nm	100% carboxylation	Cell extracts / serum samples (increased sensitivity)
C1	None	100% carboxylation	Phage binding
NTA	100 nm	Nitrilotriacetic acid	Capturing poly-HIS tags
HPA	None	Hydrophobic	Capturing Lipids
L1	100 nm	Lipophilic substances	Forming bilayers that mimic membranes
SA	100 nm	Streptavidin	Capturing biotin
AU/J1	None	None	User defined surface chemistry

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Molecular Interaction Core

Contact Information

Miriam Corti, Ph.D.
mcorti@chnola-research.org
504-896-2824

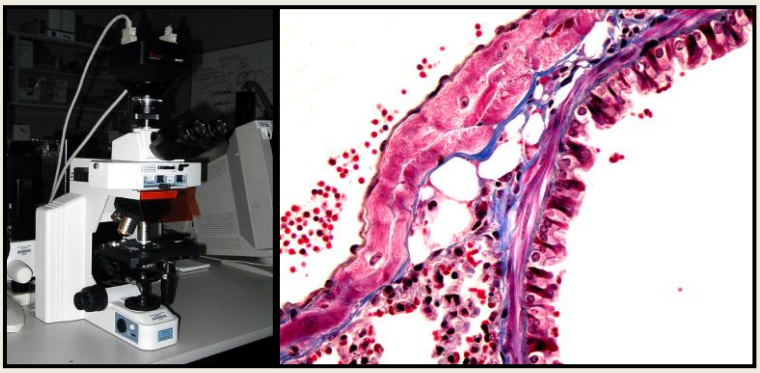
A3. Imaging Core

Louisiana Vaccine Center

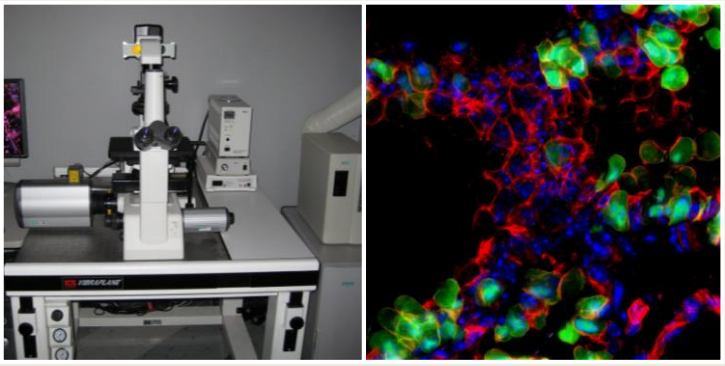
GeneTherapy LSUHSC New Orleans

Morphology & Imaging Core

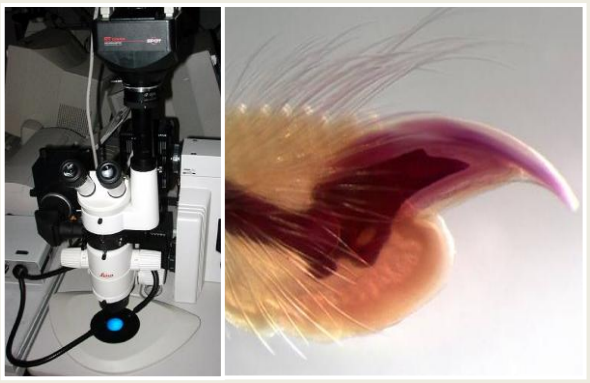
mic@lsuhsc.edu



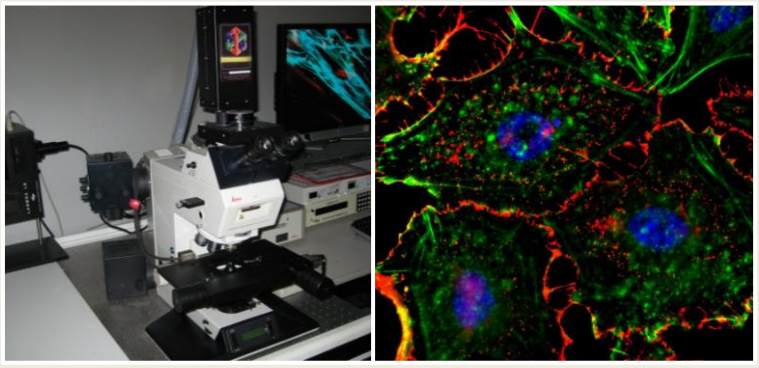
Nikon Eclipse E600 upright



Bio-Rad Radiance 2100:
laser scanning confocal

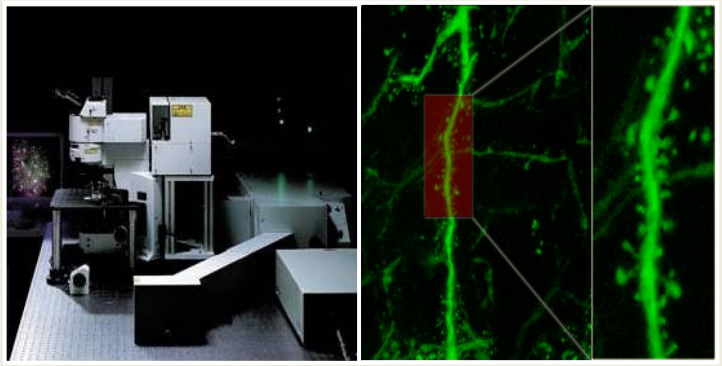


Leica Mz75 stereomicroscope

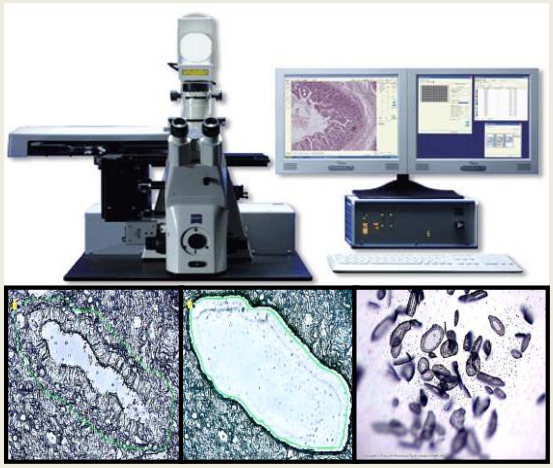


Leica DMRXA:
deconvolution systems

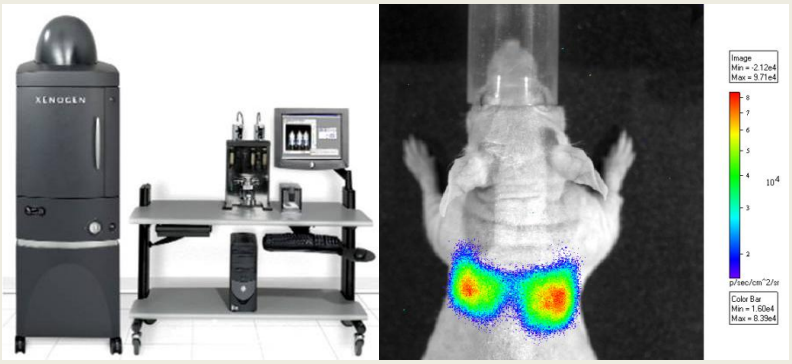
Kodak Image Station FX



Olympus Fluoview 1000 MPE



PALM Microbeam



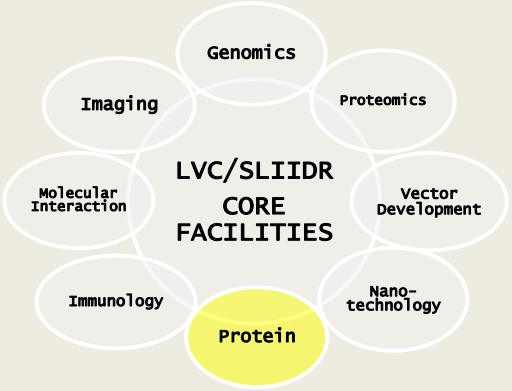
Xenogen IVIS 200

Services

Routine Histopathology	Special Preparations	Microscopy & Analysis
• Paraffin processing • Paraffin embedding • Paraffin sectioning • Frozen sections • Vibratome sections • Whole mounts • H&E stain • Organ dissection	• Immunohistochemistry (peroxidase / AP) • Immunofluorescence (single to quadruple) • In situ hybridization (DNA / RNA) • Whole mount detections • Multiple special stains (chemical / dye based) • Enzyme histochemistry • Antibody optimization	• Brightfield • 2D Epifluorescence • Stereomicroscopy • Deconvolution • Confocal • 4D timelapse • FRET • Calcium Transfer • Morphometry • (Quantitative) co-localization • Montage generation

A4. Protein Core

LVC & **SLIIDR** are working together to develop & support a series of **Core Facilities** to serve investigators in the field of bioscience with access to state-of-the-art equipment in support of their research.



PROTEIN CORE

Tulane University

Contact: 504-988-2171; afrisk@tulane.edu

PROTEIN CORE

Aim

- Facilitate protein purification for onsite or offsite Investigators
- Produce high quality protein for down-stream applications

Services

- Cloning & overexpression of protein in *E.coli*
- Large scale expression of native or tagged proteins
- Analytical or Preparative protein purification
- Lyophilization

Contact: 504-988-2171; afrisk@tulane.edu

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

PROTEIN CORE

Automated Fermentation

High volume capacity
1-10 liters

Chromatography Options

- **An-/Cation exchange**
  - HiLoad Q Sepharose 26/10, HiTrap Q/SP
  - 20µm Ceramic Hydroxyapatite
- **Gelfiltration**
  - 16/60 Superdex 75
- **Affinity**
  - (Ni^{2+}) Sepharose High Performance

BioRad BioLogic Duoflow

High flow rates,
Gradient elution capabilities

Contact: 504-988-2171; afrisk@tulane.edu

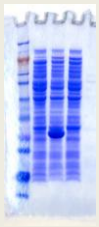
Louisiana Vaccine Center

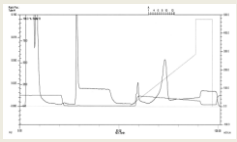
South Louisiana Institute for Infectious Disease Research

PROTEIN CORE

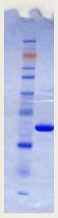
Capabilities

Small scale expression & solubility testing



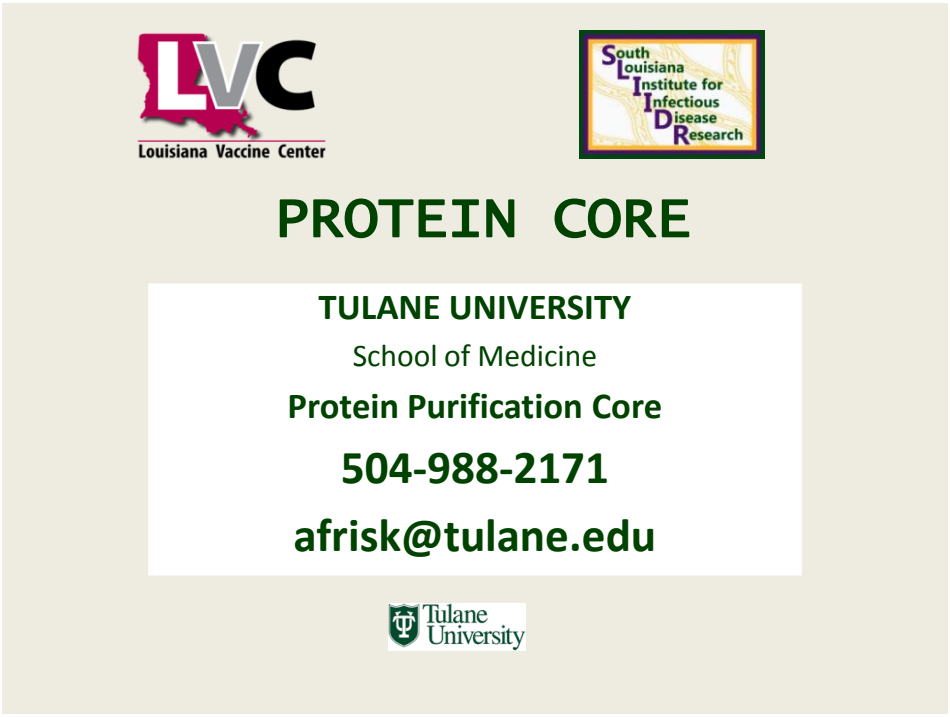


Scale-up expression & purification

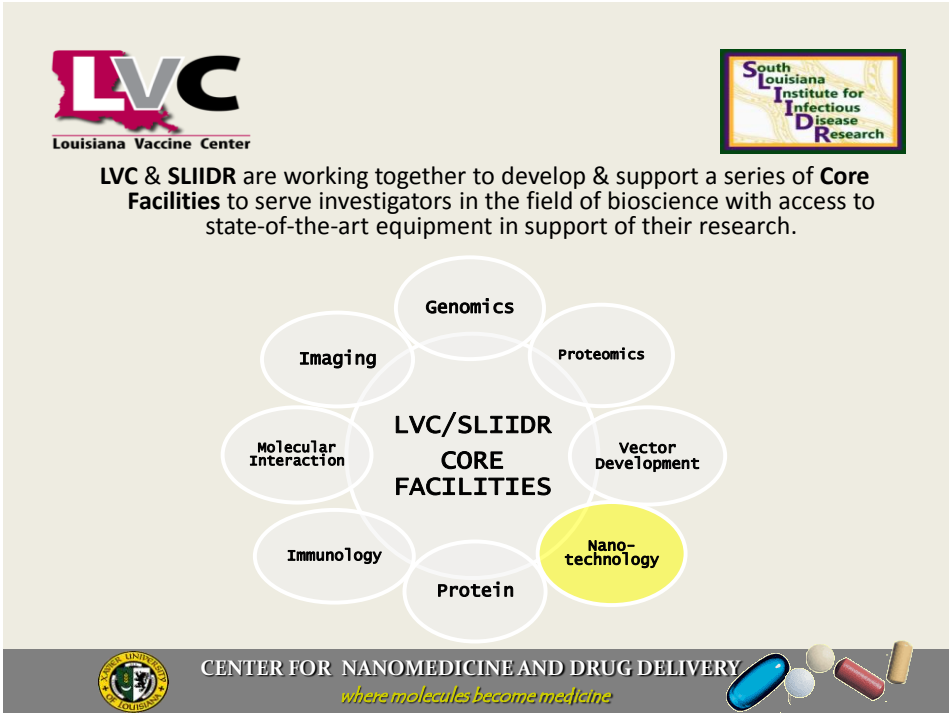


Lyophilization

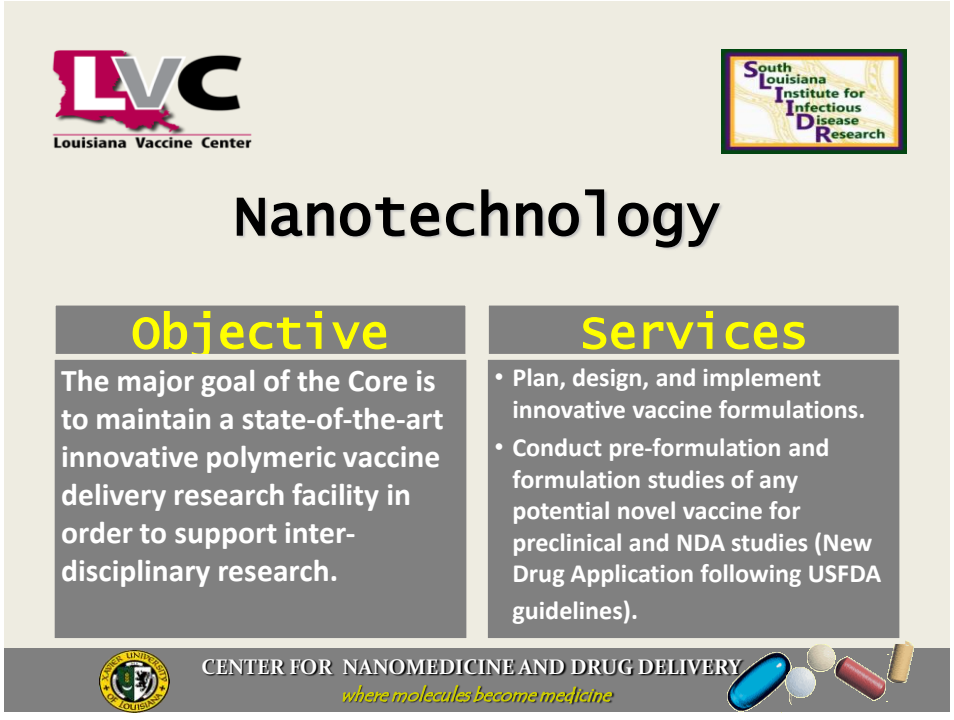
Contact: 504-988-2171; afrisk@tulane.edu



A5. Nanotechnology Core




Louisiana Vaccine Center
South Louisiana Institute for Infectious Disease Research
Nanotechnology
MISSION
It is the mission of the Vaccine Delivery/Nanotechnology Core facility to support and advance vaccine research capacity by providing novel and innovative vaccine formulations.
CENTER FOR NANOMEDICINE AND DRUG DELIVERY
where molecules become medicine


Louisiana Vaccine Center
South Louisiana Institute for Infectious Disease Research
Nanotechnology
Objective
The major goal of the Core is to maintain a state-of-the-art innovative polymeric vaccine delivery research facility in order to support inter-disciplinary research.
Services
• Plan, design, and implement innovative vaccine formulations.
• Conduct pre-formulation and formulation studies of any potential novel vaccine for preclinical and NDA studies (New Drug Application following USFDA guidelines).
CENTER FOR NANOMEDICINE AND DRUG DELIVERY
where molecules become medicine

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Available Equipment

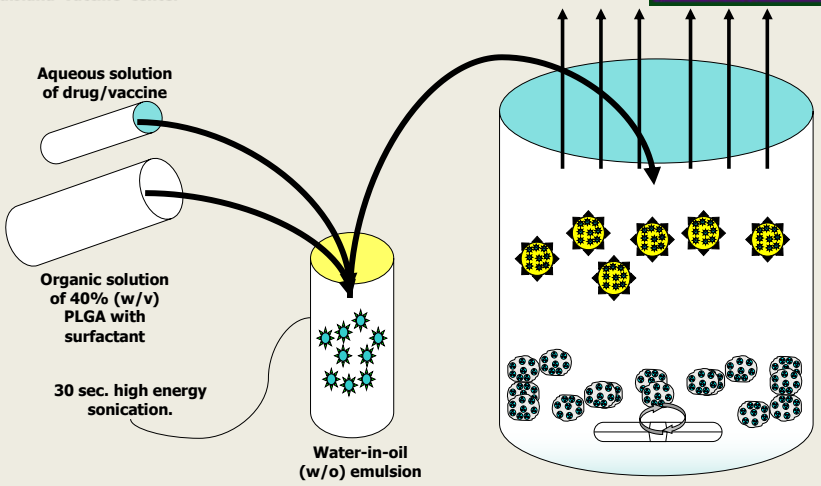
CENTER FOR NANOMEDICINE AND DRUG DELIVERY

where molecules become medicine

Louisiana Vaccine Center

Nano/Microencapsulation of drug/vaccine:
Solvent Evaporation Method

South Louisiana Institute for Infectious Disease Research



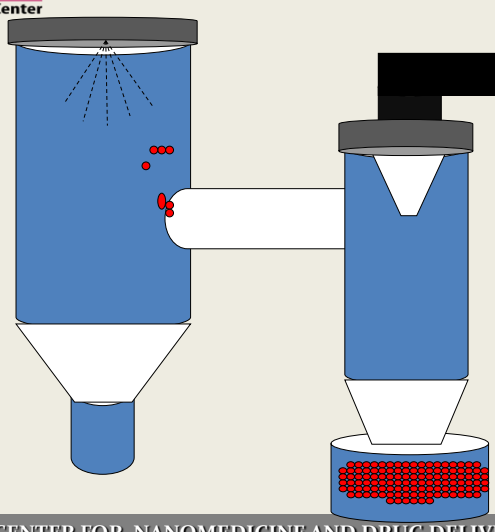
CENTER FOR NANOMEDICINE AND DRUG DELIVERY

where molecules become medicine

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Nano/Microencapsulation of drug/vaccine:
Spray Drying Method

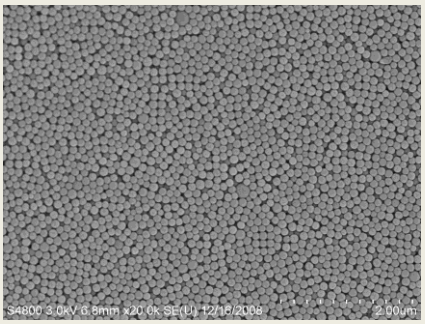


CENTER FOR NANOMEDICINE AND DRUG DELIVERY
where molecules become medicine

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Scanning Electron Microscope
Picture of PLGA/Drug (or Vaccine)
Nanoparticles



CENTER FOR NANOMEDICINE AND DRUG DELIVERY
where molecules become medicine

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Molecules to Medicine

CENTER FOR NANOMEDICINE AND DRUG DELIVERY

where molecules become medicine

Louisiana Vaccine Center

South Louisiana Institute for Infectious Disease Research

Nanotechnology

CONTACT INFO

Tarun Mandal, PhD (tmandal@xula.edu)

Phone: (504) 520-7442

Richard A. Graves, MS (rgraves@xula.edu)

CENTER FOR NANOMEDICINE AND DRUG DELIVERY

where molecules become medicine

APPENDIX B: Cooperative Pilot Research Grant Fund

B1. Cooperative Pilot Research Grant Fund Notice of Award

B2. Cooperative Pilot Research Grant Fund Awardees

B1. Cooperative Pilot Research Grant Fund Notice of Award

NOTICE OF AWARD

Cooperative Pilot Research Grant Fund

July 3, 2008

Principal Investigator:
Department
University
Address

Title: Name of Project

Budget Period: 07/01/2008 – 06/30/2009
Project Period: 07/01/2008 – 06/30/2010

We are pleased to inform you that funding has been awarded for your proposal: *Name*. This award is contingent upon budget approval by the Louisiana Board of Regents. This project is funded with the expectation that it will lead to: 1) new project or program applications funded extramurally, 2) discoveries with potential for clinical application, and/or 3) commercial development.

In accepting this award you also agree to:

1. ensure that your project complies with all relevant Institutional requirement (including IACUC, IRB and IBC approvals);
2. present a brief presentation on your project at the LVC and SLIIDR Annual Meeting on September 25, 2008 and at subsequent annual meetings as required;
3. participate in a mid-cycle pilot grant program meeting in March-April 2009 to present and discuss your progress;
4. include the following statement in any publications arising from this award: "This work was supported by the Louisiana Vaccine Center and the South Louisiana Institute for Infectious Disease Research." Both groups will also be acknowledged in any presentations arising from this award.

You are also strongly encouraged to utilize grant seeker sessions and/or grant review mechanisms provided through the South Louisiana Institute for Infectious Disease Research to assist with external grant submissions arising from this pilot award.

This is a 2-year award beginning July 1, 2008 and ending June 30, 2010. The initial award is $75,000 for the period 07/01/08 – 06/30/09. Funding for Year 2 is subject to the availability of funds and satisfactory progress reports based

partly on approved milestones. Year 1 funds may not be carried over into Year 2 without prior approval. All funds must be spent in full by the end of Year 2.

The following items will not be funded as part of the Cooperative Research Pilot Grants:

1) travel to meetings;
2) salary support for tenure and tenure-track faculty;
3) indirect costs or overhead;
4) entertainment;
5) shortfalls or deficits in budgets or unspecified contingencies.

As a condition of this award, you must provide a list of milestones for Years 1 and 2 of the project with your acceptance of this award. Funds will not be released until they are received. Progress against these milestones will be used as part of a review process to determine if the project will be continued through Year 2. A progress report in the form of an R01, R21 or equivalent research report is due by April 30, 2009 and should be submitted via e-mail to: LVC_SLIIDR_Reply@lsuhsc.edu. Progress reports will be also be required in Year 2 should funding be continued.

Please respond by July 15, 2008 with your acceptance of this award and your milestones. Your milestones should be submitted via email to pdaren@lsuhsc.edu. The signed acceptance of this award should be sent to:

Patricia D'Arensbourg
Gene Therapy Program
LSU Health Sciences Center
533 Bolivar Street
New Orleans, LA 70112

Sincerely,

Alistair Ramsay, PhD
Louisiana Vaccine Center

Paul Fidel, PhD
South Louisiana Infectious Disease Research

I agree to the requirements of the Collaborative Research Pilot Grant Award as stated in the Notice of Award.

_____ _____

Principal Investigator Date

B2. Cooperative Pilot Research Grant Fund Awardees

Proposal Title	"Burden of Disease and Etiology of Arbovirus Infections in Guinea, West Africa"
Principal Investigator	Daniel G Bausch, M.D., MPH & TM
Co-Investigators	Christopher N. Mores, SM ScD
Institution	TUHSC

Proposal Title	"Natural History of Oral HPV Infections in HIV+ individuals"
Principal Investigator	Michael Hagensee, M.D., Ph.D.
Sub-Investigators	Janet Leigh, B.D.S., D.M.D & Jeevan Yenugenti, D.D.S.
Institution	LSUHSC

Proposal Title	"Correlates of Immune Protection against Tuberculosis in BCG Vaccinated Nonhuman Primates"
Principal Investigator	Deepak Kaushal, Ph.D.
Co-Investigators	Andrew Lackner,DVM, Ph.D., ; James Blanchard,DVM, Ph.D., ; Peter Didier,DVM, Ph.D.; and Bapi Pahar,Ph.D.
Institution	TUHSC

Proposal Title	"HIV ENV Epitope Engineering"
Principal Investigator	Samuel J. Landry, Ph.D.
Institution	TUHSC

Proposal Title	"A Novel Approach to HIV Vaccine Development: Spontaneously Derived L-2 Defective Particles with 8 Essential Mutants"
Principal Investigator	Ronald Luftig, Ph.D.
Co-Investigators	Angela Amedee, Ph.D.& Qiu Zhong, M.D., Ph.D.
Institution	LSUHSC

Proposal Title	"The role of small non-coding RNAs in controlling Mycoplasma genitalium virulence factors"
Principal Investigator	Liang Ma, M.D., Ph.D.
Co-Investigators	Oliver Wessely, Ph.D.
Institution	LSUHSC

Proposal Title	"Characterization and Evaluation of Novel Subunit Vaccines Against B. pseudomallei"
Principal Investigator	Lisa Morici, Ph.D.
Co-Investigators	Dr. Lucy Freytag, Dr. Chad Roy, and Dr. Pam Kozlowski
Institution	TUHSC

Proposal Title	"Fecal Microbiota in Infants with and Without Necrotizing Enterocolitis"
Principal Investigator	Uma Pisharody, M.D.
Co-Investigators	Michael Ferris, Ph.D.& Duna Penn, M.D., MS
Institution	LSUHSC

Proposal Title	"Cellular Envelope Homeostasis Of Chlamydia Trachomatis"
Principal Investigators	Li Shen, M.D., Ph.D.& Alison J Quayle, Ph.D.
Institution	LSUHSC

Proposal Title	"Pneumocystis Colonization, Inflammation and Frailty"
Principal Investigators	David A Welsh, M.D. & Judd E Shellito, M.D.
Co-Investigators	Marco Ruiz, M.D.; Stephanie Broyles, Ph.D.; Michael Jazwinski, Ph.D.; Kyle Happel, M.D.; Kurt Varner, M.D.; and Salman Arain, M.D.
Institution	LSUHSC

APPENDIX C: Tentative Topics for the LVC Research and Development Series

LVC/SLIIDR Research Development Series

Proposed Topics

Topic	Possible Presenter
Grants.gov	Nicole Barron - LSUHSC
IACUC	Rose Castay & Dr. Fidel – LSUHSC Sheila Garrison - Tulane
IBC	Dr. Thompson – LSUHSC Lucy Freytag- Tulane
IRB	Drs. Potter & Hagensee – LSUHSC Dr. Mark James - Tulane
Clinical Trials Navigation	Barbara Kurth
Primate Center	Jim Blanchard
Material Transfer Agreements & Intellectual Property	Hardy – LSUHSC Maczuga – Tulane Steven Ceulemans
Manuscript Writing	Dr. Fidel
Grant Writing	Dr. Fidel or other
Grant/Funding Opportunities	Nicole Barron (LSUHSC)
Scientific Modeling – (animals, mathematical, computer simulation)	Dr. Hilary Thompson

APPENDIX D: Annual Meeting and Research Fair

D1. Annual Research Meeting Agenda

D2. LVC Annual Research Fair Poster

D1. Annual Research Meeting Agenda

Louisiana Vaccine Center

Annual Research Meeting
September 24 & 25, 2008
Agenda

Wednesday, September 24, 2008

7:00 p.m. **Dinner at Tony Angelo's, 6262 Fleur de Lis Drive, New Orleans**

Dr. Paul Fidel	*Dr. Alistair Ramsay*	*Dr. David Martin*
Dr. John Clements	*Dr. Paula Gregory*	*Dr. Arturo Casadevall*
Dr. Jeff Hobden	*Steven Ceulemans*	*Dr. Tarun Mandal*
Aaron Miscenich	*LVC EAC Members(2)*	*SLIIDR EAC Members (4)*

Thursday, September 25, 2008 (CSRB 563)

8:00 a.m. – 8:30 a.m. **Continental Breakfast**

8:30 a.m. – 8:50 a.m. **Directors' Overview**
Dr. Alistair Ramsay, Louisiana Vaccine Center
Dr. Paul Fidel, South Louisiana Institute for Infectious Disease Research

8:50 a.m. – 9:30 a.m. **Coordinator Presentations**
Dr. Paula Gregory, LVC Education
Dr. Jeff Hobden, SLIIDR Education
Dr. Tom Lallier, LVC/SLIIDR Research
Mr. Steven Ceulemans, LVC/SLIIDR Commercialization

9:30 a.m. – 11:30 a.m. **Cooperative Pilot Research Grant Recipients Presentations**
see attached list for complete presentation information

11:30 a.m. – 12:00 p.m. **Lunch**

12:00 p.m. – 1:00 p.m. **Infection, Immunity, and Vaccine Seminar (LVC/SLIIDR Seminar Program)**
"Thoughts on the Origin of Microbial Virulence"
Arturo Casadevall, M.D., Ph.D.
Albert Einstein College of Medicine, Bronx, NY

2:30 p.m. – 3:30 p.m. **LVC External Advisory Committee Meeting**
CSRB Room 752

Annual Research Meeting Agenda (continued)

***PRESENTATION BY PILOT GRANT RECIPIENTS**

9:30 – 9:40 a.m.	"Burden of Disease and Etiology of Arbovirus Infections in Guinea, West Africa" Daniel G Bausch, M.D., MPH & TM Department of Tropical Medicine Tulane School of Public Health and Tropical Medicine
9:40 – 9:50 a.m.	"Neutralization and Enhancement of Dengue Virus by Human Monoclonal Antibodies" John S. Schieffelin, MSPH, MD Department of Pediatrics Tulane University Health Sciences Center
9:50 – 10:00 a.m.	"Fecal Microbiota in Infants with and Without Necrotizing Enterocolitis" Uma Pisharody, M.D. Department of Pediatrics LSU Health Sciences Center
10:00 – 10:10 a.m.	"The role of small non-coding RNAs in controlling Mycoplasma genitalium virulence factors" Liang Ma, Ph.D. Department of Internal Medicine, Section of Infectious Disease LSU Health Sciences Center
10:10 – 10:20 a.m.	"Pneumocystis Colonization, Inflammation and Frailty" David A Welsh, M.D. & Judd E Shellito, M.D. Department of Internal Medicine, Section of Pulmonary/Critical Care LSU Health Sciences Center
10:20 – 10:30 a.m.	"Characterization and Evaluation of Novel Subunit Vaccines Against B. pseudomallei" Lisa Morici, Ph.D. Department of Microbiology and Immunology Tulane University Health Sciences Center
10:30 – 10:40 a.m.	"Cellular Envelope Homeostasis Of Chlamydia Trachomatis" Li Shen, M.D., Ph.D. & Alison J Quayle, Ph.D. Department of Microbiology, Immunology, and Parasitology LSU Health Sciences Center
10:40 – 10:50 a.m.	"Correlates of Immune Protection against Tuberculosis in BCG Vaccinated Nonhuman Primates" Deepak Kaushal, Ph.D. Division of Bacteriology and Parasitology Tulane National Primate Research Center
10:50 – 11:00 a.m.	"Natural History of Oral HPV Infections in HIV+ individuals" Michael Hagensee, M.D., Ph.D. Department of Internal Medicine, Section of Infectious Disease LSU Health Sciences Center
11:00 – 11:10 a.m.	"A Novel Approach to HIV Vaccine Development: Spontaneously Derived L-2 Defective Particles with 8 Essential Mutants" Ronald Luftig, Ph.D. Department of Microbiology, Immunology, and Parasitology LSU Health Sciences Center
11:10 – 11:20 a.m.	"HIV ENV Epitope Engineering" Samuel J. Landry, Ph.D. Department of Biochemistry Tulane University Health Sciences Center

D2. LVC Annual Research Fair Poster

APPENDIX E: Mycobacterium Symposium Announcement, Program and Photos

E1. Mycobacterium Symposium Announcement and Program

E2. Photos from the "Symposium on Mycobacteria, Tuberculosis and Host Defense"

E1. Mycobacterium Symposium Announcement and Program

Louisiana Vaccine Center

Louisiana Vaccine Center Symposium on Mycobacteria, Tuberculosis, and Host Defense

LSU Health Sciences Center
Medical Education Building (MEB)
1901 Perdido St., Room 6K1
Friday, November 21, 2008
Time: 12:00 p.m.

PROGRAM

Louisiana Vaccine Center Symposium on Mycobacteria, Tuberculosis, and Host Defense

12:20 – 12:35 p.m.	Welcome and Introduction	Alistair Ramsay, Ph.D. Professor of Medicine Director, Gene Therapy Program Director, Louisiana Vaccine Center
Session 1	Alistair Ramsay, Chair	
12:35 – 1:00 p.m.	"*TB: Clinical Overview*" Juzar Ali M.D., FRCP(C), FCCP LSU Health Sciences Center	
1:00 – 1:20 p.m.	"*The non-human primate model of tuberculosis*" Deepak Kaushal, Ph.D. Tulane National Primate Research Center	
1:20 – 1:40 p.m.	"*Overview of lab research*" Deepak Kaushal, Ph.D. Tulane National Primate Research Center	
1:40 – 2:00 p.m.	"*Mycobacterium tuberculosis gene-expression in response to Thioridizine*" Noton Dutta, Ph.D. Tulane National Primate Research Center	
2:00 – 2:20 p.m.	"*Stress-dependent regulation of transcription in Mycobacterium tuberculosis by SigH*" Smriti Mehra, Ph.D. Tulane National Primate Research Center	
2:20 – 2:40 p.m.	"*Immunological and molecular characterization of WT, Sig H mutant of Mycobacterium tuberculosis (Mtb) in vivo and In vitro "* Ratish Gambhira, DVM, MS Tulane National Primate Research Center	
2:40 – 3:00 p.m.	"*Alcohol and Regional T Cells in Murine Tuberculosis*" Carol Mason, M.D. LSU Health Sciences Center	
3:00 – 3:20 p.m.	**COFFEE BREAK**	

Session 2 Carol Mason, Chair

3:20 – 3:40 p.m. "*Leprosy Vaccine Initiative: From Antigen Discovery to Efficacy Testing*"
Tom Gillis, Ph.D.
Louisiana State University
Baton Rouge, LA

3:40 – 4:05 p.m. *"Prime boost vaccines against TB"*
Alistair Ramsay, Ph.D.
LSU Health Sciences Center

4:05 - 4:25 p.m. *"Neonatal vaccination against M.Tb."*
Guixiang Dai, Ph.D.
LSU Health Sciences Center

4:25 – 4:45 p.m. *"Therapeutic vaccination against tuberculosis"*
Heena Mehta
LSU Health Sciences Center

4:45 – 5:05 p.m. "*Does arginase induction in macrophages supports the growth of Mycobacterium tuberculosis*?"
Arnold H. Zea, Ph.D.
LSU Health Sciences Center

5:05 – 5:15 p.m. Concluding Remarks

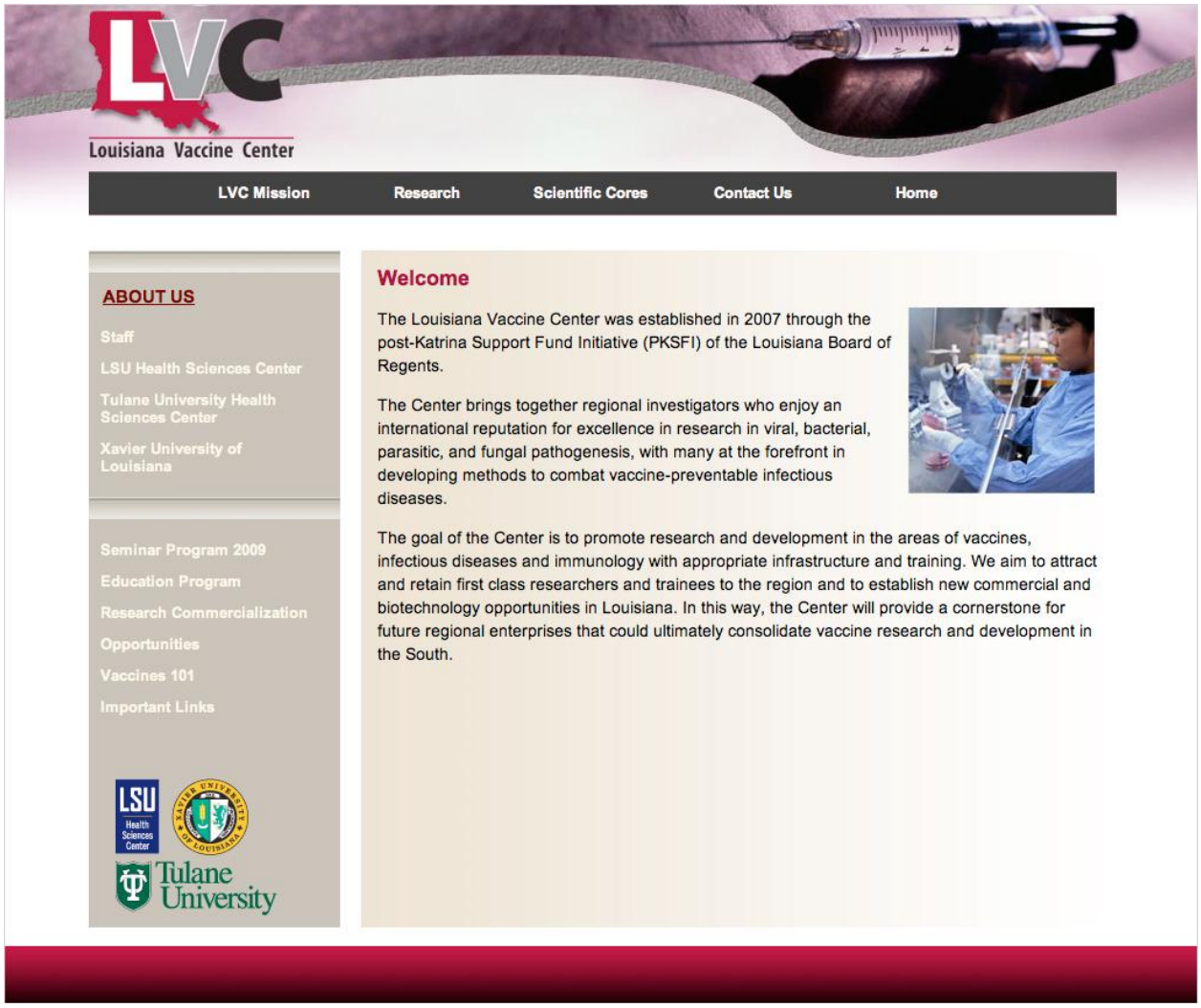
D2. Photos from Symposium

APPENDIX F: LVC Grant Seekers Meeting Schedule

Grant Seekers Meetings

Date	Name	Project Title
April 19, 2008	Dr. Bonny Dickinson	"Role of toll-like receptors and FcRn in carcinoid cancer"
July 14, 2008	Dr. Tom Wen	"BrpA in virulence modulation of Streptococcus mutans"
August 11, 2008	Dr. Sam Landry	"HIV ENV epitope engineering"
August 22, 2008	Dr. Bonny Dickinson	"Cholera toxin regulation of dendritic cell chemotaxis"
September 29, 2008	Dr. Paul Fidel	"Host response against vaginal candidiasis"
October 3, 2008	Dr. Li Shen	"Linkage between transcription regulation and virulence in *Chlamydia trachomatis*"
December 1, 2008	Drs. Angela Amedee and Patty Kissinger	"Alcohol use and shedding of HIV-1 in the female genital tract"
December 5, 2008	Drs. Jim Hill and Walter Lukiw	"Age, gender, ApoE allele and HSV-1 reactivation phenotype are linked to Alzheimer's"
March 6, 2009	Dr. Victor Hsia	"Thyroid Hormone (T3) and T3 Receptors Use Epigenetics to Control HSV-1 Gene Expression"

APPENDIX G: LVC Website Homepage (www.louisianavc.org)


LVC
Louisiana Vaccine Center
LVC Mission
Research
Scientific Cores
Contact Us
Home
ABOUT US
Staff
LSU Health Sciences Center
Tulane University Health Sciences Center
Xavier University of Louisiana
Seminar Program 2009
Education Program
Research Commercialization
Opportunities
Vaccines 101
Important Links
LSU Health Sciences Center
Tulane University
Welcome
The Louisiana Vaccine Center was established in 2007 through the post-Katrina Support Fund Initiative (PKSFI) of the Louisiana Board of Regents.
The Center brings together regional investigators who enjoy an international reputation for excellence in research in viral, bacterial, parasitic, and fungal pathogenesis, with many at the forefront in developing methods to combat vaccine-preventable infectious diseases.
The goal of the Center is to promote research and development in the areas of vaccines, infectious diseases and immunology with appropriate infrastructure and training. We aim to attract and retain first class researchers and trainees to the region and to establish new commercial and biotechnology opportunities in Louisiana. In this way, the Center will provide a cornerstone for future regional enterprises that could ultimately consolidate vaccine research and development in the South.

APPENDIX H: Interview Guide and Post-Interview Questionnaire

H1. Interview Guide

H2. Post-Interview Questionnaire

H1. Interview Guide

Interview Guide

Even though interviews will be conducted in an exploratory, observational context in which interviews will be conducted through informal discussion, an interview guide has been developed to ensure standardization between interviews and to ensure that the main interview topics are covered related to ongoing research and commercial interest:

Research Topics

1. What are your primary areas of research? areas of expertise? key equipment?
2. What would you say is your primary mission as a researcher/investigator?
3. Tell me about your ongoing research in "layman's terms" and how individuals (patients, industry, academia, etc.) could benefit.
4. Why did you get involved in the type of research you are currently?
5. What is the goal of your research?

Commercial Topics

1. Are there any tools you are developing in relation to your research? animal models? Novel inventions?
2. What types of partnerships are you looking for to further your research?
3. What do you feel it would take to move your research to the next level? more funding? New partnerships?
4. Do you feel as though your research has any clinical/translational potential?
5. Have you ever been approached by a company regarding partnering with them for advancing your research? If so, whom?
6. Do you have any contacts within the biotech community locally? nationally?
7. Are you interested in exploring the potential commercialization opportunities your research may present?
8. Do you currently have any intellectual property or licenses? Have you ever been approached about obtaining an IP or license? What was the outcome?

Interview Guide: follow-up interview

Invention disclosure questions

1. What technical details constitute this invention?
2. When / where did you make this invention exactly?
3. What is the history leading to this invention?
4. Were there any other inventors involved in this discovery? Please note that inventorship requires an intellectual contribution directly related to the discovery, not just executing an experiment.
5. What are the possible areas of commercial application of the invention?
6. Is any material used in this invention covered by a material transfer agreement and if so, in which context?
7. Have you made a patent or literature search? Has it yielded any related inventions? If so, what are the details of these technologies?
8. Has the invention been reduced to practice (assembled, tested or modeled)?
9. Have you made any public disclosure of the invention or submitted it for publication (public disclosure includes published article or abstract in a journal or proceedings; a presentation or poster at a conference; preprints distributed outside the institution; a thesis or dissertation cataloged and shelved in a public library; prototype exhibit; posting on internet; etc)? If so, what are the details and exact dates of disclosure?
10. When is your earliest planned publication of this invention?
11. Do you have an interest to personally take a license under this invention from the institution, with the intention to develop/commercialize it yourself?
12. Do you know of any firms that might be interested in licensing this technology, please elaborate?

H2. Post-Interview Questionnaire

Interview follow-up: questionnaire

Introductory email:

Thank you for allowing our Interview Team to meet with you about your past and current research projects. Our team is looking forward to following-up with you in the near future as we begin to review and assess all that we learned from our meeting. At this time, we ask that you please fill out our brief Faculty Interview Feedback Questionnaire at your convenience by utilizing the link below. Your responses will not only allow us to be able to better serve you, the investigator, but to apply what we learn from you to our future meetings with others. All information gathered from this questionnaire will be used for commercial support purposes and will be anonymous. Thank you so much for your time and responses.

http://survey.constantcontact.com/survey/a07e2hnfowafsnobuwg/start

Questionnaire

CTRECP

Clinical & Translational Research, Education and Commercialization Project

LVC/SLIIDR/CTRECP Research Investigator Interview Feedback Survey

1. Interview Feedback: How would you rate the following aspects of the recent faculty interview

	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree
The goals of the interview were sufficiently clear to me	○	○	○	○	○
The interview length was appropriate	○	○	○	○	○
The interview team was friendly and courteous	○	○	○	○	○
My questions were adequately answered	○	○	○	○	○
My expectations were met	○	○	○	○	○

2. Please provide your comments/suggestions to improve future interview.

350 character(s) left.

3. Which outcomes or support do you expect from this interview? (Check all applicable)

☐ Invention Disclosure Assistance

- [ ] Commercial grant application support (SBIR/STTR)
- [ ] Sponsored research facilitation support
- [ ] Start -up business support (Business plan writing etc)
- [ ] Leads for enhanced industry collaboration
- [ ] Other

4. Programming Feedback: Have you ever participated in any of the following programs or events (check all that apply)

- [ ] Biotech Networking Evens (NOBING)
- [ ] Industry Outreach Meetings
- [ ] NOBIC Mentor Program
- [ ] Entrepreneur SBIR/STTR Workshops
- [ ] SLIIDR/LVC grant seekers Meeting
- [ ] SLIIDR/LVC Invited speakers series
- [ ] Commercial awareness for researcher's seminar.
- [ ] None of the Above

5. Do you feel this current offering of programming meets your needs?

- [ ] Yes Completely
- [ ] Somewhat
- [ ] Neutral
- [ ] No, not at all

6. Do you have any suggestions for future commercially oriented event/seminars to better meet your needs? Please provide suggestions below:

350 character(s) left.

7. Would you like to stay informed about future events?

- ( ) yes

- ○ No

8. Please select future events you would like to be informed about (check all that apply)

- ☐ Biotech Networking Events (NOBING)
- ☐ Industry Outreach Program
- ☐ Entrepreneur SBIR/STTR workshops
- ☐ SLIIDR/LVC Grant seekers Meeting
- ☐ SLIIDR/LVC Invited Speaker Series
- ☐ Commercial Awareness for Researchers Seminar
- ☐ None
- ☐ Other

9. Contact Information:

By entering my personal information, I consent to receive email communications from the survey author's organization based on the information collected.

First Name:

Last Name:

Company Name:

Work Phone:

Email Address:

emailaddress@xyz.com

Address 1:

Address 2:

City:

State/Province (US/Canada): -- Select a state --

Postal Code:

Finish

APPENDIX I: LVC Commercialization Event Announcement

I1. Commercial Awareness for Researchers Announcement and Speaker Bio-**November 25,2008**

I2. Bridging Louisiana Bioscience Announcement and Speaker Bio-**November 25, 2008**

I3. BioTech Connect Event Announcement-**November 25, 2008**

I4. BioScience Angel Capital in New Orleans Announcement-**June 2, 2009**

I5. Innovation and Technology Leadership Announcement, Program and Speaker Bio- **June 24 and 25, 2009**

I1. Commercial Awareness for Researchers Announcement and Speaker Bio

Speaker BIO

Commercial Awareness For RESEARCHERS

TUESDAY, NOVEMBER 25TH
12P.M. – 3 P.M.

Dale Pfost, Ph.D.

CEO, Receptor BioLogix, Palo Alto – CA

Dr. Pfost is a successful serial entrepreneur in starting high technology and biotechnology companies. Over the past 25 years he has founded four companies, three of which became publicly traded. He has raised over $200 million in private and public capital in over twenty financings. He is currently the CEO of Receptor BioLogix (RBLX), a biotechnology company in Palo Alto California. He resides in California and has a house in New Orleans where his son attends Tulane. He is a licensed private pilot with an instrument rating.

Prior to RBLX, he was chairman, president and CEO of Acuity Pharmaceuticals, an ophthalmic company that was a pioneer in developing drugs based on the gene silencing technology of RNA interference. He led Acuity from start-up through the completion of Phase II trials in less than four years, merging it into publicly traded OPKO Health, Inc. in 2007 (AMEX: OPK).

Previously, Dr. Pfost was chairman, president and CEO of Orchid Biosciences, Inc., where he oversaw the company's IPO (NASDAQ: ORCH) and managed its successful repositioning as a leader in the genetic testing field. Earlier, Dr. Pfost served as president and CEO of glycobiology and proteomics firm Oxford GlycoSciences, Ltd., which went public in 1998 and was later acquired by Celltech plc.

He started his entrepreneurial career by founding his first company while working towards his Ph.D. in solid state physics from Brown University. That company, Infinitek, Inc. developed the Biomek 1000 a laboratory robotic system and was acquired by SmithKline Beckman in 1984. He led the launch of the Biomek while at Beckman where it became an industry-leading product for over two decades.

Richard Montgomery IV, J.D.

General Partner, VCE Capital, New Orleans - LA

Richard Montgomery is a partner at VCE Capital Partners, LLC, a venture capital investment advisory firm with $36 million under management and offices in Shreveport and New Orleans, Louisiana and New York City. Mr. Montgomery runs the firm's New Orleans office. VCE Capital Partners is the general partner of Louisiana Ventures, L.P. and Themelios Ventures, L.P. Prior to joining VCE Capital Partners, Mr. Montgomery was an attorney in the corporate and securities section of the New Orleans office of Jones, Walker, Waechter, Poitevent, Carrère & Denègre, LLP. His practice focused on mergers and acquisitions, corporate finance, private equity and venture capital financing transactions and entity formation. He is a member of the Louisiana State Bar Association.

Mr. Montgomery earned a J.D. in 1999 from the Louisiana State University School of Law, graduating as a member of the Order of the Coif. In law school, he was an associate on the Louisiana Law Review. Prior to that, he earned a B.A. in History from the University of Georgia.

I2. Bridging Louisiana Bioscience Announcement and Speaker Bio

Speaker BIO

Bridging Louisiana Bioscience

TUESDAY, NOVEMBER 25TH
4 P.M. – 5 P.M.

Gene D'Amour, Ph.D.

Sr. VP for Resource Development, Xavier University, New Orleans - LA

Dr. Gene D'Amour is currently Senior Vice President for Resource Development at Xavier University. His responsibilities include Research Administration, Technology Transfer, Title III, Government Affairs, and Board Relations.

Dr. D'Amour received his Ph.D. from the University of Minnesota in Philosophy of Science and Mathematical Logic in 1971. He then received a faculty appointment at West Virginia University where he was a Professor of Philosophy for nine years.

Dr. D'Amour joined the administration of Tulane University in August, 1980, where over a 22 year period he held the positions of Associate Dean of the Graduate School, Associate Provost, Vice President for Research and Project Administration and then Vice President for Institutional Program Development and Government/Agency Affairs.

Dr. D'Amour Chaired Louisiana's state-wide NSF EPSCoR committee from 1985 tell 2002. He was instrumental in organizing and chaired the Coalition of EPSCoR States, a Washington-based association established to enhance the competitiveness of scientists and engineers in states receiving low levels of federal R&D funding.

Dr. D'Amour has published one book, "The Nature of Evidence," and numerous articles spanning the Humanities, Social Sciences and Sciences. He has been a consultant to more than thirty universities, foundations and government agencies. He is a married to Carolyn Sarrat D'Amour and has three children. He has been a leader in promoting a variety of non-profit, charitable organizations in the greater metropolitan area of New Orleans.

Roy Keller

Associate Director, Louisiana Business & Technology Center, Baton Rouge – LA

Roy Keller serves as the associate director of the Louisiana Business and Technology Center, a high-tech small business incubator on the campus of Louisiana State University. He also serves as director of the Louisiana Technology Transfer Office (LTTO). The LTTO operates throughout Louisiana and also has offices at NASA's John C. Stennis Space Center and the NASA Michoud Assembly Facility in New Orleans.

Mr. Keller has been on the Board of Director's of the International Technology Transfer Society for six years and currently serves as vice president of finance. He is a board member of Partners for Stennis, a multi-state economic development organization. He also serves on the Inventions and Innovations and the State and Local Government committees of the National Federal Laboratory Consortium and was given the 2007 Outstanding Service Award by the Consortium.

Mr. Keller also currently serves as the director of the Louisiana SBIR outreach program and as the Technology Transfer director for the Louisiana NASA Epscor program.

I3. BioTech Connect Event Announcement

I4. BioScience Angel Capital in New Orleans Announcement

I5. Innovation and Technology Leadership Announcement, Program and Speaker Bio

Acquiring External Technology to Drive Innovation

Business Issues Addressed

Innovate rapidly by scouting and acquiring external technology. Obtain the tools to manage the acquisition process. Learn how to structure successful deals and manage the relationships. Integrate external technology sourcing into your business processes.

Key Benefits

Identify when outside technology is needed, how to find what you need, and how to manage the integration process.

Key Topics

Accelerating Innovation Through External Technology

- Becoming more innovative by moving to an 'open innovation' business model
- Accelerating the product development cycle using limited technical resources
- Managing risks and controlling costs

Balancing External and Internal Development Efforts

- Using the WFGM℠ model of technology acquisition: determining What you need; Finding it; Getting it; Managing relationships
- Developing a comprehensive technology strategy that involves acquisition, cross-supply, and co-development

Determining Your External Technology Acquisition Goals

- Candidate criteria: seeking value, filling gaps, managing complexity, addressing competitors, reducing costs, and hedging your bets (the portfolio concept)
- Incorporating technology roadmaps
- Establishing priorities among technology acquisition needs

Finding What You're Looking for

- Looking in other companies
- Searching in start-up companies
- Working with university faculty and tech transfer offices
- Going global: problems and considerations

Structuring the Deal

- Transitioning from one-on-one arrangements to alliance networks
- Moving from cost and supply chain management to more strategic integrated external networks
- Considering the open innovation model

Integrating External Technology Sourcing Into Your Business Processes and Managing Resulting Relationships

- Using the external technology sourcing concept to overcome traditional corporate boundaries
- Making it work: top management involvement
- Risk management

Impact of Intellectual Property Law on External Technology Sourcing

- Structuring relationships with intellectual property in mind
- Understanding the role of patent and copyright in enhancing/impeding external innovation acquisition
- Assessing the impact of IP law on external sourcing

Speaker Bio

Ora Smith, JD, consults on projects in the technology sector. His clients include companies, organizations, and universities engaged in technology development, commercialization, and transfer. Previously, he was CEO of Illinois Superconductor Corporation, (now ISCO International) a leader in using external innovation to bring high temperature superconductors into the commercial wireless equipment marketplace.

Mr. Smith served as vice president and chief marketing officer at Conductus. Both ISCO and Conductus were cited in the April 2005 Spectrum magazine as among the top seven most innovative IPO's out of 823 companies that went public from 1993-2002.

At Rockwell International, Mr. Smith was a corporate R&D lab director and the company's corporate director of external technology development. He also served as the Industrial Research Institute (IRI) Fellow in the White House Science Office while at Rockwell.

Mr. Smith was president of the Science and Technology Campus Corporation for over five years. This organization operates a research park and provides technology commercialization functions in affiliation with Ohio State University. He has served on various boards of directors and advisory boards.

Mr. Smith received his SB and SM degrees in mechanical engineering from MIT and his JD from Harvard Law School

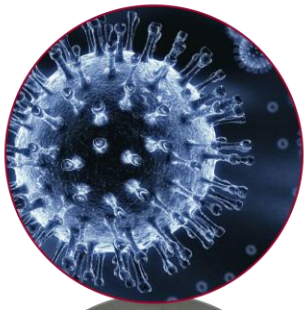
APPENDIX J: LVC Flyer

Louisiana Vaccine Center

WWW.LOUISIANAVC.ORG

The Louisiana Vaccine Center seeks to expand existing research strengths into commercial partnerships with the public and private sector to translate discoveries into products, vaccines and therapies.

New Orleans Investigators have justly earned an international reputation for research achievement in the related areas of viral, bacterial, parasitic, and fungal pathogenesis, host immunity and vaccine research. Collectively, this group with over $70M in current Federal research funding and an extensive history of executing multi-center clinical trials represents one of the most significant regional research strengths.



CORE FACILITIES

- Genomics: State-of-the-art analytical sequencing and genome analysis
- Proteomics: Biomarker and advanced antigen, antibody and protein identification and analysis
- Vector Development: Design, engineering and preparation of recombinant vaccine vectors through novel technologies
- Protein: High quality protein and antigen purification and optimization of protein expression
- Nanotechnology: Innovative vaccine delivery formulations including cell- or tissue-specific targeting
- Immunology: Multi-parameter cell sorting and quantification and analysis of immune responses
- Molecular Interaction: Concentration analysis of quality of antibody responses through Biacore® technology
- Imaging: Histopathology, state-of-the-art microscopy, and live-cell and in vivo imaging

RESEARCH & DEVELOPMENT

Particular strengths have been established in:

- HIV pathogenesis and immunity
- HIV-related respiratory infections, including tuberculosis, bacterial pneumonia and pneumocystis
- Sexually-transmitted diseases, particularly Chlamydia and human papilloma virus
- Fungal infections, particularly candidiasis and cryptococcosis
- Biodefense/Emerging infections, particularly vaccines against anthrax, plague, and smallpox
- Diseases of the oral cavity
- Ocular diseases, bacterial, fungal, and HSV viral keratitis
- Novel vaccine adjuvants and delivery systems

South Louisiana Institute for Infectious Disease Research

Our Partners

NewOrleansBioInnovationCenter

The Louisiana Vaccine Center is an initiative of the Louisiana State University Health Sciences Center, Tulane University Health Sciences Center, and Xavier University of Louisiana in New Orleans, in partnership with the New Orleans BioInnovation Center, and is supported by the Louisiana Board of Regents.

LSU Health Sciences Center | Tulane University | Xavier University of Louisiana

APPENDIX K: World Vaccine Congress Post-Event Report

Book before 3 July and save $1190

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worldvaccine CONGRESS 2009

20 – 23 April 2009, Westfields Marriott, Washington, Dulles

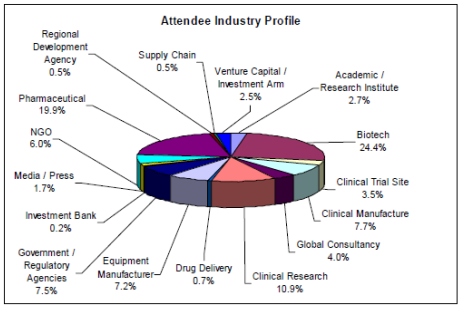
Post Event Report

Overview

Now in its 9th year, *World Vaccine Congress Washington* truly has established itself as the must attend North American vaccine conference for C-level and senior directors from vaccine manufacturers and biotech companies from around the globe.

Over the course of the 4 days, the congress attracted over **402 participants** from across the World's leading vaccine manufacturers, biotechs, governmental agencies, NGOs, research and academic institutes, venture capital and legal firms and the wider contract service and equipment manufacturer community.

In 2009 the event was scaled up to epic proportions with a **speaker faculty with no fewer than 120** of the industry's most experienced and influential stakeholders. Presenting a distinguished faculty of experts from across the regions of North America, Europe and Asia, this event provided a truly global setting for learning, debate and networking. With over 19 sessions over the 4 days and approximately 17 hours of dedicated networking time, the congress catered for all professional objectives.



"Excellent meeting"
Melinda Wharton, Acting Director, Immunization Safety Office, **CDC**

Conference topics

The three main congress days were split across 16 distinct sessions covering topics such as

- Vaccines – who's calling the shots?
- Vaccines - a role for Pharma
- Making partnerships work
- Vaccine R&D
- Redrawing the vaccine frontier
- Taking aim at novel markets
- Regulatory pathways to approval
- Influenza evolution
- Targeting biodefense markets
- R&D growth strategies
- HIV vaccines – progress and prospects
- Cancer vaccines and immunotherapy
- Vaccine clinical trials and tribulations
- Production, manufacture and capacity
- Adjuvants and delivery technologies
- Post market evaluation

In line with growing the congress and developing the most dynamic congress subjects, we once again structured a focus day on the topic of vaccine investment and funding channels. A pre-cursor to the main congress days, the event had a strong following from early stage biotechs and venture capitalists looking to uncover solutions to the current funding crisis within biotech start-ups.

Thank you to our sponsors and exhibitors: GE Healthcare, BD, Pall Life Sciences, Crucell, Synco Bio Partners, CSL Biotherapies, Health Protection Agency, Millipore, SAFC Pharma, Quintiles, Radiant Research, Accelovance, Covance, Diosynth Biotechnology, Research Across America, Lonza, SNBL Clinical Pharmacology Center, University Clinical Research, ProImmune, Schreiner MediPharm, Sterigenics, Vince & Associates, Louisiana Vaccine Center, CRF Health, Catalent, Beardsworth ..... see you all again next year!

2nd Annual ViE Awards and Gala Dinner

The *Vaccine Industry Excellence Awards*

World Vaccine Congress Washington 2009 also saw the return of the industry's only dedicated awards ceremony – ***The ViE Awards.*** Over 220 senior level executives attended this fantastic evening, where excellence in the vaccine industry was celebrated.

With an increased category line-up of 9 Award winners representing pharma, biotech, NGO and the wider service community, it adds depth to an already highly regarded congress and helps highlight the excellent progress being made in this industry.

The Judges

Many thanks to our judges:

- Lance Gordon, Ph.D., President & CEO, ImmunoBiologics Corporation
- Dr George Robertson, Senior Technical Advisor, Vaccine Development Global Program, PATH
- Dr Una Ryan, Chief Executive Officer, Waltham Technologies
- Dr William Egan, Vice President, PharmaNet Consulting
- CDR Angelda Shen, Vaccine Specialist, NVPO, US Department of Health and Human Services
- Andy Pasternak, Partner, Bain & Company
- Dr Gregory Poland, Professor of Medicine and Infectious Disease, College of Medicine, Mayo Clinic, Rochester, Mn
- Bill Enright, President & Chief Executive Officer, Vaxin
- Robert Becker, Vice President, Business Development, VaxInnate
- Dr Axel Hoos, Medical Lead, Immunology / Oncology, Bristol-Myers Squibb

The Winners

With over 300 entries and votes the awards were hotly contested. **Congratulations** to all of the finalists and of course the winner

Best Contract Research Organisation
WINNER: Accelovance

Best Contract Manufacturing Organisation
WINNER: SynCo Biopartners

Best Early-Stage Vaccine Biotech
Sponsored by ICON Clinical Research
WINNER: Sanaria

Biotech CEO of the Year
WINNER:
Dr Ronald Brus, Chief Executive Officer, Crucell

Pharma Vaccine Executive of the Year
WINNER: Mr Jean Stéphenne, President and General Manager, GlaxoSmithKline Biologicals

Best Vaccine Partnership / Alliance
WINNER:GlaxoSmithKline Biologicals and PATH Malaria Vaccine Initiative

Best Vaccine R&D Pipeline
Sponsored by Quintiles
WINNER: GlaxoSmithKline Biologicals

Best Therapeutic Vaccine (approved or in development)
WINNER: Oncophage from Antigenics

Best Prophylactic Vaccine (approved or in development)
Sponsored by CSL Biotherapies
WINNER: RotaTeq from Merck

NOMINATIONS OPEN AGAIN IN JANUARY 2010

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APPENDIX L: LVC Infection, Immunity and Vaccine Seminar Program Schedule

Infection, Immunity, and Vaccine Seminar Program - 2009

12:00 p.m. – CSRB Room 563, 533 Bolivar St., LSUHS Campus

January 29	***"Nonhuman Primate Models for AIDS Research"*** **Ron Veazey, D.V.M., Ph.D.** Chair, Division of Comparative Pathology and Professor of Pathology Tulane National Primate Research Center & Tulane University School of Medicine
February 12	***"The pathogenesis of Staphylococcus aureus infection: the battle between sarA and agr"*** **Mark S. Smeltzer, Ph.D.** Professor, Department of Microbiology and Immunology University of Arkansas for Medical Sciences
March 12	***"Prevention of mother-to-child transmission of HIV: past successes and current challenges"*** **Russell Van Dyke M.D.** Department of Pediatrics, Section of Infectious Diseases Tulane University Health Sciences Center
March 26	***A "Toll" Bridge for T cells: A novel mechanism of T cell costimulation*** **Eduardo Davila, Ph.D.** Assistant Professor, Department of Pediatrics LSU Health Sciences Center
April 9	***" Th1 and Th17 pathway in intracellular bacterial infections"*** **Shabaana A. Khader, PhD** Division of Medicine, Allergy and Immunology Children's Hospital of Pittsburgh Pittsburgh, PA
April 23	***"Antigen Structure and Epitope Dominance"*** **Samuel Landry, Ph.D.** Professor, Department of Biochemistry Tulane University School of Medicine
May 14	***"Characterization and Evaluation of Novel Subunit Vaccines against Burkholderia pseudomallei"*** **Lisa Morici, Ph.D.** Research Assistant Professor, Department of Microbiology and Immunology Tulane University Health Sciences Center

May 28	***"The Normal Vaginal Microbiome: Define "Normal""*** **Michael Ferris, Ph.D.** Assistant Professor, Department of Pediatrics & Microbiology, Immunology and Parasitology LSU Health Sciences Center
June 11	**Christopher A. Hunter, Ph.D.** Professor and Chair, Department of Pathobiology University of Pennsylvania, School Veterinary Medicine
September 29	**Roger G. Rank, Ph.D.** Professor Chlamydia Research Group Arkansas Children's Hospital Research Institute
October 22	**David Koelle, M.D.** Associate Professor of Medicine, Division of Allergy and Infectious Diseases University of Washington School of Medicine Seattle, WA hosted by Drs. Hagensee and Quayle
November 12	**Martin Blaser M.D.** Chair, Department of Medicine New York University Medical Center
December 10	**Marshall E. Bloom, M.D.** Division of Intramural Research Rocky Mountain Laboratories National Institutes of Health Hamilton, Montana