WASHINGTON SQUARE
HEALTH FOUNDATION, INC.

PREFACE

Several years ago Mr. Howard Nochumson, Executive Director of Washington Square Health Foundation brought to the Washington Square Health Foundation's Board of Directors' attention that so much information existed in bits and pieces relative to diabetes, cell biology, cell chemistry and islet cell implantation that it seemed reasonable that such knowledge could be blended wherein a functional (physiologic) cure for diabetes could become a reality in a reasonable time period.

Our Foundation's Board explored this idea and after much discussion asked itself several questions:

1. *What would be the potential result(s) if a brain trust, representing a combination of scientific expertise, could be assembled and charged with the challenge of exploring the development of a functional cure of diabetes?*

2. *What would be the chances of success if that group could meet in closed sessions for a three-day period and test the plausibility of this train of thought?*

3. *Would it be reasonable to expect that such a group of sophisticated scientists could and would shed barriers protecting personal expertise (after all, scientists are known to protect their pet projects and expertise) and thereby form a team that would be willing to push aside such barriers and work as a unit to accomplish a common goal? and*

4. *After such sessions, would they be able to state such a project is not only possible but doable – and could they provide a road map for our consideration?*

This idea and the resulting questions were eventually shared with Dr. Jose Oberholzer, Associate Professor of Surgery and Bioengineering; Director, Cell and Pancreas Transplantation; Director, Cell Isolation Laboratory, at the University of Illinois at Chicago.

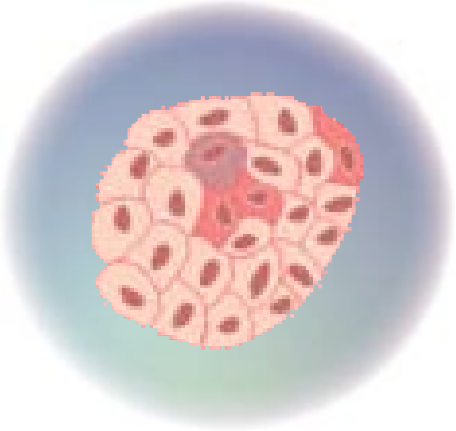
After careful study, and in consultation with colleagues whose expertise he knew was needed for such a project, he came to the Washington Square Health Foundation Board and made a presentation that convinced all of us that this project was a real "GO".

It should be acknowledged that Washington Square Health Foundation's role has been and is that of a catalyst – and as a catalyst, Washington Square Health Foundation will not fundraise for or directly administer the Chicago Project's research support.

Angelo P. Creticos, M.D.
President, Washington Square Health Foundation

The Chicago Project:
An International Effort to Create
The Functional Cure for Diabetes

University of Illinois at Chicago and
Washington Square Health Foundation



December 2004

The Chicago Project

In the last 20 years, a vast amount of scientific knowledge has been gathered about how insulin-producing cells develop, function and survive in the normal human body and how they become compromised and destroyed in diabetic patients. In recent years, interest in diabetes has intensified because it is nearing epidemic proportions: in 1985 there were 30 million diabetics; today that number has rocketed to more than 170 million. By 2025, diabetes is likely to affect 300 million people worldwide.

The need for a functional cure is critical and the most promising treatment for controlling diabetes is to replace the destroyed insulin-producing cells with functional islet cells through transplantation that are immune to destruction.

To hasten this possibility, researchers from three continents have come together to form the Chicago Project—a group of 11 highly qualified scientists who have committed themselves to achieving a functional cure for diabetes in the next five years.

Coordinated by the University of Illinois at Chicago College of Medicine, Chicago Project leaders strongly believe that the scientific community now has all the necessary ingredients to make cell-based therapy of diabetes an option for the majority of diabetic patients. Chicago Project team members are using a collaborative model to achieve a cure. By freely exchanging knowledge, team members have created a scientific alliance between institutions—a coalition that will provide for more direct and noncompetitive funding to accelerate finding a functional cure for diabetes.

Project Goal

To control patients' blood-sugar levels, the Chicago Project plans to produce in the laboratory an unlimited source of islet cells that are suitable and safe for transplantation in humans. By delivering a limitless source of pancreatic islet cells for transplantation in diabetic patients, members of the Chicago Project team offer the nation's 17 million diabetics and patients throughout the world a chance at living a normal and healthy life free of the management problems of controlling diabetes.

Islet-cell transplantation offers a cell-based, functional cure for diabetes by encapsulating cells to protect against the immune system's assaults on the recipient's cells. These encapsulated cells will be implanted in diabetic patients and will replace the missing insulin-producing cells thereby controlling blood-sugar levels.

Through international collaboration between scientists, a series of laboratory experiments will be conducted during the first four years of the project with the goal of producing human clinical trials by year five. In the fifth year, human diabetic subjects will receive islet-cell transplantation, the results of which will eventually allow for widespread clinical application of a cell-based therapy for diabetes.

Diabetes

Diabetes is a chronic disease characterized by lack of insulin— a hormone secreted by the islet cells of the pancreas that is necessary for maintaining normal blood sugar. Defects in insulin production result in hyperglycemia (high blood sugar), which can lead to long-term complications such as blindness, kidney failure, nerve damage, amputations, heart attacks and strokes.

Types

- Type I diabetes, or juvenile diabetes, is typically observed in the infant, adolescent or young adult and is due to loss of insulin-producing ß-cells in the islets in the pancreas. It is believed that the loss of ß-cells is the results of the patient's immune system erroneously destroying insulin-producing cells. Thus, patients with established type I diabetes do not produce insulin and require insulin injections to survive.
- Type II diabetes, or adult-onset diabetes, was typically observed in elderly patients presenting with obesity. Until recently, type II diabetes was thought to occur consequent to a resistance of the body to react to insulin (called insulin resistance). The treatment of type II diabetes consists of weight loss and drugs that render the body again insulin sensitive.
- New information on type II diabetes shows it is encountered at all ages as well as in lean patients. Patients with type II diabetes do not produce enough insulin and eventually stop producing insulin altogether. Understanding that the amount of insulin-secreting cells is decreased in diabetic patients at all stages of the disease explains why replacing insulin is beneficial to type II diabetic patients, too.

Insulin Treatment

Insulin injections or insulin pumps can never mimic the minute-to-minute insulin secretion of a normal pancreas. Despite improvements in insulin treatment and efforts to control blood glucose levels, long-term diabetic complications eventually occur. The burden of diabetes-related complications are enormous. The direct and indirect yearly costs related to diabetes are estimated to exceed $90 billion nationwide.

Cell-based Treatment

Diabetes can be functionally cured by the transplantation of insulin-producing islet cells, which are procured from organ donors. There are 17 million diabetic patients in the United States but only six thousand available donor organs per year. In addition, for transplantation to be successful, chronic immunosuppression must occur to prevent rejecting the foreign tissue thus causing diabetes to recur.

Immunosuppressant Drugs

Islet-cell transplantation has become a valuable option for a number of patients, though some patients experience side effects from the immunosuppressant drugs. The pharmaceutical industry is making progress to reduce the ill side effects.
While islet-cell transplantation offers the best hope for many diabetics, it is not a complete cure, as diabetes may recur if the transplanted cells are destroyed by the immune system. However, as long as the cells survive, the patient experiences a functional cure.

The Research Plan

The Chicago Project represents the largest and most focused effort of addressing the generation of pancreatic islet cells for large-scale clinical application. This project is unique in its links to the translational setting, in which cell development can be immediately tested for transplantation in large-animal models. Factors found to be important for islet-cell proliferation and differentiation will be tested in ongoing islet-cell transplant trials in humans. *No other existing research program is integrating transplantation with developmental biology, chemistry, cell biology, molecular biology and engineering in a direct collaboration*. In addition, the participating scientists are among the strongest in their respective fields and many have collaborated on previous projects. This is a major strength.

The Chicago Project will have a scientific advisory board composed of senior scientists critically reviewing the research projects and monitoring the progress.

The research plan to find a functional cure for diabetes is based on several new technologies that recently have become available. The hallmark of the Chicago Project is to use large-scale screening technologies to overcome the last hurdles for a cell-base treatment of diabetes. Instead of investigation, e.g. factors to induce cell division in a traditional way by testing, one by one, different substances, new technologies allow for screening thousands of molecules in one experiment, thereby increasing and accelerating the goal of finding the right factor.

Deepening Our Understanding

Recent advances in genetic analysis have supplied tools to explore a multitude of factors to hasten our understanding of how pancreatic cells divide in the embryo and eventually become insulin-producing cells. The Chicago Project will accelerate this research through the interaction between basic scientist working on animal models and researchers working with human material, which will allow for validating and translating knowledge gained in valuable rodent models to the human setting.

Petri Dish Gene Therapy

Many of the genes necessary to divide insulin cells are no longer active in the adult pancreas. With Lentiviral vectors, a modern tool of molecular biology, appropriate genes can be introduced that allow insulin cells to multiply. Because this procedure is conducted in the laboratory and not in the human body, the cells can be extensively tested for good function and safety.

Cell-Source Screening

The Chicago Project will focus on generating insulin-producing cells from human adult pancreases. Artificial reproduction of insulin-producing cells becomes an achievable goal when knowledge gained by developmental biologists is applied using large-scale screening technologies and the latest tools in molecular biology.

Protecting Insulin Cells

Because the bodies of diabetic patients destroy insulin-producing cells, several approaches can be used to prevent the recurrence of diabetes after the transplantation of insulin-producing cells. One method is to offer protection with microcapsules, which hinder immune cells from reaching insulin-producing cells, while still allowing free passage for smaller molecules including nutrients, oxygen and insulin. The second method includes testing drugs to reduce the effect of inflammatory substances called cytokines. Cytokines are relatively small molecules that can potentially pass through the microcapsule barrier and affect the survival of insulin-producing cells.

The Chicago Project will focus on both micro-encapsulations of the cells and drugs that can reduce the tendency of diabetic patients to destroy insulin-producing cells.

Timeline

Year 1, 2005-2006

The first six months will provide time to up-scale the capacities of all participating groups. The up-scaling is a crucial component of the Chicago Project and will allow for application of large-scale screening methods.

Year 1, Joint Research Projects

- Accelerate understanding of normal development of insulin-producing cells in mouse models
- Screen for genes and conditions allowing for generating insulin-producing human cells
- Screen for factors deleterious to islets
- Screen and select the most appropriate raw materials for encapsulation

Year 2, 2006-2007

The second year will provide the first islet-cell lines by integrating the knowledge of the developmental and molecular biologists into subprojects working on different cell types within the adult human pancreas. The encapsulation technology must be up-scaled for use in large-animal models and later in clinical trials. Appropriate large-animal models must be established to extensively test encapsulated-islet transplantation before clinical use.

Year 3, 2007-2008

In the third year, project members will test extensively the established cell lines to ensure appropriate function and safety. The best transplant site will be determined for animal models. As well, the conditions and tools for generating insulin cells will be optimized and up-scaled to prepare for preclinical experiments in larger animals.

Year 4, 2008-2009

Year four focuses on delivering a reproducible, encapsulated, functional islet-cell graft for testing in clinically relevant large-animal models. By the end of the fourth year, project members expect to identify the optimal cell sources and to establish an unlimited source of insulin-cells for clinical testing. Project members also expect to have identified strategies to prevent destruction of the insulin cells in diabetic patients.

The team must meet good laboratory and manufacturing practice conditions (regulatory standards for medical products) for the production of the insulin cells and the encapsulation process. The safety of the graft will be documented in year four before clinical Phase I safety trials can be initiated in patients.

Year 5, 2009-2010

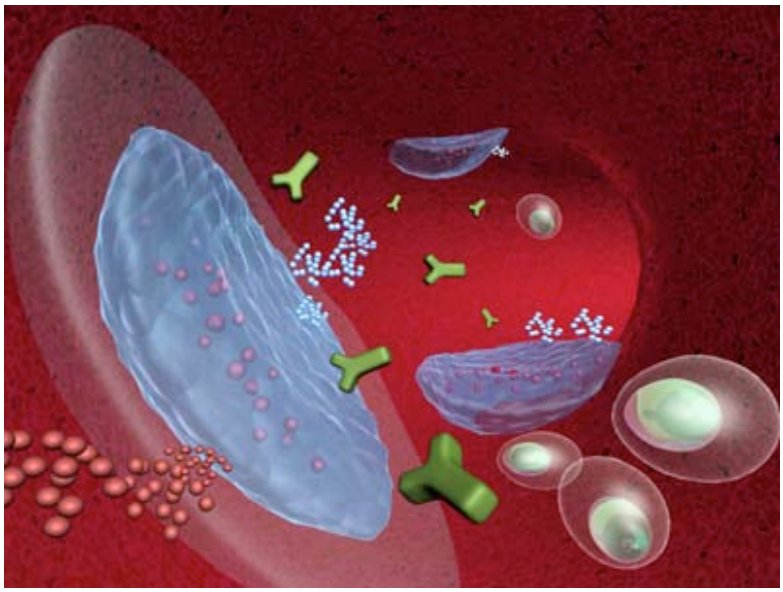
In year five of the Chicago Project, Phase I clinical trials with encapsulated islet-cell line transplants will begin in diabetic patients. The first Phase I trial will investigate how the encapsulated insulin-cells survive in a diabetic patient by implanting it under the skin and retrieving it after various periods of time.

The second Phase I trial will aim at treating diabetic patients with a sufficient amount of encapsulated insulin-cells rendering the patient independent of insulin injections corresponding to a functional cure of diabetes.

The proof of concept will allow for further development beyond the Chicago Project and allow for widespread clinical application of a cell-based therapy for diabetes.

The Final Product

Encapuslated islet-cell graft:
The cells are generated in culture systems in the laboratory and protected by a selectively permeable capsule. The insulin producing cells will allow for controlling blood glucose levels in a physiological manner. The capsule will protect against the assaults of immune cells and antibodies, but allow nutrients and insulin to pass.



The Chicago Project Team

José Oberholzer, MD, Chicago Project Coordinator,
Associate Professor of Surgery and Bioengineering;
Director, Cell and Pancreas Transplantation;
Director, Cell Isolation Laboratory,
University of Illinois at Chicago

Dr. Oberholzer received an MD from the University of Zurich, Switzerland, in 1992. From 1996 to 1998 Dr. Oberholzer was a postdoctoral fellow in islet research in the Division of Surgical Research at the University of Geneva. From 1998 to 2002 he was the director of the Islet Laboratory at the University of Geneva and the GRAGIL Islet Consortium and performed numerous islet transplants in diabetic patients. He was also the site principal investigator in the first multicenter trial for islet transplantation led by the Immune Tolerance Network. From 2002 to 2003 he was a clinical and research fellow in the transplant program at the University of Alberta in Edmonton. Today, he is an associate professor at UIC where he is involved in basic research of islet cell biology and immunology. In addition, he has trained numerous fellows in the technology of isolating human islets. As Chicago Project coordinator, Dr. Oberholzer's islet core laboratory will provide human islets to the various collaborating institutions. UIC has a large supply in altruistically donated human panceases and will be important in ensuring sufficient quantities of human tissue for research. His laboratory will also test how to generate an unlimited source of insulin-cells from human pancreases.

Gillian M. Beattie, BSc, Research Specialist,
Whittier Institute, Department of Pediatrics,
University of California-San Diego
School of Medicine, La Jolla, California

Australian Gillian M. Beattie has worked for two decades in the Whittier's Islet Cell Research Laboratory of the Department of Pediatrics at the University of California, San Diego. She is one of the world's most experience biologist in the field of ß-cell lines and researches the immortalization of differentiated human beta-cells and the differentiation of fetal islet cells. She has extensive expertise in the development of islet-cell lines and recently has been working on human embryonic stem cells.

David Hunkeler, PhD, General Director,
AQUA+TECH Specialties SA,
Geneva, Switzerland

Canada native David Hunkeler received his PhD in 1990 in acrylic water soluble polymers at McMaster University in Hamilton, Ontario, Canada. From 1991 to 1996 he was assistant professor of chemical engineering, materials science and technology

management at Vanderbilt University in Nashville, Tenn. He co-founded the NASA-sponsored encapsulation project with T. Wang and gained extensive experience in the field of microencapsulating. He developed a new capsule system that may protect transplanted islet cells from the assaults of the immune system and against recurrence of diabetes. From 1996 to 2001, Dr. Hunkeler was professor of chemistry and chemical engineering at the poly-technical school ETZLausanne, one of world's leading engineering schools. Currently, he is the general director of AQUA+TECH Specialties SA in Geneva, Switzerland. He is an expert in the purification of alginate—the most important component for microcapsules—and he has broad knowledge in all aspects of capsule technology to protect cells from the immunesystem.

Gil Leibowitzs, MD, Attending Physician,
Department of Endocrinology,Hadassah University Hospital,
Jerusalem, Israel

Gil Leibowitzs received an MD in 1982 in Israel. He is currently employed at Hadassah University Hospital in Jerusalem as attending physician in the Department of Endocrinology where he also performs human stem cell research. He has expertise in clinical and basic diabetes research. He received postgraduate training at the University of California in San Diego and has investigated the regulation of glucosestimulated insulin production and secretion in normal islets and animal models of diabetes. He has searched for strategies to render ß-cell more resistant against the toxic effects of chronic hyperglycemia. Dr. Leibowitzs is an expert in ß-cell physiology and will have two functions in the Chicago Project: investigating differentiation into insulin cells and in-depth testing of generated insulin-cell lines.

Marc Yves Donath, MD, Professor of Medicine,
Division of Endocrinology and Diabetes,
Department of Medicine, University Hospital,
Zurich, Switzerland

Marc Yves Donath received an MD from the University of Zurich Medical School in Switzerland. From 1991 to 1993 he was a research fellow at the Institute of Cell Biology at the Swiss Federal Institute of Technology in Zurich.
He performed a postgraduate research fellowship in experimental diabetology at the Hadassah University Hospital in Jerusalem from 1996 to 1998. Currently a professor of medicine in the Division of Endocrinology and Diabetes, Department of Medicine, at the University Hospital in Zurich. Dr. Donath discovered that type II diabetes is not so different from type I diabetes. He has developed means to make insulin cells more resistant against the injuries observed in the development of diabetes. Moreover, he discovered ways to make insulin cells proliferate instead of dying when exposed to the stresses commonly found in the early stages of diabetes. His role in the Chicago Project

is to find strategies to protect against inflammatory substances produced by diabetic patients that can affect the survival of insulin producing cells.

Julie Kerr-Conte Pattou, PhD,
Laboratory for Cell Therapy of Diabetes, University Hospital, Lille, France

Julie Kerr-Conte Pattou received a BS in biology at State University of New York at Albany, and an MS in physiological chemistry at the University of Wisconsin at Madison, Wisconsin. After setting up an experimental surgery lab with a French transplant surgeon in Strasbourg, Julie met her future husband, Francois Pattou, an endocrine surgeon from Lille. She finished a PhD in biology at the University of Lille in France. The couple set up a lab for the cell therapy of diabetes in 1993 at the University Hospital of Lille in France focusing on clinical islet transplantation and creating human ß-cells from precursor cells located in the pancreas of adults. She was the first to discover that the cells lining the pancreatic ducts (channels within the pancreas) in humans contain cells that can be transformed into insulin-producing cells. Her discovery has created a complete new field of research in diabetes. In the Chicago project, Dr. Kerr-Conte Pattou will investigate whether the ductal cells she discovered can be used for generating insulin-cells.

Patrick Salmon, PhD, Pharmaceutical Doctor, Scientific Supervisor, Lentiviral Vector Production Unit, Geneva School of Medicine, Geneva, Switzerland

Dr. Salmon is a pharmaceutical doctor from Rene Descartes University in Paris. He received a PhD in immunology at the Pierre & Marie Curie University in Paris in 1991, studying HIV-CD4 interactions. From 1993 to 1997, he studied T cell development, gene expression and signal transduction as a postdoctoral research fellow in the Division of Immunology, Department of Molecular & Cell Biology, at the University of California at Berkeley. In 1997, he joined the group of Didier Trono in Geneva to apply his multi-faceted experience to the development of Lentiviral vectors and use them as novel and powerful tools to permanently introduce therapeutic genes into human cells. He also developed a system using Lentiviral vectors to generate reversibly immortalized human cells from various tissues for cell therapy and biological studies. Currently, Dr. Salmon is supervising the Lentiviral Vector Production Unit at the Geneva School of Medicine in Switzerland, with a goal of providing pre-clinical batches of Lentiviral vectors to the scientific community; thus paving the way for the use of Lentiviral vectors in human medicine. He is an expert in the design and production of Lentiviral vectors for in vivo and ex vivo gene therapy. This platform will be a crucial asset for all molecular approaches for creating a human insulin-cell line, which may be ultimately used in humans.

Cameron Bruce Verchere, PhD, Associate Professor,
Department of Pathology and Laboratory Medicine,
Departments of Physiology and Surgery,
BC Research Institute for Children's & Women's Health,
University of British Columbia, BC

Dr. Verchere got a PhD at the University of British Columbia in Vancouver in 1991. From 1991 to 1996 he was a postdoctoral fellow in the Department of Medicine, Division of Endocrinology and Metabolism, at the University of Washington and VA Medical Center, in Seattle. In 1997 he completed a postdoctoral fellowship in the Laboratoires de Recherche Louis Jeantet at the University of Geneva in Switzerland. Today, he is an associate professor in the Department of Pathology and Laboratory Medicine, Faculty of Medicine, at the University of British Columbia, BC, Research Institute for Children's & Women's Health. He is a world expert on islet amyloid and his research on the subject will help prevent amyloid formation and create strategies to protect insulin cells from failing.

Gregory Stephen Korbutt, PhD, Associate Professor, Department of Surgery, University of Alberta, Edmonton;
Co-Director, Islet Isolation and Transplantation Core Laboratory, Juvenile Diabetes Research Foundation Diabetes Research Network

Dr. Korbutt earned a PhD at the Vrije University in Brussel, Belgium, in 1994. From 1994 to 1997 he was a postdoctoral fellow in the Surgical-Medical Research Institute at the University of Alberta in Edmonton, Canada. Today, he is an associate professor in the Department of Surgery of the University of Alberta in Edmonton and co-director of the Islet Isolation and Transplantation Core Laboratory at the JDRF Diabetes Research Network. He is an expert in islet morphology and physiology and has extensive experience in the field of isletxenotransplantation for which he has developed a technique to isolate newborn pig islets and differentiate them into fully functional
islets capable of curing diabetes in pigs. He also developed a technique to transplant islets with Sertoli cells, which can protect the islet graft form being attacked by the immunesystem. Although xenotransplantation of pig islets into human is discussed controversially, this approach may be the most direct way to make islet transplantation available to a larger number of diabetic patients. Dr. Korbutt will establish the large-animal models for the Chicago Project and will investigate with Dr. Julie Kerr-Conte Pattou how ductal cells form adult human pancreases as a source for generating insulin cells.

Yong Zhao, MD, Assistant Professor,
Division of Diabetes and Metabolism,
University of Illinois at Chicago

Yong Zhao received an MD in 1990 at the Weifang Medical College in Shandong, China. He earned a PhD in immunology at the Shanghai Second Military Medical School in 2000. From 2000 to 2004 he worked as a postdoctoral fellow at the Argonne National Laboratory in Illinois. He joined UIC recently as assistant professor in the Division of Diabetes and Metabolism. Dr. Zhao has discovered that ß-cell have characteristic in common with some special immune system (macrophages) and that immune cells can be transformed into ßcells. His research indicates that human ß-cells could be produced from the body's own blood cells. This groundbreaking discovery has opened completely new perspectives for the development of cell-based therapies for diabetes. Although these findings need to be confirmed and are at present still controversial, the possibilities inherent in this approach merits integration into the Chicago Project.

Jan Jensen, PhD, Assistant Professor,
Barbara Davis Center for Childhood Diabetes,
University of Colorado, Denver, Colorado

Jan Jensen earned a PhD in developmental biology in 1998 at the Hagedorn Research Institute in Denmark, an independent research component of Novo-Nordisk. His thesis focused on the developmental biology of insulin-producing cells. Since 2001, Dr. Jensen has been an assistant professor of medicine at the Barbara Davis Center for Childhood Diabetes at the University of Colorado, where he now heads a group focusing on islet cell development. He has a profound understanding of the development of the pancreas and in particular the islet cells producing insulin. This knowledge has allowed him to develop instruments to transform certain cell types within the pancreas into insulin-producing cells. Dr. Jensen's has dissected the molecular mechanisms leading to the development of ß-cells and identified a number of key elements in the gene machinery of cells that ultimately lead to their differentiation into insulin-producing cells. He is currently using large-scale bioinformatics to identify novel genes of importance to pancreatic development. He is a current member of the NIH sponsored beta-cell biology consortium and is the expert on the genes critical to pancreatic development. Dr. Jensen will coordinate the developmental biology part of the Chicago Project with a number of researchers in the United States and Europe. His observations will be instrumental for the development of fully differentiated beta-cells, which will ensure developed cells are truly capable of producing insulin in an appropriate way and in sufficient quantity.

Additional collaborators

Additional collaborators will represent groups with specific expertise in fields not represented by the participants and are/will be integrated into the Chicago Project.

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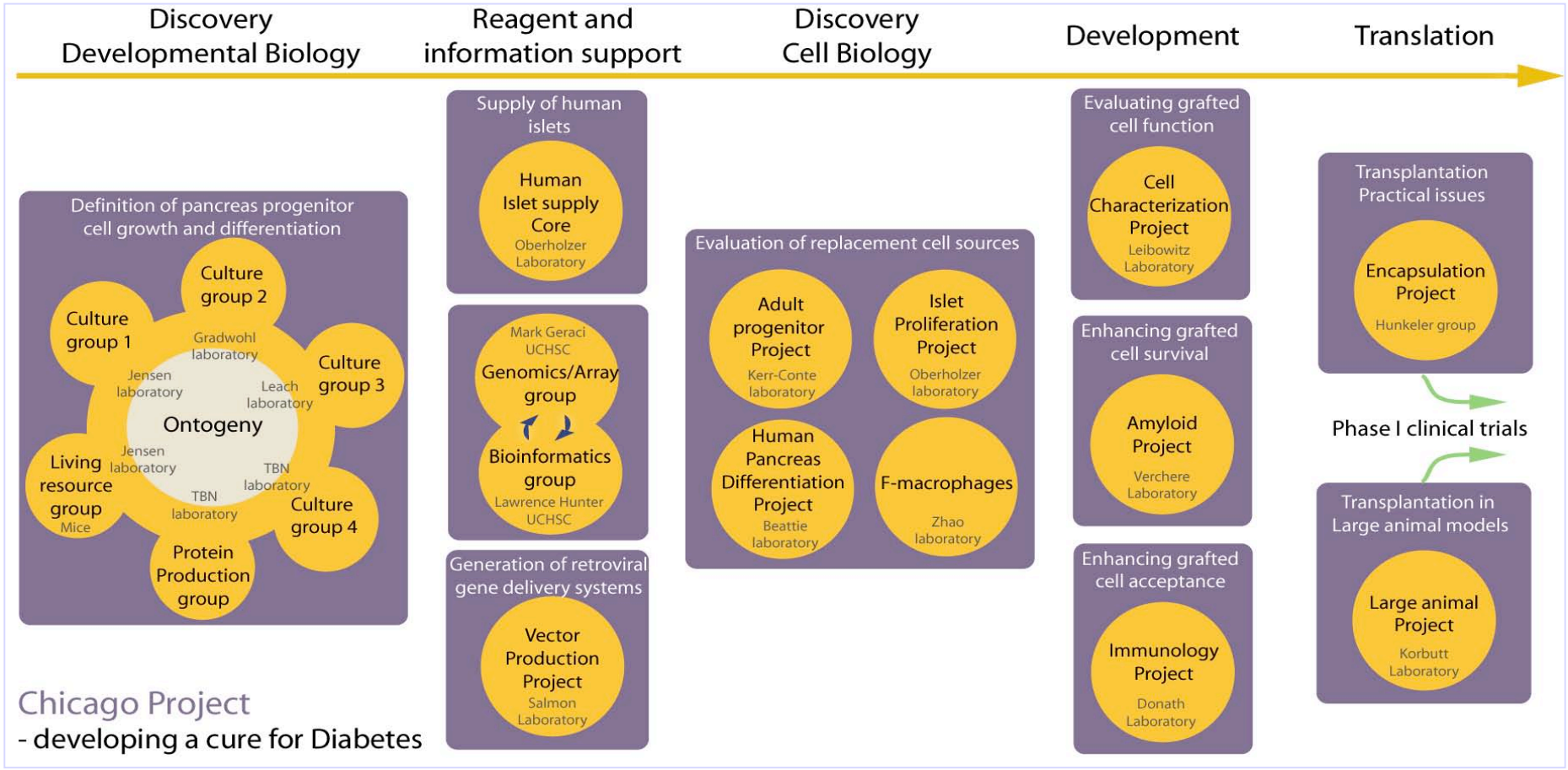
Discovery
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Reagent and
information support
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Cell Biology
Development
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Definition of pancreas progenitor
cell growth and differentiation
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UCHSC
Genomics/Array
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Lawrence Hunter
UCHSC
Generation of retroviral
gene delivery systems
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Amyloid
Project
Verchere
Laboratory
Enhancing grafted
cell acceptance
Immunology
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