CGOV Foundation

personalized medicine funding project

Genetically-targeted treatments for autoimmune illnesses – our first initiative

OVERVIEW

Personalized medicine in which a simple blood test predicts outcomes and shapes therapy is the future of medicine. The most common form of autoimmune disease is rheumatoid arthritis (RA), which affects over 2 million Canadians.

The present system for patient treatment is grossly inefficient. The goal of this project is to remove 60 per cent of the waste, saving billions of dollars in unnecessary costs to our society. Tangible results will include lowered drug costs, fewer disability insurance claims, lower benefits costs for corporations, reduced wait times to see physicians, and so forth.

Unlike anywhere in the world, world-class leaders in their fields are coming together to work on this new genetically-targeted treatment model which marries patient therapy, genetics and outcome monitoring. The creation of this model can be leveraged and used for other illnesses as well, thereby creating further savings for our healthcare system, and ultimately improving the quality of lives for patients.

THE PROJECT

The recent decoding of the entire human genome has substantially escalated researchers' capabilities of deciphering the genetic code for autoimmune diseases. This new knowledge can now be applied to the clinical (patient-related) aspects of autoimmune disease so as to determine which genes predict onset of disease, disease outcome and response to, as well as side effects of specific treatments. The goal is to use such information to tailor patient care based on individual genetic makeup.

Current treatment of patients with rheumatoid arthritis is only 40 per cent effective – implying that the majority of patients are receiving unnecessary therapy. As a result, the majority of patients rapidly have become disabled, unproductive, and hence a burden on our health care system. This inefficiency has an enormous economic impact on our society – at present estimated to be $15 billion annually for rheumatoid arthritis alone. Individualizing therapy will yield the right treatment for the right person leading to enormous cost savings to society and improved health outcomes for patients.

Applying genetic information to patient care requires the integration of clinical and genetic information. At present, patients spend no more than 15 minutes with a physician, with the physician collecting and recording information on paper. This new model will have a "point-of-contact" interactive screen for the patient to communicate his/her condition, with the physician also populating fields of information. A database is then formed with trends being followed, and treatments being corrected based on outcome assessments.

The creation of this intellectual knowledge is centered at the Rebecca MacDonald Centre for Arthritis & Autoimmune Disease (RMC) at Mount Sinai Hospital in Toronto, which receives the largest patient population in Canada for a number of autoimmune conditions. To date, data on 2,000 patients have been recorded at RMC. The ultimate scope will embody 60 rheumatologists in the GTA and over 30,000 patients. Mount Sinai Hospital also specializes in research and care for Crohn's disease, ulcerative colitis and Type 1 diabetes – making it uniquely capable of applying the "bench to bedside" translational approach to management of autoimmune diseases.

Funding is needed for the creation of the database, which will be taking information from patients being treated at the RMC, along with information acquired from the physicians and technicians. Genetic specialists apply their knowledge to the information and outcome specialists provide feedback to the physicians to modify or correct treatment. Technical expertise will be used within the Mount Sinai Hospital/University Health Network to build and modify the software as required.

UNIQUENESS

The uniqueness is three-fold. First, it is the ability to tie in the genetics with new therapies and clinical assessment with experts in their respective disciplines. Second, is the access to very well characterized clinical populations. There already is a repository of about 2,000 rheumatoid arthritis patient samples and work with a national consortium in early arthritis detection. This in turn provides the unique opportunity to determine which genes influence not only risk but also outcome and drug responsiveness. Very few sites

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have the expertise in clinical assessment and genetics to determine this. Thirdly, our experts have world class expertise in health outcomes research, which is unique because of its juxtaposition to their genetics program.

In summary, the uniqueness relates to large and well characterized clinical cohorts, our expert's leadership roles in genetics/genomics, molecular biology, health outcomes and therapeutics in rheumatoid arthritis; as well, their uniqueness relates to their capacity to integrate this expertise so as to translate their strengths into improved understanding and treatment of rheumatoid arthritis and other autoimmune diseases. The program is fully translational (bench to bedside).

LEVERAGE

The initial data collection and analysis from patients will be onsite at the RMC, eventually being collected by other practitioners affiliated with the University of Toronto. The data and intelligence will be shared with other practitioners across the country so they are able to better treat their patients.

The database model is initially being used with patients with rheumatoid arthritis. The model will then be used by practitioners treating other chronic diseases, providing further efficiencies in our healthcare system and ultimately a better quality of life for these affected patients.

Once the database creation has been funded, and intelligence and data has been collected, other parties (i.e. government and large global pharmaceutical companies) will want to pay for that knowledge, and grants will more easily be secured to ultimately help sustain the ongoing operational expense of the massive coordination of the data and maintaining and upgrading of the technology.

COST

There is a three-year cost projected for the creating and maintaining of the database which establishes the intelligence related to genetic make-up, clinical assessments, and outcomes. The costs involve hardware, software, telecommunications, and personnel. The project involves migrating databases which are being used with clinical, genetics and outcomes.

At the present time, the three-year projected costs are as follows:

	ORF/CIHR* (sample collection/ processing; molecular analysis/data mining)	Private donors (clinical collection)	CGOV Fdn (database build)	TOTAL
2009	$300,000	$150,000	$50,000	$500,000
2010	$300,000	$150,000	$50,000	$500,000
2011	$250,000	$150,000	$50,000	$450,000

*Ontario Research Fund/Canadian Institutes of Health Research

ACCOUNTABILITY

The directors of The CGOV Foundation are undertaking the task of monitoring and reporting on the progress of the project to the consortium of funders under The CGOV Foundation umbrella. They have also established lines of accountability at the project level. At present, the following plans and milestones have been established by the team of experts involved with this project:

2009 Collect genetic data on known genetic markers for their entire patient cohort of at least 1,500 patients

2010 By end of 2010, they plan to have correlated genetic and/or biochemical data with the outcomes of specific treatment protocols

2011 By end of 2011, they believe that they will have fully integrated the information within their database as a clinical tool, meaning that the database can be used in conjunction with their biologic data to facilitate improved patient care

FUTURE IMPACT

While on the surface this project seems focused on one disease (RA), the information gathered from the creation of this database can be used in the treatment other illnesses.

The future impact of funding this project will be patients experiencing more efficient and less debilitating treatments to their illnesses, there will be reduced waiting times to see specialists and receive treatments, companies will have reduced benefits costs, and our health care costs in general should decline. It's the future of medicine.