

Real World Evidence at NACTRC

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Better medicine. Better outcomes.



***"This is a local success story for an Edmonton company and the researchers that we've been working with."***

Michael Stewart, President & CEO of IMBiotechnologies and Dr. Richard Owen, Associate Professor in the Department of Radiology & Diagnostic Imaging at the University of Alberta discuss a new treatment that's being tested to relieve symptoms for men with enlarged prostates. Patient Frank Work describes his experience: "I was astounded, the effects were almost immediate."

## Real World Evidence at NACTRC

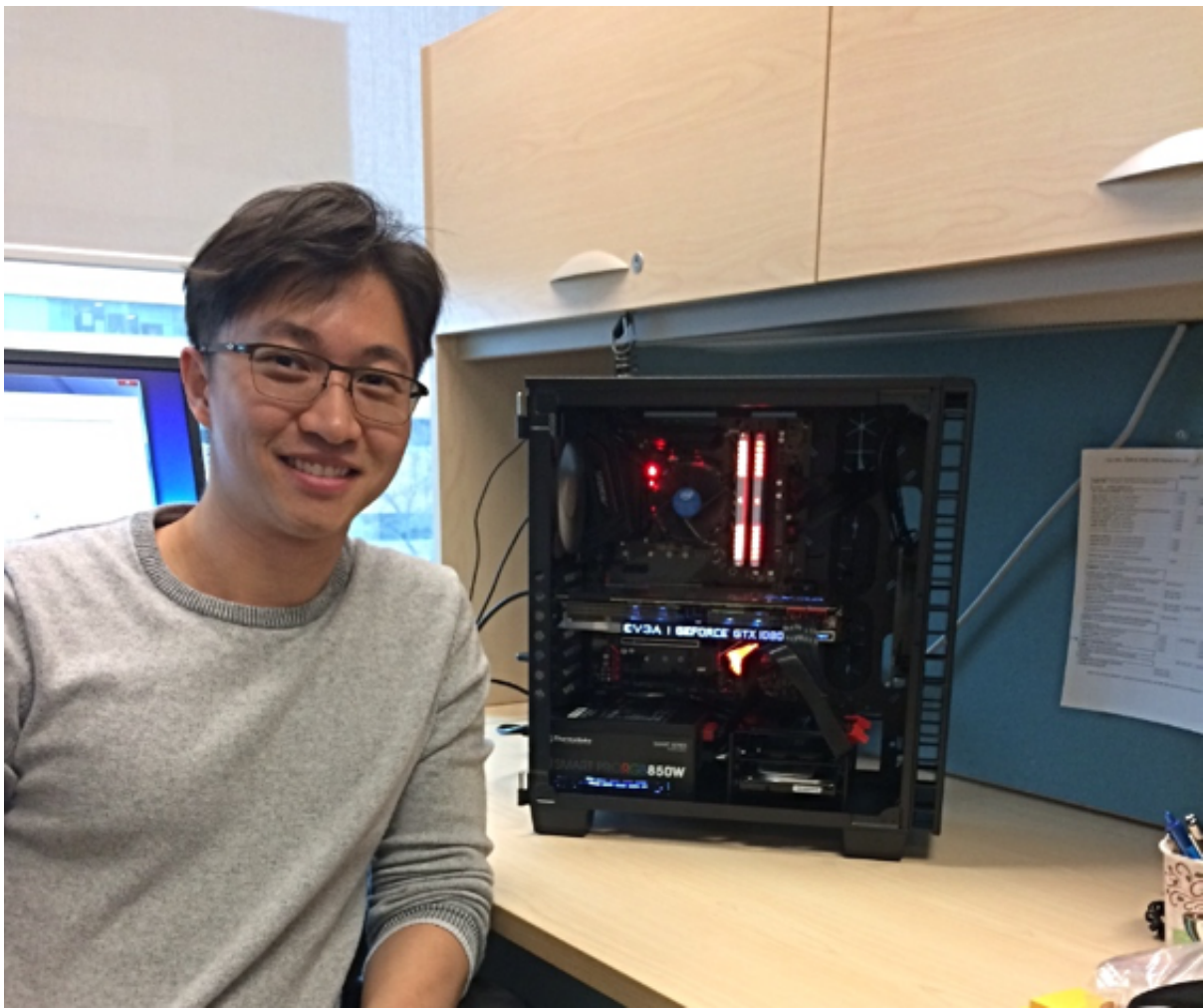
Real World Evidence (RWE) studies have been an important part of the research landscape for many years. They continue to evolve alongside their clinical trial analogues, pragmatic clinical trials (PCT), and are now beginning to inform decisions in the regulatory and clinical practice space.

Currently, regulatory bodies accept RWE studies in addition to clinical trials evidence. However, as administrative and clinical databases improve and analytic methods become more robust and sophisticated, real world evidence may soon be required as part of the regulatory approval process.

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Sanctioning drugs is a critical first step for inclusion on provincial formularies. The body responsible for this, the Canadian Agency for Drugs and Technologies in Health (CADTH), recently published the *Environmental Scan, Use of Real-World Evidence in Single-Drug Assessments*. In order to achieve this level of influence in the decision-making process, RWE studies and PCTs need to follow rigorous guidelines from the inception of the protocol and study design, and throughout the course of the study.

Subject matter experts have provided standards and guidelines for conducting high-quality observational research, such as the [Agency for Healthcare Research Quality \(AHRQ\)](#), the [United States Food and Drug Administration \(FDA\)](#), the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and the [International Society for Pharmacoepidemiology \(ISPE\)](#).



Dr. Kai Wong of the Real World Evidence Unit, fine tunes his machine learning computer.

As part of a growing menu of clinical research services, the [NACTRC RWE Unit](#) was established with skilled practitioners in a structured and integrated environment. Dr. Scott Klarenbach and Dr. Kai Wong co-lead the Unit and are supported by Dr. Karen Martins, as well as the co-located SPOR Data Platform team, led by Dr. Jeff Bakal.

NACTRC's Clinical Research Unit Edmonton (CRUE), led by Scott Jamieson, collaborates with the RWE Unit to integrate real world components into clinical trial design and establish PCTs. The RWE Unit also participates in the Alberta RWE Consortium, led by Dr. Christopher McCabe of the Institute of Health Economics (IHE). The RWE Consortium includes experts and academics from the Universities of Calgary and Alberta, as well as government agencies, such as Alberta Health, Alberta Health Services, Alberta Economic Development and Trade, and Alberta Innovates to provide a uniquely collaborative pan-provincial platform that is capable of attracting and answering research questions that have great economic and public health significance.



Welcome to the Clinical Research Corner, which is designed to provide brief updates regarding clinical research from the Office of Research, Faculty of Medicine & Dentistry (FoMD). Questions, comments or feedback? Please email [Dr. Carol Ladner-Keay](mailto:carol.ladner@ualberta.ca) (Acting Director of Clinical Research, FoMD).

## Learning Opportunities

### Clinical Research Seminar Series

Our next seminar on May 15th, 2:00 PM is on Clinical Trials Budgeting: [PI-Initiated/Grant-Funded](#). Look out for a June seminar on pragmatic clinical trials. Additional information about this seminar series is available [here](#) and slides from previous seminars are available [here](#).

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## Clinical Research In Progress

### Celebrating Success with Dr. Glen Jickling



Dr. Glen Jickling (Assistant Professor, Department of Medicine) is a clinician scientist and emerging leader in the genomics and genetics of stroke.

His translational research seeks to discover biomarkers and precision diagnostic tools for stroke and neurological disease.

He was recently awarded a Canadian Foundation for Innovation - John R. Evans Leaders Fund. The \$160,000 award is for genomics equipment that will be instrumental in developing new treatment targets and precision diagnostic tools. These tools will create a patient-focused solution to the gap that currently exists in accurately and rapidly triaging stroke patients.

Dr. Jickling's research and award was featured by [Folio](#) this month.

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## In the News

Innovators Magazine: The holy grail of gene-editing tech that can provide effective treatment for people suffering from diseases – including cancers – has moved one step closer.

<https://www.innovatorsmag.com/precision-cancer-cures-a-step-closer/>

The University of Alberta is receiving nearly \$1.5 million in federal government funding for a variety of projects, including those focused on treating people who have suffered a stroke.

<https://globalnews.ca/news/4138021/university-of-alberta-receives-1-5m-in-federal-funding-for-stroke-research/>

Cross Cancer Institute celebrates 50 years of caring, compassion and innovation

<http://albertahealthservices.ca/news/releases/2018/Page14377.aspx>

