Publishing key research indicators as part of our commitment to supporting research.

NACTRC
Northern Alberta Clinical Trials + Research Centre

Better medicine. Better outcomes.

Dr. Richard Owen, Associate Professor in the Department of Radiology & Diagnostic Imaging at the University of Alberta discusses a new treatment that's being tested to relieve symptoms for women with uterine fibroids. Patient Kelly Roy describes her experience: "I actually felt pretty honoured to be part of it, because it's a big breakthrough."

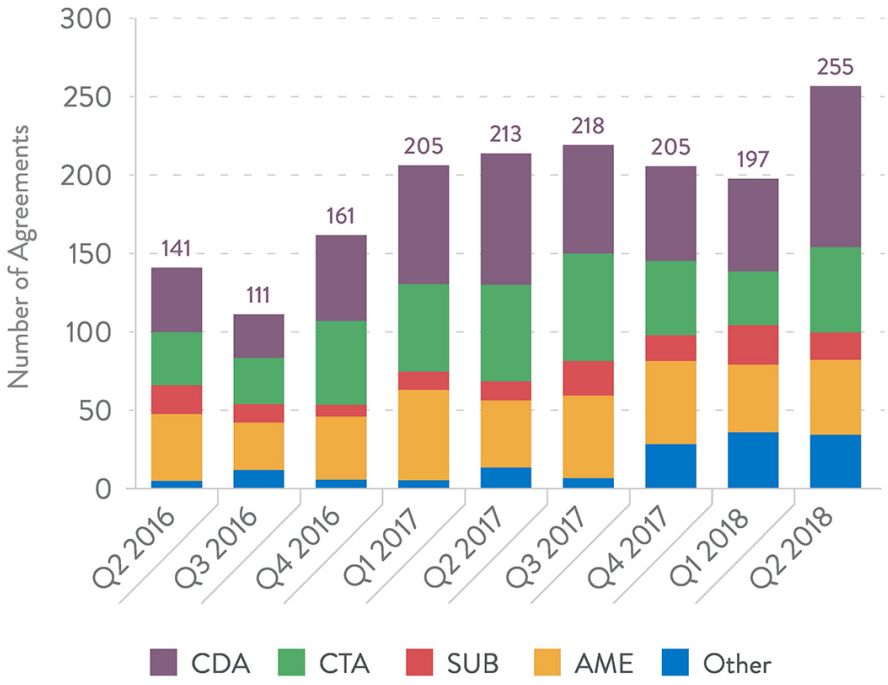
NACTRC Quarterly Updates

NACTRC is committed to providing the research community with the highest level of support. As part of this commitment, we will be publishing key indicators to our website.

The first set of indicators reflect research activity as demonstrated by new agreements per quarter. (See Figure 1). New agreements have steadily increased over the last couple of years as we continue to work closely with our partners and stakeholders to better align our efforts. Confidentiality agreements (CDA) predict future activity and we look to be even busier in the near future.

Clinical Trial Agreements (CTA) reflect increased activity with our industry partners while sub-site agreements (SUB) reflect greater involvement with other academic institutions, primarily in Canada, but also in the United States.

Figure 1
New Agreements by Quarter; April 2016 to April 2018



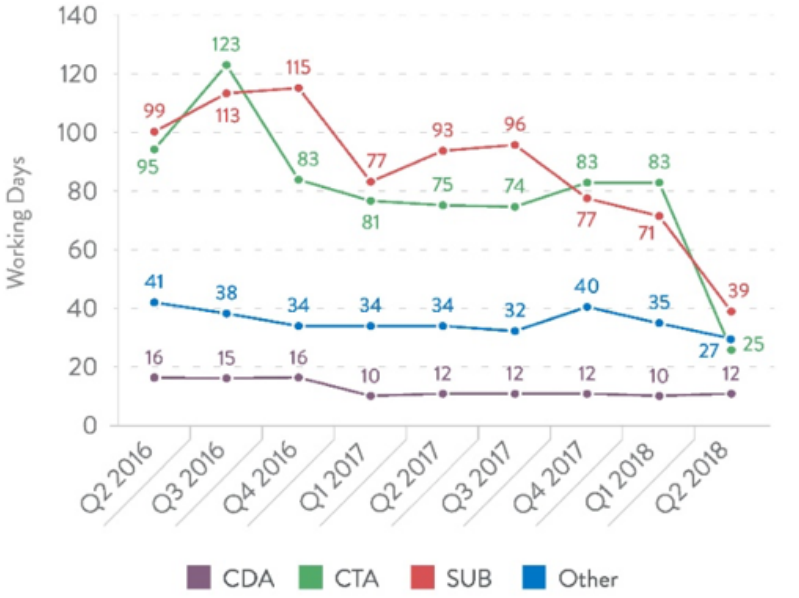
CDA: confidentiality disclosure agreements; CTA: clinical trial agreements with industry; SUB: subsite agreements with other institutions; AME: amendments; Other: includes master agreements, data transfer agreements and material transfer agreements

Turn-around-times (TAT) are key for researchers to remain competitive for grants and industry studies (See Figure 2). NACTRC recently introduced a contract specialist role to facilitate legal counsel review of agreements. Major improvements in timelines are a result of this communication between legal counsel and sponsor, as well as the emphasis on replicating new agreements from previously completed agreements.

The current quarter TATs for CTAs and SUBs are anomalously low as the proportion of replicated agreements by contract specialists are higher than completely negotiated agreements, due to a turnover in legal counsel. NACTRC recently underwent a process (lean/six sigma) review conducted by Alberta Health Services Improvement Way (AIW). This review helped to identify areas of opportunity to further reduce TATs and outliers.

Figure 2

Agreement Turn-Around-Times* by Quarter; April 2016 to April 2018



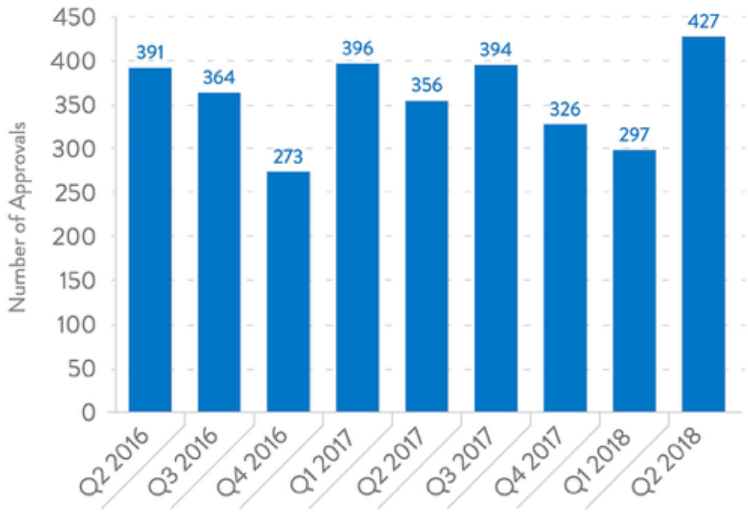
* Includes agreements replicated from previous agreements, as well as fully negotiated agreements

CDA: confidentiality disclosure agreements; CTA: clinical trial agreements with industry; SUB: subsite agreements with other institutions; Other: includes amendments, master agreements, data transfer agreements and material transfer agreements

Lastly, Area Operational Approvals (AOA), the approvals provided by the sites and programs, are trending upwards as research activity increases (See Figure 3). AOAs are facilitated by NACTRC's administrative system, (Encaps) enabling researchers to participate in and monitor their application's progress.

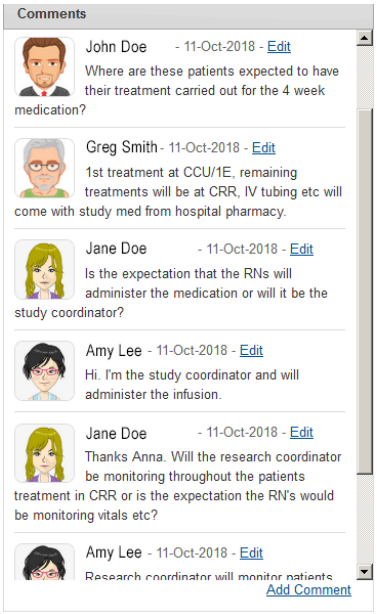
Encaps enhances efficiency and reduces administrative burden by facilitating communication and reducing duplication of effort through integration with legal, finance and ethics.

Figure 3
Area Operational Approvals by Quarter; April 2016 to April 2018



Question sets are customizable by area, and the comment log (See Figure 4) and e-notifications enable organized and timely discussion between the researchers and the area reviewer(s)/ approver(s). Areas are also able to embed important information in their questions sets, such as their area research guidelines. The final administrative approval (FAA), available by download from Encaps, shows AOAs, as well as ethics approval, financial accounts, and agreements etc. as applicable.

Figure 4



UNIVERSITY OF ALBERTA
FACULTY OF MEDICINE & DENTISTRY **Clinical Research Corner**

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 (Acting Director of Clinical Research, FoMD)

Learning Opportunities

Clinical Research Seminar Series

Our next seminar is coming up on October 4th at 2PM and is on Adaptive Clinical Trials. Look out for more seminars on topics like clinical methodology coming soon. Additional information about this seminar series is available here and slides from previous seminars are

available here.

Weiser Research Inc. Study Coordinator Training Program

NACTRC is hoting this intensive two-day training program is for Canadian study coordinators to enhance their skill set and knowledge base of clinical trial research.

Registration information and full details can be found here.

Updates

Be The Cure Health Research Database

Be The Cure is a public awareness initiative on health research. In November 2017, Be The Cure launched a user-friendly, searchable database of clinical trials in Alberta. At present, only clinical trials registered with clinicaltrials.gov are displayed. The next step is to expand to health research studies with patient participants that go beyond clinical trials. To accomplish this, Be The Cure will start receiving data from a smart form built into REMO. More information coming soon.

Clinical Research In Progress

Celebrating Success with Dr. Sean Bagshaw

Dr. Sean Bagshaw (Associate Professor and Chair, Department of Critical Care Medicine) along with a team of partners, was successful in receiving funding for the PEPTIC study through a CIHR project grant announced this summer.

The PEPTIC study is a pragmatic cluster, randomized, crossover, registry-embedded clinical trial of proton pump inhibitors (PPI) vs. histamine-2 receptor blockers (H2RB) for stress ulcer prophylaxis therapy in the intensive care unit.

This study will compare the effectiveness and safety of these two types of drugs (PPI and H2RB) used in Intensive Care (ICU) for preventing stress ulcers. Stress ulcers, which are associated with adverse outcomes, commonly occur for patients on life-support or when a patient develops a bleeding tendency due to their illness. While prevention is vital, these drugs can have adverse effects, including a risk of certain infections.

The PEPTIC study will establish which of these routinely provided prophylactic drugs leads to lower risk of serious bleeding, prolonged ventilation, C. difficile infection and hospital death.

In the June edition of the Clinical Research Seminar Series, Dr. Bagshaw presented the plan for this now funded Alberta PEPTIC trial, as a case study of a pragmatic clinical trial. This will be a pragmatic, multicenter, randomized, open-label, cluster-crossover, registry-embedded comparative effectiveness trial in 8 ICU sites within Alberta.

In this study, all data is already routinely collected via existing care systems. Furthermore, the study utilizes an innovative and pragmatic design that may transform how future trials are performed in ICU. Such a design using existing data sources and imposing no added health record access provides an innovative method to detect small, but clinically important treatment effects at comparatively lower cost than conventional randomized trials.

In the News

2018 Stollery Science Lab Distinguished Researchers

This September the Stollery Children's Hospital Foundation announced its $5-million gift to the Distinguished Researchers program at the Women & Children's Health Research Institute (WCHRI). Seven WCHRI investigators were named as the 2018 Distinguished Researchers in the Stollery Science Lab: Drs. Todd Alexander, Lisa Hartling, Shannon Scott, Michael Hawkes, Andrew Mackie, Kate Storey, and Lonnie Zwaigenbaum This program will enable the distinguished researchers to further improve pediatric health in Alberta and around the world.

Learn more about the Stollery Science Lab announcement here and see the feature on Dr. Mackie's work in Folio.

IMBiotechnologies Ltd Announces Presentation at the 2018 Cardiovascular and Interventional Radiological Society of Europe Annual Meeting (Lisbon, Portugal)

See press release here