

REB EXCHANGE

PAVING PATHWAYS

YEAR 2 REPORT | 2023



Dr. Brenda Hemmelgarn, MD, PhD

Dean and Vice-Provost, College
of Health Sciences,
University of Alberta

Dean, Faculty of Medicine &
Dentistry, University of Alberta

DEAN'S INTRO

Two years ago, Alberta saw the successful launch of the Research Ethics Board Exchange (REB Exchange). This digital tool has already lived up to its promise, supporting greater collaboration across our province by eliminating barriers to the exchange of information among participating sites.

Our community of scientific researchers knows that our best way forward is to work together. Research is not a single-person sport; it is only through working together that we can build sustainable solutions to our greatest societal challenges. And with REB Exchange, we have the tools and the systems in place to foster efficient collaboration, sparking exciting new group projects.

Here in the College of Health Sciences, the concept of collaborating across traditional boundaries is at the core of our identity. I am excited to see how the REB Exchange is helping us put the communities we serve at the centre of all we do, by easing the challenges of this work not just at the University of Alberta, but across our province to other institutions. As a medical researcher and academic leader, I know too well the hurdles that can hold up important, life-changing work.

One such hurdle is the difficulty involved in planning and managing a study that involves many sites. Being limited to a single site with a small number of patients limits our ability to generalize. But with the REB Exchange enabling multiple sites across an entire province, it increases the scope, diversity and generalizability of our work. Another hurdle is the time it takes to bring research from bench to bedside — on average, it can take up to 17 years to get a treatment from the lab to the bedside. With the REB Exchange helping facilitate clinical trials, we can more expeditiously get the results from the work we're doing and begin to get those results more quickly to the patients who need them most.

And now, I am pleased to share the news that the REB Exchange is growing to include HREBA, our colleagues for non-health research, and the University of British Columbia. Moving beyond our provincial border will significantly expand the already robust collaborative research capabilities the REB Exchange has built thus far.

The REB Exchange is a shining example of what we can do when we work together, and my hope is that in years to come it will continue to grow not just across our nation but on the international stage as well. Please enjoy reading more in the following pages about some of the exciting projects being supported by the REB Exchange.

Dr. Brenda Hemmelgarn, MD, PhD
Dean and Vice-Provost, College of Health Sciences, University of Alberta
Dean, Faculty of Medicine & Dentistry, University of Alberta

(On the cover – photo courtesy of the University of Alberta)



TOGETHER,
we're laying the groundwork
for more efficient and
effective multi-site research.



BETHECURE.CA

Participate in Research | UCalgary



Calgary Centre for Clinical Research



**A SINGLE PROVINCIAL
HEALTH AUTHORITY**

Health Information Act of Alberta

PROVINCIAL HEALTH CUSTODIANS

Alberta Health Services
Covenant Health

WORLD-CLASS RESEARCH INSTITUTIONS

University of Calgary
University of Alberta

RESEARCH ETHICS BOARDS

University of Alberta

- REB 1 + REB 2
- Health Research (Health + Biomedical)

University of Calgary

- Conjoint Health Research (CHREB)
- Conjoint Faculty Research (CFREB)

Health Research Ethics Board of Alberta

- Cancer (HREBA.CC)
- Clinical Trials (HREBA.CTC)
- Community Health (HREBA.CHC)

**INNOVATION & ENTREPRENEURIAL
RESOURCES**

Alberta Innovates

Innovate Calgary

UCeed Startup Investment Fund

COMMUNITY INVOLVEMENT

Participate in Research (UCalgary)

BeTheCure.ca

COMMITMENT TO CLINICAL TRIALS

Clinical Trials Alberta

Northern Alberta Clinical Trials
+ Research Centre (NACTRC)

Calgary Centre for Clinical Research (CCCR)

PLATFORM PROVIDER

Huron Consulting Inc.

Platforms with the power to **INTEGRATE.**

Integrations are just one of the ways Western Canada is trailblazing ways to make the Canadian research ecosystem run smoother and faster. Institutions are actively looking at ways to implement new processes without having to overhaul and adopt completely new systems which not only require steep financial investments, but also take a toll on the human resources required to support them. That's why the REB Exchange was designed to work with existing ethics platforms like the University of Calgary's IRISS, the University of Alberta's ARISE, and the University of British Columbia's RISE. Plus, the benefits don't end with ethics.

Recently, the University of Calgary launched the Alberta Health Services (AHS) module in IRISS to expedite applications for operational approvals. Not only does the module offer the same visibility into review status and direct communications with administration teams that the REB Exchange does, but it also pulls key information directly from submitted ethics applications to further reduce the need to input duplicate information. Becky Wong, Director for Health System Access with AHS has been so excited for the new module. "Launching these linked integrations through IRISS has made it more efficient and streamlined to start up studies at multiple sites across AHS. This is beneficial not only for researchers juggling multiple applications, but also to provide patients with the opportunity to participate in research for access to cutting-edge treatment options," says Becky.

"The integrated IRISS platform is saving us time and people power to launch new studies and researchers are telling us how much more intuitive the application is when preparing and submitting their request to AHS."

In addition to the AHS module, UCalgary has implemented other integrations into IRISS including biohazard certificates, Human Resources and Clinical Trial Management software, fund management systems for pre- and post-award stages, and even community recruitment initiatives like the public-facing *Participate In Research* online tool. By the end of 2023, IRISS will also host a module to connect the Cumming School of Medicine's legal team and help expedite the review of contracts and agreements.

When we invest in the right foundations, the ability to scale efficiently is real and the possibilities can grow exponentially.



BECKY WONG
Director,
Health Systems Access,
Alberta Health Services

Photo credit: Kokemor Studio



MOBILE STROKE UNIT

University of Alberta Hospital, Alberta Health Services - Edmonton Zone

INNOVATIVE INFRASTRUCTURE:

Canada's Mobile Stroke Unit

In the world of stroke treatment, time is of the essence. This is never more apparent than when dealing with acute ischemic strokes, a condition caused by a blocked artery that demands swift intervention to minimize disability and save lives.

Alberta offers researchers a unique and groundbreaking resource: the Mobile Stroke Unit (MSU) funded by the University Hospital Foundation in Edmonton. This fully-equipped stroke intensive care unit (ICU) on wheels has revolutionized stroke care in the region, reducing the time from onset to recovery through the fast administration of medication in the field. However, the MSU is not just a tool for patient care – it has emerged as a vital site for innovative research, thanks to the ambitious efforts of institutions in Western Canada.

The AcT trial, a landmark study conducted by the University of Alberta in partnership with the University of Calgary, demonstrated the potential of the MSU as a research site. This trial explored the use of Tenecteplase (TNK), a clot-busting drug commonly used for heart attacks, as a safe and effective treatment for acute ischemic strokes. The results of this trial, the largest of its kind in Canadian history, opened new doors for stroke treatment and research in Alberta and beyond.

Running a research study on a mobile unit presented a unique set of challenges. The first hurdle was gaining operational approvals for an unconventional research site. No researcher had yet applied to run a study out of an ambulance, so navigating the processes became an exercise in patience and perseverance.

“There was no box to tick in any application to request use of the MSU. We had to start from scratch and present to the provincial EMS board and show how the potential benefits of running the study wouldn't impact patient care negatively,” says Paige Fairall, study coordinator on the AcT trial. The AcT trial became a groundbreaking effort in this regard, as the first study to use the MSU as a research site.

Key to the AcT trial's success was its pragmatic approach. The research team developed simple inclusion criteria for patients, making it easier to identify and enroll eligible individuals quickly and safely. In a field where time is a critical factor, efficiency in patient enrollment is paramount. To streamline this process, the team developed a mobile app that allowed for rapid enrollment and nearly instantaneous randomization—a testament to the innovative spirit of Alberta's research community.

“This study did a lot of the legwork to pave the process for other studies to benefit from using this incredible resource,” adds Fairall. “We've seen the impact of how positive it can be on patients and are now actively looking at other studies to run on the ambulance.”

Obtaining operational approval through AHS to support research on a roving resource required innovation and creativity. Traditional research sites have well-established procedures, but integrating a mobile unit into the research ecosystem meant navigating uncharted waters. The collaborative effort of all parties involved, including researchers, healthcare providers, and regulatory authorities, was instrumental to integrate research at the point of care on the MSU.

Alberta has been at the forefront of finding ways to overcome such challenges and make improvements to research processes. The province's commitment to innovation is reflected in its willingness to adapt existing infrastructure for research purposes, a testament to its resourcefulness. The MSU is a prime example of this, evolving from a mobile unit for patient care to a hub for cutting-edge research aimed at improving outcomes for stroke patients.

Now recognized as an official site and the process for approvals established, the MSU can more easily be used for other research. One of the key factors enabling the MSU's role as a research site is its integration with technological platforms like the REB Exchange for managing multi-site studies and its connection to institutional systems like UCalgary's IRISS and UAlberta's ARISE.

These connections allow the MSU to function more easily as a research site for multi-site studies by unburdening the lead site from having to navigate unconventional approval processes. It streamlines administrative tasks and removes the ethical approval bottleneck, making it easier for researchers to leverage the MSU's capabilities. By simplifying the administrative process, the REB Exchange ensures that more studies can take advantage of unique research opportunities.

Not only does the REB Exchange allow for the streamlined management of ethics applications, it also improves the resource request and operational approval processes through Alberta's provincial health-care system, Alberta Health Services (AHS). The AHS module to request operational support from Alberta Health Services is an intuitive application form with built-in logic that is integrated with IRISS to populate the application with data pulled from ethics, simplifying the application process, reducing duplication of work and ensuring consistency in data input. Collaborating researchers benefit from these efficiencies when conducting multi-site studies, further enhancing the attractiveness of the MSU as a research site.

The use of the MSU as a research site is emblematic of the province's advancements in medical research processes. It offers a unique opportunity to gather data quickly for a condition where time is absolutely critical. In rural settings where traditional research sites may lack the resources to collect information in those crucial early moments, the MSU becomes a beacon of hope.

UAlberta has played a pivotal role in paving the way for using the MSU as a mobile research site. The AcT trial demonstrated the potential for groundbreaking research on the MSU and established a precedent. Now, the MSU is listed as an approved research site, opening the door for more studies to leverage its capabilities.

Western Canada is rapidly becoming a hub for efficient research, thanks to its investment in innovative infrastructure like the MSU and its commitment to streamlining research processes. As the West continues to lead improvements in research through technology integrations and innovative infrastructure, it is poised to make significant contributions to the advancement of medical science. The stroke ambulance is not just a unique resource – it's a symbol of Alberta's unwavering commitment to research excellence and better patient outcomes.

“This study did a lot of the legwork to pave the process for other studies to benefit from using this incredible resource.”

LIBERATE:

Conducting Research in the ICU

After working in health research for over 20 years, Dawn Opgenorth is all too familiar with the dangers of drowning in the paperwork involved in complex projects. But in recent years, Opgenorth, critical care research project manager at the University of Alberta (UAlberta), has witnessed a revolution in the management of her work. Gone are the days of file cabinets overflowing with folders and managed by one overwhelmed person, replaced by a digitalized, highly streamlined process facilitated here in Alberta by the REB Exchange. As project manager on LIBERATE — one of the first multi-site studies to take advantage of the vastly improved and efficient services offered by the REB Exchange — she sees nothing but upsides to this new approach.

LIBERATE is an intensive care-unit (ICU) study led by the UAlberta's Oleksa Rewa, an Associate Professor in the Department of Critical Care Medicine in the Faculty of Medicine & Dentistry. His team is working to determine whether an orally administered drug could reduce the need for intravenous vasopressors as a patient's blood pressure improves during their stay in the ICU. The drug, called midodrine, has most commonly been used in non-critically ill patients, but the Liberate research team wants to know if it could be used in the care of ICU patients. "There are always some risks with IVs," comments Opgenorth, "and this treatment could reduce the length of time patients receive blood pressure medications that require invasive IV access, and also hopefully reduce the time patients spend in the ICU." – A much-needed improvement to health-system efficiency. While the team does not discount the need for invasive IVs, especially when more than one medication needs to be administered very quickly, a move to midodrine when a patient is out of acute danger could be a lower-risk solution.

The LIBERATE study crosses multiple sites and the researchers are aiming to add even more in the coming months. Currently, the study involves about 65 patients in intensive care units at UAlberta, Misericordia and Grey Nuns hospitals in Edmonton, with Calgary's Rockyview General Hospital, Red Deer Regional Hospital Centre, and the Sturgeon Community Hospital soon to come on board. The team would like to expand the study to include up to 1000 patients, and to reach that goal they are hoping to bring on board sites in Saskatchewan, Ontario and as far away as Brazil.



“I’ve been involved in multi-site studies in the past,” says Opgenorth, “and there are many, many balls that you have to keep in the air.” This includes developing a protocol, determining a randomization structure, having a pharmacy develop the products that make a double blind study work, creating a database to store the research data, determining a data management plan — and ensuring all study activities meet the stringent regulatory requirements of Health Canada.

All of this, plus the many sites involved, made LIBERATE the perfect candidate for the services of the REB Exchange. “Before the REB Exchange, every site would have to do their own ethics application,” recalls Opgenorth. “It’s so much easier now. All we do is one central application.” All study sites are still able to amend it to suit their site-specific needs, but all work from the same REB approved protocol, drastically reducing not only redundancy but also the chance of errors. This combination of consistency and flexibility is “the best of both worlds,” says Opgenorth.

The REB Exchange has also supported the LIBERATE teams through the various approval processes they must complete with other organizations, such as Alberta Health Services, and their streamlined process has made it much easier to add other sites to the project — Opgenorth simply presses a button, issues the invitation, and the new site is easily added, ready to begin integrating into the study.

As the LIBERATE team became familiar with implementing the REB Exchange system, the REB Exchange team adapted as they went and Opgenorth has every confidence in the future of this approach. She is grateful for the peace of mind the REB Exchange has brought to the LIBERATE team, giving them the confidence that their study is operating at a high level at all of the sites. “I predict that future users are going to have an even more streamlined process,” she says. “I just think it is going to get more and more refined as time goes on.”

Wherever LIBERATE goes next in the world, the Alberta-based REB Exchange will be there to help untangle all of the complexities that might accompany this multi-site, ICU study, paving the way to better care for patients.

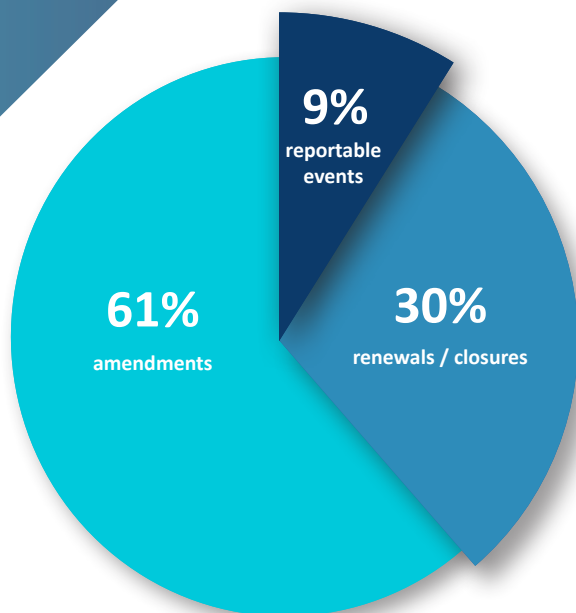
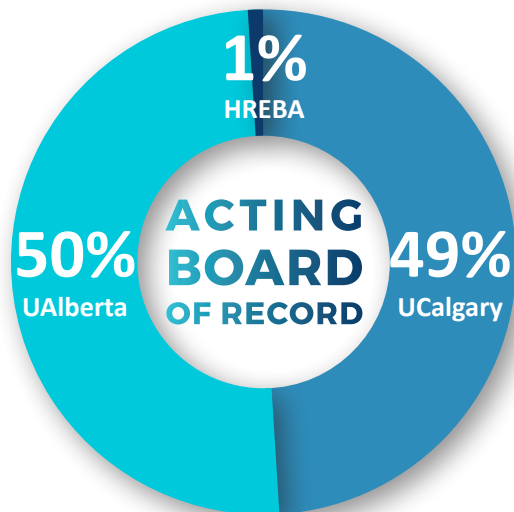
“[We’re] grateful for the peace of mind the REB Exchange has brought to the LIBERATE team, giving them the confidence that their study is operating at the same high level across all the sites.”



THE NUMBERS

As of August 2023

406 SITES



534 FOLLOW-ON SUBMISSIONS

DAYS TO DETERMINATION*

ALL SITE SUBMISSIONS

ethics review

9 researcher

1 board of record

administrative review

4 researcher

1 administration

pSITE AMENDMENTS

5 researcher

SAME DAY board of record

2 researcher

1 administration

*median

111 FUNDING SOURCES

32%

Canadian Institutes of Health Research (CIHR)

9%

Other (1% ea)

8%

Alberta Innovates

4%

Alberta Health Services (AHS)

4%

University of Calgary

3%

Alberta Children's Hospital Foundation (ACHF)

3%

Health Canada

3%

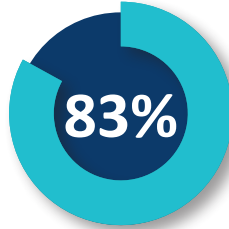
Social Sciences and Humanities Research (SSHRC)

3%

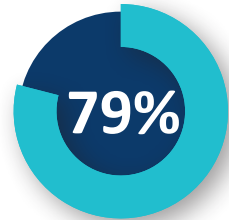
University of Alberta

3%

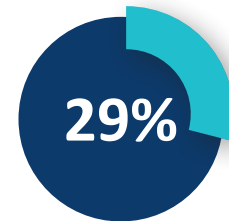
Women and Children's Health Research Institute (WCHIR)



w/ participants



funded



clinical trials

STUDY TYPES

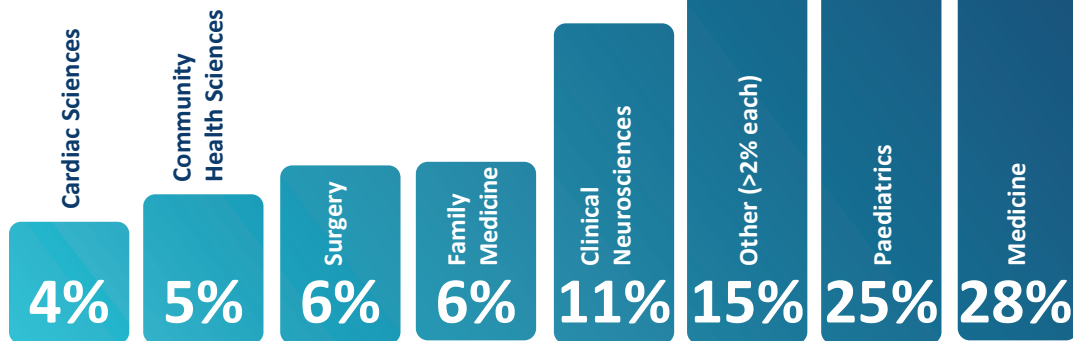
284

PRINCIPAL INVESTIGATORS

24

DEPARTMENTS

8 FACULTIES



MULTI-SITE RAPID TRIALS:

The Power of Collaboration and Innovation



REB EXCHANGE

Innovation can't be born from a vacuum. While brilliant ideas may strike individuals, the transformation of these ideas into practical and impactful solutions often necessitates the collaboration of specialized teams. An innovative solution is more than just a concept; it's a product of motivated people, the right places, and processes that can be modified and adapted as needed. This fusion of elements produces a spark capable of disrupting the status quo, which is precisely what the University of Calgary's W21C (The Ward of the 21st Century) initiative aims to achieve—improving health systems through the lens of real-world problems.

W21C is a groundbreaking initiative unique to the research and medical infrastructure at UCalgary. Through strong partnerships with Alberta Health Services (AHS), W21C aims to make care better by assembling interdisciplinary research teams that drive innovative solutions. W21C works collaboratively with academic faculty, clinicians, non-profits, and industry partners to provide evidence, feedback, and validation services for healthcare innovations.

Jill de Groot, W21C's director of development and partnerships, knows that an idea can be refined into a well-rounded solution through intersections – the vital points where resources come together and build something beautiful.

"I see our role as complementing the work experts in that field are doing," says de Groot. "W21C brings together the resources and fills in the gaps to ensure an idea can be explored from many angles. It's kind of like



MEGAN LESLIE

Co-founder and CEO, NanoTess,
University of Calgary Graduate

JULIAN MULIA

Co-founder and COO, NanoTess,
University of Calgary Graduate

we keep the machine of progress oiled and running.”

One notable arm of the machine unique to the Canadian health-care system is the Coordinated Accessible National (CAN) Health Network — a national partnership comprised of leading health organizations funded by the Canadian Federal Government. The CAN Health Network serves as a catalyst for health innovation companies in Canada by providing an integrated and receptive marketplace that removes common access barriers hindering growth and scalability.

CAN Health operates on a node-based system, wherein health systems across Canada are defined as individual nodes and identify specific problems they seek to address. CAN Health provides funding to support rapid trials aimed at finding solutions. This fast-paced approach is groundbreaking because it enables testing in one node to benefit others by allowing them to access trial data and make informed purchasing decisions without having to replicate the trials themselves. CAN Health effectively unifies health systems across Canada, facilitating collaboration and innovation on a national scale.

In 2022, AHS, serving as one of CAN Health’s nodes, identified a critical need for better wound care solutions to promote healing in complex wounds. The key to CAN Health’s success is to trial products that are near ready or already commercially available on the market in order to assess implementation feasibility and effectiveness compared to standard of care rather than starting from scratch. The next piece of the puzzle was the product and AHS came to the table prepared.

Enter NanoTess, a Calgary-based social enterprise driven by personal experience with a vision to create affordable medical technology accessible to all. Their product, NanoSALV Catalytic Advanced Wound Care Treatment Matrix, is a Health Canada-approved Class II medical device designed for the management and treatment of acute and chronic wounds.

With all the gears in place, the primary objective of the project was to determine the feasibility of implementing the product in a variety of clinical settings and to understand the effectiveness of the product with regard to wound healing. This project quickly

It is exciting to evaluate innovative products like NanoSALV and better understand how innovations work in real clinical environments. Projects such as this would not be possible without many partners coming together with a shared goal of enhancing the quality and effectiveness of care patients receive.

Dr. CHESTER HO

Principal Investigator, Cumming School of Medicine,
Department of Clinical Neurosciences,
University of Calgary

became a delicate balancing act between numerous stakeholders, each with a vested interest in the outcome. AHS sought to use the data to inform future care practices, NanoTess had a product with the potential to scale, and W21C played a critical role in facilitating the project across multiple sites in Alberta, including sites in Calgary under the direction of UCalgary’s Dr. Chester Ho working with the University of Alberta/AHS Neurosciences, Rehabilitation & Vision Strategic Clinical Network.

The project’s methodology involved recruiting patients with complex wounds, characterized by those unlikely to heal on their own, with included wounds having been present for an average of 88 weeks (1.69 years). These patients were sourced from various health-care settings, including hospitals, outpatient facilities, and long-term care facilities. The project compared wound healing while maintaining standard of care in both phases of the study, initially using best-in-class dressings for four weeks and then switching to NanoSALV (replacing the



JILL DE GROOD
Director, Development and
Partnerships, W21C,
University of Calgary

best-in-class primary dressings within standard of care) for an additional four weeks, measuring and documenting wound size weekly. The project also drew upon the specialized expertise of W21C's Human Factors team to look at the patient and provider experience of using both NanoSALV and the best-in-class dressing.

The results were impressive and significant. In just four weeks, the data showed nearly a 60% improvement in wound size with the use of NanoSALV. The application of NanoSALV produced a notable spike in healing rates, demonstrating its potential to revolutionize wound care compared to traditional dressings alone. The project also revealed improvements in wound healing across wound type and type of secondary dressing used, indicating the broad applicability of this innovative solution. When it came to patient and provider feedback, participants found that NanoSALV could be easily integrated into existing workflow practices and various wound care pathways.

Enter, the REB Exchange.

To execute a multi-site project effectively, especially one spanning seven sites across Calgary and Edmonton, efficient collaboration is paramount. The REB Exchange played a crucial role in facilitating this collaboration including expediting the ethics approval process allowing more sites to participate and enhancing data collection efficiency. The rapid trial approach of CAN Health meant timely approvals were essential to prevent potential loss of funding due to project delays. Not only were ethics approvals needing to be fast, the REB Exchange platform also enabled quick handling of reportable events and modifications, ensuring version control across all sites could be maintained. All project documentation was linked and accessible in one location, simplifying coordination and ensuring all stakeholders had access to current and synced information.

The successful outcomes of the NanoSALV project provide only one example of how Western Canada is pioneering a path to make collaboration more efficient and effective within the research ecosystem. By conducting multi-site research through the REB Exchange, the project highlights how technology solutions can facilitate communication and data exchange across healthcare systems effectively and efficiently. Utilizing tools like REB Exchange that enable collaborative and scalable evaluations of innovative products, creates the potential to move towards healthcare delivery transformation and improved patient outcomes more rapidly.

**Diverse partnerships, motivated teams,
and adaptable processes can continue
to ignite innovation that disrupts
the status quo and ultimately leads to
a brighter future for health care worldwide.**

REB EXCHANGE

> REBexchange.ca

REB Exchange is a collaboration between Alberta institutions. The initiative is funded by Alberta Innovates, the University of Calgary, the University of Alberta, and Huron Consulting, with in-kind contributions from Alberta Health Services, to collectively support research ethics harmonization in Alberta.