

CULTIVATING HEALTH THROUGH BIOMARKER DISCOVERY → INAUGURAL REPORT



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CAN GOOD IDEAS PUT INTO ACTION TOPPLE A GLOBAL EPIDEMIC? CAN OUR ROOTS AS A HEALTH RESEARCH ENTERPRISE STRETCH TO EMBRACE NEW PARTNERSHIPS? CAN BROAD LEADERSHIP AND COMMITMENT TO BIOMARKER DEVELOPMENT YIELD A NEW WAY TO EFFECTIVELY PREVENT ORGAN FAILURE? **YES.**

OUR FUTURE HAS A PAST

MILESTONES \rightarrow **ATHEROSCLEROSIS Canada Research SPECIALTY LABORATORY OPENED** Chair Program funds **PROOF CENTRE** top researchers **OF EXCELLENCE** Genome Canada & LAUNCHED **Partners fund BiT** 1995 **HEART + LUNG** 2004 02-04 **INSTITUTE FOUNDED** 2008 2003 2004 1977 2007 **JAMES HOGG iCAPTURE** PULMONARY CENTRE 1998 **BIOMARKERS IN BC BIOLIBRARY** 2000 RESEARCH FOUNDED **TRANSPLANTATION ESTABLISHED** LABORATORY (BIT) TEAM ASSEMBLED **OPENS AT ST. Canada Foundation** PAUL'S HOSPITAL **McDONALD RESEARCH** LABORATORY ESTABLISHED funding awarded



ightarrow Message from the director

Personalized medicine is a buzzword of our times. This focus of enthusiasm is taking hold throughout healthcare. In the case of the PROOF Centre of Excellence, it is our motivating force. Personalized medicine – giving the right drug in the right dose to the right patient at the right time – is also important when considering the right preventive or behavioural change. Research over the past decade has opened doors to new approaches to patient management and drug development driven by each individual's characteristics. That's what we care about at the PROOF Centre – the individual patient at risk of or suffering from heart, lung or kidney failure.

The PROOF Centre was created thanks to a strategic investment by the federal Networks of Centres of Excellence secretariat – the Centres of Excellence for Commercialization and Research. This led to the creation of the PROOF Centre as a not-for-profit society in early 2008 with a base at the Providence Heart + Lung Institute at St. Paul's Hospital and hosted by the University of British Columbia. The PROOF Centre has magnetized leaders and organizations with like minds, establishing a special inter-disciplinary hub of experts drawn from industry, academia, government, and healthcare, and also engaging patients and the public.

From the beginning, the PROOF Centre has had a clear focus on biomarkers: distinct biological indicators (cellular, biochemical or molecular) of a process, event or condition that can be measured reliably in tissues, cells or fluids. Common examples of biomarkers include elevated blood sugar and blood cholesterol – biomarkers of risk for hardening of the arteries. The majority of currently used "biomarkers" are single markers; they tell you a lot about populations, but only a little about individuals.

We see the future of biomarker discovery and development as a wholesale change in the way we use biomarkers for clinical care. Thanks to new technologies and analytical strategies and an understanding of how complex disease processes are, we now know to pursue "panels" or sets of biomarkers that work together to predict or diagnose biological processes like organ rejection and organ failure. These panels are challenging to discover and even more difficult to translate. as practical clinical tools. As such, there is a broad-based call to action; instead of dwelling on a favorite gene or pet protein alone, we must collaborate to identify sets of genes and sets of proteins in combination with current clinical tests and genotypes to make a huge leap forward in preventing, diagnosing and managing heart, lung and kidney failure.

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Bruce McManus MD, PhD Director, PROOF Centre



MESSAGE FROM THE CHAIR

Canada is renowned as a global leader in health care and life sciences research, but has lacked the support and infrastructure required to move Canadian research advances into the marketplace. The "Centres of Excellence for Commercialization and Research" vision of integrating funding from the government with industry and academia is truly unique and will help to bridge this historical gap in the process.

The birth of the Centre of Excellence for the Prevention of Organ Failure reflects this new model of thinking, and for finding answers to complex, society-wide problems. This is NOT simply a granting opportunity, and similarly, is not just another way to bring funds into academic environments where scientists will conduct research with modest expectation that work will be translated into tangible, practical solutions.

Stakeholders are engaged from various communities. Patients will be asked to volunteer their healthcare records and their tissues and fluids. Scientists will be called upon to translate their insights into practical clinical uses and to form partnerships with commercial experts and policy makers. The business and investment communities will be expected to initiate and sustain, on a profitable basis, technology solutions to the predictive, diagnostic and prognostic challenges. And healthcare administrators and professionals will be expected to implement the insights into immediately applicable interventions. As a consequence, the federal government will obtain for its citizens the most innovative, costeffective methods for controlling the epidemic of these chronic diseases. Wherever possible, this will occur by funding the discovery of the best diagnostic and therapeutic approaches derived from Canadian patients, discovered by Canadian researchers, and delivered by Canadian companies that employ Canadian-trained scientists who can find an outlet for their scientific training without having to leave the country.

An outstanding biomarker discovery and development team has been created here in Vancouver, embodied in the PROOF Centre. Investment in this team allows the recruitment of other allies to join in the fight against heart, lung and kidney failure. The PROOF Centre team could truly be writing the history books for biomarkers of health promotion, disease management and drug development.

George Schreiner MD, PhD Chairman of the Board, PROOF Centre

PLANTING THE SEEDS

PREVIOUS FEDERAL AND PROVINCIAL INVESTMENTS IN RESEARCH PLANTED THE SEEDS OF **THE PROOF CENTRE.** THE CANADA FOUNDATION FOR INNOVATION HELPED BUILD THE INFRASTRUCTURE. THE CANADA RESEARCH CHAIRS PROGRAM ATTRACTED THE BEST MINDS. NEWER INVESTMENTS BY GENOME CANADA AND PROVINCIAL FUNDERS ALL CONTRIBUTED TO THIS PRECIPICE: THE RE-THINKING OF ORGAN FAILURE.

ightarrow PLANTING THE SEEDS

Early investments

The groundwork for the PROOF Centre of Excellence was laid over ten years ago when the Canadian government began to reconsider its support for the infrastructure of Canada's research organizations. Many agreed that without considerable investment, Canada could lose its status as one of the world's leaders in research and development.

Thanks to an early Canada Foundation for Innovation award, the heart and lung research team at St. Paul's Hospital, headed by Drs. Peter Paré and Bruce McManus, was able to renew equipment and renovate much-needed space. Their "brain gain" of top-level heart and lung researchers was bolstered by the Canada Research Chair initiative to recruit global leaders in specific fields.

More than anything else, this infusion of capital and talent allowed this group of UBC researchers to imagine how technology and cross-disciplinarity could transform their research and dramatically accelerate the path towards understanding and controlling these diseases.

Cross-disciplinary research remains key

Bioinformaticians joined the team. Imaging experts, biophysicists, geneticists, and database experts signed up. Clinicians with a burning need for clinical answers came aboard. And bioethicists, attracted by the challenge, began to explore the concept of "patients as partners" in the research endeavour. Together, they began to prioritize research questions to reflect the needs of the patient population. Over that time, there was a growing realization that biomedical and socioeconomic problems related to kidney, heart and lung failure were dramatically increasing.

Biomarkers in transplantation

In the early 2000's, the team expanded by integrating with clinicians at Vancouver Hospital and immunologists at the Jack Bell Research Centre. The "Biomarkers in Transplantation" team started down the path of identifying biomarkers to replace invasive diagnostic procedures. In particular, they became interested in blood or urine tests that could diagnose or predict organ rejection after transplantation. Current practice for diagnosing rejection is a painful biopsy.

In pursuit of this end, they developed patient cohorts; they developed technological solutions to help automate and improve procedures; and they pushed themselves to understand how the work of complementary disciplines could forward their own research. Collaborations were born; teams cemented. Genome Canada and Genome BC with many partners supported this research, further leveraging the investment of previous funders.

When the National Centres of Excellence announced a new program in 2007 to build competency toward commercializing new discoveries, this UBC-based team was ready to respond rapidly to the call for proposals. In February of 2008, the team, headed by Dr. Bruce McManus, became a Centre of Excellence in Commercialization and Research. And the PROOF Centre was born.

OUR ROOTS

THE PROOF CENTRE IS A DESCENDENT OF A FAMILY OF ORGANIZATIONS. IN 1977, THE PULMONARY RESEARCH LABORATORY WAS FOUNDED AT ST. PAUL'S HOSPITAL BY DR. JAMES HOGG. THAT ORGANIZATION EVOLVED IN 1998 INTO THE MCDONALD RESEARCH LABORATORIES. IN 2003, THE JAMES HOGG iCAPTURE CENTRE ESTABLISHED UBC/ST. PAUL'S AS A CENTRE OF INNOVATION IN PURSUIT OF GENETIC AND ENVIRONMENTAL LINKS TO HEART, LUNG AND BLOOD VESSEL DISEASES.

THE GROWING SEASON

IN JUST A FEW MONTHS, THE PROOF CENTRE WENT FROM A GREAT IDEA ON PAPER TO A LIVING, BREATHING CENTRE OF EXCELLENCE FOR COMMER-CIALIZATION AND RESEARCH. OUR STRATEGY INCLUDED EXPLAINING OUR IDEA TO THE VERY BEST PEOPLE AND INVITING THEM TO JOIN. **IT WORKED.**

ightarrow THE GROWING SEASON

Team building

This brings us to the moments just after the PROOF Centre was born. Once we had fulfilled the initial administration requirements of the NCE, we set to work in earnest in the fall of 2008.

Despite few initial staff, we began by simultaneously setting up administrative structures, policy frameworks and staffing plans as well as the ways and means to reach out to partners in the academic, commercial, healthcare and policy realms.

At the very beginning we were focused on writing business plans, detailed budgets, and setting up financial systems. We also established an impressive Board of Directors and a Translational Advisory Committee within the first few months. Dr. George Schreiner, a renowned U.S.-based biomarker expert, physician, scientist, previous professor and serial entrepreneur, accepted our request to head up the Board. The Translation Advisory Committee headed by Dr. Michael Hayden, was established to evaluate all biomarker programs from a translational perspective – whether they can be efficiently moved through a commercialization pipeline *and* benefit the healthcare system.

In the first few months we also had to attract key staff members to our already solid team. Despite having a core group, we needed to add commercialization experts, health economists, a chief informatics officer, a chief scientific officer and other key professionals.

Technology investments

Technology was another issue that had to be tackled right away. In order to conduct worldleading development in this field, we needed to put the people, training and equipment in place to facilitate "high performance platforms" (alias high through-put platforms.) These platforms are technologies that process biological samples for genes, proteins and other biomaterials to quickly produce vast amounts of interpretable data. These platforms can test and then allow confirmation or rejection of their value, which is central to finding sets or panels of biomarkers that may influence organ failure. The PROOF Centre's plan was to maximize the use of existing platforms, forming partnerships that make the most of investments Canada has already made in infrastructure. This also allowed for efficiencies in time and development costs. Developing relationships with technology experts in engineering physics, chemistry, laboratory medicine, and the diagnostics industry was pivotal.

Communications and education

Attracting the right partnerships and talent requires a very clear vision. At the beginning, as a new organization, we encountered many different ideas of what the PROOF Centre was and how it did or should function. Formal education strategies and a communications plan were needed to immediately quell misconceptions and spark excitement about the real possibilities.

THE GROWING SEASON

AS OUR COMMERCIAL AND HEALTHCARE PARTNERS LEARN ABOUT OUR STRENGTHS, THEY WILL SEE THE PROOF CENTRE AS A HUB THAT CULTIVATES BIOMARKER PROGRAMS FOR IMPROVED PATIENT CARE.

From the very beginning we wanted to avoid a top down approach to educating others about the mandate and vision of the PROOF Centre. Rather. we set out to engage and interact with our stakeholders and to educate ourselves by learning from successful colleagues in related fields and other jurisdictions. To facilitate this iterative process, we hosted PROOF Centre education days on specific subjects. We heard from multiple stakeholders including clinicians, patient groups. researchers, corporations, regulators, and investors. These sessions answered many questions and posed many more for us to ponder. Best of all, they facilitated interaction, discussions, and new relationships across these various groups. Given their early success, we plan to host these inclusive "education days" on a regularly basis.

On the communications side, over our first year we devoted ourselves to developing key messaging, clear branding as well as building an easy-to-navigate, professional website. We also developed a full communications and marketing plan to guide our strategy and actions over the next few years. Slides, posters, fact sheets and other collateral material were also developed to help cement the PROOF Centre's role.

Building the commercial pipeline

While we had expertise in many areas before the PROOF Centre was born, including patient cohorts, technology platforms, and computational expertise, one of the other pressing issues was building our competency in the realm of commercialization. While many board members and other key leaders had experience with industry and the development of commercial products, a key staff position was needed to devote a full-time effort to building these networks and partnerships. With the recruitment of lawyer and biotech insider, Mariorie Co. the PROOF Centre was able to start down this path. Now, as our commercial and healthcare partners learn about our strengths. they will see the PROOF Centre as a hub that cultivates biomarker programs for improved patient care. In small teams we will shepherd our projects through biomarker discovery,



biomarker development, clinical development, regulatory filing, to clinical implementation – quickly and efficiently.

Our core business

As conceived in our original submission to the National Centres of Excellence, the PROOF Centre of Excellence will focus on heart, lung and kidney failure, all growing epidemics in Canada and around the world. Our core business is to discover, develop, commercialize and implement non-invasive tests for prevention, prediction, diagnosis, management, and treatment of diseases associated with organ failure. That means defining a clinical problem where a set of non-invasive biomarkers could change patient management for the better.

These non-invasive tests or "biomarkers" will help tailor individual treatments, advancing towards "personalized health care." By creating a hub that embraces industry, academia, policy makers, clinicians, and patients with wideranging expertise, we can speed up development of these biomarkers and apply them sooner. Our work will help improve the health of Canadians while decreasing the financial burden on our precious taxpayer-supported healthcare system.

Early successes

As mentioned earlier, one of the PROOF Centre's flagship programs of the PROOF Centre was the "Biomarkers in Transplantation" initiative. This innovative project identified biomarkers in the blood that will alert clinical transplant teams as to whether a transplanted organ is being rejected – using a simple blood test. With a multi-sectoral network of partners, the PROOF Centre is testing these gene and protein biomarker panels for their diagnostic reliability in the care of heart and kidney transplant patients.

The next phase of the work will run for two years, and will culminate with applications to Health Canada and the US Food & Drug Administration for use of the blood test in clinical care.





JANE MILLER LIVING WITH HEART FAILURE

In early 2007, Jane Miller began experiencing flu-like symptoms. Two days later she slipped into a coma, awakening a month later in the Cardiac Intensive Care Unit. Jane had suffered acute heart failure (AHF) caused by myocarditis, a viral condition that attacks the heart.

Today, Jane is on the heart transplant wait list and relies on a Ventricular Assist Device (VAD) to ensure her heart pumps effectively. VADs are one of several therapies available to heart patients like Jane, but researchers don't know which therapy is best for each patient. That's why biomarkers are central to PROOF Centre initiatives. New and specific sets of markers can guide physicians in their selection of the most appropriate therapy for individual patients, directions that are providing hope for patients like Jane who don't have the luxury of time to try out and fail one or more therapies.

Always a fighter, Jane has returned to work part-time, and she and her two children are hopeful for the future and look forward to the day when Jane is the recipient of a heart. "I have always known that life is unpredictable and precious," says Jane. "That's a lesson we should all remember."



DAVID BARKER LIVING WITH KIDNEY DISEASE

Eleven years ago, during a routine doctor's appointment to monitor his high blood pressure, David Barker learned he had a kidney disorder called IgA nephropathy. This condition occurs when IgA – a protein that helps the body fight infections – settles in the kidneys. Three years ago, David's kidney function, until then stable at 50 percent, suddenly dropped to 10 percent. While he can still live an active, healthy life managed with medication, David now has no immunity to fight infection.

"It's a roller coaster," says David. "I'm still on medication, but I'm generally okay. I don't ever want to have to rely on dialysis. Now that I'm retired from teaching, my lifelong dream is to travel." The only solution for David is a transplant.

Researchers at the PROOF Centre are striving to find an answer for David and for others who already rely on dialysis for treatment. They are working tirelessly to discover novel biomarkers to help predict the progression of kidney disease in a fashion that improves on traditional clinical and laboratory methods. They are also studying a unique biomarker profile that will help better predict progression of kidney disease.





VIVIANNE TOUPIN LIVING WITH LUNG DISEASE

Almost 20 years ago, Vivianne Toupin learned she had a serious heart rhythm disturbance. Just 48 years old at the time, she was then overwhelmed with a further diagnosis of emphysema, now know as Chronic Obstructive Pulmonary Disease (COPD).

"I am the fourth member of my family to be diagnosed with emphysema," says Vivianne. "My father and uncle, who were both smokers and grain buyers, both had it, as does my sister."

COPD affects over 74,000 people living in BC and accounts for 10,000 hospitalizations each year, making it the number one reason British Columbians are hospitalized. Unfortunately, there is still no blood test to predict who will become sick enough to be hospitalized, and no truly effective drugs to allow people with COPD live longer once they become very sick.

This is why Vivianne believes genetic research is so important. Without her diagnosis of arrhythmia, Vivianne's COPD would have gone unchecked and progressed to cause more damage. At the PROOF Centre, one of our research goals is to find new blood tests that will allow doctors to predict those at risk for COPD, help doctors diagnose people with COPD at a much earlier stage so that treatment can start much earlier, and enable doctors to prescribe the correct medication to the correct patient and determine quickly whether the drugs are working or not.

BEARING FRUIT

THE PROOF CENTRE IS ALREADY MOVING INTO A PHASE OF PRODUCTIVITY AND GROWTH. OUR GOALS FOR THE FUTURE ARE VERY SPECIFIC TO BIOMARKER DEVELOPMENT AND COLLABORATION WITH A BROAD SPECTRUM OF STAKEHOLDERS. WE EXPECT OUR PARTNERSHIPS WITH HEALTHCARE AND INDUSTRY TO GROW VERY QUICKLY AS WELL AS THE RESULTING COMMERCIALIZATION OPPORTUNITIES.



ightarrow OUR PLANS FOR THE FUTURE

Despite the effort we poured into our first phase, we took the time to listen and learn from others. One of the things we learned is the importance of engaging clinicians and adding more experts to our team in order to prioritize clinically relevant questions. Clinicians are essential to ensuring that we pursue biomarker solutions that turn out to be practical, accessible and affordable in the real world of medical practice.

We also learned that collegial partnerships beyond academics, commercial interests, and hospitals must be cultivated. Partnerships with patient groups, regulatory authorities, health authorities, not-for-profits, and provincial and federal agencies with related expertise are essential. These relationships will ensure transparency in everything we do as well as ensuring that we are accounting for and considering all barriers to the successful implementation of biomarker solutions for heart, lung and kidney disease.

Moving forward we have four priorities:

- Discover, develop, and implement biomarkers to improve care for patients with heart, kidney, and lung failure
- Develop assays for improved biomarker monitoring
- Develop biomarker implementation and commercialization partnerships
- Leverage investments and strengthen capacity, collaboration, and talent in a collegial manner

To move forward, we need your participation.

The PROOF Centre is interested in collaborating with many different groups and individuals committed to preventing heart, lung and kidney failure.

Professionals and advocates

We are setting up multi-disciplinary working groups to tackle specific aspects of the biomarker puzzle including groups to define clinical questions, groups to work on clinical development, groups to solve informatics issues, and groups to continue our efforts to engage the public.

Please contact Janet Wilson-McManus, BSc, MT Chief Operating Officer Janet.Wilson-McManus@hli.ubc.ca

Industry partners and clients

We encourage commercial partners to get in touch with us about collaborations, partnerships and the contract services we can provide using cohorts, platforms and a range of expertise.

Please contact Marjorie Co, BSc, LLB, MBA Chief Development Officer Marjorie.Co@hli.ubc.ca

Trainees

We are committed to training the next generation of biomarker experts. We encourage graduate students, post-doctoral candidates and other students and visiting scientists to reach us.

Please contact Scott Tebbutt, PhD Chief Scientific Officer Scott.Tebbutt@hli.ubc.ca



FINANCIALS



BALANCE SHEET (expressed in thousands of dollars) Year ended March 31, 2009		
		Fiscal Year 08-09
Receipts		
Cash and cash equivalents	\$	9,161
Interest receivable		113
Accounts receivable		20
Prepaids		193
	\$	9,487
Long-term investment		5,000
Capital assets, net of accumulated amortization		747
	\$	15,234
Liabilities and net assets		
Current liabilities		
Accounts payable and accrued liabilities		204
	\$	204
Deferred operating contributions	<u> </u>	13.991
Deferred capital contributions		690
Net assets		
Unrestricted		292
Invested in capital assets		57
	\$	349
	\$	15,234

STATEMENT OF RECEIPTS AND DISBURSEMENTS (expressed in thousands of dollars) Year ended March 31, 2009

	F	iscal Year 08-09
Revenue		
Amortization of deferred operating contributions	\$	980
Amortization of deferred capital contributions		297
Unrestricted contributions		744
Interest income		338
Foreign exchange gain		8
	<u>\$</u>	2,367
Disbursements		
Programs and Operations		642
Materials and Supplies		552
Equipment		48
Administrative Salaries		245
Administrative Operations		225
Hosting Conferences		8
Attending Conferences		59
Market Studies, Business Development		105
Intellectual Property		100
Space Improvements		34
	\$	2,018
Excess of revenue over expenses	\$	349

STATEMENT OF CASH FLOWS (expressed in thousands of dollars) Year ended March 31, 2009

	F	iscal Year 08-09
Cash provided by (used in):	· · · · ·	
Operations:		
Excess of revenue over expenses	\$	349
Amortization of capital assets		297
Amortization of deferred capital contributions		-297
	\$	349
Changes in non-cash operating items		
Interest Receivable		-113
Accounts Receivable		-20
Prepaid Expenses and Deposits		-193
Accounts Payable and Accrued Liabilities		204
Deferred Operating Contributions		13,991
	\$	14,218
Investments:		
Additions to capital assets		(1,044)
Additions to long-term investments		(5,000)
	\$	(6,044)
Financing:		
Capital Contributions		987
Increase in cash	\$	9,261
Supplemental information: cash received for interest	\$	225

ightarrow MAXIMIZING RESEARCH INVESTMENT



Team members in the PROOF Centre have actively engaged in working with strategic partners to ensure that new blood tests can help transform the way patients are managed. Total committed investment in the PROOF Centre to date is projected to be primarily spent on staff and facilities focused on biomarker programs. These programs include chronic kidney disease, chronic obstructive pulmonary disease, acute and chronic heart failure, and heart and kidney transplant failure as well the development of biomarker assays that can easily be used in the clinical laboratory.

Board of Directors

George Schreiner Chairman of the Board

Donald Brooks Associate Vice-President Research, University of British Columbia

Lynda Cranston President & CEO, Provincial Health Services Authority

Katherine Gibson Founding and Managing Director, Helio Consulting, Inc.

Frank Holler CEO & Partner, BC Advantage Funds Ltd. and Lions Capital Corporation

Funders

Astellas BC Transplant Genome British Columbia IO Informatics National Centres of Excellence, Centres for Commercialization and Research (CECR), Government of Canada Pfizer Canada Providence Health Care Provincial Health Services Authority St. Paul's Hospital Foundation University of British Columbia

Seigo Izumo

Former Senior Vice President, Head of Cardiovascular Therapeutics, Gilead Sciences, Inc.

Bruce McManus

Professor, UBC Department of Pathology & Laboratory Medicine; Director, Providence Heart + Lung Institute at St. Paul's Hospital; Director, The James Hogg iCAPTURE Centre, University of British Columbia – St. Paul's Hospital

Bruce Milley

Practice Review Officer, Institute of Chartered Accountants of BC and Consultant, Canadian Public Accountability Board, Vancouver, BC

Eric Olson

Professor and Chairman, Department of Molecular Biology, UT Southwestern Medical Center at Dallas

Bernard Prigent

VP & Medical Director, Pfizer Canada

Richard Rees

CEO, Institute of Chartered Accountants of BC

Carl Roy

Acting CEO, BC Transplant

Partners

Institute

Biomarkers in Transplantation (BiT) BC BioLibrary Collaboration for Outcomes Research and Evaluation (CORE) Canadian Heart Failure Network Fasken Martineau Fenwick & West LLP Human Metabolome Project James Hogg iCAPTURE Centre Libin Cardiovascular Institute of Alberta Mazankowski Alberta Heart Institute Providence Health Care Research Providence Heart + Lung Institute at St. Paul's Hospital Signals Design Group Spheromics USC/CHLA Microarray Core UVic-Genome BC Proteomics Centre Vancouver Coastal Health Vancouver Coastal Health Research Institute

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