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Human Resource and Educational Inventories to Support the Life Cycle Approach to the Regulation of Therapeutic Products

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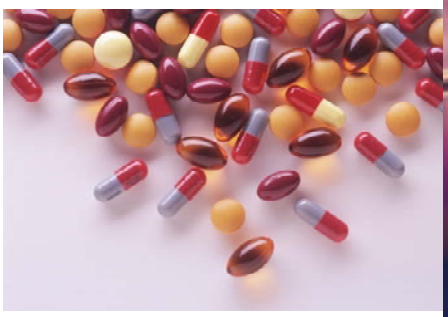

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Introduction

Health Canada has undertaken to modernize the legislation and regulation of pharmaceuticals and biologics. This will facilitate the ongoing monitoring of safety, effectiveness and quality throughout the life cycle of drug products. The life cycle phases will include pre-market applications, authorization and entry onto the market, and post-market surveillance on the safety and effectiveness of these products in the real world environment. This report is the outcome of a study commissioned by the Office of Legislative and Regulatory Modernization, Health Products and Food Branch, to evaluate whether the human resource capacity in Canada is sufficient to support the product life cycle approach to drug regulation. The project objectives were to**:**

- Establish and characterize the current human resource capacity in Canada able to conduct post-market drug safety and effectiveness studies; and
- Identify and describe the programs in Canadian post-secondary educational institutions able to train graduate students in post-market drug evaluation research methodology.

Study findings will provide a baseline for how to approach the change management aspects for the implementation of the product life cycle approach to drug regulation.

Methodology

Project development was a collaborative effort by the Office of Legislative and Regulatory Modernization, Health Products and Food Branch in Ottawa (David K. Lee (Director); Dr. Maurica Maher (Associate Director); and Robyn Brake (Project Coordinator)) and Dr. Stuart MacLeod, Executive Director of the Child and Family Research Institute (CFRI) in Vancouver. The design, conduct, management and dissemination of the project was carried out by the CFRI Working Group based in Vancouver, comprised of Dr. Stuart MacLeod (Executive Director, CFRI; Associate Dean (Research), Faculty of Medicine, University of British Columbia); Dr. Judith Soon (Senior Policy Research Officer, Policy, Planning and Outreach, Regions and Programs Branch, Western Region and Assistant Professor, Faculty of Pharmaceutical Sciences, University of British Columbia); Dr. Sunaina Sharma (Head, Policy, Planning and Outreach, Regions and Programs Branch, Western Region and Senior Advisor CFRI and Stakeholder Liaison); and Dr. Matthew Wiens (Research Assistant and Clinical Pharmacotherapy Specialist, Fraser Health Authority). The Peer Review Committee, composed of ten leading academic and professional experts from across Canada, provided ongoing advice on the conduct of the research and dissemination of study findings. Peer Review Committee members were Drs. Jean-Paul Collet (University of British Columbia); Jean Gray (Dalhousie University); Jean-Pierre Grégoire (Université Laval); Andreas Laupacis (University of Toronto); Jacques LeLorier (Université de Montréal); Colleen Maxwell (University of Calgary); Yola Moride (Université de Montréal); Robert Peterson (University of British Columbia); Jeff Poston (Canadian Pharmacists Association); and Noralou Roos (University of Manitoba).

Preliminary results of the human resource and educational institution inventories were presented to stakeholders and Peer Review Committee members during a one day workshop in Montreal, Quebec on April 18, 2009. Participant perspectives on the interim findings, practical suggestions for addressing future human resource capacity needs in Canada and discussion on ways in which Canadian researchers can contribute to the harmonization of international surveillance programs have been incorporated into this report.

The target population for the inventory of academic and health care institutional researchers was those involved with the post-market drug surveillance of safety and effectiveness utilizing clinical, epidemiological, economic and outcomes research methodology. The search strategy progressed in three phases:

- *Phase 1:* Individual researchers identified through universities, health care settings and funding agencies for pharmaceutical research were invited to participate;
- *Phase 2:* Personal contacts within professional health care organizations were invited to forward the invitation to members involved in drug evaluation research; and
- *Phase 3:* External Scientific Database Managers in the three Health Canada Directorates involved in post-market drug evaluations were invited to forward the invitation to key researchers.

An online survey instrument was designed to characterize the demographics, training and research expertise of academic and clinical researchers involved with post-market drug evaluation. Information was also gathered on the involvement of researchers in past and current consultations with Health Canada, interest in future post-market drug evaluation research and inclusion in a *Registry of Post-Market Drug Evaluation Researchers*, and barriers to data access that limited post-market drug evaluation research. The survey was pilot tested, and ethics approval was provided by the Research Ethics Boards at Health Canada, the University of British Columbia, and the Children's and Women's Health Centre of British Columbia.

The inventory of educational institutions capable of training students in the discipline of post-market drug evaluation research was web-based, with telephone follow-up where appropriate. All health-related graduate programs that taught courses in epidemiology and biostatistics were eligible, as well as graduate programs in epidemiology, public health, pharmacy, veterinary medicine and health informatics. The prevalence of relevant courses was summarized by institution and the estimated number of graduate students calculated. The six core training courses deemed essential for future post-market drug product evaluation were Epidemiology, Biostatistics, Health Economics/Pharmacoeconomics, Pharmacoepidemiology, Pharmacogenetics/Pharmacogenomics and Patient Safety/Risk Management, with pharmacovigilance being included in the latter category.

Summary of Key Findings:

1. Inventory of Post-Market Drug Evaluation Researchers

Characteristics of Academic and Health Care Researchers

- *Demographics:* The survey identified 354 researchers in eight Canadian provinces who were actively involved with drug evaluation research. Respondents were most frequently employed as a faculty member in an educational institution, a physician/clinician in a health care setting or a researcher in an academically-affiliated research centre, including academic hospitals. Male respondents were more likely than females to be over the age of 45 years.

- *Research Training:* While 139/354 (39%) of the respondents were academically-trained researchers (e.g., MSc, PhD), a high proportion of health care clinicians also had post-graduate training. Among the 147 physicians, 69% had additional post-graduate research degrees, and of the 55 Doctor of Pharmacy (PharmD) trained clinicians, 36% had post-graduate research degrees. The majority of respondents received their research training in Canada.

- *Clinical, Methodological and Special Population Expertise:* The diverse credentials of the respondents are reflected in the varied areas of research expertise. While four of the six core areas of expertise deemed critical to future post-market drug evaluation (Epidemiology, Biostatistics, Health Economics/Pharmacoeconomics and Pharmacoepidemiology) were frequently documented, Pharmacogenetics/ Pharmacogenomics and Patient Safety/Risk Management/Pharmacovigilance were rarely reported. Among special populations, research expertise involving marginalized populations and aboriginal peoples' health was low.

- *Professional Organization Best Aligned with Research Interests:* Four professional organizations, the Canadian Association for Population Therapeutics, Canadian Association for Health Services and Policy Research, Canadian Medical Association and the Canadian Society of Hospital Pharmacists reflect the primary clinical and methodological affiliations of the multidisciplinary respondents. These professional organizations have the potential to facilitate ongoing communication between Health Canada and active researchers.

- *Pre-Market Authorization Drug Evaluation Research Experience:* Among respondents involved with post-market drug evaluation research, 130/354 (37%) also have been involved with pre-market authorization drug evaluation research within the past five years. Researchers with pre-market authorization drug evaluation experience were more likely than researchers only involved in post-market drug evaluation research to be male, over 45 years of age and a physician based in a hospital/health care facility. In addition, these researchers more often have expertise in active comparator trials and clinical trial design, supervised graduate students, developed practice guidelines and

consented to participation in the private sector registry (e.g., industry, contract research organizations).

- *Post-Market Drug Evaluation Research Experience:* 285/354 (81%) of respondents had participated in post-market drug evaluation research within the past five years, most frequently in areas related to pharmacoepidemiology, adherence to drug therapy and health policy research. Methodological expertise was often noted in pragmatic real world observational studies, population health database studies and systematic reviews, all of which are central to future post-market drug safety and effectiveness research. In the broadest sense, many respondents who stated that they were not involved in post-market drug evaluation research are indeed actively engaged in closely related areas of research and have comparable academic credentials and research expertise as those who stated that they were involved. Thus, the findings of all respondents who answered the survey have been included in this report, to better inform readers on the scope and depth of researchers in this area of research.

- *Graduate Student Supervision:* 169/354 (48%) of respondents were actively supervising graduate students. Among survey respondents, the Université de Montréal, the University of British Columbia and the University of Toronto were the top three universities training MSc and PhD researchers in this area. A total of 283 MSc and 215 PhD students are currently in the process of completing graduate training across Canada.

- *Knowledge Translation Strategies:* While the traditional academic strategies of peer-reviewed publications and conference presentations continue to be frequently used, relatively new knowledge translation mechanisms such as educational sessions with decision-makers, collaborative research involving end users throughout the research process, summary briefings to stakeholders and electronic dissemination (e.g., webinars) are now recognized as fundamental components of knowledge translation and exchange strategies.

Past and Potential Future Involvement with Health Canada

- *Knowledge of Proposed Life Cycle Approach to the Regulation of Drug Products:* Only 142/354 (40%) of respondents reported being aware of the proposed regulatory modernization to the *Food and Drugs Act*, and of those, 42/142 (30%) had contributed to consultations in the past and an additional 20/142 (14%) had provided other forms of feedback (i.e. 62/354 (18%) of all respondents).

  The findings from this human capacity resource survey suggest that there is considerable clinical and academic expertise among Canadian researchers actively engaged in post-market drug evaluation research. Attracting new researchers to become engaged in Health Canada consultations and providing new opportunities for feedback may facilitate ongoing support for the life cycle approach to drug regulation.

- *Barriers to Data Access:* 147/354 (42%) of respondents reported onerous barriers to data access that impeded timely post-market drug evaluation research. Key issues identified included lack of timely and affordable access to population health data; lack of funding for primary data collection surveillance initiatives; lack of transparency related to pre-authorization and post-market data submitted to Health Canada by drug manufacturers; and burdensome personal health information legislation at a provincial level that has often created substantial challenges for accessing patient data.

- *Interest in Potential Research Opportunities with Health Canada:* 306/354 (86%) of respondents were interested in pursuing future research possibilities in the drug safety and effectiveness area. Among survey respondents, 82% consented to be included in a Health Canada registry, 77% consented to a public sector registry (e.g., governments, institutions), 75% to a not-for-profit registry (e.g., organizations, research networks) and 53% to a private sector registry (e.g., industry, contract research organizations). This reluctance to share expertise with the private sector suggests future impediments to successful life cycle product review driven as a primary responsibility of commercial sponsors.

2. Inventory of Educational Institutions

- *Institutions, Programs and Qualifications:* Twenty-three Canadian institutions have the potential to train students in post-market drug evaluation research, of which 21 have human health-related programs. Across the country, 31 MSc and PhD thesis-based degree programs are available, with an additional 19 post-BSc non-thesis Masters programs graduating students in various related disciplines. Approximately 500 thesis-based MSc and PhD students graduate annually, with an additional 400 non-thesis Masters graduates. Given the breadth of programs available, likely only a minority of students actually receive training specific to post-market drug evaluation research in these graduate programs.

- *Prevalence of Core Courses by Institution:* The prevalence of the six core courses essential for training in post-market drug evaluation was determined for the 23 educational institutions: Epidemiology (23); Biostatistics (21); Health Economics/ Pharmacoeconomics (15); Pharmacoepidemiology (4); Pharmacogenetics/ Pharmaco-genomics (4); and Patient Safety/Risk Management/Pharmacovigilance (4). While no institution offered all six courses, four institutions (McGill University, Université Laval, Université de Montréal and the University of Ottawa) offered five of the core courses. A diverse range of health-related non-core courses are also offered, which varied widely by educational institution.

Specific Recommendations

We recommend that:

1. Health Canada extend this human resource capacity survey of post-market drug evaluation researchers to provincial and federal governments, the not-for-profit sector, and contract research organizations to more accurately inventory post-market drug evaluation researchers, as many are working outside of academia and health care institutions.

2. Health Canada support a Task Force to develop a national syllabus that would guide universities interested in training highly qualified personnel able to support post-market drug evaluation studies, as few universities currently offer a comprehensive training program that focuses on all of the essential core courses.

3. Health Canada act to increase awareness of career opportunities that support post-market drug evaluation. To encourage these targeted recruitments, consideration should be given to the development of a national scholarship program for highly qualified personnel in this specialized research field. A national web-based distance education program may facilitate graduate student training in post-market drug safety and effectiveness research methodology, by enabling the utilization of highly trained Faculty members currently based at a limited number of universities.

4. Health Canada should foster effective partnerships and networking between academia and government on drug safety and effectiveness research through evidence-based practice centres modeled along the lines of the virtual Canadian Institute for Advanced Research (http://www2.cifar.ca/).

5. Health Canada, in partnership with the Canadian Institutes of Health Research, should administer funding for Canada Research Chairs in Therapeutic Risk Management in selected Canadian post-secondary institutions to encourage the development of additional expertise needed in this area.

6. Health Canada, in partnership with the Canadian Institutes of Health Research, should develop strategies to improve capacity in post-market drug evaluation research targeted at marginalized populations and aboriginal peoples' health in order to promote the health of all Canadians.

7. Health Canada, in partnership with the Canadian Institutes of Health Research, should facilitate international exchanges between highly qualified researchers in the area of post-market drug evaluation (e.g., European Medicines Agency) to encourage the uptake in Canada of progressive strategies in the area of drug safety and effectiveness research.

8. Health Canada should actively explore procedures that would enable sharing of population-based data across provincial boundaries, thus reducing barriers to data access and facilitating population health research relevant to optimal therapy.

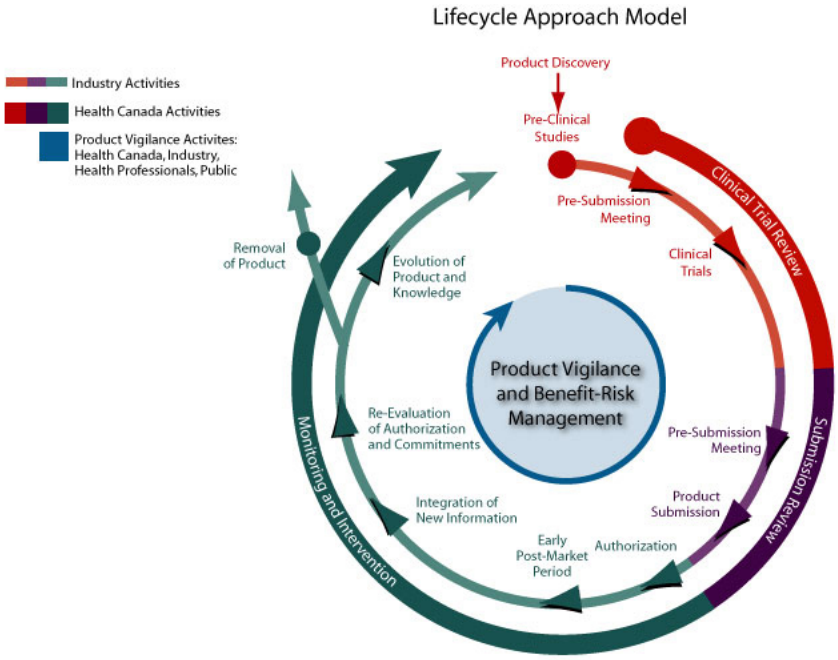
1.0 INTRODUCTION

1.1 Background

Health Canada has undertaken to modernize the legislation and regulation of pharmaceuticals and biologics.[1] This will facilitate the ongoing monitoring of safety, effectiveness and quality throughout the life cycle of these therapeutic products. The life cycle phases will include pre-market applications, authorization and entry onto the market, and post-market surveillance on the safety and effectiveness of these therapeutic products in the real world environment. This approach will support access to new therapies, the continuous monitoring, assessment and communication of product information on benefits and risks, and contribute to the safe use of therapeutic products. It is recognized that implementation of these new regulatory requirements may impact scientific experts among academia and healthcare settings through the conduct of mandated post-market drug evaluation research studies.

Presently, a sponsor (which may or may not be the pharmaceutical industry) files a New Drug Submission to Health Canada containing scientific, animal and clinical study data generated in pre-authorization phases of drug development (Figure 1).[2] Once the sponsor receives the Notice of Compliance and is authorized to market the therapeutic product, then the manufacturer is responsible for preparing periodic safety update reports which may be submitted to Health Canada upon request. The regulatory measures currently in place were initially incorporated into the *Food and Drugs Act* in the 1950s and 1960s and the *Food and Drug Regulations* were enhanced with requirements for clinical trials to establish efficacy in response to the thalidomide disaster.

FIGURE 1: The Life Cycle Approach Model



The benefits of the life cycle approach include supporting health care professionals and patients in making informed decisions based on the best information available, and in supporting the early identification of risks and implementing successful risk management activities. It is recognized that this post-market drug evaluation research will be of particular importance for chronic use drugs, special populations (e.g., children, elderly, pregnant women, rare diseases), and real world use in conditions of concomitant drug use and co-morbidity. Internationally, jurisdictions such as Europe have already begun the process of improving pharmacoepidemiological research and post-market safety surveillance through the development of the European Medicines Agency and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance.[3] In the United States, recent initiatives related to the *American Recovery and Reinvestment Act of 2009*[4] are also designed to support better decision-making that will improve health care at both the individual and population levels.[5]

In February 2006, a conference entitled "Toward a National Pharmaceuticals Strategy" was sponsored by the Centre for Health Services and Policy Research in Vancouver, BC.[6] National and international experts discussed key issues facing post-market drug evaluation research. Those deliberations helped to put into context the need for this Health Canada Report *"Human Resource and Educational Inventories to Support the Life Cycle Approach to the Regulation of Therapeutic Products"*. The conference speakers emphasized the need for monitoring real world drug safety through post-market surveillance:

> *"We have to stop thinking of the regulatory process as a black box and think of it as a continuous stream. Once products are on the market, we still need to look for evidence of safety."* *Dr. Mary Wiktorowitz*

While Health Canada was encouraged to expand the scope of its oversight role to regulate post-market Phase IV studies and facilitate dissemination of information to health care providers, it was recognized that:

> *"[R]esearch talent is in desperately short supply. Researchers are a very limited resource, and people who want to work with governments and decision-makers are at a real disadvantage in terms of their academic life."*
>
> *Dr. Geoff Anderson*

Given the intention to modernize the regulation and legislation of therapeutic products, a key question for Health Canada is whether there are adequate numbers of highly qualified academic and clinical scientists in Canada able to conduct the necessary post-market drug evaluation research mandated by the new regulatory requirements, as well as to evaluate the ongoing post-market submissions of drug safety and effectiveness research.

1.2 Project Objectives

The goal of this research was to identify and characterize the human resource pool available in Canadian academic institutions, research centres and institutes, and healthcare organizations able to support the proposed product life cycle approach to the regulation of therapeutic products.

1. The first objective was to identify researchers in Canada involved with post-market drug evaluation research, characterize the training and expertise of the researchers, document the number of graduate students being trained in this area, and determine the level of interest of researchers in becoming further involved with post-market drug evaluation research in the future.

2. The second objective was to identify educational institutions and programs in Canada able to train graduate students in post-market drug evaluation research methodology, determine program characteristics, classify relevant courses by subject area and establish the prevalence of core courses by institution.

The findings from these inventories will provide a baseline for how to approach the change management aspects for the implementation of the product life cycle approach to the regulation of therapeutic products.

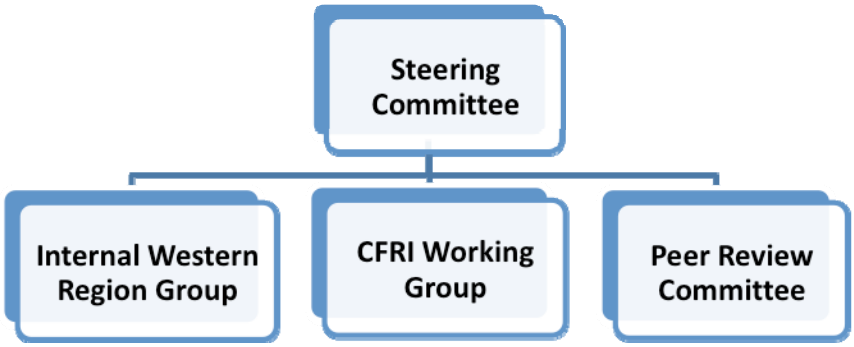
2.0 METHODOLOGY

2.1 Project Management

This research initiative was a joint project that originated with Dr. Stuart MacLeod, the Executive Director of the Child and Family Research Institute (CFRI) located at the Children's and Women's Health Centre of British Columbia in Vancouver, BC and David K. Lee, Director, the Office of Legislative and Regulatory Modernization within the Health Products and Food Branch of Health Canada. It was thought desirable to evaluate the human resource capacity available to support enhanced post-market pharmacosurveillance in preparation for legislative modernization.

The Steering Committee provided oversight for the project, and was comprised of David K. Lee (Director), Dr. Maurica Maher (Associate Director), and Robyn Brake (Project Coordinator) of the Office of Legislative and Regulatory Modernization; Dr. Stuart MacLeod (Executive Director, CFRI); and Brian Mori (Regional Director, Regions and Programs Branch, Western Region) (Figure 2). The design, conduct, management and dissemination of the project was carried out under the domain of the CFRI Working Group, which included Dr. Stuart MacLeod (Executive Director, CFRI); Dr. Judith Soon (Senior Policy Research Officer, Policy, Planning and Outreach, Regions and Programs Branch, Western Region and Assistant Professor, Faculty of Pharmaceutical Sciences, University of British Columbia); Dr. Sunaina Sharma (Head, Policy, Planning and Outreach, Regions and Programs Branch, Western Region and Senior Advisor and Stakeholder Liaison); and Dr. Matthew Wiens (Research Assistant and Fraser Health Authority).

FIGURE 2: Governance of the Human Resource Capacity Project



Advice on the development, conduct and dissemination of the survey for academic researchersand on the collection of data on educational institutions providing relevant graduate training programs was provided by the Peer Review Committee (Table 1). The committee was composed of ten academic and professional stakeholders from across Canada who had a diverse range of expertise in pharmacoepidemiology, pharmacoeconomics, outcomes research and drug policy. These experts provided an in-depth understanding of national and international issues related to the life cycle approach to drug evaluation and post-market benefit-risk management strategies. During the course of the study, two Peer Review Committee meetings were conducted via teleconference. A joint Health Canada/Child and Family Research Institute Workshop was conducted on April 18, 2009 in Montreal for members of the Peer Review Committee and other key stakeholders to provide opportunities for feedback and suggestions for next steps. To encourage open communication, the CFRI Working Group apprised the Internal Western Region Group (Regional Director and Head, Policy, Planning and Outreach) of the progress of the study as appropriate.

TABLE 1: Peer Review Committee Members

Name	Affiliation	Area of Research
Dr. Jean-Paul Collet	University of British Columbia	Pragmatic trials, pharmacoepidemiology
Dr. Jean Gray	Dalhousie University	National drug policy, clinical pharmacology
Dr. Jean-Pierre Grégoire	Université Laval	Pharmacoepidemiology
Dr. Andreas Laupacis	University of Toronto	Knowledge translation, epidemiology
Dr. Jacques LeLorier	Université de Montréal	Pharmacovigilance, economics
Dr. Colleen Maxwell	University of Calgary	Community-based research
Dr. Yola Moride	Université de Montréal	International risk management, pharmacoepidemiology
Dr. Robert Peterson	University of British Columbia	Clinical trial design, pediatric pharmacology
Dr. Jeff Poston	Canadian Pharmacist Association	Pharmaceutical policy research
Dr. Noralou Roos	University of Manitoba	Health policy research

2.2 Inventory of Post-Market Drug Evaluation Researchers

2.2.1 Scope

The CFRI Working Group was asked by the Steering Committee to compile an inventory of academic and health care institutional researchers who are involved with clinical, epidemiological, economic and outcomes research studies to optimize the use of medications. The activities involved included:

- Design an appropriate mechanism of elucidating the human resource capacity of Canadian researchers who are involved with clinical, epidemiological, economic and outcomes research studies to optimize the use of medications;
- Identify and consult with key informants in the Office of Legislative and Regulatory Modernization, government agencies, universities, colleges, and professional and academic healthcare organizations regarding the identification of individuals and organizations to be contacted for the project;
- Contact all individuals and organizations identified in Canada as having relevant life cycle approach support capacity to complete the survey;
- Conduct and analyze the information collected;
- Generate a comprehensive inventory of relevant health care professional, research and knowledge translation capabilities, including identification of professional organizations with related expertise;
- Prepare and deliver preliminary findings to Health Canada personnel, Peer Review Committee members and key academic stakeholders at a joint Health Canada/CFRI Workshop;
- Draft a report to be made available for discussion with Health Canada; and
- Provide a final report with an executive summary.

2.2.2 Participants

The target population invited to participate in the study were health researchers potentially involved in a broad sense with post-market drug evaluation research in a Canadian academic institution, research centre, research institute or a health care institutional setting. Researchers in a federal or provincial government setting, in the pharmaceutical industry or in contract research organizations were excluded from this evaluation.

The search strategy to locate researchers actively engaged in post-market drug evaluation research progressed in three phases.

- In the first phase, an extensive and diverse range of individual researchers with possible involvement in studies of approved drugs for humans was located through a variety of mechanisms, including personal contacts. Initially, each of the 21 academic institutions with graduate training programs in human health identified through the Educational Institution Inventory (see section 2.3) was reviewed. The university web-based profiles of

Faculty members in Medicine, Pharmacy, Population and Public Health, Health Services and related departments were evaluated for potential involvement in post-market drug evaluation research. Online sites of university-affiliated research centres and institutes, teaching hospitals and institutional healthcare settings were also explored and web-based profiles of researchers and clinicians reviewed. Websites of funding agencies (e.g., Michael Smith Foundation for Health Research, Alberta Heritage Foundation for Medical Research, Canadian Institutes of Health Research, Nova Scotia Health Research Foundation) were searched to locate additional researchers with successfully funded drug evaluation-related projects within the past five years. Once an individual researcher was identified, then the researcher was sent a personally addressed e-mail invitation to participate in the study, with an internet link in the message to the online-based survey (see Appendix 1A, 1B).

- The second phase of identifying potentially eligible researchers involved collaborating with healthcare organizations that had members involved in conducting clinical, epidemiological, economic and outcomes research studies designed to optimize the use of medications. These professional organizations included the Association of Canadian Academic Healthcare Organizations, the Canadian Association of Population Therapeutics, the Canadian College of Clinical Pharmacy, the Canadian Pharmacists Association, the Canadian Society of Hospital Pharmacists, the Canadian Society of Pharmacology and Therapeutics, and the Quebec Network for Medication Use Research (Réseau québécois de recherche sur l'usage des medicaments). Personal contacts within these organizations selectively forwarded the invitation to participate in the survey to individual researchers who they identified as being involved in drug evaluation research (see Appendix 1C).

- The final phase of locating experienced researchers engaged in this area of research was through the three Health Canada Directorates involved in drug assessments: the Biologic and Genetic Therapies Directorate, the Marketed Health Products Directorate, and the Therapeutic Products Directorate. In each Directorate, the Manager of the External Scientific Database forwarded the invitation to participate in the study to individual researchers within the Directorate database.

2.2.3 Survey Instrument

The self-administered online survey was designed to obtain descriptive information to further the understanding of the human resource capacity of drug evaluation researchers in Canada (see Appendix 1D). The survey instrument was constructed in eight sections. The initial section posed demographic questions related to characteristics of age, gender, principal employment role and research location. Respondents were then asked questions related to the type(s) of post-graduate degrees they had attained and the location of those training sites, to gain an appreciation for the contribution of Canadian post-graduate research training institutions to current researchers in the field. Research expertise was investigated through questions related to clinical expertise (e.g., cancer, rheumatology), methodological expertise (e.g., active comparator clinical trials, systematic reviews), and expertise among special populations (e.g., marginalized populations, senior's health). To discover the professional organizations that best

align with research in this area, respondents were requested to select the professional organization of which they were a member that best supported their research interests.
A key question incorporated into *Section 5: Drug Research Experience* (Question 5.1) asked the respondent if they had been involved in post-market drug evaluation research following completion of their post-baccalaureate studies. This question was placed at this point in the survey so that respondents would have a more comprehensive idea of the broad scope that was intended by the terminology "post-market drug evaluation research". Additional questions in this section asked whether they had been involved in pre-authorization drug research, and if yes, the types of pre-authorization research that they had conducted. Respondents were also asked questions about the length of time that they had been involved in post-market drug evaluation research, the recent conduct of post-market drug evaluation studies and information on three recent publications in this area of research. To quantify the number of MSc and PhD training opportunities currently available, respondents were asked whether they had supervised graduate students in the area of post-market drug evaluation research in the past five years. If they had, then they were asked for the number of MSc and PhD students currently being supervised, and the number of students supervised who had completed MSc or PhD qualifications within the past five years. With the increasing importance of knowledge dissemination and translation, a question was also posed on the most frequent knowledge translation strategies that the researcher had utilized.

Strategies to modernize the drug regulatory structure of Health Canada have evolved over the past two decades, with a number of previous initiatives that have engaged academic researchers in the deliberations. Questions in *Section 8: Modernization of the Food and Drugs Act* were designed to explore the familiarity that researchers had with the current initiative to modernize the *Food and Drugs Act* and whether they had been involved in consultations or other forms of feedback during previous Health Canada initiatives. Respondents were also asked if they would be willing to become involved with future post-market drug evaluation studies, and whether they would consent to be included in a *Registry of Post-Market Drug Evaluation Researchers*. Anecdotally, researchers involved with pharmacoepidemiology and other forms of outcomes research have described onerous barriers to timely access to data, particularly data housed within provincial administrative health databases. To explore this issue, an open-ended question was asked related to barriers to data access that limit the involvement of researchers in post-market drug evaluation research. The final question provided respondents the opportunity to recommend the names and contact information of colleagues involved in this area of research who might be interested in participating in the survey.

2.2.4 Pre-Testing and Pilot Testing

Pre-testing of the questions occurred in a multistage, cumulative process between November 24 and December 22, 2008. The initial pilot survey and draft letter of invitation were distributed via the SurveyMonkey.com internet-based survey program to the three Steering Committee members in the Office of Licensing and Regulatory Modernization, the ten Peer Review Committee members and six academic researchers at universities in British Columbia, Manitoba and Quebec. Respondents to the pilot test version of the survey provided constructive comments on the format, content and phrasing of questions, suggested modifications to the sections within the survey, and feedback on the time required to complete the questionnaire. Once the suggestions were incorporated into the final draft survey, the cover letter of invitation and the survey were translated into French by Health Canada translators. The translated materials were validated by two francophone members of the Peer Review Committee. A second pilot of the final version of the survey was distributed from February 18 to 22, 2009 using the Applied Research and Evaluation Services server.

2.2.5 Survey Administration

Applied Research and Evaluation Services at the University of British Columbia in Vancouver, Canada was retained as an independent third party to facilitate distribution of the internet-based survey, track the population of respondents and compile respondent data in a Microsoft Excel 2007 workbook. The predominantly close-ended questions were formatted to permit a completion time of about 10 to 12 minutes and for ease of automated data entry. The in-house Applied Research and Evaluation Services server was able to ensure the highest level of data security.

Survey distribution began on February 23, 2009 and closed six weeks later on April 4, 2009. The e-mail letter of invitation to participate included the URL address of the internet-based questionnaire (English: http://ares.ubc.ca/HealthCanada2009/DrugEvaluation_E.asp; French: http://ares.ubc.ca/HealthCanada2009/DrugEvaluation_F.asp). Non-responders were sent a follow-up e-mail reminder ten days later, with a subsequent reminder sent to remaining non-responders ten days afterwards. Reminder e-mails included additional encouragement to complete the survey, as well as the link to the online questionnaire. Return rates were monitored throughout the distribution period. English versions of the invitation were provided to all individual researchers and organizations residing in provinces other than Québec. Individual researchers and organizations based in Québec were provided with French or bilingual versions of the invitation, with online links to both the French and the English versions of the survey.

The surveys were distributed through Applied Research and Evaluation Services in three phases (see Section 2.2.2). Phase 1 involved directly e-mailing the survey to individual researchers deemed eligible to participate in the study, while in Phase 2, the survey was e-mailed to a key senior administrator (e.g., Vice President or Director of Research) within an organization, who then forwarded the invitation to researchers with encouragement to complete the brief survey. To maintain confidentiality, in Phase 3, the Health Canada

Stakeholder liaison on the project contacted the Managers of the External Scientific Databases in the Biologic and Genetic Therapies Directorate, the Marketed Health Products Directorate, and the Therapeutic Products Directorate, who then forwarded the invitation to participate to individual researchers within the Directorate database.

2.2.6 Research Ethics Board Approval

Human Ethics approval was granted by the University of British Columbia Behavioural Ethics Review Board (H08-02048) and the Children's and Women's Health Centre of British Columbia (CW09-0002). Ethics approval was also provided by the Health Canada Research Ethics Board (HC REB 2008-0044).

2.2.7 Data Analysis

Non-response to the survey was evaluated. Completed surveys were analyzed descriptively with the individual respondent as the primary unit of analysis. Frequencies and crosstabs were utilized where appropriate. Data were aggregated by participation in pre-authorization and in post-market drug evaluation research and by research affiliation for graduate student supervision.

2.3 Inventory of Educational Institutions

2.3.1 Scope

Current efforts to modernize the *Food and Drugs Act* and its regulations will greatly strengthen post-market drug evaluation activities such as pharmacovigilance and risk management. With increased post-market drug evaluation research activities, it will be imperative to ensure that adequate training sites are available throughout the country to train new researchers able to support the proposed life cycle approach to the regulation of therapeutic products. The objective of this educational institution inventory was to conduct an environmental scan of educational institutions in Canada that may be able to train students in areas of post-market drug evaluation research. Furthermore, we wished to determine the prevalence of core courses which we deemed essential in the training of post-market drug evaluation researchers.

2.3.2 Data Sources

We conducted a systematic web-based environmental scan of all Canadian educational institutions to determine which graduate programs have the capability to train students in the discipline of post-market drug evaluation research. A list of potentially eligible universities was abstracted from the 2008 MacLean's Guide to Canadian Universities.[8] Initially, all universities with Medical Doctoral programs were selected. The website of each university was examined for potential academic programs able to train researchers in the area of post-market drug evaluation research. A program of interest included any health-related graduate program that taught courses in epidemiology and biostatistics. In addition, all graduate programs in

epidemiology, public health, pharmacy, veterinary medicine and health informatics were eligible and were included.

2.3.3 Data Extraction and Analysis

Information from all eligible graduate training programs was abstracted onto Microsoft Excel 2007 worksheets [Microsoft Corporation, Redmond WA]. Program details that were recorded included numbers of graduates, the typical duration of graduate programs, contact information and related characteristics. Furthermore, program courses were reviewed and categorized into 14 course categories relevant to post-market drug evaluation research. Courses which did not fall into one of these categories were excluded. Of the 14 course categories identified, 6 were deemed to be core course categories essential to the training of researchers able to support the future requirements of the life cycle approach to post-market drug evaluation research. The core course categories were decided by consensus among the members of the CFRI Working Group investigators and included the following courses: (1) biostatistics; (2) epidemiology; (3) pharmacoepidemiology; (4) health economics and/or pharmacoeconomics; (5) pharmacogenetics and/or pharmacogenomics; (6) patient safety and/or risk management and/or pharmacovigilance.

The prevalence of courses by category was summarized by institution. Prevalence by institution rather than by graduate program was considered to be a better marker of course availability, as it was assumed that students could take courses offered by other programs at their institution.

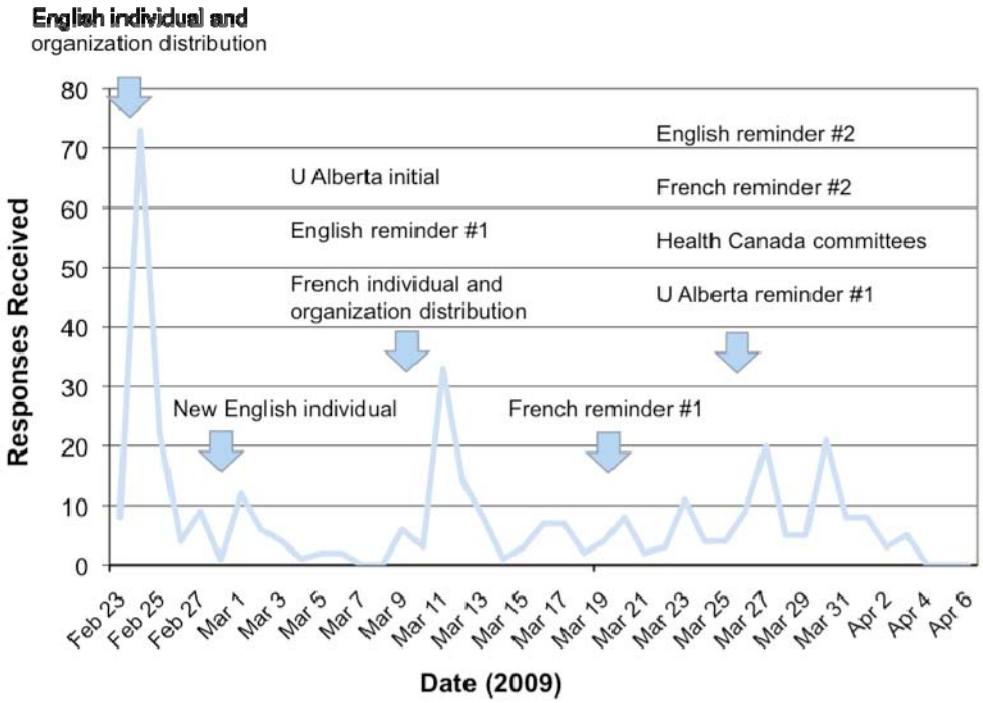
3.0 RESULTS

3.1 Inventory of Post-Market Drug Evaluation Researchers

3.1.1 Submission of Responses to the Online Survey

The timeline for the distribution of the online surveys is noted in Figure 3. Spikes in the submission of survey responses occurred within two days of distributing the invitation, with smaller peaks following the delivery of the follow-up reminders.

FIGURE 3: Online Survey Submissions



In the Phase I distribution of the survey, 777 individual researchers across Canada were personally invited to complete the survey. Of those, 138/777 (17.8% of invited participants) notified the research team either personally or by an automated email message that they would not complete the survey. Reasons included the lack of involvement in post-market drug evaluation research (60); the e-mail invitation was undeliverable after multiple attempts (38); the researcher was away for a prolonged period of time extending past the close date for the survey (34); or the researcher notified the investigator that they had retired (6).

Of the 639 invited researchers potentially available to participate in the study, 264/639 (41.3%) researchers completed the questionnaire during the survey period. Reasons for non-response were monitored and compared to the characteristics of those who did respond (Table 2). The response rates were slightly higher among those in academia and research centres than those in health care settings. The time that the invitation was distributed also had an impact on survey completion, as those who received the invitation the first week subsequently received two follow-up invitations. For a number of individuals who received the survey the first week, the follow-up reminders prompted an email reply to the investigator stating that they were not involved in post-market drug evaluation research at this time. The response rate varied between provinces, ranging from a high of 62.5% in Newfoundland to a low of 30.4% in Alberta.

TABLE 2: Evaluation of Non-Response to Individualized Invitations

Characteristic	Responders (%) (n = 264)	Non-Responders (%) (n = 375)	Individuals Invited and Potentially Eligible (%) (n = 639)
Research Location			
Academia (%)	139 (42.9)	185 (57.1)	324 (100)
Research Centre	108 (40.3)	160 (59.7)	268 (100)
Health Care Setting (%)	13 (31.0)	29 (69.0)	42 (100)
Consultant (%)	3 (100.0)	0	3 (100)
Association (%)	1 (50.0)	1 (50.0)	2 (100)
Time of survey			
February 22 - 23, 2009 (%)	220 (45.4)	265 (54.6)	485 (100)
March 9 – 11, 2009 (%)	25 (32.1)	53 (67.9)	78 (100)
March 20 – 29, 2009 (%)	19 (25.0)	57 (75.0)	76 (100)
Response rate by province			
BC	85	126	40.3
AB	35	80	30.4
SK	5	6	45.5
MB	13	9	59.1
ON	70	94	42.7
QC	28	33	45.9
NB	0	3	0
NS	18	18	50.0
NL	10	6	62.5

Survey respondents were provided with the opportunity to recommend colleagues to be invited to complete the survey. While many of the researchers recommended by respondents had already been invited to participate in the survey, the names of an additional 29 new invitees were proposed, and of those, five completed the survey.

As described in section 2.2.2, the second phase of invitations to complete the survey was distributed with the assistance of administrators within Canadian research groups and professional organizations. A total of 62 senior administrators were contacted and encouraged to distribute the survey to pertinent researchers in their organization. Eighty-seven (87) respondents completed the survey through this process. The most common work sites for the respondents who received this indirect invitation were in a health care setting (44/87 (50.6%)), followed by 21/87 (24.1%) in an academic setting, 13/87 (14.9%) in a research centre, and 9/87 (10.3%) in a variety of other work environments. It is of interest that 49/87 (56.3%) of the indirect respondents were from three specific locations: 27 affiliated with the University of

Toronto and University Health Network; 13 affiliated with McGill University; and 9 from Queen's University in Kingston.

Invitations were also extended by the Managers of the External Scientific Databases in the Biologic and Genetic Therapies Directorate, the Marketed Health Products Directorate, and the Therapeutic Products Directorate to researchers on their Expert Advisory Committees. Of the 17 respondents who self-identified as members of a Health Canada Expert Advisory Committee in their survey response, 14 had been individually invited in the first phase of the invitations and three respondents completed the survey following internal distribution by Health Canada Directorate managers.

This exploratory study was designed to locate as many researchers in Canada as possible who were actively involved with post-market drug evaluation research. By incorporating an extensive network of professional, organizational and government networks of contacts in the area, as well as actively encouraging recipients to forward the invitation and to refer colleagues to the investigators, it is anticipated that the majority of researchers actively involved with post-market drug evaluation research in Canada will have received at least one invitation to participate. Support for this claim occurred when following up with a Quebec opinion-leader actively involved in this area of research, who commented:

> *" All Quebec pharmacoepidemiologists have received multiple e-mails regarding your survey. I don't know why they haven't filled it out yet."*

Nevertheless, given that 60 researchers took the time to notify the investigators that they were not currently involved with post-market drug evaluation research, it is likely that many of the remaining non-respondents also were not actively involved in the area at this time. Thus, the 354 completed surveys form the basis for the exploration of the characteristics of health services and population health researchers currently involved with post-market drug evaluation research in Canada.

3.1.2 Demographic Overview

3.1.2.1 Age and Gender

The largest proportion of drug evaluation researchers were in the 35 to 44 year old age range (Table 3). These findings are promising, and suggest the presence of a cohort of younger researchers interested in post-market drug evaluation research who will be able to support the proposed life cycle approach to therapeutic product regulation on an ongoing basis. Among the female respondents, 75/144 (52.1%) were less than 45 years of age compared with 81/210 (38.6%) of the male respondents.

TABLE 3: Age Distribution by Gender

Demographic Characteristic	Female (%) (n=144)	Male (%) (n=210)	Total Responses (%) (n=354)
Age (years)			
< 35	16 (11.1)	13 (6.2)	29 (8.2)
35 – 44	59 (41.0)	68 (32.4)	127 (35.9)
45 – 54	46 (31.9)	65 (31.0)	111 (31.4)
> 55	21 (14.6)	59 (28.1)	80 (22.6)
Missing	2 (1.4)	5 (2.4)	7 (2.0)

3.1.2.2 Principal Employment Role

Researchers are frequently required to take on multiple roles within academia, research centres and health care settings. Survey respondents were asked to designate a principal role for their employment activities (Table 4). The most prevalent roles were those of a Researcher 103/354 (29.1%), a Faculty member 100/354 (28.2%) and a Clinician – Physician 60/354 (16.9%). While post-doctoral/medical fellows and graduate students were not individually invited during the first phase of the invitation process due to a lack of consistent contact information on institutional websites, they had the opportunity to become involved when recommended by respondents and by indirect invitation through professional, academic and health organizations.

TABLE 4: Principal Employment Role

Principal Employment Role	Total Responses (%) (n=354)
Researcher	103 (29.1)
Faculty member	100 (28.2)
Clinician – Physician	60 (16.9)
Clinician – Pharmacist	24 (6.8)
Administrator	23 (6.5)
Clinician/Scientist	16 (4.5)
Independent consultant	12 (3.4)
Post-doctoral/Medical fellow	6 (1.7)
Graduate student	5 (1.4)
Health policy decision maker	3 (0.8)
Other	2 (0.6)

3.1.2.3 Principal Research Location

Table 5 reports the type of research site that respondents designated as their principal location for the conduct of research. Educational institutions were most commonly cited (140/354 (39.5%), followed by Hospital and Health Care Settings 116/354 (32.8%), and Research Centres 61/354 (17.2%).

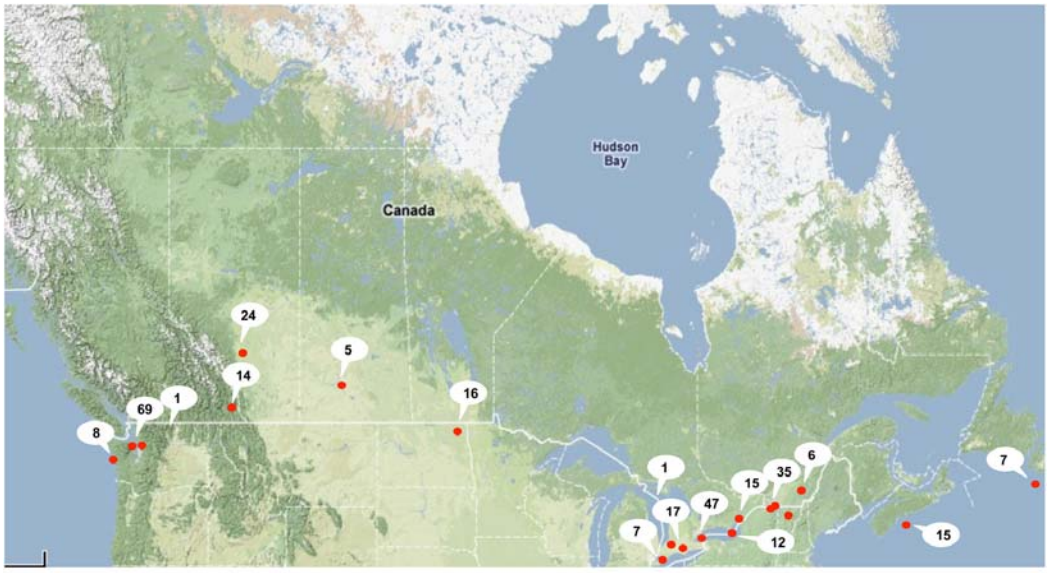
TABLE 5: Principal Research Location

Principal Research Location	Total Responses (%) (n=354)
Educational institution	140 (39.5)
Hospital/health care setting	116 (32.8)
Research Centre	61 (17.8)
Non-Profit organization	14 (4.0)
Health authority	11 (3.1)
Other	8 (2.3)
Private Practice	4 (1.1)

3.1.2.4 Geographic Location of Research Site

Survey respondents were from diverse locations across Canada, spanning from Victoria, British Columbia in the west to St. John's, Newfoundland in the east, and London, Ontario in the south and Edmonton, Alberta in the north (Figure 4). Most researchers are located in close proximity to one of the 21 educational training institutions with a focus on human research (see Section 3.2). All provinces except Prince Edward Island and New Brunswick and the three territories were represented in the survey.

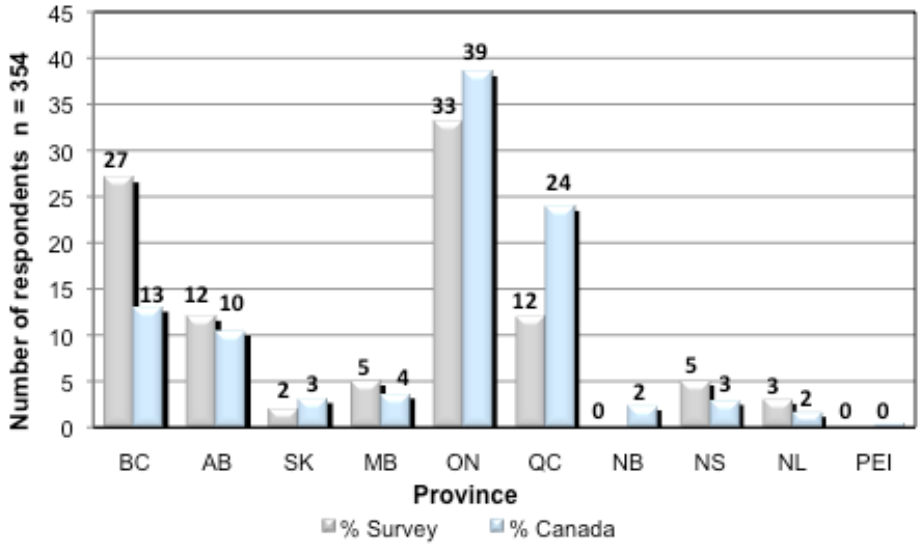
FIGURE 4: Geographic Location of Survey Respondents



3.1.2.5 Provincial Distribution of Respondents

The relative distribution of researchers across the provinces was compared to the relative Canadian population in each province (Figure 5). While the proportion of respondents in most provinces was similar to the proportion of residents in the Canadian Census 2006, British Columbia was over-represented and Quebec under-represented. As many of the active British Columbian researchers were known to the investigators, this may have contributed to the number of respondents in that province. Within Quebec, key opinion leaders in the field were involved with facilitating the distribution of the survey invitations through established professional, organizational and healthcare Quebec networks to supplement the invitations sent to individual researchers known to the investigators.

FIGURE 5: Relative Provincial Distribution of Survey Respondents



3.1.3 Training of Respondents

3.1.3.1 Academic Credentials

Three hundred and forty-two (342) of the 354 respondents (96.6%) had one or more post-baccalaureate degrees. The post-baccalaureate degrees attained by the respondents are listed in Table 6. For consistency, medical degrees are considered a post-baccalaurate professional degree. Among the respondents with professional clinical degrees, there were 147/354 (41.5%) with medical degrees and 55/354 (15.5%) with graduate PharmD degrees: one individual had both a medical and a PharmD degree. As noted in Table 6, a substantial number of physicians and PharmDs had both clinical and post-graduate academic credentials.

Among respondents, there were a total of 140 research-oriented MSc degrees. Moreover, there were an additional 62 Masters degrees in areas complementary to post-market drug evaluation research, including Public Health (17), Business Administration (12), Economics (12), Public Policy (5), Arts (9), Education (3), Health Administration (2) and Public Administration (2).

TABLE 6: Highest Academic Qualification

CLINICIANS:	Number of respondents	Total
Medical Doctor (MD):		**146**
MD	46	
MD + MSc	40	
MD + Masters (other)	11	
MD + MSc + Masters (other)	2	
MD + PhD	27	
MD + MSc + PhD	10	
MD + Masters (other) + PhD	5	
MD + MBA + LL.M.	1	
MD + ScD	4	
Doctor of Pharmacy (PharmD)		**54**
PharmD	35	
PharmD + MSc	14	
PharmD + Masters (other)	3	
PharmD + MSc + PhD	1	
PharmD + PhD	1	
Medical Doctor + PharmD + MSc	1	**1**
ACADEMICS:		
Masters Degree		**32**
MSc	21	
MSc + Masters (Other)	2	
Masters (other)	9	
Doctor of Philosophy (PhD)		**105**
MSc + PhD	39	
Masters (Other) + PhD	9	
MSc + Masters (Other) + PhD	7	
PhD	50	
Doctor of Science (ScD)		**2**
MSc + ScD	2	
OTHER EXPERTISE		
Other Post- Baccalaureate		**2**
Lawyer (LL.B, LL.M.)	1	
Biomedical engineer	1	
Non-Post-Baccalaureate		**12**
Pharmacist (BSc)	5	
Nurse	2	
Advocate - Clinical Trials	2	
Biotechnologist	1	
Economist (BSc Economics)	1	
Statistician (BSc Statistics)	1	
TOTAL		**354**

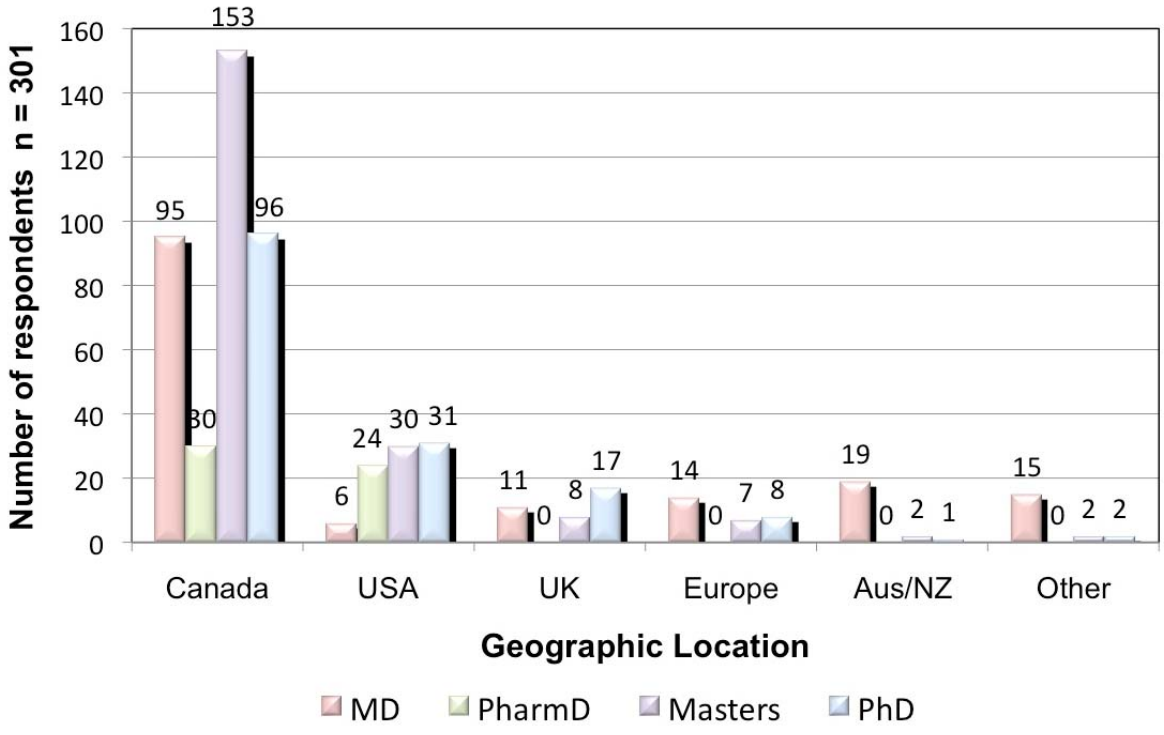
In total, 155/354 (43.8%) respondents had doctoral degrees, and of those, 149/155 (96.1%) had a PhD and 6/155 (3.9%) had a ScD. Of those with doctorates, 103 respondents had one or more additional clinical or academic credentials, enhancing their ability to bring multiple perspectives and technical skills to drug evaluation research.

Of the 12 respondents without a post-baccalaureate degree, five were pharmacists, two were nurses, two were community advocates involved with clinical trials, and the remaining respondents were an economist, a statistician and a biotechnologist. Three of the respondents with post-baccalaureate degrees had training outside of traditional scientific expertise, two as a lawyer (one also a physician) and the other as a biomedical engineer.

3.1.3.2 Geographic Location where Advanced Degree(s) Obtained

Survey respondents obtained their various post-baccalaureate degrees in the geographic locations documented in Figure 6. The majority of researchers were trained in Canada: 95/147 (64.6%) physicians; 31/55 (56.4%) PharmDs; 153/202 (75.7%) Masters; and 98/155 (61.9%) Doctorates. The relatively low number of PharmDs trained in Canada reflects that the first post-baccalaureate Canadian-trained PharmDs graduated from UBC in 1993, followed by the University of Toronto in 1994. Of interest to note, numerous researchers with multiple post-baccalaureate degrees have travelled to other countries to complete either a Masters or Doctoral degree, thus obtaining specialty training and new perspectives of value to Canadian research initiatives.

FIGURE 6: Location of Graduate Training



3.1.4 Areas of Research Expertise

3.1.4.1 Clinical Expertise

Respondents were given the opportunity to provide up to five areas of clinical expertise (Table 7). The top five areas of clinical expertise noted by the 286/354 (80.8%) respondents were Pharmacology (34.6%), Internal Medicine (23.1%), Cardiology (18.2%), Infectious Diseases (14.3%) and Mental Health (12.6%). The non-responders reflected those with Masters or Doctorates who did not have a strong clinical background in medicine, pharmacy, nursing or other health care field.

TABLE 7: Top Areas of Clinical Expertise

Clinical Expertise	Total Responses (%)* (n=286)
Pharmacology	99 (34.6)
Internal medicine	66 (23.1)
Cardiology	52 (18.2)
Infectious disease	41 (14.3)
Mental health	36 (12.6)
Cancer	35 (12.2)
Endocrine/Metabolism	33 (11.5)
Geriatrics/Gerontology	29 (10.1)
Musculoskeletal	26 (9.1)
Paediatrics	25 (8.7)
Critical Care	22 (7.7)
Rheumatology	18 (6.3)
Neurology	18 (6.3)
Pulmonology	17 (5.9)
Gastroenterology	15 (5.2)
Obstetrics/Gynecology	13 (4.5)
Hematology	11 (3.8)
Allergy/Immunology	11 (3.8)
Surgery	9 (3.1)
Anesthesia	7 (2.4)
Transplant	7 (2.4)
Orthopedics	3 (1.0)
Radiology	2 (0.7)
Ophthalmology	1 (0.3)
Other	106 (29.9)
* As researchers may select up to five areas of expertise, the percentages do not add up to 100%.	

3.1.4.2 Research Expertise

Table 8 summarizes information that respondents provided on their top five areas of research expertise. The diverse academic credentials of the respondents are reflected in the varied areas of research expertise. Three hundred and forty-six of the 354 (97.7%) respondents provided answers to this question, suggesting that the research interests of the respondents were closely aligned with the areas involved with post-market drug evaluation research.

TABLE 8: Top Areas of Research Expertise

Clinical Expertise	Total Responses (%)* (n=346)
Epidemiology[1]	119 (34.4)
Pharmacoepidemiology[4]	96 (27.7)
Health policy research	95 (27.5)
Clinical trial design	91 (26.3)
Systematic reviews	80 (23.1)
Active comparator clinical trials	69 (19.9)
Adherence to drug therapy	65 (18.8)
Health economics[3]	64 (18.5)
Health technology assessment	64 (18.5)
Adverse drug reaction monitoring[6]	62 (17.9)
Patient safety[6]	54 (15.6)
Clinical pharmacy practice	54 (15.6)
Population data management	53 (15.3)
Meta-analyses	40 (11.6)
Biostatistics[2]	37 (10.7)
Pharmacokinetics	30 (8.7)
Decision analytic modeling	27 (7.8)
Health informatics	24 (6.9)
Patient decision aids	22 (6.4)
Qualitative methodology	20 (5.8)
Toxicology	15 (4.3)
Pharmacogenetics[5]	15 (4.3)
Pharmacogenomics[5]	11 (3.2)
Risk management[6]	11 (3.2)
Risk minimization interventions[6]	9 (2.6)
Bioethics	8 (2.3)
Other	69 (19.9)

* As researchers may select up to five areas of expertise, the percentages do not add up to 100%.
[1–6] These areas of research expertise reflect the core areas evaluated in the Educational Institution Inventory: [1]Epidemiology, [2]Biostatistics, [3]Health Economics, [4]Pharmacoepidemiology, [5]Pharmacogenetics/Pharmacogenomics and [6]Patient Safety/Risk Management/ Pharmacovigilance.

In the Educational Institution Inventory, six core research areas were considered to be essential to support the proposed life cycle approach to drug regulation: Epidemiology, Biostatistics, Health Economics, Pharmacoepidemiology, Pharmacogenetics/ Pharmacogenomics and Patient Safety/Risk Management/Pharmacovigilance. Three of these core areas are represented among the top ten areas of research expertise reported by the respondents: epidemiology (34.4%), pharmacoepidemiology (27.7%) and health economics (18.5%). Other core components of adverse drug reaction monitoring (17.9%), patient safety (15.6%) and biostatistics (10.7%) were less commonly reported. The limited expertise reported by respondents in the areas of pharmacogenetics (4.3%), pharmacogenomics (3.2%), risk management (3.2%) and risk minimization interventions (2.6%) is of potential concern.

3.1.4.3 Special Populations Expertise

In the future, there will be increasing opportunities for investigation into patient safety and effectiveness among special populations of medication users. Table 9 reports the expertise in the area of special populations among the 247/354 (69.8%) respondents who answered this question. Of the five categories, Senior's Health, Women's Health, and Child and Youth Health have the highest proportion of researchers with reported expertise in these areas. Fewer respondents reported expertise in the areas of marginalized populations and in aboriginal peoples' health.

TABLE 9: Top Areas of Research among Special Populations

Expertise in Special Populations	Total Responses (%)* (n=247)
Senior's Health	111 (44.9)
Women's Health	78 (31.6)
Child and Youth Health	73 (29.6)
Marginalized Populations	57 (23.1)
Aboriginal Peoples' Health	31 (12.6)
Other	62 (25.1)
* As researchers may select up to five areas of expertise, the percentages do not add up to 100%.	

3.1.4.4 Professional Organizations Aligned with Research Interests

Researchers engaged in pharmacoepidemiology and pharmacovigilance join a variety of professional organizations to receive updates on new research initiatives, to present findings of their research, to network with likeminded colleagues and to learn state-of-the art techniques. Table 10 provides the responses of the 321/354 (90.7%) respondents who selected the name of a professional organization that the researcher felt best aligned with their research interests. The 18 professional organizations noted are those that were mentioned three or more times in the selections provided or in the "Other" box available for additional suggestions. Of the top four organizations, two (Canadian Association for Population

Therapeutics and Canadian Association for Health Services and Policy Research) focus on methodological issues related to pharmacosurveillance and to health policy research, while the other two top organizations (Canadian Medical Association and the Canadian Society of Hospital Pharmacists) reflect the primary clinical affiliations of the multidisciplinary respondents. This targeted information on key professional organizations of interest to respondents has the potential to facilitate timely and ongoing communication between Health Canada and active researchers engaged in post-market drug evaluation research.

TABLE 10: Professional Organizations Aligned with Research Interests

Professional Organization	Total Responses (%) (n=321)
Canadian Medical Association (CMA) including provincial associations	52 (16.2)
Canadian Association for Population Therapeutics (CAPT)	28 (8.7)
Canadian Society of Hospital Pharmacists (CSHP)	27 (8.4)
Canadian Association for Health Services and Policy Research (CAHSPR)	26 (8.1)
International Society for Pharmacoeconomics and Outcomes Research (ISPOR)	21 (6.5)
Canadian Society of Pharmacology and Therapeutics (CSPT)	20 (6.2)
Drug Information Association	20 (6.2)
Canadian Pharmacists Association (CPhA) including provincial associations	17 (5.3)
International Society for Pharmacoepidemiology (ISPE)	17 (5.3)
Canadian Society for Epidemiology and Biostatistics (CSEB)	10 (3.1)
Canadian Public Health Association (CPHA)	6 (1.9)
Canadian Society for Pharmaceutical Sciences (CSPS)	5 (1.6)
Canadian College of Clinical Pharmacy (CCCP)	4 (1.2)
Canadian Association for HIV Research (CAHR)	4 (1.2)
International Society of Quality of Life Research (ISOQOL)	4 (1.2)
Health Technology International (HTI)	4 (1.2)
Therapeutics Initiative (TI)	4 (1.2)
Canadian Critical Care Trial Group (CCCTG)	3 (0.9)
Canadian Diabetes Association (CDA)	3 (0.9)
Other	66 (20.6)

3.1.5 Pre-Authorization Drug Evaluation Research

3.1.5.1 Pre-Authorization Research Expertise

The proposed life cycle approach to the regulation of therapeutic products will require ongoing pre-authorization drug evaluation studies as well as expanded requirements in the post-market period. Research scientists with expertise in both pre- and post-market drug evaluation research have the potential to support the life cycle approach by reviewing new drug

submissions from the pharmaceutical industry as well as evaluating the outcomes of required post-market drug evaluation research studies.

Among survey respondents, 130/354 (36.7%) reported involvement in pre-authorization drug evaluation research within the past five years. The specific areas of pre-authorization research expertise are noted in Table 11, with efficacy, safety, dose ranging and tolerability research studies the most frequently performed.

TABLE 11: Type of Pre-Authorization Drug Evaluation Research Expertise

Type of Pre-Authorization Research	Total Responses (%) (n=130)
Efficacy (%)	105 (80.8)
Safety (%)	78 (60.0)
Pharmacokinetics (%)	34 (26.2)
Tolerability (%)	32 (24.6)
Dose Ranging (%)	32 (24.6)
Bioequivalence (%)	20 (15.4)
Pharmacodynamics (%)	15 (11.5)
Pharmacologic Actions (%)	15 (11.5)
Drug Interaction (%)	11 (8.5)
Bioavailability (%)	9 (6.9)
Drug Metabolism (%)	6 (4.6)
Metabolic Actions	4 (3.1)
Other (%)	20 (15.4)
* As researchers may select up to five areas of expertise, the percentages do not add up to 100%.	

3.1.5.2 Comparison between Respondents with and without Pre-Authorization Drug Evaluation Research Experience

The characteristics of survey respondents involved with pre-authorization drug evaluation research were compared to those of respondents who had not been engaged in this area of research in the previous five years. The characteristics noted with * in Table 12 are those in which there was a difference of at least 15 percentage points between those who were and were not involved with pre-authorization drug evaluation research. These findings suggest that individuals most commonly involved with pre-authorization research are male physicians over 45 years of age who are based in a healthcare facility. Their methodological expertise is in the area of active comparator trials and clinical trial design, which they conduct as pre- and post-market drug evaluation research. They are more frequently involved in training graduate students, in developing Practice Guidelines, in recognizing barriers to data access and consenting to being involved with the potential Private Sector Registry than respondents not engaged in pre-authorization research. The only characteristic that was less frequent among

pre-authorization researchers was expertise in the area of pharmacoepidemiology. As the survey was only distributed to those with a strong likelihood of involvement in post-market drug evaluation research, the characteristics of pre-authorization researchers in this sample are not necessarily representative of all pre-authorization researchers, rather only those likely to be involved in post-market drug evaluation research as well.

TABLE 12: Comparison between Respondents with and without Pre-Authorization Drug Evaluation Research Experience

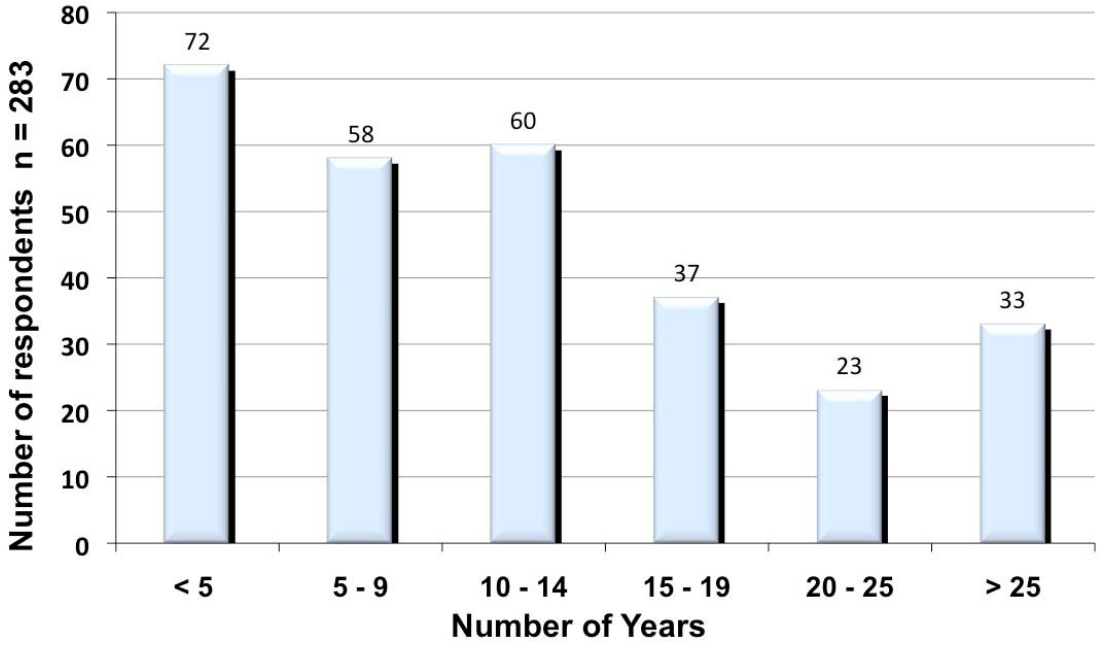
Characteristics*	With Pre-Authorization Research Experience (%) (n=130)	Without Pre-Authorization Research Experience (%) (n=224)
Age over 45 years (%)	94/128 (73.4)*	97/219 (44.3)
Male (%)	97/130 (74.6)*	113/224 (50.4)
Principal Role (%)		
Clinician – Physician	36/130 (27.7)*	24/224 (10.7)
Principal Research Location (%)		
Hospital/Healthcare Facility	58/130 (44.6)*	58/224 (25.9)
Post-Baccalaureate Degree (%)		
Medical Doctor	80/130 (61.5)*	67/224 (29.9)
Pre-Authorization Research Expertise		
Active Comparator Trials	48/126 (38.1)*	21/220 (9.6)
Clinical Trial Design	57/126 (45.2)*	34/220 (15.5)
Pharmacoepidemiology	18/126 (14.3)	78/220 (35.5)*
Professional Organization		
Canadian Medical Association	33/130 (25.4)*	19/222 (8.6)
Involved in POST-Market Research		
Yes	119/130 (91.5)*	166/224 (74.1%)
> 15 Years POST-Market Research	62/118 (52.5)*	31/165 (18.8)
POST-Market Research Expertise		
Active Comparator Trials	45/115 (39.1)*	21/174 (12.1)
Randomized Controlled Clinical Trial	64/115 (55.7)*	43/174 (24.7)
Pharmacoepidemiology	22/113 (19.5)	76/173 (43.9)*
Supervised Graduate Students		
Yes	76/130 (58.5)*	93/224 (41.5)
Types of Knowledge Dissemination		
Practice Guidelines	52/115 (45.2)*	43/183 (23.5)
Interaction with Health Canada		
Barriers to data access	65/130 (50.0)*	62/224 (27.7)
Consent to Private Sector Registry	92/115 (80.0)*	104/179 (58.1)
Characteristics reported are those with a difference of ≥ 15% between those with or without pre-authorization involvement.		
* Most frequent		

3.1.6 Post-Market Drug Evaluation Research

3.1.6.1 Post-Market Drug Evaluation Research Expertise

Of the 354 survey respondents, 285 stated that they had been involved with post-market drug evaluation research since completing their post-baccalaureate degree, and of those, 283 provided the number of years involved. Figure 7 describes the number of years experience in the post-market drug evaluation research area, with 190/283 (67.1%) of respondents involved with conducting research for less than 15 years. This finding is promising for future Health Canada initiatives with an upcoming cohort of researchers able to provide scientific support for increasing post-market drug evaluation research requirements.

FIGURE 7: Number of Years Involved in Post-Market Drug Evaluation Research



The research expertise for the 285 respondents actively involved with post-market drug evaluation research expertise is noted in Table 13, and is similar to the range of expertise noted in Table 8 for the total number of 354 survey respondents.

TABLE 13: Top Areas of Post-Market Drug Evaluation Research Expertise

Research Expertise	Total Responses (%)* (n=285)
Pharmacoepidemiology[4]	98 (34.3)
Adherence to drug therapy	89 (31.1)
Health policy research	81 (28.3)
Adverse drug reaction monitoring (pharmacovigilance)[6]	79 (27.6)
Patient safety[6]	75 (26.2)
Health economics[3]	74 (25.9)
Health technology assessment	61 (21.3)
Epidemiology[1]	58 (19.6)
Clinical pharmacy practice	37 (12.9)
Pharmacology	31 (10.8)
Pharmacokinetics	25 (8.7)
Patient decision aids	22 (7.7)
Health informatics	17 (5.9)
Pharmacogenetics[5]	14 (4.9)
Risk management[6]	14 (4.9)
Toxicology	12 (4.2)
Risk minimization interventions[6]	11 (3.8)
Bioethics	8 (2.8)
Pharmacogenomics[5]	7 (2.4)
Other	47 (16.4)
* As researchers may select up to five areas of expertise, the percentages do not add up to 100%.	
[1 – 6] These areas of research expertise reflect the core areas evaluated in the Educational Institution Inventory: [1]Epidemiology, [2]Biostatistics, [3]Health Economics, [4]Pharmacoepidemiology, [5]Pharmacogenetics/Pharmaco-genomics and [6]Patient Safety/Risk Management/Pharmacovigilance.	

The most frequent types of research methodological expertise are pragmatic real-world observational studies (49.8%), population health database initiatives (43.2%) and systematic reviews (35.8%) (Table 14). The prevalence of experience reported in the area of real world observational studies is of importance, as future research projects involving the life cycle approach may provide additional opportunities of this kind in the future.

TABLE 14: Top Areas of Post-Market Drug Evaluation Methodological Expertise

Methodological Expertise	Total Responses (%)* (n=285)
Pragmatic real world observational study	142 (49.8)
Population health database	123 (43.2)
Randomized controlled clinical trial	106 (37.2)
Systematic reviews	102 (35.8)
Case-control study	91 (31.9)
Cross-sectional study	67 (23.5)
Active comparator clinical trials	65 (22.8)
Meta-analyses	63 (22.1)
Qualitative methodology	53 (18.5)
Decision analytic modeling	44 (15.4)
Other	29 (10.2)
* As researchers may select up to five areas of expertise, the percentages do not add up to 100%.	

3.1.6.2 Comparison between Respondents with and without Post-Market Drug Evaluation Research Experience

Characteristics of survey respondents involved with post-market drug evaluation research were compared to those of respondents who had not been engaged in this area of research in the previous five years. The characteristics noted with * in Table 15 are those in which there was a difference of at least 15 percentage points between those who stated that they were or were not involved with post-market drug evaluation research. While most characteristics were similar between the two groups, respondents involved with post-market drug evaluation research were more likely to be physicians trained in Canada who worked in a healthcare facility, were involved in pre-authorization drug evaluation research and had expertise in clinical trial design and pharmacoepidemiology. They were also more frequently involved in training graduate students, interested in future involvement in post-market drug evaluation research, recognized barriers to data access and interested in being involved with the potential Health Canada Registry than respondents not engaged in post-market drug evaluation research.

Of interest is that 47/69 (68.1%) of those not currently involved in post-market drug evaluation research expressed an interest in being involved in future opportunities, with 42/69 (60.9%) stating that they would be interested in consenting to be listed on the Health Canada Registry.

TABLE 15: Comparison between Respondents with and without Post-Market Drug Evaluation Research Experience

Characteristics	With Post-Market Research Experience (%) (n=285)	Without Post-Market Research Experience (%) (n=69)
Principal Research Location		
• Hospital/Healthcare Facility	102/285 (35.8)*	14/69 (20.3)
Post-Baccalaureate Degree		
• Medical Doctor	127/285(44.6)*	20/69 (29.0)
Location of degree		
• Medical Doctor - Canada	86/127 (67.7)*	9/20 (45.0)
Research Expertise		
• Clinical Trial Design	81/281 (29.2)*	9/65 (13.8)
• Health Policy Research	68/281 (24.2)	27/65 (41.5)*
• Pharmacoepidemiology	90/281 (32.0)*	6/65 (9.2)
Involved with Pre-Authorization Research		
• Yes	119/283 (42.0)*	11/69 (15.9)
Supervised Graduate Students		
• Yes	157/285 (55.1)*	12/69 (17.4)
Interaction with Health Canada		
• Willing to be involved in POST-market research in future	259/285 (90.9)*	47/69 (68.1)
• Barriers to data access	131/285 (46.0)*	16/69 (23.2)
• Consent to Health Canada Registry	260/285 (91.2)*	42/69 (60.9)
Characteristics reported are those with a difference of ≥ 15% between those with or without post-market research involvement. * Most frequent		

In the broadest sense, many of the respondents who stated that they were not involved in post-market drug evaluation research were indeed actively engaged in closely related areas of research. Moreover, these respondents had comparable academic credentials and research expertise as those who stated that they were involved. Some respondents who felt that they were not involved in post-market drug evaluation research described their expertise as:

"Health-related quality of life outcomes research"
"Assessment of benefits and risks of health interventions, outcome assessments"
"Contextualized research synthesis to support evidence-informed decision-making"

Furthermore, when one researcher with a specialty of health services and population health research was asked if she was interested in being included in a future Health Canada Registry, she commented that:

> *"… I just don't think I have the expertise, UNLESS you describe "post-market drug evaluation research" very broadly. I intend to make more use of pharmaceutical information in the future, in the context of population-based studies".*

Thus, the findings of all respondents who answered the survey have been included in this report, to better inform readers on the scope and depth of researchers in this area of research.

3.1.7 Graduate Student Supervision

Of the 354 respondents, 169 (47.7%) were actively supervising graduate students in the area of post-market drug evaluation research. The most frequent employment role of the supervisor was as a Researcher 60/169 (35.5%), Faculty member (59/169 (34.9%) or Medical Clinician 20/169 (11.8%). The principal research location was designated as an Educational Institution for 72/169 (42.6%) respondents, a Hospital or other Healthcare Facility for 64/169 (37.9%), a Research Centre for 30/169 (17.8%) and a Health Authority for 3/169 (1.8%). Of those researchers engaged in pre-authorization drug evaluation, 76/130 (58.5%) supervised graduate students. Similarly, of those involved with post-market drug evaluation research, 157/285 (55.1%) supervised graduate students.

The number of graduate students receiving training at Canadian universities in post-market drug evaluation research is listed in Table 16. Based on the information provided by survey respondents, the top three universities training new researchers in this area are the Université de Montréal (271), the University of British Columbia (254) and the University of Toronto (244). Currently, 283 MSc students and 215 PhD students are in the process of completing graduate training, with an additional 343 MSc and 172 PhD students who completed their requirements within the past five years. As noted in Table 16, physicians and PharmDs in training are also receiving instruction in the area of post-market drug evaluation.

Nevertheless, one of the Peer Review Committee members stressed the importance of increasing the profile of this area of research in Canada among prospective graduate students. While he mentioned that there was *"raw material"* within the universities, potential graduate students are *"not well utilized and capitalized on"*.

TABLE 16: Supervision of Graduate Students in Post-Market Drug Evaluation Research within the Past Five Years

University	Supervisors	Current Graduate Students		Completed Graduate Students		Total
		MSc	PhD	MSc	PhD	
Brock University	1	2	0	2	0	4
Dalhousie University	10	11	10	34	6	80
Laurentian University	1	2	4	8	8	22
McGill University	6	12	6	13	3	42
McMaster University	12	24	17	36	10	113
Queen's University	3	5	0	3	0	10
Simon Fraser University	1	8	3	5	5	21
University of Alberta	11	10	17	29	27	111
University of British Columbia	41	44	51	32	34	254
University of Calgary	10	10	6	13	6	59
Université Laval	5	17	3	15	6	53
University of Manitoba	6	4	2	6	2	21
Université de Montréal	20	81	41	77	32	271
University of Ottawa	5	9	6	11	8	57
University of Saskatchewan	3	0	1	2	0	3
University of Toronto	28	30	45	45	24	244
University of Victoria	2	3	0	3	0	6
University of Western Ontario	4	11	3	9	1	34
Total	169	283	215	343	172	1405

In addition to the MSc and PhD graduate students noted above, 136 physicians and PharmDs are currently being supervised in the post-market drug evaluation area, and 256 physicians and PharmDs completed their post-market drug evaluation research training during the past five years.

3.1.8 Knowledge Translation Expertise

Knowledge translation activities are a critical component of ensuring that research findings are communicated to those who can benefit from the information. Table 17 summarizes the knowledge translation strategies used by respondents. While the two most frequent strategies of peer-reviewed publications (239/354 (79.9%)) and conference presentations (222/354 (74.2%)) are traditional academic mechanisms for sharing information with colleagues, summary methodologies of systematic reviews and meta-analyses are now being used routinely. Relatively new mechanisms of knowledge dissemination including educational sessions with decision-makers, collaborative research involving end users throughout the research process, summary briefings to stakeholders, media engagements and electronic dissemination (e.g., webinars) are also being used to communicate key research findings of relevance to multiple stakeholders.

TABLE 17: Knowledge Translation Strategies used with Post-Market Drug Evaluation Research

Knowledge Translation Strategies	Total Responses (%) (n=354)
Peer-reviewed journal publications	239 (79.9)
Conference presentations	222 (74.2)
Educational sessions with policy makers, practitioners and patients	121 (40.5)
Systematic reviews	98 (32.8)
Collaborative research involving end users in the research process	96 (32.1)
Practice guidelines	95 (31.8)
Summary briefings to stakeholders	92 (30.8)
Media engagement	60 (20.1)
Meta-analyses	47 (15.7)
Decision aids and rules	46 (15.4)
Use of knowledge brokers	14 (4.7)
Developing commercialization potential of discoveries	11 (3.7)
Other	9 (3.0)
* As researchers may select up to five methods of knowledge translation, the percentages do not add up to 100%.	

Many of the respondents have developed extensive experience in the knowledge dissemination area, and two researchers described their expertise in this way:

> *"I am the knowledge broker [with a] joint appointment between university and government. I involve government decision-makers in research. We … [link] confidential prescribing portraits with [tailored] educational messages …"*

> *"I'm responsible for drug strategies, treatment policies, planning, information dissemination, data capture and analysis, standards of related clinical and health services research, drug education and access, media engagement, university teaching, meetings with stakeholders…"*

Other researchers, however, are just beginning to explore knowledge dissemination as a key component of their research program:

> *"We are working on this! Especially trying to engage stakeholders"*
> *"Not there yet!"*

3.1.9 Involvement in Health Canada Consultations

To explore the knowledge of post-market drug evaluation researchers in the planned regulatory changes, respondents were asked: *"Are you familiar with the proposed modernization of the Food and Drugs Act?"* Of the 354 respondents, 142/354 (40.1%) were familiar with the proposed life cycle approach to the regulation of therapeutic products.

A related question asked those who knew about the planned regulatory change whether they had been *"involved with Health Canada consultations in the past related to the modernization of the Food and Drugs Act*?" Of those who knew, 42/142 (29.6%) had contributed to one or more Health Canada consultations in the past related to proposed changes to the *Food and Drugs Act.* This experienced group of experts represented 42/354 (11.9%) of all respondents.

Previous consultations provided as examples included participating in meetings related to:

"Marketed Health Products Directorate Therapeutics Effectiveness Workshop"
"Ethical Considerations for Post-Marketing Evaluations of Pharmaceuticals"
"Management Advisory Committee, Health Products and Food Branch"
"Expert Advisory Committee on the Vigilance of Health Products"
"Legislation addressing direct-to-consumer drug advertising"
"Advisory Group to the Public Health Agency of Canada"
"Steering Committee of Women and Health Protection"
"Working Group on Registration of Clinical Trials"
"Science Advisory Board of Health Canada"
"Round table stakeholder consultations"

Respondents who knew of the regulatory change were also asked whether they had *"provided feedback to Health Canada in any way other than consultations?"* In addition to the 42 respondents who provided consultation advice above, another 20 of the 142 (14.1%) respondents had provided feedback to Health Canada in a variety of mechanisms other than direct consultations. Such feedback had been provided during Health Canada meetings, input given on specific pharmaceutical issues, and studies conducted that were funded by the Health Canada Health Policy Research Program into drug effectiveness in "the real world".

Ongoing feedback provided by respondents included the following examples:

> *"Regular meetings with the Director General of Biologics and Genetic Therapies Directorate"*
> *"Recommended revisions to the sequence and content of approved monographs for drugs"*
> *"Shared research findings in confidence with Health Canada prior to publication"*
> *"Regular ongoing communication with Natural Health Products Directorate"*
> *"Presentation to the Parliamentary Standing Committee on Health"*
> *"Assessment of drugs for the Canadian market"*
> *"Review of industry submissions"*

Thus, a modest 62/354 (17.5%) of survey respondents had provided either consultations (42) or feedback (20) to Health Canada on a wide range of pharmaceutical issues. It was noteworthy that many of these 62 active respondents had participated on numerous senior advisory committees within Health Canada over a period of many years. Two representative examples from respondents actively engaged with advising Health Canada included:

> *"Participant in workshops; ethnographic interviewing of policy makers and regulatory scientists; fieldwork at sites of regulatory review and evaluation (pre-license); participant-observation at many Health Canada regulatory review consultations and risk meetings; etc."*

> *"On Management Advisory Committee, participated on different consultations regarding Progressive Licensing, Post-Market Surveillance, National Pharmaceuticals Strategy, worked with Office of Consumer and Public Involvement re Public Involvement Framework."*

The findings from this human capacity resource survey suggest that there is considerable clinical and academic expertise among Canadian researchers actively engaged in post-market drug evaluation research. Attracting new researchers to become engaged in Health Canada consultations and given opportunities to provide feedback may facilitate ongoing support for the life cycle approach to the regulation of therapeutic products.

3.1.10 Barriers to Data Access

Barriers to data access were reported by 147/354 (41.5%) of the respondents. As 73/147 (49.7%) of the respondents had expertise in pharmacoepidemiology and/or population data management, these experienced researchers clearly understood the issues and complexities related to accessing data from provincial and federal administrative databases and the pharmaceutical industry. Their level of frustration at the barriers was evidenced by the 140 written responses to this question.

Comments related to the barriers to data access addressed a number of key issues related to:

(1) Population-based databases:

> *"The current process for accessing population health data is quite lengthy, making it difficult to address pressing clinical questions in a timely manner."*

(2) Funding:

> *"We need to invest new monies and direct existing strategic priorities to this area."*
>
> *"Post marketing surveillance is mainly done through funding of administrative database research. There is a need to give equal importance to primary data collection surveillance initiatives since they are the only ones that can adjust for diagnosis and co-morbidity."*

(3) Pharmaceutical Industry:

> *"Full access to pre-authorization trial data; full disclosure of regulatory decision-making process associated with evaluation; conflict of interest of researchers and Health Canada personnel."*
>
> *"Lack of transparency of pre-licensing and post-licensing data submitted to Health Canada by drug manufacturers (these data are generally not available to outsiders, unlike that in the US)."*
>
> *"Non-transparency both at federal and provincial levels in terms of drug approvals and drug benefit listing approvals."*

(4) Privacy:

> *"Personal health information legislation has created huge problems for accessing patient data to do post-marketing research, even with assurances that only aggregate or non-individualized data will be published."*
>
> *"Privacy legislation limits access to genetic information in proposed pharmacogenetic research."*

(5) Province-specific comments provided insight into a range of data access barriers:

> *"We have been waiting over 14 months for data from the [BC] Ministry of Health; we have just obtained approval, but do not have the data as yet. This waiting time is not compatible with the granting cycle and makes it difficult to renew grants for future research."*
>
> *"Obtaining access to drug data from the provincial government in Alberta is time- and labor-consuming."*
>
> *"Timely and affordable access to administrative health data continues to be a big problem, especially for researchers based in Ontario. Access to data and the research agenda in Ontario is largely controlled by the Institute for Clinical Evaluative Science"*
>
> *"Provincial health databases vary across provinces in terms of what data is accessible. In Nova Scotia, prescription information is not available for the population, only subgroups, which severely limits which research questions can be addressed."*

3.1.11 Interest in Potential Research Opportunities with Health Canada

The proposed life cycle approach to the regulation of therapeutic products will require extensive support from academic and clinician scientists to evaluate new active substances and to conduct post-market patient safety and effectiveness studies. When asked whether they would be interested in being involved in future post-market drug evaluation research studies, 306/354 (86.4%) of the respondents expressed an interest. The respondents who were not interested in future post-market drug evaluation research opportunities provided a range of professional and personal reasons for this decision:

Professional reasons:

> *"Our major interest is in new drug studies."*
> *"Actuellement, domaine de pratique autre que la recherché sur l'évaluation des medicaments."*

Personal reasons:

> *"Learning to say no…too old – time for me to retire!"*
> *"Sorry I am swamped."*
> *"Too much activity already!"*
> *"Because I am now retired, my role is no longer an active one. But as a user of this kind of work (on various decision-making committees), I can provide advice to those who are still active."*

Evaluation of the responses to questions on potential future post-market drug evaluation research involvement generated findings of interest when separated by pre- and post-market drug evaluation research experience (Table 18).

TABLE 18: Interest in Future Drug Evaluation Research Opportunities with Health Canada

Respondent (n = 354)	Interested in Future Research Opportunities (%)	Health Canada Registry (%)	Public Registry (%)	Non-profit Registry (%)	Private Registry (%)
Group 1 Pre and Post n=119	Yes 108 (90.8)	Yes 105 (88.2)	Yes 101 (84.9)	Yes 97 (81.5)	Yes 82 (68.9)
Group 2 Post only n=166	Yes 151 (91.0)	Yes 144 (86.7)	Yes 136 (81.9)	Yes 133 (80.1)	Yes 81 (48.8)
Group 3 Pre only n=11	Yes 9 (81.8)	Yes 9 (81.8)	Yes 8 (72.7)	Yes 8 (72.7)	Yes 6 (54.5)
Group 4 No Pre/Post n=58	Yes 38 (65.5)	Yes 31 (53.4)	Yes 28 (48.3)	Yes 29 (50.0)	Yes 20 (34.5)
Total	Yes 306 (86.4)	Yes 289 (81.6)	Yes 273 (77.1)	Yes 267 (75.4)	Yes 189 (53.4)

Group 1: Experience with both Pre- and Post-Market Drug Evaluation Research 119/354 (33.6%)
Group 2: Experience with Post-Market Drug Evaluation Research only 166/354 (46.9%)
Group 3: Experience with Pre-Authorization Drug Evaluation Research only 11/354 (3.1%)
Group 4: No Experience with either Pre- or Post-Market Drug Evaluation Research 58/354 (16.4%)

Researchers actively involved with either pre- or post-market drug evaluation research or both (Groups 1 -3) had a similar level of interest (~ 90%) in potentially becoming involved with future research opportunities in the post-market drug evaluation stage of research.

Ongoing commitment to post-market drug evaluation research was felt to be a professional responsibility by some respondents, as evidenced by this comment:

"I am a senior clinical pharmacologist, and therefore regard such work as a duty."

Even among the respondents with no previous pre- or post-market drug evaluation experience, 38/58 (65.5%) expressed an interest in future research opportunities. The researchers with both pre- and post-market research experience were the most interested (68.9%) in providing consent for a Private Registry.

Many researchers declined to consent to being involved with a Registry that would be distributed to the private sector. Comments reflected their interest in maintaining an arms-length relationship with the pharmaceutical industry:

> "*Private sector involvement would create conflict of interest with other responsibilities."*
>
> *"I usually avoid getting involved in non-peer reviewed funding arrangements, especially those involving industry, because I do not want to be in a position that could potentially compromise my academic freedom."*
>
> *"Only interested in supporting public interests in drug research."*

Some respondents were interested in potential future research if training courses were made available, such as this researcher who stated:

> *"I am mostly involved in hospital drug use evaluation. Also, I don't consider myself a 'trained/seasoned researcher'. Would be interested in further training opportunities though, if available."*

Many survey respondents who are not currently involved with post-market drug evaluation research already have extensive clinical training and many of the necessary skills in research methodology. Moreover, they have expressed an interest in becoming increasingly involved in this area of research. Further targeted training opportunities to upgrade the knowledge of these researchers have the potential to generate highly qualified researchers in the short term. Expanded graduate student training initiatives to enhance human resource capacity will be necessary to generate the necessary human resources in the long term.

3.2 Inventory of Educational Institutions

3.2.1 Institutions and Programs

Twenty-three (23) Canadian institutions were identified that had the potential to train students in post-market drug evaluation research (see Appendix 2A). Twenty (20) institutions had programs training researchers in human health; two had separate programs for human health and for veterinary health, and one institution had a training program only for post-graduate veterinarians. Graduate programs within these institutions included Epidemiology (including veterinary), Community Health, Population and Public Health (including veterinary), Pharmacy, Health Informatics, Health Research Methodology, and Health Technology Assessment. The distribution of the educational institutions across the country is shown in Figure 8.

FIGURE 8: Distribution of Educational Institutions across Canada.

Red dots indicate human-only schools; black dots indicate veterinary- only schools, purple dots indicate veterinary and human schools.

The types of graduate degrees granted by the various institutions and programs were diverse (Table 19). The most common programs were for MSc and PhD degrees, with 31 for each offered throughout the country. There were 9 Masters of Public Health degree programs. In addition, there were 19 related degree-granting programs including post-BSc diploma programs and non-MSc Masters programs such as Masters of Health Informatics and Masters of Health Sciences. English is the language of instruction in 19 of the institutions, with courses taught in French at the Université de Montréal, Université Laval and the Université de Sherbrooke. The University of Ottawa is bilingual.

An estimated 900 students graduate from these programs annually, with the number of applicants fluctuating yearly based on issues such as funding. Approximately 500 of the students graduate with traditional thesis-based MSc and PhD degrees. The remaining programs were primarily non-thesis based masters (e.g., Masters of Public Health, Masters of Health Informatics) and graduate diploma programs. No specific information regarding the number of graduates from these programs with training in post-market drug evaluation research was available. However it is clear from the breadth of courses available at these sites (Appendix 2B), that only a small minority of students actually receive training specializing in post-market drug evaluation research. While many MSc graduate students are currently being trained in the general area of drug evaluation, there appear to be additional places available in a number of doctoral programs across the country that are not currently being utilized.

TABLE 19: Canadian Institutions with Potential to Train Graduate Students in Post-Market Drug Evaluation Research

Institution	Departments/Schools	Degrees Available	Total Grads/Year (Approx.)	PT Study Available	Thesis vs. Non-Thesis
University of British Columbia	Pharmaceutical Sciences, Population and Public Health, Bioinformatics	MSc, MHSc, MPH, PhD	100	Yes	Both
Simon Fraser University	Health Sciences	MPH, MSc	60	Yes	Both
University of Victoria	Health Information Science	MSc, PhD	10	No	Thesis
University of Northern BC	Community Health Science	MSc	6	No	Thesis
University of Alberta	Public Health, Epidemiology Pharmacy	MSc, MPH, PhD	58	Yes	Both
University of Calgary	Community Health Science	MSc, MCM, PhD	25	No	Both
University of Saskatchewan	Community Health and Epidemiology, Public Health, Pharmacy	MSc, MPH, PhD	32	Yes	Both
University of Manitoba	Community Health Science, Pharmacy	Diploma, MSc, MPH, PhD	30	Yes	Both
University of Toronto	Health Policy Management and Evaluation, Public Health, Health Informatics, Pharmacy	MSc, MHI, MHSc, MScCH	110	Yes	Both
McMaster University	Health Research Methodology	MSc, PhD	50	Yes	Thesis
University of Ottawa	Epidemiology and Community Medicine	MSc, PhD	20	No	Thesis
Queen's University	Community Health and Epidemiology	MPH, MSc, PhD	25	Yes	Both
University of Western Ontario	Epidemiology and Biostatistics	Certificate, MSc, PhD	40	Yes	Both
University of Waterloo	Applied Health Science	MSc, MPH, PhD	60 (Not known MSc, PhD)	Yes	Both
University of Guelph	Population Medicine	MSc, PhD, DVSc	30	Yes	Both

Lakehead University	Public Health	MPH	30	Yes	Both
McGill University	Epidemiology Biostatistics and Occupational Health	MSc, PhD	45	Yes	Both
Université de Montreal	Community Health, Population Health, Veterinary Medicine, Pharmacy	Diploma, MSc, PhD	200 (incl. 60+ diploma)	Yes	Both
Université de Sherbrooke	Clinical Sciences	MSc, PhD	Not known	Not known	Not Known
Université Laval	Community Health, Pharmacy	MSc, PhD	15	Yes	Thesis
Dalhousie University	Community Health and Epidemiology, Health Informatics	MSc, MHI, PhD	15	Yes	Both
University of Prince Edward Island	Veterinary Medicine	MVSc, MSc, PhD	Not Known	Not known	Both
Memorial University	Epidemiology	Diploma, MSc, PhD	Varies	Yes	Both

3.2.2 Prevalence of Courses by Institutions

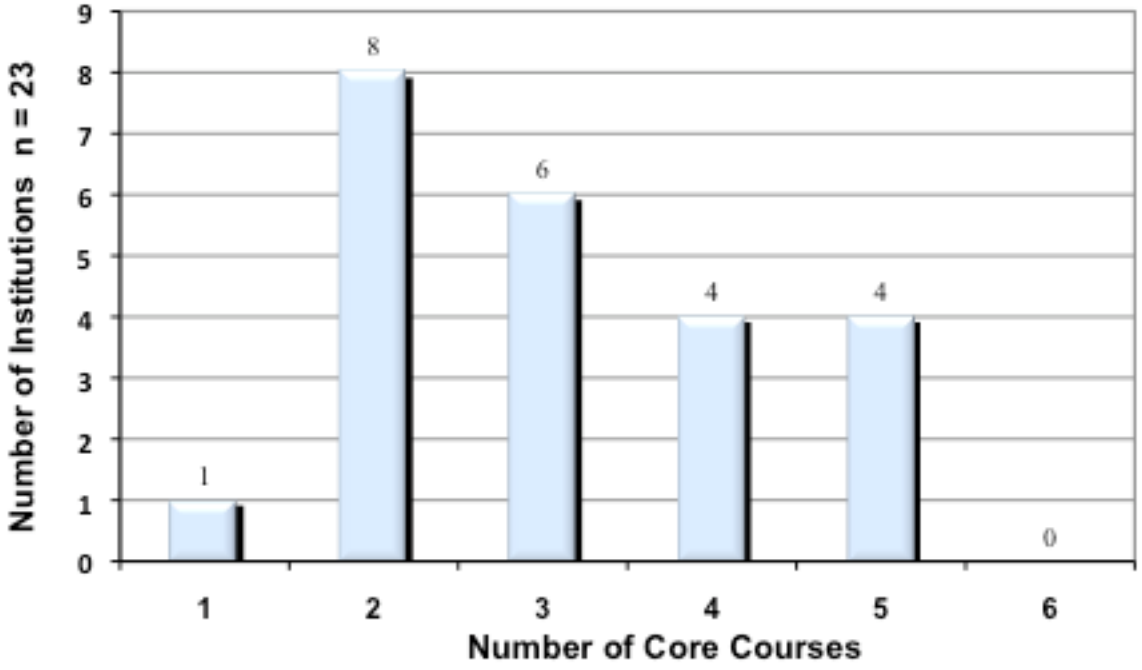
The prevalence of the six core courses was determined for each institution (Table 20). Overall, 23 institutions taught courses in epidemiology, 21 in biostatistics, 15 in health economics/ pharmacoeconomics, 4 in pharmacoepidemiology, 4 pharmacogenetics/pharmacogenomics, and 4 in patient safety/risk management/pharmacovigilance. No institution offered all 6 core courses (see Appendix 2C).

TABLE 20: Prevalence of Core Courses

Course	Prevalence (n=23)
Epidemiology	23
Biostatistics	21
Health economics/pharmacoeconomics	15
Pharmacoepidemiology	4
Pharmacogenetics/Pharmacogenomics	4
Patient safety/risk management/pharmacovigilance	4

Of the 23 institutions training researchers, McGill University, Université Laval, Université de Montréal and the University of Ottawa each provided five core courses, and the University of British Columbia, University of Alberta, McMaster University and the University of Waterloo each provided four of the core courses. The remaining 15 institutions taught three or fewer core courses (Figure 9).

FIGURE 9: Core Courses by Institution



Although apparent deficiencies in the provision of the core courses varied by institution, few dedicated courses were being provided either in the area of patient safety/risk management/ pharmacovigilance or in pharmacogenetics/pharmacogenomics. During the workshop, the importance of providing strong training in the area of health informatics was stressed, as these techniques will be required for future linkages between biological databases with genetic profiles and administrative prescription drug and medical service databases. Similarly, training in pharmacovigilance techniques utilizing administrative claims databases was considered timely, as the life cycle approach to post-market drug evaluation would provide expanded opportunities for this area of outcomes research.

At the workshop, the sharing of this information stimulated one Peer Review Committee member to suggest that:

> *"universities should focus increasingly … on improving individual coursework."*

The prevalence of the other non-core courses is described in Table 21.

Table 21: Prevalence of Non-Core Courses

Course	Prevalence (n=23)
Health policy/law	19
Qualitative research design	15
Social determinants of health	11
Health Ethics	11
Health Informatics	10
Health technology assessment	7
Knowledge transfer/translation	5
Evidence based medicine	4

3.2.3 Limitations

The primary limitation of this analysis of Canadian educational institutions was that it was sensitive rather than specific. Although all institutions with the potential to actively train individuals in post-market drug evaluation research were likely captured in this survey, it is unlikely that these institutions trained individuals specifically focused on post-market drug evaluation research. Furthermore, data gathering was primarily web-based, and thus may have missed information potentially available through an onsite evaluation of an institution. As program details and course information were not always able to be confirmed with individuals representing those programs and institutions, relevant course information may have been omitted or outdated information may have been incorporated into our findings.

4.0 JOINT HEALTH CANADA/CHILD AND FAMILY RESEARCH INSTITUTE WORKSHOP FOR KEY STAKEHOLDERS

Planning for the Health Canada/Child and Family Research Institute Workshop began in October 2008, and was designed to enable the presentation of the preliminary results of the human resource and educational institution inventories to stakeholders (see Appendix 3A). The objectives of the Workshop were to:

1. Explore the perspectives of stakeholders and the Peer Review Committee members on the inventories of researchers and of educational institutions training such researchers qualified to support the life cycle approach to the regulation of therapeutic products in Canada;

2. Obtain practical input from participants on processes to integrate current and future human resource capacity for conducting post-market drug evaluation research in Canada into the life cycle approach to the regulation of therapeutic products; and

3. Explore processes in which Canadian researchers can contribute to the harmonization of international health product surveillance programs, including uniquely Canadian opportunities.

The Workshop provided ample opportunity for Health Canada personnel, academic researchers and key stakeholders to provide feedback on the preliminary findings of the inventories and an opportunity for group discussion and agreement on potential recommendations to Health Canada with respect to the regulation of therapeutic products (see Appendix 3B).

5.0 RECOMMENDATIONS

We recommend that:

1. Health Canada extend this human resource capacity survey of post-market drug evaluation researchers to provincial and federal governments, to the not-for-profit sector and to contract research organizations to more accurately inventory post-market drug evaluation researchers, as many are working outside of academia and health care institutions.

2. Health Canada support a Task Force to develop a national syllabus that would guide universities interested in training highly qualified personnel able to support post-market drug evaluation studies, as few universities currently offer a comprehensive training program that focuses on all of the essential core courses.

3. Health Canada act to increase awareness of career opportunities that support post-market drug evaluation. To encourage these targeted recruitments, consideration should be given to the development of a national scholarship program for highly qualified personnel in this specialized research field. A national web-based distance education program may facilitate graduate student training in post-market drug safety and effectiveness research methodology, by enabling the utilization of highly trained Faculty members currently based at a limited number of universities.

4. Health Canada should foster effective partnerships and networking between academia and government on drug safety and effectiveness research through evidence-based practice centres modeled along the lines of the virtual Canadian Institute for Advanced Research (http://www2.cifar.ca/).

5. Health Canada, in partnership with the Canadian Institutes of Health Research, should administer funding for Canada Research Chairs in Risk Management in selected Canadian post-secondary institutions to encourage the development of additional expertise needed in this area.

6. Health Canada, in partnership with the Canadian Institutes of Health Research, should develop strategies to improve capacity in post-market drug evaluation research targeted at marginalized populations and aboriginal peoples' health in order to promote the health of all Canadians.

7. Health Canada, in partnership with the Canadian Institutes of Health Research, should facilitate international exchanges between highly qualified researchers in the area of post-

market drug evaluation (e.g., European Medicines Agency) to encourage the uptake in Canada of progressive strategies in the area of drug safety and effectiveness research.

8. Health Canada should actively explore procedures that would enable sharing of population-based data across provincial boundaries, thus reducing barriers to data access and facilitating population health research relevant to optimal therapy.

6.0 CONCLUSIONS

It seems very likely that Canada will continue the process already started leading to the adoption of a more modern approach to the regulation of health products. There are very high levels of support for the proposed life cycle regulatory approach which will facilitate ongoing harmonization with international initiatives in Europe, Japan, the United States, Australia, and New Zealand. It is readily apparent that legislative renewal is long overdue in this area and that the forthcoming process revision should be guided by careful consideration of desired outcomes informed by evidence.

The study described in this report was undertaken with the aim of characterizing the human resource pool available in Canadian universities and academic health science centres to support a shift to a product life cycle approach to the regulation of therapeutic products. Since human resource planning is central to the shaping of the future drug regulatory environment, a survey of Canadian training programs was also undertaken. The results of this survey can inform future targeted training initiatives designed to augment the human resource pool.

Inevitably, a survey of this type produces an incomplete picture. The authors were not successful in obtaining responses from all those individuals known in the research community with an interest in pre- and post-market drug evaluation research of therapeutic products. Furthermore, it was beyond the scope of this exercise to identify individuals working in government, the pharmaceutical and biotechnology industries, or in contract research organizations who may represent the major repository of relevant expertise in Canada.

Nonetheless, the number of highly qualified individuals identified in the survey is less than anticipated. It is impossible to avoid the conclusion that the research system supporting pre- and post-market drug evaluation for therapeutic products will be quickly overwhelmed by the introduction of a product life cycle approach unless immediate steps are taken to improve human resource planning in this critically important area.

It is evident that the existing research capacity is somewhat weighted toward more senior investigators who will reach retirement in the next 10-15 years. At the same time, the survey was able to identify only 172 PhD graduates in relevant fields over the past five years (Table 16). If it is assumed that at least half of these graduates will make a career path in government, the private sector, or in clinical health care, it is clear that we are not on a course to expand capacity in keeping with the likely demands of a product life cycle approach to drug regulation.

When the clinical expertise of reporting scientists is reviewed there is reason for concern. In particular, there are very limited numbers in some important specialty areas such as geriatrics (10% of respondents), pediatrics (9%), obstetrics (5%), and anesthesia (2%) (Table 7). A somewhat more encouraging picture emerges when the top areas of research addressing the needs of special populations are reviewed (Table 9). Of investigators responding, 45% indicated an interest in senior's health, 32% in women's health, and 30% in child and youth health.

Table 13 reports the post-market drug evaluation research expertise of respondents and indicates a particularly worrisome deficiency in pharmacogenetics and pharmacogenomics. These disciplines are taking on an increased importance in an era of personalized and predictive medicine which is likely to see increased use of biomarkers of drug safety and effectiveness. There is also an alarming shortage of expertise in the related areas of risk management, risk minimization, and toxicology. The numbers reporting in this survey appear inadequate to deal with the challenge of drug safety management in the face of conditional approval with post marketing monitoring. Only 6% of respondents indicate expertise in health informatics, although most would judge information technology to be central to the product life cycle licensing approach.

Not only do respondents lack expertise in health informatics, but they also suggest that there are major barriers to pharmacoepidemiology research in Canada, with 42% of respondents indicating that they are frustrated by important barriers to data access concerning drug use, safety, and efficacy. The clearly expressed frustration with obstacles to epidemiology research almost certainly represents a major deterrent to a career choice in pharmacoepidemiology or in other population health disciplines concerned with optimal drug therapy. This should be a cause of major concern to federal and provincial governments in Canada if they are committed to evidence-informed policies and clinical practice.

Above all, it is apparent that we are now in the midst of a rapid process of international harmonization in drug regulation and decision making. Canada must identify sufficient human resources to participate in this international process, particularly with partners in Europe and the United States. From the present survey, it can be judged that the numbers of personnel available in the future with appropriate research training are likely to be inadequate for the support of meaningful scientific partnerships. This will make it extremely difficult for Canada to align its internal expertise with that of international partners.

Many of the important conclusions derived from the survey were highlighted as recommendations from a very productive workshop conducted in Montreal on April 18, 2009. Those recommendations are integral to the future planning that should arise from this study. Canada has reached a watershed in the evaluation of therapeutic products and must now evolve if the needs of Canadian citizens are to be met.

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8.0 APPENDICES

APPENDIX 1 HUMAN RESOURCE CAPACITY INVENTORY

Appendix 1A: Cover Letter to Individual Researcher

To: [Email]

From: jasoon@interchange.ubc.ca

Subject: Inventory of Canadian Researchers in Post-Market Drug Evaluation

Body: Dear [First Name],

We are collaborating with Health Canada in compiling an inventory of researchers currently involved with post-market drug evaluation research in an academic, research or health care institutional setting. In addition, we are identifying graduate training programs available in Canada in this field.

This survey is designed to provide Health Canada with insight into the current capacity for post-market drug evaluation. In the future, these data may be used by Health Canada as a guide to recruitment of appropriate investigative teams or expert committees, and may result in new opportunities for graduate training in this area.

To access the survey, please copy and paste the link below into your browser address bar:. http://ares.ubc.ca/HealthCanada2009/DrugEvaluation_E.asp *La version FRANÇAISE est aussi offerte sur demande.*

This survey should take less than 10 minutes to complete, and asks questions about your research training and drug research experience. By completing the survey, you are providing your consent. Please be assured that your responses are confidential and will be shared only with Health Canada. Survey data will be aggregated by us and the results will be reported as an indicator of national capacity in a manner that ensures individual confidentiality.

If you have any questions regarding the survey, feel free to contact Dr. Judith Soon at jasoon@interchange.ubc.ca.

We very much appreciate your participation.

Kind regards,

Judith Soon, B.Sc. (Pharm), Ph.D., FCSHP
Assistant Professor, UBC Faculty of Pharmaceutical Sciences
Stuart MacLeod, M.D., Ph.D., FRCPC
Associate Dean (Research), UBC Faculty of Medicine, Child & Family Research Institute

Appendix 1B: Reminder Letter to Individual Researcher

To: [Email]

From: jasoon@interchange.ubc.ca

Subject: Reminder: Inventory of Canadian Researchers in Post-Market Drug Evaluation

Body: Dear [First Name],

By now you may have received our request to fill out a questionnaire that will help Health Canada determine the capacity of Canadian Researchers involved in the post-market drug evaluation research. This survey was mailed out to you on February 22 - 23, 2009.

We thank those of you who have already completed this survey. We request that those who have yet to complete this questionnaire do so at your earliest convenience, as this survey will be closed on **March 31, 2009.** The survey only takes 10 minutes to complete and can be found at the following link: http://ares.ubc.ca/HealthCanada2009/DrugEvaluation_E.asp *La version FRANÇAISE est aussi offerte sur demande.*

Please feel free to share this invitation and hyperlink with colleagues who are involved with this area of drug evaluation research.

Please be assured that your responses are confidential and will be shared only with Health Canada. Survey data will be aggregated by us and the results will be reported as an indicator of national capacity in a manner that ensures individual confidentiality.

If you have any questions regarding the survey, feel free to contact Dr. Judith Soon at jasoon@interchange.ubc.ca.

Kind regards,

Judith Soon, B.Sc. (Pharm), Ph.D., FCSHP
Assistant Professor, UBC Faculty of Pharmaceutical Sciences
Stuart MacLeod, M.D., Ph.D., FRCPC
Associate Dean (Research), UBC Faculty of Medicine, Child & Family Research Institute

Appendix 1C: Cover Letter to Organization

To: [Email]

From: jasoon@interchange.ubc.ca

Subject: Inventory of Canadian Researchers in Post-Market Drug Evaluation

Body: Dear [First Name],

We are collaborating with Health Canada in compiling an inventory of researchers currently involved with post-market drug evaluation research in an academic, research or health care institutional setting. In addition, we are identifying graduate training programs available in Canada in this field. **We seek your assistance in forwarding this survey link to members of your Staff who may be involved with post-market drug evaluation research.**

This survey is designed to provide Health Canada with insight into the current capacity for post-market drug evaluation. In the future, these data may be used by Health Canada as a guide to recruitment of appropriate investigative teams or expert committees, and may result in new opportunities for graduate training in this area.

To access the survey, please copy and paste the link below into your browser address bar: http://ares.ubc.ca/HealthCanada2009/DrugEvaluation_E.asp *La version FRANÇAISE est aussi offerte sur demande.*

This survey should take less than 10 minutes to complete, and asks questions about your research training and drug research experience. By completing the survey, you are providing your consent. Please be assured that your responses are confidential and will be shared only with Health Canada. Survey data will be aggregated by us and the results will be reported as an indicator of national capacity in a manner that ensures individual confidentiality.

If you have any questions regarding the survey, feel free to contact Dr. Judith Soon at jasoon@interchange.ubc.ca.

We very much appreciate your participation.

Judith Soon, B.Sc. (Pharm), Ph.D., FCSHP
Assistant Professor, UBC Faculty of Pharmaceutical Sciences
Stuart MacLeod, M.D., Ph.D., FRCPC
Associate Dean (Research), UBC Faculty of Medicine, Child & Family Research Institute

Appendix 1D: Survey for Post-Market Drug Evaluation Researchers

INVENTORY OF CANADIAN RESEARCHERS IN POST-MARKET DRUG EVALUATION

1. INTRODUCTION

Health Canada is currently engaged in efforts to modernize the *Food and Drugs Act* and its regulations. This initiative will result in updated regulations related to pre-market applications, authorization and entry into the market, and will greatly strengthen post-market activities such as pharmacovigilance and risk management. This life-cycle approach to the regulation of health products will help support the generation of timely, high quality knowledge on the safety and effectiveness of drugs in the real world environment.

To facilitate this initiative, the UBC Faculties of Medicine and Pharmaceutical Sciences, in collaboration with Health Canada, are compiling an inventory of researchers in academic and research institutions who are involved with post-market drug evaluation research and/or have access to real world population data.

The objectives of this project are: 1) to conduct an inventory of Canadian researchers participating in the evaluation of drugs in the post-market environment, and 2) to conduct an inventory of educational institutions providing training in these areas.

In the future, these data may be used by Health Canada as a guide to recruitment of appropriate investigative teams or expert committees, and may result in new opportunities for graduate training in this area.

Thank you for kindly participating in this Health Canada inventory of Canadian researchers.

2. BACKGROUND INFORMATION

1. Please provide your name and contact information.

Name:

Institution:

Address:

Address 2:

City/Town:

Province:

Postal Code:

Email Address:

Phone Number:

2. What is your age group?

- ○ Less than 25 years
- ○ 25 - 34 years
- ○ 35 - 44 years
- ○ 45 - 54 years
- ○ 55 - 64 years
- ○ More than 65 years

3. What is your gender?

- ○ Female
- ○ Male

4. Which category corresponds to your principal ROLE?

- ○ Administrator
- ○ Clinician - nurse
- ○ Clinician - pharmacist
- ○ Clinician - physician
- ○ Faculty member

- ○ Graduate student
- ○ Health policy decision-maker
- ○ Independent consultant
- ○ Post-doctoral fellow
- ○ Researcher
- ○ Other (please specify)

5. Which category best corresponds to your principal research LOCATION?

- ○ Education institution
- ○ Government (Federal/Provincial/Territorial)
- ○ Health authority
- ○ Hospital or other healthcare facility
- ○ Non-profit organization
- ○ Private practice
- ○ Professional association, organization or society
- ○ Research centre
- ○ Other (please specify)

6. In what province or territory is your primary work site located?

Province or territory
Nunavut
Northwest Territory
Yukon
British Columbia
Alberta
Saskatchewan
Manitoba
Ontario
Quebec
New Brunswick
Nova Scotia
Prince Edward Island
Newfoundland & Labrador

3. RESEARCH TRAINING

1. Do you have a post-Baccalaureate degree(s)?

- ○ Yes
- ○ No

2. Please specify which post-Baccalaureate degree(s) that you have completed.

Please choose all that apply.

MD/PharmD
- O Medical Doctor (MD, MBBS, MBChB etc.)
- O Doctor of Pharmacy (PharmD)

Masters
- O Master of Business Administration (MBA)
- O Master of Economics (MEc)
- O Master of Science in Nursing (MSN)
- O Master of Public Health (MPH)
- O Master of Public Policy (MPP)
- O Master of Science (MSc)

Doctorate
- O Doctor of Philosophy (PhD)
- O Doctor of Sciences (DSc/ScD)

Other (may specify more than one)

2. Where did you receive the degrees and advanced training specified above?

Country	MD/PharmD	Masters	Doctorate
Canada			
United States			
United Kingdom			
Europe			
Australia/New Zealand			

Other (may specify more than one)

4. RESEARCH EXPERTISE

1. What top five KEY WORDS would you use to describe your areas of CLINICAL expertise?

Clinical Expertise

- ○ Allergy/Immunology
- ○ Anesthesia
- ○ Cancer
- ○ Cardiology
- ○ Critical care
- ○ Endocrine/Metabolism
- ○ Gastroenterology
- ○ Geriatrics/Gerontology
- ○ Hematology
- ○ Infectious disease
- ○ Internal medicine
- ○ Mental health
- ○ Musculoskeletal
- ○ Neurology
- ○ Obstetrics/Gynecology
- ○ Ophthalmology
- ○ Orthopedics
- ○ Otolaryngology
- ○ Pediatrics
- ○ Pharmacology
- ○ Pulmonology
- ○ Radiology
- ○ Rheumatology
- ○ Surgery
- ○ Transplant
- ○ Other (please specify)

2. What top five KEY WORDS would you use to describe your areas of RESEARCH expertise?

- ○ Active comparator clinical trials
- ○ Adherence to drug therapy
- ○ Adverse drug reaction monitoring
- ○ Bioethics
- ○ Biostatistics

- ○ Clinical pharmacy practice
- ○ Clinical trial design
- ○ Decision analytic modelling
- ○ Epidemiology
- ○ Health economics
- ○ Health informatics
- ○ Health policy research
- ○ Health technology assessment
- ○ Meta-analyses
- ○ Patient decision aids
- ○ Patient safety
- ○ Pharmacoepidemiology
- ○ Pharmacogenetics
- ○ Pharmacogenomics
- ○ Pharmacokinetics
- ○ Population data management
- ○ Qualitative methodology
- ○ Risk minimization interventions
- ○ Risk management
- ○ Systematic reviews
- ○ Toxicology
- ○ Other (please specify)

3. What top five KEY WORDS would you use to describe your expertise with SPECIAL POPULATIONS?

- ○ Aboriginal Health
- ○ Child and Youth Health
- ○ Marginalized Populations
- ○ Seniors Health
- ○ Women's Health
- ○ Other (please specify)

4. What professional organization that you currently belong to best aligns with your research interests?

- ○ Canadian Association for Health Services and Policy Research (CAHSPR)
- ○ Canadian Association for Population Therapeutics (CAPT)
- ○ Canadian College of Clinical Pharmacy (CCCP)

- ○ Canadian Medical Association (CMA) including provincial associations
- ○ Canadian Pharmacists Association (CPhA) including provincial Associations
- ○ Canadian Society for Epidemiology and Biostatistics (CSEB)
- ○ Canadian Society of Hospital Pharmacists (CSHP)
- ○ Canadian Society for Pharmaceutical Sciences (CSPS)
- ○ Canadian Society of Pharmacology and Therapeutics (CSPT)
- ○ Drug Information Association (DIA)
- ○ International Society for Pharmacoepidemiology (ISPE)
- ○ International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
- ○ Society of Toxicology of Canada (STC)
- ○ Other (please specify)

5. DRUG RESEARCH EXPERIENCE

1. **Have you been involved in post-market drug evaluation research following completion of your post-graduation studies?**
   - ○ Yes
   - ○ No

2. **If YES, please state for how many years you have been involved in post-market drug evaluation research.**
   - ○ Less than 5 years
   - ○ 5 - 9 years
   - ○ 10 - 14 years
   - ○ 15 - 19 years
   - ○ 20 - 24 years
   - ○ More than 25 years

3. **Many researchers are involved with both pre-market and post-market research. Have you been involved with PRE-market drug evaluation research in the past 5 years?**
   - ○ Yes
   - ○ No

4. **If YES, in what top five subject area(s) have you conducted PRE-market drug evaluation research studies?**
   - ○ Bioavailability
   - ○ Bioequivalence
   - ○ Dose ranging
   - ○ Drug interaction

- ○ Drug metabolism
- ○ Efficacy
- ○ Metabolic actions
- ○ Pharmacodynamics
- ○ Pharmacokinetics
- ○ Pharmacologic actions
- ○ Safety
- ○ Tolerability
- ○ Other (please specify)

5. What are the top five types of POST-market drug evaluation research that you have been involved in within the past 5 years?

- ○ Adherence to drug therapy
- ○ Adverse drug reaction monitoring
- ○ Bioethics
- ○ Clinical pharmacy practice
- ○ Epidemiology
- ○ Health economics
- ○ Health informatics
- ○ Health policy research
- ○ Health technology assessment
- ○ Patient decision aids
- ○ Patient safety
- ○ Pharmacoepidemiology
- ○ Pharmacogenetics
- ○ Pharmacogenomics
- ○ Pharmacokinetics
- ○ Pharmacology
- ○ Risk minimization interventions
- ○ Risk management
- ○ Toxicology
- ○ Other (please specify)

6. What are the top five types of POST-market drug evaluation research METHODOLOGY that you have been involved in within the past 5 years?

- ○ Active comparator clinical trials
- ○ Case-control study
- ○ Cross-sectional study
- ○ Decision-analytic modelling

- ○ Meta-analysis
- ○ Population health database
- ○ Pragmatic "real world" observational study
- ○ Qualitative research
- ○ Randomized controlled clinical trial
- ○ Systematic review
- ○ Other (please specify)

7. **Please list 3 representative OPERATING GRANTS (either peer-reviewed or industry sponsored) that you have obtained as a PRINCIPAL INVESTIGATOR, CO-INVESTIGATOR OR TRAINEE in the past 5 years. For each grant, please indicate the YEAR, the TITLE and the GRANTING ORGANIZATION.**

First

Second

Third

6. GRADUATE STUDENT SUPERVISION

1. **Have you supervised Post-Baccalaureate (such a Masters, MD/PharmD (MD, MBBS, MBChB, PharmD) or Doctorate) students in the past 5 years in the area of post-market drug evaluation?**
   - ○ Yes
   - ○ No

If YES, please provide the number of Post-Baccalaureate students who you are CURRENTLY supervising.

MD/PharmD

Masters

Doctorate

2. **If YES, please provide the number of Post-Baccalaureate students who you have supervised in the past 5 years and who have COMPLETED their training.**

MD/PharmD	
Masters	
Doctorate	

7. KNOWLEDGE TRANSLATION

The Canadian Institutes of Health Research (CIHR) has referred to knowledge translation as "a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system."

1. **What are the top five types of knowledge translation strategies that you have utilized to enhance the dissemination and uptake of the findings of your post-market drug evaluation research?**
   - ○ Systematic reviews
   - ○ Practice guidelines
   - ○ Decision aids and rules
   - ○ Conference presentations
   - ○ Peer-reviewed journal publications
   - ○ Summary briefings to stakeholders
   - ○ Educational sessions with policy makers, practitioners or patients
   - ○ Media engagement
   - ○ Use of knowledge brokers
   - ○ Developing commercialization potential of discoveries
   - ○ Collaborative research involving research users in the research process
   - ○ Other (please specify)

2. **Please list 3 of your recent and representative peer-reviewed PUBLICATIONS involving post-market drug evaluation research.**

First

Second

Third

8. MODERNIZATION OF THE *FOOD AND DRUGS ACT*

1. **Are you familiar with the proposed modernization of the *Food and Drugs Act*?**
   - ○ Yes
   - ○ No

2. **If YES, were you involved with Health Canada consultations in the past related to the modernization of the *Food and Drugs Act*?**
   - ○ Yes
   - ○ No

3. **If YES, please describe your previous involvement with Health Canada consultations.**

4. **If NO, have you provided feedback to Health Canada other than consultations?**
   - ○ Yes
   - ○ No

5. **If YES, please describe how you provided feedback to Health Canada.**

6. **Would you be willing to be involved with post-market drug evaluation research studies in the future?**
   - ○ Yes
   - ○ No

7. **If NO, what factor(s) influenced your decision? Please describe.**

8. **Are there BARRIERS to data access that limit your involvement in post-market drug evaluation research?**
   - ○ Yes
   - ○ No

9. **If YES, please describe the BARRIERS that limit your involvement in post-market drug evaluation research.**

10. **Health Canada is compiling an inventory of researchers in academic and research institutions who are involved with post-market drug evaluation research. Would you consent to be included in the Health Canada REGISTRY of researchers trained to conduct post-market drug evaluation research? In the future, these data may be used by Health Canada as a guide to recruitment of appropriate investigative teams or expert committees.**
    - ○ Yes
    - ○ No

11. **If you answered NO to the inclusion of your information, what factor(s) influenced your decision? Please describe.**

12. If you answered YES to the inclusion of your information, would you consent to the distribution of your information in this Health Canada REGISTRY to:

	Yes	No
PUBLIC SECTOR (e.g., governments, institutions)	O	O
NOT-FOR-PROFIT (e.g., organizations, research networks)	O	O
PRIVATE SECTOR (e.g., industry, contract research organizations)		

13. If you answered NO to the distribution of your information, what factor(s) influenced your decision? Please describe.

14. Do you know of other researchers who would be interested in participating in the survey? If YES, please provide their name and e-mail address and we will promptly follow-up with them.

8. THANK YOU

Thank you for taking the time to complete this survey. Your input into this inventory of drug evaluation researchers in Canada is very much appreciated.

You may now click on the "Done" button to close the browser window.

If you have questions of a technical nature, please contact Adam Hunter at 604-809-8570 or ahunter@ares.ubc.ca.

If you have questions about the survey content, please contact Dr. Judith Soon at 604-807-1638 or jasoon@interchange.ubc.ca

APPENDIX 2 EDUCATIONAL INSTITUTION INVENTORY
Appendix 2A: Program Details for Educational Institutions

	University of British Columbia Pharmaceutical Sciences	University of British Columbia Population and Public Health	University of British Columbia Epidemiology	University of British Columbia Public Health	University of British Columbia Bioinformatics
Program Name	Pharmaceutical Sciences	Population and Public Health	Epidemiology	Public Health	Bioinformatics
Website	www.pharmacy.ubc.ca	www.spph.ubc.ca	www.spph.ubc.ca	www.spph.ubc.ca	www.bioinformatics.ubc.ca/
Graduate degrees granted	MSc, PhD	MSc, PhD, MD/PhD	MHSc	MPH	MSc, PhD
Graduates per year	MSc 9; PhD 11	MSc 15; PhD 10	20	25	6
Thesis (Yes/No)	Yes	Yes	No	No	Yes
Practicum (Yes/No)	No	No	No	Yes	No
Application Deadline	February 15 International; March 15 Domestic	February 01	March 01	February 01	March 15
Contact Person	Dr. Helen M. Burt	Moira Thejomayen	Moira Thejomayen	Kim Mantle	Ms. Sharon Ruschkowski
Email address	burt@interchange.ubc.ca	moira.thejomayen@ubc.ca	moira.thejomayen@ubc.ca	mph@spph.ubc.ca	bioinformaticsprogram@bcgsc.ca
Contact Phone	(604) 822-2440	(604) 822-5405	(604) 822-5405	(604) 822-9207	(604) 707-5803
Address	Faculty of Pharmaceutical Sciences University of British Columbia 2146 East Mall Vancouver BC V6T 1Z3	School of Population and Public Health University of British Columbia 5804 Fairview Avenue Vancouver BC V6T 1Z3	School of Population and Public Health University of British Columbia 5804 Fairview Avenue Vancouver BC V6T 1Z3	School of Population and Public Health University of British Columbia 5804 Fairview Avenue Vancouver BC V6T 1Z3	UBC Bioinformatics University of British Columbia 100-570 West 7th Avenue Vancouver BC V5Z 4S6
Number of applicants per year	60	70	30	260	80
Typical length of Degree	MSc 2 years; PhD 4 years	MSc 2 years; PhD 4 years	1 year	2 years	MSc 2 years; PhD 5 years
Part Time Available (Yes/No)	No	Yes MSc only	Yes	Yes	No
Language of instruction	English	English	English	English	English

	University of Victoria Health Informatics	Simon Fraser University Public Health	University of Northern British Columbia Community Health	University of Alberta Public Health	University of Alberta Epidemiology
Program Name	Health Information Science	Public Health	Community Health Science	Public Health	Epidemiology
Website	hinf.uvic.ca/index.php	www.fhs.sfu.ca/graduate-programs	www.unbc.ca/communityhealth/index.html	www.phs.ualberta.ca/index.cfm	www.phs.ualberta.ca/index.cfm
Graduate degrees granted	MSc, PhD	MPH	MSc	MPH	MSc, PhD
Graduates per year	Variable - about 10, mostly MSc	60	6	20	Variable - about 30
Thesis (Yes/No)	Yes	Yes in Thesis Stream	Yes	No	Yes
Practicum (Yes/No)	No	Yes in Practicum Stream	No	Yes	No
Application Deadline	February 28; May 31; October 31	February 01	February 15	December 15 (prelim); January 15 (final)	December 15 (prelim); January 15 (final)
Contact Person	Shawna McNabb	Jen Van Rassel	Irma Watt	Ms. Dawn Cook	Ms. Dawn Cook
Email address	hisgrad@uvic.ca	fhsgrads@sfu.ca	cmhs@unbc.ca	phs.programs@ualberta.ca	phs.programs@ualberta.ca
Contact Phone	250 721-8575	778 782-7036	(250) 960-5363	Phone: (780) 492-6407	Phone: (780) 492-6407
Address	Health Information Science University of Victoria PO Box 3050 STN CSC Victoria BC V8W 3P5	Faculty of Health Sciences Simon Fraser University Blusson Hall Room 11300, 8888 University Drive Burnaby BC V5A 1S6	Health Sciences Program University of Northern British Columbia 3333 University Way Prince George BC V2N 4Z9	University of Alberta 13-103 Clinical Sciences Building Edmonton AB T6G 2G3	University of Alberta 13-103 Clinical Sciences Building Edmonton AB T6G 2G3
Number of applicants per year	40 per entry point	250	12	180	Hundreds
Typical length of Degree	MSc 2 years; PhD 5years	2 years	2 years	1.5 years	MSc 2.5 years; PhD 4.5 years
Part Time Available (Yes/No)	No	Yes	No	Yes	Yes
Language of instruction	English	English	English	English	English

	University of Alberta Pharmacy and Pharmaceutical Sciences	University of Calgary Veterinary Medicine	University of Calgary Community Health	University of Calgary Community Medicine	University of Saskatchewan Public Health
Program Name	Pharmacy and Pharmaceutical Sciences	Veterinary Medicine	Community Health	Master of Community Medicine	Public Health
Website	www.pharm.ualberta.ca/	vet.ucalgary.ca/graduate	www.ucalgary.ca/communityhealthsciences/	www.ucalgary.ca/communityhealthsciences/	www.usask.ca/sph/graduate_programs/mph/index.html
Graduate degrees granted	MSc, PhD	MSc, PhD	MSc/PhD	MCM (only for CM residents)	MPH
Graduates per year	MSc 4; PhD 4	Goal 35-40	20-25	2	25
Thesis (Yes/No)	Yes	Yes	Yes	No	No
Practicum (Yes/No)	No	No	No	No	Yes
Application Deadline	Canadian: June 1 (prelim) for September; September 1 (prelim) for January International: April 1 (prelim) for September; July 1 (prelim) for January	January 10	January 15	N/A	February 15
Contact Person	Dr. Ayman El-Kadi	Tara Christie	Crystal Elliot	Dr. Marilynne Hebert	Patty Posnikoff
Email address	info@pharmacy.ualberta.ca	chrsttl@ucalgary.ca	chsgrad@ucalgary.ca	hebert@ucalgary.ca	school.publichealth@usask.ca
Contact Phone	(780) 492-2967	(403) 210-6628	Fax: (403) 270-7307	Fax: (403) 270-7307	(306) 966- 8544
Address	Faculty of Pharmacy & Pharmaceutical Sciences University of Alberta 3126D Dentistry/Pharmacy Centre Edmonton AB T6G 2N8	Department of Research and Graduate Education University of Calgary Room G359, Heritage Medical Research Building 3330 Hospital Drive NW Calgary AB T2N 4N1	Department of Research and Graduate Education University of Calgary Room G02, Heritage Medical Research Building 3330 Hospital Drive NW Calgary AB T2N 4N1	Masters of Community Medicine Program University of Calgary Room G02, Heritage Medical Research Building 3330 Hospital Drive NW Calgary AB T2N 4N1	School of Public Health University of Saskatchewan Health Science Building, 107 Wiggins Road Saskatoon SK S7N 5E5
Number of applicants per year	500	Brand new program	70	N/A (CM residents only)	166
Typical length of Degree	MSc 2 years; PhD 5 years	MSc 2 years; PhD 4 years	MSc 2.5 years; PhD 4.5 years	To be completed during residency	16 months - 5 years
Part Time Available (Yes/No)	No	Data not available	No	N/A	Yes
Language of instruction	English	English	English	English	English

	University of Saskatchewan Epidemiology	University of Saskatchewan School of Pharmacy and Nutrition	University of Manitoba Public Health	U of Manitoba Epidemiology	U of Manitoba Public Health
Program Name	Epidemiology	Pharmacy and Nutrition	Public Health	Epidemiology	Public Health
Website	www.medicine.usask.ca/che/	www.usask.ca/pharmacy-nutrition/gradprograms/	umanitoba.ca/medicine/chs	umanitoba.ca/medicine/chs	umanitoba.ca/medicine/chs
Graduate degrees granted	MSc, PhD	MSc, PhD	MPH	MSc PhD	Dip P.H.
Graduates per year	4	MSc 2; PhD 1	15-20	5 MSc; 2 PhD	1 or 2
Thesis (Yes/No)	Yes	Yes	No	Yes	No
Practicum (Yes/No)	No	No	Yes	No	No
Application Deadline	February 15	Applications accepted anytime	January 8	January 8	January 8
Contact Person	Cheryl Bolster	Dr. Fred Remillard	Ms. Theresa Kennedy	Ms. Theresa Kennedy	Ms. Theresa Kennedy
Email address	chep.info@usask.ca	Grad-Pharmacy-Nutrition@usask.ca	chs_graduate_prg@umanitoba.ca	chs_graduate_prg@umanitoba.ca	chs_graduate_prg@umanitoba.ca
Contact Phone	(306) 966-7944	(306) 966-6327	(204) 789-3655	(204) 789-3655	(204) 789-3655
Address	Department of Community Health & Epidemiology University of Saskatchewan Health Science Building, 107 Wiggins Road Saskatoon SK S7N 5E5	College of Pharmacy and Nutrition University of Saskatchewan 110 Science Place Saskatoon SK S7N 5C9	Medical Services Bldg. University of Manitoba S113 - 750 Bannatyne Avenue Winnipeg Manitoba R3E 0W3	Medical Services Bldg. University of Manitoba S113 - 750 Bannatyne Avenue Winnipeg Manitoba R3E 0W3	Medical Services Bldg. University of Manitoba S113 - 750 Bannatyne Avenue Winnipeg Manitoba R3E 0W3
Number of applicants per year	20	120	65 for all programs	Data not available	Those who make grade cut-off generally accepted
Typical length of Degree	MSc 2 years; PhD 4 years	MSc 2 years; PhD 4 years	2 years	MSc 2 years; PhD 4 years	1 year
Part Time Available (Yes/No)	No	No	Yes	Yes	Yes
Language of instruction	English	English	English	English	English

	University of Manitoba Pharmacy	Western Regional Training Centres	University of Toronto Clinical Epidemiology	University of Toronto Health Informatics	University of Toronto Health Technology Assessment
Program Name	Pharmacy	Health Services Research	Clinical Epidemiology	Medical Health Informatics	Heath Technology Assessment
Website	umanitoba.ca/faculties/pharmacy/programs/graduate_program.html	www.wrtc-hsr.ca/	www.hpme.utoronto.ca/about/gradprograms.htm	www.hpme.utoronto.ca/about/gradprograms/mhi.htm	www.hpme.utoronto.ca/about/gradprograms.htm
Graduate degrees granted	MSc, PhD	MSc, PhD (but via participating institutions)	MSc, PhD	MHI	MSc
Graduates per year	2 to 4	Does not add extra grads, but available to those already enrolled in a program	25-30	New - No graduates yet	New - No graduates yet
Thesis (Yes/No)	Yes	Dependant on students program	MSc optional; PhD Yes	No	Yes
Practicum (Yes/No)	No	Field placement	No	Yes	No
Application Deadline	March 01	February 28	November 15	March 01	April 01
Contact Person	Dr. Keith Simons	Isabella Losinger	Amber Gertzbein	Amber Gertzbein	Christina Lopez
Email address	simons@cc.umanitoba.ca	wrtc.hsr@ubc.ca	clinepi.grad@utoronto.ca	mhi.hpme@utoronto.ca	christina.lopez@utoronto.ca
Contact Phone	(204) 474-9306	(604) 822-2827	(416) 946-3486	(416) 946-3486	(416) 978-1108
Address	Faculty of Pharmacy University of Manitoba 750 McDermot Avenue Winnipeg Manitoba R3E 0T5	School of Population and Public Health University of British Columbia 5804 Fairview Avenue Vancouver BC V6T 1Z3	Department of Health Policy, Management and Evaluation University of Toronto 155 College Street, Suite 425 Toronto ON M5T 3M6	Department of Health Policy, Management and Evaluation University of Toronto 155 College Street, Suite 425 Toronto ON M5T 3M6	Department of Health Policy, Management and Evaluation University of Toronto 155 College Street, Suite 425 Toronto ON M5T 3M6
Number of applicants per year	Data not available	Data not available	100	100	Date not available
Typical length of Degree	MSc 2 years; PhD 4 years	As per student programs	MSc 2 years; PhD 4 years	16 months	2 years
Part Time Available (Yes/No)	No	Yes	MSc No; PhD Yes	No	Yes
Language of instruction	English	English	English	English	English

	University of Toronto Public Health	University of Toronto Pharmacy	McMaster University Health Research Methodology	Ontario Training Centre	U of Ottawa Epidemiology
Program Name	Public Health	Clinical (non Lab)	Health Research Methodology	Health Services and Policy Research	Epidemiology
Website	www.phs.utoronto.ca/Programs.asp	www.pharmacy.utoronto.ca/graduate/prospect/programs.jsp	prelude.mcmaster.ca/grad/hrm/index.html	www.otc-hsr.ca/	www.intermed.med.uottawa.ca/epid/eng/index.html
Graduate degrees granted	MSc, PhD, MHSc, MScCH	MSc, PhD	MSc, PhD	Diploma in Health Services and Policy Research	MSc
Graduates per year	50-70 (all programs)	15	MSc 30-40; PhD 10-12	Does not add extra graduates (25-30)	15-20
Thesis (Yes/No)	MSc and PhD Yes	Yes	Yes	No (but enrollment in MSc or PhD required)	Yes
Practicum (Yes/No)	Yes MHSc and MScCH	No	No	Yes	No
Application Deadline	Masters - February 01; PhD - January 15	May 01 and October 15	MSc: November 01 and February 15; PhD: February 01	March 31	January 31
Contact Person	Not stated	Tammy Chan	Ann Greene	Miguel A. Pérez	Dr Brenda J Wilson
Email address	chl.grad@utoronto.ca	pharm.sci@utoronto.ca	greenea@mcmaster.ca	mperez@mcmaster.ca	epidmsc@uottawa.ca
Contact Phone	(416) 978-2058	(416) 978-2179	(905) 525-9140 ext. 27718	(905) 525-9140 ext. 26203	(613) 562-5800 ext. 8261
Address	Department of Health Policy, Management and Evaluation University of Toronto Main Office Rm. 620 Health Sciences Building 155 College Street Toronto ON M5S 3M7	Leslie Dan Faculty of Pharmacy University of Toronto 144 College Street Toronto ON M5S 3M2	Health Sciences Centre, HSC 3N10 1200 Main Street West Hamilton ON L8N 3Z5	Ontario Training Centre Health Sciences Centre, HSC 3N10 1200 Main Street West Hamilton ON L8N 3Z5	Epidemiology Program University of Ottawa 451 Smyth Rd., Room 2135 Ottawa ON K1H 8M5
Number of applicants per year	800 (all programs)	Data not available	>200	50	150
Typical length of Degree	MSc 1 year; MHSc 2 years; PhD 5 years	MSc 2 years; PhD 4 years	MSc 1.5-2 years; PhD 4 years	2 Terms	2 years
Part Time Available (Yes/No)	Yes	Yes	Yes	Yes	No
Language of instruction	English	English	English	English	English

	University of Ottawa Population Health	Queen's University Public Health	Queen's University Epidemiology	University of Western Ontario Epidemiology	U of Western Ontario Epidemiology
Program Name	Population Health	Public Health	Epidemiology	Epidemiology	Epidemiology
Website	www.pophealth.uottawa.ca/Default.aspx?tabid=1067	meds.queensu.ca/medicine/comhepi/mphprogram.htm	meds.queensu.ca/medicine/comhepi/index.html	www.uwo.ca/epidem/Educprograms/Gradprogram/MSc_PhD.html	www.uwo.ca/epidem/Educprograms/Gradprogram/Certificate/Certificate_Prospective.html
Graduate degrees granted	PhD	MPH	MSc, PhD	MSc, PhD	Certificate
Graduates per year	3	10	MSc 15; PhD 4	20	20 - MD required for entrance
Thesis (Yes/No)	Yes	No	Yes	Yes	No
Practicum (Yes/No)	No	Yes	No	No	Yes
Application Deadline	January 31	January 31	Not Stated	February 01	February 01
Contact Person	Roseline Savage	Catherin Cook	Catherine Cook	Ms. Stephanie Zeleny	Ms. Stephanie Zeleny
Email address	pop@uottawa.ca	mphealth@queensu.ca	epid@queensu.ca	EpiBio@schulich.uwo.ca	EpiBio@schulich.uwo.ca
Contact Phone	(613) 562-5691	(613) 533-2901	(613) 533-2901	(519) 661-2162	(519) 661-2162
Address	Population Health University of Ottawa 1 Stewart Street Room 300 Ottawa ON K1N 6N5	MPH Program Queen's University 2nd Floor Abramsky Hall, Arch Street Kingston ON K7L 3N6	Epidemiology Queen's University 2nd Floor Abramsky Hall, Arch Street Kingston ON K7L 3N6	Department of Epidemiology and Biostatistics The University of Western Ontario Kresge Building, Rm K201 London ON N6A 5C1	Department of Epidemiology and Biostatistics The University of Western Ontario Kresge Building, Rm K218 London ON N6A 5C1
Number of applicants per year	25-30	200-300	>100	100	20
Typical length of Degree	4 to 6 years	16 months	MSc 2 years; PhD 5 years	MSc 2 years; PhD 4 years	1 to 2 years
Part Time Available (Yes/No)	No	No	MSc Yes; PhD No	MSc Yes; PhD No	No
Language of instruction	English	English	English	English	English

	University of Waterloo Public Health	University of Waterloo Health Sciences	University of Guelph Public Health	University of Guelph Population Medicine	Lakehead University Public Health
Program Name	Health Sciences and Gerontology	Health Sciences and Gerontology	Public Health	Population Medicine	Public Health
Website	www.ahs.uwaterloo.ca/hsg/mph/	www.ahs.uwaterloo.ca/hsg/	www.ovc.uoguelph.ca/mph/	www.ovc.uoguelph.ca/popm/studies/	mph.lakeheadu.ca/
Graduate degrees granted	MPH	MSc, PhD	Diploma, MPH	MSc, PhD, DVSc	MPH
Graduates per year	55-65 (expected once program established)	Data not available	12 to 15	MSc 8; PhD 5-7; DVSc 1-2	30
Thesis (Yes/No)	No	Yes	No	Yes (course based masters available)	Optional
Practicum (Yes/No)	Yes	No	Yes	No	No
Application Deadline	February 01	February 01	March 01	Open	February 01
Contact Person	Leanne Smith	Tracy Taves	Andrew Papadopoulos	Mary Elliott	Glenna Knutson
Email address	l8smith@healthy.uwaterloo.ca	tltaves@healthy.uwaterloo.ca	apapadop@uoguelph.ca	melliott@uoguelph.ca	mph@lakeheadu.ca
Contact Phone	(519) 888-4567 ext. 37734	(519) 888-4567 ext. 36149	(519) 824-4120 ext. 53894	(519) 824-4120 ext. 54780	(807) 343-8248
Address	Master of Public Health Program, Department of Health Studies and Gerontology University of Waterloo 200 University Avenue West Waterloo ON N2L 3G1	Department of Health Studies and Gerontology University of Waterloo 200 University Avenue West Waterloo ON N2L 3G1	Centre for Public Health and Zoonoses MacNabb House University of Guelph Guelph ON N1G 2W1	Centre for Public Health and Zoonoses MacNabb House University of Guelph Guelph ON N1G 2W1	Department of Public Health Lakehead University 955 Oliver Road Thunder Bay ON P7B 5E1
Number of applicants per year	300	Many - no estimate available	30	55 total	Data not available
Typical length of Degree	2 years full time	MSc 2 years; PhD 3-4 years	Diploma 1 year; MPH 2 years	MSc 2-4 years; PhD 6 years	2 years
Part Time Available (Yes/No)	Yes	Yes	Yes	MSc and PhD Yes; DVSc No	Yes
Language of instruction	English	English	English	English	English

	McGill University Epidemiology	McGill University Epidemiology	Université de Montréal Community Health	Université de Montréal Community Health	Université de Montréal Public Health
Program Name	Epidemiogy	Epidemiology	Community Health	Community Health	Public Health
Website	www.mcgill.ca/epi-biostat-occh/	www.mcgill.ca/epi-biostat-occh/	www.mdsocp.umontreal.ca/actualite.asp	www.mdsocp.umontreal.ca/actualite.asp	www.medsp.umontreal.ca/doctorat/mission.htm
Graduate degrees granted	MSc, PhD	Diploma	Microprogram, Diploma	Masters	PhD
Graduates per year	15 PhD; 30 MSc	Currently not offered	5 to 10	20 to 25	10 to 12
Thesis (Yes/No)	MSc Optional; PhD Yes	No project but dissertation	No	Optional	Yes
Practicum (Yes/No)	No	No	No	No	No
Application Deadline	January 15	Currently not offered	February 01	February 01	February 01
Contact Person	Not stated	Not stated	Marie Hatem	Marie Hatem	Ms France Pinsonnault
Email address	info.epid@mcgill.ca	info.epid@mcgill.ca	marie.hatem@umontreal.ca	marie.hatem@umontreal.ca	france.pinsonnault@umontreal.ca
Contact Phone	(514) 398-6258	(514) 398-6258	(514) 343-6136	(514) 343-6136	(514) 343-6111 ext. 5389
Address	McGill University Purvis Hall 1020 Pine Avenue West Montreal Quebec H3A 1A2	McGill University Purvis Hall 1020 Pine Avenue West Montreal Quebec H3A 1A2	Département de médecine sociale et préventive Université de Montréal C.P. 6128, succursale Centre-Ville Montréal Québec H3C 3J7	Département de médecine sociale et préventive Université de Montréal C.P. 6128, succursale Centre-Ville Montréal Québec H3C 3J7	Groupe de recherche interdisciplinaire en sante Université de Montréal 1420 Boul. Mont-Royal, Suite 2381 Outremont Quebec H2V 4P3
Number of applicants per year	150-200	Currently not offered	About 30	About 75	Data not available
Typical length of Degree	MSc 2 years; PhD 4-5 years	Currently not offered	4 - 8 months (full time)	2 years (full time)	5 years
Part Time Available (Yes/No)	Yes	Currently not offered	Yes	Yes	Yes
Language of instruction	English	English	French	French	French

	Université de Montréal Veterinary Medicine	Université de Montréal Pharmacy	Université de Montréal Pharmacy	Université de Sherbrooke Clinical Science	Université de Laval Epidemiology	Université de Laval Pharmacy
Program Name	Veterinary Medicine	Pharmacy	Pharmacy	Clinical Science	Epidemiology	Pharmacoepidemiology
Website	www.medvet.umontreal.ca/etudes/2_3Cycles.html	www.pharm.umontreal.ca	www.pharm.umontreal.ca	www.usherbrooke.ca/psc/	w3.fmed.ulaval.ca/dmsp//index.php?id=480	www.pha.ulaval.ca/sgc/pid/4598
Graduate degrees granted	MSc, PhD	MSc, PhD	Diploma (DESS), MSc	MSc, PhD	MSc, PhD	MSc, PhD
Graduates per year	MSc 26; PhD 7	MSc 30-45; PhD 3-7	DESS 60+; MSc 30	Data not available	MSc 7; PhD 5	Varies
Thesis (Yes/No)	Yes	Yes	No	Yes	Yes	Yes
Practicum (Yes/No)	No	No	Yes (MSc with internship only)	No	No	No
Application Deadline	February 01	February 01	March 15	Autumn term: May 1 Winter term: November 1 Summer term: March 1	February 01	February 01
Contact Person	Micheline St-Germain	Daniel Lamontagne	Robert-Georges Paradis	Stéphanie Laurendeau	Jacques Brisson	Dr Jocelyne Moisan
Email address	micheline.st.germain@umontreal.ca	scpharmaceut@umontreal.ca	pharmdevmed@umontreaal.ca	Sciences-Cliniques-Med@Usherbrooke.ca	jacques.brisson@uresp.ulaval.ca	jocelyne.moisan@pha.ulaval.ca
Contact Phone	(519) 345-8521 ext. 8520	(514) 343 6467	(514) 343 5851	(819) 564-5361	(418) 682-7392	(418) 682-7511 ext. 4654
Address	Faculté de médecine vétérinaire Université de Montréal 3200. rue Sicotte Saint-Hyacinthe Quebec J2S 2M2	Faculté de Pharmacie Université de Montréal, Pavillon Jean Coutu C.P. 6128 Succursale Centre-Ville Montréal Québec H3C 3J7	Faculté de Pharmacie Université de Montréal, Pavillon Jean Coutu C.P. 6128 Succursale Centre-Ville Montréal Québec H3C 3J7	Department of Community Health Sciences, Faculty of Medicine Sherbrooke University 3001 12th Avenue North Sherbrooke Québec J1H 5N4	Department of Social and Preventive Medicine Université de Laval 2180 Chemin Sainte-Foy Pavillon de l'Est, bureau 1108 Québec Québec G1K 7P4	Unité de recherche en santé des populations CHA de Québec Université de Laval 1050 chemin Ste-Foy Québec Québec G1S 4L8
Number of applicants per year	Data not available	MSc 100-120; PhD 30-45	DESS 155-200; MSc 35-50	Data not available	35	10
Typical length of Degree	MSc 2 years; PhD 5 years	MSc 1.5 - 2 years; PhD 3 - 4 years	DESS 1-2 years; MSc 10-12 months	MSc: 10-12 months: PhD: Data not available	MSc 2.5 years; PhD 4 years	MSc 2 years; PhD 4 years
Part Time Available (Yes/No)	Yes	Yes	Yes (DESS only)	Yes	Yes	Yes
Language of instruction	French	French	French	French	French	French

	Dalhousie University Epidemiology	Dalhousie University Health Informatics	University of Prince Edward Island Veterinary Medicine	Memorial University Epidemiology	Altlantic Regional Training Centre
Program Name	Epidemiology	Health Informatics	Veterinary Medicine	Epidemiology	Health Services Research
Website	che.medicine.dal.ca/index.php	www.healthinformatics.dal.ca	www.upei.ca/avc/info	www.med.mun.ca/getdoc/1321e03f-f52d-4c5d-8b41-e60b5e827484/Epidemiology.aspx	www.artc-hsr.ca/
Graduate degrees granted	MSc	MHI, PhD (via interdisciplinary PhD program)	MVSc, MSc, PhD	Diploma, MSc, PhD	MAHSR, PhD
Graduates per year	8	5 to 10	Data not available	Varies significantly	Does not add extra graduates (12)
Thesis (Yes/No)	Yes	MHI is thesis or internship, PhD is thesis based	MSc and PhD Yes; MVSc No	MSc and PhD Yes; Diploma No	Yes
Practicum (Yes/No)	No	Internship for MHI available	No	No for all programs	Yes
Application Deadline	March 01	August 01 for September; October 31 for January	None	May-31 for Sept F/T, July 31 for Sept P/T, Oct 31 for Jan F/T, Nov 30 for Jan P/T	March 1st at MUN and by April 1st at DAL, UNB and UPEI
Contact Person	Dr. Kathleen MacPherson	Dr. Raza Abidi	Rosemary Mciver	Dr. Gerry Mugford/ Dr. Sean Murphy	Dr. Tom Rathwell
Email address	tina.bowdridge@dal.ca	hinf@cs.dal.ca	mciver@upei.ca	gmugford@mun.caor swmurphy@mun.ca	Thomas.Rathwell@dal.ca
Contact Phone	(902) 494-3575 or (902) 494-3860	(902) 494-3686	(902) 566-0542	Dr. Mugford (709) 777-7390 or Dr. Murphy (709) 777-7226	(902) 494 6579
Address	Community Health and Epidemiology Centre for Clinical Research, 2nd and 4th Floors 5790 University Avenue Halifax NS B3H 1W5	Health Informatics Program Faculty of Computer Science 6050 University Avenue Halifax NS A1B 3V6	Office of Graduate Studies and Research Atlantic Veterinary College, UPEI 550 University Avenue Charlottetown PE C1A 4P3	Epidemiology Program Faculty of Medicine, Room H1759, Health Sciences Centre Memorial University of Newfoundland St. John's NL B3J 1R2	Atlantic Regional Training Centre 5599 Fenwick Street Halifax NS B3J 1R2
Number of applicants per year	50	40-50	Data not available	100	Data not available
Typical length of Degree	Full Time 2yrs Part Time 4yrs	MHI 2 years	Variable	MSc 2 years	Masters 2 years
Part Time Available (Yes/No)	Yes	Yes	Data not available	Yes	Yes - limited
Language of instruction	English	English	English	English	English

Appendix 2B: Course Definitions

Course Discipline	Definition
Biostatistics	Courses specific to statistical methods and their application to investigation of health outcomes and their determinants. Data collection, numeric and graphic summarization, statistical analysis and interpretation of data are included.
Decision Analysis	Decision Analysis is the discipline comprising the philosophy, theory, methodology, and professional practice necessary to address important decisions in a formal manner. It includes applications in problem solving (screening or prevention program assessment, test of treatment trade-offs, interpreting uncertain clinical data, etc). Techniques include decision tree design, sub-trees, marker models, sensitivity analysis, Monte Carlo simulation, threshold analysis, and utility assessment.
Epidemiology	The application of core epidemiological concepts and practical skills in data management, data analysis, research protocol development, and the presentation of findings for publication. Within this category, we will designate introductory courses, those dealing with primarily clinical topics, and those dealing primarily with design and analytical issues (evaluative epidemiology).
Evidence Based Medicine	Courses aiming to teach students to apply evidence gained from the scientific method to certain parts of medical practice. It seeks to assess the quality of evidence relevant to the risks and benefits of treatments (including lack of treatment). Also focuses on critical appraisal of the medical literature.
Health Economics	Concepts and tools of economic evaluation in health services research. Critical evaluation of published economic evaluations of new drugs, technologies and other health interventions. Design of economic evaluation protocols. The role of economic evaluations in the process of health care resource allocation and health policy making. Includes cost-benefit, cost-effectiveness, cost utility, and cost minimization.
Health Ethics	The identification and analysis of ethical implications of health care decision-making.
Health Informatics	The study of health-related information and ways to process and handle it, especially by means of information technology, i.e. computers and other electronic devices for rapid transfer, processing, and analysis of large amounts of data. Includes the science of arranging and organizing the product of genomic and functional genomic studies so that useful insight can result. Bioinformatics is a discipline encompassing all aspects of biologic information acquisition, processing, storage, distribution, analysis, and interpretation that combine the tools and techniques of mathematics, computer science and biology with the aim of understanding the biologic significance of a variety of data.

Health Policy and Law	Federal and provincial acts and regulations are applicable in areas such as patient rights, consent, confidentiality, medical-legal issues, risk management, credentialing, conflict of interest, contract administration, labour relations, private/public arrangements, jurisdiction, the Charter, governance, regulatory affairs, liability and malpractice. The basic history and structure of the Canadian health care system and how ideas, interests, and institutions influence major policy debates.
Health Technology Assessment	Health technology assessment ranges from assessment to establish market viability of new technologies to assessment conducted with an objective to regulate expensive technologies, using different disciplinary perspectives. Includes the methods used for conducting health technology assessment.
Knowledge Translation	Knowledge translation is the exchange, synthesis and ethically sound application of knowledge—within a complex system of interactions among researchers and users—to accelerate the capture of the benefits of research for Canadians through improved health, more effective services and products, and a strengthened health care system.
Patient Safety/Risk Management	A healthcare discipline that emphasizes the reporting, analysis, and prevention of medical errors that often leads to adverse healthcare events.
Pharmacoeconomics	Pharmacoeconomics is a branch of health economics. Pharmacoeconomics identifies, measures, and compares the costs and consequences of pharmaceutical products and services. It will describe the primary methods of pharmacoeconomic analysis.
Pharmacoepidemiology	The methodology of different epidemiologic study designs (cohort, case-control, nested-case control, case-cross over, case-time control) pertaining to adverse events, drug efficacy or patterns of drug use in a large population.
Pharmacogenetics/ Pharmacogenomics	Branch of pharmacology that deals with the influence of genetic variation (either a single gene or multiple genes) on drug response. By doing so, the aim is to develop rational means to optimise drug therapy, with respect to the patients' genotype, to ensure maximum efficacy with minimal adverse effects. Such approaches promise the advent of "personalized medicine", in which drugs and drug combinations are optimised for each individual's unique genetic makeup.
Pharmacovigilance	A branch of pharmacoepidemiology. The science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or other drug related problems.
Qualitative Research Design	Qualitative research methodologies focus on understanding human behavior. Frequently used qualitative research approaches include ethnographic research, participatory action research, grounded theory and interpretive phenomenology. Qualitative methods of gathering data include participant observation, focus group and individual interviews, field notes and reflexive journals.
Social Determinants of Health Outcomes	Paradigms based on social determinants significantly impact approaches to improving population health. Health planning and delivery models may be based on social determinants, such as social inequality, early childhood development, genetics, and the roles of work and communities.

Appendix 2C: Summary of Courses by Institution

Educational Training Available	Simon Fraser University	University of British Columbia	University of Victoria	University of Northern British Columbia	University of Alberta	University of Calgary	University of Saskatchewan	University of Manitoba	University of Toronto
Core Courses									
Biostatistics	oo	ooooo	o		oooo	oooo	oo	ooo	oooooooooo
Epidemiology									
* Introductory epidemiology	o	oo	o	o	o	ooo	o	o	oooo
* Clinical epidemiology	ooo	ooooooooo		oo	oooo	ooooooooo	ooo	ooooooooo	ooooooooo
* Evaluative epidemiology		ooooooooooo	ooo	oo	ooooo	ooooooo	ooooo	oooooooooooo	oooooooooooo ooooooooooo
Health Economics		oo			ooo	oo		o	oooo
* Pharmacoeconomics									o
Pharmacoepidemiology		o							
Pharmacogenetics/Pharmacogenomics									
Patient Safety/RiskManagement/ Pharmacovigilance					o				
Other Non-Core Courses									
Evidence Based Medicine		o		o					oo
Decision Analysis		o				o			o
Health Ethics		o	o		o		oo		oo
Health Informatics		ooooo	ooooooooo			oo	oo		oooooo
Knowledge Translation		o							oo
Health Policy and Law	oo	o	o	o	oooo	ooo	ooooo	oo	ooooooooooo
Health Technology Assessment		o	o		o				o
Qualitative Research Design	o	o		oo		o	o	o	ooooooooooo
Social Determinants of Health Outcomes	oo	ooo			o	oo		o	o
Miscellaneous	oo	o					o		ooooo
Number of CORE courses	**2**	**4**	**2**	**1**	**4**	**3**	**2**	**3**	**3**

Educational Training Available	McMaster University	University of Ottawa	Queen's University	University of Western Ontario	University of Waterloo	University of Guelph	Lakehead University
Core Courses							
Biostatistics	oooo	o	ooo	ooo	o	o	
Epidemiology							
* Introductory epidemiology	oo	oo	o	oo	oo	o	o
* Clinical epidemiology	ooo	ooo	o	o	ooo	ooooooo	o
* Evaluative epidemiology	oooooooooo	oooooooooo	oooooo	oooooo	o	oooo	oo
Health Economics	ooooo	oo	o	o	o		o
* Pharmacoeconomics							
Pharmacoepidemiology							
Pharmacogenetics/Pharmacogenomics	o	o					
Patient Safety/RiskManagement/ Pharmacovigilance		oo			o		
Other Non-Core Courses							
Evidence Based Medicine							o
Decision Analysis							
Health Ethics	o	o					o
Health Informatics	o	o	oo		o		
Knowledge Translation		o			o		
Health Policy and Law	oo	oooooo	ooo	o	o	o	o
Health Technology Assessment	oo	o					
Qualitative Research Design	oo	o	o				o
Social Determinants of Health Outcomes		o			o		
Miscellaneous	oo	oo		o		oo	
Number of CORE courses	**4**	**5**	**3**	**3**	**4**	**2**	**2**

Educational Training Available	McGill University	Université de Montréal	Université de Sherbrooke	Université Laval	Dalhousie University	University of Prince Edward Island	Memorial University
Core Courses							
Biostatistics	oooooo	oooooooo	ooo	ooooooo	oooo	oooo	o
Epidemiology							
* Introductory epidemiology	ooo	oooo	o	oo	oo	o	
* Clinical epidemiology	oooooo	ooooooooooo		oo	o	ooo	o
* Evaluative epidemiology	ooooooooooooo	ooooooooooooooooooo	oooo	ooooooooo	oooooo	o	oo
Health Economics	ooo	ooo		oo	o		
* Pharmacoeconomics	o	o					
Pharmacoepidemiology	ooo	o		ooo			
Pharmacogenetics/Pharmacogenomics	o			o			
Patient Safety/RiskManagement/ Pharmacovigilance		o					
Other Non-Core Courses							
Evidence Based Medicine							
Decision Analysis							
Health Ethics		oo	o	o			
Health Informatics					oooooo		
Knowledge Translation					o		
Health Policy and Law	oo	ooo			ooo		
Health Technology Assessment							o
Qualitative Research Design		oooo	o	o	o		
Social Determinants of Health Outcomes	o	oo			o		
Miscellaneous	o	ooo	oooo	oooo			o
Number of CORE courses	**5**	**5**	**2**	**5**	**3**	**2**	**2**

APPENDIX 3: JOINT HEALTH CANADA/CHILD AND FAMILY RESEARCH INSTITUTE WORKSHOP

Appendix 3A: Workshop Agenda

Human Resource and Educational Inventories to Support the Life Cycle Approach to the Regulation of Therapeutic Products

AGENDA

Saturday, April 18, 2009
Fairmont Queen Elizabeth Hotel, Montreal
Gatineau and St. Laurent Rooms

9:00	Morning coffee
9:10	Opening Remarks
	Nick McCandie Glusetien, Office of Legislative and Regulatory Modernization, Health Canada
9:15	Welcome and Overview of Human Resource & Education Capacity Initiative and Purpose of the Workshop
	Stuart MacLeod, Executive Director, Child and Family Research Institute
9:30	Update on Legislative Progress and How this Inventory Links to a Product Life Cycle Approach
	David K. Lee, Director, Office of Legislative and Regulatory Modernization, Health Canada
9:45	Review of Educational Capacity in Canada
	Matthew Wiens, Clinical Pharmacotherapy Specialist, Fraser Health Authority
	Commentary by Jim Blackburn
10:40	Group Discussion/Questions and Answers
	Facilitated by Nick McCandie Glustien
11:00	Health Break
11:20	Review of Human Resource Capacity in Canada
	Judith Soon, Assistant Professor, UBC Faculty of Pharmaceutical Sciences
12:00	Group Discussion/Questions and Answers
	Facilitated by Nick McCandie Glustien

12:20 Networking Lunch

13:30 Table Discussions

Discussion Group I: Practical ways to integrate human resource and educational capacity into the life cycle approach to therapeutic products activities

Discussion Group II: Explore extensions of research inventory to include pharmacy outcomes research groups, contract research organizations and pharmaceutical industry

Discussion Group III: Discuss ways in which Canadian researchers can contribute to the harmonization of international pharmacosurveillance programs.

14:30 Health Break

15:00 Plenary Reporting from each Table and Group Discussion

16:00 Next Steps Forward

David K. Lee

Stuart MacLeod

16:15 Thank You and Closing Remarks

Appendix 3B: Workshop Summary

April 18, 2009 in Montreal, Quebec

WORKSHOP SUMMARY

Why a workshop entitled "Human Resource and Educational Inventories to Support the Life Cycle Approach to the Regulation of Therapeutic Products"?

Health Canada is currently engaged in efforts to modernize The *Food and Drugs Act* and its regulations. This initiative will result in updated regulations related to pre-market applications, authorization and entry into the market, and will greatly strengthen post-market activities such as pharmacovigilance and risk management. This life cycle approach to the regulation of therapeutic products will help support the generation of timely, high quality knowledge on the safety and effectiveness of drugs in the real world environment that will be consistent with emerging global standards. At present, however, the capacity of academic researchers to conduct post-market drug evaluation research in Canada is unknown. In addition, the infrastructure of Canadian educational institutions able to train the increased numbers of qualified researchers necessary to support the life cycle approach has not yet been evaluated.

In 2008, Dr. Stuart MacLeod, Executive Director, Child and Family Research Institute located at the Children's & Women's Health Centre of British Columbia in Vancouver, BC, and David K. Lee, Director, the Office of Legislative and Regulatory Modernization within Health Canada, recognized that it would be timely to evaluate *prior* to the legislation being enacted whether the human resource capacity available would be able to cope with the additional requirements necessary to support enhanced post-market pharmacosurveillance.

This workshop was designed to present the findings of inventories of researchers involved in post-market drug evaluation of therapeutic products and of educational training programs in Canada. The outcomes of these inventories will provide a baseline for how to approach the change management aspects for the implementation of the life cycle approach to the regulation of therapeutic products. Workshop participants were given the opportunity to provide recommendations and proposed next steps for facilitating implementation of the life cycle approach to therapeutic products.

Who participated in the workshop?

Participants included three members of the Child & Family Research Institute Working Group, six members of the Peer Review Committee and 13 researchers from Canadian universities and research institutions who are actively involved in post-market drug evaluation. Also in attendance were 11 Health Canada observers from the Office of Legislative and Regulatory Modernization, Marketed Health Products Directorate, Office of Pharmaceuticals Management Strategies, Therapeutics Products Directorate, and the Western Region, Regions and Programs Branch. Funding agencies were represented by the Canadian Institutes of Health Research. Two provincial Ministry of Health decision-makers also participated. The experts invited to

contribute to the workshop were chosen due to their history in this area of post-market drug evaluation, previous working relationships with Health Canada and to ensure national representation.

What were the objectives of the Workshop?

The objectives of this workshop were to: 1) Explore the perspectives of key stakeholders and Peer Review Committee members on the inventories of researchers and of educational institutions training such drug evaluation researchers; (2) Obtain practical input on processes to integrate current and future human resource capacity for conducting post-market drug evaluation research activities in Canada into the life cycle approach to regulating therapeutic products; and (3) Explore processes in which Canadian researchers could contribute to the harmonization of international therapeutic product surveillance programs, including uniquely Canadian opportunities.

What are the benefits of the Life Cycle Approach to the Regulation of Therapeutic Products?

Dr. Stuart MacLeod, Executive Director of the Child and Family Research Institute and the Research Director for this project, provided the context for the workshop by providing an overview of the current regulatory system in Canada leading to the development of the product life cycle approach and its interplay with this current inventory project. David K. Lee, Director of the Office of Legislative and Regulatory Modernization, then described the proposed modernization of the *Food and Drugs Act* as it relates to the regulation of therapeutic products. Benefits of the product life cycle approach will include: 1) Enabling Health Canada to better serve patients, consumers and health care professionals by supporting them in making informed decisions based on the best possible information available; 2) Supporting Health Canada in early identification of risks and in implementing successful risk management activities; 3) Involving professionals, patients and consumers in decision-making opportunities regarding therapeutic products; and 4) Addressing a wide range of needs, including those of patients with rare diseases.

What academic programs are currently available in Canada to train researchers with the necessary post-market drug evaluation skills to support the product life cycle approach to the regulation of therapeutic products?

Dr. Matthew Wiens, Research Assistant on this project, and presently a Clinical Pharmacotherapy Specialist, Fraser Health Authority, presented the findings from this Health Canada-funded Educational Institution Inventory. All universities with Medical Doctoral programs were initially selected. The website of each of these universities was examined for potential academic programs able to train researchers in the area of post-market drug evaluation. A program of interest included any health-related graduate program that taught courses in epidemiology and biostatistics. In addition, all graduate programs in epidemiology, public health, pharmacy, veterinary medicine and health informatics were eligible and included. Furthermore, program courses were reviewed and categorized into fourteen (14) course categories relevant to the post-market drug evaluation research.

Twenty-three (23) Canadian academic institutions provide relevant training programs: twenty (20) institutions have programs training researchers in human health; two have separate programs for human health and for veterinary health, and one institution has a training program only for post-graduate veterinarians. The workshop addressed only those programs at institutions training researchers in human health. Six *core* academic courses were deemed to be necessary in the training of future post-market drug evaluation researchers: biostatistics; epidemiology; health economics/pharmacoeconomics; pharmacoepidemiology; pharmacogenetics/pharmacogenomics; and patient safety/management/pharmacovigilance. Of the twenty-two (22) institutions training researchers in human health, McGill University, Université Laval, Université de Montréal, and the University of Ottawa provided five core courses, and the University of British Columbia, University of Alberta, McMaster University and the University of Waterloo each provided four of the core courses. Although apparent deficiencies in the provision of the core courses varied by institution, few dedicated courses are being provided either in the area of patient safety/risk management/pharmacovigilance or in pharmacogenetics/pharmacogenomics. While many MSc graduate students are currently being trained in the area of drug evaluation, there appear to be additional places available in a number of doctoral programs across the country that are not currently being utilized.

Commentary on the findings of the inventory of educational institutions was provided by Dr. James Blackburn, Dean Emeritus of the College of Pharmacy and Nutrition at the University of Saskatchewan, and Project Lead on Strategic Planning for Canada's Academic Health Sciences Centres. Dr. Blackburn noted that the educational institution inventory identified potential gaps in the course content of a number of the programs. Only four (4) programs had a pharmacoepidemiology course, four (4) had a pharmacogenetics/pharmacogenomics course, and four (4) had developed a course in patient safety/risk management/pharmacovigilance. Fifteen (15) training programs had three or less core courses deemed important in training researchers in post-market drug evaluation. He suggested that two subject areas for consideration in the future would include the Critical Appraisal of Pharmacotherapy Literature and Drug Utilization: Patterns, Outcomes, and Issues in Drug Use Evaluation. Providing opportunities for experiential learning such as co-op placements within federal and/or provincial government departments and in pharmaceutical companies was also felt to have merit. Dr. Blackburn closed his observations by posing a question to workshop participants: In Canada, do we need a standardized educational approach to produce the "Drug Evaluation Research Expert?"

Stakeholders and academics discussed the positive value of a strong background in the basic and clinical sciences including pharmacology, pharmacokinetics, pharmaceutics, etc., taught within the disciplines of medicine and/or pharmacy as an asset to a graduate degree in this area of research. As course offerings depend on the availability of Faculty members, targeted hiring strategies were suggested to address gaps in course content. Additional strategies proposed to enhance course offerings were to develop partnerships with other academic teaching departments (e.g., pharmacology, biostatistics, economics), to provide infrastructure support to foster new course development, to involve federal government personnel (e.g., Health Canada, Canadian Agency for Drugs and Technologies in Health, Common Drug Review, Canadian Institutes of Health Research, Patented Medicine Prices Review Board) in academic

cross-appointments, secondments or visiting appointments, and to engage provincial governments in supporting training in the areas of comparator effectiveness and pharmacoeconomics. Universities were encouraged to take a broad look at their course offerings, and consider "pushing the envelope" by incorporating new cross-disciplinary offerings as electives (e.g., social sciences, bioengineering).

The importance of providing strong training in the area of health informatics was stressed, as these techniques will be required for future linkages between biological databases with genetic profiles and administrative prescription drug and medical service databases. Similarly, training in pharmacovigilance techniques utilizing administrative claims databases is considered timely, as the life cycle approach to post-market drug evaluation would provide expanded opportunities for this area of outcomes research.

Workshop participants expressed concern related to the demonstrated gap in the educational inventory with course offerings in pharmacovigilance and risk management. Proposed adoption of the life cycle approach to therapeutic product regulation in Canada will require timely and proactive risk communication to health care practitioners and patients. Both academic and government participants noted that in the future, innovative qualitative analyses will be required to incorporate patients' values and preferences into risk-benefit assessments for communication of tolerable levels of risk.

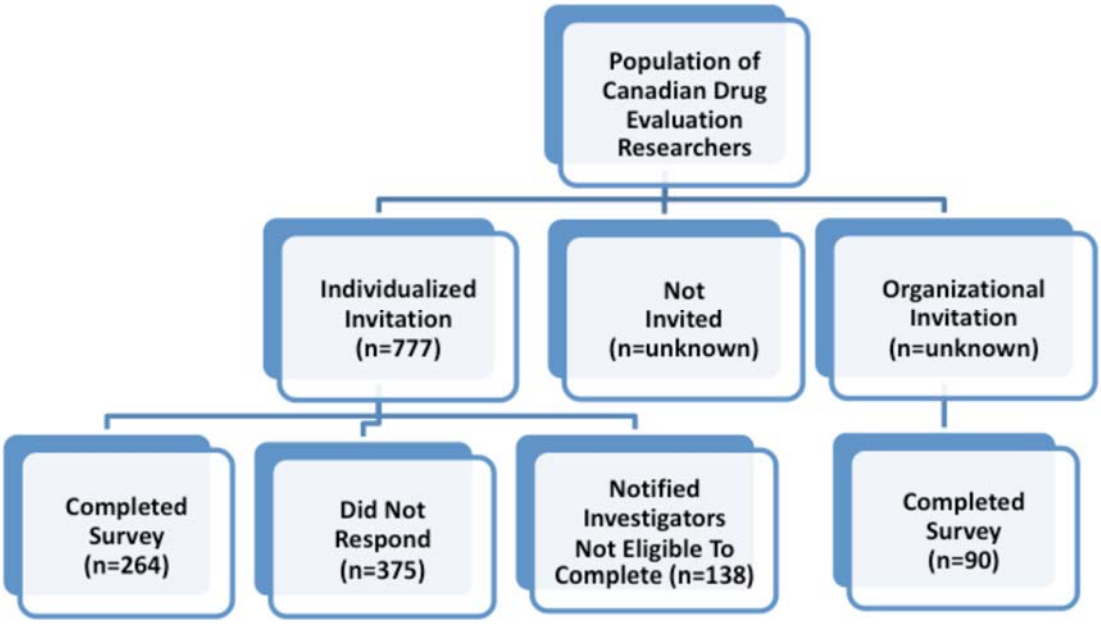
Participants also emphasized the importance of increasing the profile of outcomes research and pharmacoepidemiology among promising graduate students in Canada. It was felt that *"most folks stumble into this area"* of research, and that potential graduate students are *"not well utilized and capitalized on."*

What research expertise and experience is currently available in Canada among those who identify as actively participating in post-market drug evaluation research?

Dr. Judith Soon, Senior Policy Research Officer on this project, and presently an Assistant Professor, UBC Faculty of Pharmaceutical Sciences, presented findings of the inventory of researchers involved with post-market drug evaluation research. The search strategy for researchers involved online searches of lists of researchers within Canadian Academic Institutions, Research Centres and Institutions, Funding Agencies and Health Care Organizations. The specific research areas of interest included Health Services and Policy Research, Population and Public Health Research, and Therapeutics Research. Researchers were eligible for inclusion if they were employed in academic institutions, research centres and health care settings. Those in government, contract research organizations and the pharmaceutical industry were excluded. Ethics approval was granted by the Health Canada Research Ethics Board, UBC Behavioural Research Ethics Board, and the Children's and Women's Health Centre of BC. The survey was available in English and French and was distributed by Applied Research and Evaluation Services at the University of British Columbia.

Direct invitations to complete the survey were delivered by email to 777 researchers, of whom 138 notified researchers that they were not eligible to participate, and 264/639 completed the

survey (41% response rate). In addition, 62 Directors and Vice-Presidents of Research with the Association of Canadian Academic Healthcare Organizations (ACAHO) were encouraged to forward the invitation to appropriate researchers within their healthcare setting. Invitations were also forwarded by the Managers of the External Scientific Databases in the Biologic and Genetic Therapies Directorate, the Marketed Health Products Directorate, and the Therapeutic Products Directorate to researchers on their Expert Advisory Committees. Responses were received from 90 researchers who received a forwarded invitation, for a total of 354 completed surveys.



Survey respondents were from diverse locations across Canada, and were generally located in close proximity to the academic training locations documented in the institutional inventory. Relative to the provincial distribution of the Canadian population, researchers in British Columbia were over-represented, while those from Québec were under-represented. The largest group of respondents was aged 35 – 44 years (36%), followed by 45 – 54 years (31%), over 55 years (23%), and less than 35 years (8%). The ages of seven respondents were not reported. The principal role most commonly cited was that of a Researcher, Faculty member or a Clinician (physician, pharmacist), with the principal research location most frequently in an educational institution, hospital or health care facility, or a research centre. While the highest academic qualification for most respondents was a PhD, many physicians and PharmD-trained pharmacists had also obtained MSc and PhD research degrees. Most respondents had received their training in Canada, followed by the United States, the United Kingdom and Europe. Epidemiology (34%), Pharmacoepidemiology (28%), Health Policy Research (28%), Clinical Trial Design (26%) and Systematic Reviews (23%) were the most commonly reported areas of research expertise.

Of those who reported conducting research among a Special Population, the most commonly reported areas were Seniors Health (45%), Women's Health (32%) and Child and Youth Health

(30%). Expertise in conducting research in the areas of Marginalized Populations (23%) and in Aboriginal Peoples' Health (13%) was reported less frequently. Involvement in pre-market research was reported by 130/354 (37%) of the post-market drug evaluation researchers, most commonly to evaluate efficacy and safety of new drugs in the development phases. In the post-market drug evaluation area, respondents most commonly reported involvement with pragmatic real world studies (50%), population health databases (43%), randomized controlled clinical trials (37%), systematic reviews (36%) and case-control studies (32%). Almost 48% of respondents reported supervising graduate students, with the majority of graduate students obtaining MSc degrees. Currently, a total of 215 PhD students are being supervised by 169 graduate supervisors.

The knowledge translation strategies most frequently utilized to enhance dissemination and uptake of research findings were peer-review publications (80%), conference presentations (74%), educational sessions with policy makers, practitioners or patients (41%), systematic reviews (33%), collaborative research involving end users throughout the research process (32%) and practice guidelines (32%).

Of particular interest to Health Canada was the extent to which these experienced post-market drug evaluation researchers had previously provided input to Health Canada. Only 40% of respondents (142/354) reported that they were familiar with the proposed modernization of the *Food and Drugs Act*, and of those, 30% had previously provided consultation to Health Canada and a further 14% had provided feedback to Health Canada in other ways. About 42% of respondents reported that barriers to data access limited their involvement in post-market drug evaluation research. Eighty-six percent (86%) of respondents stated that they would be willing to be involved with post-market drug evaluation research in the future; 82% would consent to being included in a Health Canada Registry, 77% said they would consent to the distribution of the registry to the public sector, followed by 75% to the not-for-profit sector and 53% to the private sector.

In discussion following the presentation, participants felt that it was important to describe the group of researchers who had not responded to the survey. This analysis will be incorporated into the final report.

Within the area of knowledge translation, only about 32% of respondents mentioned that they enhanced dissemination and uptake of research findings by engaging in collaborative research that involved end users throughout the research process. Given the proposed change to the life cycle approach to the regulation of therapeutic products, it was felt to be important that patients and the public *"buy in"* to such a collaborative approach from the beginning of the research study.

Workshop participants acknowledged that there are substantial privacy and confidentiality issues related to accessing industry databases containing patient-specific drug-related information. In the discussion around Commercially Protected Data, workshop participants felt that Canada is more restrictive on industry data release than in other international jurisdictions. In particular, concerns were raised related to industry maintaining confidential business information on drugs that have already been approved and are on the market. Privacy and confidentiality issues also impact the availability of information from provincial administrative databases as well as those held by practitioners (e.g., physicians, pharmacists).

Confidentiality issues also impact the ability to access and share information within Health Canada. Because of maintaining privacy of the Health Canada Expert Advisory Committee members, attempts to gain approval for the Expert Advisory Committee Database Manager to distribute the invitation to this Health Canada survey to the drug experts in a confidential manner proved rather difficult. For those study participants who said that they would be willing to provide consent for involvement in a public registry, workshop participants were in support of sharing information such as generated by this inventory of researchers and educational training programs to departments within Health Canada and the Canadian Institutes of Health Research who could utilize the findings.

Electronic health data initiatives are now in the process of widespread development. Workshop participants discussed the importance of proactive decisions that need to be made to facilitate the utility of the electronic databases in the future. A positive example given was Veterans Affairs in the United States, which obtains consent for release of personal data when patients initially sign up for the e-health program.

Government stakeholders discussed the need for incorporating additional expertise into the decision-making process, and the importance of developing a *"good map of where the expertise is."* For example, *s*hould there be concern in the future regarding patient safety issues amongst a sub-population, Health Canada would like to know who to contact with specific expertise in the area. The information provided by survey respondents for this report has the potential to give assistance in this area.

This Health Canada Human Resource Capacity project started with the question: Was there an adequate number of post-market drug evaluation experts in Canada to have the ability to support the life cycle approach to the regulation of therapeutic products? Three hundred and fifty-four (354) researchers expressed an interest in this area of research by completing the survey…. is that an adequate number?

Table Discussions:

Discussion Group 1: Educational Institution Inventory summary points

1. When the Canadian Institutes of Health Research was established in 2000, separate institutes of *Aboriginal Peoples' Health* and *Gender and Health* were formed in areas for which there was little "research expertise". Participants felt that the small amount of funding provided to these institutes fostered an increase in this type of research and those who identified themselves as experts in the area. This type of priority funding was supported as a potential model for increasing research and expertise in the areas of pharmacovigilance and pharmacogenomics. *"If we allow funding to drive demand (e.g., direction of curriculum etc.)… people will go there."* While participants suggested that a new institute would be unlikely, targeted competitions in existing institutes within the Canadian Institutes of Health Research may facilitate such research in the future.

2. Rather than training researchers to be a *"jack of all trades"*, participants felt that a more productive model would be to train specialized researchers with a high level of expertise. The researchers could compete for Canadian Institutes of Health Research Team Grants rather than Operating Grants, which would encourage multidisciplinary contributions to cutting edge research questions.

3. As Canadian researchers are geographically diverse, developing creative ways to form virtual teams was felt to be important. The Canadian Institute for Advanced Research was given as a positive example. Canadian Institute for Advanced Research institutes are virtual centres of excellence that are able to underwrite the salary of academics, have a small overhead and are able to bring specific units together to plan and discuss research initiatives. Participants thought that it may be of interest for Health Canada personnel to meet with Dr. Chaviva Hošek, the Canadian Institute for Advanced Research Chief Executive Officer and President. Participants mentioned that we *"need to look at what we need in 2015 or 2020, and plan how we need to get there. No longer do we need to be impeded by geographical boundaries, because of the availability of technology."*

4. Co-operative training in the area of post-market drug evaluation research was suggested as a potential model for graduate students to get workplace experience and gain a network of contacts in this field. Nevertheless, concerns were raised in a number of areas: difficulty in locating pertinent placements; may be unaffordable for the graduate student to re-locate to another location; the student may remain in the workplace and not return to university to graduate; and placements away from the university site may potentially reduce trainee contributions to the training of more junior Masters/PhD students. The new School of Pharmacy at the University of Waterloo was given as an example of an undergraduate training program utilizing a co-op educational model that integrates classroom and applied work-based experience.

5. Due to limited resources, developing extensive course offerings at the twenty-two different institutions across Canada training drug evaluation researchers in human health is not feasible.

Participants discussed the potential to develop one exceptional program, and then offer it virtually across the country. However, it was also acknowledged that certain sites have developed their own niches, and that there can be both funding and academic issues related to students participating in course work at other academic institutions.

Discussion Group II: Human Resource Inventory summary points:

1. There appears to be a lack of awareness of Health Canada initiatives such as the proposed modernization of the *Food and Drugs Act* among Canadian academic researchers in the post-market drug evaluation field. Participants encouraged Health Canada to think outside of the box when accessing research expertise for consultations and feedback: *"If you always do what you've always done, you'll always get what you've always got."*

2. As this inventory was only conducted among academic researchers involved with drug evaluation research, it does not inform Health Canada regarding the current human resource capacity among researchers in the federal or provincial governments, pharmaceutical industry or contract research organization. Given the proposed life cycle approach to the regulation of therapeutic products, concern was expressed related to the ability of Health Canada to access sufficient trained scientists to complete all the scientific analysis and assessment required to establish the safety and effectiveness of therapeutic products for sale in Canada.

3. Health Canada was encouraged to develop relationships with academic training programs to ensure that adequate numbers of well-prepared research scientists will be available in the future to provide support for the life cycle approach to the regulation of therapeutic products (e.g., randomized comparator studies). It was suggested that a high level Task Force with Human Resources as a theme may be beneficial. An example of a connection between Health Canada and academic researchers that is working well is the Expert Advisory Committee on the Vigilance of Health Products.

4. There was perceived to be a disconnect between federal and provincial drug regulatory processes. This was considered to be a substantial barrier to the sharing of ideas and data. Positive examples of collaborations between interested parties in other jurisdictions were the European Medicines Agency (27 members and 3 observer countries) and the United States Agency for Healthcare Research and Quality that facilitates the sharing of data between states.

5. There was discussion related to the continuum of pre-market to post-market drug evaluation within the life cycle approach to the regulation of therapeutic products, and the active pre-planning that will need to occur early in the drug research process. The European Medicines Agency was given as a positive example of planned risk management strategies for potential high-risk sub-populations such as pediatrics, geriatrics and patients with genetic disorders.

6. Potential funding sources for post-market drug evaluation were explored, with discussion of the *United States Prescription Drug User Fee Act*. This Act, originally passed in US Congress in 1992, allowed the Food and Drug Administration to collect fees from drug manufacturers to fund the new drug approval process. Funding for the life cycle approach to the regulation of

therapeutic products was recognized to be a complex issue, and involves jurisdictions within the federal government outside of Health.

7. Participants noted that administrative databases are not robust enough to answer all drug safety and effectiveness questions in the post-market period. Discussion revolved around the importance of carefully designed post-market mixed-methods research that would blend both prospective observational studies with findings from administrative health databases.

Discussion Group III: Utilizing information from the "Human Resource and Educational Inventories to Support the Life Cycle Approach to the Regulation of Therapeutic Products" in Canada and internationally summary points

1. Participants felt that there were relatively few mechanisms for academics to interact directly with Health Canada. A positive example is Dr. Yola Moride, who is teaching Health Canada employees, and her graduate students participate in work-study programs with Health Canada. Occasionally, Health Canada employees participate in an Interchange Agreement with an academic institution.

2. In the future, online webinars may be used to provide information on Best Practices. An example of an agency providing such webinars is the US Agency for Health Care Quality.

3. A number of Canadian research groups (e.g., Institute for Clinical Evaluative Sciences) collaborate with international organizations such as with Richard Platt at the HMO Research Network Center for Education and Research in Therapeutics.

4. Participants suggested that future meetings to provide knowledge dissemination of Health Canada initiatives could be held as pre-conference meetings of the Canadian Association for Population Therapeutics or other relevant meetings.

5. The International Society for Pharmacoeconomics and Outcomes Research has recently developed guidelines for Good Research Practices, in the general categories of Economic Methods, Modeling Methods, and Patient Reported Outcomes & Patient Preferences (www.ispor.org/workpaper/practices index.asp). Recently, the International Society for Pharmacoeconomics and Outcomes Research held an International colloquium on standards for methodology that was very successful.

Recommendations and Next Steps

We recommend that:

1. Health Canada extend this human resource capacity survey of post-market drug evaluation researchers to provincial and federal governments, to the not-for-profit sector and to contract research organizations to more accurately inventory post-market drug evaluation researchers, as many are working outside of academia and health care institutions.

2. Health Canada support a Task Force to develop a national syllabus that would guide universities interested in training highly qualified personnel able to support post-market drug evaluation studies, as few universities currently offer a comprehensive training program that focuses on all of the essential core courses.

3. Health Canada act to increase awareness of career opportunities that support post-market drug evaluation. To encourage these targeted recruitments, consideration should be given to the development of a national scholarship program for highly qualified personnel in this specialized research field. A national web-based distance education program may facilitate graduate student training in post-market drug safety and effectiveness research methodology, by enabling the utilization of highly trained Faculty members currently based at a limited number of universities.

4. Health Canada should foster effective partnerships and networking between academia and government on drug safety and effectiveness research through evidence-based practice centres modeled along the lines of the virtual Canadian Institute for Advanced Research (http://www2.cifar.ca/).

5. Health Canada, in partnership with the Canadian Institutes of Health Research, should administer funding for Canada Research Chairs in Risk Management in selected Canadian post-secondary institutions to encourage the development of additional expertise needed in this area.

6. Health Canada, in partnership with the Canadian Institutes of Health Research, should develop strategies to improve capacity in post-market drug evaluation research targeted at marginalized populations and aboriginal peoples' health in order to promote the health of all Canadians.

7. Health Canada, in partnership with the Canadian Institutes of Health Research, should facilitate international exchanges between highly qualified researchers in the area of post-market drug evaluation (e.g., European Medicines Agency) to encourage the uptake in Canada of progressive strategies in the area of drug safety and effectiveness research.

8. Health Canada should actively explore procedures that would enable sharing of population-based data across provincial boundaries, thus reducing barriers to data access and facilitating population health research relevant to optimal therapy.