Dr. Kelvin K. Ogilvie
Chair, Standing Senate Committee on Social Affairs, Science and Technology
The Senate of Canada
Ottawa, Ontario
K1A 0A4

Dear Dr. Ogilvie:

Pursuant to Rules 12-24(1) and 12-24(3) of the Senate of Canada, I am pleased to respond on behalf of the Government of Canada to the Fourteenth Report of the Standing Senate Committee on Social Affairs, Science and Technology entitled *Canada's Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines*, tabled in the Senate of Canada on November 1, 2012.

I would like to thank the Committee for its work in studying the process to approve prescription pharmaceuticals in Canada, with a particular focus on clinical trials. The Government of Canada agrees in principle with the Committee's recommendations and recognizes that a variety of stakeholders must be engaged to improve Canada's clinical trial infrastructure. Our Government is committed to playing an active and collaborative role in improving Canada's clinical trial infrastructure, and access to innovative medicines. It is also supportive of the important and timely work of the Committee. The Committee's efforts are consistent with Health Canada's goal of providing Canadians with timely access to safe, effective, and high quality health products, and the information they need to maintain and improve their health.

Our response to the Committee's Report is presented in two sections. The first section highlights the distinct roles and responsibilities of key stakeholders. The second section responds to the Committee's recommended actions and highlights ongoing efforts to collaborate with stakeholders, increase transparency, and modernize regulatory frameworks.

For ease of reference, the Committee's recommendations are found in the Appendix to this letter.

Stakeholder Roles & Responsibilities

Canada's drug clinical trial infrastructure includes a diverse group of government bodies, business sectors, and other stakeholders who strive to bring innovative therapies to Canadian patients. Clinical trials can only be achieved through strong collaboration between drug sponsors, researchers, medical professionals, Research Ethics Boards, Health Canada, funding agencies, provinces/territories, and clinical trial participants. Given the variety and interconnectedness of these roles, the various players share responsibilities for the safety and quality of the research undertaken.

The primary role of the **Government of Canada** in the Canadian drug regulatory system is as the regulator of health products through Health Canada. The Department regulates clinical trials through a number of activities, which include: reviewing clinical trial protocols to assess the protection and safety of participants; assessing the quality of the drugs, requiring review and oversight from Research Ethics Boards; verifying the qualifications of principal investigators; and monitoring and reviewing Adverse Drug Reactions (ADRs). Through the Canadian Institutes of Health Research (CIHR), the Government of Canada plays an integral role in coordinating, encouraging, and supporting health research (including clinical research). Comprised of 13 institutes, CIHR provides leadership, funding, and support to approximately 14,000 health researchers and trainees across Canada. The Government of Canada is also responsible for reviewing and granting patents through the Canadian Intellectual Property Office, associated with Industry Canada, and granting data protection for innovative drugs through Health Canada.

The **Provinces and Territories** (P/Ts) have the primary responsibility of managing and delivering health care services within their respective jurisdictions. They also govern the practice of medicine in their jurisdiction, and provide funding to universities to support research. Aside from the potential population health benefits resulting from clinical trials, they are also key economic drivers for P/Ts. As such, many P/Ts actively promote their jurisdiction as an ideal environment to conduct clinical trials, with leading expertise in clinical trials and scientific advancement.

The **Sponsor of a Clinical Trial**, as per Division 5 of the *Food and Drug Regulations*, is the individual, corporate body, institution, or organization that is authorized to conduct a clinical trial. A sponsor's application includes information on pre-clinical studies indicating that the drug produces a desired result and is not toxic. To support this information, the sponsor must demonstrate to Health Canada that the proposed trial is appropriately designed, based on a number of factors, to show the desired outcome in a target population. Sponsors are obligated to adhere to a number of requirements during the conduct of a clinical trial, including Good Clinical Practices (GCP) for the proper use of the drugs, record keeping, and reporting of ADRs.

Health Canada does not directly influence what subpopulations (including vulnerable ones such as children, the elderly, and pregnant and nursing women) a sponsor targets for human drug clinical trials. However, the *Food and Drug Regulations* stipulate that a manufacturer must provide sufficient evidence to support the safety and clinical effectiveness of a new drug under the conditions of use recommended, in order to obtain market authorization in Canada. Therefore, a manufacturer seeking market authorization must provide clinical data from all population groups in which the use of the drug is intended. Results from clinical trials are described in the Product Monograph that is published following market authorisation in order to guide health care providers on the use of a drug in Canada. Once a drug is marketed in Canada, physicians can prescribe a drug for off-label uses (i.e., uses outside of the recommendations in the Product Monograph) under the practice of medicine. The practice of medicine is regulated by the P/T colleges of Physicians and Surgeons, and falls outside the mandate of Health Canada.

Research Ethics Boards (REBs) assess the ethical acceptability of a clinical trial, taking into account potential risks and benefits to research participants. They also evaluate other ethical

issues, such as conflicts of interest, financial agreements, and informed consent documentation. REBs provide ongoing oversight of the trials they have approved, and can retract their approval should serious concerns about the trial arise.

The *Food and Drug Regulations* stipulate that prior to commencing a clinical trial; REB approval of the clinical trial protocol must be obtained from each participating clinical site. It also states that the REB must not be affiliated with the sponsor, and outlines the board's mandate and membership composition requirements. However, the regulations do not specify detailed standards for REB review. Federally-funded research involving human participants is subject to CIHR's *Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans* (TCPS2), which was revised in December 2010. Industry-sponsored clinical trials are subject to the regulations and GCP guidelines, but not to TCPS2 unless trials are performed within an institution that receives CIHR funding.

There are two main types of REBs in Canada: institutional REBs (e.g. governments, universities, and hospitals) and, for-profit REBs (e.g. stand-alone companies and those embedded within contract research organizations). The Federal Government also has REBs, some of which include: a joint Health Canada and the Public Health Agency of Canada REB, the National Research Council REB, and the Royal Military College of Canada REB.

Qualified Investigators are physicians (or in some cases dentists) who conduct clinical trials on behalf of the sponsor. They must provide care according to GCP, monitor and report ADRs, obtain informed consent, and comply with the approved study protocols (e.g. patient selection, dosing, frequency, monitoring, etc.).

Clinical Trial Participants are the test subjects used to gather information on a product's safety and efficacy. Clinical trials are undertaken with informed and consenting human subjects according to GCP.

Recommended Actions

Enhanced Federal Government Leadership

The Government of Canada agrees in principle with the Committee's recommendation for enhanced federal government leadership. The Government of Canada, through CIHR, will continue to lead federal efforts in collaborating with stakeholders to address the clinical trial research infrastructure challenges without creating more bureaucracy or overstepping federal jurisdiction.

As mentioned by the Committee, CIHR progress can be seen through recent work with the Association of Canadian Academic Healthcare Organizations (ACAHO), Canada's Research-Based Pharmaceutical Companies (Rx&D), and other relevant stakeholders, to coordinate the first-ever Clinical Trials Summit in September 2011. CIHR continues to work collaboratively with these stakeholders to refine the Summit Action Plan, entitled To Your Health & Prosperity – An Action Plan to Help Attract More Clinical Trials to Canada. The action plan is aligned

with the Senate Committee's report, and its implementation will help to attract more clinical trials to Canada. The goals of the action plan are to reverse the downward trend of clinical trial investment in Canada, improve business operations as they pertain to cost, quality, and speed of clinical trial start up times, and create positive forward-looking business opportunities through information and incentives for global companies.

Another example of the Government of Canada's commitment to strengthen the clinical research environment in Canada, also noted by the Committee, is the recent memorandum of understanding established between CIHR and Rx&D. This will facilitate the joint investment of up to $300M ($150M from CIHR and $150M from Rx&D) in Canada between 2011 and 2016 for clinical research, and will lead to new clinical practices, innovative health policies, and better health care for all Canadians.

The Government of Canada is working in close collaboration with its provincial and territorial counterparts, and other important stakeholders, to address health research in Canada. For instance, at the last Health Ministers' Meeting (HMM) on September 28, 2012, federal, provincial and territorial Health Ministers discussed the Strategy for Patient-Oriented Research (SPOR). This initiative is a coalition of stakeholders from universities, health care organizations, clinical research, health charities, industry, federal /provincial/territorial governments, and citizens dedicated to the integration of research into care. This strategy, under the leadership of CIHR, aims to lay out a strengthened foundation for Canada through the development of new clinical research networks, support units, and training opportunities for health professionals. SPOR received strong support from provincial and territorial Health Ministers at the HMM. The objective of SPOR is to demonstrably improve health outcomes and enhance patients' health care experience through integration of evidence at all levels in the health care system. The Government of Canada has committed up to $45M annually for SPOR activities.

Mandatory Registration of Clinical Trials

The Government of Canada agrees with the Committee's recommendation for mandatory registration of clinical trials. Health Canada is exploring the development of mandatory requirements for the registration of clinical trials as part of its modernization of the *Food and Drug Regulations*. Until a mandatory requirement is implemented, sponsors are encouraged to register and disclose the results of their clinical trials in publicly accessible World Health Organization (WHO)-recognised registries. Health Canada has done this by posting a notice encouraging sponsors to register in WHO-recognised registries, and by adding a statement in the No Objection Letter (issued when a Clinical Trial Application is deemed acceptable) reminding sponsors to register in these registries.

As a first step towards improving transparency, Health Canada is publishing a database of clinical trials involving Canadian patients in Spring 2013. The database will include information about trials that Health Canada has authorized for the sale or import of a drug. With this proposal, patients, health care professionals, and the public will be able to easily access (in one location) important information related to drug clinical trials.

Establishment of REB Standards and Accreditation

The Government of Canada agrees in principle with the Committee's recommendation that a common standard should be developed for REBs in Canada that oversee clinical trials involving humans. That is why, in 2006, Health Canada commissioned the Canadian General Standards Board (CGSB) to manage the process of developing the REB standard. The CGSB established an REB standard committee (consisting of approximately 36 voting members and several observers) focused on balanced representation from key stakeholder groups. Members included representatives from the Canadian ethics review community, research organizations, government departments, industry, and patient centered groups. Although the Standing Senate Committee heard some criticism of the draft standard during its clinical trial study, it should be noted that in 2012, the standard committee passed the draft standard with 87% of voting members in favour. The majority of standard committee members believe that the standard will positively impact REBs in Canada by improving operational efficiencies and facilitating increased mutual recognition. It is anticipated the standard will be finalized in Spring 2013.

As the Senate Committee members heard, the CGSB REB standard could be used as an important framework element for developing a pan-Canadian REB accreditation system. The Government of Canada agrees in principle with the value of a third-party accreditation system in Canada for REBs overseeing clinical trials. In 2010, Health Canada, in collaboration with Industry Canada and CIHR, held discussions with several key stakeholder organizations involved with clinical REB operations in Canada. These discussions indicated a clear willingness to work together. Consequently, in late 2011, Health Canada issued a Request for Letters of Interest inviting organizations to describe how they would conceive, develop, and cost a pan-Canadian REB accreditation system. Health Canada is currently reviewing these submissions. Health Canada, together with our federal partners and provincial and territorial governments, will continue discussions with our stakeholders to explore viable options for a pan-Canadian REB accreditation system.

Furthermore, the Government agrees in principle that an accreditation system for REBs would add value to the protection of research participants and would create clinical trial efficiencies. Health Canada will explore options for potential regulatory changes that would require REBs reviewing clinical trial applications to be accredited. However, before these changes could be considered, there must be a body established in Canada that has the ability to accredit REBs.

Facilitation of Patient Recruitment

Establishment of Research Networks

The Government of Canada agrees with the Committee's recommendation for the establishment of research networks. Particularly in the area of oncology trials, well established research networks such as the Community Clinical Oncology Program, the Children's Oncology Group, and the National Cancer Institute's Clinical Trials Cooperative Group Program, have successfully provided treatment options (i.e. clinical trials) and prevention programs for cancer patients across North America.

Federal Budget 2013 announced an additional $15 million annually to support SPOR activities, which include the development of research networks. In 2011-12 SPOR initiated a process to

identify targeted patient-oriented research networks. The first SPOR network was announced in October 2012, and is a partnership between CIHR and the Graham Boeckh Foundation that will result in a $25M investment over five years to implement the "Transformational Research in Adolescent Mental Health" network. The application process to identify network participants is now underway. CIHR and its partners are currently establishing a second SPOR network in the area of community-based primary health care. Over the coming months, CIHR will be working with stakeholders to identify and prioritize other areas that will benefit from the creation of a national clinical research network. It is important to note that the creation of databases of patients willing to be considered for clinical trials is beyond the federal government's role.

In order to help reduce red tape while protecting patient safety and improve Canada's clinical trial attractiveness, a SPOR Committee has also been developing tools and strategies to expedite the ethics review of multicentre clinical trials in Canada.

Inclusion of Populations in Clinical Trial Design

The Government of Canada agrees with the Committee's recommendation that drug development should include clinical trials in all patient populations that are reasonably expected to consume the drug. This enables the development of appropriate guidance for the safe use of health products in all target patient populations. The Government of Canada also recognizes that vulnerable populations should be included in clinical trial research that is scientifically and ethically sound.

Health Canada is currently finalizing a revised version of its guidance document "Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex", which is expected to be published in 2013. This document will provide guidance to sponsors in the conduct and design of clinical trials. This guidance addresses the appropriate inclusion of women (including those who are pregnant and breast feeding) in all stages of clinical trial research in order to identify and analyze sex-related differences that may affect the safety and efficacy of a therapeutic product.

The availability of therapeutic products tested, approved, and labelled for use in children is a global concern and focus of ongoing efforts. Health Canada works with its international counterparts, such as the United States Food and Drug Administration and the European Medicines Agency, to exchange information related to paediatric drug development. In 2011, the Government of Canada commissioned the Council of Canadian Academies (CCA) to strike an independent Expert Panel to examine key science-based questions of public policy importance related to the development of therapeutic products for infants, children, and youth. The CCA will generate a report that verifies and consolidates needed information, and could cover best practices on clinical trial designs, from a global perspective.

Health Canada has also adopted International Conference on Harmonization (ICH) guidelines addressing the non-clinical and clinical requirements for drug development in women of child-bearing potential, paediatric, and geriatric populations. Additionally, Health Canada has implemented a six month extension of data exclusivity for innovative drugs with paediatric data. The purpose of these guidelines and incentives is to support data collection in all patient populations that will be treated by the drug following market authorization.

Mandated Clinical Trial Design

The *Food and Drug Regulations* identify the conditions under which Health Canada will authorize the import or sale of a drug for a clinical trial. A clinical trial sponsor is required to select scientifically necessary inclusion and exclusion criteria to support the research question and stipulate for whom the results of the study can be generalized. Health Canada also considers the potential for adverse events associated with the use of marketed health products. In cases where vulnerable subpopulations have been excluded or under-represented in clinical trials, marketed product labelling contraindication warnings could, if warranted, be issued specifically for these groups.

Amending the *Food and Drug Regulations* to add requirements for clinical trial design and market authorization could result in unintentionally limiting access to new, innovative, and safe drugs. This approach is also not consistent with international guidance related to drug development, or how comparable jurisdictions regulate drug development. Changes in this area would result in Canada being a less attractive jurisdiction for clinical trials.

Development of an Orphan Drug Policy

The Government of Canada agrees with the Committee's recommendation for the development of an orphan drug policy and acknowledges the importance of drugs for rare diseases. That is why, on October 3, 2012, a new Orphan Drug Regulatory Framework was announced, designed to approve drugs to treat small, vulnerable populations in Canada. This proposed framework was noted by the Committee in their Report, and includes important measures such as: the designation of drugs as orphan drugs to treat rare diseases; the provision for scientific and clinical protocol advice; and, the potential for reduced fees for small to medium sized enterprises. This framework has the potential to facilitate research and innovation in Canada by addressing the specific challenges faced by orphan drug clinical trials, and by integrating a scientific vision that will facilitate dialog between all stakeholders during the clinical trial and approval phase of drug development.

The Government of Canada is committed to supporting research on rare diseases and to promoting Canada as a preferred site for clinical trials on orphan drugs. In 2012, the Government of Canada announced the CIHR Team Grant: Rare Diseases – Translating Basic Biology to Enhanced Patient Care. This includes federal investments of more than $15 million over five years to support new research to help patients and families affected by a rare disease, and improve the lives of those living with these conditions. In total, nine collaborative research teams are being funded. Some of these teams are conducting important projects on the basic biology, undertaking clinical research, and conducting research on the populations affected by rare diseases. The overall objective of the research is to transform fundamental biological research into medical practice and treatments in the area of rare diseases. The research teams will investigate a range of issues related to rare diseases, including basic biological science, health services, and policies.

It is also important to note that there is no fee associated with submitting a clinical trial application to Health Canada for review. When existing user fees were updated for the human

drugs and medical device programs in 2011, fees for clinical trial applications were not included in an effort to avoid impeding research and innovation in Canada. This decision was also noted as an important element to help keep Canada's clinical trial sector internationally competitive.

Assessment of Patent Protection and Tax Incentives

In response to the Committee's recommendation regarding the assessment of patent protection and the Scientific Research and Experimental Development (SR&ED) tax incentive program, the Government is committed to maintaining a drug patent regime that encourages pharmaceutical innovation and investment in Canada, while providing for timely access to generic drugs. The Government of Canada is aware of the views of pharmaceutical industry stakeholders with respect to drug patents. Pharmaceutical industry concerns were recently discussed in the context of a study undertaken by the House of Commons Standing Committee on Industry, Science and Technology on Canada's intellectual property regime. From May to November 2012, the Committee heard from a number of stakeholders, including representatives of the pharmaceutical industry, on patent issues.

Canada's SR&ED tax incentive program is one of the most generous systems in the industrialized world for research and development (R&D). It is the single largest federal program supporting business R&D in Canada, providing more than $3.6 billion in tax assistance in 2011. Budget 2010 announced a comprehensive review of support for R&D in order to optimize the contributions of the Government of Canada to innovation and related economic opportunities for business. An Expert Panel was appointed to conduct this review in the Fall of 2010 and delivered its report in October 2011. In response to the Expert Panel's report, Budget 2012 introduced a number of measures to streamline and improve the SR&ED tax incentive program. The savings generated by these actions are being re-invested in direct support programs that will reinforce business innovation in Canada.

An assessment of patent protection and tax incentives has already been conducted through the recent House of Commons Standing Committee discussions on intellectual property, the 2011 Expert Panel examination and report on optimizing Government of Canada contributions for innovation and related economic opportunities for business, and the measures in Budget 2012 to streamline and improve the SR&ED tax incentive program. Therefore, at this time, the Government of Canada does not believe an expert advisory committee on patent protection and the SR&ED tax incentive program is needed.

Additional Observations

The Government of Canada is supportive of the clinical trial recommendations from Chapter 4 of the Fall 2011 Report of the Auditor General (AG) of Canada, and detailed responses to these recommendations were published in June 2012 in Health Canada's Office of the Auditor General (OAG) Management Response and Action Plan. In addition, an updated response was provided to the House of Commons Standing Committee on Public Accounts on March 31, 2013. This response will be posted on Health Canada's website in Spring 2013.

The Government of Canada continues to focus on modernizing food and drug regulation in Canada. Health Canada is focused on transforming nearly a dozen outdated regulations into an efficient, transparent, and comprehensively aligned regulatory system that contributes directly to the safety of Canadians and the benefits they gain from food and health products. The modernized science-based regulatory system will make the benefits, harms, and uncertainties associated with food and health products meaningfully transparent to the Canadian public. It will be sustainable and responsive to the evolution of science, patient and consumer behaviour, and practices in health care.

The Government of Canada acknowledges the importance of monitoring, measuring, and publicly reporting on activities related to clinical trials in Canada. Mechanisms are currently in place to measure and publicly report on progress, such as Health Canada's Departmental Performance Report, Health Canada's Management Response and Action Plan to the OAG review of the Human Drugs Program, and Health Canada's Summary Report of Clinical Trial Inspections.

Conclusion

The Government of Canada thanks the Committee for their important work in studying Canada's clinical trial infrastructure and access to innovative medicines. Canada's clinical trial infrastructure includes a diverse group of stakeholders who strive to bring innovative therapies to patients. Promoting good research conduct and protecting patient safety are shared responsibilities between drug sponsors, the regulator, provinces and territories, the research community, and ethics review boards. Only through committed stakeholder collaboration, will Canada be able to build a stronger and more internationally competitive clinical trial infrastructure; one that helps to introduce the latest health care innovations to patients, advance health outcomes, and ultimately improve the lives of Canadians.

I trust that this response demonstrates the Government of Canada's commitment to improve Canada's clinical trial infrastructure and access to innovative medicines by working closely with all stakeholders and jurisdictions.

Sincerely,

The Honourable Leona Aglukkaq, P.C., M.P.
Minister of Health

Attachments – Appendix – List of Recommendations

Appendix

Recommendations

1. The committee therefore recommends that the federal government assume a leadership role in facilitating, coordinating and encouraging a comprehensive clinical trials infrastructure by:
    - Establishing a National Framework for Coordinating Clinical Trials to; provide leadership, promote the importance of clinical trials and the benefits of being a participant, help to establish Canada as a preferred site for clinical trials, and provide a point of contact between industry and networks;
    - Convening the Federal/Provincial/Territorial Conference of Health Ministers to discuss initiatives in their respective jurisdictions with a view to sharing best practices and reducing duplication of efforts; and
    - Encouraging the inclusion of all relevant stakeholders in discussions, consultations and events held in respect of establishing that infrastructure.

2. The committee therefore recommends that the Minister of Health:
    - Move to immediately require clinical trial registration to the greatest degree permitted under its existing legislative and regulatory authorities;
    - Determine and propose the necessary amendments to the *Food and Drugs Act* and/or the clinical trial regulations contained in Part C, Division 5 of the *Food and Drug Regulations*, to require that manufacturers register a comprehensive set of data for clinical trial phases II and III on a WHO recognized website prior to recruiting any participants. Registration must include, but not be limited to, all results, adverse reactions, withdrawal of participants (non-identifying), and prematurely ended trials;
    - Require that all foreign clinical trials that are used to support applications for market authorizations in Canada have met equivalent registration standards; and
    - Implement measures to strictly enforce this recommendation in order to ensure transparency of the clinical trial process and of the processes at Health Canada.

3. The committee therefore recommends that the Minister of Health direct Health Canada to immediately undertake to develop an accreditation program for Research Ethics Boards. To this end, Health Canada will, as soon as possible:
    - Launch discussions, in consultation with the provinces and territories, for a national standard for Research Ethics Boards which:
        - Includes all aspects of trial review including but not limited to; contracts or clinical trial agreements with parameters on compensation and fees, informed consent, placebo versus comparative effectiveness and, review of adverse reaction reports;
        - Can be applied to the review of all clinical trials of unapproved drugs in Canada;
        - Can serve as the basis for accreditation of research ethics boards, both institutionally-based and privately run; and

- Oversee the implementation of an accreditation program for research ethics review which:
    - Assesses and awards accreditation to research ethics boards that review, approve and oversee clinical trials of unapproved drugs; and
    - Provides guidance on the training of those involved in research ethics boards.

4. The committee further recommends that the Minister of Health amend the clinical trial regulations contained in Part C, Division 5 of the *Food and Drug Regulations*, to stipulate that any reference to a research ethics board means an accredited research ethics board.

5. The committee therefore recommends that the National Framework for Coordinating Clinical Trials:
    - Encourage the creation of research networks as part of its goal of promoting the importance of clinical trials; and
    - Provide guidance to research networks on centralizing research ethics review and on creating databases of patients willing to be considered for clinical trials.

6. The committee further recommends that the Minister of Health:
    - Amend the clinical trial regulations contained in Part C, Division 5 of the *Food and Drug Regulations*, to stipulate that clinical trials must be designed to reflect the same population that can reasonably be expected to consume the drug once approved for sale in Canada; and
    - Implement modifications to its drug approval process to stipulate that market approval will only be granted if clinical trial evidence of the product's safety and efficacy includes data on all population groups that can reasonably be expected to consume that drug once approved for sale in Canada.

7. The committee therefore recommends that the Minister of Health direct Health Canada to include the following elements in its Orphan Drug Framework for Canada:
    - Creation of 'orphan drug status' for drugs in development for specified rare conditions;
    - Assistance in the design of clinical trials for investigational orphan drugs;
    - Elimination or reduction of user fees charged by Health Canada to review orphan drug submissions; and
    - Extension of market exclusivity for orphan drugs.

8. The committee further recommends that the National Framework for Coordinating Clinical Trials:
    - Promote Canada as a preferred site for clinical trials of orphan drugs; and
    - Include a requirement for consultations with stakeholders including the Canadian Organization for Rare Disorders to explore ways to improve and maximize patient recruitment to trials.

9. The committee therefore recommends that the federal government create an expert advisory committee to undertake a thorough study of the intellectual property and tax incentive issues raised by stakeholders during this study with a view to exploring options and recommending changes that will help to improve Canada's global competitiveness in drug development.

10. The committee therefore recommends that the Minister of Health direct Health Canada to immediately address the recommendations made in Chapter 4 of the November 2011 Report of the Auditor General of Canada namely to:
    - Strengthen the risk-based approach for monitoring and assessing clinical trial adverse reaction reports;
    - Establish timelines for officially notifying clinical trial sites of non-compliant ratings; and
    - Enhance public access to information on authorized clinical trials, including the results of inspections.

    The committee further recommends that the Minister of Health direct Health Canada to address additional issues highlighted in the report and take immediate steps to:
    - Realize the target of inspecting two percent of clinical trial sites; and
    - Eliminate manual data entry of adverse drug reaction reports through full implementation of electronic reporting.

11. The committee therefore recommends that the Minister of Health pursue the necessary changes to the *Food and Drugs Act* in order that the statute provide the authorities required for increased transparency, increased penalties, and other provisions critical to modernizing drug regulation in Canada.

12. The committee recommends that Health Canada establish the means to monitor and regularly measure the impact that implementing these recommendations has had on clinical trial activity in Canada and that it report publicly on this progress.