In This Issue:

- MESSAGE FROM DSEN EXECUTIVE DIRECTOR
- DSEN FUNDING NEWS
- GOVERNANCE
- DSEN EVENTS

Visit the Drug Safety and Effectiveness Network website to learn more:
www.cihr-irsc.gc.ca/e/40269.html

CIHR Funding News:
www.cihr-irsc.gc.ca/e/26626.html

CIHR Home Page:
www.cihr-irsc.gc.ca/e/193.html

Contact Us:
dsen-riem@cihr-irsc.gc.ca

Our Team:

Robert Peterson
Executive Director
robert.peterson@cihr-irsc.gc.ca

Diane Forbes
Associate Director
diane.forbes@cihr-irsc.gc.ca

Christian Brochu
Project Manager
christian.brochu@cihr-irsc.gc.ca

Siham Yasari
Project Officer
siham.yasari@cihr-irsc.gc.ca

Elisabeth Jorge
Project Officer
elisabeth.jorge@cihr-irsc.gc.ca

Message from the DSEN Executive Director:
Dr. Robert Peterson

DSEN continues to build its network architecture through two new funding opportunities launched this past spring, which will support up to five new teams. These grants are intended to provide additional method platforms for DSEN to be responsive to queries from high-level decision makers in Canada. As the grant submission date of June 1st has now passed, we are hoping for candidates’ good success in peer review, and a funding start date in Fall 2011.

These teams will be organized to comprise two additional Collaborating Centers to join the Canadian Network for Observational Drug Effect Studies “CNODES”, the first funded DSEN Collaborating Centre. While awaiting these new Collaborating Centers, we are putting additional process and policies in place to support a broad base of input from decision-makers to DSEN on relevant questions of drug safety and comparative effectiveness. This includes validating a Query Submission Template and scientific feasibility assessment first piloted last winter to create a slate of queries approved by the DSEN Steering Committee to be initiated by CNODES (see link to Minutes Feb 23, 2011). Finalizing the process to prioritize amongst multiple queries competing for DSEN resources is a key objective for the coming months. Given the expansion of method platforms in Fall 2011, we anticipate challenges in creating an efficient process to review, prioritize, and fund numerous queries.

Finally, network architecture is only one component of the DSEN. We are working within CIHR to establish funding opportunities for career development, catalyst, and development of new research methods to support post-market drug research. A number of these components are outlined in this Newsletter.

Robert Peterson MD, PhD, MPH
Executive Director, Drug Safety and Effectiveness Network

DSEN FUNDING NEWS

New Investigator Salary Award: Fall 2011 Priority Announcement - Drug Safety and Effectiveness

Application deadline: September 15, 2011
Funding start date: July 1, 2012

Priority Announcements on New Investigator Salary Award competitions offer additional sources of funding for highly rated applications that are relevant to specific research priority areas. A New Investigator is defined as a researcher who has held a full time research appointment (e.g., faculty appointment providing eligibility to apply for grants and/or supervise trainees), for a period of 0 to 60 months as of the competition deadline.

The Drug Safety and Effectiveness Network (DSEN) will provide funding for applications that have a primary focus on post-market drug safety and effectiveness. Applications must also be determined to be relevant to the following research priority areas described below:

1. Drug Safety
2. Comparative Effectiveness
New tool available to researchers

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) recently announced the release of its Guide on Methodological Standards in Pharmacoepidemiology. The guide seeks to review existing methodological guidance for research in pharmacoepidemiology and pharmacovigilance. By providing a structured architecture for thinking and learning, the guide aims to support high quality pharmacoepidemiological studies and to stimulate innovation that benefits patients and public health at large. It is ENCePPs intention to offer the researcher a single overview document and web resource. For each topic covered in this guide, readers are referred to specific existing guidance after a brief introduction or overview of the relevant text. In acknowledgement of the diverse nature and levels of expertise among present researchers in Europe, ENCePP aims at encouraging participation across the spectrum of researchers. It considers the current overview document appropriate to serve both experienced and relatively new researchers in pharmacoepidemiology.

www.encepp.eu


3. Bayesian Statistics
   o Examples of relevant areas include Bayesian methodological designs (e.g. network meta-analysis) to study post-market drug safety or comparative effectiveness. Please note that cost effectiveness studies are not eligible to this priority announcement.

4. Innovative RCT Designs
   o Examples of relevant areas include research using adaptive randomization designs, sequential analysis in RCTs or other innovative trial designs. Please note that standard fixed randomization trials and pragmatic studies are not eligible to this priority announcement.

The total amount available for this funding opportunity is $1,800,000. The maximum amount awarded for a single award is $ 60,000 per annum for up to 5 years.

More information about this funding opportunity can be found on the CIHR’s Funding Opportunities website.

Operating grant: Fall 2011 Priority Announcement - Drug Safety and Effectiveness - Innovative RCTs

Registration Deadline: August 15, 2011
Application deadline: September 15, 2011
Funding start date: April 1, 2012

Priority Announcements on CIHR Operating Grant competitions offer additional sources of funding for highly rated applications that are relevant to specific research priority areas

The Drug Safety and Effectiveness Network (DSEN) will provide funding for applications that have a primary focus on post-market drug safety and effectiveness. Applications must also be determined to be relevant to the following research priority area described below:

- Innovative Randomized Controlled Trial (RCT) Designs
  o Examples of relevant areas include research using adaptive randomization designs, Bayesian designs methodologies and/or sequential analysis in RCTs. Please note that standard fixed randomization trials and pragmatic studies are not eligible to this priority announcement

The total amount available for this funding opportunity is $600,000. The maximum amount awarded for a single award is $ 200,000 per annum for up to 3 years.

More information about this funding opportunity can be found on the CIHR’s Funding Opportunities website.

Operating grant: Fall 2011 Priority Announcement - Drug Safety and Effectiveness (Bridge Funding)

Registration Deadline: August 15, 2011
Application deadline: September 15, 2011
Funding start date: April 1, 2012

Priority Announcements on CIHR Operating Grant competitions offer additional sources of funding for highly rated applications that are relevant to specific research priority areas

The Drug Safety and Effectiveness Network (DSEN) will provide funding for applications that have a primary focus on post-market drug safety and effectiveness. Applications must also be determined to be relevant to one of the following research priority areas described below:

- Observational Studies
- Comparative Effectiveness
- Active Surveillance
- Pharmacogenomics of Adverse Drug Reactions
- Network Meta-Analysis
- Innovative RCT Designs

The total amount available for this funding opportunity is $100,000. The maximum amount awarded for a single award is $ 100,000 per annum for one year.

More information about this funding opportunity can be found on the CIHR’s Funding Opportunities website.

GOVERNANCE
Drug Safety and Effectiveness Network Steering Committee

The DSEN Coordinating Office held the 2nd meeting of the DSEN Steering Committee on February 23, 2011 at CIHR’s offices in Ottawa. An overview of the completed and launched funding opportunities led by DSEN and partners was presented. The DSEN Executive Director provided the outcome of the first round of DSEN Queries feasibility assessment. The DSEN Steering Committee ratified queries deemed feasible that will be posted on CIHR website shortly. As agreed upon, the DSEN Coordinating Office is now working with key stakeholders to develop robust and structured feasibility assessment and prioritization processes to best manage the DSEN Queries as they are received. An update on DSEN activities was provided and the report of the November 19, 2010 DSEN Methodologies in Real World Drug Safety and Comparative Effectiveness Collaborative Innovation Forum was circulated. The report is available on the DSEN website.

On June 10, 2011 DSEN held the 3rd teleconference meeting of the DSEN SC. The DSEN Coordinating Office (CO) presented the report of a contract describing options for the enacting a prioritization process for DSEN Queries. In follow up to the prioritization discussion with the DSEN SC, the DSEN CO is now working on establishing a Working Group (WG) that will define the DSEN guideline for the prioritization of the DSEN Queries. The nomination to this WG is expected to be finalized by mid July and members are expected to meet over the summer and to report back on their findings regarding the prioritization process development to the DSEN SC scheduled to meet face to face on October 28, 2011 in Ottawa.

The report of a second contract on Provincial and Territorial engagement was also tabled. As a next step the DSEN Coordinating Office is planning a webinar with public drug plan managers to continue this engagement and invite the submission of DSEN Queries.

The DSEN Coordinating Office welcomes the appointment of Mr. Paul Glover, Assistant Deputy Minister, Health Products and Food Branch (HPFB), Health Canada, as a member of the DSEN Steering Committee effective February 2011.

DSEN EVENTS

Catalyst Grant Post Market Drug Safety and Effectiveness Knowledge Translation Workshop

On March 28th, 2011 in Ottawa, DSEN held its first annual Knowledge Translation event by bringing together 13 of the 14 funded teams from the 2009 Catalyst Grant competition: “Post Market Drug Safety and Effectiveness”. The event was also attended by representatives from Health Canada, the Canadian Agency for Drugs and Technologies in Health, and CIHR partners. The 13 funded principal investigators presented their research results and participated in an open discussion on their Catalyst Grant experience.

The CIHR Catalyst Grant program provides seed money, on a short-term basis, to support health research activities which represent a first step towards the pursuit of more comprehensive funding opportunities (e.g. operating grants, team grants), such as:

- the planning and execution of pilot projects or feasibility studies aiming to generate preliminary data, observations, or knowledge;
- the planning and execution of novel projects which clearly demonstrate the potential for significant impact, but which are considered high risk in nature in that they may be unsupported by proof of concept / preliminary data;
- development and / or validation of new inventions, tools, methodologies, protocols, theoretical models or frameworks;
- planning and / or development activities of expert teams (multi-disciplinary, trans-disciplinary, etc.) coming together to address health research priorities.