



Brain Canada



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REQUEST FOR APPLICATIONS

CQDM/BRAIN CANADA/OBI PARTNERSHIP FUNDING PROGRAM 2014

FOCUS ON BRAIN

LETTERS OF INTENT

DEADLINE: AUGUST 20, 2014 AT 5 PM EDT

The “Focus on Brain” program is a major funding opportunity, which is open to multidisciplinary research teams linking Quebec and other Canadian researchers, and the academic and small and medium-sized enterprise (“SME”) sectors. Through this program we expect to identify, fund, and support the development of breakthrough technologies that enhance biopharmaceutical R&D productivity and accelerate the development of new, safe and effective drugs for disorders of the brain and nervous system.

*Three-year grants of up to \$1.5M will be awarded to approximately 7 teams proposing to **develop innovative technologies, platforms or tools** that can facilitate the discovery or the development of new drugs for application in preventing, diagnosing, or treating disorders and diseases of the brain, nervous system and special senses, including mental health disorders. Successful proposals will have outcomes with immediate application to the process of drug discovery and/or development, with potential for wide impact on biopharmaceutical research.*

*Applications will **not** be accepted for the identification or development of new drug related chemical products or substances, or for any proof-of-concept, preclinical or clinical trial studies related to specific drugs. Applications for funding research on development of new drugs for specific neurological diseases will not be accepted in connection with this RFA.*

1. Objective

CQDM and Brain Canada in partnership with the Ontario Brain Institute (OBI) (the Partners) are launching the “*Focus on Brain*” program which will support pre-competitive research with the goal of identifying, funding and supporting breakthrough technologies that enhance biopharmaceutical R&D productivity and accelerate the development of new, safe and effective drugs in neuroscience. Our ambition with this request for applications (“**RFA**”) is to attract the best Canadian scientists to develop innovative and unique multidisciplinary proposals that are clearly differentiated from other related Canadian and international research initiatives.

We are striving to develop Canadian and international networks dedicated to advancing next-generation technologies and our mindset in launching this funding opportunity is to fund research in this RFA that is truly synergistic with related neuroscience initiatives and that has very clear near-term potential to impact and to accelerate drug discovery and bring better cures to patients. Applicants are asked to clearly differentiate their proposal from existing initiatives as well as outline how their planned research could be synergistic with these initiatives. Each application will undergo a peer review process in order to determine its level of differentiation.

There is an urgent need to apply the knowledge obtained from new discoveries about the workings of the brain, and the mechanisms underlying neurological and mental health disorders, to the development of novel biopharmaceuticals. This program is intended to support research that has **scientific merit** and that has the potential **to improve and accelerate the process of discovery and development of drugs** that prevent, treat or cure brain disorders, with the expectation that this research will have a catalytic effect on identifying better approaches to the treatment of various brain disorders.

Specifically, the objective of the Focus on Brain program is to **develop innovative technologies, platforms or tools** that can facilitate the discovery or the development of new drugs for application in preventing, diagnosing, or treating disorders and diseases of the brain, nervous system and special senses, including mental health disorders.

2. Scope

The program will exclusively support pre-competitive research and is **not** intended to fund the development of drugs. Specifically this program seeks to support innovation and is focused on multi-province, multi-disciplinary translational research that will generate applicable results for the biopharmaceutical industry at the end of the project. The research funded will be milestone driven.

The research agenda for this program is broad. The program extends to all scientific and technical fields directly related to drug research and all research areas that could provide new tools for biopharmaceutical research relevant to the neurosciences, special senses, and mental health. These include, for example, biomedical engineering, nanotechnology, robotics applied to high-throughput screening, computational neuroscience, medical devices, diagnostics, imaging technologies, biomarkers, biosensors, optogenetics, *in silico* and *in vitro* screening systems, novel animal models with translational capacity, innovative statistical approaches and new clinical trial paradigms that will accelerate and reduce the costs of trials demonstrating efficacy and safety, etc. **The proposed research must address the most crucial and pressing needs of biopharmaceutical research.**

Neuroscience research in Canada is strong, but worldwide accounts for less than 5% of the global research output. The Partners are striving to develop Canadian and international networks connecting Canadian research to other major initiatives in order to advance discovery and the development of next-

generation technologies. **Through the “Focus on Brain” program, we wish to fund research that is synergistic with major Canadian and international initiatives relevant to the topic of this application, but which is clearly differentiated from them so as to avoid duplication of research efforts.** Each research proposal submitted under the RFA process must explain how it will generate clear deliverables and outcomes, with near term impacts on drug discovery and the faster development of better approaches to the prevention, diagnosis and cure of brain disorders.

Examples of projects in the neurosciences previously funded by CQDM can be found at <http://www.cqdm.org/en/projects-portfolio/>.

Exclusions: This RFA is not for the identification or development of new drug related chemical products or substances, or for any proof-of-concept, preclinical or clinical trial studies related to specific drugs. Applications for funding research on development of new drugs for specific neurological diseases will **not** be accepted in connection with this RFA.

3. Eligibility Guidelines

This program is focused on multi-disciplinary and collaborative efforts between academic institutions and SMEs. To be eligible for funding, research must be performed in Canada. OBI will be a funding partner for projects with investigators based in Ontario. For these projects, OBI will support the Ontario portion of the project. Proposals must meet the following requirements:

- Applications must be from a team of two or more eligible investigators located in two or more provinces. At least one co-principal investigator must be located in the province of Quebec.
- Eligible investigators are those:
 - Appointed by and working at a University, hospital, affiliated research institution or employed by SMEs in the field of life sciences, biotechnologies, biopharmaceuticals, medical devices, diagnostics, engineering, imaging, or contract research organizations (“**CRO**”).
- Multinational pharmaceutical companies are not entitled to receive funds from this program.
- Teams may include investigators from the academic sector only; however, since SMEs are well-placed to contribute industry know-how and to link the developed technologies, platforms or tools with potential users, they are of great importance for this program. Although not mandatory, **we strongly encourage collaborations between SMEs and the academic sector.** Please note that CQDM can finance both academic and industrial investigators. Therefore SMEs can be funded through this program to up to 50% of the overall budget; that is, SMEs can be funded by the portion of the grant provided by CQDM. Furthermore, OBI can finance both academic investigators and product development services (public or private).

4. Funding

Grants will be for a maximum of \$500,000 per year for up to three years (\$1.5M in total). The overall budget details must be clear and well justified. Depending on the quality of applications, approximately 7 grants are likely to be awarded.

Grants must be fully justifiable and may only be used to pay the reasonable costs of items that directly support the objectives of the project, including

- Salaries of research personnel necessary for the project (students, post-doctoral fellows, technical/professional assistants).
- Materials and supplies necessary for the realisation of the project.
- Provision of special services and user fees.

- Maintenance of essential equipment.
- Travelling expenses (for field work, collaborations, and presentation of results at conferences).
- Intellectual property protection costs (patent application, maintenance fees during the funding period).

Given that CQDM and Brain Canada are funded by the federal Government, grants may not be used to pay the salaries of any of the research team and staff members including, without limitation, any team leaders, applicants or co-applicants, or to pay indirect costs, such as overhead, which are already financed under other federal government programs. Acquisition costs associated with equipment are not eligible for funding under this RFA.

5. Mentors

All funded projects will be assigned a mentor from the pharmaceutical sector with experience in the drug discovery and development process. Mentors are senior scientists from CQDM's and/or OBI's industry sponsors who provide expertise and access to useful resources. Their role is to ensure that the project progresses according to the agreed project plan so that its output remains aligned and is applicable to industry drug discovery/development programs.

6. Application, review, and decision process

The funding will be awarded following a competitive process in two stages: 1. Letters of intent and 2. Full proposals.

6.1 Letter of Intent

To encourage eligible researchers to submit a wide range of creative proposals, the first stage is a brief and simple Letter of Intent (LOI), requiring a minimum of paperwork which will be available on CQDM's, OBI's and Brain Canada's website (<https://braincanada.smartsimple.ca/>). Before 5 PM EDT on August 20, 2014, applicants must submit a letter of intent describing the project to the Partners. LOIs will be evaluated primarily on potential impact on the drug discovery process, global competitiveness and innovativeness of the proposed work. The selection of the letters of intent will be overseen by a CQDM/Brain Canada/OBI joint selection committee composed of members from CQDM's strategic orientation committee (including industry and academic representatives) and Brain Canada representatives and by a panel of external pharmaceutical executives who are independent of the Partners and their membership. OBI representatives will be on the joint selection committee to assess letter of intents with Ontario investigators. Only applicants whose letter of intent is selected will be invited to submit a full project proposal.

6.2 Full proposals

Applicants whose letters of intent are considered highly promising and aligned with the program objectives will be invited to submit a full project proposal. Full proposals are due no later than 5 PM EDT on November 7, 2014. They will undergo a 3-step evaluation process: a scientific evaluation, a risk assessment, and an evaluation for potential impact on biopharmaceutical research.

Scientific review of full proposals

The scientific evaluation will be overseen by CQDM, Brain Canada and OBI (for projects with Ontario-based investigators). An independently chaired peer review committee will be convened with scientific experts from outside of Canada. The selected experts will be asked to comment on the quality of the

proposals in particular on their scientific excellence, feasibility, and impact with reference to the evaluation criteria and the chair person will report the scientific ranking of projects to the Partners. All applicants will receive anonymized reviewer comments.

The selection process shall include the following criteria:

- **Scientific merit:** creativity, novelty and significance of the proposal; differentiation of the proposed work from other international efforts; track record of participants (principal investigators and co-investigators) in producing original, high quality research; and in particular in developing technologies, platforms or tools of relevance to drug development.
- **Feasibility and efficiency:** capability and capacity to execute the project within time and budget allocated, including preliminary evidence where appropriate; clear, well-defined, deliverables and milestones linked realistically to the research plan and associated Gantt; adequacy of plans for effective management of the research team and project.
- **Positioning amongst other initiatives (collaboration between academic and private organizations is strongly encouraged):** capacity of the project to generate applicable results by the end of the project with a direct impact on drug discovery or development; its likely impact on drug discovery or development and the potential to address important unmet needs in biopharmaceutical research.
- **Added value (collaboration between academic and private organizations is strongly encouraged):** the added value of the multidisciplinary research collaboration between the research entities; potential synergies between the project and major national and international research initiatives, and how these will be realised.

Risk Assessment of full proposals

Applications that receive a high rating on scientific merit from the expert reviewers will be subject to a further evaluation to assess any potential risks that might jeopardize the successful achievement of the research project. This evaluation will be conducted by staff from the Partners and will take the form of a site visit and/or meeting between the CQDM and the principal investigator and the main co-investigators. Aspects of the proposal such as intellectual property (IP), ethics, the business profile and capacity of SME partner(s), and project management will be evaluated, and CQDM, Brain Canada or OBI may make any inquiries or request any supporting documentation which it deems necessary in order to properly evaluate an application.

Evaluation of Potential Impact on Biopharmaceutical Research

The results of both the scientific and risk assessments will be presented to the CQDM/Brain Canada/OBI joint selection committee which will evaluate the overall likely impact of the project on biopharmaceutical research and will recommend proposals for funding. The Boards of CQDM, Brain Canada and OBI will receive the recommendations of the Selection Committee and will jointly select which research projects will be funded. The Partners' decisions are final, and shall not be revisited or re-reviewed under any circumstances.

7. Grant administration, licensing policy and research agreements

Research grants awarded through the Focus on Brain program will be administered by CQDM (and OBI for projects including Ontario-based investigators) and are subject to the normal funding agreement requirements of CQDM, and shall include terms and conditions related to the following:

- **Intellectual property generated under this funding program belongs to the investigators and/or research entities and will be managed according to the policies of all the research entities involved in a funded project.** An intellectual property agreement between the research entities involved in a funded project must be in place before the CQDM (and OBI for projects with research entities based in Ontario) disburses any funds to the research entity of the principal applicant.
- Applicants and their institutions agree that a royalty free non-exclusive license option will be granted to CQDM's and/or OBI's industrial sponsors (only those that contribute financially to this program) for the use of all the results generated by the **project for R&D purposes only**. The main conditions of the end-user license option will be negotiated before the beginning of the project and will take into account pre-existing (background) intellectual property as well as the contributions of each party. **CQDM and/or OBI industrial sponsors do not have the right to commercialize the intellectual property resulting from the project or the pre-existing intellectual property**, nor does this license prevent subsequent commercialization of the intellectual property by the research entities.
- A research agreement must be signed between the Partners and the research entities within 3 months following the final confirmation of funding as a condition precedent of the funding approval. The research agreement will include, without limitations, the following aspects:
 - A clear description of the project including main steps, milestones, deliverables and the role of each investigator.
 - A detailed budget and payment schedule (quarterly) including the portion that will be allocated to each research entity.
 - A commitment from all the research entities and the investigators involved in the project to perform the research according to all relevant regulations, to maintain complete records of the research, and to disclose to the Partners additional background intellectual property that arises in the course of the project.
 - The obligation of the research entities to protect the intellectual property arising from the research project.
 - The main terms and conditions of the licence option in favor of the CQDM and OBI industrial sponsors for the use of the results generated by the project (and background intellectual property, if necessary) for research and development purposes. Basic representations and warranties by the research entities including the required rights, consents and/or approval to perform the research project.
 - The schedule of financial and scientific reports.
 - Disclosure and publication requirements, including the requirement to notify the Partners prior to presentation or publication of results, and, where necessary, to delay publication for a reasonable period to protect intellectual property: the obligation to acknowledge the Partners in all publications or presentations.
 - Confidentiality obligations.

8. Disbursement for funded projects

CQDM will, on behalf of both CQDM and Brain Canada, disburse quarterly funds based on pre-agreed terms (stipulated in the research agreement) on condition that pre-defined milestones have been achieved and scientific progress is as per the agreement. For projects with Ontario-based investigators, OBI will disburse funds directly to the Ontario-based participants.

9. Key Dates

Launch	May 26 2014
First information session	May 28 2014, 12 p.m. Annual meeting of Canadian Association for Neuroscience Montreal Hilton Bonaventure, 900 de la Gauchetière West, Montreal, Montreal Ballroom
Other information sessions	Date(s) and location(s) to be determined
Deadline for submission of the letters of intent	August 20 2014
Announcement of the selected letters of intent	Late September 2014
Deadline to submit full proposals	November 7, 2014
Final selection announcement	Early January 2015
Signature of the research agreement	Late March 2015
Earliest funding release and beginning of the projects	March 30 2015

Contact information

For further information, please contact:

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