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**REQUEST FOR APPLICATIONS**

**CQDM/BRAIN CANADA FUNDING PROGRAM 2015**

**FOCUS ON BRAIN**

**DEVELOPMENT AND COMMERCIALIZATION OF PLATFORM TECHNOLOGIES IN NEUROSCIENCES**

**LETTERS OF INTENT**

**DEADLINE: DECEMBER 15, 2015 AT 5 PM EDT**

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*The “Focus on Brain” program is a major funding opportunity, which is open to multidisciplinary research teams linking researchers from at least two Canadian provinces, 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 or improve 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 3 or 4 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.*

## 1. Objective

CQDM and Brain Canada are launching the 2015 edition of the “*Focus on Brain*” program which will support pre-competitive research with the goal of identifying, funding and supporting breakthrough technologies that **enhance and improve 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.

As research uncovers new understanding of the workings of the brain, and of the mechanisms underlying neurological and mental health disorders, there is an urgent need to apply this new knowledge to the development of pharmaceuticals and other agents which will treat these disorders. The goal of the Focus on Brain Research Program 2015 is to support research that will lead to the improvement and acceleration of the process of discovery and development for drugs that target brain disorders, believing that this approach will have a catalytic effect on the approach to treatment of the entire range of brain disorders. In an effort to bridge the gap between innovation and treatment, Focus on Brain will emphasize on translating technologies to the market, with commercial exploitation serving as an incentive and guarantee that the benefits of the technologies developed within this program will ultimately reach patients in a timely manner. Promoting commercial exploitation of the technologies developed within this program ensures its proper development, validation and availability to the various stakeholders involved in developing new drugs. Through the research we are funding, we are giving hope to the millions of Canadians who are directly or indirectly touched by diseases, disorders, and injuries of the brain, spinal cord and nervous system. Together, we will have an impact on the lives of all Canadians, and indeed, enable researchers and clinicians to make breakthrough discoveries that will have immediate applications and benefit millions of people around the world.

Specifically, the objective of the Focus on Brain program is to **develop innovative technologies, platforms or tools that can enhance, improve, accelerate and facilitate the discovery or the development of new drugs or therapeutics** for application in preventing, diagnosing, or treating disorders and diseases of the brain, nervous system and special senses, including mental health disorders. **Focus on Brain – 2015 will focus on translation of platforms technologies into products and services** that will enable drug discovery in the area of neurosciences and mental health.

With this second edition, we continue to address important gaps in the drug research and development (R&D) process, but will also be able to seize opportunities that can bring exceptional value to biopharmaceutical research. This initiative will bring socioeconomic benefits to small and medium enterprises (SMEs) and academia, and allow CQDM to establish strategic partnerships. Although not mandatory, **collaborations between SMEs and the academic sector are strongly encourage**. When applicable, this initiative should allow SMEs to achieve translation of their platform with exceptional potential to accelerate, improve or enhance drug R&D in neuroscience into a ready-to-commercialize product or service for the benefit of the entire ecosystem involved in developing new drugs. It is thus designed to bring an existing platform to its most advanced form, positioning it advantageously for commercialization. Projects funded under this initiative should not only be scientifically excellent, but should also have a definite impact on the SMEs business plan. To this end, and when appropriate, the funding from CQDM could take the form (in total or in part) of an investment.

## 2. Scope

The program will support pre-competitive research or **platforms and tools** that **can enhance, improve, accelerate and facilitate the discovery or the development of new drugs**. Although not intended to fund the development of specific new drugs or new molecular entities (NMEs), technologies with the potential to lead to the discovery of NMEs such as chemical platforms generating libraries of new compounds or technologies enabling the identification of “hits” or lead candidates are eligible. Examples of eligible projects involving NMEs could include and are not limited to a) the development of a new chemistry platform generating compounds with extended half-lives and/or improved bioavailability or b) the identification of new hits as proof of concept and/or validation of a novel screening tool.

This program seeks to support innovation and is focused on 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.

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

The research agenda for this program is broad. The program extends to all scientific and technical fields directly related to new drug discovery and development 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.

### **Exclusions:**

This RFA is not for the identification or development of specific new molecular entities (NME) against a specific target, or for any proof-of-concept, preclinical or clinical trial studies related to specific drugs. Concerning NMEs and eligibility to this program, only tools, technology or platforms that can lead to the identification of new drugs or from which a new drug could be derived (such as a new library) would be acceptable.

This program is not meant to fund fundamental research projects.  
Testing of off-label indications of an existing drug is not eligible.

### 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. Proposals must meet the following requirements:

- Applications must be from a team of two or more eligible investigators.
- 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.
- At least one investigator from the academic sector is mandatory. 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 considered to bring great added value to this program.
- Although not mandatory, **collaborations between the academic sector and SMEs are strongly encouraged**. 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.

### 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 3-4 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 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), which will be available on Brain Canada's website (<https://braincanada.smartsimple.ca/>). Before 5 PM EDT on December 15, 2015, 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, i.e. the potential to accelerate, enhance or improve the drug R&D process, global competitiveness and innovativeness of the proposed work. The selection of the letters of intent will be overseen by a CQDM/Brain Canada 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. 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 April 28, 2016. 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 and Brain Canada. 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. Soundness of the experimental design.
- **Feasibility and efficiency:** current state of development of the technology; 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.

- **Commercial opportunities and Business Plan:** The quality of the opportunities the technology will create in the biopharmaceutical R&D sector. The potential commercial value of the technology and the soundness of the technical development plan that would be required to ultimately commercialise the technology (manufacturing, scale-up, regulation, foreground and background IP, etc.), within reasonable timelines. If applicable, the completeness of the business plan and the alignment the project with corporate goals; the creation synergistic value for the organization.
- **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 or Brain Canada 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/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 and Brain Canada 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 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 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 '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 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 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.
- When applicable, the funding from CQDM could take the form (in total or in part) of an investment. Specifics of this investment will be clearly stated in the research agreement. This scenario will likely occur with projects offering clear commercial opportunities. These could include projects that are performed in either academia and/or in SMEs. With an investment, CQDM would actively promote, using all its resource and vast network, the successful commercial exploitation of the technologies developed within this program, in an effort to ensure its proper development, validation and availability to the various stakeholders involved in developing new drugs or therapies for patients. Any return on its investments would allow further funding of new technologies to continue closing the gap between innovation and commercialization.

## 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.

## 9. Key Dates

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| Launch  | September 15, 2015                       |
| Information sessions                                    | Date(s) and location(s) to be determined |
| <b>Deadline for submission of the letters of intent</b> | <b>December 15, 2015</b>                 |
| Announcement of the selected letters of intent          | March 16, 2016                           |
| <b>Deadline to submit full proposals</b>                | <b>April 28, 2016</b>                    |
| Final selection announcement                            | Mid-July 2016                            |
| Signature of the research agreement                     | Mid- October, 2016                       |
| Earliest funding release and beginning of the projects  | November, 2016                           |

## Contact information

**For further information, please contact:**

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