CQDM/CIHR COLLABORATIVE FUNDING PROGRAM IN PERSONALIZED MEDICINE TO ACCELERATE DRUG DISCOVERY

CALL FOR PROPOSALS

DEADLINE: JUNE 27TH, 2014
1) **SCOPE OF THE PROGRAM**

Personalized Medicine is developing at a rapid pace which brings new challenges as well as opportunities to the whole spectrum of therapeutic development, from basic research to its integration in the drug discovery process. It is pivotal that research and development in this area be aligned to real unmet healthcare needs and be compatible with efficient and effective translation into uses for patients.

The “**CQDM/CIHR Collaborative Funding Program in Personalized Medicine to Accelerate Drug Discovery**” program will facilitate this alignment by combining the expertise of both CQDM and its industrial sponsors, and CIHR with its deep insight into Canadian academic scientific expertise. This will build upon the extensive initiatives and multiple projects funded as part of the **CIHR Personalized Medicine Signature Initiative** (http://www.cihr-irsc.gc.ca/e/43627.html). This national program will offer public and private partners the opportunity to work together to develop **new cutting-edge technologies, computational tools and devices** that will in turn accelerate R&D in the area of personalized medicine.

The program extends to scientific and technical fields directly related to biopharmaceutical R&D and all disciplines that could provide new technologies and devices for biopharmaceutical research as described in the research agenda below. Examples include engineering, nanotechnology, computational science, medical devices, imaging, biosensors, in silico and **in vitro** screening systems, biostatistics, and improved disease-relevant animal models.

This program is **not intended to fund research on the development of specific drugs or biomarker discovery/development projects**. Rather, it aims to support the development of innovative technologies, computational tools and devices that can be used to accelerate or facilitate the discovery or the development of new treatments for patients. The aim is to promote creativity, innovation, and multidisciplinary collaborative efforts between academic institutions and private organizations [e.g., SMEs, biotech/contract research organizations (CRO)].

Successful applicants will have the opportunity to receive mentorship from CQDM’s industrial sponsors. The goal of this mentorship is to facilitate the knowledge translation of the project to increase commercialization, economic and social value of the research and can take multiple forms as seen appropriate by the applicants and CQDM’s industrial partners.

2) **PROGRAM REQUIREMENTS**

This joint funding program is designed to bolster collaborations between Canadian academic research entities and the private sector.

Each research proposal **must meet** all the following requirements:
• involve strong collaborations between researchers based at academic and private organizations;
• generate clear deliverables with immediate applications in the drug discovery and/or development process;
• be highly innovative with a strong and wide potential impact on biopharmaceutical research and the Canadian healthcare system;
• develop new cutting-edge technologies, computational tools and devices that aim to enable and facilitate further discoveries or facilitate drug development/repurposing in the specified research areas (section 3);
• involve at least one private partner who will be contributing 25% of the funding (including in-kind) at the time of application; and
• propose an adequate development plan to ensure the realization of the expected benefits.

The development plan must be milestone-defined, with appropriate descriptions of risk mitigation plans if the milestone could not be met as planned. Milestones are not technical specific aims, but rather go/no-go decision points that provide justification for continuing a project.

To be eligible for this program, research must be performed in Canada with (i) at least one researcher based at a university or affiliated research institution or hospital and (ii) at least one researcher at a:

• small and medium-sized enterprise (SMEs: up to 500 employees) from the private sector established in Canada (organizations in the field of life sciences, biotechnologies, biopharmaceuticals, medical devices, diagnostics, engineering, imaging, CROs, etc.); or
• not-for-profit organization established in Canada with important research activities.

All eligibility criteria for all CIHR research funding programs will apply to the portion of the research based at a university or affiliated research institution or hospital. The business office of the institution of an eligible Nominated Principal Applicant generally administers CIHR funds. Refer to the Individual Eligibility Requirements (www.cihr-irsc.gc.ca/e/22630.html#F10) regarding the eligibility requirements for individuals and institutions. For CIHR’s contribution, the Nominated Principal Applicant be must an independent researcher (www.cihr-irsc.gc.ca/e/34190.html#r6).

3) RESEARCH AGENDA

In an effort to bring solutions that will address the most urgent needs of biopharmaceutical research, CQDM and CIHR will fund research projects focused on the invention and development of next-generation of technologies, computational tools and devices in the following research areas:

• cancer
• infection and immunity
• neurodegeneration affecting cognition
Only projects with a well-defined near-term application deemed to significantly impact biopharmaceutical research will be funded under this program.

4) FUNDING SPECIFICS

**Duration**
- Up to 30 months

**Funds Available**
- The total budget available is up to $2.25M from CQDM and CIHR (through its Institutes of Aging; Cancer Research; Genetics; Neurosciences, Mental Health and Addiction, and Infection and Immunity)
- CQDM and CIHR will be funding projects on a 1:1 funding ratio
- This amount may increase if additional funding partners participate and/or if additional CQDM and CIHR funds become available during the competition cycle;
- It is anticipated that a minimum of three projects will be funded

**Value**
- Maximum amount that can be requested from CQDM and CIHR is $750K per project
  - Maximum CIHR contribution per project is $150K/annum for up to 30 months

**Private Sector Partners**
In addition, at least 25% of the total project cost (above and beyond the budget requested from CQDM and CIHR) must be provided by private sector partner(s) and secured by the applicant at the time of the full proposal (in cash, in kind or a combination). For example, if the budget requested by CQDM and CIHR is $750K total over 30 months, the minimum private sector contribution would be $250K total over 30 months for a total project cost of $1M. *For further information regarding acceptable matching funds, please contact CQDM.*

**Eligible costs**
Eligible costs are defined as reasonable costs for items that directly support the objectives of the project.
- Salary of research personnel necessary for the project (students, post-doctoral fellows, technical/professional assistants)
- Material and laboratory supplies necessary for the realisation of the project
- Travel expenses (field work, collaborations, conferences)
- Intellectual property costs (patent application and patent maintenance fees during the funding period)
- Administrative costs (overheads), up to 15% of the eligible research expenses for the portion of the grant provided by CQDM (50%). These costs must be directly related to the project and need to be well justified. Supporting documents regarding the overhead may have to be provided to CQDM upon request
• CIHR’s policies and general guidelines, including those specific to overhead costs, will apply to its contribution. [http://www.cihr-irsc.gc.ca/e/204.html]

Non eligible costs
• Equipment or facilities (purchase or rental)
• Salary of the principal investigator and co-investigators

5) REVIEW AND DECISION PROCESS

The funding will be awarded following a competitive process in two stages.

1) Preliminary application (Letter of intent)
Applicants must submit a letter of intent (using the form available on CQDM’s Web site at www.cqdm.org) describing the project by June 27th, 2014, at 5 PM EDT. The selection of the letters of intent will be overseen by a CQDM/CIHR advisory committee composed of members from CQDM’s strategic orientation committee (including industry and academic representatives) and CIHR representatives.

Pre-selection of the letters of intent for full application submission will be based on the following criteria:
• overall meet program and research agenda requirements (as described in sections 2 and 3);
• relevance to the research priorities listed in the research agenda section (as described in section 2);
• strong and wide impact on the drug discovery/development process; and
• involve an active collaboration with a private partner(s) who will be contributing a minimum of 25% of the funding (including in-kind).

Only applicants whose letter of intent is selected will be invited to submit a full project proposal. A maximum of 20 letters of intent will go forward to full application.

2) Full proposal
At the full proposal stage, applicants must provide confirmation that they have secured a minimum of 25% in matching funds (including in-kind) from private partner(s). This confirmation must be provided in the form of a “letter of engagement” signed by the private partner(s). The CQDM/CIHR Advisory Committee will be reviewing all letters of engagement to ensure that this requirement has been met by applicants. Only those full proposals who meet the pre-selection criteria and the matching funds requirement will go forward to peer review.

Full proposals will be evaluated by external expert peer review. The evaluators will be chosen for their specific scientific and/or industrial expertise in the field of the submitted projects. The results of the scientific evaluation will be presented to the CQDM/CIHR advisory committee who will make
recommendations to the CQDM Board of Directors and the CIHR Science Council for final approval.

Applications will be funded in rank order where only those proposals demonstrating the highest degree of overall excellence will be funded.

SELECTION CRITERIA OF THE FULL PROPOSALS

The following criteria will be used for the evaluation of the applications:

- Scientific excellence
- Creativity and innovation
- Clear well-defined deliverables and milestones
- Feasibility to execute the project within time and budget allocated
- Potential of applications in drug research:
  - Immediate impact on drug discovery or development
  - Capacity to address important unmet needs
- Competitiveness in the scientific field of the proposal
- Track record of the participants (principal investigator and co-investigators)
- Multidisciplinary and multi-organizational aspects of the research
- Adequateness of the team to performed the proposed research
- Complementarity between partners
- Alignment of the proposed research with the corporate objectives of the private partner(s) providing matching funds and the research being undertaken in the industrial setting
- Reasonable and well justified budget in terms of the anticipated level of effort and deliverables

6) LICENSING POLICY

Pre-existing intellectual property (IP) necessary for carrying out the proposed project must be free of all encumbrances.

IP generated under this funding program will belong to the inventors and their affiliated research entities. IP generated under this funding program will be managed according to the policies of all the academic or financial partners involved.

A non-exclusive license option (royalty-free) will be granted to the CQDM industrial sponsors for the use of the results for R&D purposes only. If background IP is needed to use the results, a non-exclusive license option to use the background IP will also be granted to the CQDM industrial sponsors. In this case, the use of the background IP will be negotiated between the parties. The CQDM industrial sponsors will have no right to commercialize the results or the background IP.

A research agreement will need to be signed between CQDM and all the research entities involved in the project within 3 months following the final confirmation of funding. 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;
• The main terms and conditions of the licence option in favor of the CQDM pharma sponsors for the use of the results generated by the project (and background IP, 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;
• Disclosure and publication requirements;
• Confidentiality obligations.

*A template of the research agreement will be available upon request.

7) **MONITORING OF FUNDED PROJECTS**

For all funded projects a project manager (PM) must be identified by successful applicants. This person will be responsible for co-ordination of all financial reports (required quarterly) and scientific reports (required semi-annually). The Partners will monitor the progress of the project and continuation of funding will be dependent on satisfactory progress against agreed milestones and budget.

CIHR funding will be conditional upon CQDM’s continued funding of the research project and will be released according to its standard process (http://www.cihr-irsc.gc.ca/e/805.html).

8) **SUBMISSION PROCEDURES**

An electronic version of the letter of intent must be submitted on CQDM’s secure site **by June 27th, 2014, at 5:00 PM EDT** (https://cqdm.firmex.com). Applicants must contact Eugénie Bergeron Côté at ebergeron@cqdm.org before June 20th, 2014 to obtain their username and password.

The electronic PDF version must include:

• The signed application form in PDF format. The file must be identified as follow: *Last name of PI_application.*
• Updated and complete common Canadian CV (CIHR format) of the principal investigator (PI) and all the co-investigators. The file must be identified as follow: *Last name of PI_Last name of co-investigator_CV.* Investigators working in a private company may provide a standard CV.
Please remove all the security features on the PDF version of the documents.

The application form is available at [www.cqdm.org](http://www.cqdm.org).

In order to help all applicants to better understand the specificities and objectives of this program and to help in the preparation of the letters of intent, CQDM/CIHR will organize information sessions (time and location to be confirmed). Furthermore, specific meetings could be organized on a per request basis.

### 9) TIMETABLE

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Call for proposals – launching</td>
<td>March 18th, 2014</td>
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<tr>
<td>Information sessions</td>
<td>Date and location TBD</td>
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<td>Deadline for submission of the letters of intent</td>
<td>June 27th, 2014</td>
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<td>Announcement of the selected letters of intent</td>
<td>September 11th, 2014</td>
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<td>Deadline to submit full proposals</td>
<td>November 27th, 2014</td>
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<tr>
<td>Final selection announcement</td>
<td>March 31st, 2015</td>
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<td>Signature of the research agreement</td>
<td>Three month window</td>
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<td>Funding release &amp; beginning of the projects</td>
<td>July 1st, 2015</td>
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### 10) SPONSORS OF THE PROGRAM

**CQDM**
CQDM is a pharma-based consortium active in pre-competitive research whose mission is to fund the development of innovative tools and technologies to accelerate drug discovery. Unique in the world, CQDM’s business model is based on a collaborative approach where all stakeholders share the costs of biopharmaceutical research and benefit from its results. CQDM also provides a common meeting ground where academia, governments, and the pharmaceutical and biotechnology industries converge to address numerous complex medical challenges.

**CIHR**
The Canadian Institutes of Health Research (CIHR) is the Government of Canada's health research investment agency. CIHR's mission is to create new scientific knowledge and to enable its translation into improved health, more effective health services and products, and a strengthened health care system for Canadians. Composed of 13 Institutes, CIHR provides leadership and support to more than 12,600 health researchers and trainees across Canada.

**Institute of Aging (IA)**
IA’s mandate is to ensure the availability of knowledge with respect to the determinants of active aging as well as those related to the complex health challenges of the older person with the objective of providing better prevention and intervention programs as well as a an efficient and adapted continuum of services for the older person. In collaboration with the other CIHR Institutes, the Institute of Aging seizes the opportunities and contributes to facing the challenges associated
with the aging Canadian population. The Institute of Aging is the lead with co-lead from the Institute of Neurosciences, Mental Health and Addiction in the CIHR International Collaborative Research Strategy for Alzheimer’s disease.

**Institute of Cancer Research (ICR)**
ICR is dedicated to supporting research that reduces the burden of cancer on individuals and families through prevention strategies, screening, diagnosis, effective treatment, psycho-social support systems, and palliation.

**Institute of Genetics (IG)**
IG supports research on the human and model genomes and on all aspects of genetics, basic biochemistry and cell biology related to health and disease, including the translation of knowledge into health policy and practice, and the societal implications of genetic discoveries.

**Institute of Infection and Immunity (III)**
III supports research and helps to build research capacity in the areas of infectious disease and the body's immune system. Through the Institute's programs, researchers address a wide range of health concerns related to infection and immunity including disease mechanisms, disease prevention and treatment, and health promotion through public policy.

**Institute of Neurosciences, Mental Health and Addiction (INMHA)**
INMHA supports research on the functioning and disorders of the brain, the spinal cord, the sensory and motor systems, and the mind. The burden of disease in terms of the social, economic and health care costs associated with these disorders and related illnesses are staggering and there are indications that the number of people affected either directly or indirectly will continue to increase in the years to come. The INMHA is a unique institute because, based on recent discoveries, it has been designed to address all aspects of research dealing with Brain-Mind relationships inclusive of the four pillars of the CIHR.

**For further information, please contact**

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