

LeadAction|Breast Cancer du Sein Competition

<p>DEADLINES</p> <p>Submission of Notice of Intent: March 18, 2019, 4:30 p.m.</p> <p>Submission of Complete Application: June 20, 2019, 4:30 p.m.</p>	<p>For all questions related to: IRICoR and the Competition</p> <p>Audrey Segret Project Manager audrey.segret@umontreal.ca</p> <hr/> <p>For all questions related to: Quebec Breast Cancer Foundation</p> <p>Jida El Hajjar Vice President-Investment and Health Promotion jelhajjar@rubanrose.org</p>
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COMPETITION PROMOTERS AND CONTEXT

As a project maturation cluster in the field of drug discovery, **IRICoR** is a not-for-profit organization based at the Institute for Research in Immunology and Cancer (IRIC) of the Université de Montréal. IRICoR’s mandate is to accelerate the discovery, development and commercialization of novel therapies in cancer, immunotherapy and related fields. Since 2008, IRICoR has successfully combined industry-standard business expertise and cutting-edge research. IRICoR invests in and supports particularly innovative selected projects, ensuring an effective transition of fundamental research into innovative therapies, through either co-development partnerships with the biopharmaceutical industry or the creation of spin-off companies. IRICoR provides selected academic and industry projects with access to its drug discovery network of experts and infrastructure, including one of the largest academia-based medicinal chemistry groups in Canada. IRICoR’s major funding sources for the 2018-2023 period include the Canadian government’s Centres of Excellence for Commercialization and Research (CECR) Program, the Quebec government’s programs, through the *Ministère de l’Économie et de l’Innovation* (MEI, previously the *Ministère de l’Économie, de la Science et de l’Innovation - MESI*), and collaborative partnerships with the biopharmaceutical industry.

The LeadAction|Breast Cancer du Sein Competition (the “Competition”) fits in perfectly with IRICoR’s mission. It is a great opportunity for the Centre to continue building a portfolio in breast cancer with high-value oncology and immuno-oncology projects sourced from across Canada and internationally. The Competition will be held in partnership with the Quebec Breast Cancer Foundation, a key player in Quebec.

The **Quebec Breast Cancer Foundation** is the only philanthropic organization ensuring that the benefits of its research investments in the fight against breast cancer be used in Quebec. It acts as a real scientific accelerator. Over more than 24 years, the Foundation has invested over 46 million dollars into its mission, including 30.5 million dollars distributed in the province towards funding cutting-edge research. The Foundation works hard to improve the survival rate and quality of life of breast cancer patients, while continuing to defend the right of those suffering from it to have access to the most advanced care and treatments, to be informed and to receive financial and psychological support. The Foundation works in concert with all of the players in the scientific, medical and governmental milieus in order to foster the emergence of the best practices and maximizes the impact of every dollar invested in Quebec. This collaborative dynamic promotes partnerships with institutions recognized internationally for their expertise in the breast cancer field, thus creating substantial financial leverage to support the development of research and of new therapies, for the purpose of making scientific, technological and medical innovation more quickly accessible to Quebec patients. The funds raised are also invested in developing support, educational and awareness programs. The Foundation, in collaboration with its partners, is responsible for several advances that have changed medical practices, that have made major scientific advances possible and that have had a direct impact on the quality of life and survival rate of patients.

In keeping with their respective organizational strategies, and in an effort to develop and highlight scientific research excellence in breast cancer on a path towards commercialization of innovative therapeutic solutions, IRICoR and the Quebec Breast Cancer Foundation (“Promoters”), are proud to announce the launch of the LeadAction|Breast Cancer du Sein Competition (the “Competition”).

PROJECT AND APPLICANTS’ ELIGIBILITY

The main objective of the Competition is to subsidize breast cancer research projects led by skilled scientists from Quebec and the rest of Canada. The projects must be aimed at developing highly innovative new therapies, with great commercial potential, that will pave the way, in the long-term, towards the next generation of treatments accessible to patients.

PROJECT ELIGIBILITY

<p>Competition objectives</p>	<p>The selected projects must respond to a clearly identified medical need in breast cancer and must pave the way for innovative new treatments that could have a major impact on patients, in order to maximize the socio-economic benefits in both Quebec and the rest of Canada.</p> <p>Eligible projects can be related to the development of small molecules or biotherapies (antibodies, oncolytic viruses, cell products such as stem cells or T cells, synthetic peptides, ribonucleic acid (RNA)-based approaches, etc.). This list is non-exhaustive.</p>
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The Competition aims to promote translational research projects starting at one of these following phases/stages:

- **Hit to lead transition;**
- **Lead optimization;**
- **Pre-clinical studies.**

Here are a few examples of fundable activities from these various phases/stages:

- **Hit to lead transition/Lead optimization:**
 - Design of new analogs based on hit compounds series;
 - Structure-activity relationship analysis;
 - Optimization of selective compounds aimed at greater efficiency and reduced off-target activities;
 - Etc.
- **Pre-clinical studies:**
 - *In vivo* evaluation of drug candidates;
 - Characterization of drug candidates (pharmacology, pharmacokinetics, toxicology, ADME);
 - Pharmaceutical aspects (ie: initial formulation and production of preclinical material);
 - Identification of clinical doses;
 - Etc.

Please note that in this Competition, applicants who need to use drug discovery core facilities are invited to refer to those of [the Institute for Research in Immunology and Cancer \(IRIC\) - Université de Montréal \(UdeM\)](#). In case IRIC's core facilities are not available or not relevant to a project submitted, applicants should consider the other core facilities that are part of IRICoR's network, namely:

- [The biopharmacy platform of the Faculty of Pharmacy of the Université de Montréal \(UdeM\);](#)
- [The Goodman Cancer Research Centre \(GCRC\) - McGill University;](#)
- [The Research Institute of the McGill University Health Centre \(RI-MUHC\);](#)
- [The Pharmacology Institute of Sherbrooke \(IPS\);](#)
- [Le Centre de recherche du Centre hospitalier de l'Université de Montréal \(CRCHUM\);](#)
- [Le Centre hospitalier universitaire de Québec - Université Laval;](#)
- [Research Centre - Québec Heart and Lung Institute;](#)
- [The MILA-Institut québécois d'intelligence artificielle;](#)
- [The Lunenfeld-Tanenbaum Research Institute - Mount Sinai Hospital \(Toronto\).](#)

Additional references may be provided by IRICoR upon request.

NOTE: Please note that the core facilities' services facilitate and accelerate the development of small molecules or biotherapies. The expertise of a laboratory cannot therefore replace the services proposed by specialized drug discovery core facilities.

APPLICANTS' ELIGIBILITY

Conditions

The grantee (Principal Investigator) must be a University Investigator or a Clinical University Investigator from an institution, centre, research institute or department (hereinafter "Institution") affiliated to a Quebec-based university or to a Canada-based university.

In this Competition, postdoctoral trainees are not eligible as Principal Investigators.

The managing Institution will be the employing Institution of the funding recipient.

Research team structure

The research team must be comprised of one (1) Principal Investigator.

The Principal Investigator will represent the project, manage the application and the internal scientific direction of the project.

Along with the other members of their teams (Master's, doctoral and postdoctoral students, postdoctoral fellows, research or coordination associates, research technicians, research assistants), research teams are encouraged to include newly recruited Investigators (Junior 1), young experienced Investigators (Junior 2) or experienced Investigators (Senior).

According to the needs of the project, the Principal Investigator may complete his/her team by adding collaborators from across Canada or internationally. No minimum or maximum is required.

NOTE: If the Principal Investigator is affiliated to an Institution based in a Canadian province OUTSIDE Quebec, the Principal Investigator must then integrate a collaborator affiliated to a Quebec-based Institution.

The collaborator from Canada:

- Must be from an Institution affiliated either to a Quebec-based university or to a Canada-based university;
- Must be a Canadian university faculty member;
- Must contribute significantly or provide specific expertise to the research project related to the funding application;

	<ul style="list-style-type: none"> • May manage part of the funds eventually granted, following an agreement with the managing Institution. <p>The collaborator from outside Canada:</p> <ul style="list-style-type: none"> • Must be a university faculty member; • Must contribute significantly or provide specific expertise to the research project related to the funding application; • Will not receive funding from this grant Competition.
<p>Professional Order for Clinical University Researcher in Canada</p>	<p>Individuals with the status of Clinical University Researchers must prove that they are members in good standing of the professional order governing them in Canada, have a valid license to practice in Canada and have professional liability insurance.</p>
<p>Multiple applications</p>	<p>An Investigator:</p> <ul style="list-style-type: none"> • May only submit one project to this Competition as a Principal Investigator; and • May participate in a maximum of two (2) projects as a collaborator. <p>Therefore, an Investigator may participate in a maximum of three (3) projects in this Competition.</p>
<p>Research ethics codes and institutional policies</p>	<p>The Principal Investigator must have his/her project evaluated with respect to ethics and obtain the approvals of the research ethics committees concerned before the research involving the funded project can begin.</p> <p>It remains the responsibility of the Principal Investigator to obtain the certification required for the project and to provide it to the departments concerned in his/her Institution.</p> <p>It remains the responsibility of the Principal Investigator and collaborators to respect institutional rules and policies of their institutions.</p>

REQUIRED DOCUMENTS – NOTICE OF INTENT

IRICoR and the Quebec Breast Cancer Foundation handle the management of the Competition.

Please note that in cases where the application is drafted in French, IRICoR and Quebec Breast Cancer Foundation, may request that the applicant provide an English translation for evaluation purposes.

All correspondence with IRICoR or the Quebec Breast Cancer Foundation may be conducted in French or in English.

Transmission of documents:

All documents described below must be sent by e-mail to Audrey Segret, Project Manager at IRICoR (audrey.segret@umontreal.ca).

Missing documents or forms that do not comply with the Competition rules, within the deadlines indicated, will result in the file being ineligible and will be automatically rejected. No extensions will be permitted.

All documents must be integrated into a single (1) PDF document. The Principal Investigator **contributions**, should be part of the PDF document.

The date and time of the transmission of the e-mail is proof of the date and time of the documents' filing.

Principal Investigator

The Notice of Intent should be submitted by the Principal Investigator managing the project and must include:

- Notice of Intent form;
- Free format CV (last update between June, 2016 and the Competition deadline);
- Detailed contributions (last update between June, 2016 and the Competition deadline);
- Letter of support from the university technology transfer unit (or any other equivalent entity) to which the Principal Investigator is affiliated, indicating having been made aware of the project submission.

Only Investigators whose Notices of Intent were considered to be eligible will be invited to submit a Complete Application (see the "Evaluation" Section).

IRICoR will send an e-mail confirming the acceptance or rejection of the Notice of Intent to each applicant.

REQUIRED DOCUMENTS – COMPLETE APPLICATION

Transmission of documents:

All documents described below must be sent by e-mail to Audrey Segret, Project Manager at IRICoR (audrey.segret@umontreal.ca).

Missing documents or forms that do not comply with the Competition rules, within the deadlines indicated, will result in the file being ineligible and will be automatically rejected. No extensions will be permitted.

All documents must be integrated into a single (1) PDF document. The CV of all Investigators, **including detailed contributions**, should be inserted one after the other in the PDF document.

The date and time of the transmission of the e-mail is proof of the date and time of the documents' filing.

Principal Investigator	<p>The Complete Application must be submitted by the Principal Investigator of the managing Institution and must include:</p> <ul style="list-style-type: none"> • Complete Application form; • Free format CV (last update between June, 2016 and the Competition deadline); • Detailed contributions (last update between June, 2016 and the Competition deadline); • Letter of support from the administrators of the Institution or university department in which the Principal Investigator's research will be carried out, indicating the commitment towards the Principal Investigator and the project; • For clinicians: a letter from the administrators of the clinical department or the dean of the faculty specifying the number of hours for which the applicant will be released from his/her clinical obligations to carry out the research project; • A quote presenting the costs associated with the services to be provided by the drug discovery core facilities.
Collaborators	<ul style="list-style-type: none"> • Free format CV (last update between June, 2016 and the Competition deadline); • Detailed contributions (last update between June, 2016 and the Competition deadline); • Letter of support from the administrators of the Institution or university department in which the Collaborators research work will be carried out, if necessary; • For clinicians: a letter from the administrators of the clinical department or the dean of the faculty specifying the number of hours for which the applicant will be released from his/her clinical obligations to carry out the research project.

RESEARCH LOCATION

Choice of the Principal Investigator's research location	A public or parapublic sector institution, excluding private companies.
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Change of research location	<p>IRICoR and the Quebec Breast Cancer Foundation expect that the grantee will conduct his/her project at the same Institution or university that initially endorsed the application throughout the entire grant period.</p> <p>The grantees who wish to change their research location must submit an official letter of request by e-mail to IRICoR. The request must detail the reasons for the change and describe all possible consequences on his/her research project.</p> <p>University or institutional authorities must also approve the change by notifying IRICoR in writing.</p> <p>The administration of the new research centre must also notify IRICoR in writing that they accept to host the grantee and accept rules and terms of the LeadAction Breast Cancer du Sein Competition as well as the funding agreement signed by contracting parties.</p>
Choice of the collaborator's research location	<p>A public or parapublic sector institution, excluding private companies.</p>

TERM OF THE GRANT

Term	Three (3) years, non-renewable
Funding start date	October, 2019

AMOUNT OF THE GRANT

Amount	<p>The total budget for the Competition is \$3M (50% IRICoR – 50% Quebec Breast Cancer Foundation).</p> <p><u>Hit to lead transition and/or lead optimization activities will benefit from a maximum amount of \$250,000 per year within this Competition.</u></p> <p><u>Pre-clinical research activities will benefit from a maximum amount of \$500,000 per year within this Competition.</u></p> <p><u>NOTE: The maximum amount granted in this Competition is \$1,500,000 per project over 3 years.</u></p> <p><u>NOTE: The allocated funds must be spent in Canada. Moreover, for each funded project, 50% of the funds are to be spent in Quebec towards drug discovery activities.</u></p> <p>The managing Institution will handle the transfer of funds, if necessary.</p> <p>Co-funding from other partners is not mandatory.</p> <p>Payment for the second and third year of funding will only take place after evaluation and validation of the achieved deliverables by the LeadAction Breast Cancer du Sein Review Committee (see the “Evaluation” Section for more details).</p>
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	It should be noted that when this Competition’s project funding comes to an end, IRICoR may continue to invest in selected projects based on their progression and achieved deliverables.
Indirect research costs	The amounts granted within this Competition do not cover the Institutions’ indirect research costs.

ELIGIBLE EXPENDITURES

Eligible expenditures for the Competition	<ul style="list-style-type: none"> • Scholarships, scholarship supplements and salary support (where applicable) to undergraduate, Master’s, and doctoral students, and postdoctoral fellows; • Salaries and social benefits of research or coordination associates, research technicians or research assistants; • Research material (including the purchase and housing of animals) and all other expenses required to carry out the research project, conditional upon adequate justification in the application; • Costs related to the use of drug discovery core facilities (academic or private setting in Canada). • Travel and accommodation costs within the framework of the funded project (up to 1% of the total budget); • Costs related to the acquisition of biological material from biobanks (up to 1% of the total budget); • Expenses related to the protection of intellectual property (patent filing and prosecution costs, license fees or patent agent fees).
Non-eligible expenditures for the Competition	<ul style="list-style-type: none"> • Remuneration of the Principal Investigators and collaborators; • Purchase of equipment, costs of leasing (or purchasing) facilities; • Participation in conferences and conventions; • Costs related to organizing knowledge mobilization activities; • Research activities that have already been the subject of funding will not be funded if an award has been previously granted.

EVALUATION

Notice of Intent	<p>The Notice of Intent will be used to determine the Principal Investigators’ eligibility. It will also allow the Promoters of the Competition to evaluate the administrative and scientific eligibility of the grant application in view of the Competition’s objectives.</p> <p>The Notice of Intent will enable the Promoters to select the LeadAction Breast Cancer du Sein Review Committee Members</p>
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	<p>(see below for details). The Chair of the LeadAction Breast Cancer du Sein Review Committee will validate the eligibility of the reviewers selected.</p> <p>Only applicants whose Notices of Intent are deemed eligible will be invited, by e-mail from IRICoR, to submit a Complete Application.</p>
Complete Application	<p>The Principal Investigator for the grant application, as well as the managing Institution, must remain the same as those included in the Notice of Intent.</p> <p>The modification or addition of collaborators is permitted.</p>
LeadAction Breast Cancer du Sein Review Committee	<p>The Complete Applications will be evaluated by the LeadAction Breast Cancer du Sein Review Committee (hereinafter the “Committee”) in plenary session.</p> <p>The Committee will comprise both scientific and industry independent experts from the breast cancer field.</p> <p>The scientific experts sitting on the Committee will come from Canadian and international academic and clinical settings.</p> <p>Expert members from industry will come from Canada and international and from the following fields: finance, biopharmaceutical industry, business development and entrepreneurship.</p> <p>The selection of all Committee members will be made in compliance with IRICoR’s conflict of interest policies and guidelines.</p> <p>All projects evaluated by the Committee will be processed with complete confidentiality, in compliance with the policies of IRICoR and the Quebec Breast Cancer Foundation.</p> <p>At the end of the first and second years of investment, the selected projects will be evaluated by Committee members.</p>
Evaluation criteria of the Complete Application	<p>Complete Applications will be evaluated according to well-defined criteria as follows:</p> <ul style="list-style-type: none"> • Project positioning and scientific excellence: <ul style="list-style-type: none"> ○ Context, preliminary results and relevance of the problem; ○ Clarity of scientific objectives; ○ Innovative character; ○ Development stage of the project to be funded; ○ Extent of link between target and the clinical application sought. • Scientific and technical feasibility: <ul style="list-style-type: none"> ○ Quality of the applied research methodology; ○ Relevance of the technological core facilities used in the project; ○ Identification of risks and mitigation plan; ○ Expected milestones/deliverables: specific,

measurable, realistic, and timely.

- **Experience and expertise of the research team:**
 - Achievements and scientific level of the research team (outreach at the Canadian and/or international level, etc.);
 - Involvement of early career Investigators (Junior 1 and Junior 2) (an asset).
- **Commercial potential:**
 - Ability to respond to an unmet medical need;
 - Business opportunity/market size;
 - Discussions already underway with potential private partners.
- **Competitive environment and intellectual property:**
 - Competitive advantage (direct and indirect) of the project;
 - Status of the intellectual property, if already generated;
 - Potential for creating new intellectual property.
- **Detailed budget:**
 - Adequate budget justification in line with the proposed project;
 - Financial leverage (if applicable).

It should be noted that Investigators will be assisted by the Promoters in order to properly align the project and its commercial potential with the objectives of the Competition.

MANAGEMENT OF THE AWARD AND KNOWLEDGE MOBILIZATION

Conditions for releasing the allocated funds

If a positive funding decision is made, the Principal Investigator will receive an award letter, with a copy to the managing Institution's Research Bureau, on behalf of IRICoR and the Quebec Breast Cancer Foundation. The award letter will present the specific conditions of the award as well as the project plan, as approved/modified by the Committee. The Principal Investigator will then have no more than two (2) weeks to accept or reject the grant under the conditions set forth.

A funding agreement, between IRICoR, the Quebec Breast Cancer Foundation, the Institution of the Competition grantee and affiliated institutions of the collaborators, must also be signed before the funds are released.

If the conditions for releasing the funds allocated are not met (acceptance of the award by the Investigator and signing of the funding agreement) within three (3) months, IRICoR and the Quebec Breast Cancer Foundation reserve the right to cancel the award granted.

The releasing of the allocated funds during the two years of Competition funding is conditional on the submission of the required reports in this Competition (See the section Management of the award by Promoters and reporting).

<p>Management of the award by Promoters and reporting</p>	<p>As soon as the funds are released, an official project launch meeting will be set up between the research team and IRICoR.</p> <p>Project follow-up will be ensured through meetings between IRICoR and the research team every four (4) months throughout the period of the award.</p> <p>Annual scientific and financial progress reports must be completed within the agreed timelines.</p> <p>After the 1st year of funding, if the project has not achieved the milestones expected, in keeping with the recommendations of the Committee, IRICoR and the Quebec Breast Cancer Foundation reserve the right, within one (1) month of receiving the report, to reduce or to terminate the funding granted for the 2nd year of the project.</p> <p>After the 2nd year of funding, if the project has not achieved the milestones expected, in keeping with the recommendations of the Committee, IRICoR and the Quebec Breast Cancer Foundation reserve the right, within one (1) month of receiving the report, to reduce or to terminate the funding granted for the 3rd year of the project.</p> <p>Following approval of the reports by the Committee, 85% of the funds allocated for the 3rd year of funding by IRICoR and the Quebec Breast Cancer Foundation will be paid.</p> <p>When accepting the grant, the Investigator agrees to provide, not more than three (3) months after the end of the grant, namely at the end of the three (3) years of allocated funds, a final scientific report and a final financial report. If those two reports have not been received, IRICoR and the Quebec Breast Cancer Foundation reserve the right to withhold the final payment (the remaining 15% of the allocated funds).</p> <p>Please note that Investigators who have been awarded funding may benefit from IRICoR's established expertise in milestone-based project management and strategic oversight of intellectual property throughout the course of the project.</p>
<p>Intellectual property (IP) and sharing of commercialization revenues</p>	<p>There is no obligation to hold patents or patent applications to file an application for this Competition.</p> <p>The Background IP (BIP), including all know-how developed by an Institution and required for the successful execution of the project, will remain property of the Institution. IRICoR and all project participants (research teams and their Institutions of affiliation) will need to have access to that BIP for the sole purpose of the project's development.</p> <p>As for the IP generated during the course of the project (Foreground IP (FIP)), the IP generated by the Institution where the Investigator(s) work(s) will be the property of that Institution and will be governed by the IP policy that prevails in that Institution. IP generated by multiple Institutions will be considered as joint IP in proportion to the inventive contribution of each Institution.</p>

	<p>Funding agreements between IRICoR and the Institutions involved will integrate each Institution’s IP policy and practices and will mandate IRICoR as a commercialization agent in collaboration with the technology transfer unit (or any other equivalent entity) recognized by the Institution.</p> <p>Projects having reached their milestones will benefit from access to IRICoR’s business network, thus facilitating their commercialization.</p> <p>Terms of potential revenue sharing between the Institutions involved, IRICoR and the Quebec Breast Cancer Foundation, will be negotiated on a case-by-case basis according to the projects funded and will comply with the relevant regulations of the CECR Program Guide governing IRICoR funds and with the intellectual property policies of the Quebec Breast Cancer Foundation.</p>
<p>Publications by the Investigators</p>	<p>The grantees agree to thank/recognize the contribution of IRICoR and the Quebec Breast Cancer Foundation in every scientific or electronic publication that will present the outputs obtained through work subsidized by IRICoR and the Quebec Breast Cancer Foundation.</p> <p>The grantees agree to inform IRICoR and the Quebec Breast Cancer Foundation of all scientific or electronic publications.</p>
<p>Dissemination and use of the results by the Competition Promoters</p>	<p>The grantees agree to authorize the Promoters to use reports and research outputs that have been disseminated to the public by the Investigator (as part of a scientific or electronic publication, conference, symposium or other), notably for reproduction, translation, execution or public communication purposes through any means, as well as any other form of use, provided there is no infringement of copyright law and solely for non-commercial purposes.</p>
<p>Knowledge mobilization by Investigators</p>	<p>The Promoters encourage grantees to participate in knowledge mobilization activities (transfer, sharing, development, promotion and dissemination) within the practice settings and the general public, whenever such activities are relevant.</p>

APPLICANT’S AGREEMENT

In submitting his/her application, **the Investigator** must, among other things:

- Comply with regulations governing IRICoR’s activities, as outlined in the CECR Program Guide;
- Comply with the regulations of the Quebec Breast Cancer Foundation;
- Comply with all of the conditions and requirements outlined in the Competition rules and forms;
- Submit certain additional documents related to the use of the grant, if requested by IRICoR or the Quebec Breast Cancer Foundation;
- Obtain the certification required for the project and provide it to the departments concerned in his/her Institution before beginning the project;

- Authorize IRICoR and the Quebec Breast Cancer Foundation to retain and use all personal and scientific information contained in the file, provided that individuals who are granted access to personal information respect its confidentiality.

RESEARCH INSTITUTIONS' AGREEMENT

The institutions hosting the Principal Investigator and the collaborators are required to provide the basic equipment, research facilities and administrative services required to carry out the research project.

TIMETABLE FOR THE EVALUATION PROCESS

Steps	Period	Dates
Competition launch	N/A	February 4, 2019
Deadline for submitting a Notice of Intent	6 weeks	March 18, 2019
Invitation to submit a Complete Application	4 weeks	April 17, 2019
Deadline for submitting a Complete Application	9 weeks	June 20, 2019
Evaluation by the Committee		September, 2019
Announcement of results		October, 2019