COVID-19 Response Project Guide V1.1

OVERVIEW

NGen is working with the Government of Canada to respond quickly to the COVID-19 pandemic and ensure the ongoing safety of Canadians.

We are allocating funding to those companies able to rapidly respond to the COVID-19 pandemic by building a Canadian supply of essential equipment, products, and therapeutics**.**

Projects will be selected for funding according to critical needs identified by the Government of Canada and the ability of manufacturers to produce products that are safe for both patients and health care workers.

NGen will prioritize funding for projects that can have an immediate impact between April and the end of June 2020 and will fund eligible costs for projects within this timeframe up to 100% (depending on the level of knowledge and information sharing to help Canadians).

Projects that will have an impact in the medium term – beyond the June 30 timeframe may also be considered for funding at 50%.

Projects are not expected to exceed funding of more than $5m.

We are encouraged by the volume of support and outreach that we have already received to address the COVID-19 outbreak.

It is imperative that Canada takes a coordinated approach to meet this challenge head-on. Please complete this form at https://www.ngen.ca/covid-19-response if you are able to assist with the response.

NGen will align its response and project selection with critical needs as identified by the Government of Canada and work to coordinate funding with other federal and provincial funding programs.

Who is Eligible to Apply?

Any member of the Advanced Manufacturing Supercluster may submit an application for project funding or apply to be considered as a partner or co-investor in Supercluster projects.

Register as a Supercluster member at https://www.ngen.ca/join

Recipients of Supercluster funding must be incorporated in Canada.

PROGRAM GOALS

NGen funding for approved projects will be made available through the Government of Canada's Innovation Supercluster Initiative.

The program will support Canadian companies to rapidly respond to the COVID-19 pandemic.

The program has three primary goals:

1) To support companies looking to develop and manufacture new therapeutics, equipment and products essential for COVID-19 response;

2) To support manufacturers who currently produce essential equipment and products increase product output; and,

3) To support manufacturers transitioning from production of existing products to products essential for COVID-19 response.

Critical product requirements will be identified by the Government of Canada. Current needs include:

- Virus screening tests
- Vaccines
- Antiviral and symptom management treatments (once available)
- Personal Protective Equipment, including gloves, gowns, and protective masks
- Hospital Equipment (e.g. ventilators, IV equipment, hospital beds and ICU equipment, equipment for remote facilities)
- Cleaning and Sterilization chemicals and equipment.

BASIC PROJECT REQUIREMENTS

Projects selected for funding will need to align with priorities defined by the Government of Canada.

Companies should commit to at least one of the following:
- Canadian government procurement has first right of refusal on all products produced as a result of this funding program. Companies must prioritize sales to Canadian hospitals and meet those needs before sales outside of Canada can commence
- Companies should be willing to licence and/or share new IP for rapid scaleup of production with the Government of Canada and other companies that can manufacture the new technology.

Eligible project costs are defined here: https://www.ngen.ca/covidprojectguide

Capital expenditures exceeding $1 million are eligible but require approval by Innovation, Science, and Economic Development Canada. An expedited approval process has been established with ISED.

No project management fees will be charged on NGen's COVID-19 projects.

It is expected that collaboration will be required to achieve expected project goals. However, in exceptional circumstances, NGen may fund individual company initiatives.

Project proposals should specify the transformative nature of their initiative with respect to either the development of new technologies and manufacturing processes or the ability to rapidly increase existing capacity.

NGen funding is limited. We will look to enhance funding for promising projects and full production scale up by leveraging other government funding sources.

APPLYING FOR PROJECT FUNDING

NGen has created a new process to manage and assess COVID-19 projects. This process has been designed to respond rapidly to the pandemic, but still meet key governance requirements established by the Government of Canada, including independent and evidence-based selection of projects that NGen will fund.

A dedicated portal is currently being designed and built to reflect this new process and will be launched shortly.

In the interim, NGen will work with project proponents through a secure site to develop the proposals.

PROJECT SELECTION AND CONTRACTING

- Send expressions of interest to www.ngen.ca/covid-19-response or apply on NGen's COVID-19 project portal (once operational).
- NGen will conduct a review using independent experts.
- NGen may convene an Assessment Panel to discuss projects with applicants.
- Assessment panels will recommend projects to fund.
- NGen will notify applicants of assessment outcomes.
- If approved for funding, NGen will issue a Master Project Agreement (MPA) setting out the terms and conditions linked to the funding.
- The project applicant will submit final project documents along with signed MPA.

To satisfy these requirements, project applicants must answer six questions that will inform the assessment process.

To the best of your ability, please fully address all guidance provided for each question.

Please include any other pertinent information not covered in this guidance.

This guidance is intended to be answered by all applicants and not just the lead partner, so that the impact and anticipated benefits that will accrue are well defined.

1. What COVID-19 product shortage or challenge does your project address?

Response guidance:

- Outline the objectives of the project, including the product shortage or new technology opportunity it is intended to address.
- Describe the current and expected nature of the market for the product your project is intended to address.
- Clearly define the business and or technology challenge.
- Outline the expected outcomes, timeframe, and cost for your project.

2. What is the transformational nature of the project?

Response guidance:

- Provide evidence of the technical feasibility of the technology, product or production process.
- Specify the degree of additional production capacity that will be achieved.
- Indicate how the additional capacity would be utilized after the immediate project need is fulfilled.
- Indicate any long-term benefits for Canadian manufacturers or the Canadian economy expected as a result of the additional capacity / capability that would be created through the project.
- Will the additional capacity be utilized after the immediate project need is fulfilled?
- Indicate whether the project would provide an enabling platform for further technology development in Canadian manufacturing.

3. How will Canadians benefit from the project, and over what timescale?

Response guidance:

- Describe any health care or social or humanitarian benefits as a result of this project, both inside and outside of Canada.
- Describe any longer-term benefits the project would provide Canada beyond the COVID-19 crisis.
- Will the project lead to technological and business advantages that will significantly benefits Canadians?
- Will this additional capacity / capability enable you to make a lasting and positive impact for the Canadian manufacturing economy?
- Indicate whether the project would create spin-off business opportunities (new businesses, new or expanded supplier or partner relationships) in Canada.
- Describe what sort of economic benefits that the project might deliver in terms of employment, investment, or new product mandates in Canada.
- Provide as much information as possible to allow the assessors to better understand the short- and long-term impacts that this project might have.

4. How will the results of your project be achieved?

Response guidance:

- Describe the activities that will be undertaken to ensure the stated objectives will be achieved.
- Identify partners that will be involved in the project, if any.
- Provide assurance that the product and manufacturing process can meet applicable standards and regulatory approvals.
- Outline a plan that demonstrates the ability of the project team to achieve the project outcomes within the stated timeline. Consider:
    - » the route to market, intellectual property, changes to business models or processes.
    - » measures for protection, commercialization and dissemination of the project outcomes.
    - » types of exploitation, such as licence to manufacture, manufacturing or direct sales.
- Details of planned follow-on spend if required to achieve the result.
- Describe how you will structure distribution and pricing for the products you will produce.
- Provide a plan for meeting Canadian procurement requirements for critical products related to COVID-19 response. What procurement actions with organizations or the government have been taken into consideration. What additional mechanisms would be necessary for the project to succeed?
- Demonstrate a clear understanding of the regulatory framework for the product or process and demonstrate that regulatory steps are integrated in the project plan.

- Describe the immediate needs of Canadians, that will be served by this project.
- Identify your materials and components requirements and present a plan for sourcing them over the duration of your project.
- Provide validation and evidence as much as possible for your statements.

5. What is your overall project and risk management plan?

Response guidance:

- Provide your overall project plan, including work-package descriptions and sub-tasks, and identify the key milestones and deliverables that show how the overall project will be achieved.
- Each work package should include: Description of activities, objectives and areas of work; a list of partner(s) involved if applicable; technical approach and methodologies; and key dependencies for each work-package. Where there are interdependencies between work-packages please highlight these and include in the risk management plan where appropriate.
- Describe the technical approach, project management tools, explain how and why it is appropriate for the project, how the steps in the project will be achieved, and how you will measure success.
- Describe the resource requirements for successful project completion, including how work will be shared among project participants and partners.
- Provide a risk analysis. Identify any obstacles that you foresee standing in the way of successful project completion.
- Identify key risks within the project. Consider at least the technical, regulatory, commercial, managerial and financial risks that could appear in the project and provide appropriate analysis of the likelihood and impact of each of the risks along with appropriate risk management strategies, such as mitigations.

6. Does the project team have the right skills and experience and access to facilities to deliver expected outcomes and benefits?

Response guidance:

Consider and address:

- Describe how the project has the right mix of partners and skills to deliver the project requirements successfully? Do you have the right skills for product development and appropriate manufacturing capabilities?
- Describe the testing and facility requirements in order to achieve the stated outcomes, including the suitability of the facilities and any modifications that are required.
- Describe the track record of the project team members to show your capability to develop and execute on the proposed project.

- Are the objectives and role of each participant clearly defined among members of the project team?

- Are there gaps in the expertise required to complete the project? If so, what are those gaps and how will they be addressed?

DOCUMENTS REQUIRED FOR ASSESSMENT

Templates for the assessment will be made available for download at:
https://www.ngen.ca/covidprojectguide

- Project Management Plan
- Risk Register
- Financial Workbook template in Excel
- Financial Summary template
- Application Agreement template in PDF

UPON AGREEMENT

Upon the final recommendation of an independent assessment, NGen will conclude a Master Project Agreement (MPA) with selected funding recipients detailing project requirements, reporting, and NGen's compliance obligations.