Evaluation of the National Research Council of Canada's implementation of the Biologics Manufacturing Centre program

March 2024

NRC Evaluation

About the BMC

The Biologics Manufacturing Centre (BMC) is an end-to-end biomanufacturing facility, supporting the growth of domestic biomanufacturing production capacity for the future. It ensures that vaccines and other biologics can be safely manufactured in Canada. The BMC is an important part of Canada's biomanufacturing infrastructure and a key element of the Government of Canada's Biomanufacturing and Life Sciences Strategy.

Conceived of and built during the COVID-19 pandemic, the business and governance model for the BMC was novel. The National Research Council of Canada (NRC) initially established and operated the BMC with the objective of forming an arms-length not-for-profit organization through a public—private partnership.

After the not-for-profit's establishment, the NRC transitioned operations to the BMC, while retaining ownership of the facility and equipment, and lease holding and funding responsibilities. The NRC participates in BMC oversight and governance, including serving as an observer on the BMC Board of Directors.

Key findings

Transition from the NRC to the BMC

The transition of BMC operations from the NRC to the BMC was marked by tight timeframes, novel approaches and high complexity. The emergency context surrounding the establishment and transition of the BMC to the not-for-profit partner was complex and extraordinary efforts were made to meet very short timelines.

Many strengths were identified and valuable lessons were captured in a formal lessons-learned report. Notable strengths included leadership, collaboration, a structured transition framework, and strategic approaches to efficiently transfer information technology and human resources to the BMC.



Resources (March 31, 2023)

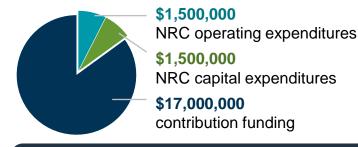
BMC operational staff: 98



Equity, diversity and inclusion

Representation of women at the BMC: 40%

Figure 1. Annual funding for the BMC



Operational funding supports the BMC in complying with its public-good mandate:

- respond to pandemic and other health emergencies
- support the development and growth of the domestic biomanufacturing capacity
- · undertake public interest projects
- complement the private sector
- create and share knowledge on good manufacturing practices

Change management was effective for the transition of personnel from the NRC to the BMC. In parallel, the NRC needed to establish an oversight function post-transition, which involved organizing an NRC secretariat for the BMC program, along with the Facilitation Committee and Site Coordination Board.

An internal working group was established in February 2023 to address NRC roles and responsibilities, transfer knowledge and develop and implement an oversight approach. During this early implementation phase, issues and risks should guide the development of appropriate steady-state oversight arrangements, prioritizing effectiveness and efficiency.



Stewardship

The accountabilities and governance for BMC operations and oversight are new and evolving. The NRC's role includes oversight as a lessor and a funder to BMC. Governance structures are in place; however, their focus is currently oriented towards issues identification and management.

As the business model and relationships mature, these bodies are well-placed for ongoing stewardship and proactive risk and results oversight. In support of this, clear authorities and an adequately resourced organizational structure should be monitored for any potential adjustments needed.

Risk management mechanisms that help to monitor both financial and operational risk will be required to assess results, risk and sustainability of the model over time.

Key stewardship mechanisms



Vision and roles

What oversight is required by the NRC and why?

NRC governance

Through what committees and supporting processes does the NRC exercise its duties relative to the BMC?

NRC responsibilities, accountabilities and authorities

Who is accountable for the BMC program and how do all accountabilities work together to ensure those charged with governance can discharge their duties?

Areas for consideration

- 1. Clarifying and documenting accountabilities for the BMC program and related oversight activities for all levels, to ensure that the NRC's overall accountability for the program is understood.
- 2. Establishing formal but efficient internal processes and information flows for monitoring the BMC's compliance, operational and financial risks to the NRC, as well as achievement of the NRC's objectives and vision.
- 3. Mandating the Site Coordination Board and the Facilitation Committee with the proactive oversight of risks, results and emerging issues, ensuring they regularly receive and review the output of the NRC's monitoring activities described in consideration 2.

About the evaluation

A detailed planning phase was conducted before the evaluation began. The scope of the evaluation was determined in consultation with management, aiming to provide value to the BMC program and offer insights for similar future endeavours.

The evaluation focused solely on the NRC's activities related to the BMC program and did not evaluate the BMC. Specifically, the scope of the evaluation included the transition from the NRC to the BMC, and the NRC's steady state stewardship and oversight arrangements.

The evaluation focused on activities up to July 31, 2023, and did not examine BMC activities that began after this date. Project management and facility construction were not examined as part of this evaluation.

Visit the evaluation page on the NRC's website to access the complete evaluation report.