Written Submission for the Pre-Budget Consultations in Advance of the Upcoming Federal Budget

By: Canexia Health

Recommendation 1: That the government create a nationwide funding program that delivers accessible and minimally invasive cancer testing to 80,000 Canadian patients over the next two years to help offset the burden on the healthcare system during the COVID-19 pandemic.

Recommendation 2: That the government earmark $60M to accelerate “Made in Canada” cancer testing innovation while creating high-knowledge jobs in this economically resilient sector.

Recommendation 3: That the government establish sustainable Canadian cancer testing and data infrastructure responsive to the needs of tens of thousands of cancer patients and thousands of researchers each year regardless of future pandemics.

About Canexia Health

Founded and headquartered in Vancouver, BC, Canexia Health offers cost-effective and clinically actionable tests to guide the diagnosis and treatment of cancer. Our vision is to make cancer testing accessible to all Canadian cancer patients via minimally invasive tests that can be run locally in urban and rural settings. We are led by a Canadian team of experts in the fields of cancer genomics, molecular diagnostics, and bioinformatics.

The Issue

COVID-19 has delayed at least 100,000 surgeries in Canada. In some areas, as much as 30% of these delays are cancer surgeries including tumour biopsies. A recent analysis found it will take up to a year to clear the current backlog of surgeries in Ontario and up to two years in British Columbia. These estimates do not include a second wave of the pandemic which could create further postponements.

Researchers from University College London quantified the potential impact to many forms of cancer treatment, including diagnostic tests and operations, as well as patients not wanting to risk going into hospital. They warn almost 18,000 *more* people with cancer in England could die as a result of the pandemic and believe countries need to rapidly understand how the emergency is affecting cancer outcomes – or risk adding cancer and other underlying health conditions to the death toll of COVID-19.

Delayed diagnosis and treatment have created a crisis for thousands of cancer patients across Canada. Cancer patients do not have time on their side, and their disease will continue to progress. Further, given their compromised immune systems, cancer patients have an estimated two-fold increased risk of contracting COVID-19 and a three-fold risk of dying compared to the general population.

A comprehensive and sustainable approach is required to address the needs of this high-risk group to mitigate their exposure, ensure uninterrupted care, and create long-term resilience within the Canadian health system.

Recommendation 1:

Government of Canada statistics describe how the burden of cancer in Canada continues to rise:

- Cancer is the leading cause of death in Canada;
- Nearly 1 in 2 Canadians will be diagnosed in their lifetime; and,
- Each year more than 200,000 Canadians will be diagnosed and 80,000 will die from the disease.

For thousands of cancer patients each year, a minimally-invasive blood draw can be performed instead of surgical tissue biopsy to enable oncologists to select treatment options as well as to monitor disease progression. Prior to COVID-19, health systems across the globe were already

adopting this innovative blood testing – known as circulating tumour DNA (ctDNA) testing – as an alternative to surgical tissue biopsy for certain cancers, including breast, lung, and colorectal cancers. COVID-19 has made it clear ctDNA testing should be a first-line alternative to surgical procedures whenever medically indicated.

In May 2020, the Digital Technology Supercluster approved a project to support a consortium of Canadian organizations led by Canexia Health to deploy and enhance its minimally-invasive ctDNA test. **In the short-term, the project is testing 2,000 patients, which will generate initial health economics data to accelerate provincial health coverage of ctDNA testing for cancer treatment selection, with the aim of making this life-saving technology available to all Canadians even after the COVID-19 pandemic recedes.**

Remote delivery of testing will extend access to Canadians living in rural areas. The project also includes technology enhancements that will expand test capabilities for a broader range of cancer types. Up to 70,000 Canadian cancer patients could benefit from this solution each year with enhancements made during the project timeframe.

Our recommendation to expand the initiative outlined above and deploy ctDNA testing for 80,000 Canadian cancer patients over the next two years will:

- Enable access for more Canadian cancer patients to critical treatment options during and after COVID-19;
- Offload health system backlogs of tissue biopsy surgeries and keep high-risk cancer patients out of hospitals (tests can instead be performed in a community lab [e.g. LifeLabs]);
- Accelerate health economic studies of ctDNA testing in Canada, further making the case of provincial health coverage for treatment selection and monitoring; and,
- Generate a rich data set for Canadian researchers to better understand cancer progression and resistance to treatment, thus spurring additional Canadian innovation.

To further quantify the potential benefits, in 2019, almost 83,000 Canadians were newly diagnosed with the three most prevalent forms of cancer: lung, breast and colorectal. Genetic biomarkers found in these three cancer types respond to proven options for approved targeted therapies. These therapies are known to improve patient outcomes by two- to threefold. Yet, it is estimated less than 10% of cancer patients in Canada are tested for actionable biomarkers.

Significant variability exists amongst Canadian provinces for access to and coverage of recommended biomarker testing. Yet ctDNA testing has been shown to be reliable in the detection of disease recurrence and resistance mutations as evidenced by reimbursement of such testing in the US for certain cancers. If an actionable cancer mutation is discovered by a ctDNA test, an oncologist can immediately recommend a targeted therapy. If no actionable mutation is found, the patient's oncologist can *then* determine if a tissue biopsy or chemotherapy is required.

Ultimately, testing 80,000 cancer patients as part of a Canada-wide funding initiative will advance adoption of two critical innovations: 1) use of ctDNA for treatment selection to bring Canada to parity with other countries, and 2) use of ctDNA for monitoring resistance and recurrence, enabling Canada to leapfrog other nations into a leadership position in cancer care.

Recommendation 2:

By understanding DNA mutations driving the growth of any given tumour, we can provide cancer treatment that specifically targets these changes and ultimately improve individual patient outcomes. Because ctDNA testing requires only a simple blood draw, it is an easily accessible method for such cancer treatment selection and monitoring. Longer term, ctDNA testing also has the potential for early cancer detection.

To illustrate, if a genetic biomarker is identified in the patient's cancer, then the patient may be treated with a targeted therapy that is associated with the identified biomarker. Cancer patients that receive targeted therapies have better outcomes than patients treated with chemotherapy. For a patient diagnosed with cancer who has already been placed on a treatment regimen, by monitoring the disease in real-time, an oncologist will be able to observe the effectiveness of the treatment and/or the relapse of the disease. An oncologist may be able to adjust the treatment earlier leading to better outcomes.

The ctDNA test offered by Canexia Health, through a growing network of Canadian partners, is currently the only commercially available ctDNA test developed in Canada that detects close to 90% of actionable mutations in cancer tissue. Every year new targeted therapies are approved by the FDA and Health Canada for genes and mutation classes, such as Piqray (approved in March 2020), which is administered to breast cancer patients with PIK3CA mutations. **Research and development are required to create a more comprehensive Canadian ctDNA test, which will be enable recommends to targeted therapies for a broader population of cancer patients. An earmark of $60M will enable such R&D activity by Canexia Health and a consortium of Canadian companies and organizations.**

Further, unlike non-Canadian offerings, Canexia Health's technology provides a complete solution (including implementation and support) for a local laboratory to set up biomarker testing in-house quickly and effectively. Setting-up complex biomarker testing using next-generation sequencing technology is challenging and requires expertise in molecular biology, clinical genomics, IT, and bioinformatics, which is the primary reason local hospitals and cancer centres do not bring testing in-house.

Research and development activity proposed herein will address these challenges and spur the Canadian economy, preparing Canadians with transferable skills in genomics, bioinformatics, and diagnostic testing for high-knowledge jobs in a resilient sector while creating a ctDNA test that is attractive for health systems globally. This will help Canada leapfrog other countries in the development of a precision oncology ecosystem necessary to improve patient outcomes and solidify the country's position as a global leader in this innovative field.

Recommendation 3:

ctDNA testing has the potential to provide long-term benefits to Canada's public health system by providing an accessible and cost-effective option to match cancer patients with treatment and to monitor the progression of their disease. It is more cost-effective for public payers; and by using a *technology transfer* model, it becomes feasible for provincial labs to adopt the technology while retaining full control of the testing process in Canada including staffing, quality control and reporting.

Currently, ctDNA test samples are routinely sent to US companies, which is neither cost-effective nor efficient and presents delays and risks to Canadian patients during COVID-19 and future crises. **Instead, establishing a comprehensive Canadian cancer testing infrastructure will enable Canadian hospitals and laboratories to run ctDNA testing in-house, which will bring greater resilience to the Canadian health system.**

Performing genomic testing in-house provides faster turnaround time and greater control than sending samples to a third-party. Samples shipped outside Canada today take over two weeks to return results. The current framework exports Canadian patients' genetic tests to companies outside of Canada and has a negative economic impact on the Canadian healthcare system. The latest data indicates this "exportation framework" cost the Ontario government $34 million and the Quebec government $21 million alone, which does not include the additional effects of lost jobs across the country. This ultimately impacts the opportunity to attract critical investments for creating and strengthening innovative health technologies and supporting infrastructure in Canada's life sciences industry.

Additional benefits to establishing a Canadian cancer testing and data infrastructure include:

- Significant cost savings based on average tissue and blood biopsy costs of $1,000 - $14,000 depending on cancer type versus Canexia Health's ctDNA test cost, which is between $300 - $900;
- Keeping testing and patient data in Canada and localized by province;
- Improved outcomes because test results are not subject to delays; and,
- An up-to-date research data set to accelerate new discoveries and advance innovative health technologies in the life sciences sector.

These efforts will also help recruit more clinical trials to Canada because there will be an existing national testing and data infrastructure that will help pharmaceutical companies stratify cancer populations for their clinical trials, thus increasing the percentage of eligible cancer patients. **Today, less than 5% of eligible cancer patients are engaged in a clinical trial in Canada.**

There is a significant opportunity to establish a responsive and sustainable Canadian cancer testing infrastructure that will enable oncologists to deliver the right treatment to cancer patients during and after this unprecedented time. The general trend for hospitals and cancer centres to bring genomic testing in-house will be a central pillar to their precision medicine initiatives.

Conclusion

As the federal government works with stakeholders to restart the Canadian economy as it recovers from COVID-19, Canadians need to know they will be supported as they deal with the long-term health and socio-economic impacts of physical and social isolation. It is critical that cancer patients have access to affordable and remote testing to protect their health over the long-term. We would like to work with the federal government to offset additional burdens on the healthcare system by ensuring vulnerable Canadians have access to life-saving technology during this unprecedented time.