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*Disruptive Diagnostics*

# Dnamx

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## Executive Summary

The CfMeDIP-seq platform enables non-invasive, early, accurate and cost-effective screening of circulating tumor-derived DNA (ctDNA).

## Team

Dr. Daniel De Carvalho, a Senior Scientist at Princess Margaret Cancer Centre, University Health Network (UHN), and Canada Research Chair in Cancer Epigenetics, is an internationally-recognized expert in cancer epigenetics. Dr. Scott Bratman, a Clinician-Scientist also at Princess Margaret Cancer Centre, UHN, is a successful entrepreneur who co-invented personalized cancer profiling through deep sequencing (CAPP-Seq), a liquid biopsy technology, developed at Stanford University and licensed to Roche.

## Market

The global liquid biopsy market in 2016 is projected to be valued at USD\$580M and is expected to grow at a compound annual growth rate (CAGR) of 23.4% to reach USD\$2,047.9M by 2022. Increasing prevalence of cancer (number of new cases expected to rise by about 70% over the next 2 decades) and increasing clinical preference for non-invasive procedures are key factors driving the growth of the liquid biopsy market.

## Clinical Need

Compared to conventional biopsies, liquid biopsies are desirable because they are non-invasive, enable repeated access, and provide a convenient window into the tumor DNA and its genetic and epigenetic features. Circulating tumor-derived DNA (ctDNA) is shed from tumor cells that undergo cell death. Detection of ctDNA is relevant in this setting as cancer is a disease of genomic alterations. As it directly assesses this circulating tumor DNA, liquid biopsy approaches provide higher specificity alongside the additional advantage of enabling personalised tumor biology information. Moreover, ctDNA detection is both convenient and non-invasive, providing higher compliance and screening accessibility, while improving cost-efficiency.

## Product

The *cell-free Methylated DNA Immunoprecipitation and high-throughput sequencing* (cfMeDIP-seq) platform performs genome-wide DNA methylation mapping using cfDNA. CfMeDIP-seq is able to detect and classify both cancer types as well as sub-types. When applied to a panel of 189 plasma samples from patients with seven cancer types (including early stage lung cancer) and healthy controls, cfMeDIP-seq correctly classified 171 out of 189 plasma samples based on cross-validation. Moreover, in early stage pancreatic cancer patients (n=200) versus healthy donors (n=200), cfMeDIP-seq detected cancer with 0.94 specificity and 0.82 sensitivity in a blinded test.

## Competitive Environment

A major drawback to the current use of liquid biopsy for cancer screening is the lack of sensitivity in detecting ctDNA within the background of mostly non-tumor-derived cfDNA. Current estimates suggest that a ctDNA test, to be useful for early detection, needs to be able to detect ctDNA at a frequency below 0.01% of the total cfDNA. Existing commercial liquid biopsy approaches that rely on detecting mutations fail to reach this detection threshold for most patients and have therefore not yet shown capacity to enable cancer screening. CfMeDIP-seq, however, has successfully been able to reach this detection threshold of 0.01%.

Another challenge with existing liquid biopsy approaches is that they lack the specificity to determine tissue of origin and tumor histology/subtype. This is due their dependence on sequencing a limited number of recurrent mutations which distinguish between tumor and normal circulating cfDNA. The cfMeDIP-seq platform instead is based on genome-wide DNA methylation mapping. It therefore leverages a larger number of epigenetic alterations that can be used to distinguish ctDNA from normal circulating cfDNA and furthermore distinguish the tissue of origin and tumor histology/subtype. Moreover, DNA methylation profiles are highly tissue-specific.

## Intellectual Property

Both a provisional and PCT application have been filed for the CfMeDIP-seq platform.

## Company Profile:

Industry: Screening & Diagnostics  
Statuses: Start-up to be incorporated

## Contact:

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## Financial Information:

Capital Sought:  
Seed round: approx. CAD\$1M  
Series A: approx. CAD\$5M

## Founders:

Drs. Scott Bratman and Daniel De Carvalho

