BioMark DIAGNOSTICS INC

we believe

CANCER
IS CURABLE

A NEXT GENERATION COMPANY
POWERED BY METABOLOMICS
AND ARTIFICIAL INTELLIGENCE

Our Mission

Provide better cancer detection, monitoring and screening solutions for hard to detect cancers

Who We Are

- Developer of a pan cancer liquid biopsy platform company with advanced near-to-market diagnostic technologies.

- Multiple IP's in detection and quantitation of metabolites.

- Hand-picked, proven, global enterprise team of scientists, engineers, and medical professionals.

Collectively over 10 patents in different stages and jurisdictions in progress

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BioMark Executive Team & Advisors

Rashid Ahmed Bux, MBA
Founder, Chief Executive Officer

Gina Huang, MBA
CFO and Project Director

Dr. Bram Ramjiawan, Ph.D.
Clinical Trial and Regulatory Expertise

Brian Cheng, MSc
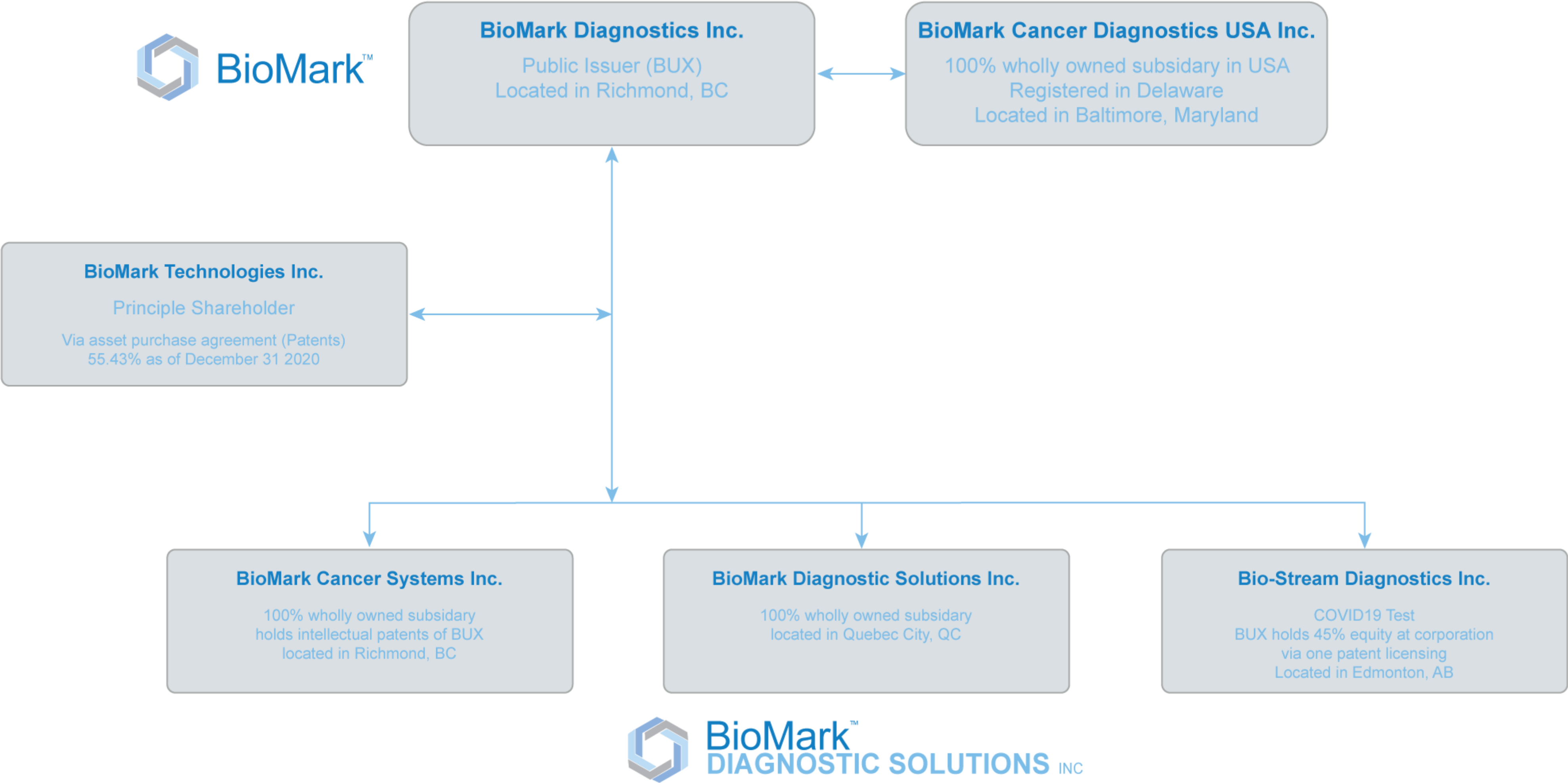Chief Technical Officer

Jean-François Haince, PhD
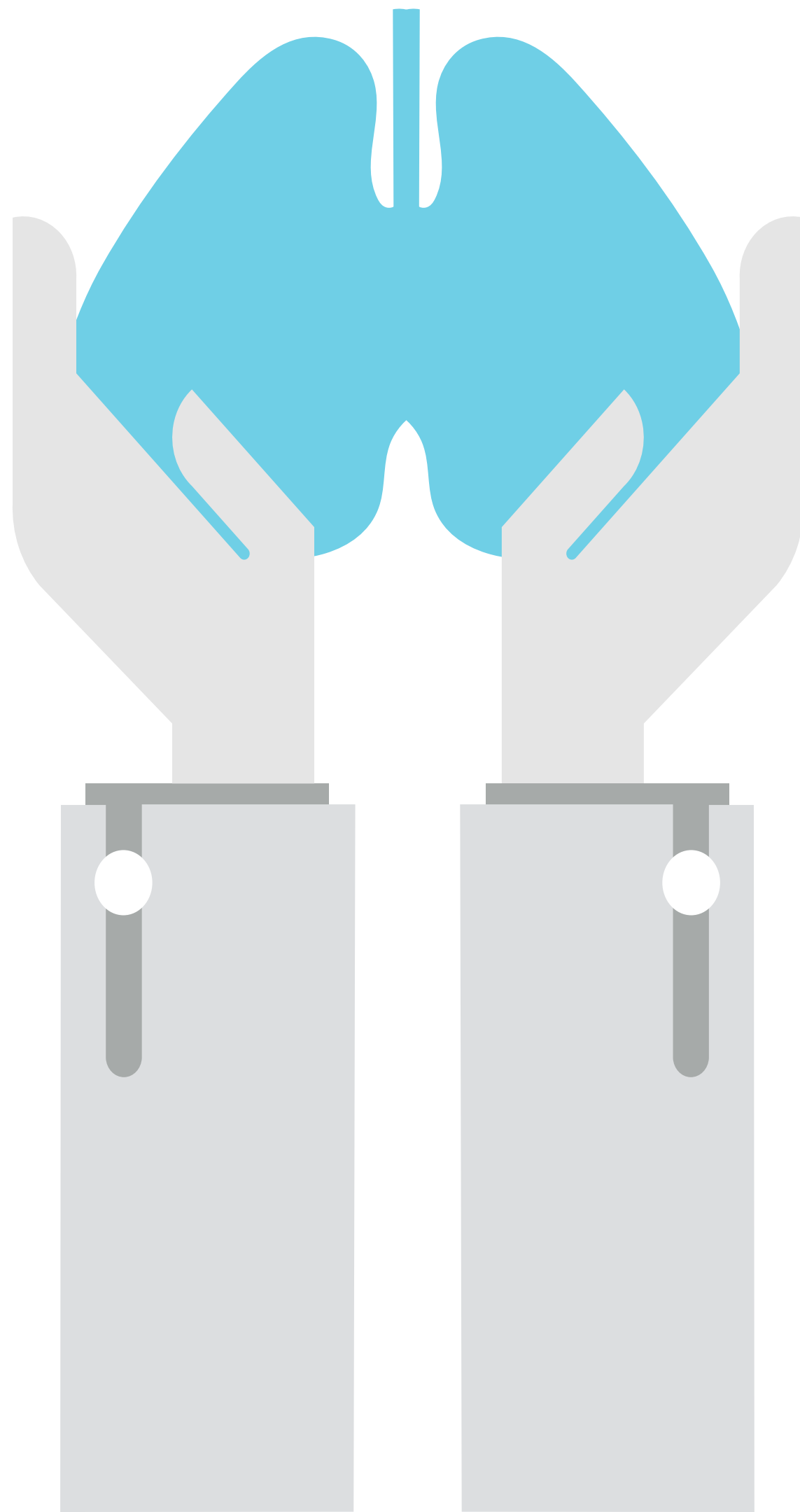Chief Scientific and Strategic Advisor

Mr. Alfred Berkeley – Strategic and financial advisor
Dr. David Wishart – Professor, Depts. of Computer Science and Biological Sciences, University of Alberta
Dr. Andrew Maksymiuk – Oncologist; Cancer Care Manitoba
Dr. Daniel Sitar – Principal Scientific Advisor / Professor Emeritus, University of Manitoba
Dr. Myron L. Weisfeldt – M.D., University Distinguished Service Professor, Professor of Medicine, The Johns Hopkins Hospital
Dr. Donald Miller – Professor, Department of Pharmacology and Therapeutics University of Manitoba
Dr. David Chen – Professor, Dept. of Chemistry, University of British Columbia
Dr. Horacio Bach – PhD, Antibody Engineering UBC

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BioMark Corporate Structure

BioMark Diagnostics Inc.
Public Issuer (BUX)
Located in Richmond, BC

BioMark Cancer Diagnostics USA Inc.
100% wholly owned subsidary in USA
Registered in Delaware
Located in Baltimore, Maryland

BioMark Technologies Inc.
Principle Shareholder
Via asset purchase agreement (Patents)
55.43% as of December 31 2020

BioMark Cancer Systems Inc.
100% wholly owned subsidary
holds intellectual patents of BUX
located in Richmond, BC

BioMark Diagnostic Solutions Inc.
100% wholly owned subsidary
located in Quebec City, QC

Bio-Stream Diagnostics Inc.
COVID19 Test
BUX holds 45% equity at corporation
via one patent licensing
Located in Edmonton, AB

Partners & Associations

- Institutions = U of Maryland; Johns Hopkins; Mt Sinai; IUCPQ; University of Manitoba; University of Alberta; UBC; University of Brescia; Université Laval

- Biopharma – 2 NDAs

- Phytronix Technologies Inc.

- Government – CIHR; CHRP; NSERC; Genome BC; Canadian Cancer Society

- Japanese based technology company

- CROs – 2 NDAs

- Medteq; CqDM

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VALUE PROPOSITION- ACTIONABLE DIAGNOSTIC TEST

Our technology solution – offers

- Early diagnosis and screening – Application in screening for late, aggressive and hard to detect cancers such as lung and brain cancers. These cancers have clearly identified populations.

- Effective monitoring tool to assess treatment efficacy earlier so as to improve tailor treatment regimen.

- Additional surveillance tool to help monitor recurrence in aggressive cancers (GBM 90%; Ovarian 85%*).

Solutions – *Continuum of care in cancer treatment and management*

Physician

Patient

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Payer

Pharma

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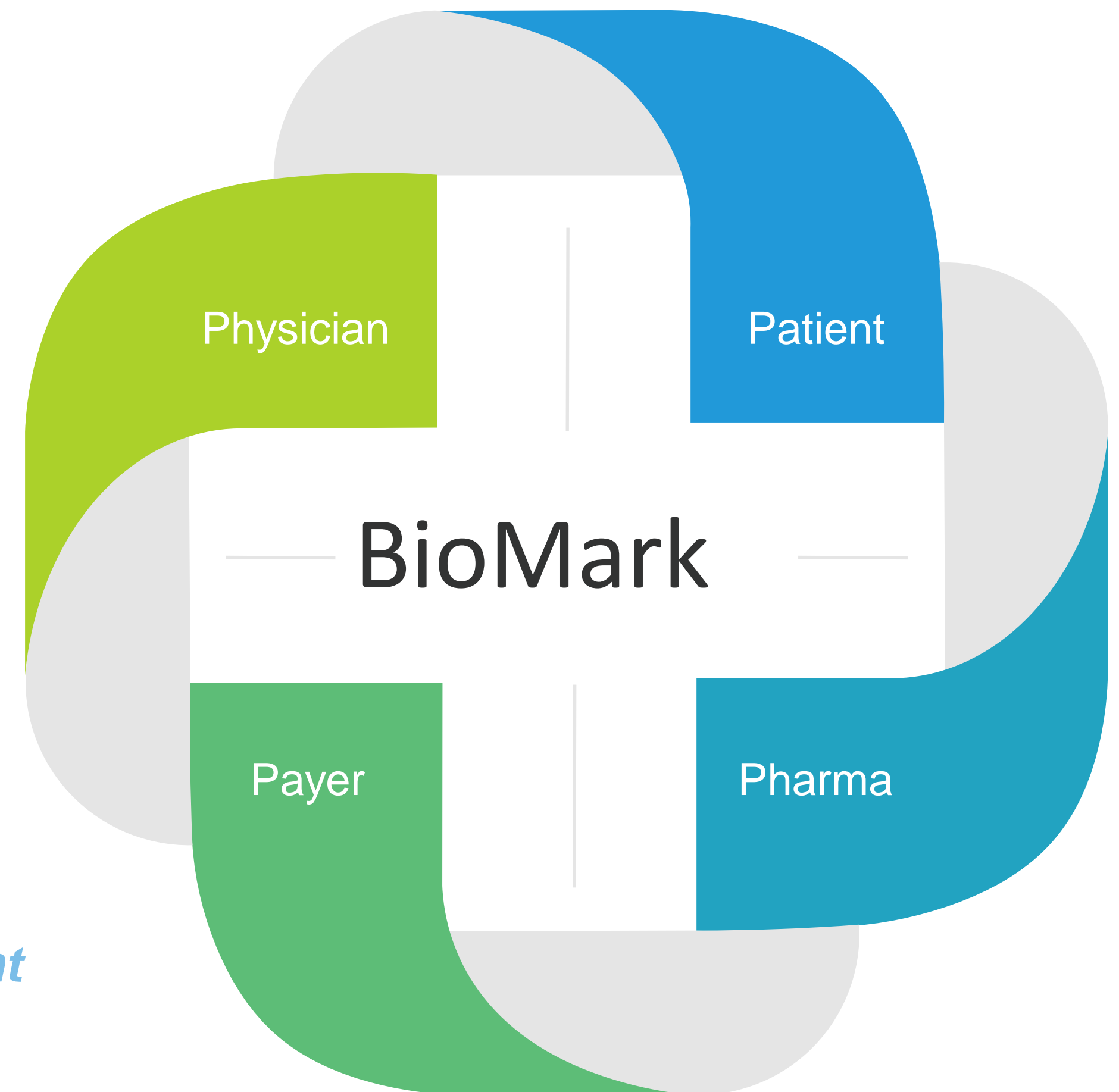
EMPOWERING
ONCOLOGISTS

novel technologies for

CANCER
SCREENING
EARLY DETECTION

Discovery & Development of Liquid Biopsy Assays

Completed Development and Validation of 2 Metabolomic Assays – Platform Play

Pan Cancer Acetyl Amantadine Assay (SSAT 1)
Use of an FDA Approved Drug As A Tracer

Multi Panel Biomarkers – First Application
Lung Cancer

Based on key discovery by Dr. Sitar UoM – Amantadine and SSAT1 (Linked to Polyamine pathway)

Recently completed a clinical trail based on a total of 450 patients after gaining CTA for phase III with focus on lung and breast and cancers

Pan Cancer application – Lung; GBM; Breast; Ovarian; Pancreatic;

Obtained ITA (Health Canada) on internal standards for quantification using LC- MS

In process to submit application to Health Canada

Revalidated and reproduced custom assay

Larger trial to set stage for commercialization at accredited company operated lab for lung screening

ML, risk scores, expanded markers, radiomics and clinical parameters – multimodal approach

Revalidated and reproduced custom assay

Strong ROC (Receiver Operating Curves)

Published in high impact journals
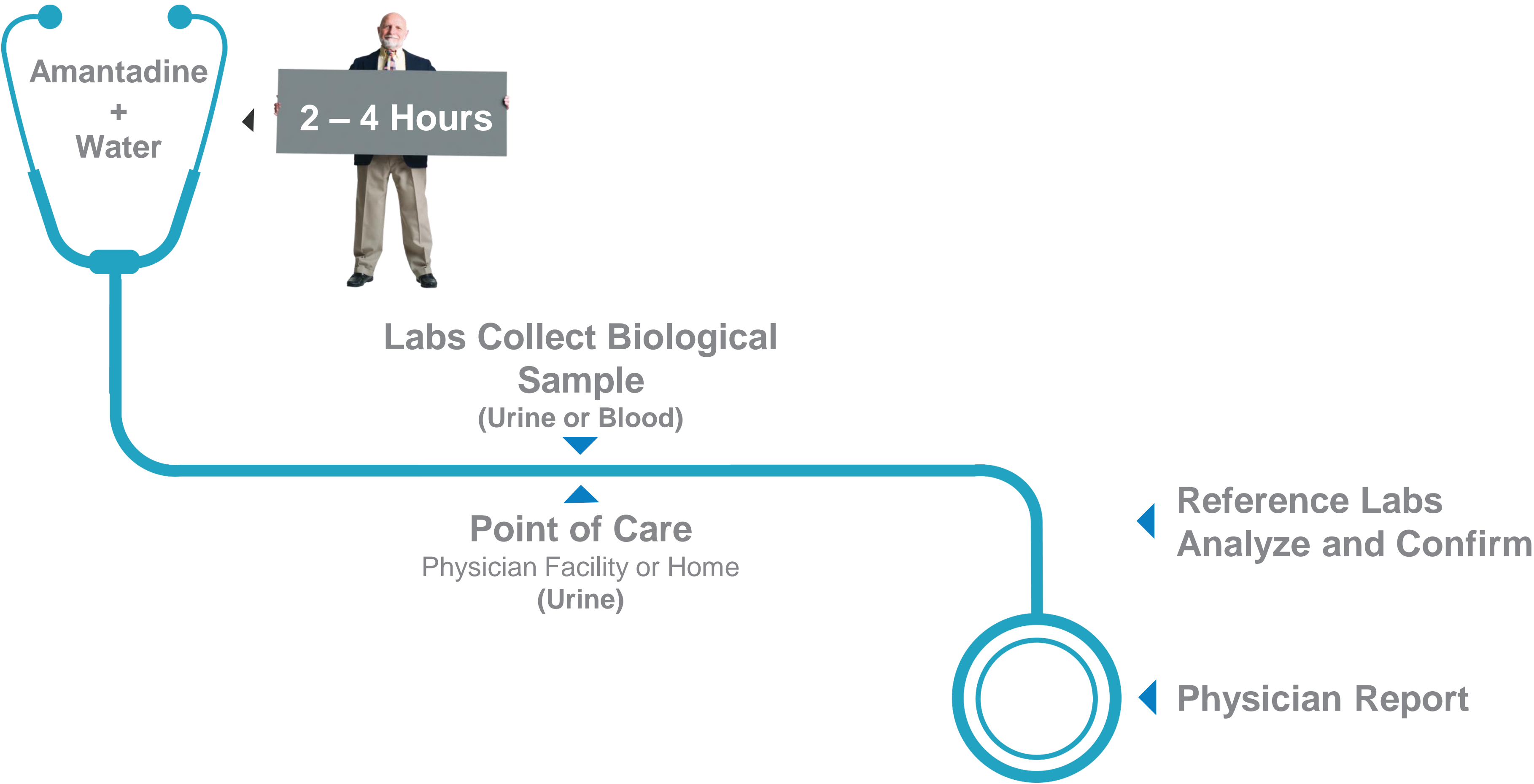
Both discoveries supported by multiple patents

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Assay I

Pan Cancer Acetyl Amantadine Assay (SSAT 1)

Convenient & Non-Invasive
SSAT 1 AMANTADINE ASSAY

Amantadine + Water

2 – 4 Hours

Labs Collect Biological Sample
(Urine or Blood)

Point of Care
Physician Facility or Home
(Urine)

Reference Labs Analyze and Confirm

Physician Report

Current SSAT1 Amantadine/Rimantadine Assay Activities

Phase III
Clinical Trial

Urinary Excretion of Acetylamantadine by Cancer Patients

Health Canada & Ethics Approval, in Canada & Bangladesh.

Next Steps

Completed clinical trial preparing submission package to Health Canada

Clinical Trial
Response to Chemo & Radio Therapy for Lung Cancer*

CancerCare Manitoba

Health Canada & Ethics Approval; Started patient recruitment.

Mini Pilot – Encouraging results; Published results

Next Steps

Multi site and increase patient recruitment

Use of SSAT 1
For GGM

The use of SSAT 1 based biomarkers to assess surgical resection and determine potential physiological and anatomical correlation as a guide and complimentary tool to existing procedure.

Health Canada Trial Approval (ITA)

Next Steps

Patient recruitment commenced at CancerCare Manitoba

*This study was undertaken to determine if amantadine metabolism to AA can detect changing activity of SSAT1 that is present in malignancy during a chemotherapy regimen

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Measuring Response to Treatment for Lung Cancer Using SSAT Assay
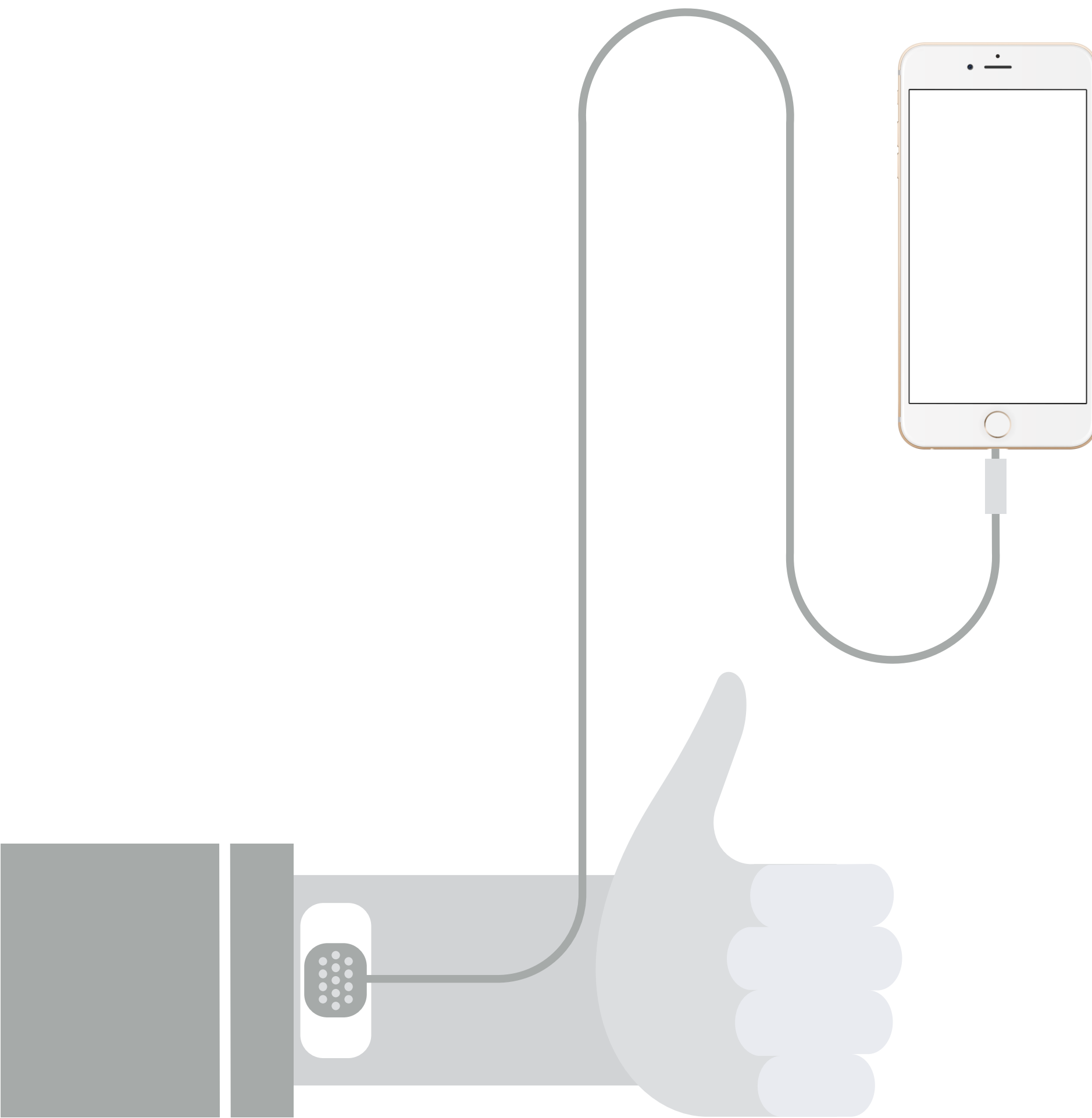
MARKET FOCUS:

BioMark's assay will be used to predict response and outcome of systemic therapy for patients on chemotherapy, immunotherapy and radiotherapy treatment.

How ? Determine concurrence to SSAT1 concentration in urine or plasma. Status -Conducted a successful pilot study and published paper in Feb 2021

Next Steps: Increase patient numbers at additional sites

Positive results impact:

- Modify / Personalize treatment for patients earlier

- Reduce costs associated with expensive therapies with an annual cost estimated at about $100K / patient

- Positively impact quality of life for patients

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Application Leveraging of SSAT Assay – (GBM) Market
Activities and Potential Outcomes

Our Value Proposition - Develop better diagnostic tools to assess progression and response to treatment. No paradigm shift for many years

Glioblastoma is the most common primary malignant form of brain cancer. Despite technological advances in surgery and radio-chemotherapy, glioblastoma remains largely resistant to treatment. The standard treatment for glioblastoma is surgery. The choice of drug therapy for glioblastoma is still limited to a handful of compounds. There is over 90% recurrence rate.

Sponsored research - Secured Canadian government grants to support clinical research

Current Activities- Conducting clinical trails at CancerCare Manitoba

Conducting research on therapeutic intervention using proprietary nano lipids delivery system

Partnership – Johns Hopkins; University of Maryland and CancerCare Manitoba;

Orphan Status – rare disease would help support regulatory status. Expedited trials and FDA acceptance

Unique Underserved Attractive Market

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Assay II

Targeted BioMarker Panel for Early Detection of Lung Cancer Using Liquid Biopsy

Targeted Metabolomics Lung Cancer Trials

Data Summary

Total Subjects: 257

Normal: 60

Lung Cancer: 197
(emphasis on Stages 1 and 2)

*Samples and data obtained from IUCPQ bio bank

Metabolomics Analysis: Human plasma samples* were analyzed using custom developed assay for several putative lung cancer biomarkers.

Results: Strong AUROC For Early-Stage Detection

PERFORMANCE OF LOGISTIC REGRESSION MODEL A			
	AUC	**SENSITIVITY**	**SPECIFICITY**
TRAINING/ DISCOVERY	0.974 (0.965 ~ 0.982)	0.937 (0.920 ~ 0.954)	0.922 (0.895 ~ 0.950)
10-FOLD CROSS-VALIDATION	0.959 (0.923 ~ 0.995)	0.919 (0.919 ~ 0.976)	0.900 (0.807 ~ 0.993)

Logistic regression based optimal model for stages I + II NSCLC detection: **metabolites only**

| PERFORMANCE OF LOGISTIC REGRESSION MODEL B			
	AUC	**SENSITIVITY**	**SPECIFICITY**
TRAINING/ DISCOVERY	0.982 (0.975 ~ 0.990)	0.960 (0.946 ~ 0.974)	0.944 (0.921 ~ 0.968)
10-FOLD CROSS-VALIDATION	0.965 (0.930 ~ 1.000)	0.930 (0.930 ~ 0.984)	0.925 (0.843 ~ 1.000)

Logistic regression based on optimal model for stages I + II NSCLC detection: **metabolites plus smoking history**

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Lung Cancer – The Big Picture

Lung cancer has been the most common cancer in the world for several decades and accounts for 1 in 5 of all cancer deaths.

Worldwide, three people die from lung cancer every minute

More than 2/3^{rds} of patients are diagnosed with lung cancer at a later stage when their survival chances are much lower
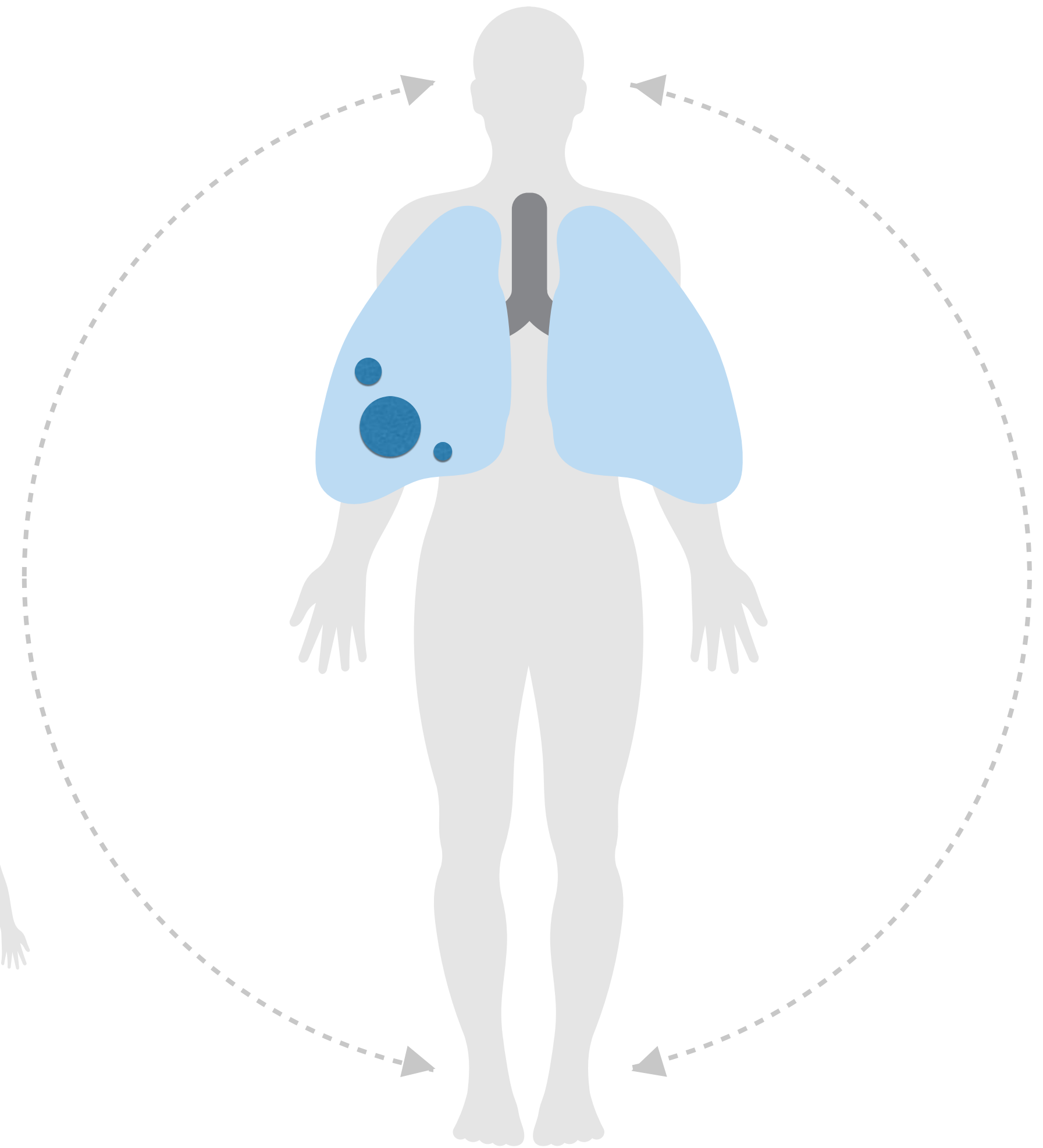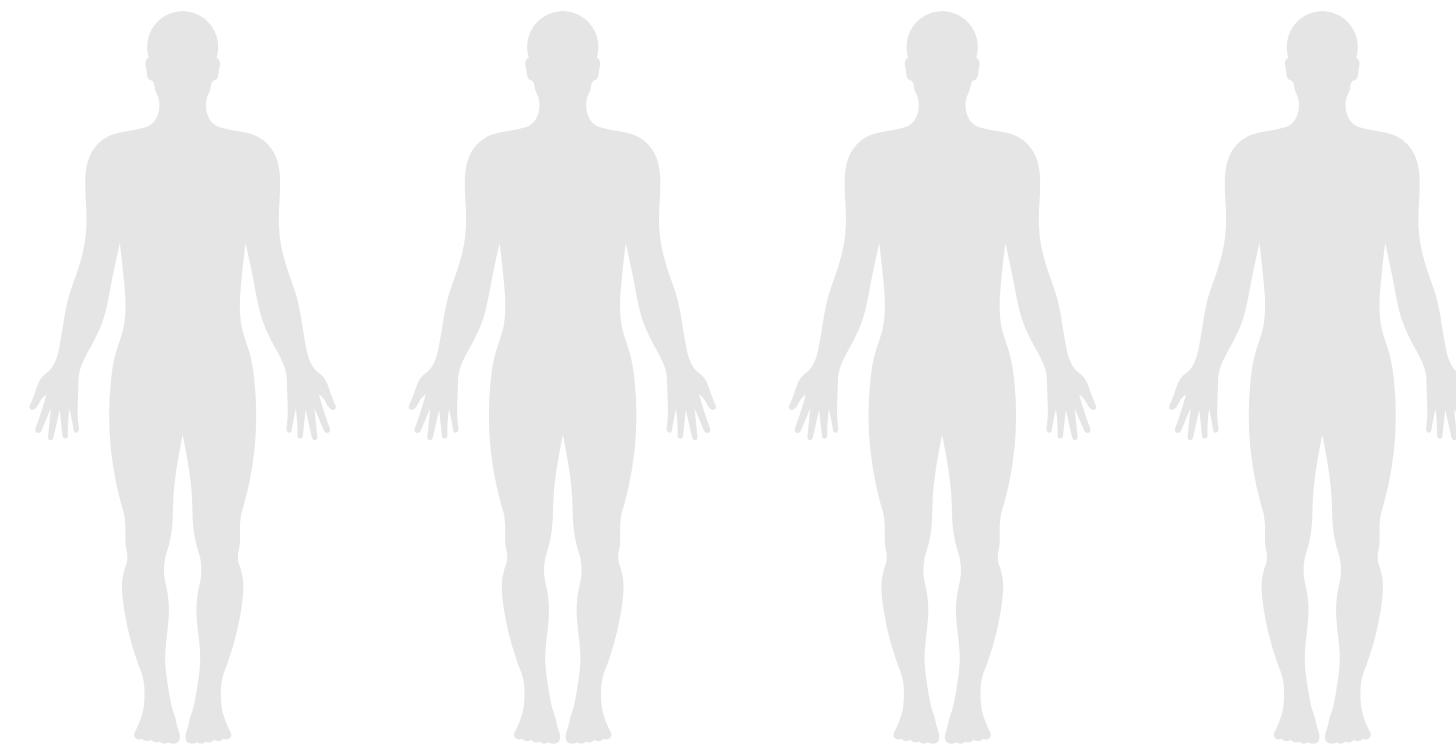
5 Year Relative Survival Rates (%)

Importance of Stage Shifting – Early Detection is Critical to Save Lives

STAGE	LUNG (NSCLC)	BREAST	PANCREATIC
1 A	92	100	37
1 B	68		
2 A	60	93	12
2 B	53		
3 A	36	72	3
3 B	26		
4	10	22	

Lung Cancer Market Highlights
Commercialization Roadmap

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Target - Lung Cancer Screening in US for identified high risk groups to complement LDCT Scan

- Estimated Population Size : 8 million

- Current Uptake 3%; 18% cancers detected are indolent; over diagnosis

- Imaging is used for Screening – Low Dose CT Scan (Helical CT) – reduces mortality in high risk groups by 15-20%;

Challenges– High false positives; Costs

BioMark's Lung Cancer Solution
Commercialization Roadmap

Solution:

- Use BioMark's assay that is cost effective and can potentially reduce false positives and negatives associated with LDCT Scans. *(reduce and manage diagnostic dilemma) – rule in /out*

- Can use as routine test

- Following patients with abnormalities that are difficult to confirm using CT scans

The lung cancer metabolites are easily measured using quantitative mass spectrometry (MS) methods with standard instruments used in diagnostic clinical laboratories across Canada and USA.

- ✓ *the amount of blood required (<20 μL),*

- ✓ *the expected cost of the test ($350)*

- ✓ *the time to perform the test (<5 minutes on an MS instrument and LDTD proprietary platform)*

Much faster, cheaper and less invasive than any other known or proposed lung cancer test, including biopsies, X-rays, LDCT and other molecular based assays.

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Next Commercialization Steps for Early Lung Cancer Detection

- Sponsored Lung Cancer Trial

- Assemble a pan Canadian multidisciplinary team of experts

- Source samples from IUCPQ Biobank - (1500 samples)

- Timing: April- July 2021

- Set up lab in Quebec for sample analysis -2nd. Quarter 2021

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Projected Lung Cancer Market Entry & Revenue Model

| ACTIVITY	MARKET	REVENUE SOURCE	TIMING
VALIDATE MARKERS TARGET FOR ITA / LDT CERTIFICATION AT BIOMARK'S LAB IN QUEBEC USING NEW LDTD TECHNOLOGY	CANADA-QUEBEC		2021/22
PROVIDE TEST SERVICE FROM REGISTERED CLINICAL LAB OPERATION IN QUEBEC	CANADA-QUEBEC LUNG CANCER SCREENING	• SALES OF LDT TEST • LICENSING	2022/23
LICENSE ASSAYS FOR LUNG CANCER TO CLIA LABS IN US	HOSPITAL LAB OR DIAGNOSTIC COMPANIES	• LICENSING ROYALTY • TEST & MS INTERNAL STANDARD	2023/24
MONITORING FOR EARLY RECURRENCE WITH SMART ALGORITHMS/OMICS PANEL	LAB, OR DIAGNOSTIC AND INSURANCE COMPANIES	• LICENSING ROYALTY • TEST • MONITORING SERVICE	TBD

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Impending Catalyst – Short Terms

Lung Cancer

- Set operations in Quebec to accelerate commercialization efforts. Secured soft landing support fund in Feb 2021

- Seek non dilutive government grants for lung cancer study. $150K confirmed with additional + $4,2M pending

- Lung Cancer new panel development – expand to 300 metabolites developed at TMIC to be used in upcoming lung cancer studies at IUCPQ

- Build certified lab facilities in Quebec to provide tests services for lung cancer screening using new proprietary technologies that offer higher sensitivity and throughputs. Lab space leased in May 2021

- Seek and partner with US labs and service providers that can offer services - in discussions with some CLIA lab operators

GBM – Leverage SSAT Platform

- Obtained Health Canada No Objection Letter for GBM trials at CancerCare Manitoba. Patient recruitment underway. Study funded by CHRP $750K Grant secured.
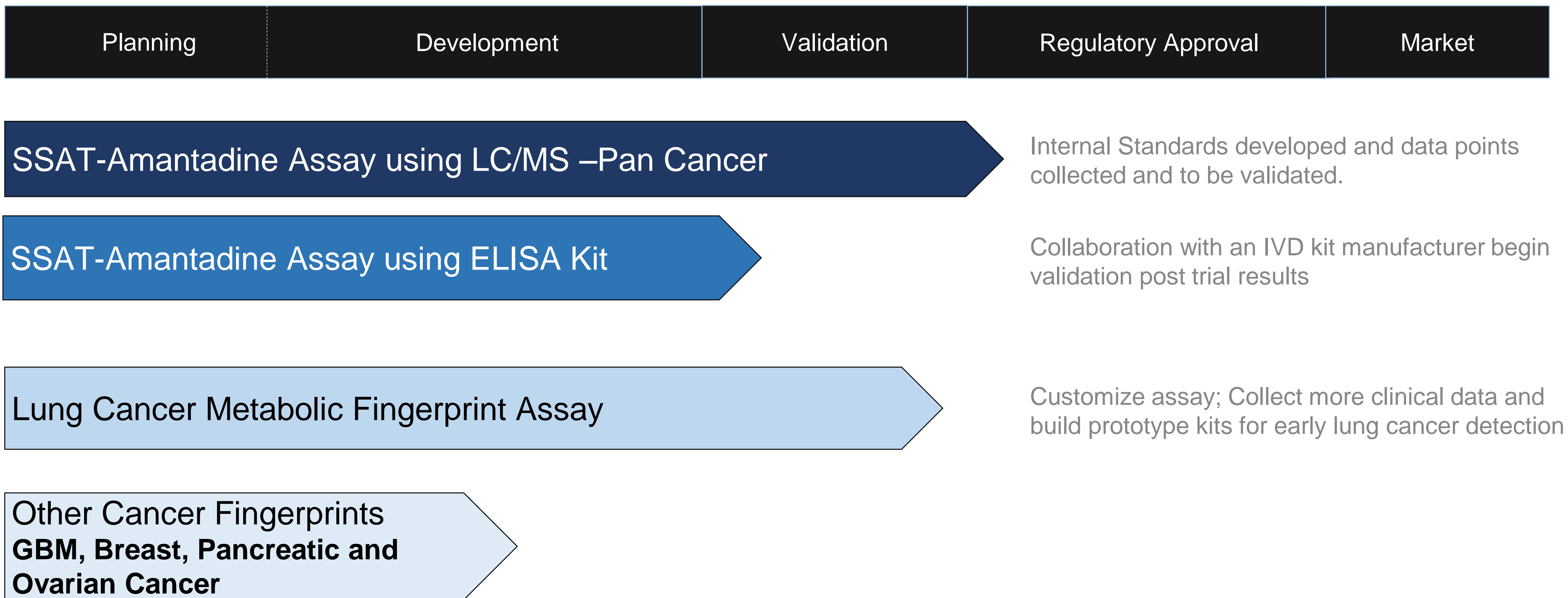
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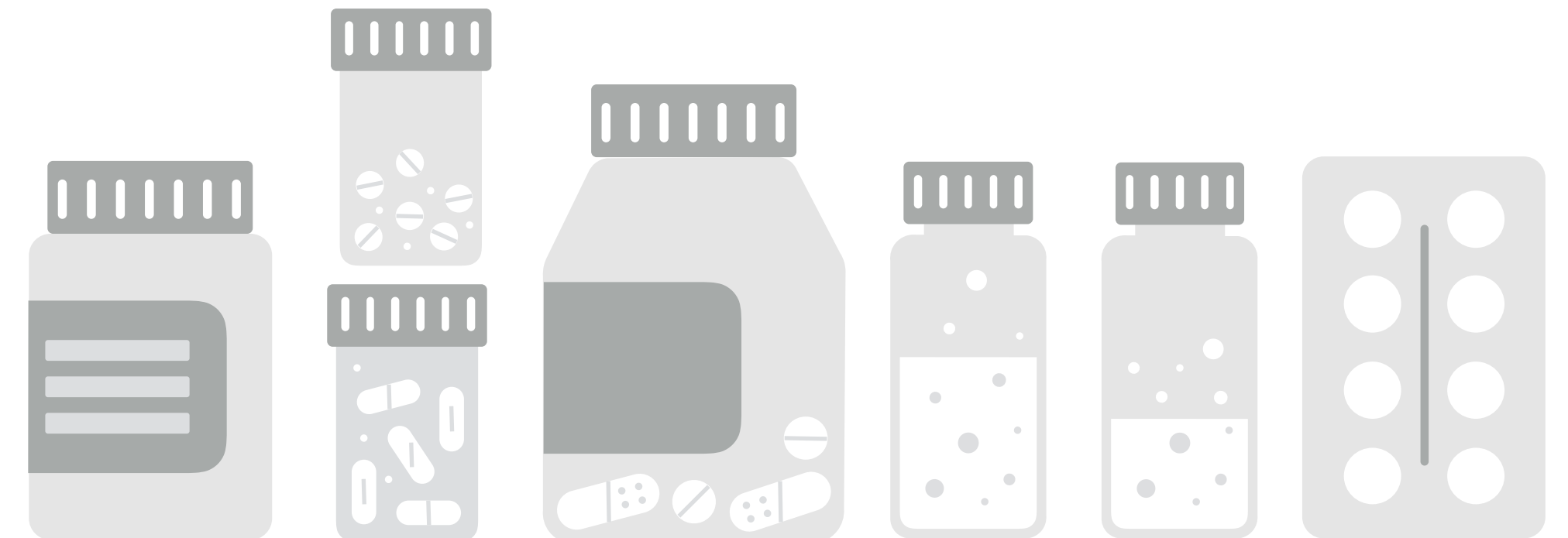
BioMark Cap Table Summary

- Trading Symbols: **CSE: BUX / OTCMKTS: BMKDF / FSE: 20B**

- Common Shares Issued and Outstanding: **77, 974,229**

- Warrants (@ $0.45): **1,147,579**

- Options   (@ $0.15 - $0.30): **4,195,000**

- Insiders ownership: **60%**

- Capital Raised (to-date): **CAD $ 12 m**

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Technology Platform & Product Pipeline

Planning	Development	Validation	Regulatory Approval	Market

SSAT-Amantadine Assay using LC/MS –Pan Cancer

Internal Standards developed and data points collected and to be validated.

SSAT-Amantadine Assay using ELISA Kit

Collaboration with an IVD kit manufacturer begin validation post trial results

Polyamine and other Pathways

Lung Cancer Metabolic Fingerprint Assay

Customize assay; Collect more clinical data and build prototype kits for early lung cancer detection

Other Cancer Fingerprints
GBM, Breast, Pancreatic and Ovarian Cancer

Regulatory and Commercialization Timelines

| Activities	Expected Timing
SSAT Assay Regulatory Submission	
Health Canada Submission	1Q21
Health Canada Approval Decision	2Q21
Commence Commercialization	4Q21
Lung Cancer – Monitoring Response to Chemo/Radio Treatment	
Peer Reviewed Publication	1Q21
Expand trial - Amend and apply for ERB and Health Canada NOL	1Q21
Commence larger multi-site trial - IUCPQ	3Q21
Early Lung Cancer Detection and Screening	
Expand technology partnership	1Q21
Build lab infrastructure and hire staff in Quebec – secure lab space and equipment for pre commercialization sample analysis	1Q21
Commence and complete large Medteq sponsored research (1500 samples)	3Q21
Lab certification	1Q22
Present data to regulatory agencies	2Q22
Introduce test / Commercialization with IUCPQ as beachhead	4Q22
Commence and complete large multimodal sponsored trial in Quebec in 8 hospitals – sponsored research involving 4000 samples	3Q21+

Rashid Bux

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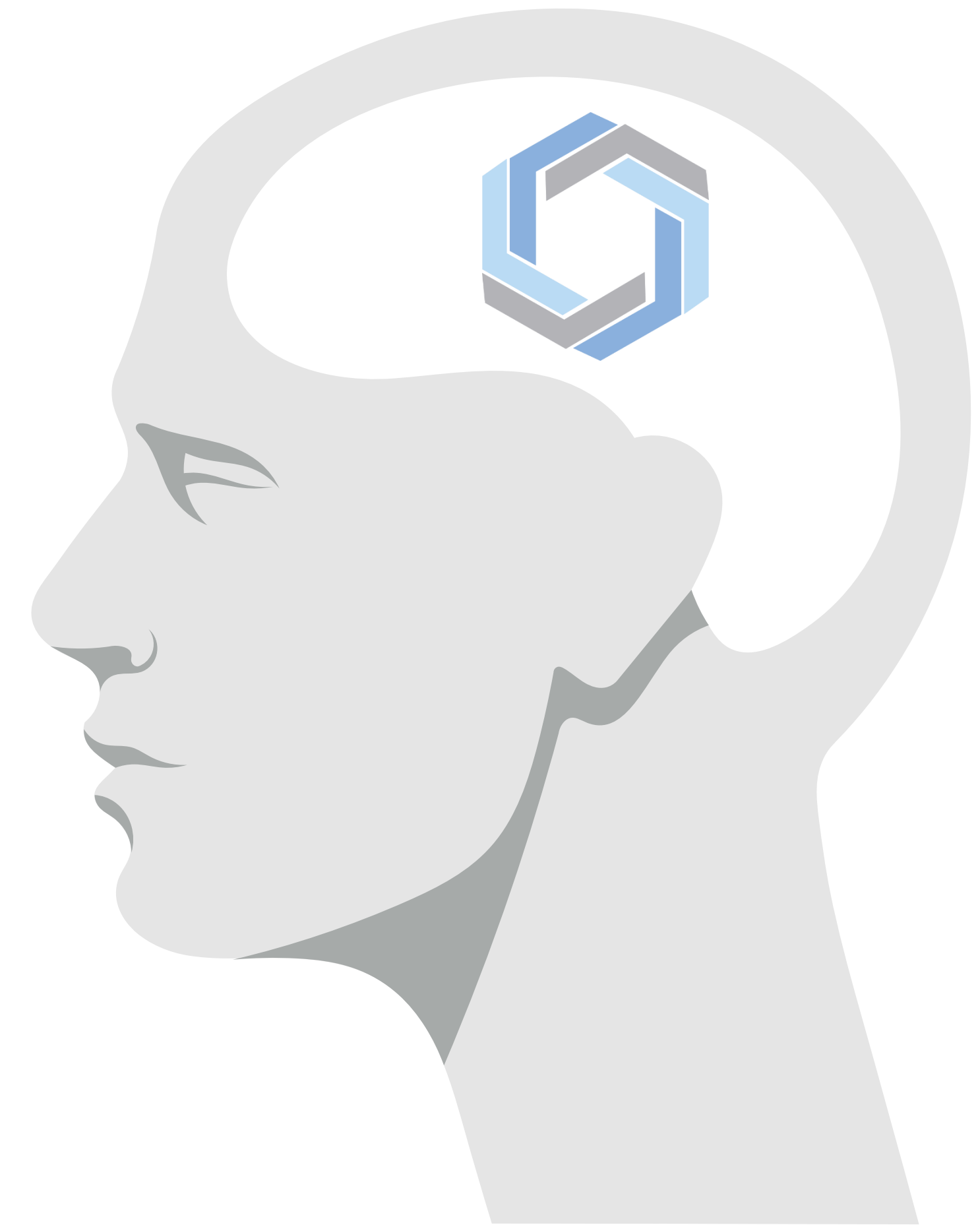
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