



Diagnosing Cancer EARLY with Microbiome-Driven Liquid Biopsy

Sandrine Miller-Montgomery, Pharm.D. Ph.D.
President and CEO



2021 Unicorn
Battle
Silicon Valley
Winner



2021 Diagnostic
Winner



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Plenty of Resources On Cancer Dx... with Little Progress in Early Detection



19

MILLION

New cancer cases
worldwide each year

10

MILLION

Cancer **deaths** each year

4

MILLION

Preventable Cancer deaths each year
with early detection



Have researchers been focusing on the
**wrong biomarkers in liquid biopsy for early
cancer detection?**

Micronoma™

Microbiome-driven liquid biopsy



Small volume of blood



Currently focused on lung cancer



True early stage detection



Can traditional liquid biopsy reliably detect a cancer at Stage I?



With a typical mutation frequency of 0.1%, minimum volume of blood to have a chance to capture the 1 mutation in the tube is:

Example of tumor size

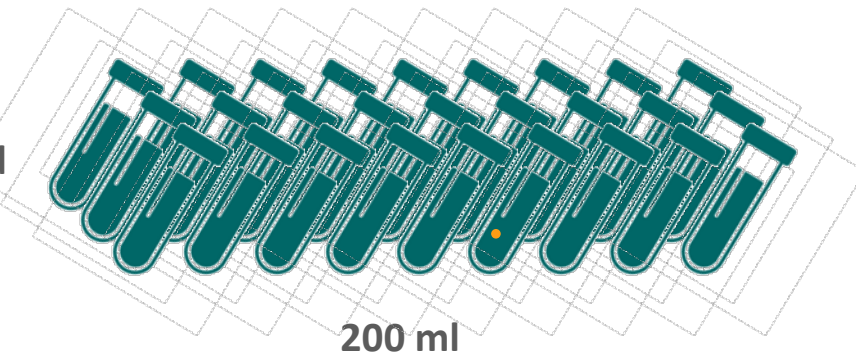


0.5 cm



2.5 cm

Blood needed



200 ml



7 ml

High Risk of False Negative:
Assumes that THE ONE mutant genome equivalent is not lost anywhere in the sample process!

High Risk of False Positive:
Assumes Mutant is NOT coming from clonal hematopoiesis

Avanzini, S. et al. A mathematical model of ctDNA shedding predicts tumor detection size. *Sci Adv* **6**, 2020
Abbosh, C. et al. *Phylogenetic ctDNA analysis depicts early-stage lung cancer evolution*. *Nature* **545**, 2017

Voice of Clinicians – Why not Multiple Cancer Assays?



Multiple Cancer assay

vs

Specific Cancer assay

Example of clinical presentation



In which population are the assays validated?

Lung Cancers vs
Healthy controls or other cancers

Lung Cancers vs
Benign Lung Diseases

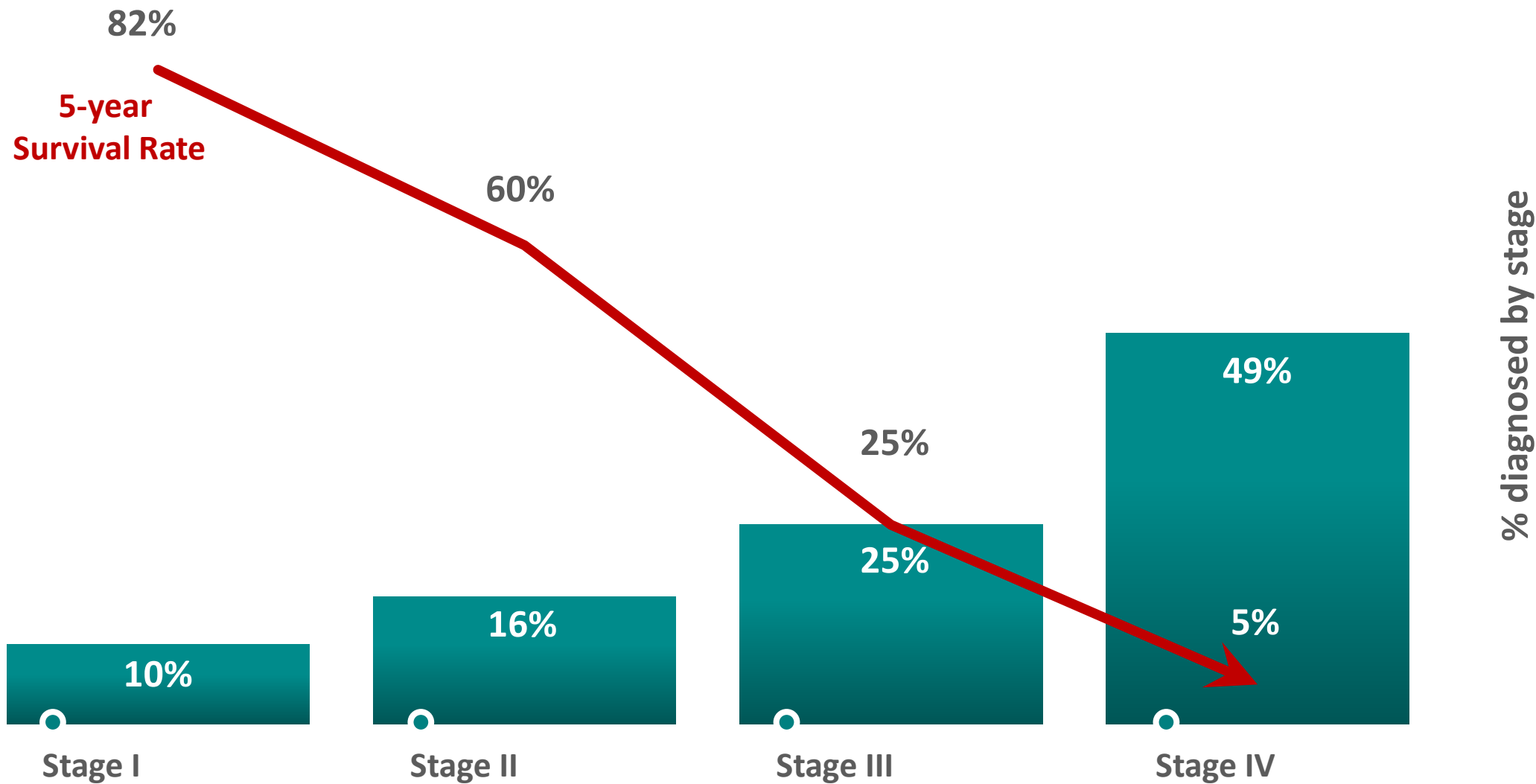
Clinical relevance

Clinician already knows patient is
NOT healthy and UNLIKELY to have a
cancer in other organs at this stage –
Assay is NOT relevant

Lung scan may show nodules, but
are these MALIGN or BENIGN?
Assay is highly relevant



Why a focus on Lung Cancer – 25% of all cancer deaths in US



Current Standard of Care for Lung Cancer Diagnostic



LD CT Scan

- \$300
- 15M eligible in US (50+ y.o., 20-year-pack smokers)
- Only ~5% compliance

If nodule found

Based on risk calculators

1- LDCT or Chest Xray (cost efficient and safe, but not specific for malignancy)

OR

2- PET/CT (costly and higher radioactivity, but not suited for adeno or stage I due to low sensitivity)



Tissue Biopsies

- \$6,500 if no complication, \$26,000 with complications (20%) (e.g. pneumothorax, infection disease)

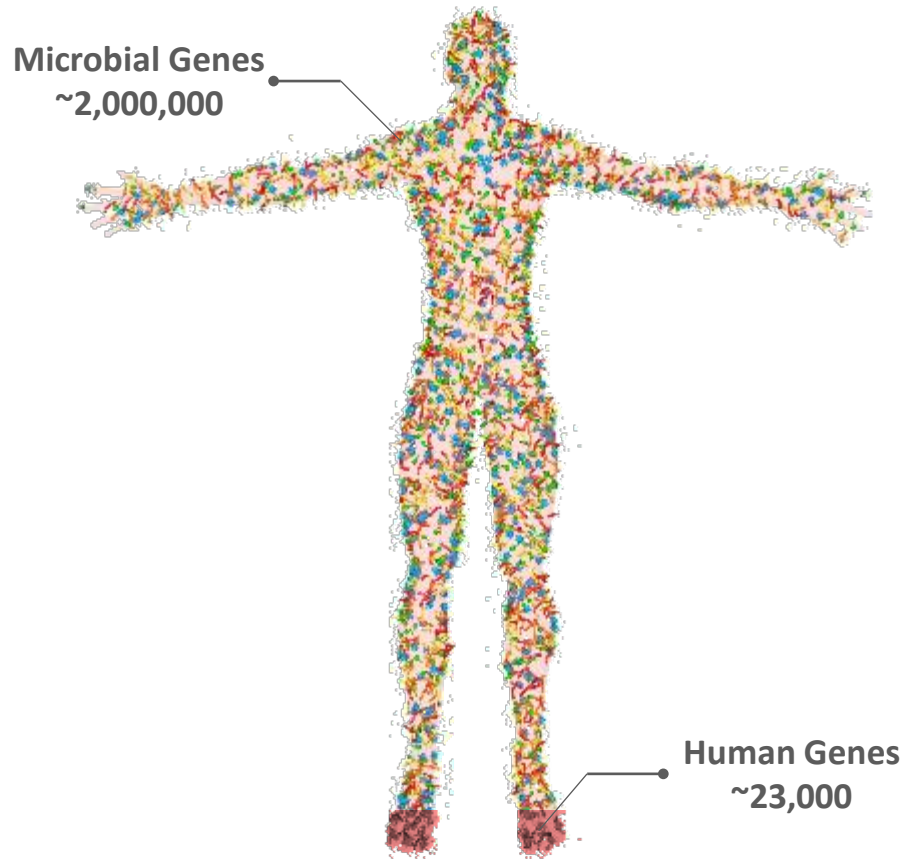
Tissue Biopsy reveals 95%+ of LD Ct Scan Nodules are benign... Only 5% are LC!

Clinicians need a new diagnostic tool, which is 1) **minimally invasive**,
2) compatible with **early stage of the disease**, AND
3) performing on **Adenocarcinoma Stage I** and other subtypes and stages

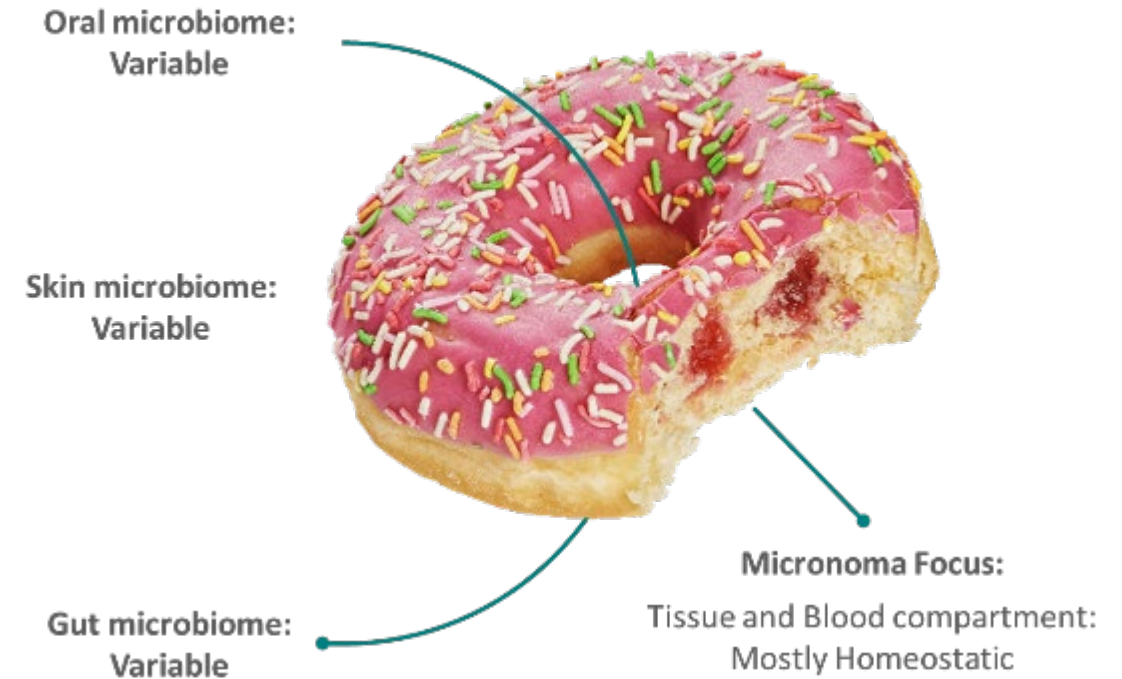
Microbiome-Driven Liquid Biopsy



99% microbial and 1% human by gene count



Focus on circulating microbiome
for stronger signal



Oncobiota™ Platform Overview – Patent pending



Minimally Invasive

Start with as little as 400µl of plasma



Micronoma Sample Prep

Extract nucleic acid, prepare NGS library prep and controls for maximum contamination elimination (noise reduction)



NGS On Existing Platforms

Generate NGS shotgun data with proprietary analysis methods



Cancer/Non Cancer Likelihood Report

Provide actionable results with clinically relevant performances.

3 UC San Diego IP exclusively licensed
6 Micronoma patents filed

Micronoma Founders' Research Published in Nature, March 2020

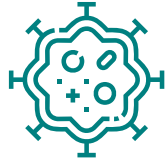


The Cancer Genome Atlas (TCGA) includes data and metadata on:



**33 DIFFERENT
TUMOR TYPES**

... based on paired tumor and normal tissue sets collected from



**10 RARE
CANCERS**



11, 000 PATIENTS

using



7 DIFFERENT DATA TYPES

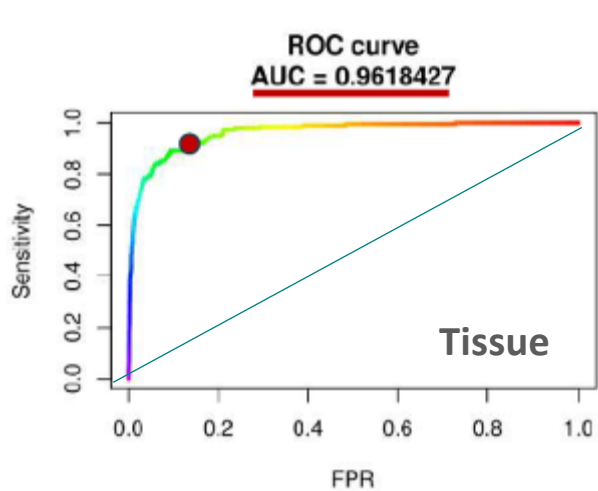
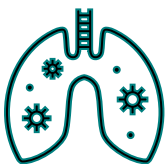


<https://www.nature.com/articles/s41586-020-2095-1>

CONCLUSIONS

- ✓ Do tumor tissues have microbial content?
YES
- ✓ Is this content specific to the cancer type?
YES
- ✓ Can we distinguish cancer tissue from adjacent healthy tissue using the microbial markers?
YES
- ✓ Can we predict a cancer from blood microbial profiles?
YES

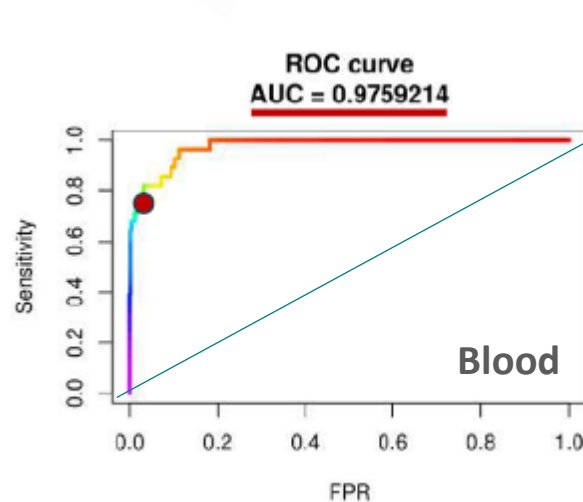
Micronoma Shows High Diagnostic Value: TCGA Lung Example



		Reference	
		LC	Control
Predicted	LC	162	187
	Control	42	3777

Sensitivity: 79%

Specificity: 95%



		Reference	
		LC	Control
Predicted	LC	21	9
	Control	7	522

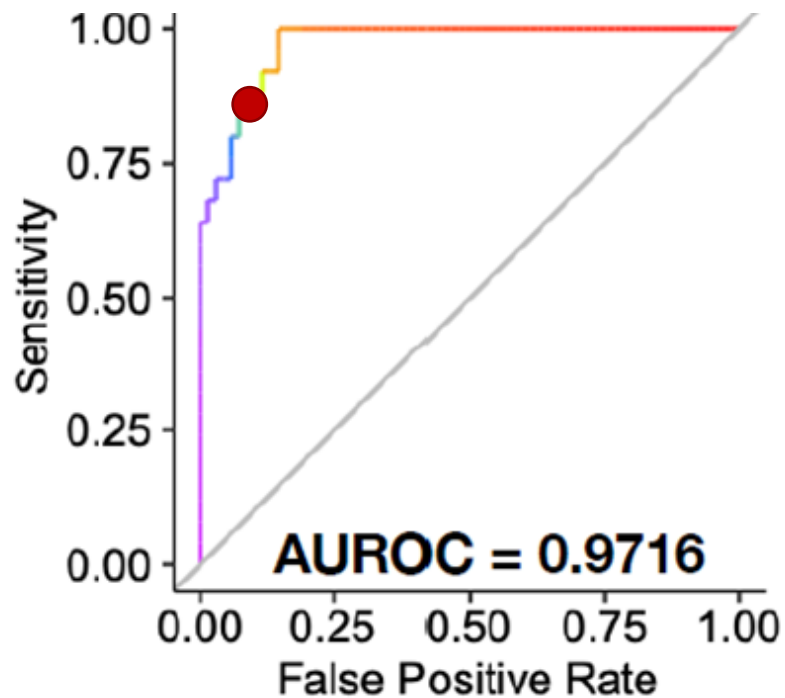
Sensitivity: 75%

Specificity: 98%

Discovery of new diagnostic approach

Results for other 30+ cancer types analyzed can be found at
http://cancermicrobiome.ucsd.edu/CancerMicrobiome_DataBrowser

Results of Oncobiota™ on UC San Diego Plasma Samples comparing Lung Cancer Patients vs Healthy Controls



		Reference	
		LC	Healthy Control
Predicted	LC	22	5
	Healthy Control	3	64

Sensitivity: 88%

Specificity: 92.8%

Results validated with new set of samples

Latest data - Unpublished



✓ Validation focus on Lung Cancer

- Plasma
- Shotgun



✓ ~1,000 Cancer and Controls

- Multiple cancer types (Adenocarcinoma, Squamous Cell), including many early stages
- Age, gender, ethnicity matched controls
- Multiple control types (Healthy, non-cancerous lung diseases)

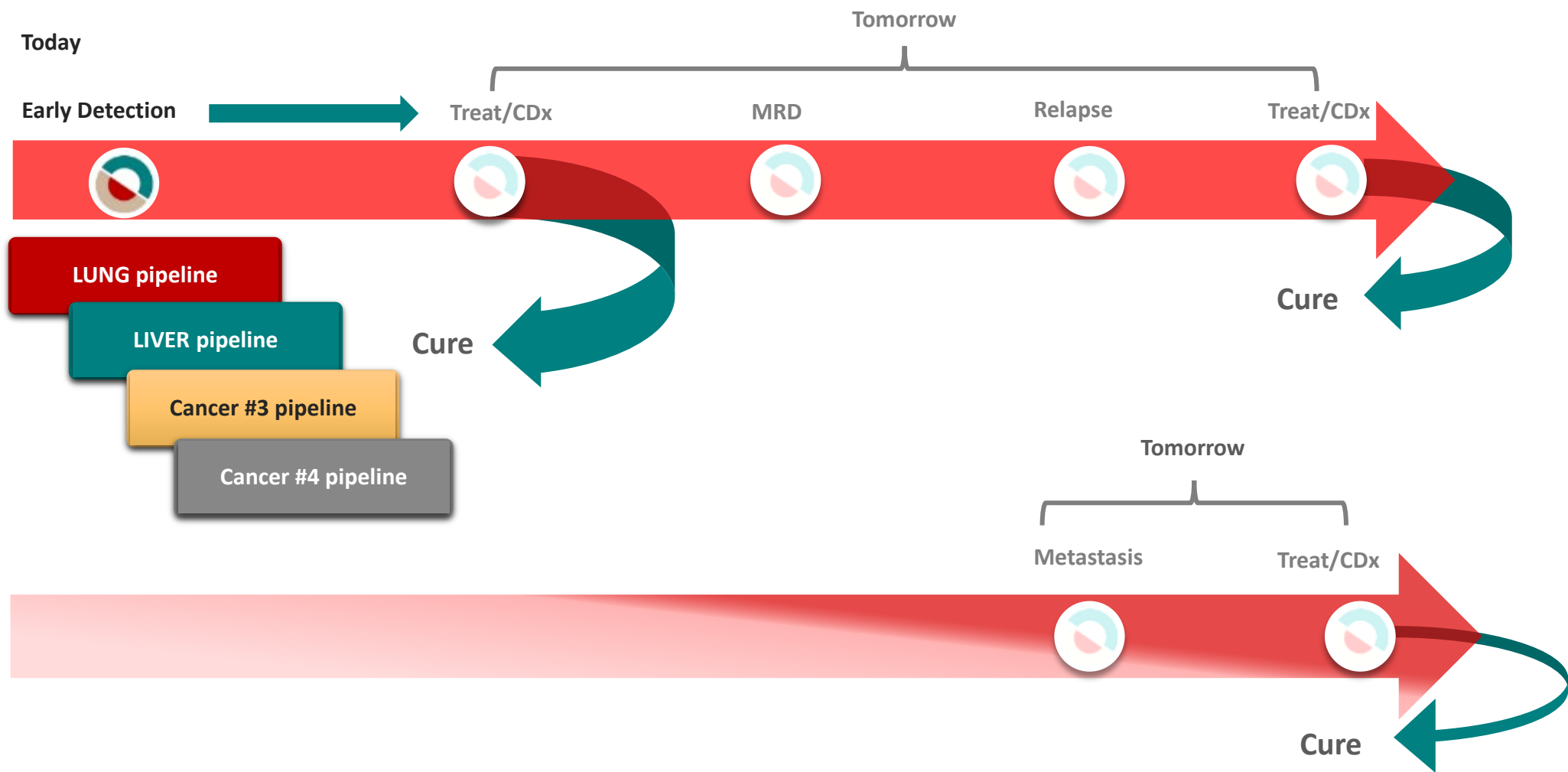
Healthy

Benign

Cancer

Micronoma Platform Expansion

Cancer Management Tools supporting the Entire Patient Journey



Leadership Team



Sandrine Miller-Montgomery
Pharm.D., Ph.D.

Founder, Board Member
President and CEO

- Industry Pedigree (Invitrogen, Illumina, Abbott)
- Two Exits by Acquisition (Helixis, MOBIO)



Greg Poore, Ph.D.

Founder, Board Member
Chief Analytics Officer

- Patent inventor
- Entrepreneur (Vigor Inc.)



Rob Knight, Ph.D.
UC San Diego,
Center for Microbiome Innovation

Founder and Advisory Board

- Microbiome Key Opinion Leader
- Patent Inventor
- Entrepreneur (Biota Inc.)



Eddie Adams, Ph.D.

Chief Scientific Officer

- Expertise in developing diagnostic solution for early detection of bloodstream infection
- Successfully developed and commercialized kits for microbiome analysis



Darryl Garrison

Chief Operation Officer

- Established Many CLIA diagnostic laboratories for major clinical cancer diagnostic companies (Clariant, Neogenomics, Dermtech)



Martin Blaser, M.D.

Professor at Rutgers University
Chairman of the SAB

- Microbiome Expert
- Pioneer of cancer and microbe interaction (role of H. pylori in stomach cancer)



Leena Das-Young, Pharm.D.

Founder RaniBio,
Advisor Springboard Enterprises

- GM & Chief Lunar Officer at Guardant Health
- VP, Late Phase Strategy & Dev Group, Oncology at Pfizer



Ravid Straussman, Ph.D.

Weizmann Institute
of Science Israel

- Cancer Expert
- Author of Science article – May2020
"The human tumor microbiome is composed of tumor type-specific intracellular bacteria"



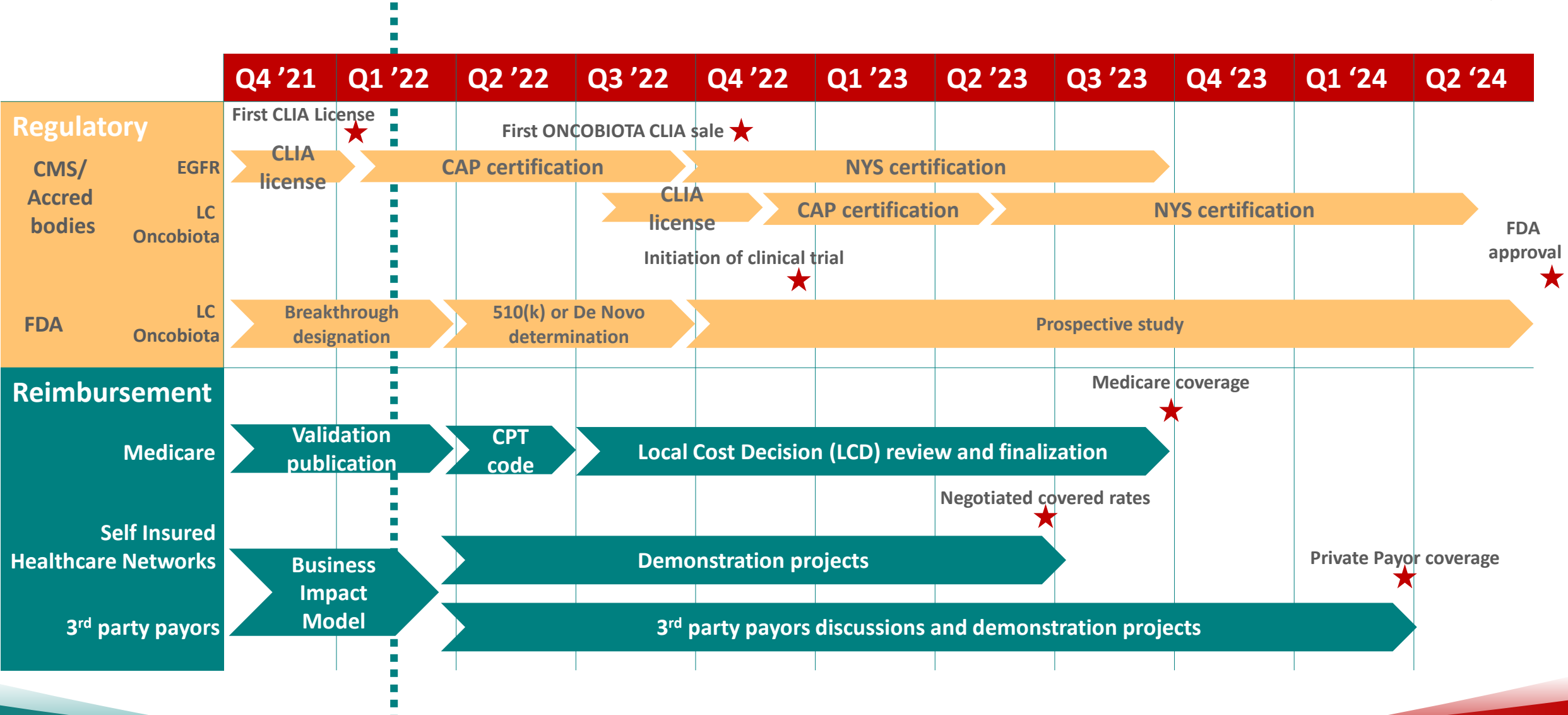
**Jennifer Wargo,
M.D., M.M.Sc.**

MD Anderson Cancer Center

- Clinical Oncologist
- Work at the crossroad of Oncology, Immunotherapy and Microbiome

Scientific Advisory Board

Oncobiota^{LUNG} - Path to full commercialization



Funding and Board of Directors



Raised \$17.5M to date



Including March 2022 \$11M notes



Magda Marquet, Ph.D.
Chairman of the Board



Sandrine Miller-Montgomery,
Pharm.D., Ph.D.
President and CEO



Greg Poore, Ph.D.
Chief Analytics Officer



Chidozie Ugwumba
SymBiosis VC



Aleksei Cremo
SymBiosis VC

EXECUTIVE SUMMARY - Microbiome-Driven Liquid Biopsy



Large unmet need

- ✓ 4M preventable cancer deaths
- ✓ No sensitive and specific early detection method available for many cancers



Competition weaknesses

- ✓ Doesn't work well at stage I
- ✓ Not validated in a manner that meet clinicians need



Path to CMS reimbursement

- ✓ Emulate other CDx liquid biopsy providers
- ✓ Submission for FDA Breakthrough Designation



Large addressable market

- ✓ \$2B+
- ✓ 20% CAGR and accelerating



Unique Oncobiota™

- ✓ Microbiome-Driven Liquid Biopsy – Expert team
- ✓ Independent from tumor size



Strong and durable momentum

- ✓ Cancer is not going away
- ✓ Large investments and M&A in liquid biopsy indicate needs for solution and market is not saturated



Fast revenue stream

- ✓ First significant US revenue in 2024
- ✓ Projected revenues \$100M+ by 2027



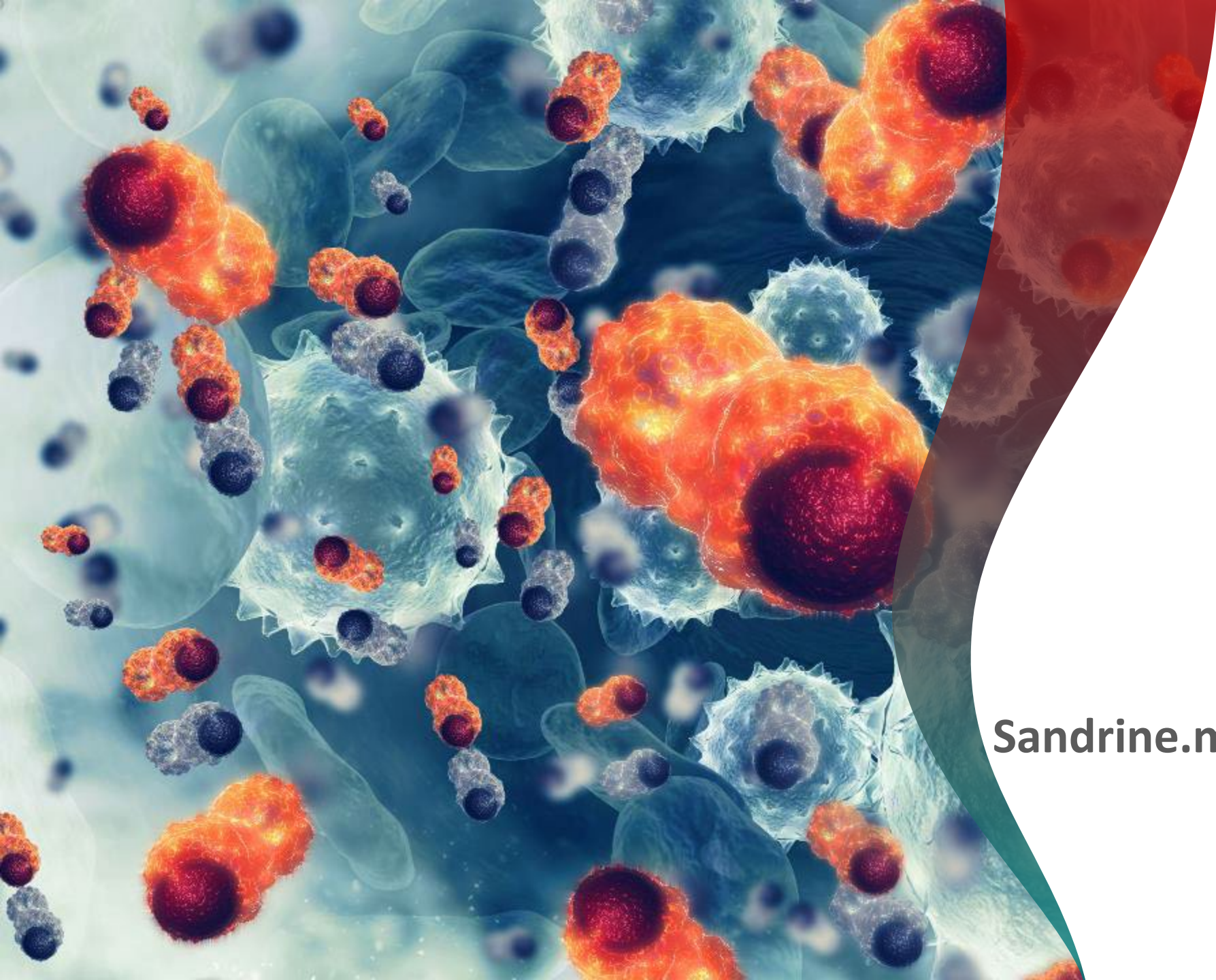
Rapid access to market

- ✓ Under LDT/CLIA, CAP certification
- ✓ Oncobiota^{LUNG} first assay to market with more following shortly



Upsides beyond Early Dx

- ✓ Metastasis Tissue of Origin project
- ✓ Partnership with Pharma on Clinical trial rescue

A microscopic image showing various cell clusters. Some cells are large and orange with dark, dense nuclei, while others are smaller and blue. The background is a light blue, translucent fluid. A large, curved, semi-transparent red shape is on the right side of the image, partially overlapping the text area.

Micronoma™

Questions?

Contact me:

Sandrine.miller@micronoma.com