
CALVIRI.
Let’s end cancer.

The Problem:
10 Million People Die from Cancer Each Year

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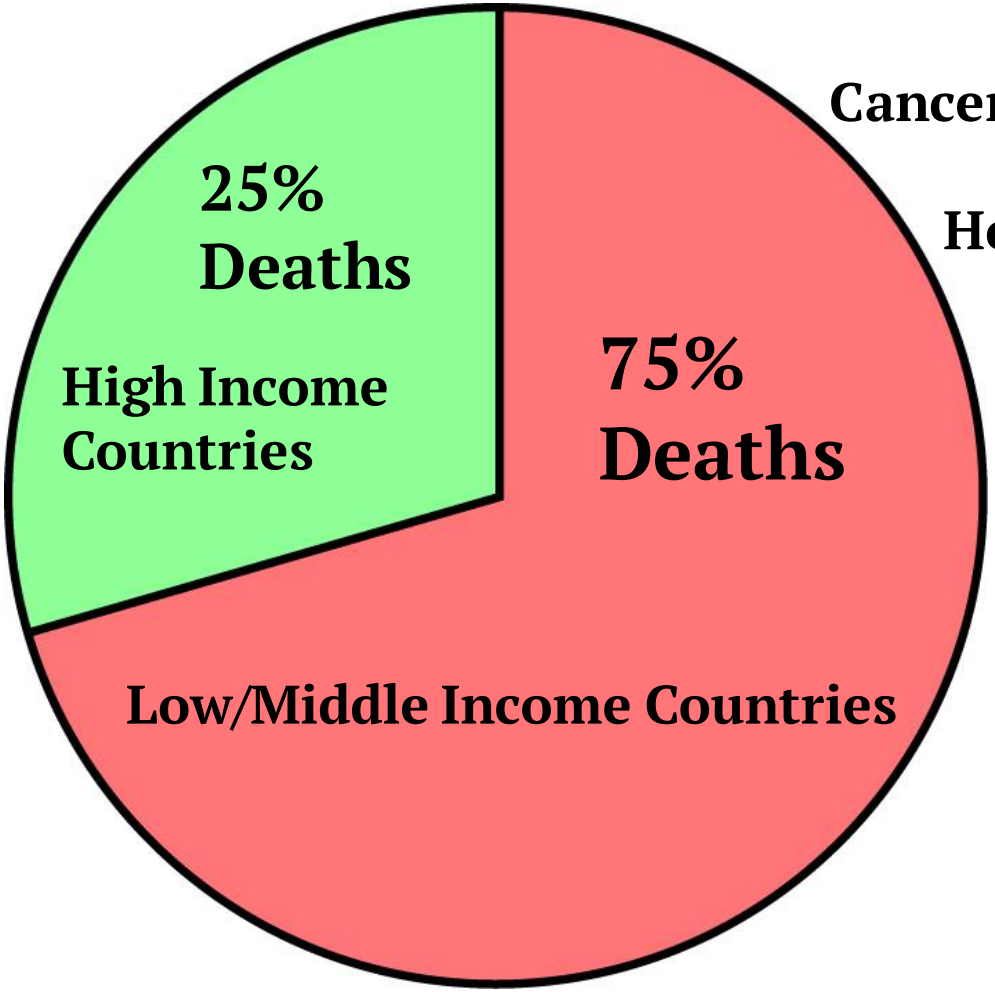


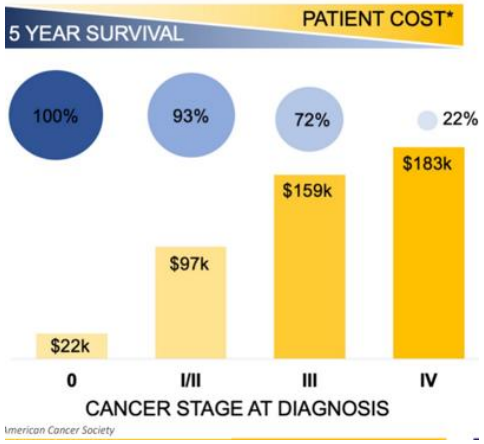
Cancer is an Ugly Disease

How Do We End it Worldwide?

Simple Solution:

1. Early Detection

Detect Cancer at Stage 1



We are Developing Simple, Antibody-Based Blood Tests for Cancer Screening

=The Only Tests with High Sensitivity for Stage 1 Cancers

2. Vaccine to Treat

Treat with Off-the-Shelf Vaccine

We are Developing Vaccines to Treat All Stage 1 Cancers

=The Only Pre-Made Vaccines for Any Cancer

1. Early Detection of Cancer

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<u>Challenge</u>:
Sensitive detection of cancers at Stage 1

<u>Calviri's Solution</u>:
Antibody Comprehensive Early Diagnosis (ACED) Arrays
=The only diagnostic with high sensitivity for Stage 1 tumors

Antibodies against tumor-specific peptides are highly informative biomarkers for early-stage cancer diagnosis

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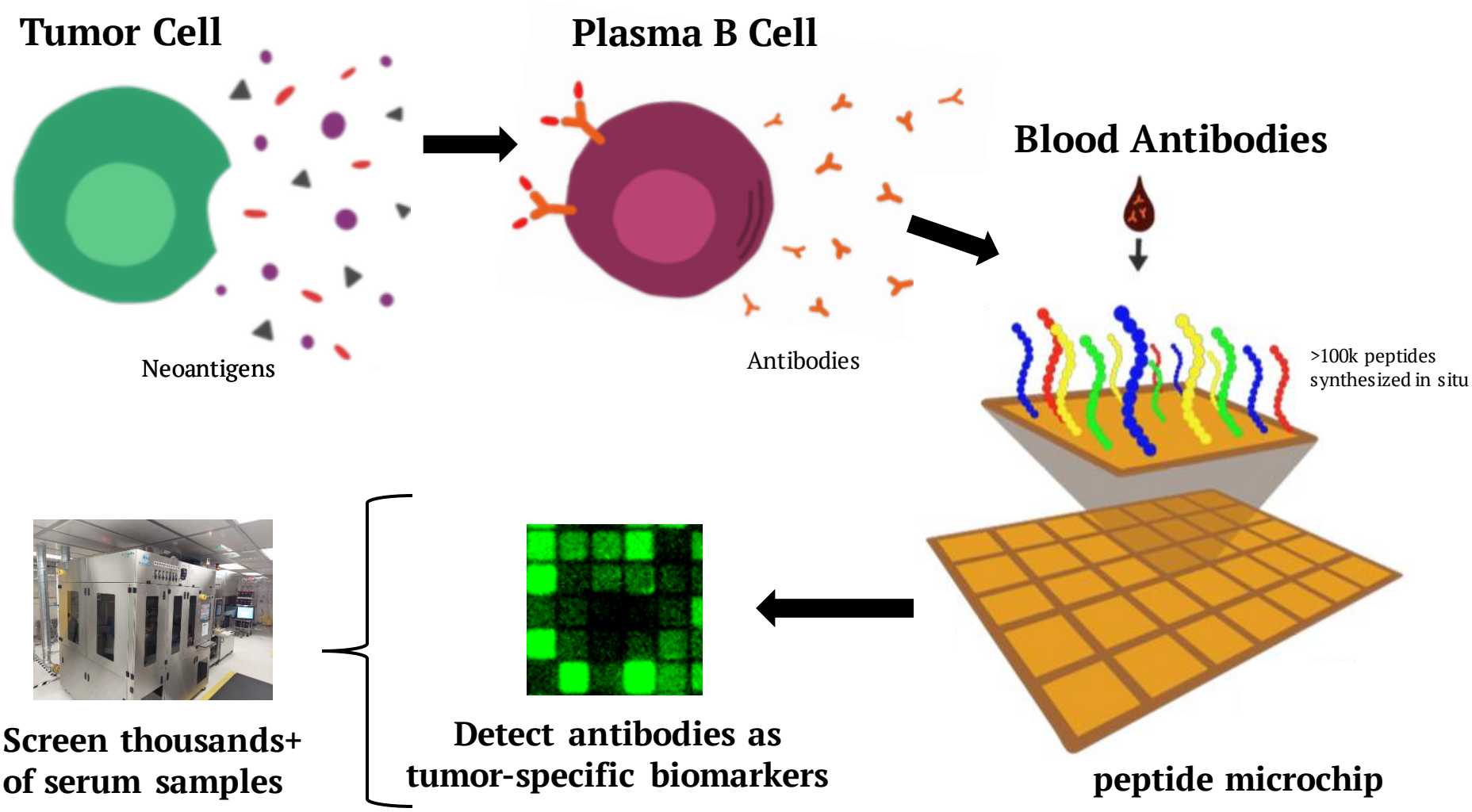

Diagnosis of Human Smoldering Multiple Myeloma

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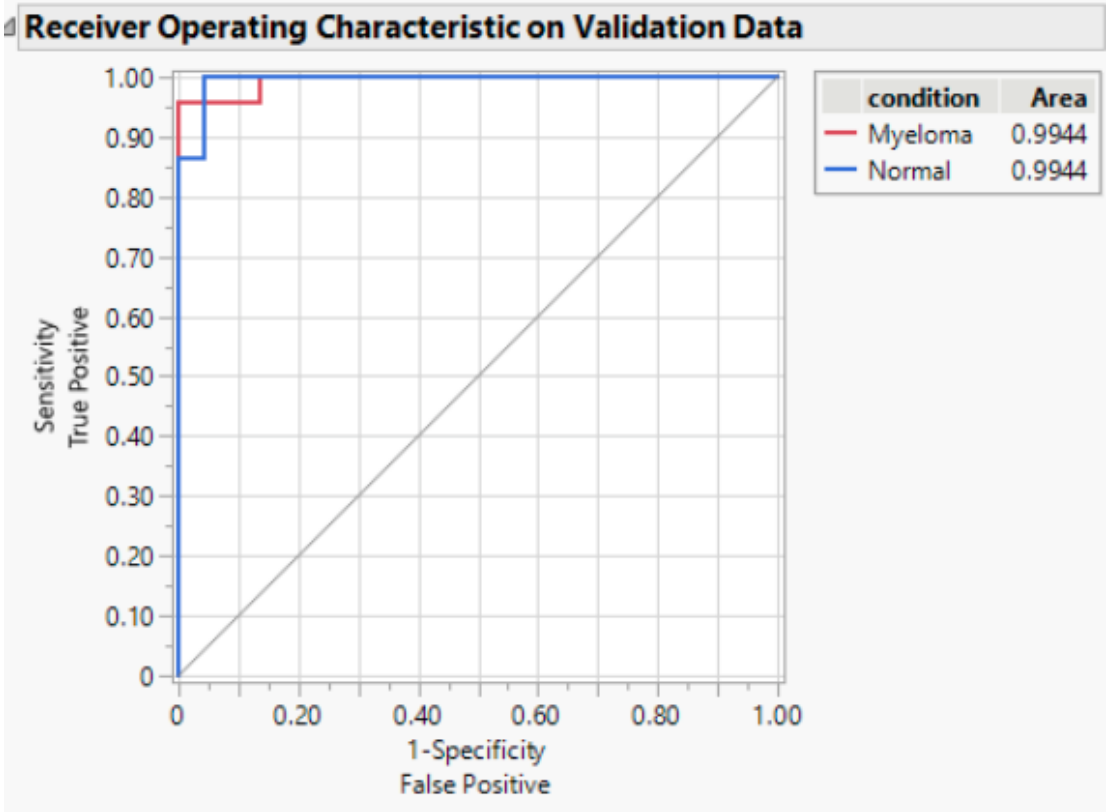
Validation test: model outcome



Model performance

100% sensitivity
95% specificity
95% accuracy

Early-Stage Diagnostic Competition

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Specifications	Calviri (Antibody)	Grail (ctDNA)
Sensitivity stage 1	>95%	<50%
Blood Volume	5µl (2000x less)	>10ml
Price	~$100	$1000

2. Multi-Cancer Therapeutic Vaccine for Stage 1 Tumors

- **Challenge:**

  Identify neoantigens shared across different patients and different tumor types

- **Calviri's Solution:**

  Discovery of a new source of shared neoantigens

  =Only Calviri can make a stage 1, multi-cancer vaccine

Calviri's Products are Based on RNA-Error Derived Neoantigens (REDNs)

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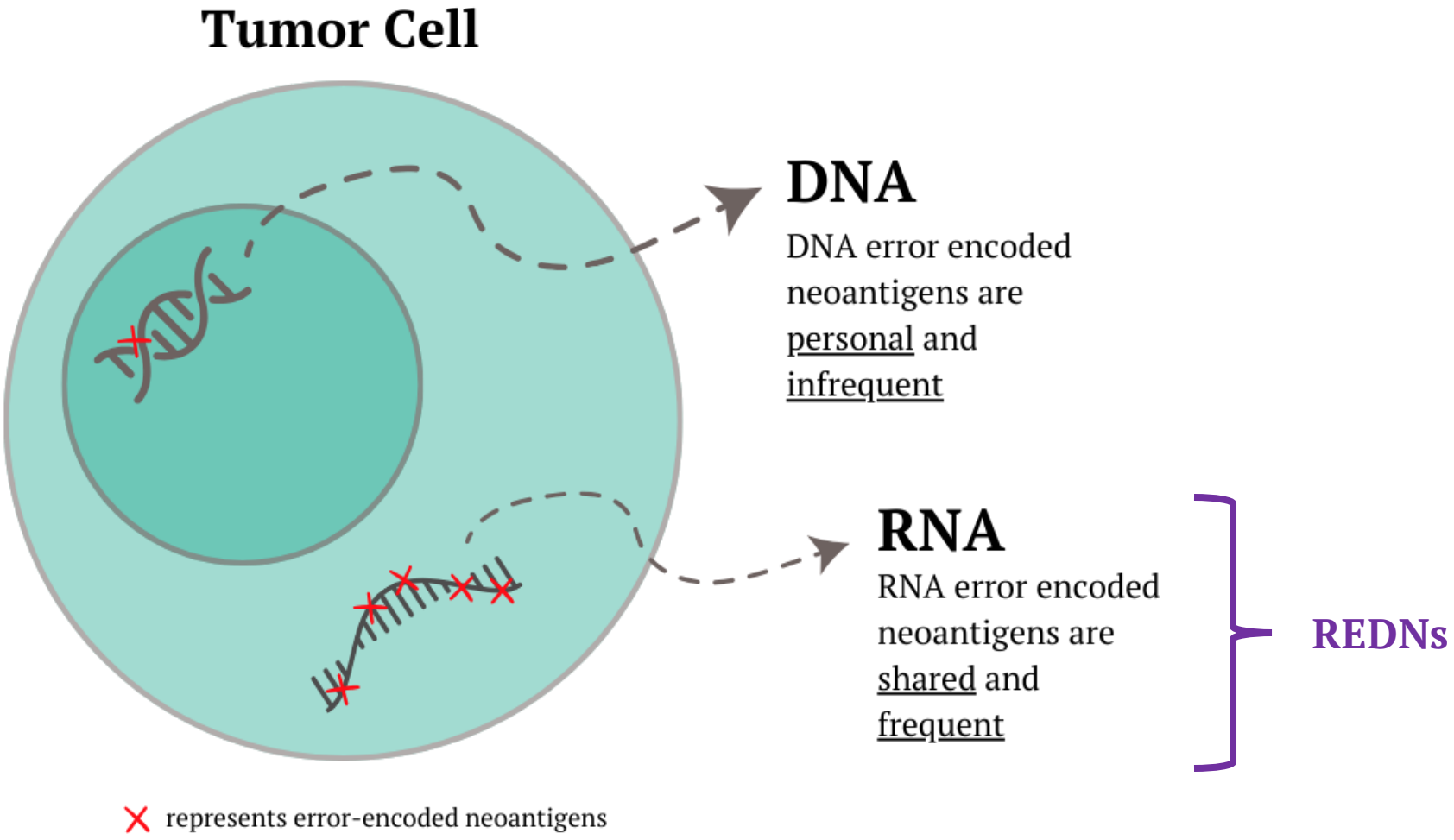

Our Pre-Clinical, Published Studies Show Potential of REDNs

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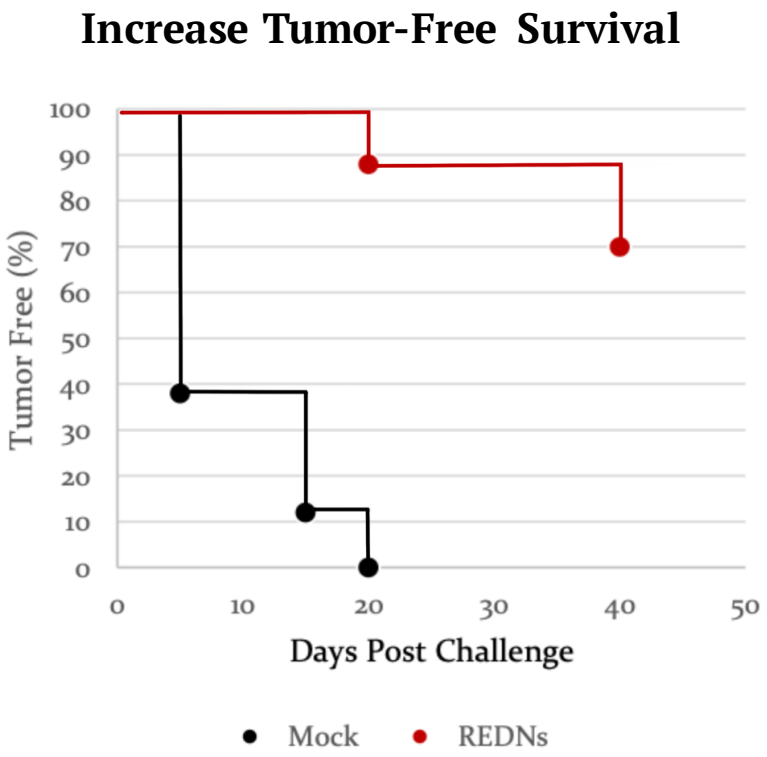
Three shared REDNs protect in multiple mouse models of cancer



Conclusion: Shared REDNs are ideal components for off-the-shelf (pre-made) cancer vaccines

Challenge: How to screen thousands of tumors for REDNs that are *Broadly Shared and Immunogenic*

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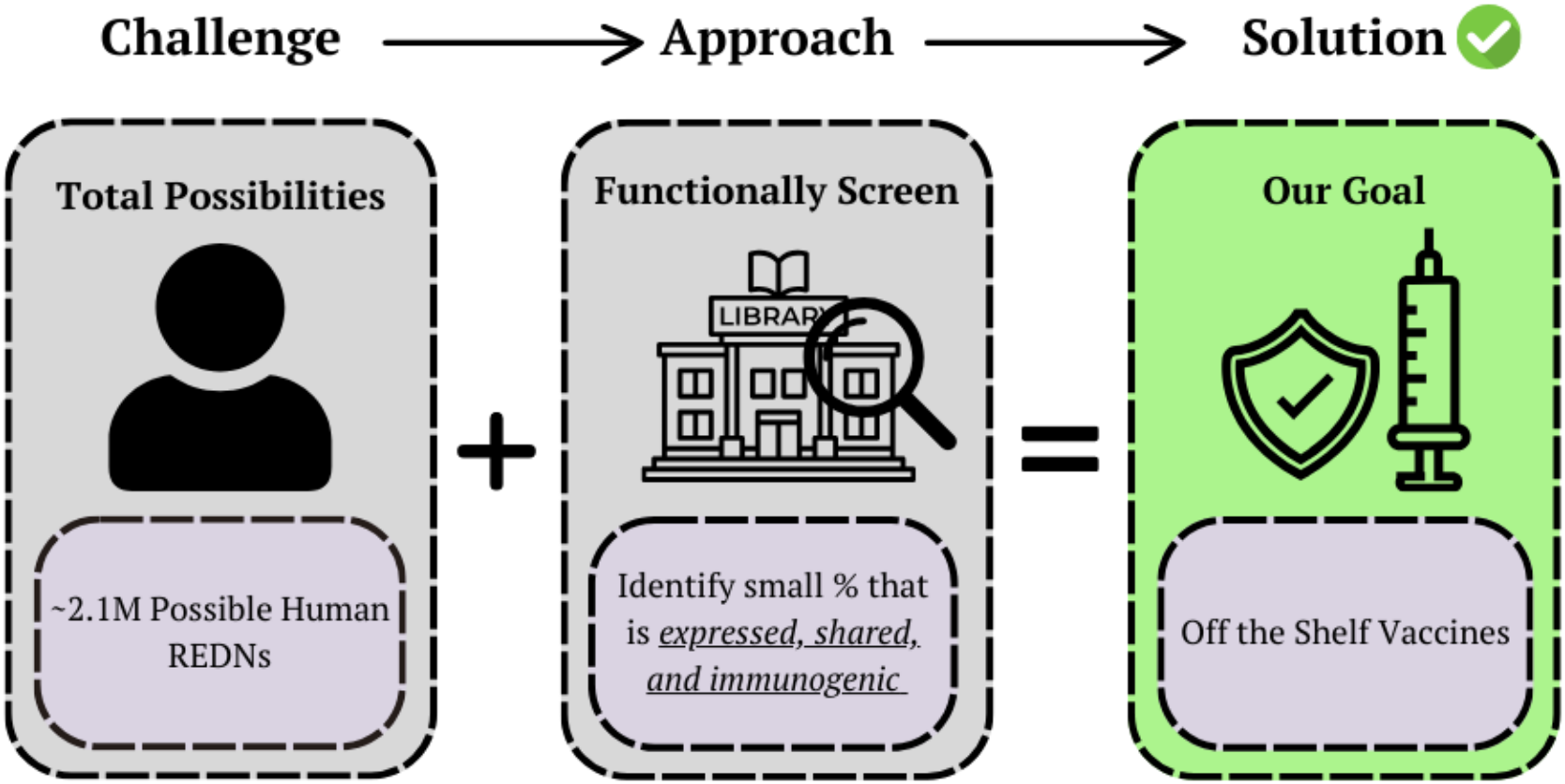

Solution: Screen for anti-REDN antibodies on REDN microchips

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Tumor Cell

Neoantigens

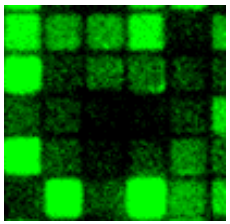
Plasma B Cell

Antibodies

Blood Antibodies

>1MM different REDN peptides synthesized in situ

Screen thousands+ of serum samples



Measure all neoantigens made by tumor

REDN Microchip

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Competition for Therapeutic Vaccines

CALVIRI	Moderna/BioNtec
Pre-Made	Personal
Simple	Months to make each
$1,000	$200,000
Any Stage, Including Stage1	Only Late Stage
NO ICI	Requires ICI

ICI = Immune checkpoint inhibitor, eg Keytruda

Only Calviri Can Produce a Pre-Made Vaccine for Stage 1 Tumors

Value of Calviri's Human Products (US only)

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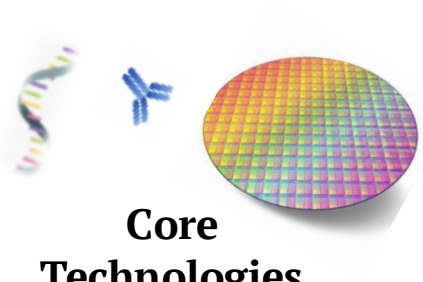
Product	Market	Price	Estimated Value
Human Stage 1 Therapeutic Vaccine	2M cancers/yr	$1000	**$2B**
Human Stage 1 Diagnostic Test	150M > 40 yro	$100	**$15B**
Total Estimated US Market Value			**$17.B**

Fastest Path to Getting Our Products to Humans is through Dogs

Calviri's Business Strategy: Dogs to Humans



Core Technologies & Discoveries

Enable

- Early-Stage Diagnostic
- Off-the-Shelf Therapeutic and Preventative Vaccines

- Demonstrate Safety
- Proof of Efficacy
- Early Revenues
- Regulatory: USDA for Vaccines
- No Regulatory for Diagnostics

2024-2026

Facilitate & Fund

- Human Clinical Trials
- Early-Stage Diagnostic
- Off-the-Shelf Therapeutic and Preventative Vaccines

2025→

Calviri is Developing a Multi-Cancer Diagnostic for Stage 1 Tumors in Dogs

Tumor type	Status
Mast Cell	**Done**
Osteosarcoma	**Done**
Soft Tissue Sarcoma	**Done**
Hemangiosarcoma	**Done**
Lymphoma	*In Progress*
Breast	*In Progress*
Melanoma	*In Progress*

Early Diagnosis of Dog Hemangiosarcoma (HSA)

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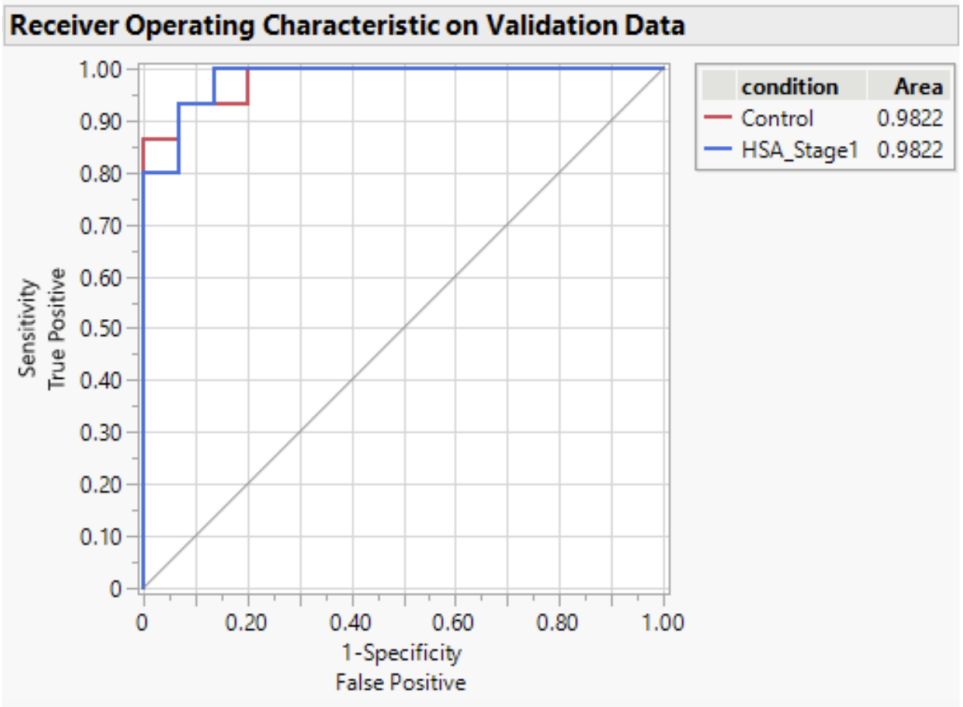
Accurate detection of canine stage 1&2 HSA

Validation test: model outcome



Model performance

100% sensitivity

87% specificity

94% accuracy

Early Diagnosis of Dog Cancers

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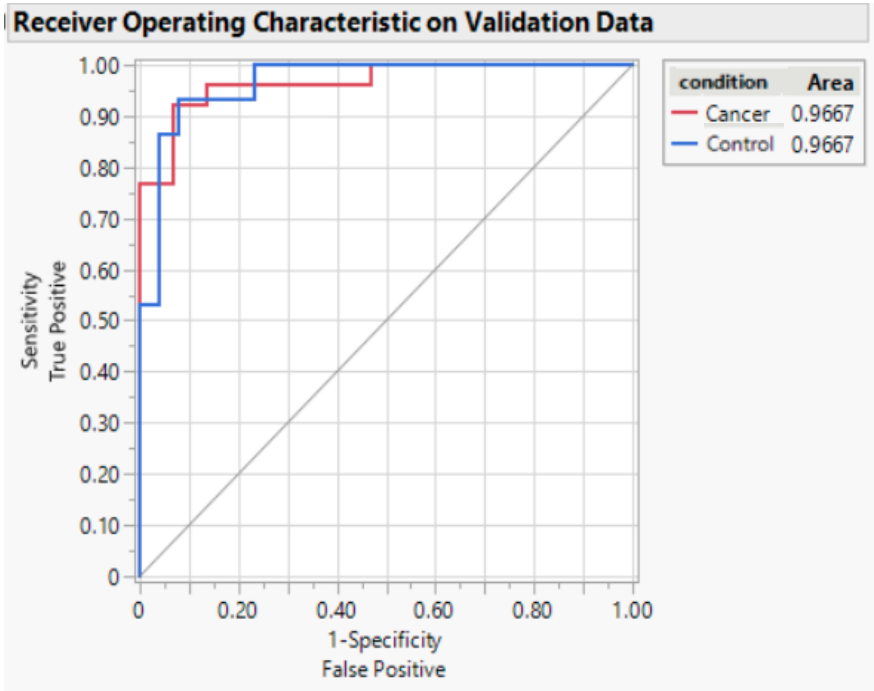
Accurate detection of early-stage canine cancers (MCT + HSA) vs. non-cancer

Validation test: model outcome



Model performance

96% sensitivity

87% specificity

93% accuracy

Calviri is Developing Multi-Cancer, Pre-Made Therapeutic and Preventative Vaccines

Vaccine Type	Status
Therapeutic, All cancers	Clinical Trial 2024-26
Preventative Vaccine, All cancers	Clinical Trial Done 5/2024 SAFE and EFFECTIVE

Calviri Tested a Vaccine to PREVENT Cancer in the World's Largest Dog Cancer Trial

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Biggest in the world

Calviri is conducting the world's largest study, Vaccine Against Canine Cancer Study (VACCS) among 800+ dogs
We are in the 5th year of the 5-year trial

All major cancers

Objective is to test the efficacy (over 5 years) of a preventative vaccine against the 8 most common cancers in a double blind, equal arms study

$6.4 million

Study funded by a $6.4M grant from
Open Philanthropy Project and Calviri, Inc.

800 dogs

804 Dogs Fully Enrolled
No Vaccine Safety Issue
Possible extension to 6 years

Clinical research sites

FLINT ANIMAL CANCER CENTER
COLORADO STATE UNIVERSITY

COLLEGE OF VETERINARY MEDICINE AND BIOMEDICAL SCIENCES
COLORADO STATE UNIVERSITY

UCDAVIS VETERINARY MEDICINE

SCHOOL OF VETERINARY MEDICINE
Advancing animal and human health with science and compassion

VACCS Preventative Cancer Vaccine Trial Tumor Results

HSA, Sarcoma and MCT (incidence)	Tumor			Total	
	Placebo	**Vaccine**		Placebo	Vaccine
Total*	**84**	**47**		389	375
6 Month Tumor**	**84**	**36**		389	364
30% NVR***	**84**	**25**		411	353

* Dogs in the vaccine arm developing tumors during vaccination were deleted

** Dogs in vaccine arm developing tumors in the first 6m were deleted

*** Vaccinated dogs that did not develop an immune response and had at tumor were included in the controls

Pre-Made_Vaccine Can Prevent Cancer Incidence and Death – Up to 70% Reduction

- **Improvements can be Made to Components and Delivery Method to Increase Vaccine Takes**

Value of Calviri's Dog Products (US only)

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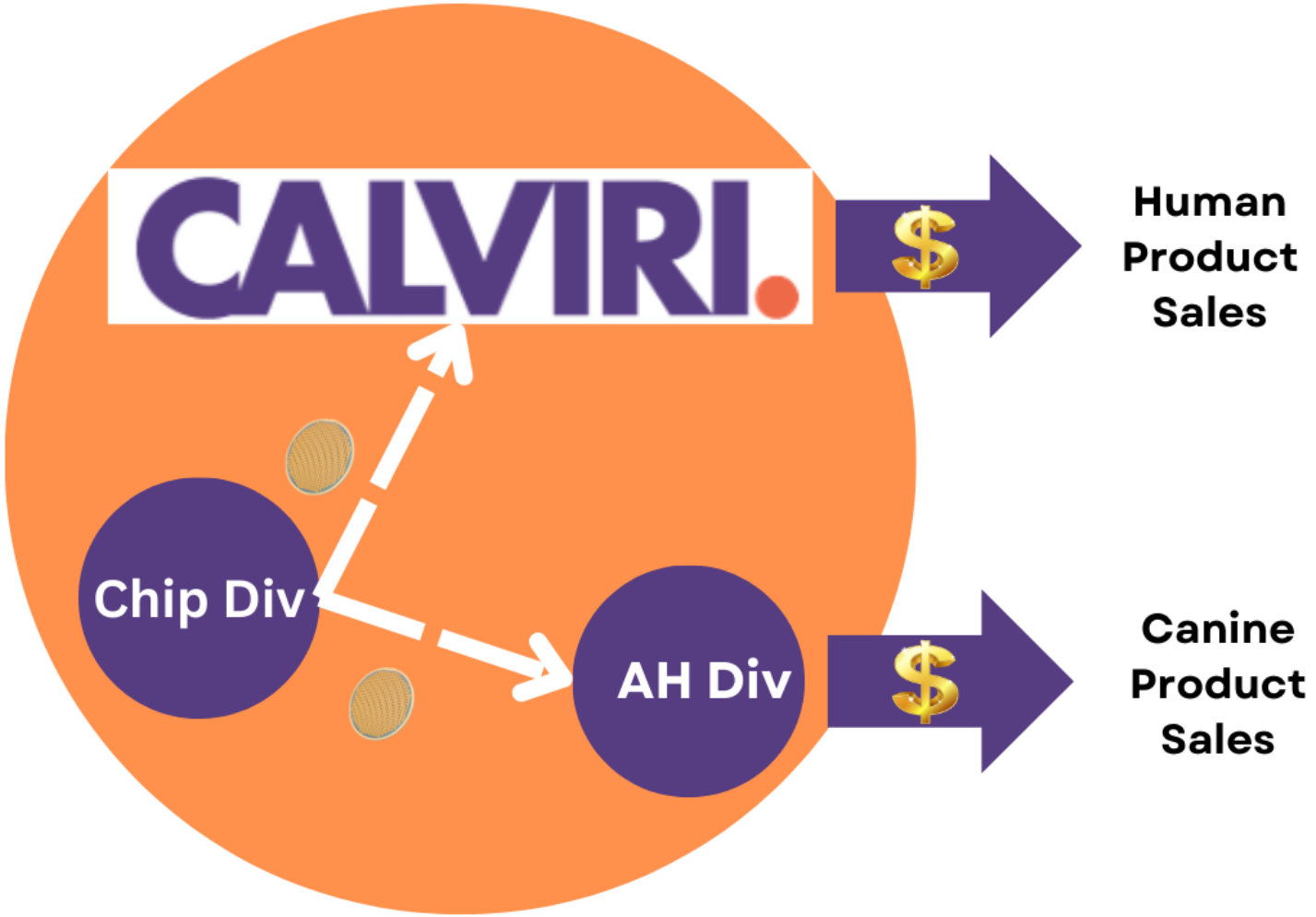
Product	Market	Price	Estimated Value
Dog Preventative Cancer Vaccine	45M > 5yro	$250 every 2 yrs	**$5.5B**
Dog Stage 1 Therapeutic Vaccine	6M cancers/yr	$250	**$1.5B**
Dog Stage 1 Diagnostic Test	45M > 5yro	$100 1/year	**$4.5B**
Total Estimated US Market Value : Animal Health			**$11.5B**

Business Plan



Calviri Will Bring Dog and Human Products to Commercialization and Control Chip Production

Calviri Today

- **Formed: 2018**
- **Funding: $24M (+ $6.4M non-dilutive)**
  Private Investors/Family Offices (30)
  Common Stock, No Debt
- **People: 25**
- **Business Development: Term Sheet Dog Therapeutic Vaccines**
  Term Sheet Dog Preventative Vaccine
  Negotiations with Diagnostic Strategic
- **IP: 60 Patents Granted/Pending for Diagnostics and Vaccines**
  Chip Production Protected by Trade Secrets

Major Near-Term (18 mos.) Milestones

- Commercial Sales of Dog Diagnostic
- Commercial Sales of Dog Pre-Made Preventative Vaccine
- Initiate Dog Pre-Mad Therapeutic Vaccine Trial
- Establish Scaled Manufacturing for Diagnostic
- Expand Management Team
- Large Scale Demonstration of Human Diagnostic

Leadership Team

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Existing

Stephen Albert Johnston,
Calviri CEO, Co-Founder,
60 patents, member National Academy of Inventors

Kathryn Sykes, Ph.D.,
Calviri V.P., Research & Product Dev't,
Co-Founder

Terrence O'Neil,
Calviri Director of Operations

Growth

COO

CMO

VP, BD

Board of Directors

Jeff Le Benger, MD
Calviri Chairman of the Board,
Executive Chairman of the board Summit Health

Kathryn Sykes, Ph.D.,
Calviri V.P., Research & Product Dev't,
Co-Founder

Michael McCallister
CEO & Chairman of the Board, Humana (retired); Board of Directors for Zoetis, Inc.

Stephen Albert Johnston,
Calviri CEO, Co-Founder, 60 patents, member National Academy of Inventors

Michael Chambers
Founder Aldevron
Former CEO and Chair of BOD

Jacque Sokolov, M.D.
Chairman at SSB Solutions; Phoenix Children's Hospital; GlobalMed; Veterans Accountable Care Group, LLC

Scientific Advisory Board

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John Ballantyne, Ph.D.

Founder / former SO of Aldevron
>23' years experience

John Ballantyne, Ph.D., has over 23 years of experience in the development and manufacture of DNA, RNA and proteins across the research, diagnostic and licensed drug product spectrum. He co-founded Aldevron (now a Danaher operating company) directly out of graduate school in 1998 and has served as its Chief Scientific Officer since inception. Much of his focus outside of industrialization of biologicals manufacturing has been dedicated to working with military researchers to produce countermeasures to high threat/weaponizable viruses and in the development of systems for "n of 1" therapies in the oncology space. Dr. Ballantyne also has an interest in the anti-cancer and molecular-adjuvanting properties of a novel class of superantigens and has supported the technical and clinical maturation of these moieties through his research and development group for over a decade. His areas of expertise include large-scale biologicals production, purification systems and novel ligand/matrix designs, pharmacokinetics, and clinical path forward design and support. Dr. Ballantyne received his undergraduate degrees in Pharmacy at the Central Institute of Technology and the University of Otago in New Zealand and his doctorate from the Department of Pharmaceutical Sciences at North Dakota State University.

Steven W. Dow, DVM, Ph.D.

Director of the Center for Immune and Regenerative Medicine at CSU

Steven W. Dow, DVM, Ph.D., is currently a professor of immunology in the Department of Clinical Sciences and the director of the Center for Immune and Regenerative Medicine at Colorado State University (CSU). The Dow Laboratory at CSU investigates tumor immune responses and develops new cancer immunotherapies. The laboratory also develops immunotherapies to prevent respiratory tract infections in cattle, dogs and cats, as well as for treatment of ocular viral infections and ocular cancer in horses and cats. A third program focuses on stem cell therapy for treatment of chronic infections and for wound healing, with studies in rodent models and pet dogs. Dr. Dow received his DVM from the University of Georgia and completed a residency in small animal internal medicine at Colorado State University. He then completed a PhD program in Comparative Pathology in the laboratory of Ed Hoover at Colorado State University. After that, Dr. Dow completed a post-doctoral fellowship at the National Jewish Center in the laboratory of Dr. Terry Potter, before joining the faculty of the Department of Clinical Sciences at CSU in 2002.

Stan Lapidus

Founding CEO of Cytyc Corp. and EXACT Sciences
Inventor and >35 years' experience

Stan Lapidus, is an inventor and entrepreneur who currently serves on a number of healthcare and medical technology boards. He was the founding CEO of three medical diagnostics companies. Two of them have been among the most successful diagnostics startups of all time: Cytyc Corp., which he founded in 1987, revolutionized early detection of cervical cancer through its development of the modern Pap test – the ThinPrep. The two ThinPrep prototypes are at the Smithsonian's American Museum of National History. EXACT Sciences, which he founded in 1995, pioneered non-invasive early detection of colorectal cancer through its Cologuard test. Since its introduction, Cologuard has become the fastest growing test in the history of the diagnostics industry. Stan holds 37 patents, primarily in methods for early detection of cancer. He served as an instructor at MIT from 2001 to 2017. Stan graduated from Cooper Union in New York City with a BS degree in electrical engineering.

Peter P. Lee, M.D.

Chair of Department of Immuno-Oncology,
Beckman Research Institute of City of Hope

Peter P. Lee, M.D., is currently the chair of the Department of Immuno-Oncology at Beckman Research Institute of City of Hope and a beneficiary of The Christopher Family Endowed Innovation Fund for Alzheimer's Disease and Breast Cancer Research in Honor of Vineta Christopher. He is co-leader of the Cancer Immunotherapeutics Program, professor in the Department of Hematology & Hematopoietic Cell Transplantation and the Billy and Audrey L. Wilder Professor in Cancer Immunotherapeutics. Dr. Lee received his medical degree at University of California San Diego and completed fellowships at both Stanford University and University of California San Francisco. The focus of his research is on understanding how cancer impacts host immune responses in patients, with the goal of developing novel treatments to restore/enhance immune function in cancer patients.

Terry A. McInnis, M.D., MPH, CPE

President / founder Blue Thorn Inc.
>25 years' experience

Terry A. McInnis, M.D., MPH, CPE, is currently President and Founder of Blue Thorn Inc. Dr. McInnis interacts nationally with government, providers, payers, academia, patient advocacy groups, and plans to help forge a more financially sustainable and quality enhanced delivery system. Dr. McInnis has over 25 years of senior executive and clinical experience in various employer, military (US Air Force - Flight Surgeon), and hospital/group practice health management segments. Prior to joining GSK, she was the Corporate Medical Director for Michelin North America where she helped engineer the redesign of the healthcare benefits for nearly 50,000 beneficiaries and worked as a committee member of the National Business Group on Health's- An Employer's Guide to Behavioral Health Services. Earlier as GE Power Systems Assoc. Medical Director and Health Care Manager, Dr. McInnis was responsible for the occupational health and employee programs in addition to the successful re-bid and risk-reward contracting of the medical benefits for all GE beneficiaries. Dr. McInnis received her Doctor of Medicine degree from Wake Forest Medical School being designated a NIH student clinical scholar. She completed a residency in Occupational Medicine as an OPSF scholar, and a MPH (high honors) at the University of Oklahoma. She is Board Certified in Preventive and Occupational Medicine, a Fellow of the American College of Occupational and Environmental Medicine, and a Former Course Advisor to the Department of Continuing Education of Harvard University.