

TOWN HALL TALKS

USC School
of Pharmacy



Two Unexpected *Transformative Healthcare Events* Precipitated by the COVID-19 Pandemic

September 15, 2020

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SSB Solutions, Inc.

USC Town Hall Talks – Presentation Overview

- **Introduction**

- Acceleration of Telemedicine Adoption – *GlobalMed*[®] Case Study

- Cancer ImmunoSignature Companies Lead “Next Generation”
Diagnosis and Vaccine Development – *CALVIRI* Case Study

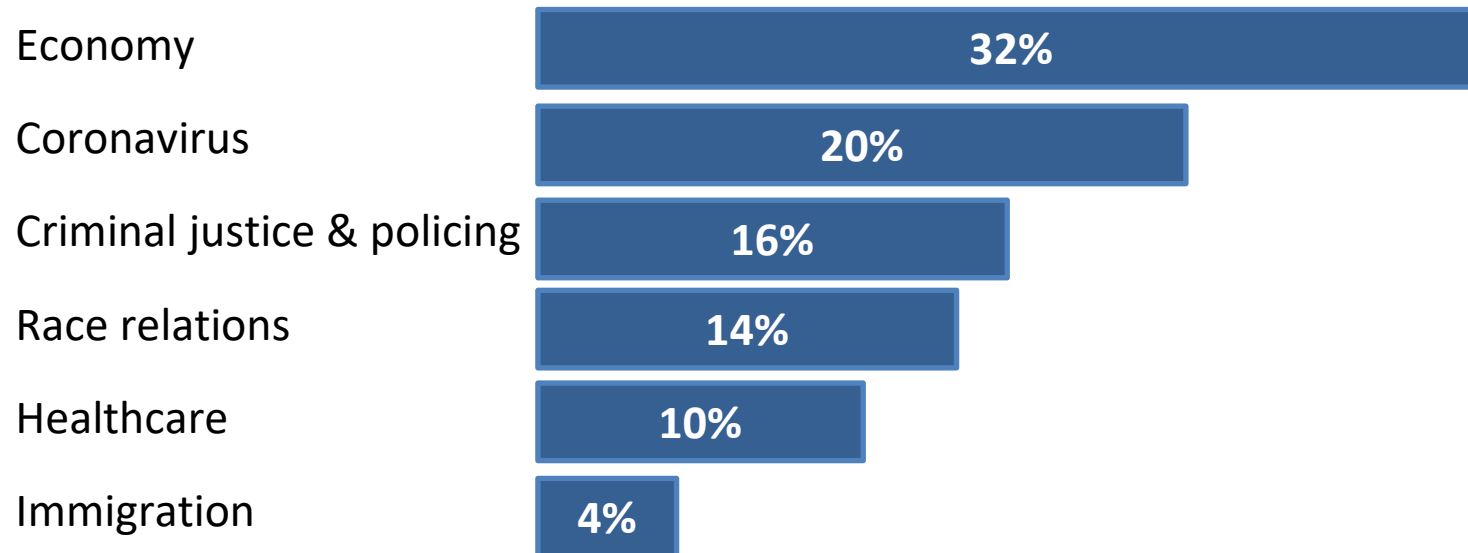
- Conclusions

Introduction

– Where You Stand Depends on Where You Sit

C. Everett Dirksen, US Congressman and Senator

US Electorate as of September 2020*



*Source: Kaiser Family Foundation Health Tracking Poll (conducted 8/28 – 9/3/2020).

Introduction

Two “Unexpected” Transformative Healthcare Events

– **The first unexpected *Transformative Healthcare Event* has been the successful “Acceleration of Telemedicine Adoption.”** The availability of Telemedicine has been technically feasible/available for 10+ years and 4 million tele-visits occurred in 2019 in the Veterans Administration Health system alone. The VA will see at least 10 million visits in 2020. We as a society will never completely go back to in-person healthcare as we knew it pre COVID-19.

– **The second *Transformative Healthcare Event* was precipitated by the gross under investment in antibiotics and infectious disease research solutions for at least the last 10 years. As a result, when COVID-19 hit all of the advanced immunotherapy diagnosis and vaccine work were largely focused on early cancer detection and cancer vaccines.** Cutting edge organizations such as Moderna, Pfizer, CALVIRI, etc. have used cancer ImmunoSignature capabilities for novel COVID-19 solutions. Thus, as a result, many “new” COVID-19 diagnostic tests and vaccines being produced are utilizing cancer knowledge and technology that were never originally intended for use in the infectious disease sector.

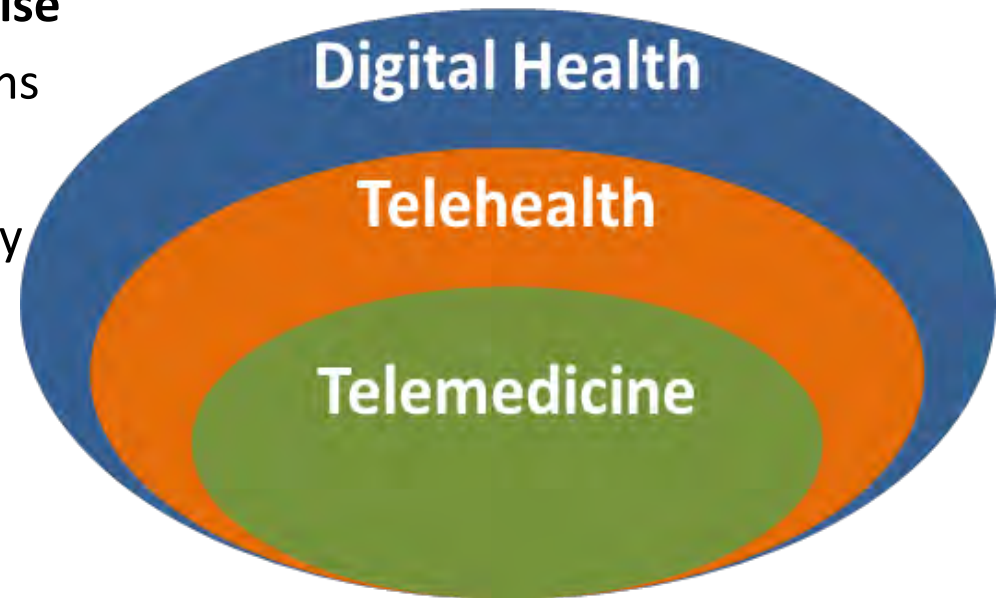
We will cover these unexpected events in two case studies involving: 1) **GlobalMed®** – The exclusive provider of telemedicine to the Veterans Administration (\$100 Billion/year health system) and 2) **CALVIRI** – One of the most advanced ImmunoSignature companies with advances in diagnosis and vaccine technology for cancer and COVID-19.

USC Town Hall Talks – Presentation Overview

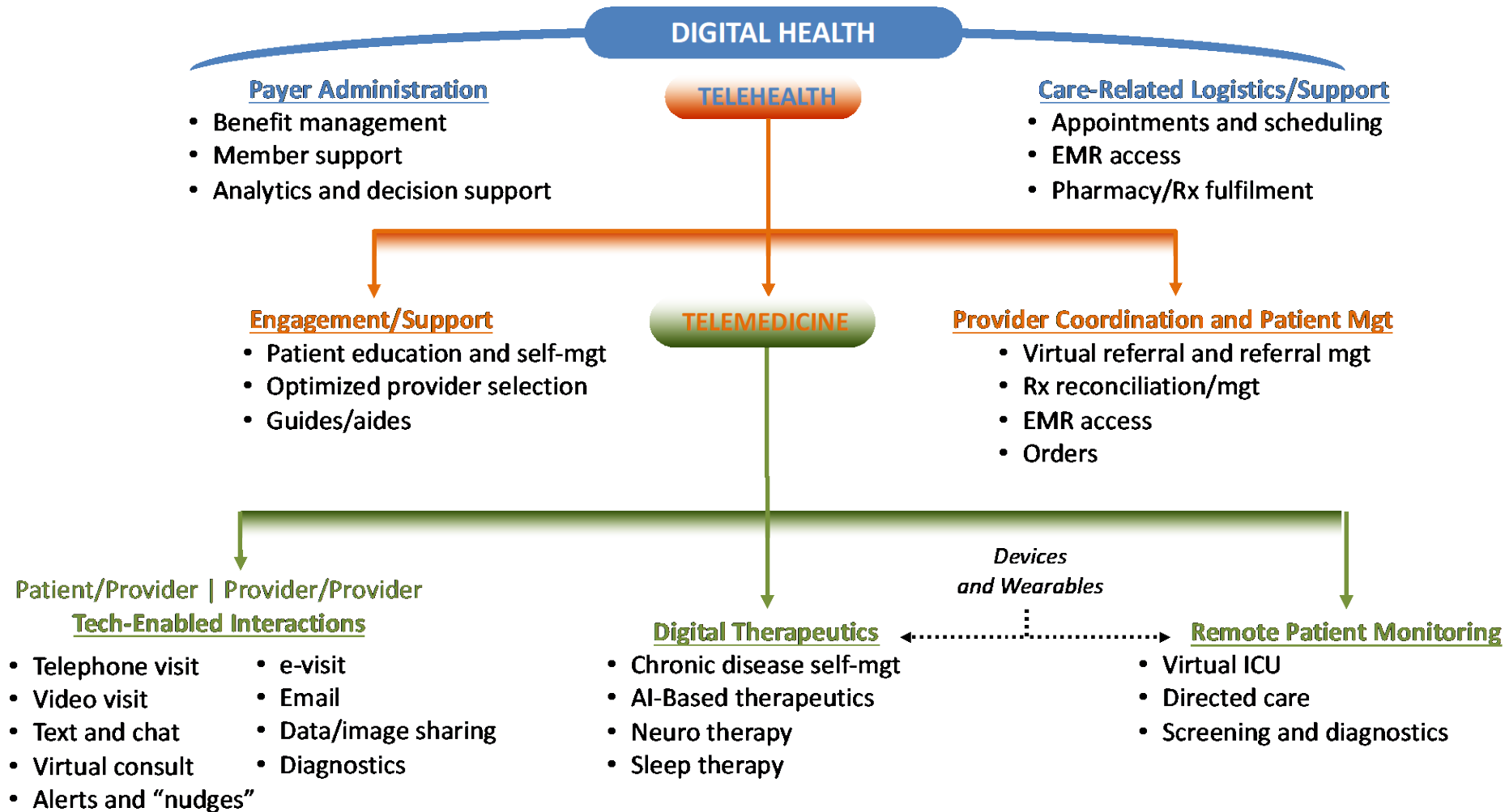
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Framework for Sorting Key Terms and Concepts

Despite a plethora of terms and definitions used by various stakeholders across the health care landscape, **there are not as yet standardized definitions for the collective set of tools, applications and technology-enabled services that comprise this growing arena of care delivery and support.** The terms “digital health”, “virtual care”, “telehealth”, and “telemedicine” are often used broadly and interchangeably referring to emerging tools and services helping payers, providers and patients manage health and health care.



Digital Health/Telehealth/Telemedicine



GlobalMed[®] Case Study

SEPTEMBER 2020

Two Unexpected Transformative Healthcare Events Precipitated by the COVID-19 Pandemic

Transparency of Presentation Content:

Board Member of *GlobalMed*[®] will discuss technology of this company.

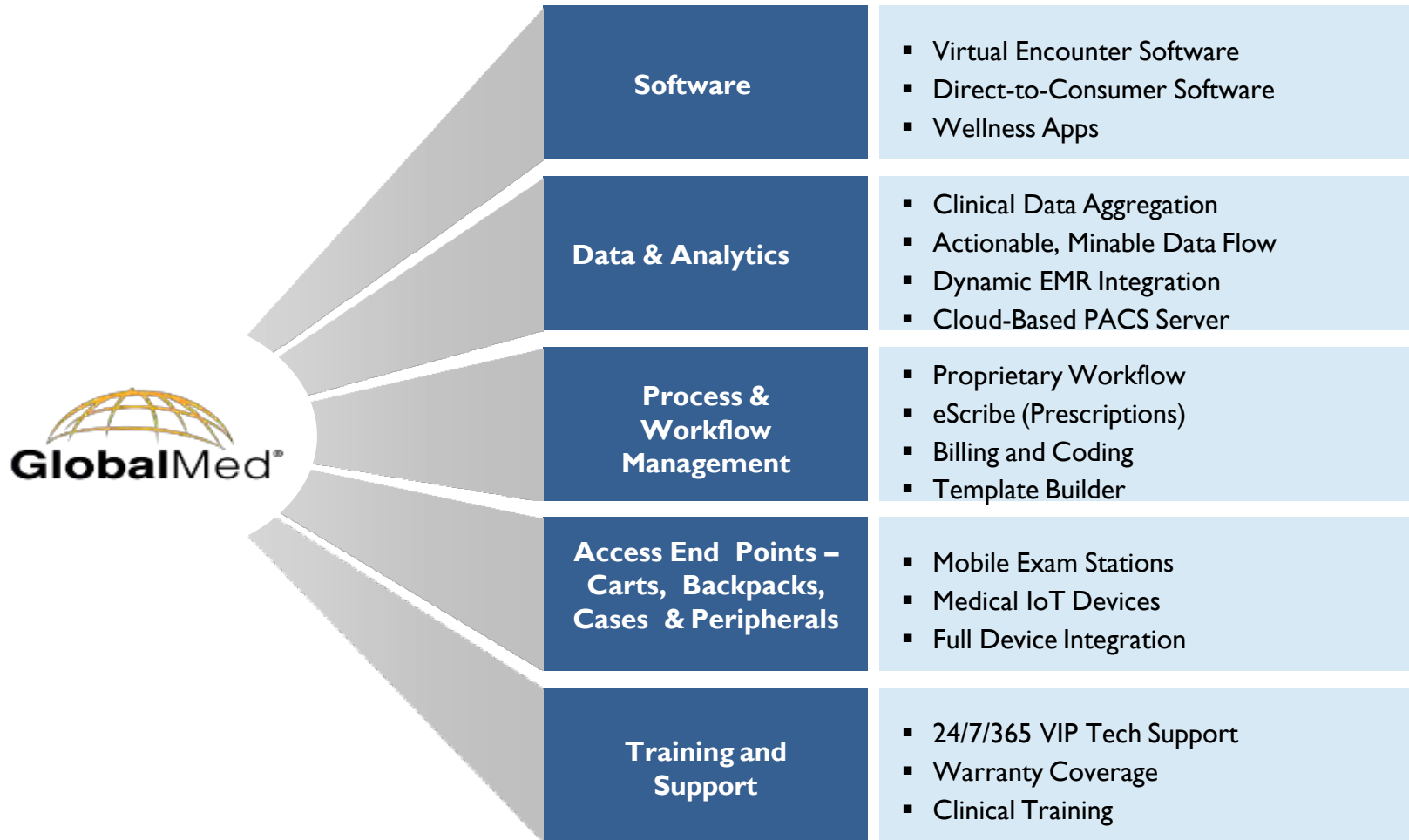
Advanced Complex Care Management Model

We have always known that 5% of the population consumes 50% of all healthcare dollars. These vulnerable populations need advanced complex care in order to deliver efficient and effective patient outcomes, which has been highlighted during the COVID-19 Pandemic.


Companies like *GlobalMed*[®] are the only "Advanced Complex Care Platforms/Technologies" that can address these patient needs and deliver "Hospital at Home", Single Site Complex Care, virtual Chronic Care Management, and the "New" Healthcare Digital Front Door.

GlobalMed® – Acute Complex Care Telemedicine

GlobalMed® empowers providers with data-capturing technology on one vertically integrated, real-time healthcare delivery system providing access to virtual care at any location




Highlights




~\$89M of R&D Spend to Date

DHA
Authority to Operate
The first Telemedicine Company with a U.S. Gov't Authority to Operate (ATO)


25
Software Developers Currently on Staff




U.S. Federal Government Security Standards



Configurable to Client Systems and Embedded Patient Data



Total Infrastructure Communication Capability Across Any Bandwidth and Domain



Comprehensive Suite of Best-in-Class Peripherals




Patient and Payor Pain Points Addressed

GlobalMed's platform addresses the crucial needs of vulnerable patient populations and payors

	Convenience	Access	Ease of Use	Best Possible Care	Connected Experience	Cost Savings
Pain points	<ul style="list-style-type: none"> Significant time and energy required to see physicians in person across multiple separate encounters 	<ul style="list-style-type: none"> Difficult to find right specialists or book appointments Physician shortage / access problem highlighted by COVID 	<ul style="list-style-type: none"> Clunky and difficult to access and use virtual care offerings 	<ul style="list-style-type: none"> Variance in care across providers and settings 	<ul style="list-style-type: none"> Data Siloed between different providers 	<ul style="list-style-type: none"> High rates of costly hospital re-admissions High Transportation costs
GlobalMed® Solutions	<ul style="list-style-type: none"> Virtual convenience eliminates travel and waiting time Multiple levels of care delivered in single encounter Easy links to follow-up and discharge through mobile application 	<ul style="list-style-type: none"> Fast access to the right specialists at the right time with no setting or location barriers Full care team coordinated around the patient 	<ul style="list-style-type: none"> Simple hyperlinks, single sign on and easy to use interface create seamless and error-free experience Provider and patient matched and connected as available 	<ul style="list-style-type: none"> Most advanced technology used to ensure data driven optimal health care delivery Technology removes geographic restrictions of seeing best-in-class providers opportunities and better outcomes 	<ul style="list-style-type: none"> Easy access to longitudinal view of patient history Relevant diagnoses, diagnostics, and imagery at provider's fingertips during encounter leads to better outcomes 	<ul style="list-style-type: none"> Reduce re-admission rates Reduce patient transportation costs Reduce length of hospital stays Reduce amount of inpatient services needed

Acute Complex Care Requires Best-In-Class Healthcare Access Stations and Peripherals

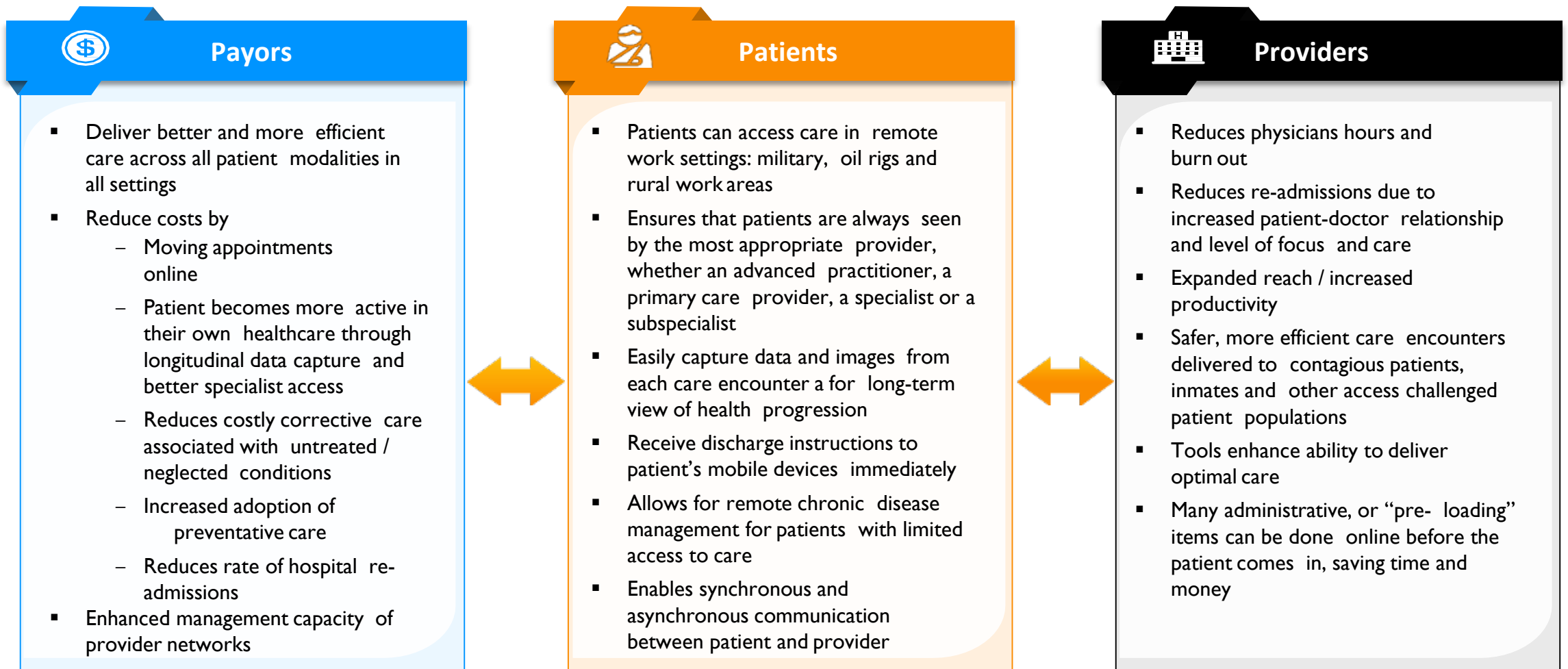
Highly engineered system stations for care encounters and integrated medical devices for real-time clinical data capture

	ClincialAccess Station® (CAS)					
System Stations						
Use Case	Work Horse	Lite Version of Work Horse	Space Saver	Mobile	Mobile / Home Health	Audiology Specific
Seamlessly Connects to Existing Infrastructure, Allowing Optimization of Future and Historical Investments						
	Exam Cameras	Stethoscopes & Spirometers	Ultrasound Devices	Vitals and ECG	Audiology	Dental Devices
Peripheral Devices	  	 	 	 		 
Select Use Cases	   	 	   	  	  	 

- Customizable healthcare delivery stations for broad virtual health needs
- Seamless connectivity between provider, software, delivery station, peripherals and data capture
- Broad array of use cases beyond traditional video consults
- Unique IP for certain medical device peripherals

Comprehensive Care Integration

GlobalMed® has a clear value proposition: its solutions enhance the outcomes and workflows of payors, patients and providers with the ability to manage the most acute complex care patients

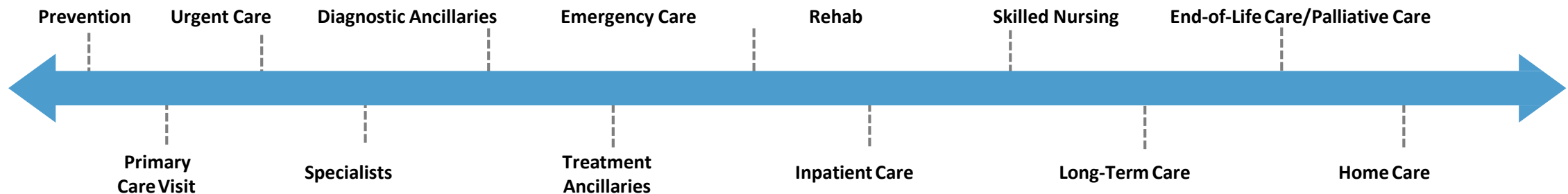


Transforming Care Delivery Across Settings

GlobalMed's® unique virtual care solutions are transforming care delivery across different care settings in the healthcare ecosystem

Healthcare Reform and Cost Reduction	Chronic Disease Management	Increasing Patient Consumerism	Population Health Management
<ul style="list-style-type: none"> ▪ Shift in payment models toward rewarding quality of care; risk sharing entities ▪ Providers incentivized to minimize costs while maintaining the highest quality of care ▪ Virtual Health a “Force Multiplier” for risk-bearing providers to manage at-risk population 	<ul style="list-style-type: none"> ▪ Efficient management of chronic patient’s health status and driving medical adherence ▪ Minimizing utilization of higher cost resources ▪ At-risk patients can receive more frequent, lower cost interventions and preventive care to improve outcomes 	<ul style="list-style-type: none"> ▪ Growing direct to consumer models address consumer demand for greater control and convenience of healthcare across the care continuum ▪ Virtual Health delivers convenient, quality care on demand ▪ Consumers more cost conscience as they utilize more healthcare services 	<ul style="list-style-type: none"> ▪ Expanded access to care for patient populations with limited access to the traditional healthcare system ▪ Improved care coordination, workflow, and patient journey ▪ Telehealth leverages provider resources more efficiently to improve outcomes

Offering the Best Care Throughout a Patient’s Journey



Telemedicine Industry Momentum

Favorable Industry Tailwinds in Virtual Care

Expanding Universe of Funding Sources	Increasing Provider Adoption	Proven Results	Disruptive Players are Finding Unique Ways to Deliver Care to Populations in Need	Expansion of 5G Can Improve Access to Care
<ul style="list-style-type: none"> Expanded Medicare coverage All 50 states and DC offer some reimbursement for certain virtual care offerings 42 states require commercial health plans to cover services delivered via virtual care 	<ul style="list-style-type: none"> 76% of US hospitals connected with patients and consulting practitioners at a distance through video and other technology in 2017 Adoption of virtual care services or solutions in inpatient settings increased to 85% in 2019 22% of physicians used video visits to see patients in 2019 	<ul style="list-style-type: none"> Intermountain Healthcare, Mayo Clinic, Jefferson Health and others have documented cost savings driven by virtual care In particular, Avera Health has noted significant findings across multiple areas of care using its eCARE platform 	<ul style="list-style-type: none"> As part of Best Buy's acquisition of GreatCall, aging adults and senior care communities now has access to Best Buy's Geek Squad MAVEN Project, a non-profit organization that uses virtual care technology to remotely connect experienced, volunteer, retired physicians with nurse practitioners, physician assistants and physicians at underserved clinics across the country 	<ul style="list-style-type: none"> By the end of 2024, ~270 million people in North America will have a 5G subscription Rural Digital Opportunity Fund The LIFT America Act

COVID-19 Crisis Momentum

- The unprecedented surge in patients during the COVID-19 outbreak stressed major telehealth providers' technical infrastructure and the supply of physicians prepared to deliver care
 - In the aftermath of COVID-19, hospitals and health systems will be looking to strengthen infrastructure and GlobalMed® is poised to take advantage
- The demand for In-Home Telehealth technology also skyrocketed
 - Face-to-Face visits by a physician or approved practitioner qualifying a patient for home health care may now be preformed via telehealth
- Providers and Policymakers are playing catch-up with telehealth technologies and are just beginning to recognize that they are essential solutions for the healthcare industry
- COVID-19 highlighted the lack of endpoints within hospitals to be able to implement telemedicine and access to broadband

GlobalMed's® Positive Impact on COVID-19

GlobalMed® is one of the few End-to-End platforms with proven and scalable capabilities to care for the world's most vulnerable

1

GlobalMed's® Positive Impact on COVID-19

<p>eNcounter® NOW a free simplified video conferencing solution that connects providers and patients</p>	<p>COVID-19 Resource Hub a repository of education to track and share the latest telehealth news, policy, and reimbursement changes with prospects and customers</p>	<p>30-Minute Free Consultations expert guidance for a simple video standup to complex deployments and unique use case exploration</p>	<p>Protecting Our Essential Workers we have established safe distance guidelines for production workers, provided private workspaces for high-risk employees, installed hand sanitizer stations, provided disinfectant sprays/wipes in addition to masks and gloves. Implemented a 72 hour quarantine on all shipments received from COVID-19 epicenters</p>
<p>Clinical Guidance adapting to changing best practices in patient care led by Dr. Dean Smith, MD, Chief Medical Officer</p>	<p>Grants and Scholarships assistance with filing for FCC and other telemedicine grants</p>	<p>COVID Credits new customers receive reduced implementation fees, free licenses</p>	

2

Rapid COVID-19 Mitigation Partnership Model

GlobalMed® responded quickly to COVID-19 mitigation efforts forming a three-way partnership with Let's Talk Interactive (Medical Group) and the State of Florida

- Combining clinical resources, technology and support from three organizations to provide timely support for local and state-wide response to COVID pandemic
- Partnership efforts focused on using telemedicine to:
 - Quickly and efficiently divert seniors away from hospitals to alternative sites of care for non-COVID health issues that can be managed in an ambulatory or home-based setting
 - Extend capacity of healthcare workforce by enabling self-quarantined healthcare providers to continue to practice virtually from home



- Partnership participants and Roles:
 - GlobalMed®**: Telemedicine access stations, software, training, and support
 - Let's Talk Interactive**: Clinical services and providers to support virtual consultations
 - State of Florida**: Department of Preparedness

The Impact of GlobalMed's® Platform on COVID-19

- Isolate, monitor, and track infected patients
- Protect physicians and Advanced Caregivers
- Reduce transport and demand on first responders
- Earlier intervention and more frequent visits
- Reduce risk and offer care to exposed staff
- Keep hospital beds open for critically ill
- Connect families to patient and provider
- Save lives and significantly reduce costs



Conclusion:

The acceleration of telemedicine adoption at multiple levels all the way from HIPAA compliant “FaceTime” to Advanced Complex Care Solutions such as GlobalMed[®] has reset the expectations across the entire Digital Health spectrum of care. Patients, providers and payors will ultimately find a new equilibrium but no one is looking to the future of healthcare that does not include a substantial role for Telemedicine.

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CALVIRI

Case Study

END DEATHS FROM CANCER

Revolutionary Discoveries and Inventions for New Diagnostics and Vaccines for Cancer

Transparency of Presentation Content:

Board Member of CALVIRI will discuss technology of this company.

RNA and COVID-19 Vaccines:

A Strange Turn of Technologies

In 1992 the First Report of Gene/Nucleic Acid/DNA Vaccination Offered to Revolutionize Vaccines

nature

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Journal information ▾

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Published: 12 March 1992

Genetic immunization is a simple method for eliciting an immune response

De-chu Tang, Michael DeVil & Stephen A. Johnston

Nature 356, 152–154 (1992) | Cite this article

443 Accesses | 1198 Citations | 12 Altmetric Metrics

Abstract

To produce an immune reaction against a foreign protein usually requires purification of that protein, which is then injected into an animal. The isolation of enough pure protein is time-consuming and sometimes difficult. Here we report that such a response can also be elicited by introducing the gene encoding a protein directly into the skin of mice. This is achieved using a

Introduction of a plasmid encoding a foreign Protein creates an immune response.

Vaccines would be simple and inexpensive

Their production would be standardized

New vaccines could be developed very quickly

No cold chain required.

Gene Vaccines Were IDEAL

But Gene Vaccines Encountered the “Simian Barrier”

They Work Great in Any Animal



West Nile Virus Vaccine

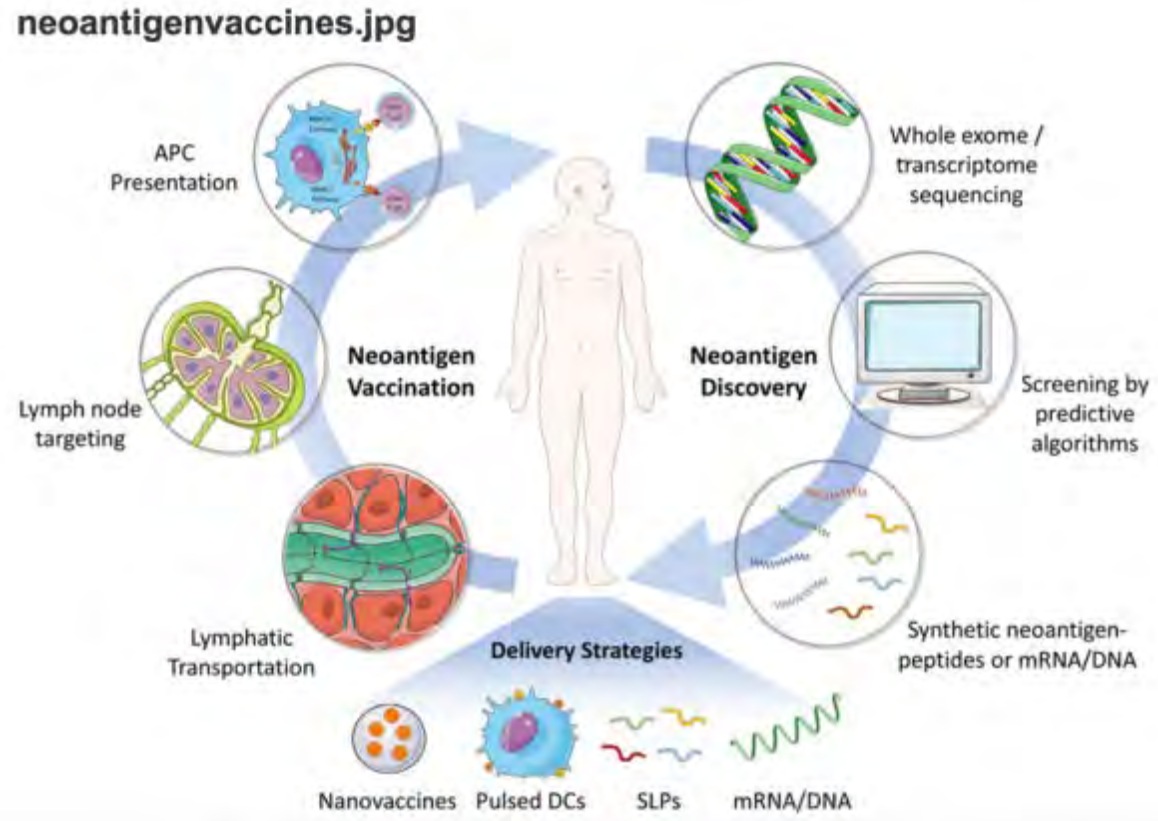


Melanoma Cancer Vaccine

Except Humans and Monkeys. 100s of Clinical Trials, NO Success

Solution: Skip the DNA, Go Straight to RNA

Personal Cancer Vaccines Strategy of Moderna/BioNtech



Faced with Needing to Make Vaccines for Each Person Fast

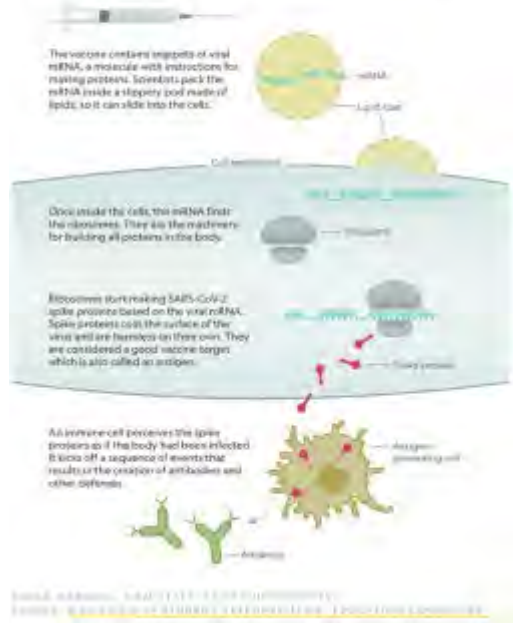
Moderna/BioNtech Developed Technologies To Quickly Scale RNA Production

COVID-19 Strikes: Project Warp Speed for Vaccine

Two Leading COVID-19 Vaccines are RNA-based From Cancer Vaccine Companies

The promise of mRNA vaccines is changing how we think about COVID-19 immunization.

The most traditional methods of vaccine development introduce the body to either an inactivated or weakened form of a virus or to one of its viral proteins. The immune system responds by producing antibodies that recognize particular proteins of the virus. These antibodies could fight future infections as long as the virus doesn't evolve. mRNA vaccines take a novel approach that has never been licensed for human use. Their development is faster as it bypasses the more laborious tasks of inactivating viruses or isolating proteins.



Pfizer, BioNTech start their COVID-19 vax phase 3

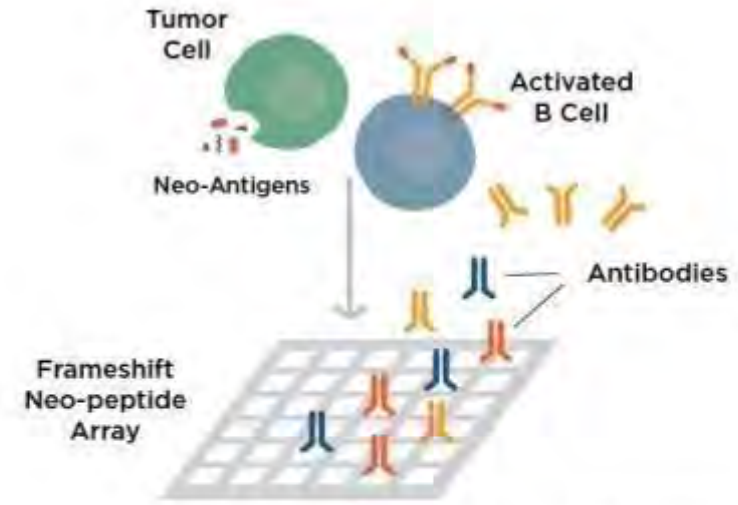
Moderna Announces Phase 3 COVE Study of mRNA Vaccine Against COVID-19 (mRNA-1273) Begins

CALVIRI Capitalizes on RNA Frameshift Errors to Make New Products Against Cancer

Approach

- Tumor cells release frameshift peptides, which are neoantigens to a patient's immune system; B cells produce antibodies specific to the neoantigen
- CALVIRI produces microarrays with all possible RNA-error generated frameshift peptides, and a small sample of patient blood is applied
- Peptide/antibody binding profiles associated with a cancer serve as a diagnostic; bound peptides serve as compositions for both therapeutic and preventative cancer vaccines

Cancer Detection Platform



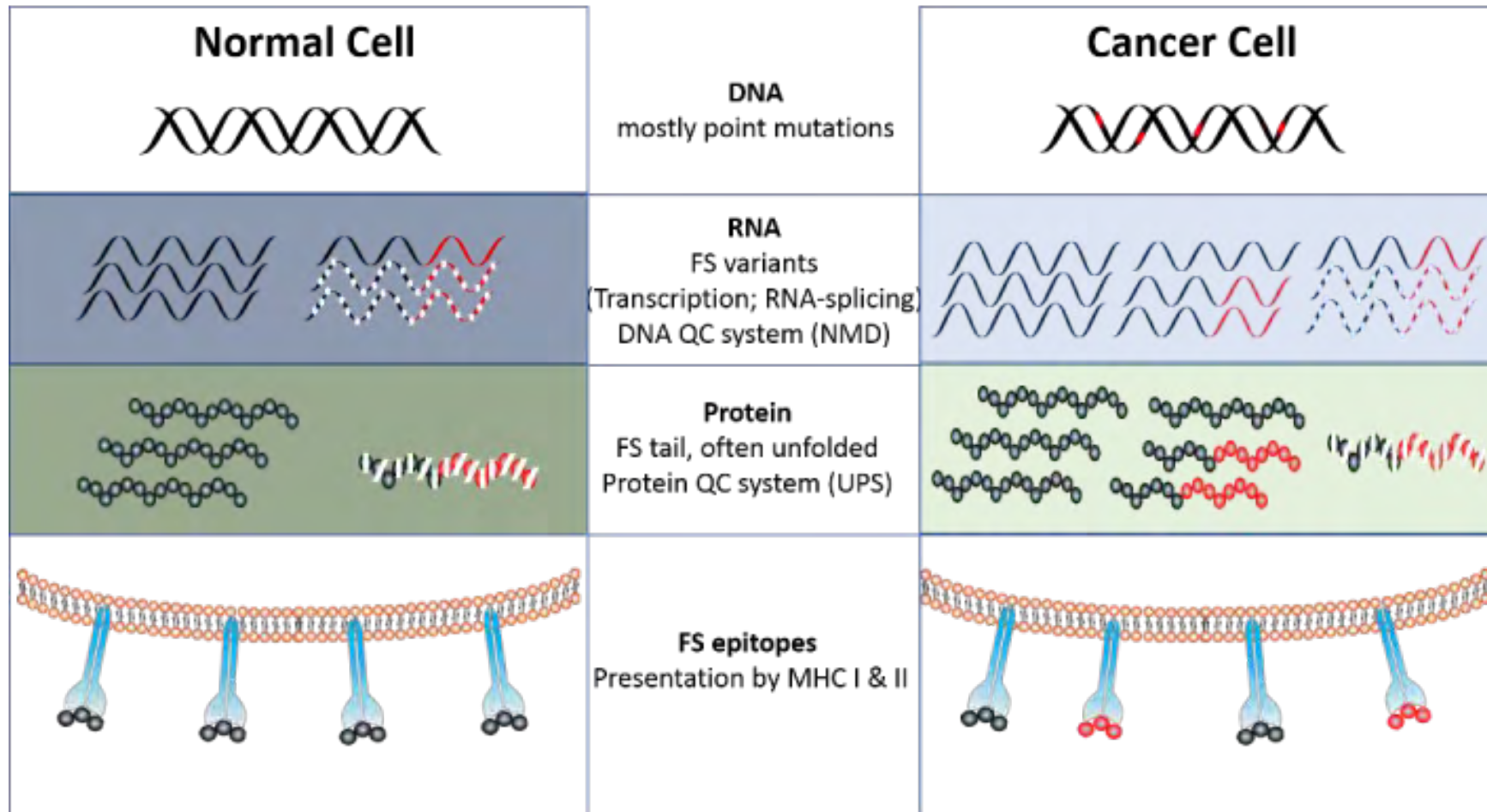
APPLICATIONS



RNA and COVID-19 Diagnostics:

**Technology for Early Detection of Cancer
Pivots to COVID-19 Diagnostics**

Early Detection of Cancer Made Possible by Discover of Recurrent RNA Variants in Tumors

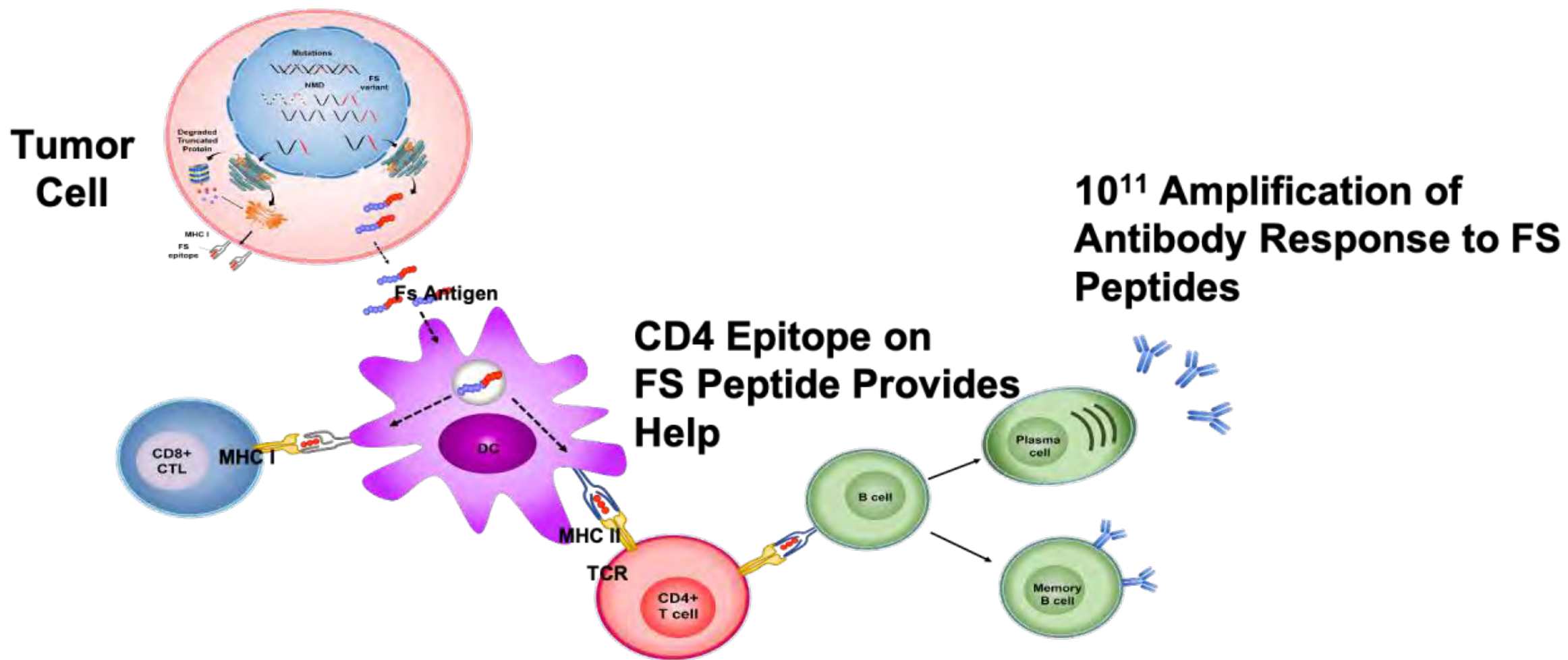


IN TUMORS:

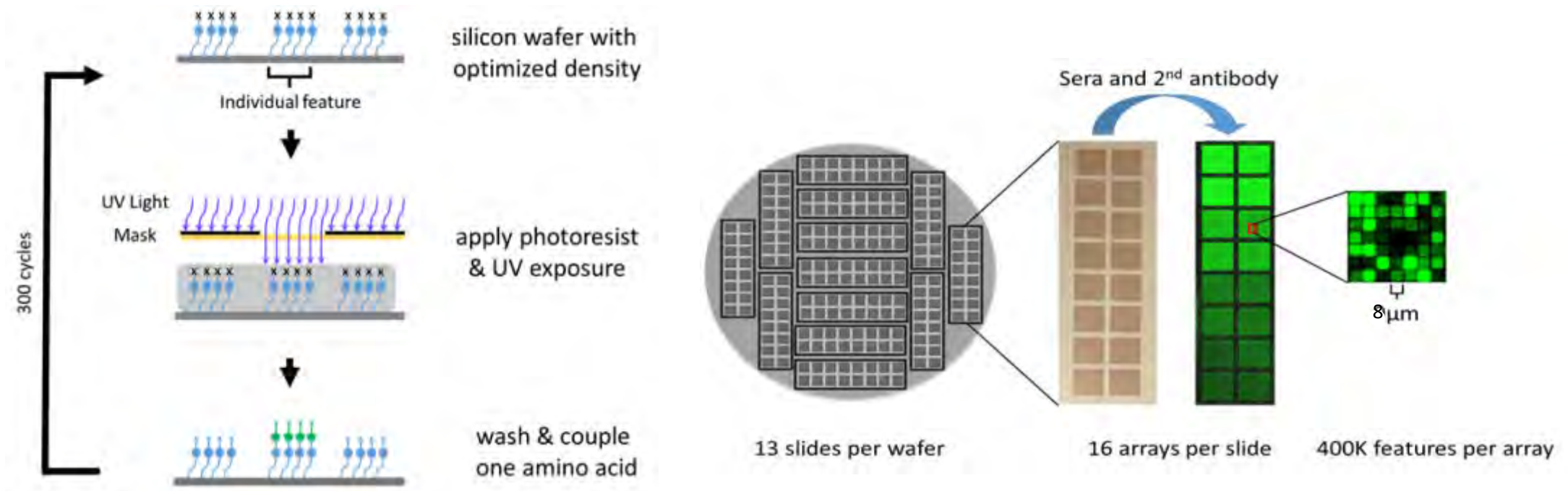
DNA Mutations are Personal

RNA Variants are Recurrent

Antibodies are Produced in the Patient to the RNA-based NeoAntigens



ImmunoSignature Peptide Arrays Can Capture All the Diversity of Antibodies to Tumor Peptides



- Peptides are synthesized on **silica wafers** by photolithography
- Each array displays 400,000 peptides spanning ~220,000 potential FS neoantigens

ARRAY

- Wafers are diced into silica slides that enable 64 arrays to be assayed in a single cassette
- Workflow resembles that of an **ELISA**

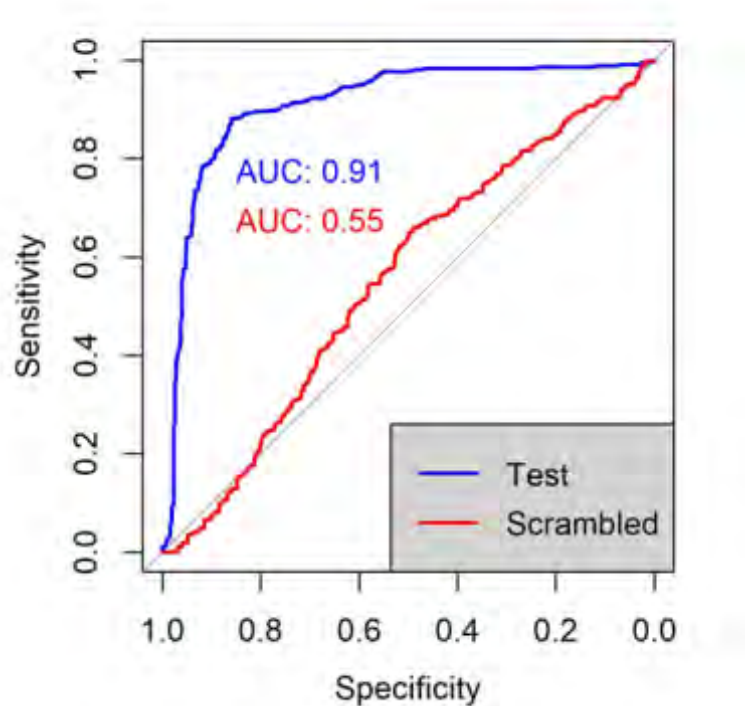
ASSAY

- Peptide bound antibodies are detected fluorescently and quantified by a scanner
- The **digitized immune response** is analyzed

ANALYSIS

ImmunoSignature Arrays Can Detect Cancer, Including Early Disease

ROC* Curve Analysis: Detection of Stage 1 Breast Cancer vs. Non-Cancer



Results: **91% Accuracy** 42 Cancer, 42 Control
 Analysis: 10-fold cross validation by SVM with 500 selected FSPs

*ROC: radio operator characteristics

Performance Summary

Cancer Diagnosed	# of Cancer Serum samples/# of Controls	Stage Cancer	Accuracy
Breast	64/40	Pre-Stage I	95%
Breast*	42/42	Stage I	91%
Colorectal	30/20	Stage I-IV	96%
Pancreatic	29/42	Stage I-IV	98%

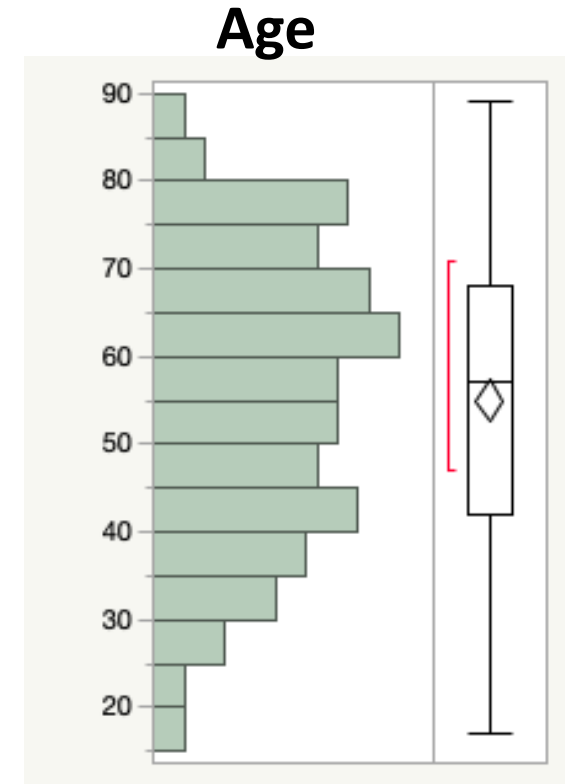
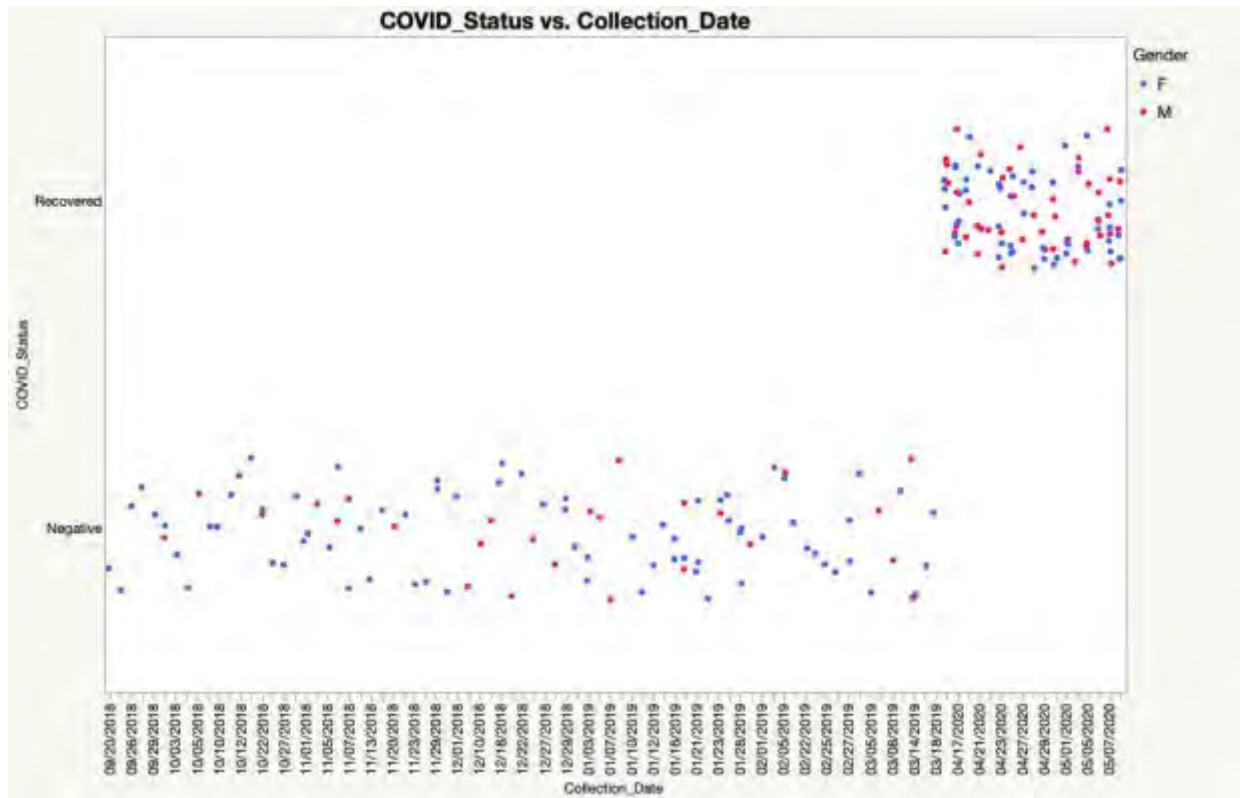
* ROC Curve shown on left

NB: Statistics From Leave-One-Out Retesting with selected signature FSPs, Due to Small Sample Size.

COVID-19 Strikes: Rapid Need for Serological Diagnostics

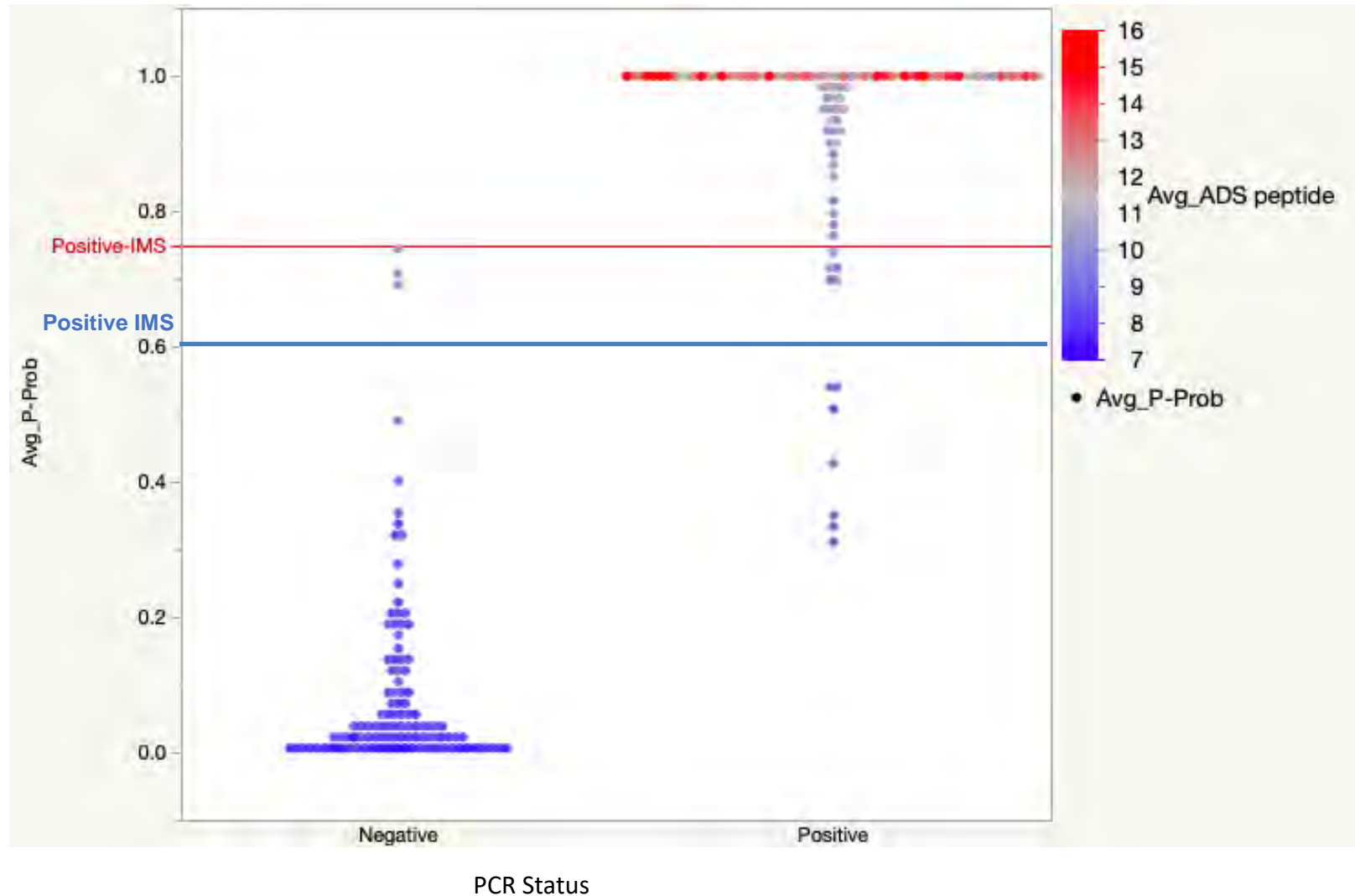
Who Has Been Exposed and What Will Happen To Them?

ImmunoSignatures Are Directly Applied to COVID-19 Diagnosis



- **PCR Positive samples were collected from convalescent donors 28 days post positive test**
- Negative plasma samples (n=100) collected from 9/20/18 to 3/18/19 by Bloodworks NW
- SARS-CoV-2 positive plasma samples (n=100) collected from 4/16/20 to 5/8/20 by Bloodworks NW

CALVIRI Diagnostic Technology/IMS is Quantitative But Can Be Designed as a Cut-Off Test for COVID Positive vs. Negative (like an ELISA)



Advantages of IMS COVID Diagnostic

- 30x more sensitive
- Can Detect Infection Early
- Distinguish Disease Severity
- Tell Good/Bad Vaccine Response

*Emergency Use
Application (EUA) filing
with FDA 9/21/20*

CALVIRI Conclusion:

The COVID-19 Pandemic Has Demonstrated the Remarkable Plasticity of The BioTechnology/BioMedical Community To Respond To A Crisis Quickly

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USC Town Hall Talks – Conclusions

1. Post COVID-19 pandemic changes in healthcare will be widespread at multiple patient, provider and payor levels and are largely unknown and underappreciated
2. The “Law of Unexpected Consequences” is already in full swing regarding the economy, the corona virus out break, and the peripheral ramifications
3. Unexpected Consequences can set the stage for unexpected accelerating of positive clinical opportunities
 - “No Armies Are Stronger Than An Idea Whose Time Has Come”
C. Everett Dirksen, US Congressman and Senator

Questions and Answers

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Town Hall Talks

