

LIGHTNING TALKS

Monday, October 29
1:00 PM

#BARDA2018





BARDA INDUSTRY DAY

Generation of a T Cell-Targeting Influenza Vaccine

Daniel F. Hoft, M.D., Ph.D. & Christopher S. Eickhoff, M.S.
Saint Louis University Center for Vaccine Development

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



Saint Louis University Center for Vaccine Development

Generation of a T cell-targeting influenza vaccine

Universal Influenza Vaccine Development

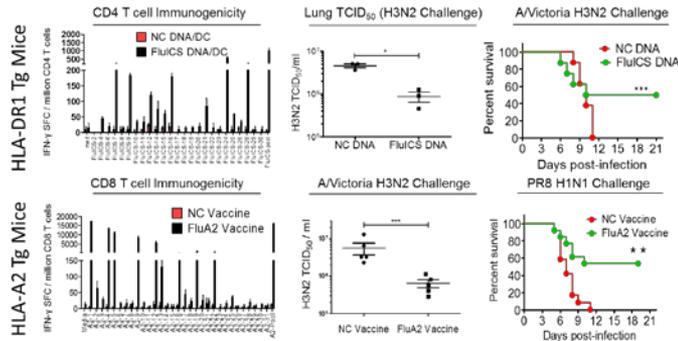
Center for Vaccine Development
Extended Stay Research Center

Preclinical Development

Clinical Development

EpiVax Immunoinformatics →
T cell-targeted vaccine

Clinical Vaccine Center &
Human Influenza Challenge Unit



- VTEU since 1989
- Extensive phase I –III experience
- \$6-8 million extramural funding per year
- Urgent national preparedness trials
- SLU investment of ~\$400,000
- Upgraded HVAC system → aerosol containment
- Negative pressure / Double-door entrances

Interested in industry, government and academic partners to further pursue this **universal influenza vaccine strategy**

Interested in conducting **human influenza challenge studies** with government, industry, and foundation support



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ImplaVax[®] Solid Dose Vaccine Technology

David Hipkiss
Enesi Pharma Limited

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ImplaVax® Solid Dose Vaccine Technology

Making a Material Impact on BARDA's DRIVE Strategy



1 Unit Solid Dose Vaccine

2 Single Use Disposable Cassette

3 Reusable Actuator (1,000x)

www.enesipharma.com



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Rapid Tissue Health Assessment with Spatial Frequency Domain Imaging (SFDI)

Amaan Mazhar, Ph.D.
Modulated Imaging, Inc.

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Proven Technology: Clarifi™

Innovative camera system based on Spatial Frequency Domain Imaging (SFDI) provides rapid, noninvasive wide-field assessment of tissue health

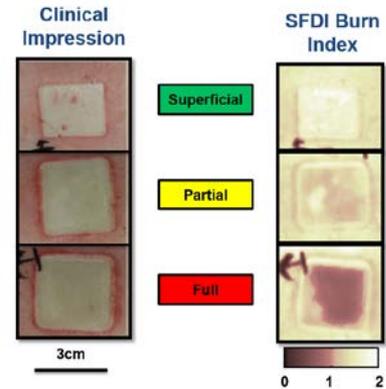


MODULATED
IMAGING
SEE BEYOND

IMAGING BURN SEVERITY

MEASUREMENTS

- HbO_2 - OXYHEMOGLOBIN
- HbR - DEOXYHEMOGLOBIN
- Sto_2 - TISSUE OXYGEN SATURATION
- HbT_1 - TOTAL PAPILLARY HEMOGLOBIN
- HbT_2 - TOTAL RETICULAR HEMOGLOBIN



Mazhar et al. (2014). JBO 19(8) 086019

SFDI can quantify circulatory compromise in a number of applications. Published SFDI studies in assessment of peripheral vascular disease, diabetes complications, and burn severity.





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Pharmaceuticals-on-Demand via Integrated Continuous Manufacturing (ICM)

Bayan Takizawa, MD, MBA
CONTINUUS Pharmaceuticals

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CONTINUOUS ICM Pilot Plant

CONTINUOUS™
pharmaceuticals



www.continuouspharma.com
btakizawa@continuouspharma.com



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Synthetic Biology: Addressing Mission-Critical Needs

David Borhani
Ginkgo Bioworks

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1,000,000
100,000
10,000

Foundry
Unit Ops
per month

2015 2016 2017 2018

25x higher
output per
person than
conventional
biotechs

Exponential
growth:
100x in
3 years





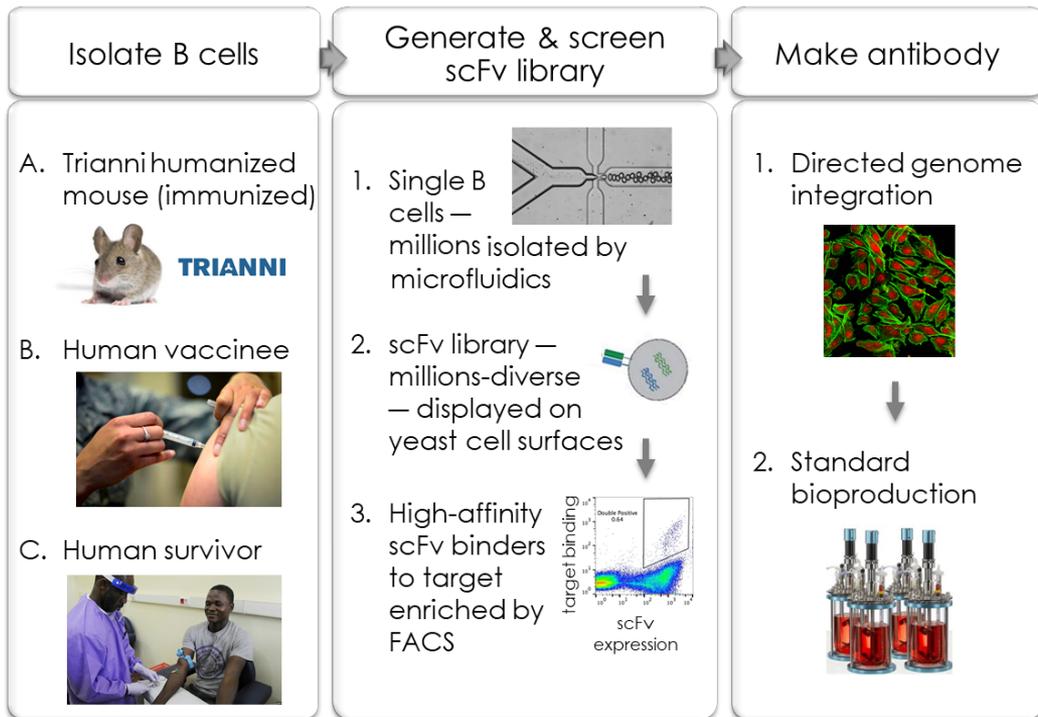
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Rapid Response Antibody Therapeutics with GigaGen Surge

Sheila Keating, Ph.D. MSPH
GigaGen, Inc.

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Capabilities

- Antigen → full-length antibody production in 3 months
- Rapid development of mAb and pAb therapeutics

Desired Teaming

- Antigen discovery & vaccine development
- *In vitro* neutralization
- Animal efficacy
- Regulatory and CMC
- Large-scale production

Contact

- **GigaGen**, South San Francisco, CA
- Sheila Keating, PhD
- skeating@gigagen.com



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Identification and Clinical Management of Immune Suppression in Sepsis

Donald Kosiak, MD, MBA, FACEP, CPE
Leidos Inc.

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We Will Do Better





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aSeptiMab® A Targeted Immunotherapeutic to Stop Sepsis Prior to Organ Damage and Dysfunction

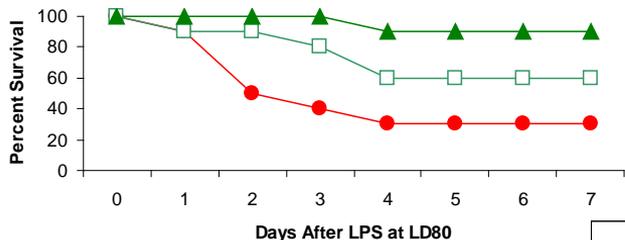
Robert Webber, Ph.D.
Research & Diagnostic Antibodies

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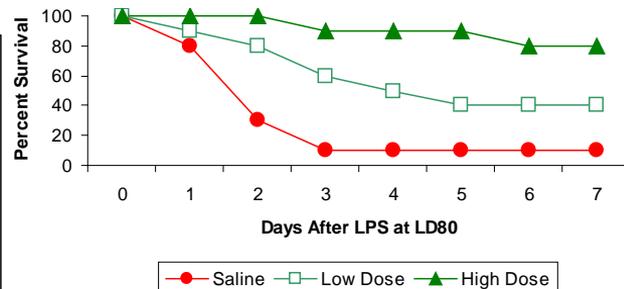
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Treatment at 0 Hrs after LPS

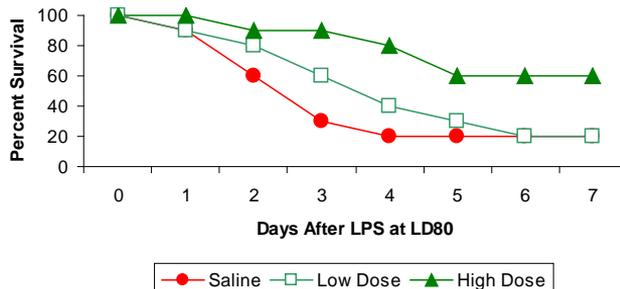


Kaplan-Meier Curves for aSeptiMab[®] Intervention After LD₈₀ Dose of LPS

Treatment at 2 Hrs after LPS



Treatment at 6 Hrs after LPS



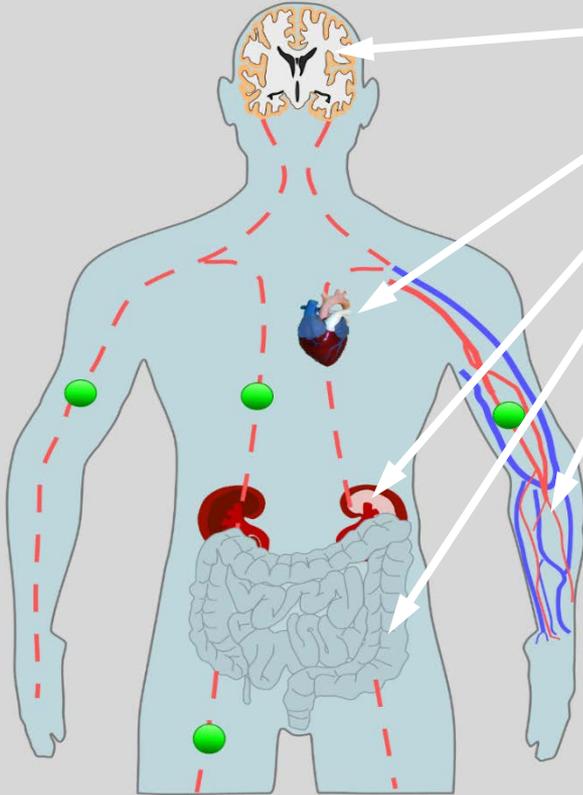
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Circulating Microvesicle-Associated iNOS Causes the Sepsis Cascade

Kills Cells and Damages Organs



MV-A iNOS kills cells and produces microperforations

Leakage through microperforations

Multiple Organ Failure

DEATH



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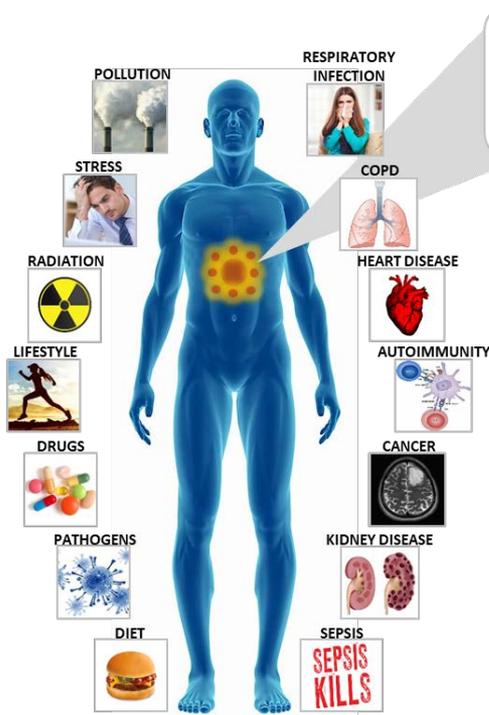
Host Gene Expression to Discriminate Bacterial from Viral Infection

Geoffrey Ling, M.D., Ph.D.
PREDIGEN

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Host gene expression to predict disease and manage health



Host Gene Expression

- Specific to threat/illness
- Highly accurate
- For diagnosis, prediction, and monitoring

Measuring host response 'signatures' allows for immediate and accurate identification of inciting insult, enabling early, appropriate treatment

- Scientists at Predigen have pioneered this approach, with over a decade of experience and biospecimens from >10,000 patients
- We are developing gene expression tests for sepsis and presymptomatic bacterial/viral infections
- Our aim is to enable 'field forward' and at-home tests that are accurate, rapid, affordable and easy to use
- To date, we have achieved AUCs of 0.9-0.99 in multiple studies

predigen

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DRIVING INNOVATION

