Making vaccines “on demand”
A potential solution for emerging pathogens and biodefense?
Anne S. De Groot1,2, Leo Einck1, Leonard Moise1, Michael Chambers3,
John Ballantyne3, Robert W. Malone4, Matthew Ardito1 and William D. Martin1
1EpiVax, Inc.; Providence, RI, USA; 2Institute for Immunology and Informatics,
University of Rhode Island, Providence, RI, USA, 3Aldevron, Inc.; Fargo, ND USA; 4WCCT Global, Inc.; Costa Mesa, CA USA

INTRODUCTION
The integrated US Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has made great strides in strategic preparedness and response capabilities. There have been numerous advances in planning, biothreat countermeasure development, licensure, manufacturing, stockpiling and deployment. Unfortunately, structural delays in the conventional vaccine design, development, manufacture, clinical testing and licensure processes remain significant obstacles to an effective national biodefense rapid response capability, especially in the case of “novel pathogens” such as the avian-origin influenzas H7N9 and H5N1. In order to allow for an appropriately rapid response to biowarfare or novel emerging pathogenic threats, EpiVax suggests restructuring the vaccine development process to utilize computational vaccine design tools and rapid production technologies. While these string-of-epitope vaccines are by no means “standard,” their 60-day start-to-finish timeline and 24-hour genome to DNA plasmid design process would represent a two-fold faster response over the current standard.

FastVax Approach for “Vaccines On Demand”

Genome-derived, epitope-driven vaccine strategy (GD-EDV):
DNA – chain of epitopes, or peptide in liposomes
ICS-optimized proteins in Virus-like protein (VLP)
ICS-optimized whole proteins

What Makes FastVax Possible?

DESIGN
- High throughput computing
- Immunoinformatics
- Vaccine Design Algorithms
- Predictable Immunogenicity

MANUFACTURING
- Standardized DNA vaccine plasmid with cassette payload
- Electronic transfer of vaccine sequence for rapid scale up production
- FDA pre-inspected facilities
- Low infrastructure delivery vehicles

TESTING
- Accelerated FDA review for “emergency use authorization”
- Sanofi Pasteur VaxDesign’s MIMIC Assays/“Mock up” approval/surrogate testing endpoint

GENES-TO-VACCINES APPROACH

Timeline
Traditional Vaccine Development
Zero – Hours Months Years
Virus isolation
Genome sequencing
Design
Manufacturing
Testing
Deployment

FastVax Design
Zero – Hours Days Weeks Months
Design: 24 hours from genome to DNA plasmid
Production: 3-4 weeks to produce over one million doses per facility with scale up DNA production
Deployment: Regional manufacturing and accelerated FDA testing allow deployment as soon as 60 days after case one

CONCLUSIONS
- Multiple challenge studies have shown that T cell driven vaccines can effectively protect against human pathogens
- Despite strain-to-strain variation at the protein level, immunoinformatics tools can be used to identify highly conserved T cell epitopes that are immunogenic and broadly representative or universal
- DNA-based vaccines limit the antigenic load, allowing for more cost and time effective production and deployment.
- There is a critical national need for an accelerated vaccine design, development and production process that can be accomplished in weeks, not months, in the event of a serious infectious disease outbreak or biowarfare attack.