Health Affairs Biodefense Summit

Healthcare and Biodefense Innovation Panel

Kimothy Smith (chair)
James (Jim) Wilson
Leo Einck
David Noll

Overview

- Brief Introduction by the Chair
- Four topics
  - Point of care (POC)/Point of Need (PON) Molecular Diagnostics (MDx)
    - Kimothy Smith, Chief Technology Advisor to PositiveID Corporation
  - Infectious Disease and Antibiotic Resistance Forecasting
    - Jim Wilson, CEO, M2, Inc., and Director, Nevada State Infectious Disease Forecast Station
  - Vaccine Design
    - Leo Einck, Director of Business Development and Federal Business, EpiVax, Inc.
  - Role of Vaccine Platform Manufacturing Technology
    - David Noll, Strategic Advisor on Biotechnology and Pharmaceutical Industries, Tiber Creek Partners, LLC

Overview (cont'd)

- Each topic will be given approximately 15 minutes
  - 1 minute for Panelist to introduce themselves and present a biosketch
  - 9 minutes to present their topic
  - 5 minutes for questions and discussion – primarily from the audience
- Audience participation is requested!
- Disagreements are normal and welcome but, please conduct yourselves in a professional and collegial manner, e.g., better than Presidential Debate participants

Brief Introduction

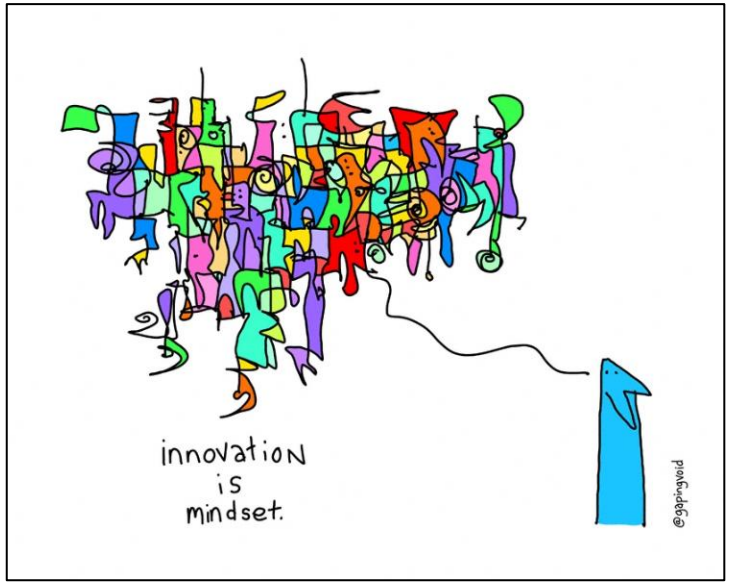
- Innovation
  - Defined simply as a "new idea, device, or method”
  - Also, the application of better solutions that meet new requirements, or previously unarticulated needs
- Disruption
  - Disruption “Guru” Clayton Christensen says that, “…disruption displaces an existing market, industry, or technology and produces something new and more efficient and worthwhile. It is at once destructive and creative.”
- Panelists have been asked to present in their topics
  - The Innovation or innovative technology
  - Potential disruptions and challenges
  - Subsequent impacts to medical care, biodefense, and military/defense applications and markets – the lead-in to questions, comments, and discussion

Biosketch – Kimothy Smith

- Education
  - BS Biochemistry
  - DVM
  - PhD in Epidemiology
- Past Experience
  - Department of Homeland Security
    - Science and Technology Directorate, Office of Research and Development
    - Office of Health Affairs
  - Lawrence Livermore National Laboratory
    - Chem-Bio National Security Program
    - Counterterrorism and Incident Response Division
- Current Affiliations
  - PositiveID Corporation
  - Desert Research Institute
  - University of Nevada Reno

The Innovation – POC/PON MDx

- Point of Care/Point of Need Diagnostic Platforms have the potential to
  - Improve patient treatment outcomes
  - Bring substantial savings in overall healthcare costs
- Broad categories of POC/PON Dx devices include
  - Lateral flow devices
  - Desktop and handheld platforms
  - Emergent molecular diagnostic POC systems
  - Wearables
- Broad range of potential applications beyond clinical Dx



Hugh MacLeod

The Drivers – POC/PON MDx

- Even though POC tests may (for now) cost more on a per test basis, the cost savings realized by reduced doctor visits and laboratory overhead costs need to be factored in to understand the overall equation
- [POC MDx] is one of the innovations that can potentially have impact on quality of care, as well as on system redesign and a more patient centered approach to care*
- The world will be short 12.9 million healthcare workers by 2035**
  - There will be a shift toward accurate, intuitive tests that can be operated by less skilled personnel and patients outside of a centralized laboratory

*US National Library of Medicine, National Institutes of Health, 2013
**WHO Report, 2013

Examples – POC/PON MDx

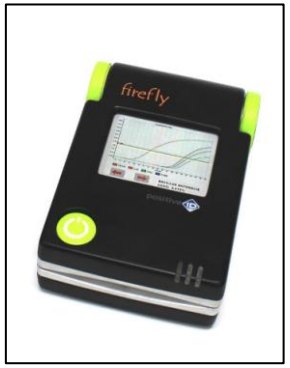
Spartan Biosciences, Inc.
Spartan Cube

bioMérieux
Biofire FilmArray

Roche Diagnostics
cobas Liat

Alere, Inc.
Alere i

Luminex Corp.
Aries



PositiveID Corp.
Firefly Dx

Examples only, not an exhaustive list. Images are not to a common scale.

The Challenges, Disruptions, and Impacts

- Challenges
  - Design
  - Portability
  - Ease of use
  - Sensitivity, specificity, PPV, LOD
  - Assays
  - Sample prep
  - Cost of unit and per test
  - Reimbursement
  - Incorporation in EMR
- Disruptions
  - How to incorporate into system? Where?
  - Interpretation of results? Who?
  - Centralized laboratory
  - Change patient treatment? Less contact (less revenue to doctors)?
- Impacts
  - Can the Warfighter (and or support to) carry and use? What's the cost/benefit?
  - Is there a benefit to military medicine and an improvement to quality of care and health outcomes?
  - Can costs be driven down enough to use POC/PON MDx routinely? What would the target price be?
  - Beyond infectious disease diagnostics and detection?

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Thank you for your kind attention!

Questions, Comments, Discussion?