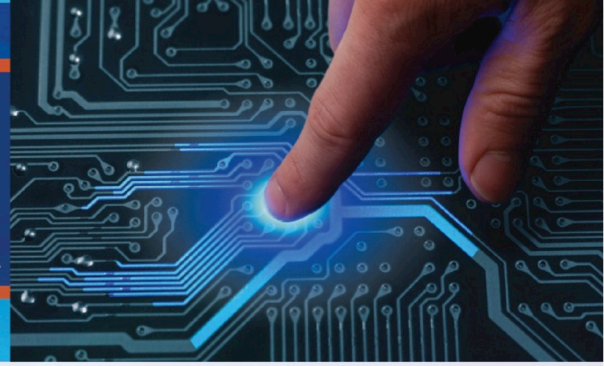
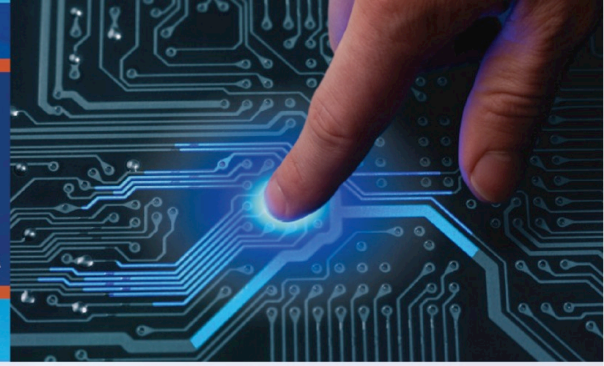
FDA/PhUSE Annual
Computational Science Symposium
March 19 - 20th 2012
Silver Spring Civic Center | Silver Spring Maryland, USA



CBER Progress and Next Steps

Mark Walderhaug, PhD
Associate Director for Risk Assessment
Office of Biostatistics & Epidemiology
Center for Biologics Evaluation & Research



The findings and conclusions in this presentation have not been formally disseminated by the Food and Drug Administration and should not be construed to represent any Agency determination or policy.

Biological Products Regulated by CBER

- Vaccines (preventative and therapeutic)
- Blood, blood components, and derivatives
- Allergenics
- Cell and Gene Therapies
- Tissues
- Xenotranplantation Products
- Related Devices (including certain *in vitro* diagnostics)

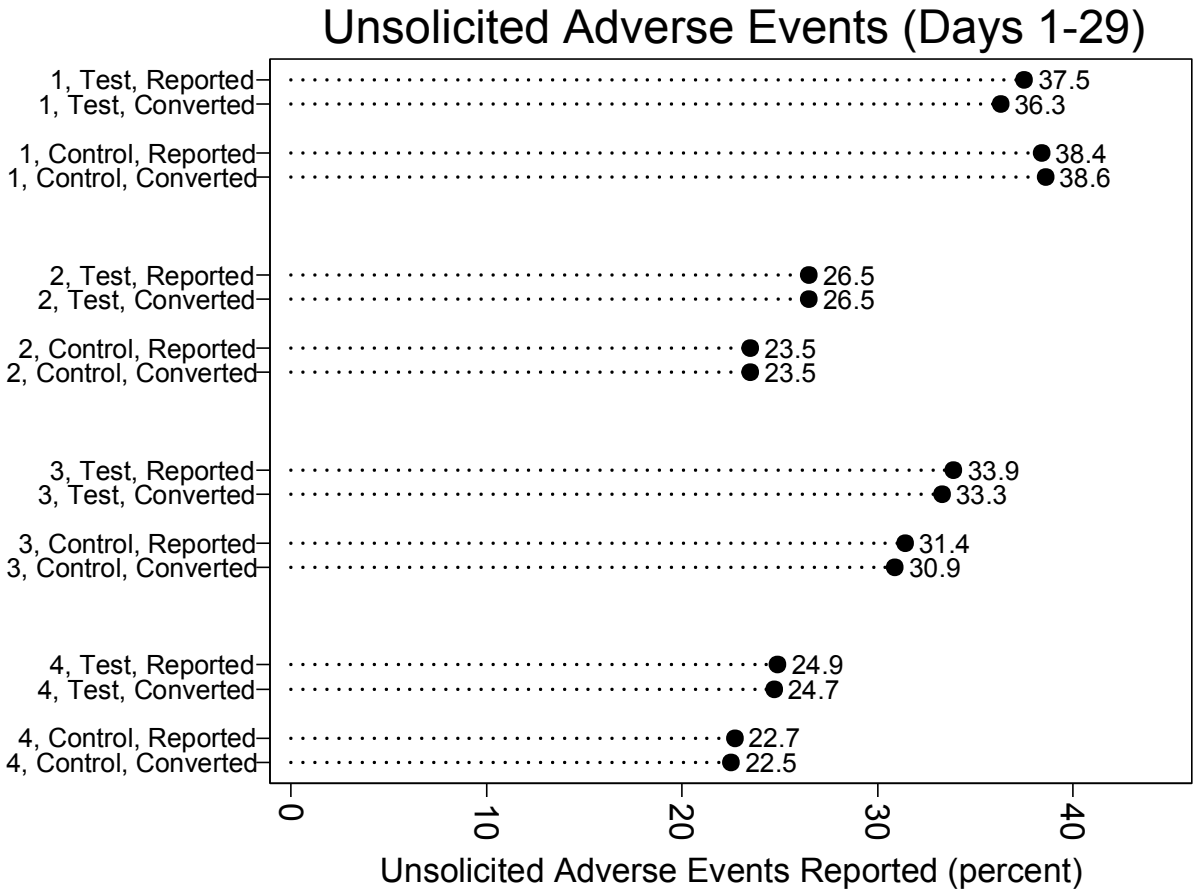
CBER's Vision

- Innovative Technology for Advancing Public Health
  - Protect and improve public and individual health in the U.S. and, where feasible, in the world.
  - Facilitate the development, approval, and access to safe and effective products and promising new technologies
  - Strengthen CBER as a preeminent regulatory organization for biologics
- Computational Science advances CBER's Vision

Regulatory Review Support

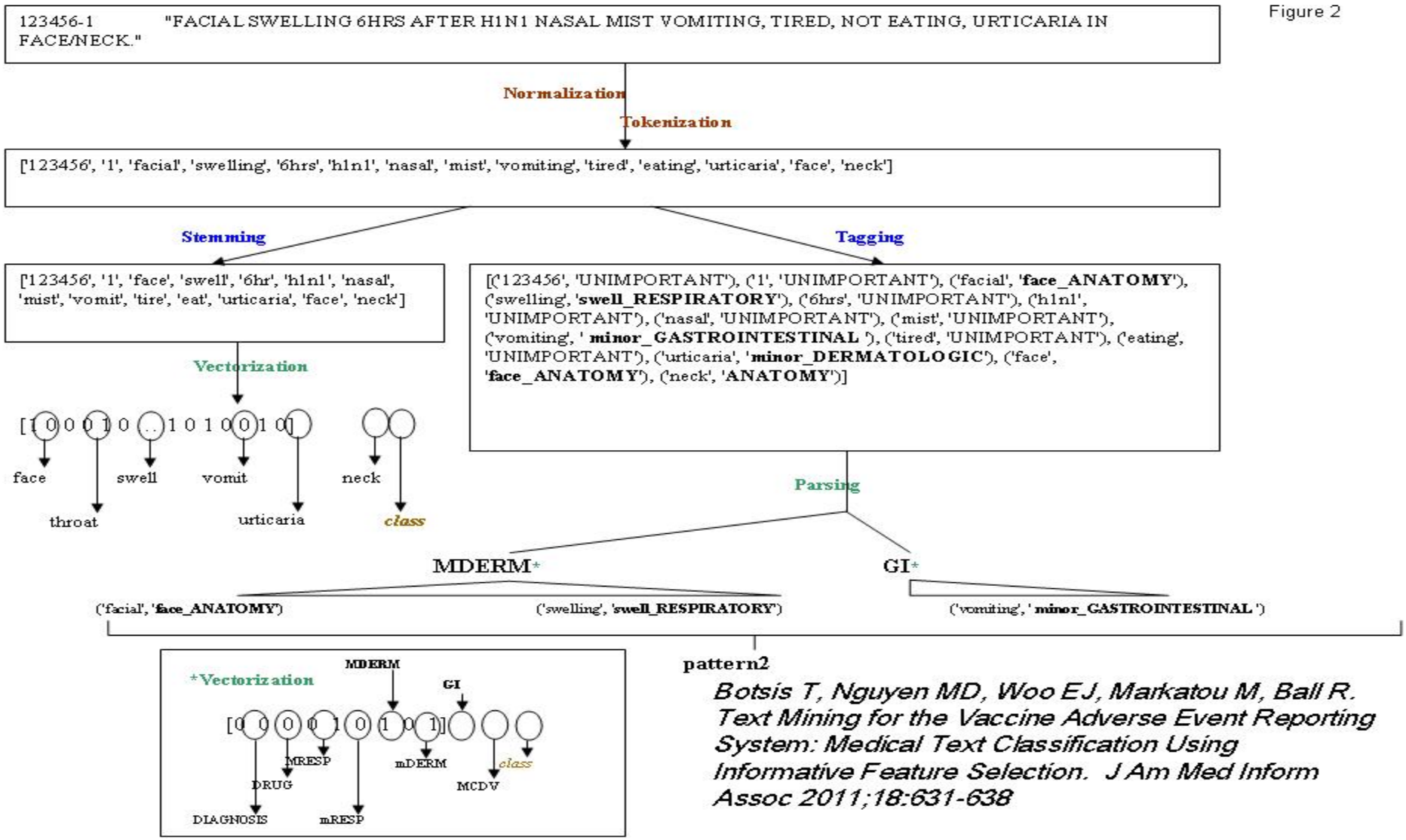
- Janus
- CDISC
- Legacy Data Conversion
- Tools
  - Spotfire
  - Amalga
  - In-house tools

Legacy Data Conversion



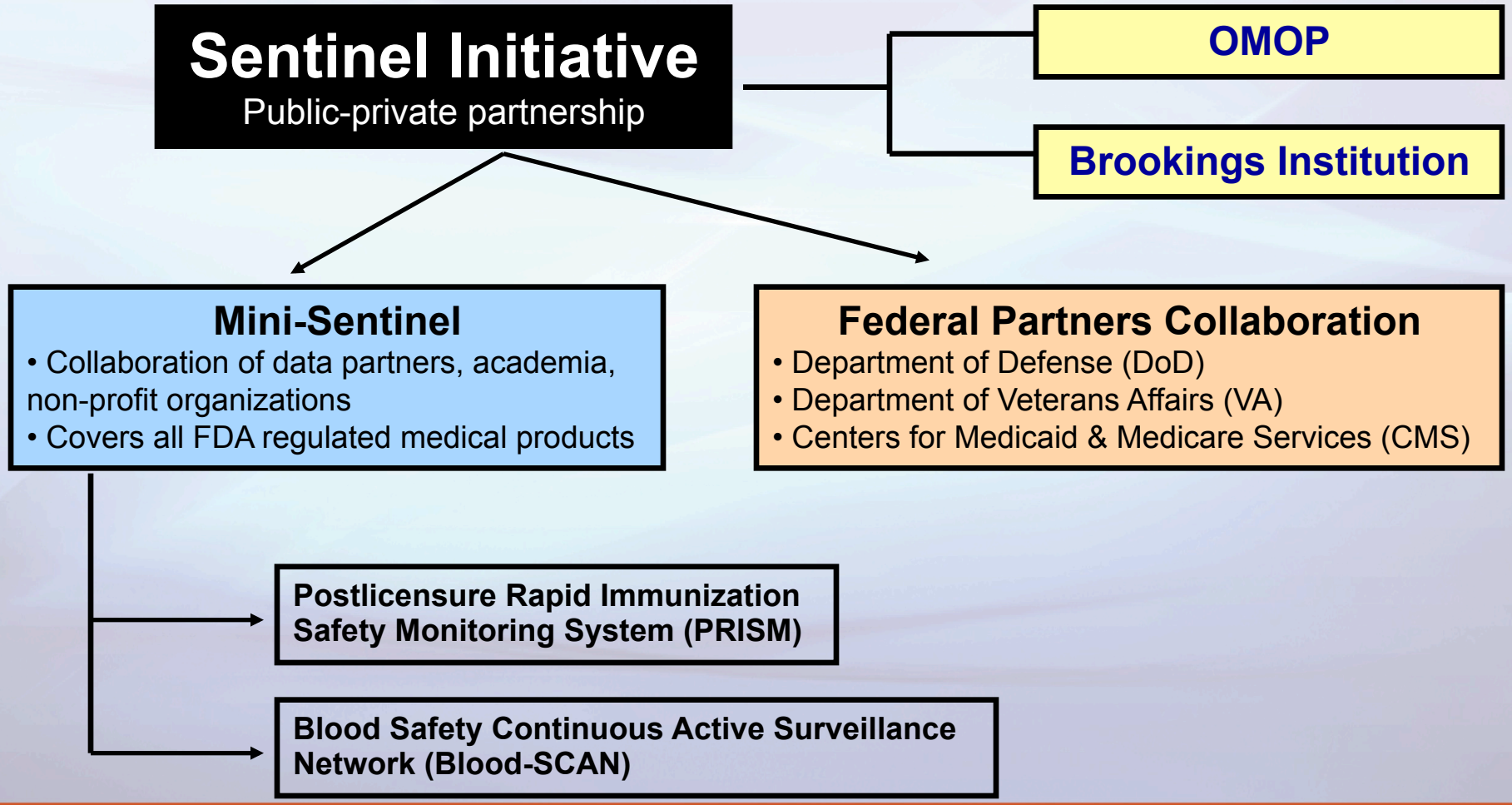
In-house tools: Text Mining

Figure 2



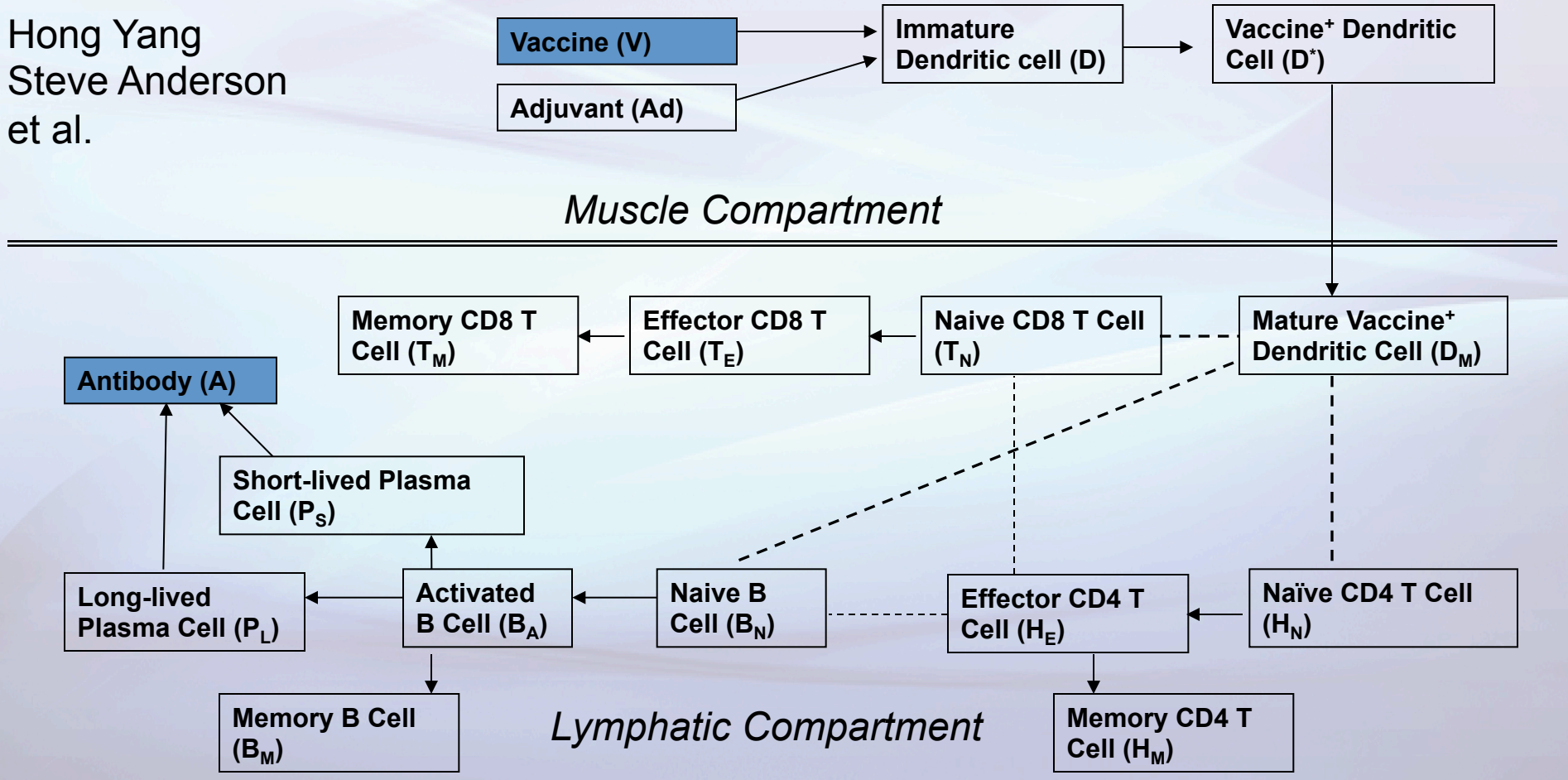
Botsis T, Nguyen MD, Woo EJ, Markatou M, Ball R. Text Mining for the Vaccine Adverse Event Reporting System: Medical Text Classification Using Informative Feature Selection. J Am Med Inform Assoc 2011;18:631-638

Regulatory Science



Immune System Modeling

Hong Yang
Steve Anderson
et al.



Innovative Environments

Instruments at core facility

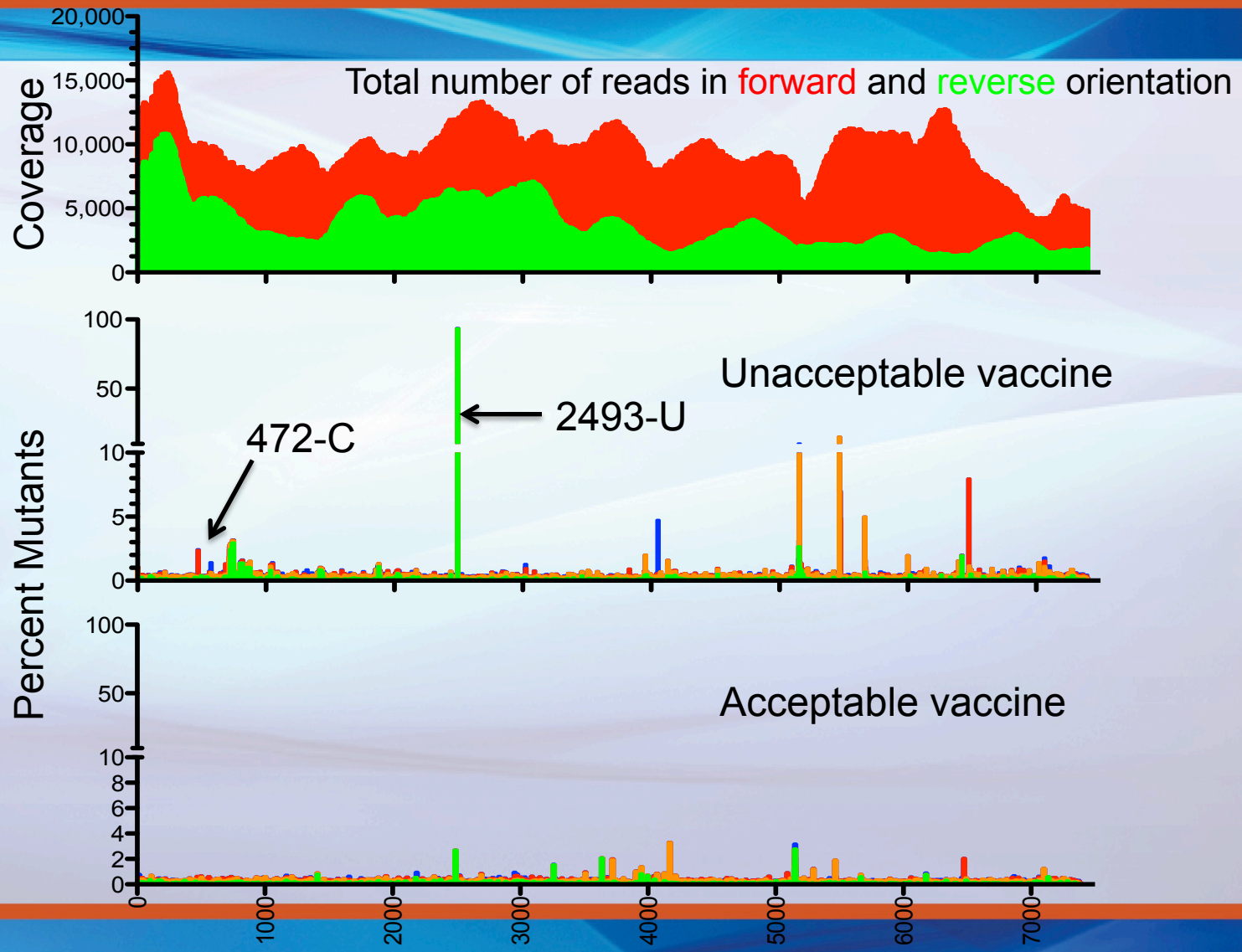
High Performance
Integrated
Virtual
Environment

web-browser

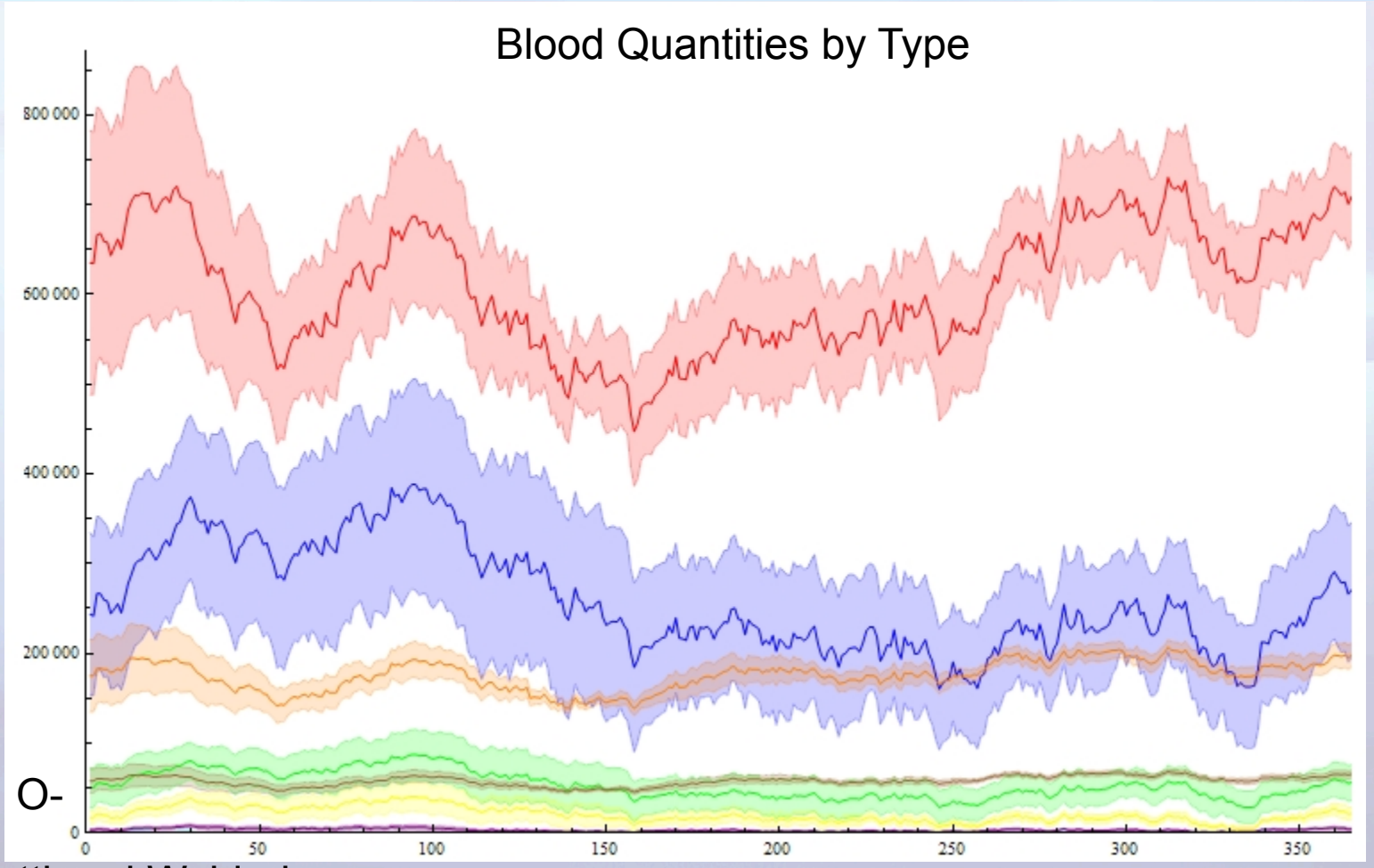
Simonyan, Wilson, & Chumakov

Deep-sequencing analysis of Oral Poliovirus Vaccine

A. Neverov and K. Chumakov. Massively parallel sequencing for monitoring genetic consistency and quality control of live viral vaccines. *PNAS : 107(46) 20063–20068 (2010)*



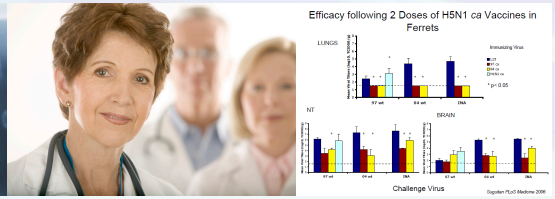
Simulation of the Blood Supply



Simonetti and Walderhaug

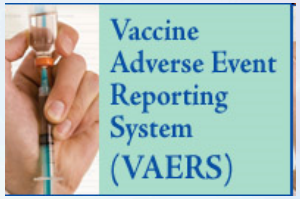
Safety through the Lifecycle

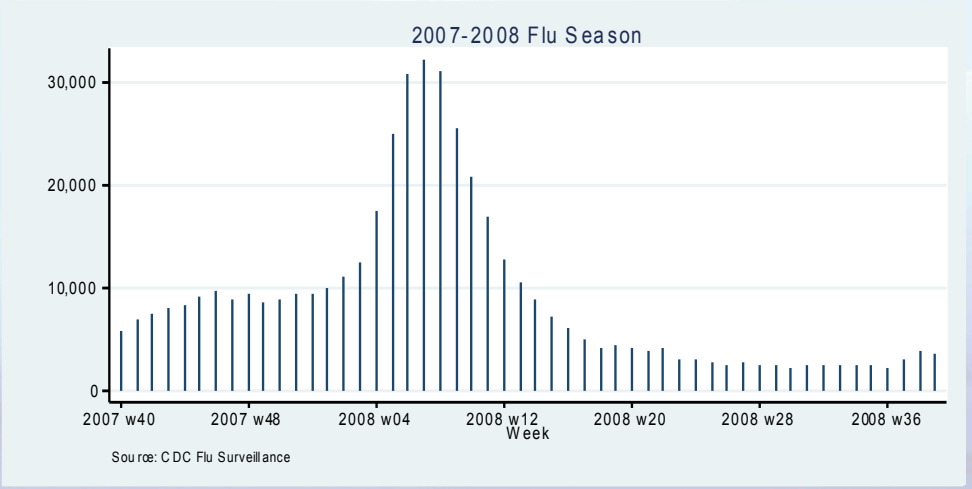
Clinical Trials



Approved

Post-market Surveillance





- Illnesses
- Hospitalizations
- Deaths
- Adverse Events

Richard Forshee & David King

Conclusions

- Computational Science has significant impacts on CBER Regulatory Review and Science by allowing CBER to do more in protecting public health
- Computational Science blurs the line between regulatory review and regulatory science
- CBER is working to develop an integrated strategic plan for information technology
- CBER will continue to work with other Centers and stakeholders to contribute to and to leverage data standards, patient-centered outcome research, and tools in support of public health