



*The Global Event
for Biotechnology*

May 18–21, 2009, Monday–Thursday
Georgia World Congress Center
Atlanta, GA USA



Heal, Fuel, Feed
The World.

Transforming the Research Paradigm

21st Century Models to Unify Discover Research and Clinical Care

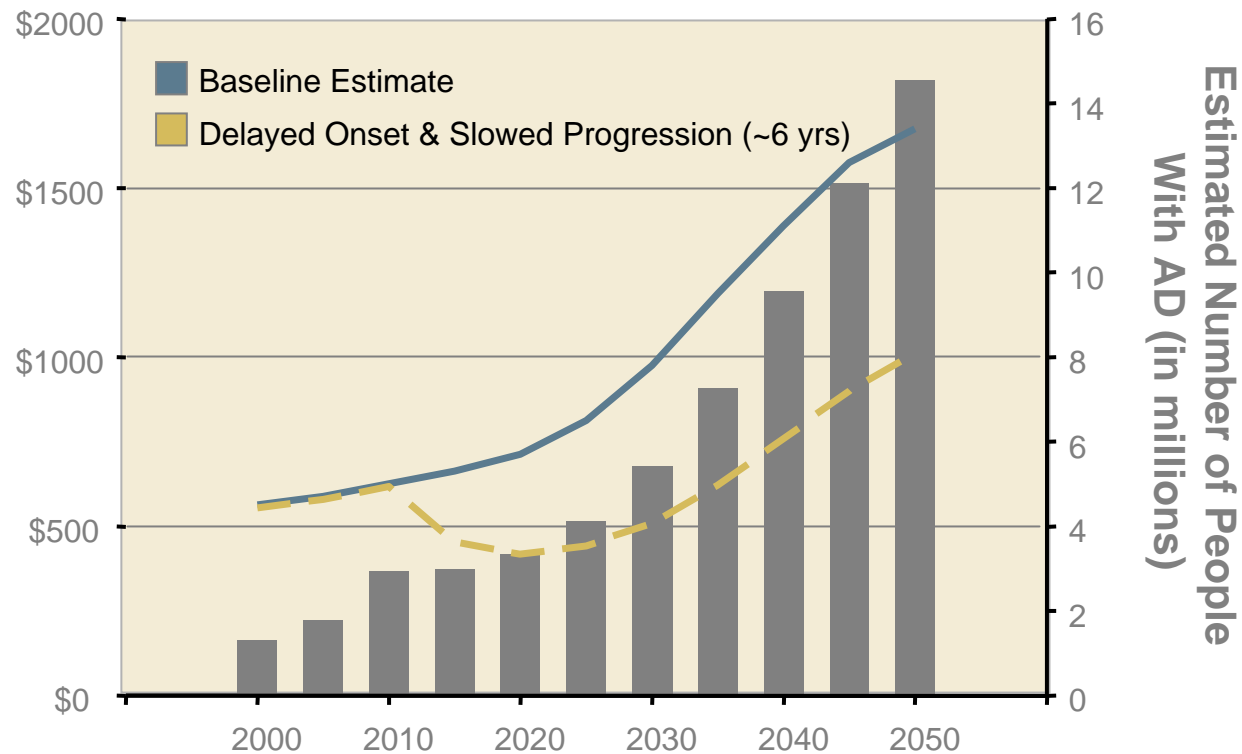
Date: Tuesday, May 19th

Time: 10:00 am

Speaker: Dietrich Stephan, Ph.D. (Ignite Institute and
Co-founder, Chief Scientific Officer, Navigenics)

The Problem

In 'Boomer' Diseases, such as Alzheimer's, Impact and Costs Will Escalate Dramatically Without New Interventions



Adapted from The Lewin Group Report, June 2004, "Saving Lives. Saving Money: Dividends for Americans Investing in Alzheimer Research," The Alzheimer's Association (http://www.alz.org/Resources/FactSheets/Lewin_FullReport1.pdf)

Let us Change That Future

IGNITE is a unique non-profit medical research institute in the national capital area aimed at alleviating human suffering and transforming the health care system using a *new* strategy:

Personalized Medicine





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INDIVIDUALIZED HEALTH

Vision and Strategy

- **Vision**

- A world with less individuals afflicted with horrific diseases such as Alzheimer's, diabetes, cancers, autism and other chronic disease
- Decreased costs for caring for an individual so that we can provide excellent care to more

- **Strategy**

- Research to understand the sub-types of common disease and how to diagnose and treat them
- Extend the healthy lifespan through **preventive personalized genomic medicine in the clinic**
- Improve efficiency in care delivery and optimization through private HIT
- Compress the time and cost of illness at the end of life

Issues: Personalized Preventive Genomics



- **Informed consent**
 - Test
 - Test refinement
- **Analytic validity**
 - Genotyping
 - Sequencing
 - IVDMIA
- **Clinical validity**
 - Prospective efficacy trials (monogenic vs. complex)
 - ROC curves on primary data
- **Physicians are not equipped**
 - CME
 - Clinical Centers of Excellence (Mayo, Harvard, Scripps, etc)
 - Grass-roots
- **Professional access**
 - Physicians
 - Counselors
- **Regulation**
 - FDA (c-path, usds)
 - States



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- **Privacy/Security**
 - Must exceed financial industry standards (2FA)
 - Regular security audits
 - HIPAA compliant
 - Genome belongs to person
 - Comply with law
- **No commercial exploitation**
 - Service business
 - No commoditization of data
- **CDS**
- **No quantitative traits**
 - Slippery slope
- **No under-age members**
 - Unable to give informed consent
- **No ancestry interpretations**
 - Learn from out 25 years of history in monogenic disease
- **No family units**
 - Non-paternity issues

The Epicenter of Health Care Transformation Located in the National Capital Area



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Igniting INOVAtion. Empowering Care.