

Comparative Effectiveness Research and Personalized Medicine: **Policy, Science, and Business**

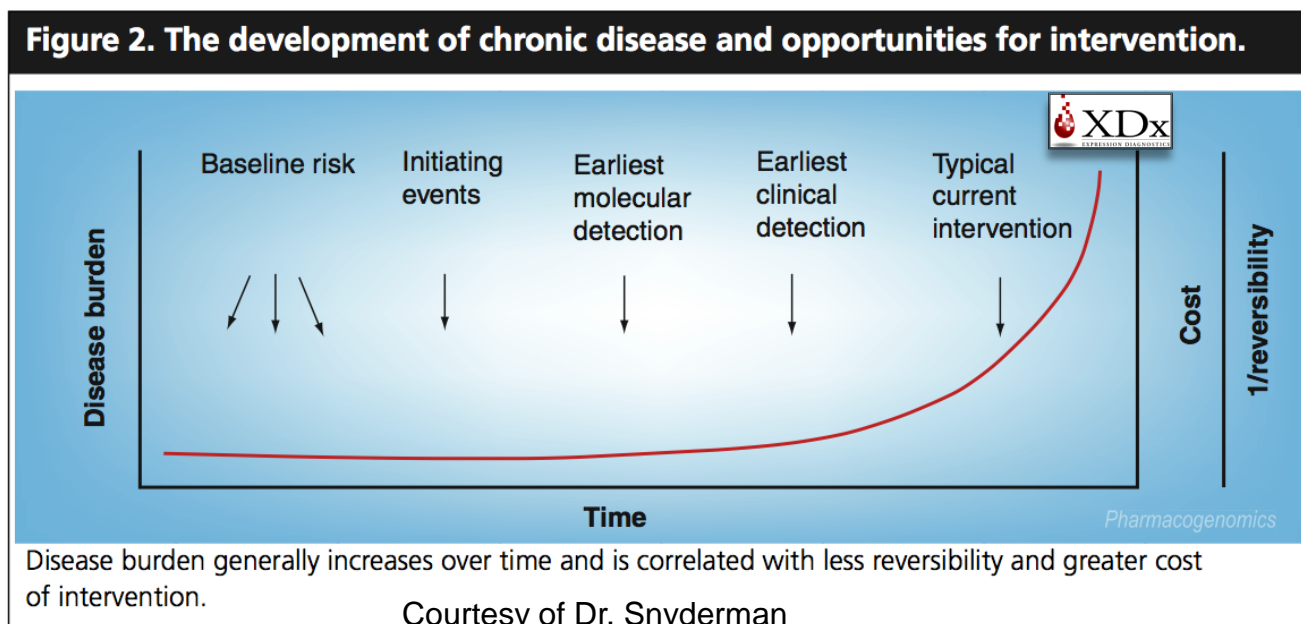
*Business Implications of Comparative Effectiveness
Research with Stratified Populations*

October 28, 2009

- Founded in 2000, XDx, Inc. is a molecular diagnostics company based in Brisbane, CA, USA.
- XDx applies modern genomics technologies to the development of molecular diagnostic assays that translate a patient's immune status into clinically actionable information.

Molecular Diagnostic and Personalized Medicine

- Care is focused on late-stage treatment: pathology, severe clinical manifestations, organ dysfunction
- New Dx technologies offer the opportunity to reduce health care costs, patient morbidity and mortality



Heart Transplantation

- Patients receive a transplanted heart and are subjected to a life-long treatment of immunosuppression to avoid rejection
- A regular assessment of risk for acute cellular rejection is used to adjust management strategy (e.g. immunosuppression)
- Patients undergo frequent invasive endomyocardial biopsies (30+ in 5 years):
 - 1/week Month 1
 - 1/month Year 1
 - 1/quarter Years 2-5

Endomyocardial Biopsy



AlloMap® Molecular Expression Testing

AlloMap® features:

- Tests for low probability of acute cellular rejection
- Uses a blood sample rather than heart tissue sample
- Measures expression of 20 genes by quantitative real-time PCR
- Reports a single score (0-40)
- Performed in XDx CLIA certified laboratory
- Cleared by FDA (IVDMIA class II) on Aug. 26th 2008

Comparative Effectiveness Research

Invasive Monitoring Attenuation through Gene Expression

- 12 U.S. Heart Transplant Centers
- 600 Heart Transplant recipients enrolled and randomized into two arms
 - Biopsy Arm: Patients are managed with biopsies
 - AlloMap[®] Arm: Patients are managed with AlloMap[®]
- Goal of IMAGE study is to demonstrate the non-inferiority of clinical outcomes of heart transplant recipients managed with the AlloMap[®] test compared to endomyocardial biopsy



AlloMap Molecular Expression Testing

AlloMap® is objective (Physicians)

- 99% Negative Predictive Value

AlloMap® is non invasive (Patients)

- Simple blood draw

AlloMap® is cost efficient (Payers)

- List price: \$3,200