Translational Medicine: Making the Right Candidate Selection

Opening Remarks
J. Fred Pritchard, Ph.D.
June 5, 2013
Drug Discovery and Development is a Process

- Studies of Disease Mechanisms
- Molecular Studies
- Animal Studies
- Target Identification
- Hits to Leads
- Lead Optimization
- High Throughput Chemistry
- Product Development

**Discovery**

- Human Proof of Concept and Dose Response
- Registration and Approval for Marketing
- Pivotal Efficacy and Safety
- Human Safety/Tolerance PK

**Development**

- Translational Medicine
- Postmarketing Surveillance and Product Lifecycle
The Pressure is On for Proof-of-Concept!

- **Increase in novel new drugs from discovery research**
- **More difficult disease states to study and treat**
- **Greater regulatory expectations on clinical trials**
- **Need for more informed decisions at clinical proof-of-concept**
- **Increased cost of clinical research**
- **Regulatory acceptance of adaptive-like study designs**
- **Expanding universe of new technology applications**

Innovation
What is a **better** decision?

- One made earlier
- With greater confidence
- More efficiently

Better data, faster, cheaper

Game Changing Innovation
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