Establishing Precompetitive Collaborations to Stimulate Genomics Driven Drug Development

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IOM Workshop

Duke Medicine
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The Productivity Problem

Booth and Zemmel, Nature Reviews in Drug Discovery 3:451-6, 2004
Precompetitive Collaboration

“Precompetitive collaboration should be viewed as a tool for creating and unlocking value, in both economic and human terms, and as a critical driver for the success of the biomedical enterprise.”

Wagner: CPT 2010 87:511

“Competitors share early stages of research that benefit all”

Weber: The Success of Open Source 2004
Opportunities for Pharma

- Biospecimens
- Model systems
- Targets
- Probes
- Clinical and molecular data
- Preclinical models
- Software
- Clinical trials data
Examples...Lessons Learned?

- Innovative Medicines Initiative
  - Address bottlenecks in safety, efficacy, pre-clinical toxicity biomarkers
- Biomarkers Consortium
  - Predictive biomarkers: T2DM, breast cancer, sarcopenia, atherosclerosis
- Predictive Safety Testing Consortium
  - Liver, muscle, vascular, renal, carcogenicity
- GSK-Novartis
  - Malaria small molecules (ChEMBL)
- Coalition Against Major Disease
  - Shared Alzheimer’s database
  - Develop quantitative disease models
Biobanking in the U.S. (ca. 1999)

<table>
<thead>
<tr>
<th>Type of Repository</th>
<th>Number of Cases</th>
<th>Number of Specimens</th>
<th>Cases per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Tissue Banks, Repositories and Core Facilities</td>
<td>&gt;2.8 million</td>
<td>119.6 million</td>
<td>390,790</td>
</tr>
<tr>
<td>Longitudinal Studies</td>
<td>&gt;340,088</td>
<td>508,088</td>
<td></td>
</tr>
<tr>
<td>Pathology Specimens</td>
<td>&gt;160 million</td>
<td>&gt;160 million</td>
<td>&gt;8 million</td>
</tr>
<tr>
<td>Newborn Screening Laboratories</td>
<td>&gt;13.5 million</td>
<td>&gt;13.5 million</td>
<td>&lt;10,000 to &gt;50,000</td>
</tr>
<tr>
<td>Forensic DNA Banks</td>
<td>1.4 million</td>
<td>1.4 million</td>
<td></td>
</tr>
<tr>
<td>Sperm, Ovum, and Embryo Banks</td>
<td>&gt;&gt;200</td>
<td>&gt;9,900</td>
<td>&gt;9,900</td>
</tr>
<tr>
<td>Umbilical Cord Blood Banks</td>
<td>&gt;18,300</td>
<td>&gt;18,300</td>
<td></td>
</tr>
<tr>
<td>Organ Banks</td>
<td>&gt;75,500</td>
<td>&gt;75,500</td>
<td></td>
</tr>
<tr>
<td>Blood Banks</td>
<td>~12 million</td>
<td>~12 million</td>
<td></td>
</tr>
<tr>
<td>Grand Total</td>
<td>&gt;178 million</td>
<td>&gt;307.1 million</td>
<td>&gt;20.5 million</td>
</tr>
</tbody>
</table>


Accumulation rate (circa 1999): approx. 9 million per year
**Creation of a national network of existing biobanks**  
Purported foundation for a national network:

<table>
<thead>
<tr>
<th>Study</th>
<th>Year biospecimen collection began</th>
<th>Total cohort size</th>
<th>No. with stored biological samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Professionals Follow-Up Study</td>
<td>1986</td>
<td>52,000</td>
<td>30,000</td>
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<tr>
<td>Nurses’ Health Study I</td>
<td>1989</td>
<td>122,000</td>
<td>63,000</td>
</tr>
<tr>
<td>Washington County Study</td>
<td>1989</td>
<td>33,000</td>
<td>33,000</td>
</tr>
<tr>
<td>Women’s Health Study</td>
<td>1992</td>
<td>40,000</td>
<td>28,000</td>
</tr>
<tr>
<td>Women’s Health Initiative</td>
<td>1993</td>
<td>162,000</td>
<td>162,000</td>
</tr>
<tr>
<td>NCI PLCO Study</td>
<td>1994</td>
<td>155,000</td>
<td>70,000</td>
</tr>
<tr>
<td>Nurses’ Health Study II</td>
<td>1996</td>
<td>116,000</td>
<td>60,000</td>
</tr>
<tr>
<td>American Cancer Society CPS-II LifeLink Study</td>
<td>1998</td>
<td>184,000</td>
<td>109,000</td>
</tr>
<tr>
<td>Multiethnic Cohort Study</td>
<td>1996</td>
<td>215,000</td>
<td>80,000*</td>
</tr>
<tr>
<td>Vitamins and Lifestyle (VITAL) Cohort</td>
<td>1999</td>
<td>78,000</td>
<td>54,000</td>
</tr>
<tr>
<td>Agricultural Health Study</td>
<td>1999</td>
<td>90,000</td>
<td>35,000</td>
</tr>
<tr>
<td>Southern Community Cohort Study</td>
<td>2002</td>
<td>90,000*</td>
<td>80,000*</td>
</tr>
<tr>
<td>Black Women’s Cohort Study</td>
<td>2005</td>
<td>59,000</td>
<td>41,000*</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>-</strong></td>
<td><strong>1,396,000</strong>*</td>
<td><strong>845,000</strong></td>
</tr>
</tbody>
</table>

*Expected totals upon completion

Patient Enrollment and Samples Pharma Co and Academic Health Center

β Pharma Co
- β~32,000 patients in clinical trials per year
  - β Specimens collected on some
  - β>> 1 M banked specimens linked to clinical trial data
  - β Generally in single bank
  - β Limited access

β Academic Health Center
- β~45,000 patient in trials and registries
  - β Specimens collected on some
  - β>> 1M samples banked some linked to specific phenotypes
  - β Generally fragmented
  - β Limited access
Why are biospecimens so important?

- Target Discovery
- Target Validation
- Biomarkers for decision making
- Pharmacodynamic
- Pharmacogenomic
- Predisposition
- Prognosis
- Efficacy/monitoring
- Discovery, replication, validation
Value Proposition – from specimens and their derived data

- Patient
  - Better treatments, diagnostics, use of their samples and data, personalized treatment

- FDA
  - Opportunities for standards and regulatory policy

- Pharma
  - Biomarkers, targets, pathways, disease biology and mechanisms, leading to more efficient drug discovery and development process, targeted therapies, opportunity to reduce spend internally, innovation

- Diagnostic Co
  - Portfolio of potential diagnostic products, reduction in risk for discovery process

- Academia / Health Systems
  - Data, knowledge, basis for exploration and hypothesis generation, funding, more effective diagnoses and treatment, innovative discovery, accessible data

- Society
  - All constituents give back to society as an ROI
Genetic variation in IL28B predicts hepatitis C treatment-induced viral clearance


LabCorp Service Announcement

LabCorp Launches Interleukin 28B Polymorphism (IL28B) Genotype Test to Support Individualized Treatment Decisions for Patients with Hepatitis C Viral Infection.

As a specialty provider of HCV testing services, LabCorp is committed to being at the forefront of new tests and technologies to support HCV-treating physicians and their patients. Beginning July 12, 2010, LabCorp will be one of the first clinical reference laboratory to offer the IL28B polymorphism (rs12979860) genotype test.
Today’s Agenda and Goals

- Recap of NCPF meeting in February
- Requisites for successful precompetitive collaboration
- Framework of collaborations with the pharmaceutical industry
- Biospecimens and data
- Panel Discussion
- Summary and Conclusions
Working Group

Adam Berger - NAS
Stephen Eck - Lilly
Geoff Ginsburg - Duke
Erin Hammers - NAS
Lyla Hernandez - NAS
Garry Neil – J&J
Aidan Power - Pfizer
Laura Rodriguez - NIH
Kevin Shulman - Duke
Sharon Terry – Genetic Alliance
Martha Turner - ANA
Issam Zineh - FDA