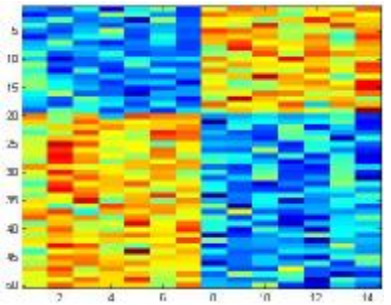


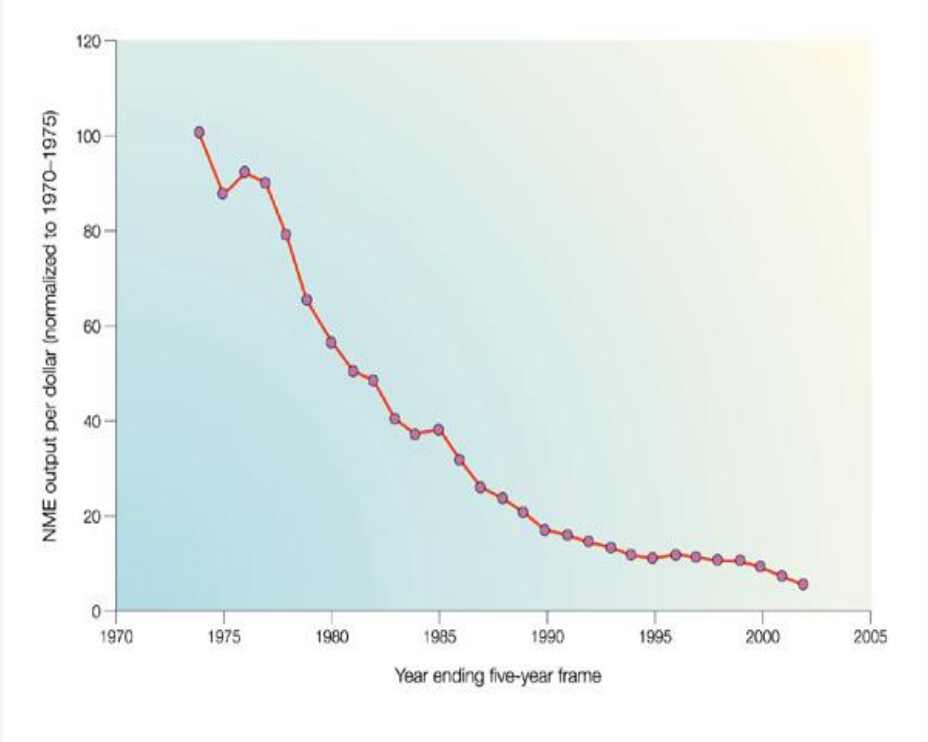
Establishing Precompetitive Collaborations to Stimulate Genomics Driven Drug Development

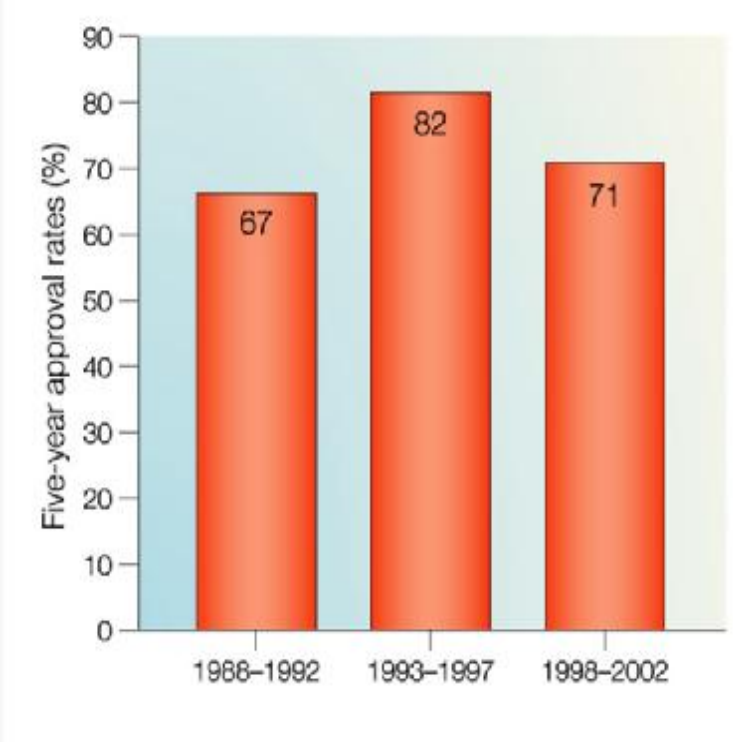
Geoffrey S Ginsburg, MD, PhD
Director, Center for Genomic Medicine
Professor of Medicine and Pathology
Duke University

IOM Workshop

July 22, 2010

The Productivity Problem





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

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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

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Opportunities for Pharma

- Biospecimens
- Model systems
- Targets
- Probes
- Clinical and molecular data
- Preclinical models
- Software
- Clinical trials data

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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

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Biobanking in the U.S. (ca. 1999)

Table 2. Stored Tissue Samples in the United States

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

SOURCE: E. Eiseman and S. Haga, RAND Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples, MR954OST, p.141. Santa Monica, CA: RAND Corporation. Copyright 1999 RAND Corporation.

§ **Accumulation rate** (circa 1999): approx. 9 million per year

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Creation of a national network of existing biobanks

Purported foundation for a national network:

Existing large US cohort studies with biospecimen repositories containing blood and/or DNA samples

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

*Expected totals upon completion

Source: Willett, W. C. et al. (2007) "Merging and Emerging Cohorts," *Nature*, 445, 257-258.

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Patient Enrollment and Samples Pharma Co and Academic Health Center

- Pharma Co
  - ~32,000 patients in clinical trials per year
    - Specimens collected on some
  - >> 1 M banked specimens linked to clinical trial data
  - Generally in single bank
  - Limited access
- Academic Health Center
  - ~45,000 patient in trials and registries
    - Specimens collected on some
  - >> 1M samples banked some linked to specific phenotypes
  - Generally fragmented
  - Limited access

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Why are biospecimens so important ?

- Target Discovery
- Target Validation
- Biomarkers for decision making
- Pharmacodynamic
- Pharmacogenomic
- Predisposition
- Prognosis
- Efficacy/monitoring
- Discovery, replication, validation

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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

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The Potential

nature

LETTERS

Genetic variation in *IL28B* predicts hepatitis C treatment-induced viral clearance

Dongliang Ge[1], Jacques Fellay[1], Alexander J. Thompson[2], Jason S. Simon[3], Kevin V. Shianna[1], Thomas J. Urban[1], Erin L. Heinzen[1], Ping Qiu[1], Arthur H. Bertelsen[4], Andrew J. Muir[2], Mark Sulkowski[2], John G. McHutchison[2] & David B. Goldstein[1]

nature

LETTERS

Genetic variation in *IL28B* and spontaneous clearance of hepatitis C virus

David L. Thomas[1], Chloe L. Thio[2], Maureen P. Martin[3], Ying Qi[3], Dongliang Ge[3], Colm O'hUigin[3], Judith Kidd[4], Kenneth Kidd[4], Salim I. Khakoo[5], Graeme Alexander[6], James J. Goedert[7], Gregory D. Kirk[8], Sharyne M. Donfield[9], Hugo R. Rosen[10], Leslie H. Tobler[11], Michael P. Busch[11], John G. McHutchison[12], David B. Goldstein[3] & Mary Carrington[3]

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.

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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

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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

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