The Time is Now: Engineering in Biology, Medicine and Economics

EMBS

April 10, 2008

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Disclaimer: The views expressed here are Ted's and not OCD's or Johnson & Johnson's

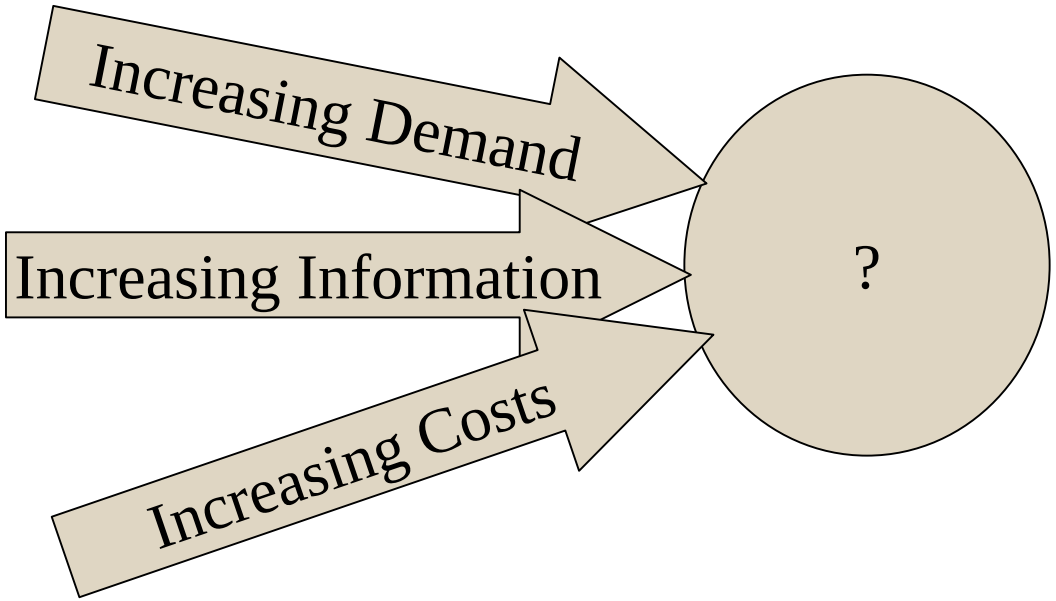
The Challenge

Today

- Aging population
- Significant unmet needs
- Increasing consumer awareness
- New technologies
- Rising healthcare costs

Future

- Personalized medicine with improved patient outcomes
- Lower healthcare costs
- Prevention instead of treatment



Longer Healthier Lives for More People Globally

Example Unmet Needs

- Medical:
  - 30% - 50% of patients currently don't know they are diabetic or pre-diabetic
  - Up to 30% of statins, 35% of ACE inhibitors and 50% of tricyclic antidepressant prescriptions are of limited or no benefit
  - About 4% of all prescriptions result in adverse reactions to the prescribed drug

- Economic Implications:
  - Cardiovascular disease is the #1 cause of death costing the healthcare system over $400B
  - 18+M diabetics & 50+M pre-diabetics in US alone costing healthcare system over $100B annually

Engineering in the Clinical Lab

VITROS 5,1 FS

MicroSlide™

MicroTip™

MicroSensor™

~80 Assays
10+ Protocols
455 Assemblies
1MM Lines of Code

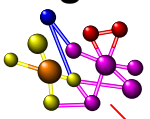
Disciplines

- Real-time control
- Thermal management
- Scheduling
- User Interfaces
- Optics & Sensing
- Biologic Fluids
- Test Result Management

Engineering in the Clinical Lab

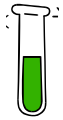
Our products include Chemistry, Robotics, Sensors and Software
With precision control over fluids, thermal, optics and acoustics

Reagents



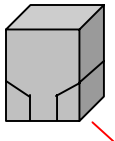
Dose Reponse Cu
Antibody Properti
Label Properties

Patient Samples



Analyte Concentration
Interferences
Viscosity

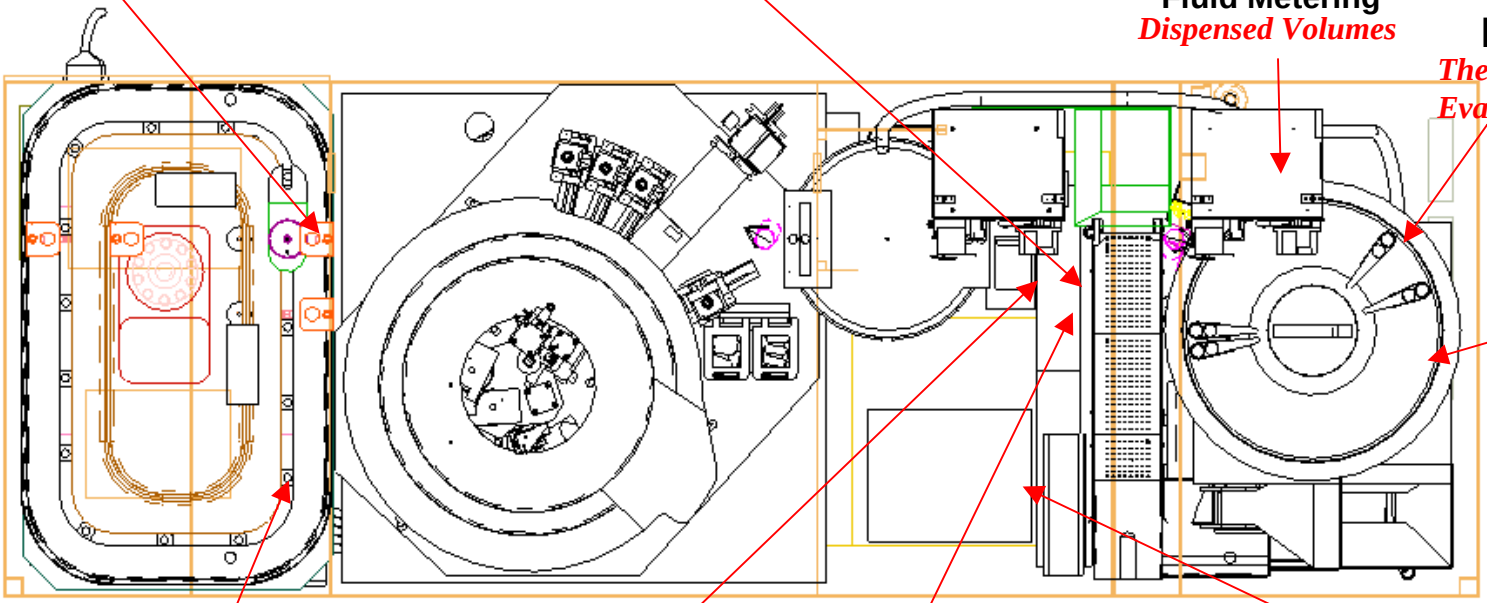
Reaction Cuvette



Optical Absorbance
Thermal Properties
Alignment
Path Length

Fluid Metering
Dispersed Volumes

Reagent Pack
Thermal Properties
Evaporation Control



Reagent Supply
Temperature
Evaporation

Sample Handler

Photometer
Photometer Noise

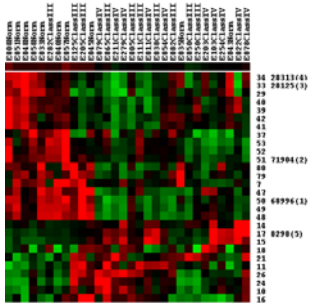
Cuvette Incubator
Temperature Control
Evaporation Control

Master Computer
Read times
Rate Algorithm
Cal/Predict Algorithm

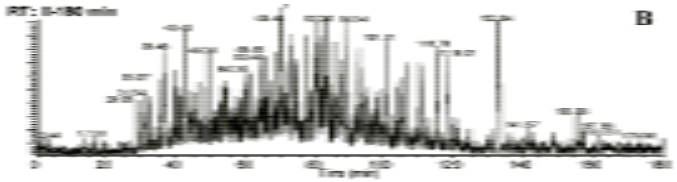
Instrument (Mechanical and Software)

New Sensors & More Information

- MicroArrays



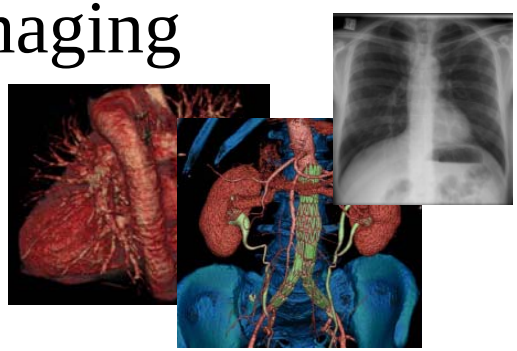
- Mass-spec



- Lab Automation

- Biometric Data

- Imaging



- Information Technology

EMRs

Microsoft HealthVault

WebMD

patientslikeme

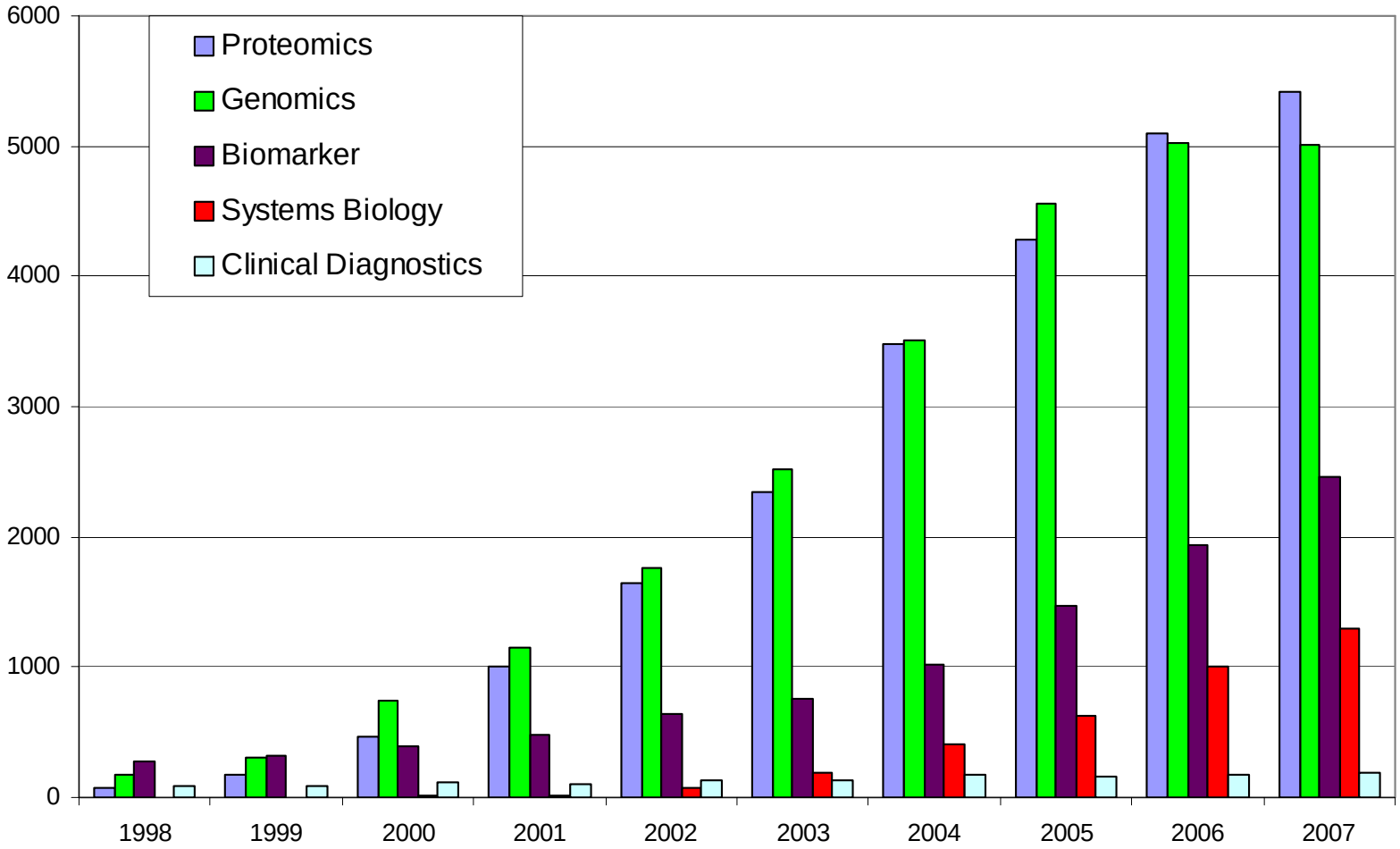
DIABETESPHD
PERSONAL HEALTH DECISIONS

Many Technology Players

- Abaxis, Inc.
- Abbott Laboratories
- Accumetrics Incorporated
- Accurex Biomedical Pvt. Ltd.
- AccuTech, LLC 10
- Acon Laboratories, Inc.
- Adeza Biomedical
- Advantage Diagnostics Corporation
- Alfa Scientific Designs
- A. Menarini Diagnostics
- American Bio Medica Corporation
- American Bionostica, Inc.
- Ameritek, Inc. 19
- Ani Biotech Oy (Ltd.)
- Array Medical
- Avitar, Inc.
- Avox Systems, Inc
- Axis-Shield PoC AS
- Bayer Diagnostics
- Beckman Coulter, Inc.
- Biex, Inc.
- Binax Inc.
- Biomerica, Inc.
- Bio-Rad Laboratories
- BioScan Screening Systems, Inc.
- Biosite Incorporated
- BioSource Europe S.A.
- Calypte Biomedical Corporation
- Care Diagnostica International
- Chematics, Inc.
- Chiron Corporation
- Cholestech
- CooperSurgical, Inc.
- Cozart Bioscience Limited
- Cygnus, Inc.
- Dade Behring, Inc.
- Denka Seiken Co., Ltd.
- Diagnostic Chemicals Limited
- Diagnostic Products Corporation
- Diametrics Medical, Inc.
- Empyrean Bioscience
- Enterix Pty Ltd
- Erich Jaeger GmbH
- Genzyme Diagnostics
- Gryphus Diagnostics, LLC
- HandyLab, Inc.
- Helena Laboratories Corporation
- HemoCue AB
- Home Access Health Corporation
- Hunter Diagnostics Ltd
- Hypoguard USA, Inc.
- IMI International Medical Innovations Inc.
- ImmunoScience, Inc.
- Instrumentation Laboratory Company
- International Technidyne Corporation
- Kyowa Hakko Kogyo Co. Ltd.
- LifePoint, Inc.
- LifeScan, Inc.
- Lifestream Technologies, Inc.
- Litmus Concepts, Inc.
- Matritech, Inc.
- Medical Services International, Inc.
- Mediwatch Plc 79
- MedMira Laboratories
- Medtox Diagnostics, Inc.
- Medtronic MiniMed
- Meretek Diagnostics
- Meridian Bioscience, Inc.
- Metrika Inc.
- Micronics, Inc.
- Molecular Diagnostics
- Murex Biotech Limited
- New Horizons Diagnostics Corporation
- Nova Biomedical Corporation
- Optical Sensors Incorporated
- OraSure Technologies
- Orgenics Ltd.
- Ostex International, Inc.
- PharmaNetics, Inc.
- Philips Medical Systems
- Progen Biotechnik GmbH
- Provalis Diagnostics
- Quidel Corporation
- Radiometer A/S
- Response Biomedical Corp.
- Roche Diagnostics International AG
- Saliva Diagnostic Systems
- Savyon Diagnostics Ltd.
- Shanghai Kehua Bioengineering Co. Ltd.
- Spectral Diagnostics Inc.
- Stanbio Laboratory
- SunTech Medical
- SYN-X Pharma Inc.
- TheraSense
- Thermo BioStar, Inc.
- Trinity Biotech Plc
- Unipath Management Ltd.
- YD Diagnostics
- Zer Hitech Ltd.
- ZymeTx, Inc.

2005 data

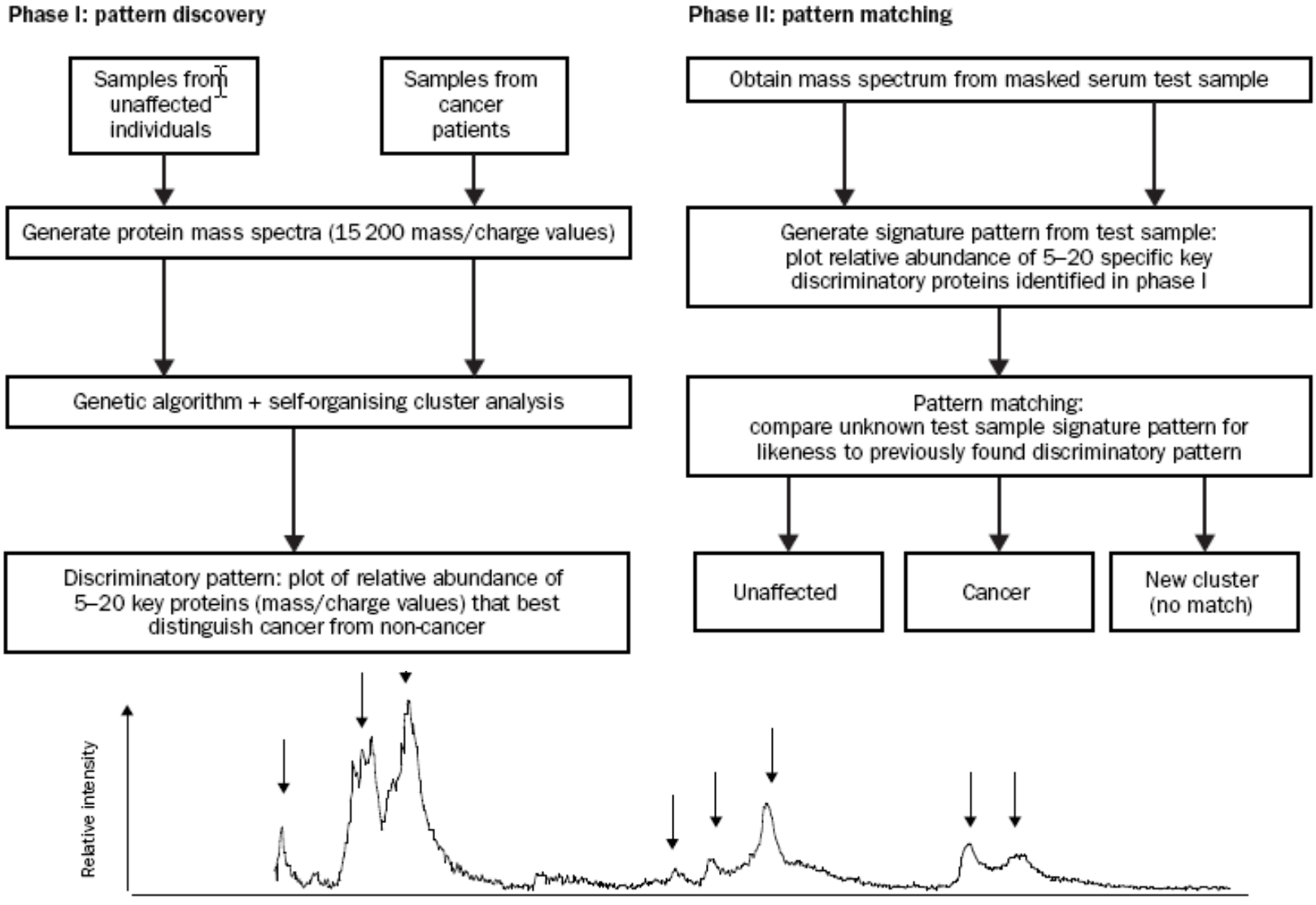
The information explosion



Source: Pubmed

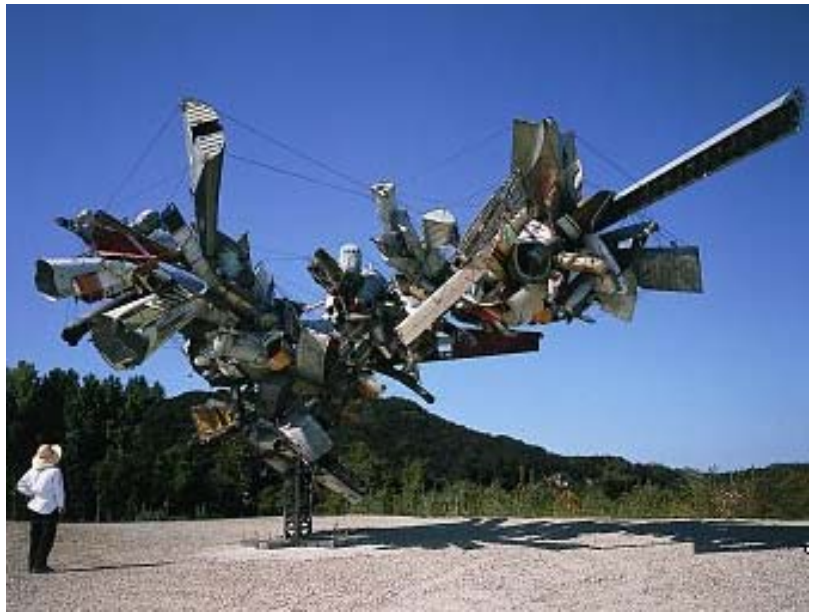
A New-Technology Example?

Petricoin et al, THE LANCET • Vol 359 • February 16, 2002



The genome is a parts list

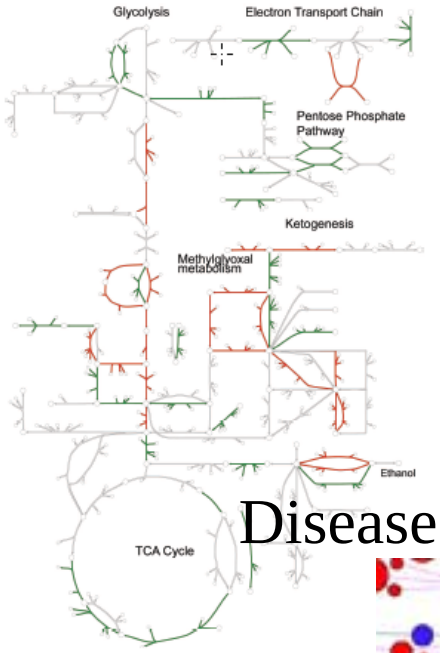
"If you take an airplane, a Boeing 777, in one sense you'd know a lot. You'd know 100,000 components that have got to be there, screws and wires and the rudders and things like that. On the other hand, I bet you wouldn't know how to put it together. And I bet you wouldn't know why it flies… but you'd be crazy not to start with a parts list". – Eric Lander 2001



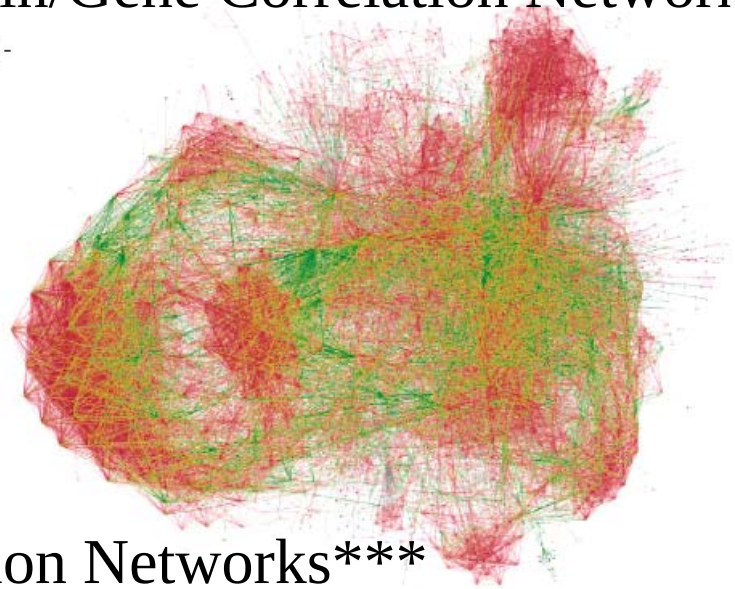
Nancy Rubins Sculpture

Analyte-Process-Disease Relationships

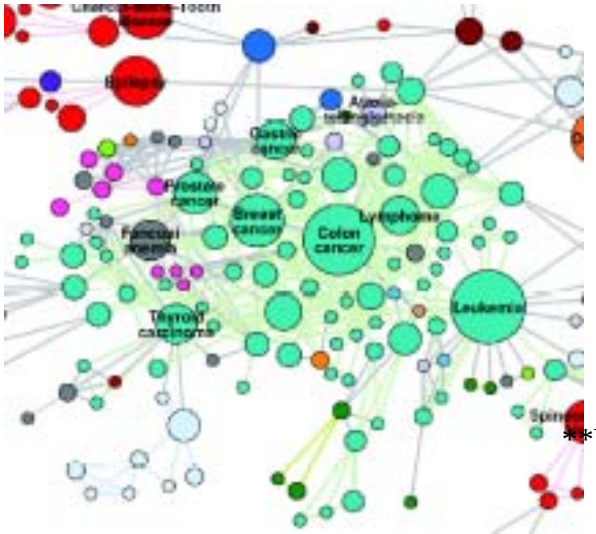
Metabolic Networks*



Protein/Gene Correlation Networks**



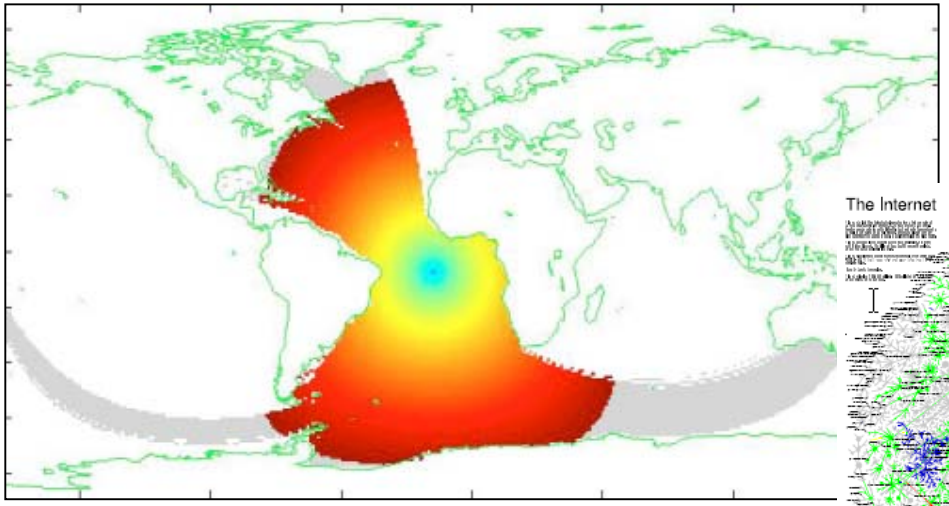
Disease Correlation Networks***



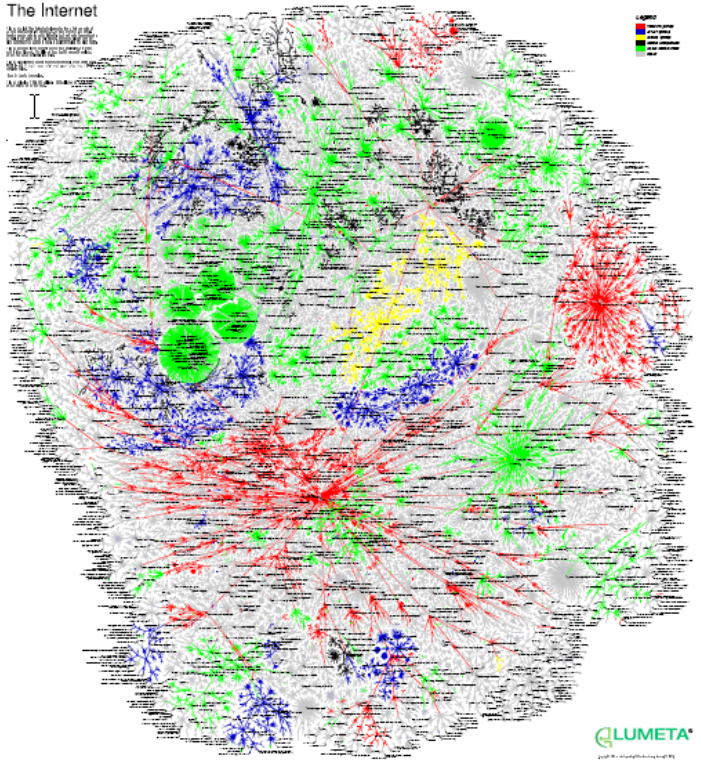
*Duarte, PNAS, vol. 104 no. 6 2007
**Van der Greef, J Proteome Res Vol. 6, No. 4, 2007
*** Goh, PNAS vol. 104 no. 21, 2007

Integrating disciplines and large datasets

Acoustics, Oceanography



Networking



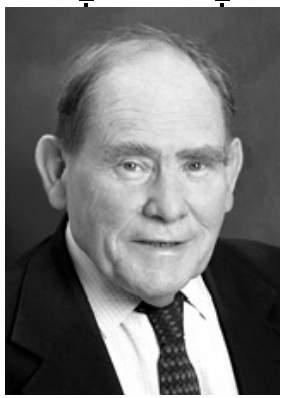
But that's not all …..

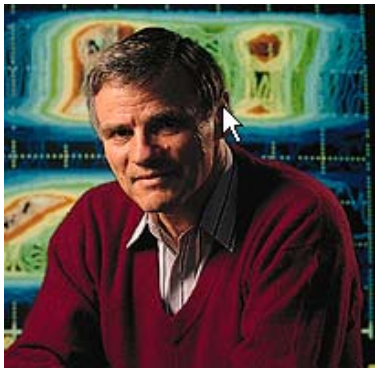
- When is a test or procedure of medical value? Early or late? For the whole population?
- When is a test or procedure of economic value? Early or late? For the whole population?
  - Today, 70% of decisions are made on laboratory diagnostics, while they account for less than 1% of the hospital budget

New sophisticated devices and diagnostics will only be successful if they are linked to BOTH Medical Outcomes and Economic Outcomes

What's the path forward?

- "The problem of biology is not to stand aghast at the complexity but to conquer it" – Sydney Brenner, April 2004





- "We knew we'd have to integrate chemistry with engineering with computer science with biology"
  - Lee Hood

The time is now to apply engineering principles to these large problems and move beyond "localized solutions"

Engineering has much to contribute

- Structured methods for large problems, large teams, multiple disciplines
- Top-Down vs Reductionist Methods
- Making sense of very large data sets
- Scoping level of complexity to level of need
- Understanding and enforcing the values of standards

Opportunities & Challenges

- Opportunities
  - Communicate & drive understanding of the value of standards
  - Architecture
  - Apply the power of modeling (bio, med, econ)
  - Continue with localized technology solutions
- Challenges
  - Technical
  - Learning to speak new languages
  - Leading well beyond the engineering community

Thank you