ASU Complex Adaptive Systems Initiative
Arizona State University

Burrill & Company
Life Sciences: Venture Capital, Private Equity, Merchant Banking, Media

Sustaining Healthcare Innovation in an Era of Constraint

Dr. George Poste
Director, Complex Adaptive Systems Initiative
and Del E. Webb Chair in Health Innovation
Arizona State University
george.poste@asu.edu
www.casi.asu.edu

6th Annual Burrill Personalized Medicine Meeting
Burlingame, California 27 September 2010

Major Challenges in Healthcare

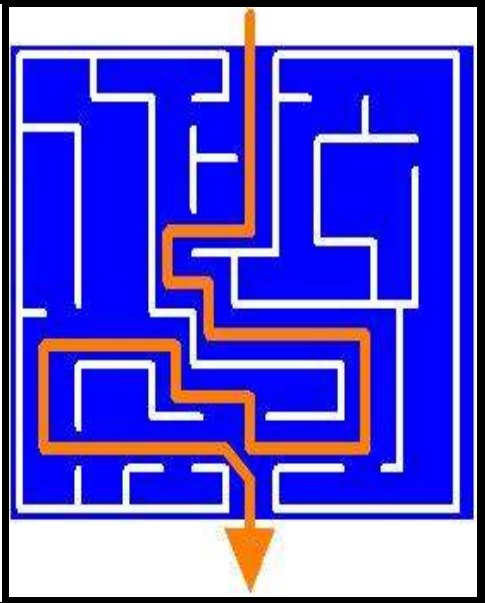
Cost	Demographics	Access	Variation in Clinical Practice
			

Major Challenges in Healthcare

Inefficient Use of Information

Fragmented Care Versus Integrated Care

Duplication, Defensive Medicine & Waste

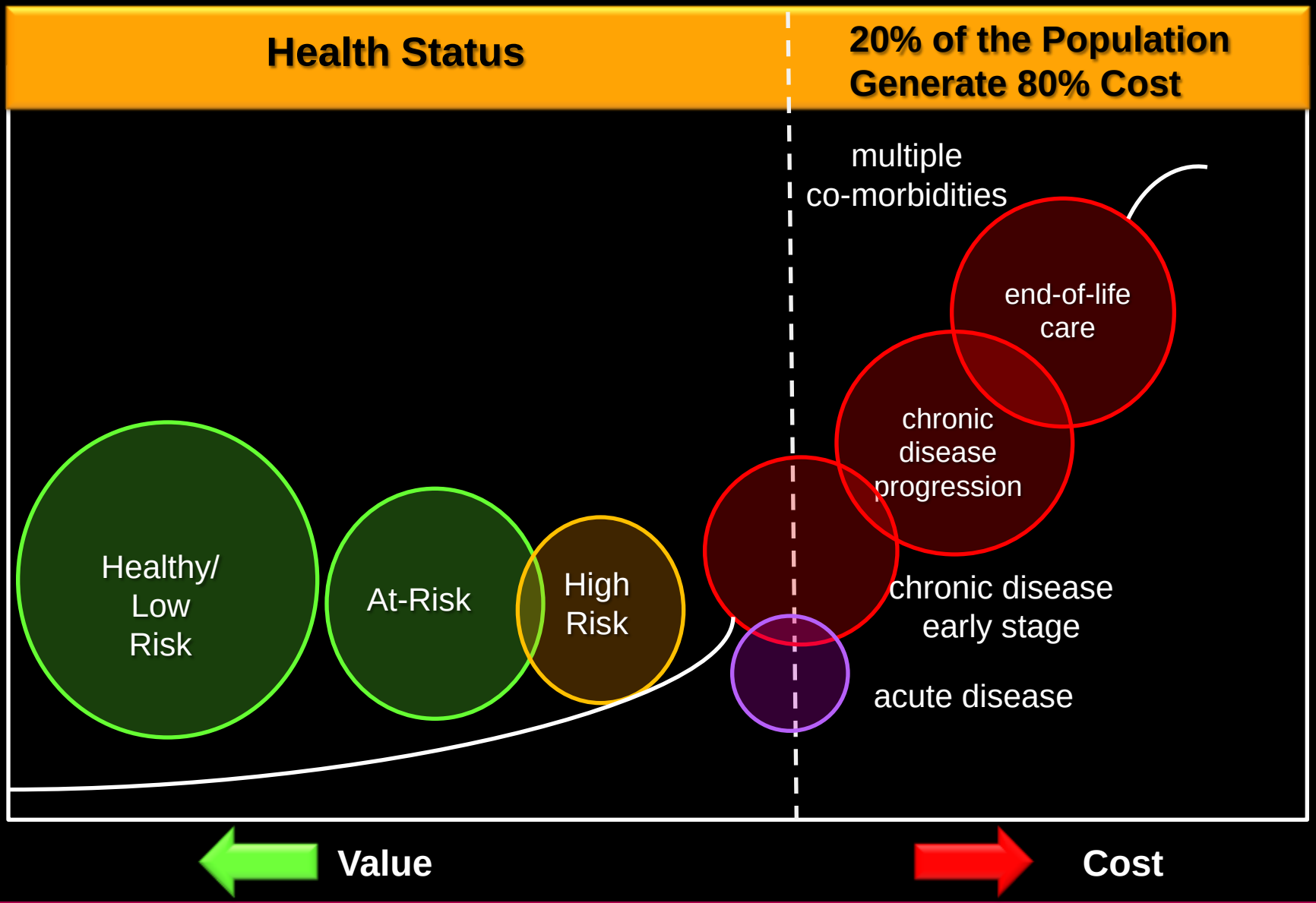


Protracted Adoption of Innovation

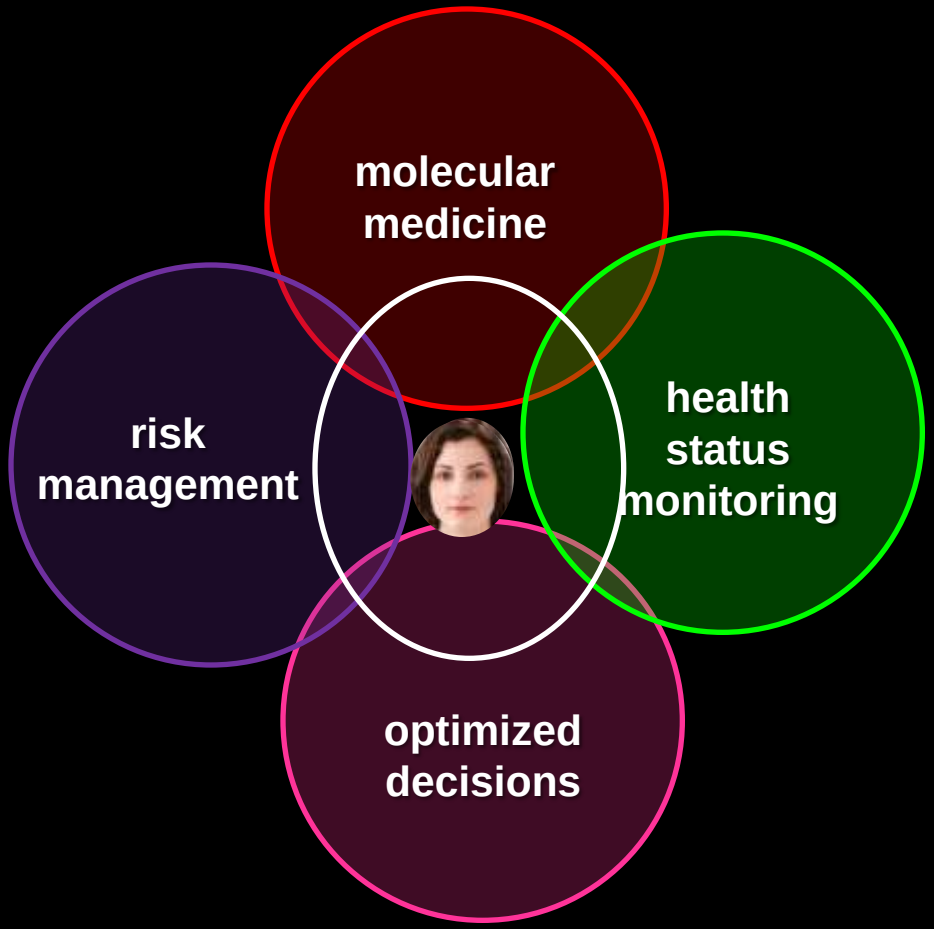
New Priorities in Biomedical Innovation

- historical “progress at any price” in an environment that largely ignored cost
- shift to increasing value-conscious environment
  - improved outcomes at same or lower cost
  - reducing cost with same quality (common in sectors other than healthcare)

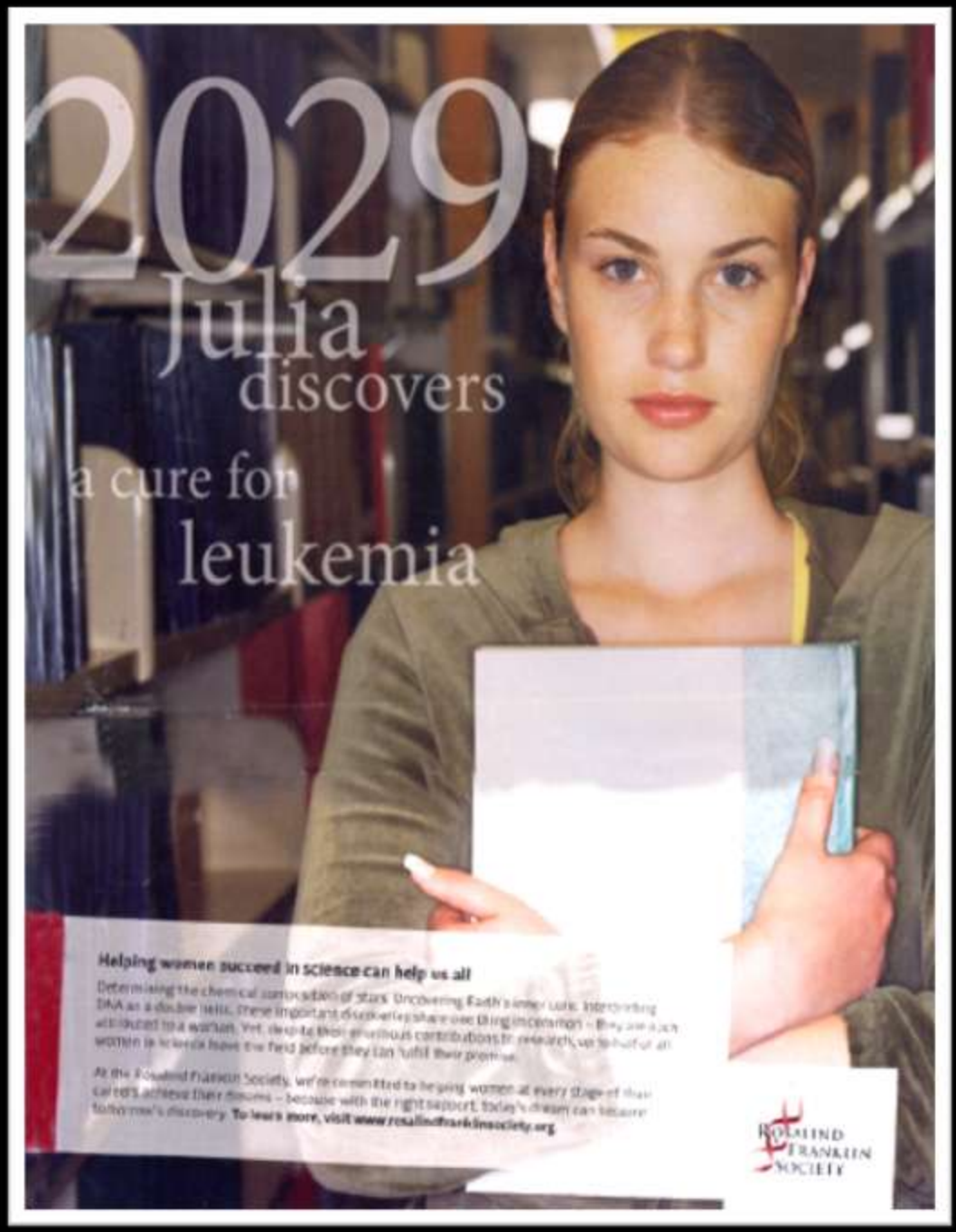
The Economic, Social and Clinical Benefits of Proactive Mitigation of Disease Risk and Chronic Disease Co-Morbidities



The Key Strategic Elements in the Evolution of Healthcare: Consumer: Patient Centric Care



Molecular Diagnostics:
The Key Value Driver in
Improving Healthcare and Maximizing Wellness


2029
Julia
discovers
a cure for
leukemia
Helping women succeed in science can help us all
ROSALIND FRANKLIN SOCIETY

Drug Discovery: Only for the Bold!

- sustained ‘high risk’ exercise
- biological complexity of chronic diseases and likely multi-focal target requirements
- uncertainty of ‘high reward’ absent increased predictability and evidence of clinical and economic benefits
- no obvious immediate technological solutions to dramatically shorten the protracted R&D cycle
- risk of shifting the current ‘valley of death’ to ‘valley of dearth’
- strategic imperative to define clear value propositions for new Rx

Biodiversity, Complexity and the Challenge of Genotype-Phenotype Prediction

- non-linear relationship between genotype and phenotype
- formidable challenges for biomedical and mathematical sciences
  - individual diversity in genome organization (SNPs, haplotypes, CNVs)
  - gene-gene interactions
  - epigenetics and imprinting
  - non-coding RNA regulatory networks
  - gene-environment interactions
  - gene-Rx interactions

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  - gene-environment interactions
  - gene-Rx interactions

- has the gap between basic science and therapeutic applications widened?
- how can complexity be stratified to identify tractable approaches for diagnosis, therapy selection and disease risk predisposition?

Optimizing The Efficiency of Healthcare Delivery and Maximizing Wellness

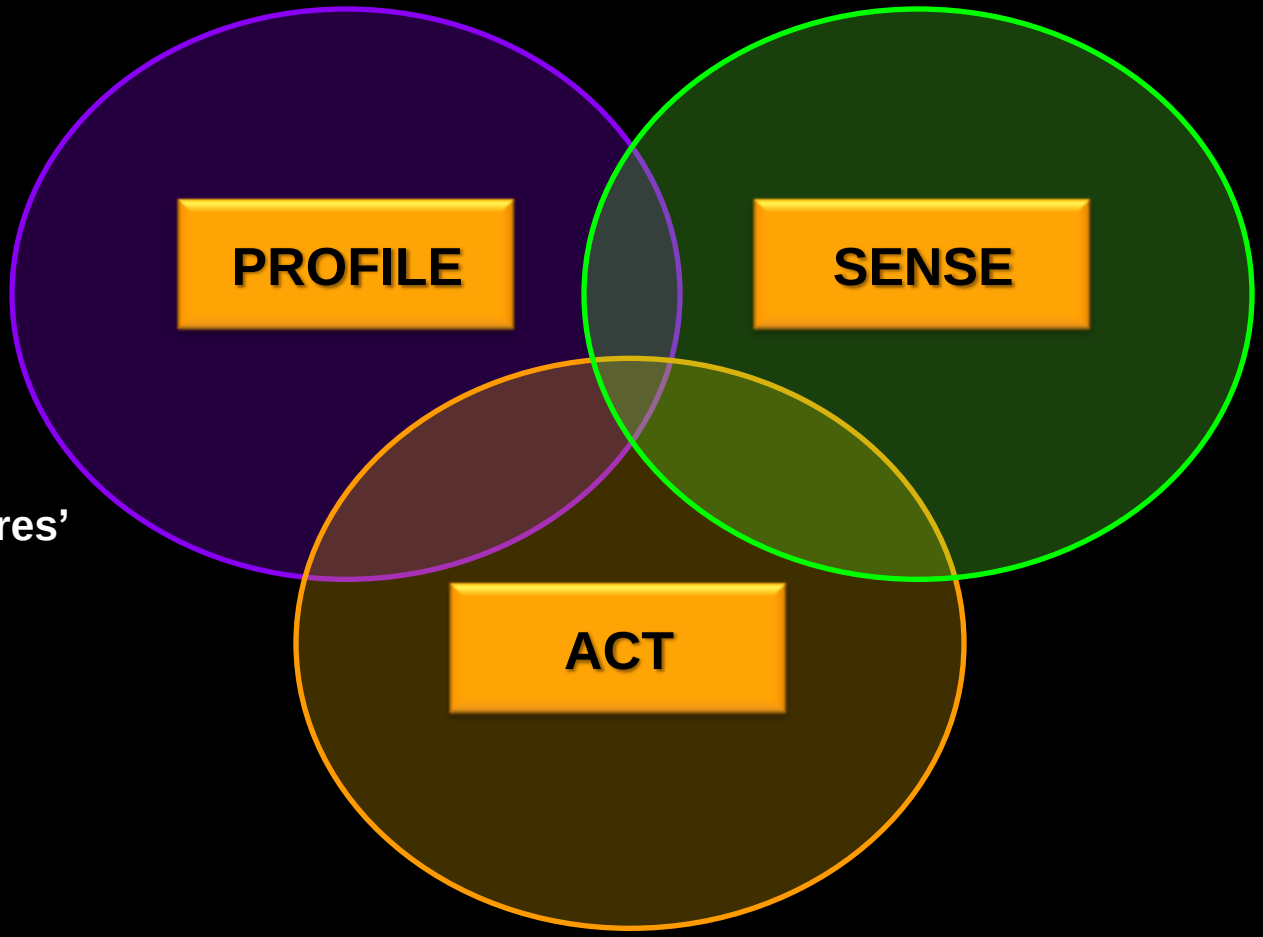
Let's Get Serious About Success:
A '18-S' Prescription!

Signatures

Mapping the Molecular Signatures of Disease: Building Integrated End-to-End Systems as the Foundation of Personalized Medicine

ID patterns of pathway and network dyregulation in disease

– "biosignatures'



automated platforms for rapid detection of multiplex analytes

rapid analytics and customized data formats/visualization to guide optimum decisions by clinicians, patients and payors

Biomarkers and Personalized Medicine: Promises, Pitfalls and Unrealized Potential

"The stark reality is that although academic conception
of new biomarkers is fertile,
their gestation is generally interminable"

Dr. Janet Woodcock
FDA
Clin. Pharm. Therap. (2009) 86, 13

"We're trying to get a complete picture
of where we are in the protein diagnostics business
which, by the way, is not in a good place."

"The FDA has approved one and half new (biomarker)
proteins per year,
flat, for the last 15 years
…that pretty much proves
that there's something wrong in the biomarker pipeline"

Genome Technology April 2010 p. 35

Disease-Associated Biomarkers and Validation of Novel Molecular Diagnostics

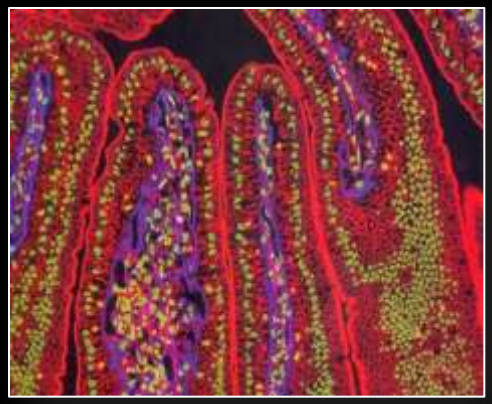
- literature dominated by anecdotal studies
  - academic laboratories
  - small patient cohorts
  - lack of standardization
  - poor replication and confirmatory studies
- very few biomarkers subjected to rigorous validation
  - inadequate stringency in clinical phenotyping
  - case-control studies with sufficient statistical power
- widespread lack of understanding of regulatory requirements in academic research community
  - complexities imposed by multiplex tests
  - new regulatory oversight (IVDMIAs)

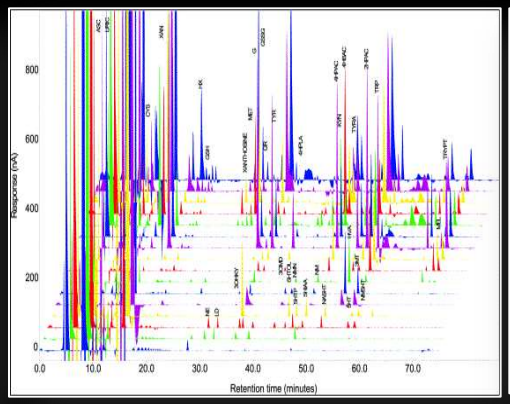
Success Demands a Systems-Based Approach

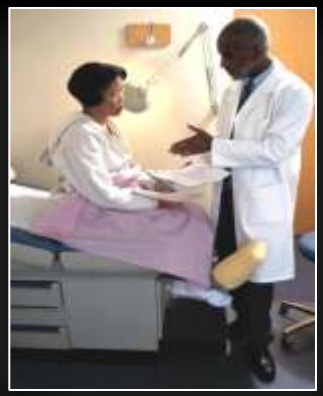
Adoption of New Technologies Demands a 'Systems' Approach to Life Cycle Analysis (LCA)

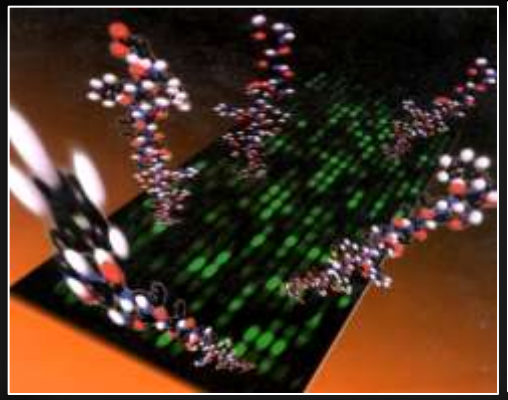
- discovery
- translation and validation
  - efficacy, safety
  - technical, clinical, regulatory
- qualification
  - levels of regulatory approval (CLIA, 510(k), PMA)
  - fit-for-purpose, clinical context
- value
  - clinical, patients, payors, society
- business model and ROI

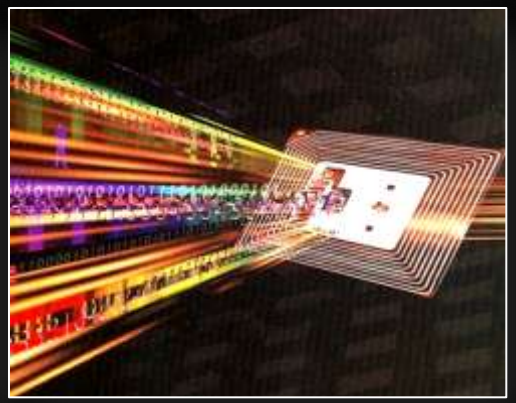
Identification and Validation of Disease-Associated Biomarkers: Obligate Need for a Systems-Based Approaches











Biospecimens and Molecular Pathway Analysis

Biomarker Validation and Multiplex Assays

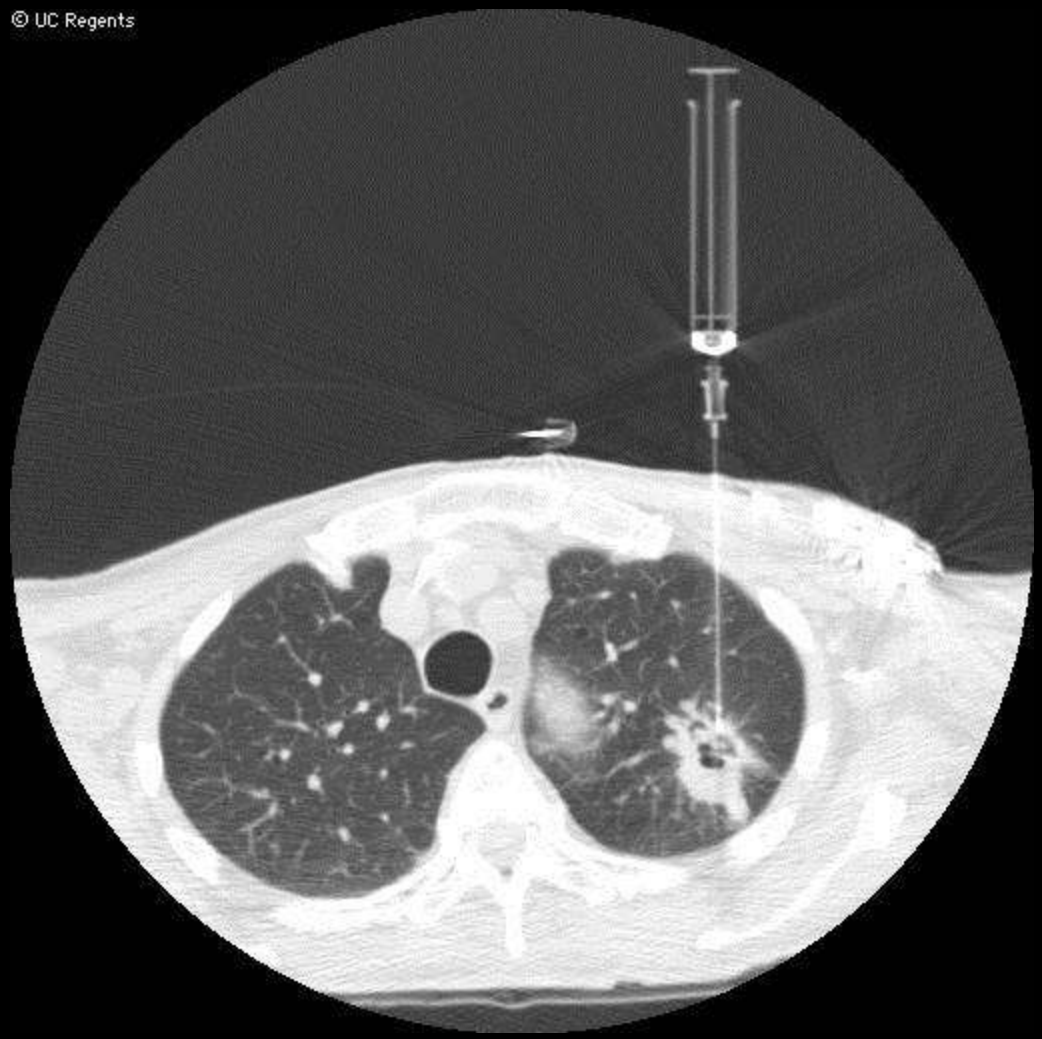
Instrumentation and Informatics

Clinical Impact and Patient Monitoring

Sourcing

Specimens

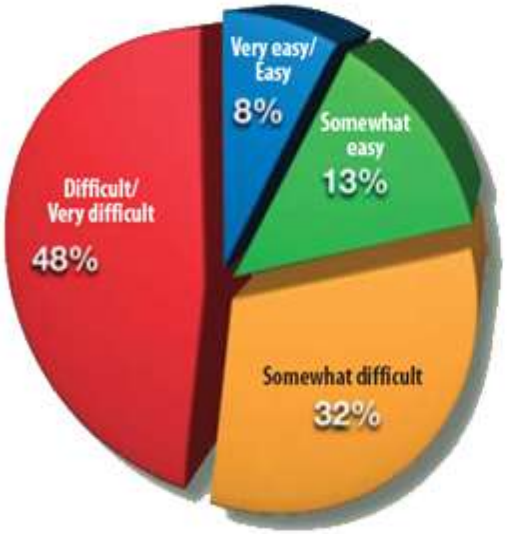
Standards
and
Standardization



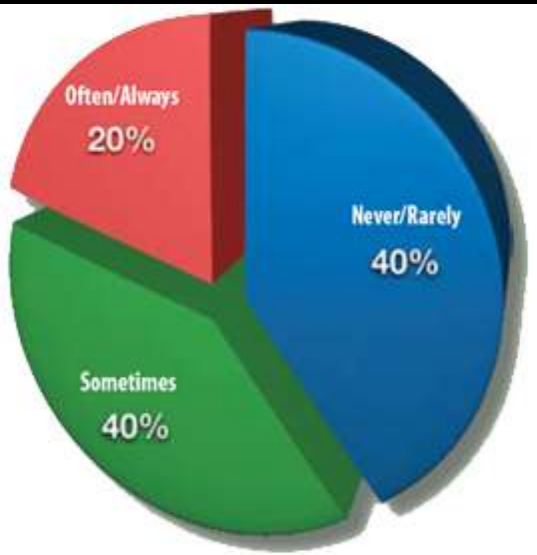
Source: http://i.bnet.com/blogs/ct-guided-percutaneous-lung-biopsy.jpg?tag=content;col1

Access to Quality Biospecimens for Medical Research: A Critical 'Choke Point' in Biomedical Research

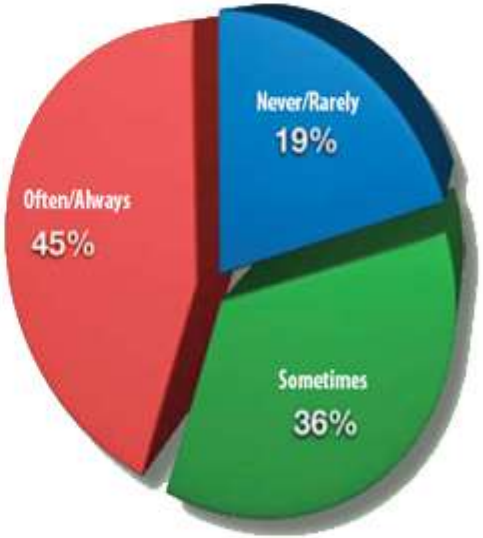
Ease of Acquiring the Quality of Biospecimens



Question Their Data Because of the Quality of Biospecimens



Limit Research Scope of Work Due to the Shortage of Quality Biospecimens



Source: Office of Biorepositories and Biospecimen Research, 2009.
http://biospecimens.cancer.gov/cahub/

Challenges Associated With Legacy Biobanks and "Samples of Convenience"

- highly variable storage, curation and clinical annotation
- investigator/institutional 'territorality' (cf. WU case)
- ambiguous and varied informed consent provisions
  - disease specific versus blanket 'research use'
- limited longitudinal sampling and correlation with clinical outcomes
- relative absence of normal tissue cohorts

The Importance of Standardized Methods and Data Tracking Systems for Biobanks

- PHOEBE (EU)
  - Promoting Harmonization of Epidemiological Biobanks in Europe
- NCI Office of Biorepositories and Biospecimen Research
  - National Biospecimen Network, caHUB
- BBMRI
  - Biobanking and Biomolecular Resources Research Infrastructure
- P3G
  - Public Population Project in Genomics

Stringency

- standards
- relevance

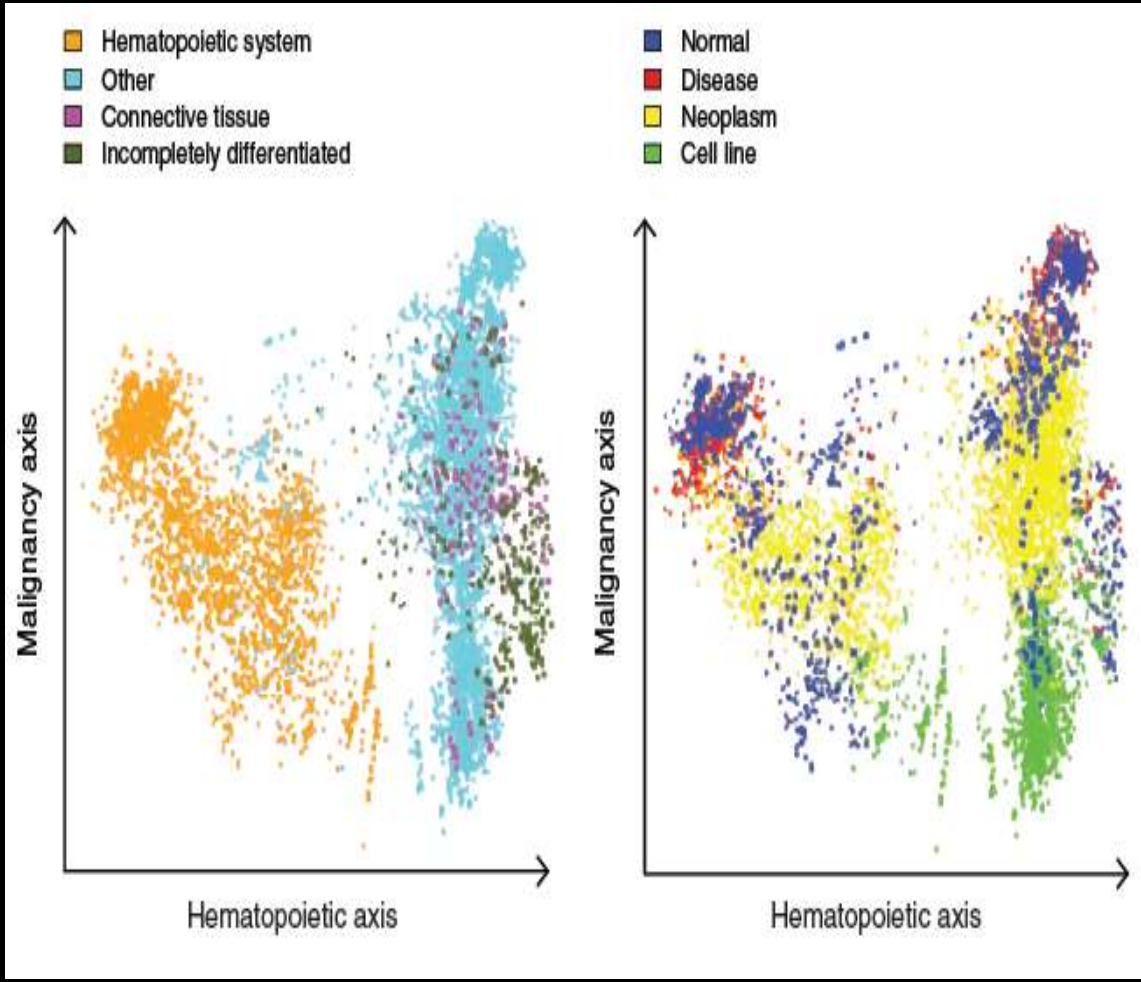
“The study of cancer cells in two dimensions seems quaint if not archaic”

T. Jacks and R.A. Weinberg (2002) Cell 111, 923

“Medline search reveals that more than 80% of cancer and molecular biologists still use two-dimensional techniques”

D.W. Hutmacher (2010) Nature Materials 9, 90

A Global Map of Human Gene Expression
M. Lukk et al. (2010) Nature Biotech. 28, 322



http://www.ebi.ac.uk/gxa/array/U133A

- 5372 microarray samples
- 206 different laboratories
- 163 different laboratories
- 369 cells, tissues, disease states and cell lines
- solid tissue cell lines cluster together rather than with respective tissues of origin or neoplasms from same lineage
  - 1217 genes upregulated in all cell lines
  - cell cycle, division and mitosis genes

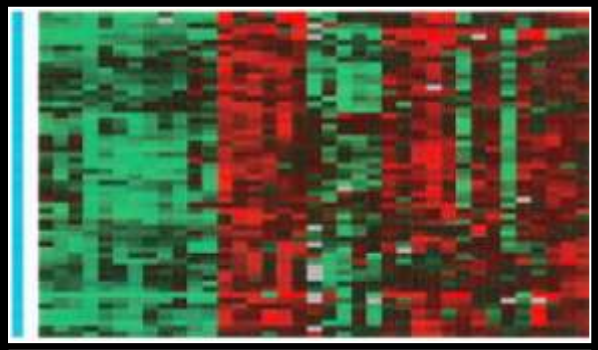
Mixed-Up Cell Lines

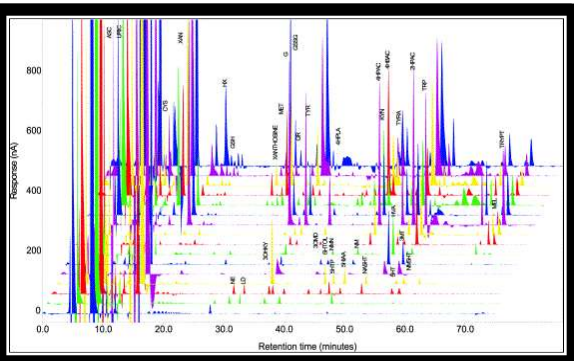
- risk of cross-contamination of cell cultures
- 50 years of warnings
  - overgrowth by HeLa cells as ‘early culprit’
- ECV 304
  - “immortalized normal endothelial cells”: over 1000 papers
  - Wilhelm Dirks (1999) revealed as human bladder carcinoma
  - 80 papers in 2008/2009 still referencing as endothelial cells
- contamination of mesenchymal stem cell lines
  - therapeutic implications and regulatory oversight
- obligate requirement for STR profiling
- obligate adoption of validation criterion for publication

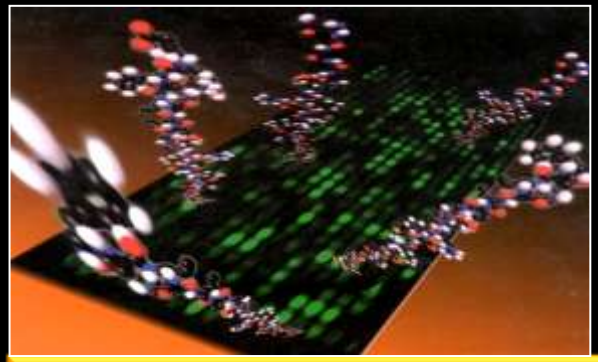
Setting Standards for Assay Platforms and Informatics

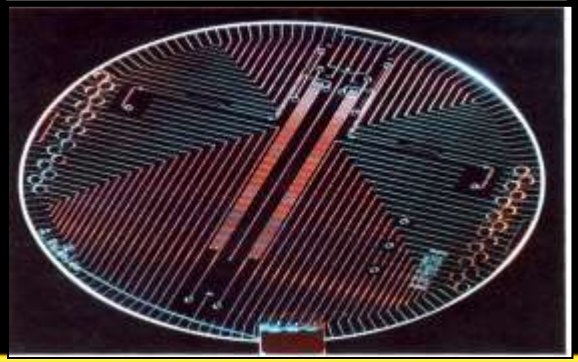
Complex Biosignature Profiling

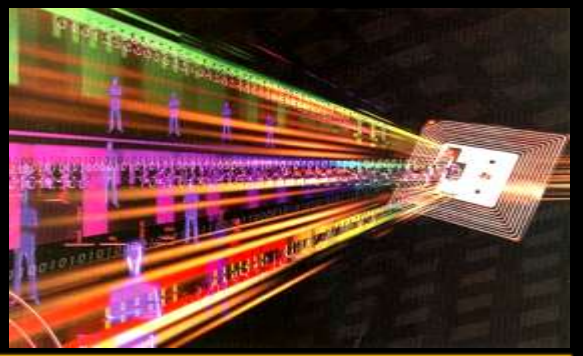
genomics	proteomics	immunosignatures











Signature Detection, Deconvolution and Multivariate Analysis

automated, high throughput multiplex assays	novel test formats and devices (POC)	new algorithms For complex signal/deconvolution

Enterprise Grade Biospecimen Collection, Management and Analytics: Controlling Pre-analytical and Analytical Variability

- standards, standards, standards!
  - consent and diverse regulatory/legal compliance needs
  - collection, transport, processing, analysis
  - storage and curation
  - chain of custody
  - longitudinal tracking of specimen samples, aliquots
  - integration of clinical and non-clinical data sets
  - systems integration LIMS/CTMS, GLP/GCP
  - facile data transfer to regulatory dossier/clinical EMR
  - suitability for mega-and meta-data analyses

Common Problems in MS-Based Proteomics

A.W. Bell et al. (2009) Nature Methods 6, 423

- evaluation of test sample of 20 purified proteins at 5 pmole equimolar abundance
- 7/27 labs with initial correct characterization
- raw data from all sufficient to identify full 20 protein catalog and 22 derivative 1250 Da peptides
- diverse and poorly standardized databases and search engines as principal sources of erroneous reporting
  - variation in curation, annotation, comprehensiveness

- real world challenges: high complexity samples and large preanalytical (collection/storage) sample variation

- education and training to use complex technologies
- publication standards, formats and open-source dbases

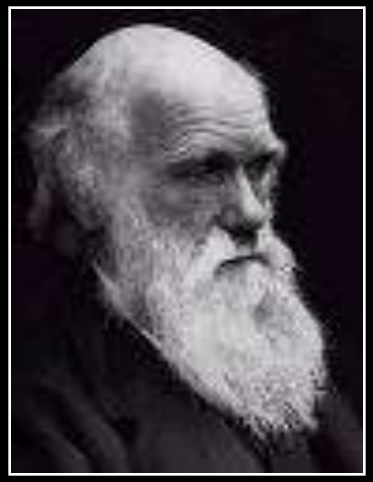
“We may be lost,
but we’re having a good time”

Yogi Berra

Systems Biology

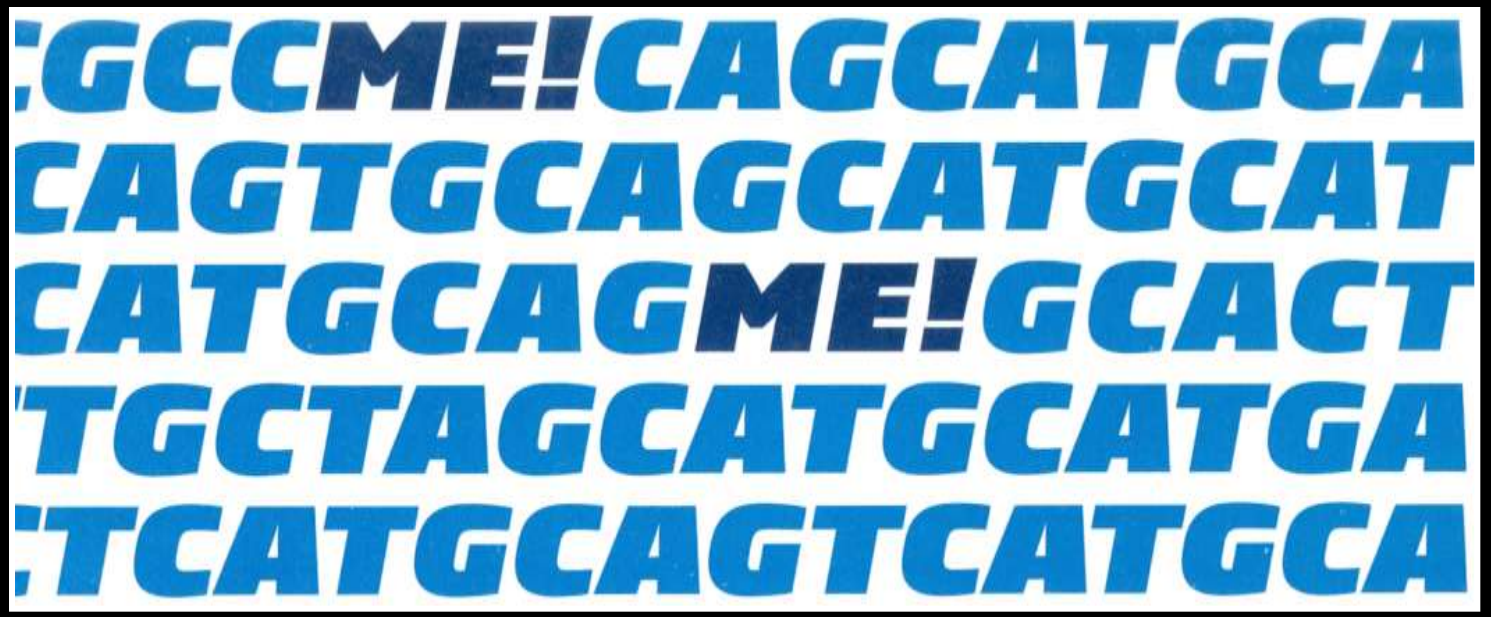
Mapping Biological Pathways and the Generation of Complex Network Behaviors

Mapping Human Diversity



“Our ignorance of the laws of variation is profound”

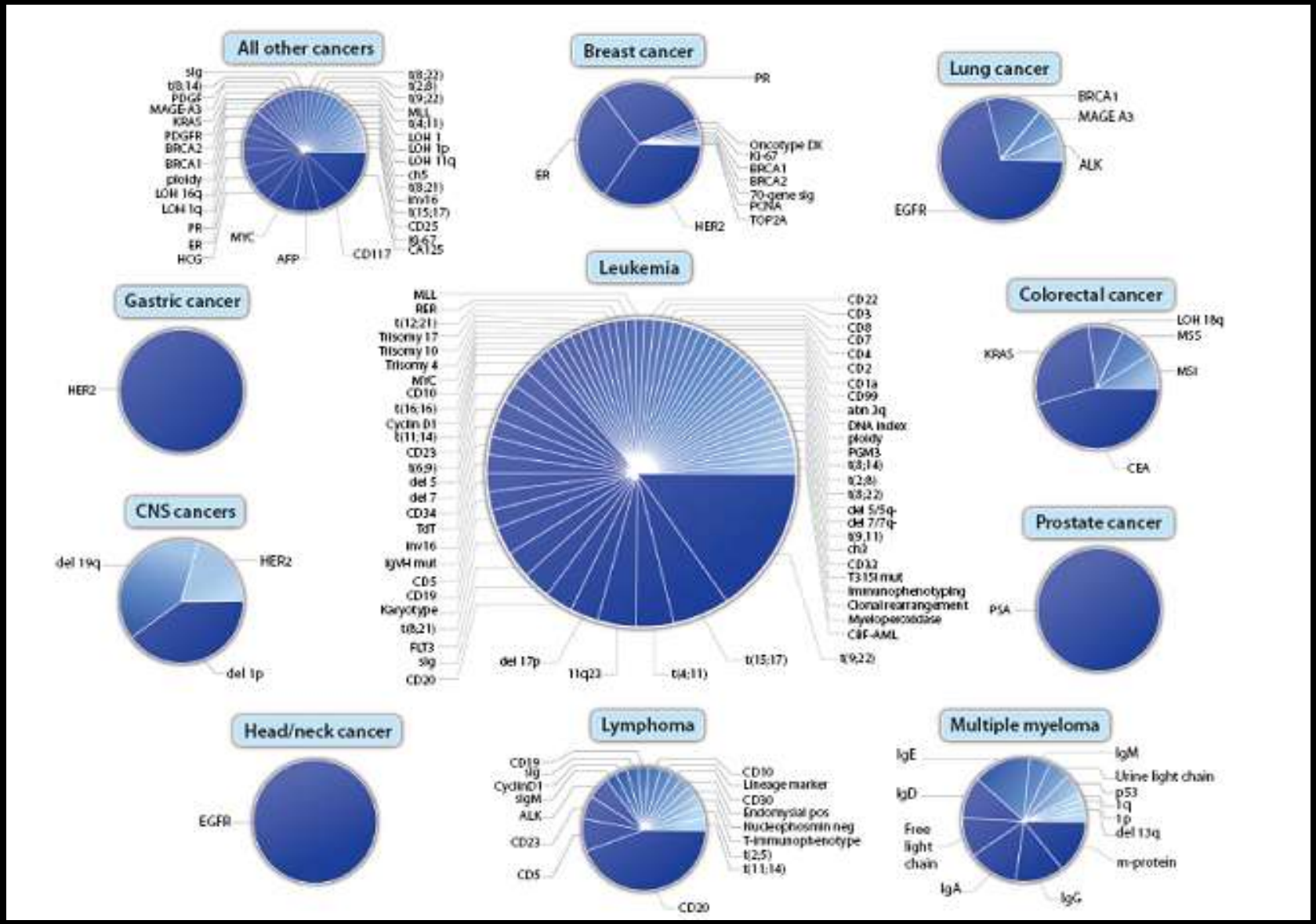
Charles Darwin



Genome Wide Association Studies of Disease Susceptiblity

- 400 alleles reported for 75 diseases in 230 GWAS studies
- scale, power, logistical complexity, cost and replication
- very large sample sizes for common risk alleles and testing 500K SNPs
  - OR 1.3 requires sample size of 1000 and
    OR 1.1 10,000 samples
- sample pooling
  - Institutional differences in clinical phenotyping
  - impact of imputation for mixed ethnic populations
- limited clinical utility since ORs are very small
- account for only very small fraction of purported heritability of disease susceptibility
- targeted at independent effects of single genes and no insight into interaction effects
  - epistasis, rSNPs in intergenic ‘deserts’, CNVs, epigenetics and imprinting
  - challenge of replication

Identification of Genomic Markers in Human Malignancies
From R. Sikovski and Ba Yao (2010) Sci. Trans. Med 2, 1

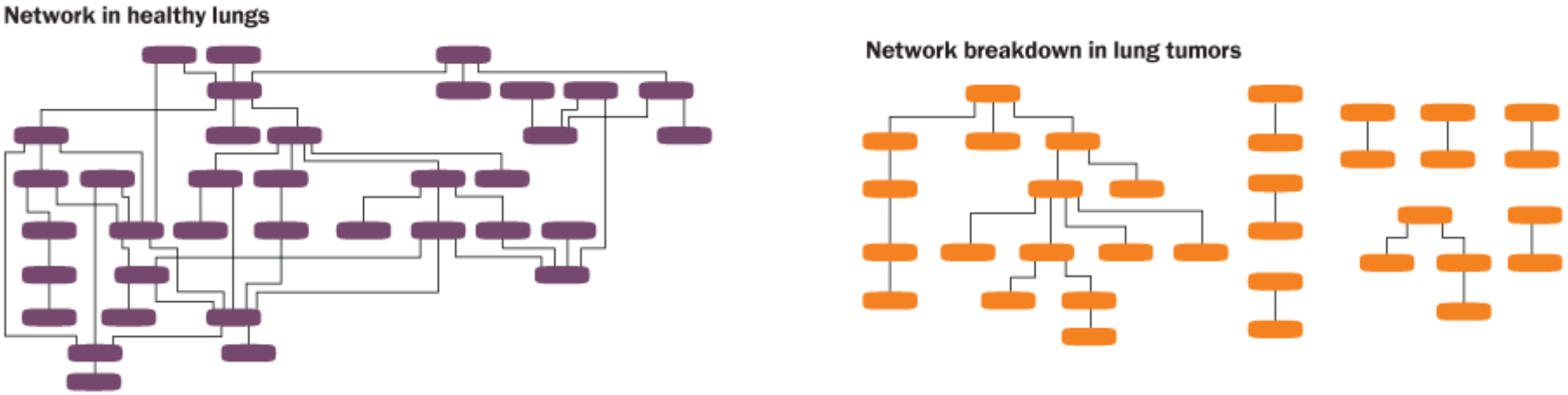


Mapping Disease-Associated Pathway and Network Perturbations:

Different Challenges for MDx Versus Rx

- intrinsic complexity of biological heterogeneity
  - molecular pathway/network perturbations
  - inter-patient variation
  - intra-patient variation with disease progression/Rx
- molecular diagnostic profiling will yield products more rapidly than the quest for novel Rx
  - Rx efficacy: action at multiple target sites?
  - Rx safety: interaction promiscuity for efficacy increases AE risk

Disruption of miRNA Connectivity in Lung Cancer



Adapted from: S. Volinia et al. (2010) Genome Research 20, 589 and T. H. Saey Science News 8/28/10

http://www.sciencenews.org/view/access/id/62153/name/microrna_network.gif

Selection

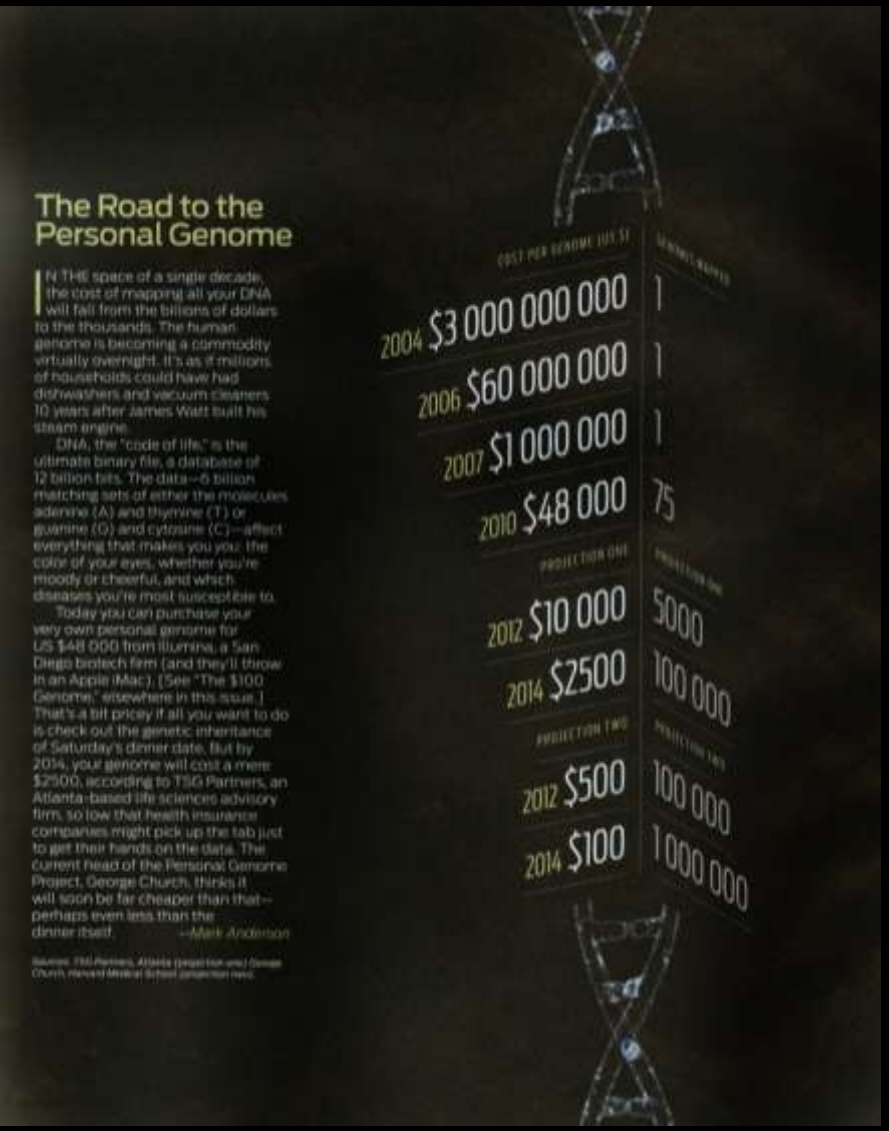
Stratification

Subtypes

The Excessive Time And Cost Of Clinical Trials and High Failure Rates

- ‘all comers’ design versus enrichment/adaptive trials with most relevant cohorts (disease subtypes)
- inadequate phenotyping of trial populations (clinical, molecular profiling)
- insufficient knowledge of molecular pathway and redundancy in mediating non-responsiveness
- cost/delay imposed by variation in recruitment enrollment
- limited patient/MD awareness of trial enrollment outside of academic medical centers
- standards for global clinical trials

Sequencing



Will Lost Cost Whole Genome Sequencing Change Everything?

Source: Sequencing; IEEE Spectrum 2/10

Next-Gen and Third Generation Genome Sequencing

GnuBio

The Views on Genome Sequencing and Clinical Diagnostics (From: In Vivo September 2010, p.62

"Not only is there a fundamental issue of whether sequencing is clinically useful, there are huge technical issues that will take a long time to solve to get robust enough for routine clinical use"

David Altshuler, Broad Institute
Co-Chair 1000 Genome Project

"Financially, next-gen sequencing is already at the point that allows you to move it into clinical programs
Our focus in on utilization of next-generation sequencing for whole transcriptome profiling and mutation analysis …..as the future for our business."

Randy Scott
Executive Chairman, Genomic Health

Baby Steps in Whole Genome Sequencing for Personalized Medicine

$1000 genome
(fully costed)

+

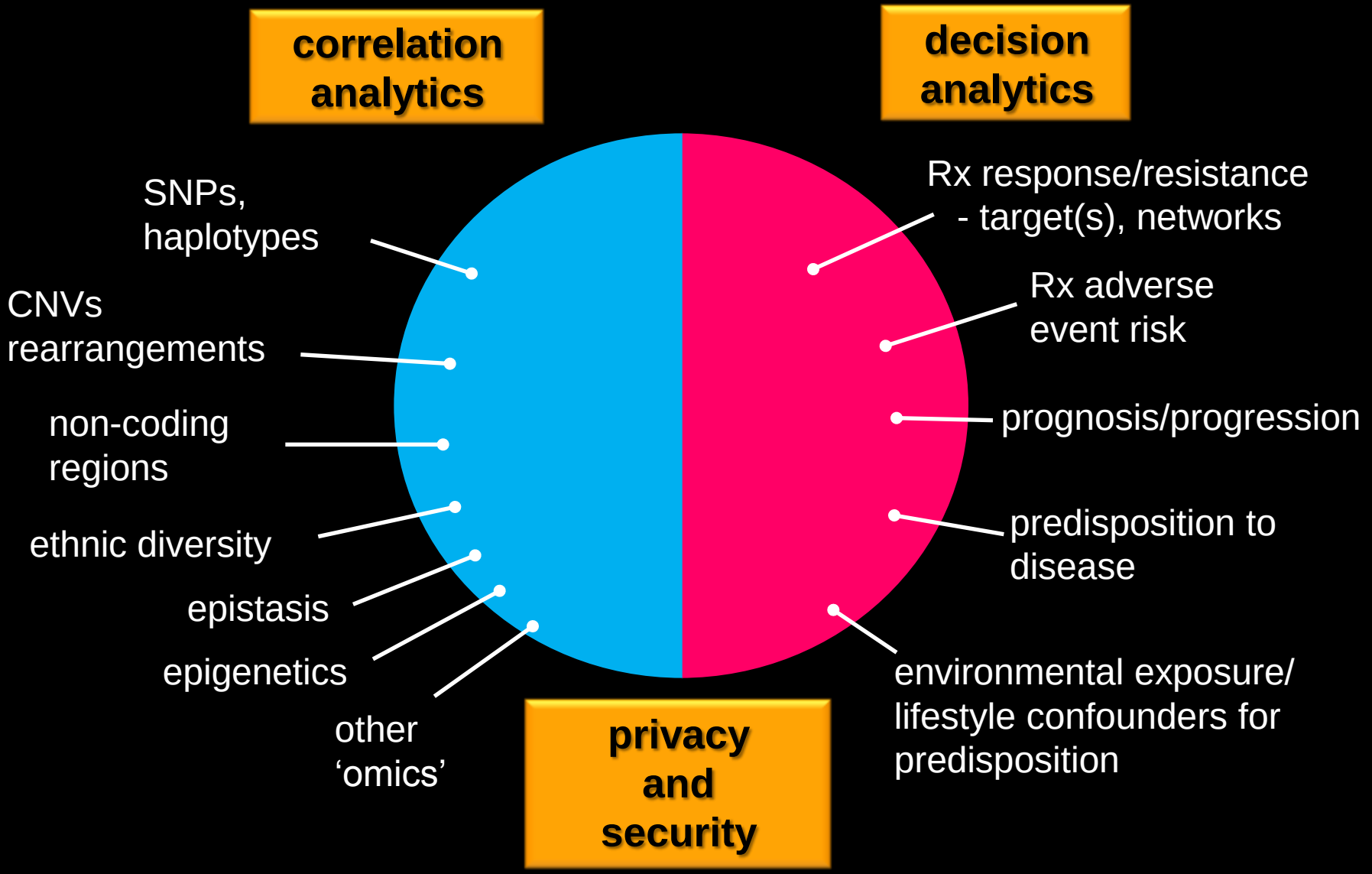
1000
genomes

= ?

Now Comes the Hard Part!
Large Scale WGS and the Primacy of Standards

- acquisition of rigorously phenotyped/matched/consented normal and disease samples
- standardization of pre-analytical and analytical methods and data reporting
- curation, ontologies, annotation, analytics for large scale databanks and federations
- new statistical/mathematical/computational approaches for multivariate, non-linear events
- regulatory validation of analytics
- customized data for different decision categories and decision-makers

Whole Genome Sequencing and Molecular Medicine: Dependency on Large Scale (Massive) Data Annotation and Analytics



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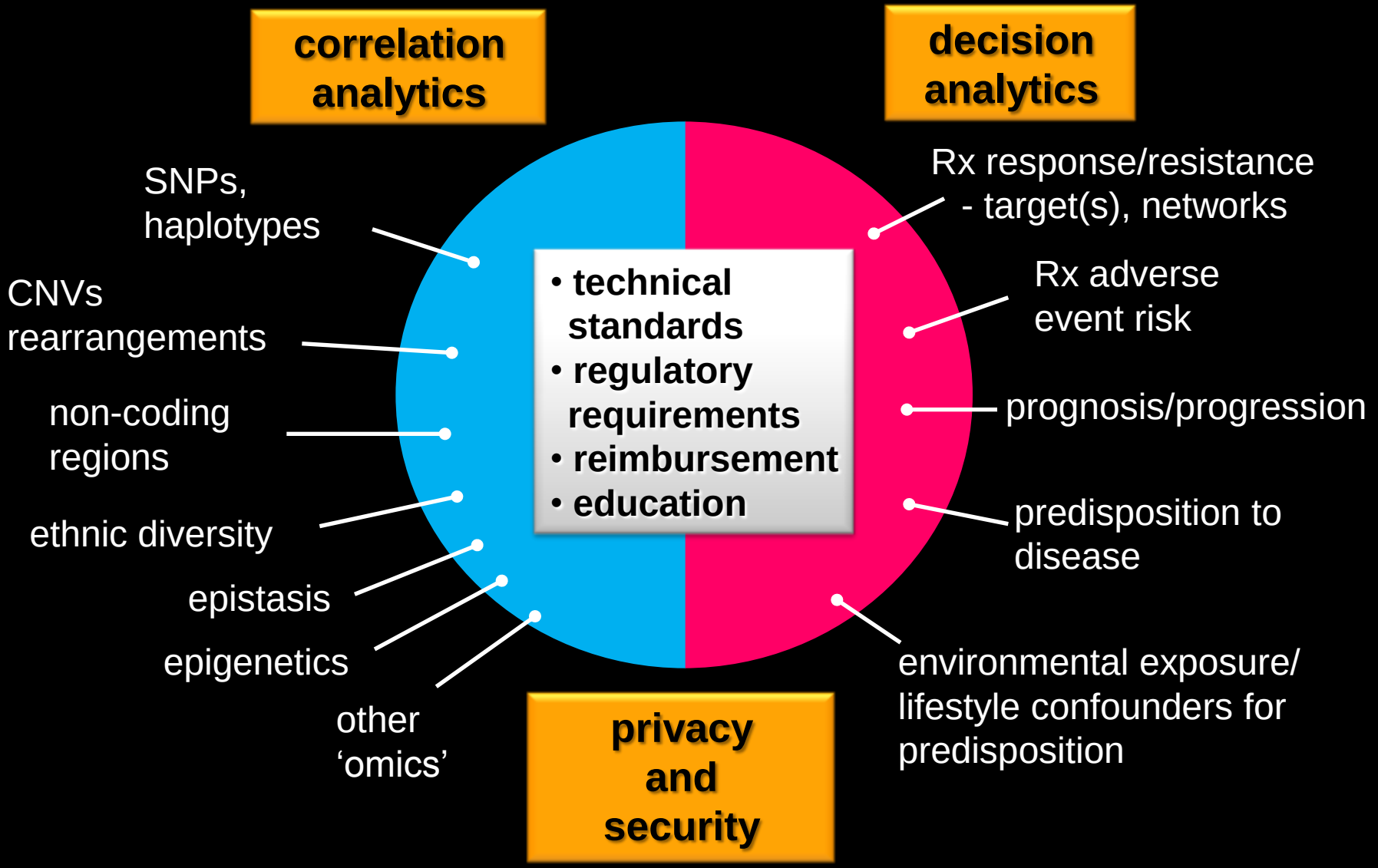


Standards for ‘Omics’ Data Cross-Domain Integration, Open-Source Data Sharing and Computational Analysis

Semantics

OBO Foundry Ontologies
Nature Biotechnology 25, 1251 - 1255 (2009)

The Open Biomedical Ontologies

Cell Ontology (CL)

Gene Ontology (GO)

Foundational Model of Anatomy

ZFIN

Zebrafish Anatomical Ontology

Chemical Entities of Biological Interest (ChEBI)

Disease Ontology (DO)

Plant Ontology (PO)

Sequence Ontology (SO)

Ontology for Clinical Investigations (OCI)

The Open Biomedical Ontologies

Common Anatomy Reference Ontology

The Open Biomedical Ontologies

Environment Ontology

Ontology for Biomedical Investigations

Phenotypic Quality Ontology (PATO)

Protein Ontology (PRO)

OBO Relation Ontology

RNA Ontology (RnaO)

Mining The Data Deluge:

- nomenclature ontologies
- liberate intelligence from multiple source formats
- interoperability challenges
- early discovery (chaos) vs. clinical trials (CDISC) vs. healthcare (HL7, SNOMED)
- urgent imperative for methodological, ontological and data storage format standards

Scale and Statistics

Validation of Disease-Associated Biomarkers

- disease related differences are small compared to range of biological variability in the population
- many variables behave as QTLs with graded continuum rather than binary normal: disease separation
- the high dimensionality small sample size (HDSS) problem
  - high number of variables (2000-10000) and low sample size (10-100)
  - increased risk of selection of variables due to chance (overfitting)
- statistical powering
  - “the 20:200:2000 rule”
- new regulatory complexities for multiplex ‘signatures’ as next-generation diagnostic tests/biomarkers

Speed

Specter for the Cure

Specter for the Cure - Cures Acceleration Network (CAN) Act
Turning Research into Cures

The Distressing State of Investigational Cancer Drug Trials in the USA

- Armitage report 1997 and IOM report 2010
  - need to reduce ‘Tower of Babel’ in clinical cancer research
- Sateren et al. 2002 J. Clin. Oncol. 20, 2109
  - less than 5% cancer patients enrolled in trials
- Durivage et al. 2009 J. Clin. Oncol. 27, 337s
  - 2685 industry and NCCN trials at 14 cancer centers
  - 1455 (54.2%) failed to accrue a single patient
- Dilts et al. 2009 J. Clin. Oncol. 27, 1761
  - 296 to 481 steps to activate trials by NCI-STEP and/or cooperative groups
- NCI Operational Efficiency Working Group 2010
  - timelines that trials must achieve otherwise automatic termination

Safety

Genetic Associations in Drug-Induced Liver Injury: Polymorphisms in Drug Metabolism Enzymes

Drugs	High-risk genotypes
Perhexiline	CYP2D6*3, *4, *5, and *6
Carbamazepine	GSTM1 null
Tacrine	GSTM1 and T1 null
Troglitazone	GSTSM1 and T1 null
Diverse	GSTM1 and T1 null
Methotrexate	GSTM1 non-null, RFC1 G80A
Anti-TB drugs	NAT2*5, *6, *7, CYP2E1 c1/c1, MnSOD T/C or C/C, GSTM1 null
Diclofenac	UGT2B7*2, CYP2C8 haplotype, ABCC2 C24T
Tolcapone	UGT1A haplotype
Indinavir	UGT1A1*28, UGT1A3 T66C-UGT1A7 T57G UGT1A1*6
Atazanavir	UGT1A1*28, UGT1A3 T66C-UGT1A7 T57G
Azathioprine	TPMT*3A and *3C

from: Y-S Huang (2010) Pers. Med. 7, 5

Genetic Associations in Drug-Induced Liver Injury: Polymorphisms in Immune-Related Pathways

Drugs	High-risk genotypes
Flucloxacillin	HLA-B*5701
Amoxicillin	HLA-DRB1*1501-DRB5*0101-DQB1*0602
Clavulanate	HLA-DQA1*0102-DQB1*0602
Ticlopidine	HLA-A*3303, HLA-DQB1*06
Ximelagastran	HLA-DRB1*07, HLA-DQA1*02
Anti-TB drugs	HLA-DQB1*0201
Diverse	HLA-DRB1*15, DQB1*06
Diclofenac	IL-10-627A and IL-4-590T
Tacrine	IL-6-597A-572G-174G haplotype

from: Y-S Huang (2010) Pers. Med. 7, 5

- third leading US Rx
- $9 billion annual sales
- biologically inactive dosage form
  - hepatic metabolic activation by CYP2C19
- carriers of loss of function CYP2C19 alleles non-responsive
  - 30% European ancestry, >50% Asians
- FDA black box warning (March 2010)
  - risk in ‘poor metabolizers’
- slow uptake of routine genotyping
- new momentum from launch of Medco and CVS/Caremark genotyping services?

Sales

If You Build It Will They Pay?
Adoption of Disruptive Innovation

- new technology/service that simplifies a complex/costly problem
- business model that allows market adoption of the simplified solution at low(er) cost
- incentivized supply and demand to reinforce the disruption

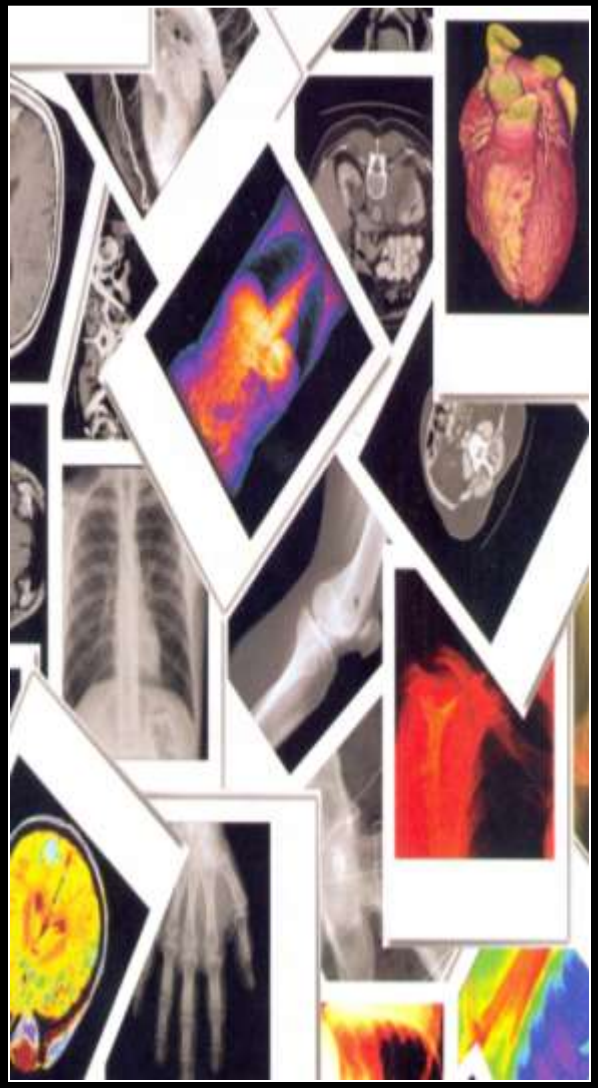
If You Build It, Will They Pay?
Adoption of Disruptive Innovation

- new technology/service that simplifies a complex/costly problem
- business model that allows market adoption of the simplified solution at low(er) cost
- incentivized supply and demand to reinforce the disruption

"If it isn't billable – it isn't going to happen"

- value-based versus cost-based reimbursement
- new billing codes
- reimbursement for professional analysis of remote patient monitoring data streams

How Much New Technology Can We Afford?



NICE Gets Nasty (or Rational?)

What Are We Willing to Pay for Added Months of Survival in Cancer

Lifetime cost above standard care	If cancer is on par with other diseases ($150,000 per life year gained), months of added overall survival benefit needed	Treating cancer as worthy of much higher reimbursement ($250,000 per life year gained), months of added overall survival benefit needed
$50,000	4 months	2.4 months
$100,000	8 months	4.8 months
$150,000	12 months	7.2 months
$200,000	16 months	9.6 months
$250,000	20 months	12 months
$300,000	24 months	14.4 months
$350,000	28 months	16.8 months
$400,000	32 months	19.2 months
$450,000	36 months	21.6 months
$500,000	40 months	24 months

Source: Pink Sheet 13 Sept 2010. Adapted from S. Ramsey, FHCRC, ASCO 2010

Dr. Donald Berwick

“I have a very romantic view of the NHS”

Interview in Health Affairs
April 2010

Current Payor Value Propositions Do Not Align with Clinical/Economic Value of Molecular Diagnostics

The Imperative for Value-Based Pricing versus Current Cost-Based Models

- inadequate US Medicare coding and payment mechanisms
  - out moded, out-dated, lacking in transparency, inconsistently applied
- inappropriate assignment of existing CPT codes to new tests
- engagement of third party payers who derive economic/clinical value from new Dx

Services

Wellness:

The Most Broad and Most Valuable Definition of Successful Healthcare

Consumers at the Center

Engaging Consumers and Patients for Wellness and Greater Responsibility for Mitigation of Health Risk(s)

- entitlement mentality
- lack of accountability
- lack of transparency in pricing and evidence-based performance to guide choice
- cost-shifting
  - a negative but blunt economic driver
- economic incentives
  - positive drivers for wellness
  - employers, payors, taxation policies
- providing tools and information to support informed choices and improved outcomes tracking

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INADEQUATE OPTIONS/SYSTEMS FOR ROUTINE REMOTE HEALTH STATUS MONITORING

Sensors

Sensor Networks for Remote Health Status Monitoring
Wireless Integrated Data Systems

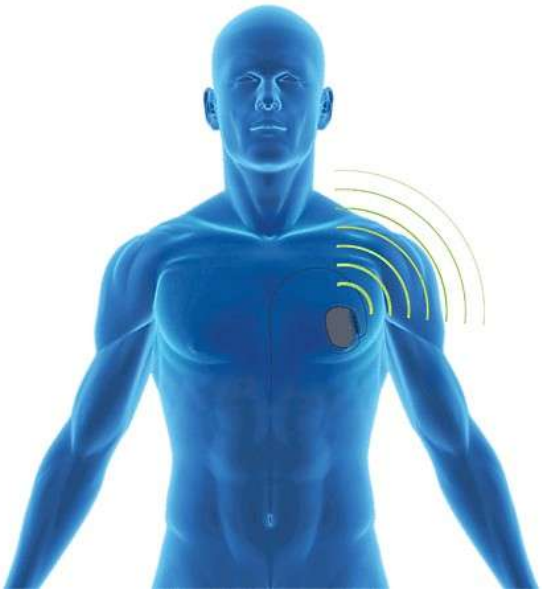
- geolocation data (where)
- temporal information (when)
- contextual information (what)

Personal Health Systems: On-Body: In-Body Sensors (OBIBs)

- wearable
- portable/mobile
- point-of-care
- implantable
- multi-parametric
- interoperability with electronic records

Mobile Health (mHealth)

m.Health



Remote Health Monitoring and Chronic Disease Management

Lifestyle and Fitness

Information for Proactive Health Awareness (Wellness)

Major Target Markets for Wireless Medicine

Disease	*Patients	Parameter
Alzheimer's	5 million	vital signs, location, activity, balance
Asthma	20 million	respiratory rate, FEV, air quality, oximetry, pollen count
Breast CA	3 million	ultrasound self-exam
COPD	10 million	respiratory rate, FEV, air quality, oximetry
Depression	19 million	medication compliance, communication
Diabetes	21 million	glucose, hemoglobin ATC
Heart Failure	5 million	cardiac pressures, weight, blood pressure fluid status
Hypertension	74 million	continuous blood pressure monitoring, medication compliance
Obesity	80 million	smart scales, caloric in/out, activity
Sleep Disorders	15 million	sleep phases, quality, apnea, vital signs

From: West Wireless Health Institute, Medtech Insight, August 2009

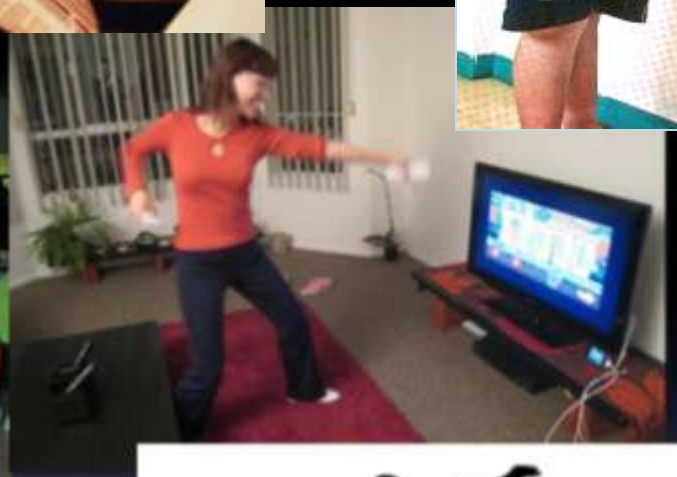
The Costs of Non-Compliance with Rx Regimens

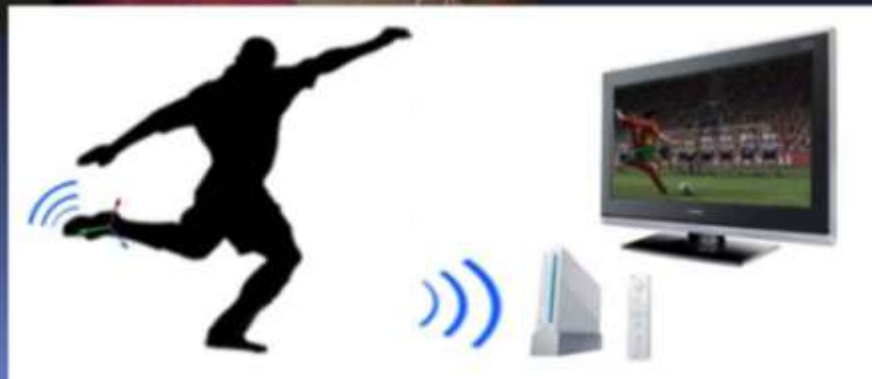
- $177 billion projected cost
- 20 million workdays/year lost (IHPM)
- 40% of nursing home admissions
- projected 45-75% non-compliance (WHO)
- 50-60% depressed patients (IHPM)
- 50% chronic care Rx (WHO)

Intelligent Medicine Dispensers for Enhanced Rx Compliance

http://hypedesire.blogtv.com.pt/img/image/HypeDesire/2009/abril/glowcap3.jpg

Gaming for Health:





Wii Fit Plus

Wireless Devices for Health Status Monitoring

Zio™ Patch

Personal Health

“This isn’t a device it’s a service.”

Jeff Bezos
CEO, Amazon

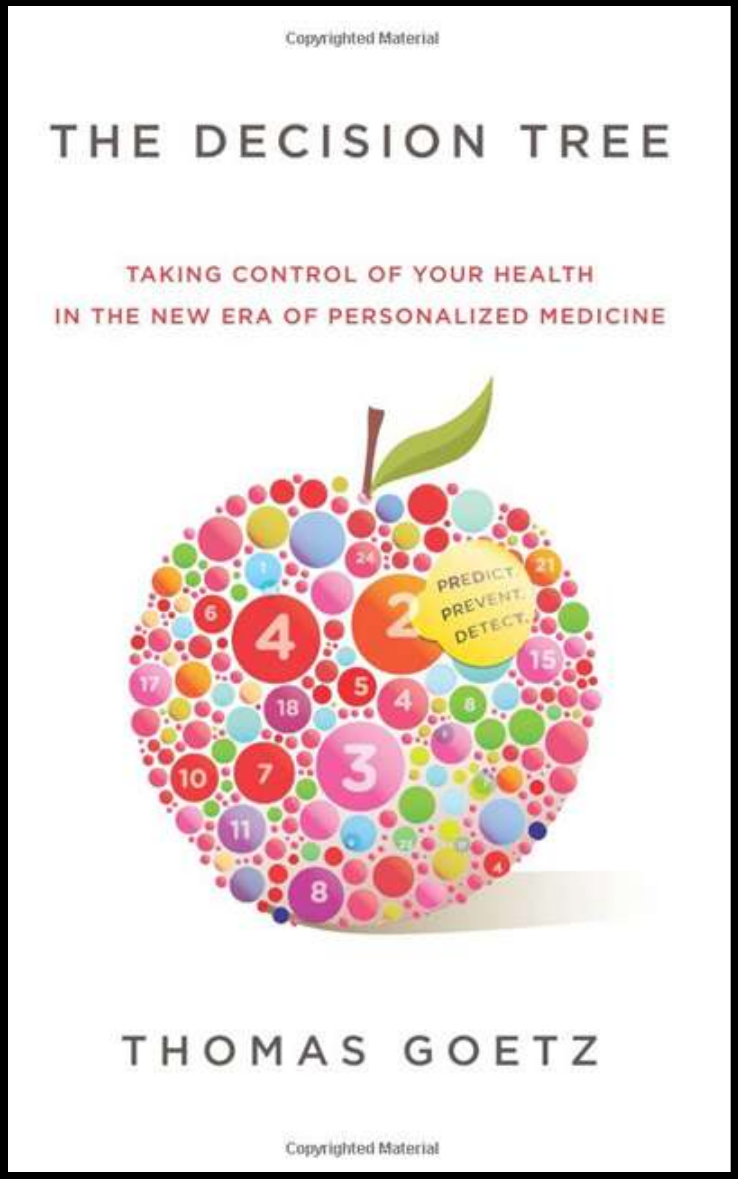
You, Me and Health in a Networked World

- mobile
- multimedia
- monitored
- measured
- me, and those like me
- multiple markets of one, but primarily ME!

Social Media
and
Social Networks

Social Networks and Consumer: Patient Empowerment

Source: R&D Directions May 2010



"Real personalized medicine should begin long before we're faced with pharmacology"

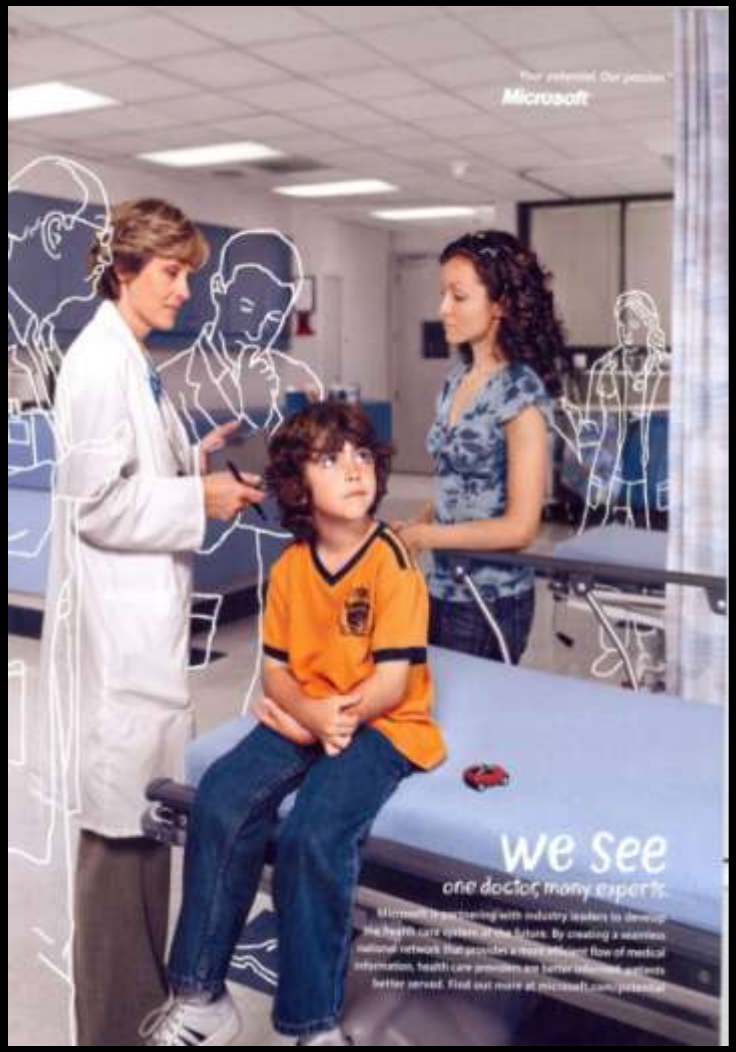
"Our health information is too important to leave to an archaic, insular system.

If there's no longer a need to rely solely on a doctors advice for treatment and care, why should we be expected to artificially limit our options."

Thomas Goetz
Deputy Editor of Wired

The Decision Tree: Taking Control of Your Health in the New Era of Personalized Medicine (Hardcover)
Thomas Goetz (Author) . Image Source: Amazon.com

Virtual Medicine Networks: Increasingly Integrated Care and Continuity of Care



- rapid, real time access
- clinical specialties
- health records
- lab data
- drug interactions
- electronic Rx prescribing

Integration of Services
and
Simplification of Services

Demographic Trends and the Clinical and Economic Burden of Complex, Chronic Conditions/Co-Morbidities

- 23% Medicare beneficiaries have 5 or more conditions
- polypharmacy and AEs
- poor patient compliance
- multiple physician/venue encounters
- poor communication/ coordination between siloed healthcare services
- procedure-based reimbursement versus care continuum integrated

‘The Medical Home’: Integrated Care Services for Independent Living

Deloitte.

Connected Care

Technology-enabled Care at Home

Produced by the
Deloitte Center
for Health Solutions

Audit . Tax . Consulting . Financial Advisory.

State of Technology in Aging Services According to Field Experts and Thought Leaders

By:
Majd Alwan, Ph.D.,
Center for Aging Services Technologies (CAST)
American Association of Homes and Services for the Aging (AAHSA)

and

Jeremy Nobel, M.D., M.P.H.,
Harvard School of Public Health

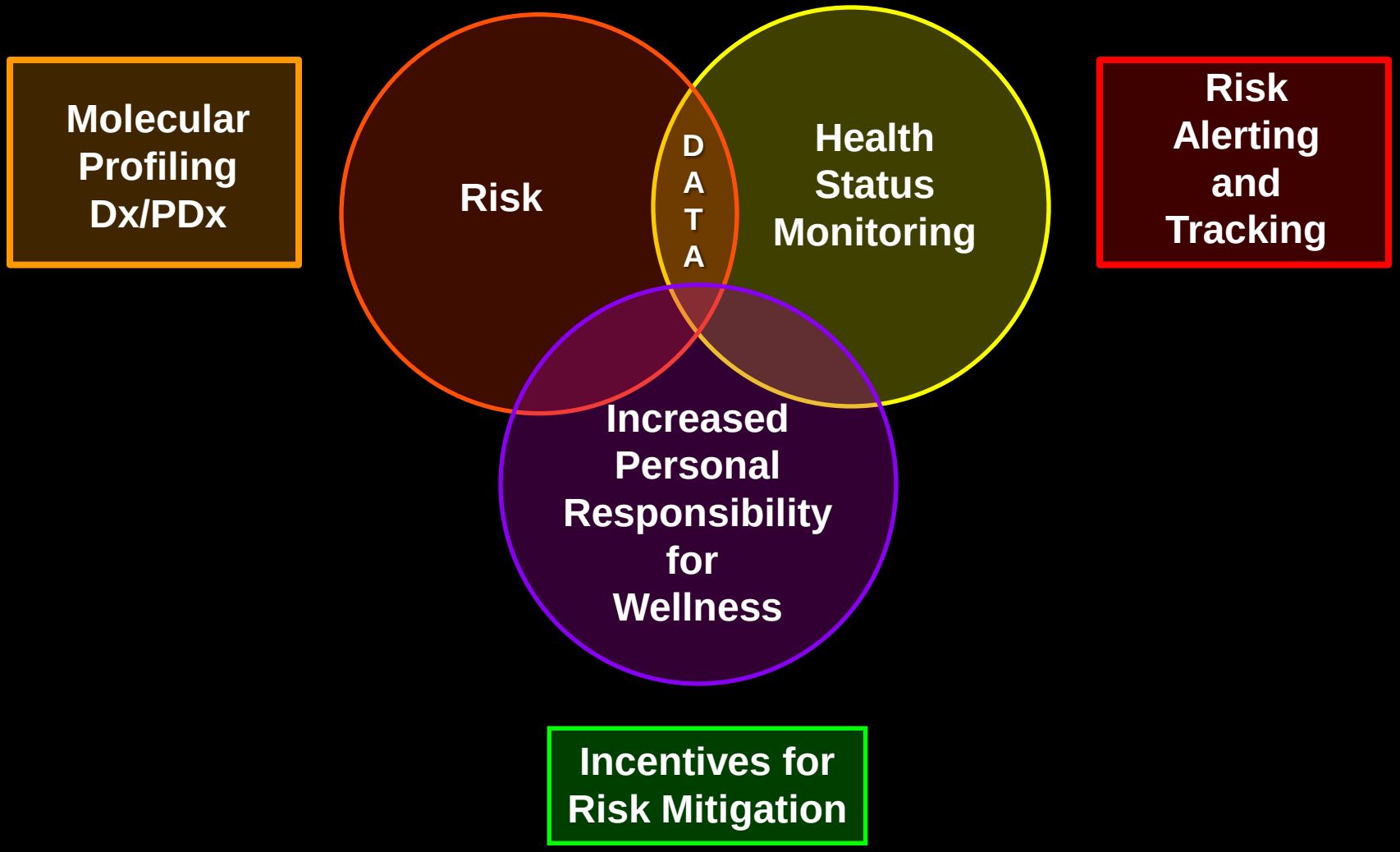
Report Submitted to: Blue Shield of California Foundation

February 2008

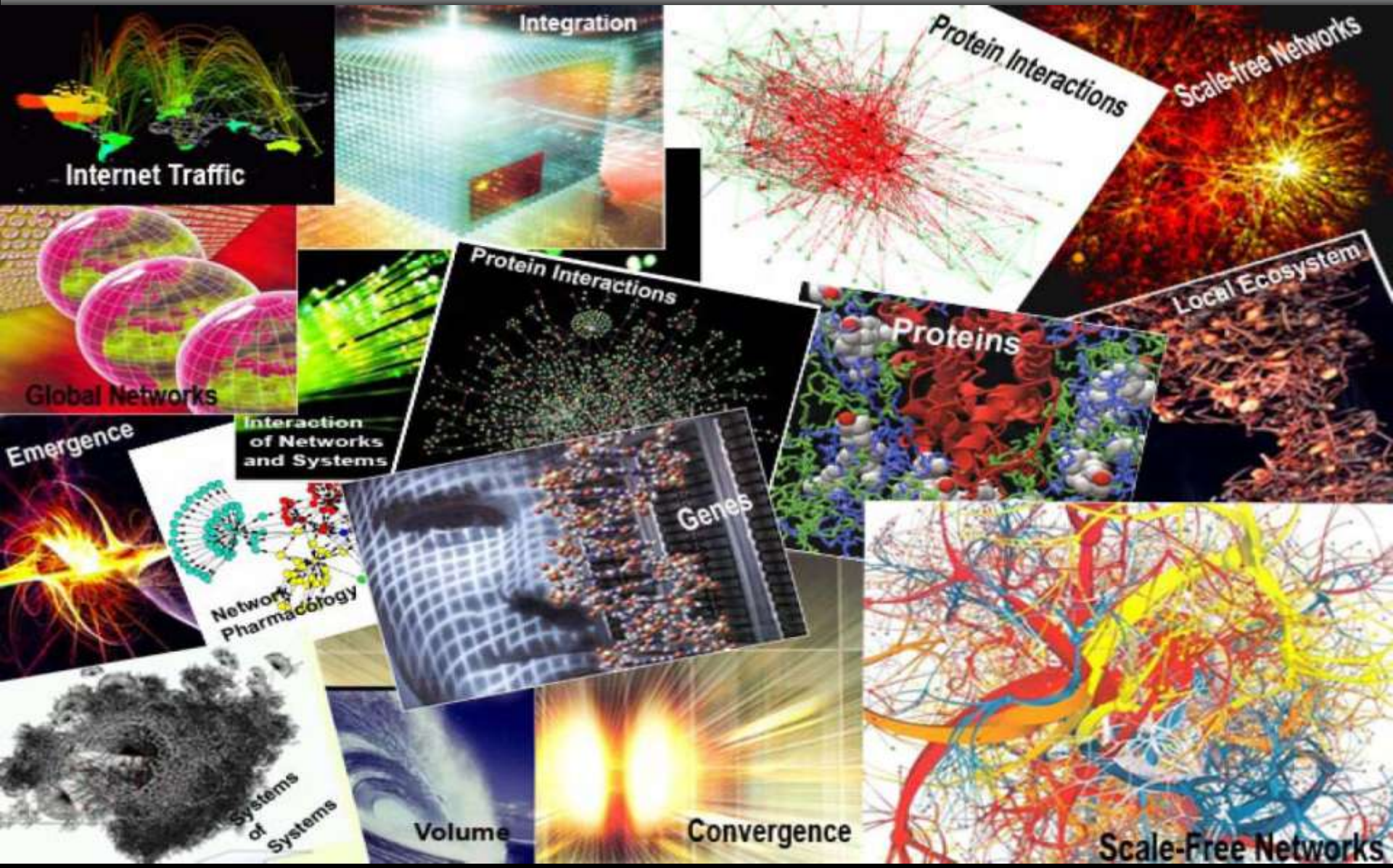
cast™
Center for Aging Services Technologies

In-Home Health Connection: Engaging the Elderly

Molecular Diagnostics and Health Information Systems as the Key Elements in the Evolution of Integrated Healthcare Delivery



Data: The Fastest Growing Resource on Earth

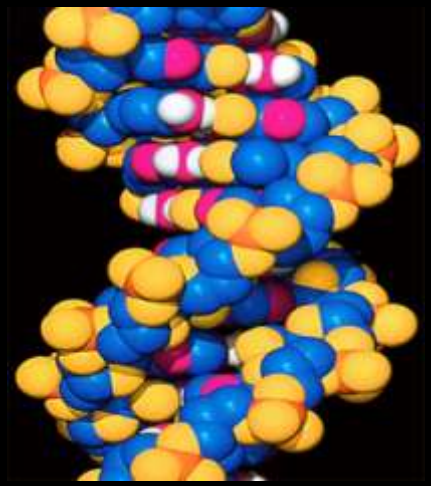


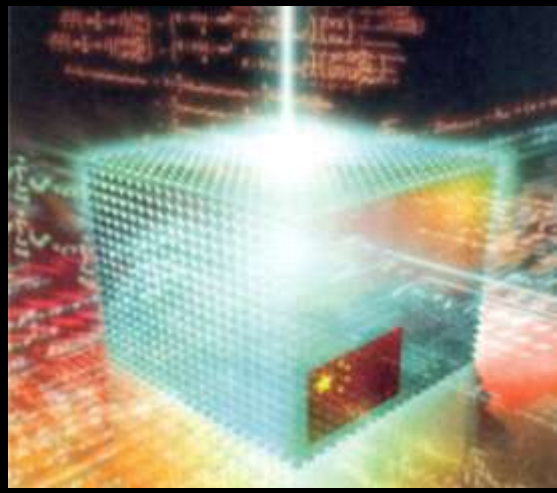
“Managing Mega-Data”

volume

scale

global networks

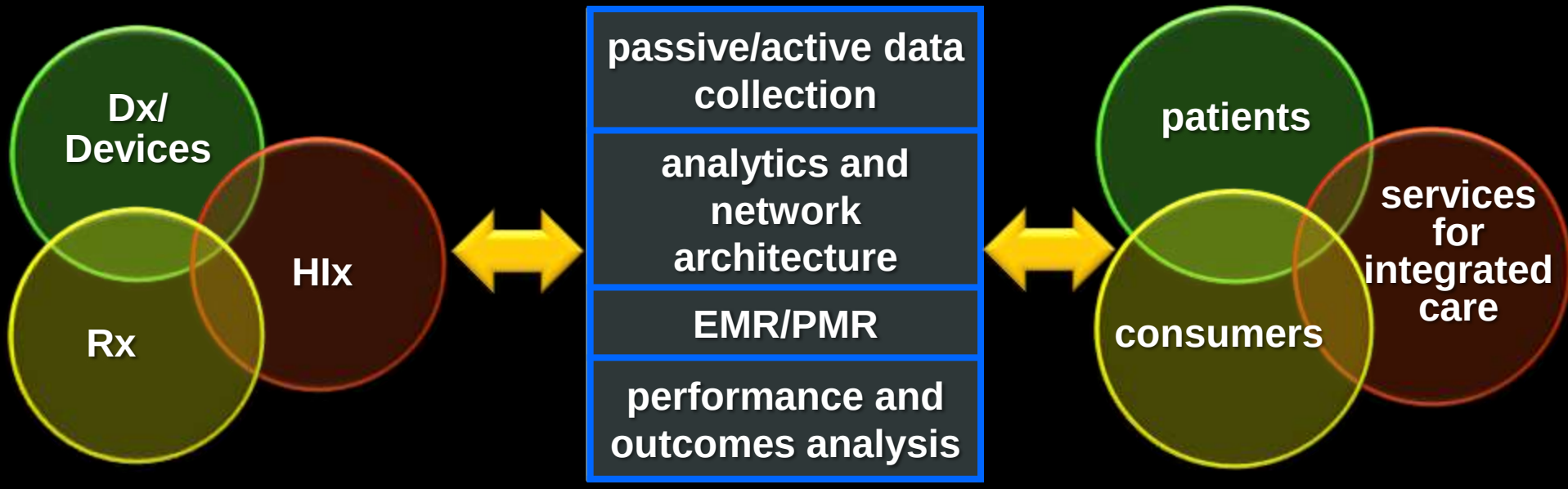




heterogeneity

integration

A New Healthcare Ecosystem Arising From Technology and Market Convergence



Integrated Technology Platforms

Data Mining and Integration Services

Increasingly Targeted Care and Efficient Use of Finite Resources

The Expanding Universe of Health Information Resources: Redefining Physician:Patient Relationships

• MD-centric monopoly	→	• patient-centric markets
• paternalistic decisions and passive patients	→	• engaged patients/consumers
• institutional control	→	• individual custody
• paper records	→	• EHR/PMRs
• fragmented information and portability barriers	→	• seamless integration and mobility
• centralized testing analysis and expert interpretation	→	• increasingly decentralized, automated analysis and decision algorithms • remote health status monitoring

Sociology

Certain Death in Uncertain Time: Balancing Hope and Harsh Reality in Terminal Illness

"I respect the seriousness of death
I've had many occasions to meditate on its intrusions.
….the way the message was delivered.
Frankly, it made me furious."

Sen. Edward Kennedy
True Compass. A Memoir. 2009

Patients

- want information regarding treatment options
- increasingly informed about options via web sources but want professional input to assist in interpretation
- generation-dependent preference/expectancy for shared role in decision-making
- improved outcomes and increased compliance when patients are engaged and informed

- major cultural gap in professional-patient interactions
- time and cost to healthcare professionals
- lack of professional familiarity/competencies in molecular medicine

The Too Often Overlooked Communication Interaction Gap in Healthcare and Patient Safety

- "do you understand": physician paternalism and patient timidity
  - a dangerous combination
- impact on increased incidence of Rx/treatment errors, non-compliance and hospital readmissions
- challenge for healthcare professionals
  - time and money but large component originates in culture/training
  - often hold different perception to patients and priorities versus increasing problem in managing chronic disease and multiple co-morbidities
- the sociology of medical training and practice
  - hierarchical, authoritarian, paternalistic
  - inadequate focus on team-based healthcare delivery

SILOS
and
THE SOCIOLOGY OF RESEARCH AND CLINICAL MEDICINE

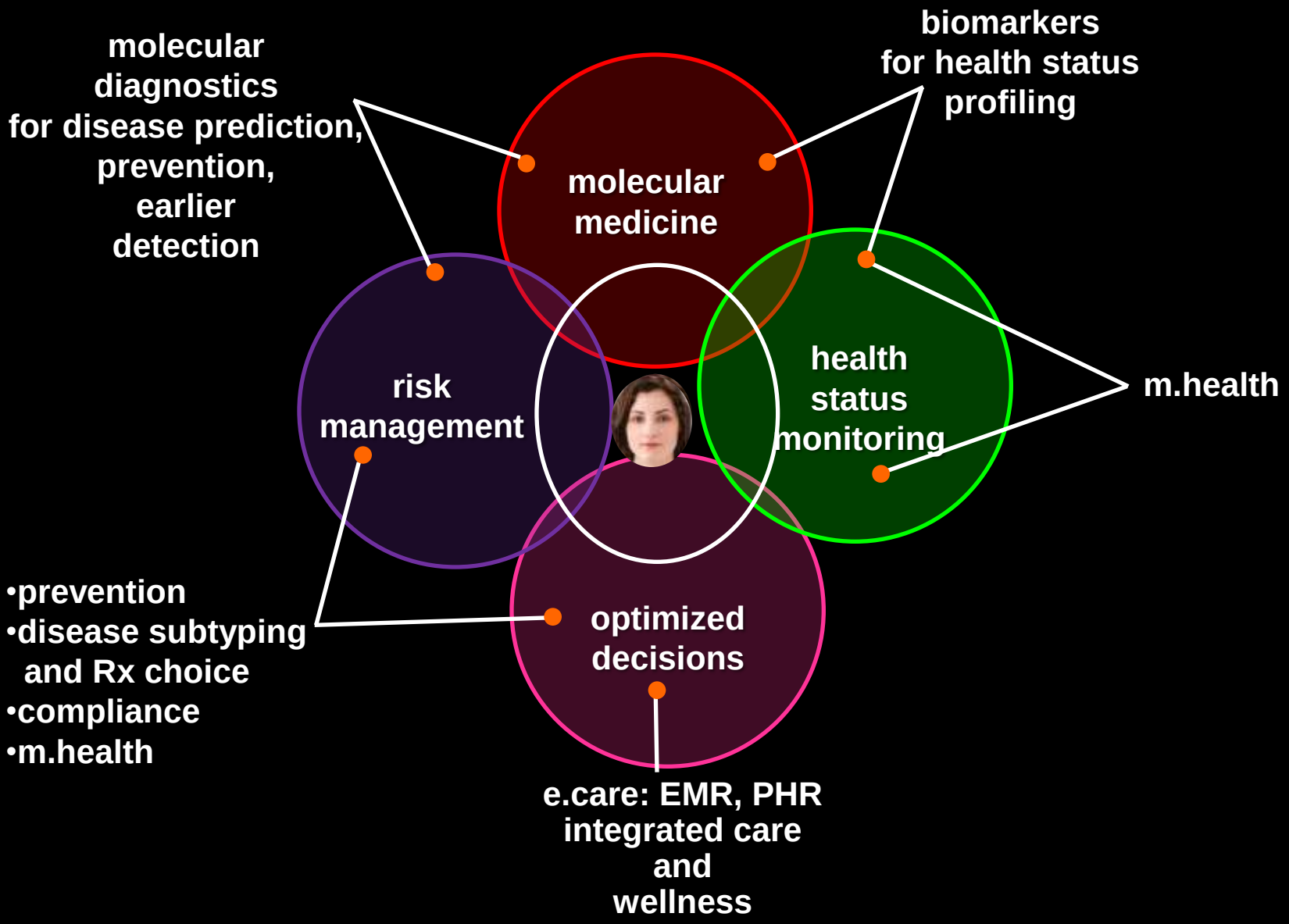
Forging a New R&D Framework for Biomedical Research and Public Health

- fragmented, uncoordinated, siloed R&D activities versus systems-based integration
  - dominance of investigator-driven research via funding decentralized academic laboratories
  - alarming lack of standardization of methods, tools and data reporting
  - poor data replication and barrier to metaanalysis
  - insufficient use of public:private partnerships to drive scale and standards

Forging a New R&D Framework for Biomedical Research and Public Health

- leverage still unique and unmatched capabilities
  - intellectual and cultural capital
  - financial and infrastructure resources
- aggressive reform of national research planning, organization and funding
  - coordinated, multidisciplinary programs with requisite scale
  - increasing standardization as foundation for proficient assembly/analysis of large scale data
  - obligate engagement of private sector partnerships to receive funding
  - authority and accountability
- imperative for radical and, by definition, disruptive changes

The Key Strategic Elements in the Evolution of Healthcare




Success
Services
Silos
Statistics
Significance
Semantics
Signatures
Security
Surrogates
Scale
Samples
Systems
Sequencing
Standardization
SocialMedia
Signals
Stratification
Speed
Solutions
Standards
Selection
Sales