

Technology Acceleration and Convergence: The Evolution of Novel Platforms for Improved Healthcare Delivery

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Burrill LP & Advisory Board Meeting
Cavallo Point, California: 20 April 2010

Major Challenges in Healthcare

Cost



Demographics



Access



Variation in Clinical Practice



Major Challenges in Healthcare



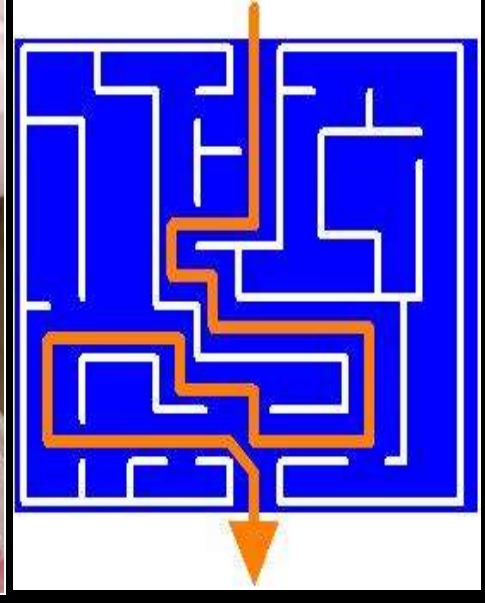
**Inefficient
Use of
Information**



**Fragmented
Care Versus
Integrated Care**



**Duplication,
Defensive
Medicine & Waste**

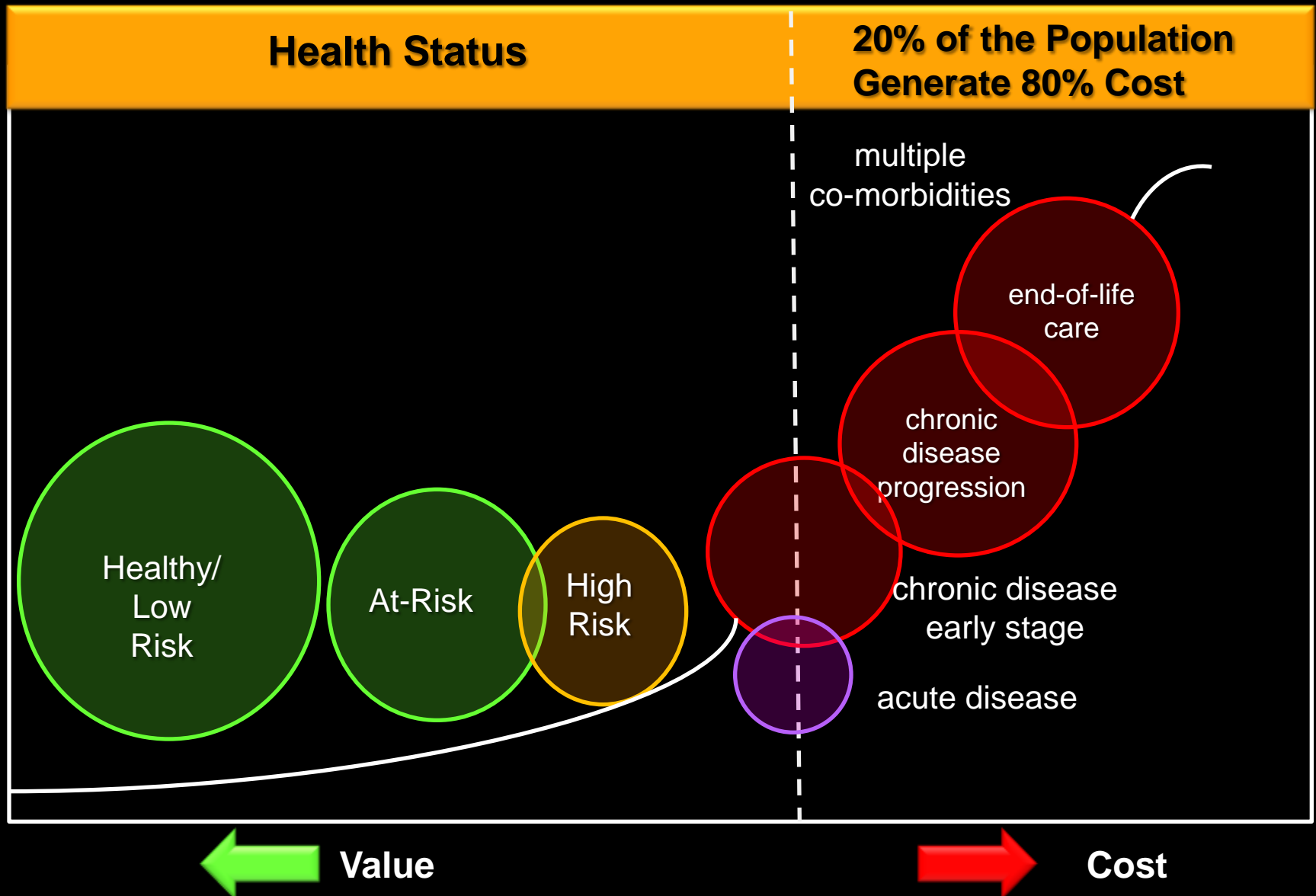


**Protracted
Adoption of
Innovation**

The Patient Protection and Affordable Care Act: Signed Into Law 23 March 2010



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

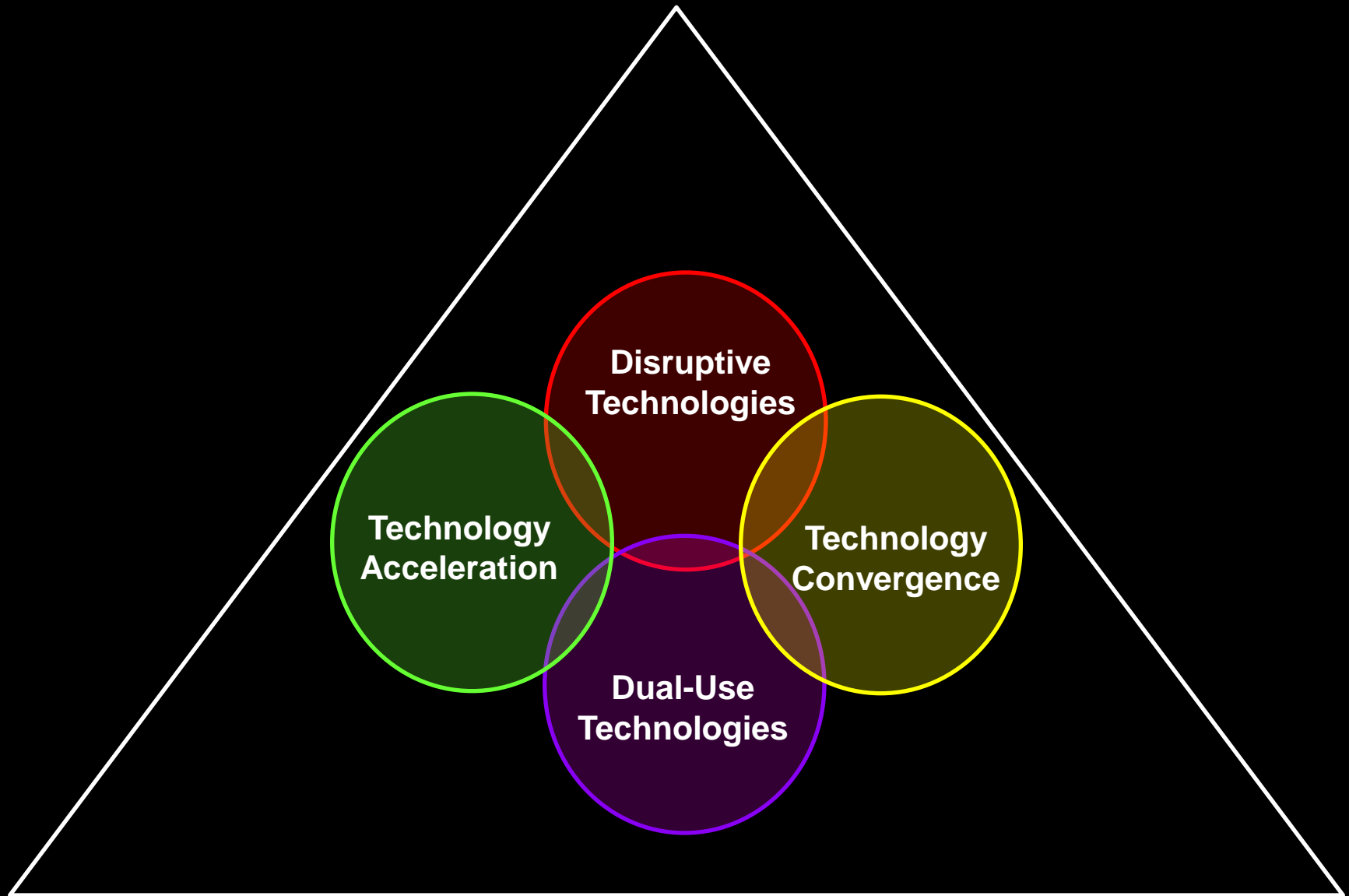


Reasonable Expectations for Rational Healthcare

- what works?
- why it works?
- who it works for?
- what works best?
- when should it be used optimally?
- validated evidence
- mechanism of action
- personalized medicine
- comparative effectiveness
- best practice guidelines, standard-of-care and malpractice

VALUE

The Strategic Environment for Technology

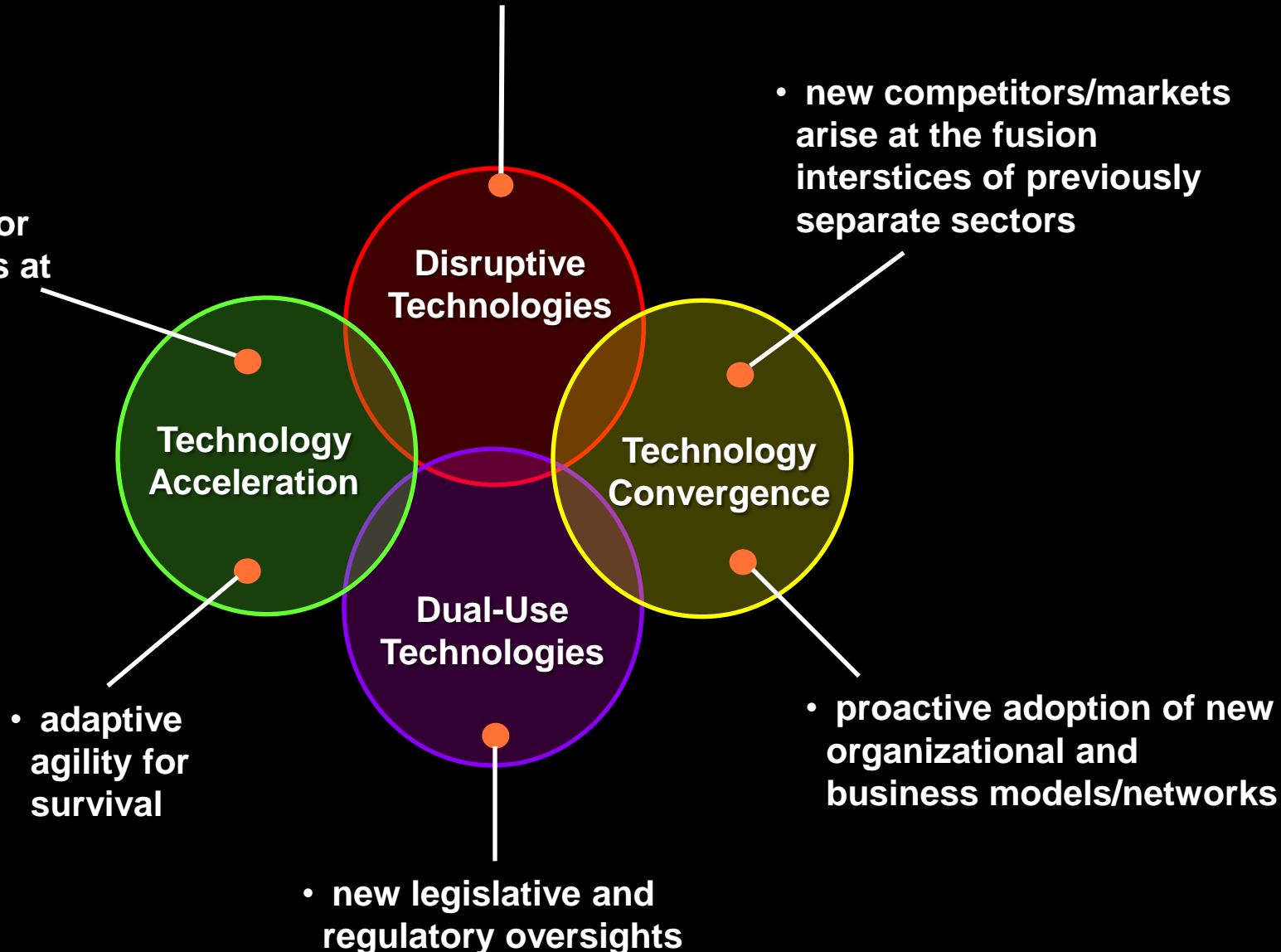


The Strategic Environment for Technology

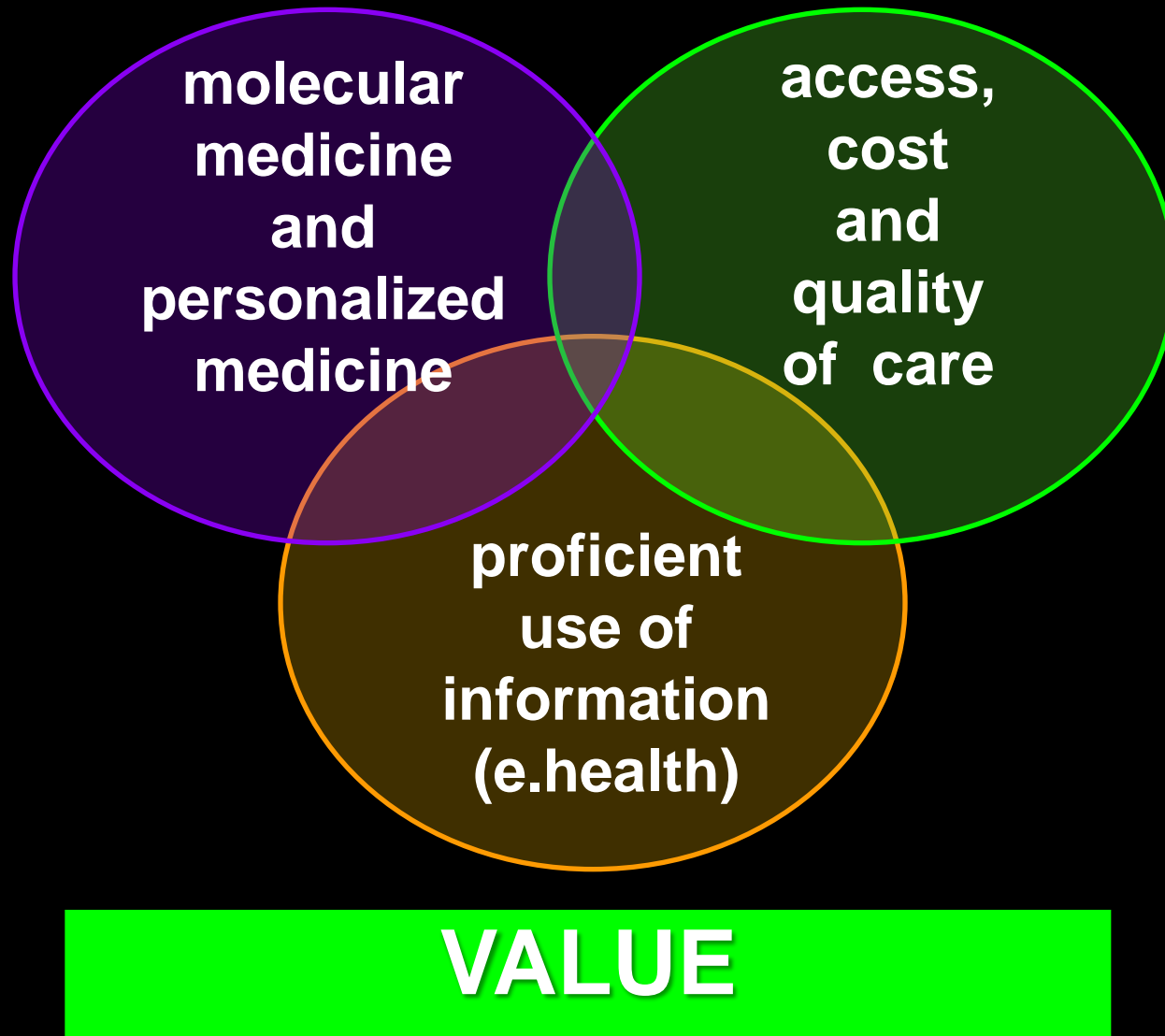
- creative destruction, discontinuity, dislocation, inflection/tipping points, 'Black Swans'

- competition within a sector always arises at the margin

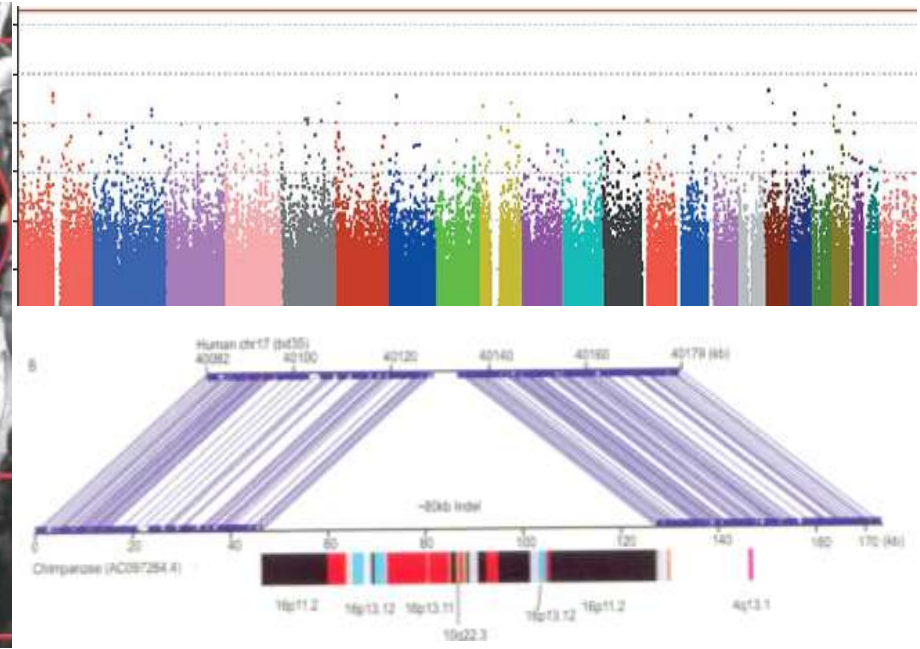
- new competitors/markets arise at the fusion interstices of previously separate sectors



The Three Convergent Forces Shaping the Evolution of Healthcare

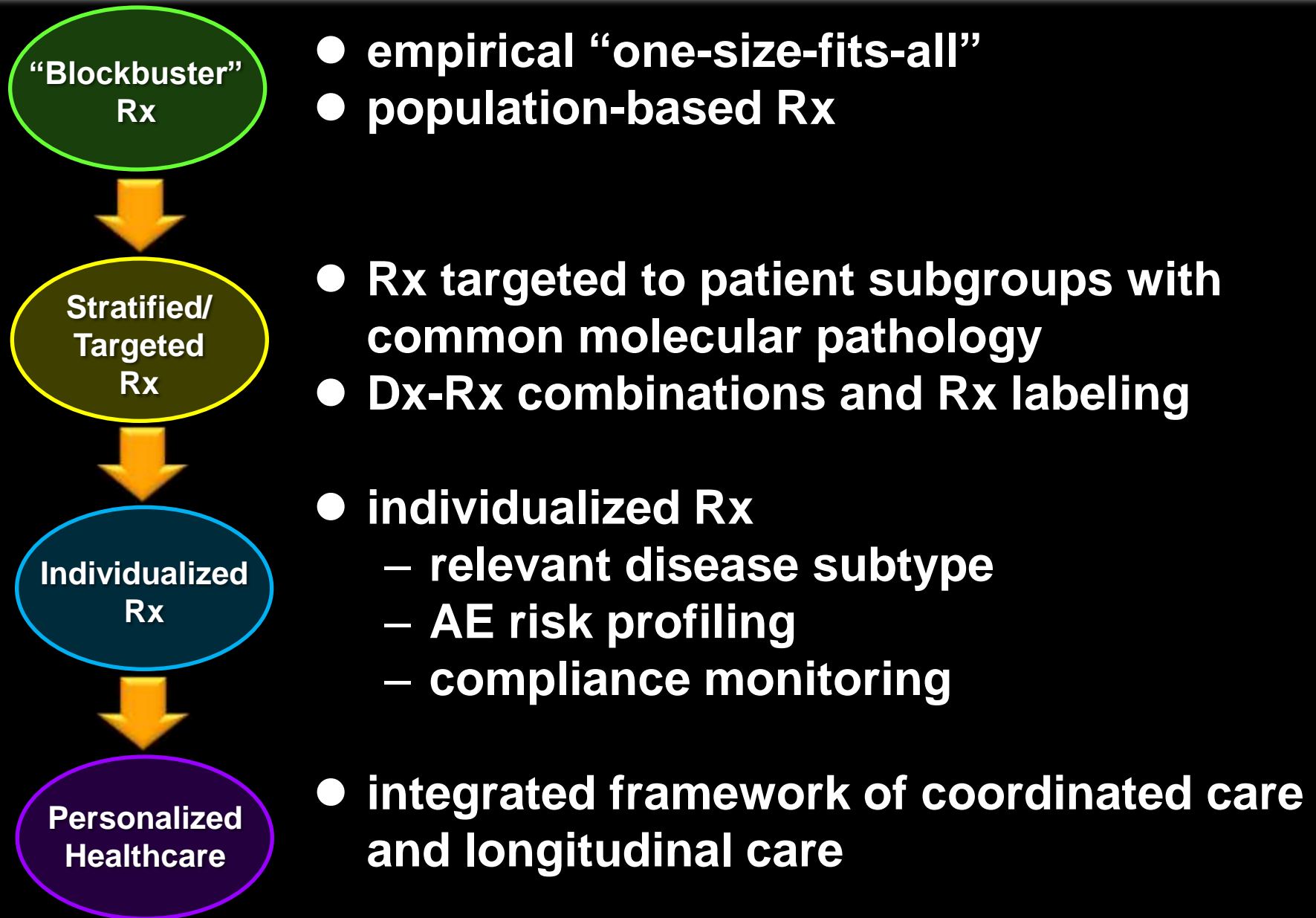


Personalized Medicine and Technological and Commercial Discontinuities in Healthcare Markets



Establishing a Long-Term Strategy and New Value Propositions in a Short Term Environment

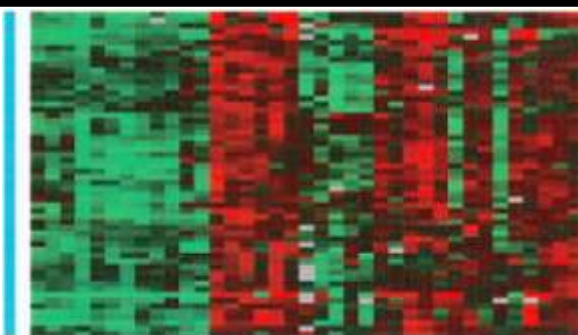
The Evolving Market for (Bio)Pharmaceutical Therapies



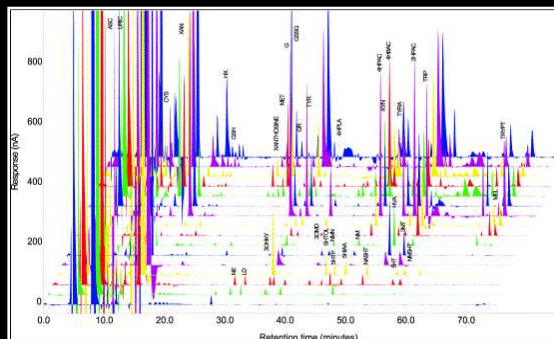
Molecular Diagnostics and Miniaturized Devices: A Key Future Driver in the Healthcare Value Chain

Complex Biosignature Profiling

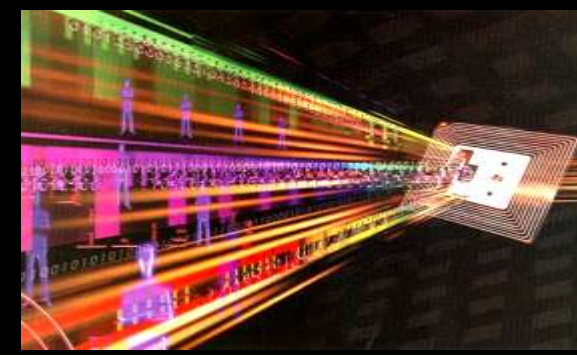
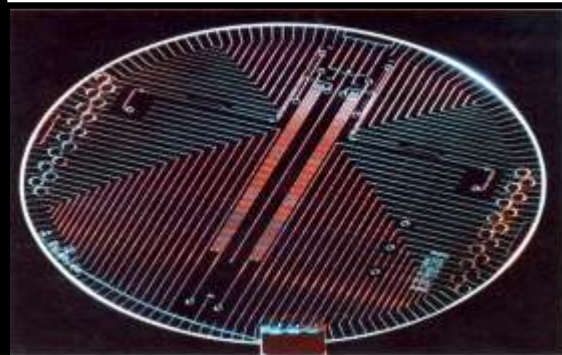
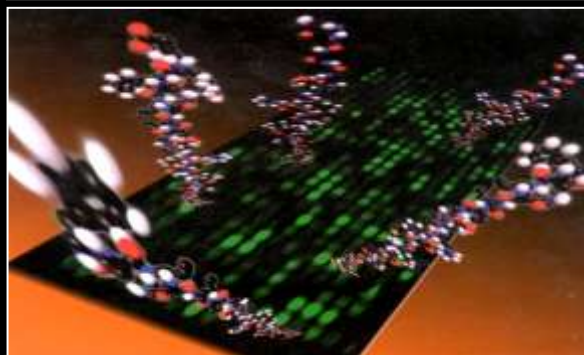
genomics



proteomics



immun signatures



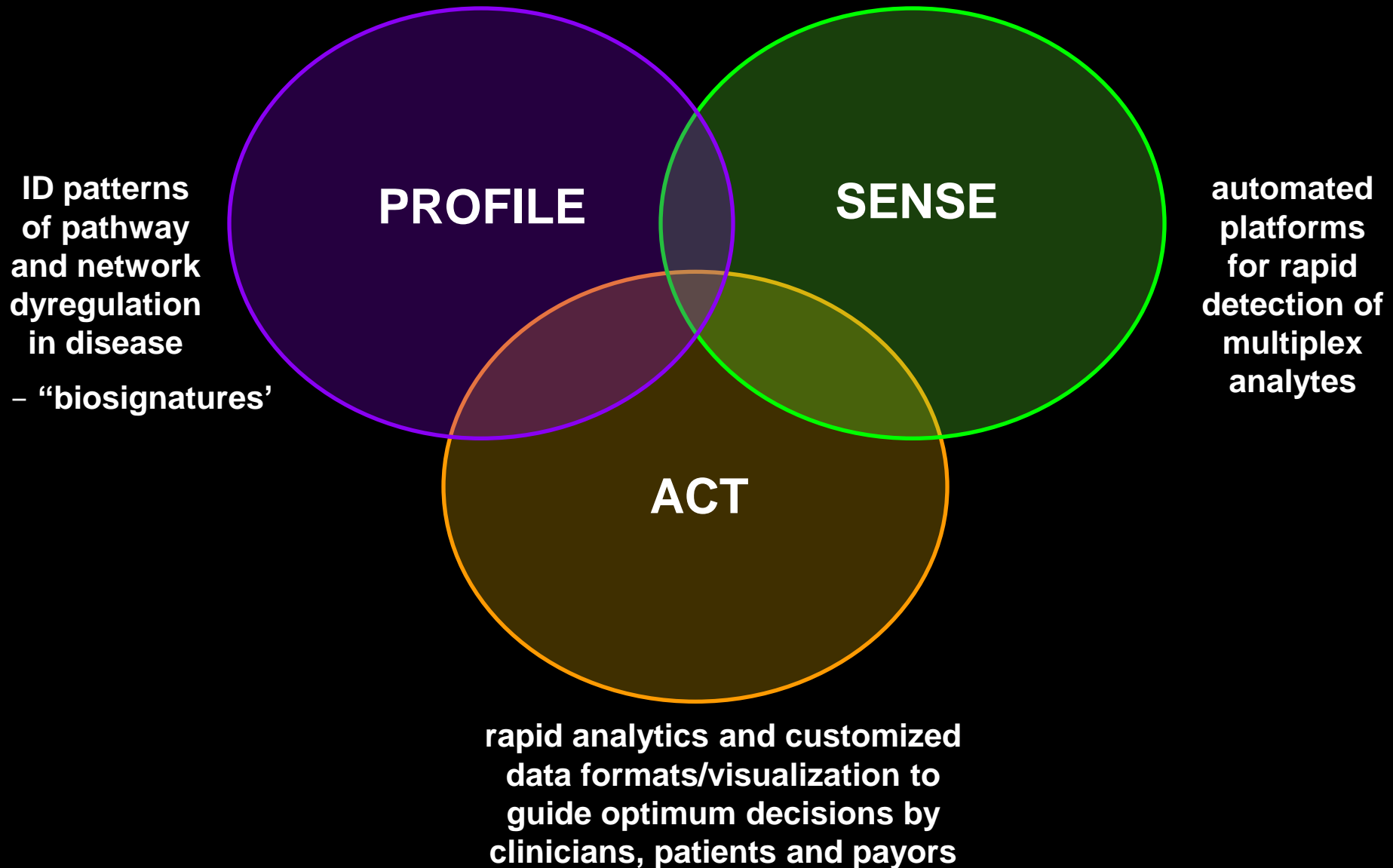
Signature Detection, Deconvolution and Multivariate Analysis

automated,
high throughput
multiplex assays

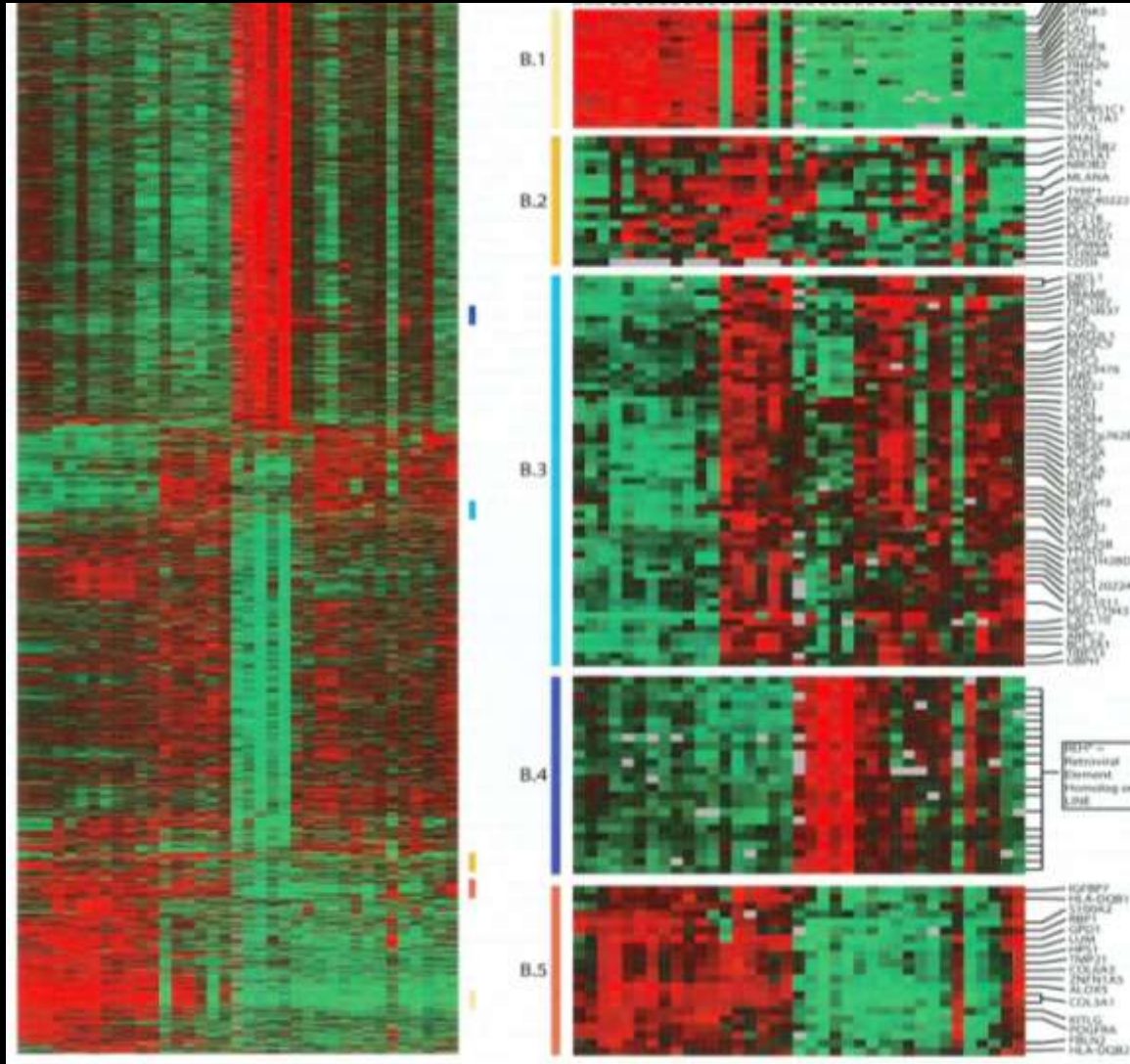
novel test formats
and devices (POC)

new algorithms
For complex
signal/deconvolution

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



Disease Subtyping: Next-Generation Molecular Diagnostics (MDx) and A New Molecular Taxonomy of Disease

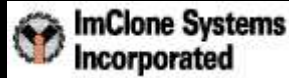


MDx Platforms

- massive parallelism
- miniaturization
- automation
- rapid
- POC

**RIGHT Rx
for
RIGHT DISEASE
SUBTYPE**

K-RAS Profiling and Anti-EGFR Monoclonal Antibody Therapy



- higher response in patients with K-RAS versus mutant-K-RAS
- estimated \$604 million/year savings (ASCO)

clinical guidelines



- regulatory endorsement in product labeling



- payor adoption

Development of Companion Diagnostics and Dx Test Validation Standard



- ODAC rejection (3/2010) of *Omapro* for Gleevec-resistant CML due to T315I mutation
- failure to use single standardized assay for all patients
 - peripheral blood versus bone marrow
 - 1/3 tested locally; 2/3 tested centrally
 - centralized labs used different assays with 100 fold sensitivity difference for the mutation

Molecular Medicine and Rational Therapeutics: Targeted Rx and Rise of Molecular Diagnostics and Patient Profiling

- **opening era in linking disease molecular pathology to rational Rx**
- **increasing payor, regulatory and public pressures for reliable ID of Rx-responsive patients**
- **demand for Dx-Rx combinations will intensify**
- **Dx-Rx combination will become an obligate element of NDA/BLA submission and product labeling**
- **development of Dx-Rx combinations as intrinsic components of R&D programs for investigational Rx**

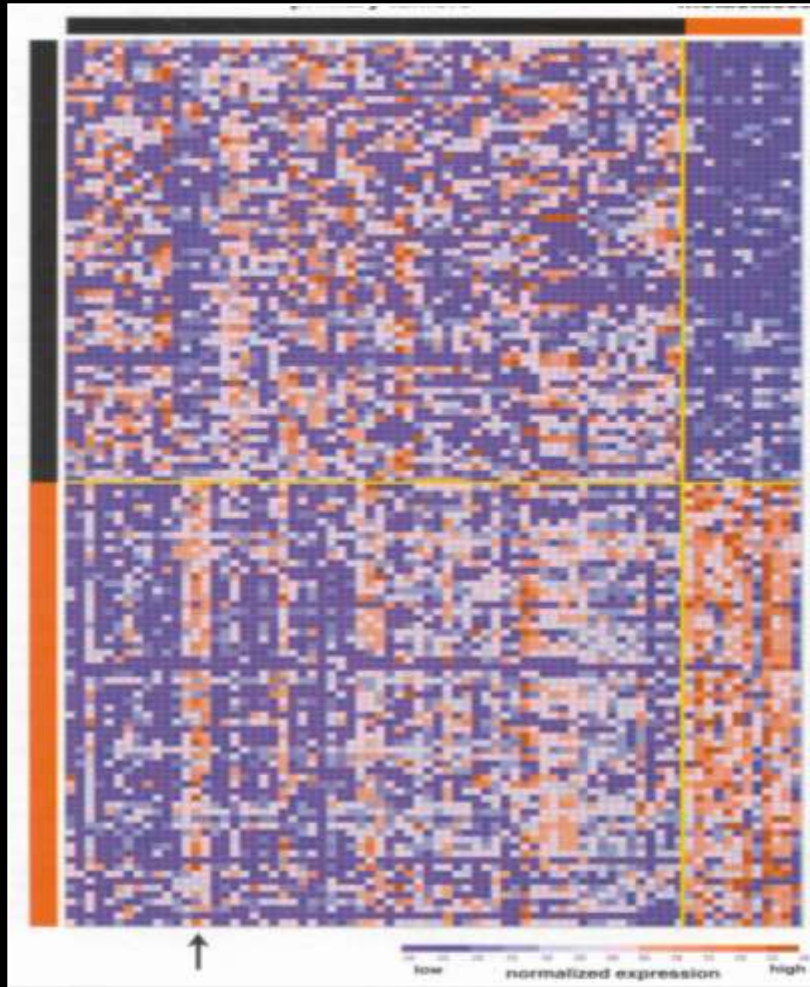
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**The New Reality (S. Burrill):
Companion Therapeutics Selected by Precision MDx**

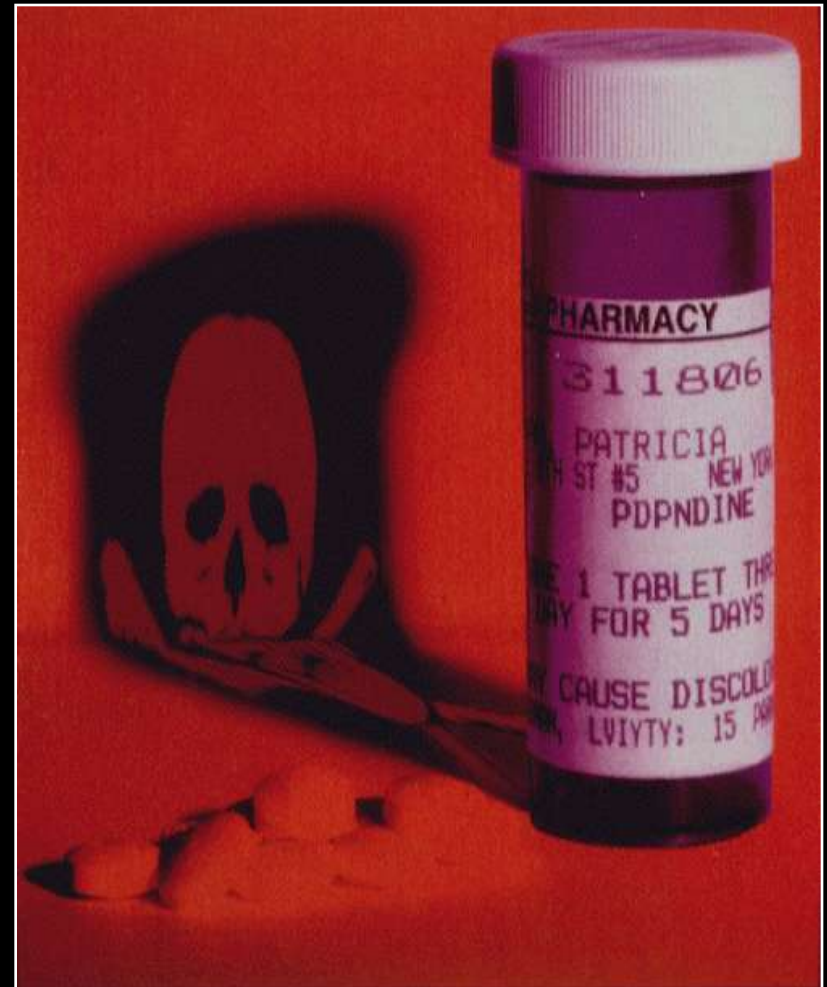
From Pharmaceuticals to Pharmasuitables

Disease Subtyping:



Right Rx for Right Disease

Individual Variation and AE risk

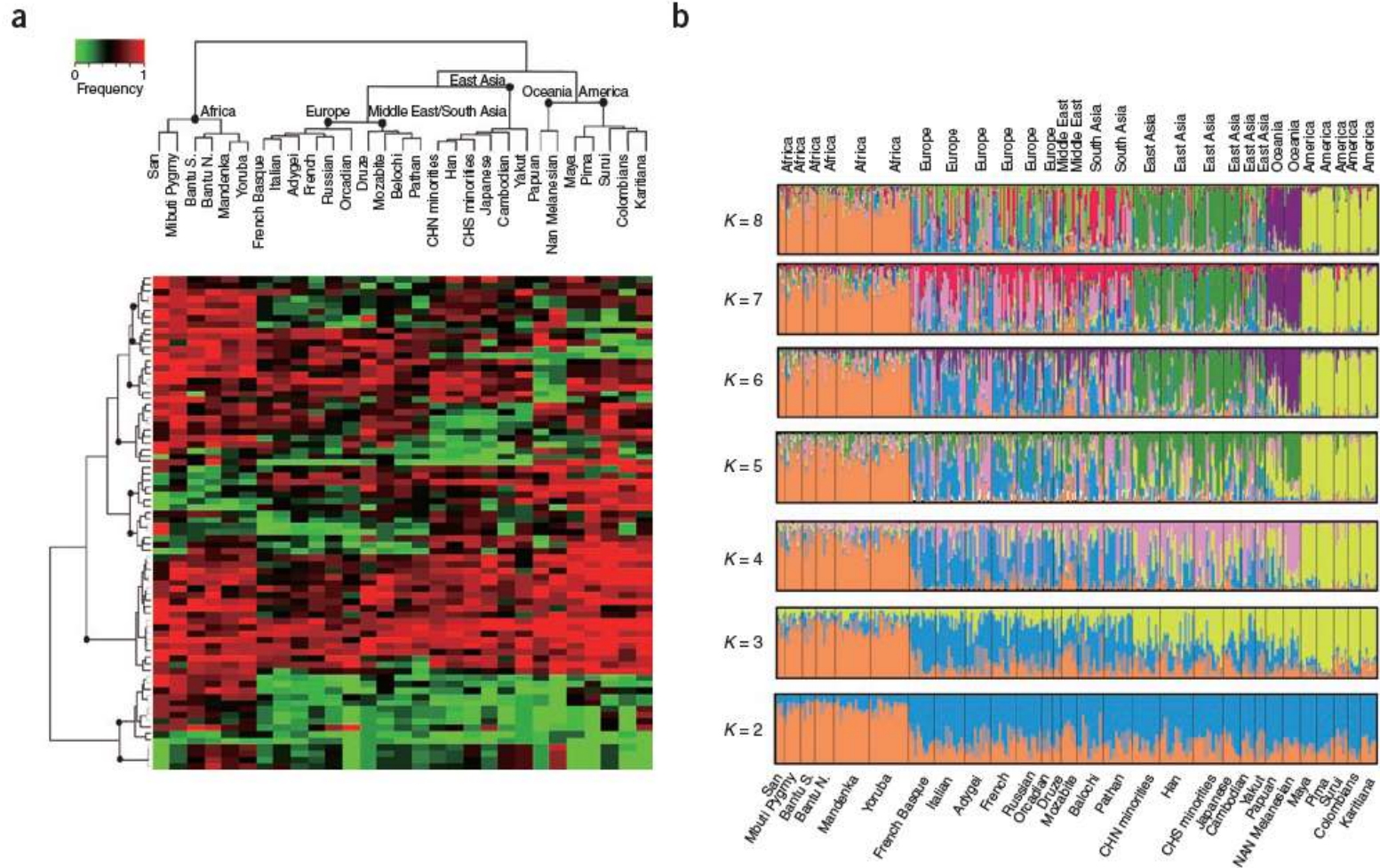


Right Rx for Right Patient

Molecular Diagnostics and Pharmacogenetic Profiling to Identify Individuals at Risk for Rx Adverse Events

- **broader, more complex profiling platforms than MDx assays for ID of drug targets**
 - **number of isoforms for DMPK enzymes and scale of individual variation within populations**
- **ID of slow metabolizer genotypes**
- **unknown effects of genetic and environmental confounders in AD(M)E beyond genetic variation in drug-metabolism (I-III) repertoire**
- **growing recognition of importance of variation in HLA alleles as additional risk factor**

Mapping the Human Pan-Genome: Identification of Ethnic Differences and Implications for Rx Efficacy and Safety

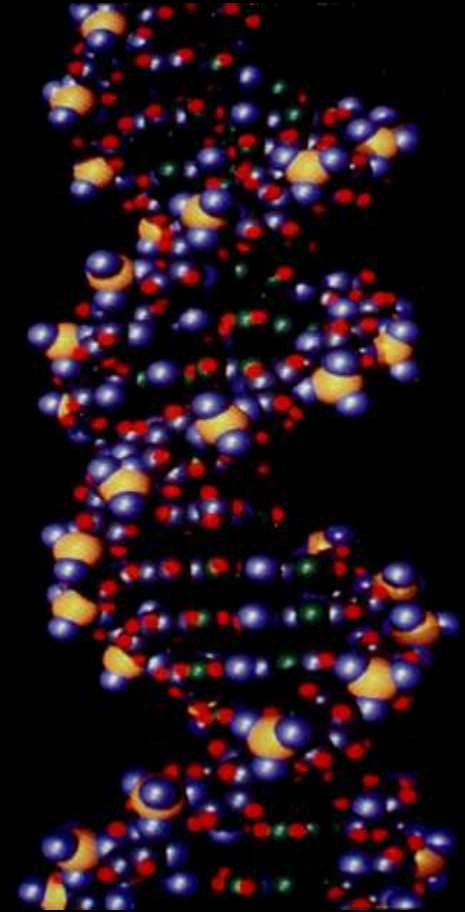


From: Ruiqiang Li et al. (January 2010) Nature Biotech. Vol. 28, p. 59

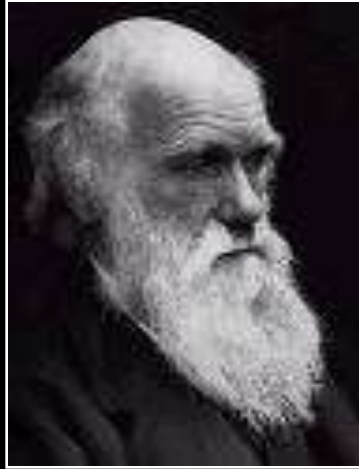
Mapping Human Genetic Diversity

- transcending PC and “biological egalitarianism”
- non-trivial genetically-based biological variation exists in individuals and groups
- ignoring such variations is illogical, poor science, poor clinical medicine and potentially dangerous
- mapping group genetic diversity is fundamental knowledge
 - human evolution and trait acquisition
 - interplay of genomes and environment in determining outcomes
 - variations in disease susceptibility, xenogeneic metabolism and clinical decisions for optimum treatment

The Hunt for Gene Loci Associated with Complex Human Diseases



Mapping Human Diversity



“Our ignorance of the laws of variation is profound”

Charles Darwin

**CGCCME!CAGGCATGCA
CAGTGCCAGGCATGCAT
CATGCCAGME!GCACT
TGCTAGGCATGCATGA
TCATGCCAGTCATGCA**

Disease Predisposition Risk Profiling for Common, Multigenic Late-Onset Disorders

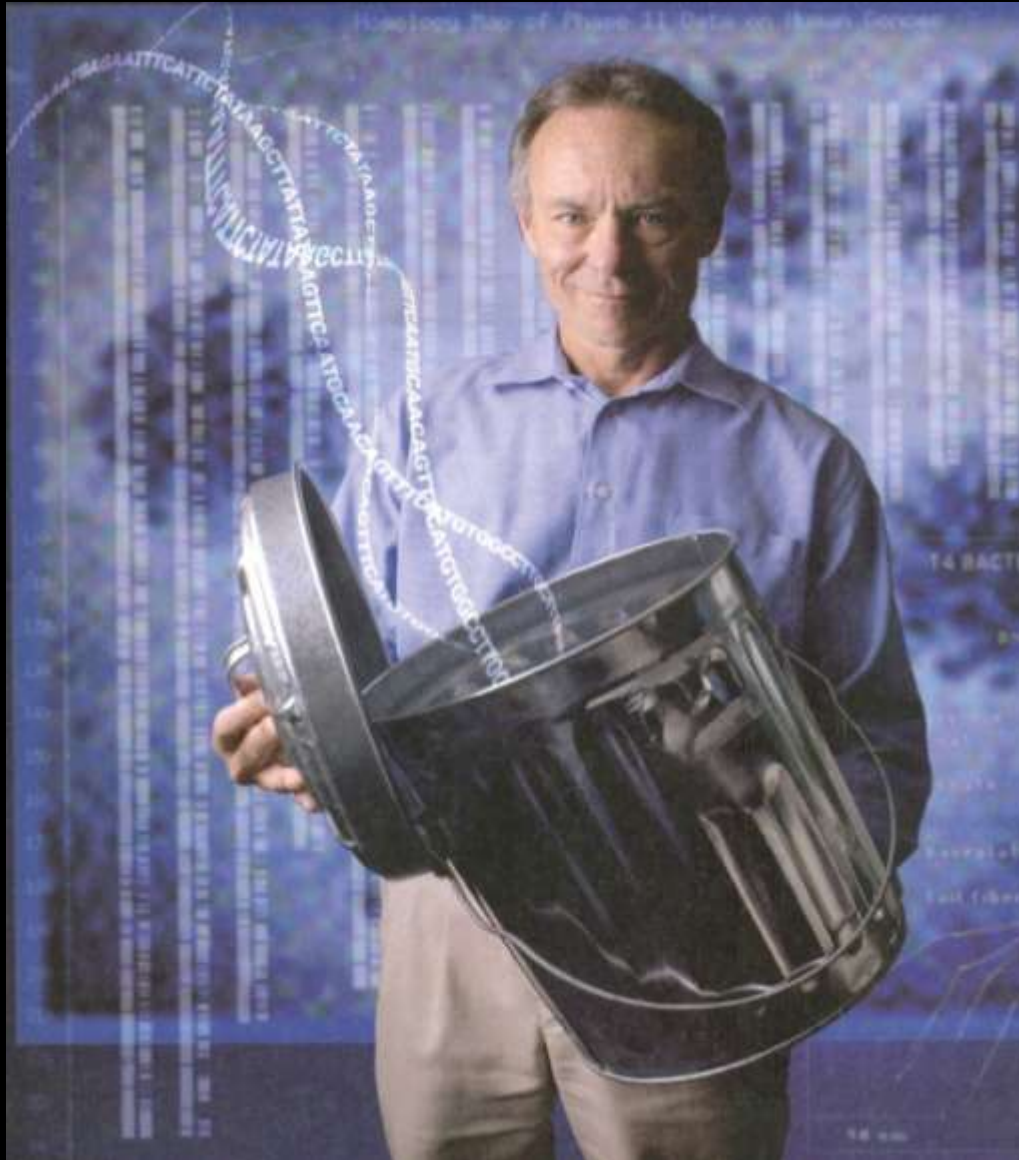
- **slower evolution than many predict**
- **Genome-Wide Association Studies (GWAS)**
 - **high cost and to date low yield in terms of clinically exploitable markers**
 - **disease origins from multiple low penetrance alleles versus small, dominant set of high penetrance alleles**
- **substantial ambiguities regarding probabilistic risk of overt disease**
 - **epistasis**
 - **epigenetics**
 - **environmental confounders**
 - **source of poor replication of GWAS studies?**

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The premature quest to provide consumer genomic testing (CGx) for future risk of major diseases

Mapping the Complexity of Genome Organization



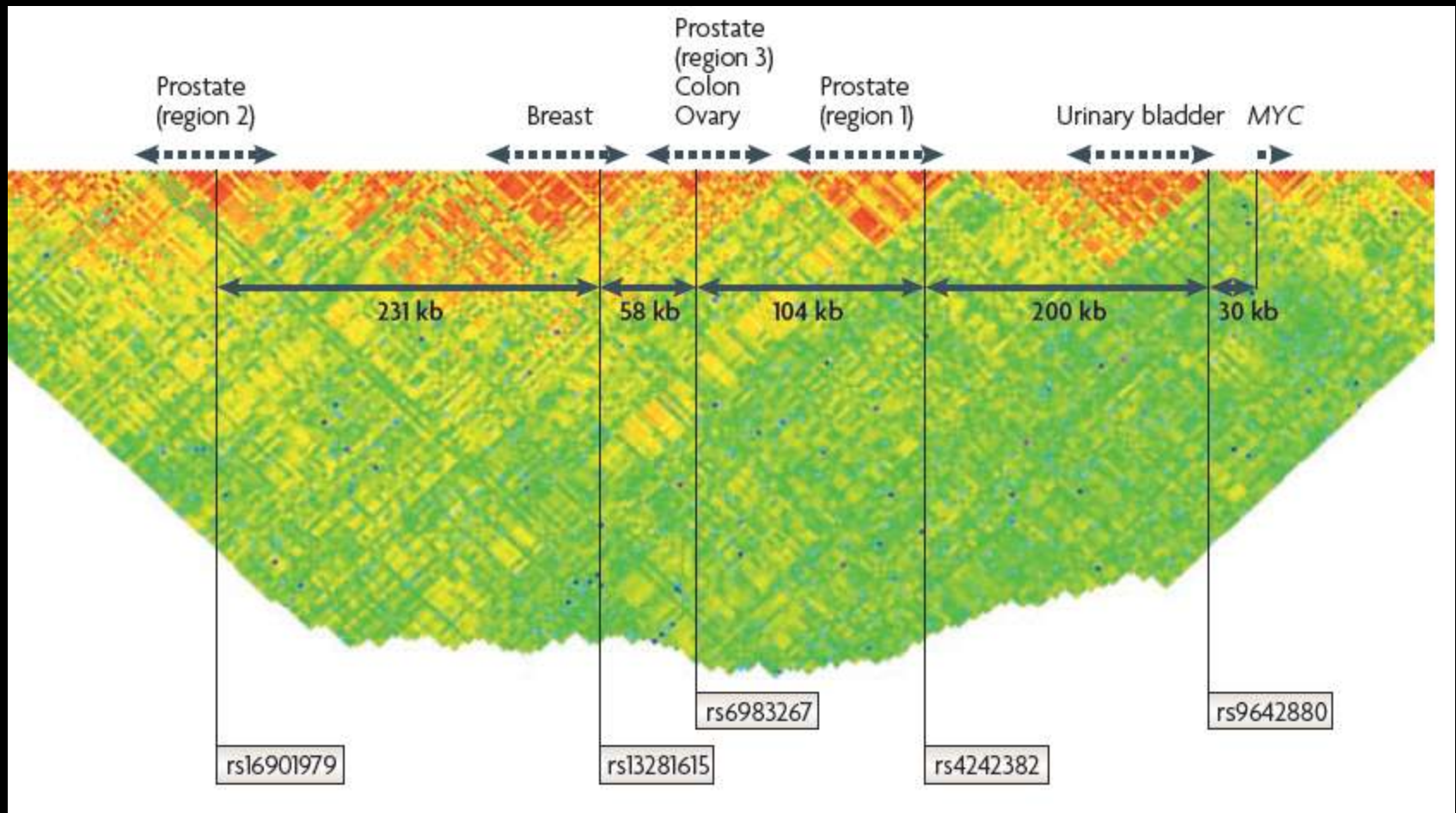
- recognition of increasing levels of organizational and regulatory complexity
 - haplotypes
 - CNV
 - indels
 - RNA universe
 - ‘dark’ elements
 - epistasis
 - epigenetics
 - nuclear compartmentalization and *trans*-expression

miRNAs Associated with Solid Cancers

Tumor	miRNA	Function
Breast cancer	miR-21, miR-125b	oncomiR
Breast cancer metastasis	miR-335, miR-206, miR-126	metastasis suppressor
Lung adenocarcinoma	let-7a, miR-143, miR-145	tumor suppressor
Lung adenocarcinoma	miR-17-92 cluster, miR-106b/93/25 cluster	oncomiR
Pancreatic ductal carcinoma	miR-196a, miR-196b	oncomiR
Ovarian carcinoma	miR-199a/b, miR-140, miR-145, miR-204, miR-125a/b	tumor suppressor
Ovarian carcinoma	miR-141, miR-200a/b/c	oncomiR
Hepatocellular carcinoma	miR-21, miR-224, miR-34a, miR-221/222, miR-106a, miR-203	oncomiR
Hepatocellular carcinoma	miR-122a, miR-422b, miR-145, miR-199a	tumor suppressor
Thyroid papillary cancer	miR-146b, miR-221, miR-222, miR-181b, miR-155, miR-224	oncomiR

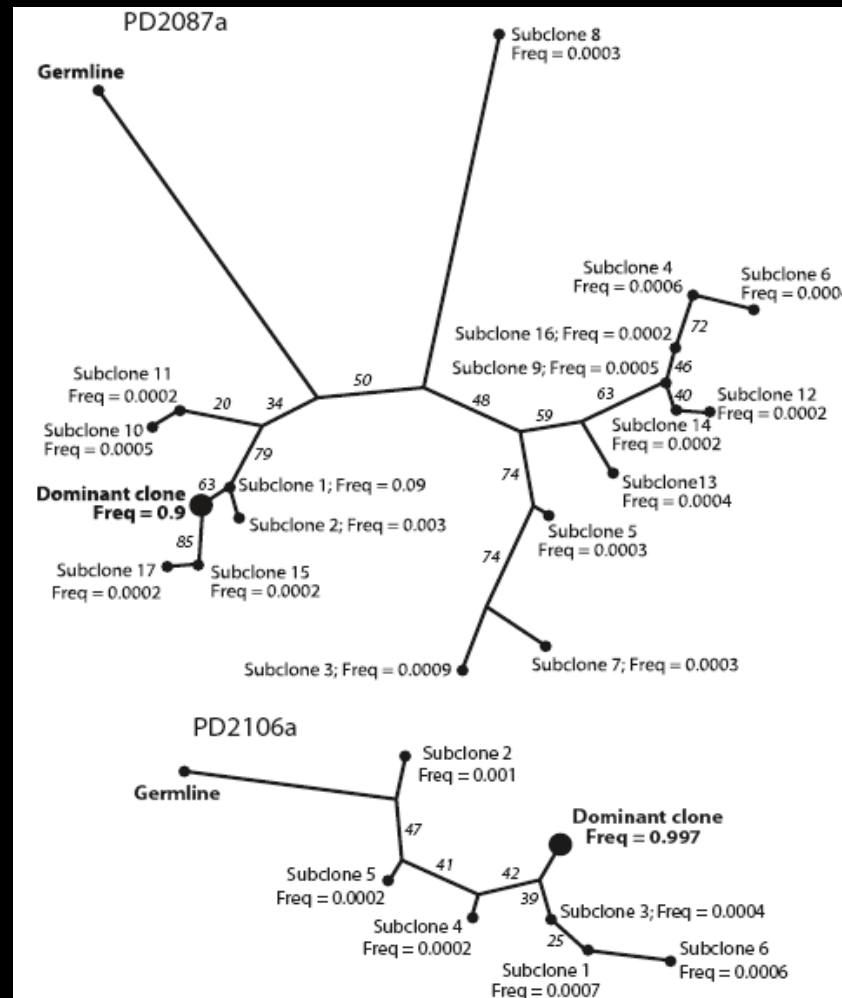
From: M. Galasso et. al. (2010) Genome Medicine 2, 12

Gene Deserts: The 8q24 Region and Cancer Susceptibility



From: J. P. A. Ioannidis et al. (May 2009) Nature Rev. Genetics 10, 318

Unrooted Parsimony Tree Profiles for Clonal Evolution in B-Cell Chronic Lymphocytic Leukemia Revealed by Ultra-Deep Genome Sequencing



From: P. J. Campbell et al. (2008) PNAS 105, 13081
Length of branch is proportional to number of
varying bases (evolutionary distance)

The Race for Low Cost ($\$ < 1000$) Whole Human Genome Sequencing



life
technologies™



illumina®



454
SEQUENCING Roche



IBM



Electronic
Bio
Sciences



pb PACIFIC
BIOSCIENCES™



Complete
genomics



BioNanomatrix



ion torrent
△ ★ ▲ ○ × □ + ≈

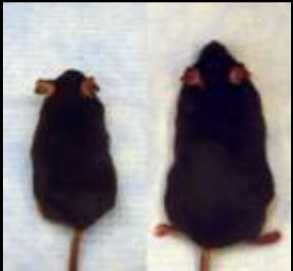


imagination at work

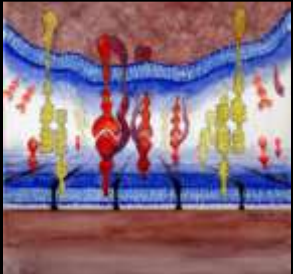


Helicos
BioSciences Corporation

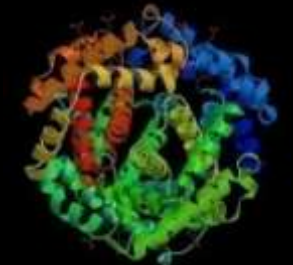
The Evolution of Drug Discovery



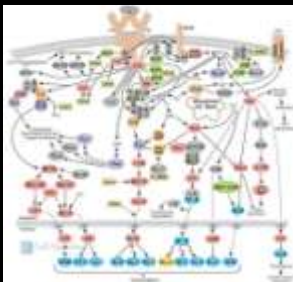
- empirical screening



- cellular/receptor pharmacology

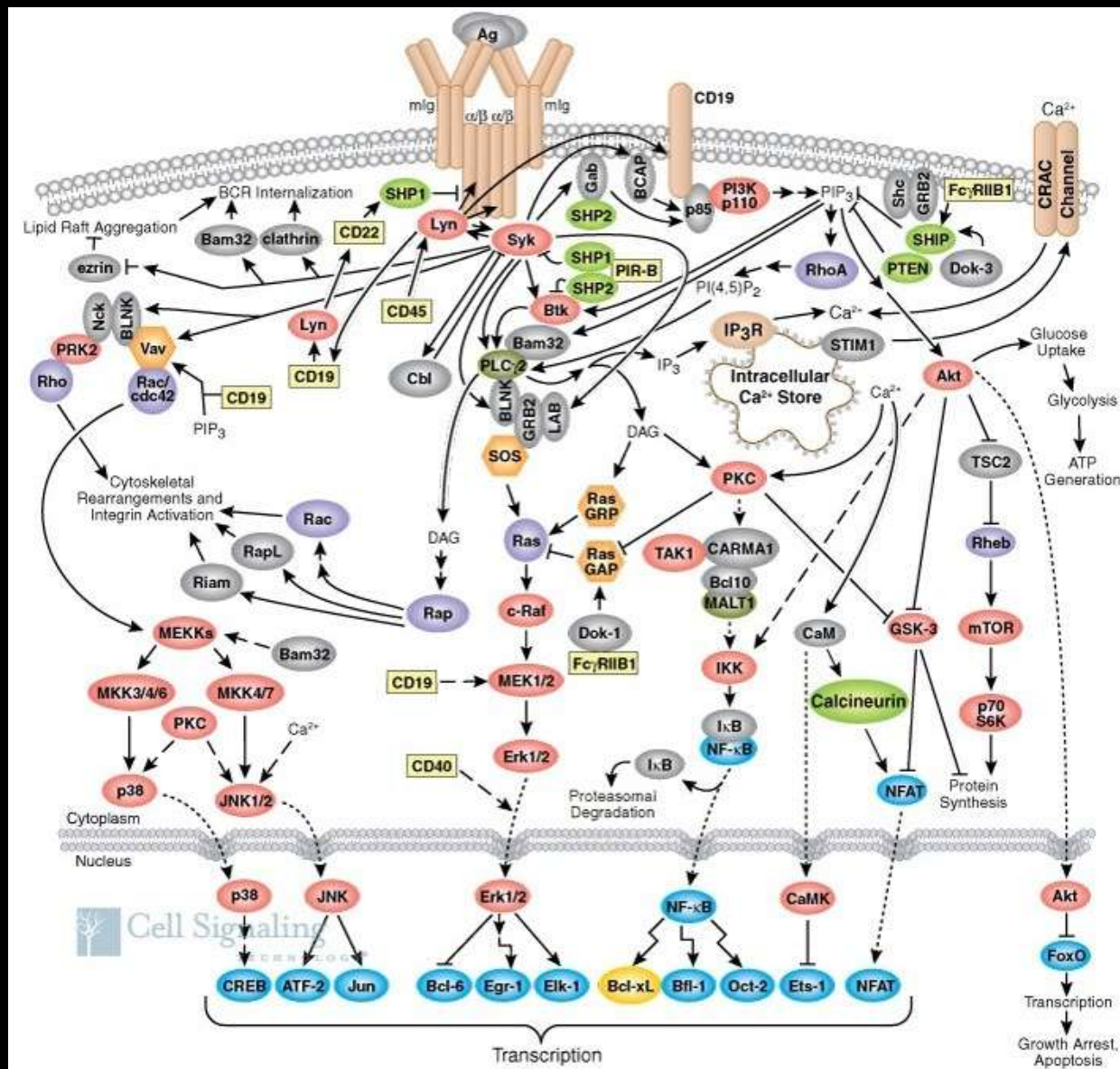


- genomics and individual molecular targets

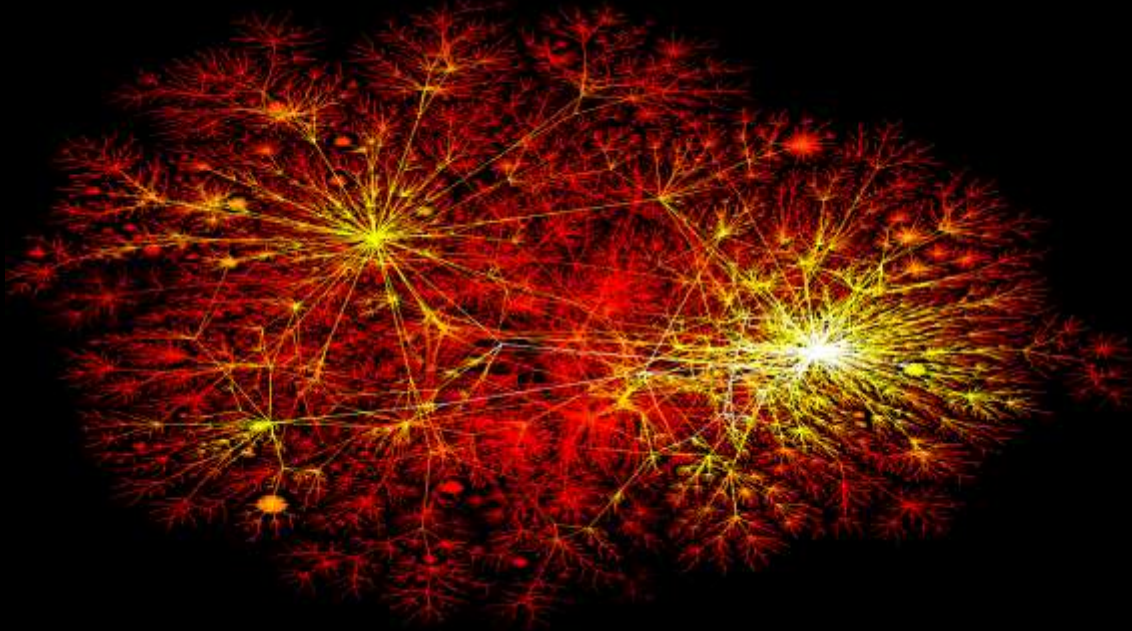


- molecular pathways

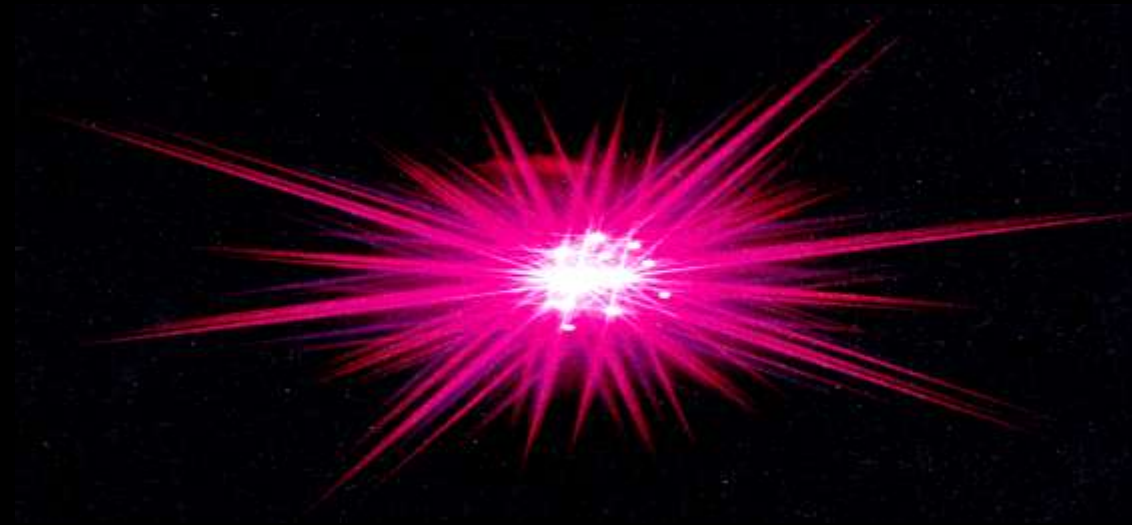
Systems Biology: Mapping Biological Pathways and the Generation of Complex Network Behaviors



Molecular Pathways and Network Analysis: Systems Pharmacology



**Deconvolution
of Signaling
Networks
in Disease**



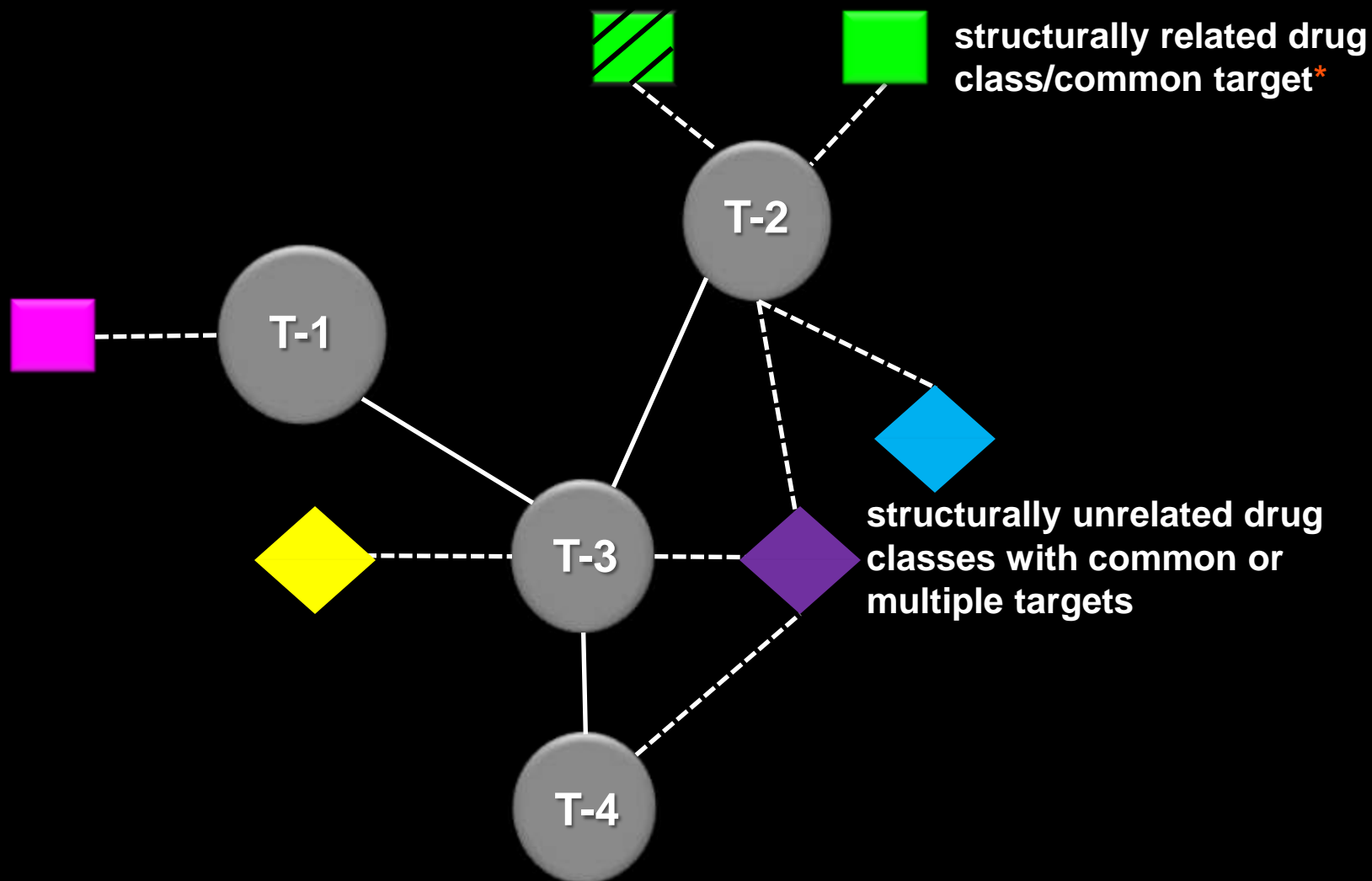
**Identification
of
'Fragile'
Nodes/Pathways
for
Targeted Rx**

Target-Protein Networks

Network Pharmacology and Drug Discovery: Key Principles

- **there are few single molecular targets for Rx action**
- **effective Rx requires modulation of pathways**
- **there are no linear pathways, only networks and subnetworks**
- **there are also highly interconnected networks/subnetworks between tissues**
 - **e.g. modulation of liver network induces changes in pancreatic islet network**

Mapping Pharmacogenomic Molecular Networks



*Tanimoto coefficient of 166 structural features

Building Pharmacogenomic Drug: Network Datasets



83,338 concept terms for subtree of pathology descriptors

DRUGDEX

4068 concept terms matched to SNOMED-CT

**Drug-Disease
Knowledge Base
(DrDKB)**

726 diseases/2022 drugs

PharmGKB
Pharmacogenomics Knowledge Base

3517 approved drug indications, 8130 off label uses



12,460 genes (proteins)/400 drugs

The Complexity of Cancer Genomes

LUNG CANCER

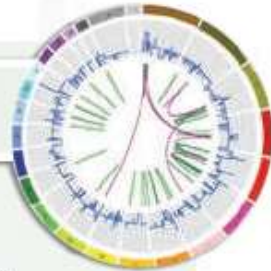
Cancer: small-cell lung carcinoma

- Sequenced: full genome
- Source: NCI-H209 cell line
- Point mutations: 22,910
- Point mutations in gene regions: 134
- Genomic rearrangements: 58
- Copy-number changes: 334

Highlights:

Duplication of the *CHD7* gene confirmed in two other small-cell lung carcinoma cell lines.

Source: E. D. Pleasance et al. *Nature* 463, 184-190 (2010).



SKIN CANCER

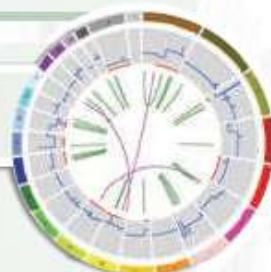
Cancer: metastatic melanoma

- Sequenced: full genome
- Source: COLO-829 cell line
- Point mutations: 33,345
- Point mutations in gene regions: 292
- Genomic rearrangements: 51
- Copy-number changes: 41

Highlights:

Patterns of mutation reflect damage by ultraviolet light.

Source: E. D. Pleasance et al. *Nature* 463, 191-196 (2010).



BREAST CANCER

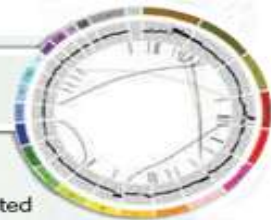
Cancer: basal-like breast cancer

- Sequenced: full genome
- Source: primary tumour, brain metastasis, and tumours transplanted into mice
- Point mutations: 27,173 in primary, 51,710 in metastasis and 109,078 in transplant
- Point mutations in gene regions: 200 in primary, 225 in metastasis, 328 in transplant
- Genomic rearrangements: 34
- Copy-number changes: 155 in primary, 101 in metastasis, 97 in transplant

Highlights:

The *CTNNA1* gene encodes a putative suppressor of metastasis that is deleted in all tumour samples.

Source: L. Ding et al. *Nature* 464, 999-1005 (2010).



BRAIN CANCER

Cancer: glioblastoma multiforme

- Sequenced: exome (no complete Circos plot)
- Source: 7 patient tumours, 15 tumours transplanted into mice (follow-up sequencing on 21 genes for 83 additional samples)
- Genes containing at least one protein-altering mutation: 685
- Genes containing at least one protein-altering point mutation: 644
- Copy-number changes: 281

Highlights:

Mutations in the active site of *IDH1* have been found in 12% of patients.

Source: E. R. Mardis et al. *N. Engl. J. Med.* 361, 1058-1066 (2009).

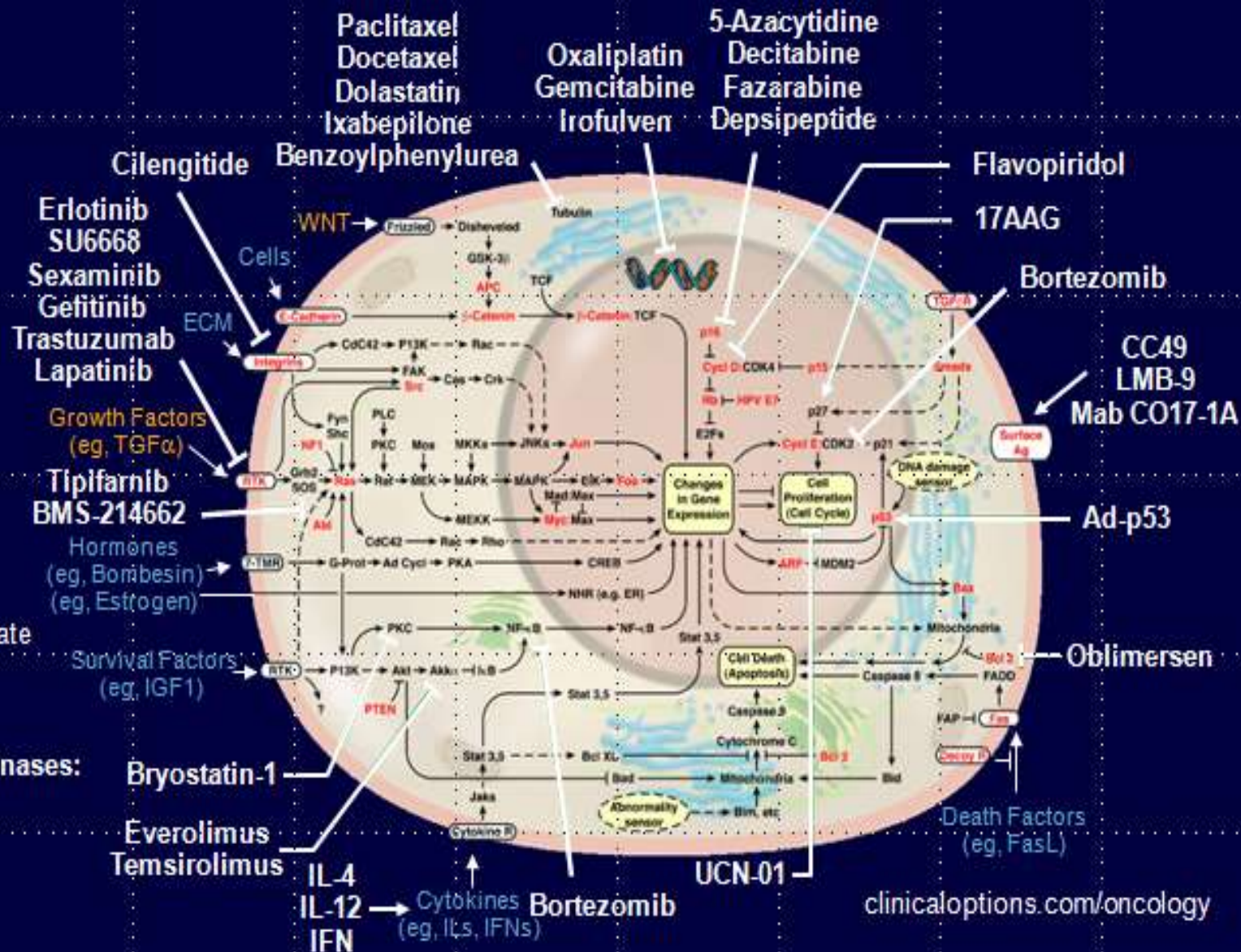
Selected Targeted Agents With Potential as Breast Cancer Therapeutics

Angiogenesis:

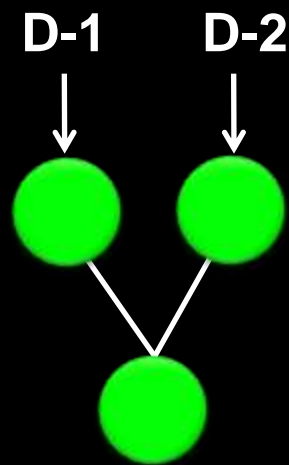
Sexaminib
SU6668
Bevacizumab
HuMV833
Cilengitide
Vitaxin 2
CAI
Endostatin
Angiostatin
Thalidomide
Neovastat
2-Methoxy Estradiol
Sorafenib
Sunitinib
Vandetanib
Motesanib diphosphate

Matrix Metalloproteinases:

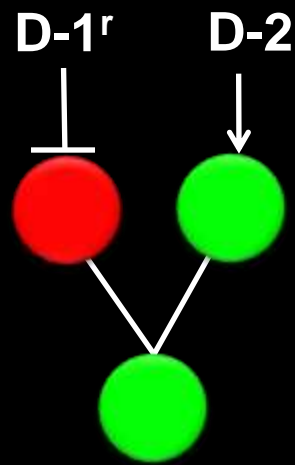
Batimastat BB-94
Marimastat BB-2516
BMS-275291
BAY 12-9566
COL3



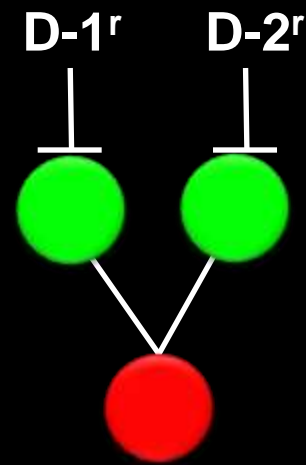
Network Pharmacology, Pathway Redundancy and Drug Resistance (D^r)



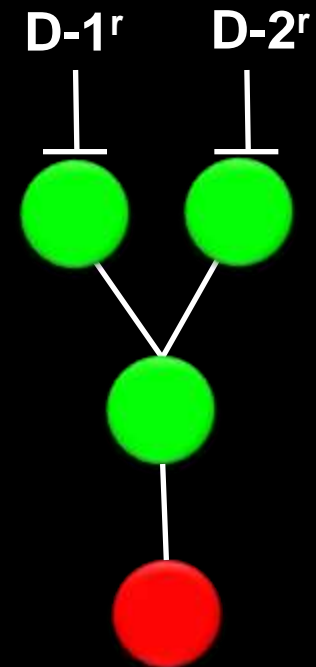
susceptible
to both
D-1/D-2



mutation
confers
resistance
to D-1



distal pathway
mutations
confer resistance
to both D-1/D-2



Systems Pharmacology and Molecular Pathways Network Analysis

- **‘connectivity’ maps**
 - correlations between genomic signatures and sets of proteins involved in Rx action
- **Rx ‘promiscuity’**
 - spectrum of ‘target’ effects required for optimum efficacy
 - network redundancy and Rx non-responsiveness/resistance
- **Rx ‘pleiotropy’**
 - off-target effects and adverse event risk(s)
- **‘synthetic lethal’ screening**
 - ID new Rx oncology targets in co-dependent genes required for cell survival
- **‘minimum knockout’ modeling**
 - ID/predict smallest number of drug targets to fully block a cellular process

High Content Cellular Screens: Cyto-omics

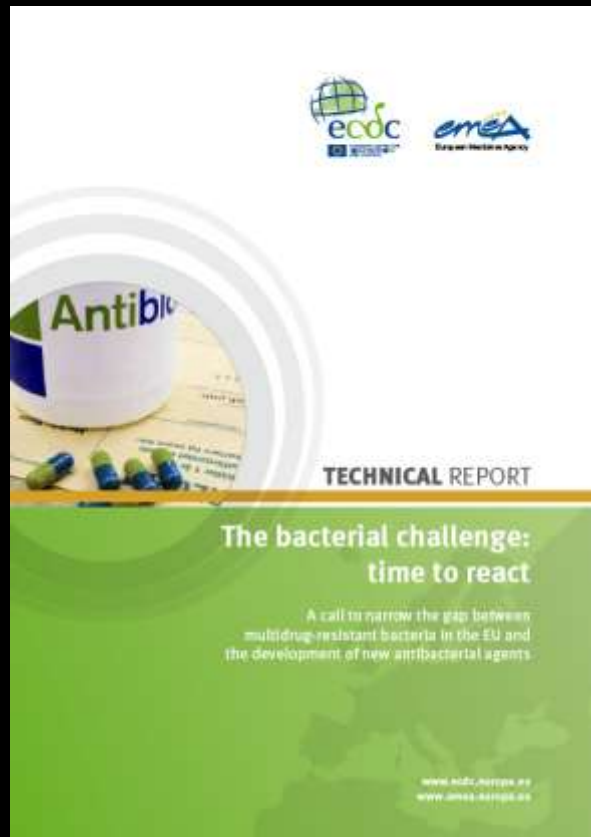
- rapid expansion of single cell analysis methods
- linking gene expression to functional pathways/ networks/ compartments
- obvious requirement to validate in vitro/ex vivo phenotypes to events in vivo
 - higher level of ‘stochastic’ drift in vitro?
 - failure of 2D cultures to mimic complex signaling environment of organized multi-cellular tissues
- parallel evolution of technologies for imaging in vitro and in vivo for biomarker validation

New Incentives for R&D Investment in Diagnostics, Drugs and Vaccines to Outpace Infectious Diseases



The Valley of Dearth: The Consequence of Declining R&D Investment in Antibiotic Discovery*

- 75% decrease in antibacterials approved from 1983 to 2009
- only 16 agents currently in Phase II / III clinical trials
 - only 3 as new ‘classes’ with novel mechanisms of action
 - absence of agents for therapy of AMR in Gram-negative bacilli
 - lack of systemic agents in advanced development for organisms resistant to all current antibacterials



* source: H.W. Boucher et. al. (2009) Clin. Inf. Dis. 48, 1

The Growing Challenge Posed by Antimicrobial Drug Resistance (AMR)



NO ESCAPE

Enterococcus faecium

Staphylococcus aureus

Klebsiella Pneumoniae

Acinetobacter baumannii

Pseudomonas aeruginosa

Enterobacter species





New US-EU Task Force (2 Nov. 2009)

- encourage R&D on new antimicrobial drugs
- yet to be defined strategy/funding



The 10 X '20 Initiative (20 Nov. 2009)

- grand challenge to develop 10 new antibiotics by 2020



Multi-Country Program on AMR (12 Jan. 2010)

- € 12.4 million

Public Response to H1N1 Vaccine for Pandemic Protection



**“Millions demand it,
millions refuse it,
and millions don’t know what to think”**

John Carroll

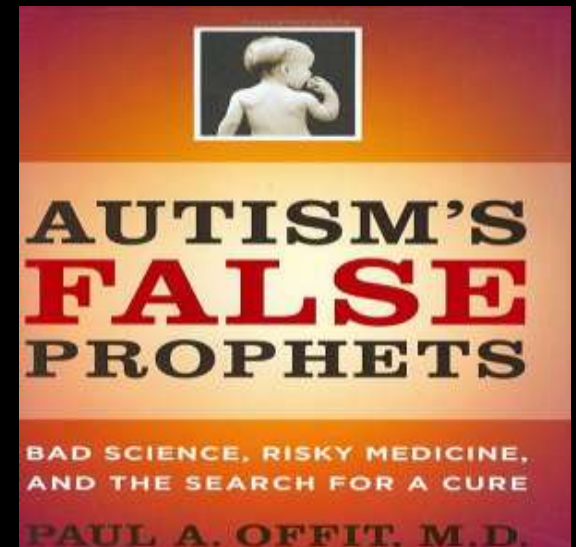
Editor, FierceBiotech (23 Oct. 2009)

Vaccine Safety: Informing the Misinformed



Deesillustration.com

Vaccine Safety: Media Sensationalism and Celebrity Quackery



“Faked Pandemics- a Threat for Health”



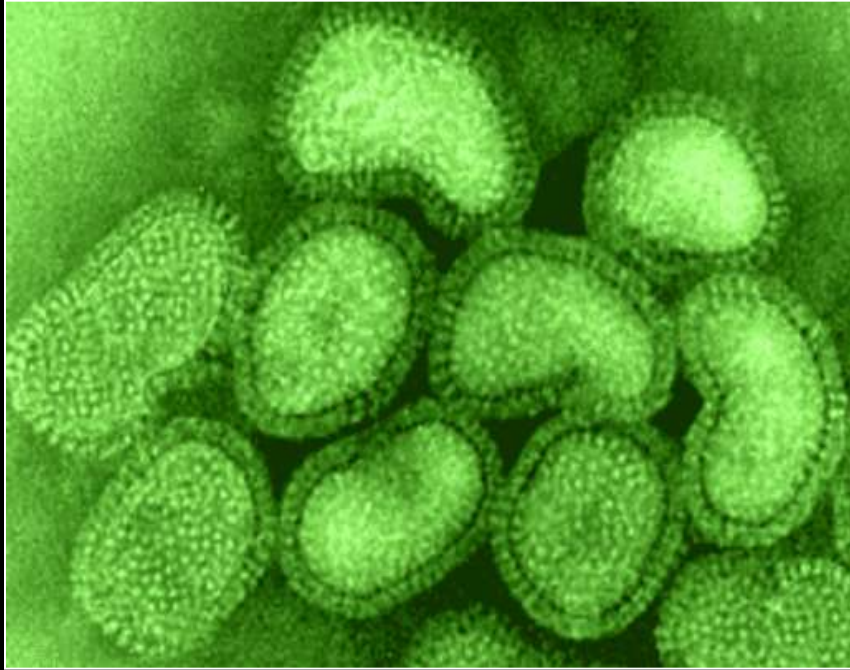
- **Motion to COE by Wolfgang Wodarg, Chair, Healthcare Committee, January 2010**
- **“WHO in cooperation with some big pharmaceutical companies and their scientists re-defined pandemics and lowered the alarm threshold”**
- **“Those standards forced politicians..... to sign marketing commitments for vaccines against swine flu and spend billions to catch up with the alarming scenario that big pharma, media and WHO are spreading”**

Source: Scrip News 6 Jan. 2010

Media Sensationalism and Public Response to H1N1 Threat

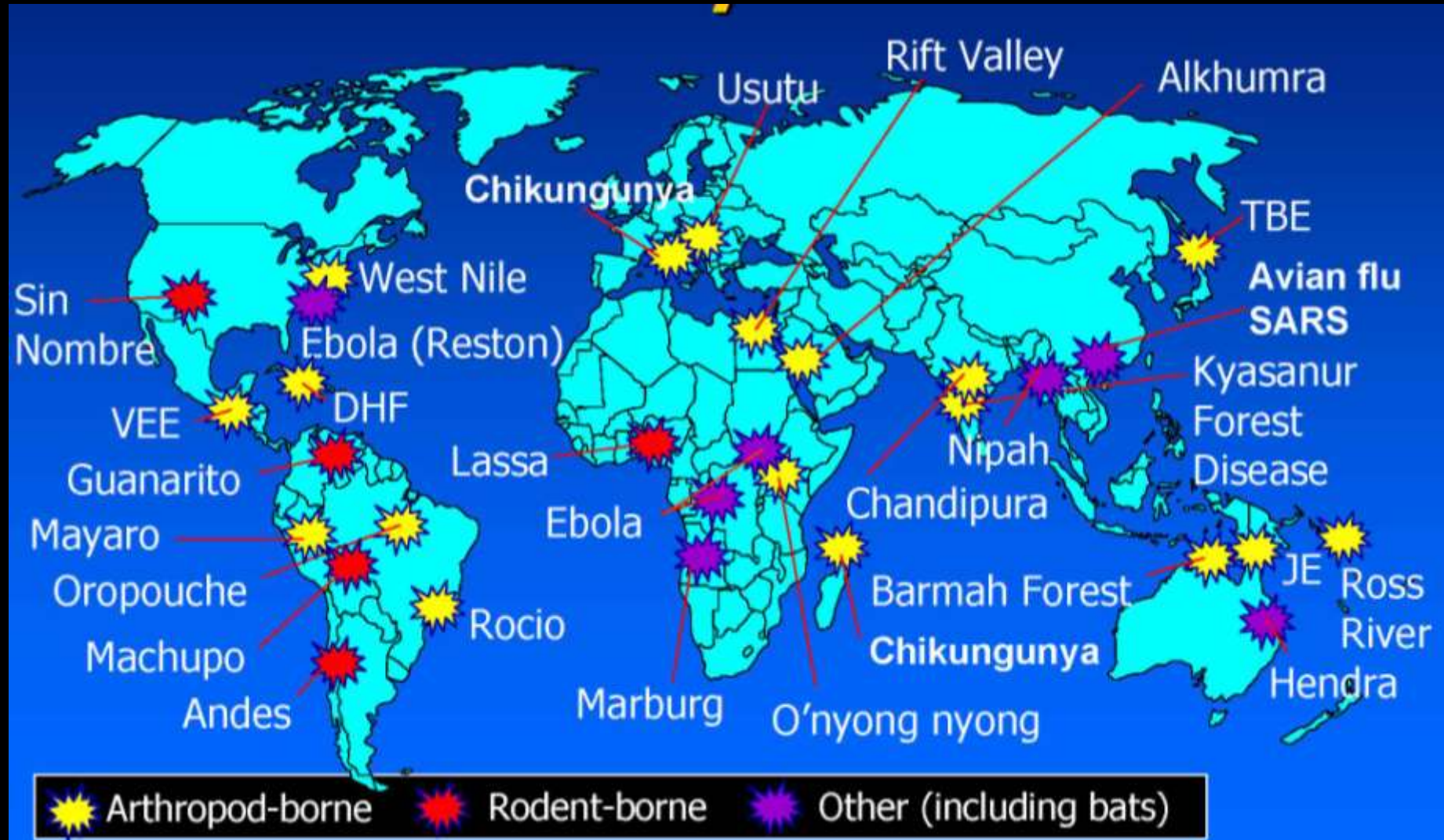


Maintaining Global Preparedness for a High Virulence Pandemic



- H1N1: high transmissibility - low virulence/mortality
- H5N1: low transmissibility – high virulence/mortality
- H5N1 x (H1N1) or (X): potential for devastating pandemic

Emerging Infections:



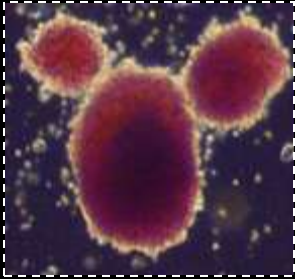
Combating “Agent-X”

- **new infectious agent**
 - **natural or nefarious origin**
- **highly virulent, high transmissibility**
- **major gaps in public health preparedness**
 - **outmoded vaccine technologies and production methods**
 - **inadequate scale of vaccine manufacturing infrastructure**
 - **cost and lead time for new vaccine production facilities**
 - **lack of novel Rx classes**
 - **high cost and protracted R&D cycles**
- **inadequate investment incentives**
- **public policy neglect**

The Evolution of Drug Discovery



- **systems biology**
 - elucidation of biological networks and their regularity



- **regenerative biology**
 - reprogramming cell function and directed differentiation (ESC/iPS)

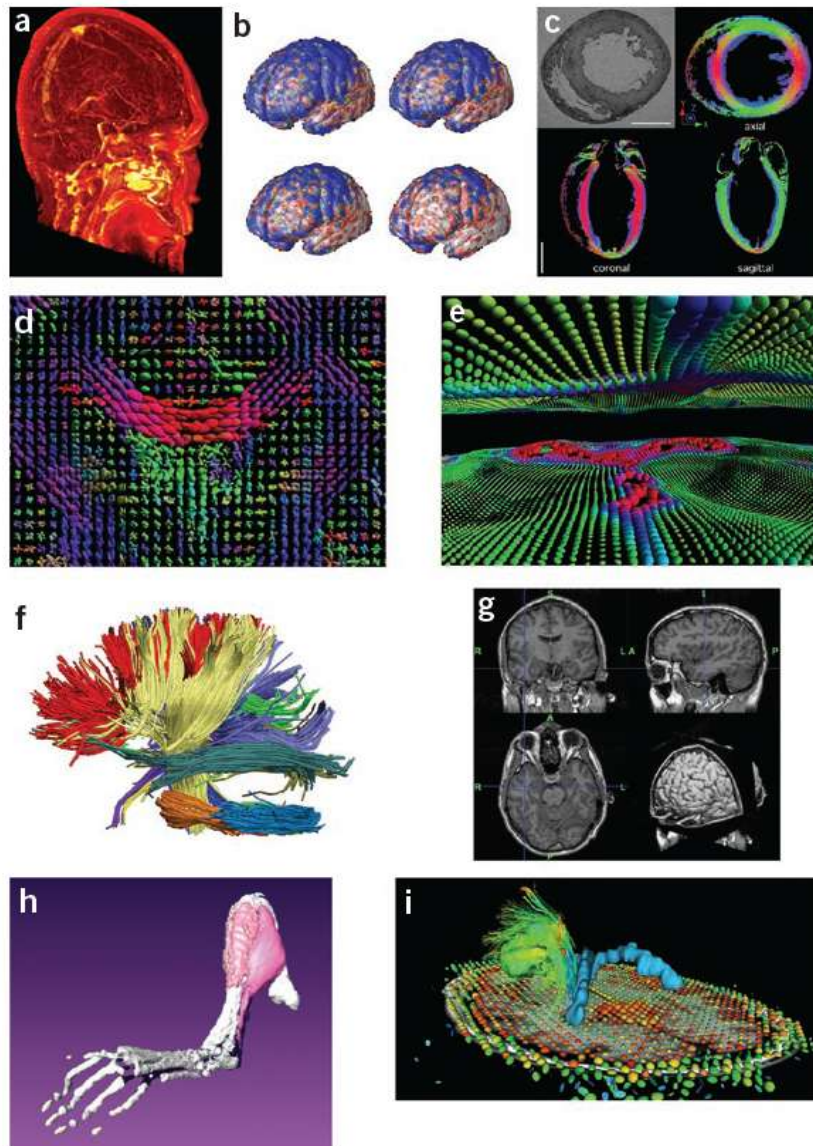


- **synthetic biology**
 - de novo design of novel organisms and a new industrial ecology



- **predictive biology**
 - information flow in complex adaptive systems

New Imaging Technologies



In Theater Imaging and Surgical Robotics



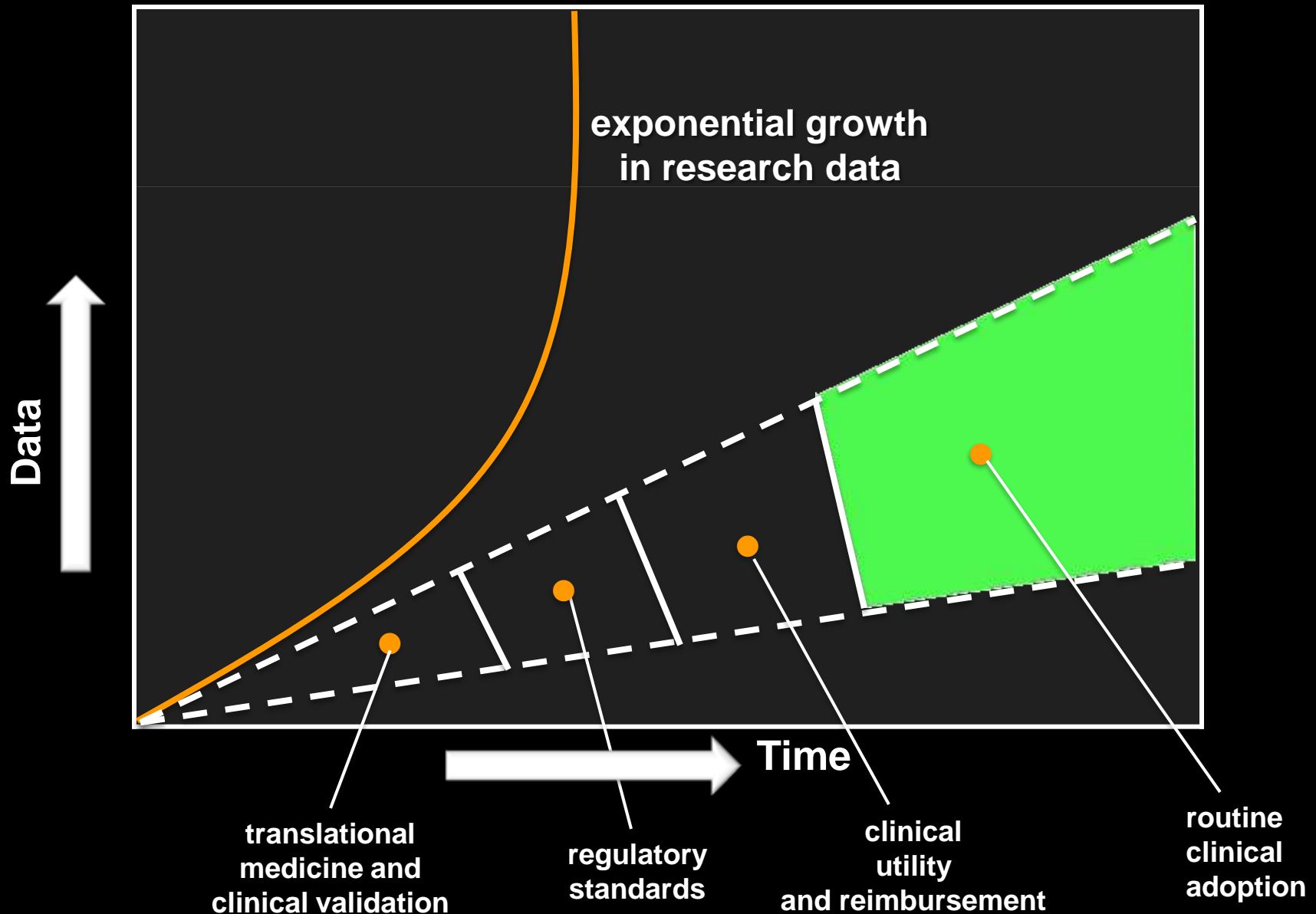
**“Biomedical research in academia has been very successful
in generating an immense amount of information,
leading to a **true revolution in molecular medicine**”**

S. Albani and B. Prakken

Nature Medicine (2009) 15, 1006

TRUE OR FALSE?

The Trajectories for Molecular Medicine

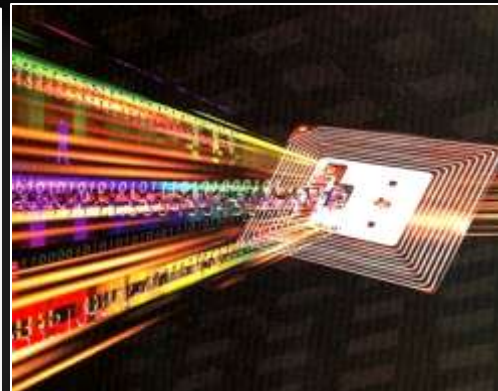
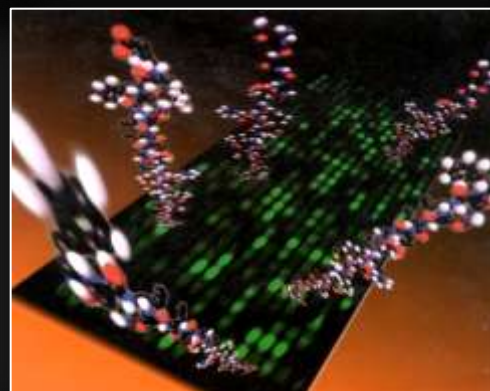
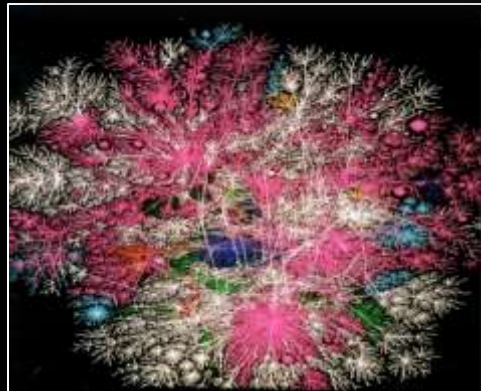
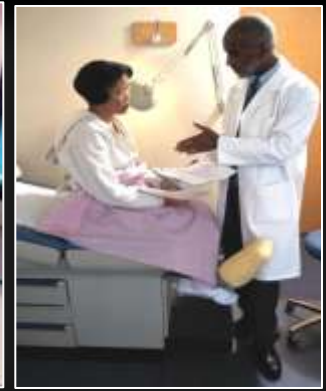
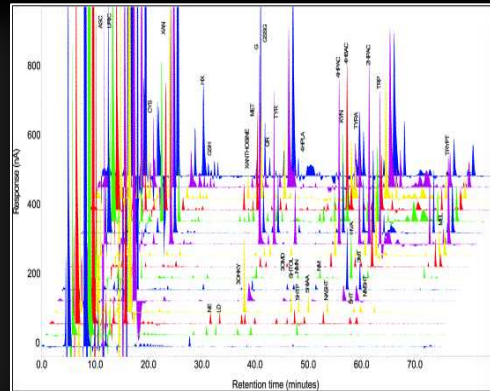
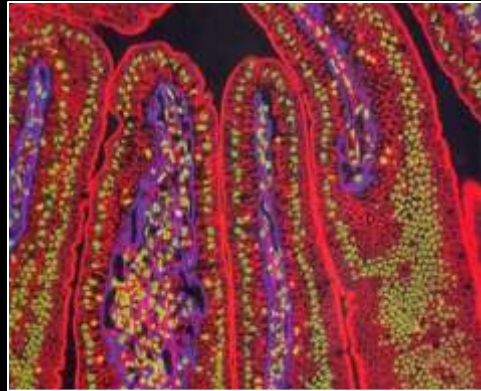


Knowledge and Evidence Doesn't Translate Easily into New (or Rational) Behaviors

- **science (impact is too often unknown or abstract)**
- **industry (incremental timidity driven by short-term focus on markets and stock valuation)**
- **payors (cost control)**
- **physicians and healthcare professionals (status, revenue and recognition)**
- **patients (unaware and uninvolved in healthcare decisions)**
- **politicians (populism and short-term fixes)**

**The Pragmatic Challenge:
Who Pays, Who Benefits and Who Decides?**

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



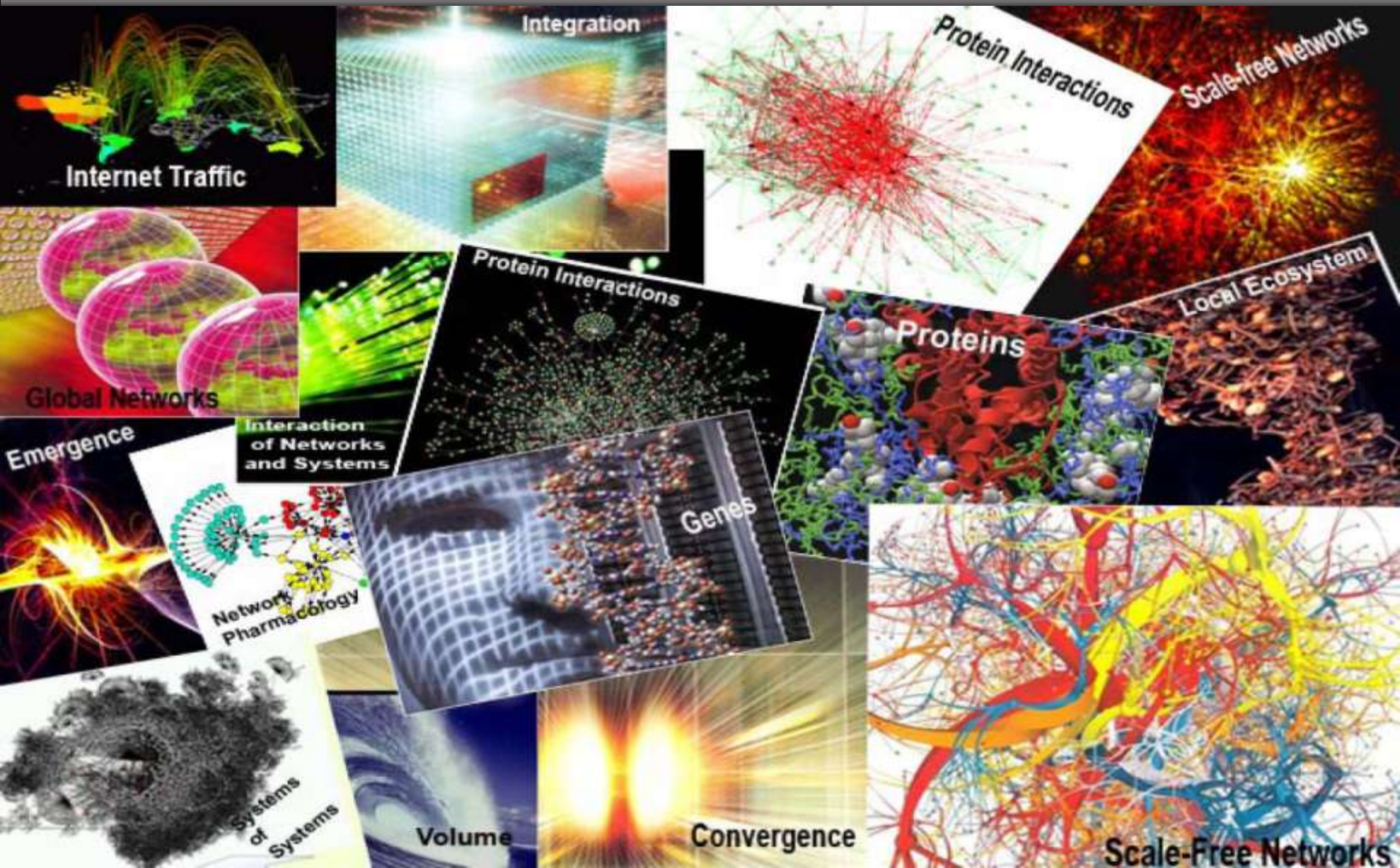
**Biospecimens
and
Molecular
Pathway
Analysis**

**Biomarker
Validation
and
Multiplex Assays**

**Instrumentation
and
Informatics**

**Clinical
Impact
and
Patient
Monitoring**

Data: The Fastest Growing Resource on Earth



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



OBO Foundry Ontologies

Nature Biotechnology 25, 1251 - 1255 (2009)



The Open Biomedical Ontologies

Cell Ontology (CL)

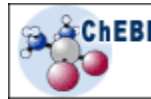


Gene Ontology (GO)

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)

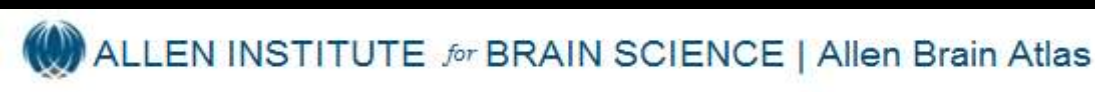
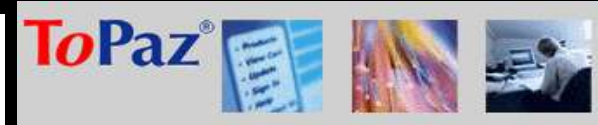


**OBO Relation
Ontology**

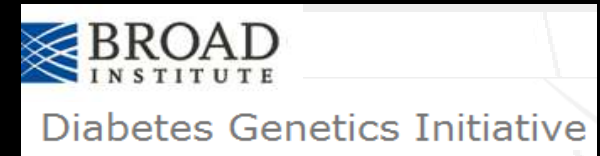


**RNA Ontology
(RnaO)**

The Rise of Open-Source Networks and Consortia



FDA/Severe Adverse Events (SAE) Consortium



“Managing Mega-Data”: (Who Knows Wins)

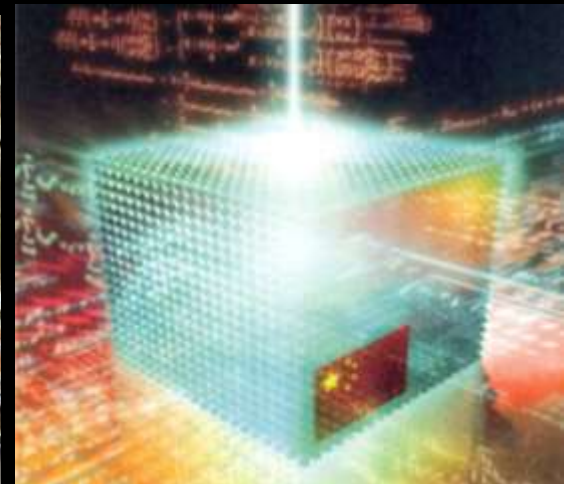
volume



scale



global networks



heterogeneity

integration

How Much New Technology Can We Afford?



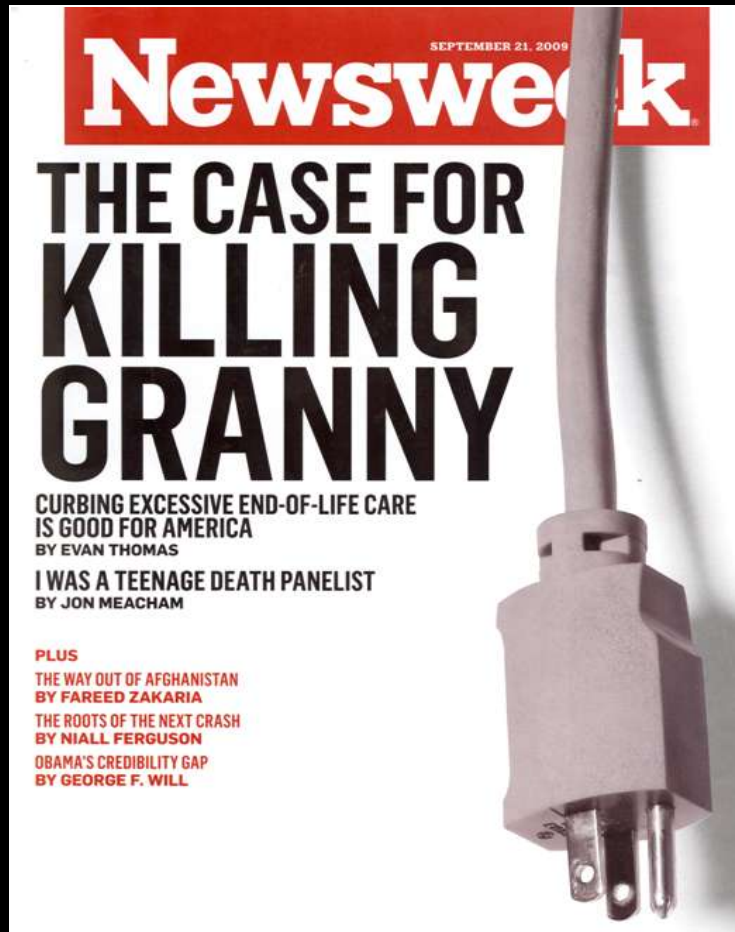


“We must acknowledge that the cost of drug discovery is becoming outrageous and, if it continues to grow at the present rate, new drugs will be unaffordable for any country in the world.”

**Sir Michael Rawlins
Chairman,
UK National Institute for Health
and Clinical Excellence (NICE)**

Nature Rev. Drug Disc. (2009) 8, 692

UK National Institute for Health and Clinical Excellence (NICE)



Nice Gets Nasty (or Rational?)



Knowing What Works (or Doesn't)

- Pervasive Inefficiencies and Errors in Healthcare Created by Empirical Care and Lack of Robust Outcomes and Performance Data



Comparative Effectiveness Research (CER)

- **superficial appeal of rational policy belies the complexity of rigorous CER**
 - endpoints/outcomes
 - methodological and reporting standardization
 - stringency of patient selection/treatment regimen/compliance
 - prospective versus retrospective data
- **payor engagement and impact on reimbursement policies**
 - predisposition to chose lower cost intervention(s)?
 - risk of abuse and rationing of care

WHO SETS PRIORITIES AND EVALUATION CRITERIA?

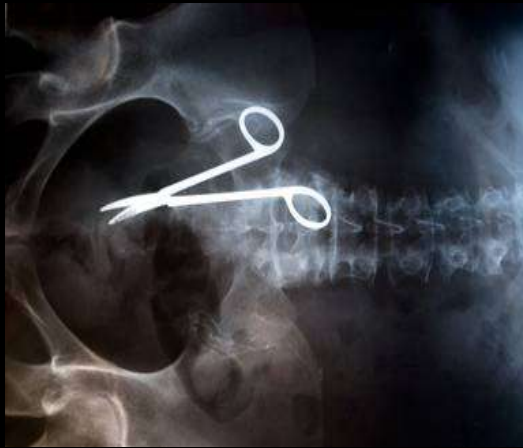
Who Defines Best Practices?



- controversy over US Preventive Task Force (USPTF) recommendations on mammograms for women age 40-49
- endorsed by ACP
- opposed by ASCO and NCCN
- USPTF did not address cost but it dominated public debate
- “should policy makers set a price on saving a life?”

Patient Safety: The Dimension of the Problem

Overt Error



Non-Compliance



Adverse Rx Event



**Hospital-Acquired
Infections**

**Cost of Hospital
Re-admissions**

**Inaccurate, Inaccessible
or Ignored Information**

Wellness:

**The Most Broad and Most Valuable
Definition of Successful Healthcare**

Consumers at the Center

Consumer Behavior and Healthcare Costs



“diabetesity” \$200 billion



**smoking \$190 billion
alcohol \$20 billion**

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)**

Health Status Monitoring and the Promotion of Wellness

**On-Body: In-Body Sensors (OBIBs)
and
Remote Monitoring of Health Status**

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)

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 A1C
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

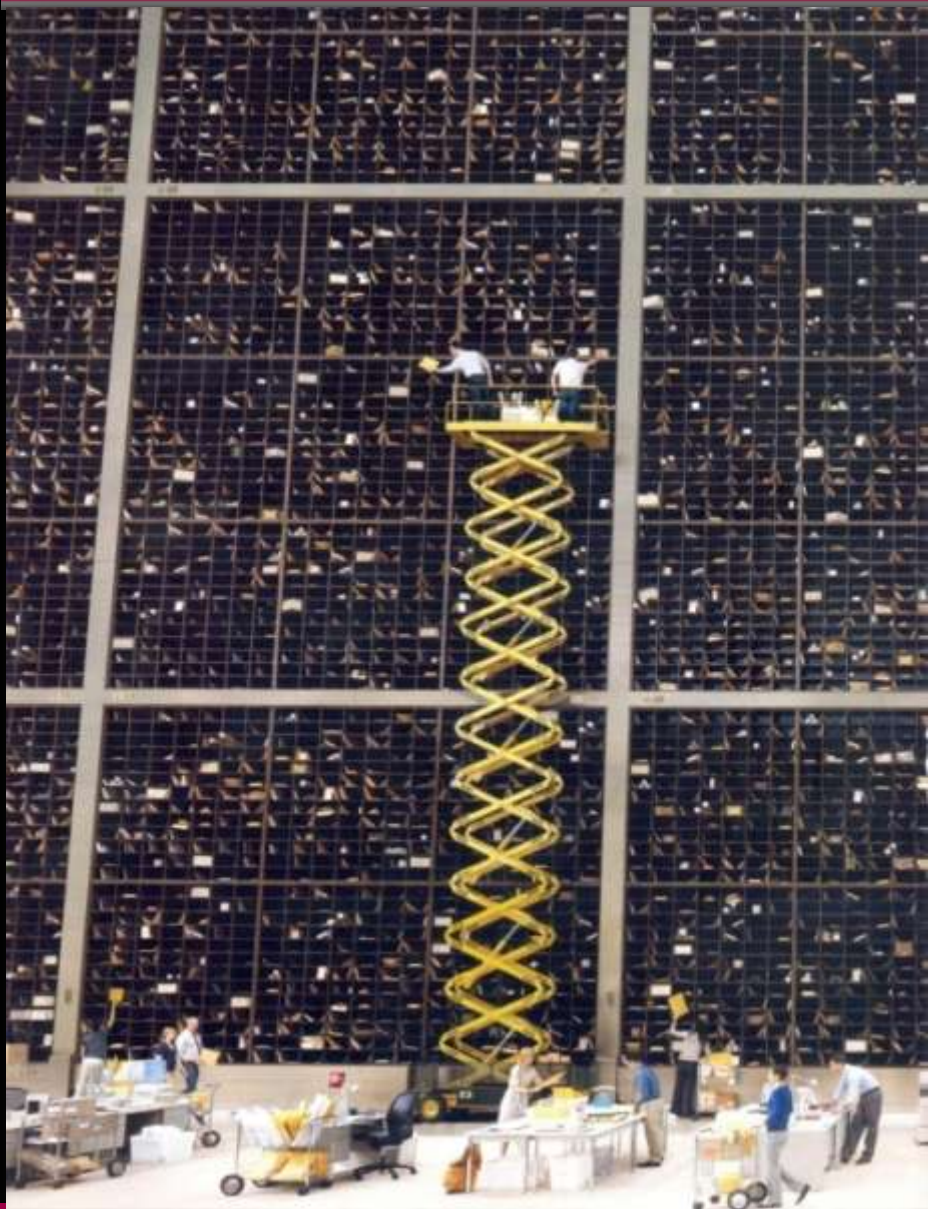
OBIBs: The Need for New Reimbursement and Regulatory Policies

- **first generation remote health monitoring devices**
- **MD payment for analysis of data streams from remote monitoring**
 - **Cardionet, Medtronic**
- **White House Broadband Plan (3/16/10)**
 - **FDA and FCC to establish oversight process for e.health devices**
 - **HHS to develop reimbursement methods to accelerate adoption**
 - **FCC to allocate wireless spectrum for BANs**

The Infocosm: Emerging Networks of Global Connectivity



Healthcare Records: Proliferating Paper and Primitive Electronic Systems



“Meaningful Use” EHR Incentive Programs Funded by ARRA 2009



- **proposed rule and fact sheet comment deadline 2/28/10**
- **www.cms.hhs.gov/recovery/11-healthit.asp**

Health Information Technology *and*
For the Future of Health Care



- **interim final rule: comment deadline 2/28/10**
- **<http://healthit.hhs.gov/standardsandcertification>**

Telecommunications and Media Industry Convergence: Implications for Healthcare

Copyrighted Material

THE DECISION TREE

TAKING CONTROL OF YOUR HEALTH
IN THE NEW ERA OF PERSONALIZED MEDICINE



THOMAS GOETZ

Copyrighted Material

“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

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

Deputy Editor of Wired

Wireless Technologies: Consumer and Clinical Markets Converge



e-Patient Revolution



Pharma and Healthcare Social Media (Non-Brand Sponsored) Patient Communities



social network about
Empowering cancer
patients to make
informed decisions



blog and social network
about Multiple Chemical
Sensitivity.



healthcare social utility
designed to connect
people
Humanizing Healthcare



Community network
share stories,
encouragement and
friendship



anonymously track and
compare health data, to
make more informed
treatment decisions and
contribute data to
research



campaign to pull our
community together and
offer a brighter, more
positive view of autism



information source
online community
advanced (metastatic)
breast cancer patients,
caregivers



Information and
resources for people with
disabilities



Place to submit, retrieve
and share information
and well-wishes
surrounding a loved
one's health
circumstances



Share information
learn about cancer
across the web



expert-guided
communities where you
have access to
authoritative information
about health topics



Discussion board
anonymously share
health informatio

Cancer Survivors Network

Discussion board
featured on cancer
survivors



social network where
like-minded people can
communicate with each
other and offer peer
support



communicate
about drug safety



helps cancer patients and
caregivers get
personalized information
about the disease, and
share that information



safe, anonymous, online
support groups focused
on over 500 specific
challenges



Discussion board
featured on diabetes



Discussion groups and
forums



search engine for
Americans interested in
purchasing safe, low-cost
prescription drugs from
prescreened international
pharmacies



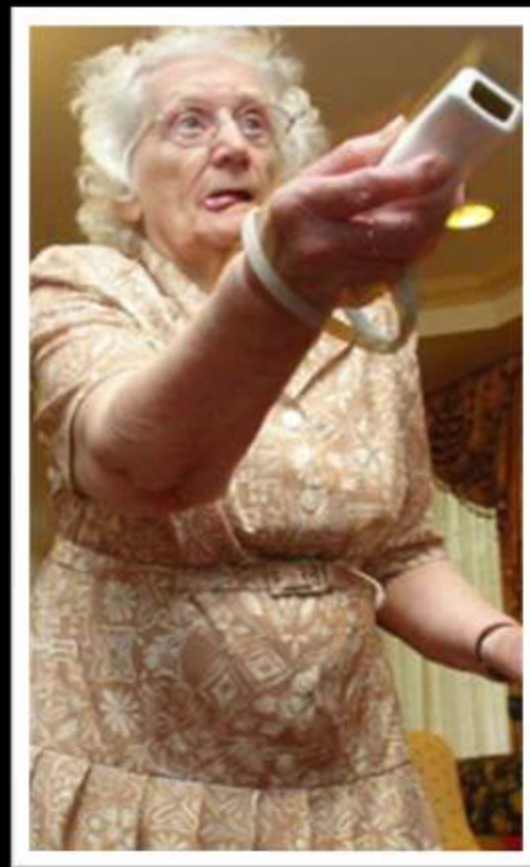
Social network patients,
families, friends and
professionals
Struggling with
disorders and chronic
illness

In-Home Health Connection: Engaging the Elderly





Wii **Fit** Plus



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

The Doctor Will See You Online

The logo for American Well, featuring the text "AMERICAN WELL" in a serif font with a small star above the "i" in "WELL".

AMERICAN WELL

The logo for RelayHealth, featuring a stylized blue "X" icon followed by the text "RelayHealth" in a sans-serif font, with "Relay" in blue and "Health" in orange.

RelayHealth

The logo for Medem, featuring a stylized red circular icon with three overlapping loops, followed by the text "Medem" in a serif font, with "Connecting Physicians and Patients" in a smaller sans-serif font below it.

Medem
Connecting
Physicians and Patients

- immediate access to care for patients
- patients submit medical records to company
- flexible engagement of MDs for additional income generation
- complementary tier of access
- billing and insurance services
- liability issues

The Dominant Future Element in Primary Healthcare Delivery???

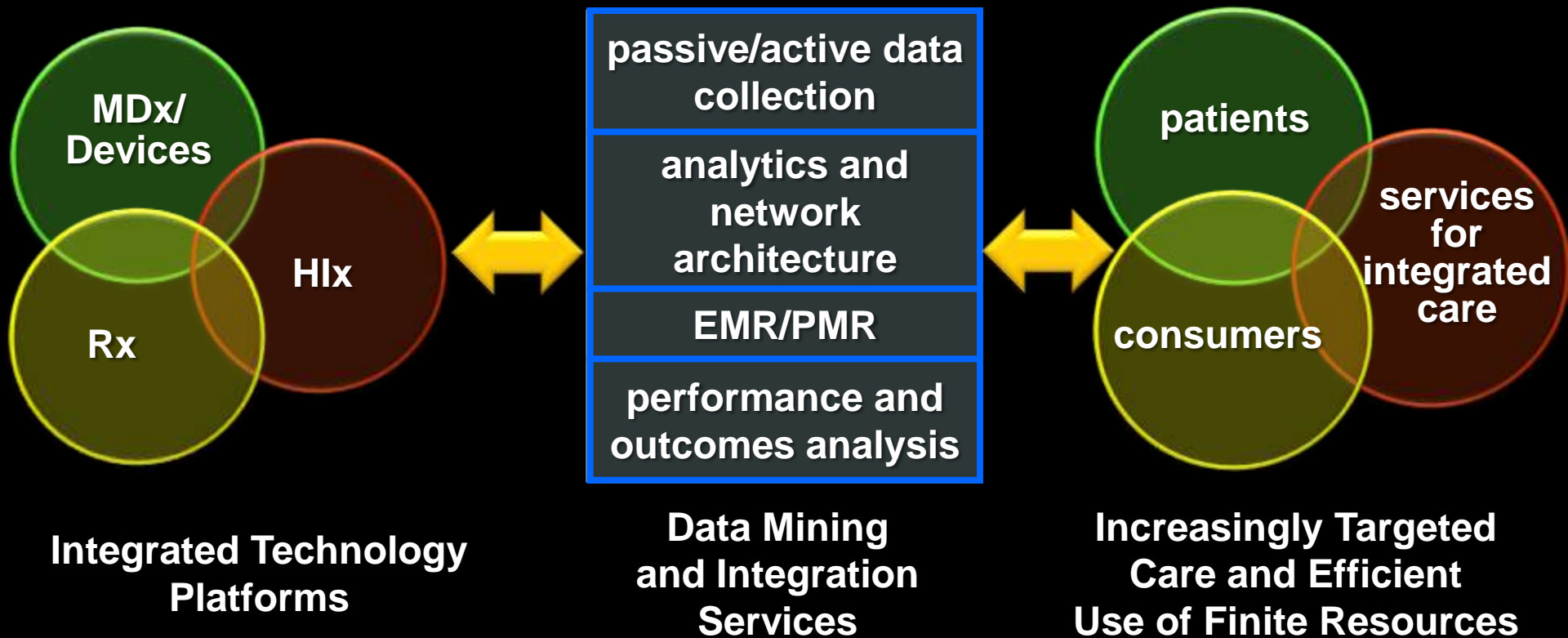
Walgreens
As far as you want to go.™

CVS
CAREMARK

WAL★MART®
Save money. Live better.™



A New Healthcare Ecosystem Arising From Technology and Market Convergence



Sustaining Innovation: Research, Reimbursement and Regulation

Research

- **national resources network for biomedical R&D**
- **expanded private: public partnerships**
- **reform of academic funding model to promote interdisciplinary research**

Reimbursement

- **value-based pricing**
- **new coding for molecular medicine**
- **new models for HTA and CER**

Regulation

- **rebalancing benefit: risk evaluation and abandonment of 'zero-risk' delusion**
- **validation standards for Dx-Rx and high complexity Rx**

Genes and Intellectual Property



14 March 2000



SACGHS

5 February 2010 Report



29 March 2010 SDNY Court Decision



16 April 2010 WSJ Editorial

The Coming Convergence in Healthcare Delivery

Technologies

- biotechnology, medicine, engineering, computing, telecommunications and social media

Clinical Practice

- molecular medicine and increasingly customized care
- diagnostic, drug and device combinations
- POC testing and remote monitoring
- reduced error and improved compliance
- improved outcomes

Realigned Incentives

- integrated care for complex chronic diseases
- earlier disease detection and risk reduction
- wellness versus illness
- remote health status monitoring

The Coming Convergence in Healthcare Delivery

Consumers

- increased personal responsibility for health
- new incentives for wellness/compliance
- remote health status monitoring

Connectivity

- integrated care networks for chronic disease
- social media networks and informed consumers
- new supplier networks of specialized turnkey expertise
- value added 'content' services for clinical data mining
- clinical decision-support systems