PanOmics, Informatics, Economics, Ethics and Politics: The Five Forces Shaping the Evolution of Precision Medicine

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DEPARTMENT OF COMPUTATIONAL MEDICINE AND BIOINFORMATICS (DCM&B)
UNIVERSITY OF MICHIGAN MEDICAL SCHOOL

Challenges Facing U.S. Healthcare

- Balancing Infinite Demand versus Finite Resources
- From Volume-Based FFS Care to Value-Based Care
- From Reactive, Episodic Interventions in Disease Episodes to Proactive Continuity of Care Services
- Improving Outcomes at Lower Cost and Realizing the Wellness Premium
- Technology, Innovation and New Value Propositions in Healthcare

Demographics and the Clinical and Economic Challenges to U.S. Healthcare

wellness with longevity and high QOL

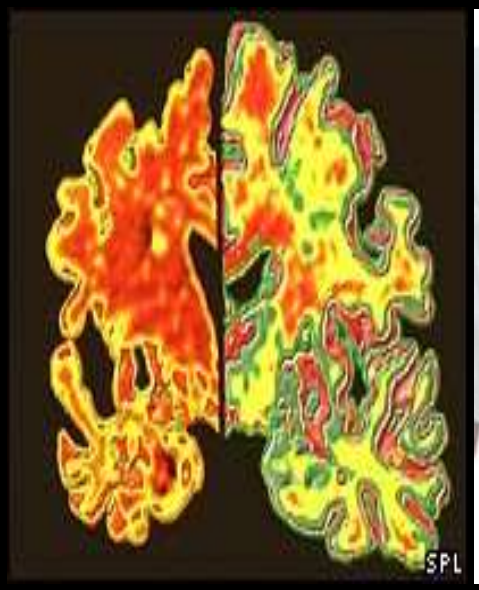
or

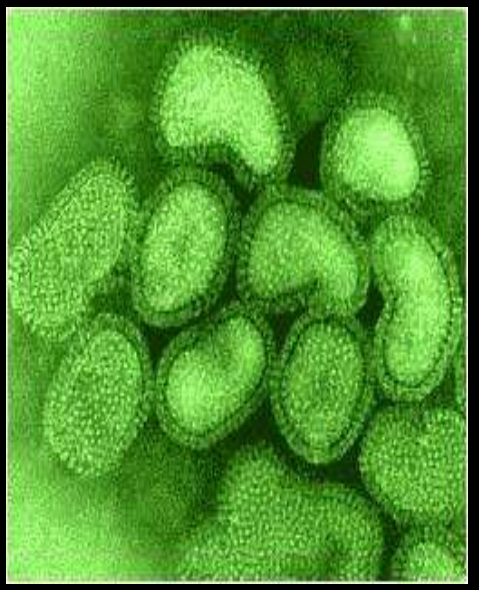
multiple co-morbidities and low QOL

?

?

Unmet Medical Needs and Disease Burden: Confronting the Largest Economic Disruptions to Achieve Sustainable Healthcare





cancer	neurodegeneration	cardio-vascular/ metabolic disease	infectious disease wildcard

Precision Medicine:
Major New USG Funding Initiatives

Precision Medicine Initiative
January 30, 2015

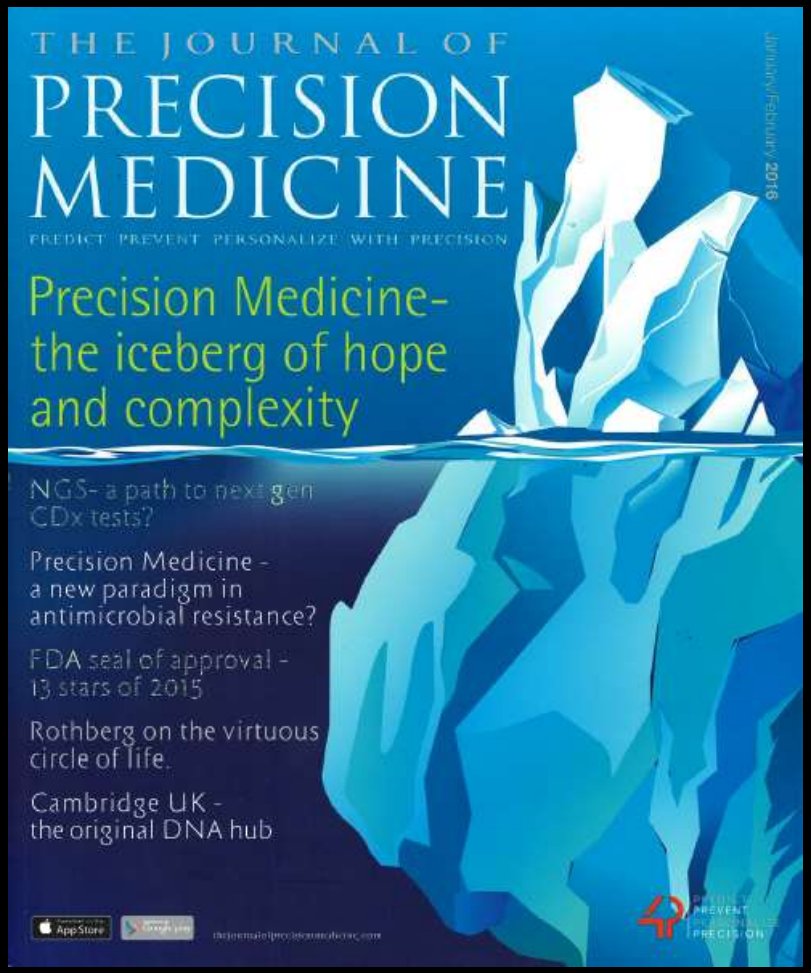
July 22, 2015

The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine

Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH

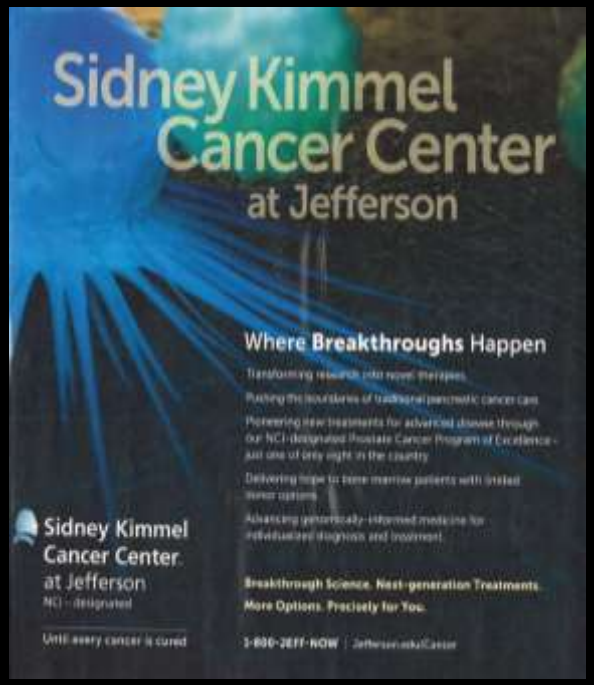
September 17, 2015

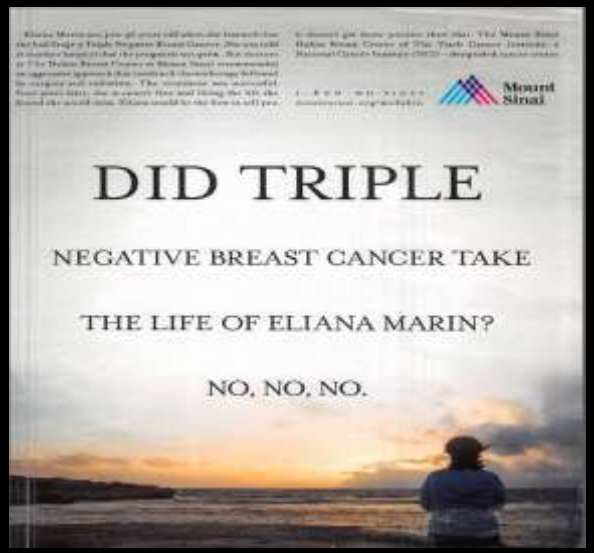
Precision Medicine:
Not If, But…



- what?
- when?
- how?
- who?
- value?

The Ethics of Hype and Hope





Precision Medicine

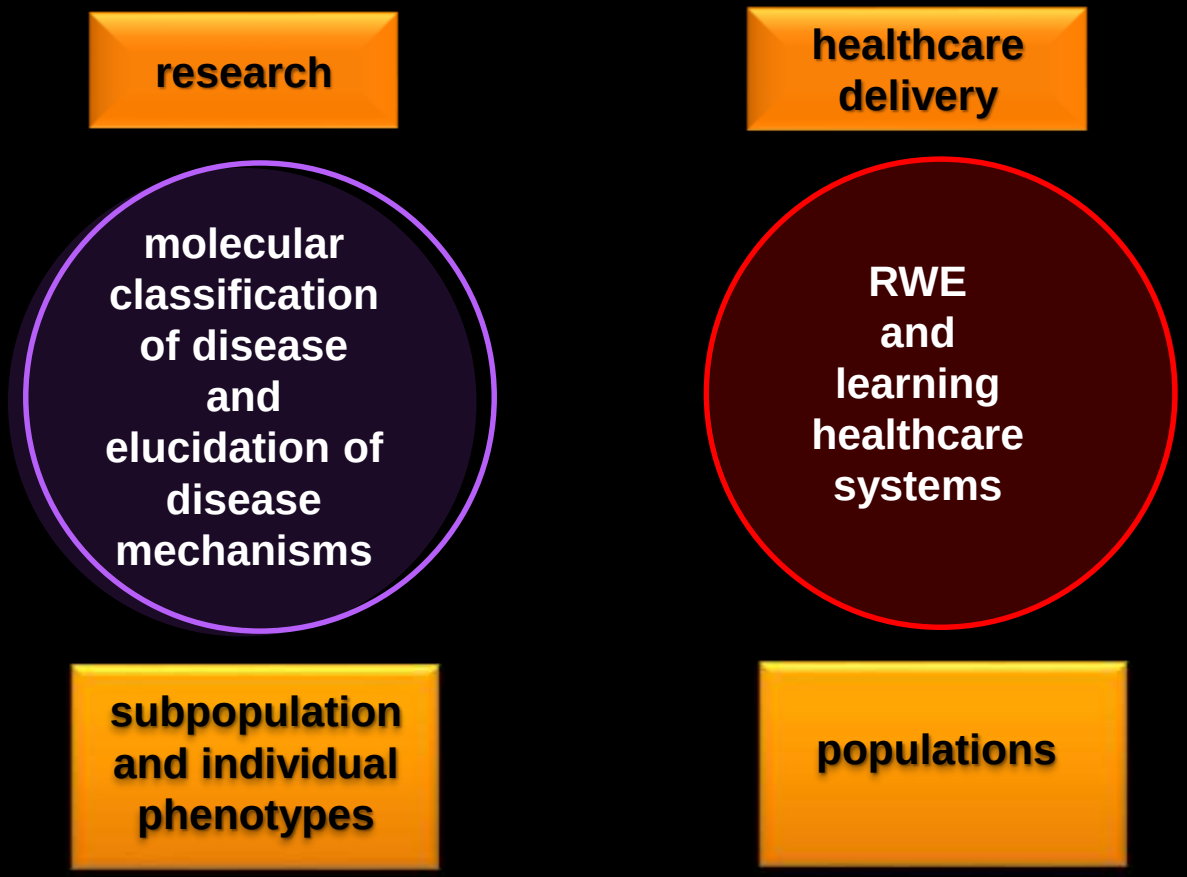
research

molecular classification of disease and elucidation of disease mechanisms

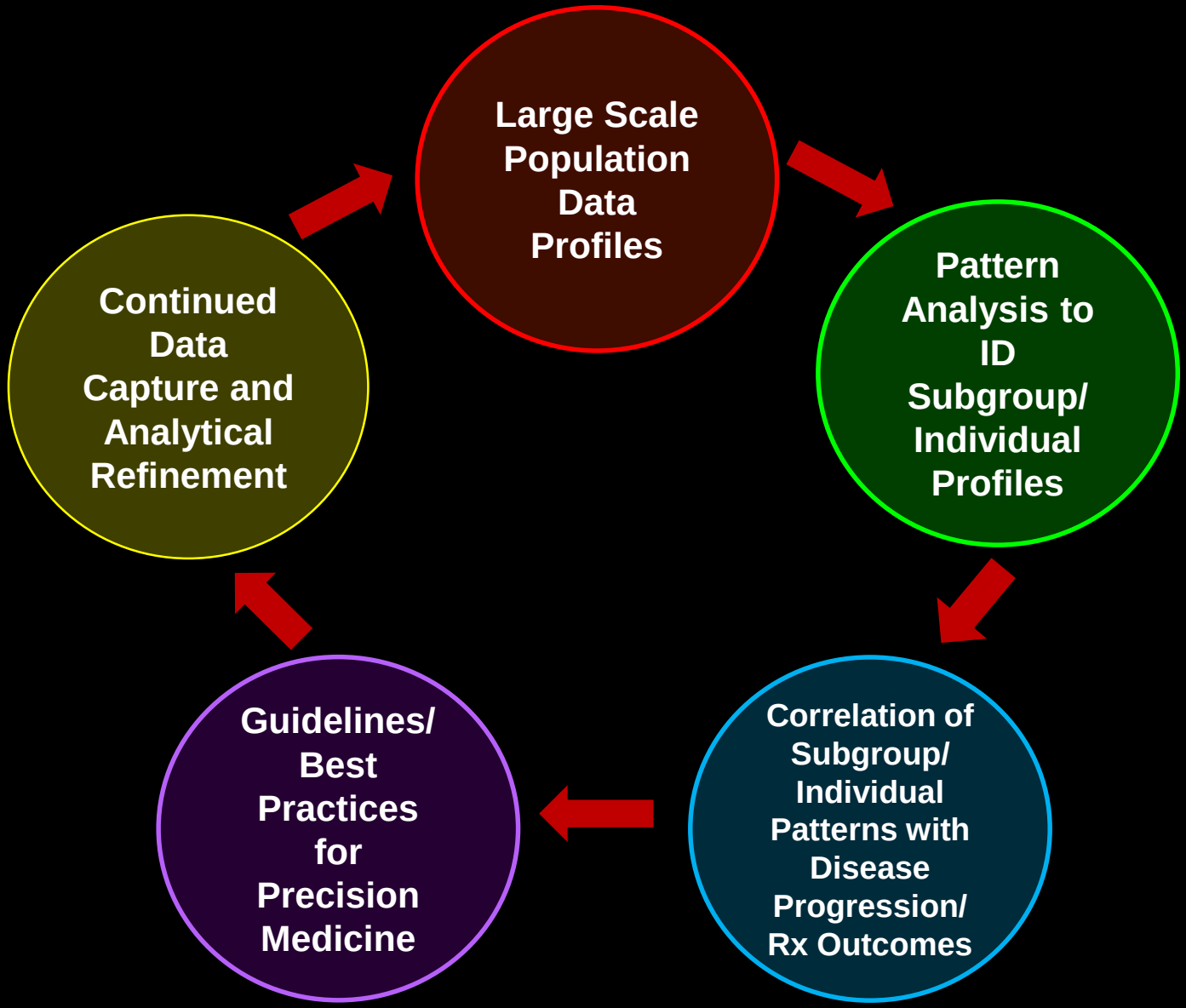
healthcare delivery

RWE and learning healthcare systems

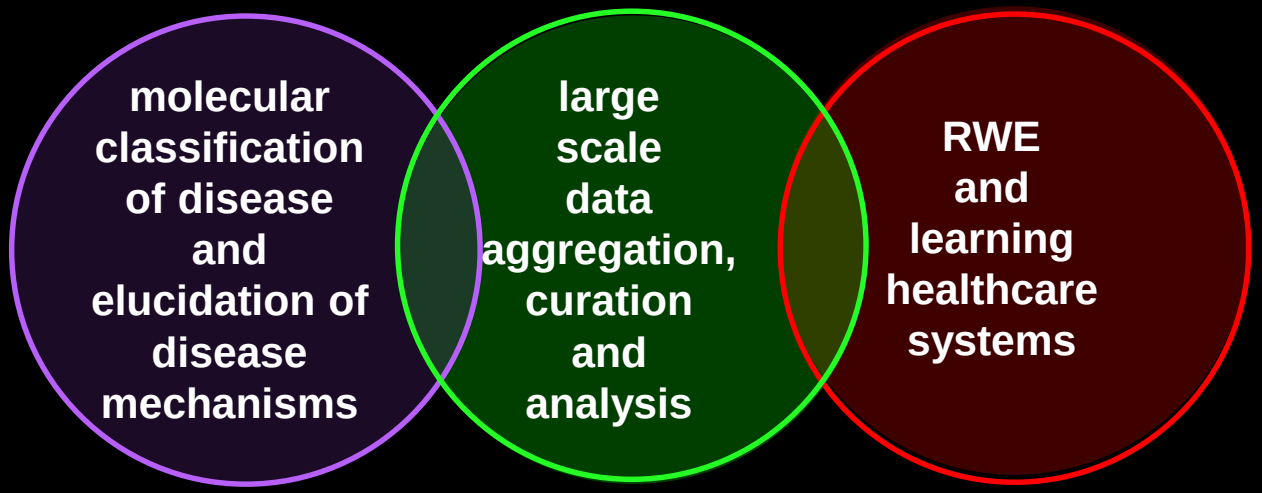
Precision Medicine



The Virtuous Circle of Data on Population Health and Individuals in Driving Precision Medicine

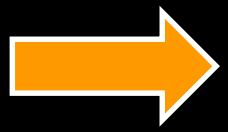


Precision Medicine and Data-Intensive Computational Medicine: Evolving Inter-Dependencies



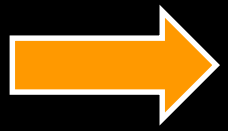
Precision Medicine, Digital Health and A Learning Healthcare System

qualitative, descriptive information of uncertain quality and provenance



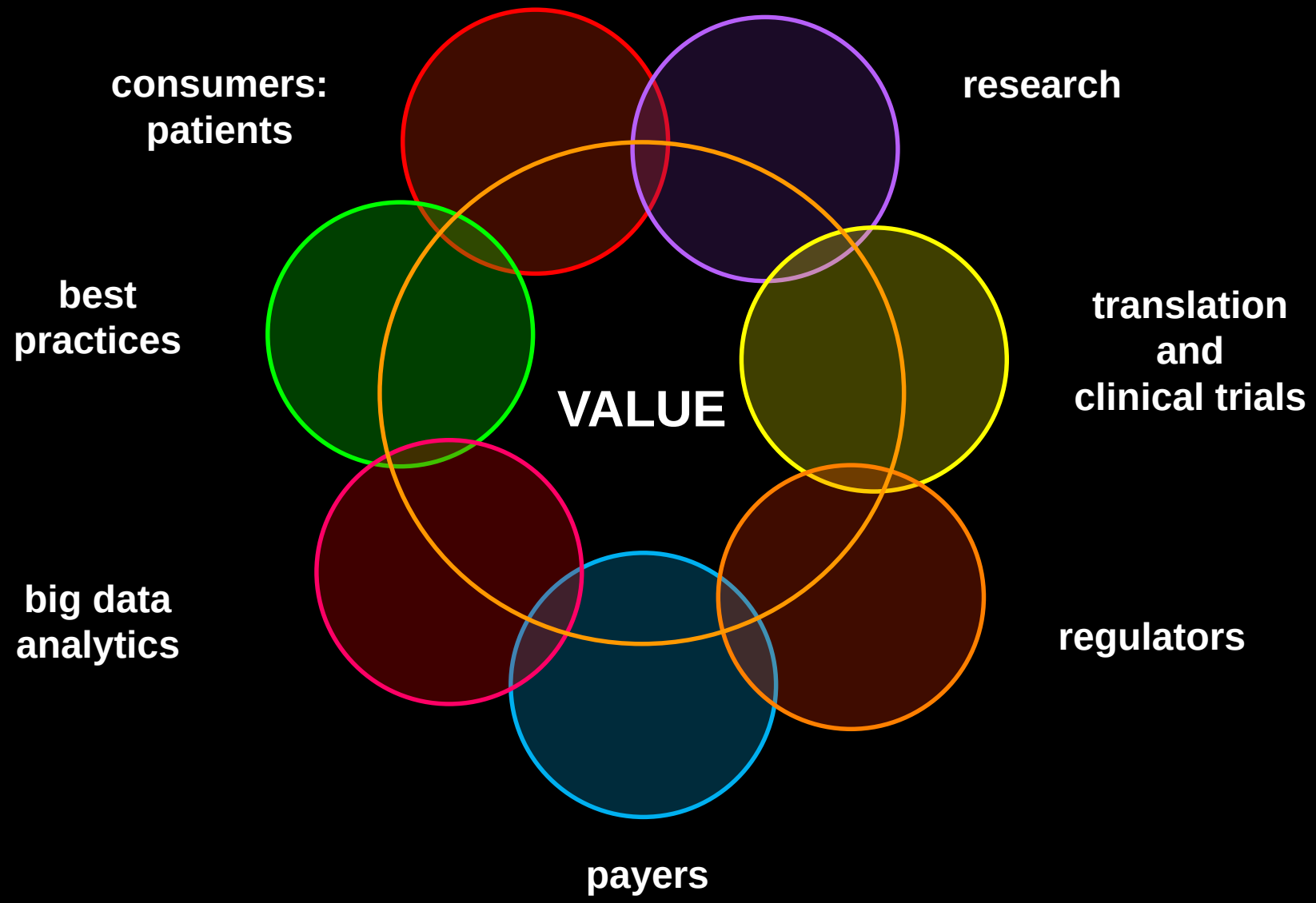
quantitative data of known provenance and validated quality

complex ecosystem of largely unconnected data sources

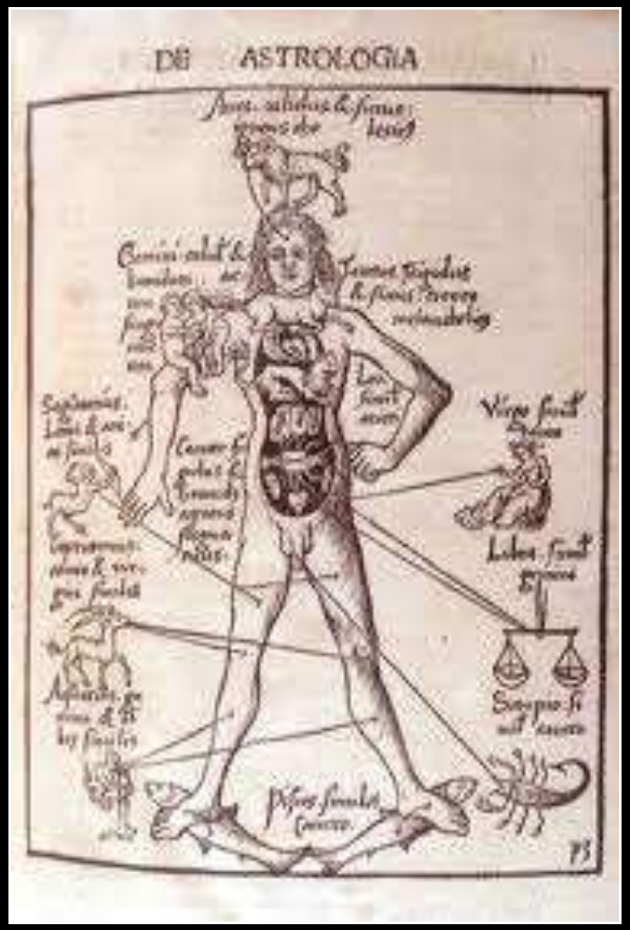


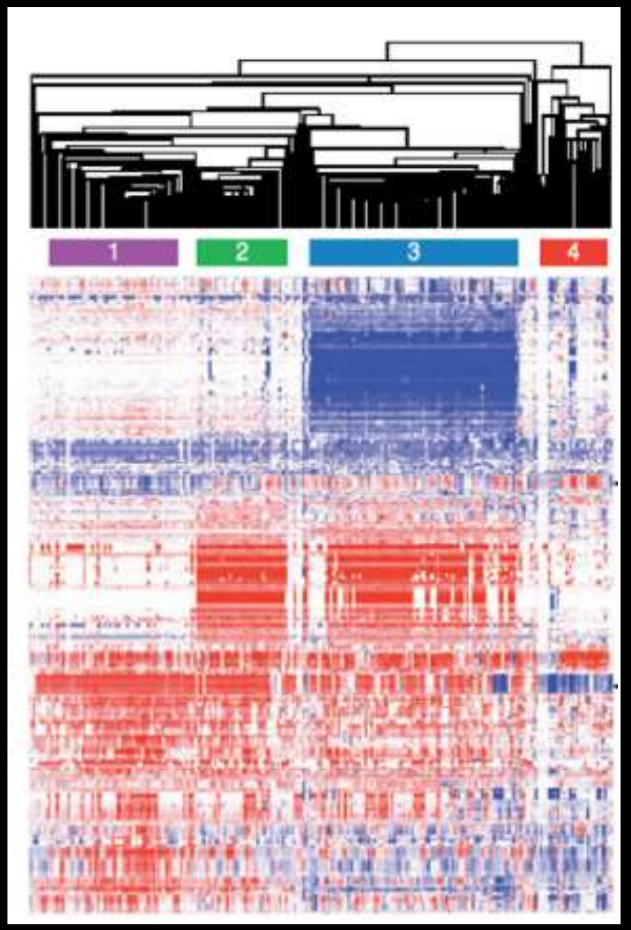
evolving, inter-connected networks of data sources for robust decisions and improved care

Healthcare as a Complex Information Ecosystem



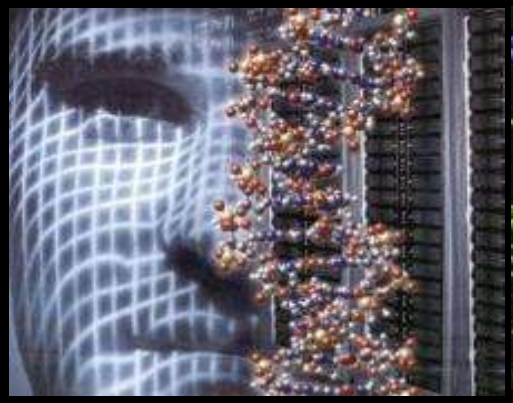
Medical Progress:
From Superstitions to Symptoms to Signatures

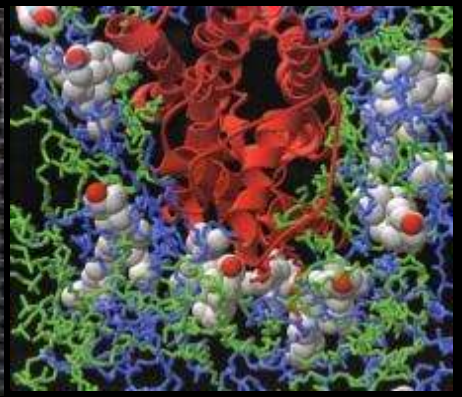


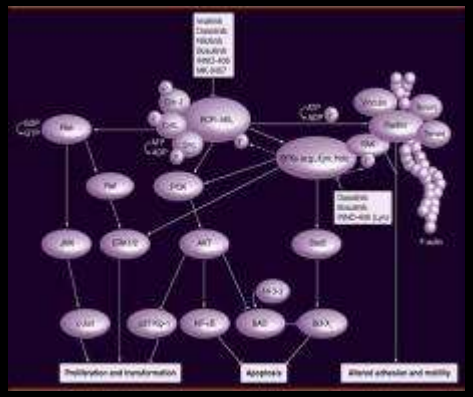


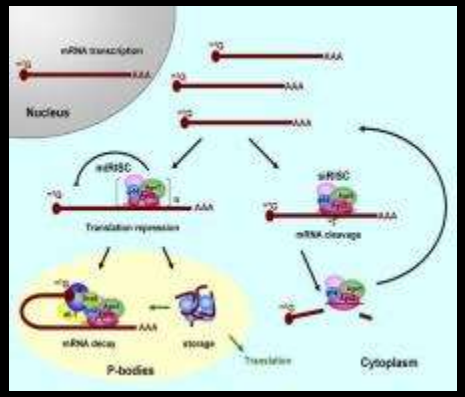
Precision Medicine: PanOmics Profiling and Mapping the Disruption of Molecular Signaling Networks in Disease

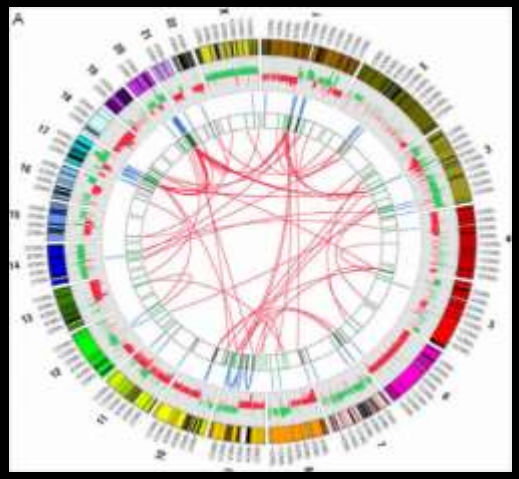
(Epi)Genomics	Proteomics	Molecular Pathways and Networks	Network Regulatory Mechanisms







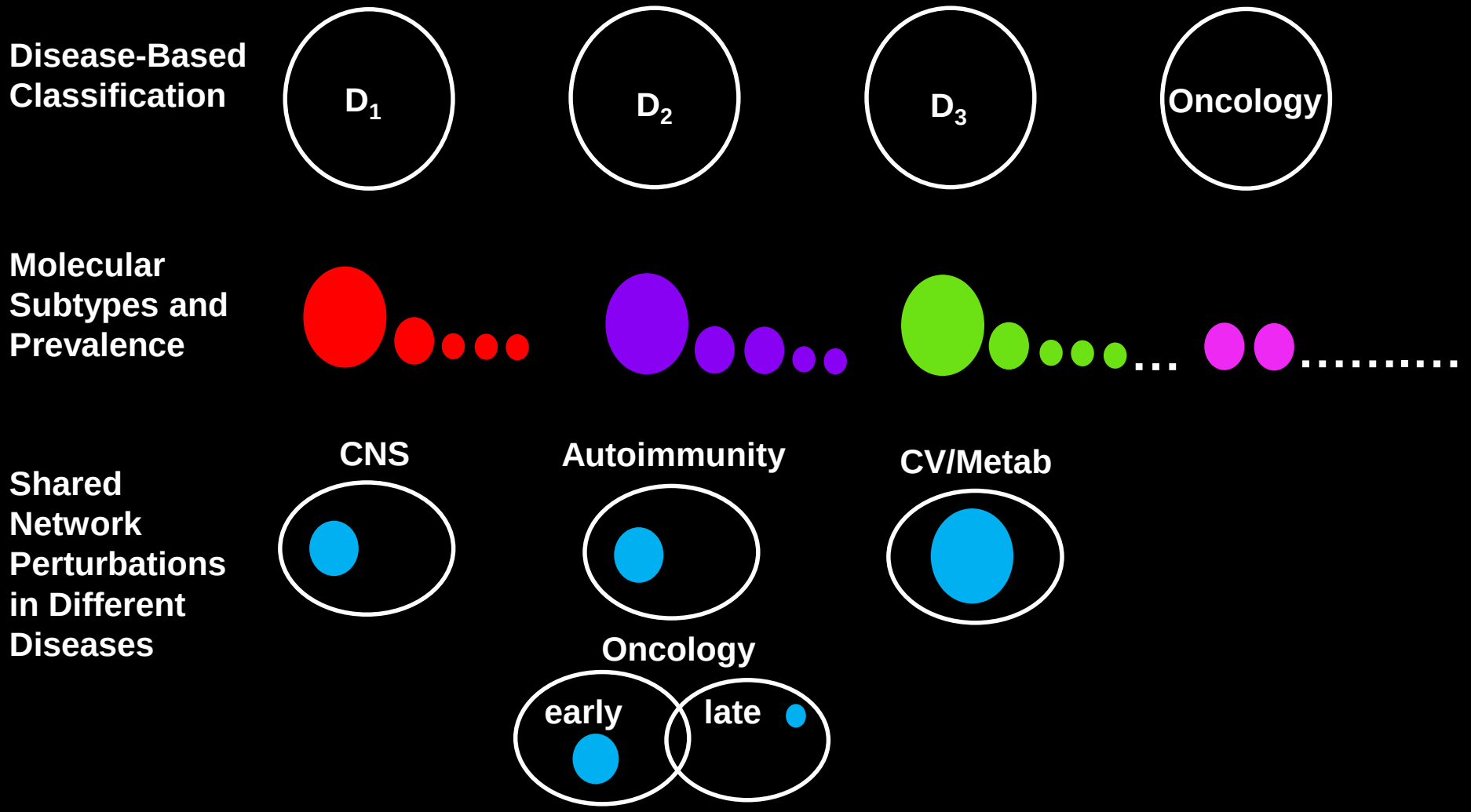




ID of Causal Relationships Between Network Perturbations and Disease

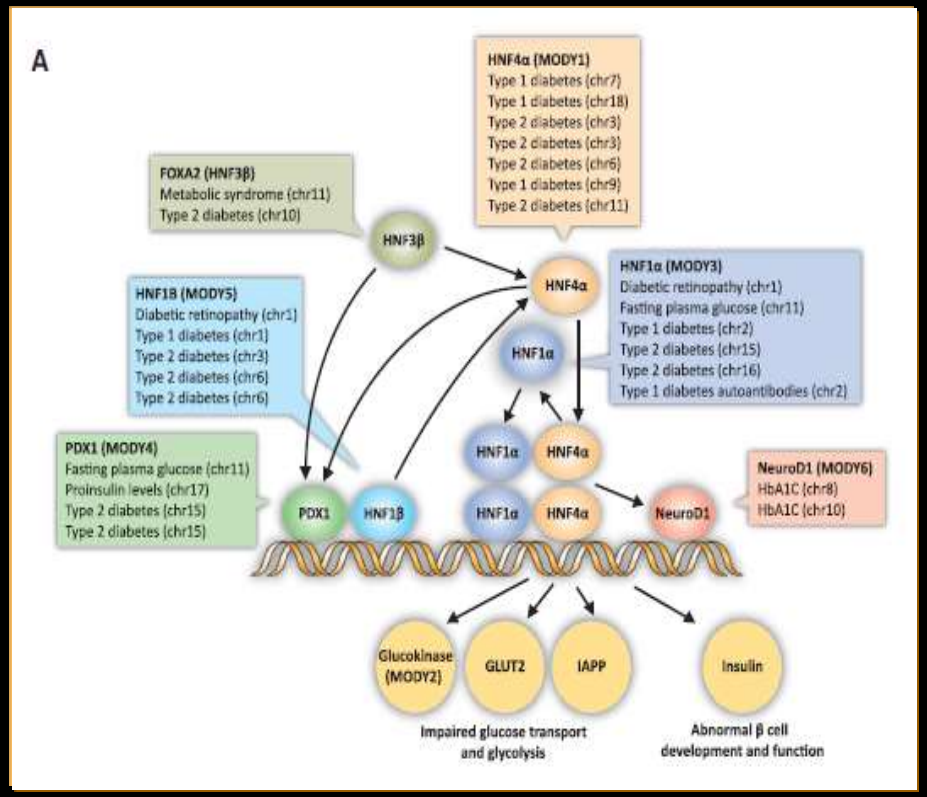
Patient-Specific Signals and Signatures of Disease or Predisposition to Disease

Precision Medicine: Molecular Subtypes, Endophenotypes and the Dynamic Range of Clinical Phenotypes

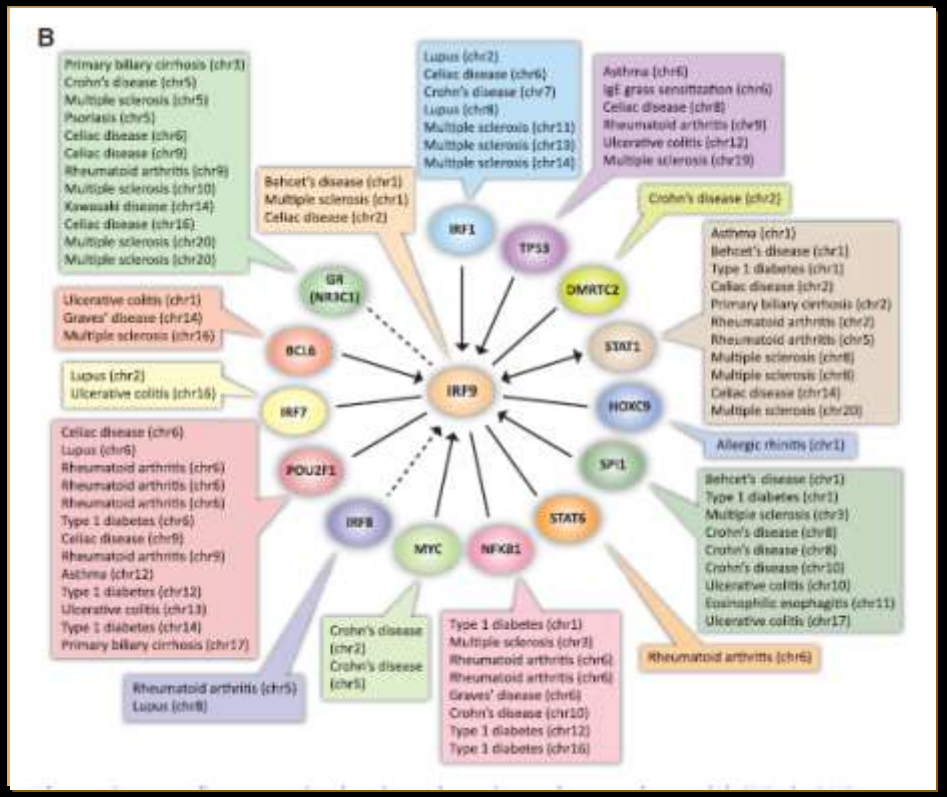


Genome Variants in Related Disease Categories Cluster in Shared Gene Regulatory Networks

Diabetes



Autoimmune Disorders



M. T. Maurano et al. (2012) Science 337, 1190

dbSNP

- over 150 million variants (2016)
- over 6 million coding variants
  - one variant every 5 or 6 base pairs
  - single variant may affect multiple transcripts/genes
- over 80 million variants lie outside coding exons
- over representation of NW European, East African and East Asian population groups
- challenge of variant filtering and robust taxonomy of variants of pathogenic significance

Genome Sequencing and Big Data
(Z.D., Stephens et al. (2015) PLOS Biology)

- **3.6 petabases of raw sequence data**
  - **c.250,000 individual human genomes**
  - **c.32,000 microbial genomes**
  - **c.5,000 plant and animal genomes**
- **Omics maps catalog of worldwide sequencers**
  - **2500 instruments, 1000 centers in 55 countries**
  - **capacity of c.35 petabases/year**
- **Illumina X-Ten systems**
  - **c.2 petabases/year per machine**
- **current doubling time c.7 months**

- 1 exabase of sequence/year in 5 yrs
- 1 zettabase of sequence/year by 2025

plus

- projected 100 million to 2 billion human genomes sequenced by 2025
- multiple sequencing: genome, transcriptome, microbiome

New Alliance for Large Scale Acquisition and Analysis of Cancer Genomics Data (8 Jan. 2017)

IBM Watson Health

- machine and artificial intelligence algorithms

illumina®

- BaseSpace™ Sequence Hubs
- TruSight Tumor 170 Panel
- GRAIL ™

PHILIPS

- IntelliSpace clinical informatics platform

Ignoring Biological Complexity

Genes For ….
The Overly Simplistic and Deterministic Dangers of a Genome-Sequence Centric Perspective

The Over-Simplified Perspective That
While Exome-and Whole Genome-Sequencing
Will Reveal the Full Etiology of Disease Pathogenesis

The Reductionist, Simplistic Obsession With Genome Sequencing

Precision Medicine: The Complexity of Genotype-Phenotype Relationships

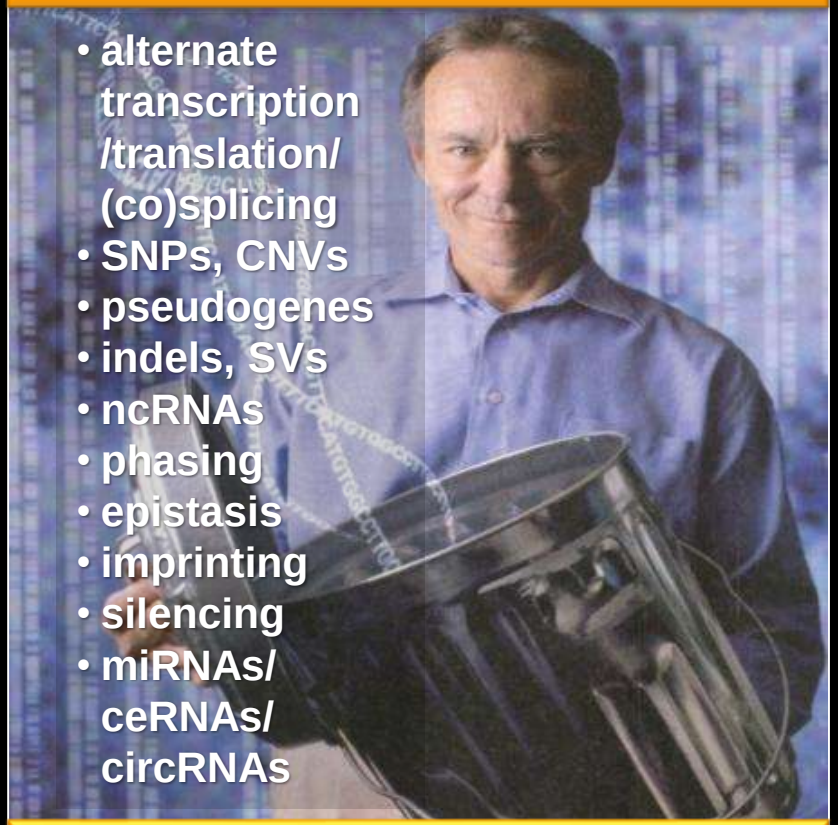
Genome Sequencing Alone Will Not Suffice:
The Need for Deep Phenotyping

Understanding the Complex Interplay Between PanOmics, Environment and Behavior

Phenome-Association Data (PheWAS):
Integration of panOmics Profiling with Clinical Disease Progression and Treatment Outcomes

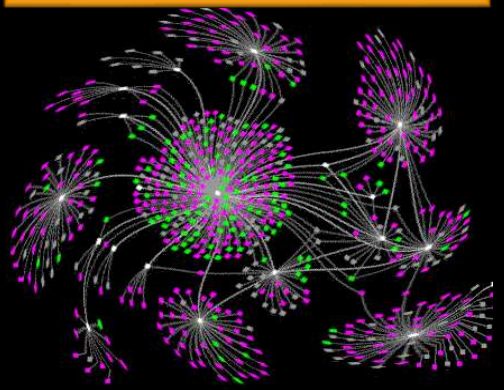
Individual Variation, (Epi)Genome Complexity and the Challenge of Genotype-Phenotype Predictions

Junk No More: Pervasive Transcription

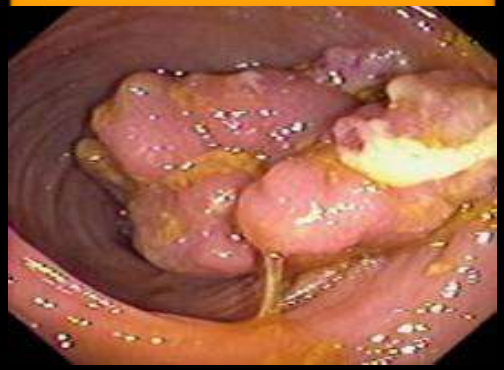


recognition of (epi)genome organizational and regulatory complexity

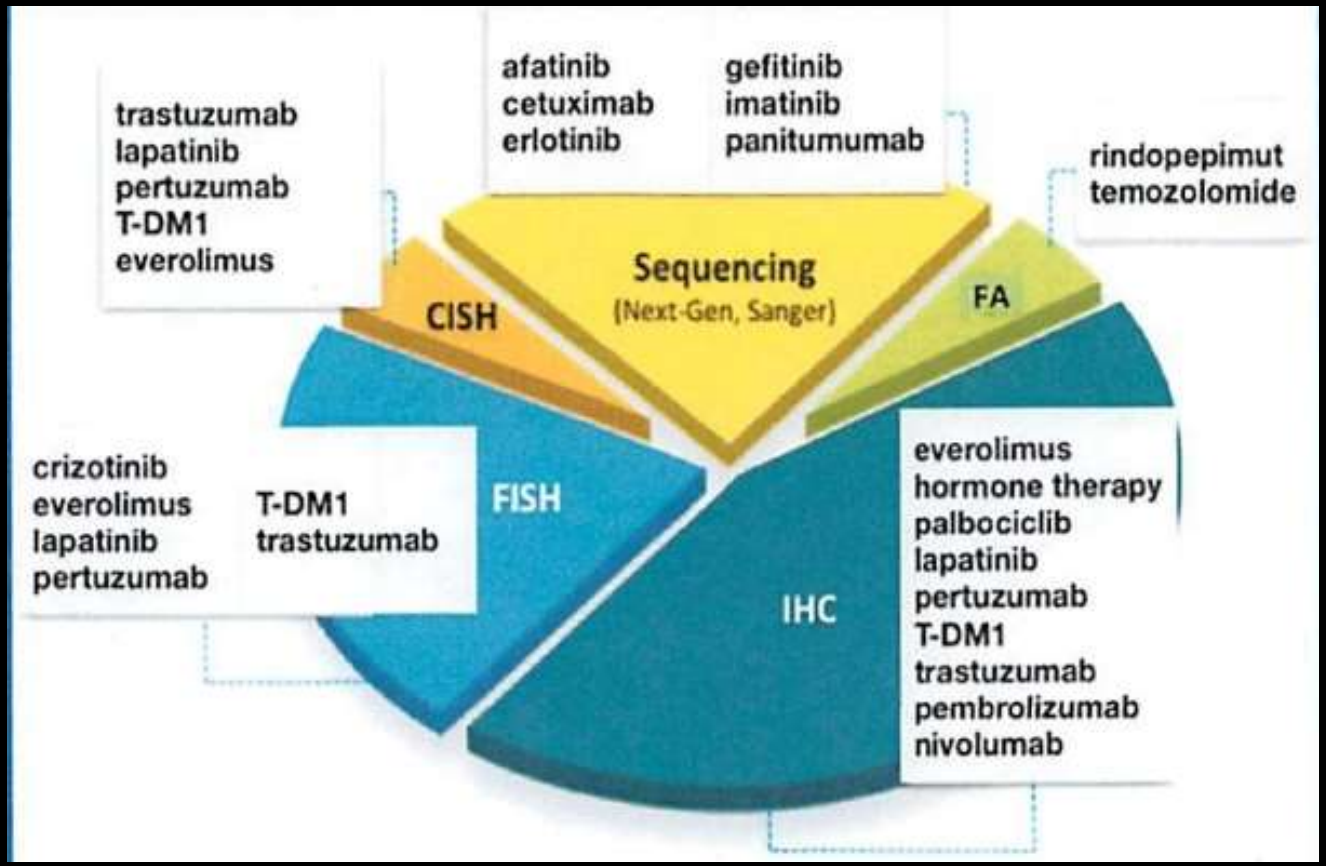
Cell-specific Molecular Interaction Networks



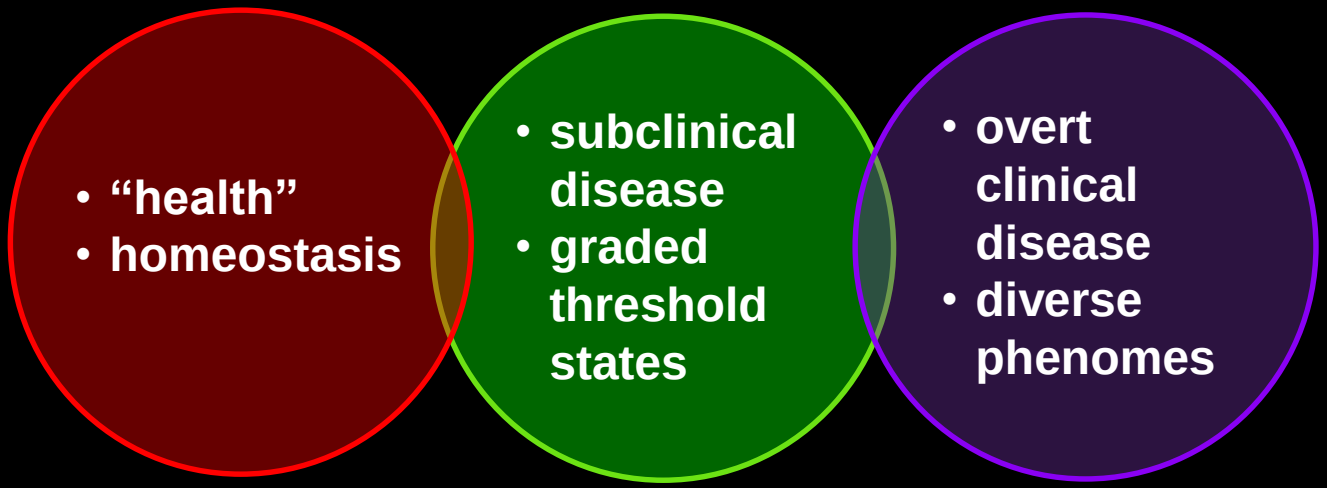
Perturbed Networks and Disease



Adoption of NCCN Guidelines and FDA Companion Diagnostics Requires panOmics Profiling for Comprehensive Oncology Treatment Selection

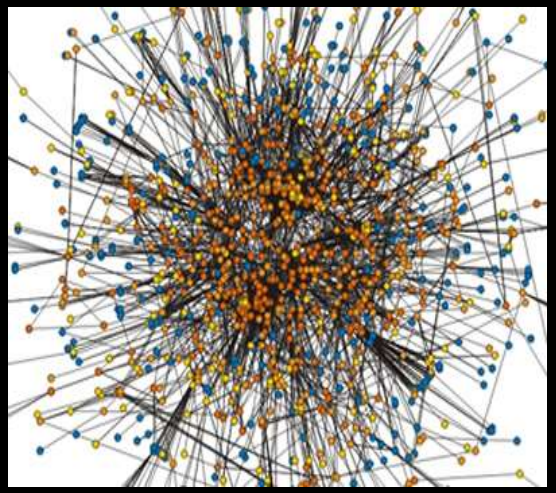


Precision Medicine:
Mapping Biological Signaling (Information) Networks

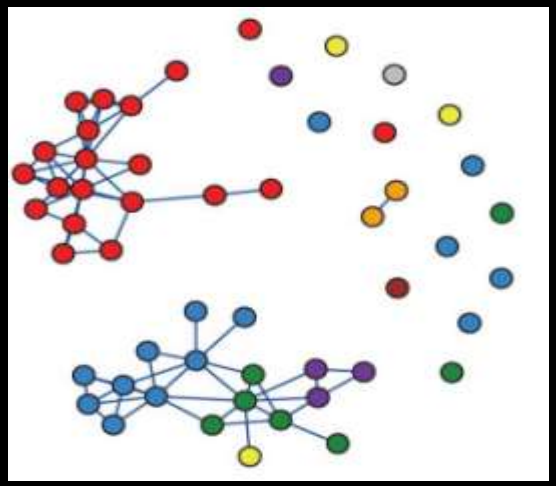


Precision Medicine: Understanding Network Organization and Dynamics in Complex Adaptive Systems

- deconvolution of complex adaptive networks
  - spatial
  - temporal

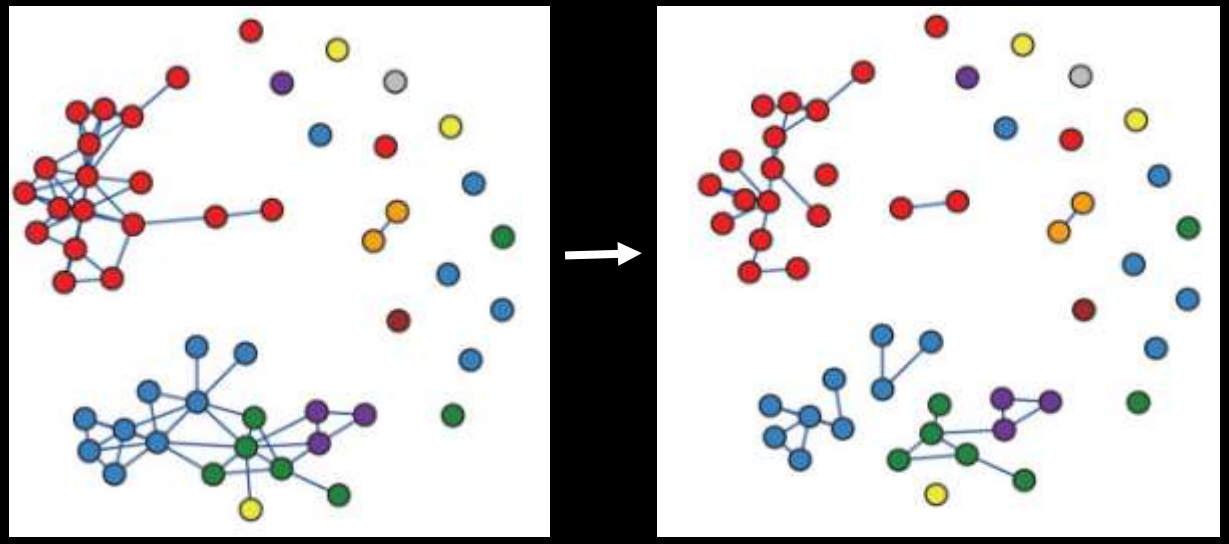


- mapping the topology of molecular signaling(information) in health and disease pathways and networks



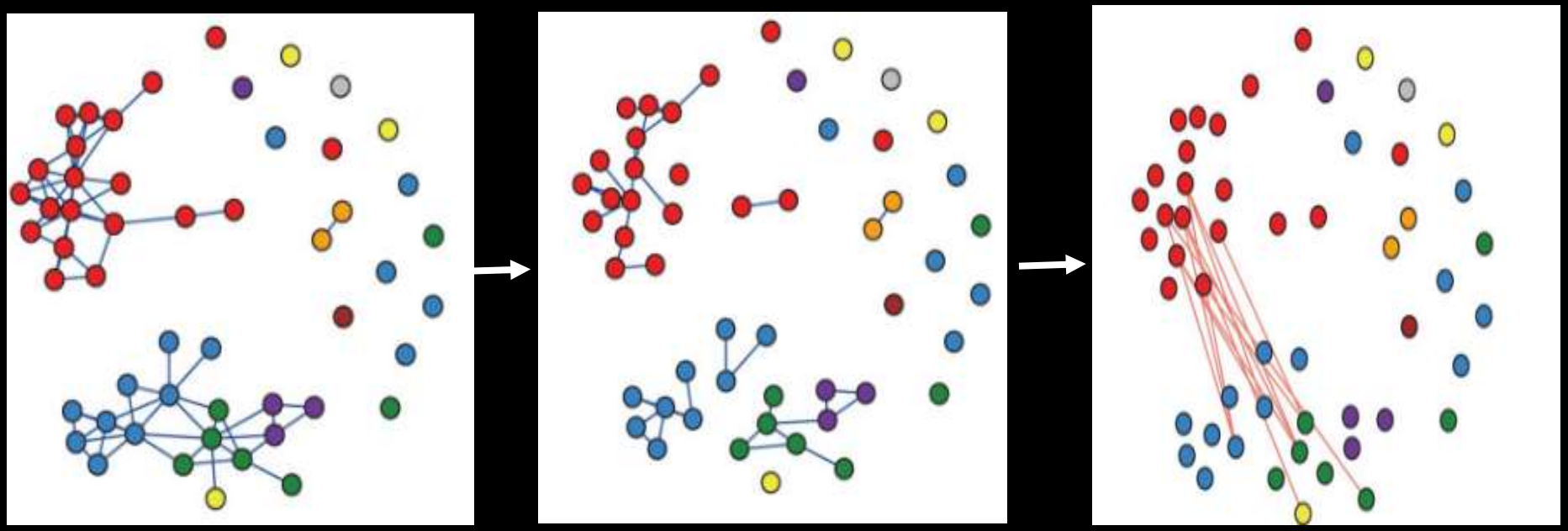
Precision Medicine: Understanding Network Organization and Dynamics in Complex Adaptive Systems

increased predictive accuracy of pending state shifts (emergence) and probabilistic most likely trajectories



X X´

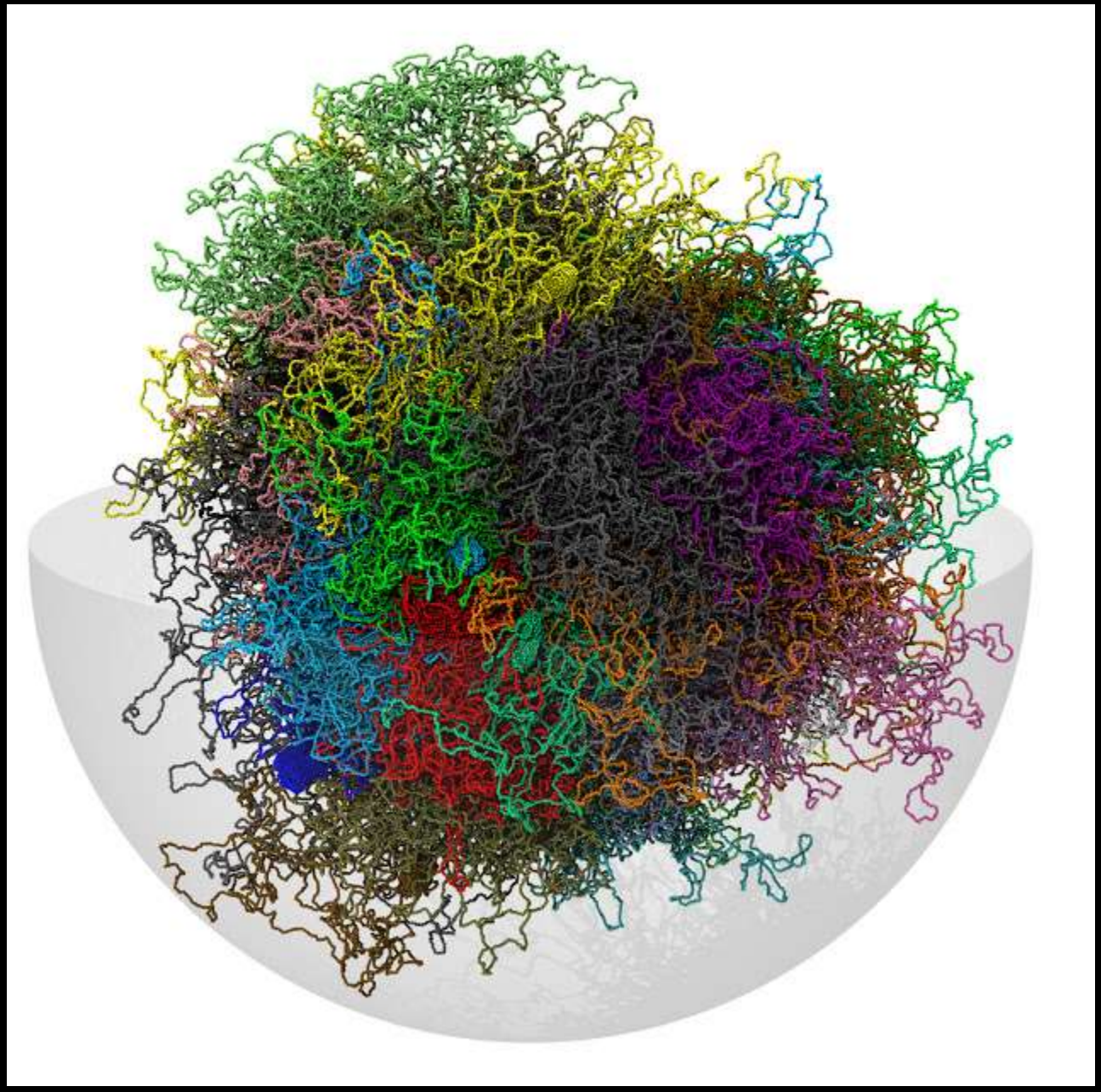
Precision Medicine: Understanding Network Organization and Dynamics in Complex Adaptive Systems



X X´ X´(d) Vs. X´(nd1) X´(nd2) X´(nd…n)

new analytical tools for proactive monitoring of systems state space(s) and timely intervention(s) to channel emergent behavior to most desired trajectories

Neighbor Maps: 3-D and 4D Genomes



Source: International School of Advanced Studies (SISSA) [October 26, 2016]

Mapping Genotype-Phenotype Relationships and Disease Risk:

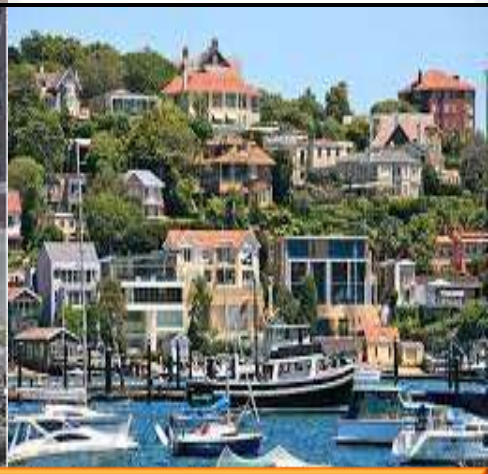
Systematic Integration of Diverse Data for Population Health Analytics

Continuity of Care Record: From Womb to Tomb



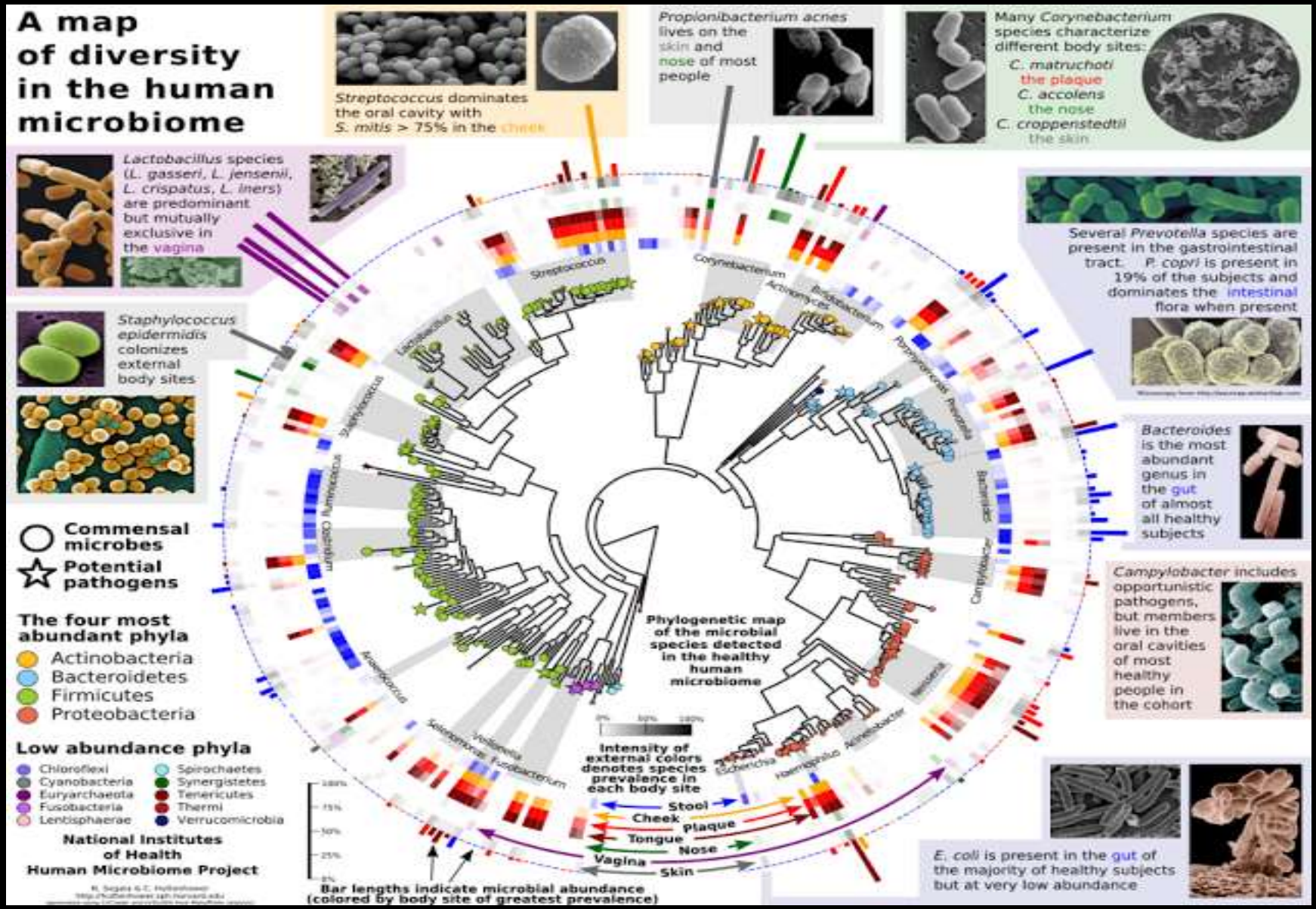




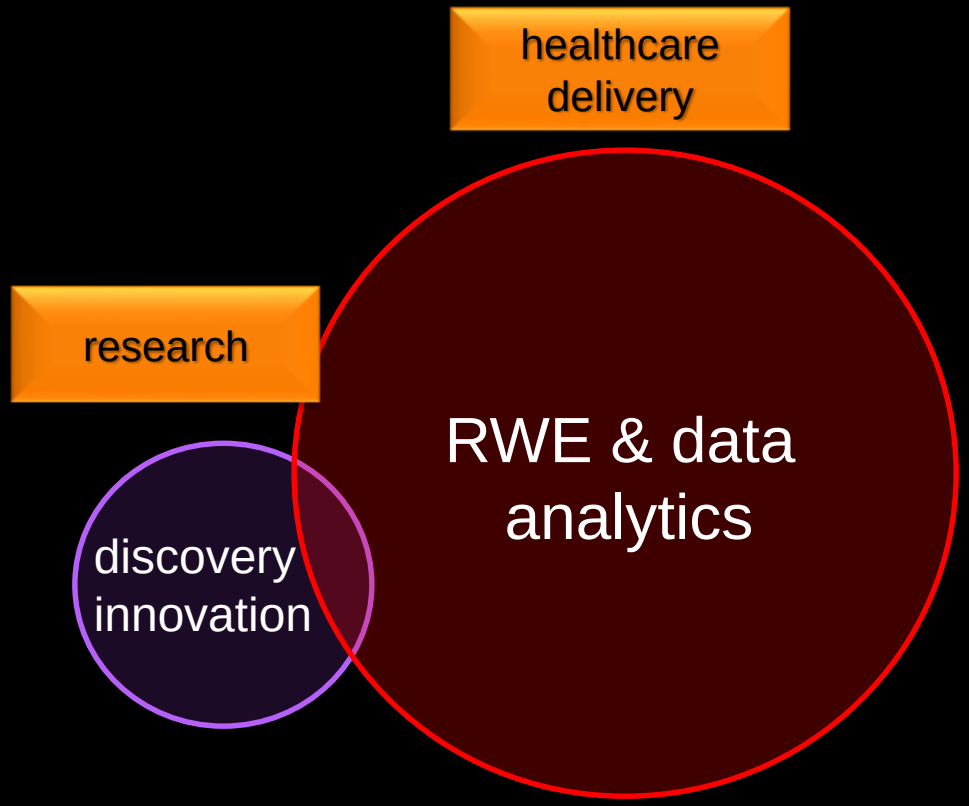
Behavior

Environment



- nutrition
- autoimmunity
- obesity
- neuroimmunology
- Rx response

The Trajectory for Precision Medicine: Era One



- **improved outcomes, quality and resource allocations**
- **lower cost**

A Larger Return from Analysis of Real World Data Than panOmics-Driven Innovations?

Invasion of the Body Trackers: Changing The Touch Points in Healthcare Delivery

Healthcare Beyond The Clinic

Remote Health Status Monitoring

Smartphones, Wearables, Devices and Digital Services

M4: Making Medicine More Mobile

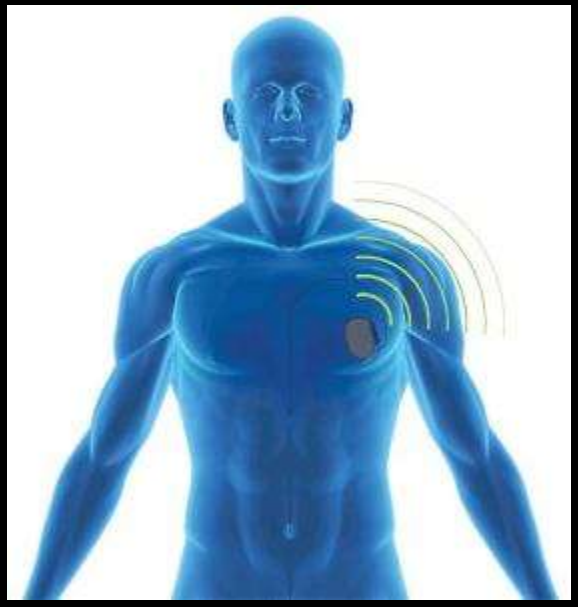
Social Spaces Become Quantifiable

- who knows why people do what they do?
  - the fact is that they do!
- these actions can now be traced and measured with unprecedented precision
- with sufficient data, the numbers reveal increasingly predictable behavior and individual risk patterns
- new ethical and legal issues
  - consent, privacy, surveillance, security

Applications of Sensors, Mobile Devices and Wearables in Improved Treatment Adherence and Risk Reduction

- engage and educate patients in personal health management
- remote tracking of health status
  - on-body: in-body, ambient environment
- improve adherence to prescribed treatment plans
- real time, longitudinal incentives for compliance and behavioral changes
- data capture
  - feedback, intervention alerts
  - aggregated, de-identified metadata for observational research

m.Health



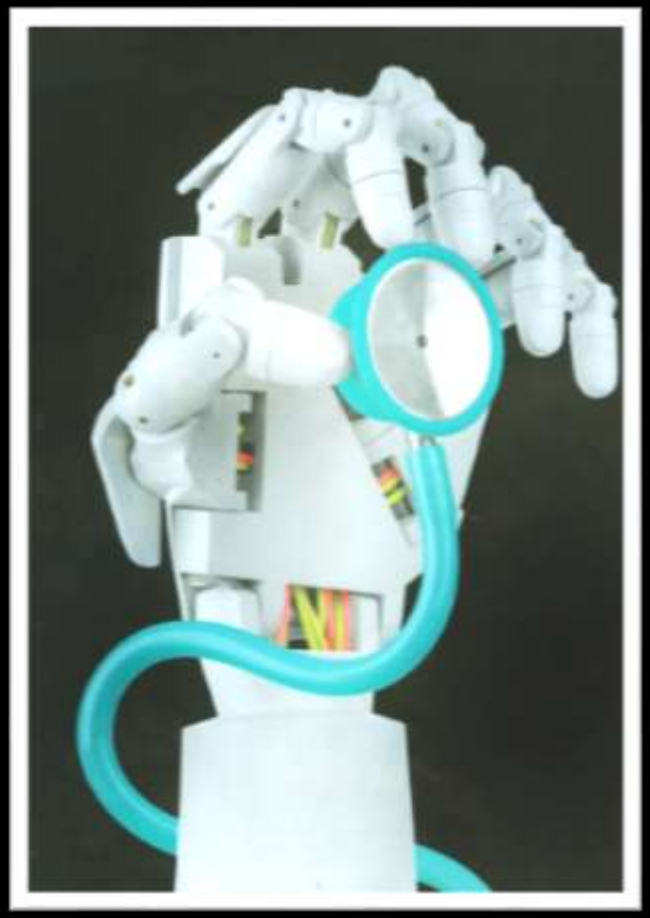
Real Time Remote Health Monitoring and Chronic Disease Management

Lifestyle and Fitness

Information for Proactive Health Awareness (Wellness)

“Medical Selfies”: The Proliferation of Mobile Devices in Healthcare

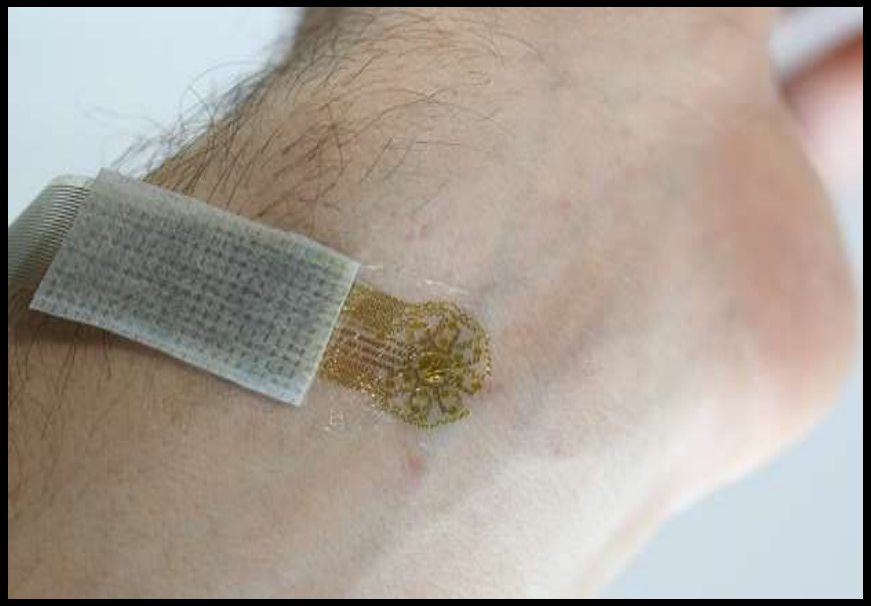
Robotics: Telemedicine and Home Healthcare

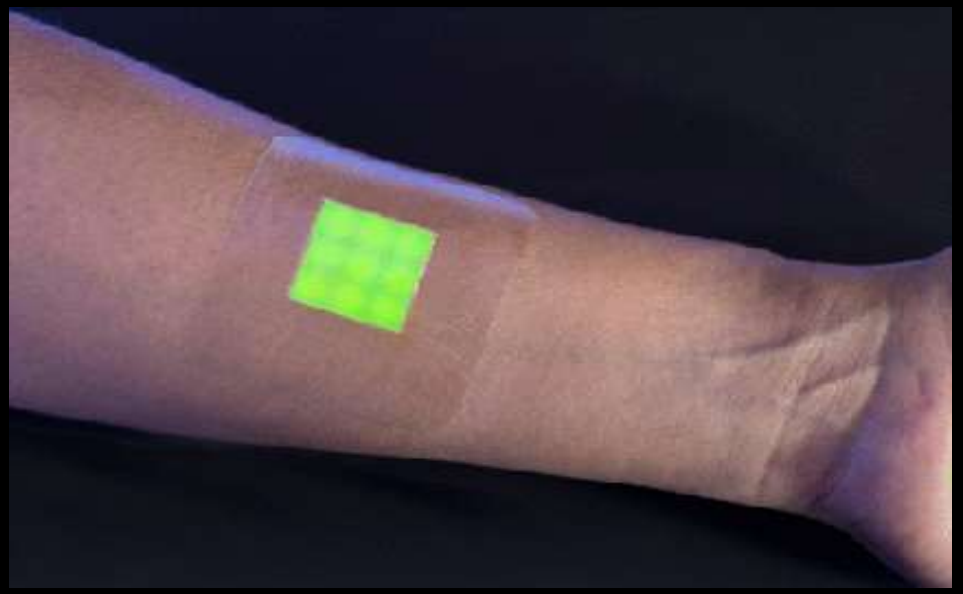


Virtual Healthcare

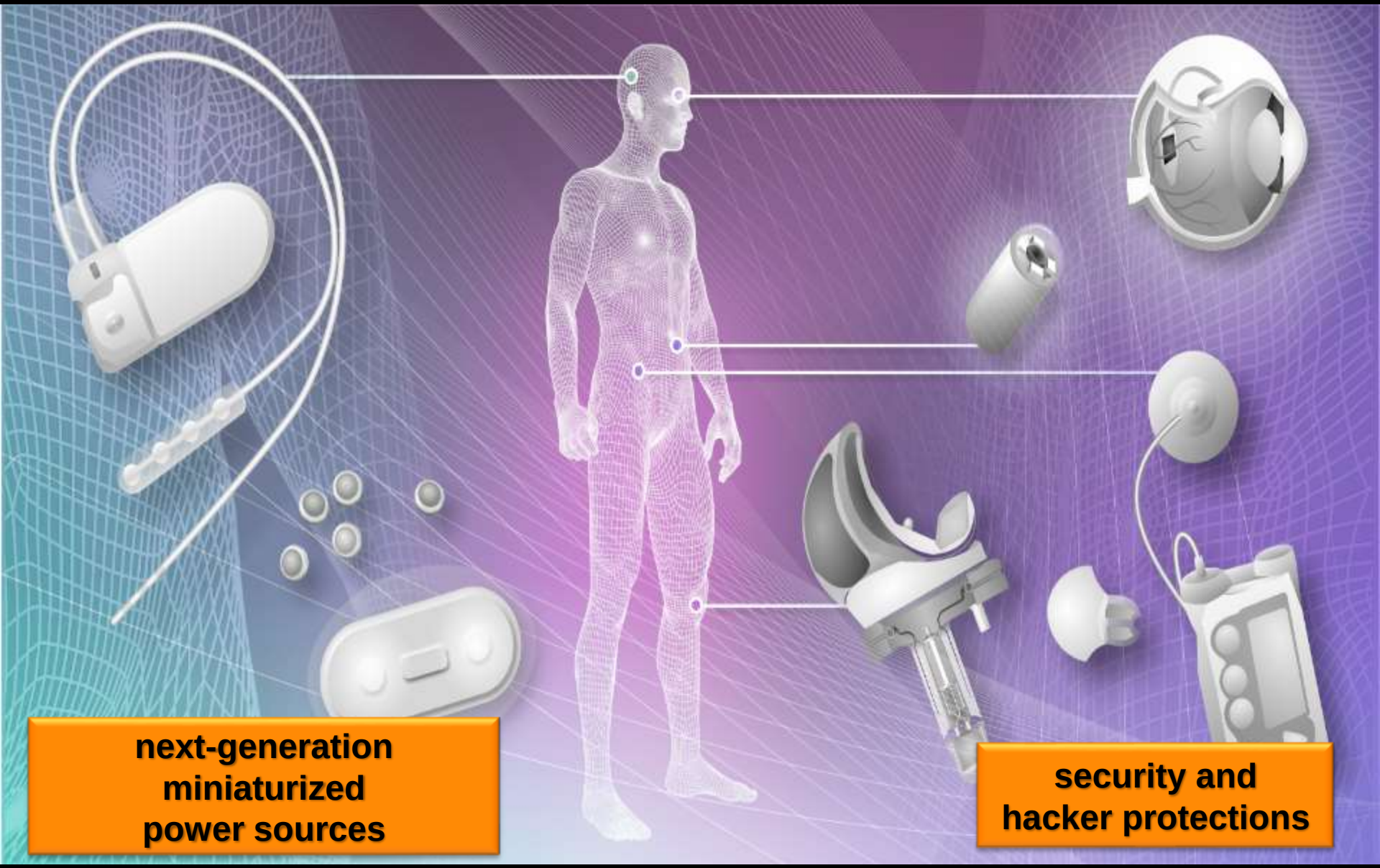
- subscription based service
- virtual consultants: video, voice, chat via smartphone, tablet, computer
- 100,000 US-licensed MDs
- 3,000 cities in all 50 states
- 100 cities world wide

Smart Materials for Improved Therapeutic Adherence

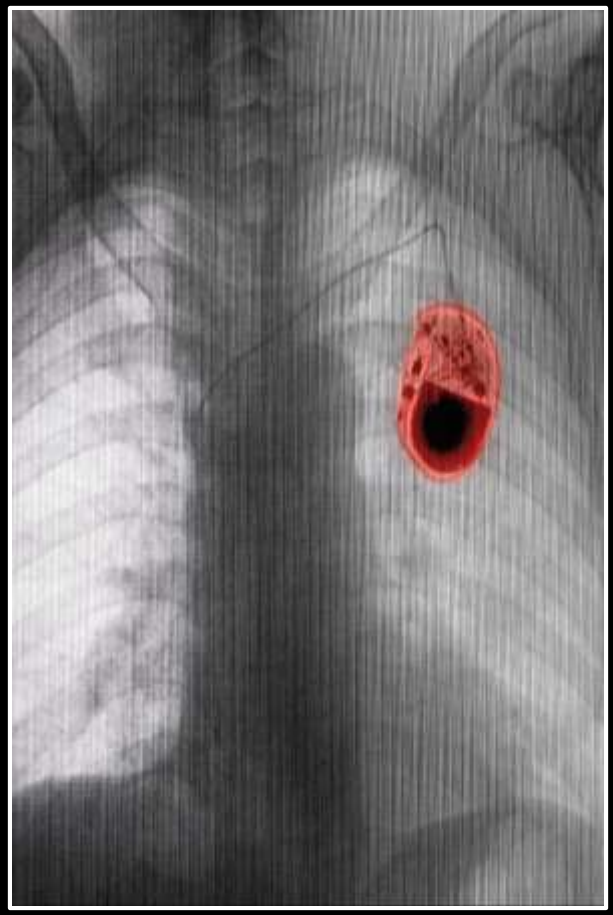




Implantable Devices and Wireless Monitoring (and Modulation)



Software Security in Medical Devices



Gray Technologies and Aging in Place: Independent But Monitored Living for Aging Populations

Rx adherence

cognitive stimulation

in home support and reduced readmissions

reduced office visits

Digital Personal Assistants

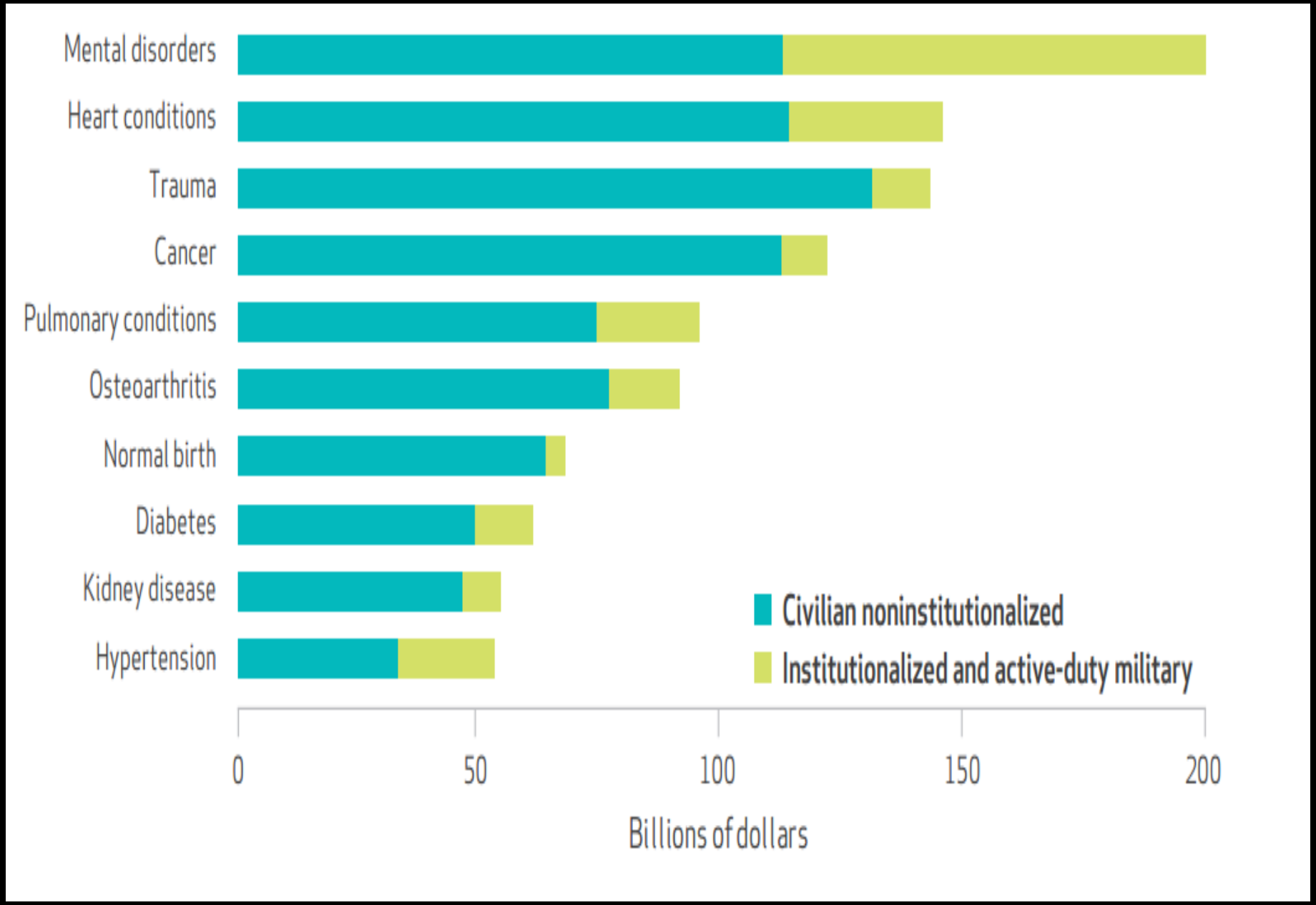
An Apps-Based Information Economy in Healthcare

- theoretical rationale but integration of data with EHR platforms poses numerous challenges
  - lack of developer access to high quality healthcare data to validate App platforms
  - cross-platform standardization and application programming interfaces (APIs)
  - regulation: accuracy, reliability, security and privacy regulation compliance
- FDA focus on Apps that transform phone/tablet into a regulated medical device
- renewed FTC interest on Apps making unsubstantiated claims

Mobile Apps, Wearables, Sensors and Continuous Health Status Monitoring

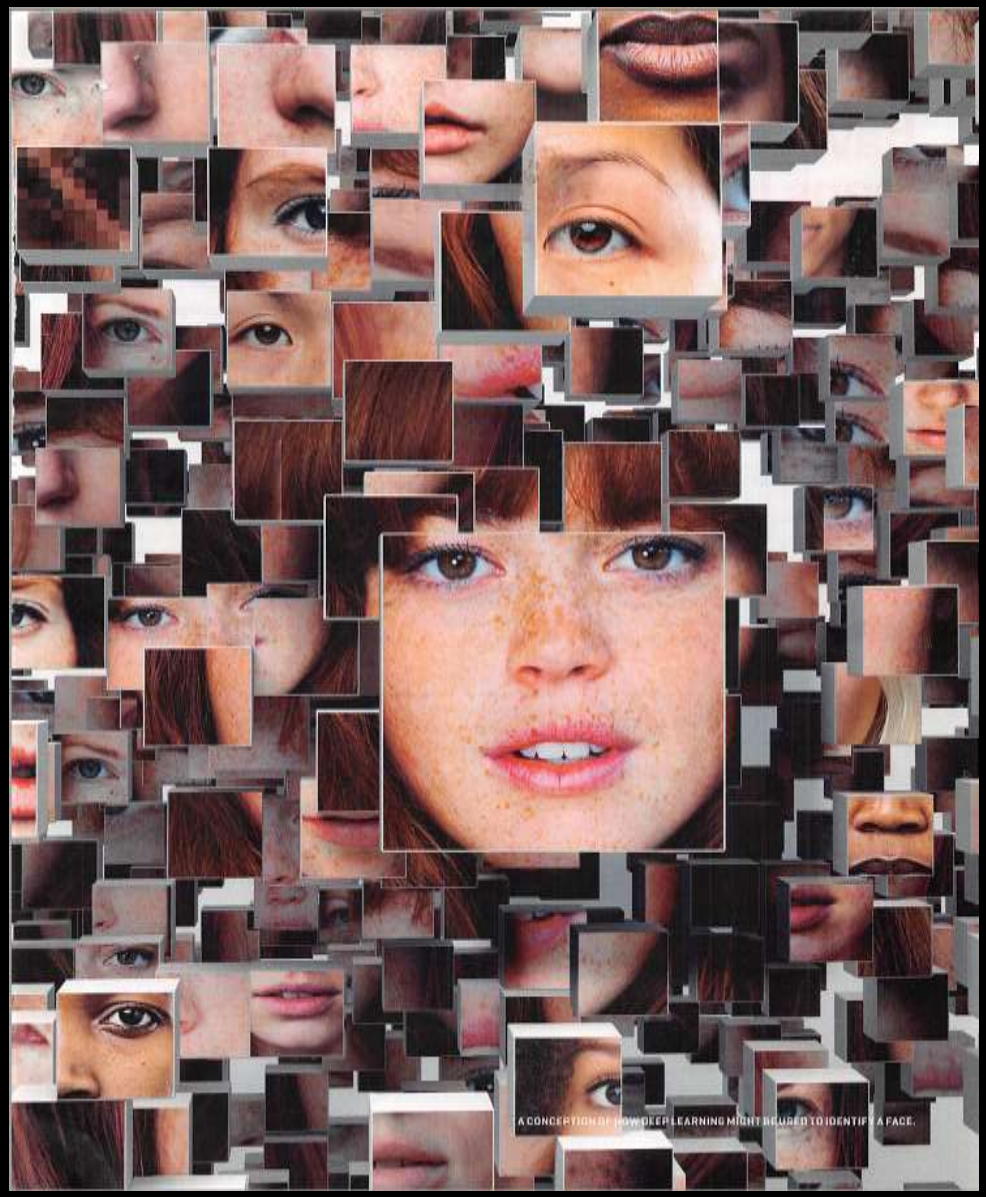
- who sets the standards?
- who integrates and interprets the data?
- who pays?
- who consents?
- who owns the data?

Informational Technology and Behavioral Health



From: C. Roehrig (2016) Health Affairs 35, 1130

Machine Intelligence and Facial Recognition Technologies



Computational Analysis of Facial Expressions, Voice, Social Interaction Patterns in Diagnostic Profiling of Psychiatric Disorders

- high variation in assessment of same patients by different psychiatrists
- major need for objective measurements of nuanced behavior
  - gaze
  - speech prosody (rhythm, tone, volume)
  - stimulus response reactions and interaction speed
- AI and learning from large video banks
  - bipolar disorder, schizophrenia, depression
  - suicidal ideation
  - PTSD
- signal alerts to care teams when interventions indicated


"Do you solemely swear to have no involvement in your own care?"

Patients Are No Longer Patient for Solutions

Patient Communities and Disease Advocacy Groups

Increased Patient Engagement in Care Decisions and Disease Management

Empowered Patients: Social Networking Sites (SNS) and Their Role in Clinical Care

- logical extension of rapid rise of web/apps in mainstream culture to healthcare
- increasingly proactive and engaged consumers/patients/families
- more transparent information on treatment options, cost and provider performance
- new clinical practice tools to optimize physician: patient relationships
- improved recruitment of patients into investigational and pragmatic clinical trials
- Ux

Now Comes the Hard Part!

Driving Precision Medicine and Large Scale Data Analytics into Routine Clinical Practice

Integration of Rapidly Expanding and Increasingly Diverse Datasets for Longitudinal Observational Studies and Continuity in Care Delivery

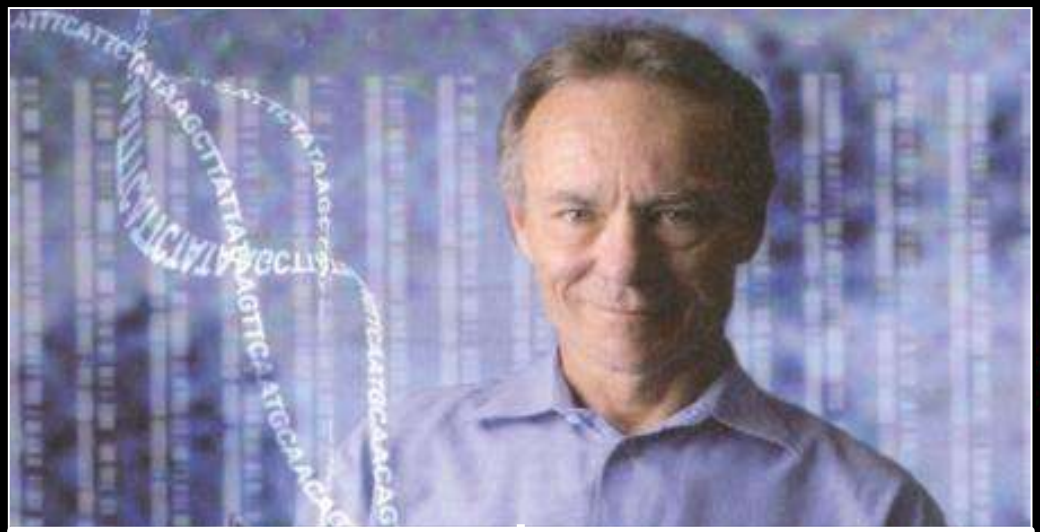
New Incentives and New Delivery Models

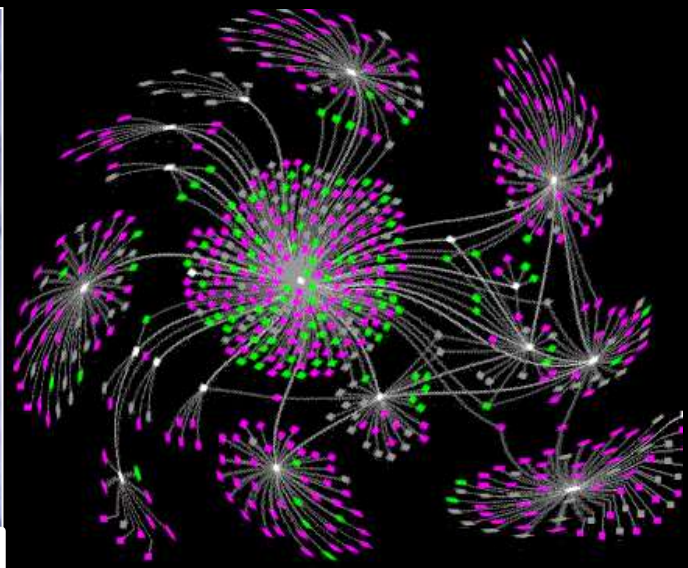
New Participants and New Business Models

“If only Hewlett Packard (HP)
knew what HP knows,
we’d be three times more productive (profitable).”

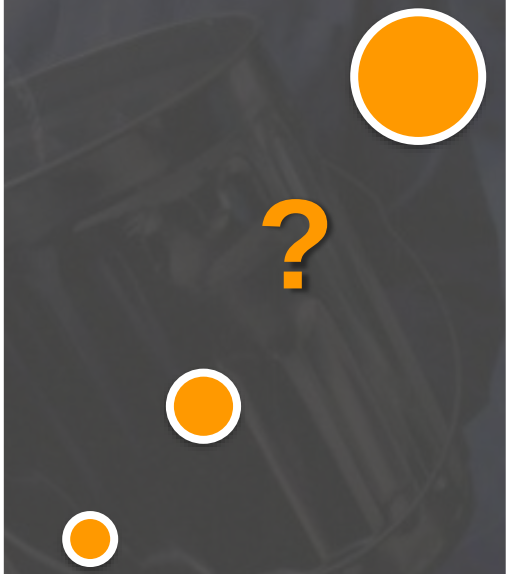
Lew Platt
Former CEO, Hewlett Packard

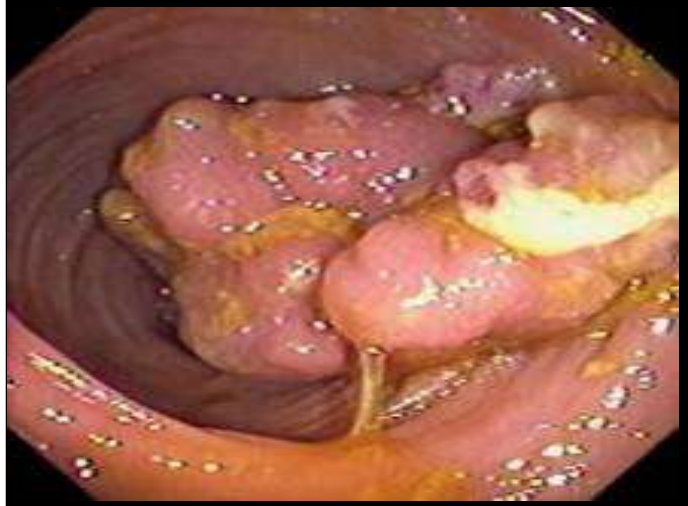
The Challenge of Translation of Burgeoning Datasets Into Clinically Relevant (Actionable) Knowledge



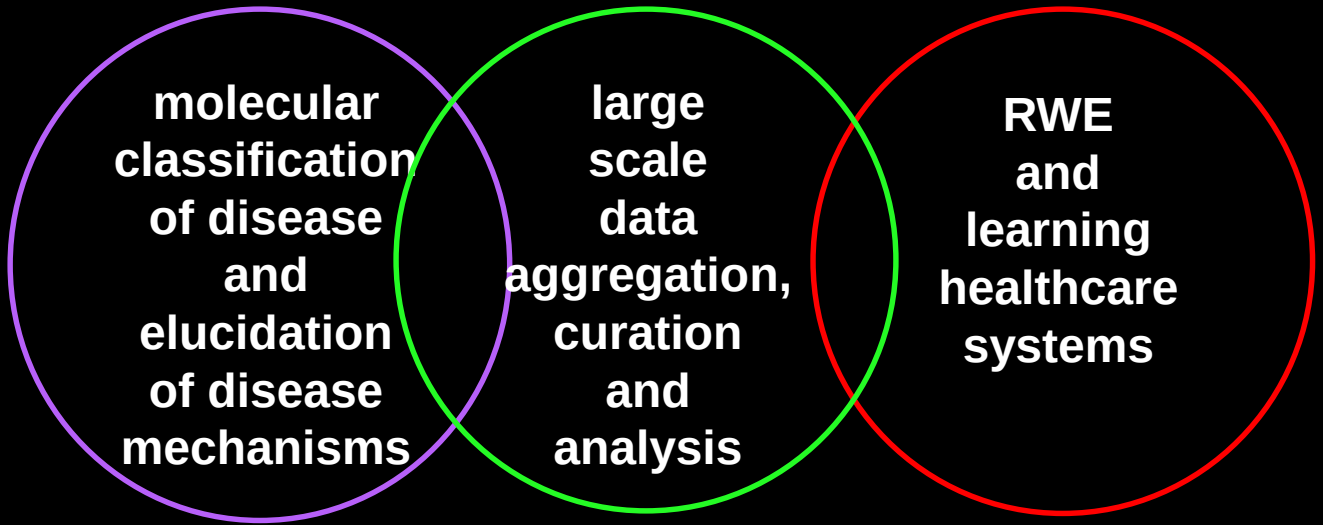


- Data Generation
- Reliability and Robustness
- Biological Insight
- Clinical Utility





Precision Medicine and Computational Medicine: Evolving Inter-dependencies



- unprecedented scale
- standards and db inter-operability
- open data and sharing
- cloud computing
- data science
- machine/artificial intelligence
- decision-support

Real World Data (RWD) and Real World Evidence (RWE)

Integration of Diverse Data Sources on Effectiveness, Cost and Utilization of Healthcare Resources

Population Health Research and Precision Medicine: Blurring the Boundaries Between Research and Clinical Care

- every encounter (clinical and non-clinical) is a data point
- every individual is a data node
- every individual is a research asset
- every individual is their own control

Real World Evidence (RWE):Data Sources

- EHRs
- Claims Data
- Pharmacy Data
- Prospective Observational Data
- Disease Registries
- Mobile Devices
- Patient Reported Data
- Social Media

Real World Evidence (RWE): Identification of Unmet Needs and Tracking Provider Performance

- Incidence and Prevalence
- Burden of Disease
- Co-morbidities
- Subpopulations
- Socio-economic Disparities
- Clinical Practice Patterns
- Outcomes
- Cost
- Trends Analysis

Drivers of Open Data Initiatives and Development of Real World Evidence and Practice

- Federal open data initiatives
  - meaningful use EHR data
  - OpenFDA, FDA Sentinel
  - access to CMS data
  - 21st Century Cures and FDA expansion of product labeling based on RWE
- expansion of clinical trial data access
  - PhRMA-EFPIA principles for trial data sharing
  - Yale YODA project
  - 21st Century Cures Bill and publication of trial data

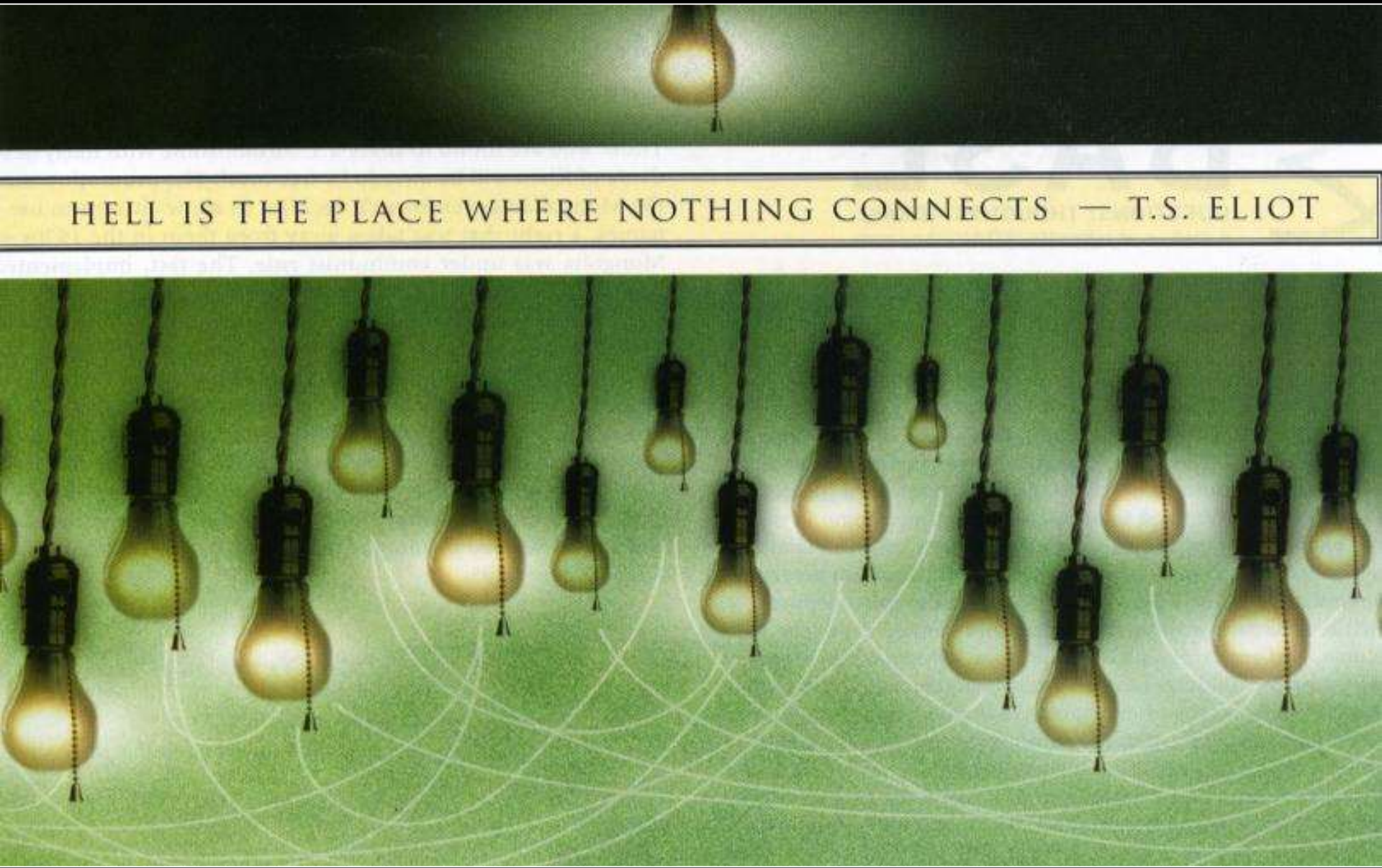
Consortia for Multi-site Clinical Data Research

- Building Modular Pediatric Chronic Disease Registries for QI and CE Research (at Cincinnati Children's Hospital Medical Center [CCHMC])
- Comparative Outcomes Management with Electronic Data Technologies (COMET)
- High Value Health Care Collaborative (HVHC)
- Mini-Sentinel
- Pediatric Health Information System Plus (PHIS+)
- SCAlable National Network for Effectiveness Research (SCANNER)
- Surgical Care and Outcomes Assessment Program Comparative Effectiveness Research Translation Network (SCOAP CERTAIN)
- VA Informatics and Computing Infrastructure (VINCI)
- Washington Heights Initiative Community-Based Comparative Effectiveness Research (WICER)

The Increasingly Blurred Line Between Classical Investigational Clinical Research and New Approaches to RWE Analysis

- historical role of clinical trials as highly controlled, regulated system largely separate from medical practice
- precision medicine and new clinical trial designs
  - disease subtyping and patient segmentation on basis of distinct molecular phenotypes
- rise of pragmatic trials, registries and observational trials for RWE capture and analysis
  - new questions about consent, identification, risks and benefits
  - who is the research subject: patients, clinicians or both?

The Problem With Real World Data is the Real World

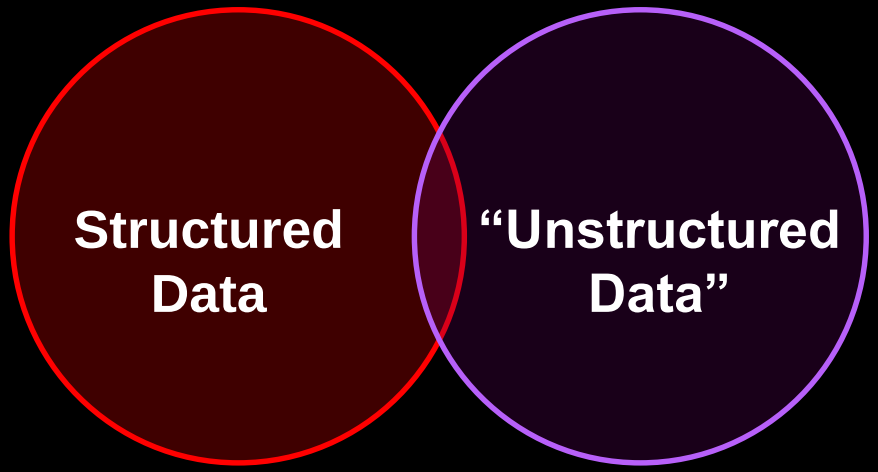

HELL IS THE PLACE WHERE NOTHING CONNECTS — T.S. ELIOT

Silos Subvert Solutions:
Protecting Turf and Sustaining the Status Quo

Data Tombs:
The Current Status of Too Much Biomedical Research and Clinical Data

- unstructured (semantic chaos)
- hoarded (limited sharing)
- siloed (poor integration)
- incompatible (data formats, db interoperabilities)
- variable quality (lack of standardization and the reproducibility problem)
- immobile (inadequate infrastructure for large scale data transfer)
- static (episodic snap shots of dynamic disease processes)

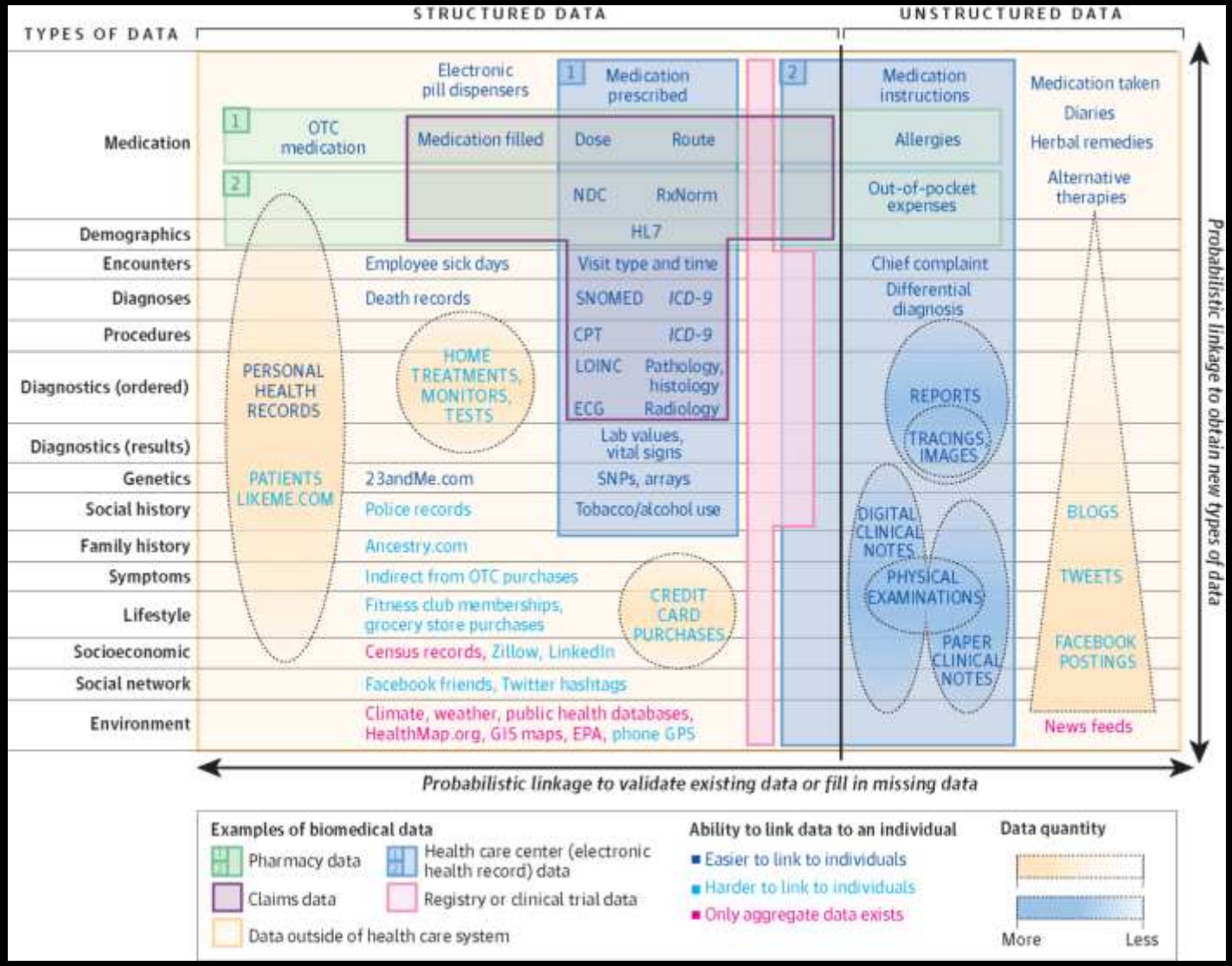
Large Scale Analytics



- predefined EMR fields
- diagnostic codes
- medical and pharmacy chains data
- m.health

- EMR open text fields
- m.health
- PRO
  - social media
  - support groups
- published literature

The Diversity of High Value Data Sources in Healthcare: The Integration Challenge

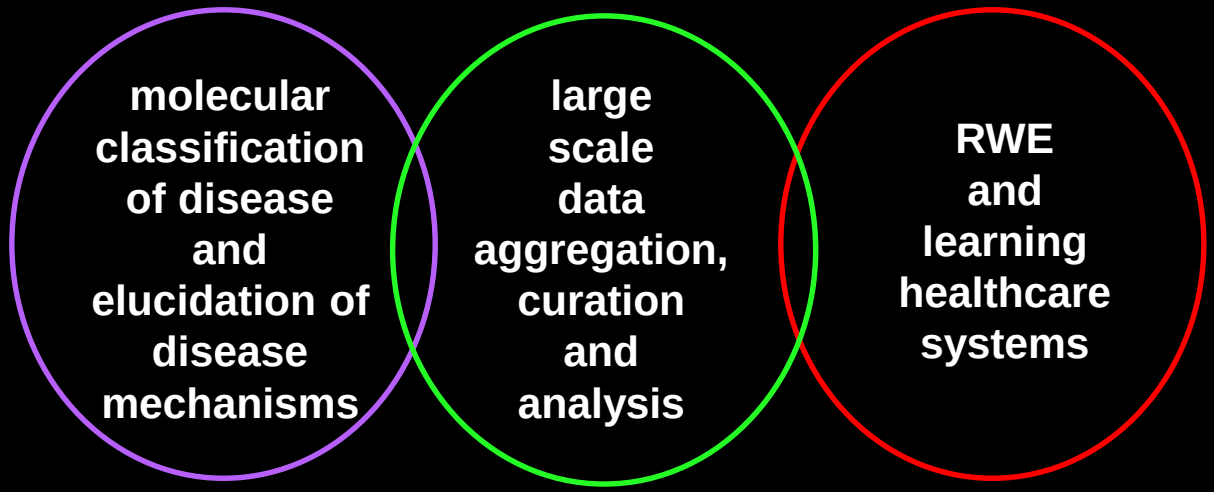


G. M. Weber et al. JAMA. 2014;311(24):2479-2480. doi:10.1001/jama.2014.4228

Building the “Data Commons” Infrastructure

- how will access to comprehensive data sources and multiple databases needed for population health analytics be implemented?
- how can proprietary databases be integrated into an open infrastructure?
- compulsory access schemes versus incentives for sharing?

Precision Medicine and Computational Medicine: Evolving Inter-dependencies

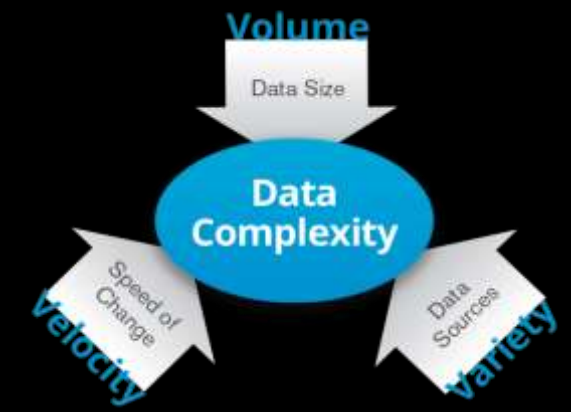


The Big Data Challenge

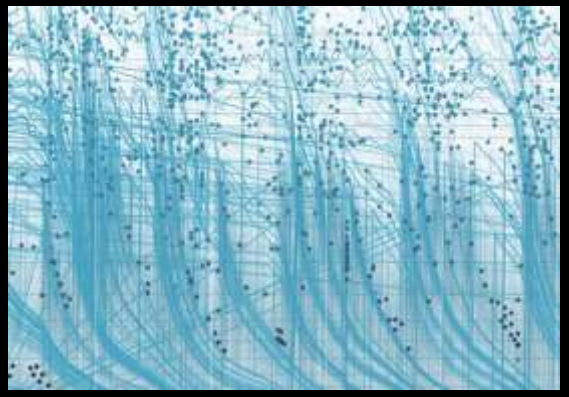
V6: volume, variety, velocity, veracity, virtualization, value
D3: distributed, dynamic, decision support
I3: infrastructure, investment, intelligent systems

The Unavoidable Data-Intensive Evolution of Healthcare: Major Challenges Ahead

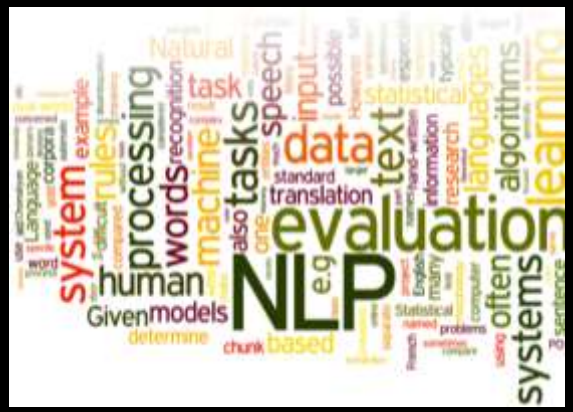
PB and TB Data Streams



Ontologies and Formats for Data Integration



Longitudinal Data Migration and Inter-operable Dbases



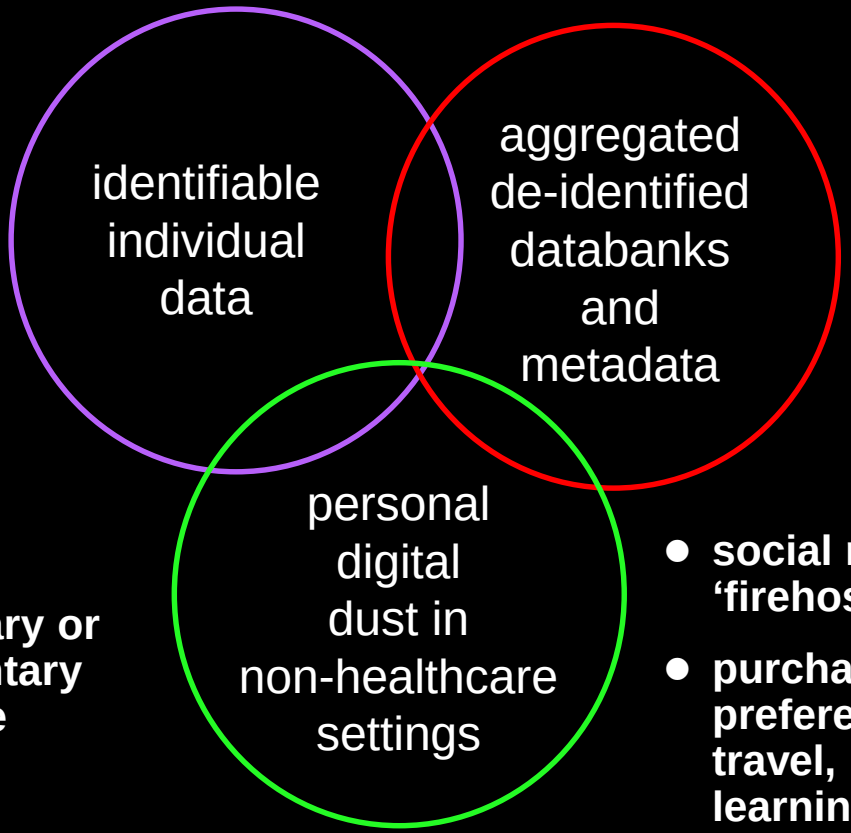
New Data Analytics, Machine Learning, NLP Methods

Infrastructure, Storage and Privacy

Data Science and Data Scientists

Security of Health Data in the Cloud

Protection and Privacy Provisions for Personal Healthcare Data



- **informed consent**
- **legal provisions/ penalties for breach**

- **variable levels of consent**
- **probabilistic, multi-parameter individual ‘match’**

- **voluntary or involuntary capture**

- **social media ‘firehose’**
- **purchasing food preferences travel, political learnings**

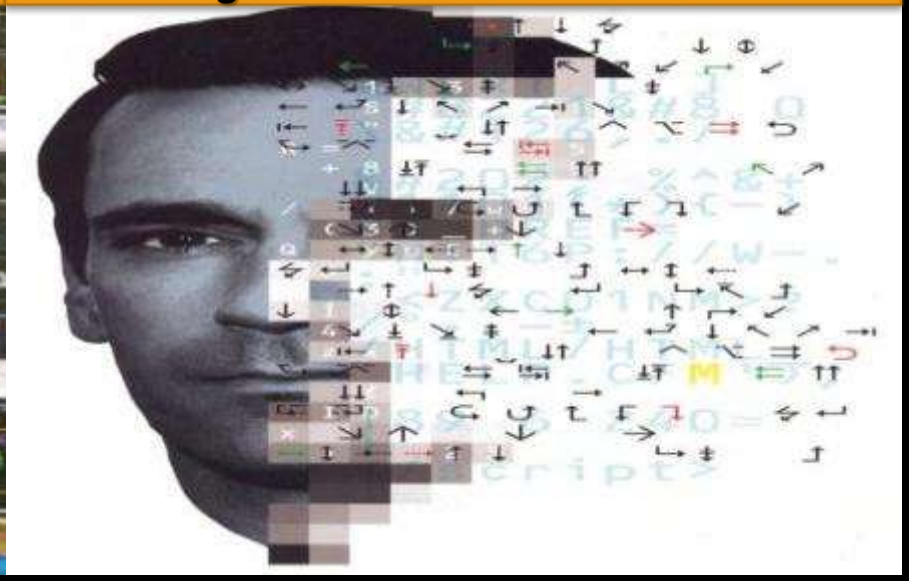
- **‘exposome’ profiling and escalating prospect of individual match**

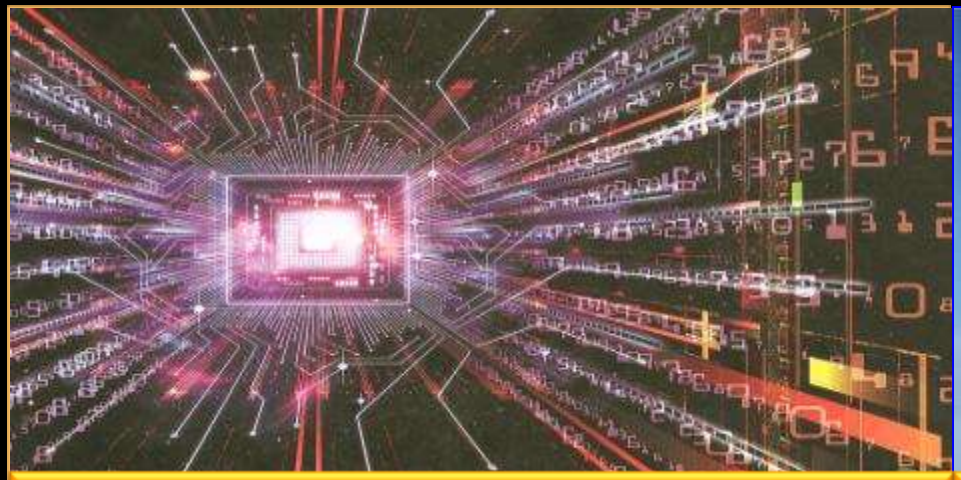
Why Anonymous Data Isn’t (or Won’t Soon Be!)

Technology Acceleration and Convergence: The Escalating Challenge for Professional Competency, Decision-Support and Future Medical Education Curricula

Data Deluge

Cognitive Bandwidth Limits





Automated Analytics and Decision Support

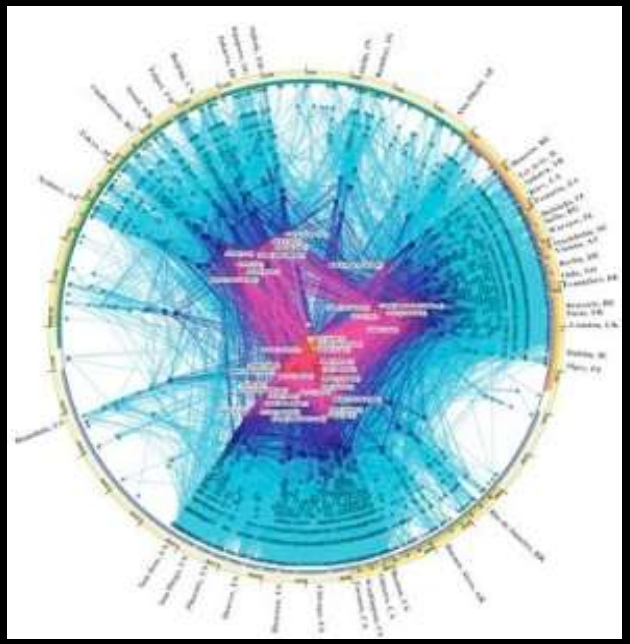
Facile Formats for Actionable Decisions

The Quest for Robust Evidence
When Drinking from the Fire Hose

The Pending Era of Cognitive Computing and Decision-Support Systems: Overcoming the "Bandwidth" Limits of Human Individuals

- limits to individual expertise
- limits to our multi-dimensionality
- limits to our sensory systems
- limits to our experiences and perceptions
- limits to our objective decision-making

The Emergence of Big Data Changes the Questions That Can Be Asked



Isolated Data	Complex Networked Data	Complex Computational Data

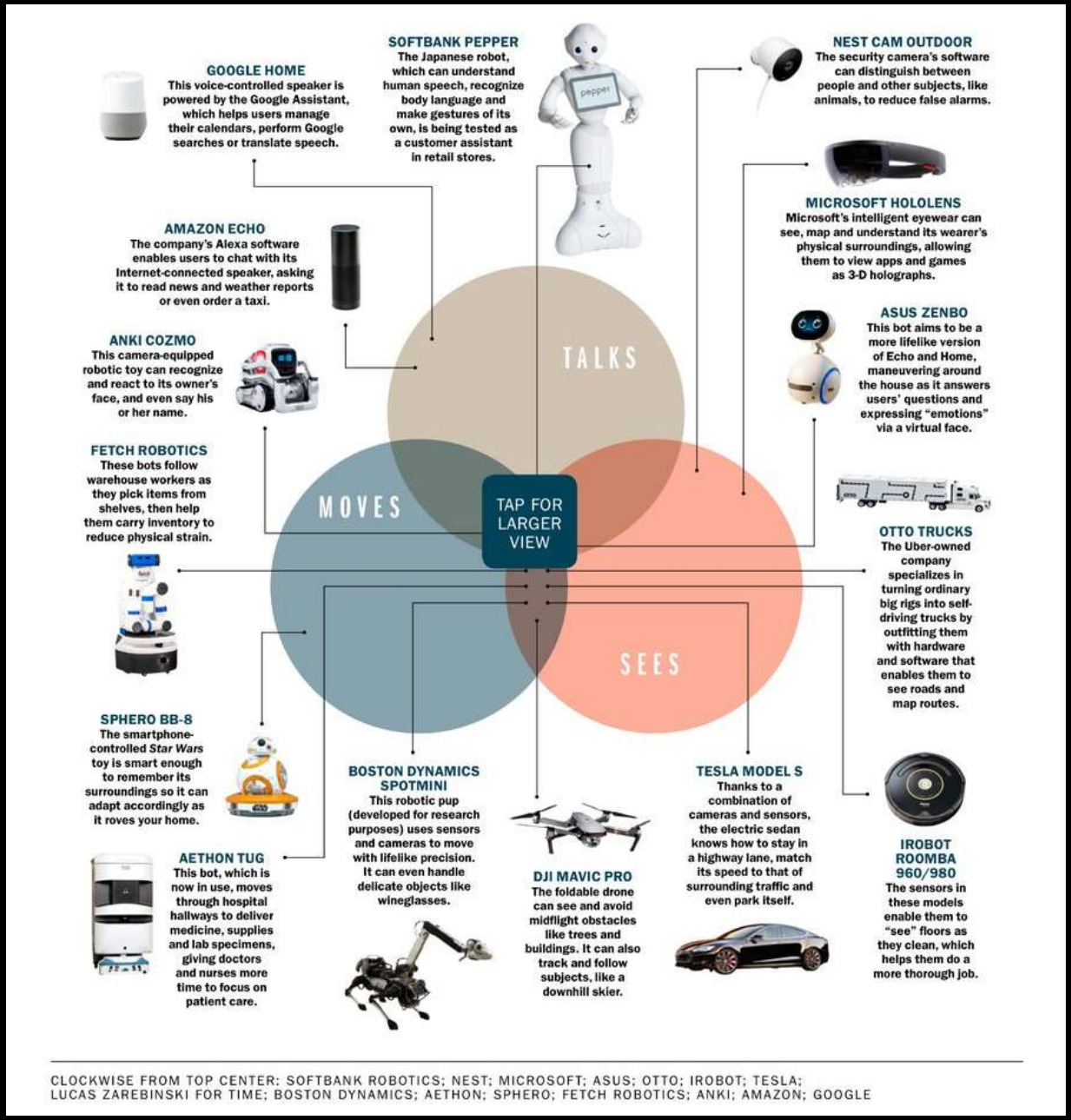
The Future of ‘Search’ and ‘Retrieval’

Deep Understanding of Content and Context

Collapse Time to Decision: Intelligence at Ingestion

Automated and Proactive Analytics:
Why Wait for the Slow Brain to Catch Up to the Fast Machine

Artificial Intelligence Reaches The Marketplace

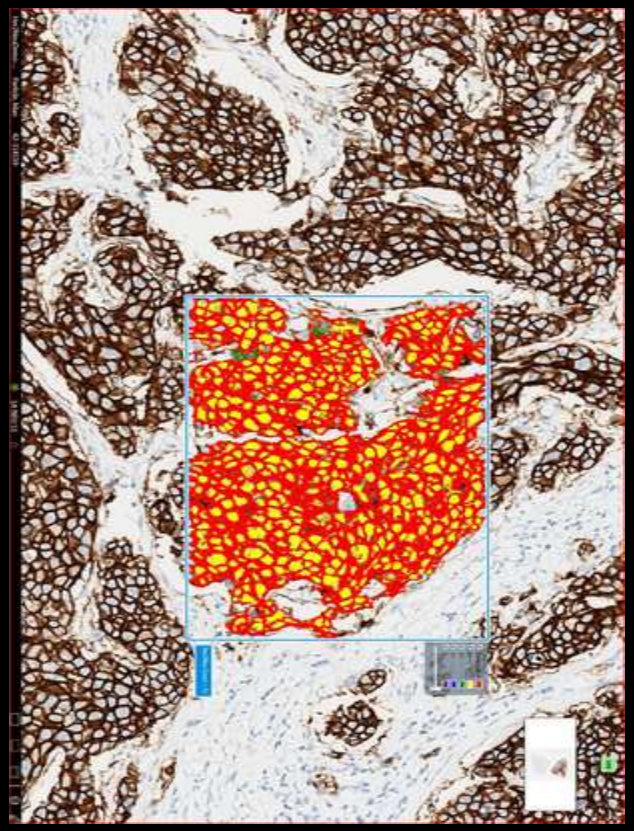


CLOCKWISE FROM TOP CENTER: SOFTBANK ROBOTICS; NEST; MICROSOFT; ASUS; OTTO; IROBOT; TESLA; LUCAS ZAREBINSKI FOR TIME; BOSTON DYNAMICS; AETHON; SPHERO; FETCH ROBOTICS; ANKI; AMAZON; GOOGLE

Automated Learning Systems: The Future of 'Search' and Decision Support

- deeper understanding of content and context
  - structured text plus natural language processing of unstructured inputs
- search all things
  - integration of traditional document semantic sources with video, objects, speech
- why should you have to ask first?
  - smart machines and understanding where/what the user is doing
- why wait for the slow brain to catch up to the fast machine (S. Redmore, Lexalytics)

Deep Learning and Image Recognition for Biomedical Diagnosis and Disease Staging



- digital pathology
- radiology
- ophthalmology
- cardiovascular architecture

Human-Smart Machine Interactions

Deep Learning, Machine Learning and Artificial Intelligence in Data Analytics and Decision Support

"I Can't Let You Do That Dave"

Automated Decision Support Tools and "Gated Autonomy" in the Management of Complex Systems

Living in a World Where the Data Analytics and Interpretation Algorithms Are Obscure to the End User

- ceding decision authority to computerized support systems
- culturally alien to professionals in their claimed expertise domain but they accept in all other aspects of their lives
- who will have the responsibility for validation and oversight of critical assumptions used in decision tree analytics for big data?
  - regulatory agencies and professional societies ?
  - humans?
  - machines?

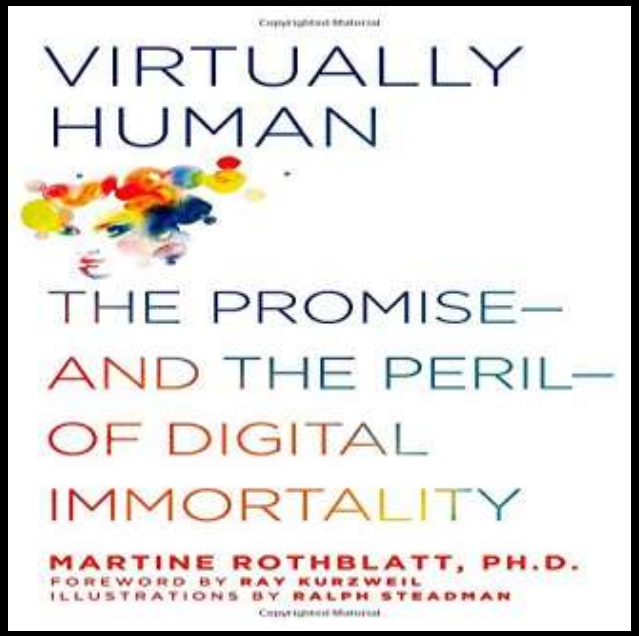
Digital Health, Automation and the Future Work Force

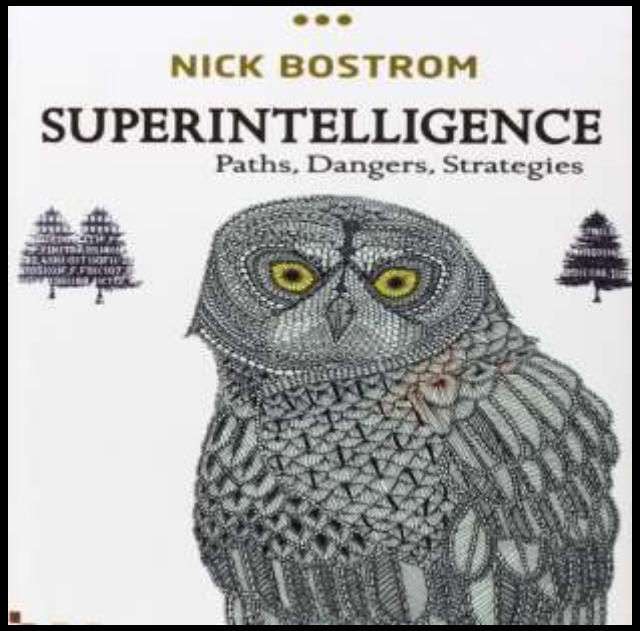
- low and mid-skilled workers at risk of replacement
- digitization of tasks and/or analyses
- value-added human involvement will prosper leaving others redundant
- lessons from the 19th-20th century industrial era
  - 100 years for government to establish requisite worker education and literacy levels
- 21st century
  - need for a faster redesign of education

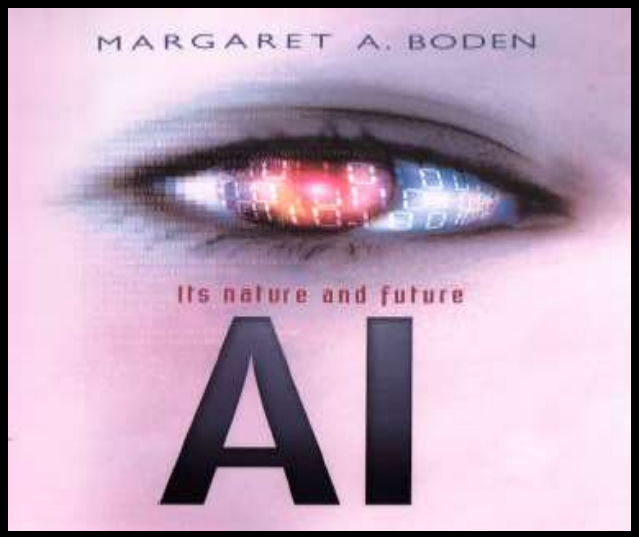
New Ethical and Legal Complexities in the Application of Machine Learning and Artificial Intelligence for Large Scale Data Analysis

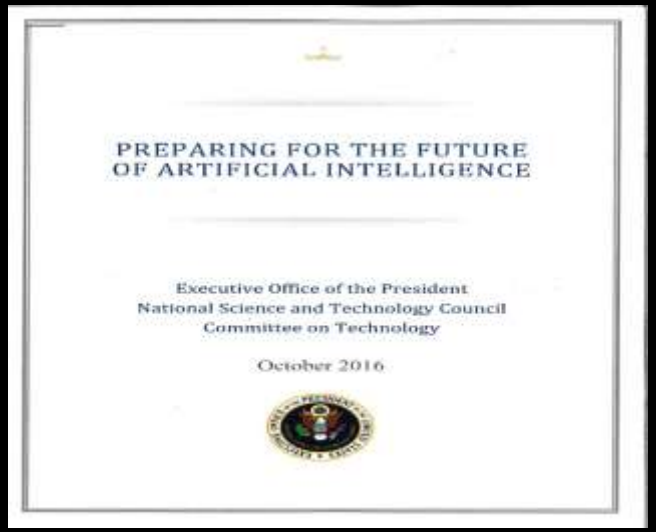
- privacy and surveillance
- discrimination
- unemployment
- persuasion-coercion
- addiction
- manipulation of perceived reality(ies)
- us and them: seamless integration or conflict
- existential risk(s)

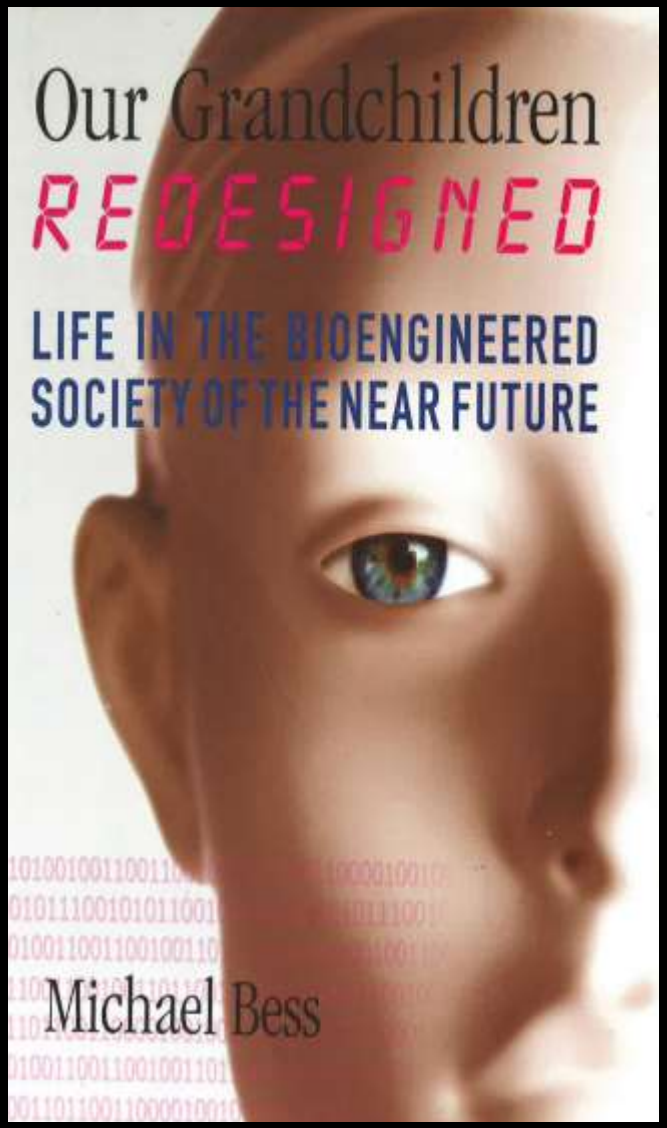
Deep Learning, Smart Machines and Ethical, Legal and Socio-Cultural Complexities

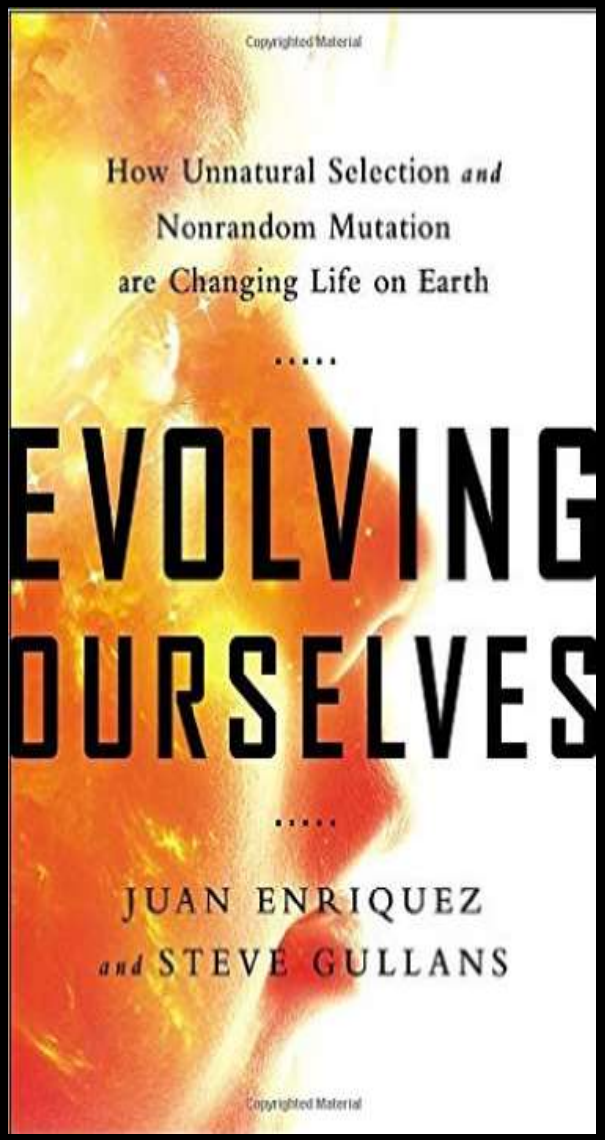









Our Grandchildren
REDESIGNED
LIFE IN THE BIOENGINEERED SOCIETY OF THE NEAR FUTURE
Michael Bess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How Unnatural Selection and Nonrandom Mutation are Changing Life on Earth
EVOLVING OURSELVES
JUAN ENRIQUEZ and STEVE GULLANS
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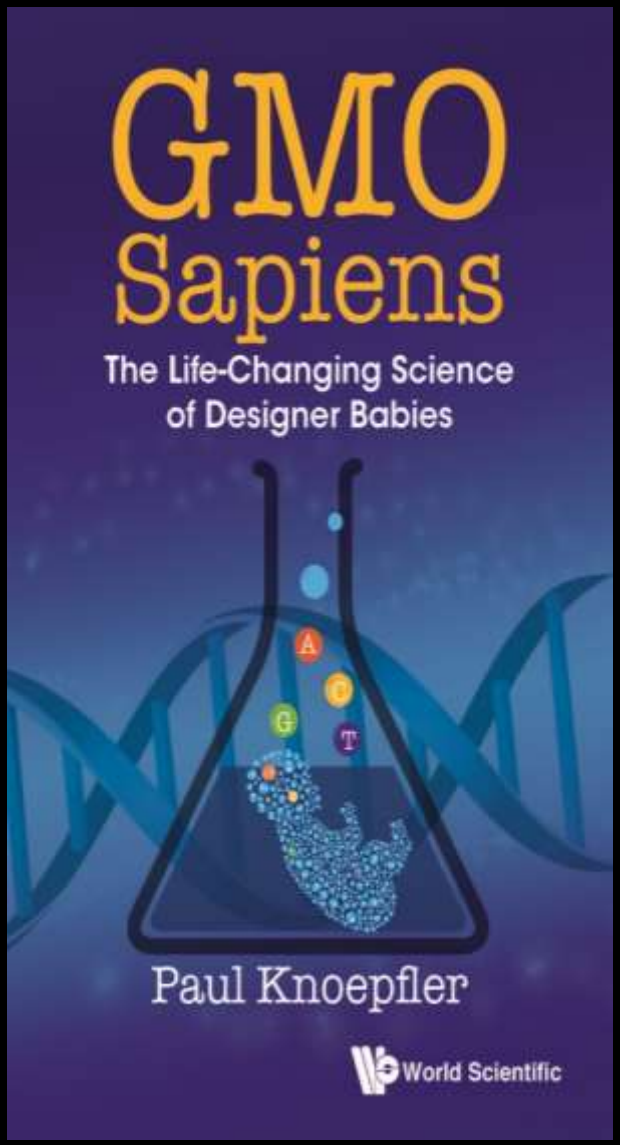
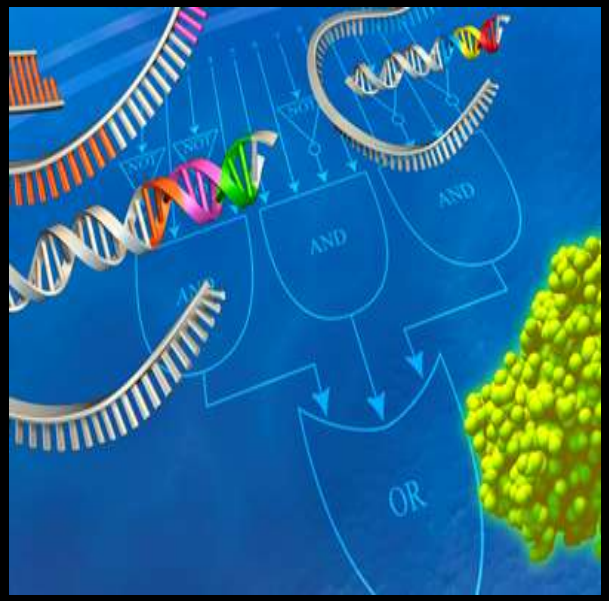
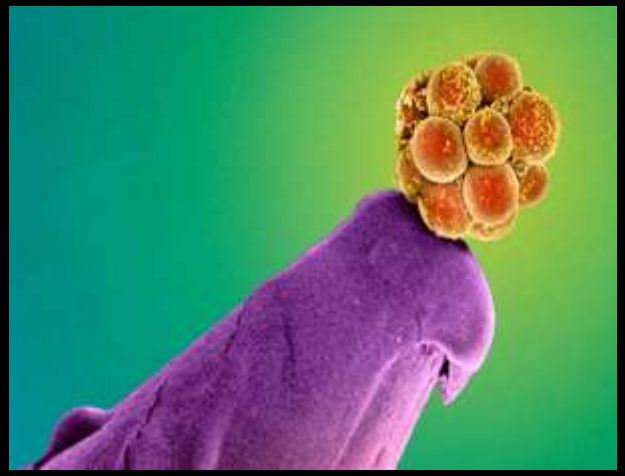
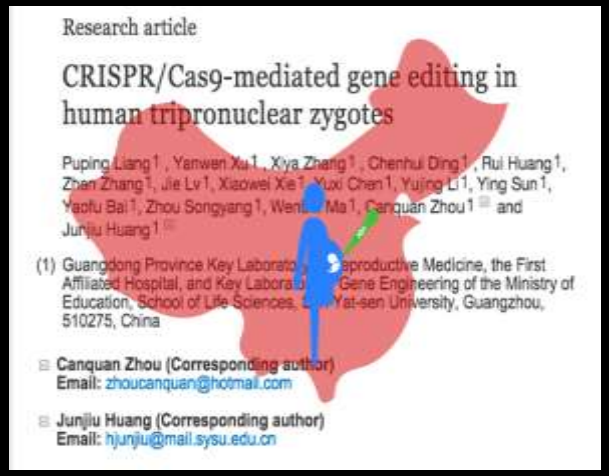

GMO Sapiens
The Life-Changing Science of Designer Babies
Paul Knoepfler
World Scientific

Precision Genomic Modifications
New Therapeutic Strategies Plus Complex Ethical and Legal Issues






Research article

CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes

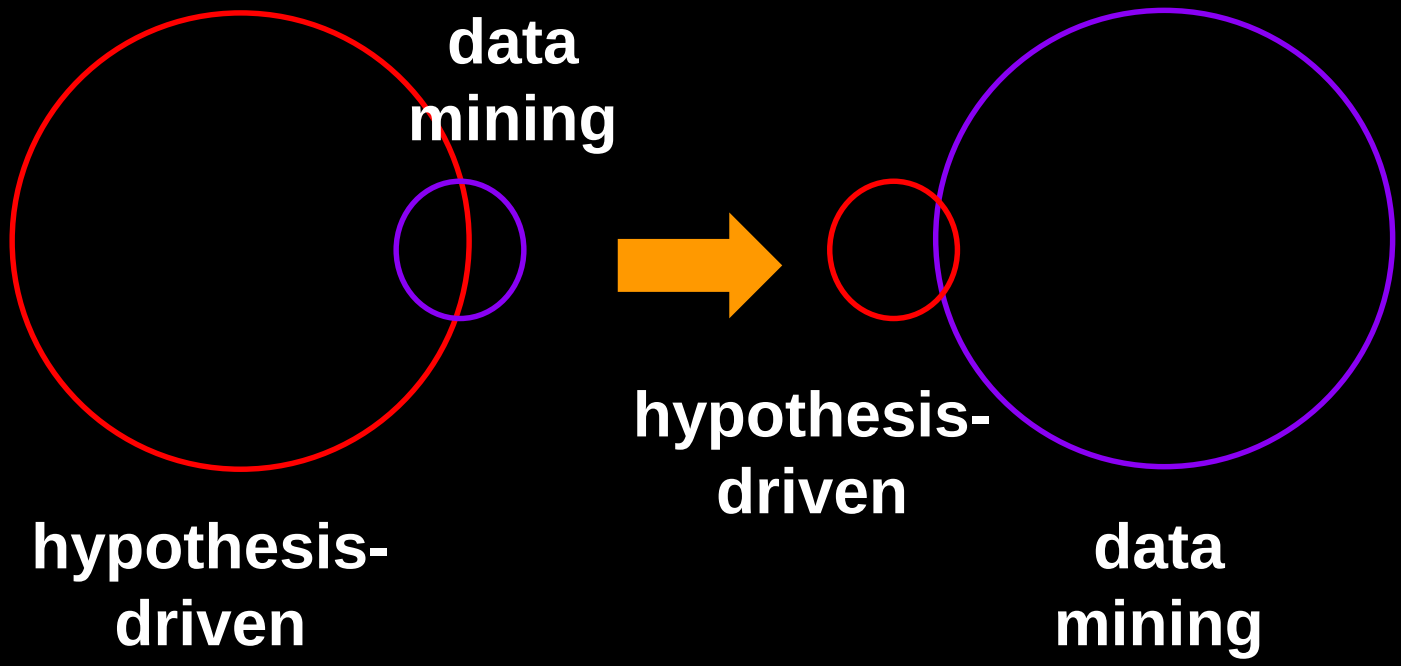
Puping Liang[1], Yanwen Xu[1], Xiya Zhang[1], Chenhui Ding[1], Rui Huang[1], Zhen Zhang[1], Jie Lv[1], Xiaowei Xie[1], Yuxi Chen[1], Yujing Li[1], Ying Sun[1], Yaofu Bai[1], Zhou Songyang[1], Wenbin Ma[1], Canquan Zhou[1] and Junjiu Huang[1]

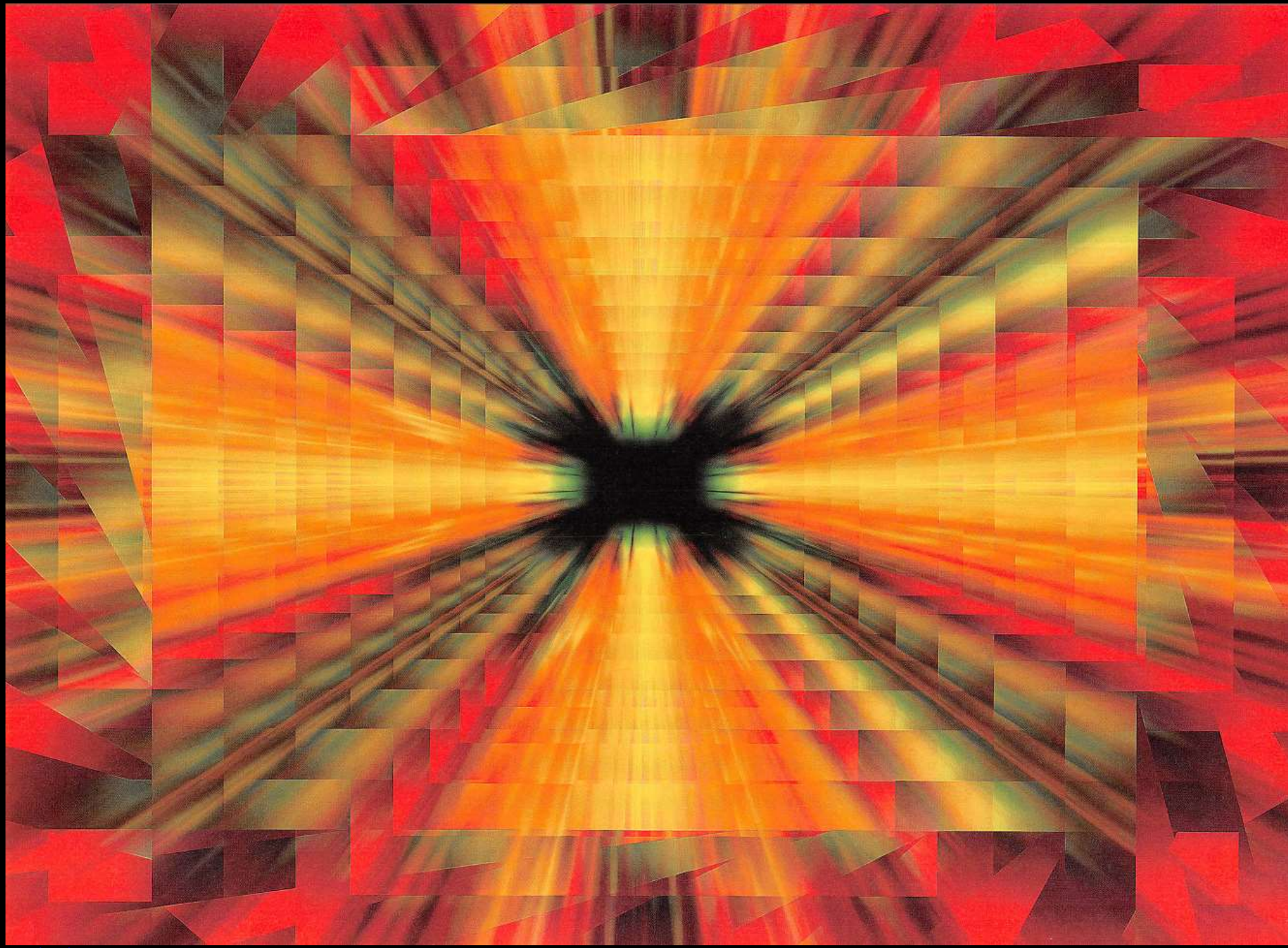
(1) Guangdong Province Key Laboratory of Reproductive Medicine, the First Affiliated Hospital, and Key Laboratory of Gene Engineering of the Ministry of Education, School of Life Sciences, Sun Yat-sen University, Guangzhou, 510275, China

Canquan Zhou (Corresponding author)
Email: zhoucanquan@hotmail.com

Junjiu Huang (Corresponding author)
Email: hjunjiu@mail.sysu.edu.cn

A Pending Transition in Scientific Research?

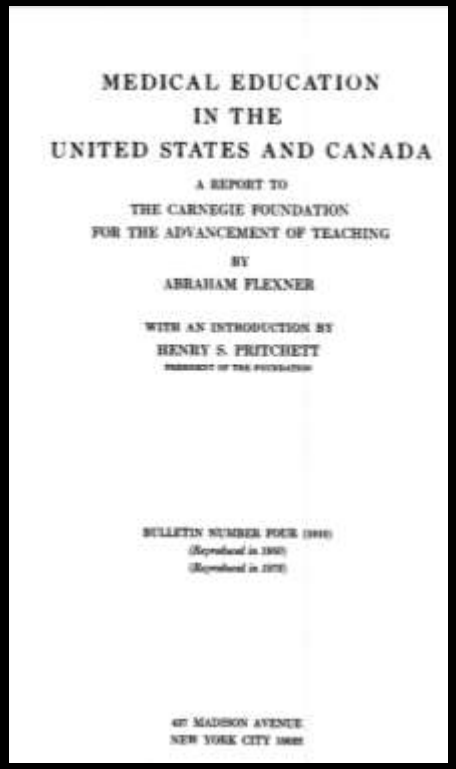


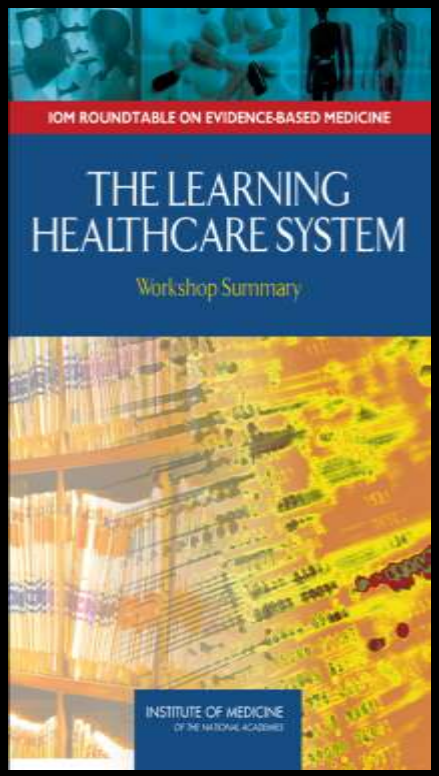


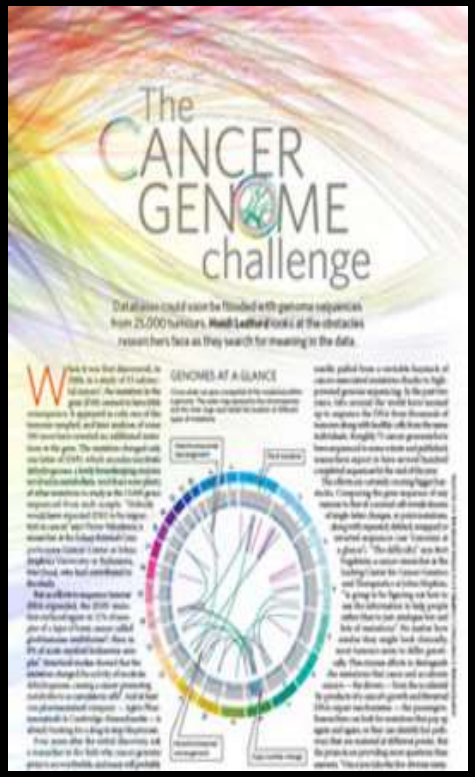
acceleration

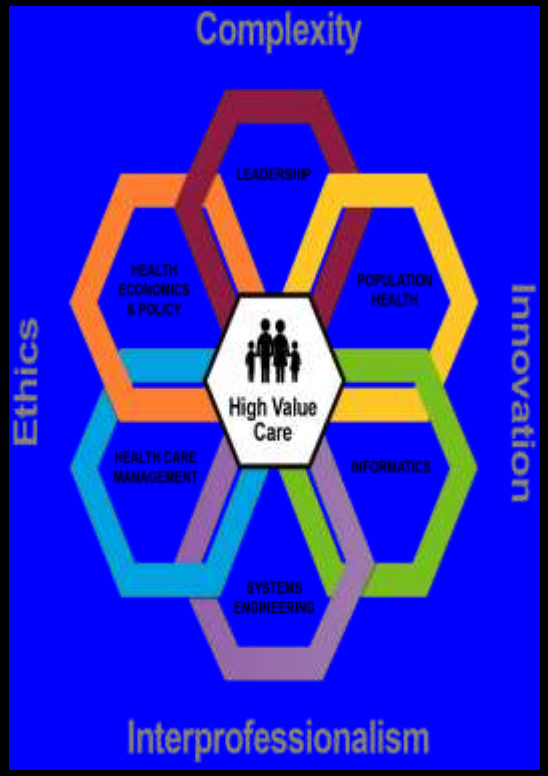
Communications ACM 2016 59, 47

Major Transitions in Medical Education and Healthcare


MEDICAL EDUCATION
IN THE
UNITED STATES AND CANADA
A REPORT TO
THE CARNEGIE FOUNDATION
FOR THE ADVANCEMENT OF TEACHING
BY
ABRAHAM FLEXNER
WITH AN INTRODUCTION BY
HENRY S. PRITCHETT
BULLETIN NUMBER FOUR
(Reproduced in 1965)
(Reproduced in 1972)
437 MADISON AVENUE
NEW YORK CITY

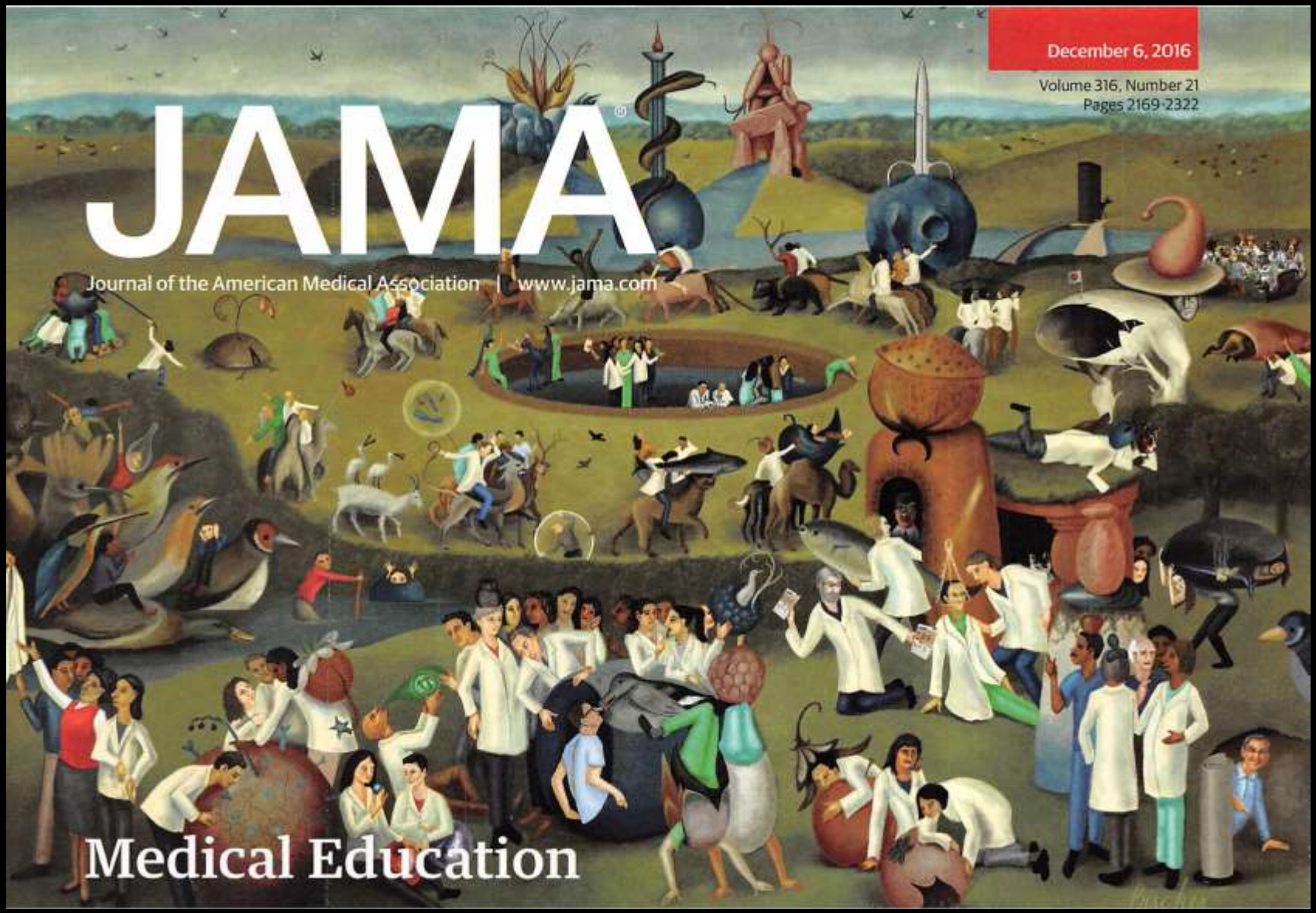






1910-present	2000 - present	2010 - ?
(science-centric)	healthcare as a learning system (data-centric)	network topologies and dynamics in complex adaptive systems (network-centric) education, R&D and care delivery

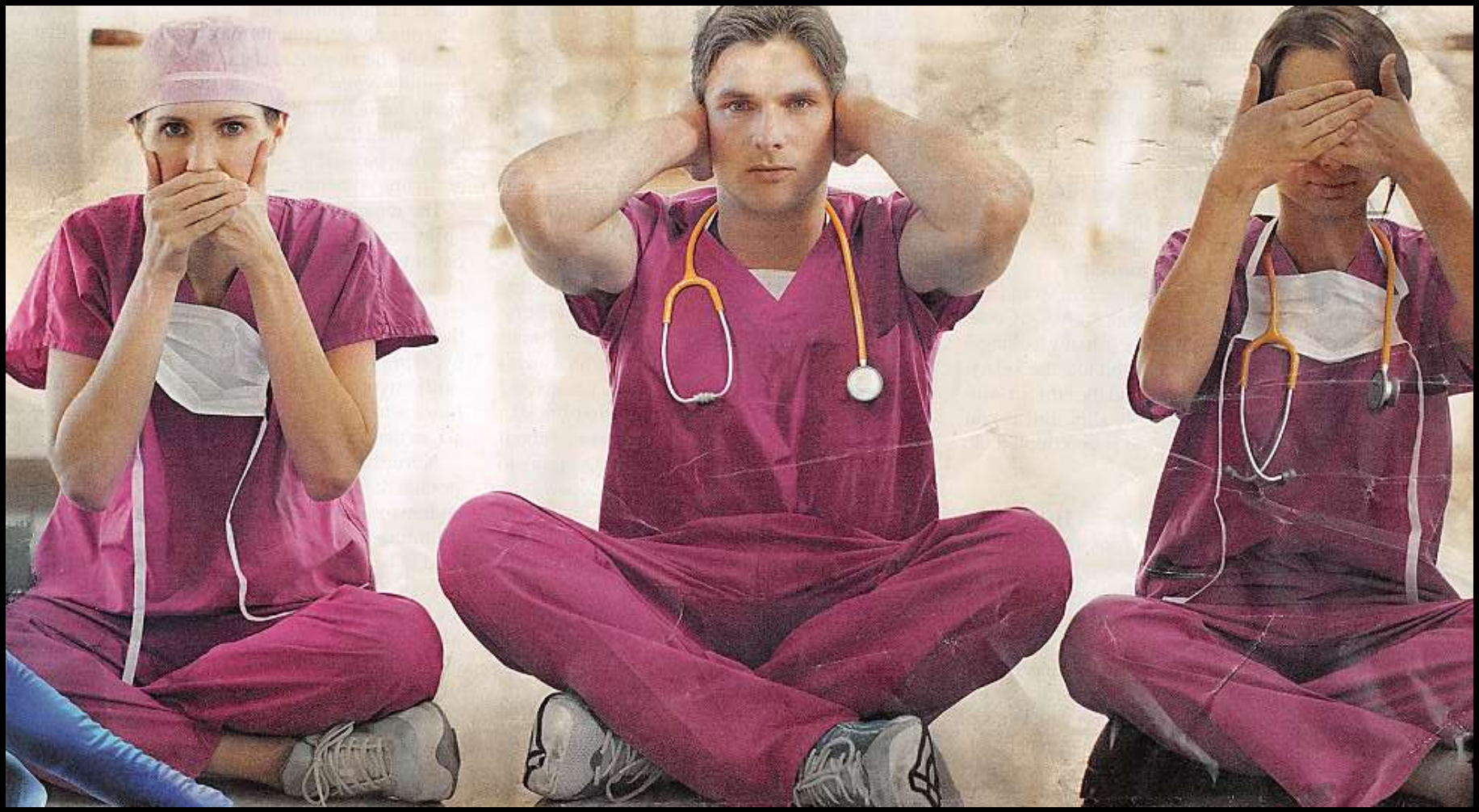
"The Callroom of Earthly Delights"
R.M. Golub and K. Bucher: JAMA 316, 2171



December 6, 2016, Vol 316, No. 21, Pages 2171-2322 | Medical Education


CHANGE
is good
you go first

DNR



Denial

Negativity

Resistance

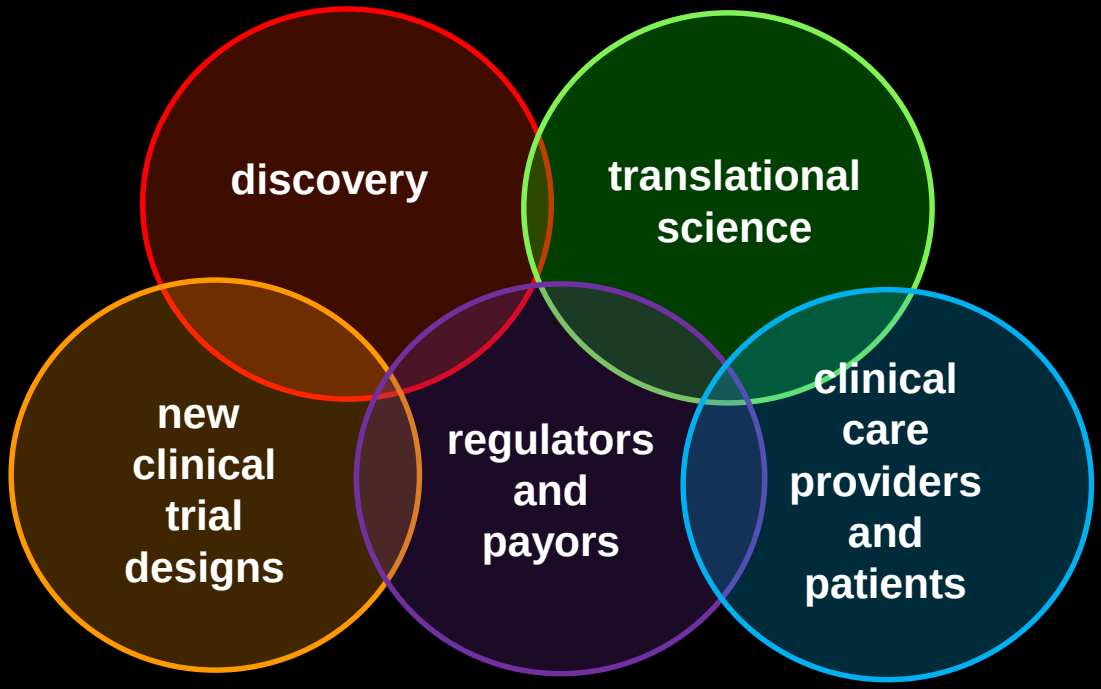
Precision Medicine

The Intellectual Foundation for a New Era in Clinical Medicine and Public Health

the Rise of Data-Intensive Medicine and Digital Healthcare

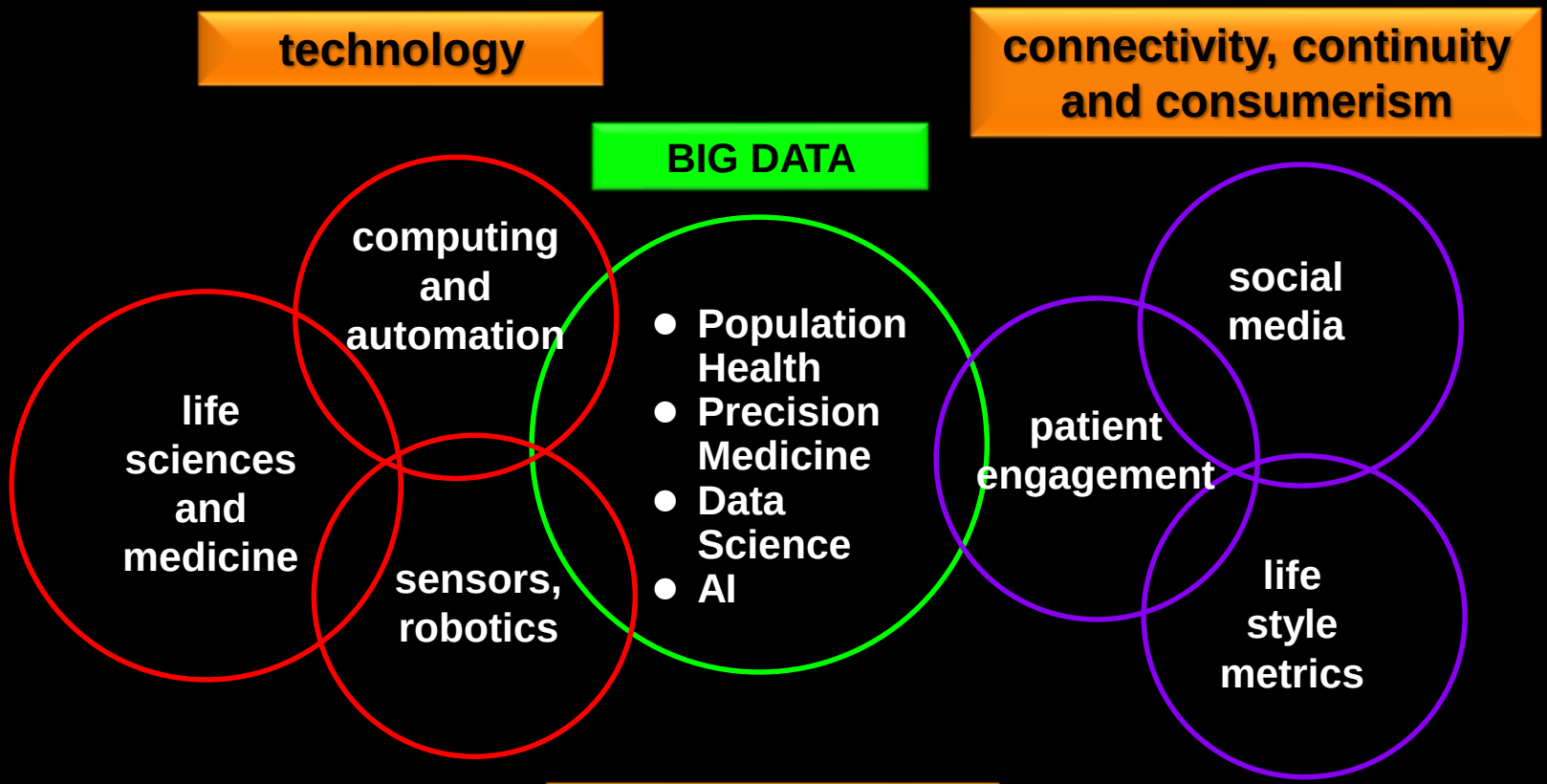
Profound Economic, Organizational, Cultural Ethical Implications for Future Healthcare Delivery Channels and Professional Competencies

Precision Medicine



The Need for Systems-Based Planning to Integrate New Competencies Across the Entire Continuum from Discovery to Clinical Care

Convergence



Slides available @ http://casi.asu.edu/