



Challenges in Healthcare Innovation in An Era of Technology Acceleration, Convergence and New Value-Based Services

### Dr. George Poste, DVM, PhD

Chief Scientist, Complex Adaptive Systems Initiative and Regents Professor of Health Innovation
Arizona State University
george.poste@asu.edu
www.casi.asu.edu

EMED 227/127: HEALTH CARE LEADERSHIP
Stanford University School of Medicine
Li Ka Shing room 102
23 January 2019

### 100 Years of America's Top 10 Companies

#### 1917



U.S. Steel \$46.4B



American Telephone & Telegraph \$14.1B



Standard Oil of N.J. \$10.7B



Bethlehem Steel \$7.1B



Armour & Co. \$5.8B



Swift & Co. \$5.7B



International Harvester \$4.9B



E.I. du Pont de Nemours \$4.9B



Midvale Steel & Ordnance \$4.8B



U.S. Rubber \$4.6B

Assets (\$ bn) Inflation adjusted September 2017



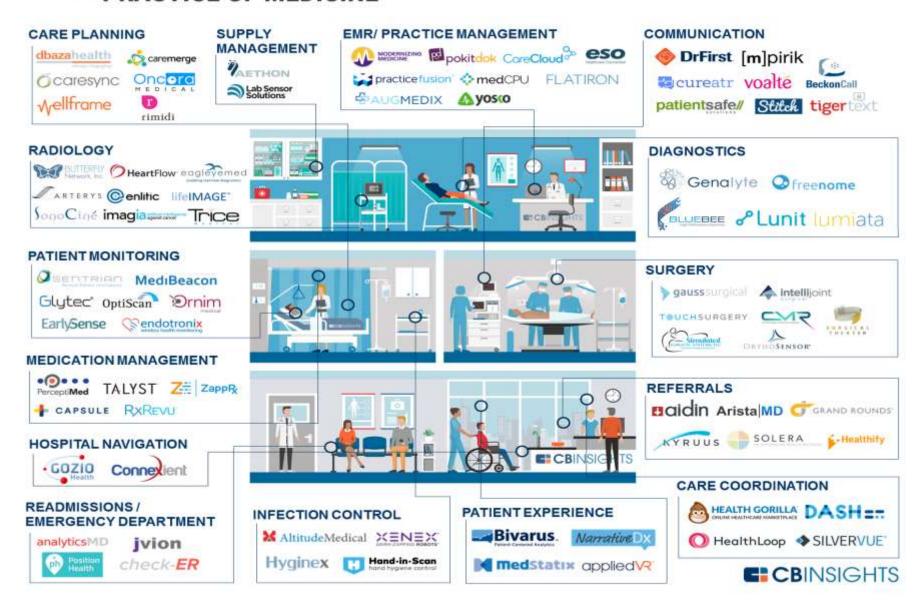
September 2017

#### Industry Tech Conglomerate Medical Oil & Gas Financial Services Film Rubber





### THE DIGITAL HOSPITAL: 82 COMPANIES REINVENTING THE PRACTICE OF MEDICINE



### THE US DIGITAL HEALTH ECOSYSTEM 2019

#### INCUMBENT PAYERS

#### STARTUP PAYERS

#### INCUMBENT PROVIDERS







#### STARTUP PROVIDERS

DISTRIBUTORS























U.S. Department





#### CONSUMER DEVICES







#### TELEMEDICINE

#### MEDICAL DEVICES

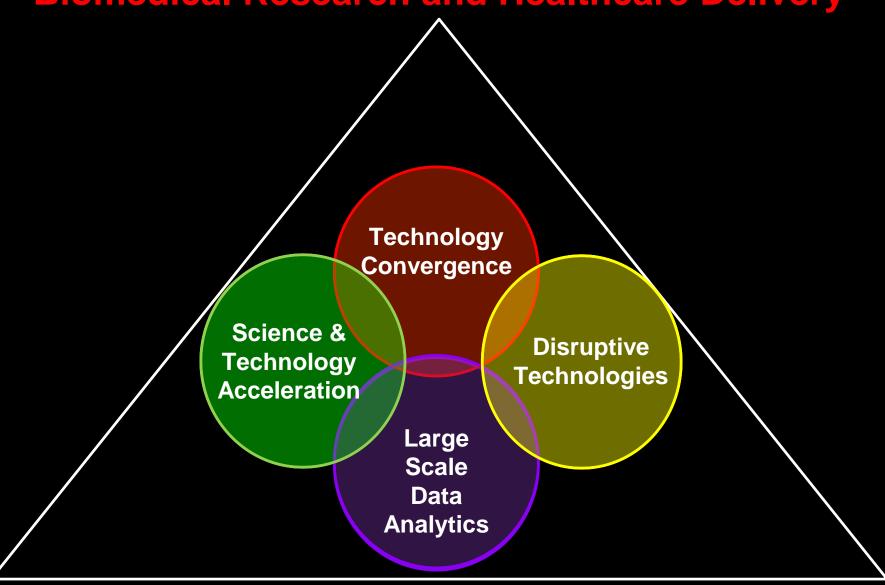






BUSINESS INSIDER

# The Strategic Environment for Biomedical Research and Healthcare Delivery



## **Industry Career Experience**















**Diade**xus







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illumına<sup>®</sup>











- largest US public university
- fastest growth in research revenues of any US university



# A New American University: A Purposeful, Radical Strategic Redesign

Party School



Strategic Premise That Many
Features of Contemporary Academia
Lack the Agility to Address
the Forces Reshaping Research
and Education

Silos Subvert Solutions



Ambitious Focus on
Cross-Disciplinary/Cross-Sector
R&D and
Use-Inspired Applications
for Major Unmet Needs



### **A Transformative Decade**

# National Science Foundation (NSF) Higher Education Research and Development (HERD) Rankings

Total Research Expenditures: 44 of 876 ahead of













Total Research Expenditures among Institutions without a Medical School: 9 of 718 ahead of









Science for the benefit of humanity





Non-Medical School Expenditures: 22 of 876 ahead of





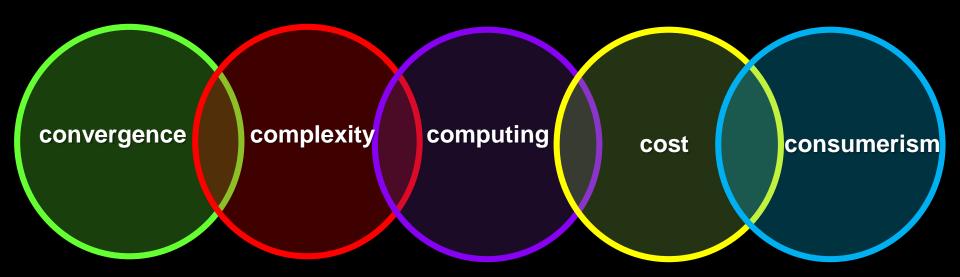




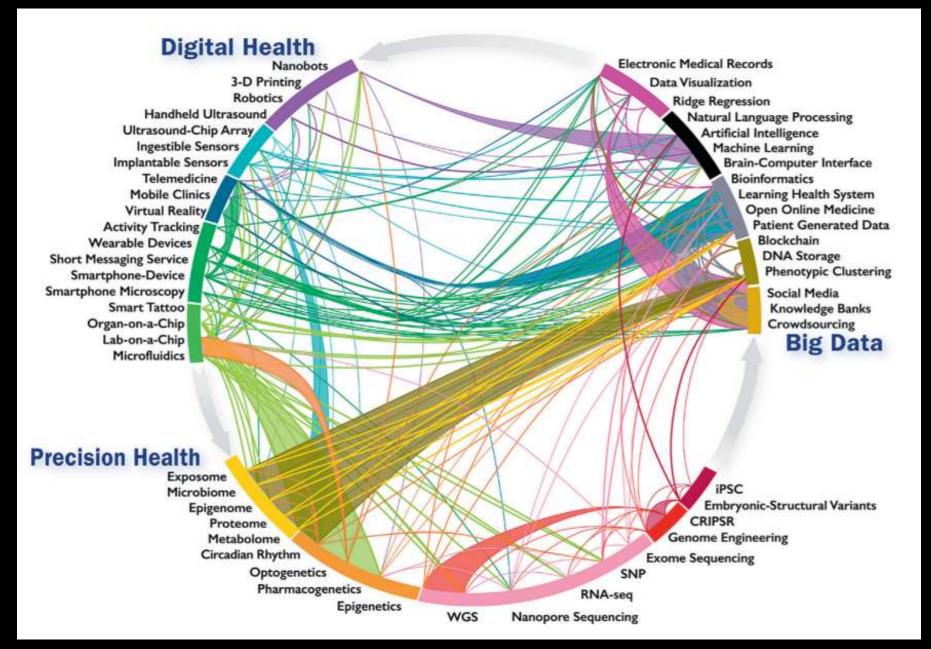




## The Strategic Landscape for Healthcare



### Convergence: Precision Health, Digital Health and Big Data



# Molecular medicine and information-based targeted healthcare Nature Biotechnology, 16 (Supplement), 19-21.

The convergence of genomics and informatics heralds a new era of biomedical research, offering unbridled opportunities for bioentrepreneurs.

George Poste

The accelerating momentum of technological innovation in the life sciences has been accompanied by equally profound changes in the competitive landscape for industrial R&D. New entrepreneurial companies have emerged on an unprecedented scale to exploit advances in molecular biology, genomics, combinatorial chemistry, robotics, microelectronics, and informatics to generate

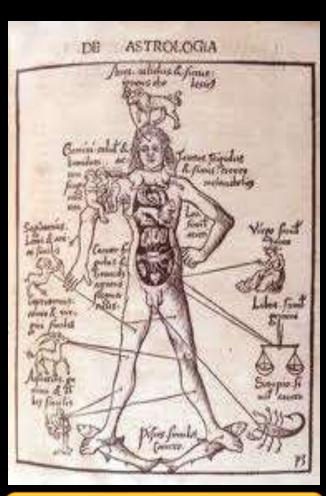
The development of informatics tools to annotate, archive, and analyze the vast volume and diversity of datasets that will be generated will be a key factor in research progress.

new products and services for medicine, agri- prediction and the prevention of

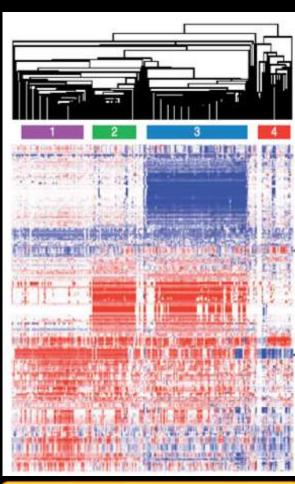
Future progress will depend pri-Product 1998 Medicine 2008 databases. applications smart cards diagnostics counseling disease package insert management protocols, patient information

### **The Path to Precision Medicine:**

### From Superstitions to Symptoms to (Molecular) Signatures







humors; astrology, shamanism, sin and divine fare

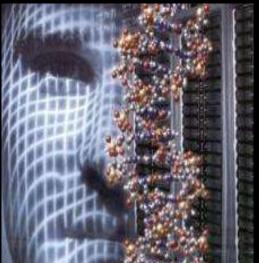
biochemistry and organ-based pathophysiology

molecular biology and multi-omics profiling

## **Precision Medicine:**

(Epi)Genomics

MultiOmics Profiling of Molecular Signaling Networks and Disruption in Disease







Patient-Specific Signatures of Disease or Predisposition to Disease

00111111011000000000000000011110000

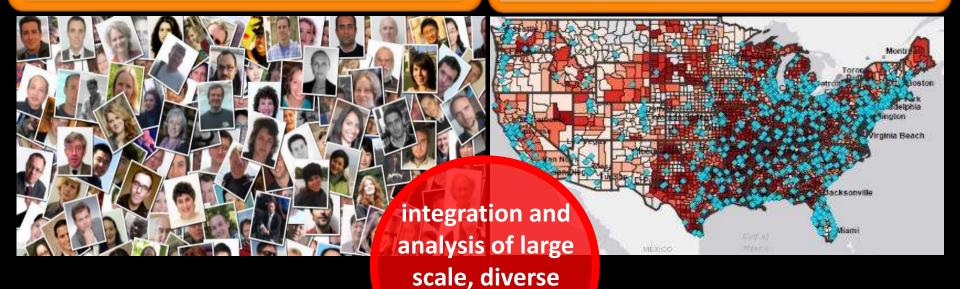
- terabytes per individual
- zettabyte yottabyte population databases

Big (Messy) Data

# Precision Medicine and Digital Medicine: Evolving Inter-Dependencies

**Individual Data** 

**Population Databanks** 



**Deep Phenotyping:** 

data categories

integration of (epi)genomic and multiOmic profiles, clinical, environmental and socio-behavioral data

- anticipated expansion of molecular data profiles on millions of individuals
- value will reside in defining robust correlations with clinical outcomes and integration into clinical workflows
- transitioning from the current black box of multiOmics signatures of unknown significance to increasingly accurate causal associations and clinically actionable information
- risk mitigation

# Precision Medicine and Digital Medicine: Evolving Inter-Dependencies

**Individual Data** 

**Population Databanks** 



"digital siblings and imputed phenotypes"

matching individual profiles to 'best fit' data cohorts
 to identify risk and selection of optimum treatment regimens

The 'Analyte Space' for Profiling Health Status and Risk Monitoring



Stakeholder Perceptions of the Use of Mobile Technology in Clinical Trials <u>Ethical and Privacy Considerations of Mobile Technology</u> by Camille Nebeker

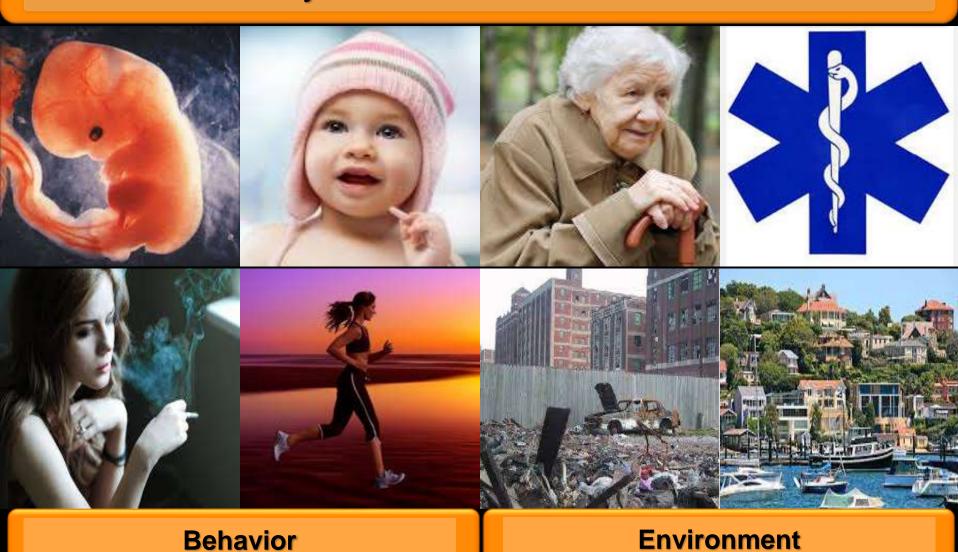
- multiOmics
- clinical phenotypes

**RISK** 

- social determinants of health
- exposome

## The "Geno-Enviro-Pheno' Triad

Systematic Integration of Diverse Data for Population Health Analytics
Continuity of Care Record: From Womb to Tomb



## The Growing Burden of Chronic Disease

cancer neurodegeneration cardiovascular/metabolic disease mental illness

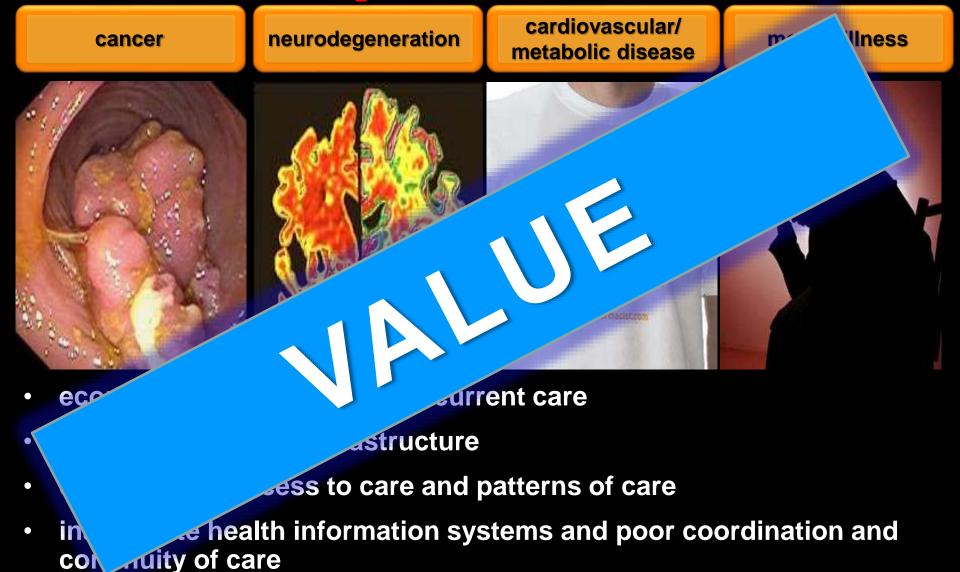
Diabetes + Obesity

DIABESITY

The Anacles of Pharmacist.com

- economic unsustainability of current care
- insufficient clinical infrastructure
- disparities in access to care and patterns of care
- inadequate health information systems and poor coordination and continuity of care
- cost of innovation (Rx price as political target)
- rise of consumerism in healthcare and entry of new corporate players

## The Growing Burden of Chronic Disease



- cost of innovation (Rx price as political target)
- rise of consumerism in healthcare and entry of new corporate players

## **Precision Health and Digital Health**

**Expanding 'The Analyte Space'** in Health and Disease

**Monitoring Health Beyond the Clinic** 

- the majority of events that influence wellness/disease risk and treatment adherence occur largely outside of formal interactions with the healthcare system
- daily decisions by individuals have greater effects on their health than decisions controlled by the healthcare system

# "People Analytics" and Large Scale Databanks: Blurring the Boundaries Between Medical Research, Clinical Care and Daily Life

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

## 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
- the confessional of social media
- the blurring of private and public spaces
- complex ethical and legal issues
  - consent, privacy, security, surveillance

# Leadership and Vision: Joint University Task Force in Biomedical Innovation













## Joint University Biomedical Innovation Task Force: Chair: Dr. G. Poste

- digital platforms to reduce hospital readmission(s)
  - CHF, behavioral health
- design of multiplex sensors and diagnostics for remote health status monitoring
  - RWE-observational protocols to meet new payer and biopharma/device company needs
- robotics and human-machine interactions
- clinical data analytics for proactive risk identification and mitigation in high risk, high complexity participants/settings

# Healthcare Beyond the Clinic Changing The Touch Points in Healthcare Delivery

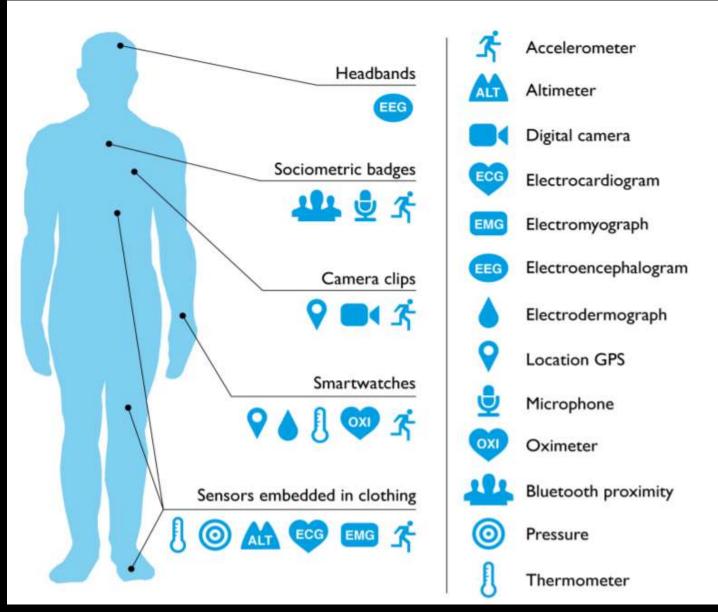
**Remote Health Status Monitoring** 

Smartphones, Wearables, Devices and Telemedicine Services

**AORTA: Always On, Real Time Access** 

M4: Making Medicine More Mobile

## Wearables and Health Status Monitoring



## **Wellness Apps for Fitness, Diet and Exercise**









## **Building Value in Wellness Apps and Wearables**

- clinical value still viewed as marginal by many physicians/payers
- lack of robust RCT data on improved outcomes
- need for third party evaluation and/or regulation
  - accuracy, security and privacy
- vulnerability of many current Apps, devices and text messaging to hacking
- lack of policy transparency for sharing of consumer-patient data with third parties by Apps developers and data aggregators

# Current Limitations of Consumer-Based Wearables for Health Status Monitoring

- restricted analyte menu
- limited data integration into EHR and alerts for anomaly events requiring prompt intervention
- inadequate incentives: users, payers and physicians
- rapid abandonment and lack of user 'stickiness'

# Remote Health Monitoring and Reduction in Hospital Readmissions

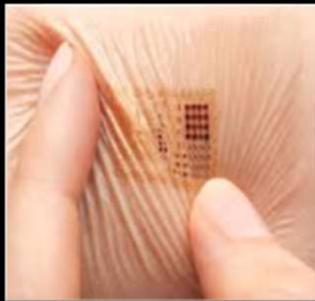
### **Readmission Rates**

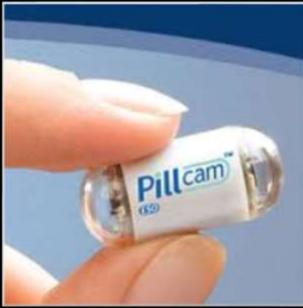
```
# 1 CHF (22 - 30%)
# 2 behavioral health and substance abuse (20 - 26%)
# 3 respiratory (158 - 26%)
# 4 diabetes mellitus (15 - 22%)
# 5 acute renal failure (15 - 22%)
```

## **Remote Monitoring of Health Status**













### **Trends in Sensors and Devices**

- real time data
- miniaturization
- automation
- multiplex analytes
- wireless
- power source
- patient comfort
- interactive
- security

## The Eldercare Gap

10,000

boomers turn 65 every day

**79%** 

 increase in boomers age 80 or older from 2010 to 2030

1%

 projected increase in number of caregivers aged 45 to 64 from 2010 to 2030

348,000

 projected number of home health aides needed in next decade

## Grey Technologies and Ageing in Place: Independent But Monitored Living for Ageing Populations



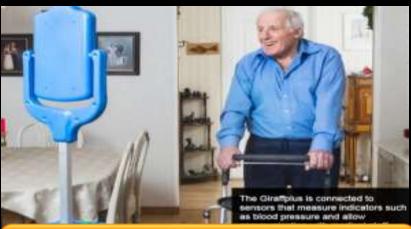
Rx adherence



cognitive stimulation



in-home support and reduced readmissions



reduced office visits

## The Growth of Telehealth and Telemedicine: Expanding the Care Space

- estimated use by 60% healthcare institutions and 50% hospitals\*
- virtual consults in Kaiser Permanente exceeded inperson visits in 2016
- healthcare consumerism and Ux
- 21<sup>st</sup> Century Cures Act and efficacy evaluation projects for Medicare services
  - investment by larger enterprises in centralized telehealth command centers
    - service provision across broad geographies including international
- MD/HCP certification and cross-state licensure

## "The Medical Virtualist" and "Website Manners": The Next Clinical Specialty?

- M. Nochounite et al. JAMA (2017)e17094
- the rise of virtual consultants
  - tertiary to primary care
  - investment by larger enterprises in centralized telehealth command centers
    - service provision across broad geographies including international
  - lack of direct training of MD/HCPs in using virtual systems for patient consultations (website manner)
    - multi-specialty, multi-skill teams
  - MD/HCP certification and cross-state licensure

## **Smart Devices for Automated Drug Delivery** and Improved Therapeutic Adherence









Propeller Health

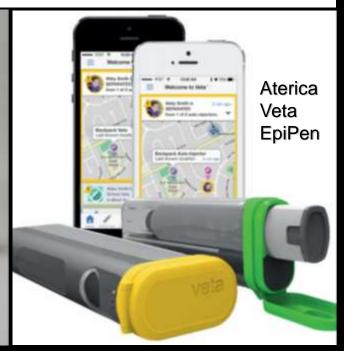
Gecko (now Teva)

CapMedic

Biocorp Inspair







## Chatbots and Support Robots in Healthcare



























Sir Martin and Icon-Bosch CEO discussing partnership on smart dashboards

Vehicles will soon be our most connected device and a hub for our personal data.

Consumers spend an enormous amount of time in the car and will soon be able to use that time more wisely-feeding vital information into a system that can provide encouragement and assistance for living a healthier life.

"Imagine a vehicle that knows whether you're stressed and nudges you to take a breath before the next scheduled appointment. Because it can read your pulse and see your upcoming schedule. A vehicle that can adjust ambient lighting, sounds, and even scents to soothe the driver and passengers. A vehicle that becomes a key component of an active yet balanced lifestyle, working in unison with smart devices in the home and with wearables to generate a more holistic picture of one's vital data." — Mercedes Benz



## 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?

## Regulatory Issues in Digital Health

- Apps used as accessory to regulated medical device
- Apps which transform mobile platform into a regulated device
- application of existing FDA risk-based complexity thresholds (510K vs PMA)
- new requirements for software review and constant Vn updates
- security and privacy
- SEC/State AG enforcement of false claims

## **Defining Value**

- direct acute care savings
  - reduced ER visits, rehospitalization
  - services with easily captured financial metrics
- more complex clinical and econometric evaluation for chronic conditions
  - weight control, HbA1c moderation
  - improved Rx adherence
  - symptom scale improvements in mental health
  - QOL
  - earlier return to workforce/school and duration of benefit
  - 'spillover' benefits on co-morbidities













































































































































































## **Digital Platforms and Clinical Trials**

- faster recruitment by improved screening of potential subjects
- remote health status monitoring, real time data uploads and additional PRO data
- reduced cost and cycle times by fewer site visits
- improved patient compliance with study protocol
- enhanced patient retention by use of virtual visits to reduce time and cost of travel to trial centers

## Digital Platforms in Behavioral Health

## Digiceuticals: Software as Therapy





"We envision empowering individuals with digital therapeutic solutions that address underlying motivational and technical deficits by deciphering neural pathways that support motivation, decision-making and reinforcement to prompt health."

Dr. Ben Wiegand
Global Head, Janssen R&D
World Without Disease Accelerator
PharmaVoice 2017



## About Prescription Digital Therapeutics



#### Prescription Digital Therapeutics, or PDTs, are a new therapeutic class.

Similar to traditional biologics or drugs, PDTs:

- Directly treat serious diseases
- Are built under current Good Manufacturing Practices
- Demonstrate safety and efficacy in randomized clinical trials
- · Receive labeled claims from the FDA
- · Are used by physician prescription
- Are reimbursed as products, via Pharmacy and Medical benefits
- Have barriers to entry that span regulatory exclusivity and intellectual property

### **Digital Therapeutics Alliance**

































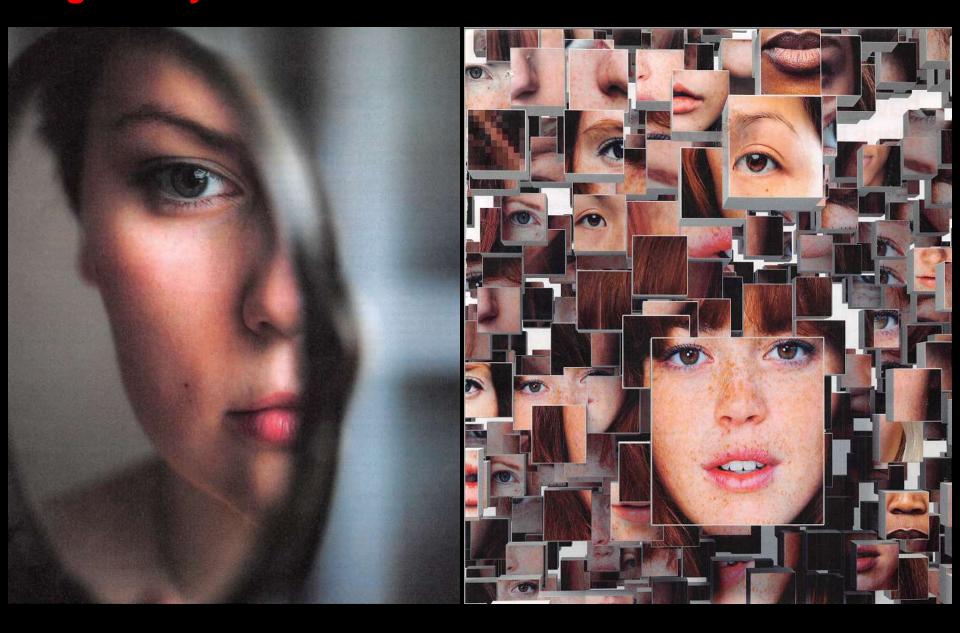








## Digital Psychiatry: Digital Psychometrics and Evaluation of Mental Illness



### Behavioral Health Resources: Disturbing Trends

- more than 60% of practicing psychiatrists are 55 or older
  - one of the highest proportions among all clinical specialties
- number of public inpatient psychiatric beds has decreased by 17% since 2010
- 42 states have less than half of the minimum recommended public hospital psychiatric beds
  - 50 beds/100,000 people
- HHS analysis (Nov. 2016)
  - projected need for up to 10,000 providers to the seven behavioral health professions by 2025 to meet demand

### **Digital Psychometrics and Mental Illness**

- high variation in assessment of same patients by different psychiatrists
- objective measurements of nuanced behavior and visit deltas
  - (micro) saccades, facial dynamics,
  - motor functions, gait
  - speech prosody (rhythm, tone, volume)
  - stimulus response reactions and interaction speed

### **Digital Psychometrics and Mental Illness**

- interaction with digital assistants/chatbots
- machine learning and AI analytics of large video banks
  - bipolar disorder, schizophrenia, depression
  - suicidal ideation
  - PTSD
- signal alerts to care teams when immediate intervention indicated



## Next-Generation Non-Surgical Neurotechnology (N³) Program

- brain-machine (computer) interface technologies
- non-invasive interfaces
- "minimally invasive" technologies
  - ingest chemical compounds that enable external sensors to read brain's activity
- bidirectional information links



#### **Robotics and Human-Machine Interactions**

Brain-Machine Interface Technologies Augmented Sensory, Motor and Cognitive Functions

## **Robot–Human Directed Interactions**

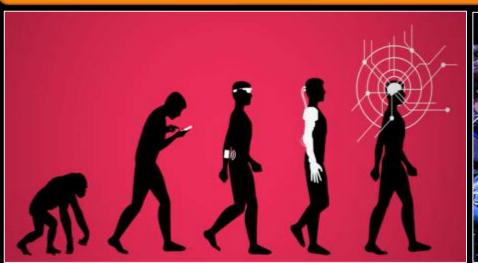








#### Co-evolution of Human-Machine Interactions, Robotics and Augmented Cognition





**VR/AR/MR** and Preparation for Complex Procedures









http://fortune.com/2019/01/09/virtual-reality-surgery-operating-room/

## **VR/AR and Neuromodulation**



- promote behavior change via altered sensory inputs and feedback
- mental illness: PTSD, physical rehabilitation, substance abuse and pain control



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

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

- logical extension to healthcare of rapid rise of web/apps in mainstream culture
- increasingly proactive and engaged consumers/patients/families
- greater access to information on treatment options, cost and provider performance
- new clinical practice tools to optimize physician-patient relationships
- Ux and formation of senior executive level Chief Patient Experience Officer posts in large provider organizations

### **Major Investments in Digital Health by Major Corporations** From Within and Outside of Traditional Healthcare Services































### **Amazon and Healthcare**













# Strategic Acquisitions and Alliances and Entry into Diverse Healthcare Services

- leverage distribution logistics and supply chain scale
- AWS, cloud storage and large scale data analytics
- 310M active customers, 100M Amazon Prime members
- Alexa-Al
  - in-home health concierge and support services?
  - real time HCP resource?
- disintermediation of PBMs and pharmacy wholesalers (PillPack)?
- claims administration and processing (AWS) and new insurance offerings (AMZ-JPM-BH)?
- Whole Foods and creation of new primary care sites?

### **Making Alexa HIPPA Compliant**

#### **HIPAA** Compliance Lead

Job ID: 602824 | Amazon.com Services, Inc.

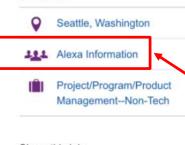


Apply now

#### DESCRIPTION

The HIPAA Compliance Lead is an experienced HIPAA professional who will own and operate the security and compliance elements of a new initiative. You will work alongside product managers, software developers, bizdev, and legal teams to ensure that our services are in compliance with HIPAA security and privacy requirements. Core responsibilities include:

- · Creating a HIPAA security and compliance program to ensure that technology and business processes meet our HIPAA Business Associate Agreement (BAA) requirements, as well as all applicable federal and state laws, regulations and standards.
- Managing all aspects of the program, including employee education and training, monitoring and auditing, conducting and documenting investigations, addressing violations, and monitoring corrective actions.
- · Tracking & reporting against the program's operational readiness goals, to ensure all milestones are met, and that blocking issues are escalated and resolved effectively.
- · Delivering data analysis, metrics and executive dashboards for the program.
- Owning and managing stakeholder communications, providing status as needed and be the point of contact for questions and concerns.
- · Maintaining the program's audit- and inspection-readiness posture.
- · Monitoring relevant federal and state regulations, and modifying the compliance program to accommodate any changes.
- · Acting as a consultative resource for health care regulatory matters.



Share this job

Job details









Was removed after reporters saw the listing

### **Amazon Echo and Home Care**

#### **Development of Third-Party Alexa Apps**



Allows seniors to verbally report medical data, get exercise and adherence reminders, call a caregiver, and coordinate transport



#### Mayo Clinic First Aid

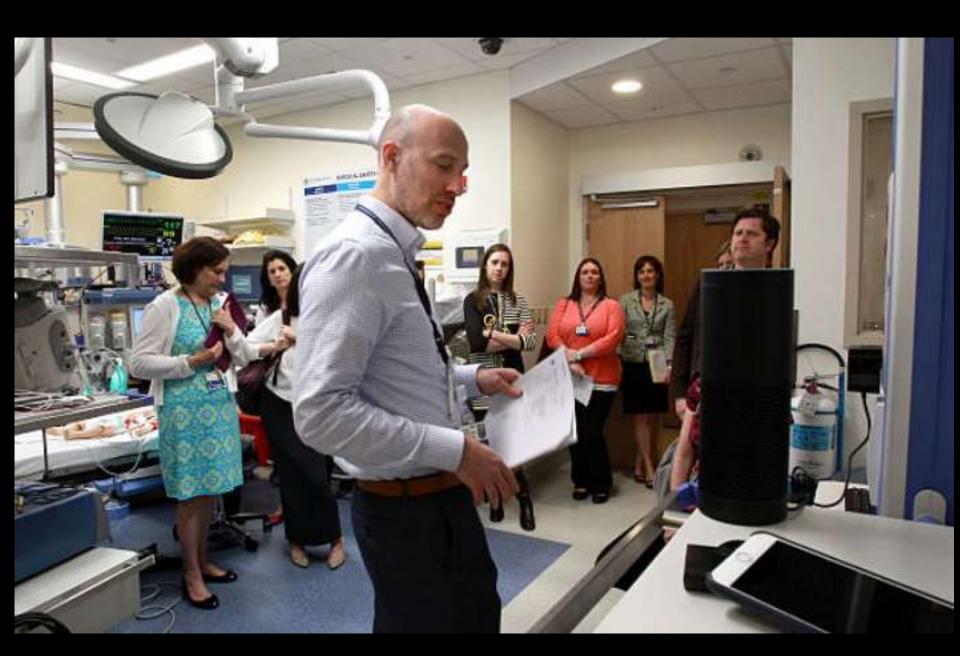
"Tell me about spider bites"

"Help for a burn"



#### Ask My Buddy

"Alexa, ask My Buddy to alert everyone."

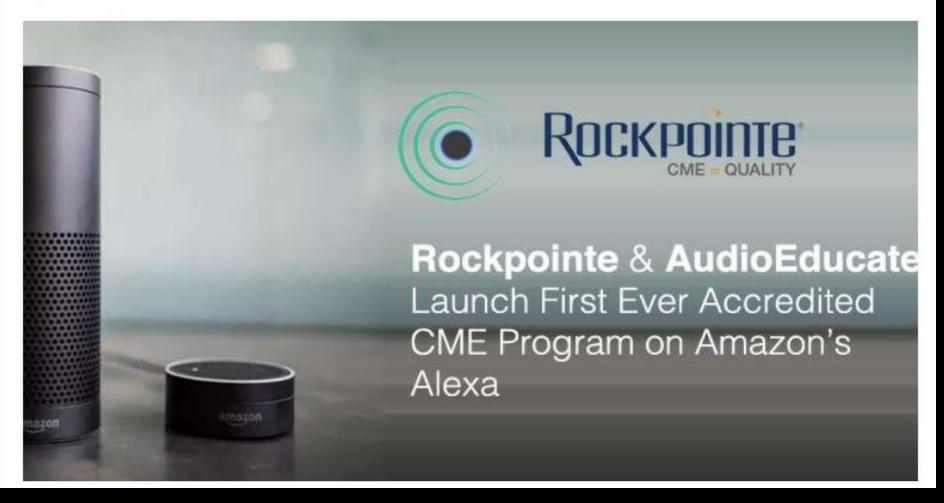


### Rockpointe and AudioEducate Launch First Ever Accredited CME Program on Amazon's Alexa



By Thomas Sullivan - Last Updated Jul 9, 2018





## The Next Competitor for Amazon?





### **BIG TECH IN HEALTHCARE**

How the Big Four tech companies are transforming healthcare in the US

	Alphabet	amazon	Ć	
Strengths	Google Cloud Platform     Al     Cloud infrastructure     Verily Life Sciences	AWS     Alexa     Supply delivery	iPhone consumer base     Apple Watch     App Store frameworks	Azure     Healthcare NExT     Microsoft Genomics
Weaknesses	Fragmentation     Limited clinical evidence     of platform effectiveness	Limited clinical evidence of platform effectiveness     Health system relationships	Audience limited to iOS     Limited clinical evidence of device effectiveness	Muted customer awareness     Small developer community
Opportunities	Population health     Precision medicine     Clinical decision support	Medical supply services     Personalized health benefits	<ul> <li>Personalized health insurance</li> <li>Remote patient monitoring</li> <li>mHealth</li> </ul>	Population health     Precision medicine     Clinical decision support
Threats	AWS' and Microsoft's laas     Data security     Consumer trust	Google's and Microsoft's laaS Incumbent M&A activity Consumer trust	Competing device manufacturers     Non-iOS ecosystem growth     Consumer trust	AWS' and Google's laaS     Data security     Consumer trust



### **Digital Therapeutics Formularies**

**Digital Platforms Formularies** 

## **Digital Platform Formularies**

- analogy with current Pharmacy and Therapeutics ("P&T") Committees
- well developed P&T ecosystem for therapeutics
  - FDA approval
  - SOC guidelines
  - data available for comparative evaluation
  - facile integration into workflow and EHR
  - coding schemes for reimbursement
- comparable and robust ecosystem not yet available for digital platforms

# The Principal Forces Shaping Biomedical R&D and Healthcare Delivery

- sensors
- smart implants

engineering and device-based medicine

- remote health monitoring
- telemedicine
- robotics

molecular (precision)
medicine

- panOmics profiling
- analysis of disruption in biological networks

information-based healthcare

- m.health/e.health
- data- and evidencebased decisions and Rx selection

**BIG DATA** 

outcomes-based healthcare and sustainable health

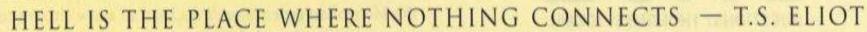
new value propositions, new business models and services

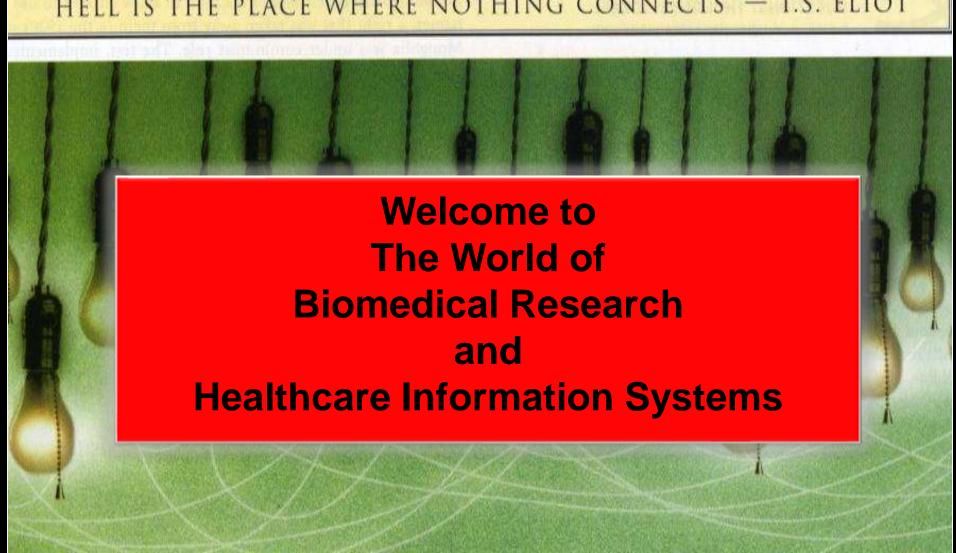
## **Now Comes the Hard Part!**

Driving Precision Medicine and Data-Driven Healthcare Into Routine Clinical Practice

## **Now Comes the REALLY Hard Part!**

The Problem with Real World Data is the Real World



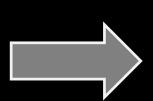


## The Health Information Supply Chain

- fragmented, disconnected, incomplete and inaccurate data
- incompatible data formats as barrier to data integration and sharing
- obstacles to EHR integration of new data classes (multi-Omics; wearables, IoMT)
- legislative barriers to data transfer based on well intentioned privacy protections (HIPAA)
- organizational, economic and cultural barriers to open data sharing
- static episodic snap shots of complex dynamic systems (patients and delivery channels)

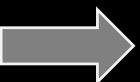
# Precision Medicine and Digital Health: Building a Learning Healthcare System

qualitative,
descriptive
information of
variable quality and
provenance



quantitative data of known provenance and validated quality

of largely unconnected data sources



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

# Precision Medicine and Computational Medicine: Evolving Inter-dependencies

molecular classification of disease and elucidation of disease mechanisms

large
scale
data
aggregation,
curation
and
analysis

RWE and learning healthcare systems

### The Big Data Challenge

V7: volume, variety, velocity, veracity,

visualization, virtualization, value

D3: distributed, dynamic, decision support

13: infrastructure, investment, intelligent systems

# Integration of Molecular Profiling, Clinical and Social Data for Computable Disease Phenotypes

- need for generalizable computational infrastructure for diverse deep phenotyping data classes
  - HL7 Fast Healthcare Interoperability Resources (FHIR)
- 21<sup>st</sup> Century Cures Act requirements for EHR interoperability
- increased payer focus on RWE and value-based contracts
  - new RWE observational trial designs and patient registries

### From Bedside to Bench

- reverse engineering of disease mechanisms from multi-dimensional profiling of disease sub(cohorts)
- increased focus on capture of high quality RWE via observational trials and patient registries
- end-to-end integration of diverse data classes
  - clinical, socio-behavioral, familial pedigrees
  - multiOmics
- dynamics longitudinal mapping of disease risk, progression and outcome patterns
- premium on more systematic and standardized clinical phenotyping

# The Increased Importance of Real World Data (RWD) and Evidence (RWE)

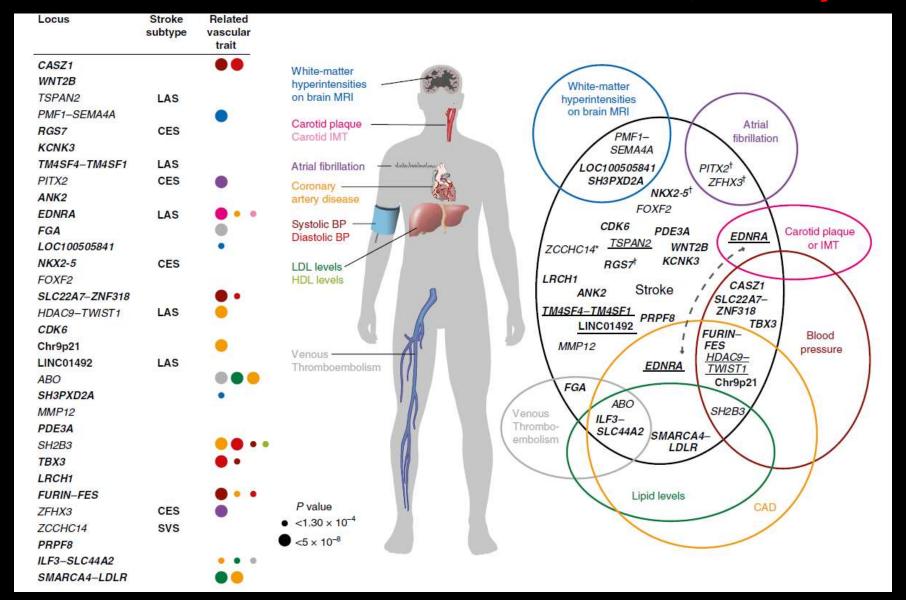


- expanded payer requirements to demonstrate efficacy/utility/value in intended-use population(s) with different characteristics to investigational trial population(s)
  - age, co-morbidities, polypharmacy
  - clinical setting (AMCs, community hospitals, primary care)
- analyze treatment outcomes in sub-populations
- quantify treatment outcomes for value-based contracting

### Use of RWE in Regulatory Decisions Regarding Rx Efficacy

- FDA and payer receptivity to use of external (virtual) control arms generated from EHRs
- Rx approval from single arm trials and RWE-generated historical trials
  - Blincyto for ALL (blinatumomab: Amgen)
  - Bavencio for Merkel cell carcinoma (avelumab: Pfizer-Merck KGAA)
  - Tecentriq (atezolizumab) for 2L NSCLC (Roche-Genentech-Flatiron)\*
  - Alecensa (alectinib) for NLSC (Roche-Flatiron)\*
  - Opdivo (nivolumab) for esophageal cancer (BMS-Flatiron)\*

## Genetic Overlap Between Stroke and Related Vascular Traits at 32 Genome Loci for Stroke Profiled in 520,000 Subjects



### Nature (2018) 562, 203

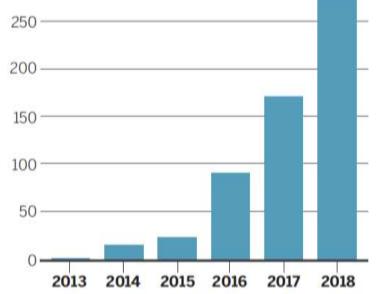
# The UK Biobank resource with deep phenotyping and genomic data

Clare Bycroft<sup>1,13</sup>, Colin Freeman<sup>1,13</sup>, Desislava Petkova<sup>1,12,13</sup>, Gavin Band<sup>1</sup>, Lloyd T. Elliott<sup>2</sup>, Kevin Sharp<sup>2</sup>, Allan Motyer<sup>3</sup>, Damjan Vukcevic<sup>3,4</sup>, Olivier Delaneau<sup>5,6,7</sup>, Jared O'Connell<sup>8</sup>, Adrian Cortes<sup>1,9</sup>, Samantha Welsh<sup>10</sup>, Alan Young<sup>11</sup>, Mark Effingham<sup>10</sup>, Gil McVean<sup>1,11</sup>, Stephen Leslie<sup>3,4</sup>, Naomi Allen<sup>11</sup>, Peter Donnelly<sup>1,2,14</sup> & Jonathan Marchini<sup>1,2,14</sup>\*



### **Engine of productivity**

Published papers based on the UK Biobank's bounty of health and genetics data are piling up fast, in part because the data are freely available.



Science 04 Jan 2019:

Vol. 363, Issue 6422, pp. 18-20

DOI: 10.1126/science.363.6422.18



# Big Data and Social Determinants of Health (SDOH)

- lifestyle information on 280 million Americans
- "psychographic" analytics used in other sectors to ID/influence specific individuals
- claims to integrate 442 separate attributes to calculate an individual's health risk score\*
- 'stealth' entrant and complex consent and privacy issues

\*M.L. Millenson (2018) NEJM Catalyst 5 June 2018

# Protection and Privacy Provisions for Personal Healthcare Data

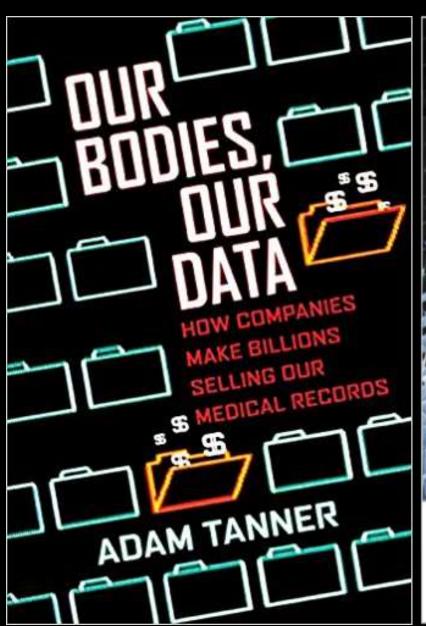
- informed consent
- legal provisions/ penalties for breach

identifiable individual data

aggregated de-identified databanks and metadata

- variable levels of consent
- probabilistic, multiparameter individual 'match'

## Data Brokers and 'Selling-On"





THE RISE, FALL AND RISE AGAIN OF **23ANDME** 

### **National Security Implications of Genome Data on Populations**

### **Population Databanks**

### **Individual Profiles**





**Foreign Access to Data** 

**Data Security** 

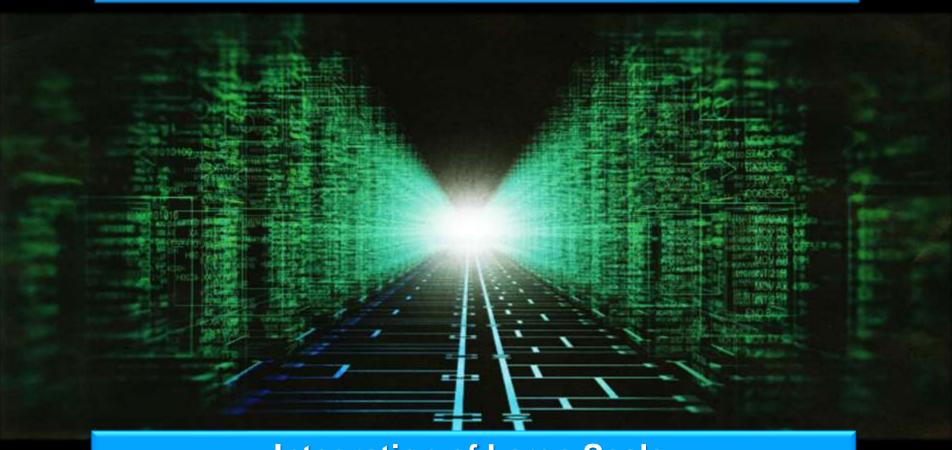






## Big Biology and Biomedicine Meets Big Data

The Pending Zettabyte Era 1,000,000,000,000,000,000,000



**Integration of Large Scale, Multi-Disciplinary Datasets** 

# Artificial Intelligence, Pattern Analysis and Medical Practice



"I don't think any physician today should be practicing without artificial intelligence assisting in their practice. It's just impossible otherwise to pick up on patterns, to pick up on trends to really monitor care."

Bernard J. Tyson
CEO, Kaiser Permanente
Cited in Forbes: The Future of Work
1 March 2017



"By far the greatest danger of artificial Intelligence is that people conclude too early that they understand it."

Eliezer Yudkowsky

Machine Intelligence Research Institute, Berkeley
O'Reilly Artificial Intelligence Conference

May 2017



### 60+ STARTUPS USING DEEP LEARNING

#### CORE AI: COMPUTER VISION



#### CORE AI: OTHER



#### BI, SALES & CRM



#### **CORE AI: VOICE** INTERFACE



#### **ROBOTICS & AUTO**

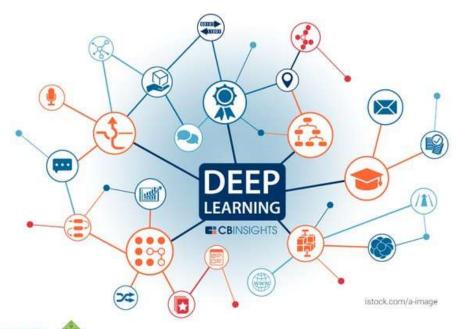






#### **HEALTHCARE**





#### SECURITY



OTHER

S Alpaca indico

( Iris Automation

#### E-COMMERCE

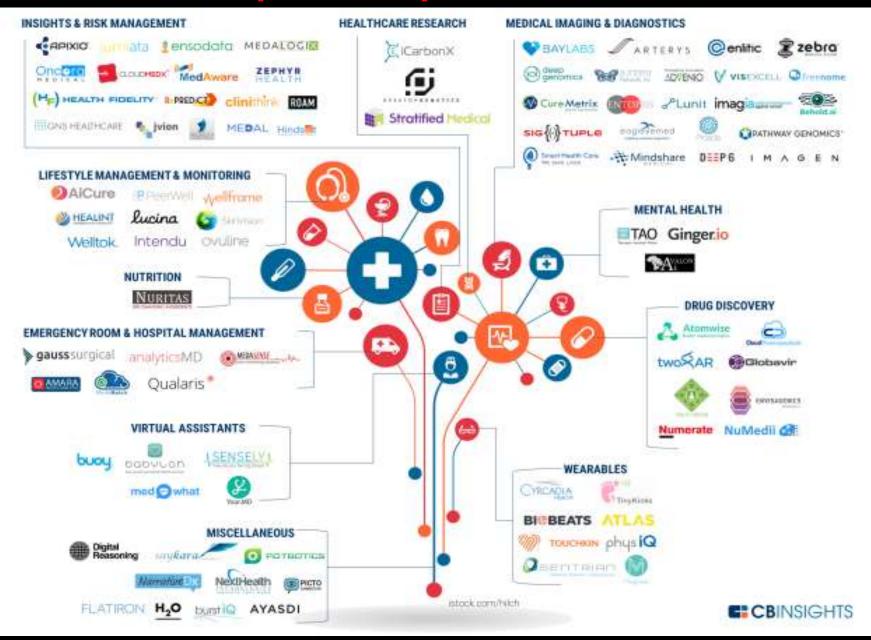








## 90+ Startup Al Companies in Healthcare



### Machine Learning and Image Analysis in Clinical Medicine



- large scale training sets and classification parameters
- standardized, reproducible and scalable
- 260 million images/day for \$1000 GPU

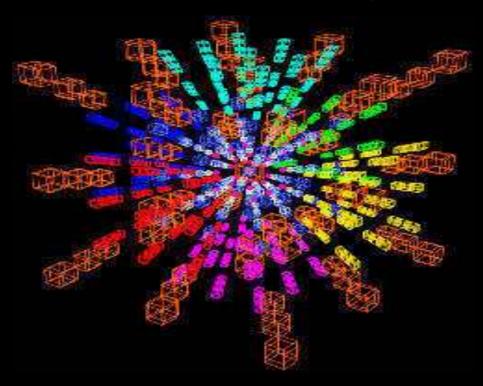
The Future of 'Search' and 'Retrieval'

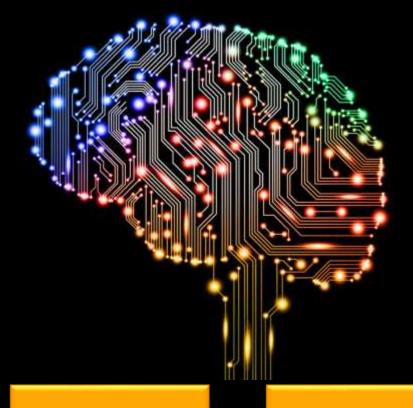
**Deep Understanding of Content and Context** 

Collapse Time to Decision: Intelligence at Ingestion

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

## Automated Context: Data Finding Data "Intelligence at Ingestion"





Feature
Extraction
and
Classification



**Context Analysis** 



Persistent Context



Relevance MappingLearning

Learning Systems



Situational Awareness

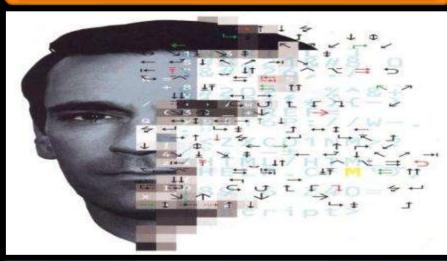
Rapid,
Robust
Decisions

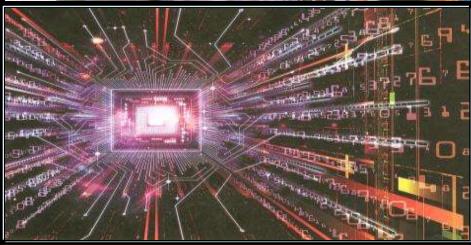
# Technology Acceleration and Convergence: The Escalating Challenge for Professional Competency, Decision-Support and Future Medical Education

### **Data Deluge**







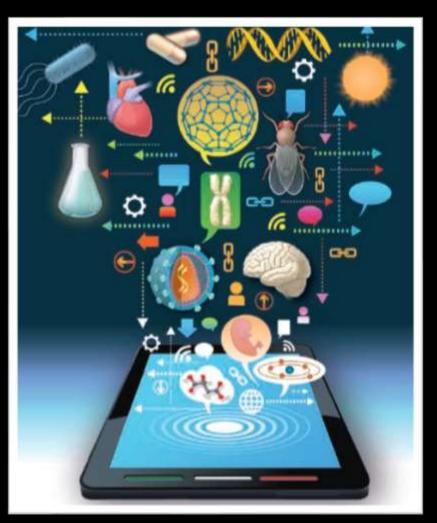




**Automated Analytics and Decision Support** 

**Facile Formats for Actionable Decisions** 

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

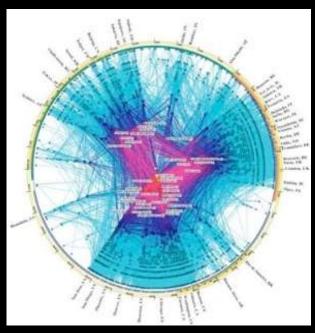


- limits to individual expertise
- limits to our multi-dimensionality
- limits to our sensory systems
- limits to our cognitive experiences and perceptions
- limits to our objective decision-making

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







Isolated Data

Complex Networked Data

Complex Computational Data

# A Pending Transition in Biomedical Research and Clinical Care Decisions?

- descriptive qualitative data
- hypothesis-driven inquiry

- quantitative data
  - large scale data mining
- automated analytics
- clinical decision support systems

hypothesis-driven dominant

data mining dominant

# "Digital Darwinism": A Looming Digital Divide

- understanding data structure and its productive application/customization for improved decisions and clinical outcomes will become a critical institutional competency
- major skill gaps and personnel shortages in biomedicine
- training of a new cadre of data scientists (medical and non-medical)
- institutions lacking adequate computational infrastructure and critical mass in data analytics will suffer 'cognitive starvation' and relegation to competitive irrelevance

### **Just What the Data Ordered**

### Machine Intelligence and Algorithms for Clinical Diagnosis and Treatment Decisions

**Black Box Medicine?** 

### Internal IBM Documents Reveal IBM Watson Recommended "Unsafe and Incorrect' Cancer Treatment



C. Ross (2018) STAT 25 July

- training used synthetic case histories versus RWE
- statistically underpowered training cohorts
  - 635 lung, 106 ovarian
- input from too few physicians (typically 1-2) on recommendations for each cancer type
- "raises serious questions about the process for building content and the underlying technology."

## 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?

# Machine Learning (ML), Artificial Intelligence (Al) and Healthcare

- how will ML-Al algorithms/decision analytics be validated/regulated?
- how will ML-Al tools be integrated into current work flow?
- will radical reorganization/re-training be required?
- how will ML-Al platforms alter payment schemes?

# Machine Learning (ML), Artificial Intelligence (AI) and Healthcare

- which clinical specialities/processes be at risk of replacement by ML-Al and when?
- how will professional competencies in using ML-Al decision-support tools be developed and sustained?
  - MD curriculum, CME
  - non-medical data science professionals
- what new malpractice liabilities will emerge by failure to use/interpret ML-AI platforms

## "Explainable AI" Keeping Humans in the Decision Loop



- need to better characterize the evolution of decision algorithms
- deconvolution of how and why machine learning algorithms reach flawed conclusions
- broad national security issues related to data integrity
- concern over Al-directed manipulation of social networks, advertising and personal data
- corruption of critical military and civilian systems and decision tools

### The Future of Work and The Future Workforce



Independent Task Force Report No. 76

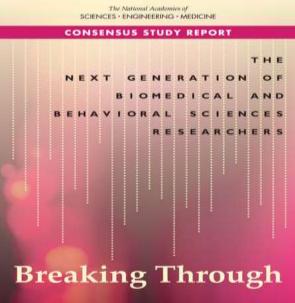
#### The Work Ahead

Machines, Skills, and U.S. Leadership in the Twenty-First Century

John Engler and Penny Pritisker, Closes Edward Alden, Project Director Laura Taylor-Kale, Deputy Project Director

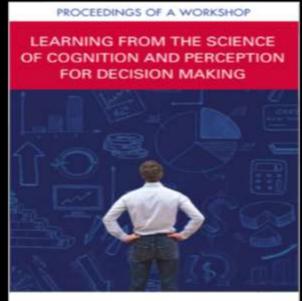
Cognitive Diversity: AI & The Future of Work







Global strategy on human resources for health: Workforce 2030



The factoreal Assistance of SCENCES - ENGINEERING - MEDICINE

#### PROCEEDINGS OF A WORKSHOP

MOTIVATION NATIONAL ARTIFICIAL SKILLS RECRUITMENT SECURITY INTELLIGENCE GROWTH ANALYSIS TEAM SCIENCE KNOWLEDGE CAREER COMMUNICATION ARRIVES ACTIVABLE AUTOMATION SELECTION EXPERIENCE INTELLIGENCE SENSEMAKING GROWTH MANAGEMENT ANALYSIS TRAINING DIVERSITY CAREER LEADERSHIP AULITIES WORKFORCE SKILLS TEAMWORK EDUCATION

WORKFORCE DEVELOPMENT
AND INTELLIGENCE
ANALYSIS FOR NATIONAL
SECURITY PURPOSES

The National Academies of SCIENCES - ENGINEERING - MEDICINE

THEN COMMUNICATION

### **New Patterns of Learning**





#### **Major Transitions in Medical Education and Healthcare**



UNITED STATES AND CANADA

A REPORT TO

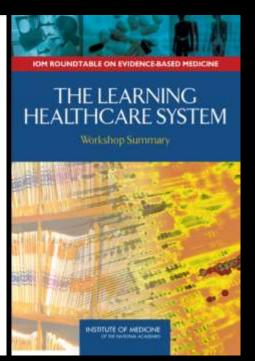
THE CARNEGIE POUNDATION FOR THE ADVANCEMENT OF TEACHING

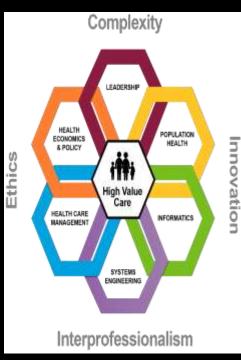
ABRAHAM FLEXNER

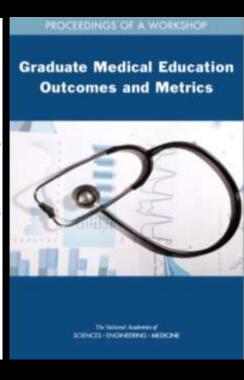
WITH AN INTRODUCTION BY HENRY S. PRITCHETT PROBEST OF THE PERSONS

SCLLATIN NUMBER FORE (1968) (Republish in 1970) (Republish in 1970)

OF MADONON ATENUE NEW YORK CITY DOOR







1910 - present

2000 - present

2015 - ?

(science-centric)

healthcare as a learning system (data-centric)

mastery of escalating complexity and massive data (network-centric)

### Major Opportunities (and Needs) in Education and Training in Complexity Science, Computing and Decision Science

- online interactive learning
- web-based collaboration tools
- multi-institutional education and training
- externships, public: private partnerships for future workforce preparation

### Six "...ates" for Survival in a Data-Intensive Ecosystem

- navigate
- integrate
- authenticate
- collaborate
- innovate
- differentiate

# The Future of Healthcare: Precision Medicine and Digital Medicine

new technology platforms automation and computing **multiOmics** profiling sensors, robotics

the expanded care space

wearables, sensors, telemedicine

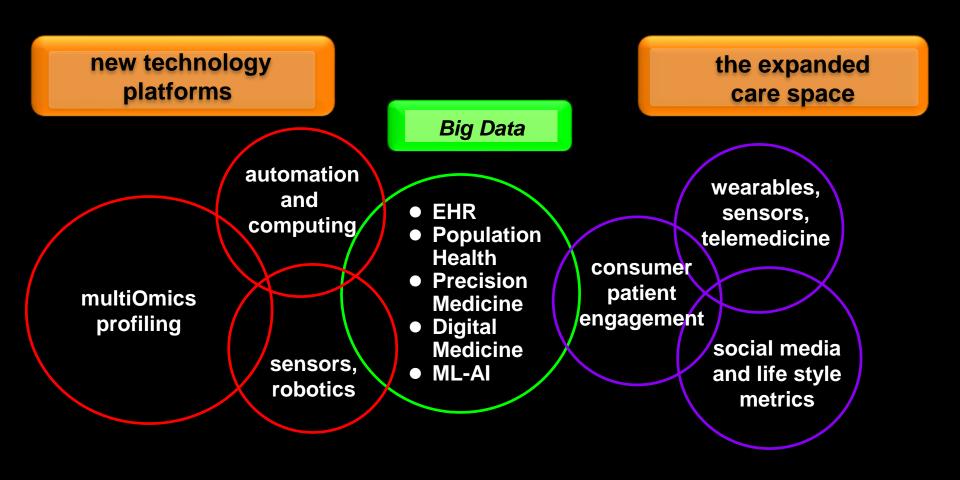
consumer patient engagement

social media and life style metrics

deep phenotyping and risk profiling

remote monitoring of health status

## The Future of Healthcare: Precision Medicine and Digital Medicine



deep phenotyping and risk profiling

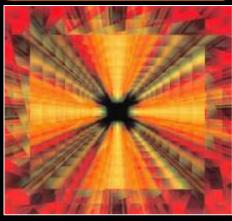
analytics for improved decisions and clinical outcomes at lower cost (value)

remote monitoring of health status

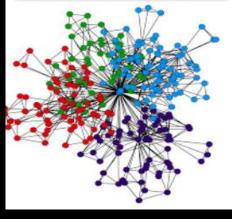
#### The Evolution of Data-Intensive Precision Medicine

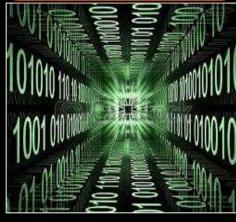
Technology Convergence and Acceleration Mapping Geno-Phenotype Complexity Topology of Biological Information Networks

V7 Big Data



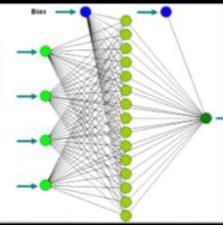












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Data Security and Privacy

**Robotics and Human Machine Interactions** 

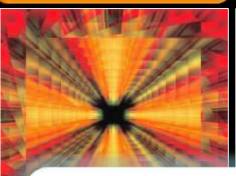
Artificial Intelligence and Decision Support

Ethics, Risk and Regulation

#### The Evolution of Data-Intensive Precision Medicine

Technology Convergence and Acceleration Mapping Geno-Phenotype Complexity Topology of Biological Information Networks

V7 Big Data





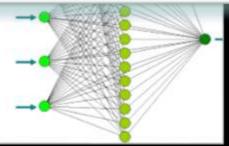




Slides Available @ http://casi.asu.edu/presentations







Data Security and Privacy

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Artificial Intelligence and Decision Support

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