

# The Galileo Project

# Digital Health

Implementation of Regulatory Information & Submission Standards  
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- Can you imagine a world in which all health systems use the same data elements and collect the same data for the same purposes and have agreements in place that permit sharing and access to data for research while protecting patient privacy?
- What might be the impact on you, if this were true?
- Might this be true in 5 years, 10 years, 20 years, 50 years, or never?



# Mirror, Mirror, 2021 Reflecting Poorly

	AUS	CAN	FRA	GER	NETH	NZ	NOR	SWE	SWIZ	UK	US
Overall	3	10	8	5	2	6	1	7	9	4	11
Access to care	8	9	7	3	1	5	2	8	10	4	11
Care process	6	4	10	9	3	1	8	11	7	5	2
Admin Efficiency	2	7	6	9	8	3	1	5	10	4	11
Equity	1	10	7	2	5	9	8	6	3	4	11
Health care outcomes	1	10	6	7	4	8	2	5	3	9	11

Source: Eric C. Schneider et al., *Mirror, Mirror 2021 — Reflecting Poorly: Health Care in the U.S. Compared to* (Commonwealth Fund, Aug. 2021). <https://doi.org/10.26099/01DV-H208>





# The Galileo Project

*How do we fix the Health Care System?*

- The Galileo Project has as its objective to define the PERFECT Health System.
  - Health Care is a sub-component.
- The goal is not to address perceived problems of today, but to step into the future.
- Have held two “thinking aloud” Zoom sessions involving over 25 clinicians in 2020 and one additional session in 2021 with over 20 primarily Allied Health Staff
  - Invited initial thoughts shared in group
  - Divided into 5 breakout groups. Panelists were leaders of the breakout groups.
- Only constraints
  - Can’t say “you can’t do that because ...”
  - Can’t say “that’s impossible”
  - No boundaries – no comment is out of scope.



# Why Galileo?



- The present healthcare system is broken, and our approach to fixing it is flawed.
- We focus most frequently on the wrong problem.
- We focus on a single problem, and we are constrained by having to fit the solution into an existing system.
- We start with an assumed solution and attempt to solve the problem within the capabilities of whatever solution we have decided to use.
- We start with what we have and know, rather than looking for the best solution.



# Why we are not solving problems



- We spend much of our time and money doing work-arounds rather than facing the true hard problem.
- We tackle today's problem with tools from yesterday.
- We assume the barriers that currently exist are here to stay, and anything new we do must fit within those boundaries.
- We provide multiple different solutions then spend even more time in trying to harmonize the multiple solutions.
- We never look to see if someone else has solved the problem or are at least currently addressing it.



# Life today



- Physician and nurse burnout are prevalent.
- There is no equity in health care today.
- Most popular EHR systems are aged (EPIC – 1976).
- New technology is not being used.
- Reimbursement drives what data is collected and how it is coded. Claims databases are used for observational research.



You can't get the perfect  
system by fixing  
today's system.





# The first step toward perfect **PATIENT FIRST**

- Without patients, we would not need a health care system.
- Therefore, patients should be the center piece of the perfect system.
- We must approach every function from that perspective.
- What should we do to provide the most value to the patient?



# Perfect - for the patient

- There must be equity in health and health care.
- Access to care – whenever and wherever it is needed
- Service rendered cannot be influenced by what the insurance will pay but what is needed
- The appropriate medicine or treatment must be available to every person
- Health literacy is essential, therefore taught



# More for the patient

- Patient navigation of the system should be enabled.
- Bring clinicians to patient, not patient to clinician.
- Mental Health should be an equal service.
- Virtual visits
- Home hospitalization whenever possible
- Once health system accepts a patient, it should accept full responsibility for that person



# New Voices must be accommodated

- Patients, consumers, citizens or what ever we wish to call them have an influence in health and health care.
- “Googling” has opened the knowledge and understanding of disease for the non-professional to change the communication between physician and patient.
- Shifting care outside traditional settings
- Data collected and analyzed in real time becomes more responsive.
- Patients want to push this data back into their EHR.
- Wearable sensors enable real-time detection of problems



# Patient Communication

- Every patient should have access to the Internet.
- Every patient should have a device capable of digital communication and interaction.
  - Smart phone
  - iPad
  - Computer
- Patient should have access to all their health data, delivered in an understandable language.



# COMMUNITY



- The community engages in the health system.
- The community must accept equal responsibility for the patient with the health system.
- This responsibility means issues of transportation, access to health food, access to social events, access to parks for exercise, and provide person safety and health and education.



# What is a perfect health system for clinicians?

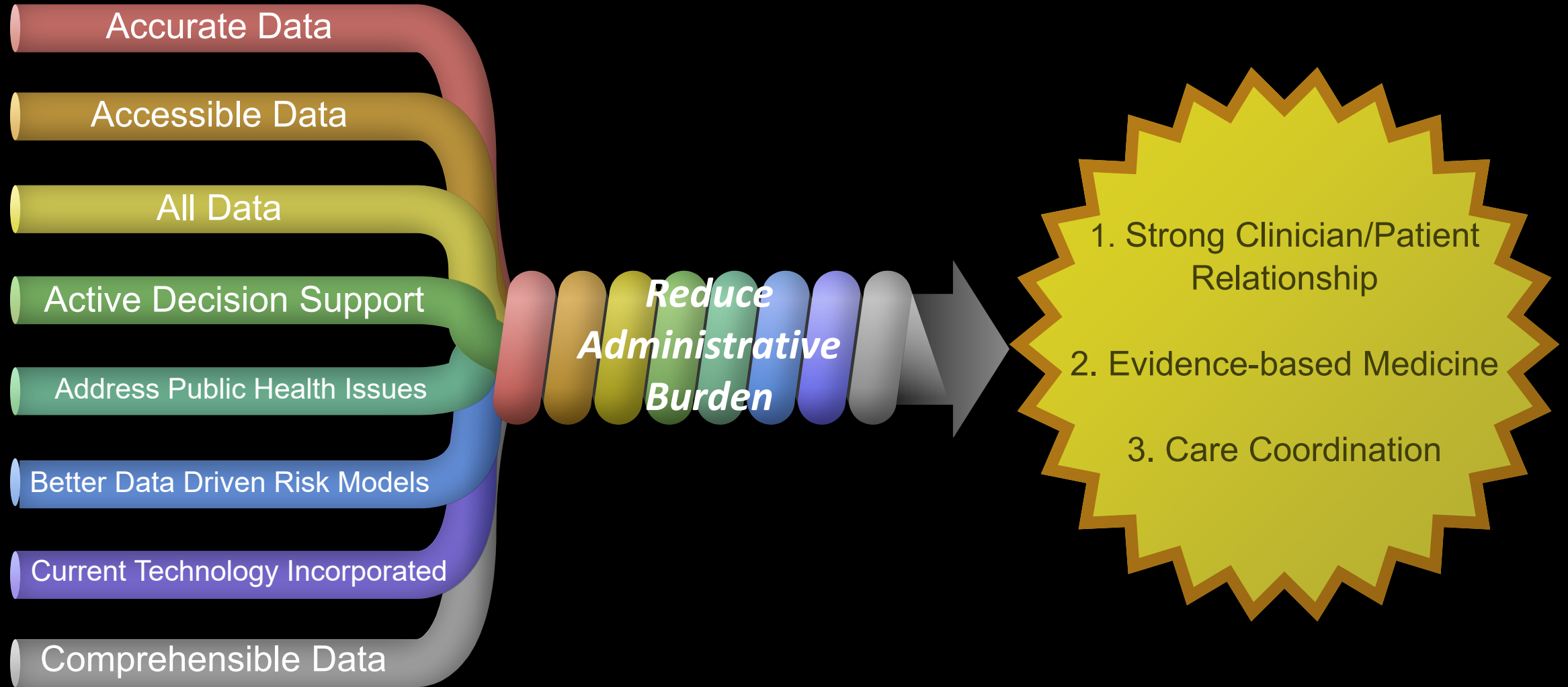
- Access to any and all data about a patient.
- Longitudinal presentation of patient data, aggregated across all sources
- High quality and trustable data available when and where needed.
- Presentation of data as the clinician wants to see it.
- We all speak the same language – a seamless world of data.
- New forms of data capture – much data capture is automated.
- Use of AI to reduce finding the right data among Big Data.





# Clinicians and the Health Care System.

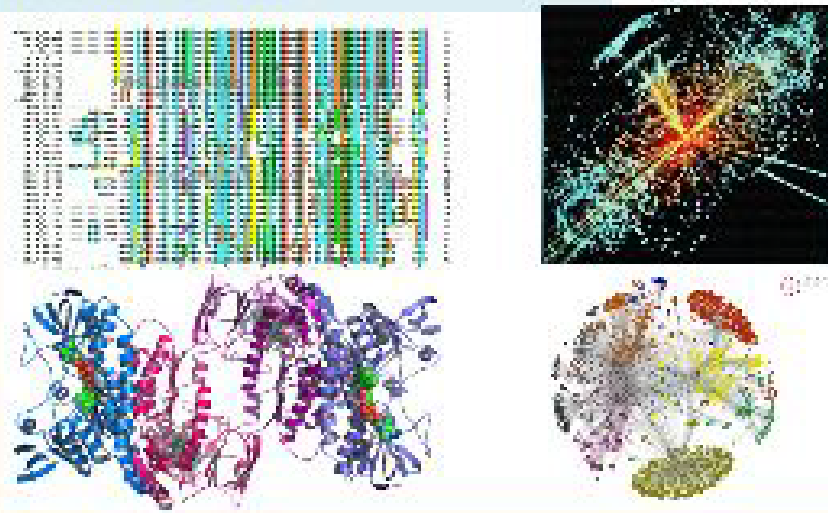
*What do clinicians want?*





# What they are faced with: Today everything is a source of data

## Scientific Data



## Digital Media



## REQUIRES

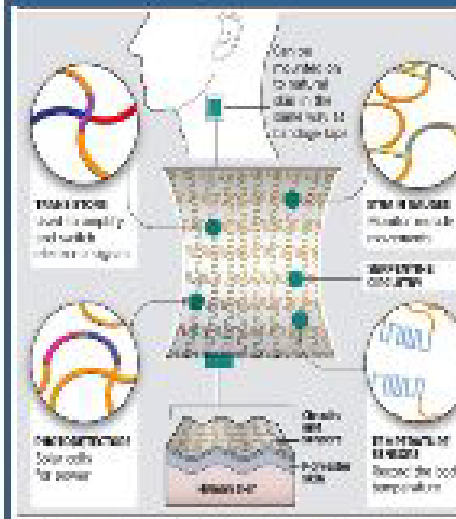
- Data Liquidity
- Data Sharing
- Data Standards

## Human Sensors



Source: Sajal Das, Kevin Marzullo

## Health Care



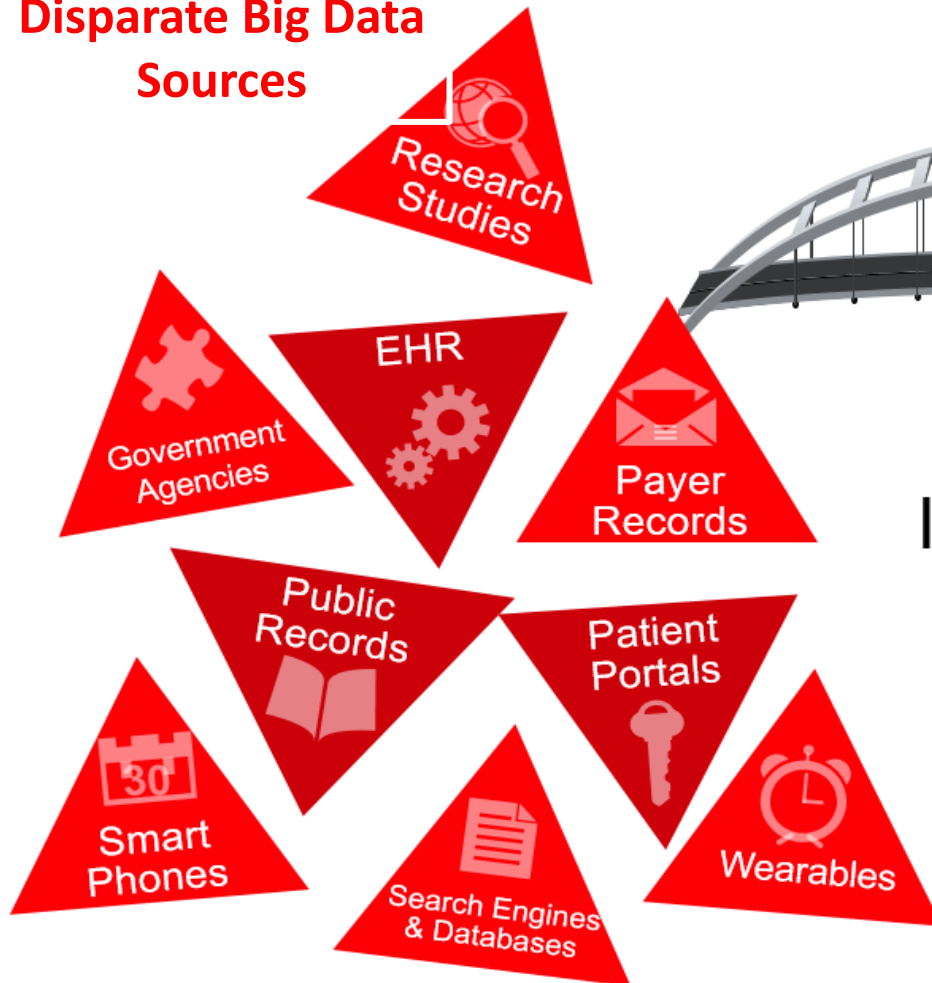
## Public Health



# Clinicians and the Health Care System.

*What do clinicians want?*

## Disparate Big Data Sources



## Systemic Big Data Integration



## Integrated "Universal" Big Data System



# Technology and the Health Care System

*What do clinicians and patients want?*

## EHR Technology Building Blocks

- Storage: Cloud versus Standard
- Data Exchange Standards
  - HL7
  - SMART on FHIR
  - CDS Hooks
- Data Metadata Tagging Standards (LOINC, ICD10, RxNorm etc)
- Data Lakes
- NLP/AI/Voice Recognition
- Effective User Interface



**Support Human Cognitive Understanding and Actions**

# Galileo Project

- Who should define the perfect health system?
  - Patients – but which patients?
  - Community – but who in community?
  - Clinical Professionals including affiliated professionals
  - Payors
  - Government including regulators



# Galileo Brainstorming Groups

- Physicians, PAs
- Allied Health Professionals
- Nurses, NPs, Midwives
- Older people
- Race minorities (together or separate)
- Disparities
- LGBTQ+
- Community Group
- Technical (IT and data scientists)
- Medical Students
- Teenagers
- Local public health groups
- Mothers with children, 5 yo
- Pregnant women
- Nursing home residents
- Clinical Workflow
- Local Public Health

# The Human Metric Project

- If we knew everything about a person, could we do a more optimal job of guiding an individual to the highest quality of life and the longest possible length of life? That is the basis of the human metric project.
- But this project is more than that. It identifies the types of data we must collect – clinical, behavioral, social determinants of health, economic, geospatial, genomic, and environment.
- It addresses first issues of common and consistent data elements, including a common language. It addresses how data is collected. It addresses how data are used. It addresses various packaging of data.



# A Perfect World



- Common set of data elements with rich attributes including a data numeric identifier
- Embedded knowledge within data elements
- Standardize data collection – methods, data elements, and contents
- Establish trust, data quality, consistency
- Full provenance – know how, when and where data collected



# Data elements value enhanced



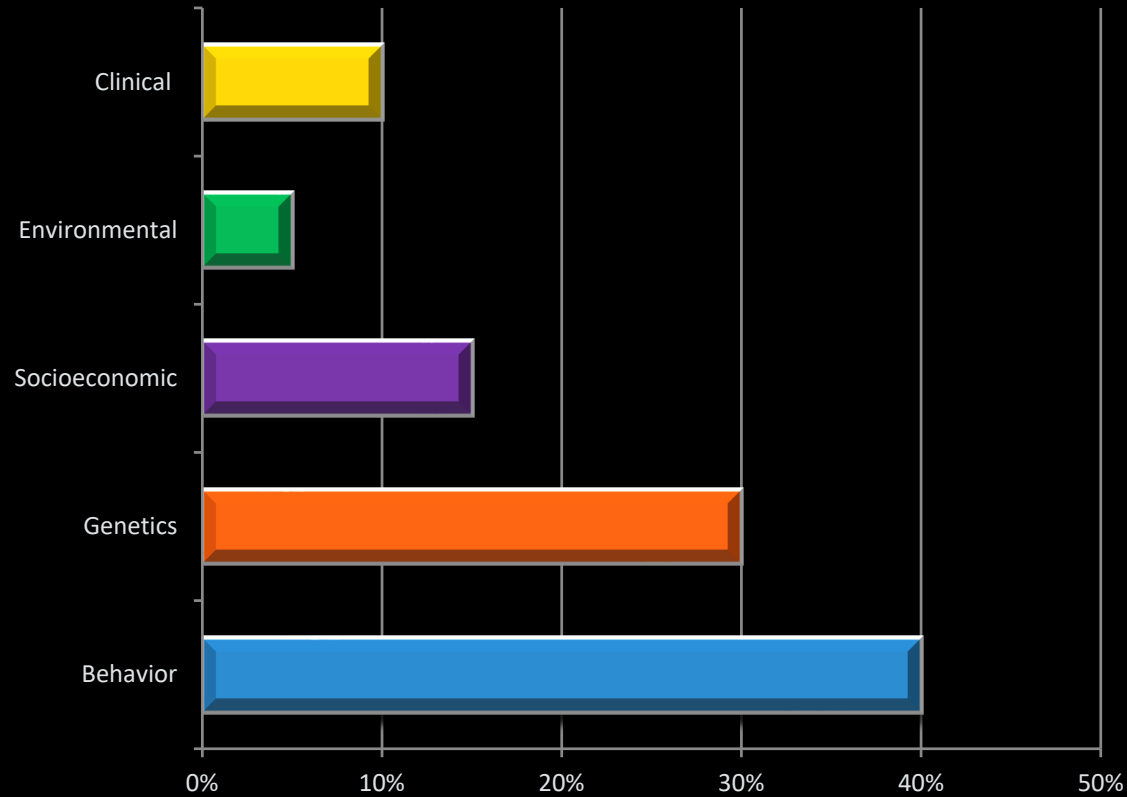
- Create structured sets of data elements into larger groupings
  - Simple cases such as blood pressure, heart murmurs
  - More complex sets such as echocardiogram, cardiopulmonary exercise testing
  - Structures to capture complex phenomena yet are easy to work with
  - Functional sets such as well baby work-up, pediatric growth, kidney function, maternal health
  - Phenotypes – diagnostic, treatment, monitoring
  - Tracking Covid patients (and others) across time and space
  - Registries
  - Computable knowledge built into the data element
  - Any defined purpose for a standardized grouping of data elements





# New kinds of data

## Social Determinants of Health

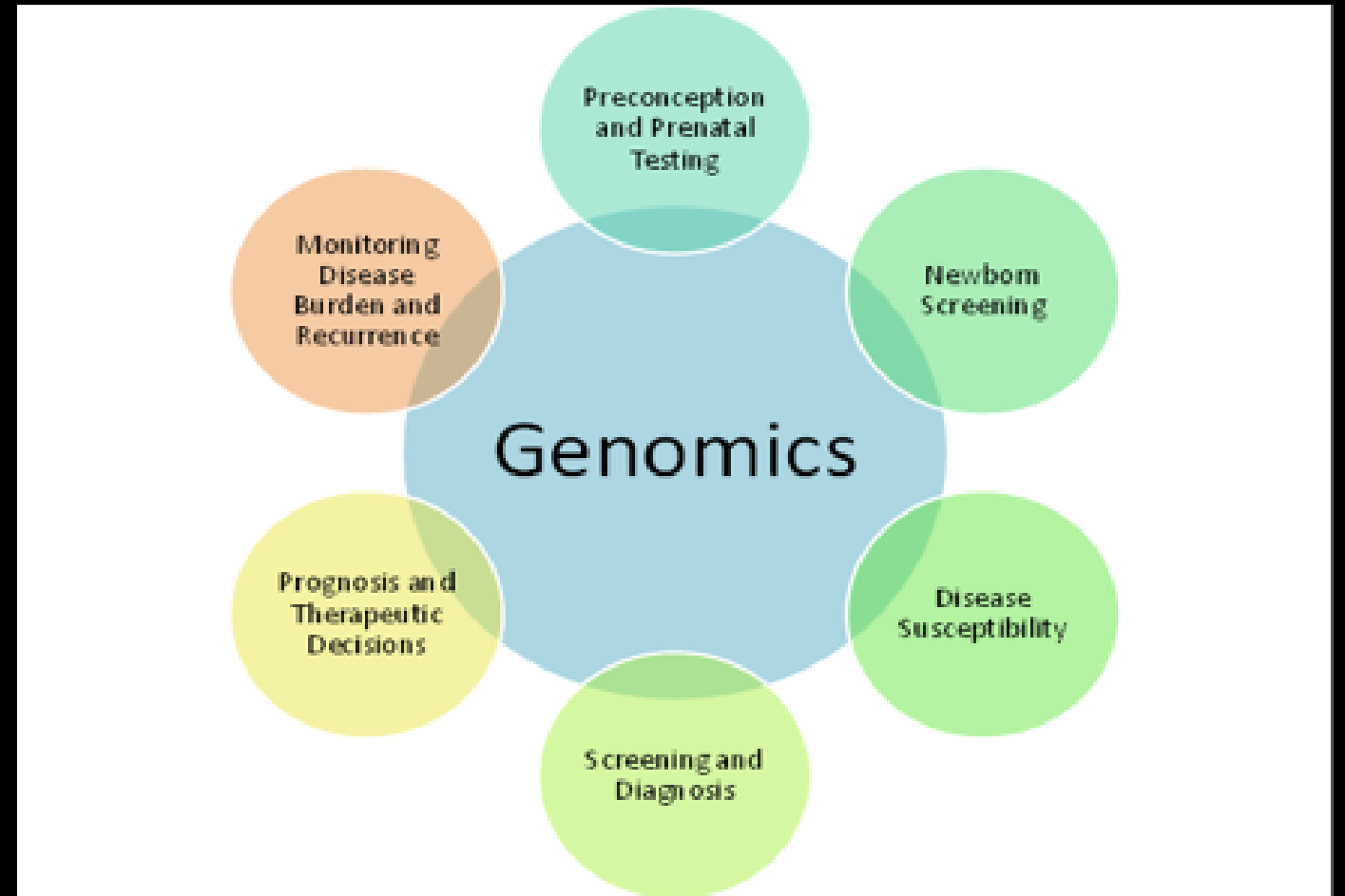


Impact on quality and length of life





Widening Impact from  
pre-birth and  
throughout life

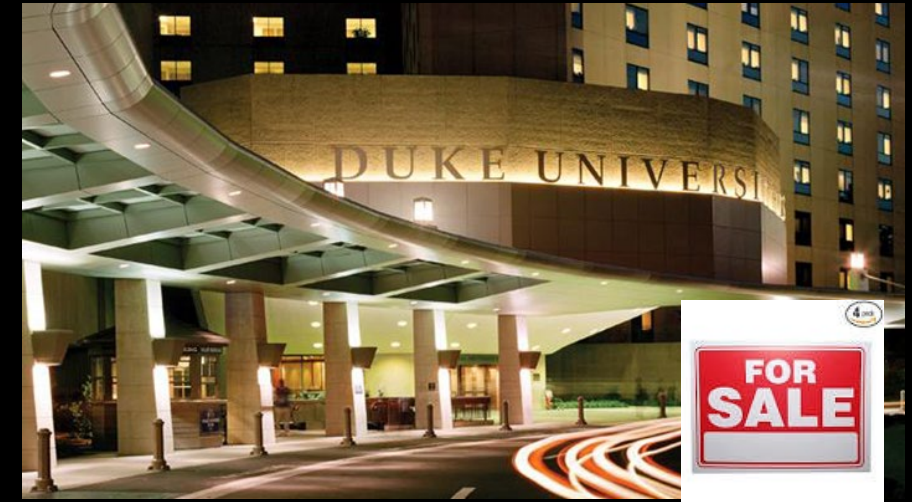


Source: MINC



# Mobile Devices

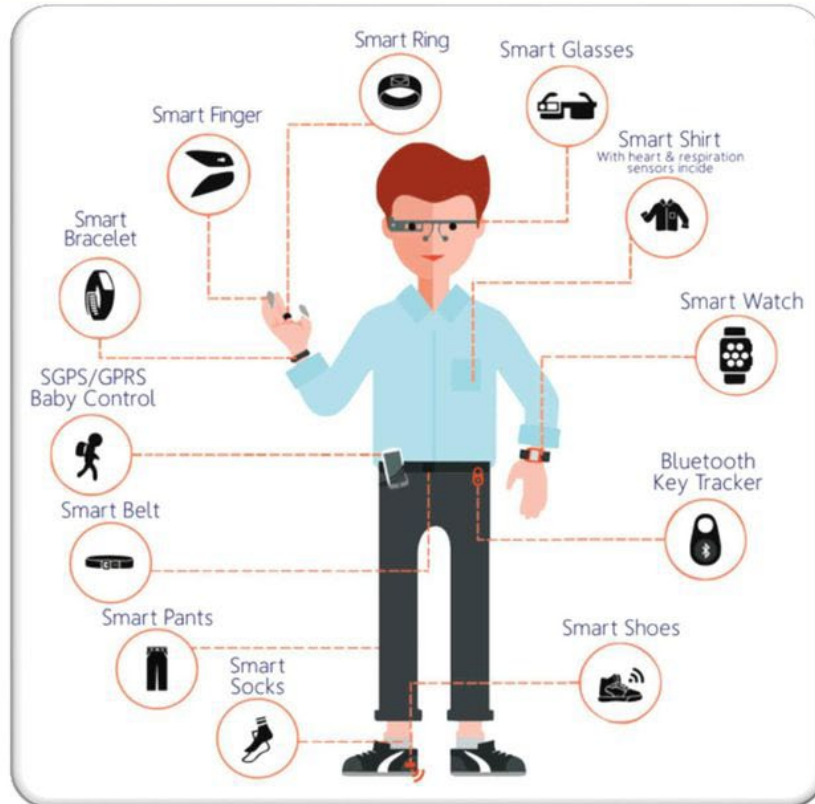
- The ubiquity of smart phones has changed communications between and among groups. A virtual visit will replace an office visit.
- Wearable sensors will give real time data about the person resulting in early interventions.
- Smart phone apps can be used for data collection by text, check boxes, and photographs with sufficient resolution to make clinical diagnoses in many areas such as dermatology.
- Smart phones can be used for education, behavior modification, and more.



Brick and mortar institutions will be replaced by virtual healthcare systems.



## Types of Wearable Medical Devices based on site of Application



Measure your blood oxygen level with a revolutionary sensor and app. Take an ECG anytime, anywhere. Check your heart rate. Along with other innovations like mindfulness and sleep tracking to keep you healthy from head to toe. Series 7 puts more health insights in sight.

# The New EHR

- Supports multiple use of data rather than secondary use.
- All data related to the patient is stored in a single virtual container labeled data box.
- Data box performs REST services – Create, read, update, delete
- Data storage is independent of data use.
- Use functionality is performed independently by functional apps.
  - Permits keeping up with new technology and new requirements
  - Allows specialization of data presentation and use
  - Enables competitive market
- Supports query based interactions: pull over push

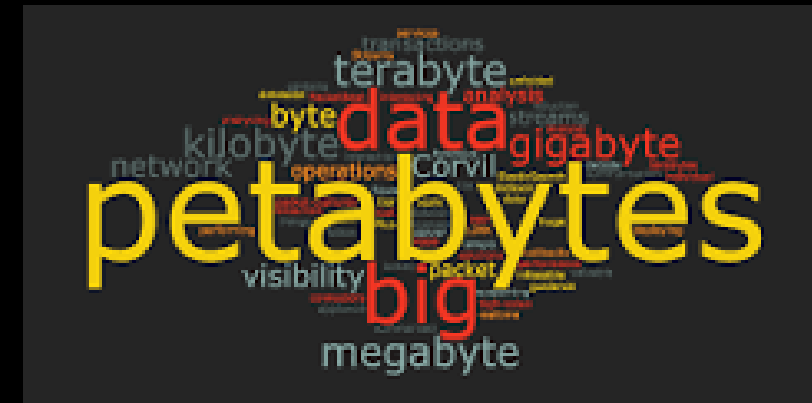


# Big Data and Its Impact

- Big Data is a consequence of more things that create data and more initiatives to merge data.
- For a single patient, we are talking about petabytes of data; for a aggregated database of multiple patients, we are talking about exabytes or more.
- Computable knowledge is an award of Big Data.
- Requires new and innovative methods of analyses to create new knowledge
- NoSQL databases making their appearances to provide higher speed necessary for analyses.



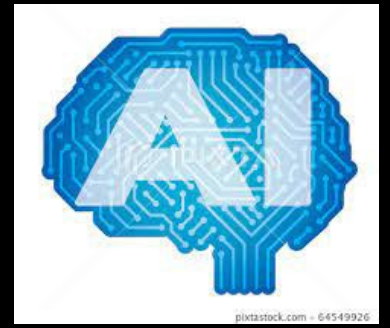
COVID requires tracking patients and aggregation of data across multiple sites.



In 2020, we create 463 exabytes of new data daily.



# Artificial Intelligence



- Knowledge exceeds the ability of humans to use available facts to make decisions
- Computers are becoming able to learn from data and knowledge that is available on the internet and other sources. Computers are becoming self-aware. Create new knowledge.
- Driver for new groups entering the HIT marketplace: Google, Apple, Microsoft, Amazon, others
- When will computers become smarter than humans?
- What will be the role of computers vs humans?





# Artificial Intelligence at Duke



- Researchers at Duke use the tools of artificial intelligence to assist with various important societal problems, including healthcare, antibiotic and cancer resistance, criminal justice, detecting fake news, allocation of public resources to those who need them, environmental sustainability, energy reliability, and political districting. For many of these applications, it is essential that the system satisfy certain interpretability, transparency, morality and/or fairness conditions.

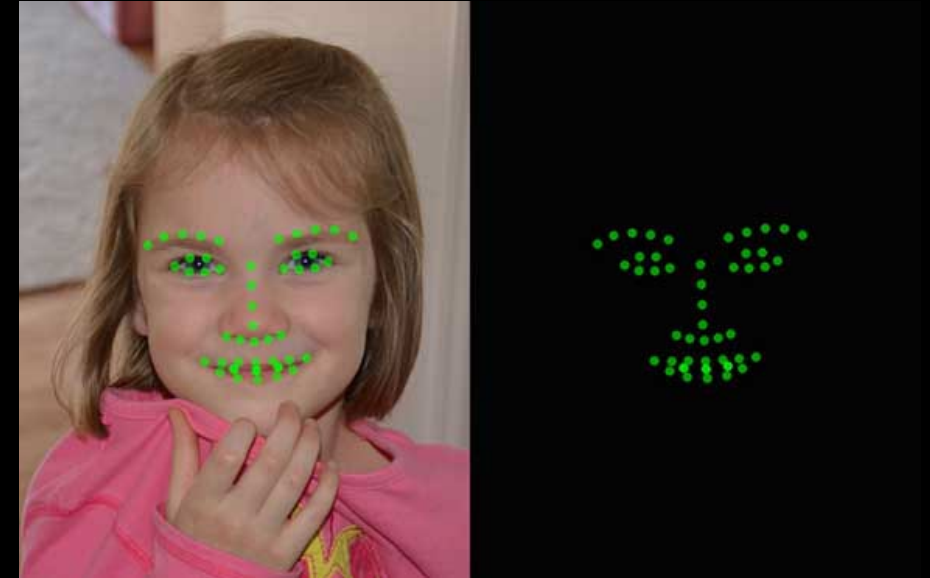
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# Some projects at Duke

- Autism
- Patterns in electronic health records
- Management of opioids
- Medication management
- Ophthalmology
- Radiology
- Exercise physiology
- FORGE
- Duke Institute for Health Innovation



# So, what can we expect?

- "Soon, it will be hard to imagine a doctor's visit, or a hospital stay that doesn't incorporate AI in numerous ways. With healthy clinical evidence, we'll see AI become more mainstream in various clinical settings, creating a positive feedback loop of more evidence-based research and use in the field. In addition, AI and ambient sensing technology will help re-humanize medicine by allowing doctors to focus less on paperwork and administrative functions, and more on patient care.

Pete Durlach, senior vice president for healthcare strategy and new business development at Nuance.



# Perfect and the future

- Society should demand the perfect system.
- Can we make the changes necessary to enable the perfect system?
- How much will the transition cost?
- Should it be global?
- Who will be the leaders?



# What does this mean to IRISS and the FDA?

- Access to more data of higher quality and consistency establishing trust.
- Receiving data from clinical trials directly and automated.
- Increasing use of AI with decisions and contact directly involving patients new regulations and responsibilities.
- New tools to more quickly make decisions?
- Constant vigilance to make sure regulations enhance and not limit of delay advances in health and health care.
- You are the experts. What do you think?



Be bold in pursuing what others believe is unrealistic because this will achieve more than being bland and unimaginative. Janna Cachola

Galileo Team

- Dr. Genie McPeck Hinz
- Dr. Stephen Keir
- Dr. Lori Orlando
- Dr. James Tcheng
- Dr. Vivian West
- Dr. Ed Hammond

*Thank You!*

