Treating Data as an Asset: Data Entrepreneurship in the Service of Patients

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Data & Digital Transformation: How are patients changing?

They are active, connected, informed and savvy.
Ill Literates or Illiterates? Investigating the eHealth Literacy of Users of Online Health Communities.
Petric G, Atanasova S, Kamin T

The younger & next generation is very different.
Exploring the digital technology preferences of teenagers and young adults (TYA) with cancer and survivors: a cross-sectional service evaluation questionnaire.

The reliability of patient reported outcomes is still highly variable.
The Impact of Participation in Online Cancer Communities on Patient Reported Outcomes: Systematic Review.
van Eenbergen MC, van de Poll-Franse LV, Heine P, Mols F

They desire price transparency but do not yet understand how to shop.
Patients’ views on price shopping and price transparency.
Semigran HL, Gourevitch R, Sinaiko AD, Cowling D, Mehrotra A

Direct-to-consumer R&D is becoming mainstream.
The RUDY study: using digital technologies to enable a research partnership.
Harriet J A Teare, et al

The #1 reason patients use pharmacies is information.
How is product selection and delivery changing?

80 Million Prime Subscribers Ready for Amazon's Pharmacy?
Moyet Moken, Jun. 9, 2017

What will that look like?

Bayer Aspirin Regimen, Low Dose (81 mg), Enteric Coated, 300 Count
Bayer 4.7 out of 5 stars 1,170 customer reviews, | 67 answered questions
#1 Best Seller in Aspirin

Top customer reviews

4.0 out of 5 stars It's aspirin! By Serge Mikhaylov on December 9, 2016

1.0 out of 5 stars The Bayer product is great, but I received the bottle with the security ... By SILVIA DE BARRAZA on August 29, 2016

1.0 out of 5 stars Short expiration date By Joyce Koppel on January 25, 2014
Patients are sharing their data and collaborating enthusiastically in open science and open data
Data Transformation of Clinical Trials

- Predictive Trial Modeling & Simulation
- Targeted Patient Enrollment
- Clinical Trial Oversight & Monitoring
- Data Flow & Learning Health (functional & organizational)
- Ability to Scale Up and Down to Meet Demand
- Collaboration with Partners and Industry
Deep human data phenotyping and molecular profiling strategies are becoming ubiquitous


The only 100% common element of digital transformation across all industries is data.

**Harvard Business Review**
What the Companies on the Right Side of the Digital Business Divide Have in Common
Robert Bock, Marco Iansiti, Karim R. Lakhani... “differentiate themselves from competitors based on their data platform.”

**Forbes**
The Power Of Digital Transformation In A Data-Driven World
Peter Bendor-Samuel. “digital transformation journey moves an organization from a process-defined world to a data-driven world”

**Information Age**
Data science needs to be a fundamental component of any digital transformation effort.
Ben Rossi

**HIT Consultant**
Why Data Block Is the Leading Cause of Death for Digital Health Startups.
by Our Thought Leaders

**MobiHealth News**
Five digital health trends investors are watching in 2017
By Skip Fleshman February 16, 2017. “#3 Data Integration and Analytics”
In Stunning Win For Open Science, Johnson & Johnson Decides To Release Its Clinical Trial Data To Researchers

Matthew Herper, Forbes Staff
I cover science and medicine, and believe this is biology's century.

PHARMA & HEALTHCARE | 1/30/2014 @ 7:09AM | 17,254 views

The NEW ENGLAND JOURNAL of MEDICINE

Perspective
October 24, 2013

Access to Patient-Level Trial Data — A Boon to Drug Developers
Hans-Georg Eichler, M.D., Frank Pétavy, M.Sc., Francesco Pignatti, M.D., and Guido Rasi, M.D.

The provision of access to clinical trial results that include patient-level data is generating much debate. A growing chorus of transparency advocates is pushing for open access to these data...
Highly Turbulent Regulatory Environment

FOR IMMEDIATE RELEASE
February 11, 2019

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Proposes New Rules to Improve the Interoperability of Electronic Health Information

New innovations in technology promote patient access and could make no-cost health data exchange a reality for millions

The U.S. Department of Health and Human Services (HHS) today proposed new rules to support seamless and secure access, exchange, and use of electronic health information. The rules, issued by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), would increase choice and competition while fostering innovation that promotes patient access to and control over their health information. The proposed ONC rule would require that patient electronic access to this electronic health information (EHI) be made available at no cost.

In the Wake of GDPR, Will the U.S. Embrace Data Privacy?

privacy rights of Europeans can be upheld in the context of the age of "big data."

Fury awaits Facebook CEO Mark Zuckerberg ahead of his May visit to Brussels.
Is health-care data the new blood?

Eric Perakis  Andrea Coravos

Open Access  Published: May, 2019  DOI: https://doi.org/10.1016/S2589-7500(19)30001-9
Most Data about our Patients, and Us, are Not in our Medical Records

Under-Used Data
- Bibliometric/Scientometrics
- Social Media
- Competitive Intelligence
- Consumer Behavior
- Siloed Data

Over-Used Data
- PubMed: Single Papers
- ClinicalTrials.gov: Single Trials

Under Translated Data
- Genetics/Genomics
- Geospatial
- Phenotyping
- Molecular Imaging
- Digital Sensors
- Anecdotal Learning
Data Architecture and Knowledge Management

**Architecture:**
- Simplified technology stack
- Enterprise R&D Data
- Cloud/SaaS based
- Scalable demand based model
- Built for purpose solutions
- Search, NLP, Machine Learning

**Standards and Governance:**
- Leverage industry data standards and formats for internal use and exchange with partners
- Ontology for data concepts and metadata
- Master data management
- Single source of truth
- Role-based access

**Delivery:**
- Agile Methodology
- Technology and skill aligned partners
- Common infrastructure and platforms
- Road map and prioritized portfolio
- Security and Compliance built-in
- User experience
1. What roles and committees are there for implementing data governance?
2. How is data stored and maintained, and what constitutes the truth in the organization?
3. How to guarantee data is accurate and suitable for analysis? Who owns the data?
4. How do users get access to the data they need & no more than that, & how do they use it in modelling & reporting?
5. How to guarantee data remains private, secure and compliant with regulations?
We have no clear or common frameworks for cyber threats in healthcare. Yet with US hospitals currently having on average 10-15 connected devices per bed, we desperately need them.
## Cyber Time in 2017

| Technology Time | **7 years or older**: age of systems for 61% of daily MS security updates  
**5 years or older**: age of 69.82% of current MS Operating instances  
**100-120 days**: average lag time from receipt-to-installation of a security patch  
**Daily**: an average of 15 security patches are received  
**Daily**: 44% of security operations managers see at least 5000 security updates |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cyber-Threat Time | **8 months-3 years**: duration of average zero-day attack  
**310 days**: how long cybercriminals know about a hacker-discovered-vulnerability before the public or vendor  
**Weekly**: 1-2 zero-day vulnerabilities are exploited  
**2-3 days**: a new Adobe vulnerability is discovered  
**Daily**: 200,000 new malware samples are captured  
**Daily**: 4000 new ransomware attacks  
**Minute**: 400 new threats (of all types) are launched |
| Regulatory & Standards Time | **3.8 years**: average time between federal cyber law updates since HIPAA (1996)  
**2 years**: time between significant updates to NIST cyber/guides standards  
**1 year**: time from commission-to-report of the HHS Healthcare Cyber Task Force |
Cloud computing reduces HIPAA compliance risk in managing genomic data
September 4, 2013

“...a review of data on HIPAA breaches published by the US Department of Health and Human Services (HHS) shows that these concerns are Misplaced.

In fact, by using a cloud-based service with an appropriate security and compliance infrastructure, an organization can significantly reduce its compliance risk...”
A cybersecurity primer for translational research.

Perakslis ED¹, Stanley M².

Data are Assets

Technology is an Expense
1. Break down the macro and micro silos of healthcare data
2. Keep patients safer
3. Crowdsoure the most difficult problems
4. Aggregate, align and donate to friends and freaks
5. Catch a thief
6. Out-shout medical misinformation
7. Shrink space and time to improve research access
8. Nourish your family but read the label
9. Disable the surveillance state and stand up for patient/consumer rights
10. Discover new math
Entrepreneurial Idea #1: Break Down the Macro and Micro Silos of Healthcare

We characterize **macro silos** as data technology platforms and/or knowledge structures that are completely non-overlapping or intentionally isolated and/or competitive and de-incentivized by design. Examples:

- IOS v. Android
- Medical practice and biomedical product development
- Healthcare and non-healthcare

We characterize **micro silos** as data that can be utilized across fragmented but somewhat similar and overlapping constructs. Examples:

- Local MRI center that is not connected to major local hospitals
- Clinical trials data from different sponsors on similar drugs
- Competitive software sub-ecosystems like clinical trials management and HER
- Independent grants and clinical studies

Example – PCRF Linking Initiative
Applications
Applications received: 2346
Applications under review: 306
Participants accepted: 1030

Evaluations
Participants evaluated: 735
Participants diagnosed: 222
Participants with exome or genome sequencing complete: 682
Participants with metabolic analyses complete: 113
Participants with variants studied by the Model Organisms Screening Center: 96
Participants with samples in the Central Biorepository: 516

Data Sharing
Manuscripts published: 27
Participants with data submitted to dbGaP: 150
Participants with data submitted to PhenomeCentral: 491
Participants with variants in ClinVar: 28*

*Note: only proband data is reported here

https://undiagnosed.hms.harvard.edu/
Fact 10: Administrative errors account for up to half of all medical errors in primary care.

Recent literature reviews have revealed that medical errors in primary care occur between 5 and 80 times per 100,000 consultations. Administrative errors—those associated with the systems and processes of delivering care—are the most frequently reported type of errors in primary care. It is estimated that from 5 to 50% of all medical errors in primary care are administrative errors.

Areas of potential for improvement for most hospitals:

- **Nonpunitive Response to Error**: 47% of respondents indicated that event reports are not held against them and that mistakes are not kept in their personnel file.
- **Handoffs and Transitions**: 48% of respondents indicated that information is not lost during transfers or shift changes.
- **Staffing**: 53% of respondents reported that there is sufficient staff to handle the workload.

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*https://www.who.int/features/factfiles/patient_safety/en/*

E3: Crowdsource the Most Difficult Problems

On this page, you will find information about a UDN participant.
Sharing information on this website is not a requirement of UDN participation. Only descriptions about participants who give explicit consent will appear here.

Female, age 5 with global developmental delay, rhythmic and repetitive movements (stereotypic movements), and difficulty feeding

Date of Report
Feb 01, 2018

Description
Shortly after birth, the patient was noticed to have decreased tone and difficulty breathing. She struggled to drink from a bottle and would breathe liquids into her airway (aspirate). At 6 months, a G tube was placed. Currently she struggles with chewing and swallowing and is unable to drink out of a cup or straw.

The patient said her first words at 13 months and began walking at 22 months. She gets tired easily (easy fatigability) and makes rhythmic and repetitive movements with her upper and lower limbs (stereotypic movements).
E4: Aggregate, Align and Donate to Friends & Freaks

MMRF CoMMpass Study Data Featured at AACR 2019

The 2019 American Association for Cancer Research (AACR) meeting took place March 28–April 3 in Atlanta. This gathering of over 30,000 cancer clinicians and researchers featured four presentations made possible by researchers using data from our CoMMpass Study, which is the largest genome database in all of cancer. CoMMpass continues to be an invaluable resource for investigators to use to test new hypotheses and accelerate precision medicine treatments into the clinic for all myeloma patients. Below are summaries of the four CoMMpass Study presentations:

Analysis of CoMMpass genomic data has revealed 12 subtypes of myeloma. Myelomas also occur more frequently in males and in African Americans. A group from the Translationl Genomics Research Institute (TGen) analyzed the data from 207 CoMMpass patients to look at the contribution of variations in normal DNA sequences in this increase in incidence. They found

Freakonomics

Book by Stephen J. Dubner and Steven Levitt

Book preview
51/393 pages available

4/5 · Goodreads

90% liked this book

Google users

A **honeypot** is a computer or computer system intended to mimic likely targets of cyberattacks. It can be used to detect attacks or deflect them from a legitimate target. It can also be used to gain information about how cybercriminals operate.

Like mice to cheese-baited mousetraps, cybercriminals are attracted to honeypots — not because they’re honeypots. The bad guys think the honeypot is a legitimate target, something worthy of their time. That’s because the bait includes applications and data that simulate a real computer system.

https://us.norton.com/internetsecurity-iot-what-is-a-honeypot.html
E6: Out-Shout Medical Misinformation

• Positive Imagery
• Education
• Political Action
• Big Tech Activism
• Social Voice
• Cyber Warfare Techniques against nation-state actors
• …
E7: Shrink Space and Time to Improve Research Access

- Minimize the Regulatory Regime Chasm between Medical Practice and Biomedical Products R&D
- Disrupt the Clinical Trials Industrial Complex
- Virtual teleporter from work or the soccer field to the clinical trial and back.

https://blog.andreacoravos.com/software-enabled-clinical-trials-8da53f4cd271
What is a personal health record?

A personal health record, or PHR, is an electronic application through which patients can maintain and manage their health information (and that of others for whom they are authorized) in a private, secure, and confidential environment.

For information about PHRs and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, please view the U.S. Department of Health and Human Services (HHS) Office for Civil Rights’ guidance on this topic.

Picnic Health narrows its focus to helping cancer patients with their patient records

How Accurate Are Online DNA Tests?

Geneticist and author Adam Rutherford examines the evidence
E9: Disable the Surveillance State & Stand Up for Patient/Consumer Rights

Privacy Project @PrivacyProject · 11h
From @DKThomp for @TheAtlantic: “If you have a hard time understanding the meaning of privacy and the scale of digital surveillance in the modern age—and let’s face it, who doesn’t?—consider a toy named Cayla”

Why Surveillance Is the Climate Change of the Internet
The Atlantic podcast Crazy/Genius returns to explain how privacy became the most important idea on the Internet—and why it’s still so confusing.
theatlantic.com

Brave Bosom @BraveBosom · 13h
Wowza: FTC Members Unanimously Press Congress for Tough National Privacy Protections gizmodo.com/ftc-members-un... via @gizmodo

FTC Members Unanimously Press Congress for Tough National Priva...
All five members of the Federal Trade Commission appeared Wednesday before the House Communications and Technology Subcommittee. One ... gizmodo.com
To Your Health
Cancer researchers: It’s time to pay more attention to ‘miracle’ patients. By Erin Blakemore

Emily Whitehead, right, beat cancer through immunotherapy. She’s pictured onstage with Lady Gaga at the launch of the Parker Institute for Cancer Immunotherapy. (Jonathan Leibson/Getty Images for Parker Media)
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