Open Source Healthcare

Juhan Sonin
v.04, 16.May.19

goinvo.com

Design Studio

MIT

2.009 Product Design

Disclosures

Blind-ish Trust

No involvement in investments since 1995

Academic Appointment @ MIT

Own $1.8M/yr business

70% of revenue from commercial, 30% from org + gov

Patents & personal health data are licensed under open source

juhan@mit.edu
@jsonin

Medicine is a noble profession.

Sir Thomas Browne, 1635

Healthcare is a noble business.

CIO, Boston-based Hospital, 2019

Yes, it is noble.

And there are plenty of blisters
using that nobility ethos as cover,
as a shield, to obscure their activities.

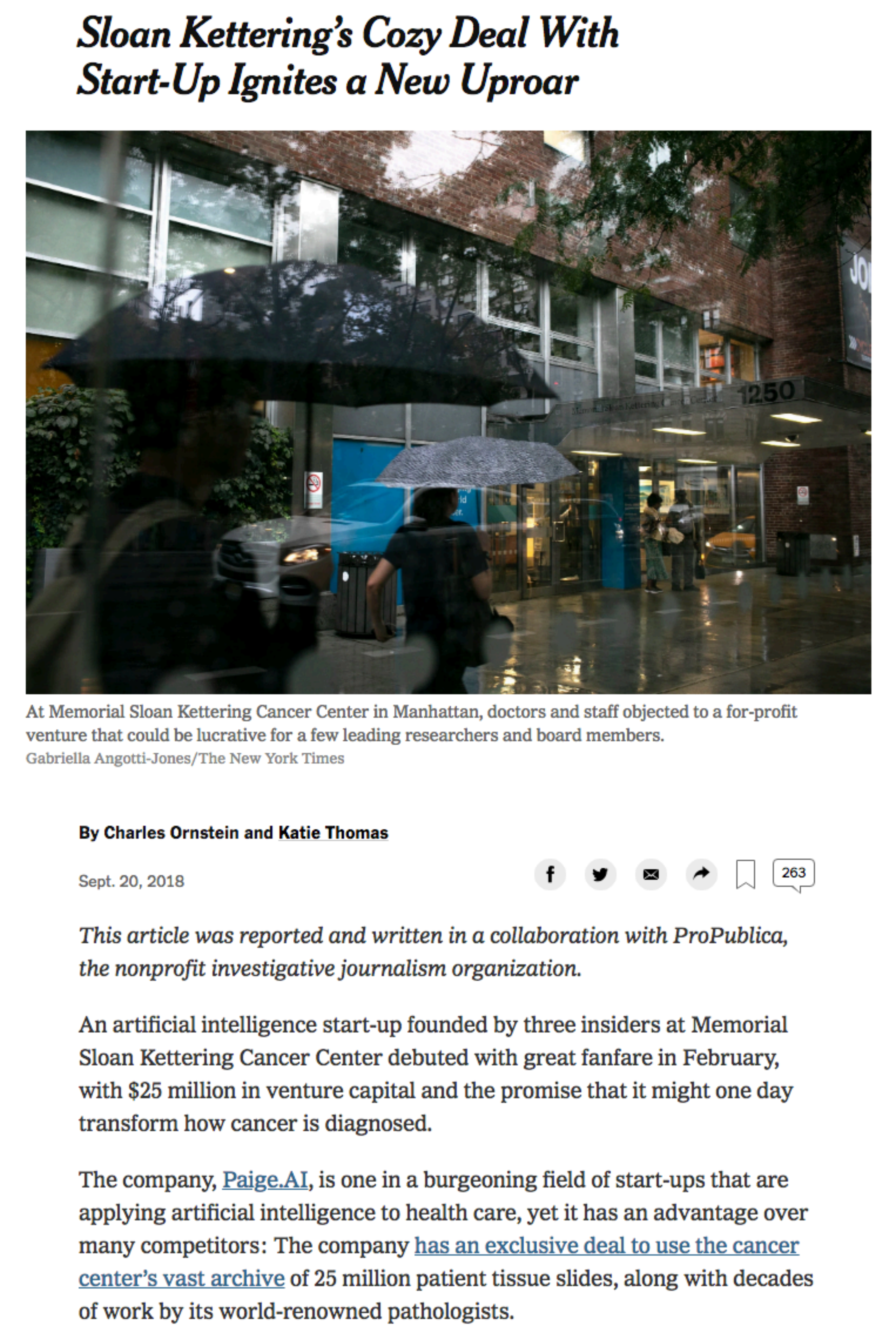
25%

healthcare GDP

Juan Enriquez

1%

of Global GDP



Sloan Kettering's Cozy Deal With Start-Up Ignites a New Uproar

At Memorial Sloan Kettering Cancer Center in Manhattan, doctors and staff objected to a for-profit venture that could be lucrative for a few leading researchers and board members.

Gabriella Angotti-Jones/The New York Times

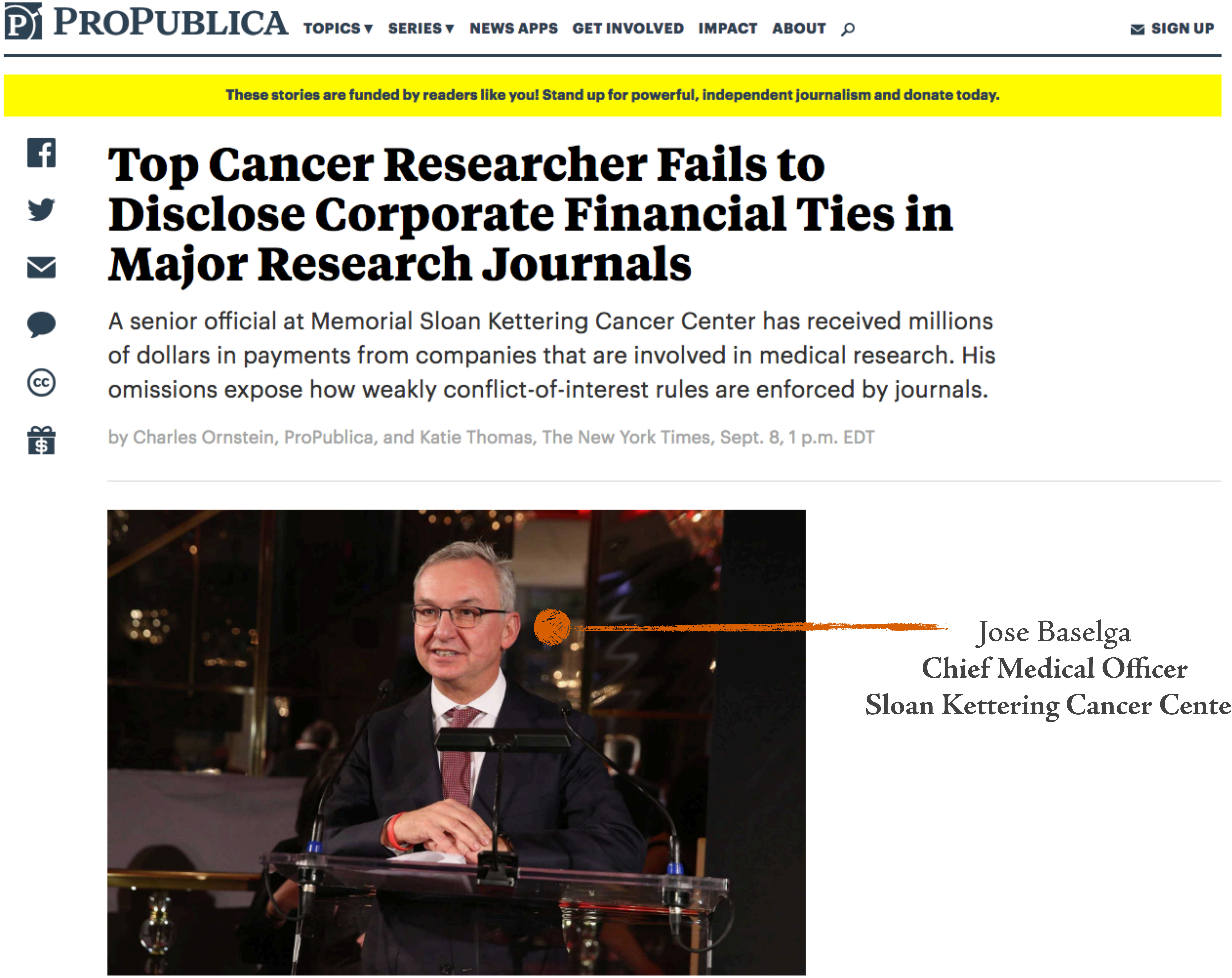
By Charles Ornstein and Katie Thomas

Sept. 20, 2018

This article was reported and written in a collaboration with ProPublica, the nonprofit investigative journalism organization.

An artificial intelligence start-up founded by three insiders at Memorial Sloan Kettering Cancer Center debuted with great fanfare in February, with $25 million in venture capital and the promise that it might one day transform how cancer is diagnosed.

The company, Paige.AI, is one in a burgeoning field of start-ups that are applying artificial intelligence to health care, yet it has an advantage over many competitors: The company has an exclusive deal to use the cancer center's vast archive of 25 million patient tissue slides, along with decades of work by its world-renowned pathologists.



These stories are funded by readers like you! Stand up for powerful, independent journalism and donate today.

Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals

A senior official at Memorial Sloan Kettering Cancer Center has received millions of dollars in payments from companies that are involved in medical research. His omissions expose how weakly conflict-of-interest rules are enforced by journals.

by Charles Ornstein, ProPublica, and Katie Thomas, The New York Times, Sept. 8, 1 p.m. EDT

Dr. José Baselga, pictured in November 2015. (Cindy Ord/Getty Images for Revlon)

Jose Baselga
Chief Medical Officer
Sloan Kettering Cancer Center

https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties

An Assault on Ethics

Broke hospital Conflict of Interest rules:

Board/advisory roles with Roche + Bristol-Myers Squibb

Ownership stake in cancer therapy startups

Payments received from companies connected to cancer research in his articles (published by Cancer Discovery, of which he was one of the two editors in chief)

Public positive spin on two Roche-sponsored clinical trials (without COI recognition that for the past 4 years, he's received $3+MM from Roche)

https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties

The New York Times

ProPublica

The company, Paige.AI, is one in a burgeoning field of start-ups that are applying artificial intelligence to health care, yet it has an advantage over many competitors: The company has an exclusive deal to use the cancer center's vast archive of 25 million patient tissue slides, along with decades of work by its world-renowned pathologists.

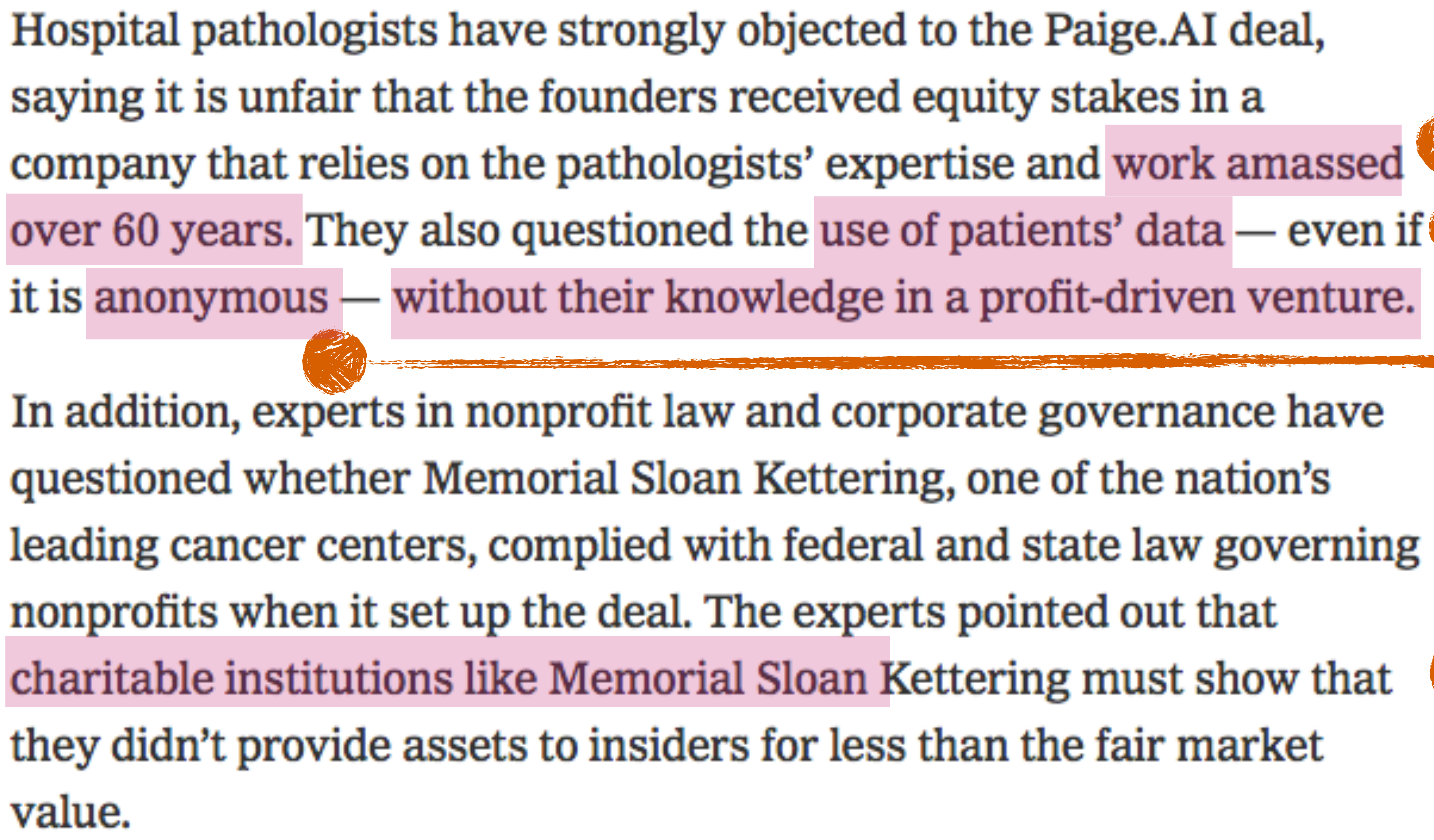
Memorial Sloan Kettering holds an equity stake in Paige.AI, as does a member of the cancer center's executive board, the chairman of its pathology department and the head of one of its research laboratories. Three other board members are investors.

Paid for by the public

Patient data owned by hospital

100s of clinicians encoded/decoded/ researched the data

Making the rich, richer



Hospital pathologists have strongly objected to the Paige.AI deal, saying it is unfair that the founders received equity stakes in a company that relies on the pathologists' expertise and work amassed over 60 years. They also questioned the use of patients' data — even if it is anonymous — without their knowledge in a profit-driven venture.

In addition, experts in nonprofit law and corporate governance have questioned whether Memorial Sloan Kettering, one of the nation's leading cancer centers, complied with federal and state law governing nonprofits when it set up the deal. The experts pointed out that charitable institutions like Memorial Sloan Kettering must show that they didn't provide assets to insiders for less than the fair market value.

Work by many, paid for by grants

Again, patient data owned by hospital

Aint no such thing as Anonymity

The Gold Rush in the land of non-profits

No competitive bidding before licensing the data to a single company, Paige.AI

Thomas Fuchs, head of the MSK computational pathology lab and a co-founder of Paige.AI.

Hiding in plain sight

Research Intern

Siemens Corporate Research

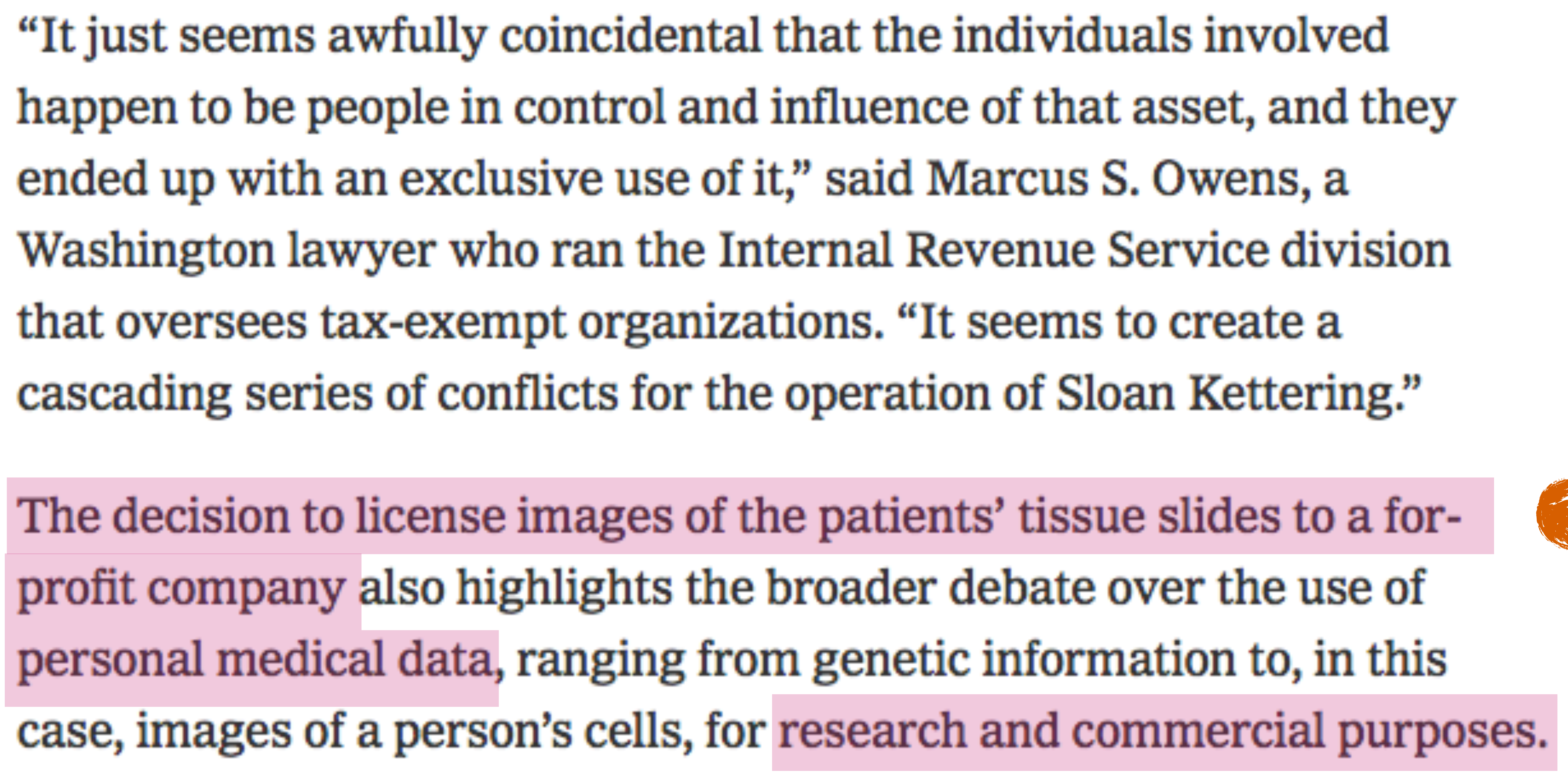
2004 – 2005 · 1 yr

Princeton, NJ, USA

CEO

nautikon technologies

2000 – 2005 · 5 yrs



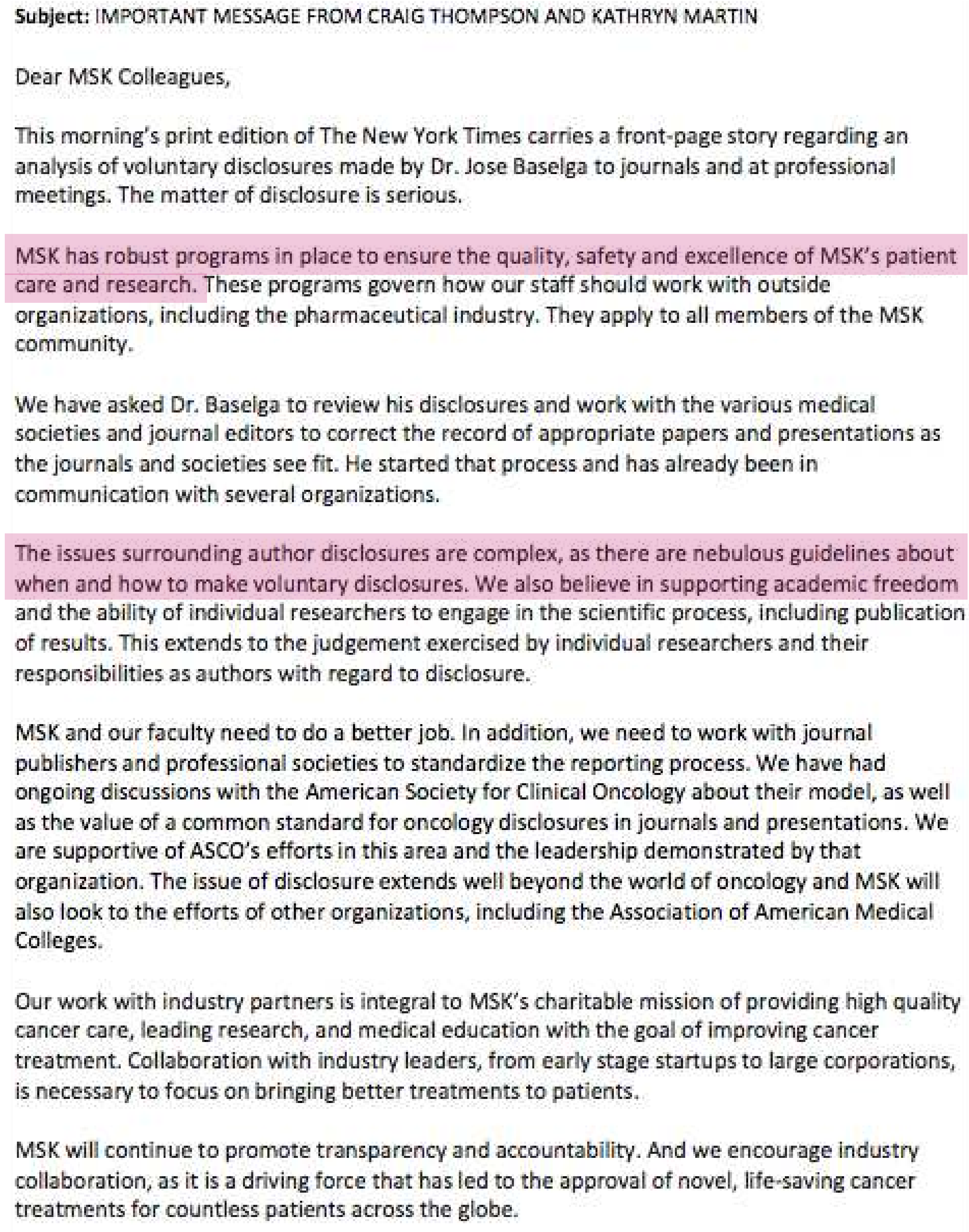
“It just seems awfully coincidental that the individuals involved happen to be people in control and influence of that asset, and they ended up with an exclusive use of it,” said Marcus S. Owens, a Washington lawyer who ran the Internal Revenue Service division that oversees tax-exempt organizations. “It seems to create a cascading series of conflicts for the operation of Sloan Kettering.”

The decision to license images of the patients’ tissue slides to a for-profit company also highlights the broader debate over the use of personal medical data, ranging from genetic information to, in this case, images of a person’s cells, for research and commercial purposes.

Data Use Agreement keeps patients out of control

What kind of design is this?

Letter from the CEO + COO



Subject: IMPORTANT MESSAGE FROM CRAIG THOMPSON AND KATHRYN MARTIN

Dear MSK Colleagues,

This morning's print edition of The New York Times carries a front-page story regarding an analysis of voluntary disclosures made by Dr. Jose Baselga to journals and at professional meetings. The matter of disclosure is serious.

MSK has robust programs in place to ensure the quality, safety and excellence of MSK's patient care and research. These programs govern how our staff should work with outside organizations, including the pharmaceutical industry. They apply to all members of the MSK community.

We have asked Dr. Baselga to review his disclosures and work with the various medical societies and journal editors to correct the record of appropriate papers and presentations as the journals and societies see fit. He started that process and has already been in communication with several organizations.

The issues surrounding author disclosures are complex, as there are nebulous guidelines about when and how to make voluntary disclosures. We also believe in supporting academic freedom and the ability of individual researchers to engage in the scientific process, including publication of results. This extends to the judgement exercised by individual researchers and their responsibilities as authors with regard to disclosure.

MSK and our faculty need to do a better job. In addition, we need to work with journal publishers and professional societies to standardize the reporting process. We have had ongoing discussions with the American Society for Clinical Oncology about their model, as well as the value of a common standard for oncology disclosures in journals and presentations. We are supportive of ASCO's efforts in this area and the leadership demonstrated by that organization. The issue of disclosure extends well beyond the world of oncology and MSK will also look to the efforts of other organizations, including the Association of American Medical Colleges.

Our work with industry partners is integral to MSK's charitable mission of providing high quality cancer care, leading research, and medical education with the goal of improving cancer treatment. Collaboration with industry leaders, from early stage startups to large corporations, is necessary to focus on bringing better treatments to patients.

MSK will continue to promote transparency and accountability. And we encourage industry collaboration, as it is a driving force that has led to the approval of novel, life-saving cancer treatments for countless patients across the globe.

"MSK has robust programs in place to ensure the quality, safety, and excellence of MSK's patient care and research."

"The issues surrounding author disclosures are complex, and there are nebulous guidelines about when and how to make voluntary disclosures. We also believe in academic freedom…"

Excuse by chaos.

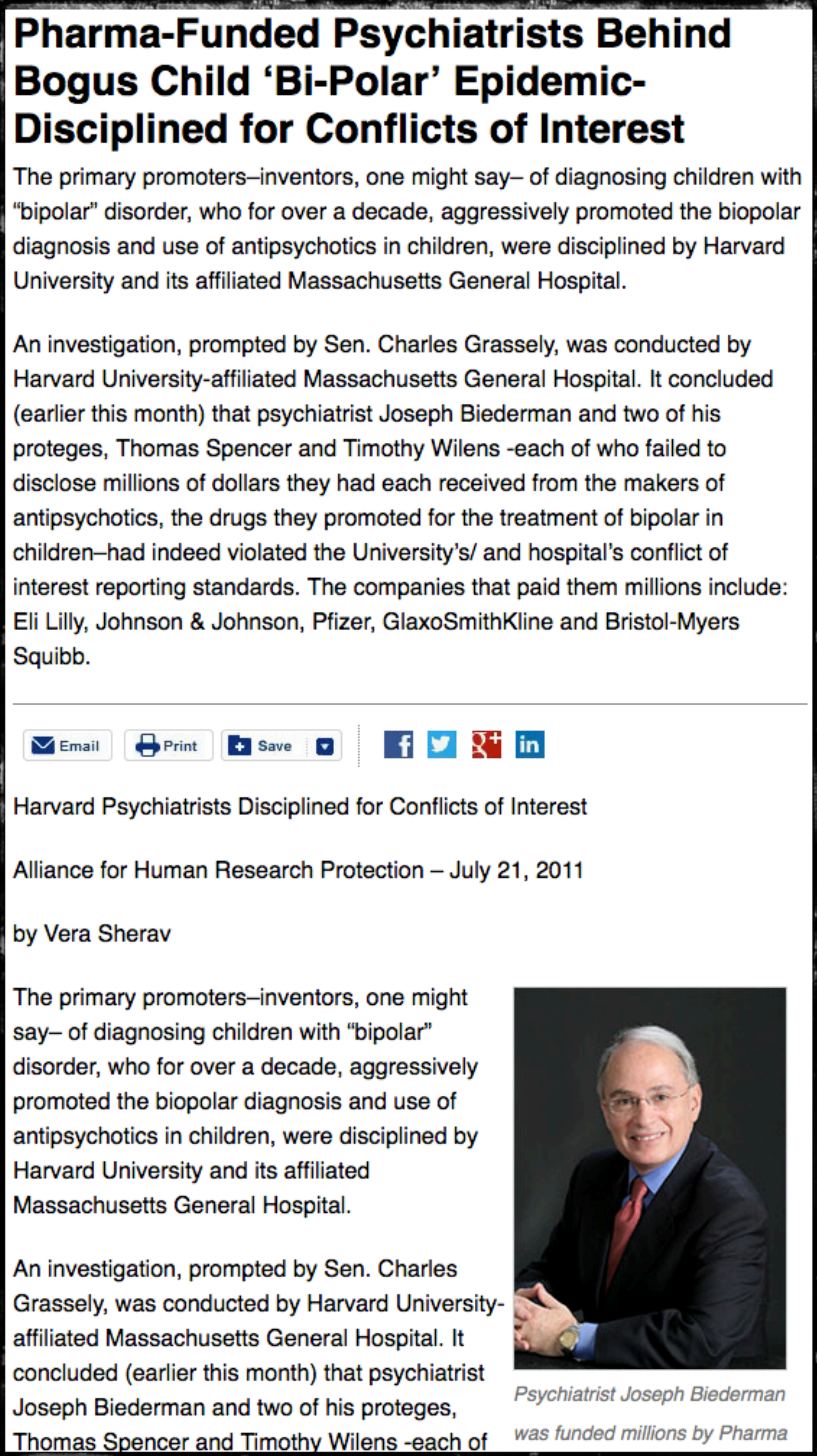
Reporting guidelines = "complex" and "nebulous."

Hospitals own the data
Patients have no ownership rights

IP, patents owned by executives
Funded by the public

Abuse of public funding for private gain
Corporate welfare

The rush for $$ over everything else
Ethics as situationally optional



Pharma-Funded Psychiatrists Behind Bogus Child 'Bi-Polar' Epidemic- Disciplined for Conflicts of Interest

The primary promoters–inventors, one might say– of diagnosing children with "bipolar" disorder, who for over a decade, aggressively promoted the biopolar diagnosis and use of antipsychotics in children, were disciplined by Harvard University and its affiliated Massachusetts General Hospital.

An investigation, prompted by Sen. Charles Grassely, was conducted by Harvard University-affiliated Massachusetts General Hospital. It concluded (earlier this month) that psychiatrist Joseph Biederman and two of his proteges, Thomas Spencer and Timothy Wilens -each of who failed to disclose millions of dollars they had each received from the makers of antipsychotics, the drugs they promoted for the treatment of bipolar in children–had indeed violated the University's/ and hospital's conflict of interest reporting standards. The companies that paid them millions include: Eli Lilly, Johnson & Johnson, Pfizer, GlaxoSmithKline and Bristol-Myers Squibb.

Harvard Psychiatrists Disciplined for Conflicts of Interest

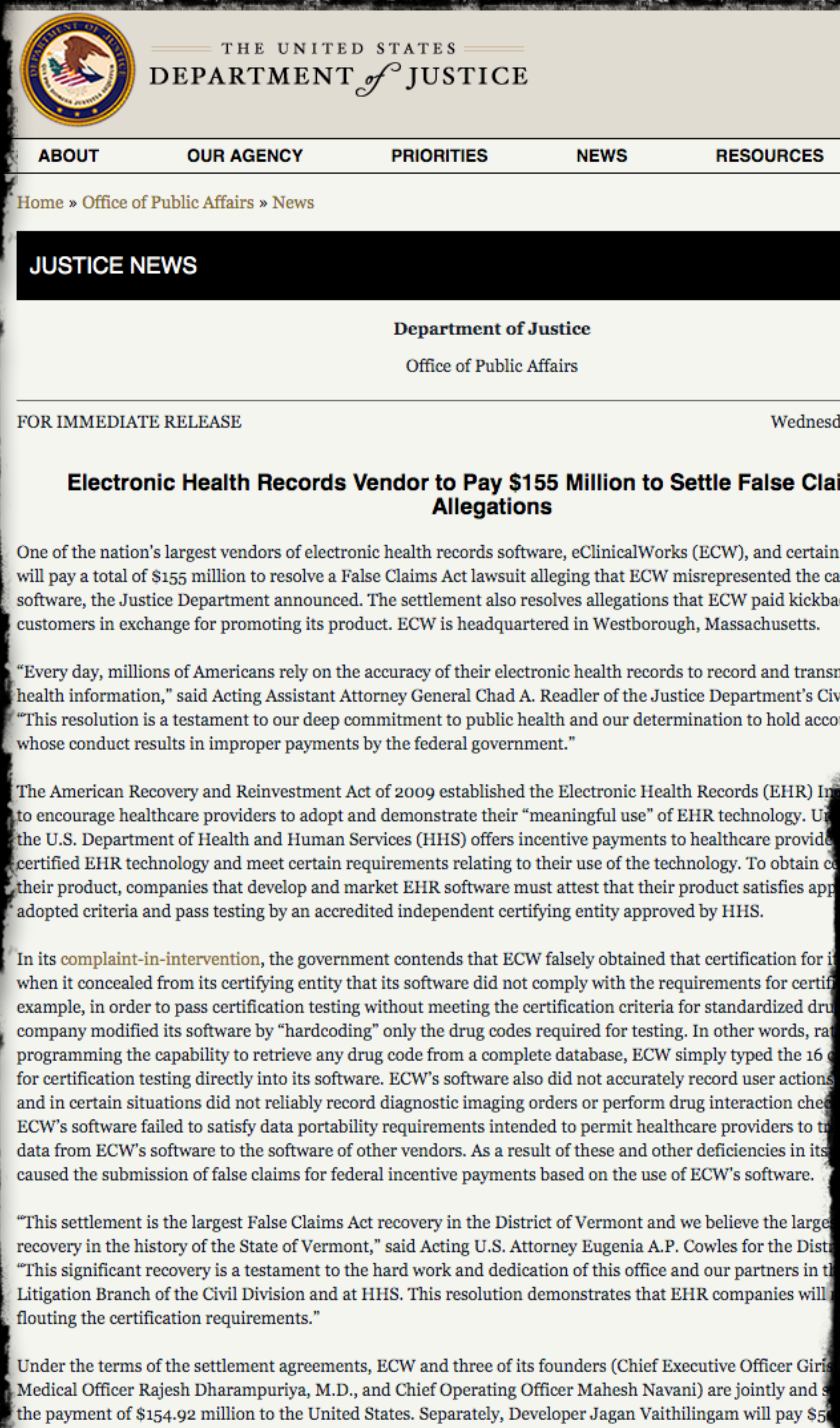
Alliance for Human Research Protection – July 21, 2011

by Vera Sharav

The primary promoters–inventors, one might say– of diagnosing children with "bipolar" disorder, who for over a decade, aggressively promoted the biopolar diagnosis and use of antipsychotics in children, were disciplined by Harvard University and its affiliated Massachusetts General Hospital.

An investigation, prompted by Sen. Charles Grassely, was conducted by Harvard University-affiliated Massachusetts General Hospital. It concluded (earlier this month) that psychiatrist Joseph Biederman and two of his proteges, Thomas Spencer and Timothy Wilens -each of

Psychiatrist Joseph Biederman was funded millions by Pharma



Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, May 31, 2017

Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations

One of the nation's largest vendors of electronic health records software, eClinicalWorks (ECW), and certain of its employees will pay a total of $155 million to resolve a False Claims Act lawsuit alleging that ECW misrepresented the capabilities of its software, the Justice Department announced. The settlement also resolves allegations that ECW paid kickbacks to certain customers in exchange for promoting its product. ECW is headquartered in Westborough, Massachusetts.

"Every day, millions of Americans rely on the accuracy of their electronic health records to record and transmit their vital health information," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "This resolution is a testament to our deep commitment to public health and our determination to hold accountable those whose conduct results in improper payments by the federal government."

The American Recovery and Reinvestment Act of 2009 established the Electronic Health Records (EHR) In
to encourage healthcare providers to adopt and demonstrate their "meaningful use" of EHR technology. U
the U.S. Department of Health and Human Services (HHS) offers incentive payments to healthcare provid
certified EHR technology and meet certain requirements relating to their use of the technology. To obtain c
their product, companies that develop and market EHR software must attest that their product satisfies ap
adopted criteria and pass testing by an accredited independent certifying entity approved by HHS.

In its complaint-in-intervention, the government contends that ECW falsely obtained that certification for i
when it concealed from its certifying entity that its software did not comply with the requirements for certif
example, in order to pass certification testing without meeting the certification criteria for standardized dru
company modified its software by "hardcoding" only the drug codes required for testing. In other words, ra
programming the capability to retrieve any drug code from a complete database, ECW simply typed the 16
for certification testing directly into its software. ECW's software also did not accurately record user actions
and in certain situations did not reliably record diagnostic imaging orders or perform drug interaction che
ECW's software failed to satisfy data portability requirements intended to permit healthcare providers to t
data from ECW's software to the software of other vendors. As a result of these and other deficiencies in its
caused the submission of false claims for federal incentive payments based on the use of ECW's software.

"This settlement is the largest False Claims Act recovery in the District of Vermont and we believe the large
recovery in the history of the State of Vermont," said Acting U.S. Attorney Eugenia A.P. Cowles for the Dist
"This significant recovery is a testament to the hard work and dedication of this office and our partners in t
Litigation Branch of the Civil Division and at HHS. This resolution demonstrates that EHR companies will
flouting the certification requirements."

Under the terms of the settlement agreements, ECW and three of its founders (Chief Executive Officer Giri
Medical Officer Rajesh Dharampuriya, M.D., and Chief Operating Officer Mahesh Navani) are jointly and s
the payment of $154.92 million to the United States. Separately, Developer Jagan Vaithilingam will pay $5

Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, February 6, 2

Electronic Health Records Vendor to Pay $57.25 Million to Settle False Claims Act Allegations

Greenway Health LLC (Greenway), a Tampa, Florida-based developer of electronic health records (EHR) software, will pa
$57.25 million to resolve allegations in a complaint filed by the United States under the False Claims Act alleging that
Greenway caused its users to submit false claims to the government by misrepresenting the capabilities of its EHR produ
"Prime Suite" and providing unlawful remuneration to users to induce them to recommend Prime Suite, the Justice
Department announced today.

"Electronic health records are critically important to the health care decision process, and both patients and providers rel
on these technologies to safely and accurately record and transmit vital health information," said Assistant Attorney Gene
Jody Hunt of the Department of Justice's Civil Division. "This resolution demonstrates our continued commitment to
pursue EHR vendors who misrepresent the capabilities of their products, and our determination to promote public health
while holding accountable those who seek to abuse the government's trust."

The American Recovery and Reinvestment Act of 2009 established the Medicare and Medicaid EHR Incentive Program to
encourage healthcare providers to adopt and demonstrate their "meaningful use" of EHR technology. Under the program
the U.S. Department of Health and Human Services (HHS) made incentive payments available to eligible healthcare
providers that adopted certified EHR technology and met certain requirements relating to their use of the technology. To
obt ain certification for their product, companies that develop and market EHR technology are required to demonstrate t
their product(s) satisfies all applicable HHS-adopted certification criteria. Developers must first pass testing performed b
an independent, accredited testing laboratory authorized by HHS, and then obtain and maintain certification by an
independent, accredited certification body authorized by HHS.

In its complaint, the government contends that Greenway falsely obtained 2014 Edition certification for its product Prime

---

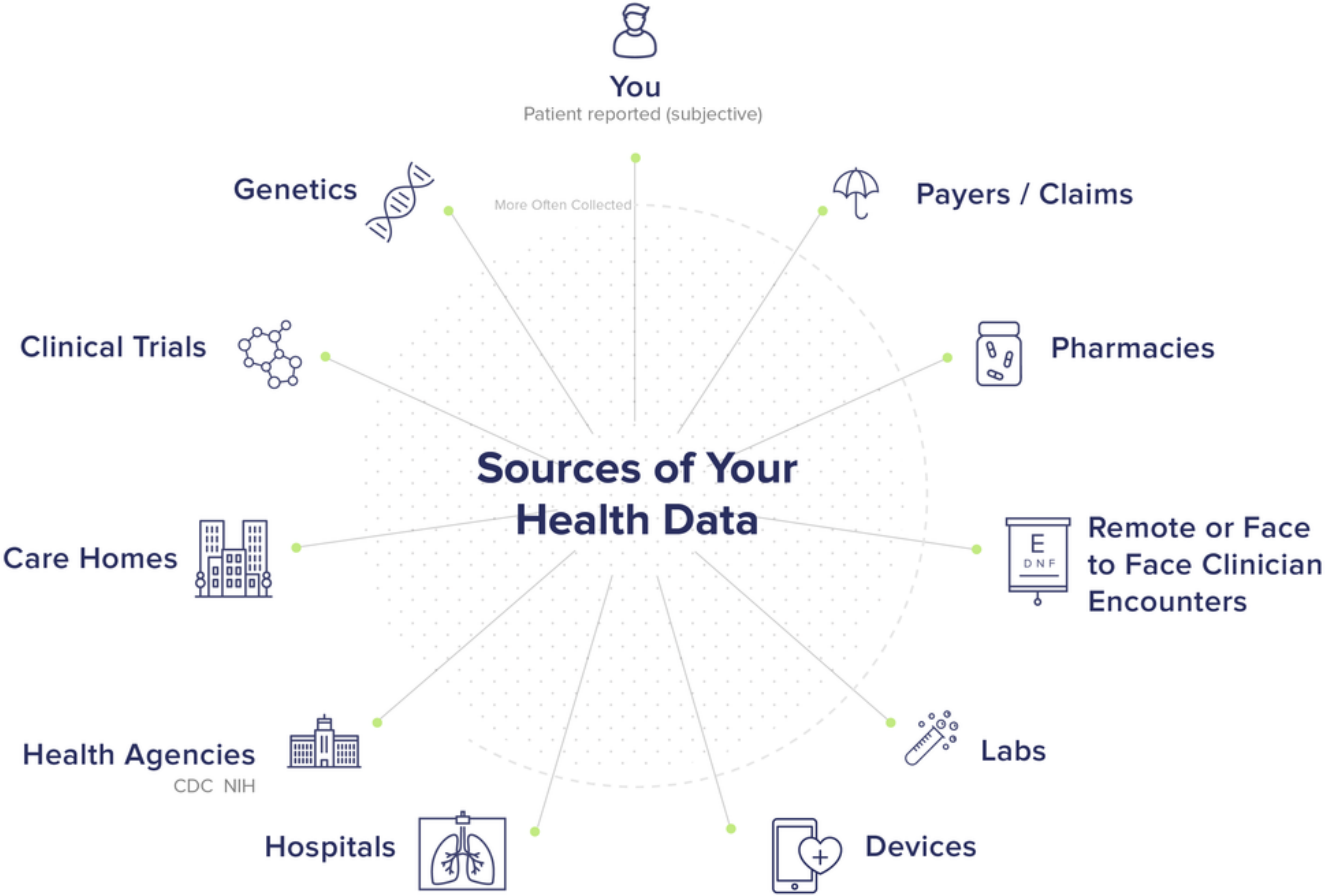
BRIEF

Walgreens pays $270M to settle Medicaid fraud allegations

We are complicit.

We, United Statesians,
are sloughing data everywhere,
without rights,
and it feeds Kendall Square,
Mountain View, and Moscow.

Health Data is any information
about a person's life
that assists in making decisions
about health and wellness.



Sources of Your Health Data

You

Patient reported (subjective)

More Often Collected

Payers / Claims

Pharmacies

Remote or Face to Face Clinician Encounters

Labs

Devices

Hospitals

Health Agencies

CDC NIH

Care Homes

Clinical Trials

Genetics

WHO USES MY HEALTH DATA?

SCENARIO

At an appointment with my doctor, who...
1. reviews my blood test results
2. diagnoses IBS, and
3. prescribes Bentyl

1 PRIMARY DATA SOURCES

THE PROVIDER GROUP

medical encounter note including name, dob, diagnoses, prescription, doctors name, when and where I saw my doctor, etc.
Many provider groups sell de-identified patient data.

THE PHARMACY

my prescription includes my name, dob, my doctor's name, medication, dose, etc.
75% of all retail pharmacies "send some portion of their electronic records" to at least one data miner.[11]

THE LAB

my blood sample and identification including my name, dob, sex, ordering physician, etc.
In 2015, nearly **1/2** of all labs send data to Iqvia (was IMS), labs send data to other data miners as well.[13]

MY INSURER

medical claim from my provider to my insurer including the coded services provided during the encounter
More than 60 health plans sell data to at least one data broker. This accounts for about **60%** of all US medical claims transactions.[4]

2 SECONDARY DATA SOURCES

THE EHR COMPANY

Electronic Health Record (EHR) companies have access to and sometimes ownership of the data in their EHRS.[13]
Many will de-identify and sell my healthcare data. The Practice Fusion model was one of the first to sell data to pharma and advertise drugs directly to providers.

PHARMACY BENEFIT MANAGERS

PBMs collect pharmacy data from claims.
They sell data to pharma companies who are interested to learn where their drugs are doing well vs poorly. **85%** of PBMs sell to ExamOne who sells 7 years of an individual's prescription history to life and health insurers.[13]

MY BANK

Throughout the process, my bank tracks copays with my doctors office and pharmacy. It also has record of my monthly premiums with my insurer.
Many banks sell customer data.

3 GROUPS WITH ACCESS

HEALTH IT MIDDLE-MEN

Health IT middle men offer services such as data warehousing, analytics, performance management solutions, claims processing, transition support to value-based payment models, and revenue optimization. They are used by provider groups, pharamacies, insurers, and more.

What PHI or de-identified health information they have access to and sell has not been measured to date. The total number of middlemen companies who can access, use, and/or sell my data is unknown.

Examples of Health IT middle men who work with health data:

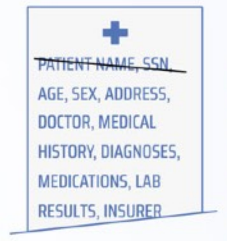
McKESSON
Celanese
NantHealth
nextgen healthcare
RWS
OPTUM
HARRISHEALTH SYSTEM
navicure Collect more. Stress less.
Cotiviti

THE GOVERNMENT

Federal and State health departments maintain Public Use Files (PUF), de-identified and limited datasets to support researchers (ex: utilization and spending data aggregated at[2] the prescriber, drug name, and generic name levels).

Federal or State data sets with Patient Health Information (PHI) can be accessed through IRB approval or other application approach.

4 DATA BROKERS



DATA MINERS

Data miners use de-identified data including longitudinal records that track my longterm health and switch my name for a number. Data comes from my medical organization, pharmacy, insurance company, federal and state health department data, and more.[5]

Even de-identified, this data can provide valuable, population health insights and demographic profiling for individuals.

IQVIA
Symphony Health
LexisNexis
prognos

DATA BROKERS

Data brokers sell identified profiles. In 2014, the FTC reported that Acxiom had "over 3,000 data segments for nearly every U.S. consumer."[7]

Data brokers gather health data and health related digital footprint data, such as health related purchases, consumer genetic testing, and apps. EliteMate, a dating service, sells a list of individuals and their mailing addresses with AIDS/HIV.[10, 13]

ExamOne
acxiom
CROSSIX
CentraForceHealth Precise. Predictive. Powerful.

5 DATA USERS

CLINICAL RESEARCH

Research Centers
Researchers use many data sources including Federal and State data sets, clinical study reports, and more. Some data brokers will give research centers a discount on population health data.[11]

MARKET ANALYSIS AND TARGETED ADVERTISING

Pharmaceutical companies
Population health data can help pharma companies determine which drugs to develop or invest in. Data inform Pharma where certain drugs are doing poorly and need more marketting. Profiles on doctors prescribing practices lead pharma companies to target certain providers to increase sales.[13] Pharma can also cross-reference de-identified and identified records from Miners and Brokers in order to learn more about individual customers.

Marketers
Marketers use health data to target consumers. For example, marketers have purchased "sick lists" of people presumed to have a certain ailment from Acxiom.[6]

Digital Advertising (Facebook, Google, Amazon, etc)
Most have thier own sources of data but are interested in purchasing health data. In Feb of 2019, Facebook was caught matching ovulation health data from an app called Flo to their own users presumably for targeted advertising.[9]

RISK PROFILING

EHRs, Hospitals, and Physician Groups
It is often harder for doctors to get data about their patients from within the health system than from the outside. Re-identified data can flesh out a patient's record. Population data can predict patient risk. Some data brokers include "criminal records, online purchasing histories, retail loyalty programs and voter registration data" in their reports.[8]

Health Insurance
The ACA denies health insurers to exclude patients with pre-existing conditions. However, payers are interested in getting risk scores for their patient populations to manage populations, determine an individual's premium charges, and even deny coverage.[1, 13]

Car Insurance, House Insurance, Life Insurance, Job application, Cell phone or utility company
When assessing cutomers' financial risk, insurers and even employers may purchase health risk profiles.

Q **Is it difficult to re-identify data?**

Researchers have long demonstrated that it is not difficult to re-identify de-identified data.[10] One study found that "63% of the population can be uniquely identified by the combination of their gender, date of birth, and zip code alone."[3]

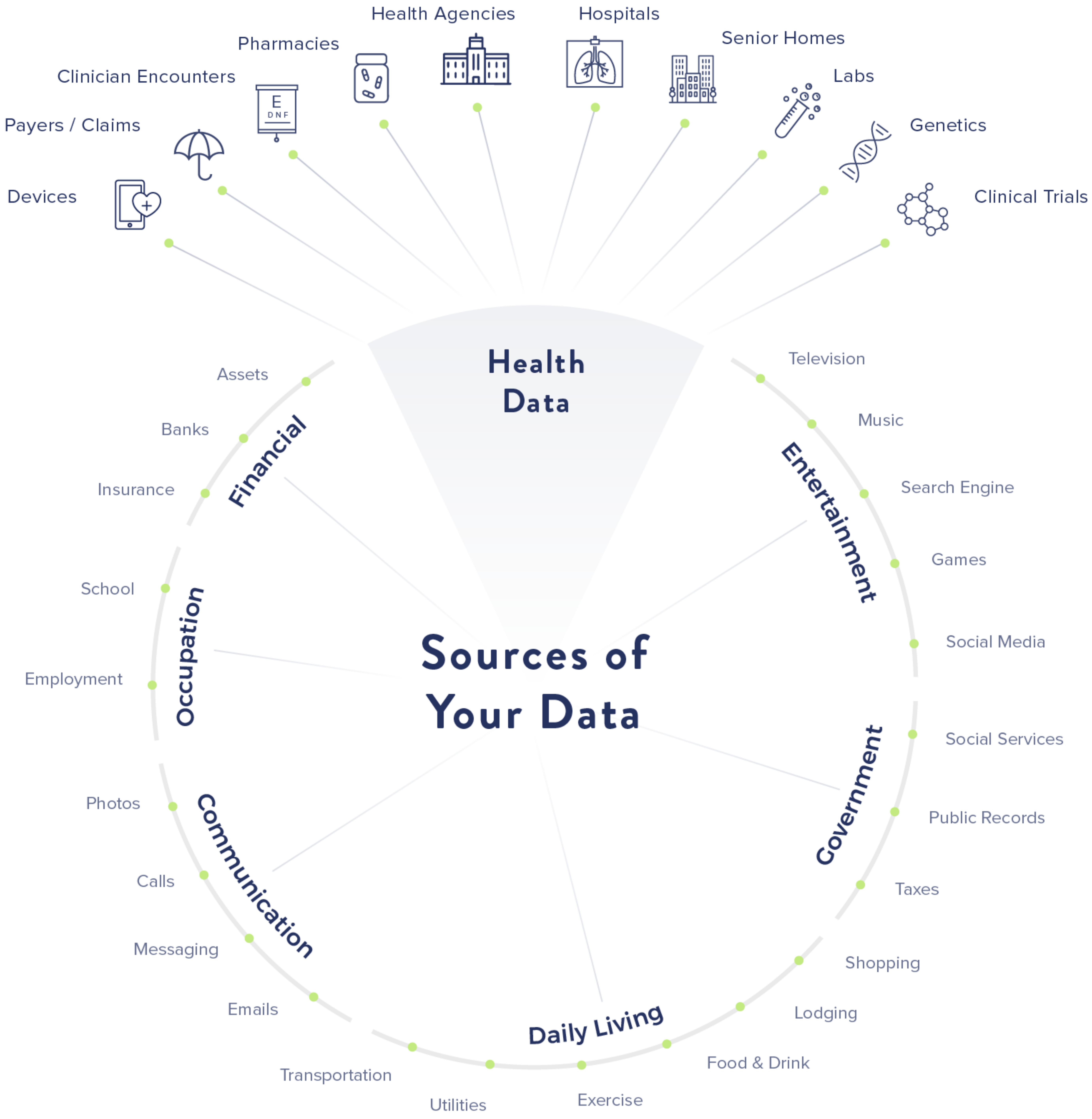
HIPAA AND MY MEDICAL RECORD

Medical records can contain history of my health events including hospitalizations, diagnoses, medication lists, family history. In 1996, HIPAA ruled that medical record data could be shared if it was de-identified by removing name and a few other personally identifying data.

MY DIGITAL FOOTPRINT

Social media companies, banks, apps on your phone, browser trackers, and other companies that have access to your digital foot print sell your data. HIPAA doesn't regulate this data even though it can paint a vivid picture of your health. The data may also be used to re-identify de-identified healthcare data.[12]

goinvo



Sources of Your Data

Health Data

- Devices
- Payers / Claims
- Clinician Encounters
- Pharmacies
- Health Agencies
- Hospitals
- Senior Homes
- Labs
- Genetics
- Clinical Trials

Entertainment

- Television
- Music
- Search Engine
- Games
- Social Media

Government

- Social Services
- Public Records
- Taxes

Daily Living

- Shopping
- Lodging
- Food & Drink
- Exercise
- Utilities
- Transportation

Communication

- Emails
- Messaging
- Calls
- Photos

Occupation

- Employment
- School

Financial

- Insurance
- Banks
- Assets

2000-2020

Does "patient data ownership" turn "the age of healthcare surveillance" into a net positive?

Giving Patients Control of Their EHR Data

David Blumenthal, MD, MPP and David Squires, MA

The Commonwealth Fund, New York, NY, 10021 USA.

J Gen Intern Med 30(Suppl 1):S42–3
DOI: 10.1007/s11606-014-3071-y

The question of whether patients should be able to control the information in their electronic health records (EHR) provokes strong opinions. Some argue that the information rightfully belongs to patients, and they should be able to decide what is recorded and who can access it. Some clinicians, however, argue that because they have a duty to provide their patients with the best possible care, doctors should have unfettered or nearly unfettered access to any information needed to meet that obligation.

In our view, the patient's right to control their own health information dominates. As Dr. Donald Berwick has eloquently professed, clinicians are guests in their patients' lives.[1] And as guests, they must respect the rules and wishes of their hosts, even when those preferences strike caretakers as misguided and even when they may compromise the patient's well-being.

Every day, patients choose (openly or covertly) not to follow clinicians' recommendations—indeed, not to seek care at all. Caretakers have no right to overrule those wishes, even when they profoundly disagree. The idea of force-feeding patients medications or dragging them in handcuffs into the operating room would never occur to us. Assuming patients are mentally competent, we respect their right to control their bodies and their health care fates.

So it should be with their health data. It is perfectly reasonable for patients to be concerned about the deeply personal information contained in their records. Who has access to that information may have ramifications in the patient's life, both inside and outside the health system, that clinicians cannot fathom. The person best positioned to make judgments about the use of their data—and the only person with the right to make that judgment—is the patient.

This view is reflected in the Fair Information Practice Principles adopted in 2008 by the Office of the National Coordinator for Health Information Technology, which underlie the federal government's efforts to encourage privacy, transparency, and accountability for electronic health information. Among these is the principle of *individual choice*—that "individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their individually identifiable health information"[2]

With rights, however, come responsibilities. When patients' decisions affect the well-being of others, then the rules change. An individual who has been exposed to Ebola cannot restrict access to that information. A patient who is actively abusing substances should not be allowed to withhold that information from clinicians who may, as a result, unwittingly perpetuate illegal behavior—and endanger third parties who may be affected by the intoxication of the patient.

Furthermore, in controlling their health information, patients assume responsibility for the consequences of their choices. They cannot hold caretakers legally or professionally liable for negative outcomes that stem from lacking information that is purposefully missing or hidden. Patients must accept the attendant risks associated with their data decisions.

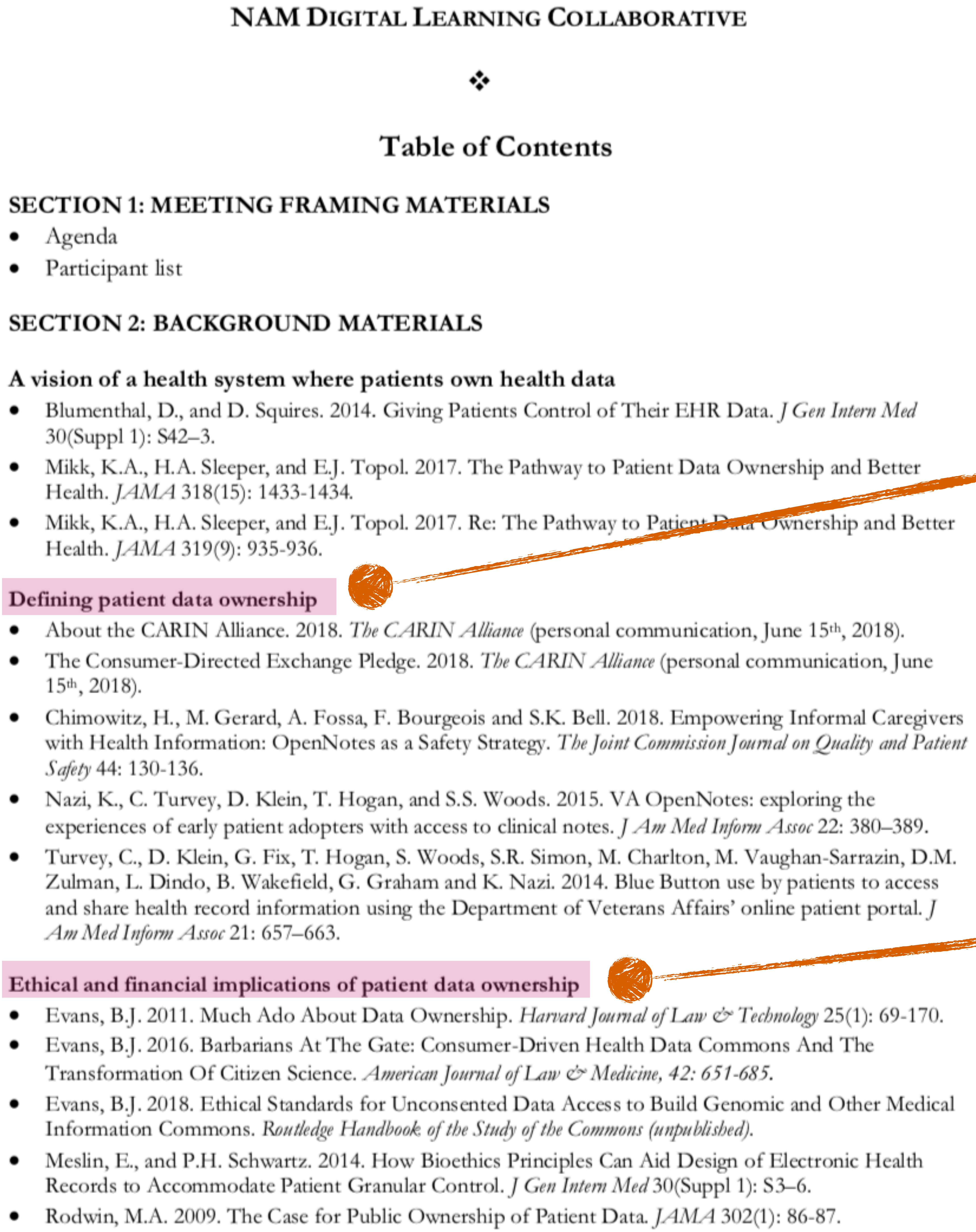
However, patients cannot competently assess those risks unless they are meaningfully informed of the consequences of restricting access to their electronic records. This poses a considerable challenge; most patients (and, indeed, most caretakers) currently have little understanding of how health information is shared and used. Kelly Caine et al., in this issue, describe how initially half of the patients participating in the Eskenazi Health study had little or no idea what was contained in their EHR, and none were fully informed about who had access to it.

Furthermore, knowing what is in one's health record is insufficient to give patients a sense of *why* certain caretakers may need certain information. The ways in which caretakers use information are often non-linear and unpredictable. For example, knowledge of drug side effects and their interactions with other medications changes over time. A patient's decision to withhold data about a sensitive medication—such as a psychotropic or HIV-related drug—may have later consequences that neither patients nor clinicians could have anticipated. Beyond this, when evaluating a patient, experienced clinicians often rely on an array of data, including information not obviously related to the current problem, to raise and evaluate hypotheses about diagnosis and treatment.

Communicating to patients the inherent risks and potential consequences of their decisions is a challenge, but has ample precedent in modern medicine: the informed consent process. Clinicians have not always been expected seek their patients' permission when providing invasive care. Only in 1914 did the courts rule that a surgeon performing an operation without the patient's consent commits an assault.[3] The need for informed consent has since become ingrained in the medical

NATIONAL ACADEMY OF MEDICINE

28 Jun 2018



NAM DIGITAL LEARNING COLLABORATIVE

❖

Table of Contents

SECTION 1: MEETING FRAMING MATERIALS

- Agenda
- Participant list

SECTION 2: BACKGROUND MATERIALS

A vision of a health system where patients own health data

- Blumenthal, D., and D. Squires. 2014. Giving Patients Control of Their EHR Data. *J Gen Intern Med* 30(Suppl 1): S42–3.
- Mikk, K.A., H.A. Sleeper, and E.J. Topol. 2017. The Pathway to Patient Data Ownership and Better Health. *JAMA* 318(15): 1433-1434.
- Mikk, K.A., H.A. Sleeper, and E.J. Topol. 2017. Re: The Pathway to Patient Data Ownership and Better Health. *JAMA* 319(9): 935-936.

Defining patient data ownership

- About the CARIN Alliance. 2018. *The CARIN Alliance* (personal communication, June 15th, 2018).
- The Consumer-Directed Exchange Pledge. 2018. *The CARIN Alliance* (personal communication, June 15th, 2018).
- Chimowitz, H., M. Gerard, A. Fossa, F. Bourgeois and S.K. Bell. 2018. Empowering Informal Caregivers with Health Information: OpenNotes as a Safety Strategy. *The Joint Commission Journal on Quality and Patient Safety* 44: 130-136.
- Nazi, K., C. Turvey, D. Klein, T. Hogan, and S.S. Woods. 2015. VA OpenNotes: exploring the experiences of early patient adopters with access to clinical notes. *J Am Med Inform Assoc* 22: 380–389.
- Turvey, C., D. Klein, G. Fix, T. Hogan, S. Woods, S.R. Simon, M. Charlton, M. Vaughan-Sarrazin, D.M. Zulman, L. Dindo, B. Wakefield, G. Graham and K. Nazi. 2014. Blue Button use by patients to access and share health record information using the Department of Veterans Affairs' online patient portal. *J Am Med Inform Assoc* 21: 657–663.

Ethical and financial implications of patient data ownership

- Evans, B.J. 2011. Much Ado About Data Ownership. *Harvard Journal of Law & Technology* 25(1): 69-170.
- Evans, B.J. 2016. Barbarians At The Gate: Consumer-Driven Health Data Commons And The Transformation Of Citizen Science. *American Journal of Law & Medicine, 42: 651-685.*
- Evans, B.J. 2018. Ethical Standards for Unconsented Data Access to Build Genomic and Other Medical Information Commons. *Routledge Handbook of the Study of the Commons (unpublished).*
- Meslin, E., and P.H. Schwartz. 2014. How Bioethics Principles Can Aid Design of Electronic Health Records to Accommodate Patient Granular Control. *J Gen Intern Med* 30(Suppl 1): S3–6.
- Rodwin, M.A. 2009. The Case for Public Ownership of Patient Data. *JAMA* 302(1): 86-87.

Defining patient data ownership

Ethics and $$ implications

“Patients should own their data.”

Elizabeth Nabel in 2017, President of Brigham Health
and
Seema Verma in 2018, Administrator of CMS

This ain't property ownership.

Patient Data Ownership in Massachusetts

Patients co-own or fully own every health data point about themselves.

Health data generated about the patient by a provider is co-owned by both parties.

Health data generated by the patient is fully owned by the patient with a right
to possess, share, sell, or destroy.

VIEWPOINT

The Pathway to Patient Data Ownership and Better Health

Katherine A. Mikk, JD
Open Health Services, The MITRE Corporation, Bedford, Massachusetts.

Harry A. Sleeper
Open Health Services, The MITRE Corporation, Bedford, Massachusetts.

Eric J. Topol, MD
Scripps Translational Science Institute, La Jolla, California.

George Neyarapally, PharmD, MPH, JD
Open Health Services, The MITRE Corporation, Bedford, Massachusetts

Digital health data are rapidly expanding to include patient-reported outcomes, patient-generated health data, and social determinants of health. Measurements collected in clinical settings are being supplemented by data collected in daily life, such as data derived from wearable sensors and smartphone apps, and access to other data, such as genomic data, is rapidly increasing. One projection suggests that a billion individuals will have their whole genome sequenced in the next several years.[1] These additional sources of data, whether patient-generated, genomic, or other, are critical for a comprehensive picture of an individual's health.

Enabling access to personal health data, clinical or patient-generated, may benefit patients and health care professionals. Research is beginning to show that providing patients with their complete health data may help improve their health. For example, timely access to laboratory results can increase patient engagement.[2] Access to physician notes after appointments appears to encourage individuals to improve their health and participate in decision-making, with electronically engaged patients demonstrating more successful medication adherence, quality outcomes, and symptom management.[3] Economic benefits may include the avoidance of duplicative imaging or laboratory tests.[4] Clinicians may also benefit from more informed patients. For example, they may score higher in quality performance programs because patients who are more informed may better adhere to treatment plans and hence may improve clinician scores. Despite growing evidence of such benefits, albeit with limited patient outcomes, and legislative and regulatory initiatives that facilitate electronic patient engagement, patients' access to a complete, longitudinal digital health record remains rare. While such access may be possible for certain patients who receive care within a few select health systems, it remains elusive for many others, including patients who have changed physicians, lived in different places, have multiple chronic conditions, or who have had services provided outside of a clinical setting such as through a home health service.[5]

Patients need and deserve the opportunity to control their health data.

Health care, under pressure to embrace interoperability, is poised for transformation. The potential for future system improvements is vast, but depends, in part, on increased patient participation. Health care must find a way to shift from "the doctor will see you now" to "the patient will see the doctor now."[6] Patients need engagement beyond passively receiving services, but this will be challenging until they can easily access and use their health data. For this to proceed, control of health data must be transferred to the patient or the patient's authorized representative.

More specifically, to obtain active patient engagement and health system improvement, 3 components are necessary: (1) common data elements that enable the sharing and merging of health data from multiple sources; (2) a patient encounter data receipt, comprised of relevant health data from each health care encounter, automatically pushed to the patient's complete digital health record; and (3) a contract between patients and third-party health data managers (eg, health care organizations and commercial entities) that enables individuals to control their longitudinal digital health record. Most of these components already exist in some form, requiring only minor adjustments to effect health system transformation.

Clinicians, patients, and health care systems need a way to efficiently receive, integrate, understand, compute, and use digital health data from other practitioners and health encounter locations. This requires the merging of what is often disparate data from multiple sources, and the most effective way to do this is to establish common data elements agnostic of any particular vendor's electronic health record (EHR) system.

With widespread implementation of common data elements and value sets, semantic and clinical interoperability can be achieved, and health information can be merged, while maintaining data integrity. New initiatives, such as the Standard Health Record,[7] that focus on standardizing data within health records instead of solely on exchange standards enable the development of one complete, digital health record per patient containing health data merged from all of a patient's clinicians and related health data sources. For example, applying common data elements to platforms can enable patients to add patient-generated data into the record in addition to clinician-generated data. With its common, unifying template, the Standard Health Record can also support a host of secondary uses, such as patient-centered outcome research, precision medicine, and precision public health surveillance. This common digital health data language is also anticipated to reduce translation and comprehension errors.

Common data elements have legislative and regulatory support. For example, one Meaningful Use objective is to provide patients with the ability to view, download, or transmit certain health information, including vital signs and laboratory test results. Section 4003 of the 21st Century Cures Act also requires the Department of Health and Human Services to evaluate the need for a "core set of common data elements and associated value sets" to enhance the exchange of structured health information.

Corresponding Author: Katherine A. Mikk, JD, MITRE Corp, 202 Burlington Rd, Bedford, MA 01730 (kmikk@mitre.org).

3 components are necessary:

(1) **common data elements** that enable the sharing and merging of health data from multiple sources;

(2) a **patient encounter data receipt**, comprised of relevant health data from each health care encounter, automatically pushed to the patient's complete digital health record; and

(3) a **contract** between patients and third-party health data managers (eg, health care organizations and commercial entities) that enables individuals to **control their longitudinal digital health record.**

Encounter

Patient DUA

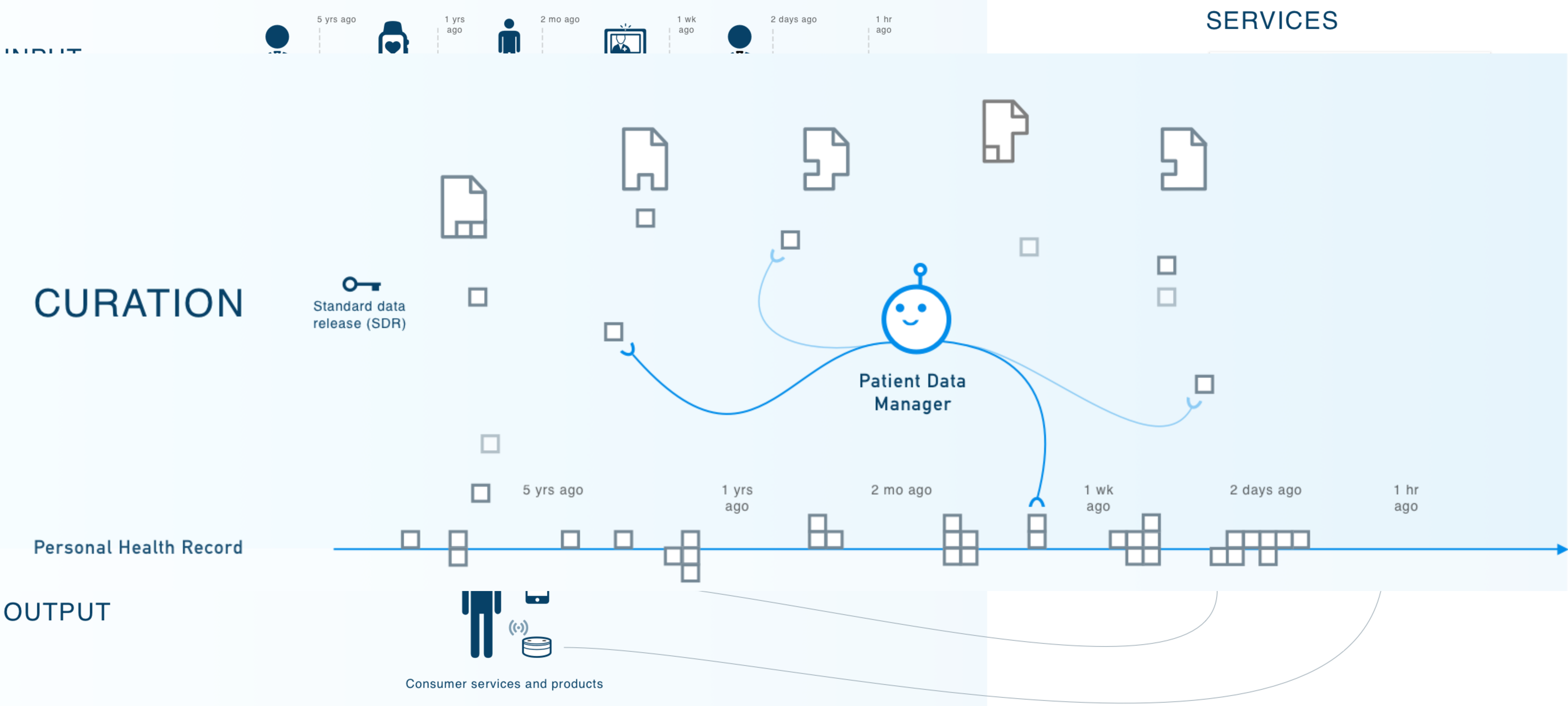
Patient Data Manager

Patient Data Receipt

Patient Health Record

PATIENT DATA MANAGER SYSTEM DIAGRAM v01

15.MAY.19



INPUT

5 yrs ago
1 yrs ago
2 mo ago
1 wk ago
2 days ago
1 hr ago

SERVICES

CURATION

Standard data release (SDR)

Patient Data Manager

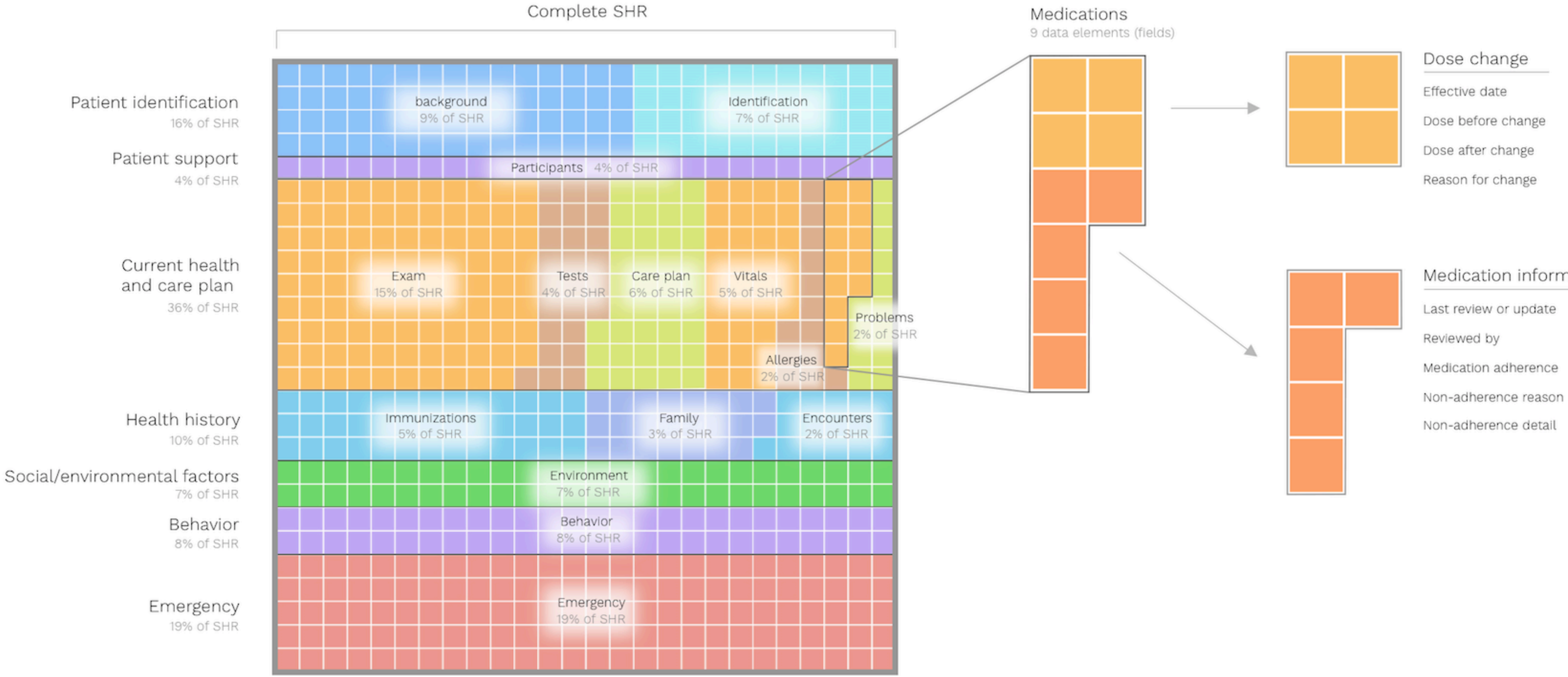
5 yrs ago
1 yrs ago
2 mo ago
1 wk ago
2 days ago
1 hr ago

Personal Health Record

OUTPUT

Consumer services and products

Data Completeness



Complete SHR

Patient identification
16% of SHR

Patient support
4% of SHR

Current health and care plan
36% of SHR

Health history
10% of SHR

Social/environmental factors
7% of SHR

Behavior
8% of SHR

Emergency
19% of SHR

background
9% of SHR

Identification
7% of SHR

Participants 4% of SHR

Exam
15% of SHR

Tests
4% of SHR

Care plan
6% of SHR

Vitals
5% of SHR

Problems
2% of SHR

Allergies
2% of SHR

Immunizations
5% of SHR

Family
3% of SHR

Encounters
2% of SHR

Environment
7% of SHR

Behavior
8% of SHR

Emergency
19% of SHR

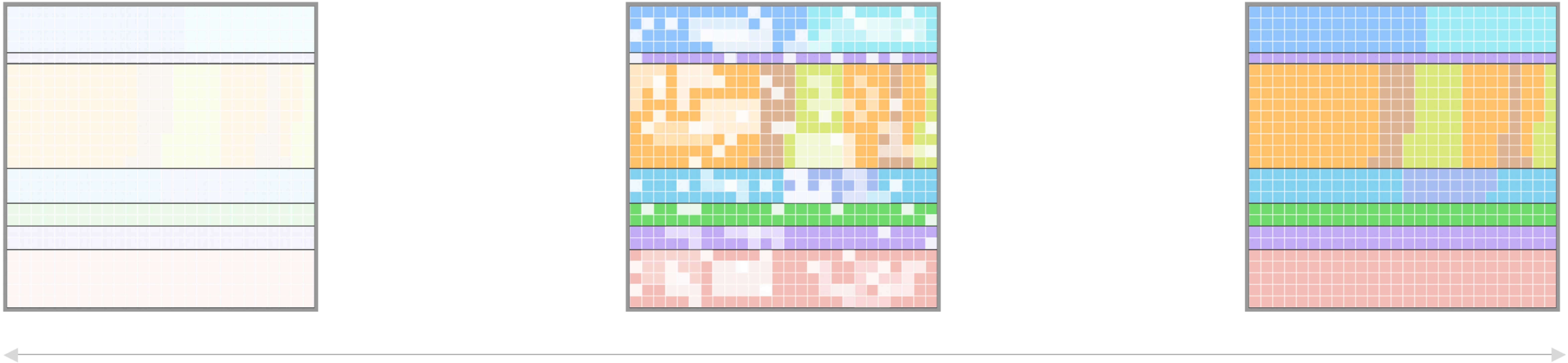
Medications
9 data elements (fields)

Dose change
- Effective date
- Dose before change
- Dose after change
- Reason for change

Medication inform
- Last review or update
- Reviewed by
- Medication adherence
- Non-adherence reason
- Non-adherence detail

The macro categories to the left are from the SHR v01 ppt. Categories found in the SHR v02 xl file were nested under related categories from SHR v01

Data Completeness Continuum

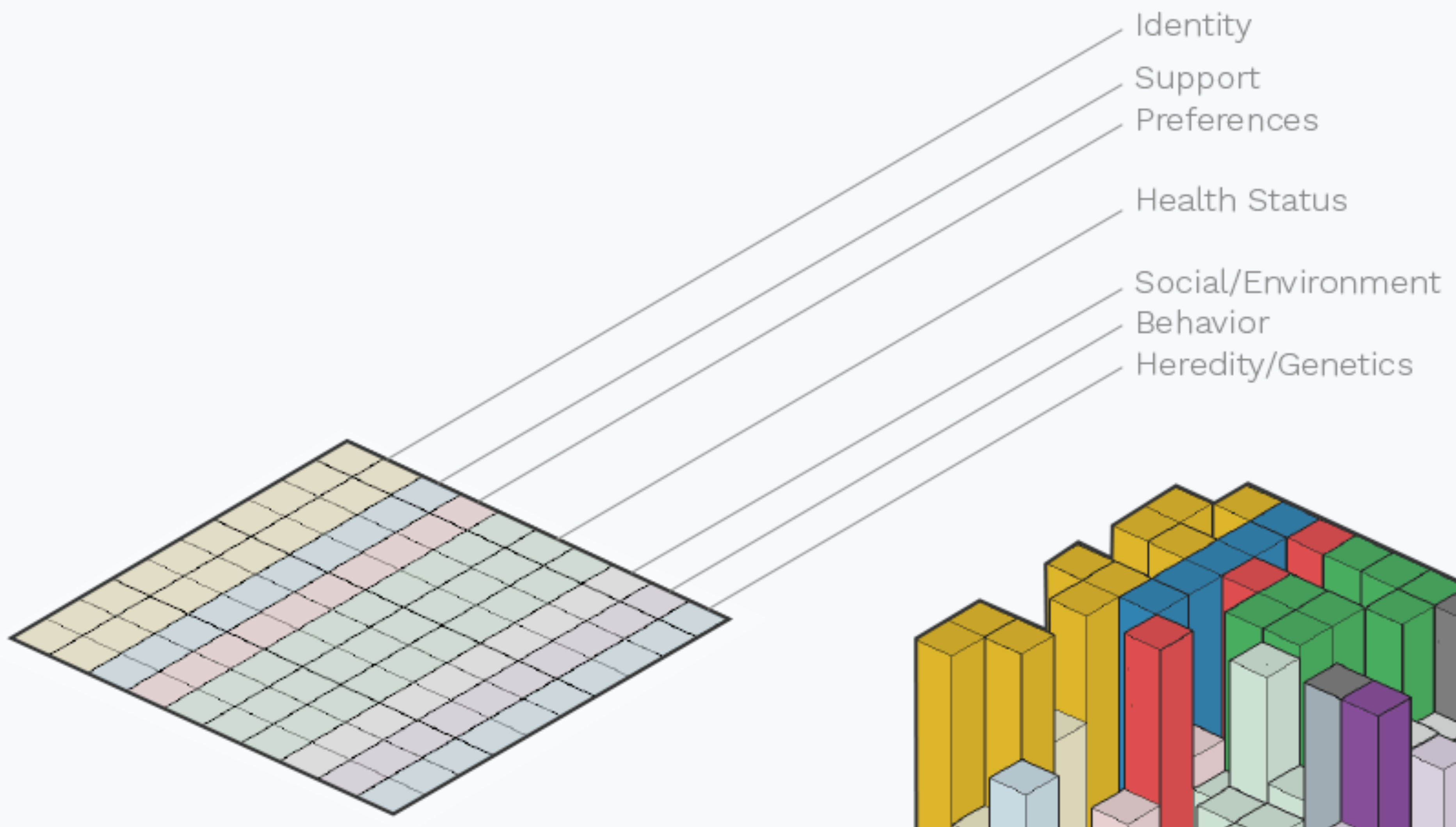


Empty

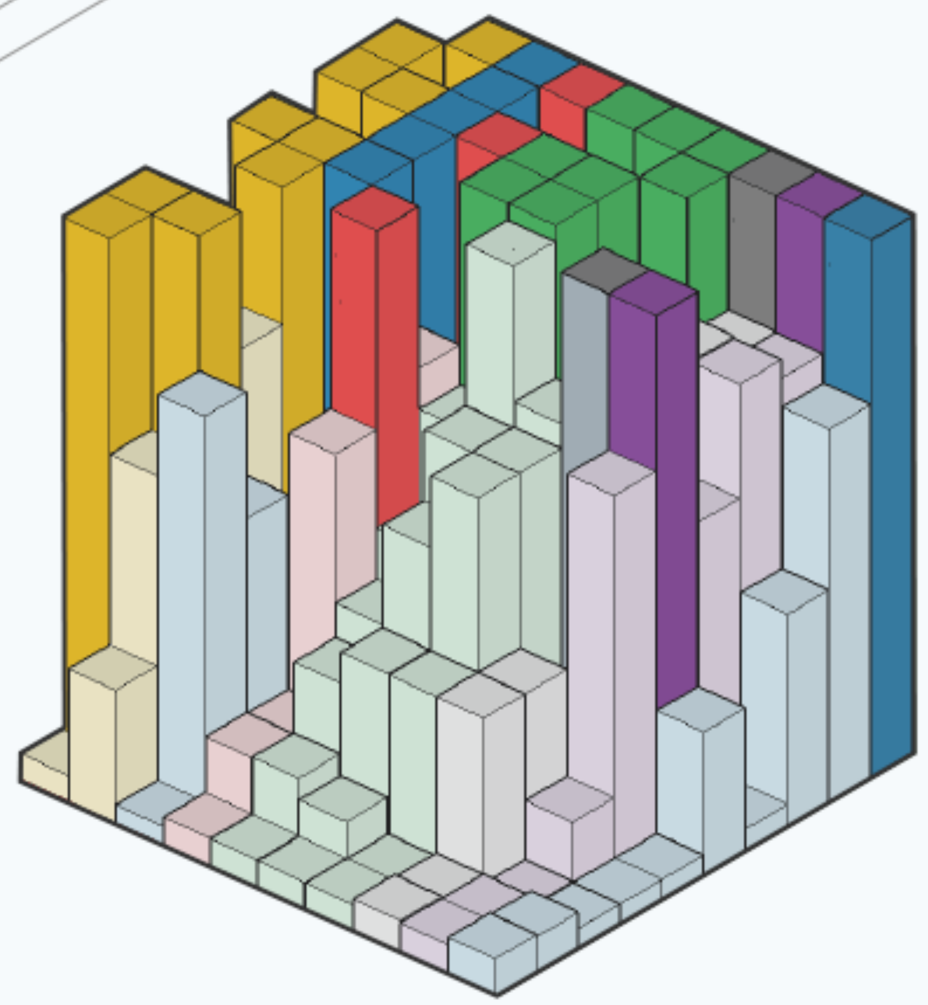
Half complete

Complete

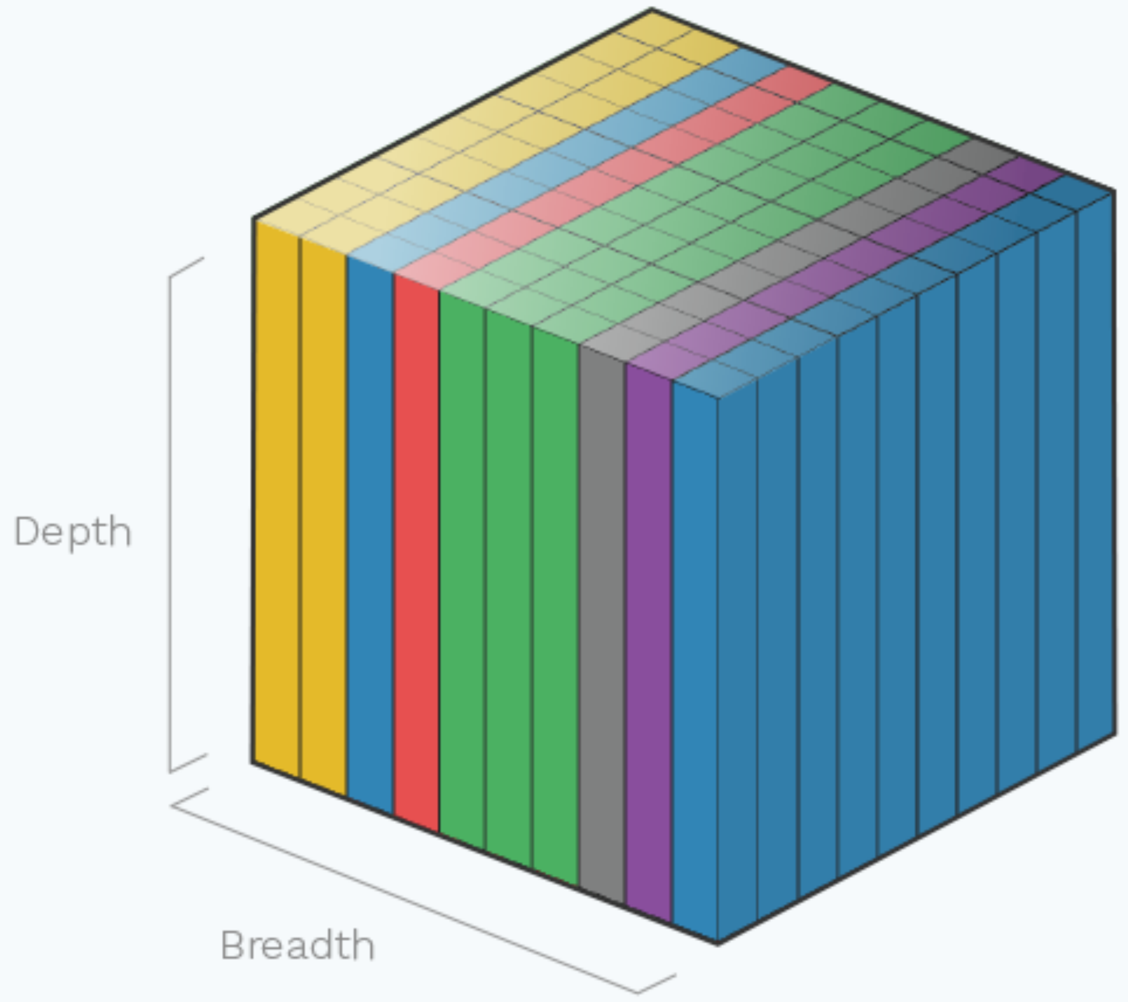
Data Completeness Continuum



Empty record

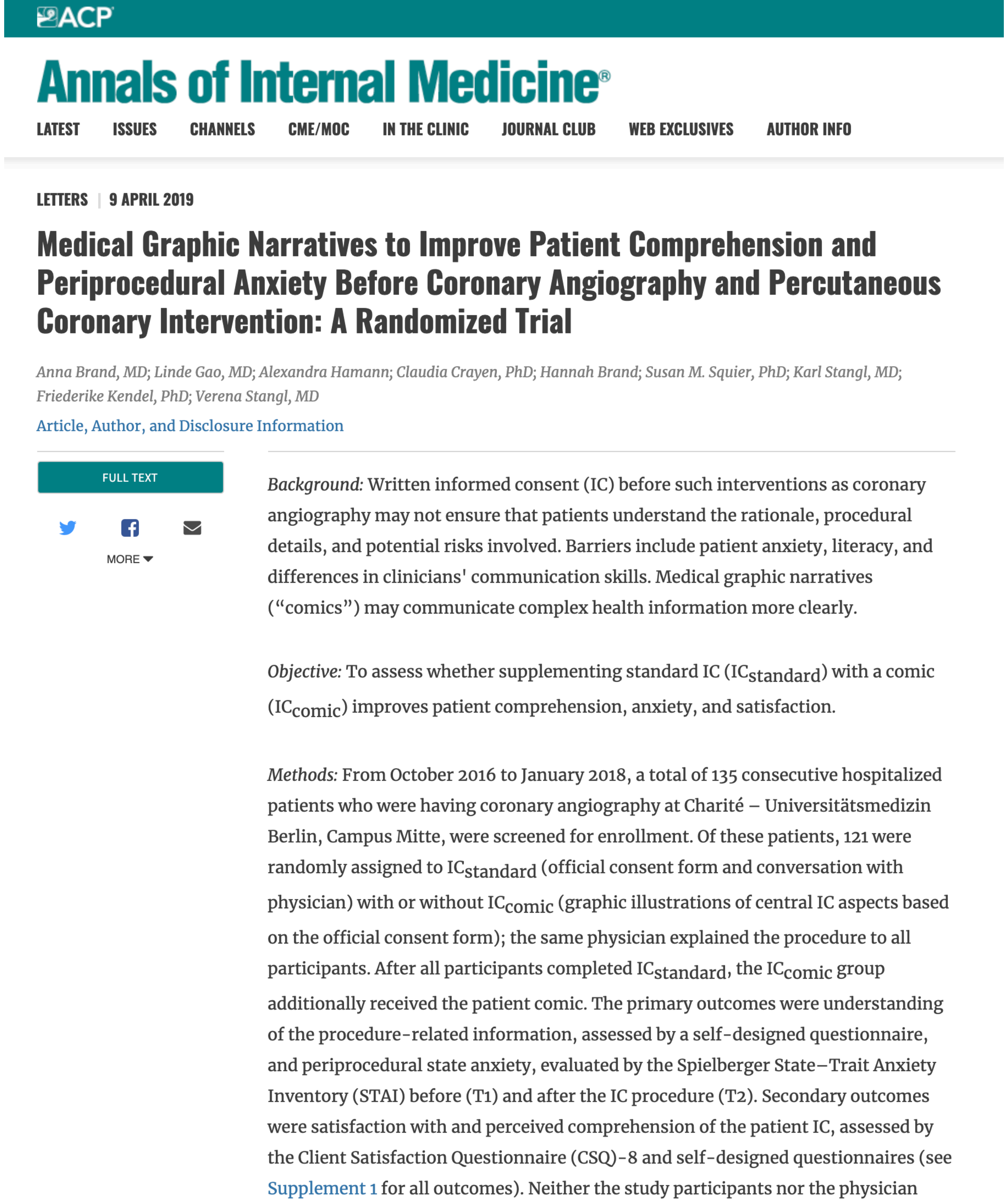


Partial record



Complete record

a side note…



Annals of Internal Medicine®

LETTERS | 9 APRIL 2019

Medical Graphic Narratives to Improve Patient Comprehension and Periprocedural Anxiety Before Coronary Angiography and Percutaneous Coronary Intervention: A Randomized Trial

Anna Brand, MD; Linde Gao, MD; Alexandra Hamann; Claudia Crayen, PhD; Hannah Brand; Susan M. Squier, PhD; Karl Stangl, MD; Friederike Kendel, PhD; Verena Stangl, MD

Article, Author, and Disclosure Information

Background: Written informed consent (IC) before such interventions as coronary angiography may not ensure that patients understand the rationale, procedural details, and potential risks involved. Barriers include patient anxiety, literacy, and differences in clinicians' communication skills. Medical graphic narratives ("comics") may communicate complex health information more clearly.

Objective: To assess whether supplementing standard IC ($\text{IC}_{\text{standard}}$) with a comic ($\text{IC}_{\text{comic}}$) improves patient comprehension, anxiety, and satisfaction.

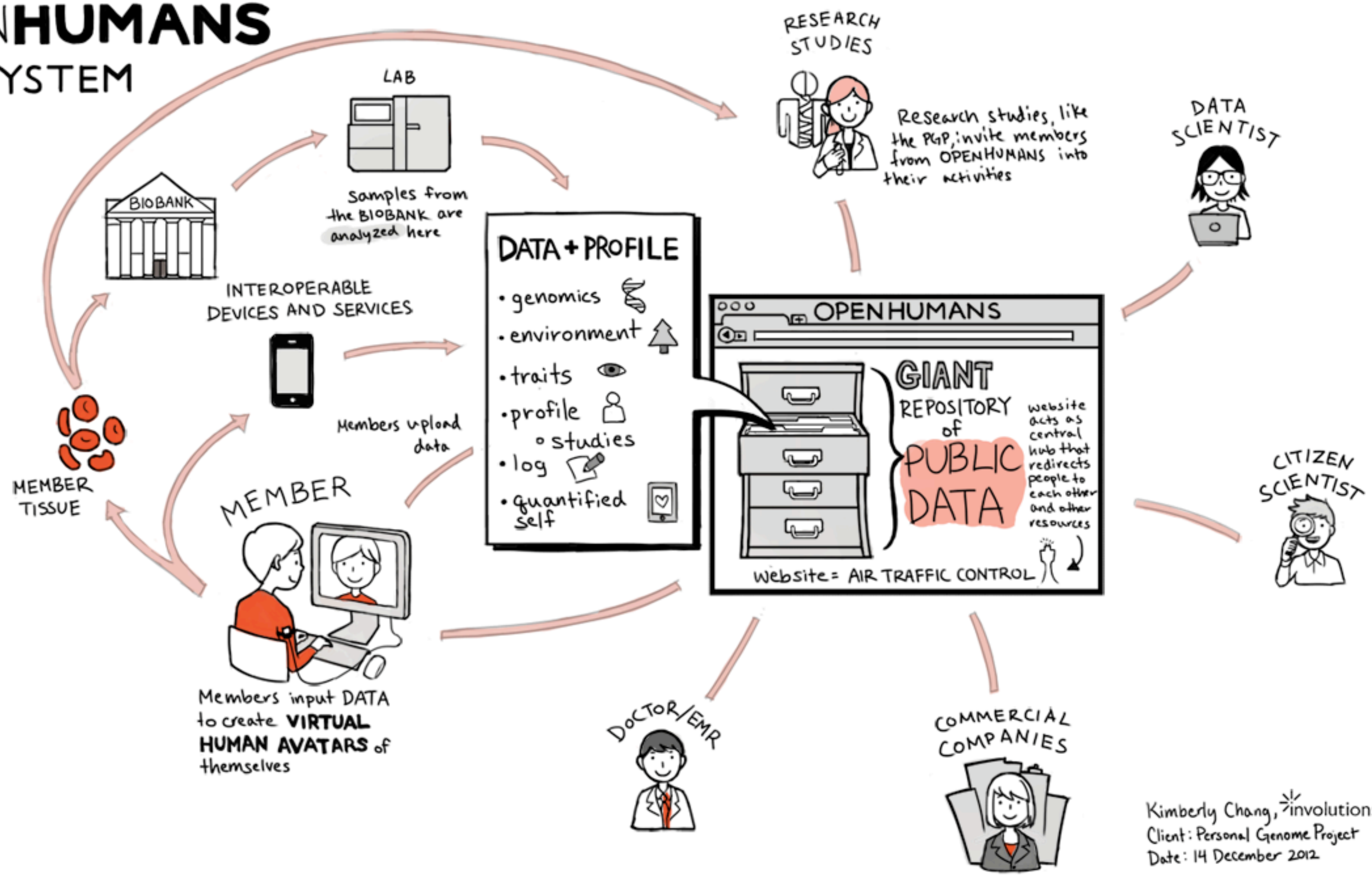
Methods: From October 2016 to January 2018, a total of 135 consecutive hospitalized patients who were having coronary angiography at Charité – Universitätsmedizin Berlin, Campus Mitte, were screened for enrollment. Of these patients, 121 were randomly assigned to $\text{IC}_{\text{standard}}$ (official consent form and conversation with physician) with or without IC_{comic} (graphic illustrations of central IC aspects based on the official consent form); the same physician explained the procedure to all participants. After all participants completed $\text{IC}_{\text{standard}}$, the IC_{comic} group additionally received the patient comic. The primary outcomes were understanding of the procedure-related information, assessed by a self-designed questionnaire, and periprocedural state anxiety, evaluated by the Spielberger State–Trait Anxiety Inventory (STAI) before (T1) and after the IC procedure (T2). Secondary outcomes were satisfaction with and perceived comprehension of the patient IC, assessed by the Client Satisfaction Questionnaire (CSQ)-8 and self-designed questionnaires (see Supplement 1 for all outcomes). Neither the study participants nor the physician

Drawing pictures helps comprehension.

...duh.

Yet, academics, scientists, execs++ need evidence (like this) to get graphic storytelling included as part of products.

the OPEN**HUMANS** ECOSYSTEM



samples from the BIOBANK are analyzed here

Members upload data

Members input DATA to create **VIRTUAL HUMAN AVATARS** of themselves

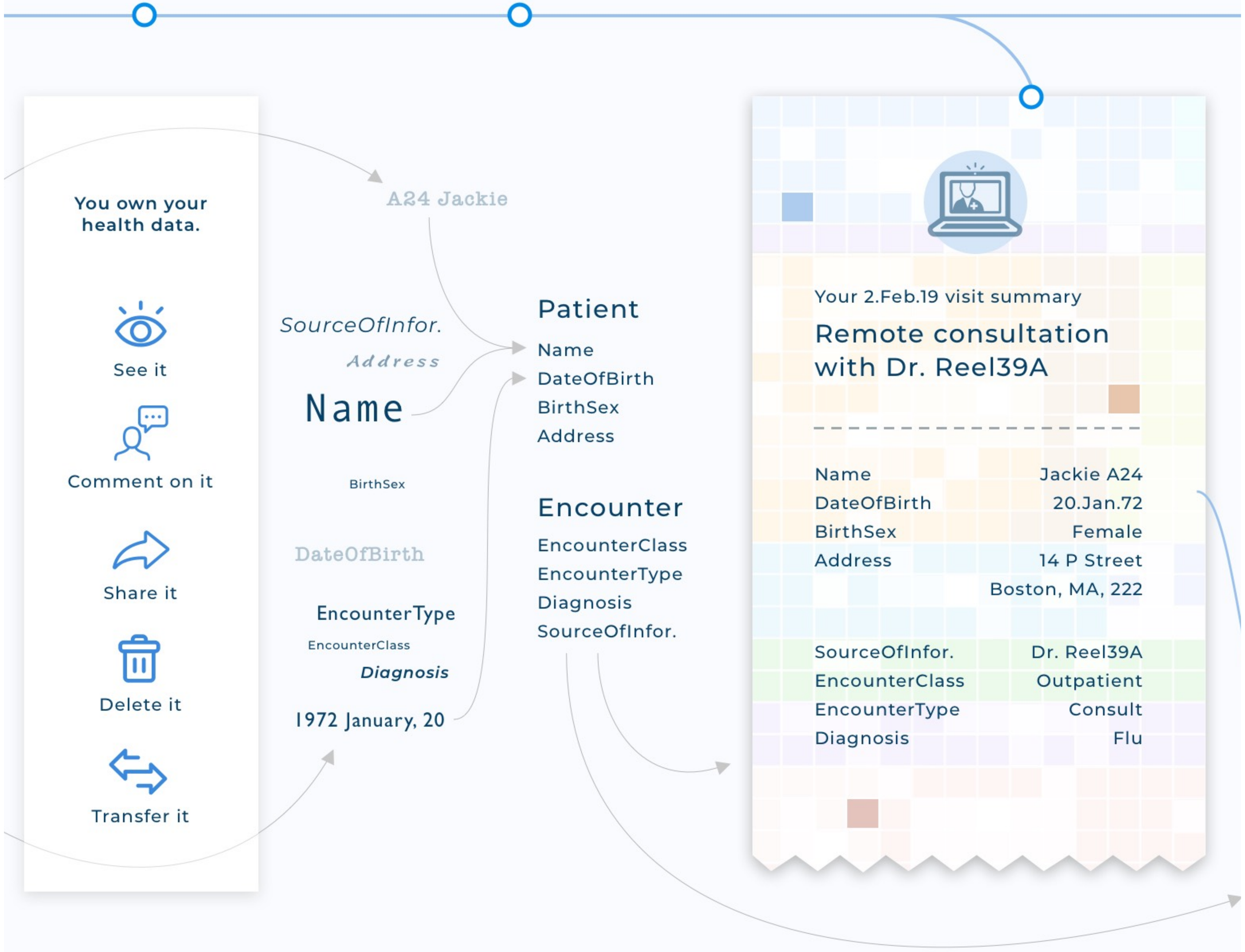
Research studies, like the PGP, invite members from OPENHUMANS into their activities

website acts as central hub that redirects people to each other and other resources

website = AIR TRAFFIC CONTROL

Kimberly Chang, involutionstudios
Client: Personal Genome Project
Date: 14 December 2012


Rx
EXERCISE IS MEDICINE
BRING THE EXAM ROOM TO ME
PETER SMITH
EXAMINE YOURSELF
DO WHAT MAKES YOU HAPPY
MANAGE DEATH



Patient DUA

You own your health data.

- See it
- Comment on it
- Share it
- Delete it
- Transfer it

Patient Data Manager

Patient

- Name
- DateOfBirth
- BirthSex
- Address

Encounter

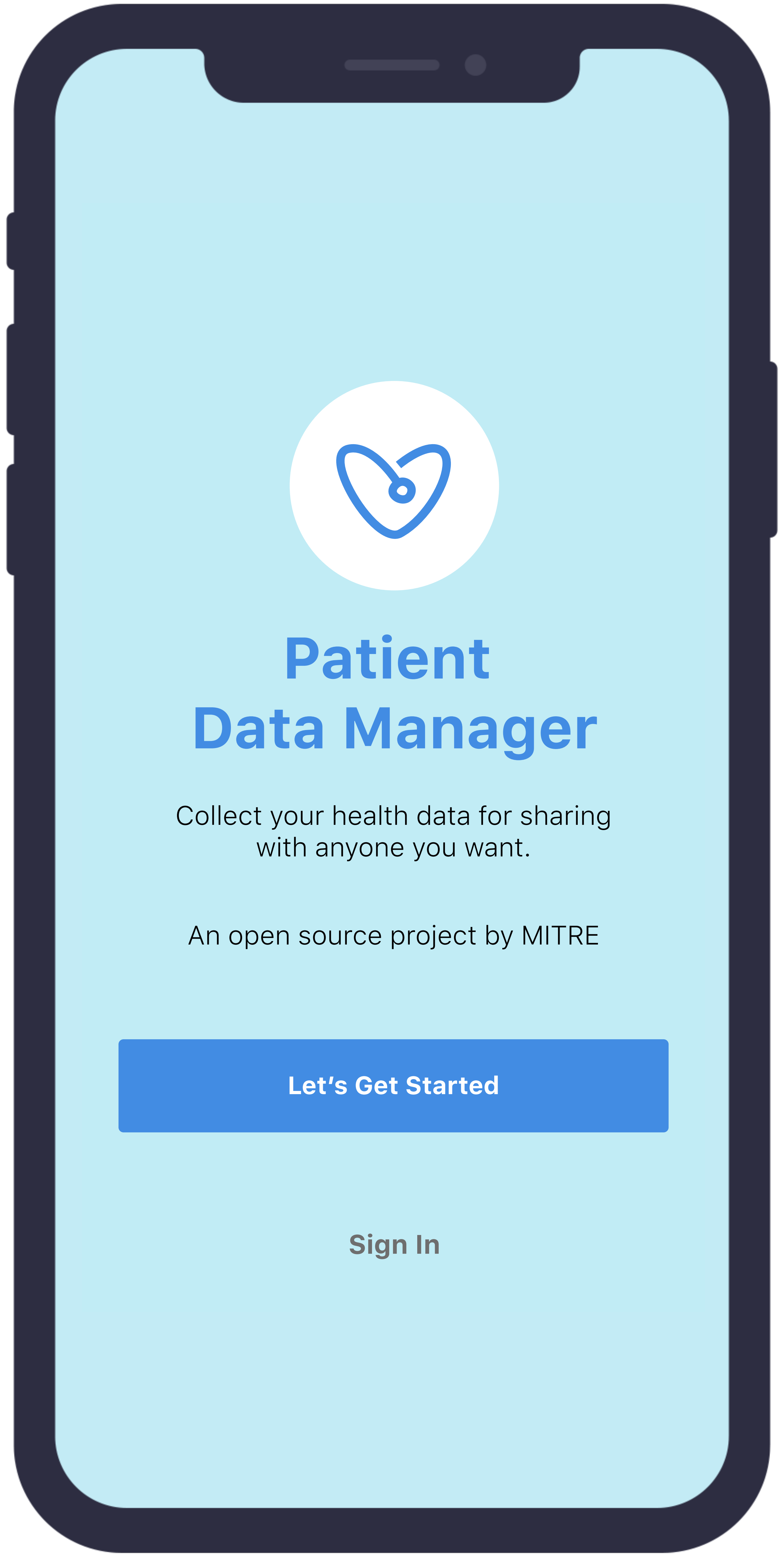
- EncounterClass
- EncounterType
- Diagnosis
- SourceOfInfor.

Patient Data Receipt

Your 2.Feb.19 visit summary

Remote consultation with Dr. Reel39A

Name	Jackie A24
DateOfBirth	20.Jan.72
BirthSex	Female
Address	14 P Street Boston, MA, 222
SourceOfInfor.	Dr. Reel39A
EncounterClass	Outpatient
EncounterType	Consult
Diagnosis	Flu



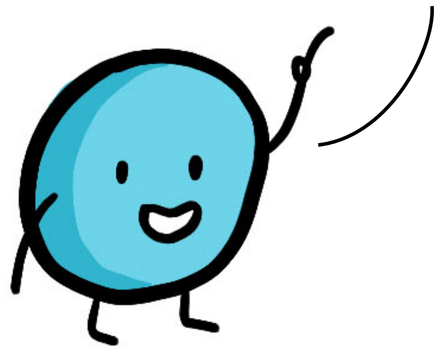
Patient Data Manager

Collect your health data for sharing with anyone you want.

An open source project by MITRE

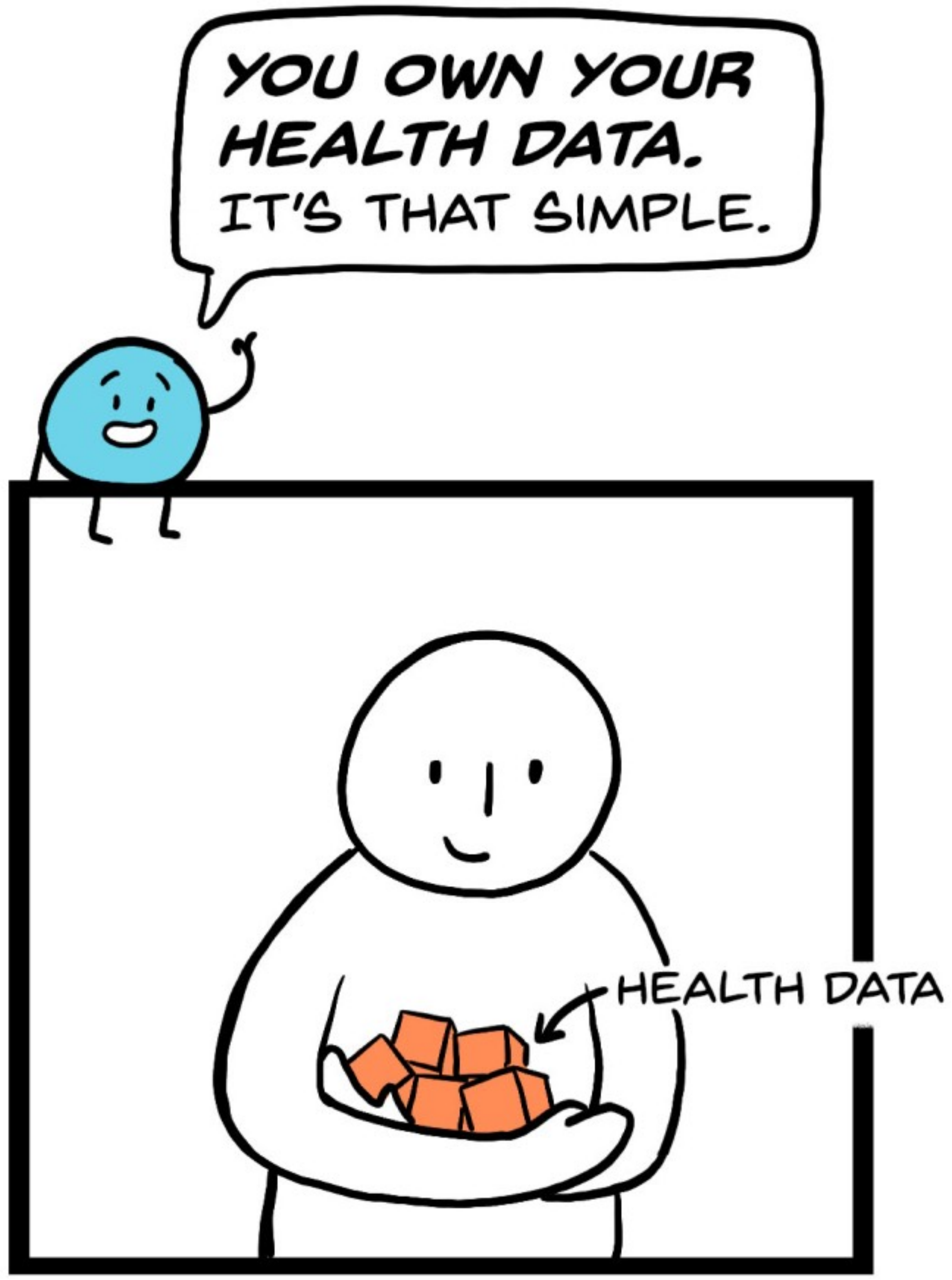
IT'S YOUR DATA.

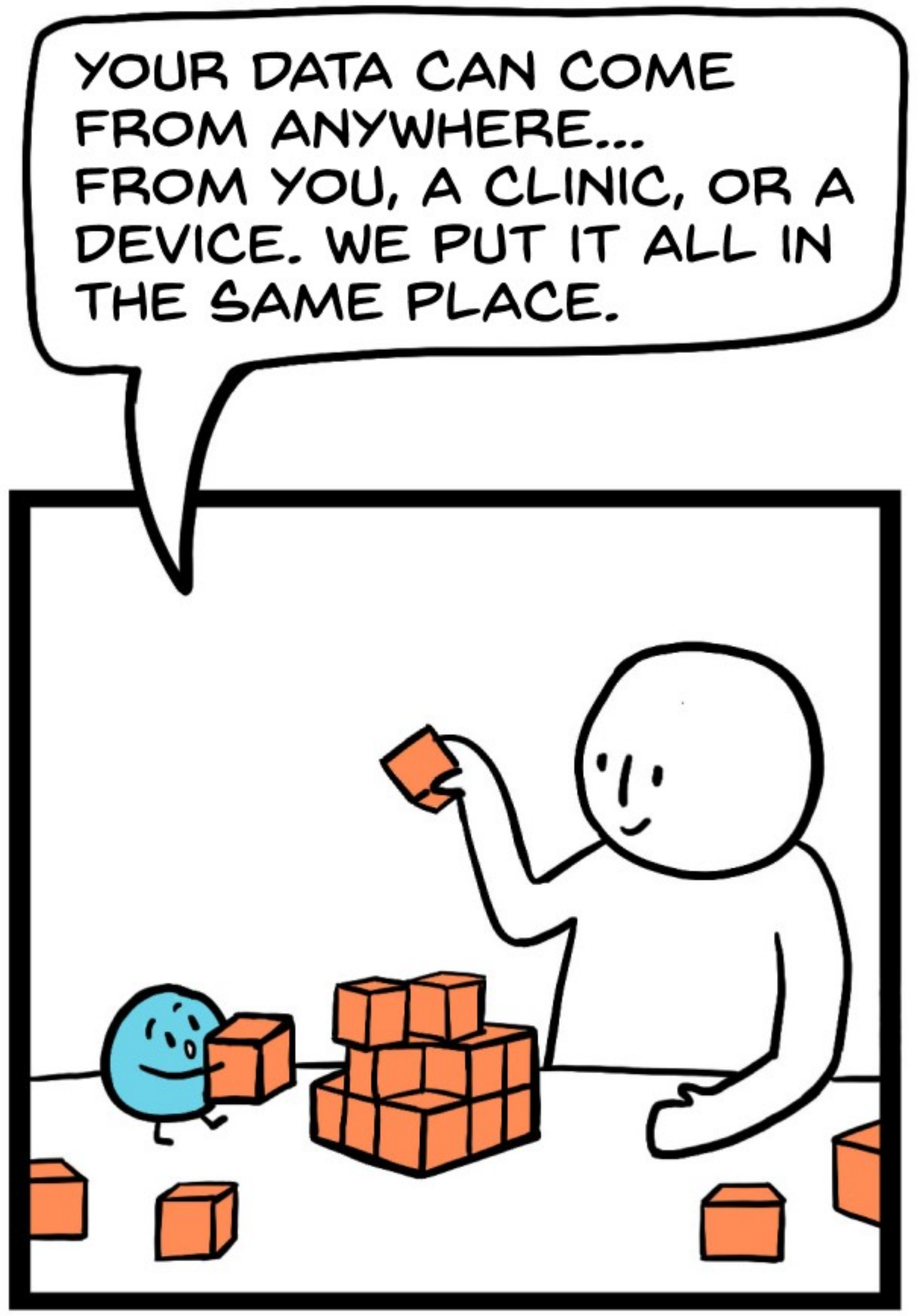
WE JUST MANAGE IT.

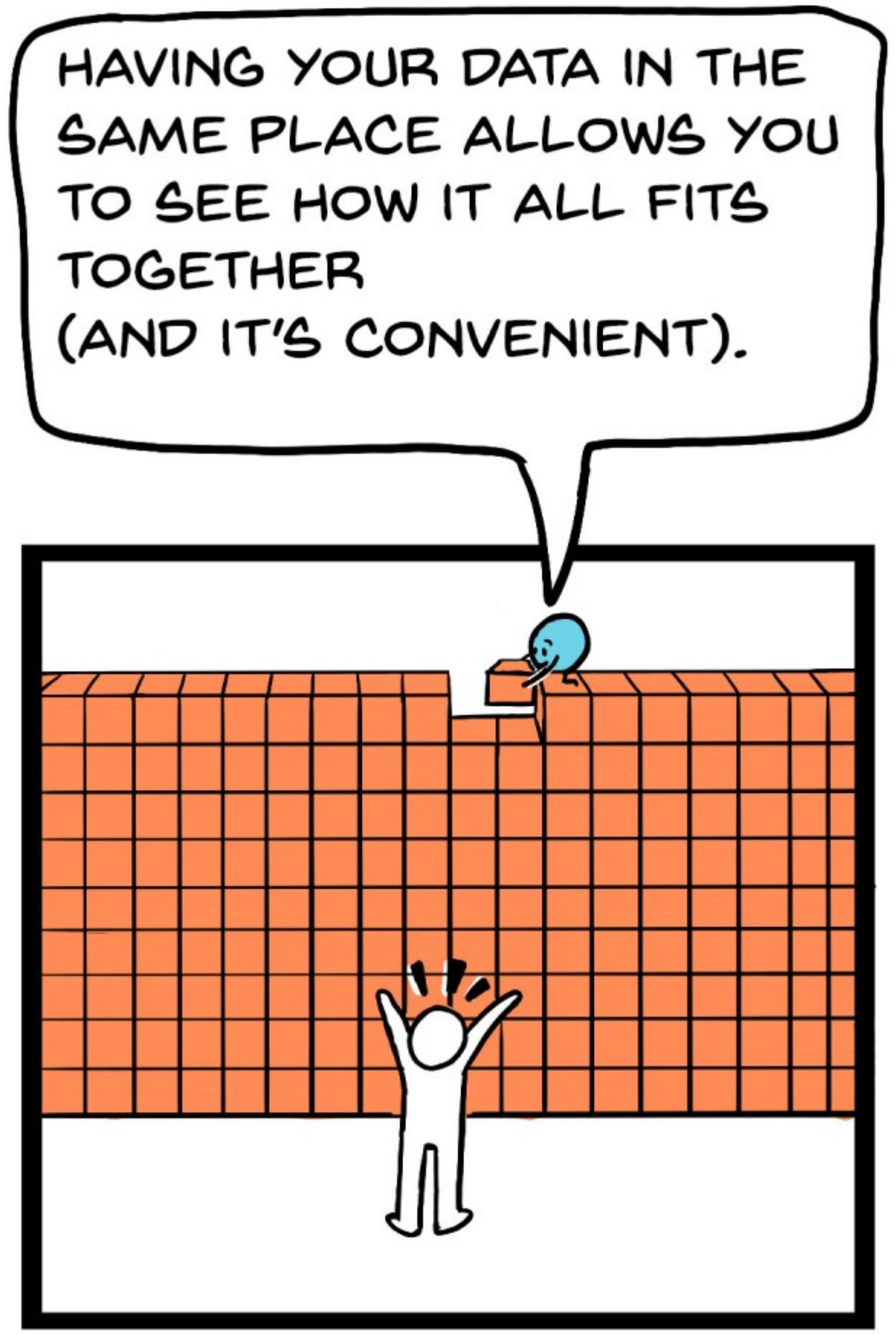


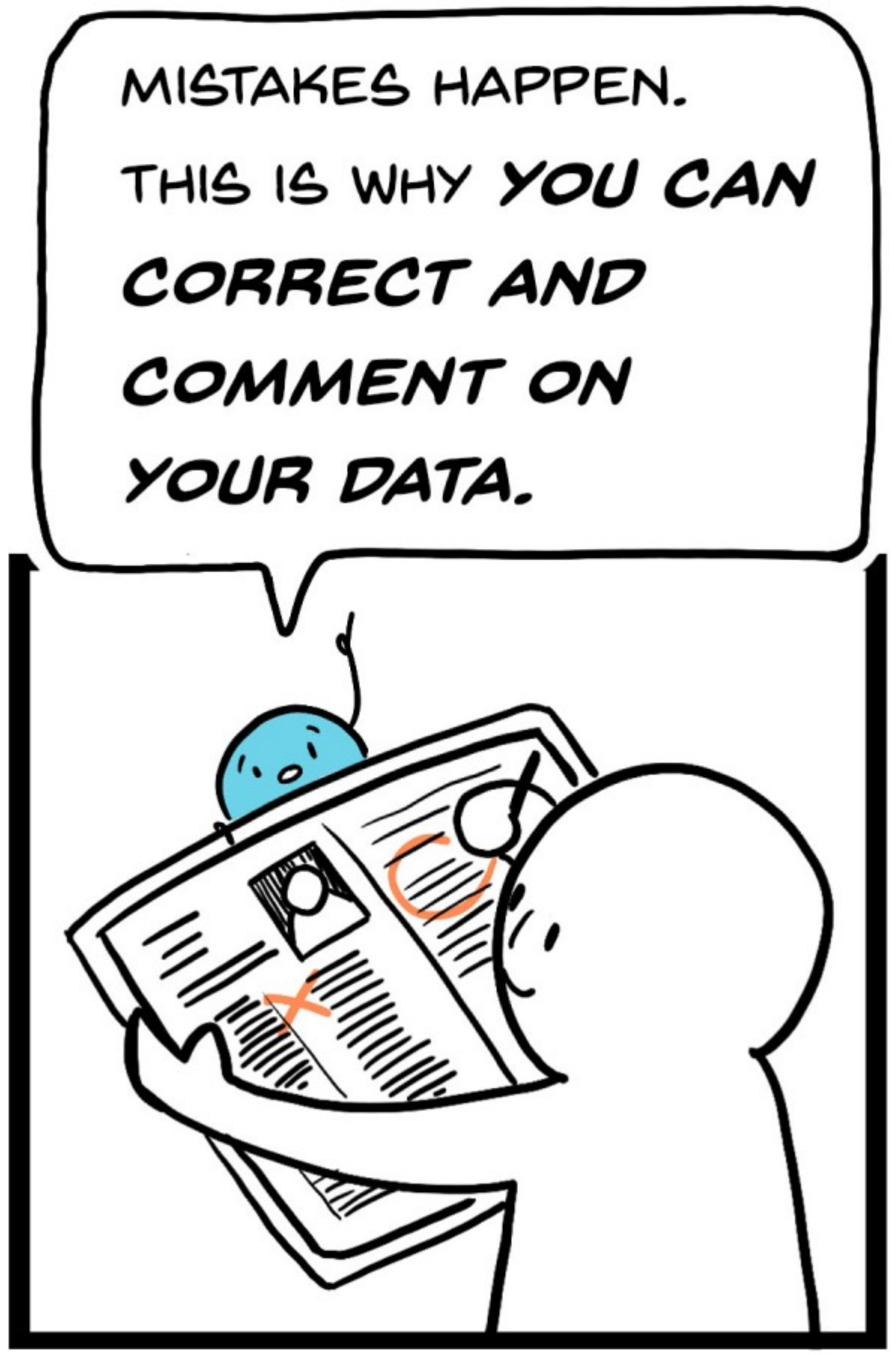
KNOW YOUR RIGHTS
IN 3 MINUTES.

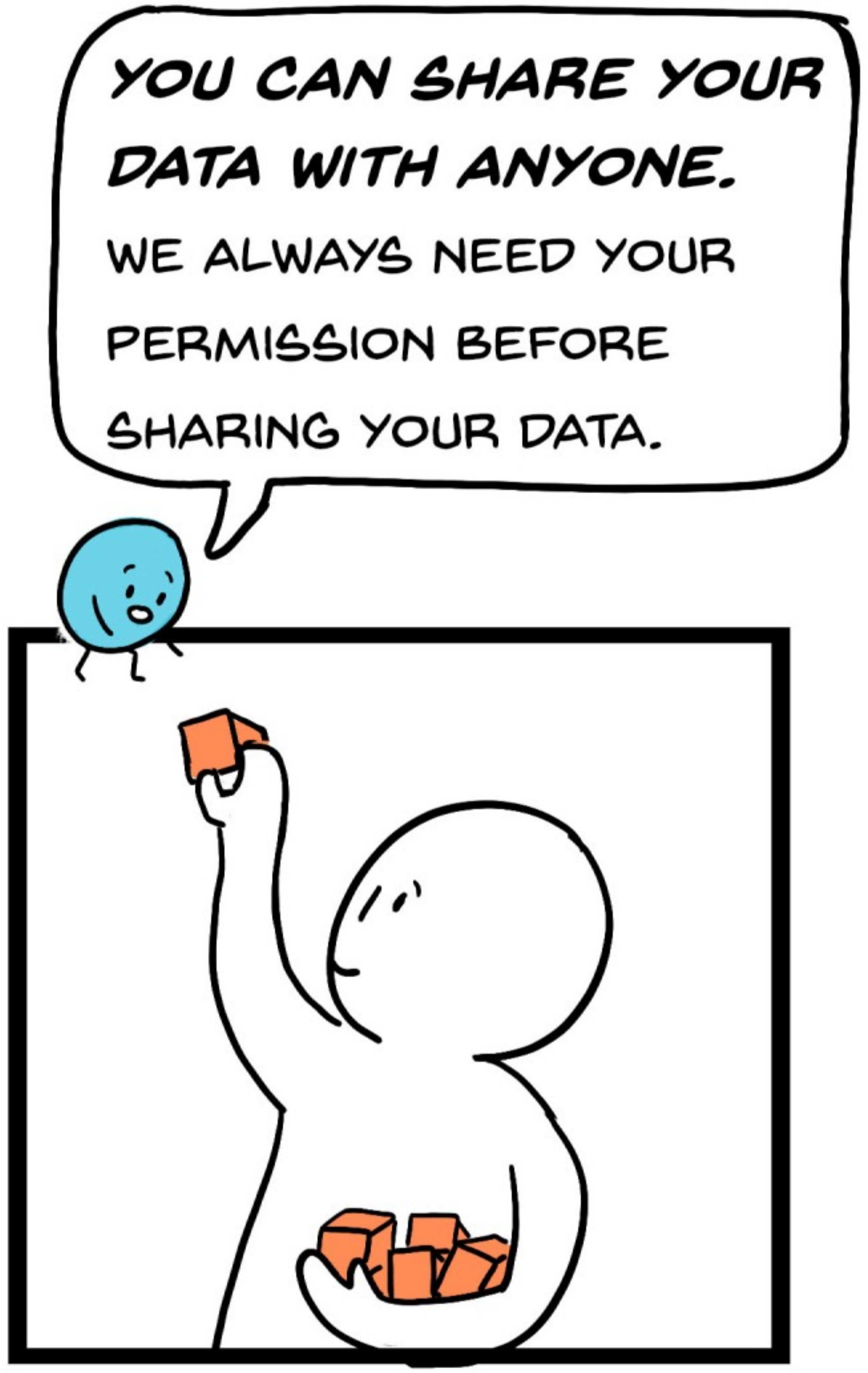
Next →

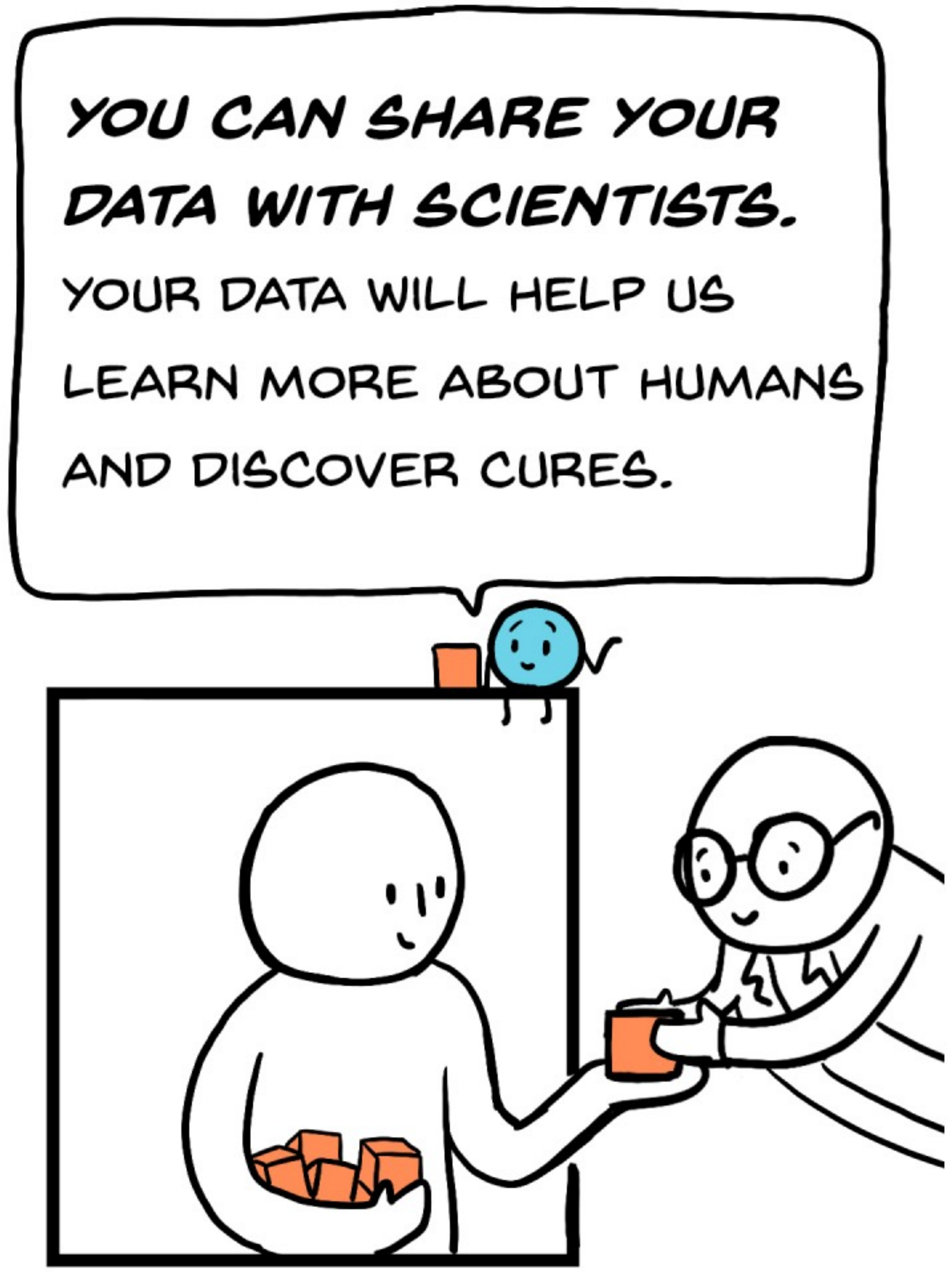

YOU OWN YOUR HEALTH DATA.
IT'S THAT SIMPLE.
HEALTH DATA

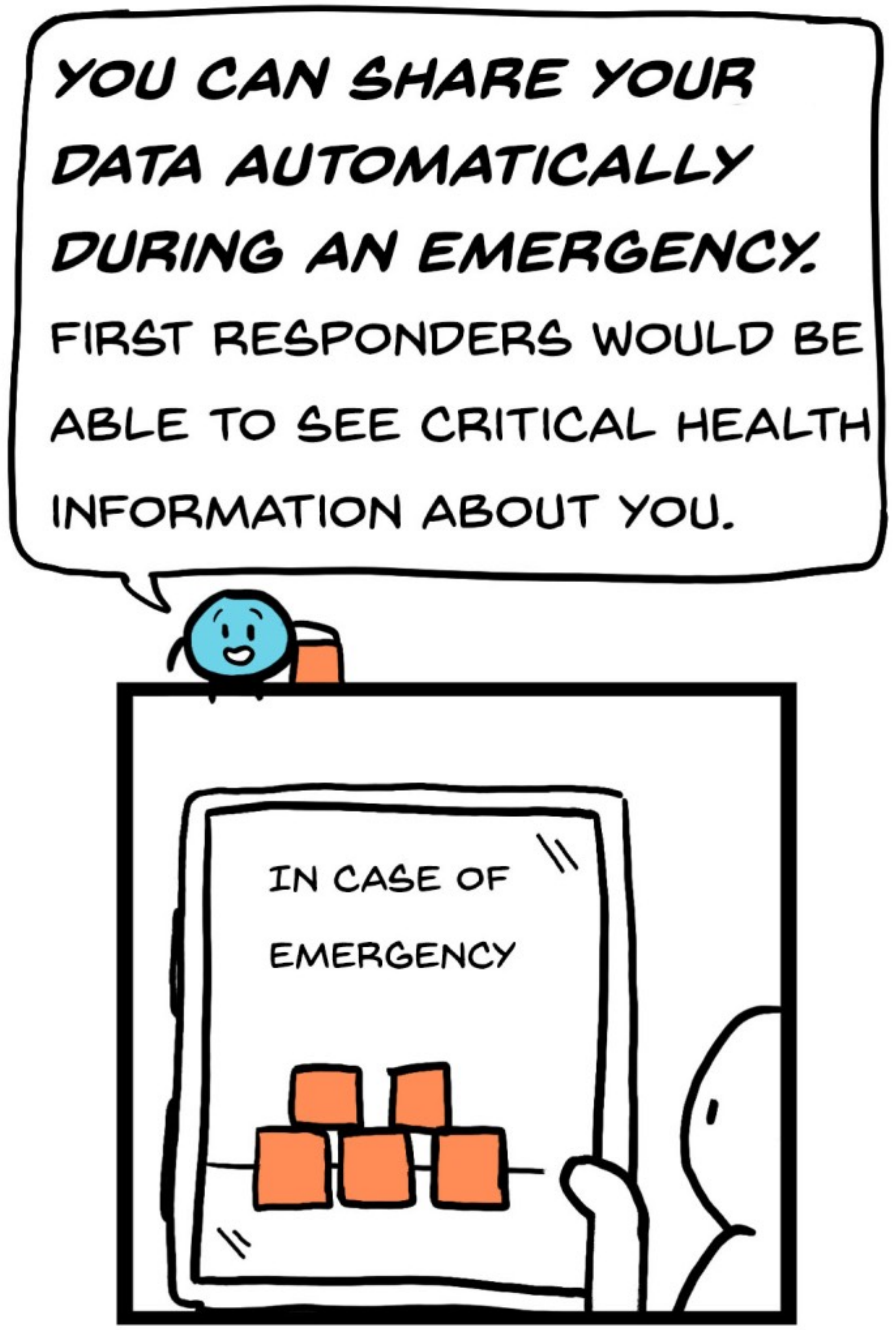

YOUR DATA CAN COME FROM ANYWHERE... FROM YOU, A CLINIC, OR A DEVICE. WE PUT IT ALL IN THE SAME PLACE.

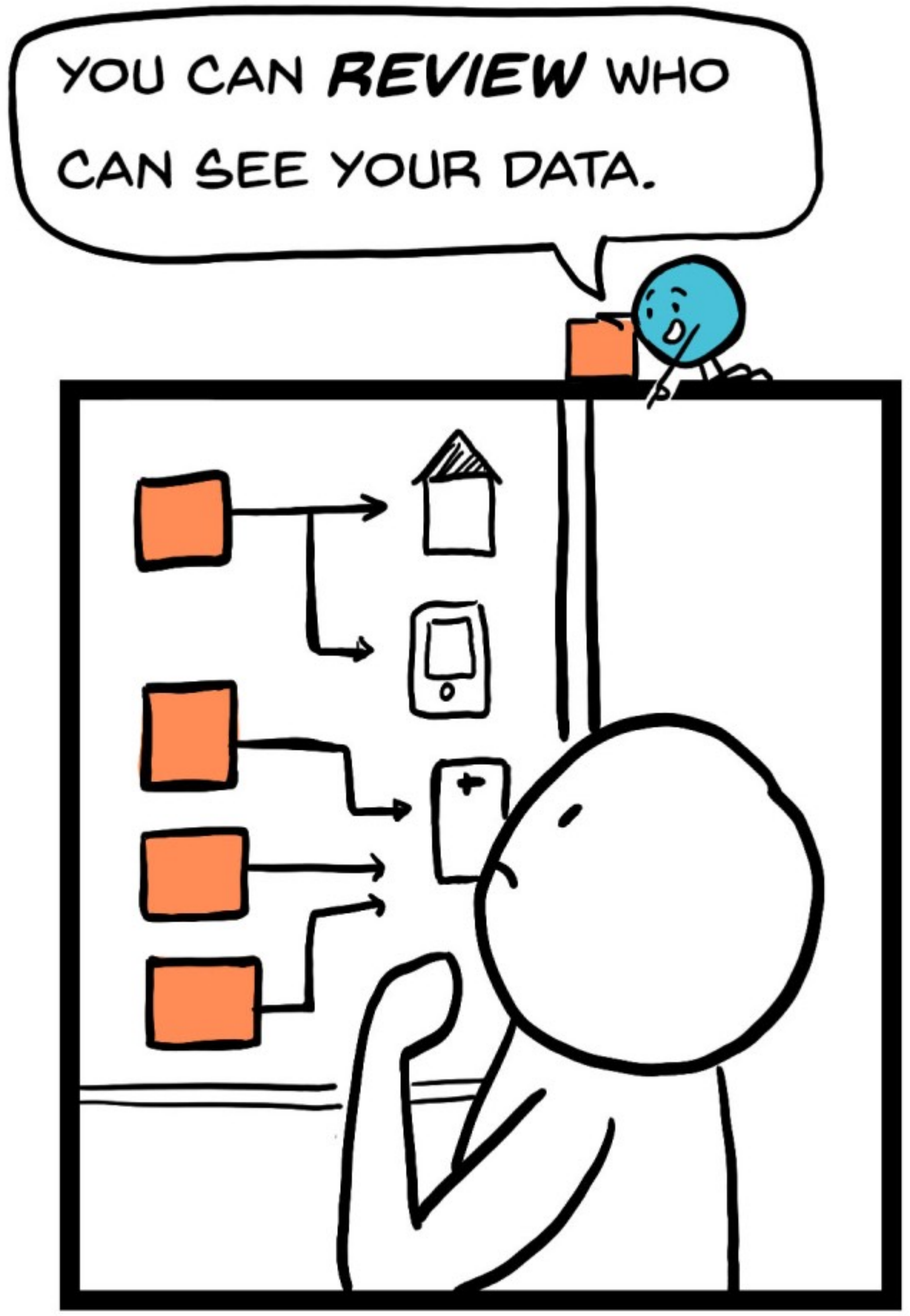

HAVING YOUR DATA IN THE SAME PLACE ALLOWS YOU TO SEE HOW IT ALL FITS TOGETHER (AND IT'S CONVENIENT).

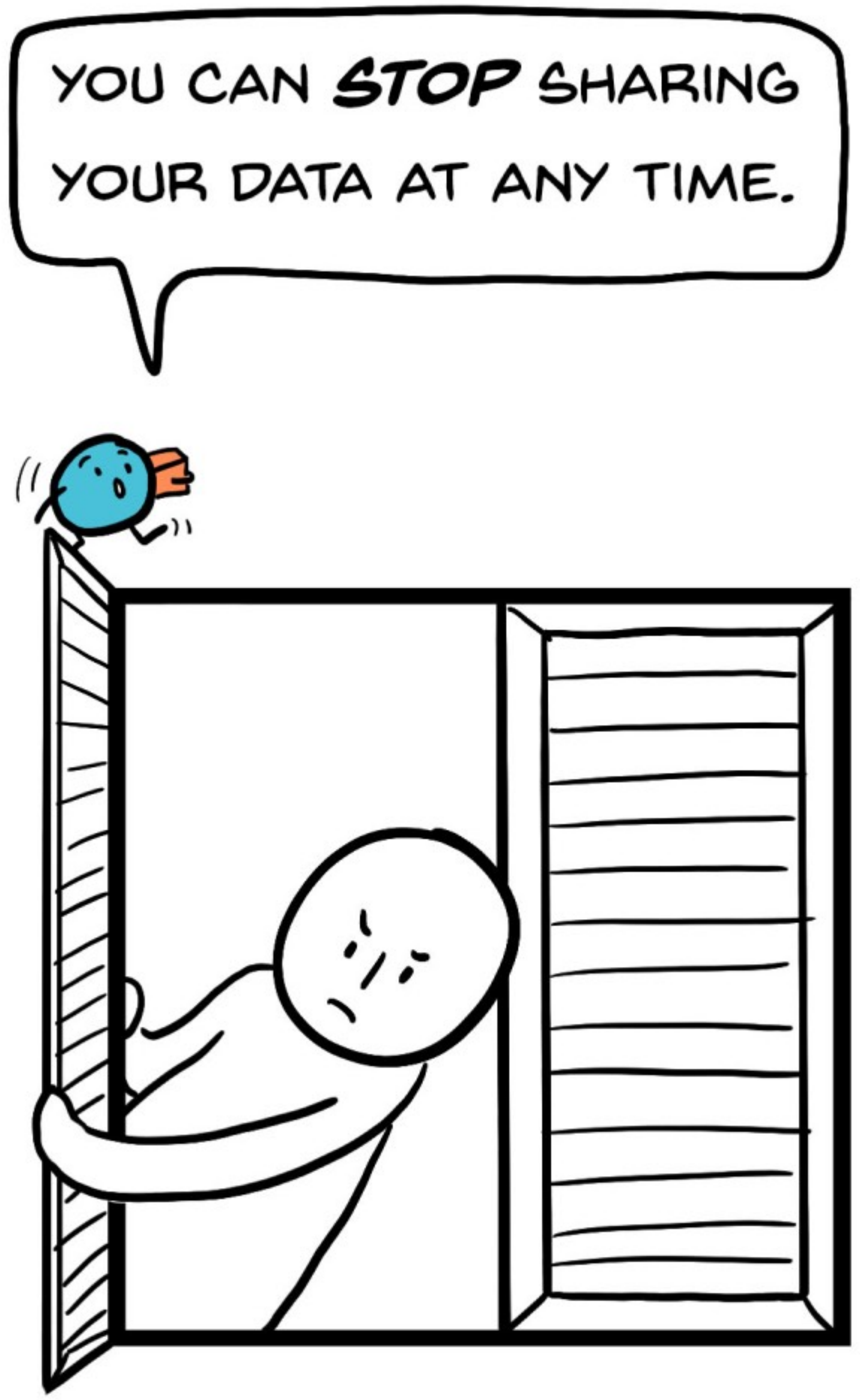

MISTAKES HAPPEN. THIS IS WHY YOU CAN CORRECT AND COMMENT ON YOUR DATA.

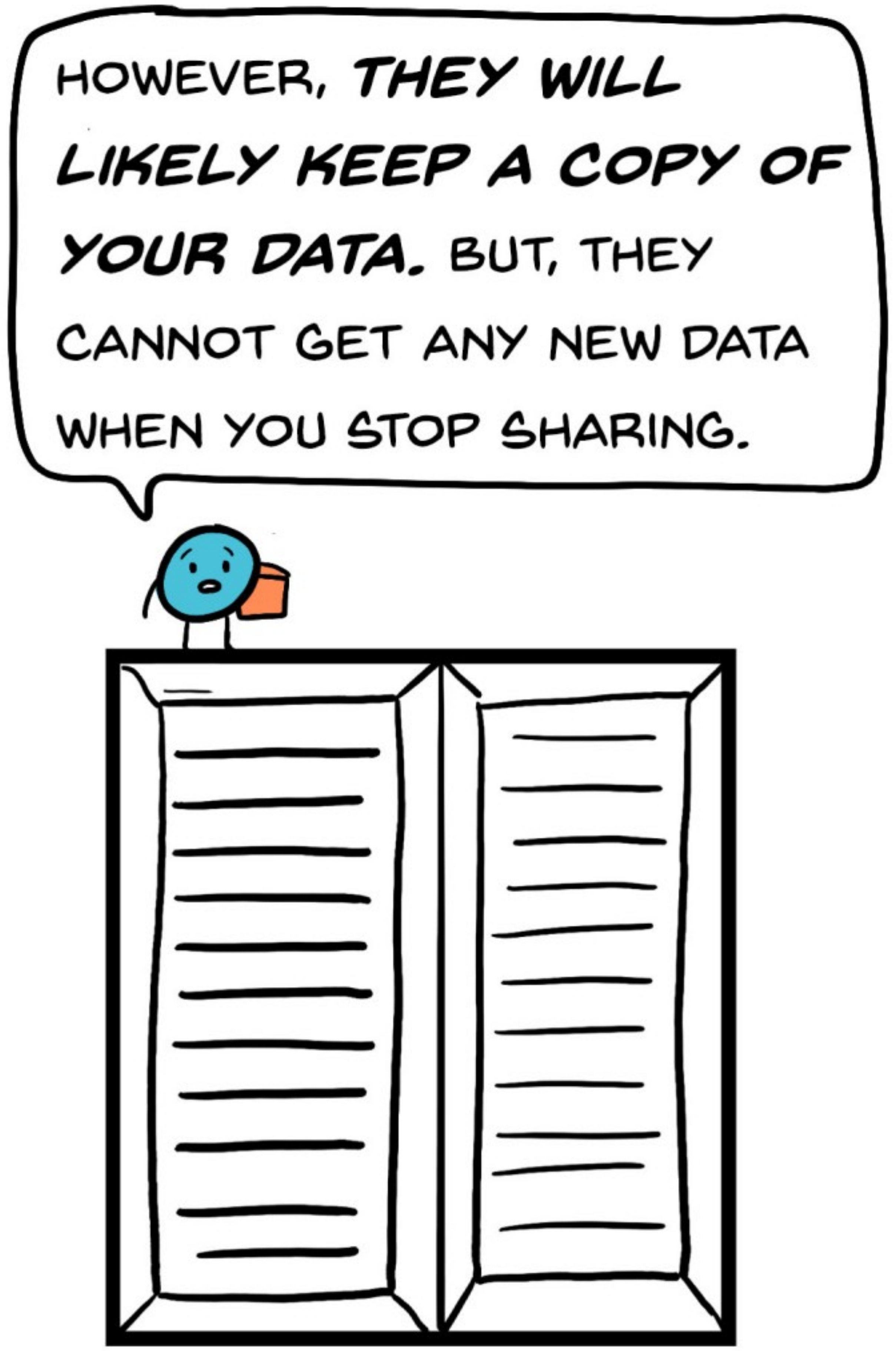

YOU CAN SHARE YOUR DATA WITH ANYONE.
WE ALWAYS NEED YOUR PERMISSION BEFORE SHARING YOUR DATA.


YOU CAN SHARE YOUR DATA WITH SCIENTISTS. YOUR DATA WILL HELP US LEARN MORE ABOUT HUMANS AND DISCOVER CURES.

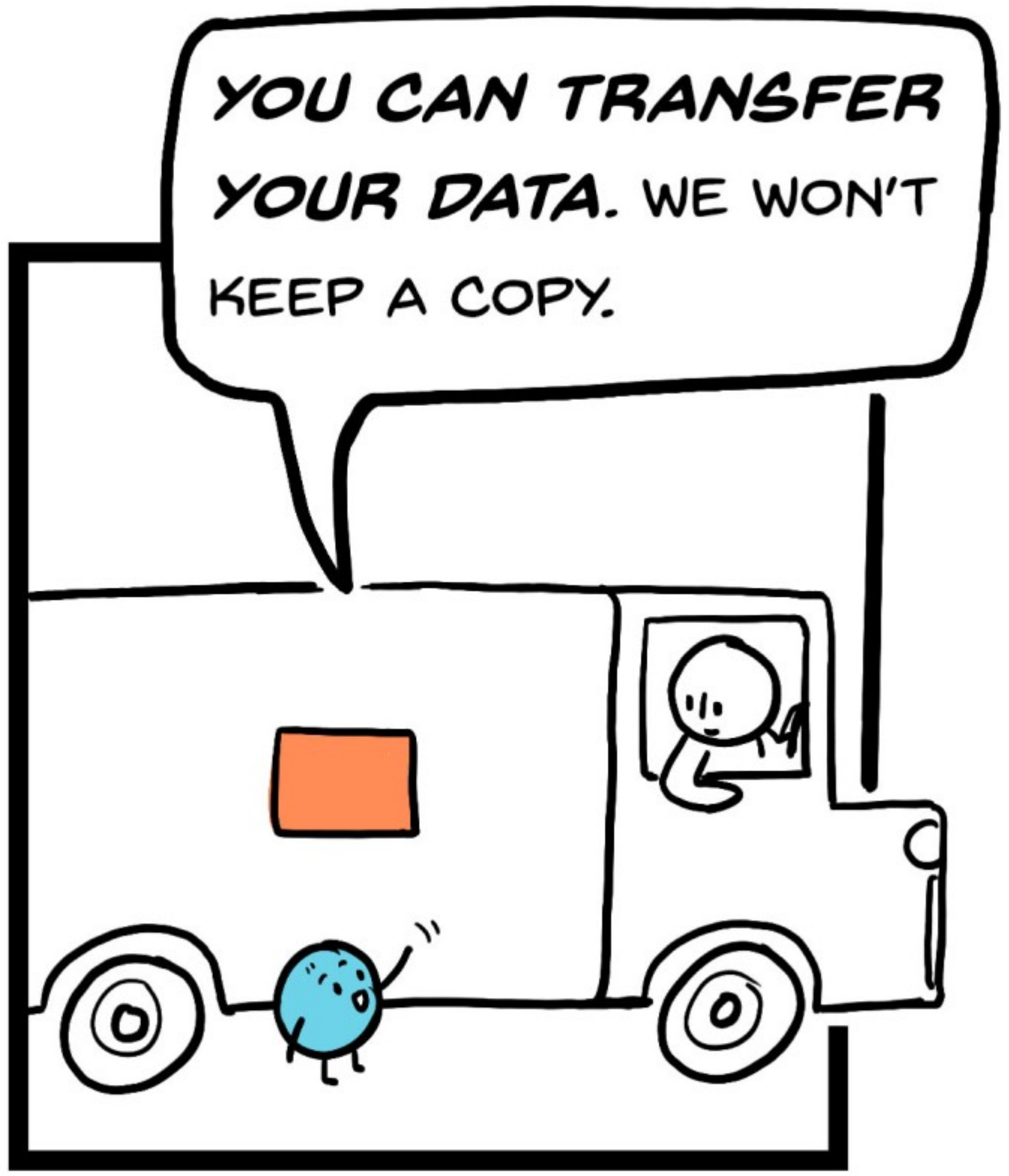

YOU CAN SHARE YOUR DATA AUTOMATICALLY DURING AN EMERGENCY. FIRST RESPONDERS WOULD BE ABLE TO SEE CRITICAL HEALTH INFORMATION ABOUT YOU.
IN CASE OF EMERGENCY


YOU CAN **REVIEW** WHO CAN SEE YOUR DATA.


YOU CAN STOP SHARING YOUR DATA AT ANY TIME.


HOWEVER, **THEY WILL LIKELY KEEP A COPY OF YOUR DATA.** BUT, THEY CANNOT GET ANY NEW DATA WHEN YOU STOP SHARING.

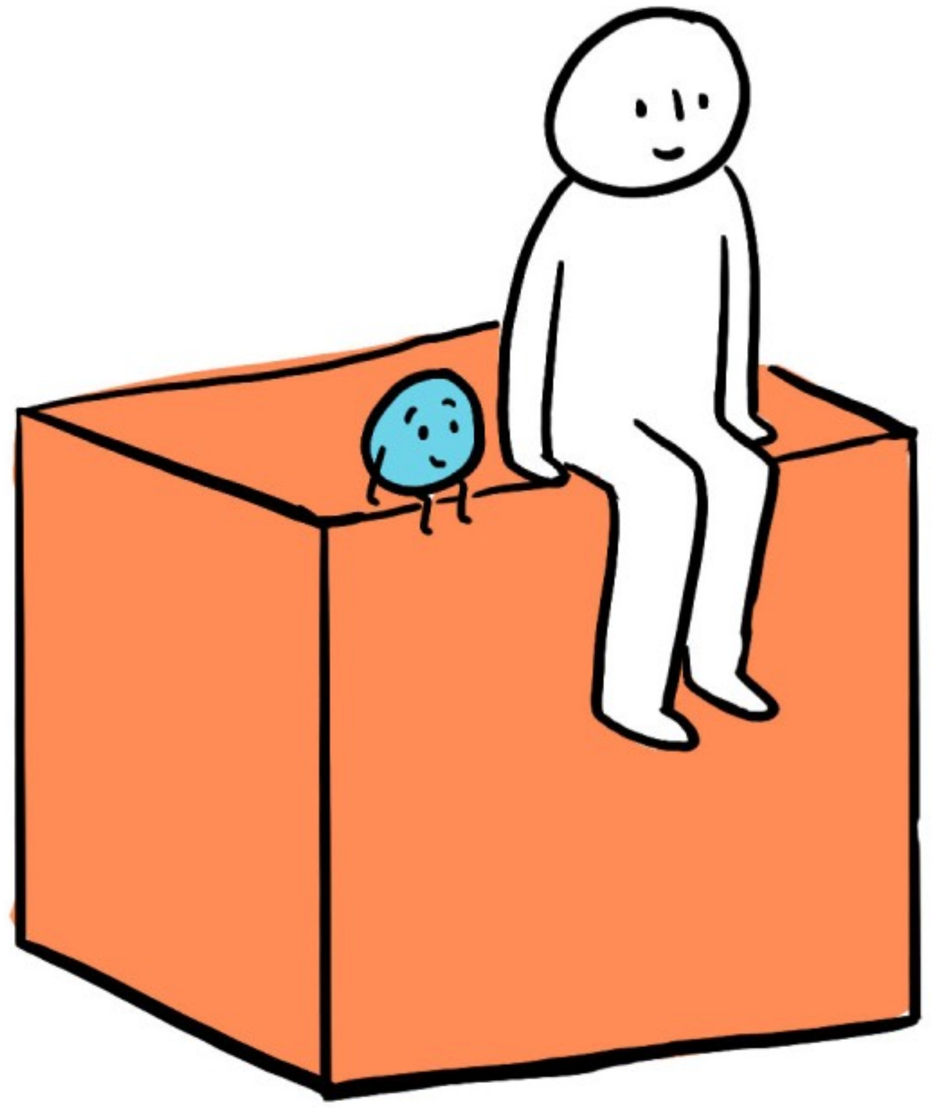

YOU CAN DELETE YOUR DATA. WE WON'T KEEP A COPY.
POOF!


YOU CAN TRANSFER YOUR DATA. WE WON'T KEEP A COPY.


THE PATIENT DATA MANAGER IS RESPONSIBLE FOR KEEPING YOUR DATA SAFE. ***YOU CAN HOLD US ACCOUNTABLE*** IF THERE IS A DATA BREACH FROM THIS APPLICATION.

IT'S YOUR DATA.

YOU ARE IN
CONTROL.



Signature

Type your full name to sign

☐ By checking this box, I understand and agree to the terms of the Patient Data Use Agreement and acknowledge that typing my name above represents my electronic signature.

Get control of your health data!

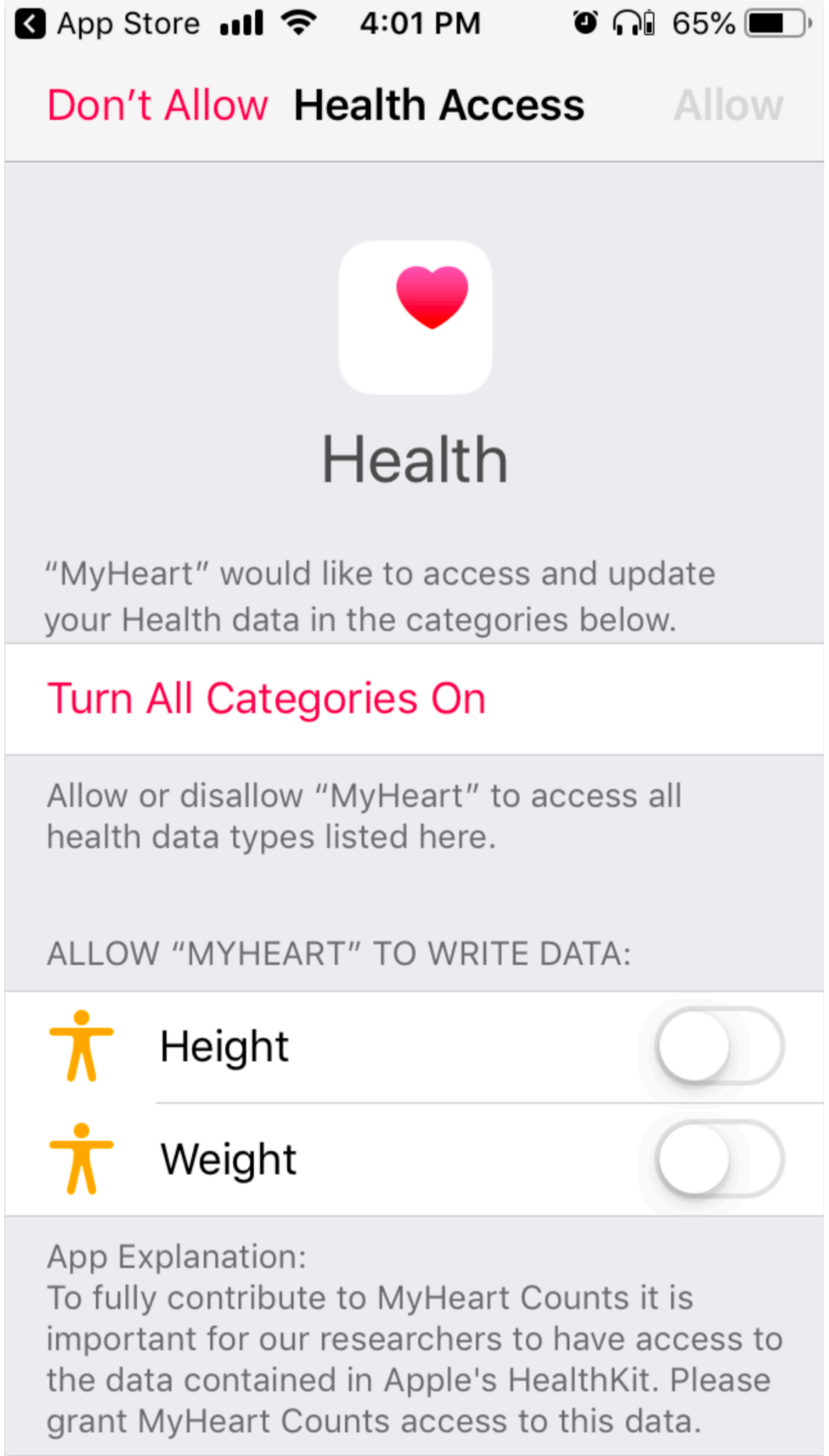
Create your account with the Patient Data Manager.

Email

Password

Now let’s connect your first source of health data.

On the next screen, you’ll see the health data already on your phone using HealthKit. Select the data you want to own.



“MyHeart” would like to access and update your Health data in the categories below.

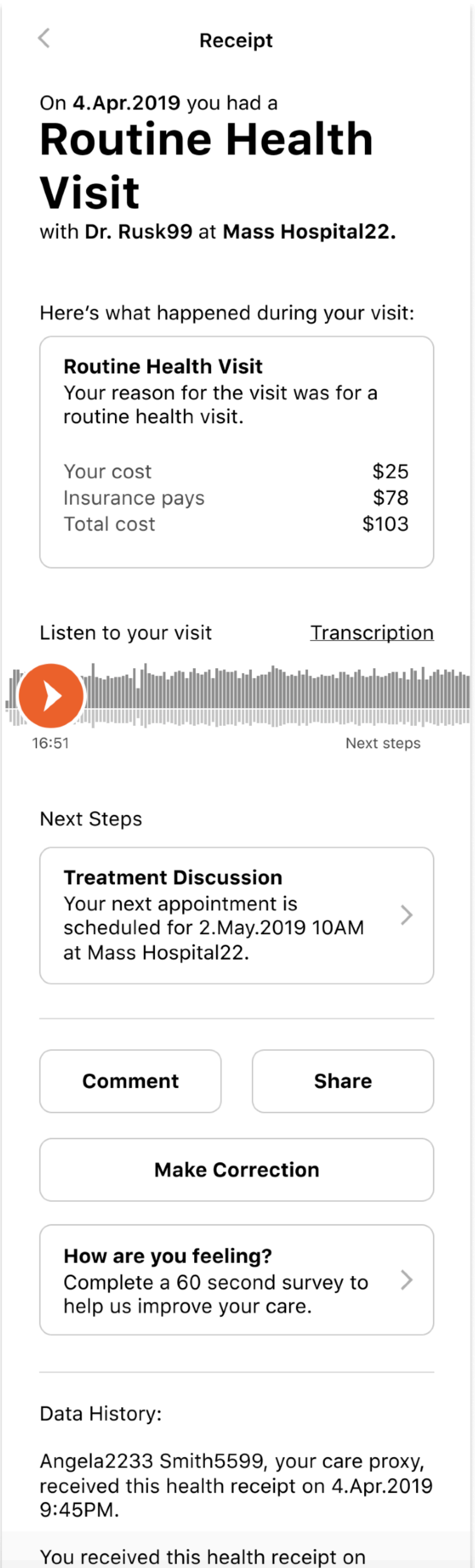
Allow or disallow “MyHeart” to access all health data types listed here.

ALLOW “MYHEART” TO WRITE DATA:

Height ○

Weight ○

App Explanation:
To fully contribute to MyHeart Counts it is important for our researchers to have access to the data contained in Apple's HealthKit. Please grant MyHeart Counts access to this data.



On **4.Apr.2019** you had a

Routine Health Visit

with **Dr. Rusk99** at **Mass Hospital22.**

Here's what happened during your visit:

Routine Health Visit
Your reason for the visit was for a routine health visit.

Your cost	$25
Insurance pays	$78
Total cost	$103

Next Steps

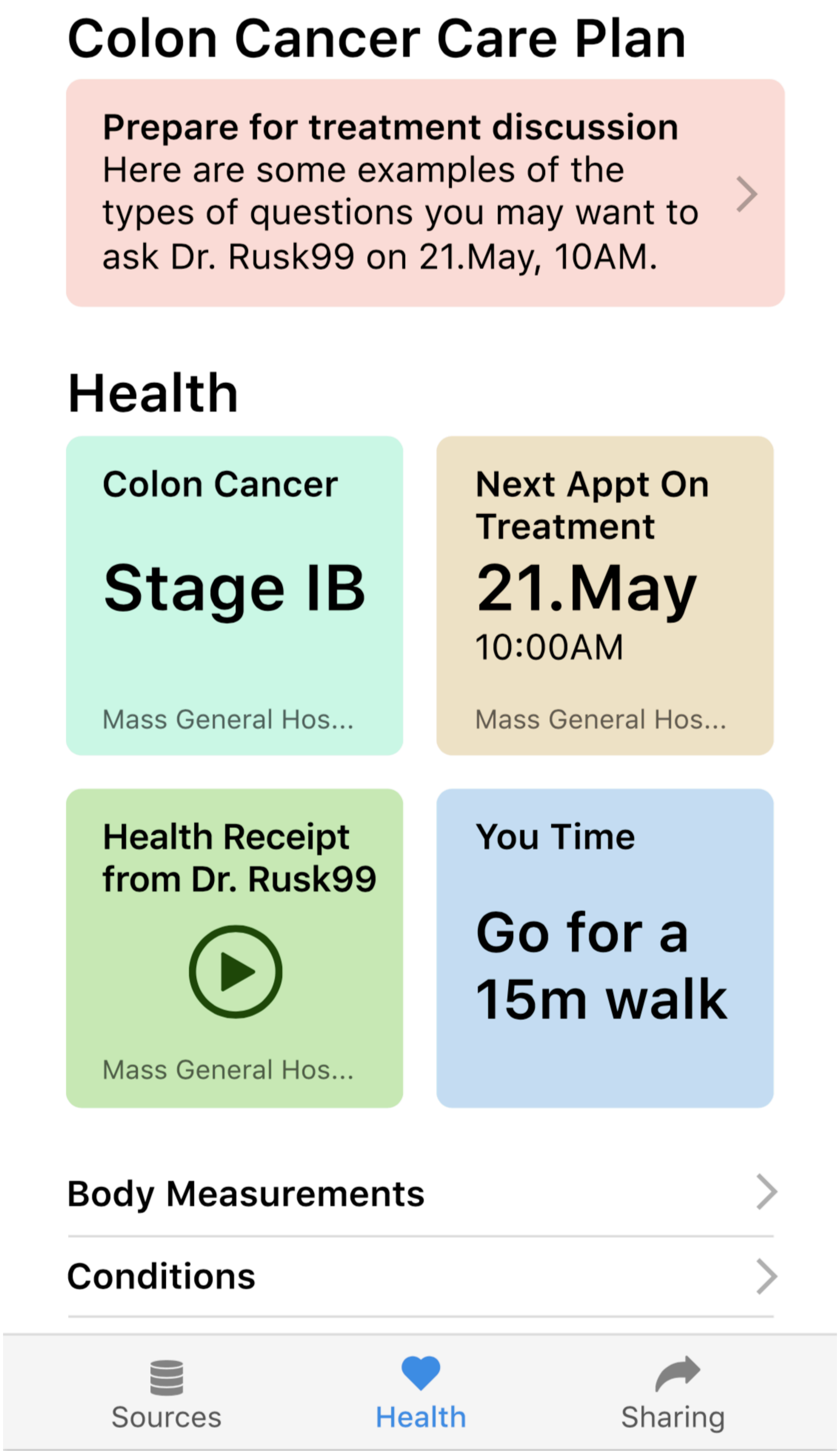
Treatment Discussion
Your next appointment is scheduled for 2.May.2019 10AM at Mass Hospital22.

How are you feeling?
Complete a 60 second survey to help us improve your care.

Data History:

Angela2233 Smith5599, your care proxy, received this health receipt on 4.Apr.2019 9:45PM.

You received this health receipt on



Colon Cancer Care Plan

Prepare for treatment discussion
Here are some examples of the types of questions you may want to ask Dr. Rusk99 on 21.May, 10AM.

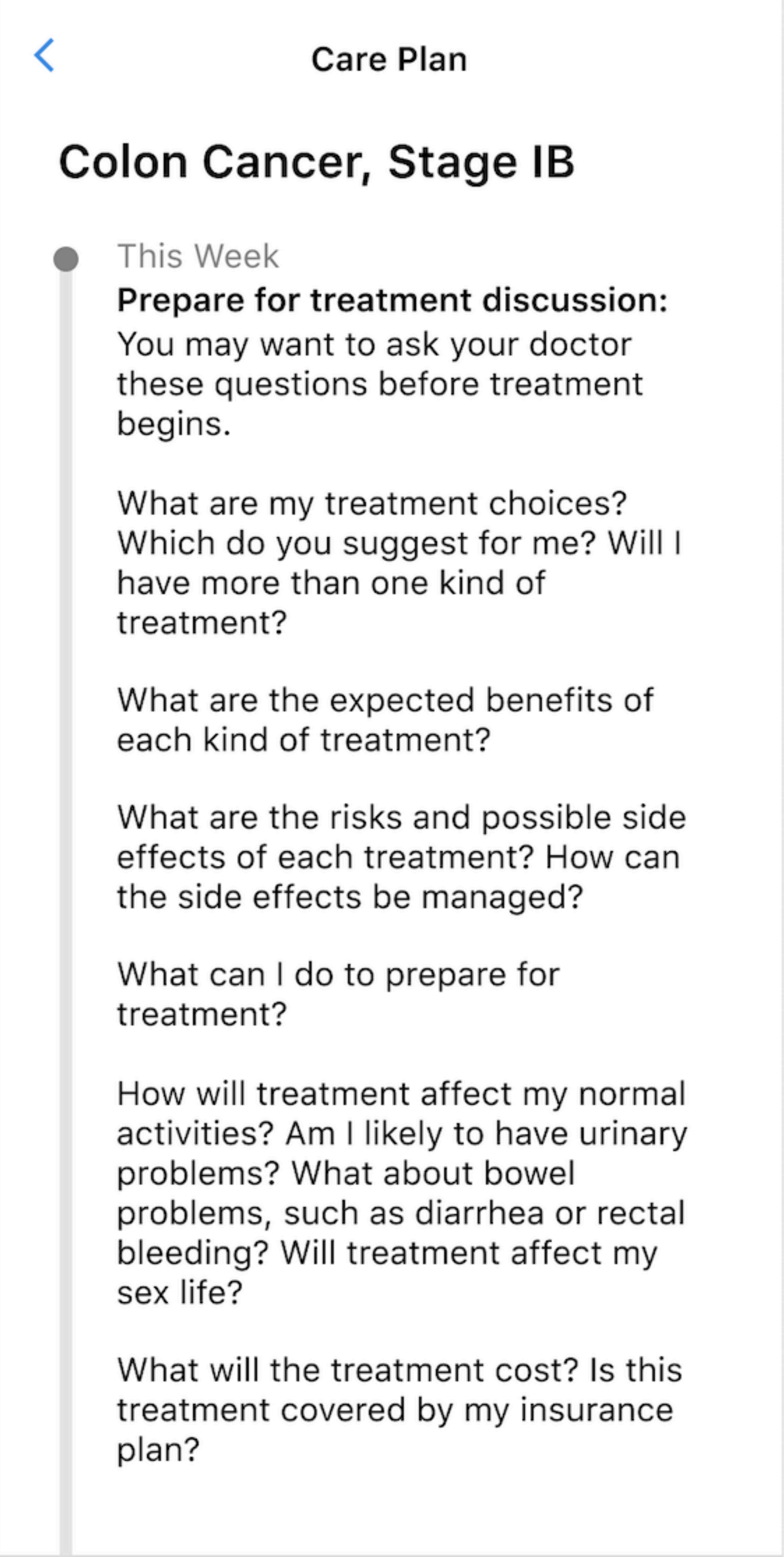
Health

Colon Cancer
Stage IB
Mass General Hos...

Next Appt On Treatment
21.May
10:00AM
Mass General Hos...

Health Receipt from Dr. Rusk99
Mass General Hos...

You Time
Go for a 15m walk



Colon Cancer, Stage IB

This Week

Prepare for treatment discussion:
You may want to ask your doctor these questions before treatment begins.

What are my treatment choices? Which do you suggest for me? Will I have more than one kind of treatment?

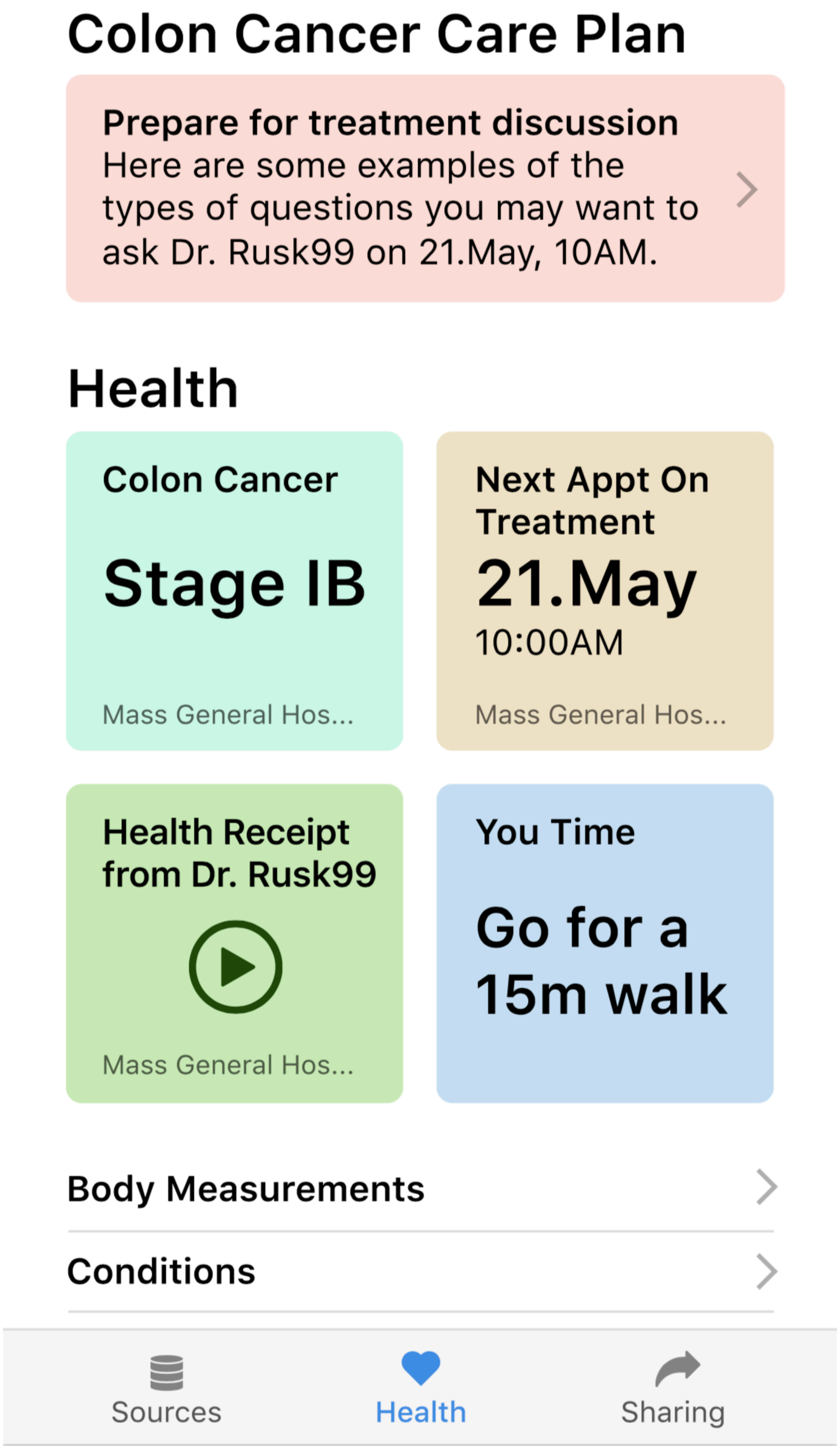
What are the expected benefits of each kind of treatment?

What are the risks and possible side effects of each treatment? How can the side effects be managed?

What can I do to prepare for treatment?

How will treatment affect my normal activities? Am I likely to have urinary problems? What about bowel problems, such as diarrhea or rectal bleeding? Will treatment affect my sex life?

What will the treatment cost? Is this treatment covered by my insurance plan?



Colon Cancer Care Plan

Prepare for treatment discussion
Here are some examples of the types of questions you may want to ask Dr. Rusk99 on 21.May, 10AM.

Health

Colon Cancer
Stage IB
Mass General Hos...

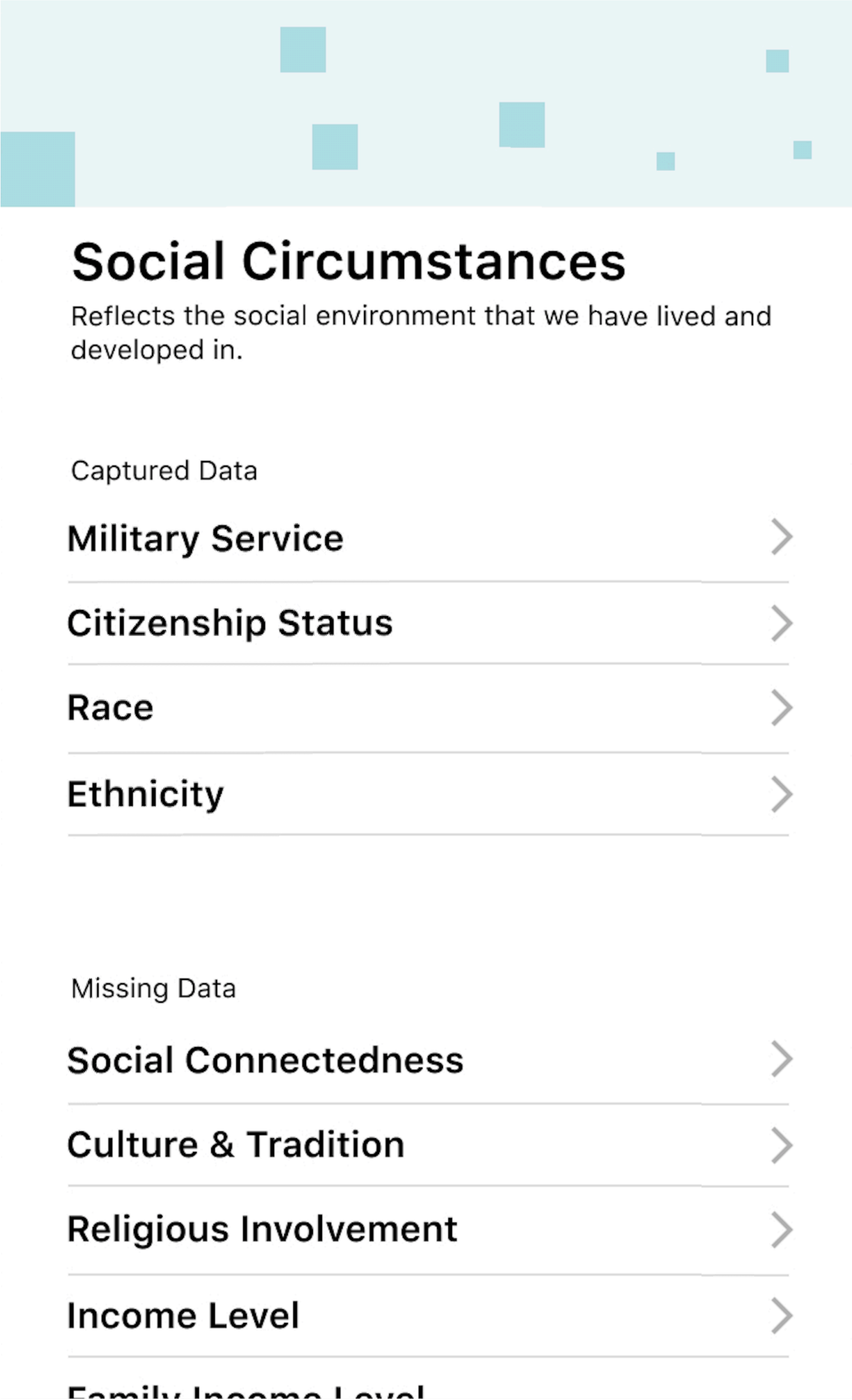
Next Appt On Treatment
21.May
10:00AM
Mass General Hos...

Health Receipt from Dr. Rusk99
Mass General Hos...

You Time
Go for a 15m walk

Body Measurements

Conditions



Social Circumstances

Reflects the social environment that we have lived and developed in.

Captured Data
- Military Service
- Citizenship Status
- Race
- Ethnicity

Missing Data
- Social Connectedness
- Culture & Tradition
- Religious Involvement
- Income Level
- Family Income Level

Patient Data Use Agreement Checklist

Authority and/or control over data explicitly stated in agreement

No data from the health record may be shared or used without the patient's explicit permission

Can share data with other parties without limitation

Can compartmentalize data to share limited portions with identified parties

Can revoke a third party's access to health record data and prohibit future sharing

Can annotate data in health record (while raw data maintained to maintain integrity)

Can delete all data

Can change PDMs

Can grant permission for emergency access to health record according to circumstances patient determines

Can donate or transfer data at death

Can get an accounting of disclosures/audit log at any time

Can get additional information about a disclosure upon request

Can hold Patient Data Manager (PDM) accountable for breach or malfeasance

Should have adequate notice of PDM termination of agreement and mechanism for transferring or saving health record

Can modify sharing and compartmentalization choices at any time

Additional considerations for patient data ownership:

Create a new category of IP law
…where property could be time-limited like copyright, allowing data to become publicly available after some time

Public ownership of anonymized data in aggregated databases

3rd party that aggregates and holds patient medical data, provides access to the data at the direction of patient

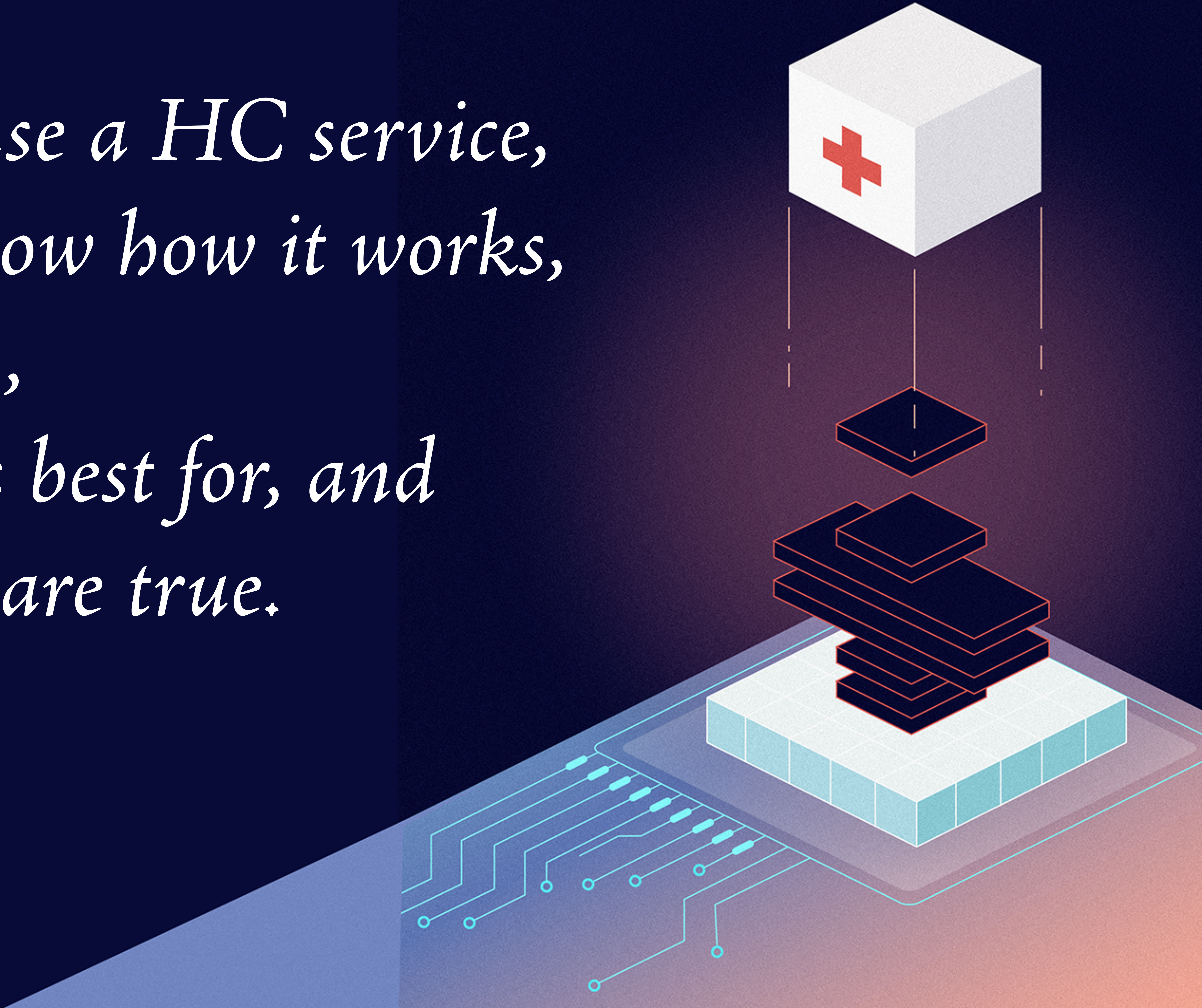
The last frontier for capitalism to sell:
the human mind.

We demand patient data ownership rights.

data use agreement . org

And about those machines and models that process my data and poop out my care plan…

When you use a HC service,
you don't know how it works,
why it works,
who it works best for, and
if the results are true.

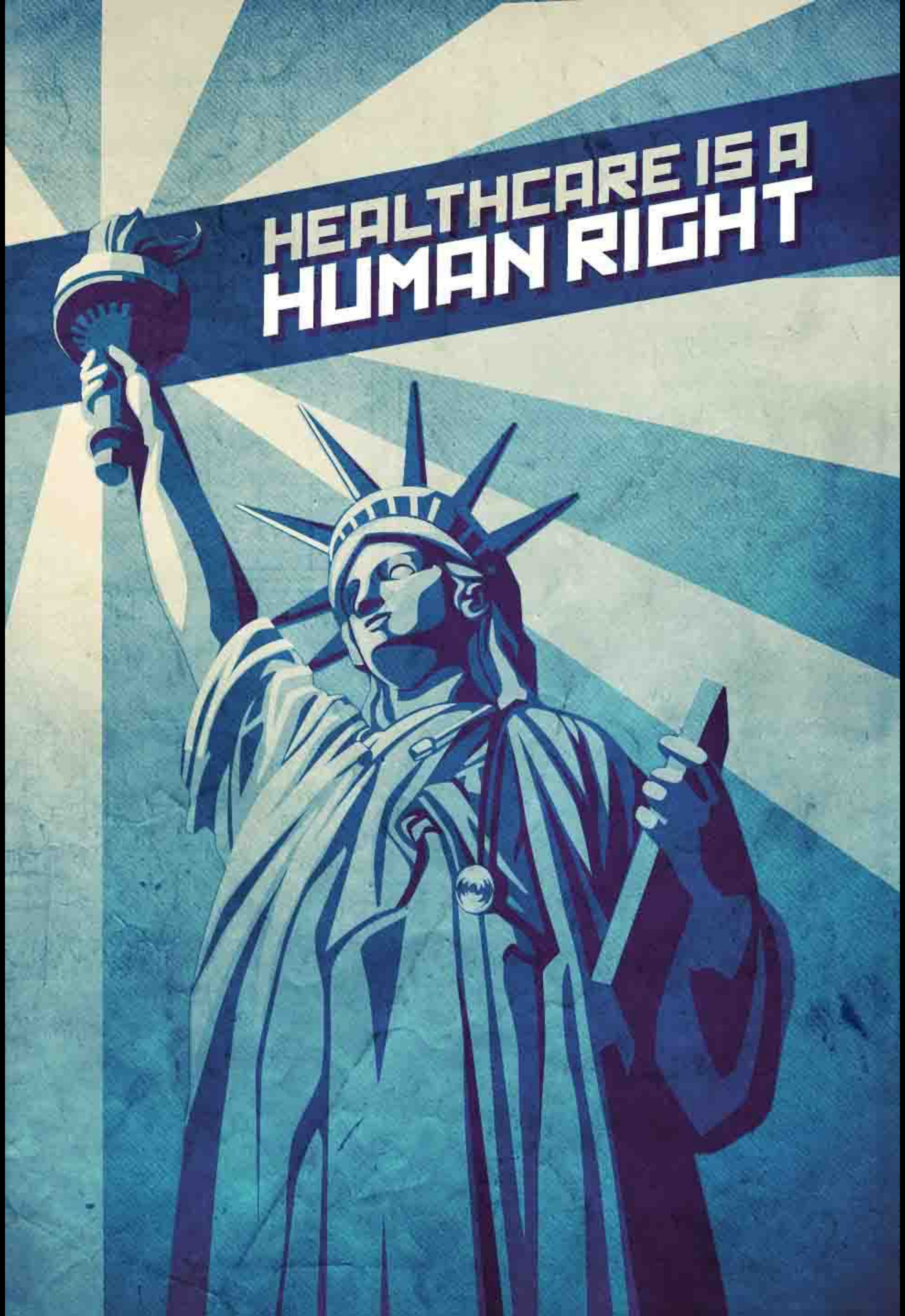


I will share my medical knowledge for the benefit of the patient and the advancement of healthcare

Declaration of Geneva, 1948

Our black box algorithm risk-adjusts and care plans for half of US residents.

PBM, 2018


HEALTHCARE IS A
HUMAN RIGHT

If healthcare is so noble,
if it’s key to our life on earth,
if we don’t have choice…

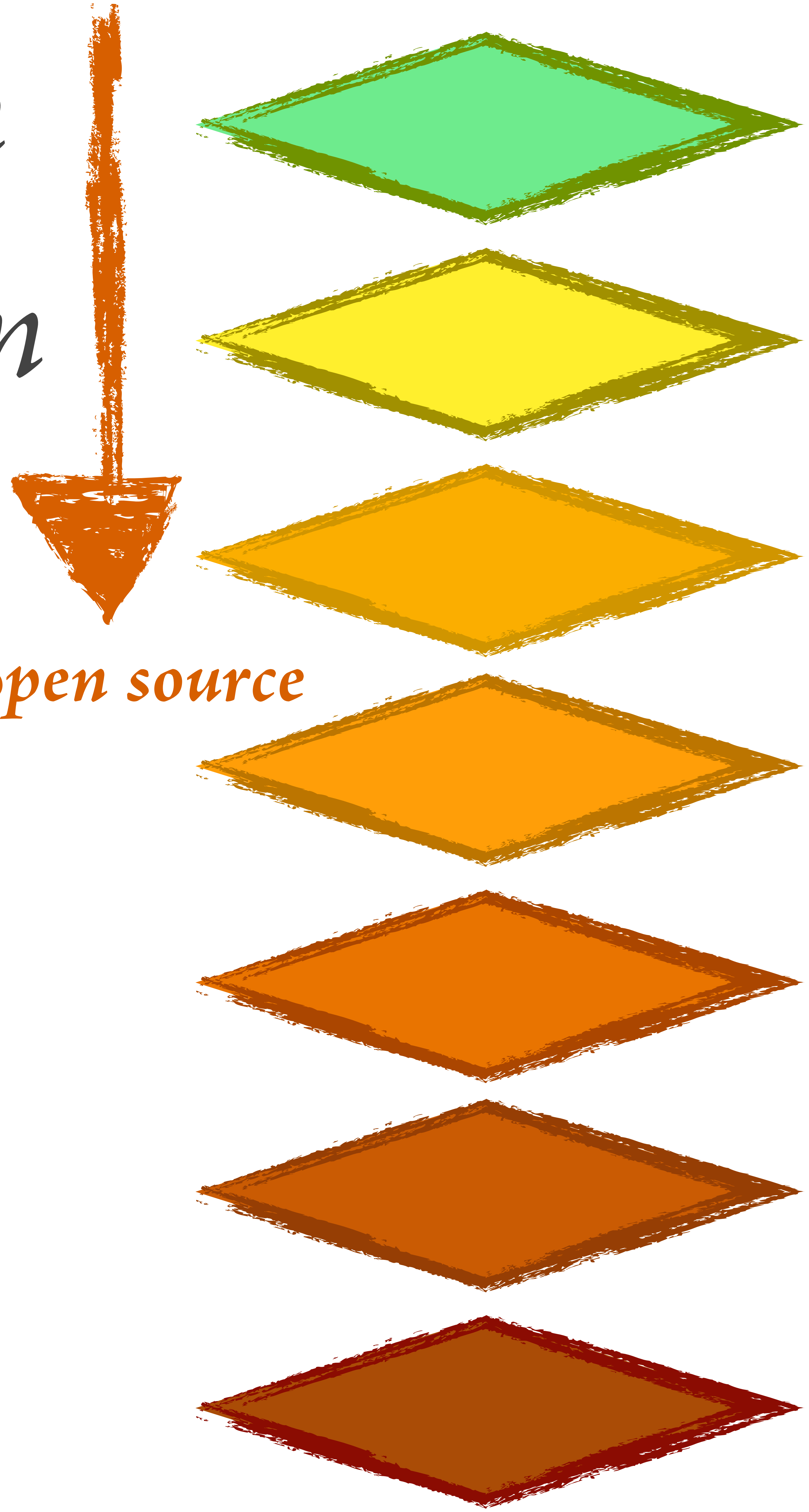
…we demand healthcare to be open.

infrastructure, access

The Internet ^ is

… open source

… a human right.



Application	*Human-computer interaction layer, where apps can access the network services*
Presentation	*Ensures that data is in a usable format, where data encryption can occur*
Session	*Maintains connections, responsible for controlling ports + sessions*
Transport	*Transmits data using transmission protocols (TCP, UDP)*
Network	*Decides which physical path the data will take*
Data	*Defines the format of data on the network*
Physical	*Transmits raw bit stream over a physical medium*

Android

Apache

Arduino

Linux

MySQL

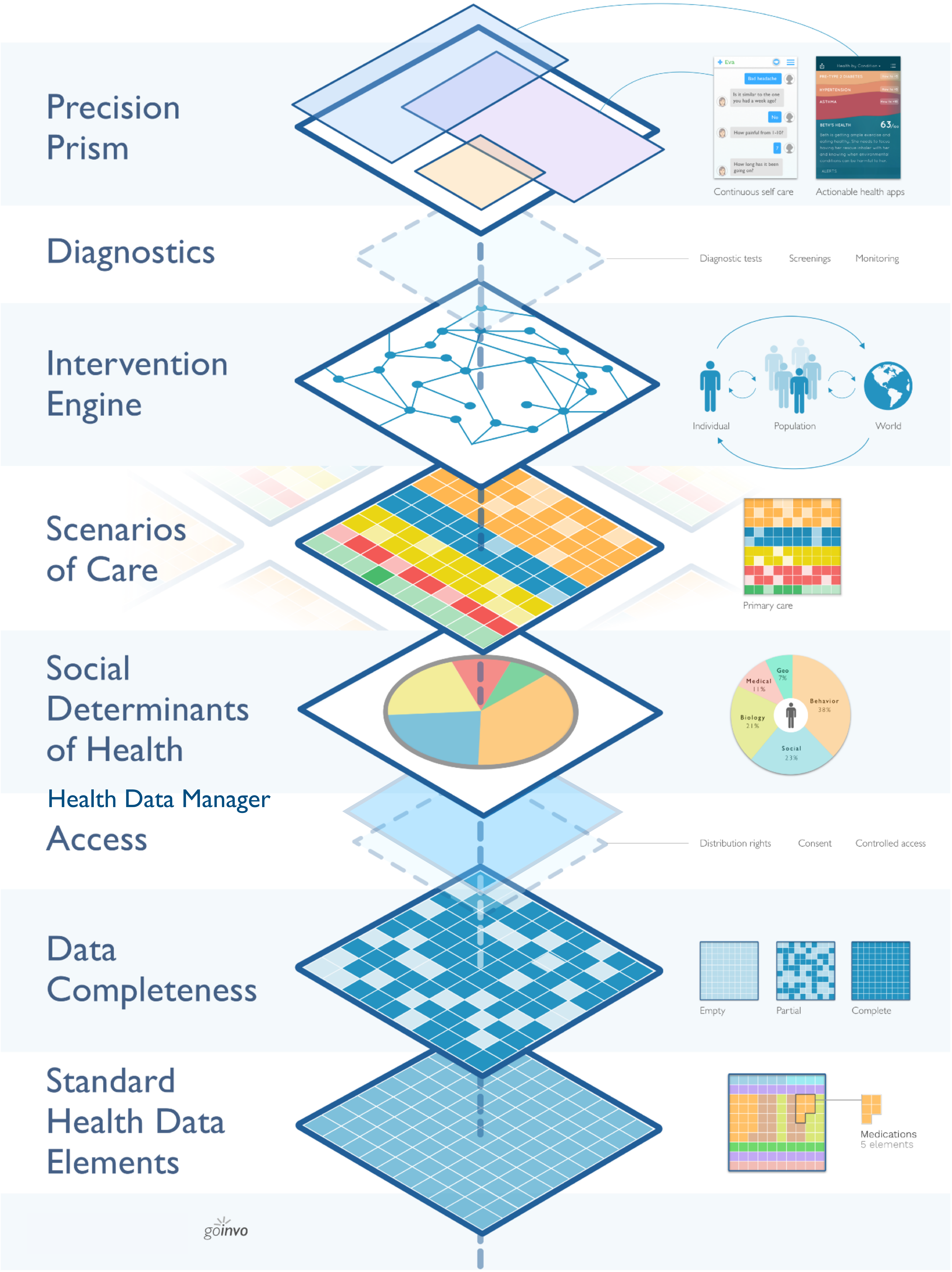
Open Gov

PLOS

W3C

Wikipedia

HEALTHCARE SYSTEM MODEL


Precision Prism

Diagnostics

Intervention Engine

Scenarios of Care

Social Determinants of Health

Health Data Manager

Access

Data Completeness

Standard Health Data Elements

most healthIT is closed

should be open source

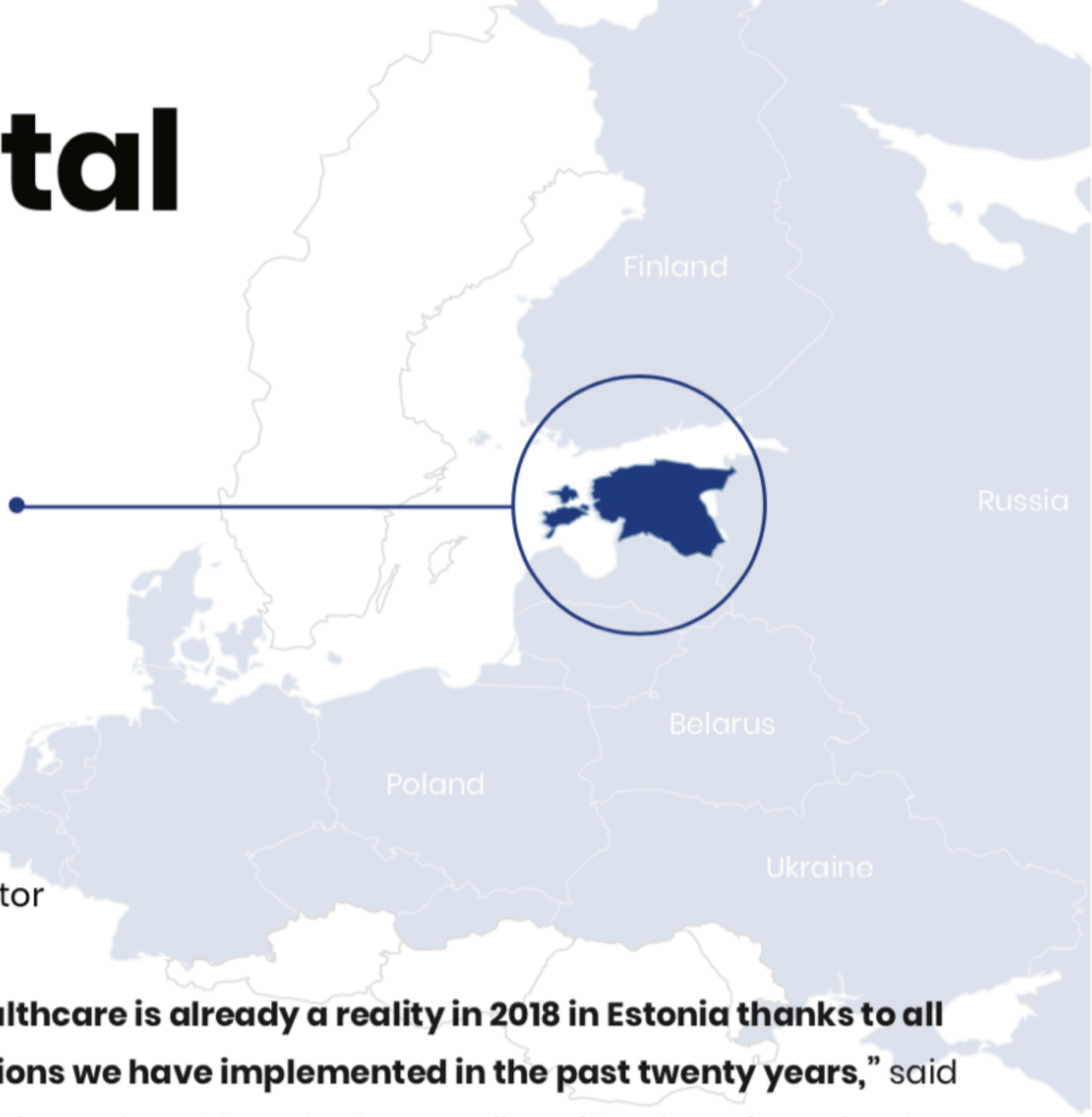
Eric Topol

“We have anti-open source.”

National Digital Healthcare the Estonian Experience

Liis Hinsberg Shea

Former Estonian Health System Communication Director



In Estonia,

95%
of health data is digitized

99%
of prescriptions are digital

100%
of billing is done electronically

94%
of citizens are covered by national healthcare

"Digital healthcare is already a reality in 2018 in Estonia thanks to all the e-solutions we have implemented in the past twenty years," said Estonia's Minister of Health and Labor Ms Riina Sikkut in an interview last year[i]. Funnily enough, that statement was more newsworthy to people outside of Estonia than people living there and using e-government and e-health services on a daily basis. Estonians are very comfortable using e-services and sharing their data when necessary. Citizens are brought up with the philosophy that we own our data, however, it's both the public and private sector's job to use this data in the best way possible—to run our shared services smoothly and improve life in Estonia.

Data travels on a digital highway

Most public records in Estonia use the government's open source data platform, the X-road or X-tee* data platform for both public and private data. The platform links individual servers, letting information live locally, but can be requested by different participants. The public sector uses X-tee for different registries like the Population Registry, Health Insurance Registry. Private Sector companies in energy, telecom and banking use the platform. Over 900 organizations use it daily[ii]. The main user interface for citizens, enterprises and public officials is the State Portal "eesti.ee".

Everyday services that people need are all online and necessary information or forms are pre-populated. When you vote, the e-voting platform already knows the necessary data. When you file taxes, the tax forms are filled out for you. You don't have to insert any data more than once and there is no duplicate data.

* *Until 2018, it was named X-Road in English. Since 2018, however, X-Road is only used to refer to the technology developed together by Estonia and Finland through Nordic Institute for Interoperability Solutions. The Estonian X-tee is now also called X-tee in English.*

Estonia

- **All residents**

$1.7B
annual budget for all healthcare services

0.9%
Administrative overhead for Healthcare budget

1.2MM
or 94% of all Estonians and residents are covered by national Healthcare

$79
is the average cost per outpatient encounter

United States

- **Medicaid, Medicare**

$1.3T
annual budget for Medicare + Medicaid healthcare services

8%
Administrative overhead for HHS/CMS budget

108MM
or 33%of all US citizens and residents are covered by national Healthcare

$121
is the average cost per outpatient encounter

- **Private**

$1.2T
annual budget for private health insurance

15%
Administrative overhead for HHS/CMS budget

156MM
United States citizens and residents are covered by private Healthcare

$160
is the average cost per outpatient encounter

FHIR

Open Humans

HealthKit

openEMR

SageBionetworks

Standard Health Record

Synthea

Health Picture
Intervention Engine
Behavior Model
Treatment Agent
Diagnosis Generator
Patient Reported Outcome Pump
Review of Systems Sniffer
Determinants of Health Score
Patient Data Manager
Consent Routines
Patient Health Receipt
Patient Data Use Agreement
Data Completeness
Patient Health Record
Common Data Elements

Open Source Healthcare Services

“Epic EHR should be open source.”

Elizabeth Nabel, President of Brigham Health, 2017

“Open source is fundamental.
The fact that we don’t have open healthcare
reflects the deepness of our problem.”

Eric Topol, Scripps Institute, 2018

Healthcare and public health
are a utility,

a human right, and

too important to be closed.

We live in a closed healthcare system.
The algorithms that drive our care,
to our clinical and life data,
to hospital and [illegible] pricing,
are governed by black box services.

By design, these closed systems
[illegible] design [illegible] out
of the decision-making process,
[illegible]
for [illegible] (vs optimized
health outcomes).
The crooked biases built into software,
implemented with intent or accidentally,
need interrogation, citizen collaboration,
and correction.

It’s [illegible]
Or more likely, [illegible]
[illegible]
We demand [illegible] ‘healthcare’
services [illegible]
to inspect and correct bias,
to be accessible for rapid innovation
and evolution,
and to become more valuable as
more patients, clinicians,
companies, and governments
engage in healthcare for all.

Open Source Healthcare.org

Special thanks to:
Eric Benoit,
Edwin Choi,
Patricia Nguyen,
Jen Patel Sobus,
Craig McGinley,
Sharon Lee,
Jon Follett,
Daniel Reeves,
Sarah Kaiser,
Bryson Wong,
Mark Kramer,
Kathy Mikk,
Andre Quina,
Parsuree Vatanasirisuk,
George Neyarapally,
Eric Topol,
Harry Sleeper

Juhan Sonin
juhan@mit.edu