

Access to Real World Data Is Not Sustainable Without Transparency and Inclusion



Craig H Lipset
@craiglipset
15 June 2021

Craig Lipset: About Me

Board Member



Faculty



Advisor



Formerly



Trends in Life Sciences

Data Sciences



On Being and Becoming
a Data Science Company

How Real World Data Are Changing
the Pharmaceutical Industry

RWE Alliance Aims to Boost Policies
and Practices Around
Real-World Evidence

Patient Engagement



Pfizer: Putting the Patient at the Center
of its Drug Development Universe

Janssen Works to Develop More
Patient-Centric Method

UCB: Patient-Centricity Should Move
a Business Forward

Trends in Life Sciences Moving in Opposite Directions



Promise of Real World Data in Clinical Trials



Study Design
& Planning



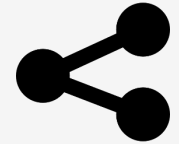
Recruitment
& Screening



eSource
& Data Capture



Synthetic Arms
& Trials



Engagement
& Data Return

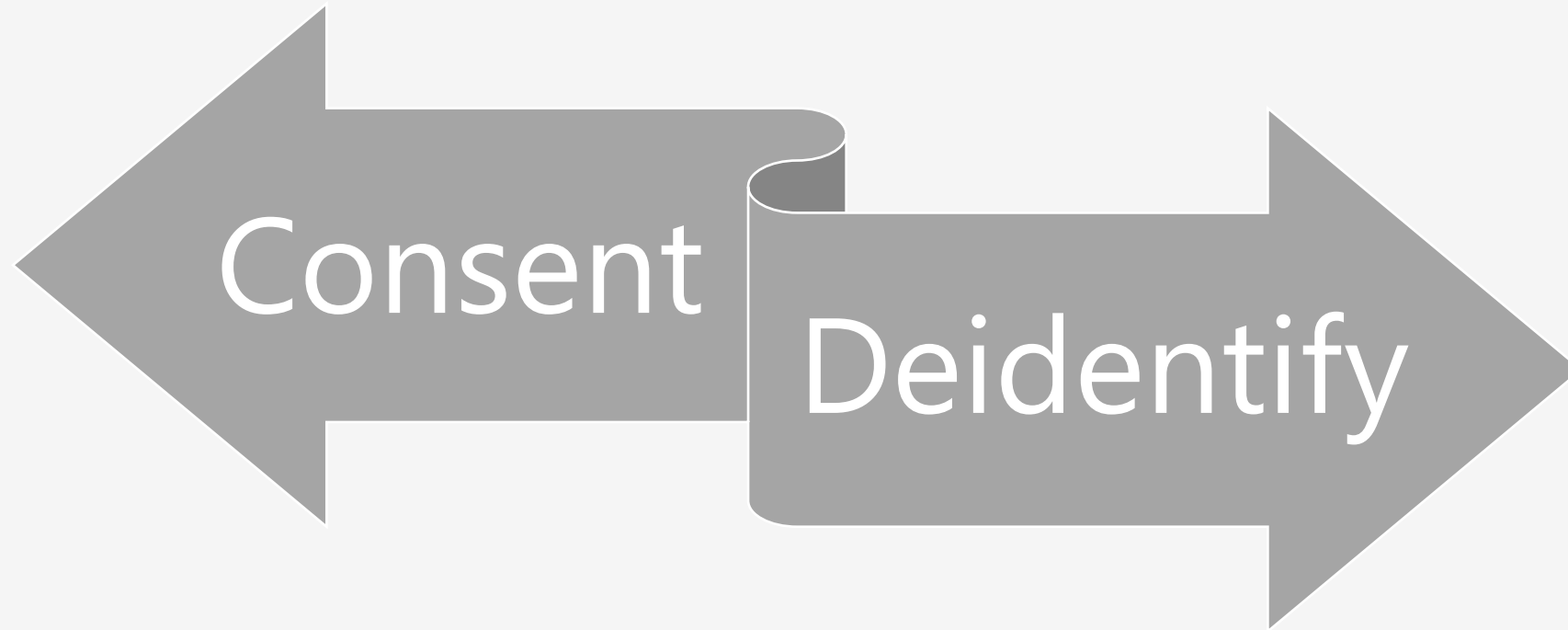
Aggregated Deidentified Data vs Protected Health Information



HIPAA defines Protected Health Information to include:

1. Name
2. Region (smaller than a state)
3. Date
4. Phone #
5. Fax #
6. Email address
7. Social security #
8. Medical record #
9. Health insurance #
10. Account #
11. Certificate / license #
12. Vehicle identifiers
13. Device identifiers
14. Web URLs
15. IP address
16. Biometrics
(finger, retinal, voice print)
17. Full face photo
18. Any other unique # or
characteristic
(other than a unique code)

Permissions and Patient Data



Use cases for prospective clinical trials and research are uniquely positioned to leverage consent & permissions

Data Deidentification: Technology vs Policy



Mid-1990's Massachusetts Group Insurance Commission released anonymized hospital data for state employees for research purposes

MIT graduate student Latanya Sweeney spent \$20 to buy the voter roles for the city of Cambridge, and combined these data sets to quickly reidentify Massachusetts Governor Weld's health data

In 2000 Sweeney showed that 87% of Americans could be reidentified using only 3 bits of information (zip code, birth date, sex)

Data Deidentification: Technology vs Policy

Risks to Patient Privacy: A Re-identification of Patients in Maine and Vermont Statewide Hospital Data

Ji Su Yoo, Alexandra Thaler, Latanya Sweeney, and Jinyan Zang

10.6% of Vermont hospital data can be reidentified using newspaper data

Article | [Open Access](#) | Published: 23 July 2019

Estimating the success of re-identifications in incomplete datasets using generative models

Luc Rocher, Julien M. Hendrickx & Yves-Alexandre de Montjoye 

[Nature Communications](#) **10**, Article number: 3069 (2019) | [Cite this article](#)

99.98% of Americans can be reidentified in any data set using 15 demographics

December 21, 2018

Feasibility of Reidentifying Individuals in Large National Physical Activity Data Sets From Which Protected Health Information Has Been Removed With Use of Machine Learning

Liangyuan Na, BA¹; Cong Yang, BS²; Chi-Cheng Lo, BS²; [et al](#)

[» Author Affiliations](#) | [Article Information](#)

JAMA Netw Open. 2018;1(8):e186040. doi:10.1001/jamanetworkopen.2018.6040

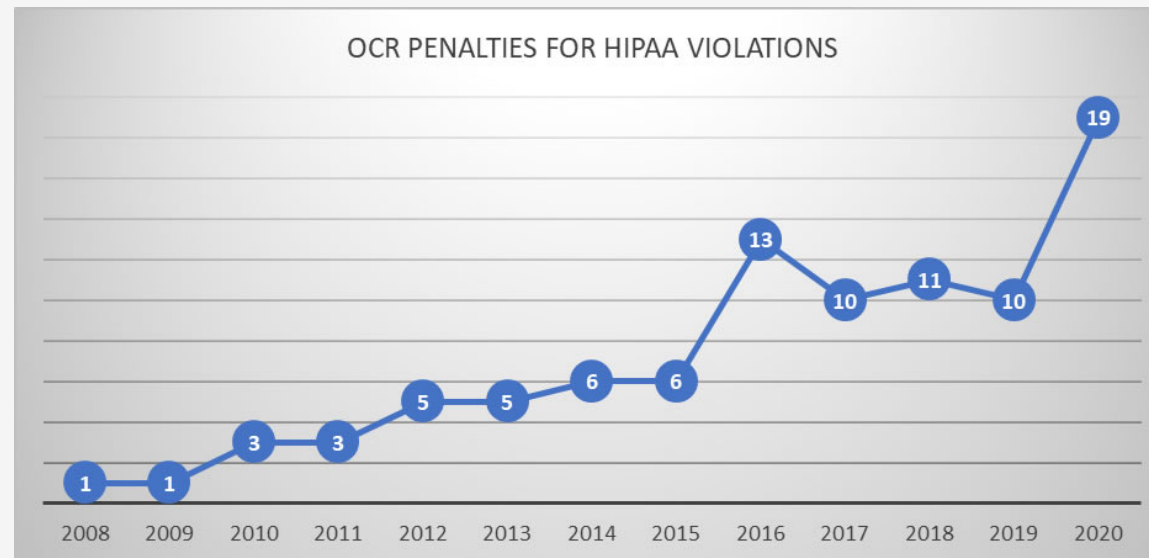
>94% of adults and >85% of children reidentified using activity data

Data Deidentification: Technology vs Policy

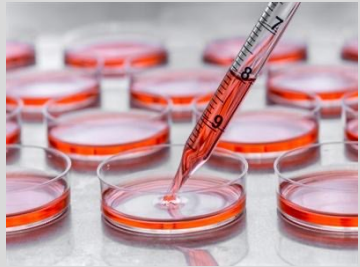
Department of Health & Human Services (HHS) Office of Civil Rights (OCR) handles enforcement of HIPAA
Fines range from \$100 to \$50,000 per violation (varying based on willful neglect / effort to correct)

State Attorneys General can also issue HIPAA-related violations
Fines range from \$100 to \$25,000 per violation

Department of Justice handles criminal enforcement
Penalties span 1-10 years in jail (varying based on personal gain / malicious intent)



Learning from the Immortal Life of Henrietta Lacks



1951
Cervical Cells

Available as a by-product of care
Retained without awareness
Positive impact on research
No transparency with the source



2020
Personal Health Data

Available as a by-product of care
Retained without awareness
Positive impact on research
No transparency with the source

Henrietta Lacks 2.0

Revealed: 50 million Facebook profiles harvested for Cambridge Analytica in major data breach

Whistleblower describes how firm linked to former Trump adviser Steve Bannon compiled user data to target American voters

The Hidden Trade in Our Medical Data: Why We Should Worry

For-profit companies use our anonymized medical data in a huge secondary market. Advances in computing make it increasingly possible for outsiders to identify people from among the hundreds of millions of patients in dossiers, putting intimate secrets about our bodies and minds at risk

Hospital execs say they are getting flooded with requests for your health data

PUBLISHED WED, DEC 18 2019-8:27 AM EST | UPDATED WED, DEC 18 2019-7:02 PM EST

Majority of Health Apps Share User Data, Without Transparency

A recent study published in BMJ found that 79 percent of health apps studied by researchers routinely shared user data, but were far from transparent about the practice.

NEWS • 19 NOVEMBER 2019

Google health-data scandal spooks researchers

Scientists fear the controversy over the Nightingale project will undermine trust in research.

Blurred Lines Between Deidentified Data and PHI

HIPAA and the Leak of “Deidentified” EHR Data

Kenneth D. Mandl, M.D., M.P.H., and Eric D. Perakslis, Ph.D.

The permissible sharing of patient data among health care organizations and their business associates for treatment, payment, and operations purposes has led to a torrent of electronic health record (EHR) data flowing out of health care provider silos. The Health Insurance Portability and Accountability Act (HIPAA) also permits business associates to deidentify data on behalf of a

health care provider, insurance plan, or clearinghouse (so-called covered entities); once data are deidentified, the business associate may use them freely, unless it is contractually prohibited from doing so. Organizations that don't qualify as business associates under HIPAA may also gain access to and use deidentified data sets. Such policies have enabled the rise of a multibillion-dollar industry

comprising dozens of aggregation companies and hundreds more companies using various tools and technologies to aggregate, link, and monetize data. This phenomenon is amplified by the commercial production since the mid-1990s of information technologies and Clinical Health Data. The passage of 2009 began the widespread adoption

Health care institutions could better protect their own interests and patients' privacy by treating deidentified data more similarly to protected health information. First, institutions should inform patients — using consent documents and privacy notices — that their data may be used to support a learning health system and, when appropriate, may be shared with commercial parties.

N ENGL J MED 384;23 NEJM.ORG JUNE 10, 2021

The New England Journal of Medicine

Opportunities for Use of Permissioned Health Data



Not all RWD use cases require high volumes of deidentified data

Using Real World Data for Good Should be Celebrated

Pfizer wins expanded Ibrance approval using real world data

Published April 5, 2019



[Ned Pagliarulo](#)
Lead Editor



Norbert Nagel, Mörfelden-Walldorf, Germany

Dive Brief:

- Pfizer on Thursday secured an expanded U.S. approval for its breast cancer drug Ibrance to men, relying not on clinical study but rather on data from electronic health records and postmarketing reports detailing real-world use of the therapy.

Should Patients Be Able to Sell Their Health Data?

You can now make money selling your own health data, but should you?

TREATMENTS

If Your Medical Information Becomes A Moneymaker, Could You Get A Cut?

October 15, 2018 · 4:45 PM ET
Heard on [All Things Considered](#)

TECHTANK

Who should profit from the sale of patient data?

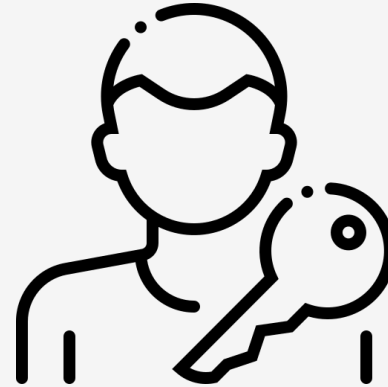
Niam Yaraghi · Monday, November 19, 2018

Begin With Transparency and Permission



Transparency

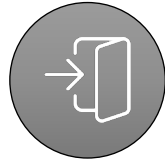
Share openly when
using my health data



Permission

Ask permission before
using my health data

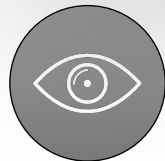
Health Data : Credit Data



Data is
accessible



Ability
to verify



Ability to "see"
who has accessed



Ability to
"lock" access

Begin With Transparency and Permission



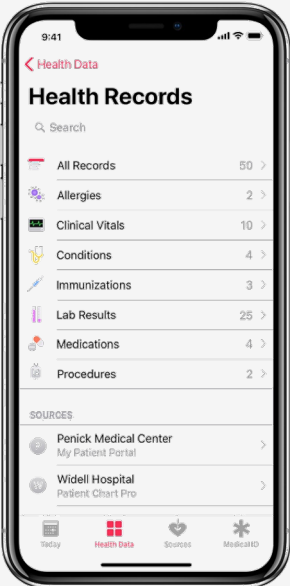
Will I Be Asked for Consent Before My Digital Twin Enrolls in a Clinical Trial?

Published on May 9, 2019

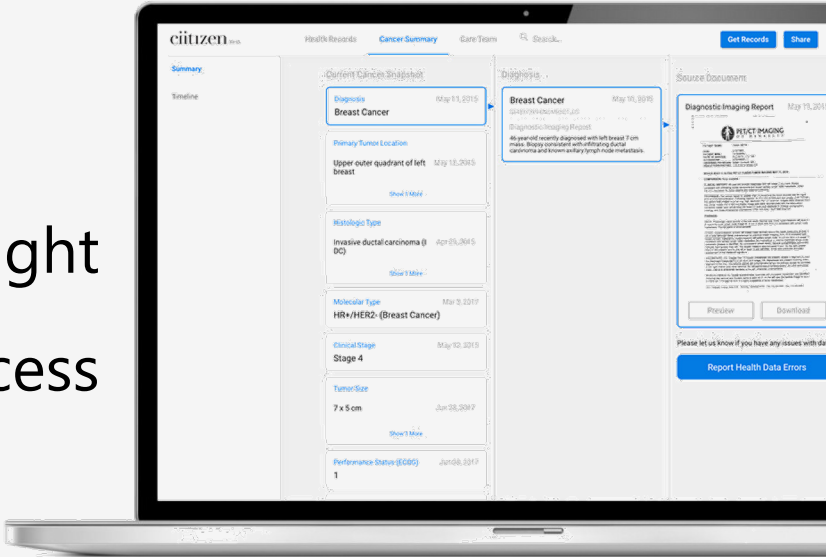
[Edit article](#) | [View stats](#)

Permission and Sharing Data for Prospective Studies

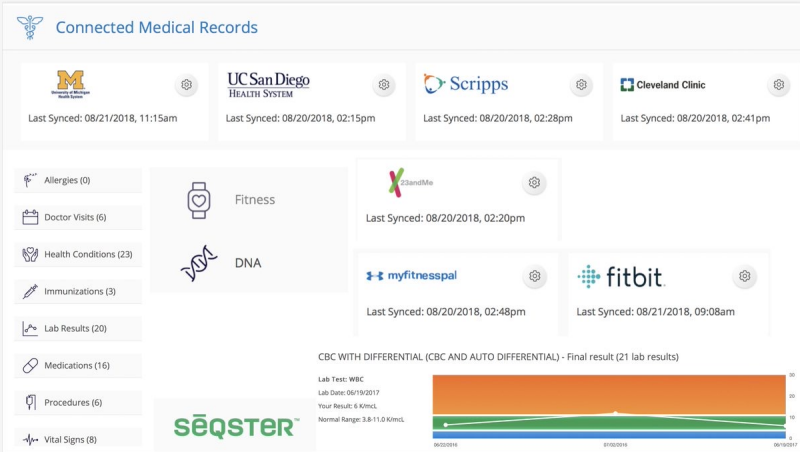
Patient
Portals



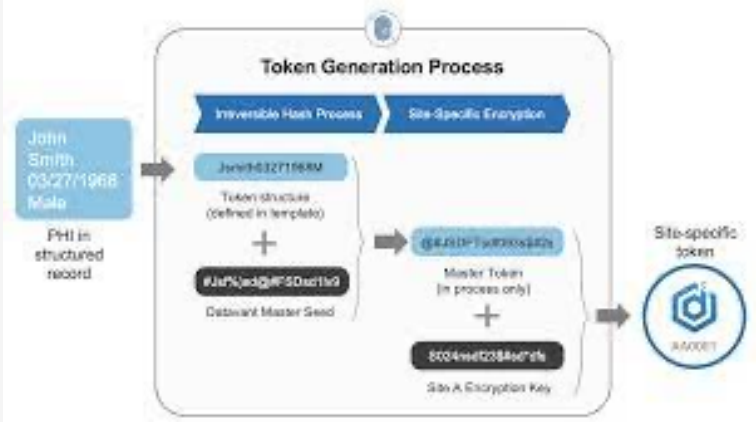
HIPAA Right
of Access



FHIR/EHR
Connectivity



Tokenization of
Aggregated Data



Patients are the Ideal Aggregators of their Diverse Health Data



Electronic Health
Records



Imaging/Diagnostic



Self-Reported Data



Self-Trackd Data
(Wearables/Sensors)



Molecular Profiles



Consumer Data



Environmental Data

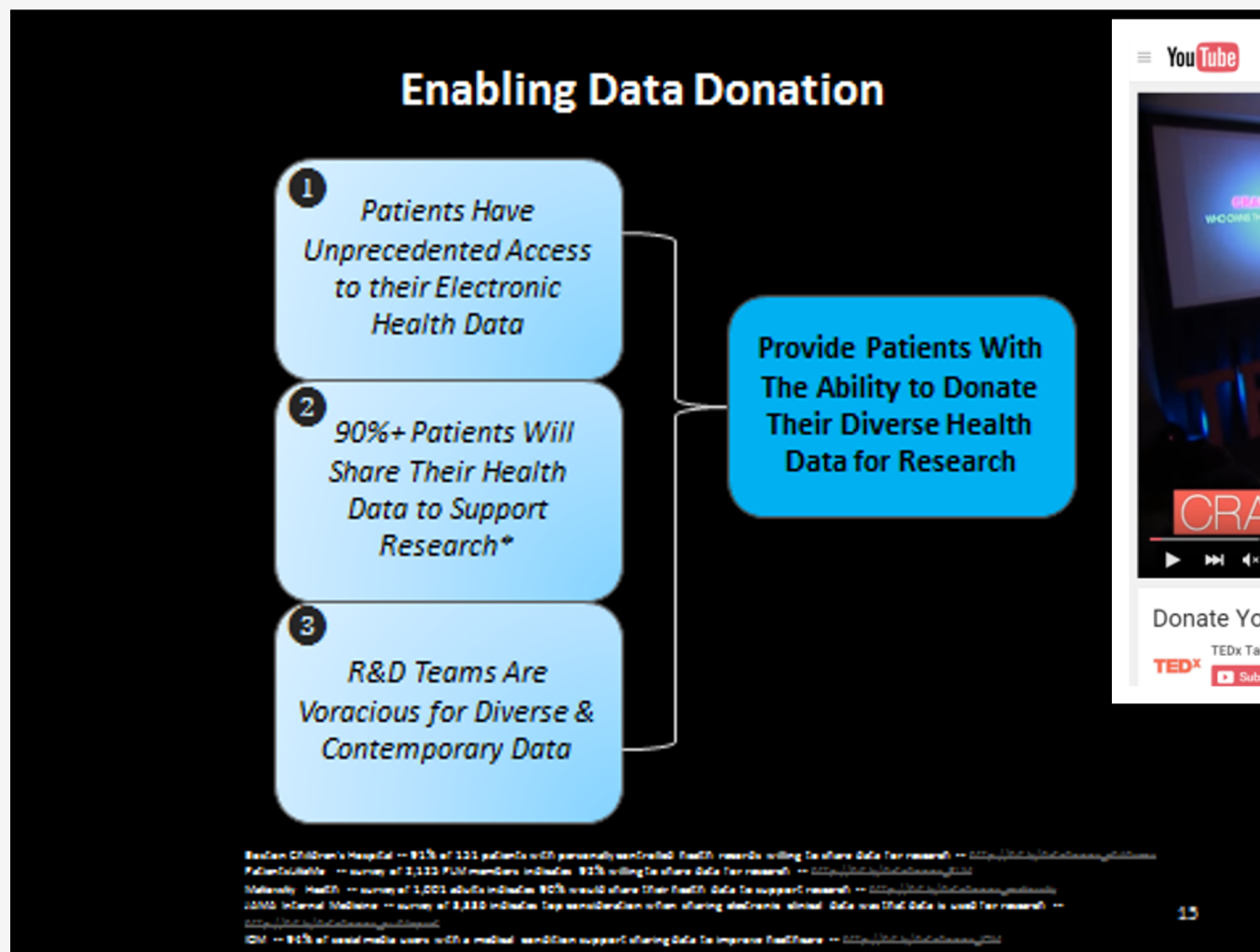


Social Determinants

9 out of 10

people with access to their health data will share their data to support research as long as privacy preferences are maintained

Patients are the Ideal Aggregators of their Diverse Health Data



Patient Health Data Evolution & Revolution

data
access

data
privacy

data
sharing

data
ownership

2010

11

12

13

14

15

16

17

18

2019

Blue Button launched for CMS and VA data return

First monetary penalty by OCR to provider for failing to respond to right of access

Blue Button at VA reaches 1 million registered

HHS ONC launches Blue Button+

HL7 publishes FHIR draft standard

NPWF launches GetMy HealthData

EU GDPR adoption

Meaningful Use Stage 1 provides patients EHR data access

Aetna launches Blue Button for 36M people

United Health launches Blue Button for 26M people

Precision Medicine Initiative announced

NIH and ONC launch Sync for Science

Apple launches iOS 11.3 Health Records beta

Facebook / Cambridge Analytica scandal

EU GDPR implementation

NIH's All of Us Research Program launches

US HHS launches MyHealthData and Blue Button 2.0

California Consumer Privacy Act signed to law

"Interoperability & Patient Access" Rule Proposed by CMS

Multiple state hearings on Health Information Property acts

California Governor calls for "Digital Dividend"

Ontario privacy commissioner investigates medical record sales

WSJ report on apps sharing w/Facebook w/o consumer knowledge

US policy

EU policy

state/province

non-profit

payer

consumer

Craig Lipset [@craiglipset]
Bray Patrick-Lake [@BrayPatrickLake]

How might we...

How might we use transparency and bilateral data sharing
to support participant retention and engagement strategies?

Post-Study Deliverables to Participants

90%

of participants want
to know the results
of their clinical trials

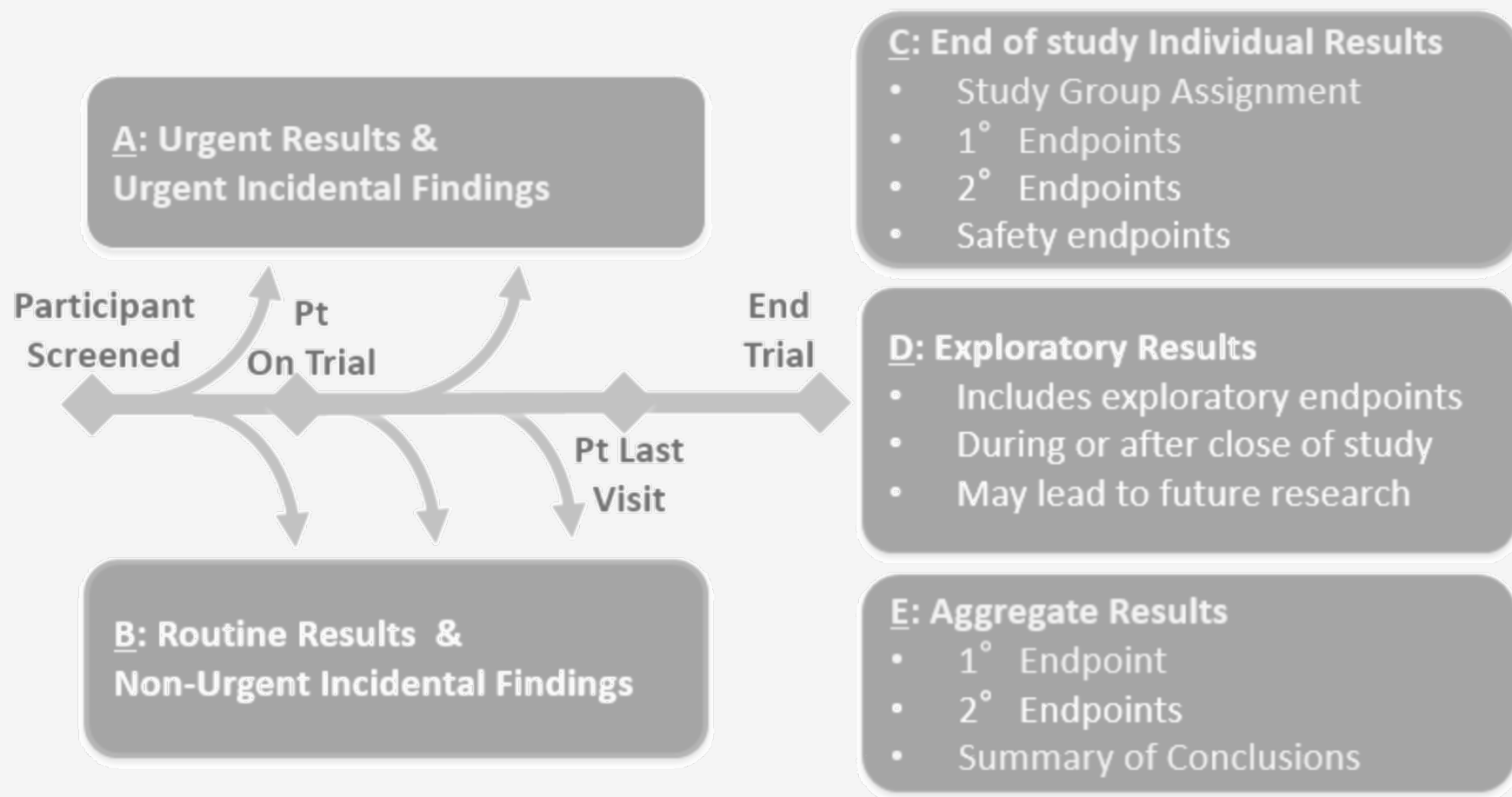
93%

of participants never
learn study results from
study staff or sponsor

98%

of study staff support
providing results to
participants

Post-Study Deliverables to Participants



Post-Study Deliverables to Participants

治験結果

治験を依頼した会社: ファイザー株式会社
治験を行なった薬剤: 国内治験番号:
治験実施計画書番号:
治験日:

Clinical Trial RESULTS

PFIZER CLINICAL TRIAL
Research Sponsor: Pfizer
Drug Studied: Pregabalin (Lyrica*)
National Clinical Trial #: NCT01057693
Protocol #: A0081242
Study Date: March 2010 to January 2012

Thank you!

As a clinical study volunteer, you belong to a large community of volunteers around the world. You help researchers answer important health questions and help them discover new medical treatments.

Thank you for participating in the clinical trial for the drug pregabalin, which took place between March 2010 and January 2012. Pregabalin is also known by its brand name, Lyrica*. It is a prescription medicine used in adults to treat the pain of damaged nerves in their arms, hands, legs or feet, caused by diabetes.

Pfizer, the sponsor of this trial, thanks you for your help and thinks it is important for you to know the results of your trial. An independent non-profit called CISCRP prepared this summary of the trial results for you. We hope it helps you to understand and feel proud of your key role in medical research. If you have questions about the results, please speak with the doctor or staff at your trial site.



ご協力、ありがとう

この度は、治験にご協力いただいた規模で実施され、研究を見だし、新しい薬物療法の開発に貢献しました。この抗生物質、外傷、アレルギー、2012年10月に終了した者の皆様に、外傷、アレルギーの調査にご協力いただき、ありがとうございました。

ファイザーは、この治験の依頼者として、治験結果の報告の要約は、独立非営利組織の協力のおかげで、医学が、おわかりいただけたと信じています。治験実施施設の医師と話し合ってください。

Pfizer Link

Update your profile | Logout

Home | About Clinical Trials | Health Resources | Study Results | Find A Clinical Trial

Welcome, <user name>

 View My Study Results

 Blue Button Download My Data
What is this?

 Research a Condition

Health Picture

ME US

Approx time to complete 6~8min

START NEW TEST

ADD ASSESSMENT +

Pain Interference

Your average score is 63 Your current score is 63

66
65
64
63
62
61

11/06/16 11/21/16 12/28/16 03/01/17

CreakyJoints

ME US

Blog Feed Twitter Feed

Community Question - Hot or cold for joint pain?

Written by CreakyStaff on

We asked our facebook community: When your joints hurt do you prefer hot or cold therapy. Here's what people said. The post Community Question - Hot or cold for joint pain? appeared first on CreakyJoints.

10 Facts about Gout

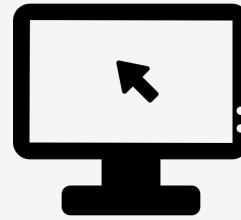
Written by CreakyStaff on

Dr. David O'Reilly a friendly rheumatologist from the UK recently published some facts about gout. Click to learn more. The post 10 Facts about Gout appeared first on CreakyJoints.

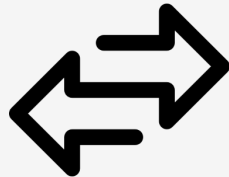
Data Return to Participants: Attributes



Temporal



Study vs. Patient Portals



Interoperable



Global

Industry Collaboration

PATIENT DATA ACCESS INITIATIVE

Sharing individual research data with study participants

[About PDAI](#) [Our history](#) [News & Events](#) [Our members](#) [Our principles](#) [Resources](#)

OUR MEMBERS



Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.



At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.



At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us.

A hand holding a smartphone with a medical app interface, overlaid with text about personal health data.

Patients in full control of their
PERSONAL HEALTH DATA
will be a
KEY DRIVER
of the future of
medicine development.

Transparency & Inclusion Are the Critical Enablers



Transparency and Inclusion

Are the Critical Enablers for the Sustainable Future of Access
to Real-World Data

Future Road Map



Lead with
Transparency



Seek Bilateral Data
Sharing with Patients



Prioritize
Permissioned Data



Encourage Data-
Enabling Patients

Our Access to Real World Data Is Not Sustainable Without Transparency and Inclusion



Craig H Lipset

@craiglipset

15 June 2021