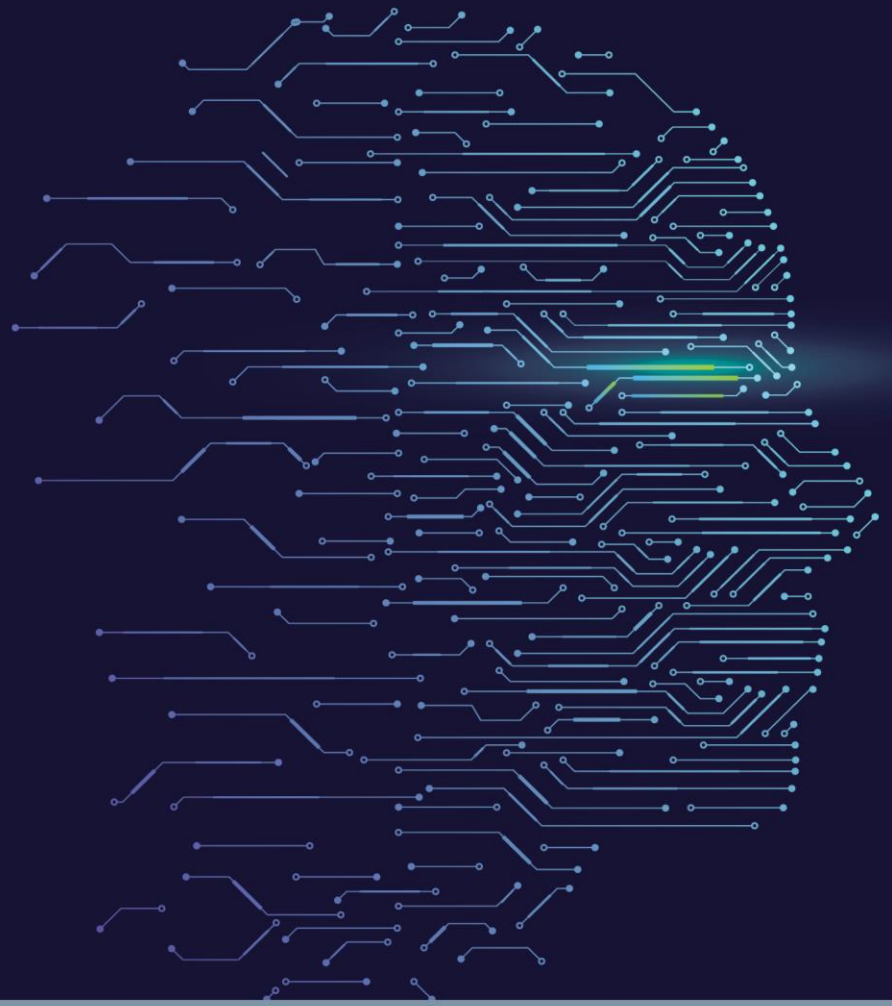
2019 IMAGING INFORMATICS SUMMIT



Stakeholders and Claimjumpers in Data Sharing

Juan Carlos Batlle, MD, MBA, M. Bioethics

Associate Professor, FIU College of Medicine

Chief of Radiology, Doctors Hospital

Chief of Thoracic Imaging, Baptist Health South Florida

Chair, ACR Data Sharing Workgroup

ACR® American College of Radiology

WASHINGTON

Disclosures

- Baptist Health partnership with Watson Health
- Radiology group passive investment in Cleerly
- Internal AI Incubator at my parent corporation Mednax/Vrad
- No personal relevant disclosures

Learning Objectives

- Delineation of stakeholders and perspectives
- Examples of pitfalls in vendor-provider negotiation
- Practical approach to contract negotiation

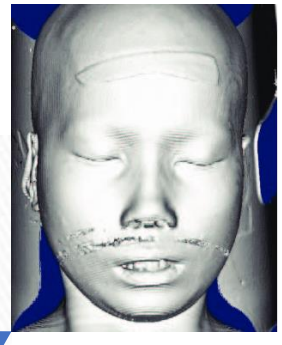
“Data”

http://generated.photos

Deidentification

- 18 HIPAA PHI identifiers → if removed then “safe harbor” protection
- Includes ALL dates

- Name
- Postal address
- Day and Month of dates
- Telephone number
- Fax number
- E-Mail address
- URL address
- IP address
- Social security number
- Account numbers
- Medical record number
- Insurance IDs
- Device identifiers and their serial number
- Biometric identifiers
- Full face photos and other comparable images
- Any other unique identifying number, code or characteristic
- Certificate/license numbers
- Vehicle Vin numbers including license plates



ScienceAsia April 2016

Who owns the data?

- IMS Health - $2.6B in revenue, $10.3B market cap
- 75% of all US pharmacies send data to IMS
- Data HIPAA-compliant: year of birth, gender, partial ZIP, doctor's name
  - E.g., ~51yo male patient of Dr. Smith living in 331XX has the following meds….

- 2011 Sorrell v IMS Health Inc.
  - Vermont statute restricted sale, disclosure and use of records revealing individual prescribers' practices (Prescription Confidentiality Law)
  - "Speech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment."

For Sale: Your Medical Records" in Scientific American 314, 2, 26-27 (February 2016)

MATT DINERSTEIN, individually and on behalf of all others similarly situated,

Plaintiff,

v.

GOOGLE, LLC, a Delaware limited liability company, and THE UNIVERSITY OF CHICAGO MEDICAL CENTER, an Illinois not-for-profit corporation, THE UNIVERSITY OF CHICAGO, an Illinois not-for-profit corporation,

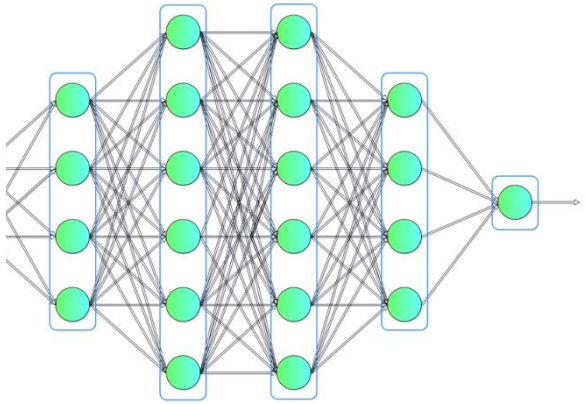
Defendants.

- Patient records U Chicago EHR 2009-2016
- Deidentified but: “detailed datestamps and copious free-text notes”
- That data called the “Holy Grail of health information for any data miner.”
- University Notice of Privacy Practices: “will obtain your written permission … for the sale of your medical information.”

How Companies Match Data

THE UNIVERSITY OF CHICAGO MEDICINE

a. Patient demographics;
b. Provider orders;
c. Diagnoses;
d. Procedures;
e. Medications;
f. Laboratory values;
g. Vital signs; and
h. Flowsheet data.[24]



- Email and social media content
- Smartphone apps
- Fitness trackers
- Any device with GPS
- Web browser cookies / device fingerprinting
- Wifi networks in range
- Internet of Things

1996 Bentley College Commencement

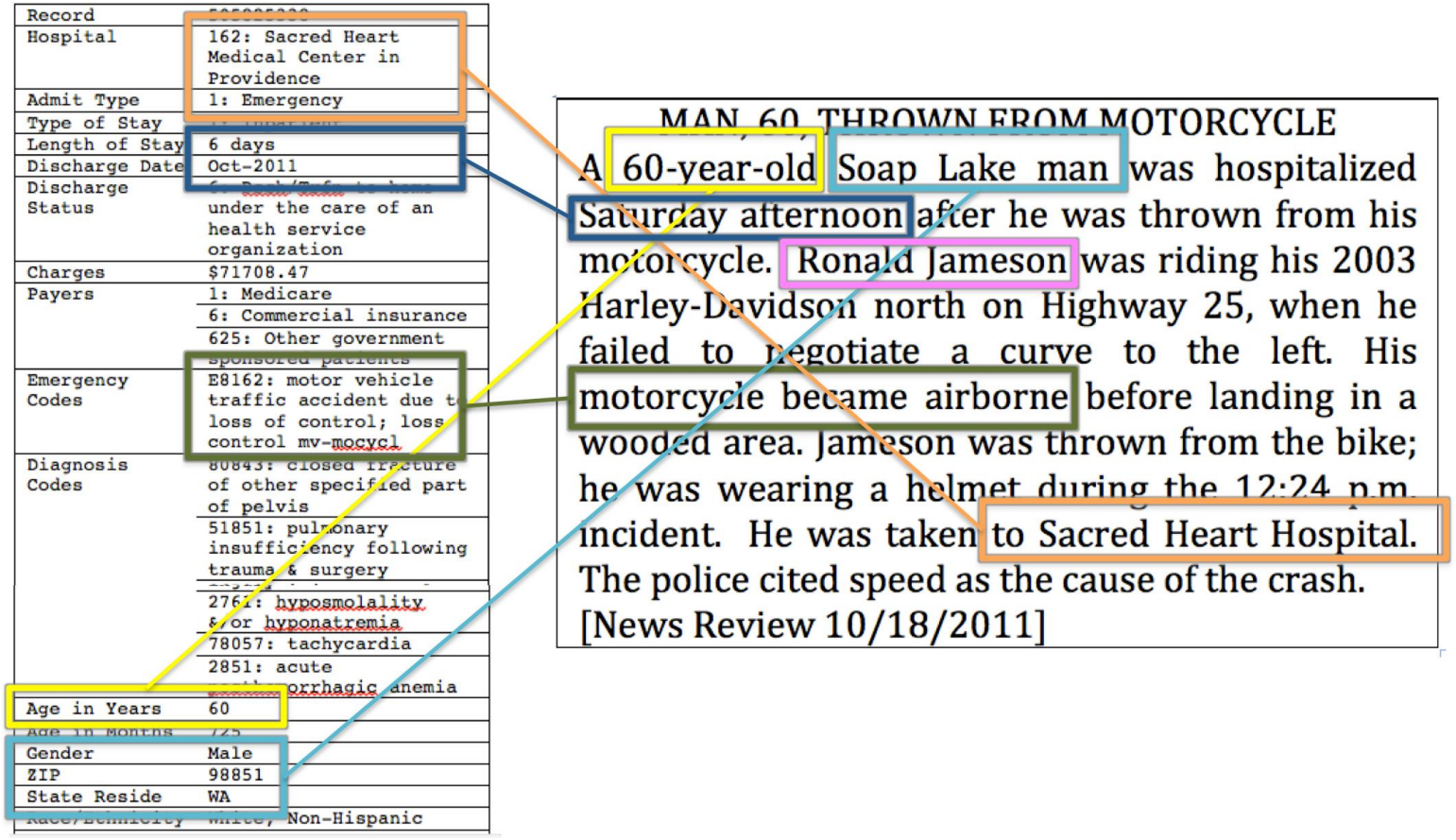
- Mass. Governor William Weld awarded honorary law degree

Weld Deidentification

- MIT graduate student Latanya Sweeney (now Harvard professor and Director of Harvard Data Privacy Lab)
- Compared deidentified hospital data from Massachusetts Group Insurance Commission to voter list for Cambridge
- Based on date of birth, gender and ZIP, 1 record matched
- Gave governor's office a list of prescriptions Weld took home
- Led to HIPAA Privacy Rule 1.2.1 in 1996 → into effect 2003

Ongoing work in reidentification

- Illinois (2006)
  - Newspaper FOIA for neuroblastoma pt data
- Washington State (2015)
  - $50 for patient-level dataset
  - Matched 35 of 81 news stories (43%)
- Maine/Vermont (2018)
  - Maine Health Data Org 2010 data $1,125
  - 28% of news stories (still 3% with Safe Harbor applied)
- States *not* bound by HIPAA



Record	[redacted]
Hospital	162: Sacred Heart Medical Center in Providence
Admit Type	1: Emergency
Type of Stay	[redacted]
Length of Stay	6 days
Discharge Date	Oct-2011
Discharge Status	[redacted] under the care of an health service organization
Charges	$71708.47
Payers	1: Medicare 6: Commercial insurance 625: Other government [redacted]
Emergency Codes	E8162: motor vehicle traffic accident due t[redacted] loss of control; loss control mv-mocycl
Diagnosis Codes	[redacted] of other specified part of pelvis 51851: pulmonary insufficiency following trauma & surgery [redacted] 2761: hyposmolality &/or hyponatremia 78057: tachycardia 2851: acute [redacted] orrhagic anemia
Age in Years	60
Age in Months	[redacted]
Gender	Male
ZIP	98851
State Reside	WA
[redacted]	[redacted] Non-Hispanic

MAN, 60, THROWN FROM MOTORCYCLE

A 60-year-old Soap Lake man was hospitalized Saturday afternoon after he was thrown from his motorcycle. Ronald Jameson was riding his 2003 Harley-Davidson north on Highway 25, when he failed to negotiate a curve to the left. His motorcycle became airborne before landing in a wooded area. Jameson was thrown from the bike; he was wearing a helmet during the 12:24 p.m. incident. He was taken to Sacred Heart Hospital. The police cited speed as the cause of the crash. [News Review 10/18/2011]

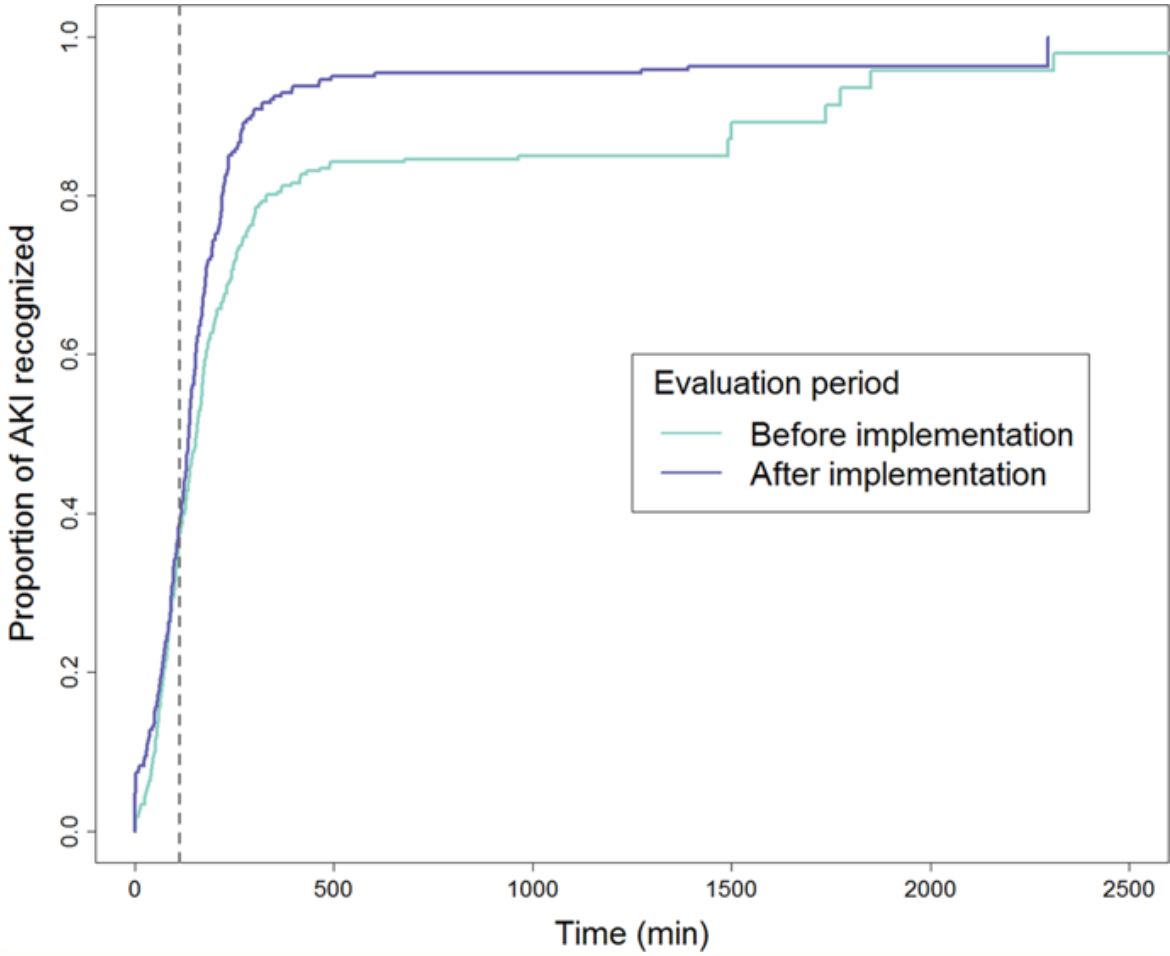
Yoo J, Thaler A, Sweeney L, Zang J. Risks to Patient Privacy: A Re-identification of Patients in Maine and Vermont Statewide Hospital Data. *Technology Science*. 2018100901. October 09, 2018.

How non-identifiable is enough?

- Ad Hoc Workgroup of Secondary Uses of Health Data 2007: 0.04% of Safe Harbor datasets could re-identify based on year of birth, gender and three-digit ZIP
- Vanderbilt study modeling Safe Harbor reidentification risk 0.01-0.25% (2 out of 15K)
- University of Chicago 2011: 0.22% re-identification risk comparing hospital records to market research data
- Bottom line: Beware “deidentified”, but 100% deindentifiability unlikely and impractical

A Study in Data Use Agreement
DeepMind "Streams" at Royal Free Hospital, London

- Software predicts which inpatients will develop acute kidney injury within 48hrs → mobile notifications
- Used US Veterans Affairs database for machine learning (703K patients, 6% women)
- Originally formulaic, eventually incorporated AI with 50-60% accuracy at best



npj Digital Medicine (2019) 67

DeepMind AI “Streams” at Royal Free Hospital, London

- 2017 Information Commissioner’s Office Findings
  - Did not inform patients about data sharing with DeepMind
  - Excessive sharing of data
  - Insufficient auditing and transparency
  - Opaque opt-out
  - Commissioner: “It’s not a choice between privacy or innovation. The price of innovation didn’t need to be the erosion of legally ensured fundamental privacy rights".

DeepMind: “[We] underestimated the complexity of the NHS and of the rules around patient data. We got that wrong, and we need to do better.”

DeepMind AI "Streams" at Royal Free Hospital, London

- 2015 Original Agreement: 7 pages

Royal Free London NHS
NHS Foundation Trust

INFORMATION SHARING AGREEMENT

Purpose of this document

This document describes the minimum arrangements for regularly or routinely sharing person identifiable information (PID) with non NHS bodies for the Direct Care of the Patient. It is to be used as the basis of agreements made about specific services with individual non NHS bodies and/or Data Processors. In those agreements all its provisions from paragraph 3 onwards must be included (unless otherwise approved by the trust's Caldicott Guardian or CISO). The sections in boxes are to be composed to suit the specific information sharing agreement.

Parties to the agreement

Party A	Party B
Royal Free, Barnet & Chase Farm Hospitals Royal Free London NHS Foundation TrustHS Pond St Hampstead London NW2 2QG	Google UK Limited Belgrave House 76 Buckingham Palace Road London SW1W 9TQ

1. HL7 feeds: Live from either source system or integration engine - via VPN
    a. All ADT
    b. ORU-RO1 (Results)– Pathology and Radiology
    c. Relevant specification and mapping documents for all the above
2. CDS / SUS submission - via VPN or SFTP
    a. APC – Completed inpatient episodes
    b. CC – Critical Care
    c. AAE – Accident and Emergency
    d. Relevant specification and mapping documents for all the above
3. Last 5 years archival data of all the above, in any defined format, to aid service evaluation and audit of the new product.

Signed for and on behalf of the Processor:

Signature: .....
(Authorised signatory)

Print name: MUSTAFA SULEYMAN
Position: CO-FOUNDER / HEAD OF APPLIED AI
Date: 29/09/2015

DeepMind AI "Streams" at Royal Free Hospital, London

2016 Revision Agreement: 13 pages

- Explict compliance with ICO and Data Protection Law
- Creation of bilateral Information Governance Board meeting monthly

(a) only process the Personal Data for and on behalf of the Controller, strictly in accordance with the written instructions of the Controller, unless required to do otherwise by UK law, in which case the Processor shall inform the Controller of that legal requirement before processing the Personal Data otherwise than in accordance with the Controller's instructions (unless that law prohibits such information on important grounds of public interest);

(b) disclose the Personal Data only to its personnel and subcontractors who have a need to know such information in order to perform the Services under the Services Agreement, and who have undergone appropriate information governance training and have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;

(c) process the Personal Data only for the purposes of providing the Services under the Services Agreement;

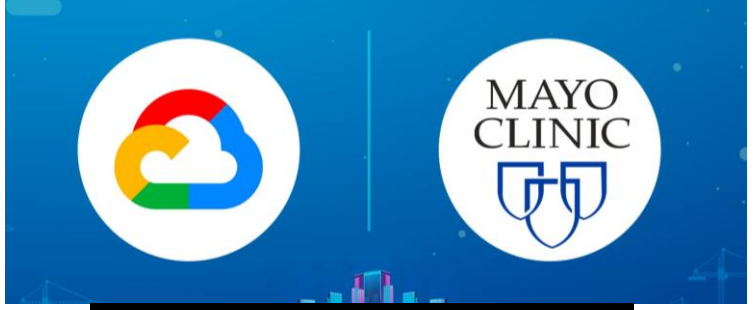
(d) implement and maintain appropriate technical and organisational security measures to safeguard the Personal Data from unauthorised or unlawful processing or accidental loss, damage or destruction, as more fully set out in Schedule 2 and the Services Agreement;

(e) not engage any subprocessors without the Controller's prior written consent and, in the event of subprocessing, ensure the same data protection obligations as are imposed on the Processor under this Agreement are imposed on the subprocessor by way of a written contract with the Processor. The Processor shall remain fully liable to the Controller for the acts or omissions of any subprocessor;

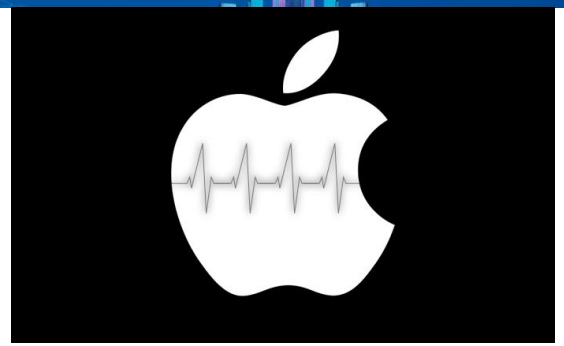
(f) taking into account the nature of the processing and the information available to the Processor, assist the Controller (as reasonably requested by the Controller) in ensuring compliance with its obligations under the Data Protection Legislation in relation to security, data breach notification, data protection impact assessments and prior consultation, if and to the extent such obligations apply to the Controller under the Data Protection Legislation;

Recent Comment on DeepMind / Royal Free

- National Data Guardian, Dame Fiona Caldicott
  - Psychiatrist, previous Chair of Oxford University Hospitals NHS Trust, previous Chair of landmark committee for protection of patient information in the UK
  - "My panel and I disagreed with one of [the ICO auditor's] key arguments: that whether or not confidentiality has been breached should be judged from the point of view of the clinician's conscience, rather than the patient's reasonable expectations. It is my firm view that it is the patient's perspective that is most important when judgments are being made about the use of their confidential information… Patients' reasonable expectations are the touchstone of the common law duty of confidence." –August 23, 2019
- DeepMind was allowed to keep the data;
  2017 agreement to own FHIR API to Royal Free



How Google and Mayo Clinic will transform the future of healthcare



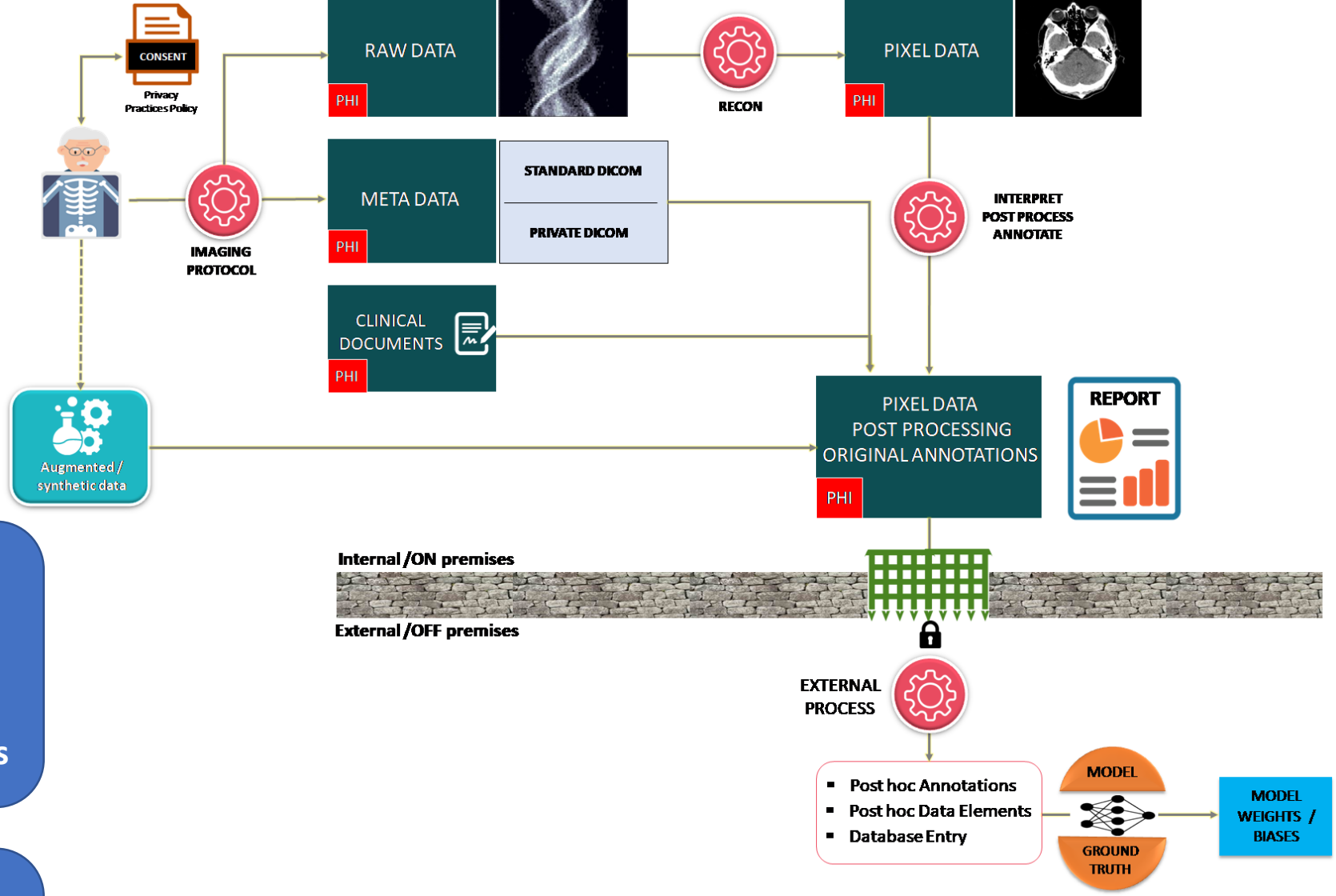
Cleveland Clinic puts EHR data onto iPhone with Apple Health Records

FHIR

Ricky Bloomfield
@rickybloomfield
Follow

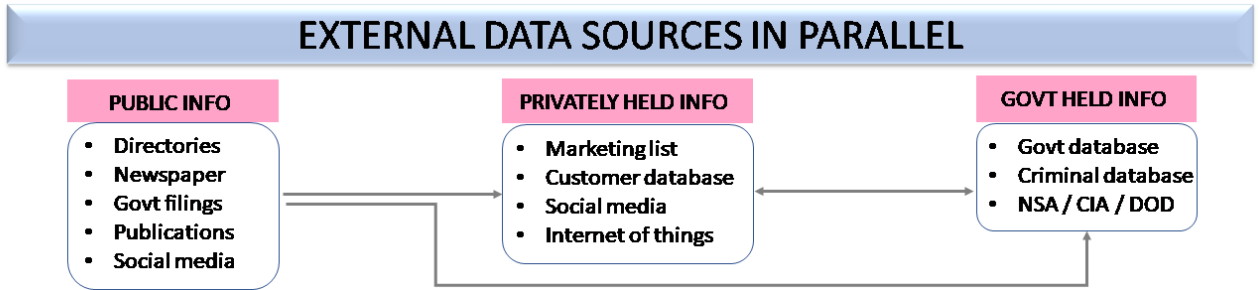
Spy shots from the Apple Health team parking lot. Now that's some #FHIR dedication! 🤓 How do you show off your inner #FHIR geek? @HL7 @ONC_HealthIT @SMARTHealthIT

Data Chain of Custody



BAA (Business Associate Agreement) binds data partner to Covered Entity so as to include partner under HIPAA requirements

TPO (Treatment, Payment Operations) : HIPAA exception to allow PHI to be used among entities



ACR Data Sharing Workgroup

- Identify challenges
- Propose solutions
- Best practices
- Sample documents and language

PRIVACY
- Deidentification/anonymization
- Encryption/transmission
- Safe harbor HIPAA

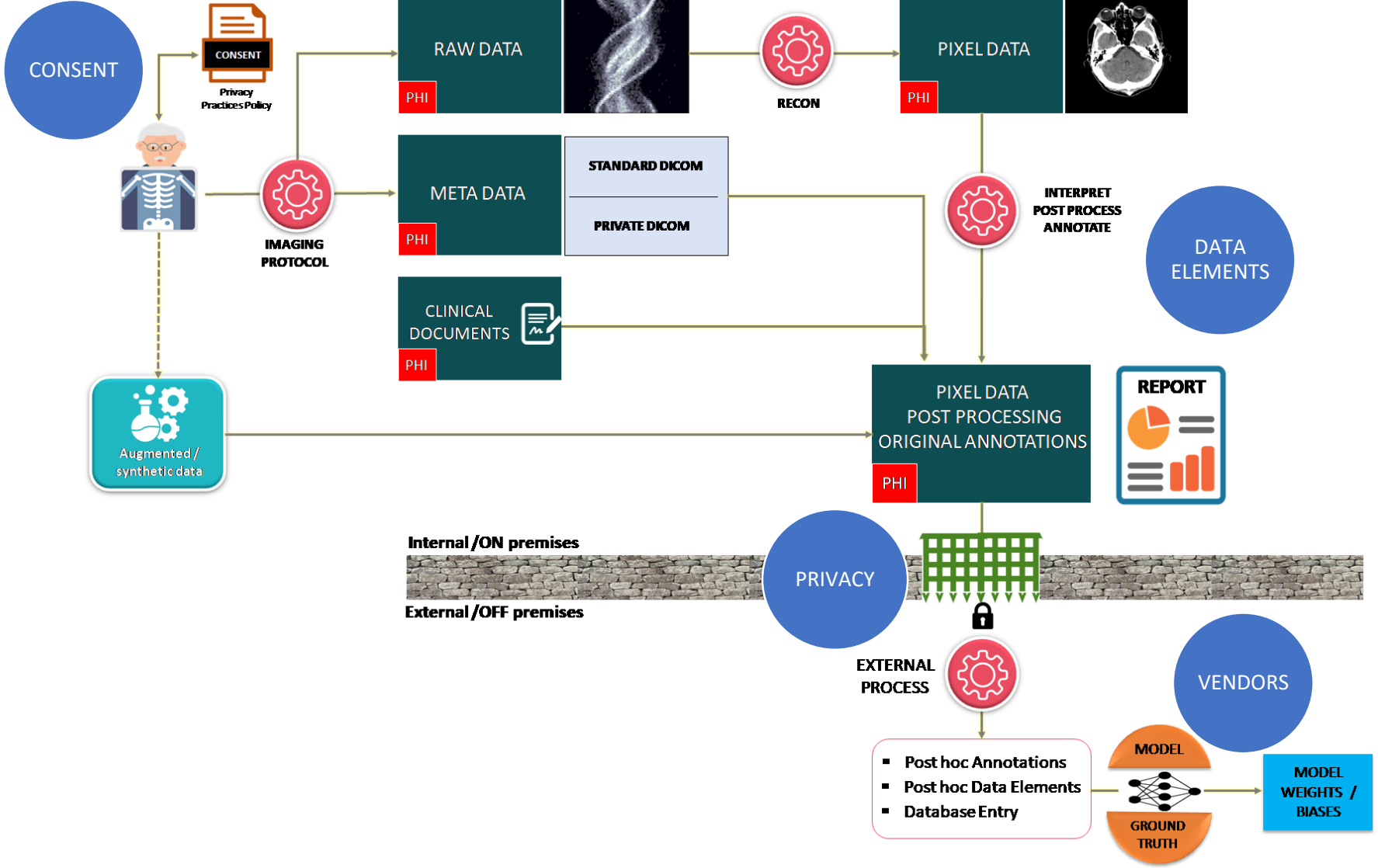
VENDORS
- Rules of engagement
- Exclusivity of contracts
- Data use agreements

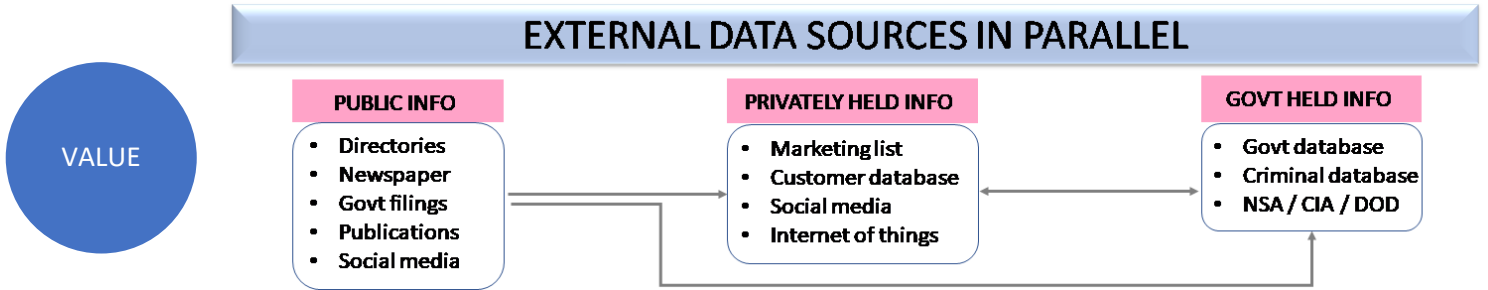
CONSENT
- Approval from IRB or other entity
- IRB template
- Patient consent / blanket auth.
- 'Privacy practices'

DATA ELEMENTS
- Data level definitions
- Ownership according to data level
- Structure of data
- Annotation of data
- RadLex
- *Adding* ML-relevant metadata

VALUE
- Monetization of data
- Patient participation
- Downstream data use/reuse

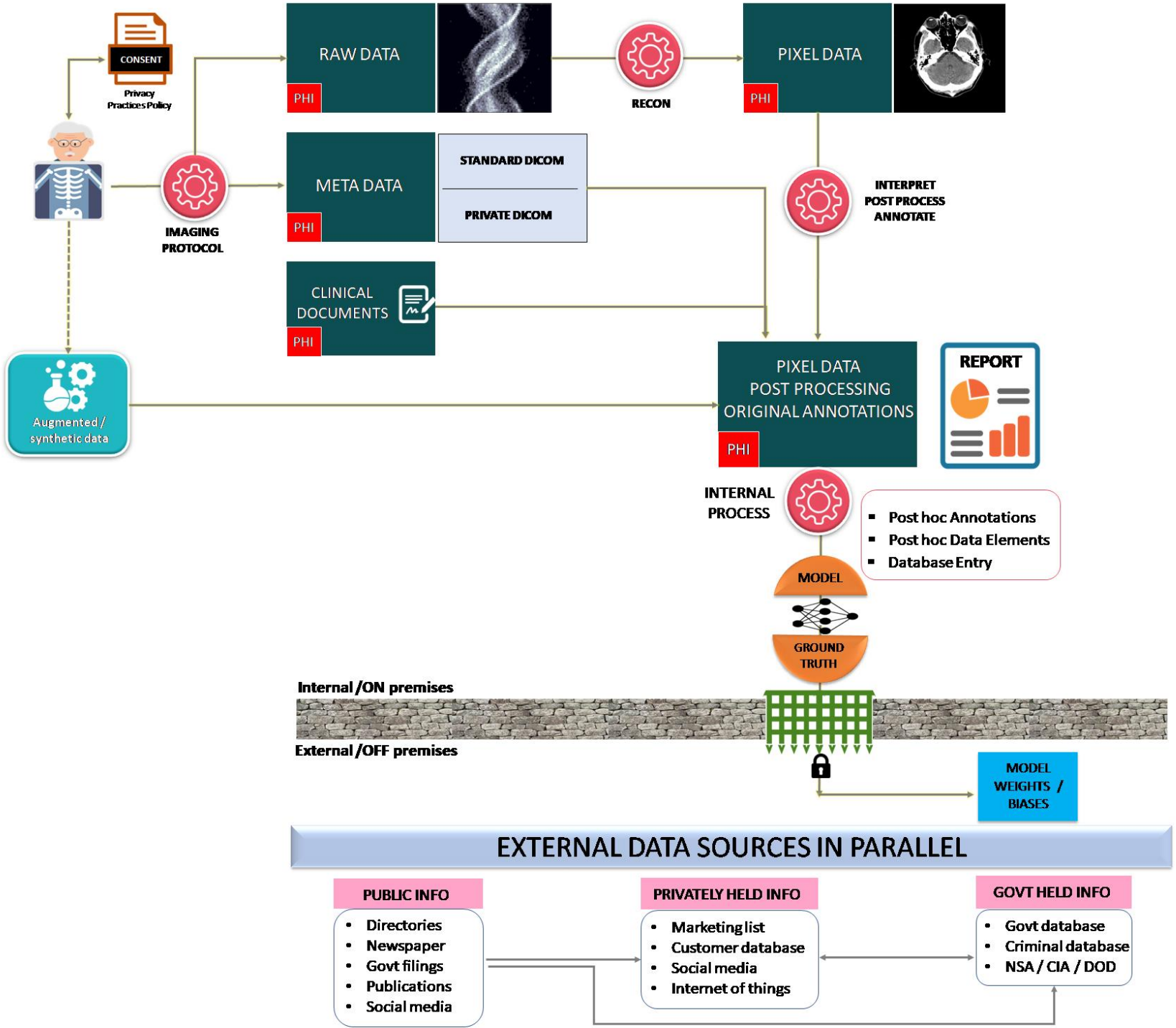
Data Chain of Custody





Push wall outward

- Federate data
- Export model tweaks
- Avoid data exposure



MEDNAX Radiology AI Incubator

vRad Dataset
- Massive scale
- Diverse

Developer Data Sharing
- Share data with partner
- Partner builds model
- We use the model

Data Curation
- Image annotation services
- Direct physician engagement

Data Validation
- Developer model testing
- “In the wild” model validation
- We use the model

Improving Patient Care Today

PRIVACY

- Deidentification, Encryption, Federation, No Re-ID attempts

VENDORS

- Data Use Agreements – Exclusivity, Duration, Sublicensure

CONSENT

- Privacy Practices Policy, Data Governance Board, Adaptive Consent

DATA ELEMENTS

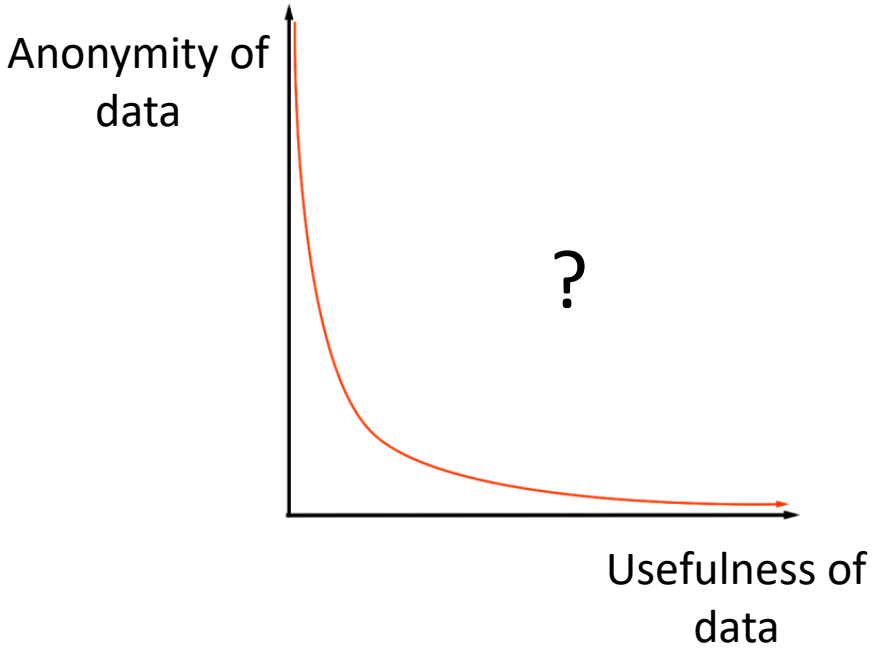
- Lexicons/Ontologies, Annotation discussion, Watermarking

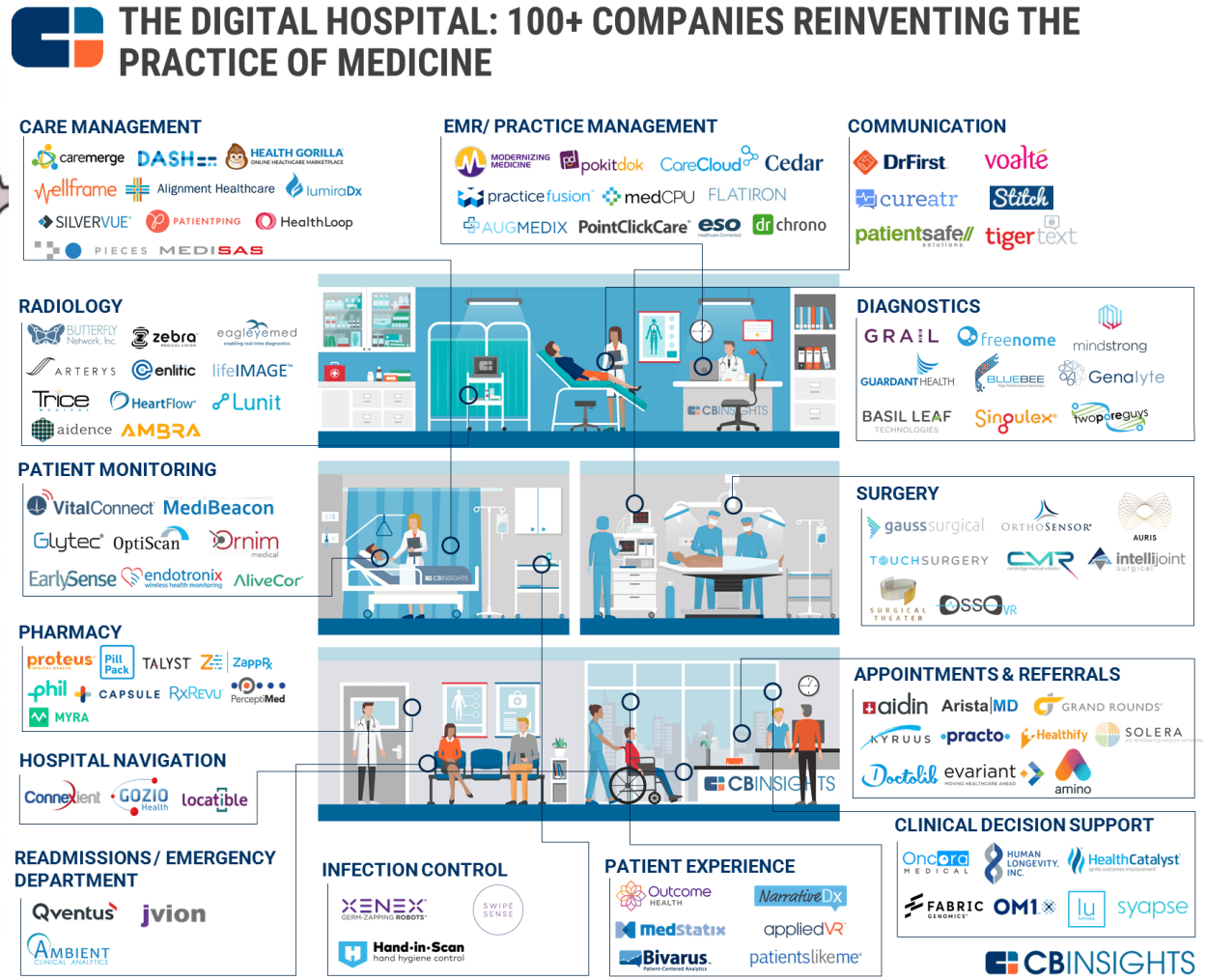
VALUE

- Medical records valuable. Patient protection even more so.

Challenges

- Difficulty in true anonymization
- Need for strong encryption / auditing
- Need for strong contracting / DUA
- Data export represents the largest vulnerability
- Balkanization of federated data
- Annotation/ground truth variability





Agfa healthcare blog 2017

CB Insights July 2017

CMS Blue Button 2.0

- FHIR API
- Beneficiary can view/share claims data
- 53 million patients
- 4yrs of Medicare A/B/D data

EUROPEAN MEDICINES AGENCY
Clinical data

Help

Site wide search

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Clinical reports for Truxima - Initial marketing authorisation

All information published on the website is correct at the time of publication. For the current status of this product, please see 'Find medicine' or the EMA website.

Enter a search term to identify the documents containing this term.

Search

Any text or keyword search looks for matches in both the document title and the document content.

Upgrade your access

The protocol and protocol amendments, sample case report form and documentation of statistical methods are incorporated in the documents under 'Clinical Study Report'.

Collapse all

Clinical overview +
The clinical overview provides a critical analysis of the clinical data in the eCTD.

Clinical summary +
The clinical summary provides a detailed factual summary of the clinical information in the eCTD.

Clinical study reports −
A clinical study report (CSR) on a clinical trial is a detailed document about the methods and results of a trial.

- m5332-ctp1011-p-app1611-protocol.pdf
- m5332-ctp1011-p-app1612-crf.pdf
- m5332-ctp1011-p-app1619-sap.pdf
- m5332-ctp1011-p-csr-body.pdf
- m5351-ctp1012-s-csr-body.pdf

Product name
Truxima

MAH
Celltrion Healthcare Hungary Kft.

Active substance
RITUXIMAB

ATC code
L01XC02

Number of Documents
32

Procedure type
Initial marketing authorisation

Publication year
2018

Product Status
Authorised

Type
B

Article 58
No

EMA procedure number
EMEA/H/C/004112/0000

See the European Public Assessment Report (EPAR) on the EMA website

CELLTRION, Inc.
Protocol: CT-P10 1.2

Listing
Clinical chemistry result

Patient No.	Age/Sex/ Race	Visit	Date/Time of Sample	Laboratory Test	R
[redacted]		Cycle 1	[redacted]	Sodium	1
				Potassium	4
				Chloride	1
				Bicarbonate	2
				Blood Urea Nitrogen	1
				Creatinine	0
				Glucose	9
				AST (SGOT)	2
				ALT (SGPT)	2
				Alkaline Phosphatase	5
				Total Bilirubin	0
				LDH	1
				Calcium	8
				Magnesium	0
				Phosphorous	4
				Total Protein	6
				Albumin	3
				Uric Acid	3

- EMA Rule 70
- Within 6 months of market auth, individual patient data needs to be published

Thank you!