# Building Bridges Between Technical Data Privacy Capabilities and Legal Requirements

Bradley Malin, Ph.D.

Professor of Biomedical Informatics, Biostatistics, & Computer Science

Co-Director, Health Data Science Center

Vanderbilt University

30 November 2018

### **EMA Policy 0070**

- Push to publicly disseminate clinical trials data
- Phase 1: Publication of clinical study reports only
- Phase 2 (future): Publication of individual-level records



2 October 2014 EMA/240810/2013

European Medicines Agency policy on publication of clinical data for medicinal products for human use

POLICY/0070 Status: Adopted

Effective date: 1 January 2015 Review date: No later than June 2016

Supersedes: Not applicable



#### https://clinicaldata.ema.europa.eu/web/cdp/home

Home Find Clinical Data ✓ About ✓



#### Data on this website

This website contains clinical data published under the European Medicines Agency (EMA) policy on the publication of clinical data. The clinical data have been submitted by pharmaceutical companies to support their marketing applications for human medicines under the centralised procedure and have been assessed by the Committee for Human Medicinal Products (CHMP).

EMA is the first regulatory authority worldwide to provide such broad access to clinical data.

For more information on the clinical data on this website, see Clinical data available.

For more information on EMA and its policy on the publication of clinical data, see the

#### Latest clinical data published

Ameluz (5-AMINOLEVULINIC ACID) EMEA/H/C/002204/II/0020 published 12 November 2018

Truxima (RITUXIMAB)
EMEA/H/C/004112/0000 published 9
November 2018

Alecensa (ALECTINIB) EMEA/H/C/004164/0000 published 17 October 2018

Lucentis (RANIBIZUMAB) EMEA/H/C/000715/II/0061 published 9 October 2018

Movymia (TERIPARATIDE) EMEA/H/C/004368/0000 published 2 October 2018

Terrosa (TEDIDADATIDE)

Log in with an EMA account

EMA account holders should log in with their login credentials.

Username
This field is required.

Forgot username

Password
This field is required.

Forgot password

Not sure if you have an EMA account?

Remember me

Login

No EMA account?

New users need to create an EMA account

to access clinical data on this website. Once

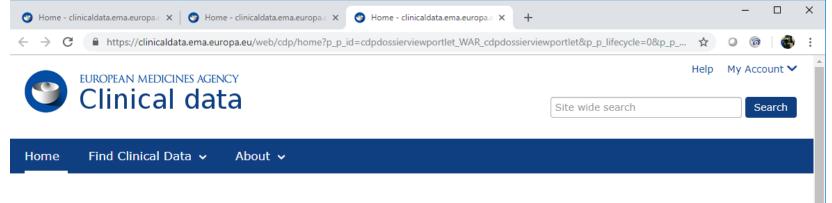
Create EMA account

you have created an EMA account, please

return to this page to log in.



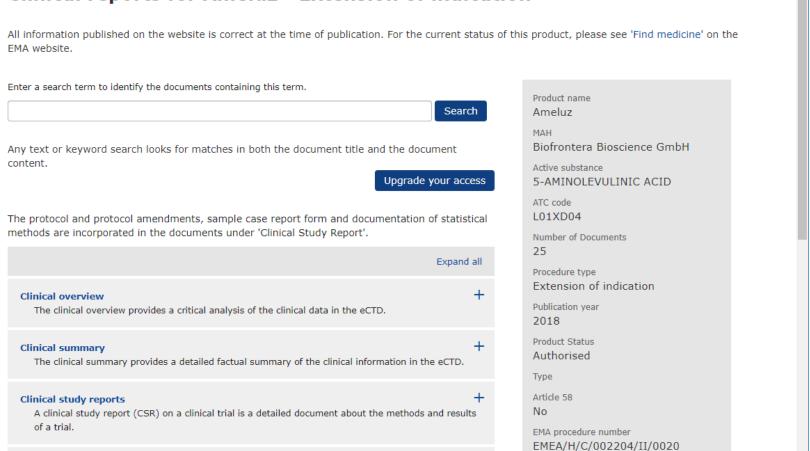
Terms of use



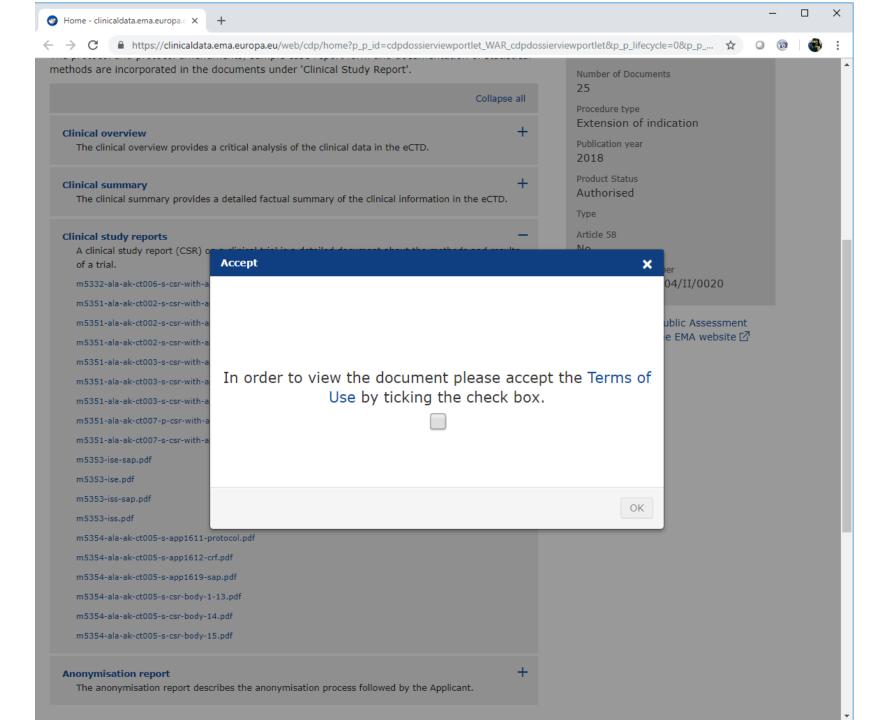
#### Clinical reports for Ameluz - Extension of indication

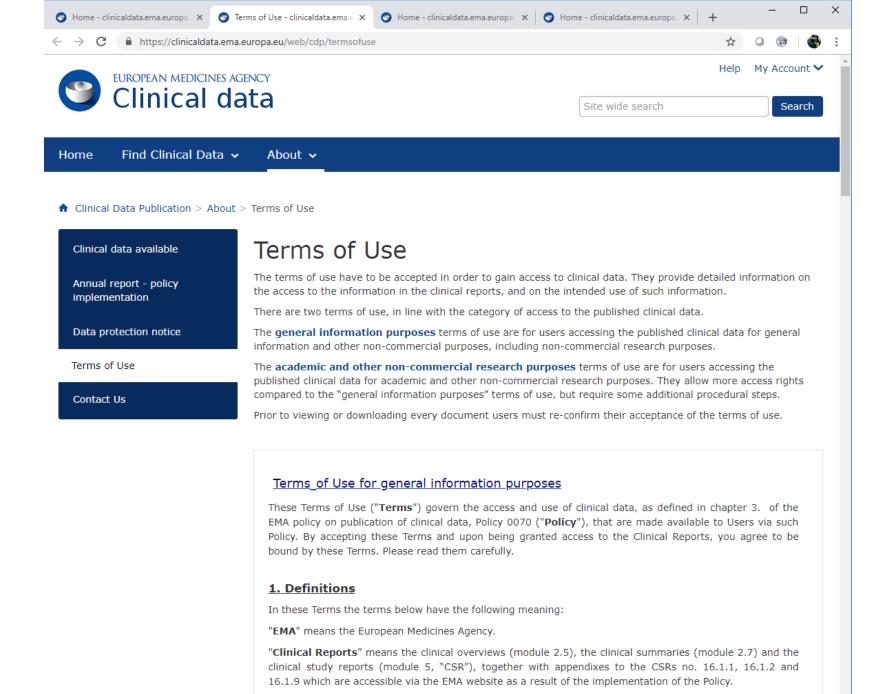
The anonymisation report describes the anonymisation process followed by the Applicant.

Anonymisation report

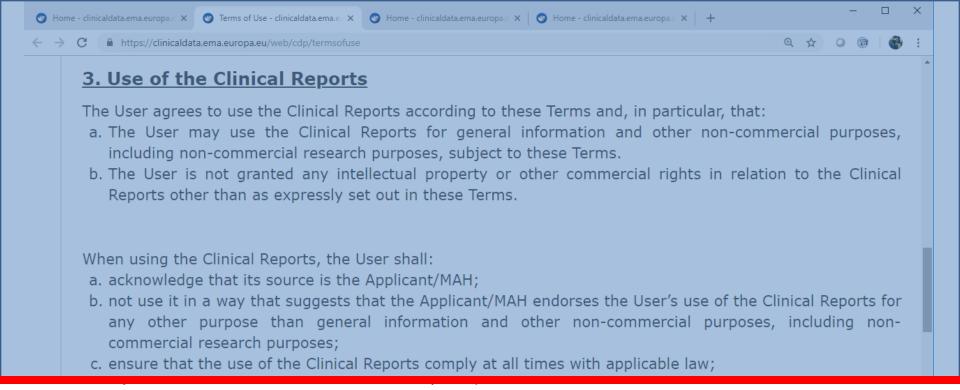


See the European Public Assessment





"Applicant/MAH" means the natural or legal person(s) or organisation(s) that submitted the Clinical



 e. not seek to re-identify the trial subjects or other individuals from the Clinical Reports in breach of applicable privacy laws.

The User may not:

- use the Clinical Reports to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world;
- share the User's username, password or other account details with a third party or otherwise provide a third party with access to the User's account;
- make any unfair commercial use of the Clinical Reports.

If the User fails to accurately complete the registration process, comply with these conditions, or uses the Clinical Reports in breach of these Terms, the rights to access and use the Clinical Reports will be revoked.

#### 4. Warranties and liability

#### EMA Policy 0070: Drawing a Line

 Push to publicly disseminate clinical trials data

 April 2017 – guidance on how to share data

Risk of re-identification:
 no worse than 0.09



11 April 2017 EMA/90915/2016 Version 1.2 published 12 April 2017

External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data en.pdf







ABOUT ~ FUNDING ~

**NEWS, EVENTS, & MEDIA** 

JoinAllofUs.org >

Search





#### The future of health begins with you

The All of Us Research Program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine.

**JOIN NOW** 

Interested in the All of Us Research Program?

**LEARN MORE** 

Sign up to be notified of announcements, events, funding news and more.

SUBSCRIBE

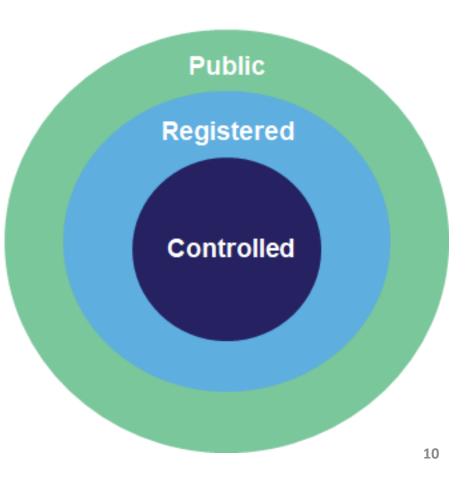




#### Tiered Levels of Access

- Public
  - Can be accessed without logging in
  - Summary statistics only
- Sandbox Environments (on Google Cloud)
  - Registered
    - Individual level records with minimal risk to participant identification
  - Controlled
    - Individual level records with more risk to participant identification, but expected to be low









SHIPS

### A "Quasi-identifier" Conundrum

ZIP Code

Birthdate

Gender

Ethnicity

Visit date

Diagnosis

Procedure

Medication

Total charge

Name

Address

Date registered

High Profile

Re-identification

Party affiliation

Date last voted

Hospital Discharge Data Voter List



# 5-Digit US ZIP Code

+ Birthdate

+ Gender

63-87% of USA estimated to be unique

# Set the World

on



Forbes Billionaires Innovation Leadership Money Consumer Industry Lifesty

### Harvard Professor Re-Identifies Anonymous Volunteers In DNA Study



Adam Tanner Contributor ①
Apr 25, 2013, 03:47pm • 22,581 views

f

A Harvard professor has re-identified the names of more than 40% of a sample of anonymous participants in a high-profile DNA study, highlighting the dangers that ever greater amounts of personal data available in the Internet era could unravel personal secrets.

in

From the onset, the Personal Genome Project, set up by Harvard Medical School Professor of Genetics George Church, has warned participants of the risk that someone someday could identify them, meaning anyone could look up the intimate medical histories that many have posted along with their genome data. That day arrived on Thursday.



Harvard Professor Latanya Sweeney

# Re-identification possible with Australian de-identified Medicare and PBS open data

Using publicly known information, a team of researchers from the University of Melbourne have claimed to reidentify seven prominent Australians in an open medical dataset.



By Chris Duckett | December 18, 2017 -- 01:01 GMT (17:01 PST) | Topic: Security



The dataset containing historic longitudinal medical billing records of one-tenth of all Australians, approximately 2.9 million people, has been found to be re-identifiable by a team from the University of Melbourne, with information such as child births and professional sportspeople undergoing surgery to fix injuries often made public.

The team, consisting of Dr Chris Culnane, Dr Benjamin Rubinstein, and Dr Vanessa Teague, warned that they expect similar results with other data held by the government, such as Census data, tax records, mental health records, penal data, and Centrelink data.

"We found that patients can be re-identified, without decryption, through a process of linking the unencrypted parts of the record with known information about the individual such as medical procedures and year of birth," Dr Culnane said.

"This shows the surprising ease with which de-identification can fail, highlighting the risky

# [Your Favorite Feature] Distinguishes You!!

- Demographics (Sweeney '97; Bacher '02; Golle '06; El Emam '08; Koot '10; Li '11, Sweeney '13)
- Diagnosis Codes (Loukides '10; Tamersoy '10, '12; Heatherly '16)
- Laboratory Tests (Cimino '12; Atreya '13)
- DNA (Malin '00, Lin '04; Homer '08; Gymrek '13, Ayday'14, Huttenhower '15; Shringapure '15; Lippert '17, Erlich '18)
- RNA (Backes '16a; Backes '16b)
- Proteome (Li '16)
- Health Survey Responses (Solomon '12)
- Pedigree Structure (Malin '06, Ayday '13)
- Location Visits and Mobility Traces (Malin '04; Golle '09; El Emam '11; de Montjoye '15; Kondor '17; Murakami '17)
- Movie Reviews (Narayanan '08)
- Social Network Structure (Backstrom '07; Narayanan '09; Yang '12; Cecaj '14, '16)
- Search Queries (Barbaro '06)
- Internet Browsing (Malin '05; Eckersley '10; Banse '11; Herrmann '12, Olejnik '12; Kirchler '16; Riederer '16)
- Smart Utility Meter Usage (Buchmann '12; Faisal '15; Tudor '15)

# Given Enough Time, Effort, Incentive, & Money...

# Possible

# doesn't imply

Probable

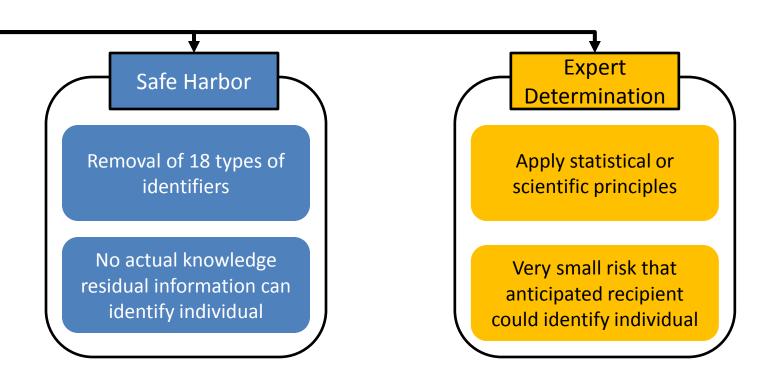
### What is "Anonymisation"?

#### **According to EU** (Data Protection Directive → GDPR):

"principles of protection shall not apply to data rendered anonymous in such a way that the data subject is no longer identifiable"

#### **According to the US Health Insurance Portability & Accountability Act (HIPAA):**

"information that does not identify an individual and ... no reasonable basis ... information can be used to identify an individual"



# US National Institutes of Health Data Sharing Policies

- 2003 Final Data Sharing Policy:
  - Studies with > \$500k/yr → Investigators must have data sharing plan or explain why it's not possible
  - Recommends sharing data devoid of identifiers
- 2007 GWAS Policy and 2014 Genome Data Sharing Policy
  - Studies involving > \$0
  - Recent considerations for extending this to all sequencing data
- Identifiable?





HIPAA

# HIPAA Privacy Rule Allows Secondary Uses of Data

Identified Patient Data

- Waiver of consent: data is "on the shelf"
- Consent is impractical to obtain

Limited Data Set

- Removal of 16 designated attributes
- Recipient signs data use contract

"De-identified"

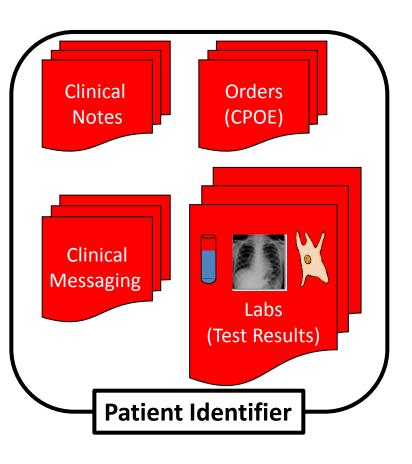
Data

- Option 1: Safe Harbor
- Option 2: Expert Determination

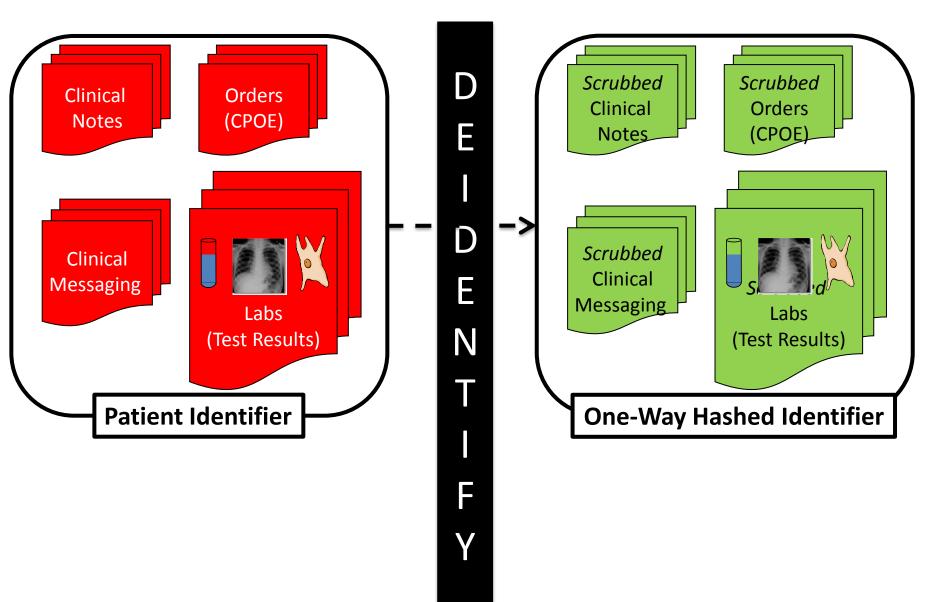
# A Recipe for De-identification

Field	Detail	•
Names	Related to patient (not provider)	
Unique Numbers	Phone, SSN, MRN,	
Internet	Email, URL, IP addresses,	
Biometrics	Finger, voice,	
Dates	Less specific than year Ages > 89	HIPAA Limited Dataset
Geocodes	Town, County, Less specific than Zip-3 (assuming > 20,000 people in zone)	
"Catch all"	"Any other unique identifying number, characteristic, or code"	HIPAA
		Safe Harbor

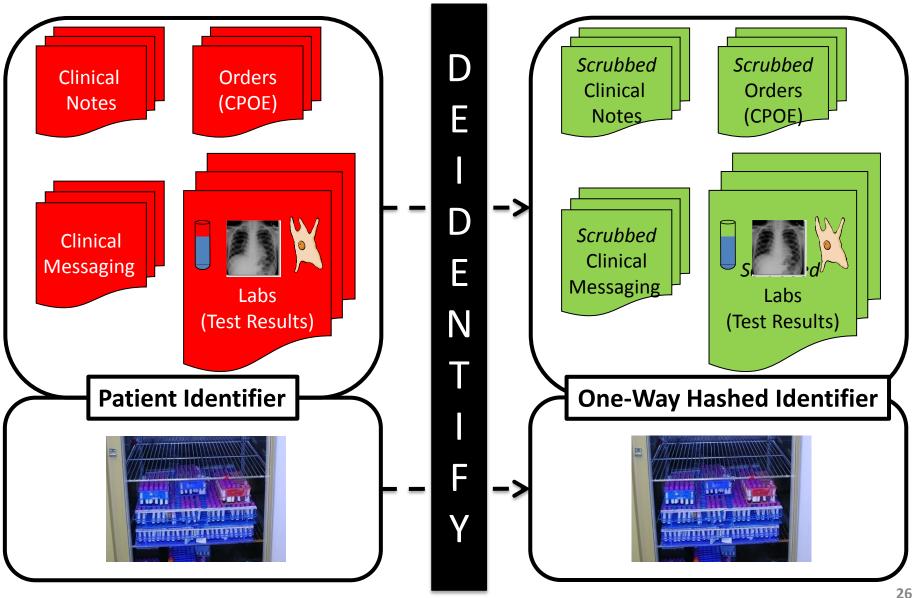
#### Vanderbilt's Research Derivative



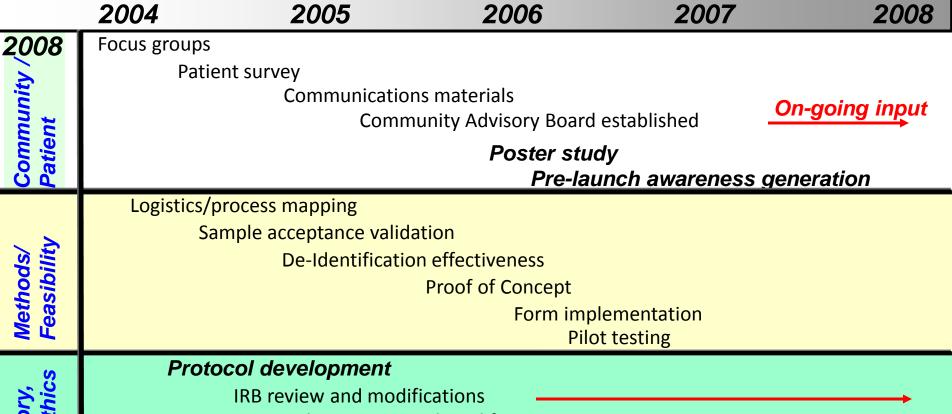
# Vanderbilt's Synthetic Derivative



#### Vanderbilt's BioVU



#### Vanderbilt De-identified EMR + DNA

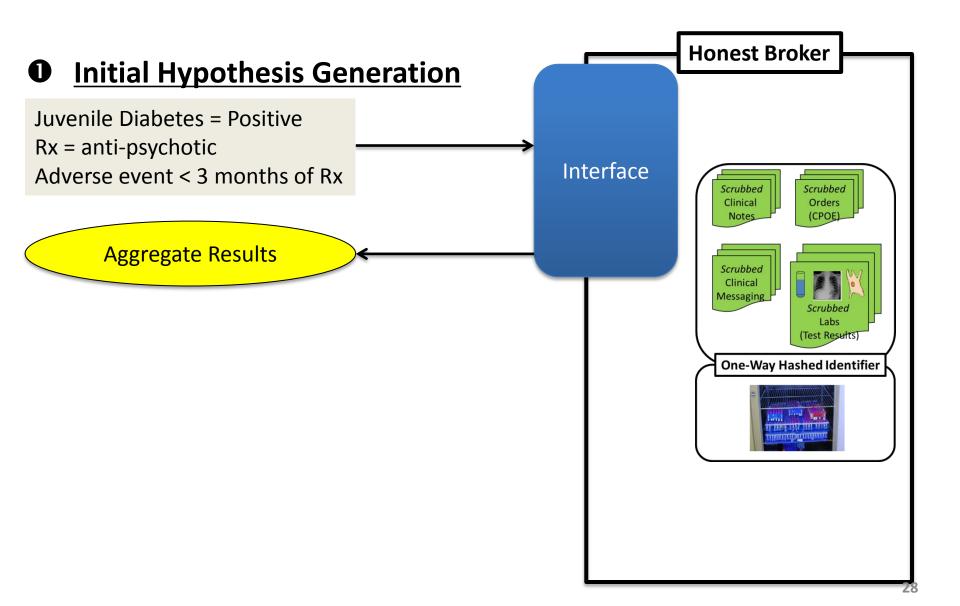


live setting

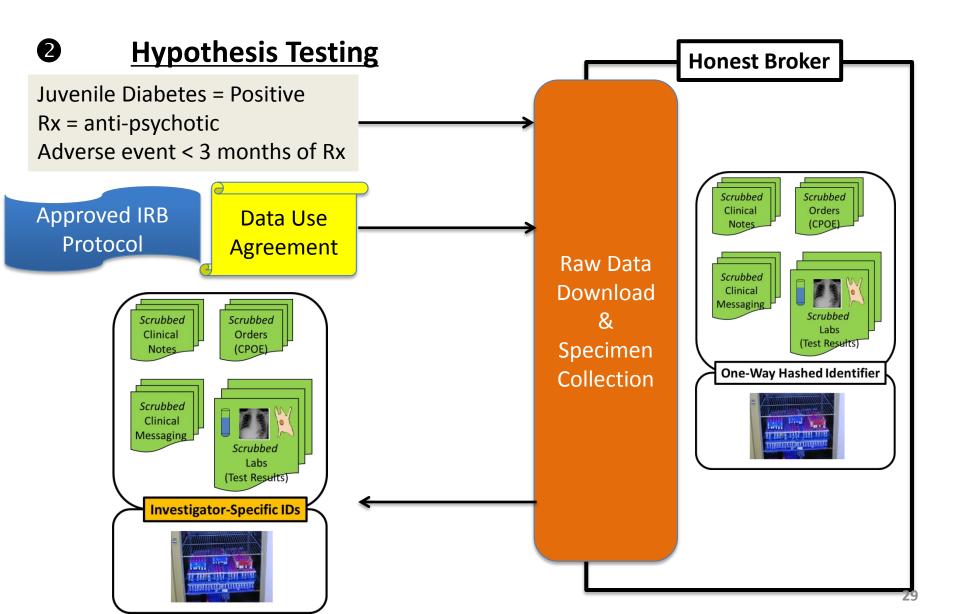


Legal, Ethics Ethics review and modifications Legal review and modifications Final IRB approval OHRP confirmation Sample accrual begins Demonstration proj. Patient research,

#### A Two Tier Access Model



#### A Two Tier Access Model



#### **Original PHI**

```
Smith, 61 yo ...
daughter, Lynn, to ...
oncologist Dr. White ...
5/13/10 to consider ...
SWOG protocol 1811, ...
was randomized 5/10 ...
to call Mr. Smith on ...
PLAN: Dr White and I ...
```

#### **Original PHI**

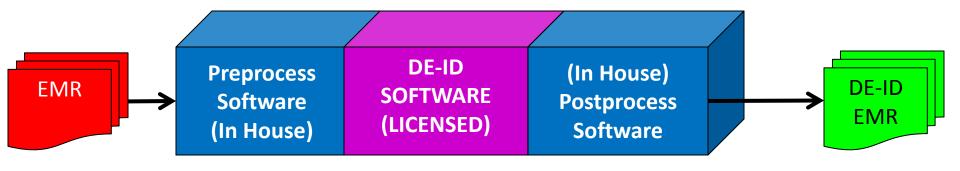
#### **Redacted PHI**

```
Smith, 61 yo ....
                            **pt name<A>, **age<60s> yo ...
daughter, Lynn, to ...
                            daughter, **pt name<B>, to ...
                            oncologist Dr. **MD_name<C> ...
oncologist Dr. White ...
5/13/10 to consider ...
                            **date<5/28/10> to consider ...
                            SWOG protocol **other id, ...
SWOG protocol 1811, ...
was randomized 5/10 ...
                           was randomized 5/10 ...
                           to call Mr. **pt name<A> on ...
to call Mr. Smith on ...
PLAN: Dr White and I ...
                           PLAN: **MD name<C> and I ...
```

#### Rules

- Dictionaries
- Regular Expressions
- Lexicons
- Exclusions
- Note-specific rules
- Site-specific rules

#### Vanderbilt Scrubbing Process (Simplified)



Redact all Safe Harbor features ... shift dates random offset in [-365,0)

Recall = 0.999

#### Rules

- Dictionaries
- Regular Expressions
- Lexicons
- Exclusions
- Note-specific rules
- Site-specific rules

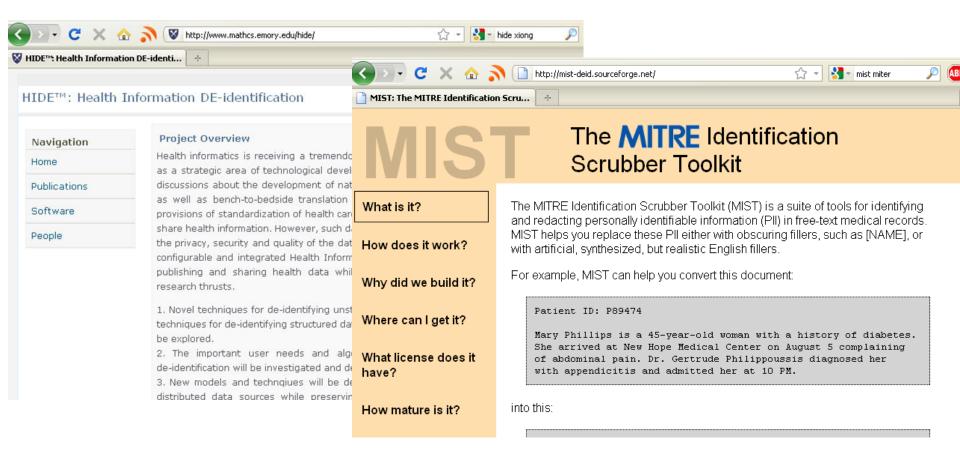
#### Machine Learned

- Naïve Bayes
- Decision Trees / Stumps
- Support Vector Machines
- •
- Conditional Random Fields

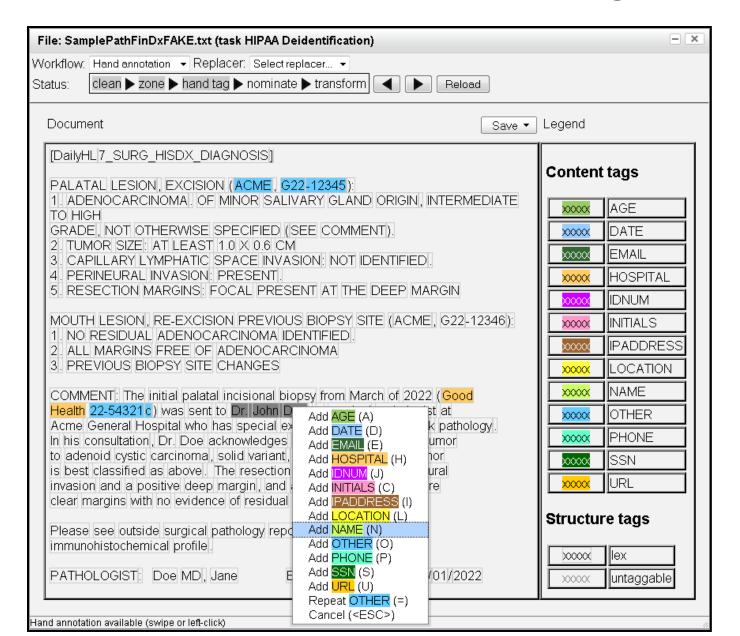
# Software: From Theory to Practice

HIDE (Gardner & Xiong 2009)

MIST (Aberdeen et al 2010)



#### MIST Installation & Training



## Does MIST Work? (Vanderbilt EMR)

	Discharge	Laboratory	Letter	Order	All
Train	200	400	200	400	1200
Test	50	100	50	100	300
Precision	0.946	0.905	0.931	0.993	0.943
Recall	0.986	0.966	0.956	0.999	0.978

Precision: 0.91 – 0.99

Recall: 0.95 - 0.99

### **Redaction Has its Limits**

#### **Original PHI**

#### \*\*Redacted PHI & Leaked PHI

```
Smith, 61 yo ....
                            **pt name<A>, **age<60s> yo ...
daughter, Lynn, to ...
                            daughter, Lynn, to ...
oncologist Dr. White ...
                            oncologist Dr. **MD name<C> ...
5/13/10 to consider ...
                            **date<5/28/10> to consider ...
SWOG protocol 1811, ...
                            SWOG protocol **other id, ...
was randomized 5/10 ...
                            was randomized 5/10 ...
                            to call Mr. **pt name<A> on ...
to call Mr. Smith on ...
PLAN: Dr White and I ...
                            PLAN: Dr White and I ...
```

#### Redaction Has its Limits

**Original PHI** 

\*\*Redacted PHI & Leaked PHI

## Unknown residual re-identification potential (e.g. "the Senator's wife")

```
to call Mr. Smith on ... to call Mr. **pt_name<A> on ...

PLAN:Dr White and I ... PLAN:Dr White and I ...
```

### Policy:

Data Use Agreements

## Redaction Has its Limits... but it Isn't the Only Option

#### **Original PHI**

# Smith, 61 yo ... daughter, Lynn, to ... oncologist Dr. White ... 5/13/10 to consider ... SWOG protocol 1811, ... was randomized 5/10 ... to call Mr. Smith on ... PLAN:Dr White and I ...

## \*\*Redacted PHI & Leaked PHI

```
**pt_name<A>, **age<60s> yo ...
daughter, Lynn, to ...
oncologist Dr. **MD_name<C> ...
**date<5/28/10> to consider ...
SWOG protocol **other_id, ...
was randomized 5/10 ...
to call Mr. **pt_name<A> on ...
PLAN:Dr White and I ...
```

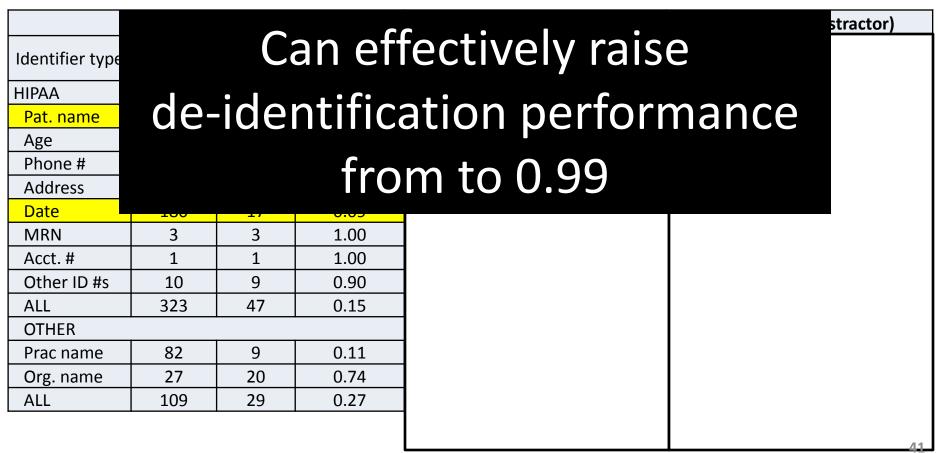
## Surrogate PHI & Hidden PHI

```
daughter, Lynn, for ... oncologist Dr. Howe ... 5/28/10 to consider ... SWOG protocol 1798, ... was randomized 5/10 ... to call Mr. Jones on ... PLAN:Dr White and I ...
```

Idea: Inject surrogated information to hide the leaks!

## Hiding in Plain Sight [HIPS]

- Added a surrogation component to MIST\*
- ~130 oncology notes from Group Health Coop of Puget Sound
- \*MIST forced into a dumbed-down state for assessment

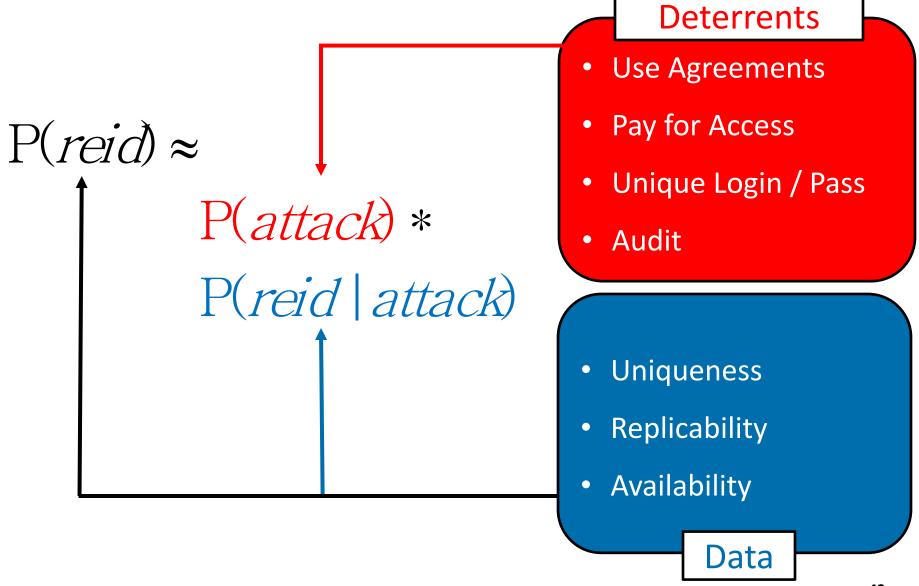


Carrell et al., JAMIA 2013

## HIPAA Expert Determination (abridged)

Certify via "generally accepted statistical and scientific principles & methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information."

## A Simplified View on Risk



## A "Quasi-identifier" Conundrum

ZIP Code

Birthdate

Gender

Ethnicity

Visit date

Diagnosis

Procedure

Medication

Total charge

Name

Address

Date registered

High Profile

Re-identification

Party affiliation

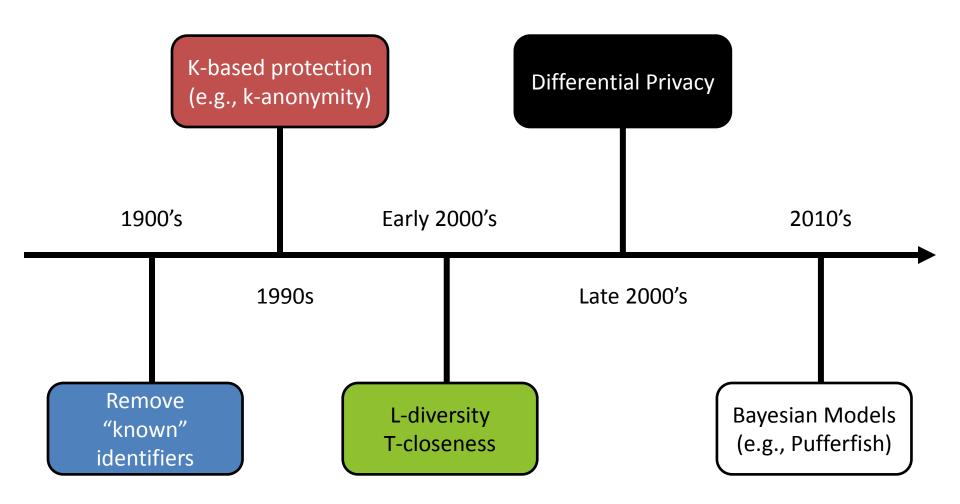
Date last voted

Hospital Discharge Data Voter List

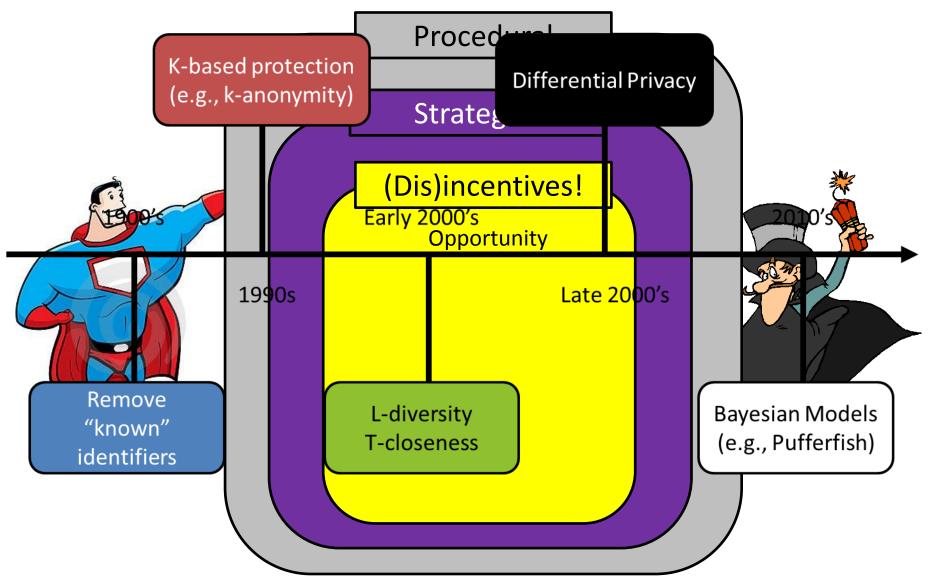
## Availability of Demographics Varies...

	Illinois	Minnessota	Tennessee	Washington	Wisconsin
WHO	Registered Political Committees (ANYONE – In Person)	MN Voters	Anyone	Anyone	Anyone
Format	Disk	Disk	Disk	Disk	Disk
Cost	\$500	\$46; "use ONLY for elections, political activities, or law enforcement"	\$2500	\$30	\$12,500
Name	•	•	•	•	•
Address	•	•	•	•	•
Date of Birth	•	0	•	•	
Sex	•		•	•	
Race			•		
Phone Number	•	•			

## Technical Approaches to Privacy



## An Augmented View of Data Privacy



**Sharing Strategy 1** 

Utility 1

*Risk* ???

**Attack Strategy A** 

Utility A

Risk A

## Strategies:

- Generalize Demographics
- Perturb Statistics
- Apply Data Use Agreement

• • •

- Charge for Access

**Attack Strategy B** 

Utility B

Risk B

**Attack Strategy C** 

Utility C

Risk C

Recipient

**Publisher** 

**Sharing Strategy 1** 

Utility 1

*Risk* ???

**Attack Strategy A** 

Utility A

Risk A

**Attack Strategy B** 

**Utility B** 

Risk B

Recipient's

**Best Strategy** 

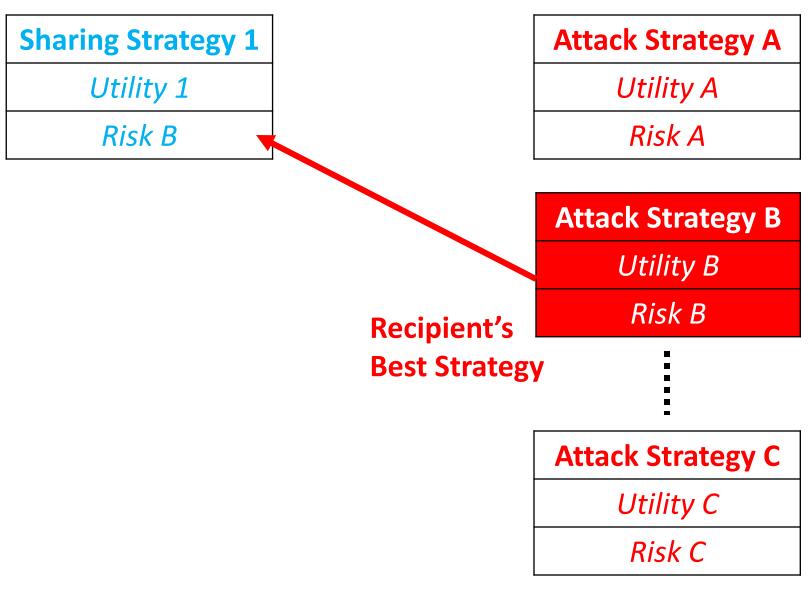
**Attack Strategy C** 

Utility C

Risk C

49

Publisher Recipient



**Publisher** 

Recipient

**Sharing Strategy 1** 

Utility 1

Risk B

**Sharing Strategy 2** 

Utility 2

*Risk* ???

**Attack Strategy A** 

Utility A

Risk A

**Attack Strategy B** 

Utility B

Risk B

-

**Attack Strategy C** 

Utility C

Risk C

**Publisher** 

Recipient

**Sharing Strategy 1** 

Utility 1

Risk B

Recipient's Best Strategy

**Attack Strategy A** 

Utility A

Risk A

**Sharing Strategy 2** 

Utility 2

Risk A

**Attack Strategy B** 

**Utility B** 

Risk B

•

**Attack Strategy C** 

Utility C

Risk C

**Publisher** 

Recipient

Clare	•	Character	<b>.</b>	4
Shar	ing	Stra	tegv	
	0		01	

**Utility 1** 

Risk B

#### **Sharing Strategy 2**

**Utility 2** 

Risk A

#### **Sharing Strategy Z**

Utility Z

Risk Z

**Publisher** 

**Sharing Strategy 1** 

Utility 1

Risk B

**Sharing Strategy 2** 

**Utility 2** 

Risk A

**Sharing Strategy Z** 

Utility Z

Risk Z

**Publisher** 

Choose strategy that maximizes overall benefit

Optimizes the Risk-Utility tradeoff

{Date of Birth, Gender, Geocode, Race}

- ~30,000 Census records
- Average Payoff Per Record

- \$1200: Benefit per record
- \$300: Cost per violation
- \$4: Access cost per record





Help | Sign

★ Bookmark this 5

 People Search
 Background Check
 Criminal Records
 Reverse Lookup
 Intelius Premier
 Identity Protection
 Employee Screening

 People Search
 Email Lookup
 Social Network Search
 Property Records
 24-Hour People Search Pass

#### People Search - Updated Daily, Accurate and Fast!

#### **People Search**

First Name	M.I.	Last Name required	City and/or State	
				Search

#### **Reverse Phone Lookup**

<b>\</b>	Phone Number ( Search

#### More ways to get info you need:

- Perform a Background Check
- Run a Background Check by SSN
- Perform an Address Lookup
- Do a Reverse Phone Lookup

#### What is People Search?

It's a confidential way to find people so you can reconnect or just get more info on a person. People Search reports can include phone numbers, address history, age & date of birth, relatives, and more. Find a person you're curious about – search today!



#### What is Reverse Phone Lookup?

It's a confidential way to find out who a phone number belongs to. Reverse phone search works for landline, unlisted & non-published numbers, and cell phone lookups. Reports can include phone type, owner name, address & more. Curious? Do a phone number lookup!



### **Game Variations**

- Safe Harbor (SH) Game
  - Defender shares data according to federal policy
- Basic Game
  - Defender shares data to maximize overall payoff
- SH-Friendly
  - Defender constrains strategy space to disclose no greater detail than SH
- No Attack
  - Defender constrains strategy space to disclose no greater detail than SH

- ~30,000 Census records
- Average Payoff Per Record

- \$1200: Benefit per record
- \$300: Cost per violation
- \$4: Access cost per record



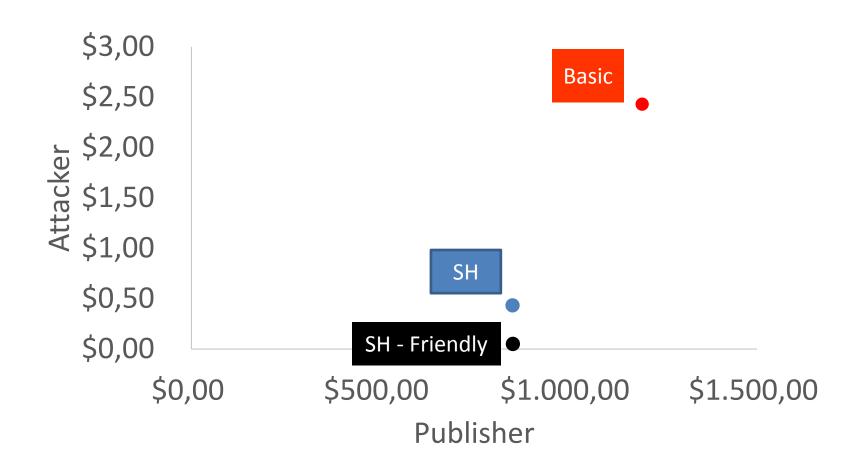
- ~30,000 Census records
- Average Payoff Per Record

- \$1200: Benefit per record
- \$300: Cost per violation
- \$4: Access cost per record



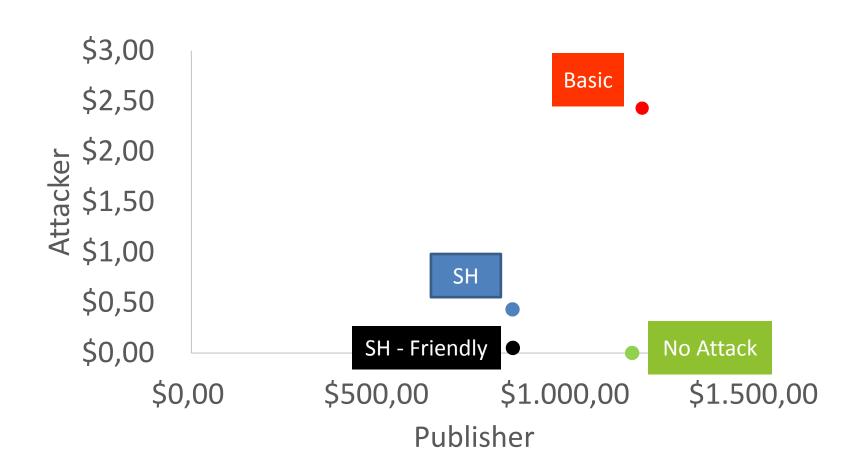
- ~30,000 Census records
- Average Payoff Per Record

- \$1200: Benefit per record
- \$300: Cost per violation
- \$4: Access cost per record



- ~30,000 Census records
- Average Payoff Per Record

- \$1200: Benefit per record
- \$300: Cost per violation
- \$4: Access cost per record



Home Overview Anonymization tool API Development Downloads Imprint

Sign up for our newsletter to receive notifications about new releases, presentations and publications.

### ARX

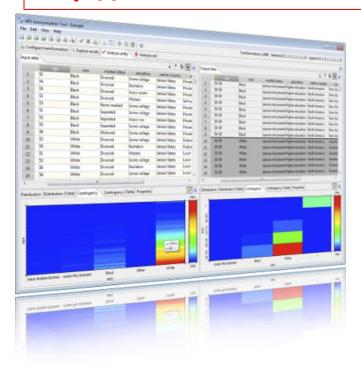
#### **Data Anonymization Tool**

ARX is a comprehensive open source software for anonymizing sensitive personal data. It supports:

- Risk-based anonymization using super-population models, strict-average risk and k-map
- Syntactic privacy models, such as k-anonymity, \u00b3-diversity, tcloseness, δ-disclosure privacy and δ-presence
- Semantic privacy models, such as  $(\epsilon, \delta)$ -differential privacy
- Methods for optimizing the profitability of data publishing based on monetary cost-benefit analyses
- Data transformation with generalization, suppression, microaggregation and top/bottom-coding as well as global and local recoding
- · Methods for analyzing data utility
- · Methods for analyzing re-identification risks

The software is able to handle very large datasets on commodity hardware and it features an intuitive cross-platform graphical user interface. You can find further information here, or directly proceed to our downloads section.

#### http://arx.deidentifier.org/



## **Anonymisation is NOT a Panacea**

- There is <u>always</u> a risk of re-identification
- But risk exists in any security setting
- The challenges are
  - Determine an appropriate level of risk
  - Ensure accountability

Combine with data use agreements

 Risk is proportional to anticipated recipient trustworthiness (public vs. vetted investigator)

## Acknowledgements

- Kathleen Benitez
- Ellen Wright Clayton, M.D., J.D.
- Josh Denny, M.D.
- Xiaofeng Ding, Ph.D. (U. So. Australia)
- Khaled El Emam, Ph.D. (U. Ottawa)
- James Gaupp, M.S.
- Aris Gkoulalas-Divanis, Ph.D. (IBM)
- Jonathan Haines, Ph.D.
- Paul Harris, Ph.D.
- Raymond Heatherly, Ph.D.
- Murat Kantarcioglu, Ph.D. (U. of Texas)

#### eMERGE Teams

- Boston Children's Hospital
- Children's Hospital of Philadelphia
- Cincinnati Children's Hospital
- Geissinger Health System
- Group Health Research Institute / U. Washington
- Marshfield Clinic
- Mayo Clinic
- Mt. Sinai Medical Center / Columbia University
- Northwestern University
- Vanderbilt University

- Klaus Kuhn, M.D. (TUM)
- Jiuyong Li, Ph.D. (U. So. Australia)
- Grigorios Loukides, Ph.D. (Kings College London)
- Dan Masys, M.D. (U. Washington)
- Steve Nyemba, M.S.
- Fabian Prasser (TUM)
- Dan Roden, M.D.
- Latanya Sweeney, Ph.D. (Harvard U.)
- Acar Tamersoy (Georgia Tech)
- Weiyi Xia, Ph.D.
- Yevgeniy Vorobeychik, Ph.D. (Washington Uni. St. Louis)
- Zhiyu Wan, M.S.

#### **Funding**

- NHGRI @ NIH
  - U01 HG006385 (eMERGE)
  - U01 HG006378 (VGER)
  - RM1 HG009034 (GetPreCiSe)
- NLM @ NIH
  - R01 LM009989

## Questions?

b.malin@vanderbilt.edu

Center for Genetic Privacy and Identity in Community Settings http://www.vumc.org/getprecise/

Vanderbilt Health Data Science Center http://www.vumc.org/heads/

Vanderbilt Health Information Privacy Laboratory http://www.hiplab.org/