

Double Your Research Productivity by Leveraging Proposed Changes to the Common Rule

March 29, 2016



PROMETHEUS | RESEARCH
Integrating data for extraordinary outcomes



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The promise of efficient research is best realized through the **sharing** and **reuse** of data. This is the challenge, and the opportunity, that **inspires everything we do.**

Roadmap

A key regulation is set to **change**



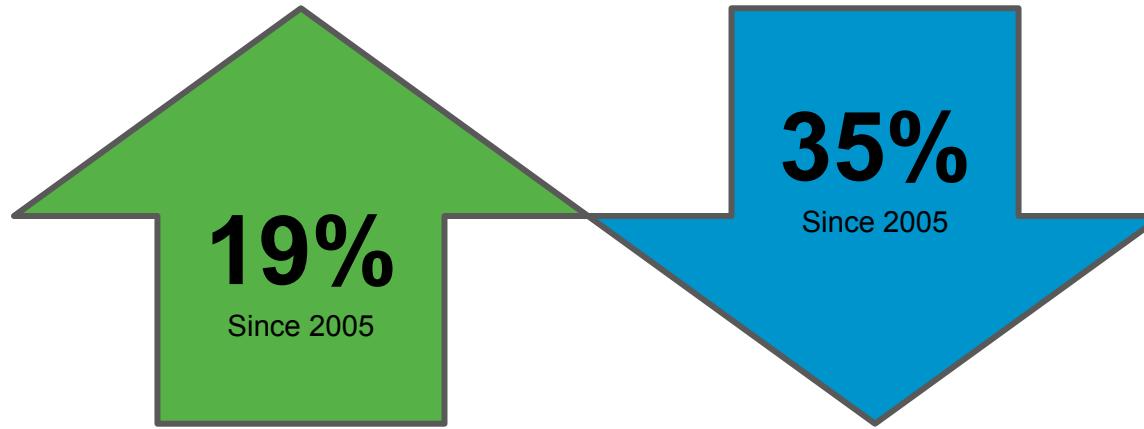
Bringing opportunities to **double research productivity**



Best practices exist to **boost productivity** today
and **leverage** the new opportunities

Publication Data Shows Collaboration is Up

Authors per-Article



Single Author Articles

Research data generation is expanding at an astounding rate

BIOMEDICAL BIG DATA EXPLOSION

NIH National Center for Biotechnology Information DATA STORAGE

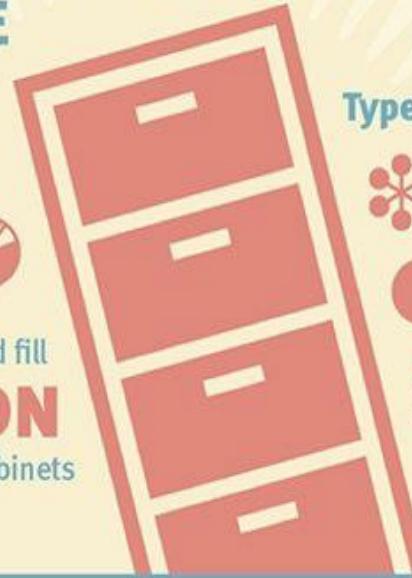
In 1990 fit on
3 floppy disks



In 1993 fit on
1 CD-ROM



In 2014 could fill
400 MILLION
4-drawer filing cabinets



Types of BD2K Awards



Enabling Data Utilization



Analysis Methods and Software



Enhancing Training



Centers of Excellence



Big Data to Knowledge (BD2K) is an initiative of the National Institutes of Health

Current Landscape

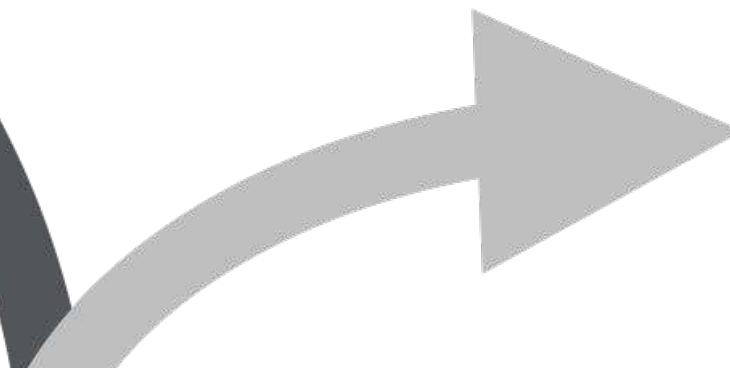
Investigators are **collaborating** more than ever

+

Studies are **generating** more data than ever

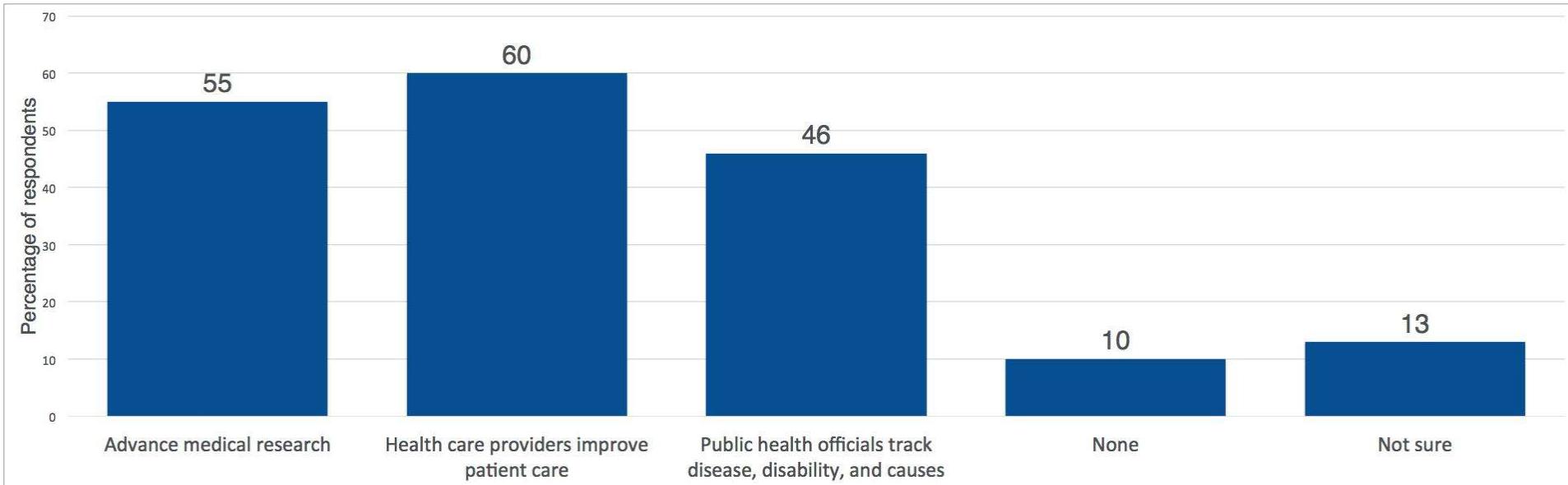


Option A: De-identify



Option B: Recontact

Reasons People are Willing to Share Personal Health Information



Common Rule Refresher

1964-1979: Declaration of Helsinki and Belmont Report articulates the basic ethical principles for human subjects research, and describes the need for IRBs

1964-1979

1991: HHS and 14 additional Federal agencies align their statutes with The Common Rule, as described in HHS Title 45 CFR 46 Subparts A, B, C, & D

1991

1981

1981: U.S. Department of Health and Human Services (HHS) and U.S. Food and Drug Administration (FDA) align their regulations with these ethical principles

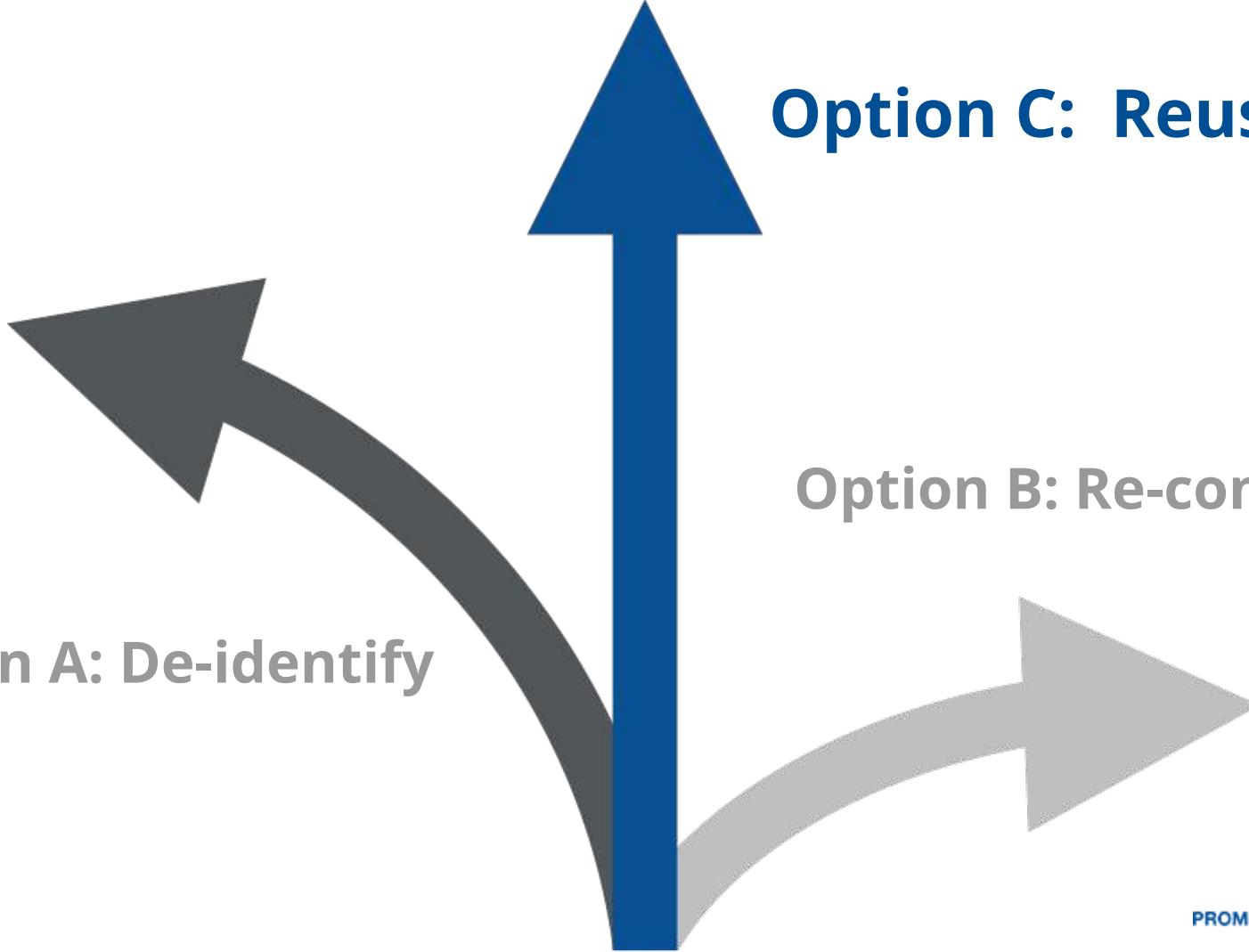
2015

TODAY: HHS and 15 additional Federal agencies publish a Notice of Proposed Rulemaking (NPRM) in the Federal Register, describing regulatory changes intended to better address the challenges and opportunities of modern research

Proposed Changes to the Common Rule

1. Improve informed consent
 2. Require informed consent for the use of stored biospecimens but allow "**broad consent**" for unspecified future use
 3. **Exclude** some activities from coverage by the Common Rule
 4. Add more categories of **Exempt** research, including ...
 - secondary research use of identifiable private information **originally collected as part of a non-research activity**, where notice of such possible use was given; and
- **storing or maintaining biospecimens and identifiable private information for future, unspecified secondary research studies**, or conducting such studies, when a **broad consent** template to be promulgated by the Secretary of HHS is used, information and biospecimen privacy safeguards are followed, and limited IRB approval of the consent process used is obtained.

Result: A rational liberalization of the rules for reusing research data and biospecimens



Option C: Reuse

Option B: Re-contact

Option A: De-identify



Public Opinion



Government Regulation



Research Infrastructure

With the right infrastructure . . .

- **Governance** at your research center allows for data sharing and reuse
- Data and research assets from multiple studies are centralized across all data types
- Data is optimized for reuse
- Data reuse is the norm not the exception



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Centralized Data Management Process

1. Data and Assets from Multiple Sources are Centralized



Data

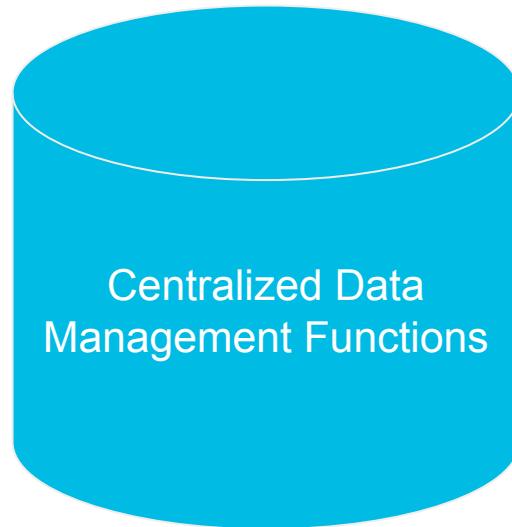


Participants



Biospecimens

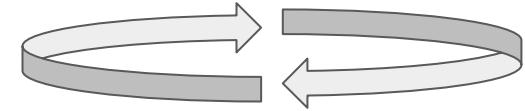
2. Data is optimized for sharing and reuse in a central repository via a central process



3. Data is available for reuse for many purposes



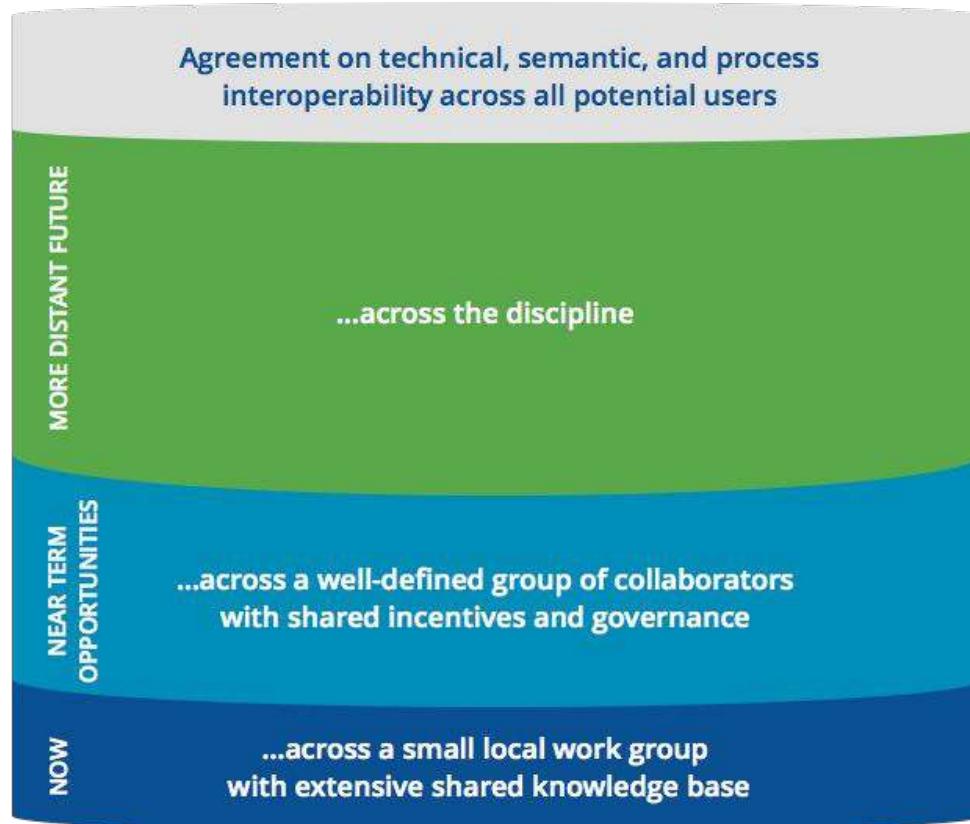
Data is available for many uses



Results can be integrated back into the central system

Levels of Data Reuse

- Global
(everyone in the world)
- Discipline-wide
- Research Network-wide
- Center-wide
- Lab-wide (big lab)
- Lab-wide (small lab)
- Local (immediate collaborators)
- One researcher



Humorous Aside: Data Reuse and “Research Parasitism”

Re·search Par·a·site

/rē,sərCH perə,sīt/ *noun*

Someone who uses (available) data to challenge conclusions or to answer new research questions

Humorous Aside: Data Reuse and “Research Parasitism”



Re·search Par·a·site

/rē,sərCH perə,sīt/ noun

Someone who uses (available) data to challenge conclusions or to answer new research questions

Sci·en·tist

/sīən(t)əst/ noun

Someone who uses (available) data to challenge conclusions or to answer new research questions.

1

Governance
Strategy

2

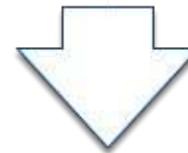
Data & Asset
Centralization
Strategy

3

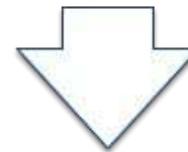
Implementation:
Technology &
Processes

4

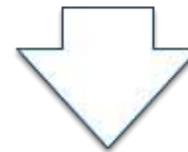
Adoption &
Change in Norms



Centralized Research Assets, Data, & Research Management Functions, Organized for Reuse



Data Reuse, More Transparency/Accountability, Higher Throughput



A research environment where investigators have access to the cumulative research output of the entire center, integrated across studies, data-types, and specimens, immediately available for reuse

What does increased productivity look like?

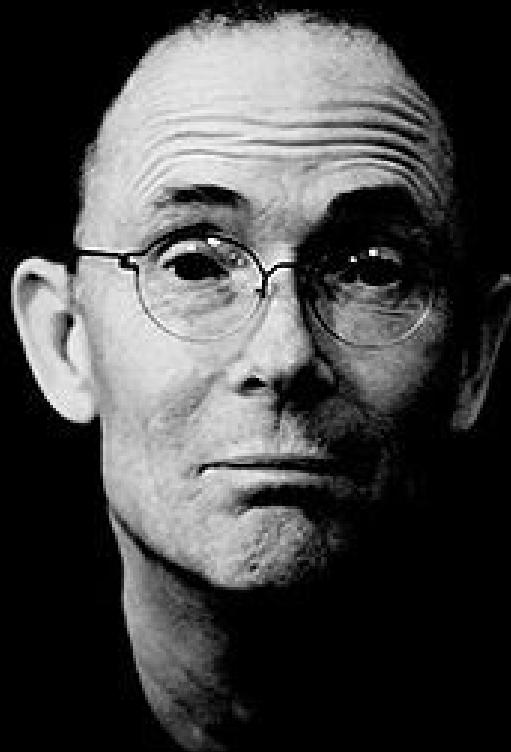


- **More research** projects per research team
- Move from **hypothesis to research faster**
- **More efficient data** collection/data analysis
- **Reduced participant burden**

The future has arrived—

it's just not evenly
distributed yet.

- William Gibson



Case Study: Center Not Ready

Midsized Neurodevelopmental Center

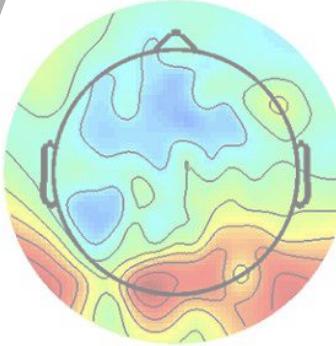
1,000 children seen per-year

30% participate in research

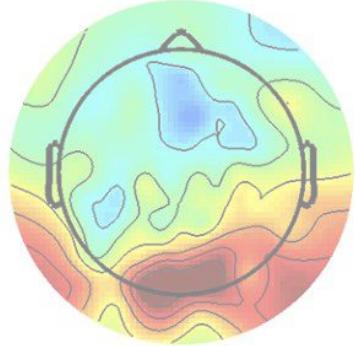
10 active studies

6 investigators

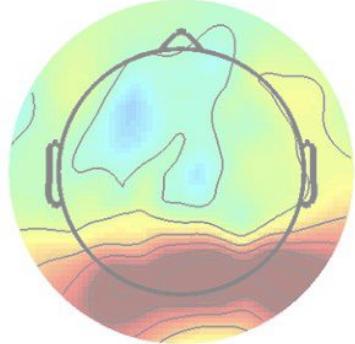
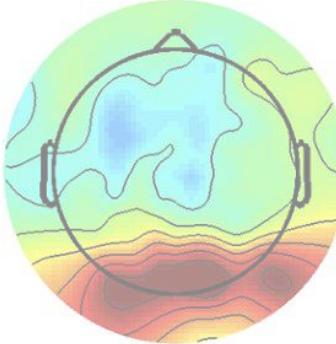
4 research disciplines



2



3.9



Case Study: Center Not Ready

Study-based Research Infrastructure

Consent optimized for **recontacting** by original labs

Ad hoc Data Reuse Policies

Data is stored as hundreds of **disparate** files in **inconsistent** locations; identifying and accessing data for reuse is **difficult** and **time consuming**

Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing button at the bottom.

Project title:

Title to be displayed on project webpage

Purpose of this project:
(How will it be used?)

---- Select One ----

Design your project:

STEP 1: Choose the type of project you want to build [Tell me more](#)

- Single Survey
- Data Entry Forms (e.g. traditional database)
- Single Survey + Data Entry Forms (e.g. pre-screening survey with follow-up data capture)

STEP 2: Choose collection format for data entry forms [Tell me more](#)

- Classic (each form available for use once for each subject)
- Longitudinal / repeating forms (each form available for

Enable the scheduling module? [Tell me more](#)

Case Study: Center Ready

Large Neurodevelopmental Center

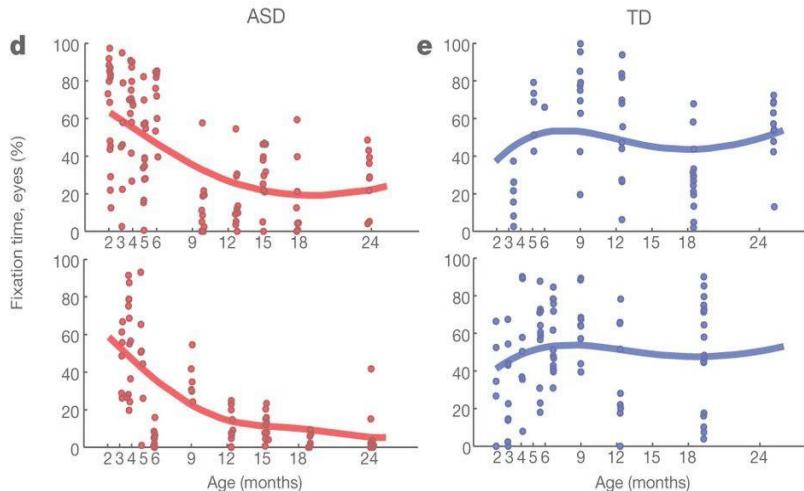
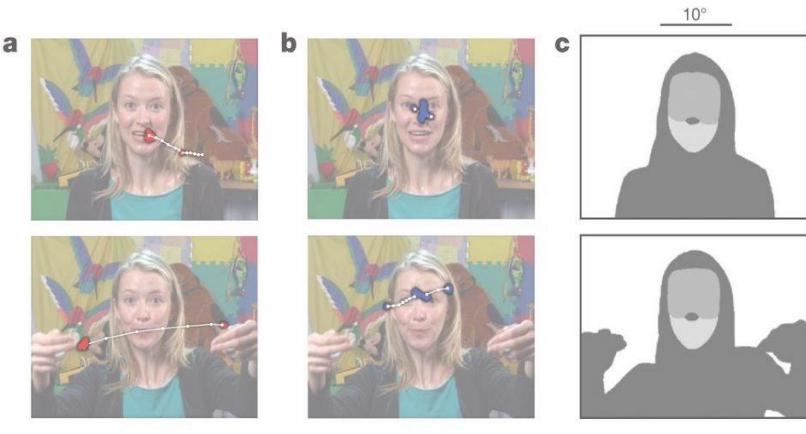
5,500 children seen per-year

41% participate in research

20 active studies

12 investigators

8 research disciplines



Case Study: Center Ready

Centralized Research Infrastructure

“Global” Consent for Characterization Data

“No Scooping or Parasites” Data Reuse Policies

All of their **data**, from all of their **studies**,
is catalogued and optimized for **reuse** in
any IRB-compliant research endeavor

The screenshot shows a software interface for managing research participants. At the top, there are tabs: All individuals, Enroll New, Participants, Identities, Relationships, and Experiments. The 'Participants' tab is selected. Below the tabs, a sidebar on the left lists various participant details: Select Individual (Ernest Peters), Enrollments, Appointments, To-Do List, Legacy IDs, Communication Log, Consents, Assessments, Samples, Experiments, Genetic Variants, and Genetic Result. On the right, the main panel displays 'Contact Information' for Ernest Peters, including fields for First Name, Last Name, Middle Name, RexSurvey Login, Birthdate, Sex, Deceased, Death Date, Phone numbers, Email, Address, City, and State. There are also buttons for Edit Participant Details, Edit RexSurvey Login, and Contact.

Contact Information	
First Name	Ernest
Last Name	Peters
Middle Name	Carl
RexSurvey Login	carl.peters@yahoo.com
Birthdate	2018-05-25
Sex	Male
Deceased	
Death Date	
Phone(s)	(215)225-2051 (Work), (963)390-1226 (Home), (278)667-5213 ★ (Cell)
Email(s)	jlee17@global.com
Address	6961 Buhler Point
City	New Orleans
State	AL

Lessons Learned

- Governance
 - Consent strategy
 - Data sharing agreements
 - Credit-sharing policies
 - Ignore the goats
- Centralized Data Management
 - Global (center-wide) individual identifiers
 - Data and assets linked to individuals, across studies (and also to specific study requirements)

Configure Appointments Reports

Study Reports >

Enrollment Report

Consort Diagram

Racial Categories	Ethnicity			
	Not Hispanic or Latino			Hispanic
	Female	Male	Unknown/ Not Reported	Female
American Indian/ Alaska Native				
Asian	15	5		
Native Hawaiian or Other Pacific Islander				
Black or African American	45	35		
White	85	25		15
More Than One Race				15
Unknown or Not Reported	25			
Total	170	25		30

Lessons Learned

- Data Reuse
 - Start with low hanging fruit: characterization data, common instruments; move to expensive measurements (MRIs, lab visits)
 - Make sure your infrastructure supports the common case: instrument collected for one study can be used for another
- Other: use keystone projects to create infrastructure and build consensus

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Summary

The Common Rule is set to **change**



Opportunities to **double research productivity** will be streamlined



A **modern research infrastructure** that boosts productivity today
and can leverage the new opportunities

Multiply the Value of Your Data by Bridging the Clinic and Research Divide

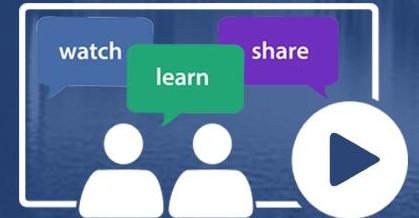
May 2016



PROMETHEUS | RESEARCH

We manage data for extraordinary outcomes

WEBINAR
SERIES



Thank you

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Q&A

Resources & Next Steps

Attend our next webinar

- Reserve your spot for our next webinar: *Bridging the Clinic & Research Divide*

Follow-up reading

- White Paper: Secondary Data Analysis - More Research with Less Data
- White Paper: Managing the Challenges of Modern Research Surveys
- Blog Post: Appreciating the complexity of clinical nomenclatures

For customized help with your data centralization strategy, schedule time to speak with one of our clinical research analysts:

- David Voccolla (David@PrometheusResearch.com)
- Julie Hawthorne (Julie@PrometheusResearch.com)

Thank you

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