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The New World in Cancer Surveillance: Accommodating Patient Privacy and Drug Safety Studies

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LEADING RESEARCH…
MEASURES THAT COUNT

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Patient Privacy and Drug Safety

- **Background**
  - Implementation of the HIPAA privacy rule in 2003 has had a measurable impact on the ability to conduct research; however, this impact is inadequately characterized when conducting research with cancer registries
- **Objective**
  - Assess the potential impact of various patient access pathways across registries that contribute cases to a long-term cancer surveillance study

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- **Methods**
  - Descriptive analyses of the different patient access pathways and their impact on interview completion rates
- **Factors considered**
  - Patient access pathway
  - Year registry began participating (i.e., lag time); primary study seeks to interview all patients diagnosed from 2003 onward irrespective of registry participation date

Source of Data for Assessment

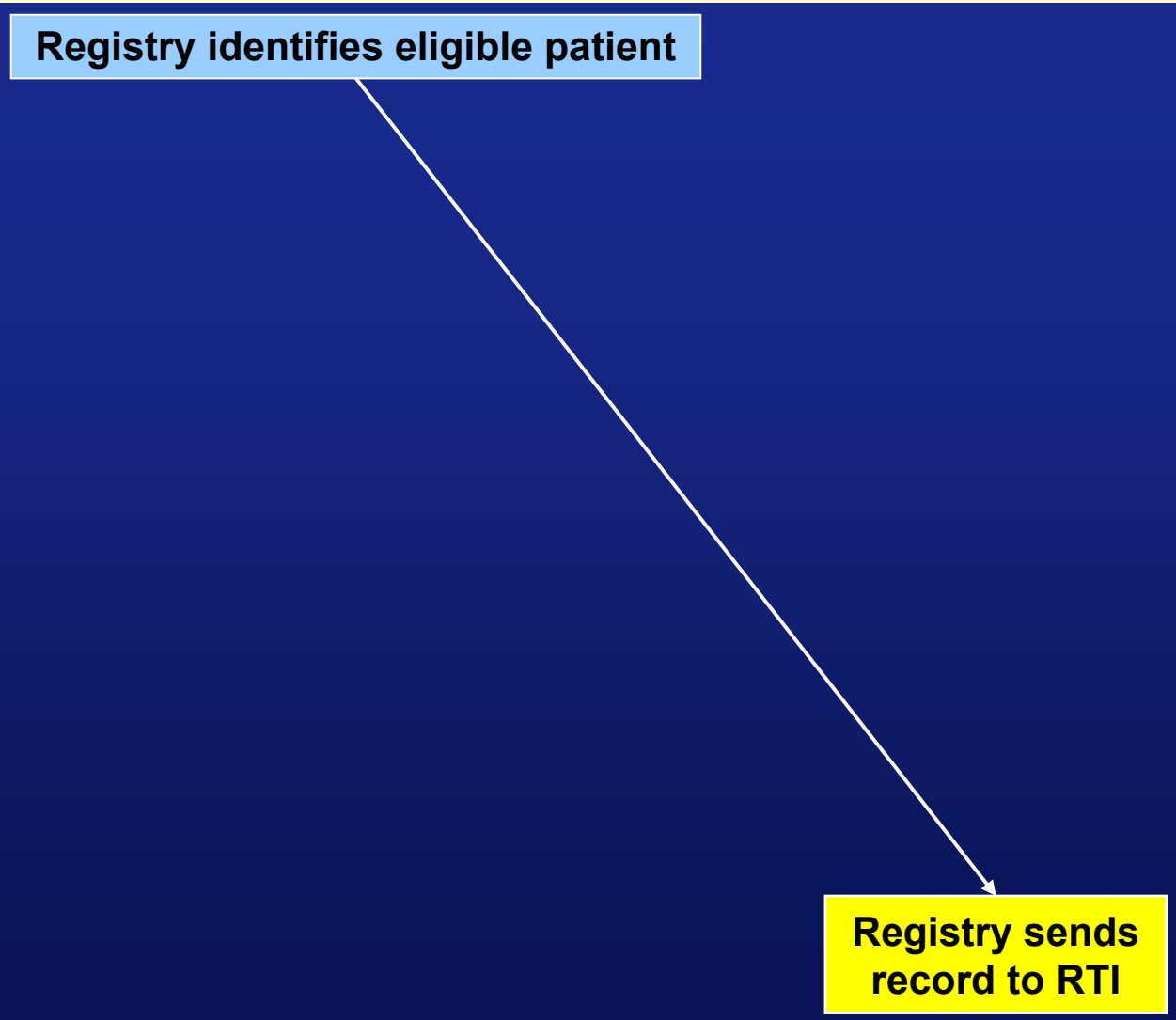
Osteosarcoma Surveillance Study

- **Primary objective**
  - Identify approximately 40% of newly diagnosed cases of osteosarcoma among men and women aged 40 years and older
  - Determine incident osteosarcoma cases, if any, who have a history of Forteo treatment
- **Secondary objective**
  - Systematically collect, for descriptive epidemiology purposes, additional patient information including demographics, other drug treatments, and comorbid conditions

Patient Access Pathways

- General Types
  - MD notification required
  - Patient release required
  - MD notification and patient release required
  - MD permission to contact patient required
  - MD permission to contact patient and patient release required

Example: Patient Access Pathway



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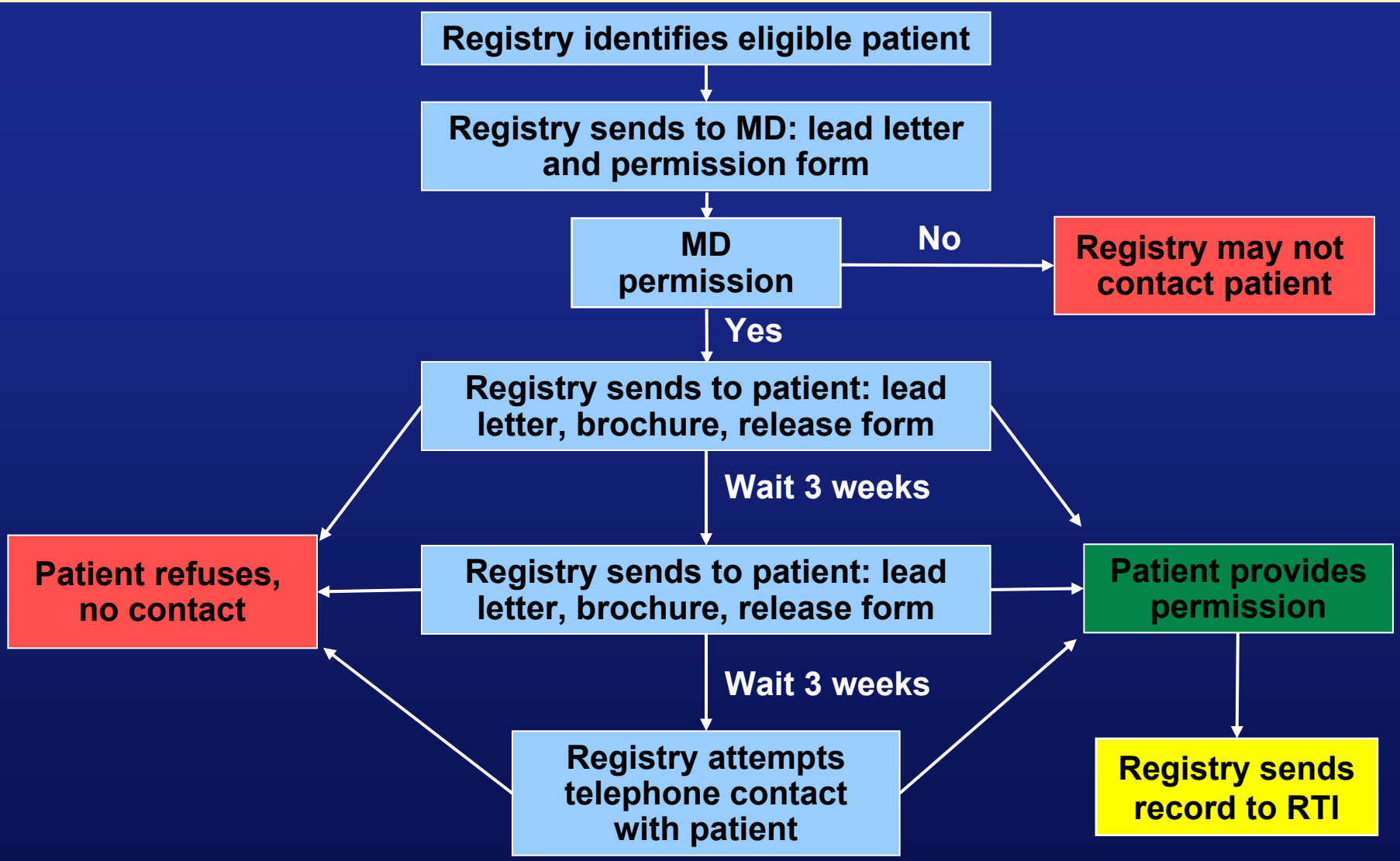
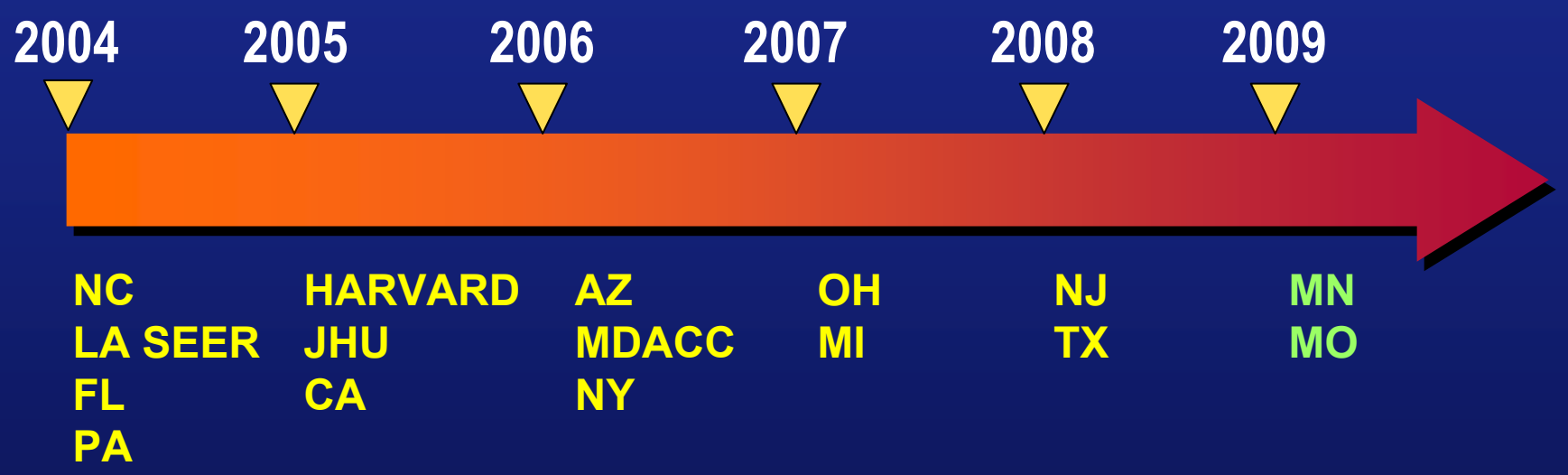


When Did Registries Begin Participating?

When Did Registries Begin Contributing Cases?



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Cumulative Coverage

US: Registries	Estimated Annual Avg. # Adult Osteosarcomas[a]	Cumulative % of US Cases (N = 290)
Arizona State Registry	4	1%
Los Angeles SEER	10	5%
California State Registry	23	13%
Florida State Registry	22	20%
Harvard	16	26%
Johns Hopkins	5	28%
MD Anderson	22	35%
Michigan State Registry	10	39%
NCCCR/Duke/UNC	6	41%
New Jersey State Registry	9	44%
New York State Registry	25	52%
Ohio State Registry	11	56%
Penn. State Registry	20	63%
Texas State Registry	17	69%

[a] As reported to RTI by US state-based cancer registries for age 40 and older (1998-2003)

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Impact of Patient Access Pathway on Interview Rate

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Impact of Patient Access Pathway on Study Accrual

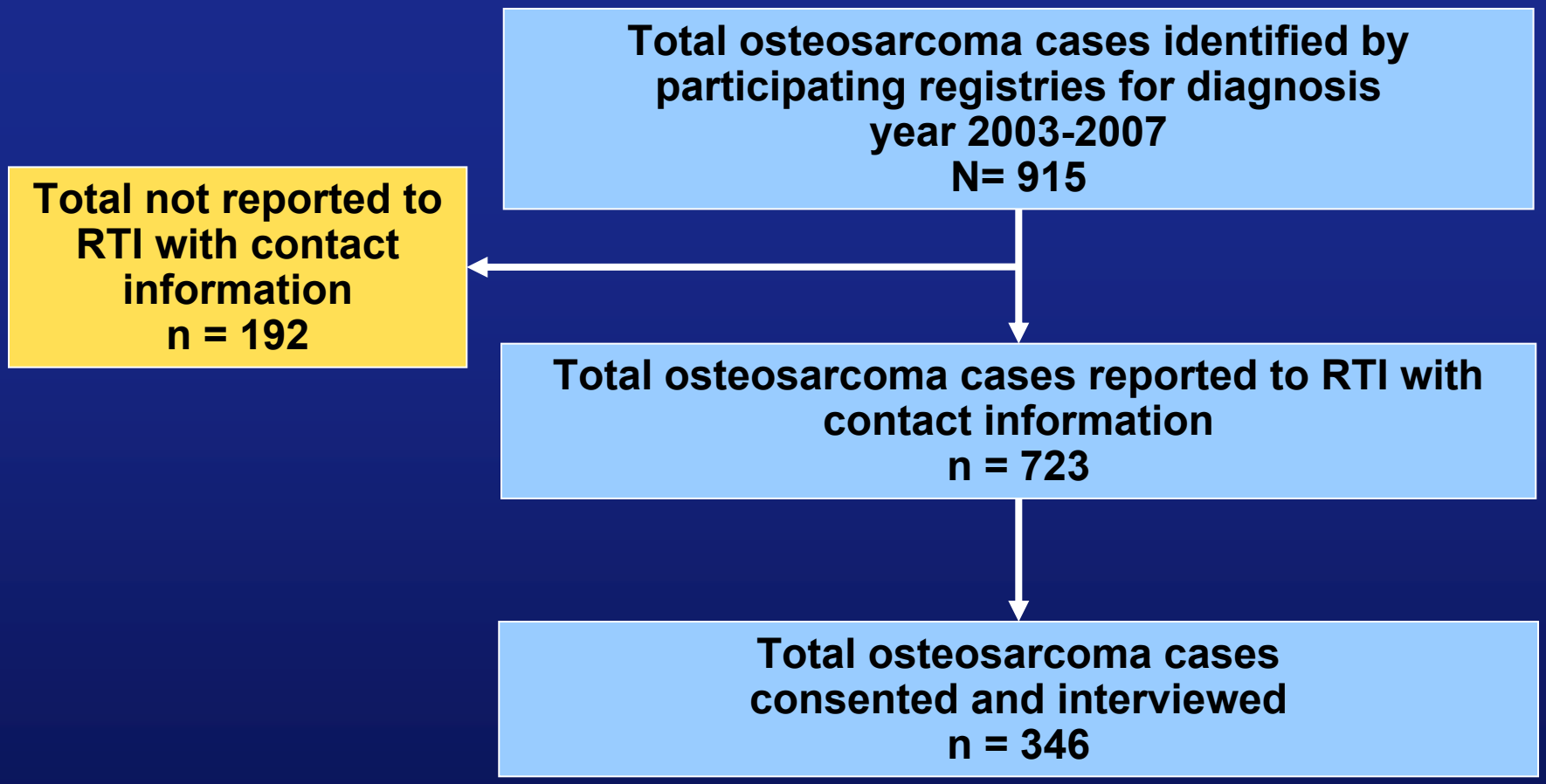

Diagram excludes 6 interviewed cases diagnosed in 2008 and 2009 due to reporting lag.

Results

Patient Access Pathways

Process Required to Obtain Patient Information	Number of Registries
MD notify only	4
Patient release only	3
MD notify and patient release	2
MD permission	4
MD permission and patient release	1
Total	14

Patient Access Pathway and Interview Rate

Registry	Type of Patient Access Pathway	Total Identified	Total Interviewed	Interview Rate[a]
North Carolina	MD notify only	40	23	58%
CA - LA SEER	MD notify only	42	23	55%
Arizona	MD notify only	21	9	43%
California	MD notify only	148	63	43%
New York	MD notify and patient release	126	54	43%
MD Anderson	Patient release only	90	36	40%
Harvard	MD permission	47	19	40%
Pennsylvania	Patient release only	75	28	37%
New Jersey	MD permission and patient release	32	11	34%
Johns Hopkins	MD permission	3	1	33%
Michigan	MD notify and patient release	75	24	32%
Florida	Patient release only	119	37	31%
Ohio	MD permission	50	12	24%
Texas	MD permission	47	6	13%
Total		915	346	38%

[a] Interview rate among identified cases = (# interviewed)/(# identified by participating registries)

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Interview Rate by Year Registry Added

Year Registry Added (No.)	Total Identified	Total Interviewed	Interview Rate[a]
2004 (4)	276	111	40%
2005 (3)	198	83	42%
2006 (3)	237	99	42%
2007 (2)	125	36	29%
2008 (2)	79	17	22%
Total (14)	915	346	38%

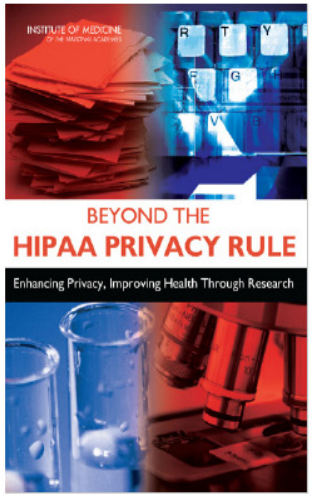
[a] Interview rate among identified cases = (# interviewed)/(# identified by participating registries)

Conclusions

Institute of Medicine Report

Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research

Our modern electronic world has many benefits and conveniences; emails can be checked from a mobile device and patients provide their medical histories online. But this free flow of information also creates privacy concerns; the risks of data security breaches, identity theft, and discrimination are real. Privacy protections are needed, but they can also impede the flow of information, with negative consequences. In health



- **Committee concluded: "HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, the HIPAA Privacy Rule impedes important health research."[a]**

[a] Institute of Medicine (IOM). 2009. Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research. Washington, DC: The National Academies Press.

Patient Privacy and Drug Safety

- **Conclusions**
  - Complexity of the patient access pathway appears inversely related to interview rate
  - Interview rates trended lower at registries where MD permission was required
  - Year registry began participating appeared related to interview rate; however, registries with less complex requirements were recruited first (confounds lag time)
  - Results support conclusions in recent IOM report that an overly cautious approach to HIPAA is impeding research

Thank You!

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