Clinical Trial Data Sharing: Perspectives From Participants and PCORI

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Study Team

Stanford Project Team

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Van Lieou

SPRC Trial Teams

Indiana University CTSI Trial Teams

Tufts Trial Teams

Greenwall Foundation

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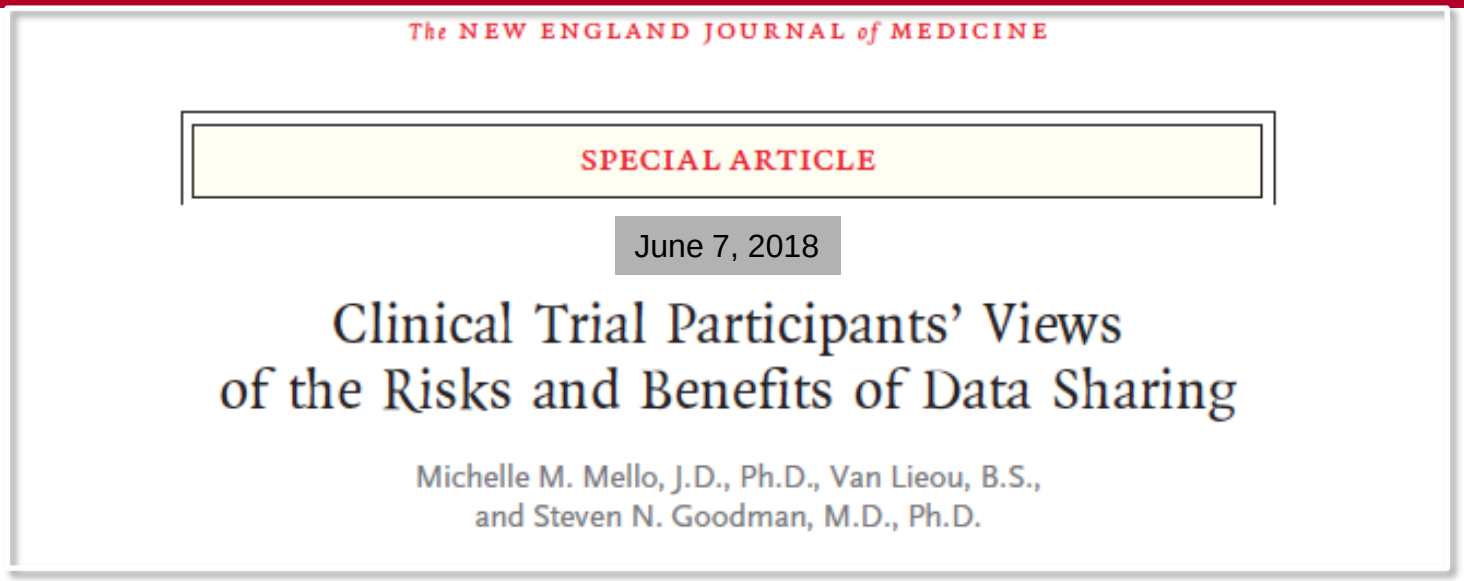
Context

- Broad movement toward participant-level data sharing
- Concerns about privacy, informed consent, and system governance
- Little is known about trial participants' views
- Trial sponsors and investigators often invoke participants' interests as a reason not to share, or to limit what is shared



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SPECIAL ARTICLE

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Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing

Michelle M. Mello, J.D., Ph.D., Van Lieou, B.S., and Steven N. Goodman, M.D., Ph.D.

Study questions:

1. How do trial participants perceive the balance of risks and benefits from data sharing?
2. How great a concern are privacy intrusions and breaches?

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Survey Methods

- Trial PIs recruited based on personal contacts

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- $40 incentive given with initial invitation
- Up to 2 reminders mailed to nonresponders
- Data were hand-entered into REDCap and audited for accuracy

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Sample Characteristics

	n	Completion Rate (%)
Full sample	**771**	**79.2**
Mail survey	350	64.0
In-clinic survey	421	98.0

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Topics of Participants' Trials

Health Issue	%
Nutrition/weight/vitamins	22.3
Diabetes	22.3
Cardiovascular	9.2
Aging/ neurodegenerative disease/ memory	8.3
Tobacco use	6.7
Liver disease	6.4
Mental illness	5.3
Cancer	5.1
Kidney disease	3.4
Lung disease	2.9
Alcohol use	2.2
Bone disease	1.7
Other	3.7

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Demographic Snapshot

	%
Fair or poor self-reported health status	22.3
Female	49.9
Age: <25 25-44 65+	8.3 60.7 31.0
Hispanic	13.3
Race: White Black Native American Asian	67.2 14.7 6.6 3.2
Education: No college College graduate	21.9 50.7
Household income: <$25,000 > National median ($55,000)	23.3 49.0
Ever had personal information stolen or breached	45.7

Percentages may not sum to 100 due to rounding, omitted categories, or blank responses.

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Clinical Trial Participation

	%
Who participated in the trial?	
Me only	90.2
My child only	7.1
Other person only	1.6
Me plus someone else	0.7
Unsure	0.5
In last 2 years, participated in a trial as:	
A person with the health condition being studied	41.5
A healthy volunteer or a person at risk for developing the health condition being studied	55.1
Both	3.4

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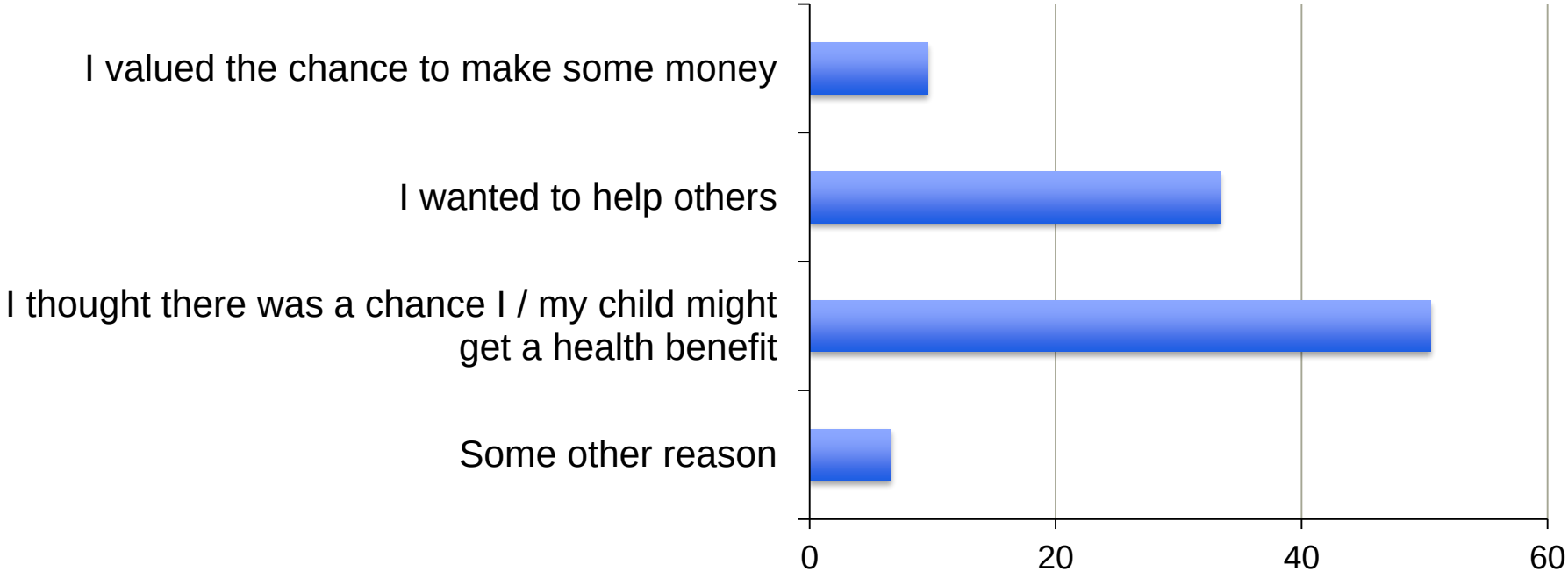
Primary Reason for Trial Participation

Thinking about the most recent clinical trial you/your child participated in, what was the most important reason you decided to be in the study?



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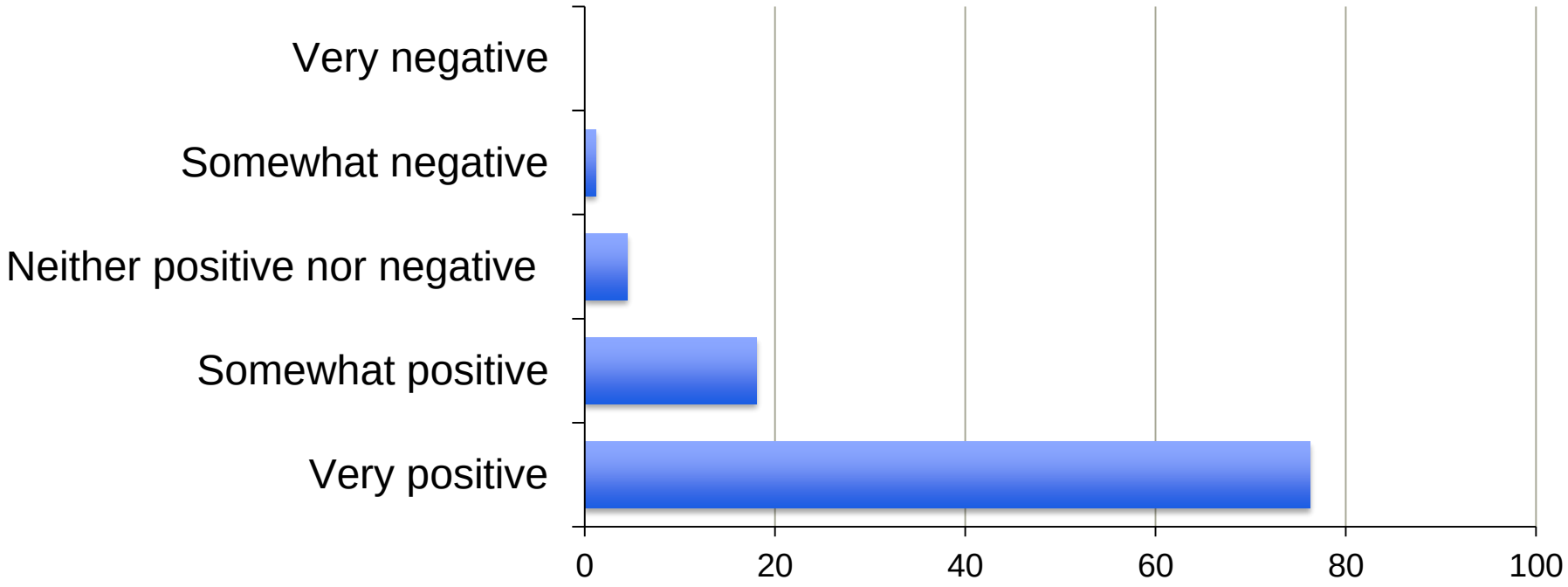
Impressions of Trial Participation

Overall, how would you describe your / your child's experience(s) as a clinical trial participant?



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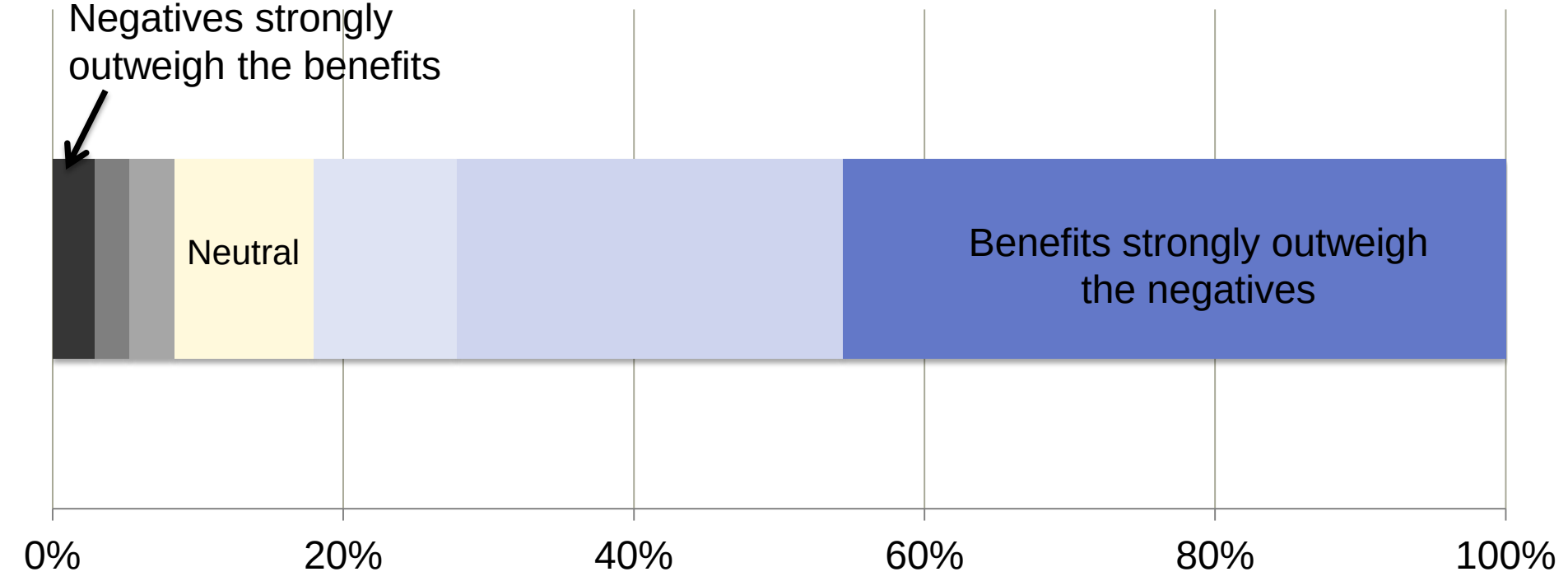
Overall Attitude to Data Sharing

Overall, how do you think the potential benefits of sharing anonymous, individual clinical trial data weigh against the potential negative consequences?



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Predictors: Negative Aspects of Data Sharing Outweigh Benefits

- Few significant predictors, but low proportion with negative views could have made subgroup differences hard to detect.
- More likely to feel that negatives outweigh benefits if:
  - Concerned about risk of reidentification (OR=2.9)
  - Concerned about risk of information theft (OR=2.6)
- Those with a college degree less likely to feel this way (OR=0.22)

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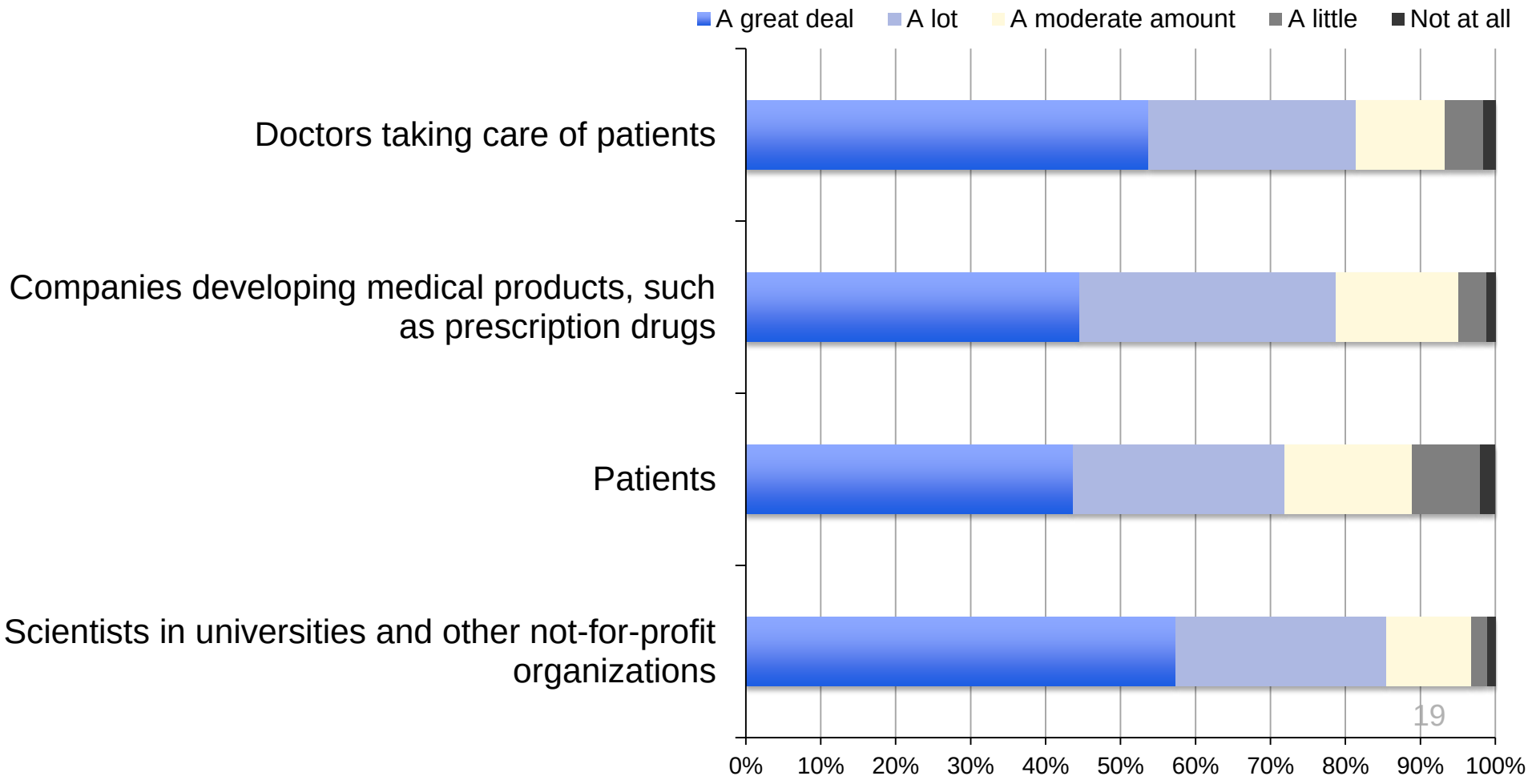
Who Benefits From Data Sharing

How much do you think the following groups could benefit from sharing anonymous, individual clinical trial data?



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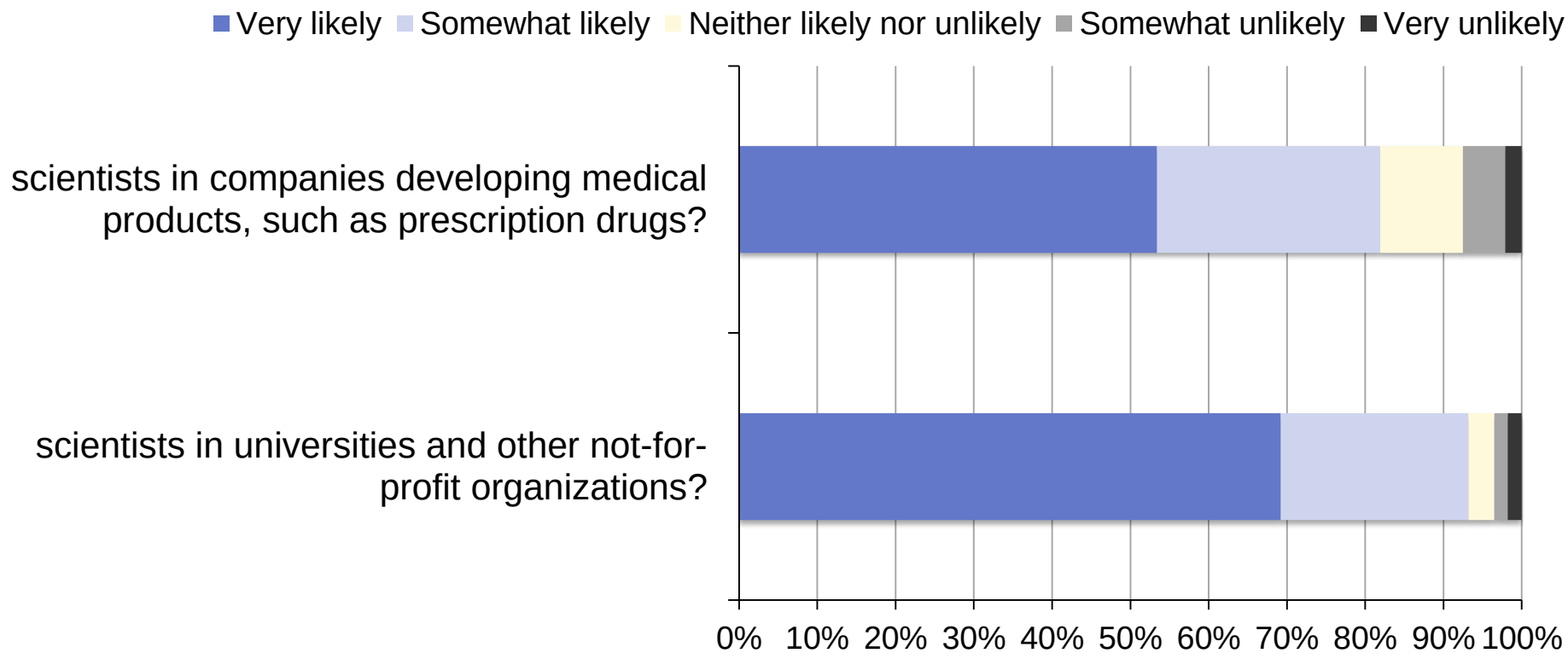
Does the Recipient Matter?

How likely would you be to allow your anonymous, individual clinical trial data to be shared with...



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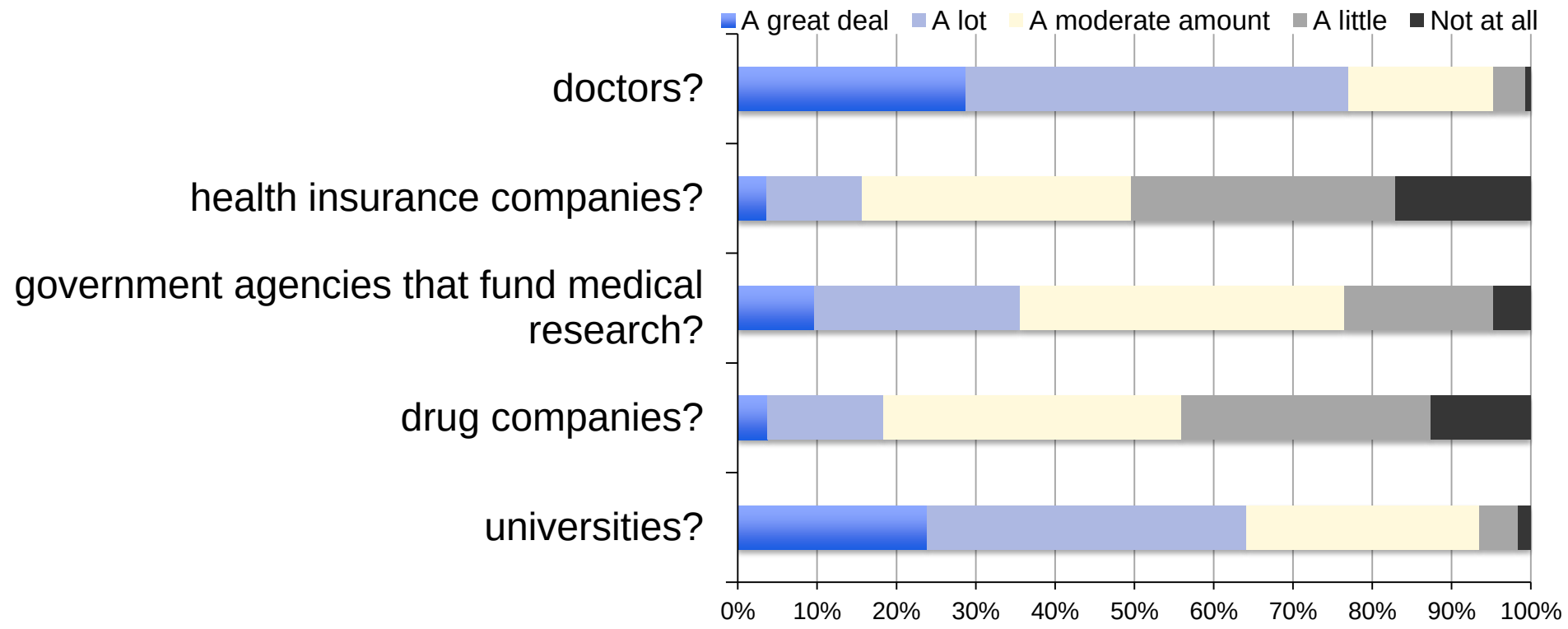
Trust in Institutions

How much do you trust ...



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Predictors of Being Unlikely to Share Own Data

- With drug company scientists:
  - Feeling that other people generally can't be trusted (OR=3.5)
  - Having low trust in drug companies (OR=3.1)
- With scientists in not-for-profit settings:
  - Feeling that other people generally can't be trusted (OR=7.0)
  - Those with a college degree were less likely to be unwilling to share (OR=0.24)

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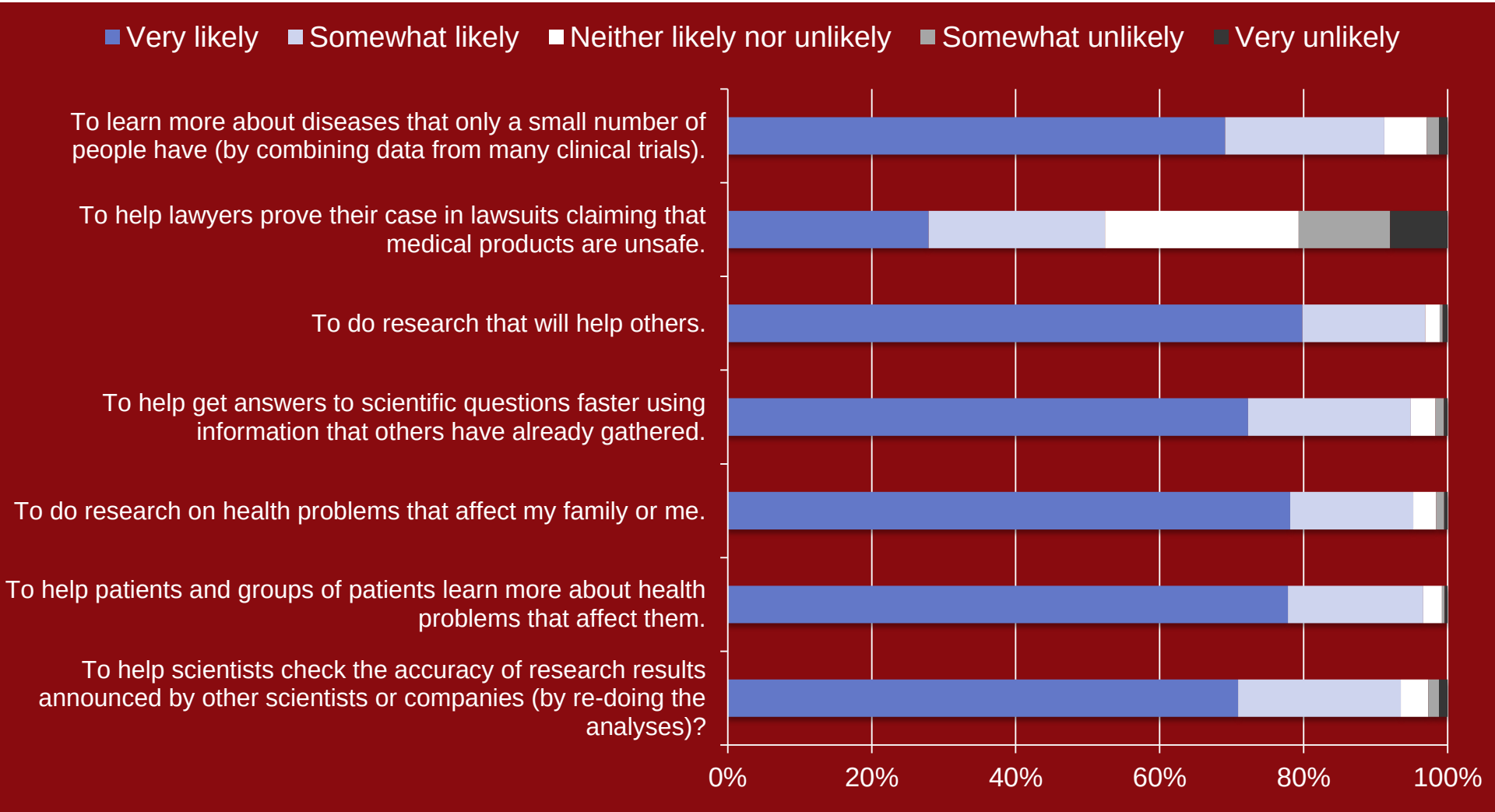
Does the Type of Use Matter?

How likely would you be to allow your anonymous, individual clinical trial data to be used in the following ways?



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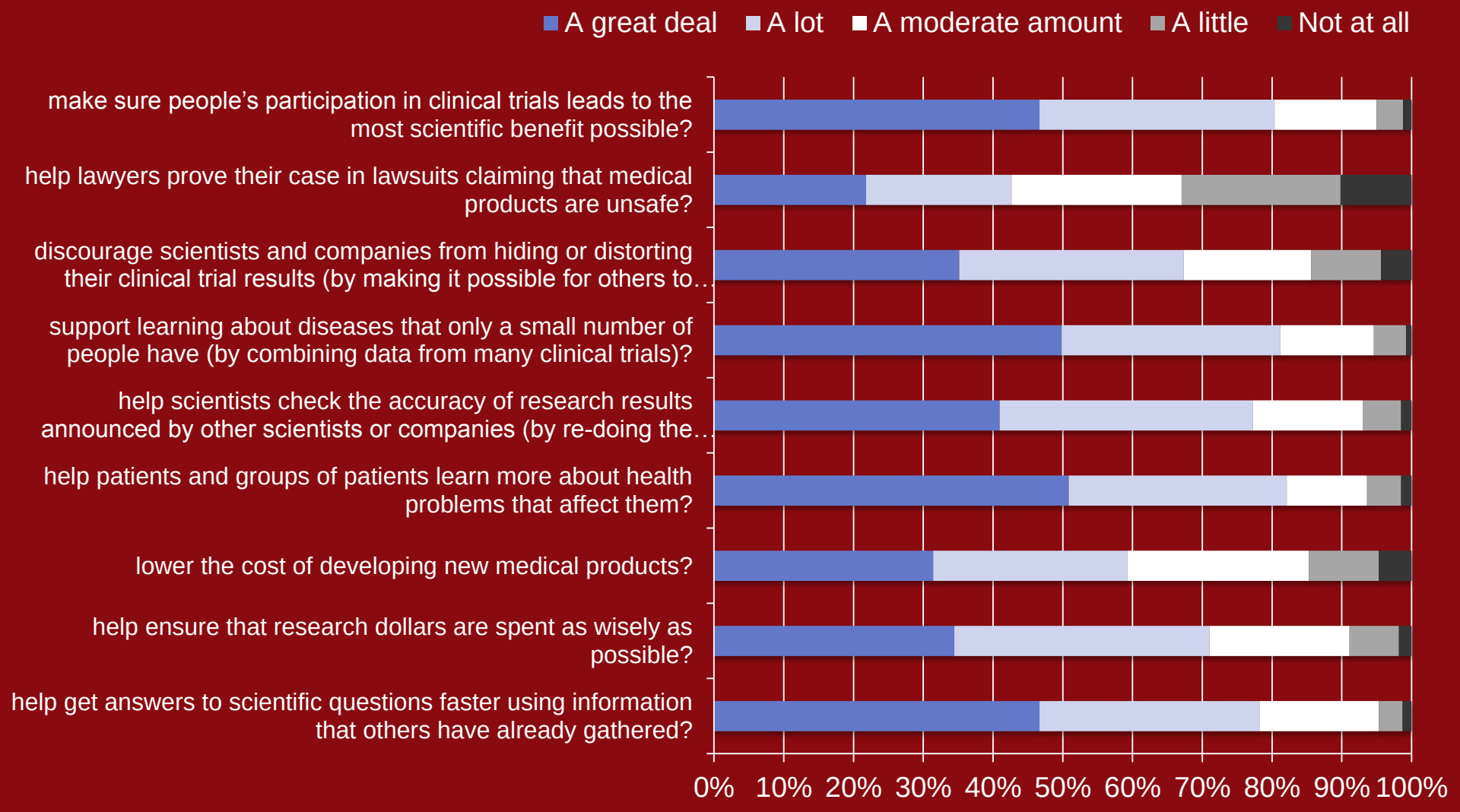
Benefits of Data Sharing

How much do you think sharing anonymous, individual clinical trial data can...



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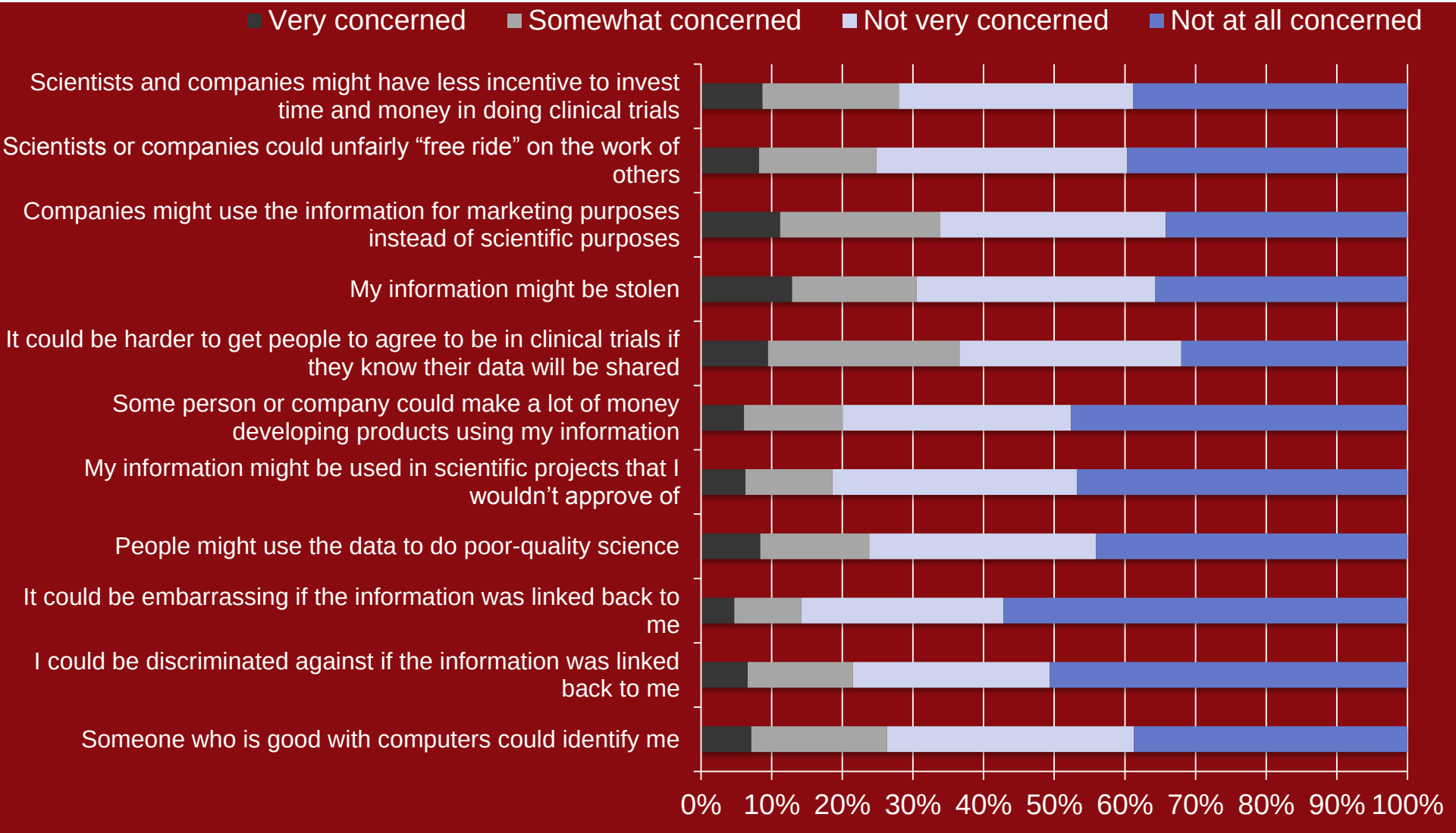
Data Sharing Risks

How concerned are you about the following potential consequences of sharing anonymous, individual clinical trial data?



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Limitations

- Possible nonresponse bias
- Comprehension problems?
- Sicker participants might have different views

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In the Bullpen

- What if specific consent for data sharing wasn't obtained?
- Do participants prefer to be asked for consent or merely informed of data sharing?
- Is blanket consent for future uses acceptable?
- Should data sharing systems be open access?

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Key Takeaways

- Participants see the benefits of data sharing as greatly outweighing the risks.

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- High willingness to share data, even where no prospect of benefit to self/family.
  - See benefits in terms of future clinical care, as well as scientific discovery.

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Key Takeaways

- Low concern about companies' use of data, despite low trust
  - Lawyers are a different story!

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- Proportion concerned about risks is surprisingly low (25% somewhat, 10% very).

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Strategies for Trialists

- Ensure that trial participation is a positive experience

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Strategies for Trialists

- Ensure that trial participation is a positive experience
- Don’t be deterred by privacy anxieties
- Frame the ask with specific information about the benefits of data sharing and the scientific cost of opt outs
- Stress your desire to make the most of their contribution to science

PCORI Data Sharing Policy: Current status

Steven Goodman, MD, PhD
Professor and Associate Dean
Stanford University School of Medicine
Vice-chair, PCORI Methodology Committee

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Policy for Data Access & Data Sharing: Background

- **PCORI is committed to open science.**
  - To allow reproduction of original analyses
  - To enable conduct of additional analyses

- **Policy developed with input from expert advisory group and Research Transformation Committee (RTC)**
  - Informed by public comment period and a pilot project involving data repositories and PCORI-funded researchers
  - Informed by other funders/regulators of clinical research, including Gates Foundation, European Medicines Agency, and NIH.

- **Designed to evolve, based on future experience.**

PCORI POLICY for DATA MANAGEMENT & DATA SHARING

VALUES STATEMENT: The Patient-Centered Outcomes Research Institute (PCORI) is committed to the principles of open science, particularly maximizing the utility and usability of data collected in research projects that PCORI funds. PCORI seeks to encourage scientifically rigorous secondary use of clinical research data to foster advances that will ultimately improve clinical care and patient outcomes. As such, PCORI believes it is important for our research awardees to systematically create and preserve research data and data documentation in order to facilitate data sharing.

Data Sharing Pilot Project

PCORI Awardees:

- 5 awardees participated: 3 completed studies and 2 ongoing large, pragmatic studies
- Awardees were selected to represent a diversity of therapeutic areas, study designs (both observational and RCTs) and data sources (EHR, claims data, imaging data)

Data Repositories:

- Multi-Regional Clinical Trials (MRCT) Center, Brigham and Women's Hospital
- ICPSR at the University of Michigan

Data Sharing Pilot Project (2)

MRCT:

- Focused on governance issues and documents – Data Use Agreement (DUA), Data Contributor Agreement (DCA), Informed Consent Forms (ICF)

ICPSR:

- Worked with 4 awardees to archive data of varying types
- Documented the experience to enable PCORI to plan for broader data sharing activities
- Created a demonstration repository for PCORI, initially for internal review and use

Data Sharing Pilot Project: Lessons Learned, I

- **Data Governance**
  - Variability in understanding of data package and data sharing terms
  - DCA, DUA and ICF are valuable documents for setting expectations
  - PCORI awardees desire recognition when data used in secondary research

- **Lessons for Data Submission**
  - Preparing data for submission takes time and expertise
  - Curation and review of submitted data is critical
  - Target date for releasing data (embargo) is needed

Data Sharing Pilot Project: Lessons Learned, II

- **Implementation of data sharing for clinical research requires careful deliberation about the details:**
  - Cannot direct researchers to deposit their data "somewhere" and declare victory
  - Data curation and ability of repository to work with researchers is critical
  - It's not just the dataset… it's the whole data package
  - Data discoverability & intelligibility are the name of the game

Data Sharing Pilot Project: Lessons Learned, III

- **Considerations for Informed Consent**
  - Provide explanations of "your" data, coded data, de-identified data and anonymized data
  - Provisions to respect participant autonomy and privacy
  - Minimal but non-zero risk of re-identification
  - Minimal but non-zero risk of privacy breach
  - Opt-out provision for secondary use of collected data

Final policy will address:

- Description of the full data package (full analyzable dataset, study protocol, metadata, data dictionary, full statistical analysis plan, and analytic code)
- PCORI commitment to provide funds for the time/effort of investigators to prepare their data for sharing
- Terms of data deposition and data availability
- Informed consent
- Terms of the data request process, as well as review of requests and requestor qualifications
- Applicability of the policy to studies using EHR and other health systems data

Thank you!
Questions?