

# Risks and Benefits of Data Sharing from Clinical Trials: Do Participants See Them the Way an Ethical Review Committee Thinks They Do

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*(With special thanks to Nikhil Mistry and Michael Esterlis)*

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# Case Study

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*Investigator contacts REB/IRB to get approval to release patient level data from a study approved in 2008*

Data requested includes Baseline data, demographics, body weight, lipids and meds, HbA1c, blood lipids, BP, and clotting factors and changes over time

Journal requested the release of data to evaluate the study because of a previous retraction of similar work (related to statistical error).

Consent form says “You understand that your data will be treated with confidence and your samples for analysis will be labeled with an alphabetic and numeric code. Your blood results and other relevant data will be made known to you at the end of the study. At your request, these data may be shared with whomever you designate as responsible for your routine medical care. The St. Michael’s Research Ethics Board and Health Canada may view the results for monitoring purposes.

**No other parties will have access to your data”**



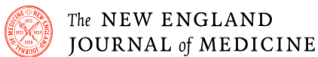
*What should we do??*



# The Reality

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- Increasing number of funders and journals have policies on data sharing
- As of January 2019, ICMJE requires that new clinical trials include a data sharing plan for trial registration



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EDITORIAL

## Data Sharing and the *Journal*

Jeffrey M. Drazen, M.D.

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May 12, 2016

N Engl J Med 2016; 374:e24

DOI: [10.1056/NEJMe1601087](https://doi.org/10.1056/NEJMe1601087)

“We want to clarify, given recent concern about our policy, that the *Journal* is committed to data sharing in the setting of clinical trials. As stated in the Institute of Medicine report from the committee on which I served and the recent editorial by the International Committee of Medical Journal Editors (ICMJE), we believe there is a moral obligation to the people who volunteer to participate in these trials to ensure that their data are widely and responsibly used. *Journal* policy will therefore follow that outlined in the ICMJE editorial and the IOM report: when appropriate systems are in place, we will require a commitment from authors to make available the data that underlie the reported results of their work within 6 months after we publish them.”



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# NEJM - A participant perspective

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

## 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.

June 7, 2018

N Engl J Med 2018; 378:2202-2211

DOI: 10.1056/NEJMsa1713258

- Survey of recent/current study participants at 3 US academic medical centers (9 PIs)
- All were enrolled participants (or were parents of enrolled participants) in an interventional clinical trial within the past 2 years
- Community based trials (smoking cessation, diabetes prevention) and hospital based trials (kidney disease, cancer)
- Consent and \$40 gift card
- 79% response rate
- n=771.
- Appropriate distribution of sex, age, socioeconomic status, education



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# NEJM - A participant perspective on data sharing

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## RESULTS

Less than 8% of respondents felt that the potential negative consequences of data sharing outweighed the benefits. A total of 93% were very or somewhat likely to allow their own data to be shared with university scientists, and 82% were very or somewhat likely to share with scientists in for-profit companies. Willingness to share data did not vary appreciably with the purpose for which the data would be used, with the exception that fewer participants were willing to share their data for use in litigation. The respondents' greatest concerns were that data sharing might make others less willing to enroll in clinical trials (37% very or somewhat concerned), that data would be used for marketing purposes (34%), or that data could be stolen (30%). Less concern was expressed about discrimination (22%) and exploitation of data for profit (20%).



## Survey on Sharing Data From Clinical Trials

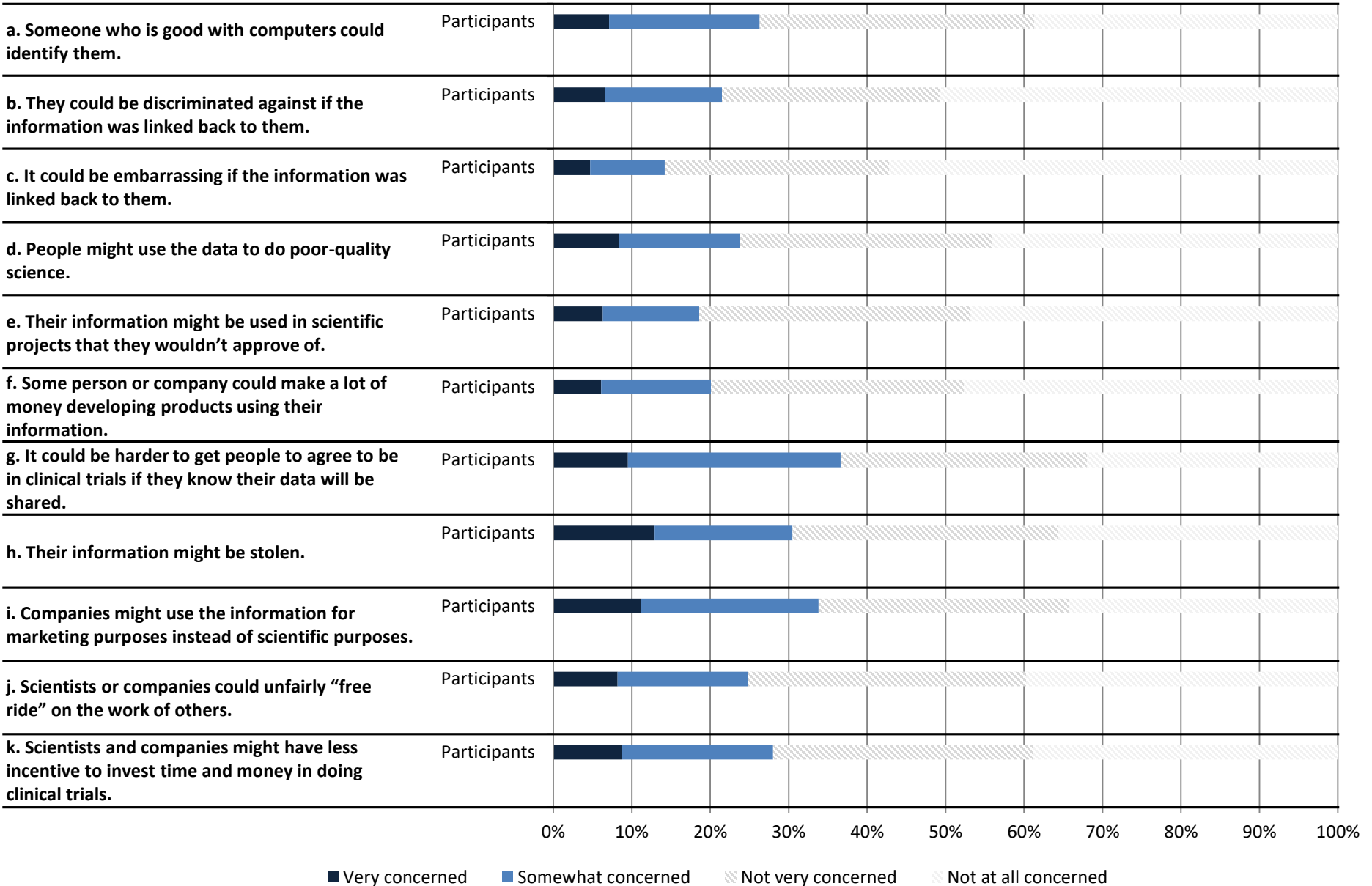
1. How concerned do you think clinical trial participants are about the following potential consequences of sharing anonymous, individual clinical trial data?

Very concerned    Somewhat concerned    Not very concerned    Not at all concerned

- Anonymous survey sent to all Research Ethics Board (REB) members and staff
- 70% response rate
- REB approval obtained

# Level of Concern about Potential Consequences of Data Sharing

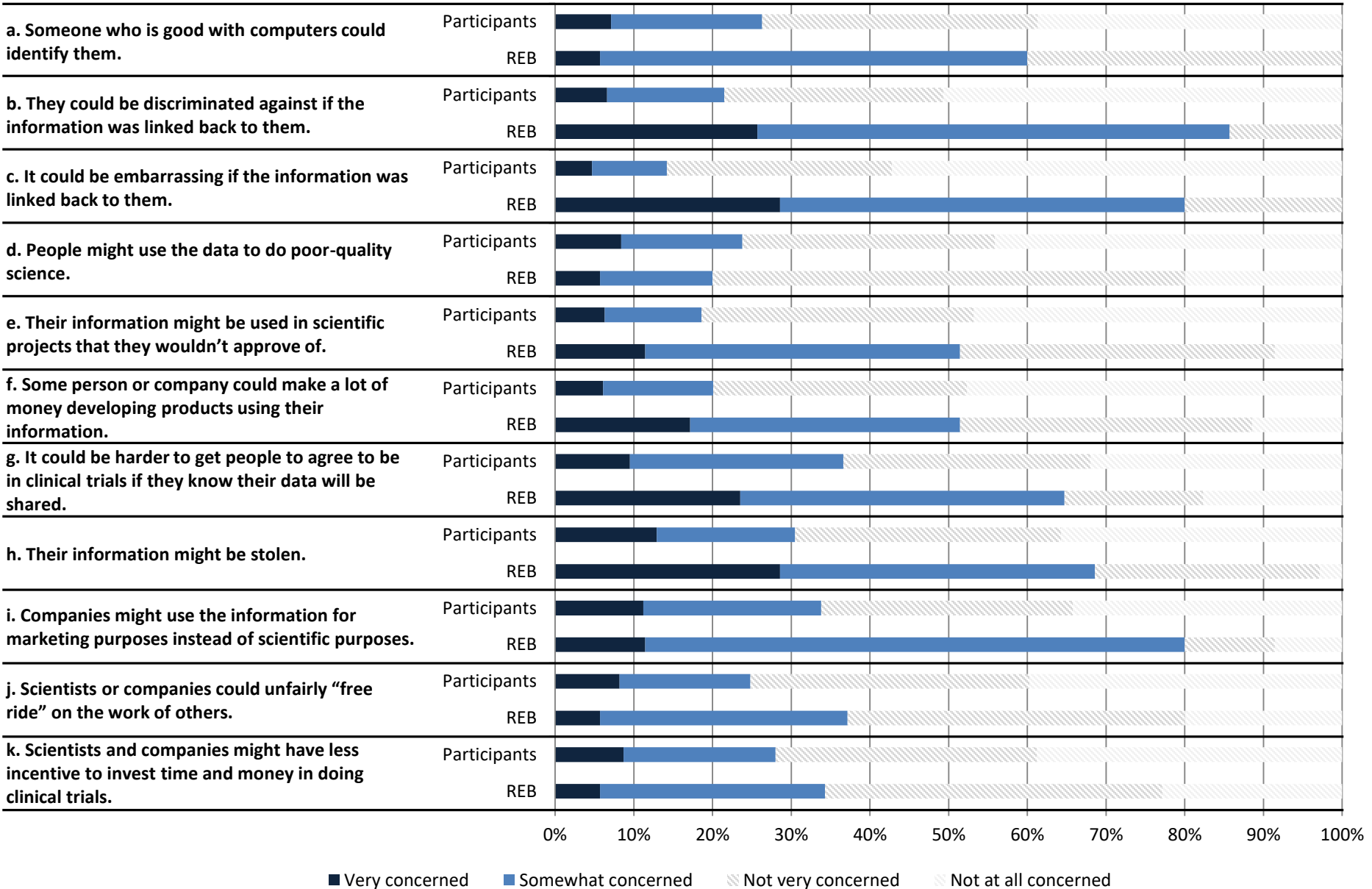
## Participant View





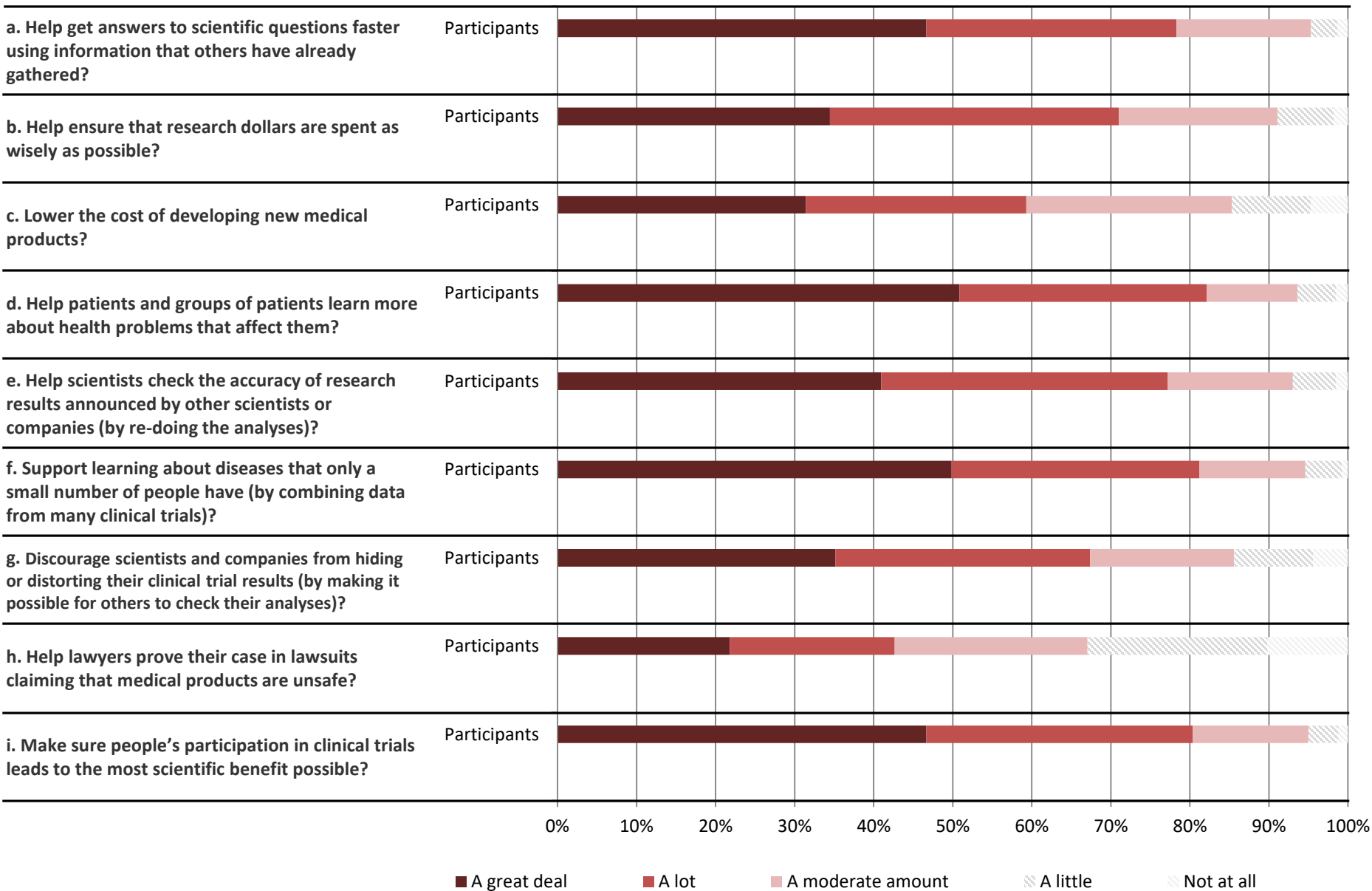
# Level of Concern about Potential Consequences of Data Sharing

## Participant View and REB Prediction of Participant View



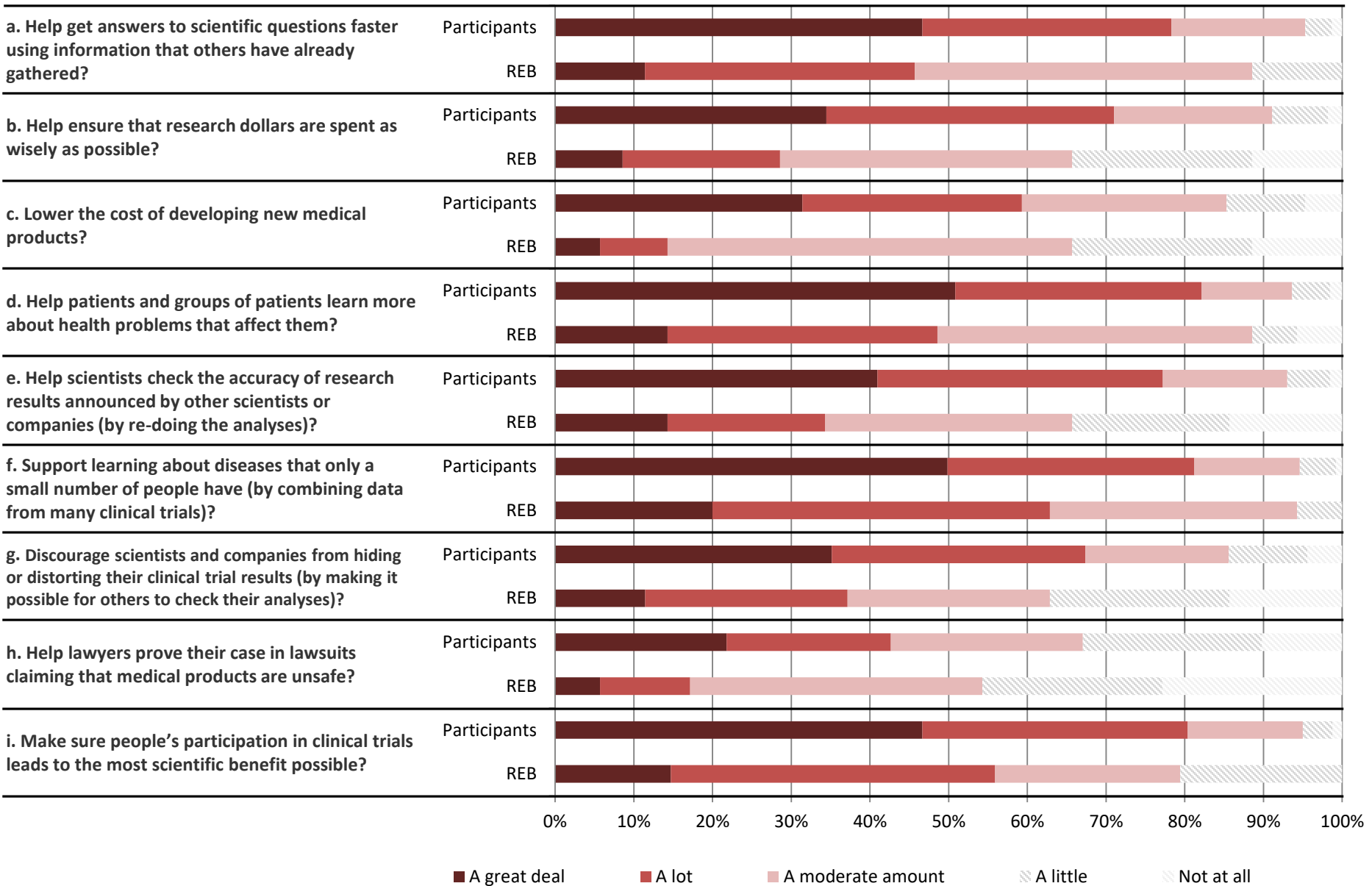
# Perceived Benefits of Data Sharing

## Participant View



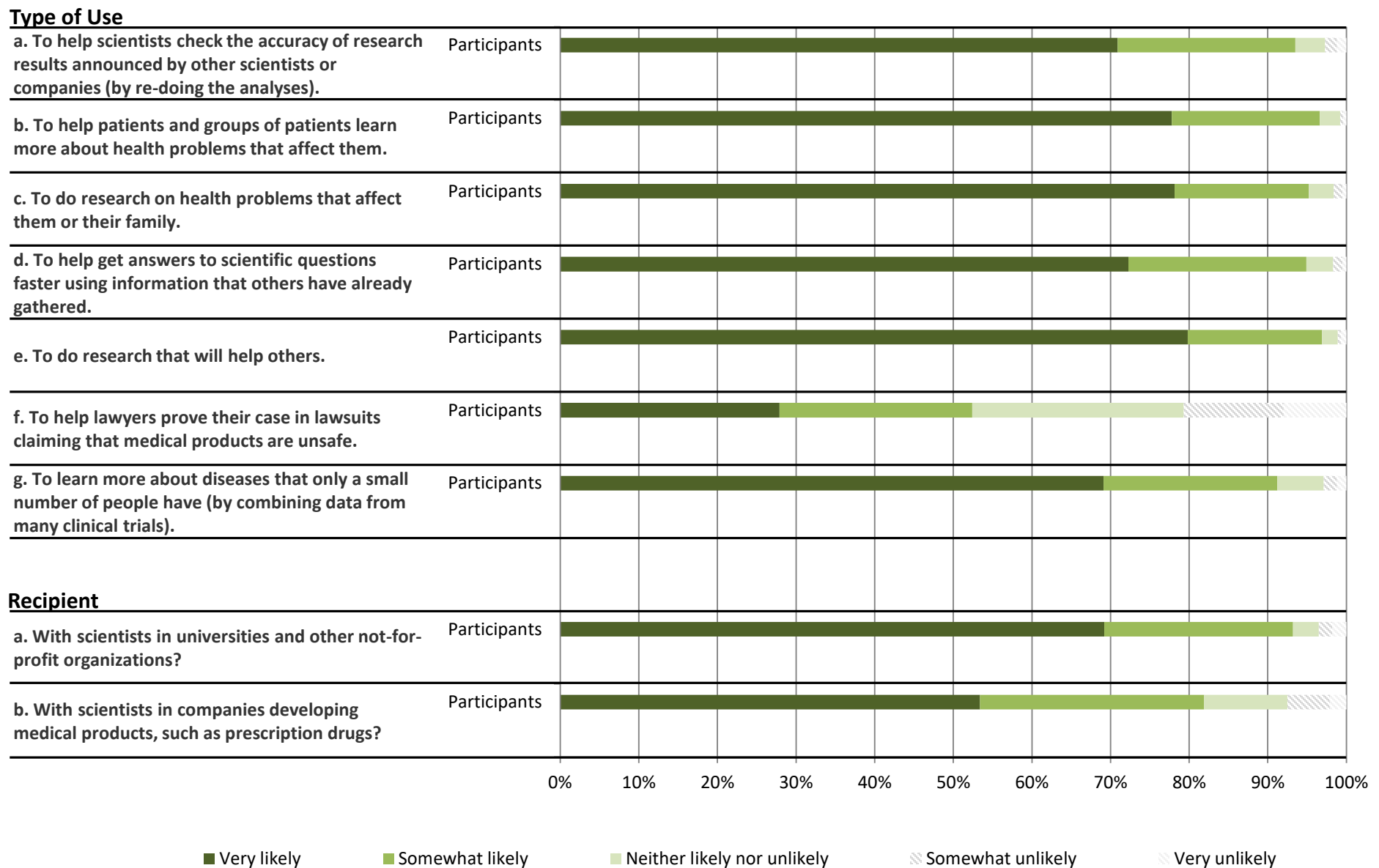
# Perceived Benefits of Data Sharing

## Participant View and REB Prediction of Participant View



# Willingness of Clinical Trial Participants to Share Their Data According to Type of Use and Recipient

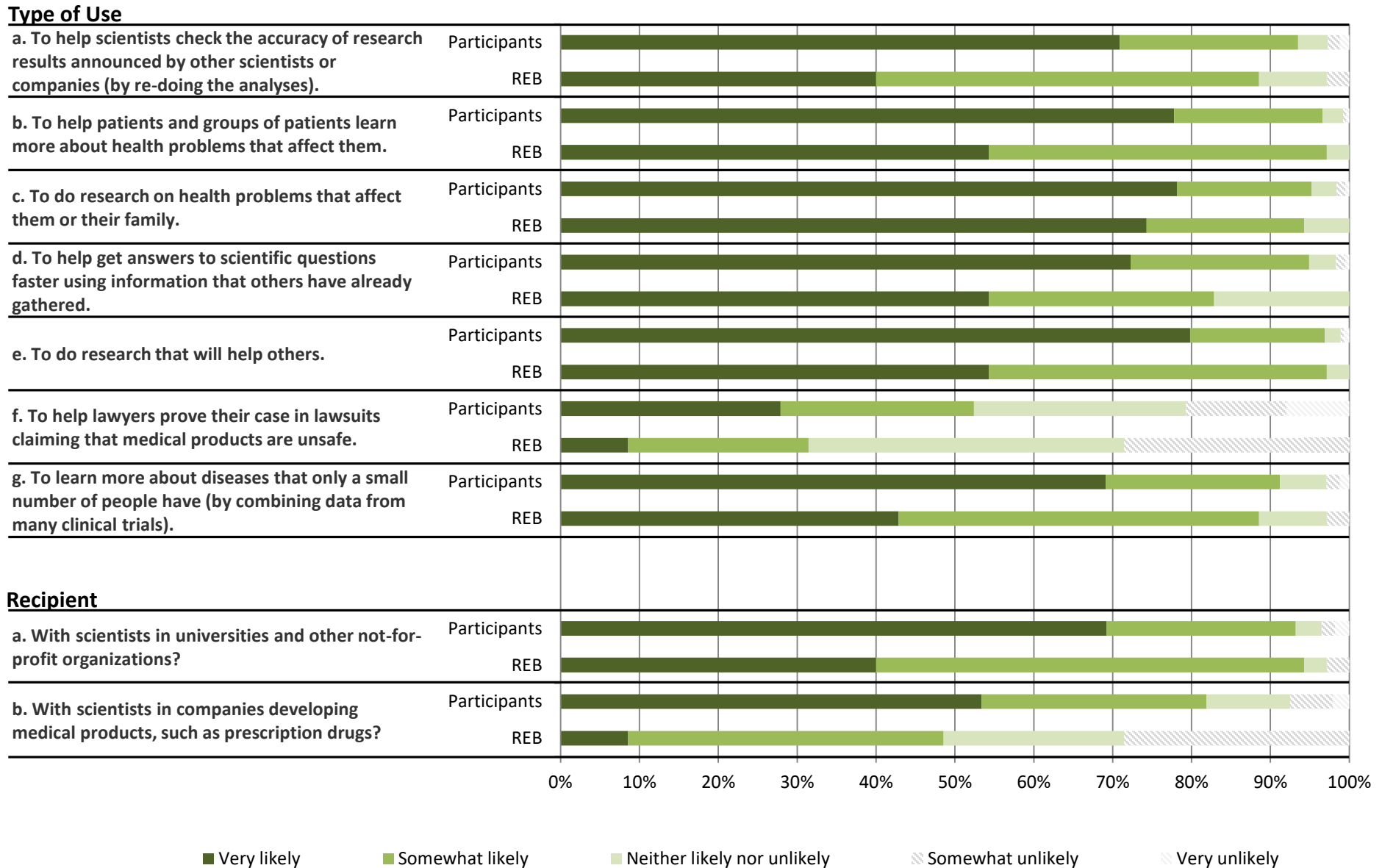
## Participant View



# Willingness of Clinical Trial Participants to Share Their Data

## According to Type of Use and Recipient

### Participant View and REB Prediction of Participant View



# Unanswered questions

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- What should research participants know about data sharing?
- What should be in the consent?
- Should there be an institutional policy and who should approve it?
- Who will pay for costs of data sharing?
- Who will monitor data sharing?



# Going Forward

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## Data sharing language suggested

“The authors believe in the principle of making data freely available but this was not anticipated or specifically approved by the St. Michael’s Hospital Research Ethics Board at the time the study was initiated. However, specific requests received by the authors for data sharing for purposes such as data verification and meta-analysis will be considered by the St. Michael’s Hospital Research Ethics Board on an individual basis under defined and mutually agreed-upon conditions.”



# Bottom Line

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- Views of the REB may not always be consistent with that of research participants
- Changes with respect to data sharing are coming/here
- REB needs to be educated on data sharing
- Balance societal, researcher and patient interests
- Some are embracing change, others are not
- An important component of ethical research conduct
- Data sharing needs to be anticipated and accommodated in protocol review and ICF





# Thank you



# Questions?