



Decoding 100 clinical trials to plain English

Maria Cristina Maldonado-Barreno

The University of Texas MD Anderson Cancer Center- Radiation Oncology Department

Background: What do we know about Clinical trials?

Clinical trials are medical research involving real patients used to evaluate the safety and efficacy of new experimental trials. ClinicalTrials.gov is a database available to the public that disseminates clinical trial information and assists researchers with participant recruitment. Because there is such a large variety of syntax and readability, it might be difficult for non-experts to identify whether patients are eligible for specific trials. The public's understanding of the clinical trial eligibility criteria used for participation is unknown, and the requirements can be hard to decipher.

Method: Where do we come in?

Using the eligibility NCI survey on Redcap, we will decode 100 clinical trials on lung cancer from clinicaltrials.gov. The survey asks a series of questions about eligibility to determine which patients are eligible for the study. The comprehensibility of the eligibility criteria is assessed using categorical and numerical measures about cancer stage, metastatic role, biomarkers, therapies, age, gender, and performance status.

Results

As a high school student, I found biomarkers and the role of metastases to be the most difficult to comprehend because of my lack-

of scientific expertise. I used the internet to learn about medical language and terminology, intricate human anatomy, and biological molecules found in lung cancer. I also read a few lung cancer-related medical publications, which gave me more insight into what I was reading.

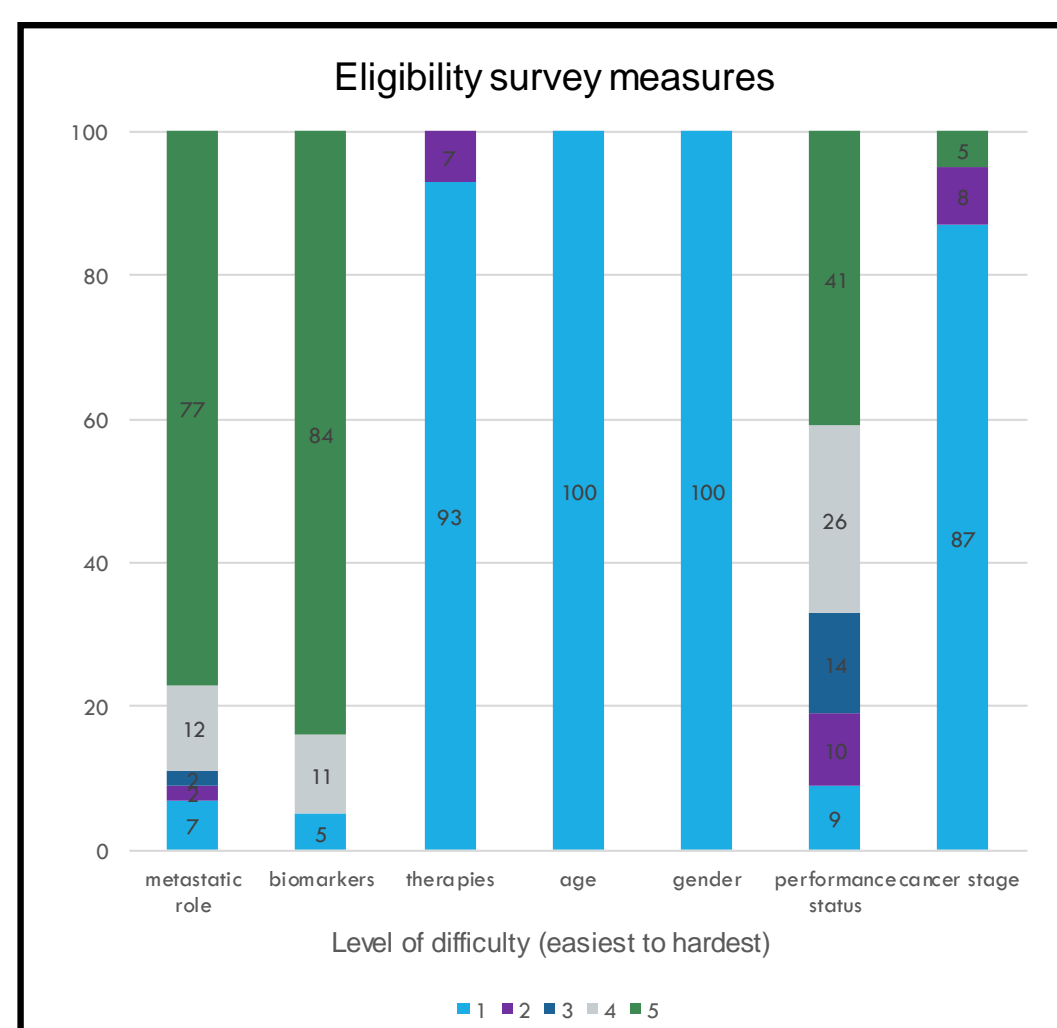


Fig. 1 100 RedCap Lung cancer trial surveys eligibility categorical measures comparison among categories on a range of levels of difficulty.

Based on my data, age, therapies, cancer stage, and gender were the most straightforward requirements to understand from the webpage. The mean value for these categories in this data is level 5- the most arduous level of difficulty. One of the factors that may influence this is that clinicaltrials.gov is not very direct when it comes to biomarkers, performance status, and metastatic role. Unlike the easiest measures that I understood, the information for the more challenging categories was scattered throughout the page. The most comprehensive categories have a mean of level 1, which is the easiest level of understanding. Our findings imply that non-experts reading eligibility criteria have many readability inconsistencies.

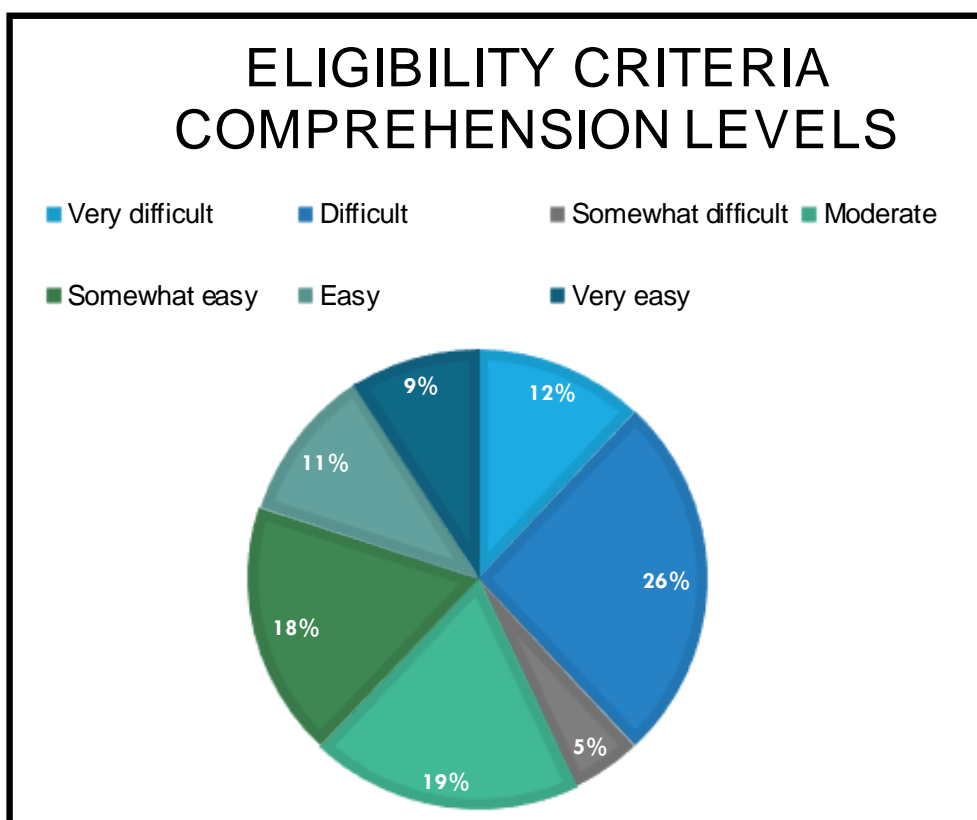


Fig. 2 My comprehension levels representing on 100 clinical trials eligibility criteria.

The majority of clinical trials- a total of 43%- were in the range of difficulty (Somewhat difficult, difficult, and very difficult). 38% makes up the easy range, Somewhat easy, easy, and very easy. The remaining 19% consists of what I considered moderately challenging, the middle range.

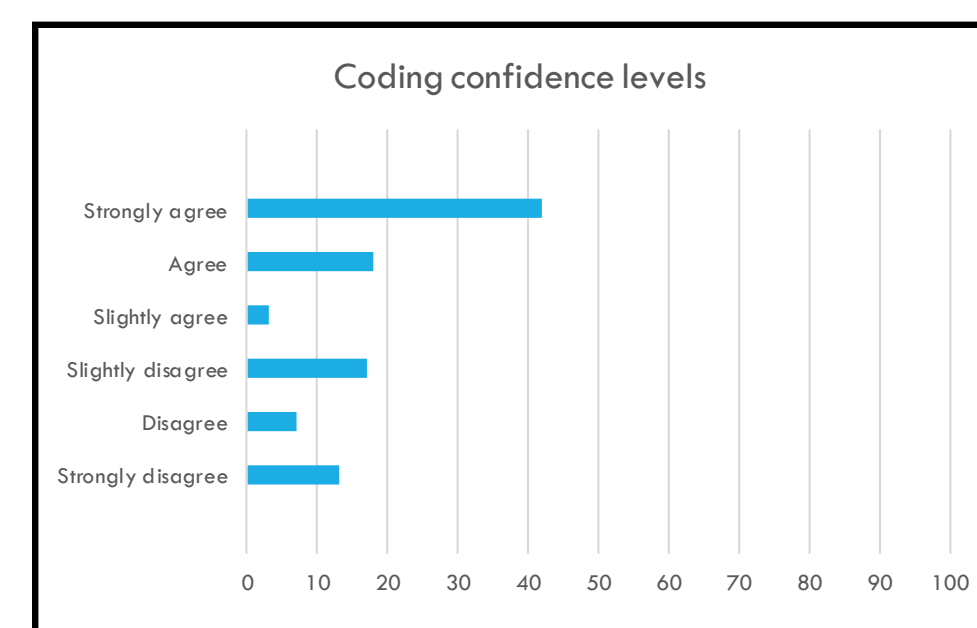


Fig. 3 Graph represents my confidence level regarding my accuracy of the 100 surveys coded.

After completing a survey for a clinical trial, I use a scale of Strongly Agree to Strongly Disagree to determine how certain I am in my accuracy. Unlike my previous data, this data assesses accuracy rather than difficulty. I am 62% confident that the data I decoded is accurate. Because I constantly had to google material I had not previously heard of, there is a 38 percent level of uncertainty. However, I took the time to meticulously analyze the trials and learned about lung cancer; I believe it is reasonable to claim that I am confident in my decoding skills.

Conclusions

If you do not have an extensive scientific background, clinical trials on clinicaltrials.gov can be arduous to comprehend the material. If patients want to be part of clinical trials, the website needs to be improved because it is hard to understand with little to no deep scientific understanding. To keep the eligibility criteria section simple: medical jargon should be avoided. I believe if Clinicaltrials.gov made sections clearer, non-experts would be able to comprehend more and not get lost in medical jargon. Based on my research, I came to the conclusion that the categories that are evidently listed are the ones one can comprehend the most. As a result of our data, I believe that the eligibility criteria should be standardized in order to increase the number of qualifying patients enrolled in clinical trials. Fewer than 1 in 20 adult cancer patients enroll in cancer clinical trials. Patients are often fearful of participating in clinical trials, but with clear information cancer patients can potentially increase that statistic.

Acknowledgments

Special thanks to MD Anderson, Dr. Fuller, Mike Rooney, all those who I have had the pleasure to work alongside in this project, and to the people who have supported me through my research experience.

References

- 1) Unger, J. M., Cook, E., Tai, E. and Bleyer, A. (2016). The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies. American Society Of Clinical Oncology Educational Book, 36, 185-198. doi: 10.14694/edbk_156686