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## INTRODUCTION

The increasingly high incidence and prevalence for macular degeneration (MD), coupled with its economic burden, reinforces the importance of physicians needing reliable clinical evidence for effective patient-care. To address inconsistencies in clinical trial reporting, organizations such as COMET (Core Outcome Measures in Effectiveness Trials) advocate for the use of core outcome sets (COSs).<sup>11</sup> A COS is developed through the consultation of patients, researchers, and physicians in an effort to standardize outcome reporting and improve overall study quality.<sup>11</sup> The effectiveness of COSs has been supported by Kirkham *et al.*'s analysis of COS compliance in rheumatoid arthritis clinical trials, but other research has shown the adoption of COSs can be delayed.<sup>12,13</sup> It is currently unknown whether the MD COS has been widely adopted in clinical trials, prompting our study.<sup>14</sup>

## OBJECTIVES

The aim of this study is to evaluate the uptake of COS by MD clinical trial and to provide insight into which outcomes of the COS are most often measured.

## METHODS

- Screened ClinicalTrials.gov for clinical trials evaluating outcomes for patients with MD
- Extracted seven domains from our COS for each included trial
- Performed a data analysis using an ITSR

## RESULTS

Figure 1: Flowchart of Inclusions and Exclusions

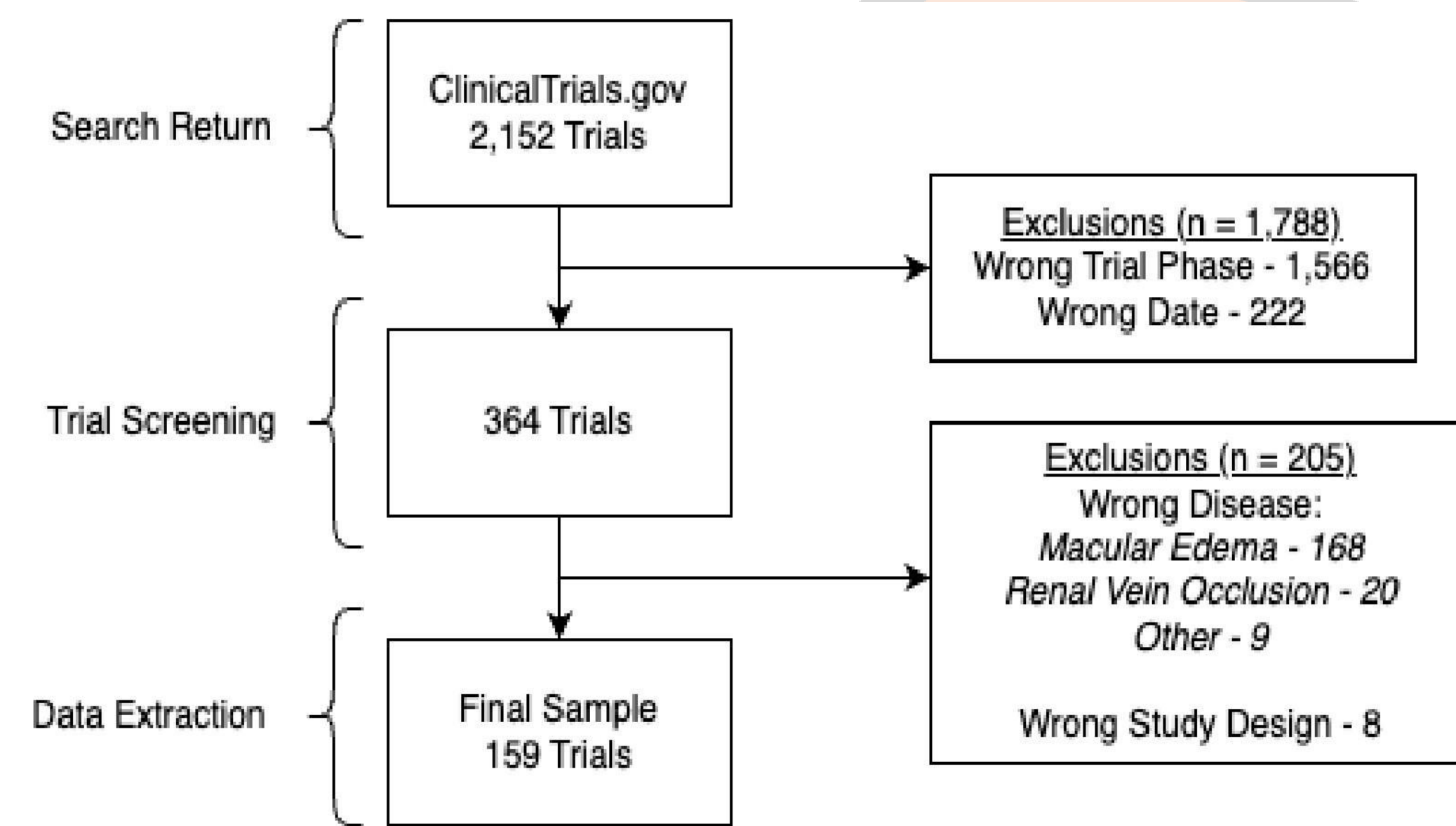


Figure 2: Interrupted Regression Analysis of findings per month

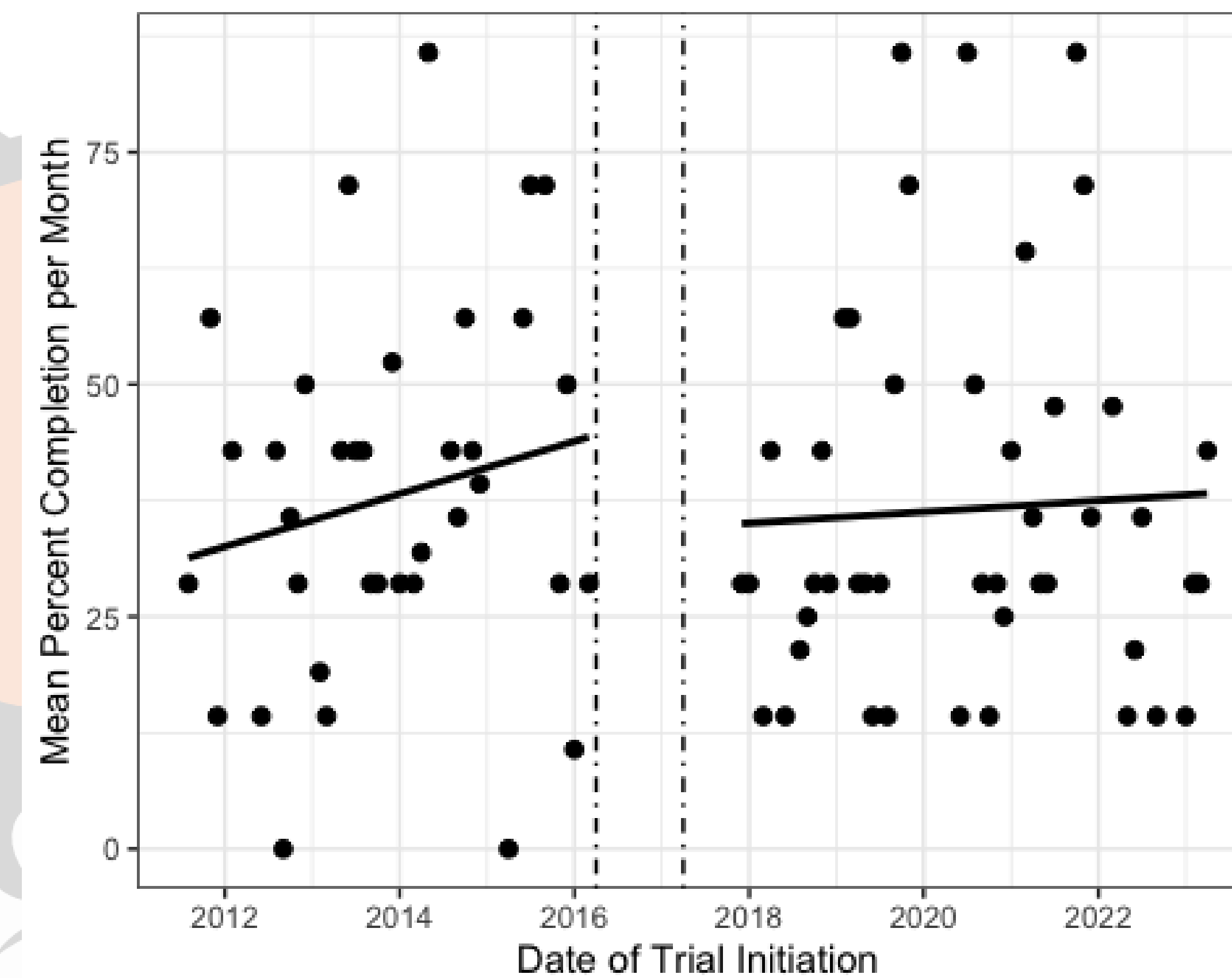
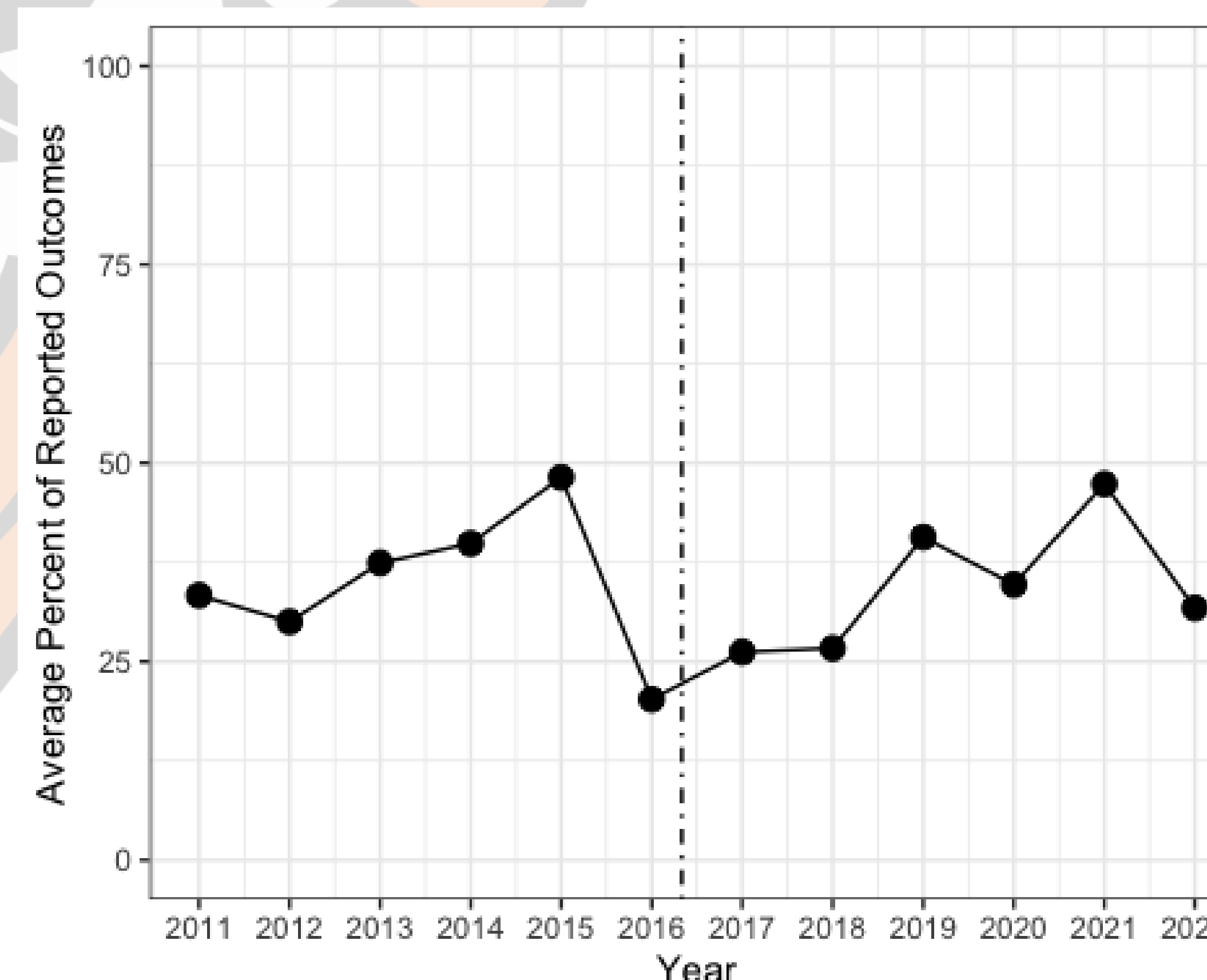


Table 3. Frequency of Outcome Set Uptake

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Visual Functioning and Vision Related Quality of Life	Distance Visual Acuity, n (%)	
	Yes	139 (87.4)
	No	20 (12.6)
	Mobility and Independence, n (%)	
No	129 (81.1)	
Yes	30 (18.9)	
Emotional Well-being, n (%)	No	126 (79.2)
	Yes	33 (20.8)
Reading and Accessing Information, n (%)	No	126 (79.2)
	Yes	33 (20.8)
Disutility of Care	Number of Treatments, n (%)	
	No	127 (79.9)
	Yes	32 (20.1)
Complications of Treatment, n (%)	No	83 (53.2)
	Yes	73 (46.8)
	Not Applicable	3
Disease Control	Presence of Fluid, Edema, or Hemorrhage, n (%)	
	No	101 (64.7)
	Yes	55 (35.3)
	Not Applicable	3

Figure 3: Average % of reported outcomes per year.



## CONCLUSION

- There were no discernable patterns in COS adherence in MD clinical trials.
- We provide speculation that previous patterns recorded were a result of endorsements of outcomes from commercial drug regulators, not COSs.
- We suggest further studies be done on COSs in relation to the recommended outcomes of regulatory agencies.
- We also recommend that those developing COSs seek out regulatory agencies' endorsements of their COSs.

## REFERENCES



## ACKNOWLEDGEMENTS

Jon Goodell, MISLT, AHIP  
Vassar Research Team

