



## INTRODUCTION

- Inclusion of PROs in novel immune targeted trials influence multiple Stakeholders who use PRO evidence for Decision Making
- Significant heterogeneity and several areas of deficiency in the reporting of PROs across cancer trials have been identified in prior reviews<sup>1,2</sup>, indicating the need for adherence to reporting guidelines.

## OBJECTIVES

- To evaluate the adherence of reporting Patient Reported Outcomes (PROs) to the 2013 CONSORT PRO extension, CONSORT-Outcomes 2022 extension, and ISOQOL standards in Randomized Control Trials (RCTs) among Aggressive Large B Cell Lymphoma (LBCL) patients.

## METHODS

### Search & Study Selection

- A literature search was performed on PubMed, Embase, Cochrane library between 2013 and 2022.
- Search terms were designed to include RCTs in Aggressive LBCL patients with a PRO endpoint

### Data analysis

- Trial frequencies and percentages were reported for data items.
- Individual item compliance was rated "good", "moderate", "poor" when  $\geq 80\%$ , 50–79% and  $\leq 49\%$  of RCTs respectively addressed the CONSORT 2013 and 2022 items checklist according to Mercieca-Bebber et al<sup>3</sup>

## RESULTS

- PROs were secondary endpoints in all the included ten studies
- The most consistently reported items with good overall compliance to CONSORT-PRO and CONSORT-outcomes extension were P6ai-evidence of PRO instrument (10/10), 13ai-participants reporting PRO data at baseline (9/10; 90%) and at subsequent time-points (13aii; 10/10), P20-PRO-specific limitations (8/10; 80%) and 6a.5-state the timepoints used for analysis (10/10)
- The least frequently reported items with poor compliance to CONSORT-PRO extension were P2bi-PRO hypothesis present (1/10; 10%), P2bii-PRO domains specified in the hypothesis (1/10; 10%), and P6aiii-mode of administration specified (3/10; 30%)
- Items specific to missing data such as P12a-statistical approach for dealing with missing data specified (3/10; 30%) in CONSORT-PRO, 12a.3- describe the methods used to handle missing outcome items or entire assessments (2/10; 20%) in CONSORT- 2022 Outcomes extension and statistical approaches for dealing with missing data (3/10; 30%) in ISOQOL, were poorly reported across all RCTs

## CONCLUSION

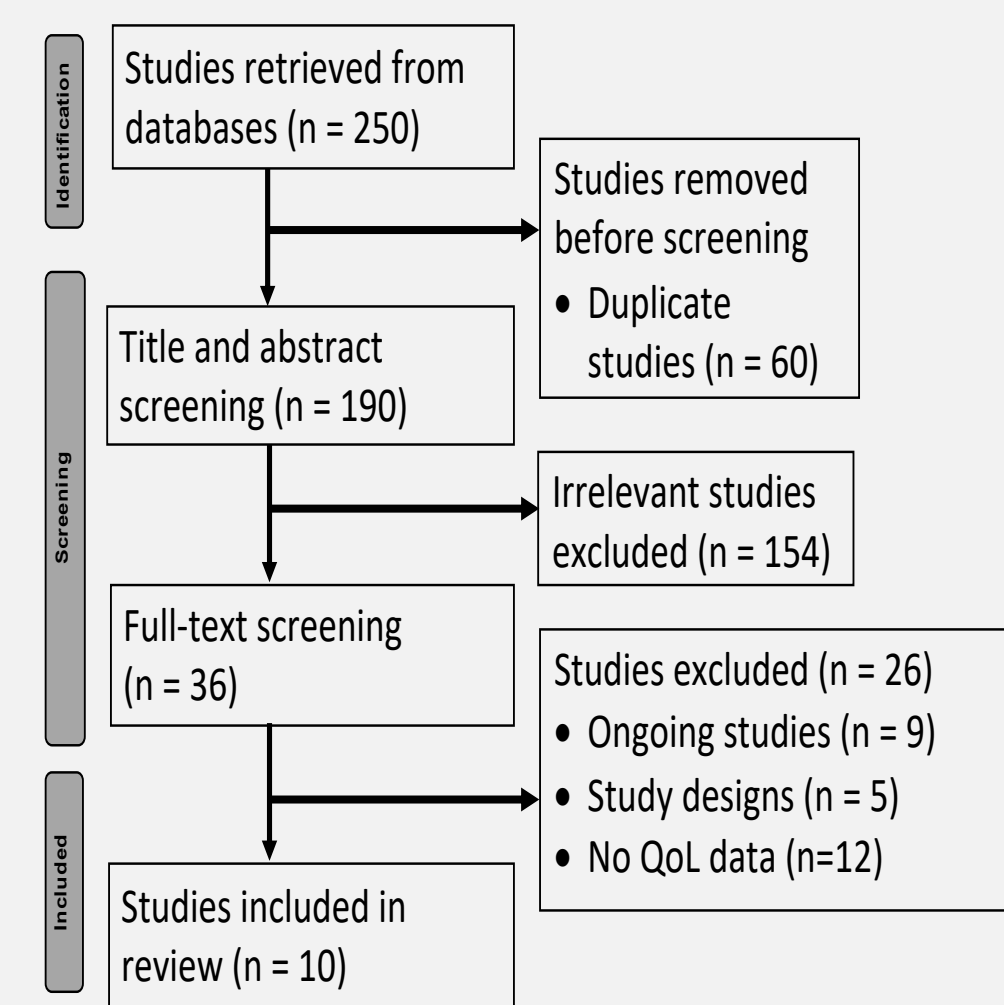
- Our study highlights the importance of following PRO Reporting guidelines, ensuring consistency in generating and reporting PRO data in DLBCL RCTs, and further aid decision makers and trialists to better interpret and design PROs in the future.

## REFERENCES

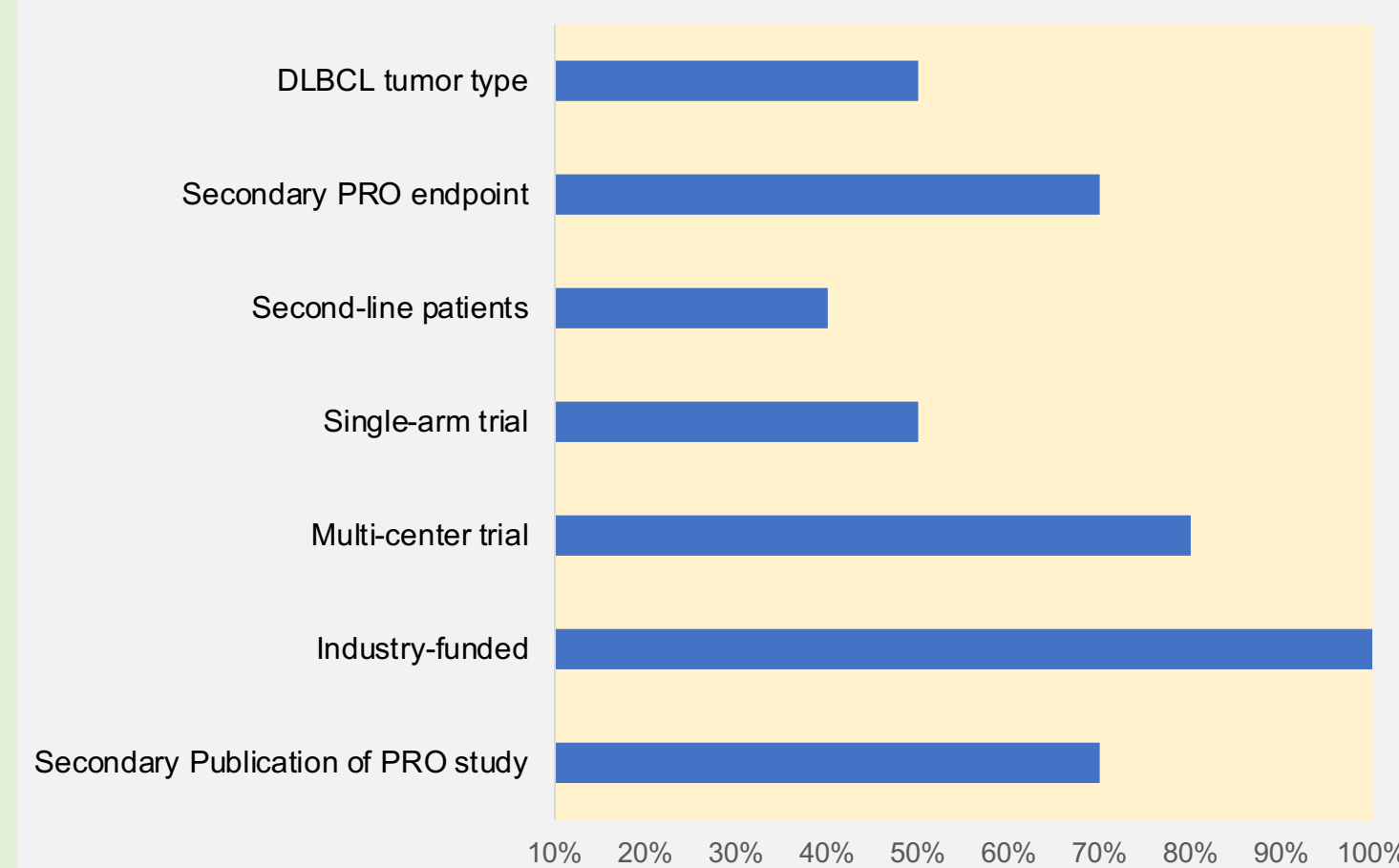
1. Fallowfield, L., *Quality of life assessment using patient-reported outcome (PRO) measures: still a Cinderella outcome?* Annals of Oncology, 2018. **29**(12): p. 2286-2287.
2. Marandino, L., et al., *Deficiencies in health-related quality-of-life assessment and reporting: a systematic review of oncology randomized phase III trials published between 2012 and 2016.* Annals of oncology, 2018. **29**(12): p. 2288-2295
3. Mercieca-Bebber, R., et al., *Best Practice for PROs—Reporting Taskforce.* Preliminary evidence on the uptake, use and benefits of the CONSORT-PRO extension. Qual Life Res, 2017. **26**(6): p. 1427-1437.

## RESULTS

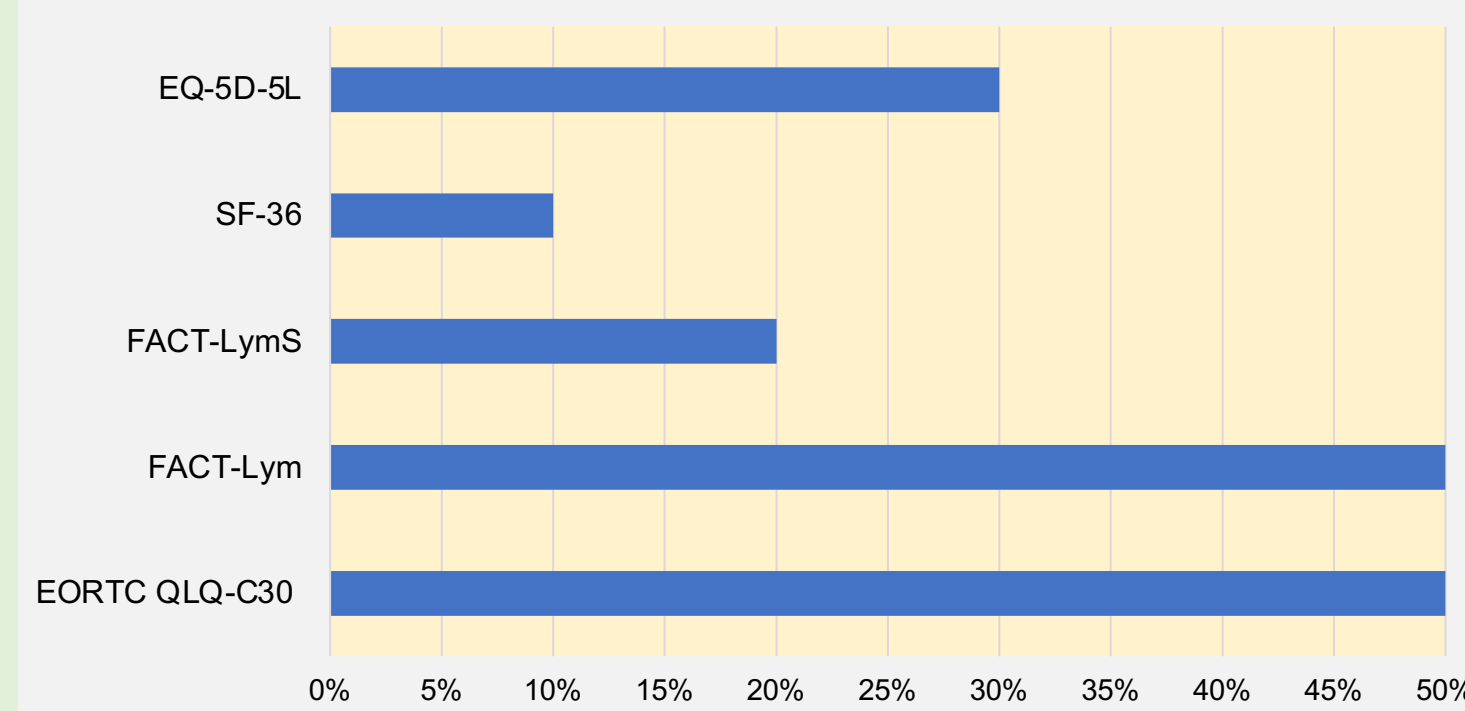
Fig 1: PRISMA chart



### Study characteristics



### QOL questionnaires



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## RESULTS

### CONSORT-PRO 2013

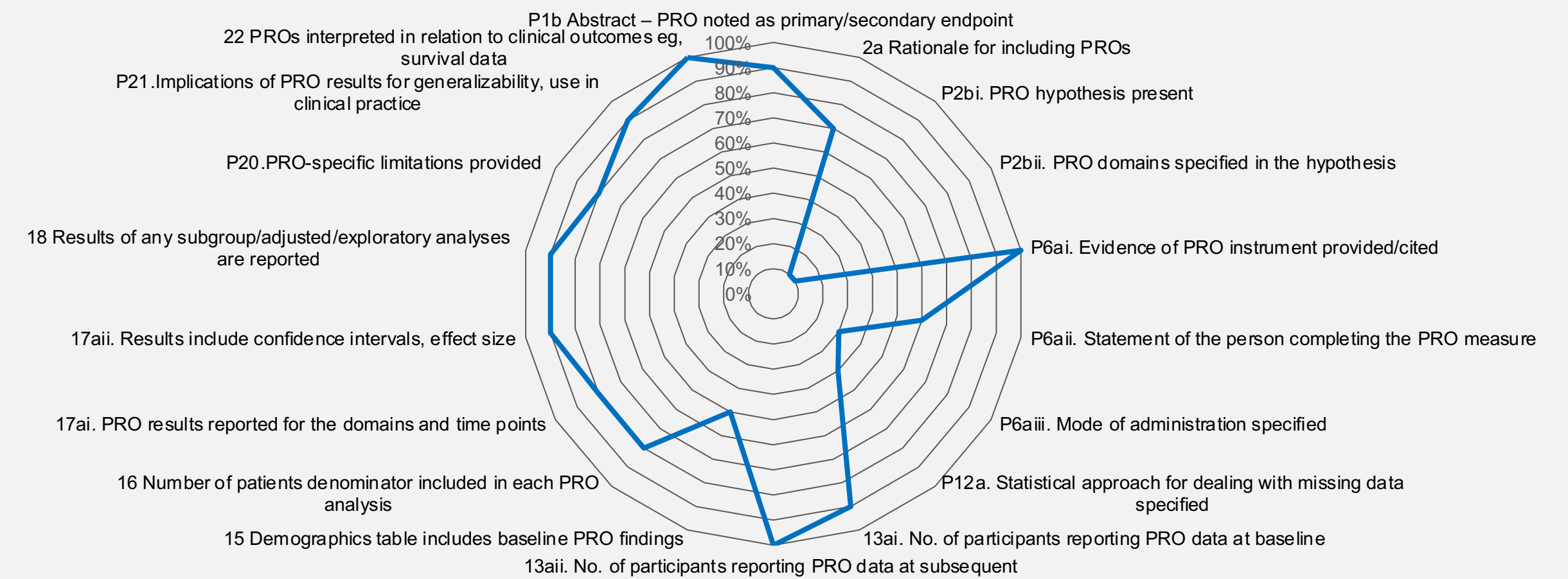


Fig 2: Radar plot showing mean score for each elements across CONSORT-PRO 2013 checklist

### CONSORT-2022 OUTCOMES

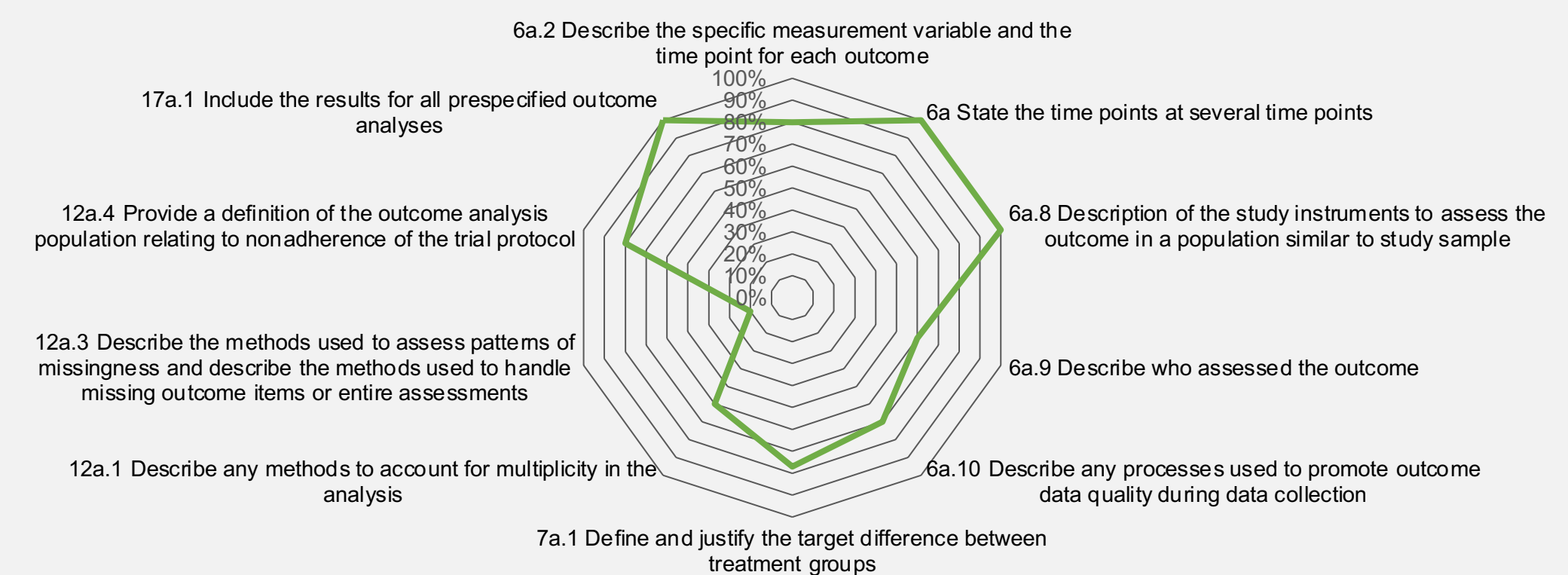


Fig 3: Radar plot showing mean score for each elements across CONSORT-2022 outcomes checklist

### ISOQOL

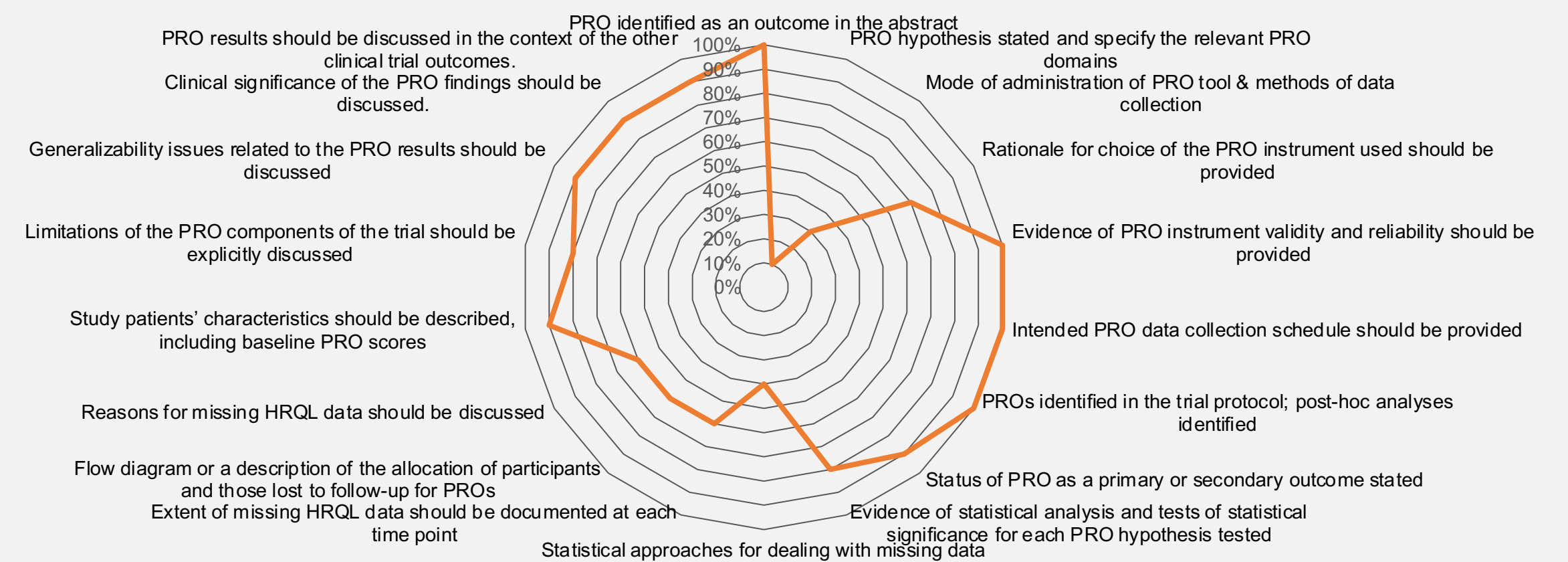


Fig 4: Radar plot showing mean score for each elements across ISOQOL checklist