Core Outcome Sets in Cancer Clinical Trials: Current Status and Future Opportunities

Authors: <u>A. Lawlor¹</u>, S. MacLennan², J. Bogaerts³, S. Litiere³, J. Lehmann⁴, P. Szturz⁵, M. Van Hemelrijck¹

Affiliations: ¹Transforming cancer OUtcomes through Research (TOUR), King's College London, London, UK; ²Academic Urology Unit, University of Aberdeen, Aberdeen, Scotland, ³European Organisation for Research and Treatment of Cancer (EORTC), Brussels. Belgium; ⁴University Hospital of Psychiatry II, Medical University of Innsbruck, Innsbruck, Austria; ⁵Department AB, Medical Affairs Oncology, Stockholm, Sweden.



Introduction

- Outcome selection in clinical trials is often based on researcher's preference, leading to inconsistent outcomes reported, and variability in the definitions or instruments used across trials.
- Core outcome sets (COS) offer a solution to this problem.
- A COS is a minimum set of standardised and agreed-upon
- The European Organisation for Research and Treatment of Cancer (EORTC), is an independent cancer research organisation, which evaluates new cancer treatments in collaboration with the pharmaceutical industry and patients.
- The EORTC currently do not have an official position on the use of COS in their trials.

outcomes that should be measured and reported in all clinical trials in specific areas of health or health care.

 We aimed to 1) establish the availability of COS for each tumour type and 2) assess COS uptake within EORTCaffiliated clinical trials.

Methods

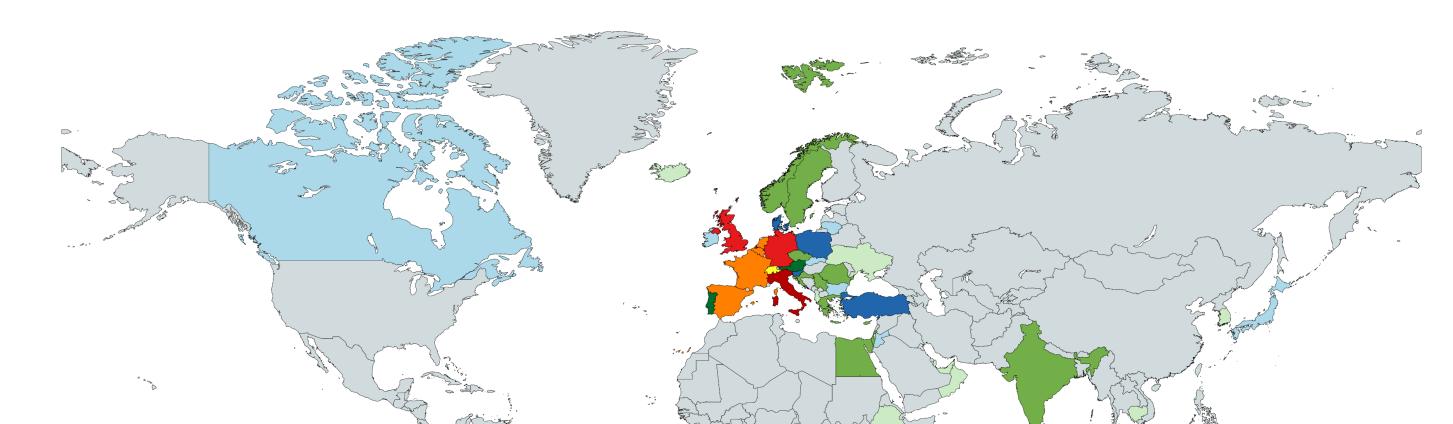
Review of the COMET database

- Core Outcome Measures in Effectiveness Trials (COMET) collates known and in-development COS into one database.
- The COMET database was searched for cancer-specific COS in June 2023.

Assessment of COS uptake in EORTC clinical trials

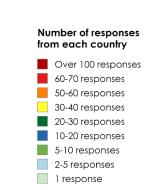
- EORTC members were queried on their awareness and use of COS over two survey questions.
- The survey was shared with 3733 EORTC members on November 28th, 2023, and closed on April 5th, 2024.

Results



Assessment of COS uptake in EORTC clinical trials

- The majority of EORTC trialists described COS as 'outside their area of expertise' (352 [50%]) or reported no available COS for their disease speciality (162 [23%]).
- Almost a fifth (126 [18%]) reported not using a relevant COS.
- A tenth (68) stated that they use an available COS.



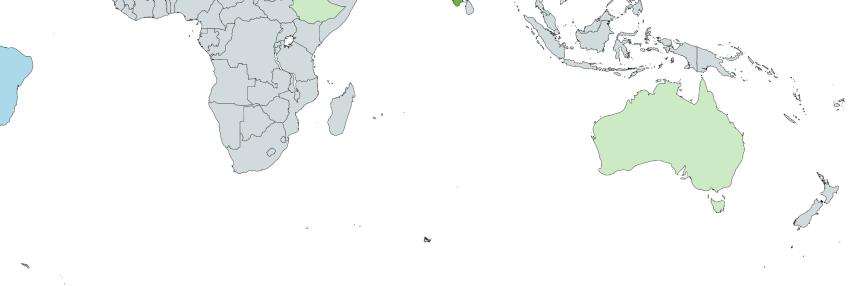
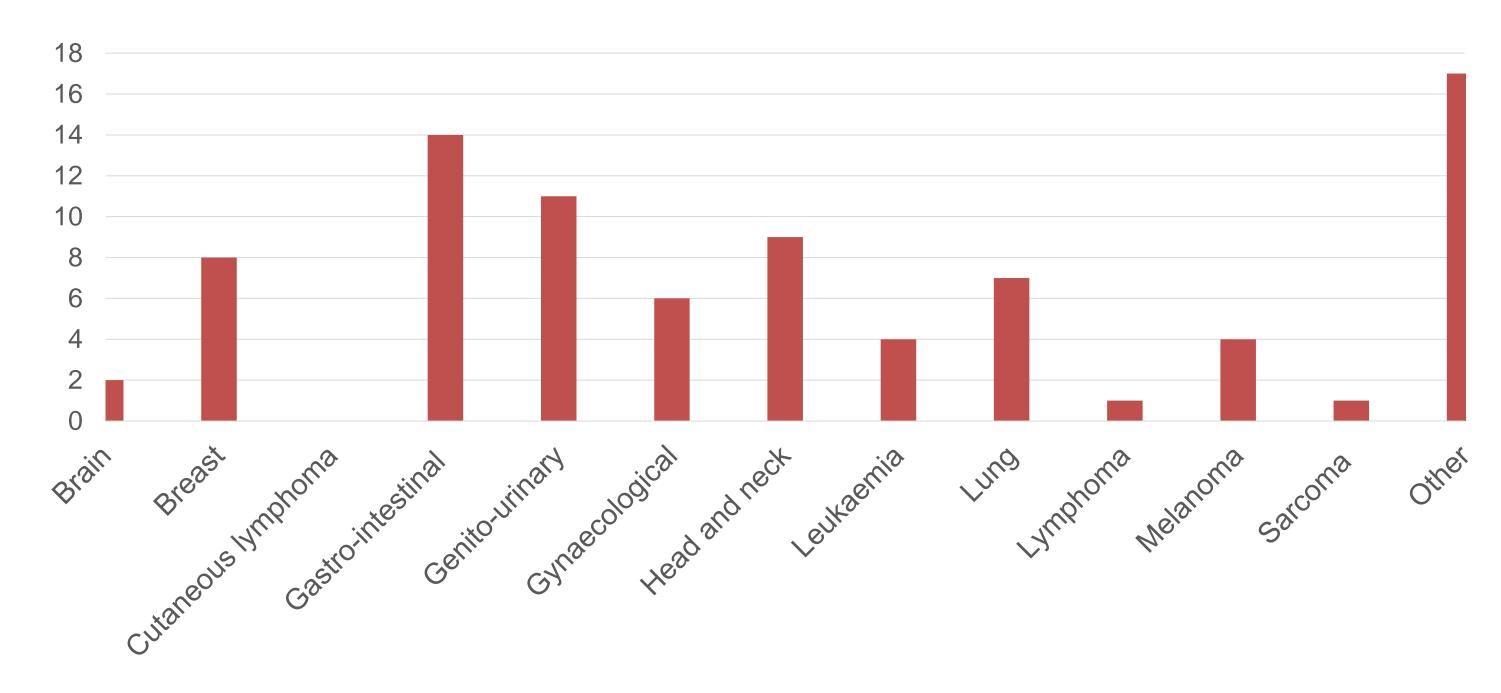


Figure 1: Participant geography reported

- A total of 710 EORTC members (19%) answered the COS questions.
- Most respondents were physicians (93%) working in Europe (93%).
- Breast, genito-urinary, gastrointestinal tract, and lung were the most common cancer specialties respondents work within.

Review of the COMET database



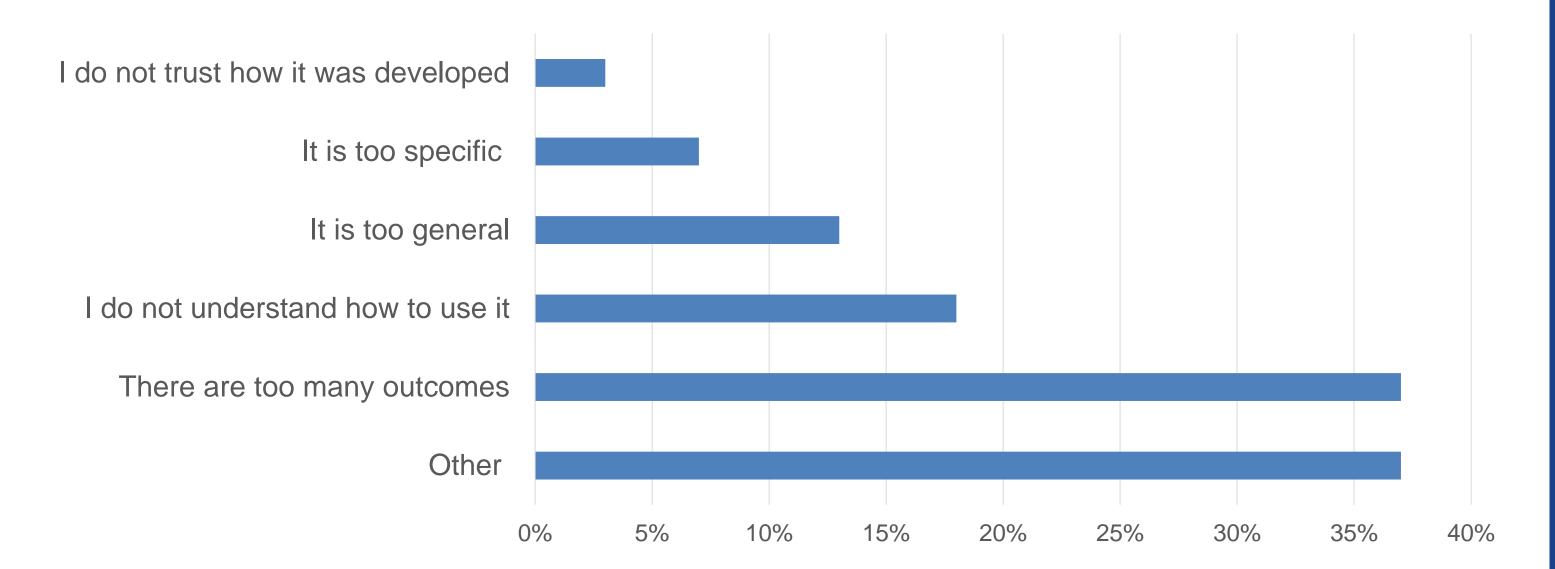


Figure 3: Reasons respondents chose not to implement a COS

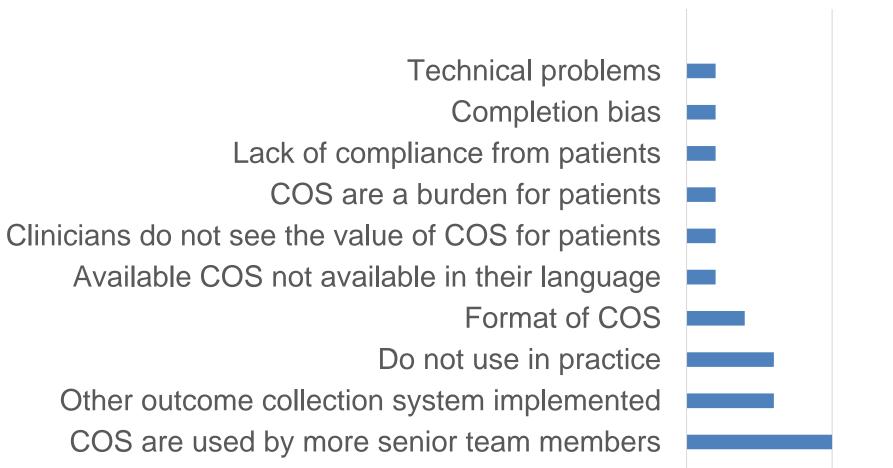


Figure 2: Number of COS per tumour type available on the COMET database

- A total of 85 cancer-related COS were identified.
- Most COS were completed (61 [72%]) or ongoing (22 [26%]), with two (2%) in the planning phase.

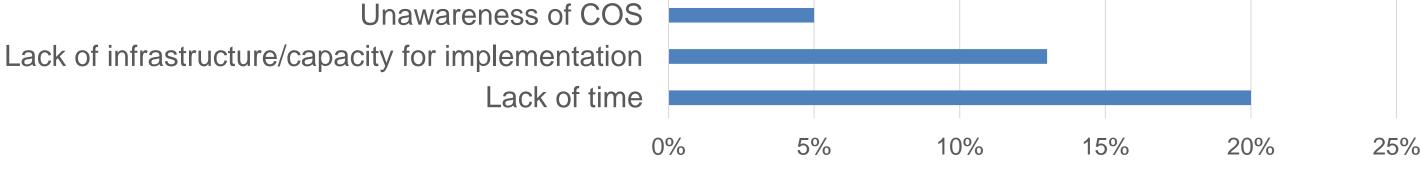


Figure 4: Trialists open-ended responses as to why they do not implement a COS

Conclusion

- To improve COS implementation in cancer clinical trials, COS must be available, trialists must be aware and understand COS, and barriers to COS uptake must be addressed.
- Widespread uptake of COS is possible; relevant COS are reported in over 80% of rheumatoid arthritis trials.