

The Red Hat Group: an initiative to promote broader uptake of core outcome sets through the healthcare research ecosystem

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Background

- **Core outcome sets (COS)** for trials are the minimum set of outcomes that should be measured and reported in all clinical trials in a specific condition. COS can be developed for research, routine care, or both. This allows research to be compared and combined as appropriate, and would ensure that **all** studies provide usable information.
- In the decade leading up to 2019, **uptake** of the rheumatoid arthritis COS in clinical trials was maintained at just over 80% (1). Those commercially funded were more likely to plan to measure the outcomes, probably influenced by **EMA** and **FDA** endorsement of the COS. Uptake is much lower in other clinical areas where assessed, however, and action is needed.
- The landscape surrounding COS has developed significantly over the last five years. Recognition of the potential influence and levers that may incentivise broader uptake of COS across the healthcare research ecosystem is increasing.

Red Hat Group

The Red Hat Group (RHG) was formed at the COMET VII meeting in Amsterdam in 2018, and comprises several initiatives related to improving choice of outcomes in health research – COMET, OMERACT, CS-COUSIN, GRADE, CMTP, COSMIN, CDISC and SONG.

Aims

The initial objective is to work together on a project to share knowledge and understanding of mechanisms to promote uptake of COS in comparative effectiveness research.

Core Outcome Set-STAndards for Development (COS-STAD)

recommendations were established to:

- improve the methodological approach for developing COS,
- and help users assess whether a COS has been developed using a reasonable approach.

The COS-STAD minimum standards for COS development identify **patients, health professionals** and **those who should use the COS in their research** as **key stakeholder groups** to include (2).

In the context of the COS-STAD Delphi exercise, consensus was not quite reached that **'users of the research that should have used the COS'** must be included (2).

Experience of engaging users such as **regulatory bodies, HTA organisations, and clinical guideline development groups** in COS development has been limited to date. The Red Hat Group aims to explore necessary and sufficient conditions for broad endorsement and uptake of COS by these groups.

Methods

- Survey of COS developers about their implementation strategies.
- All groups are identifying their spheres of influence to identify a strategy for improving uptake for two specific COS:
 - osteoarthritis and type II diabetes.
- Plenary panel discussion at OMERACT 2020.

References

1. Kirkham JJ, Bracken M, Hind L, Pennington K, Clarke M, Williamson PR. Industry funding was associated with increased use of core outcome sets. *J Clin Epidemiol.* 2019;115:90-7.
2. Kirkham JJ, Davis K, Altman DG, Blazeby JM, Clarke M, Tunis S, et al. Core Outcome Set-STAndards for Development: The COS-STAD recommendations. *PLoS Med.* 2017;14(11):e1002447.

