

Reporting Factorial Trials (RAFT): Development of Extensions to CONSORT 2010 and SPIRIT 2013 Statements

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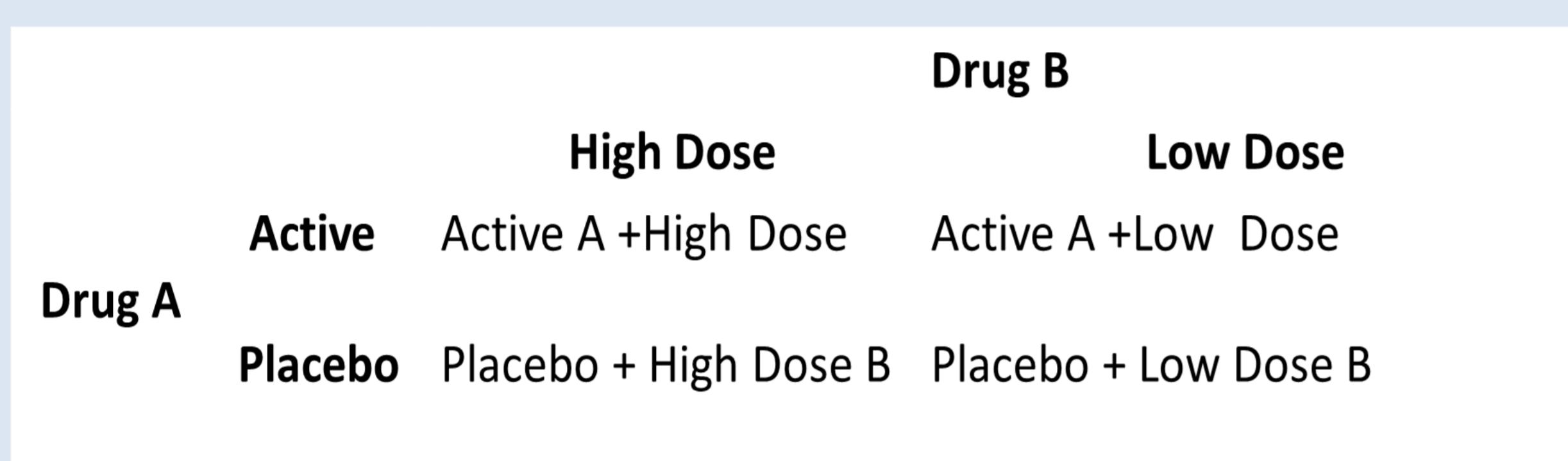
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Summary

- Factorial trials have specific reporting requirements
- The RAFT team are developing SPIRIT [1] and CONSORT [2] extensions to improve the reporting of factorial trials
- Our three-stage approach is summarised here

Background

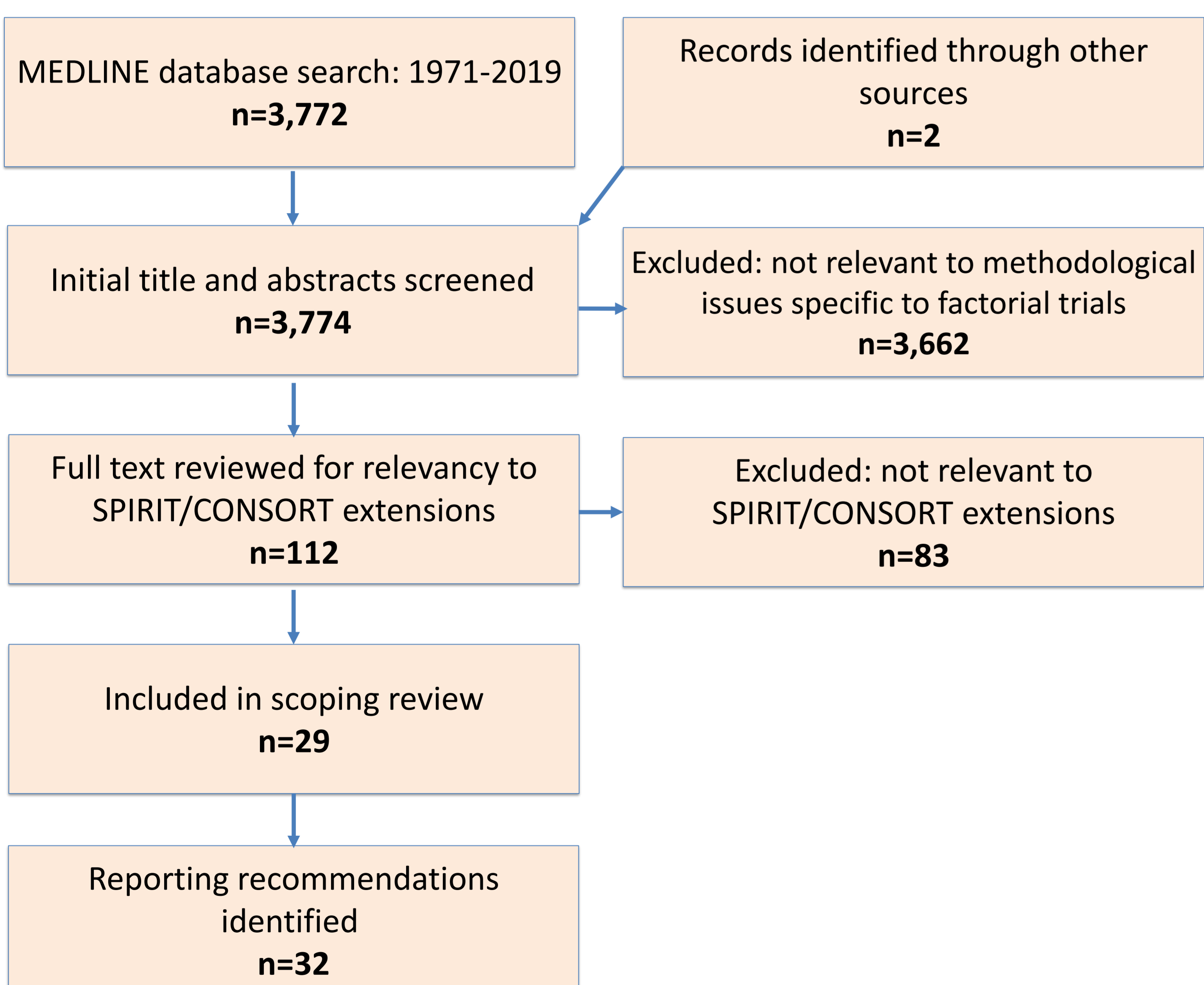
Factorial Trials: ≥2 interventions are assessed within a single study. This introduces methodological complexities and distinct reporting requirements.



Stage 1: Scoping Review

Objective: Develop a 'long-list' of reporting issues to be considered in the SPIRIT and CONSORT extensions.

Figure 1: PRISMA flow diagram

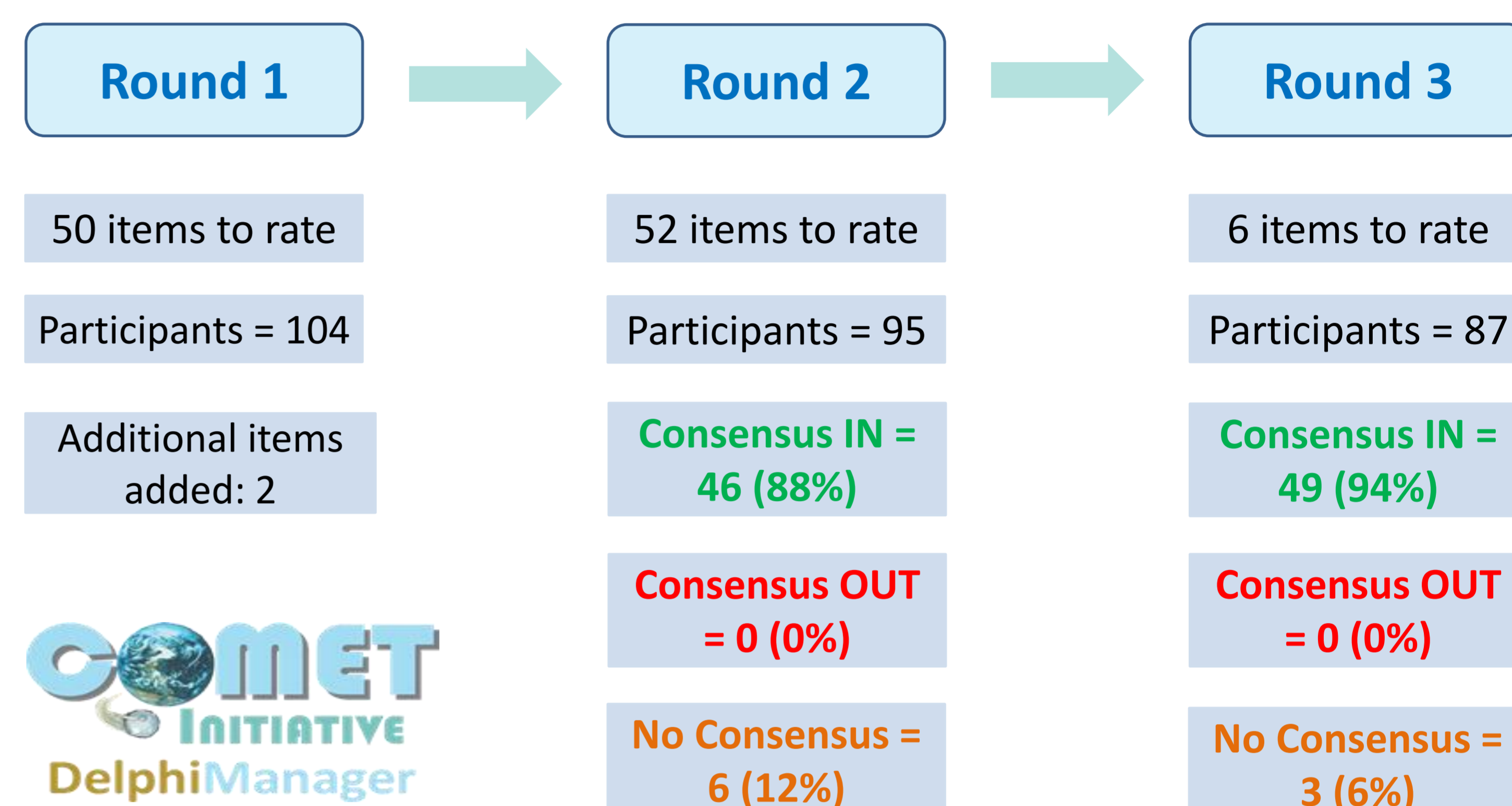


Outcome: The 32 reporting recommendations were developed into a 'long-list' of 50 concepts for further review.

Stage 2: Delphi Survey

Objective: Reduce the 'long-list' developed in stage 1 to a 'short list' through a consensus-based approach

Figure 2: Summary of the Delphi process



Outcome: Concepts that reached consensus were removed after round 2. After round 3 three concepts did not reach consensus. The resulting 'short-list' was reviewed by the Clinical Research Team (CRT) prior to stage 3

Stage 3: Guideline Writing Workshop

Objective: Develop the 'short-list' of concepts from stage 2 into SPIRIT & CONSORT checklist items and the Explanation & Elaboration (E&E).

Members: Experts in guideline reporting, journal editors and factorial trials (n=6) joined the CRT (n=9)



Outcome: Refinement of item wording for the extension checklists and associated documents

NEXT STEPS

The SPIRIT and CONSORT extensions for factorial trials are anticipated to be published in 2023.



References

- Chan, A. W., Tetzlaff, J. M., Gøtzsche, P. C., Altman, D. G., Mann, H., Berlin, J. A., ... & Moher, D. (2013). SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*, 346.
- Schulz, K. F., Altman, D. G., Moher, D., & CONSORT Group*. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Annals of internal medicine*, 152(11), 726-732.