Open consultation: WHO International Clinical Trials Registry Platform guidance for reporting summary results in clinical trial registries

Please rate the importance of the following elements.

Category	Element	Fields/response options
Status and dates	1. Whether trial was stopped early, and why	● Completion status: ○ Completed as planned ○ Stopped early (provide reason – safety, recruitment, efficacy, other) ○ Withdrawn (no participants enrolled)
	2. Dates of reporting results	● Journal publication status: ○ Not yet submitted ○ Submitted (date) ○ Published (date and URL) ● Date of submitting results to registry (auto-populated) ● Date of posting of results in registry (auto-populated)
Participant flow	3. Progress of participants from study enrolment to primary analysis (based on CONSORT flow diagram)	For each group, numbers of participants who: ● Were allocated to intervention ● Did not receive allocated intervention (give reasons) ● Did not complete follow-up (give reasons including due to adverse events) ● Were excluded from analysis (give reasons)
Baseline data	4. Characteristics of participants at baseline	For each group, descriptive summary statistics for: ● Age ● Sex ● Other relevant demographic and study-specific characteristics
Outcome definitions	5. Definition of each primary and secondary outcome (based on WHO Data Set items 19 and 20)	● Specification (primary, secondary) ● Specific measurement variable ● Time point of analysis

Outcome results	6. Summary results by group for each outcome and analysis population	● Analysis population (e.g., all randomized participants in their original assigned group) ● Binary/categorical data: ○ Number of participants with and without the outcome event ● Continuous data: ○ Number of participants ○ Average value (e.g., mean, median) ○ Measure of dispersion (e.g., standard deviation, interquartile range)
	7. Results of comparisons between groups for each outcome and analysis population	● Names of groups being compared (e.g., for multi-arm trials) ● Effect measure (odds ratio, relative risk, hazard ratio, rate ratio, risk difference, difference in means, other) ● Effect size ● Confidence interval and level (e.g., 95%) ● P-value (optional)
Statistical framework	8. Whether the trial was designed to evaluate superiority, non-inferiority, or equivalence	● Framework (superiority, non-inferiority, equivalence, other)
Adverse events	9. Unfavourable changes in health (e.g., new/worsening symptom, abnormal laboratory findings) in each group, regardless of causal relation to the study intervention	Numbers and percentages of participants by group: ● Deaths ● Serious adverse events (overall and by type) ● Other adverse events by type and severity
Public and patient engagement	10. Meaningful and active collaboration of the public and patients in planning, designing, and conducting research	Were the public and patients engaged in shaping: ● Research objectives (Y/N) ● Study design (Y/N) ● Study conduct (Y/N)
Competing interests	11. Financial relationships that create the potential for conflicts of interest	● Any competing interests ○ No ○ Yes (please describe)

Study protocol	12. Full study protocol and statistical analysis plan	● Document upload or URL link to most recent protocol and statistical analysis plan, including version number, date, and history of amendments

Additional elements.

13. What important elements should be added that are relevant to the reporting of results in registries?

14. Any additional comment.