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.

<table>
<thead>
<tr>
<th>Category</th>
<th>Element</th>
<th>Fields/response options</th>
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</table>
| 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   ○ Withdrawn (no participants enrolled)                                                                                                                                     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)  |
<table>
<thead>
<tr>
<th>Study protocol</th>
<th>12. Full study protocol and statistical analysis plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Document upload or URL link to most recent protocol and statistical analysis plan, including version number, date, and history of amendments</td>
</tr>
</tbody>
</table>

Additional elements.

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

14. Any additional comment.