

## World Health Organization (WHO)/International Committee of Medical Journal Editors (ICMJE) – ClinicalTrials.gov Cross Reference

WHO Trial Registration Data Set (v 1.3.1) <sup>1</sup>	ClinicalTrials.gov Registration Data Element(s) <sup>2</sup>
1. Primary Registry and Trial Identifying Number	ClinicalTrials.gov Identifier (NCT Number) - <i>assigned by system</i>
2. Date of Registration in Primary Registry	<i>Generated by system</i>
3. Secondary Identifying Numbers	<a href="#">Unique Protocol Identification Number</a> , <a href="#">Secondary IDs</a>
4. Source(s) of Monetary or Material Support	<a href="#">Name of the Sponsor</a> , <a href="#">Collaborators</a>
5. Primary Sponsor	<a href="#">Name of the Sponsor</a>
6. Secondary Sponsor(s)	<a href="#">Collaborators</a>
7. Contact for Public Queries	<a href="#">Facility Contact</a> OR <a href="#">Central Contact Person</a>
8. Contact for Scientific Queries	<a href="#">Overall Study Officials</a>
9. Public Title	<a href="#">Brief Title</a>
10. Scientific Title	<a href="#">Official Title</a>
11. Countries of Recruitment	<a href="#">Facility Information - Country</a>
12. Health Condition(s) or Problem(s) Studied	<a href="#">Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study</a>
13. Intervention(s)	<a href="#">Intervention Type</a> , <a href="#">Intervention Name(s)</a> , <a href="#">Intervention Description</a> , <a href="#">Arm or Group/Interventional Cross-Reference</a> , <a href="#">Arm Title</a> , <a href="#">Arm Type</a> , <a href="#">Arm Description</a>
14. Key Inclusion and Exclusion Criteria	<a href="#">Eligibility Criteria</a> , <a href="#">Sex/Gender</a> , <a href="#">Age Limits</a> , <a href="#">Accepts Healthy Volunteers</a>
15. Study Type	<a href="#">Study Type</a> , <a href="#">Allocation</a> , <a href="#">Masking</a> , <a href="#">Interventional Study Model</a> , <a href="#">Primary Purpose</a> , <a href="#">Study Phase</a>
16. Date of First Enrollment	<a href="#">Study Start Date</a>
17. Sample Size	<a href="#">Enrollment</a>
18. Recruitment Status	<a href="#">Overall Recruitment Status</a>
19. Primary Outcome(s)	<a href="#">Primary Outcome Measure Information</a> - Title, Description, Time Frame
20. Key Secondary Outcomes	<a href="#">Secondary Outcome Measure Information</a> - Title, Description, Time Frame
21. Ethics Review	<a href="#">Human Subjects Review</a>
22. Completion Date	<a href="#">Study Completion Date</a>
23. Summary Results	<a href="#">ClinicalTrials.gov Results Data Elements</a>
24. IPD Sharing Statement	<a href="#">IPD Sharing Statement</a> – “Plan to Share IPD: Yes” or “Plan to Share IPD: No” required by ICMJE

<sup>1</sup> WHO Trial Registration Data Set: <http://www.who.int/ictpr/network/trds/en/index.html>

<sup>2</sup> ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies: <http://prsinfo.clinicaltrials.gov/definitions.html>