

## CTRI Dataset and Description

CTRI Field	Description
UTRN <sup>WHO</sup> *	<p>Universal Trial Reference Number.</p> <p>The UTRN is a number, obtained by the trial's sponsor or principal investigator from <a href="http://www.who.int/ictrp/registration/utrn/en/index.html">http://www.who.int/ictrp/registration/utrn/en/index.html</a> as the first step in registering a trial on the CTRI. The UTRN will then become part of the trial's international identity along with the CTRI registration number. A trial may have a UTRN but may not be fully registered in the CTRI and receive only a provisional CTRI number unless all required dataset items are fully disclosed.</p>
Title of study <sup>WHO</sup> *	<p>Title intended for the lay public in easily understood language.</p> <p><b>Example:</b> A clinical trial to study the effects of two drugs, ramipril and candesarten in patients with high blood pressure and type 2 diabetes mellitus.</p>
Scientific Title of Study <sup>WHO</sup> *	<p>Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.</p> <p><b>Example:</b> A randomized double-blind placebo controlled crossover clinical trial to compare the safety and efficacy of Ramipril and Candesartan in hypertensive patients with type 2 diabetes mellitus.</p> <p><b>Acronym</b> RACE</p>
Secondary IDs, if any <sup>WHO</sup>	<p>Any other identifying numbers, such as protocol number or any other Trial Registry Number, if registered in another Registry, such as ClinicalTrials.gov, ACTR, ISRCTN etc. There is no limit on the number of Secondary ID numbers that can be provided.</p> <p>In case of a multi-country trial, if the country of origin is, say</p>

	<p>USA, the trial may have already been registered in ClinicalTrial.gov. However, the Indian arm of that trial needs to be registered in India as well. In this case, the ClinicalTrials.gov identifying number would be this trial's Secondary ID number.</p> <p>Select NIL if there are no secondary IDs.</p>
Principal Investigator's Name and Address	Address to include contact telephone and fax numbers and email id. For a multi-center study, enter the contact information for the lead Principal Investigator or overall Trial Coordinator.
Contact Person (Scientific Query) <small>WHO</small>	Email address, telephone number, Fax No and postal address, and affiliation of the local person (in case of multi-country trial) to contact for scientific queries about the trial (local principal investigator, medical contact of sponsor). May or may not be the same as the Principal Investigator in case of single country trial.
Contact Person (Public Query) <small>WHO</small>	Email address, telephone number, Fax No and postal address and affiliation of the contact who will respond to general queries, including information about current recruitment status. This may or may not be the same as the contact person for scientific queries.
Source/s of Monetary or Material Support <small>WHO</small>	Major source(s) of monetary or material or infrastructural support for the trial (e.g., funding agency, foundation, company, hospital, university, etc).
Primary Sponsor <small>WHO</small>	<p>The individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting).</p> <p>The Primary Sponsor is responsible for ensuring that the ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.</p> <p>In commercial trials, the primary sponsor is normally the</p>

	<p>main applicant for regulatory authorization to begin the study. It may or may not be the main funder.</p> <p>In investigator initiated trials, the principal investigator is the primary sponsor, though the institution may be the funder.</p>
Secondary Sponsor <sup>WHO</sup>	<p>Name and address of additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship.</p> <p>A secondary sponsor may have –</p> <ul style="list-style-type: none"> <li>• agreed to take on all the responsibilities of sponsorship jointly with the primary sponsor;</li> <li>• to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group;</li> <li>• to act as the sponsor’s legal representative in relation to some or all of the trial sites; or to take responsibility for the accuracy of trial registration information submitted.</li> </ul>
Countries of Recruitment <sup>WHO</sup>	<p>The countries from which participants will be are intended to be, or have been recruited.</p> <p>E.g.: India-for trials conducted only in India; India, USA, France-for multi-country trials</p>
Site/s of study	<p>First list all site/s within the country including the site address as well as the complete address, email, telephone number and Fax No of responsible contact person at each site.</p> <p>For multi-country trials, list all site/s within each country (if available) including the site address as well as the complete address, email, telephone number and Fax No of responsible contact person at each site.</p>
Name of Ethics Committee and approval status*	<p>Provide name of Ethics Committee from whom approval has been sought; for multi-centre trials, add names of all ethics committee from whom approval has been sought; also provide approval status, i.e. submitted for approval or</p>

	approved. Please send the ethics committee approval documents to: Clinical Trials Registry- India, National Institute of Medical Statistics
Regulatory Clearance obtained from DCGI*	Mention whether approval has been taken from DCGI or not. Please forward approval letter to: Clinical Trials Registry-India, National Institute of Medical Statistics.
Brief Summary	<p>Short description of the primary purpose of the protocol, including a brief statement of the study hypothesis.</p> <p><b>Example:</b> This study is a randomized, double blind, parallel group, multi-centre trail comparing the safety and efficacy of Ramipril 2.5 mg daily and Candesartan 16 mg daily for 12 months in 500 patients with diabetes and hypertension that will be conducted in five centers in India, three in France and five in USA. The primary outcome measures will be all-cause mortality at five years and Mean Beck Depression Score at 18 weeks. The secondary outcomes will be all-cause mortality at 6 months and 1 year; and Mean glycosylated hemoglobin A1C at 4 and 8 weeks.</p>
Health Condition/Problem studied <sup>WHO</sup>	<p>State the primary health condition(s) or problem(s) studied. If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g., preventative or screening interventions), enter the particular health condition(s) or problem(s) being prevented or screened</p> <p><b>Example:</b> Type 2 Diabetes Mellitus; Hypertension</p>
Study Type <sup>WHO</sup>	<p>Please enter here whether the trial is a single arm study, a controlled non-randomized trial or a randomized controlled trial.</p> <p>A single arm study is one in which all participants are given the same intervention. Trials in which participants are assigned to receive one of two or more interventions are NOT single arm studies. Crossover trials are NOT single arm studies.</p>

	<p>A trial is "randomized" if participants are assigned to intervention groups using a method based on chance (e.g., random number table, random computer-generated sequence, minimization, adaptive randomization).</p> <p>An active controlled trial compares standard or other treatment with the experimental treatment.</p> <p>A multiple arm trial may also include a placebo comparison</p> <p><b>Examples:</b></p> <p>Single arm trial</p> <p>Non-randomized, placebo controlled trial</p> <p>Non-randomized, active controlled trial</p> <p>Non-randomized, multiple arm trial</p> <p>Randomized, parallel group, placebo controlled trial</p> <p>Randomized, parallel group, active controlled trial</p> <p>Randomized, parallel group, multiple arm trial</p> <p>Randomized, crossover trial</p> <p>Cluster randomized trial</p> <p>Randomized factorial trial</p>
<p>Intervention and Comparator agent <a href="#">WHO</a></p>	<p>Enter the specific name of the intervention(s) and the comparator/control(s) being studied. Use the International Non-Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g., "low-fat diet, exercise").</p> <p>The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that intervention, or enter</p>

	<p>"placebo" or "no treatment" as applicable.</p> <p>For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc).</p> <p><b>Example:</b>  Ramipril  2.5 mg od for 12 months</p> <p>Candesartan  16 mg od for 12 months</p>
<p>Key inclusion /Exclusion Criteria  WHO</p>	<p>Inclusion and exclusion criteria for participant selection, including age and sex.</p> <p><b>Example:</b>  Inclusion criteria</p> <p>Adult males or females aged between 20 and 60 years of age with a diagnosis of type 2 diabetes mellitus and hypertension</p> <p>Hypertension defined as systolic blood pressure of 140 mmHg or diastolic blood pressure of 90 mmHg</p> <p>Diabetes defined as those patients with fasting glucose levels of <math>\geq 126</math> mg/dl or random blood glucose <math>&gt;</math> or <math>= 200</math> mg/dl, HbA1c <math>&gt;</math> or <math>= 6.5\%</math>, 2 h blood glucose on 75 g oral glucose tolerance test (OGTT) <math>&gt;</math> or <math>= 200</math> mg/dl, or current treatment with hypoglycemic therapy).</p> <p><b>Exclusion Criteria:</b>  A history of coronary heart disease or stroke, serum creatinine <math>\geq 1.5</math> mg/dl, albuminuria <math>\geq 40</math> <math>\mu</math>g/min, and use of lipid-lowering drugs, aspirin, or other antihypertensive agents.</p>
<p>Method of generating randomization sequence</p>	<p>The method used to generate the random allocation sequence.</p> <p>The main purpose of randomization is to eliminate selection bias and balance known and unknown confounding factors in order to create a control group that is as similar as possible</p>

	<p>to the treatment group. Methods for randomly assigning participants to groups, which limits bias, include the use of a table of random numbers and a computer program that generates random numbers. Methods of assignment that are prone to bias include alternating assignment or assignment by date of birth or hospital admission number.</p> <p><b>Example:</b>  Coin toss, lottery, toss of dice, shuffling cards etc  Random number table  Computer generated randomization  Permuted block randomization, fixed  Permuted block randomization, variable  Stratified randomization  Stratified block randomization  Adaptive randomization, such as minimization  Other, describe</p>
Method of allocation concealment	<p>Any method whereby allocation of the next participant is known beforehand, such as alternation or an open list of random numbers, may prompt investigators to select the next participant according to conscious or unconscious needs that can seriously bias the selection process. Concealment of the randomization sequence is critical to prevent selection bias. Adequate allocation concealment is a pre-requisite for adequate blinding.</p> <p>Adequate allocation concealment methods include:</p> <ul style="list-style-type: none"> <li>• centralized (e.g. allocation by a central office unaware of subject characteristics)</li> <li>• pharmacy-controlled randomization</li> <li>• pre-numbered or coded identical containers which are administered serially to participants</li> <li>• on-site computer system combined with allocations kept in a locked unreadable computer file</li> <li>• sequentially numbered, sealed, opaque envelopes</li> </ul>

	<p>Allocation concealment that is prone to bias include</p> <ul style="list-style-type: none"> <li>• alternation</li> <li>• case record numbers</li> <li>• dates of birth or day of the week</li> <li>• an open list of random numbers and</li> <li>• any procedure that is entirely transparent before allocation</li> </ul>
Blinding and masking	<p>Blinding refers to methods used to prevent participants and investigators from knowing what interventions are being used. Open trials do not use blinding. Masking refers to the methods used to camouflage interventions to achieve blinding.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Open label</li> <li>• Participant blinded</li> <li>• Investigator blinded</li> <li>• Outcome assessor blinded</li> <li>• Participant and outcome assessor blinded</li> <li>• Participant, investigator and outcome assessor blinded</li> <li>• Participant, investigator, outcome assessor and data-entry operator/statistician blinded</li> </ul>
Primary Outcome/s <sup>WHO</sup>	<p>Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention. The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention(s).</p> <p>Enter the names of all primary outcomes in the trial as well as the pre-specified timepoint(s) of primary interest. Be as</p>

	<p>specific as possible with the metric used (e.g., “% with Beck Depression Score &gt; 10 ”rather than just “depression”).</p> <p><b>Examples</b>  Outcome Name: all-cause mortality, Time-points: 5 years; or  Outcome Name: Mean Beck Depression Score, Time-point: 18 weeks.</p>
Secondary Outcome/s <small>WHO</small>	<p>Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at time-points of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at time-points other than those of primary interest (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: all-cause mortality at 1 year, 3 years), or may involve a different event, variable, or experience altogether (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: hospitalization rate at 5 years).</p> <p>Enter the name and time-point(s) for all secondary outcomes of clinical and/or scientific importance.</p>
Target sample size <small>WHO</small>	<p>Total number of participants that this trial plans to enroll. This is a numbers only field</p> <p><b>Example</b> 500</p>
Phase of Trial *	<p>Phases of investigation, usually applied to a drug trial</p> <p><u>Phase 1</u>: includes initial study to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients (such as those testing anticancer or anti-HIV drugs) . Trials are often dose ranging trials which are done to determine the maximum dose of a new medication that can be safely given to a patient.</p> <p><u>Phase 1 / Phase 2</u>: for trials that are at a combined stage of phases 1 and 2</p>

	<p><u>Phase 2</u>: includes controlled clinical study conducted to evaluate/test the effectiveness of a new drug/medication or intervention for a particular indication or indications in patients with the disease or condition being studied and to determine the common short-term side effects and risks</p> <p><u>Phase 2 / Phase 3</u>: for trials that are at a combined stage of phases 2 and 3</p> <p><u>Phase 3</u>: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of a new drug/medication or intervention, including possible adverse reactions. It is also to provide an adequate basis for physician labeling</p> <p><u>Phase 3 /Phase 4</u>: for trials that are at a combined stage of phases 3 and 4</p> <p><u>Phase 4</u>: post-marketing study to delineate additional information. Trials are done to monitor the toxicity, risks, utility, benefits and optimal use after the efficacy of the drug/medication or intervention has been proven</p> <p><u>Not applicable</u>: this selection is for a non-drug trial</p> <p><b>Example</b> Phase 3</p>
Date of first enrollment <sup>WHO</sup>	Anticipated or actual date of enrollment of the first participant
Estimated duration of trial	Specify the expected time duration of trial, starting from enrollment of first patient to final submission of report.
Status of Trial <sup>WHO</sup> *	<ul style="list-style-type: none"> <li>○ <b>Not yet recruiting</b>: Yet to initiate patient enrolment</li> <li>○ <b>Open to recruitment</b>: Participants are currently being recruited and enrolled</li> <li>○ <b>Temporary halt or suspended</b>: There is a temporary halt in recruitment and enrolment but potentially will</li> </ul>

	<p>resume</p> <ul style="list-style-type: none"><li>○ <b>Terminated:</b> Recruiting or enrolling participants has halted and will not resume</li><li>○ <b>Closed to recruitment of participants:</b> Follow-up continuing</li><li>○ <b>Closed to recruitment of participants:</b> Follow-up complete</li><li>○ <b>Completed:</b> Closed to recruitment of participants and data analysis complete</li></ul>
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For any clarifications please contact –

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