CTRI Dataset and Description

CTRI Field	Description
Public title of study	Title intended for the lay public in easily understood language. **Example:** A clinical trial to study the effects of two drugs, ramipril and candesartan in patients with high blood pressure and type 2 diabetes mellitus.
Scientific title of study Acronym, if any	Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available. **Example:** 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. **Acronym** RACE
Secondary IDs, if any	Secondary ID is any number that is associated with a clinical trial, 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. In case of a multi-country trial, the trial may have already been registered in another registry such as the www.ClinicalTrials.gov. However, the trial, if also being conducted in India needs to be registered in the CTRI as well. In this case, the ClinicalTrials.gov identifying number would be this trial's Secondary ID number. **Universal Trial Number** UTN (earlier known as UTRN) may be obtained from http://apps.who.int/trialsearch/utn.aspx Please quote the obtained UTN number under SECONDARY ID. Currently obtaining the UTN is not mandatory **If there are no secondary IDs** select NIL from the drop down list and type in NIL in the corresponding box.

Principal Investigator's name and address	Details should include name, official address, affiliation and designation, contact telephone and fax numbers and email ID. For a multi-center study, enter the contact information for the lead Principal Investigator (PI) or overall Trial Coordinator. Designated person must be from India (for trials being conducted in India). This is not a mandatory field.
Contact person (Scientific Query)	Details should include name, official address, affiliation and designation, 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 PI.
Contact person (Public Query)	Details should include name, official address, affiliation and designation, email address, telephone number, Fax No and postal address 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	Major source/s of monetary or material or infrastructural support for the trial (e.g., funding agency, foundation, company, hospital, university, etc).
Primary sponsor	Name and address of 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). The Primary Sponsor is responsible for ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main source of funding. In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main source of funding. In investigator initiated trials, the principal investigator is the primary sponsor, though the affiliated institution may be the main source of funding, and acknowledged under "Source/s of Monetary or Material Support".

Secondary Sponsor	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. A secondary sponsor may have – • Agreed to take on all the responsibilities of sponsorship jointly with the primary sponsor; • To form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; • 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.
Countries of recruitment	Select from drop down list, countries from which participants are intended to be, or have been recruited. E.g.: India - for trials conducted only in India; India, USA, France - for multi-country trials (as the case may be)
Site/s of study	List all site/s within India including the site address as well as the complete address, email, telephone number and Fax No of responsible contact person at each site (This individual should be a medically qualified person and to whom the EC approval is addressed, i.e. the PI; in case a separate person is mentioned, the PI should also be mentioned in any of the other contact person details ("PI or Overall trial coordinator, Contact Person (Scientific query or Public query). **For PMS trials** with hundreds of trial sites, site details may be 'copy-pasted' in the Brief summary, specifying the few initiated sites under "Site/s of study"
Name of Ethics Committee and approval status	Provide name of Ethics Committee (EC) from whom approval has been sought; for multi-centre trials, add names of all ECs from whom approval has been sought; also provide approval status, i.e. submitted for approval or approved with date. As per the DCGI notice File No. ECR/Misc/Indt EC/007/2013 dated 30/07/2013, no clinical trial shall be approved by IEC(Independent Ethics Committee). Accordingly select 'NO' for IEC. Therefore henceforth all clinical trials should be approved by Institutional Ethics Committee.

	Mention EC approval status of each site separately even if it is "under review" and/or from the same IEC (please mention the city from which the IEC functions). **For PMS trials "Not applicable" or "No objection certificate obtained" as appropriate.**
Regulatory clearance obtained from DCGI	Mention whether approval has been taken from Drugs Controller General (India) [DCGI] or not. If DCGI has been notified, the same should be selected. **It is the responsibility of the Sponsor to ascertain whether or not DCGI approval is required for a particular trial**.
Health condition/problem studied	State the category of trial participant: Healthy human volunteers or patients. Once patients is selected, the International Classification of Diseases-10 coded drop down list provided up to a maximum of four levels of disease categories. Sometimes the relevant disease category maybe available in the third or fourth category. For example: For dental trials, choose *Diseases of digestive system (K series)* and then *Diseases of Oral cavity and salivary glands* and at the third level the appropriate disease classification for study. For Surgical/anaesthesia trials, the appropriate health condition would be available under *(PCS) ICD 10 Procedure Coding System Codes* For studies in pregnant participants, please choose Patients and then the appropriate condition from the O series related to pregnancy
Study type	Please indicate if trial part of post-graduation thesis. Please choose "Yes" if study is part of post-graduation thesis. Please note that all thesis based clinical studies including MSc/DM/PhD etc would be classified as "Yes" purely for categorization purposes.

	Please select whether the trial is an Interventional trial, Observational trial or Post marketing surveillance **Interventional Trial:** An interventional trial is one that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effect on outcomes. Choose the intervention that is best suited for the trial, more than one option may be selected according to the intervention/s being used; e.g. Drug & Ayurveda **Observational Trial** An observational trial is one where no experimental intervention or treatment is given to human participants. In this type of trial, the investigator only observes the effect of a risk factor, diagnostic test, or treatment on a particular outcome. Choose the intervention that is best suited for the trial. PMS: Post marketing surveillance study Choose a Study Design from the list provided **Examples:** Single arm trial Non-randomized, placebo controlled trial Non-randomized, active controlled trial Non-randomized, multiple arm trial Randomized parallel group trial Randomized, parallel group, placebo controlled trial Randomized, parallel group, active controlled trial Randomized, parallel group, multiple arm trial Randomized, crossover trial Cluster randomized trial Randomized factorial trial
Intervention and comparator agent	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"). 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 "placebo" or "no treatment" as applicable. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc). **Example:** Ramipril 2.5 mg OD for 12 months Candesartan 16 mg OD for 12 months For observational trials, NIL may be mentioned with trial details mentioned in the Brief Summary.
Inclusion/ Exclusion criteria	Inclusion and exclusion criteria for participant selection, including age and sex. Age and sex to be mentioned in specific boxes. **Example:** Inclusion criteria Adult males or females with a diagnosis of type 2 diabetes mellitus and hypertension Hypertension defined as systolic blood pressure of 140 mmHg or diastolic blood pressure of 90 mmHg Diabetes defined as those patients with fasting glucose levels of $\geq$ 126 mg/dl or random blood glucose > or = 200 mg/dl, HbA1c > or = 6.5%, 2 h blood glucose on 75 g oral glucose

	tolerance test (OGTT) > or = 200 mg/dl, or current treatment with hypoglycemic therapy). **Exclusion Criteria:** A history of coronary heart disease or stroke, serum creatinine ≥1.5 mg/dl, albuminuria ≥40 µg/min, and use of lipid-lowering drugs, aspirin, or other antihypertensive agents. **Please separate each criteria by using the "Enter" button**
Method of generating randomization sequence	The method used to generate the random allocation sequence. The main purpose of randomization is to eliminate selection bias and balance known or unknown confounding factors in order to create a control group that is as similar as possible 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. **Example:** 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
Method of allocation concealment	Concealment of the randomization sequence is critical to prevent selection bias. Adequate allocation concealment is a pre-requisite for adequate blinding. Adequate allocation concealment methods include:

	• centralized (e.g. allocation by a central office unaware of subject characteristics) • pharmacy-controlled randomization • pre-numbered or coded identical containers which are administered serially to participants • on-site computer system combined with allocations kept in a locked unreadable computer file • sequentially numbered, sealed, opaque envelopes Allocation concealment that is prone to bias include • alternation • case record numbers • dates of birth or day of the week • an open list of random numbers and • any procedure that is entirely transparent before allocation
Blinding/masking	Blinding refers to methods used to prevent participants and investigators from knowing what interventions are being used to reduce bias. Open trials do not use blinding. Masking refers to the methods used to camouflage interventions to achieve blinding. Examples: • Open label • Participant blinded • Investigator blinded • Outcome assessor blinded • Double blind double dummy • Participant and Investigator blinded • Participant and outcome assessor blinded • Participant, investigator and outcome assessor blinded • Participant, investigator, outcome assessor and data-entry operator/statistician blinded
Primary outcome/s	Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention. The primary outcome could be the

	outcome used in sample size calculations, or the main outcome/s used to determine the effects of the intervention/s. Enter the names of all primary outcomes in the trial as well as the pre-specified timepoint/s of primary interest. Be as specific as possible with the metric used (e.g., "% with Beck Depression Score > 10 "rather than just "depression"). **Examples** Outcome Name: all-cause mortality, Time-points: 5 years; or Outcome Name: Mean Beck Depression Score, Time-point: 18 weeks.
Secondary outcome/s	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). Enter the name and time-point(s) for all secondary outcomes of clinical and/or scientific importance.
Target sample size	Total number of participants that the trial plans to enroll. **For global/multi-country trials**, enter both Total sample size and Target sample size from India. This is a numbers only field. **Example** Target sample size **120** India **500** Total **For trials being conducted only in India**, target sample should be same under both columns Target sample size **120** India **120** Total
Phase of trial	Phases of investigation, usually applied to a drug trial

	Phase 1: includes initial study to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing does, 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. Phase 1 / Phase 2: for trials that are at a combined stage of phases 1 and 2 Phase 2: 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 Phase 2 / Phase 3: for trials that are at a combined stage of phases 2 and 3 Phase 3: 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 Phase 3 /Phase 4: For trials that are at a combined stage of phases 3 and 4 Phase 4: Studies (other than routine surveillance) performed after drug is marketed and is related to the approved indication. 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. N/A (Not applicable): This selection is for a non-drug trial, BA/BE trial. Post marketing surveillance: Routine surveillance trials after marketing approval

	Example Phase 3
Date of first enrollment	Select anticipated or actual date of enrollment of the first participant from the calendar. **For global/multi-country trials**, both global trial start date as well as start date in India should be mentioned. **Example** **date of first enrollment** 02/05/2009 **India** 15/06/2010 **Global**
Estimated duration of trial	Specify the expected time duration of trial, starting from enrollment of first patient to final submission of report.
Recruitment status of trial	Indicate status of trial. **For global/multi-country trials** enter status of global arm as well as Indian arm o **Not Yet Recruiting**: Yet to initiate patient enrolment o **Open to Recruitment**: Participants are currently being recruited and enrolled o **Suspended**: There is a temporary halt in recruitment and enrolment but potentially will resume o **Completed**: Closed to recruitment of participants and data analysis complete • **Closed to recruitment of participants**: Follow- up continuing • **Other(Terminated)**: Recruiting or enrolling participants has halted and will not resume ***Additional Note***: Once a study is completed or terminated, the registered trial status must be updated accordingly. Subsequently two additional data set fields will be displayed which are to be filled as appropriate. **Date of Study Completion (India)** **Date of Study Completion (Global)** The date of study completion is the date of last visit of last trial participant (even if trial was terminated). For a detailed definition visit WHO's ICTRP (https://prsinfo.clinicaltrials.gov/definitions.html#PrimaryCompletionDate).

	For trials which are being conducted only in India, Date of Study Completion (Global) would be Not Applicable. AND **Final Enrolment numbers achieved (Total)** **Final Enrolment numbers achieved (India)** For global i.e. multi-country trials, both global and India final and actual enrolled number of patients should be mentioned. For trials which are being conducted only in India, the same number should be mentioned in both the above sections.
Brief Summary	Short description of the primary purpose of the protocol, including a brief statement of the study hypothesis. Include publication/s details (link/reference), if any. **Example:** This study is a randomized, double blind, parallel group, multi-centre trial 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.
Publication	Publication which arise directly out of this trial results are to be mentioned. If there are none yet, please mention NIL
Individual Participant Data (IPD) Sharing Statement	Data sharing plan is a requirement of the International Committee of Medical Journal Editors (ICMJE) for interventional clinical trials which begin enrolling participants on or after 1 January 2019. Please note that the data sharing plan may change after registration and during the publication process but should be accordingly updated in the CTRI records as well as reflected in the statement published with the manuscript. Data sharing plan details must indicate whether individual de-identified participant data will be shared ("undecided" or "will be finalized later" is not acceptable); what data in particular will be shared; when, where and how these will be shared,

	conditions if any for full access, whether additional documents such as protocol, etc. will be also available are to be detailed

For any clarifications please contact –

Clinical Trials Registry – India
National Institute of Medical Statistics
Indian Council of Medical Research
Ansari Nagar
New Delhi-110029
India
Telephone: 91-11-26588725, 01126588905
Email: ctri@gov.in