

Please note: This document includes the definitions and explanation of the data items to be completed when submitting a clinical trial for registration on the ANZCTR. The information requested is based on the definitions and set requirements for trial registration from the International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO) trial registration minimum data set.

Mandatory data items for trial registration with the ANZCTR are marked in **BOLD**.

Data Item	Definition/Explanation
1. Public title	Title of the study is intended for the lay public and should be in easily understood language. It is the title chosen by the researcher(s). Acronyms should not be used in this field. This field will be displayed on the main search page of the WHO search portal.
2. Study title in 'Participant-Intervention-Comparator-Outcome (PICO)' format	This is the scientific name of the study provided by the principal investigator or sponsor. This title must be in PICO format including the name of the intervention, the condition being studied, and the primary outcome to be assessed. The registrant does not have to use this title for their publication, ethics application or any other documents.
3. Secondary IDs	<p>Other identifying numbers and issuing authorities other than the ANZCTR if any. For example, if the trial has already been registered with another registry, for example, ISRCTN or ClinicalTrials.gov, the secondary ID number and organisation name should be listed. There is no limit on the number of Secondary identifying numbers that can be provided.</p> <p>It is possible that the trial may not have a secondary ID. Please include the text 'Nil' if there are no secondary IDs.</p> <p>Enter only one identifying number and issuing authority in the box (one at a time). Click "Add" to add more boxes if the study has multiple identifying numbers and issuing authorities. There is no limit to the number of Secondary ID entries (boxes) that can be added.</p>
4. Trial acronym	If the study has trial acronym, enter in this section. Otherwise, please leave it blank.
5. Health condition(s) or problem(s) studied	<p>Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented.</p> <p>Enter only one health condition or problem studied in the box (one condition per box). Click "Add" to add more boxes if the study has multiple health conditions or problems studied. The form allows <u>maximum of 20 entries</u> (boxes) for the health condition(s) or problem(s) studied.</p>
6. Condition category and Condition code	<p>Choose the most appropriate condition category (1st level) and condition code (2nd level) for the study from the list.</p> <p>Click "Add" to add more boxes if the study has multiple condition categories and condition codes. The form allows <u>maximum of 3 sets of entries</u> for the condition category and condition code.</p>

Data Item	Definition/Explanation
<p>7. Description of intervention(s) / exposure</p>	<p>Describe the specific name of the intervention(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. <u>If the intervention consists of several separate treatments, list them all in one line separated by commas</u> (e.g., "low-fat diet, exercise").</p> <p>For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc)</p> <p>For an observational study, this is a description of the condition observed. The duration of the observation must also be described.</p>
<p>8. Intervention code</p>	<p>Choose the most appropriate intervention code for the study from the list if it is an interventional study. If it is an observational study, please choose "Not applicable – Observational study".</p> <p>The form allows <u>maximum of 3 entries</u> for the intervention code.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Not applicable – Observational study <input type="checkbox"/> Diagnosis <input type="checkbox"/> Early detection / screening <input type="checkbox"/> Prevention <input type="checkbox"/> Treatment: drugs <input type="checkbox"/> Treatment: surgery <input type="checkbox"/> Treatment: devices <input type="checkbox"/> Treatment: other <input type="checkbox"/> Rehabilitation <input type="checkbox"/> Lifestyle <input type="checkbox"/> Behaviour <input type="checkbox"/> Other interventions
<p>9. Comparator / control treatment</p>	<p>Describe the specific name of the comparator/control treatment being studied. The control intervention(s) or comparator(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", "standard treatment" or "no treatment" as applicable.</p> <p>Describe other details of the comparator/control treatment as applicable (what placebo used or what the standard treatment is, dose, duration, mode of administration, etc).</p>
<p>10. Control group</p>	<p>A "control" group is the type of treatment to which the intervention is being compared. Also known as a "comparator" group. Choose the most appropriate description of the study's control group from the list.</p> <p><u>Placebo</u>: an inactive or sham treatment that has no treatment value is given to the subjects, such as sugar pill or saline solution. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment.</p> <p><u>Active</u>: when the control treatment is active. This includes standard care, alternate forms of treatment, no treatment given, or if patients act as their own control (crossover study).</p> <p><u>Uncontrolled</u>: when there is no control group, as in single group trials. The same intervention is applied to all subjects in the study.</p> <p><u>Historical</u>: a group of people who received their care in the past, i.e., not at the same time as the people receiving the intervention. This selection is not applicable if the trial is a randomised controlled trial.</p> <p><u>Dose comparison</u>: the comparator group receives the same treatment as the intervention group, but in a different dose. Dose, duration and mode of</p>

Data Item	Definition/Explanation
	administration for both the intervention and control groups need to be described in the intervention field.
<p>11. Primary outcome and Timepoint (s)</p>	<p>Primary outcome(s) is the outcome which provides the primary measure of the effectiveness (or lack of effectiveness) of the intervention. In many studies, more than one variable is used as a primary outcome measure. <u>The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effect of the intervention(s).</u></p> <p>Provide specific names of all primary outcomes of the trial, one at a time, e.g., “% with Beck depression score > 10” rather than just “depression”. Instrument(s) to be used for the assessment/measurement needs to be included/described where possible.</p> <p>For each outcome, also provide all the timepoints at which it is to be measured.</p> <p>Enter only one primary outcome in the primary outcome box (one at a time) and the timepoint(s) at which this particular outcome is measured in the timepoint box. Click “Add” to add more boxes if the study has multiple primary outcomes. The form allows <u>maximum of 3 sets of entries</u> for the primary outcome and timepoint.</p> <p><u>Examples:</u></p> <p>Primary Outcome 1: all cause mortality Timepoint: at one year after randomisation</p> <p>Primary Outcome 2: mean Beck depression score Timepoint: at baseline and at 6, 12, and 18 weeks after intervention commencement</p>
<p>12. Key secondary outcome(s) and Timepoint (s)</p>	<p>Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at timepoints of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at timepoints 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>Provide only specific key secondary outcomes of the trial. Instrument(s) to be used for the assessment/measurement needs to be included/described where possible. For each outcome, also provide all the timepoints at which it is to be measured.</p> <p>Enter only one secondary outcome in the secondary outcome box (one at a time) and the timepoint(s) at which this particular outcome is measured in the timepoint box. Click “Add” to add more boxes if the study has multiple secondary outcomes. The form allows <u>maximum of 20 sets of entries</u> for the key secondary outcome(s) and timepoint(s).</p> <p><u>Examples:</u></p> <p>Secondary Outcome 1: cardiovascular mortality Timepoint: at 6 months after randomisation</p> <p>Secondary Outcome 2: functional status Timepoint: at baseline and at 4 and 18 weeks after intervention commencement</p>
<p>13. Key inclusion criteria</p>	<p>Summary of key inclusion criteria of patient characteristics that determine eligibility for participation in the study.</p>
<p>14. Age</p>	<p>Specify age range of the study's participants.</p> <p>Enter the numbers for minimum and maximum ages and choose the unit to specify the period (for the age) from the list; Years, Months, Weeks, Days,</p>

Data Item	Definition/Explanation
	<p>Hours, No limit, N/A. If there is no age limit for either minimum or maximum age or both leave the box(es) for the number(s) blank and select "No limit" from the unit of measurement list for either minimum or maximum age or both.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Weeks <input type="checkbox"/> Days <input type="checkbox"/> Hours <input type="checkbox"/> No limit <input type="checkbox"/> N/A <input type="checkbox"/> Not stated <p><u>Examples:</u></p> <p>Minimum age: 18 Years Maximum age: No limit</p> <p>Minimum Age: 20 Weeks Maximum Age: 6 Months</p> <p><u>Note:</u> The selection "Not stated" is only relevant to trials registered prior to this additional data item on the registration form, and when the registrant did not include this information elsewhere on the registration form. It should <u>not</u> be selected for prospective trials submitted for registration.</p>
15. Gender	<p>Choose the appropriate description for gender of the study's participants.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Males <input type="checkbox"/> Females <input type="checkbox"/> Both males and females
16. Healthy volunteers?	<p>Specify whether or not the study includes healthy volunteers.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No
17. Key exclusion criteria	<p>Summary of key exclusion criteria of patient characteristics that determine eligibility for participation in the study.</p>
18. Study type	<p>Choose the appropriate study type from the list.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Interventional <input type="checkbox"/> Observational <p>Interventional Study - Any research study that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effect on outcomes. Interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral approaches, process-of-care changes, preventive care, diagnostic procedures.</p> <p>Observational Study - A study in which no experimental intervention or treatment is applied. The investigator <u>observes</u> the effect of a risk factor, diagnostic test, or treatment on a particular outcome, e.g., the relationship between smoking and heart attacks. It involves observing without altering or influencing that which is being observed. For example, in an observational study, the researchers examine and report on what is happening, without controlling the course of events. Certain outcomes are measured but no attempt is made to affect the outcome (for example, no treatment or no experimental intervention is given).</p>
19. Purpose of the study	<p>If the study is an interventional study, choose the most appropriate purpose of the study from the list.</p> <p><u>Treatment:</u> study designed to evaluate one or more interventions for treating a</p>

Data Item	Definition/Explanation
	<p>disease, syndrome or other health condition(s).</p> <p><u>Prevention</u>: study designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.</p> <p><u>Diagnosis</u>: study designed to evaluate one or more interventions aimed at identifying a disease or health condition.</p> <p><u>Educational / counselling / training</u>: study designed to assess one or more interventions in an educational, counselling or training environment.</p>
<p>20. Allocation to intervention</p>	<p><u>Randomised controlled trial</u> means that allocation of subjects into different groups (i.e., intervention and control) was random or by a method based on chance.</p> <p><u>Nonrandomised trial</u> means that allocation of subjects into different groups (i.e., intervention and control) is expressly or deliberately done, and is not random or by chance.</p> <p><u>Note</u>: Trials with quasi-randomisation allocation procedures such as allocation by hospital record number, birth date or alternate days of the week, do not qualify as a randomised trial. Therefore, these studies should be classified as nonrandomised trials. These studies are, however, controlled clinical trials (CCTs) and are eligible for registration on the ANZCTR.</p>
<p>21. Describe the procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)</p>	<p>If “Allocation to intervention” is randomised controlled trial, describe the method of allocation concealment.</p> <p>Allocation concealment means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, to which group the subject would be allocated. Allocation was concealed if it was done by, for example:</p> <ol style="list-style-type: none"> 1. sealed opaque envelopes 2. numbered containers 3. central randomisation by phone/fax/computer 4. allocation involved contacting the holder of the allocation schedule who was “off-site” or at central administration site. <p>If concealment was not carried out, the text “Allocation is not concealed” should be stated for this section.</p>
<p>22. Describe the methods used to generate the sequence in which subjects will be randomised (sequence generation)</p>	<p>If “Allocation to intervention” is randomised controlled trial, describe the method of sequence generation.</p> <p>This is the method used to create the random order for the allocation of subjects into different groups. This random order of sequence generation is only relevant if allocation to intervention is “Randomised controlled trial”.</p> <p>Examples of the random order generation include (but are not limited to):</p> <ol style="list-style-type: none"> 1. Simple randomisation by using a randomisation table from a statistic book 2. Simple randomisation by using a randomisation table created by a computer software (i.e., computerised sequence generation). 3. Simple randomisation by using procedures such as coin-tossing and dice-rolling 4. Permuted block randomisation 5. Dynamic (adaptive) random allocation methods such as Minimisation <p>If stratified allocation was employed in the study, specify factor(s) used for the stratification. Examples of factors include centre, age gender or previous treatment can be used for the stratification.</p> <p>Quasi-randomisation allocation procedures or inappropriate randomisation methods such as allocation by hospital record number, birth date or alternate days of the week, do not qualify as a random order generation.</p>

Data Item	Definition/Explanation
23. Masking / blinding	<p>Masking / blinding: knowledge of the interventions assigned to subjects. This means the person in question (subjects, therapist (clinician), assessor or data analyst) did not know which group the subject had been allocated to. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blinded if the subject was blinded.</p> <p><u>open (masking not used)</u> - all involved in the study know the identity of the intervention assignment. Subject, therapist (clinician), assessor and data analyst are not blinded.</p> <p><u>blinded (masking used)</u> - when one or more of the parties (subjects, therapist (clinician), assessor or data analyst) is/are blinded or unaware of the intervention assignment.</p> <p>If "blinded (masking used)" option was chosen above, please tick who is/are blinded (choose all that apply), from the list.</p> <ul style="list-style-type: none"> <input type="checkbox"/> the people receiving the treatment/s (subjects) <input type="checkbox"/> the people administering the treatment/s (therapist or clinician) <input type="checkbox"/> the people assessing the outcomes (assessor) <input type="checkbox"/> the people analysing the results/data (data analyst)
24. Assignment	<p>Choose the most appropriate description of the study's assignment from the list.</p> <p><u>Single Group</u>: all participants receive the same intervention throughout the study. Trials in which participants are assigned to receiving one of two or more interventions are not single group studies. Crossover trials are not single group studies.</p> <p><u>Parallel</u>: different groups of participants receive different interventions during the same time span of the study.</p> <p><u>Crossover</u>: all participants receive all the interventions in different sequences during the study. They act as their own control.</p> <p><u>Factorial</u>: participants are randomly allocated to receive either no intervention, one or some interventions, or all interventions simultaneously.</p> <p><u>Other</u>: None of the selections provides an appropriate description of the study's assignment. If "Other" is selected for the study's assignment, please give a brief description of the study's assignment in "Other design feature".</p>
Other design feature	Specify other design feature if "Other" is selected for Assignment.
25. Type of endpoint(s)	<p>Choose the most appropriate description of the study's endpoint(s) from the list.</p> <p><u>Safety</u>: to show if the intervention is safe under conditions of proposed protocol/use</p> <p><u>Efficacy</u>: to measure an intervention's influence on a disease or health condition</p> <p><u>Safety/efficacy</u>: combination of safety and efficacy</p> <p><u>Bio-equivalence</u>: scientific basis for comparing generic and brand name drugs</p> <p><u>Bio-availability</u>: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body</p> <p><u>Pharmacokinetics</u>: the action of a drug in the body over a period of time including the process of absorption, distribution and localisation in tissue, biotransformation, and excretion of the compound</p> <p><u>Pharmacodynamics</u>: action of drugs in living systems</p> <p><u>Pharmacokinetics / Pharmacodynamics</u>: combination of pharmacokinetics and pharmacodynamics</p>

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26. Purpose	<p>If the study is an observational study, choose the most appropriate purpose of the study from the list.</p> <p><u>Natural history</u>: study designed to investigate a disease or condition through observation under natural conditions (i.e., without intervention)</p> <p><u>Screening</u>: study designed to assess or examine persons or groups in a systematic way to identify specific markers or characteristics (e.g., for eligibility for further evaluation)</p> <p><u>Psychosocial</u>: study designed to observe the psychosocial impact of natural events</p>
27. Duration	<p>If the study is an observational study, choose the most appropriate duration of the study from the list.</p> <p><u>Longitudinal</u>: study in which participants are evaluated over long period of time, typically months or years</p> <p><u>Cross-sectional</u>: study in which participants are evaluated at one point in time - usually over a short period of time, typically up to 10 weeks</p>
28. Selection	<p>If the study is an observational study, choose the most appropriate sample selection of the study from the list.</p> <p><u>Convenience sample</u>: participants or populations are selected at the convenience of the investigator or primarily because they were available at a convenient time or place. The investigators make little or no effort to insure that sample is an accurate representation of some larger group or population</p> <p><u>Defined population</u>: participants or populations are selected based on predefined criteria</p> <p><u>Random sample</u>: participants or populations are selected by chance in a manner such that all samples of a population have an equal chance of being selected</p> <p><u>Case control</u>: participants or populations are selected to match control participants or populations in all relevant factors except for the disease; only the case participants or populations have the disease</p>
29. Timing	<p>If the study is an observational study, choose the most appropriate timing of the study from the list.</p> <p><u>Retrospective</u>: study that observes events in the past</p> <p><u>Prospective</u>: study that observes events in real time (may also occur in future)</p> <p><u>Both</u>: study that combines retrospective and prospective observation</p>
30. Phase	<p>Phases of investigation, usually applied to a drug trial.</p> <p><u>Not applicable</u>: this selection is for a non-drug trial</p> <p><u>Phase 0</u>: includes exploratory, first-in-human trials. Phase 0 trials are also known as human microdosing studies and are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was anticipated from preclinical studies. Exploratory trials are conducted before traditional dose escalation and safety studies and gives no data on safety or efficacy, being by definition a dose too low to cause any therapeutic effect.</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. Trials are often dose ranging/escalating 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 studies conducted to evaluate/test the</p>

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	<p>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 labelling</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>
31. Anticipated or actual start date	Estimated enrolment date (dd/mm/yyyy) of the first participant. This could be actual trial start date if the trial is registered after commencement.
32. Target sample size	<p>The total number of subjects the investigators plan to enrol before closing the trial to new participants.</p> <p><u>Note</u>: This is a “number only” field (e.g. 25)</p>
33. Recruitment status (at time of registration)	<p>Choose the most appropriate description of the study’s recruitment status at the time of registration from the list.</p> <ol style="list-style-type: none"> 1. Not yet recruiting - participants are not yet being recruited or enrolled 2. Open to recruitment - participants are currently being recruited and enrolled 3. Temporary halt or suspended - there is a temporary halt in recruitment and enrolment but potentially will resume 4. Terminated - recruiting or enrolling participants has halted and will not resume 5. Closed to recruitment of participants: follow-up continuing - closed to recruitment of participants and follow-up is still continuing 6. Closed to recruitment of participants: follow-up complete - closed to recruitment of participants and follow-up is complete 7. Completed - closed to recruitment of participants and data analysis complete <p><u>Note</u>: Items 3 & 4 are only available when Registrants update their trial.</p>
34. Funding source(s)	<p>Major source(s) of monetary or material or infrastructure support for the trial (e.g., funding agency, foundation, company, hospital, university, etc.). This refers to the name of the organisation(s) that provided funding for the study.</p> <p><u>Funding type</u>: choose the most appropriate type of the study’s funding source from the list.</p> <p><u>Name of funding source</u>: enter only one name of the study’s funding source (one at a time).</p> <p><u>Address of funding source</u>: enter the address of the study’s funding source listed in the “Name” section.</p> <p><u>Country of funding source</u>: choose the country of the study’s funding source listed in the “Name” section from the list.</p> <p>Click “Add” to add more boxes if the study has multiple funding sources. The form allows <u>maximum of 20 sets of entries</u> for the funding source(s).</p>
35. Primary sponsor	<p>The individual, organisation, group or other legal person taking on the responsibility for securing the arrangements to initiate and/or manage a study, including arrangements to ensure that the design of the study meets appropriate standards and to ensure appropriate conduct and reporting. The primary sponsor is normally the main applicant or principle investigator for</p>

Data Item	Definition/Explanation
<ul style="list-style-type: none"> ▪ Country 	<p>regulatory authorisation or funding to begin the study. The primary sponsor is responsible for ensuring that the trial is properly registered. It may or may not be the main funder.</p> <p><u>Primary sponsor type</u>: choose the most appropriate type of the study's primary sponsor from the list.</p> <p><u>Name of primary sponsor</u>: enter only one name of the study's primary sponsor.</p> <p><u>Address of primary sponsor</u>: enter the address of the study's primary sponsor listed in the "Name" section.</p> <p><u>Country of primary sponsor</u>: choose the country of the study's primary sponsor listed in the "Name" section from the list.</p> <p>The form allows <u>only one entry</u> for primary sponsor. For additional sponsors, please refer to the secondary sponsor(s) section.</p>
<p>36. Secondary sponsor(s)</p> <ul style="list-style-type: none"> ▪ Sponsor type ▪ Name ▪ Address ▪ Country 	<p>Additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to jointly take on responsibilities of sponsorship. A secondary sponsor may have agreed to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group and/or to act as the sponsor's legal representative in relation to some or all of the trial sites. A secondary sponsor may take responsibility for the accuracy of trial registration information submitted.</p> <p><u>Secondary sponsor type</u>: choose the most appropriate type of the study's secondary sponsor from the list.</p> <p><u>Name of secondary sponsor</u>: enter only one name of the study's secondary sponsor (one at a time).</p> <p><u>Address of primary sponsor</u>: enter the address of the study's secondary sponsor listed in the "Name" section.</p> <p><u>Country of primary sponsor</u>: choose the country of the study's secondary sponsor listed in the "Name" section from the list.</p> <p>Click "Add" to add more boxes if the study has multiple secondary sponsors. The form allows <u>maximum of 20 sets of entries</u> for the secondary sponsor(s).</p>
<p>37. Other collaborator(s)</p> <ul style="list-style-type: none"> ▪ Collaborator type ▪ Name ▪ Address ▪ Country 	<p>Additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to jointly take on responsibilities of sponsorship. A collaborator may have agreed to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group and/or to act as the sponsor's legal representative in relation to some or all of the trial sites.</p> <p><u>Collaborator type</u>: choose the most appropriate type of the study's collaborator from the list.</p> <p><u>Name of collaborator</u>: enter only one name of the study's collaborator (one at a time).</p> <p><u>Address of collaborator</u>: enter the address of the study's collaborator listed in the "Name" section.</p> <p><u>Country of collaborator</u>: choose the country of the study's collaborator listed in the "Name" section from the list.</p> <p>Click "Add" to add more boxes if the study has multiple collaborators. The form allows <u>maximum of 20 sets of entries</u> for the other collaborator(s).</p>
<p>38. Has the study received approval from at least one ethics committee?</p>	<p>Choose the appropriate answer from the list.</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If "<u>Yes</u>" has been selected, please provide the following information:</p>

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	<p><u>Name of ethics committee</u>: enter only one name of the ethics committee (one at a time).</p> <p><u>Address of ethics committee</u>: enter the address of the ethics committee listed in the “Name” section.</p> <p><u>Country of ethics committee</u>: choose the country of the ethics committee listed in the “Name” section from the list.</p> <p><u>Date of approval</u>: enter the date when the ethics approval has been obtained.</p> <p><u>HREC Number</u>: enter HREC identification number (Human Research Ethics Committee Identification Number). This number is assigned to the ethics application either at the time of submission or granting approval.</p> <p>Click “Add” to add more boxes if the study has received ethics approval from multiple ethics committees. The form allows <u>maximum of 50 sets of entries</u> for the ethics committees.</p> <p>If “<u>No</u>” has been selected, it is <u>mandatory</u> to provide the date when the ethics application was submitted or the date which the trial’s primary sponsor or their representatives intend to submit an ethics application in “Date submitted/Date which intend to submit to ethics committee” section.</p>
<p>39. Countries of recruitment</p>	<p>Choose the appropriate answer from the list to specify if the recruitment site(s) is within or outside Australia. Please tick both boxes if the recruitment sites are within and outside Australia.</p> <p><input type="checkbox"/> Australia <input type="checkbox"/> Outside Australia</p> <p>If “<u>Australia</u>” has been selected, please specify the postcode(s) of the area(s) where the participants is/will be recruited for the study. Click “Add” to add more boxes for the postcodes if the study has multiple recruitment sites. The form allows <u>maximum of 50 entries</u> for the postcodes.</p> <p>If “<u>Outside Australia</u>” has been selected, it is mandatory to list all country(s) that the participants is/will be recruited for the study by choosing the country’s name from the list. Please also specify the state/province within each particular country. Click “Add” to add more boxes for the countries and their state/province if the study has multiple recruitment sites. The form allows <u>maximum of 50 sets of entries</u> for the countries of recruitment and their state/province.</p>
<p>40. Brief summary</p>	<p>Short description of the primary purpose of the study, including a brief statement of the study hypothesis, intended for the lay public.</p>
<p>41. Trial website</p>	<p>If the study has a trial website, enter the web address / URL (Uniform Resource Locator) in this section. Otherwise, please leave it blank.</p>
<p>42. Presentations / publication list</p>	<p>If the study has a list of presentations/publications, enter these details in this section. Otherwise, please leave it blank.</p>
<p>43. Contact person for public queries</p>	<p>Name, address, telephone number, fax number and email address of the contact person who will respond to general queries, including information about current recruitment status. Only professional contact details should be provided.</p> <p>Telephone and fax numbers should be entered in the following format: +Country code Area code Number.</p> <p><u>Examples</u>: +61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>
<p>44. Contact person for scientific queries</p>	<p>Name, address, telephone number, fax number, email address and affiliation of the person to contact for scientific inquiries about the trial (e.g., principal</p>

Data Item	Definition/Explanation
	<p>investigator, medical director for the study at the sponsor). For a multi-centre study, enter the contact information for the lead Principal Investigator or overall medical director. Only professional contact details should be provided.</p> <p>Telephone and fax numbers should be entered in the following format: +Country code Area code Number.</p> <p><u>Examples:</u> +61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>
45. Contact person responsible for updating information	<p>Name, address, telephone number, fax number, email address and affiliation of the person to contact for updating the trial information after the trial has been registered with the ANZCTR. Only professional contact details should be provided.</p> <p>Telephone and fax numbers should be entered in the following format: +Country code Area code Number.</p> <p><u>Examples:</u> +61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p> <p>If the contact person responsible for updating information is the same person as the contact person for public queries OR contact person for scientific queries, please leave this section blank.</p>