

**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** with asterisks (\*).

Data Item	Definition/Explanation
1. <b>Public title</b> *	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. <b>Study title in 'Participant-Intervention-Comparator-Outcome (PICO)' format</b> *	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 participant group involved, 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. <b>Secondary IDs</b> *	Identifying numbers issued by authorities other than the ANZCTR if any. For example, if the trial has already been registered with another registry such as ISRCTN or ClinicalTrials.gov, the secondary ID and full name of the issuing authority should be provided.  It is possible that the trial may not have a secondary ID. Please include the text 'Nil known' if you do not know of any secondary IDs.  Enter only <b>one</b> secondary ID and issuing authority per box. 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.
4. UTN	The Universal Trial Number (UTN) is a unique number which aims to facilitate the unambiguous identification of clinical trials registered in Primary Registries in the WHO registry network and displayed on the WHO International Clinical Trials Registry Platform's (ICTRP) Search Portal. A UTN should be obtained early in the history of a trial and should be used every time the trial is identified. To obtain a UTN please go to: <a href="http://apps.who.int/trialsearch/utn.aspx">http://apps.who.int/trialsearch/utn.aspx</a>
5. Trial acronym	If the study has a trial acronym, enter in this section. Otherwise, please leave blank.
6. <b>Health condition(s) or problem(s) studied</b> *	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.  Enter only <b>one</b> 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.
7. <b>Condition category and Condition code</b> *	Choose the most appropriate condition category (1 <sup>st</sup> level) and condition code (2 <sup>nd</sup> level) for the study from the list.  Click "Add" to add more boxes if the study has multiple condition categories and

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	condition codes. The form allows <u>maximum of 3 sets of entries</u> for the condition category and condition code.
8. <b>Description of intervention(s) / exposure *</b>	<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. If there are multiple treatment arms, please label with subheadings (e.g. Arm 1, Arm 2, etc.)</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>
9. <b>Intervention code *</b>	<p>Choose the most appropriate intervention code from the list for interventional studies. For observational studies please select “Not applicable – Observational study”.</p> <p>The form allows a <u>maximum of 3 entries</u> for the intervention code. Click “Add” to add more boxes.</p> <p><u>Not applicable – Observational study</u>: study in which no experimental intervention or treatment is applied. The investigator observes 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.</p> <p><u>Diagnosis</u>: study designed to evaluate one or more interventions aimed at identifying a disease or health condition.</p> <p><u>Early detection / screening</u>: study that involves the systematic examination of a group of participants, in order to separate well persons from those who have an undiagnosed pathologic condition or who are at high risk. It could also refer to the initial evaluation of an individual, intended to determine suitability for a particular treatment modality or to detect specific markers or characteristics that may require further investigation.</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>Treatment: drugs</u>: study designed to assess the effect(s) of one or more chemical or biological agents including vaccines.</p> <p><u>Treatment: surgery</u>: study designed to assess the effect(s) of one or more manual or operative surgical techniques, whether it be in the fields of cosmetic, elective, experimental, plastic, or replacement surgery (which are performed to diagnose, treat, or prevent disease or other abnormal conditions).</p> <p><u>Treatment: devices</u>: study designed to evaluate the use of any physical item used in medical treatment whether it be an instrument, piece of equipment, machine, apparatus, appliance, material or other article, and whether it is used alone or in combination with the intention of preventing, diagnosing, treating, and curing a disease or condition. Examples include: artificial limbs, contact lenses, ventilators, catheters, implants, vibration therapy machines.</p> <p><u>Treatment: other</u>: studies that do not fall under the broad definitions of drug, surgical, or device trials. Examples include interventions such as exercise, physiotherapy, cognitive therapy, special diets, herbal medicines, web-based treatments, motivational classes, music therapy, stem cell interventions.</p> <p><u>Rehabilitation</u>: studies designed to evaluate one or more interventions which aim to restore the physical or mental health, function and quality of life in participants who have had or are currently suffering from an illness or injury. Rehabilitation may be performed through physical therapy (e.g. physiotherapy, chiropractic) and/or education (e.g. diet and exercise advice/counselling).</p>

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	<p><u>Lifestyle</u>: studies designed to investigate the effect of interventions which relate to a way of life or style of living. Interventions may aim to alter the attitudes, habits and values of a person or group, and how these participants cope with their physical, psychological, social, and economic environments on a day-to-day basis. Examples include diet and nutrition plans, exercise or physical activity programs, quit smoking programs.</p> <p><u>Behaviour</u>: studies designed to assess the effect of interventions which aim to elicit or modify mental or physical actions, responses or conduct in a person or group. Examples of behavioural interventions include cognitive behavioural therapy, exercise behaviour interventions, and breast feeding behavioural interventions.</p> <p><u>Other interventions</u>: studies that do not fit under any of the above categories. This should only be selected when no other options are adequate. Examples include interventions using prayer, and singing.</p>
10. <b>Comparator / control treatment *</b>	<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 is used or what the standard treatment is, dose, duration, mode of administration, etc).</p>
11. <b>Control group *</b>	<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 control group, such as sugar pill or saline solution.</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 for randomised controlled trials. The source and time period that historical data was collected needs to be described in the comparator field.</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 administration for both the intervention and control groups need to be described in the intervention and comparator fields.</p>
12. <b>Primary outcome and Timepoint (s) *</b>	<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 &gt; 10" rather than just "depression".</p> <p>Instrument(s) to be used for the assessment/measurement needs to be included/described where possible. For each outcome, also provide all timepoints at which it is to be measured.</p> <p>Enter only <b>one</b> 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>

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	<p><u>Examples:</u></p> <p>Primary Outcome 1: all cause mortality as assessed by data linkage to medical records</p> <p>Timepoint: at one year after randomisation</p> <p>Primary Outcome 2: mean Beck depression score</p> <p>Timepoint: Baseline, and at 6 and 12 weeks after intervention commencement</p>
<p><b>13. Secondary outcome(s) and Timepoint (s) *</b></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>Instrument(s) to be used for the assessment/measurement needs to be included/described where possible. For each outcome, also provide all timepoints at which it is to be measured.</p> <p>Enter only <b>one</b> 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 a <u>maximum of 20 sets of entries</u> for the secondary outcome(s) and timepoint(s).</p> <p><u>Examples:</u></p> <p>Secondary Outcome 1: knee pain as assessed using a Visual Analogue Scale</p> <p>Timepoint: at 6 months after randomisation</p> <p>Secondary Outcome 2: functional status as assessed using the Eastern Cooperative Oncology Group (ECOG) Performance Status scale.</p> <p>Timepoint: Baseline, and at 4 and 8 weeks after intervention commencement</p>
<p><b>14. Key inclusion criteria *</b></p>	<p>Summary of key inclusion criteria of patient characteristics that determine eligibility for participation in the study.</p>
<p><b>15. Minimum age *</b></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. If there is no age limit for either minimum or maximum age or both leave the boxe(s) for the number(s) blank and select “No limit” from the unit of measurement list.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Years</li> <li><input type="checkbox"/> Months</li> <li><input type="checkbox"/> Weeks</li> <li><input type="checkbox"/> Days</li> <li><input type="checkbox"/> Hours</li> <li><input type="checkbox"/> No limit</li> </ul> <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><b>16. Maximum age *</b></p>	<p>Specify age range of the study’s participants.</p>

Data Item	Definition/Explanation
	<p>Enter the numbers for minimum and maximum ages and choose the unit to specify the period (for the age) from the list. 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.</p> <p> <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 </p> <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>
17. <b>Gender *</b>	<p>Choose the appropriate description for gender of the study's participants.</p> <p> <input type="checkbox"/> Males  <input type="checkbox"/> Females  <input type="checkbox"/> Both males and females </p>
18. <b>Healthy volunteers? *</b>	<p>Specify whether or not the study includes healthy volunteers.</p> <p> <input type="checkbox"/> Yes  <input type="checkbox"/> No </p>
19. <b>Key exclusion criteria *</b>	<p>Summary of key exclusion criteria of patient characteristics that determine eligibility for participation in the study.</p>
20. <b>Study type *</b>	<p>Choose the appropriate study type from the list.</p> <p> <input type="checkbox"/> Interventional  <input type="checkbox"/> Observational </p> <p><u>Interventional Study:</u> 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><u>Observational Study:</u> 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 (i.e. no treatment or no experimental intervention is given).</p>
21. <b>Purpose of the study *</b>  <i>(Only available when <b>Interventional</b> is selected for '20. Study type')</i>	<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 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</p>

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	interventions in an educational, counselling or training environment.
<p>22. <b>Allocation to intervention *</b> (Only available when <b>Interventional</b> is selected for '20. Study type')</p>	<p>Choose the appropriate type of 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>23. Describe the procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)</p> <p>(Only available when <b>Interventional</b> is selected for '20. Study type')</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"> <li>1. sealed opaque envelopes</li> <li>2. numbered containers</li> <li>3. central randomisation by phone/fax/computer</li> <li>4. allocation involved contacting the holder of the allocation schedule who was "off-site" or at central administration site.</li> </ol> <p>If concealment was not carried out, the text "Allocation is not concealed" should be stated for this section.</p>
<p>24. Describe the methods used to generate the sequence in which subjects will be randomised (sequence generation)</p> <p>(Only available when <b>Interventional</b> is selected for '20. Study type')</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. Examples of the random order generation include (but are not limited to):</p> <ol style="list-style-type: none"> <li>1. Simple randomisation using a randomisation table from a statistic book</li> <li>2. Simple randomisation using a randomisation table created by computer software (i.e. computerised sequence generation).</li> <li>3. Simple randomisation using procedures like coin-tossing and dice-rolling</li> <li>4. Permuted block randomisation</li> <li>5. Dynamic (adaptive) random allocation methods such as Minimisation</li> </ol> <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>
<p>25. Masking / blinding</p> <p>(Only available when <b>Interventional</b> is selected for '20. Study type')</p>	<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 (e.g. 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</p>

Data Item	Definition/Explanation
	<p>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> <p><input type="checkbox"/> the people receiving the treatment/s (subjects)</p> <p><input type="checkbox"/> the people administering the treatment/s (therapist or clinician)</p> <p><input type="checkbox"/> the people assessing the outcomes (assessor)</p> <p><input type="checkbox"/> the people analysing the results/data (data analyst)</p>
<p>26. Assignment</p> <p><i>(Only available when <b>Interventional</b> is selected for '20. Study type')</i></p>	<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 <b>simultaneously</b>.</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 the "Other design features" field below.</p>
<p>27. Other design features</p> <p><i>(Only available when <b>Interventional</b> is selected for '20. Study type')</i></p>	<p>Specify other design features if "Other" is selected for Assignment.</p>
<p>28. Type of endpoint(s)</p> <p><i>(Only available when <b>Interventional</b> is selected for '20. Study type')</i></p>	<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>
<p>29. Statistical Analysis/ Methods</p> <p><i>(Only available when <b>Interventional</b> is selected for '20. Study type')</i></p>	<p>Provide a brief summary of the statistical methods and/or analysis plan to be used to evaluate the data.</p>
<p>30. Purpose</p>	<p>If the study is an observational study, choose the most appropriate purpose of the</p>

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<p><i>(Only available when <b>Observational</b> is selected for '20. Study type')</i></p>	<p>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>
<p>31. Duration</p> <p><i>(Only available when <b>Observational</b> is selected for '20. Study type')</i></p>	<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>
<p>32. Selection</p> <p><i>(Only available when <b>Observational</b> is selected for '20. Study type')</i></p>	<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 ensure that the 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>
<p>33. Timing</p> <p><i>(Only available when <b>Observational</b> is selected for '20. Study type')</i></p>	<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>
<p>34. Phase</p>	<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 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>

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	<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>
35. <b>Recruitment status*</b>	<p>Choose the most appropriate description of the study's recruitment status at the time of registration from the list.</p> <p><u>Recruiting</u>: participants are currently being recruited</p> <p><u>Not yet recruiting</u>: participants are not yet being recruited</p> <p><u>Active, not recruiting</u>: study is ongoing (i.e. participants are being treated or examined), but participants are not currently being recruited or enrolled</p> <p><u>Completed</u>: closed to recruitment of participants and data analysis complete</p> <p><u>Enrolling by invitation</u>: participants were/are being/will be invited to participate from a predetermined population</p> <p><u>Suspended</u>: there is a temporary halt in recruitment and enrolment but potentially will resume</p> <p><u>Terminated</u>: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated</p> <p><u>Withdrawn</u>: study halted prematurely, prior to enrolment of first participant</p> <p><u>Closed: follow-up continuing</u>: closed to recruitment of participants and follow-up is still continuing</p> <p><u>Closed: follow-up complete</u>: closed to recruitment of participants and follow-up is complete</p>
36. <b>Anticipated date of first participant enrolment *</b> (dd/mm/yy)	<p>Estimated enrolment date (dd/mm/yyyy) of the first participant.</p> <p>For studies involving secondary analysis of data (e.g. meta-analysis), please specify the anticipated start date of data collection.</p>
37. Date of first participant enrolment (dd/mm/yy)	<p>Actual enrolment date (dd/mm/yyyy) of the first participant.</p> <p>For studies involving secondary analysis of data (e.g. meta-analysis), please specify the actual start date of data collection.</p>
38. Anticipated date of last participant enrolled (dd/mm/yy)	<p>Anticipated end date</p> <p>The anticipated date that recruitment into the trial will cease.</p>
39. Actual date of last participant enrolled (dd/mm/yy)	<p>Actual end date</p> <p>The actual date that recruitment into the trial will cease.</p>
40. <b>Target sample size *</b>	<p>The total number of subjects the investigators plan to enrol before closing the trial to new participants. <u>Note</u>: This is a "number only" field (e.g. 25)</p>
41. <b>Recruitment sites *</b>	<p><b>Recruiting in Australia</b></p> <p>Tick this box if your study is/was or will be recruiting from within Australia</p>

Data Item	Definition/Explanation
	<p><b>Outside Australia</b></p> <p>Tick this box if your study is/was or will be recruiting from countries outside Australia</p> <p><u>Recruitment States:</u> Tick the boxes corresponding to all recruiting States within Australia. (Only available when <b>Recruiting in Australia</b> is selected for '41. Recruitment sites')</p> <p> <input type="checkbox"/> NSW    <input type="checkbox"/> VIC    <input type="checkbox"/> QLD    <input type="checkbox"/> ACT  <input type="checkbox"/> NT    <input type="checkbox"/> SA    <input type="checkbox"/> TAS    <input type="checkbox"/> WA </p> <p><u>Recruitment hospital(s)</u> <i>Full name only:</i> Type the <b>full name</b> of the recruiting hospital(s) for this trial, and click on the matching option that appears on the list to add it to this form. E.g. instead of "RPA", please enter "Royal Prince Alfred Hospital". (Only available when <b>Recruiting in Australia</b> is selected for '41. Recruitment sites')</p> <p><u>Recruitment postcode(s):</u> Type the 4-digit postcode for the suburb where recruitment will occur, and click on the matching option that appears on the list to add it to this form. (Only available when <b>Recruiting in Australia</b> is selected for '41. Recruitment sites')</p> <p><u>Other Country:</u> <b>Recruitment outside Australia: Country, State</b></p> <p>Click this button to include recruitment countries for this trial outside of Australia, along with their corresponding states/provinces. (Only available when <b>Outside Australia</b> is selected for '41. Recruitment sites')</p>
<p>42. <b>Funding source(s) *</b></p> <ul style="list-style-type: none"> <li>▪ <b>Funding type</b></li> <li>▪ <b>Name</b></li> <li>▪ <b>Address</b></li> <li>▪ <b>Country</b></li> </ul>	<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 <b>one</b> name of the study's funding source (one at a time).</p> <p><u>Address of funding source:</u> enter the address of the named funding source.</p> <p><u>Country of funding source:</u> choose the country of the named funding source 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>
<p>43. <b>Primary sponsor *</b></p> <ul style="list-style-type: none"> <li>▪ <b>Sponsor type</b></li> <li>▪ <b>Name</b></li> <li>▪ <b>Address</b></li> <li>▪ <b>Country</b></li> </ul>	<p>The individual, organisation, group or other legal person taking on 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 regulatory authorisation or funding to begin the study. <b>The primary sponsor is responsible for ensuring that the trial is properly registered.</b> 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 <b>one</b> name of the study's primary sponsor.</p> <p><u>Address of primary sponsor:</u> enter the address of the named sponsor.</p>

Data Item	Definition/Explanation
	<p><u>Country of primary sponsor</u>: choose the country of the named sponsor 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>44. <b>Secondary sponsor(s) *</b></p> <ul style="list-style-type: none"> <li>▪ <b>Sponsor type</b></li> <li>▪ <b>Name</b></li> <li>▪ <b>Address</b></li> <li>▪ <b>Country</b></li> </ul>	<p>Additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to jointly take on responsibilities of sponsor-ship. 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 <b>one</b> name of the study's secondary sponsor (one at a time).</p> <p><u>Address of secondary sponsor</u>: enter the address of the named sponsor.</p> <p><u>Country of secondary sponsor</u>: choose the country of the named sponsor 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>45. Other collaborator(s)</p> <ul style="list-style-type: none"> <li>▪ Collaborator type</li> <li>▪ Name</li> <li>▪ Address</li> <li>▪ Country</li> </ul>	<p>Additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to jointly take on responsibilities of sponsor-ship. 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 <b>one</b> name of the study's collaborator (one at a time).</p> <p><u>Address of collaborator</u>: enter the address of the named collaborator.</p> <p><u>Country of collaborator</u>: choose the country of the named collaborator 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>46. <b>Has the study received approval from at least one ethics committee? *</b></p>	<p>Choose the appropriate answer from the list.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If "<u>Yes</u>" has been selected, please provide the following information:</p> <p><u>Name of ethics committee</u>: enter only <b>one</b> name of the ethics committee (one at a time).</p> <p><u>Address of ethics committee</u>: enter the address of the named committee.</p> <p><u>Country of ethics committee</u>: choose the country of the named committee from the list.</p> <p><u>Date of approval</u>: enter the date when the ethics approval has been obtained.</p> <p><u>Date submitted/date which intend to submit to Ethic Committee</u>: enter the date when the ethics approval has been obtained.</p> <p><u>HREC Number</u>: enter Human Research Ethics Committee (HREC) 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 approval from multiple ethics committees. The form allows <u>maximum of 50 sets of entries</u> for the ethics</p>

Data Item	Definition/Explanation
	<p>committees.</p> <p>If “No” 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 “<b>Date submitted/Date which intend to submit to ethics committee</b>” section.</p>
47. <b>Brief summary *</b>	Short description of the primary purpose of the study, including a brief statement of the study hypothesis, intended for the lay public.
48. Trial website	If the study has a trial website, enter the web address / URL (Uniform Resource Locator) in this section. Otherwise, please leave it blank.
49. Trial related presentations / publication list	If the study has a list of presentations/publications, enter these details in this section. Otherwise, please leave it blank.
50. Public Notes	This field is for any extra, miscellaneous text you'd like included within this trial registration which is not relevant elsewhere on this form. Anything placed here WILL be publicly viewable.
51. Private Notes	This field is for any extra, miscellaneous text to be included within this trial registration not relevant elsewhere on this form. Anything placed here will NOT be publicly viewable, but will be available to ANZCTR staff.
52. <b>Principal Investigator *</b>	<p>Title, name, address, country, telephone number and email address of the principal investigator of the study. Professional contact details should be provided.</p> <p>Address should include street name, street number, town/city, state/province and postcode where applicable. Alternatively, private bag/locked bag/PO Box addresses are also accepted.</p> <p>Telephone and fax number should be entered in the format +Country code, Area code, Number.</p> <p>Examples:</p> <p>+61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>
53. <b>Contact person for public queries *</b>	<p>Name, address, telephone and fax numbers 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 format +Country code, Area code, Number. <u>Examples:</u></p> <p>+61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>
54. <b>Contact person for scientific queries *</b>	<p>Name, address, telephone and fax numbers, email address and affiliation of the contact person for scientific inquiries about the trial (e.g. principal investigator, medical director for the study). 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 format +Country code, Area code, Number. <u>Examples:</u></p> <p>+61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>

Data Item	Definition/Explanation
55. Contact person responsible for updating information	<p>Name, address, telephone and fax numbers, email address and affiliation of the person to contact for updating trial information after registration with the ANZCTR. Only professional contact details should be provided.</p> <p>Telephone and fax numbers should be entered in the format +Country code, Area code, Number. <u>Examples:</u></p> <p>+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>