Data field definitions

This document includes the definitions and explanation of the data fields to be completed when submitting a record 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 Data Set.

Mandatory data items for trial registration with the ANZCTR are marked in BOLD and with an asterisk (*).

Data item	Definition / explanation
Step 1: Titles & IDs	
Public title *	The public title of the study is intended for the lay public and should be in easily understood language. An informative public title should include at least 2 of the following components: participants, intervention/exposure, and main outcome of the study. Acronyms should be defined at first use. This field will be displayed on the main search page of the WHO ICTRP Search Portal.
Scientific title *	The scientific title is intended for use in grant and ethics applications. It should contain information on the participants in the study, the intervention(s)/exposure(s) and the primary outcome(s) to be assessed.
Secondary IDs *	Identifying numbers issued by authorities other than the ANZCTR if any. This includes: * Trial registration numbers issued by other registries (both Primary and Partner Registries in the WHO Registry Network, and other registries) * Identifiers assigned by the sponsor (record sponsor name and sponsor-issued trial number (e.g. protocol number)) * Identifiers issued by funding bodies, collaborative research groups, etc. * This does not include ethics identification numbers – these should be provided in the relevant Ethics section in Step 9. All secondary identifiers will have 2 elements: an identifier for the issuing authority (e.g. NCT, ISRCTN) plus a number. 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 **one** secondary ID and issuing authority per box. Click "Add new secondary ID" to add more boxes if necessary. There is no limit to the number of Secondary ID entries (boxes) that can be added.

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 ICTRP Search Portal. A UTN should be obtained from https://trialsearch.who.int/utn.aspx early in the history of a trial and should be used every time the trial is identified.
Trial acronym	A trial acronym is a word formed from the initial letters of the several words in the name, which identifies the specific trial, e.g. ACT (Angioplasty Compliance Trial). If there is no trial acronym then please leave this field blank.
Linked study record	If this trial is linked to a parent study, sub-study or follow-up study then please provide the identifying number (or citation if no identifying number available) for the linked study.
Step 2: Health condition	
Health condition(s) or problem(s) studied *	Primary health condition(s) or problem(s) studied (e.g. depression, breast cancer, medication error). For studies conducted in healthy volunteers, enter the health area under investigation and/or the health condition(s) for which the intervention may be indicated and/or the health condition(s) being prevented. Enter only **one** health condition or problem per box. Click “Add new health condition” to add more boxes. The form allows a maximum of 20 entries (boxes).
Condition category and condition code *	Choose the most appropriate condition category (1st level) and condition code (2nd level) from the list. **Note:** the full list is available at the end of this document. Click “Add new condition category/code” to add more boxes if necessary. The form allows a maximum of 10 sets of entries.
Step 3: Intervention/exposure	
Study type *	Choose the appropriate study type from the list. Interventional: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effect on outcomes. Interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural approaches, process-of-care changes, preventive care, diagnostic procedures. Observational: A 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 (i.e. no treatment or experimental intervention is given).
Patient registry (Only available when **Observational** is selected for '**Study type**' in step 3)	For observational studies only, check the 'Patient registry' box if this record describes a study that is considered to be a patient registry. A patient registry is an organised system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions.
Target follow-up duration (Only available when **patient registry** is selected in step 3)	For patient registries, the anticipated time period over which each participant is to be followed. Provide a number and select a unit of time (weeks, months, years).
Description of intervention(s) / exposure *	Describe the specific intervention(s) being studied. Please provide sufficient detail so that information will be meaningful to ANZCTR users (refer to TIDieR checklist). **Brief name**: Provide the name or a phrase that describes the intervention. If there are multiple intervention arms, please label with subheadings (e.g. Arm 1, Arm 2, etc.). Note: there is a separate field below for details of comparator/control treatment(s). Intervention names should be consistent throughout the form. Avoid using alternative intervention names for clarity. For drug trials: Provide the International Non-proprietary Name (INN) of each drug (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. For each intervention drug, please also specify: - the **dose** administered, e.g. 5mg once daily; - the **duration** of administration, e.g. 4 weeks; - the **mode** of administration, e.g. oral tablet, intravenous infusion. For non-drug trials: For each intervention, briefly describe: - any physical or informational **materials** that will be used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers; - each of the **procedures**, activities, and/or processes used, including any enabling or support activities; - **who** will deliver the intervention and if relevant, their expertise, e.g. dietician with minimum 5 years' experience;

	- the **mode of delivery** (such as face to face or by some other mechanism, e.g. internet or telephone) and whether it will be provided individually or in a group; - the **number of times** the intervention will be delivered and over what period of time including the number of sessions, their schedule, and their **duration, intensity, or dose**; e.g. 8 x 1 hour sessions, once/ week for 8 weeks, then once/month for 4 months. - the **location** where the intervention occurs, e.g. urban antenatal clinic, participant's home, high school, etc. For all trials: If the intervention is planned to be **personalised**, titrated or adapted to individuals or groups of individuals in the intervention arm, then describe what, why, when, and how this will occur. If intervention **adherence** or fidelity will be assessed, describe how and by whom, and if any strategies will be used to maintain or improve fidelity, describe them. For observational studies: Provide a brief description of the condition observed and/or the exposure. The duration of observation must also be described.
Intervention code *	Choose the most appropriate intervention code(s) from the list. The form allows a maximum of 3 entries. Click "Add new intervention code" to add more boxes. Note that only the first 3 codes are available for observational studies. Not applicable: study in which no experimental intervention or treatment is applied. This selection is not available for interventional studies. Diagnosis / prognosis: study designed to evaluate one or more tests aimed at identifying a disease or health condition, or determining a patient's prognosis. Early detection / screening: 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. Prevention: study designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. Treatment: drugs: study designed to assess the effect(s) of one or more chemical or biological agents including vaccines. Treatment: surgery: study designed to assess the effect(s) of one or more manual or operative surgical techniques, whether in the fields of cosmetic, elective, experimental, plastic, or replacement surgery (performed to diagnose, treat, or prevent disease or other abnormal conditions).

	Treatment: devices: 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. Treatment: other: 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. Rehabilitation: 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). Lifestyle: 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. Behaviour: 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. Other interventions: studies that do not fit under any of the above categories. This should only be selected when no other options are adequate. Examples include prayer, singing, driving.
Comparator / control treatment *	For controlled trials, the identity of the comparator/control arm should be clear. The comparator/control(s) is/are the treatments against which the study intervention is being compared (e.g. placebo, no treatment, active control). If an active control is used, be sure to provide the specific name of the treatment. For each comparator/control treatment, describe the details as applicable, following the TIDieR Checklist (e.g. dose, duration, mode of administration, etc). If the study is uncontrolled then please enter the text “No control group” or similar.
Control group *	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. Placebo: an inactive or sham treatment that has no treatment value is given to the control group, such as sugar pill or saline solution. Active: 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). Uncontrolled: when there is no control group, as in single group trials. The same intervention is applied to all subjects in the study. Historical: 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 / control treatment' field. Dose comparison: the comparator group receives the same treatment as the intervention group, but in a different dose.
Step 4: Outcomes	
Primary outcome(s), assessment method and timepoint(s) *	Primary outcome(s) is the outcome(s) 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. 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). Provide specific names of all primary outcomes, one at a time, e.g. "% with Beck depression score > 10" rather than just "depression". All outcomes should be provided in an objective form without indicating suspected or hypothesised results, e.g. "Change in blood glucose" or "proportion of participants with a reduction in blood glucose" rather than "reduced blood glucose". Methods to be used for the assessment/measurement need to be included / described, e.g. serum assay, MRI scan, 100mm visual analogue scale. If a questionnaire is used, the name of the questionnaire should be provided (if validated) or indicate whether it was designed specifically for the study. For adverse events provide examples of known/possible adverse reactions/events and how they will be assessed. For each outcome provide all timepoints at which it is assessed in the 'Timepoint' box. Timepoints should be specific, for example "7 days post commencement of intervention" rather than just "7 days". For primary outcomes assessed at multiple timepoints, please also specify the primary timepoint, if applicable, e.g. "1 hour, 3 hours (primary timepoint) and 6 hours post dose". Enter only **one** primary outcome per box. Click "Add new primary outcome" to add more boxes if the study has multiple primary outcomes. The form allows a maximum of 3 sets of entries for the primary outcome and timepoint.

	Examples: *Primary Outcome 1:* Hospital length of stay *Assessment method:* assessed by data linkage to medical records *Timepoint:* at one year after randomisation *Primary Outcome 2:* Depression *Assessment method:* Hospital Anxiety and Depression Scale *Timepoint:* Baseline, 6 weeks (primary timepoint) and 12 weeks after intervention commencement
Secondary outcome(s), assessment method and timepoint(s) *	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: hospitalisation rate at 5 years). Methods to be used for the assessment/measurement need to be included / described. For each outcome, also provide all timepoints at which it is assessed in the 'Timepoint' box. Enter only **one** secondary outcome per box. Click "Add new secondary outcome" to add more boxes if the study has multiple secondary outcomes. The form allows a maximum of 40 sets of entries for the secondary outcome(s) and timepoint(s). If there are no secondary outcomes then enter the text 'Nil'. Examples: *Secondary Outcome 1*: Knee pain *Assessment method:* 100mm Visual Analogue Scale (VAS) *Timepoint*: at 6 months after randomisation *Secondary Outcome 2*: Quality of life *Assessment method:* SF-36 Quality of Life Questionnaire *Timepoint*: Baseline, and at 4 and 8 weeks after intervention commencement
Step 5: Eligibility	
Key inclusion criteria *	Summary of key inclusion criteria of patient characteristics that determine eligibility for participation in the study.
Minimum age *	Specify minimum age of eligible study participants. Enter the number and choose the appropriate unit from the list. If there is no minimum age limit leave the box for the number blank and select "No limit" from the unit of measurement list. ☐ Years ☐ Months

	☐ Weeks ☐ Days ☐ Hours ☐ No limit
Maximum age *	Specify maximum age of eligible study participants. Enter the number and choose the appropriate unit from the list. If there is no maximum age limit leave the box for the number blank and select "No limit" from the unit of measurement list. ☐ Years ☐ Months ☐ Weeks ☐ Days ☐ Hours ☐ No limit
Sex *	Choose the appropriate selection for sex of the study's participants. ☐ Males ☐ Females ☐ Both males and females
Can healthy volunteers participate? *	Indicate whether healthy volunteers may participate in this study. Studies where the Inclusion Criteria requires pregnant women or those with any condition, including non-debilitating conditions (e.g. myopia, smoking, etc.), are not considered healthy volunteer studies and should respond "No" to this question. ☐ Yes ☐ No
Key exclusion criteria *	Summary of key exclusion criteria of patient characteristics that determine eligibility for participation in the study. These should not simply be the opposite of the inclusion criteria.
Step 6: Study design	
Purpose of the study * (Mandatory when **Interventional** is selected for '**Study type'** in step 3)	Choose the most appropriate purpose of the study from the list. Treatment: study designed to evaluate one or more interventions for treating a disease, syndrome or other health condition(s). Prevention: study designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. Diagnosis: study designed to evaluate one or more interventions aimed at identifying a disease or health condition. Educational / counselling / training: study designed to assess one or more interventions in an educational, counselling or training environment.
Allocation to intervention *	Choose the appropriate type of allocation to intervention. Randomised controlled trial means that allocation of subjects into different groups (i.e. intervention and control) was random or by a method based on chance.

(Mandatory when **Interventional** is selected for '**Study type** in step 3**'**)	Non-randomised trial 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. Note: 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 non-randomised trials.
Allocation concealment (Only available when **Interventional** is selected for '**Study type'** in step 3)	Only applicable for randomised controlled trials. 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: 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. If concealment was not carried out, the text "Allocation is not concealed" should be stated for this section.
Sequence generation (Only available when **Interventional** is selected for '**Study type'** in step 3)	Only applicable for randomised controlled trials. 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): 1. Simple randomisation using a randomisation table from a statistic book 2. Simple randomisation using a randomisation table created by computer software (i.e. computerised sequence generation) 3. Simple randomisation using procedures like coin-tossing and dice-rolling 4. Permuted block randomisation 5. Dynamic (adaptive) random allocation methods such as Minimisation If stratified allocation was employed in the study, specify factor(s) used for the stratification. Examples of factors that can be used for stratification include centre, age, gender or previous treatment. 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.
Masking / blinding (Only available when **Interventional** is selected for	Masking / blinding is when the person in question (participant, therapist/clinician, assessor or data analyst) did not know which group the participant had been allocated to. For 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.

'**Study type'** in step 3)	Open (masking not used) - all involved in the study know the identity of the intervention assignment. Participant, therapist/clinician, assessor and data analyst are not blinded. Blinded (masking used) - when one or more of the parties (participants, therapist/clinician, assessor or data analyst) is/are blinded or unaware of the intervention assignment. If "Blinded (masking used)" option was chosen above, please tick who is/are blinded (choose all that apply), from the list. ☐ the people receiving the treatment/s (participants) ☐ the people administering the treatment/s (therapist/clinician) ☐ the people assessing the outcomes (assessor) ☐ the people analysing the results/data (data analyst)
Assignment (Only available when **Interventional** is selected for '**Study type'** in step 3)	Choose the most appropriate description of the study's assignment from the list. Single group: 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. Parallel: different groups of participants receive different interventions during the same time span of the study. Crossover: all participants receive all the interventions in random order or in a specific sequence (non-randomised) during the study. They act as their own control. Factorial: participants are randomly allocated to receive either no intervention, one or some interventions, or all interventions combined. For example in a 2x2 factorial trial of diet and exercise for weight loss, participants would be allocated to: diet alone, exercise alone, both diet and exercise, or neither. In this way it is possible to test the independent effects of diet and exercise on the outcome, i.e. weight loss. Other: None of the selections provide 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.
Other design features (Only available when **Interventional** is selected for '**Study type'** in step 3)	Briefly describe other design features if "Other" is selected for Assignment above.
Phase* (Mandatory when **Interventional** is selected for	Phases of investigation generally only apply to drug trials for the purposes of this registration form. Not applicable: this selection is for a non-drug trial. Phase 0: includes exploratory, first-in-human trials. Phase 0 trials are also known as human micro-dosing studies and are designed

'**Study type'** in step 3)	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. Phase 1: 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. Phase 1/Phase 2: for trials at a combined stage of phases 1 and 2. Phase 2: 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. Phase 2/Phase 3: for trials 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 labelling. Phase 3/Phase 4: for trials at a combined stage of phases 3 and 4. Phase 4: 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.
Type of endpoint(s) (Only available when **Interventional** is selected for '**Study type**' in step 3)	Choose the most appropriate study endpoint(s) from the list. Safety: to show if the intervention is safe under conditions of proposed protocol/use. Efficacy: to measure an intervention's influence on a disease or health condition. Safety/efficacy: combination of safety and efficacy. Bio-equivalence: scientific basis for comparing generic and brand name drugs. Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body. Pharmacokinetics: 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. Pharmacodynamics: action of drugs in living systems.

	Pharmacokinetics / pharmacodynamics: combination of pharmacokinetics and pharmacodynamics.
Statistical methods / analysis	Provide a brief description of how the number of participants needed to achieve study objectives was determined, including clinical and statistical assumptions supporting any sample size calculations. A brief summary of the statistical methods and/or analysis plan to be used to evaluate the data also need to be provided.
Purpose (Only available when **Observational** is selected for '**Study type'** in step 3)	If the study is an observational study, choose the most appropriate purpose of the study from the list. Natural history: study designed to investigate a disease or condition through observation under natural conditions (i.e. without intervention). Screening: 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). Psychosocial: study designed to observe the psychosocial impact of natural events.
Duration (Only available when **Observational** is selected for '**Study type'** in step 3)	If the study is an observational study, choose the most appropriate duration of the study from the list. Longitudinal: study in which participants are evaluated over long period of time, typically months or years. Cross-sectional: study in which participants are evaluated at a particular point in time.
Selection (Only available when **Observational** is selected for '**Study type'** in step 3)	If the study is an observational study, choose the most appropriate sample selection of the study from the list. Convenience sample: 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. Defined population: participants or populations are selected based on predefined criteria. Random sample: participants or populations are selected by chance in a manner such that all samples of a population have an equal chance of being selected. Case control: 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.
Timing (Only available when **Observational** is	If the study is an observational study, choose the most appropriate timing of the study from the list. Retrospective: study that observes events in the past.

selected for '**Study type'** in step 3)	Prospective: study that observes events in real time (may also occur in future). Both: study that combines retrospective and prospective observation.
Step 7: Recruitment	
Recruitment status *	Choose the most appropriate description of the study's current recruitment status from the list. Not yet recruiting: participants are not yet being recruited Recruiting: open for recruitment and the first participant has been enrolled Active, not recruiting: closed to recruitment and participants are being treated or examined Completed: the study has concluded normally; participants are no longer being treated or examined (i.e. follow-up and data collection are complete) Withdrawn: study halted prematurely, prior to enrolment of first participant Suspended: there is a temporary halt in recruitment and enrolment but potentially will resume Stopped early: recruiting or enrolling participants has halted prematurely and will not resume
Data analysis? (Only available when **Stopped early** is selected for '**Recruitment status**' in step 7)	Choose the most appropriate option from the dropdown menu: ☐ No data analysis planned ☐ Data collected is being analysed ☐ Data analysis is complete
Reason for early stopping/ withdrawal (Only available when **Withdrawn** or **Stopped early** is selected for '**Recruitment status'** in step 7)	Please tick all that apply: ☐ Lack of funding/staff/facilities ☐ Participant recruitment difficulties ☐ Safety concerns ☐ Other reasons/comments(please specify)
Date of first participant enrolment *	This is defined as the date of randomisation of the first participant for randomised trials. For non-randomised studies, it is defined as the date that the first participant commences treatment/intervention/ exposure. **Anticipated date** (dd/mm/yyyy) is mandatory if recruitment has not started.

	Actual date (dd/mm/yyyy) is mandatory once recruitment has started. For studies involving secondary analysis of data, please specify the anticipated/actual start date of data collection.
Date of last participant enrolment	The **anticipated date** (dd/mm/yyyy) that recruitment into the study will cease. The **actual date** (dd/mm/yyyy) that the final participant was enrolled into the study. This is mandatory for studies which have completed recruitment. For studies involving secondary analysis of data, please specify the anticipated/actual end date of data collection.
Date of last data collection	The **anticipated date** (dd/mm/yyyy) of last data collection for last participant. The **actual date** (dd/mm/yyyy) of last data collection for last participant.
Target sample size *	The total number of participants the investigators plan to enrol before closing the trial to new participants. Note: This is a “number only” field.
Accrual to date	The total number of participants who have been enrolled into the study to date. This is mandatory for studies with ongoing recruitment, and for studies with suspended recruitment. Note: This is a “number only” field.
Final sample size	The final number of participants enrolled into the study at close of recruitment. This is mandatory for studies which have completed recruitment. Note: This is a “number only” field.
Recruiting in Australia (Recruitment sites)	Tick this box if your study is/was or will be recruiting from within Australia.
Recruitment states * (Mandatory when ‘**Recruiting in Australia**’ is selected in step 7)	Tick the boxes corresponding to all recruiting states within Australia. ☐ NSW ☐ VIC ☐ QLD ☐ ACT ☐ NT ☐ SA ☐ TAS ☐ WA
Recruitment hospitals (Only available when ‘**Recruiting in Australia**’ is selected in step 7)	Type the full name of the recruiting hospital(s), 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". If the site you wish to enter does not appear, then please email us at info@anzctr.org.au.

Recruitment postcode(s) (Only available when '**Recruiting in Australia**' is selected in step 7)	Type the four-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.
Outside Australia (Recruitment sites)	Tick this box if your study is/was or will be recruiting from countries outside Australia. Select the appropriate recruitment country from the drop-down list and enter the state/province of recruitment (free text). If there is more than one country of recruitment outside Australia, please click on the "Add new country" button.
Step 8: Funding & Sponsors	
Funding source(s) *	Major source(s) of monetary or material or infrastructure support for the study, including in-kind support. Funding type: choose the most appropriate type from the list. ☐ Government body ☐ Hospital ☐ University ☐ Commercial sector/industry ☐ Charities/societies/foundations ☐ Other collaborative groups ☐ Self funded/unfunded ☐ Other **Note**: The selection 'Self funded/unfunded' applies to studies which are either funded by an individual person or not funded at all. Name of funding source: enter only **one** per box. Country of funding source: choose the appropriate country from list. Click "Add new funding source" to add more boxes if the study has multiple funding sources. The form allows maximum of 20 sets of entries.
Primary sponsor *	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 principal investigator for 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. Primary sponsor type: choose the most appropriate type from the list. ☐ Government body ☐ Hospital ☐ University

	☐ Commercial sector/industry ☐ Charities/societies/foundations ☐ Other collaborative groups ☐ Individual ☐ Other Name of primary sponsor: enter only one name of the study's primary sponsor. Country of primary sponsor: choose the appropriate country from list. The form allows only one entry for primary sponsor. For additional sponsors, please refer to the secondary sponsor(s) section.
Secondary sponsor(s) *	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. **Note**: The primary and secondary sponsors should not be the same. Secondary sponsor type: choose the most appropriate type from the list. ☐ Government body ☐ Hospital ☐ University ☐ Commercial sector/industry ☐ Charities/societies/foundations ☐ Other collaborative groups ☐ Individual ☐ Other ☐ None Name of secondary sponsor: enter only **one** name of the study's secondary sponsor per box. Country of secondary sponsor: choose the appropriate country from list. Click "Add new secondary sponsor" to add more boxes if the study has multiple secondary sponsors. The form allows maximum of 20 sets of entries for the secondary sponsor(s).
Other collaborator(s)	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. Collaborator type: choose the most appropriate type from the list.

	☐ Government body ☐ Hospital ☐ University ☐ Commercial sector/industry ☐ Charities/societies/foundations ☐ Other collaborative groups ☐ Individual ☐ Other Name of collaborator: enter only **one** name of the study's collaborator per box. Country of collaborator: choose the appropriate country from list. Click "Add new other collaborator" to add more boxes if necessary. The form allows maximum of 20 sets of entries.
Step 9: Ethics & Summary	
Ethics application status *	Select the appropriate option from the list. Not yet submitted: You intend to submit to at least one ethics committee, but have not yet done so. **Note**: If this option is selected it is mandatory to provide the date which the trial's primary sponsor or their representatives intend to submit an ethics application in the 'Submit date' field. Submitted, not yet approved: You have submitted an application to at least one ethics committee, but have not yet received approval. **Note**: If this option is selected it is mandatory to provide the date when the ethics application was submitted in the 'Submit date' field. Approved: You have received full ethical approval for this study from at least one ethics committee. **Note**: If this option is selected it is mandatory to provide the date when the ethics approval was granted in the 'Approval date' field. Not required: Ethics approval not required for this study. **Note**: If this option is selected it is mandatory to provide the reason(s) why ethics approval is not required in the 'Public notes' field in Step 9 of the form.
Ethics committee details* (mandatory, except when '**Not required**' selected for Ethics application status)	Please also provide the following information: Country of ethics committee: please choose the appropriate country from list first. Name of ethics committee: please select ethics committee from drop-down menu. Note if your ethics committee is not available from this list, please select 'Other (ethics committee name not available in list)' and then the name of the ethics committee will need to be manually entered below. Contact details of ethics committee: if the ethics committee is selected from the drop-down above, this will automatically be entered. If the ethics committee is not available from the drop-down, please manually enter the website or the full address of the named ethics committee, including street number and name, suburb/town city, postcode and state/province (where applicable).

	Alternatively PO Box/Locked Bag/Private Bag addresses are also permitted. Submit date: enter the date that the ethics committee application was submitted, or is planned to be submitted. **Note**: This field is mandatory when either 'Not yet submitted' or 'Submitted, not yet approved' has been selected for ethics application status above. Approval date: enter the date that the ethics committee application was approved. **Note**: This field is mandatory when 'Approved' has been selected for ethics application status above. Approval ID: enter the approval ID assigned to the ethics application by the ethics committee at the time of granting approval. **Note:** This field is not mandatory. Click "Add new ethics committee" to add more boxes if the study has received approval from multiple ethics committees. The form allows a maximum of 50 sets of entries.
Brief summary *	Short description of the primary purpose of the study, including a brief statement of the study hypothesis, intended for the lay public. Ensure that the information provided in the brief summary is consistent with study design, intervention description and study outcomes provided in the form. This information may be displayed on other websites (such as Australian Clinical Trials: https://www.australianclinicaltrials.gov.au/) to facilitate recruitment.
Trial website	If the study has a trial website, enter the web address/URL (Uniform Resource Locator) in this section. Otherwise, please leave blank.
Trial related presentations / publication list	Please note that it is **no longer possible** to add trial related presentations/publications in this field. Please add these in Steps 11 (Data sharing statement) and/or 12 (Summary results) instead. It is still possible to remove text from this field. This field will only appear for trials registered prior to 2024 with pre-existing information in this field.
Public notes	This field is for any extra, miscellaneous text you would like included within the trial registration record which is not relevant elsewhere on this form. Anything placed here **WILL** be publicly viewable.
Private notes	This field is for any extra, miscellaneous text you would like included within the trial registration record which is not relevant elsewhere on this form. Anything placed here **will NOT** be publicly viewable, but will be available to ANZCTR staff.
Attachments	Please note that it is no longer possible to add attachments to this field. Please use the study-related documents field in Step 11 (Data sharing statement) and/or the publications fields in Step 12 (Summary results) instead. It is still possible to remove attachments from this field if necessary. Attached files **WILL** remain publicly available via your trial's ANZCTR registration record.

	This optional section was previously used to upload any relevant documents (e.g. trial protocol, ethics approval forms, blank clinical record forms). Files are in PDF or Word with a maximum size of 15MB per file. It is the responsibility of the registrant to ensure that any uploaded documents continue to comply with copyright regulations.
Step 10: Contacts	
Principal investigator *	Title, name, address, country, telephone number and email address of the principal investigator of the study. Functional/institutional contact details should be provided. Address should include work organisation/affiliation, street number and name, suburb/town city, postcode and state/province (where applicable). Alternatively PO Box/Locked Bag/Private Bag addresses are also permitted. Telephone numbers should be entered in the format +country code, area code, number, for example: +61 2 9562 5333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA) **Note:** The information provided here is functional and not personal; therefore it is recommended to provide institutional and not personal information. By providing this information the registrant consents that the information provided can or may be published on a public website. Once provided, the information cannot be redacted or anonymised, even to comply with new privacy legislation such as the European General Data Protection Regulation (GDPR). Note that while the current contact information may be modified at any time, all information published on the ANZCTR remains in the public domain, whether as part of the audit trail in historical versions of the record or in the most recent version of the record.
Contact person for public queries *	Title, name, address, telephone number and email address of the contact person who will respond to general queries, including information about current recruitment status. Functional/institutional contact details should be provided. Address should include work organisation/affiliation, street number and name, suburb/town city, postcode and state/province (where applicable). Alternatively PO Box/Locked Bag/Private Bag addresses are also permitted. Telephone numbers should be entered in the format +country code, area code, number, for example: +61 2 9562 5333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA) **Note:** The information provided here is functional and not personal; therefore it is recommended to provide institutional and not

	personal information. By providing this information the registrant consents that the information provided can or may be published on a public website. Once provided, the information cannot be redacted or anonymised, even to comply with new privacy legislation such as the European General Data Protection Regulation (GDPR). Note that while the current contact information may be modified at any time, all information published on the ANZCTR remains in the public domain, whether as part of the audit trail in historical versions of the record or in the most recent version of the record.
Contact person for scientific queries *	Title, name, address, telephone number and email address 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. Functional/institutional contact details should be provided. Address should include work organisation/affiliation, street number and name, suburb/town city, postcode and state/province (where applicable). Alternatively PO Box/Locked Bag/Private Bag addresses are also permitted. Telephone numbers should be entered in the format +country code, area code, number, for example: +61 2 9562 5333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA) **Note:** The information provided here is functional and not personal; therefore it is recommended to provide institutional and not personal information. By providing this information the registrant consents that the information provided can or may be published on a public website. Once provided, the information cannot be redacted or anonymised, even to comply with new privacy legislation such as the European General Data Protection Regulation (GDPR). Note that while the current contact information may be modified at any time, all information published on the ANZCTR remains in the public domain, whether as part of the audit trail in historical versions of the record or in the most recent version of the record.
Step 11: Data sharing statement	
Will the study consider sharing individual participant data? *	Indicate whether researchers will consider sharing of individual participant data (IPD) publicly available for this trial. IPD refers to raw line-by-line data collected from each participant. ☐ Yes ☐ No If 'No' is selected, please provide reasons/comments for why the IPD are not planned to be shared.

Will there be any conditions when requesting access to individual participant data?* (Mandatory when '**Yes**' is selected for **IPD** question in Step 11)	Please select and/or describe: • Who can request access to the individual participant data, e.g. anyone, researchers or others. • Any conditions required for requesting access to individual participant data, e.g. no requirements, requires review on a case-by-case basis by the trial custodian, sponsor or data sharing committee, etc.
What individual participant data might be shared? * (Mandatory when '**Yes**' is selected for **IPD** question in Step 11)	Please select and/or describe what data might be shared, e.g. all de-identified individual participant data, de-identified individual participant data for all outcomes, etc.
What types of analyses could be done with individual participant data? * (Mandatory when '**Yes**' is selected for **IPD** question in Step 11)	Please select and/or describe if there is a specific type of analysis for which the data are/will be available, e.g. any type of analysis, systematic reviews and meta-analysis, etc.
When can requests for individual participant data be made (start and end dates)? * (Mandatory when '**Yes**' is selected for **IPD** question in Step 11)	Please outline both the start and end date for the timeframe of data availability, i.e. beginning and end dates for when the data is expected to be available, e.g. Immediately following publication, no end date; Beginning 3 months and ending 5 years following main results publication; no end date determined etc.
Where can requests to access individual participant data be made, or data be obtained directly?* (Mandatory when '**Yes**' is selected for **IPD** question in Step 11)	Please specify how/where data are/will be shared e.g. data repository, data sharing request system, journal publication or its supplementary materials, email of trial custodian, sponsor or committee, etc.
Are there extra considerations when requesting access to individual participant data?*	Please indicate whether there are extra conditions researchers should be aware of when requesting access to individual participant data available for this trial, that are not described in the data sharing fields above. ☐ Yes

(Mandatory when '**Yes**' is selected for **IPD** question in Step 11)	☐ No If 'No' is selected, please describe the relevant additional conditions.
What supporting documents are/will be available?	Please provide details of all types of supporting information that will be shared. To add a supporting document, please click on the 'Add New Supporting Document +' button. Choose the appropriate type(s) from the drop-down list in the 'Type' column: ☐ Analytic code ☐ Clinical study report ☐ Data dictionary ☐ Ethical approval ☐ Informed consent form ☐ Statistical analysis plan ☐ Study protocol ☐ Other (please specify)† † If 'Other' is selected, please note that it is **mandatory** to specify the other type of document that is/will be available in the 'Other details' column. Once 'Type' has been selected, please indicate how the corresponding document can be obtained, e.g. citation, link, email, other, attachment. Note that it is mandatory to provide details for at least **one** of these. If no other supporting documents are/will be made available, please click 'next step' to proceed. For citations, it is mandatory to provide the year of publication, a full citation or direct link to the citation. For other details, use this field to describe how the document is/will be available if no citation, link, or attachment is available or this document is not available via email request. For any attachments uploaded, please note it is the responsibility of the registrant to ensure that any uploaded documents comply with copyright regulations. All files attached will be publicly available via the trial ANZCTR registration record. Attached files cannot exceed the maximum size of 35MB per file.
Step 12: Study results	
As per WHO recommendations, study results need to be made publicly available in a timely manner following study completion. Please provide details of all types of study results that are available by clicking on the 'Add New Study Result +' button. Choose the appropriate type(s) from the drop-down list in the 'Type' column: ☐ Appendices ☐ Basic results (using this template) ☐ Book ☐ Conference abstract ☐ Conference poster ☐ Funder report ☐ Interim results article ☐ Plain language summary	

- ☐ Protocol
- ☐ Statistical analysis plan
- ☐ Study results article
- ☐ Supplementary materials
- ☐ Thesis
- ☐ Other files

Once ‘Type’ has been selected, please indicate whether the results have been peer reviewed and how they can be obtained, e.g. DOI, citation or other details, attachment. Note that it is mandatory to provide details for at least one of these.

For any attachments uploaded, please note it is the responsibility of the registrant to ensure that any uploaded documents comply with copyright regulations. All files attached will be publicly available via the trial ANZCTR registration record. Attached files cannot exceed the maximum size of 35MB per file.

Condition categories and Condition codes

Condition category (level 1)	Condition code (level 2)
Alternative and complementary medicine	Spiritual care
	Herbal remedies
	Other alternative and complementary medicine
Anaesthesiology	Anaesthetics
	Pain management
	Other anaesthesiology
Blood	Haematological diseases
	Anaemia
	Clotting disorders
	Normal development and function of platelets and erythrocytes
	Other blood disorders
Cancer	Any
	Biliary tree (gall bladder and bile duct)
	Bladder - transitional cell cancer
	Bone
	Bowel - anal
	Bowel - back passage (rectum) or large bowel (colon)
	Bowel - small bowel (duodenum and ileum)
	Brain
	Breast
	Cervical (cervix)
	Children's - brain
	Children's - leukaemia & lymphoma
	Children's - other
	Head and neck
	Hodgkin's
	Kidney
	Leukaemia - acute leukaemia
	Leukaemia - chronic leukaemia
	Liver
	Lung - mesothelioma
	Lung - non small cell
	Lung - small cell
	Lymphoma (non Hodgkin's lymphoma) - high grade lymphoma
	Lymphoma (non Hodgkin's lymphoma) - low grade lymphoma
	Malignant melanoma
	Myeloma
	Neuroendocrine tumour (NET)
	Non melanoma skin cancer
	Oesophageal (gullet)
	Ovarian and primary peritoneal
	Pancreatic
	Penile (penis)
	Prostate
	Sarcoma (also see 'Bone') - soft tissue
	Stomach
	Testicular
	Thrombocythaemia
	Thyroid
	Womb (uterine or endometrial cancer)
	Other cancer types

Condition category (level 1)	Condition code (level 2)
Cardiovascular	Coronary heart disease
	Diseases of the vasculature and circulation including the lymphatic system
	Hypertension
	Other cardiovascular diseases
	Normal development and function of the cardiovascular system
Diet and nutrition	Obesity
	Other diet and nutrition disorders
Ear	Deafness
	Other ear disorders
	Normal ear development and function
Emergency medicine	Resuscitation
	Other emergency care
Eye	Diseases / disorders of the eye
	Normal eye development and function
Infection	Acquired immune deficiency syndrome (AIDS / HIV)
	Sexually transmitted infections
	Other infectious diseases
	Studies of infection and infectious agents
Inflammatory and immune system	Rheumatoid arthritis
	Connective tissue diseases
	Autoimmune diseases
	Allergies
	Other inflammatory or immune system disorders
	Normal development and function of the immune system
Injuries and accidents	Fractures
	Poisoning
	Burns
	Other injuries and accidents
Human genetics and inherited disorders	Down's syndrome
	Cystic fibrosis
	Other human genetics and inherited disorders
Mental health	Depression
	Schizophrenia
	Psychosis and personality disorders
	Addiction
	Suicide
	Anxiety
	Eating disorders
	Learning disabilities
	Autistic spectrum disorders
	Other mental health disorders
	Studies of normal psychology, cognitive function and behaviour
Metabolic and endocrine	Diabetes
	Thyroid disease
	Metabolic disorders
	Other metabolic disorders
	Other endocrine disorders
	Normal metabolism and endocrine development and function
Musculoskeletal	Osteoporosis
	Osteoarthritis
	Other muscular and skeletal disorders
	Normal musculoskeletal and cartilage development and function

Condition Category (level 1)	Condition code (level 2)
Neurological	Dementias
	Transmissible spongiform encephalopathies
	Parkinson's disease
	Neurodegenerative diseases
	Alzheimer's disease
	Epilepsy
	Multiple sclerosis
	Other neurological disorders
	Studies of the normal brain and nervous system
Oral and gastrointestinal	Inflammatory bowel disease
	Crohn's disease
	Other diseases of the mouth, teeth, oesophagus, digestive system including liver and colon
	Normal oral and gastrointestinal development and function
Physical medicine / rehabilitation	Physiotherapy
	Speech therapy
	Occupational therapy
	Other physical medicine / rehabilitation
Public health	Epidemiology
	Health promotion/education
	Health service research
	Other public health
Renal and urogenital	Kidney disease
	Pelvic inflammatory disease
	Other renal and urogenital disorders
	Normal development and function of male and female renal and urogenital system
Reproductive health and childbirth	Fertility including in vitro fertilisation
	Contraception
	Abortion
	Fetal medicine and complications of pregnancy
	Normal pregnancy
	Mammary gland development
	Menstruation and menopause
	Breast feeding
	Antenatal care
	Childbirth and postnatal care
	Complications of newborn
	Other reproductive health and childbirth disorders
Respiratory	Asthma
	Chronic obstructive pulmonary disease
	Sleep apnoea
	Other respiratory disorders / diseases
	Normal development and function of the respiratory system
Skin	Dermatological conditions
	Normal skin development and function
	Other skin conditions
Surgery	Surgical techniques
	Other surgery
Stroke	Ischaemic
	Haemorrhagic
Other	Conditions of unknown or disputed aetiology (such as chronic fatigue syndrome/myalgic encephalomyelitis)
	Research that is not of generic health relevance and not applicable to specific health categories listed above