

Please note: The information requested for the data items is based on the definitions and set requirements for trial registration of the International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO) trial registration minimum data set.

For the definition/explanation of the data items, please refer to the document named "ACTRDataFieldExplanation.doc" which can be download from the ANZCTR home page under "How do I register a trial?".

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

Data Item	Trial Information
1. Public title	[Free text]
2. Study title in 'Participant-Intervention-Comparator-Outcome (PICO)' format	[Free text]
3. Secondary IDs	[Free text] Provide one identifying number and issuing authority per line. Include the text 'Nil' if the trial has no secondary IDs.
4. Trial acronym	[Free text] Leave blank if there is no trial acronym.
5. Health condition(s) or problem(s) studied	[Free text] Provide one health condition or problem studied per line.
6. Condition category and Condition code	Choose the most appropriate condition category (1 st level) and condition code (2 nd level) for the study from the list at the end of this document. The form allows <u>maximum of 3 sets of entries</u> for the condition category and condition code.
7. Description of intervention(s) / exposure	[Free text] <u>If the intervention consists of several separate treatments, list them all in one line separated by commas</u> (e.g., "low-fat diet, exercise").
8. Intervention code	Choose the most appropriate intervention code for the study from the list. The form allows <u>maximum of 3 entries</u> for the intervention code. <input type="checkbox"/> Not applicable – Observational study <input type="checkbox"/> Diagnosis <input type="checkbox"/> Early detection / screening <input type="checkbox"/> Prevention

Data Item	Trial Information
	<input type="checkbox"/> Treatment: drugs <input type="checkbox"/> Treatment: surgery <input type="checkbox"/> Treatment: devices <input type="checkbox"/> Treatment: other <input type="checkbox"/> Rehabilitation <input type="checkbox"/> Lifestyle <input type="checkbox"/> Behaviour <input type="checkbox"/> Other interventions
9. Comparator / control treatment	[Free text]
10. Control group	Choose the most appropriate description of the study's control group from the list. <input checked="" type="checkbox"/> Placebo <input type="checkbox"/> Active <input type="checkbox"/> Uncontrolled <input type="checkbox"/> Historical <input type="checkbox"/> Dose comparison
11. Primary outcome and Timepoint (s)	[Free text] Provide one primary outcome in one line and the timepoint(s) at which this particular outcome is measured in the next line. The form allows <u>maximum of 3 sets of entries</u> for the primary outcome and timepoint. <u>Examples:</u> Primary Outcome 1: all cause mortality Timepoint: at one year after randomisation Primary Outcome 2: mean Beck depression score Timepoint: at baseline and at 6, 12, and 18 weeks after intervention commencement
12. Key secondary outcome(s) and Timepoint (s)	[Free text] Provide one secondary outcome in one line and the timepoint(s) at which this particular outcome is measured in the next line. The form allows <u>maximum of 20 sets of entries</u> for the key secondary outcome(s) and timepoint(s). <u>Examples:</u> Secondary Outcome 1: cardiovascular mortality Timepoint: at 6 months after randomisation Secondary Outcome 2: functional status Timepoint: at baseline and at 4 and 18 weeks after intervention commencement
13. Key inclusion criteria	[Free text]
14. Age	[Free text] Specify age range of the study's participants. If there is no age limit for either

Data Item	Trial Information
	<p>minimum or maximum age or both, "No limit" should be stated.</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> <p>The units that the period (of the age) can be specified are listed below</p> <ul style="list-style-type: none"> ▪ Years ▪ Months ▪ Weeks ▪ Days ▪ Hours ▪ No limit ▪ N/A
15. Gender	<p>Choose the appropriate description for gender of the study's participants.</p> <p><input checked="" type="checkbox"/> Males</p> <p><input type="checkbox"/> Females</p> <p><input type="checkbox"/> Both males and females</p>
16. Healthy volunteers?	<p>Specify whether or not the study includes healthy volunteers.</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
17. Key exclusion criteria	[Free text]
18. Study type	<p>Choose the appropriate study type from the list.</p> <p><input checked="" type="checkbox"/> Interventional</p> <p><input type="checkbox"/> Observational</p>
19. Purpose of the study	<p>If the study is an interventional study, choose the most appropriate purpose of the study from the list.</p> <p><input checked="" type="checkbox"/> Treatment</p> <p><input type="checkbox"/> Prevention</p> <p><input type="checkbox"/> Diagnosis</p> <p><input type="checkbox"/> Educational / counselling / training</p>
20. Allocation to intervention	<p>If the study is an interventional study, choose the most appropriate allocation to intervention from the list.</p> <p><input checked="" type="checkbox"/> Randomised controlled trial</p> <p><input type="checkbox"/> Nonrandomised trial</p>
21. Describe the procedure for enrolling a subject and allocating the treatment (allocation	<p>[Free text]</p> <p>Leave blank if the study is nonrandomised trial</p>

Data Item	Trial Information
concealment procedures)	
22. Describe the methods used to generate the sequence in which subjects will be randomised (sequence generation)	<p>[Free text]</p> <p>Leave blank if the study is nonrandomised trial</p>
23. Masking / blinding	<p>If the study is an interventional study, choose the appropriate masking/blinding from the list.</p> <p><input checked="" type="checkbox"/> open (masking not used)</p> <p><input type="checkbox"/> blinded (masking used)</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>
24. Assignment	<p>Choose the most appropriate description of the study's assignment from the list.</p> <p><input checked="" type="checkbox"/> Single Group</p> <p><input type="checkbox"/> Parallel</p> <p><input type="checkbox"/> Crossover</p> <p><input type="checkbox"/> Factorial</p> <p><input type="checkbox"/> Other</p>
Other design feature	<p>[Free text]</p> <p>Specify other design feature if "Other" is selected for Assignment.</p>
25. Type of endpoint(s)	<p>Choose the most appropriate description of the study's endpoint(s) from the list.</p> <p><input checked="" type="checkbox"/> Safety</p> <p><input type="checkbox"/> Efficacy</p> <p><input type="checkbox"/> Safety/efficacy</p> <p><input type="checkbox"/> Bio-equivalence</p> <p><input type="checkbox"/> Bio-availability</p> <p><input type="checkbox"/> Pharmacokinetics</p> <p><input type="checkbox"/> Pharmacodynamics</p> <p><input type="checkbox"/> Pharmacokinetics / Pharmacodynamics</p>
26. Purpose	<p>If the study is an observational study, choose the most appropriate purpose of</p>

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	<p>the study from the list.</p> <p><input checked="" type="checkbox"/> Natural history</p> <p><input type="checkbox"/> Screening</p> <p><input type="checkbox"/> Psychosocial</p>
27. Duration	<p>If the study is an observational study, choose the most appropriate duration of the study from the list.</p> <p><input checked="" type="checkbox"/> Longitudinal</p> <p><input type="checkbox"/> Cross-sectional</p>
28. Selection	<p>If the study is an observational study, choose the most appropriate sample selection of the study from the list.</p> <p><input checked="" type="checkbox"/> Convenience sample</p> <p><input type="checkbox"/> Defined population</p> <p><input type="checkbox"/> Random sample</p> <p><input type="checkbox"/> Case control</p>
29. Timing	<p>If the study is an observational study, choose the most appropriate timing of the study from the list.</p> <p><input checked="" type="checkbox"/> Retrospective</p> <p><input type="checkbox"/> Prospective</p> <p><input type="checkbox"/> Both retrospective and prospective</p>
30. Phase	<p>Phases of investigation, usually applied to a drug trial.</p> <p><input checked="" type="checkbox"/> Not applicable</p> <p><input type="checkbox"/> Phase 0</p> <p><input type="checkbox"/> Phase 1</p> <p><input type="checkbox"/> Phase 1 / Phase 2</p> <p><input type="checkbox"/> Phase 2</p> <p><input type="checkbox"/> Phase 2 / Phase 3</p> <p><input type="checkbox"/> Phase 3</p> <p><input type="checkbox"/> Phase 3 /Phase 4</p> <p><input type="checkbox"/> Phase 4</p>
31. Anticipated or actual start date	[Date in dd/mm/yyyy] format.
32. Target sample size	[Number, e.g. 25]
33. Recruitment status (at time of registration)	<p>Choose the most appropriate description of the study's recruitment status at the time of registration from the list.</p> <p><input checked="" type="checkbox"/> Not yet recruiting</p> <p><input type="checkbox"/> Open to recruitment</p>

Data Item	Trial Information
	<input type="checkbox"/> Temporary halt or suspended <input type="checkbox"/> Terminated <input type="checkbox"/> Closed to recruitment of participants: follow-up continuing <input type="checkbox"/> Closed to recruitment of participants: follow-up complete <input type="checkbox"/> Completed <p><i>Note:</i> Items 3 & 4 will only be available for when the information of all registered trials on the ANZCTR is updated.</p>
<p>34. Funding source(s)</p> <ul style="list-style-type: none"> ▪ Funding type ▪ Name ▪ Address ▪ Country 	<p><u>Funding type:</u> choose the most appropriate type of the study's funding source from the list.</p> <p><input type="checkbox"/> Government funding body e.g. NHMRC, ARC, Cancer Council</p> <p><input type="checkbox"/> Hospital</p> <p><input type="checkbox"/> University</p> <p><input type="checkbox"/> Commercial sector/Industry</p> <p><input type="checkbox"/> Charities/Societies/Foundations</p> <p><input type="checkbox"/> Other Collaborative groups e.g. Cochrane Collaboration</p> <p><input type="checkbox"/> Self funded/Unfunded</p> <p><input type="checkbox"/> Other</p> <p><u>Name of funding source:</u> provide one name of the study's funding source (one at a time).</p> <p>[Free text]</p> <p><u>Address of funding source:</u> provide the address of the study's funding source listed in the "Name" section.</p> <p>[Free text]</p> <p><u>Country of funding source:</u> provide the country name of the study's funding source listed in the "Name" section from the list.</p> <p>[Free text]</p> <p>If the study has multiple funding sources, please provide a complete set of the information for each funding source.</p> <p>The form allows <u>maximum of 20 sets of entries</u> for the funding source(s).</p>
<p>35. Primary sponsor</p> <ul style="list-style-type: none"> ▪ Sponsor type ▪ Name ▪ Address ▪ Country 	<p><u>Primary sponsor type:</u> choose the most appropriate type of the study's primary sponsor from the list.</p> <p><input type="checkbox"/> Government funding body e.g. Department of Health, Cancer Council</p> <p><input type="checkbox"/> Hospital</p> <p><input type="checkbox"/> University</p> <p><input type="checkbox"/> Commercial sector/Industry</p> <p><input type="checkbox"/> Charities/Societies/Foundations</p> <p><input type="checkbox"/> Other Collaborative groups e.g. Cochrane Collaboration</p> <p><input type="checkbox"/> Individual</p> <p><input type="checkbox"/> Other</p> <p><u>Name of primary sponsor:</u> provide only one name of the study's primary</p>

Data Item	Trial Information
	<p>sponsor.</p> <p>[Free text]</p> <p><u>Address of primary sponsor</u>: provide the address of the study's primary sponsor listed in the "Name" section.</p> <p>[Free text]</p> <p><u>Country of primary sponsor</u>: provide the country name of the study's primary sponsor listed in the "Name" section from the list.</p> <p>[Free text]</p> <p>The form allows <u>only one entry</u> for primary sponsor. For additional sponsors, please refer to the secondary sponsor(s) section.</p>
<p>36. Secondary sponsor(s)</p> <ul style="list-style-type: none"> ▪ Sponsor type ▪ Name ▪ Address ▪ Country 	<p><u>Secondary sponsor type</u>: choose the most appropriate type of the study's secondary sponsor from the list.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Government funding body e.g. Department of Health, Cancer Council <input type="checkbox"/> Hospital <input type="checkbox"/> University <input type="checkbox"/> Commercial sector/Industry <input type="checkbox"/> Charities/Societies/Foundations <input type="checkbox"/> Other Collaborative groups e.g. Cochrane Collaboration <input type="checkbox"/> Individual <input type="checkbox"/> Other <input type="checkbox"/> None <p><u>Name of secondary sponsor</u>: provide only one name of the study's secondary sponsor (one at a time).</p> <p>[Free text]</p> <p><u>Address of primary sponsor</u>: provide the address of the study's secondary sponsor listed in the "Name" section.</p> <p>[Free text]</p> <p><u>Country of primary sponsor</u>: provide the country name of the study's secondary sponsor listed in the "Name" section from the list.</p> <p>[Free text]</p> <p>If the study has multiple secondary sponsors, please provide a complete set of the information for each secondary sponsor.</p> <p>The form allows <u>maximum of 20 sets of entries</u> for the secondary sponsor(s).</p>
<p>37. Other collaborator(s)</p> <ul style="list-style-type: none"> ▪ Collaborator type ▪ Name ▪ Address ▪ Country 	<p><u>Collaborator type</u>: choose the most appropriate type of the study's collaborator from the list.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Government funding body e.g. Department of Health, Cancer Council <input type="checkbox"/> Hospital <input type="checkbox"/> University <input type="checkbox"/> Commercial sector/Industry <input type="checkbox"/> Charities/Societies/Foundations <input type="checkbox"/> Other Collaborative groups e.g. Cochrane Collaboration

Data Item	Trial Information
	<p><input type="checkbox"/> Individual</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> None</p> <p><u>Name of collaborator</u>: provide only one name of the study's collaborator (one at a time). [Free text]</p> <p><u>Address of collaborator</u>: provide the address of the study's collaborator listed in the "Name" section. [Free text]</p> <p><u>Country of collaborator</u>: provide the country name of the study's collaborator listed in the "Name" section from the list. [Free text]</p> <p>If the study has multiple collaborators, please provide a complete set of the information for each collaborator.</p> <p>The form allows <u>maximum of 20 sets of entries</u> for the other collaborator(s).</p>
<p>38. Has the study received approval from at least one ethics committee?</p>	<p>Choose the appropriate answer from the list.</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If "Yes" has been selected, please provide the following information:</p> <p><u>Name of ethics committee</u>: provide only one name of the ethics committee (one at a time). [Free text]</p> <p><u>Address of ethics committee</u>: provide the address of the ethics committee listed in the "Name" section. [Free text]</p> <p><u>Country of ethics committee</u>: provide the country name of the ethics committee listed in the "Name" section from the list. [Free text]</p> <p><u>Date of approval</u>: provide the date when the ethics approval has been obtained. [Free text]</p> <p><u>HREC Number</u>: provide HREC identification number (Human Research Ethics Committee Identification Number). This number is assigned to the ethics application either at the time of submission or granting approval. [Free text]</p> <p>If the study has received ethics approval from multiple ethics committees, please provide a complete set of the information for each ethics approval obtained.</p> <p>The form allows <u>maximum of 50 sets of entries</u> for the ethics committees.</p> <p>If "No", please provide [Date in dd/mm/yyyy format] the "Date submitted/Date which intend to submit to ethics committee". [Date in dd/mm/yyyy] format.</p>
<p>39. Countries of recruitment</p>	<p>Choose the appropriate answer from the list to specify if the recruitment site(s) is within or outside Australia. Please tick both boxes if the recruitment sites are</p>

Data Item	Trial Information
	<p>within and outside Australia.</p> <p><input type="checkbox"/> Australia <input type="checkbox"/> Outside Australia</p> <p>If “Australia” has been selected, please specify the postcode(s) of the area(s) where the participants is/will be recruited for the study. If the study has multiple recruitment sites, please provide a postcode for each recruitment site.</p> <p>[Free text]</p> <p>The form allows <u>maximum of 50 entries</u> for the postcodes.</p> <p>If “Outside Australia” has been selected, a list all country(s) that the participants is/will be recruited for the study <u>must</u> be specified. Please also specify the state/province within each particular country.</p> <p>[Free text]</p> <p>The form allows <u>maximum of 50 sets of entries</u> for the countries of recruitment and their state/province.</p>
40. Brief summary	[Free text]
41. Trial website	<p>[Web address / URL (Uniform Resource Locator)]</p> <p>Leave blank if there is there is no website for the study.</p>
42. Presentations / publication list	<p>[Free text]</p> <p>Leave blank if there is no presentations/publication generated from the study.</p>
43. Contact person for public queries	<p>[Free text - Name, address, telephone number, fax number and email address]</p> <p>Telephone and fax numbers should be entered in the following format: +Country code Area code Number.</p> <p><u>Examples:</u> +61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>
44. Contact person for scientific queries	<p>[Free text - Name, address, telephone number, fax number and email address]</p> <p>Telephone and fax numbers should be entered in the following format: +Country code Area code Number.</p> <p><u>Examples:</u> +61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>
45. Contact person responsible for updating information	<p>[Free text - Name, address, telephone number, fax number and email address]</p> <p>Telephone and fax numbers should be entered in the following format: +Country code Area code Number.</p> <p><u>Examples:</u> +61 2 95625333 (for Sydney, Australia) +1 310 8298781 (for Santa Monica CA, USA)</p>

Condition category and Condition code

Condition Category (level 1)	Condition code (level 2)
Alternative and complementary medicine	Spiritual care
	Herbal remedies
	Other alternative and complementary medicine
Anaesthesiology	Anaesthetics

Condition Category (level 1)	Condition code (level 2)
	Pain management
	Other anaesthesiology
Blood	Haematological diseases
	Anaemia
	Clotting disorders
	Normal development and function of platelets and erythrocytes
	Other blood disorders
Cancer	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)
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

Condition Category (level 1)	Condition code (level 2)
Ear	Deafness
	Other ear disorders
	Normal ear development and function
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
Thyroid disease	
Metabolic disorders	
Other metabolic disorders	
Normal metabolism and endocrine development and function	
Musculoskeletal	Osteoporosis
	Osteoarthritis
	Other muscular and skeletal disorders
	Normal musculoskeletal and cartilage development and function
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
Crohn's disease	
Other diseases of the mouth, teeth, oesophagus, digestive	

Condition Category (level 1)	Condition code (level 2)
	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
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