

This document is a data dictionary for fields that are available for download in the ANZCTR. For a complete list of definitions and explanations of all data fields completed when submitted a record for registration on the ANZCTR, please use the data field definition document available [here](#) on the ANZCTR website.

Table1: Trial tab

Tab name: TRIAL Description: Characteristics of the trials			
Variable name	Description	Values	Notes
Trial ID	Unique trial ID, also known as the request number (Note: this is different to the registration number (ACTRN))	Integer	
ACTRN	Registration number	ACTRN followed by a 12-digit number	Some ACTRN have a 'p' on the end, indicating provisional registration. This means that the study has not yet received ethics approval.
SUBMIT DATE	Date of submission	dd/mm/yyyy hh:mm:sec	
APPROVAL DATE	Data of registration	dd/mm/yyyy hh:mm:sec	
STUDY TITLE	Study title	String	The public title of the study is intended for the lay public and should be in easily understood language.
SCIENTIFIC TITLE	Scientific Title	String	The scientific title is intended for use in grant and ethics applications. It also includes the participant group, intervention, and primary outcome.
UTN	Universal trial number	String	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
TRIAL ACRONYM	Trial acronym	String	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)
LINKED STUDY	Identifying number of a parent study, sub-study or follow-up study	String	
INTERVENTIONS	Description of the specific intervention(s) being studied.	Free Text	
COMPARATOR	Description of comparator	Free text	The comparator/control(s) is/are the treatments against which the study intervention is being compared (e.g. placebo, no treatment, active control).
CONTROL	Type of Control	Active Uncontrolled Placebo Historical Dose comparison	A "control" group is the type of treatment to which the intervention is being compared, also known as a "comparator" group. 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. Note: Only 1 selection is allowed per record
INCLUSIVE CRITERIA	Inclusion criteria	String	Summary of key inclusion criteria of patient characteristics that determine eligibility for participation in the study.
MIN AGE	Minimum age of eligible study participants	Numeric	Not available means there was no age limit in the study
MIN AGE TYPE	The format that minimum age has been recorded in	Year Months Weeks, Days Hours No limit Not stated	"Not stated" is no longer available and it only belongs to older records
MAX AGE	Maximum age of eligible study participants	Numeric	Not available means there was no age limit in the study
MAX AGE TYPE	The format that maximum age has been recorded in	Year Months Weeks, Days Hours No limit	"Not stated" is no longer available and it only belongs to older records

		Not stated	
INCLUSIVE GENDER	Gender of study participants	Both males and females Males Females	
HEALTHY VOLENTEERS?	Indicate whether healthy volunteers may participate in this study	Yes No	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 they have been recorded as "No".
EXCLUSIVE CRITERIA	Exclusion criteria	String	Summary of key exclusion criteria of patient characteristics that determine eligibility for participation in the study
STUDY TYPE	Study type	Interventional Observational	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. Observational: A study in which no experimental intervention or treatment is applied. It involves observing without altering or influencing that which is being observed.
PURPOSE	Purpose of the study	Treatment Educational/ counselling/ training Diagnosis Prevention	Note: Only one selection is allowed per record
ALLOCATION	appropriate type of allocation to intervention	Randomised controlled trial	Randomised controlled trial means that allocation of subjects into different groups

		Non-randomised trials	<p>was random or by a method based on chance.</p> <p>Non-randomised trial means that allocation of subjects into different groups is expressly or deliberately done, and is not random or by chance.</p> <p>Note: Trials with quasi-randomisation allocation procedures do not qualify as a randomised trial.</p>
CONCEALMENT	Allocation concealment	String	<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.</p> <p>Note: Only applicable for randomised controlled trials.</p>
SEQUENCE	This is the method used to create the random order for the allocation of subjects into different groups	String	<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>
MASKING	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	<p>Blinded (masking used)</p> <p>Open (masking not used)</p>	<p>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.</p> <p>Note: 1. Only applicable for randomised controlled trials. 2. Only available when Interventional is selected for study type.</p>

ASSIGNMENT	The most appropriate description of the study's assignment	Single group Parallel Crossover Factorial Other	<p>Single group: all participants receive the same intervention throughout the study.</p> <p>Parallel: different groups of participants receive different interventions during the same time span of the study.</p> <p>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.</p> <p>Factorial: participants are randomly allocated to receive either no intervention, one or some interventions, or all interventions combined.</p> <p>Other: None of the selections provide an appropriate description of the study's assignment</p> <p>Note: Only available when Interventional is selected for study type</p>
OTHER DESIGN FEATURES	Other comments about the design of the study	String	<p>Note: Only available when Interventional is selected for study type</p>
ENDPOINT	The most appropriate study endpoint(s)	Safety Efficacy Safety/efficacy Bio-equivalence Bio-availability Pharmacokinetics Pharmacodynamics	<p>Safety: to show if the intervention is safe under conditions of proposed protocol/use.</p> <p>Efficacy: to measure an intervention's influence on a disease or health condition.</p> <p>Safety/efficacy: combination of safety and efficacy.</p> <p>Bio-equivalence: scientific basis for comparing generic and brand name drugs.</p> <p>Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body.</p>

			<p>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.</p> <p>Pharmacodynamics: action of drugs in living systems.</p> <p>Note: Only available when Interventional is selected for study type</p>
PHASE	The trial phase.	Phase 0 Phase 1 Phase 1/Phase 2 Phase 2 Phase 2/Phase 3 Phase 3 Phase 3/Phase 4 Phase 4 Not applicable	<p>Phase 0: includes exploratory, first-in-human trials.</p> <p>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.</p> <p>Phase 1/Phase 2: for trials at a combined stage of phases 1 and 2.</p> <p>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.</p> <p>Phase 2/Phase 3: for trials at a combined stage of phases 2 and 3.</p> <p>Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has</p>

			<p>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.</p> <p>Phase 3/Phase 4: for trials at a combined stage of phases 3 and 4.</p> <p>Phase 4: post-marketing study to delineate additional information.</p> <p>Not applicable: this selection is for a non-drug trial.</p> <p>Note: 1. Phases of investigation generally only apply to drug trials for the purposes of registration. 2. Only available when Interventional is selected for study type</p>
STATISTICAL METHODS	A brief summary of the statistical methods and/or analysis plan to be used to evaluate the data.	String	
MASKING1(PARTICIPANTS)	Indicates if the participants were blinded	TRUE FALSE	
MASKING2(CLINICIAN/THERAPIST)	Indicates if the clinicians/therapists were blinded	TRUE FALSE	
MASKING3(OUTCOMES ASSESSORS)	Indicates if the outcomes assessors were blinded	TRUE FALSE	
MASKING4(DATA ANALYST)	Indicates if the data analysts were blinded	TRUE FALSE	
PATIENT REGISTRY?	Indicates if this record describes a study that is	TRUE FALSE	A patient registry is an organised system that uses observational methods to collect uniform data prospectively for a population

	considered to be a patient registry.		defined by a particular disorder/disease, condition, or exposure and that serves a predetermined scientific, clinical, or policy purpose. Note: Only available when Observational is selected for study type
REGISTRY FOLLOW-UP	For patient registries, the anticipated time period over which each participant is to be followed.	Numeric	Only applicable if TRUE selected for 'PATIENT REGISTRY' field above.
REGISTRY FOLLOW-UP TYPE	For patient registries, the type of anticipated time period over which each participant is to be followed.	Weeks Months Years	Only applicable if TRUE selected for 'PATIENT REGISTRY' field above.
PURPOSE(OBSERVATIONAL)	Purpose of the study	String	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. Note: Only available when Observational is selected for study type
DURATION(OBSERVATIONAL)	Duration of the study	Numeric	Note: Only available when Observational is selected for study type
SELECTION(OBSERVATIONAL)	Sample selection of the study	Convenience sample Defined population	Convenience sample: participants or populations are selected at the convenience

		Random sample Case control	<p>of the investigator or primarily because they were available at a convenient time or place.</p> <p>Defined population: participants or populations are selected based on predefined criteria.</p> <p>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.</p> <p>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.</p> <p>Note: Only available when Observational is selected for study type</p>
TIMING(OBSERVATIONAL)	Timing of the study	Retrospective Prospective Both	<p>Retrospective: study that observes events in the past.</p> <p>Prospective: study that observes events in real time (may also occur in future).</p> <p>Both: study that combines retrospective and prospective observation.</p> <p>Note: Only available when Observational is selected for study type</p>
ANTICIPATED START DATE	Anticipated date of randomisation of the first participant for randomised trials. For non-randomised studies, it is defined as anticipated date that the first participant commences	dd/mm/yyyy	

	treatment/intervention/exposure		
ACTUAL START DATE	Actual date of randomisation of the first participant for randomised trials. For non-randomised studies, it is defined as the actual date that the first participant commences	dd/mm/yyyy	
ANTICIPATED END DATE	Anticipated date that recruitment into the study will cease.	dd/mm/yyyy	
ACTUAL END DATE	Actual date that the final participant was enrolled into the study	dd/mm/yyyy	
TARGET SAMPLE SIZE	The total number of participants the investigators plan to enrol before closing the trial to new participants.	Numeric	
FINAL SAMPLE SIZE	The final number of participants enrolled into the study at close of recruitment.	Numeric	
CURRENT SAMPLE SIZE	The total number of participants who have been enrolled into the study to date.	Numeric	
ANTICIPATED LAST VISIT DATE	Anticipated date of last data collection for last participant.	dd/mm/yyyy	

ACTUAL LAST VISIT DATE	Actual date that last data was collected for the last participant.	dd/mm/yyyy	
RECRUITMENT STATUS	The study's current recruitment status	Not yet recruiting Recruiting Active, not recruiting Completed Withdrawn Suspended Stopped early	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	Data analysis status	No data analysis planned Data collected is being analysed Data analysis is complete	This variable is only available when Stopped early is selected for 'Recruitment status'
WITHDRAWN REASON	Reason for early stopping/withdrawal	Lack of funding/staff/facilities	This variable is only available when Withdrawn or Stopped early is selected for Recruitment status

		Participant recruitment difficulties Safety concerns Other reasons/comments(please specify)	
WITHDRAWN REASON(OTHER)	Reason for early stopping/withdrawal	String	It is only available if, Other reasons/comments is selected in the withdrawn reason field
RECRUITMENT COUNTRY	Indicate where recruitment occurred	Australia Outside Australia, outside	
RECRUITMENT STATE	Indicate in which state of Australia did the recruitment occurred	NSW VIC QLD ACT NT TAS WA	Trials may include any combination of States and territories
PRIMARY SPONSOR	Specifies the type of primary sponsor	Government body Hospital University Commercial sector/industry Charities/societies/foundations Other collaborative groups Individual Other	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.

PRIMARY SPONSOR NAME	Name of the study's primary sponsor.	String	
PRIMARY SPONSOR ADDRESS	The full address of the primary sponsor	String	The full address of the primary sponsor, including work organisation/affiliation, street number and name, suburb/town city, postcode and state/province
PRIMARY SPONSOR COUNTRY	Country of primary sponsor	String	
ETHICS STATUS	Ethics application status	Not yet submitted Submitted, not yet approved Approved Not required	
BRIEF SUMMARY	Short description of the primary purpose of the study	String	This includes a brief statement of the study hypothesis, intended for the lay public.
TRIAL WEBSITE	Web address/ URL of the trial (if applicable)	String	
PUBLICATION	Trial related presentations / publication	String	This is a legacy field which was replaced the DATA SHARING STATEMENT and SUMMARY RESULTS tab in October 2018.
PUBLIC NOTES	Miscellaneous text that trialist would like included within the trial registration record which is not relevant elsewhere on this form	String	

Table2: Secondary ID tab

Tab name: SECONDARY ID Description: Information on secondary ID Note: Studies may include more than one secondary ID			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
Secondary ID	Identifying numbers issued by authorities other than the ANZCTR if any. Such as WHO, sponsors, funding bodies, etc.	String	All secondary identifiers will have 2 elements: an identifier for the issuing authority (e.g. NCT, ISRCTN) plus a number.

Table3: Health condition tab

Tab name: HEALTH CONDITION Description: Characteristics of primary health conditions in the trial			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
HEALTH CONDITION	Primary health condition(s) or problem(s) studied	String	Studies can include more than one health condition

Table4: Condition code tab

Tab name: CONDITION CODE Description: Condition category and code of the trial, please see Data item definitions available on the ANZCTR for a full list of condition/code combinations.			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number

CONDITION CATEGORY	The most appropriate condition category	String	Trials can include more than one category
Condition code	The most appropriate condition code	String	Trials can include more than one code

Table5: Intervention code tab

Tab name: INTERVENTION CODE Description: Characteristics of interventions of trials			
Variable name	Description	Values	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
INTERVENTION CODE	The most appropriate intervention code	Not applicable Diagnosis / prognosis Early detection / screening Prevention Treatment: drugs Treatment: surgery Treatment: devices Treatment: other Rehabilitation Lifestyle Behaviour Other interventions	<p>Not applicable: study in which no experimental intervention or treatment is applied. This selection is not available for interventional studies.</p> <p>Diagnosis / prognosis: study designed to evaluate one or more tests aimed at identifying a disease or health condition, or determining a patient's prognosis.</p> <p>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.</p> <p>Prevention: study designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.</p> <p>Treatment: drugs: study designed to assess the effect(s) of one or more chemical or biological agents including</p>

			<p>vaccines. Treatment: surgery: study designed to assess the effect(s) of one or more manual or operative surgical techniques.</p> <p>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.</p> <p>Treatment: other: studies that do not fall under the broad definitions of drug, surgical, or device trials.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Other interventions: studies that do not fit under any of the above categories. This should only be selected when no other options are adequate.</p> <p>Note: Trials may include more than one intervention code</p>
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Table6: Outcome tab

Tab name: PRIMARY OUTCOME Description: Characteristics of the primary outcomes in the trials Notes: Trials can include maximum of 3 primary outcomes			
Variable name	Description	Values	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
OUTCOME	Primary outcome(s) is the outcome(s) which provides the primary measure of the effectiveness (or lack of effectiveness) of the intervention	String	
TIMEPOINT	All timepoints at which the primary outcome is assessed	String	

Table7: Secondary outcome tab

Tab name: SECONDARY OUTCOME Description: Characteristics of secondary outcomes of the trials Notes: Trials can include maximum of 40 secondary outcome and timepoints			
Variable name	Description	Values	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
OUTCOME	Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at timepoints of secondary interest.	String	
TIMEPOINT	All timepoints at which the secondary outcome is assessed	String	

Table8: Hospital tab

Tab name: HOSPITAL Description: information regarding the recruiting hospital of the trials Notes: Trials may include more than one hospital			
Variable name	Description	Values	Notes
TRIAL ID	Unique Trial ID	Integer	6-digit number
HOSPITAL	The full name of the recruiting sites (e.g. hospital and clinics)	String	

Table9: Postcode tab

Tab name: POSTCODE Description: information regarding the postcode where recruiting of the recruitment will occur inside Australia			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
POSTCODE	The four-digit postcode for the suburb where recruitment will occur	'4-digit postcode' – 'Suburb name'	

Table10: Country outside Australia tab

Tab name: COUNTRY OUTSIDE AUSTRALIA Description: information regarding the country other than Australia in which recruitment will occur Notes: Trials may include more than one country			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
COUNTRY	Countries outside Australia	String	
STATE	State or province of that country	String	

Table11: Funding sources tab

Tab name: FUNDING SOURCE Description: Information regarding funding sources of study Notes: Trials may include up to 20 sets of entries			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
FUNDING SOURCE TYPE	Major source(s) of monetary or material or infrastructure support for the study	Government body Hospital University Commercial sector/industry Charities/societies/foundations Other collaborative groups Self-funded/unfunded Other	The selection 'Self-funded/unfunded' applies to studies which are either funded by an individual person or not funded at all.
FUNDING SOURCE NAME	Name of funding source	String	
FUNDING SOURCE ADDRESS	The full address of the named funding source	String	The full address of the funding source, including work organisation/affiliation, street number and name, suburb/town city, postcode and state/province
FUNDING SOURCE COUNTRY	Country of funding source	String	

Table12: Secondary sponsors tab

Tab name: SECONDARY SPONSOR Description: information regarding the secondary sources of the study Notes: Studies can include maximum of 20 secondary sponsors			
Variable name	Description	Values	Notes

TRIAL ID	Unique trial ID	Integer	6-digit number
SECONDARY SPONSOR TYPE	Type of secondary sponsor	Government body Hospital University Commercial sector/industry Charities/societies/foundations Other collaborative groups Other None	Additional individuals, organisations or other legal persons, that have agreed with the primary sponsor to jointly take on responsibilities of sponsorship.
SECONDARY SPONSOR NAME	Name of secondary sponsor	String	
SECONDARY SPONSOR ADDRESS	Address of secondary sponsor	String	The full address of the secondary sponsor, including work organisation/affiliation, street number and name, suburb/town city, postcode and state/province
SECONDARY SPONSOR COUNTRY	Country of secondary sponsor	String	

Table13: Other collaborators tab

Tab name: OTHER COLLABORATOR Description: information regarding other collaborators involved in the study Notes: Trial may include maximum of 20 other collaborators			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
OTHER COLLABORATOR TYPE	Additional individuals, organisations or other legal persons, if any, that have	Government body Hospital University	

	agreed with the primary sponsor to jointly take on responsibilities of sponsorship	Commercial sector/industry Charities/societies/foundations Other collaborative groups Other None	
OTHER COLLABORATOR NAME	Name of other collaborator	String	
OTHER COLLABORATOR ADDRESS	Address of other collaborator	String	The full address of the other collaborator, including work organisation/affiliation, street number and name, suburb/town city, postcode and state/province
OTHER COLLABORATOR COUNTRY	Country of other collaborator	String	

Table14: Ethics committees tab

Tab name: ETHICS COMMITTEE Description: information regarding ethics committees approval Notes: Trials may include a maximum of 50 entries			
Variable name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
ETHICS COMMITTEE NAME	Name of ethics committee	String	
ETHICS COMMITTEE ADDRESS	Address of ethics committee	String	The full address of the ethics committee, including street number and name, suburb/town city, postcode and state/province

ETHICS COMMITTEE COUNTRY	Country of ethics committee	String	
ETHICS SUBMIT DATE	the date that the ethics committee application will be/ was submitted	dd/mm/yyyy	
ETHICS APPROVAL DATE	the date that the ethics committee application was approved.	dd/mm/yyyy	
HREC APPROVAL ID	The approval ID assigned to the ethics application by the ethics committee at the time of granting approval.	String	

Table15: Contacts tab

Tab name: CONTACTS Description: Contact detail of main contact of the trials			
Variable name	Description	Values	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
TYPE	Type of contact	Principal investigator Public Queries Scientific queries Updating information	Note: "Updating information" is no longer available and only belongs to old records
TITLE	Title of the contact	A/prof Dr Miss Mr Mrs Ms Prof	

NAME	Name of contact	String	
ADDRESS	Address of contact	String	Include work organisation/affiliation, street number and name, suburb/town city, postcode and state/province
COUNTRY	Country of contact	String	
PHONE	Phone number of contact	+country code, area code, number	
FAX	Fax number of contact	+country code, area code, number	
EMAIL	Email of contact	String	

Table16: Data sharing statement tab

Tab name: DATA SHARING STATEMENT Description: information regarding how and where the data will be shared Note: These fields did not exist prior to October 2018.			
Variables name	Description	Value	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number
IPD AVAILABILITY	Indicates whether there is a plan to make individual participant data (IPD) publicly available for this trial	IPD and related data dictionaries are available IPD is not available Undecided	Due to new regulations “Undecided” option has been removed
DATA TO BE SHARED	Indicate what data will be shared	String	
TIMEFRAME	outlines the timeframe of data availability	String	

AVAILABLE TO WHOM?	Specifies who can/will be able to access the data	String	
FOR WHAT TYPES OF ANALYSES?	Indicates if there is a specific type of analysis for which the data are/will be available	String	
MECHANISIM	Specifies how/where data are/will be shared	String	
SUPPORTING DOCUMENTS	All types of supporting information that will be shared	No other documents available Study protocol Statistical analysis plan Informed consent form Clinical study report Ethical approval Analytic code Other (please specify)	
OTHER DOCUMENTS	Specifies other type of supporting document	String	If “Other (please specify)” was selected in SUPPORTING DOCUMENTS field this variable is mandatory.
IPD COMMENTS	Other comments regarding the IPD	String	

Table17: Summary results tab

Tab name: SUMMARY RESULTS Description: brief summary of where and how the results were published Note: These fields did not exist prior to October 2018.			
Variable name	Description	Values	Notes
TRIAL ID	Unique trial ID	Integer	6-digit number

RESULTS PUBLISHED IN JOURNALS?	Indicates whether any study results have been published in a peer-reviewed journal	Yes No	
RESULTS PUBLISHED ELSEWHERE?	Indicates whether any study results have been published in other sources	Yes No	
RESULTS ATTACHMENT	A URL where the results can be found	String	
RESULTS SUMMARY	A brief summary of the main results of your study	String	