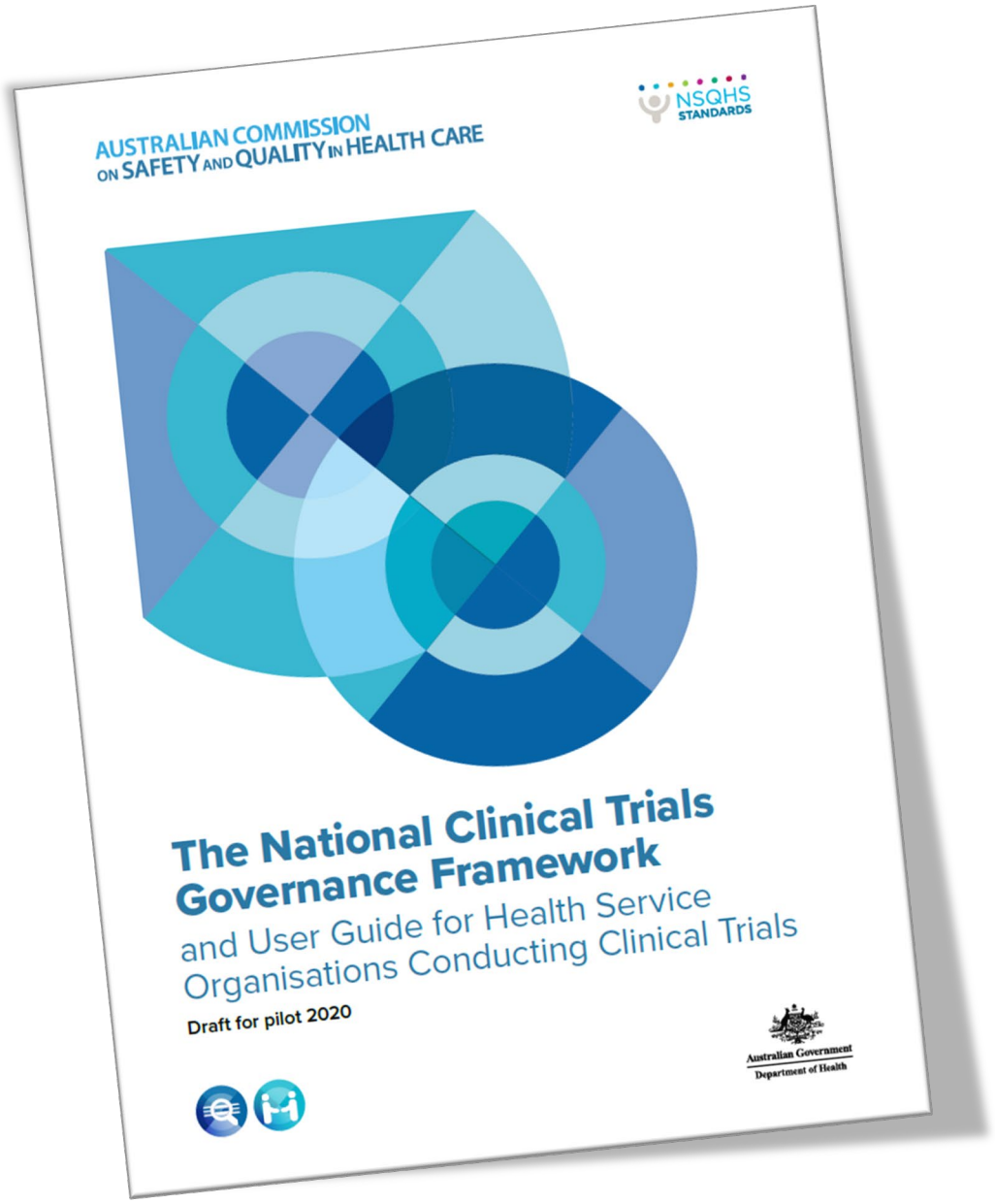
VCCC Alliance

Overcoming cancer together

MACH Melbourne Academic Centre for Health

METRICS AND YOU



About the VCCC Alliance

The Victorian Comprehensive Cancer Centre (VCCC) Alliance is a powerful partnership of 10 leading research, academic and clinical institutions, working together to fundamentally reshape the way we tackle cancer. Through strategic and structured collaboration, the VCCC Alliance drives change at a system level. Its innovative and integrated approach helps accelerate the translation of cutting-edge scientific evidence into better outcomes for people affected by cancer.

About the MACH group

The Melbourne Academic Centre for Health (MACH) is an NHMRC recognised Advanced Health Research and Translation Centre. The mission of MACH is to improve health and wellbeing by integrating medical research, education, and clinical care.

They undertake a variety of projects to further this mission, as well as to support its partner hospitals and research institutes. MACH convenes a range of committees that address gaps in the Australian healthcare and health research systems.

References

Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework (NCTGF) and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022.

With thanks to:

The VCCC Alliance Enhance Business Capabilities Working Group:

Marian Lieschke (Chair). Members: Anne Woollett, Carole Mott, Carolyn Stewart, Christine Brooks, Chris Packer, Christie Allan, Duncan Colyer, Eleonora Kay, Jhodie Duncan, Heike Raunow, Jacqui Waterkeyn, Kathleen Wilkins, Kaya Gardiner, Kaye McDowall, Marie Luci, Sarah Rathjen (MCRI).

Bernadette Aliprandi-Costa from the Australian Commission on Safety and Quality in Healthcare.

Contents

The purpose of this workbook

This booklet has been designed to help and support Research Offices (ROs), Clinical Trials Units (CTUs), and other departments that run clinical trials within health settings or academic institutions.

Whilst it is appreciated that not all trial units will have a dedicated systems in place which may impact the ease of collecting metrics, the guidance compiled here is not intended to only be exclusive to established CTUs.

This booklet has been developed to:

- Assist CTUs and other departments by highlighting their mandatory reporting requirements
- Explain metrics that are mandatory or suggested in the NCTGF
- Describe the metrics and how often these are to be reported
- Provide examples of metrics that can assist in better business development
- Demonstrate where metrics can be found
- Understand who is responsible for reporting metrics
- Present a list of common definitions associated with clinical trials and metrics.

For quick reference to the Minimum Data Set for Metrics, please refer to p10.

PART I

Metrics – an introduction

Clinical trial metrics are data points that provide insight into operational performance, and are powerful tools for assessing progress, decision-making, and measuring the strength of evidence used in clinical trials. There are several reasons for collecting metrics.

The Australian Commission on Safety and Quality in Healthcare's National Clinical Trials Governance Framework (NCTGF) outlines how clinical trials are to be more cohesively embedded into routine health service provision, including required operational metrics that incorporate the National Aggregate Statistics (NAS).

Metrics may be collected for local quality improvement or reported to other external bodies for specific purposes. As instruments to measure the effectiveness of a process, metrics are most useful when clearly defined at the outset of a study and selected for their relevance. For example, clinical trials units undertaking cancer clinical trials report various metrics annually to the Health Department. This booklet will include dedicated sections that highlight these requirements.

Metrics can also be used for business or quality improvement purposes within the unit or organisation.

The metrics required for these purposes have been captured in a Minimum Data Set (MDS), developed by the VCCC Alliance and MACH. This MDS will provide a benchmark from which CTUs and departments will be able to determine their own reporting requirements.

The collection, recording and reporting of appropriate data metrics include mandatory requirements and those recommended for the successful running of a clinical trial department. It is outside the scope of this booklet to give detailed reasons behind why each metric should be collected.

Background

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for the formulation of standards relating to healthcare safety and quality matters under the National Health Reform Act 2011. This includes coordinating the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme, which provides for the national coordination of compliance with applicable Government standards, known as accreditation.

Some of the AHSSQA scheme standards especially relevant in this context include:

- The National Safety and Quality Health Service (NSQHS) Standards, including Partnering with Consumers, which seeks to provide a nationally consistent statement of the level of care consumers can expect from health service organisations;
- The National Clinical Trials Governance Framework standards, which embed clinical trials into routine health service provision and strengthens the clinical and corporate governance arrangements for governments, hospital administrators, health services, private companies, trial sponsors and trial investigators.

It is mandatory for all public and private Health Service Organisations (HSOs) to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards. Where a HSO also conducts clinical trials, they must be accredited against the NCTGF. Each standard is made up of "actions" and a set of operational specifications is followed to ensure the goal of that standard is met. An accredited organisation is one that can provide evidence, to an Accrediting Agency, that it has processes in place which comply with each action under a standard. Once accredited, an organisation is issued with an accreditation Certificate with reviews and mid-cycle assessments conducted at regular intervals.

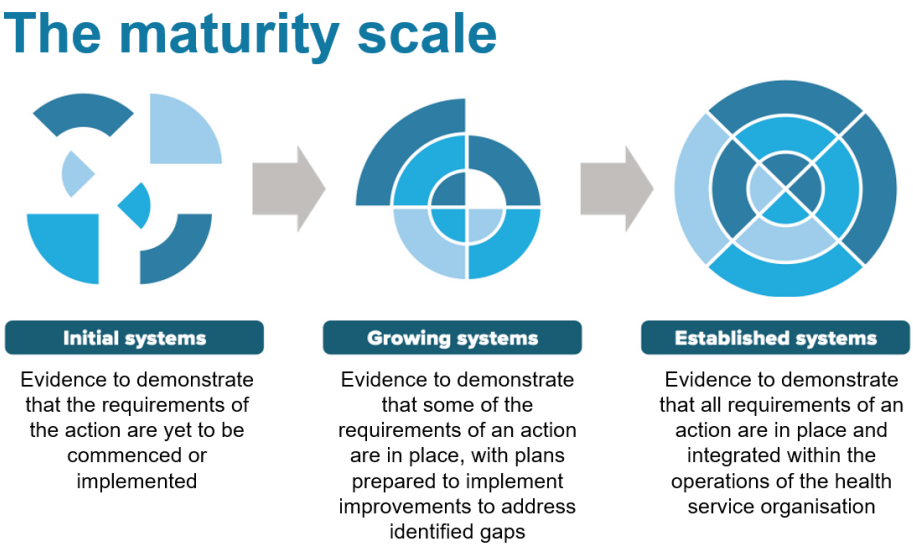
Compliance may be tested in different ways: by a federal government regulatory authority (e.g., the FDA or TGA) as an Inspection, by a Sponsor or third-party provider as a Good Clinical Practice audit, or by a notified body who ensure HSOs comply with standards applicable to their operations.

It is important to note that accreditation is not the same as an Inspection or an audit. Inspections and audits are generally study-specific and part of a vendor (sponsor or CRO) or a Regulatory Authority's quality assurance. They may also involve in-depth reviews of quality systems, including snapshot assessments or longitudinal evaluations of a project throughout its life cycle, in contrast to accreditation, which is not project specific.

Assessments

Short notice assessments will be implemented in 2023 so that HSOs are 'accreditation ready' at any time. This includes 48-hour notice, a desktop review, and then the physical visit. For the first three-year assessment cycle, HSOs will be assessed as either having initial systems, growing systems, or established systems in place.

"The Maturity Scale" – Australian Commission on Safety and Quality in Health Care.



Beyond this, HSOs will transition fully to assessment under AHSSQA Scheme and be assessed as either having met, met with recommendations, or not met the actions within the Governance Framework, and receive 60 business days to remediate.

The AHSSQA Scheme requires all hospitals and day procedure services to be assessed by onsite assessment. To ensure consistency, the Australian Commission on Safety and Quality in Health Care (the Commission) has developed a sampling methodology to be applied by all accrediting agencies when preparing for site assessment. Termed service sampling, this requires the following:

- Organisational chart
- Strategic and operational plan
- Executive and/or governing body details
  - List of departments or specialty areas conducting trials (e.g., Neurology, oncology, endocrinology)
  - Clinical trial name
  - Clinical trial phase (i, ii, iii, iv)
  - Sponsor type (e.g., Commercial, university, hospital) and sponsor name
  - Principal investigator (name and position)
  - Number of staff allocated to each trial
  - Number of patients enrolled in each trial
  - Number of Aboriginal and Torres Strait Islander patients enrolled in each trial.

For a HSO with up to 100 clinical trials to be assessed, the following calculation will be used: five (5) clinical trials plus one quarter of all remaining clinical trials are to be assessed, (rounded up to the nearest whole number). For health services with more than 100 clinical trials to be assessed, sampling will be capped at 30 trials.

Please note the metrics listed above have been captured in the Minimum Data Set as "Mandatory" with an asterisk to differentiate that this is required due to the Service Sampling Request, and not mandatory as outlined by the NCTGF.

Types of metrics

Depending on 'who' requires the metrics, these are identified in the Minimum Data Set and the Glossary as:

- Metrics: NCTGF Mandatory (*) – These are metrics mandated by the NCTGF. These metrics were previously captured as NAS metrics. Please note that * denote metrics that are not expressly listed within the NCTGF but are requested in the Service Sampling Guide by ACSQHC.
- Metrics: NCTGF Suggested – These are metrics suggested by the NCTGF or mentioned in Operational Metrics Tool. These are considered as useful relative to project goals, for instance, to identify where process improvements can be made or resource allocations can be changed; to establish performance benchmarks, and/or to effectively manage workload across teams.
- Metrics: CTU Improvement – These are metrics considered important when running a Clinical Trials Unit. These are helpful for business and quality improvements.
- Metrics: Cancer Census Data – These are metrics collected by Cancer Trials Australia on behalf of the Department of Health for the Annual Victorian Cancer Clinical Trials Census, and for regular updates to the Victorian Cancer Trials Link (VCTL).
- Metrics: Contributory – These are metrics that contribute to other metrics and are not metrics in their own right. An example is the date of an HREC submission.
- Metrics: Identifier – Identifiers are elements or part of bigger metrics used to help to identify the metric. This would include the HREC number.
- Metrics: Study vs Site – Study level metrics are collected about the study as a whole, while site level metrics are related to the activity of the study at a particular site.

See Part II of this booklet for additional common definitions associated with clinical trials and metrics collection.

Potential sources of metrics

For many metrics, there can be more than one source for the data. Sources for metrics can also provide data for multiple fields in the Minimum Data Set. For example, Clinical Trial Management Systems (CTMS) can provide information on many areas of Trial Information, Recruitment, Ethics and Governance and Finance. It will be up to your individual site to determine the best way that the metrics are collected and/ or collated.

The potential sources for the data can include:

- Electronic Medical Record (EMR)
- Ethical Review Manager (ERM)
- Clinical Trial Management Systems (CTMS) e.g., Clinibase
- Ethics data bases such as ReDA
- Internal spreadsheets.

WHERE is the data found?

The 'Potential sources of metrics' section above provides an overview of where the data is found. Different departments may have access to and collect this information from various sources for their own uses and reporting. The Ethics and Governance section of the Minimum Data Set, for example, includes data fields that can be utilised by a variety of departments (RO or CTU). Some of this information may be available from more than one department or from more than one data source, and it is important to realise the best place from which to access the data. For example, the same data is captured on both the Human Research Ethics Application (HREA), found in the Research Office, and in a Clinical Trials Unit's Clinical Trial Management System (CTMS). Depending on who is requesting the data, the CTMS may be more accessible than the information in the HREA.

Generally, if it is known what information each department holds, these departments are better able to be contacted and the information shared. This can include reporting to the HSO executive. Who reports this data will be explained below.

WHO reports the data?

Depending on the data collected, the structure of your CTU or department may determine who reports it and to whom. Reporting is generally the role of the Research Office and the Clinical Trials Unit.

As an example, some HSOs have a directorate that is reported into, such as a cancer directorate. Some HSOs will report directly to the Executive. This may be the responsibility of the Research Office or the Clinical Trials Unit. The reporting may be related to the NCTGF mandatory requirement, although additional information may be requested.

Cancer CTUs will have other reporting requirements, such as to the Annual Victorian Cancer Clinical Trials Census or to the Regional Trials Network. The MDS can be used to provide a benchmark to help inform CTUs and departments to develop workflows to outline who is responsible for individual reporting requirements.

The workflow you choose will depend on factors including:

- What data your department is already collecting and reporting
- Which data sources are currently being utilised
- Which department is considered responsible for each type of report

- The reporting structure at your organisation.

Using the Minimum Data Set (MDS) Tables

The following tables are quick references **only** of the Minimum Data Set. These have been organised by metric category: Trial Information, Recruitment, Ethics and Governance, Finance and Safety. For definitions, the usefulness of a metric, for example where this data may be found, and for further information, please refer to the online hosted resource Clinical Trial Innovations | Research and Translation | VCCC Alliance.

Please note also that X* denotes metrics that are not expressly listed within the standards but have been requested in the Service Sampling Guide for the NTCGF.

For ease of reference, the following legend applies (terms listed alphabetically):
X = Indicates metric required
X* = Metrics required in Service Sampling
CTU = Clinical Trial Unit
CTMS = Clinical Trial Management System
EMR = Electronic Medical Record
HREA = Human Research Ethics Application
NEAF = National Ethics Application Form
RO = Research Office
RTN Vic = Regional Trial Network – Victoria
NCTGF = National Clinical Trials Governance Framework

See Part II of this booklet for additional common definitions associated with clinical trials and metrics collection.

Minimum Data Set: Trial Information Metrics

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Scientific Title		X	X	X		X	RO or CTU	Protocol	Site	RO or CTU
Acronym or Short Title		X	X	X		X	RO or CTU	Protocol	Site	RO or CTU
Trial registration # (ACTRN)				X		X	RO or CTU	ANZCTR	Site	RO or CTU
Trial registration # (NCT)				X		X	RO or CTU	ClinicalTrials.gov	Site	RO or CTU
Trial registration # (Other)		X		X		X	RO or CTU	Protocol	Site	RO or CTU
Registration under Clinical Trial Notification Scheme (CTN)		X				X	RO	Sponsor, Feasibility documents	Site	RO or CTU
Registration under Clinical Trial Approval Scheme (CTA)		X				X	RO	Sponsor, Feasibility documents	Site	RO or CTU
Phase (Metric 1)	X	X	X	X	X	X	RO or CTU	Protocol	Site	RO or CTU
Study type		X	X			X	RO	NEAF/HREA	Site	RO or CTU
Trial type				X			RO	NEAF/HREA	Site	RO or CTU

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Teletrial: Primary or Satellite Site			X	X	X		RO or CTU	HREA	Site	RO or CTU
Teletrial format					X		CTU	RGO documentation	Study	RO or CTU
MMM Code					X		CTU	Postcode data from CTMS	Site	CTU
Overall status of trial			X	X			CTU	CTMS, internal spreadsheet	Study	RO or CTU
Site status		X	X	X			CTU	CTMS, internal spreadsheet	Site	RO or CTU
Common Scientific Outcome (CSO) category			X	X			Cancer specific CTU	ClinicalTrials.gov, ANZCTR, internal database	Study	CTU
Major sponsor type (Metric 1)	X	X	X	X			RO or CTU	Protocol, CTMS	Site	RO or CTU
Name of sponsor	X*		X				RO or CTU	Protocol	Site	CTU
Type(s) of funding	X*		X				CTU	Sponsor contract	Study	RO or CTU
Funder(s) of trial			X				RO	Internal spreadsheet	Site	CTU

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Start date of the trial				X			RO	Sponsor	Study	CTU
End date of the trial				X			RO	Sponsor	Study	CTU
Completed hospitals				X			RO	HREC, Sponsor	Study	CTU
Not yet recruiting hospitals				X			RO	Sponsor	Study	CTU
Recruiting hospitals			X	X			RO	ClinicalTrials.gov, ANZCTR	Study	CTU
Closed hospitals				X			RO	HREC, Sponsor	Study	CTU
Patient sex (as per trial eligibility criteria)			X	X			CTU	Eligibility criteria in the protocol	Site	CTU
Clinical Trial Department	X*	X	X			X	RO or CTU	HREA, CTU internal spreadsheets	Site	CTU
Date selected by trial sponsor			X				CTU	Internal spreadsheet in CTU	Site	CTU
Disease type			X	X			RO or CTU	HREA	Site	CTU

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Tumour type			X	X			Cancer specific CTU	HREA	Site	CTU

Minimum Data Set: Recruitment Metrics

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Total anticipated recruitment for trial (NAS metric 6)	X	X	X				CTU/Sponsor	Protocol	Study	RO or CTU
Total actual recruitment for trial (NAS Metric 6)	X	X					CTU/Sponsor	EMR, Sponsor, annual project progress report	Study	RO or CTU
Anticipated recruitment at site (NAS Metric 7)	X	X	X		X		CTU	Sponsor, Feasibility documents	Site	RO or CTU
Actual recruitment at site (NAS metric 7)	X	X	X				RO or CTU	EMR, CTMS, internal spreadsheets, Annual Reports	Site	RO or CTU
Total NEW participants YYYY	X	X	X	X (Annual)			CTU	EMR, CTMS, internal spreadsheets, Annual Reports	Site	RO or CTU
Number of potential participants screened at site (Screen Failures)		X	X				CTU	Screen Fail logs, CTMS	Site	CTU
Total FOLLOW UP patients			X	X			CTU	CTMS, EMR, internal spreadsheets	Site	CTU

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Time to First Patient First Visit (FPFV)		X	X				CTU	CTMS, EMR, internal spreadsheets	Site	CTU
Site Initiation Visit			X		X		CTU	CTMS, internal spreadsheets	Site	CTU
Year of birth for each NEW participant			X	X (Annual)	X		CTU	CTMS, EMR	Site	CTU
Residential postcode for each NEW participant			X	X (Annual)	X		CTU	CTMS, EMR	Site	CTU
Aboriginal/Torres Strait Islander and First Nations	X*		X				CTU	EMR	Site	CTU
Culturally and Linguistically Diverse (CALD)			X				CTU	EMR	Site	CTU

Minimum Data Set: Safety Metrics

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Clinical Incidents		X	X				RO or CTU	Annual reports, sponsor/ regulatory audit reports, internal reporting	Site	RO or CTU

Minimum Data Set: Ethics and Governance Metrics

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
Mode of HREC review		X	X			X	RO	Feasibility documents, HREA	Site	RO or CTU
Low risk		X	X				RO	HREA	Site	RO or CTU
Reviewing HREC state		X					RO or CTU	HREA	Site	RO or CTU
Reviewing HREC		X	X			X	RO	Feasibility documents, HREA	Site	RO or CTU
HREC meeting date		X					RO or CTU	Feasibility documents, HREA	Site	RO or CTU
HREC submission date		X	X			X	RO	Feasibility documents, HREA	Study	RO or CTU
HREC validation date		X				X	RO	Ethics Approval letter	Study	RO or CTU
HREC approval date		X	X			X	RO	Ethics Approval letter	Site	RO or CTU
HREC reference number		X	X	X		X	RO	Ethics Approval letter	Site	RO or CTU
SSA reference number		X	X			X	RO	RGO Approval letter	Site	RO or CTU

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
SSA submission date		X	X			X	RO	RGO Approval letter	Site	RO or CTU
SSA validation date		X	X			X	RO	RGO Approval letter	Site	RO or CTU
SSA authorisation date		X	X			X	RO	RGO Approval letter	Site	RO or CTU
Derived Metrics										
Overall Study Start-Up Timeline (Regulatory Timeline) – Without Clock (NAS Metric 2)	X		X				RO	Derived from metrics above and captured in feasibility, Research Office	Study	RO or CTU
HREC and SSA/Site Assessment Approval Timeline – With Clock (NAS Metric 3)	X		X				RO	Derived from metrics above and captured in feasibility, Research Office	Study and Site	RO or CTU
HREC Approval Timeline Without Clock (NAS Metric 4a)	X	X	X				RO	Derived from metrics above and captured in feasibility, Research Office	Study	RO or CTU
HREC Approval Timeline With Clock (NAS Metric 4b)	X	X					RO	Derived from metrics above and captured in feasibility, Research Office	Study	RO or CTU
SSA/Site Authorisation Timeline – Without Clock (5a) From HREC Approval Date/SSA Validation Date (NAS – Metric	X	X	X				RO	Derived from metrics above and captured in feasibility, Research Office	Site	RO or CTU
SSA/Site Authorisation Timeline – With Clock (5b) From HREC Approval Date/SSA Validation Date (NAS Metric 5)	X	X	X				RO	Derived from metrics above and captured in feasibility, Research Office	Site	RO or CTU
Number of trials pending site authorisation by reporting period and /or year to date		X	X				RO or CTU	Derived from metrics above and captured in feasibility, Research Office	Site	RO or CTU

Minimum Data Set: Finance Metrics

Metric	WHO requires the data?						WHERE is the data?			WHO reports the data?
	NCTGF Mandatory*	NCTGF Suggested	CTU Improvement	Cancer Census Data	Teletrials / RTN Vic	Contributory / Identifier	Who keeps the data?	Example data sources	Study or Site Level?	
FTE on trial	X*	X	X				CTU	Internal spreadsheet	Site	CTU
Trials cost		X	X				CTU	Internal spreadsheets, CTMS	Site	CTU
Total Inbound (internal and external) Investment Annually (FY) Actual/Planned (NAS Metric 8)	X		X				CTU	CTMS, internal spreadsheets	Site	RO or CTU

PART II

Glossary

This glossary draws on work by the Clinical Oncology Society of Australia (COSA) Australasian Teletrials Model with additional information from the Victorian Comprehensive Cancer Centre (VCCC) Alliance on Teletrials SOP, originally developed in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU).

ABORIGINAL AND TORRES STRAIT ISLANDER STATUS

See **FIRST NATIONS**

Metrics: CTU Improvement, Metrics: Teletrials

ACCREDITING AGENCY

Approved accrediting agencies assess health service organisations to the National Safety and Quality Health Service (NSQHS) Standards and/or the Multi-Purpose Services (MPS) Module. These agencies are approved by the Australian Commission on Safety and Quality in Health Care (the Commission) following application and review by an approval panel.

AMENDMENT

A written description of a change(s) to or formal clarification, often in relation to the PROTOCOL. The Protocol amendment must be formally approved by a HREC prior to being enacted. The protocol amendment may also result in an updated PATIENT INFORMATION AND CONSENT FORM.

ANNUAL VICTORIAN CANCER CLINICAL TRIALS CENSUS SPECIFIC METRICS

Cancer Trials Australia is responsible for collection of data towards the Annual Victorian Cancer Clinical Trials Census on behalf of the Department of Health. These metrics are used to support the evaluation of the Victorian Cancer Plan(s), for program evaluation. External Organisations and individuals interested in understanding/informing their work in clinical trials can also request a de-identified dataset through Cancer Trials Australia. Below are some metrics that are provided directly towards the Census.

COMMON SCIENTIFIC OUTCOME (CSO) CATEGORY

This is a data point collected for the Census. Options include: biology, etiology, prevention, early detection diagnosis and prognosis, treatment, cancer control survivorship and outcomes research, scientific model systems.

Metrics: Cancer Census Data

COMPLETED / CLOSED HOSPITALS

This is the list of sites that have recorded that they have closed out, completed or archived the trial in question at their site.

Metrics: Cancer Census Data

DISEASE TYPE / TUMOUR STREAM

This metric groups the cancer type that is being studied. Options include: blood/myeloma/lymphoma, bowel (colorectum), brain and spinal cord, breast, female reproductive organs, head and neck, lung, multiple, sarcoma, skin, stomach and upper gastrointestinal, urinary system.

Metrics: Cancer Census Data, Metrics: CTU Improvement

END DATE OF THE TRIAL

This is the latest documented end date of the trial at a recorded Victorian site (i.e., the date the last Victorian site is completed/closed). This is not site specific.

Metrics: Cancer Census Data

PARTICIPANT GENDER

This is a record of the eligibility criteria at a trial level, not at a participant level. For example, if both males and females are eligible for a breast cancer study, or if it is just females.

Metrics: Cancer Census Data

OVERALL STATUS OF THE TRIAL

The overall status of the trial is not site specific; this is captured under SITE STATUS. Overall Status of the Trial captures a change in status of the trial as a whole at Victorian sites. The options of the overall status include: not yet recruiting, recruiting, recruitment on hold, closed, completed.

Metrics: Cancer Census Data

RECRUITING AND NOT YET RECRUITING HOSPITALS

This site-specific notification for CANCER TRIALS AUSTRALIA is used to inform the OVERALL STATUS OF THE TRIAL. The site status can be used to keep platforms, like the VCTL, up to date.

Metrics: Cancer Census Data

SITE STATUS

The site status of the trial reflects changes in the status of the trial at the site, and that site only. The options include: Open to Accrual, Closed to Accrual, Completed.

Metrics: Cancer Census, Metrics: CTU Improvement

START DATE OF THE TRIAL

This is the first documented date the trial was open at any recorded Victorian site. This is not site specific.

Metrics: Cancer Census Data

TRIAL TYPE

Trial type relates to the treatment being a systemic therapy, medicine, radiotherapy, surgery, or a combination of these. Some reporting may require that the trial type is 'treatment' or 'non-treatment'. This provides context to the COMMON SCIENTIFIC OUTCOME category.

Metrics: Cancer Census Data, Metrics: CTU Improvement

APPROVING AUTHORITIES

Approving authorities are legal entities (public or private institutions or organisations) where trials are conducted. For INVESTIGATOR INITIATED TRIALS and REGISTRY TRIALS the HEALTH SERVICE ORGANISATION or CLINICAL TRIAL SITE that is the approving authority may also be the SPONSOR. In such cases the governing body ensures that its overarching governance and quality management systems delineate its responsibilities as a trial SPONSOR from its responsibilities as a CLINICAL TRIAL SITE and ensures that the requirements of sponsorship can be met.

ASSOCIATE INVESTIGATOR (AI)

Any individual member of the CLINICAL TRIAL TEAM who is suitably qualified, delegated and supervised by the PRINCIPAL INVESTIGATOR to perform trial-related procedures and/or to make trial-related decisions e.g., associates, residents, research fellows. In ICH GCP the term Sub Investigator is used. In the Australian context, the role of an Associate Investigator is also used interchangeably for this position.

AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY (AHPRA)

Working with 15 National Health Practitioner Boards, the Australian Health Practitioner Regulation Agency (AHPRA) is the national organisation responsible for implementing the National Registration and Accreditation Scheme (the National Scheme) across Australia.

CLINICAL INCIDENTS

Clinical Incidents is defined as "an event or circumstance that resulted, or could have resulted, in unintended and/or unnecessary harm to a person and/or a complaint, loss or damage". It is suggested that a summary of data collated from clinical trial annual reports, sponsor and regulatory audit reports, and reports of clinical incidents that are monitored by managers and the governing body is recorded.

Clinical incidents in this regard can include the reporting of SUSARS and SERIOUS BREACHES.

Metrics: NCTGF Suggested, Metrics: CTU Improvement

CLINICAL REGISTRY

A database that collects clinical information for a specific area of interest able to support a variety of research questions. A clinical registry can be designed to be disease, health services or product specific.

CLINICAL TRIAL / CLINICAL RESEARCH

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

Clinical trials include but are not limited to:

- Surgical and medical treatments and procedures
- Experimental drugs and diagnostics
- Biological products
- Medical devices
- Health-related service changes
- Health-related preventative strategies

- Health-related educational interventions

The terms clinical trial, clinical study, research study, and research project are synonymous in this document. Clinical trials are a type of research that studies new tests and treatments and evaluates effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, and preventive care. It is important to recognise which term is being used in which context.

CLINICAL TRIAL PARTICIPANT/SUBJECT

An individual who has CONSENTED (i.e., signed a consent form) and agreed to participate in a CLINICAL TRIAL. If a potential participant/subject does not meet eligibility, they are a SCREEN FAIL. A clinical trial participant can be in the treatment or FOLLOW UP stage. The term SUBJECT is primarily used by Sponsors. Clinical Trial Participants are counted in various metrics.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

CLINICAL RESEARCH COORDINATOR (CRC) / CLINICAL TRIAL COORDINATOR (CTC)

A member of the clinical trial workforce who works at a clinical research site under the immediate direction of a Principal Investigator, and whose research activities are conducted in accordance with Good Clinical Practice guidelines, the National Statement, and the National Clinical Trials Governance Framework. May also be called “Clinical Study Coordinator” or “Trial Coordinator” or “Research Coordinator” or “Research Nurse”.

CLINICAL TRIAL APPROVAL (CTA) AND CLINICAL TRIAL NOTIFICATION (CTN) SCHEME – (previously Clinical Trials Exemption (CTX) scheme)

The Clinical Trial Approval scheme is established under the Therapeutic Goods Act 1989 (Cth) and is an approval process administered by the TGA. Under the scheme, a sponsor seeks approval to supply “unapproved” therapeutic goods in a clinical trial. Registration under the either schemes are required for NCTGF data collection.

Metrics: Identifier

CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)

A software system where CLINICAL TRIAL activity can be planned, recorded, and used for reporting purposes. This can be on a PARTICIPANT or STUDY level. CTMS can also be used for billing. CTMS can vary widely.

CLINICAL RESEARCH ORGANISATION (CRO)

An Australian person or an organisation (commercial, academic, or other) contracted by the Global Sponsor to perform one or more of a Sponsor’s trial related duties and functions in Australia.

CLINICAL TRIAL RESEARCH AGREEMENT (CTRA)

A legally binding agreement that defines and manages the relationship between Sponsor and Institution where the Sponsor may be providing the study drug or device, the financial support and/or proprietary information and the Institution may be providing data and/or results, publication, or input into further intellectual property. The agreement covers matters such as confidentiality, intellectual property, ownership of data, insurance, and indemnity. The Medicines Australia CTRA is the recommended Standard form.

CLINICAL TRIAL DEPARTMENT /UNIT

A department in a health service organisation where members of the clinical trial workforce perform clinical trial-related duties, including the management, examination and/or treatment of participants. The department must provide security for the storage of the test article and must be staffed with members of the clinical trial workforce who are clinically qualified to perform required procedures described in the protocol. In addition, the department must provide adequate storage for all study related materials with appropriate working space for sponsor monitoring. See: SAFE ENVIRONMENT

CLINICAL TRIAL PROJECT REFERENCE GROUP (CTPRG)

A group comprising of senior officials from the Commonwealth, State, and territory health departments and the NMHRC. Taking a strategic focus, the CTPRG engages with the clinical trials industry, its partners, and key stakeholders (including consumers and registry groups) to assist in a broad range of clinical trial activities from redesigning, streamlining, and raising awareness. The CTPRG are responsible for developing the NAS metrics.

CLINICAL TRIAL TEAM

The clinical trial team includes members of the clinical trial workforce, identified by the PRINCIPAL INVESTIGATOR, who are responsible for participant care, study coordination, data collection and data management. Members of the clinical trial team may be the CLINICAL RESEARCH COORDINATOR, INVESTIGATOR, clinical trial pharmacist or Clinical Trial Assistant. Their responsibilities in the clinical trial will be outlined on the DELEGATION LOG.

Metrics: NCTGF Suggested, Metrics: CTU Improvement

COOPERATIVE or COLLABORATIVE (RESEARCH) GROUP (CRG)

An academic and/or non-commercial entity responsible for Sponsoring, initiating, managing, developing, and coordinating the Study. It can also be an informal group who form a collegiate to facilitate collaborative research between organisations.

CONSENT

See **INFORMED CONSENT** or **PARTICIPANT INFORMATION CONSENT FORM**

COORDINATING PRINCIPAL INVESTIGATOR (CPI)

The term Coordinating Principal Investigator (CPI) is a term used in Australia in the context of the National Mutual Acceptance NMA scheme to describe the Investigator responsible for the conduct of the study and coordination of Investigators at different sites participating in a multicentre trial. This includes

coordination of all HREC processes, such as the initial submission and any required notifications throughout the trial. However, the CPI cannot be responsible for trial activity at a site except the site where they act as the Principal Investigator.

CORE IDENTIFIERS

Core identifiers are components that help identify a trial and are unique to that trial. These are collected as part of mandatory reporting (e.g., NCTGF) and other reporting (e.g., Annual Victorian Census) as they help to identify the trial being reported on.

ACRONYM or SHORT TITLE

The official Acronym or Short Title used in a study's SCIENTIFIC TITLE. Remains a consistent and unchanging identifier across study sites and submissions, therefore often included in most metric reporting data sets. See also: PROTOCOL NUMBER.

Metrics: Identifier

HREC REFERENCE NUMBER

This is the unique number that the HREC will ascribe the trial or research when reviewing it. The number may reflect the type of review, place of the review, project number and the year of the review e.g., HREC/RMH/22642/2021. Some sites may have their own specific numbering identifiers e.g., 2017/125.

Metrics: Identifier

SSA REFERENCE NUMBER

This is the unique number that the RGO will ascribe the trial or research when reviewing it. The number may reflect the type of review, place of the review, project number and the year of the review e.g., SSA/RMH/22642/2021. Some sites may have their own specific numbering identifiers e.g., 2017/125.

Metrics: Identifier

PHASE – CORE IDENTIFIER

The 'phase' of the trial denominates which stage the trial is in the research process and each trial has a defined phase from Phase 0 to Phase IV. The phase is noted in the protocol usually/noted in the Scientific Title.

NAS definition: Number of new trials per trial phase (by trial type 'medicine' only): FTIH/FTIP, Phase 1, Phase 2, Phase 3, Phase 4, Total

Metrics: NCTGF Mandatory, Metrics: Identifier, Metrics: Cancer Census Data

SCIENTIFIC TITLE

Official term for the title of a study. The Scientific Title should include the study's ACRONYM/SHORT TITLE if there is one.

Metrics: Identifier

SHORT TITLE

See **ACRONYM**.

TRIAL REGISTRATION

The Trial Identification / Trial ID number. These are the identifiers used when registering a trial with Clinicaltrials.gov, ANZCTR or others including Eudra-CT or the protocol number.

Metrics: Identifier

CULTURALLY AND LINGUISTICALLY DIVERSE (CALD)

Australia's population includes many people who were born overseas, have a parent born overseas or speak a variety of languages. Together, these groups of people are known as culturally and linguistically diverse (CALD) populations. The Australian Bureau of Statistics (ABS) defines the CALD population mainly by country of birth, language spoken at home, English proficiency, or other characteristics (including year of arrival in Australia), parents' country of birth and religious affiliation (ABS 1999). Country of birth is the most common data element among Australian Institute of Health and Welfare.

Metrics: CTU Improvement

DELEGATION LOG

A list of appropriately qualified and trained members of the clinical trial workforce to whom the PRINCIPAL INVESTIGATOR has delegated significant study-related duties and functions. The Delegation Log documents which study-specific roles and responsibilities are assigned to each member of the CLINICAL TRIAL TEAM. Delegation Logs must be actively maintained (not constructed retrospectively), so there is evidence of appropriate delegation before any trial activities are undertaken and throughout the trial as members of the clinical trial team change over time. Each entry is signed and dated by the delegates and countersigned by the PRINCIPAL INVESTIGATOR.

DOCUMENTATION

All records, in any form (including, but not limited to, written, electronic, magnetic, optical records, scans, x-rays and electrocardiograms) that describe or record the methods, conduct, results of and information about a trial.

ESSENTIAL DOCUMENTS

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. They may be subject to, and should be available for, audit by the Sponsor's auditor and inspection by the REGULATORY AUTHORITY(ies). Essential Documents for the trial should be supplemented or may be reduced where justified (in advance of study initiation) based on the importance and relevance of the specific documents to the study.

ELECTRONIC MEDICAL RECORD (EMR)

An electronic medical record (EMR) is a digital version of a paper chart that contains all a patient's medical history. A record of the CLINICAL TRIAL PARTICIPANT's stage (CONSENT, ENROLLED, RANDOMISED or FOLLOW UP) will be captured in the EMR.

ENROLLED

A participant has enrolled onto a study once they have consented, been screened, and met all eligibility criteria.

Metrics: Cancer Census Data, Metrics: CTU Improvement,

Metrics: NCTGF Mandatory

Number of new PARTICIPANTS ENROLLED on to a CLINICAL TRIAL and TRIAL UNIT for the reporting period and year to date.

Metrics: NCTGF Suggested

ERM (ETHICS RM / ETHICAL REVIEW MANAGER)

An Ethics Application System. Research proposals are submitted through the ERM to the HREC. ERM is used in public hospitals in Queensland, Victoria and at Mater Research (Brisbane, QLD).

FEASIBILITY

A process to determine if a site is adequately equipped and has the appropriate facilities to conduct a specific study. Considerations include secured storage for all study related materials, access to patient population under study, sufficient staffing to conduct study related procedures, data collection and reporting, and space for sponsor monitoring. See SITE QUALIFICATION VISIT

FINANCE

Various metrics are collected by the NCTGF around finances. These will be captured below:

EXPECTED INCOME

Total expected inbound investment (internal and external) annually by trial, trial unit, hospital, jurisdiction.

Calculation: (targeted number participants at this site) x (per participant payment) AND (pharmacy investment amount) AND (pathology investment amount) AND (total any other income).

Metrics: NCTGF Mandatory, Metrics: NCTGF Suggested,

Metrics: CTU Improvement

FULL TIME EQUIVALENT (FTE) ON TRIAL

This metric aims to collect the total FTE of staff in the CLINICAL TRIAL TEAM from the CLINICAL TRIAL DEPARTMENT. The staff should be documented on the DELEGATION LOG.

Metrics: NCTGF Suggested, Metrics: CTU Improvement

Proportion of enrolments to total Full Time Equivalent (FTE) trial coordinator or staff member with functions undertaking trial recruitment for the reporting period and/or year to date.

Metrics: NCTGF Suggested

Clinical trials financial reconciliation by clinical trial and trial unit for the reporting period and/or year to date.

Metrics: NCTGF Suggested

TOTAL INBOUND (INTERNAL AND EXTERNAL INVESTMENT) ANNUALLY

Total actual inbound investment (internal and external) annually by trial, trial unit, hospital, jurisdiction, and nationally. Add any expected payments to be received for the trial; this information is included in the clinical trial research agreement and financial summary and is available from clinical trial coordinators. This information will support internal organisation financial tracking.

Calculation: (targeted number participants at this site) x (per participant payment) AND (pharmacy investment amount) AND (pathology investment amount) AND (total any other income).

Metrics: NCTGF Mandatory, Metrics: NCTGF Suggested,

Metrics: CTU Improvement

TRIAL COST

This a trial specific measurement that will indicate if the trial is cost negative, cost neutral or cost positive.

Metrics: CTU Improvement

FIRST NATIONS

First Nations, or Aboriginal and Torres Strait islander, is a self-identified status. In CLINICAL TRIALS it is a metric that can be used to understand the rate of clinical trial RECRUITMENT within the population. This information can then be used to better understand equity issues in clinical trials.

Metric: CTU Improvement, Metrics: Teletrials

FIRST TIME IN HUMAN (FTIH)

The first time an unapproved INVESTIGATIONAL MEDICINAL PRODUCT is administered to a healthy human.

Metrics: Contributory

FIRST TIME IN PATIENT (FTIP)

The first time an unapproved INVESTIGATIONAL MEDICINAL PRODUCT is administered to a human with a medical condition.

Metrics: Contributory

FOLLOW UP

The stage in a clinical trial after the treatment phase ends. The length of the follow up stage is determined by the protocol. This is a metric captured in some reporting requirements. For the Victorian Cancer Census, Cancer Trials Australia calculates the total number of follow up patients in a reporting year. This refers to the number of patients who consented to trial participation prior to the 1st of January AND are still receiving treatment or participating in follow up data monitoring activities between the 1st of January and 31st of December in a trial that is either open to accrual (recruiting) or closed to accrual (not recruiting).

Metrics: Cancer Census Data, Metrics: CTU Improvement

FUNDER OF A TRIAL

The funder of a study can be different to the Sponsor of that study. The funder is the body that is actually paying for the study. It may be a pharmaceutical company, a grant or philanthropy. It is important for trials departments to understand the difference between FUNDER OF A TRIAL and SPONSOR as this has implications for the effective running of a trials unit or department. Note that MAJOR SPONSOR TYPE and NAME OF SPONSOR are captured elsewhere.

Metrics: CTU Improvement

GENDER

The Australian Bureau of Statistics defines gender as social and cultural differences in identity, expression and experience as a man, woman, or non-binary person. A person's gender may differ from their sex and may also differ from what is indicated on their legal documents. Clinical trials frequently have inclusion or exclusion criteria surrounding participant sex.

GOOD CLINICAL PRACTICE (GCP) ICH GCP E6 (R2) / ICH GCP

GCP is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that involve participation of humans. GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of clinical trial participants are protected. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data generated from the clinical trials are credible.

In Australia, the NATIONAL STATEMENT exceeds the minimum requirements for HRECs set out in ICH GCP and is the Australian standard against which all research involving humans, including research, is reviewed. GCP training is required by everyone directly associated with a clinical trial (generally those named on the DELEGATION LOG). GCP training is required to be updated every three years.

HUMAN RESEARCH ETHICS APPLICATION (HREA)

Developed by the NHMRC the HREA is a form designed to ensure that correct and concise information is provided to the HREC, allowing for timely and efficient review.

INTERNATIONAL CONFERENCE ON HARMONISATION GOOD CLINICAL PRACTICE (ICH GCP)

See **GCP**.

INFORMED CONSENT

A process by which a potential study participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the respective person's decision to participate. Informed consent is documented by means of a written, signed, and dated PARTICIPANT INFORMATION AND CONSENT FORM.

Metrics: CTU Improvement

INSTITUTION

An institution can be the Health Care Organisation or University where the CLINICAL TRIAL takes place. The institution may also refer to the SPONSOR of the CLINICAL TRIAL.

INVESTIGATIONAL MEDICINAL PRODUCT (IMP)

An investigational medicinal product is any pharmaceutical substance or placebo that is being tested or used in CLINICAL TRIAL. This can include products that already have been approved.

INVESTIGATOR

See **ASSOCIATE INVESTIGATOR, PRINCIPAL INVESTIGATOR OR SUB INVESTIGATOR**

INVESTIGATOR INITIATED TRIAL (IIT)

A CLINICAL TRIAL established and managed by non-pharmaceutical researchers, such as clinicians and researchers working in a health institution. Most IITs are designed to support the development of new clinical practice guidelines or compare the effectiveness of existing treatments.

MODIFIED MONASH MODEL (MMM)

The Modified Monash Model (MMM) is used to define whether a location is a city, rural, remote, or very remote. The model measures remoteness and population size on a scale of Modified Monash (MM) category MM 1 to MM 7. MM 1 is a major city and MM 7 is very remote. The MMM is used in TELETRIALS for funding.

Metric: CTU Improvement, Metrics: Teletrials

NAME OF SPONSOR

See **SPONSOR**.

NATIONAL AGGREGATE STATISTICS (NAS)

The National Aggregate Statistics (NAS) are a set of eight metrics collecting national-level data that informs key strategic and operational objectives to drive quality improvement within the sector (particularly around approval timelines) and position Australia as a preferred location for trials. The eight NAS metrics include metrics to measure clinical trial activity, timelines for trial start-up measured by mandatory approval processes for clinical trials to be conducted in Australia, and associated recruitment and investment levels. A set of mandatory governmental metrics that are captured through the CTPRG. The NAS data help provide national picture of all clinical trial activity. The NAS metrics are now captured as part of the NCTGF.

NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK (NCTGF)

The National Clinical Trials Governance Framework is a key initiative developed by the Australian Commission on Safety and Quality in Health Care on behalf of all jurisdictions to support the delivery and integration of high-quality clinical trials service provision into routine hospital care for improved patient outcomes. The National Clinical Trials Governance Framework is aligned with the National Safety and Quality Health Service (NSQHS) Standards in particular Standard 1: Clinical Governance and Standard 2:

Partnering with Consumers. Once embedded, just as health service organisations need to meet requirements of the NSQHS Standards when they are accredited, the actions in the National Clinical Trials Governance Framework will also be mandatory for health service organisations and trial sites providing clinical trial services.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL (NHMRC)

The NHMRC is an independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing. It is the main statutory authority of the Australian Government responsible for medical research.

NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH 2007 (UPDATED 2018) (NATIONAL STATEMENT)

The National Statement is the principal ethical guideline setting out the requirements for the ethical design, review and conduct of human research in Australia (including clinical trials). It is authored by the NHMRC, the Australian Research Council (ARC) and Universities Australia. The National Statement exceeds the minimum requirements for HREC set out in ICH GCP and is, therefore, the Australian standard against which all research involving humans is reviewed.

PARTICIPANT

A clinical trial participant is someone who has signed a consent and agreed to participate in a clinical trial or has been included in a trial where a trial has a valid waiver of consent approved by the HREC.

PARTICIPANT SCREENING LOG

A document used to record the identification of participants who have entered pre-trial screening.

PARTICIPANT ENROLMENT LOG

A document used to record the chronological enrolment of participants by unique clinical trials identifier code.

PARTICIPANT IDENTIFICATION LIST

A confidential document that the INVESTIGATOR/Institution keeps of the names of all trial participants linked to their corresponding unique clinical trials identifier code. It allows an INVESTIGATOR/Institution to reveal the identity of any participant if necessary, and to make future contact if required.

PATIENT

A patient is a person receiving or registered to receive medical treatment. When a patient is consented to a clinical trial, they become a PARTICIPANT.

PARTICIPANT INFORMATION AND CONSENT FORM (PICF)

The written information approved for use to provide trial specific information to potential participants and to record their decision to participate. The PICF must be approved by an HREC and an RGO prior to use.

POSTCODE

The residential postcode for a clinical trial participant. This is a metric often used to understand how clinical trial recruitment is progressing in rural and regional areas. The information may be captured periodically.

Metrics: Cancer Census Data, Metrics: CTU Improvement, Metrics: Teletrials

PRINCIPAL INVESTIGATOR (PI)

The Principal Investigator (PI) is the Investigator responsible for the overall conduct, management, monitoring, and reporting of a trial at their own site.

PROGRESS REPORTS and ANNUAL REPORTS

Periodic reports completed by CLINICAL TRIAL DEPARTMENTS and provided to HRECs and RESEARCH GOVERNANCE OFFICES. The reports detail the status of the study and include RECRUITMENT numbers and the OVERALL STATUS OF THE TRIAL (for the HREC) and the SITE STATUS (for the Research Governance Office).

PROTOCOL

A detailed clinical trial plan that mandates the objective(s), design, methodology, statistical considerations, and organization of a trial. The document includes the purpose and procedures of the research and who can be part of the trial. The Protocol provides the rationale, design, methodology for the trial conduct, who may participate in a trial, the length of a trial and the schedule of tests, procedures, medications and dosages, method of analysis, monitoring of data safety and quality. The Sponsor of the trial is responsible for the Protocol. The Protocol must be formally approved by the HREC prior to commencement of the clinical trial.

RANDOMISATION LIST

A decoded list of randomisation identifiers that is locked away from all personnel who must remain blinded during the clinical trial.

RANDOMISED / RANDOMISATION

The process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments to reduce bias. Once a participant has CONSENTED, SCREENED (meeting all eligibility criteria) and ENROLLED, they can be randomised.

RANDOMISED REGISTRY CLINICAL TRIAL (R-RCT/REG-RCT)

A CLINICAL TRIAL that is embedded within a CLINICAL REGISTRY. Patient presentation, treatment or outcome data is captured in a clinical registry rather than a standalone trial database. An investigational drug is not involved. Registry Trials can be either a randomised (Randomised-Registry Clinical Trial (R-RCT/Reg-CT) or a single arm study (R-CT/Reg-CT). A registry trial can answer important clinical questions in a real world setting at a low cost.

RECRUITMENT

Recruitment reflects the PARTICIPANT / SUBJECTS that enter a clinical trial or study.

Various metrics are collected which indicate recruitment at a site and trial level:

TOTAL ANTICIPATED RECRUITMENT FOR TRIAL (NAS Metric 6)

This is the predicted overall number of participants recruited to a clinical trial by trial phase and sponsor type for the trial, jurisdiction and nationally for the reporting period.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

TOTAL ACTUAL RECRUITMENT FOR TRIAL (NAS Metric 6)

This is the actual overall number of participants recruited to a clinical trial by trial phase and sponsor type for the trial, jurisdiction and nationally for the reporting period.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

ANTICIPATED RECRUITMENT AT SITE (NAS Metric 7)

This is the predicted overall number of participants recruited to a clinical trial by trial phase and sponsor type for the trial unit and hospital (site) for the reporting period. This information is required for departmental sign-offs and governance approval by the RESEARCH GOVERNANCE OFFICE.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

ACTUAL RECRUITMENT AT SITE (NAS Metric 7)

The is the running total/cumulative count of participants actually recruited to a clinical trial by trial phase and sponsor type for the trial unit and hospital (site) for the reporting period. This information is provided to the RESEARCH GOVERNANCE OFFICE on PROGRESS REPORTS and ANNUAL REPORTS. This is distinct from TOTAL NEW PARTICIPANTS.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement,

Metrics: Cancer Census Data, Metrics: Teletrials

SCREEN FAILURES AT SITE

The number of participants who have signed a consent form, therefore potential participants screened is a record of the number of CONSENTS signed at a site. Not all participants will be ENROLLED or RANDOMISED onto a study. They will become a SCREEN FAILURE.

Metrics: CTU Improvement

TOTAL NEW PARTICIPANTS (BY YEAR) AT SITE

This is a periodic count of participants recruitment in a given calendar year at each site.

Metrics: NCTGF Suggested, Metrics: CTU Improvement,

Metrics: Cancer Census Data

TOTAL FOLLOW UP PARTICIPANTS

This is a count of participants that enter the FOLLOW UP phase of a trial in a given calendar year.

Metrics: CTU Improvement, Metrics: Cancer Census Data

FIRST PATIENT FIRST VISIT (FPFV)

The FPFV capture the first participant on study that has CONSENTED, ENROLLED, and RANDOMISED. SPONSORS often want this information to understand how quickly a trial is recruiting at each CLINICAL TRIAL SITE. It is often taken from SIV.

Metrics: NCTGF Suggested, Metrics: CTU Improvement

REGIONAL TRIAL NETWORK VICTORIA (RTN-VIC)

The Regional Trial Network – Victoria is a partnership between six clinical trial sites in regional Victoria and Cancer Trials Australia. It was originally funded by the Cancer Council Victoria and the Victorian Cancer Agency (VCA).

REGISTRY TRIAL

See RANDOMISED REGISTRY CLINICAL TRIAL (Reg-RCT/RRCT).

REGULATORY AUTHORITY

Bodies having the power to regulate. This includes the TGA, FDA, EMA and MHRA.

REGULATORY TIMELINES

See **RESEARCH OFFICE METRICS**

RESEARCH DATABASE (REDA)

ReDA is a clinical trial management system used by some research offices who use it for the following purposes:

- Tracking the studies that are submitted
- Tracking the work that is done on those studies by their staff
- Collecting and reporting on metrics
- Collecting timelines
- Collecting basic recruitment numbers.

RESEARCH OFFICE

The Research Office is responsible for reviewing different types of clinical trials for their own site or on behalf of other sites. Here we will look at some of the roles within the Research Office and the types of review. A separate section will highlight the metrics associated with the Research Office.

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

An independent body constituted of medical/scientific professionals and non-medical/non-scientific members. Their responsibility is to review and approve/provide opinion on the PROTOCOL and other participant facing documents, including the PATIENT INFORMATION AND CONSENT FORM in accordance with the NATIONAL STATEMENT.

RESEARCH GOVERNANCE OFFICE (RGO)

A site is responsible for the conduct of research at their site. The research governance office (RGO) addresses the management of site risk, site resource and required regulatory reporting.

RESEARCH GOVERNANCE OFFICER

The Research Governance Officer is the individual appointed within an organisation who is responsible for the assessment of applications for site authorisation and who provides administrative oversight of authorised research projects. Research Governance considers legal compliance, financial management, accountability, and risk management associated with research at a participating site.

REVIEW TYPES

LOW RISK

According to the NATIONAL STATEMENT, research is low risk where the maximum foreseeable risk is discomfort. These studies often do not follow the same reviewing methods as interventional trials as they can be reviewed out of session. Check with your local HREC to see how this applies to you if you want to do this kind of research.

Metrics: CTU Improvement

LEAD SITE / LEAD HREC / REVIEWING HREC

In a MULTI-SITE APPLICATION this is the name of the LEAD HREC reviewing the Ethics Application on behalf of all participating sites. In a SINGLE-SITE APPLICATION, this will be the HREC of the only site involved.

Metrics: Identifier, Metric: CTU Improvement

MODE OF HREC REVIEW

HRECs either review a trial as part of the NATIONAL MUTUAL ACCEPTANCE (see also MULTI-SITE APPLICATION), or as a SINGLE-SITE APPLICATION.

Metrics: Identifier, Metric: CTU Improvement

MULTI-SITE APPLICATION

Multi-site or SINGLE SITE applications are known as the MODE OF HREC REVIEW. The NATIONAL MUTUAL ACCEPTANCE (NMA) scheme allows one HREC to review and provide approval for other sites within the NMA. The HREC that is receiving the application on behalf of the other sites is called the REVIEWING HREC.

The HREC application is provided to the HREC on the HUMAN RESEARCH ETHICS APPLICATION (HREA). Note that each site that has been approved as part of a multi-site application will still need to undertake their own individual RESEARCH GOVERNANCE process at their site. Also see SINGLE-SITE APPPLICATION.

Metrics: Identifier, Metric: CTU Improvement

NATIONAL MUTUAL ACCEPTANCE (NMA)

The NMA scheme provides the framework for single scientific and ethical review of multi-centre human research projects in publicly funded health organisations of participating jurisdictions. For HREC reviews of human research to be accepted under the NMA scheme, the HREC conducting the review must be under

the authority of an Institution certified under the NHMRC National Certification Scheme, and also a Certified Reviewing HREC under the NMA scheme.

There are some exceptions to single scientific and ethical review and details can be found on jurisdictional health websites.

SINGLE-SITE APPPLICATION

A Single Site Application is used where only one site is participating in a study. Governance will usually occur at the same time as the ethical approval. The HREC application is provided to the HREC on the HUMAN RESEARCH ETHICS APPLICATION (HREA).

Metrics: Identifier, Metrics: CTU Improvement

RESEARCH OFFICE METRICS

Various metrics are collected by the NCTGF around the submission and reviewing by the Research Office. These cover both HREC and SSA review, and will be captured below:

HREC VALIDATION DATE

The is the date that the study is accepted for review by the Reviewing HREC.

Metrics: Contributory

HREC APPROVAL DATE

This is the date that the HREC approved the study.

Metrics: Contributory

SSA SUBMISSION DATE

This is the date that the study/research was submitted to the RGO for review.

Metrics: Contributory

SSA VALIDATION DATE

This is the date that the study is accepted for review by the RGO.

Metrics: Contributory

SSA AUTHORISATION DATE

This is the date that the RGO approved the study.

Metrics: Contributory

OVERALL STUDY START UP TIMELINE (REGULATORY TIMELINE) – WITHOUT CLOCK (NAS Metric 2)

Metric 2 provides a proxy for study start up timeline by measuring the timeline for the two mandatory approval/regulatory processes for clinical trials in Australia: from HREC submission to date of first SSA/site authorisation at any site. The period commences at HREC submission and the date for the first SSA/Site assessment authorisation is the endpoint.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

ETHICS AND SSA/SITE ASSESSMENT APPROVAL TIMELINE – WITH CLOCK (NAS Metric 3)

This reflects overall study start up, same as Metric 2, but includes an administrative clock which distinguishes the responsibility for time between the administering organisation and the INVESTIGATOR/ CLINICAL RESEARCH or CLINICAL STUDY COORDINATOR/SPONSOR/CRO. The start of the process is the date of HREC submission, and the completion is the date of the first site authorisation/approval. This metric measures the overall regulatory process and is the same as the information in Metric 2 but with clock in use (for HREC time only) and the interval deducted when the responsibility for the HREC application is with the INVESTIGATOR/ CLINICAL RESEARCH or CLINICAL STUDY COORDINATOR/SPONSOR/CRO. Therefore, this is a measure of administration time.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement.

ETHICS APPROVAL TIMELINE WITH / WITHOUT CLOCK (NAS Metric 4a and 4b)

Metric 4a – Ethics approval timeline Without Clock

Time in days from Ethics Cut-off Date/Submission Closing Date to the Ethics Approval Clock Stop Date 'Without clock' operating. This includes HREC submission date, validation, HREC review, request for further information, responses from applicants, and final ethics approval. This does not measure intervals when the clock is stopped and re-started during ethics review where there is a request for information from investigator/trial coordinator/ sponsor/CROs.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

Metric 4b – Ethics approval timeline With Clock

Time in days from Ethics Cut-off Date/Submission Closing Date to Ethics Approval Clock Stop Date. This includes HREC submission date, validation, HREC review, request for further information, responses from applicants, and final ethics approval. This metric measures the Ethics Submission and approval process and is the same as the information in Metric 4a but 'With Clock' allows measurement and deduction of the time intervals between request and receipt of further information from investigator/trial coordinator, sponsor/CRO and this interval is deducted from the overall time period. Therefore, this is a measure of administration time.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

SSA / SITE AUTHORISATION TIMELINE – WITHOUT CLOCK FROM HREC APPROVAL DATE/SSA VALIDATION DATE (NAS Metrics 5a and 5b)

Metric 5a – SSA/site authorisation timeline from HREC approval date - Without Clock

Time from Date of HREC approval to SSA Authorisation Date, 'Without clock' operating, without deduction of intervals when the clock is stopped and re-started for the SSA/site assessment authorisation process. This measures the time take for SSA/site assessment alone. This includes RGO submission, validation, RGO review, request for further information, responses from applicants, CEO/delegation decision, and SSA/site assessment/research governance authorisation. The metric measures the total timeline (i.e., 'Without Clock' only), as there is no prescribed submission date for SSA processes, and therefore no defined start point. There is inconsistent use of the stop and re-start clock function across jurisdictions and sites and therefore the clock was not used in the SSA process measure for this report.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

Metric 5b – SSA/site authorisation timeline from SSA Validation Date - Without Clock

Measuring the time to process an SSA/Site assessment application from validation to approval, 'Without Clock' operating – without deduction of intervals when the clock is stopped and re-started for the SSA/site assessment authorisation process. SSA validation date is the first date that may appear in electronic information systems for SSA applications. This measures the time taken for SSA/site assessment alone. This includes RGO submission, validation, RGO review, request for further information, responses from applicants, CEO/delegation decision, and SSA/site assessment/research governance authorisation. The metric measures the total timeline (i.e., 'Without Clock' only), as there is no prescribed submission date for SSA processes, and therefore no defined start point. There is inconsistent use of the stop and re-start clock function across jurisdictions and sites and therefore the clock was not used in the SSA process measure for this report.

Metrics: NCTGF Mandatory, Metrics: CTU Improvement

ADDITIONAL METRICS SUGGESTED IN THE NCTGF:

- Number and median calendar days from HREC approval to site-specific assessment submission year to date (include trial type [i.e., multi-centre clinical trials approved via the NMA scheme)
- Median calendar days from local site-specific assessment submission to authorisation by clinical trial
- Number of trials pending site authorisation by reporting period and /or year to date
- Median calendar days from recruitment open date to first participant on trial by clinical trial and trial unit for the reporting period and/or year to date
- Median calendar days from recruitment open date to first participant on trial by clinical trial and trial unit for the reporting period and/or year to date

Additional Metrics: NCTGF Suggested

RISK ASSESSMENT

Risk assessment is the assessment, analysis, and management of risks. It involves recognising which events may lead to harm in the future and minimising their likelihood and consequence. Risk assessment is a regulatory and legislative requirement.

RISK MANAGEMENT

Risk management is the design and implementation of a program to identify and avoid or minimise risks to patients/participants, employees, volunteers, visitors, and the organisation. Risk management is a regulatory and legislative requirement.

SAFE ENVIRONMENT

A treatment space in a health service organisation where members of the clinical trial workforce perform clinical trial related duties, including the management, examination and/or treatment of participants. The space must be a facility that is clinically appropriate to perform required procedures described in the protocol, fit for purpose, and is a safe environment for the delivery of care. In addition, the site must provide adequate storage for all study related materials with appropriate working space for sponsor monitoring.

SCREENED/SCREEN FAIL

After a participant has been CONSENTED, they are screened for the study. A participant needs to meet all eligibility criteria. If they do not meet the eligibility criteria, they will be a SCREEN FAIL. This information will inform the metrics captured under RECRUITMENT.

Metrics: CTU Improvement

SERVICE SAMPLING

Refers to the sampling methodology to be used by accrediting agencies when sampling clinical trials at accreditation assessment, as outlined by the Australian Commission on Safety and Quality in Healthcare (ACSQHC, or the Commission). This includes NCTGF mandatory data along with additional information.

Metrics: NCTGF Mandatory*

SERIOUS BREACHES

A 'Serious Breach' is defined as being a breach of GOOD CLINICAL PRACTICE or PROTOCOL which has an impact on the safety or rights of a clinical trial PARTICIPANT, and the reliability or efficacy of the data generated in the CLINICAL TRIAL. These can be captured as CLINICAL INCIDENT.

SEX

The Australian Bureau of Statistics defines a person's sex as being based on their sex characteristics, such as their chromosomes, hormones and reproductive organs, whereas gender is about social and cultural differences in identity, expression and experience as a man, woman or non-binary person. A person's gender may differ from their sex and may also differ from what is indicated on their legal documents. Clinical trials frequently have inclusion or exclusion criteria surrounding participant sex.

SHORT TITLE

The abbreviated project or PROTOCOL title /CLINICAL TRIAL acronym or study ID reference.

Metrics: Identifier

SITE ACTIVATION

Following the SITE INITIATION VISIT, once the SPONSOR will confirm that the site is 'activated' and able to commence RECRUITMENT. The aspects that can impact on Site Activation include the availability of the IP and confirmation of the DELEGATION LOG

Metrics: CTU Improvement, Metrics: Contributory

SITE CLOSE-OUT

Conducted at the end of a study. The purpose is to ensure the completeness of all activities including the collection and verification of study data, the final counting and disposition of the investigational product and the verification of complete and accurate investigator files of essential documents.

Metrics: CTU Improvement, Metrics: Cancer Census Data

SITE INITIATION VISIT (SIV)

A visit conducted at the start of a study. The purpose is a thorough review of the protocol and study related procedures. All study site personnel meet to clarify the actual process of implementing the protocol.

Metrics: CTU Improvement

SITE QUALIFICATION VISIT

A feasibility process conducted to determine that the clinical investigational site is adequately equipped and has appropriate facilities to conduct a specific study. Qualified sites should have ample secured storage for all study related materials, access to patient population under study, sufficient staffing to conduct study related procedures, data collection and reporting, and have space for sponsor monitoring. See **FEASIBILITY**.

SITE SELECTION DATE

The date that a CLINICAL TRIAL SITE / DEPARTMENT has been selected by the SPONSOR of the trial to participate in their trial.

Metrics: CTU Improvement

SOURCE DATA

All information in original records of a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.

SOURCE DOCUMENTS

Original documents (where the Source Data was first recorded), data, and records (e.g. medical/hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). The principles apply to all records referenced irrespective of the type of media used. Source Documents substantiate the existence of the participant and integrity of trial data collected.

SPONSOR

All clinical trials conducted in Australia must have a trial Sponsor that is an Australian entity (an overseas company cannot be the Sponsor of a trial in Australia). Under the TGA CTN or CTA schemes the MAJOR SPONSOR TYPE may include individuals, companies, institutions, or organisations, including CONTRACT RESEARCH ORGANISATIONS (CRO). A Sponsor takes on the responsibility for securing the arrangements, the initiation, continued management, and/or financing of a clinical trial. However, the FUNDER OF A TRIAL may be different to the NAME OF SPONSOR. This distinction is important with implications for the effective running of a CLINICAL TRIALS UNIT or department.

The ultimate responsibility for the quality and integrity of the clinical trial data resides with the trial Sponsor. The trial Sponsor retains overall responsibility for all delegated functions in accordance with the Guidelines for GOOD CLINICAL PRACTICE (GCP) and the International Organisation for Standardisation for

trials under the CTN or CTA schemes. This also applies when a non-commercial trial Sponsor delegates activities to a COORDINATING PRINCIPAL INVESTIGATOR, TRIAL COORDINATING CENTRE or CRO.

Metrics: NCTGF Mandatory, Metrics: Identifier,

Metrics: CTU Improvement

SPONSOR TYPE

The major sponsor relates to the type of organisation that is sponsoring the study. Note that NAME OF SPONSOR and FUNDER OF TRIAL are captured elsewhere.

NAS Definition: Metric 1a: Number of new clinical trials per sponsor type: Collaborative Group, Commercially Sponsored, Institution, Investigator Initiated Group, Other, Total

Metrics: NCTGF Mandatory, Metrics: Identifier,

Metrics: CTU Improvement

STUDY TEAM

This incorporates all the clinical trial team members listed on the delegation log of an individual study.

STUDY TYPE

The Study Type notes if the CLINICAL TRIAL involves a drug and/or a device, radiotherapy, surgery, treatment, or diagnostic procedure. This classification may also include post-trial activities such as observational research, developing a registry and other post-marketing surveillance activities. It is important to note if the CLINICAL TRIAL is FIRST TIME IN HUMAN (FTIH) or FIRST TIME IN PATIENT (FTIP).

SUB-INVESTIGATOR (SI)

See **ASSOCIATE INVESTIGATOR**.

SUBJECT

This is a term often used by Sponsors when referring to a PARTICIPANT.

SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR)

An adverse reaction that that is both Serious and Unexpected. All suspected unexpected serious adverse reactions that are fatal or life threatening occurring in Australian participants must be reported to the Therapeutic Goods Administration, immediately, but no later than 7 calendar days after being made aware of the case. All other Australian SUSARs, no later than 15 calendar days after being made aware of the case.

TELEHEALTH

Telehealth allows you to consult a healthcare provider by phone or a video call. Telehealth can be a key component of a TELETRIAL and utilised in aspect of other CLINICAL TRIALS.

Metrics: Teletrials

TELETRIAL

A CLINICAL TRIAL using a Primary and Satellite site model. A Teletrial allows a clinician at a larger centre (the primary site) to enrol, consent and treat patients on CLINICAL TRIAL in partnership with smaller regional and rural centres (satellite sites), allowing patients to participate closer to home. This group of sites operating under the teletrial model is called a teletrial cluster.

Metrics: CTU Improvement, Metrics: Teletrials

THERAPEUTIC GOODS ADMINISTRATION (TGA)

The Therapeutic Goods Administration (TGA) is the Australian Government Department of Health agency responsible for the regulation of, supply, import, export, manufacturing, and advertising of therapeutic goods in Australia.

TRAINING LOG

A record of all training relating to a specific clinical trial undertaken by a trial staff member who has been delegated clinical trial related duties. The log documents the date, the training undertaken, who gave the training with a signature of both trainer and trainee and is kept current for the duration of the clinical trial.

VCCC Alliance

Overcoming cancer together

Supported by

VICTORIA State Government

VCCC Alliance members

Peter Mac Peter MacCallum Cancer Centre Victoria Australia

The Royal Melbourne Hospital

The University of Melbourne

the women's the royal women's hospital

WEHI brighter together

The Royal Children's Hospital Melbourne

Western Health

St Vincent's Hospital Melbourne

Austin Health

murdoch children's research institute