# Intern Learning Areas & Responsibilities:
# 2023 SKILLED Clinical Trial Assistant Internship

The Victorian Comprehensive Cancer Centre Alliance (VCCC Alliance) is once again offering SKILLED Clinical Trials Assistant Internships to suitable applicants across Victoria. The Clinical Trial Assistant (CTA) Internship provides an opportunity for graduates with an Honours tertiary degree in science or a healthcare discipline to develop their skills and experience towards a future career as a Clinical Trials Assistant.

Internship placements will commence on 13th February 2023 and are available at metropolitan Melbourne and Victorian Regional clinical trial sites. Regional placements are likely to be in Ballarat, Geelong, Shepparton Traralgon and Wangaratta.

Regional and metro placements are advertised separately on SEEK, and both **close on Tuesday 4th October 2022 at 9am**. To apply, please follow the instructions provided via our VCCC Alliance ads on SEEK:

- Metropolitan: https://www.seek.com.au/job/58516786

- Regional:

  Geelong & Ballarat: https://www.seek.com.au/job/58516801

  Shepparton & Wangaratta: https://www.seek.com.au/job/58516830

  Traralgon: https://www.seek.com.au/job/58516852

Applicants who are successful in gaining one of these highly sought-after placements, will participate in a practical internship that provides supervised training and experiential learning based at either a Melbourne Metropolitan or Victorian Regional clinical trial related host site. Placements are structured to enhance future job readiness and employment opportunities in the clinical trial sector.

During the placement, CTA Interns will learn about and gain supervised experience in the duties and accountabilities of the CTA role, experiencing how a CTA acts as the main conduit between clinical trial sponsors to assist with onsite trial monitoring processes and deliverables.

## 2023 SKILLED Clinical Trial Assistant Internship Program

### Integrated and Supervised Onsite Training: Learning Areas and Responsibilities

The following information outlines the key areas of learning, learning activities and the responsibilities the intern will undertake during their internship program. CTA Interns are supported by a host site supervisor who will provide coaching support, direction and guidance throughout the internship program. Each Intern will also be supervised by and learn from an experienced onsite clinical trial staff.

## Internship Program Summary

The Clinical Trials Assistant (CTA) Intern completes an initial one-week induction program followed by a structured site experience which integrates formalised learning and practical placement experience. During this program, the CTA Intern will experience how a clinical trial unit functions and will specifically

learn how to assist in providing administrative and clerical support to ensure effective and efficient team operations. With the support and guidance of experienced team members, the CTA intern will under supervision: assist in maintaining appropriate regulatory documents and ensuring regulatory compliance in the conduct of clinical trials; act as the main communication conduit between clinical trial sponsors; gain an overview and learn the importance of the CTA role during their internship.

## Reporting

The CTA Intern will report to and follow the directions of the nominated host site supervisor.

## Immunisation Risk Category Description

Category A: Position involving direct patient contact, potential for exposure to blood, body fluid, human tissue specimens during course of a normal working day.
(Use of Personal Protective Equipment will be a requirement and training will be provided)
https://www2.health.vic.gov.au/public-health/immunisation/adults/vaccination-workplace/vaccination-healthcare-workers

## Intern Key Relationships:

**Internal Key Contacts at Placement Host Site**
Clinical Trial Unit (or other host site) Manager and supervisor/s, Team Leaders, Site Staff, Principal Investigators, Ethics Submission Coordinator, Clinical staff & Health Information Services**:**
**Other, likely external contacts**
Clinical trial participants, Clinical trial sponsor representatives, Public and Private Hospitals, Clinical Specialists and General Practitioners, Pathology services, Cancer Trials Australia, and other Health Professionals.

## Key Learning and Practice Areas and Responsibilities:

All learning and practice areas listed will be undertaken under the direct or indirect supervision of onsite experienced trial staff.

### Learning and Practice Area: Clinical Trials Administration

The Intern will learn to assist with the administrative support required for the smooth functioning of clinical trials team members, including but not limited to:

- Administration activities and processes necessary to assist clinical trial unit staff with the day to day running of multiple clinical trials
- Interpreting the needs and priorities within the team to provide effective administrative support
- Allocating trial-related tasks to ensure they are met within designated timelines, in an organized manner and in accordance with International Conference for Harmonization (ICH) guidelines for Good Clinical Practice (GCP) to ensure the safety and protection of trial participants and the integrity of trial data subsequently collected.
- Maintaining regulatory files in accordance with ICH GCP and the sites Unit's Standard Operating Procedures (SOPs).

- Administration of electronic and hard copy filing in a timely manner and in accordance to regulatory requirements.
- Effectively coordinating onsite monitoring visits.
- Co-ordinating financial processes in compliance with site polices and regulatory guidelines.
- Developing and learning how to implement tools/processes to oversee and facilitate patient reimbursement.

**Learning and Practice Area: Database/s and Clinical Trial Management System Support**

The Intern will learn to assist with the management and maintenance of Clinical Trial Management Systems, which will include learning about and gaining experience in:

- How to use and access relevant systems/databases.
- Providing support and acting as a resource to clinical trial unit staff in the use of the clinical trial management systems.
- Learning about data entry requirements and entering accurate data into relevant clinical trial unit database/s within allocated timelines.
- Ensuring all data entered is accurate and verifiable against source data. Providing support to unit staff in the entry of data into relevant unit database/s.
- Ensuring all requests for data entry are responded to and completed within allocated timelines.
- Undertaking appropriate training where required allowing access to appropriate databases.
- Understanding confidentiality and privacy requirements of data handled., applying learnings gained throughout the internship to achieve high standards in the quality if clinical trial data entered.

**Learning and Practice Area: Teamwork**

The Intern will gain experience in the necessities and practicalities of teamwork and cooperation in a functioning clinicals unit by:

- Participating in appropriate quality assurance activities.
- Participate in clinical trial unit and team meetings.
- Taking responsibility for developing and maintaining a productive functioning relationship with other interns, staff within the site/department/host site health service and those indirectly associated with the site such as clinical trial Investigators, Clinical Research Organisations (CROs), Clinical Research Associates and trial sponsors. Exercising well developed verbal and written communication skills.
- Communicating respectfully, proactively and openly, listening actively and asking questions.
- Communicating with a wide range of individuals at various levels of seniority with confidence and respect.
- Maintaining confidentiality and displaying discretion in dealing with staff and patients alike.

**Learning and Practice Area: Organisation, Problem Solving and Prioritisation Skills**

The Intern will gain practical experience in the necessities of being organised and able to prioritise and problem solve in an active clinical trial unit environment by:

- Learning about activity timelines and deadlines and about the priorities required in a clinical trials unit and how to apply those priorities.
- Experiencing the pressures of both quality and time required to meet consistently high standards in a clinical trials unit and learning to manage those pressures.
- Utilising excellent organisational and forward planning skills within the scope of the internship
- Maintaining appropriate task and activity planning and utilization of tracking tools
- Preserving high standards in quality clinical trial data entered by the intern.

## Intern Responsibilities

Successfully selected CTA Interns will be required to:

- Demonstrate and role model site values while on placement
- Comply with all Clinical Trial Unit (CTU) site Policies and Procedures.
- Comply with the Requirements of the National Safety & Quality Health Service Standards.
- Complete and maintain all mandatory training relevant to the host site and the internship.
- Contribute to a safe and healthy working environment
- Report unsafe work practices through the incident reporting system provided by the host site
- Promote a no blame culture of safety and wellbeing.
- Maintain working knowledge of onsite emergency procedures and location of emergency equipment.
- Take all reasonable steps to prevent bullying, discrimination and harassment throughout the internship
- Observe child safe principles and expectations for appropriate behaviour toward and in the company of children.
- Be able to travel between sites, if necessary, for the internship training (COVID-19 restrictions permitting).

**General Conditions:**

All Clinical Trial Units/host sites strongly support clinical trial participants in expressing their wishes and values. Sites have a zero tolerance of child abuse, and all allegations and safety concerns will be treated very seriously. For more information refer to Site's Child Safe Policy.

All Clinical Trial Units/host sites are an equal opportunity employer and committed to providing interns a placement environment which is free from bullying, harassment, or discrimination. All sites are a smoke-free environment.

***Host sites reserves the right to modify learning areas, activities, practice areas and responsibilities as required, and the intern will be consulted if and when this occurs.***