The Victorian Comprehensive Cancer Centre (VCCC) alliance is changing the way we tackle cancer in Victoria. Clinical trials form a critical bridge between research and practice, progressing treatments and care standards into better outcomes for patients. Through innovative programs, enhanced awareness, improved data and processes, and a strengthened clinical trials workforce, the VCCC aims to increase patient participation in cancer clinical trials.

Expanding Victoria’s clinical trial activity calls for a highly trained workforce, capable of meeting the increasing demand. The VCCC Development of Clinical Trials Workforce Capacity and Capability Program, has established internships, in partnership with the Parkville Cancer Clinical Trials Unit (PCCTU).

The internships provide both theoretical and hands-on learning for positions of high demand, increasing employability and providing opportunities within the sector.
SKILLED CLINICAL TRIAL ASSISTANT INTERNSHIP

Cohort
> BSc (Hons) or higher

Internship program
> Intensive, accelerated learning
> Developed and run in collaboration with Parkville Cancer Clinical Trial Unit
  ~ 24 and 40 week program
  ~ 2-week orientation
  ~ Competency based training

Orientation program – 2 weeks
Knowledge
✓ An introduction to clinical trials
✓ Running a clinical trial from A-Z
✓ The regulatory environment of clinical trials
✓ Ethics and governance submissions
✓ Safety reporting in clinical trials
✓ Monitoring and auditing clinical trials

Practical skills
✓ Trial related communications/coordination
✓ Software/databases used in trials
✓ Managing study files
✓ Data management and patient confidentiality
✓ Post-approval reporting (the role of a clinical trial assistant)
✓ Effective communication with monitors
✓ Site initiation visits (SIVs) from a monitor's perspective
✓ Site monitoring visits
✓ Site file workshop
✓ Archiving workshop

On-the-job supervised training
Develop practical skills
✓ Supervised to develop CTA skill-set
✓ Competence assessed

Site improvement project
Interns identify and implement a quality or efficiency improvement at their site.

Additional training
✓ TransCelerate accredited Good Clinical Practice (GCP) workshop: Peter MacCallum Cancer Centre
✓ Interpreting protocols, ethics applications, patient informed consent, negotiation skills workshop: Cancer Trials Australia
✓ Safe Transport of Infectious Substances by Air Course: 2019 Civil Aviation Academy Australasia Pty Ltd
✓ Communication: Cancer Council Victoria
✓ Paediatric Clinical Trials: The Royal Children’s Hospital
✓ Research Ethics Office: Murdoch Children's Research Institute

One of the most important aspects of the whole program is the outstanding level of support given by both the VCCC and PCCTU staff. I believe this is fundamental to my ability to start in this role. – Intern
SKILLED STUDY COORDINATOR INTERNSHIP

Cohort

- PhD under submission

Internship program

- Intensive, accelerated learning
- Developed and run in collaboration with Parkville Cancer Clinical Trial Unit
  - 40-week program
  - 2-week orientation
  - Competency based training

Orientation program – 2 weeks

Knowledge

- An introduction to clinical trials
- Running a clinical trial from A-Z
- The regulatory environment of clinical trials
- Ethics and governance submissions
- Safety reporting in clinical trials
- Monitoring and auditing clinical trials
- Good Clinical Practice (GCP) training

Practical skills

- Trial related communications/coordination
- Software/databases used in trials
- Mastering your protocol workshop
- Site file workshop
- Data management & patient confidentiality
- Post-approval reporting (the role of a site coordinator)
- Effective communication with monitors
- Site initiation visits (SIVs) from a monitor’s perspective
- Patient management – attend clinics
- Preparing for site monitoring visits
- Trial kits management
- Tumour assessments (RECIST and non-solid disease assessment)
- Common Terminology Criteria for Adverse Events (CTCAE)

On-the-job supervised training

Develop practical skills

- Supervised to develop study coordinator skill-set
- Competence assessed

Site improvement project

Using their research skills, interns identify and implement a quality or efficiency improvement at their site.

Additional training

- TransCelerate accredited Good Clinical Practice (GCP) workshop: Peter MacCallum Cancer Centre
- Cancer Trials Australia workshop: Interpreting protocols, ethics applications, patient informed consent, negotiation skills workshop: Cancer Trials Australia
- Introduction to cancer – Overview of cancer epidemiology, cell physiology, carcinogenesis, treatment options and the impact of cancer on patients: Peter MacCallum Cancer Centre
- Managing difficult conversations about cancer with patients and their families workshop: Cancer Council Victoria
- Safe Transport of Infectious Substances by Air Course: 2019 Civil Aviation Academy Australasia Pty Ltd
- Online Clinical Research Coordinator Training: Advantage Clinical
- Paediatric Clinical Trials: The Royal Children’s Hospital
- Research Ethics Office: Murdoch Children’s Research Institute

“The program is first class and ensures that the trainees have a sound knowledge base, as well as a good level of understanding of all the key components when beginning. – Supervisor”
Clinical Trial Assistant
Competency framework

A. Study management
   - Resources/financial management
   - Communication/coordination
   - Data collection and documentation

B. Laboratory operations
   - Handling biological samples

C. Interaction with participants
   - Informed consent process
   - Communication

D. Regulatory management
   - Ethics and regulation compliance

E. Professional skills
   - Professional development

5 core areas
8 competencies, each with a set of abilities.

Study Coordinator
Competency framework

A. Scientific thinking
   - Protocol compliance

B. Study management
   - Resources/financial management
   - Communication/coordination
   - Data collection and documentation

C. Laboratory operations
   - Handling biological samples
   - Performing laboratory process

D. Interaction with participants
   - Informed consent process
   - Management of clinical trial patients
   - Patient recruitment

E. Regulatory management
   - Ethics and regulation compliance

F. Professional skills
   - Professional development

6 core areas
11 competencies, each with a set of abilities and examples of skills and tasks.
Building a clinical trial talent pipeline in partnership with the Parkville Cancer Clinical Trials Unit (PCCTU)

Lack of experienced employees for clinical trial units to employ

Two cancer clinical trial streams
- Clinical trial assistant
- Study coordinator

Scientists with an interest in clinical trial careers without a pathway

Competency based
Tailored competency frameworks for each role have been developed with a quantitative assessment grading system, based on relevant international competencies.

Internship model to build a highly skilled, clinical trial workforce
The Victorian Comprehensive Cancer Centre (VCCC) is a powerful alliance of 10 leading research, academic and clinical institutions working together to accelerate and amplify leading-edge cancer research, knowledge and expertise to benefit the Victorian community.

With the support of the Victorian Government, the VCCC seeks to reinforce Victoria’s position at the forefront of research-led, consumer-informed, cancer prevention, detection, treatment and patient care.

The SKILLED Clinical Trials Internships program is part of the MTPConnect Researcher Exchange and Development within Industry (REDI) initiative, funded through the Australian Government’s Medical Research Future Fund.

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