

Cancer treatment clinical trial activity in Victoria

2016 – 2018



Acknowledgements

The Cancer Trials Management Scheme (CTMS) is supported by the Victorian Government.



We would like to thank the clinical trial units across Victoria, who regularly report clinical trial activity data to Cancer Council Victoria, as well as the external and internal reviewers of this report.

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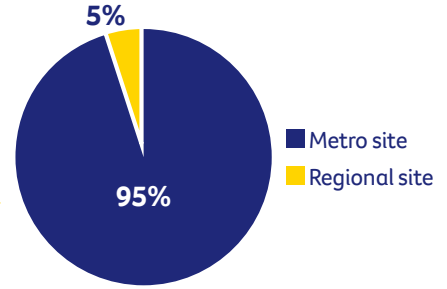
At a Glance

Victorian cancer clinical trial activity (2016 – 2018)

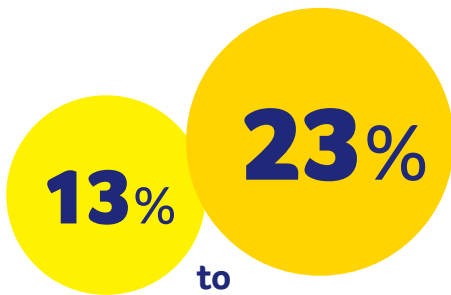
Between 2016 and 2018, **43** clinical trial units reported data to Cancer Council Victoria, about the number of patients recruited into cancer treatment trials in Victoria.

During this time, **5215** cancer patients were newly recruited to an interventional trial for their cancer treatment;

95% of these patients were recruited to trials in metropolitan units.



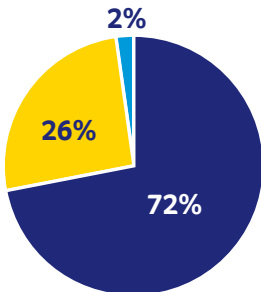
The proportion of clinical trial participants living in regional Victoria who were recruited into clinical trials in regional trial units increased from



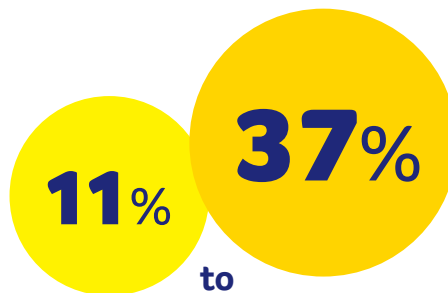
Blood & breast cancer trials recruited the highest number of patients, together accounting for nearly **50%** of recruited patients over the 3-year period.



Just over **70%** of all trials were commercially sponsored by a for-profit company.



Clinical trial recruitment for people aged 15 – 17 years more than **tripled** between 2016 and 2018, from



- Commercial Sponsor
- Non-Commercial Sponsor
- Both



Foreword

Cancer Council Victoria and the Victorian Government are committed to improving participation and reducing inequities in access to cancer clinical trials in Victoria; evidenced in [our submission to](#) and the publication of the Victorian Government's [Victorian cancer plan 2020-2024](#).

With support from the Victorian Government, Cancer Council Victoria has monitored cancer clinical trial activity and recruitment in Victoria for more than three decades. During this time, we have partnered with up to 43 clinical trial units, across 27 health services in Victoria, to report annual clinical trial recruitment data and keep up-to-date an online and mobile clinical trials search platform, the [Victorian Cancer Trials Link](#). This platform aims to connect patients and health professionals with treatment opportunities available in cancer clinical trials.

The present report, [Cancer treatment clinical trial activity in Victoria 2016-2018](#), summarises data reported to Cancer Council Victoria about the type of clinical trials investigating cancer treatments across these trial units, and the demographics of patients recruited into these clinical trials. The provision of readily accessible and reliable data on the breadth of clinical trials available to the sector is an important tool to inform access to clinical trials for people affected by cancer and provides an important benchmark for sector activity in Victoria, particularly in the wake of COVID-19.

In 2016, we introduced 'postcode' and 'year of birth' metrics to our dataset, which have allowed us to report trends in clinical trial recruitment by patient age and geography. This change informs our advocacy efforts to improve access to clinical trials, including for regional and remote, and adolescent and young adult patients. Understanding where people are travelling from to receive access to clinical trials will continue to be important as we see telehealth/teletrials increasingly used to enable patient care close to home.

Whilst trends for Aboriginal and culturally diverse Victorians participating in clinical trials are not currently captured, we remain committed to improving opportunities for these patients to receive equitable access to clinical trials. This includes advocating for improved data collection and reporting to inform patient and sector awareness of available clinical trials in Victoria. We also recognise a need for greater infrastructure to support the collection of data on other clinical trials in the sector, including trials focussed on improving outcomes in palliative and supportive care.

Although limited to reporting on treatment intervention trials only, we hope this report sheds light on the significant cancer clinical trial activity occurring in Victoria and informs further capacity building in the sector to improve access to cancer clinical trials.

Jeremy Millar

Professor Jeremy Millar
Chair, Cancer Council Victoria



Professor Euan M Wallace AM
Secretary, Department of Health & Human Services

Background:

The Cancer Trials Management Scheme (CTMS) was first introduced in 1988 by Cancer Council Victoria's Clinical Network, formerly known as the Victorian Cooperative Oncology Group. It was established with the aim of increasing overall participation in cancer clinical trials, monitored through the collection of site-specific data. Each year, trial units are asked to submit data about the number and type of clinical trials available at their unit, as well as the number of recruited patients, their year of birth and postcode of home address. Currently, these data are limited to cancer treatment (intervention) trials only.

In 2009, the CTMS was integrated with the [Victorian Cancer Trials Link \(VCTL\)](#), an online and mobile clinical trials search platform. Clinical trial units participating in the CTMS are encouraged to provide at least monthly updates to Cancer Council Victoria about the status of trials that are recruiting cancer patients. This information is uploaded onto the VCTL, providing access to patients and health professionals who may be searching for information about the treatments available in clinical trials in Victoria. The website also links to general cancer information and support resources for people affected by cancer.

The VCTL is the base repository for the CTMS. Each year, data uploaded on the VCTL are exported into a pre-populated spreadsheet and distributed to participating clinical trial units for data entry. These data are returned to Cancer Council Victoria and collated into a spreadsheet capturing annual clinical trial activity across the state (Figure 1).

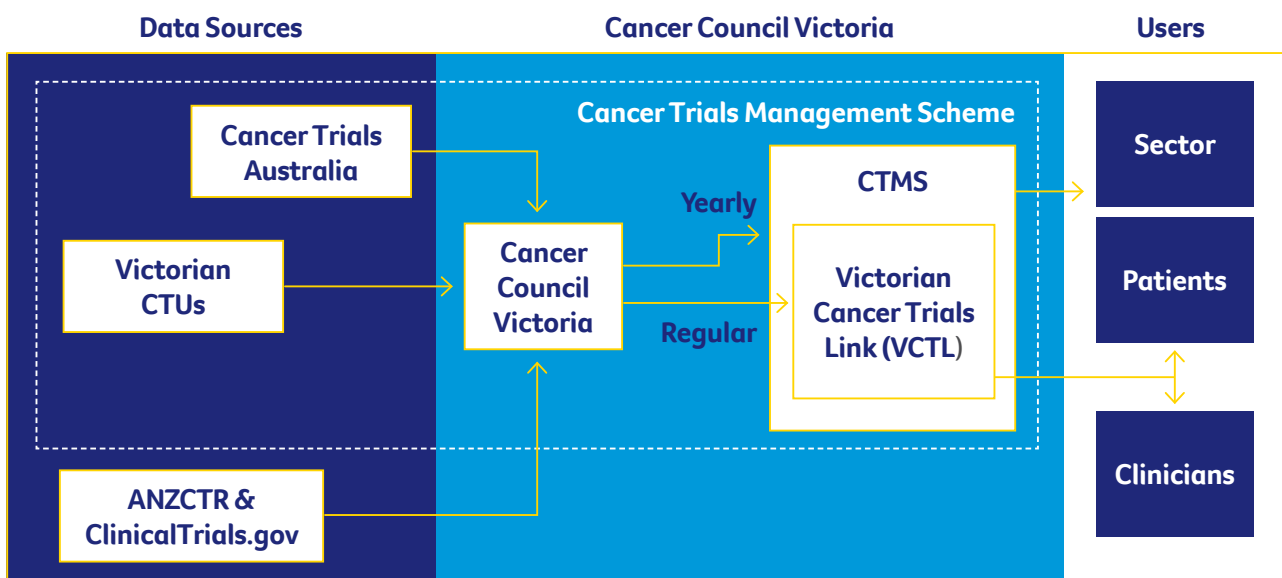


Figure 1: Integration of the VCTL and CTMS data collection process.

This report presents the most recent data reported to Cancer Council Victoria, showcasing clinical trial activity and recruitment in Victoria for years 2016, 2017 and 2018. Throughout this report, we use the number of new cancer diagnoses reported to the Victorian Cancer Agency in each reporting year, as a denominator for the number of people recruited into cancer clinical trials. This is a commonly used metric; however, we acknowledge that not all cancer patients will be eligible for or be recruited into a clinical trial in the same year that they were diagnosed. We are also cognisant this dataset does not capture activity data outside of the 43 trial units (across 27 health services) involved in the CTMS, does not capture data on non-treatment related trials and does not capture Victorian patients enrolled on trials outside of Victoria.

As this is the first time we have reported on clinical trial recruitment stratified by patient age (year of birth) and geography (postcode), we recommend this report not be directly compared to earlier data analyses. Similarly, there are no nationally consistent data sets to which activity in this report can be directly compared to activity in other jurisdictions.

Clinical trial activity (2016 – 2018)

Recruitment into Victorian cancer clinical trials

The total number of new cancer diagnoses in Victoria, as reported by the Victorian Cancer Registry, has steadily increased from 33,037 cases in 2016 to 35,203 cases in 2018. The number of unique clinical trials, (meaning trials that recruited at least one patient in a reporting year not including duplicate counts of trials being conducted across multiple units in Victoria), also increased, from 281 unique clinical trials reported in 2016 to 347 unique clinical trials reported in 2018. The percentage of cancer patients recruited into Victorian clinical trials, compared to the number of people newly diagnosed with cancer in the same year, has remained relatively steady, ranging between 4.6% (n=1718) and 5.4% (n=1907) over the three-year period (Figure 1). Although not directly comparable, this is slightly lower than the proportion of patients recruited into clinical trials in NSW on average during the same period (7.6%).

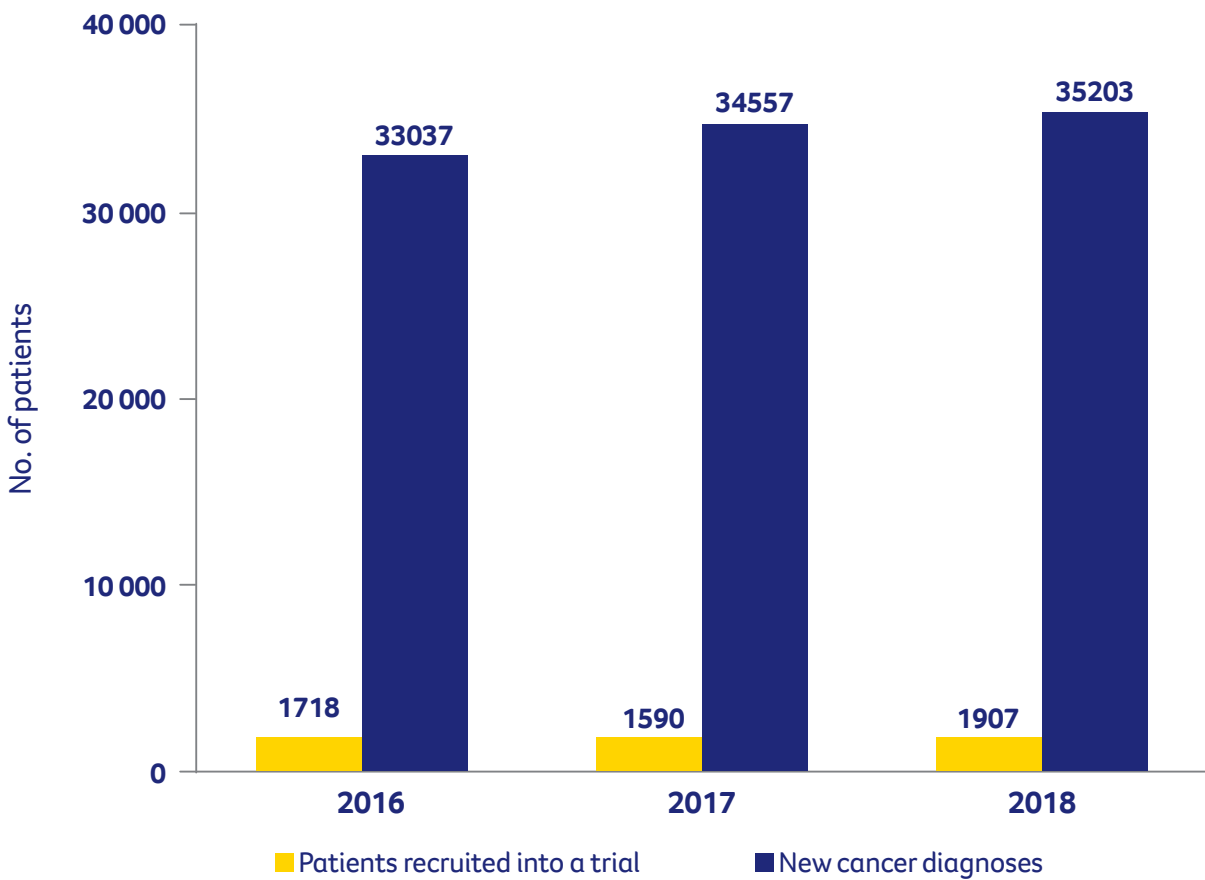


Figure 1. Number of new cancer diagnoses compared to the number of new patients recruited into a clinical trial

Geographic distribution

Between 2016 and 2018, the proportion of cancer patients enrolled in clinical trials and living in metropolitan Melbourne (including Geelong), regional Victoria and interstate have remained consistent. The majority of patients recruited into Victorian clinical trials (70%) lived in a Metropolitan area (Figure 2).

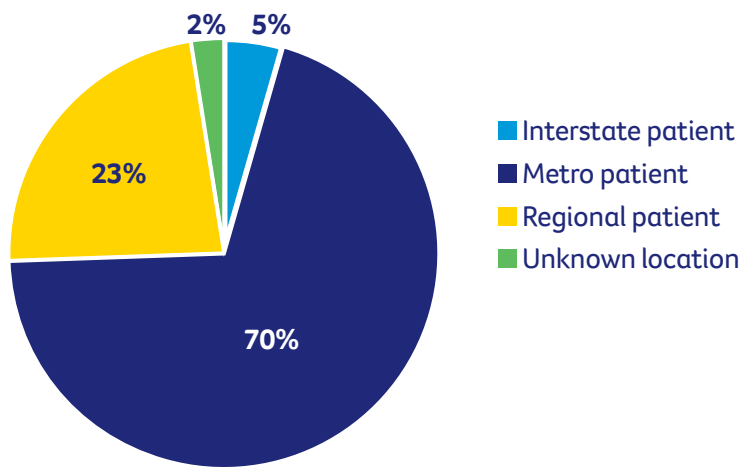


Figure 2. Geographic distribution of cancer clinical trial participants between 2016 and 2018. Data have been averaged over the three reporting years.

Most patients (95%), regardless of the region in which they lived, enrolled in clinical trials at metropolitan units between 2016 and 2018. Of the regional patients who enrolled in clinical trials between 2016 and 2018, less than 20%, on average, enrolled in clinical trials at a regional unit. However, since 2016, the percentage of regional clinical trial participants enrolled in clinical trials at regional units has increased from just under 13% (n=50) to 23% (n=102) (Figure 3).

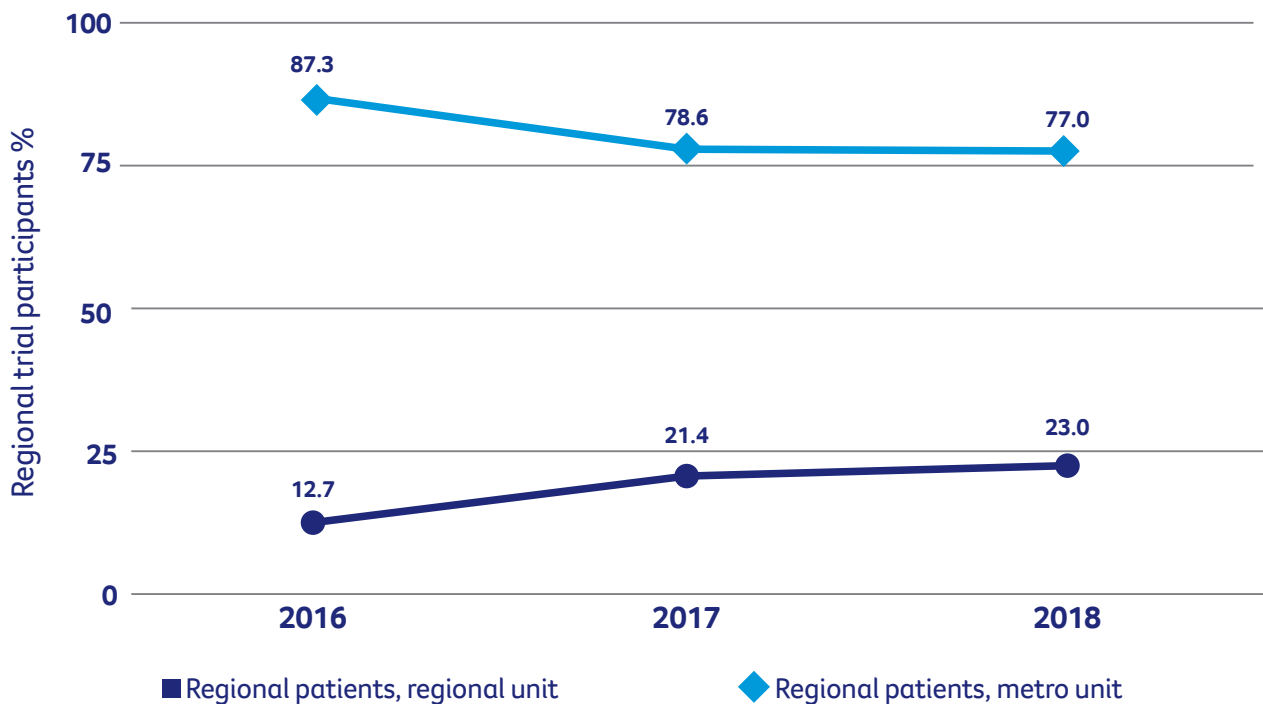


Figure 3. Percentage of regional patients recruited to clinical trials at metropolitan versus regional units for 2016, 2017 & 2018.

Interstate patients made up a small percentage (4-6%) of total new cancer clinical trial recruits in Victoria. In the 2016-2018 period, the majority of interstate patients enrolled in Victorian clinical trials resided in NSW. Most interstate patients participated in clinical trials conducted at metropolitan units, however a small number of patients from bordering states (NSW and SA) were enrolled in trials at regional units.

The Metropolitan Integrated Cancer Service (MICS) areas had a higher overall occurrence of new cancer diagnoses than the Regional Integrated Cancer Service (RICS) areas (Figure 4; Appendix B). The percentage of cancer patients residing in Barwon South-West RICS (excluding Geelong) that participated in clinical trials was consistently larger than for any of the other ICS (Integrated Cancer Services) areas over the three years (~8%). However, data in this report have not been standardised with population data about the number of Victorians that reside within the Victorian ICS regions; and trends associated with these groupings could be an artefact of population size.

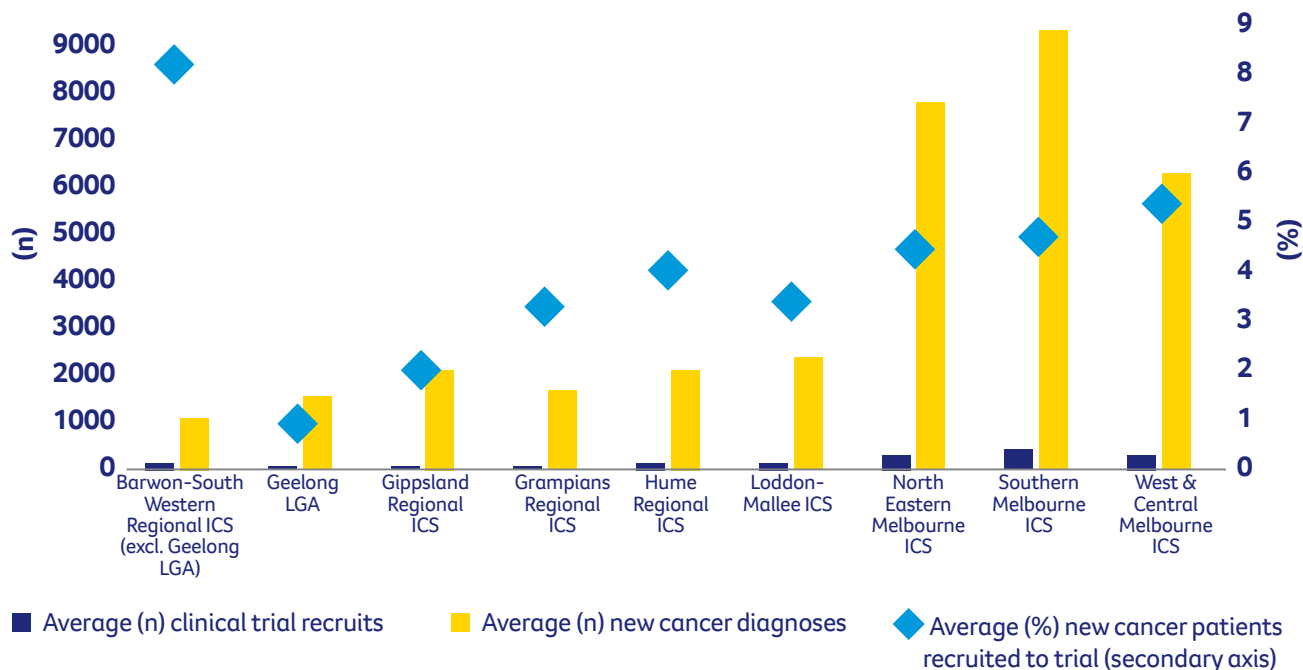


Figure 4. Summary of new cancer diagnoses and clinical trial recruits that reside within Regional and Metropolitan Victorian Integrated Cancer Service regions.

Overall patients that resided in MICS areas had slightly higher recruitment into clinical trials than cancer patients in RICS areas (Figure 5). There was a slight increasing trend in the recruitment of cancer patients living in MICS and RICS areas being recruited into clinical trials between 2016 and 2018.



Figure 5. Percentage of cancer patients residing in Metropolitan Integrated Cancer Services (MICS; including Geelong) and Regional Integrated Cancer Services (RICS; excluding Geelong) recruited into clinical trials

By tumour stream*

*For the purposes of this report, we have grouped cancers into ‘tumour streams.’ Where a clinical trial is recruiting across tumour streams, we have classified this as ‘multiple.’

Unique trials by tumour stream

On average, the highest number of unique trials available in Victoria were for people with haematological cancers, cancers of the urinary system, breast cancer and lung cancer, or were open to multiple cancer types (Figure 6; see Appendix A for tumour streams).

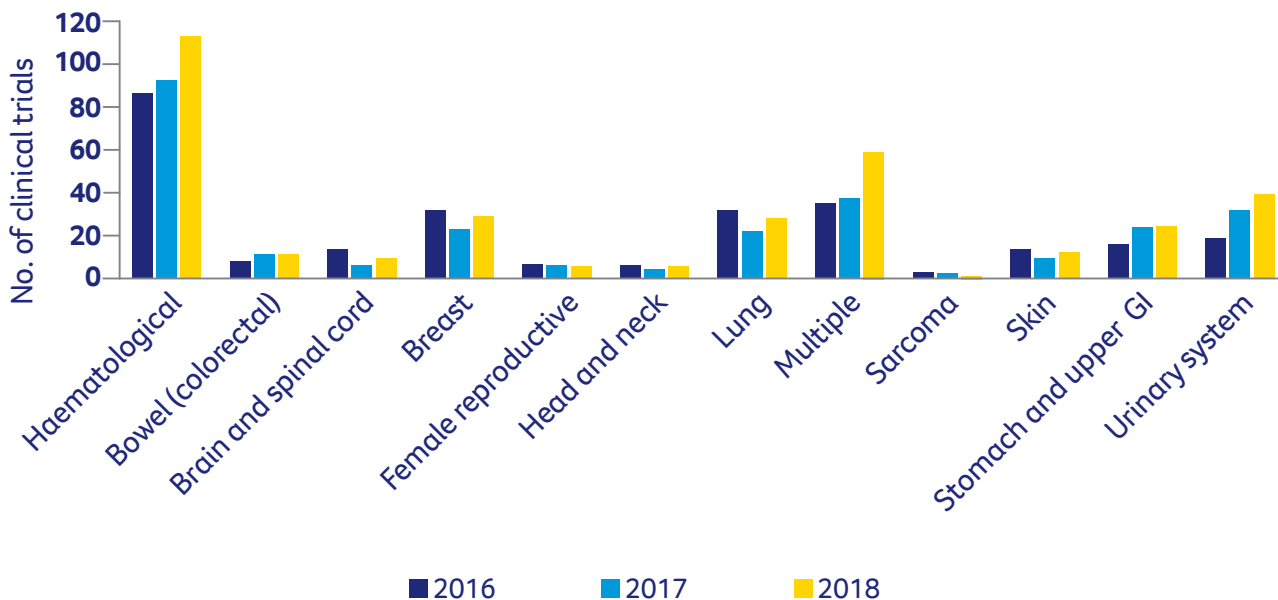


Figure 6. Number of unique clinical trials available in Victoria per tumour stream between 2016–2018

New diagnoses and patient recruitment by tumour stream

Between 2016–2018, the five tumour streams with the highest cumulative number of new cancer diagnoses were (listed from highest to lowest):

1. **Urinary system**, accounting for 20.3% of total number of new diagnoses
2. **Haematological**, accounting for 13.7% of total number of new diagnoses
3. **Breast**, accounting for 13.5% of total number of new diagnoses
4. **Bowel (colorectal)**, accounting for 12% of total number of new diagnoses
5. **Skin**, accounting for 9.2% of total number of new diagnoses.

The five tumour streams with the highest cumulative proportion of patients participating in clinical trials were (listed from highest participation to lowest):

1. **Haematological**, accounting for 33% of all enrolled patients
2. **Breast**, accounting for 15.2% of all enrolled patients
3. Trials studying treatments for multiple types of cancers (typically early phase trials), accounting for 13.8% of all enrolled patients
4. **Urinary system**, accounting for 9.4% of all enrolled patients
5. **Bowel (colorectal)**, accounting for 8% of all enrolled patients.

The tumour streams with the highest cumulative proportion of patients participating in clinical trials relative to new cancer diagnoses was:

1. **Haematological**, where 11.9% of patients with this type of cancer participated in clinical trials
2. **Brain and spinal cord**, where 5.9% of patients with brain or spinal cord cancer participated in a clinical trial. And,
3. **Breast**, where 5.5% of patients with breast cancer participated in a clinical trial.

The remaining tumour streams have between 1.2 to 3.3% of patients participating in clinical trials (Figure 7).

The tumour streams with the highest average recruitment rate (calculated as the number of patients recruited into a clinical trial, divided by the number of unique trials available for that tumour stream) are Bowel (11.9 patients per clinical trial), Breast (8.9 patients per clinical trial) and Skin (6.8 patients per clinical trial).

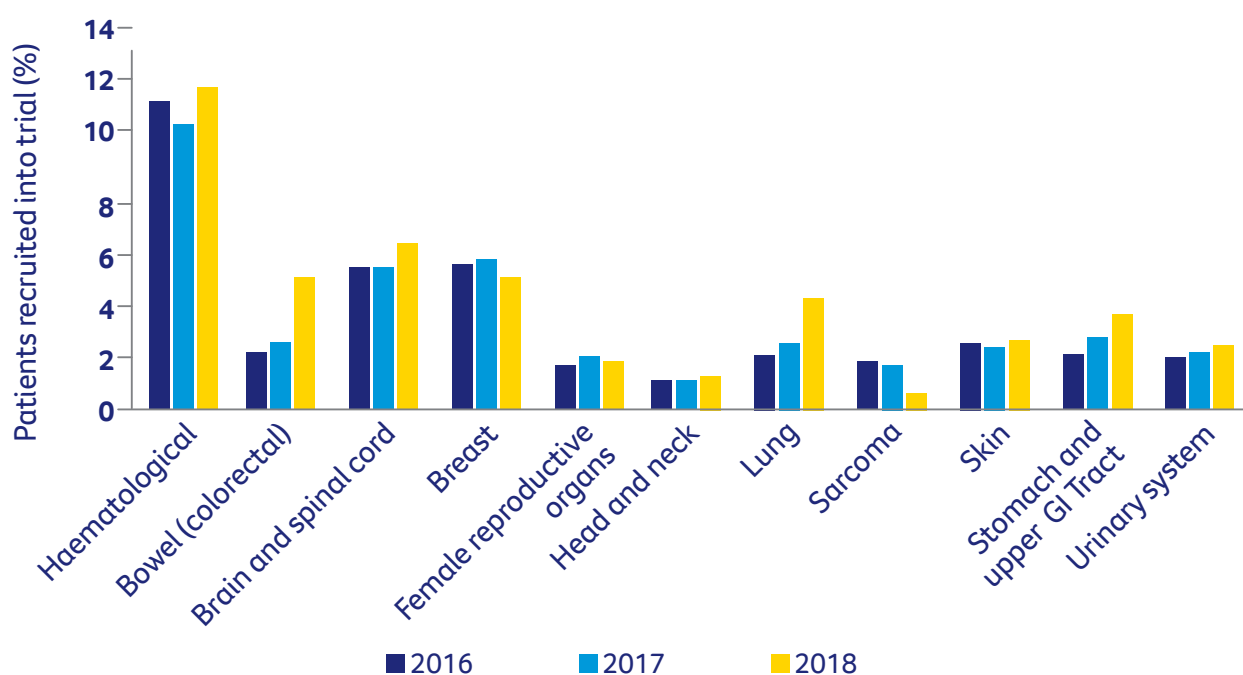


Figure 7. The percentage of patients recruited into clinical trials by tumour stream

By phase and sponsor

Unique trials by phase and sponsor

On average the largest number of unique clinical trials available in Victoria between 2016 and 2018 were Phase III (n=126), Phase II (n=72) and Phase I (n=61) trials. Over the three-year period, Phase I trials showed the most notable increase, from 47 unique trials in 2016 to 82 unique trials in 2018. The majority of unique Phase I trials available during this time, on average, were haematological (38%, n=23) or studying treatments for multiple types of cancer (42%, n=26).

Between 2016 and 2018, the majority of unique clinical trials (between 70.0 to 72.7%) were commercially sponsored. Approximately one quarter of clinical trials (between 24.5 to 27.4%) were non-commercially sponsored, by cooperative groups or independent investigators. Only a small proportion (between 0.3 to 3.4%) had a commercial and non-commercial sponsor (Figure 8).

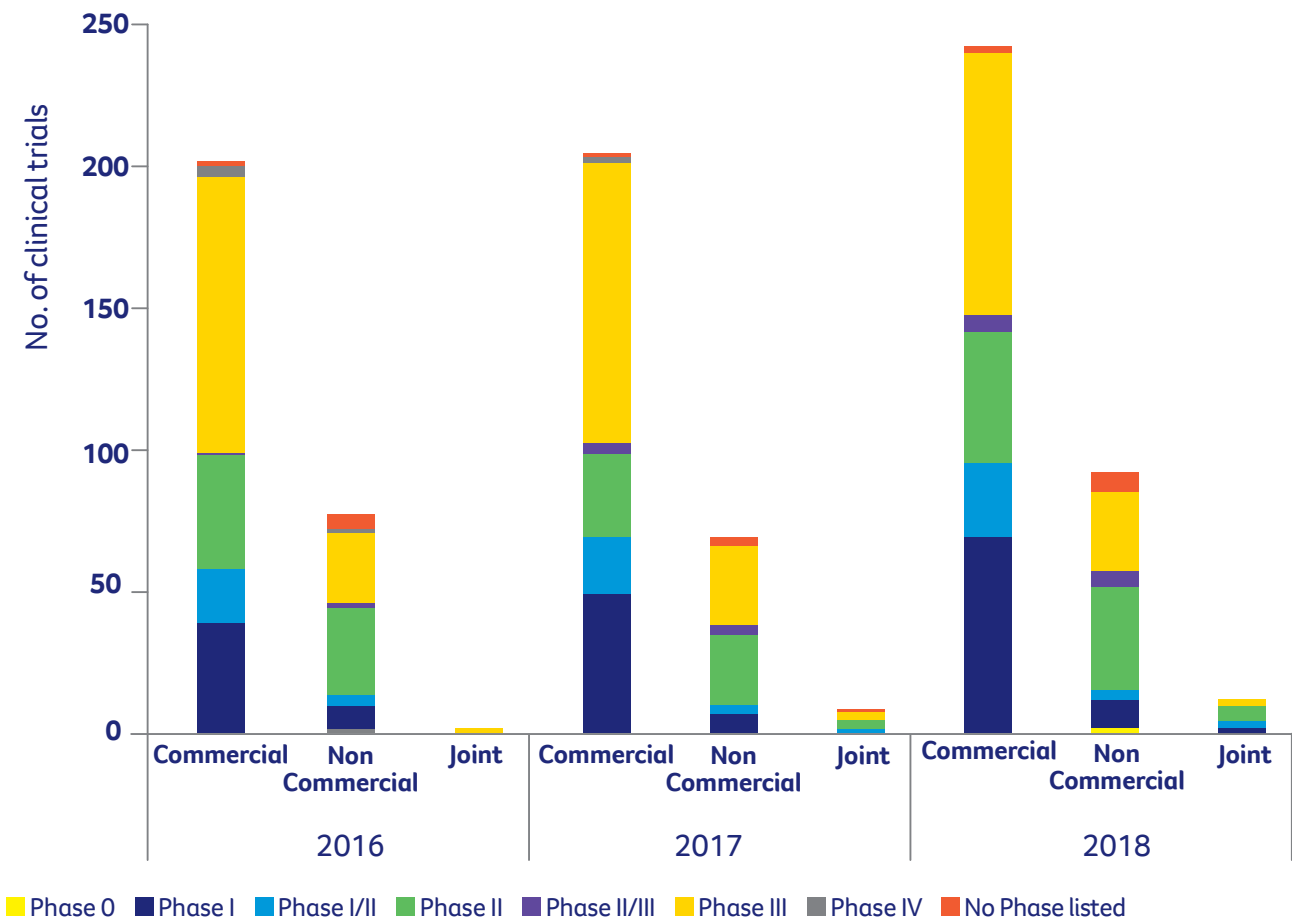


Figure 8. Unique clinical trials by sponsor type and phase.

Unique trials by intervention

From 2017 onwards, unique trials could be separated according to whether they contained systemic therapy, radiation therapy or surgical interventions. On average between 2017 and 2018, 87% of unique clinical trials administered systemic therapy interventions (Figure 9).

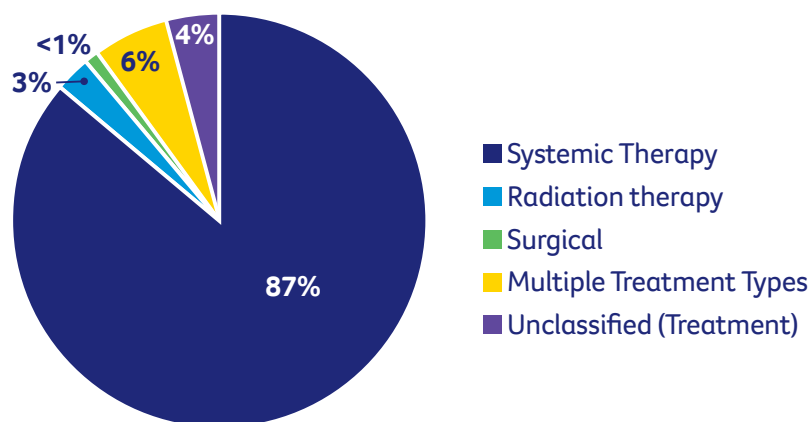


Figure 9. Unique clinical trials by treatment intervention, on average 2017-2018.

By participant age

New diagnoses and patient recruitment by patient age

On average, the following age groups experienced the highest number of new cancer diagnoses between 2016 and 2018; 60-74 (n=13,890), 75+ (n=10,884) and 26-59 (n=9,231) respectively. These age groups also reported the highest number of clinical trial recruits, on average over the three years; 60-74 (n=776), 26-59 (n=580) and 75+ (n=256) respectively. The age groups with the highest percentage of patients participating in clinical trials is 0-14 and 15-17 years, comparative to the new diagnoses of cancer in these age groups (Figure 10). The age group with the highest percentage increase in patients participating in clinical trials since 2016 is the 15-17 age category, which has more than tripled over the three-year period (Figure 10). However, data in this report have not been standardised with population data about the number of Victorians that comprise these age groups; and trends associated with these groupings could be an artefact of population size.

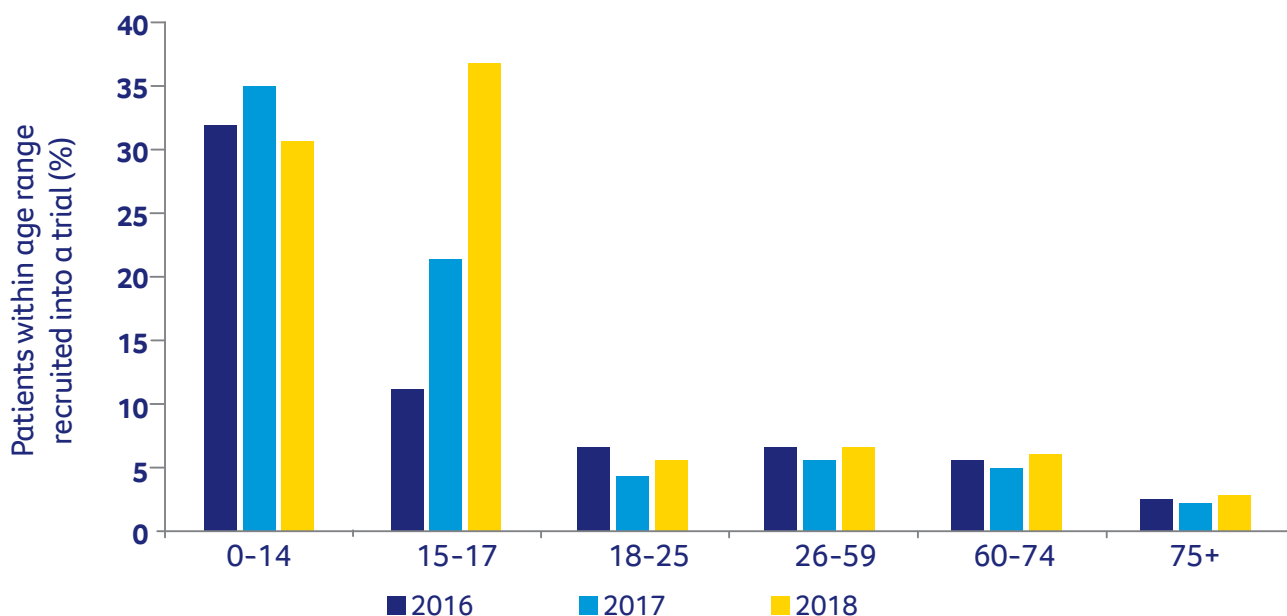


Figure 10. Percentage of cancer patients within an age range recruited into a clinical trial.

Summary

While the number of people recruited into cancer clinical trials increased in Victoria between 2016 and 2018, trial enrolment remained low, with the proportion of recruited patients compared to the number of newly diagnosed patients remaining consistent. With the number of unique clinical trials continuing to increase in Victoria, the sector must work together to continue to raise awareness of clinical trials to support patient access.

By introducing postcode and year of birth to our data set in 2016, we have been able to observe trends in recruitment by patient age and geography. Pleasingly, this includes an increase in the proportion of regional clinical trial participants being recruited into clinical trials closer to home – a trend that will be important to monitor as the uptake of telehealth/teletrials is increased with the aim of reducing geographical barriers to clinical trial participation. We also observed an increase in the proportion of adolescents (aged 15-17 years) participating in clinical trials during this time. Both of these trends are encouraging as we know these patients participate in clinical trials to a lesser extent than their metropolitan and paediatric counterparts, potentially contributing to poorer cancer outcomes for these patients.

Although these data continue to be a valuable resource for monitoring cancer clinical trial activity in Victoria, there are inherent limitations with the current data set and manual processes have limited data capture and comparability across years. For example, while we know culturally and linguistically diverse and Aboriginal Victorians are often under-represented in cancer clinical trials, current demographic data are limited, and we are unable to report on activity by ethnicity. In order to improve participation and reduce inequities in access to cancer clinical trials, this, amongst other barriers to opportunity and awareness must be addressed. Opportunities to benchmark and compare Victorian clinical trial activity with other jurisdictions are also limited, as there are currently no nationally consistent data sets available.

The Victorian cancer plan 2020-2024 prioritises improving participation and reducing inequities in access to clinical trials. To support equity of access, improvements to clinical trial data collection and reporting in Victoria are required. This report provides important data to continue efforts to raise awareness of clinical trials, as well as providing a baseline to monitor progress towards achieving the Victorian cancer plan's priority to improve participation and reduce inequity in clinical trial participation.



Appendix A:

Glossary of terms

Cancer Council Victoria:

A non-profit organisation that has been leading the fight against all cancers for more than 80 years in the areas of research, patient support, cancer prevention and advocacy. Cancer Council Victoria's mission is to prevent cancer, empower patients and save lives.

Cancer Trials Management Scheme:

Used to describe the process of reporting clinical trial activity and recruitment data to Cancer Council Victoria. Established in 1988 with the aim of increasing participation in clinical trials, monitored through the collection of site-specific data. Currently, 43 clinical trial units report data to Cancer Council Victoria in the Cancer Trials Management Scheme (CTMS).

Phase:

After being tested in a laboratory, new treatments are usually tested on people across four phases of clinical trials. **Phase I trials** involve small numbers of patients and are usually undertaken to find the safest dose, to assess the risks and understand the side effects of a treatment. **Phase II trials** generally test how well a treatment works with specific types of cancer; this phase of trial also involves smaller numbers of patients. **Phase III trials** compare new treatments with best standard treatments; these trials aim to recruit a much higher number of patients than early phase trials and usually involve randomisation. **Phase IV trials** are undertaken once a treatment has been licensed; these trials provide important information about safety, side effects and long-term risks and benefits of treatment. In this report, we only highlight data for Phase I, Phase II and Phase III trials, as these trials were the most commonly available in Victoria between 2016 and 2018.

Recruitment:

Percentage of cancer patients recruited in a clinical trial compared to the number of new cancer diagnoses in the same year.

Recruitment rate:

Percentage of cancer patients recruited in a clinical trial compared to the number of unique trials available.

Sponsor:

An individual, organisation or group taking on the responsibility for securing the arrangements to initiate, manage and finance a clinical trial. The sponsor may be 'commercial' (such as a pharmaceutical company) or 'non-commercial' (such as an independent investigator/researcher, hospital or cooperative group).

Tumour Stream:

For the purposes of this report, we have group cancers into ‘tumour streams.’ Where a clinical trial is recruiting across tumour streams, we have classified this as ‘multiple’.

Tumour Stream:	Explanation:
Haematological cancers	Clinical trials including people with leukaemia, lymphoma (including Hodgkin’s Disease), multiple myeloma, other forms of blood cancer/disease (including myelodysplasia).
Bowel (colorectum)	Clinical trials including people with cancers of the colon, rectum, colorectum or anus.
Brain and spinal cord	Clinical trials including people with cancers of the brain and spinal cord.
Breast	Clinical trials including people with breast cancer.
Female reproductive organs	Clinical trials including people with cancers of the cervix, fallopian tube, ovary, uterus (including sarcoma), endometrium or other (including vagina and vulva).
Head and neck	Clinical trials including people with cancers of the head and neck. This includes cancers of the eye (ocular), mouth (oropharynx and oral cavity), nose (nasopharynx), throat (hypopharynx), voice box (larynx) or other (such as the thyroid and salivary glands).
Lung	Clinical trials including people with lung cancer (non-small cell, small cell, mesothelioma or other).
Multiple	Clinical trials recruiting across more than one tumour stream.
Sarcoma	Clinical trials including people with bone and soft-tissue sarcoma, rhabdomyosarcoma, gastrointestinal stromal tumour or other.
Skin	Clinical trials including people with cancers of the skin.
Stomach and upper gastrointestinal	Clinical trials including people with cancers of the pancreas, liver, gallbladder, bile duct, stomach (including gastro-intestinal stromal tumours), oesophagus or gastro-oesophageal junction.
Urinary system	Clinical trials including people with cancers of the bladder, prostate, testis, kidney or penis.

Unique trials:

Clinical trials that have recruited at least one patient in a reporting year, not including duplicate counts of trials being conducted across multiple units in Victoria.

Victorian Cancer Trials Link:

A searchable portal of cancer clinical trials available in Victoria, available online and in mobile form.

Victorian Cancer Agency:

Funded by the Victorian Government, the Victorian Cancer Agency invests in projects and initiatives that rapidly translate research into treatments and approaches that improve clinical practice and care of cancer patients.

Victorian Cancer Registry:

A recognised leader in the collection and provision of data for cancer control nationally and internationally. Established in 1939, the Victorian Cancer Registry is the longest running comprehensive cancer registry in Australia and among the oldest continuously operating registries in the world.

Appendix B

Map of Integrated Cancer Service (ICS) regions within Victoria

