



Reflecting on six years of clinical trial activity and access in Victoria (2016-2021)



Acknowledgements

Acknowledgement of Country

Cancer Council Victoria acknowledges the Traditional Owners of the land and water ways on which we work and live. We pay our respects to Elders past and present and those emerging, and extend that respect to all other Aboriginal and Torres Strait Islander Peoples.

Acknowledgement of contributors

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

**VICTORIAN
CANCER
AGENCY**



We would like to thank the Victorian Government and broader cancer clinical trials sector in Victoria, including the clinical trial units who regularly reported data to Cancer Council Victoria, for their significant contribution to this report.

©Cancer Council Victoria 2023
October 2023 Cancer Council Victoria, East Melbourne


Suggested citation:

Cancer Council Victoria. Reflecting on six years of clinical trial activity and access in Victoria (2016-2021). Cancer Council Victoria, East Melbourne, Victoria, 2023.

Report prepared by:

Taylah Wynen, Clinical Trials Lead
Amy Shelly, Head of Research Governance and Optimal Care

Published by Cancer Council Victoria

 Level 8, 200 Victoria Parade,
East Melbourne Victoria 3002
Australia

cancervic.org.au

For enquiries, contact Cancer Council Victoria via email to Research Governance RGU@cancervic.org.au.

Contents

Acknowledgements	2
Activity snapshot	4
Foreword	5
Introduction	7
About Cancer Council Victoria.....	7
About this report.....	7
Limitations.....	7
Impact of the COVID-19 pandemic.....	8
Clinical trial activity (2016–2021)	9
Recruitment into Victorian cancer treatment clinical trials.....	9
Recruitment by geography.....	10
Interstate participants	12
Recruitment by region.....	12
Recruitment by trial unit location	13
Case study: Regional Trials Network – Victoria	15
By tumour stream.....	16
Unique trials by tumour stream	16
Tumour streams with highest recruitment.....	17
By participant age.....	20
By phase, sponsor and intervention	22
Case study: Accessing cancer clinical trials for people of the West.....	23
By trial unit location.....	25
Trends at regional units	26
Trends at metropolitan units	27
Discussion	29
Appendix A: Glossary of term	30
Appendix B: Data tables	33
References	43

Activity snapshot



This report includes data from 37 Victorian clinical trial units on recruitment into cancer treatment trials in 2016 – 2021.



During this time, 10,105 people with cancer across these units were recruited into a clinical trial for their cancer treatment.



The number of participants recruited into a clinical trial increased from 1,552 in 2016 to 2,044 in 2021 (32% increase).



22% (n=2,265) of clinical trial participants lived in regional Victoria.



Most clinical trial participants (94%, n=9,452) were recruited to clinical trials at metropolitan units.



The proportion of clinical trial participants recruited to clinical trials at regional units increased between 2016 (4.2%) and 2020 (8.0%), but decreased in 2021 (5.1%).



Interstate participants made up 4.7% of the participants recruited in Victoria during 2016 and 2021. People travelled from ACT, NSW, QLD, SA, WA and Tasmania to participate in a clinical trial in Victoria.



The number of unique¹ clinical trials increased from 265 in 2016 to 409 in 2021 (54% increase).



Most unique clinical trials, on average, were recruiting for haematological cancers (31%, n=103), multiple types of cancer (17%, n=56), or cancers of the urinary system (11%, n=35).



Early phase trials experienced the greatest increase in the number of unique trials.



70% of unique clinical trials were commercially sponsored.



90% of unique clinical trials assessed systemic therapy interventions.



Two-thirds (68%) of all unique clinical trials available during 2016 and 2021 were commercially sponsored trials assessing systemic therapy interventions.

¹Trials that recruited at least one participant in a reporting year, not including duplicate counts of trials being conducted across multiple units in Victoria. Please refer to Appendix A for a complete glossary of terms.

Foreword

Cancer trials are vital in advancing new treatments for cancer patients.

A partnership between scientists and cancer patients, clinical trials provide hope for people affected by cancer now and into the future.

This report highlights the activity and recruitment that has occurred in cancer treatment clinical trials in Victoria between 2016 and 2021. During this time, 10,105 people with cancer participated in cancer treatment clinical trials in Victoria. The number of participants recruited into a clinical trial annually increased from 1,552 in 2016 to 2,044 in 2021, an increase of 32%. The number of unique clinical trials available each year to Victorians increased from 265 in 2016 to 409 in 2021 – a 54% increase. These increases in activity are significant given the challenges faced by the community and healthcare sector as a result of the COVID-19 pandemic.

Cancer Council Victoria has been working with clinical trial units in the Cancer Trials Management Scheme for over three decades. During this time, reported data have been used to inform sector planning and investments, and to help people find available clinical trials on the Victorian Cancer Trials Link.

For many years, the Cancer Trials Management Scheme has been the most comprehensive source of clinical trial activity and recruitment data collected in Victoria. However, as the clinical

trials sector continues to grow, we recognise the data, and the systems we use to collect it, must grow with it.

From 2023, Cancer Council Victoria will no longer collect these data. Instead, this activity will be transitioned, with support from the Victorian Government, through the Victorian Cancer Agency, to Cancer Trials Australia.

Cancer Council Victoria will continue to support people affected by cancer to become aware of and access clinical trials in Victoria. We know, through recent research, that this continues to be a challenge for people with cancer. We look forward to working with Cancer Trials Australia to ensure collected data continues to meet the needs of the sector and inform the work that we do.

We are grateful for the time and resources that participating clinical trial units have invested in reporting data to us over the years. Data of this nature requires considerable commitment, patience, and diligence to collect. We look forward to continuing to work with clinical trial units to share their clinical trial activity with people affected by cancer and health professionals via the Victorian Cancer Trials Link, which is undergoing an exciting rebuild this year.

We also acknowledge the Victorian Government through the Victorian Cancer Agency for their ongoing support of our clinical trials portfolio, and patients and cancer scientists for their commitment in advancing cancer treatments.



A handwritten signature in black ink that reads "Todd Harper".

Todd Harper AM
CEO Cancer Council Victoria

Clinical trials are at the heart of better healthcare and better patient outcomes.

This is nowhere more true than in cancer care. The astounding advances in survival rates we have seen for so many cancers in recent years is because of the new knowledge clinical trials have given us. But more than that, health services that have lots of clinical trials running have better patient outcomes, even for those

whose care is not part of a clinical trial. They are safer hospitals, and more efficient. Better places to work and better places to be a patient. So I am delighted to see that this report shows ever increasing clinical trial activity and involvement across our state, particularly in rural and regional Victoria. I look forward to the time when patients ask “why am I not in a clinical trial?” We will ALL be the better for it.



A handwritten signature in blue ink that reads "Euan M Wallace".

Professor Euan M Wallace AM
Secretary, Department of Health

“

Being involved in this trial was initially a little daunting but as the program evolved, I found I was being cared for and guided by a caring and professional team that were quick to respond to any issues that we encountered quickly and proficiently.

The continued on-going care adds to the feeling of wellness right through the journey. Knowing that the trial also locks in future reviews leaves one with a feeling of genuine relief in knowing that my best interests are right at the forefront for the team members.

I would recommend clinical trial participation if offered to anyone as you will be cared for and managed by a team of qualified and caring professionals.”

- Gary, clinical trial participant

Introduction

About Cancer Council Victoria

Cancer Council Victoria is a non-profit cancer organisation dedicated to world-leading cancer research, prevention, and support, since our establishment in 1936. Our mission is to prevent cancer, empower patients and save lives.

We are committed to increasing investment in clinical trials, improving awareness and access for all Victorians and diversifying cancer research. We work collaboratively with government and the healthcare sector to help patients access clinical trials that may help them to live well and live longer.

Find out more at

cancervic.org.au/research/clinical-trials

About this report

This report highlights some of the significant activity and achievements that have been made to improve access to cancer treatment clinical trials in Victoria between 2016 and 2021. It shares data from 37 clinical trial units who participated in Cancer Council Victoria's Cancer Trials Management Scheme (CTMS) during this time.

Each year, participating clinical trial units report data on the number and type of cancer treatment clinical trials available at their unit. In addition to the number of recruited participants on clinical trials, information about the participant's year of birth and residential postcode is also recorded.

Limitations

Data included in this report is limited to cancer treatment (intervention) trials only, i.e. systemic therapies, radiation therapy and surgery. The types of trials excluded from this analysis include trials solely focused on prevention, diagnosis, screening, supportive care and palliative care, rollover and expanded access studies and registry trials. Please refer to Appendix A for a glossary of terms. We caution against comparing these data to data sets in other jurisdictions as the definitions and scope of data included may differ.

Reporting years are from 2016 to 2021 (including all activity, relevant to cancer treatment clinical trials, between the 1st of January 2016 to the 31st of December 2021). Data in this report may differ from previous reports, as the number of trial units and trial data have been cleaned for consistency across



years. We therefore caution direct comparison with previous reports.

To enable comparison across years, we have excluded data from six clinical trial units who did not consistently provide data during the reporting period. Therefore, this report does not reflect all trial activity during this time.

Data in this report have not been standardised with population data but, where relevant, have been compared to the number of new cancers diagnosed in Victoria each year, as reported by the Victorian Cancer Registry. This is a commonly used metric; however, we acknowledge that not all people with cancer will be eligible for, or be recruited into, a clinical trial in the same year that they were diagnosed.

Impact of the COVID-19 pandemic

COVID-19 has had a significant impact on cancer diagnoses, and the delivery of cancer screening, treatment and care in Victoria. At the end of 2021 there were an estimated 3,864 fewer cancer diagnoses than expected,ⁱ suggesting people may be at a higher risk of not having their cancer detected early. During the pandemic, we responded to around 30,000 enquiries to our cancer information and support service,ⁱⁱ and heard firsthand how the rapid implementation of public health measures, hospital visitor

restrictions policies, vaccinations, and alternative ways of delivering care during the pandemic impacted people affected by cancer and the sector more broadly. We also heard of potential disruption to the delivery of cancer clinical trials.

In June 2020, and in collaboration with the Victorian Government through the Victorian Cancer Agency, we surveyed members of the Victorian clinical trials sector to understand if and how the COVID-19 pandemic impacted the delivery and recruitment of cancer clinical trials.ⁱⁱⁱ We heard from over forty clinicians and clinical trial unit staff, who let us know the pandemic presented both challenges and opportunities for the sector. Key challenges included the closure or suspension of clinical trial recruitment, changes to workforce and protocol compliance, and impacts to annual budgets. Key opportunities included the rapid implementation of telehealth to support the delivery of clinical trials, changes to streamline ethics and governance procedures and the acceptance of remote monitoring by sites and sponsors.

While we are unable to draw direct links between activity data and external factors, this report provides a snapshot of clinical trial activity that occurred during the COVID-19 pandemic.



Clinical trial activity (2016-2021)

Recruitment into Victorian cancer treatment clinical trials

The number of people diagnosed with cancer recruited into cancer treatment clinical trials has increased from 1,552 in 2016 to 2,044 in 2021 (32% increase) (Figure 1). Over the same period, the total number of new cancer diagnoses, as reported by the Victorian Cancer Registry, increased from 33,624 in 2016 to 36,974 in 2021 (10% increase).

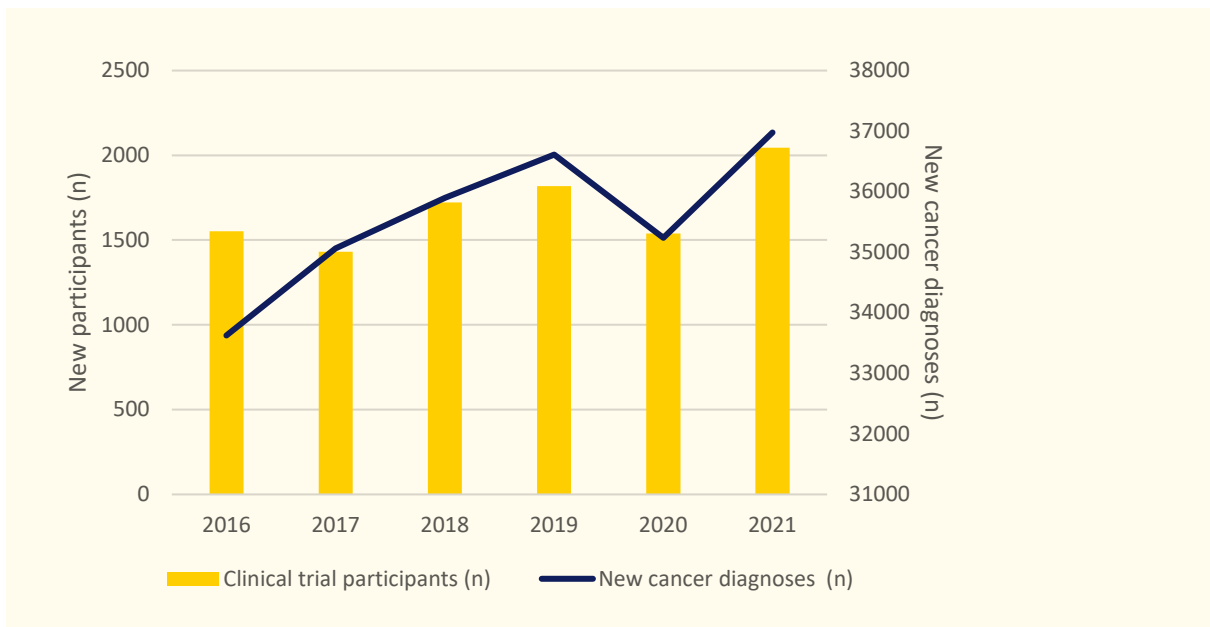


Figure 1. Number of new participants and new cancer diagnoses, 2016-2021.

The percentage of people diagnosed with cancer recruited into clinical trials remained relatively steady during the reporting period, increasing slightly from 4.6% in 2016 (1,552/33,624) to 5.5% in 2021 (2,044/36,974) (Figure 2).

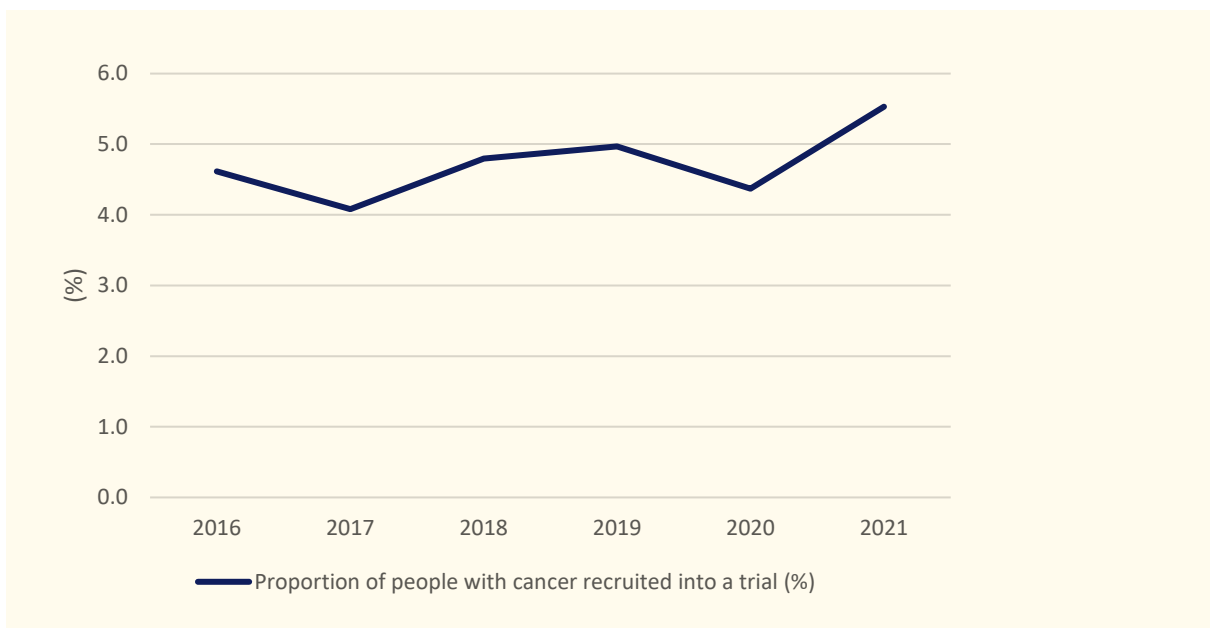


Figure 2. Proportion of people with cancer recruited to a clinical trial, relative to new cancer diagnoses, 2016-2021.

The number of unique clinical trials (meaning trials that recruited at least one participant in a reporting year, not including duplicate counts of trials being conducted across multiple units in Victoria) increased from 265 in 2016 to 409 in 2021 (54% increase) (Figure 3).

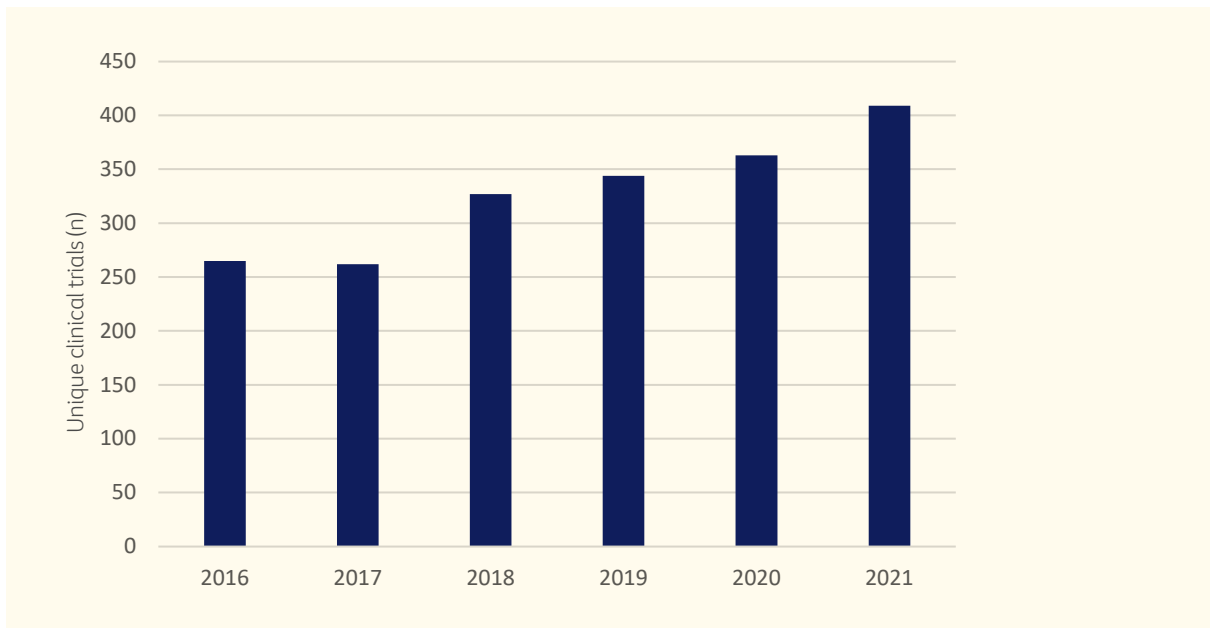


Figure 3. Number of unique clinical trials, 2016-2021.

Recruitment by geography

On average, 71% of people with cancer recruited into Victorian cancer clinical trials lived in metropolitan areas² (Figure 4).

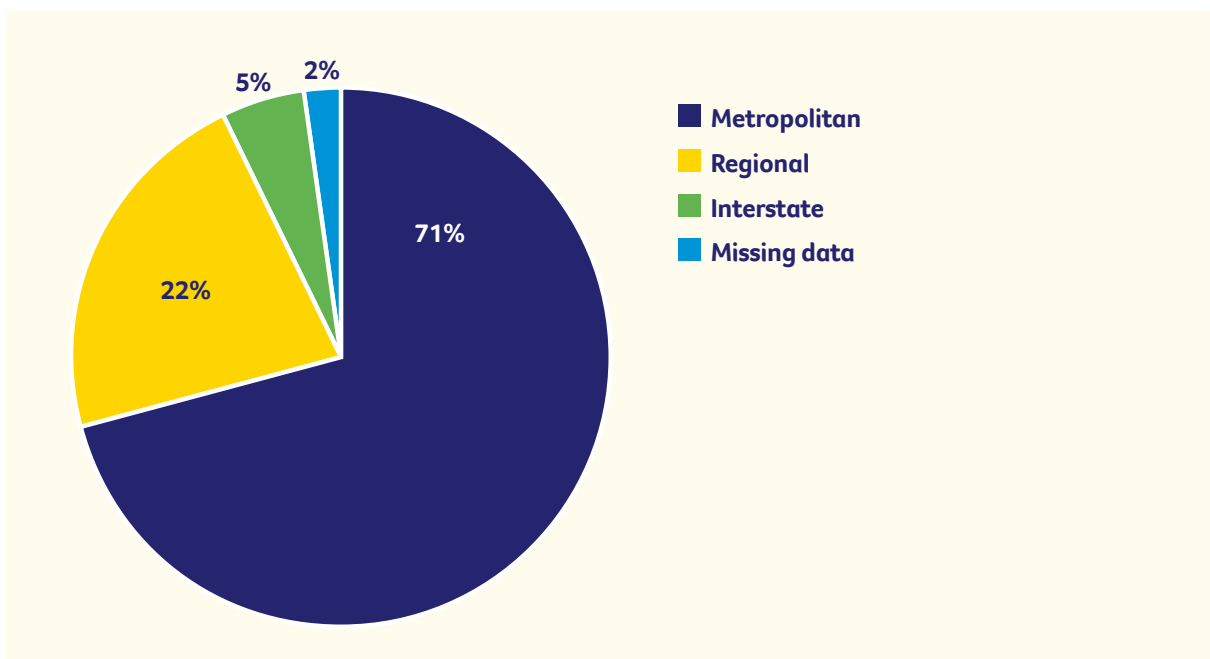


Figure 4. Geographic distribution of new participants' residential location, 2016-2021. Data have been averaged across the six reporting years.

² Please refer to the glossary of terms in Appendix A for definitions of metropolitan and regional.

The number of regional participants increased from 356 in 2016 to 432 in 2021 (21% increase). The number of metropolitan participants increased from 1,102 in 2016 to 1,512 in 2021 (37% increase). There were decreases in recruitment for both metropolitan and regionally based participants in 2017 and 2020 (Figure 5).

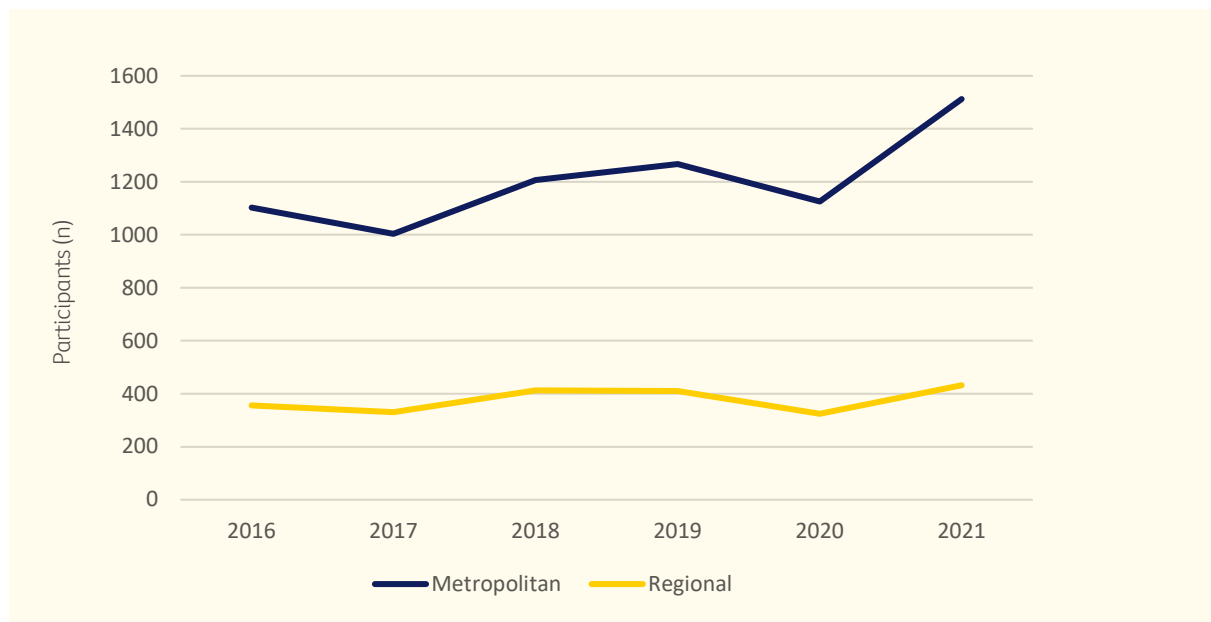


Figure 5. Number of new metropolitan and regionally based participants, 2016-2021.

The proportion of recruited metropolitan and regionally based participants remained relatively stable over the reporting period (Figure 6); on average 24% (n=378) of participants were recruited from regional Victoria.

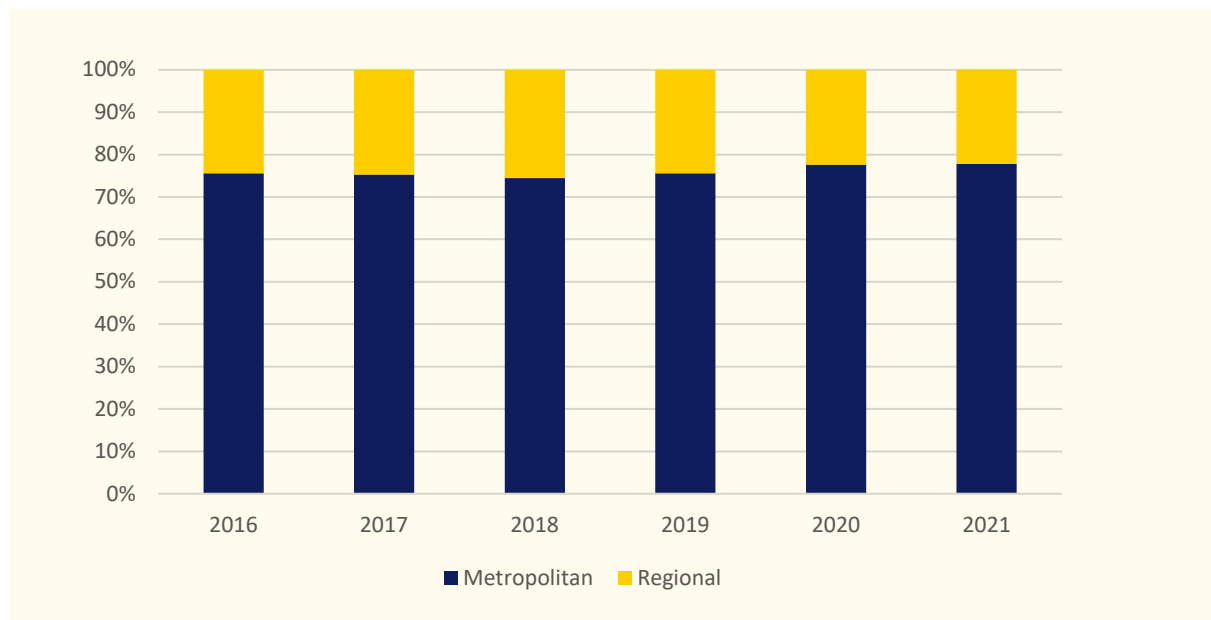


Figure 6. Proportion of metropolitan and regionally based participants, 2016-2021.

Interstate participants

Interstate participants made up 4.7% of those recruited into cancer clinical trials in Victoria during 2016 and 2021. The number of interstate participants increased from 66 in 2016 to 113 in 2019, before reducing to 63 in 2021 (Figure 7).

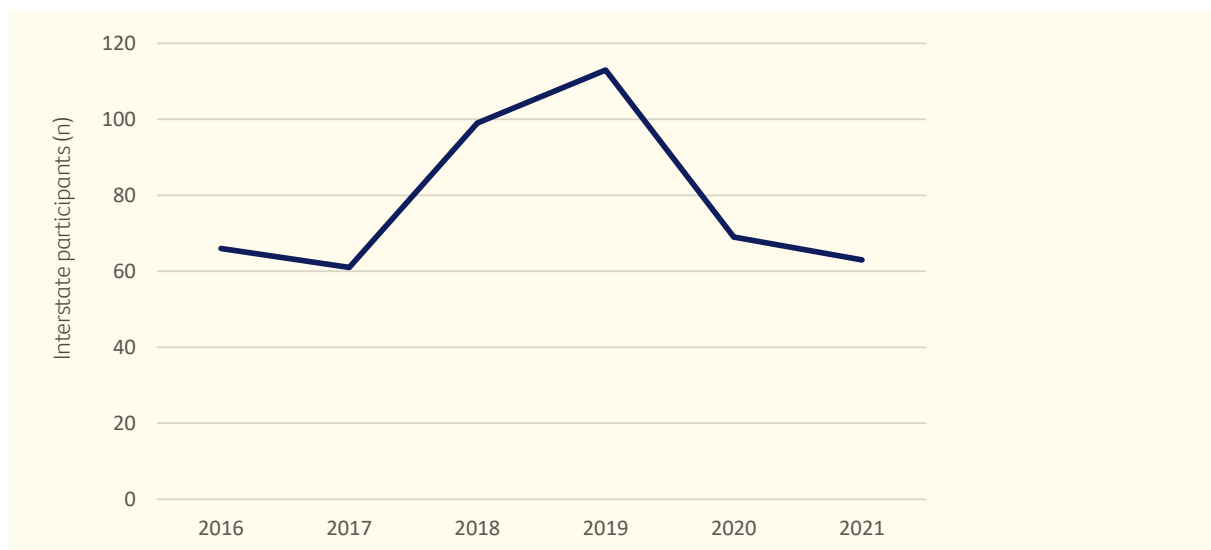


Figure 7. Number of new interstate participants enrolled in clinical trials in Victoria, 2016–2021.

On average, most interstate participants lived in New South Wales (49%), followed by Tasmania (21%). The majority (82%) of interstate participants enrolled into clinical trials at metropolitan clinical trial units. All interstate participants who enrolled at regional units were from neighbouring states: 81 participants from New South Wales and <5 participants from South Australia.

Recruitment by region

On average, the Barwon South Western region (excluding Geelong region) had the highest proportion of residents with cancer participating in a clinical trial (6.5%) compared to the number of people diagnosed with cancer in that region (Figure 8).

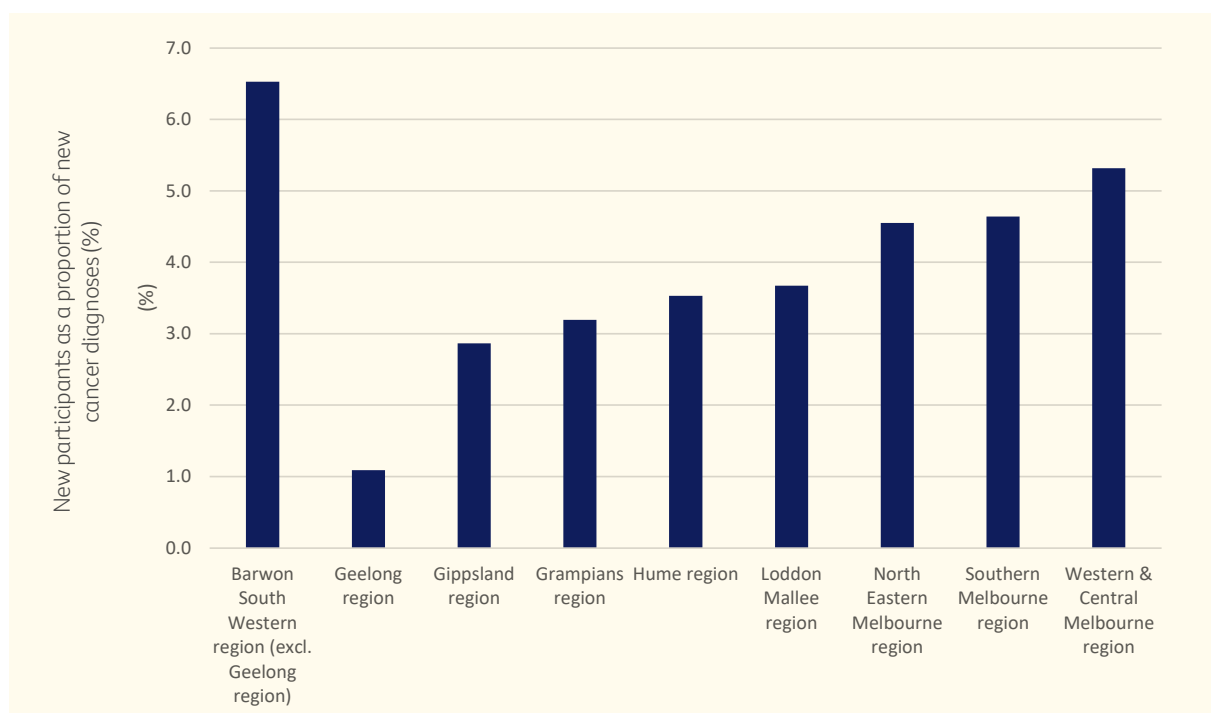


Figure 8. Proportion of people with cancer recruited into a clinical trial, relative to new cancer diagnoses, by region, 2016–2021. Data have been averaged across the six reporting years and excludes interstate participants and missing data.

While most regions saw a reduction in the proportion of residents with cancer recruited into a clinical trial (relative to new cancer diagnoses) in that region in 2020, Geelong, Gippsland and the Southern Melbourne region all experienced a steady increase in 2020 (Figure 9). All regions except Hume experienced an increase in this proportion in 2021.

On average, people diagnosed with cancer residing in metropolitan areas had higher recruitment into clinical trials than those living in regional areas (4.5% vs. 3.7%).

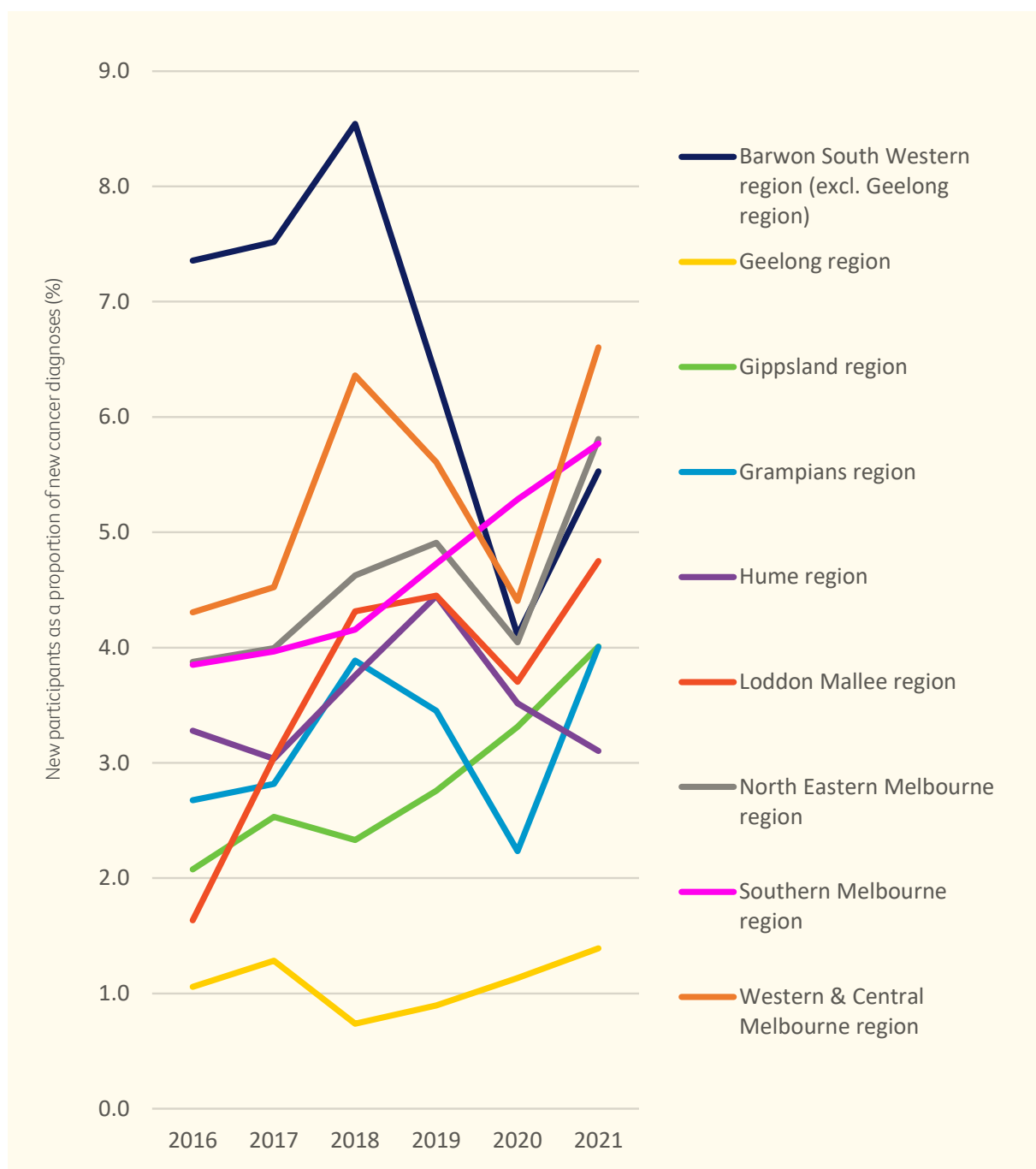


Figure 9. Proportion of people with cancer recruited into a clinical trial, relative to new cancer diagnoses, by patient residential region, 2016–2021.

Recruitment by trial unit location

Most new participants (94%, n=9,452) enrolled in clinical trials at metropolitan units, regardless of whether they lived in a metropolitan area, in a regional part of the state or interstate. The proportion of new participants recruited to clinical trials at regional units increased between 2016 and 2020 (from 4.2% to 8.0%), before decreasing in 2021 (to 5.1%) (Figure 10).

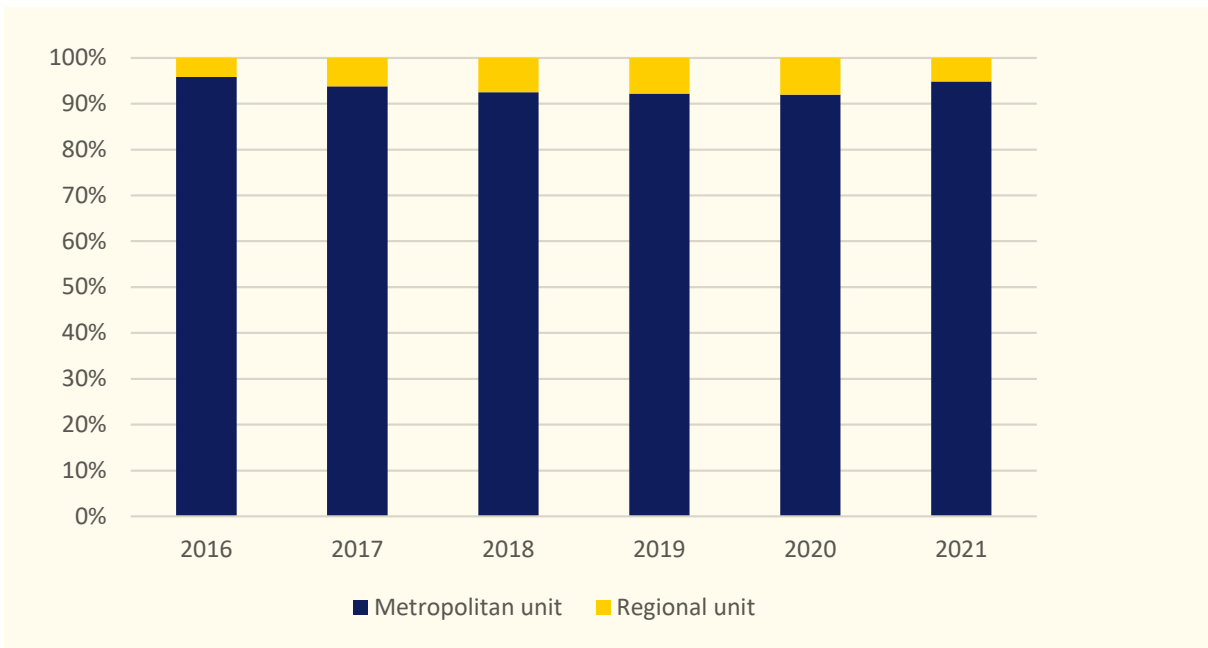


Figure 10. Proportion of new participants recruited to clinical trials at metropolitan and regional units, 2016-2021.

The number of regionally based participants enrolling in trials at regional units increased from 51 in 2016 to a peak of 121 in 2019, before decreasing to 94 in 2021 (Figure 11). On average, less than a quarter (24%, n=90) of regionally based participants enrolled in a trial at a regional trial unit. Almost no metropolitan based participants, on average, enrolled at regional trial units (n=<5, <1%).

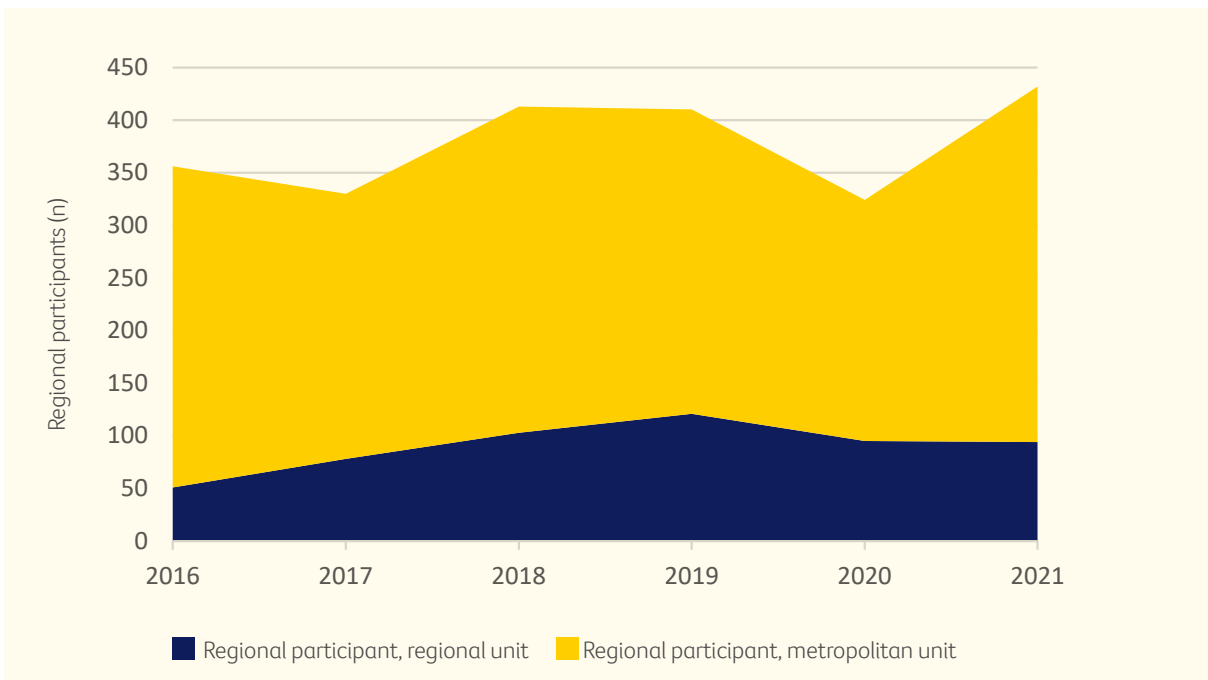


Figure 11. Number of regionally based participants recruited at metropolitan and regional clinical trial units, 2016-2021.

Case study: Regional Trials Network – Victoria

The establishment of the network was funded (2017) by Cancer Council Victoria and the Victorian Government acting through the Victorian Cancer Agency.

The project:

The Regional Trial Network - Victoria was created to improve access and recruitment to high-quality cancer clinical trials for rural and regional Victorians. It brought together five regional clinical trial sites (Albury Wodonga, Shepparton, Ballarat, Bendigo and Warrnambool) plus Geelong, covering an area of 141,000 km², and a population of 1.4 million, with about 7,200 cancer diagnoses each year.

The need:

Clinical trials play a critical role in answering questions about the prevention, diagnosis and treatment of cancer, as well as improving psychological, supportive and palliative care outcomes, however not everyone has the same opportunity to take part. People living in regional and rural Victoria often face greater barriers to clinical trials, due to their location and a lack of available services.

The impact:

- The Regional Trials Network – Victoria aimed to increase the number of clinical trials available to regional and rural patients, by providing centralised expertise and support to clinical trial units in regional Victoria.
- It is now a well-established network for regional clinical trial units.
- Since establishment in 2017, there has been an increase in clinical trials at participating regional clinical trial sites and an increase in recruited participants.
- The network piloted telehealth technology to undertake trials activity and reduce the burden of travel for patients allowing them access to cutting-edge cancer treatments.
- Following the success of this project, The Regional Trials Network – Victoria (through Border Medical Oncology Research Unit, led by A/Prof Craig Underhill) was awarded \$18.6 million in federal funding through the Medical Research Future Fund (MRFF) to bridge the metro-regional clinical trials gap by 2025. This project has, amongst other things, added the Mildura Base Hospital and enhanced Latrobe Regional Hospital as new sites to the Regional Trial Network – Victoria. It has also introduced seven unique health services research programs increasing the number of available trials and improving access for patients, in regional Victoria.
- The network has also been successful, in partnership with Peter MacCallum Cancer Centre, at attracting funding via two additional federal MRFF grants in the domains of pancreatic cancer and pharmacogenomics.
- The Victorian Government also allocated \$2.447 million to the Regional Trials Network-Victoria to increase access to clinical trials and teletrials for regional Victorians diagnosed with cancer. The funding allocated through the 2020-21 State Budget also supported fast-tracking of the Clinical Trials Unit at Mildura Base Public Hospital and improving capacity at Latrobe Regional Hospital.

“This Cancer Council Victoria and Victorian Cancer Agency grant provided us with the start-up funding we needed to demonstrate what could be done to increase clinical trial activity and collaboration in the regions. It has enabled us to apply for and be awarded a significant Australian Government grant that now allows us to extend our work and importantly hopefully save the lives of more regional Australians with cancer.” – A/Prof Craig Underhill

By tumour stream

For the purposes of this report, we have grouped cancers into tumour streams. Where a clinical trial was recruiting across more than one tumour stream, we have classified this as 'multiple'. Please refer to Appendix A for details of which cancers we have grouped within each stream.

Unique trials by tumour stream

Haematological cancers consistently had the greatest proportion of unique clinical trials available in Victoria from 2016 to 2021 (Figure 12). On average, trials for haematological cancers made up 31% of all unique clinical trials available, followed by trials recruiting across multiple tumour streams (17%) and cancers of the urinary system (11%).

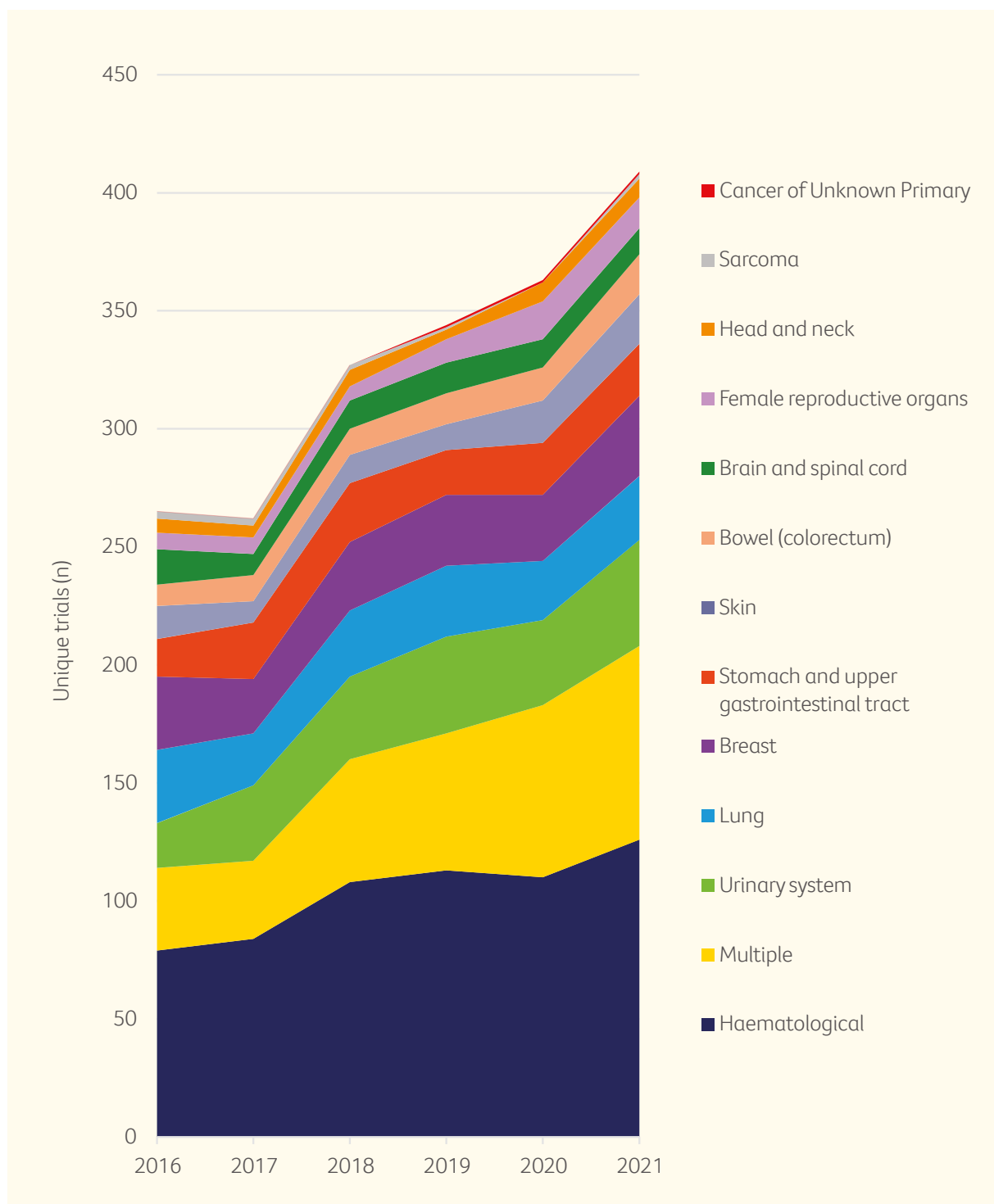


Figure 12. Number of unique trials by tumour stream, 2016–2021.

The tumour streams with the least number of unique trials available, on average, were cancers of unknown primary location (0.3%), sarcoma (0.7%) and head and neck cancers (1.9%). These three tumour streams also accounted for the smallest proportion of new clinical trial participants, on average.

Tumour streams with highest recruitment

This section focuses on the five tumour streams with the highest recruitment, for a full list of recruitment activity by tumour stream see data tables in Appendix B.

Figures 13 to 17 demonstrate the annual number of new participants and number of unique clinical trials available per tumour stream, as well as the annual recruitment rate (that is, the number of new participants relative to the number of unique trials available for that tumour stream).

The tumour streams with the highest average recruitment rate in the reporting period mirrored the tumour streams with the highest average number of new participants, except for skin cancer. Skin cancer had the third highest average recruitment rate (6.4 new participants per unique trial available), but the 7th highest average number of new participants.

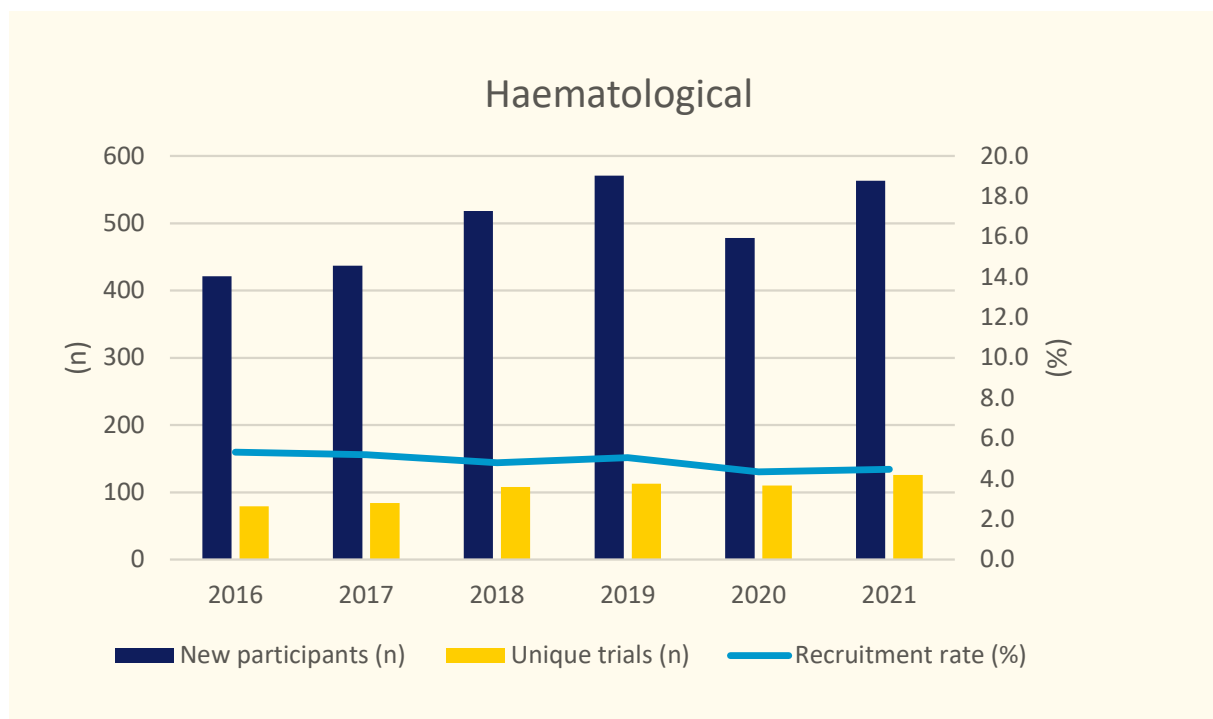


Figure 13. Number of new participants, unique trials, and recruitment rate for haematological cancer trials, 2016-2021.

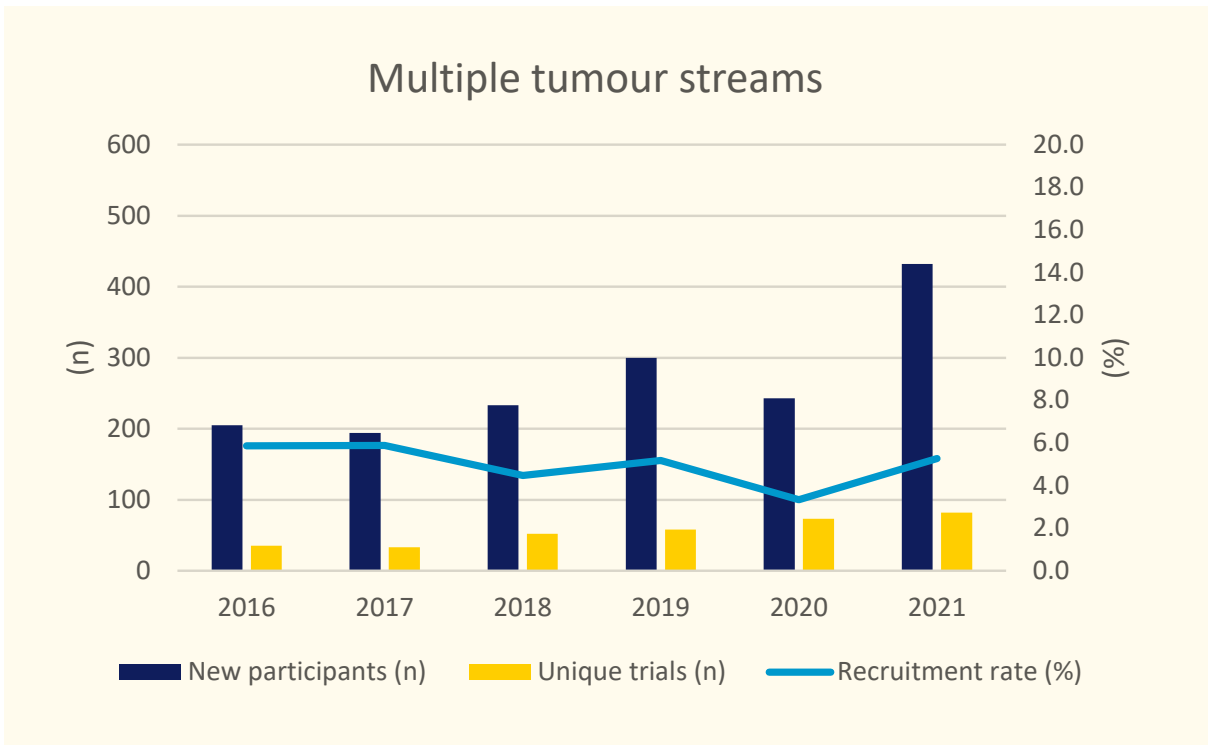


Figure 14. Number of new participants, unique trials, and recruitment rate for trials recruiting across multiple tumour streams, 2016-2021.

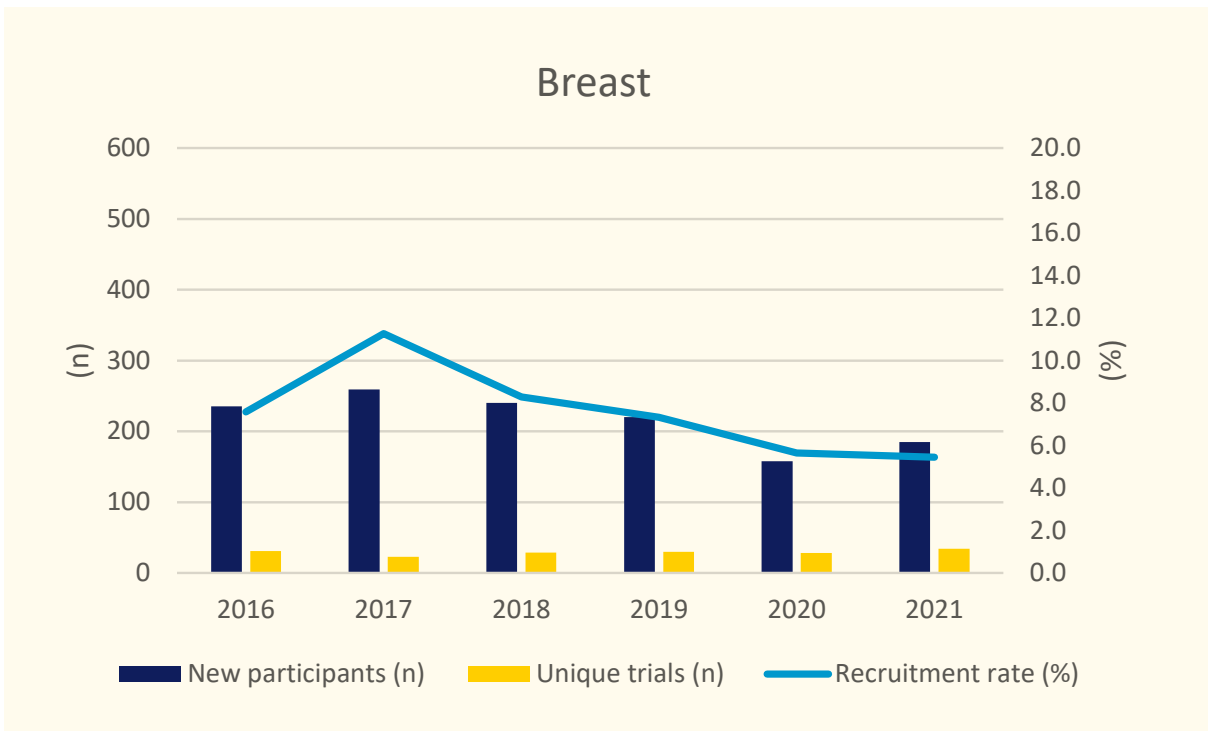


Figure 15. Number of new participants, unique trials, and recruitment rate for breast cancer trials, 2016-2021.

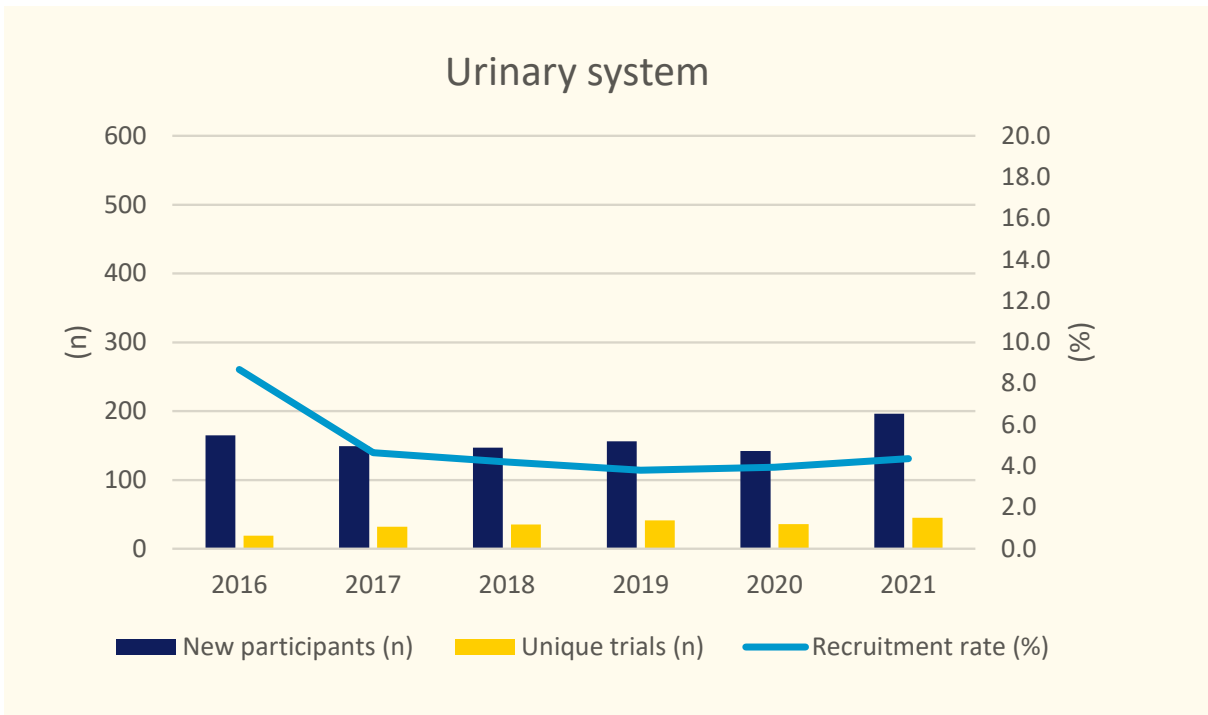


Figure 16. Number of new participants, unique trials, and recruitment rate for trials treating cancers of the urinary system, 2016-2021.

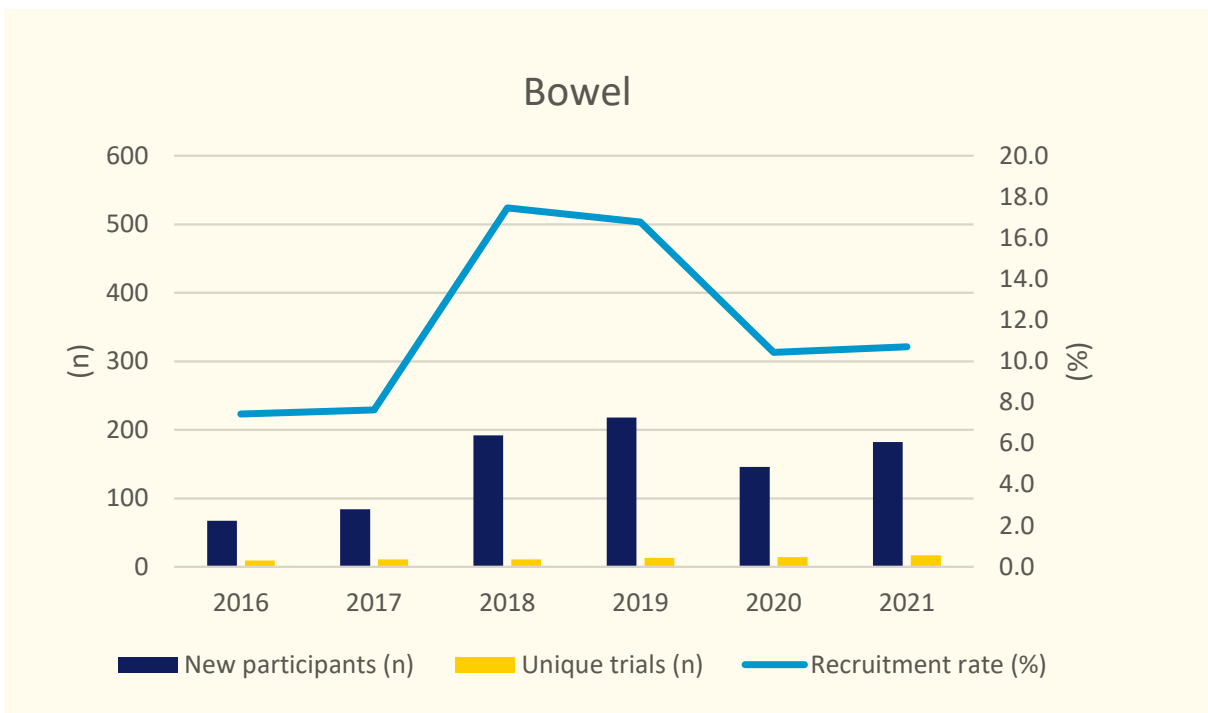


Figure 17. Number of new participants, unique trials, and recruitment rate for bowel cancer trials, 2016-2021.

By participant age

Older adults (aged 60-74) had both the highest average number of new participants and highest average number of new diagnoses (Table 1).

Age group	Average number of new participants	Average number of new cancer diagnoses
0 – 14	56	190
15 – 17	12	50
18 – 25	18	248
26 – 59	572	9,304
60 –74	741	14,397
75+	256	11,379

Table 1. Number of new participants and number of new cancer diagnoses by age group, 2016-2021. Data have been averaged across the six reporting years.

The groups with the greatest proportion of people with cancer participating in clinical trials, on average, were children (aged 0-14 years) (29%) and adolescents (aged 15-17 years) (23%) (Figure 18). Participation rates for those aged 75 and older may be low compared to new diagnoses as a result of co-morbidities potentially limiting eligibility.

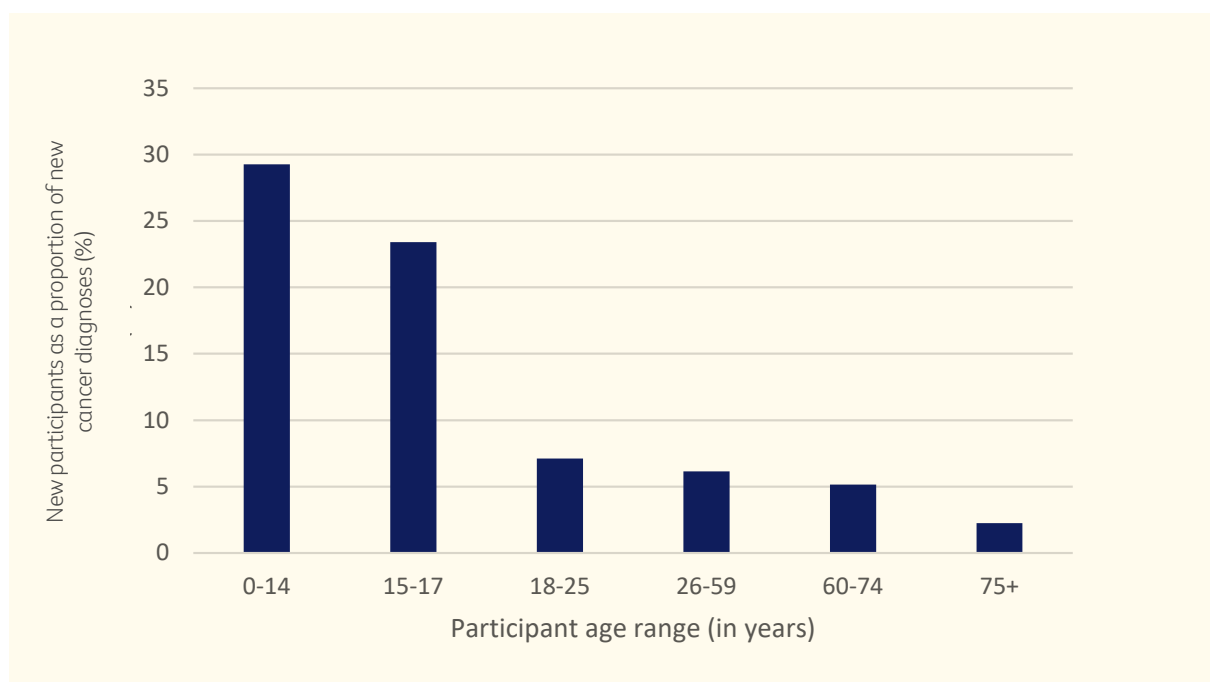


Figure 18. Proportion of people with cancer recruited to a clinical trial, relative to new cancer diagnoses, by age range, 2016-2021. Data have been averaged across the six reporting years.

These younger age groups consistently had a higher proportion of people with cancer recruited into a trial, compared to the older age groups, between 2016 -2021. However, there were also greater fluctuations in the proportion of people recruited over this time compared to the older age groups (Figure 19).

These younger age groups have fewer new cancer diagnoses; both children (aged 0-14) and adolescents (aged 15-17) were <1% of total new cancer incidence, on average.

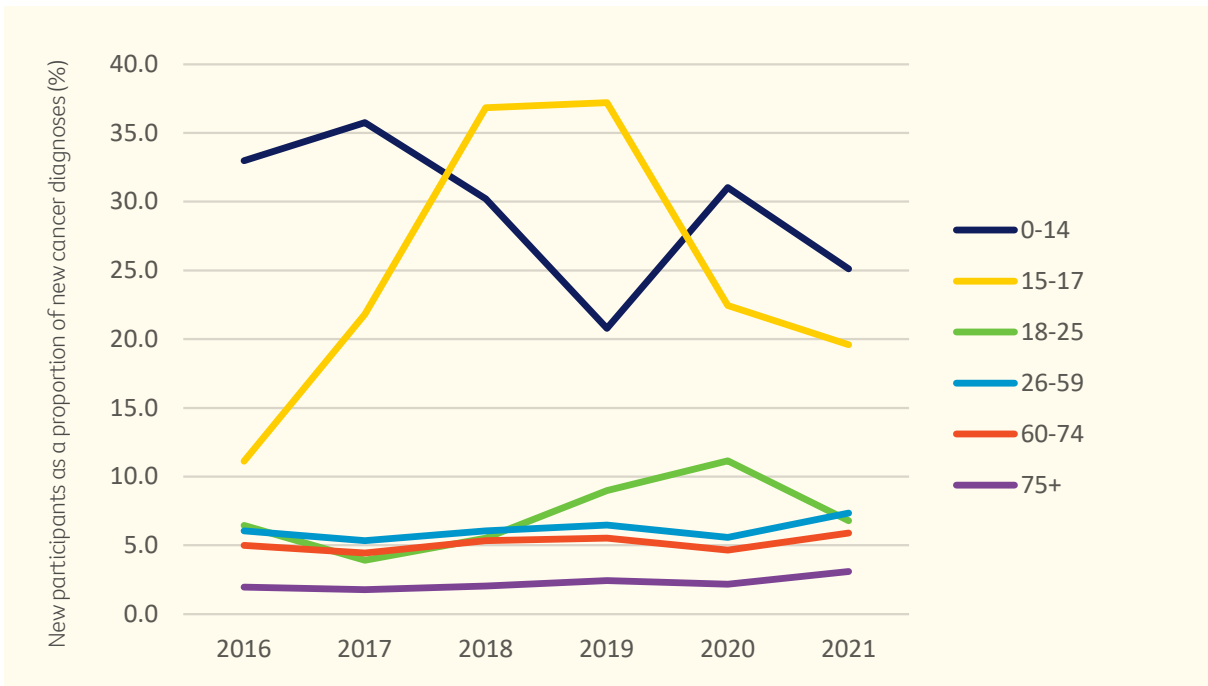


Figure 19. Proportion of people with cancer recruited into a clinical trial, relative to new cancer diagnoses, by age range, 2016-2021.

The majority of clinical trial participants, regardless of age, were recruited at metropolitan units (all >90%). In the two youngest age groups, no clinical trial participants were recruited at regional units (Figure 20).

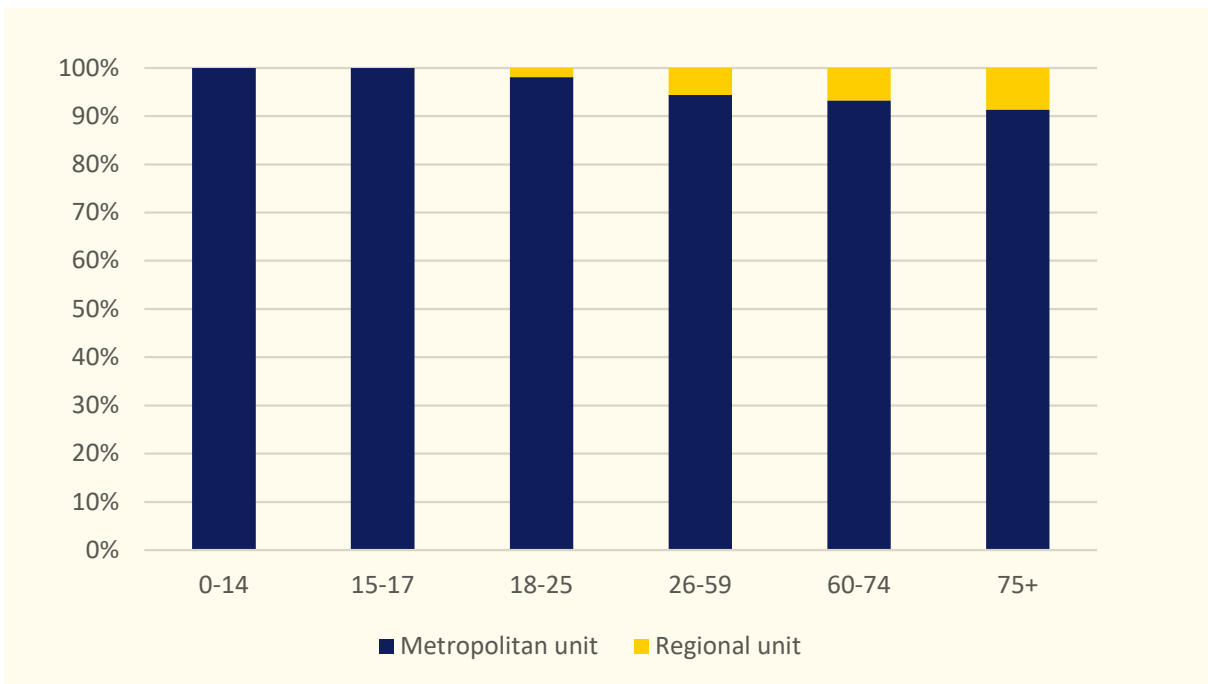


Figure 20. Proportion of new participants within an age range recruited to trials at metropolitan and regional units, 2016-2021.

By phase, sponsor and intervention

While there have been increases in the number of cancer treatment intervention trials across most trial phases between 2016 and 2021 (in line with the overall increase in unique clinical trials), this increase is most pronounced in early phase trials (Figure 21). Phase I trials have more than doubled from 47 trials in 2016 to 101 trials in 2021, and Phase I/II trials have almost tripled from 23 trials in 2016 to 64 trials in 2021.

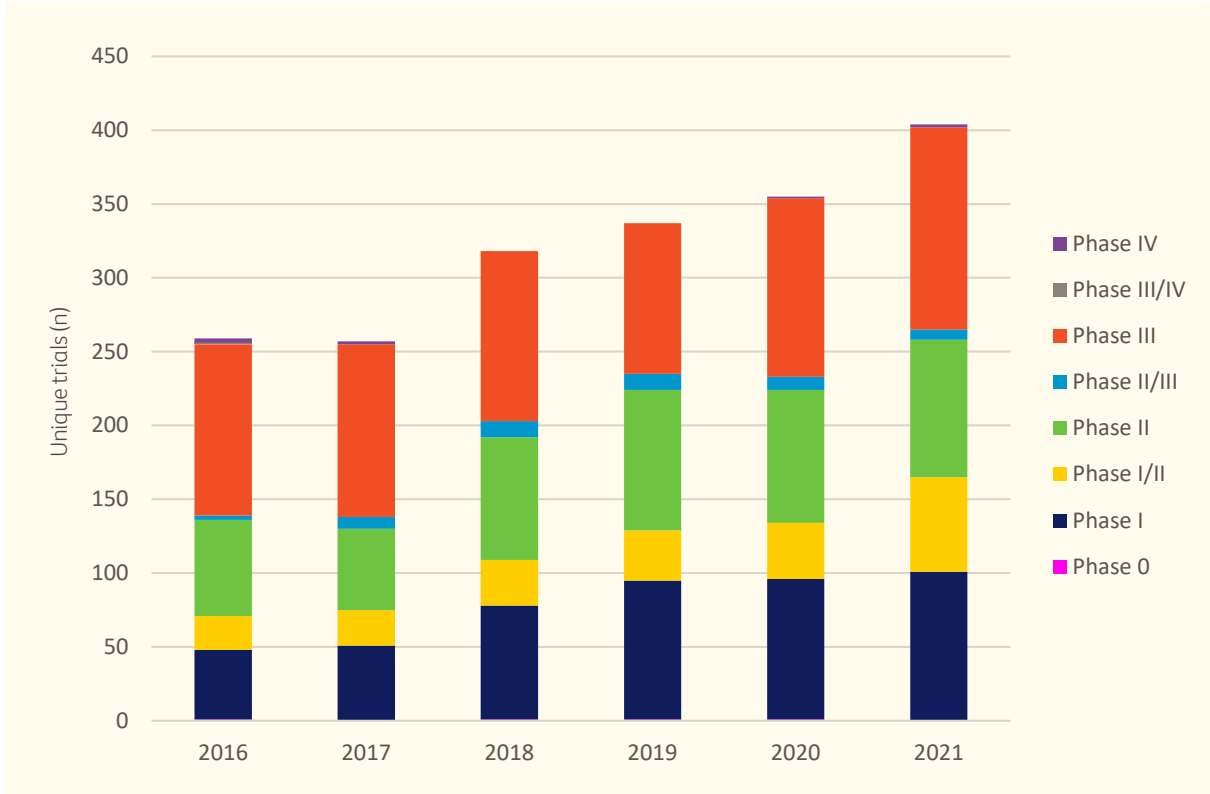


Figure 21. Number of unique trials by phase, 2016-2021. Data where the phase is unknown (n=10) or is not applicable (n=30) have been excluded.

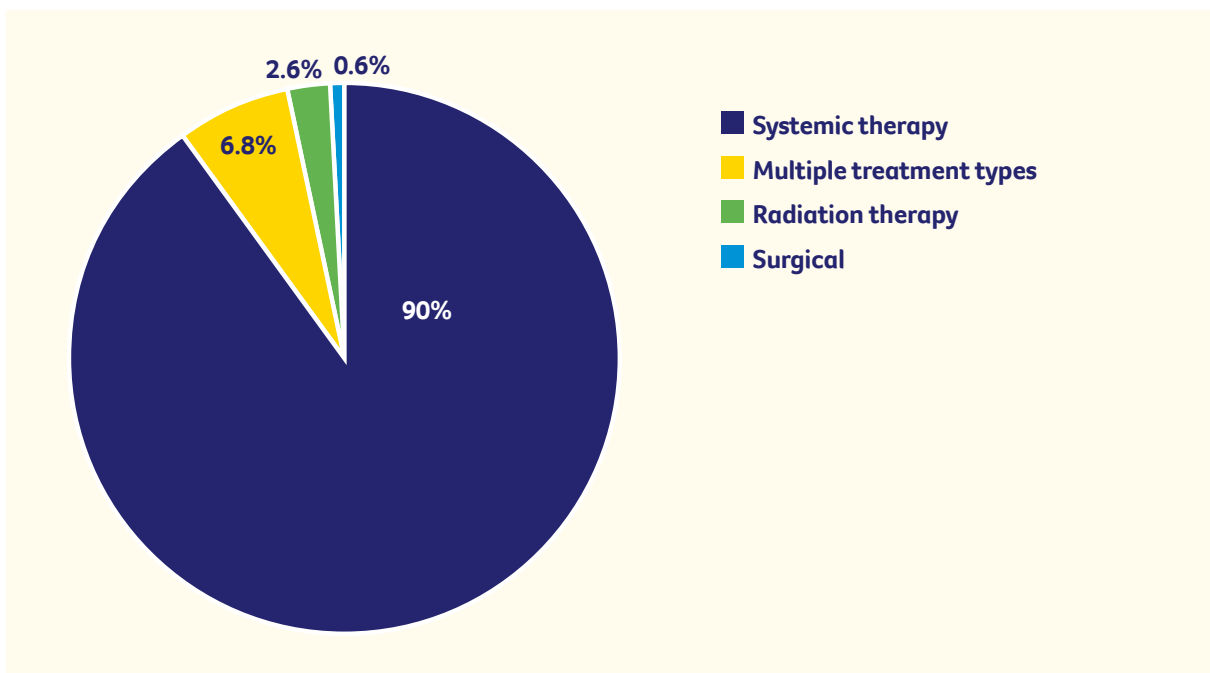


Figure 22. Proportion of unique clinical trials by treatment intervention, 2016-2021. Data have been averaged across the six reporting years and excludes trials where the treatment intervention was undefined (n=4).

Case study: Accessing cancer clinical trials for people of the West

Funded (2017) by Cancer Council Victoria and the Victorian Government acting through the Victorian Cancer Agency.

The project:

To improve patient access to high quality cancer clinical trials by building capacity of Western Health's cancer clinical trials unit, increasing opportunities for culturally and linguistically diverse (CALD) patients to participate and providing infrastructure to support increased recruitment to a wide variety of clinical trials. This includes trials focussed on early phase drug development, trials that are investigator initiated or cooperative group funded and trials that involve multiple disciplines (in addition to medical oncology).

The need:

Western Health comprises three hospitals based in the regions of western Melbourne where 38% of people speak a language other than English at home, covering more than 100 languages and dialects. Despite having a large and growing population in this catchment, Western Health only recruits 3.8% of eligible cancer patients to clinical trials.

Currently Western Health runs a higher percentage of non-sponsored trials (45%), when compared to larger centres like Peter Mac. This exemplified the importance of having an effective early phase trials unit, as it provides a platform for greater financial security (and sustainability) which offsets the costs of running lesser funded multidisciplinary/non-commercial clinical trials.

Western Health needed to build capacity of its cancer unit to deliver high quality, Phase I clinical trials to improve outcomes for cancer patients in the western region of Melbourne and improve opportunities to deliver non-commercially funded (i.e. investigator initiated or cooperative group funded) clinical trials and trials in multiple disciplines.

The impact:

- Western Health were able to put the people and infrastructure in place to run early phase clinical trials, before seeking sponsorship funding to attract and sustain this type of activity.
- A Phase I clinical lead role was established and funded to work on clinical trials.
- Research nurses were able to have dedicated time to work on trials and attend clinics to upskill in early phase trials.
- Leveraging a Victorian Comprehensive Cancer Centre (VCCC) project, Western Health recruited an early phase clinical trial coordinator to monitor and share clinical trial activity between three different health services (Austin, Peter Mac and Western).
- The growth of Western Health's non-pharmaceutical clinical trial portfolio was supported, enabling collaboration and increased activity across disciplines.
- Strategies to improve trial participation for CALD patients was evaluated.

“Thanks to the support we received, we have been able to enrol more patients, including CALD patients onto clinical trials. Cancer Council Victoria's support for our phase I program has given patients access to new drugs early in the development process.” – Dr Dishan Herath

On average, 90% of unique trials available between 2016 and 2021 were evaluating systemic therapy interventions (Figure 22). This does not include the portion of trials featuring multiple treatment types that may also include a systemic therapy intervention. The number of unique trials involving a systemic therapy intervention (only) increased from 236 in 2016 to 373 in 2021 (Figure 23).

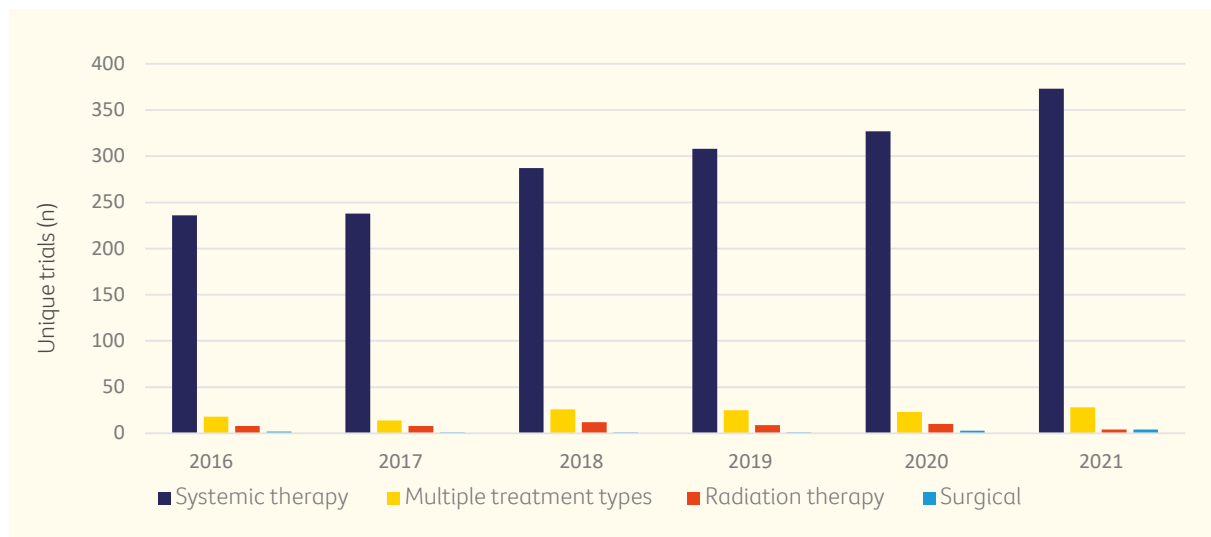


Figure 23. Number of unique clinical trials by treatment intervention type, 2016-2021. Trials where the treatment intervention was undefined have been excluded (n=4).

Most unique clinical trials were sponsored by commercial entities between 2016 and 2021: on average, 70% of trials were commercially sponsored.

The proportion of trials that are commercially sponsored remained relatively steady across the reporting period, however the proportion of trials that are non-commercially sponsored decreased slightly from 28% in 2016 to 22% in 2021. The proportion of trials that were jointly funded between commercial and non-commercial entities increased slightly from 1% in 2016 to 5% in 2021.

Systemic therapy interventions are the most common intervention tested amongst all sponsor types, but by far are the most favoured intervention of commercial sponsors; on average 96% of commercially sponsored trials were for systemic therapies (Figure 24).

Commercial sponsorship of systemic therapy trials increased by 61% between 2016 and 2021 (180 trials in 2016 vs. 290 trials in 2021), while their sponsorship of other treatment modalities remained relatively consistent.

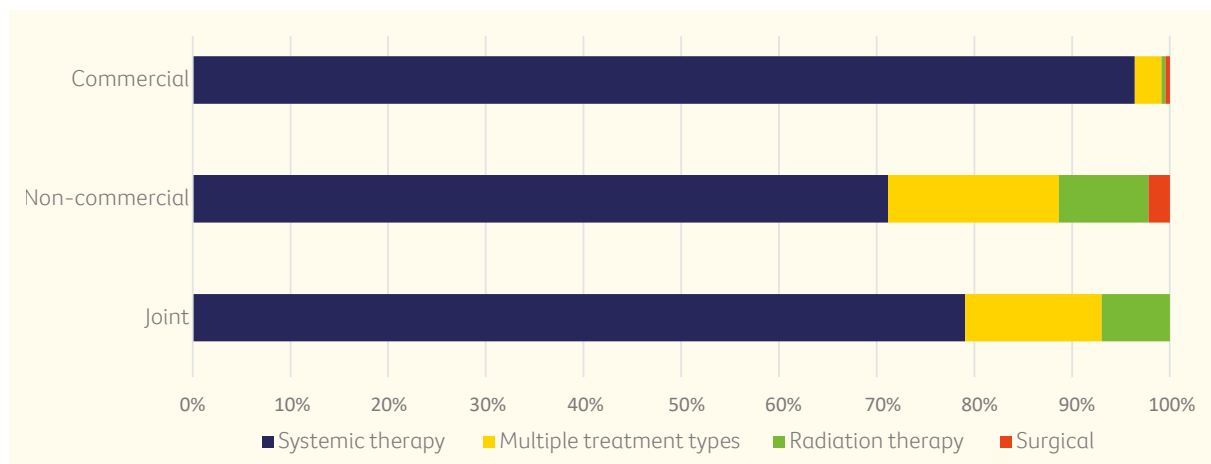


Figure 24. Proportion of unique clinical trials by treatment intervention for each sponsor type, 2016-2021. Data have been averaged across the six reporting years and excludes trials where the treatment intervention was undefined (n=4).

By trial unit location

Please note, in this section of the report the term ‘*recruiting trials*’ is introduced. Recruiting trials are clinical trials that have recruited at least one participant in a reporting year, including duplicate counts of trials being conducted across multiple sites in Victoria. This differs from a unique trial, used elsewhere in the report, as a unique trial does not include duplicate counts of trials being conducted across multiple units. Recruiting trials allow additional data points to be analysed at the unit level. Please do not compare unique trials with recruiting trials when reviewing this report.

State-wide data³

The number of recruiting clinical trials increased from 410 in 2016 to 612 in 2021 (49% increase). The number of recruiting trials at metropolitan units increased from 378 trials in 2016 to 560 trials in 2021 (48% increase); while the number of recruiting trials at regional units increased from 32 trials in 2016 to 52 trials in 2021 (63% increase) (Figure 25).

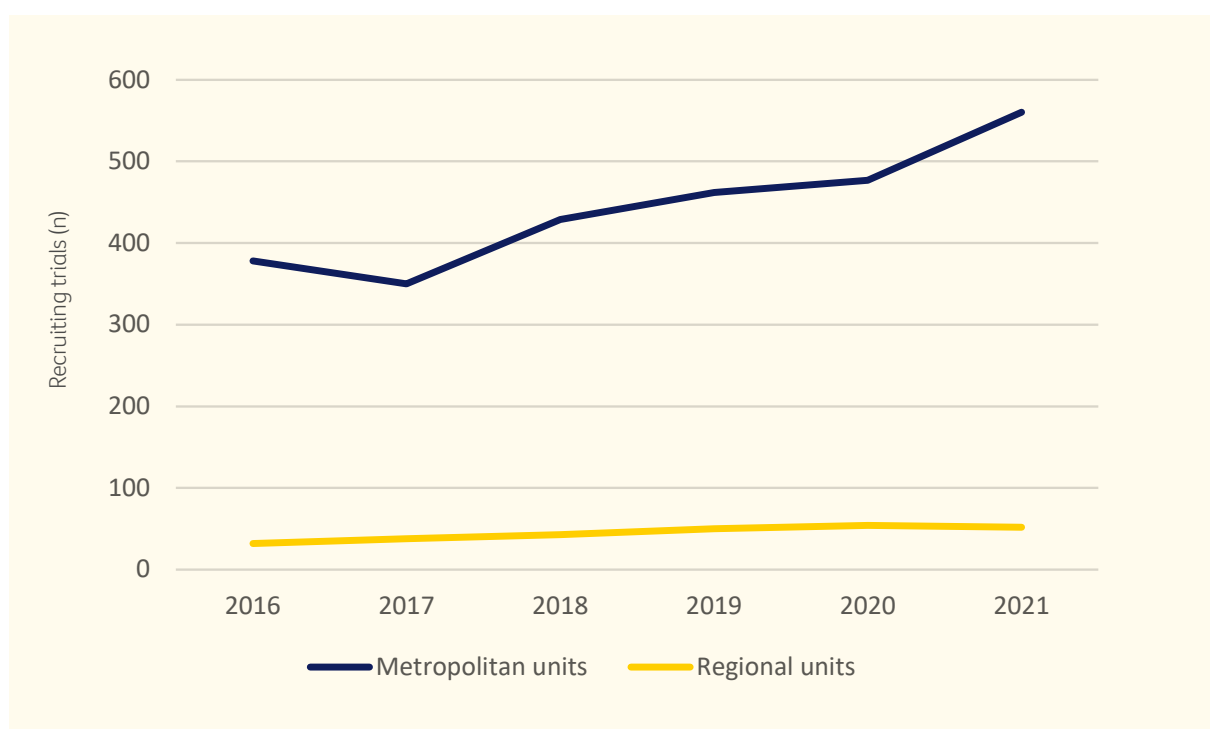


Figure 25. Number of recruiting clinical trials at metropolitan and regional trial units, 2016-2021.

Western & Central Melbourne ICS region consistently had the greatest number of recruiting trials during the reporting period (Figure 26). Southern Melbourne ICS region saw the greatest increase in recruiting trial activity, increasing from 106 trials in 2016 to 206 trials in 2021 (94% increase).

³ Please note, no data were reported from the Gippsland Regional ICS (GRICS) region through the Cancer Trials Management Scheme between 2016 and 2021.

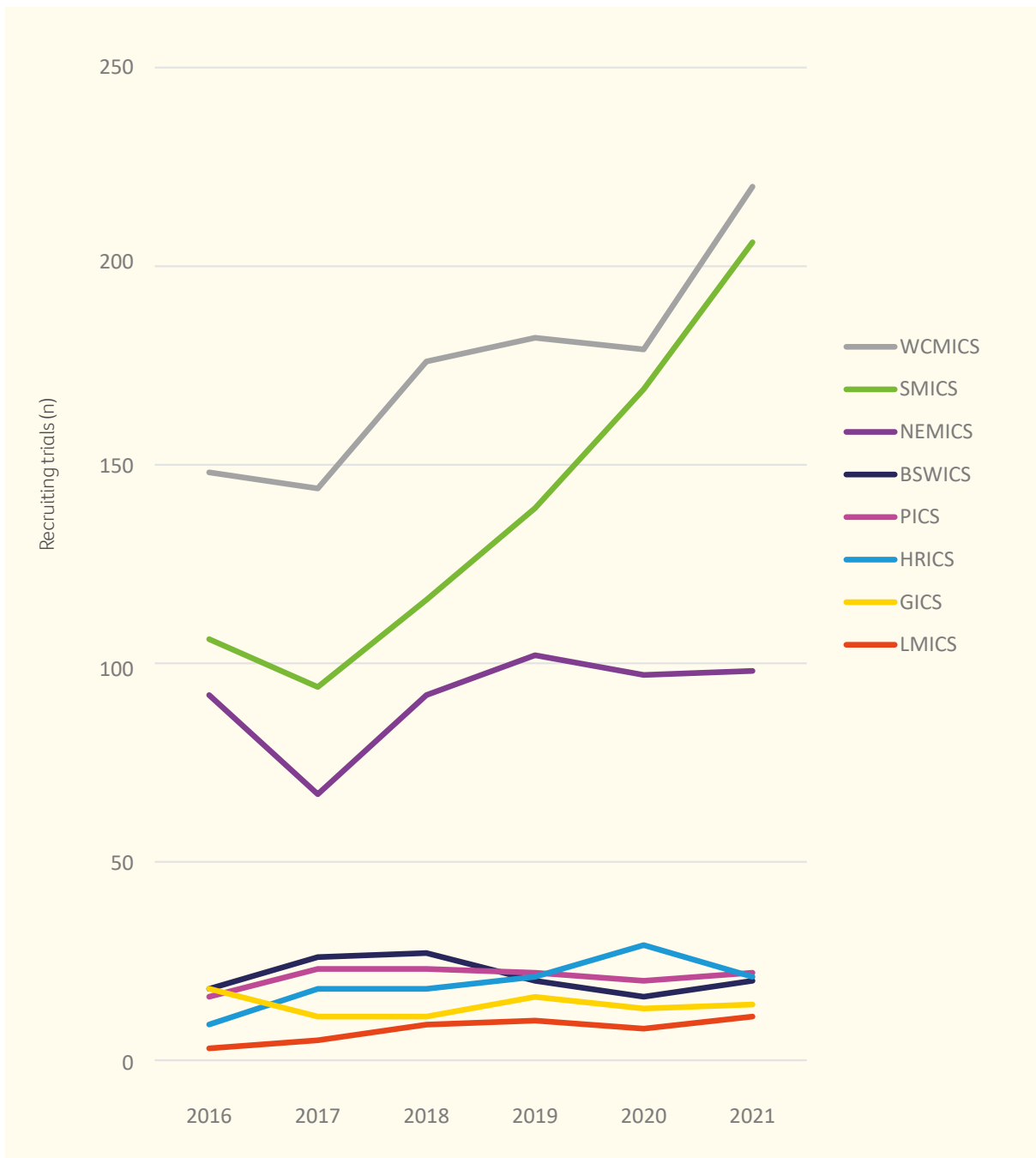


Figure 26. Number of recruiting clinical trials by trial unit Integrated Cancer Service region, 2016-2021.

Trends at regional units

The tumour streams with the greatest number of recruiting trials at regional units, on average, were bowel (colorectum) (n=9), cancers of the urinary system (n=7) and lung cancer (n=7). Bowel cancers saw the greatest increase in the number of recruiting trials at regional units, from 4 trials in 2016 to a peak of 14 trials in both 2019 and 2020, before decreasing to 10 trials in 2021.

The number of phase II recruiting trials increased from 3 trials in 2016 to 21 trials in 2021, becoming the phase with the greatest proportion of recruiting trials in 2021 (40%) (Figure 27). Phase III trials previously made up the greatest number of recruiting trials at regional units, but decreased from 24 trials in 2016 to 19 trials in 2021.

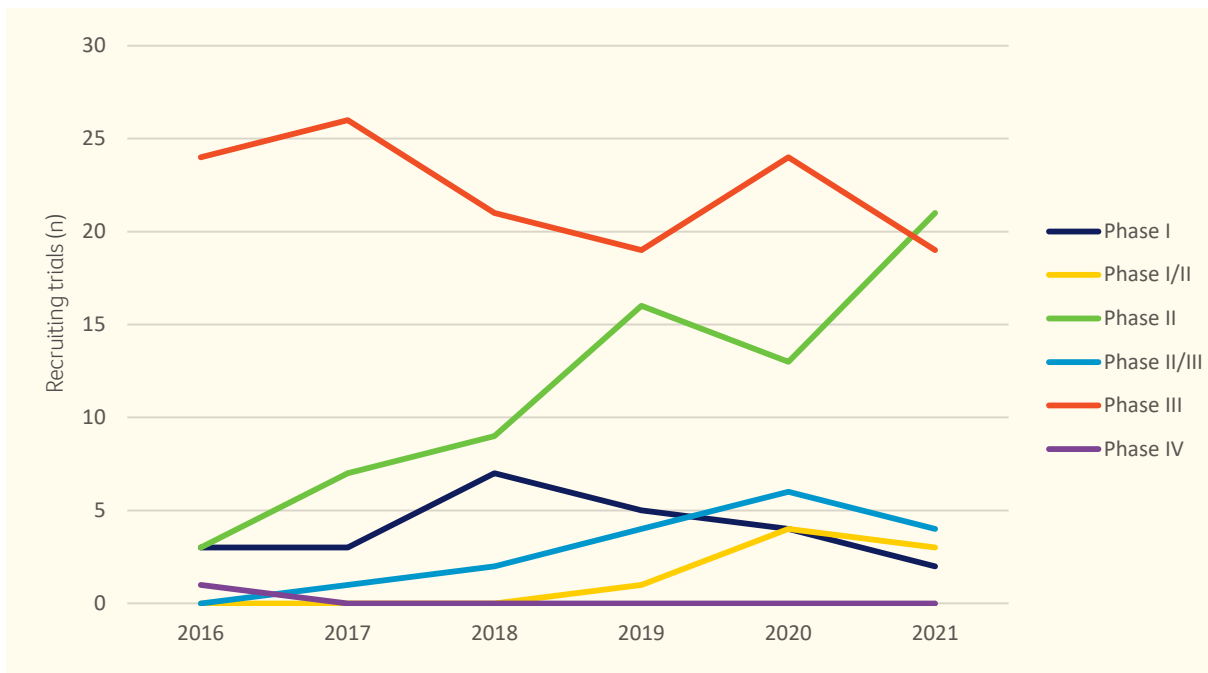


Figure 27. Number of recruiting clinical trials at regional units by phase, 2016-2021.

Commercial sponsors were consistently the greatest funder of trials at regional units (Figure 28). The number of recruiting trials at regional units sponsored by non-commercial entities increased by 140% between 2016 and 2021. In 2021, there were 25 commercially sponsored and 24 non-commercially sponsored recruiting trials at regional units.

Almost all recruiting trials at regional units between 2016 and 2021 were for systemic therapy interventions alone (96%). There were no trials testing only surgical interventions at regional units during the reporting period.

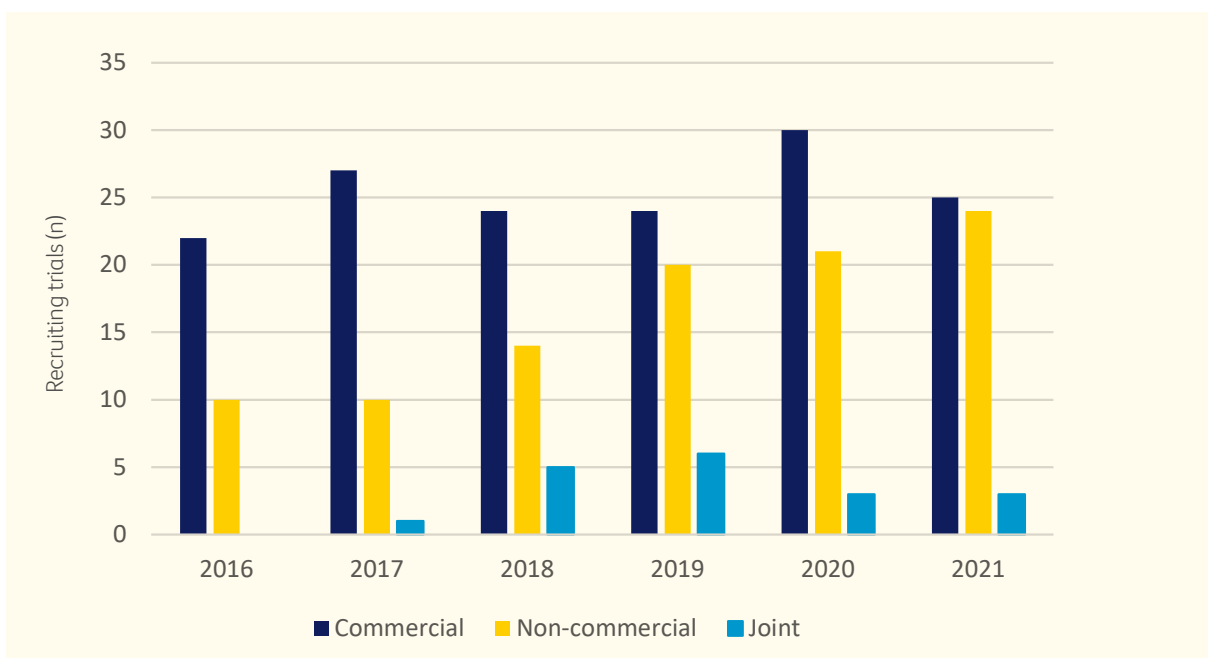


Figure 28. Number of recruiting clinical trials at regional units by sponsor type, 2016-2021.

Trends at metropolitan units

The tumour streams with the highest number of recruiting trials at metropolitan units were different to those at regional units. On average, haematological cancers (n=145), trials recruiting across multiple tumour streams (n=66) and breast cancers (n=46) had the greatest number of recruiting trials at metropolitan units.

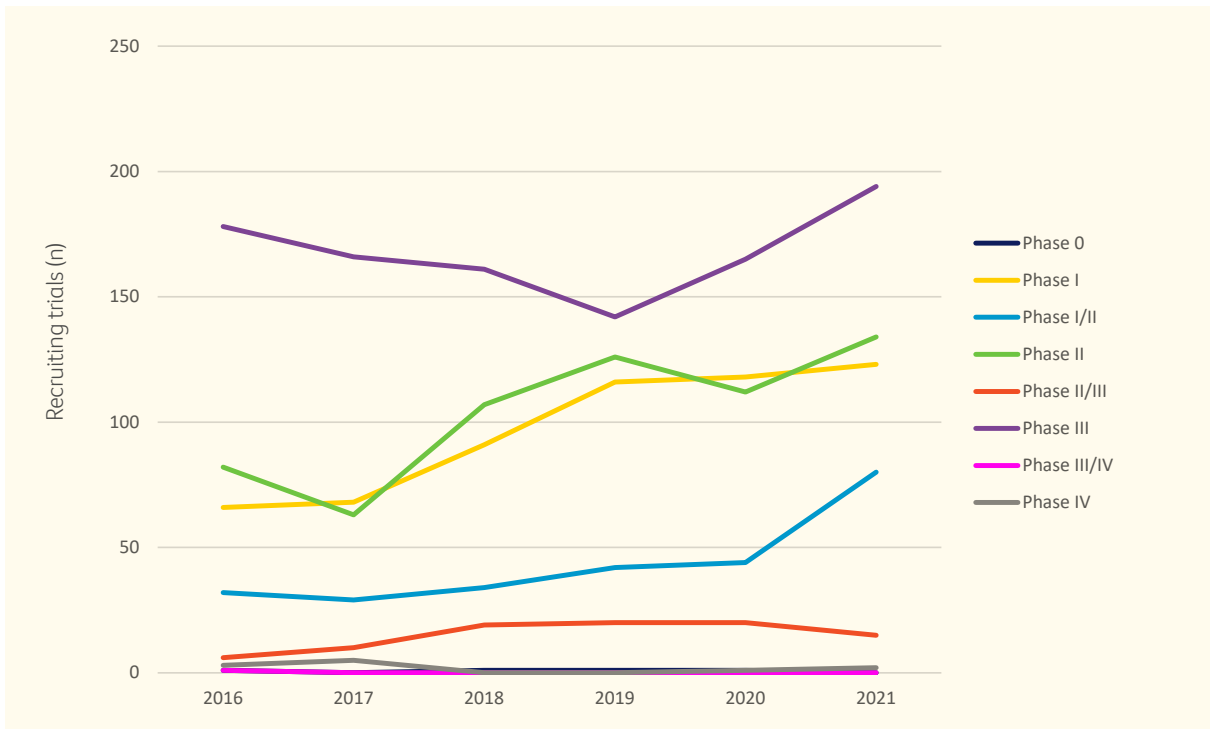


Figure 29. Number of recruiting clinical trials at metropolitan units by phase, 2016-2021.

Phase III trials were the most common type of recruiting trial at metropolitan units during the reporting period (Figure 29). Phase III trials made up 38% of the total number of recruiting trials at metropolitan units between 2016 and 2021. Early phase (Phase I, Phase I/II and Phase II) trials saw increases in the number of recruiting trials available at metropolitan units between 2016 and 2021.

While the number of recruiting trials that were non-commercially or jointly sponsored increased between 2016 and 2021, commercial sponsors remained the main sponsor of recruiting trials at metropolitan units (Figure 30).

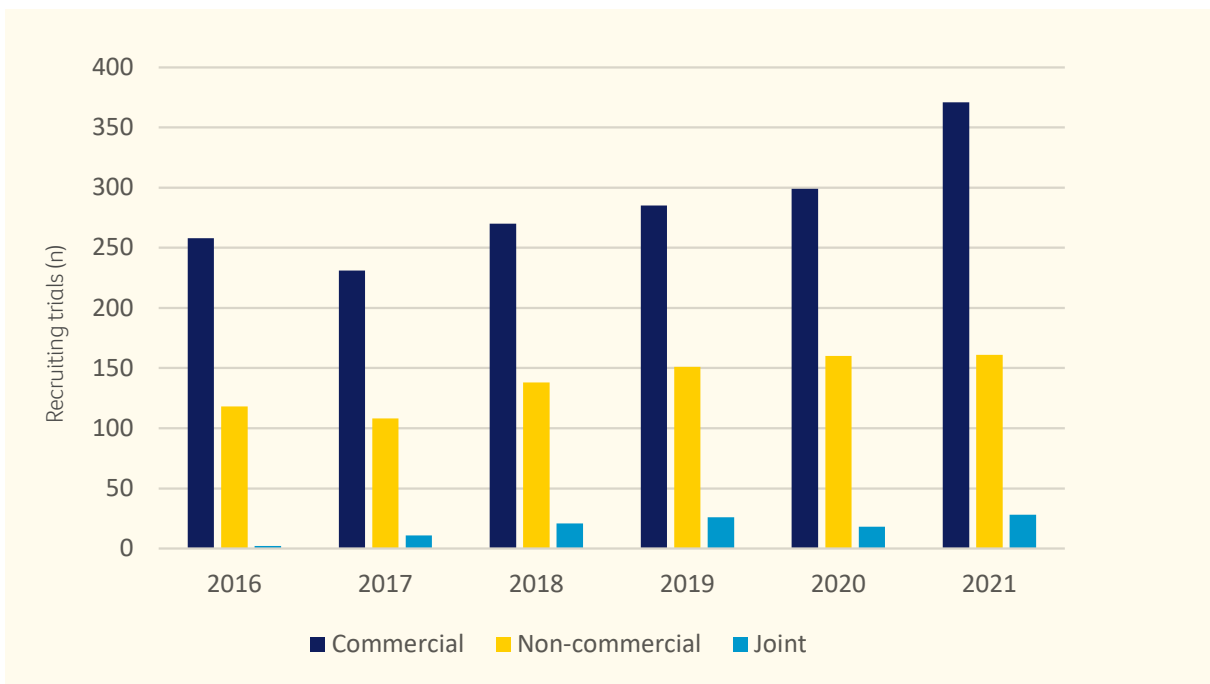


Figure 30. Number of recruiting clinical trials at metropolitan units by sponsor type, 2016-2021.

Discussion

Over the past six years, there has been significant activity and investment in the clinical trials sector in Victoria. As a result, we have seen a 32% increase in the number of people with cancer recruited into a cancer treatment clinical trial between 2016 and 2021. However, with less than 5% of Victorians diagnosed with cancer participating in cancer treatment clinical trials each year (on average), more work is needed to improve participation and reduce inequities in access to cancer clinical trials in Victoria.

Despite an overall increase in the number of people participating in clinical trials over the reporting period, decreases were observed in both 2017 and 2020. Whilst we are unable to directly correlate these decreases to external factors, it is probable that restrictions implemented in response to the COVID-19 pandemic contributed to the decrease observed in 2020. As mentioned earlier in the report, members of the Victorian clinical trials sector reported key challenges such as the suspension of clinical trial recruitment, changes to workforce and protocol compliance, and the impacts to annual budgets.

Recruitment decreased from 1,818 new participants in 2019 to 1,539 participants in 2020 (15% decrease). This decrease occurred across geographic demographics, with metropolitan, regional and interstate participation all decreasing in 2020. However, whilst recruitment of people living in both metropolitan and regional areas of Victoria increased in 2021, the number of interstate participants continued to decrease that year. This is likely to be influenced by the restrictions to interstate travel during this time, and the lockdowns within Victoria in response to COVID-19 outbreaks.

While the number of unique clinical trials available in Victoria decreased slightly in 2017, there was a steady increase in the number available from then on. Haematological cancers consistently had the greatest proportion of unique trials available during the reporting period and, on average, accounted for 31% of all unique trials available.

On average, the majority of clinical trial participants were from metropolitan areas (71%), and almost all new participants were recruited at metropolitan units regardless of where they lived (94%). There were some differences in the types of recruiting trials most commonly available at metropolitan and regional units. On average, regional units had the highest number of recruiting trials for cancers of the bowel, urinary system and lung; while metropolitan

units more commonly had trials for haematological cancers, trials recruiting across multiple tumour streams, and breast cancers.

Recruiting trials at both metropolitan and regional units were mainly sponsored by commercial entities, however by 2021 there was almost an equal number of non-commercially sponsored trials at regional units. For most of the reporting period Phase III trials were the most common type of recruiting trial at both metropolitan and regional units, however in 2021 Phase II trials became the most commonly available trial at regional units.

Early phase unique trials saw the greatest increase in number over the reporting period, with Phase I trials more than doubling and Phase I/II trials almost tripling from 2016 to 2021. The majority of cancer treatment clinical trials were for systemic therapy modalities (90%) and were commercially sponsored (70%), on average.

In this report we comment on the differences in clinical trial recruitment by geography and age. However, it is important to recognise that these are not the only factors that determine access to clinical trials, with Aboriginal and Torres Strait Islander people,^{iv} people from culturally and linguistically diverse communities^v and people living with a disability^{vi} amongst those who face greater barriers to participation. Unfortunately, data collected in the Cancer Trials Management Scheme between 2016 and 2021 does not capture the demographic detail required to comment on the recruitment of these participants.

In line with the Victorian cancer plan 2020-2024, we recognise that to inform future research priorities and access we need to improve not only the data we collect, but the systems we use to collect it. We look forward to supporting these necessary improvements, by working closely with the Victorian Government acting through the Victorian Cancer Agency to transition the collection of clinical trial activity and recruitment data to Cancer Trials Australia.

Continued collaboration across the sector is needed to further build the profile of Victoria's important clinical trial activity, improve equity of access to trials, enhance our workforce, and ultimately improve the outcomes for people affected by cancer. Cancer Council Victoria will continue support people affected by cancer to access clinical trials by providing trusted information and support, including on the Victorian Cancer Trials Link website.

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, support, cancer prevention and advocacy. Cancer Council Victoria's mission is to prevent cancer, empower patients and save lives.

Cancer Trials Management Scheme

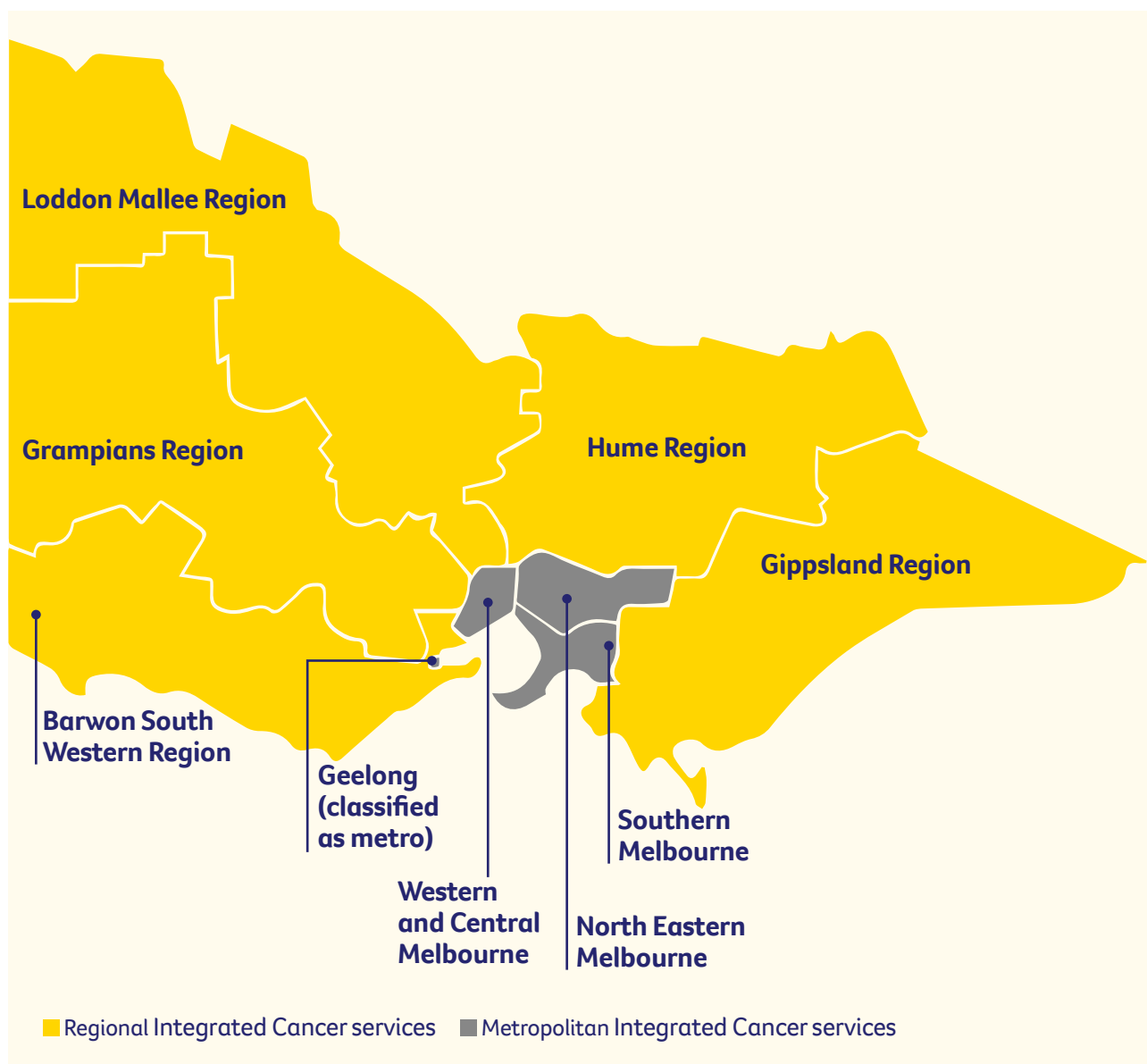
Used to describe the process of reporting clinical trial activity and recruitment data to Cancer Council Victoria. Established in 1988 with the aim of increasing participation in clinical trials, monitored through the collection of site-specific data. Currently, 37 clinical trials units report data to Cancer Council Victoria through the Cancer Trials Management Scheme (CTMS).

Intervention

A process or action that is the focus of a clinical study.

Integrated Cancer Service

The Victorian Government established the Integrated Cancer Services (ICS) in 2005 to facilitate the provision of cancer care in eight geographic regions in Victoria, depicted below. For the purposes of this report, Geelong, which is part of Barwon South Western Region, has been classified as metro.



Metropolitan area

People are classified as residing in a metropolitan area if their residential postcode falls within a metropolitan ICS region or Geelong LGA.

New participants

The number of patients that have consented to trial participation between the 1st of January and 31st of December in the relevant reporting year.

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 participants 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 participants. **Phase III trials** compare new treatments with best standard treatments; these trials aim to recruit a much higher number of participants 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.

Radiation therapy

Treatment using a controlled dose of radiation to kill cancer cells or damage them so they cannot grow, multiple or spread. Most forms of radiation therapy use focused, high-energy x-ray beams. Radiation therapy is a localised treatment, which means it generally affects only the area being treated.

Recruiting trials

Clinical trials that have recruited at least one participant in a reporting year, including duplicate counts of trials being conducted across multiple sites in Victoria.

Recruitment

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

Recruitment rate

Number of new clinical trial participants per tumour stream divided by the number of unique trials available for that tumour stream.

Regional area

In this report, people are classified as residing in a regional area if their residential postcode falls within a regional ICS region, with the exception of Geelong LGA which has been classified as metropolitan.

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).

Surgery

Treatment involving a surgeon or surgical oncologist removing cancer from the body or repairing a part of the body affected by cancer.

Systemic therapy

Treatment using substances that travel through the bloodstream, reaching and affecting cells all over the body.

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’.

Tumour stream	Explanation
Haematological	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.
Cancer of Unknown Primary	Clinical trials including people with cancers of unknown primary location.
Female reproductive organs	Clinical trials including people with cancers of the cervix, fallopian tube, ovary, uterus (including sarcoma of the uterus), endometrium or other (such as 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 (such as Kaposi sarcoma).
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 gastrointestinal 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 website of cancer clinical trials available across Victoria, as well as clinical trials information and support resources.

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 people with cancer.

Victorian Cancer Registry

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

Appendix B: Data tables

Where relevant, we have reported '<5' for data elements that contain less than 5 people.

Table 2. Number of new participants and newly diagnosed tumours, 2016–2021.

Newly diagnosed tumours data sourced from Victorian Cancer Registry, January 2023.

	2016	2017	2018	2019	2020	2021	Total
New participants	1,552	1,431	1,721	1,818	1,539	2,044	10,105
Newly diagnosed tumours	33,624	35,064	35,896	36,612	35,236	36,974	213,406

Table 3. Number of unique clinical trials, 2016–2021.

	2016	2017	2018	2019	2020	2021
Unique clinical trials	265	262	327	344	363	409

Table 4. Number of new participants by patient residential region, 2016–2021.

	2016	2017	2018	2019	2020	2021	Total
Metropolitan	1,102	1,004	1,206	1,267	1,126	1,512	7,217
Regional	356	330	413	410	324	432	2,265
Interstate	66	61	99	113	69	63	471
Missing data	28	36	<5	28	20	37	152
Total	1,552	1,431	1,721	1,818	1,539	2,044	10,105

Table 5. Number of new interstate participants by patient residential state, 2016–2021.

	2016	2017	2018	2019	2020	2021	Total
ACT	<5	<5	0	7	<5	0	11
NSW	23	26	63	48	46	34	240
QLD	<5	11	10	9	<5	7	43
SA	<5	12	<5	6	6	<5	34
TAS	8	9	20	36	12	18	103
WA	<5	0	<5	0	<5	0	5
Interstate (unspecified)	24	<5	0	7	<5	<5	35
Total	66	61	99	113	69	63	471

Table 6. Number of new participants by patient residential region and trial unit location, 2016–2021.

	2016		2017		2018		2019		2020		2021		Total
	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	
Metropolitan	1,100	<5	1,001	<5	1,203	<5	1,266	<5	1,124	<5	1,511	<5	7,217
Regional	305	51	252	78	310	103	289	121	229	95	338	94	2,265
Interstate	64	<5	56	5	77	22	93	20	43	26	53	10	471
Missing data	18	10	33	<5	<5	<5	28	0	20	0	37	0	152
Total	1,487	65	1,342	89	1,592	129	1,676	142	1,416	123	1,939	105	10,105

Table 7. Number of new participants by patient residential region, 2016–2021.

	2016	2017	2018	2019	2020	2021	Total
Barwon South Western region (excl. Geelong region)	76	89	102	78	50	70	465
Geelong region	16	21	12	15	19	25	108
Gippsland region	43	56	52	63	73	98	385
Grampians region	43	46	67	61	39	73	329
Hume region	63	64	86	98	74	72	457
Loddon Mallee region	38	75	106	110	88	119	536
North Eastern Melbourne region	303	319	374	409	319	469	2,193
Southern Melbourne region	350	374	407	467	502	576	2,676
West & Central Melbourne region	269	290	413	376	286	442	2,076
Interstate	66	61	99	113	69	63	471
Missing data	285	36	<5	28	20	37	409
Total	1,552	1,431	1,721	1,818	1,539	2,044	10,105

Table 8. Number of newly diagnosed tumours in Victorian patients, 2016–2021, by Integrated Cancer Service and year.

Source: Victorian Cancer Registry, January 2023

	2016	2017	2018	2019	2020	2021	Total
Barwon–South West RICS (excl. Geelong)	1,033	1,184	1,194	1,228	1,217	1,266	7,122
Geelong	1,512	1,637	1,626	1,672	1,676	1,797	9,920
Gippsland RICS	2,070	2,211	2,230	2,283	2,204	2,445	13,443
Grampians RICS	1,607	1,633	1,724	1,767	1,746	1,822	10,299
Hume RICS	1,922	2,108	2,289	2,204	2,104	2,319	12,946
Loddon–Mallee RICS	2,325	2,461	2,457	2,472	2,376	2,505	14,596
North Eastern MICS	7,817	7,987	8,086	8,334	7,883	8,076	48,183
Southern MICS	9,091	9,428	9,792	9,878	9,496	9,985	57,670
Unknown ICS	<5	<5	<5	70	40	66	185
West & Central MICS	6,246	6,411	6,494	6,704	6,494	6,693	39,042
Total	33,624	35,064	35,896	36,612	35,236	36,974	213,406

Table 9. Number of unique clinical trials by tumour stream, 2016–2021.

	2016	2017	2018	2019	2020	2021
Haematological	79	84	108	113	110	126
Bowel (colorectum)	9	11	11	13	14	17
Brain and spinal cord	15	9	12	13	12	11
Breast	31	23	29	30	28	34
Cancer of unknown primary location	0	0	0	1	1	1
Female reproductive organs	7	7	6	10	16	13
Head and neck	6	5	7	4	8	8
Lung	31	22	28	30	25	27
Multiple	35	33	52	58	73	82
Sarcoma	3	3	2	1	0	2
Skin	14	9	12	11	18	21
Stomach and upper gastrointestinal tract	16	24	25	19	22	22
Urinary system	19	32	35	41	36	45
Total	265	262	327	344	363	409

Table 10. Number of new participants by tumour stream, 2016–2021.

	2016	2017	2018	2019	2020	2021	Total
Haematological	421	437	518	571	478	563	2,988
Bowel (colorectum)	67	84	192	218	146	182	889
Brain and spinal cord	60	30	34	46	42	49	261
Breast	235	259	240	220	158	185	1,297
Cancer of unknown primary location	0	0	0	5	5	<5	13
Female reproductive organs	23	23	17	38	80	76	257
Head and neck	41	17	23	13	19	16	129
Lung	141	74	131	103	60	125	634
Multiple	205	194	233	300	243	432	1,607
Sarcoma	14	17	6	<5	0	6	46
Skin	95	74	88	57	106	111	531
Stomach and upper gastrointestinal tract	85	73	92	88	60	100	498
Urinary system	165	149	147	156	142	196	955
Total	1,552	1,431	1,721	1,818	1,539	2,044	10,105

Table 11. Number of new participants by age range, 2016–2021.

	2016	2017	2018	2019	2020	2021	Total
0-14	63	64	58	37	58	53	333
15-17	7	12	14	16	11	10	70
18-25	17	10	14	21	29	15	106
26-59	552	496	571	606	510	696	3,431
60-74	665	627	772	839	663	882	4,448
75+	208	198	234	282	245	371	1,538
Missing data	40	24	58	17	23	17	179
Total	1,552	1,431	1,721	1,818	1,539	2,044	10,105

Table 12. Number of newly diagnosed tumours, by age range, 2016–2021.

Source: Victorian Cancer Registry, January 2023

	2016	2017	2018	2019	2020	2021	Total
0-14	191	179	192	178	187	211	1,138
15-17	63	55	38	43	49	51	299
18-25	264	255	254	234	260	221	1,488
26-59	9,129	9,284	9,445	9,358	9,134	9,475	55,825
60-74	13,311	14,135	14,486	15,203	14,258	14,990	86,383
75+	10,666	11,156	11,481	11,596	11,348	12,026	68,273
Total	33,624	35,064	35,896	36,612	35,236	36,974	213,406

Table 13. Number of new participants by trial unit location and age range, 2016–2021.

	2016		2017		2018		2019		2020		2021		Grand Total
	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	Metro unit	Regional unit	
0-14	63	0	64	0	58	0	37	0	58	0	53	0	333
15-17	7	0	12	0	14	0	16	0	11	0	10	0	70
18-25	17	0	9	<5	14	0	21	0	28	<5	15	0	106
26-59	533	19	471	25	532	39	559	47	480	30	664	32	3,431
60-74	638	27	582	45	708	64	772	67	614	49	835	47	4,448
75+	199	9	185	13	208	26	254	28	214	31	345	26	1,538
Missing data	30	10	19	5	58	0	17	0	11	12	17	0	179
Grand Total	1,487	65	1,342	89	1,592	129	1,676	142	1,416	123	1,939	105	10,105

Table 14. Number of unique trials by phase, 2016–2021.

	2016	2017	2018	2019	2020	2021
Phase 0	1	0	1	1	1	0
Phase I	47	51	77	94	95	101
Phase I/II	23	24	31	34	38	64
Phase II	65	55	83	95	90	93
Phase II/III	3	8	11	11	9	7
Phase III	116	117	115	102	121	137
Phase III/IV	1	0	0	0	0	0
Phase IV	3	2	0	0	1	2
Not applicable	5	3	6	6	6	4
Unknown	1	2	3	1	2	1
Total	265	262	327	344	363	409

Table 15. Number of unique trials by treatment intervention, 2016–2021.

	2016	2017	2018	2019	2020	2021
Systemic therapy	236	238	287	308	327	373
Multiple treatment types	18	14	26	25	23	28
Radiation therapy	8	8	12	9	10	4
Surgical	2	1	1	1	3	4
Treatment (undefined)	1	1	1	1	0	0
Total	265	262	327	344	363	409

Table 16. Number of unique trials by sponsor type, 2016–2021.

	2016	2017	2018	2019	2020	2021
Commercial	188	188	227	233	250	299
Non-commercial	75	66	86	92	98	90
Joint	2	8	14	19	15	20
Total	265	262	327	344	363	409

Table 17. Number of recruiting trials by trial unit location, 2016–2021.

	2016	2017	2018	2019	2020	2021
Metropolitan unit	378	350	429	462	477	560
Regional unit	32	38	43	50	54	52
Total	410	388	472	512	531	612

Table 18. Number of recruiting trials by trial unit Integrated Cancer Service Region, 2016–2021.

Please note, no data were reported from the Gippsland Regional ICS (GRICS) region through the Cancer Trials Management Scheme between 2016 and 2021.

	2016	2017	2018	2019	2020	2021
Barwon South Western Regional ICS (BSWICS)	18	26	27	20	16	20
Grampians ICS (GICS)	18	11	11	16	13	14
Hume Regional ICS (HRICS)	9	18	18	21	29	21
Loddon Mallee ICS (LMICS)	3	5	9	10	8	11
North Eastern Melbourne ICS (NEMICS)	92	67	92	102	97	98
South Melbourne ICS (SMICS)	106	94	116	139	169	206
Western & Central Melbourne ICS (WCMICS)	148	144	176	182	179	220
Paediatrics ICS (PICS)	16	23	23	22	20	22
Total	410	388	472	512	531	612

Table 19. Number of recruiting trials at regional trial units by tumour stream, 2016–2021.

	2016	2017	2018	2019	2020	2021
Haematological	5	6	5	4	5	8
Bowel (colorectum)	4	4	10	14	14	10
Brain and spinal cord	0	0	0	1	0	1
Breast	2	4	4	5	7	7
Female reproductive organs	0	1	1	1	2	3
Lung	10	7	7	7	4	8
Multiple	2	2	3	4	8	6
Skin	0	0	1	1	5	2
Stomach and upper gastrointestinal tract	3	7	6	2	3	2
Urinary system	6	7	6	11	6	5
Total	32	38	43	50	54	52

Table 20. Number of recruiting trials at regional trial units by phase, 2016–2021.

	2016	2017	2018	2019	2020	2021
Phase I	3	3	7	5	4	2
Phase I/II	0	0	0	1	4	3
Phase II	3	7	9	16	13	21
Phase II/III	0	1	2	4	6	4
Phase III	24	26	21	19	24	19
Phase IV	1	0	0	0	0	0
Not applicable	1	1	4	5	3	3
Total	32	38	43	50	54	52

Table 21. Number of recruiting trials at regional trial units by sponsor type, 2016–2021.

	2016	2017	2018	2019	2020	2021
Commercial	22	27	24	24	30	25
Non-commercial	10	10	14	20	21	24
Joint	0	1	5	6	3	3
Total	32	38	43	50	54	52

Table 22. Number of recruiting trials at regional trial units by treatment intervention, 2016–2021.

	2016	2017	2018	2019	2020	2021
Systemic therapy	31	37	41	47	53	49
Multiple treatment types	1	0	1	2	0	2
Radiation therapy	0	1	1	1	1	1
Total	32	38	43	50	54	52

Table 23. Number of recruiting trials at metropolitan units by tumour stream, 2016–2021.

	2016	2017	2018	2019	2020	2021
Haematological	112	117	147	166	150	179
Bowel (colorectum)	13	17	28	29	33	33
Brain and spinal cord	18	11	14	16	15	16
Breast	39	43	42	46	49	55
Cancer of unknown primary location	0	0	0	1	1	1
Female reproductive organs	11	8	6	12	19	18
Head and neck	8	7	10	4	10	9
Lung	36	24	35	31	26	34
Multiple	48	43	55	70	80	98
Sarcoma	5	5	2	2	0	3
Skin	19	12	15	13	27	31
Stomach and upper gastrointestinal tract	28	25	29	25	27	27
Urinary system	41	38	46	47	40	56
Total	378	350	429	462	477	560

Table 24. Number of recruiting trials at metropolitan units by phase, 2016–2021.

	2016	2017	2018	2019	2020	2021
Phase 0	1	0	1	1	1	0
Phase I	66	68	91	116	118	123
Phase I/II	32	29	34	42	44	80
Phase II	82	63	107	126	112	134
Phase II/III	6	10	19	20	20	15
Phase III	178	166	161	142	165	194
Phase III/IV	1	0	0	0	0	0
Phase IV	3	5	0	0	1	2
Not applicable	7	5	12	13	14	8
Unknown	2	4	4	2	2	4
Total	378	350	429	462	477	560

Table 25. Number of recruiting trials at metropolitan units by sponsor type, 2016-2021.

	2016	2017	2018	2019	2020	2021
Commercial	258	231	270	285	299	371
Non-commercial	118	108	138	151	160	161
Joint	2	11	21	26	18	28
Total	378	350	429	462	477	560

Table 26. Number of recruiting trials at metropolitan units by treatment intervention, 2016-2021.

	2016	2017	2018	2019	2020	2021
Systemic therapy	336	319	369	411	427	504
Multiple treatment types	29	19	42	35	32	41
Radiation therapy	9	10	16	14	15	10
Surgical	2	1	1	1	3	5
Treatment (undefined)	2	1	1	1	0	0
Total	378	350	429	462	477	560

References

- ⁱ Victorian Cancer Registry. (2022). *Cancer In Victoria, 2021*. Cancer Council Victoria. <https://www.cancervic.org.au/downloads/cec/cancer-in-vic/Cancer-in-Victoria-statistics-and-trends-2021.pdf>
- ⁱⁱ Cancer Council Victoria. (2022). *Cancer, COVID-19 and You – 2022 Report*. Cancer Council Victoria. <https://www.cancervic.org.au/downloads/get-support/covid-19/Cancer-COVID-You-Report.pdf>
- ⁱⁱⁱ Cancer Council Victoria. (2020). *Impact of COVID-19 on cancer clinical trials in Victoria*. Cancer Council Victoria. <https://www.cancervic.org.au/downloads/vctl/covid-and-clinical-trials.pdf>
- ^{vi} Green, M. & Cunningham, J. (2022). *Consultancy Report to inform the Steering Committee of the ReViTALISE Project: Aboriginal and Torres Strait Islander People with Cancer – Clinical Trial Access Initiative*. Report prepared for Border Medical Oncology Research Unit by the Menzies School of Health Research, March 2022. Border Medical Oncology Research Unit, Albury Wodonga, and Menzies School of Health Research, Melbourne. https://www.menzies.edu.au/icms_docs/332413_Aboriginal_and_Torres_Strait_Islander_People_with_Cancer_Clinical_Trial_Access_Initiative_Consultancy_Report_for_ReViTALISE_Project_July2022.pdf
- ^v Hughson, J., Woodward-Kron, R., Parker, A., Hajek, J., Bresin, A., Knoch, U., Phan, T. & Story, D. (2016). A review of approaches to improve participation of culturally and linguistically diverse populations in clinical trials. *Trials*, 17(263). Doi: 10.1186/s13063-016-1384-3
- ^{vi} Shariq, S., Pinto, A. M. C., Budhathoki, S. S., Miller, M. & Cro, S. (2023). Barriers and facilitators to the recruitment of disabled people to clinical trials: a scoping review. *Trials*, 24(171). <https://doi.org/10.1186/s13063-023-07142-1>