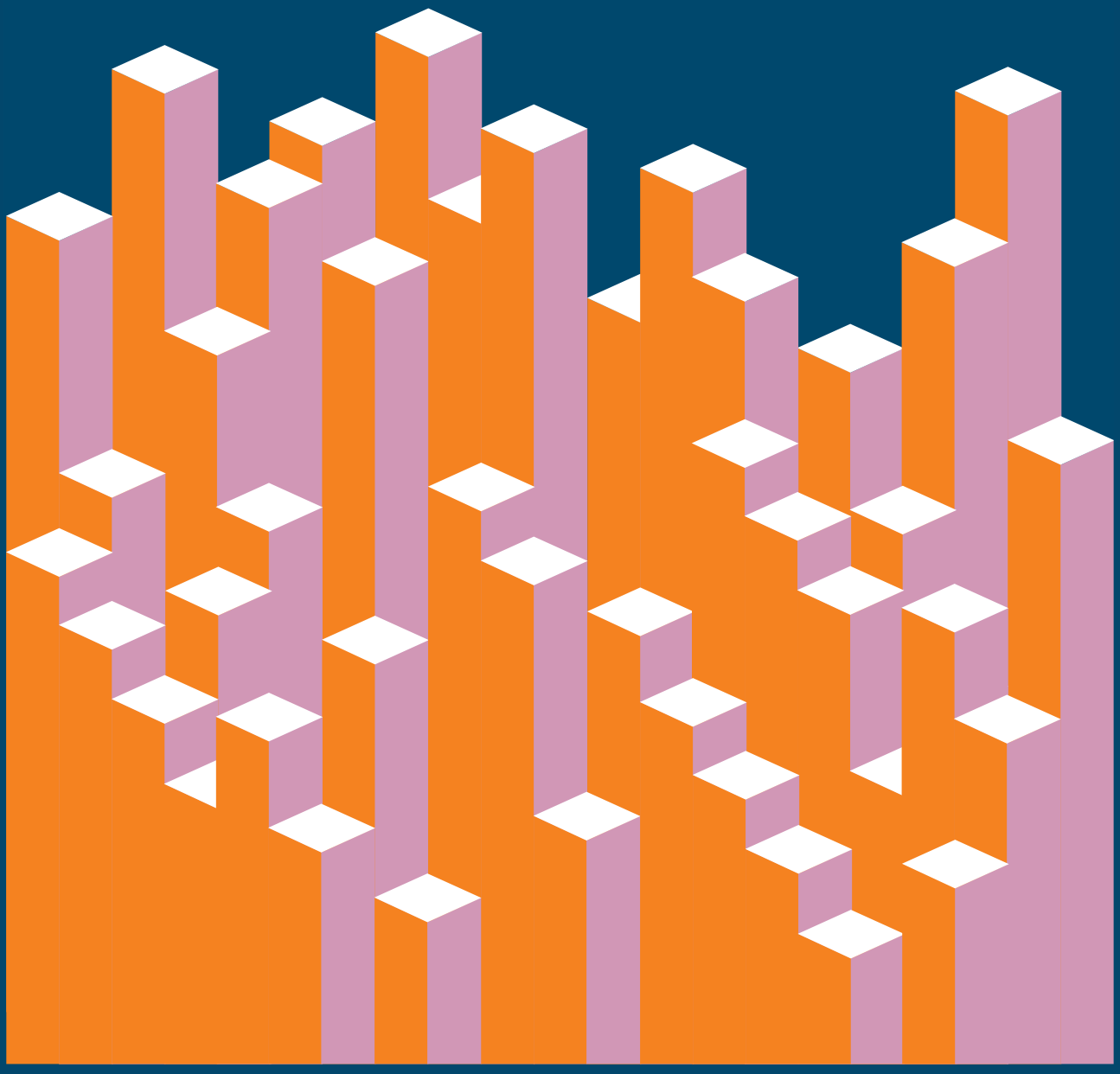
Annual Victorian Cancer Clinical Trials Census

Cancer Trials Australia

Trends in Victorian cancer clinical trial participation 2022-24



Acknowledgement of Country

Cancer Trials Australia acknowledges Aboriginal and Torres Strait Islander peoples as Australia's first communities, and as the Traditional Custodians of the lands on which we live and work. Connection to community is central to the life, culture and continuing traditions of First Nations peoples. We pay our respects to all Elders past, present and emerging, and to the communities we have the privilege of working with.

Acknowledgement of Support

The Annual Victorian Cancer Clinical Trials Census is supported by the Victorian Government.

VICTORIA State Government

Acknowledgement of Predecessor

We acknowledge Cancer Council Victoria's significant leadership in this space, having the foresight to initiate the Cancer Trials Management Scheme in 1988 to document cancer clinical trial participation across Victoria, and managing that program for over 30 years.

Contents

Foreword

This report represents a significant development within our growing Victorian clinical trials sector, towards the capacity for deeper analysis of annual trends in cancer clinical trials and the participants who benefit.

We firstly would like to acknowledge the many years of work undertaken by Cancer Council Victoria that underpins this project; the effort, and foresight, to collect and curate multiple years of study and participant data describing participation in cancer trials across Victoria has been necessary for many agencies to showcase progress and achievement against their own projects, and has enabled representation of the work of many thousands of Site and Sponsor staff across our State.

We would also like to acknowledge the progressive vision of the Cancer Trials Australia Board, and of our colleagues within the Victorian Cancer Agency, who remain willing to support ambitious data projects in the belief that painting the picture of clinical trials in Victoria will assist us all in delivering better treatment options for cancer patients.

And last but not least, we sincerely thank the research staff that generate all the activity that is reported here; this is a challenging space, with many demands on your time, and many hands held out requesting your data. This ongoing project is really about representing you, your effort, and your dedication to your participants, in the hope that it enables you to expand resources, infrastructure, treatment options and opportunities for all Victorian cancer patients and their families.

Kurt Lackovic
Chief Executive Officer
Cancer Trials Australia

Emily England
Information Systems Manager
Cancer Trials Australia

Sector Advocacy and Development

Cancer Trials Australia (CTA) was originally established in 1993 as the Centre for Developmental Cancer Therapeutics (CDCT), to offer clinical trial sites a co-ordinated and dedicated resource team to manage clinical trial administration, including ethics and governance submissions, budget and contract negotiations and financial management of their clinical trial activity.

In addition to its clinical trial administration services, CTA has been involved in a number of significant sector development initiatives since its inception including; implementing the Mutual Acceptance Program (MAP) across its Members; assisting with the development of a standard clinical trial agreement template for sponsored trials now known as the Medicines Australia Standard Clinical Trial Research Agreement template; the development of a First Time in Human (FTIH) protocol to enable Human Research Ethics Committees (HRECs) to strengthen their capacity to review Early Phase research; developing a pre-screening protocol, to allow patients to be screened at their local hospital for clinical trial participation at another hospital; convening a Phase 1 Fellowship Program to increase capacity for sites to coordinate FTIH trials; administering a range of projects aimed at increasing clinical trial education and capacity building through Victorian Comprehensive Cancer Centre initiatives and most recently the coordination of the Australian Clinical Trials Education Centre (A-CTEC) to support a dedicated Learning Management System (LMS) hosting a suite of evidence-based, interactive clinical trial education opportunities for Australian clinical trial staff.

This sector development work is undertaken against the background of CTA's day-to-day administrative management of clinical trials for our Member sites, where ethics and governance submissions are co-ordinated, budgets and contracts negotiated, and financial management of trial activity is undertaken. All of these core activities are underpinned by constantly evolving processes, systems and applications.

To facilitate trial financial management, over many years CTA has supplied a series of electronic applications to sites for recording of clinical trial participants and the activities they undertook as part of their trial experience. This enables CTA to generate invoices to Sponsors to recoup the cost of work undertaken by clinical trial sites. Towards the end of 2020, CTA began significant, strategic investment into our information management systems, specifically to improve the capacity for financial data management and interrogation. This involved a major project to develop and launch a new custom database application, **Clinibase**, built throughout the 2021 year in partnership with Cardiobase, a Melbourne-based healthcare solutions company. This project was completed in 2022 after transitioning all of CTA's financial management sites to the new application.

Due to the enhanced ability to interrogate the data collected within Clinibase, the application was increasingly recognised as a valuable data resource, describing participant recruitment and activity across a growing number of Victorian trial sites.

Data Reporting through Clinibase

Data collection and reporting on annual trends in cancer clinical trials across Victoria has been undertaken by Cancer Council Victoria (CCV) since 1988, via their Cancer Trials Management Scheme. Supported by the Victorian Government through the Department of Health, for many years this data collection remained the only source of comprehensive, annual, state-wide data on the cancer clinical trial sector.

In late 2022, after CTA's successful transition to Clinibase, the potential for Clinibase to function as the basis for collecting Victoria-wide clinical trials activity was explored; data demands from the sector were becoming increasingly granular and the CCV mechanism of collection and collation was labour intensive, requiring considerable staff time, effort, and commitment.

Clinibase was already in use by the majority of Victoria's clinical trial sites, and the majority of clinical trial activity undertaken across the state was already being captured directly within that application. Importantly, Clinibase offered a user interface where sites could self-maintain ongoing data-entry throughout the year and included a range of in-built reporting and data visualisation tools that could be utilised internally for a sites' own benefit. The opportunity for Clinibase to act as a source for sites to manage multiple data requests, both for internal and external reporting was attractive, as well as CTA's ability to generate cross-site data sets with reduced effort.

One of the main advantages of utilising Clinibase is that participant data is collected throughout the year, and highly validated where sites use Clinibase in their day-to-day operations. This reduces double handling as reports can be produced as needed, directly from the source data. Another benefit is that the data is maintained in a "per participant" format, meaning that granular segmentation can be undertaken, allowing us to pivot the data to gain deeper insights.

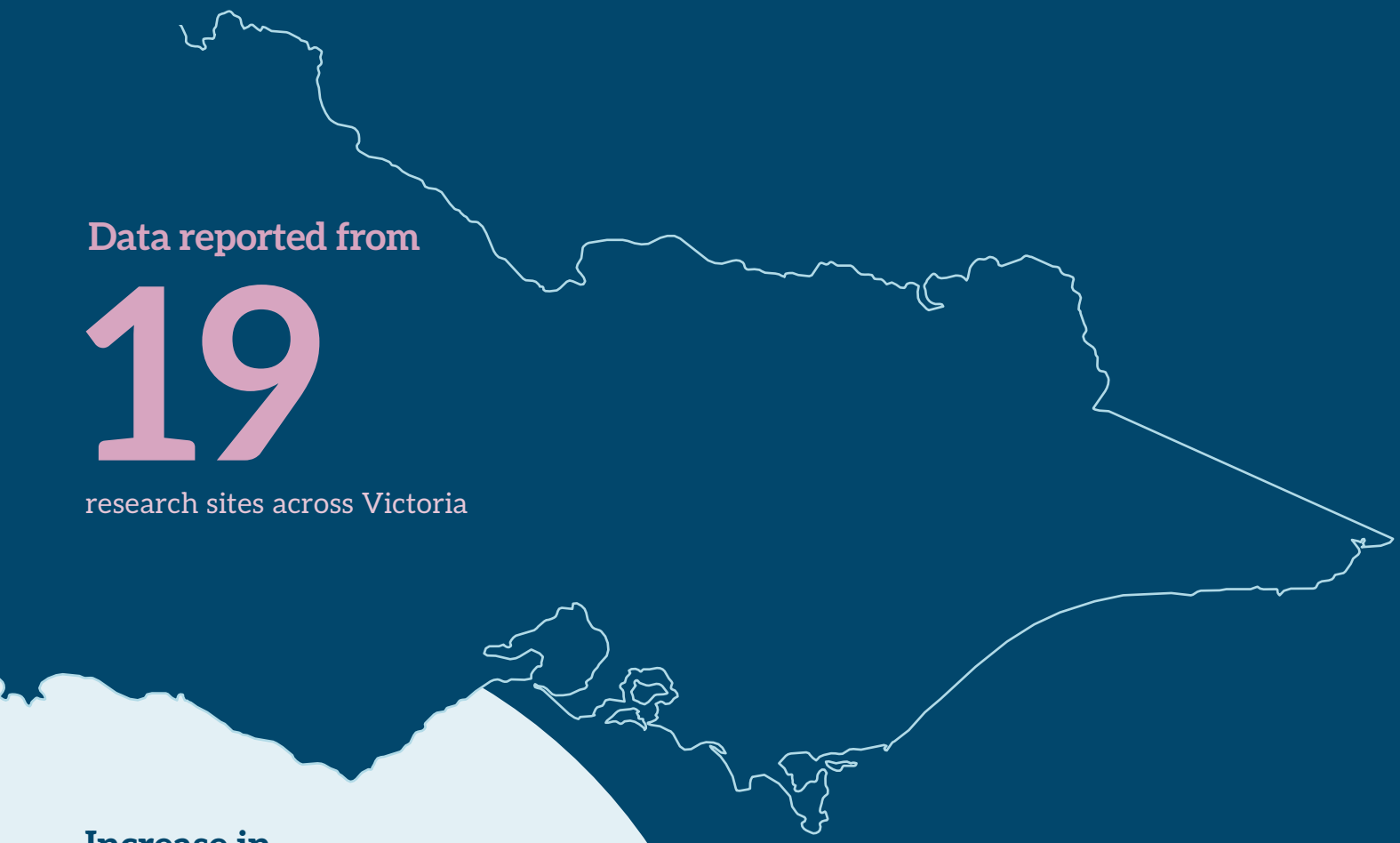
After positive discussions with CCV and with support from the Victorian Cancer Agency, CTA assumed responsibility for state-wide data collection from 1 January 2023, including the 2022 calendar year reporting period, establishing the Annual Victorian Cancer Clinical Trials Census program.

This data ultimately belongs to each clinical trial site; CTA acts as a data custodian to provide this aggregated, anonymised data set for wider sector use. To ensure appropriate permission is gained for this function, Data Sharing Agreements have been executed with all participating sites. This process has taken significant effort, and our thanks go to all site staff who have helped shepherd their Data Sharing Agreement through various legal, cybersecurity and governance approval processes.

Participation in the Annual Victorian Cancer Clinical Trials Census and representation in this report is a choice that sites are free to make, and their ability to provide historical data is often dependent on their own internal capacity, prior data collection methodologies, and progress of their Data Sharing Agreement.

It is important to recognise that not all Victorian clinical trial sites are as yet represented within this data set. Based on the 2021 data collected by Cancer Council Victoria, CTA has executed Data Sharing Agreements with 19 sites, covering 96% of the previous data set, and is currently able to data match to 76% of the previous participant cohort. In addition, Clinibase holds data for an additional four sites who were not represented in the prior CCV data set. CTA continues moving positively forward with remaining Victorian sites and looks forward to future iterations of this report – where possible we will back fill data to allow for updated comparisons. For these reasons, it is difficult to make direct 1:1 comparisons between this data and the prior CCV data set; we have instead focused on a 3-year trend of the 19 Victorian sites currently within Clinibase, to enable the most accurate analysis of change over time.

At a Glance



Data reported from

19

research sites across Victoria

Increase in recruitment by

21%

to oncology/haematology clinical trials across 2022-24

Commercially sponsored trials

61%

of participants were recruited to commercially sponsored clinical trials in 2024

FTIH trials grew by

49%

across 2022-2024

Rural/regional

20%

In 2024, 20% of all clinical trial participants were involved in a trial at a rural or regional research unit

Females

53%

Female participation grew across this reporting period, now comprising 53% of known gender participation

First Nations people

1%

First Nations participation grew from 0.5% to 1% across 2022-24

Non-commercially sponsored trials

75%

of recruitment in rural/ regional settings was to non-commercially sponsored clinical trials in 2024

Rural and regional travellers

237

participants per annum on average travel from a rural/regional setting to participate in a clinical trial at a metropolitan site, predominantly for Early Phase commercially sponsored trials

Trial sponsorship

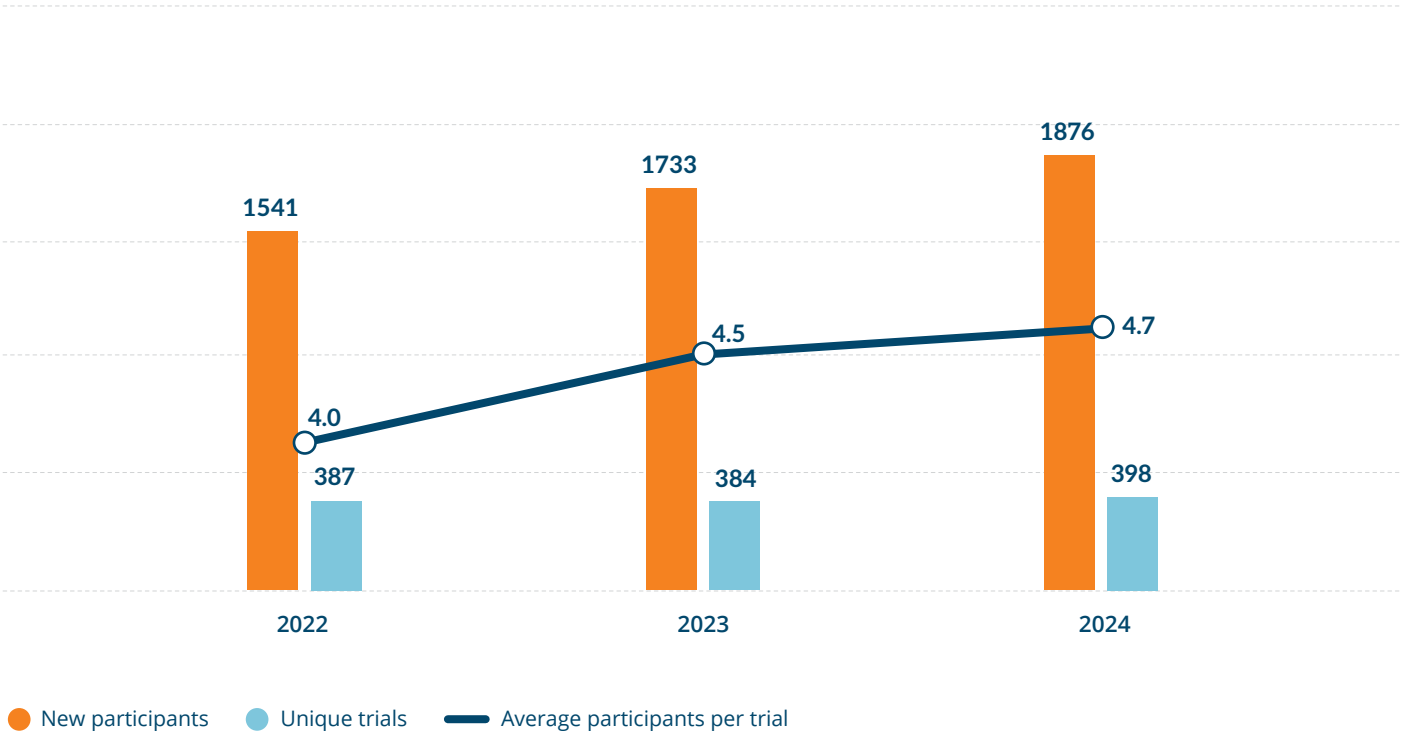
50%

of commercially sponsored clinical trials are sponsored by large pharmaceutical companies

The majority of commercially sponsored clinical trials originate from the USA

New Participants and Recruiting Trials

Figure 1: Number of new participants and unique trials that recruited new participants



We are pleased to report a continuing steady increase in recruitment year-on-year, growing from 1,541 to 1,876 over the 3-year period represented; an increase of more than 21% (Figure 1).

These participants were recruited to between 387 and 398 unique recruiting clinical trials across this period, with average participant recruitment rising from 4.0 participants per recruiting trial in 2022 to 4.7 per recruiting trial in 2024.

The term "unique trial" represents a single clinical trial protocol, not including duplicate counts of trials being conducted across multiple clinical trial sites in Victoria.

The term "recruiting trial" represents a unique trial that recruited participants during any time in any one reporting year, regardless of the year the trial opened.

Please note that these definitions depart slightly from the prior Cancer Council Victoria definitions as, for clinical trial sites using Clinibase in their standard workflow for study start-up, CTA is also able to report data on unique trials that did not recruit during any one reporting year (refer to Figure 3).

Trial Availability

Figure 2: Number of sites opening each unique recruiting trial

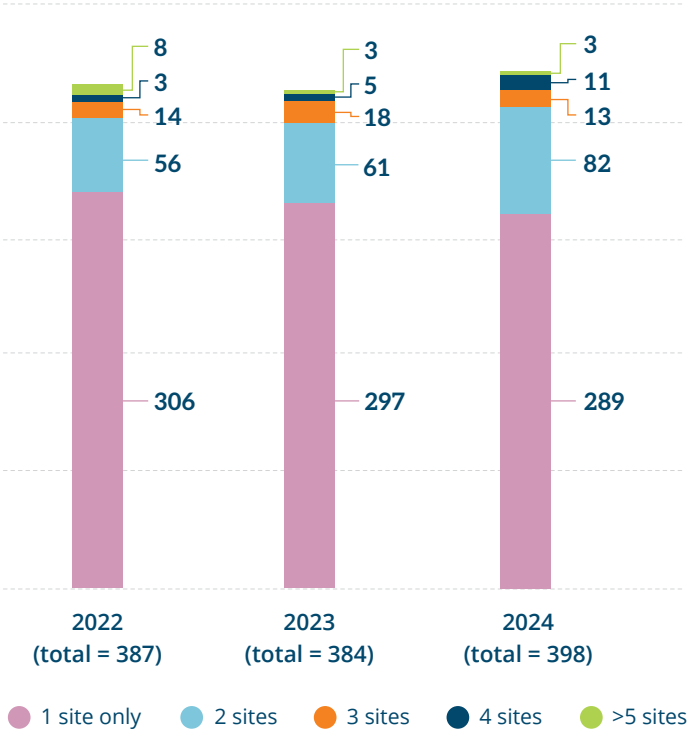
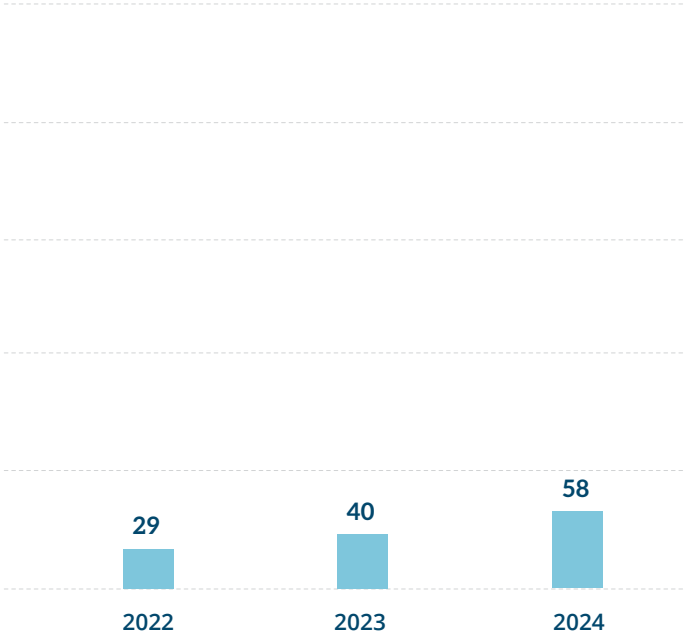


Figure 3: Number of unique trials open to accrual during any year, with 0-recruitment each year



From 2022 to 2024, the vast majority of unique trials were open to recruitment at only a single site within the Census sites cohort (Figure 2). However, the proportion of unique trials open at 2 or more sites increased from 21% in 2022 to 27% in 2024. While it is important to note that these analyses will undercount multi-site availability at sites not represented in the census cohort, it is clear that unique trials undertaken in Victoria are predominantly offered at a single Victorian site.

Analysis of trials that were available ie "Open to Accrual" but did not recruit a participant in a given calendar year is not traditionally undertaken, as there is a general focus on recruitment as the starting point for data collection. This method under-represents trial availability across the sector.

This is especially important when understanding trial availability for rare cancers, which may remain open but may not recruit for many years, to facilitate recruitment of eligible participants as they are identified.

This is also an important factor when looking at multi-site trials, when recognising that a trial may recruit participants at one site, but not another.

As there are a sub-set of sites that use Clinibase in their standard workflow for study start-up, for the first time we can now present data on trials running at individual sites that did not recruit a patient during a given calendar year (Figure 3).

These trials represent significant ongoing work undertaken by Victorian clinical trial sites, to hold trials open with very minimal financial compensation, as clinical trial payments are predominantly associated with participant visits.

The COVID-19 pandemic saw many trials remain open for longer than anticipated, as global recruitment targets were slower to achieve, which may have contributed to an excess of non-recruiting trials in the years immediately post COVID-19. Formal trial closeout can also be delayed when resources are limited, as it requires significant administrative effort at the site.

Early Phase Trials

Figure 4: Participant recruitment by Phase and year

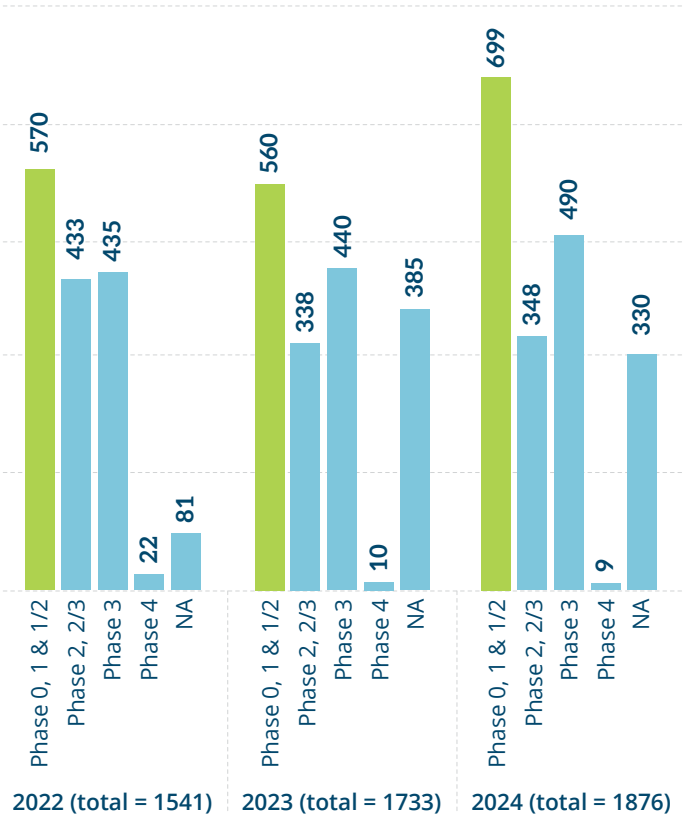
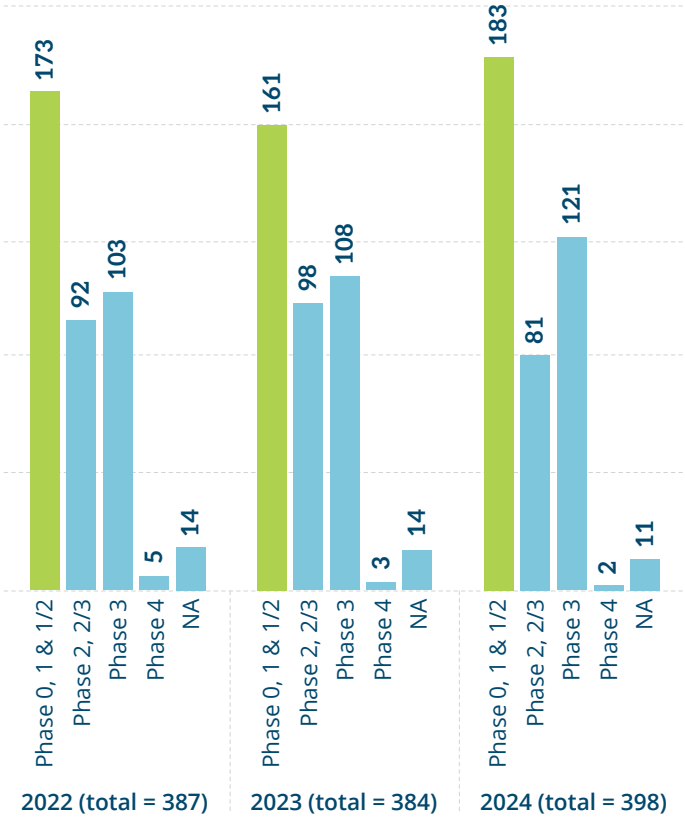


Figure 5: Number of unique recruiting trials by Phase and year



Over the past 10 years, Australia has developed a reputation as a destination of choice for the conduct of commercially sponsored clinical research, in particular Early Phase clinical trials. In fact, growth in clinical trials across Australia between 2015-2022 sits second only to China.[1] Furthermore, on a per capita basis, Australia now attracts more commercially sponsored clinical trials than any other country.[2]

The growth in Australian clinical trials across this period is predominantly due to growth in Phase 1 trials (9.5% per annum), with some growth seen in Phase 2 trials, and no growth or declines observed in later Phase trials.[2] Key reasons for growth in Early Phase trials across Australia include the speed with which trials can be initiated, lower clinical research costs including access to a Research and Development Tax Incentive, and the quality of data produced, which is accepted globally. In addition, the strength of engagement with clinician-researchers, knowledgeable clinical trial staff, experienced Australian clinical trial networks, as well as world-class universities and medical research institutes also underpin this. These reasons ensure Australia now ranks #3 in the world for total number of commercially sponsored Phase 1 trials initiated per annum, behind the much larger USA and China.[3]

In oncology specifically, a study of trends in Phase 1 oncology trials initiated across Australia between 2012-2022 demonstrated a substantial increase in the number of trials (31.7% per annum), with growth driven predominantly by emerging biopharmaceutical companies from Asia. Most of these studies were initiated in Melbourne and Sydney, with very few including regional sites.[4]

[1] Clinical Trials Arena, The great wall: why overseas sponsors are yet to fully tap into China's clinical trial resources, May 2022.
[2] MTPConnect_2024_AustraliasClinicalTrialsSectorReport.pdf viewed 13 April 2025 https://www.mtpconnect.org.au/images/MTPConnect_2024_AustraliasClinicalTrialsSectorReport.pdf
[3] Rescuing patient access to industry clinical trials in the UK viewed 13 April 2025 https://www.abpi.org.uk/publications/rescuing-the-uk-industry-clinical-trials/
[4] Hitchen N, Shahnam A,Manoharan S, et al. Trends in Phase 1 oncology clinical trials across Australia; Analysis of ClinicalTrials.gov 2012–2022. Asia-Pac J Clin Oncol. 2024;1-7. https://doi.org/10.1111/ajco.14100

Figure 6: Proportion of participant recruitment to FTIH trials as a sub-set of Phase 0, 1 and 1/2 trials

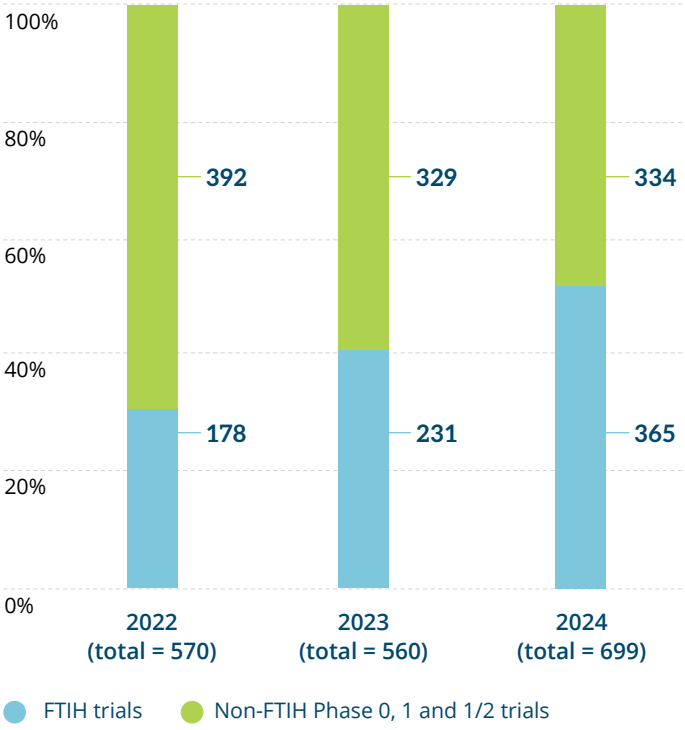
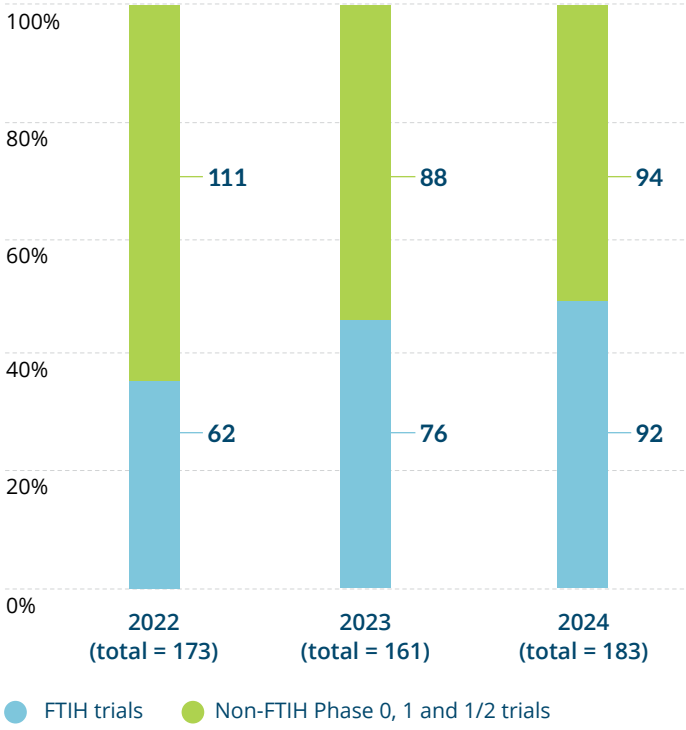


Figure 7: Proportion of unique recruiting FTIH trials as a sub-set of Phase 0, 1 and 1/2 trials



Specific initiatives have also sought to enhance the number of Early Phase trials available in Victoria; CTA has supported development of a First Time in Human (FTIH) protocol to enable Human Research Ethics Committees (HRECs) to strengthen their capacity to review Early Phase research and has convened a Phase 1 Fellowship Program to increase capacity for Victorian sites to coordinate FTIH Trials. CTA also contributed to the Early Phase Clinical Trials Guidance within the Scientific Expert Review Toolkit established by the Victorian State Government in 2019, which supports and supplements quality and safety decision-making in the ethics review process within Victoria. This allows for trials to be approved by ethics committees without the need for IND/FDA approval, allowing Victorian sites to gain expedited access to Early Phase trials.

Early Phase trials are vital to our participants – they deliver novel therapies to patients faster.

In Figures 4 to 7 we have defined Phase 0, Phase 1 and Phase 1/2 as "Early Phase" trials and compared these to later Phase trials. Not Applicable (NA) is used to describe trials without defined Phases, including for example neo-adjuvant and expanded access trials.

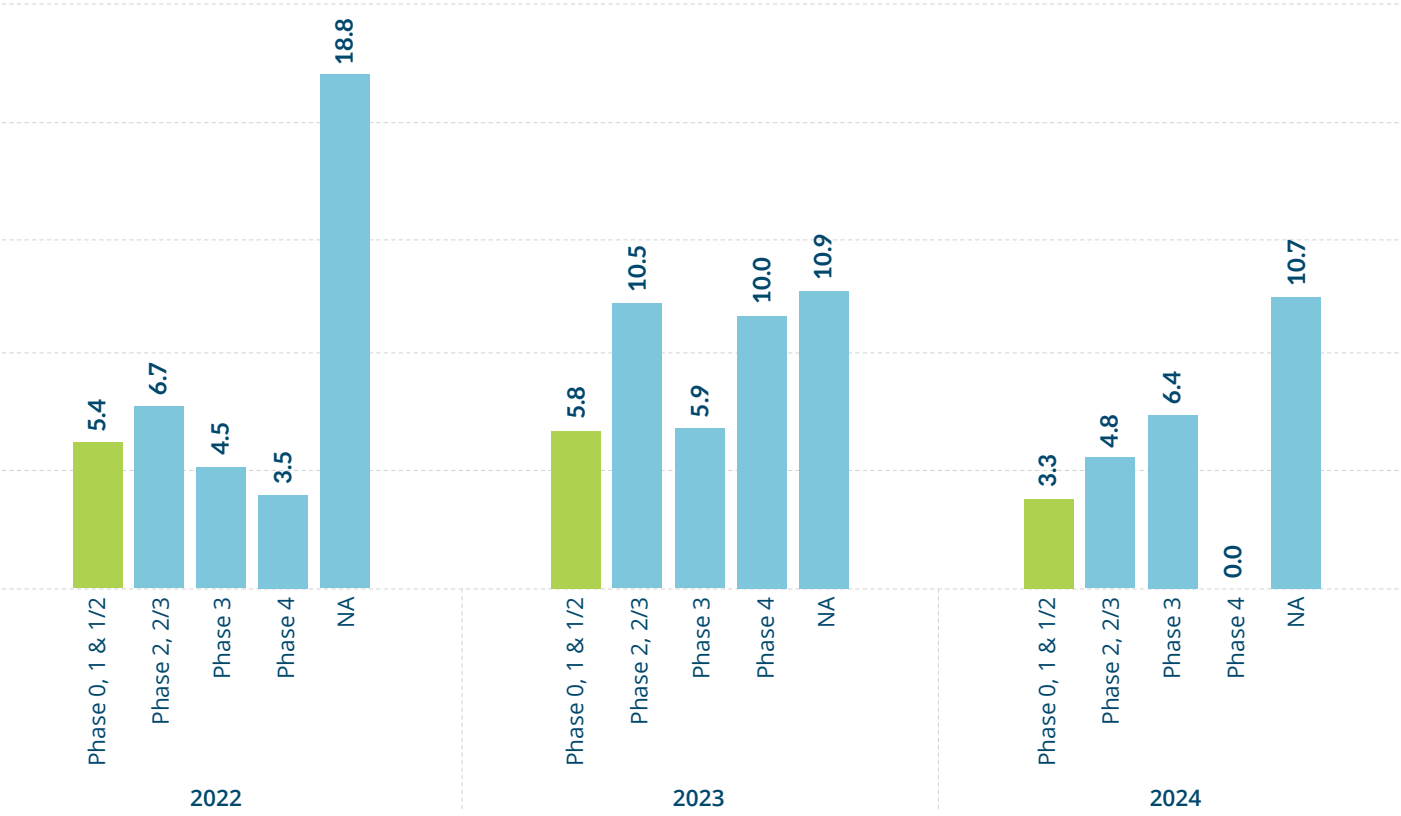
Figure 4 shows recruitment to Early Phase trials increased from 570 in 2022 to 699 in 2024, representing 37% of participants in both years.

When analysing Figure 5, the proportion of unique Early Phase trials also remained steady at 45% in 2022 and 46% in 2024.

While the relative proportion of Early Phase trials and participants remained steady, the profile of this Phase group changed, with a higher proportion of FTIH trial participation; total recruitment to FTIH trials doubled between 2022 and 2024, and the number of unique FTIH trials increased by 49% (Figures 6 and 7).

Early Phase Trials (continued)

Figure 8: Average number of participants per "Closed to Accrual" trial



Given the focus on Early Phase trials, an interesting question is often asked regarding their propensity for recruitment compared to later Phase trials. With available data in Clinibase, which includes a wider set of data points throughout the life of each trial, we can show evidence that Early Phase trials do tend to recruit equal or fewer participants on average compared to later Phase trials, but this is perhaps not as pronounced as previously thought (Figure 8).

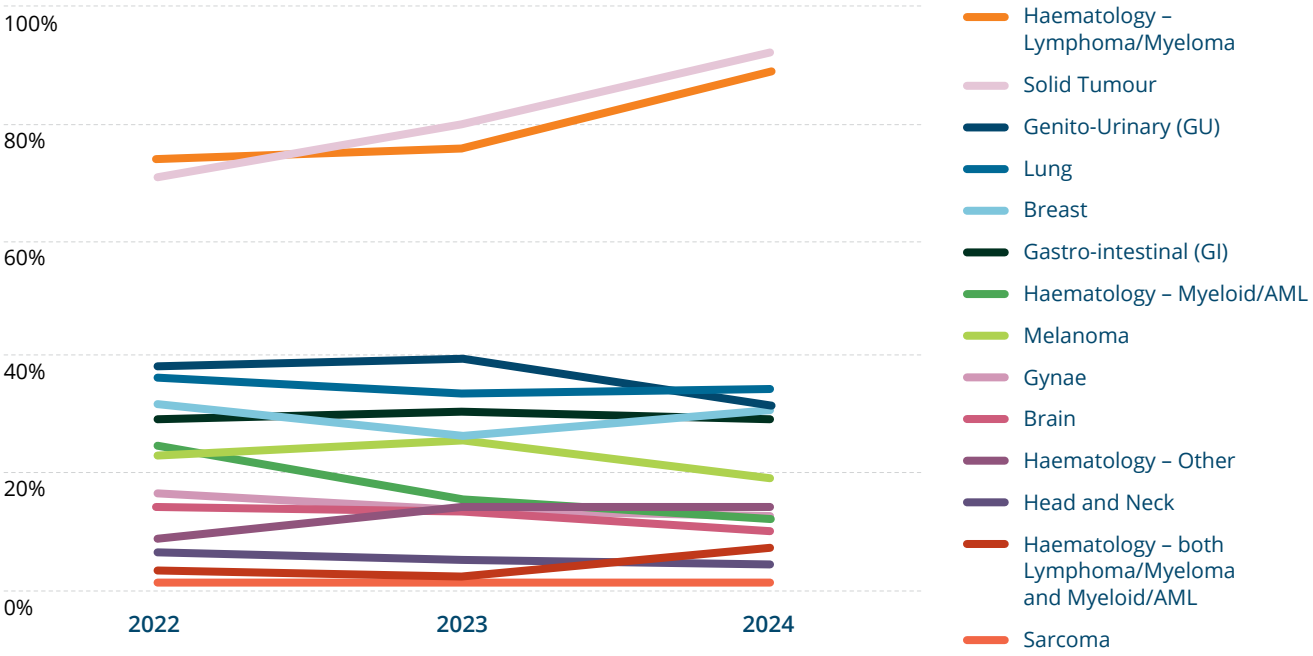
This is an important point to recall when reviewing overall recruitment numbers year-on-year – with a trending increase and focus on initiating Early Phase trials, we may see a corresponding flattening of total recruitment numbers in future year analyses.

The higher average number of Early Phase recruits in 2022 and 2023, compared to 2024 may be indicative of the extended time trials remained open after the COVID-19 pandemic, however we are unable to make further conclusions about the impact of this variable with the existing data set; CTA will watch this metric with keen interest as further census data years are reported.

Please note in this analysis, to correct for trials that are mid-recruitment, where patients are still being actively approached, this data set only represents trials that completed recruitment 2022 – 2024, grouped by the year that the trial was "Closed to Accrual". These trials may remain active for many years while managing and monitoring participants that were recruited.

Tumour Stream

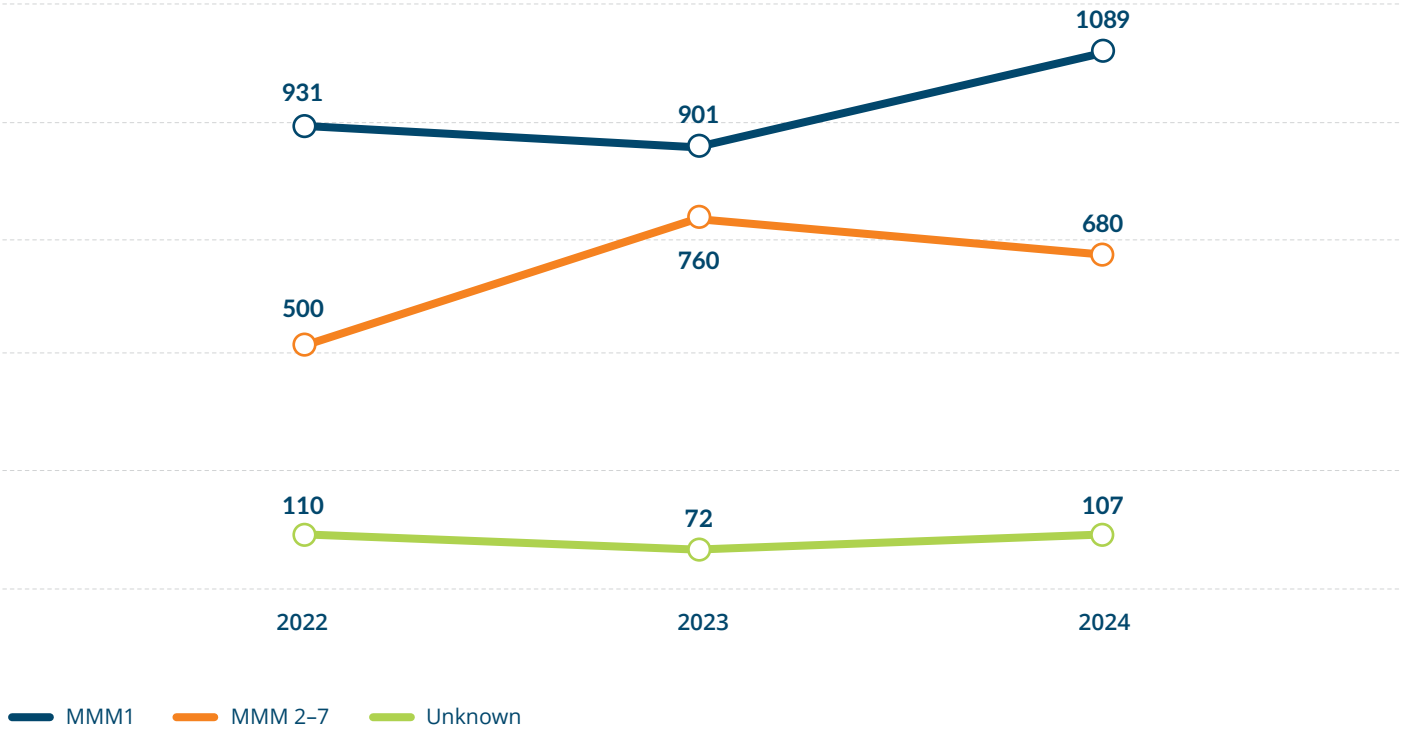
Figure 9: Proportion of unique trials that recruited participants by tumour stream



The relative proportion of trials across most tumour streams remained consistent across this reporting period, however there was an increase seen in Solid Tumour trials by 30% and Lymphoma/Myeloma trials by 20% (Figure 9).

City to Country

Figure 10: Number of new participants by residential address MMM code



As referenced in the Victorian Cancer Plan 2020-2024, an area of ongoing and significant focus is the equitable provision of trials to regional participants.[5]

Many initiatives across the state continue to contribute to the achievement of this outcome, and CTA warmly recognises the efforts of all regional site staff to increase their capacity and expertise in delivering trials, as well as metropolitan site staff who facilitate and advocate for travel support for regional participants.

This census references the Modified Monash Model[6] for classification of participant residential postcodes in regional and rural areas.

Goal five of the Victorian Cancer Plan was to increase the overall number of new clinical trial enrolments in rural and regional areas of Victoria by 30%. [5]

The Annual Victorian Cancer Clinical Trials Census was proud to contribute data to the recent Victorian Cancer Plan Progress Report, indicating that regional recruitment grew 120% between 2016 and 2023.

Where did trial participants come from?

Over the 3-year span of this census, we recorded 2,921 new Metropolitan clinical trial participants (MMM1) and 1,940 new Regional clinical trial participants (MMM2-7); a proportion close to 40% recruited from rural and regional residential postcodes (Figure 10).

Please note some of our census sites were unable to provide a residential postcode for trial participants at this time due to data privacy restrictions, these participants have been labelled unknown.

[5] victorian-cancer-plan-2020-2024_improving-cancer-outcomes-for-all-victorians.pdf viewed 13 April 2025 https://www.health.vic.gov.au/victorian-cancer-plan
[6] www.health.gov.au/topics/rural-health-workforce/classifications/mmm viewed 13 April 2025

Figure 11: Number of new participants recruited by site location

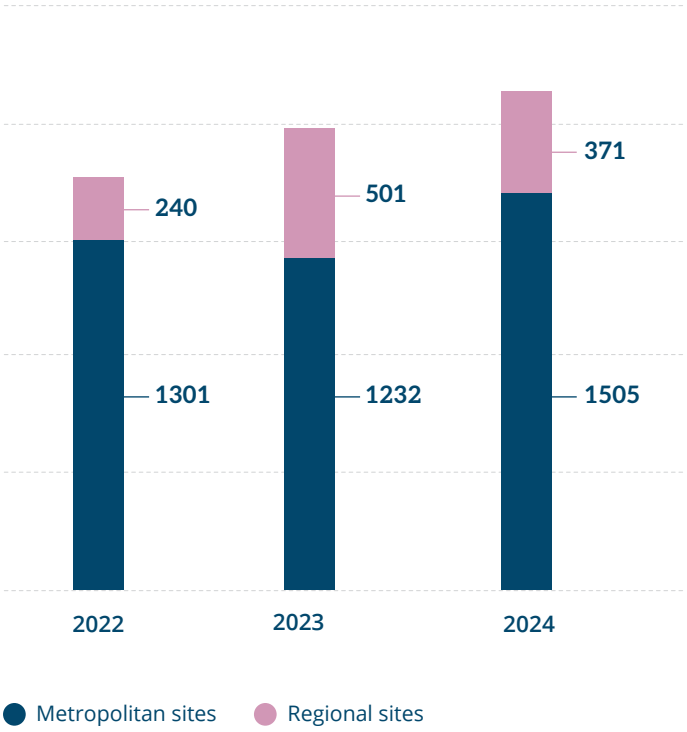
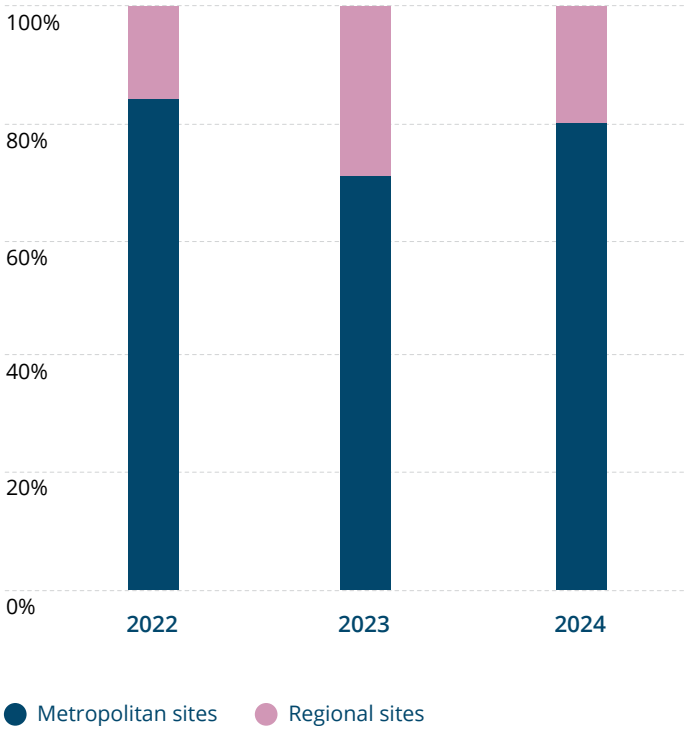


Figure 12: Proportion of new particpants recruited by site location



Where were trial participants treated?

Of the 1,876 clinical trial participants recruited across Victoria in 2024, 20% participated in a trial at a regional site location, a decrease on the 29% in 2023, but increase on 16% in 2022 (Figures 11 and 12).

Across Generations

Figure 13: Number of new participants recruited by age group

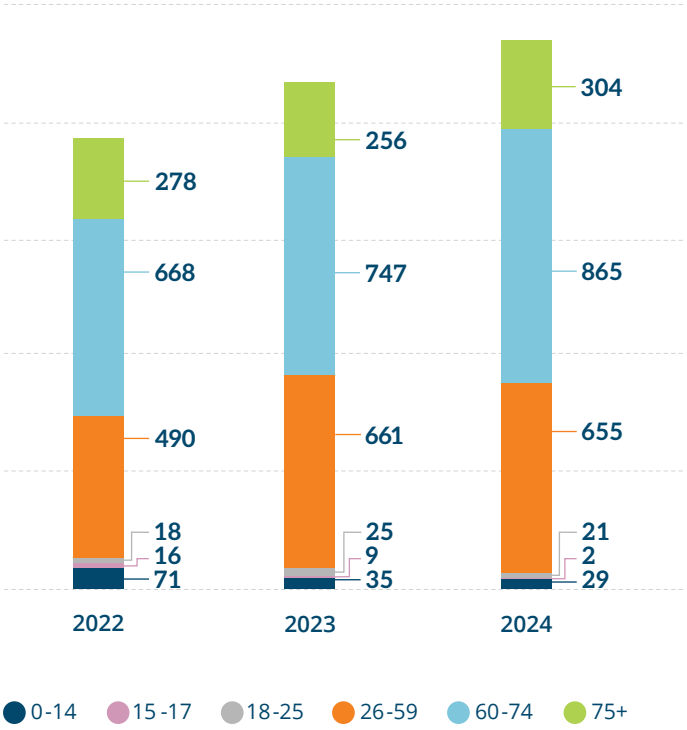
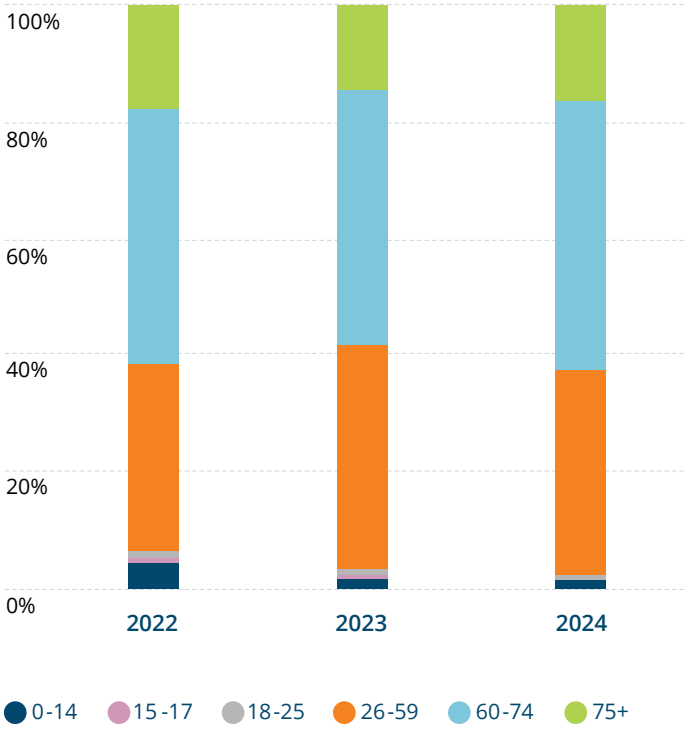
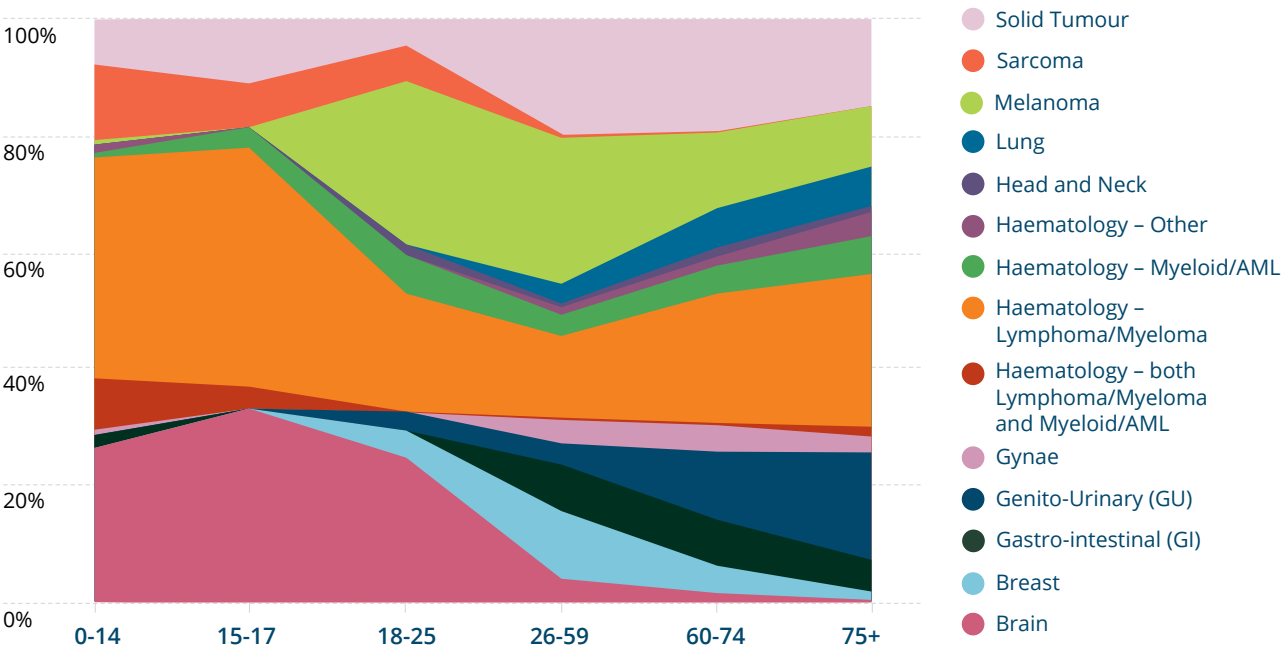


Figure 14: Proportion of new participants recruited by age group



The spread of age ranges across the 3-year census span remained relatively stable, with the highest representation of clinical trial participants being in the 60-74 year age group (Figures 13 and 14).

Figure 15: Proportion of participants recruited by age group per tumour stream



While Figure 9 showed the proportion of unique trials by Tumour Stream, it is also possible to extend this analysis to show Tumour Streams which are most represented in trials undertaken for participants in each age group (Figure 15).

Gender Representation

Figure 16: Number of new participants by gender

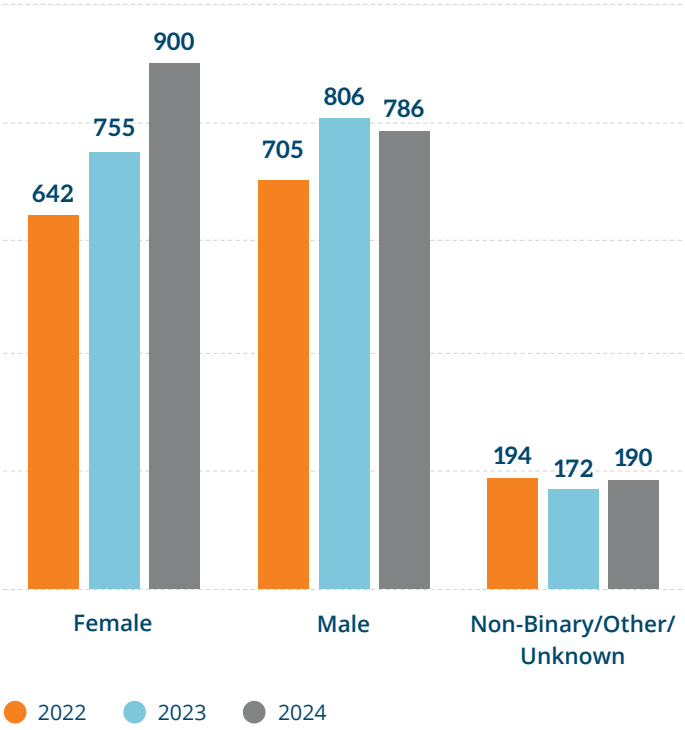
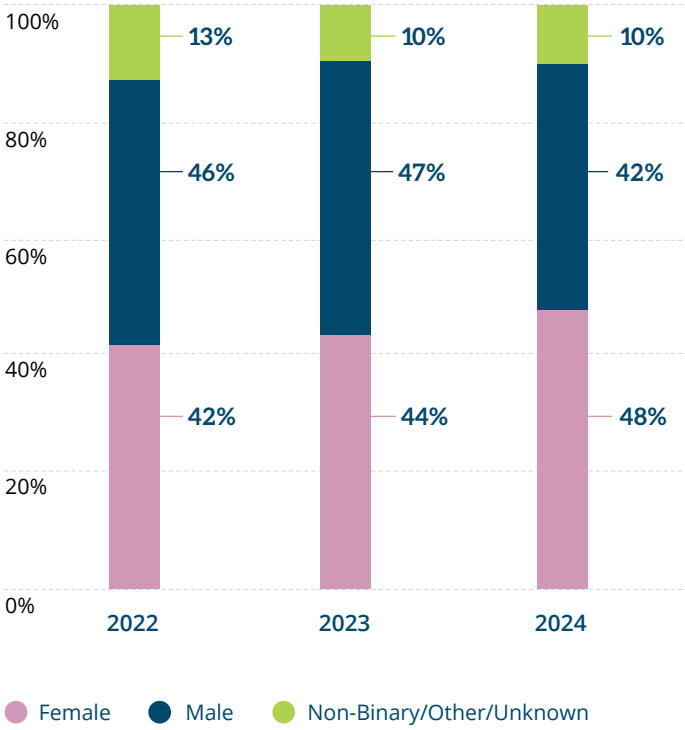


Figure 17: Proportion of new participants by gender



Figures 16 and 17 indicate that over the 3-year span of this census we have seen an increase in recruitment of female clinical trial participants, rising to 48% of total participants in 2024 (or 53% of known gender).

Please note there were fewer than five participants registered per year as Non-Binary, these participants have been grouped within the category Non-Binary/Other/Unknown. Please also note some of our census sites were unable to provide gender for participants at this time due to data privacy restrictions, these participants have been grouped within Non-Binary/Other/Unknown.

First Nations Participation

Figure 18: Number of new First Nations participants

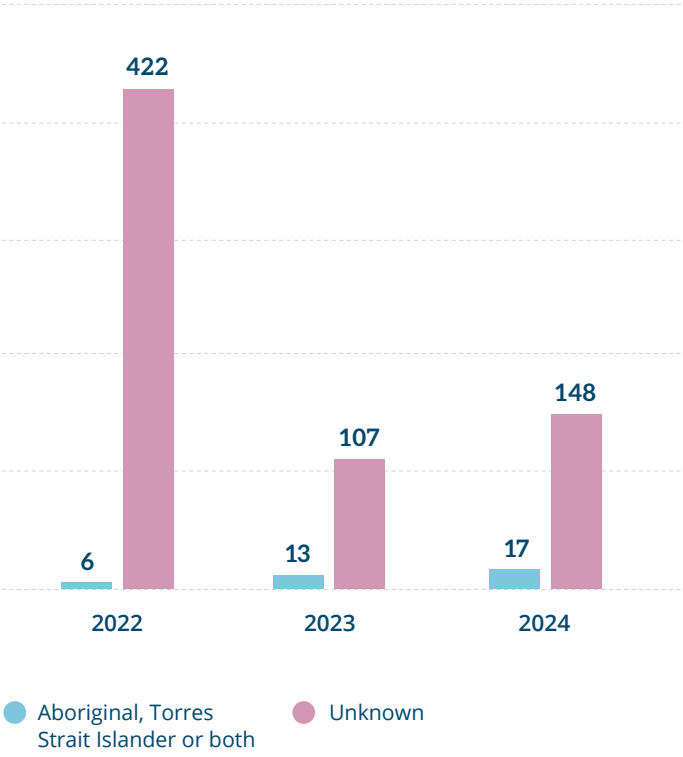
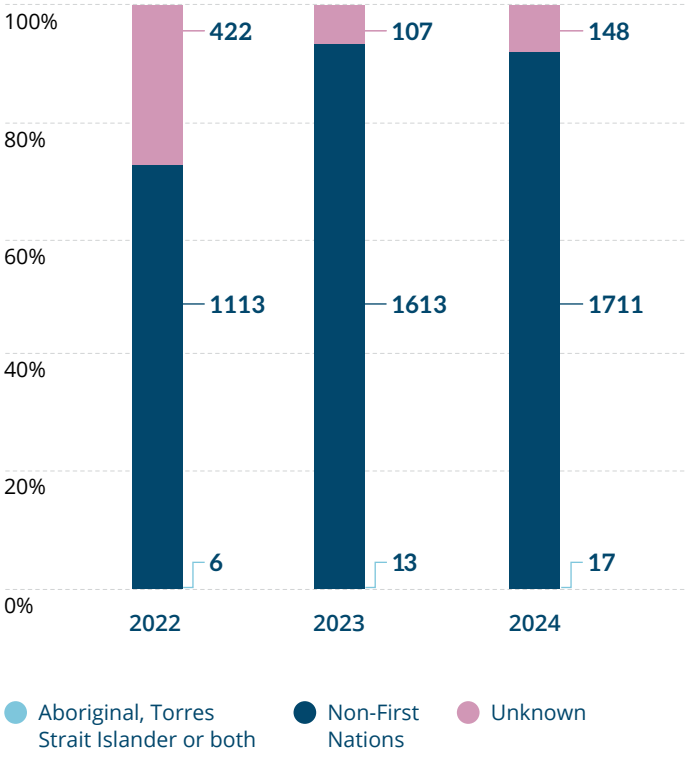


Figure 19: Proportion of First Nations participants



Aboriginal and Torres Strait Islander peoples are more likely to be diagnosed with cancer, have poorer survival outcomes, and die from cancer when compared to non-Indigenous Australians.[7] Every day around five Aboriginal and Torres Strait Islander people are diagnosed with cancer.[7] Furthermore, Aboriginal and Torres Strait Islander people are approximately 40% more likely to die from cancer than non-Indigenous Australians, and that gap is widening.[7] At present, cancer is the leading cause of death among Aboriginal and Torres Strait Islander peoples, accounting for 23.4% of all losses.[8]

Improving equity in cancer outcomes for First Nations peoples is central to the Australian Cancer Plan.[9]

We were pleased to see a significant increase in recording whether a clinical trial participant identifies as Aboriginal and/or Torres Strait Islander over the 3-year span of this census, as well as an increase in the number of First Nations peoples recruited to cancer clinical trials across Victoria (Figures 18 and 19).

CTA welcomes additional initiatives seeking to improve cancer outcomes for First Nations peoples.

[7] Australian Institute of Health and Welfare 2021. Cancer in Australia 2021. Cat. no. CAN 144, viewed 13 April 2025; www.aihw.gov.au/reports/cancer/cancer-in-australia-2021
[8] Australian Institute of Heath and Welfare (AIHW) 2023a, Profile of First Nations people, AIHW, Canberra, viewed 13 April 2025, www.aihw.gov.au/reports/australias-welfare/profile-of-indigenous-australians
[9] Australian Cancer Plan, viewed 13 April 2025 www.australiancancerplan.gov.au

Cultural Diversity

Figure 20: Number of participants by language spoken at home

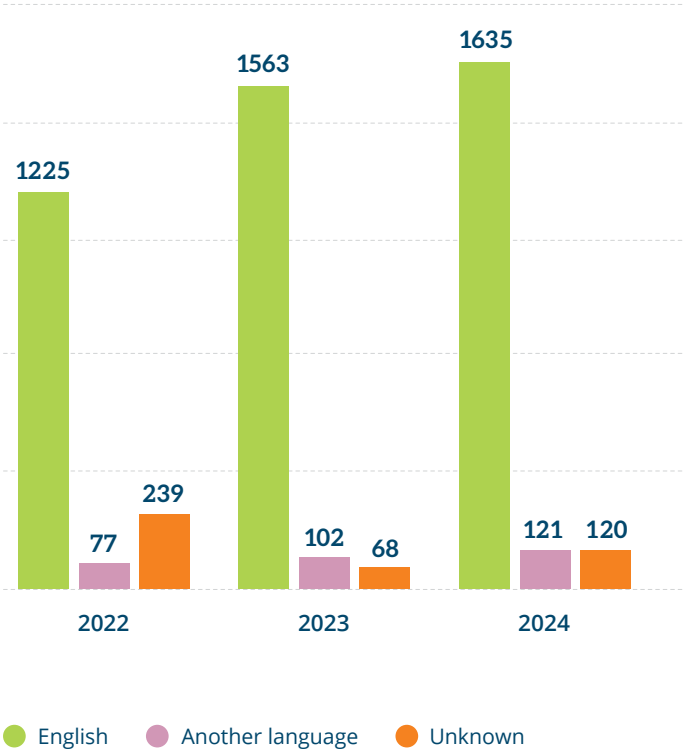
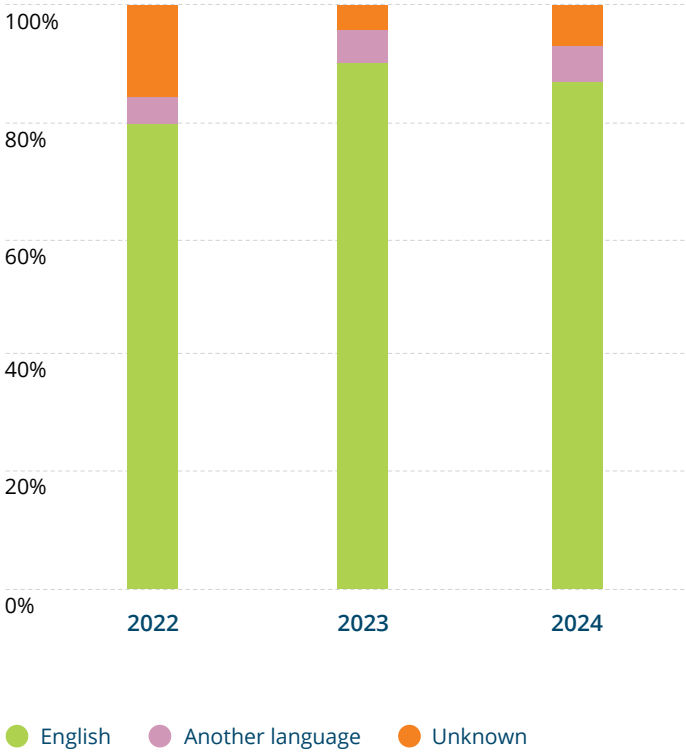


Figure 21: Proportion of participants by language spoken at home



Australia's population is diverse; in 2021, 28% of Australia's resident population were born overseas and 22% of people living in Australia who were Australian born have one or both parents born overseas.[10,11] However, national health data on populations of people from diverse backgrounds is sparse.[12] The data that is available indicates that people from diverse backgrounds experience greater adversity in accessing culturally responsive care and information due to communication barriers, poorer health literacy, and cultural variations.[13,14,15,16]

One indicator of cultural diversity of clinical trial participants that is captured within Clinibase is Language Spoken at Home; this helps inform our knowledge of trends and focus efforts on populations that may be under-represented in clinical trials. Over the 3-year span we saw a slight increase in participants who spoke a language other than English at home (Figures 20 and 21).

Improving cultural diversity of clinical trial participation remains an area of focus for Victorian clinical trial sites.

[10] Australian Bureau of Statistics 2022. Cultural diversity: Census. Accessed: October 2022; https://www.abs.gov.au/statistics/people/people-and-communities/cultural-diversity-census/2021#cite-window1
[11] Australian Bureau of Statistics 2022. Snapshot of Australia. Accessed: October 2022; https://www.abs.gov.au/statistics/people/people-and-communities/snapshot-australia/2021
[12] Australian Institute of Health and Welfare 2022. Reporting on the health of culturally and linguistically diverse populations in Australia: An exploratory paper. Cat. no. PHE 308, Accessed: October 2022; https://www.aihw.gov.au/reports/cald-australians/reporting-health-cald-populations
[13] Scanlon B, Brough M, Wyld D and Durham J. Equity across the cancer care continuum for culturally and linguistically diverse migrants living in Australia: a scoping review. Globalization and Health. 2021;17(1):87.
[14] Khatri RB and Assefa Y. Access to health services among culturally and linguistically diverse populations in the Australian universal health care system: issues and challenges. BMC Public Health. 2022;22(1):880.
[15] O'Callaghan C, Dharmagesan GG, Roy J, Dharmagesan V, Loukas P and Harris-Roxas B. Enhancing equitable access to cancer information for culturally and linguistically diverse (CALD) communities to complement beliefs about cancer prognosis and treatment. Supportive Care in Cancer. 2021;29(10):5957-5965.
[16] Skaczkowski G, Pejoski N, Kaur J, White V, Livingston PM and Wilson C. Distress and problem assessment among people living with cancer from Culturally and Linguistically Diverse backgrounds. Psychooncology. 2020;29(10):1662-1669.

Trial Sponsorship

Figure 22: Proportion of recruitment to commercially sponsored versus non-commercially sponsored trials

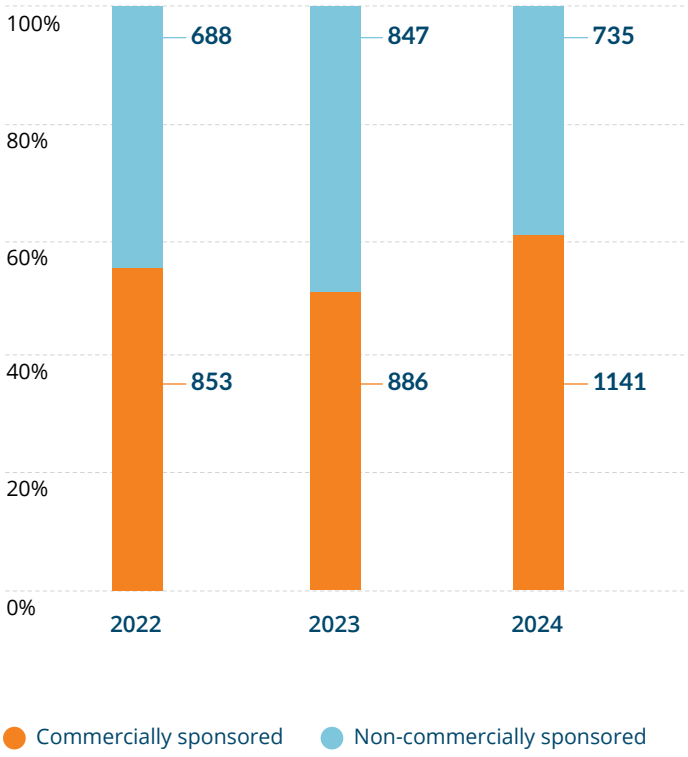
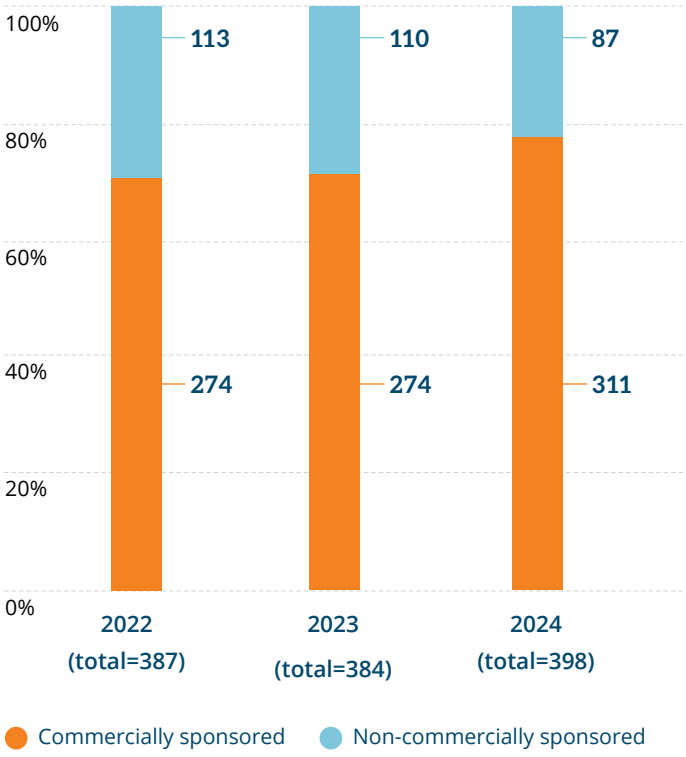


Figure 23: Proportion of unique recruiting commercially sponsored versus non-commercially sponsored trials



In any analysis of a trial portfolio, an important dimension is the source of trial sponsorship. When reviewing participant recruitment to commercially sponsored versus non-commercially sponsored trials (Figure 22), we can see that the majority of participants were recruited to commercially sponsored trials in any one year – 55% in 2022, 51% in 2023, and rising to 61% in 2024.

Figure 23 highlights that participants were recruited to a larger number of unique recruiting commercially sponsored trials resulting in an average of 3.1 to 3.6 participants, whereas an average of 6.1 to 8.4 participants were recruited to unique recruiting non-commercially sponsored trials for the same period.

Trial Sponsorship and Site Location

Figure 24: Proportion of recruitment at metropolitan and regional sites for commercially sponsored and non-commercially sponsored trials

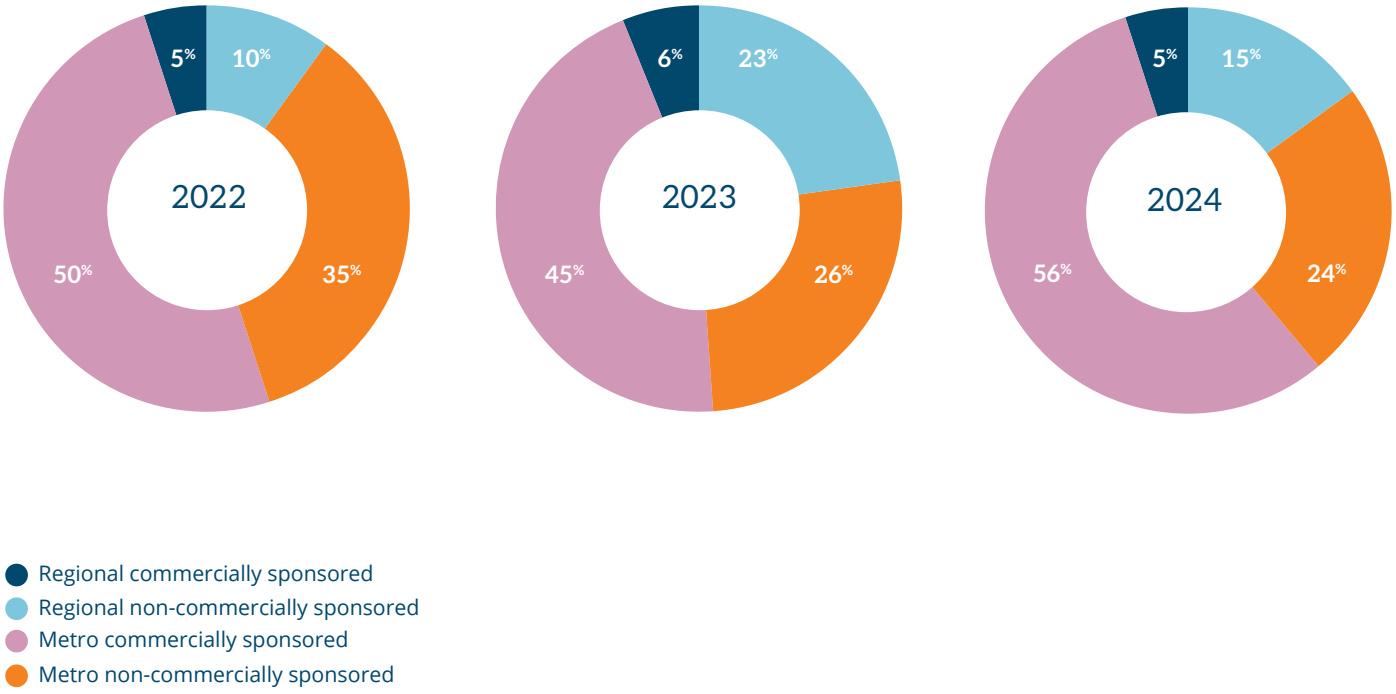


Figure 24 highlights that the majority of clinical trial recruitment that occurs in a regional setting is for non-commercially sponsored clinical trials.

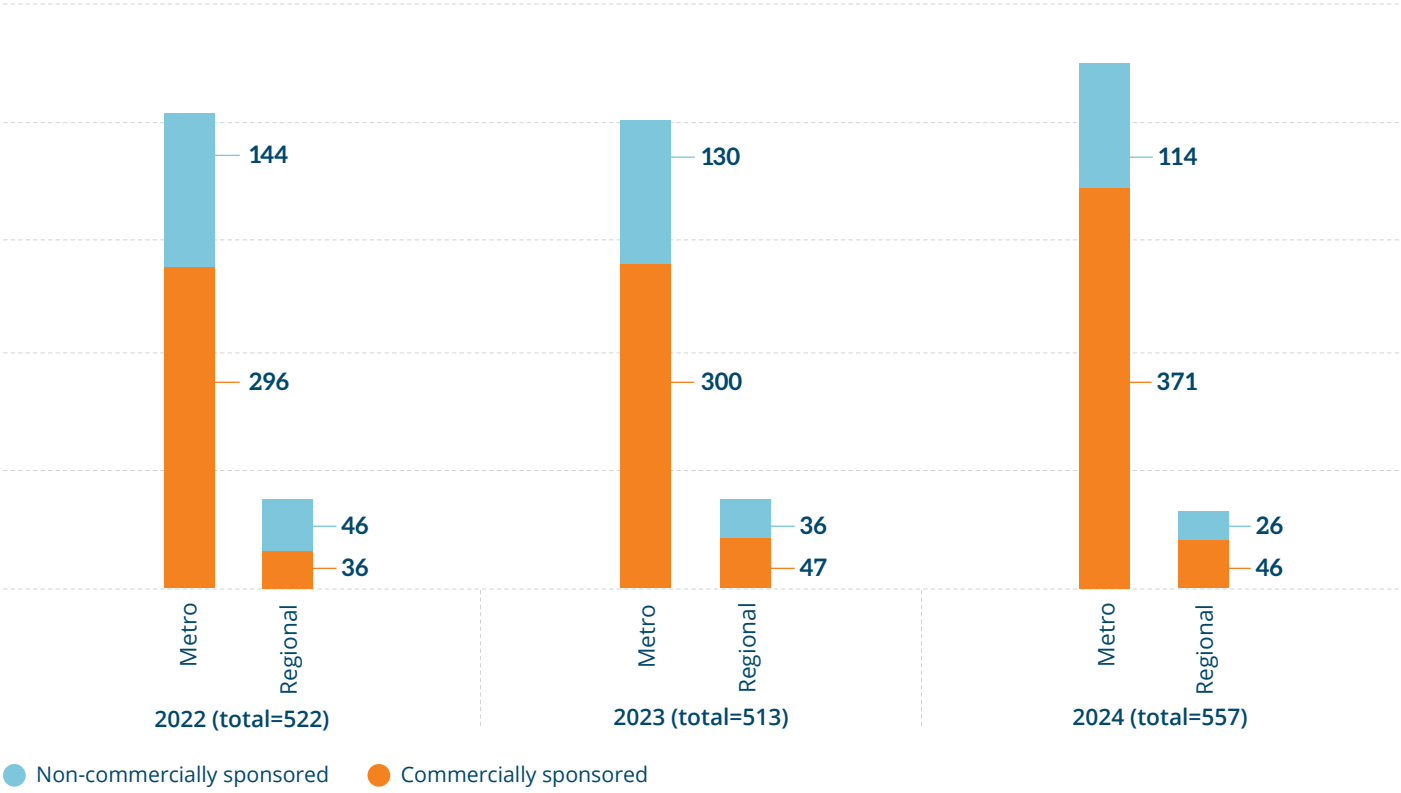
Across this reporting period, 5-6% of all Victorian participants in oncology clinical trials were recruited to commercially sponsored studies at regional trial sites. This is in contrast to the 45-56% of all Victorian participants in oncology clinical trials that were recruited to commercially sponsored trials in a metropolitan setting.

When reviewing recruitment to regional sites across each year, 65% was to non-commercial trials in 2022, 79% in 2023 and 75% in 2024. Whereas across metropolitan hospitals, the proportion of participants recruited to non-commercially sponsored trials is far less, and has decreased across the Census period from 41% in 2022, 36% in 2023, down to 30% in 2024.

There is already a common understanding across our sector that regional sites are under-represented in recruitment to commercially sponsored clinical trials. We acknowledge and applaud the significant and continuing efforts of many colleagues across our sector in tackling this ongoing and important issue.

Non-commercially sponsored trials are important trials; they are relatively easier to be selected for as a participating site, can be simpler to initiate, often provide drug access that would otherwise not be available to a patient, extend sector knowledge and provide valuable evidence for timing pre-and post-surgery, dose pacing and combination regimes, and are important for sites increasing their overall trial portfolio. However, such trials rarely cover their costs within trial units, placing a significant financial burden on trial units to support non-commercially sponsored activity.

Figure 25: Number of non-unique trials by year, sponsorship type and site location that recruited participants



A function of trial availability

To confirm clinical trial recruitment is directly related to the types of trials available to potential participants, we reviewed the sponsorship of trials available in both regional and metropolitan settings.

Figure 25 demonstrates that across metropolitan settings, commercially sponsored clinical trials constitute 67% to 76% of the recruiting cancer clinical trial portfolio across the 3-year census span. Whereas in regional settings such trials constituted 43% of the trial portfolio in 2022, 56% in 2023 and 64% in 2024.

This is a positive trend for regional trial sites, as increasing the portfolio of commercially sponsored clinical trials will help ensure the long-term financial sustainability of regional trial sites. Ideally this increased commercially sponsored trial availability will translate to increased recruitment to such trials over future years.

Please note that this analysis does not count by unique trial as it is necessary to accurately represent trials that recruited participants across both metropolitan and regional research sites.

Rural/Regional Travellers

Figure 26: Number of participants with a rural or regional residential address recruited at metropolitan sites

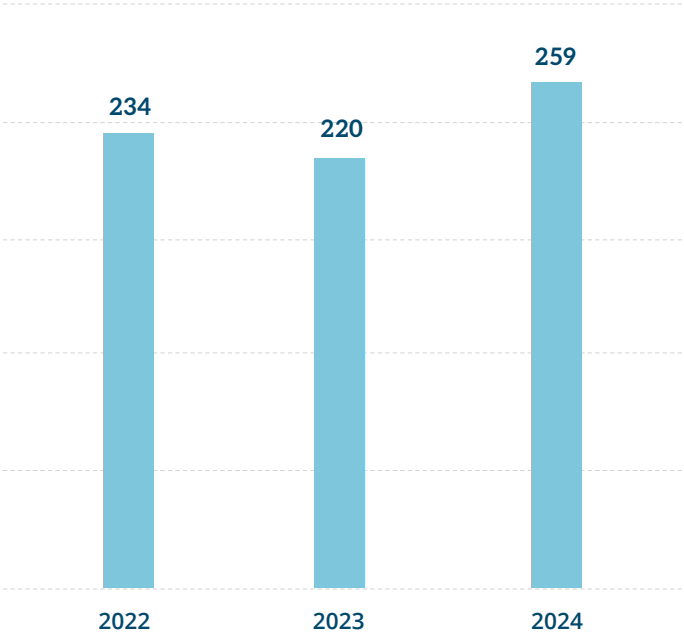
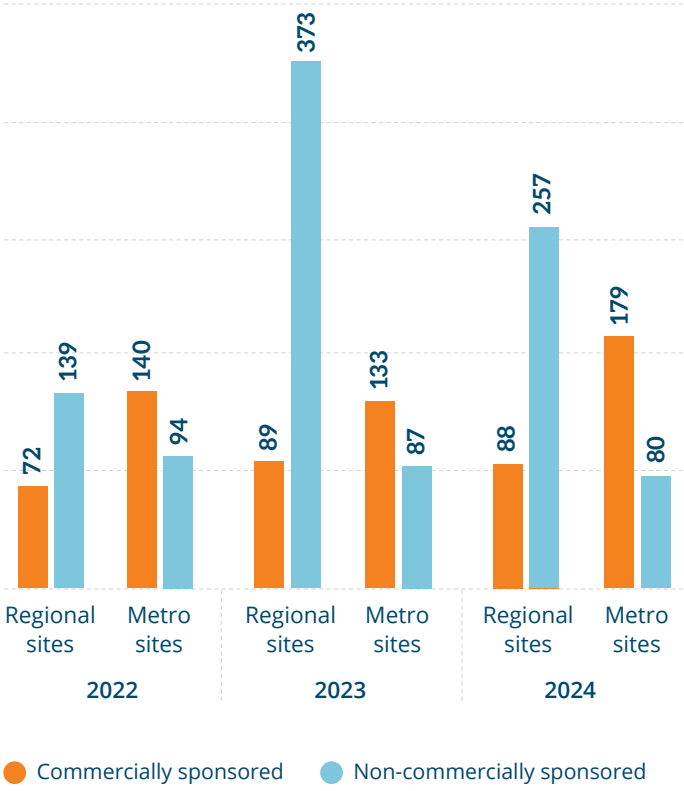


Figure 27: Number of participants with a rural or regional residential address recruited at metropolitan or regional sites by sponsorship type



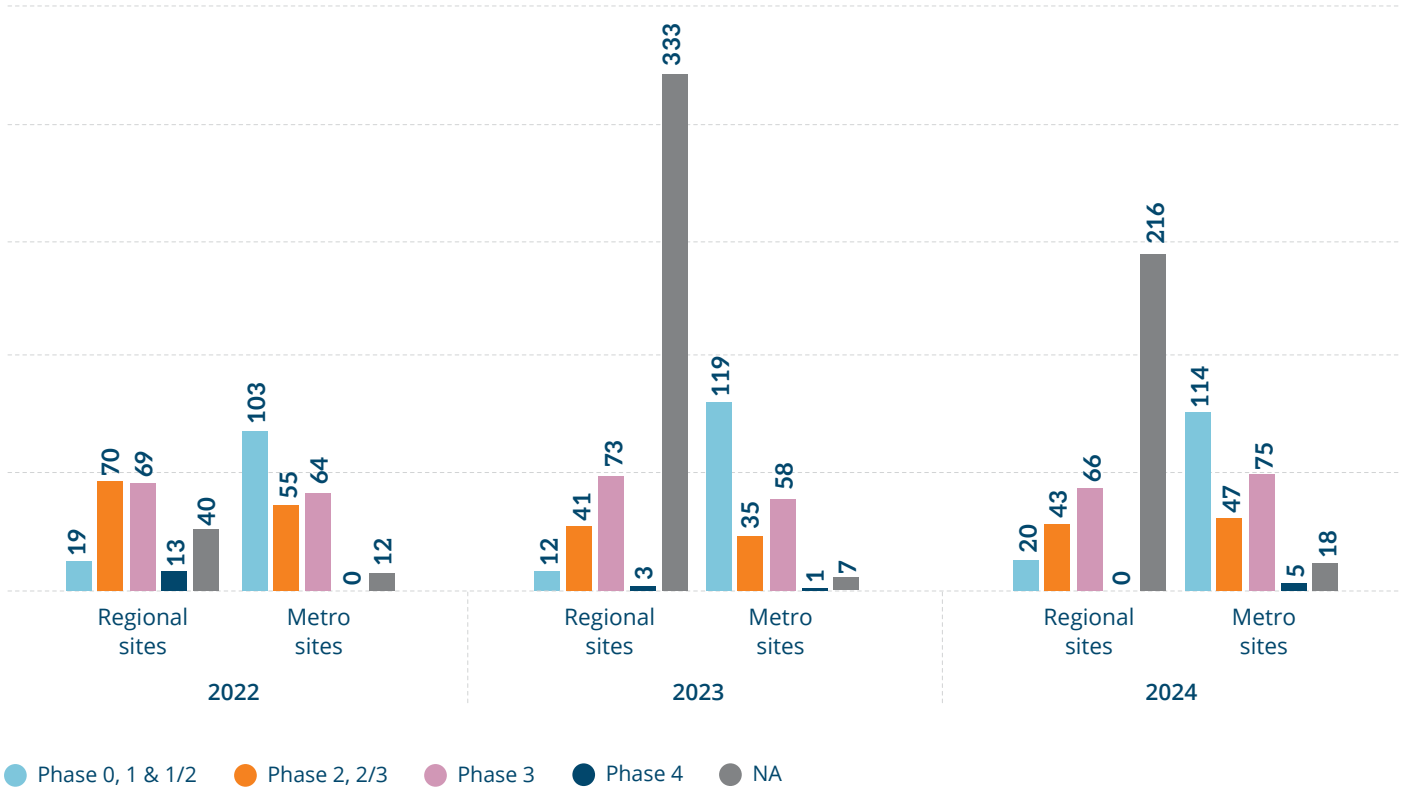
We noted earlier in Figure 2 that specific trial accessibility is largely site-specific, with the majority of trials opening at a single site. Coupled with rigorous inclusion and exclusion criteria, this often necessitates travel for participants from rural and regional residential postcodes (defined as MMM2-7) to access a clinical trial.

Figure 26 demonstrates that between 220 and 259 regional or rural participants per annum were recruited to a clinical trial at a metropolitan site across this 3-year census.

More likely to travel to access commercially sponsored clinical trials

Moreover, of the rural/regional based participants that were recruited at metropolitan trial sites, the largest proportion were recruited to commercially sponsored clinical trials, in contrast to recruitment at regional sites, which were predominantly to non-commercially sponsored trials.

Figure 28: Number of participants with a rural or regional residential address recruited at metropolitan or regional sites by Phase



More likely to travel to access Early Phase trials

Of the rural/regional based participants that were recruited at metropolitan trial sites, the largest proportion were recruited to Early Phase trials each year (Figure 28).

Source of Commercially Sponsored Clinical Trials – Size of Sponsor

Figure 29: Proportion of commercial trials sponsored by large pharmaceutical companies

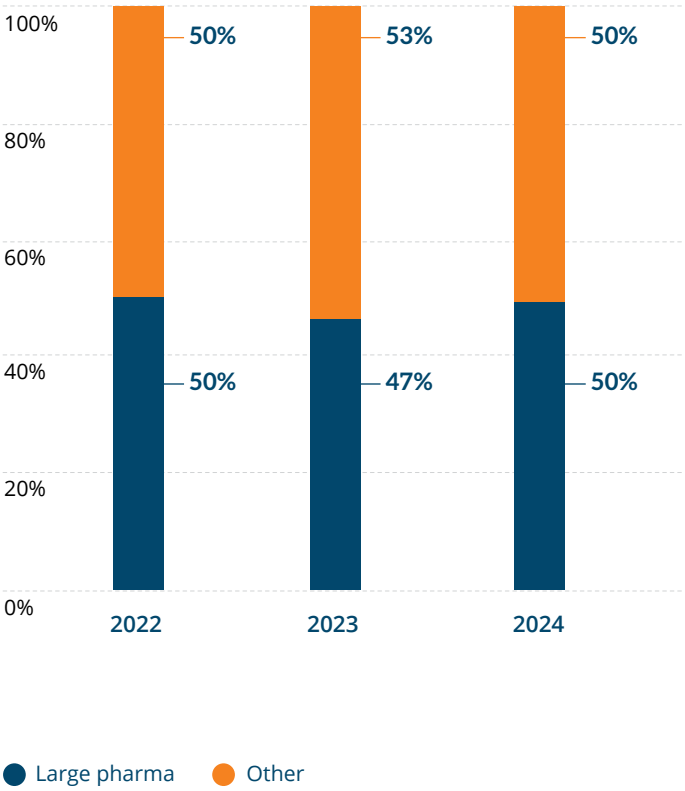
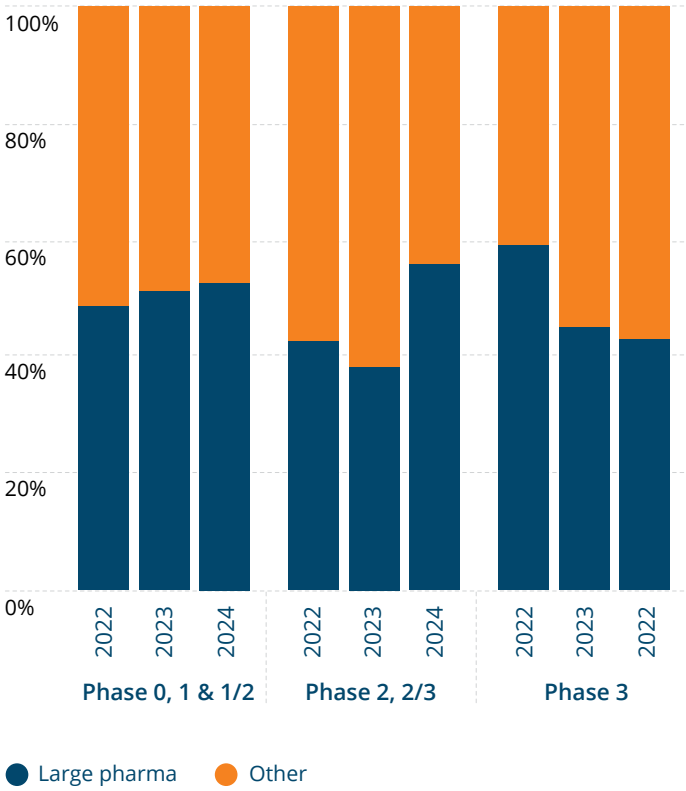


Figure 30: Proportion of commercial trials sponsored by large pharmaceutical companies by Phase



Globally, from 2014 to 2023, the proportion of commercially sponsored clinical trials initiated by large pharmaceutical companies across all tumour streams has decreased from 50% to 27%.[17] Large pharmaceutical companies were defined as those companies with greater than $10bn in annual sales.

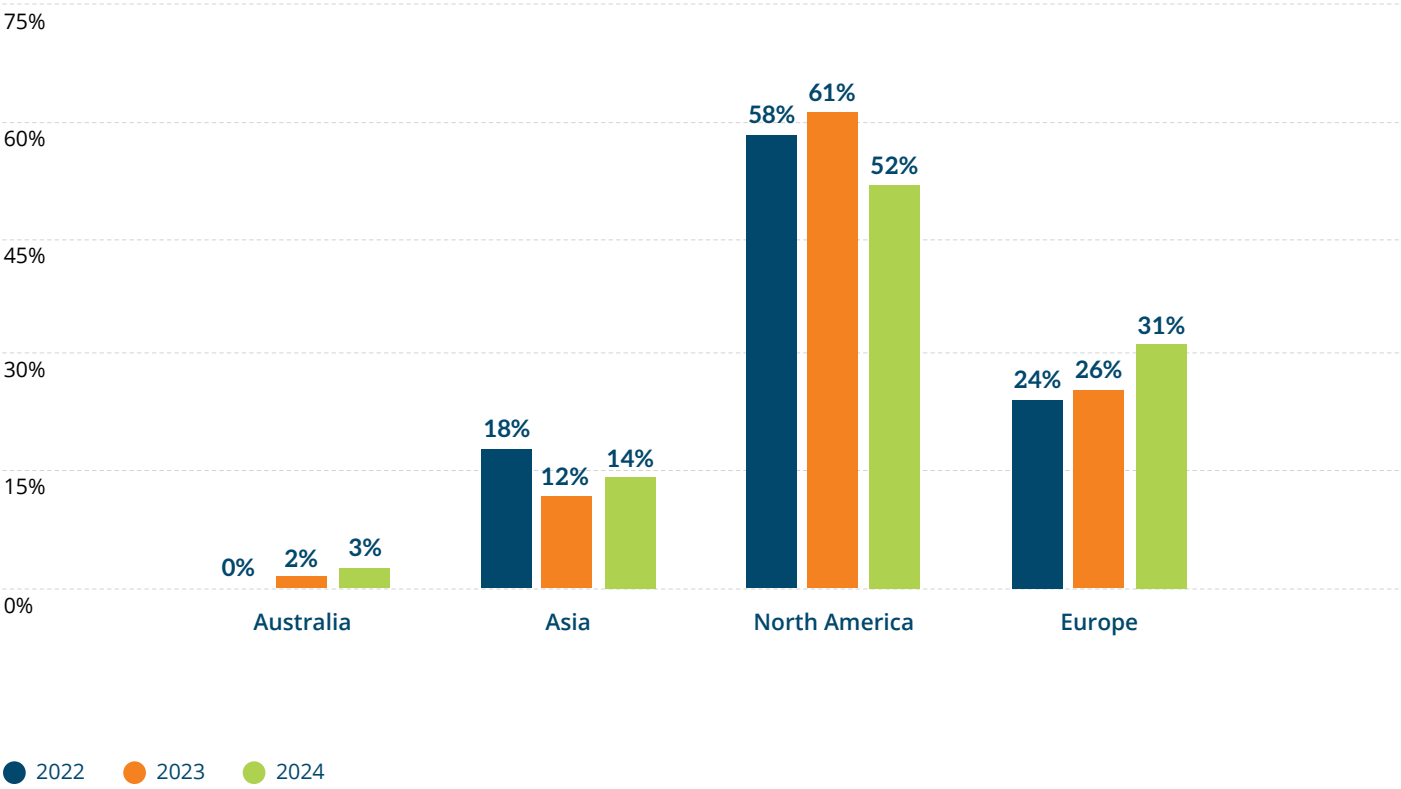
In Victoria, sponsorship of cancer clinical trials by large pharmaceutical companies remained steady at between 47-50% across 2022 to 2024 (Figure 29).

When further segmenting this by Phase, we see that large pharmaceutical companies remain active across all Phase groups (Figure 30).

[17] Annual trend report from the IQVIA Institute for Human Data Science, Feb 22, 2024, viewed 13 April 2025 Global Trends in R&D 2024: Activity, productivity, and enablers - IQVIA

Source of Commercially Sponsored Clinical Trials – Sponsor Region

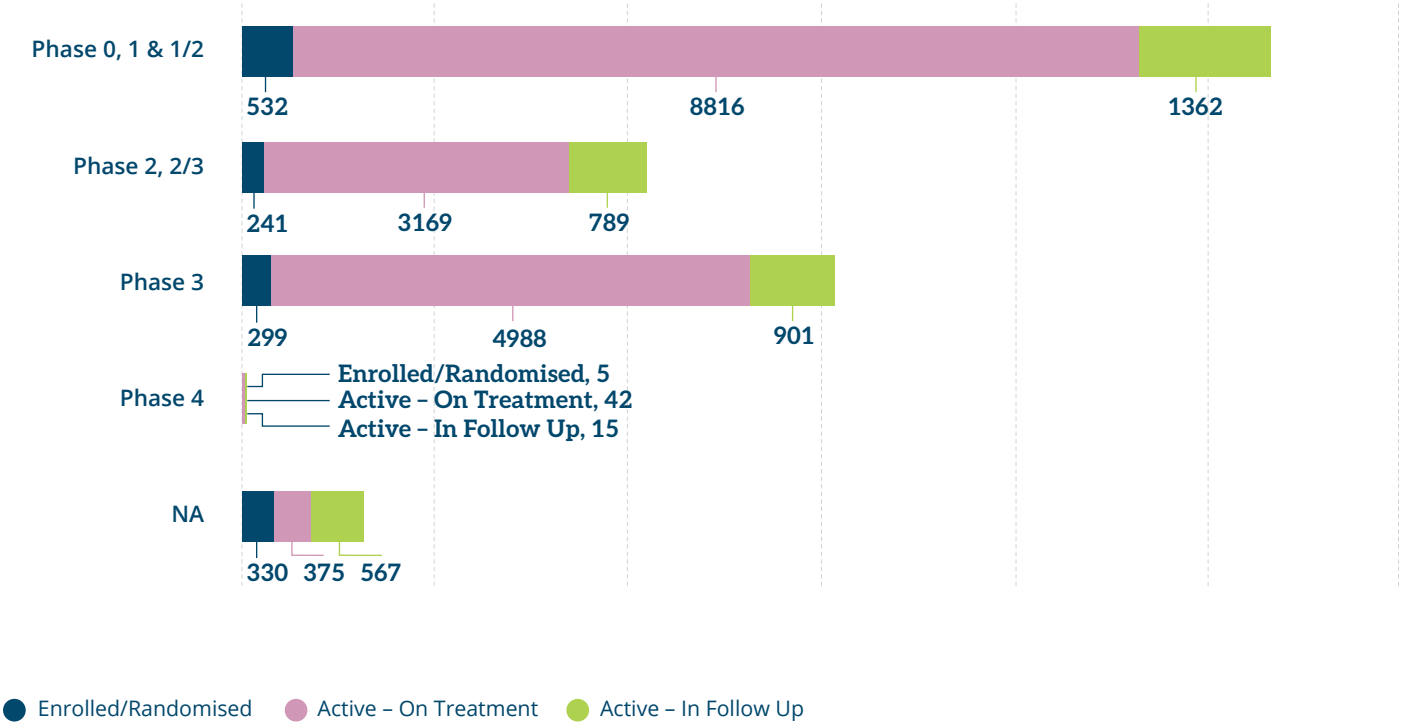
Figure 31: Proportion of commercial trials by Sponsor location



For the first time we are also able to report the proportion of commercial trials sponsored by companies headquartered in various global regions (Figure 31). Over recent years we have experienced an increase in trials from European sponsors, believed to be due to a number of factors including Brexit and the war in Ukraine, as well as the Victorian and Federal Governments increased focus on marketing our clinical trial ecosystem in Europe. It remains to be seen how recent and ongoing political changes within the USA may influence the future composition of commercially sponsored trials across Victoria.

More Than Recruitment

Figure 32: Number of participant visits across 2024 by visit type



Traditionally, trial activity and measurement of success within this sector has been reported through the number of participants recruited per annum, however, it is important to recognise that recruitment represents just a fraction of work undertaken by a clinical site.

With available data from sites that use Clinibase in their standard workflow for study start-up and financial management, which includes a wider set of data points throughout the life of each trial, we can report participant visit type.

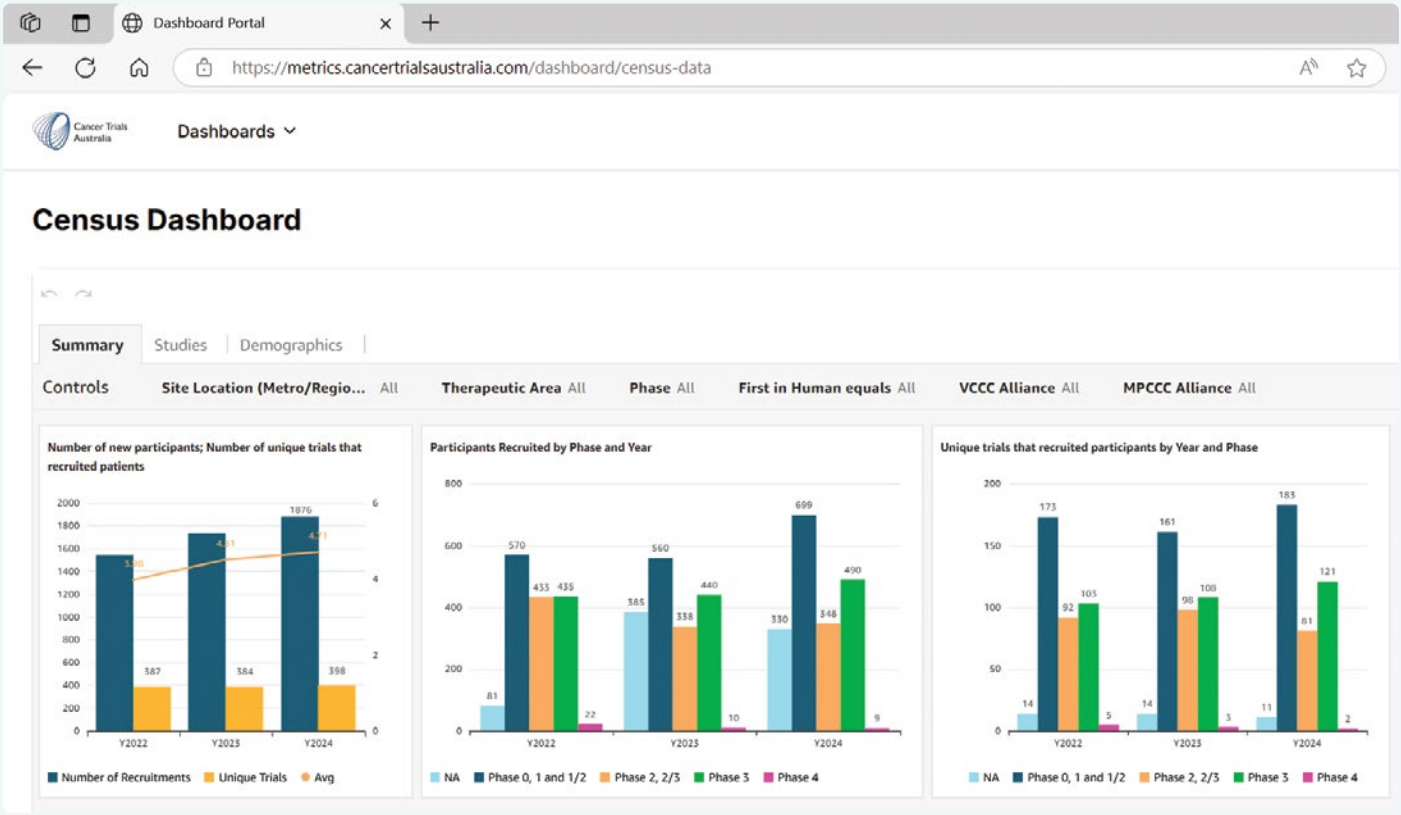
Across the available 2024 data, we recorded 1,407 new participants and 21,024 "On Treatment" or "Follow Up" visits undertaken – a recruitment-to-visits ratio of almost 1:16, and when looking at Phase 3 trials alone this rose to 1:24 (Figure 32).

Reporting the number of visits and type more broadly captures the workload of a clinical trials unit, however, it is also important to recognise not all visits are equal e.g. a single Phase 1 "On Treatment" visit can represent significantly more study coordinator and clinician hours, participant face-to-face time and workload around clinical management, compared to a Phase 3 "On Treatment" visit.

When coupled with the data presented previously regarding a propensity for lower-than-average recruitment to Early Phase trials (Figure 8), this data becomes extremely important for balancing understanding of relatively lower recruitment numbers with the increased workload placed on managing Early Phase participants. In future years, CTA plans to explore this area further to determine the magnitude of work undertaken per visit, towards a deeper measure of sector workload.

Census Dashboard

As part of Cancer Trials Australia's custodianship of this data set, we are pleased to provide ongoing access to the sector, to allow key stakeholder groups to assess the impact of their dedicated efforts in improving trial availability and recruitment.



A dynamic dashboard is available at https://metrics.cancertrialsaustralia.com/ which contains anonymised data relating to this report.

Towards the Future

This project presents a unique opportunity to provide meaningful analysis for sites in their pursuit of the best treatment options for their patients.

Cancer Trials Australia is incredibly proud to present this data, showcasing the hard work and dedication of all participating sites. Work continues to secure 2022-2024 data from additional sites and departments.

We thank everyone who has contributed to this project to-date and look forward to future editions.
For further information regarding this report, or to discuss accessing the available data set, please contact:

Emily England
Information Systems Manager
Cancer Trials Australia
Emily.England@ctaust.org

Index of Figures

^These Figures contain data from 15 of the 19 clinical sites that provided data to support this census, as those 15 sites utilise Clinibase in the day-to-day management of their clinical trial portfolio.

P: 61 3 8559 7244
General enquiries: info@ctaust.org
www.cancertrialsaustralia.com