

Alfred Health

# Evaluation of the TrialHub Pilot Program

## Final Evaluation Report

8 May 2025

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# Infographic

## The TrialHub Initiative

An Australian-first clinical trial (CT) partnership model established by Alfred Health and funded for 6 years by the Australian Government Department of Health and Aged Care.

## Objective

To improve access & increase participation in CTs for people who live outside of metro areas, identify as First Nations and/or other disadvantaged Australians, & have been diagnosed with rare cancers & diseases, prostate cancer, melanoma, & other key conditions.

## Partnerships

Established with Alfred Health as the primary site, alongside flagship sites: Bendigo Health, Latrobe Regional Health, Northern Health, Peninsula Health (Rosebud Hospital), Mildura Base Public Hospital & Bass Coast Health.\*

## TrialHub's Impact

### Evaluation Findings:

#### Developed workforces

- **61% CT staff increase** across flagship sites
- Capability framework & training programs built sustainable infrastructure

#### Established partnerships & collaborations

- **32 partnerships** with sites, not-for-profits & International organisations
- **48 Sponsor relationships** supported

#### Expanded community engagement

- **Ambassador program** engaged community via word-of-mouth
- **Tailored resources** targeted at diverse populations

#### Increased CT activity

- **138 new CTs since 2020**
- Diversified CT portfolios
- Increase in CT complexity

#### Improved CT access

- **Reduced travel time for participants**
- Teletrials & decentralised models enhanced CT access

#### Implemented unique approach

- Comparisons with other initiatives show **THs distinct & effective approach** centering mentorship & capability building

#### Created sustainable impact

- **Diversified income streams** for ongoing activity
- Established sustainable networks and relationships

### National Impacts:

#### Specialised workforce training programs:

- Pharmacy Train the Trainer program
- Regional Fellowship program
- Monash University-credentialed courses

Communication strategy with clear, common message shared with the community

Collaborative standardisation of teletrial resources

Clinical Trial Capability Framework used nationally

National Clinical Trial Governance Framework mentoring leadership

Rare Cancer Clinical Trials Alliance

Consumer-led communication for International CTs Day

## Conclusion & Opportunities

### TrialHub has effectively

- **Enhanced workforce capability** across sites
- **Enhanced CT access** through technologies
- **Increased CT activity** in areas of need
- **Identified opportunities** for ongoing CT quality improvement
- **Developed local and international partnerships**
- **Promoted CT value** CTs across target populations
- **Expanded geographical access** to CTs across priority areas

### Further impacts possible through

- Further **collaborative integration** with other programs
- Continued **workforce sustainability** efforts
- **Expanded community engagement** & outreach
- Increased **network expansion**
- **Enhanced diversification** of CT portfolios
- **Capability framework** refinement

Source: Adapted from [TrialHub Impact Brochure](#)

\*Note: This evaluation includes the 'flagship regional sites', including Bendigo Health, Latrobe Regional Health, Northern Health and Peninsula Health

# Executive summary

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## Context

TrialHub is an Australian-first clinical trial (CT) partnership model, established in November 2019 and funded by the Australian Government through the Community Health and Hospitals Program (CHHP). Based at Alfred Hospital, TrialHub has formed partnerships with six flagship sites: Bendigo Health, Latrobe Regional Hospital, Northern Health, Peninsula Health (Rosebud Hospital), Mildura Base Public Hospital, and Bass Coast Health.<sup>1</sup>

TrialHub aimed to improve access to and participation in CTs for underserved populations, including those living in outer metropolitan, regional, rural, and remote areas; Aboriginal and Torres Strait Islander communities; and individuals diagnosed with rare cancers, prostate cancer, melanoma, and other priority conditions. To achieve this, TrialHub supported flagship sites to become financially sustainable CT units that can independently attract funding or collaborate with established trial centres. This involved workforce development, strategic partnerships, infrastructure enhancement, and targeted promotional activities to ensure equitable access to high-quality CTs across Victoria.

## Independent evaluation

The independent evaluation, conducted from August 2021 to March 2025, assessed TrialHub's impact on capability building, partnerships, community engagement, trial activity, and sustainability. Evaluation activities included periodic reporting of CT activity across six intervals between September 2022 and March 2025. Data collection involved surveys completed by CT participants (N=267), CT staff (N=160), and training participants (N=83), along with analysis of trial activity, workforce, and funding data. Flagship site managers provided sustainability assessments, and qualitative insights were gathered through targeted case studies (with flagship site representatives) and stakeholder interviews (e.g., representatives from non-flagship sites, related programs, etc.). An interactive evaluation dashboard supplemented these findings, enabling ongoing tracking of TrialHub's performance against key indicators at each flagship site and across Victoria. This document represents the final evaluation report.

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<sup>1</sup> Mildura Base Public Hospital and Bass Coast Health are not included in the evaluation agreement between TrialHub and HealthConsult and as such, unless explicitly mentioned, do not form part of the analysis presented in this report.

# Summary of findings

- 1. Workforce development:** TrialHub has significantly enhanced workforce capability by establishing professional development pathways, creating structured training programs, and implementing mentoring relationships between metropolitan and regional sites (i.e., flagship and non-flagship sites). Since 2022, flagship sites have increased staff numbers by 61%, with notable growth in lead investigators (148% increase). Training program opportunities have created sustainable workforce development infrastructure that enables sites to respond effectively to staffing challenges.
- 2. Partnerships and collaboration:** TrialHub has fostered extensive collaborative networks, supporting 32 formal partnerships across health services, not-for-profit organisations, and international bodies. This network approach has created a more adaptive CT ecosystem where regional sites increasingly function as peers rather than remaining dependent on metropolitan services. TrialHub has also supported sites' business development and sponsor engagement activities. Notably, a sponsor workshop facilitated industry connections, helping regional sites attract commercial trials that enhance their financial sustainability.
- 3. Community engagement and CT promotion** Innovative engagement strategies, including the Ambassador Program featuring former trial participants, structured communication plans, and tailored resources for diverse communities have increased CT awareness and participation. Flagship sites have developed capabilities to align CT portfolios with local health priorities through community input, enhancing relevance and participation rates.
- 4. CT activity:** Since 2020, 138 new CTs have opened across flagship sites, with significant portfolio diversification beyond oncology. Sites have progressed to more complex trial types, demonstrating increased maturity and capability. Common cancers represent the majority of CTs (80%), with trials for rare cancers now established across the network.
- 5. CT access:** TrialHub has expanded geographical access to trials, with participation extending to outer metropolitan and regional areas. Teletrials and decentralised models have reduced travel barriers for patients, with eight teletrials activated across flagship sites. Innovative care models have allowed patients to receive specialised treatment phases at metropolitan centres while maintaining ongoing care at local flagship sites.
- 6. Program impact and sustainability:** Sites have diversified their income streams, reducing reliance on grants by attracting CT funding or forming partnerships with other CT units to sustain their research activities. The capability framework developed by TrialHub, now recognised internationally, provides a structured approach to assess and develop CT

capabilities in outer metropolitan and regional health services, and is aligned with the National Clinical Trials Governance Framework.<sup>2</sup>

- 7. Comparison to other initiatives:** Unlike other CT initiatives (e.g. National One Stop Shop (NOSS)) that focus primarily on administrative streamlining or telehealth technologies, TrialHub's distinctive approach emphasises direct health service mentoring, workforce capability building, and financial sustainability. This complementary strategy addresses fundamental capability barriers that otherwise limit the effectiveness of system-level solutions.

## Conclusion

TrialHub has supported a transformation of the clinical trial landscape across Victoria by building sustainable CT capabilities in regional and outer metropolitan health services. This independent evaluation confirms TrialHub has achieved its core objectives while creating lasting structural change that extends trial participation well beyond major metropolitan centres. TrialHub's evidence-based approach offers a proven model that could be expanded nationally to address healthcare inequities while strengthening Australia's position in the global CTs sector.

**Future opportunities** to build upon TrialHub's achievements include:

- strategic integration with complementary national initiatives (e.g., NOSS)
- expanding the network to support smaller regional centres through tiered mentoring models
- strengthening workforce sustainability through formalised professional development pathways
- diversifying trial portfolios to address local health priorities
- enhancing community engagement with tailored strategies for diverse populations
- refining the capability framework to maintain alignment with national standards.

These coordinated efforts would further extend equitable access to CTs while building Australia's reputation as a preferred location for innovative research.

Realising these opportunities will require sustained funding support, strategic partnerships, and ongoing commitment to TrialHub's collaborative approach to building CT capabilities in outer metropolitan, regional, and rural Victoria.

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<sup>2</sup> National Clinical Trials Governance Framework, developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC), provides national standards for the governance, oversight, and management of CTs. Its primary goal is to enhance the safety, quality, efficiency, and effectiveness of CTs conducted in Australian health services. The framework outlines responsibilities, processes, and performance indicators to ensure that CTs are appropriately integrated into health service operations, promoting transparency, accountability, and continuous quality improvement across the CT landscape in Australia.

# 1. Introduction

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## 1.1. Project background

On 3 August 2021, Alfred Health engaged HealthConsult to conduct an:

### ***"Evaluation of the TrialHub Pilot Program"***

TrialHub is an Australian-first clinical trial (CT) partnership model established in November 2019 in recognition of the need for developing effective and supportive pathways to ensure trial capability growth and sustainability. The pilot program received six years of funding (initially \$24.6 million revised to \$16 million in August 2023) from the Australian Government Department of Health (the Department) as part of the Community Health and Hospitals Program (CHHP). The original activity workplan was revised and approved by the Department in September 2023 to reflect the revised funding.

TrialHub's objective was to improve access and increase participation in CTs for people who:

1. live in outer metropolitan, regional, rural, and remote areas
2. identify as First Nations people and/or other disadvantaged Australians
3. have been diagnosed with rare cancers and/or diseases, prostate cancer, melanoma, and other key identified areas.

TrialHub aimed to achieve this objective by supporting regional/rural CTs units to become self-sustainable and financially viable (i.e., capable of attracting funding for CTs or partnering with other CTs units to maintain existing CTs activity). To date, TrialHub has formed formal partnerships with outreach 'flagship' sites, including Bendigo Health, Latrobe Regional Hospital, Northern Health, Peninsula Health (Rosebud Hospital), Mildura Base Public Hospital and Bass Coast Health.<sup>3</sup> TrialHub has supported these flagship sites to become financially sustainable CT units.

## 1.2. Evaluation aim and questions

This independent evaluation, which aims to assess the impact of TrialHub, commenced in August 2021. The independent evaluation has included periodic reporting of TrialHub's impact on CT activity in Victoria (in September 2022, March 2023, September 2023, March 2024, September 2024, and March 2025). Due to a reduction in funding, an economic evaluation of the TrialHub model, which was being separately commissioned, was unable to be completed.

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<sup>3</sup> Mildura Base Public Hospital and Bass Coast Health are not included in the evaluation agreement between TrialHub and HealthConsult and as such, unless explicitly mentioned, do not form part of the analysis presented in this report.

The evaluation activity was guided by seven key evaluation questions (KEQs):

1. Has TrialHub provided tools and resources to build workforce capability to support investigator-initiated CTs?
2. Has TrialHub developed local and international partnerships and collaborations that enhance Australia as a preferred provider of CTs?
3. Has the use of technologies enhanced access to CTs in agreed priority areas of prostate and rare cancers, melanoma and other disease groups approved by the Department in outer metro, regional, and remote areas?
4. Has TrialHub promoted the value of CTs to the broader population? Has this resulted in improving access and CTs participation?
5. Has TrialHub increased CTs activity in areas of need (i.e., outer metro, regional, rural, and remote areas)?
6. What impact on access to cancer CTs has TrialHub had for patients within agreed priority areas of prostate cancer, melanoma, rare cancers, rare diseases, and other priority areas in outer metropolitan, regional and remote areas of Victoria?
7. Has TrialHub identified opportunities to augment ongoing quality improvement for investigator-initiated and commercially sponsored CTs?

## 1.3. Structure of this report

This Final Report consolidates the key project findings. Data informing this report includes surveys completed by:

- CT participants (N=267 across all reporting periods)
- CT staff (N=160 across all reporting periods)
- CT training participants (N=83 across all reporting periods).

CT activity, workforce, and funding data were provided by the flagship site managers, who also completed the Program Sustainability Assessment Tool (PSAT). Additionally, data for this report was obtained by HealthConsult via case studies (with flagship site representatives) and stakeholder interviews (e.g., representatives from non-flagship sites, related programs, etc.) conducted in March 2025.

This report is supplemented by an interactive TrialHub evaluation dashboard developed by HealthConsult that compiles data collected from the completed survey periods (see Appendix A) and enables tracking of TrialHub's progress at each flagship site and across the state.

For the logic model and evaluation framework please refer to Appendix B and C, respectively.



The report is structured as follows:

- **Chapter 2: Workforce development.** Examines TrialHub's workforce development initiatives that enhanced regional CT capabilities.
- **Chapter 3: Partnerships and collaboration.** Explores how TrialHub fostered regional networks, facilitated industry connections, and supported partnerships with various health services and organisations to enhance CT activities and access across participating sites.
- **Chapter 4: Community engagement and CT promotion.** Details TrialHub's communication and engagement strategies to promote CT awareness and participation across partner sites.
- **Chapter 5: CT activity.** Examines the growth in CT activity across flagship sites, portfolio diversification, and progression to more complex trial types demonstrating increased site maturity.
- **Chapter 6: CT access.** Examines TrialHub's impact on improving CT access for patients in areas of need through innovative care models including teletrials and addressing geographical barriers to participation.
- **Chapter 7: Program impact and sustainability.** Examines TrialHub's contribution to quality improvement, funding diversification, and development of sustainable CT infrastructure across participating sites.
- **Chapter 8: Comparative analysis of TrialHub and related national initiatives.** Compares TrialHub's approach with other national initiatives, highlighting its distinctive focus on health service mentoring, capability building, and financial sustainability.
- **Chapter 9: Conclusion and future opportunities.** Summarises TrialHub's transformative impact and identifies strategic opportunities for further enhancing CT access, workforce development, partnerships, and community engagement.

## 2. Workforce development

This Chapter examines how TrialHub's workforce development initiatives have created the essential foundation upon which expanded CT capabilities have been built across flagship sites and explores the impact of these activities on workforce retention, professional standards, and overall CT delivery capabilities.

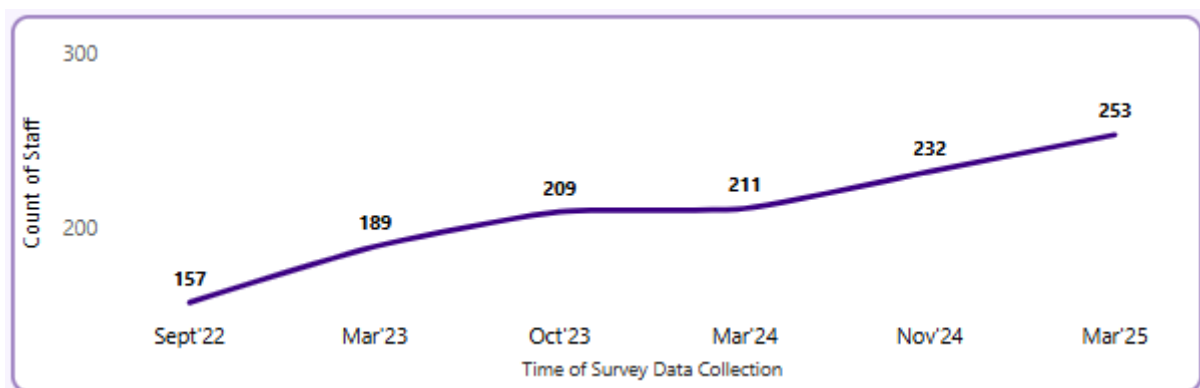
### 2.1. Building workforce development infrastructure

Workforce development represents the cornerstone of sustainable CT programs, particularly in regional and rural health settings where access to specialised expertise has traditionally been limited. As part of TrialHub's strategic approach, workforce development addresses the fundamental challenge of building and maintaining a skilled CT workforce.

TrialHub's workforce development activities have evolved beyond ad-hoc training to establish structured pathways. The program's systematic approach includes baseline needs assessments, tailored educational resources, staged implementation plans, and ongoing evaluation – all customised to meet the unique requirements of sites with varying levels of CT maturity. In establishing this foundation, TrialHub has addressed a significant gap in Australian CT education.

Since September 2022, flagship sites (Bendigo Health, Latrobe Regional Health, Northern Health and Peninsula Health) have collectively added 96 staff to support CT activity and operations in their CT units, which represents an overall 61% increase in CT unit staffing (Figure 1).

**Figure 1: CT staff (personnel) at TrialHub flagship sites**



Source: HealthConsult, Ongoing site survey on CT Workforce development

**TrialHub's distinctive approach focused on infrastructure supporting comprehensive, ongoing local workforce development**, rather than simply providing funding for additional positions.

This included:

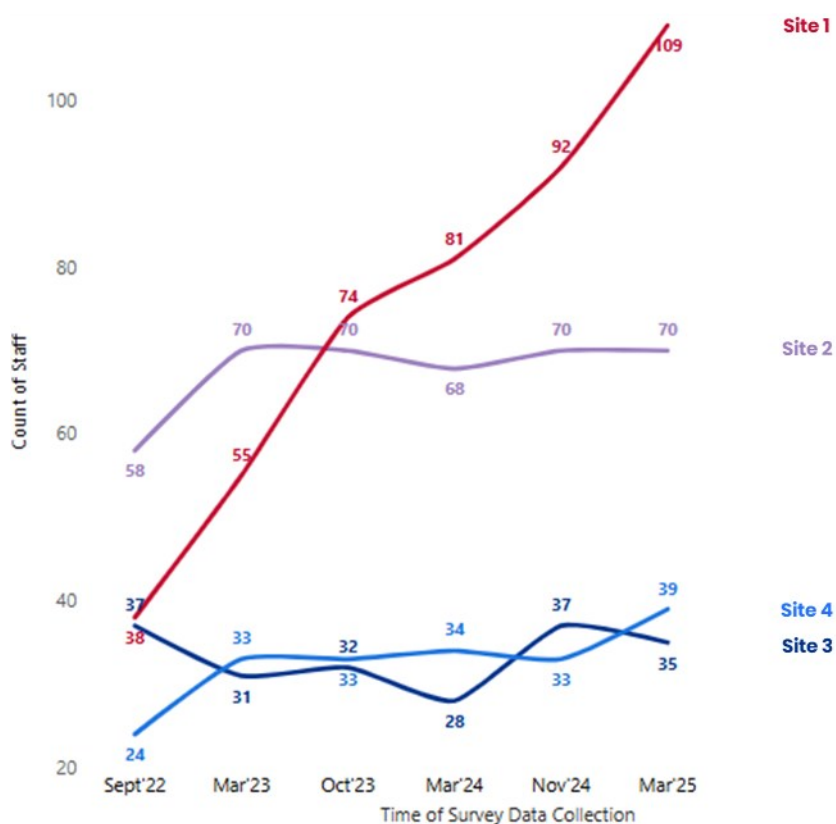
- direct on-site engagement with health services
- understanding and encouraging local ambitions for CT delivery
- executive education about the value of CTs to health services
- developing comprehensive workforce plans
- providing targeted support where required.

*"It's actually not enough just to throw money at sites and to start doing trials. It's such a more complex problem to fix that requires a much more comprehensive appreciation of the workforce that's actually required."*

TrialHub representative

TrialHub's flagship sites have been able to increase or maintain their CT workforce (Figure 2). Latrobe's CT staffing levels have increased significantly while the other sites have successfully maintained their overall staffing levels. Interviewed site representatives highlighted this as an achievement attributable to TrialHub's support, noting that they are not as vulnerable to staff shortages due to the workforce development infrastructure that TrialHub has helped create.

**Figure 2: CT staff (personnel) across reporting periods by TrialHub site**



Source: HealthConsult, Ongoing site survey on CT Workforce development

**TrialHub supported sites to assess staffing levels and skills to understand their overall CT capacity** which helped provide clarity on their workforce development needs. This built sites' internal capabilities to understand their workforce development needs and therefore to respond appropriately to any staffing and training requirements over time. TrialHub worked with its flagship sites to build sustainable staffing models, create formalised tools and to implement and maintain these. TrialHub also shared key workforce development tools. For instance, Bendigo Health representatives commented that TrialHub's induction program and upskilling strategy were particularly beneficial to ongoing workforce development efforts. Similarly, Latrobe Regional Health appreciated the workforce development groundwork laid through TrialHub's support.

*"TrialHub helped establish good foundations that will enable continued operations without support."*

Latrobe Regional Health representative

**TrialHub took a stepwise engagement approach** with each site which incorporated:

- Mentorship
- In-house training program strategies
- Ongoing professional development.

This approach was guided by close engagement with individual CT units and health service organisation governance bodies, enabling education programs driven by CT needs as well as oversight strategies for upskilling at each site. Site activity engagement sessions were tracked to map the progress of upskilling implementation and informed the development of the capability framework.

**The capability framework developed by TrialHub** provides a structured approach to assess and develop CT capabilities in outer metropolitan, regional and rural health services. The capability framework is focused on trial operations, including the minimum support services, staffing, safety standards and other requirements to ensure safe and appropriately supported CT operations within a health service.

The framework applies a maturity model that evaluates sites across five capability levels (Level 0 – 4): (0) formative, (1) developing, (2) established, (3) high performing, and (4) leading. It identifies six core factors that are pivotal for site development: infrastructure, leadership and culture, organisational support, technologies, staff skills, and networks and collaboration. The structured assessment allows for targeted, stage-appropriate support rather than applying a one-size-fits-all approach, ensuring that resources are allocated efficiently to match each site's development needs.

**TrialHub's approach emphasised embedding capability building within organisational practice.** For instance, through establishing internal mentoring relationships across teams. In

particular, the TrialHub Senior Education Manager was recognised for enhancing upskilling and CT workforce development capabilities.

*"We have built upskilling capabilities through the TrialHub Senior Education Manager, including workforce development across the organisation through mentoring, in more than just in the cancer space."*

Latrobe Regional Health representative

## **The capability framework supports compliance with the Clinical Trials Governance**

**Framework.** The capability framework was mentioned by several interviewed site representatives as particularly useful in supporting their adherence to CT Governance standards, important for overall CT capability.

*"We've got an MOU going to our research steering committee that is proposing that we're supported for TrialHub's Senior Education Manager to be seconded to Bendigo Health for a day a week to help implement the workforce capability framework. We know we need to work on it to achieve compliance and professionally develop our team."*

Bendigo Health representative

Additionally, the capability framework was highlighted as important for CT unit capabilities and sustainability, as it assisted with garnering executive-level support and CT buy-in when executives understood its alignment with broader required clinical standards. TrialHub's approach foregrounded the importance of hospital executives' engagement and the need to educate executives about CTs' benefits for overall health service quality.

*"[Prior to TrialHub there was] almost complete absence of executive understanding of what a trial was even at large health services. It's important to have top-level board and executive buy-in for developing CT capabilities."*

TrialHub representative

## **2.2. Staffing, training and professionalisation**

TrialHub established new senior positions across sites and supported staff training, further study and formal credentialling to build skills and credibility to conduct CTs. Taken together, these initiatives have built CT capabilities, and enhanced staff professional development, with the added benefit of this aiding recruitment and retention by enhancing the attractiveness of CT roles and career pathways not previously available or accessible to many in regional areas.

### **2.2.1. Additional staffing and senior positions**

Sites reflected that the establishment of new positions and additional resourcing within their CT units had positive impacts upon internal unit growth and capability.

**TrialHub contributed to increases in overall staffing levels**, including by directly funding a total of 33 positions. However, there is uncertainty about what will happen to these staff positions, with some sites reporting they will be maintained while others express doubt about their future status. TrialHub's activities also indirectly supported seven additional roles which were needed due to increased CT activity resulting from the capability uplift. These positions included those supporting CT unit growth, such as CT unit managers, CT coordinators, research nurses, administrative support, educators, implementation officers, research fellows, research governance officers, communications roles, project managers, and regional care navigators.

**Employing senior staff brought considerable skills and experience** into CTs, which contributed to overall CT capacity and workforce capability. The number of senior staff has increased considerably in the flagship sites (Table 1). For instance, the number of lead investigators has more than doubled (increase of 148%) from 31 in September 2022 to 77 in March 2025. New positions were also established in the sites. Staff are now employed in CT specific roles including administrative and CT assistants, CT educators, CT unit managers, data managers, and ethics coordinators.

**Table 1: CT workforce at TrialHub flagship sites**

Role	Sept'22	Mar'23	Oct'23	Mar'24	Nov'24	Mar'25
Administrative Assistant	0	2	2	2	2	2
Clinical Trial Assistant	0	2	1	3	2	2
Clinical Trial Coordinator	19	18	20	19	21	21
Clinical Trial Educator	0	0	0	1	1	1
Clinical Trial Unit Manager/Research Manager	0	4	4	4	4	4
Data Manager	0	1	1	1	2	2
Day ward chemotherapy nurse	30	47	47	47	47	50
Ethics Coordinator/Submission Specialist	0	3	3	3	3	3
Lead Investigators	31	35	48	47	59	77
Other	1	1	7	8	8	6
Research Fellow / ECR / Research trainees	13	8	10	7	11	12
Research nurse	10	7	8	11	10	10
Specialist Practitioner	53	61	58	59	62	63
<b>Total</b>	<b>157</b>	<b>189</b>	<b>209</b>	<b>211</b>	<b>232</b>	<b>253</b>

Source: HealthConsult, Ongoing site survey on CT Workforce development

An interviewee commented that while Bendigo Health has had a CT unit for over 20 years, their capability and staffing capacity only improved due to the introduction of dedicated senior positions, which have enabled significant growth in their CT operations. These additional resources strengthened the existing team and helped broaden the number of CTs, which was also seen to have increased staff satisfaction.

*"I would say that it wouldn't have been possible to have those positions in that time frame. [It] means we had more resources to then increase our CT capability and capacity, rather than it grow organically and more slowly."*

Bendigo Health representative

In particular, the establishment of Research Fellow positions associated with the fellowship program (outlined further in section 2.2.2) was seen as key to sites' workforce capacity and capability to lead CTs.

*"We have fellowships now in hematology organised through partnership which has developed our workforce capacity."*

Latrobe Regional Health representative

An interviewed Bendigo Health representative commented that the establishment of a Research Fellow position was one of the most crucial components of TrialHub as it enhanced their site's CT capability.

*"Before TrialHub, we didn't have a Research Fellow at all. This has been incredibly useful because she could help direct people to which CTs were available, and this bolstered capacity to look after own CTs, which made a huge impact."*

Bendigo Health representative

A representative from Northern Health reported that the fellowship program for medical staff had strengthened their site's capacity. TrialHub funding also allowed the fellowship position to be split, enabling senior expertise to be shared across multiple areas.

*"TrialHub funding enabled splitting the fellowship position to cover both oncology and haematology."*

Northern Health representative

Overall, employing additional staff and particularly the additions of senior staff, including through the fellowship programs, brought resourcing, skills and experience into CTs, which contributed to overall CT capacity and workforce capability.

### 2.2.2. Professional development

**TrialHub provided professional development support for early career researchers** (ECRs) to coordinate CTs. This was in part aimed at attracting skilled researchers to career opportunities and development pathways, generally uncommon in regional areas. TrialHub intentionally took a focus on medical workforce retention in regional settings by providing support for internal career advancement through building CT coordination and leadership experience, rather than simply funding further coordination positions. One TrialHub representative highlighted the importance of structured programs to support the professional development of ECRs through

providing more career advancement opportunities than are often available in regional areas, thereby supporting position attractiveness and retention.

Interviewed representatives across multiple sites commented that associate investigators were given the opportunity, supported by TrialHub, to step up and lead their own CTs. This developed their confidence and experience in conducting investigator-initiated CTs.

*"I am now the primary investigator on a few trials, which probably wouldn't have been the case without the education and support of TrialHub."*

Peninsula Health representative

TrialHub's support of associate investigators leading CTs worked to address study coordinator and CT leadership shortfalls across the sector, which can have consequences for trial activity.

*"I think the main limiting factor in most sites nowadays is good study coordinators and you see that from Peter Mac to Monash, through everywhere. We had to cap trial enrolment because there weren't enough good study coordinators."*

Peninsula Health representative

Enhancing the leadership capabilities of staff through focusing on their professional skill development was viewed by site representatives as enhancing sites overall capacity and capability to conduct CTs.

### 2.2.3. Training and credentialling

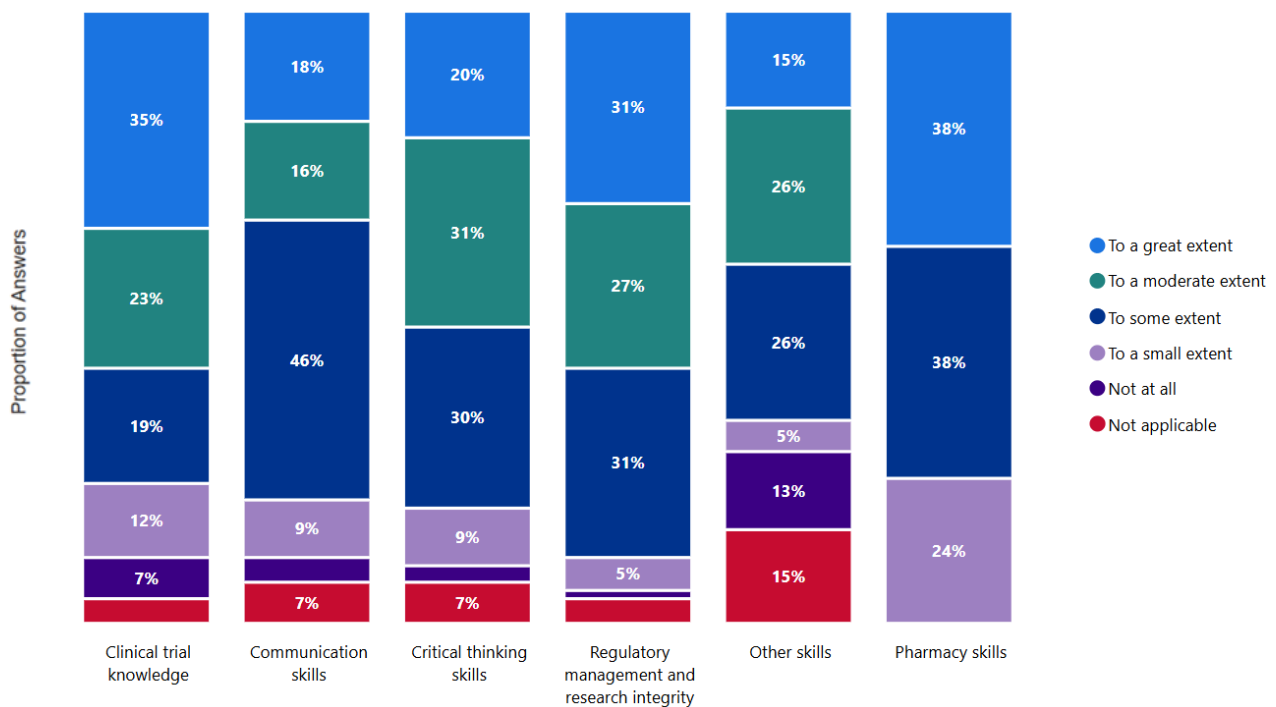
**TrialHub supported access to specialised training programs** for different groups of staff including CT nurses and pharmacists. These programs included:

- Fellowship programs
- CT Coordinator (CTO) education and mentoring program
- Pharmacy Train the Trainer program.

Training participants reported enhanced skills because of their participation. When asked to indicate the extent to which specific skills increased due to their participation in training, most respondents (94%) noted improvements in regulatory management and research integrity, demonstrating the impacts of training activities in supporting alignment with CT standards (Figure 3).



**Figure 3: Extent of skill enhancement among CT training participants**



Source: HealthConsult, Training Participant Survey, n=74

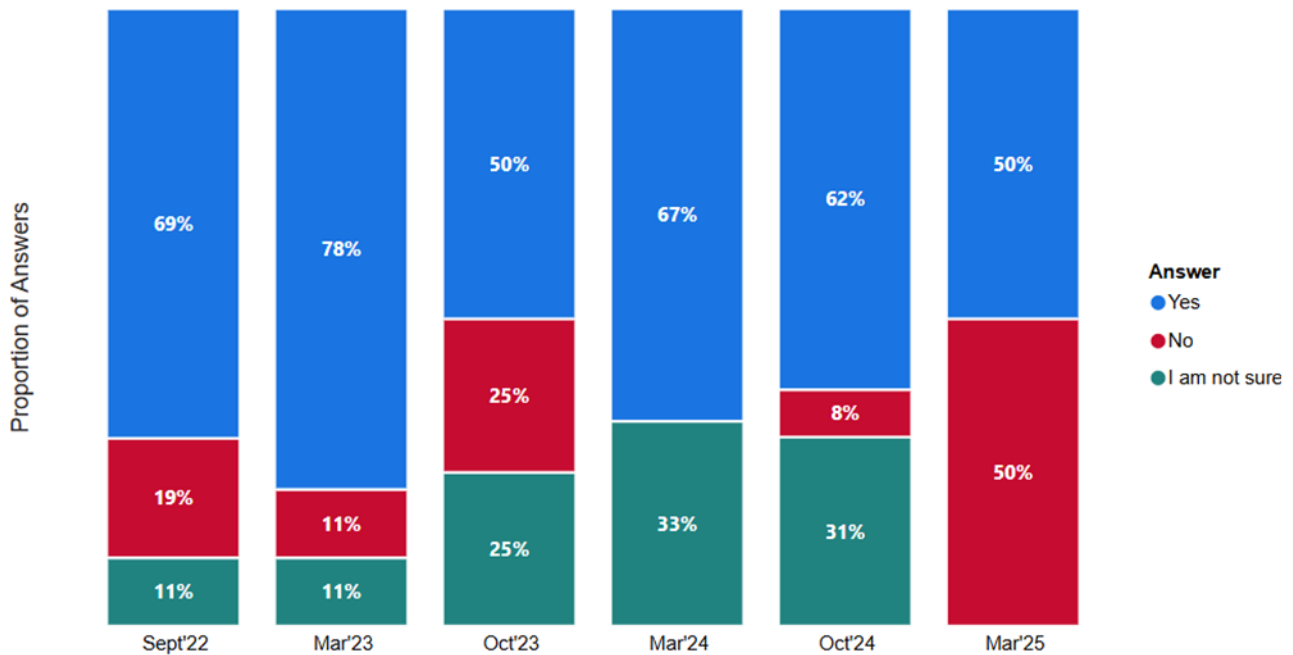
**TrialHub’s fellowship programs supported ECRs to advance to research fellowship**, and provided needed CT supports across the flagship sites. TrialHub’s Fellowship programs focused on expanding professionals’ networks through mentoring, training, and onsite support to enhance competencies. Fellowship programs were offered to support Clinical Coordinators and Oncologists. TrialHub supported:

- 17 ECRs to complete the fellowship program
- an FTE of 12 was provided by these individuals across 4 sites.

Notably, five of these fellows were retained by the sites after completing their fellowships and have contributed a total of 96 additional months of work. This equates to approximately 8 years of total additional fellowship work time when combined.

**TrialHub supported staff’s access to CT specific training resources.** Training participants were asked whether they had noticed an increase in available training resources about CTs. Across each survey period, at least half of training participants responded ‘Yes’ (Figure ). In total across all survey periods 67% (n=47) of participants responded ‘yes’, 16% (n=11) responded ‘no’, and 17% (n=12) were unsure whether they had noticed an increase in available CT training resources.

**Figure 4: Perceived increase in available CT training resources over time**



Source: HealthConsult, Training Participant Survey, n=70

TrialHub shared an education package with flagship sites to support CT Oncologists. This was developed and trialled in Alfred Health, and greatly appreciated by the sites, who commented that they would not have had capacity to develop such training internally.

*TrialHub has developed an education package for CT oncologists which has been shared with us. Trial coordinators in oncology have been working with TrialHub and having input into the education program. We wouldn't have the resources to develop that, so to be able to hook into something already developed and trialled amongst staff at the Alfred has been brilliant and is needed.*

Peninsula Health representative

**TrialHub advocated for an education and accreditation strategy** to support the professionalisation of CT specific workforces. TrialHub partnered with Monash University to develop educational offerings aligned with the capability framework. The Monash partnership enabled:

*"A professional development program through the Uni that includes micro credentialled courses as well as a Master of Clinical Research methods and all those education offerings which provide specific training in CT management, so the fundamentals of CTs for people that want to get involved. We also have more developed master classes around protocol development, local oversight, etc."*

Monash University representative

Through higher education and credentialling, career pathways are more established and attractive, particularly to CT coordinators. Such attractiveness can increase the likelihood that staff will be retained and continue to operate CTs in regional areas.

**The Pharmacy Train the Trainer program** developed and supported CT pharmacy capability through building expertise in both CTs and pharmacists' delivery of CT-related educational programs. Through Alfred Health, pharmacy staff received credentials and training, including guidance on physical CT setup requirements and approaches for them to train others. Specifically, the program involved:

- **Site credentialling** through an initial site visit, mapping of relevant resources, a site assessment, learning package delivery (videos, readings and checklist) and a final assessment
- **Staff/Pharmacist credentialling** through on-site observation at Alfred Health, access to online learning modules and final assessment
- **Trial credentialling** initiated alongside the activation of a new trial and to include virtual consultations and mentoring for pharmacy staff up to 12 months.

**A total of 17 pharmacists have been accredited** via the Train-the-Trainer program. The program has been adopted by all major regional Victorian Health services (nine services), and has received interest regarding expansion to New South Wales, Darwin and presentations of the model in Western Australia and Queensland.

Pharmacy is a key area required for CT capacity, as many new CTs are drug-based and require this expertise. Interviewed site representatives highlighted impacts resulting from increased pharmacist credentialling including:

- Practical increases in capacity due to more pharmacy support
- Less vulnerability to staff shortages due to now having multiple pharmacists credentialled
- Strengthened credibility to conduct CTs, particularly as pharmacists can speak to their credentials when interviewed.

*"Previously our capacity was limited. We have three pharmacists now that are trained and involved in CTs. This was a real enabler for capacity."*

Bendigo Health representative

The Train the Trainer program exemplifies TrialHub's workforce development capability building approach as it targets sites' fundamental abilities to continually support, develop, and train their workforces sustainably, mediating against future workforce shortages.

*"The clinical train the trainer pharmacy program has been crucial to us developing our capacity. In smaller sites expertise is critically dependent on one or two people, so we've lost one pharmacist. But a new pharmacist came on board and was able to do the train the trainer program, and we didn't have such a huge impact because of this. Normally it's much more detrimental when someone leaves."*

Latrobe Regional Health representative

Overall, TrialHub's facilitation of training programs were highlighted as key to the building of capability and overall successes of CT units.

## 2.3. Mentorship and support

TrialHub effectively promoted mentorship, both internally within sites and in structured partnership programs between sites, particularly tied to the Alfred Health. This effectively supported the growth of CT units. All interviewed site representatives emphasised considerable positive impacts of mentoring arrangements and support and appreciated being able to ask questions or request advice on CT-related challenges.

*"TrialHub was a shoulder to lean on as we grow through uncharted territory. Being able to check in and troubleshoot as well as ask questions has been hugely beneficial."*

Latrobe Regional Health representative

**Mentoring relationships between Alfred Health and regional sites** (i.e., flagship and non-flagship sites) were emphasised as particularly important, enabling CT units' access to considerable expertise and experience, enhancing overall capability.

*"It has been beneficial, mainly the mentoring in rural settings. It has allowed me to connect with metro colleagues; most important thing was how to make a trial centre attractive to sponsors. It's opened avenues that wouldn't have been available otherwise. One-on-one mentoring has been great having that senior support, makes it a lot easier to walk through doors yourself in the future. A lot of it was keeping myself up to date with standards at other centres, it was really good for me."*

Peninsula Health representative

These mentoring relationships also facilitated resource sharing, particularly from Alfred Health to regional sites (i.e., flagship and non-flagship sites). For instance, Alfred Health shared their approaches to conducting CTs, including developing required processes and protocols.

*“TrialHub for me was more about the personal contact and sitting in on the Alfred meetings, to hear how to approach a feasibility study that didn’t directly impact me. To be able to see how a tertiary centre reviews a trial protocol and sees where it fits into a matrix. A lot of different resources now that I use.”*

Peninsula Health representative

**Staff could also draw on cross-site mentors’ experience and expertise** to develop their skills and solve issues they may not have been able to without support. This was emphasised as particularly useful for flagship sites.

*“TrialHub allowed us access to the network of expertise. The research team were provided with links to people with broad expertise to troubleshoot with and get ideas.”*

Bendigo Health representative

Through involvement with TrialHub, sites were able to harness networked expertise, which was seen as invaluable for supporting decision making and problem-solving abilities, both key to building CT capability.

*“Education benefits extended beyond formal programs (such as research nurses and CTOs) to include access to experts who could provide just-in-time advice and problem-solving support which has provided a valuable knowledge network”*

Bendigo Health representative

### **TrialHub established the following mentorship structures:**

- Research Fellows across the flagship sites received supervision from both internal consultants and early phase trial consultants from Alfred Health
- Mentoring programs between the Alfred Health and pharmacy departments at multiple sites, seen as “invaluable” for new CT pharmacists
- Monthly mentoring workshops to support site accreditation
- Mentoring centred around sites workforce development initiatives, supporting infrastructure and processes related to the capability framework
- Mentoring regional staff in commercial sponsor negotiations.

**Mentorship to support accreditation developed and strengthened sites’ awareness of and adherence to professional standards**, which is key to appropriately conducting CTs. The monthly accreditation workshops involved principal investigators across each organisation. This was seen as helpful organisation-wide in the flagship sites as it enabled appropriate consideration of processes and wording, as well as increased awareness of accreditation requirements. Sites were also able to ask questions and receive tailored support from to troubleshoot processes or reporting challenges.

*"Anyone who needed upskilling and mentoring – we could ask the Alfred group. If we had an area of weakness, the arrangement could facilitate additional training. We could ask if people could shadow or be mentored."*

Bendigo Health representative

**TrialHub's impact has extended beyond its immediate network**, as emphasised by an interviewed representative from Goulburn Valley Health (Shepparton). Goulburn Valley Health received assistance with accreditation through TrialHub's regional mentoring program, involving their research office and other regional CT departments in a collaborative approach to accreditation. TrialHub also supported Goulburn Valley Health to access pharmacy training. The recognition of value outside the flagship sites demonstrates the program's success in building self-sustaining systems of collaborative growth and capability.

Alfred Health has also experienced positive outcomes resulting from the relationships built through TrialHub.

*"We've seen softer benefits from connections back to Alfred Health, including broader clinical connections, support and advice for complex patients"*

Alfred Health representative

Some sites noted a shift in the nature of their mentoring relationship with Alfred Health over time, highlighting that they now feel that the relationship facilitates bi-directional impacts, indicating the efficacy of TrialHub's model in building their overall capability to also contribute to networked expertise.

*"TrialHub has been instrumental to our ability to grow and instil confidence in us. I value the relationships. We were initially being led but we've transitioned, our opinions are respected and valued, and I don't always get that in other larger programs. Even though they're metro they're kind of local. Good engagement with clinicians. We will grow even if TrialHub aren't there and that's a credit to them, that they've supported us to build enough internal structure to continue to grow."*

Latrobe Regional Health representative

Overarchingly, interviewed site representatives emphasised the value of mentorship which provided personalised support and upskilling targeted to their specific needs. Mentoring relationships were seen as fundamental to the success of TrialHub in building sites' overall CT capacity and workforce development capabilities.

## 3. Partnerships and collaboration

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This Chapter examines how TrialHub's partnership model has evolved from the initial hub-spoke model to more complex collaborative networks, and explores how these partnerships have enhanced CT activity, knowledge transfer, and sustainability across participating sites.

### 3.1. Regional collaboration

At its core, TrialHub operates through a coordinated partnership approach with regional and rural health services to support CT access beyond metropolitan centers. These strategic relationships create the necessary infrastructure for knowledge transfer, resource sharing, and capability building across diverse healthcare settings. By facilitating connections, TrialHub has created pathways for expertise exchange, protocol sharing and collaborative CT delivery.

Beyond health service partnerships, TrialHub has actively facilitated connections between flagship sites and industry sponsors (e.g. through sponsor workshops), creating visibility and commercial opportunities that enhance financial sustainability. These industry relationships represent a critical step in the maturation of regional sites (i.e., flagship and non-flagship sites).

The collaborative approach extends to strategic networks (e.g., Australian Teletrial program), alliances (e.g., Victorian Rare Cancer Clinical Trials Alliance (VRCCTA)), and international connections (including, UK, NZ) to address specific gaps in CT access.

**TrialHub fostered networked regional collaboration** which has significantly strengthened CT capacity and capability across participating sites. Moving beyond a hub-and-spoke model, TrialHub actively supported the formation of peer-to-peer networks between regional health services, with networks built on trust, mutual support, and shared expertise.

*"The hub-and-spoke model wasn't just about connecting sites but establishing dynamic connections with ongoing interface between groups to ensure a sense of belonging, community, and reduce isolation."*

Alfred Health representative

Through structured support and strategic facilitation, TrialHub has enabled regional sites (i.e., flagship and non-flagship sites) to collaborate more effectively, resulting in the pooling of knowledge, skills, and resources. Sites now increasingly turn to each other for guidance on CT implementation, governance processes, feasibility assessments, and workforce training. This culture of collaboration increased the overall confidence, maturity and cross-site support of regional trial units.

*"TrialHub established a platform amongst regional centres, to allow for discussions about the pragmatics and running CTs. I don't think we would have that outside of TrialHub. That was of value. Those discussions are really important in a regional context. People need a psychologically safe space."*

Bendigo Health representative

**Regional partnerships have fostered broader clinical connections** beyond TrialHub and CTs, creating a more cohesive healthcare ecosystem. Improved communication and collaboration across services was seen as enhancing regional workforce development by helping to attract and retain skilled staff who value access to professional networks and innovative CT and research opportunities.

**Some flagship sites are now mentoring other services** not formally part of the TrialHub initiative. With increased confidence and capability, some sites are supporting peers in setting up CT infrastructure or explore CT-related technologies or areas for the first time. For instance, Bendigo is now working with Echuca Regional Health, helping them establish CT capabilities for the first time. Plans are underway for teletrial collaborations between Bendigo Health and Echuca Regional health which will extend CT access to another regional community.

**TrialHub acted as a central point of CT coordination**, promoting information sharing between sites. This resulted in increased awareness of CTs across the state. Interviewed site representatives emphasised the value of their resulting connectedness. They were able to understand patient needs and then direct them to suitable CTs being conducted at other sites.

TrialHub developed, connected with and supported CT networks, ensuring sites' awareness of new developments in CTs and activity being conducted, so that patients could be appropriately connected to relevant CTs, and duplication of CTs activity was minimised. As part of these activities TrialHub:

- Founded the **VRCCTA** – which facilitated information sharing enabling cross-referrals of patients with rare cancers.
- Collaborated with the **Regional Trial Network** and together provided funding to Latrobe Regional Health and Mildura Base Public Hospital to co-leverage and diversify their funding, with signed Memoranda of Understanding agreements (MOUs) between health services.

**Some sites were able to establish or strengthen existing partnerships beyond TrialHub** due to increased support and capacity resulting from TrialHub. Latrobe Health established partnerships with Monash Partners and other metropolitan hospitals conducting CTs. Their site representative highlighted TrialHub's role in supporting these partnership establishments.

*"TrialHub functioned as a neutral person, as a navigator and coordinator, enabling partnerships to form more easily."*

Latrobe Regional Health representative



A Northern Health representative commented that they were able to establish partnerships and become involved with the Victorian Comprehensive Cancer Centre (VCCC) and the Walter and Eliza Hall Institute of Medical Research because they had adequate resourcing and capacity, directly due to TrialHub funding.

**TrialHub's approach emphasised collaboration over competition.** For instance, TrialHub collaborated with the Regional Victorian Trials Alliance Linkages, Innovation, Special populations, Equity (ReViTALISE) project in Mildura to integrate mentoring and regional network efforts.

*"TrialHub has been truly collaborative – leveraging off each other's programs without duplication."*

Regional Trials Network Victoria representative

Interviewed site representatives consistently appreciated TrialHub's collaborative approach, highlighting how it harnessed collective efforts, strengthening overall CT system capabilities.

*"An unexpected positive outcome of TrialHub has been the strong collaborations between funded programs."*

Goulburn Valley Health representative

Site representatives also noted that TrialHub made considerable efforts to avoid duplication with other funded networks and programs, listen to sites' development needs, then develop strategies based around these.

*"We do have other collaborative partnerships in this space [...] and sometimes there's overlap in aims. But TrialHub has been adaptable and has been a more intimate relationship to help our capacity for independent growth. The other programs are more top down, focused on key targets. TrialHub's partnership is collaborative, they really listen to us and understand why things aren't working so we find solutions."*

Latrobe Regional Health representative

TrialHub's approach was seen by interviewees as having fostered a more collaborative and effective regional health CT system, with impacts for health services and hospitals beyond TrialHub's sites alone.

## 3.2. Partnerships and business development

**TrialHub actively supported the development of partnerships** centred around CT activity, both across flagship sites and the broader healthcare ecosystem. Appendix B provides detail regarding formal and informal partnerships supported by TrialHub. Overall, TrialHub supported 15 partnerships with non-TrialHub sites, 13 with Not-for-Profit organisations, and 4 with international networks and organisations.

**TrialHub facilitated relationship building and networking to attract CT sponsorship**, including with international sponsors.

*“Building relationships, such as IQVIA has meant we understand more about things like advertising to sponsors.”*

Latrobe Regional Health representative

Specific sponsorship relationships are listed in Appendix E. Several of these are international companies, demonstrating the reach of business development supported by TrialHub.

Interviewed site representatives noted that TrialHub and the exposure to expertise at Alfred Health supported their collaborative efforts to attract sponsorship.

*“Linking me in with the team, mainly at Alfred, meant collaboration was a lot easier. There was talk of joint studies in Bendigo. Bendigo would never be able to open this trial alone but because of the relationships garnered in TrialHub and communication that happened, there was a relationship where patients could have their first treatment at Alfred and then be transferred back to Bendigo. It opened up options for the regional centres and their patients. The team at Alfred was very keen to share their trial list and if I wanted to reach out to a sponsor, they were very open to that. It opened options with centres at Peninsula.”*

Peninsula Health representative

Connections between sites and with sponsors expanded sites’ business development potential and CT portfolios (Note: this is further discussed in section 5.2).

**TrialHub acted as a central point of coordination and advocacy** for flagship sites to attain commercial and international sponsorship for their CTs. These sponsors may previously have overlooked non-metropolitan Australia.

*“TrialHub has assisted us by approaching pharmaceutical companies and suggesting regional centres. That doesn’t usually happen.”*

Bendigo Health representative

TrialHub enabled sites to engage in early-phase conversations, understand sponsor expectations, and align their internal processes to international CT market standards. These activities were seen as important for CT unit capability and maturity and attracting further investment.

*“More advocacy from TrialHub could be a very powerful force and could unite several voices to make sponsors more aware.”*

Peninsula Health representative

Some interviewed site representatives saw further opportunities for TrialHub to expand their advocacy efforts and do more to expose their work and connect them with sponsors.

**A dedicated sponsor workshop** was organised by TrialHub, which brought together representatives from regional health services and pharmaceutical companies. Flagship sites were able to showcase their site capabilities and network for business development. Several of the site representatives commented that this was their first opportunity for direct engagement with international sponsors. The workshop led to relationships between sites and sponsors which in some cases resulted in CT opportunities.

*"We participated in a sponsor workshop and discussed how we do organisation wide CTs. We had follow up from multiple sponsors after that, including from a pharmaceutical company regarding two potential trials."*

Bendigo Health representative

#### **Sponsor workshop outcomes included:**

- Flagship sites' direct exposure to pharmaceutical sponsors and contact with research organisations that would have been difficult for sites to reach independently.
- Ongoing relationships and potential CT opportunities resulting from several contacts initiated at this event.
- Flagship sites built their understanding of how they can strengthen their profile documentation (e.g. improving site CVs) to attract future CTs.

*"I met a sponsor I'd never heard of. We continued dialogue and have now opened two trials with them. They're both teletrials which we've never been able to do before. It's led to an enhanced relationship with a commercial sponsor we never had."*

Latrobe Regional Health representative

Expanding international engagement contributed to broader business development outcomes. With greater sponsor interaction, flagship sites gained clarity on market expectations, appropriate documentation to promote CTs and engage sponsors, and opportunities to diversify their CT portfolios. This was seen by site representatives as enhancing the commercial sustainability of their CT units and working to embed CTs within regional hospitals' priorities.

## 4. Community engagement and CT promotion

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This Chapter examines how TrialHub's community engagement and promotion strategies have evolved across partner sites, the challenges encountered in engaging diverse communities, and the impact of these activities on CT awareness and participation rates in participating regions.

### 4.1. Innovative CT promotion

Community engagement and CT promotion represent essential components of increasing trial participation and enabling equitable access. Even with robust capabilities and technologies in place, CT programs cannot succeed without effective engagement of potential participants, clinicians, and the broader community.

Through structured communication plans with consistent messaging, TrialHub has supported partner sites in developing tailored promotional activities across diverse channels, including central websites and standardised information resources. A particularly innovative aspect of TrialHub's community engagement strategy has been the Ambassador Program, which amplifies authentic patient voices in CT promotion.

Overall, interviewed site representatives emphasised that TrialHub's support was highly impactful in driving community engagement, and embedding it within regular activities.

*"TrialHub have worked really hard in this space for us. Prior to their involvement, community engagement wasn't prioritised."*

Bendigo Health representative

**TrialHub worked with sites to develop structured communication plans** with consistent messaging across health services. These strategically took a two-pronged approach:

- **Internal:** Building awareness and pride within health services about CT programs
- **External:** Community-facing communications with clear points of contact.

This multi-faceted approach sought to maximise possible touchpoints with community and expand awareness of CTs, to extend access opportunities.

Sites have conducted varying levels of internal and external communications to engage community. While Bendigo Health, Northern Health, and La Trobe Regional Health have conducted considerable engagement activities to promote CTs internally and externally, at Peninsula Health, a TrialHub-supported plan is underway to increase staff and community awareness.

*"We're just about to embark on a communication plan to better inform our consumers and staff about trials at Peninsula Health – that's part of a bigger process that TrialHub have been able to resource and enable. [...] People don't know Rosebud takes part in CTs too, not just in oncology but in other specialties as well. Greater publicity about our capabilities would certainly improve our chances of recruitment."*

Peninsula Health representative

**TrialHub conducted targeted health professional engagement**, through internal communications to promote CTs within health services, so that staff across the sites could direct patients to appropriate CTs. TrialHub also facilitated outreach activities targeting clinicians external to the sites, in recognition of their role in engaging with community. These included information sessions for GPs to inform staff about current CTs, so that they promote local trials to patients instead of referring them to metropolitan hospitals.

**TrialHub worked closely with flagship sites to establish consistent and trusted information using technology.** This includes the development of external websites and standardised patient resources to help regional health services better communicate their CT offerings. For instance, TrialHub provided advice and content for updating Bendigo Health's website section on CTs. TrialHub built sites' understanding of the importance of clear, consistent information accessible on the internet.

*"We're making sure all the information on our CT [web]site is patient-focused and sponsor-friendly."*

Bendigo Health representative

These resources ensured the public could be directed to trusted information, boosting perceptions of CTs and enhancing overall understandings. TrialHub also helped implement communications campaigns on social media about trial activities.

*"We now post stories online, send newsletters to GPs, and even present at community settings [...] to try break down stigma."*

Latrobe Regional Health representative

These activities and have helped to disseminate information and address prevailing stigma and misconceptions about trials, while enhancing transparency and trust.

**TrialHub's Ambassador Program empowered former trial participants to become advocates** for CT participation. These ambassadors share their personal stories to inform, encourage, and inspire others in their communities. The program was seen as highly effective by interviewed site representatives.

*"Having ambassadors speak honestly and truthfully has been incredibly powerful, because it's not a softened message, it's a message that comes from the heart."*

TrialHub representative

While the Ambassador Program was seen as impactful, some challenges emerged regarding its sustainability. An interviewed site representative commented that the program may benefit from further information, tools and resources to guide ongoing implementation.

*"We had three ambassadors from Gippsland, but now we're down to one. I feel like the Ambassador Program has been a bit vague – it needs more supporting documents, or a toolkit help sites establish their own ambassador program."*

Latrobe Regional Health representative

**TrialHub strategically promoted word-of-mouth community outreach**, in recognition that this remains the most effective form of community engagement in many regional areas. To target word-of-mouth engagement, TrialHub promoted community-based storytelling and created spaces where research staff, clinicians, and participants could interact directly with the public and raise awareness of local CT activity while answering any questions.

For instance, a community engagement event was held in Bendigo at a local tennis centre, which featured ambassadors, researchers, and staff discussing the impact of trials. At another community event, in Traralgon (Latrobe Regional Health), a hospital champion shared their experiences to try help demystify some of the myths about trials.

TrialHub also supported the creation of key spokespeople for specific cancer types—like rectal cancer and melanoma, who were then featured in promotional materials and the media to demystify trials and increase public engagement.

**TrialHub supported engagement with culturally and linguistically diverse (CALD) and First Nations communities** across the flagship sites. At one site, a comprehensive survey involving patients, interpreters, and clinicians was conducted to identify key barriers to trial participation. These insights informed the development of multilingual materials and targeted video content, which was seen by interviewed site representatives to have significantly improved trust and access for CALD communities.

*"We've successfully recruited non-English speaking patients to trials. A lot of it is to do with trust, not just language. Having on-site interpreters has been crucial, and the multilingual videos have helped tremendously."*

Northern Health representative

TrialHub supported Bendigo Health to develop a culturally appropriate brochure for Aboriginal and Torres Strait Islander communities, designed in collaboration with a local artist.

*"We're looking forward to launching the Aboriginal-specific brochure. It's been good progress—developed with consumers and TrialHub, and it's almost ready."*

Bendigo Health representative

While community engagement can be challenging to quantify, several sites have started tracking website traffic, social media metrics, and public engagement as indicators of reach and awareness.

*"We're keeping records on hits to our website, how many media articles are out there—it's helping us measure community engagement."*

Bendigo Health representative

Overall, across the flagship sites, TrialHub was credited with shaping significant improvements in community engagement.

*"We've upped our community engagement. The communication and engagement side has improved – it's now part of how we do things, and that's largely thanks to TrialHub."*

Bendigo Health representative

## 4.2. Meeting community need

One of the most valuable outcomes of TrialHub's community engagement activities has been the ability to better understand local health needs and tailor CT offerings accordingly. By embedding community-informed processes into CT planning and development, TrialHub has enabled regional health services to raise awareness about trials and in some cases, actively shape them to reflect the health issues prevalent in specific regional communities where CTs are being conducted.

**A data profiling workshop** was facilitated by TrialHub at Bendigo Health, which reviewed health, wellbeing, and social determinants data across the region. TrialHub facilitated the mapping of these community priorities against current CT offerings to identify gaps and inform future trial selection.

*"We're grouping the priority areas and mapping what the gaps are then working forward from there. It's helping us shape our portfolio based on what people in our community actually need."*

Bendigo Health representative

At Latrobe Regional Health, a similar approach has seen CT selection based on local demographic and disease data.

*"We selected trials based on chronic disease prevalence in our region, particularly cancer. We used registry data to identify the types of cancer presenting at our centre—and one of our trials achieved the highest recruitment in the state because it directly matched the needs of our community."*

Latrobe Regional Health representative

TrialHub also helped the site build capacity in high-priority clinical areas such as respiratory disease.

*"It's a large need in our community, and TrialHub came back to us with five different trials we could consider."*

Latrobe Regional Health representative

To further capture community CT needs, Bendigo Health conducted a series of community engagement activities, including a public feedback campaign conducted in the hospital foyer.

*"We had over 80 responses. People told us their priority needs were mental health—especially dementia—women's health, like endometriosis, and cancer. Now we're actively looking for trials in those areas."*

Bendigo Health representative

The impact of these efforts also extends to First Nations communities. With TrialHub's support, sites have opened their first Aboriginal and Torres Strait Islander trial for diabetes, needed amongst this population, while also developing culturally appropriate resources to improve trust and participation.



## 5. CT activity

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This Chapter examines the patterns of CT activity growth across TrialHub's flagship sites, analysing both quantitative measures of increased CT numbers and qualitative aspects of portfolio development, therapeutic diversity, and strategic alignment with population needs.

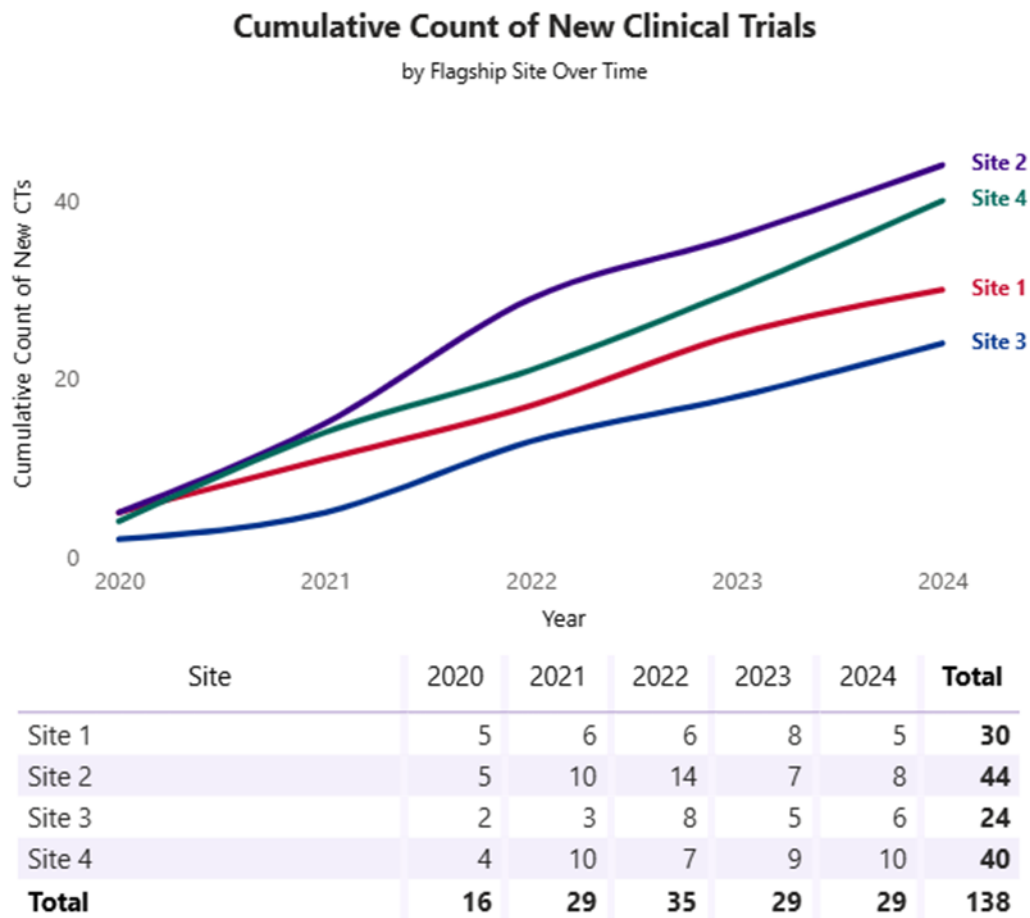
### 5.1. Increased number of CTs

Since its inception, TrialHub has strategically focused on supporting its partner sites in building sustainable CT portfolios, employing a capability-based approach that matches trial opportunities to sites' readiness and local population needs.

TrialHub's effectiveness ultimately lies in its impact on actual CT activity across participating sites in outer metropolitan, regional, and rural areas. Increasing the number, diversity, and accessibility of CTs in these traditionally underserved regions, represents the operational manifestation of improved capabilities, technologies, partnerships, and community engagement.

CT activity has increased across TrialHub's flagship sites since 2020. As of March 2025, 169 clinical trials were recorded across TrialHub's flagship sites, representing a 42% increase from the 119 trials documented in September 2022 (Table 2 in Appendix A). This growth trend aligns with the cumulative count of new CTs by flagship sites over time (Figure 5).

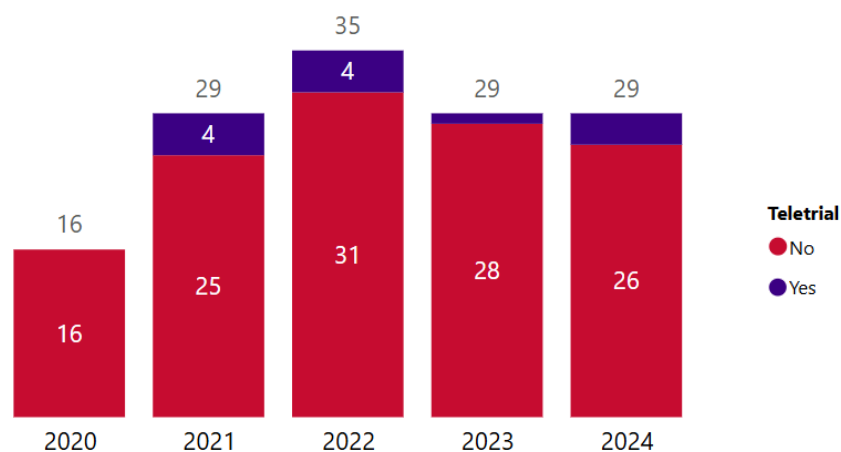
Figure 5: Cumulative count of new CTs by flagship site over time



Source: HealthConsult, Ongoing site survey on CT activity

Since 2020, 138 new CTs of various trial phases have opened across TrialHub's flagship sites (Figure 6). These trials were strategically placed based on TrialHub's capability framework, which evaluates sites according to their capacity, specialised skills, and available workforce. In 2024, 29 CTs were opened to recruitment compared to 16 trials in 2020. The greatest number of newly opened trials was reported at Bendigo Health (n=44) and Peninsula Health (n=40).

Figure 6: Number of new CTs, including teletrials



Source: HealthConsult, Ongoing site survey on CT activity

As of late 2024, eight teletrials have been activated across the four flagship sites, with five currently open to accrual (i.e., recruiting participants) and three closed to accrual. Another five teletrials are open at Mildura Base Public Hospital and Bass Coast Health.

## 5.2. Expanded and diversified CT portfolios

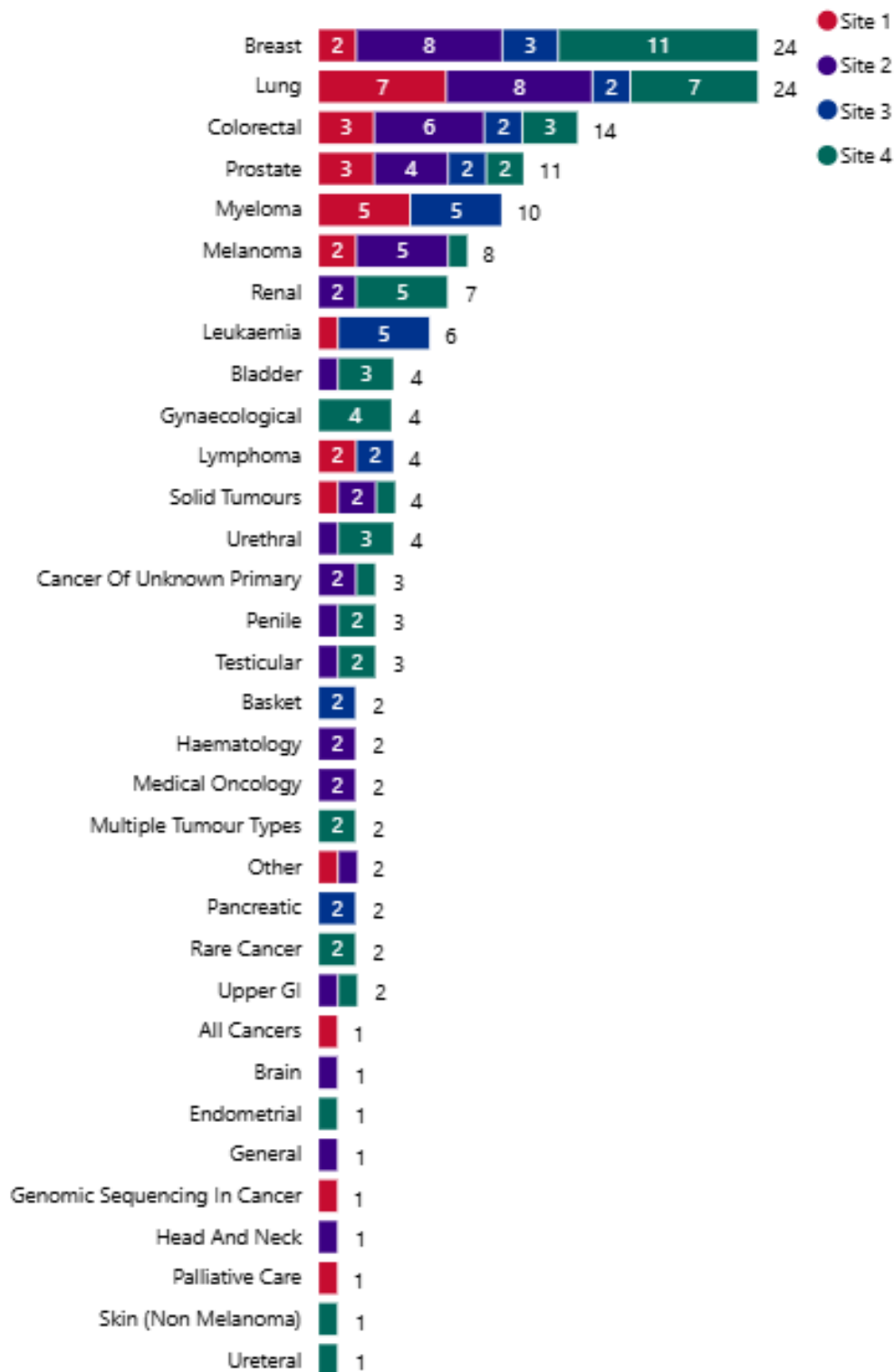
Interviewed stakeholders noted that there has been substantial growth in CT portfolios.

**A wide variety of CT types is being conducted at flagship sites** with breast and lung cancer trials (n=24, respectively) leading the portfolio, followed by colorectal cancer (n=14), prostate cancer (n=11) and myeloma (n=10) (Figure 7). The diverse range of cancer types demonstrates TrialHub's commitment to comprehensive cancer research and shows how all flagship sites have developed their CT portfolio.

*"Cancer trials were most impacted and supported by TH, but the learnings from that certainly help the organisation as well."*

Bendigo Health representative

Figure 7: Type of trials being conducted at flagship sites

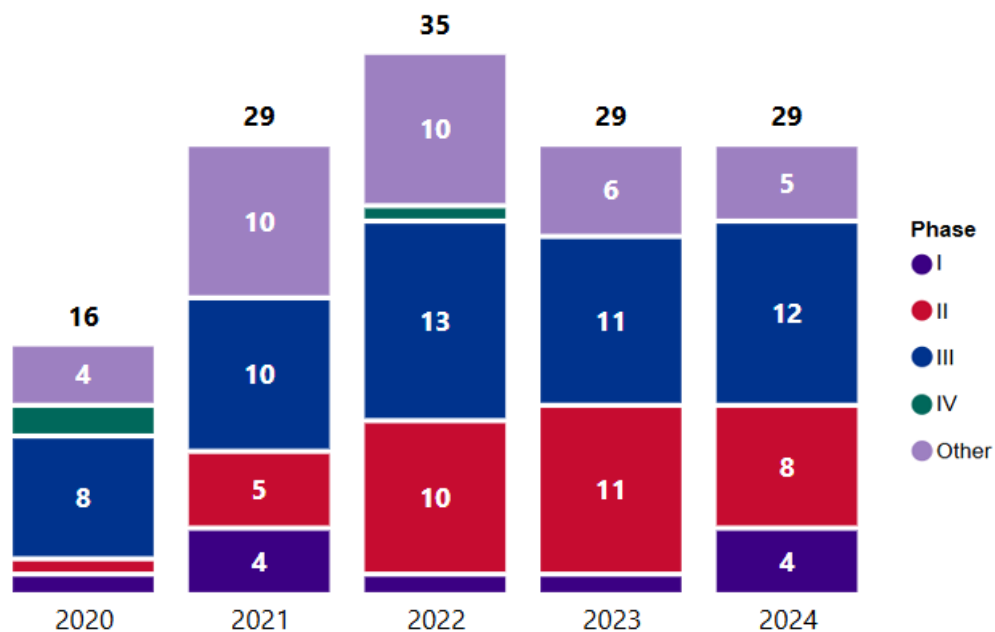


Source: HealthConsult, Ongoing site survey on CT activity

**Flagship sites are undertaking CTs across various trial phases**, predominantly phases II and III (Figure 8). However, sites have started to implement more sophisticated feasibility selection processes, with multi-disciplinary teams now involved in trial selection decisions. This has led to

a shift toward more complex studies, particularly Phase I, which typically enrol fewer patients but command significantly higher per-patient funding, often reaching \$20,000 per participant.<sup>4</sup>

**Figure 8: CTs by phase across all TrialHub flagship sites**



Source: HealthConsult, Ongoing site survey on CT activity

Interviewed site representatives viewed the progression towards more complex trials as clear evidence of significant maturity and development within the CT units. Northern Health has completed its first Phase 1 trial, while Latrobe opened its first Phase 1 trial last year (2024) after previously focusing primarily on Phase 3, 4 and some Phase 2 trials. This capability building has been supported through TrialHub’s mentoring and collaboration with Alfred Health, providing flagship sites with the confidence to undertake higher-risk trials knowing they have expert support available.

Across TrialHub’s flagship sites, common cancers represent the majority (n=110 out of 138) of CTs. Less common cancers (n=18 out of 138) and unspecified cancers (n=11 out of 138) only represent a small group of CTs, with rare cancers (n=8 out of 138) representing the smallest group (Figure 9, top bar chart)<sup>5</sup>. This distribution is mirrored in participation figures, where common cancers account for an even larger proportion (n= 1,479 out of 1,794) of total participants (Figure 9, bottom bar chart).

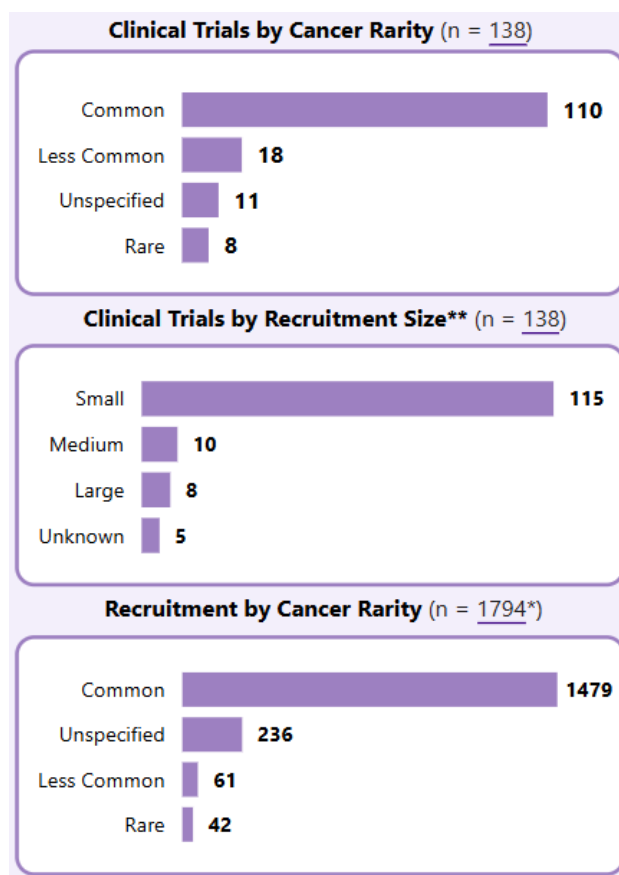
Most CTs (n=115 out of 138) are small (<20 participants). Medium CTs (20–80 participants) only represent a small group of CTs (n=10 out of 138), closely followed by large trials (>80

<sup>4</sup> Per-patient funding information has been provided by TrialHub

<sup>5</sup> Classified according to definitions used by Cancer Council ([Rare cancers | Cancer Council](#)) and Australian incidence rates (Cancer data in Australia, Data - Australian Institute of Health and Welfare).

participants, n=8 out of 138)<sup>6</sup>, reflecting the specialised nature of regional CT activity and complex eligibility criteria associated with cancer trials (Figure 9, middle bar chart).

**Figure 9: CT by cancer rarity, recruitment size, and participants by cancer rarity**



Source: HealthConsult, Ongoing site survey on CT activity

\*\* Small Trials are <20 participants, medium between 20–80 & large CTs are >80

\* Recruitment does not include recruitment numbers from Registry Non-Interventional Sponsor Type CTs.

Additionally, it should be noted that the number of unique participants is as indicated 1,794. The sum of the bars in the bottom bar chart 'Recruitment by Cancer Rarity (n\*=1794)' totals 1,818, which reflects the number of participants across cancer rarity categories, not unique participants. Some participants were counted in multiple categories if their recruitment covered different cancer subtypes (e.g., both colon and rectal cancers).

<sup>6</sup> Size classification based on typical phase I and phase II trial sizes ([Sample size calculation in medical studies – PMC](#))

## 6. Access to CTs

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This Chapter examines TrialHub's impact on CT recruitment and geographical access, analysing CT participation trends, and exploring CT access enablers, including technology (teletrials).

### 6.1. CT recruitment and regional access

TrialHub's vision was to improve equity of CT access for all Australians with a focus on those who live in outer metropolitan, regional, rural, and remote areas. The 'tyranny of distance' has historically limited trial participation for many Australians, particularly those in regional, rural, and remote communities.<sup>7</sup>

Through innovative care models and strategic technology implementation, TrialHub has facilitated teletrial opportunities across Victorian, interstate, and international boundaries while leveraging digital platforms to create sustainable pathways for patient participation beyond metropolitan centres.

**CT participant recruitment has grown since 2020 in agreed priority areas**, including rare cancers and diseases, melanoma, and prostate cancer (Figure 10). The cumulative recruitment growth at TrialHub's flagship sites (Figure 10, right line graph) is in line with increased trial activity (Figure 10, left line graph) and a CT portfolio that represents a strategic choice by sites to align their research activities with community needs.<sup>8</sup>

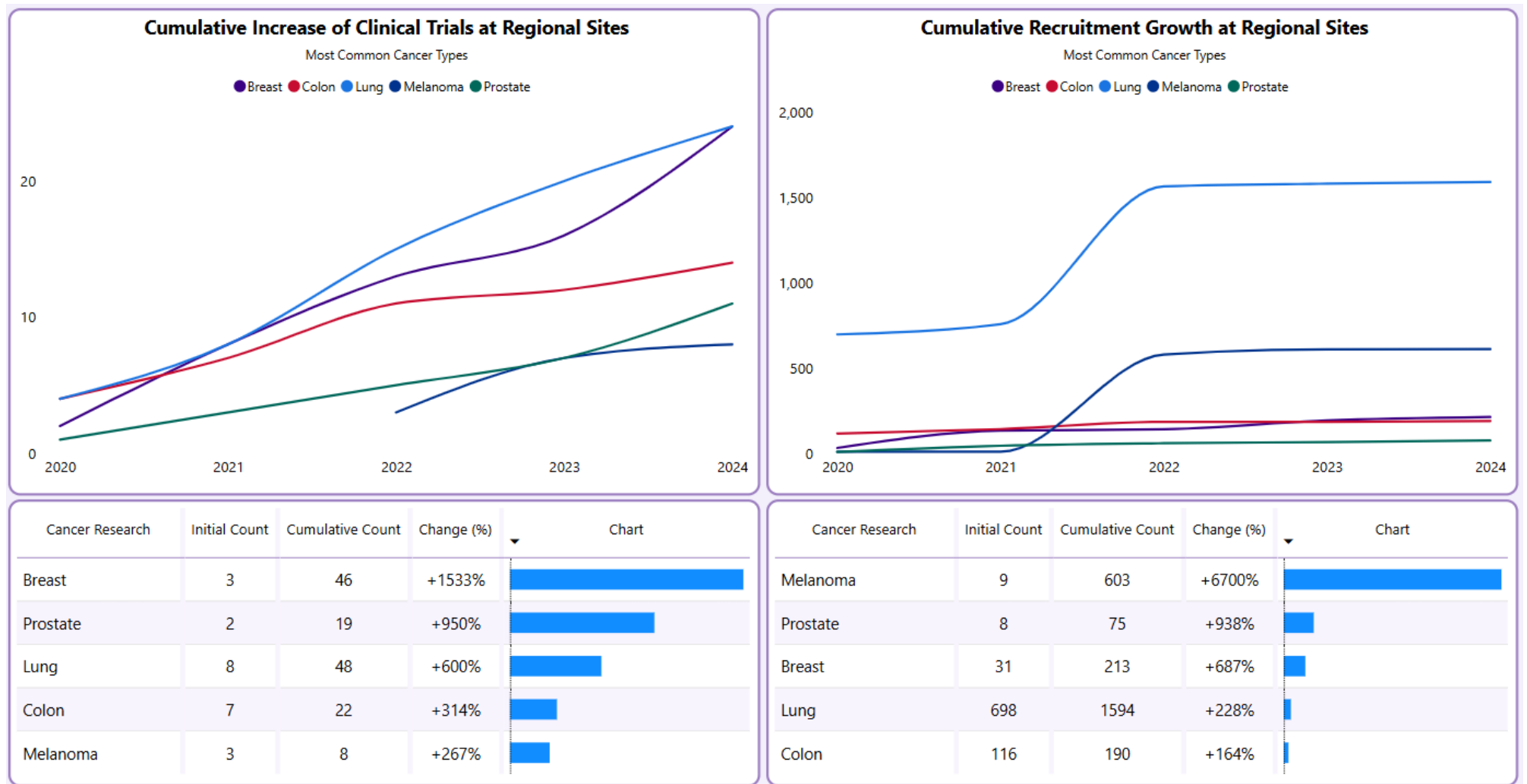
A Northern Health representative reported they have successfully expanded into new tumour streams, particularly prostate cancer, which was not previously available, along with increased breast cancer trials. This diversification ensures patients can now access CTs across all major tumour streams including lung and prostate cancers.

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<sup>7</sup> De Sair, C. (11 December 2023). Telehealth: Defeating the tyranny of distance. Partyline, 85. National Rural Health Alliance. Retrieved from <https://www.ruralhealth.org.au/partyline/article/telehealth-defeating-tyranny-distance>

<sup>8</sup> Data gaps in recruitment reporting have been identified at some flagship sites due to various factors including sponsor restrictions on data release, access limitations for site managers, and repeated documentation across collection periods. Known challenges exist in capturing data for CALD populations and Aboriginal and Torres Strait Islander peoples, which is consistent with broader discussions on this issue and supported by site-reported information.

Figure 10: Cumulative CT increase and recruitment growth at TrialHub flagship sites

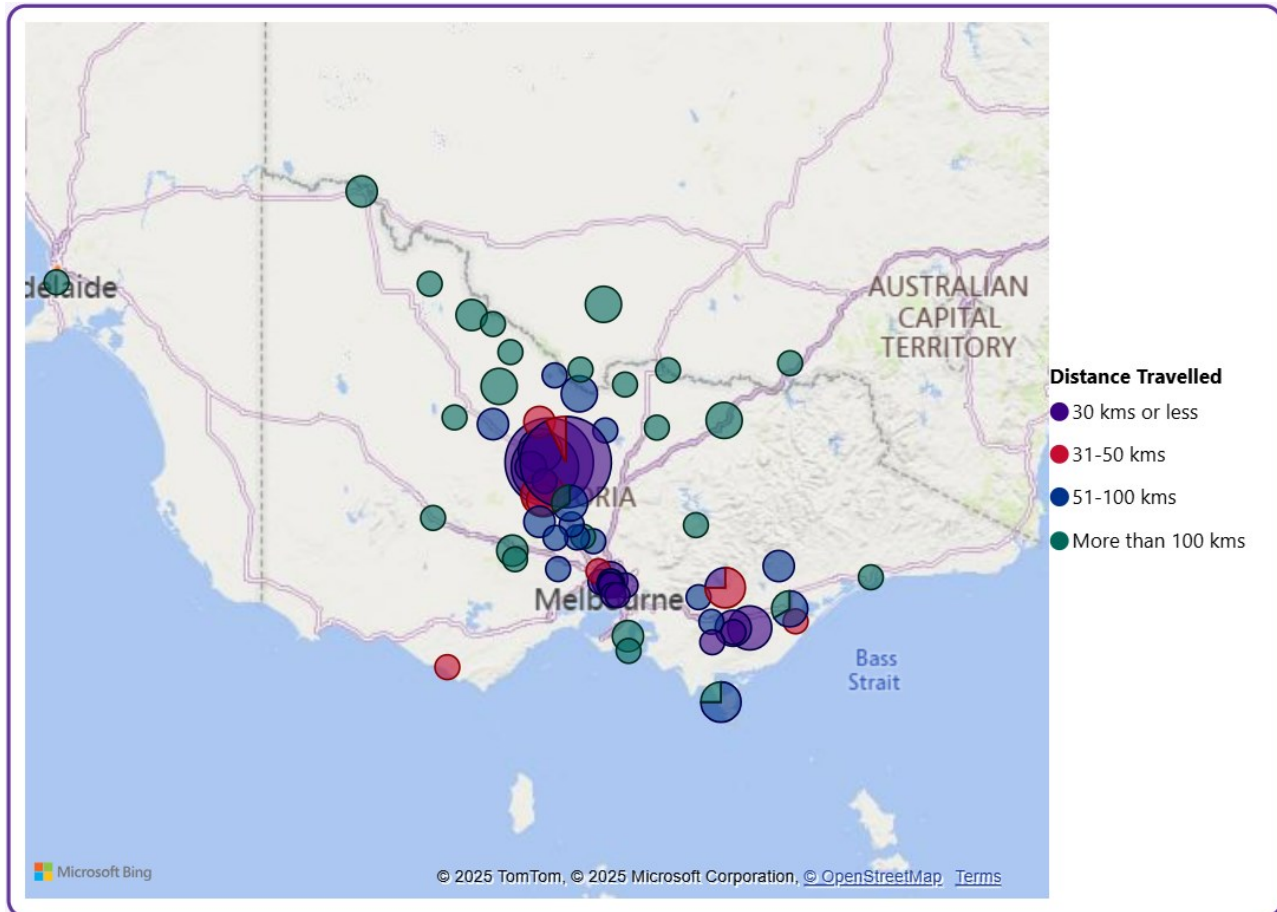


Source: HealthConsult, Ongoing site survey on CT activity



**TrialHub demonstrated increased participation from patients in outer metropolitan and regional areas** (Figure 11), including Modified Monash Model (MMM) 4 and 5. Participants who lived in Mildura, Loddon Valley, East Gippsland and the Murray region in NSW travelled the longest to participate in CTs and one participant was from Adelaide.

**Figure 11: Geographic distribution of CT participants at TrialHub flagship sites**



Source: HealthConsult, CT participant survey (n=267 participants)

The participation profile across different regions, including outer metropolitan and regional areas, suggests the TrialHub program successfully supported expansion of CT access beyond major metropolitan centres.

*"Proximity reduced barriers."*

CT participant

In total, 267 CT participants responded to the CT participant survey since September 2022. More women (n=152, 57%) than men (n=115, 43%) took part in the survey. Most participants were aged between 55-65 years (n=80, 30%) and 65-74 years (n=83, 31%).

Of the 267 CT participants, 45% (n=120) travelled 50km or less to attend their CT appointments. Of those who responded to the question (n=180) 'If you had to travel further to receive

treatment, would you still be able to take part in the trial?', 45% (n=81) said they would participate, but it would not be easy.

*"It is very hard for people aged in their eighties to travel to Melbourne, which prevents me as I am 84 years old in June 2025 and need transport to take me at a lot of cost."*

CT participant

Interviewed site representatives noted that the growing participant numbers and willingness to provide feedback to patient surveys, including the CT participant evaluation survey indicate increased community engagement with and awareness of CTs.

## 6.2. Access enablers

The implementation of teletrials and supporting technologies represent key enablers for CT access beyond metropolitan centres as they help address geographical barriers and enhance participation opportunities for patients in regional and outer metropolitan areas.

### 6.2.1. Teletrials and decentralised models

While programs like the Australian Teletrial Program (ATP) focus on improving CT access through teletrials and decentralised models, TrialHub takes a complementary but distinct approach – providing direct health service mentoring, workforce development and firsthand capability building support.

From the interviews, one site representative noted:

*"[The] partnership with Alfred Health on a rare cancer trial has created a new care model where patients can be identified locally but receive specialised treatment phases at the metropolitan centre. This model allows initial screening and the first two treatment cycles to occur at Alfred, with patients returning to Bendigo for cycle 3 onwards."*

Bendigo Health representative

**The hub-and-spoke approach** enables patients to access specialised care at metropolitan centres when necessary while maintaining their connection to local health service for ongoing treatment. Bendigo Health has also implemented an innovative approach to manage this process efficiently:

*"Bendigo has implemented an innovative 'paused' governance approach where they complete initial approval but pause other administrative requirements until the patient approaches cycle 2, reducing the burden of maintaining an open but inactive trial."*

Bendigo Health representative

The evolution of these models has led to cascading benefits, with initially supported sites now themselves becoming supporters of other regional centres. One example is Bendigo Health now

working with Echuca Regional Health to help establish CT capabilities there for the first time, with plans for teletrial collaborations in advanced stages. This approach has potential for further expansion to even smaller rural sites including Swan Hill and Kerang.

**The impact of telehealth on enhancing access is still evolving**, as noted by interviewed site representatives:

*"I don't think telehealth has made a huge difference in enhancing access yet. Telehealth is still reasonably new. I think there's been some resistance with pharmaceutical companies. There's infrastructure and governance that needs to be set up though."*

Bendigo Health representative

This is reflected in CT staff survey responses. When asked whether they provided CT-related care as part of a teletrial, 24% of the 160 survey respondents across all reporting periods answered 'yes'. However, TrialHub's role in facilitating these models was frequently highlighted, with one representative stating:

*"I don't think this would even be a possibility without TrialHub, e.g., if I was just trying to organise it without the Alfred."*

Bendigo Health representative

### 6.2.2. Technology solutions

**Technologies and digital solutions utilised across the TrialHub network** included social media, communications tools, and online learning platforms. For example, the CTs Refer app was mentioned as having increased visibility of available trials for both potential participants and referring clinicians. CT staff reported that phone calls, video conferencing and study management tools (i.e., SiteDocs) remain the most popular technologies when providing care, especially teletrials.

However, technology implementation has not been without challenges. Several stakeholders noted that infrastructure investment was limited by grant parameters, creating obstacles for implementing novel digital technologies. Additionally, health services' existing technology ecosystems sometimes limited integration.

*"Tech wise - TrialHub has probably had a minimal impact. We have our own EPR and regional community platform. It's very stand-alone technology to our organisation."*

Bendigo Health representative

**Physical infrastructure development has complemented digital technologies** in enabling expanded access. Site representatives reported creating new dedicated research spaces, including areas specifically designed for seeing trial patients. The introduction of specialty trials (e.g., dermatology) required specific equipment and resources that were successfully implemented with support from TrialHub.

## 7. Program impact and sustainability

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This Chapter examines TrialHub's impact and assesses the sustainability outlook for participating sites.

The sustainability of CT activities beyond the initial program support represents a critical measure of TrialHub's long-term impact. While capability building and increased trial activity demonstrate immediate program success, the ability of participating sites to maintain and further develop their CT programs independently speaks to the transformative nature of TrialHub's approach and its potential to create lasting change in Australia's CT landscape.

TrialHub has approached sustainability through a multifaceted strategy that includes supporting financial independence, establishing robust frameworks, cultivating partnerships, and creating connected communities of practice that extend beyond program funding.

### 7.1. Program impact

**TrialHub has driven quality improvement** by establishing foundational structures that enable sites to conduct high-quality CTs meeting national standards.

*"From my perspective, it's been an impactful intervention. It allowed us to overcome some challenges, including providing resources, and it gave us access to experts in the field. Even when you're working with other organisations, that level of dedicated support and finances doesn't happen, especially in regional areas."*

Bendigo Health representative

Central to this impact has been the capability framework, developed collaboratively with participating sites to define the essential requirements for CT unit development, growth, and long-term success in non-metropolitan areas.<sup>9</sup>

**The emphasis on building lasting capability rather than providing temporary resources** has been a distinguishing feature of TrialHub's approach. By empowering sites to own the change process rather than imposing solutions, TrialHub has fostered sustainable quality improvements. This approach has contributed to a shift in perspective among health service executives, who increasingly view CTs as valuable strategic assets rather than financial burdens.

To systematically evaluate progress toward sustainability, the evaluation utilised the Program Sustainability Assessment Tool (PSAT), which enabled sites to assess their sustainability capacity across eight domains using scores between 1 (to little or no extent) and 7 (to a very

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<sup>9</sup> Woollett, A., et al., 2023. A capability framework to inform the fundamental requirements for clinical trial unit development, growth and long term success in outer metropolitan and rural areas. Contemporary Clinical Trials Communications, 32, p.101072.

great extent). Three flagship sites completed the PSAT survey at baseline (2022), midpoint (2023) and 2025 (Figure 12).

**Figure 12: Flagship sites self-assessment via the PSAT**

Site 1 PSAT Scores by Year				Site 2 PSAT Scores by Year				Site 3 PSAT Scores by Year			
Domain	2022	2023	2025	Domain	2022	2023	2025	Domain	2022	2023	2025
Communications	↓ 3.3	↓ 3.0	↑ 5.6	Communications	↘ 3.1	↓ 1.8	↗ 4.2	Communications	↓ 3.7	↓ 3.3	↗ 5.0
Environmental Support	↗ 4.8	↑ 5.8	↑ 5.4	Environmental Support	↗ 4.7	↑ 5.0	↑ 5.0	Environmental Support	↗ 4.8	↗ 5.6	↗ 5.0
Funding Stability	↘ 4.3	↗ 4.7	↘ 3.8	Funding Stability	↗ 3.9	↑ 4.8	↗ 4.0	Funding Stability	↘ 4.4	↑ 6.1	↓ 3.8
Organisational Capacity	↗ 4.9	↑ 5.1	↗ 4.9	Organisational Capacity	↘ 3.5	↑ 5.6	↗ 4.3	Organisational Capacity	↗ 5.3	↑ 5.8	↘ 4.0
Partnerships	↑ 5.7	↘ 4.3	↑ 5.1	Partnerships	↗ 3.9	↑ 5.5	↑ 5.6	Partnerships	↗ 5.0	↑ 6.5	↘ 4.5
Program Adaptation	↗ 4.4	↗ 4.7	↑ 5.2	Program Adaptation	↗ 3.9	↑ 4.8	↑ 5.5	Program Adaptation	↘ 4.6	↗ 5.6	↗ 5.2
Program Evaluation	↗ 4.7	↗ 4.5	↑ 5.5	Program Evaluation	↘ 3.2	↑ 5.0	↑ 5.2	Program Evaluation	↗ 4.9	↗ 5.5	↓ 3.0
Strategic Planning	↘ 4.3	↗ 4.7	↗ 4.5	Strategic Planning	↘ 3.3	↑ 4.8	↑ 4.8	Strategic Planning	↘ 4.3	↑ 6.3	↗ 5.0

Source: HealthConsult, Program sustainability assessment survey (n=34 survey responses)

Generally, scores improved since 2022, particularly in domains including Communications, Program Adaptation and Strategic Planning. Strengths across the sites included Environmental Support and Program Adaptation, while there remained ongoing need for support in Funding Stability and Organisational Capacity.

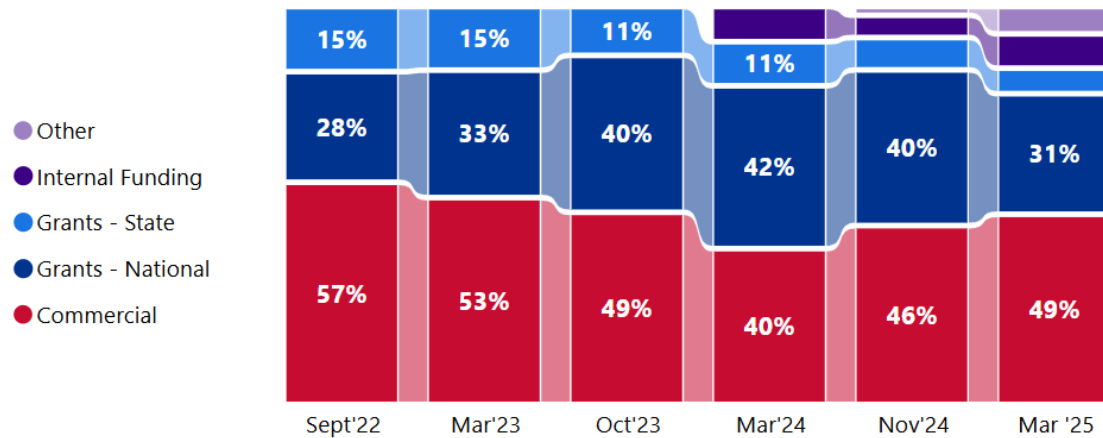
## 7.2. Financial sustainability

### 7.2.1. Funding diversification

A critical component of sustainability has been the diversification of CT funding sources.

**TrialHub sites have successfully reduced their reliance on grant funding**, increasing from three funding sources in 2022 to five in 2025 (Figure 13). This diversification reflects greater financial viability for participating sites.

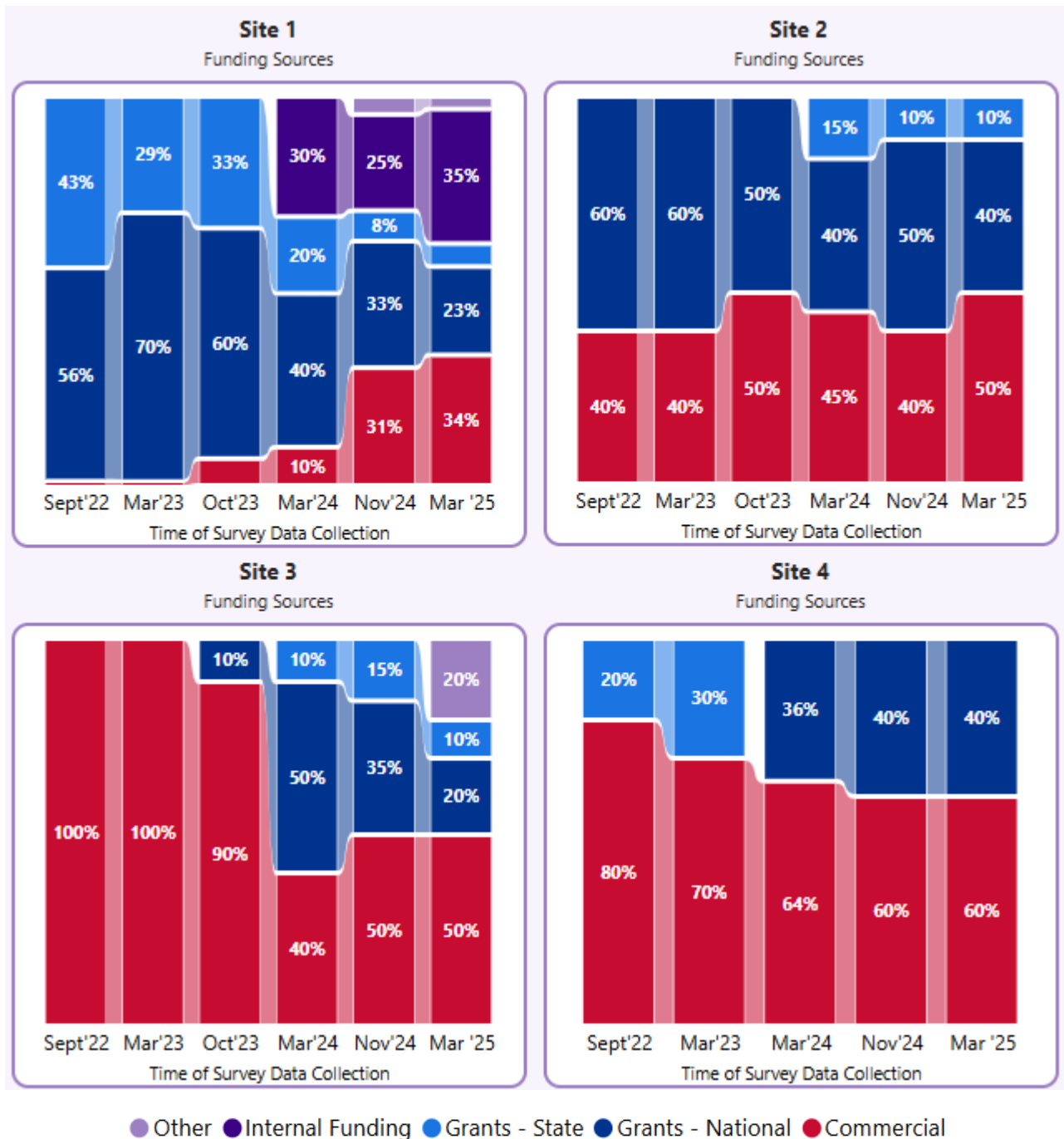
**Figure 13: CT funding sources at TrialHub's flagship sites**



Source: HealthConsult, Ongoing site survey on CT financials

Northern Health has transformed from being 100% commercially funded in 2022 to a more balanced portfolio with 50% commercial funding in 2025 and three new funding sources. Similarly, Latrobe has reduced reliance on grants from 100% to 57%, introducing three new funding sources (Figure 14). This diversification creates resilience against changes in any single funding stream.

Figure 14: CT funding sources by TrialHub flagship site



Source: HealthConsult, Ongoing site survey on CT financials

Site representatives reported significant progress toward financial self-sufficiency, with one site noting their unit is now *"quite safely in the black financially"* and able to hire additional CT staff funded solely through trial revenue. TrialHub has supported this through several key strategies:

- **Developing robust financial management practices:** Sites reported learning to maximise trial funding by tracking milestones and implementing proper invoicing procedures.

- **Strategic portfolio development:** Recognising that cancer trials alone (representing only 18% of all trials) are insufficient for regional service sustainability, TrialHub has encouraged diversification into non-cancer therapeutic areas.
- **Commercial trial attraction:** Sites have been supported to attract and manage industry-sponsored trials that generate profits that can then subsidise other important but less profitable studies.

Despite these successes, regional sites (i.e., flagship and non-flagship sites) continue to face challenges in attracting sufficient commercial trials. As one site representative noted:

*"There's a challenge outside of metro with attracting commercial trials and having enough commercial trials to financially support a CT unit."*

Non-flagship site representative

### 7.2.2. Sustainability outlook

**The sustainability outlook varies considerably across participating sites**, reflecting their different maturity levels and local contexts. For example, Bendigo Health and Northern Hospital are likely sustainable due to their ability to attract independent industry-sponsored studies. Latrobe Regional Health has achieved self-sustainability by expanding beyond cancer trials.

While financial support may end, a Latrobe Regional Health representative emphasised the value of the relationships built through TrialHub: *"We've built connections with the other TrialHub sites. Now we reach out to each other."*

TrialHub's sustainability approach stands out within the CT ecosystem, with one stakeholder noting: *"I've never heard anyone but TrialHub talking about [sustainability] as a goal for some of the outer metro and regional sites."* This focus on long-term viability rather than short-term outcomes distinguishes the program and suggests potential for creating lasting change in Australia's CT landscape.



## 8. Comparative analysis of TrialHub and related initiatives

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This Chapter examines TrialHub in comparison with related programs, including the ATP, the National One Stop Shop (NOSS), and the ReViTALISE project, to understand if TrialHub offers a unique or duplicative proposition and/or whether it has differential impact.

### 8.1. Comparative approaches to increasing access to CTs

The Australian CTs landscape features several government-funded initiatives aimed at improving access to CTs, particularly for underserved populations in regional, rural, and remote areas.

Between 2019 and 2021, the Commonwealth Government established multiple programs (including TrialHub) to address inequities in CT access:

- **ATP:** A multi-jurisdictional initiative focused on extending trial reach through telehealth technologies.<sup>10</sup>
- **NOSS:** A national health and medical research platform that streamlines administrative processes for CTs through a single national workflow.<sup>11</sup>
- **ReViTALISE:** Targeting to improve CT access for and participation of regional Victorians.<sup>12</sup>

**These initiatives take complementary but distinct approaches** to TrialHub, and have received significant federal funding to addressing CT access inequities.

#### Operational focus

- TrialHub's approach centres on direct health service mentoring and building sustainable local capabilities.
- In contrast, NOSS focuses on streamlining administrative processes through technology solutions. However, one stakeholder noted in consultation: *"NOSS risks increasing inequities rather than decreasing inequities"* without programs like TrialHub that develop local capabilities to utilise such systems effectively.

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<sup>10</sup> Australian Teletrial Program 2024, retrieved from: <https://australianteletrialprogram.gov.au/>

<sup>11</sup> Australian Commission on Safety and Quality in Health Care. Consultation Report – Requirements for the National One Stop Shop, the National Clinical Trials Front Door and core elements of the National Site-Specific Assessment. Sydney: ACSQHC; 2022.

<sup>12</sup> Menzies School of Health Research. Aboriginal and Torres Strait Islander People with Cancer – Clinical Trial Access Initiative: Consultancy Report for ReViTALISE Project, 2022.

- The ATP adopts what one interview participant characterised as more of a "fly-in, fly-out model" that extends trial reach and has created connections with remote sites across multiple jurisdictions, which however, remain dependent on hub support rather than becoming self-sustaining.

### Geographic and therapeutic focus

- While most initiatives began with a particular geographic or therapeutic focus, TrialHub has recognised early that diversification is essential for regional sustainability and has supported its flagship sites expanded beyond cancer trials into other therapeutic areas.
- ReViTALISE primarily addresses oncology trials in rural Victoria.
- ATP spans multiple jurisdictions but has retained a primary focus on extending existing trial designs rather than developing local trial capabilities.

### Workforce development

A critical differentiator for TrialHub is its comprehensive workforce development strategy that addresses capability gaps across all levels:

- **Executive buy-in:** Building understanding of CTs' value to health services
- **Pharmacy expertise:** Specialised train-the-trainer program with pharmacy mentoring
- **Medical research leadership:** Research fellow programs to develop local investigators
- **Professional networking:** Creating connections to prevent isolation of regional staff
- **Operational capability:** Practical training in budgeting, negotiation and trial management.

This approach recognises that position funding alone is insufficient. One stakeholder noted:

*"It's actually not enough just to throw money at sites and to start doing trials. It's such a more complex problem to fix that requires a much more comprehensive appreciation of the workforce that's actually required."*

Stakeholder

TrialHub's distinction lies in its focus on building skills that enable workforce retention in regional areas. Another stakeholder commented: *"[The program] has enabled professionals to remain in regional settings who otherwise would have returned to metropolitan areas"* through the professional support and connectivity TrialHub provided.

In comparison, the NOSS consultation report identified workforce as a critical issue but focused on "professional pathways to support research sites" rather than direct capability building while the ATP and ReViTALISE programs have focused more on creating funded positions without the same emphasis on mentoring and sustainability planning.

## Capability framework development<sup>13</sup>

A significant TrialHub innovation has been the development of a structured capability framework for CT sites:

- co-designed based on data collected in Victoria during the 2020–2021 period
- CT unit capability framework based on a maturity model
- internationally recognised and adopted in multiple jurisdictions
- aligned with the National Clinical Trials Governance Framework
- provides measurable benchmarks for site development.

This framework has gained international recognition, with one stakeholder noting:

*"TrialHub has, for the first time ever, internationally, put together a model of how to map capability at various sites."*

Stakeholder

Another stakeholder acknowledged:

*"The TrialHub capability framework will be an effective tool for determining site readiness in terms of National Clinical Trial Governance Framework as well."*

Stakeholder

## Funding and resource utilisation

An important consideration when comparing these initiatives is their relative funding levels and how resources were allocated to achieve outcomes. The various programs received different levels of funding:

- TrialHub: \$16 million (with \$2.4 million allocated to physical infrastructure)
- ReVITALISE: \$18.6 million
- ATP: \$75.2 million

Each program allocated these resources differently based on their approach to improving CT access. With \$13.6 million available for operational activities after infrastructure costs, TrialHub's approach has focused on strategic mentorship and capability building across multiple regional health services (for more details see section 8.2 TrialHub's point of difference below).

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<sup>13</sup> Woollett, A., et al., 2023. A capability framework to inform the fundamental requirements for clinical trial unit development, growth and long term success in outer metropolitan and rural areas. Contemporary Clinical Trials Communications, 32, p.101072.

## 8.2. TrialHub's point of difference

The evidence from analysis of stakeholder interviews, review of program documentation and comparative analysis reveals four key differences that define TrialHub's unique value proposition:

- 1. Capability-building vs. system solutions:** While the NOSS and other initiatives address administrative barriers through technology, TrialHub addresses capability barriers through direct mentoring and support. These approaches are complementary rather than competitive.
- 2. Sustainability focus:** TrialHub's explicit focus on supporting sites to become financially sustainable CT units distinguishes it from programs that create ongoing dependency on government funding.
- 3. Whole-of-service approach:** Rather than focusing solely on CT coordinators or investigators, TrialHub works across all levels of health services, from executives to pharmacists to operational staff, recognising that successful trial implementation requires system-wide capability.
- 4. Knowledge propagation philosophy:** TrialHub's commitment to open sharing of resources, frameworks and expertise (both nationally and internationally) has created disproportionate impact relative to its funding level.

One stakeholder acknowledged recognition of TrialHub's distinctive contribution:

*"I am a huge fan of the work they have done and how they have done it, and I would like to continue to work with them."*

Related program representative

TrialHub's distinctive value lies in its hands-on, frontline approach. TrialHub embeds directly within clinical settings, working shoulder-to-shoulder with healthcare teams to build practical capabilities where they matter most – where CTs happen.

# 9. Conclusion and future opportunities

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## 9.1. Conclusion

Based on the KEQs that have guided the evaluation activity, the evaluation has found:

### 1. Has TrialHub provided tools and resources to build workforce capability to support investigator-initiated CTs?

Yes. TrialHub has enhanced workforce capability through professional development pathways, training programs, and mentoring relationships. Staff numbers increased by 61% since 2022, with lead investigators growing by 148%. The internationally recognised capability framework, Pharmacy Train-the-Trainer program, and fellowship opportunities have created sustainable workforce development infrastructure.

### 2. Has TrialHub developed local and international partnerships and collaborations that enhance Australia as a preferred provider of CTs?

Yes. TrialHub has supported 32 formal partnerships across health services, not-for-profit organisations, and international bodies. The sponsor workshop connected regional sites with pharmaceutical companies, resulting in new commercial trial opportunities. Regional sites now function increasingly as peers rather than dependents of metropolitan centers.

### 3. Has the use of technologies enhanced access to CTs in agreed priority areas?

Yes. Eight teletrials have been activated across flagship sites. Innovative care models enable patients to receive specialised treatment phases at metropolitan centers while maintaining ongoing care at local facilities. While technology adoption continues to evolve, TrialHub's approach demonstrates effective implementation when supported by appropriate capability building.

### 4. Has TrialHub promoted the value of CTs to the broader population, improving access and participation?

Yes. TrialHub implemented structured communication plans, developed websites and standardised resources, and created the Ambassador Program featuring former trial participants as advocates. Sites have developed culturally appropriate resources for diverse communities, contributing to increased trial participation.

### 5. Has TrialHub increased CTs activity in areas of need?

Yes. Since 2020, 138 new clinical trials have opened across flagship sites, with significant portfolio diversification. Geographic distribution of participants shows increased representation from outer metropolitan and regional areas, including MM 4 and 5 regions.

## 6. What impact on access to cancer CTs has TrialHub had for patients within agreed priority areas?

TrialHub has expanded geographical access to cancer trials across priority areas. Portfolio development includes breast and lung cancer trials (24 each), colorectal cancer (14), prostate cancer (11) and myeloma (10). Common cancers represent 80% of CTs, while trials for rare cancers are now established across the network.

## 7. Has TrialHub identified opportunities to augment ongoing quality improvement for CTs?

Yes. The capability framework provides measurable benchmarks for site development aligned with national governance standards. Sites have implemented improved administrative processes, diversified income streams, and reduced reliance on grants, with Program Sustainability Assessment Tool scores showing improvement since 2022.

## 9.2. Further need and opportunity

Building on TrialHub's demonstrated impact, several strategic opportunities exist to extend and enhance its work:

### 1. Collaborative program integration.

TrialHub can create further value through strategic alignment with complementary national initiatives:

- Leverage ATP infrastructure to expand teletrials and decentralised trial models
- Partner with ReViTALISE to enhance engagement with First Nations and CALD communities
- Integrate with the NOSS to streamline administrative processes while maintaining focus on capability building.

### 2. Network expansion.

The success of flagship sites creates a foundation for wider impact:

- Support flagship sites to mentor smaller regional and rural health services, following the successful model of Bendigo Health's work with Echuca Regional Health
- Develop tiered support models that match capability-building resources to site maturity levels
- Ensure appropriate resourcing for mentoring activities that extend beyond primary partnerships.

### 3. Workforce sustainability.

Continued investment in workforce development remains critical:

- Formalise and expand professional development pathways, including micro-credentialling and specialist training programs
- Maintain ongoing assessment of workforce training needs to address emerging capability gaps

- Establish structured career progression pathways to retain skilled staff in regional areas.

**4. Diversified CT portfolios.** Strategic portfolio development is essential for long-term viability:

- Expand beyond cancer trials to include high-burden chronic diseases prevalent in regional communities
- Develop capabilities in therapeutic areas aligned with local population health needs
- Establish formal processes for community input into trial selection and design to ensure relevance.

**5. Enhance community engagement and outreach.** Strengthening community connections and formalising engagement approaches will increase trial participation and awareness:

- Formalise the Ambassador Program with comprehensive implementation toolkits that enable sites to identify community members with CT experience to advocate for trial participation
- Develop tailored engagement strategies for diverse communities, particularly those with less frequent health service contact
- Co-design culturally appropriate information with First Nations and CALD communities to enhance understanding of CT benefits
- Establish partnerships with local health services, Aboriginal Medical Services, ACCHOs, and multicultural organisations to extend trial awareness through existing trusted channels
- Create standardised communication resources and strategies for health services to effectively promote trial value to diverse stakeholders
- Implement metrics to measure community engagement effectiveness and document successful strategies for replication.

**6. Capability Framework refinement.** The capability framework requires ongoing refinement:

- Maintain regular updates to the Capability Framework to reflect emerging standards and technologies
- Ensure alignment with the National Clinical Trials Governance Framework
- Develop implementation guides for sites at different maturity levels
- Share framework methodology nationally to support standardised capability assessment.

Realising these opportunities will require sustained funding support, strategic partnerships, and ongoing commitment to TrialHub's collaborative approach to building CT capabilities in outer metropolitan, regional, and rural Victoria.

# Appendix A TrialHub performance summary

TrialHub's performance against the key performance indicators is presented in Table 2.

**Table 2: TrialHub activities against performance indicators since September 2022**

Survey	KPI	September 2022	March 2023	September 2023	March 2024	September 2024	March 2025
Flagship site staff survey	Survey respondents	35	37	33	19	16	20
	Respondents aware of TrialHub	89% (31 of 35)	97% (36 of 37)	94% (31 of 33)	84% (16 of 19)	100% (16 of 16)	100% (20 of 20)
	Respondents who provided CT-related care [% in a teletrial]	91% (32 of 35) [29% (10 of 35)]	97% (36 of 37) [32% (12 of 37)]	88% (29 of 33) [21% (7 of 33)]	84% (16 of 19) [11% (1 of 19)]	75% (12 of 16) [19% (3 of 16)]	80% (16 of 20) [25% (5 of 20)]
	Most commonly represented disciplines	46% CT coordinator, 31% specialist	57% CT coordinator, 27% specialist	48% CT coordinator, 24% specialist	42% CT coordinator, 32% specialist	56% CT coordinator, 19% specialist	45% CT coordinator, 19% specialist
	Whether TrialHub increased CT activity	40%	41%	48%	47%	94%	75%
	More patients are participating in CTs in key areas <sup>14</sup>	43%	38%	45%	37%	69%	45%
CT participant survey	Survey respondents	18	34	19	15	22	159
	Age	67% 55–74 years old	59% 55–74 years old	64% 55–74 years old	67% 55–74 years old	59% 55–74 years old	60% 55–74 years old
	Gender	56% female, 44% male	38% female, 62% male	42% female, 58% male	40% female, 60% male	55% female, 45% male	65% female, 35% male

<sup>14</sup> The key areas are prostate cancer, melanoma, rare cancers or rare diseases.



Survey	KPI	September 2022	March 2023	September 2023	March 2024	September 2024	March 2025
	<b>Distance travelled to CT site</b>	<b>44%</b> <30 kms	<b>47%</b> <30 kms	<b>26%</b> <30 kms	<b>47%</b> <30 kms	<b>%</b> <30 kms	<b>35%</b> <30 kms
	<b>CT participation – most common reasons</b> (N=184 across all periods)	<ul style="list-style-type: none"> <li>• Potential benefit to others from the knowledge gained by the study (82%)</li> <li>• I would receive a higher level of care/follow-up (44%)</li> <li>• My doctor recommended that I participate (38%)</li> </ul>					
<b>Training participant survey</b>	<b>Survey respondents (participants)<sup>15</sup></b>	<b>41</b>	<b>16</b>	<b>4</b>	<b>6</b>	<b>14</b>	<b>2</b>
	• Trial coordinator education program	<b>63%</b> (n=26)	<b>56%</b> (n=9)	<b>75%</b> (n=3)	<b>67%</b> (n=4)	<b>71%</b> (n=10)	<b>100%</b> (n=2)
	• Pharmacy train the trainer program	<b>29%</b> (n=12)	<b>6%</b> (n=1)	<b>25%</b> (n=1)	<b>17%</b> (n=1)	<b>14%</b> (n=2)	n=0
	<b>How training participants learned about the training program</b>	<b>39%</b> TrialHub, <b>22%</b> My hospital <b>20%</b> Alfred Health	<b>13%</b> TrialHub, <b>38%</b> My hospital, <b>6%</b> Alfred Health	<b>25%</b> TrialHub, <b>50%</b> My hospital	<b>17%</b> TrialHub, <b>50%</b> My hospital <b>33%</b> Alfred Health	<b>29%</b> TrialHub, <b>43%</b> My hospital <b>21%</b> Alfred Health	<b>100%</b> My hospital
	<b>Sufficient support to apply the concepts learned</b>	<b>44%</b>	<b>44%</b>	<b>75%</b>	<b>50%</b>	<b>64%</b>	<b>50%</b>
<b>Ongoing site survey</b>	<b># CTs at sites</b> [# Open to recruitment]	<b>119</b> [63]	<b>101</b> [60]	<b>119</b> [60]	<b>135</b> [52]	<b>147</b> [57]	<b>169</b> [55]
	<b># CT workforce at sites (Personnel count)</b>	<b>157</b>	<b>189</b>	<b>209</b>	<b>211</b>	<b>232</b>	<b>253</b>
	<b># participants recruited</b> [cumulative]	<b>595</b> (reporting period of first progress report)	<b>174</b> [769]	<b>306</b> [1,075]	<b>238</b> [1,313]	<b>192</b> [1,505]	<b>414</b> [1,919]

<sup>15</sup> A decline in training participation was expected as most of the CT staff were recruited in late 2022, early 2023. Please see the CT workforce personnel count trend. The changing employment of staff also means different staff are interviewed in each round of data collection.

Survey	KPI	September 2022	March 2023	September 2023	March 2024	September 2024	March 2025
	# CT participants at sites] <sup>16, 17</sup>						
	% of CT funding source that is commercial	57%	53%	49%	40% <sup>18</sup>	46% <sup>18</sup>	49%

<sup>16</sup> A survey trial initially reported at Latrobe Regional Hospital in Survey Period 1 – Sept’22 was removed from the dashboard in November 2023 as it was not reported in subsequent survey periods.

<sup>17</sup> Several trials were re-categorised to 'registry non-interventional' sponsor type in Survey Period 4– Mar’24 and excluded from all reporting periods.

<sup>18</sup> The apparent decline in commercial funding during 2024 reflects strategic diversification rather than reduced trial activity. Sites are expanding funding streams through grants and partnerships while implementing robust feasibility processes and pursuing higher-value studies, including Phase I trials.

# Appendix B Logic model

## Pilot Trial Hub Program Logic

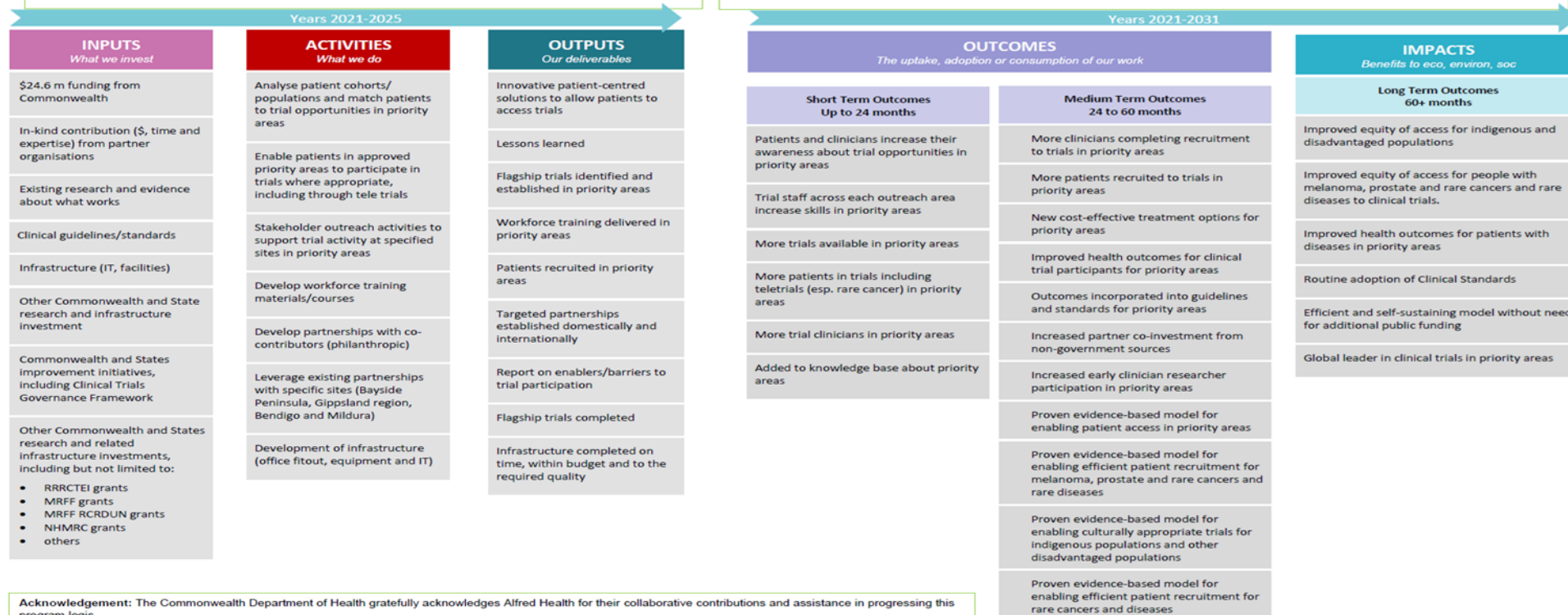
Objectives: Improve access and increase participation in clinical trials in agreed priority areas. Priority areas are defined by 1) Research: rare cancers, rare diseases, prostate cancer, melanoma, and other priority areas as may be agreed by the Department.

2) Geographic regions: outer metro, regional, rural and remote areas and 3) Population groups: indigenous and other disadvantaged Australians.

**PARTICIPATION: Clinicians, Pharmacists, Trial Coordinators and Patients**

**Assumptions:** target groups will participate in/complete training program. Outreach activities at specified sites will result in improved recruitment and clinician engagement, partner organisation will be involved.

**External Factors:** Funding and contracts, changing demographics, research and evidence on melanoma, prostate cancer and rare cancers and rare diseases.



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# Appendix C Evaluation framework

Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
<b>1. What impact on access to cancer clinical trials has TrialHub had for patients with agreed priority areas of prostate cancer, melanoma, rare cancers, rare diseases, and other priority areas (as agreed by the Department of Health) in outer metropolitan, regional and remote areas of Victoria?</b>									
• Description of processes of identification and access to any independent clinical trials, including within prior programs at flagship sites, within the agreed priority areas				✓			✓		Descriptive statistics of quantitative data and thematic analysis of quantitative data. Compare across different case study sites.
• Perception of communities indicating they have improved access to clinical trials and Provision for feedback concerning areas for improvement (1. & 2.)					✓				
• Increased evidence for methodologies to improve recruitment in agreed priority research area trials (2.)	✓								
• Improved patient-reported access to trials at agreed hospital axes and sites in agreed priority areas (2.)					✓				
• Description of issues/opportunities in relation to access at Baseline at each case study site. • Description of TrialHub activities in relation to access at midpoint evaluation at each case study site • Description of TrialHub impact on access at endpoint at each case study site								✓	Narrative analysis
<b>2. Has the use of technologies enhanced access to clinical trials in agreed priority areas of prostate and rare cancers, melanoma and rare cancers, rare diseases, and other priority areas (as agreed by the Department of Health)?</b>									
• Description of technologies used to enhance access to trials (Teletrials, data platforms etc)	✓			✓			✓		Review documentation, and answers to relevant questions in the flagship site staff survey, and discuss processes during case studies, to develop process maps to describe recruitment to Teletrials at flagship sites and use of technology. Compare across different case study sites.

Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
<ul style="list-style-type: none"> <li>Flagship site staff perception on the extent to which technologies enhanced flagship sites' capacity and capability to participate in Teletrials</li> </ul>							✓		Analyse using descriptive statistics.
<ul style="list-style-type: none"> <li>Identification of factors that influenced patient access to clinical trials, and number of these that relate to technologies used in Teletrials</li> </ul>	✓				✓		✓		Analyse individual data sources (using descriptive statistics for quantitative data or thematic analysis for qualitative data) and triangulate information. Compare across different case study sites.
<ul style="list-style-type: none"> <li>Extent to which the Teletrial model has contributed to trial cost effectiveness and value (5.)</li> </ul>				✓					Present cost effectiveness findings carried out independent of this evaluation (out of scope for this evaluation).
<ul style="list-style-type: none"> <li>Description of issues/opportunities in relation to use of technologies at Baseline at each case study site.</li> <li>Description of TrialHub activities in relation to use of technologies at midpoint evaluation at each case study site</li> <li>Description of TrialHub impact in relation to use of technologies at endpoint at each case study site</li> </ul>								✓	Narrative analysis
<b>3. Has TrialHub increased trial activity in areas of need (i.e., outer metro, regional, rural, and remote areas)?</b>									
<ul style="list-style-type: none"> <li>Description of engagement processes and interventions (community awareness events, in services to staff, etc) focused on:               <ul style="list-style-type: none"> <li>improving awareness of trial opportunities for Aboriginal and Torres Strait Islander people and other underserved populations</li> <li>enhancing the understanding of the opportunities and barriers for Aboriginal and Torres Strait Islander people to participating clinical trials (2.)</li> </ul> </li> </ul>	✓	✓		✓	✓		✓	✓	Analyse individual data sources (using descriptive statistics for quantitative data or thematic analysis for qualitative data) and triangulate information.

Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
<ul style="list-style-type: none"> <li>Increase in patients recruited to trials in agreed patient-outreach hospital axes by the agreed priority areas (18. &amp; 3.):               <ul style="list-style-type: none"> <li>Increase in recruitment to trials based on geographic regions</li> <li>Increase in recruitment to trials in defined population groups</li> </ul> </li> </ul>	✓	✓		✓			✓	✓	
<ul style="list-style-type: none"> <li>Increase in early clinician researcher trial participation at agreed hospital axes and sites in the agreed priority research areas (3.)</li> </ul>	✓	✓		✓			✓	✓	
<ul style="list-style-type: none"> <li>Flagship trials identified and established in the agreed priority research areas and increased across all axes (7.)</li> <li>An increase in trials in agreed priority research areas (7.)</li> <li>An increase in new trials, and new arms of existing trials and numbers by agreed priority research areas (7.)</li> </ul>		✓		✓					
<ul style="list-style-type: none"> <li>Description of issues/opportunities in relation to overall trial activity at Baseline at each case study site.</li> <li>Description of TrialHub activities in relation to trial activity at midpoint evaluation at each case study site</li> <li>Description of TrialHub impact on trial activity at endpoint at each case study site</li> </ul>								✓	Narrative analysis
<b>4. Has TrialHub promoted the value of clinical trials to the broader population? Has this resulted in improving clinical trial participation?</b>									
<ul style="list-style-type: none"> <li>Identification of source of knowledge of clinical trials in priority areas by clinicians involved in the trials and patients accessing the trials</li> </ul>					✓		✓		Descriptive statistics on quantitative data and thematic analysis on qualitative data.
<ul style="list-style-type: none"> <li>Download rates and other Google Analytics/ social media data showing changes over time (e.g. increase in search volume of 'TrialHub' since its commencement, relative to other related searches (e.g. 'clinicaltrials.gov Australia', 'human clinical trials', 'clinical trial data' etc))</li> </ul>			✓						Descriptive statistics, including presenting data to show changes over time.

Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
• Trial staff report increased awareness about trial opportunities by agreed priority research areas, geographic regions and population groups (9.)	✓						✓		
• Clinician's report increased awareness about trial opportunities in agreed patient-outreach hospital axes and sites by agreed priority research, geographic regions, and population groups (9.)	✓								
• Patients reporting increased awareness about relevant trial opportunities by agreed priority research areas (10.)					✓				
• Patients and clinicians report increased awareness regarding trial opportunities (21.)					✓		✓		
<ul style="list-style-type: none"> <li>• Description of issues/opportunities in relation to promotion of clinical trials at Baseline at each case study site.</li> <li>• Description of TrialHub activities in relation to promotion of clinical trials at midpoint evaluation at each case study site</li> <li>• Description of TrialHub impact on promotion of trials at endpoint at each case study site</li> </ul>								✓	
<b>5. Has TrialHub developed partnerships and collaborations that enhance Australia as a preferred provider of clinical trials and led to subsequent economic benefits?</b>									
• Increase in total trial participation by patients in the agreed priority research areas in geographic regions and population groups, including via Teletrials (4.)	✓	✓		✓		✓	✓		Analyse individual data sources (using descriptive statistics for quantitative data or thematic analysis for qualitative data) and triangulate information. Compare across different case study sites.
• Increase in partner collaboration across the TrialHub network (4.)		✓		✓					
• Increase in awareness of Teletrials within metropolitan, outer metropolitan and regional Victorian clinical sites (4.)	✓	✓		✓			✓		

Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
<ul style="list-style-type: none"> <li>Partnerships and collaborations established to facilitate and enable trials in the agreed priority areas and patient-outreach hospital axes and regions, including (6.):               <ul style="list-style-type: none"> <li>➤ Each of the agreed priority area</li> <li>➤ Domestic/national / international partnerships</li> <li>➤ Philanthropic</li> <li>➤ Industry partnerships</li> <li>➤ Non-industry partnerships</li> </ul> </li> </ul>	✓	✓		✓			✓		
<ul style="list-style-type: none"> <li>Increase in partner co-investment from non-government sources in the agreed priority research areas (6. &amp; 15. &amp; 16.)</li> </ul>	✓	✓		✓			✓		
<ul style="list-style-type: none"> <li>(Contracts and Grants) Increase in grants and research income supporting the conduct of clinical trials (13.)</li> </ul>	✓			✓			✓		
<ul style="list-style-type: none"> <li>Description of issues/opportunities in relation to partnerships and collaborations at Baseline at each case study site.</li> <li>Description of TrialHub activities in relation to partnerships and collaborations at midpoint evaluation at each case study site</li> <li>Description of TrialHub impact in relation to partnerships and collaborations at endpoint at each case study site</li> </ul>								✓	Narrative analysis
<b>6. Has TrialHub provided tools and resources to build workforce capability to support investigator-initiated trials?</b>									
<ul style="list-style-type: none"> <li>Pharmacy trial staff, and trial Coordinator's report increased clinical trial skills (1.)</li> </ul>						✓			Analyse individual data sources (using descriptive statistics for quantitative data or thematic analysis for qualitative data) and triangulate information. Compare across different case study sites.
<ul style="list-style-type: none"> <li>All trial clinicians stated they developed increased clinical trial skills and knowledge (1.)</li> </ul>						✓			
<ul style="list-style-type: none"> <li>Increase in early clinical researcher trial participation at agreed hospital axes (1.)</li> <li>Increase in overall trial staff at agreed hospital axes (1.)</li> <li>Increase in site staff working in the agreed priority research areas (1.)</li> </ul>		✓		✓					
<ul style="list-style-type: none"> <li>Increase in available training resources for trial staff in the agreed priority research areas (1.)</li> </ul>		✓		✓			✓		



Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
• Increase in number of staff, including clinicians, in outreach trial sites (19.)		✓		✓					
• More early clinician researchers in the agreed priority research areas including geographic locations and research areas (20.)		✓		✓					
<ul style="list-style-type: none"> <li>• Description of issues/opportunities in relation to workforce at Baseline at each case study site</li> <li>• Description of TrialHub activities in relation to workforce at midpoint evaluation at each case study site</li> <li>• Description of TrialHub impact on workforce at endpoint at each case study site</li> </ul>								✓	Narrative analysis
<b>7. Has TrialHub identified opportunities to augment ongoing quality improvement for both investigator initiator and commercially sponsored trials?</b>									
• Improvements in administrative processes associated with clinical trial activation (e.g., cost, complexity and time commitment required)		✓						✓	Describe administrative processes associated with clinical trials at each flagship site and compare changes/ identify improvements over time, between baseline, midpoint and endpoint data collection.
• Identification of duplication and overlap between TrialHub and other programs in the CT sector				✓				✓	Content analysis and thematic analysis
<ul style="list-style-type: none"> <li>• Extent to which TrialHub's structures and processes can be maintained into the future once the TrialHub funding ends</li> <li>• Extent to which health professionals reported improvement in opportunities to augment knowledge to conduct clinical trials in the partner sites</li> </ul>	✓							✓ (PSAT)	Analyse results of the Program Sustainability Assessment Tool (PSAT) questions as per the tool. Thematic analysis of stakeholder/ case study sites opinions about how sustainable the model is without the TrialHub funding.
• Identification of strategies to optimise the sustainability of clinical trials units at flagship site once the TrialHub funding ends	✓							✓ (PSAT)	
• TrialHub fit out of the administration area completed on time, within original budget and to the required standard (8.)				✓ November 2024					Analyse individual data sources (using descriptive statistics for quantitative data or thematic analysis for qualitative data) and triangulate information. Compare across different case study sites.
• Flagship sites operating under capability criteria, ensuring the delivery of safe and appropriate clinical trials (2.)	✓ End-point only								

Key Performance Indicators	Interviews	Secondary data	Google Analytics	Document review	Clinical trial	Training participant	TrialHub site staff	Case studies	Analysis
• National guidelines and standards adopted across Flagship TrialHub sites (2.)	✓			✓					
• Research papers/clinical audits reporting clinician implementation of changes in clinical practice based on trial operations (2.)		✓		✓					
• All flagship sites maintain compliance with National Standards and Guidelines (2.)	✓			✓			✓		
<ul style="list-style-type: none"> <li>• Description of issues/opportunities in relation to quality improvement at baseline at each case study site</li> <li>• Description of TrialHub activities in relation to quality improvement at midpoint evaluation at each case study site</li> <li>• Description of TrialHub impact on quality improvement at endpoint at each case study site.</li> </ul>								✓	

# Appendix D TrialHub partnerships

Figure 15: Partnerships supported by TrialHub

Site partner	Non-TrialHub site	Consumer group	Not for profit	International
<ul style="list-style-type: none"> <li>Latrobe Regional Health</li> <li>Bendigo Health</li> <li>Peninsula Health</li> <li>Northern Health</li> <li>Bass Coast Health</li> <li>Mildura Base Public Hospital</li> </ul>	<ul style="list-style-type: none"> <li>Walter and Eliza Hall Institute of Medical Research (WEHI)</li> <li>Austin</li> <li>Peter Mac Callum</li> <li>Cabrini</li> <li>Monash Health</li> <li>Eastern Health</li> <li>Goulburn Valley health</li> <li>Grampian Health</li> <li>Barwon Health</li> <li>Western Health</li> <li>Bairnsdale Community hospital</li> <li>West Gippsland Health Group</li> <li>Central Gippsland Health</li> <li>Murdoch Children's Research Institute (MCRI)</li> <li>NT Health</li> </ul>	<ul style="list-style-type: none"> <li>Engage Rare</li> <li>Cancer Council Victoria</li> <li>Rare Voice Australia</li> <li>Rare Cancers Australia</li> </ul>	<ul style="list-style-type: none"> <li>Regional Trials Network</li> <li>Biogrid</li> <li>Australian Teletrial Program (ATP)</li> <li>OMICO</li> <li>Safer Care Victoria</li> <li>Monash Partners Comprehensive cancer consortium</li> <li>Cancer Trials Australia</li> <li>Cancer institute NSW</li> <li>NSW Rural, Regional and Remote Clinical Trial Enabling Program (NSW RRR program)</li> <li>Australian Clinical trials Education Centre</li> <li>Victorian Comprehensive Cancer Centre</li> <li>Australian Clinical Trials Alliance (ACTA)</li> <li>Movember</li> </ul>	<ul style="list-style-type: none"> <li>New Zealand Department of Health</li> <li>International Accrediting Organisation for Clinical Research UK (IAOCR)</li> <li>African Clinical Research Network</li> <li>Society for Clinical Research Sites (SCRS)</li> </ul>

Source: TrialHub

# Appendix E Sponsor relationships

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The following sponsorship relationships are associated with the TrialHub network's CT activity:

<b>1.</b> 3T Biosciences	<b>13.</b> Bayer	<b>25.</b> George Clinical	<b>37.</b> Paraxel
<b>2.</b> AbbVie	<b>14.</b> BeiGene	<b>26.</b> Gilead	<b>38.</b> Pfizer
<b>3.</b> Adaptimmune	<b>15.</b> BioNTech	<b>27.</b> GSK	<b>39.</b> PPD (CRO)
<b>4.</b> Allucent (CRO)	<b>16.</b> BMS	<b>28.</b> HUTCHMED (Biotech company)	<b>40.</b> Regeneron
<b>5.</b> Alterome Therapeutics	<b>17.</b> Boehringer Ingelheim	<b>29.</b> ICON (CRO)	<b>41.</b> ROCHE
<b>6.</b> Amgen	<b>18.</b> Clinipace	<b>30.</b> IQVIA (CRO)	<b>42.</b> Sanofi
<b>7.</b> Antengene	<b>19.</b> Daiichi-Sankyo	<b>31.</b> Jassen (J & J)	<b>43.</b> Second Life Therapeutics, Inc
<b>8.</b> ArmStrong Clinical	<b>20.</b> Elevation Oncology	<b>32.</b> Medpace (CRO)	<b>44.</b> Southern Star Research (CRO)
<b>9.</b> Ascentage	<b>21.</b> Eli Lilly	<b>33.</b> MERCK Group	<b>45.</b> SyneosHealth
<b>10.</b> Astra Zeneca Alexion	<b>22.</b> ERASCA	<b>34.</b> MSD	<b>46.</b> Taiho
<b>11.</b> Avance Clinical	<b>23.</b> Fortrea	<b>35.</b> Novartis	<b>47.</b> VacV
<b>12.</b> AVEO (biotech in Oncology at Boston)	<b>24.</b> Genentech	<b>36.</b> Novotech	<b>48.</b> Xencor

Source: TrialHub