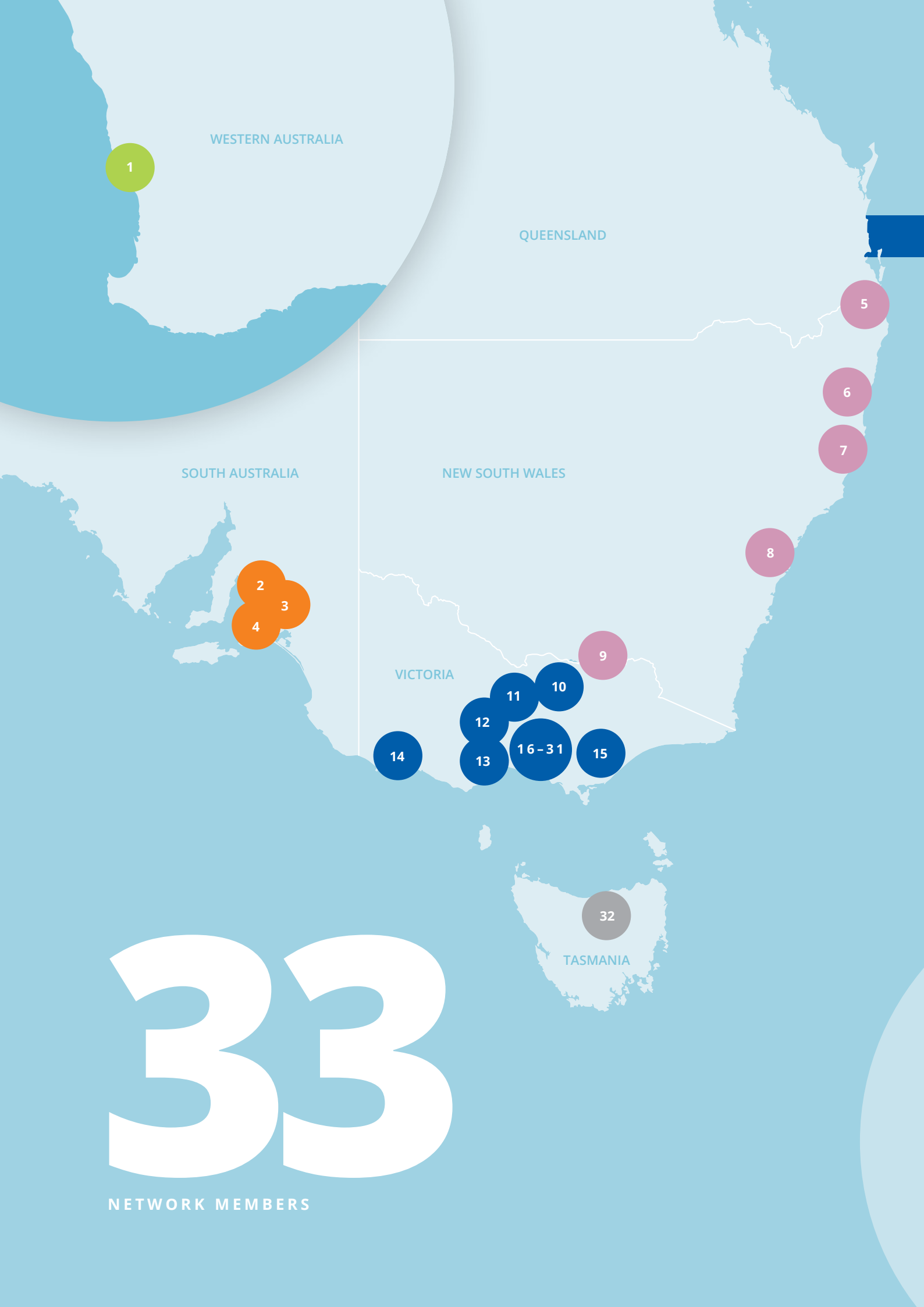
2021 ANNUAL REPORT

- 19 YEARS OPERATING
- 33 NETWORK MEMBERS
- 1600+ TRIALS OPENED
- 11,000+ PATIENTS ENROLLED

TO IMPROVE PATIENT CARE BY ENABLING THE WORLD'S BEST CLINICAL TRIALS

Cancer Trials Australia



33

NETWORK MEMBERS

OUR NETWORK MEMBERS

1. Linear Clinical Research
2. Calvary Central Districts Hospital
3. Lyell McEwin Hospital
4. Cancer Research South Australia
5. The Tweed Hospital
6. Coffs Harbour Health Campus
7. Port Macquarie Base Hospital
8. Chris O'Brien Lifehouse
9. Border Medical Oncology
10. Goulburn Valley Health
11. Bendigo Health
12. Ballarat Health Services
13. Barwon Health
14. South West Healthcare
15. La Trobe Regional Hospital
16. Alfred Health
17. Austin Health
18. Cabrini Health
19. Epworth Healthcare
20. Melbourne Health
21. Monash Health
22. Murdoch Children's Research Institute
23. Olivia Newton-John Cancer Research Institute
24. Peninsula Health
25. Peninsula Oncology Centre
26. Peter MacCallum Cancer Centre
27. Royal Children's Hospital
28. Royal Women's Hospital
29. St Vincent's Institute
30. The Walter and Eliza Hall Institute of Medical Research
31. Western Health
32. Launceston General Hospital
33. Auckland City Hospital

CONTENTS

CHAIRPERSON'S REPORT

JAYESH DESAI
BOARD CHAIRPERSON

It is with great pleasure that I pen my first Cancer Trials Australia Chairperson's report, to preface our 2021 Annual Report.

As per our Constitution, Andrew Scott stepped down from the CTA Board in August 2021, at the conclusion of his second successive term. I would like to take the opportunity to acknowledge the significant contribution Andrew Scott has made in shaping this organisation over many, many years, the last six of which were as our Board Chairperson. Andrew has helped ensure that I have inherited a particularly strong organisation, that is very well managed. I would also like to thank my fellow Directors for their important contributions throughout the previous year; Colin Nugent, Mark Shackleton, Zee Wan Wong, Michelle Gallaher, Craig Underhill and Tim Murphy, as well as our newest Director, Clare Scott, who joined the CTA Board in August 2021.

In 2021 CTA expanded Membership with the addition of Cancer Research South Australia and the La Trobe Regional Hospital, propelling us to 33 Members across five Australian states and New Zealand. Our growth continues into 2022, welcoming one additional Member in the first quarter alone.

CEO Kurt Lackovic and the entire CTA team continue to impress the Board with their ability to achieve consistent growth in both CTA's Membership and services, even against the backdrop of a second year of COVID-19 related restrictions. CTA service metrics grew further in 2021, once again matching or exceeding our year-on record in all key performance indicators. The management team has elaborated on this success in subsequent sections of this Annual Report.

Our strategic investment in information management systems continued throughout 2021, with the development of a fit for purpose software solution to manage clinical trial participation data, reduce administrative burden at clinical sites and improve data insights gathered across our clinical trial portfolio. This application, Clinibase, has been successfully rolled out to all service Members over the past 12 months, and on-going development continues in partnership with Melbourne-based health solutions provider, Cardiobase. Additional information can be found further into this Annual Report.

CTA remained prominent at both national and international conferences, albeit largely via virtual formats due to COVID-19 related travel restrictions. Our staff also continued to represent Members' interest on a range of committees and advisory groups, including the Australian Clinical Trials Alliance reference group, CT:IQ, and AusBiotech's Clinical Trials Advisory Group.

Cancer Trials Australia continues to ensure Australia remains a destination of choice for international clinical trial sponsors, securing earlier access to novel therapies for Australian cancer patients. The organisation remains extremely well positioned to continue providing value for money services to support clinical trial activity across our expanding Membership.

I wholeheartedly congratulate both CTA management and all CTA staff for their achievements across 2021, as well as acknowledge all Network Member personnel for the hard work required to ensure CTA's ongoing success.

REVIEW OF OPERATIONS

KURT LACKOVIC
CHIEF EXECUTIVE OFFICER

I signed on to lead this organisation just over five years ago, without the knowledge that a global pandemic would affect two of those years. However, despite COVID related restrictions, CTA has not only continued to flourish, but has had a significant hand in ensuring the entire clinical trial sector has maintained momentum throughout the past two years, including capitalising on Australia's enviable position as a relatively low COVID-impacted jurisdiction. I remain both incredibly privileged to lead our dedicated and growing team, and proud of what we have continued to achieve together across 2021.

Andrew Scott chaired the Board sub-committee that appointed me to this role in January 2017. Andrew has been a staunch supporter of CTA since our inception almost 20 years ago, and I will miss our regular interactions and in particular Andrew's sound advice. I have been fortunate to work with our incoming Board Chairperson, Jayesh Desai, for over 10 years across multiple roles. Jayesh has been a large part of CTA over many, many years, and I look forward to the opportunity to work even more closely with Jayesh as CTA's Board Chairperson. I would also like to welcome Clare Scott to the CTA Board. Clare is an experienced clinician-researcher, and former WEHI colleague, who will ensure the interests of our growing Medical Research Institute Members are effectively represented.

Across 2021 CTA's Membership expanded, all expiring service agreements were renewed for three additional years, and our service metrics grew again. There was a 31% increase in trial feasibilities, comprising predominantly Phase 1/2 studies. We coordinated a total of 250 HREC/Governance submissions across our service Members in 2021, up 9% compared to 2020. Post approval activity continued to steadily increase, with a record total of 1,246 amendments submitted in 2021, up 12% compared to 2020. Cash transferred to our Member sites grew 16% to a new record of over $34M.

Our continued growth was achieved against the backdrop of a transformative information systems project. Together with Melbourne-based healthcare solutions company Cardiobase, we developed a customised software solution called Clinibase, which was subsequently deployed across our Victorian and New South Wales service Members, in both metropolitan and regional settings. Clinibase significantly reduces administration of tracking and managing participant activity data for clinical trials, and improves data insights gathered for trials, with ongoing updates planned. You can read further details about this transformation on pages 20 to 23.

I was also pleased to work closely with our staff and Board Members to redefine our Vision and Mission and I am delighted to now formally launch these modern statements, which reflect the evolution of CTA over recent years:

Vision: To improve patient care by enabling the world's best clinical trials

Mission: To deliver excellence in clinical trial management and advance the Australian trial sector

Building on this work, towards the end of 2021 all CTA staff came together to identify new corporate values and associated behaviours, to align with our revised vision and mission statements.

The values adopted by our staff were:

- **Shared Purpose**
- **Integrity**
- **Collaboration**
- **Adaptability**
- **Compassion**

Work on incorporating these values into everyday life at CTA will continue into 2022.

Continual improvement is a necessity in today's world, and in 2021 CTA worked closely with the Parkville Cancer Clinical Trial Unit (PCCTU), the Royal Melbourne Hospital Human Research Ethics Committee, and Peter MacCallum Cancer Centre Human Research Ethics Committee on a First in Human/Phase 1 study initiative. A refined submission workflow was developed and piloted for these pivotal studies, leading to a significant reduction in start-up timelines and ensuring global competitiveness. Pleasingly, two of the pilot studies achieved global recognition for being the first in the world to initiate. Well done to all involved!

To round out the year, in December 2021 we secured significant co-funding from the Victorian Department of Health via the Victorian Cancer Agency to extend and expand our Advanced Training and Education Program in Early Phase Oncology Trials. Over the next two years, dedicated Phase 1 Fellows will ensure enhanced capability to support FTIH/Phase 1 trials at one regional and four metropolitan Victorian hospitals.

Clinical trials offer hope, often including access to novel, potentially life-saving therapies. CTA continues to ensure Australia is successful in attracting the best clinical trials on a competitive global stage, for the benefit of Australian patients. We continue to focus on (i) providing cost efficient and timely services to our expanding Membership, (ii) strategic investment in information systems that support our Members, as well as (iii) further enhancing our communication and advocacy voice with Members, industry, and government. Continuing to nurture tight links with both State and Federal governments will allow CTA to add further value in the evolving Australian clinical trial landscape, which now also includes Federal initiatives such as the National Clinical Trial Governance Framework and the One Stop Shop.

The CTA management team have expanded on their respective areas of responsibility further in this report, covering Clinical Trials Start-Up activity, Member Network Activities, Finance, Information Systems and Human Resources. I would like to thank all CTA staff, as well as all Network Member personnel, for the hard work that is essential to enable the CTA network to continue to flourish.

MANAGEMENT REPORTS

Member Network Activities

In 2021, CTA welcomed two new Members to our network: Cancer Research South Australia and La Trobe Regional Hospital. This brings our Membership to a total of 33 across metropolitan, regional, and international sites.

Our regional Member base now covers the entire patient catchment of Victoria, and we are proud to support these sites as they expand their trial portfolios and offer greater oncology trial access to regional cancer patients.

The easing of COVID-19 restrictions in early 2021 enabled our CTA network Research Managers to attend our Annual Manager's Forum in person. This was once again a successful event due to its focus on topical issues and the opportunity for engaging discussions. Attendees collectively reviewed the impact and learnings of the COVID-19 pandemic, discussed sponsor relationship management, Genetically Modified Organism (GMO) and Registry trials, and were informed on BiTE compounds and their long-term immunotherapy effects. A facilitated Business Continuity Planning workshop was also well received.

A notable advantage of our network is leveraging the collective research experience amongst Members, and this was evident in discussions regarding the Sponsor-initiated Shared Investigator Platform (SIP) developed by TransCelerate. On behalf of our Member sites, CTA compiled and coordinated a letter to Sponsor organisations outlining the sites' experience with SIP to date, and proposed recommendations for its immediate improvement. Sponsors then formed their own working group to discuss these issues and have committed to work in partnership with both TransCelerate and CTA Members to ensure SIP updates improve the sites' experience.

A total of 38 quarterly meetings were coordinated and hosted for our 11 stream-based Tumour Groups. These forums continued to provide an opportunity for

Members to discuss current and upcoming trials, as well as the impacts and challenges of COVID-19 on both the sites and trial participants.

In March, CTA hosted a dinner for the Tumour Group Chairs to discuss how to maximise clinician engagement in these forums. To further encourage Member involvement, it was recommended that Research Fellows from each site join the meetings to present on a current study or research proposal. These forums were also seen as an ideal networking opportunity for Fellows.

In 2021, we welcomed Mark Voskoboynik as Chair of the Genito-Urinary Tumour Group meeting, with Ben Tran moving to Chair the Phase 1 / Early Drug Development Tumour Group, as Jayesh Desai took on the role of CTA Board Chairperson.

We would like to thank the following Tumour Group Chairs for their ongoing commitment and participation during the year: Professor Hui Gan (Brain), Dr Belinda Yeo (Breast), Dr Margaret Lee (Gastro-Intestinal), Associate Professor Sumitra Ananda (Gynaecology), Dr Michael Dickinson (Haematology – Lymphoma/ Myeloma), Dr Chun Fong (Haematology – Myeloid/AML), Professor Danny Rischin (Head and Neck), Dr Muhammad Alamgeer (Lung), Dr George Au-Yeung (Melanoma), Dr Mark Voskoboynik (Genito-Urinary) and Associate Professor Ben Tran (Phase I/Early Drug Development).

Trial Feasibilities

CTA continues to promote the capacity and experience of its Member sites to trial sponsors. The ongoing collaborative relationships between CTA, local and global sponsors and CROs has ensured that CTA is regularly approached to recommend sites for trial feasibilities.

During 2021, there was a 31% increase in the number of trial feasibilities sent to CTA, comprising predominantly Phase 1/2 studies.

Our Member sites reported that it was increasingly time consuming and ineffective for them to complete an informed review of blinded feasibilities, due to the lack of study drug or trial information. CTA has endorsed this position by recommending to sponsor organisations that only unblinded feasibilities be circulated.

Patient recruitment

In 2021, there was the continuing requirement for clinical research staff and hospital units to move from clinical trial management to support the front-line response to the COVID-19 pandemic. Clinical trial operations were, at times, scaled back or suspended, and sites routinely reviewed and assessed their trial portfolio such that patients could receive trial treatment safely while managing the changing COVID-19 requirements. Despite changing requirements, patient accrual grew 11% across 2021.

It has been a pleasure collaborating with our Members across 2021. It is also especially gratifying to see how CTA's contribution continues to support the best clinical trial options for Australian cancer patients.

NICOLA HOWELL
CLINICAL TRIALS START-UP MANAGER

Clinical Trials Operations

Challenges associated with the COVID-19 pandemic have led to many operational changes in clinical trials, with our sector progressing further over the past two years than ever before. The pressure to adapt clinical trial delivery has dismantled previously perceived barriers, whilst maintaining research integrity. By focussing on common goals, collaboration, technology and building solid foundations to evaluate our progress, the ongoing advancement of clinical trials is assured.

The ongoing disruption of COVID-19 sparked a spirit of greater collaboration and innovation between CTA and our Member sites and despite the obstacles, resulted in increased start-up activity across the network. We achieved an overall increase of 9% in the number of studies approved to open when compared to 2020. We coordinated a total of 250 HREC/Governance submissions across our service Members. Post approval activity continued to steadily increase, with a record total of 1,246 amendments submitted in 2021, a growth of 12% compared to 2020.

There was an 8% increase in the number of clinical trial agreements negotiated and executed across 2021. We have also observed greater efficiency gains in the use of electronic signature platforms, resulting in a 30% reduction in the time taken to fully execute agreements. This has contributed to an overall improvement in the timelines between governance submission and approval.

Platforms to deliver telehealth and electronic systems for source data and regulatory documents now provide an efficient and effective solution to maintain clinical trials activity, at a time when restrictions challenged the viability of face-to-face trial operations. This sector has shown that we are able to evolve and involve patients in ways never previously seen, resulting in more efficiently managed clinical trials with expanded treatment options.

Out of necessity, clinical research sites have also rapidly adopted teletrials, resulting in a dispersed, decentralised model of operation. In 2021, CTA was involved in the coordination of seven teletrial submissions with five studies now open to recruitment across our Membership, providing greater access to clinical trials in regional and rural areas. Whilst we have come a long way in implementing teletrial frameworks for several Australian states, further improvements can be made to the regulatory and governance requirements that are impacting on the overall start up timelines for teletrials. CTA continues to support our Member sites to work on these, in partnership with all relevant external stakeholders.

In 2021, CTA worked in partnership with the Parkville Cancer Clinical Trial Unit (PCCTU), the Royal Melbourne Hospital Human Research Ethics Committee, and Peter MacCallum Cancer Centre Human Research Ethics Committee on a First in Human/Phase 1 study initiative. A Phase 1 working group was established to focus on minimising start-up timelines to remain globally competitive. This involved refining the submission workflow to reduce unnecessary roadblocks in the submission pathway and aligning HREC expectations to ensure expedited review of First in Human/Phase 1 clinical trials. In order to achieve these goals, CTA established a dedicated First In Human/Phase 1 project team to foster stronger collaboration between sponsors, researchers and the Parkville precinct HREC's. We have already seen significant improvements in the timelines for this important group of trials and achieved global recognition for being the first in the world to initiate two such studies.

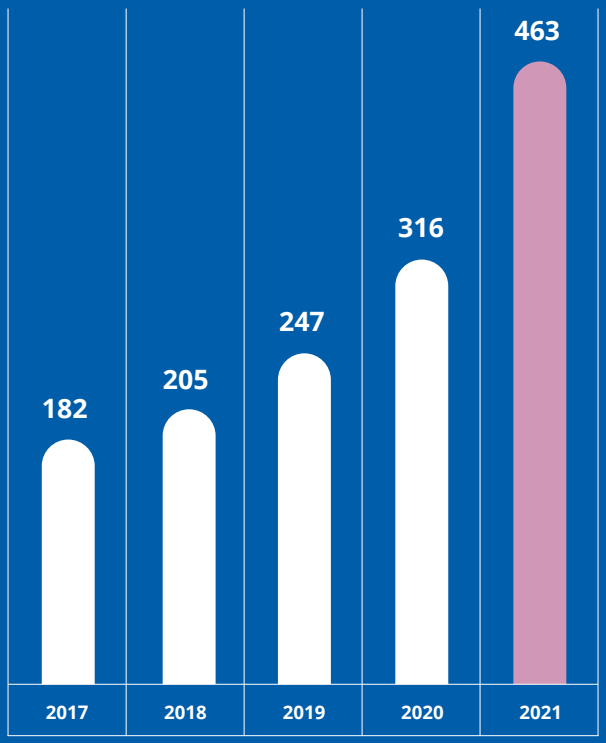
As a member of CT:IQ, CTA has also been involved in "The InFORMed Project," that aims to develop a more simplified, participant-friendly, national Participant Information and Consent Form (PICF) template. There is a collective view amongst clinical trial stakeholders that the current template requires a significant overhaul to create a shorter, less complex version. As part of the InFORMed Project team, a literature review into the regulations surrounding informed consent has been conducted, a survey for consumers and stakeholders regarding current PICF views has been developed and a survey analysis plan has been completed. The next phase of the project is to develop the written content for an improved PICF template and obtain NHMRC endorsement to replace the existing 2012 template.

The historic events of the last two years have proven to be the impetus needed to bring more innovation, responsiveness, and inclusiveness into clinical research. With combined dedication and effort, we can continue to optimise our clinical trial processes and the team at CTA is excited be part of the ongoing evolution of clinical research within Australia.

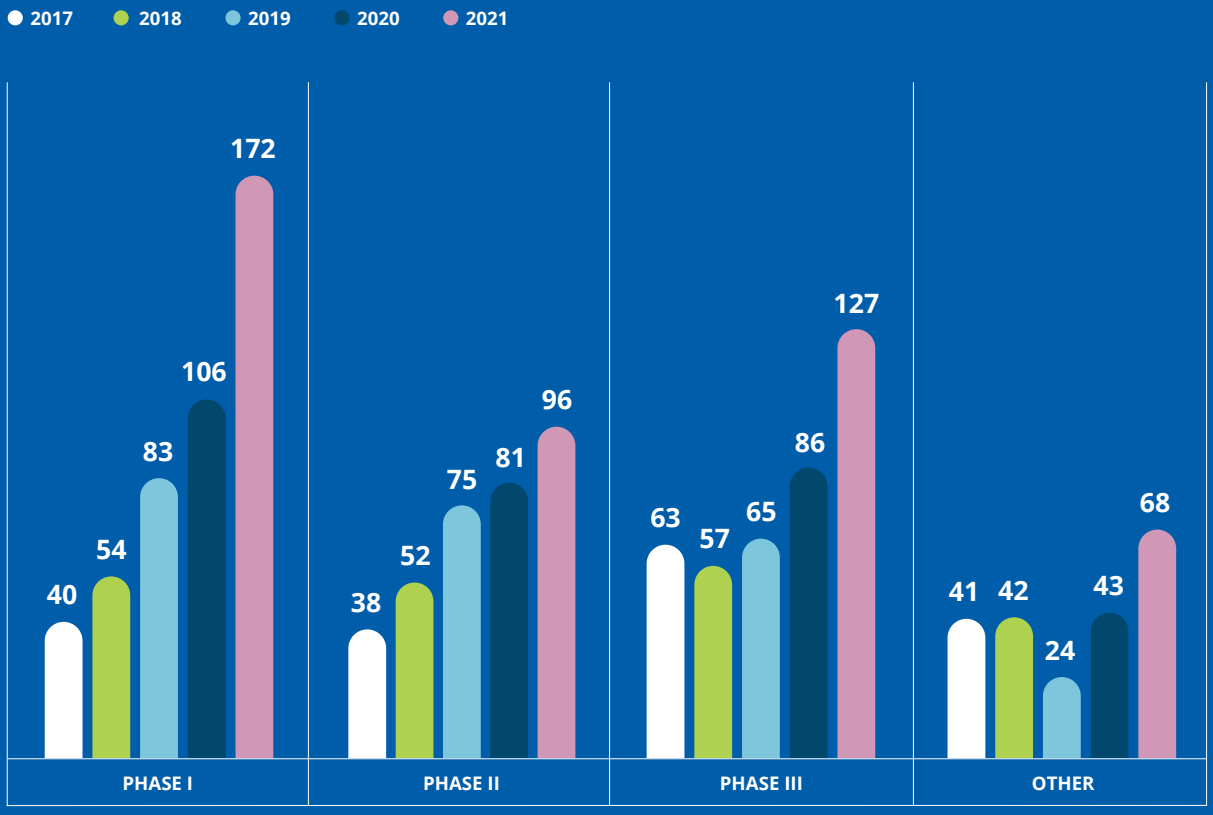
I would like to take this opportunity to acknowledge and thank the entire Operations team for their hard work and dedication in continuing to provide a high-level of service to our Members during another challenging year for all.

MARIE LUCI
OPERATIONS MANAGER

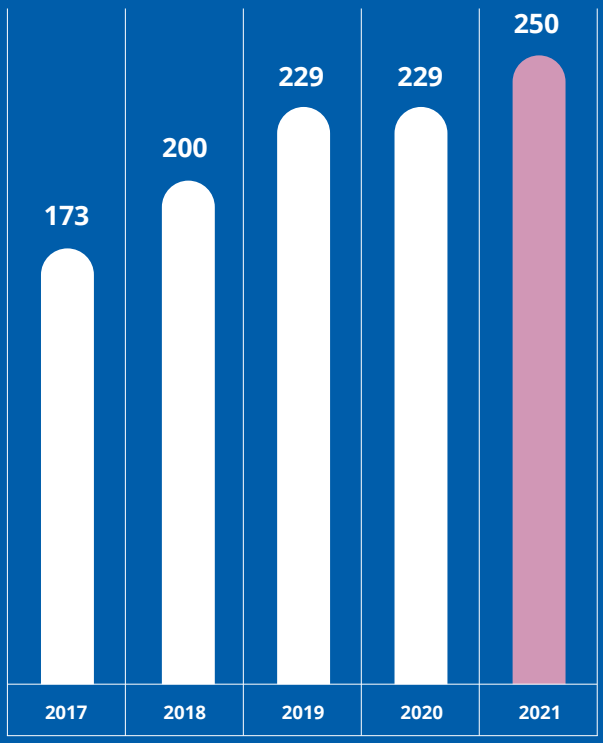
OPEN TO ACCRUAL CANCER TRIALS SUPPORTED BY CTA



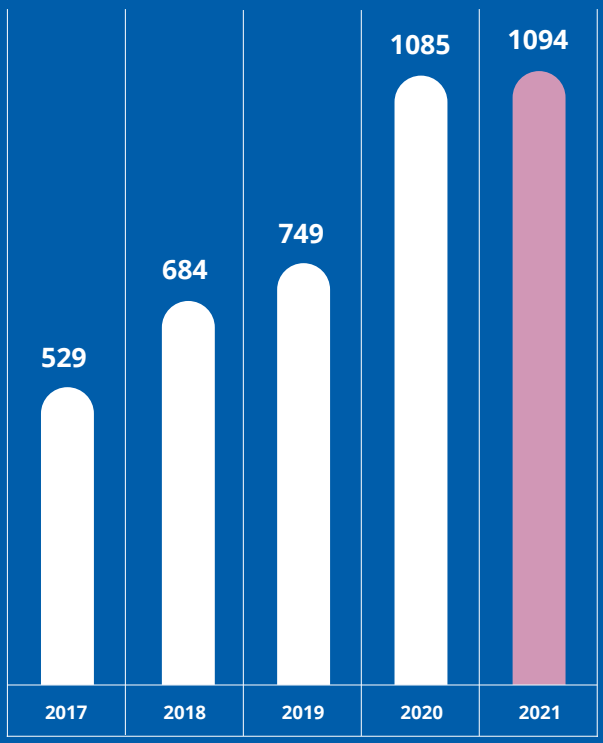
OPEN TO ACCRUAL CANCER TRIALS SUPPORTED BY CTA – BY PHASE



CTA SUPPORTED START-UP ACTIVITY FOR CANCER TRIALS



AMENDMENTS APPROVED



Finance

The Finance team has again achieved an unqualified audit report through management of excellent processes, systems and reconciliations to meet audit standards.

Whilst we worked predominantly from home throughout 2021, the year presented some additional workload over business as usual. In parallel to managing invoicing for approximately 510 commercially sponsored clinical trials and 185 non-commercially sponsored clinical trials across our Membership, we also supported the migration of all service sites and their clinical trial portfolios across to Clinibase. This required the finance team to be heavily involved in development and review throughout the year and I wish to thank both the CTA project team and all of our Member sites for their hard work during this migration period.

Despite our support of the migration to Clinibase, efficiency increased in the finance team during 2021, with cash transfers to Member sites growing to over $34m, an increase of 16% on the previous year.

As an additional benefit to our Member sites, CTA has continued to use its cash to invest in sites by transferring funds to Members on a bi-monthly basis, irrespective of whether the invoice has been paid to CTA by the Sponsor. The regular transfer of funds to our sites, means that in many cases, the site has been paid before CTA. CTA is well experienced in debtor collection, managing this service on behalf of our sites, with no bad debts recorded throughout 2021. This service is provided interest free to all our service Member sites, significantly reducing their cash flow risk.

In addition, the CTA Finance team are responsible for the CTA payroll and our salary packaging arrangement with Remunerator. The Finance team are responsible for preparation of the annual CTA budget, 6+6 re-forecast, and supporting the Finance and Audit Sub Committee through the preparation of agendas and minutes.

Our main workload and core function, however, continues to be the finance and associated debtor collection services for our Member Sites. We aim to ensure the timely cost recovery of all trial activity on behalf of our Member sites, in accordance with contractual terms. Contractual agreements with sponsors continue to be complex, with many different items required to be tracked in support of invoicing. Our transition to Clinibase has put us in a stronger position than ever before to manage these increasing complexities.

I take the opportunity to thank my staff for their excellent contribution throughout the 2021 financial year.

MICHELLE BUTTON
FINANCE MANAGER

Information Systems

In a year punctuated by COVID related lockdowns, evolving travel and working restrictions, and flurries of face-to-face opportunities, CTA managed to deliver one of the largest information systems transformations we have undertaken in a decade. As showcased in the article on page 20 CTA is pleased to report on this significant achievement within this year's Annual Report.

Clinibase is CTA's new database application for collection of participant activity, built throughout the 2021 year in partnership with Cardiobase, a Melbourne-based healthcare solutions company. After an initial scoping exercise and injection of custom functionality, CTA migrated all Member sites and their data from our previous platform into Clinibase. Additional staff were recruited to support the migration project, including staff seconded from Cardiobase. A cross-functional team comprising staff from CTA Budget and Contracts, Finance, and Information Systems were brought together as the project working group, ensuring the system met our diverse and unique needs. Throughout the migration, feedback was continually sought from sites, hospital IT departments and users, to improve functionality, provide training and support, and ensure the application met the stringent cybersecurity and privacy requirements defined by each clinical site.

While Clinibase was primarily built for collecting data to support administrative services for our Members, the application will also allow Member sites to collect and report on a range of trial metrics, many of which will support their accreditation requirements under the new National Clinical Trials Governance Framework, due for implementation from mid-2022. One of the distinct benefits of partnering with a local, trusted software company, is that the resulting product is not static, meaning CTA is able to define and release new features and functionality throughout 2022 and beyond. The entire project team is to be congratulated on a stunning effort in a very challenging year.

CTA's staff continued to thrive under our working-from-home and office hybrid model, with our IT infrastructure delivering on vital stability and portability. Central to our ongoing capability to pivot and adapt, was our previous investment in establishing policies and staff support structures, including a full hardware allocation to all staff, Office365, Teams, SharePoint and OneDrive, Atlassian's Jira and Confluence, and MYOB Advanced. All of which enabled staff to maintain equivalent access to documentation, internal communications and operational oversight while working from home. Our extensive cybersecurity measures allowed our ongoing work to remain tightly protected and additional phishing exercises were coordinated to drill CTA's response to any cyberthreat.

CTA's expansion of Atlassian's Jira continued, allowing transparent and powerful tracking of work in progress across our start-up efforts in both the Ethics & Governance and Budgets & Contracts teams. This granular understanding of our work product cycle provides a powerful ability to analyse bottlenecks and improve performance against strategic goals. In 2021, the reach of this tool was extended into further supporting the Finance team through provision of data for invoicing Start-Up and Amendment fees, as well as real-time status data directly to our Member sites.

PowerBI, a dashboard analytics tool, draws together separate datasets arising from Jira, Clinibase, MYOB Advanced, and site-supplied datasets to provide a powerful mechanism for analyses, generating trend analysis by year, team and disease indication over revenue, timeline, patient accrual and study status data, and identification of under-performing studies and data collection gaps. Sites continued to rely heavily on these tools to track the impact of COVID-19 lockdowns on patient activity and trial cost recovery.

The SiteDocs electronic document management project continued to grow, with the inclusion of additional departments at hospitals already utilising the platform. A self-funding Maintenance Program was designed and adopted, allowing CTA to continue to provide advocacy and training to Member sites for this application.

I would like to sincerely thank the Information Systems team and our external partners for their foresight and dedication to improving CTA capability in this area.

EMILY ENGLAND
INFORMATION SYSTEMS MANAGER

Human Resources

Despite the disruption caused by several COVID-19 enforced lockdowns throughout 2021, CTA again increased in size – starting the year with 40 staff and ending it with 47. This growth was in response to both higher levels of trial activity at Member sites and planned increased investment in our information systems.

It was reassuring to see low staff turnover in 2021, attributable to a number of initiatives introduced and implemented by CTA throughout the year, such as increased job security through the offer of permanent over fixed-term employment, increased salaries and benefits, more professional development opportunities and greater flexibility in working arrangements.

Following on from a comprehensive review of CTA's employment contract templates conducted late in 2020, underpinned by expert external advice, 21 staff transitioned from fixed term to permanent employment. Almost 50% of our staff are now on permanent employment contracts, compared with less than 10% at the start of 2021.

Due to the success of remote working in 2020 (supported by positive feedback received via staff surveys), a decision was made early in 2021 to maintain hybrid working arrangements, irrespective of COVID-19 related restrictions. Other policy initiatives implemented in 2021 included an increase in the amount of paid parental leave available to staff.

There was also a much higher investment in professional development, with more than 50% of our staff attending external training across a range of topics, including Good Clinical Practice, Mental Health First Aid, Negotiating Skills and First Time Supervision courses, both virtually and in-person where possible.

A team building activity was held in early April, where staff were able to enjoy a lively lunch together before embarking on a horticultural adventure, building individual terrariums for raising at home. These featured in brightening home working spaces during subsequent lockdowns.

Pleasingly, CTA was able to hold an in-person AGM in mid May 2021, and staff were invited to attend. Attendees heard from inspirational speakers Dr Amanda Caples, Victoria's Lead Scientist, and Professor Andrew Roberts regarding the remarkable 35 year development of Venetoclax, through work at CTA Member, Walter and Eliza Hall Institute (WEHI), and subsequent trials which were supported by CTA.

A virtual team-building event took place in September, resulting in 40+ different painted interpretations of Van Gough's 'Starry Nights' masterpiece, allowing staff to take time away from their busy workloads to do something fun and creative.

In November, CTA staff were invited to attend a half-day workshop, during which they identified new corporate values, and associated behaviours, to align with revised Vision and Mission Statements endorsed by the Board earlier in the year. The values adopted by our staff were Shared Purpose, Integrity, Collaboration, Adaptability and Compassion. Work on incorporating these values into everyday life at CTA will continue into 2022.

The year was brought to a positive close with an end of year celebration, where staff met and mingled face-to-face, to share in their individual and collective achievements and to look forward to the year ahead.

SUSY MONTAGNER
HUMAN RESOURCES MANAGER

BOARD SUB-COMMITTEE REPORTS

Finance and Audit Sub-Committee Report

The Finance and Audit Sub-Committee (FASC) held four formal meetings throughout 2021, as well as regular ongoing contact and interaction with CTA management. The FASC assessed the financial performance of the Company including cash flow, profit and loss, balance sheet performance and all capital investment propositions. The FASC also considered both internal and external risks to the business, ensuring these were reported and recorded. All existing risks were reviewed and updated where necessary to ensure management maintained a current Risk Register. The potential impact of COVID-19 was again assessed as a significant business risk in 2021, as it was the previous year. The Committee's advice and recommendations were provided to management and the CTA Board.

The CEO, Kurt Lackovic, and the Finance Manager, Michelle Button attended all the FASC meetings during the year and continued to maintain the excellent standard of accurate financial information and reports. The FASC assisted management in the preparation and presentation of forecasts and the annual budget, particularly with respect to business assumptions and potential risks.

Total clinical trials funding revenue administered by the company for the year was $39,973,613 (2020: $34,834,218) an excellent result given the possibility that revenue could have been severely reduced due to the second year of COVID related restrictions.

While the Net Loss for the 2021 year was -$166,857 compared to a Net Profit in 2020 of $326,256, the 2021 result was in fact a considerable improvement ($213,789) over the 2021 Budgeted Loss of -$380,646. The 2021 budget had included significant software and system development costs, together with additional resourcing provisions. It was pleasing to recover the majority of this investment in the same financial year.

The quality of administration of clinical trials by CTA will continue to underpin success into the future. Investment in financial and other reporting systems in 2021 have resulted in a significant upgrade to CTA's data capture and reporting capability. These have been rolled out within the timeframes forecast and have successfully mitigated any risk associated with that transition. CTA's strong financial position will allow continuing improvements into the years ahead.

Strategic alliances and a focus on Government advocacy has continued to ensure CTA maintains its position to add significant value to its Members, beyond service provision.

Despite the volatilities in overseas markets, exchange rate uncertainties are essentially neutralised by contracts being written in local currency, together with a continued focus on cost management.

CTA ended the year with a very sound financial position, with total equity of $4.51m decreased marginally compared to 2020 ($4.67m), driven by the investments noted above. The cash reserve has been essential to act as a buffer and safety net for the timing of cash flows that remained unpredictable in an expanding customer base, and has enabled the financing of site operating costs before sponsor payments were received. This in turn provides ongoing reassurance in an environment of some uncertainty around future business forecasts.

The ratio of current assets to current liabilities was 1.55 (2020: 1.68), well above the planned threshold of 1.25. Management continued to maintain strong control over debtors, which remains a challenge in a cost competitive environment.

CTA remains income tax exempt, as a charity under the requirements of the Australian Charities and Not-For-Profit Commission.

Management is congratulated on yet another unqualified audit report, delivered by Deloitte. The FASC wishes to acknowledge the high accounting and financial management standards set by Michelle Button, Finance Manager, and Kurt Lackovic, CEO, and to thank their teams in assisting in these endeavours in a challenging work environment. I also acknowledge the efforts of my fellow FASC members, Michelle Gallaher and Tim Murphy and thank them for their invaluable contributions. The Committee was pleased to advise the Board to accept the 2021 results and is well positioned to face 2022 with confidence under the leadership of Kurt Lackovic and his team.

COLIN NUGENT
CHAIR, FINANCE AND AUDIT SUB-COMMITTEE

Performance and Remuneration Sub-Committee Report

The Performance and Remuneration Sub-Committee met twice in 2021, to set CEO KPIs, subsequently review CEO performance against those KPIs, as well as review policies associated with CTA staff remuneration. The Committee also oversaw the selection and appointment of a replacement Board Member in 2021, in response to Andrew Scott reaching the conclusion of his two consecutive terms, the maximum permitted under our Constitution. The Committee thanks Andrew wholeheartedly for his significant contribution to CTA over an extensive period and welcomes Clare Scott as our incoming Board Member from August 2021. I was pleased to accept the role of Chairperson, Performance and Remuneration Sub-Committee from October 2021.

The Committee was also delighted to receive updates regarding professional development for CTA staff throughout 2021, which continued despite COVID-19 related restrictions.

JAYESH DESAI
CHAIRPERSON, PERFORMANCE AND REMUNERATION SUB-COMMITTEE

ENSURING ACCESSIBILITY OF RELEVANT DATA:

How a new software solution was developed to improve management of Australian clinical trials

Gaining a birds-eye-view of clinical trials across the country is a goal we all have a stake in. And being able to discern trends and conduct in depth analyses that can in turn influence policy and support growth across our sector is the ultimate aim. Now, after 18 months of dedicated work by specialist teams at Cancer Trials Australia (CTA) and Cardiobase—a Melbourne-based healthcare solutions company— we are one step closer to realising this goal.

"For many years we sub-licenced an established clinical trial management system (CTMS) to our Member hospitals throughout Australia" said Kurt Lackovic, CEO of CTA.

"We were able to prove the utility of a coordinated approach to trial management, as well as centralise the dedicated support required to underpin the use of a CTMS, across hundreds of clinical trials undertaken at clinical sites across multiple Australian states. However, that CTMS was not designed for an Australian context, nor did we have the ability to evolve it to meet emerging requirements. We sought a solution to both improve the quality and timeliness of data capture, as well as enable us to better utilise the data that our hospital Members collect." said Kurt.

Together, CTA and Cardiobase developed a customised software solution called Clinibase, which is now deployed across Victorian and New South Wales hospitals in both metropolitan and regional settings. Clinibase significantly reduces the administrative burden and improves data insights gathered for trials, with ongoing updates planned.

Clinibase collects vitally important data, including how many trials are recruiting, the types of trials being undertaken, how many patients have been recruited, the type of patients being recruited, the length of time a participant spends on trial and how much work the study coordinators need to undertake for any one clinic visit, among many other key metrics.

Much of the groundwork for this partnership was laid with the help of CTA's Information Systems Manager, Emily England, who began sounding out potential technology partners to work with side by side on the project.

"The world has changed; we can no longer be tolerant of 'dead end data' that just sits inside a system and isn't fully used or understood," said Emily.

"While we have always utilised the data collected to support our management services for Members, we knew there was so much more untapped potential for analysis, and for the system to extend into providing additional functionality and context for study coordinators and nurses, so they could more easily focus on their patient-facing work. We also wanted a system that was so user friendly and readily adopted, that it would propel us towards the ultimate goal of being able to show the full picture of clinical trials across the country."

"Building a custom software solution from scratch requires a cross-functional team with vision and grit, coupled with a proven, strong understanding of the real experience of end users, the clinical sites themselves; this is where CTA and Cardiobase really came together - we needed a partner that knew our sector intimately and that had a true Australian focus in their sights."

"Initially our work with CTA was scoping the issue, to really understand the obstacles and drivers," said Jason Wagstaff, CEO of Cardiobase. "We quickly came up with elegant solutions and it was clear that we were onto a real winner"

"This project had a genuine 'start-up' pace and spirit to it, which allowed us to relentlessly focus on the outcomes resulting in a solution that has transformed people's work," said Jason.

"We were excited at the outset because this project gave us the chance to work with committed individuals who wanted to innovate across the whole system. We liked the fact that CTA came to us with a genuine opportunity—no one had considered the nuanced clinical and administrative problems that they were working towards solving, and our partnership was able to work on that holistically," said Jason.

Requirements of various user types were defined, and the subsequent proof-of-concept system was piloted at a single, clinical trial site in February of 2021. The initial results were so successful that the trial site switched over to the proof-of-concept software the following week. Fast forward to January 2022, and all of CTA's service Members are now successfully utilising Clinibase.

"The system we have now supports totally different conversations about the role that data plays in improving the way we all work together," said Emily England.

"We can now use the data captured within Clinibase to give back to our Members – providing them with deeper business intelligence, and freeing them further to focus on their clinical work," said Emily.

"We can now use the data captured within Clinibase to give back to our Members – providing them with deeper business intelligence, and freeing them further to focus on their clinical work."

“We saw the opportunity to create technology that would support and enable agility and innovation. Clinical trials continually evolve, so it’s a huge advantage to have a solution that can accommodate change over time, and be expanded to collect additional data points as the need arises.”

The entire rollout to clinical sites occurred during COVID-19 lockdowns, which against all the odds did not hinder the fast delivery schedule. And what’s more, the solution continues to be consistently upgraded and evolved to keep pace with the ever-changing nature of clinical trials, something that was out of reach with the previous system.

Chief Operating Officer at Cardiobase, Mark Johnson, knew that the system had to hit the ground running if it was to be a success from the outset.

“Without access to a partnership that allows CTA and Members to innovate, the rapid pace of clinical trial work is constrained. And that’s not ideal for anyone,” said Mark.

“We saw the opportunity to create technology that would support and enable agility and innovation. Clinical trials continually evolve, so it’s a huge advantage to have a solution that can accommodate change over time, and be expanded to collect additional data points as the need arises. We can evolve the product as legislation, trial design and guidelines change, right where the activity is happening,” said Mark.

“We are using cutting edge technology here, a best-of-breed solution and we provide functionality releases very quickly, several times a week in fact. It’s continual integration and deployment, feature by feature,” said Mark.

The data collected through Clinibase, and the insights that affords, are vitally important. This allows critical oversight of clinical trials across many Australian hospitals. “The world is hungry for useful data. State governments are now asking for more detailed information to help improve decision-making, and we can now support our Members in providing this. CTA’s driving principle is to improve access for Australians — while this is focussed mainly on improving patients’ access to emerging therapies and increasing hospitals’ access to appropriate funding and resources, it also includes ensuring decision-makers’ have access to trusted, reliable data,” says Kurt.

Clinibase’s customised reporting functionality will also support users with mandated reporting as part of the *National Clinical Trials Governance Framework* (NCTGF). The NCTGF, which will be implemented across Australia later this year, seeks to help reduce clinical trial start-up times, optimise pre-approval and recruitment timeframes, and improve consistency in trial delivery. Reporting of metrics associated with clinical trial activity will feature in the accreditation of hospitals that conduct clinical trials.

With a robust, fit-for-purpose software solution now supporting the conduct of clinical trials across multiple states, Australia is even more attractive as a destination of choice for global biotech and pharmaceutical companies to undertake their clinical activities, which is something CTA has championed since its inception almost 20 years’ ago. And ultimately, it is Australian patients that are the beneficiaries.

BOARD OF DIRECTORS

Professor Andrew Scott AM (Chairperson until 25 August 2021)

MBBS, MD, FRACP, FAHMS, FAANMS, FAICD, DDU

Appointed as Director: 25 August 2015
Term concluded: 25 August 2021

Head, Tumour Targeting Laboratory, Olivia Newton-John Cancer Research Institute, 2015 to present.
Medical and Scientific Director, Department of Molecular Imaging and Therapy, Austin Health, 2015 to present.
Professor, Faculty of Medicine, University of Melbourne, 2007 to present.
Professor, School of Cancer Medicine, La Trobe University, 2015 to present.
Director, Australian Nuclear Science and Technology Organisation, 2008 to Oct 2021.

Meetings attended:
Directors 

Associate Professor Jayesh Desai (Chairperson from 25 August 2021)

MBBS, FRACP

Appointed as Director: 25 November 2020

Jayesh has extensive experience in translational research applied to early drug development, particularly in sarcomas and in colorectal cancer. He heads the Phase I/Early Drug Development program, is Deputy-Director of the Parkville Cancer Clinical Trials Unit (PCCTU), leads Peter Mac's efforts in its formal engagements with Industry Alliances and Partnerships and has recently been appointed as the Associate Director Clinical Research at Peter MacCallum Cancer Centre.

Jayesh has been the Chair of the Cancer Trials Australia (CTA) Phase I Drug Development Program for a number of years, and has been Principal Investigator on 30 clinical trials over the last 5 years including 25 Phase I and First in Human Trials. These have been both investigator initiated, as well as commerically sponsored trials with Pharma and Biotechs, across a broad array of agents including kinase inhibitors and novel immuno-oncology agents/combinations. He has authored/co-authored approximately 130 publications in journals including the New England Journal of Medicine, Nature, The Lancet and the Journal of Clinical Oncology.

Meetings attended:
Directors 

Colin Nugent

B COM, CA (SA), ACA

Appointed as Director: 22 July 2015

Colin is a current member of the Australia & New Zealand Institute of Chartered Accountants and owns a consulting practice offering strategic and financial services to the healthcare sector.

Colin is a "Big 4" trained Chartered Accountant, graduated from the University of Cape Town and gaining his CA (SA) membership. He obtained his Australian ACA accreditation in 1983.

Colin has extensive commercial and technical experience across a broad range of national and global companies. The last 25 years have been spent in the Healthcare space with companies such as Ipsen, Kendle (now INC Research), Medisence (Abbott Labs), holding financial, director and board positions in these and other organisations.

Meetings attended:
Directors 

Associate Professor Zee Wan Wong

MBBS, MRCP, FAMS, GDA, FRCP, FRACP, GAICD

Appointed as Director: 4 July 2018

A/Prof Zee Wan Wong commenced her role as the Head of Oncology Unit at Peninsula Health in 2017. She holds a joint appointment as Adjunct Clinical Associate Professor with Monash University. Subsequently, she was appointed as Joint Clinical Director of Southern Melbourne Integrated Cancer Services (SMICS), is a member of the Monash Partners Comprehensive Cancer Consortium (MPCCC) Governance Group and Executive Committee as well as the Victorian Tumour Summits Steering Committee. She continues to teach at the Department of Rural Health, University of Melbourne Medical School as a Senior Lecturer. In addition, Zee Wan also consults at The Bays Hospital.

At Cancer Council Victoria (CCV), Zee Wan is a Clinical Advisor for the Clinical Network and a member of the Medical and Scientific Committee. She is a member of the AGITG Lower GI Working Party and also holds memberships with ASCO, ESMO, MOGA, COSA, BCT and ALTG. She has published in numerous peer-reviewed journals and is a reviewer for several journals including The Breast, Internal Medicine Journal and Frontiers In Oncology. She has presented at national as well as international oncology conferences.

During the pandemic year, Zee Wan has had the opportunity to co-chair the Victorian COVID-19 Cancer Network (VCCN) Taskforce and chair the Telehealth Expert Working Group simultaneously. She also contributes to the Cancer Expert Reference Group in Victoria as a member.

Meetings attended:
Directors 

Professor Mark Shackleton

MBBS, PhD, FRACP

Appointed as Director: 24 May 2017

Prof Mark Shackleton is the Director of Oncology at Alfred Health, a Professor of Oncology at Monash University, Chair of Melanoma and Skin Cancer Trials Ltd, and Head of the Cancer Development and Treatment Laboratory at Monash University's Central Clinical School. After training in medical oncology at the Ludwig Institute in Melbourne, Prof Shackleton undertook PhD studies at the Walter and Eliza Hall Institute of Medical Research and post-doctoral work at the University of Michigan, USA. He was awarded the 2006 Victorian Premier's Award for Medical Research, a 2010 NHMRC Achievement Award, a 2011 Pfizer Australia Fellowship, and in 2012 was awarded the Australian Science Minister's Prize for Life Scientist of the Year.

Meetings attended:

Directors 

Professor Craig Underhill

MBBS, FRACP

Appointed as Director: 24 May 2017

Craig Underhill is Director of Cancer Services at Albury-Wodonga Regional Cancer Centre; Clinical Director, Hume Regional Integrated Cancer Services and Regional Oncology Lead for the Victorian Comprehensive Cancer Centre (VCCC). He holds a conjoint appointment at the University of NSW Clinical School in Albury and La Trobe University. In 1999 Dr Underhill was the founding partner in the Medical Oncology Practice (Border Medical Oncology) and established an independent Not-For-Profit Clinical Trials Unit (Border Medical Oncology Research Unit), has VMO appointments at Albury Wodonga Health (Albury Wodonga Campus) Murray Valley Private Hospital, and Albury-Wodonga Private Hospital. The Research unit led by Dr Underhill has twice been awarded NSW Premier's Award for innovation in Cancer Clinical Trials.

Craig has developed partnerships with the private sector to improve local access to cancer services, fostered shared care arrangements between local public and private health care providers, has also built linkages and better referral pathways between metropolitan and regional centres. He has collaborated on national guidelines/service frameworks on the management of febrile neutropenia, quality of multidisciplinary meetings and the use of telehealth in clinical trials. His achievements in research collaborations have led to changes in practice in the care of patients with cancer, including the introduction of new standards and models of care including tele-trials.

Meetings attended:

Directors 

Michelle Gallaher

Dip App Sci (Orth), Grad Dip Bus, MBA, GAICD, Fellow AIM

Appointed as Director: 23 September 2015

With over 25 years of experience in the biopharmaceuticals and healthcare sector, Michelle is an award-winning and recognised leader in the Australian health innovation industries and currently CEO of an ASX listed health technology company, Opyl Limited.

For the past 15 years Michelle has worked at an executive level in biopharma industry and national medical research initiatives with experience in scale strategy, financial governance, marketing and data/ digital transformation. Michelle holds an allied health qualification in applied science from La Trobe University, a Postgraduate Diploma in Business from RMIT, a Global Executive MBA from Monash University is a Graduate of the Australian Institute of Company Directors and a Fellow of the Australian Institute of Management

Michelle has served on numerous government and health industry advisory boards and committees. Michelle is co-founder of Women in STEMM Australia, Telstra Victorian Business Woman of the Year and Entrepreneur of the Year in 2017 and was inducted into the Victorian Honour Roll for Women for her services to the biotech industry and women in STEMM.

Meetings attended:

Directors

Tim Murphy

BSc(Hons), M Mkt, FAICD

Appointed as Director: 8 October 2019

Tim is currently the General Manager - Blood Cancer Partnerships at Leukaemia Foundation and Chairman, ARMI at Monash University. He is a politically astute executive with extensive experience working with the C-suite and the Boardroom to manage corporate issues in regulated environments. Broad local and international (London, Brussels) experience in effective stakeholder engagement and political advocacy.

Strong background in high growth, merger, consolidation, and downsizing global and national business environments. Expertise in multiple sectors, especially healthcare.

A passionate strategic thinker who develops high performing teams and works cross-functionally to ensure the long-term viability of the organisation. A Fellow of the Australian Institute of Company Directors with a Bachelor of Science (Hons) & Master of Marketing from Melbourne Business School.

Meetings attended:

Directors 

Professor Clare Scott

MBBS, PhD, FRACP

Appointed: 25 August 2021

Professor Clare Scott holds the Chair in Gynaecological Cancer at the University of Melbourne and is Joint Division Head of Clinical Translation and a Laboratory Head at the Walter and Eliza Hall Institute of Medical Research and Medical Oncologist at the Peter MacCallum Cancer Centre, Royal Women's and Royal Melbourne Hospitals. She has 25 years' experience in clinical cancer genetics, including working in Familial Cancer Clinics. Her clinical expertise is in gynaecological cancers and coordinating care for patients with rare cancers. Her laboratory focuses on drug resistance in ovarian cancer and other rare cancer types, generating patient-specific models to understand and avert resistance to targeted therapeutics. In particular, she has been a leader in developing PARP inhibitor therapy for ovarian cancer, which has resulted in unprecedented efficacy. She has 125 career publications with an H-Index of 56.

Professor Scott chairs the Australia New Zealand Gynaecological Oncology Group, the COSA Rare Cancer group and the Board of the International Rare Cancer Initiative (IRCI) and has been awarded Clinical Fellowships from the Victorian Cancer Agency (2011, 2017), the Sir Edward Dunlop Cancer Research Fellowship from the Cancer Council Victoria (2012), an Investigator Grant from the NH&MRC (2021) and in 2018, the Jeannie Ferris Recognition Award in Gynaecological Cancer from Cancer Australia. She is a Fellow of the Australian Academy of Health and Medical Sciences.

Meetings attended:

Directors 

Dr Kurt Lackovic

PhD, MBA, GAICD

Appointed: Company Secretary, appointed 30 January 2017

Dr Kurt Lackovic has been CEO of Cancer Trials Australia since January 2017. He has spent his entire career in medical research. His education includes a PhD in chemistry, international post-doctoral experience in medical genomics and early stage drug discovery, graduating from the Australia Institute of Company Directors in 2014, and in March 2018 completed his MBA at Melbourne Business School, where he graduated on the Dean's list.

Dr Lackovic has published 26 peer-reviewed articles across multiple research areas, possesses extensive expertise in leading complex academic and clinical programs, strong connections to industry, and strategic linkages to senior executives in Government and major teaching Hospitals. He is a member of the Licensing Executives Society of Australia and New Zealand, American Society of Clinical Oncology, Society for Clinical Research Sites and AusBiotech's Clinical Trial Advisory Group.

Meetings attended:

Directors 

CORPORATE GOVERNANCE

The Board focuses on the objectives and values for which CTA was created and that remain important to its Members and stakeholders and thus ensures that Member value is protected and enhanced. The Board supports the principles of the ASX Corporate Governance Councils Principles of Good Corporate Governance and Best Practice Recommendations.

CTA is not a listed company and as such is not required to report on these principles; however, the Board has applied the principles where relevant to a Not-For-Profit company limited by guarantee.

The Board ensures that CTA management and staff maintain regular reporting practices and comply to the highest level of corporate ethics. The Board is comprised of Member and Independent Directors with extensive commercial and Member organisation experience. The Directors ensure they bring an independent judgment to bear in decision-making. Management provides the Board and its sub-committees with information in a form, timeframe and quality that enables them to effectively discharge their duties.

In particular the Board:

- Appoints and manages the CEO
- Approves corporate strategy
- Approves the business plan and budget
- Approves significant corporate policies

The CEO is responsible for the day-to-day management of CTA with all powers and delegations authorised by the Board.

Board Structure and Standards

The Board comprises up to eight members. Five Board members are nominated by the Member institutions and the Board appoints up to three Independent Directors. The profiles and qualifications of the Directors are detailed in this report. All Directors are required to disclose to the Board any areas where they may have a Material Personal Interest. If issues arise at Board meetings they are dealt with according to The Corporations Act Cth (2001).

The CEO is responsible for implementing the corporate strategy approved by the Board, execution of all operations and the management of staff, delivering the objectives within the constraints of a budget approved by the Board, and is assisted in the process by the Finance and Audit sub-committee.

CTA Current Member Directory

Cancer Trials Australia Member Sites

Prof Mark Shackleton
Alfred Health

Dr Michelle Wilson
Auckland City Hospital

Dr Niall Tebbutt
Austin Health

Dr Stephen Brown
Ballarat Health Services

Dr Philip Campbell
Barwon Health

Dr Rob Blum
Bendigo Health

Dr Craig Underhill
Border Medical Oncology

Prof Gary Richardson
Cabrini Health

Dr Rohit Joshi
Calvary Central Districts Hospital

Dr Rohit Joshi
Cancer Research South Australia

Assoc Prof Lisa Horvath
Chris O'Brien Lifehouse

Ms Belinda Kendall
Coffs Harbour Health Campus

Mr Gary Layton
Epworth Foundation

Dr Javier Torres
Goulburn Valley Health

Ms Jhodie Duncan
La Trobe Health

Ms Sarah Coulson
Launceston General Hospital

Mr Jayden Rodgers
Linear Clinical Research

Dr Rohit Joshi
Lyell McEwin Hospital

Dr Sarah Rickard
Melbourne Health

Prof Eva Segelov
Monash Health

Ms Carolyn Stewart
Murdoch Children's Research Institute

Prof Andrew Scott
Olivia Newton-John Cancer Research Institute

Dr Zee Wan Wong
Peninsula Health

A/Prof Vinod Ganju
Peninsula Oncology Centre

Prof Linda Mileshkin
Peter MacCallum Cancer Centre

Dr Stephen Begbie
Port Macquarie Hospital

Ms Kahlia Fox
Royal Children's Hospital

Dr Sue Anne McLachlan
St Vincent's Institute

A/Prof Ian Collins
South West Healthcare

Ms Orla McNally
The Women's

Prof Ehtesham Abdi
The Tweed Hospital

Dr Anne-Laure Puaux
Walter and Eliza Hall Institute of Medical Research

Dr Dishan Herath
Western Health

Current Tumour Group Chairpersons

Prof Hui Gan
Brain Cancer

Dr Belinda Yeo
Breast Cancer

Dr Margaret Lee
Gastro-intestinal Cancer

A/Prof Sumitra Ananda
Gynaecological Cancer

Dr Michael Dickinson
Haematology – Lymphoma/Myeloma

Dr Chun Fong
Haematology – Myeloid/AML

Prof Danny Rischin
Head and Neck Cancer

Dr Muhammad Alamgeer
Lung Cancer

Dr George Au-Yeung
Melanoma

A/Prof Ben Tran
Phase I/Early Drug Development

Dr Mark Voskoboynik
Uro-Oncology

Cancer Trials Australia

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