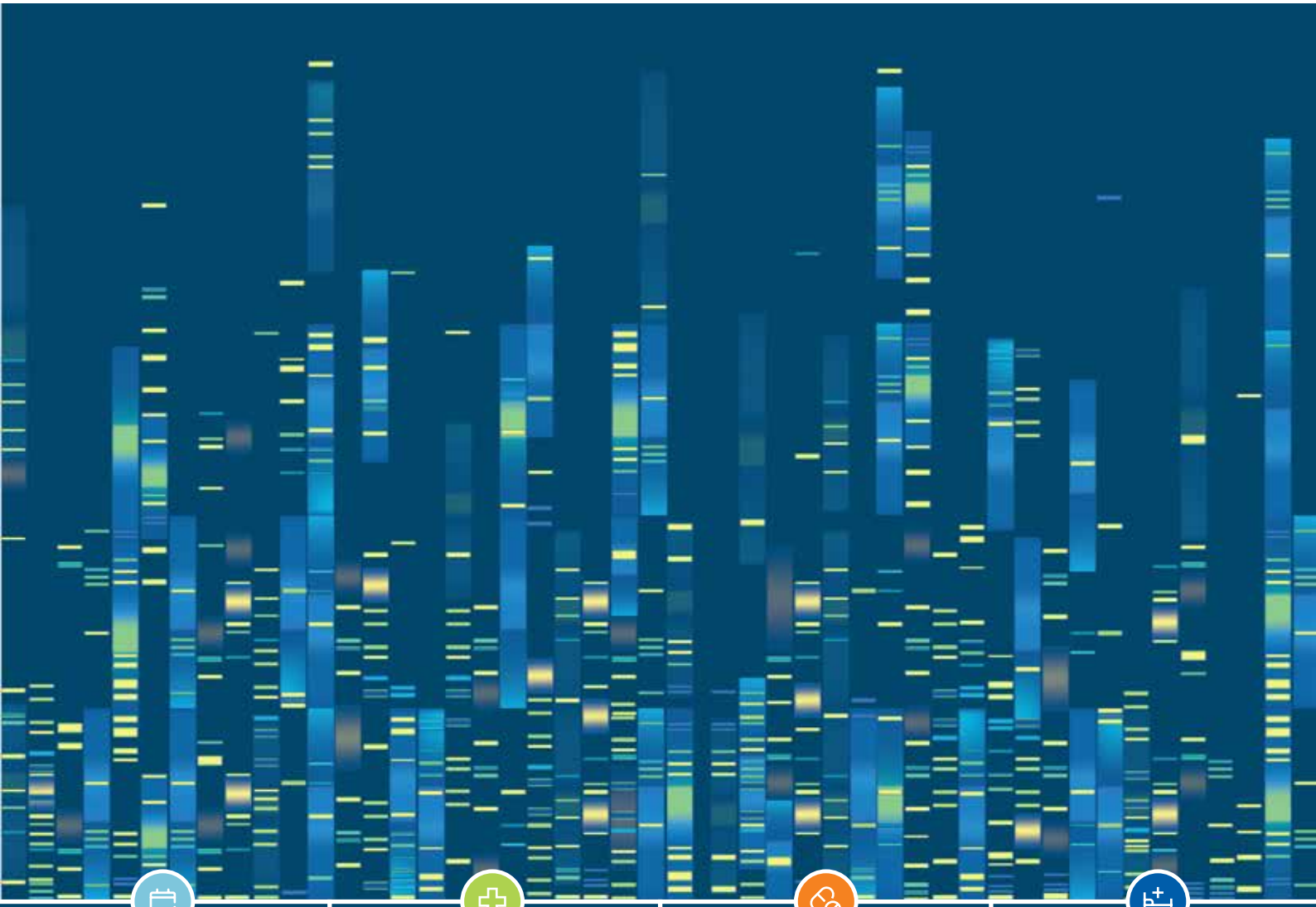
2020 Annual Report

Cancer Trials Australia

YOUR PARTNER OF CHOICE FOR CLINICAL TRIALS



18	32	1600+	10,500+
YEARS OPERATING	NETWORK MEMBERS	TRIALS OPENED	PATIENTS ENROLLED


WESTERN AUSTRALIA
1
QUEENSLAND
5
6
7
SOUTH AUSTRALIA
2
3
4
NEW SOUTH WALES
8
9
VICTORIA
10
11
12
15–30
14
13
31
TASMANIA

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. Alfred Health
16. Austin Health
17. Cabrini Health
18. Epworth Healthcare
19. Melbourne Health
20. Monash Health
21. Murdoch Children's Research Institute
22. Olivia Newton-John Cancer Research Institute
23. Peninsula Health
24. Peninsula Oncology Centre
25. Peter MacCallum Cancer Centre
26. Royal Children's Hospital
27. Royal Women's Hospital
28. St Vincent's Institute
29. The Walter and Eliza Hall Institute of Medical Research
30. Western Health
31. Launceston General Hospital
32. Auckland City Hospital

CONTENTS

CTA service metrics

grew

further in 2020, once again matching or exceeding our yearly record in all key performance indicators.

Chairperson's Report

It is with great pleasure that I pen my fifth and final Cancer Trials Australia Chairperson's report, to preface our 2020 Annual Report.

As per our Constitution, I will be stepping down from the Board in August of 2021, at the conclusion of my second successive term. I thank my fellow Directors for their important contributions throughout 2020; John Seymour, Mark Shackleton, Zee Wan Wong, Craig Underhill, Colin Nugent, Tim Murphy and Michelle Gallaher, as well as our newest Director, Associate Professor Jayesh Desai, who joined the Board in December 2020. I would also like to take the opportunity to acknowledge the significant contribution John Seymour has made in helping shape this organisation over his two consecutive terms as a CTA Director.

In 2020 CTA expanded Membership with the addition of the Royal Children's Hospital, Launceston General Hospital and our first international Member; Auckland City Hospital, which propels the organisation to 32 Members across five Australian states and New Zealand. Our growth continues into 2021, welcoming one additional Member in the first quarter alone.

CEO Kurt Lackovic and the entire CTA team have impressed the Board with their ability to continue to grow CTA's Membership and services, in a particularly challenging year; CTA service metrics grew further in 2020, once again matching or exceeding our yearly record in all key performance indicators.

The Board also recognises both the recent and ongoing strategic investment in information management systems, which ensured CTA adapted well to the challenges throughout 2020. The ability to rapidly transition to working from home ensured uninterrupted support of all service Members, allowing sustained focus on accurate and timely administration of an expanding trial portfolio across our Membership. Our established, strong links with both Sponsors and Contract Research Organisations were essential to our success, as well as leveraging the significant value offered through our Tumour Group network to maintain and promote awareness of trial activity.

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

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

I heartily congratulate both CTA management and all CTA staff for their achievements in 2020, as well as acknowledge Network Member personnel for working hard to ensure CTA's ongoing success.

ANDREW SCOTT
BOARD CHAIRPERSON

Review of Operations

While I have always felt privileged to have the opportunity to lead Cancer Trials Australia, this year, I am especially proud of how the entire CTA team dealt with the exceptional and unprecedented events of 2020.

Few organisations had contingency plans covering a global pandemic; however, I am pleased to report that CTA was well prepared, and therefore able to maintain all operations with minimal impact. This was greatly attributed to our staff who are to be commended on their ability to rise to the challenge, adapt and thrive in constantly changing operating conditions over the year.

The 2020 calendar year saw further growth at Cancer Trials Australia, both in CTA's Membership as well as in the delivery of administrative services to our Members. I am pleased that, despite the challenges presented by COVID-19 in 2020, three additional members joined CTA throughout the year. New service agreements were executed in 2020, and all expiring service agreements were renewed, highlighting the ongoing value-add CTA is providing for our service Members. I look forward to continuing to nurture strong relationships with all Members within our expanding network.

In October 2020, we marked a significant milestone; the recruitment of the 10,000th Australian oncology patient to clinical trials managed on behalf of our Member network of hospitals across the country. We took the opportunity to mark this occasion with an article looking back on how we started and confirming what it means to contribute to the progression of science and cancer therapy in Australia. You can find the article on pages 18 to 21.

As detailed further into this report, CTA service metrics improved across 2020, on the back of consistent growth over the previous three years. Open to accrual clinical trials increased 28% across 2020, patient recruitment increased 13%, protocol amendments jumped 45%, and contracts executed grew 12%. The CTA Finance team administered almost $35M on behalf of our Members, up 3% on the previous year. Our increased activity throughout 2020 necessitated additional staff, with our team growing by four employees across the year, and our combined efforts led to the generation of another healthy surplus for reinvestment to further benefit our CTA Members.

Consistency at Board level continued in 2020. After only one Board level change in 2019, we welcomed Associate Professor Jayesh Desai to the Board in 2020, replacing John Seymour who retired from the Board after two successive terms. I thank John for his considerable contribution to CTA over many years, and wise counsel throughout, and look forward to working even more closely with Jayesh, who has had a long association with CTA, primarily in his capacity as Chair of our Phase 1 Tumour Group.

Investment in our Information Systems remained a focus across 2020, building on investments in both infrastructure and software over recent years. Expanding our use of Atlassian's Jira continued, including the addition of its sister product Confluence. Our cybersecurity measures were further enhanced, and new applications were deployed. The VCCC funded SiteDocs project achieved its ambitious target of deploying SiteDocs, in a harmonised fashion, across 15 Victorian hospitals.

Management at CTA have expanded on their respective areas of responsibility further in this report, covering Clinical Trial Start-Up activity, Finance, Information Systems and Human Resources.

Clinical trials offer access to novel, potentially life-saving therapies, and due to the strength of the CTA network behind our Members, have been successfully attracted to Australia on the competitive global stage, for the benefit of Australian patients. CTA continues to focus on (i) providing cost efficient and timely services to our expanding Membership, (ii) strategic investment in information systems that support our Members, (iii) expansion of services offered, including for investigator-initiated trials, (iv) strategic selection of additional Members, as well as (v) 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.

Finally, I would like to take the opportunity 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.

KURT LACKOVIC
CHIEF EXECUTIVE OFFICER

Management Reports

CLINICAL TRIAL START-UP

MEMBER NETWORK ACTIVITIES

In 2020, CTA welcomed three new Members to our network: Launceston General Hospital, Royal Children's Hospital and our first international Member, Auckland City Hospital. This brings our membership to a total of 32 network Members across some of the largest and most highly regarded medical institutions in Australia and New Zealand. With the strength of our growing membership, we can continue to effect positive change through our collaboration on important projects and ongoing endeavours in advocacy.

A total of 33 quarterly meetings were successfully coordinated and hosted for our 11 stream-based Tumour Groups. Whilst the main focus of these meetings was to discuss current and upcoming trials, they also provided the opportunity for Members to collaborate on strategies to manage their trials under ever-changing COVID-19 implications and restrictions. The pandemic presented unique challenges, and the strength of the CTA network was especially evident throughout 2020, as our Members worked more closely together to share their experiences and expertise.

We would like to thank the following Tumour Stream Chairs for their continued support and engagement throughout 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), Associate Professor Jayesh Desai (Phase I/ Early Drug Development) and Associate Professor Ben Tran (Uro-Oncology).

TRIAL FEASIBILITIES

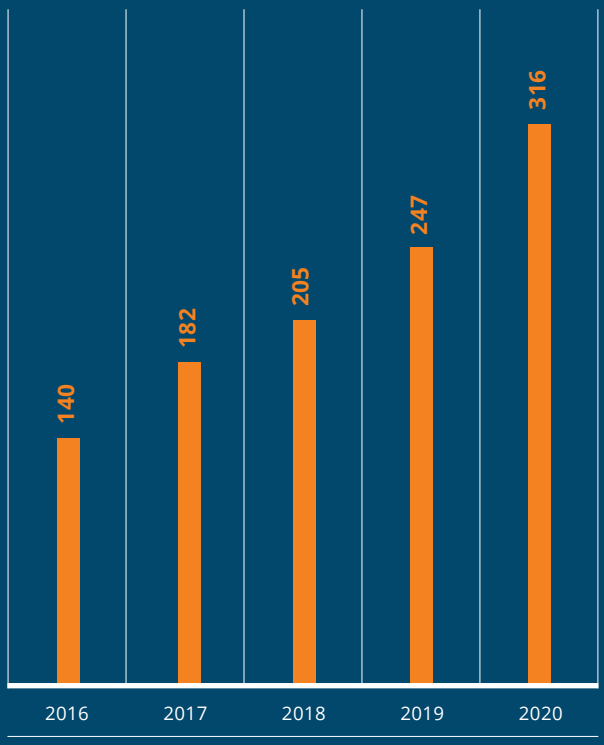
CTA continues to maintain collaborative relationships with sponsors, acting as an advocate for sites and working to create new opportunities where possible. During 2020, CTA was a key stakeholder in the Regional Trials Network project, which aims to increase regional patient access to clinical trials and to promote regional centres as sites for sponsor consideration. CTA significantly contributed to the success of this pilot project and the RTN has subsequently been awarded additional grant funding for the next iteration. CTA is proud to support this important initiative to increase cancer clinical trial access for regional patients.

PATIENT RECRUITMENT

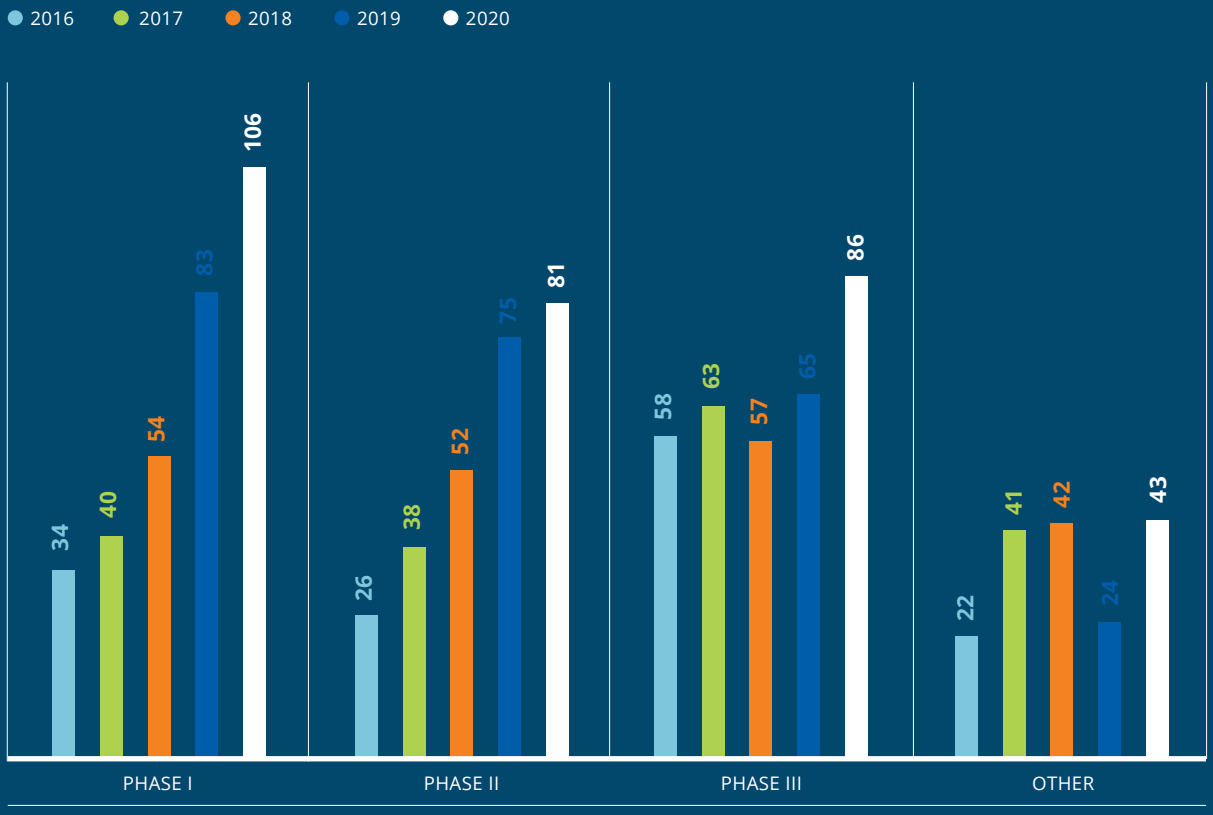
The deployment of clinical research staff to support the COVID-19 pandemic front line response and the strict physical distancing requirements necessitated that clinical trial operations be scaled back significantly at all Member sites for some periods during 2020. As a result, many Member sites temporarily suspended recruitment to clinical trials at the height of the pandemic. A hybrid model was adopted where possible, in keeping with a proportionate approach to risk assessment, ensuring each study was considered on an individual basis.

Despite this, it is pleasing to report that our Member sites more than made up for this delay once restrictions eased, achieving a 28% increase in the number of open to accrual trials supported by CTA when compared to 2019. Phase 1 studies increased by 28%, Phase 2 studies increased by 8% and Phase 3 studies increased by 32%. This attributed to a 13% increase in cancer patient recruitment.

OPEN TO ACCRUAL CANCER TRIALS SUPPORTED BY CTA



OPEN TO ACCRUAL CANCER TRIALS SUPPORTED BY CTA – BY PHASE



ETHICS AND GOVERNANCE SUBMISSIONS

While the pandemic postponed the initiation of some new trials across our service sites, the total number of study submissions remained consistent when compared to the previous year. There was also 4% growth in the number of studies approved to open.

The impact of COVID-19 on submission and approval timelines across the whole pipeline was evident. Ethics and governance submissions that impacted on the safety and wellbeing of participants were prioritised, with unavoidable delays then experienced in the review and approval of all other research submissions. As a result, our overall start-up approval timelines were slightly affected during this period.

We continue to experience an increase in protocol amendment submissions each year, with a 45% increase observed in 2020. This has had a significant impact on workload, necessitating the need to re-evaluate our staff placement and responsibilities. We also experienced an influx in the submission of administrative amendments in response to urgent safety measures, facilitation of home visits, telehealth and other ad-hoc noting items directly related to the COVID-19 pandemic.

We were pleased to support the submission of the first Phase 1 teletrial study at Alfred Health with the satellite hub at The Royal Hobart Hospital. This teletrial format was necessitated by COVID-19 travel restrictions, which prevented a patient travelling from Tasmania to Melbourne to receive study treatment. The combined and coordinated efforts of CTA, the Investigators, sites, the Pharmaceutical company and HREC/Governance offices ensured that the patient continued to have access to the best treatment option.

BUDGETS AND CONTRACTS

In 2020, we experienced a 12% increase in the total number of contracts executed when compared to the previous year. We also experienced an increase in the number of requests to modify site contracts for open studies due to critical changes required in response to the COVID-19 pandemic. This involved inclusion of telehealth visits and remote monitoring fees.

The pandemic forced our industry to rapidly evaluate and improve the way we communicate and manage clinical trials. This incredibly pragmatic approach will see lasting efficiencies gained in our work practices; technology adoption provided many solutions to the challenges presented and we have now adapted to new ways of working whilst continuing to deliver a high- quality service to our Member sites. Many sites and sponsors adopted electronic or digital signatures, perhaps earlier than they would have otherwise, greatly improving the turnaround time for execution of regulatory and contractual documentation.

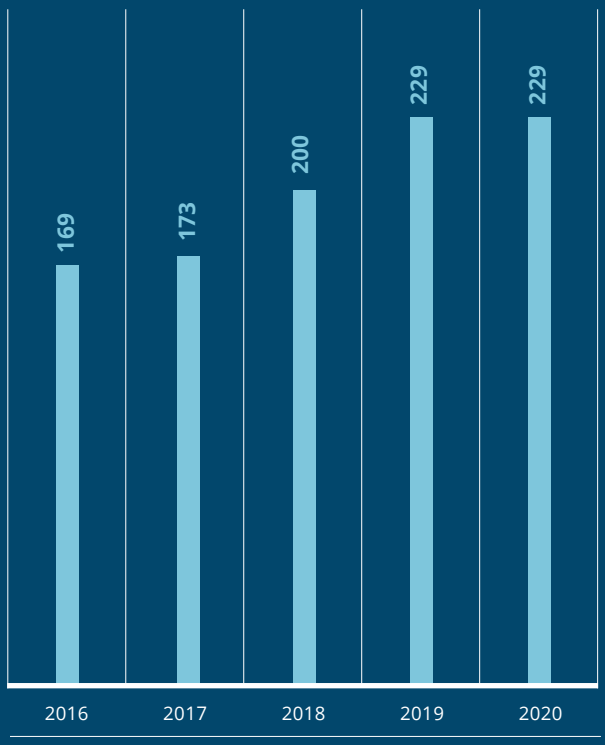
Whilst occasionally difficult and effort consuming, everything we have now learned during this turbulent time will increase efficiency and accelerate adoption of more effective ways to manage clinical trials. Issues that had long been on the periphery were forced into the spotlight and innovative solutions were identified to the industry's lasting benefit.

We would like to take this opportunity to acknowledge and thank our teams for their hard work and dedication in continuing to provide a high-level service to our Members during what was a very difficult and challenging year for us all.

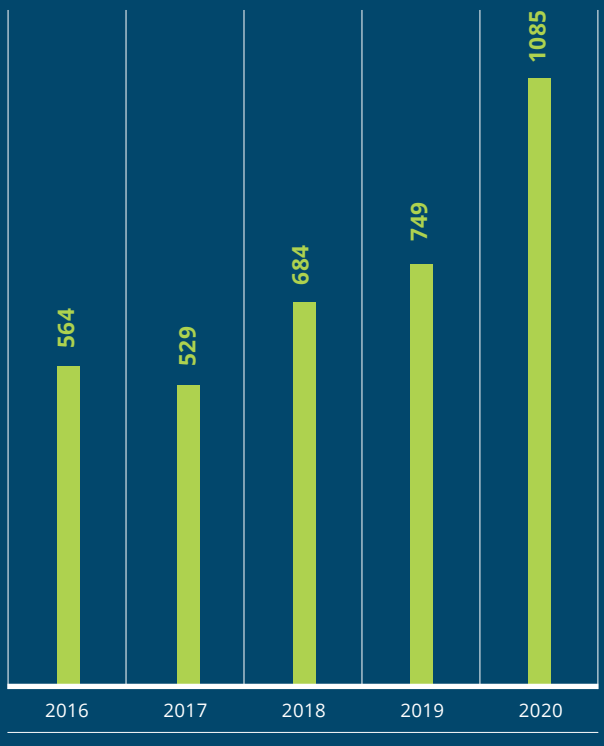
NICOLA HOWELL
CLINICAL TRIALS START UP MANAGER

MARIE LUCI
CLINICAL TRIALS CONTRACTS MANAGER

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.

The 2020 year presented some challenges, necessitating the Finance team to move swiftly to a work from home arrangement, which enabled us to streamline into paperless processes throughout the year, with minimal impact on revenue and invoicing. Central to this rapid adaptation was our previous deployment of MYOB Advanced, which allowed continued and undiluted access to our financial records and operations.

Throughout the year, CTA Finance continued to manage the invoicing process for approximately 500 sponsored trials and approximately 200 non-commercially sponsored trials, across 15 of our Member sites including metropolitan sites: Peter McCallum Cancer Centre, The Royal Women's Hospital and The Royal Melbourne Hospital (PCCTU), Western Health, Cabrini Health, Alfred Health and the Epworth along with workload expanding to service a greater number of regional centres, now including Barwon Health, Bendigo Health, South West Healthcare (Warrnambool), the Tweed Hospital and Goulburn Valley Health in Shepparton.

Despite the impacts of COVID-19, throughput increased in the Finance Team during 2020, with cash transfers to member sites of nearly $30M, an increase of 10% 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 the year. This service is provided interest free to all of our service Member sites, significantly reducing their cash flow risk.

In addition, the CTA Finance team are responsible for CTA payroll and the salary packaging arrangements with Remunerator. The Finance team are responsible for preparation of the annual CTA budget, 6+6 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 clinical trials conducted by our Members. We aim to ensure full expense recovery and timely invoicing on behalf of our Member sites, in accordance with contractual terms. Contractual agreements with sponsors continue to be complex, with many different items to be tracked for invoicing, and our continuing focus is to work with our Member sites to ensure accurate and timely data entry. Each year we continue to finesse and improve on these processes, to help manage the various clauses that are present in clinical trial research agreements.

I take the opportunity to thank my staff for their excellent contribution throughout the 2020 financial year.

MICHELLE BUTTON
FINANCE MANAGER

INFORMATION SYSTEMS

The onset of COVID-19 in January 2020 caused an evolutionary pressure on the structure of many workplaces, unlike anything that has ever been seen. At the close of 2020, Information Systems within CTA had experienced an incredible pivot, evolving rapidly from an office-based environment to one that was fully remote. Due to previous investment in infrastructure and software, we were able to adapt and thrive as a team, while maintaining our full suite of operations. Central to this was our previous adoption of Office365, including Teams, SharePoint and OneDrive, and Atlassian's Jira which enabled staff to maintain equivalent access to documentation, internal communications and operational oversight while working from home. Our laptop fleet and associated peripherals was expanded to cover all staff, and in doing so, our reliance on hospital IT infrastructure was removed. CTA provided expanded policies, necessary equipment and tailored helpdesk support to allow staff to set up safe and comfortable working from home spaces.

Our extensive cybersecurity measures allowed our ongoing work to remain tightly protected and two additional phishing exercises were held to drill CTA's response to a cyberthreat. We overhauled our Staff Onboarding process to better support staff commencing with CTA while working from home and adoption of software packages such as AdobeSign for electronic signatures added further efficiencies to day-to-day operations.

These positive sentiments should not however, diminish the difficulty of this rapid evolution; CTA staff are to be commended for their resilience, diligence, trust and determination during a time that was stressful and painful on many fronts.

CTA's expansion of Atlassian's Jira continued, allowing transparent and powerful tracking of work in progress across our start-up efforts in the Budgets and Contracts, and Ethics and Governance teams. Further development of Jira included embedding Finance and Start-Up Activation processes for the first time. This granular understanding of our work product cycle provides a powerful ability to analyse bottlenecks and improve performance against strategic goals. In 2020, the reach of this tool extended further into provision of real-time, on-demand reporting to sites using Jira's sister application, Confluence, and significant version and feature upgrades were undertaken.

Our dashboard analytics tool, Microsoft's Power BI draws together separate datasets arising from Jira, Velos eResearch, financial and site-supplied datasets to provide a powerful mechanism for analysis, allowing trend analysis by year, team and disease indication over financial indicators, patient accrual and study status data, and identification of under-performing studies and data collection gaps. Sites relied heavily on these tools to track the impact of COVID-19 lockdowns on patient activity and trial revenue.

The SiteDocs project introduced in the previous annual report continued to grow, with its ambitious roll out plan realised, and additional sites recruited. The project was widely lauded as essential to site operations during periods of lockdown and also provided a secure portal for remote monitoring. The VCCC funded project is scheduled for completion in January 2021 and as such, towards the end of 2020, work commenced on designing a self-funding Maintenance Program that will allow CTA to continue to provide advocacy and training to sites in this application.

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

EMILY ENGLAND
INFORMATION SYSTEMS MANAGER

HUMAN RESOURCES

The overnight transition made by our staff, from working at our offices to working from home, was the key challenge posed by the global pandemic for CTA. This transition was successfully navigated by having the right planning, infrastructure, systems, policies, and procedures in place, of which the latter two were developed in consultation with staff.

CTA's success during this enforced period of working from home was also due to the increased level of communication between managers and their staff, and between the CEO and his direct reports, using virtual platforms such as MS Teams and Zoom.

An Employee Assistance Program, run by Melbourne-based external providers, was also introduced in April 2020, to provide additional support for staff and buffer negative impacts on their physical and mental health, posed by COVID-19 related restrictions. Anonymised reports show that this service was utilised throughout the year, confirming its value as an ongoing investment in the wellbeing and health of our staff.

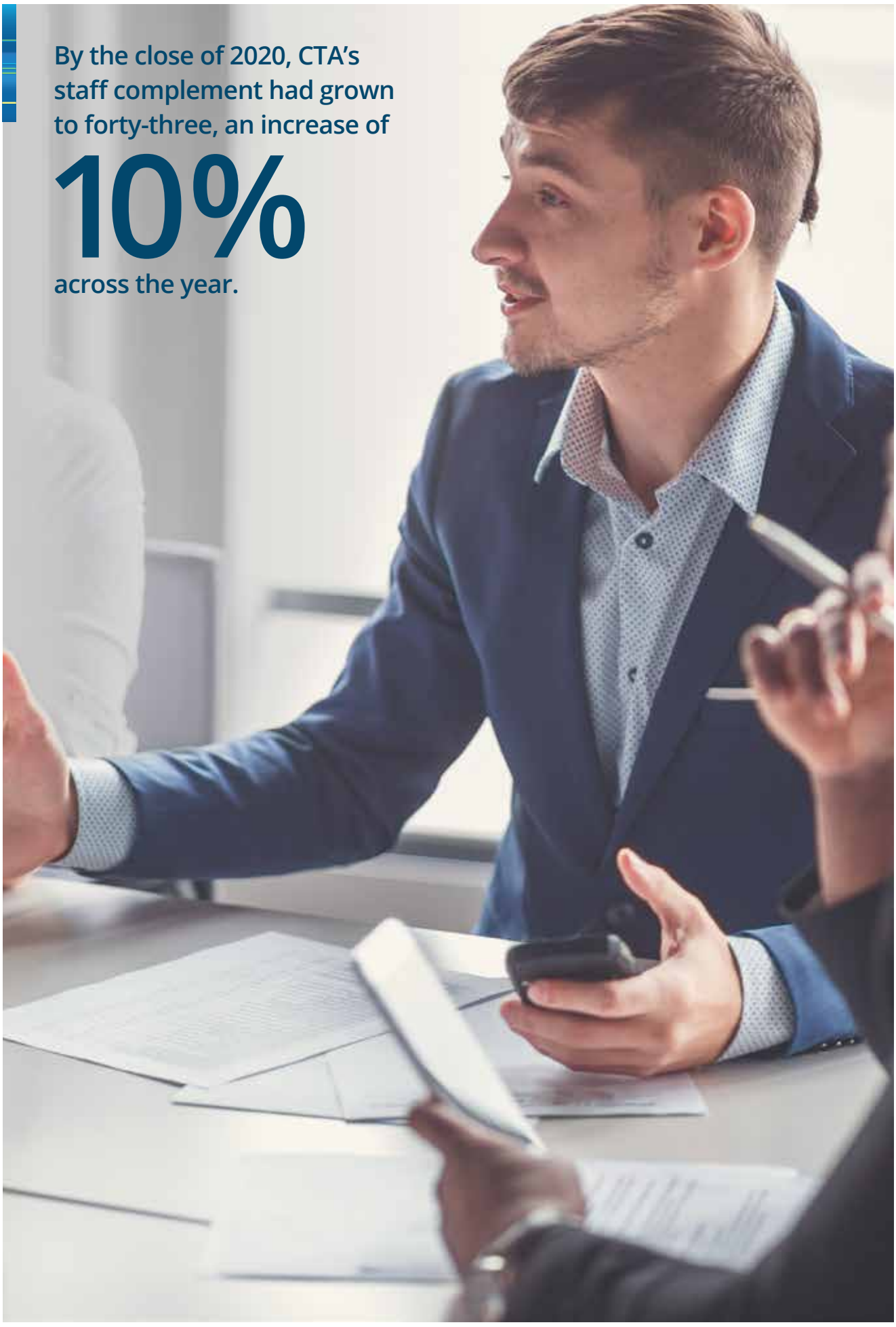
Opportunities for staff professional development were understandably limited due to the restrictions imposed by COVID-19. However, plans are already in place to ensure that professional development for staff is prioritised in 2021.

Towards the end of 2020 and with the assistance of external experts, CTA undertook a thorough review of our employment contract templates, the purpose of which was to ensure compliance with relevant statutes and legislation and provide the basis for transitioning staff to permanent employment, particularly in cases where employees have been working for CTA under several back-to-back fixed term contracts.

Considerable efforts were also made to maintain a sense of unity and camaraderie across the company, through staff participation in various in-house 'non-work'-related activities, as well as an online team-building session half-way through the year. This was especially important for staff who commenced while on-site office restrictions were in effect through the middle of the year, requiring additional time spent training and onboarding new staff via virtual platforms. Once restrictions were lifted in late November, all staff were invited to attend an off-site end-of-year celebration and team activity to acknowledge and thank everyone for their efforts throughout a difficult year.

By the close of 2020, CTA's staff complement had grown to forty-three, an increase of 10% across the year. Learnings from the training content and methodology developed throughout 2020, as well as further refinement of recruitment processes, transformed the way we now approach these activities, resulting in greater consistency and improved efficiency in how we recruit and on-board new staff.

SUSY MONTAGNER
HUMAN RESOURCES MANAGER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Board Sub-Committee Reports

FINANCE AND AUDIT SUB COMMITTEE REPORT

The Finance and Audit Sub-Committee (FASC) held four formal meetings throughout 2020, as well as regular ongoing contact and interaction with CTA management. The CEO, Kurt Lackovic, and the Finance Manager, Michelle Button, attended all FASC meetings throughout the year and continued to maintain their excellent standard of accurate financial information and reports.

The FASC oversaw the financial performance of CTA, including cash flow, profit and loss, balance sheet performance and all capital investment propositions. The FASC also considered potential internal and external risks to the business and assisted management in maintaining a current Risk Register, the potential impact of COVID-19 on CTA being one of the most significant risks of 2020. The FASC's advice and recommendations were provided to management and the CTA Board.

The FASC meeting agendas included a rigorous review of operating performance compared to budget, the company's financial position and debtor management. 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 $34,834,218 (2019: $33,912,908); an excellent result given the possibility that revenue could have been severely reduced due to the COVID-19 pandemic. The surplus for the year was $326,256 (2019: $525,106).

The quality of administration of clinical trials by CTA will continue to underpin success into the future. Investment in financial and other reporting systems have continued in 2020, to drive greater efficiencies and continuous improvement in reporting accuracy and relevance to stakeholders. The strong financial position maintained will allow this improvement to continue into the years ahead.

Strategic alliances and focus on Government advocacy has continued, albeit with COVID-19 challenges in 2020, to ensure CTA is well positioned to add value to its Members. CTA's communication presence, both internally and externally, has greatly assisted in achieving this.

As has been the trend over a number of years, exchange rate uncertainties are essentially neutralised by contracts being written in local currency, together with a continued focus on cost management.

The Company ended the year with a very sound financial position, having $7.42M in cash reserves (2019 $7.15M). Total equity of $4.67M increased over 2019 ($4.35M), driven by the better than budgeted surplus for 2020.

The cash reserve continued to act as a buffer and safety net for the timing of cash flows that remained unpredictable, and enabled financing of operating cost before sponsor payments were received. This in turn provides ongoing reassurance in an environment of increased uncertainty around future business forecasts caused by many factors including COVID-19.

The ratio of current assets to current liabilities was 1.68 (2019: 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. The FASC wishes to acknowledge the high accounting and financial management standards set by Michelle Button, Finance Manager, and Kurt Lackovic, CEO, and thanks their teams in assisting in these endeavours.

The FASC was pleased to advise the CTA Board to accept the 2020 results. And despite the challenges caused by the impact of COVID-19, CTA is well positioned to face 2021 with confidence under the continued leadership of Kurt Lackovic and his team.

COLIN NUGENT
B COM, CA (SA), ACA
CHAIRPERSON, FINANCE AND AUDIT SUB COMMITTEE

PERFORMANCE AND REMUNERATION SUB COMMITTEE REPORT

The Performance and Remuneration Sub Committee met twice in 2020, 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 2020, in response to John Seymour reaching the conclusion of his two consecutive terms, the maximum permitted under our Constitution. The Committee thanks John wholeheartedly for his significant contribution to CTA over an extensive period.

The Committee was also pleased to receive updates regarding professional development for CTA staff throughout 2020, which continued on a more limited basis than usual, due to COVID-19 related restrictions.

ANDREW SCOTT
CHAIRPERSON, PERFORMANCE AND REMUNERATION SUB COMMITTEE

"We created this organisation for the love and respect of clinical trials, because we recognised there was a need to collaborate to **improve** outcomes for patients".

PROFESSOR MARK ROSENTHAL

10,000th

Australian patient accrued by ground-breaking cancer trials collaborative

In a major milestone for Australian cancer patients, the not-for-profit, member-based organisation, Cancer Trials Australia (CTA), has recently marked the recruitment of the 10,000th oncology patient to clinical trials managed on behalf of their strong Member network of hospitals across the country.

These trials offer access to novel, potentially life-saving therapies, and due to the strength of the Network behind them, have been successfully attracted to Australia on the competitive global stage for the benefit of Australian patients.

Professor Mark Rosenthal, former CEO and former Chairperson of CTA, says Australia's highly competitive cancer research capabilities are thanks to the tenacity and generosity of a small group of researchers that came together in the early 1990s: "We were a small academic group that was, in retrospect, extraordinary," he says.

Becoming an incorporated entity some 17 years ago has brought with it many changes, but it has not fundamentally changed the intent or culture of CTA as an organisation.

"We were firmly not-for-profit from the outset and we have always been member-based so we've grown an incredibly powerful network out of the desire to connect clinicians with similar interests and skills for the common good," says Professor Rosenthal. "In many ways we were the birthplace of many experimental cancer treatments and we remain a great advocate for patients and cancer treatment. We created this organisation for the love and respect of clinical trials, because we recognised there was a need to collaborate to improve outcomes for patients," says Professor Rosenthal.

With more than 1,000 commercially sponsored clinical trials under their belt, CTA's Members have earned an enviable reputation as global leaders in the field. Their clinicians have become highly sought-after advisors for biotechnology and pharmaceutical companies, seeking to design effective trials, ensuring effective treatments are available faster.

"A spectrum of highly trained professionals is really what allows us to do the work that we do. The fact that hospitals now have research fellows embedded within them, and that these people can see first-hand how research is done — that helps to build our local capability and ultimately directly benefits patients," says Professor Andrew Scott, current Chair of CTA, who has been involved in the organisation since its inception.

"During trials, a lot of time is spent doing things that are not related at all to the research itself, from budgeting, contracts, ethical frameworks and financial management. The CTA team has always taken this incredible administrative burden away from the researchers, allowing them to focus on what they do best," says Professor Rosenthal.

"From a researcher's perspective, to know CTA provides a pathway for rapid translation of discoveries to the market is something we can all be proud of. Through its professional and driven support of this industry, CTA allows the discoveries of Australian researchers to be studied here and not just disappear overseas," says Professor Scott.

Professor Rosenthal agrees: "Thirty years ago, no one had the expertise here in Australia that was needed to take molecules from bench to bedside, with all the associated concept and protocol development. Now, in collaboration with biotech companies both in Australia and all over the world, we have 600 trials currently open across CTA Members, and some 40% of these are early phase or first-time-in-human trials; they are the great grandchildren of CTA, that are only possible because of the work that went before them," says Professor Rosenthal.

One of the greatest strengths of the CTA model has been its ability to consistently make the set-up of Phase 1 oncology trials fast and efficient. The strengthening of this capability, and its application to more than the oncology field of medicine is part of the future direction of the organisation.

"Here in Australia we have many advantages. Of course there are organisations that undertake similar work overseas, but CTA is able to bring new trials rapidly into the clinic thanks to our extensive expertise, highly professional staff, and the strength of the network we've built across our hospitals," says Professor Scott.

"One of the most important outcomes of our work is that it has also created a generation of highly qualified clinical nurses and data managers, who engage directly with patients and underpin the quality of our clinical research," says Professor Scott.

Associate Professor Jayesh Desai, Chair of CTA's Phase 1 trial group, agrees, saying the generosity of CTA's network of researchers and clinical staff has always been a key element of its success. "Our network is really collegiate. We have all benefited from having something that goes beyond us as individuals alone. It's highly specialised work and it requires immense skill and support."

"When we work with biotech and pharma, the value they get from working with us instead of going somewhere else is that we are already part of a strong network, so we get along well, we respect each other, and we enjoy working together. There is a lot of value-add that stems from that, because we are in constant communication. The strength of our collaboration helps us compete with massive cancer centres in Boston or New York," says Desai.

"The fact that we have managed to build this infrastructure has allowed us to benefit in a way that is way beyond what we could have achieved as individuals. Our people are fantastic and have incredible skills and knowledge, but they are also generous. The culture rewards people that are generous in that way. You're not on your own as an expert and that ultimately means you're a better doctor."

For patients, CTA's network and the trials themselves have offered enormous benefits.

"When patients join a trial, their care is absolutely first class. Many patients have an altruistic element to their participation in a trial. They figure that even if it may not help them directly, it might help someone else. So, that sense of purpose can be a real positive during treatment," says Professor Rosenthal.

"However, our approach has always been to genuinely look to improve the outcomes for every trial participant. We recruit patients into trials that we genuinely have reason to believe will help them, so the culture and approach of our work is quite unique," says Professor Rosenthal.

Desai explains too that the way trials are run is critical to ensuring good patient outcomes: "We are able to initiate trials efficiently and the patient opportunities this has provided are enormous. Navigating the health system is tough, but in a trial, you have a whole medical team around you. It provides an incredible support structure."

"Trials can be transformative for patients and their families, but they have also helped to build and make my career, so that I can give back. I look after my patients better because of the access to knowledge that I've had," says Desai.

Broadening access to treatments remains a key focus for Cancer Trials Australia.

"One of our key achievements has been to improve access to new treatments for Australian cancer patients. Experimental treatments are now available at any time during the patient's journey. They don't have to miss out because they don't live in Melbourne, or because of financial constraints," says Professor Rosenthal.

"Designing trials requires a seamless, intimate interaction between scientists, clinicians, companies and many others to plan the best way to deliver the trial. It's a complex process that we have mentored many people through. We have also ensured inclusion of rural and regional sites in studies now and telehealth has enabled new reach for our work," says Professor Scott.

The future for CTA's work looks bright.

"Earlier this year we added our first international member, the Auckland City Hospital in New Zealand, so our work is now making impacts beyond Australia," says CTA's Chief Executive Officer, Dr Kurt Lackovic.

"Over recent years we have also expanded our support beyond oncology, ensuring a consistency and quality of approach in other therapeutic areas such as cardiology."

"With the implementation of a national clinical trial governance framework across Australian hospitals in 2021, CTA is well positioned to ensure hospital executives have the necessary oversight of clinical trials, and that thousands more Australian patients will benefit from access to such trials over coming years."

Board of Directors

PROFESSOR ANDREW SCOTT AM (CHAIR)
MBBS, MD, FRACP, FAHMS, FAANMS, FAICD, DDU

Appointed as Director: 25 August 2015

Head, Tumour Targeting Laboratory, Olivia Newton-John Cancer Research Institute, 2015 to present.
Medical 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 present.

Meetings attended:
Directors 
PRSC 

TIM MURPHY
AICD 2004, MASTERS OF MARKETING, MELBOURNE BUSINESS SCHOOL, BACHELOR OF SCIENCE (HONS)

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 
FASC 

PROFESSOR JOHN SEYMOUR
MBBS, FRACP, PHD

Appointed as Director: June 2014

Professor John Seymour AM is a clinical haematologist and Associate Director of Clinical Research at the Peter MacCallum Centre, and the Director of the integrated Haematology Department of the Peter MacCallum Cancer Centre & the Royal Melbourne Hospital. He received his MB, BS degrees from the University of Melbourne in 1987, completed a translational research fellowship at the MD Anderson Cancer Center in Houston, and subsequently received their Distinguished Alumnus award in 2011. He also completed PhD studies in the pathobiology of haematopoietic growth factors at the Ludwig Institute for Cancer Research.

Professor Seymour is a member of several national and international scientific committees including, Cancer Australia Advisory Groups, the Scientific Advisory Committee for the International Conference on Malignant Lymphoma, Medical Advisory Board of the Lymphoma Coalition, and the Board of Directors of the International Extranodal Lymphoma Study Group. He served for more than a decade as Executive member and Chairman of the major national clinical trials co-operative group in haematologic malignancies, the Australasian Leukaemia & Lymphoma Group. He is a frequent invited speaker nationally and internationally, is a member of numerous professional societies, an Editor-in-Chief of Leukemia & Lymphoma, and currently on the editorial boards of Blood and the British Journal of Haematology. He has authored 18 book chapters, >500 peer reviewed publications (with >24,000 literature citations), and >700 conference abstracts. Actively involved in a broad range of collaborative research, Professor Seymour has been has been the principal investigator on >85 clinical trials and chief investigator on competitive grants awarded >AUD$18 million funding in the last 10 years. In 2015 he was awarded Membership of the Order of Australia, and elected to the Australian Academy of Health and Medical Sciences for his contributions to the field.

Meetings attended:
Directors 

COLIN NUGENT
B.COM, MEMBER OF INSTITUTE OF CHARTERED ACCOUNTANTS IN AUSTRALIA (CA)

Appointed as Director: 10 June 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 
FASC 
PRSC 

ASSOCIATE PROFESSOR ZEE WAN WONG
MBBS MRCP FAMS GDA FRCP FRACP

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.

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 past 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 

MICHELLE GALLAHER
DIP APP SCI (ORTH), GRD DIP BUS, MBA, GAICD, FELLOW AIM

Appointed as Director: 12 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 and a Global Executive MBA from Monash University.

Michelle has served on numerous government and health industry advisory boards and committees, currently serving as a NED on the boards of Praxis Australia, Medtech Actuator and the lifesciences executive committee of Springboard Enterprises Australia. Michelle is also co-founder and co-chair 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 in 2018 for her services to the biotech industry and women in STEMM. Michelle is a GAICD and FAIM.

Meetings attended:
Directors 
FASC 

DR. CRAIG UNDERHILL
MBBS, FRACP

Appointed as Director: 24 May 2017

Dr 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. 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 (Borer Medical Oncology Research Unit), has VMO appointments at Albury Wodonga Health (Albury Wodonga Campuses) 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. He completed his Bachelor of Medicine and Surgery in 1987 at Melbourne University and became a Fellow of the Royal Australasian College of Physicians in 1997. In the mid 90's Dr Underhill worked as the Senior Clinical Research Registrar at Guy's Hospital, London.

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 

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, a Victorian Cancer Agency Clinical Research Fellow, Chair of the Australian and New Zealand Melanoma Trials Group and Head of the Cancer Development and Treatment Laboratory at the Monash Central Clinical School at Alfred. After training in medical oncology and at the Ludwig Institute in Melbourne, Dr. 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. His laboratory focuses on understanding mechanisms of cancer initiation and propagation.

Meetings attended:
Directors 

ASSOCIATE PROFESSOR JAYESH DESAI
MBBS FRACP

Appointed as Director: 25 Nov 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 1st in human trials. These have been both investigator initiated, as well as collaborative 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 

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 23 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 
FASC 
PRSC 

The Board ensures that CTA management and staff maintain regular reporting practices and

comply

to the highest level of corporate ethics.

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 Babak Tamjid
Goulburn Valley Health

Ms Sarah Coulson
Launceston General Hospital

Mr Jayden Rodgers
Linear Clinical Research

Dr Rohit Joshi
Lyell McEwin Hospital

Dr Angela Watt
Melbourne Health

Dr 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

Dr Vinod Ganju
Peninsula Oncology Centre

Prof Danny Rischin
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

Dr 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

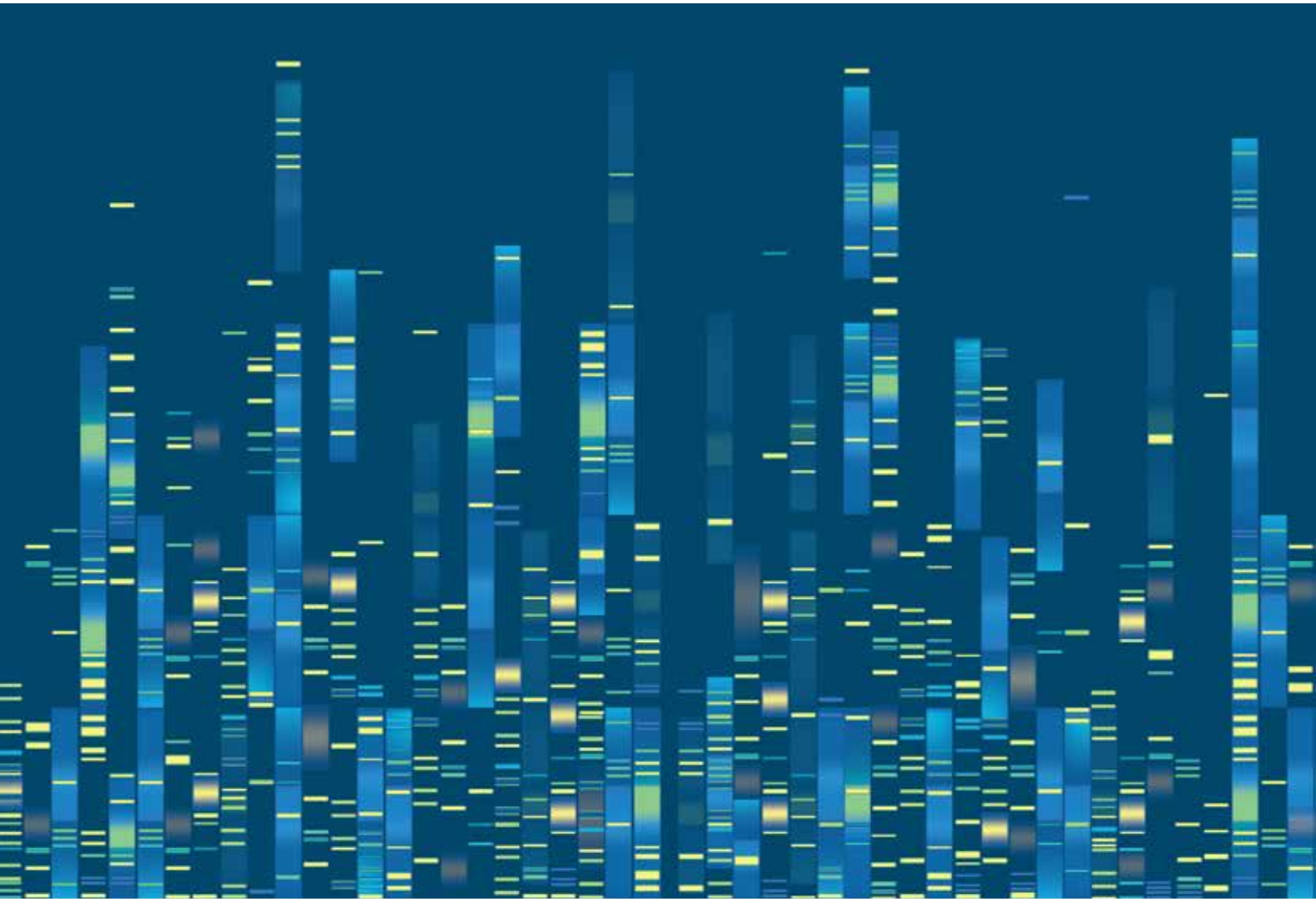
Dr Muhammad Alamgeer
Lung Cancer

Dr George Au-Yeung
Melanoma

A/Prof Jayesh Desai
Phase I/Early Drug Development

Dr Ben Tran
Uro-Oncology

Cancer Trials Australia



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