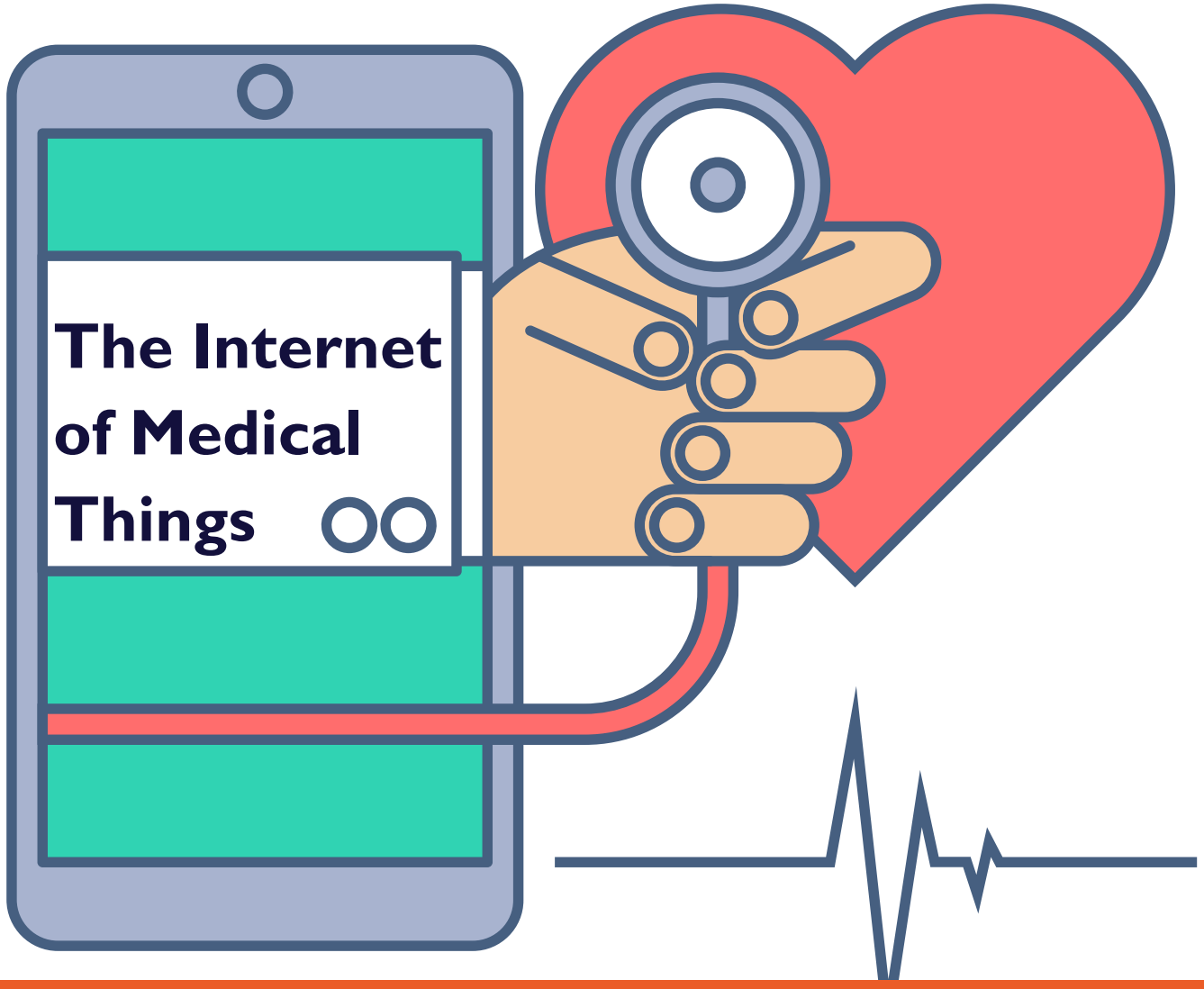
AN ARCS AUSTRALIA LTD PUBLICATION FOR MEDTECH, BIOTECH AND PHARMACEUTICAL SECTOR PROFESSIONALS

COGNITIO



In this issue

ARCS AUSTRALIA®

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GuildLink powers the better use of medicine, by improving the way Australian pharmaceutical companies educate, engage and connect with pateints and key industry stakeholders.

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CONTENTS

ARCS AUSTRALIA®
Professional Development in Therapeutics™

ARCS Business Office
Suite 802, 28 Clarke Street
Crows Nest NSW 2065
Phone: 02 8905 0829
Email: arcs@arcs.com.au
Web: www.arcs.com.au

Editors
Shanny Dyer
Candice Monaghan

Advertising
Candice Monaghan
Phone: 02 8905 0829
Email: candicemonaghan@arcs.com.au

Designer
You Tarzan Pty Ltd

President's Report

As our calendar year end fast approaches, I encourage you to reflect on your professional development aspirations.

The 2017 ARCS Annual Conference certainly offered opportunity to learn and network. It was a roaring success. With over 80 sessions, 164 speakers and 1,000 delegates over the three days, the buzz was evident. We have many to thank – the ARCS team, for their dedication and expertise; members of the National Conference Advisory Panel, who provided invaluable input to programme; speakers and session chairs. We must also recognise the valuable role of the conference sponsors and exhibitors and thank them for their support. As a Board, we are privileged to observe how the passion and dedication of staff and volunteers culminates into a highly-regarded event. I'm confident next year's conference, 21 - 23 August, will be just as exciting.

I am proud to reflect on ARCS's journey – whilst educating and connecting members remain core pillars, ARCS is cementing its place as a key stakeholder in the healthcare sector.

We are delighted with the response to our inaugural CRO forum and ARCS CEO Breakfasts, which brought together stakeholders in leadership roles to share areas of common concern and to advocate for our sector. I am reminded of this quote from the well-known 7 Habits book authored by Stephen Covey, which captures the essence our leaders bring to these discussions:

"Proactive people are still influenced by external stimuli, whether physical, social, or psychological. But their response to the stimuli, conscious or unconscious, is a value-based choice or response" [1]

Since our last Cognitio issue, the Board farewelled Lucas Litweka, who stood down to focus on professional and family commitments, and welcomed back Robert Kent who was an ARCS Board member from 2014 to 2016. In line with our constitution, the Board appointed Robert as Lucas' replacement, for the remainder of Lucas's term. We also progress with our search for an Independent Director, and look forward to providing further information in due course.

Looking ahead, we have our Annual Members' Meeting (AMM) on the 23 November in Melbourne. Our AMM is the new expression of our Annual General Meeting, aligned with the constitutional changes endorsed by members at the 2016 AGM. Whilst in the past members voted either in person at the AGM or by proxy, this year neither of those voting methods will be employed. Instead, we are introducing electronic voting - for the first time, members will cast their vote electronically prior to the AMM, with the expectation that results will be announced at the AMM. The electronic voting process will be managed by a third party to ensure process integrity.

Nominations will open for four Director positions. The Board would welcome nominations from full or life members who have a passion for healthcare, leadership and governance. Perhaps joining the ARCS Board of Directors would complement your professional development aspirations.

Mary Nteris PhD, GAID
President, ARCS Australia

1. Covey, S, 2004, The 7 habits of highly effective people, Free Press , p 72.

CEO's Report

I really enjoyed catching up with you at the Annual Conference and we have had some very good feedback – so much so, we have already announced the dates for next year's ARCS Annual Conference -21-23 August 2018! In this edition of Cognito, we have encapsulated some of the conference activities in photos on page 12-13. We also have a white paper provided by Frost & Sullivan following the plenary session by Rhenu Bhalla – this paper captures some of the key indicators for our sector and provides great insights – well worth the read.

I am also pleased to include a series of discussion papers focusing on clinical trials in rural and remote areas of Australia. This is an important step in our continued goal of equity in healthcare access.

With all that is going on, I must say that it is truly a very exciting time to be in this sector. Our working title is the 'medtech, biotech and pharma' (MTP) sector, but we are so much more than that- we are effectively at the core of the healthcare industry – and with that we have a fundamental premise that the patient is at the heart of our every decision. Many of us work in global companies but we as individuals know that Australians expect the highest quality of care, access to the best treatments and world class drugs and devices. Given this there can be no reason for us not to expect this given the astonishing technologies around us.

However, despite us wanting the best outcome for patients, there remains a conflict and a prevailing culture of competition over collaboration and this creates a tension that stifles progress. The tension is the need to have control over our 'turf' and to provide predictability and control to industry and government stakeholders, and at the same time remain agile enough to capitalise on new technology, new discoveries and to be a disruptor rather than be disrupted.

I believe the turning point will come when key influencers in the industry can truly collaborate, put aside their fears and vulnerability and work towards a real and sustainable healthcare system where government (both state and federal), hospitals, pharmacists, GPs, specialists, nurses, universities, companies, consultants, patients, and carers work together towards a breakthrough and lead us through the predictability/agility challenge.

When we can do this, the healthcare sector will undergo a fundamental transformation in healthcare delivery. The quality and accessibility of healthcare will dramatically improve and Australia will become a mandatory destination for clinical research and we will be world leaders, having created a backbone of an advanced civilisation.

That might sound dramatic, but we have a responsibility – we all live in a very, very privileged society. In the sector we work, most of us enjoy an unenviable life style and we should not take this for granted. As leaders in our sector, we need to take responsibility to put aside our fears and be fearless in our leadership. Let's start the journey, let's think differently, let's think collaboratively.

ARCS has been around for 33 years and has provided a focus of early career education, industry led and case-study driven. However ARCS can be so much more. Our members are at the core of the industry. Our members are individuals, however as a collective, we are a united voice. ARCS can be and is now, a place for these conversations, a united voice that can provide direction to the sector, to improve the industry and provide better healthcare for all Australians.

I look forward to continuing this discussion with you and catching up with you at future events.

Shanny Dyer and the ARCS Team

The Internet of Medical Things

Digital Transformation Creating Waves in the Clinical Trials and Drug Development Industry

The global pharmaceutical industry is undergoing a huge paradigm shift in drug development. Patent expiries of blockbuster drugs, increased focus on specialty products, and technological disruptions are forcing the transformation of the industry at an unprecedented pace. In the US, Donald Trump's presidency is leading to tighter regulations and drug pricing policies, creating a more intense environment for pharmaceutical companies across all areas including research and development and clinical trials. These trends, coupled with the costs of drug discovery and development and scrutiny on in-house R&D, are driving the need to reinvent the pharmaceutical industry.

Five key themes for innovation and transformation in the pharmaceutical industry are:

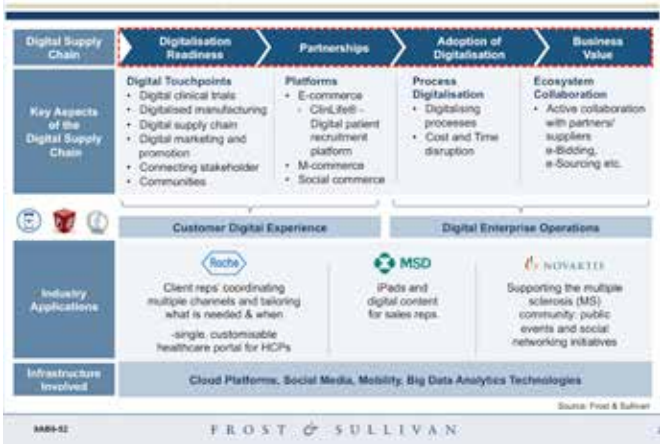
1. **Focus on Core Areas:** With an aim at product portfolio expansion, pharmaceutical companies worldwide are increasingly focusing on areas such as orphan diseases and biologics to develop innovative next-generation products.

2. **Value Chain Excellence:** A steady shift towards automation with major pharma companies exploring technology applications across various aspects of drug development. For example, using computer-aided software for process monitoring and specialised manufacturing techniques to improve the success rates of clinical trials.

3. **Strategic Collaborations/Alliances or Partnerships:** Given the complex industry framework, more collaborations among market participants across research, technology, distribution or cost areas are likely, to heighten exposure to key technologies, therapeutic areas, and aid in expanding geographical presence, in particular, gaining access to certain remote locations and populations.

4. **Beyond the Pill Service & Solutions:** A strategic option to enhance patient treatment services and safeguard customer loyalty from patient and profit perspectives. The shift from volume- to value-based delivery is taking place with the changing pharmaceutical landscape. Steps in this direction include collaborations with CROs, CMOs, academia as well as enhancing technology access to providers.

5. **Digital Footprint:** Applying automation/digitalisation in various pharmaceutical operations is expected to result in quicker and easier execution of drug development and market access. Centralisation of pharmaceutical operations and access to mobile apps/platforms for real-time clinical trial information are some benefits of digitisation, alongside access to cloud platforms and digital gadgets to complete automation of the care delivery model.



Impact of Digitisation on Clinical Trials

While digitisation is leading to the rapid transformation of multiple industries, the life sciences and pharmaceutical companies remain hesitant to adopt new technologies in age-old processes. However, the slow and expensive drug discovery and clinical trial process are increasingly prompting a change in the culture and workflow of pharmaceutical companies.

To address these challenges of slowing innovation and growth, pharmaceutical companies are steadily integrating computational methods and predictive analytics techniques into trial design, execution, and analysis, to improve productivity and success rates of clinical trials, bringing about a paradigm shift in the clinical trial process.

Expansion of clinical trial services in early stages of drug development, the emergence of virtual biotech, out-licencing, and risk sharing between pharma and CROs are disrupting traditional business models. They are also opening up greater opportunities for companies in terms of access to a broader market, newer areas such as commercial and

post-launch activities, bioanalytical testing and development services, and partnerships with small- to mid-sized biotech and virtual pharma customers.

Globalisation of clinical trials, a prerequisite for drug development, continues to bolster outsourcing of research and drug clinical testing to drug development companies and CROs with a vast geographical footprint, instead of employing their in-house R&D resources. Offering specialised research technologies for drug development could increase the competitiveness of outsourcing companies against in-house R&D services. The ever-evolving industry paradigm is resulting in significant opportunities and partnerships for innovative drug development and CRO companies from small to mid-sized biotech and virtual pharma customers.

Digital tools and platforms are transforming the clinical trial process with the potential to improve the processes further. Digitisation can be applied in each step of the clinical trial process starting from protocol development or clinical trial design, to patient recruitment, clinical data collection, and analysis.

Digital trial set-up allows investigators to remotely monitor patients, improving patient-physician connectivity. Technology platforms like Wearable Health Monitoring Devices can alert the investigators of any untoward incidents, abnormal vital signs or potential complications, making the trials much safer. Patients can also be monitored outside the clinical trial setting; it does not require the patient to come onsite, lessening patient's participation burden while improving compliance. Electrocardiogram (ECG) monitoring wearables by companies such as AliveCor and LifeWatch assist patient monitoring in clinical trials. Remote trials could be the future of clinical trial set-up, as they make it easier for more patients to participate, are highly time- and cost-efficient, and extremely scalable. In June 2016, eClinicalHealth successfully conducted an entirely remote online clinical trial called VERKKO, a phase IV trial for diabetes.

Integrated Healthcare: The Future of Healthcare Service Delivery

The Internet of Medical Things continues to evolve and impact the future of medicine and care delivery. More companies are focusing on integrated solutions, with payers/patients taking centrestage, given patients' growing interest in the way treatment is carried out and involvement in the decision-making process. Social media and mobile health platforms show immense potential as an effective platform to connect directly with patients and transform the way both research and treatment are carried out.

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, works in collaboration with clients to leverage visionary innovation that addresses the global challenges and related growth opportunities that will make or break today's market participants. For more than 50 years, we have been developing growth strategies for the global 1000, emerging businesses, the public sector and the investment community.

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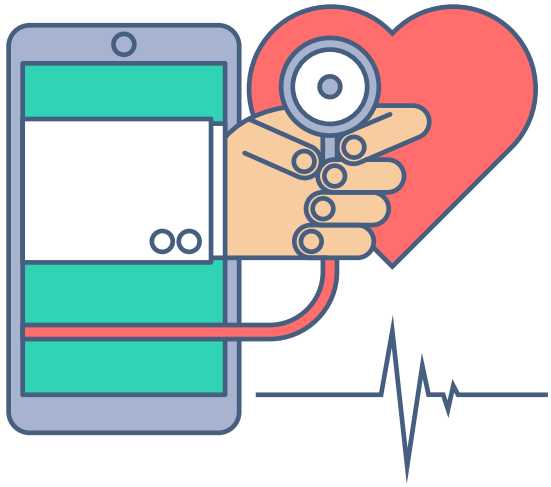
Mobile Research NURSING in Australia

Bringing the clinical trial to the patient



By **Helen Springford**, *Vice President of Strategic Development and* **Peter Allan**, *Research Nursing Project Manager at Illingworth Research Group Limited.*

Introduction

Access to clinical trials in countries with densely populated cities and small rural communities is relatively easy for potential participants. Sites have access to the required population making recruitment less of an obstacle. A large country such as Australia with a dispersed population has challenges. Many live in rural areas. Sites can be a vast distance from patient homes. It is therefore not a surprise to learn that this can make clinical trial recruitment, retention, and overall logistical strategy more difficult.

With younger generations moving to cities[1], and with many conditions seen predominantly in older people, this leaves behind an ageing population in rural communities who are distanced from clinical trial participation.

Data has indicated that just under half of all phase three clinical trials conducted in Australia failed to meet their patient recruitment targets.[2] It may be that in some cases, failing to include or target rural populations is contributing to this.

Rural and regional issues

Some of the most common barriers for clinical trial participation among rural communities is the inconvenience, the cost of travel, the time needed to travel to site and the disruption to the patient and family this causes.[3]

A survey conducted by MD group in 2016[4] supported this. It showed that half of clinical trials experience patient drop out due to travel difficulties. 32.3% of patients said travel difficulties were to blame. No less than 35.5% cited the need to travel to the site for post clinical follow up assessments as being the cause for drop out.

When judged against developed countries Australia has the lowest number of publications reporting on clinical trials carried out in rural areas. This included both the USA and Canada.[5] Advice from the Australian government for clinical trials[6] does little to encourage rurally based patients to take part. It alludes to the fact that, in many cases travel and accommodation costs are paid for by the participant. It is also their responsibility to either organise this with the trial sponsor, or find additional support themselves.

How can rural population participation be improved?

There are already significant changes taking place and technological solutions (telehealth) are a common theme:

- Smartphone applications that offer physicians greater access to the clinical trials available to their patient.[7]
- The Australian Tele-Trial Model[8] has been developed to extend access to clinical trials for cancer patients in remote areas

While these innovations are welcome, there are practical issues to consider such as internet access or connectivity speed.

Illingworth Research Group provides a hands-on service where mobile research nurses conduct 'off-site' study visits. The research nurses carry out clinical trial visits in the comfort of a patient's home, workplace, school or safe location of their choice, enabling patients to enter clinical trials previously too inconvenient to participate in. This in turn assists the sites since it expands the patient population available for recruitment into clinical trials, increasing the likelihood that enrolment targets will be met.

Many clinical trial protocols include visits that are of a routine nature (from regular blood sampling to reconstitution and administration of Investigational Medicinal Product (IMP)). They do not require specialist equipment or medical assessment. The aim is to perform such visits in a convenient location for the patient, which results in increased patient

recruitment and retention. The associated inconvenience of repeated visits to site, (a deciding factor for many patients), is carried by the research nurse provider. The site team also benefit from this adjunct service as it frees up their time to screen and enrol higher numbers of patients than they may otherwise have done.

Mobile research nurses

Illingworth Research Nurses are registered general nurses, with the necessary clinical trial experience to provide a quality service outside of the typical clinical study environment. They become an integral part of the study team approved by the relevant hospital and, as such are named on the site's delegation of duties log, undergo pre-study training and maintain strong communication with the site team.

Research nurse selection is based on experience in the therapeutic area and geographical location to the patient. They are local to their home removing the need for frequent travel and associated costs to the patient.

The success of the Royal Flying Doctor Service is a perfect example of how important and effective a mobile medical service can be in an emergency medical and primary healthcare situation.

Mobile research nurse capabilities

Although performed outside of the clinic environment, the visit procedures occur as they would do at the study site. This includes IMP administration and patient assessment after dosing to identify any reactions. (Note that serious adverse events are reported to the investigator immediately and appropriate action taken where necessary.) During this time source data can be checked and sample preparation can take place. All the visit logistics are handled by Illingworth. The research nurse carries portable equipment for assessment of vital signs; centrifuges for blood sample preparation; and paperwork and packaging to transfer samples via courier for refrigerated or dry ice delivery to the laboratory after the visit. Data can be entered directly on to electronic Case Report Form (eCRF), or alternatively, paper CRFs or source documents can be completed and scanned to site for entry with original copies returned by courier later.

Expansion within rural Australia

Expansion of mobile research nursing within rural Australia is limited due to the current number of experienced research nurses available in rural areas. In other countries, Illingworth has identified local experienced nurses with a desire to move into clinical trials and provided key training including accompanied off-site visits with experienced mobile research nurses, GCP, study documentation, patient safety assessments, issue management, and IMP chain of custody etc.

Illingworth are working with ARCs and others to explore the possibility of setting this up in Australia to service participants living in remote areas.

This is beneficial on many fronts, with motivated local nurses gaining otherwise out of reach experience and most importantly, a wider distribution of research nurses available to perform mobile visits to patients who otherwise wouldn't have access to clinical trials.

Summary

Australian clinical trials suffering from poor recruitment and retention. Many rural and regional populations are isolated from potentially life-saving treatment through clinical trial participation. There is quite clearly much more that could be done to help to resolve both issues.

Even without a large network of research nurses based in rural areas, having mobile research nurses travel from major cities enables expansion of the current geographical area from which patients are selected and recruited.

Rather than put unnecessary financial or physical burden on patients who may be young, old or incapacitated through their illness why not adopt innovative solutions outside of the 'normal' clinical trial mindset?

We need to take the trial to the patient.

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If you are a registered nurse and interested in joining our mobile research nurse group, please contact Juliet Hulse, Director of Research Nursing at juliet.hulse@illingworthresearch.com to register your interest and for more information.

The Australian TELE-TRIAL MODEL

Access to clinical trials closer to home using tele-health

Co-authors of the Australasian Tele-trial Model:

Professor Sabe Sabesan, Professor John Zalcberg, Professor Ian Olver, Associate Professor Eva Segelov, Professor Tim Price, Dr Craig Underhill, Professor Stephen Ackland, Professor Ian Davis, Dr Rob Zielinksi, Ms Rhonda DeSouza, Professor David Goldstein

Background

It is recommended by leading authorities, such as the National Comprehensive Cancer Network (www.nccn.org) and Cancer Research UK,[1] that support for the provision of clinical trials to people diagnosed with cancer is a core component of providing optimal cancer care through specialist cancer centres, hospitals and other treatment facilities. Indeed, in many cases such guidelines recommend participation in clinical trials as the best option for many cancer patients.

However, as with access to specialist care, patients living outside of major metropolitan centres face many barriers in accessing clinical trials. Barriers to participation include the limited availability of trial sites closer to home and the increased cost and inconvenience of travel to major centres where the trials are taking place.[2, 3]

While it may be reasonable to establish clinical trials units in large regional cancer treatment centres, the logistics of maintaining a suitably trained workforce and undertaking the ethical and regulatory responsibilities of clinical trials may be difficult in smaller rural and regional sites with limited resources and low patient numbers.

Tele-oncology models of care have been shown to satisfy many specialist healthcare needs of rural and regional patients in countries with large rural populations.[4] Using tele-oncology models many cancer centres have been able to facilitate the administration of complex chemotherapy in rural and regional areas.[5-7]

The Australasian Tele-trial Model has been developed by the Clinical Oncology Society of Australia (COSA) Regional and Rural Group in consultation with clinical trial sponsors, clinicians, health administrators and regulatory bodies.[8] Utilising tele-health and tele-oncology the model outlines a feasible and effective tele-health strategy to increase access to clinical trials closer to home, while at the same time ensuring the proper conduct of cancer clinical trials. This model also has the potential to connect larger centres even within the same city and improve the rate of recruitment to highly specialised clinical trials, including rare cancer trials.

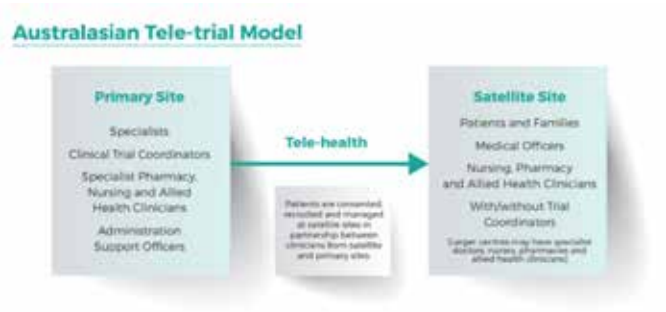
The core principles of the tele-trial model are:

1. To increase accessibility to trials thereby reducing the need for people with cancer to travel to larger centres to attend study related visits and undertake study related procedures. Using tele-oncology models, there is an opportunity for patients from rural or regional sites to be recruited, consented, treated and attend follow-up visits – a hub-and-spoke approach between a primary trial site and a satellite site. The roles and responsibilities for each site need to be clearly defined at the outset of each trial and appropriately contracted (Figure 1).

2. To develop collaboration and networking between regional/rural and metropolitan centres, and between tertiary centres even within the same metropolitan setting, with the aim of delivering greater engagement in research activity, improving adherence to evidence based practice, improving the rate of recruitment of patients into clinical trials, reducing the disparity in cancer outcomes for geographically dispersed populations, building clinical trial capacity, and providing trial-related training.

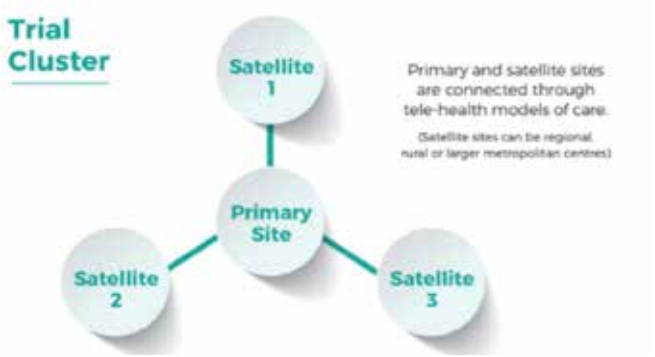
3. To articulate the relationship between the primary site and satellite site as a trial cluster. The trial cluster co-ordinates the trial across multiple sites including a primary site and one or more satellite site(s), ideally through streamlined trial processes (Figure 2). A trial cluster may exist in the following settings: a) larger metropolitan centres as primary sites with other metropolitan centres as satellites even within the same city; b) larger metropolitan centres or large regional centres as primary sites with smaller regional or rural sites as satellites; or c) larger regional centres as primary sites with metropolitan centres as satellites in an attempt to improve the capabilities and community profile of regional centres.

Figure 1: Australasian Tele-trial Model



Adapted from Sabesan S and Zalcberg J. Telehealth models could be extended to conducting clinical trials: A Teletrial approach, European Journal of Cancer Care, in press 2016.

Figure 2: A tele-trial cluster



Implementation of this model nationwide, requires the following:

i) Adoption of the Australasian Tele-Trial Model as part of standard practice by cooperative trial groups, the pharmaceutical industry, researchers, governments, regulatory bodies, hospitals and insurers.

ii) Inclusion of central review processes for site specific authorisations within clusters.

iii) Development of overarching contracts for the Australasian Tele-Trial model between sites within clusters in order to simplify the contract processes at local, state and national levels.

iv) Exploration of the feasibility of adopting remote monitoring systems by sponsors and auditing authorities.

There are clear advantages for Australia to develop a more flexible approach to the conduct of trials given our relatively small population and geographic barriers to recruitment. Recruiting specific patient cohorts is an ever-present challenge and without multi-site collaboration Australia is less attractive to international trial sponsors which limits the availability of experimental, life-saving treatments. Developing these clinical trial networks through models like this tele-trial concept, can better promote our capacity to support a wider range of trials.

The Tele-Trial Project – A pilot implementation of the Australasian Tele-Trial Model

COSA was successful in securing funds from an MTPConnect grant and consortium partners to lead the national implementation of this model in 2017-2019. Consortium partners include Rare Cancers Australia, Cancer Voices Australia, Australian Institute of Tropical Health and Medicine, Garvan Institute, Walter and Eliza Hall Institute of Medical Research, ICON Cancer Care, St John of God Hospital, Medicines Australia and four pharmaceutical companies (AbbVie Pty Ltd, Janssen, Novartis and Pfizer).

The project will further develop the core principles of the model through the selection of suitable trials from cancer trials groups and industry and the establishment of trial clusters in New South Wales, Victoria and Queensland. A number of regional centres across Australia are already in the process of establishing tele-trial procedures or conducting tele-trials and another key aim will be to consolidate these efforts and collaborate on governance arrangements.

For more information about this initiative please contact the Co-chairs of the project Professor Sabe Sabesan Sabe.Sabesan@health.qld.gov.au or Professor John Zalcberg john.zalcberg@monash.edu. Alternatively you can contact the COSA Tele-trial Project Manager Chantal Gebbie Chantal.gebbie@cancer.org.au

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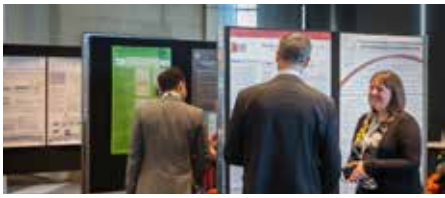
ARCS Annual Conference 2017

Royal Randwick, Sydney

It was great to see so many of you in August. The conference had a real buzz to it and we hope you enjoyed it as much as we did.

Here are some photos of the highlights!


2017 ARCS




Education


Biosimilars naming consultation (closes 8 Sep 17)


Storage, Management & Real-time


guildlink
Medicine Information Solutions

2017 ARCS Awards

Sector Advocate Award

"It would like to express my thanks to both ARCS and MTP Connect for sponsoring these awards. I would also like to thank and acknowledge the fellow members of the R&D Taskforce who have also made significant contributions to reforming the clinical research sector over a number of years."

David Lloyd, Managing Director, Southern Star Research Pty Ltd

"I very much value that this award signals recognition from industry peers and support of my work, as part of the MA/MTAA R&D Taskforce, to continually improve the environment for clinical trials in Australia. I would thank ARCS for creating a Sector Advocate Award and MTPConnect as award sponsor."

Mitch Kirkman, Development QA Manager, IM NCQ, Noravtis

David & Mitchell collect their 'Sector Advocate Award'

Favourite Clinical Trial Sponsor (Pharma/Biotech/Device)

"It is an honour to receive this award and comes as recognition of the fantastic work everyone in the team puts in each and every day. We are focussed on enabling development of our eline by 'Putting the Patients at the Centre of our Work' and 'Being the Sites Preferred Sponsor'. The Australian clinical trials environment is complex, dynamic and challenging, and we look forward to continuing to partner with all in the Australian clinical trial ecosystem in advancing development of new treatments for Australian patients."

David Wilks, Bristol-Myers Squibb

Favourite Investigational Site Award

Suzanne Elliot collects the Favourite Investigational Site for Gallipoli Medical Research Foundation Greenslopes Hospital

Best Exhibition Space Award

"This year marked our twentieth ARCS conference and the first since our rebrand, so PMP had a refreshed image this year. We're delighted that our ARCS network responded so positively to the new look and winning Best Exhibition Space was the perfect end to another great conference."

Dr Glenn Carter, Managing Director, Pharmaceutical & Medical Professionals

Favourite CRO, Consultancy or Partner

"Biotech Regulatory Solutions are very proud to have received the MTPConnect ARCS Award. Thank you to our clients and peers for your support. It has been a great 10 years working together to enable medicines (innovative, generic and biosimilars) and other therapeutic goods to become available to Australian & New Zealand patients. Thank you again to ARCS and MTP Connect for your support of industry."

Katy King, Principal Consultant, Biotech Regulatory Solutions

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Ashleigh Prest, STADA Pharmaceuticals Australia collects her scholarship for the application titled Strategy for the cultivation of talent amongst students and young professionals within ARCS and across STEM specialties .

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ARCS Conference **Dinner**

Game of Thrones themed gala dinner. Thanks for coming - we had a blast!

Transcelerate Overview

By Carlo Maccarrone M.Pharm. PhD, ACF
Asia Pacific Regional Director, Clinical Operations, GSK

In 2012, key leaders from leading biopharmaceutical companies across the globe came together to create TransCelerate BioPharma Inc., a unique nonprofit focused on addressing inefficiencies, and advancing innovation in research and development.

TransCelerate fosters extensive collaboration across global R&D practices – working together with global health authorities, industry groups, research organisations, investigative sites, patient engagement organisations and academia. It is through engagement with all stakeholders, in addition to the expertise and passion of its members, that solutions are identified, shaped, and delivered to the industry. TransCelerate currently has 19 member companies [refer infographic].

To best achieve its vision of accelerating and enhancing the research and development of innovative new therapies, TransCelerate has identified five strategic priorities for its clinical portfolio:

- Improve the Site Investigator Experience as they work with sponsors to execute clinical trials
- Facilitate the sharing of clinical trial related information as appropriate amongst industry stakeholders
- Enable the industry to move toward greater harmonisation of clinical trial processes
- Through collaboration, enhance sponsor efficiencies to reduce investigator and Patient burden, delivering innovative drugs to patients faster and safely
- Improve the patient experience by decreasing patient burden, enabling a better-informed patient and improving clinical research awareness, study participation and engagement

TransCelerate currently has 19 initiatives within its clinical portfolio, aligned to these strategic priorities:

Improve the Site Investigator Experience

- **Investigator Registry:** In collaboration with DrugDev, this initiative is working to streamline clinical trial processes by allowing TransCelerate Member Companies to pool business and contact data from consenting investigators together into a centralised, cloud-based resource.
- **The Shared Investigator Platform:** To address the administrative burdens faced by clinical trial sites, and revolutionise the relationship between Sponsors and Investigators, TransCelerate and multiple technology partners undertook the Shared Investigator Platform initiative. The platform is now available for participating sponsors and investigator sites to conduct studies through an innovative, cloud-based solution.
- **Site Qualification and Training:** This initiative has created model tools and forms that reduce the time Site staff spends on clinical trial site qualification and training, and therefore allow for more focus on protocol-related work.

Facilitate the Sharing of Information and Enable Harmonisation of Clinical Trial Processes

- **Clinical Data Standards:** In collaboration with CDISC (Clinical Data Interchange Standards Consortium) and many other industry organisations, this initiative aims to develop industry-wide data standards in priority therapeutic areas to support the exchange and submission of clinical research and meta-data, while improving patient safety and outcomes.
- **Common Protocol Template:** Increasing complexity in clinical trial protocols makes implementation and reporting difficult for sites, regulators and patients. This initiative is working with industry stakeholders and regulators to create a model clinical trial protocol template containing a common structure and model language.
- **Comparator Network:** Pharmaceutical companies spend millions each year purchasing commercial marketed products for use in clinical studies. TransCelerate's Comparator Network provides an established channel through which participating member companies can reliably and rapidly source quality comparator products from each other for use in clinical trials.
- **Placebo and Standard of Care (PSoC) Data Sharing:** The PSoC initiative has created a platform that enables participating member companies to share placebo and standard of care data. It aims to advance clinical research through improved clinical trial design, faster clinical trial execution, a better understanding of disease, and improved study participant experience.

Enhance Sponsor Efficiencies

- **Clinical Data Transparency:** This initiative has published various assets that provide guidance and model approaches for redacting privacy information found in clinical study reports, anonymizing patient level data shared with the broader healthcare community, and preparing and distributing layperson summaries to the general public and study participants.
- **eSource:** Although regulators have urged increased use of eSource for several years, application of the use of electronic sources of data for clinical trials has been slow to be adopted across the industry. This initiative seeks to assist member companies, and ultimately other trial sponsors to influence more efficient data gathering practices to benefit patients, sites and sponsors.
- **Quality Management System:** Currently, there is no industry-wide framework for clinical quality management that aims to address quality and monitor and improve performance in complex clinical development-specific environments. Through partnerships with regulators and other stakeholders, this initiative has aimed to explore ways to improve quality across the industry.
- **Risk-Based Monitoring:** The Risk Based Monitoring (RBM) Initiative was established in 2012 as one of TransCelerate's five initial projects designed to create efficient and effective solutions in the R&D industry. This initiative has developed model guidelines for targeted, risk-based clinical trial monitoring, ultimately aiming to improve data quality and patient safety.

Improve the Patient Experience

- **Clinical Research Access and Information Exchange (CRA&IE):** The CRA&IE initiative seeks to provide a better window into information about clinical research and trial options while also contribute to a more rewarding clinical trial experience via better exchange of information with trial participants.
- **Clinical Research Awareness:** Clinical trial participation is often not considered by patients or their healthcare providers and is driven by, among other factors, a lack of familiarity and general public engagement with clinical research. This initiative seeks to educate the public about clinical research and encourage conversations about clinical trials between patients and their healthcare providers.
- **eConsent:** While the shift to digital technologies is pervasive across multiple industries, the informed consent process for clinical trials has been historically paper-based. This initiative will develop practical guidance on efficient processes and potential multimedia components that are available to sponsors to facilitate broad, voluntary adoption of patient eConsent.
- **eLabels:** The eLabels initiative will help the industry progress on the journey to digitally supported, patient-centric clinical supply chains. The main output is not an eLabeling system, specifications or a standard, but an implementation toolkit to facilitate voluntary, modular adoption of eLabeling and to assist in regulatory engagement.
- **Patient Experience:** This initiative is in the process of developing tools for clinical teams to engage patients in the study design and execution stages of clinical trials and increase the patient centricity of study programmes. These tools will enable greater patient engagement and partnership with sponsors to design and execute clinical protocols that create better patient experiences.
- **Patient Technology:** This initiative strives to address the barriers to the use of patient technologies in clinical trials. It aims to enable and accelerate patient-facing technology in support of an improved patient experience and richer data collection in clinical research.

Following the success of its clinical portfolio, TransCelerate has launched projects within the preclinical and patient safety spaces. In 2015, BioCelerate was launched as a subsidiary of TransCelerate, aimed at making early stage R&D more efficient to create a meaningful difference in drug development. Two pharmacovigilance projects have also been undertaken:

- The Interpretation of Pharmacovigilance Regulations initiative hopes to share expertise to more efficiently and effectively meet the intent of pharmacovigilance requirements
- The Value of Safety Information Data Sources initiative seeks to identify sources of safety information for single high-value valid cases and develop a proposed method for aggregate reporting of lower value cases.

TransCelerate continues to take its collaborative approach to identify, prioritise, design, and facilitate implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines. As the organisation continues to progress on current initiatives, TransCelerate is actively assessing ideas from across the industry aimed at improving the health of people around the world.

For more information around TransCelerate and its initiatives, please visit www.TransCelerateBioPharmaInc.com.

Follow TransCelerate's social media for the latest updates

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TransCelerate BioPharma Inc.

ARCS new members

Member Name	Organisation
Ali Abdelghany	University Of Queensland
Mounie Abraham	ARCS Australia Ltd
Aselle Adaim	Sirtex Medical Limited
Lara Aghajanian	THEMA Consulting
Sana Ahmad	Merck Sharp & Dohme
Naseem Ali	Ppdi
Amasy Alkhateeb	The George Institute
Felicity Allen	GlaxoSmithKline Consumer Healthcare Australia
Terri Allen	Reckitt Benckiser
Jason Amies	ARCS Australia Ltd
Mary Hazel Amper	Medical Developments International Limited
Amelia Andronis	George Clinical
Jonathan Armstrong	Scientia Clinical Research
Stefanie Auf der Mauer	360 Knee Systems
George Azoury	RQSolutions Pty Ltd
Madonna Azzi	Phebra Pty Ltd.
Kaylee Azzopardi	Swisse Wellness
Angelina Balangue	Novartis Pharmaceutical Australia
Renae Beardmore	KPMG
Nikola Belic	NOVOTECH (AUSTRALIA) PTY LIMITED
Bianca Benassi-Evans	CSIRO
Philippa Bendin	Novotech
Caroline Benyamin	Novartis Pharmaceuticals Australia
Fabienne Bereiter	Sanofi
Angela Biggs	Cryosite
Rebecca Blangiardo	Ensign Laboratories Pty Ltd
Jose Manuel Blasco Baselga	Bristol-Myers Squibb
David Bowling	George Clinical
Ian Boyd	Ian Boyd Consulting
Andre Brewty	Rmit University
Jacqui Brown	Norgine
Stephanie Buisson	INC Research
Rosanda Buljubasic	Seqirus Australia
Radhika Butala	Macquarie University
Linda Calabrese	Five Corners Pty Ltd
Marielou Camara	Clinical Network Services
Deirdre Carr	Novartis Pharmaceuticals Australia
Tracy Carthew	Department of Defence/ ADFMIDI
Sarina Caruso	The Hydration Pharmaceuticals Trust
Fernanda Carvalho	Baxter Healthcare
Julie Cassar	Janssen Cilag
Joanne Challinor-Rogers	Dentsply Sirona Pty Ltd
Ron Chan	Phebra Pty Ltd
Ling Shan Chan	MSD Australia
Elaine Chan	Sypharma Pty Ltd
Pauline Chan	Novartis Pharmeceuticals Australia Pty Ltd
Neha Charya	Roche Products Pty Limited
Shruti Chaturvedi	Abbvie Pty Ltd
Lilee Chew	Novotech
Keng Yih Chew	MyLab Patholgy Pty Ltd
Depinder Chhibber	Aspen Pharmacare Australia Pty Ltd
Carlos China	Pfizer Ltd
Swamy Chintapatla	
Suah Choi	Novo Nordisk
Vandana Choudhary	Alexion Pharmaceuticals Australasia Pty Ltd
Cindy Chu	Allergan Australia Pty Ltd
Charissa Clay	INC Research
Sharyn Conners	Datalytics Pty Ltd
Ingrid Cook	Bristol-Myers Squibb
Sara Corcoran	Consultant
Sharmaine Crooks	Australian Imaging

Member Name	Organisation
Rosalie Cull	Tudorrose Consulting Pty Ltd
Diana Cundall	Medical Developments International Limited
Geoffrey Cupit	360 Knee Systems
Silas D'onofrio	Celgene Pty Ltd
Serena Dal Forno	Medlab Clinical
Elizabeth Dale	Elizabeth Dale Consulting
Timothy Darmanto	PharmaCare Labs Pty Ltd
Danica Dawidowicz	Olympus Australia
Leonore de Boer	N/A
Sarah Deacon	Boehringer Ingelheim Pty Ltd
Jane Deane	Seqirus Australia
Jyoti Devara	Willamstown Road Dental Surgery
Carolina Diaz	ARCS Australia Ltd
Vy Do	Olympus Australia
Deborah Donaghy	Boehringer Ingelheim Pty Ltd
Alana Donaldson	Celgene
Sally Doyle	George Clinical
Sheryl Dunlop	Zimmer Pty Ltd
Merricc Edgar-Hughes	Bayer Australia Ltd
Kelly Isabelle Lily Edinburg	ReSQ Clinical Research Pty Ltd
Diah Elhassen	Takeda Pharmaceuticals
Mardi Elkheir	GlaxoSmithKline Australia Pty Ltd
Ahmed Mohamed Fathalla Helal Elsayed	Monash University
John Emmerson	London Agency
Angela Farahbakht	Aspen Pharmacare Australia Pty Ltd
Chris Farley	Design + Industry
Alexandra Farrall	N/A
Nikki Farrar	George Clinical
Wilma Fernandes	Novartis Pharmaceuticals Australia
Gracinda Ferreira	Freelancer_Consultant
Chantal Ferris-Hayes	Celgene Pty Ltd
Olivia Flynn	Alphapharm Pty Ltd
Robert Forbes	Robert Forbes & Associates Pty Ltd
Joanna Forbes	The George Institute For Global Health
Megan Ford	QuintilesIMS
Lara Forgan	University Of Sydney
Jill Forrest	
Michelle Frost	PATH Practice
Alejandra Gallardo-Godoy	AGG
Laurence Garceau	Regulatory Par Excellence
Hannah Garcia	Takeda Pharmaceuticals Australia Pty Ltd
Chantelle Gardiner-Mann	Ipsen
Rebecca Gaudin	Johnson & Johnson
Mariana Gebara-Coghlan	Abbvie Pty Ltd
Natalie Giebel	Medical Developments International
Deborah Gietzel	Wesley Medical Research
Kim Gillies	Medical Device Research Australia Pty Ltd
Hardeep Gim	Know My Health
Maria Gomes	MSD Australia
Ramesh Govindan	Novotech
Rory Graham	Mapi
Nicole Grings Schmidt	Novartis Pharmaceuticals Australia
Rui (Phoebe) Gu	Kingsway Compounding
Dina Guo	Medlab Clinical
Catherine Gwynne	Australian Self-Medication Industry Limited
Michael Haberl	GlaxoSmithKline Consumer Healthcare Australia
Simone Hall	InVentiv Health
Nosheen Hameed	Seqirus Australia
Margaret Hames	Guildlink Pty Ltd
Zoe Harrison	CMAX Clinical Research Pty Ltd
Antonio Hellebuyck	PPD Australia Pty Ltd

Member Name	Organisation
Suji Hettiarachchi	George Clinical Pty Ltd
Caroline Hewson	Ego Pharmaceuticals
Francis Hinds	Servier
Madeline Hintz	Novotech
Su Leen Ho	Icon Clinical Research Pty Ltd
Diane Hodgson	Apotex Pty Ltd
Edwin Hoe	PPD Australia Pty Ltd
Anna Holmes	Alexion Pharmaceuticals Australasia Pty Ltd
Connor Holmes	Atlantis Healthcare
Zachias Hopkins	University of Technology, Sydney
Annelize Howell	Sanofi
Candice Howells	On Q Recruitment
Zoe Hudson	Roche Products Pty Limited
Toby Hunt	Boehringer Ingelheim
Elizabeth Hutchings	Writesource Medical Pty Ltd
KRISTINA ILIEVA	Apotex Pty Ltd
Adriana Ioan	Pfizer Ltd
Fabio Iochpe Wainstein	University of Technology, Sydney
Ramon Ippolito	Surgical Specialties
David Irving	Australian Red Cross Blood Service
Mohammad Islam	Intersect Australia
Dianne Jackson-Matthews	ERA Consulting (Australia) Pty Ltd
Karen James	Inova Pharmaceuticals (Australia) Pty Ltd
Melissa Jarvis	Department Of Health WA
Matylda Jaworski	MED-EL Implant Systems Australasia Pty Ltd
Sanjaykumar Jayaswal	PPD Australia Pty Ltd
Kay Jennings	Bristol Myers Squibb
Angela Johns	Novotech
Menai Johnson	Sanofi
Nicole Johnston	Alcon Laboratories (Aust) Pty Ltd
Sylvie Jonckeau	CSSi
Anne Jones	Acrapack Pty Ltd
Harriet Jones	Janssen Cilag
Fiona Jonker	Icon Cancer Foundation
Ankit Joshi	Bristol Myers Squibb
Karyn Joyner	Sphere
Divya Kalla	Australian Pharmaceutical Manufacturers
Ruchi Kanojia	R&D Policy Pharmacy Pharmaceutical Solutions
Hewitt Kelemwork	Novotech
Ide Kennedy	University Of Sydney
Joanne Kenny	Priceline Pharmacy
Parmiss Keyhani	Bristol Myers Squibb
Ismail Khan	Roche Products Pty Limited
Hong Ngoc Khuu	Peter Kolb Pharmacy Amcal
Anouk Koopman-Daemen	Boehringer Ingelheim
Dora Kosmidis	CSL Behring
Devika Krishnamurthy	Mundipharma
Nikita Kumari	Novotech
Belinda Kwok	Cochlear Limited
William Lam	Pfizer Ltd
Amanda Lam	Astrazeneca
David Lam	Self
Kate Larsen	Medical Developments International
Navinisha Lee	Bristol-Myers Squibb
Marcia Lee	IDT Australia Limited
Hui-Hui Lee	Alexion Pharmaceuticals Australasia Pty Ltd
Leah Levin	Five Corners
Siew Kim Lim	Primo Moraitis Fresh
Jenny Lim	Generic Partners
Lily Ling	Celgene Pty Ltd
Kelly Lipson	Janssen Cilag

Member Name	Organisation
David Lloyd	Southern Star Research
Narelle Loewy	Commercial Eyes
Jenny Loffell	Bristol-Myers Squibb
Anna Lor	Phebra
Sandrien Louwaars	CPR Pharma Services Pty Ltd
Fiona Love	Ihmri
Bertrand Yew Kian Loyeung	University of Technology Sydney
Le Quan (Jenny) Ly	George Clinical
Michelle Major	Parexel
Leila Mapson	Clinical Captured Pty Ltd
Grace Mason	Mylan New Zealand Ltd
Tina Mason	Commercial Eyes
Owen Matheson	Australian Imaging
Aastha Mathur	Vitex Pharmaceuticals
Rod Matthews	Impact Human Performance Technologies
Aujoni Mauro	Sanofi
Diana Maydelman	Celgene Pty Ltd
Andrea McCracken	Seqirus Australia
Mark McGinnis	University Of Sydney
Gabrielle McKee	Clinical Network Services
Sarah McMillan	Hudson Institute of Medical Research
Carole McNally	Merck Serono Australia Pty Ltd
Divya Mehra	Lundbeck Australia Pty Ltd
Eliza Miller	Deakin university
Brenley C Milsom	Advantage Medical Products Consulting Pty Ltd
Candice Monaghan	ARCS Australia Ltd
Julie Monk	CSL Limited
Mudassar Mor	Novotech
Shannon Morrison	PSI CRO Australia Pty Ltd
Lamie Morrison	Bms
Maedeh Najafi	University Of New South Wales
Neelma Narayan	INC Research
Michelle Nash	Emeritus Research
Kishani Navaratnam	Consulate General of Canada
Erum Naz	TGA
John Nguyen	Medartis
Tiffany Nguyen	Specialised Therapeutics Australia Pty Ltd
Thoa Nguyen	Sanofi
Tuan Nguyen	Medlab Clinical
Liza Nguyen	Bristol-Myers Squibb
Joanne Nimmo	St Jude Medical
Connor Nolan	University Of Sydney
Corrin O'Brien	Galderma Australia Pty Ltd
Joanne O'Brien	Prince Of Wales Hospital
Anne O'Shea	O'Shea & Assocs Pharmaceutical Consultants P/L
Sachin Ojha	Ascend Biopharmaceuticals Ltd
Veronika Olajcova	George Clinical
Hui Xin Ong	University Of Sydney
Maxine Orre	Vertex
Jasnel Ortencio	Bristol-Myers Squibb
Julie-Anne Oxford	Uni of the Sunshine Coast Clinical Trials
Anneline Padayachee	Aspen Pharmacare Australia Pty Ltd
Sheona Page	Uni of the Sunshine Coast Clinical Trials
Claire Page	Generic Partners
Trish Palmer	Palmer Health Outcomes Pty Ltd
Adarsha Pandalai	Novartis Pharmaceuticals Australia
Anna Paonne	Guildlink
George Papadopoulos	Emerald Corporate Group Pty Ltd
Kate Pascall	QuintilesIMS
Arti Patel	Novotech Australia
Lynda Paton	Amgen

ARCS new members

Member Name	Organisation
Sarah Payne	Alexion Pharmaceuticals Australasia Pty Ltd
Kristina Pearce	Alexion Pharmaceuticals Australasia Pty Ltd
Montse Pena	Reckitt Benckiser
Michelle Phan	Mundipharma
Karen Philippe	Novartis Pharmaceuticals Australia
Joshua Pike	PPD Australia Pty Ltd
Louise Pirc	Novotech
Patricia Plenge	St Vincent's Hospital
Judith Pottinger	Mylan New Zealand Ltd
Yi Wan Quah	The Walter and Eliza Hall Institute of Medical
Gracia Quek	Roche Products Pty Limited
Daniel Rae	Orthotech Pty Ltd
Madiha Rahman	Mundipharma
Vinay Ram	Inova Pharmaceuticals (Australia) Pty Ltd
Felix Ram	Mylan New Zealand Ltd
Leena Ramani	Sandoz Pty Ltd
Priyanka Ranjan	AMP
Mehdi Rasoli Pirozyan	University Of New South Wales
Yameena Ratnayake	Generic Health Pty Ltd
Kate Pascall	Celgene Pty Ltd
Ma. Christina Rivera	PPD Australia Pty Ltd
Helen Rodgers	Sunshine Coast Hospital & Health Service
Tami Rose	Roche Products Pty Limited
Natalie Ruffles	SFI Research Pty Ltd
Bret Ryder	Indivior
Brooke Ryder-Smith	Roche Products Pty Limited
Qatan Sagaale	Telethon Kids Institute
Yael Sagi	Roche Products Pty Limited
Abil Saj	Genome Institute Of Singapore
Shweta Sakode	GlaxoSmithKline Australia Pty Ltd
Ramez Salib	N/A
Natalie Saltalamacchia	Novotech (Australia) Pty Ltd
Kylie Sandy-Hodgetts	Curtin University
Saima Sazzad	Medical Developments International
Rebecca Schnabel	Allergan Australia Pty Ltd
Evelyn Shankaran	Guildlink Pty Ltd
Derek Siegers	Merck Sharp & Dohme
Clive Simon	The SPD Company Pty Ltd
Shirley Sin	Abbvie Pty Ltd
Hannah Sinclair	CTI Clinical Trial and Consulting Services
Ursheila Singh	GlaxoSmithKline Consumer Healthcare Australia
Romit Singh	Macquarie University
Vineet Singh	Apotex
Sara Sjoquist	George Clinical
Catie Smith	NIIT
David Smith	Sirtex Medical Limited
Aisling Smyth	Inova Pharmaceuticals (Australia) Pty Ltd
Mushtaq Sobhan	On Q Recruitment Pty Ltd
Jaya Soma	Servier
Shari Stathis	Astrazeneca
Jennifer Steinmetz	Janssen Cilag
Marina Steplyuk	Novartis
Darryn Steyn	Collective Care
Jelena Stoimenovski	CS Executive Group inc. ChemSkill
Robert Stringer	Capital K Consulting
Noor Hidayatul Aini Suaini	Murdoch Children's Research Instiute, Univer-
Vaishali Subbaraman	Roche Products Pty Limited
Gabrielle Sunarko	N/A
Vera Surakova	Parexel
Abani Surendran	University of Technology Sydney

Member Name	Organisation
David Sylvester	The Medicines Company
Julia Szczepanski	Abbvie Pty Ltd
Sam Szczepanski	Sanofi
Stephanie Tan	Royal North Shore Hospital , Renal Research
Daniel Tan	St. Jude Medical Australia Pty Ltd
Ei-Ling Tan	The Clinical Trial Company, ANZ
Guy Tancock	Servier
Michael Tapner	Sirtex Medical Limited
Kanchan Tate	Community Pharmacy
Michele Thai	Aspen Pharmacare Australia Pty Ltd
Han Sui The	Galderma Australia Pty Ltd
Audrey Thomson	Biotron Limited
Vivian Tiong	N/A
Vivien Tong	The University Of Sydney
Angela Tong	Novartis Pharmaceuticals Australia Pty Ltd
Helen Toy	AstraZeneca Pty Limited
Rebecca Tronnberg	Novartis
Heidi Tsang	Royal North Shore Hospital
Nhat Tu	Sanofi
Julie Tu	Apotex
Rowena Tucker	Children's Medical Research Institute
Graeme Tucker	Lighthouse Institutional Review Centre - Trad-
Sandy Tuckwell	OnQ Recruitment
Michele Tychsen	(None)
Diana Ubiparipovic	SFI Research
Sharmila Uthayakumar	Bristol Myers-Squibb
Michael Valente	Mylan Australia
Daniela VanVuuren	Novartis Pharmaceuticals Australia
Alexandra Varanaki	Seqirus
John Varigos	Mediclin Pty Ltd
Cathryn Vaux	GlaxoSmithKline Australia Pty Ltd
Theresa Wade	Writesource Medical Pty Ltd
Daria Wain	Pharma To Market Pty Ltd
Judith Walker	Clinipace Worldwide
Tiffany Walker	University Of Sydney
Monica Walsh	Novotech
Emma Warren	Hera Consulting
Roshi Weeratunge	Servier
Penny West	Sacred Heart Supportive and Palliative care
Joanne White	Novotech
Elizabeth White	N/A
Cameron White	INC Research
Vicki Willacy	INCResearch/inVentivHealth
Kelley Wilson	Gilead Sciences Pty Ltd
Tony Wilson-Williams	Mylan Health Pty Ltd
Sze Sze Wong	Bayer Australia Ltd
Annie Wong	Medsurge Healthcare Pty Ltd
Angela Wong	Seqirus Australia
Andy Xie	George Clinical
Prabhakar Yadav	INC Research/inVentiv Health
Dilruba Yasmeen	Yasmeen & Associates Pty ltd
Jing Ye	Guildlink Pty Ltd
Paul Young	University Of Sydney
Hsiu-Chun (Tony) Yuan	Eli Lilly Australia
Carol Yuan	Sypharma Pty Ltd
Tara Zammit	George Clinical
Xiaoyi Zeng	N/A
Tia Zhuo	Unemployed
Raha Zolghadri	OnQ Recruitment
Eliza Zychska	Abbott Australasia Pty Ltd

Meet the Members

George Kalatzis

I'm a gregarious, uncannily talkative postgraduate science student currently conducting doctoral studies in the Neuroscience Research Unit at the University of Technology, Sydney (UTS). Prior to embarking on my PhD, I completed two undergraduate degrees: Bachelor of Medical Science and Bachelor of Medical Science (Honours). In a nutshell, my PhD research seeks to explore cognitive function, better known colloquially as brain function, in diabetes mellitus and hypertension using simple and non-invasive cognitive measures. Both these chronic conditions have been implicated with accelerating conversion to Alzheimer's disease, and so the importance of such research in light of increasingly unsettling trends of growing incidences in neurodegenerative diseases cannot be stressed enough.

A few short weeks ago I received an email from ARCS, who were searching for volunteers to volunteer at a major pharmaceutical conference being held in Sydney. It was here that my journey with ARCS commenced. Uniting major pharmaceutical companies and key opinion leaders from multiple areas of the industry, the three-day conference spotlighted the highly dynamic nature of the pharmaceutical landscape, critical changes in clinical trial drug development, and, of importance, the tectonic influence technology has played in improving patient health therapeutic outcomes in clinical settings. Recognising the vast opportunities and the smorgasbord of career positions available in the ever-changing pharmaceutical industry, I hastily registered to become an ARCS member to broaden my outlook on the pharmaceutical landscape and deepen my understanding of the mechanics of the industry. And becoming an ARCS member simplified everything.

As with most enjoyable activities study must one day come to an end, and one lingering question repeatedly raised that looms over the shoulders of every PhD student- and every university student regardless of their level of study- is the career path one intends on pursuing following study completion. Attending the ARCS conference considerably changed my outlook on the direction I'd like to pursue in future, and so in 5 years time I would like to pursue a career as a Medical Science Liaison (MSL). From communicating advances in pharmacological therapies and drug development professionally to scholarly audiences, to liaising with key opinion leaders in particular fields, the challenging and communicable nature of the role appeals to me appreciably. Requiring a doctoral degree as a minimum requirement, the nature of the role furthermore means I can draw upon all the knowledge and key graduate skills developed during both my undergraduate and postgraduate studies.

Megan Truong

I am currently doing a PhD in drug discovery investigating new antimicrobial alternatives for cryptococcal meningitis – a particularly fatal disease in the HIV/AIDS community. On the side, I work for the faculty of science at UTS and am a teaching associate for undergraduate microbiology and pharmacology subjects.

I came to know ARCS simply because there was an opportunity to volunteer at their Annual Conference this year. During that experience, I was able to meet and network with many people with varying backgrounds and expertise. Coincidently enough, I was really lucky to re-connect with professionals I met at a previous conference! I thoroughly enjoyed getting to know every individual I met, learning about what they do, how they got there and if they had any advice they could impart. This was a great eye-opener for me about what options are there post-PhD, other than academia. Apart from what I might want to do for a long-term career, this experience and exposure got me thinking about the community I was to be a part of, the people I want to work with, and most importantly, what kind of difference do I want to make in this world. These subsequently triggered more questions like, how I can make the most of my best skillsets, to get where I want to be.

Hopefully, these questions will be figured out and unfolded into a strong career in five years time, whatever that may be. At this stage I am unsure – but I can guarantee that my PhD will definitely be done, it'll be medical/science/pharmaceutical-based career, involving lots of people/patient interactions and it will be challenging but nonetheless fun. It's going to be big and it's going to be exciting!

George & Megan with Liga Hegner

2018 ARCS

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ARCS Head Office

Suite 802, 28 Clarke Street, Crows Nest NSW 2065

Phone: 02 8905 0829

Email: arcs@arcs.com.au

Web: www.arcs.com.au