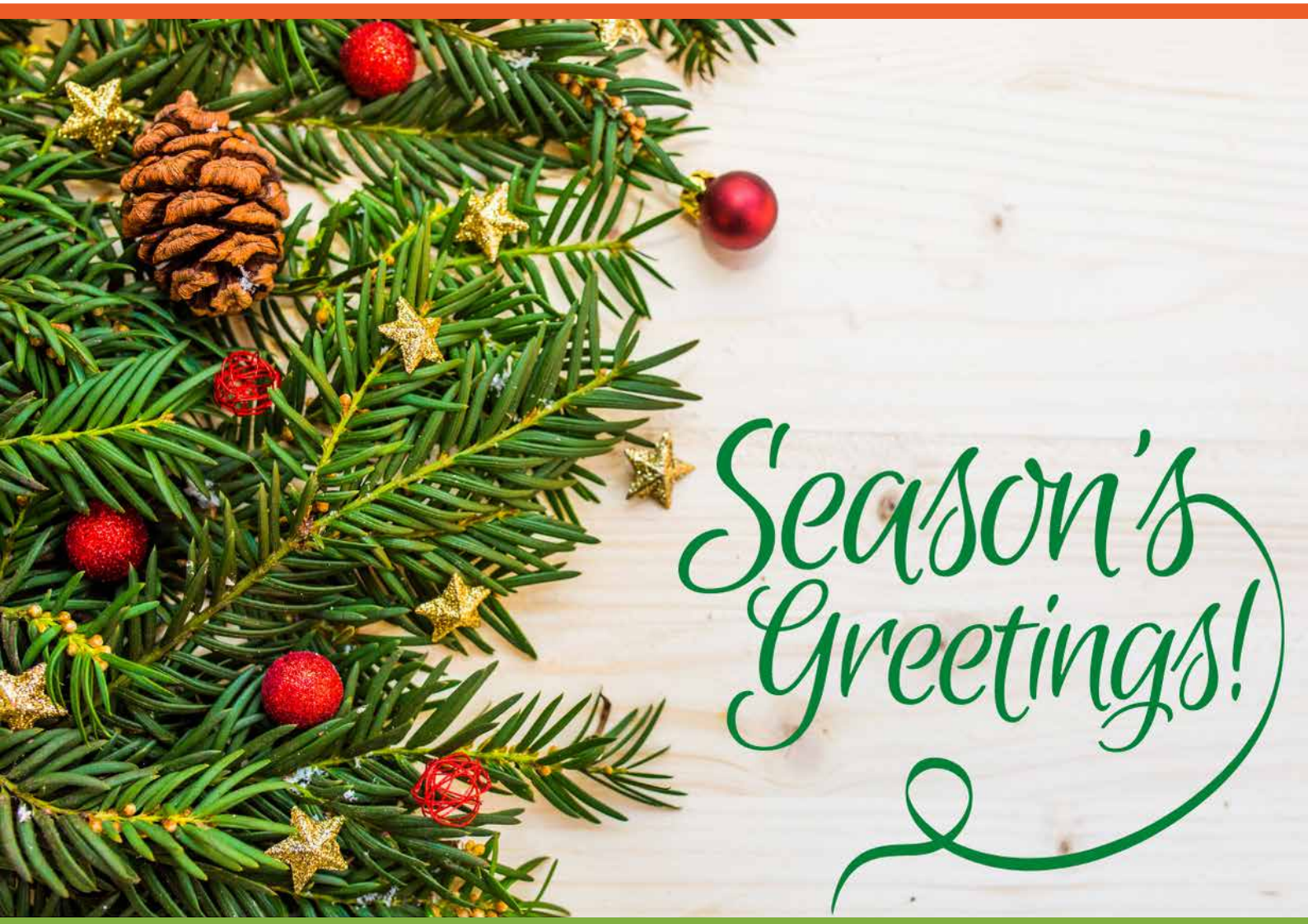
AN ARCS AUSTRALIA LTD PUBLICATION FOR MEDTECH, BIOTECH AND PHARMACEUTICAL SECTOR PROFESSIONALS

COGNITIO



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ARCS AUSTRALIA®

SUMMER 2020 ISSUE NUMBER 42 ISSN 2208 -1607

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ARCS AUSTRALIA®

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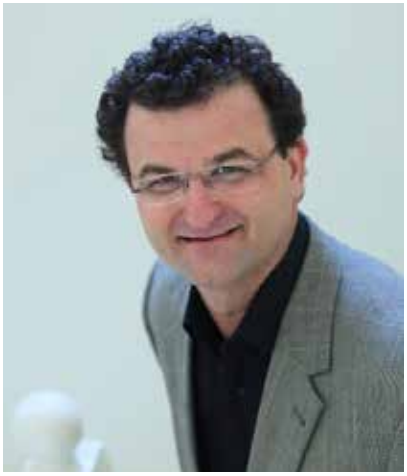

Welcome to the Summer edition of Cognitio, the last edition for 2020 and the last ARCS Presidents' Reports for myself. This year has brought unprecedented disruption and great changes to our personal and work lives. We all have had to adapt in one way or another to what is referred to as the 'new normal'. Those who could, started working from home and those who couldn't, faced an especially stressful situation. The health and medical sector was not immune. Australia has come through the year in a better shape than most other countries throughout the World but we seem to be paying a price for that success, with economic decline, increased debt due to stimulus and support programs and an increase in mental health related issues. These are all things that will take years to overcome.

However, there is hope to return to our 'old normal' with the news of potentially vaccine candidates and their clinical trial results. Hopefully 2021 will be a year of new beginnings, where we will keep the lessons learnt from this year to move forward.

This is my last Presidents' Report and I would like to reflect on my past 5 years as an ARCS Board member and President before I hand the reigns to the new President, Andrew Carter (Commercial Eyes), Allowing me some latitude, the ARCS Board has successfully navigated the appointment and re-appointment of our CEO, Shanny Dyer who has delivered on the shared vision and strategy over the years. ARCS financial position has remained strong under challenging circumstances over the years, whilst delivering high quality educational materials and training for our members. The very successful Annual Conference became a stand-out event on the healthcare calendar, and we hope to return with that success at the ICC in the coming years. And lastly, during the past year the Board has worked tirelessly to navigate the Association through the extraordinary circumstances brought upon our sector by the COVID-19 pandemic to maximise all available financial assistance options and managed ARCS's assets and operations.

I'd like to thank the present and past Board members that I had the pleasure of being associated with, the ACRS CEO and the ARCS team for their support during my tenure as Board Director and President. But most of all I'd like to thank you, the ARCS members, for your trust in electing me and your continued support of the association.

The new board will bring new initiatives, strategies and ideas to develop the sector further, and I look forward to hearing about these as an ARCS member!

I wish everyone a wonderful festive season and a happy, healthy and prosperous 2021!

George Papadopoulos , Past President, ARCS Australia

Members may contact the ARCS Board directly at board@arcs.com.au at any time.

President's Report

As the newly appointed President of ARCS Australia, I want to use my first contribution to *Cognitio* to highlight the impact of our retiring directors, to welcome three new directors to the Board and to outline to members some of the outcomes of our November 2020 Board meeting.

Firstly, I want to acknowledge the significant contribution that George Papadopoulos (President), Alex Leung (Company Secretary and Committee Chair) and Elizabeth Joshi (Committee Chair) have made to the ARCS organisation over the past five years.

The role of director is a big commitment and requires the investment of time, skills, and experience. George, Alex and Liz have been highly engaged and effective directors and made a significant and lasting contribution. In addition to their director responsibilities, each took on board leadership roles and participated in a broad range of ARCS activities. Their dedication and passion for ARCS is noteworthy and on behalf of my fellow directors and all members, I say a big 'thank you' to each of them for their service.

This year, eight members nominated to fill three director vacancies. Receiving this number of nominees is a strong indicator of the willingness of members to contribute to the governance and leadership of ARCS Australia. This is highly commendable, and I thank each nominee for putting up their hand up to be involved. I would also like to thank the ARCS members who participated in the voting process. Voting is an essential member contribution to the ARCS governance process.

Each of our new directors brings a strong blend of skills and experience that together with the current directors, forms a very capable and diverse board. To Adele, Arthur and Orin, congratulations on being elected as directors, ARCS will benefit from your involvement.

The board met on 26 November and made several significant decisions. The Board endorsed the continuation of the Governance Committee (Chaired by Robert Kent, Vice President), the Finance Risk and Audit Committee (Chaired by Arthur Brandwood) and established a new committee focused on Strategic Initiatives (Chaired by Marisa Peterson). The Board also agreed to expand Shanny Dyer's role to include Company Secretary responsibilities and worked through a revised budget that considers the business uncertainty and organisational challenges brought about by the wide ranging COVID19 restrictions across Australia's states and territories.

2020 has been tough for all types of businesses and professional membership organisations have been hit hard. That said, through the leadership of our CEO, the ARCS team has taken these challenges in their stride. The team have introduced and are mastering new technology and are delivering programs, workshops, and connecting our members at major events in innovative and contemporary ways.

I want members to know that the Board is aspirational and focused on driving both membership and organisational growth. Much of what we have learnt this calendar year will form the foundation of how we engage with a much bigger and increasingly diverse membership in the future.

Importantly, a professional membership organisation needs to be proactive, to regularly engage with members and respond to member's needs in a timely way. We also need to create and tailor membership services to meet a wide range of professional development needs.

Lastly, ARCS Australia will continue to be a strong voice for its members. Ensuring that the essential work our members do is acknowledged and supported by industry, government, and the broader community. To enable this, we need to challenge convention and our current business model needs to evolve. To enable this, the Board has committed to a major review of the ARCS Australia objectives and strategy in the first quarter of 2021.

Please enjoy this edition of the eJournal *Cognitio* and I encourage you to connect with me and the Board with your suggestions and comments at board@arcs.com.au.

Andrew Carter President, ARCS Australia

CEO's Report

This is the last edition of the journal for 2020 – a year we will not forget – but one we need to learn from and innovate.

Everyone of us has been touched by COVID. At the time of writing, we have 3 strong vaccine candidates developed by companies in our sector. Australia has signed agreements with the manufacturers of these vaccines to ensure access for Australians. It is also pleasing to see that Australia has an important stake in the development of a vaccine candidate with a binding Heads of Terms between the Australian Government and CSL/Seqirus for the University of Queensland vaccine candidate. The Government[1] has now entered a final supply agreement with CSL/Seqirus around the supply of 51 million doses of the University of Queensland (UQ)-CSL COVID-19 vaccine candidate, including key terms to support clinical and technical development activities for the vaccine candidate. Phase IIb/III trials of the UQ vaccine candidate are scheduled to start in early December 2020 in numerous countries and over more than 100 sites. The study will evaluate efficacy, immunogenicity and safety in adults aged 18 years and above.

This shows the strength of our medical research in Australia. These successes are despite the very real challenges we all face due to commercialisation of our research. The discovery phase is rich with outcomes that don't get translated to market ready products. Australia could be more successful if it embraced a national approach to all aspects of research and development because simply, Australia is too small an ecosystem to have the diversity, skills, knowledge and experience to do it alone. We would be far more effective if we worked together as a nation.

However, we are still, to this day, victims of our federated system of government that enables each jurisdiction to drive its own course when a national approach to trials and best practice in our health system would have made us a force to be reckoned with. The patient is waiting!

Individually, our people- our skilled and dedicated workforce, knuckled down and worked incredibly hard to work through the system to get COVID treatments and vaccine trials underway as well as, importantly, keeping those life-saving trials open for those who needed them. A big thank you to all involved in this process. But as we have seen reported in the media[2], we have let Australia down by a lack of national leadership and a desire for each research centre to obtain funding for COVID related studies, with little or no co-ordination to ensure the value of the studies would contribute to the body of knowledge – in short, the current system encourages researchers to work in silos in an inefficient and wasteful (and potentially unethical) manner. This was a short-sighted approach enabled by a lack of national leadership. The patient is waiting!

If there is one thing to learn from this pandemic it is that we need a national clinical trial strategy. A strategy that would still encourage competition but ensure that our precious public funding is spend wisely and that patient's rights are respected.

As an outcome of the ARCS Summit in October we have called for the formation of a working group to develop the principles of a national approach and build a sustainable and economically viable approach to clinical trials. It is a long time coming but there should be no excuse – we have seen the ramifications of its absence. The patient is waiting!

And while I am on the case, let's also talk about manufacturing. Having come from a GMP manufacturing background, I really think we need to support innovators who could build capacity and capability in Australia – if they were appropriately supported. There are a number of very successful contract manufacturing facilities in Australia however they are niche and relatively small. Facilities such as CSL are successful as they have government guarantee agreements in place and co-funding agreements to build new facilities.[3] As we now can see, having these capabilities and reserve capacity is essential for national security. The government wouldn't think of allowing the Australian Defence Force to fail because they are not commercially viable. But we know that the biggest threat to our people and our economy most recently has been disease not war.

MTPConnect's interim workforce report[4] has also highlighted the shortage of skilled people in GMP manufacturing and clinical trial design. However, where is the depth in GMP manufacturing that will support these trained people?

We will have interesting times ahead.

If I don't get another chance, I hope you all get a good break from work and ensure you recharge your batteries for 2021.

Shanny Dyer and the ARCS Team

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Clinical Trials Review
ARCS Virtual Summit Oct 2020

Over 1,000 attendees were treated to an outstanding review of the current clinical trials landscape by sector and government leaders, who also provided an inspiring update on imminent plans to address regulatory and jurisdictional hurdles that have constrained the sector for decades.

Dr Aliprandi-Costa, Manager, the Australian Commission on Safety and Quality in Health Care (ACSQH) discussed the National Clinical Trials Governance Framework, initiated with the objective of developing a national approach to the accreditation of health services for the conduct of clinical trials. The September 2020 pilot governance framework program includes input from 14 sites and 30 health services organisations and will report its findings in March 2021.

It is envisaged that a new, strategic and holistic approach to the conduct of clinical trials will address important issues, such as universal systems and infrastructure, policies and processes, incident and risk management, workforce safety, quality and training. Measurable operating efficiencies will be regularly reported via a web portal that will enable end-users to continue to meet accreditation standards. The beneficiaries from national clinical trial accreditation standards will be patients, consumers, clinical trial staff and all other stakeholders, ultimately leading to improving health outcomes for all.

Since February, the impact of COVID-19 has been acutely felt by all healthcare sector workers. However, the pandemic has been the catalyst for overdue change in the clinical trials arena. Experts provided an update on National Projects to Improve the Clinical Trial Landscape. Dr Allyson Essex highlighted the importance of clinical trials to the federal government, indicated by the inception of National Cabinet in March 2020. It aims to ensure national consistency by working closely with state and territory jurisdictions to overcome historic governance and access problems, which to date have slowed the pace of clinical trials, which is costly and inefficient.

The re-vitalisation of clinical trials, including streamlining of processes, implementation of digital strategies, including tele-trials, and cross-jurisdictional working groups is extremely welcome. Addressing a national electronic clinical trial registration system to replace the current state-based systems, such as Regis, ERM will take time. However, key stakeholders and decision-makers are acutely aware of the urgency required to address legacy issues that constrain clinical trial progress.

During the Summit, we witnessed clear demonstrations of leadership from key senior executives from federal and state governments, affiliated organisations and industry who are all committed to positioning Australia as a leading destination for clinical trials.

Promotion of collaboration and commercialisation, with access to global supply chains, ensuring fit-for-purpose management and workforces will underpin our global competitiveness. Aligning funding and knowledge are priorities. Australia's proactivity in researching a COVID-19 vaccine is an example of our ability to respond promptly while preserving research integrity.

The ARCS Criteria Program, COSA tele-trials, QUT Adaptive Clinical, Digital Health CRC's Clinical Data and Analytics Platform (CDAP), CT:IQ's e-consent and enhancing clinical trial recruitment projects are just some examples of projects that highlight the benefits of collaboration.

In addition, during June ARCS worked with 14 CROs to develop the CRO Position Statement. The paper highlighted that the COVID-19 pandemic will stimulate transformational disruption, and appropriate adaptation by the clinical trials sector is needed to ensure the successful management of clinical trials during the pandemic and beyond. It was agreed that a national approach to the harmonisation of clinical trial activities must be embedded in the future to ensure Australia remains open for business.

To address an important career development gap, the ARCS Signature Course is currently under development, which will provide a customised leadership program for aspiring health sector leaders. We heard from several sector leaders who highlighted the importance of:

- critical thinking skills
- embracing technological change
- personal leadership training
- looking after self
- empathy
- curiosity
- taking an enterprise wide view
- building networks
- dealing with crises and change
- influencing for positive outcomes
- problem solving skills
- taking measured risks.

ARCS is collaborating with numerous key opinion leaders and senior executives to devise a highly regarded, customised program that will be available to aspiring health sector leaders. We will keep our members advised of important milestones in due course.

Over the week it was very clear that the clinical trial sector is replete with innovative and passionate professionals. Despite its many obvious negative effects, the pandemic has catalysed the clinical trials sector for positive change. We can look forward to the ongoing development of new technologies, practices, organisational and cultural changes for the benefit of those working within the sector and society in general.

Phillipa Lee
COO, ARCS

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Right Data at the Right Time

Real world evidence in market access for cell and gene therapies and governance

Australian paediatric patients with acute lymphoblastic leukaemia became the first to be treated with an approved CAR-T cell therapy, Kymriah, earlier in 2020, and a second, Yescarta was also recommended for listing. This year also saw the first gene therapies, Luxturna, for inherited eye disesase, and Zolgensma for spinal muscular atrophy considered by the PBAC. There is a strong pipeline of cell and gene therapies, which focuses on haematological cancers (leukaemia, lymphoma, myeloma), solid tumours and rare inherited conditions.[1]

Cell and gene therapies have been widely publicised as potential cures for previously incurable or untreatable conditions. If proven, these benefits may justify the hefty price tags of up to $2 million USD that have been reported. Clinical trial designs for cell and gene therapies are typically subject to uncertainties, however, due to small patient populations, single arm trials and limited follow-up, which create challenges in demonstrating their effectiveness at the time reimbursement is sought.

Enter real world evidence (RWE). Internationally, health technology assessment (HTA) agencies are updating methods and investing in data infrastructure to meet the upcoming challenges of novel technologies.

RWE is accepted by the PBAC and MSAC and occupies three main roles in the HTA process:

1. Characterising the patient population

- Registry data may be used to estimate patient numbers and characteristics, including the often complex eligibility criteria for cell and gene therapies (genotype, severity of condition)
- Patient surveys, including collection of PROMs (patient-reported outcomes measures) and PREMs (patient-reported experience measures) assist in understanding the patient experience, disease burden, adequacy of existing treatment options and the impact of the condition on daily life.

2. Contextualising trial results in Australian clinical practice

- Studies using real world data (RWD) from healthcare service datasets and medical records may assist in understanding the patient pathway and standard of care in Australia – these should be informed and validated by expert Australian clinicians
- "External comparators" are emerging in some clinical trials and have been used to support conditional approvals by the FDA – for example, based on the medical records of a matched cohort, although such approaches are not yet in common practice.

3. Post-marketing efficacy, safety and potential follow-up care

- PBAC or MSAC may recommend a therapy, conditional upon the collection of patient outcome data, with reassessment after a set time period (two years for Kymriah and Yescarta)
- Managed entry, or risk-sharing, agreements enable the risk associated with uncertainties in the clinical data to be shared between the payer (government) and manufacturer while additional evidence is generated.

Australia has rich healthcare data

Australia's RWD sources include hospital administrative datasets, which are aggregated by the Australian Institute of Health and Welfare, Medicare, private health insurance claims and patient registries. Linked data, to provide a full picture of resource utilisation, is not routinely available and, where possible, requires substantial resources and costs.

Australian patient registries have expanded in recent years, and now encompass many of the genetic conditions that may be treated with gene therapies in the future. Registries are an important RWD source, as the ICD-10 coding used to report diagnoses in hospitals is not granular enough to describe eligible patients for cell and gene therapies.

In addition to the Bone Marrow Transplant Recipient Registry being used to collect post-marketing data for Kymriah, these include the Australian Bleeding Disorders Registry (haemophilia), Haemoglobinopathy Registry (beta-thalassaemia and sickle cell disease), Australian Inherited Retinal Disease Registry and DNA Bank, the Immunodeficiency Disease Registry and national registries for Duchenne muscular dystrophy and spinal muscular atrophy.

My Health Record also holds potential for streamlining future post-marketing studies, a use that is permitted in the Framework to guide secondary use of My Health Record data. This is a relatively new source that has not yet been widely utilised to support reimbursement applications.

NICE is reviewing its Methods to better manage uncertainty and utilise RWE for innovative technologies

NICE, England's HTA agency, is currently conducting a comprehensive Methods Review, with the consultation period closing on 18 December 2020. The preamble to the consultation document states that the methods should be "flexible, agile and robust, to support rapid patient access to clinically and cost-effective health technologies in the ever-changing health and care landscapes. They must be evidence based and future proof." [2]

NICE will consult on proposals to provide committees with flexibility to accept greater uncertainty and risk in appraising innovative therapies and to more clearly define the circumstances in which RWE may be most valuable. While the uses for RWE are not new (and broadly align to those outlined above), many will welcome more detailed guidance on how the quality of RWE will be assessed and incorporated into reimbursement decisions.

CanREValue is a pan-Canadian collaboration to incorporate RWE into cancer drug funding decisions

CanREValue brings together researchers, HTA agencies, payers, patients and caregivers to develop a nationally consistent and integrated approach to developing RWE. Like Australia, Canada's healthcare system has devolved authorities to provinces, which can lead to inconsistencies in data collection.

This collaboration aims to establish a framework for RWE generation that draws on existing administrative health databases, such as cancer registries, hospital records and insurance claims. RWE generated through the framework will be used to conduct post-marketing reassessments, providing greater flexibility in reimbursement, including potential innovative funding mechanisms.[3]

Making progress on RWE in Australia

HTA agencies in Australia and internationally stress the importance of high quality and transparent RWE sources. RWE is a supplement to randomised controlled trial data for good reasons. Lack of randomisation means there is potential for bias, which must be acknowledged – we must be clear about what the study can tell us and what it can't.

In planning a strategy for reimbursement, high quality RWE studies require careful planning and execution:

1. Research questions should be clear, focused and add to the clinical data from the perspective of decision makers – look at analogue decisions and seek early advice where possible
2. Engage stakeholders, including patient advocacy groups and clinicians, and establish appropriate governance to ensure expectations are met and the study runs smoothly
3. Be pragmatic about the data that can be collected within an appropriate timeframe – focus on the right data at the right time.

Australia has rich healthcare data, which is underutilised in reimbursement decisions today. Internationally, greater value is being placed on the role of RWE to support reimbursement for novel technologies. As the NICE Methods Review consultation progresses over 2021, so will our own consultation process on the Parliamentary Inquiry into approval processes for new drugs and novel medical technologies, and the subsequent National Medicines Policy review. RWE must be firmly on the agenda.

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Katrina Lapham
Biointelect

The Future of Clinical Trials in a Post-COVID world

COVID-19 has turned the world upside down; it would be hard to convince our former selves how much the world would fundamentally shift just one year ago. As expected, the healthcare industry has borne the brunt of this pandemic with overwhelming patient numbers and limited resources putting almost insurmountable pressure of the industry. This impact has also hit clinical trials, causing increasing concerns across the industry.

Countries all around the world including Australia, note a variety of impacts on clinical trials including difficulty recruiting and enrolling patients, increasing costs of personal protective equipment and patients access to testing sites.

With the redirection of resources and temporary halting of in-person visits, studies in other therapeutic areas have been unavoidably constrained. The Australian Cancer Council reports that there has been a 30 to 50 percent decline in the number of patients entering into cancer tests and operations during the pandemic.

From March through to May 2020, elective procedures and in-person patient visits were halted to reduce the risk of viral transmission, medical staff were directed to conserve personal protective equipment (PPE) and more health-care workers were asked to be available for the enormous clinical impact of COVID-19.

In fact, according to Medidata's research, enrolling and recruiting new patients is the highest impact on trials as a result of COVID-19, with almost 40 percent of trial organisations halting patient recruitment for ongoing trials.

Nevertheless, the responses to the pandemic have also introduced innovations that will advance the conduct of clinical research. And the positive sentiment is reflected in the outlook of those within the industry. Medidata's research shows that almost 60 percent of trial investigators are feeling optimistic about the future of testing.

Australia leads the way

According to the Health Minister, Greg Hunt, Australia's handling of the pandemic has put the country in a prime position to become a leader in future medical research and clinical trials, bringing not only new medicines but new jobs to the country.

In comparison with the rest of the world, Australia is considered to be a successful example of well controlled COVID-19 response. Now that the country is opening up internal borders and is even looking to create a travel 'bubble' with countries such as Japan and New Zealand, there are new possibilities for the healthcare industry.

This success positions Australia well to be at the forefront of clinical research and development. With a robust public and private healthcare system Australia is in the fortunate position to be considering growth opportunities in healthcare.

Accelerating innovation

Although recruitment and enrolment for most other studies stopped during the early stages of the pandemic, the clinical testing industry developed new approaches to conduct remote visits. Using telehealth, use home-based testing or monitoring technologies, and also curb side or courier pick-up and delivery for participant samples and investigational products.

Medidata research reveals that globally, 40 percent of testing organisations switched patient visits to virtual, 33 percent extended patient visit windows and 27 percent shipped IMP direct to patients.

It's clear that Investigators, coordinators and clinicians have a renewed sense of urgency and purpose to use science to solve problems that are important to patients and the public. Innovative technologies that can track and forecast critical information to benchmark results and allow organisations to make quicker real time decisions are crucial to this rapidly changing industry.

Travel will continue to be a concern into the future with the lack of a vaccine making predictions of the borders reopening almost impossible to map. For clinical sites, monitoring is made all the more difficult as participants aren't able to visit due to restrictions. This can significantly hamper both the participation and success of a trial. To combat this, remote site documentation and data sharing through secure browser-based uploads serve as an alternative to physical sites.

Where we go from here

Even before the pandemic outbreak clinical trial participation was a growing concern. Now that we are facing a global catastrophe it has never been more important for clinical trials to have a robust participation base.

Collaboration tools that bridge the gaps between different lab and countries, driving innovation in the spirit of collaboration are key to equipping researchers with the right data to make inroads in health research. Then the analytics that can be incorporated into these tools will provide a new layer of depth and insight into both trials and ultimately solutions for patients.

As we look down the lens into 2021, clinical trials are in the spotlight. As we have the world's attention, we must raise the awareness of the issues faced and also the innovative new solutions rolled out by leading companies.

Mark Glover, *Country Manager Australia and New Zealand, Medidata, a Dassault Systèmes company*

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Five ways the COVID-19 pandemic has changed clinical trials

In the six months since the first recorded COVID-19-related death, the virus has infected over 16.5 million people around the world. Of those, more than 650,000 have died. These are official numbers; real numbers are likely much higher.

Researchers and clinicians have rallied to find an effective COVID-19 treatment, registering thousands of clinical trials. Meanwhile, in some parts of the world, such as the US, India and Brazil, confirmed case numbers continue to rise.

It's this desperate need to find COVID-19 treatments that's improved how clinical trials are conducted, says the Kolling Institute's Professor of Medicine Carol Pollock, who is also a nephrologist at Sydney's Royal North Shore Hospital and has been involved in clinical trials for decades.

"COVID-19 has allowed a lot more agility in the health system in general, with more telehealth, for instance. By necessity, we've changed the way we do clinical trials for the better too," she says.

Sharing is caring

The most significant change in Pollock's COVID-19-era clinical trial experience is increased collaboration and cooperation – not only between clinical trial teams, but also hospital departments.

Clinical trials have traditionally been 'siloed', with each department focused on their own studies. Now, at Royal North Shore Hospital, representatives from each clinical trial running onsite, meet weekly to discuss among other things, how they can help each other.

"This is incredibly helpful because somebody might say, 'I know someone who is an expert in in-depth statistical analysis', or, 'I've got patients that might be suitable for your trial' and so on," Pollock says.

This is another COVID-19-related change to clinical trials – previously, sharing patients simply wasn't the done thing. "Trial recruitment almost used to be competitive," Pollock says. "If I wanted a patient with diabetes in my trial, then that would mean the endocrinologist couldn't have them in their trial because I would have snaffled them first."

Now, clinical trials are more likely to embrace patient co-enrolment. Unlike conventional recruitment, where a participant is ineligible to participate in another study, co-enrolment encourages patients to take part in two or more. That could be, for example, an intervention study, such as the CLARITY trial, which investigates how blood pressure drugs affect COVID-19, alongside another that tracks antibody production.

To ensure the co-enrolment process is as patient-friendly as possible, staff at trial sites assess potential participants and present them with a list of compatible studies. That way, patients – who may be extremely unwell – are approached, receive information and give consent once.

Fast to start, quick to adapt

The need for clinical trial speed has prompted rapid ethics approvals – not because there's less oversight, but because ethics committee members are increasingly part of research meetings.

"We've had representatives from the ethics committee sitting in on our weekly research meetings, so they're able to take any roadblocks back to the committee and figure out a solution," Pollock says.

This means a site-specific ethics clearance that used to take a minimum of two months can now be finalised in a matter of weeks.

The integrated format also helps researchers understand the ethics committee's view, Pollock adds: "They see what our problems are, we see what their problems are, and then we're both invested in trying to solve the issue."

More research teams are planning studies using adaptive design, where a trial is tweaked as it progresses based on new knowledge. This is especially important in new diseases such as COVID-19, where the standard treatment everyone receives, known as background therapy, can quickly change as fresh research comes to light.

Pollock and her colleagues meet weekly to discuss latest literature and trends, and adjust background therapy accordingly.

Patients can directly influence how a study is run through patient and community input. What researchers and clinicians want to discover from a clinical trial isn't necessarily what the community at large considers important, Pollock explains, and that issue isn't limited to COVID-19-related studies.

"We might use mortality as an endpoint, but patient representatives might say, 'I care more about whether I can sleep at night', or, 'I care whether I can get back to work.' This often changes the way you run the trial."

COVID-19 has, in a few short months, killed hundreds of thousands of people. Millions more who have recovered will likely be saddled with long-term health issues. But there is a silver lining Pollock hopes will remain after the pandemic is over.

"The impetus has really been to do what we need to do and make sure we're on top of everything," she says. "We're all in it for the same endpoint, and research has benefited from that mindset."

Bel Smoth
NSW Health

New South Wales

With 8 million people, one third of Australia's population resides in NSW, more than Singapore and Hong Kong

NSW has the most highly skilled workforce in Australia and is home to three of Australia's top five highest ranked research universities

NSW researchers are globally recognised as key opinion leaders in gene & cell therapy, vector engineering, as well as oncology, neuroscience, cardiovascular medicine, infectious diseases & medtech

NSW's long-term investment in a strong networked system, alongside significant workforce and leadership development, has supported the State's effective respsonse to COVID-19

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ARCS Life Membership

At the 2020 AGM the Board awarded ARCS Life Membership to past-President Mary Nteris and former Vice-President Kaylene O'Shea. Mary served for four years on the Board from December 2013, with the final two years as President from December 2015-17. Kaylene was an ARCS Board member from December 2014 until December 2019. She served on a range of committees and, most recently, was Vice-President until her retirement. The announcement by the Board is acknowledgement and recognition of Kaylene and Mary considerable work for and contribution to ARCS and the sector.

Patient Partnership to Create a Consumer Confidence Index for the Clinical Trials Industry

The pharmaceutical research sector is increasingly focusing on the benefits of patient-centricity, whereby patients and/or caregivers are involved in and engaged with their care. It is recognised that involving the patient perspective in the research and development (R&D) phase, both benefits patients by ensuring their needs and priorities are met, as well as the industry by contributing to the successful commercialisation of products.

Pharmaceutical companies have an opportunity, by involving patients in the R&D phase, to make better products from the beginning, and to ensure successful trials phases. Assessing the feasibility of administration, visit schedule and the usability of diary and ePRO devices can have impacts on recruitment, retention and compliance.

The trials site does not have influence over the product itself and protocol-mandated aspects of the trial, but there are several things within its control, which can impact the experience for participants, and the success of the trial at the site. Further, in the National Clinical Trials Governance Framework, currently being piloted, one of the prescribed actions to support safe and high-quality clinical trial service provision, is the systematic solicitation of feedback from clinical trials participants, their carers and their families.

USC Clinical Trials is developing a Consumer Confidence Index (CCI) for the Clinical Trials Industry. The aim of this project is to deliver a validated patient experience survey, providing an index score and offering trials sites real-time, meaningful feedback on their performance. For the index to be truly reflective of the patient voice, the index is being created in partnership with patients, following Patient Focused Medicines Development Patient Engagement Quality Guidance, and incorporating resources and recommendations available from the Australian Clinical Trials Alliance and CT:IQ's Consumer Involvement and Engagement Toolkit.

A Patient Experts group has been established. We invited 10 participants to engage in one-hour, one-to-one focus sessions. Participants were representative - an equal mix of genders, age groups (ages ranged from 24 to 74), and, had participated in a range of clinical trials with different indications: anti-wrinkle injections, coeliac, hypertriglyceridemia, osteoarthritis, pterygium and a healthy volunteer study for prevention of respiratory illness in the elderly. The group included one parent who had completed trials herself and had enrolled her children on a paediatric influenza vaccine trial, and this participant represented the caregiver voice.

For the purposes of this activity, participants were considered experts, by virtue of having participated in one or more clinical trials before. To build on their capability for meaningful collaboration participants were given self-training documents written in plain language to prepare for their participation, including definitions of clinical trials technical terms and a who's who of the clinical trials site.

Participants met with one facilitator and one scribe. The one hour was divided between approximately 30 minutes of semi-structured, open questions indirectly related to the survey, and directly related to the participants' trials experience, and then 30 minutes where they were presented with the stimulus - the drafted survey - and had the opportunity to comment on aspects of the survey, including, language, layout and methods of delivery, and also to workshop the wording of the questions. The scribed notes were combined with the facilitator's notes. Importantly, patients were thanked in writing and were paid for their time, funded by the ARCS Osmond Russell Scholarship grant.

The direct manipulations made by the Patient Experts to the stimulus will be considered and incorporated into the finalised draft of the survey. The collated data from the semi-structured part of the sessions will be analysed for themes evidently important to participants in their clinical trials experience, to ensure these sentiments are reflected in the survey. The survey will be piloted and validated at USC Clinical Trials in late 2020 and into 2021.

The lessons learned from the Patient Partnership exercise and the results from the CCI pilot will be shared more broadly with the ARCS community in future editions of Cognitio.

Sarah Piplica, BHlthSci, MPH, *University of the Sunshine Coast (USC) Clinical Trials & Osmond Russell Memorial Scholarship recipient 2019*

Acknowledgements

Thanks goes to the Patient Experts, without whom this activity would not have been possible.

Thank you also to ARCS for supporting this activity through the Osmond Russell Scholarship grant, to Prof Karen Woolley and Dr Janelle Bowden for pointing us in the right direction to resources and training to perform effective patient partnership, Lucas Litewka for continuing to champion the Consumer Confidence Index and Fiona Groom for her assistance in organising and scribing the focus sessions.

ARCS Submission: Inquiry into approval processes for new drugs and novel medical technologies in Australia

In October 2020 ARCS Australia provided a submission to the Inquiry into approval processes for new drugs and novel medical technologies in Australia to the House of Representatives, Standing Committee on Health, Aged Care and Sport to bring attention to important issues and areas critical to our sector's future.

The COVID-19 pandemic has been a transformational disruption for all aspects of society including the healthcare sector. The sector has adapted quickly to the pandemic, for example in ensuring the successful continuation and management of clinical trials during the acute phase of the pandemic.

The greatest opportunities for improvement and innovation in our healthcare system lie in the systematic application of evidence-based healthcare, driven by the best clinical research. Support for innovation in the healthcare sector is vitally important to keep the Australian healthcare system at the forefront of innovation and R&D. It supports and underpins the medical research and healthcare sectors which leads to breakthroughs in Australian innovation and commercialisation success.

Clinical trials remain critical in bringing innovative drugs, vaccines, medical devices and diagnostics, and therapies to consumers and patients throughout Australia, in a safe and regulated manner. Given the predicted impact of COVID-19 on the health system and services, organisations in the sector are working with doctors, research nurses and clinical trial sites to address disruption of normal research activities.

It is recommended that the Federal Government allocates resources to support and implement policies and processes to nationally coordinate the delivery of clinical trials in Australia, for the benefit of patients and to further develop the clinical trials sector.

Key points from the submission include:

1. The needs of the patient are a priority in decision making in the formation of legislation, policies, standards and guidances.
2. A recognition that the pandemic has been catastrophic in its impact - economically, environmentally and socially, but that a systematic and national response can ensure long-term sustainability and future prosperity, if the learnings from the pandemic are realised.
3. Australia's response considers the global setting and in the right areas either aligns or, as necessary, leads the development of international regulations, standards and guidances.
4. Australia establishes a taskforce to consider sovereignty issues in relation to our country's ability to secure the future health and wellbeing of all Australians. This would include, but is not limited to:
    a. Areas of research, development and commercialisation that ensure Australia's leading role in health and medical research, supports the developing and emerging MTP Sector through critical infrastructure, such as:
        i. R&D tax incentive scheme that ensures.
            1. Global competitiveness of medical and clinical research in Australia.
            2. Supporting the development of a therapeutic and medical device manufacturing sector.
        ii. Resources at the TGA being sufficient to maintain a strong focus on continuous improvement and strategic focus.
            1. Initiatives such as the Advanced Therapies Unit are critical to success.
            2. IT infrastructure at the TGA needs a major overhaul.
    b. Review and assess the governance structure of committees whose role it is to recommend products for therapeutic benefit in Australia.
        i. This review would consider the changing landscape of novel therapies including cross functional drugs, devices, and software as a service model.
        ii. It should also consider the need to reshape the funding models to ensure that the focus of the committees prioritise the country's health needs as opposed to being driven by companies' international product portfolios.
    c. The power of analytics on population data be harnessed, ensuring legislated privacy and cyber security is maintained, for the good of the nation.
        i. The establishment of a national health data platform that provides best practise, standards-based functionality that drives efficiencies in integrating new technologies and therapies into day to day medical practices.

To access the submission please follow this link (member login required).

Interviews with the New Board

Arthur Brandwood

1. **Explain a bit about yourself and your professional background? What is your educational background and how has professional development help shaped your career path?**

   I started my career in Zoology. When I realized that the only job I wanted was already occupied by David Attenborough (who, 40 years later, still has it) I moved off into the area of biomaterials and medical devices and have been there ever since. So that made me both scientist and engineer, and it's been a fascinating journey – in University research, start up companies, government and then most recently 20 years in regulatory consulting with the great team at Brandwood CKC. One thing I have always believed is that change is normal. You never know what's around the corner and you have to keep learning to go forwards. Continuing professional development has been a constant for me for nigh on 40 years.

2. **What do you like most about working in the health sector? What motivates you?**

   It's the intellectual challenge and stimulation that comes from the combination of the opportunity to work with some really interesting people on constantly reinvented and new technology – and all for the public good.

3. **How long have you been an ARCS member and how did you become involved in its activities?**

   I've been involved with ARCS since back when I was with TGA in the late 1990s, but have really become heavily engaged in the past 5 years or so – participating in and providing some of the educational activities and events of course. But one of the things I have been most proud of is being involved in the industry partnership scheme with Brandwood CKC being one of the earliest involved.

4. **Why have you become an ARCS Director?**

   It's a combination of wanting to contribute and having a vision for where the organisation should go next, and asking, "what can I do to help?". ARCS has made enormous advances over the past few years under the leadership of Shanny Dyer and the prior boards. It's now gained a national voice and is primed to provide a much more comprehensive and integrated education and training to the industry. At the same time COVID has been a real challenge to ARCS, as it is for all membership associations. Given both the massive opportunity and the looming threat, I am keen to be a part of driving that next stage of development while ensuring the organisation remains stable in these very difficult times.

5. **What is your vision for the future of the health sector and how can ARCS be a part of it?**

   As Australia's traditional manufacturing sectors declined, medtech and pharma have become the largest single manufacturing and export sector in Australia. This has brought the attention of both federal and state governments and more money to stimulate further growth. It's an exciting time, but the opportunity needs to be seized and properly directed. ARCS must be a part of it -through being a vocal and credible policy voice on how industry development can be achieved. Key questions are : How should we respond locally to international trends and needs of a global industry (e.g. through support to our clinical trials sector), how do we ensure recognition of the importance of the professional workforce in that industry, and how does ARCS build world class training services so our members are best equipped to seize the opportunities offered?

Interviews with the **New Board**

Adele Hosseini

1. **Explain a bit about yourself and your professional background?**

   I am a pharmacist with PhD in Pharmacy and close to 30 years' experience across all stages of R & D. I have over 17 years foundation in leadership, global clinical research, regulatory affairs and university lecturing, providing exposure across pharmaceuticals, clinical research organisation, medical devices and academia. I started my career as a CRA many years ago and progressed into the more senior roles over years. I am currently the Chief Scientific Officer at Bod Australia leading the R&D program and drug development strategy to meet the company's mid and long-term goals.

2. **What is your educational background and how has professional development help shaped your career path?**

   I have a Bachelor, Master and PhD in Pharmacy from Sydney University. When I finished my PhD, I worked as a lecturer there for a few years before I decided to move into the industry. Professional development and specifically ARCS training programs had a significant impact on my careers progression. I remember my very first ARCS CRA workshop all that many years ago and how it assisted me with my career goal in industry.

3. **What do you like most about working in the health sector? What motivates you?**

   Helping individuals to improve their health and enjoy their life has always been very fulfilling for me. I feel that I have the opportunity to dedicate myself to overcoming various challenges both social and medical and in doing so I can potentially make a life-altering impact on the community. I am passionate about helping people and making a difference in their life, I know it sounds cliché but that's what gets me up every morning.

4. **How long have you been an ARCS member and how did you become involved in its activities?**

   I have been ARCS member since very early 2000. I've always understood the power of association and networking, so it was a no brainer for me to join ARCS to have access to the wealth of experience and learn from others.

5. **Why have you become an ARCS Director?**

   ARCS has been instrumental in my career progression. I wanted to be able to give back and contribute what I have learned as a leader.

6. **What is your vision for the future of the health sector and how can ARCS be a part of it?**

   My vision is to inspire hope, and contribute to health and wellbeing of people by providing the best way forward to bring solution to people's medical challenges through education and research. ARCS mission is to provide education, career pathway, professional development and advocacy to the healthcare sector which is well aligned with my vision.

Interviews with the New Board

Orin Chisholm

1. **Explain a bit about yourself and your professional background? What is your educational background and how has professional development help shaped your career path?**

   I am an experienced regulatory scientist with expertise in registering innovative medicines in oncology and women's health across both large and small biopharmaceutical organisations. I have been in regulatory affairs since 2000. I am a well-recognised educator in pharmaceutical medicine, medical affairs, regulatory affairs, personalised medicine, oncology and gene technology and am currently the Program Director for the Master of Pharmaceutical Medicine program at UNSW. I recently completed three years on the Gene Technology Technical Advisory Committee of the Office of the Gene Technology Regulator. I am a recipient of the TOPRA (The Organisation for Regulatory Affairs Professionals, UK) Award for Excellence in Regulatory Affairs Education and I am a Senior Fellow of the Higher Education Academy (UK). I am on the editorial boards for the Regulatory Affairs Professionals Association (RAPS, USA), Frontiers in Pharmacology and Frontiers in Medical Technology, as well as being a reviewer for Therapeutic Innovation and Regulatory Science and Pharmaceutical Medicine. I have an adjunct appointment at Arizona State University, USA, where I teach global regulatory affairs leadership.

2. **What is your educational background and how has professional development help shaped your career path?**

   I have a Bachelor of Science degree with Honours in Biochemistry and a PhD in the Molecular Biology of Cancer from the University of Sydney as well as a Graduate Certificate in University Learning and Teaching from UNSW Sydney. Throughout my career I have undertaken both formal education as well as many short courses where necessary to increase my career potential. Both have been particularly important during career transition points.

3. **What do you like most about working in the health sector? What motivates you?**

   I am motivated by making a difference to patients either directly through my work in regulatory affairs and bringing new medicines to market or indirectly by facilitating the development of knowledge and expertise in my students, so that they can improve their ability to make a positive impact in the health sector through their careers.

4. **How long have you been an ARCS member and how did you become involved in its activities?**

   I have been an active member of ARCS since I entered the industry in 2000. I worked with ARCS to develop the application to MTPConnect to receive funding for the successful CRITERIA project - Building clinical trial capability and capacity to grow the MTP sector. I worked with ARCS to deliver appropriate candidates to the program. I regularly promote the ARCS conference to students at UNSW and I have been an exhibitor at the ARCS conferences for several years. In 2019, I co-chaired the session on Regulation, ethics and reimbursement of novel biological therapies in Australia.

5. **Why have you become an ARCS Director?**

   I have become an ARCS Director to help develop the mission, vision and values of the organisation and further education and training for professionals in the medical technology and pharmaceutical industry. I hope to leverage my ties with other organisations (such as TOPRA, DIA, APPA and RAPS) to facilitate cooperation between them and ARCS to build the ARCS brand profile. I hope to utilise my experience in development of education programs and obtaining funding to improve the offerings by ARCS.

6. **What is your vision for the future of the health sector and how can ARCS be a part of it?**

   My vision for the future of health is for a much more patient-centred healthcare system, that is seamlessly digitally integrated across all jurisdictions in Australia. I envision a learning healthcare system with research embedded in everyday care of patients and a system where physicians are compensated on outcomes achieved for their patients rather than the current pay-for-service model.

   ARCS can be a part of this system by advocating for greater education and training for this sector, for greater coordination of clinical research across the healthcare sector in Australia and by providing the education and training needed to improve the capacity of this sector to deliver benefits to Australian patients and the Australian economy.

Meet the Convenors

Samantha Flynn

If you are passionate about the sector and would like to contribute towards educating your colleagues and ensuring that the highest standards and best industry practices are followed, consider volunteering with ARCS. We are always looking for volunteers to support our activities. Some of the ways you could volunteer include become an interest area convenor. Below is an interview with Samantha Flynn (convenor and ARCS Life member) providing an overview of what's involved and the benefits for professional development.

Explain a bit about yourself and your professional background?

I started in the industry back in 1996 as a CTA, moved through CRA and PM roles in CRO and ARO and am currently Director of Project Management for ICON. I manage CTMs and PMs in ANZ and South East Asia and also have responsibility for ICON's Australia and New Zealand offices.

What is your educational background and how has professional development help shaped your career path?

I wanted to work in pharmaceutical development since high school, so did a Bachelor of Science majoring in Pharmacology, and entered the industry shortly afterwards. More recently I completed a Graduate Certificate in International Business Management which helped me with the more strategic, leadership and financial aspects of my current role. I'm a big believer in the "Never Stop Learning" mantra.

How long have you been an ARCS member?

Since 1996 I think!

Why have you become an ARCS convenor?

Initially I saw it as a good way of networking and building contacts – which it is! - but there's also an element of self-indulgence about it. I get to explore and discuss topics that interest me, and share that with others. Honestly I feel I get more out of it than what I put in.

Which interest area do you look after and what have been some of the highlights?

Leadership is something I'm passionate about and so the Leadership IA fits really well. The highlights have been seeing new people join and watching them develop into leaders themselves. It's really satisfying.

What does the role of a convenor include?

My wonderful co-convener (Sebastien Ducarme from Roche) and I are both self-improvement and learning junkies, and always keep an eye out for any articles/books/thought leaders/topics of interest then share with each other the ones that have stood out for us. We then find relevant speakers or develop these into presentations and discussion points ourselves. If there are challenges we are facing in our own work, chances are others are too so we'll plan a session around addressing those.

What do you like most/least about working in the health sector?

The work is meaningful, and it is satisfying to see the outcomes of our research translated into benefits for patients. On the frustrating side, it would be helpful to have more of a national approach to clinical trials in Australia, rather state by state. But it's improving (slowly)!

What motivates you to volunteer for the benefit of the sector?

Volunteering is something I've done since I was a teenager, and continue to do now outside of the sector as well. I believe the only way things improve is when people who care get involved and make changes. There is so much that needs improving, why not get involved?

What changes have you seen since you have been involved in your sector?

It finally feels like technology is being embraced by the health sector; I feel we've been lagging behind other industries in regards to the possibilities tech can bring. The COVID pandemic has been a wakeup call to show what can be possible if we think outside the box for healthcare. Things like e-consent, telehealth, data collection from wearables – this would all have been considered fantasy 26 years ago when I started in the industry!

How do you see the skills for a career in leadership need to change in the future?

We did an Interest Area meeting on this just recently! What resonated most with us was that leaders will need to be truly authentic, to be comfortable sharing their feelings, to deeply care about their teams and provide a safe environment where people feel they belong. Good leadership is no longer about power and control; it's about service and support.

Any other observations that you would like to share with ARCS members and those thinking about volunteering?

Honestly, go for it! It's great for networking and self-development.

We are currently looking for convenors for several interest areas. If you are interested in learning more, contact Joe Badolato on joebadolato@arcs.com.au or access the ARCS website.

Partner with us

ARCS has been actively building partnerships with key stakeholders in the healthcare sector. We believe that we can make a difference to the sector and adding value to its members for example through education opportunities.

The partnership program aims to:

- **Influence.** Aim to innovate and lead change by working closely with the government to streamline processes across jurisdictions.
- **Sector hub.** Unify the various associations and stakeholder who work across the sector to ensure that common goals are agreed and put forward strongly to government.
- **Professional development.** Tailor programs that engage and up-skill. The training provides opportunity to share experiences and case studies, and importantly build the collegiate networks.
- **Application of knowledge.** Provide forums and summits to facilitate discussions with key stakeholders such as clinical sites, government, universities and hospitals.
- **Professional recognition.** Further develop a system to recognise our frontline clinical staff, giving them recognition for the extra skills they have and the role they play in clinical research.
- **Educating for today and the future.** Build an internship program that will screen and train a pool of new staff.

Partners will benefit from:

- Site licences for ARCS webinars
- Workshop attendance
- Significant customised pricing for conference attendance for large groups
- Access to executive briefing sessions (including the CEO breakfast)
- Preferential access to sponsorship and exhibition opportunities
- ARCS Partner badge/banner for use in communications/ social media
- A seat at the table in shaping our future
- Access to other ARCS partners who are leaders in their fields.

Partners can be organisations who are integral to our members learning, development and educational needs. There are established principles and criteria for partners.

Partners need to be:

- Leaders in their field
- Act with integrity
- Provide educational opportunities for ARCS members

Would you like to know about partnering with ARCS Australia? Please contact Shanny Dyer, CEO ARCS, on arcs@arcs.com.au for more information.

ARCS would like to thank the following partners:

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