



**2013/2014  
PERFORMANCE  
HIGHLIGHTS**

**2085**  
Members

**95**  
Number of educational events held

**780**  
Number of attendees at conferences

**1581**  
Number of attendees at interest area  
committees

**92%**  
Average quality rating of educational events

## WHO WE ARE

ARCS is a leading independent not-for-profit association that focuses on delivering professional development and member representation within the therapeutics sector.

As a not-for-profit organisation, ARCS is funded by its members and currently represents more than 2,000 personnel within the sector. ARCS' role is pivotal both in educating newcomers to the industry as well as providing continuous support throughout their careers with ongoing professional development.

## WHAT WE DO

We provide high-quality training and professional development within the therapeutics sectors.

We encourage and foster the exchange of information via leading-edge conferences, seminars and networking events.

We act as an impartial information portal to provide awareness of relevant government, research and industry activities.



## EVENTS AND INITIATIVES

During the 2013-14 financial year we had a number of successful events including our second ever dedicated health economics conference in Canberra, September 2013; and our first AGM (and education day) in Melbourne in November 2013 which was followed by our Melbourne Annual Dinner. The financial year was closed in June 2014 by our Sydney congress, with a return to the fabulously renovated Royal Randwick and involved clinical research, medical information, medical affairs, pharmacovigilance, medical writing and management streams. Over 500 delegates from industry, hospitals and other research sites and government attended, with over 90 local and international speakers organised across six streams covering a broad range of topics.

All clinical education for site staff was upgraded for compliance with the TransCelerate standards and in June we launched our certification programme for those working in clinical research as monitors, project managers and senior personnel. Additionally, we developed the clinical certification pathways for study coordination after consultation with members and senior members in management positions. The programme will provide members with professional recognition for their knowledge, experience and commitment to continuing professional development.

## RESEARCH AND REPRESENTATIONS

The ARCS Business Office staff worked on a number of initiatives related to our therapeutics environment. These involved:

- research, consultation and completion of research governance report for the Department of Innovation and Industry - our first for government
- providing feedback and suggestions on state and commonwealth clinical research initiatives
- a working party giving feedback on NEES/eCTD
- support for industry managers collaborating on CLEVER, for consumer safety reporting
- engagement with regulators on electronic submissions
- delivery of a workshop with the Department of Innovation and Industry designed to provide advice to small businesses in the medtech industry
- consolidation of RMP requirements in a template for industry
- two \$10,000 scholarships offered to two ARCS members for research purposes (the Research Scholarship and the Osmond-Russell Scholarship).

## THE OFFICE AND THE TEAM

For those of you who have joined us at the ARCS Business Office for training this year you will have seen that we've made some changes to the office layout, which has helped to improve the trainee and office experience.

During the year we welcomed Belinda King back from maternity leave and also a new member of staff Jonathan Mondejar. Jonathan is project managing our new website and database project.

The team is working hard on implementing the new ARCS website and database which we plan to launch in the first quarter of 2015.

## THE FUTURE

The aforementioned website and database is the largest initiative we're working on, which is taking many hundreds of man hours but promises to transform the member experience, particularly for the website.

Like the 2012-13 financial year we will return to a format of two congresses for 2014-15 and we are organising in the order of 250 leading domestic and international speakers.

We will be pushing ahead with building our interest area teleconferences, a hit with many of the interest area groups so far - this year's number of attendees reached record levels of participation.

We are building collaborations with like-minded organisations, with a view to boosting our activities for site staff, medical affairs, quality, and medical devices. We will also be working towards some organic growth for the complementary medicines, risk-based monitoring and others.



## DIRECTORS' REPORT

The Directors of ARCS Australia Limited (ARCS) present this report and the Financial Statements of the Company for the year ended 30 June 2014.

### I. DIRECTORS 2013/2014

The details of the Directors who held office during or since the end of the financial year are provided below. Nine Board meetings in total were held from July 2013 to June 2014.

Board elections were held at the AGM on 28 November 2013. Four positions were declared vacant and there were eight nominations for the role of Director. A poll was conducted to determine which nominees would fill the four vacant positions. Following election at the AGM Carlo Maccarrone and Mary Nteris commenced their terms on 28 November 2013, while Ailsa Surman and Judy Bingham were returned to the Board. Lesley White resigned from the Board on 19 May 2014. Tamara Miller resigned from the Board after the end of the financial year.

	Commencement	Cessation	Board Meetings		Key Activities
			A	B	
Judy Bingham <sup>a,b</sup>	1 Jul 2013 <sup>1</sup>		8	9	Company Secretary Chair, Audit & Risk Management Committee
Katrina Campion <sup>c</sup>	1 Jul 2013 <sup>1</sup>	1 Jul 2013 <sup>1</sup>	4	5	
Miriam Dwyera <sup>a,c</sup>	1 Jul 2013 <sup>1</sup>	28 Nov 2013	4	5	Vice President Chair, Membership & Education Committee
Sally Kinrade <sup>b,c</sup>	1 Jul 2013 <sup>1</sup>		7	9	Chair, Membership & Education Committee
Carlo Maccarrone <sup>c</sup>	28 Nov 2013		4	4	
Tamara Miller <sup>c</sup>	1 Jul 2013 <sup>1</sup>		4	9	
Mary Nteris <sup>a,c</sup>	28 Nov 2013		4	4	
Melanie Seeger <sup>c</sup>	1 Jul 2013 <sup>1</sup>		7	9	
Ailsa Surman <sup>a,b</sup>	1 Jul 2013 <sup>1</sup>		9	9	President Chair, Corporate Governance Committee
Lesley White <sup>a,b,c</sup>	1 Jul 2013 <sup>1</sup>	19 May 2014	7	8	Vice President Chair, Corporate Governance Committee

A – Number of meetings attended                      B – Number of meetings held during the time the director held office during the year

<sup>1</sup>Directors were appointed prior to start of financial year

<sup>a</sup> Corporate Governance Committee

<sup>b</sup> Audit & Risk Management Committee

<sup>c</sup> Membership & Education Committee

## **Judy Bingham – Director, Company Secretary, Chair Audit & Risk Management Committee**

Judy is an independent consultant to the biopharmaceutical industry, supporting companies plan and manage development and life cycle programmes, including regulatory strategy and clinical development planning.

Until March 2011, Judy held the position of Senior Director Kendle Consulting for Kendle International in the Asia Pacific region. In this role, she was responsible for the leadership of regulatory and medical affairs consulting services. Prior to joining Kendle, Judy gained extensive experience in clinical research and development, in business development, medical affairs and health economics at CSL and Faulding (now Hospira), and as Director of Pharmacy at Peter MacCallum Cancer Centre.

Judy is a registered pharmacist and has a bachelor of pharmacy from Monash University. Her post-graduate qualifications include a masters in health science, fellowship of the Society of Hospital Pharmacists of Australia and company directors course diploma from the Australian Institute of Company Directors.

Judy has been involved with ARCS for over 15 years and a Board member since 2011. She is a member of the Audit & Risk Management Committee, the Corporate Governance Committee and is currently the ARCS Company Secretary.

## **Katrina Campion – Director**

Katrina has worked in the pharmaceutical industry for more than 20 years, and has been involved with ARCS in some active capacity for most of this time. Katrina served as a member of the Melbourne Education Subcommittee for many years, and for more than a decade has been a member of the ARCS Australia Board. Katrina has qualifications in nursing, social research and public health, is a graduate of the Australian Institute of Company Directors (GAICD) and Certified ARCS Australia Fellow (ACF). Katrina was ARCS Australia President 2007-2011. She remained a Director on the ARCS Australia Board until the AGM in 2013.

## **Miriam Dwyer – Director, Chair Membership & Education Committee, Vice President (to 28 Nov 2013)**

Miriam is currently the Chief Executive Officer of the Gallipoli Medical Research Foundation, based at Greenslopes Private Hospital in Brisbane. This foundation currently supports five academic research units (Liver Research Unit, led by Prof Darrell Crawford, Respiratory Research Unit, led by Dr Rachel Thompson, Ophthalmology Research Unit, led by Dr Chris Layton, Liver Cancer Unit led by Dr Jason Steel, and the PTSD Initiative led by Prof Bruce Lawford). Working closely with the Chair of the Board of Directors, Miriam provides direction and leadership to the formulation and achievement of the GMRF's goals and objectives. She leads the senior executive team and assumes overall responsibility for the operation of the GMRF in consultation with the GMRF executive. She oversees all operational elements of the foundation's clinical trials unit, including feasibility assessments, contract negotiations, resource management and project delivery.

While on the ARCS Board, Miriam chaired the Membership and Education Committee, and was appointed Vice President of ARCS in 2012 until the AGM in 2013.

## **Sally Kinrade – Director**

Sally is Clinical Research Director at Medicines Development Ltd. She has extensive experience in pharmaceutical development, scientific communication and market strategy. Prior to joining Medicines Development, she was Chief Operating Officer at Phosphagenics Limited, a publically listed Australian biotechnology company with development projects in Phases 1 and 2. With over 20 years in the industry, Sally's previous experience includes clinical research, brand planning and medical affairs roles with GlaxoSmithKline. She has also operated as an independent consultant on projects for industry, government and research organisations.

Sally is a pharmacist and holds a master of public health.

Sally was appointed a Director of ARCS in July 2012 and was elected to the Board in November 2012. In September 2012 Sally completed a two day training course for board members of not for profit organisations. Sally is current Chair of the Membership and Education Committee.

### **Carlo Maccarrone – Director**

Carlo Maccarrone has 25 years' experience in the pharmaceutical industry and has been a continuous member of ARCS throughout that time. He is currently the Associate Director, Clinical Research at GSK Australia, and in this role has management responsibility for a team of clinical research professionals that conduct clinical trials from Phases I to IV in Australia and New Zealand – which span a number of therapy areas.

Carlo trained as a pharmacist before completing a master of pharmacy degree at the Victorian College of Pharmacy (Monash University), and a PhD at Melbourne University. He began his career in academic research before joining the pharmaceutical industry as a consultant in 1988. He then joined GSK where he held a variety of positions in clinical research, the management of pharmaceutical development (formulation) and academic research alliances.

Carlo was elected to the Board of ARCS in November 2013 and has since completed a two-day governance foundations for not-for-profit Directors – at Australian Institute of Company Directors. Carlo is an ARCS Australia Certified Fellow (ACF) and has been a member of the ARCS Membership & Education Sub-Committee.

### **Tamara Miller – Director**

Tamara has over 13 years' experience in the clinical research industry, having held project management roles in the UK, USA and Australia. Currently, Tamara is Project Management Director for the APAC region at ICON Clinical Research. Tamara's project management skills and experience cover all functional areas of clinical research, including clinical, regulatory, medical affairs, pharmacovigilance, compliance, data management and biostatistics. Holding a BSc in biomedical science, Tamara is a member of the Australian Institute of Project Management and a member of the Project Management Institute. Tamara was elected to the Board in November 2012 and has served on the Membership and Education Committee.

### **Mary Nteris – Director**

Dr Mary Nteris is the Associate Director of Regulatory Affairs, ANZ, at Hospira. She has almost 20 year' experience in the pharmaceutical industry, having worked in both the clinical research organisation and pharmaceutical organisational sectors in the regulatory affairs discipline. Her experience covers oversight for regulatory strategy and submissions across ANZ and Asia (excluding Japan).

Mary was elected to the ARCS Board in November 2013, and is a representative on the Corporate Governance and Membership and Education Committees.

### **Melanie Seeger – Director**

Melanie is a Senior Manager, Industry Relations, with Celgene Pty Ltd. With over 25 years' experience in the pharmaceutical industry, Melanie worked in various roles covering both commercial and medical functions including sales, medical information and communications and medical affairs before moving into the Industry Relations field. In addition, Melanie has experience in the planning and delivery of healthcare programmes in the primary care setting.

Melanie holds a bachelor of science, a master of public health and a Certificate IV in assessment and workplace training. A member of ARCS for many years, Melanie has been active in various interest area groups. Melanie was elected to the ARCS Board in November 2012 and is a member of the Membership and Education Committee.

### **Ailsa Surman – President, Chair Corporate Governance Committee**

Ailsa has worked in the pharmaceutical industry in Australia, New Zealand and the UK for 20 years, in a variety of areas including medical information, pharmacovigilance and regulatory affairs. She has degrees in biochemistry and pharmacology. In her role of Senior Manager Regulatory Affairs, Ailsa leads the regulatory affairs function across Australia and New Zealand at Biogen Idec Australia. Ailsa has been a member of ARCS since arriving in Australia in 2005, and was co-convenor of the Regulatory Education Sub-Committee for three years. Ailsa joined the ARCS Board in 2009 and was appointed President in October 2011.

## **Lesley White – Director, Vice President (from 28 Nov 2013)**

Lesley has 20 years' experience working in the pharmaceutical industry both in Australia and the UK. Lesley is currently a Director of Solve Consulting. Previously she held the position of Regional Director of Regulatory Affairs for ANZ, Japan and Asia with Hospira. In this role she was responsible for all regulatory activities across the region in support of the company's generic, proprietary, biosimilar and medical device portfolios and oversaw 75 staff across 10 countries. In her role Lesley is responsible for all agency interactions, strategy development, product compliance and lifecycle management, budgeting and resource management. Lesley is also a graduate of the Australian Institute of Company Directors (GAICD). Lesley has been a member of ARCS since 2004 and became a Director of ARCS in 2012. Lesley served as the Vice President and Chair of the Corporate Governance Committee.

## **2. COMPANY SECRETARY**

The appointed Company Secretary is Judy Bingham, effective 20 December 2012.

## **3. SHORT- AND LONG-TERM OBJECTIVES AND STRATEGY**

The objective of the Company is the promotion of education about the development and quality use of therapeutic goods. This includes providing support in the form of networking opportunities, representation of member interests, education and information services for the benefit of its members, and for interested non-members. Members include those contributing scientific services and expertise to the therapeutics development process and/or utilisation of pharmaceuticals and medical devices/diagnostics. Members of ARCS may work in areas including, but not limited to, regulatory affairs, clinical research, health outcomes, pharmacovigilance, medical affairs, and the provision of medical information.

The objective of ARCS is to advance our members' professional interests and provide a forum for education and exchange of information. This includes the following goals:

- To extend membership to all those interested in the development and quality use of therapeutic goods, with a focus on Australia
- To provide and promote education in the areas of regulatory affairs, clinical research, health economics, medical information and other disciplines which support the development and quality use of therapeutic goods - training opportunities are open to both members and non-members
- To foster exchange of information and experience in order to enhance professional competency
- To provide an information portal to maintain awareness of current government, research and industry activities relevant to the membership
- To establish effective communication with other organisations and stakeholders influencing the therapeutics development industry

## **4. PRINCIPAL ACTIVITIES**

The company's principal activities during the year were:

- Holding the first of the two 2014 Annual Scientific Congresses in Sydney in June 2014, with an event that focussed on clinical research and related areas. A second event was held after the end of the financial year in Canberra and focussed on regulatory affairs, quality and health outcomes
- Provision of education and networking events in the form of training workshops, seminars, webinars, and evening updates
- Developing updated and/or new education events and workshops, including new technical and soft skill courses
- Facilitating discussions between member groups in the form of Interest Area Committee Meetings, with significantly increased attendance numbers
- Facilitating growth of communication and engagement between site and sponsor clinical research personnel
- Facilitating regional networking events
- Development and adoption of a communications plan, which led to streamlining of existing communications and introduction of a monthly newsletter
- Significant work to scope, develop and implement an updated member database and website
- Completion of a review of the rental market, followed by a commitment to the existing premises and reconfiguration of the office space that enhances the learning experience and provides internal efficiencies
- Internal audit of all ARCS business processes

These activities have assisted the company in achieving its objectives by

- Providing high quality, relevant and current education programmes that are targeted to specific member groups
- Providing opportunities for members to exchange information
- Providing information relevant to members
- Representing member interests in significant areas
- Returning an operating profit of \$58,527

## 5. PERFORMANCE MEASURES

The company measures performance as follows:

- Number of members
- Delivery of education events to each participant group
- Attendance at education and networking events
- Quality rating of education events
- Cost effectiveness of education events
- Opening rates and click-through for ARCS communications
- Effectiveness of financial control measures
- Ongoing financial viability of the company

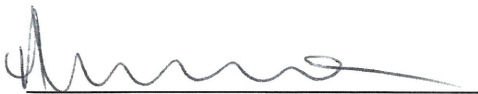
## 6. MEMBERS' GUARANTEE

In accordance with the company's constitution, each member is liable to contribute an amount not exceeding \$10.00 in the event that the company is wound up. On the basis of membership numbers at 30 June 2014, the total amount members would contribute is \$20,850.

## 7. AUDITORS' INDEPENDENCE DECLARATION

The lead auditors' independence declaration for the year ended 30 June 2014 has been received and is attached.

This Directors' Report is made and signed in accordance with a resolution of the Board of Directors made pursuant to section 298(2) of the Corporations Act.



Director



Director

Dated this 21st day of 2014





[www.arcs.com.au](http://www.arcs.com.au)

T: 02 8905 0829

F: 02 8905 0830