2021 Conference Program

From pandemic to recovery – building Australia's competitive advantage post COVID

7-9 June 2021, ICC Sydney

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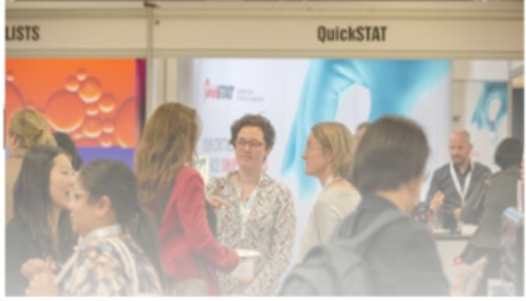

About the ARCS Conference

For over 35 years, ARCS Australia has been bringing together a vibrant and diverse community of professionals working in academia, government, biotech and pharmaceutical companies, hospitals and healthcare settings and other organisations to showcase and support the development and regulation of therapeutic goods.

Delegates come from a cross-section of the healthcare sector including clinical research, regulatory affairs, pharmacovigilance, medical affairs/MSLs, medical technology, health economics and quality/ GMP. They include senior executives through to recent graduates.

This pandemic has exemplified the need for translational medical research, clinical trials and key infrastructure that can be mobilised in a time of crisis. On top of this we have an ageing population and rising prevalence of chronic diseases, juxtaposed with a need for critical infrastructure investments, technological advancement, evolving care models, staff shortages, and the expansion of healthcare systems in developing markets. These elements create opportunity and uncertainty.

2021 ARCS
ANNUAL CONFERENCE

The 2021 ARCS Annual Conference brings together industry, regulator, academia and researchers to educate, network and unite in a time of change. It will provide essential and timely information in each of the key educational areas – particularly as we traverse the issues associated with the COVID-19 pandemic as well as other local and international issues. A strong and compelling line up of international speakers will provide a global perspective joined by high profile Australian experts.

The program has been developed with input from the broader sector to ensure it focuses on areas of greatest need for those working in clinical research, pharmacovigilance, regulatory affairs for and timely access to medicine and devices and patient and consumer representatives.

Refer to the key streams below to identify sessions in the program:

	Clinical Research
	Medicines and medical devices reimbursement
	Pharmacovigilance
	Innovations in R&D
	Regulation of prescription and non-prescription medicines
	MedTech start-ups/SMEs stream
	Careers stream

Time	Session Stream	
9:00 - 10:15	**A01.** A national approach to clinical trials:A federal update	
	A02. Clinical session to be announced	
	A03. MD reimbursement session to be announced	
	A04. Pharmacovigilance session to be announced	
	A05. Innovations in R&D session to be announced	
	A06. Innovations in R&D session to be announced	
	A07. Session to be announced	
10:15 – 11:00	**Morning Tea**	
11:00 – 12:00	**A08.** A national approach to clinical trials: State update (part 1)	
	A09. Clinical session to be announced	
	A10. MD reimbursement session to be announced	
	A11. Partnerships & collaborations in pharmacovigilance	
	A12. The evolving role of Real-World Evidence in Australia – where are we now (part 1)	
	A13. Innovations in R&D session to be announced	
	A14. Session to be announced	
12:00 – 13:30	**Lunch**	
13:30 – 14:30	**A15.** A national approach to clinical trials: State update (part 2)	
	A16. Costing clinical trials for industry & investigator-initiated trials	
	A17. Robotic surgery outcomes from different platforms	
	A18. Pharmacovigilance in action	
	A19. Putting precision medicine in context (part 1)	
	A20. Innovations in R&D session to be announced	
	A21. Session to be announced	
14:30 – 14:45	**Session change over**	
14:45 – 15:45	**A22.** A national approach to clinical trials: Pulling it all together	
	A23. Resource compliance & governance in clinical trials - Stretching the rubber band	
	A24. MSAC guidelines update	
	A25. Pharmacovigilance reflections on 2020	
	A26. Putting precision medicine in context (part 2)	
	A27. Innovations in R&D session to be announced	
	A28. Session to be announced	
15:45 – 16:15	**Afternoon Tea**	
16:15 – 17:30	**P01.** Session to be announced	**P02.** Session to be announced

Time	Session Stream	
9:00 - 10:15	**B01.** General update on manufacturing - regulations and process	
	B02. Regulatory prescription medicines session to be announced	
	B03. Regulatory device session to be announced	
	B04. How eConsent is being used in Australia to support clinical trials	
	B05. Trial start up with the end in mind (part 1)	
	B06. How the customer determines product development and business strategies for medtech start-ups	
	B07. Session to be announced	
	S01. Session to be announced	
10:15 – 11:00	**Morning Tea**	
11:00 – 12:00	**B08.** Clinical trial manufacturing	
	B09. Regulatory prescription medicines session to be announced	
	B10. Medical technology sector update	
	B11. International & national initiatives improving clinical trials in Australia	
	B12. Trial start up with the end in mind (part 2)	
	B13. An overview of regulatory requirements for medical device start-ups for Australian and international markets	
	B14. Session to be announced	
	S02. Session to be announced	
12:00 - 13:30	**Lunch**	
13:30 – 14:30	**B15.** Counterfeit and illegal importation	
	B16. Regulatory medicines session to be announced	
	B17. EU MDR: Are we there yet (part 1)?	
	B18. National Clinical Trial Governance Framework (part 1)	
	B19. Remote monitoring in a post-COVID world: The collaborative approach (part 1)	
	B20. The critical importance for medtech start-ups of embracing quality management in medical device development	
	B21. Session to be announced	
	S03. Session to be announced	
14:30 – 14:45	**Session change over**	
14:45 – 15:45	**B22.** Supply chain management during pandemic – 2020 review	
	B23. Regulatory medicines session to be announced	
	B24. EU MDR: Are we there yet (part 2)?	
	B25. National Clinical Trial Governance Framework (part 2)	
	B26. Remote monitoring in a post-COVID world: The collaborative approach (part 2)	
	B27. Considerations for medtech start-ups when raising capital	
	B28. Session to be announced	
	S04. Session to be announced	
15:45 – 16:15	**Afternoon Tea**	
16:15 – 17:30	**P03.** Session to be announced	**P04.** Session to be announced

Time	Session Stream	
9:00 - 10:15	**C01.** Appealing a TGA decision - tips and tidings	
	C02. Accelerated regulatory approval pathways for new medicines in Australia	
	C03. Medicinal cannabis product regulation in Australia	
	C04. Regulating software: A moving goal post	
	C05. Update from the Office of HTA and Medicines Australia	
	C06. Innovations in R&D session to be announced	
	C07. Session to be announced	
10:15 – 11:00	**Morning Tea**	
11:00 – 12:00	**C08.** Labelling updates: New CMI and PI requirements	
	C09. Prescription medicines sector update	
	C10. Regulatory non-prescription medicines session to be announced	
	C11. The race for Point of Care COVID test	
	C12. Consumer-led evidence development to inform reimbursement value judgement	
	C13. Innovations in R&D session to be announced	
	C14. Session to be announced	
12:00 – 13:30	**Lunch**	
13:30 – 14:30	**C15.** Embracing international work sharing	
	C16. eSubmission regional developments & updates (AU, China and APAC)	
	C17. Non-prescription medicines sector update	
	C18. Custom made medical devices	
	C19. Spotlight on reimbursement of rare diseases	
	C20. Innovations in R&D session to be announced	
	C21. Session to be announced	
14:30 – 14:45	**Session change over**	
14:45 – 15:45	**C22.** Panel discussion with regulatory leaders	
	C23. Medicine Shortages Information Initiative	
	C24. Clinical evidence requirements for complementary medicines	
	C25. Regulatory device session to be announced	
	C26. Registration & reimbursement of gene and cell therapies: Opportunities and challenges?	
	C27. Innovations in R&D session to be announced	
	C28. Session to be announced	
15:45 – 16:15	**Afternoon Tea**	
16:15 – 17:30	**P05.** Session to be announced	**P06.** Session to be announced

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