Day 1: 23 May 2022 program

2022 ARCS ANNUAL CONFERENCE

Time	Session Title	Session Stream	Room
8:45 – 10:30	**A01.** How to improve patient outcomes through regulations in the digital world		Pyrmont Theatre
10:30 – 11:15	Morning Tea		Exhibition Hall
11:15 – 12:15	**A02.** What's happening at the TGA's Manufacturing Quality Branch	Manufacturing	Parkside 2
	A03. Regulatory update from the Medical Devices Authorisations Branch	Regulatory Devices	Parkside 1
	A04. The future of regulatory affairs	Regulatory	Pyrmont Theatre
	A05. Regulation of cell and gene therapy	Prescriptions Medicines Regulation	C2.2+C2.3
	A06. Medicinal cannabis: The changing landscape	Non-prescription Medicines Regulatory	C2.5+C2.6
	A07. The local MTP ecosystem and market trends for entrepreneurs and founders.	Entrepreneurship, Innovation & Commercialisation	C2.4
12:15 – 1:30	Lunch		Exhibition Hall
1:30 – 2:30	**A08.** New frontiers and challenges in manufacturing mRNA and regenerative medicines	Manufacturing	Parkside 1
	A09. Software-based Medical Devices (SbMDs) – Current considerations of the regulatory mindset in the design and development of software products	Regulatory Devices	Pyrmont Theatre
	A10. Regulatory aspects of vaccine development	Prescriptions Medicines Regulation	Parkside 2
	A11. Regulatory updates from the TGA Complementary and Over the Counter Medicines Branch	Non-prescription Medicines Regulatory	C2.2+C2.3
	A12. Who is the customer? How to position my technology and product?	Entrepreneurship, Innovation & Commercialisation	C2.5+C2.6
2:30 – 2:45	Session change over		
2:45 – 3:45	**A14.** Knowledge management	Manufacturing	C2.5+C2.6
	A15. Adoption of software as medical devices: Drivers and barriers	Regulatory Devices	Pyrmont Theatre
	A16. Regulation of personalised medical devices (including 3D-printed devices)	Regulatory	C2.4
	A17. Medicine shortage management: Working together for effective management	Prescriptions Medicines Regulation	Parkside 2
	A18. Complementary medicines regulatory hot topics	Non-prescription Medicines Regulatory	C2.2+C2.3
	A19. Product development strategy: From bright idea to commercial success	Entrepreneurship, Innovation & Commercialisation	Parkside 1
3:45 – 4:15	Afternoon Tea		Exhibition Hall
4:15 – 5:15	**A20.** Industry 4.0: Insights from the MTP forum	Manufacturing	C2.4
	A21. Establishment of the Australian Unique Device Identification (UDI) system for medical devices: A regulator and industry perspective	Regulatory Devices	Parkside 2
	A22. Regulatory update from New Zealand and MedSafe	Prescriptions Medicines Regulation	Pyrmont Theatre
	A24. Plant medicinal: From traditional use to prescription	Non-prescription Medicines Regulatory	C2.5+C2.6
	A25. Product development strategy: From bright idea to commercial success (continued)	Entrepreneurship, Innovation & Commercialisation	Parkside 1
5:15 – 6:15	Welcome Reception		Exhibition Hall

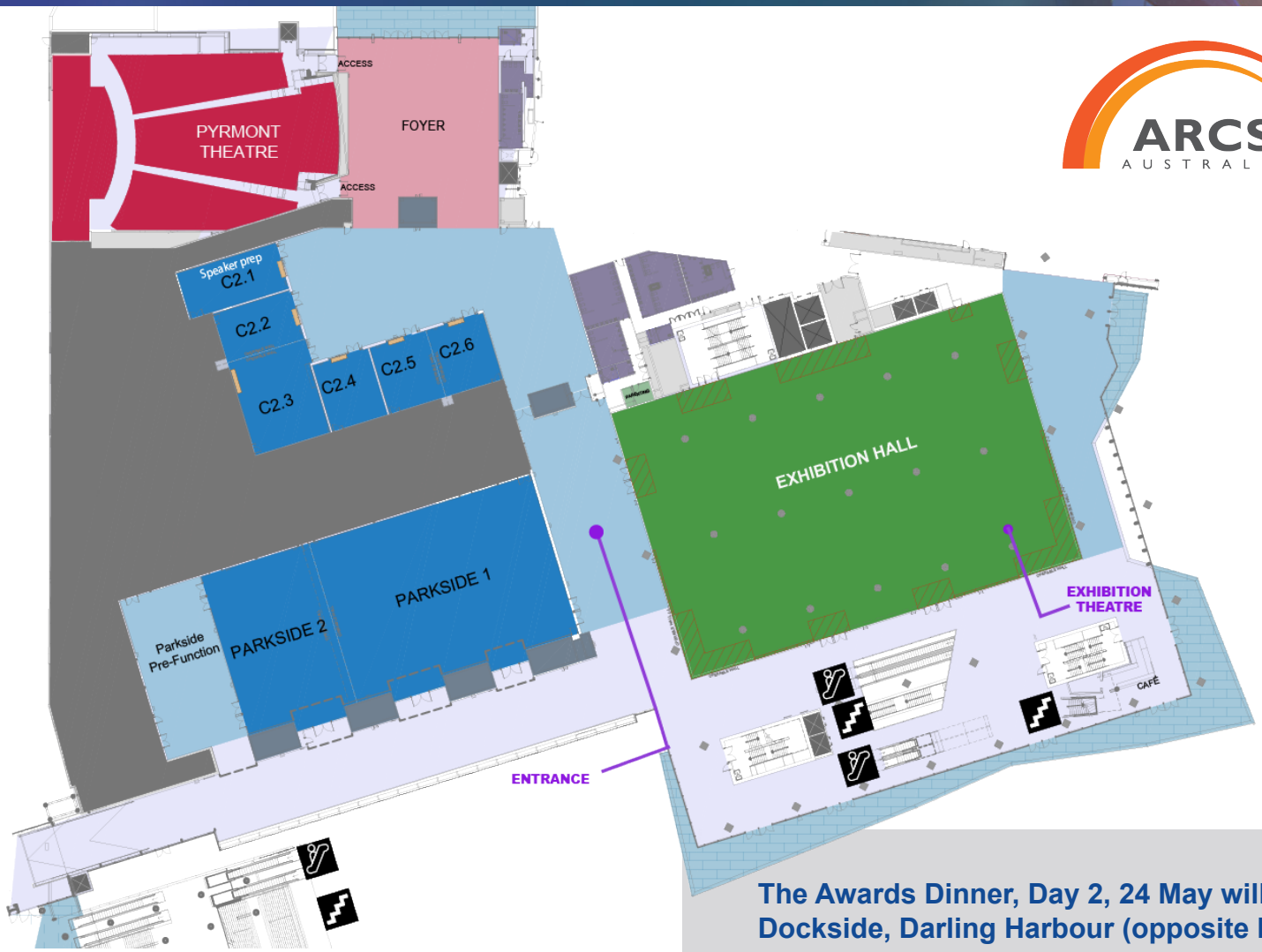
Day 2: 24 May 2022 program

2022 ARCS ANNUAL CONFERENCE

Time	Session Title	Session Stream	Room
8:45 – 10:30	**B01:** New Frontiers: Delivering better health for all Australians		Pyrmont Theatre
10:30 – 11:15	Morning Tea		Exhibition Hall
10:40 – 11:10	**D03.** Managing Australian specific data requirements for reimbursement and market access strategies		Exhibition Theatre
11:15 – 12:15	**B02.** Launch of the National Clinical Trials Governance Framework and national initiatives	Clinical Research General	Parkside 1
	B03. Real World Evidence in the regulatory context for medical devices	Regulatory Devices	Parkside 2
	B04. National Medicines Policy update	Medicine Reimbursement	Pyrmont Theatre
	B05. Opportunities and challenges of running intra-tumoral injectable early phase clinical trials with focus on genetically modified organisms trial treatment	R&D Innovations	C2.5+C2.6
	B06. Spotlight on advanced therapeutics in NSW	Medical Affairs / MSL	C2.4
12:15 – 1:30	Lunch		Exhibition Hall
12:45 – 1:15	**D04.** The Strategic Agreement and the future of Australian medicines access		Exhibition Theatre
1:30 – 12:30	**B09.** Launch of the National Clinical Trials Governance Framework and national initiatives (continued)	Clinical Research General	Parkside 1
	B10. EU-MDR: Emerging issues	Regulatory Devices	Parkside 2
	B11. Update from the Prescription Medicines Branch of the TGA	Prescription Medicines Regulation	Pyrmont Theatre
	B12. Timely access of medicine: Research insights and strategies	Medicine Reimbursement	C2.5+C2.6
	B13. Leading in a hybrid work environment	Leadership, Wellness & Resilience	C2.4
	B14. Translational medicine: Genomics and clinical trials	R&D Innovations	C2.3
	B15. Transferable skills: What can clinical research and regulatory associate experiences bring to medical affairs?	Medical Affairs / MSL	C2.2
2:30 – 2:45	Session change over		
2:45 – 3:45	**B16.** Clinical research round up: What's new in 2022	Clinical Research General	Parkside 1
	B17. Post-market surveillance – Considerations for sponsors of medical devices and diagnostic products in Australia and beyond	Regulatory Devices	Parkside 2
	B18. Facilitated regulatory pathways	Prescription Medicines Regulation	Pyrmont Theatre
	B19. From HTA to healthcare sustainability	Medicine Reimbursement	C2.5+C2.6
	B20. A model to build trust and healthy influence	Leadership, Wellness & Resilience	C2.3
	B21. Translational Medicine: Policies and regulations to support innovation	R&D Innovations	C2.4
	B22. Promoting best practice amongst infield medical affairs personnel: An Australian perspective	Medical Affairs / MSL	C2.2
3:45 – 4:30	Afternoon Tea		Exhibition Hall
4:30 – 5:30	**B23.** Clinical research round up: What's new in 2022 (continued)	Clinical Research General	Parkside 1
	B24. EU-MDR: Emerging issues (continued)	Regulatory Devices	C2.5+C2.6
	B25. Facilitated regulatory pathways (continued)	Regulation of medical devices	Pyrmont Theatre
	B26. The evolving role of Real World Evidence in supporting access to medicines	Medicine Reimbursement	Parkside 2
	B27. Connecting people to strategy in a corridor conversations	Leadership, Wellness & Resilience	C2.3
	B28. Spotlight on medical device trials and theranostics research	R&D Innovations	C2.4
	B29. The critical role medical affairs plays during early product development	Medical Affairs / MSL	C2.2
5:30 – 6:30	Networking Function		Exhibition Hall
6:30 – 9:30	Awards Dinner		Dockside, Darling Harbour

Day 3: 25 May 2022 program

Time	Session Title	Session Stream	Room
8:45 – 10:30	**C01.** Enabling true patient centricity through Real World Evidence		Pyrmont Theatre
10:30 – 11:15	Morning Tea		Exhibiton Hall
10:40 – 11:10	**D06.** Decentralised clinical trials, telemedicine, and home monitoring		Exhibiton Theatre
11:15 – 12:15	**C02.** Remote monitoring: Working toward a new normal	Clinical Research Operations	Parkside 2
	C03. Innovations in trial design (rapid fire session)	Clinical Research Operations	C2.5+C2.6
	C04. Lessons learnt implementing site electronic systems in clinical research	Data,Technology & Informatics in Clinical	C2.3
	C05. Significant safety issue reporting: Changes to the pharmacovigilance guidelines for sponsors	Pharmacovigilance	Parkside 1
	C06. Update on Prostheses List reform: Implications for consumers, hospitals and industry	Medical Device Reimbursement	C2.4
	C07. Trial and site optimisation (rapid fire session)	General Interest	C2.2
	S01. Introduction to the MTP sector and career pathways	Careers and the MTP sector	Exhibiton Theatre
12:15 – 1:30	Lunch		Exhibiton Hall
12:45 – 1:15	**D07.** Transform your clinical trials with the Veeva Digital Trials Platform		Exhibiton Theatre
1:30 – 2:30	**C08.** Trial and site optimisation (rapid fire session)	Clinical Research Operations	Parkside 2
	C09. Future-proof yourself: What's here to stay post-COVID for site audits and regulatory inspections?	Clinical Research Operations	C2.3
	C10. eSolutions - implementing change	Data,Technology & Informatics in Clinical	C2.5+C2.6
	C11. Medicine and vaccine adverse event reporting and data: Now and into the future	Pharmacovigilance	Parkside 1
	C12. Update on Prostheses List reform: Implications for consumers, hospitals and industry (continued)	Medical Devices Reimbursement	C2.4
	C13. Addressing workforce capacity and capability in the MTP sector	General Interest	C2.2
	S02. Introduction to the MTP sector and career pathways (continued)	Careers and the MTP sector	Exhibiton Theatre
2:30 – 2:45	Session change over		
2:45 – 3:45	**C14.** Your teletrial roadtrip	Clinical Research Operations	Parkside 2
	C15. Injury in clinical trials: Can we handle this better?	Clinical Research Operations	C2.5+C2.6
	C16. The QPPV: An Australian perspective	Pharmacovigilance	Parkside 1
	C17. Bridging the gap: A practical discussion on evidence requirements for MSAC applications	Medical Devices Reimbursement	C2.3
	C18. Addressing workforce capacity and capability in the MTP sector (continued)	General Interest	C2.2
	S03. Making the move: Putting your best foot forward!	Careers and the MTP sector	Exhibiton Theatre
3:45 – 4:15	Afternoon Tea		Exhibiton Hall
4:15 – 5:15	**C20.** Connecting and progressing teletrials in Australia	Clinical Research Operations	Parkside 2
	C21. Prêt-à-porter eRegulation and governance	Clinical Research Operations	C2.3
	C22. New technologies enabling clinical trials (rapid fire session)	Data, Technology & Informatics in Clinical	Parkside 1
	C23. Assessing exposures to medicines during pregnancy: An evolving landscape	Pharmacovigilance	Pyrmont Theatre
	C24. Medical technologies innovation and healthcare sustainability	Medical Devices Reimbursement	C2.4
	C25. The InFORMed project workshop: Redesigning consent to research – HAVE YOUR SAY!	General Interest	C2.5+C2.6
	S04. Why it all really matters	Careers and the MTP Sector	C2.2
5:15 – 6:30	Closing Reception		Pyrmont Theatre Foyer



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The Awards Dinner, Day 2, 24 May will be at Dockside, Darling Harbour (opposite ICC)

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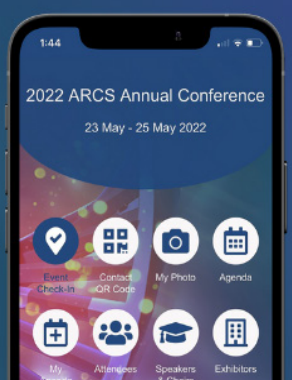

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