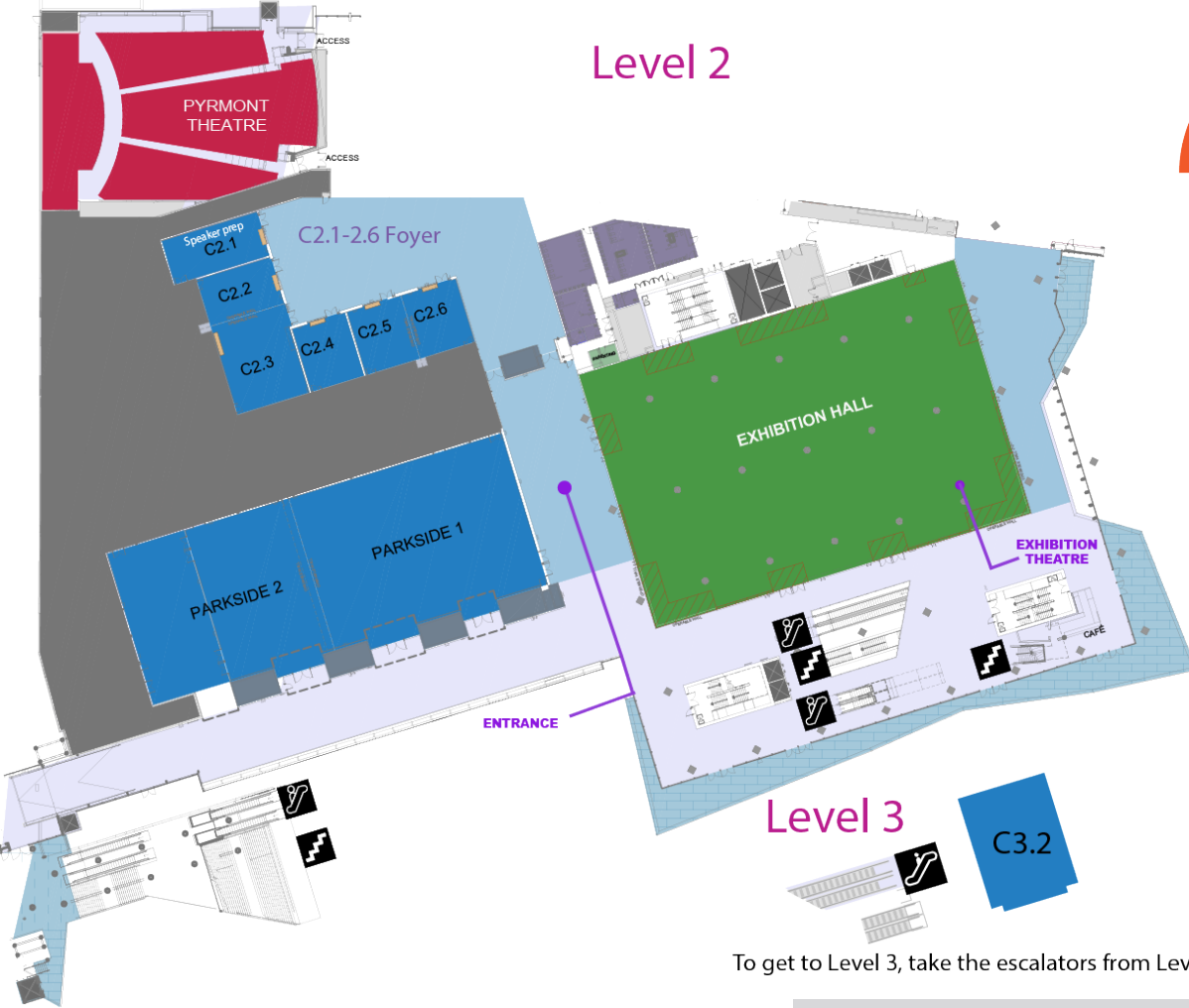| Time	Session Title	Session Stream	Room
8:45 – 10:30	**A01.** Better patient outcomes: Do we need a new approach to regulatory decisions for emerging technologies across the product life?	Plenary Session	Pyrmont Theatre
10:30 – 11:15	Morning Tea		Exhibition Hall
10:40 – 11:10	**D01.** Building capabilities in senior leaders		Exhibition Theatre
11:15 – 12:15	**A02.** Critical thinking in GMP	GMP/Manufacturing	C2.4
	A03. GMP clearance for regulatory professionals	Prescription Medicines Regulation	Pyrmont Theatre
	A04. Update from the Complementary and Over the Counter Medicines Branch at TGA	Non-Prescription Medicine Regulatory	C2.5+C2.6
	A05. Appealing TGA decisions & navigating Section 60 Reviews for devices and medicines	Regulatory Medicines and Devices	Parkside 2
	A06. Practical implementation of IVDR and its impact in Australia	Regulatory Devices	C3.2
	A07. Effective medical information communication	Medical Information	Parkside 1
	A08. How to build strategic and value-based partnerships	Leadership, Wellness & Resilience	C2.2+C2.3
12:15 – 1:30	Lunch		Exhibition Hall
12:45 – 1:15	**D02.** The road to professionalism		Exhibition Theatre
1:30 – 2:30	**A09.** Update from the TGA Manufacturing Quality Branch	GMP/Manufacturing	Parkside 1
	A10. An update on the regulation of gene therapies in Australia	Prescription Medicines Regulation	C2.2+C2.3
	A11. Real-World Evidence and permitted indications of complementary medicines	Non-Prescription Medicine Regulation	C2.4
	A12. Prescription medicines sector update	Regulatory Medicines	Pyrmont Theatre
	A13. Overseas device registration pathways	Regulatory Devices	C2.5+C2.6
	A14. Digital solutions & medical information	Medical Information	C3.2
	A15. The power of influence	Leadership, Wellness & Resilience	Parkside 2
2:30 – 2:45	Session change over		
2:45 – 3:45	**A16.** Recall reforms	GMP/Manufacturing	C2.2+C2.3
	A17. Overseas medicine registration pathways	Prescription Medicines Regulation	Pyrmont Theatre
	A18. New substance applications to vary the permissible ingredients determination	Non-Prescription Medicine Regulation	C2.4
	A19. Streamlining the development of prescription medicines: Peptides to biosimilars to GMOs	Regulatory Medicines and Devices	C2.5+C2.6
	A20. Learnings and best practices for compliance with "patient-matched" devices	Regulatory Devices	Parkside 2
	A21. The evolving medical information landscape	Medical Information	Parkside 1
	A22. Neuroscience "FISH" and the "Circle of Excellence"	Leadership, Wellness & Resilience	C3.2
3:45 – 4:15	Afternoon Tea		Exhibition Hall
4:15 – 5:15	**A23.** Good Manufacturing Practice (GMP) compliance signals	GMP/Manufacturing	Parkside 2
	A24. Overseas medicine registration pathways (continued)	Prescription Medicines Regulation	Pyrmont Theatre
	A25. Systematic literature reviews for OTC and complementary medicines	Non-Prescription Medicine Regulation	C2.5+C2.6
	A26. Emerging medical device technologies and use of real-world data	Regulatory Devices	Parkside 1
	A28. The value of medical information: Vendor implementation and partnerships	Medical Information	C3.2
	A29. A leader worth following: How to effectively lead, inspire and influence others	Leadership, Wellness & Resilience	C2.2+C2.3
5:15 – 6:15	Welcome Reception		Exhibition Hall

Time	Session Title	Session Stream	Room
8:45 – 10:30	B01: Inclusion, diversity and equity: Walking the talk & making it real	Plenary Session	Pyrmont Theatre
10:30 – 11:15	Morning Tea		Exhibition Hall
10:40 – 11:10	D03. The road to professionalism		Exhibition Theatre
11:15 – 12:15	B02. Can clinical trials be low risk in Australia and why is this question so important?	Clinical Trial Landscape	C2.2+C2.3
	B03. Emerging technologies and clinical operations	Clinical Research Operations	Pyrmont Theatre
	B04. An update on clinical evidence guidelines for medical devices	Medical Devices Regulation	C2.5+C2.6
	B05. Hot topics in perscription medicines	Prescription Medicines Regulation	Parkside 1
	B06. Update on Australia's Health Technology Assessment (HTA) review	Health Technology Assessment	C3.2
	B07. Evolution of the pharmacovigilance role	Pharmacovigilance	Parkside 2
12:15 – 1:30	Lunch		Exhibition Hall
12:45 – 1:15	D04. Strategies for the importation on unlicensed medicines into the UK		Exhibition Theatre
1:30 – 12:30	B09. Clinical research landscape wrap up (part 1)	Clinical Trial Landscape	C2.2+C2.3
	B10. Revisions to the National Statement on Ethical Condict in Human Research	Clinical Research Operations	Parkside 1
	B11. Medical devices regulatory update from TGA	Medical Devices Regulation	C2.5+C2.6
	B12. Update from the Prescription Medicines Branch of the TGA	Prescription Medicines Regulation	Pyrmont Theatre
	B13. National Medicines Policy - Where to from here?	Health Technology Assessment	C2.4
	B14. Real-World Evidence, geonomics and precision medicine: Using data to deliver the future of Australia healthcare	Access and New Technologies	C3.2
	B15. Pharmacovigilance: Australian perspectives	Pharmacovigilance	Parkside 2
2:30 – 2:45	Session change over		
2:45 – 3:45	B16. Clinical research landscape wrap up (part 2)	Clinical Trial Landscape	C2.2+C2.3
	B17. Complex study designs: Considerations for HREC, governance and trial conduct	Clinical Research Operations	Parkside 1
	B18. Use of overseas evidence to support medical device registration in Australia	Medical Devices Regulation	C2.5+C2.6
	B19. Medicine labelling: Update on the implementation of TGO91/92	Prescription Medicines Regulation	Parkside 2
	B20. Consumer involvement & HTA	Health Technology Assessment	C2.4
	B21. Managing uncertainty with faster access: Can we achieve both?	Access and New Technologies	C3.2
	B22. Pharamacovigilance update from the TGA	Pharmacovigilance	Pyrmont Theatre
3:45 – 4:30	Afternoon Tea		Exhibition Hall
3:55 – 4:25	D05. Launch of the ARCS white paper "Common Terminology for Decentralised Trials"		Exhibition Theatre
4:30 – 5:30	B23. Clinical research landscape wrap up (part 3)	Clinical Trial Landscape	Parkside 1
	B24. Updates on clinical trial inspections and the CTA scheme	Clinical Research Operations	Pyrmont Theatre
	B25. Regulatory update from the Medical Devices Survellance Branch	Medical Devices Regulation	C2.5+C2.6
	B26. Transitioning from provisional to full approval	Prescription Medicines Regulation	Parkside 2
	B27. Valuing life: Dcision-making for drugs in Australia: A retrospective analysis (2020-2022)	Health Technology Assessment	C3.2
	B28. Reimbursement & advanced therapeutics	Access and New Technologies	C2.4
	B29. Pharmacovigilance: Global perspectives	Pharmacovigilance	C2.2+C2.3
5:30 – 6:30	Networking Function		Exhibition Hall
6:30 – 9:30	Awards Dinner		Starship Cruise

Time	Session Title	Session Stream	Room
8:45 – 10:30	**C01.** Cybercrime: The new pandemic!	Plenary Session	Pyrmont Theatre
10:30 – 11:15	Morning Tea		Exhibiton Hall
10:40 – 11:10	**D06.** TriNetX, a real-world data platform and South Western Sydney Local Health District early adoption and implementation		Exhibiton Theatre
11:15 – 12:15	**C02.** Implementing new technologies in clinical trials: Your questions answered	Clinical Research Operations	Parkside 1
	C03. Improving access to clinical trials for specific population	Diversity, Inclusiveness & Consumer Engagement	Pyrmont Theatre
	C04. Initiatives, collaborations and partnerships	Clinical Workforce and Capacity	C2.5+C2.6
	C05. Start with the product: Overview and building value on your path to market	SMEs support	C2.4
	C06. Spotlight on GMO & vaccine trials	Innovation on R&D/ General Interest	Parkside 2
	C07. Closing the communication gap - Get your message accross the 1st time!	Leadership, Wellness & Resilience	C2.2+C2.3
	S01. Careers and the MTP sector (part 1)	Careers and the MTP sector	Exhibiton Theatre
12:15 – 1:30	Lunch		Exhibiton Hall
12:45 – 1:15	**D07.** How SWSLHD have embraced modern technologies to transform their clinical trials process		Exhibiton Theatre
1:30 – 2:30	**C09.** From the desk of the "Commission"	Clinical Research Operations	Parkside 1
	C10. Engaging participants throughout clinical research	Diversity, Inclusiveness & Consumer Engagement	Pyrmont Theatre
	C11. Forget the rest! Hire the best!	Clinical Workforce and Capacity	C2.4
	C12. Telling the value story: Regulatory CMC and Patients	SMEs support	C2.5+C2.6
	C13. Precision Health: Integrated Risk Score - Clinical and digital health application	Innovation on R&D/ General Interest	Parkside 2
	C14. Fearless feedback	Leadership, Wellness & Resilience	C2.2+C2.3
	S02. Careers and the MTP sector (part 2)	Careers and the MTP sector	Exhibiton Theatre
2:30 – 2:45	Session change over		
2:45 – 3:45	**C16.** Implementation of the National Clinical Trials Governance Framework	Clinical Research Operations	Pyrmont Theatre
	C17. Spotlight on early phase research and cancer patients	Diversity, Inclusiveness & Consumer Engagement	Parkside 1
	C18. Resourcing and skilling of the clinical workforce	Clinical Workforce and Capacity	C2.2+C2.3
	C19. Telling the value story: Understanding the customer	SMEs support	C2.4
	C20. Precision Health; Integration of geonomics into clinical research through empowering ethics committees to review geonomics applications	Innovation on R&D/ General Interest	C2.5+C2.6
	C21. Shaping the future of Research & Development by rebooting our communication and collaboration	Leadership, Wellness & Resilience	Parkside 2
	S03. Careers and the MTP sector (part 3)	Careers and the MTP sector	Exhibiton Theatre
3:45 – 4:15	Afternoon Tea		Exhibiton Hall
4:15 – 5:15	**C23.** Redesigning consent to research: Simplifying participant information	Clinical Research Operations	Parkside 1
	C24. Consumer involvement and co-creation: Barriers and and challenges, tools, and opportunities	Diversity, Inclusiveness & Consumer Engagement	Parkside 2
	C25. Professionalising the clinical research sector	Clinical Workforce and Capacity	C2.2+C2.3
	C26. Delivery, growth and international expansion: Access to funding and resources	SMEs support	C2.5+C2.6
	C27. This session has been left intentionally blank	Innovation on R&D/ General Interest	
	C28. This session has been left intentionally blank	Leadership, Wellness & Resilience	
	S04. Careers and the MTP sector (part 4)	Careers and the MTP Sector	C2.2
5:15 – 6:30	Closing Reception		C2.1-6 Foyer

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Level 2

PYRMONT THEATRE

ACCESS

ACCESS

Speaker prep

C2.1

C2.1-2.6 Foyer

C2.2

C2.3

C2.4

C2.5

C2.6

EXHIBITION HALL

EXHIBITION THEATRE

CAFÉ

PARKSIDE 2

PARKSIDE 1

ENTRANCE

Level 3

C3.2

To get to Level 3, take the escalators from Level 2.

The Awards Dinner on 7 June 2023 will be held on board Starship to cruise Sydney Harbour.

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