PHASE I CLINICAL TRIALS DOWN UNDER

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Nucleus Network

Supported by Victoria Government Trade and Investment Office in Tokyo, Life Science Innovation Network Japan, Inc. (LINK-J) and Australian Trade and Investment Commission (Austrade)

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Agenda

3pm	**Registration**
4pm	**Welcome and Introduction** ***Adam Cunneen, Victoria Government Trade & Investment Office in Tokyo***
4:15pm	**Phase I Clinical Trials in Australia** ***Jeffery Wong , Director of Business Development (APAC)***
	Jeffery Wong is the Director of Business Development (APAC) at Nucleus Network with 14 years of early phase clinical trials experience. His experience expands from Clinical Operations and Development as well as in Project Management. He has a Bachelors Degree in Pharmaceutical Sciences and a Masters Degree in Business and Biotechnology."
	Australia continues to be a preferred destination for companies to undertake their Phase I clinical Trials. Rapid ethics approval and a simple notification to the Therapeutic Goods Administrations means that from submission to FPFD will only take on average 6 weeks. Further to this the clinical trial application only requires the IB, Protocol and PICF with no need to prepare an IMPD or IND application. To facilitate rapid approval there are specific considerations in trial design, these will be described in the presentation along with relevant trial set up considerations. The data from the Australian study can then be used to support your IND or IMPD application allowing companies to speed up their drug development process.
4:50pm	**Phase 1 - Investigational Product Management and Regulatory** ***Dr. Jon Fairweather, Business Development / Technical Services Executive, PCI Clinical Services***
	Jon Fairweather is Business Development, Technical Services Executive at PCI Pharma Services for Australia and New Zealand. Jon is responsible for facilitating cGMP Investigational Medicinal Product supply for use in early phase clinical trials through manufacturing, packaging and storage and distribution. He has worked within PCI as Director of Projects, and prior to this has held former roles including company director, COO, BDM, CMC Manager and research scientist at various life science companies. Jon thrives on accelerating products through clinical development locally and growing these opportunities globally.
	Australia over the last 20 years has grown to become a destination of choice for the conduct of early phase clinical trials. This has been particularly the case of West Coast US pharma who have identified the specific advantages of this region. This presentation will provide an overview of the regulatory and investigational product management requirements in Australia. It will provide up to date information on the regulatory framework for clinical trials in Australia and compare and contrast this with the EU/US requirements. It will also describe the various options for investigational product management, including importing, just in time manufacture, GMP requirements for Phase I and labelling. Attendees should leave with a good understanding of the regulatory and investigational product requirements for Australia.
5:25pm	**The Cost of your Trial in Australia** ***Simone Quin, Partner, Prime Accounting and Business Advisory Services***
	Simone's experience is with fast-growing technology and scientific research companies, involved in securing and structuring funding, managing legal and taxation compliance and commercialisation to market. Simone is a distinguished alumni of a global accounting firm, and has previous government and early stage commercialisation experience before joining Prime in 2015. Simone is a registered tax agent, chartered accountant and holds a Certificate of Public Practice in Australia. In 2019 she assisted over 200 companies to benefit from the R&D tax incentive program in Australia.
	Australia's R&D tax incentive program has made Australia one of the most attractive locations in the world for companies to undertake their R&D activities. Foreign owned companies can now access the program and claim cash for amounts spent on R&D in both Australia and overseas. The R&D tax incentive refund can provide eligible applicants with a cash refund of up to 43.5% of the amount spent annually on eligible R&D activities. This presentation will explore the eligibility requirements of this program.
6 - 8pm	**Closing Remarks and Networking Event**

For more information, please email:
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