Clinical Trials Research Professionals
Clinical Professional Day

Monday 14 November 2016

Meeting Room 7
Gold Coast Convention & Exhibition Centre

08:30 – 08.45	**Registration**
08.45 – 10:15	**GCP Refresher** **Eleanor Allan, Caledonian Clinical Training** We will take a walk through the history of GCP, review investigator site personnel responsibilities as well as some interesting examples and case studies. This session will be interactive so be prepared to share your own experiences and bring your questions to this session and the next!
10:15 – 10:30	**Morning Tea**
10:30 – 12:30	**GCP in Practice** **Eleanor Allan, Caledonian Clinical Training** The focus of this session will be on recent updates to GCP guidelines (expected release November 2016). We will apply the updates to case scenarios and discuss your own real-life challenges. Time will be available for group discussion so bring your own challenging issues for a solution-focussed discussion in the context of GCP. These GCP Refresher sessions meet TransCelerate training criteria, attendees who complete the sessions will receive a certificate that is valid for 3 years.
12:30 – 13:30 **13.00 – 13.30**	**Lunch** **COSA Clinical Trials Research Professionals Group Annual General Meeting**
13.30 – 15:15	**Update on Immunotherapy Treatment in Clinical Trials** **Dr Matthew Chan, Gosford Hospital and** **A/Professor Rina Hui, Westmead Hospital** There has been tremendous progress in the field of cancer immunotherapy as it has moved recently into the mainstream for the treatment of many cancers. During this session Dr Matthew Chan and A/Prof Rina Hui will present an overview of current progress through local and international clinical trials, lessons learned and future prospects for cancer immunotherapy. There will be a focus on interesting case studies and there will be time for questions and further discussion with the presenters.
15:15 – 15:30	**Afternoon Tea**
15:30 – 17:00	**Risk-Based Monitoring – Application and implementation** **Elizabeth Wilson, Sites Relationship Manager ANZ, Quintiles, Brisbane** Risk-Based Monitoring (RBM) is increasingly gaining momentum. This approach to monitoring is supported by regulatory authorities and represents a significant change in the way clinical studies are monitored. We will explore the impact on the role of site staff and trial sponsors and, in particular, review the implementation status of RBM in Australia and New Zealand and available tools and guidelines.

Registration fee: $50 for COSA ASM registered delegates
$150 for non-COSA ASM registered delegates

For delegates attending the COSA ASM you can select to attend a workshop as an add-on during the registration process or by logging back on to your registration profile as a returning delegate. Click here to register or log in to your profile. Not going to the conference but wanting to attend this workshop? Click here to arrange.

[Draft program as at 27 October 2016. Subject to change]

Speaker and facilitator biographies

Ms Eleanor Allan

Following graduation from the University of Aberdeen with an honours degree in Microbiology, Eleanor commenced work in the pharmaceutical industry and has worked in both pre-clinical drug development and clinical research roles since 1986. For the past twenty years she has specialised in clinical research training and clinical trials auditing. In October of 2000 she set up her own consultancy business, Caledonian Clinical Training, focusing on process improvement and quality management. She has trained and audited diverse groups including Sponsors, CROs, investigators, study coordinators, academic research groups and ethics committees both in Asia and Australia.

A/Prof Rina Hui

A/Prof Rina Hui, MBBS FRACP PhD, is a senior medical oncologist at the Crown Princess Mary Cancer Centre, Westmead Hospital, Sydney, Australia and Clinical Associate Professor at the University of Sydney. After completing her medical degree at University of Sydney and specialist training at Royal North Shore Hospital, Rina undertook translational research in breast cancer at the Garvan Institute of Medical Research and received her PhD in 1999. Rina currently serves on the written examination committee for the Royal Australasian College of Physicians. Her main clinical interests are lung and breast cancers. She is the founding Coordinator of the Western Sydney Lung Cancer Service, a member of the Australasian Lung Cancer Trials Group and the Australia and New Zealand Breast Cancer Trials Group. Rina is principal investigator on many clinical trials in lung and breast cancers, including phase I, II and III immunotherapy clinical studies in non-small cell lung cancer, HER2 positive and triple negative breast cancer.

Dr Matthew Chan

Dr Matthew Chan is currently a Staff Specialist in Medical Oncology at the Central Coast Cancer Centre, Gosford Hospital; Conjoint Lecturer at the University of Newcastle; and Honorary Associate at the NHMRC Clinical Trials Centre, University of Sydney. He completed his Advanced Training in Medical Oncology within the Sydney West Cancer Network (Crown Princess Mary Cancer Centre (CPMCC), Nepean Cancer Care Centre, Blacktown Oncology Unit) and was awarded his FRACP in 2013. He has previously worked as a Clinical Research Fellow with the Australasian GastroIntestinal Trials Group (AGITG) and the Australasian Lung Cancer Trials Group (ALTG) through the NHMRC Clinical Trials Centre, as well as a Clinical Trials Fellow at the Crown Princess Mary Cancer Centre, Westmead Hospital where he was involved with the phase 1, 2 and 3 studies of immune checkpoint inhibitors and molecularly targeted therapies. He has also completed a Masters of Clinical Trials Research through the University of Sydney in 2013. Matthew is currently a Principal Investigator and Sub-Investigator on both pharmaceutically sponsored and collaborative group sponsored phase 1b, 2, and 3 clinical trials at Gosford Hospital. He is proud to work in association with the dedicated Cancer Clinical Trials team at the Central Coast Local Health District who were presented with the Innovations in Cancer Clinical Trials Award at the NSW Premier's Awards for Outstanding Cancer Research this year.

Ms Elizabeth Wilson

Elizabeth worked initially in hospital and retail pharmacy roles before moving to the pharmaceuticals industry and worked in various clinical development and management roles with Agenix Ltd, Progen Pharmaceuticals Industries Ltd and Quintiles. Elizabeth is currently the Australia and New Zealand Sites Relationship Manager for Quintiles. Quintiles Transnational is a Fortune 500 company and the world's largest provider of biopharmaceutical development and commercial outsourcing services, with a network of more than 32,000 employees conducting business in approximately 100 countries. Elizabeth completed her degree in Pharmacy (University of Queensland) and has Post Graduate qualifications in clinical pharmacy. She has spent many years focusing on clinical hospital pharmacy and drug development particularly in the area of Clinical Cancer Services for both paediatric and adult patients. Her main focus in her current role is to work in clinical trials with sponsors and sites to help bring new pharmaceutical product entities to patients within Australia and New Zealand.