Clinical Professional Day Workshop Report

Risk-Based Monitoring and GCP Coordinators Training Workshop
Monday 16th November 2015

Hosted by the:
COSA Clinical Trials Research Professionals Group

The Clinical Trials Research Professionals Group coordinated a Clinical Professional Day (CPD) workshop for COSA members on Monday 16th November prior to the COSA Annual Scientific Meeting in Hobart. The workshop, entitled **Risk-Based Monitoring and GCP Coordinators Training Workshop** was very well attended. The CTRPG Executive is grateful for the funding awarded by COSA to support the CPD and for the contribution of two very experienced and enthusiastic trainers who facilitated the workshop.

During the morning session Elizabeth Wilson, Sites Relationship Manager from Quintiles presented an overview of the key principles for risk-based monitoring, which is changing the way clinical trials are conducted. During this session participants learned that this approach is supported by regulatory authorities and applies risk management principles to the planning, design and oversight of clinical trials. Trial sponsors are moving to a centralised monitoring process which utilises electronic systems, and away from the traditional reliance on costly data monitoring visits on-site. It is now possible for sponsors to gather data on performance across trial sites in real time and apply monitoring and medical review processes that are tailored to the trial and which focus oversight activities on preventing or mitigating risks to data quality, subject protection and trial integrity.

Workshop participants gained insight into how risk-based monitoring is currently being implemented by trial sponsors and factors that should be considered when trial feasibility is assessed, budgets are developed, and staff training is provided to support participation in trials at site level. It was acknowledged that research units may need to update their standard operating procedures to incorporate the risk-based monitoring process and should continue to work closely with industry and collaborative group trial sponsors to ensure process improvements are achieved.

Angela Giagodi, the Director of Creative Touch Coaching and Training, then presented a refresher on Good Clinical Practice which, as promised was fun and interactive. Angela began the session with an overview of the history of GCP. A number of case scenarios were presented which led to some innovative discussion on possible solutions to common challenges that arise in oncology trial management. Many of the participants shared their prior experiences as they worked through site, investigator and sponsor responsibilities in the context of GCP. Angela employed innovative training techniques and tools to help workshop participants focus on how to ensure compliance with GCP, to identify and avoid unnecessary activities and to work more efficiently with trial sponsors.

Evaluation

The workshop was attended by 25 people from clinical research units and collaborative research groups throughout Australia. Interaction was encouraged by the use of varied training techniques and all participants were able to contribute throughout the day. At the end of the workshop participants were invited to give feedback and to note whether they intended to implement any of the tools or information provided during the sessions at their workplaces. A clear majority of the respondents 'strongly agreed" (highest ranking) that the workshop was well organised, that the content met their expectations and the materials and activities were relevant and helpful. All the feedback received was positive, comments included: "quizzes were effective and fun"; "GCP refresher helpful"; "interaction and case scenarios were fun"; "practical implications of RBM interesting"; "environment relaxed and collaborative"; "gained ideas for process improvements"; and, interest was expressed in receiving further updates on the status of "risk-based monitoring implementation".

Conclusion

The workshop provided a valuable opportunity for the CTRPG Executive to meet COSA members and to convey the aims of our Group which are to achieve and promote excellence in clinical cancer research through education, the provision of relevant information, training and leadership. There is a well-recognised need to improve the efficiency of clinical trial processes in Australia, particularly for investigator initiated studies. Our workshop achieved its stated objectives and the feedback received indicates our members would appreciate an update on the implementation of risk-based monitoring, which the CTRPG Executive is keen to facilitate during 2016.

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