Clinical Trials and How to Support Them: An Awareness Session for Staff Working in Research-Active Healthcare Organisations

Duration: 1-hour interactive session with Q&A plus review of optional course resources.

Description: The Australian Commission on Safety and Quality's National Clinical Trials Governance Framework (NCTGF) seeks to embed clinical trials into the core fabric of health service provision.

This session supports the implementation of the NCTGF by raising awareness of clinical trials among the health workforce. A workforce that is adequately informed about clinical trials will help improve the safety and quality of trials, ultimately accelerating the generation of high-quality evidence that informs care and service delivery.

Who should attend: The session is relevant to 'non-trial' personnel with roles that may impact an organisation's clinical trial services, including ward staff, outpatient staff, service department managers and admin/logistics/clerical staff.

The session will also serve as Good Clinical Practice (GCP) training for staff carrying out trial-related activities within their *usual care competencies*.[1] Such 'GCP Lite' training is recommended in the forthcoming revision of ICH GCP.[2]

Session objectives:

- Improve awareness of clinical trials and the benefits that trials bring to the healthcare organisation and its patients.
- Improve awareness of the research office and its role.
- Provide an overview of aspects of the trial regulatory framework that staff with patient contact should know (e.g. adverse event notification/good documentation practice).
- Ensure that clinical trials are considered in relevant organisational service provision (e.g. validation of computerised systems).

Certification: Attendees will receive a certificate of attendance upon course completion.

[1]. An activity that a person is competent to carry out (e.g., through current staff training/experience and facilities), even if this activity is not carried out in quite the same way and/or at the same point in the care pathway as if the study had not taken place.

[2] 'Trial-related training to persons assisting in the trial should correspond to what is necessary to enable them to fulfil their delegated trial activities that go beyond their usual training and experience'. (ICH E6 R3 draft May 23)

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