Who does what in a clinical trial?

For a clinical trial to be conducted effectively and efficiently, it is desirable to establish a number of committees to oversee different components of the study conduct. Key committees would include

- a trial management or steering committee (TMC)
- an independent data safety monitoring committee (IDSMC)
- an outcomes assessment committee

### Trial Management or Steering Committee

This committee would comprise the principal investigator, key clinicians who have contributed to the protocol development or who may also be recruiting into the study. Other members include the study statistician and the trial coordinator. The function of this committee would include

- assisting in the development of (and approve) the final protocol and any ongoing amendments
- monitoring the progress of the trial with respect to: recruitment; treatment delivery; protocol violation; completeness of data; site specific issues (e.g. ethnic requirements)
- reviewing and monitoring the study specifically in relation to the overall safety of treatment (toxicity profiles etc) and any serious adverse events
- if interim analyses (safety and efficacy) are called for in the protocol, advising on the nature and extent of data to be collected and analysed
- if appropriate, considering and acting on recommendations of the IDSMC and ethics committees
- providing a plan for study completion – presentation, manuscripts, etc
- reviewing abstracts and publications
- developing the terms of reference for the IDMC with respect to the study

### Independent Safety Data and Monitoring Committee (IDSMC)

This committee should comprise of at least 2 key members with expertise in the disease under investigation and a biostatistician (or if appropriate, a clinical epidemiologist). Other key members might include clinical or biological experts in clinical areas closely allied to the study question (e.g. geneticist, cardiologist, surgeon, etc)

#### Responsibilities

- conduct independent review of safety
- assess the impact of safety and efficacy information from similar emerging studies of the indication and intervention
- review the recruitment and trial quality with respect to
  - number of subjects accrued
  - the number and timing of outcome and safety assessments
  - The potential for study quality to be compromised by delinquent sites, protocol violations and clinical practices
  - The degree of unblinding (in a blinded study)
  - The ability of the study to achieve its stated objective
- make decisions according to sound scientific principles regarding the termination, modification or continuation of the study. This may include changes to the treatment regimen or delivery, study design frequency of assessment or further interim analyses.
- make recommendations to the TMC on the results of the deliberation of the IDSMC.
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Outcomes Assessment Committee
This group would comprise at least three members with clinical or scientific expertises in assessment of the study outcomes (tumour response, stroke, MI, pain, cosmesis, etc)

Responsibilities
- adjudication of primary outcomes (events) blinded (where possible) to treatment received
- resolve any uncertainties in the classification of events
- review the secondary outcomes as required
- document procedures and algorithms for classification of outcomes

Statistical monitoring of the trial includes
- tracking forms completion against what would be expected to be completed
- reviewing discrepancies in data capture (aberrant values, distribution of measurements)
- monitoring data delinquency, unblinding rates and timeliness of outcome assessments
- monitoring the safety of the study including toxicity, serious adverse events and protocol violation.

Study (Trial) Coordinating Centre
This centre includes staff responsible for the study conduct. This may be either a central site or comprise staff located at different institutions (different clinical areas).

Responsibilities include
- registration and/or randomisation of patients
- ensuring adequate supply of treatment and/or re-supply as necessary
- collection and processing of data forms
- data entry and query resolutions
- liaising with laboratories and pharmacies to ensure timely treatment distribution of clinical results
- feedback to sites regarding data and trial quality
- training and monitoring of study procedures (adherence to protocol, etc)
- provisions of study materials and study updates (newsletters etc)

Contact the Outreach team (trials@ctc.usyd.edu.au) or go to the CTC website (www.ctc.usyd.edu.au/our-research/ctc-outreach.aspx) for further advice.