



5 thoughts on early phase trials

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Patients accrual is a challenge

- Patients don't register when you want them
- If the DLT window is long and several patients arrive close together, not much information to inform dose decision

Active input from all PIs

- Dose decisions are the responsibility of all PIs
- TCs to decide dose are frequent
- Generally, set up weekly and cancel if not needed

Every time a patient is recruited, a dose decision is needed

Results known throughout trial

- Primary outcome is the MTD
- Every time a patient is recruited, best estimate of MTD calculated
- So primary analysis carried out many times during the trial
- Safety data also scrutinised

Statistically intensive

- Model-based designs are statistically intensive
- Statistician needed on demand each time a patient is recruited
- Each design is unique, but scope for off-the shelf designs

Quick data entry

- Each dose decision is based on all previous patients information
- Data needs to be entered quickly
- But also, accept data verbally over the phone

