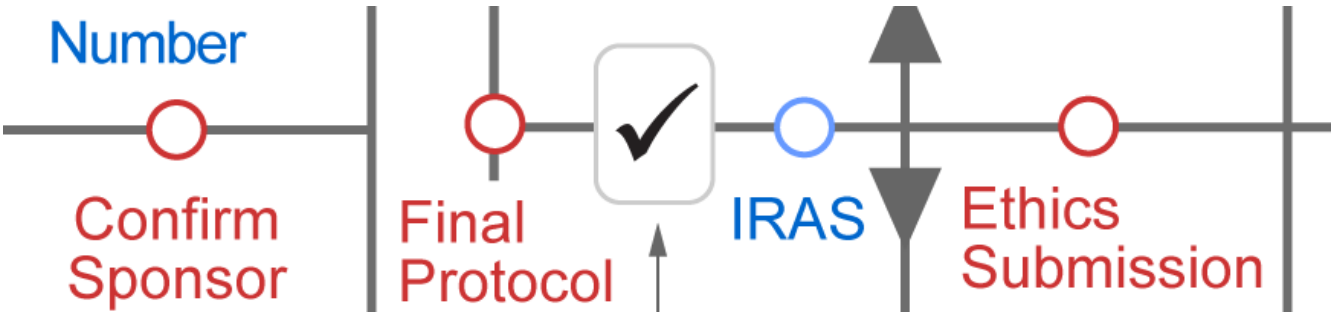
Routemap

CI Checklist Before Seeking Approval



Trial Planning Phase

The following checklist for Chief Investigators has been designed as a means of checking that the necessary documentation required for the permissions and approvals process are in place. This occurs after the Final Protocol and precedes IRAS. The Chief Investigator Checklist Before Seeking Approval is a standard process which is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Chief Investigator Checklist (before seeking approvals)

- Sponsor(s) identified and agreements for allocation / delegation of responsibilities (if necessary) are in place
- Arrangements for appropriate Patient and Public Involvement
- Input from a statistician secured
- Peer review complete
- Arrangements for a data monitoring committee, steering group and/or management group in place (with consent from members)
- Trial risk assessment carried out, trial management systems and monitoring plan/arrangements in place
- Funding secured

- Trial Registration (before the first participant is recruited and no later than six weeks after)
- R&D and local NHS support departments (e.g., pharmacy, labs, radiology etc) consulted and capacity available
- Contracts and agreements in place including third party agreements where outsourcing of any trial specific test/services is required
- Insurance and indemnity arrangements in place (non-NHS)
- CVs of investigators (signed and dated)
- Arrangements for trial supplies in place
- Arrangements for pharmacovigilance considered
- Systems in place to ensure trial will be conducted to the principles of GCP and Clinical Trials Regulations
- Trial Master File established
- Protocol and associated documents (see relevant stations):
    - End of trial defined
    - Safety reporting section of the protocol outlining definitions and reporting requirements
    - All written information provided to/viewed by subjects (e.g. Participant information sheets, consent forms, patient diaries, recruitment advertisements) finalised and version controlled
    - All other relevant trial documentation finalised, and version controlled e.g. questionnaires, case report forms, trial specific SOPs
    - Investigator's brochure or Summary of Product Characteristics (or equivalent) developed/identified.