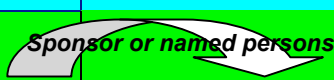


Summary of responsibilities of sponsors, persons named as responsible for GCP, and investigators in a clinical trial under the UK Regulations implementing EU Directive 2001/20/EC

Key points

- Directive 2001/20/EC defines a sponsor as an *individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial*;
- A group could take on the roles and responsibilities of sponsorship¹.
- The parties to a group could agree in writing to allocate these roles and responsibilities to particular persons and organisations; and each party would then be responsible for the roles and responsibilities it takes on.
- Sponsors could also delegate responsibilities for which they remain ultimately responsible.
- Before initiating a trial, the sponsor should define, establish and allocate all trial-related duties and functions. The trial protocol would include a scheme of allocation and delegation.
- The diagram shows how the UK Regulations would enable a group requesting a Clinical Trial Authorisation to allocate responsibilities of sponsorship in three sets: authorisation; GCP; and pharmacovigilance.

The UK Regulations would enable allocation of sponsorship responsibilities		
Sponsorship responsibilities could be allocated in three sets: authorisation; GCP and conduct; and pharmacovigilance.	Clinical Trial Authorisations (CTA) could name persons (other than sponsors) responsible for duties relating to GCP and conduct of the trial.	These investigator responsibilities correspond to the sets of sponsorship responsibilities.
Authorisation Request CTA Allow inspection Notify CTA amendments Notify protocol amendments Notify end of trial		Request ethical review of the protocol
GCP and conduct GCP arrangements IMPs free of charge Urgent safety measures	 <i>Sponsor or named persons</i>	Obtain consent Urgent safety measures
Pharmacovigilance Record adverse events Record/report SUSARS Tell investigators of SUSARS Enter SUSARS on EMEA database Annual list, safety report		Report SUSARs to sponsor Report other adverse events according to protocol Supply information on deaths

¹ Among other possibilities, the investigator may take on sponsorship responsibilities