



Division of Responsibilities Guidance Notes

Division of Responsibilities (DoR)

The aim of this document is to outline the duties undertaken in a clinical trial. It allows for the Sponsor, CI, CTU and third parties to clarify who will be responsible for specific duties. Once signed it is an agreement between the Chief Investigator, Clinical Trials Unit and Sponsor on who is responsible for each duty.

The following is a guidance sheet of things to think about when completing the Division of Responsibilities.

When completing the DoR

How to complete

- The top section listing, date of document and study identifiers should be completed
- To assign a responsibility to one of the parties a 'x' should be placed in the appropriate cell
- If third parties are involved in the trial, they can be listed by adding them to appropriate column under delegated duties. In a multi-centre trial host organisation or participating site should be represented.
- Only the 'master list' tab needs to be completed
- This list of duties are not to be treated as an exhaustive list, other tasks may be involved. Suggestions on other duties to think about and add to the DoR where required can be found on the second tab 'suggested additional items'
- If additional tasks / items are added to the template these should be highlighted in red
- Three examples of DoR are available on request for reference outlining the usual division of duties that would be expected in a clinical trial and can be used as a guide. The examples are as follows:
 - One listing two responsible parties the CI and Sponsor
 - The other lists three responsible parties the CI, Sponsor and CTU
 - The third lists the CI, Sponsor, CTU and host organisation as responsible parties

Limitation / Assumptions

- The document is aimed at clinical trials but can be used for non-CTIMPs. In this case n/a should be used when sections are not applicable.
- Similarly if the study is a device trial the DoR can be modified accordingly using n/a where applicable and the items in the 'suggested additional items' tab
- Consideration should be given if this document is used when the Sponsor is not the University of Oxford.

When signing off the DoR

- The top level, subdivision, Sponsor, CI and CTU columns will be extracted and placed in a word document with signature boxes by a member of CTRG for sign off.
- Any delegated duties listed on the master list will help with contract negotiation