

Sponsor Reference Number	IRAS number	Short Title/Acronym	Chief Investigator

## Central/Trial Management Delegation of Activities

All members of staff must personally complete the DoA Log by hand and have it countersigned and dated by an appropriate and senior representative of the trial management function<sup>1</sup> (^this will also act as the start date – no research-related activities should be undertaken prior to this date). All relevant training must be completed **before** they undertake any activities. The original copy of this log must be retained within the Trial Master File.

The log must be maintained prospectively and should be reviewed regularly for completeness and accuracy. End dates must be added as individuals cease working on the research and/or once the research has ended. If more than one page is required, the pages must be marked accordingly (e.g., Page 1 of 2).

Tables 1 and 2 should be completed once and they apply to all pages of the DoA.

**Table 1 Roles\*:** Additional roles and their abbreviation should be added to the empty boxes.

STM = Senior Trial Manager	TM = Trial Manager	TA = Trial Administrator	S = Statistician
CRA = Clinical Research Associate	DM = Database Manager	DD = Database Developer	

**Table 2 Delegated activities#:** Additional activities can be added to the empty boxes.

1 Trial Management	2 Trial Administration	3 Essential Record (i.e., TMF) maintenance	4 Protocol and document development	5 CRF Development	6 Database Development, Amendment and Maintenance
7 Data Management, Entry and Storage	8 Regulatory Approval coordination	9 Vendor Management	10 IMP Management	11 Sample Management (i.e., coordination of transfer)	12 Quality Assurance
13 Site Monitoring	14 Randomisation System Development	15 Statistical Analysis	16 Archiving	17 Pharmacovigilance	18 Data Query (raising and resolution)
19 Confirming recruitment activity (i.e., CPMS)	20 Reports (i.e., funder)	21	22	23	24
25	26	27	28	29	30

<sup>1</sup>This individual should be someone who:

- Has **direct oversight** of the trial management individual(s) and activities being delegated; and
- Can **confirm the competence, training, and suitability** of the staff performing those tasks.

Such as a Senior Trial Manager, CTU Director, or Head of Quality (or equivalent).

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