

Task Description	Record each time the task is performed				Office Use Only
	Job Title/Role within Trial	Description of Activity	Date	Time in Minutes	
Section 14 - Monitoring / Audit Visits					
14.1 Plan and prepare for monitoring and audit visit					
14.2 Collect individual patient files / notes for monitoring and audit visit					
14.3 Participate in external monitoring and audit visit (i.e. from trials centre)					
14.4 Participate in internal monitoring and audit visit (i.e. from hospitals research governance coordinator)					
14.5 Resolve queries post monitoring and audit visit (please detail routine data queries in section 17.6)					

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14.6 Update in house databases					
14.7 File study related documents					
14.8 Other related tasks					
Section 15 - Protocol Amendments					
15.1 Preparation and submissions of protocol amendments					

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15.2 Update of study documents following amendments					
15.3 Participate in in-house meetings to discuss protocol amendments					
15.4 Subsequent training following study amendments					
15.5 Review the protocol and trial arrangements during the study (study overall)					
15.6 Other related tasks:					

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Section 16 – Financial Management					
16.1 Review financial arrangements					
16.2 Raise an invoice					
16.3 Other related tasks					
Section 17 – Other Trial Administration					
17.1 Prepare / restock study packs / paperwork					

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17.2 Photocopy file / fax / post / send study documents					
17.3 Maintain site file					
17.4 Add details to databases and study logs					
17.5 Compile and send annual report (eg. local ethics, host organisation / research and development department)					

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17.6 Resolve routine data queries (please detail queries post monitoring and audit visit in section 14.5)					
17.7 Other related tasks					
Section 18 – Communication / Training relating to the trial					
18.1 Telephone (Please indicate which group the activity takes place with (Doctor, Trial Centre /Sponsor, Hospital or other)					
18.2 E-mail (Please indicate which group the activity takes place with (Doctor, Trial Centre /Sponsor, Hospital or other)					
18.3 Letter (Please indicate which group the activity takes place with (Doctor, Trial Centre /Sponsor, Hospital or other)					

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18.4 Face to face discussion (Please indicate which group the activity takes place with (Doctor, Trial Centre /Sponsor, Hospital or other)					
18.5 Training					
Section 19 - Miscellaneous					
19.1 Other tasks					