

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 1 - Protocol Evaluation					
1.1 Reading Protocol					
1.2 Initial assessment of feasibility by the research team					
1.3 In house meetings to assess feasibility of trial					
Section 2 – Preparation of submissions					
2.1 Preparation of the trial documentation and submission to ethics committee for approval					

Task Description	Record each time the task is performed				Office Use Only
	Job Title/Role within Trial	Description of Activity	Date	Time in Minutes	
2.2 Preparation of the trial documentation and submission to (e.g. Host organization / research & development department) for approval					
2.3 Preparation of the trial documentation and submission to other committees (please specify)					
2.4 Attendance / Presentation to various committees (e.g. Local ethics / research and development department)					
2.5 Completion of applications to various regulatory agencies (e.g. ARSAC)					

Task Description	Record each time the task is performed				Office Use Only
	Job Title/Role within Trial	Description of Activity	Date	Time in Minutes	
2.6 Other related tasks:					
Section 3 - Preparation of financial agreements/Clinical Trials Agreement (Contract)					
3.1 Identify and record cost variables (time, investigations, and extra medical tests and extra resources)					
3.2 Meetings with various partners for preparation of financial contracts / Clinical Trial Agreements					
3.3 Organize Clinical Trial Agreement including insurance and trial indemnity arrangements					
3.4 Other related tasks					

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 4 - Meeting and Training					
4.1 External investigator meeting					
4.2 In house meetings for information, training and activation of trial					
4.3 Organize and hold a trial setup meeting					
4.4 Other related tasks:					

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 5 - Administrative / IT preparations					
5.1 Preparation of Investigator and Trial Site File					
5.2 Collection and filing of study specific documents					
5.3 Development of study specific paperwork, (e.g. flow sheets, patient screening log, Study synopsis, source data sheets, nursing protocol, visit schedules, adverse event scoring list, tumor evaluation forms etc)					
5.4 Co-ordinate and ensure sufficient trial supplies e.g. drug supplies, CRF's, blood sampling kits)					

Task Description	Record each time the task is performed				Office Use Only
	Job Title/Role within Trial	Description of Activity	Date	Time in Minutes	
5.5 IT preparation (i.e. databases) Tracking systems, automatic patient schedule development, training for Remote Data Capture etc					
5.6 Other related tasks:					
Section 6 - Miscellaneous					
6.1 Other tasks:					