R&D Monitoring Plan for RD&E Sponsored CTIMP / Sponsored Non-IMP Drug Research / Sponsored Device Research / Sponsored Non-CTIMP

The frequency and type of monitoring visits is determined by a risk assessment of the trial. Monitoring will be undertaken by a combination of *trial oversight committees, central and on-site monitoring* (delete as applicable) and will occur at the frequency detailed below.

The interval for monitoring visits may be longer or shorter than stated, dependant on subject enrolment rate, quality issues, trial site compliance or other trial site issues.

Any significant deviation from the planned monitoring timelines will be explained and documented in the monitoring visit report and the monitoring plan, and plan amended if appropriate.

If the site does not enrol any patients or enrolment has stopped, regular monitoring visits will not be scheduled. If there is an extended gap in trial activity the Monitor will re-inspect the study to ensure that feasibility of the site is still appropriate and that site staff are appropriately trained when trial activities recommence.

MONITORING PLAN – STUDY OVERVIEW						
Study Title						
Investigator			**MREC Ref**		**R&D Ref**	
Planned number of patients			**Planned recruitment period**		**Estimated no. of sites**	
Version/ date risk assessment			**Risk Level**		**Type of study (CTIMP, device)**	
Monitor		**Start Date of Study**		**Predicted End Date of Study**		

MONITORING PLAN			
Type of Monitoring		**Responsible**	**Monitor Activity & Frequency**
Trial Oversight Committee	TMG		• *Detail frequency of meetings*
	TSC		• *Detail frequency of meetings*
	DMC		• *Detail frequency of meetings*
Initiation & Training	Site feasibility questionnaire		• *Detail when questionnaire sent out and what its used for*
	Trial initiation/ investigator training		• *Detail type of Initiation (eg meeting, teleconference etc) and any topics to be covered eg-* • *Provision of & training on site file & template documents,* • *SAE reporting, annual reporting to regulatory bodies ,* • *Issues regarding consent,* • *Discussion regarding storage of drugs.*

	Green light Procedure		• *How will other sites be allowed to proceed*
	On-going training		• *Detail any on-going training requirements (eg protocol updates, addition of new or temporary staff*
Central Monitoring (can include a copy of a central monitoring report) *Insert trial specific monitoring requirements as identified in the risk assessment.*	Frequency		• *Describe in what format will central monitoring be undertaken and frequency*
	Source Data Verification & Data Review		• *Specify key data to be checked, how it will be checked and frequency*
	Periodic review of SAE reporting		• *What is being reported and how often.* • *Indicate whether cross site checks of SAE data is being performed*
	IMP accountability		• *Indicate whether IMP accountability records are to be collected from sites & frequency this is to be done.*
	Review of eligibility prior to randomising		• *Detail eligibility checks to be performed at randomisation*
	Enhanced safety monitoring		• *Detail as applicable if other regular contact is being made eg weekly/monthly calls to sites.*
On-site Monitoring *Insert trial specific monitoring requirements as identified in the risk assessment*	Type (routine and/or triggered) & frequency		• *Indicate whether routine and/or triggered visits will be performed and define how often eg after first patient, at defined regular intervals* • *If multicentre what percentage of sites will be routinely monitored on site and rationale of how will they be picked*
	Triggers for on-site monitoring (if applicable)		• *List triggers for on-site monitoring eg protocol/GCP non-compliance, recommendation by central monitoring, recommendation TSC, TMG*
	Source Data Verification & Data Review		• *Detail list of source documentation & key data to be reviewed eg Consent Documents, Case Report Forms and Medical Records. Use of database?*
	Safety Reporting		• *Detail what checks of SAE data will be performed*
	IMP accountability		• *Detail whether visits to Pharmacy are required and what needs to be checked*
	Sample management		• *Detail whether a visit to the labs/service department is required and what checks of sample records are to be made*
	Essential docs from Site File		• *Reference any checklists to be used*

Trial Closure	Findings complete		• *Ensure all previous monitoring findings have been met.*
	CRFs complete & data verified		• *Ensure all CRFs are completed, all consent is present & filed.* • *Final review of data entered onto study database for analysis* • *SAEs have been appropriately reported & filed*
	IMP		• *All drug stock has been verified/accounted for and destroyed*
	Samples & equipment		• *Detail what will happen to samples eg destroyed* • *List any equipment that may need to be returned & how this will be verified*
	Site Files		• *Ensure all site files (including pharmacy) are ready for archiving*

This monitoring plan has been reviewed and approved by the R&D Directorate Manager

Signature: **PRINT NAME:**	**Date:**

Amendments/deviations to this monitoring plan have been reviewed and approved by the R&D Directorate Manager

MONITORING PLAN AMENDMENTS/ DEVIATIONS		
Amendment/ deviation description ***Please circle as applicable -*** ***Planned / Unplanned***		
Signature: **PRINT NAME:**		**Date:**
Amendment/ deviation description ***Please circle as applicable -*** ***Planned / Unplanned***		
Signature: **PRINT NAME:**		**Date:**