Short title	
ReDA Number	
EudraCT Number	
CI name	
Main Point of Contact	
Location of meeting	

Current visit date(s):	
Visit attendees (names/roles):	

Item	(Any item marked "No" requires a comment)	Yes	No	N/A	Comment
1.0	**STUDY DETAILS**				
1.2	Protocol discussed?				*NB this should include explanation of the study. If the protocol is about an area/specialism/ topic GCP manager and or Monitor is unfamiliar with a separate session should be arranged with the CI to ensure understanding*
1.3	Phase 1?				*Phase 1 – is this in a hospital setting? Any non-NHS sites. Consider requirement for emergency provision – Crash/999. Grab bag - troll is required. Risk assessment is required in non-NHS sites.*

1.4	Any conflict of interest? Does the CI or any other investigator / collaborator have any personal involvement (e.g. financial, sharing holding, personal relationship, in the funding, drug device, or sponsor organization that may give rise to a conflict of interest?)				*Could this impact the Intellectual property? Is the person who is doing safety evaluation have a conflict of interest? (check against question 48 on IRAS form)*
1.5	Study procedures discussed: Please specify				*Distinguish between what is standard care and what is part of the protocol. Personnel authorized to take consent.*
1.6	Study specific SOPs discussed? Please List:				
1.7	Randomization procedures in place, (if electronic system validated)?				
1.8	Any radiation / scans that are above standard care (at any sites) that will require ARSAC licenses				
1.9	Code break procedures in place, and tested (if electronic system validated)?				
1.10	Questionnaires and additional tools: Please specify				
1.11	Number of sites				*NHS and Non-NHS sites, international countries (EU and non-EU) sites*
1.12	Recruitment & participant population discussed, including feasibility of meeting targets				*Patient pathways, conflicting studies, reporting first patient consented, reporting portfolio study figures monthly to R&D.*
1.13	Healthy volunteers?				*If so consider TOPs – over volunteer register. Risk assessment of emergency provision if not in NHS Trust (including if in CTU). Will they require copy of passport and driving license to confirm ID Contact the GP to confirm medical history – as no medical records. Look at Phase 1 accredited unit guidelines as exemplar of what the MHRA look for in healthy volunteer studies.*
2.0	**IMP**				
2.1	What are the IMP/NIMPs?				
2.2	What are the vendor responsibilities?				
2.3	IMP labeling approved by sponsor pharmacists?				
2.4	Is any input into the EU required? Who?				

2.5	Technical Agreement – specialist pharmacist involved?				
2.6	Clear process for recall defective IMP?				
2.7	Who is responsible for IMP management in international sites?				
2.8	IMP supply and management discussed?				
2.9	Reference safety Information				*Specify*
2.10	Arrangement s for SMPC/IB updated				
2.11	IMP manual (site)				
2.12	IMP Management plan (co-ordination)				*Discuss storage, temperature monitoring, standard stock, ordering, and receipt. If single site are they merging IMP manual and management plan into one?*
2.13	Sponsor Pharmacy representative Final approval				*Date if given/ actions if outstanding*
3.0	**DOCUMENTATION**				
3.1	TMF present?				*Reviewed by Monitor create separate report if needed*
3.2	TMF set up incompliance with SOP45				
3.3	Version control discussed?				
3.4	Study emergency Out of Hours contact in place and tested? (Documented evidence in TMF)				
4.0	**AMENDMENTS**				
4.1	Amendments process discussed (as per JRMO SOPs)?				*Sponsorship approval, REC and MHRA, and site approval processes notifying sites of amendments,*
4.2	Discuss pending amendments				*Sponsor has authorization to withhold greenlight where substantial amendments are outstanding*
4.3	Adherence to Sponsor SOPs discussed?				
4.4	Non-conformance discussed (as per Non-				

	Conformance SOP)?				
5.0	**DELEGATION**				
5.1	Conditions of sponsorship discussed?				
5.2	Sponsor to CI delegation discussed and reviewed?				
5.3	The requirement to comply with JRMO SOPs				*Ensure that the CI and team are aware of the JRMO SOPs, the website.*
5.4	Conditions of sponsorship and delegation resigned by CI?				
5.5	CI training completed and due?				*Insert date and date of next GCP and CI refresher due dates*
5.6	CI meeting discussed				*Approximate date*
5.7	Trial unit/group specific SOPs discussed and relation to JRMO QMS? Detail unit/group:				
5.8	Sponsor has received a signed copy of the coordination delegation log				
5.9	Role of CTU discussed				*If applicable*
5.10	Role of NCCs discussed				*International studies only*
6.0	**CONTRACTS**				
6.1	Contracts checklist competed and signed?				
7.0	**SITE ACTIVATION**				
7.1	Site activation checklist agreed				
7.2	Site activation process discussed				
7.3	Source data and record keeping discussed? Detail method of source documentation:				*Creation of source documentation list needed*
7.4	SIV presentation seen or discussed				*JRMO monitor and GCP manager to be invited to Barts/Local SIV as part of sponsor oversight and monitor training*

7.5	Training Log for all site staff and expectations of site specific training				*See Training Log in SOP – Essential documents. This is NOT GCP training but protocol and trial delegated training.*
8.0	**MONITORING**				
8.1	Monitoring plan present and signed by CI and Sponsor?				*Date and version. Does the proposed monitoring seem reasonable? Look at phase of study and treatment period.*
8.2	Monitor training appropriate?				*CV and training record to be collected. Are shadowed visits planned for inexperienced monitors?*
8.3	Adequate resources and staff to perform monitoring?				
8.4	GCP inform CI's team of Sponsor's right to audit				
9.0	**PHARMACOVIGILANCE**				
9.1	Pharmacovigilance arrangements discussed? Confirmation of what constitutes day zero for reporting SAEs and SUSARs for all sites				*Specify if any change to SAE form has been agreed, discuss PV reporting for international sites (where applicable)*
9.2	AE recording				
9.3	SAE and SUSAR reporting				
9.4	24-hour unblinding (unless exceptional circumstances)				*SOP required for unblinding.*
10.0	**ANNUAL REPORTS**				
10.	Reda updated with reminders?				*Date of First DSUR :* *Date of first APR:*
10.2	Anticipated end date discussed				*Consider end of funding (see Reda), correlates with REC / R&D end dates and study feasibility*
11.0	**DATA**				
11.1	Data collection (CRF/eCRF) tools ready for use?				*Specify version and date*
11.2	Data collection (CRF/eCRF) tools signed by CI and statistician?				
11.3	Database to be used?				*Specify*

11.4	Database ready and validation paper work present?				*JRMO IT to confirm in writing*
11.5	Discussed frequency of data entry and data lock, end of trial.				
11.6	Independent review of CVS (Sponsors IT rep where relevant)				*See SOP 38*
12.0	**TRIAL COMMITTEES**				
12.1	Trial committees set up and first meeting date scheduled set as per protocol?				*List committees*
12.2	Members list and charters completed for all committees				*Draft version pending first meeting is acceptable, frequency of meetings discussed and logged by GCP team*
12.3	CVs (signed and dated) and Conflict of interest forms collected				*Pending first meeting is acceptable*
12.4	Reda updated with reminders of committee dates for the duration of study				
13.0	**LABORATORIES AND GENERAL FACILITES (e.g. imaging)**				
13.1	Details of laboratories and collection areas:				
13.2	Sample and laboratory collection SOPs in place and discussed?				
13.3	Laboratory/Pathology approval received				
13.4	Relevant material's transportation/transport discussed				*Between locations between sites and between NHS/non-NHS sites*
13.5	Supplying of kits to sites (where relevant)				*Discuss expiry dates on any kits – ensuring this is QC'd before going to site. Inclusion of this in the site agreement. Consider expiration of blood test kits.*
13.6	End of trial destruction/banking of tissue discussed				
13.7	Imaging				*Test scans for quality and PID where scans/software is study specific. Test of transfer of scan to the lead site. Check that no PID is leaving site. SOP required.*
14.0	**EQUIPMENT**				

14.1	List study specific equipment to be used, standard care and research (including medical/clinical equipment and non-medical equipment i.e. laptops & non-electronic kit)				*Multisite – will sites be provided with kit/equipment?*
14.2	Equipment storage location and custodian identified				
14.3	MHRA approval (where relevant)				
14.4	Provision of equipment discussed (loaned, gifted, bought, donated, standard care). Is the equipment standard at all sites?				*Where loaned from another department, external party, Delivery receipts, returns process (where loaned),*
14.5	Confirmation of equipment indemnity				*MIA where on loan or gifted*
14.6	Study specific SOP in place				
14.7	SOP XX of equipment and maintenance complied with?				*Standard annual maintenance checks, unless specified otherwise by Sponsor's clinical Physics representative.*
14.8	Frequency of equipment maintenance recorded by monitors				
14.9	Approved by Sponsor's clinical Physics representative?				
14.10	Research team's equipment training and frequency of training discussed				*Frequency, by whom, training logs*

Summary of actions needed		Person delegated
1		
2		
3		
4	*Please add more rows as necessary*	

Signature:
Print name
Date: