SOP 410 Appendix 2 Agenda for Site Initiation

Agenda for Site Initiation	
Protocol Title	
Protocol Number / EudraCT reference	
IRAS	
Local reference	
Principal Investigator	
Meeting Date / Start Time	

Attendees		
Name	**Role / Title**	**Representing**

	Topic	Presenter	Duration
1	Welcome and Opening Comments: 1.1 Statement of visit objectives 1.2 Review of agenda		
2	Introductions & Roles and Responsibilities *(Consider using the Delegation of Responsibilities Log to guide some of the introductions.)*		
3	Investigator Responsibilities 3.1 Good Clinical Practice (GCP) 3.2 Records Retention		
4	Protocol Overview 4.1 Type of study 4.2 Study objectives 4.3 Enrolment 4.3.1 Recruitment Screening/Consort targets 4.3.2 Plans for reporting recruitment 4.4 Informed Consent Discussion 4.5 Key inclusion/exclusion criteria 4.6 Study visit schedule/schedule of events		
5	SOPs and Study Procedures 5.1 Review / Patient pathway 5.2 Discussion of procedure for handling updates to study specific SOPs; Working Practice documents and other study specific information		
6	Safety: Definitions, Collection, and Reporting 6.1 Adverse Events (AEs) 6.2 Serious AEs (SAEs) 6.3 Unanticipated Problems: Urgent safety measures and protocol violations 6.4 Queries resulting from the above		
7	Data Collection/Source Documentation 7.1 Paper or Electronic Data Capture (eDC) CRF discussion 7.2 Source Documents (definitions of and retention of) 7.3 Query process, Data query form (template)		

8	Investigational Product (if applicable) 8.1 Description of Product 8.2 Review of Investigator Brochure (IB) or SmPC (if applicable), Reference Safety Information (RSI) 8.3 Storage 8.4 Dosing Instructions 8.5 Dispensing 8.6 Accountability 8.7 Return/Destruction Considerations 8.8 Authorisation of release		
9	Specimen Processing (if applicable) 9.1 Collection 9.2 Storage 9.3 Transport		
10	Clinical Monitoring 10.1 Contacts 10.2 Responsibilities of 10.3 Frequency (to be discussed and confirmed after site visit) 10.4 Close out procedures (see **SOP 335**)		
11	Investigator Site File Review 11.1 Structure of the File as well as Essential Documents to include- Ethics approval, NHS permission, MHRA authorisations (See **SOP 305**)		
12	Tour of Facilities (if appropriate)		
13	Closing/Review of Action Items		