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	Overview 3.1 Trial overview 3.2 Trial background 3.3 Trial outcomes		
4	Trial Documentation 4.1 Investigator Site File (ISF) 4.2 Version control 4.3 File notes 4.4 Correspondence 4.5 Training records 4.6 Delegation log 4.7 Amendments		
5	Enrolment 5.1 Inclusion/exclusion criteria 5.2 Screening log 5.3 Informed consent 5.4 Randomisation		
6	Data Collection/Source Documentation 6.1 Visit schedule 6.2 Study assessments 6.3 Source Documents 6.4 Case Report Form (CRF) completion		

7	IMP/Medical device/Intervention 7.1 Description of Product 7.2 Review of Investigator Brochure (IB) or SmPC (if applicable), Reference Safety Information (RSI) 7.3 Storage 7.4 Dosing Instructions 7.5 Dispensing 7.6 Accountability 7.7 Return/Destruction Considerations 7.8 Authorisation of release 7.9 Concomitant medication		
8	Safety: Definitions and Reporting 8.1 Adverse Events (AEs) and Serious Adverse Events (SAEs) 8.2 Safety reporting		
9	Monitoring & Audit 9.1 Monitoring: Purpose and process 9.2 Monitoring: Frequency 9.4 Audit: Purpose and process		
10	Reports & End of Trial 10.1 Annual Progress Reports 10.2 End of Study Report 10.3 Publications 10.4 Archiving		
11	Tour of Facilities (if appropriate)		
12	Closing/Review of Action Items		