To add notes, the PDF must be opened in an apropriate program that is used for PDFs (Internet explorer, Microsoft Edge and Chrome do not allow you add notes to a PDF. When opened you may then right click in one of the comments box and there should be an option to add notes.

Top Tips: Site Initiation Visit

Meeting Purpose:	**The purpose of a Site Initiation Visit (SIV) is to prepare and set up a research site to conduct a study. It ensures the investigator and site research staff are familiar with study documentation, investigational medicinal product (if applicable), administrative procedures and that they are aware of the investigators responsibilities regarding compliance with the clinical protocol and the care of study subjects. The meeting must occur prior to patient recruitment starting.**	**Comments**
Meeting Preperation:	Set a date. A mutually convenient meeting date should be agreed with the site and the sponsor which ensures as many members of the team are available to attend as possible. Remember to contact other departments that may be involved in certain procedures for the study, as you will need to either invite them to the main initiation visit or allow time for the sponsor to visit them while the sponsor is on site.	
	Invite attendees. It is mandatory for the Chief Investigator (if employed at the site), Principal Investigator and all key staff working including staff from supporting services departments on the study to attend the SIV meeting. Ensure that those invited to the meeting are familiar with the trial protocol and advise them to bring any queries with them to the meeting.	
	Disseminate agenda. A full agenda should be sent out to site prior to the meeting.	
	Prepare documentation. All essential documents should be in place prior to, or collected during, the meeting. These include but are not limited to all approvals and regulatory documentation, favourable SSI, laboratory manuals, CRF's, completed delegation logs, verification of GCP, any outstanding CV's and confirmation that capacity is in place to support the study.	
	All study supplies should have been delivered to site prior to the meeting unless pharmacy SIV takes place later.	
Meeting Format:	**Usually the meeting is run formally including a sponsor presentation. The study team should have their local issues/questions ready prior to the meeting and raise any issues that arise during the sponsor presentation. The following issues must be covered:**	
	Clinical protocol requirements:	
	•Protocol objectives and confirmation of patient numbers at site (is proof required?)	
	•Study timelines	
	•Has recruitment begun locally/nationally	
	•Inclusion/exclusion critieria	
	•Study procedures	
	•Visit schedules	
	•Reporting of protocol violations	
	•Protocol amendments	
	•Protocol deviations (reason)	
	•RT scanning/reporting	
	•Central labs/facilities	
	•Equipment and clinical kit provision and training	
	•Confirmation of patient numbers by site	
	Investigator brochure.	
	Use and maintenance of the Investigator Site File. Previously unsigned agreements will be obtained (CTA, FDA 1572, Financial Disclosures, etc).	
	Responsibilities regarding the informed consent process.	
	Subject recruitment regarding agreed target and procedures for identifying potential subjects.	
	Safety reporting.	
	Drug storage and release.	
	Requirements regarding source data verification and minimum medical record entries. A source data verification agreement form may be completed detailing where source data will be found.	
	CRF completion, study worksheets	
	Regulatory requirements.	
	The role of any special investigations or procedures used during the course of the clinical study.	
	The role of other site personnel (research nurse, SSCs, etc). A delegation of duties and authorised signatories log will be completed by all staff involved in the study. Any previously uncollected CVs will be obtained.	
	Procedures and responsibilities for delivery, storage, dispensing, accountability and collection of any IMPs (if applicable).	
	Training on IVRS (Interactive Voice Response Systems) and/or eCRFs if applicable. Consider whether training on these systems will be delivered on discs, at the investigator meeting or during the initiation. If delivered during the initiation visit, ensure that all site staff are then promptly provided with user ids and passwords. (NB: The PI should always receive training and a password on such systems if in use, as they take overall responsibility for the data entered and this is often a common audit finding if the investigator has been found never to have accessed the system). IT firewalls and access to be considered.	
	Timing and requirement for monitoring visits and any remote monitoring arrangements and requirements. Ensure contracts stipulate the correct monitoring to take place. Consideration to be given to space, allocation of nurse/PI time.	
	Finance: confirmation of payments including payments to service depts, how and when will payments be made (collection of CRF, completion of study therapy, monitoring visits and invoice sponsor), patient travel (how much, % paid, ethics approved?)	
	Requirements for audit.	
	Inspection of facilities for all departments involved.	
	A visit sign in log to be completed to record who attended the meeting	
	Review of the CRF in detail. Specify expected data entry points and ranges. Highlight acceptable completion and correction procedures and data lock timescales.	
	Visits to pharmacy may take place during the SIV, however it may be conducted nearer the time of recruitment (i.e. upon the first patient being screened if there is a few weeks between screening and randomisation)	
	If unavailable during the initiation visit, a visit should be scheduled to other internal or external facilities involved in the study, e.g. hospital or central labs, radiology, etc. Study documentation relating to this/these will be reviewed and evidence of calibration should be discussed. Additional visits may add to set up delays and should be kept to a minimum.	
Meeting follow-up:	A site initiation report should be completed by the CRA following the visit and sent to the Principal Investigator to address any queries before signatures are obtained from the PI and sponsor. Once finalised the original report should be filed in the Trial Master File and a copy filed in the investigator site file.	