

Through discussion with the sponsor, determine the following:

Yes	No	N/A		Comments/Notes
			With whom does the sponsor wish to meet? (Investigator and Coordinator should always be involved. Pharmacist and other personnel, such as technicians or phlebotomists may be involved.)	
			Which facilities and equipment or instrumentation will be observed, and is any other special equipment required? (Typically, exam rooms, drug and document storage areas, monitor work location, laboratories, or procedure rooms are visited)	
			How much time does the sponsor expect to spend on the visit?	
			Will there be a formal meeting and, if so, what is the agenda?	
			What does the sponsor require for the investigator's demonstration of adequate subject population?	

Prepare a list of questions to be addressed during the pre-study meeting, based on your review of the protocol and other documents, covering each of the following topics:

Yes	No	N/A		Comments/Notes
			Case report forms	
			Source documents required	
			Drug supplies	
			Laboratory supplies and procedures required	
			Special tests required	
			Details on specific subjects and their eligibility (from a chart review)	
			Requirements for sponsor monitoring visits	