



FEASIBILITY QUESTIONNAIRE

Received from Sponsor/CRO after Site expresses interest in a trial. We complete as much information as possible before contacting PI to assist with remaining questions. Timely turnaround (typically 24 hours) is important and can impact whether our Site is ultimately selected to conduct the trial.

INTERIM MONITOR VISITS
Throughout the trial, a monitor comes to audit charts and meet with the CRC and PI regarding trial progress. PI portion of these visits conveniently takes place at PI office



PROTOCOL/SYNOPSIS REVIEW

After signing the CDA and receiving the protocol or trial synopsis, PI is given approximately 2 days to review the information and decide if he/she is interested in the trial.

CLOSE-OUT VISIT
After all data has been collected, a monitor will come to our Site to officially close out the trial. Every trial document must be officially closed out during this visit so PI will sign a lot of paperwork. PI portion of this visit can conveniently take place at PI office.



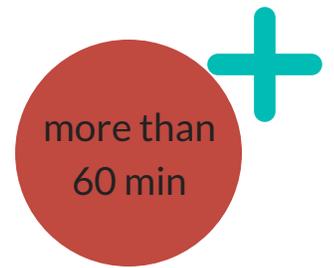
PRE-SELECTION VISIT

A monitor comes to our Site to assess if we can successfully conduct the trial. PI will meet with the monitor to discuss protocol issues. PI portion of this visit can conveniently take place at PI office,



SITE INITIATION VISIT

A monitor comes to our Site to ensure that we have the means to conduct every element of the study. This is the final visit before we can begin enrolling patients. PI portion of this visit can conveniently take place at PI office.



INVESTIGATOR'S MEETING

The purpose of this meeting is to conduct training and learn the protocol and study procedures. This meeting may take place at a remote location for one or two full days. Alternatively, it may be in the form of a one or two hour webinar.



PAPERWORK

Typical tasks include reviewing AEs and SAEs to determine causality, reviewing and signing monitor reports after monitor visits, signing IND safety reports, and lab reports. Paperwork is typically batched at the Site and delivered to the PI on a bi-weekly basis. The PI will be required to log on to an electronic database (EDC) to signoff on all data that has been entered. Depending on the trial, this can occur as frequently as once a week or as infrequently as once a trial.

PATIENT PROCEDURES

Typically, a patient physical and certain other procedures can be conducted at the research Site by our physician. The Sponsor/CRO and the trial protocol will dictate which procedures need to be conducted and by whom.



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