Clinical Research Timeline

The process of being awarded a trial and completing all study start-up elements is highly involved. Completing each element in a timely manner is of the utmost importance. Delays during start-up can cause delays in patient enrollment, making it difficult to achieve enrollment goals and collect adequate trial data.

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Initial Interest

IACT contacts Principal Investigator (PI) with a 1-2 sentence trial lead. Is the PI interested and have a patient database in the trial diagnosis? A quick reply is essential.

CDA

If PI is interested, a Confidentiality Disclosure Agreement is signed and a trial synopsis is obtained. A trial synopsis contains more information about the trial specifics and can be 1-10 pages in length.

PI Questionnaire

Inquires about PI's patient database metrics and standard of care for the diagnosis, general information about research facility and staff, and prior research experience. 1 week turnaround.

Pre-Selection Visit

If Sponsor wants to move forward with our Site, IACT sets up a Pre-Selection Visit. During this PSV, the monitor (Clinical Research Assistant/CRA) assesses the Site's ability to successfully conduct the trial.

Trial Awarded

An official letter is receiving stating that the Sponsor has chosen IACT to conduct the trial. PI must compile a list of potentially qualified patients before the Site Initiation Visit (SIV) takes place.

Final Feasibility Review

Comprehensive analysis conducted by IACT to definitely decide if we should accept the trial. Attendees include business development, regulatory, budgets and contracts, recruitment, and medical.

Budget Negotiation

The trial budget outlining specific payment structure for various trial elements is analyzed and a counter offer returned.

Investigator's Meeting

Protocol and study procedures are reviewed and training conducted. Can require PI to travel to a 1-2 day event, or it can consist of multiple hours of online training. Must be done prior to SIV.

Regulatory

IACT ensures that all Institutional Review Board (IRB) documents are signed by PI, completed and submitted. PI's timely cooperation is essential. Once IRB has approved, the SIV can be scheduled.

Initiate Recruitment Efforts

Sometime between the Final Feasibility and SIV, the PI and IACT work together to pull a list of patients that may qualify. Screening of patients should begin before enrollment opens.

Site Initiation Visit

IACT staff organizes an SIV for the Monitor to visit the Site to examine the facility and ensure that the Site has everything needed to conduct every element of the trial protocol.

Enrollment

We can begin enrolling patients in the study as soon as the investigational product is received. Completing all pre-study elements and being prepared to begin enrolling as soon as possible is essential to a trial's success.

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