Trial Development Overview

COTC Trial Development Overview

The process associated with the launch of a COTC study involves 4 distinct steps. Following the completion of a two-way confidentiality and disclosure agreement between the CCR-Comparative Oncology Program and the trial sponsor, **the Concept Discussion Phase** begins. This phase allows the sponsor to convey the obstacles that currently exist in a drug development path and then allows the COP to discuss mechanisms that may allow a comparative and integrated approach that includes pet animals with cancer to answer these questions. An essential component of these early discussions is the identification of data necessary to support the rationale for a specific study. Both the COP and the sponsor will utilize this discussion phase to determine if there are reasons to halt discussions based on feasibility or inadequate data or support. Following these initial discussion the **Trial Overview Phase** is initiated. The Trial Overview is similar to a Letter of Intent in its nature, and is drafted by both the COP and sponsor. It serves to refine the specific questions (prioritized) that are needed for progression of a development effort. It outlines a concept of a clinical trial to answer these questions and when completed is associated with a draft trial budget. Input on preliminary studies needed to launch the study and inclusion of biological endpoints to compliment a given study are received from the Comparative Oncology Trials Consortium Pharmacodynamic Core The finalized Trial Overview and the associated budget is reviewed by both the COP and sponsor. An essential part of this review is that the outcome of the study is uniquely necessary to advance the development of the therapeutic agent under consideration. Following approval of the Trial Overview, the COP will initiate the **Protocol and Data-base Build Phase**. This includes:

- development of a text version of the protocol
- completion of eCRF and monitoring process
- completion of trial SOPs
- selection of COTC sites needed/interested in the proposed study
- completion of ACUC approval steps at selected institutions
- training of COTC sites on the protocol, eCRFs and SOPs

Once completed the study is formally opened for accrual. The COP and sponsor are able to follow the progress of the trial in real-time through the web-enabled reporting system. Weekly conference calls are scheduled to discuss data as they emerge and institute protocol adjustments or modifications if needed. Following completion of the study, analysis of the data and next steps are considered. The COP and sponsor then determine what venues and mechanisms are optimal to present data to the community.