1. Pharmaceutical Collaborators are responsible for providing scientific review of the investigator-submitted LOI proposals received form the NCI and rendering a decision to the NCI on approval/dis-approval within a 60-day time-frame by submission of the drug commitment form.
2. If a proposal is approved, Clinical Investigator will develop the protocol with the Pharmaceutical Collaborator(s). The initial protocol draft as well as the final Pharmaceutical Collaborator approved version of the protocol must be provided to the NCI for NCI Formulary agent forecasting purposes.
3. Pharmaceutical Collaborator will work with NCI on agent forecasting and provision of agent supplies to NCI to support approved proposal during protocol development.
4. Pharmaceutical Collaborator provides all initial necessary agent information to NCI and throughout course of trial (e.g., IB updates, agent lot certificates of analysis, cGMP certification, stability test results) to facilitate conduct of protocol and agent distribution.
5. Pharmaceutical Collaborator provides approval of final version of protocol to Clinical Investigator and NCI and supports Cancer Center/Clinical Investigator’s IND filing by provision of cross-reference authorization for the Pharmaceutical Collaborator(s) IND or Drug Master File to the extent required for conduct of the clinical investigation.
6. Pharmaceutical Collaborator will approve all protocol amendments prior to implementation of the amendment by the Clinical Investigator.
7. Pharmaceutical Collaborator will receive clinical trial data reports and safety data from the IND sponsor.
8. Pharmaceutical collaborator will be responsible for making arrangements with the clinical sites to audit the conduct of the research and to obtain updates on ongoing clinical trials at times convenient to the clinical sites, if required.  Collaborator may also make arrangements with research sites to audit and verify raw data and source documents, at the completion of a protocol and at the collaborator’s expense, to the extent necessary to verify compliance with the federal regulations, Good Clinical Practice (GCPs) and the protocol to ultimately ensure patient safety.
9. In the event that collaborator informs the FDA of any serious and unexpected adverse events involving the Formulary Agent(s) that arise outside of the Formulary protocol, collaborator must notify the IND sponsor and DCTD at the same time.