1. Eligible investigators are to submit proposals for single-center studies to the NCI Formulary LOI Coordinator, [Cancer Therapy Evaluation Program, Protocol and Information Office](mailto:pio@ctep.nci.nih.gov). Investigators should reference the NCI Formulary agent(s) page(s) to review if any required information exists to include in the proposal submission to facilitate its review by the Pharmaceutical Collaborator(s).
2. The proposal may contain agents available from the NCI Formulary or agents from the NCI Formulary in combination with other marketed agents, or agents from the NCI Formulary in combination with other IND agents (if approved by all parties). Main member ETCTN and NCTN sites are responsible for provision of any marketed agents identified in the proposal that are not available through the NCI Formulary.
3. CTEP will forward the proposal to the NCI Formulary Pharmaceutical Collaborator(s) for review.
4. Pharmaceutical Collaborators are responsible for providing scientific review of the proposals and rendering a decision on approval/dis-approval within a 60-day time-frame.
5. If a proposal is approved by the Pharmaceutical Collaborator, the 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.
6. All required NCI standard language for NCI Formulary protocols must be incorporated into protocol document and informed consent prior to NCI acknowledging the NCI Formulary protocol is ready for activation.
7. During development of NCI Formulary protocol, Clinical Investigator will execute a NCI Formulary Material Transfer Agreement with the NCI, which outlines the institution and Clinical Investigator responsibilities for conduct of the NCI Formulary protocol.
8. Institution/Clinical Investigator will be responsible for filing an IND to the U.S. FDA to conduct the clinical investigation in accordance with obligations of 21 CFR Part 312, and will be responsible for all regulatory submissions to the FDA concerning the protocol. Institution/Clinical Investigator will obtain cross-reference authorization for the Pharmaceutical Collaborator(s) IND or Drug Master File to the extent required for conduct of the clinical investigation. Institution/Clinical Investigator is responsible for providing all FDA correspondence related to their IND filing and NCI Formulary protocol to Pharmaceutical Collaborator.
9. Clinical Investigator and identified sub-investigators are required to register with the NCI for the purposes of identifying Clinical Investigators qualified to participate on the NCI Formulary Study and for the purpose of trial conduct using NCI’s clinical trial infrastructure, but are also required to complete and maintain their own Form FDA 1572 and Form FDA 3455 as sponsor-investigator in accordance with 21CFR312 and 21CFR54, respectively. Clinical Investigator as a sponsor-investigator must maintain an accurate list of sub-investigators participating in the clinical investigation and their identified roles and responsibilities on the NCI Formulary protocol.
10. Clinical Investigator is responsible for submission of approved protocol to all appropriate IRBs and obtaining such approval to conduct the clinical investigation.
11. The FDA acknowledgement of IND filing letter, FDA IND safe-to-proceed notice, IRB approval, IBC approval (if required), acknowledgement from the Cancer Center the NCI Formulary protocol data submission set-up is complete for reporting to the clinical data reporting system and the Pharmaceutical Collaborator(s) approval of the protocol must be provided to the NCI prior to NCI’s acknowledgment of the protocol being ready for activation and making the NCI Formulary agents available for the investigation.
12. Clinical Investigator will be responsible for submitting the NCI Formulary protocol to clinicaltrials.gov within twenty-one (21) days of initiating patient enrollment and providing the results reporting as required. No such submission will be made until after the NCI Formulary protocol is approved by Pharmaceutical Collaborator.
13. During conduct of the trial, Clinical Investigator must:
    1. Submit all adverse events to the FDA as the sponsor in compliance with both 21 CFR § 312.32 and §312.33 and forward copies of all such reports to Pharmaceutical Collaborator within 24 hours of FDA notification.
    2. Submit the required protocol data, including routine and expedited adverse event reports, at specified intervals, to the NCI and the NCI Pharmaceutical Collaborator(s). Clinical Investigator is also responsible for all required regulatory submissions to the FDA as the IND sponsor.
    3. Notify Pharmaceutical Collaborator within twenty-four (24) hours of becoming aware of any product complaint related to a NCI Formulary Agent.
    4. Notify NCI and Pharmaceutical Collaborator of any change in the protocol status or IND status.
    5. Submit copies of IRB continue review approval to NCI and Pharmaceutical Collaborator.
    6. Submit copies of any protocol amendments to the NCI that affect NCI Formulary Agent supply requirements or add participating investigators, prior to implementation of the amendment.
    7. Submit copies of all protocol amendments to the Pharmaceutical Collaborator for approval prior to implementation of the amendment.
    8. Submit copies of any publications as defined in the NCI Formulary Material Transfer Agreement.
    9. If requested by NCI, forward copies of all safety reports submitted to the FDA per 21 CFR 312.32 to NCI for any NCI Formulary Agent that is also subject to a DCTD-sponsored IND.