**How are agents in the NCI Formulary different from other NCI CRADA agents?**

Agents will be provided under a separate CRADA for Formulary protocols. The IND for the protocol is held by the investigator/institution conducting the study.

**What is the process for a company to provide drug(s) to the NCI Formulary?**

Companies should express initial interest by submission of the NCI Formulary agent pledge letter. Upon receipt, NCI will begin negotiations with the company to execute a CRADA to support Formulary protocols with the agent(s).

**Will collaborator enter into agreements with the sites?**

The collaborator will execute a CRADA with the NCI for the Formulary agents. The NCI will execute a NCI Formulary Material Transfer Agreement with the investigator/site. The collaborator does not need to execute separate agreements with the sites.

**Is the company required to provide funding to the site?**

No, the company is not required to provide funding to the site.

**If a site requests funding for the protocol at the time of the LOI submission and collaborator agrees, how is it managed?**

If collaborator agrees to provide funds to a site, the funds can be managed through the NCI Formulary CRADA to avoid a separate agreement.

**Can collaborators communicate directly with investigators?**

Yes, direct discussions between the collaborator and investigators will be required.

**When should the collaborator expect NCI to arrange initial shipments?**

NCI will arrange initial agent shipments with the collaborator once the first proposal (LOI) for the agent is approved. If the NCI Formulary agent is also subject to an existing CRADA with CTEP, DCTD, NCI, separates supplies of agent to support the NCI Formulary CRADA are required.

**Is there a limit to how many or how few agents a collaborator can provide to the NCI Formulary?**

No, there is no limit to the number of agents provided by a collaborator.

**Will sites outside the US be participating in this initiative?**

No, the protocols will only be conducted at U.S. NCI-designated Cancer Centers.

**Who will review and approve proposals submitted by investigators?**

The collaborator(s) providing the agent(s) will review the investigator-submitted proposals and render a decision within 60 days of receipt of the proposal form the NCI.

**Will the collaborator be made aware of adverse events?**

Yes, the collaborator will be informed of all routine adverse events submitted through the clinical data reporting system. The collaborator will be copied on all serious adverse events submitted through the NCI CTEP AERS expedited adverse event reporting system.

**What will collaborators be expected to provide with each lot of agent?**

* Lot release Certificate of Analysis
* cGMP certificate if compliance
* Formulary Agent Material Safety Data Sheet
* Collaborator test results of ongoing stability testing for each product lot.

**What materials/documentation will collaborator be expected to provide?**

* Agent supplies and accompanying required documentation
* Investigator’s Brochure (IB) and all updates.
* Cross-reference letter to its Investigational New Drug Application (IND) or Master File for each Formulary Agent(s) to FDA with a copy to the Approved Investigator to file in the investigator-sponsored IND for the clinical trial(s).

**Will collaborators receive updates on approved studies?**

Collaborators will be able to access ongoing Formulary clinical trial data submissions through the Theradex Web-Reporting tool.

**Will collaborator have an opportunity to review publications by investigator on the provided agent?**

Yes, collaborators will be able to review Investigator publications to ensure no confidential information is included.

**Will collaborators have a right to data generated under the protocol using the provided agent?**

Yes, collaborator will have a right to data generated as specified in the Intellectual Property Option to collaborator.

**Who will be responsible for distributing the agent to approved investigators?**

NCI Pharmaceutical Management Branch (PMB) will distribute the agent to the investigators.