NIH NATIONAL CANCER INSTITUTE

Industry Relationship Guidelines for NCI Clinical Trials Network Groups

Introduction

Clinical trials, which are funded by a cooperative agreement or individual grant or contract award, often utilize one or more investigational agents which are proprietary to a pharmaceutical and/or a biotech company (hereinafter, Collaborator). In this circumstance, the NCI has negotiated and executed a collaborative agreement, either a **Cooperative Research and Development Agreement (CRADA)** or a Clinical Trials Agreement (CTA), for the clinical co-development of the agent. The CRADA is a statutorily based mechanism created under the Federal Technology Transfer Act of 1986 for the purpose of facilitating Government-Industry collaboration and technology transfer. The CTA is an NCI-initiated mechanism for the clinical co-development of an agent.

Each CTA or CRADA defines certain obligations for the government and the Collaborator. Generally, these obligations focus on intellectual property and data rights, which may arise pursuant to these studies. Under federal funding agreement guidelines and the agreements in place between the Network Groups and the NCI, certain obligations and guidelines apply to the Network Groups. Compliance with any of the guidelines (in particular, publication review, data access, and intellectual property licensing) is mandatory for the Network Group. Although these guidelines have been written to address NCI Network Group-Industry interactions, much of the material contained in this document is also applicable to other NCI funded networks (for example, ETCTN, CITN, PBTC), individual cancer centers and clinical investigators.

In accordance with the following obligations and guidelines, each approved protocol contains the NCI standard language for protocols, stating the existence of relevant agreement(s). A summary of these obligations and guidelines follows.

Contents

1. Proprietary Agent(s)

Often, the agent provided under a protocol sponsored by the NCI is proprietary. The agent has been provided either by the NCI or by the Collaborator for the sole purpose of the studies specified by the protocol. Neither the NCI nor the Network Group may use the agent outside the scope of the protocol, nor can the agent be transferred or licensed to any party not participating in the studies under the protocol.

2. Confidentiality

In the course of any clinical study which is subject to a CTA or a CRADA, the NCI is required to maintain Collaborator information relating to the agent as proprietary and confidential. The duration of the confidentiality generally shall be a minimum of three years and is extendable until the NCI and the Collaborator agree that the data no longer remains confidential. Confidential information that is made available to any Network Group by the Collaborator and the NCI shall be labeled **"CONFIDENTIAL."** The Network Group shall either be required to maintain the confidentiality of the material or, at its option, decline acceptance to any confidential materials. All protocol documents, including Investigator's Brochures, for studies utilizing investigational agents under a collaborative agreement are also confidential and must not be shared or distributed without the permission of the NCI.

As part of the NCI review and audit of records, the FDA, the NCI, and the Collaborator will have access to medical records that identify patients. Such records are confidential, and no information which identifies a patient will be released without authorization.

3. Indemnification / Liability

The government is prohibited by statute from indemnifying any party without specific legislative authority and consultation with the United States Department of Justice. Government liability for its own actions is usually limited by the Federal Tort Claims Act.

4. Intellectual Property and Extramural Inventions

Under the Bayh-Dole Act (see 35 U.S.C. 201 et seq.) and 37 Code of Federal Regulations Part 401, Network Groups or member institutions have the right to elect title to any invention they discover in the performance of a study under NCI sponsorship. The Network Group's institutions agree to grant Collaborators the rights described in the **CTEP IP Option to Collaborator**.

Clinical investigators are required to report any inventions relating to studies under an NCI-funded protocol through the iEdison reporting system at: **https://public.era.nih.gov/iedison/index.jsp** for additional inquiries please contact the: Division of Extramural Inventions & Technology Resources (DEITR), Office of Policy for Extramural Research Administration (OPERA), Telephone: 301-435-1986, Email: **inventions@nih.gov**. The report should be in sufficient detail so as to enable the government to evaluate any potential contributions in the technological advances by NCI scientists. To allow more effective evaluation, the NCI requests that the clinical investigator send an additional confidential copy of the invention report to: **NCICTEPACG@mail.nih.gov**

5. Exclusive Access to Proprietary Data

Under a collaborative clinical development agreement, the NCI agrees to make all data in the NCI's possession and control available exclusively to the Collaborator for regulatory filings related to the agent. In the case of Network Groups, clinical data and results and raw data will be provided exclusively to the NCI, the Collaborator, and the FDA, as appropriate and until publication of the results. This provision does not affect the investigator's right to publish or present as described in the standard protocol language. This statement ensures that data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI, the FDA, and the Collaborator until publication of the results, and addresses the needs of the Collaborator to have access to the patient records and raw data for regulatory purposes. The Collaborator has the opportunity to contact the Network Group or Network Group's institution (subject to the terms of Articles 6 and 7, below) in order to negotiate and secure rights to the data generated by that Network Group under a Protocol.

When a clinical protocol involves either an agent, which is proprietary to another company, or involves another NCI collaborative effort, the data will be shared with all NCI collaborators providing agents for the clinical trial.

6. Procedures Under Which the Collaborator May Contact Network Groups, Member Institutions or Individual Clinical Investigator(s)

As the study sponsor, the NCI provides the initial notice to Network Groups regarding all protocol issues, as well as issues related to rights to data under a CRADA or a CTA. Without prior authorization from the Regulatory Affairs Branch (RAB) of CTEP, the Collaborator is not permitted to contact Network Groups or member institution(s) directly to obtain protocol information, to arrange on-site data audits, or to discuss any other protocol or amendment matters. The NCI will contact the Network Group to discuss the nature of the request prior to authorizing the Collaborator to contact the Network Group. For all studies under a Data Safety and Monitoring Committee, the collaborator will only have access to data and the ability to arrange on-site audits after release of the data by the DSMC. If a Network Group is contacted directly by the Collaborator and that Group has not had prior notice of the nature of the contact from the NCI, the Group should refer the Collaborator to RAB, NCI. After subsequent discussions with the Collaborator, RAB will then provide notice to the Network Group of the nature of the Collaborator's request and provide authorization, if appropriate, to the Collaborator to contact the Network Group.

Subject to the restrictions noted above, the Collaborator will then have the opportunity to contact the Network Group directly in order to secure rights to data owned by the clinical investigator or clinical investigator's institution and developed in conjunction with the NCI-sponsored trials.

7. Nature and Form of Information Supplied to the Collaborator

The Collaborator may make only reasonable requests for access to Network Group data during the conduct of the trial. The information shall be provided according to a mutually agreed upon plan between the NCI, the Collaborator, and the Network Group. The information provided will be in accordance with the guidelines and policies of the responsible Data Monitoring Committee as described by the NCI Network Group Data Monitoring Committee policy. In general, this consists of

daily SAE reports and quarterly updates of enrollment and demographics until study completion. A Network Group should be reasonably compensated for costs associated with providing raw data.

8. Network Group — Collaborator Agreements

If a Network Group is entering into a discreet agreement with a Collaborator for a Group IND trial, or for supplemental funding or correlative studies for a protocol under an NCI collaborative agreement, the Network Group is responsible for providing a copy of the draft agreement to RAB/ NCI for review and comment prior to execution. NCI will review to ensure that the agreement conforms to NCI and NIH guidelines for NCI funded studies and CTEP policy.

9. Data Sharing

In order to comply with NIH and NCI clinical data sharing policies, within 6 months of the publication of the primary endpoint manuscript, the underlying, de-identified patient level data must be submitted to an NCI controlled access database to be made available to approved researchers, following Collaborator review of the dataset. Collaborators may request such data submission be delayed up to a maximum of thirty-six months if Collaborator is using the data to support a regulatory filing to health authorities. In addition, in accordance with the NIH genomic data sharing policies, certain de-identified genomic data will also be submitted to a controlled access genomic database.

10. Publications

The Network Groups maintain full rights to present and publish the data from any protocol sponsored by the NCI. However, the Collaborator will be provided manuscripts from the trials for advisory review and comment prior to submission for publication. Under NCI Industry agreements, the Collaborator is not permitted to edit or require changes except that information proprietary to the Collaborator may be redacted. Any manuscripts reporting the results of a clinical trial should be provided to CTEP for immediate delivery to Collaborator for advisory review and comment prior to submission for publication. Collaborator will have thirty (30) days from the date of receipt for review. An additional thirty (30) days may be requested in order to ensure that confidential and proprietary data, in addition to the company's intellectual property rights, are protected. Abstracts presented by investigators will be sent to CTEP for forwarding to the Collaborator for courtesy review as soon as they are received, preferably at least three (3) business days prior to submission, but prior to presentation or publication. Before submitting a paper for publication or otherwise publicly disclosing information concerning an agent under an NCI collaborative agreement, the Network Group or Investigator must send the proposed publication to NCI at: **NCICTEPpubs@mail.nih.gov** for review by NCI and the Collaborator. Any such agreement must flow down the data and IP provisions described herein.

11. Financial Disclosure

NCI will collect financial disclosure information to assist Collaborators in complying with the FDA regulations. This information will be collected on an annual basis when the Form FDA1572 is updated.