Policy Name: Industry Documents	**Policy Number:** 13.1
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13 Industry Relations

Either Alliance or the National Cancer Institute (NCI) serve as the regulatory sponsor for Alliance studies, depending on who files the Investigational New Drug (IND) or Investigational Device Exemption (IDE) to research the agent. Regardless, the NCI serves as Alliance's governing entity, providing necessary trial infrastructure and research grants to support these studies. Regardless of industry collaboration status, Alliance member institutions participating on NCORP/NCTN trials follow the Alliance Policies and Procedures per their membership.

Alliance trials may involve working with pharmaceutical, biotech or other health-related industry companies (hereinafter, Industry). These partnerships allow access to investigational agents or devices that are relevant to Alliance research interests and provide financial support for trial components that are unfunded or under-funded. Financial support may be sought by Alliance to offset costs associated with non-standard elements of Alliance trials such as procedures associated with study development, trial activation and implementation, trial management, data management, study monitoring, research-specific medical tests, subsidiary laboratory studies, statistical analyses and other related activities.

Negotiations with Industry are managed through the Alliance Central Protocol Operations Program. Study chairs and committee chairs are not authorized to negotiate or sign agreements on behalf of Alliance.

The Federal principles governing study contributions from Industry in oncology trials are well-established and described in the "NCI –Network Group – Industry Relationship Guidelines" that can be accessed via the following:

http://ctep.cancer.gov/IndustryCollaborations2/guidelines.htm

The "NCI – Network Group – Industry Relationship Guidelines" includes information on NCI and Industry's collaboration to co-develop an agent. The co-development collaboration is formalized via a Cooperative Research and Development Agreement (CRADA) or sometimes a Clinical Trials Agreement (CTAs). 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.

If the NCI were to distribute drugs for an Alliance trial, independent of a CRADA or CTA, the basic tenets of these agreements still apply to Alliance/Industry collaborations.

13.1 Industry Documents

Alliance for Clinical Trials in Oncology Foundation (Foundation) is a tax-exempt, nonprofit organization dedicated to supporting the research and educational initiatives of the Alliance.

For studies supported by Industry, a legal agreement is required before funds (or agent/device) can be provided to the Foundation.

Additional documentation, such as a memorandum of understanding with Alliance regarding drug, device or services may be required for certain studies. Examples of documents and associated information are provided below.

13.1.1 Letter of Support

For a trial needing Industry support, Alliance requires a Letter of Support from the industry collaborator. The Letter of Support is not considered a legally binding document. However, the Letter of Support is a formal document that must be accepted by the Central Protocol Operations Program. A Letter of Support or an acceptable alternative may be provided as part of concept submission to NCI.

An acceptable Letter of Support should entail accurate information pertaining to the device/agent and associated funding components that the industry partner will support. Without an accepted Letter of Support, Alliance may not be able to allocate appropriate resources or be able to obtain concept approval from NCI which are needed to proceed with trial development.

13.1.2 Protocol Document

When a study agent is provided by NCI – including agent provision per CRADA or CTA between the NCI and Industry – standard language is included in the protocol document. The template for the standard language is in the "NCI Standard Protocol Language for Collaborative Agreements" document which can be accessed via the following:

https://ctep.cancer.gov/ProtocolDevelopment

The language in the protocol document may be modified when the study agent's distribution and management is the responsibility of Alliance.

13.1.3 Legal Agreement for Provision of Financial Support

The agreement details the terms of the financial support (or in-kind support of the provision of the agent). These terms include funding amount, description associated with the funding, milestone payment schedule, safety/FDA reporting requirements, data sharing (if applicable), study and agreement termination conditions, scope/statement of work and the responsibilities of each party. The agreement is between Industry and the Foundation and is legally binding.

13.1.4 Memorandum of Understanding Regarding Drug, Device or Services Provision

When appropriate, Alliance may utilize a Memorandum of Understanding to enter into with one or more parties. The Memorandum of Understanding is used to provide a general outline of the intent and general terms of a collaboration amongst various parties prior to further collaboration for development of a trial or negotiation of the main research agreement. This may be used to supplement a legally binding agreement, such as with international, non-member collaborators. This document may entail information regarding the following:

- The structure and function of Alliance
- The drug, device or service that will be utilized/implemented
- The specific study for which the drug, device or service is utilized for
- Reference to the Alliance Policies and Procedures, as appropriate

Policy Name: Confidential and Proprietary Information	**Policy Number:** 13.2
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13.2 Confidential and Proprietary Information

Prior to discussions with Industry or provision of the study concept/protocol documents for review by Industry, the Alliance requires Industry to enter into a confidentiality or nondisclosure agreement with Alliance.

At the institutional level, for all studies involving collaboration with Industry, it is the responsibility of all site staff to maintain confidentiality of proprietary, trade secret, or other private information. Confidential and proprietary industry information is strongly discouraged from inclusion in study protocol documents. Should it be absolutely necessary for study activities, Industry is asked that any confidential information be indicated as such with appropriate watermarks or other acceptable reference to its confidentiality.

Similarly, Alliance study personnel must maintain confidentiality of Industry information, as applicable. Study chairs must abide by Alliance Group policy which requires strict confidentiality of study information (see Section 6). The Alliance statistician conducts all interim analyses, if applicable for a study, in a confidential manner. No one other than those explicitly authorized to be part of the monitoring process has access to the results.

All authorized personnel are required to maintain strict confidentiality throughout their deliberations. Results are released only after authorization has been granted. Any violation of these confidentiality obligations is considered a serious offense.

Policy Name: Data Ownership in the Context of Industry Collaboration	**Policy Number:** 13.3
Section: Industry Relations – 13	**Date Revised:** May 2, 2025

13.3 Data Ownership and Release in the Context of Industry Collaboration

Data sharing requirements and agreements related to Alliance studies (including translational research studies) are governed by Alliance and NCI data sharing policies (see Section 15). Pursuant to NCI policy, Alliance retains ownership of data resulting from Alliance trials and complies with federal requirements to release study results data to the NCTN/NCORP Data Archive and www.ClinicalTrials.gov, after data have been released by the Data and Safety Monitoring Board (DSMB) and the primary endpoint data have been published, as applicable.

The manuscript of primary study results is usually published within 12 months of DSMB release (see Section 10). Datasets corresponding to the primary endpoint manuscript for Phase III trials can be requested directly from the NCTN/NCORP Data Archive, which may be accessed via the following:

https://nctn-data-archive.nci.nih.gov/

For trial data that are not available in the NCTN/NCORP Data Archive, datasets corresponding to the primary endpoint manuscript may be requested from Alliance by Industry. These primary endpoint data are available after the primary endpoint manuscript publication. All other data sharing is dependent on the protocol and the trial-specific statistical analysis and publication plans.

Industry data requests or transfers require a written request to the Alliance Data Sharing Committee and a feasibility review with the Alliance Statistics and Data Management Center. Further review by NCI may be needed too. Data sharing may require supplemental funding, involving an agreement, for the staff effort and development of associated materials for these data-related activities.

Policy Name: Standard Reporting to Industry Collaborators	**Policy Number:** 13.4
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13.4 Standard Reporting to Industry Collaborators

Alliance may routinely provide accrual summary reports to Industry on a quarterly basis, as documented in an executed agreement with Industry. Accrual reporting entails cumulative enrollment of the overall study. Depending on the circumstance, Alliance may consider requests to provide Industry with other accrual information or alternative frequency.

Safety reporting, such as for serious adverse events (SAEs), may also be provided to Industry. Requests from Industry on specifications of safety reporting should be discussed and final determination documented, such as in an agreement.

In addition, Alliance may provide the Annual Study Summary Report to Industry, which is generated by the Alliance Statistics and Data Management Center, at a timeframe preliminarily established by Alliance – typically in quarter 4 of the year. The Annual Study Summary Report entails study-specific information consistent with the IND Annual Report to FDA.

Other reporting requests from Industry must entail valid justification. Alliance will consider trial confidentiality, DSMB requirements, and NCI policy adherence for such requests. Any additional reports that Alliance is amenable to providing must be documented, such as in an executed agreement.

Policy Name: Indemnification	**Policy Number:** 13.5
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13.5 Indemnification

Alliance and the Foundation will not assume responsibility or be liable for any acts or omissions of Industry with respect to the conduct of Alliance studies. The Alliance and the Foundation will not assume responsibility or be liable or offer indemnification to Industry on behalf of Alliance members or overarching NCTN Participating Institutions for any Participating Site activities at their facilities.

Industry is responsible for providing Alliance with appropriate representations and warranties under any agreements with the Foundation that the Study agent is appropriately manufactured. Industry is required to ensure handling according to Good Clinical Practice/Good Manufacturing Practice guidelines and any applicable regulatory requirements and laws related to the appropriate manufacturing, design, and handling of the agents.

Alliance requests that Industry indemnify all investigators against loss related to the agent provided by Industry. This includes Industry assuming responsibility for drug information in the Investigator's Brochure as well as for product liability issues, should there be a manufacturing or design defect or issue with the provided agent.

Policy Name: Intellectual Property and Patent Rights	**Policy Number:** 13.6
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13.6 Intellectual Property and Patent Rights

An invention resulting from work performed by an Alliance investigator generally is the property of either the investigator or the Alliance institution with which they are affiliated. Alliance requires investigators to disclose any inventions or discoveries resulting from Alliance studies (aka "Intellectual Property") to the Alliance group chair, regardless of whether it is patentable or not. The disclosure should be submitted in writing within ninety (90) calendar days of the discovery thereof.

Once notified, the Alliance group chair and investigator(s) will confer to establish next steps. The planning of next steps includes determining the most appropriate institutional personnel to meet with regarding matters of recognition and remuneration related to the patenting, licensing, exploitation or commercialization of the Intellectual Property. Alliance and Alliance member institutions are required to follow their terms of award, as applicable, for NCTN and NCORP requirements of all NCI/NCORP supported studies and are required to adhere to the Alliance Policies & Procedures, including those related to Intellectual Property.

The NCI's Cancer Therapy Evaluation Program "Intellectual Property Option to Collaborators" ("CTEP IP Option")" is required for all Industry partnerships and collaborations on government-supported studies and is reflected in legally binding agreements. More information regarding the CTEP IP Option can be found at the following:

https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm

Policy Name: Publication of Study Results	**Policy Number:** 13.7
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13.7 Publication of Study Results

Alliance requires that its investigators have the absolute right to publish all study results which is consistent with the traditional principle of academic freedom; the right of the public to know about government-funded trial results; and the policy of major medical journals.

A copy of the draft manuscript is provided to Industry at least thirty (30) calendar days prior to the planned publication submission for advisory review and so that Industry can review for the disclosure of Industry proprietary information.

Abstracts are also provided to Industry for courtesy review at least three (3) business days prior to presenting or publishing.

During this review, Industry has the right to request that publication be delayed for at least thirty (30) calendar days in order to ensure that Industry's intellectual property rights are protected (i.e., if patent-related action is necessary).

NCI's summary of publication obligations and guidelines for industry collaborators that Alliance must adhere to can be found at the following:

https://ctep.cancer.gov/industryCollaborations2/guidelines.htm

Policy Name: Use of Agent/Devise Provided by Industry Collaborator	**Policy Number:** 13.8
Section: Industry Relations – 13	**Date Revised:** December 16, 2024

13.8 Use of Agent/Devices Provided by Industry Collaborator (Industry)

Participating institutions, its investigators and study teams may not use any agent/device for any other purpose outside the scope of the protocol. Participating institutions, its investigators and study teams cannot submit claims for reimbursement to any governmental healthcare plan, third-party, commercial healthcare insurers or the patient enrolled for any item or service supplied at no charge for study-specific activities.