



National
Comprehensive
Cancer
Network®

NCCN Oncology Research Program (ORP)

**Streamlining the Evaluation and
Development of Promising New
Cancer Treatments**



NCCN.org

NCCN Oncology Research Program (ORP)

NCCN ORP Mission Statement

The NCCN ORP strives to improve the quality of life for patients and reduce cancer-related deaths by advancing cancer therapies through research. We believe we can achieve this goal by supporting oncology preclinical, translational, and clinical research at NCCN Member Institutions. We recognize the importance of developing and maintaining strong alliances with industry and actively facilitating collaborations between academia and industry drug developers making important scientific strides in the field of oncology. It is NCCN's vision to have the NCCN ORP become a Center for Excellence in the United States for providing outstanding research and research services.

The NCCN Oncology Research Program (ORP) has developed a comprehensive program of scientific advisors and research platforms to foster the development of world-class therapies to treat people with cancer. The program has been successful in bringing together leading academic scientists, clinicians, and pharmacists to work with pharmaceutical and biotechnology companies dedicated to developing effective new treatments for cancer. The NCCN ORP's core services focus on assisting companies with drug development plans and strategies, facilitating the conduct of preclinical, translational, and clinical research at NCCN Member Institutions, ensuring that results of funded research projects are publicly disseminated, and working with the research community to develop oncology research best practices.

NCCN ORP Overview:

- NCCN ORP Drug Pipeline Review Research Services
- Research Platforms & Services
 - Investigator Initiated Research Grant Model
 - Drug Development Research Grant Model
- Research Boards & Committees
 - Scientific Advisory Boards (SABs)
 - Requests for Proposals (RFP) Development Teams (RFPDTs)
 - Protocol Development Teams (PDTs)
 - Scientific Review Committees (SRCs)

NCCN ORP Drug Pipeline Review Research Services

The NCCN ORP establishes Scientific Advisory Boards (SABs) to provide advice and direction to industry collaborators developing new and innovative oncology drugs and biologics. SABs are made up of notable academic scientific, clinical, and pharmacy experts in oncology. Each SAB is unique with leading experts specifically matched to the drug development plans and strategies of the company. The principal mission of each SAB includes:

- reviewing the quality and relevance of the scientific and technical information being used or proposed as the basis for drug development
- assisting in advancing the development of preclinical and clinical-stage product candidates
- reviewing research programs and advising industry on specific clinical and scientific matters related to oncology drug development
- assisting in developing an academic and industry approach to drug development

Research Platforms & Services

Investigator Initiated Research Grant Model

This model facilitates the post-approval evaluation of oncology drugs through investigator initiated research. Grants support the exploration of new avenues of clinical investigation that answer important scientific questions and improve patient care. Studies evaluate new combinations of drugs, mechanisms of action of specific agents, drug resistance, or explore extended uses for specific agents. Research is conducted using the following process which is modeled similar to a NIH Study Section:

- The NCCN ORP works with industry collaborators to identify their research needs and then organizes a RFP Development Team. The team consists of experts with the necessary experience and qualifications to review existing data for the drug to be studied and to formulate a RFP
- The NCCN ORP announces the RFP to investigators at NCCN Member Institutions
- A Scientific Review Committee (SRC) made up of leading peer reviewers evaluate, score and rank proposals and award funding to the most promising and scientifically meritorious proposals
- The NCCN ORP facilitates initiation of the research studies, including contracting and regulatory oversight
- The NCCN ORP oversees the conduct of the approved research studies which includes quarterly reports and disbursing grant funds according to achievement of important benchmarks
- The NCCN ORP supports the publication of results of the studies



Research Platforms & Services



Drug Development Research Grant Model

This model facilitates preclinical, translational, and clinical research for oncology drugs in development. Grants support research performed either as investigator initiated trials or as industry sponsored trials. The investigator holds the IND for investigator initiated trials and the company holds the IND for industry sponsored trials.

The NCCN ORP works with industry collaborators to identify their research needs and facilitates meetings of expert teams to work in one of the following pathways:

Proposal Driven Pathway

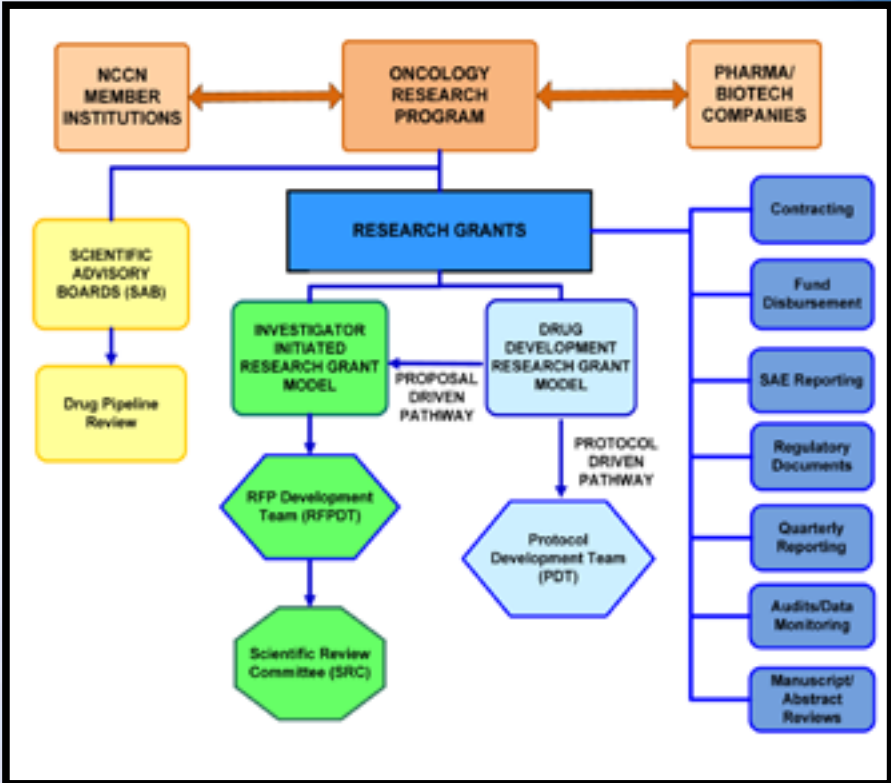
This pathway essentially uses the Research Grant Model process in that experts on the RFP Development Team formulate the Request for Proposals (RFPs) to solicit proposals for investigator initiated clinical trials. The NCCN ORP organizes Scientific Review Committees (SRCs) made up of leading peer reviewers to evaluate, score and rank proposals and award funding to the most promising and scientifically meritorious proposals. Since drugs studied in the Drug Development Model are unapproved, the industry collaborator has greater input in clinical trial oversight as it pertains to drug safety and dose escalation issues. The NCCN ORP also provides research services for data monitoring and auditing as necessary.

Protocol Driven Pathway

Experts on a Protocol Development Team (PDT) work hand-in-hand with industry collaborators to develop one or more specific protocols and identify site(s) to conduct studies either as investigator initiated or industry sponsored research. The NCCN ORP:

- facilitates study initiation including contracting and regulatory oversight
- oversees the conduct of the clinical trials and provides auditing/monitoring services, data safety oversight, statistical analysis, and other research services as needed
- disburses grant funds according to achievement of important benchmarks
- supports the publication of results of the studies

NCCN Oncology Research Program (ORP) Schema



Research Boards & Committees

Scientific Advisory Boards (SABs)

Highly distinguished scientific advisors in oncology representing the country's top academic institutions serve as advisors on drug-specific scientific advisory boards for Drug Pipeline Review. The NCCN ORP works with industry collaborators to identify and enlist key thought leaders to serve on these boards from NCCN Member Institutions.

RFP Development Teams (RFPDTs)

These are committees of expert leaders from NCCN Member Institutions who guide the development of Requests for Proposals (RFPs). The committees focus on formulating projects around the research priorities established through discussions with industry collaborators. Team members specialize in the scientific or clinical research areas of interest to oversee the development of RFPs which elicit proposals that yield studies of high scientific and clinical value. Grantor representatives serve as members of the teams in an advisory capacity.

Protocol Development Teams (PDTs)

Experts with expertise in specific scientific and clinical areas form teams to work with industry collaborators to design protocols and identify Study Chairs or Principal Investigator(s) to conduct studies. Industry collaborators participate in meetings and, depending on whether a study is to be conducted as an investigator initiated trial or as an industry sponsored trial, may serve in either an advisory or a decision-making role.

Scientific Review Committees (SRCs)

The NCCN ORP establishes qualified Scientific Review Committees (SRCs) to conduct the peer review of research proposals received in response to RFPs. SRC members are from NCCN Member Institutions and have expertise in the specific therapeutic areas relevant to the research project. The NCCN ORP SRC review process meets the general NIH standards of peer review and funding by meeting the following three criteria:

- 1) the peer review system uses external reviewers and is free of conflict-of-interest
- 2) the ranking or rating system in the review process is based on the scientific merit of the proposed research
- 3) the funding system is based primarily on the peer review ranking or rating of the research application.

The NCCN ORP requires major reviews by two (2) members of the SRC with discussion and ranking of proposals by all members of the SRC. Grantor representatives serve in an advisory capacity to these committees and are given the opportunity to review each of the proposals prior to the formal review. Grantors may request elimination of particular proposals from scientific review if they duplicate already well-studied concepts or raise safety concerns.

NCCN ORP Conflict of Interest Policy

Integrity, objectivity, and absence of self-dealing are essential at all levels and in all aspects of NCCN's activities, including those of the NCCN ORP. NCCN and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics.

Members of NCCN ORP scientific committees may face real or apparent conflicts of interest with grantors, investigators or institutions. The NCCN ORP has a Conflict of Interest Policy that sets forth principles and procedures to ensure that the personal financial and professional interests of scientific committee members do not compromise the objectivity with which recommendations for research and approval of projects are made. The NCCN ORP posts disclosures of scientific committee members on its website and provides appropriate oversight, limitations, or prohibitions in accordance with this policy.

This policy applies to all members of NCCN ORP scientific committees, including Scientific Advisory Boards, RFP Development Teams, Protocol Development Teams, Scientific Review Committees and any ad hoc committees with a scientific focus making decisions and recommendations related to NCCN ORP research projects.





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The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice so patients can live better lives.

Your Best Resource in the Fight Against Cancer®

Let the NCCN ORP put our expertise to work for you!

To learn how we can help you develop and evaluate your promising new pharmaceutical or biological agent, contact the NCCN ORP at 215.690.0230 or oncologyresearch@nccn.org.