

P01 Technical Assistance Webinar

Friday, May 17, 2024, 2:00 – 3:00 p.m. ET

Research Program Project Grant (P01) Overview

Speaker:



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Overview: NCI Research Program Projects (P01)

Division of Cancer Control and Population Sciences
National Cancer Institute

NCI Encourages More Collaborative Research to Accelerate Cancer Science

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April 13, 2023, by Drs. Phil Castle, Jim Doroshow, Dan Gallahan, Katrina Goddard, and Toby Hecht

In this issue of the NCI Bottom Line blog, read why NCI leaders are encouraging investigators to apply for a program project (P01) grant. P01 grants involve the type of broad, multidisciplinary collaboration likely to yield meaningful results for cancer science and patients.



From left to right, Philip E. Castle, Ph.D., M.P.H., James Doroshow, M.D., Dan Gallahan, Ph.D., Katrina A. B. Goddard, Ph.D., and Toby T. Hecht, Ph.D.

<https://www.cancer.gov/grants-training/nci-bottom-line-blog/2023/nci-encourages-more-collaborative-research-to-accelerate-cancer-science>

Program projects

- New website to provide guidance
- New fact sheet
- Accelerated ARA approval process
- Pop sci study section?

NIH NATIONAL CANCER INSTITUTE Division of Cancer Control and Population Sciences

Program Project Grant (P01) Process

The P01 grant supports multidisciplinary research programs with a strong central theme and synergistic interaction between individual projects. Pre-application guidance, which consists of initial contact with the program director (PD) followed by a pre-application meeting, is intended to help investigators submit the best-quality application. This document describes the Division of Cancer Control and Population Sciences (DCCPS) pre-submission process and timeline to assist investigators with developing a P01 application, submission, review, selection for funding, or a resubmission.

[Learn more about the application process and contacting NCI program directors and officers](#)

KEY FEATURES OF A RESEARCH PROGRAM PROJECT (P01)

A P01 multi-project application leverages integration and synergy to address aims that could not be accomplished without the structure of the program project. Several features distinguish a P01 from other funding mechanisms: (1) a P01 must consist of a minimum of three scientifically meritorious projects, and (2) each project within a P01 is similar to the traditional research grant application (R01) in the sense that each project has specific objectives, aims, a fully developed research plan, and a separate budget. However, each project in a P01 takes place in the broader environment of the overall program goals. A program project application may include shared resource cores that provide administrative, laboratory and/or clinical facilities, equipment, and/or services to be shared by two or more projects.

INTEGRATION AND SYNERGY

- The P01 application should be viewed as a confederation of interrelated and complementary research projects that demonstrate synergy, which is one of its key defining features.
- Synergy in a program project can be described as follows: While each project should be capable of standing on its own scientific merit, the combined research being conducted should allow progress to occur at a greater rate and result in a greater contribution to program goals than if each project were pursued separately.

Examples of synergy include, but are not limited to, the following:

- Sharing preliminary data, samples, reagents, pathogens, human subject population(s), technologies, research approaches, data management/analytical tools, and model organisms, which may impact the direction of science and research outcomes in the programs

Before You Apply

CONTACT A PROGRAM DIRECTOR

Always email the PD first to discuss your scientific proposal. Those who do not already have an assigned PD are invited to review information about staff in the various [DCCPS programs](#) to identify PDs with related scientific responsibilities. Send the PD a one- to two-page summary of your program project in advance of the call.

During the initial call, the PD will discuss whether the P01 is the correct mechanism for the proposed project, the requirements of the P01 mechanism, the importance of integration of the research projects within a P01, budget recommendations, and the timeline and next steps for a presubmission meeting.

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INVESTIGATOR MEETING WITH NCI STAFF

- Determine readiness, integration, and size and scope of the proposed work.
- Provide tips to avoid common mistakes and errors, as well as tips on items that can enhance the P01 application.
- Provide an opportunity for the investigators/team to ask NCI/NIH staff clarifying questions.

of Your Application

In the overall program project. Cores that provide innovative approaches and unique, cutting-edge technology receive a superior rating.

- Integration receives a verbal rating: highly integrated, integrated, or not integrated.
- If the application does not receive a favorable score (less than 30), the PI should contact the program director and consider revising and resubmitting:
 - Review the summary statement and address concerns.
 - Make changes to the P01 in response to review. These may include changing a project/core, adding a new core or dropping a component that did not review well; or adding a new project that is better aligned with the current proposal.
 - The PI should update the application to reflect changes in the science.

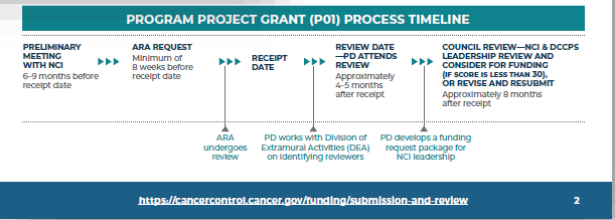
receipt dates Contact PD 7-10 months before receipt date.

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www.cancer.gov/grants-training/nci-bottom-line-blog

cancercontrol.cancer.gov/funding/submission-and-review/investigators-planning-submit-program-project-grant-p01-dccps-guidance

P01: Research Program Projects

- P01 series grants support multidisciplinary or multifaceted research programs that have a focused theme
- Each component project should be directly related to and contribute to the common theme
- Program projects may address any of the broad areas of cancer research, including (but not limited to) cancer biology, prevention, screening/early detection, diagnosis, treatment, and control. Basic, translational, clinical, and/or population-based studies are appropriate.

P01: Research Program Projects are not

P30	<p>Center Core Grants</p> <ul style="list-style-type: none">•To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem.•The core grant is integrated with the center's component projects or program projects, though funded independently from them.
P50	<p>Specialized Center</p> <ul style="list-style-type: none">•To support any part of the full range of research and development from very basic to clinical.•May involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort.•The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area.•Receive continuous attention from staff funding IC.•Centers may serve as regional or national resources for special research purposes.

P01: Research Program Projects

- Basic, translational, clinical, and/or population-based studies in all of these research areas are appropriate.
- Each Program Project application must consist of at least three projects, maximum is six.
- The projects must share a **common central theme, focus, and/or overall objective**.
- The multi-project P01 application should be viewed as a confederation of interrelated research projects, each capable of standing on its own scientific merit, but complementary to others in the program such that the overall research is *synergistic* rather than additive.

P01: Research Program Projects

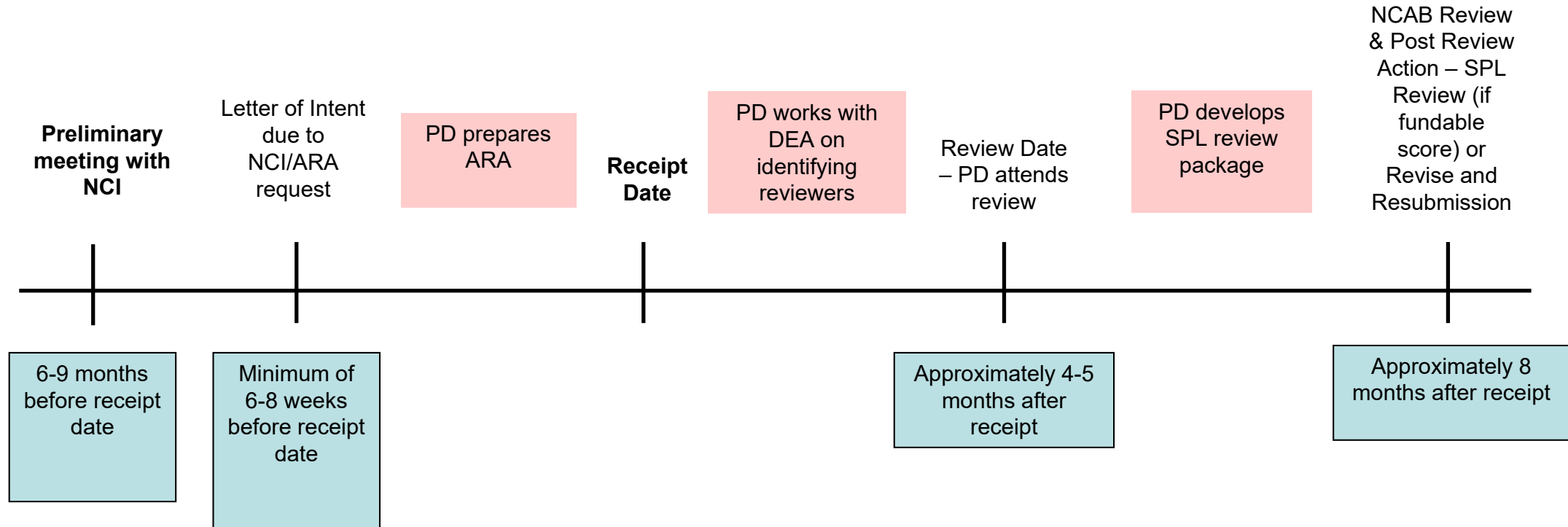
- The individual projects should be interrelated such that the combined research efforts produce synergy and allow progress to occur at a greater rate and result in a greater contribution to program goals than if each project were pursued separately.
- One or more Shared Resource Cores if needed for the proposed research.
- New cores may be proposed and/or existing institution cores may be augmented to support the proposed research.

Getting started

Talk to the program director early in the process:

- To gauge NCI's interest before investing time and resources in developing an idea further!
- To determine how to navigate the NCI process, timeline, review and award.

Timeline for P01 submission, review and award



P01 Pre-Meeting

The Pre meeting is mandatory and is designed to:

- Determine if the proposed research has significant scientific interest to NCI
- Identify areas of concern or areas the PI(s) need to clarify
- Solicit input from other NCI or NIH staff with an interest in the P01
- Identify areas the PI need to strengthen in proposal
- Identify NCI/NIH resources that can support the proposed work
- Identify P01 and grantsmanship criteria the PI should address in the proposal

Pre-submission work with Program Staff

- PI identifies an area of research and submits a 3-5 page document with the abstract/description-size and scope of the program and number of projects to the PD
- PD discusses with PI appropriateness of this direction of research for the portfolio/NCI
- PD sets up the presubmission meeting- timelines, PI material for review
- PD decides which NCI staff should be invited
- Determine where the proposal should reside
- PI develops P01 and makes pre-application presentation at the NCI program group/branch in person(s) or over the webex, etc.

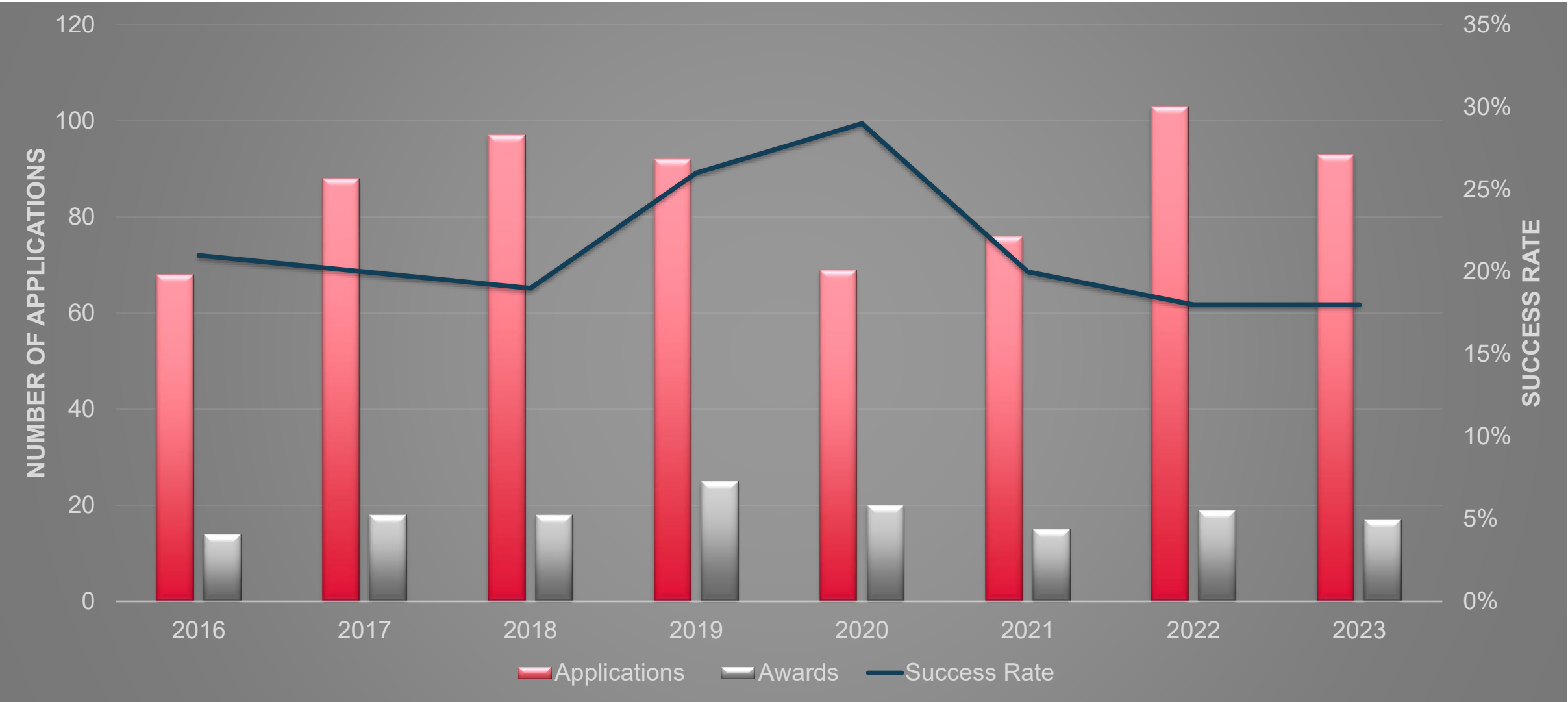
Review

- P01s are reviewed by a NCI Special Emphasis Panels (SEPs)
- Applications receive an overall score (not percentiled)

Post Review: Funding consideration

- If any component of a P01 is not recommended for further consideration the entire application is no go
- Projects scored up to 30 are submitted for review by division and NCI leadership
- PD writes 3-4 pages justification for funding P01 project
- P01 projects are discussed following PD presentation at the Division and NCI Leadership (SPL) meetings
- Funding of P01 requires approval of SPL and NCAB

NCI P01 Applications, Awards and Success Rates (2016-2023)

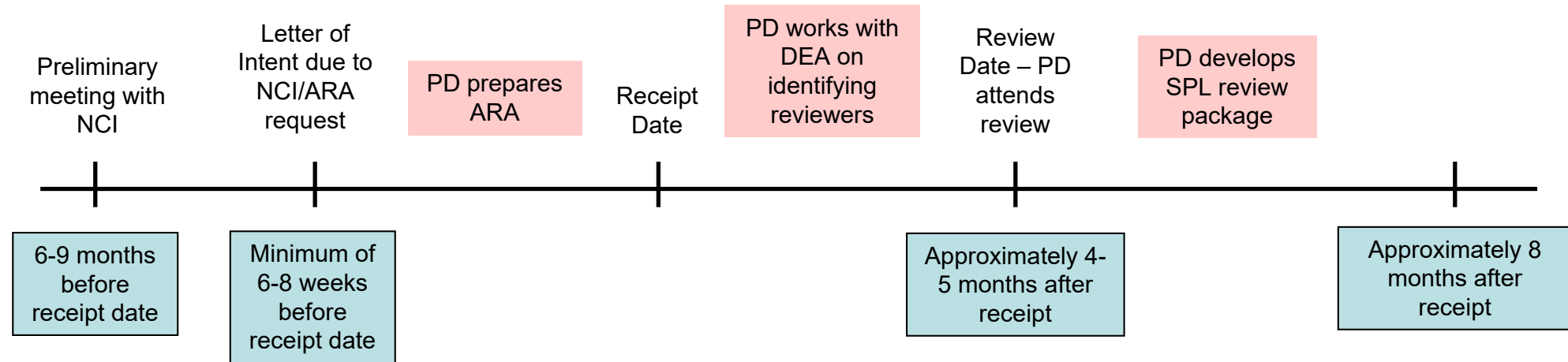


Tips for P01 Applicants:

P01 Preparation Points to Consider:

- Grants are highly competitive
 - Senior PIs
 - 22% average success rate (FY19-FY23)
- Review is extremely rigorous
 - Done by NCI special emphasis panel
- Don't rush applications – apply after:
 - Preliminary data is complete
 - IRB and IACUC approvals are obtained
 - All points from NCI staff meeting and advisory groups have been addressed

Prior to First NCI Contact:



- **P01 Idea:**
 - **Is the topic of interest to NCI?**
 - **Are the personnel & resources available?**
 - **What specific initiatives does it address?**

Basic Information for the NCI Pre-Submission Meeting:

- **Clearly State Overall Program Objectives and Goals (what & why?)**
- **Investigators & Performance Sites (who & where?)**
 - helps if you send your CVs and current grant status of the investigators to the Program Director, so NCI can get to know the group.
- Anticipated submission date & estimated costs (when & how)
- Description of Individual Program Projects and Cores (how details):
 - Project 1: Title and PI
 - Project 2: Title and PI
 - Project 3: Title and PI
 - Core A, B, C
- Projects should be robust enough to stand on their own

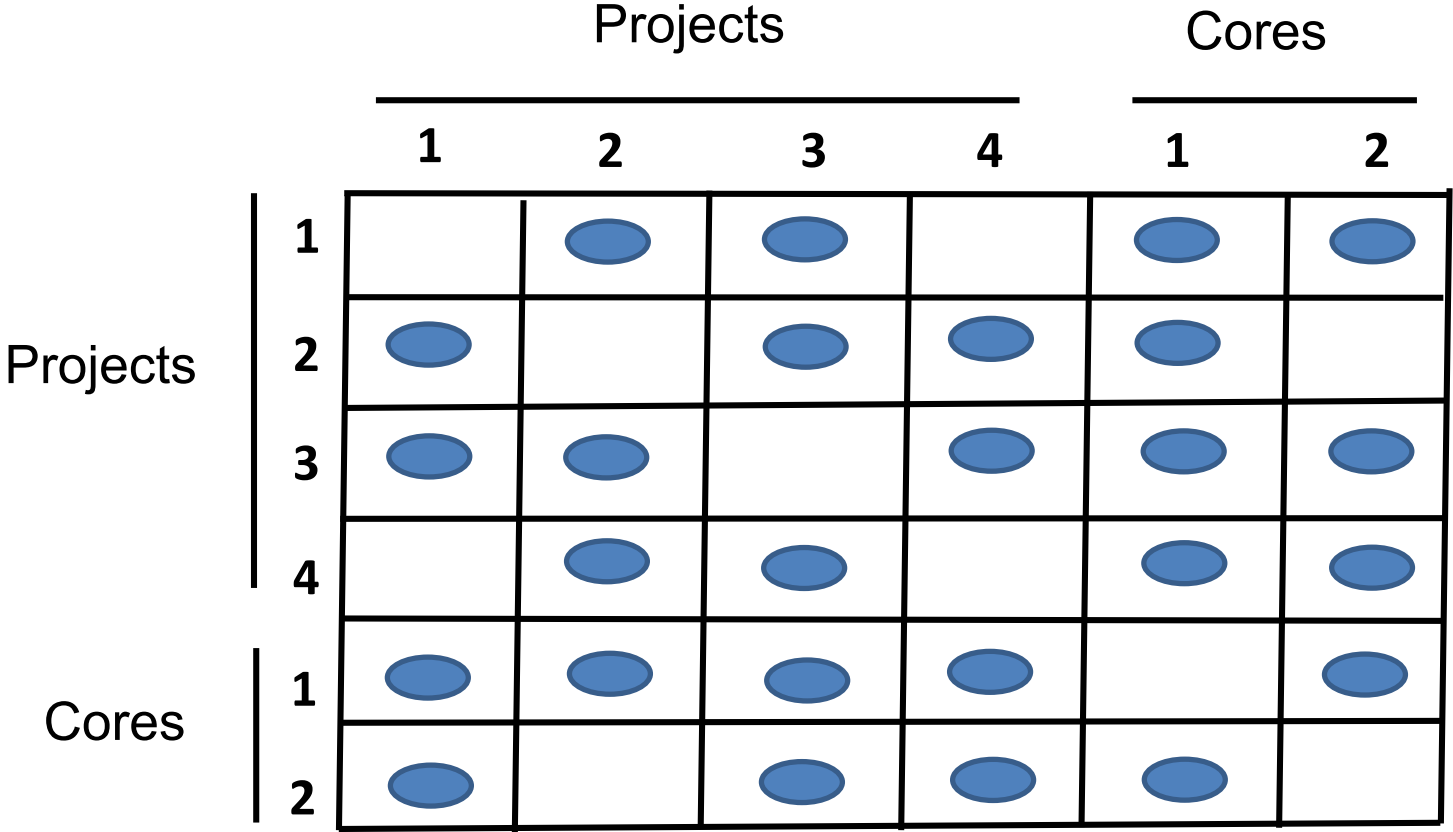
Characteristics of Successful P01 Applications:

- Grant should be the PI's major research focus
- All Project and Core leaders should have own independent funding
- Should have an advisory board from outside your own Institution – people who have the expertise and who can give you their feedback
- Projects and cores are **highly integrated, synergistic, and translational**
- Projects and cores have innovative conceptual and technical components
- Strong Institutional commitment to the Program

Critical P01 Review Issues:

- Identify the common theme or “unifying” hypothesis that links the individual projects.
- Why is this question significant to answer?
- How are the projects integrated? (i.e. how is the sum greater than the parts)
- What is the most critical piece of preliminary data that the team has to convince us that this P01 is worth the money?
- Indicate existing areas of collaboration, emphasizing co-publications.
- A detailed diagram indicating integration between projects and cores is useful.

Example of Integration Diagram:



Cores:

- An administrative core is required
- Cores may be:
 - a) service oriented
 - b) scientific/developmental
 - e.g. they may help you develop a new method for using archival tissue, for example.
- Identify each core leader's qualifications.
- Articulate how the activities of the core will facilitate the various Program Projects.
- Describe whether the program establishes a new core or leverages an existing core.

Summary:

- Call Your Program Director for Advice!
- P01 Application Process is Highly Competitive
- Plan Ahead
- Emphasize (Demonstrate) **Synergy & Integration**
- Indicate Significance – How Will Project Discoveries Move the Field Forward?

Reference websites

- <https://grants.nih.gov/grants/guide/pa-files/PAR-23-059.html>
- www.cancer.gov/grants-training/nci-bottom-line-blog
- cancercontrol.cancer.gov/funding/submission-and-review/investigators-planning-submit-program-project-grant-p01-dccps-guidance
- <https://healthcaredelivery.cancer.gov/funding/guidance.html>

Thank You

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[cancer.gov](https://www.cancer.gov)

1-800-4-CANCER