

Endocrine Society comments in response to [NOT-OD-26-095](#), “Request for Information: Input on Potential NIH Funding Approaches to Support the Development of Future Clinical Trial Investigators”

Response was informed by members of the Research Affairs Core Committee (RACC).

Comments were submitted electronically via online submission form on September 30, 2026.

Clinical Trial Training and Career Development

NIH seeks input on considerations for supporting the development of independent clinical trial investigators under these funding models. Responses may address training, mentorship, transition to research independence, or other factors relevant to preparing investigators to lead clinical trials.

K awards funded by the NIH are essential mechanisms supporting the development of research skills and independence to become clinical researchers. Direct experience leading the design and implementation of a clinical trial is a necessary part of the professional development and independence of clinical researchers. While our understanding is that NIH aims to change the training environment for the development of clinical researchers, we note that NIH’s definition of a “clinical trial” encompasses a wide breadth of activities involving human participants. Consequently, the impacts of the proposed changes will broadly affect the training of clinical researchers and physician-scientists.

We are concerned that the separation of clinical trials leadership from the K award itself will negatively affect the professional development of physician-scientists by increasing their overall training period and therefore dissuade trainees from pursuing careers as physician-scientists. Moreover, NIH has not provided adequate justification for the proposed changes to K awards or clearly explained how these changes and the proposed new approaches will benefit trainees. It is also unclear why clinical trials, and no other research awards, are targeted in this way. **We urge NIH to reconsider its approach and preserve the existing criteria for K awards that allow mentees to lead clinical trials under a mentor’s guidance.**



Proposed Funding Approaches

NIH seeks input on the design of the two proposed funding models. Responses may address the suitability of each model for its intended investigator population, eligibility criteria, timing of support, peer review considerations, transition between phases, budgetary or administrative features, and other recommendations to improve the proposed models. NIH also welcomes suggestions for alternative funding models.

The Endocrine Society is concerned about both proposed approaches described below.

Approach 1 – Mentored K Award + Limited-Competition Clinical Trial Research Project Grant (RPG):

If NIH's goal is to support aspiring independent clinical researchers through mentored awards, we do not understand why clinical trials would require a separate grant with additional uncertainties, review processes, and administrative burdens. It is also unclear if the scientific merit, aims, and progress of a K award are defined and evaluated through peer-review separately from the evaluation of the scientific merit, aims, and progress of the actual clinical trial. If an investigator can secure a K award for training but is unable to secure a separate R Award to conduct independent research, the time and money invested in the K award will not serve the goal of the trainee or NIH. Indeed, learning how to design and lead clinical research studies is a core requirement for physician-scientists. Separating the training process from the research question in this way, with additional delays in receiving the R award, could introduce complications if the awards do not overlap in time. For instance, if it takes multiple rounds for a trainee to secure an R award, they may no longer have protected time to dedicate at later stages of their research project. Separating research funding from mentored training supported by a K award risks interrupting the momentum that clinicians have built that could be used to transition to independence. Thus, preserving a K awardee's opportunity to gradually build their independence under guided mentorship is imperative for their success.

Approach 2 – Phased Transitional Award

While a trainee can learn how to conduct research by observing and participating in a mentor's clinical trial, we maintain that K awards are best utilized to support trainees



who are interested in pursuing their own original research questions. A phased transition award would unnecessarily delay progress towards the demonstration of independent investigation skills.

General Comments Relevant to Both Approaches

Both approaches introduce unnecessary delays towards leadership of a clinical trial and place additional barriers toward completion of a physician-scientist's training without any obvious benefit. Our members report that trainees often benefit from leading an observational or ancillary study earlier in their career under the guidance of a mentor; K awards as currently constructed are appropriate funding mechanisms for protected time and resources to support research activity. Importantly, both approaches introduce additional administrative requirements, whether it is due to applying for a separate R award or demonstrating, through completion of undefined "programmatic milestones," the readiness of a trainee to lead their own clinical research. We also note that both approaches rely on mechanisms and details that are not yet defined, making it difficult to evaluate either approach. For instance, NIH should describe in detail what a proposed companion R award would entail, how long each phase of a phased award should last, and other details that would help trainees and mentors anticipate the impacts on their research and careers.

Other Suggestions for Optimizing the Development of Clinical Trialists

NIH seeks any other relevant input related to how best to support the development of researchers who will lead or participate in running well-designed, efficient clinical trials that produce important information for improving clinical practice and human health.

It is important to evaluate any specific proposed policy changes within the context of other policy changes being proposed or adopted by the NIH or throughout the Federal Government to appreciate the potential impact of these proposed changes. For example, if a cap on the number of research project grants an investigator can hold is implemented, separating K awards from R awards as described in Approach 1 will reduce the total number of projects that a clinical investigator can contribute to. We suggest that NIH delay implementation of these policies until the full impact of other



proposed changes such as the proposed changes to the Uniform Guidance for Federal Financial Assistance are resolved.

Our members suggest that the main barrier to the successful utilization of K awards is inadequate funding. In addition to salary support, a good training environment for physician-scientists and clinical researchers may require e.g., consumable lab and clinical research supplies and equipment. Instead of making wholesale changes to the K award program by creating barriers to leadership of clinical trials as described in the proposed approaches, NIH should evaluate whether K awards are adequately resourced to meet the training needs of clinical researchers and consider providing additional funding for these programs. Indeed, adequate federal funding for physician-scientists through programs like K awards is essential to ensuring that the medical research enterprise investigates the breadth of diseases that affect Americans, including those for which there is limited market incentive. Relying on industry-academic partnerships or other models where private funding would supplant clinical research training may introduce biases and priorities that do not reflect the entire spectrum of public health needs and scientific opportunities.

In conclusion, supporting a strong pipeline of physician-scientists and clinical researchers through the K award program is necessary to maintain a cohort of professionals who can serve not only as the next generation of leaders in drug, device, or other therapeutic development but also as translators of scientific discoveries to patient care. We urge NIH to maintain the current structure of K awards, permitting leadership in clinical trials upon receipt of a K award, and reconsider the proposed approaches until NIH can adequately provide sufficient details and justification for proposed changes, including the anticipated benefit to trainees.