



# American Society of Hematology

Helping hematologists conquer blood diseases worldwide

## **American Society of Hematology's (ASH) Response to National Institutes of Health (NIH) Request for Information on Potential NIH Funding Approaches to Support the Development of Future Clinical Trial Investigators**

***Submitted Electronically on September 30, 2026***

### **Background**

The National Institutes of Health (NIH) [announced](#) that the agency is updating its Career Development (K) Award programs. The updates would include consolidating individual K notice of funding opportunities (NOFOs), eliminating the requirement for data management and sharing (DMS) plans on Ks, and clarifying allowable uses of K award funds for clinical trial activities. These changes will take effect beginning with application due dates on or after October 12, 2027.

Notably, K award funds may no longer support clinical trials, clinical trial feasibility studies, or ancillary studies to existing clinical trials. NIH instead encourages K awardees to gain clinical trial experience by participating in mentor-led trials or securing separate funding to lead a trial as PI. In light of this change, NIH is seeking public input through a Request for Information (RFI) on alternative funding models to support the career development of independent clinical trial investigators.

### **ASH Response**

*The following includes ASH's response to NIH's request, which was submitted electronically on September 30, 2026, via the NIH's submission platform. Please note, each response was capped at 500 characters.*

#### **1. 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.***

On behalf of the American Society of Hematology (ASH), we appreciate the opportunity to provide comments on the changes to the current K award mechanism and provide further suggestions on optimizing support for the development of clinical trial investigators.

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematology (non-malignant) conditions like sickle cell disease (SCD). In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, transfusion medicine, and gene and cell therapies. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

K awards are a critical pathway for developing independent hematology clinical trial investigators. ASH is extremely concerned that NIH's changes to K awards would no longer support clinical trials, clinical trial feasibility studies, and ancillary studies to existing trials. These changes could unintentionally weaken the pipeline of physician-scientists and other researchers training to lead independent clinical trials. K awards, especially the K23 mechanism, serve an important role not only by providing protected research time for physician scientists, but also by allowing early-career investigators to progressively demonstrate independence in leading pilot trials, clinical trial feasibility studies, or ancillary studies while working within a mentored environment. Because the core purpose of mentored K awards is to help early-career investigators build an independent research portfolio, restricting K awardees' ability to lead clinical trial activities could make it more difficult for them to demonstrate independence from their mentors, compete successfully for subsequent R-level funding, obtain faculty positions, and establish themselves as independent investigator-initiated trialists.

Hematology, transplantation, and cellular therapy research depends on physician-scientists who can translate research findings into clinical care, yet these investigators often face long training pathways, high clinical workloads, and limited sources of early-stage trial funding. By removing this valuable funding source for gaining clinical trial leadership experience and collecting preliminary data for larger trials, NIH could narrow the pipeline, particularly for K08/K23 physician-scientists. In turn, this could weaken the transition from mentored research training to true research independence at precisely the career stage when investigators must begin building the record of leadership needed to sustain independent clinical trial careers. These changes could push trainees toward laboratory-focused research or out of the clinical trialist pathway altogether.

## **2. 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 two proposed alternate funding mechanisms cannot replace the support for clinical trials and related activities provided by the current K awards. Participating in a mentor-led clinical trial provides valuable experience, but it is not equivalent to assuming responsibility for designing, conducting, and leading a study. ASH is concerned that restricting K awardees from gaining this valuable leadership experience could make it more difficult for investigators to establish an independent research portfolio, compete for subsequent independent funding, and pursue careers as clinical trial investigators. Furthermore, given the scarcity of secure separate funding for junior faculty to lead a trial as a PI, this change exacerbates current challenges in developing the next generation of clinician investigators.

We recognize NIH's concern that the support provided through existing K awards is generally insufficient to finance an adequately powered interventional clinical trial with sufficient rigor and reproducibility. However, funding limitations should not preclude K awardees from conducting meaningful clinical trial-related research. Typically, K award applicants are members of a larger team where support for initiating and executing a clinical trial comes from additional avenues of support. Building meaningful scientific investigations around clinical trials can be rewarding and productive experiences that are well within K award goals. Pilot trials and feasibility studies often

supported by K awards are critical for setting up success for future clinical trials. One ASH member shared that they led a Phase I trial with supplemental resources provided by their mentor. The success of that study generated critical preliminary data that helped the investigator secure their first R01 to support a follow-up Phase II trial. Since then, the investigator has built a successful career leading multiple investigator-initiated trials. Without the K award, which provided both the opportunity to generate Phase I study results and valuable hands-on experience leading a clinical trial, their mentor would not have been able to support these activities, and the investigator may ultimately have pursued a different career path.

Several ASH members note that standard K award support can be insufficient for well-powered interventional trials, but favor enhanced or supplemental funding models over removing mentored clinical trial leadership opportunities. ASH recommends increasing the level of funding available for K awards to support more adequately powered and rigorously designed clinical trials and related activities because a limitation of the current K award is that it only provides \$25-50K for research activity, which is not sufficient for a robust lab program or a trial.

K awards also provide protected time and investigator support while mentors, institutions, or complementary funding sources provide trial infrastructure, personnel, biostatistical expertise, and other resources. NIH should preserve the ability of K awardees to conduct pilot trials, feasibility testing, and ancillary studies to existing trials, as well as mechanistic, observational, or correlative studies that prepare trainees to design and lead rigorous independent studies.

While NIH's proposed approaches are not appropriate substitutes for clinical trials supported by K awards, a phased mentored K-to-independent research project grant pathway may offer a promising additional opportunity for trainees, provided it is adequately funded & designed to facilitate rather than delay independence.

### **3. 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.***

Overall, ASH recommends that NIH strengthen, not eliminate, the K award as an important pathway for developing independent clinical trial investigators, while providing additional valuable opportunities for K awardees to gain progressively greater responsibility for clinical research. Given existing funding limitations, it is reasonable to expect a K award applicant to present a credible plan for funding the clinical investigation, and this plan could serve as one metric in the evaluation process. A phased K-to-research project grant approach that is proposed by NIH could serve as a valuable opportunity for physician-scientists, in addition to the current approach. For these programs to be successful, NIH should establish clear and achievable transition milestones, provide robust training in clinical trial design, methodology, statistics, regulatory requirements, and execution, and preserve protected research time during the transition, and ensure that the subsequent funding mechanism does not adversely affect Early Stage Investigator (ESI) eligibility. Also, this new pathway should provide additional resources for clinical trials, rather than simply shifting clinical trial costs to academic institutions, which could disadvantage investigators at smaller or less-resourced institutions.