

# **Strengthening Institutional Capacity to Conduct Global Cancer Research in Low- and Middle-Income Countries (D43 Clinical Trial Not Allowed)– RFA-CA-20-031**

## **Frequently Asked Questions**

The purpose of this Funding Opportunity Announcement (FOA) is to establish an institutional program for mentored training in global cancer research. This program will support mentored research training led by U.S.-based cancer research-intensive institutions working in collaboration with institutions in low- and middle-income countries (LMICs). These training programs will be built upon the U.S. institutions' pre-existing training infrastructure and research collaborations with LMICs and will leverage these resources to expand the global cancer research workforce both in the U.S. and in LMICs. The overarching goal of this initiative is to build capacity to conduct innovative and collaborative global research projects that will contribute to the advancement of basic, clinical, translational, and population-based cancer research in LMICs. We acknowledge that this goal can be achieved in many ways using several types of collaborative relationships between U.S. and LMIC institutions.

Please find below our responses to Frequently Asked Questions, which includes those posed during the informational webinar held on May 18, 2020. This list is intended to provide potential applicants with additional information and clarification about the program.

## **Definition of an LMIC**

### **How is an LMIC defined for this FOA?**

LMICs are defined by the World Bank classification system, according to Gross National Income per capita as "low-income," "lower-middle-income," and "upper-middle-income". In this program, consistent with NIH and Fogarty programs, "Eligible LMICs" do not include G20 countries in the "upper-middle-income country" category (UMIC) for funding (except for Sub-Saharan Africa). G20 UMIC sites may be involved as additional training sites if no faculty or trainees from that G20 UMIC institution are supported by the proposed D43. For details on the D43 definition of "eligible LMIC" used in this FOA see [Notice of Change in Country Eligibility for Fogarty International Training Grants](#).

## **Eligibility of Applicant Institutions**

### **Are the primary applicant and the contact PI required to be from a U.S. institution?**

Yes. The primary applicant and the contact PI must be from a U.S. institution that is proposing a training program in collaboration with a specific LMIC institution.

### **Is it required that the primary applicant and the contact PI be from an NCI-designated Cancer Center?**

No. Applicants from any U.S. institution engaged in cancer research are eligible.

**Can multiple U.S. institutions be part of the application?**

Yes. We recognize that key personnel and experts serving as mentors and investigators may be in different U.S. institutions.; however, the PI must describe and provide justification for working with other U.S. institutions to support the goals of the proposed research training in the relevant sections of the application.

**Can multiple LMIC institutions be part of the application?**

Yes. Strengthening research training in LMIC institutions and providing mentored research opportunities to U.S. and LMIC trainees in LMICs are important goals of this initiative. We expect that there will be one primary LMIC institution which will serve as the main collaborator of the U.S. applicant institution. The role of additional trainees or key personnel from other LMICs may be included in the justification.

**Can the U.S. institution collaborate with an LMIC institution with whom they have worked in the past, but are not actively collaborating at the time of submission?**

Yes. U.S. institutions may collaborate with an LMIC institution with whom they have worked in the past. Applicants are encouraged to outline the past collaborative work in detail and provide a rationale of how the proposed D43 will build on the past work.

**Can US institutions with experience in global cancer research and research training collaborate with a LMIC institution/s with whom they have not worked before?**

We recognize that many US institutions may have had select interactions, such as workshops and planning calls for collaborative research, but have not yet established a collaborative research program with an LMIC institution/s. If the PDs/Pis from the U.S. and the proposed LMIC institution can document how these interactions help strengthen the collaborative research and build workforce capacity, this will be considered an eligible application. However, programmatically we feel that a collaboration that is being developed only for the purpose of applying to this program may not be competitive in review. In this scenario, the US institution may consider applying with an institution in an LMIC with whom they have collaborated in the past and involve trainees from the 'new LMIC' as a way of strengthening existing research collaborations.

**Can institutions in LMICs that are subsidiaries of U.S. institutions be the primary collaborating LMIC institution?**

While we recognize that many universities have established entities in LMICs to serve as extensions to their U.S. facilities, these entities are not considered eligible LMIC institutions. We expect that collaborations will take place with LMIC institutions that are independently dedicated to research and scholarship so that sustained capacity development takes place both for the LMIC institution and individuals.

**Is it mandatory to have a U.S. institution applicant? What is the objective?**

Yes. A U.S. institution must be the primary applicant. The goal of this initiative is to develop capacity in U.S institutions (as well as LMIC institutions) to conduct collaborative cancer research.

## **Eligibility for Program Directors/ Principal Investigators [PD(s)/PI(s)]**

### **What are the criteria for PD/PI in this program?**

We invite any individual with skills, knowledge, and resources to carry out the proposed training program to apply.

### **Are multiple PDs/PIs allowed?**

Yes. Collaborative arrangements for the FOA are left to the applicants and must be supported in their proposal. For a multiple PD/PI (MPI) application you must include a leadership plan that clarifies the role of the PIs in training and mentorship.

### **What are the requirements of PD/PI having an active research award/program?**

From past NIH and NCI experience, an important facilitator of successful research training is one where research training takes place in the context of a research program. An active research portfolio also helps establish the expertise of the PD/PI in terms of her/his ability to lead a program, collaborate with colleagues, and guide students.

Active research is defined as a grant that will end only after the D43 begins. This includes grants that are in a no-cost extension year at the time of submission.

We recognize that the following scenarios of active research/award program are possible.

1. PDs/PIs have an active research program in the U.S. and/or in an LMIC, such as an R01 grant or cooperative award in the topic of focus for the D43.
2. PDs/PIs have an active research training program in U.S. and/or in LMIC

PD/PIs in either of the above scenarios are eligible to apply. These awards need not be supported by NIH.

### **Does the active project need to involve the LMIC institution(s) proposed for the training?**

It is not required for the active project to involve the LMIC institution.

### **What if, in the application, the U.S. PD/PI has no active grant, but the LMIC PD/PI has an active grant or research program?**

An application with at least one PD/PI, either U.S. or LMIC, with an active grant is eligible. While this is an eligible application, the applicants are advised to review the scoring criteria so that the leadership in the U.S. and LMIC can propose a training program that will be able to build the workforce capacity in a specific cancer research area in alignment with the overall goals of the FOA.

### **Is it expected that the PD/PI of the applicant institution has conducted research training in the past?**

It is not expected that the PD/PI has held an institutional training grant. However, we expect that that the PD/PI has expertise in the topic of training proposed in the application and has conducted research in that topic.

**In a multi-PI application, is it a requirement that all PIs have funded research or funded training programs?**

This is not a requirement. As mentioned in the FOA, it is important to provide a rationale for the multiple PIs and how their experience will be brought to bear in the proposed program.

**Eligibility of Preceptors and Mentors in the D43**

**Who are eligible mentors in this program?**

In a training award, preceptors and mentors are key as they provide expertise and guidance on conducting research. Eligible preceptors and mentors are individuals who have expertise in a cancer research topic of focus in the application and funding available to support the number and level of trainees. Preceptors and mentors should also have a strong record as researchers. Further, they should have a track record of training individuals at the levels that are being proposed in the program including short term trainees. We expect that most if not all mentors have research or research training experience in the LMIC/s that are part of the application and on topics that are the focus of the application.

**Do all mentors need to have existing research funding to train mentees?**

No, not all mentors need to have existing research funding; however, we expect that most mentors will have research funding. This will enable to mentors to offer guidance on career development and research programs that is grounded in their own research experience.

**Eligibility of Trainees in the D43**

**Who can be trained under this program?**

In the context of this FOA, "trainees" are individuals both from the U.S. applicant institution and the collaborating LMICs. The applicant can propose to train pre-doctoral and postdoctoral candidates. Pre-doctoral trainees must be enrolled in a program leading to a master's degree, Ph.D., or an equivalent research doctoral degree program. Postdoctoral trainees must have received a Ph.D., M.D., D.D.S., or comparable doctoral degree from an accredited domestic or foreign institution. Postdoctoral trainees also include clinical fellows and clinicians in residency training. In this program, US trainees can only be at the postdoctoral level; LMIC trainees can be trained at both the predoctoral and the postdoctoral level.

**Is it mandatory to have a U.S. trainee in this program?**

No. It is not mandatory that U.S. trainee/s be part of the award. The goal of the program is to build capacity of U.S. institutions collaborating with LMIC institution/s to conduct cancer research. Training U.S. trainees may be included where it supports career development of the trainee to do international research and further develops collaborations in the LMIC/s.

**Do specific trainees need to be identified, or is indication of a source of trainees (school of medicine, university etc.) sufficient?**

Applicants are advised not to name specific trainees. Applicants are encouraged to discuss trainee selection process and selection criteria to describe the source/pool of trainees available (if available) and to outline who they will be selected in the program.

**Can the U.S.-based trainees be international students?**

U.S. based trainees in this program must be at the postdoctoral level and can be postdoctoral candidates from other countries (either from LMIC institutions that are part of the application or other countries). Please justify in the application the rationale for selecting this trainee/s, the commitment of the U.S. institution to their learning, trainee commitment to collaborative cancer research in the LMIC institution/s that are part of the program.

**Are junior faculty eligible for training (do they qualify as postdoctoral trainees)?**

Junior faculty (defined as individuals who have completed their doctorate and in academic appointment/s at the time of the training) may participate in the program. If the applicants determine that further training is needed for junior faculty, they should provide a justification. Junior faculty, with justification, can also avail of research experiences allowed in this program to facilitate their career development.

**Can institutions propose training of health care providers to strengthen/improve the quality of care in LMIC settings?**

No. The purpose of this grant program is to develop a trained workforce for cancer research. We expect that trainees will develop skills and be mentored to propose research questions that can contribute to the advancement of cancer control in LMIC settings. While we recognize that there is a dearth of trained oncologists and cancer care delivery professionals in LMICs, this program does not allow for training in treatment or care delivery.

**Other Training Related Questions**

**Where will the training take place?**

We recognize that training needs vary based on the research area(s) of interest to the U.S.-LMIC collaboration. As such, applicants have the flexibility to decide where and what types of training are needed to develop research capacity. Training can take place either in the U.S. applicant institution or at the primary collaborating LMIC institution. Other institutions can also serve as training sites as long as the application includes a rationale for this decision.

**What type of support for training does this program provide?**

Broadly, training support includes tuition and fees for degree-granting and certificate programs, research costs, research relevant travel support, and effort of mentors and faculty. Training support also includes protected time for trainees to conduct research training. Please refer to Section 2 of the FOA under Other Award Information for more details.

## **Types of Training**

**The FOA refers to three types of training – long-term, medium-term, and short-term training. Should an application contain all three types of training?**

These types of training are all options to build capacity. We are not specifying any requirements regarding the number of these types of training, nor are we requiring that an application should have all three. We recognize that each collaboration will come with its own specific requirements for capacity building. For instance, depending on the research area for which a particular LMIC needs to strengthen capacity, there may be need for more degree programs; in others, there may be a need to train more in-country lab technicians or community health workers. We are leaving it to the applicant to make this decision on the types of training and the combination they want to implement in this program. Applicants should also provide a rationale for the training plan or approach they propose.

**The FOA notes that training for mentorship is encouraged. Can we train mentors in this program?**

Mentors cannot be formally trained in this program. That said, we recognize that there is an opportunity to informally provide mentorship guidance during the grant period. Discussions via conference calls, experienced faculty devoting some of their effort to mentor newer mentors, sharing lessons in mentorship at side meetings in conferences that faculty and key personnel plan to attend, and taking advantage of existing regional networks to focus on mentorship are all examples of the types of informal mentorship that we encourage.

**The RFA mentioned a requirement for ‘full-time training’. Would it not be permitted for residents/fellows to engage in research training alongside clinical training with protected time?**

We understand that many LMIC trainees who are clinicians will have patient responsibilities. Additionally, U.S. trainees who are clinicians and work in LMIC settings may be called on to see patients. Applicants are encouraged to justify the division of effort of trainees and ensure that effort to build research capacity is significant.

**Is south-to-south training allowed?**

The primary applicant institution can work with multiple LMIC institutions. Hence, trainees from multiple LMIC institutions are allowed.

**Do foreign PhD students need to be registered in the U.S. PhD program?**

Not necessarily. The collaborating institutions in the application can decide where training takes place and who might serve as mentors in order to further the research training goals.

**Do specific trainees need to be named?**

Specific trainees must not be named in the application. Please provide a discussion on training pool from which selection of trainees will take place, recruitment and selection criteria and the role of the Training Advisory Committee in these processes, if such as committee is being proposed.

**Can data managers/clinical research associates be included as trainees? Can nurse researchers without a PhD be included as trainees?**

Yes, data managers/clinical research associates and nurse researchers without a PhD can be included as short-term trainees. If you want to include them as medium- or long-term trainees, please provide a justification as to how this training can help build and sustain capacity for research in the collaboration.

**Synergies with existing or past research training awards**

**Can you provide more specifics about how this award could synergize with the Fogarty D43 award? Could the LMIC institution be a recipient of both awards, and if so, what would this look like?**

Synergizing with existing training awards from Fogarty or other funding agencies is important. Drawing from the pool of mentors and/or trainees in past programs for the cancer D43, such as gathering cancer related descriptive data; testing research hypothesis developed based on research experiences or clinical observations from past D43s; exploring models of mentorship for cancer research based on past training experiences; and working on developing specific competencies for cancer research based on past training are some examples of how past training programs might be leveraged for the cancer D43.

**If our U.S. academic institution already has a non-cancer D43 training grant, would it be responsive to propose collaborative efforts between the existing program and our proposed D43 cancer training proposal?**

Yes. Building on past research training, both cancer and non-cancer related, is key. An application that proposes collaborations between existing and proposed cancer trainings would be responsive.

**Application Preparation**

**Is there a difference in how an application is written for a research grant vs. a research training grant?**

Yes, there is a difference. In a cancer research grant, applicants propose to test hypotheses or evaluate interventions; however, in a research training grant, applicants propose specific training activities to develop or expand capacity to conduct cancer research.

**Where can I find guidance as I write my grant application?**

A D43 grant is an institutional research training grant that allows for foreign trainees. NIH has guidelines for how research training grants are written and specific guidance on the D43: <https://grants.nih.gov/grants/how-to-apply-application-guide.html>. Applicants must follow these guidelines. In addition, additional guidance for applicants is provided in the sections of the D43 FOA. We encourage you to review both the NIH guidelines and the complete FOA for information that will help in preparing a responsive application. Please note that a recent NIH notice provides new guidance on training areas to address in institutional research training grant

applications (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-090.html>). These include minor modifications to the training data tables section (<https://grants.nih.gov/grants/forms-f/data-tables.htm>). Training data tables provide an opportunity to the applicant to communicate the strength of the proposal by noting faculty research and research training support, as well as past capacity building outputs from trainees.

## **Application Review**

### **Are the review criteria for the D43 different from research grants?**

Yes, **D43 review criteria is different from criteria for research grants**. The D43 is an institutional training award, and applicants will be reviewed to evaluate the strength of the proposed training and mentorship program. The reviewers will consider specific areas in the following categories, (Training Program and Environment, Program Director/Principal Investigator, Preceptors and Mentors, Trainees and Training Record) as these components are central to developing a strong research training program. . The specific criteria under each category are provided in the review criteria section – Part 2, Section 5 of the FOA.

## **Key Dates**

Applications are due on July 24, 2020 and June 24, 2021. We will assemble a Special Emphasis Panel to review the submission for secondary review by the January 2021 Council, with the anticipated funding date in March 2021.

## **Budget**

### **How many grants will be funded?**

We anticipate funding up to four grants in the first round and up to three grants in the second round, depending on available funds.

### **Are indirect costs allowed in U.S. institutions?**

Yes. Indirect costs are allowed at 8% per NIH policy on research training grants.

### **For the list of "eligible costs" listed on the prior slides, are those the ONLY allowable costs? Are there costs allowed for equipment?**

For budget information under this RFA see <https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-031.html> under Section II. Training equipment (up to \$5000) is listed as an allowable cost.

### **Are stipends, etc. included as eligible costs to allow a trainee to get clinical residency training (i.e. oncology training) in another country when, for example, it is not available in the LMIC?**

The focus of this program is on research training only. Clinical training of any kind will not be supported.

## **Grant Submission**

### **Will there be an extension of receipt date?**

At the time of the webinar, the due date remains July 24, 2020 for the first round. We recognize that this program was developed prior to the current pandemic outbreak and was posted just as the global shutdowns related to covid-19 were underway. We recognize that these disruptions affect the ability to collaborate internationally in many ways. This is being handled uniformly across the NIH with regular updated guidance from the NIH Office of Extramural Research (OER) – <https://grants.nih.gov/policy/natural-disasters/corona-virus.htm> This guidance would also be applicable to the D43 program.

### **Are resubmissions allowed? Will there be an opportunity for competitive renewal?**

Applicants not funded in the first round can submit a new application to round two. Currently, there is no process for a competitive renewal application. At the programmatic level, we remain committed to grow this training program; however, it is too early to tell whether competitive renewals will be allowed in the future or other funding opportunities will be introduced.