# Frequently Asked Questions for NOT-CA-13-015

### 1. What is the definition of a low and middle income country?

a. For this RFA, low and middle income countries are defined as indicated by the World Bank . "Upper-middle income" is included in the definition of "middle income."

## 2. May I work with LMIC investigators in the UH2 phase?

Applicants *must* work with LMIC investigators in the UH3 phase to demonstrate the suitability of the technology for application in the low resource setting. Applicants may also elect to work with LMIC investigators in the UH2 phase.

3. Must the U.S. and LMIC groups have previous joint publications in order to submit an application for RFA-CA-13-015?

No. Either new or existing collaborations with LMIC investigators are allowed; however, LMIC collaborators should provide a letter of intent demonstrating their commitment to collaborate with the U.S. team.

- **3.** Can I propose to develop a new technology in the UH2 phase if I can do this within budget? No. Applicants must have an existing prototype in the UH2 phase that will be adapted to LMIC settings. However, development of adjunct enabling technologies to enhance the existing prototype is allowed.
- 4. May applicants skip the UH2 phase and proceed directly to the UH3 phase? Does the UH2 phase need to be a full two years?

An investigator may not proceed directly to the UH3 phase but the UH2 phase does not need to last a full two years. However, if the UH2 phase is less than two years, the transition to the UH3 phase will not occur until approximately two years after the notice of grant award.

5. What types of cancer are eligible under this RFA? What is the definition of a treatable cancer in an LMIC?

Any type of cancer that can be prevented, cured, treated (so as to substantially improve survival and/or quality of life), or palliated within the LMIC setting is eligible under this RFA.

6. Does the industrial partner have to be located in the LMIC?

There are no specific requirements for the physical location of the industrial partner; however, the industrial partner must have "expertise in fabrication, help with governmental regulation approvals including in-country regulatory expertise, and prepare, disseminate, and sustain the technology for clinical use."

# 7. What is required for the business plan? Is a complete business plan needed for the UH2 phase?

A preliminary business plan outlining the proposed approach for commercializing the technology in the LMIC of interest is required at the time of application submission. A more detailed business plan will be required in order to transition to the UH3 phase.

#### 8. What is the role of the NCI in these awards?

Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project. NCI program staff will provide awardees advice on protocol design, experimental and clinical approaches, consult on updates to project milestones, facilitate interactions among investigators, provide subject matter expertise (both global health expertise and specific technical competencies), and assist investigators in reaching the benchmarks and timelines outlined in their awards by providing oversight (please see the RFA Administrative and National Policy Requirements).

#### 9. Will the RFA be reisussed?

The NCI Board of Scientific Advisors approved three award cycles for this program; however, the NCI must confirm annually that sufficient funds are available to support each possible reissuance.

#### 10. What is the definition of "low cost"? Is it dependent upon a particular LMIC?

The definition of a low cost technology depends both on the technology and the specific LMIC setting. Applications should focus on technologies that can be made inexpensive enough to allow widespread adoption and use in the LMIC setting.

# 11. How will the review of applications be handled?

The NCI will convene a Special Emphasis Panel to review applications submitted to this RFA.