

Advancing Biomedical Research to Improve Health at Home and Abroad

The scientific discoveries and technological advances in diagnostic ultrasonography chronicled in the current issue of *Global Heart* are impressive. These advances have now made highly portable, pocket-sized point-of-care (POC) ultrasound devices for patient evaluation and management possible. However, translating investigator-initiated fundamental scientific discoveries and technological advances into commercially viable diagnostic devices is no simple task. In fact, it is a well-recognized hurdle for many academic research scientists that one investigator recently characterized as “the valley that sits between innovation and commercialization” [1]. Traditional biomedical research funding is typically exhausted before the innovative products gain the interest of commercial investors. Additionally, commercial investors are increasingly becoming more risk averse with respect to such early-stage innovation at the same time as drug and device manufacturers are reducing their investments at this early stage of research development. As a result, many promising ideas never materialize into diagnostic and therapeutic devices and drugs for patient care.

Recognizing this hurdle, the National Heart, Lung, and Blood Institute (NHLBI) established the NIH Centers for Accelerated Innovations (NCAI) program [2]. The goal of this program is to specifically address the gap in the commercialization pipeline between scientific discovery and company formation in order to support the long-term goal of more rapidly and effectively moving breakthrough innovations to available products that will improve patient care and advance public health [3]. The program specifically targets technologies and therapeutics that are poised for proof of concept, prototype development, and feasibility studies [3]. This program holds tremendous promise for transformational change in the way fundamental scientific discoveries move from the laboratory into commercial products [4]. In essence, providing support for this endeavor will enable biotechnology, drug, and device manufacturers to pick up promising compounds and devices that have been effectively “de-risked” by academic investigators and get them to market [5].

The 3 NCAI grantees, currently supported by the NHLBI with grants totaling \$31.5 million over 7 years, include the Boston Biomedical Innovation Center, the Cleveland Clinic Innovation Center, and the University of California Biomedical Research Acceleration, Integration, and Development Center for Accelerated Innovation. These centers will focus on investigators with research projects that have progressed to a point where a potential commercial product can be envisioned but additional development efforts are required to demonstrate feasibility or proof of concept and commercial potential [3]. Importantly, they will provide educational and mentoring opportunities in entrepreneurship tailored to the needs of the research and technological innovator [3]. This bold initiative is consistent with recommendations made by

the Accelerated Innovations Program Working Group that advised the NHLBI on the framework, structure, key components and their functions, as well as critical processes and resources for success [3].

Another NHLBI Working Group that focused on onsite tools and technologies for clinical cardiovascular research and POC convened in June 2012 to discuss the development and application of POC technologies as tools for diagnosis and monitoring in the clinical cardiovascular research setting. The Working Group defined POC testing as “convenient and immediate clinical diagnostic and laboratory testing at or near the site of patient care using portable, transportable, handheld instruments and analysis test kits” [6]. Table 1 provides examples of current active funding opportunities from the NHLBI to support research using advanced technologies to develop novel POC devices, tools, and technologies for screening, detection, evaluation, or treatment of heart, lung, and blood diseases and sleep disorders.

The World Health Organization has identified diagnostic, therapeutic, and assistive devices, tools, and medicines as 1 of the 6 principal building blocks of health systems [7]. Strengthening health systems and assuring equitable access, availability, affordability, and appropriate use of these devices, especially in low- and middle income countries (LMICs), is an important challenge [8]. In this regard, 2 caveats are worth emphasizing. First, the pursuit of innovative diagnostic devices should not be at the expense of appropriate use of existing tools, techniques, and devices. In many settings, particularly in low-income countries, assuring access to physical examination and basic diagnostic tools such as the chest radiograph and electrocardiogram take precedence. Second, it is best to demonstrate objectively that the use of these novel devices and technologies leads to health benefit before their widespread adoption. As an example, the NHLBI is currently funding the PROMISE (PROspective Multicenter Imaging Study for Evaluation of Chest Pain) Trial, which has successfully enrolled 10,000 patients and is testing whether the use of computed tomography angiography (as compared to traditional diagnostic approaches) leads to improved clinical outcomes (www.promisetrial.org). Research studies like these can help avoid inappropriate proliferation and use of diagnostic tools [9].

In addition to improved access to these devices and technologies, assuring an adequate and prepared workforce for the prevention and treatment of cardiovascular diseases as well as the conduct of locally-relevant basic, clinical, and population science research is just as crucial. In partnership with the NIH Fogarty International Center, the NHLBI supports several global health programs that focus on strategic research capacity and training needs of LMICs. Two examples of training programs are the Global Health

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TABLE 1. Funding opportunities to support research using advanced technologies to develop novel point-of-care (POC) devices and tools and technologies for heart, lung, and blood diseases and sleep disorders

Title	FOA Number	Issuing Institute	Released	Opens	Expires	Activity Code
Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care SBIR (R43/R44)*	RFA-HL-14-011	NHLBI	08/15/2013	09/15/2013	10/16/2015	R43/R44
Developing a Point-of-Care Device for the Diagnosis of Sickle Cell Disease in Low Resource Settings SBIR (R43/ R44)†	RFA-HL-14-010	NHLBI	07/08/2013	09/23/2013	10/24/2015	R43/R44
Technologies To Assess Sleep Health Status in Populations (R43/R44)‡	RFA-HL-14-013	NHLBI	09/13/2013	10/15/2013	11/14/2015	R43/R44
Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care STTR (R41/R42)¶	RFA-HL-14-017	NHLBI	08/15/2013	09/15/2013	10/16/2016	R41/R42

FOA, funding opportunity announcement; SBIR, small business innovation research; STTR, small business technology transfer; RFA, request for applications.
 *<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-011.html>.
 †<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-010.html>.
 ‡<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-013.html>.
 ¶<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-017.html>.
 Source: NHLBI, <http://grants.nih.gov>.

Program for Fellows and Scholars (GHPFS) and the Medical Education Partnership Initiative (MEPI). The GHPFS provides focused mentoring for postdoctoral and doctoral level

trainees in global health research at established research training sites in LMICs. The program currently supports 5 support center consortia partnered with 74 research training

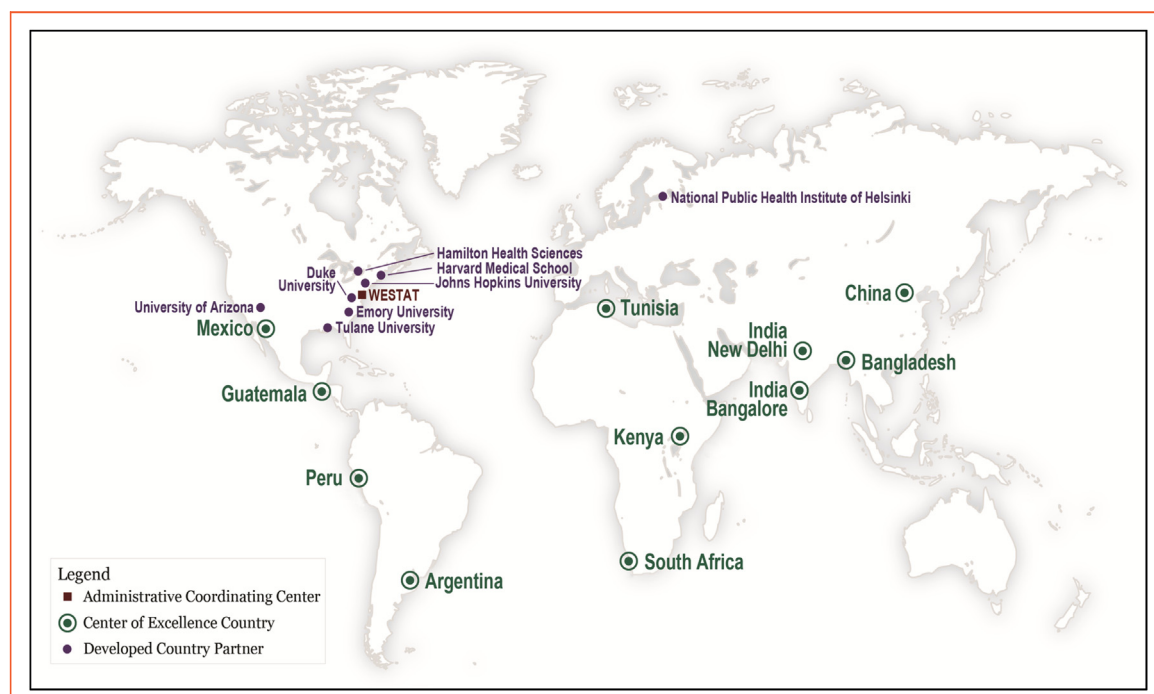


FIGURE 1. The National Heart, Lung, and Blood Institute/United Health Group Centers of Excellence and Developed Country Partner geographical regions.

sites in 27 LMICs on 4 continents. The MEPI program provides direct support for developing or expanding and enhancing transformative models of medical education in Sub-Saharan Africa by strengthening clinical and research capacity as part of a retention strategy for faculty of medical schools and clinical professors [10].

In addition to training programs, the NHLBI also partners with the Fogarty International Center and other NIH institutes to support global health research. For example, the NHLBI currently funds research programs in Argentina, Ghana, Kenya, and Peru as part of the Global Alliance for Chronic Disease (GACD) research program in hypertension prevention and control in 15 LMICs. Each research project is conducted through a partnership between investigators in a developed-country institution and investigators and institutions in an LMIC [11]. Current projects are funded by 4 of the GACD members, with an investment of more than \$21 million over the next 3 to 5 years [11]. The NHLBI also currently supports research and training through the NHLBI/United Health Group Collaborating Centers of Excellence (COEs) (Fig. 1). In this endeavor, each of the 11 COEs collaborates with research institutions in developed countries to build research and training infrastructures and to conduct research to improve the prevention and treatment of chronic cardiovascular and lung diseases in their respective country [12]. The research themes addressed include dietary risks for cardiovascular diseases, the health impact of indoor air pollution, and the validation of nonlaboratory screening tools.

The programs and initiatives described here help support the NIH mission of turning scientific discoveries into health. They advance biomedical research at home and abroad by facilitating rapid commercialization of innovative devices, tools, and medicines to improve patient care. Most importantly, through funding for research, training, and education, these programs also invest in the most valuable asset of all, the men and women who make up the clinical and biomedical research workforce at home and abroad.

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