



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE



CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING  
Center established by Novartis Vaccines and Diagnostics of Cambridge, Massachusetts

Centers for Innovation in Advanced Development and Manufacturing are part of a national strategy recommended in the August 2010 *Public Health Emergency Medical Countermeasures Enterprise Review*. The review found that the nation needed a nimble, flexible capacity to produce medical countermeasures rapidly for any threat, known or unknown, including a novel, naturally occurring emerging infectious disease. The Center established by Novartis will meet this need in the following ways:

**CONSTRUCTING NEW AND/OR RETROFITTING EXISTING BIOPHARMACEUTICAL FACILITIES TO AUGMENT CURRENT U.S.-BASED CAPACITY**

Novartis will design, renovate, and commission a clinical trials material filling suite in its existing pilot plant in Holly Springs, N.C., with an expected operational opening by 2014. This suite will provide clinical investigational lots of chemical, biological, radiological, and nuclear (CBRN) medical countermeasures. On a routine basis, Novartis will design, construct, and commission a technical services building in Holly Springs with an expected opening by 2014. This facility will support manpower and maintenance requirements of the pilot plant for advanced development of CBRN medical countermeasures.

**PROVIDING ADVANCED DEVELOPMENT AND MANUFACTURING CORE SERVICES**

Upon HHS request, Novartis will provide product development core services to advance a biopharmaceutical product candidate to FDA licensure or approval using its entire pilot plant facility and all of the experienced support resources within the organization.

**PROVIDING BIOPHARMACEUTICAL PRODUCTION SURGE CAPACITY**

In addition to the company's existing U.S. government pandemic influenza projects and commercial influenza vaccine interests, Novartis is committed to manufacture at least 50 million finished doses of pandemic influenza vaccines at the Holly Springs facility within four months of pandemic onset, with the first doses available within 12 weeks. Novartis will use its existing commercial manufacturing facilities, operating at a higher scale, to meet this surge requirement.

**DEVELOPING THE BIOTECH WORKFORCE**

Novartis will augment its existing successful workforce development program to accommodate personnel related to the Center's operations. Working with North Carolina State University of Raleigh, N.C. and Duke University of Durham, N.C., Novartis will provide a workforce training program for future biopharmaceutical product development and manufacturing workers.

**ABOUT THIS CONTRACT, HHSO100201200003I**

The Center demonstrates a long-term public-private partnership committed to national health security. The contract builds on progress HHS has made to protect the public from acts of bioterrorism, pandemic influenza, and emerging infectious diseases. This is a cost sharing contract. HHS will invest \$59,840,746 over a base period of four years. Novartis will provide 31 percent of the overall construction costs. After that base period, HHS has the option to extend the contract annually over the total contract period up to 25 years. These options could be exercised with task orders for operational readiness reimbursement, development and manufacturing core services, warm base maintenance, surge manufacturing, and/or workforce development.

