

Request for Proposal (RFP) Number 15-100-SOL-00015

Advanced Development of Broad-Spectrum Influenza Monoclonal Antibodies

Date: August 5, 2015

Prospective Offerors:

This RFP represents the Department of Health and Human Services commitment to support the advanced development of new monoclonal antibodies with novel mechanisms of action that exhibit broad-spectrum neutralizing activity across Influenza A subtypes, and treat infected individuals with a focus on the severely ill, hospitalized population with the goal of U.S. licensure and a plan for U.S. supply of these monoclonal antibodies during a pandemic. Supported activities may include Phase 2 and 3 clinical studies, process development and validation, non-clinical testing and regulatory activities. The primary purpose of the HHS/BARDA initiative is to fully develop the proposed broad-spectrum influenza monoclonal antibody candidate.

This RFP includes Mandatory Criteria for Eligibility which is located in Section M, Article M.2.

Any amendments to this RFP will be posted on the Federal Business Opportunities website (www.FedBizOpps.gov). No other notice shall be given to prospective Offerors and it is incumbent on Offerors to make periodic inquiries.

Prospective Offerors are advised that HHS is operating under stringent security requirements applied to all incoming mail and packages. This includes all proposals submitted under HHS solicitations by regular mail, express mail delivery or hand-delivered by an Offeror or by a courier service. Please note that personal identification of couriers or Offerors is required for delivery of proposals.

In accordance with the attached RFP, Offerors are required to submit their proposals to the Contracting Officer no later than **September 21, 2015, at 12:00PM EST**.

Any questions concerning the RFP should be submitted in writing to Sherica Teshome no later than **August 21, 2015** via email at Sherica.Teshome@hhs.gov. Questions should be marked "Questions Regarding RFP-15-100-SOL-0015". All questions and answers will be made available via the FebBizOpps website.

Letters of intent to submit a proposal must be received by **September 11, 2015**. The Proposal Intent Response Sheet is located in the RFP as Attachment 3. Please note that your expression of intent is not binding but will greatly assist us in planning for the proposal evaluation process.