Clinical trial leads to FDA approval of better anthrax vaccine regimen

The Emory Vaccine Center was a primary participant in the CDC’s Anthrax Vaccine Research Program (AVRP), which recently resulted in U.S. Food and Drug Administration (FDA) approval of a much improved vaccine regimen.

BioThrax (AVA, anthrax vaccine adsorbed) was originally licensed by manufacturer Emergent BioSolutions in 1972 and is the only vaccine licensed in the United States for protecting humans against anthrax. Until now, it had a lengthy six-dose primary series at 0, 0.5, 1, 6, 12 and 18 months, with subsequent annual boosters. The vaccine was administered subcutaneously, and full protection against anthrax was not considered achieved until 18 months after the initial dose.

In May 2012 the FDA approved changes in the administration of BioThrax to a more manageable three-dose primary series of intramuscular injections at 0, 1, and 6 months, with a booster series at 12 and 18 months and at one-year intervals for those who remain at risk. Individuals are considered protected after the three-dose primary immunization series – a full year sooner than previously specified.

The CDC AVRP was initiated in 1999 under a Congressional mandate to document the safety and immune effectiveness of AVA and to evaluate the potential for reducing the number of doses and switching to intramuscular administration. The clinical study was conducted from 2002 to 2009, and Emergent BioSolutions submitted its supplement in 2010.

BioThrax, which is made from a non-virulent strain of *Bacillus anthracis*, is primarily important for protecting military personnel deployed to high-risk areas. Since 1998 more than 11 million doses have been administered to more than 2.7 million military personnel.

“We are very proud of the Emory Vaccine Center’s participation in this important program,” said director Rafi Ahmed, “and I would particularly like to acknowledge the work of Chris Ibegbu, Bob Mittler, and John Altman from the EVC.”