

Dr. Claudia Golenda of the Walter Reed Army Institute of Research (WRAIR), US Army Medical Research & Materiel Command wins the FLC Mid-Atlantic Region Outstanding Technology Transfer Professional Honorable Mention Award

The Mid-Atlantic Region of the Federal Laboratory Consortium this year presented the Outstanding Technology Transfer Professional Honorable Mention Award to Dr. Claudia Golenda of the Walter Reed Army Institute of Research (WRAIR), US Army Medical Research & Materiel Command.

The Outstanding Technology Transfer Professional Award recognizes the efforts of a technology transfer professional — who is a member of the FLC—who has demonstrated outstanding work in transferring a technology in a manner significantly over and above what was called for in the normal course of their work. Nominees must have demonstrated outstanding leadership, inventiveness and perseverance.

The development and commercialization of a new treatment for severe malaria is relevant for American soldiers. Dr. Claudia Golenda, the Chief at the Office of Research and Technology Applications (ORTA) at the Walter Reed Army Institute of Research (WRAIR), has successfully written and coordinated a CRADA, with a pending exclusive patent license agreement, that involves private company Sigma Tau Pharmaceuticals, Inc., working towards producing an FDA licensed drug for the treatment of severe malaria utilizing the medicine Intravenous (IV) Artesunate.

In 2003 a malaria outbreak greatly affected US forces when 80 out of 220 marines deployed to Liberia contacted *falciparum* malaria. The Center for Disease Control reported in 2005 that two of the seven malaria deaths in the United States were due to the lack of availability of IV-quinidine (currently the only FDA-approved treatment for severe malaria, which also has serious life threatening side effects). Four to eight deaths occur annually in the US as a result of misdiagnosed or delayed treatment.

The goal of the three way CRADA between WRAIR, the U.S. Army Medical Materiel Development Activity (USAMMDA), and Sigma-Tau Pharmaceuticals, Inc. is to develop a USFDA-approved, affordable intravenous artemisinin derivative that will reduce mortality from severe malaria, with minimal risk for neurotoxicity. Having a treatment that is in an intravenous form (as opposed to the pill that is currently available) will have significant impact on children (who need to take the drug intravenously) and the vast majority of patients with severe malaria who are in a coma and can not take the pill form. Sigma Tau will support research at WRAIR with over 1.5 million dollars under the CRADA. Sigma-Tau has also submitted an application for an exclusive patent license agreement with the goal of commercializing the resulting severe malaria treatment in both the United States as well as other countries of the world. Once completed, it will be the first patent license for a malaria product.

Golenda, who has been the ORTA at WRAIR for over six years, had to overcome several obstacles in order to successfully orchestrate the cooperative research agreement. In the

early stages of putting the CRADA in place, Golenda realized that the intellectual property to be associated with the agreement was the result of a contract between WRAIR and a private company. Dr. Golenda contacted the company and facilitated the assignment of rights to the US government. At this time Golenda discovered that the private company, while a US corporation, was an Italian company. At this point it was necessary to notify the Trade representative and obtain concurrence in order to enter into a CRADA with a foreign partner.

Another unusual aspect to this CRADA was the inclusion of USAMMDA. Golenda recognized that USAMMDA was the official representative of the US Army Surgeon General for the FDA Investigational New Drug Application. WRAIR had conducted several clinical trials, but only USAMMDA could officially turn over the clinical trial data to Sigma Tau. Having three parties involved in the CRADA required extensive coordination on Golenda's part.

Under the agreement, Sigma-Tau will be responsible for the commercial development and manufacturing of IV Artesunate once approved by the FDA. In March 2006, an Orphan-Drug designation was granted for IV Artesunate for the immediate treatment of malaria. Sigma-Tau plans to submit an application for FDA review in 2008.

Golenda's integral role in the Sigma-Tau agreement is just one of many successful partnerships she has facilitated. She developed and implemented procedures for evaluating CRADAs that allowed for a more efficient and effective flow. In addition she maintains superb budgeting practices, recovering as much costs as possible under all agreements. Traditionally, the Statement of Work on a CRADA was written very broadly – Dr. Golenda writes very narrow SOWs in order to ensure that inventions can be used with other CRADA partners, licensed out or utilized in other ways. The Sigma-Tau CRADA is an outstanding representative of implementation of all three of these factors that benefit both the warfighter and the civilian populations.

The Federal Laboratory Consortium is comprised of the technology transfer offices of all of the Federal laboratories throughout the country while its Mid-Atlantic Region focuses on the 70 Federal laboratories in DC, DE, MD, PA, VA and WV.

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