



To: la Kamarauli

Eastern Europe and Central Asia Regional Pharmacovigilance Workshop: Implementation of active TB drug-safety monitoring and management (aDSM) for New Drugs and Shorter Treatment Regimens for MDR TB

Location: Almaty, Kazakhstan

The InterContinental Hotel, Zheltoksan St 181

Meeting Date: June 13-15, 2018

Dear la Kamarauli,

We are pleased to invite you to participate in the "Eastern Europe and Central Asia Regional Pharmacovigilance Workshop: Implementation of active TB drug-safety monitoring and management (aDSM) for New Drugs and Shorter Treatment Regimens for MDR TB", funded by the USAID TB CARE II project.

As many countries are now introducing new drugs (NDs) and shortened treatment regimen (STR) for the management of DR-TB, there are major challenges with understanding and properly implementing aDSM. This workshop is organized as part of the Bedaquiline Donation Program's technical assistance to strengthen the capacity of countries introducing ND and STR to monitor patients' safety and report adverse events using the WHO aDSM framework.

The purpose of this workshop is to discuss key issues, share experiences, and lessons learned from countries that have implemented aDSM, potential interventions, and rationale for stronger aDSM systems to ensure patients' safety and appropriate utilization of ND and STR. This workshop will also identify opportunities for effective collaboration between the National Tuberculosis Programs and National Drug Regulatory Agencies to support the introduction of new drugs and regimen and implementation of aDSM activities.

This workshop will provide a clear understanding of the WHO aDSM framework implementation at the country level and support the development of country specific roadmaps and actions for effective aDSM implementation. Country representatives are expected to present on their country's pharmacovigilance status. Detailed instructions will follow once invitees are confirmed. The country roadmaps will be as tools to strengthen across all stakeholders and organizations to ensure that eligible patients are able to access NDs/STR and that aDSM systems and reporting structures are established and strengthened. The preliminary agenda is attached.

National team composition should include National Tuberculosis Program representatives (including the Drug Resistant TB Coordinator), and a national drug regulatory agency representative. In total, USAID will support the participation of 5 representatives from each country. USAID will also extend invitation to relevant implementing partners to attend at their own expense.



TB CARE II

Please confirm your workshop attendance at the earliest possible.

We look forward to your participation.

Kind regards,

Refiloe Matji, MD

TB CARE II Project Director