Launch of the Good Participatory Practice Guidelines for TB Drug Trials

The Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens initiative launches guidelines that will facilitate the involvement of communities and participants in the conduct of TB drug trials.

WASHINGTON, DC (October 1, 2012) – As partners of the Critical Path to TB Drug Regimens (CPTR) initiative prepare to gather for their annual meeting, the members of one of the initiative's Workgroups is launching a set of guidelines that will help change the way TB drug trials are conducted.

Working in close collaboration with AVAC, the Stakeholder and Community Engagement Workgroup (SCE-WG) has adapted the UNAIDS-endorsed *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* to the specific context of TB drug trials. The *Good Participatory Practice Guidelines for TB Drug Trials* (GPP-TB) provide guiding principles and practice standards for stakeholder engagement as an integral part of TB drug trials. Stakeholder engagement refers to any form of consultation, collaboration, and partnership put in place to enable a dialogue between all parties having a stake in a specific trial. The goal is to reach a point where that project is understood, acceptable, and meaningful to all. In TB trials, resources to support researchers interested in engaging local communities have been limited. These guidelines thus address a critical need that was revealed by interviews conducted with prominent members of the TB research community.

Dr. Jim Lavery, Associate Professor at the University of Toronto, Research Scientist at St. Michael's Hospital and co-chair of the SCE-WG, hopes the GPP-TB will help call attention to the importance of stakeholder engagement in TB drug research: "There is more and more emphasis on the importance of stakeholder engagement in clinical trials, but this is the first time we have guidelines that are designed specifically for TB trials. Incredible work with communities has already been done in some TB projects, but few experiences have been shared with others. So until now, there has been a lack of shared understanding of what stakeholder engagement should look like in TB drug trials. The GPP-TB represents a terrific head-start for the CPTR as it will help create a common language for trial implementers, their sponsors, and relevant stakeholders."

Jane Reese-Coulbourne, Executive Director of the Reagan-Udall Foundation for FDA and co-chair of the SCE-WG, recognizes that the launch of these guidelines is only the first step towards more consistent incorporation of stakeholders' interests in TB drug trials: "In the coming months, we will be focusing on the implementation of these guidelines by developing relevant tools and materials. Already, it has been very motivating to work with early reviewers to refine the guidelines and make them as useful as possible. In particular, meeting with the community engagement officers of the various African sites of the REMox TB trial helped gear the guidelines towards the practical concerns of those working on the ground with communities. As more experience conducting stakeholder engagement in TB drug trials become available, the guidelines will only become more refined and relevant."

The full version of the *Good Participatory Practice Guidelines for TB Drug Trials* can be found http://bit.ly/SiLzAb. Any questions, comments, and feedback can be directed to info@gpptb.org.

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About Critical Path to TB Drug Regimens

CPTR is a cross-sector initiative that aims to speed the introduction of shorter, safer, more effective new TB drug regimens. This effort brings together leading international pharmaceutical companies, public health experts, civil society organizations, and U.S. and other regulatory authorities to: 1) expedite testing of promising TB drug candidates in combination; 2) identify new regulatory pathways and other tools that will accelerate the development process; and 3) deliver dramatically improved treatment to TB patients worldwide. CPTR was co-founded in 2010 by the Bill & Melinda Gates Foundation, the Critical Path Institute, and the TB Alliance to expedite testing of promising TB drug candidates in combination, regardless of sponsor, and to optimize the regulatory and other infrastructure so that new drug regimens are developed, approved, and made available to those that need them as quickly as possible.

About AVAC

Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of AIDS vaccines, male circumcision, microbicides, pre-exposure prophylaxis (PrEP) and other emerging HIV prevention options as part of a comprehensive response to the pandemic.