WORKING GROUP ON NEW TB DRUGS

TERMS OF REFERENCE

Clinical Trials Capacity Subgroup

This subgroup aims to identify, highlight and address issues in the clinical trials of TB drugs that correspond to the aims of the WGND. Its objectives are :

Objectives:

- Identify bottlenecks and roadblocks faced by those involved in TB drugs clinical trials;
- Work towards addressing regulatory issues in TB drug development and harmonization of clinical guidelines and IP rights;
- Convene seminars and workshops to bring together government officials, regulators, NTP managers and researchers to establish strong links and identify ways to improve regulatory and/or government institutional requirements;
- Address specific and often marginalized issues in TB clinical trials such as trials for pediatric TB;
- Identify clinical trial sites for carrying out clinical studies for TB drug development and making this information publicly available (to complement the 80 site assessment performed by the Global Alliance for TB Drug Development);
- Establish clinical site selection criteria which should at minimum include:
    - the full description of the site infrastructure (clinical, lab, data management, administrative, etc.),
    - the ability to understand GCP/GLP,
    - the level of preparedness to undertake various trial phases,
    - how regulatory issues can be met,
    - the level of training to be conducted.
- Develop interventions that will advance and/or complete the site preparation process for dozens of sites to carry out trials for susceptible or drug-resistant TB. Interventions could include sponsorship of regional training at trail sites in synergy with FHI, USAID, TBCAP, EDCTP, World Bank, RESIST-TB.

Members: The Clinical Trials Capacity Subgroup comprises representatives with specific programmatic, clinical, scientific, managerial, and advocacy expertise. Its membership rests with individuals with specific areas of expertise relevant to clinical trials for drug development.