

# Clinical Trials for MDR-TB

Sub-groups 1 & 2 of  
Group 3

# Initial trial: Proposed Designs

- OBR/SOC vs. OBR/SOC + new agent
  - Immediate empiric regimen, followed by individualized with DST results
  - ITR
  - STR
- Questions remain about which rapid tests & endpoints (bacteriological endpoints)
- Randomization prior to DST

# Goals

1. Improve outcomes
2. Shorten treatment (benefits to completion)
3. Reduce toxicity

# Who

- Broad: all patients with TB presenting in designated window should be screened for RIF resistance at dx
  - New
  - Previously treated
  - Chronic
- Full DST (1<sup>st</sup>- & 2<sup>nd</sup>-drugs) on all with RIF resistance

# Benefits of broad inclusion

- Completed trials
- Can accrue faster
- Site-friendly (acceptance to investigators and activists)
- Generalizable
- More relevant for policy

# Other complementary studies

- Animal studies: efficacy of new drugs with existing 2<sup>nd</sup>-line and 3<sup>rd</sup>-line
- Dosage optimization (animal, EBA)
- Endorsed 14-day EBA?
- Cross-resistance among quinolones & rifamycins

# WHERE

- GLC-approved sites likely to be able to be educated to achieve GCP/GLP standards
- E.g., Peru, Philippines, Russia, Latvia, Bangladesh,

# Ways of to make most of trial: factorial design

	Novel	Placebo
Moxi		
Oflox		

# More mileage: new dx

- New assays for drug resistance
- Could store specimen for well-characterized specimen banks