Study 31/A5349:
Rifapentine-containing Treatment Shortening Regimens for Pulmonary Tuberculosis

ACTG
AIDS CLINICAL TRIALS GROUP

Study Background & Objective(s)

Background:

- The standard course of treatment for drug-susceptible TB is 6 months, despite many attempts to shorten it
  - This has been the case for nearly 50 years
- Rifapentine-based regimens have potent antimycobacterial activity that may allow for a shorter course in people with drug-susceptible TB

Study Objective:

- Determine whether treatments that include rifapentine with or without moxifloxican can provide durable TB cure in 4 months in people with drug-susceptible TB

Dorman, Nahid, et. al. for A5349 team; *NEJM* 2021

Study Details

- Study 31/A5349 was led by the CDC Tuberculosis Trials Consortium (TBTC) in collaboration with the ACTG
- Phase 3, open-label, randomized controlled clinical trial
- Took place in 13 countries, included more than 2,500 participants age 12 and older, including 193 people living with HIV
- ACTG sites enrolled two-thirds of participants (N=1617)
- Presented in at Union World Conference on Lung Health in October 2020
- Published in NEJM in June 2021

Dorman, Nahid, et. al. for A5349 team; *NEJM* 2021

Key Findings

- 4-month regimen of rifapentine, isoniazid, pyrazinamide, and moxifloxacin (RPT-MOX) was non-inferior to currently recommended 6-month regimen of rifampicin, isoniazid, ethambutol, and pyrazinamide for drug-susceptible pulmonary TB
- RPT-MOX was also safe and well-tolerated by study participants
- A second four-month regimen of rifapentine, isoniazid, pyrazinamide, and ethambutol did not meet the non-inferiority margin

Dorman, Nahid, et. al. for A5349 team; *NEJM* 2021

Importance & Next Steps

- This paradigm-shifting study demonstrates the feasibility of decreasing the length of TB treatment by one-third
  - A profound advancement in the management of a disease that continues to proliferate globally
- Shorter duration of TB treatment means it will be easier for individuals to complete treatment without missing doses
  - Ultimately may be more cost-effective

Dorman, Nahid, et. al. for A5349 team; *NEJM* 2021