TB Alliance

Pretomanid Regimen Updates

Mel Spigelman
SHA Mid-year Webinar
June 23, 2022

Nix-TB Results

New England Journal of Medicine, March 2020

PARTICIPANTS

109 enrolled

71 with **XDR-TB**

65%

38 with **TI/NR* MDR-TB**

34%

RESULTS

90% had **favorable outcomes**

XDR-TB

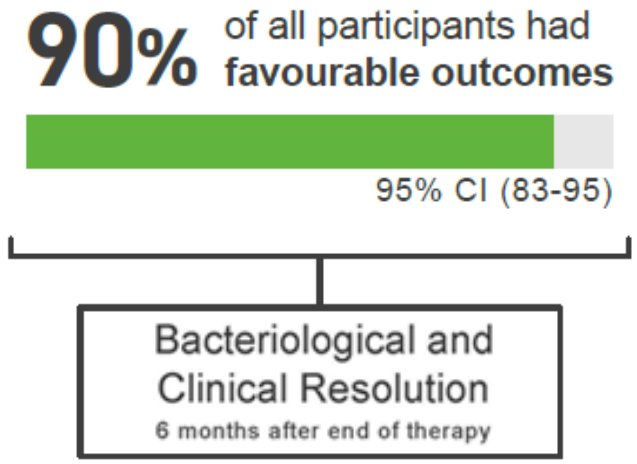
89%

79-95 (95% CI)

TI/NR* MDR-TB

92%

79-98 (95% CI)

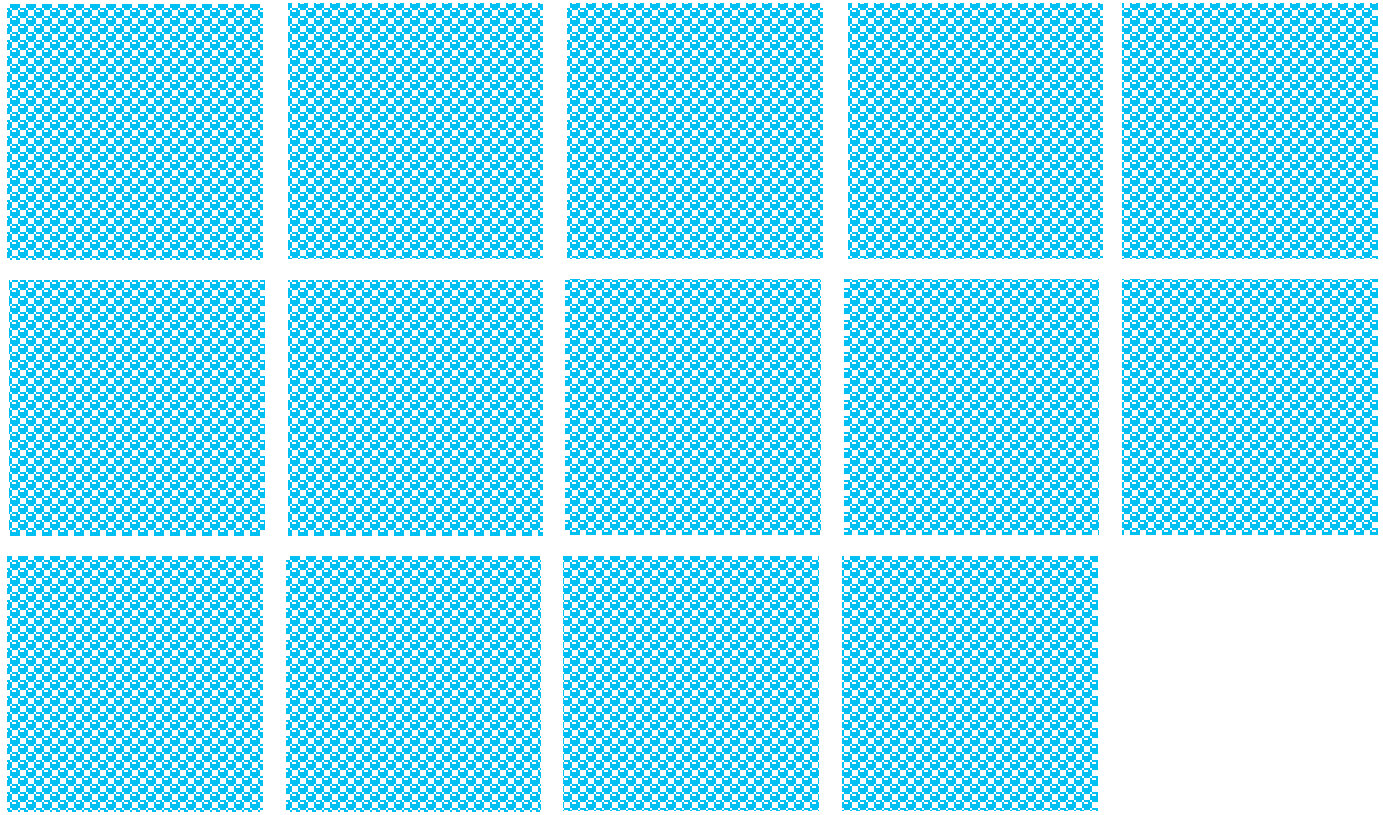


*Treatment-intolerant or non-responsive MDR-TB
Using definition of XDR-TB prior to 2020

Lightening the Load for Patients with Highly Drug-Resistant TB

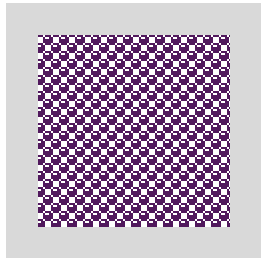
Historic Treatment Efforts

14,000+ Pills, 18 Months or Longer, ~30% success



The BPaL Regimen

<750 Pills, 6 Months, ~90% success



Pretomanid

- Pretomanid is the first new drug to be approved by the U.S. FDA for drug-resistant TB not based on a surrogate endpoint

- First drug approved for treatment of DR-TB as part of a specific regimen
  - BPaL regimen (bedaquiline, pretomanid, linezolid), three-drug, all-oral, six-month regimen studied in the Nix-TB clinical trial

Source: Conradie et al. Bedaquiline, pretomanid and linezolid for treatment of extensively drug resistant, intolerant or non-responsive multidrug resistant pulmonary tuberculosis. *N Eng J Med* 2020;382:893-902.

BPaL Evidence from Clinical and Preclinical Studies

Data presented to WHO Guideline Development Group

NixTB ZeNix TB Practecal

- Preclinical testicular toxicology data
- Male hormonal changes during clinical trials
- Paternity Survey

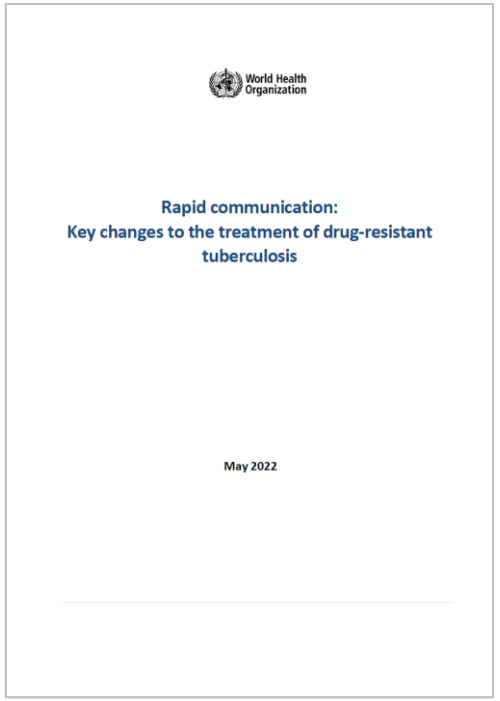
The International Journal of Tuberculosis and Lung Disease

Male reproductive hormones in patients treated with pretomanid

Boekelheide K, et al. Male reproductive hormones in patients treated with pretomanid. *Int J Tuberc Lung Dis* 2022; 26(6)558-565.

WHO Rapid Communication: Key Changes to treatment of DR-TB

- "The 6-month BPaLM regimen, comprising bedaquiline, pretomanid, linezolid (600 mg) and moxifloxacin, may be used programmatically in place of 9-month or longer (>18 months) regimens…" (p.5)
- "This regimen may be used without moxifloxacin (BPaL) in the case of documented resistance to fluoroquinolones (in patients with pre-XDR-TB)…." (p.5)
- "New data on the safety of pretomanid based on hormone evaluations in four clinical trials and a paternity survey were also assessed; these data have largely alleviated previous concerns on reproductive toxicities…" (p.4)



Rapid communication: key changes to the treatment of drug-resistant tuberculosis. Geneva: World Health Organization; 2022 (WHO/UCN/TB/2022.2)

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Thank you!