

TB Alliance Overview

Putting science to work
for better, faster TB cures

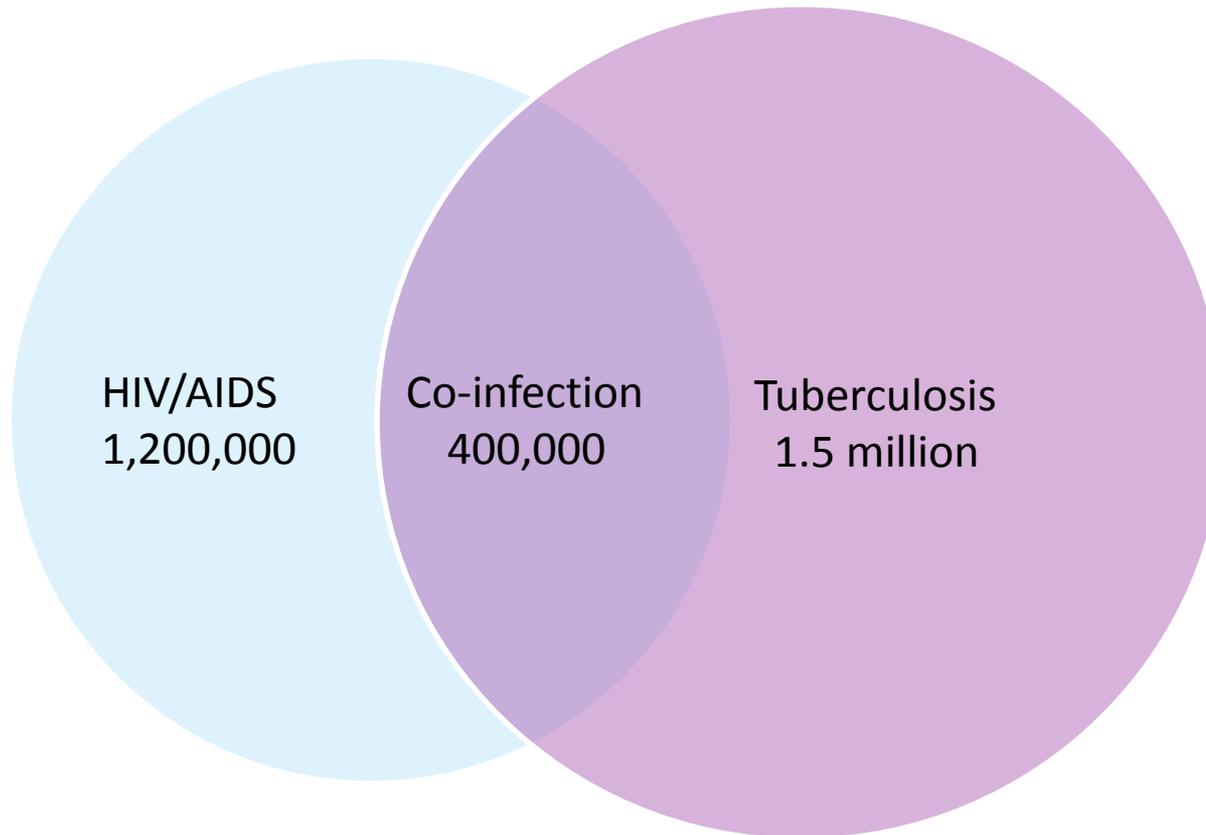


TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

TB is the Leading Infectious Disease Killer

Number of deaths worldwide (WHO Global TB Report 2015)



Without new tools, we cannot stop this global health threat

Our Vision: Better TB Medicines for All

Dedicated to the discovery and development of better, faster and affordable TB drugs that are available to all who need them

OUR VISION FOR TB TREATMENT

The infographic is set against a dark purple background. It features a central light yellow rounded rectangle containing four rows of icons and text. Each row represents a pillar of the vision: 1. 'SIMPLE' is represented by an icon of seven orange pills in a 2x3 grid. 2. 'SHORT' is represented by an icon of a calendar. 3. 'ACCESSIBLE' is represented by an icon of a person handing a pill to a child. 4. 'MILLIONS OF LIVES SAVED' is represented by an icon of a group of people.

- SIMPLE**
- SHORT**
- ACCESSIBLE**
- MILLIONS OF LIVES SAVED**

Collaborative Model Built to Drive Impact

A network of global partners

- As a not-for-profit Product Development Partnership, we collaborate with public and private partners to advance TB drug R&D and access
 - PDPs are a proven model to drive research for neglected diseases
 - PDPs have accelerated promising products more quickly and cost-effectively than either public or private sector entities acting alone
- Substantial leveraging of donor funding with partner contributions



TB Alliance Supporters and Collaborators



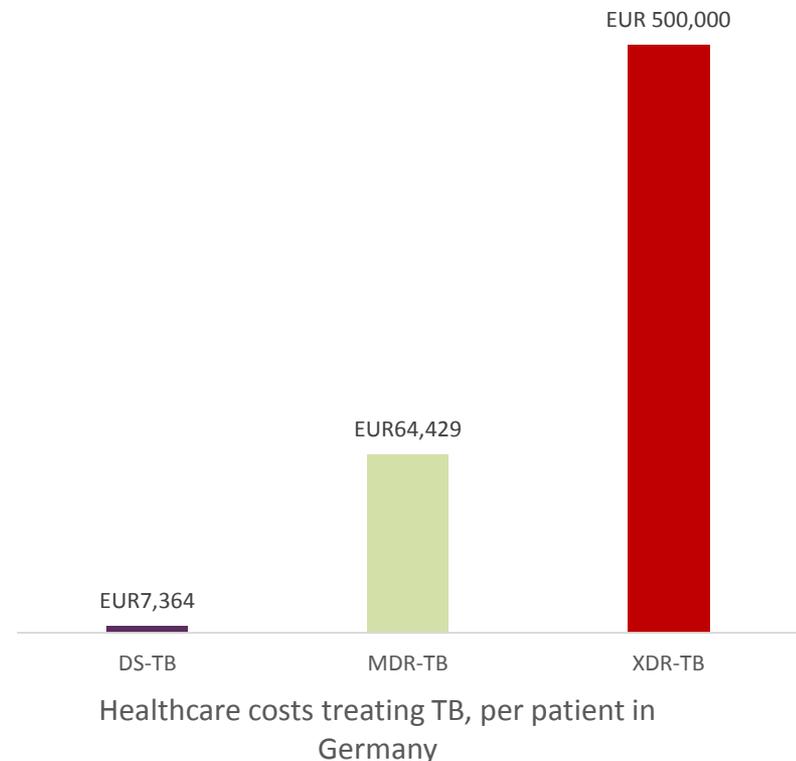
Indonesia Health Fund



TB and current treatment

benchmark

- 9.6 million new drug-sensitive TB cases per year: needs four drugs for 6 months, with an intensive and follow-up phase, weight banded
- Multi-drug resistant TB needs six months of injections plus at least 5-6 drugs for a minimum of 9 months but often 2 years or more. Only about 20% of patients get treated and of those only 50% are successfully cured
- XDR is virtually impossible to treat: 89% patients fail treatment of which 73% die within 5 years.
- Both MDR and XDR need hospitalization and isolation wards for infection control
- Until recently there were no formulations for children



Childhood TB medicines: Achieving “AAA Mandate”

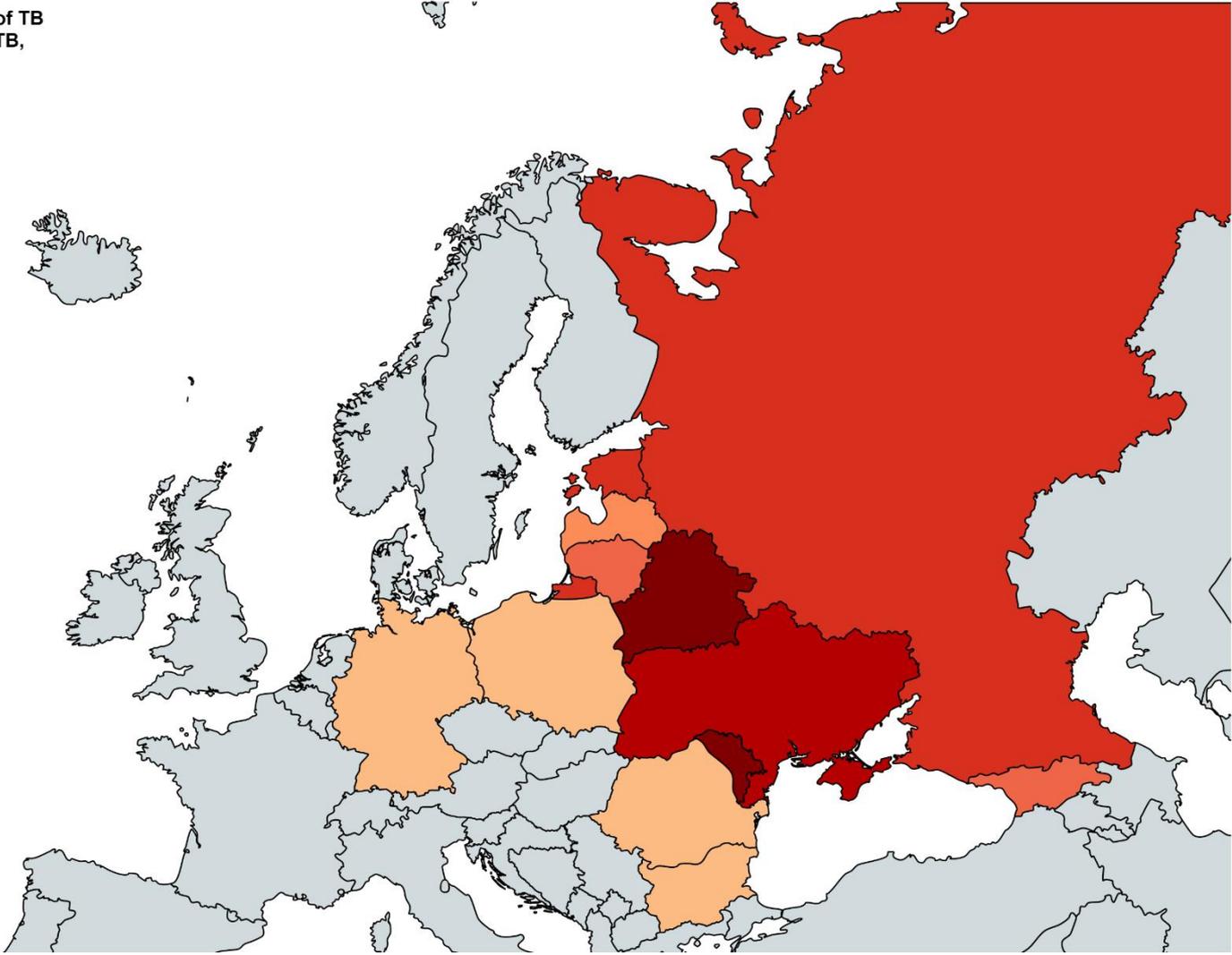
INADEQUATE PEDIATRIC TREATMENT → **NOW AVAILABLE**

 <p>INCORRECT DOSES</p>	 <p>BROKEN PILLS</p>	 	
 <p>CRUSHED PILLS</p>	 <p>BAD TASTE</p>		

Growing TB drug resistance

Estimated proportion of TB cases that have MDR-TB, Europe Region

- >24%
- 20-23%
- 16-19%
- 12-15%
- 8-11%
- <0-3%



Growing TB drug resistance

- Germany has seen a steady decline over the years 2001 to 2009 (4,444), but there has been a small rise again over the last five years
- In Germany, like everywhere globally, there is a growing threat from drug-resistant TB
- Especially acute is also the situation on the Eastern borders with almost 8,000 DR-TB cases notified per year
- ROI of investment in TB Alliance: new drugs could potentially save EUR 7.5 billion over the next 35 years

Shorter, simpler treatment for XDR-TB

bedaquiline, pretomanid, and linezolid



One day of XDR-TB treatment



One week of Nix-TB regimen

Status of Participants in Nix-TB Trial

- 30 patients completed 6 months of all oral treatment
 - No participants required longer than 6 months of treatment
 - No relapses to date
 - Linezolid dosing adjustments needed but manageable
- 11 patients on treatment
- Extremely sick patients
 - 4 deaths (3-7 weeks on treatment)

This could potentially be

>90%

Success rate!

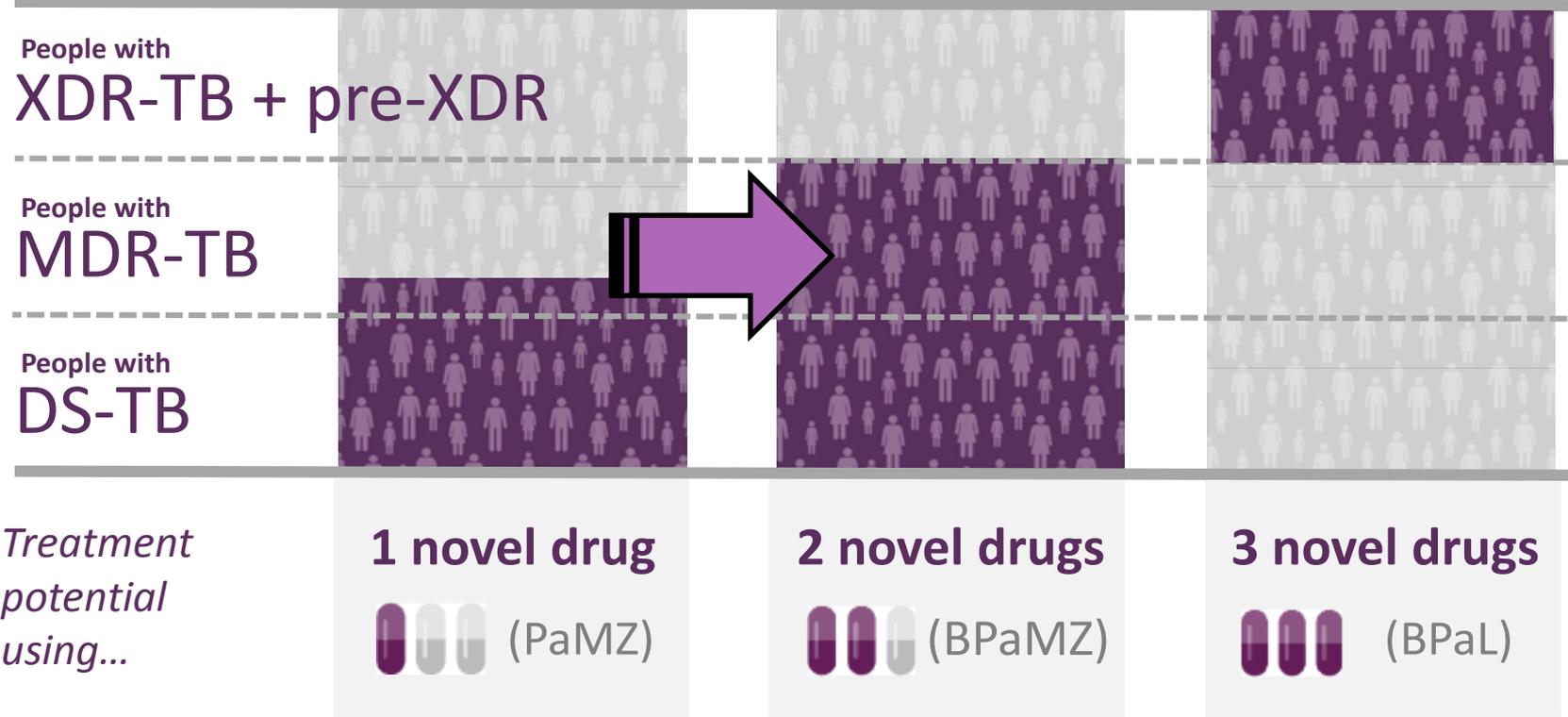
NC-005 trial: BPaMZ

Phase 2b trial using bedaquiline, pretomanid, moxifloxacin and pyrazinamide

- 2-month Phase 2b trial completed; Enrolled both drug-sensitive and drug-resistant patients (10 sites in South Africa, Tanzania, and Uganda)
- BPaZ and BPaZM active and well tolerated, with 3-4 month cure
- BPaZM shows the most promising data from any TB phase 2 trial in history: in MDR patients
- Next step is getting funding for a phase 3 trial to confirm and register this new regimen



TB Alliance Immediate Clinical Strategy





Thank you!



TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT