

endTB treatment sites will be in 16 countries, 13 of which are among the list of 27 countries with the highest burdens of MDR-TB.

In most countries, **PIH, MSF, or IRD** will directly implement endTB activities.

In all countries, **PIH, MSF or IRD** will work closely with the **National TB Programs** and other national authorities.

### Where will endTB operate?

#### Early-adopter sites (16 sites)

**PIH:** Lesotho, Kazakhstan, Peru

**PIH supervised:** DPRK, Ethiopia, Nepal

**MSF:** Armenia, Belarus, Georgia, India, Kenya, Kyrgyzstan, Myanmar

**IRD:** Bangladesh, Indonesia, Pakistan

#### Clinical trials sites (5 sites)

**PIH/MSF** (Site selection in process)

### endTB Leadership Team

<u>MSF</u>	<u>PIH</u>	<u>IRD</u>
Francis VARAINE	Michael RICH KJ SEUNG	Aamir KHAN

### The endTB consortium:



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endTB aims to be a comprehensive project to find shorter, less toxic and more effective treatments for drug-resistant TB, through access to new drugs, clinical trials, and advocacy at country & global level



**16 countries, 3 partners**  
(PIH - Partners In Health, MSF - Médecins sans Frontières, IRD - Interactive Research and Development)



**600 MDR patients** will be enrolled in the clinical trial



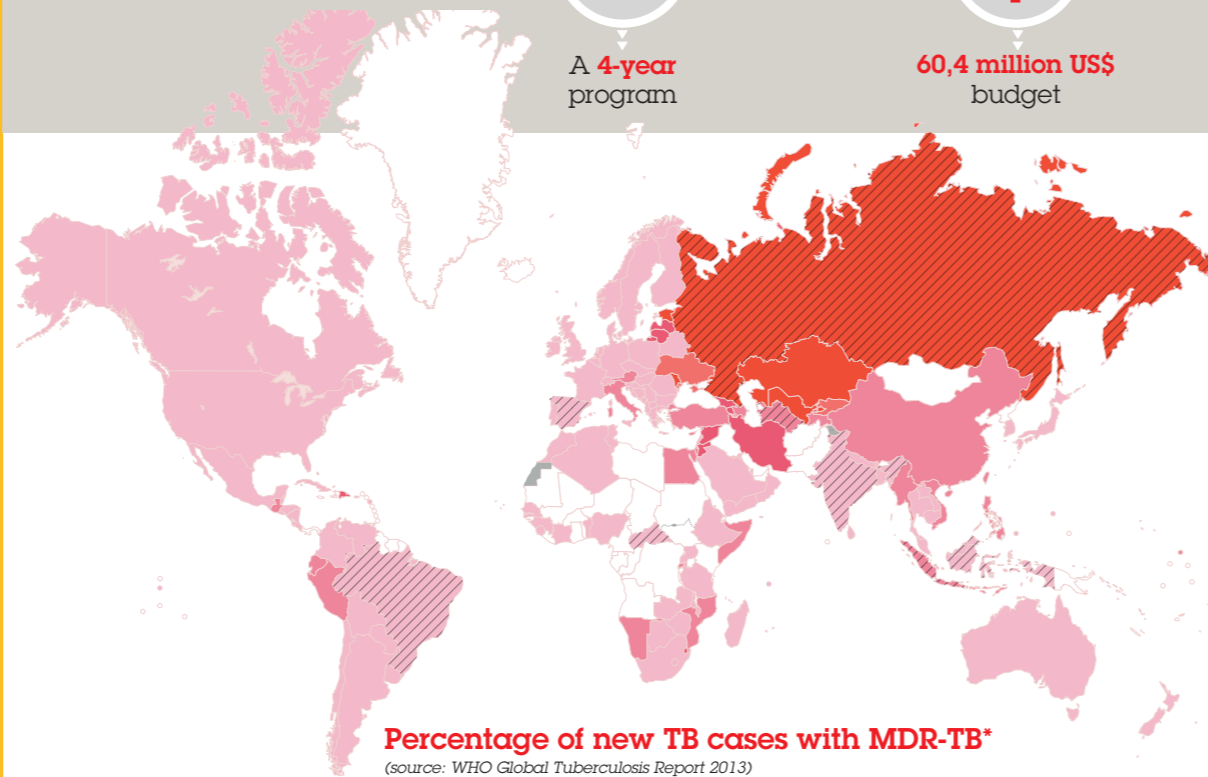
**2600 MDR-TB patients** will be enrolled on treatment with new drugs, including bedaquiline and delamanid



**A 4-year program**

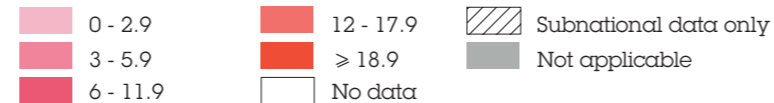


**60,4 million US\$ budget**



#### Percentage of new TB cases with MDR-TB\*

(source: WHO Global Tuberculosis Report 2013)



\* Figures are based on the most recent year for which data have been reported, which varies among countries.

### CONTACTS

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# endTB

expand **new drug markets** for **TB**



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## Why endTB?

The fundamental problem limiting access to MDR-TB treatment is the **absence of an effective, user-friendly treatment regimen.**

Of the 450,000 estimated MDR-TB patients in 2012, only 21% were actually diagnosed correctly with the disease. Only 17% ever received treatment with second-line TB drugs.



An even smaller proportion received treatment with quality-assured second-line TB drugs.

**MDR-TB treatment is extremely challenging to administer.** An intramuscular injection is required daily for eight months.

The remaining drugs are oral but some have to be taken twice daily, for a **total duration of 18-24 months.** Every dose of the regimen needs to be directly observed by a health worker.

**A safe and effective MDR-TB treatment regimen is no longer just a dream.** New TB drugs, however, will not automatically make regimens simpler without a **concerted effort to develop simplified regimens.**

Manufacturers are focused on bringing single TB drugs to market and less interested in learning how to combine drugs into effective regimens. Furthermore, few clinical trials are focused on MDR-TB; those that are will take years to start and finish and are mostly aimed at finding a single regimen, leaving open many questions about how to use new drugs effectively. This evidence gap is a major market shortcoming that prevents acceptance of new drugs and regimens by National TB Programs.

## What will endTB do?

**The endTB project consists of:**

**1. Treatment with new TB drugs and close monitoring in early adopter sites**  
endTB will enroll a minimum of 2 600 patients in 16 countries<sup>1</sup> on MDR-TB treatment with new drugs. Each patient will be monitored closely for response to treatment and for potential adverse events.

**2. Simplification of MDR-TB treatment around a few priority regimens**  
Five clinical trials sites will be selected to implement a study of the safety and efficacy of at least six new 'user-friendly' MDR-TB treatment regimens, each containing one new drug (stage 1). A second study will explore regimens combining both new drugs (bedaquiline and delamanid) if studies planned and underway do not contraindicate their combination (stage 2). The first study is expected to start enrollment in the second half of 2015, and enroll approximately 400 patients. The second study is expected to enroll approximately 200 patients.

1. Peru, Lesotho, Kazakhstan, Kenya, Georgia, Armenia, Kyrgyzstan, India, Myanmar, Belarus, Pakistan, Indonesia, Bangladesh, Democratic People's Republic of Korea, Nepal, and Ethiopia



## Objectives of endTB



The aim of endTB is to obtain **increased uptake of new TB drugs as part of treatment regimens that are more effective and less toxic, through:**

- 1 IMPROVED** evidence on the safety & efficacy of new TB drugs and regimens.
- 2 ACCELERATED** uptake of new drugs (short-term) and regimens (long-term) in endTB countries.
- 3 BROADER** evidence-based WHO recommendations for use of new TB drugs.

**3,200 patients will directly benefit from treatment with new TB drugs that they otherwise would not have received. Improved treatment outcomes will result in decreased morbidity, mortality, and MDR-TB transmission for these patients and their families. This represents a direct public health effect of introducing treatment with new drugs.**

**3. Reduced country-level barriers to uptake of new TB drugs in all endTB countries**

endTB will facilitate importation of new and companion TB drugs into countries where they may not be currently marketed or registered; assist NTPs in rewriting national guidelines to integrate new TB drugs and regimens; participate in crafting country-specific advocacy plans; and assist NTPs to include financing for new TB drugs in existing MDR-TB program budgets.

**4. Supportive global policies and structures in place to facilitate the adoption of new TB drugs.**

endTB will regularly review the evidence generated by treatment activities as well as the study, and present this evidence to normative stakeholders such as the WHO. endTB will also encourage information - and data - sharing among early - adopter countries, and disseminate information related to new TB drug price reductions and patent barriers.



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