

# Progress Toward Appropriate Medicines for Childhood TB

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October 27, 2014

Childhood TB Subgroup Meeting



**TB ALLIANCE**

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

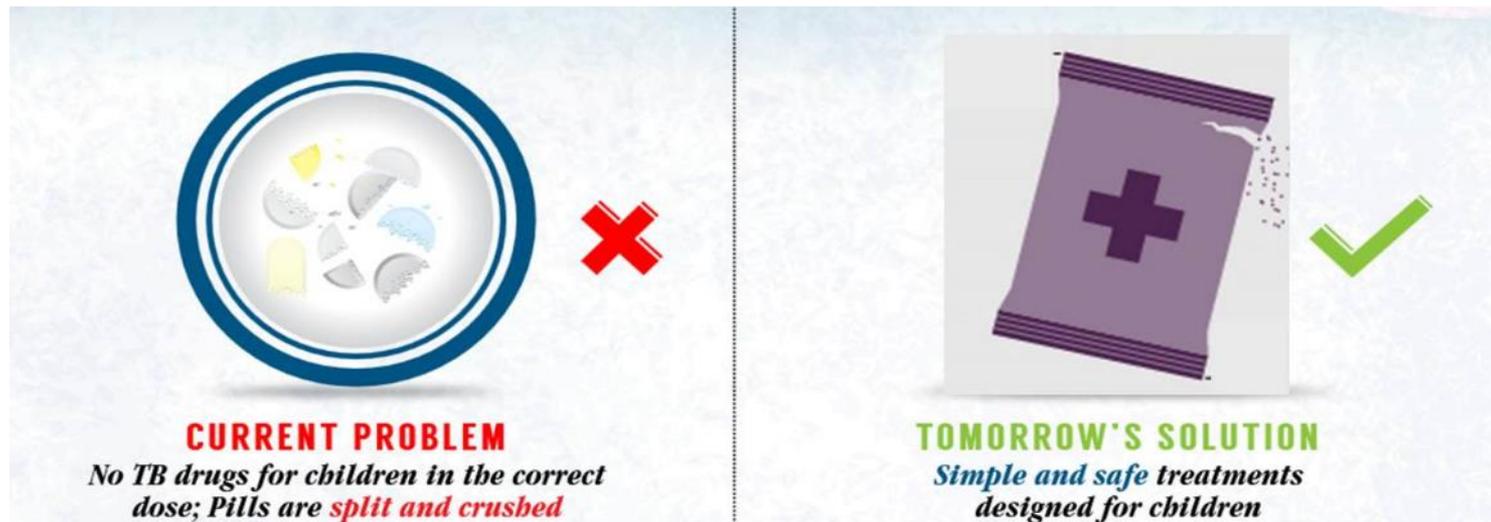


**USAID**  
FROM THE AMERICAN PEOPLE

# The Problem

Children with TB are the neglected of the neglected

- **The market for pediatric medicines is “broken” and needs repair and requires:**
  - Better estimates of how many children get TB and where they are located
  - Clarity on drug registration pathways
  - Consistency of treatment policies and practices
  - Prioritization by governments, donors, in-country stakeholders (i.e., NGOs, private sector) and drug companies



# Overview

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## Speeding Treatments to End Pediatric TB (STEP)-TB

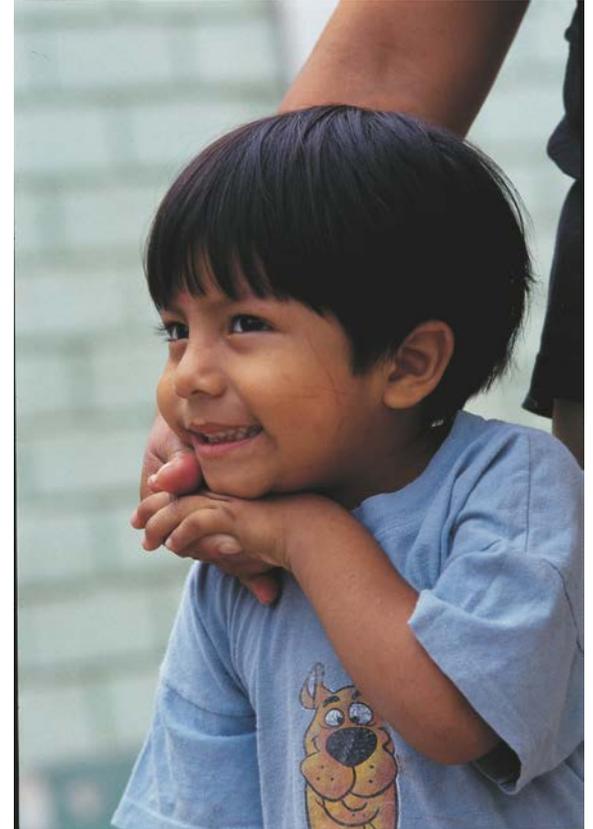
### Unmet Medical Need

*Not enough kids being treated – and not being treated appropriately*

### Goal

*Increase access to correctly dosed, properly formulated, affordable, high quality pediatric TB medicines*

### Implementing Partner



# Three Key Outcomes

## Scope of Pediatric Initiative

### Market Catalyzed

- Market Research--How many patients? Where? How are they currently being treated?
- Manufacturers' commitments
- Momentum and visibility

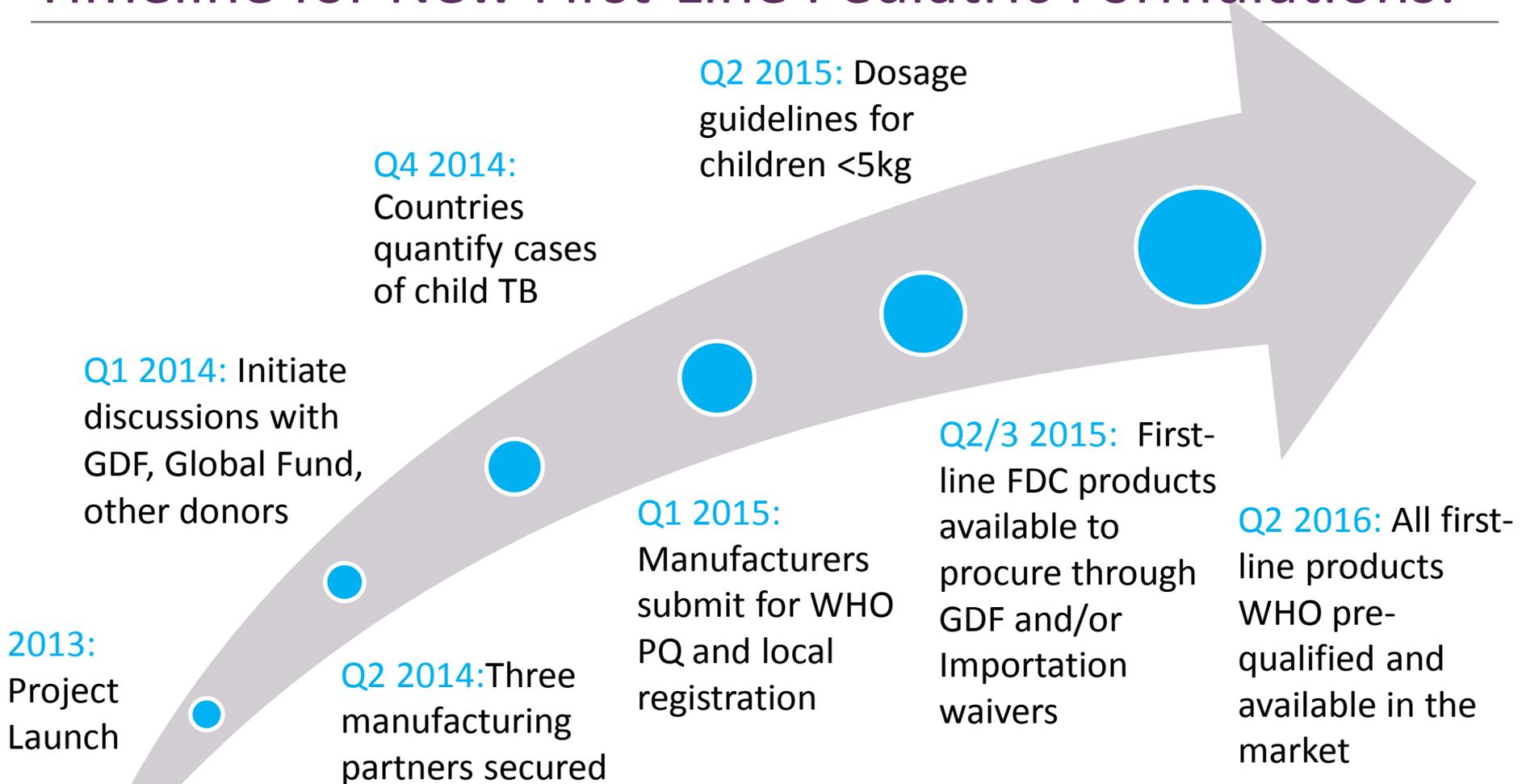
### Drugs Available

- Correct dosage & dispersible form for HRZ, HR, and E
- Shorten gap between approval of adult products vs. pediatric products

### Uptake Influenced

- Global treatment guidelines adopted
- National guidelines developed and health workers trained
- Child TB included in NSPs and Global Fund Concept Notes
- Funding committed for product and implementation

# Timeline for New First-Line Pediatric Formulations:



# Market Catalyzed

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STEP-TB Project aims to achieve the following goals

- ❖ Conduct market studies to understand the fundamental size, scope and dynamics of the pediatric TB market
- ❖ Collaborate with 2 to 3 manufacturers to produce high quality HRZ, HR, and E in the correct dosages and formulations for children on a global scale
- ❖ Build relationships with local manufacturers meeting international quality standards where appropriate
- ❖ Link to markets (countries and global purchaser Global Drug Facility)
- ❖ Disseminate market data & regulatory pathway findings to countries, researchers, manufacturers

# Market Catalyzed

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## Progress to Date

- Market Intelligence
  - Modeling of the pediatric TB Burden (WHO, Sheffield University/Imperial College, Yale/Harvard)
  - Understanding the role of the non-NTP sector and the extent of underreporting in target pediatric TB Markets (Inventory Protocol Workshop)
  - Market sizing tool to synthesize data and refine estimates
  - Country landscaping pulling information from multiple sources to fully understand the policy, supply management/procurement, and regulatory process of the 22 HBCs
- 3 manufacturer commitments secured; facilitating relationships with global manufacturers and local manufacturers/distributors in key markets
- Web portal launched; Pediatric Advisory Group established; Thought Leader Webinar Series; awareness materials and video

# Drugs Available

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STEP-TB Project aims to achieve the following goals

- ❖ Manufacturing and introduction of new pediatric formulations of existing first-line TB drugs
- ❖ Determine the core regulatory data required for approval of new pediatric medicines
- ❖ Creating evidence to inform the development of dosing guidelines for children weighing less than 5kg
- ❖ Planning for use of new regimens in children (i.e., Pa-M-Z, bedaquiline)

# Key Product Information

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## ☐ Rifampicin 75 mg + Isoniazid 50 mg + Pyrazinamide 150 mg

## ☐ Rifampicin 75 mg + Isoniazid 50 mg

- Availability: mid to late 2015 through Expert Review Panel (ERP) and through Global Drug Facility (at least one manufacturer)
- Registration: submit for WHO Prequalification by early 2015 (at least two manufacturers); pursue local registrations in parallel
- Formulation: dispersible; flavors—mango, strawberry, raspberry
- Price: close to currently available pediatric products, dependent on anticipated volumes

## ☐ Ethambutol 100 mg

## ☐ Isoniazid 100 mg

- Availability/Registration: later timeline—6-12 months behind FDCs; one manufacturer committed
- Formulation: dispersible
- Price: close to currently available products, dependent on anticipated volumes

# Drugs Available

## Progress to Date

- Delineating the registration requirements in the target markets for the new pediatric formulations
- Conducting the pharmacokinetics study of first-line treatment at current dosing recommendations in infants less than 12 months
- Planning for a consensus panel on the use of moxifloxacin in children to be held in mid-2015
- Partnering with Janssen on the pediatric development of bedaquiline
- Outlining an accelerated pediatric development pathway for new pediatric medicines and regimens currently in the pipeline



# Uptake Influenced

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STEP-TB Project aims to achieve the following goals

- ❖ Identify and map pediatric TB purchaser landscape
- ❖ Encourage widespread adoption of pediatric treatment guidelines, development of national guidelines and training tools
- ❖ Encourage use of new formulations
- ❖ Identify and reduce barriers to product uptake
- ❖ Work with countries to include childhood TB into national strategies/plans, budgets, and grant applications/renewals
- ❖ Identify funding sources to procure new pediatric formulations

# Uptake Influenced

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## Progress to Date

- WHO issued comprehensive Childhood TB guidelines and training materials
- Held two consultations to set priorities and develop action plans for childhood TB
  - Western Pacific Region (WPR): 8 countries were represented
  - Eastern Mediterranean (EMR), South East Asia (SEAR) Regions (with select WPR countries): 11 countries were represented
- Continued collaboration with the Global Drug Facility (GDF) to prepare for the introduction of the new pediatric formulations
- Several efforts underway to ensure countries are including pediatric TB in GFATM concept notes
- Engagement of the Global Fund, other donors, and partners with in-country experience in product introduction

# MANDATE

Maternal and Neonatal  
Directed Assessment  
of Technology

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RTI  
INTERNATIONAL

BILL & MELINDA  
GATES foundation

***MANDATE (Maternal and Neonatal Directed Assessment of Technology) was built because there was NO quantitative process currently exists to evaluate and prioritize technology development options based on the potential to save maternal, fetal and newborn lives in low-resource settings.***

# MAPIT (MODEL FOR ASSESSMENT OF PEDIATRIC INTERVENTIONS FOR TUBERCULOSIS)

Where and how to allocate resources to have the greatest impact on Pediatric TB morbidities and mortalities?

Morbidity and Mortality impact on **individuals:**

- Children

Impact in different **settings:**

- Hospitals
- Clinics
- Homes

What types of **technologies or interventions:**

- Preventatives
- Diagnostics
- Therapeutics
- Transfers

Impact in high-mortality **regions:**

- 22 High Burden Countries

Provide a tool for quantitative assessment of where innovation might have the greatest potential to reduce pediatric TB morbidity and mortality

# Video: Anatomy of Neglect

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- Click the link below to view the video:
  - <https://www.youtube.com/watch?v=o8zr50Mcuok>



Thank you!

For more information on  
childhood TB go to:  
[tballiance.org/children](https://tballiance.org/children)



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