Market Access

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TB Alliance Stakeholders Association Meeting
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TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Role of Market Access

TB Alliance Committed to changing the way TB Drugs are developed

Role of Market Access
Ensure that all Patients, who could benefit, get rapid and sustainable access to TB Drugs, at the right price

Our Commitment

Affordability	TB has its greatest impact on poor and vulnerable populations. Our commitment means that new TB treatments must be affordable for even the poorest patients
Availability	New and improved TB therapies will only get to the people who need them if they are adopted by global, national, and local regulatory bodies
Adoption	We will not be satisfied until improved TB cures are in the hands of those who need them

Rapid Access

Focus of Market Access

Pediatric Reformulation

2016

PaMZ

2019

Pediatric Reformulations

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Speeding Treatments to End Pediatric TB (STEP)-TB

Goal

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

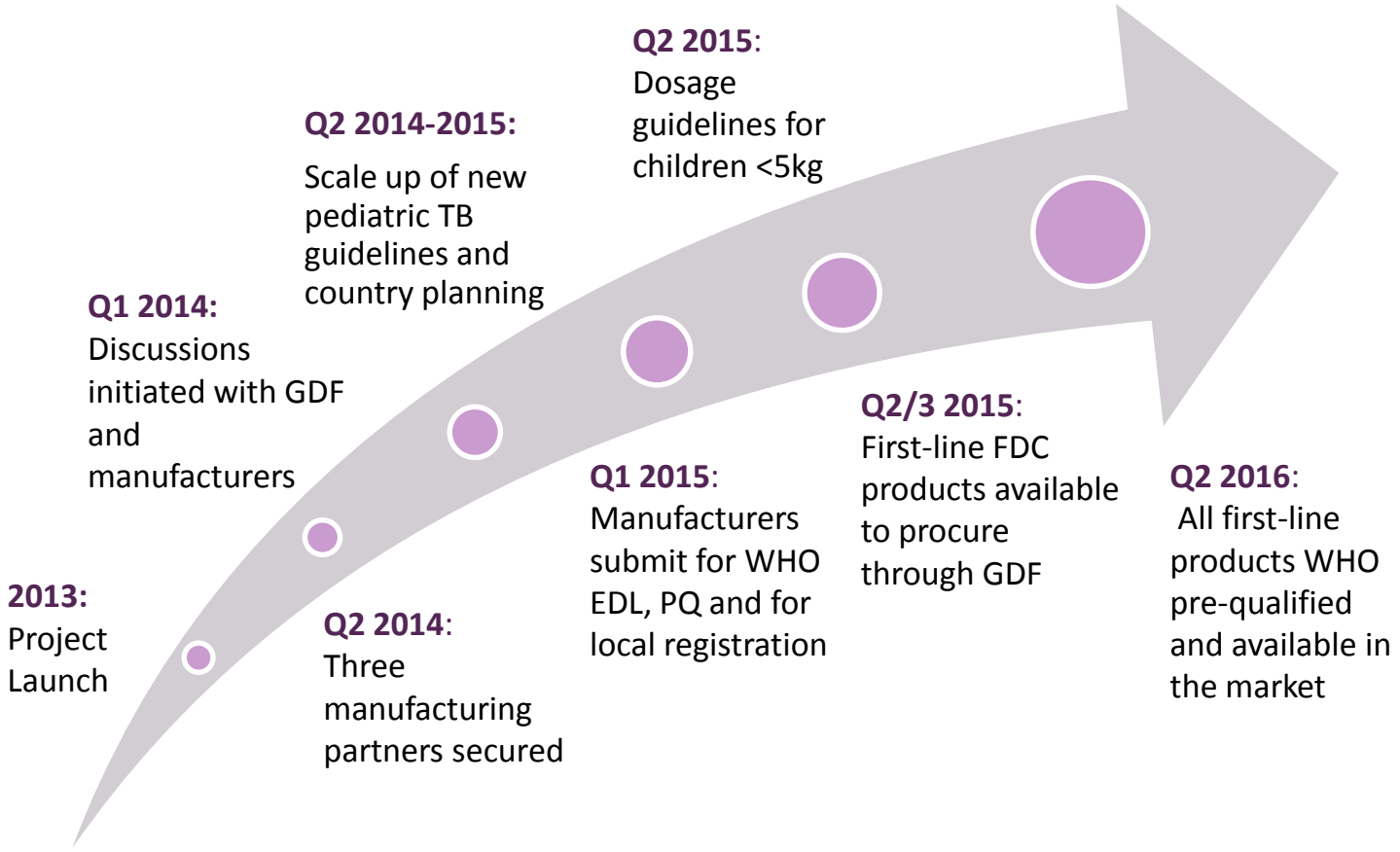
Implementing Partners

World Health Organization

& manufacturers

Challenges in Pediatric TB Markets

Timeline for New First-Line Pediatric Formulations



Pediatric Initiatives

Key Outcomes

Market Catalyzed

- **How many patients? Where? Current treatment practices?**
- **Momentum and visibility Manufacturers commitments (advisory group, etc.)**

– Established advisory group
– Drive visibility through content of web presence, journal publications, etc.
– Conduct market intelligence studies (e.g. Inventory Studies, Consumption Studies)

Drugs Available

- **Existing: Correct dosage & dispersible form**
- **New: Shorter gap between adult and pediatric formulations**

– Commitment from Manufactures secured
– Dosage included in Childhood TB policy guidelines issued globally by WHO in early 2014
– Influencing adoption through regional meetings and training
– PK study underway to inform dosage guidelines for infants

Uptake Influenced

- **Global policy issued and adopted at country levels**
- **Product available through Global Drug Facility (GDF)**
- **Funding lined up for product**

– Active engagement in Janssen pediatric clinical development program (bedaquiline)
– Expert panel planned on utilization of moxifloxacin in children
– Internal strategy developed for pediatric clinical development
– Established working relationship with both the GDF and the Global Fund
– Initiated procurement and regulatory landscaping of high burden countries
– Studies underway to understand and navigate potential bottlenecks to uptake

Mid- 2013 → **Mid- 2016**

Preparing for PaMZ

Preparing for the introduction of PaMZ

Road to Patient Impact

Manufacturing	Regulatory	Policy and Funding	Procurement	Diagnosis	Product Uptake
• Sign–up Manufacturers to manufacture PaMZ • Commitment from Manufacturers to manufacture quality product • Ensure appropriate pricing for PaMZ	• Secure FDA and EMA registration • Secure WHO PQ • Ensure WHO EML inclusion • Secure Country Registrations	• Work with WHO to ensure that PaMZ is included in WHO guidelines • Work with WHO to provide technical support at the country level for the adoption of guidelines • Work with Global Fund and countries to ensure that PaMZ is included in concept notes	• Quantify Market Size for PaMZ • Forecast Country needs • Conduct Country Procurement Landscaping • Ensure PaMZ is included in GDF Procurement Plan • Ensure Product on Country EML • Ensure Product part of Country Tender Specifications	• Work in partnership with BMGF and Diagnostic Partners to develop an improved diagnostic to be available at the launch of PaMZ	• Launch Task Force to coordinate activities to ensure the timely launch and appropriate uptake of PaMZ • Provide technical support to navigate procurement bottlenecks and drive uptake of new formulations

Mid- 2019

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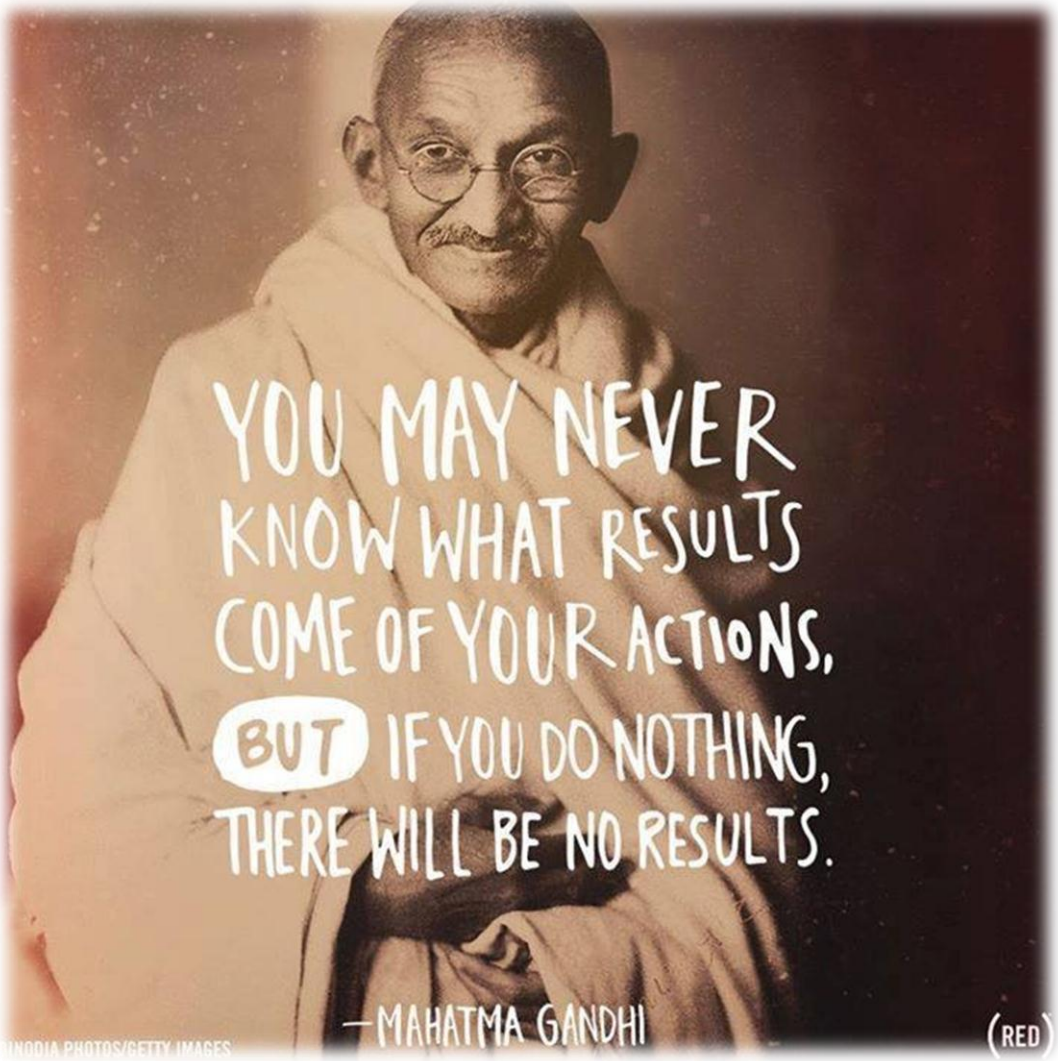
Assessing Formulation Acceptability

Stakeholder Consultation: Key Decisions for Formulating Tomorrow's Drugs


YOU MAY NEVER KNOW WHAT RESULTS COME OF YOUR ACTIONS, BUT IF YOU DO NOTHING, THERE WILL BE NO RESULTS.
—MAHATMA GANDHI
(RED)