

Global Drug Facility (GDF)

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37th Meeting of the Stop TB Partnership Coordinating Board

Brasilia, Brazil

7 February, 2024

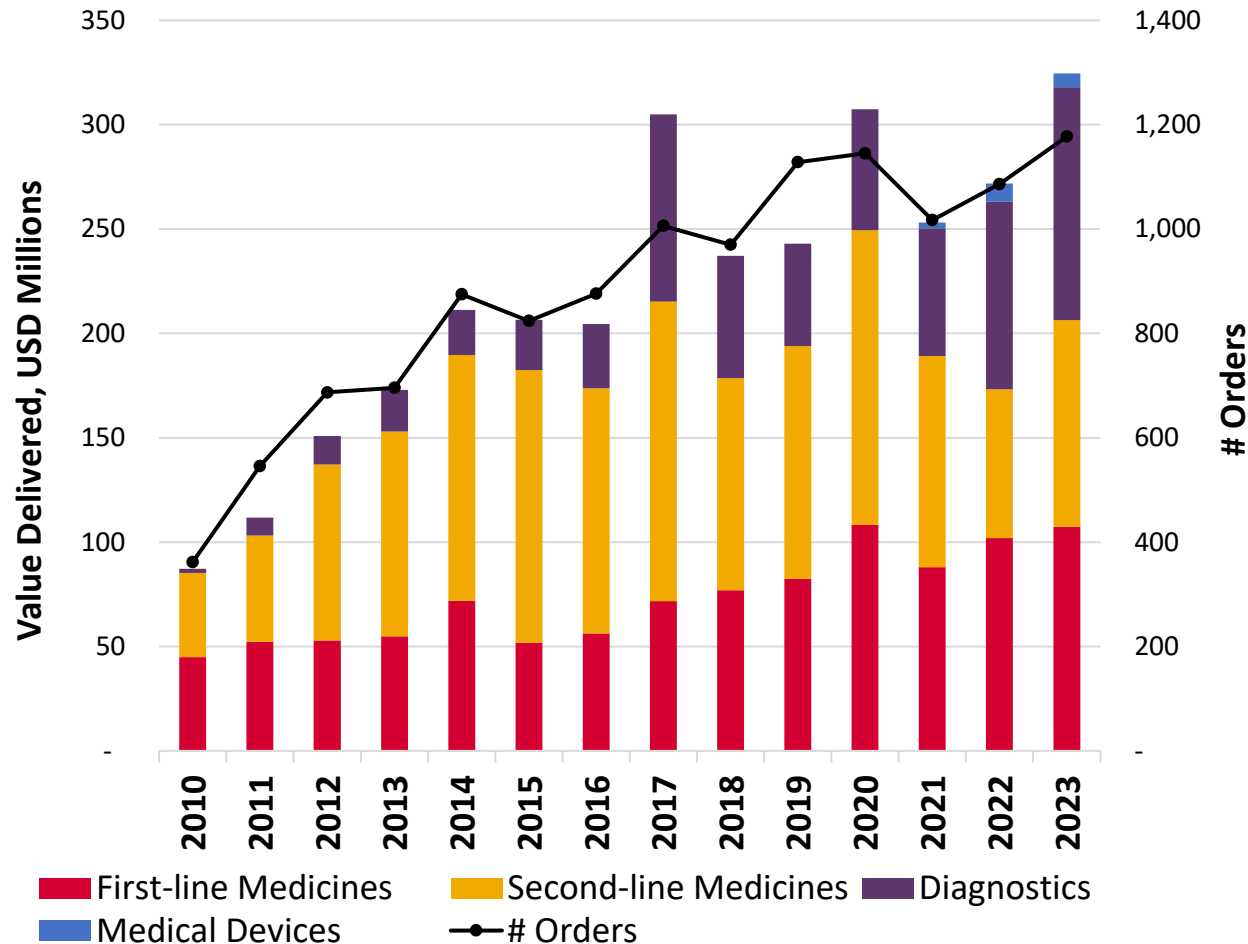
GDF Session Outline

- I. 2023 Key Achievements
- II. 2023 Main Challenges Encountered in Promoting Access to TB Products, and How Best to Address These Challenges
- III. Discussants, Questions & Answers

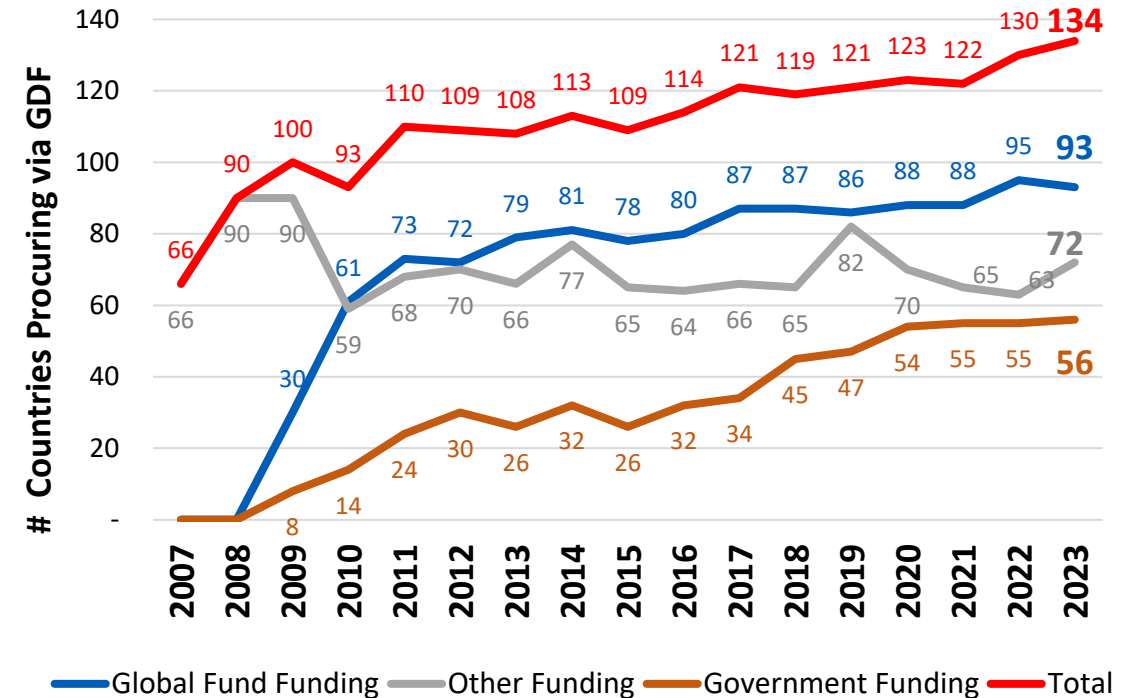
I. GDF's Key Achievements for 2023

2023 – A Record-Breaking Year for GDF Supply of TB Products

2023: GDF delivered ~1,200 orders for TB products valued at \$324 million



Countries Procuring via GDF, by Funding Source, 2007-2023



Delivered to 134 countries, including:

- 56 with domestic funding
- 9 high-income countries
- 14 clinical research projects

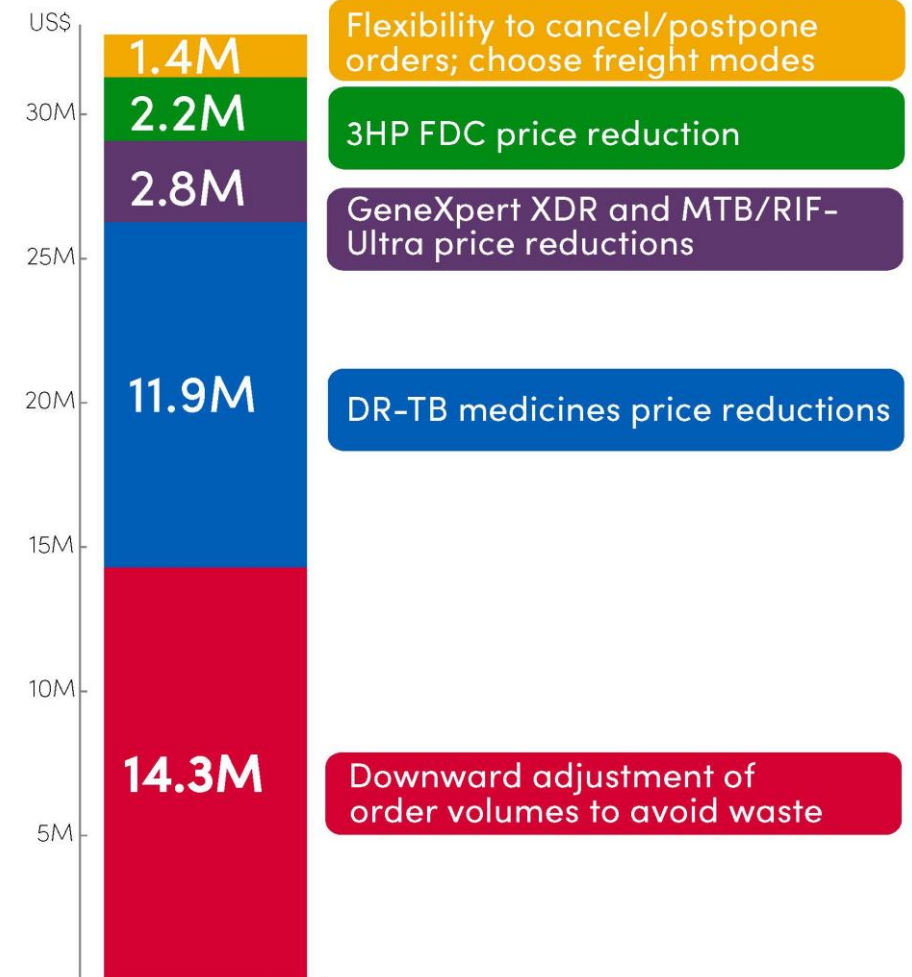
2023 – A Year of Dramatic Price Reductions and Significant Savings

	<u>OLD</u> Lowest Price per Treatment Course	<u>NEW</u> Lowest Price per Treatment Course	Price Reduction
Bedaquiline	\$289	\$130	↘ 55%
Delamanid	\$1,700	\$1,190	↘ 30%
3HP	\$14.25	\$9.99	↘ 30%
GeneXpert MTB/RIF	\$9.98/test	\$7.97/test	↘ 20%
GeneXpert XDR	\$19.80/test	\$14.90/test	↘ 25%

BPaLM lowest price now \$426 per treatment course

PRICES

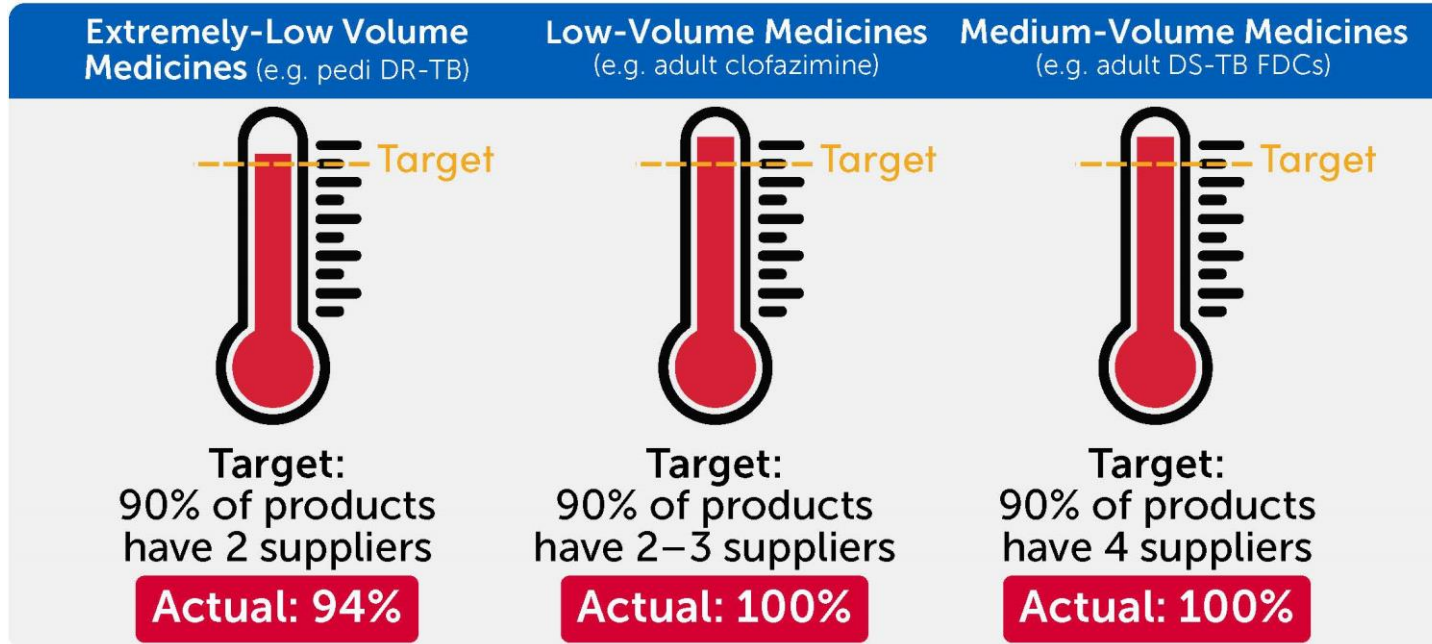
GDF Savings Over US\$ 32 Million in 2023



GDF Budgeting and regimen prices can be found here: <https://www.stoptb.org/buyers/plan-order>

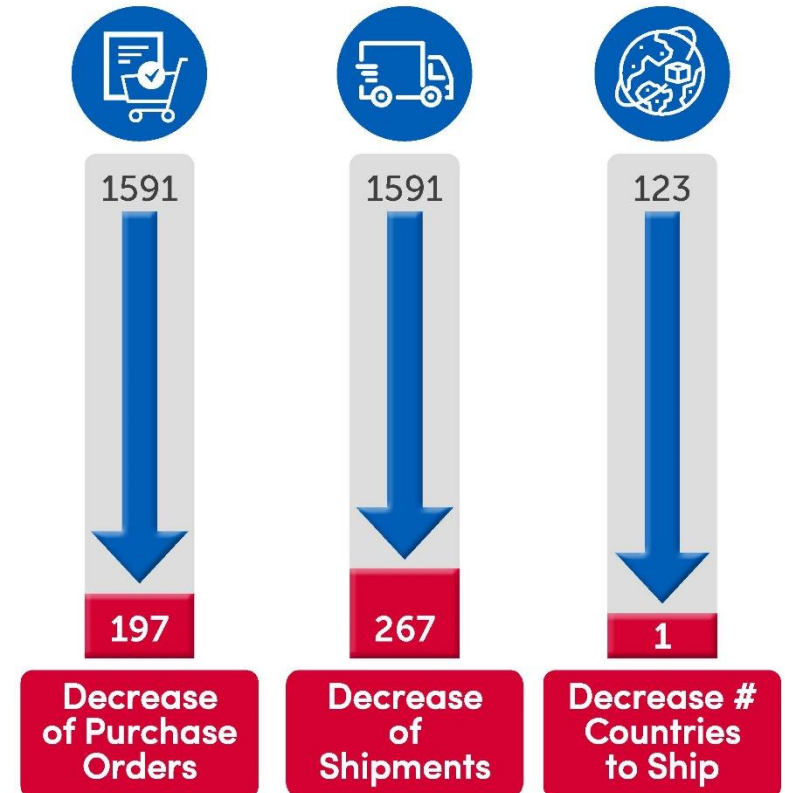
GDF Surpassed Supply Security Targets & Maximized Stockpile Efficiency

GDF Supply Security Results, TB Medicines



↑
Demand of only 500-1,000 treatments per year

GDF Stockpile Eases Supply Chain Management for Suppliers



GDF risk-sharing decreases suppliers' waste and transactional costs, leading to lower medicine prices

GDF Prevention of Stockouts

GDF Averted Potential Stockouts in 128 Countries By Accommodating Emergency Orders



...And Averted an Additional 41 Potential Stockouts in 18 GDF Priority Countries By Other Means

Pediatric DR-TB Initiative Surpassed All Milestones

Treatments Delivered

GDF delivered child-friendly formulations for DR-TB treatment to an est.

6,500
children



Including an est.
2,000
treatment courses using
child-friendly
bedaquiline
*(AVAILABLE SINCE
JUNE 2020)*

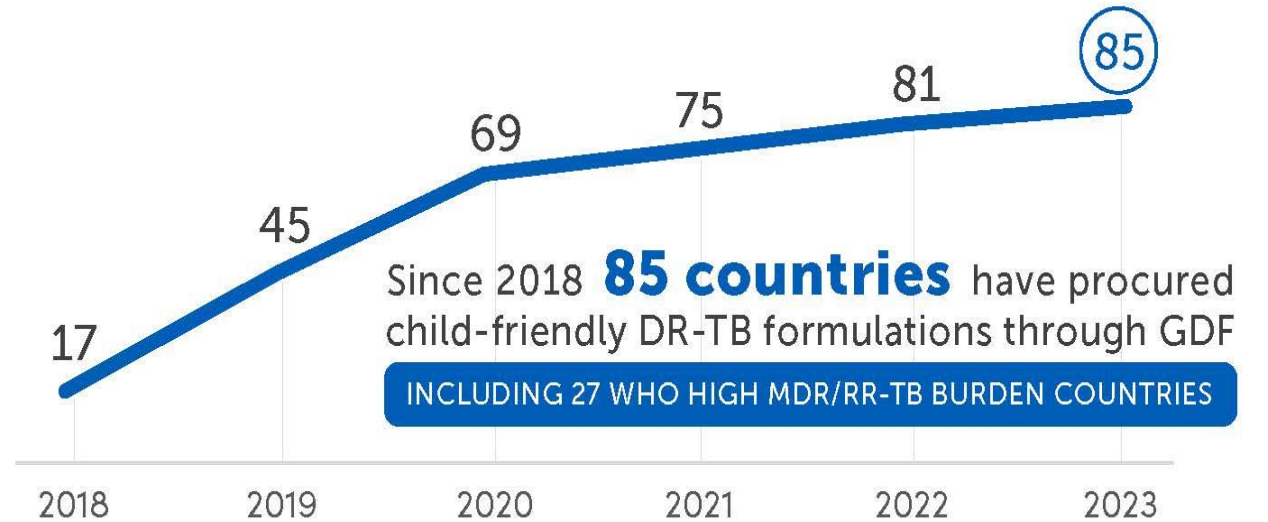
Including an est.
1,000
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child-friendly
delamanid
*(AVAILABLE SINCE
NOVEMBER 2021)*

Formulations Available

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Countries Procuring












Jointly funded by:



TB Procurement and Market-Shaping Action Team (TPMAT) Remained Aligned & Coordinated with WHO, Global Fund, and other Stakeholders

>20 Recommendations Accepted by WHO and Global Fund

5 New TB Medicine Formulations Launched & Added to GDF Catalog

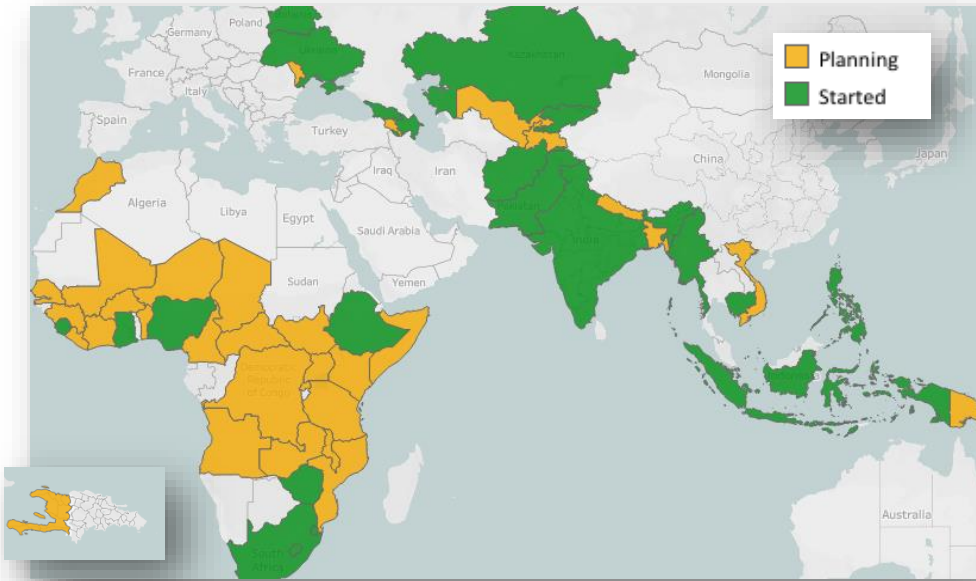
2023 TPMAT Recommendations Accepted		2023 TPMAT Product Achievements	
 <p>WHO Essential Medicines List</p>	Add pretomanid 200mg for use in BPaL(M) for DR-TB	 	<p>3 Medicines WHO-Prequalified:</p> <ul style="list-style-type: none"> • Linezolid 150mg dispersible tablet • Bedaquiline 100mg tablet • Rifapentine 300mg tablet
 <p>WHO Essential Medicines List for Children</p>	<p>Remove age restrictions on bedaquiline and delamanid in children for DR-TB</p> <p>Remove non-optimized paediatric formulations (e.g. non-dispersible, liquids)</p>	 	<p>2 Medicines Approved by Global Fund Expert Review Panel:</p> <ul style="list-style-type: none"> • 2nd Paediatric 3-FDC (rifampicin/isoniazid/pyrazinamide) • Rifapentine 150mg dispersible tablet
 <p>Expert Review Panel Expressions of Interest</p>	<p>15 Medicines for standard list</p> <p>2 Medicines for Priority List:</p> <ul style="list-style-type: none"> • Clofazimine 50mg dispersible tablet • Rifapentine 150mg dispersible tablet 	 	<p>All above medicines added to the GDF Medicines Catalog</p>

GDF Passed Another ISO Audit with Zero Non-Conformities



Scale-Up of New, Short Regimens for DR-TB and TB Prevention

BPaLM*

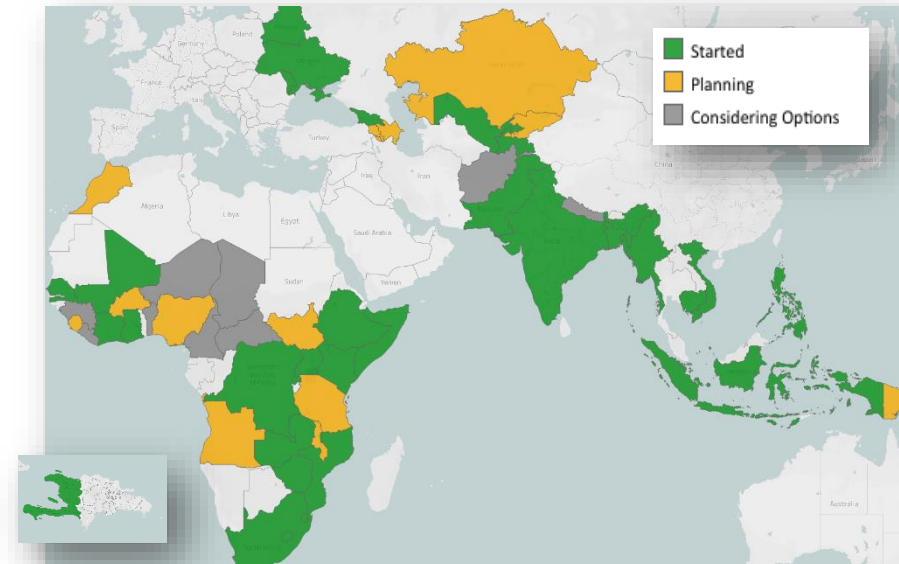


BPaLM Scale-Up Status in 53 Priority Countries:

- 21/53 countries have started
- 32/53 countries have plans to start

And, 61 countries ordered 60,000 Pretomanid treatments via GDF for use in BPaLM regimens**

3HP (3 months of rifapentine/isoniazid)*



3HP Scale-Up in 53 GDF priority countries

- 31/53 countries have started
- 13/53 countries have plans to start
- 9/53 countries considering options

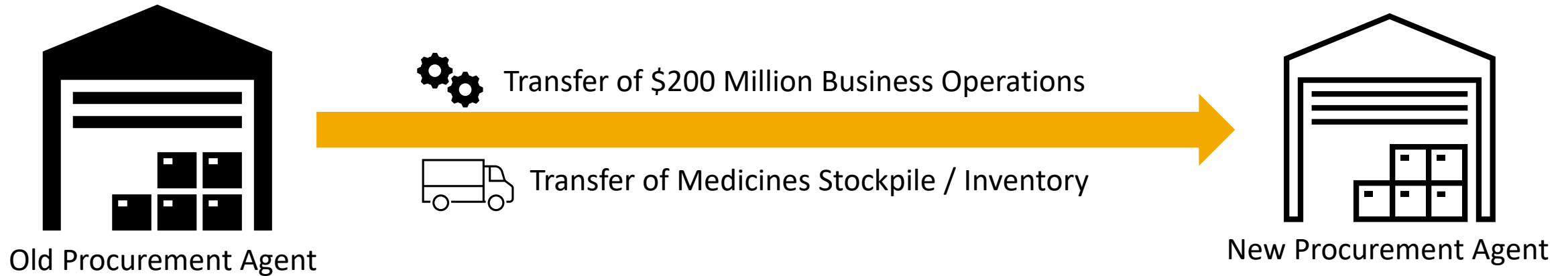
And, 40 countries ordered 780,000 3HP treatment regimens for TB Preventive Treatment***

USAID supporting 11 high-burden countries with procurement of 1.7 million 3HP treatments in 2024

II. 2023 Main Challenges Encountered in Promoting Access to TB Products, and How Best to Address These Challenges

- Transition of old Procurement Agent to New Procurement Agent
- Global supply constraints, domestic procurement
- Optimizing Use of Savings from Price Reductions

Medicines Procurement Agent (PA) Transition



Goal: Seamless transition to ensure business continuity, maintain client confidence, uphold mission to promote access

Challenges:

- Simultaneous mgt of 2 PAs
 - Phase-Out Old PA
 - Phase-In New PA

Risks:

- Stockouts & treatment interruptions
- Delay in new product introduction & scale-up
- Failure to meet GF grant, USAID project deadlines
- Wasted medicines in stockpile
- Negative impact on client satisfaction
- Failure to pass Dec ISO audit

Management:

- Established **Hypercare:** systematic, ultra-scrutiny and monitoring of all 1,200 orders across both PAs to detect and resolve issues that could lead to delays.

Global Supply Constraints

Medicines

Pretomanid

Fixed-Dose Combination (FDC)
Medicines for Drug-Sensitive TB



Global shortage of active
pharmaceutical ingredients
needed to produce medicines

GDF Response

- Data sent by countries is analyzed to prioritize & ration medicines to meet scale-up plans & avoid stockouts
- Send multiple small shipments instead of 1 large shipment
- Monthly production planning with suppliers
- Addition of medicines to GDF Strategic Rotating Stockpile
- Interventions to address API shortage

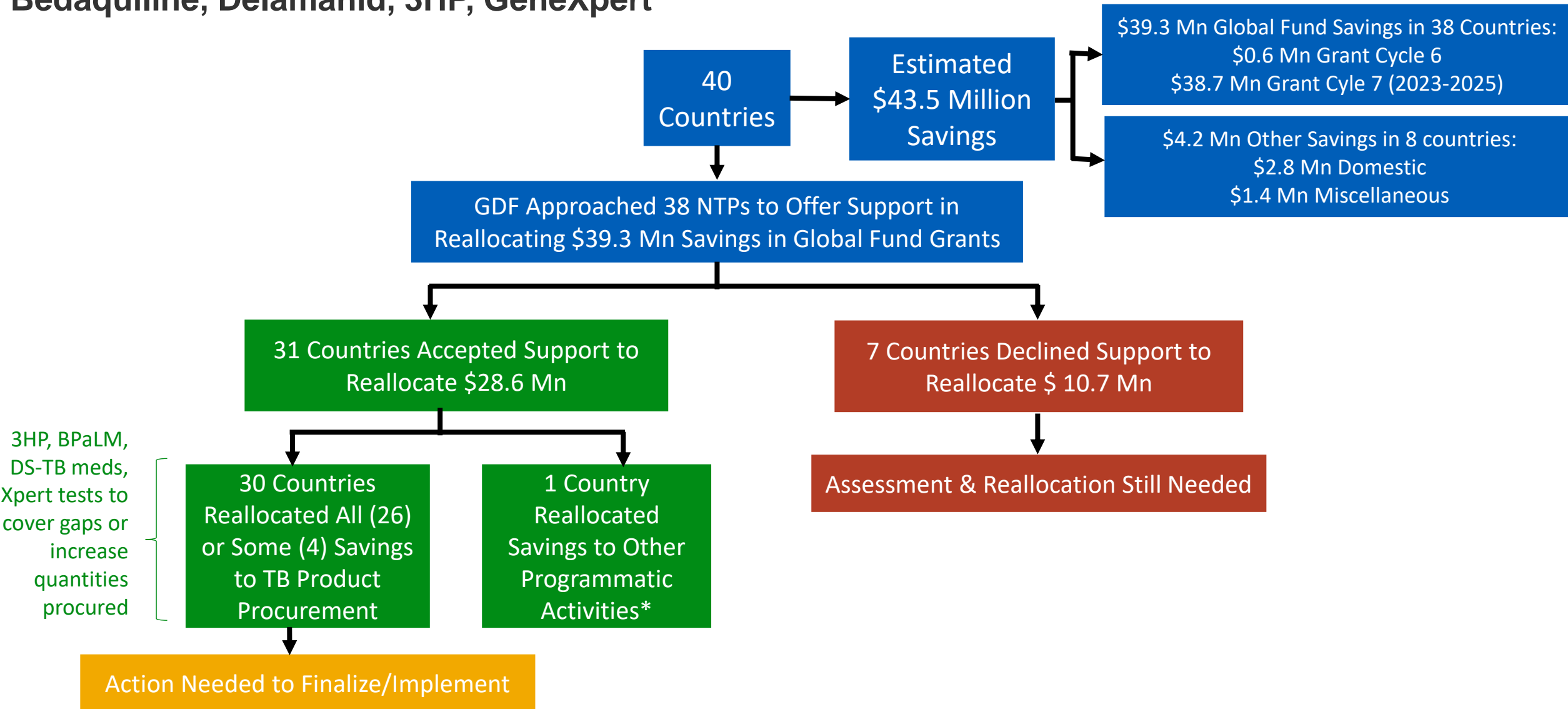
Challenges

- When there are global supply constraints, NTPs procuring domestically also have difficulty securing medicines in a timely manner
 - GDF can serve as a safety net for these countries by way of emergency procurement. The more notice and the more data shared, the better GDF can support
- Some NTPs not eager to share data for products procured outside GDF

2023 Overview of Domestic Financing & Procurement of TB Medicines in 53 GDF Priority Countries*

Numbers being validated.

Reallocation of Savings From Price Reductions in Global Fund Grants: Bedaquiline, Delamanid, 3HP, GeneXpert



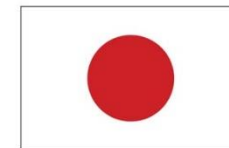
Thank you

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Acknowledgements

With thanks to the:

- Entire GDF staff
- National TB Programmes, suppliers, and and partners who contributed to 2023 results
- Donors who funded and supported this work



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the People of Japan