

GDF Key Updates, Achievements, and Remaining Challenges

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Stop TB Coordinating Board, 12 December 2019

Jakarta

GDF One-Stop-Shop: Product Catalog Updates & Plans

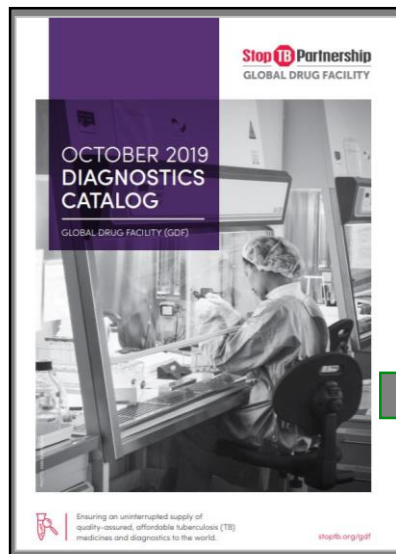
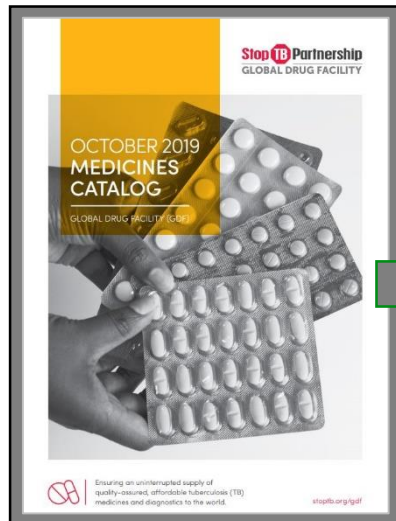
REMOVED

Medicines

- ← Kanamycin
- ← Capreomycin
- ← Rifampicin/INH
150mg/150mg
- ← Ethionamide 125mg
- ← Pyrazinamide 150mg

Diagnostics

- ← Omnigene-Sputum



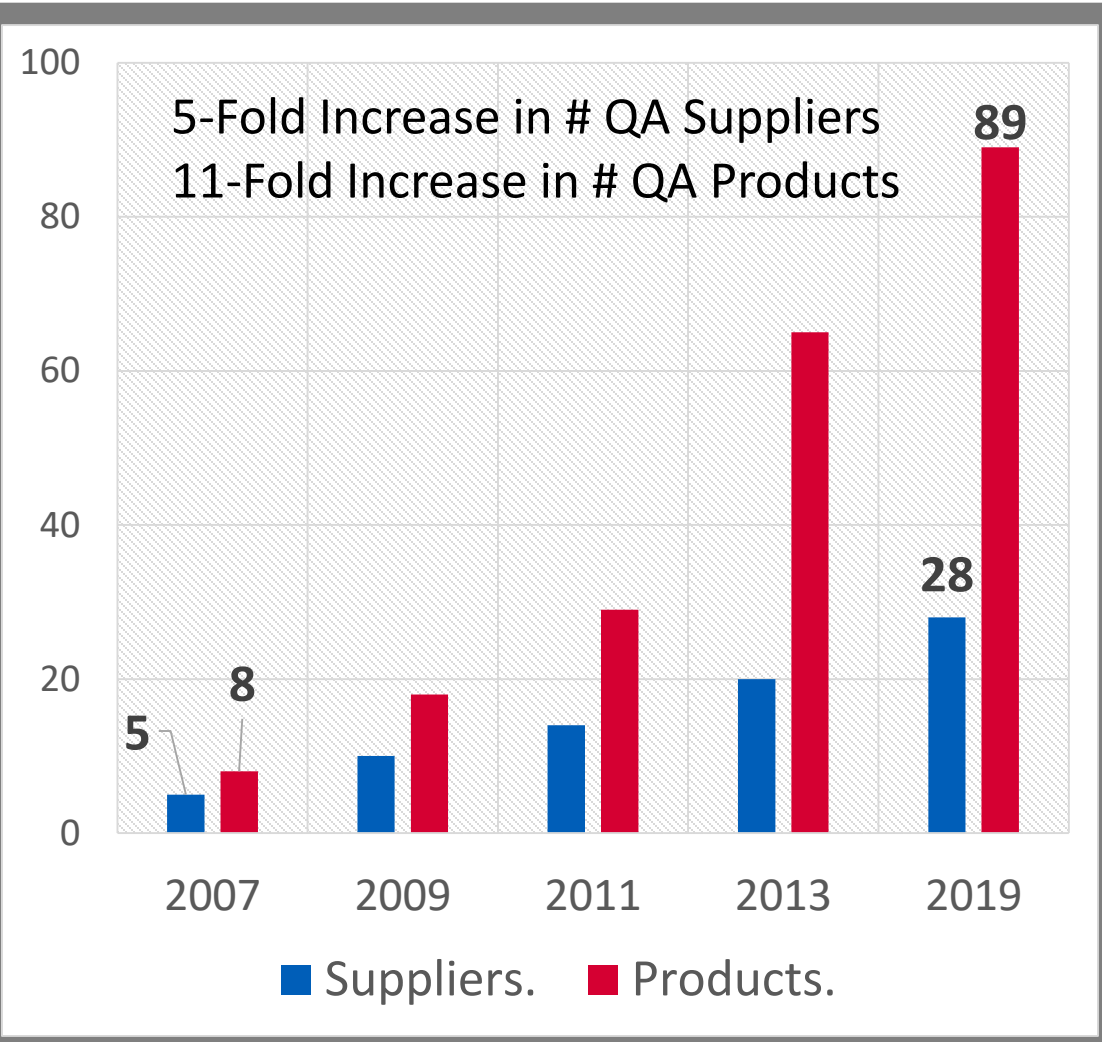
ADDED

Medicines

- SMX/TM
- Levofloxacin
- Moxifloxacin
- Clofazimine
- Cycloserine
- Ethambutol
- Pyrazinamide
- Ethionamide
- Isoniazid
- Rifapentine
- Pretomanid

Diagnostics

- Pure drug linezolid
- GeneXpert Edge
- IGRA (QFT-Plus)



*Pending WHO Recommendation

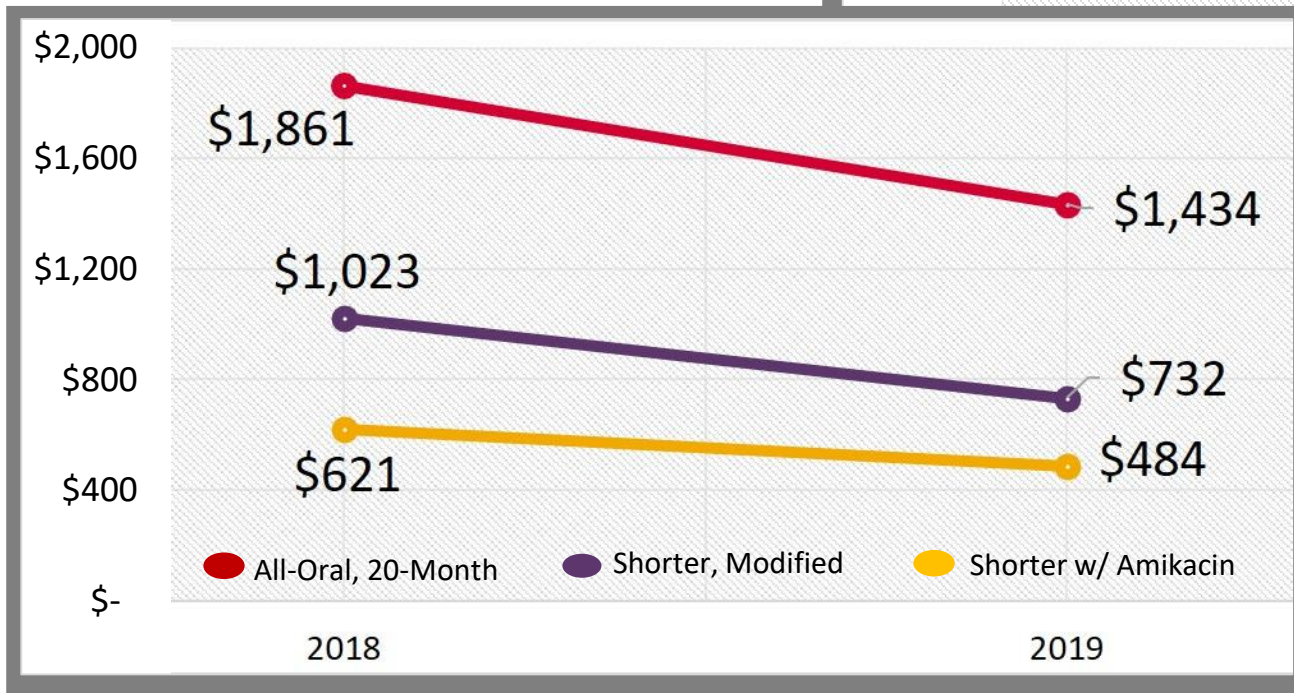
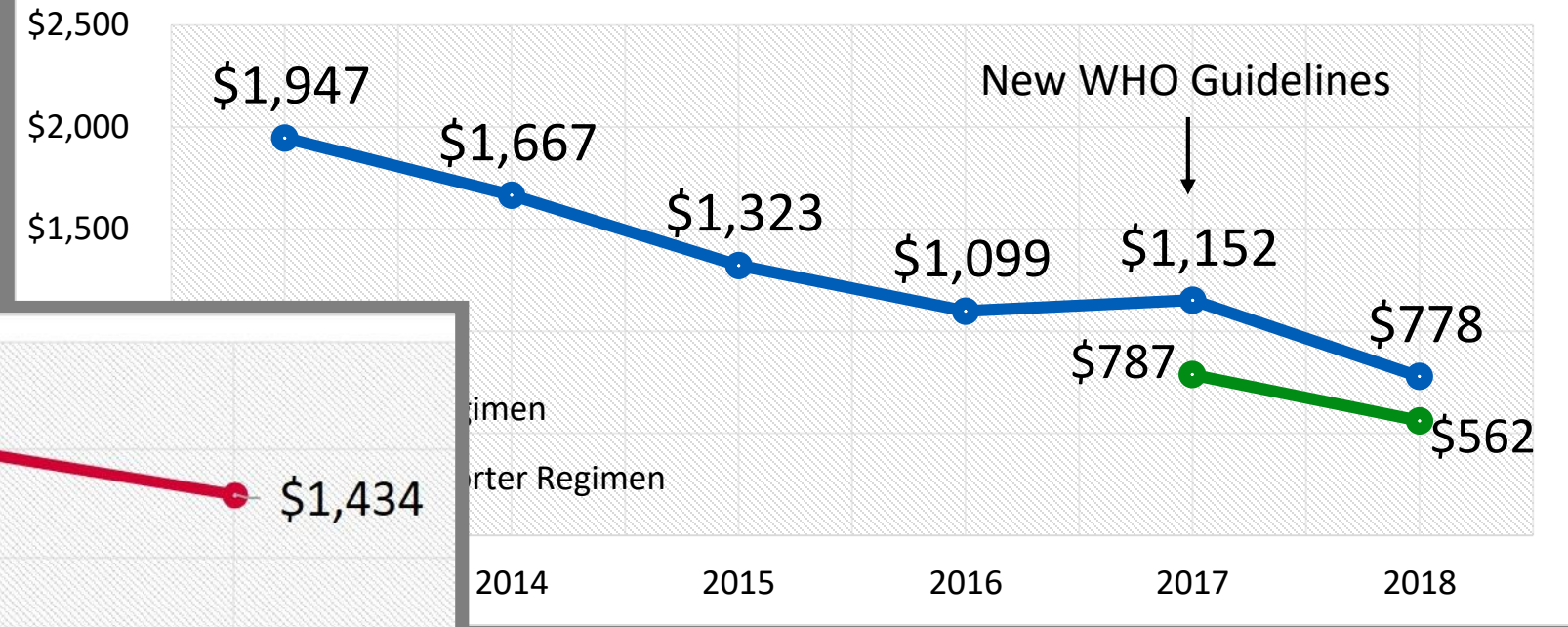


GDF SLD Price Reductions

Past WHO-Recommended Regimens

60% Decrease in SLD Prices

2018 WHO-Recommended Regimens



Up to 29% Decrease in SLD Prices in 2019

GDF Savings of ~\$84 Million over 2018-2019

\$52 Mn Savings from GDF SLD Tenders

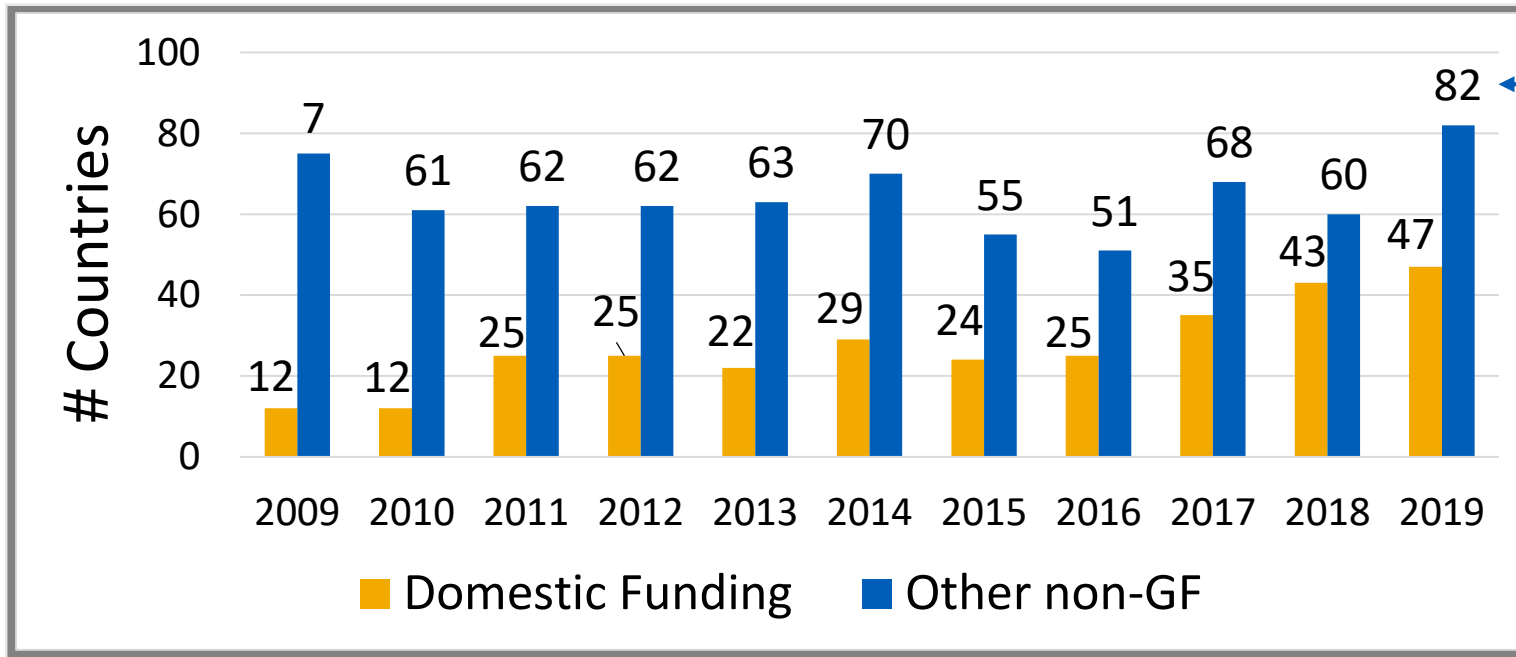
2018		2019	
Estimated*	Actual	Estimated*	Actual
\$33 million	\$36 million	\$16.5 million	TBD

*Estimated at tender award based upon forecast, supplier allocation, price; Does not include savings from 2018 BDQ price decreases post-donation

\$32 Mn Savings from GDF's Order Management & Flexible Procurement Systems

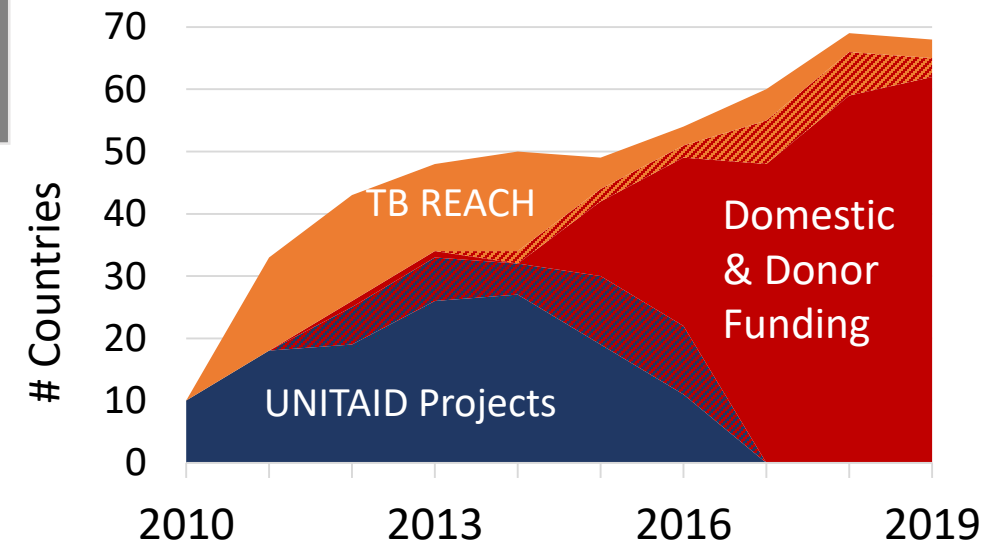
Intervention	Year	
	2018	Q1-Q3 2019
Pre-order Adjustment	\$9,188,953	\$10,939,181
Order Cancellation	\$1,158,120	\$1,122,467
Order Reallocation	\$2,807,372	\$1,333,269
Order Postponements	\$4,644,673	\$975,184
Subtotal	\$17,799,118	\$14,370,101
Total	\$32,169,219	

Trends in Countries Procuring via GDF with Non-Global Fund Financing



← Including ~20 Clinical Trials

Expanding GDF Client Base for Diagnostics Procurement



2019 GDF Client Satisfaction*

Category	Result
Simple procurement process	96%
Timely & clear communication	97%
Products arrived at date agreed	93%
Satisfied with product quality	99%
No damage to product or package	94%
Shipment documentation complete & accurate	100%
GDF responsive & flexible	98%
GDF service compared to other orgs	97%
Will use GDF services again	99%



*Annual client satisfaction survey as per ISO Standard Operating Procedures

TPMAT Results: WHO-GF-GDF Harmonization using TB Medicines Dashboard

2018-2019 Changes:

GDF Catalog: 7 products removed, 15 added

Essential Medicines List: 35 changes

WHO Prequal EOI: 20 changes

Global Fund ERP EOI: 5 priority products approved

DR-TB Adult | DS-TB Adult | LTBI Adult | DR-TB Pediatric | DS-TB Pediatric | LTBI Pediatric | Prod

Adult Drug-Resistant TB Medicines Dashboard

This Dashboard has been developed by Stop TB Partnership/Global Drug Facility in collaboration with USAID, the World Health Organization, and the Global Fund. Stop TB Partnership/Global Drug Facility licensed the TB Medicines Dashboard under a Creative Commons Attribution-NonCommercial license.

Status

- Yes
- No
- Rejected
- Ineligible for inclusion
- N/A

Medicines	WHO Guidelines (DR-TB '16)	WHO Guidelines (DR-TB '19)	EML submitted	EML (2019)	M	V	G			
Capreomycin 500mg vial	Yes	No	No	No	No	N/A	Yes	No	Ineligible for inclusion	No
Capreomycin 1000mg vial	Yes	No	Yes	No	No	N/A	Yes	Ineligible for inclusion	Ineligible for inclusion	Yes
Clofazimine 50mg tablet/capsule	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Clofazimine 100mg tablet/capsule	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Cycloserine 125mg capsule	Yes	Yes	Yes	Yes	Yes	N/A	Yes	Yes	No	Yes

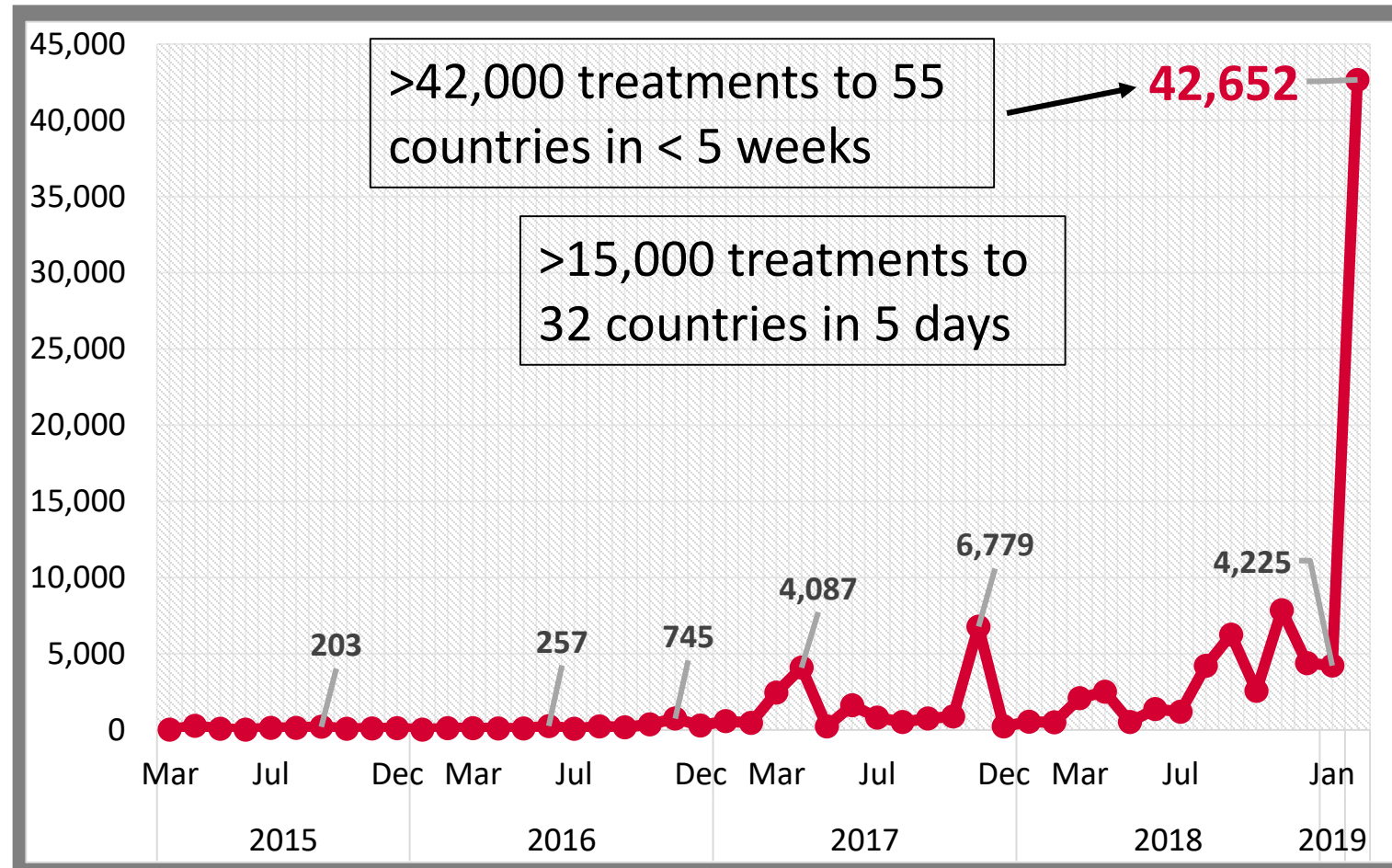
Equitable Allocation of USAID-Janssen Bedaquiline Donation

Donation Timeline

Mar 2015	30,000 treatments over 3 years
May 2018	30,000 treatments added, extended to 4 years
Feb 2019	30,000 treatments added
Mar 2019	15,000 treatments added for 5 Mar 2019 deadline
TOTAL	105,000 treatments over 4 years

- Rapid situational analyses of >80 countries
- Triangulation of inventory, enrolment, existing orders to meet demand ACROSS ALL COUNTRIES thru Jun 2020

Monthly Bedaquiline Orders



TB Markets: Inherently Small and Fragmented; Require Global Coordination

MEDICINES



- **Small Market Size:**
 - Fraction of the size of HIV or Malaria
- **Markets Fragmented Across:**
 - >20 DR-TB regimens & >50 products
 - Quality Status: Internationally QA'd & locally QA'd products
 - Buyers (GDF, domestic) for Internationally QA'd products
- **Suppliers:**
 - Don't see TB as high profit
 - Medicines "made to order"; no stock held leading to long lead times
 - Supply security is main priority



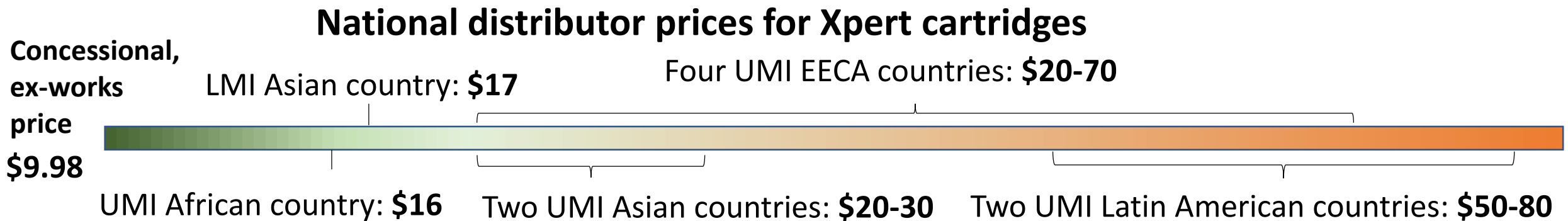
DIAGNOSTICS

- Three suppliers hold virtual **monopolies** for the three main TB diagnostic tests
- No consensus among main donors and buyers on best approach to improve service and maintenance or warranty costs
- **Small volumes** for many products
- Unknown quality of generic lab supplies procured by some programs

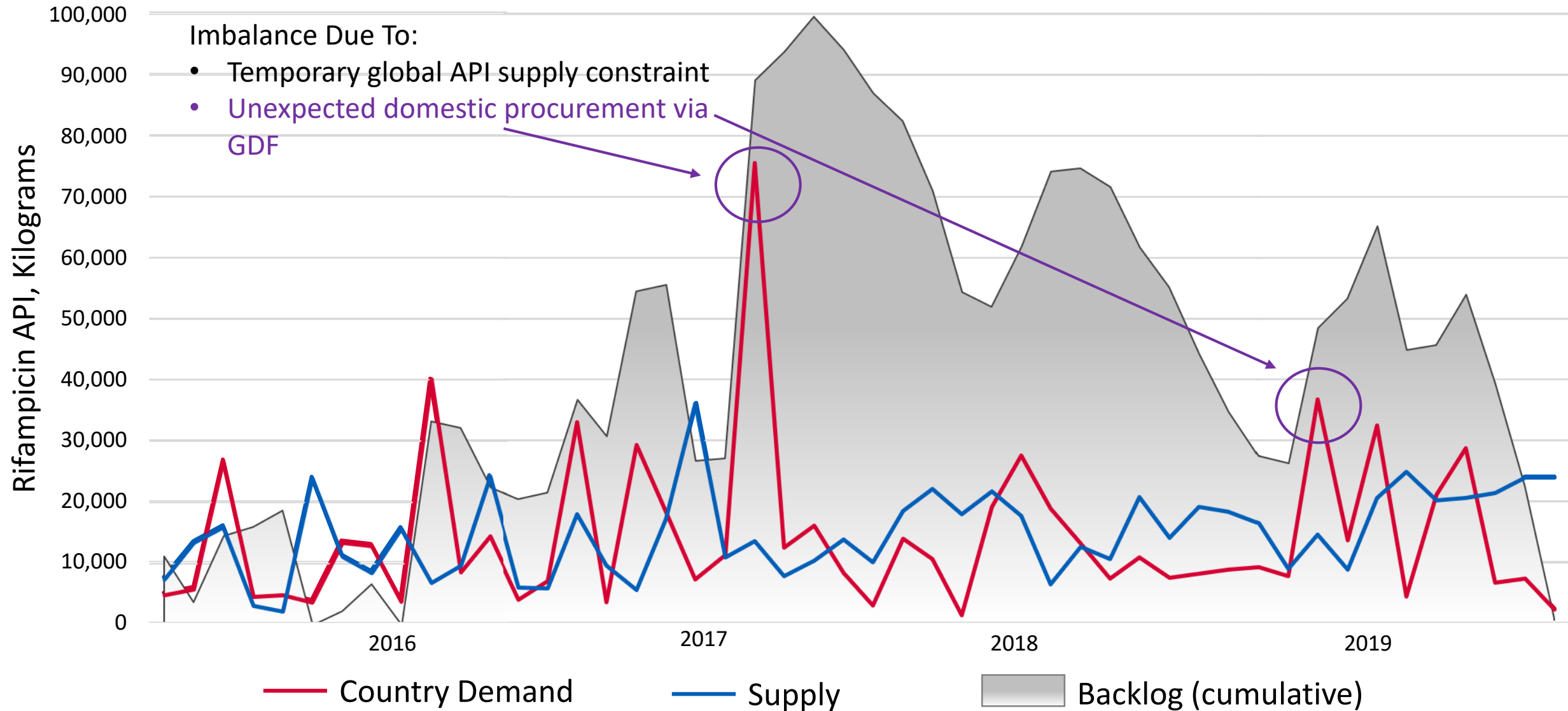


Domestic Procurement of TB Medicines and Diagnostics 2017 – Q3 2019

- 16 failed tenders
- Failed deliveries, despite successful tenders, due to lack of product registration
- 35 countries procured medicines of unknown quality
- 10 countries procured products that are not WHO-recommended
- High prices paid through local agents & distributors for certain medicines and diagnostics
- 25 countries experienced medicine stock-outs or shortages
- Slow uptake of new regimens, medicines, formulations

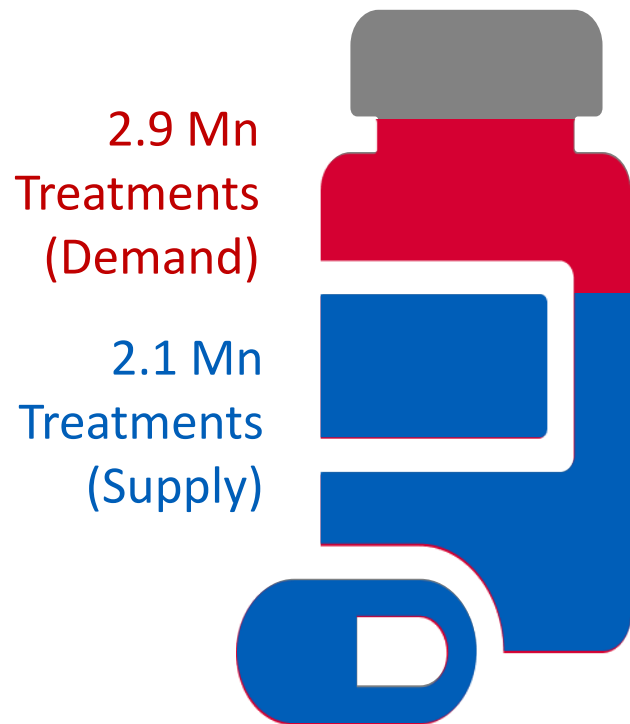


Rifampicin: Demand vs Supply Imbalance



GDF's Response & Results During FLD Supply Constraint

2018 Imbalance*



GDF Response

- Weekly prioritization & rationing of orders for countries with high-risk of stockout
- Sending lots of smaller shipments instead of large shipments
- Monthly production planning with suppliers
- Addition of FLDs to GDF Strategic Rotating Stockpile
- Interventions to address API shortage

GDF Results

- All clients got what they needed
- 594 shipments to 86 countries
- Accommodated requests for emergency orders
 - Delivered to 19 countries in <60 days
- **No stockouts** in GDF client countries
- **>65 stockouts averted**

*Nov 2017 – Oct 2018

FLD Supply Situation – Looking Forward

Challenges Going Forward

- Insufficient visibility on demand; suppliers unable to plan in advance to meet 2020 needs
 - No means to anticipate large orders from domestic buyers
 - Increase in GF procurement via GDF at end-of-grant cycle in 2020; and,
- Increased use and production of rifapentine likely to further complicate coordination and production planning of FLDs

Approaches to Address Challenges

- Add FLDs to GDF Strategic Rotating Stockpile (SRS)
- Work with GF to get end-of-grant procurement estimates & timelines for top 10 countries
- Encourage pooled procurement of rifapentine is conducted by GDF
- Establish ProCureTB Network of large domestic buyers
- Move discussion towards uninterrupted access and sustainable supply. Don't just focus on price.

ProCureTB Network

Composition

Procurement officials from key countries with high burdens of TB (high demand)

Aim

Provide a peer-to-peer platform to support national & global procurement of TB medicines & diagnostics and ensure suppliers are able to meet TB medicine needs of all buyers.

Objectives

- Coordinate timing of orders to suppliers;
- Share information on price, availability, and product quality issues; and,
- Develop global demand forecasts.

Logistics

- Stop TB Partnership's Global Drug Facility (GDF) will serve as the Secretariat;
- In-person meetings will be held on the side of the Stop TB Collaborating Board meetings

Paediatric DR-TB – Setting the Context

The numbers:

- ~25,000 children < 15 years old become newly sick with Drug-Resistant TB every year
- No data on # young children (<5 yo); estimates 10-12,000 get DR-TB every year, with only 500 receiving treatment
- UNHLM Target: Treat 115,000 children with DR-TB by 2022, including ~47,000 young children < 5 yo

The products:

- Until now, young children were treated with injections and suboptimal adult formulations that needed to be crushed or broken and have a bitter taste
- In 2018, the world's first-ever, child-friendly formulations for DR-TB were developed



Stop TB's GDF Pediatric DR-TB Initiative

Funded by the Government of Japan and USAID



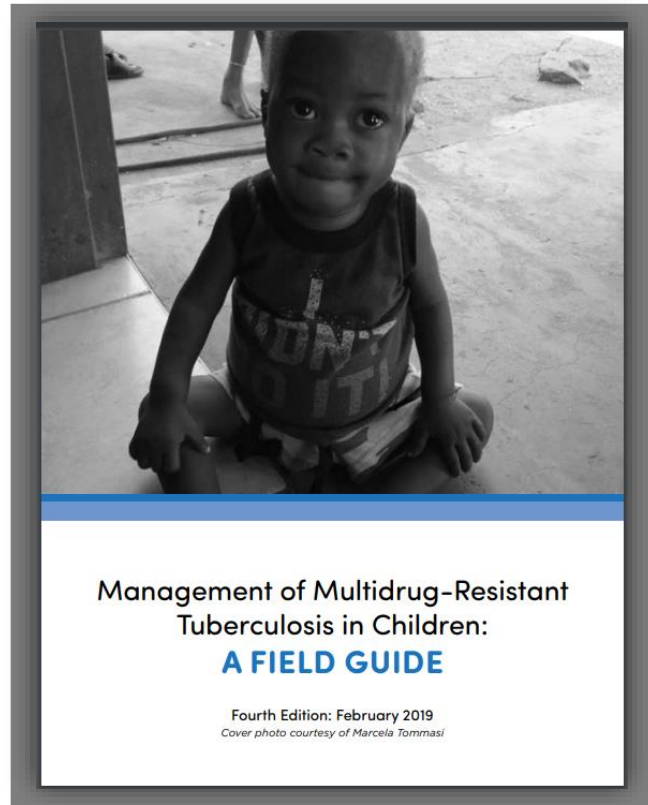
Develop clinical and technical support materials for countries

Find & quantify demand, then provide grants for procurement of medicines

Plan production to match demand;
Conduct pooled procurement

Generate & disseminate evidence on use (e.g., acceptability) of new formulations

Clinical & Technical Support Materials



February 2019 Update of
Sentinel Project Field Guide



- Drug Information Materials
- Standard Operating Procedures for Administration (English, French, Russian)

Results to Date



GDF negotiated substantial price reductions of 30% to 85%

56 countries procured these new formulations: 16 in 2018, 40 in 2019

56



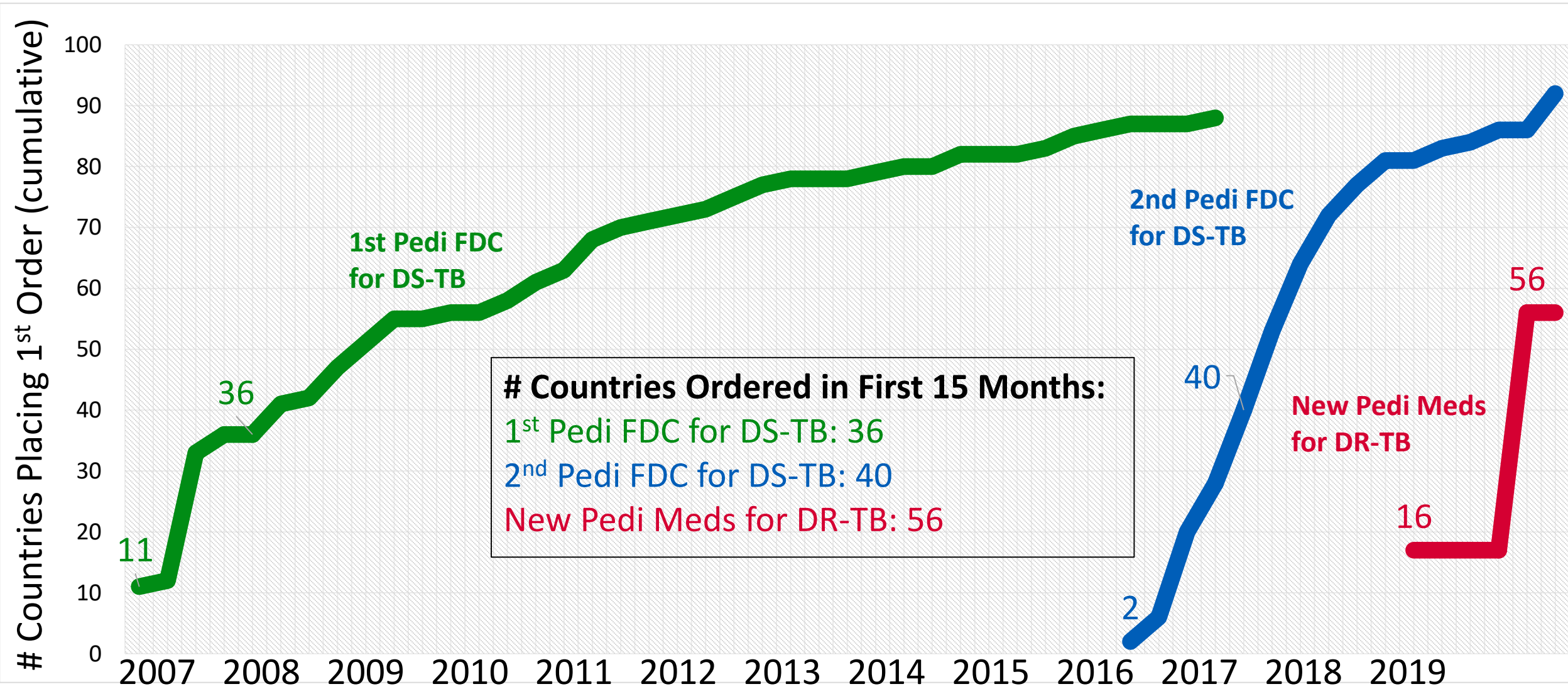
1,100 pediatric DR-TB were procured:
2-times the annual # of kids treated globally

56 Countries Procuring Child-Friendly DR-TB Formulations



- | | | |
|-------------------|-------------------------|------------------|
| 1. Afghanistan | 21. India | 41. Senegal |
| 2. Angola | 22. Indonesia | 42. Sierra Leone |
| 3. Armenia | 23. Kazakhstan | 43. Somalia |
| 4. Azerbaijan | 24. Kenya | 44. South Africa |
| 5. Bangladesh | 25. Kyrgyzstan | 45. Sri Lanka |
| 6. Belarus | 26. Laos | 46. Tajikistan |
| 7. Benin | 27. Lesotho | 47. Tanzania |
| 8. Botswana | 28. Liberia | 48. Thailand |
| 9. Burkina Faso | 29. Malawi | 49. Timor-Leste |
| 10. Cambodia | 30. Mongolia | 50. Turkmenistan |
| 11. Cameroon | 31. Morocco | 51. Uganda |
| 12. Chad | 32. Mozambique | 52. Ukraine |
| 13. Côte d'Ivoire | 33. Myanmar | 53. Uzbekistan |
| 14. DRC | 34. Namibia | 54. Viet Nam |
| 15. Eswatini | 35. Niger | 55. Zambia |
| 16. Ethiopia | 36. Nigeria | 56. Zimbabwe |
| 17. Georgia | 37. Pakistan | |
| 18. Ghana | 38. Papua New Guinea | |
| 19. Guinea | 39. Republic of Moldova | |
| 20. Haiti | 40. Rwanda | |

Introduction of New Pediatric TB Formulations

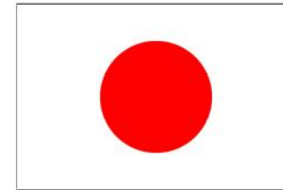


It's Time to End Drug-resistant TB in Children

The Pediatric DR-TB Initiative **is only possible** thanks to the support provided by USAID and the Government of Japan



USAID
FROM THE AMERICAN PEOPLE



FROM THE PEOPLE OF JAPAN



Thank you!

ありがとうございました！

Terima kasih!

Dr Brenda Waning

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