

Global Drug Facility (GDF) – Market Updates on Key TB Products and Procurement Trends

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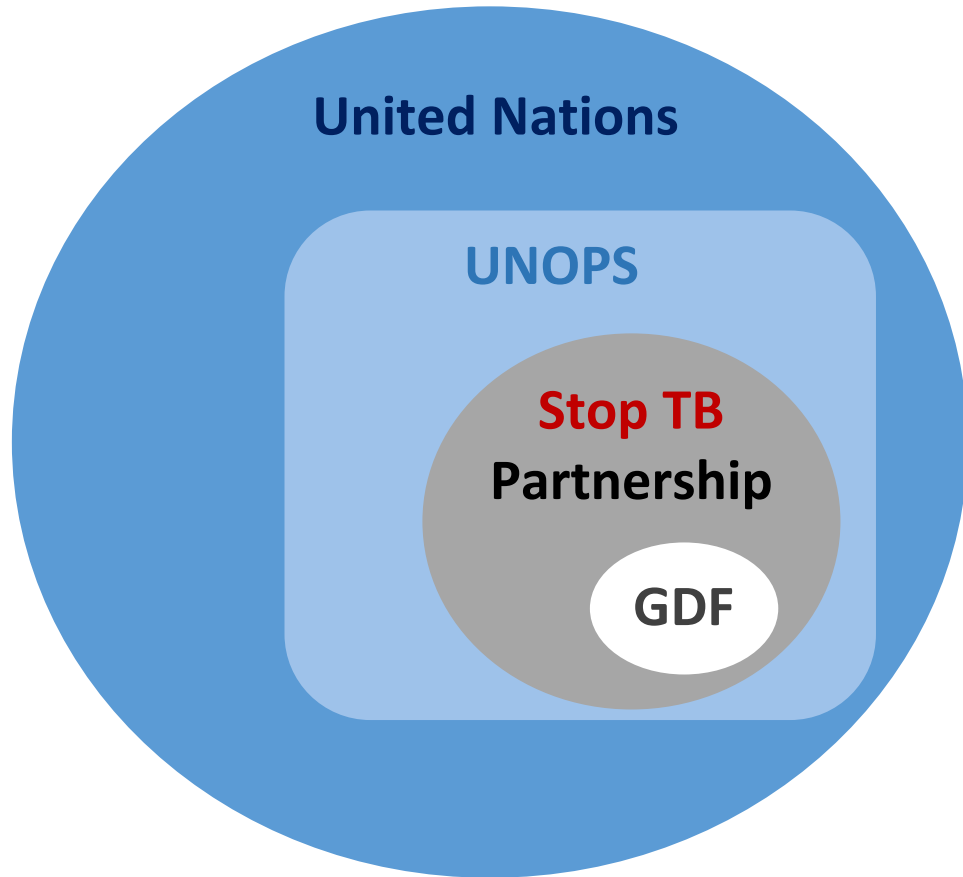
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Joint UNICEF-UNFPA-WHO meeting, 10 March 2022, Virtual meeting

The Global Drug Facility (GDF) – Who we are



- Established in 2001
- Largely funded by USAID
- ISO9001:2015 certified
- Integrated pooled procurement mechanism

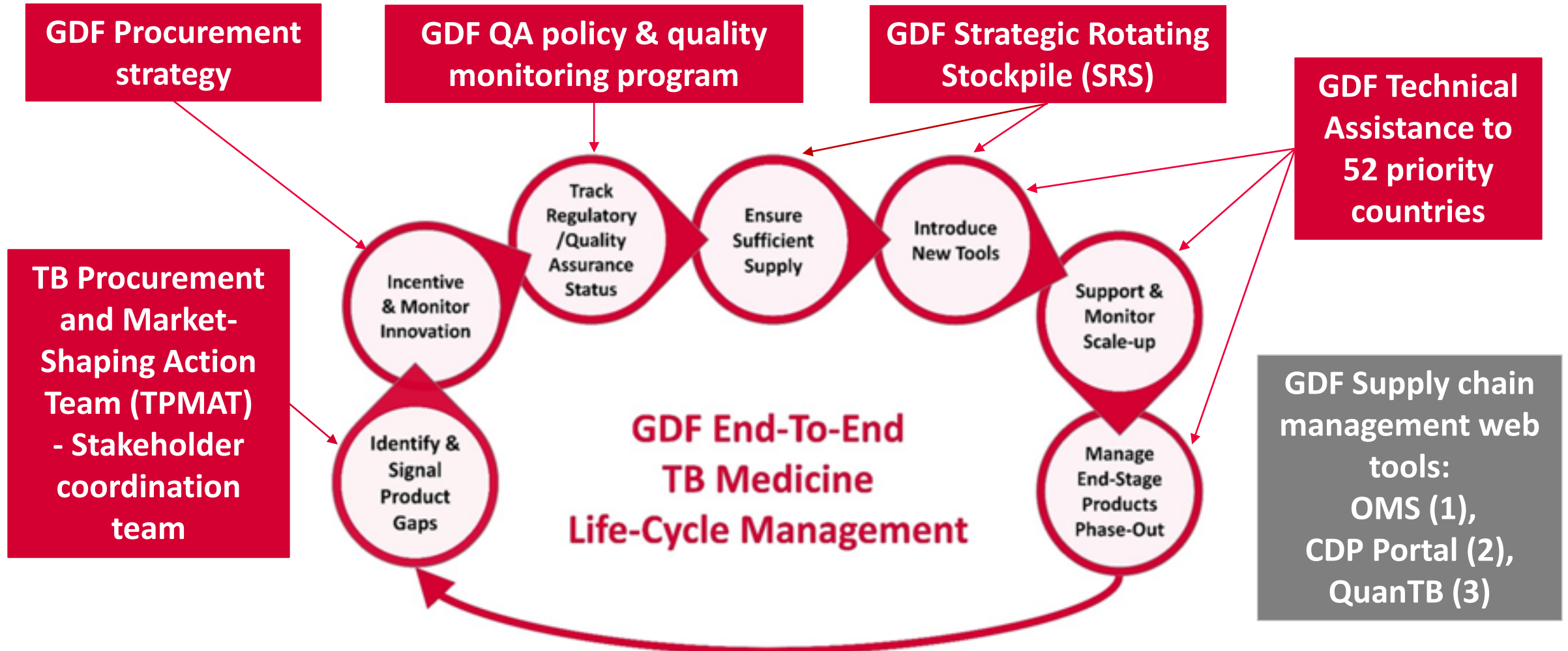


GDF Mission

Facilitate world-wide, equitable access to TB products, including new tools, across the public and private sector

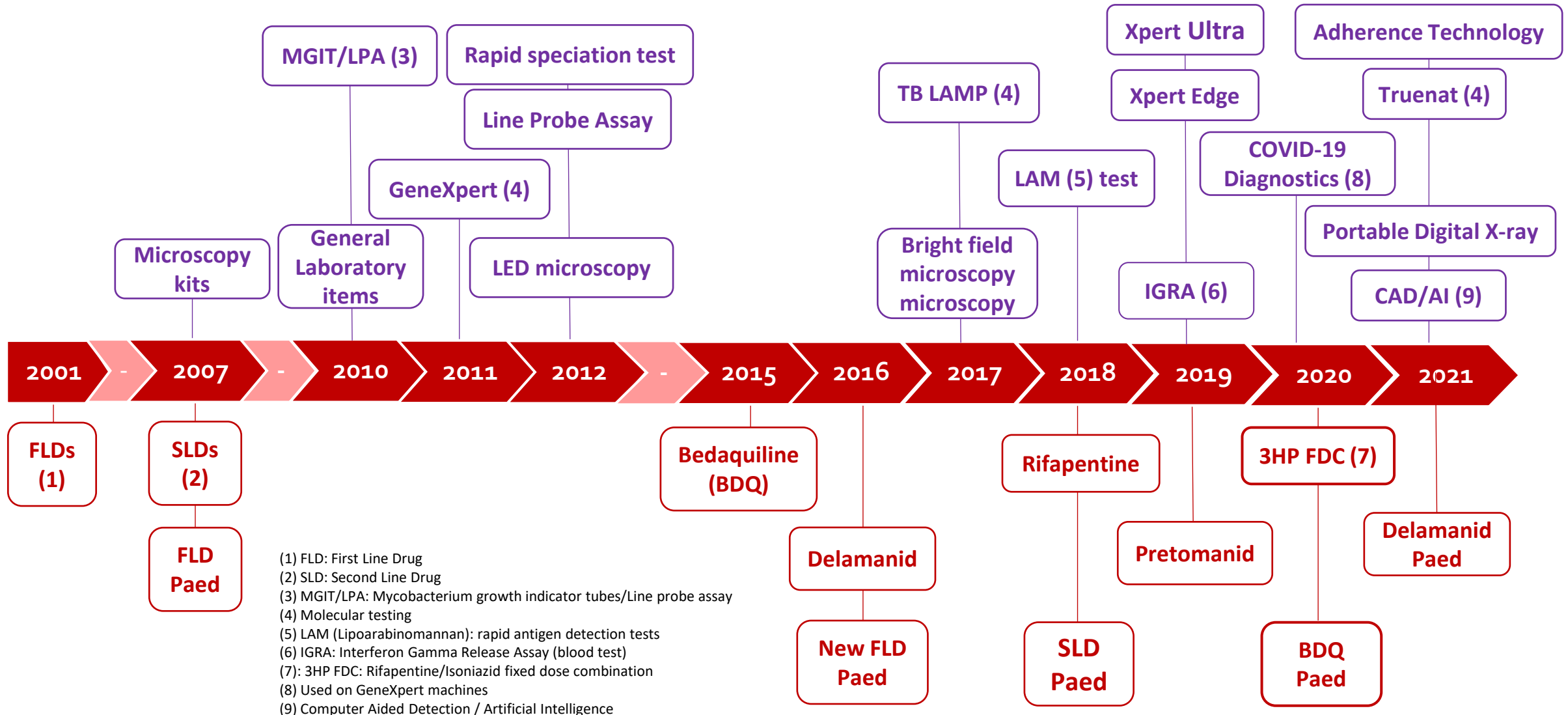
GDF Operational Model: Integrated Pooled Procurement mechanism

Integrated across the full product life-cycle

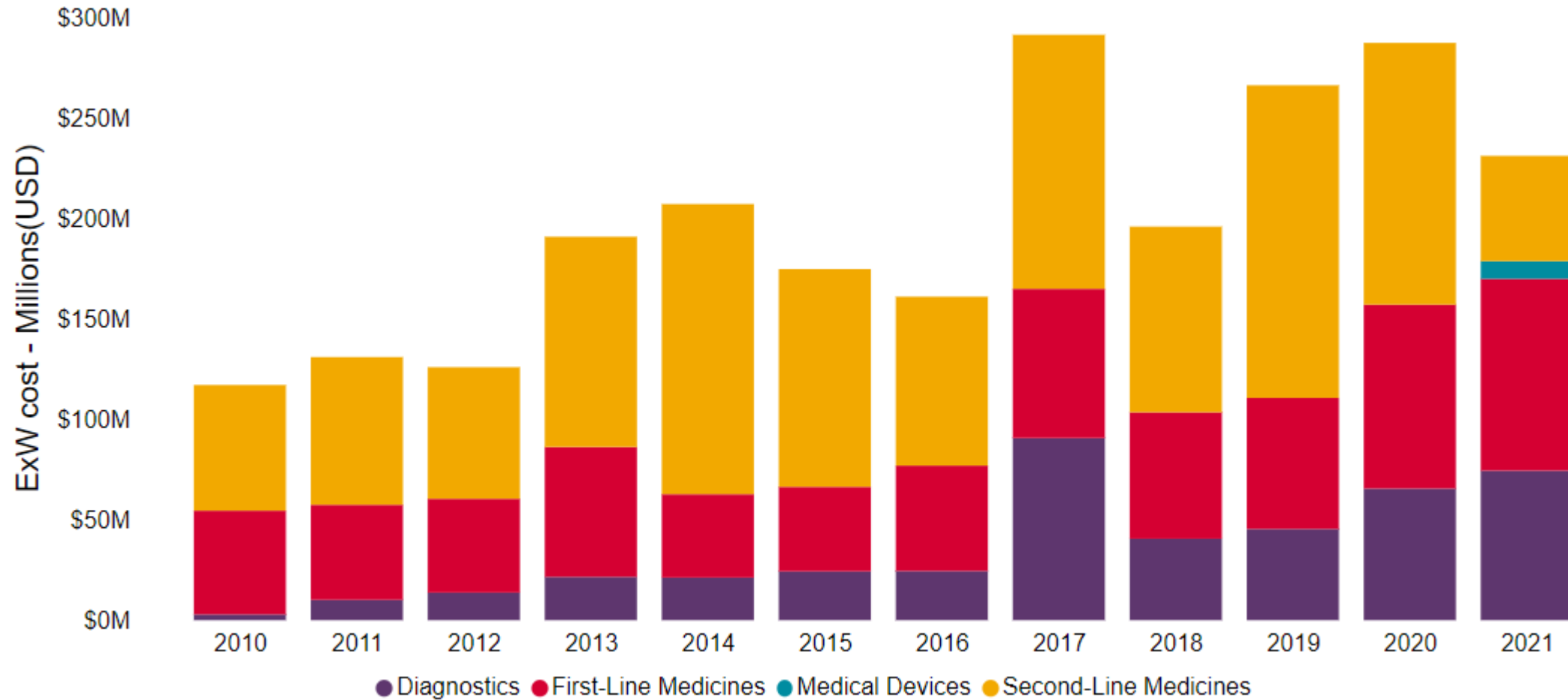


(1) Online system to manage orders with clients and suppliers (2) Online system to manage product life cycle with suppliers (3) Quantification tool for TB medicines

Procurement Trends – Products GDF supports



Procurement Trends – Value of Procurement

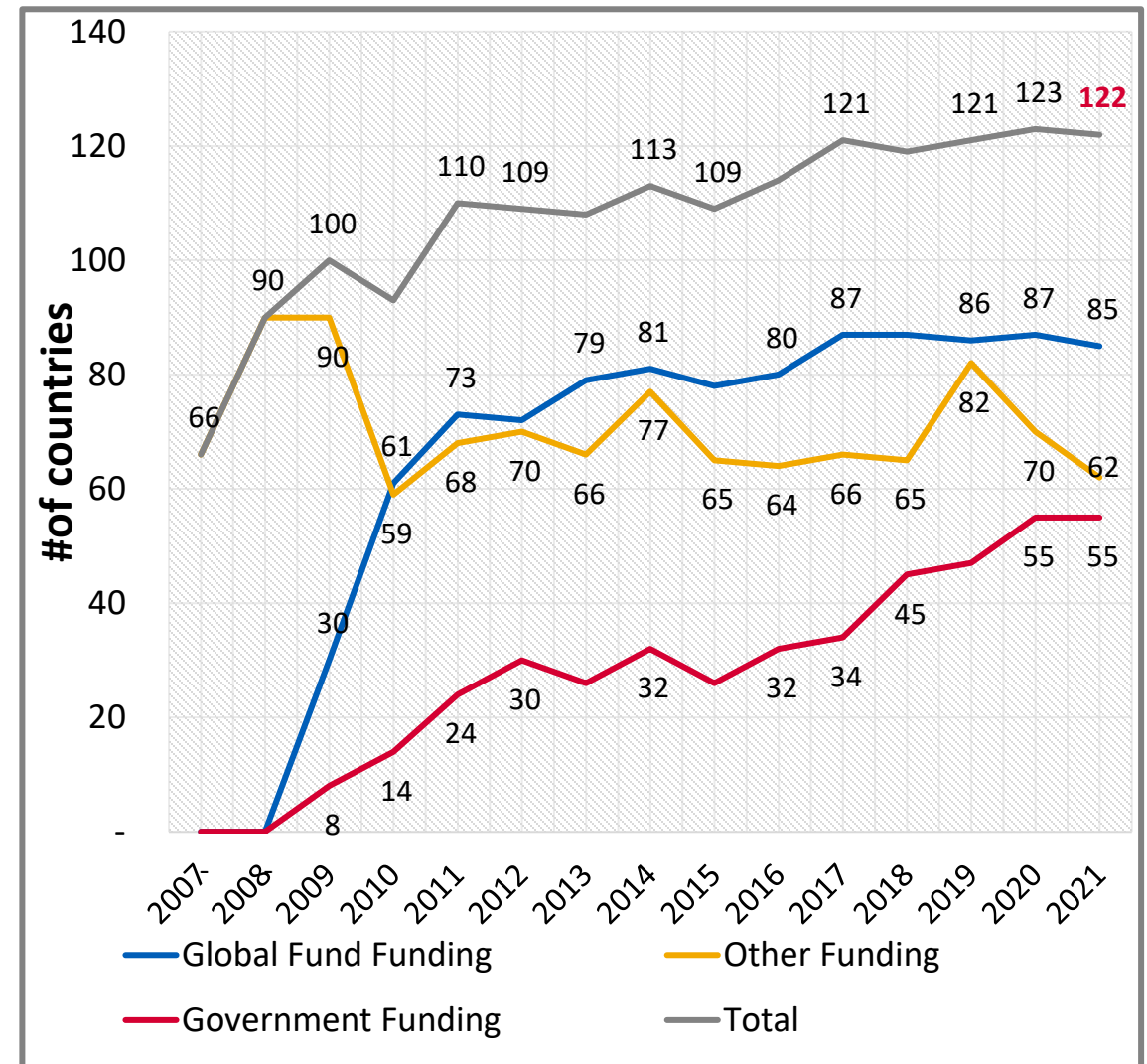


Procurement Trends – Countries and Programmes Supported

GDF can support **ANY country** (when procurement from GDF aligns with national laws and regulations)

UN High-Level Meeting on TB 2018 “We, Heads of State and Government and representatives of States and Governments [...] (15) **encourage all nations** to use the Global Drug Facility.”

GDF supports countries in **all WHO regions**



GDF Value Add – Strategic Rotating Stockpile



The SRS is physical stock that GDF owns and maintains in its warehouse. SRS is used to:

- Respond to emergency orders from programmes
- Decrease lead time
- Consolidate multiple products into one order for programmes

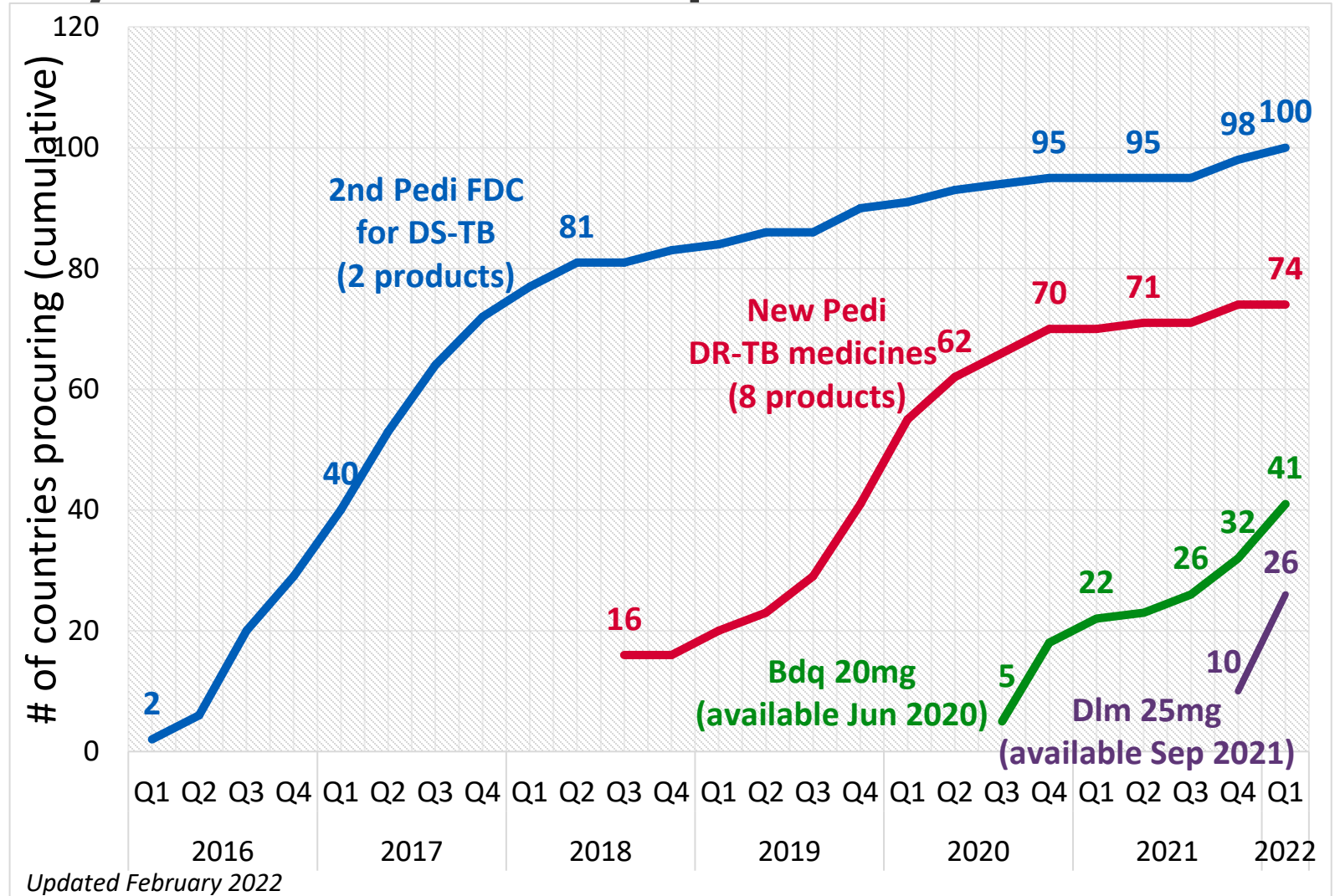
For suppliers, product inclusion in the SRS means:

- Less variation in quantities purchased from suppliers, more consistent ordering
- POs in line with batch size/production plan
- SRS can absorb client's postponements, cancellations of orders
- One place to ship product
- SRS can serve the smallest orders (even 1 pack) regardless of supplier MOQ
- Launch of new product with uncertain/low demand

GDF Value Add – Launch Pad Approach to new Tool Introduction - Child-friendly formulations example

Launch Pad Approach:

- Identify early adopters, consolidate initial demand
- Source products (initial forecast, negotiate price/terms, production planning)
- Policy support for introduction
- Support procurement
- Monitor scale-up



GDF Value Add – Upstream Coordination, Harmonization, Prioritization

- Partner Coordination with TPMAT (donors, implementors, civil society, programmes)
- Global Fund
 - Supported GF to develop the ERP mechanism, ERP ad-hoc review for priority products
 - Add recommendations for TB products for each ERP Expression of Interest
- WHO PQ – ensure EOI is aligned with guidance, priorities
- WHO Model Essential Medicines List – ensure EML reflects guidance, priorities TB Medicines Dashboard – updated regularly



Ensures consistent messaging to suppliers on products to develop

Pediatric 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 to fight AIDS, TB & Malaria. Stop TB Partnership/Global Drug Facility licensed the TB Medicines Dashboard under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License.

Medicines	WHO Guidelines (DR-TB '19)	WHO Guidelines (DR-TB '20)	EMLc submitted	EMLc (2021)	WHO PQ EOI (2021)	WHO PQ Dossier Under Review	WHO PQ listed	Global Fund List of Pharmaceutical Products	Global Fund ERP EOI (Sep 2021)	Global Fund ERP approved	GDF Catalog	Status
Bedaquiline 20mg tablet	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
Bedaquiline 100mg tablet	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
Clofazimine 50mg tablet/capsule	Yes	Yes	Yes	Yes	Yes	Ineligible	Yes	Yes	Yes	No	Yes	No
Cycloserine 125mg capsule	Yes	Yes	Yes	Yes	Yes	Ineligible	Yes	Yes	Yes	No	Yes	No
Delamanid 25mg dispersible tablet	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes	No

DR-TB: Drug-Resistant TB
EMLc: Essential Medicines List
EOI: Expression of Interest
ERP: Expert Review Panel
SRA: Stringent Regulatory Authority
WHO PQ: World Health Organization Prequalification of Medicines Programme

Updated version October 2021

Stop TB Partnership GLOBAL DRUG FACILITY | World Health Organization | The Global Fund To Fight AIDS, Tuberculosis and Malaria

GDF Key Priorities in 2022

- Continue to coordinate upstream harmonization and prioritization in preparation for new WHO Guidelines and Rapid Communications
- Continue to support countries to prepare and implement PSM transition plans for new medicines and regimens as WHO Guidelines and Rapid Communications are released
- Product Priorities are communicated on TPMAT website, WHO PQ EOI and GF ERP EOI and include:
 - Paediatric 3-FDC for treatment of TB (rifampicin/isoniazid/pyrazinamide 75/50/150mg dispersible tablet)
 - Rifapentine formulations for TB Preventative Treatment (1HP and 3HP) and treatment of TB (300mg rifapentine) for adults and children (150mg rifapentine dispersible tablet)
 - Key medicines for drug resistant TB that are single source (bedaquiline, delamanid, cycloserine 125mg)
- Other product priorities GDF is monitoring
 - Point of care or near point of care nucleic acid detection tests for TB and resistance
 - Imaging technologies and artificial intelligence/computer-aided detection of TB software

Key Messages

- GDF is an integrated pooled procurement mechanism that has the tools and resources to manage the entire TB product lifecycle from end-to-end
- GDF's value add includes its ability to have clear coordinated messaging on product priorities, ability to catalyse introduction of new tools, and the tools to support new product introduction and avoid stockouts
- GDF continues to expand its product catalog to align with WHO recommendations on prevention, diagnosis and treatment of TB
- GDF is able to serve all countries (in alignment with national laws and regulations)
- GDF ensures priority products are clearly communicated across different channels and is transparent on how to become a supplier and publicly posting all procurement notices

How to Become a GDF Supplier

GDF encourages new suppliers of TB products to enter the market. Full eligibility criteria are available here: <https://www.stoptb.org/global-drug-facility-gdf/suppliers> . In summary, a supplier must:

- Manufacture or supply a TB product that supports ending TB
- Meet GDF's Quality Assurance criteria

GDF posts all procurement notices at the following links:

- TB Medicines: <https://www.stoptb.org/suppliers/procurement-notices>
- TB Diagnostics, medical devices and other health products:
<https://www.ungm.org/Public/Notice?agencyEnglishAbbreviation=UNOPS>

Thank You!

Acknowledgment:

Thanks to GDF staff who contributed directly or indirectly to this presentation



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