

Global Drug Facility (GDF) 2020 updates

Magali BABALEY

Strategic Procurement and Business Intelligence (SPBI) Manager

Stop TB Partnership, Global Drug Facility (GDF) team

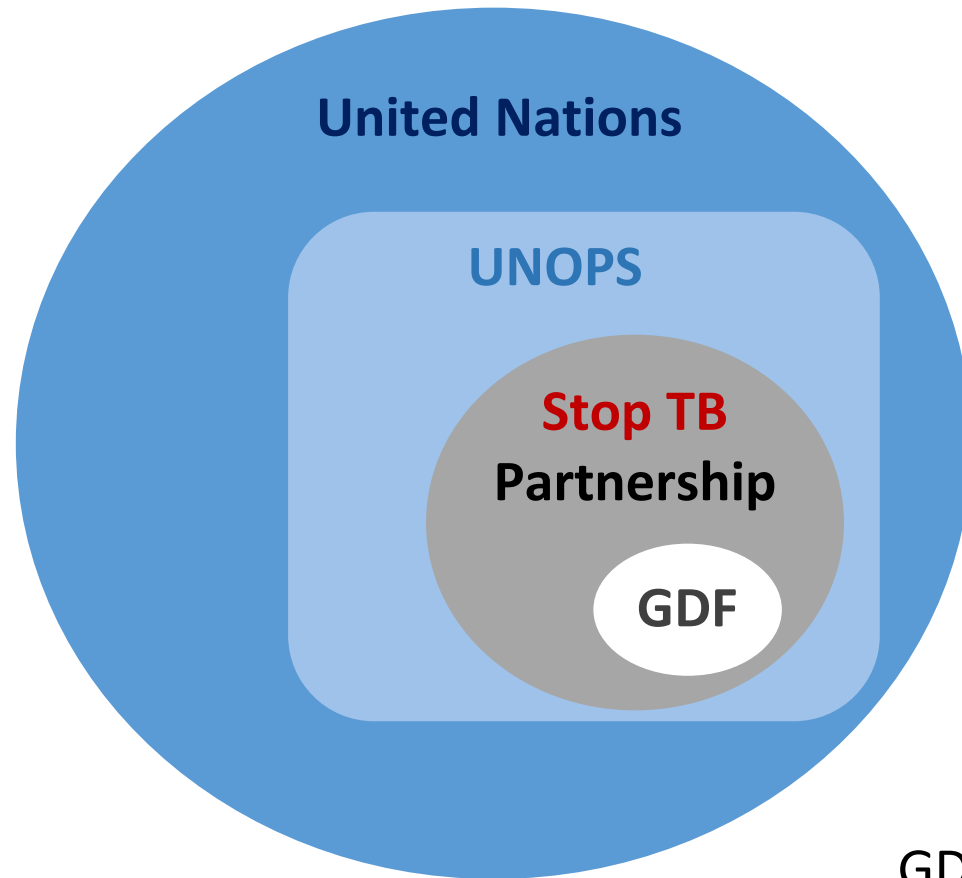
Joint UNICEF-UNFPA-WHO meeting, 2 December 2020, Virtual meeting

Session overview

1. Who is StopTB/GDF?
2. GDF 2020 key highlights amid Covid-19
3. GDF key messages to suppliers

1. Who is StopTB/GDF ?

Stop TB Partnership and its Global Drug Facility (GDF)



- GDF was established in 2001
- Part of the United Nations
- Within the Stop TB Partnership which is hosted by United Nations Office for Project Services (UNOPS)
- Largely funded by USAID
- GDF is ISO9001:2015 certified



GDF is an **Integrated Pooled Procurement mechanism** that facilitates access to quality-assured TB products with sustainable affordable prices to countries

<http://www.stoptb.org/gdf/>

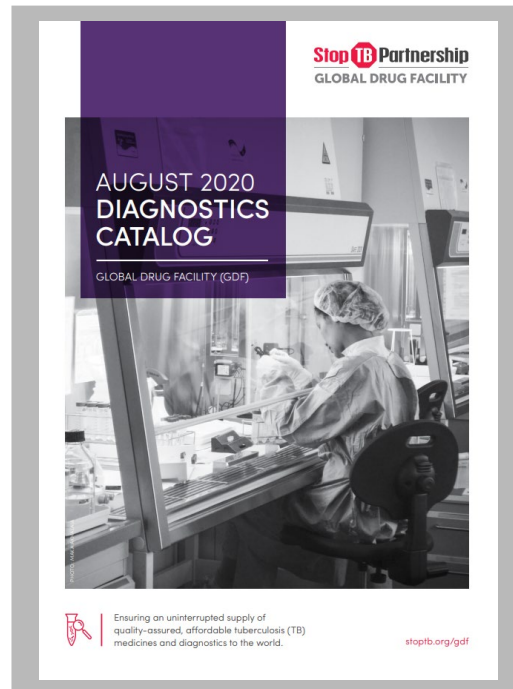
GDF portfolio

GDF Catalogs

TB Medicines Catalog



TB Diagnostics Catalog



GDF Technical Information Notes

provide guidance to countries on how to plan orders as well as links to key resources

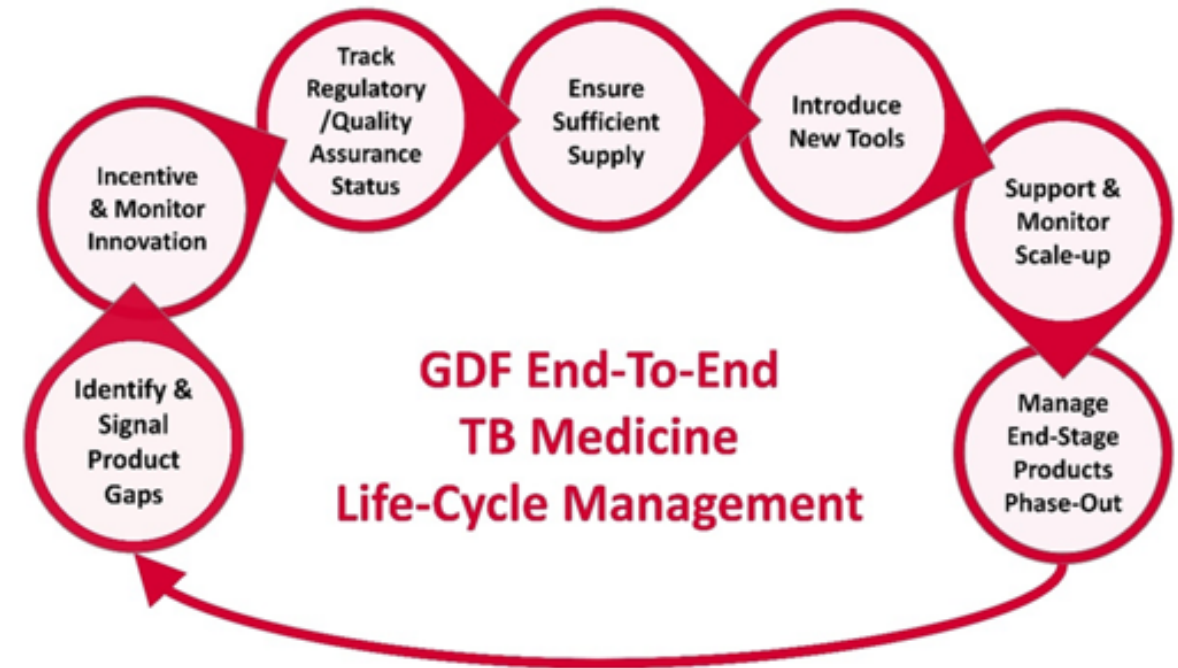


http://stoptb.org/gdf/drugsupply/product_catalog.asp

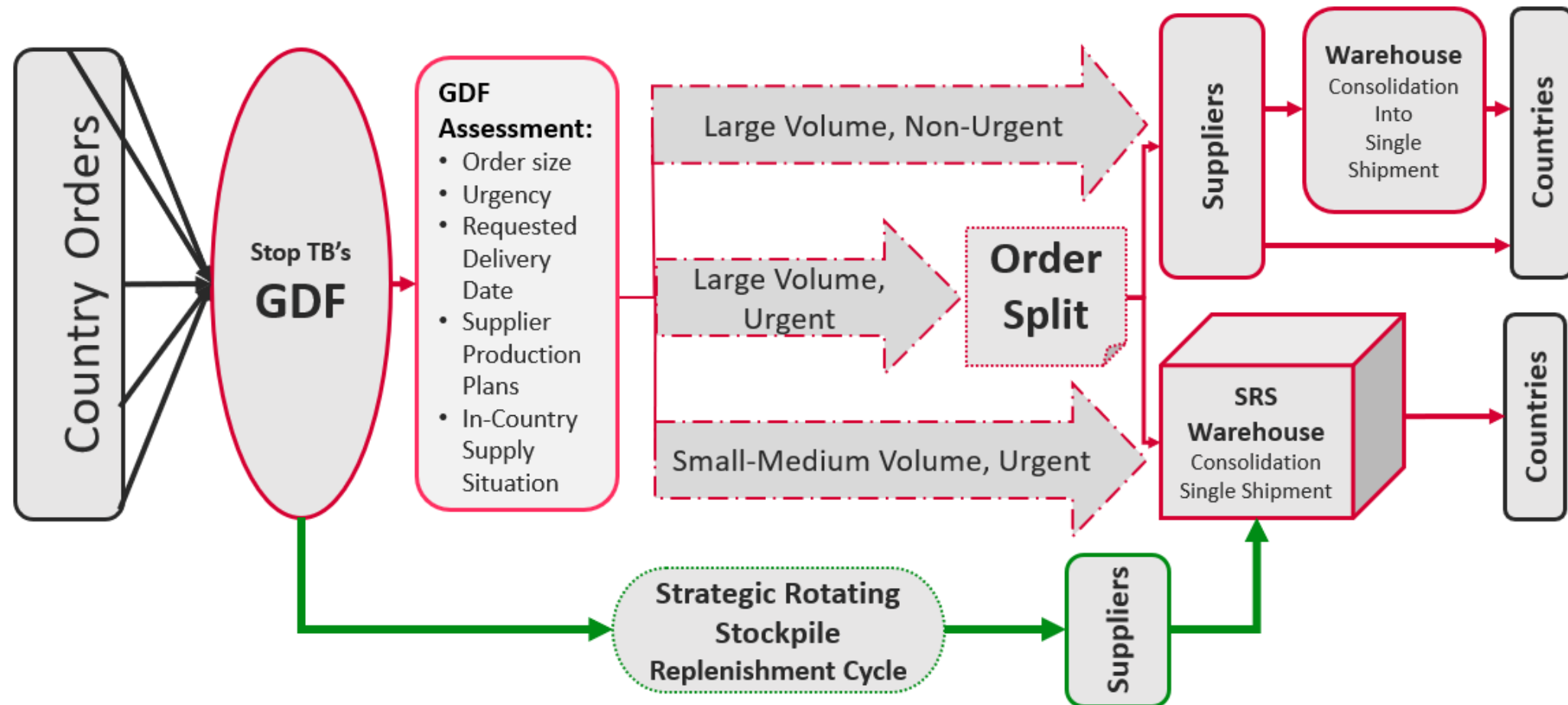
GDF Operational Model: Integrated Pooled Procurement mechanism

End-to-End oversight by GDF of the supply chain of TB products

- ❑ GDF informs suppliers about TB products needed to guide supplier investment strategy
- ❑ GDF provides incentives to suppliers via its procurement strategy to support supplier interests and encourage new suppliers to enter in the TB market
- ❑ GDF has a Strategic Rotating Stockpile (SRS) which helps improve supply planning and reduce costs for suppliers
- ❑ GDF facilitates country introduction of new TB products developed thanks to the introduction in GDF catalog, the provision of Technical Assistance to countries for uptake and the provision of Grants



GDF, a unique logistic model to better serve its clients



GDF's SRS is a physical inventory of TB medicines owned by GDF and stored at the warehouse of IDA Foundation, GDF's contracted procurement agent.

2. GDF 2020 key highlights amid Covid-19

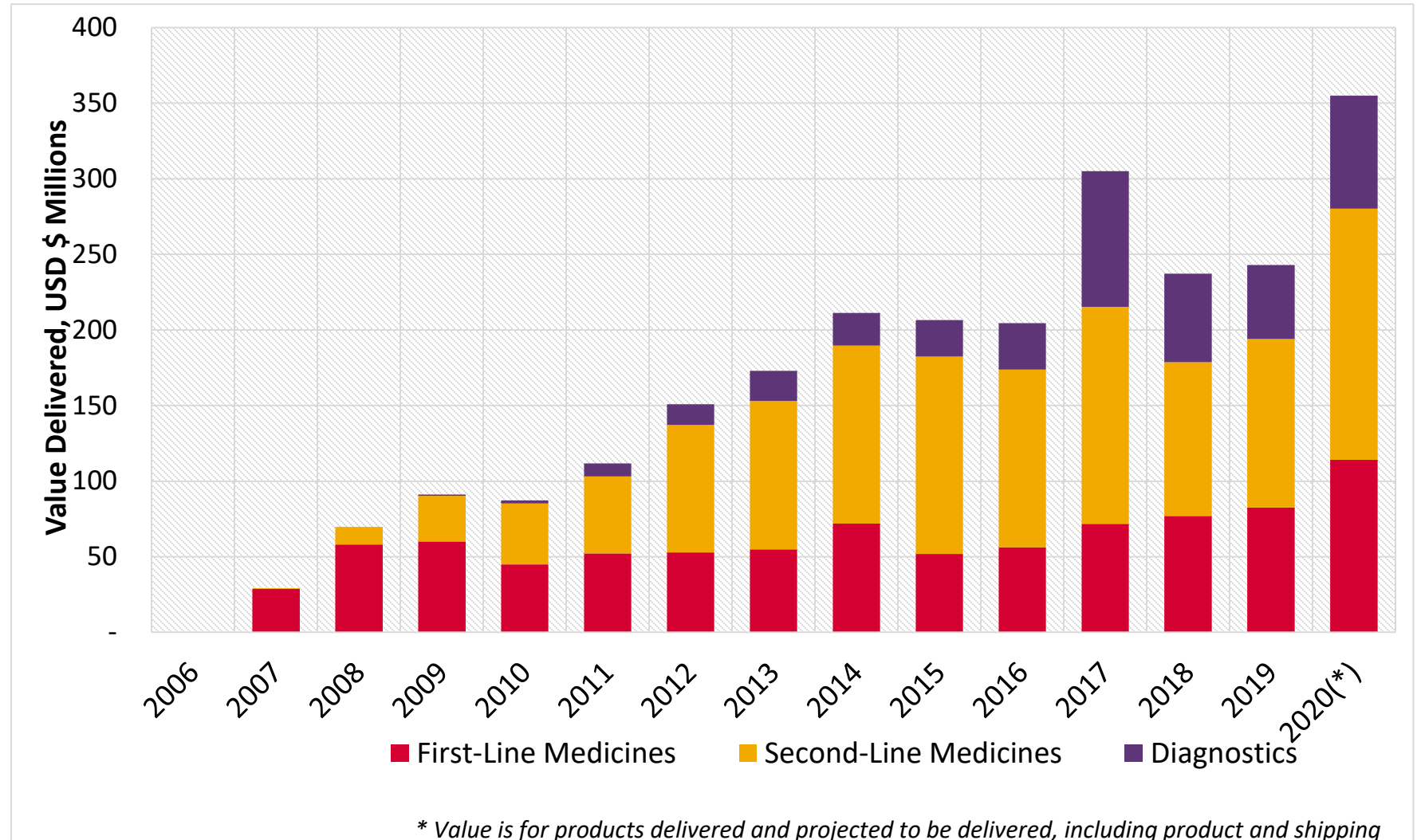
New GDF Record in 2020: US\$ 355 Million TB Products delivered to 142 Countries amid Covid-19

GDF on track to deliver:

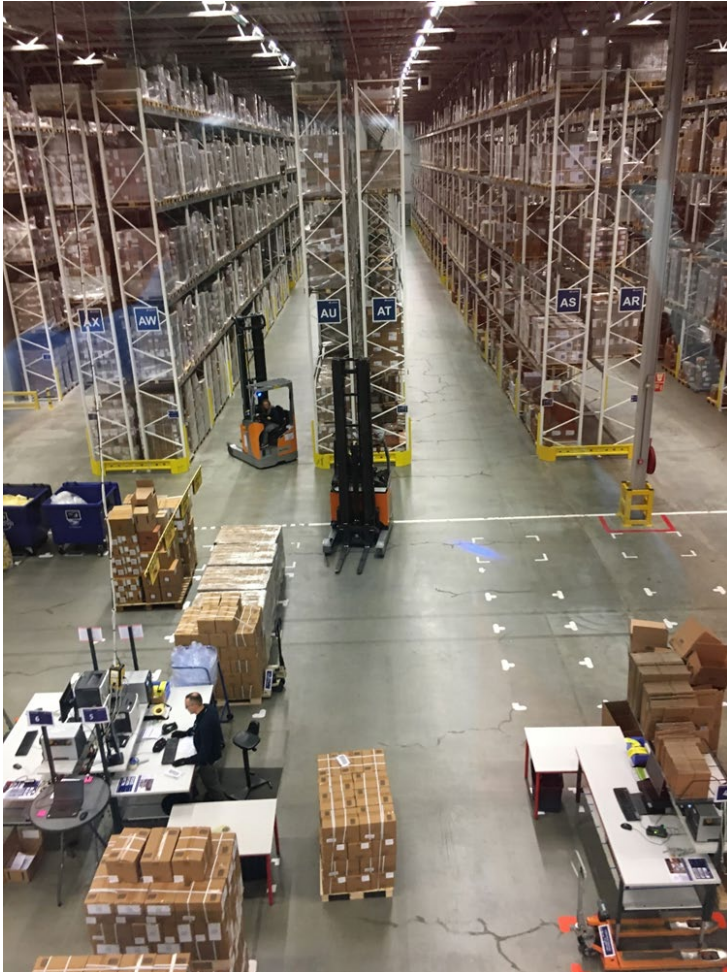
- US\$ 280 million worth of medicines
- US\$ 75 million worth of diagnostics
- 46% increase compared to 2019

Clients include:

- 86 Global Fund Principal Recipients in countries
- 65 countries supported by other funding sources
- **54 countries procuring with domestic funds**
- +20 clinical trials



Strategic Rotating Stockpile (SRS): Optimized for further stockout protection



Orders served by the SRS can typically be delivered in **less than three months**, compared to orders served using traditional procurement mechanisms which are typically delivered in six months.

Owning a physical medicine inventory allows GDF to continue to **respond to emergencies** even when – as has been the case under COVID-19 lockdown measures – suppliers are no longer able to manufacture medicines at full capacity.

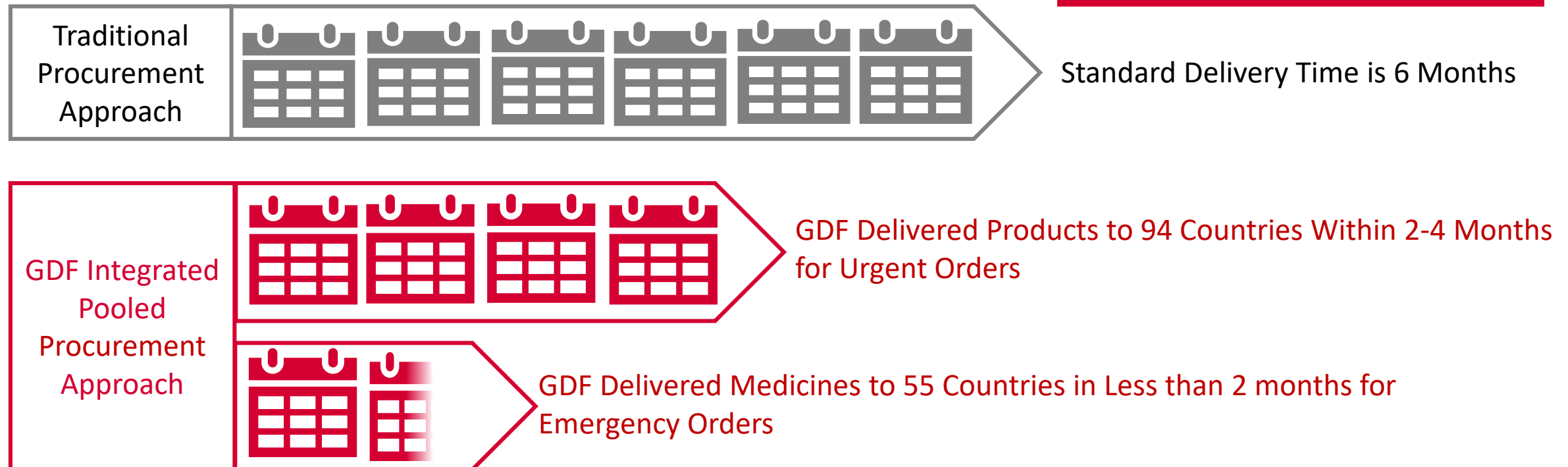
In 2020, GDF has started to add **First-Line medicines** in SRS (for Drug-Sensitive TB patients) and additional **safety stock** for **Second-Line medicines** (for Resistant-Drug TB patients)

GDF Approach Minimizes Risks of Diagnostics and Treatment Interruptions even under supply chain constraints



GDF Averted 102 Potential
TB-product Stockouts in 2020

Thanks also to a strong GDF
partnership with its
procurement agent/suppliers
and its clients



*Data covers Jan-Sep 2020 period

3. GDF key messages to suppliers

GDF need additional suppliers and formulation for TB medicines

GDF is looking for additional suppliers or new formulations for the products below

Product Type	INN/strength/form
Adult SLDs	Bedaquiline* 100mg tablet
	Delamanid* 50mg tablet
Adult LTBI	Rifapentine 300mg (1) scored tablet
	Rifampicine 300mg scored tablet
Pediatric LTBI	Rifapentine 150mg Dispersible tablet
Pediatric SLDs	Cycloserine 125mg capsule
Others	Pyridoxine 10mg tablet scored
	Pyridoxine 50mg tablet scored

For suppliers of Rifampicin-based products and interested to develop Rifapentine, GDF requests suppliers to ensure that production capacity of Rifampicin-based products will not be impacted

* IP = Intellectual property constraints; (1) These formulation are eligible for the Ad hoc Review Process:

Nitrosamine concerns for rifapentine and rifampicin

- ❑ On 26/08/2020, FDA announced that they became aware of nitrosamine impurities in certain samples of rifampicin (1-methyl-4-nitrosopiperazine - MeNP) and rifapentine (1-cyclopentyl-4-nitrosopiperazine - CPNP). FDA will not object to certain manufacturers temporarily distributing rifampin containing MeNP below 5 parts per million (ppm) and Rifapentine containing CPNP below 20 ppm (FDA update on 29/10/2020) until they can reduce or eliminate the impurity. .
- ❑ For WHO PQPed rifampicin and rifapentine products, WHO PQP/MED* requests manufactures to provide risk assessment reports for CPNP/MeNP impurities by the end of Dec 2020.

GDF urges manufacturers of Rifampicin and Rifapentine to complete the risk assessment ASAP for API/FPP and provide the results to regulators for immediate actions, to mitigate/avoid supply interruption of these TB products

**WHO PQP/MED: <https://extranet.who.int/pqweb/news/nitrosamine-concerns-rifapentine-and-rifampicin>*

GDF CDP* Portal: New GDF tool to communicate and exchange information with suppliers

- Web platform to ease and ensure quality, reliability and accuracy of data/information/documents shared between GDF and suppliers on TB medicines
- Pilot phase to start
- Suppliers will also be able to automatically submit their Technical Bids via this new tool during GDF tender process

* CDP: Central Data store and analysis Platform

Welcome to Global Drug Facility

How to become a StopTB/GDF suppliers for TB medicines or TB diagnostics and laboratory supplies ?

All information about eligibility criteria and GDF procurement are available at the following link <http://www.stoptb.org/gdf/becomeSupplier.asp>

Where to find StopTB/GDF procurement notices?

All StopTB GDF Procurement notices are available at the following link
http://www.stoptb.org/gdf/drugsupply/procurement_notice.asp
<https://www.ungm.org/Public/Notice?agencyEnglishAbbreviation=UNOPS>

Who to contact for further information?

For any further information re GDF procurement, please send an email to:

Magali Babaley, SPBI manager, magalib@stoptb.org

Kaspars Lunte, Global sourcing Officer, kasparsl@stoptb.org

Bibiana Angarita, Diagnostic procurement Officer, bibianaaz@stoptb.org

Nigor Muzafarova, Lead product quality Officer, nigorsultonm@stoptb.org

Thanks for your attention