Improving Access for Quality-Assured TB Medicines and Diagnostics

Update on GDF Activities, Challenges & Perspectives

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Stop TB Partnership Board Meeting - Paris

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Outline

1. Key milestones reached in 2014 & update on GDF successful transition to UNOPS.
2. Key highlights on GDF Market Shaping Activities.
3. Looking forward: what are the perspectives on TB commodities & upcoming GDF challenges?
4. Discussion / Q&A.

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GDF Strategic Objectives

1. **Save lives** by ensuring an uninterrupted supply of quality-assured, affordable anti-TB drugs and diagnostics to population in need

2. **Strengthen national drug supply management systems** and sustainable procurement capacity by providing tailored technical assistance, innovative tools to countries/organizations in need and enhance partners' engagement for technical and financial support

3. **Contribute to TB commodities market shaping** by linking strategic interventions on the demand and supply sides with stakeholders/partners, focusing on market analysis, supply security, suppliers engagement, affordable and sustainable prices, innovation and new products introduction/uptake by countries

4. **Maximize impact and value for money** by enhancing efficiency/effectiveness of operations focusing on quality of services and clients/partners feedback

Key GDF Milestones

133 countries benefited from GDF procurement / bundled mechanism with

- > 24 M Adult FLDs
- > 1,3 M pediatric treatments
- > 150,000 SLDs patient treatments

=> 26M treatments delivered since GDF inception in 2001

GDF's market shares in 2013 (for public sector) are:

25% **for FLDs** (all notified cases)

33% **for SLDs** (cases reported on treatment)

51% **for paediatrics** (all notified cases)

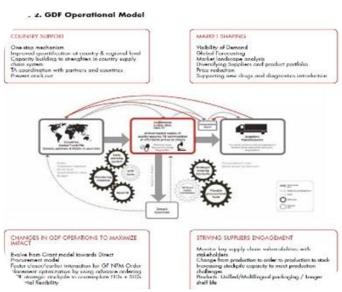
Savings Generated from Price Reduction in 2014

Year	Units	Products costs in 2011 prices, $	Products costs in 2014 prices, $	Savings, $
2014 YTD July	177,015,081	89,748,879	68,432,028	21,316,851

Key GDF Milestones since last Board Meeting

GDF successfully transitioned from WHO to UNOPS

without any commodity supply disruption to countries nor operations discontinuity for TA & market shaping



continuing its reorganization started in 2012 towards a more strategic model focused on:

- Evolving country needs
- Market dynamics
- Looking ahead at post 2015 TB Strategy & Challenges
- Value for money / cost efficiency

with a renewed team demonstrating a high level of technical expertise & commitment

Highlighting 10 key GDF achievements ensuring operations continuity under UNOPS rules & regulations as per Q1 2015 (1)

1. GDF results and strategic orientations discussed & reviewed with stakeholders during GDF Strategic Advisory Committee in September 2014
2. Within transitioning period, GDF launched 1 ITB for FLDs and 2 ITBs for SLDs with
   - 14 Long Term Agreements (LTA) for First Line Drugs (FLD) amended / signed
   - LTAs for Second Line Drug (SLD) amended + 26 LTA for SLD under signature
   - 2 LTAs for procurement agents amended
   - Tender for selecting a wholesaler for laboratory supply adjudicated & LTA signed
3. Contracts for procurement agents extended & transferred to UNOPS
4. New KPIs for monitoring the performance of suppliers and procurement agents
5. Amendment & transfers of all current country orders / on-going grants agreements

Highlighting 10 key GDF achievements ensuring operations continuity under UNOPS rules & regulations as per Q1 2015 (2)

6. Revision of internal template forms for Direct Procurement and Grant requests

7. Organization of Diagnostic Procurement transfer from GIZ to GDF (Internal procurement) following the end of contract with GIZ end of Q1 2015

8. Tender for pre-shipment inspection and quality control agents jointly launched and adjudicated with Global Fund

9. Positive recommendation for GDF 9001 ISO certification maintenance after new QS audit – GDF and UNOPS are 2 ISO certified organizations

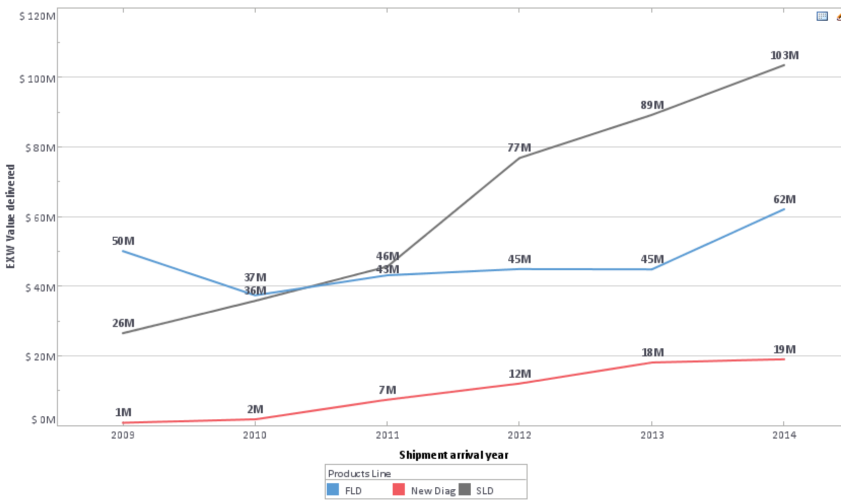
10. Development of a new pricing policy for SLDs Strategic Rotating Stockpile management - under revision

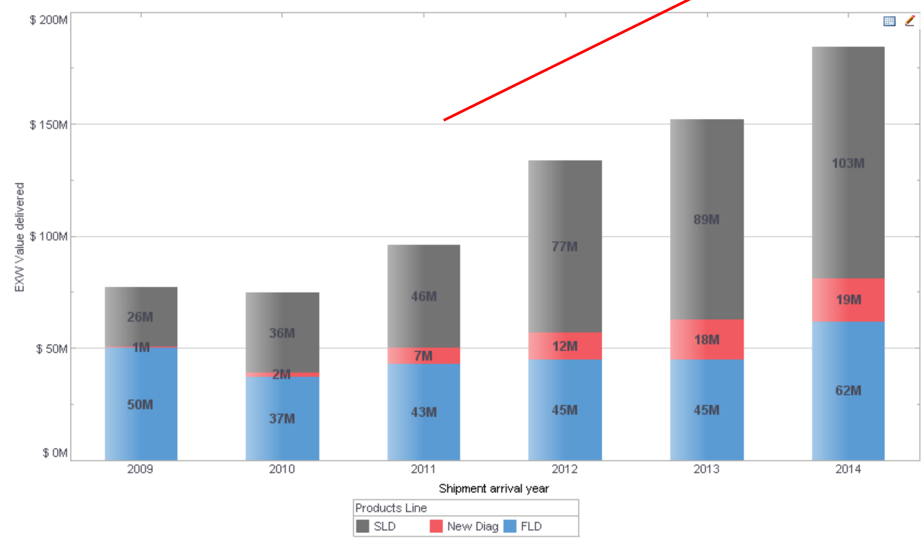
Update on GDF Technical Assistance Activities

- TA framework reformulation with new tools and enhanced information systems for more agile data sharing in line with country profiles development and harmonization of DM activities with other TA partners
  - QuanTB roll-out with MSH-SIAPS
  - Early Warning System
  - Workshop in Ethiopia for GDF consultants with partners (KNCV, UNION, MSH…)
  - Co-organization of the Global TB Conference with MSH/SIAPS in Bangkok for 15 high level country representatives (NTPs & PSM specialists) & partners
- 43 Monitoring Missions conducted in 2014 and 7 in Q1 2015
- Support to NFM of GF for concept notes development
- Collaboration with Usaid funded PQM program on market shaping
- Operational support for the launch of USAID / Janssen donation on Bedaquiline donation set up & functional as per 1st of April 2015

Orders Delivered in USD all fees incl. per Line / Year

GDF volume in 2014 has nearly doubled compared to 2011





Order Delivered Value EXW per Line per Year							
Products Line	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**Grand Total**
FLD	$ 50,025,019	$ 37,341,647	$ 43,090,679	$ 44,883,113	$ 44,795,042	$ 62,063,168	$ 282,198,668
New Diag	$ 740,627	$ 1,725,567	$ 7,367,615	$ 12,000,174	$ 18,042,117	$ 18,983,468	$ 58,859,568
SLD	$ 26,464,891	$ 35,755,281	$ 45,587,507	$ 76,771,954	$ 89,171,855	$ 103,452,841	$ 377,204,328
Grand Total	$ 77,230,537	$ 74,822,494	$ 96,045,802	$ 133,655,241	$ 152,009,013	$ 184,499,476	$ 718,262,564

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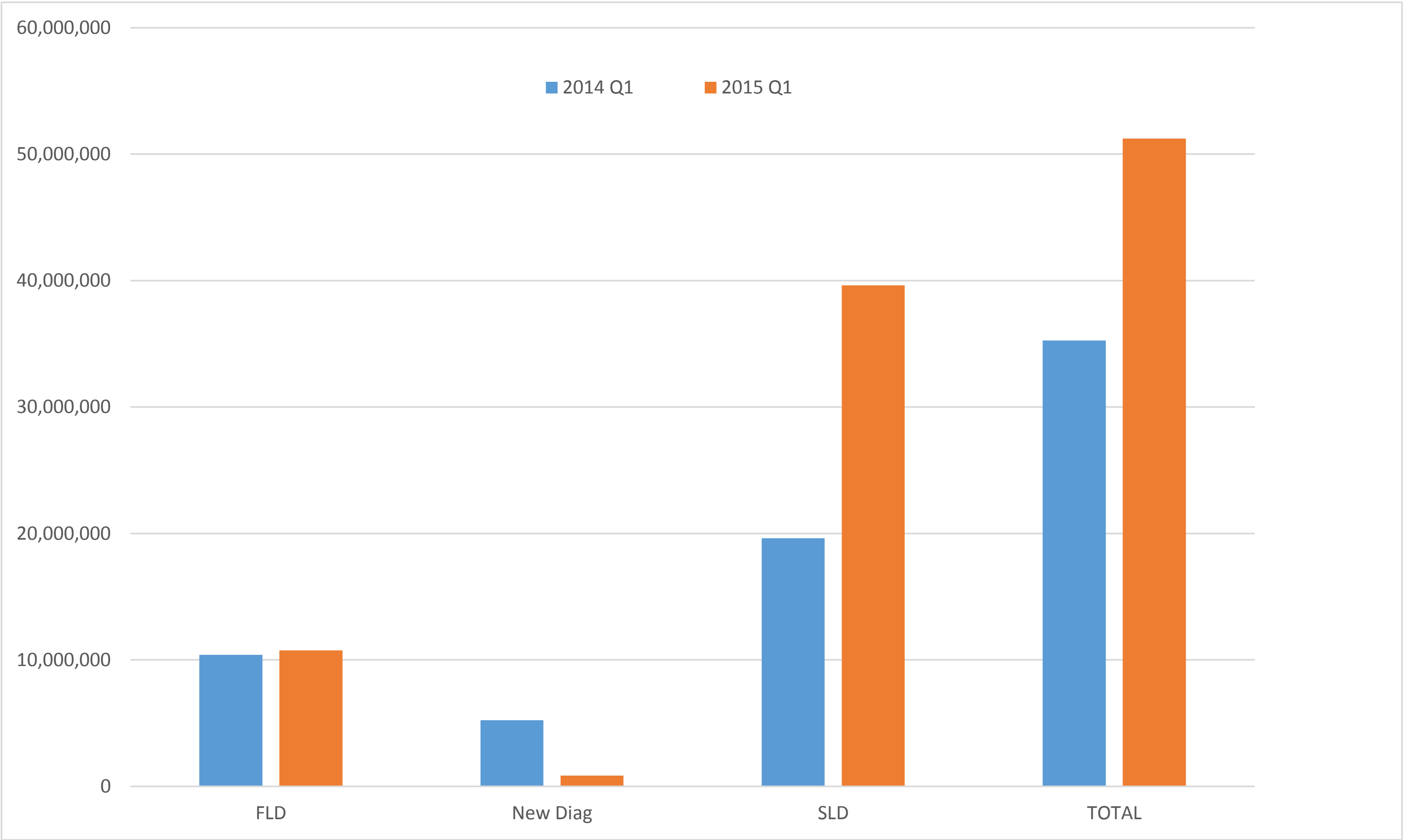
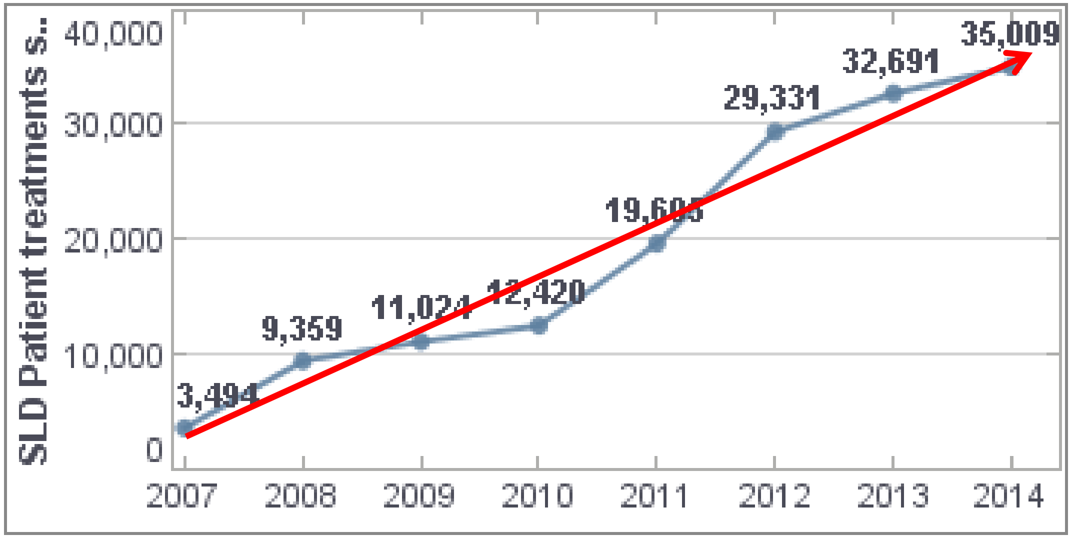
Comparing Q1 2014 / 2015
Orders Placed in USD, All Fees included



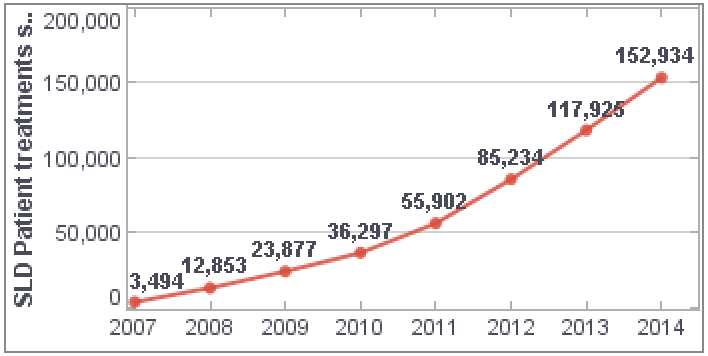
MDR Treatments delivered

6 months IP until 2012, 8 months thereafter

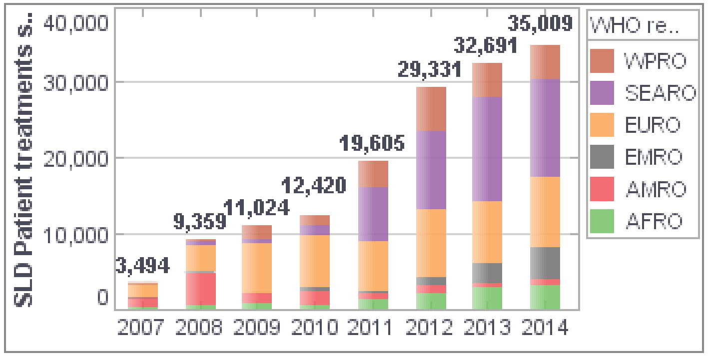
SLD Patient treatments supplied by year



SLD cumulative Patient treatments supplied per year



SLD Patient treatments supplied per year by regions



Live Report 20.02.2015

https://extranet.who.int/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/MDR+Patient+treatments+supplied+-+method+Injectable+standard+180-240dose+Rev+3.0&userid=GDF_ro&password=gdfread1

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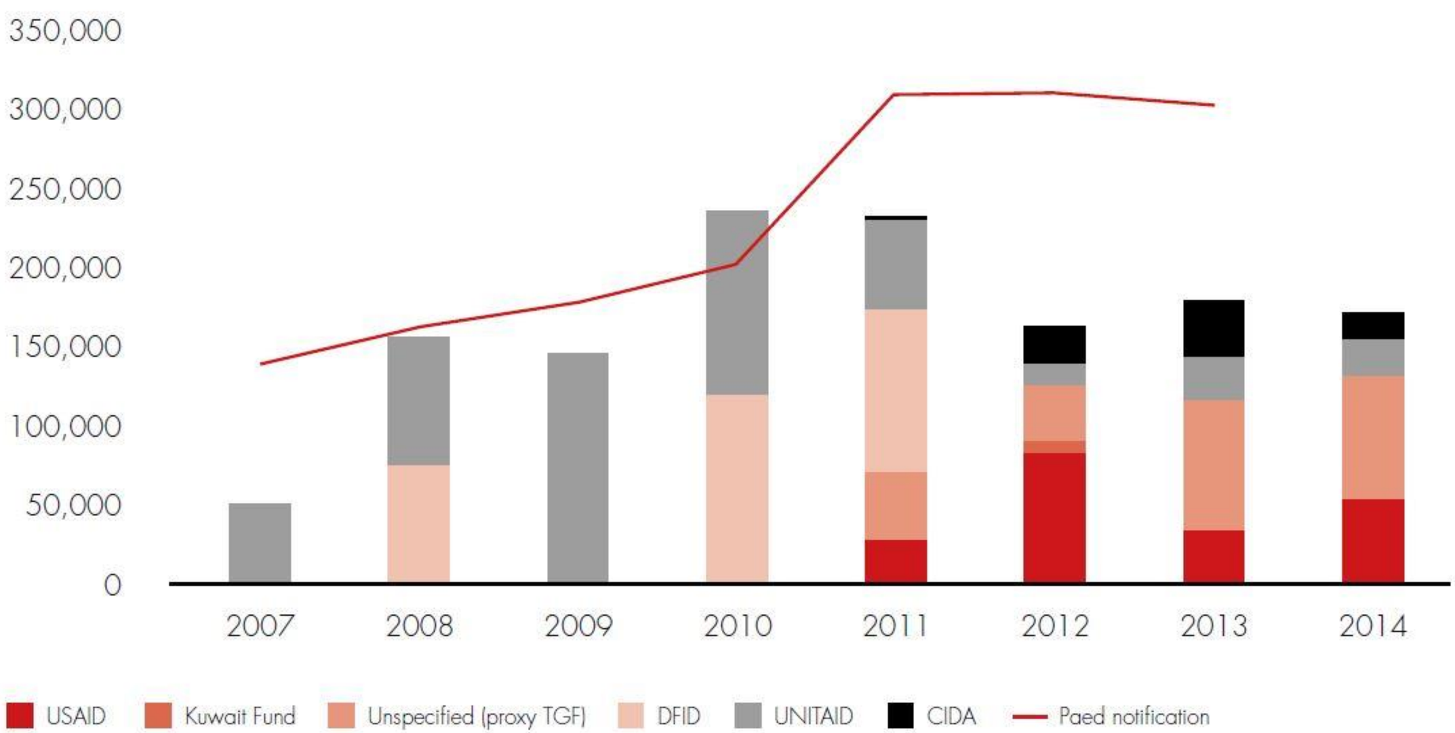
Total Pediatric Treatments supplied by Donor 2007-2014

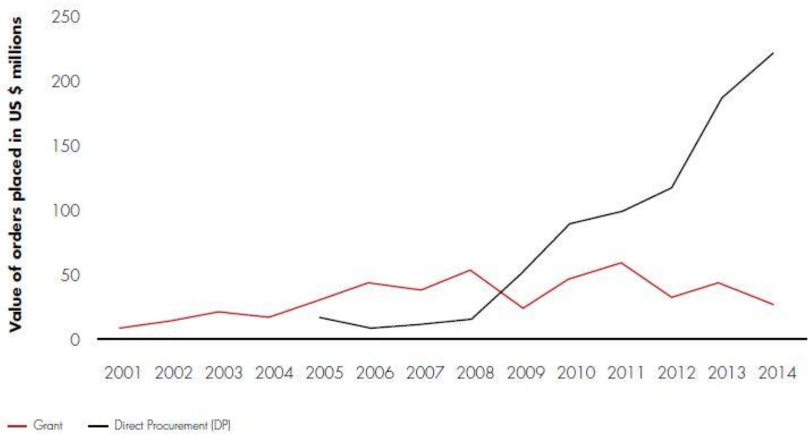
Figure 8. Paediatric patient treatments delivered by GDF versus global paediatric notification



GDF evolving operational model at light of TB commodity landscape changes

- **Monitoring TB markets dynamics and trends to better serve countries**
  – Countries using GDF mechanism shifted from grants to direct procurement over last years
  – MICs are graduating from donor financing and using domestic funding
  – New medicines and diagnostic tools are being introduced

Figure 4. GDF Procurement Services



Cost Product ExWorks USD	Order Date Placed With Suppliers Year				Grand Total
Country Name	2011	2012	2013	2014	
India	$18'891'739	$ 6'458'040	$ 19'899'407	$ 78'124'882	$123'374'068
Pakistan	$ 1'071'763	$ 7'974'640	$ 13'278'435	$ 14'713'271	$ 37'038'110
China	$10'520'827	$ 5'186'861	$ 16'046'172		$ 31'753'860
Uzbekistan	$ 7'275'306	$ 7'202'594	$ 11'986'384	$ 4'718'686	$ 31'182'970
Kazakhstan	$ 3'748'514	$ 8'232'158	$ 4'893'836	$ 1'068'503	$ 17'943'011
Ukraine	$ 835	$ 2'586'668	$ 2'741'584	$ 11'927'365	$ 17'256'453
Myanmar	$ 694'828	$ 1'715'643	$ 3'840'922	$ 10'378'707	$ 16'630'099
Philippines	$ 9'575'637	$ 154'049	$ 4'847'851	$ 1'622'565	$ 16'200'102
Tajikistan	$ 3'296'652		$ 5'453'389	$ 4'527'759	$ 13'277'800
Kyrgyzstan	$ 1'893'641	$ 3'068'678	$ 4'179'233	$ 3'481'647	$ 12'623'199

=> Implies changing GDF operational model with key new tools

- Enhanced Strategic Rotating Stockpile in value (2x) and composition
- New stockpile policies
- Flexible Procurement Fund to guarantee orders & allow countries to use GDF according to public accounting rules (no advanced payment)
- Support & provide renewd TA to countries on key challenges like forecasting aligning new tools (QuanTB or drug management systems) with partners
- New Information Platforms
- Monitoring Global Demand Trends

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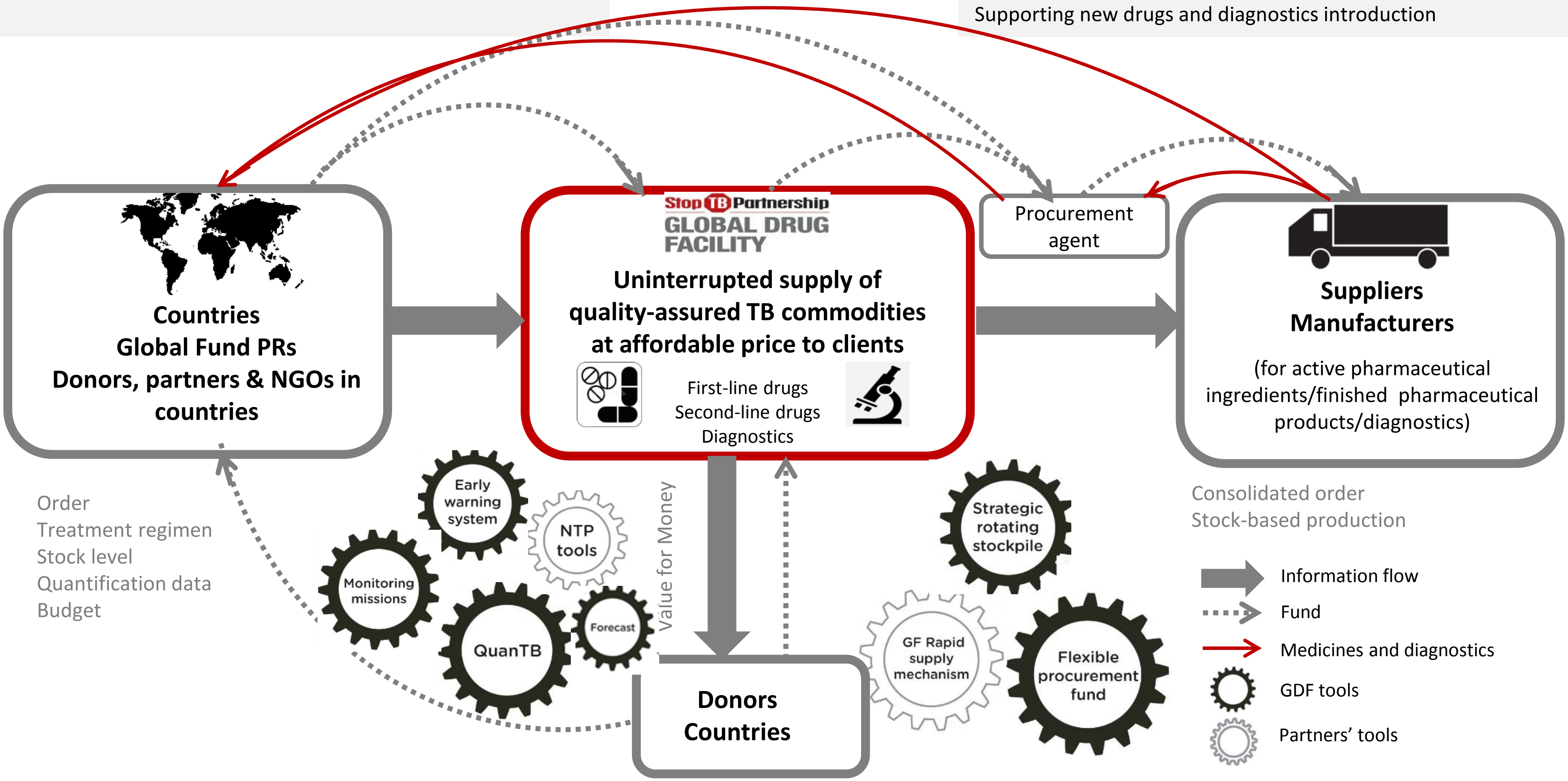
Country Support

One-stop mechanism
Improved quantification at country & regional level
Capacity building to strengthen in-country supply chain system
TA coordination with partners and countries
Prevent stock out

Market Shaping

Visibility of Demand
Global Forecasting
Market landscape analysis
Diversifying Suppliers and product portfolio
Price reduction
Supporting new drugs and diagnostics introduction



Changes in GDF operations to maximize impact

Evolve from Grant model toward Direct Procurement model
Foster closer/earlier interaction for GF NFM Order placement optimization by using advance ordering
GDF strategic stockpile to contemplate FLDs + SLDs
Financial flexibility

Striving suppliers engagement

Monitor key supply chain vulnerabilities with stakeholders
Change from *production to order* to *production to stock*
Increasing stockpile capacity to meet production challenges
Products: Unified multilingual packaging/ longer shelf life

Highlighting GDF Market Shaping Activities towards increased supply security and MDR-TB costs decreases

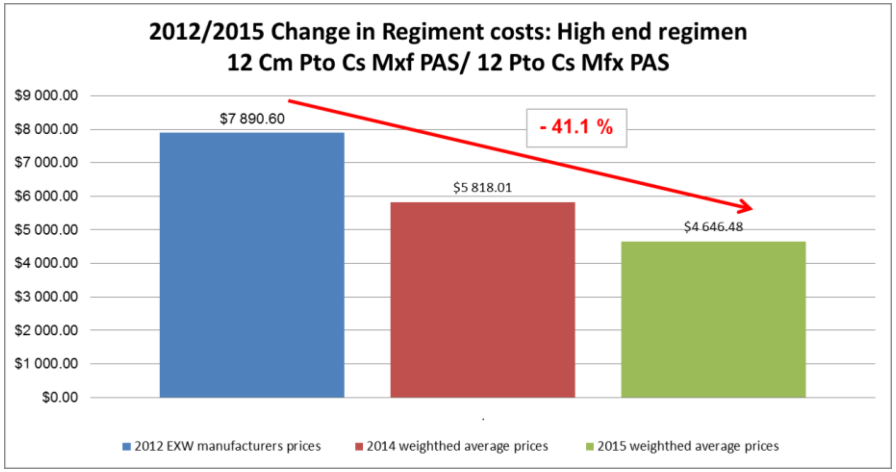
- Increased SLDs supply security (26 products – 12 suppliers => more than x 2 since 2011)
- Significant price reductions achieved => more than 21 M USD savings in 2014 on SLDs
- Reductions in lead times with SLDs Strategic Rotating Stockpile
- Decreased stock-outs with a risk management approach for sensitive products (Km/Cfx)
- Supporting market entry of new manufacturers for both active principle ingredients and finished pharmaceutical products

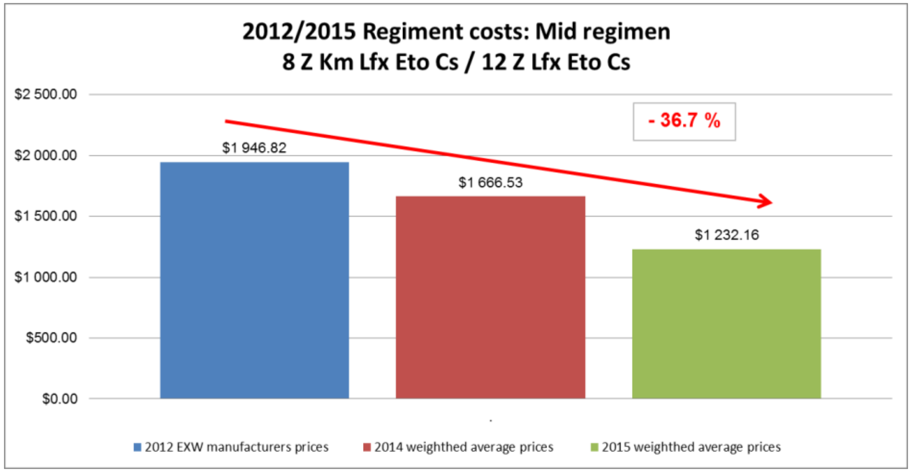
Cycloserine Example:

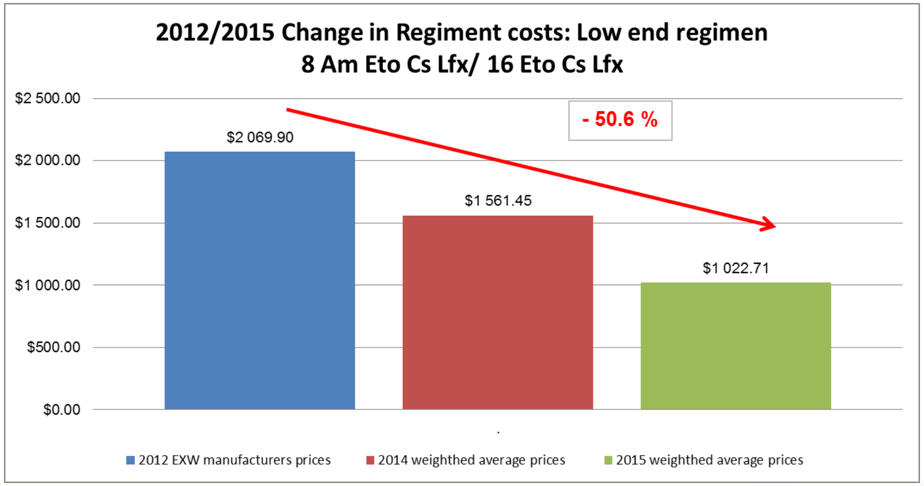
	Price, USD	vs 2010 (%)
Median Price 2010	**0.599**	0%
Median Price 2014	**0.42**	**-30%**
2015 ITB (India)	**0.26**	**-57%**
2015 ITB (ROW)	**0.20**	**-67%**

- More sustainable supply of Cs API: there are 3 API manufacturers (Dong A, Shasun and Macleods), with Enzychem of South Korea expected to file API PQ around June 2015
- GDF dramatically reduced the price of Cycloserine capsule, **by -66.6%,** since last 5 years through regular ITBs fostering market competition

GDF price reductions: regimen examples







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Value for money: Savings on MDR-TB Treatments (1)

- GDF 2015 price reductions could provide savings of **7 million USD per 10.000 patient treatments** if compared with 2013 (based on mid range treatment regimen)

Regimens cost, USD	2013	2014	2015
High	7891	5818	4645
Mid	1947	1667	1232
Low	2070	1561	1023

Savings per Regimen, USD	2014 vs 2013	2015 vs 2014	2015 vs 2013
High	-2073	-1173	-3245
Mid	-280	-434	-715
Low	-508	-539	-1047

Savings per 10.000 treatments, USD	2014 vs 2013	2015 vs 2014	2015 vs 2013
High	-20 725 900	-11 725 300	-32 451 200
Mid	-2 802 900	-4 343 700	**-7 146 600**
Low	-5 084 500	-5 387 400	-10 471 900

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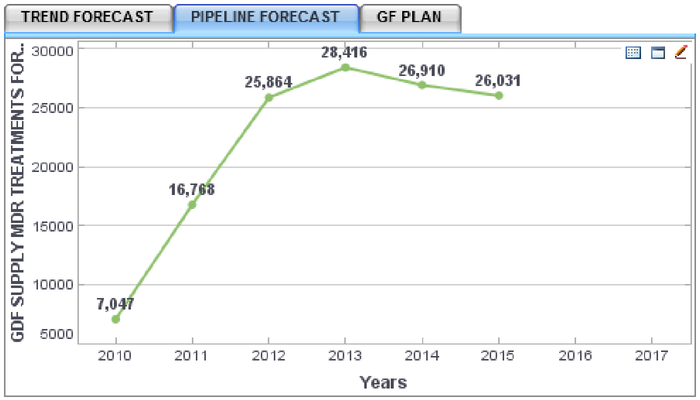
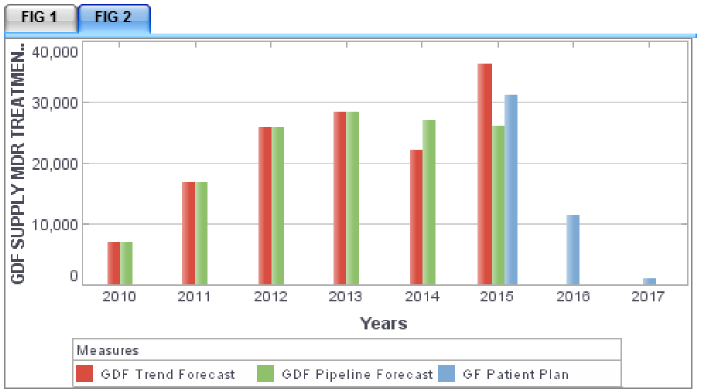
Impact of GDF savings on MDR-TB Treatments (2)

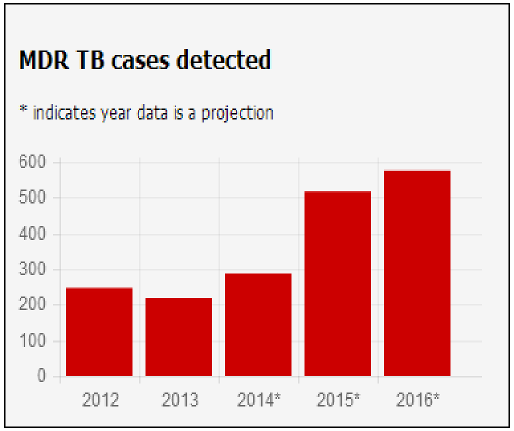
H/M/L regimen costs definition:	
	USD
High costs	3501-6000
Medium costs	2001-3500
Low costs	1400-2000

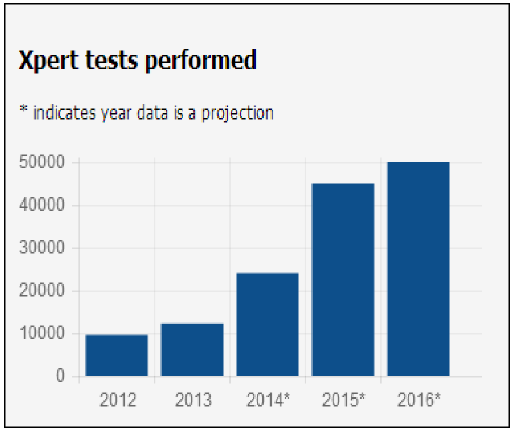
Country	*Main regimen/s*	*Costs 2012*	*Costs 2013*	*Costs 2014*	*Costs 2015*	*% change 15/14*	*Trend*
Azerbaijan	12 Z-Ami-Lfx-Eto-Cs-PAS / 12 Z-Lfx-Eto-Cs-PAS	4 541	4 195	3 746	3 456	-8%	
Bangladesh	8 Z-Km-Lfx-Eto-Cs / 16 Z-Lfx-Eto-Cs	2 221	2 085	1 880	1 360	-28%	
Belarus	8 Cm-Lfx-Eto-PAS-Cs-Z/12 Lfx-Eto-PAS-Cs-Z	4 519	4 432	3 839	3 423	-11%	
	8 Cm-Mfx-Eto-PAS-Cs-Z-AmxClv/12 Mfx-Eto-PAS-Cs-Z-AmxClv	5 835	5 306	4 347	3 818	-12%	
Ethiopia	8 Z-Cm-Lfx-Pto-Cs / 12 Z-Lfx-Pto-Cs	2 849	2 860	2 360	1 666	-29%	
Georgia	12 Z-Km-Lfx-Pto-Cs-PAS / 12 Z-Lfx-Pto-Cs-PAS	4 805	4 578	4 255	3 920	-8%	
	12 Z-Cm-Lfx-Pto-Cs-PAS / 12 Z-Lfx-Pto-Cs-PAS	5 977	5 920	5 109	4 475	-12%	
India	6 Km-Lfx-Eto-Cs-Z-E/18 Lfx-Eto-Cs-E	2 319	1 804	1 829	1 460	-20%	
	9 Km-Lfx-Eto-Cs-Z-E/18 Lfx-Eto-Cs-E	2 777	2 198	2 231	1 810	-19%	
Indonesia	6 Km-Lfx-Eto-Cs-Z-(E) / 12 Lfx-Eto-Cs-Z-(E)	1 737	1 629	1 482	1 085	-27%	
Kazakhstan	12 Z-Cm-Pto-Cs-PAS-Lfx/12 Z-Pto-Cs-PAS-Lfx	5 977	5 920	5 109	4 475	-12%	
	12 Z-Am-Pto-Cs-PAS-Lfx/12 Z-Pto-Cs-PAS-Lfx	4 682	4 348	3 892	3 528	-9%	
Kenya	8 Km-Pto-Lfx-Cs-Z/12 Pto-Lfx-Cs-Z	2 074	1 973	1 799	1 304	-28%	
	8 Cm-Pto-Lfx-Cs-Z/12 Pto-Lfx-Cs-Z	2 849	2 860	2 360	1 666	-29%	
Kyrgyzstan	8 Cm-Lfx-Cs-Pto-Z-PAS / 16 Lfx-Cs-Pto-Z-PAS	5 288	5 173	4 515	3 983	-12%	
Moldova	8 Cm-Eto-Lfx-Cs-Z-E/16 Eto-Lfx-Cs-Z-E	3 097	2 890	2 545	1 788	-30%	
Mongolia	9 Z-Km-Lfx-Eto-Cs/15 Lfx-Eto-Cs-Z	2 296	2 160	1 957	1 598	-18%	
Myanmar	6 Am-Lfx-Eto-Cs-Z/14 Lfx-Eto-Cs-Z	1 739	1 573	1 333	886	-34%	
	6 Am-Lfx-Eto-Cs-PAS-Z/14 Lfx-Eto-Cs-PAS-Z	3 527	3 273	2 933	2 703	-8%	
Pakistan	8 Am-Lfx-Eto-Cs-Z-PAS/16 Lfx-Eto-Cs-Z-PAS	4 284	3 972	3 557	3 279	-8%	
Philippines	6 Km-Lfx-Pto-Cs-Z/12 Lfx-Pto-Cs-Z	1 771	1 679	1 519	1 074	-29%	
Tajikistan	11Cm-Lfx-Pto-Cs-Z-PAS/13Lfx-Pto-Cs-Z-PAS	5 805	5 733	4 960	4 352	-12%	
Ukraine	8 Z-Km-Lfx-Eto-Cs/12Z-Lfx-Eto-Cs	1 950	1 838	1 670	1 236	-26%	
	8 Z-Km-Lfx-Eto-Cs-PAS/12 Z-Lfx-Eto-PAS-Cs	3 738	3 538	3 270	3 053	-7%	
Uzbekistan	8 Z-E-Cm-Lfx-Pto-Cs/14 E-Z-Lfx-Pto-Cs	3 083	3 075	2 566	1 814	-29%	
VietNam	8 Km-Lfx-Pto-Cs-Z-E/14 Lfx-Pto-Cs-Z-E	2 302	2 181	1 997	1 443	-28%	

GDF Market Shaping Activities: Towards improved Forecast Monitoring Country Level









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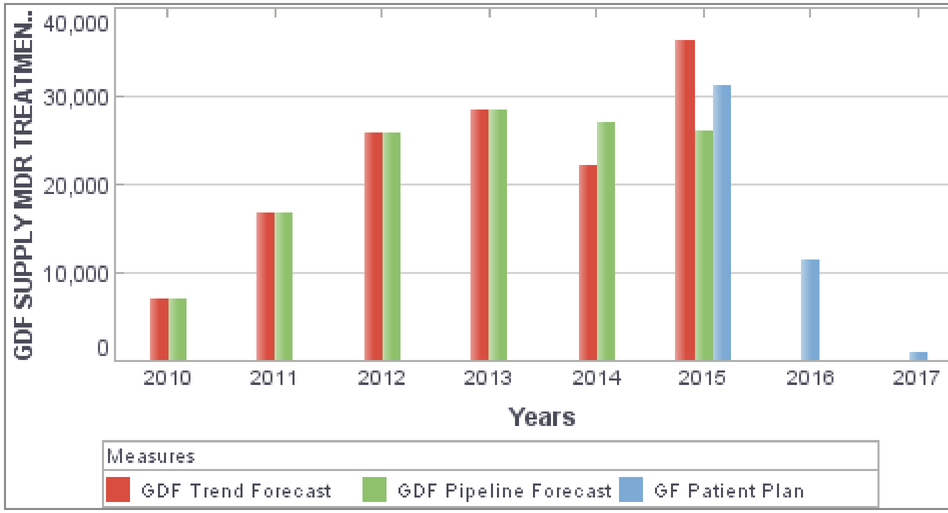
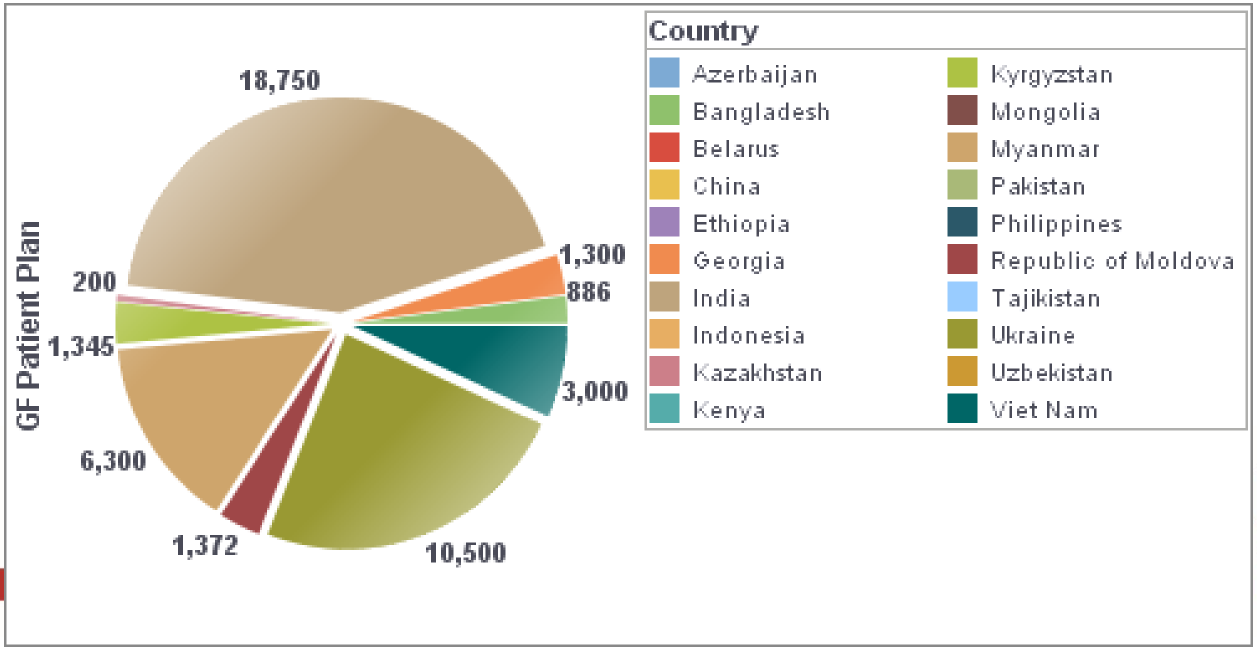
GDF Market Shaping Activities: Towards improved forecast monitoring Aggregating Countries supplies for a Global View





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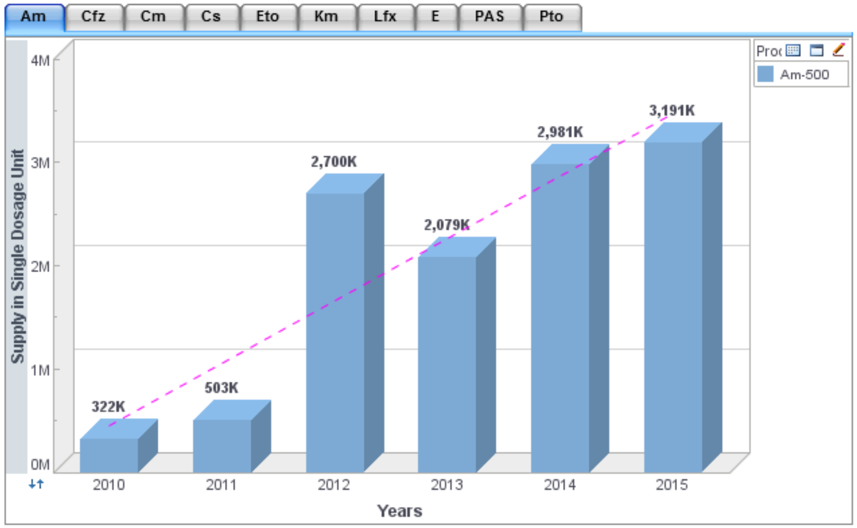
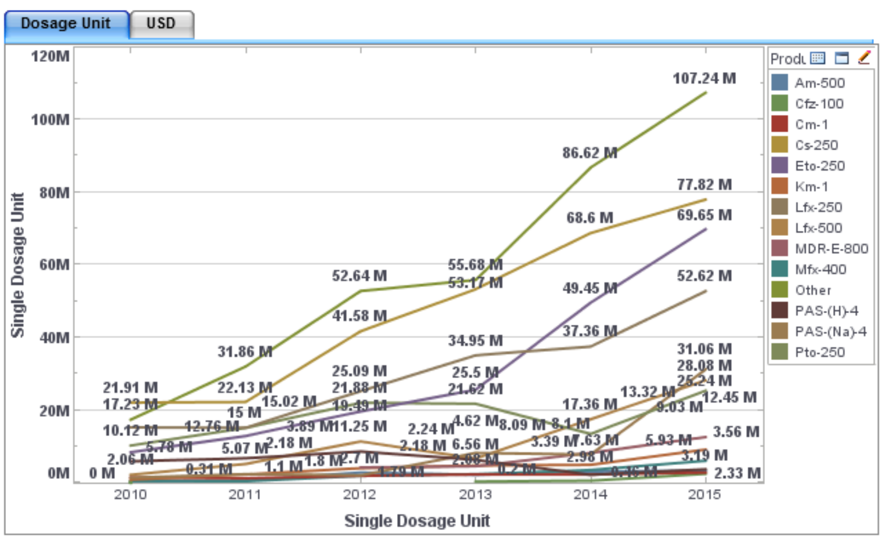
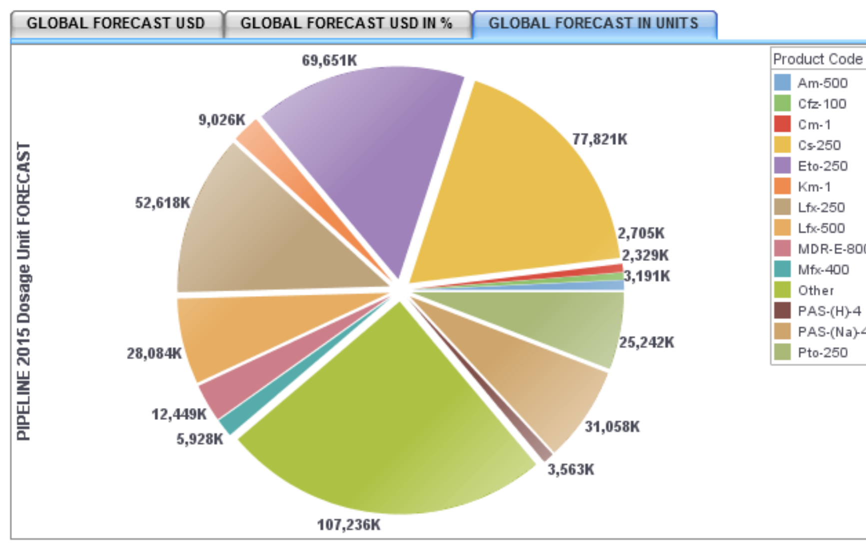
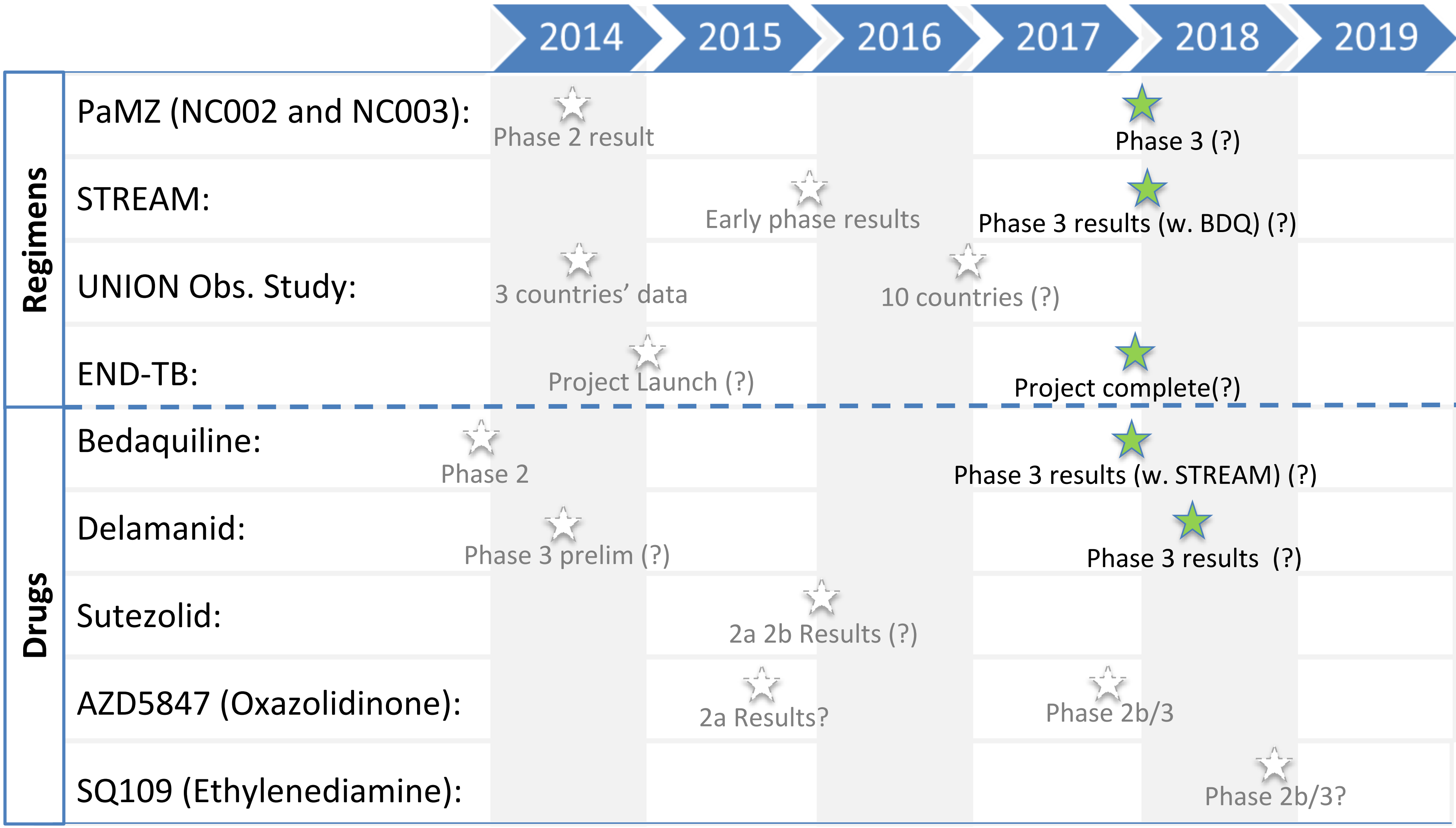
GDF Market Shaping Activities: Towards improved forecast monitoring
Anticipating Global Demand & Trends







Looking forward: new developments in the pipeline for DR-TB therapy imply new strategic supply chain approaches

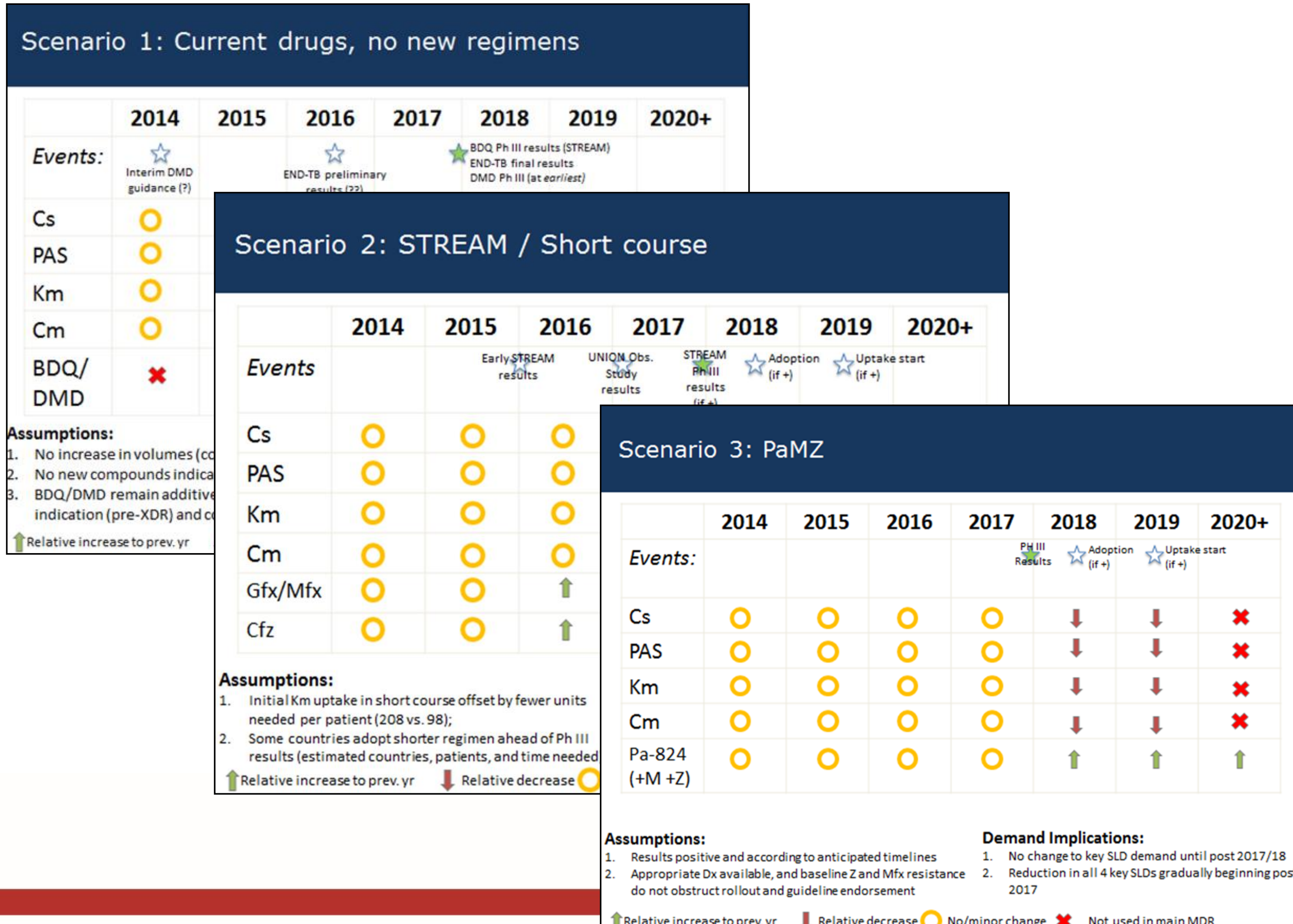


Best case estimates. Sources: *TB Alliance; Working Group on New TB Drugs, IUTLD, etc.*

Source: CHAI-GDF/CHAI joint SLD landscape analysis, presented GDF Strategic Advisory Committee meeting, September 2014

LEGEND: Interim; "Game changer"

Specific scenarios are being assessed with partners for the timing and impact on existing procurement patterns & changes



Source: CHAI - GDF/CHAI joint SLD landscape analysis, presented GDF Strategic Advisory Committee meeting, September 2014

Looking forward : Significant changes in procurement patterns unlikely to happen until 2017+

There are a few possible products / new regimens with 'interim' result scenarios that may impact the current SLDs market:

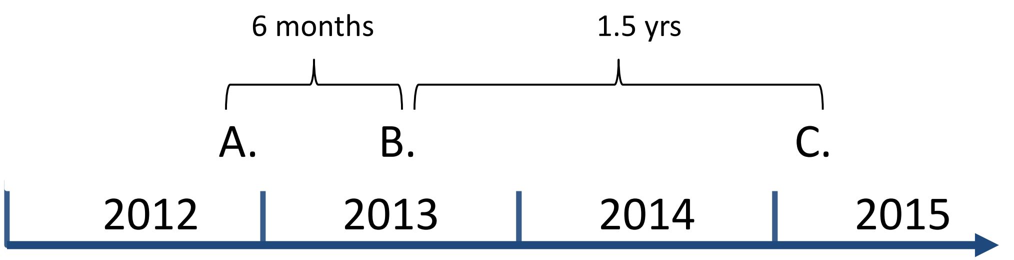
- **STREAM Short Course** **(20 to 9 months regimen will decrease volumes but can be offset by market growth)**
- **Bedaquiline / Delamanid** **(early implementing countries experience => regimen changes with greater efficacy)**
- **PaMZ** **(to be confronted with impact of DST availability + country resistance profiles)**
- **END-TB Results** **(potential for greater use of Group 5 Agents and new drugs introduction)**

Positive results will influence some NTP decisions, but it will take time

- Not all GDF countries will shift, especially not ahead of WHO guidelines
- Uptake requires KOL engagement, registration, guideline changes, provider training and awareness, change procurement, etc. (min.1.5-2+ years to start gradual uptake)
- Require close market monitoring from GDF and partners as per joint work with CHAI

The Bedaquiline experience confirms this expectation:

A. SRA approval (December 2012)
B. WHO interim guidance (June 2013)
C. Earliest early adopter (Vietnam) 1st shipment in Q1 2015



From CHAI - GDF/CHAI joint SLD landscape analysis, presented GDF Strategic Advisory Committee meeting, September 2014

Current Status on BDQ orders through GDF (Q1 2015)

Country	OrderNumber	EstimatedDeparture	Sum of QuantityOrdered
Belarus	BLR/DP/14/4120	3/12/2015	186
		6/20/2015	186
Bolivia	BOL/DP/15/4612	(blank)	1
Cameroon	CMR/DP/14/4556	(blank)	13
Cote d'Ivoire	CIV/DP/15/4590	(blank)	11
France	FRA/DP/15/4660	(blank)	10
Georgia	GEO/DP/14/4356	3/15/2015	30
	GEO/DP/14/4364	3/24/2015	68
	GEO/DP/14/4376	11/25/2015	68
Indonesia	IDN/DP/14/4465	6/9/2015	50
	IDN/DP/14/4466	9/28/2015	50
Myanmar	MMR/DP/14/4284	5/26/2015	3
	MMR/DP/14/4285	9/27/2015	3
	MMR/DP/14/4286	2/26/2016	2
	MMR/DP/14/4287	7/28/2016	2
Nigeria	NGA/DP/14/4523	5/28/2015	11
Papua New Guinea	PNG/DP/15/4659	(blank)	9
Philippines	PHL/DP/14/4165	(blank)	35
	PHL/DP/14/4166	(blank)	40
United Republic of Tanzania	TZA/DP/15/4666	(blank)	2
Uzbekistan	UZB/DP/14/4158	5/25/2015	60
Viet Nam	VNM/DP/15/4627	(blank)	106
Grand Total			**946**

Possible GF grant reprogramming through NFM when countries access BDQ donation program

ISO 9001 CERTIFIED QUALITY MANAGEMENT SYSTEM

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GDF Perspectives & Challenges (1)

Paradigm shift for SLDs country demand to consider

- SLDs availability not anymore the main barrier for MDR-TB scale-up
  - market dynamics evolving (x 2 in 5 years to 650 M USD?) with more competition
  - but still a low growth on MDR-TB scale-up
  - impact of large MDR country exits from QA market still to monitor
- An increased number of countries placed orders according to targets and not to real number of patients enrolled leading to several orders postponement / cancelation requests recently
- Need for an increased and coordinated TA at country level & partners alignment to improve diagnostics & treatment capacity with a greater role for GDF to play:
  - as a platform for knowledge sharing & best practices dissemination with efficient & supportive tools harmonized with partners
  - to provide sustainable supply chain strengthening
  - to support new products access & uptake strategies
  - to provide market analysis with partners to maintain suppliers engagement

GDF Perspectives & Challenges (2)

Supporting uptake & roll-out of new drugs and diagnostics is key for GDF & partners

- Continuity of diagnostics supply after Expand TB / TB Expert projects ending
- Internalization of diagnostics procurement (in-house)
- Expansion of diagnostics catalogue (portable X-ray / LTBI tests, new tools)
  - paediatric new formulations for rapid country uptake with partners like TB Alliance
  - Bedaquiline & Delamanid
- Monitor & manage the trends for TB drugs demand / supply with partners like CHAI through enhanced Information Systems with partners alignment
- Support access strategies to countries with partners on key successful planning steps for early uptake such as:
  - adoption in guidelines & therapeutic committees
  - regulatory issues & registration
  - sustainable procurement facilities & market dynamics drivers like supply security & costs
  - Integrate MICs shifts from donor funded model to domestic use (financial flexibilities like current Usaid guarantee fund and work towards scalability with partners like BMGF)
  - monitor country uptake and disseminate best practices & lessons learned fostering South to South cooperation

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Discussion / Q&A

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