Improving Access for Quality-Assured TB Medicines + Diagnostics

Update on GDF
New Strategic Direction

Achievements, Challenges
&
Perspectives

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Stop TB Coordinating Board - Ottawa - July 2013

What is the Global Drug Facility?

An initiative of the Stop TB Partnership (2001), mainly funded by Usaid and CIDA, with projects supported by Unitaid & Koweit Fund, hosted in WHO and managed by the Stop TB Partnership

An operating mechanism to support the Stop TB Strategy:

- **expanding access to quality-assured first (FLD) and second-line TB drugs (SLD) and diagnostics**,
- **contributing to the development of sustainable procurement and supply management for countries in need**

GDF began supplying FLDs in 2001, and in 2008 added the supply of SLDs, pediatric TB medicines and diagnostics and is a major source for GeneXpert

ISO 9001 CERTIFIED ISO QUALITY MANAGEMENT SYSTEM

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What is GDF Mandate today?

GDF is more than a traditional procurement mechanism – it is a **one-stop access for provision of medicines and diagnostics** through:

- **Emergency one year grants** - bridge TB program gaps for FLDs
- **Grants for FLDs to continue for 1 more year to allow for proper phase-out**
- **Grants for SLDs: under discussion with donors**
- **Direct procurement (DP)** – TB program buys FLDs, SLDs, Diagnostics through GDF
- **In-country technical assistance** in procurement and supply chain management

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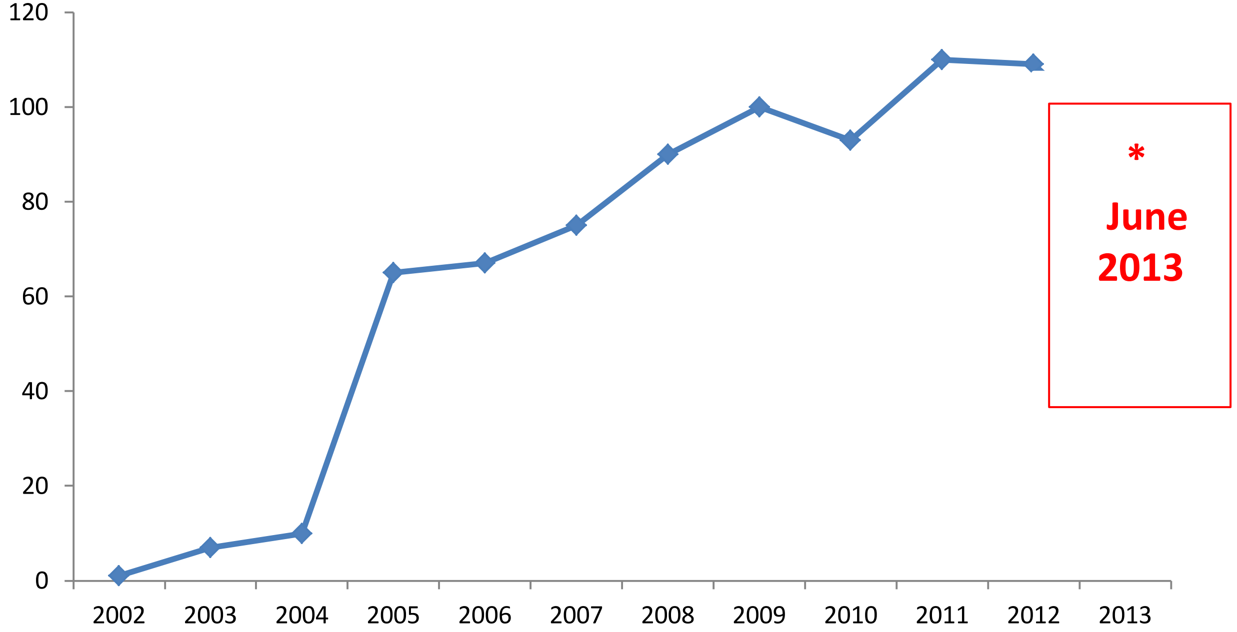
Number of Countries who adopted GDF Services by Year (2002 – 2012)



A total of 128 different countries received the benefits from the procurement system and the multiple advantages offered by GDF across the years

Source: GDF OMS Data / June 2013

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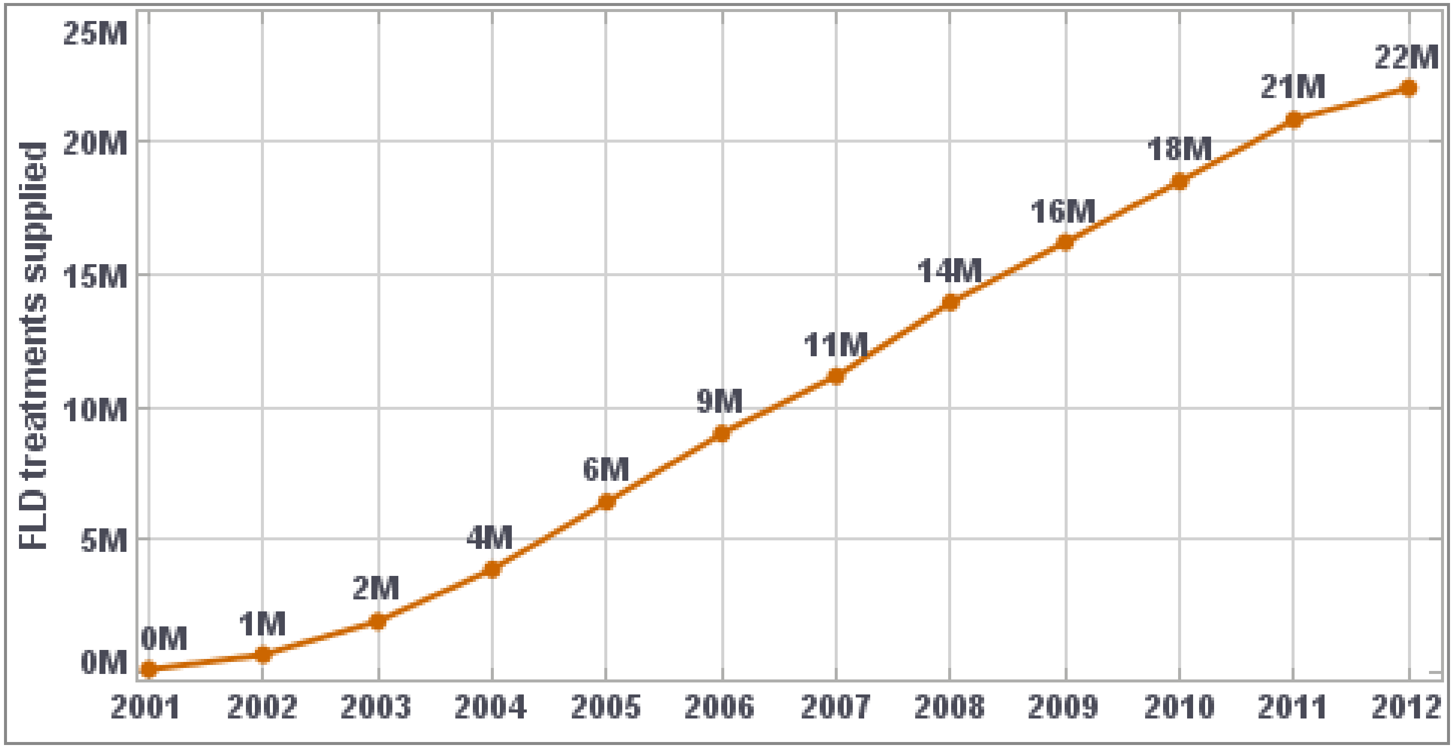
Total Patient Treatments Supplied 2001-2012
First Line Drugs



Live Report June 2013
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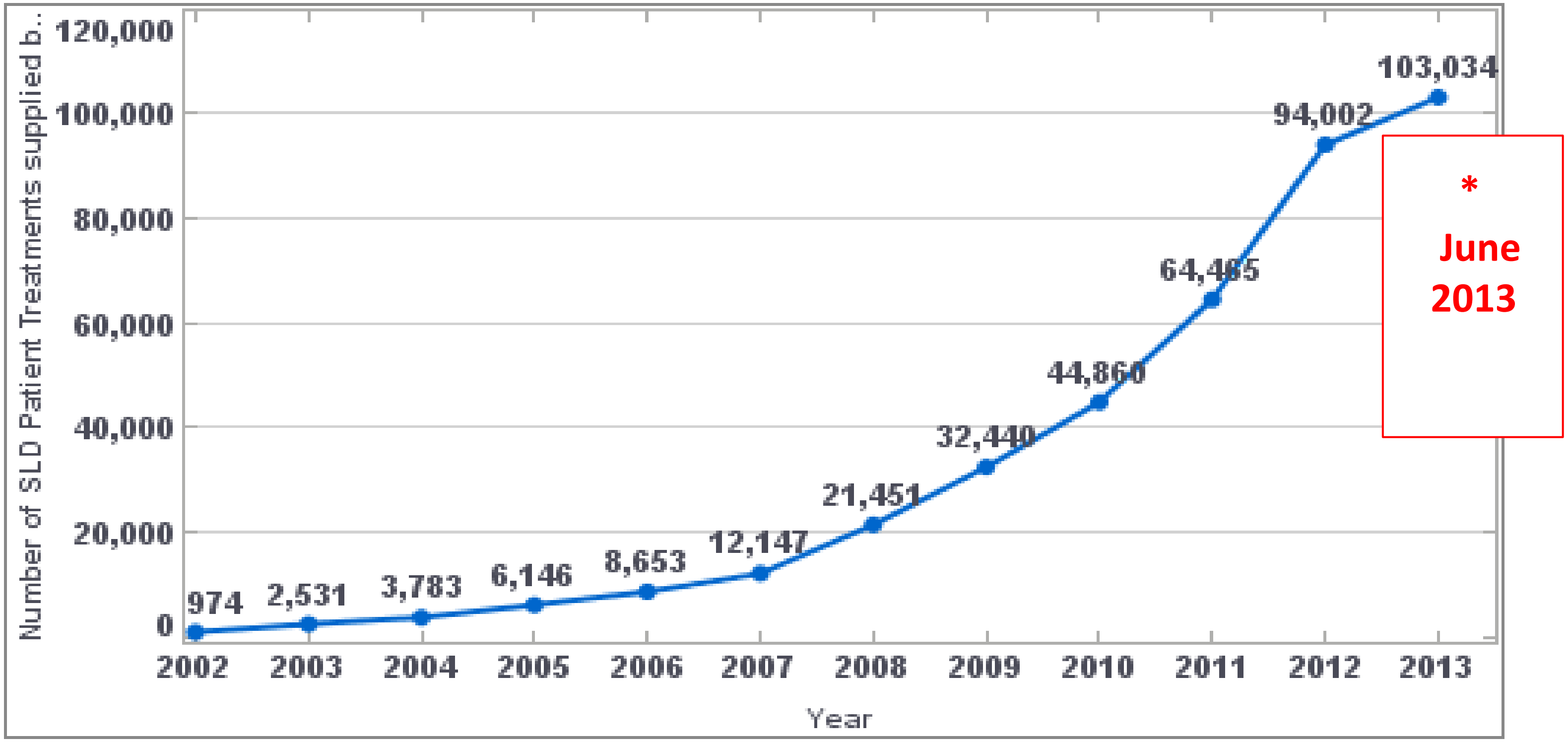
Total Patient Treatments Supplied 2001 - 2013
Second Line Drugs



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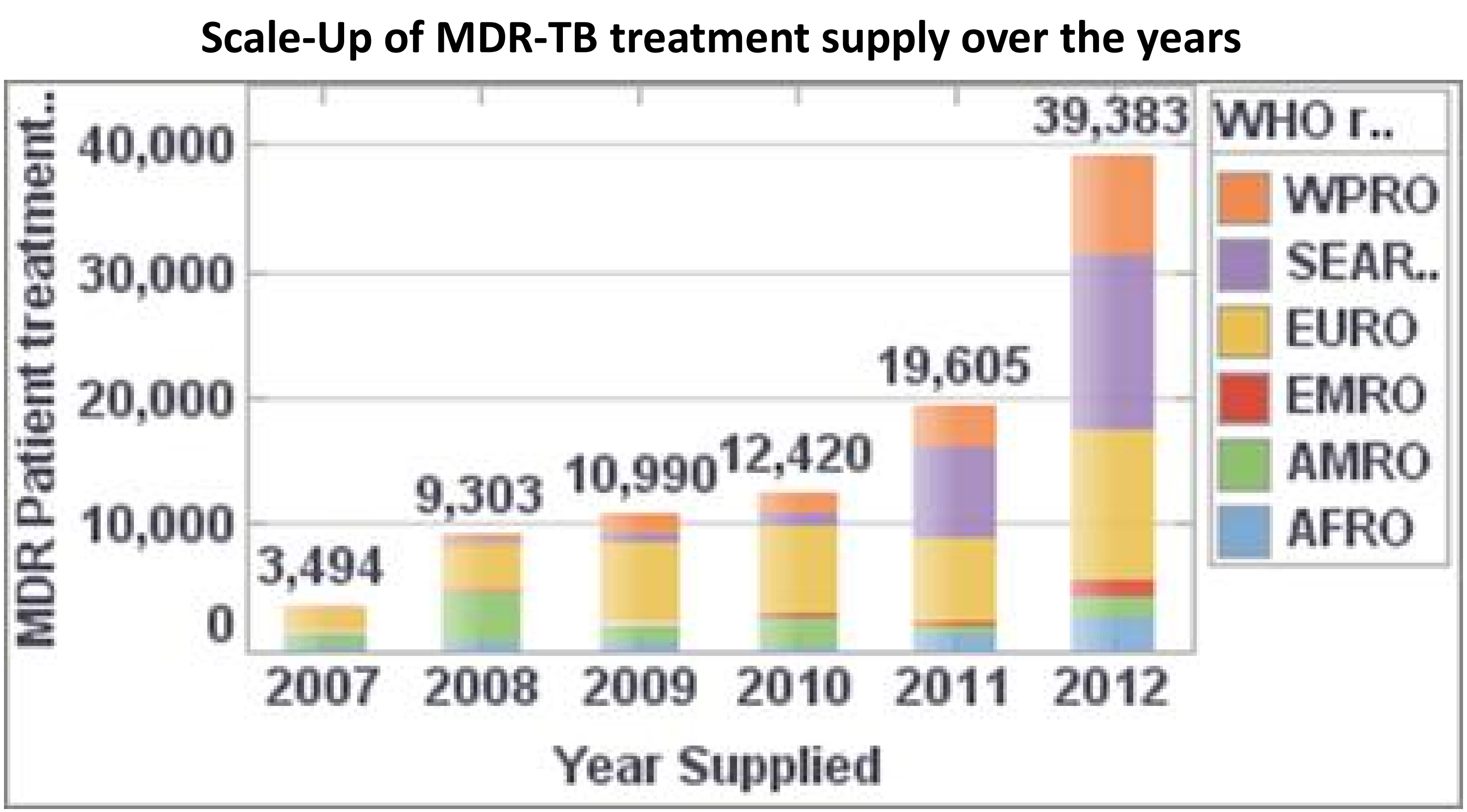
Scale-Up of MDR-TB treatment supply with GDF medicines over the years



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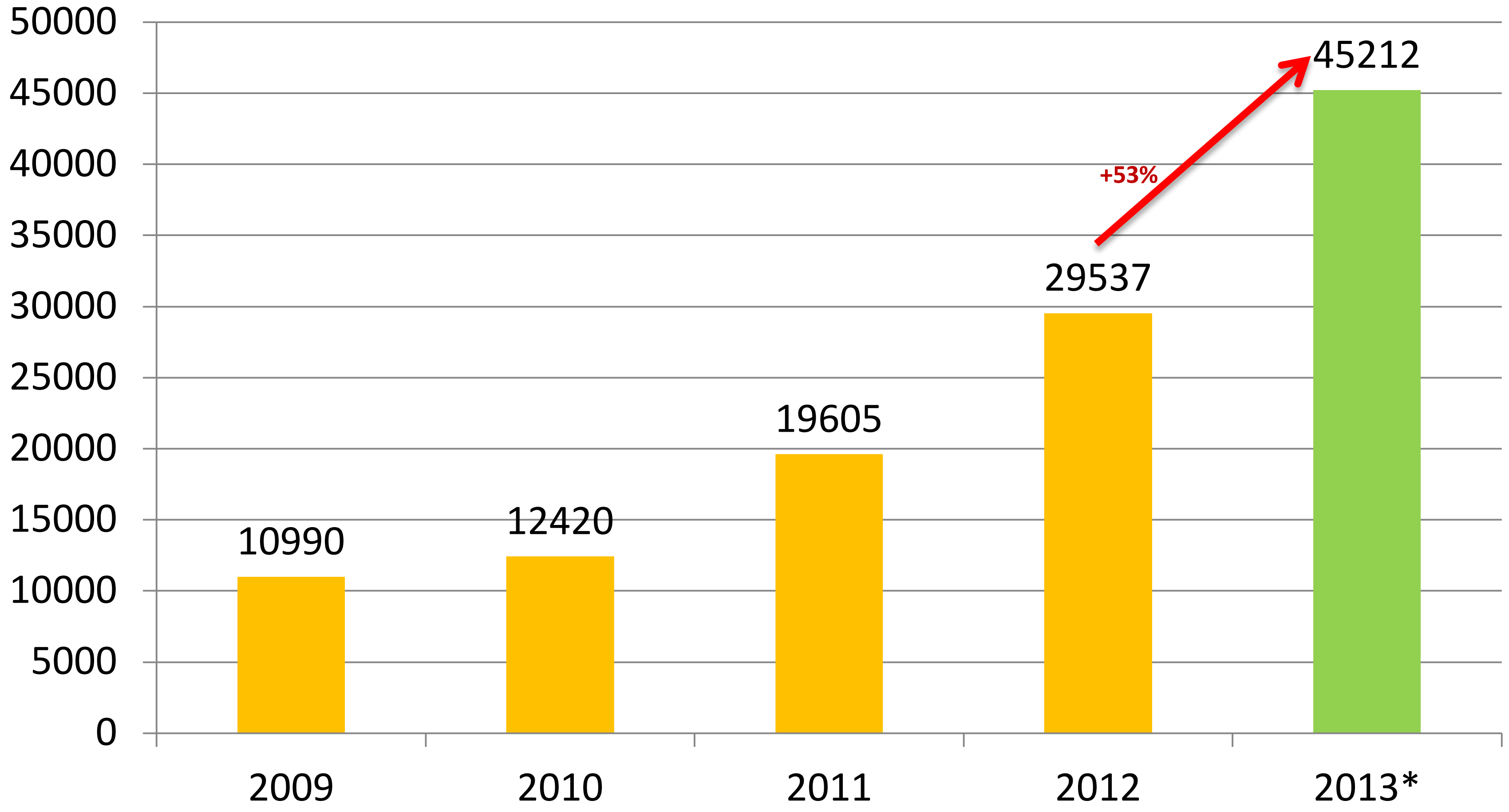
SLD Patient treatments supplied by GDF and current projections for 2013



* Estimated, based on constant 2012 value and 15675 DR-TB treatments planned for India

Note: Method 6 months intensive phase injectables up to 2011, 8 months from 2012

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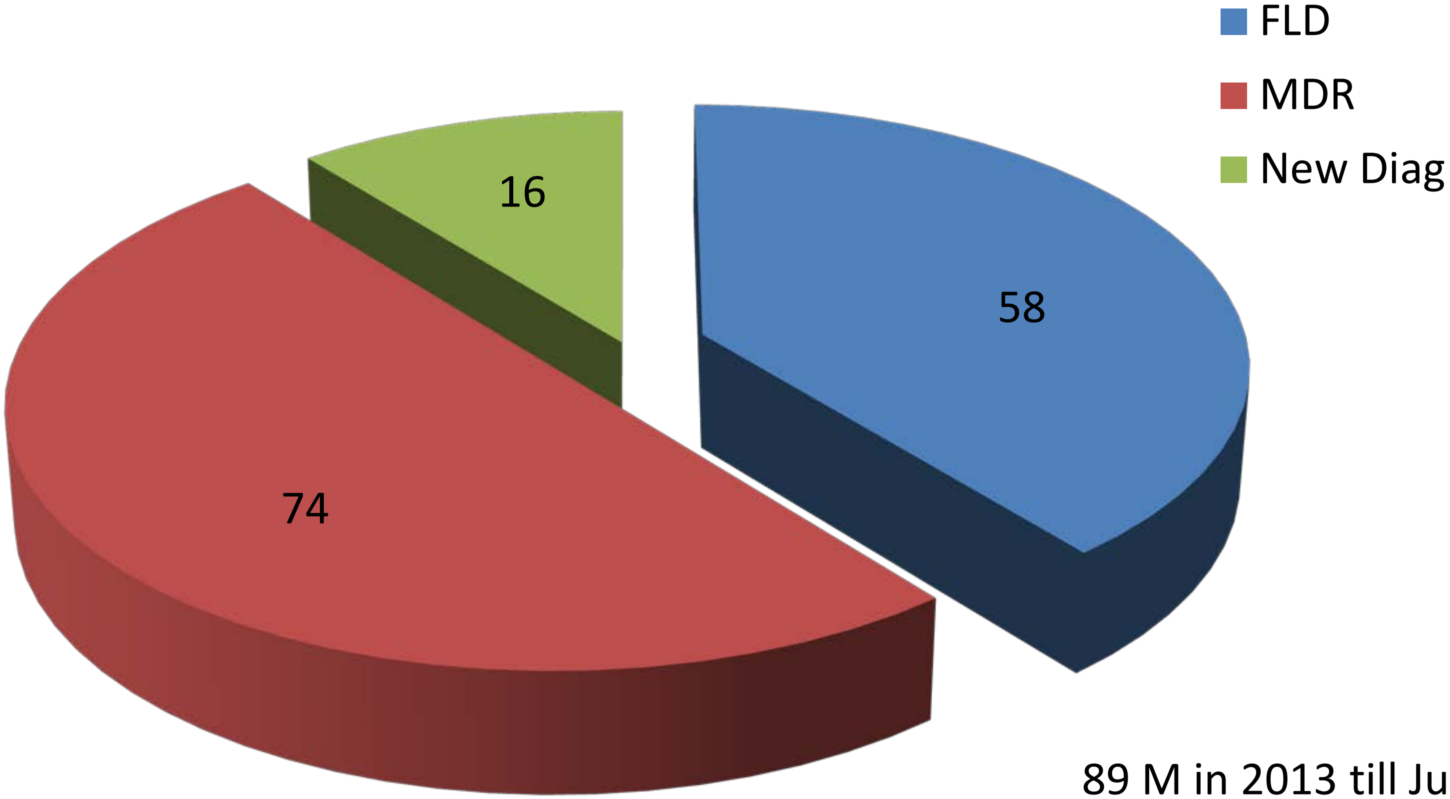
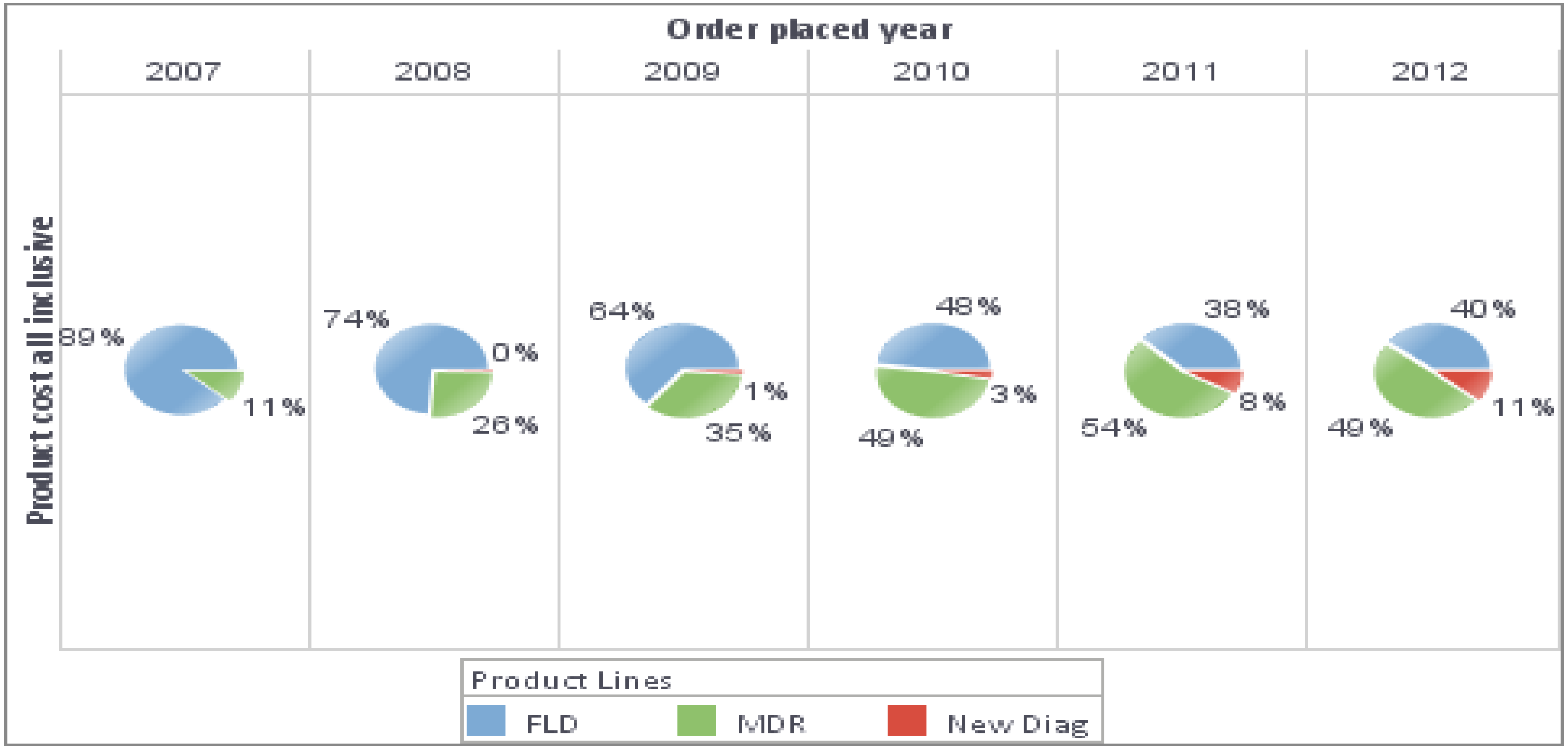
Value of Orders Placed 2012 (mUSD)



89 M in 2013 till June 2013

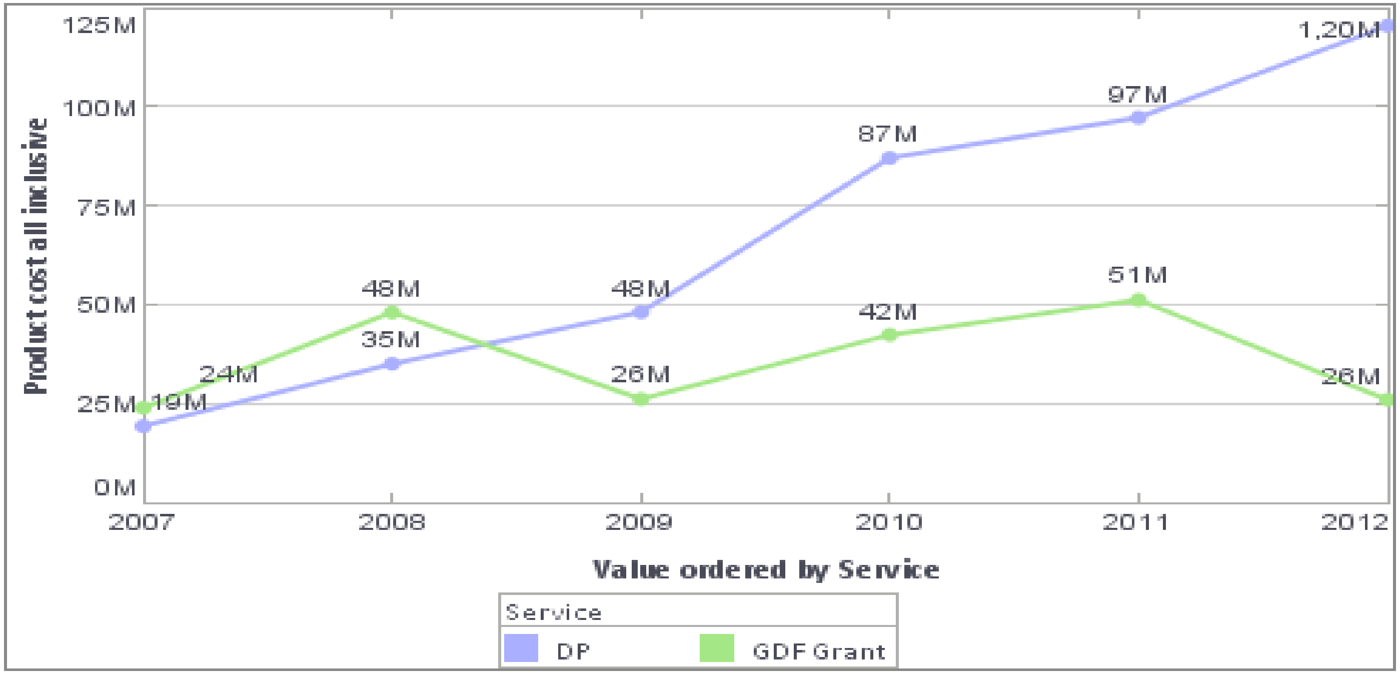
GDF order placed value all inclusive – By Product Line July 3, 2013



Live Report July 2013

http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/All+inclusive+values+of+products+ordered+by+Line+and+Country&userid=GDF_ro&password=gdfread1

GDF order placed value all inclusive – By financial service June 3, 2013



Live Report June 2013

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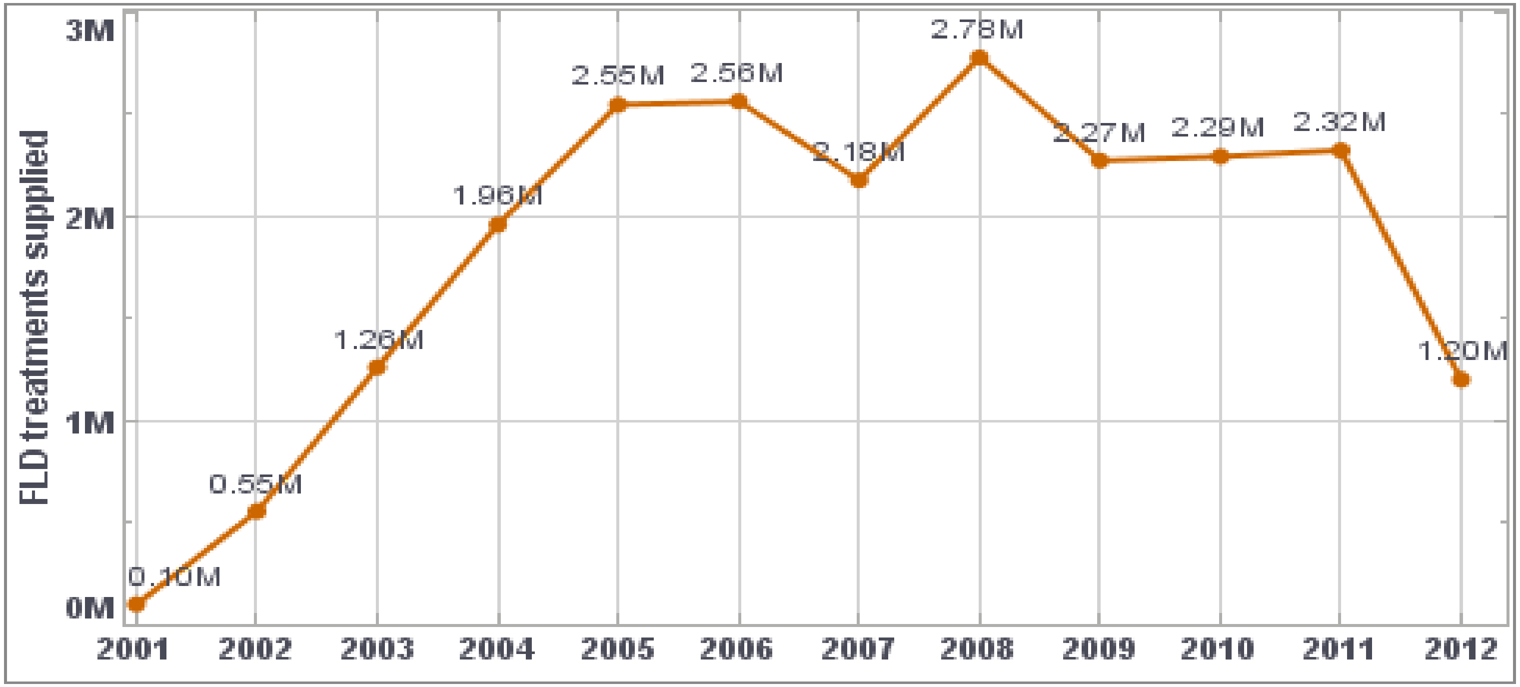
Patient Treatments Supplied per Year
First Line Drugs



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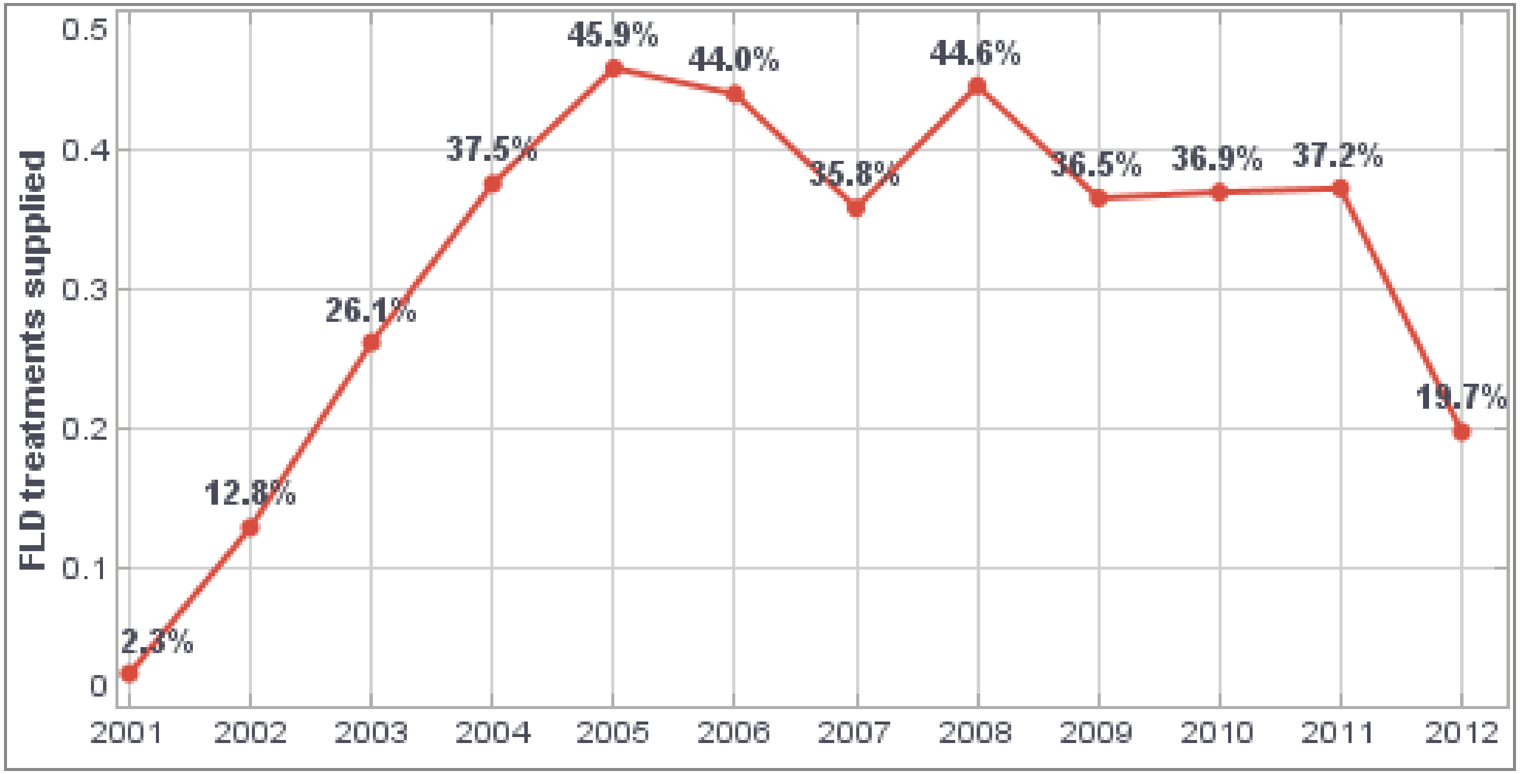
GDF FLD Market Share of Notified Cases



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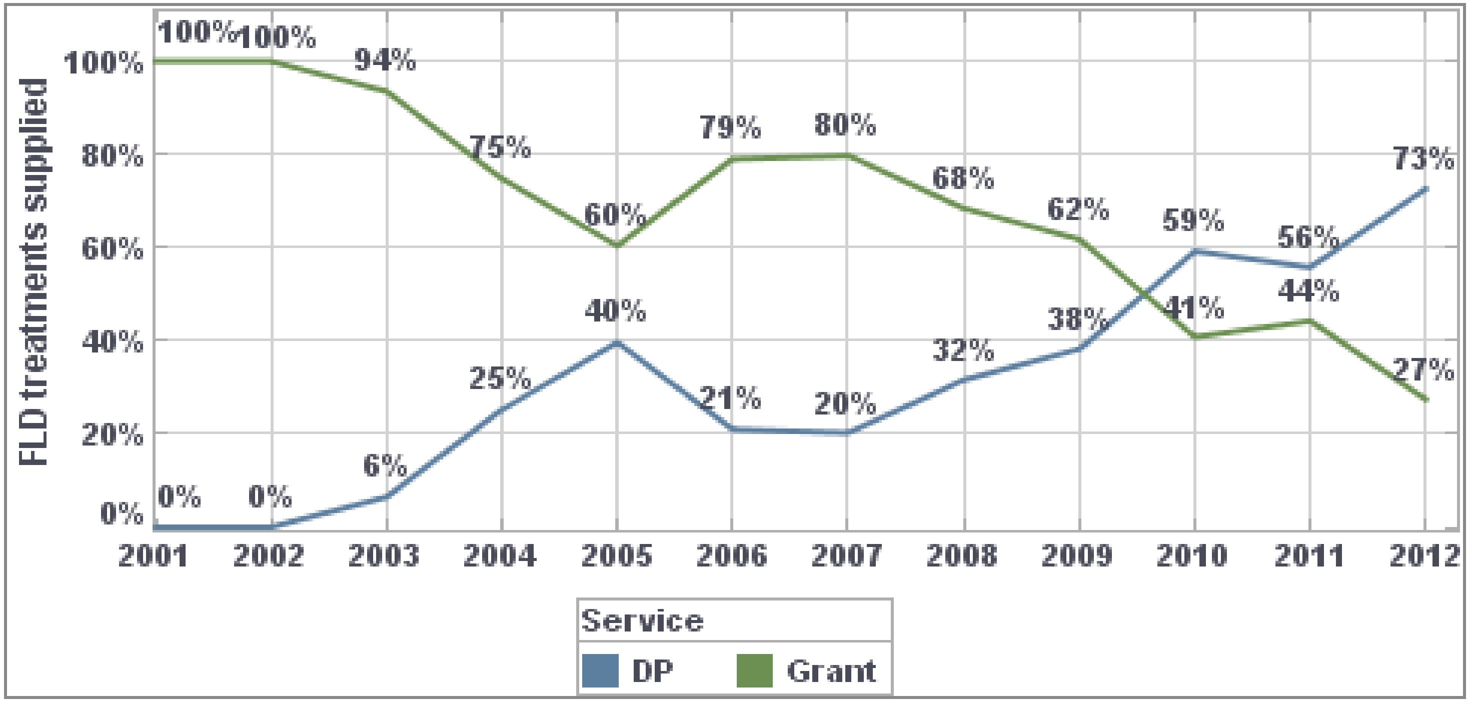
Percentage of FLD Treatments Supplied per Year by Service



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Patient Treatments Supplied per Year
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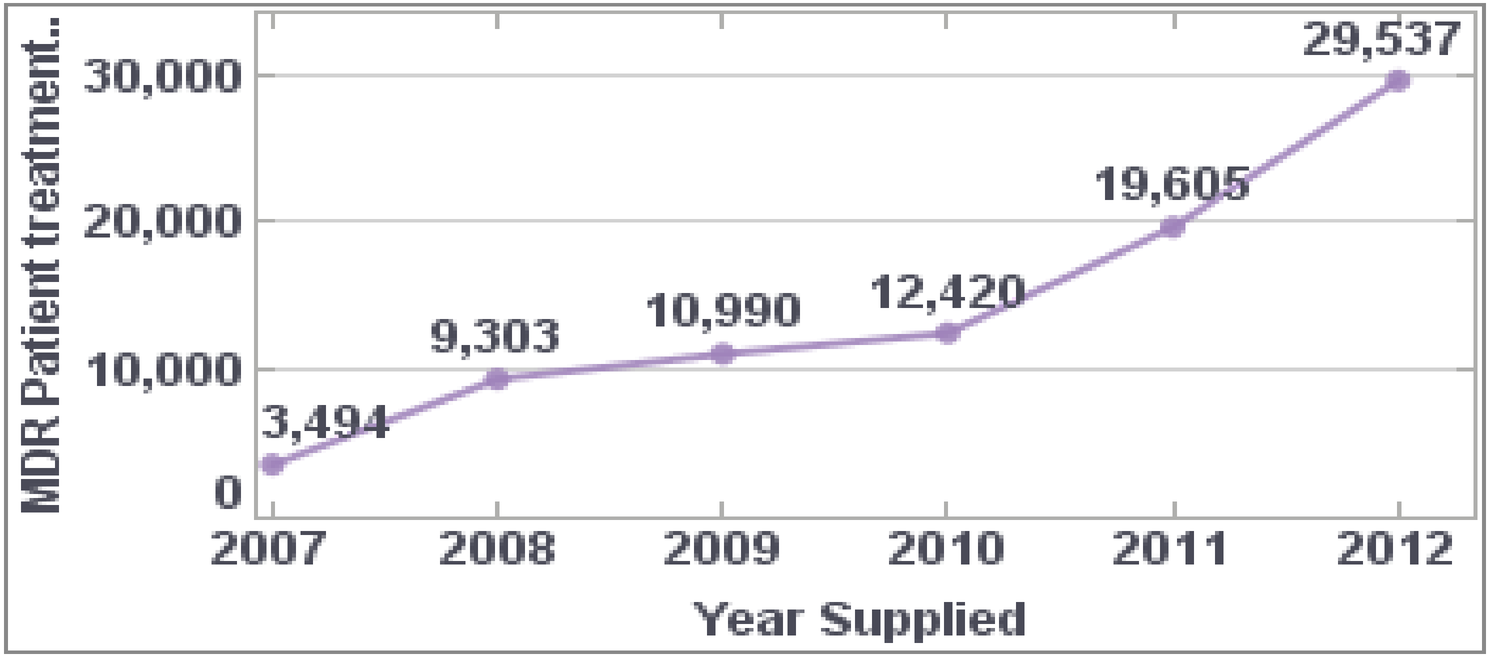

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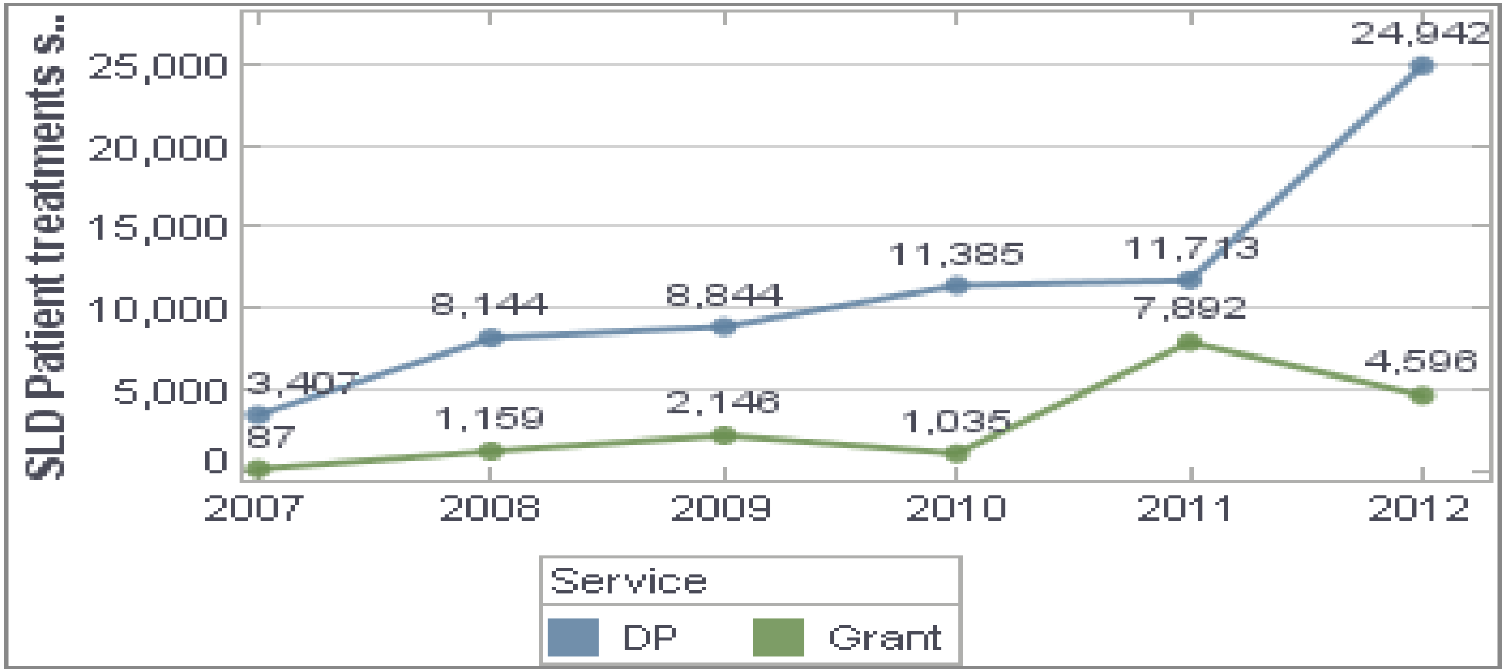
Patient Treatments Supplied per Year by Service Second Line Drugs



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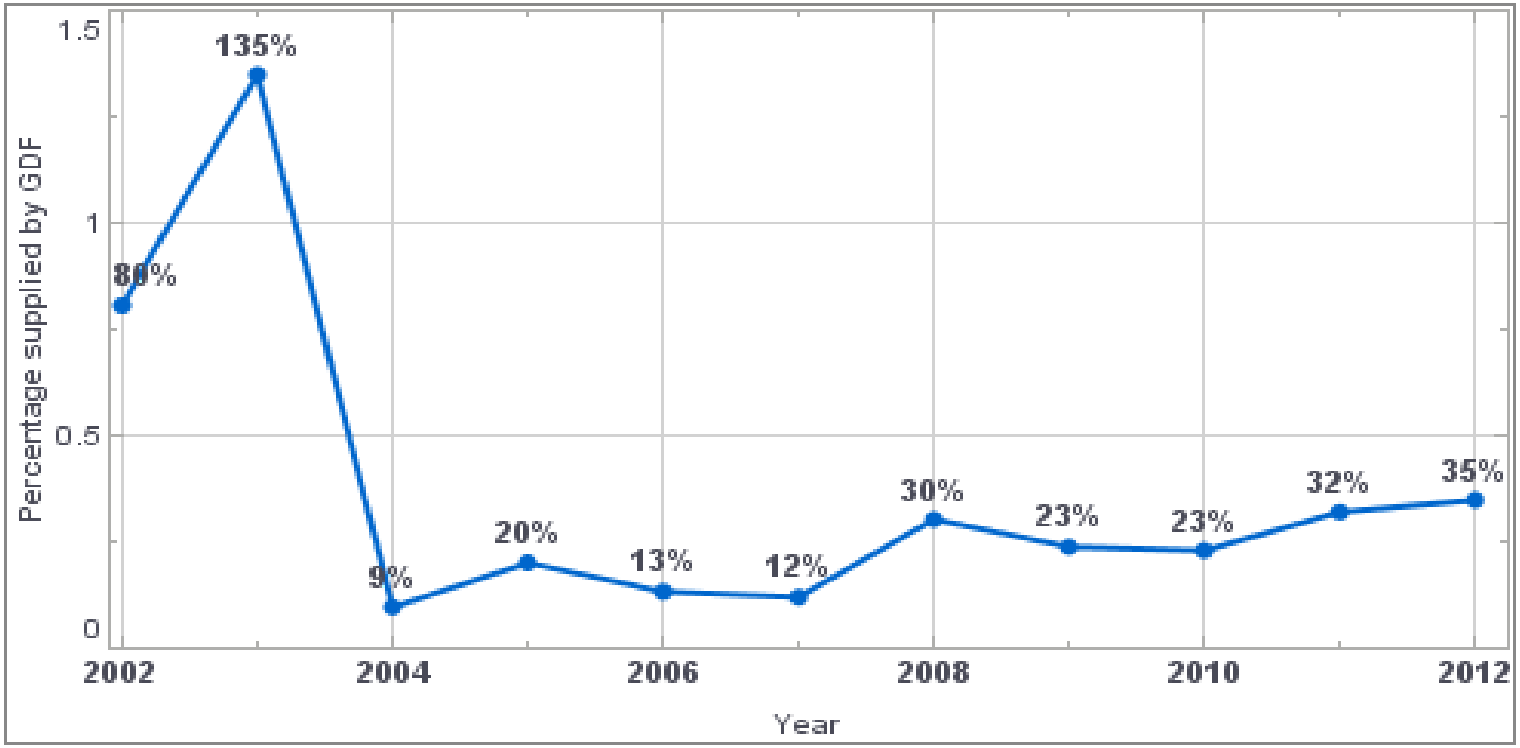
GDF SLD Market Share of Notified Cases



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GDF Strategic Direction and Framework (2013-2016)

Universal access for quality assured TB medicines and diagnostics for GDF clients

Partner Linking

Services and Products

Product Quality Assurance

Market Shaping

New TB Tools

Capacity Building

Evidence from Countries

Market Research & Forecasting

Main GDF Achievements since last Stop TB CB

1. Focus on services delivery & Operations => Results

Key Milestones

>M US$ 89 since 2013 (vs M US$ 151 in 2012)

New Pas / LTAs signed
TRC 28 finalized / TRC 29 planned

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Lead times decreasing

Support to TBREACH, TBEXPERT and EXPANDTB

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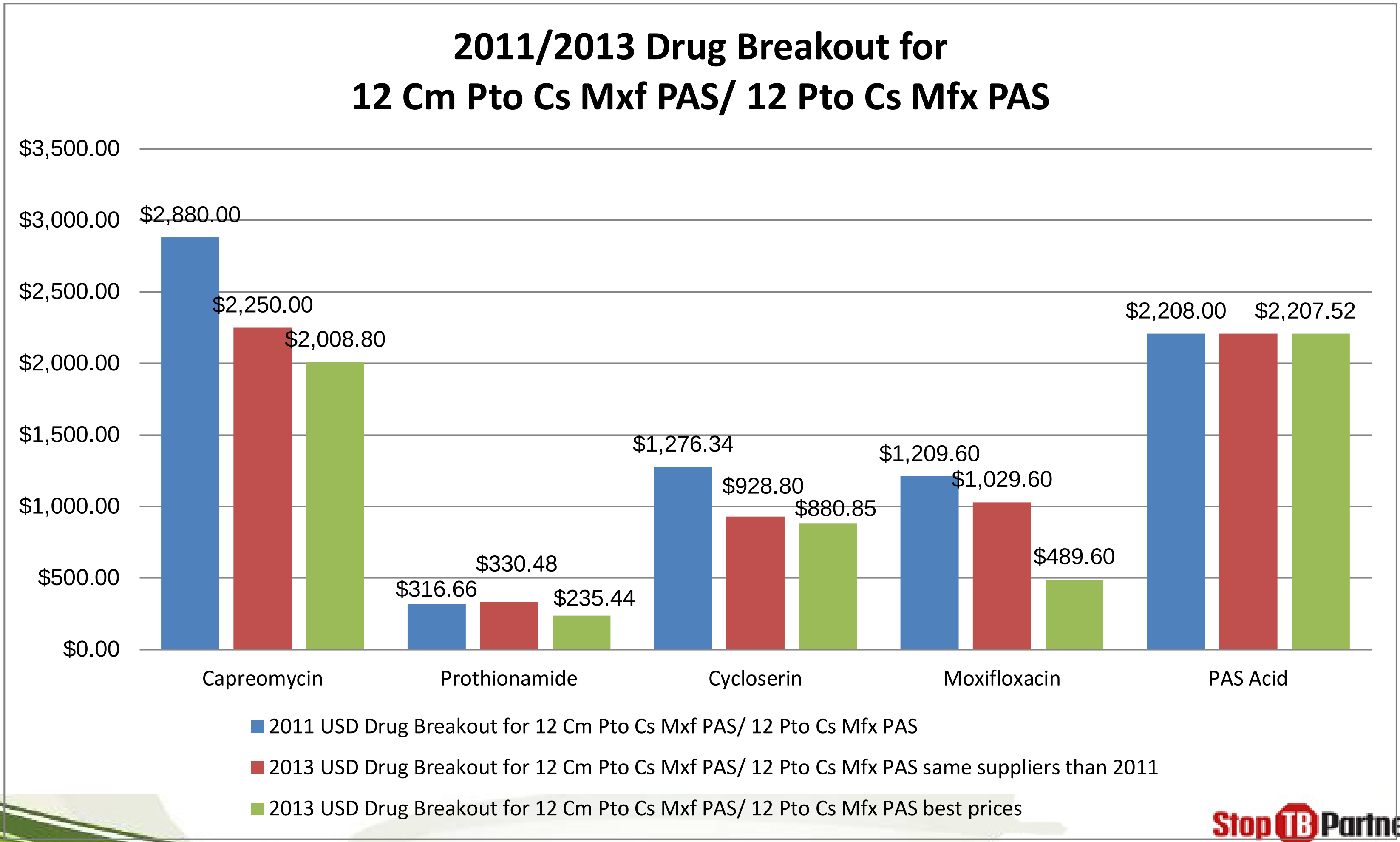
GDF Impact on SLD Dynamics: 2011 vs. 2013 treatment cost comparison / High end regimen



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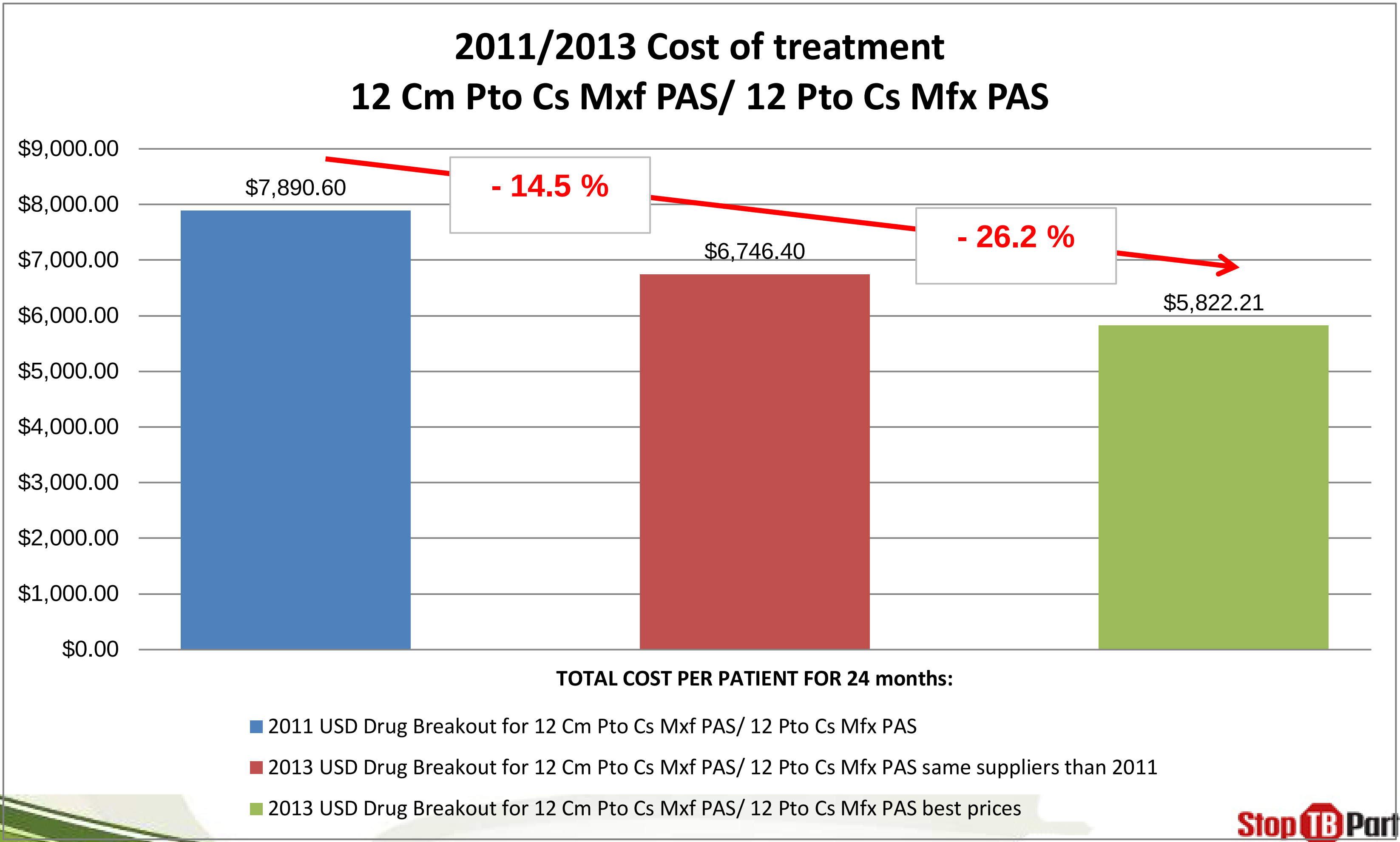

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Update on specific medicines

- **Group 5 Medicines now available through:**
  - **Linezolid**
  - **Clofazimin**
  - **Imipinem /cilastatin**
- **Rifabutin currently being added to GDF catalogue**
- **Partial regimens now available to countries**

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2. Moving ahead with the new strategic framework implementation

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New Tools and Monitoring Model for Countries

Translate the key data of # of months of stock on hand into the country classification:

- Reaching 8 months or Less than 8 months : **Red alert** (urgent imminent risk of shortage: immediate action taking for new drugs supply)
- Between 8 and 12 months: orange alert (action taking is required to ensure next supply will meet current needs, and revising stock levels is urgently needed)
- 12 months or more supply : green light situation - smooth supply guaranteed for more than 1 year

Strategic interventions & new tools to avoid stockouts

- **On-going discussion for a flexible Procurement Fund and Strategic Stockpile for FLDs + SLDs + Diagnostics with TGF and donors**

- **New Forecasting Tools + Early Warning Stockout System**: GDF and its partners are developing new forecasting systems to quantify needs for the coming years and these systems are continuously being improved upon, esp. for SLDs

- **Promoting M&E systems inter-operability** for better data exchange and SLDs consumption at country and global level

- **Information sharing and in country partners leveraging:** closer monitoring model of in country supply chains information being implementing with RSOs, and partners collaboration (WHO, rGLCs, Donors funded programs like TB CARE, Technical Agencies, NGOs, Regional Association, Private sector…

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GDF Quality objectives – Performance commitments

GDF commits to 3 main quality objectives:

1. Product quality — Quality assurance & control
2. Service quality
   - Fast deliveries
   - Satisfied clients
   - Technical assistance
3. Lowest Prices — Pooled procurement

GDF ISO 9001 QMS = Quality & transparency

GDF commits to transparency & improvement

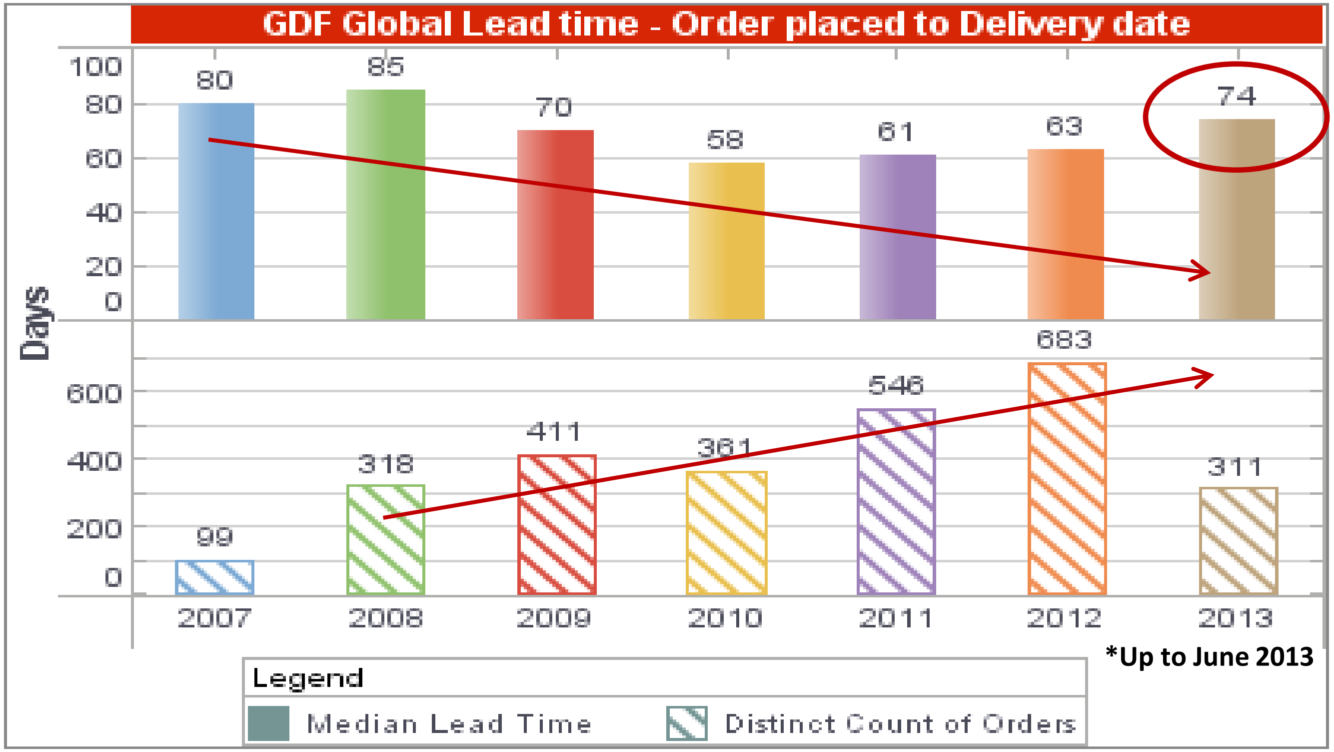
1. Systemic
2. Live
3. Comparable

Transparency

Improvement

Performance

GDF Operations-Lead time order to delivery



- Regular
- Urgent
- Emergency
- Stockpile
- All lines
- All services

Source web report : 2007-2013- on June 3 2013
http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/Delivery_dashboard_order_placed_to_delivery_rev1&userid=GDF_ro&password=gdfread1

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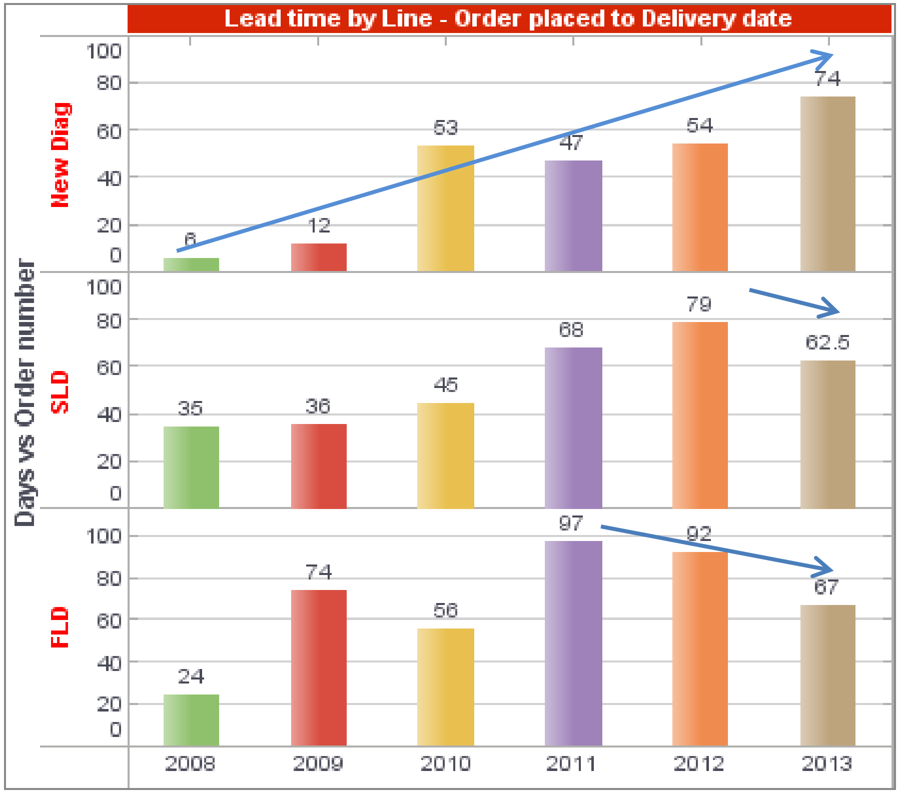
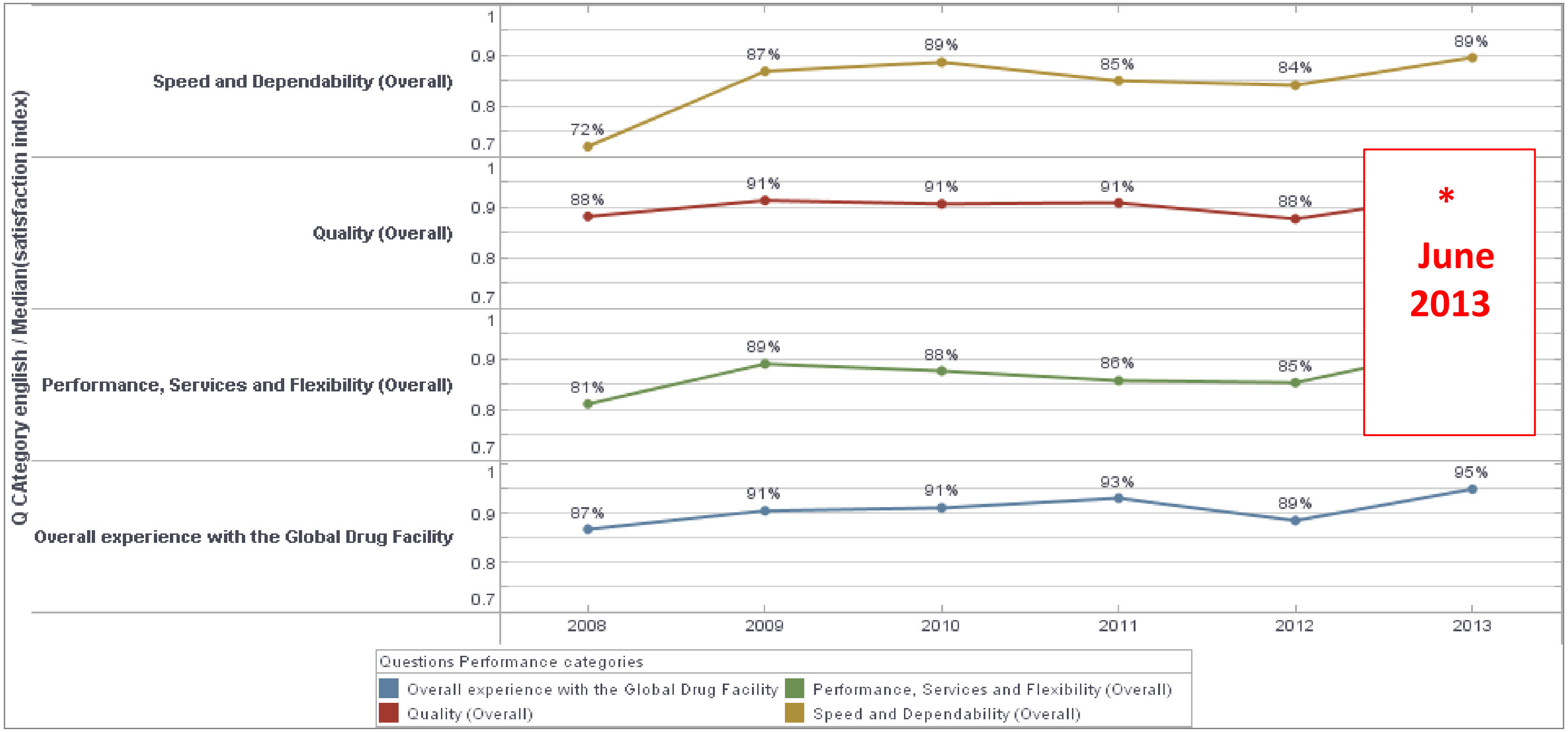


Median increase of Lead time due to production difficulty with TB REACH Supplier – which affect all lead times.

Issue was resolved in March 2013.

Source web report : 2007-2013- on June 3 2013
http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/Delivery_dashboard_order_placed_to_delivery_rev1&userid=GDF_ro&password=gdfread1

GDF ISO 9001 – Client satisfaction by Service Categories



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3. Focus on data analysis / evidences from countries to better adapt GDF model

Consultancy on stock-outs root causes – on-going

Consultancy on SSP+FPF (final stage of selection)

TA activities back on board

Stock-outs Early-warning System + e&M Health Project

New Communication Strategy with partners and civil society

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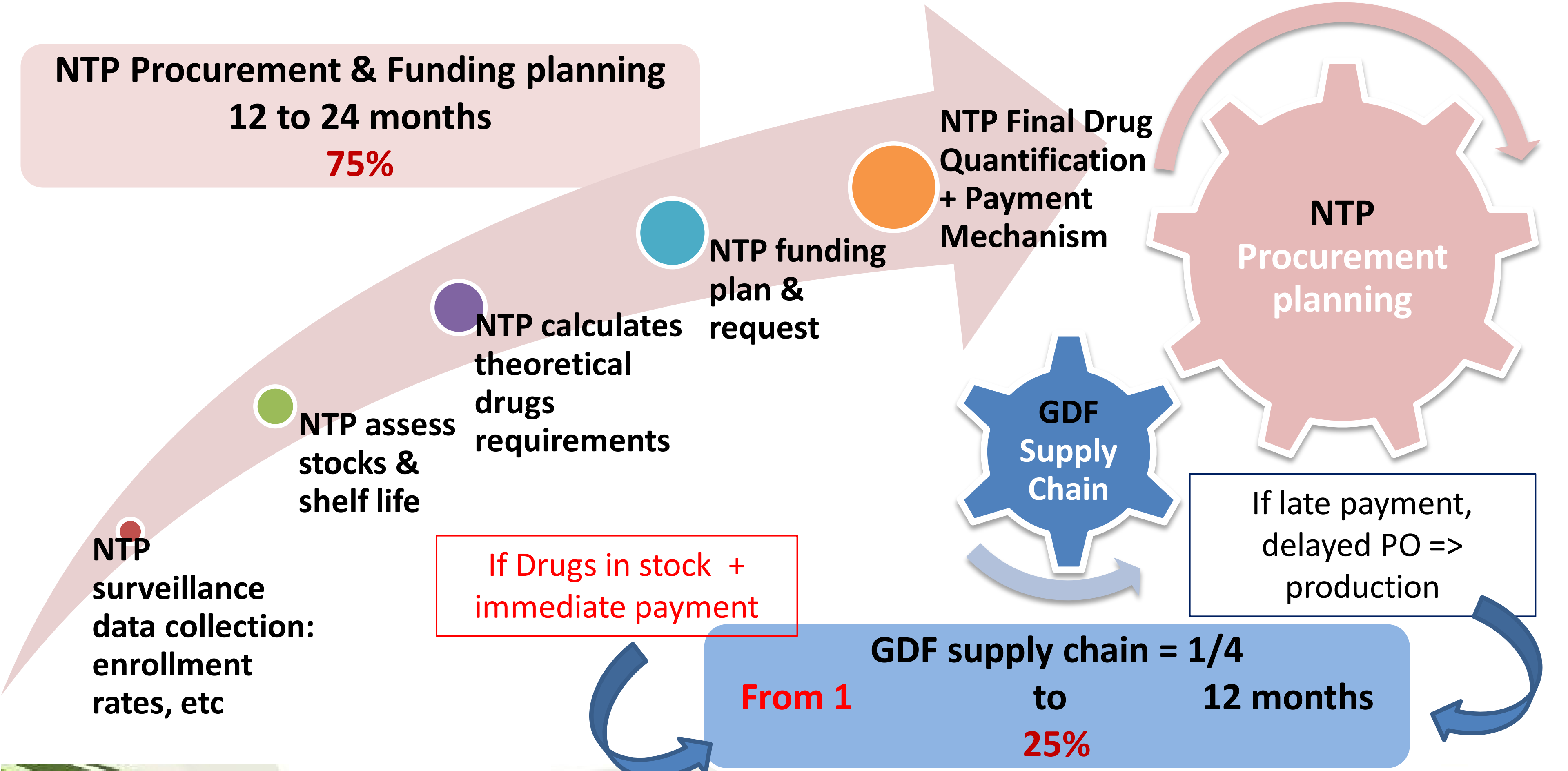
TB Supply Chain Process

GDF procurement process is only a small share of the overall procurement system



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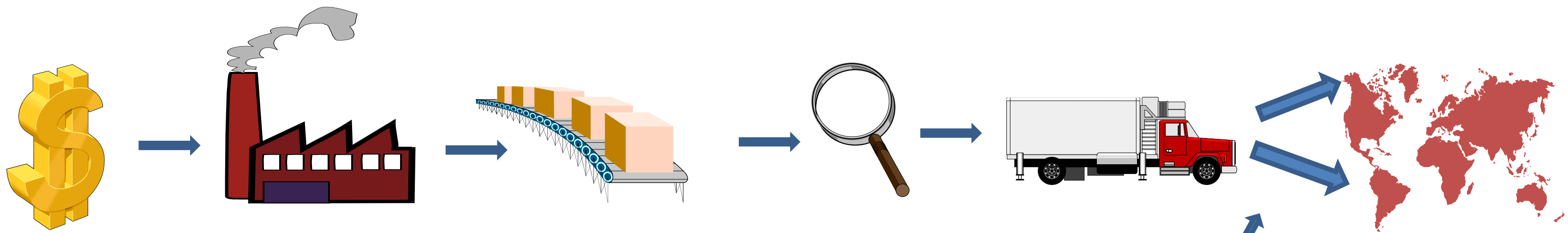
Current TB Supply Chain Process



Order is placed and Payment received

Order is processed by manufacturer

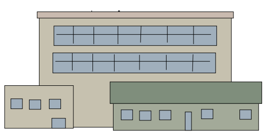
Product is manufactured

Product is inspected

Product is dispatched

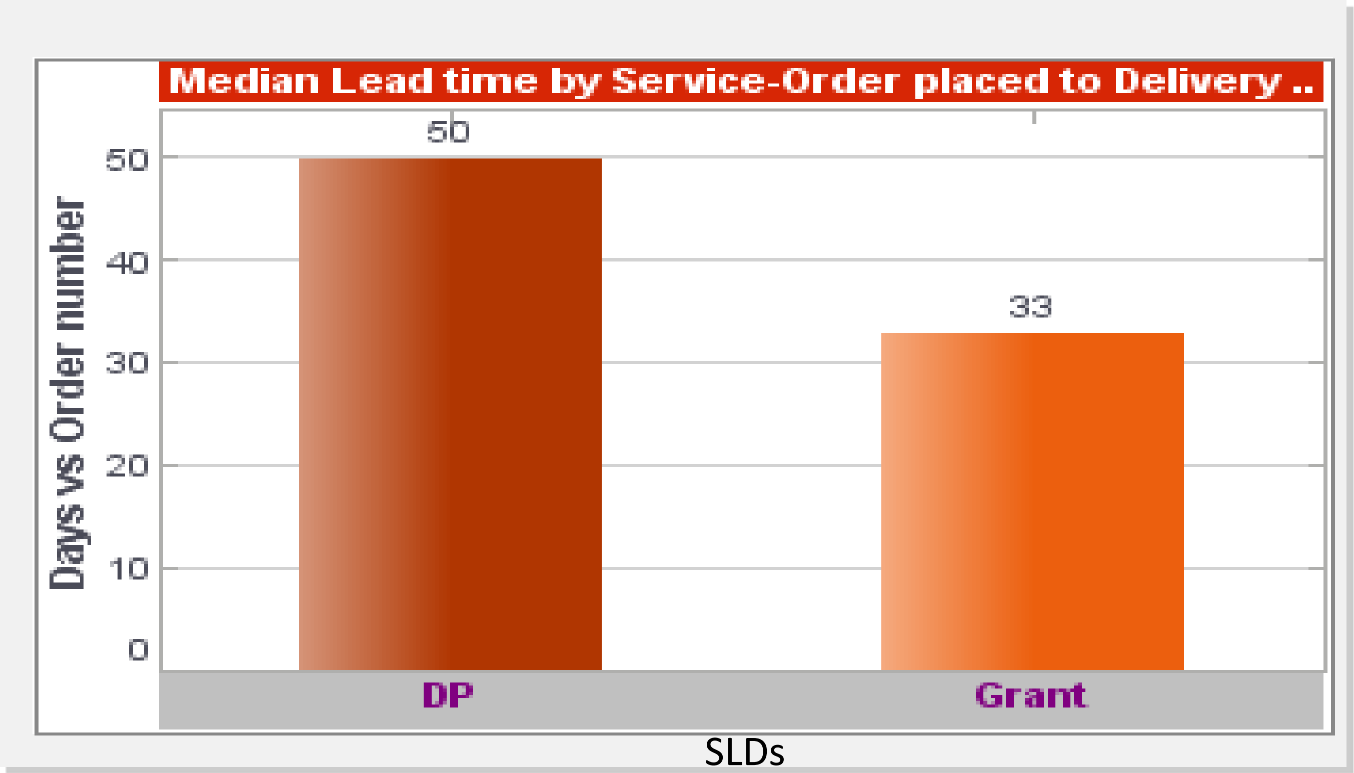
Country receives product

~6 months



Limited quantities of medicines are available in the Strategic Revolving Stock for emergencies

GDF delivers emergency orders from SLD *stockpile* in 33-50 days



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Stock-outs root causes : Main findings

- From a total of 65 reported stock outs from 2007-2013:
  - 54 were confirmed by different documents
  - 10 were confirmed as Non-stock-outs
  - 1 report was related with laboratory material - no to medicines procurement.

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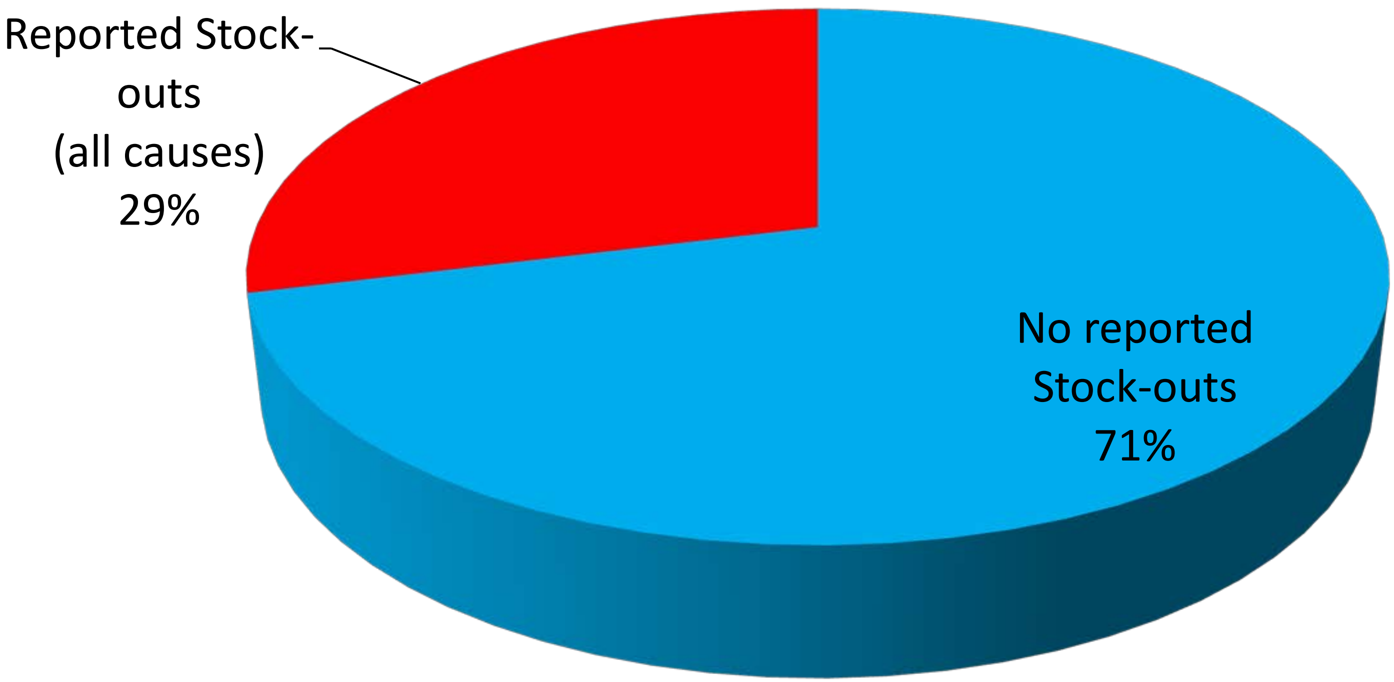
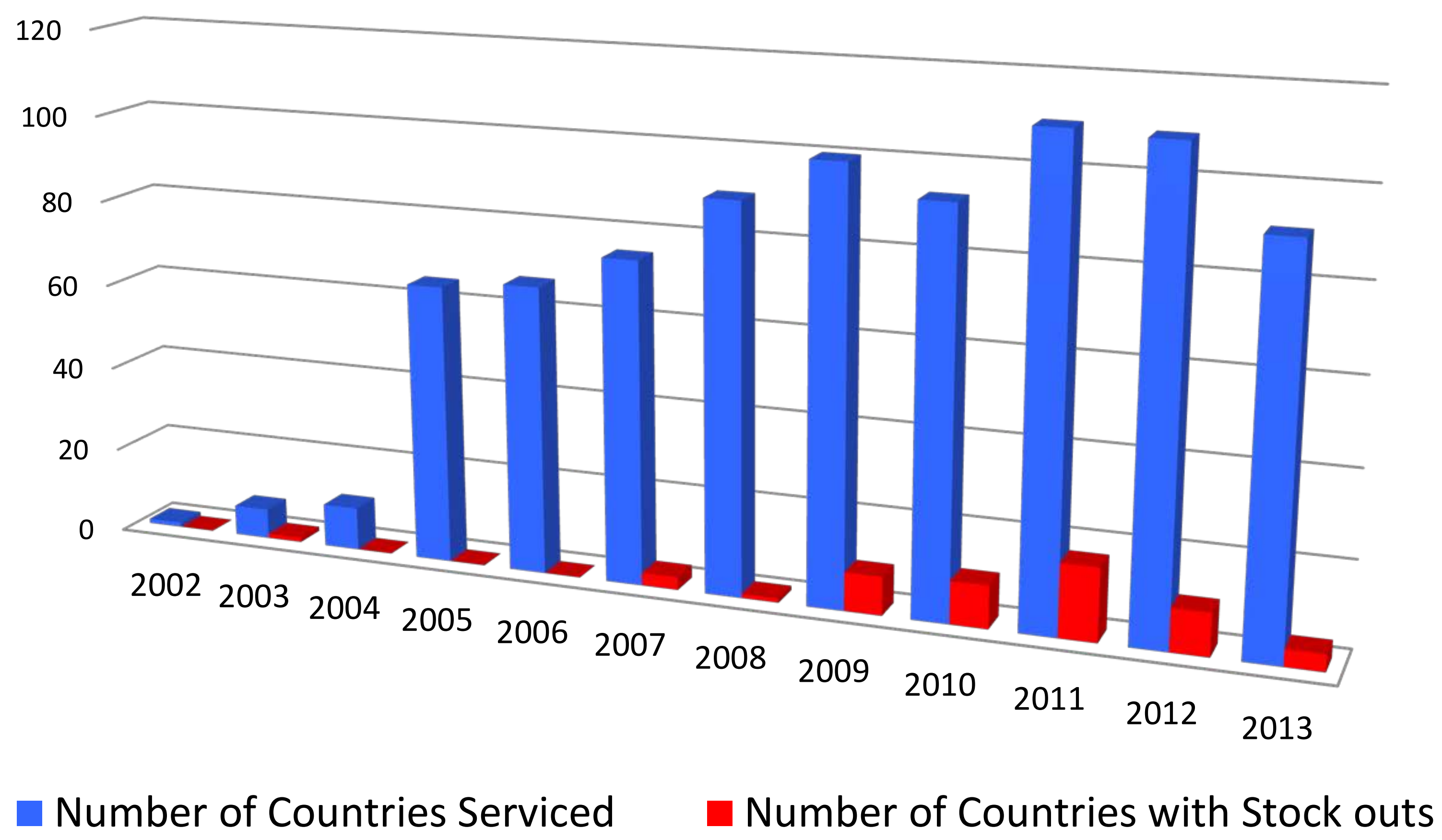
Percentage of Countries with Stock-outs (2007 – 2013)



Number of Countries Receiving Services from GDF and Number of Stock-outs per Year



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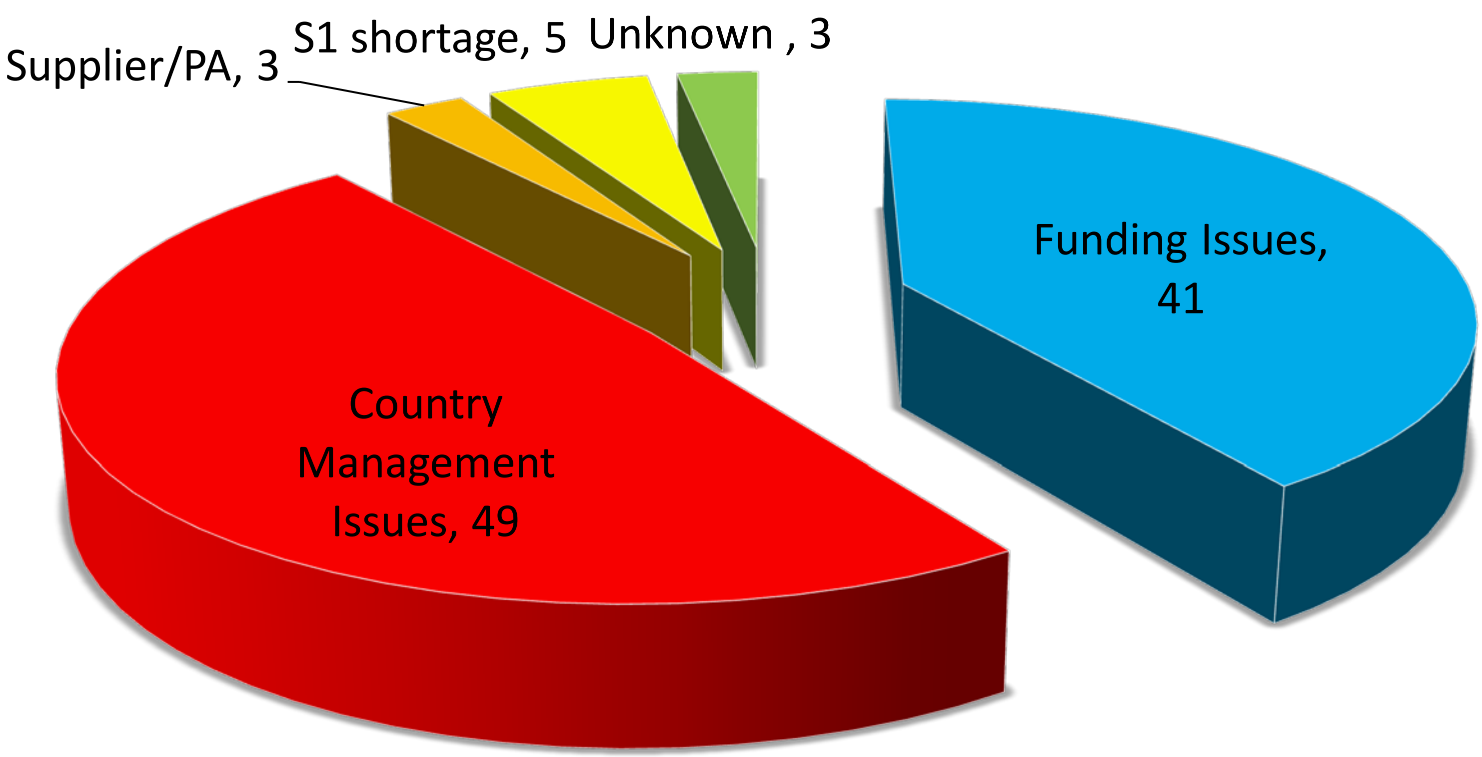
Countries with Stock-outs per Primary Cause (%)



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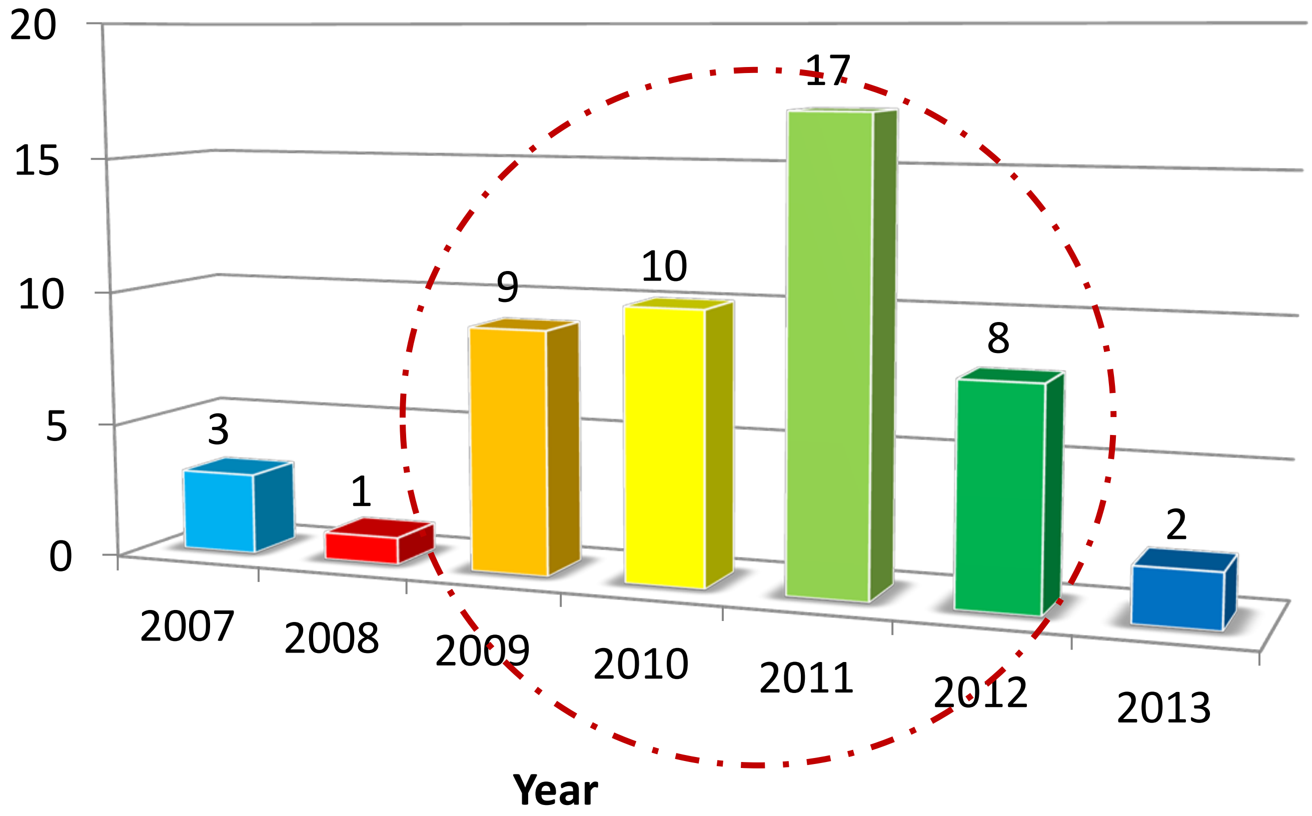
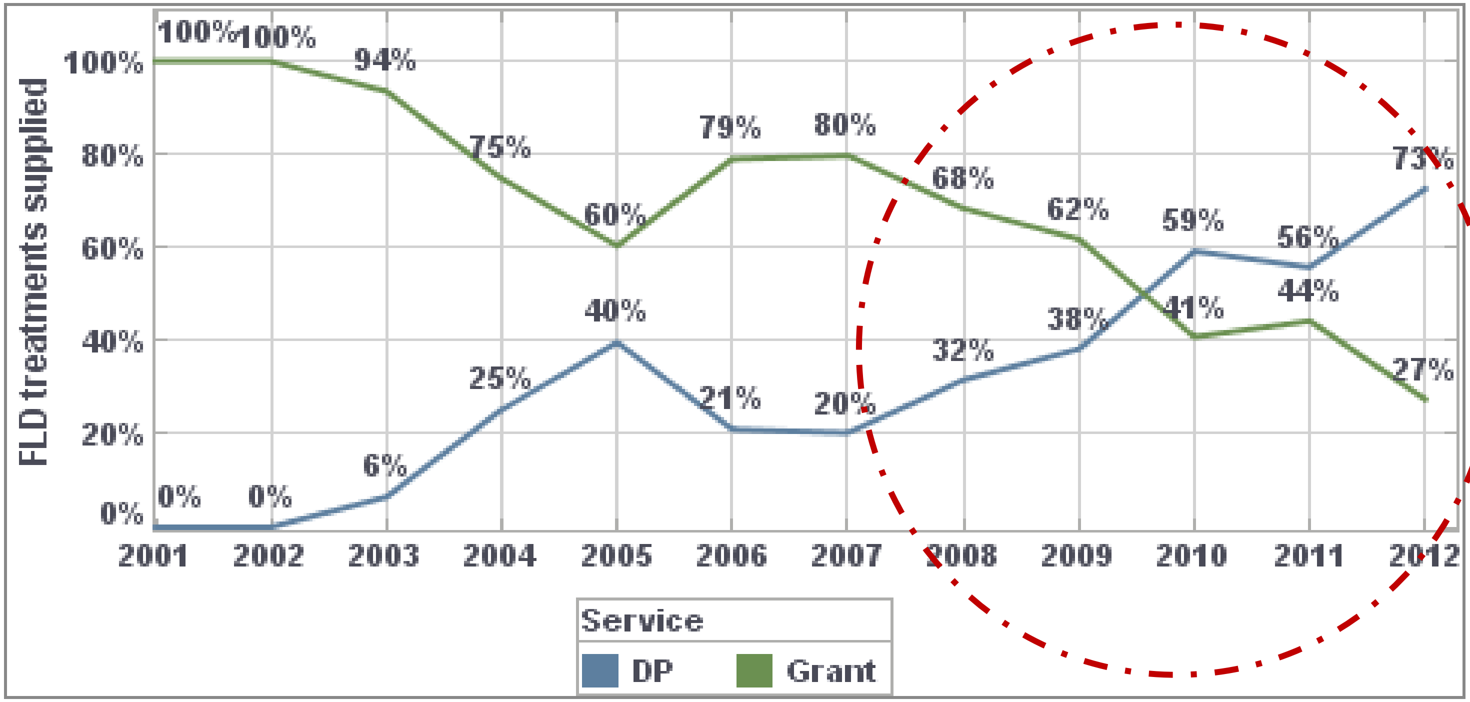


Percentage of FLD Treatments Supplied per Year by Service



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Lessons Learned so far…

- Funding availability is key but technical support and close monitoring are crucial to implement a good management system at the country level to avoid stock outs.

- Standardized methods for information collection, data management and close monitoring + early information sharing with stakeholders / in country partners at all cycle steps are key to avoid stock-outs

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Lessons Learned so far…

- Efficient planning at country level and stakeholder coordination should help to align the different processes for the supply chain and to maintain a healthy buffer stock
- Flexible Procurement Fund and Strategic Stock Pile are key interventions to implement to avoid stock-out risks
- GDF will continue to invest with partners in strategic research / data / market dynamics monitoring as a basis for reshaping operations

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Consultancy on SSP+FPF (final stage of selection)

TA activities back on board

Stock-outs Early-warning System + e&M Health Project

New Communication Strategy with partners and civil society

4. Aligning forces & partners for anticipating future demand / supply landscape

Discussion for rational introduction models for new TB drugs (*bedaquiline / Delamanid*)

Stakeholders Meeting suppliers & donors& partners

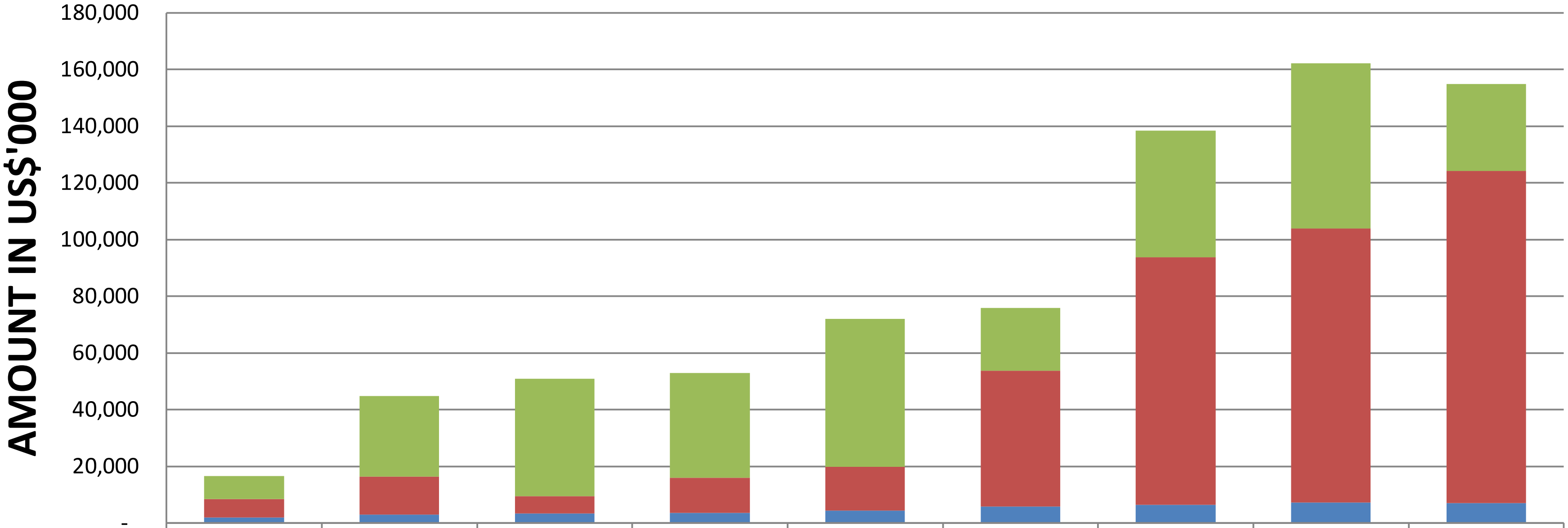
Strategic meetings with WB – PAHO on harmonization and capacity building / landscape

Linking GF portfolios Managers/grant Mngt\

Cooperation' s agreements being concluded: with CHAI (SLDs), TB Alliance and STPHI (paediatrics)

Update on GDF main achievements: cost efficiency data

EXPENDITURE TRENDS: ACTIVITY VRS PROCUREMENT



	2004	2005	2006	2007	2008	2009	2010	2011	2012
GRANT	8,000	28,367	41,344	36,847	52,098	22,134	44,598	58,164	30,631
DP	6,613	13,433	6,165	12,500	15,463	47,979	87,254	96,672	117,252
ACTIVITY	1,918	2,980	3,368	3,565	4,421	5,804	6,494	7,329	7,051

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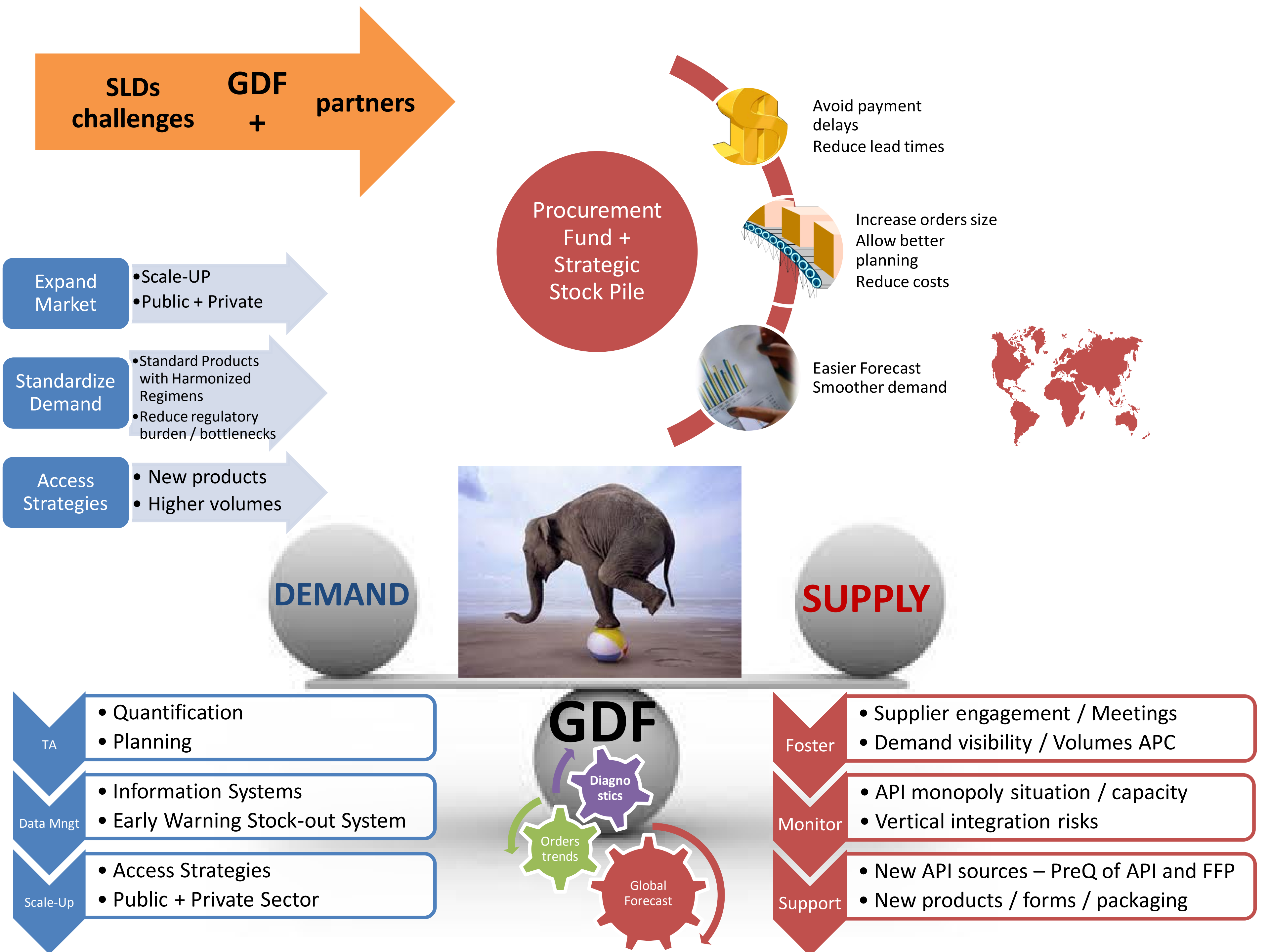
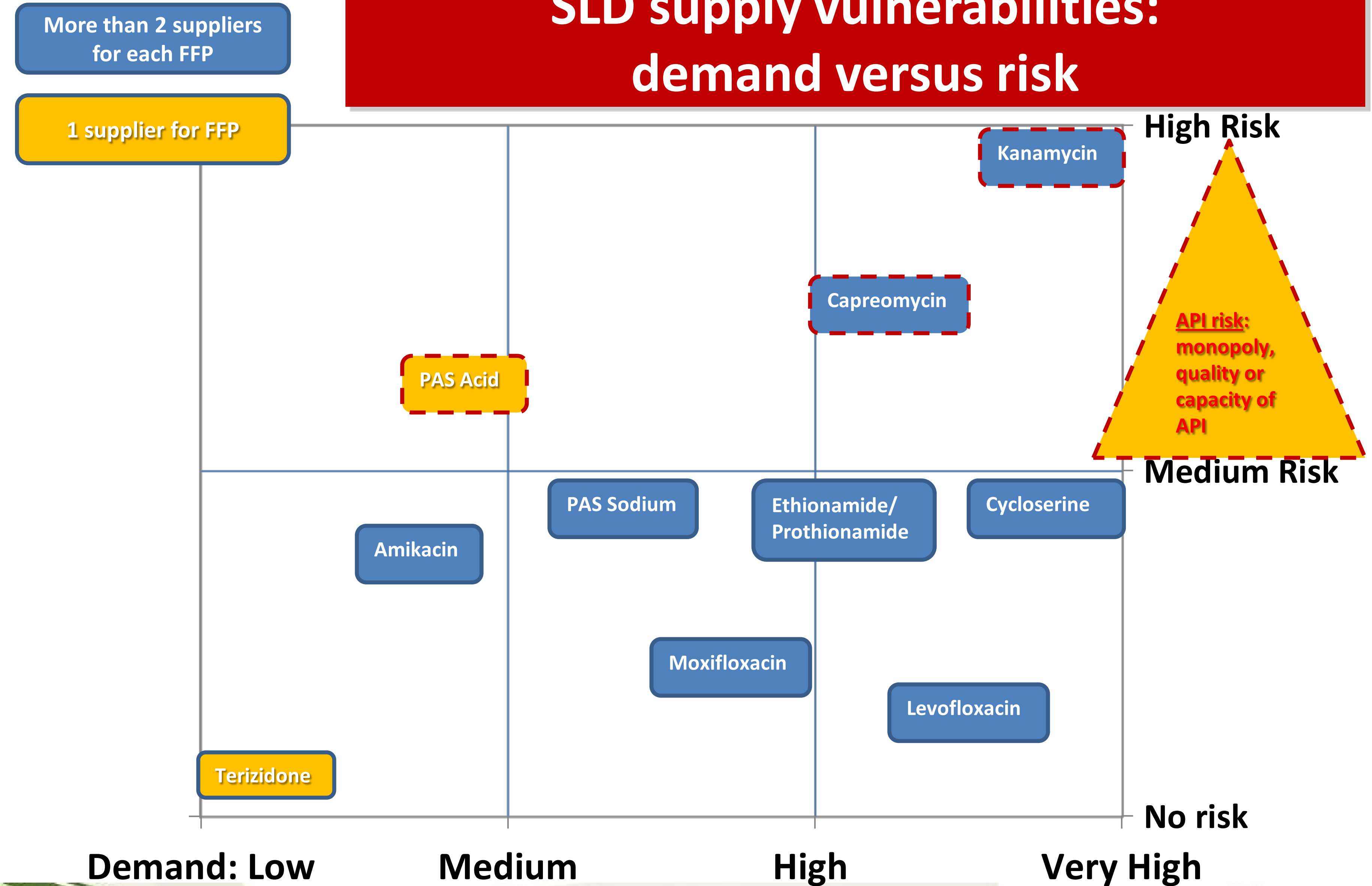
Main GDF Achievements since last Stop TB CB

	1. Focus on services delivery & Operations => Results	2. Moving ahead with the new strategic framework implementation	3. Focus on data analysis / evidences from countries to better adapt GDF model	4. Aligning forces & partners for anticipating future demand / supply landscape
				
Key Milestones	>M US$ 89 since 2013 (vs M US$ 151 in 2012) New Pas / LTAs signed TRC 28 finalized / TRC 29 planned X 2,4 # suppliers / 2009 X 3,2 # products / 2009 SLD treatment price reduced up to 27% (2012 vs 2013) Lead times decreasing Support to TBREACH, TBEXPERT and EXPANDTB	Closer country monitoring & support (New RSOs + New quantification tools) Merging FLDs/SLDs/Diag. Concept note on the global strategic stockpile + flexible procurement fund + discussions engaged with donors New organogram /TORs ISO 9001 status maintained New ordering system neing developed	Consultancy on stock-outs root causes – on-going Consultancy on SSP+FPF (final stage of selection) TA activities back on board Stock-outs Early-warning System + e&M Health Project New Communication Strategy with partners and civil society	Discussion for rational introduction models for new TB drugs (*bedaquiline / Delamanid*) Stakeholders Meeting suppliers & donors& partners Strategic meetings with WB – PAHO on harmonization and capacity building / landscape Linking GF portfolios Managers/grant Mngt Cooperation' s agreements being concluded: with CHAI (SLDs), TB Alliance and STPHI (paediatrics)
Remaining Challenges	Paediatric Grants at risk (Unitaid $ ending 2013) FLDs Grants / Emergency Gaps at risk SLDs grants ending (Unitaid $ ending 2013)	GDF remains highly understaffed (13 vs 24) Urgent need of hiring LT staff for current vacant LT positions	In country supply chain issues still a barrier Context of current GF procurement Strategic Stockpile and Flexible procurement fund urgently needed	SLDs still fragmented and fragile market Innovative actions required on demand + supply side GeneXpert /Diagnostic monitoring is key for accurate forecast


SLDs challenges
GDF +
partners
Procurement Fund + Strategic Stock Pile
Avoid payment delays
Reduce lead times
Increase orders size
Allow better planning
Reduce costs
Easier Forecast
Smoother demand
Expand Market
•Scale-UP
•Public + Private
Standardize Demand
•Standard Products with Harmonized Regimens
•Reduce regulatory burden / bottlenecks
Access Strategies
• New products
• Higher volumes
DEMAND
SUPPLY
GDF
Diagno stics
Orders trends
Global Forecast
TA
• Quantification
• Planning
Data Mngt
• Information Systems
• Early Warning Stock-out System
Scale-Up
• Access Strategies
• Public + Private Sector
Foster
• Supplier engagement / Meetings
• Demand visibility / Volumes APC
Monitor
• API monopoly situation / capacity
• Vertical integration risks
Support
• New API sources – PreQ of API and FFP
• New products / forms / packaging

SLD supply vulnerabilities: demand versus risk



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New approaches with Unitaid : GDF potential contribution to the paediatric TB drugs market

- On-going study commissioned to assess current status of last advice uptake by countries
- New formulations projected to be only available Q2 2016
- Expected that GF will incorporate paediatrics into new grants
- GDF potential contribution to Global TB Alliance project
  - Innovative packaging / kits
  - Support to countries with new tools for planning / forecast uptake and roll-out at country level
  - Pool procurement and prices decrease / market shaping activities
  - 5 Year project > 1.ground work/2.planning/3.uptake/4.implementation 5.ME/transitioning

New approaches with Unitaid : involving private sector to drive demand for IQA SLDs

- Donor-supported market only provide access to 19% of MDR-TB burden, mainly via the public sector

- Private sector is using drugs of unknown quality + not WHO recommended regimens
- Private sector is accountable for an important segment of SLDs drugs / BRICs like India, Russia - countries like Philippines, Vietnam, Indonesia currently scaling-up their MDR-TB programs with PPM interactions
- Attracting this segment by offering subsidized IQA SLDs to private clinics to drive demand for IQA SLDs is a possible exploratory pilot intervention

Main recommendations for the way forward (1)

1. Staffing GDF with the right mix of skills (FT and ST staff)
2. Empower a manager with acting capacity to conduct reforms
3. Focus and engage on the 2 interventions considered as of high impact by suppliers and countries:

Strategic Stock Pile + Flexible Procurement Fund

These interventions require donors multi-year high level commitment and a sustainable coordinated support from partners to bring results:

- Role of GF => major funding agency to countries for drugs procurement
- Role of other donors like Usaid, CIDA, Kuwait Fund, Unitaid (sustain initial projects) => operational sustainability
- Role of GDF and partners: Development of innovative management model with situation room / Early Warning Stock-out system + disseminating country monitoring framework

ISO 9001 CERTIFIED ISO QUALITY MANAGEMENT SYSTEM

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Main recommendations for the way forward (2)

5. Ensure gaps / short falls for FLDs/SLDs/Paediatrics will be covered through grants for countries still depending on GDF / donors => shared responsibility

- GF grants to cover all medicines (including some buffer)
- Other donors to ensure emergency grants => available

6. Continue to explore new mechanisms for new TB drugs introduction => markets

7. GDF to continue as a catalyst/platform for leveraging synergetic partners activities

8. Keep current ''open'' agenda with partners on market research, producing evidences and data from countries

Discussion

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