

Subject: Information Note – Sourcing & Market Dynamics Strategic Review Process

I am pleased to share that, from the **1st to the 3rd of October 2014**, the Global Fund Sourcing Team will introduce Strategic Review Meetings in Sourcing and Market Dynamics. This is a new collaborative mechanism which can help the Global Fund, to achieve common objectives and eliminate duplicity of effort, together with interested Partners. There are four components of our Strategic Review Process. These are:- continued **capability** development; **coordination**, **connection** and **cooperation**, among those who opt to participate in the Strategic Reviews.

Background

The Global Fund Procurement Transformation process has resulted in increased operational and strategic capability, in bringing health commodities to the countries we serve. Simultaneously, we have strengthened key elements required to ensure program scale-up, over time. Such elements include rapid and appropriate task execution; and development of an in-depth knowledge of manufacturer capacity - and of the COGs¹ of core products we procure. New skill sets within the procurement team, have also enabled leverage and application of important thought leadership in market-shaping and in other areas, such as partnership building, (from multiple external sources).

Coordination

Looking back over the past 18 months; The Global Fund seeks to implement Strategic Review Meetings as a mechanism to facilitate improved sharing and coordination. The anticipated review meetings will help us to harmonize our approaches, in that time and frequency spent together will enable:- i) information sharing and learning; ii) agreement and division of labor for future activities; iii) decisions on mutual performance indicators and reporting, to increase accountability; and iv) concurrence on feasible timelines for joint interventions. Ultimately, this coordination will help to increase transparency in the lifecycles of the drugs, pipelines, supply chains and services relevant to Global Fund and Partner activities in HIV/AIDS, TB and Malaria.

Connection

The Process will fundamentally serve as a connector of the intelligence and strengths created from The Global Fund's current activities - to the competencies and strengths of our key Partners.

In greater detail, we envisage the review and connection process as follows:-

- A regular review, twice annually, with representation from interested parties and partners:-

¹ COGs - Cost of goods sold

- i) This reviews would take place over two or three days with content divided along the lines of organization and process; the three disease areas; indirect procurement; and final results as compared against objectives.
 - ii) The first day will be a review of all current Global Fund activity in terms of sourcing / procurement and supply chain with a candid review of performance, successes and failures and opportunities for improvement. Days two and three will be deep dives into specific topics of interest to partners with a view to launching a greater level of market dynamics understanding, collaboration and integration.
 - iii) There are three communities that have shown interest to come together to increase the reach of our work. They are, our “thought leadership” partners such as UNITAID, CHAI and GATES; our leverage partners such as PEPFAR, DFID and large country procurers; and the private sector. Analysing competencies/ capabilities and building more complementary relationships among these communities would help greatly, in responding to gaps and problems in procurement, and in market dynamics - as we search for feasible, cost-effective solutions.
 - iv) It is envisaged that the data and coordination that the review process would provide, will enable a much clearer definition of the work we do, to support access related decisions - to be taken by the governing body, of Global Fund Procurement and Supply Management activities.
- *Specific expected outcomes of the Strategic Review Process are:-*
 - Reduced Costs with embedded capability
 - Facilitated innovation throughout the product lifecycles
 - Creation of product market & supply experts
 - Ownership of relationships, up and downstream
 - Simple user designed processes
 - Comprehensive market intelligence
 - Speed to market would improve exponentially!
 - A single logical flow parallel to product life-cycle
 - Single understanding of the market needs and requirements to fulfill common objectives, timelines and reporting
 - Seamless workflow

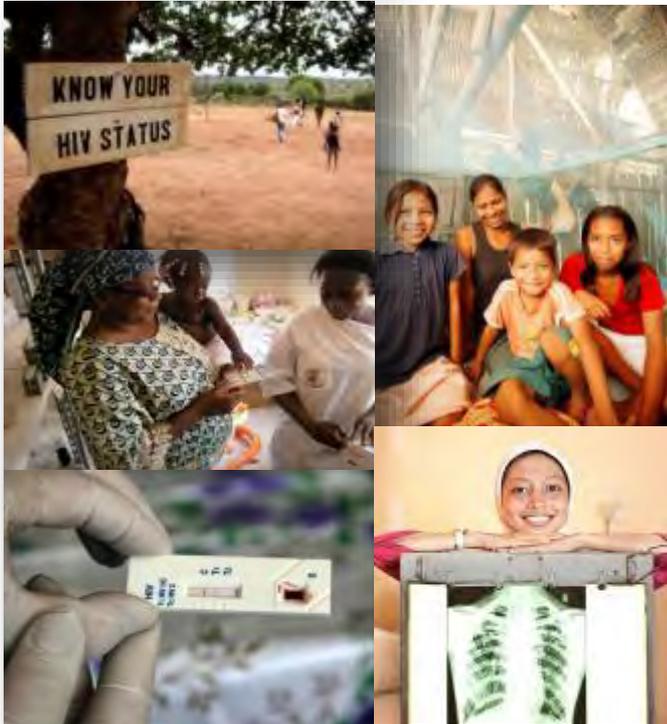
Cooperation

As previously stated, introduction of structured review meetings in sourcing and market dynamics, can help the Global Fund and Partners share data, information, ideas and activities. To be highly productive, the 1 – 3 October 2014 meetings will be chaired by Todd Summers, in a cooperative environment. I hope you will join the Global Fund Sourcing Team, to work in an open and collaborative manner. This will escalate the opportunities for optimization in our joint current /future activities; - and help to define who should own fulfilment of which activities, with shared accountability, timelines and reporting.

Kind regards,

Christopher Game

Chief Procurement Officer (CPO)



GF Strategic Reviews in Procurement and Market Dynamics Day 1

Co-hosted with UNITAID

Starling Hotel, Geneva

1 October 2014

Day 1 - Agenda

Type	Time	Topic
●	08.30 – 08.55	Registration: (Coffee and Tea available)
●	09.00 – 09.20	Welcome and Introductions - Speakers and Organizations. Speed networking
●	09.20 – 09.40	Opening Remarks and Overview of Agenda
●	09.40 – 10.00	Overview of Sourcing and Market Dynamics at the Global Fund
●	10.00 – 10.20	Overview of UNITAID - and Market Dynamics
●	10.20 – 10.40	A Personal Story : GF Impact - Obatunde Oladapo
●	10.40 – 11.00	Coffee/ Tea break
●	11.00 – 11.25	Keynote Address
●	11.25 – 11.45	Feedback Session 1: Q&A
●	11.45 – 13.15	Sourcing Transformation across HIV, TB and Malaria - Q&A
●	13.15 – 14.15	Lunch
●	14.15 – 15.10	Supply Chain Presentations and Action Lab
●	15.10 – 16.00	The E-marketplace - and Idea Lab
●	16.00 – 16.20	Coffee/tea break
●	16.20 – 17.15	Feedback Session 2: Q&A – including response to twitter wall
●	17.15 – 17.30	Closing Remarks
●	18.00 – 20.00	Reception at the Starling Hotel

Purpose of the Strategic Review Meetings

To identify effective and efficient ways to leverage thought leadership – and for stakeholders to support each other, in harmonizing approaches.

Welcome

125 attendees from **45** organisations with **34** speakers

Aidspan

AMDS

CDC

CHAI

DFID

DNDi

Eli Lilly Foundation

Friends of the Global
Fight

G Alliance for TB drug
development

Gates Foundation

Ghana

GIZ

Global Development

Global Fund

Global Fund SIIC

IDA Foundation

KNCV

LSHTM

McKinsey

MMV

MSF

MSH

NICE

Nigerian CS &
Activists Network

PAHO

PEPFAR

OGAC

PFSCM

PMI

RBM

South Africa

Stop TB Partnership

Stop TB Partnership
(GDF)

TAG

Tropmed Pharma

UNAIDS

UNDP

UNICEF

UNITAID

United States

Pharmacoepia (USP)

UNOPS

USAID

USG TB

WFP

WHO

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Sourcing Update on Transformation and Strategy

Christopher Game,
Chief Procurement
Officer

September 2014

1. Introduction and Background

2. Organization

3. Direct Procurement

4. Supply Chain

a. Upstream

b. Downstream

c. Compliance

5. Systems and Tools

a. 100 Things

b. Strategy Tool kit

c. Amazon.com for Aid / Indirect Procurement

d. Training

Stepping back: why is the Global Fund involved in Sourcing?

Over the last 7 years, the Board determined that the **organization should play a greater role in procurement and market shaping** of health products that it finances with 4 objectives¹

- 1. Accelerate the introduction and maturation** of new, more cost-effective products;
- 2. Ensure recipients procure the most cost-effective,** WHO-recommended health products or regimens that meet the Global Fund quality assurance policies;
- 3. Strengthen countries' capacity** to implement strategic procurement practices;
- 4. Ensure the continued availability, affordability, and innovation of products,** including those for which there are not currently sustainable market conditions. through multiple approaches

¹ GF/B23

Procurement 4 Impact (P4i) approach follows 6 objectives fully aligned with the Global Fund' strategy

1 The Global Fund will become the **benchmark organisation** in the sector for **Sourcing and Procurement**

2 Using **simple, clear leading edge processes and tools** designed by and for the organisation

3 With **measurable performance** in value and lives saved



6 **Minimising waste** and eliminating non value adding activities

5 Ensuring **effective governance** and **watertight compliance**

4 Building **collaborative relationships** with partner agencies, suppliers and donors

Stepping back: why does procurement matter?

36.8%



70.0%

**Rate of orders delivered On
time and in Full (OTIF)**

**And while some of this performance will reflect in the quality of lives of patients,
much of it will reflect in the mitigation created by countries to deal with it**

Global Fund has stepped up its sourcing and procurement strategy through a *Procurement 4 Impact (P4i)* transformation

One Sourcing team dedicated to fundamentally change the way we work across the supply chain to **increase access to products**



Earlier involvement and closer collaboration with manufacturers

Improving our purchasing capability and changing our contracting models

Optimising the international supply chain to reduce cost and improve quality and efficiency

Better planning and scheduling to support continuity of supply

Delivering more products at the right time and place to more people

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Sourcing team is gradually building expertise and knowledge at all supply chain levels

Team re-organized and reinforced...

- (In)Voluntary Pooled Procurement, Corporate procurement and Amfm merged into one single Sourcing team
- New Indirect / Direct Sourcing, Supply Chain, and Business Intelligence teams created, with greater capability
- We have created product, market and supply experts (e.g., Business Planning and analysis, Active Pharmaceutical Ingredients and Formulation)



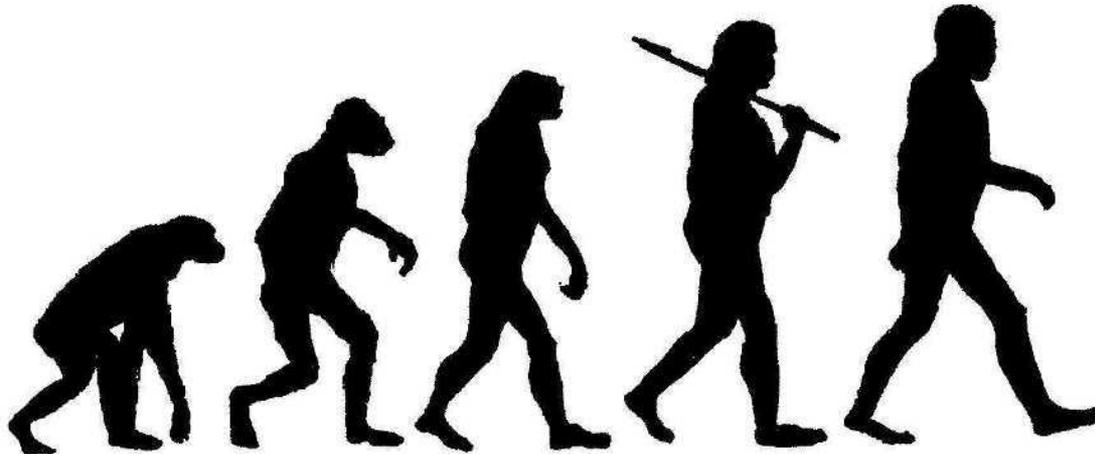
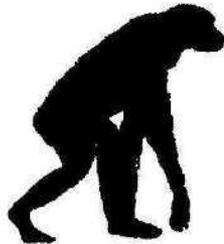
With greater responsibilities...

- Spend under control is increasing, PP up to \$1.2Bn
- Relationships upstream and downstream are accountable
- Changing the locus of control from manufacturer to buyer

Snapshot in time versus DNA



Snapshot or Project based work often lacks the consideration of the evolution of product lifecycles, data, funding, potential for industrialization and scale up etc.

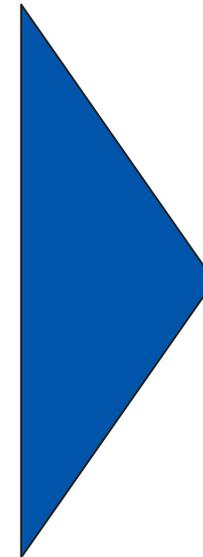


Capability has to be embedded, part of or organizational DNA

What does this mean.....



- *Insourcing of Sourcing*
- *Pooled disbursement*
- *Scale & Leverage*
- *Organization and Tools*



**Become a
Customer
of Choice**

Insourcing of Sourcing

- **Voluntary Pooled Procurement has evolved into Sourcing**
- **Team with greater capability**
- **Spend under control is increasing**
- **We have created product, market and supply experts**
- **Relationships upstream and downstream are “owned”**
- **Reduced agency costs**
- **Changing the locus of control from manufacturer to buyer**



Pooled disbursement

- **The award of framework agreements based upon multiple requirements from multiple countries**
- **Direct payment to vendors = improved funds flow**
- **The ability to leverage fragmented spends**
- **The ability to incentivize desirable behaviors or performance**



Scale & Leverage



- **Partnering at various levels with donors and partner organizations**
- **Harmonized specification**
- **Harmonized demand**
- **Control – GF and partners dictate parameters**
- **Protecting Innovation**
- **Reduced Lead times 9mths-6mths-4mths**

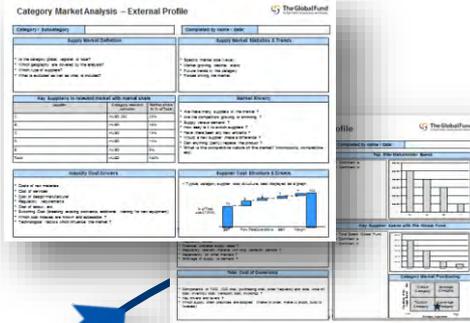
Organization and Tools



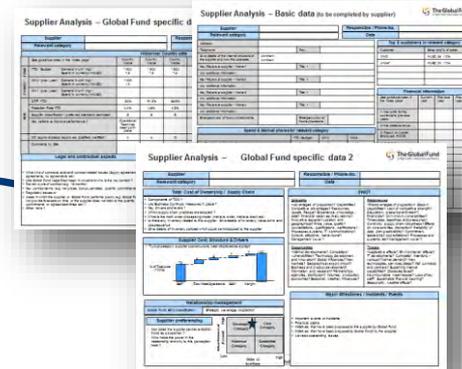
- **Comprehensive market intelligence**
 - **Upstream Active Pharmaceutical Ingredient and Formulation**
 - **Cost of goods sold transparency**
 - **Downstream supply chain**
- **Track and trace**
- **Reference App.**
- **Tender and E-Procurement capability**
- **Rapid Supply Mechanism**
- **e-Marketplace**

A Rigorous Foundation.....More from Tala later!

Market Analysis

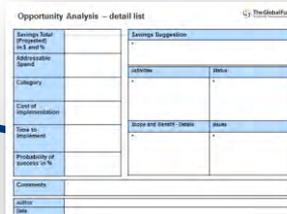
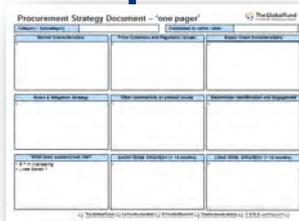


Supplier Analysis



Our Strategic Cycle

One Page Strategy



Opportunity Analysis



API & Formulation Review

Review and Shape: Strategic Review Meeting

Strategic review

- Held twice a year in Geneva for 2 or 3 days
- Linked to an FOPC or SIIC meeting (before or after)
- Held over three days
- Independently Chaired
- Attended by partners, donors, normative agencies, implementing countries, consultants
- Draws on UNITAID collaboration

Day 1

- Critical review of previous 12 months and outline of activity for next 12
 - HIV
 - Malaria
 - Diagnostics
 - TB
 - Supply Chain
 - E-Marketplace

Days 2 & 3

- Deep dive with all concerned partners into a specific topic, pre-selected on a needs basis by the Global Fund and UNITAID.

Day 2

- Day 2 will cover HIV diagnostics.

Day 3

- Day 3 will cover TB

The UNITAID MOU

Shaping Markets for Increased Access

The basis of the Partnership

Ensure more rapid development and uptake of high-quality medicines and diagnostics through market-shaping activities that increase access among underserved populations.

Promote simpler treatment, including fixed-dose combinations and point-of-care diagnostics that improve adherence and reduce pill burden and opportunity costs for patients.

Improve the value-for-money of donor investments by achieving greater market effect and public health impact.

1 Identify opportunities for strategic cooperation in market-shaping and access interventions

2 Identify opportunities for strategic cooperation in market intelligence activities

3 Measure market and public health impact.

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Direct sourcing aims at optimizing upstream sourcing and procurement of health products

- **Reviewing suppliers, formulators and API manufactures' COGS, process and capacity.**
- **Shifting from market based to COGS based pricing structures**
- **Ensuring sustainability and the best possible value for money.**
- **This is has been achieved by in-sourcing sourcing**
- **Creating Scale and leverage**
- **Improving funds flow**
- **Engaging and contracting directly with manufacturers**
- **Improving forecasting and closing down fragmentation**
- **Making us a customer of choice**

P4i Transformation – Strategy meets Delivery

	Market Analysis	Supplier Analysis	API & Form	Strategy	Partnering	Opportunity Analysis	Project	Implementation	Repeat Cycle
Malaria	Green	Green	Green	Green	Green	Green	Green	Green	Red
HIV	Green	Green	Green	Green	Green	Green	Green	Red	Red
TB	Green	Green	Yellow	Green	Yellow	Red	Red	Red	Red
Diagnostics / Machine	Green	Green	Yellow	Yellow	Yellow	Red	Red	Red	Red
Diagnostics / RDT	Yellow	Yellow	Red	Red	Yellow	Red	Red	Red	Red
Indirect Spend	Green	Green	Green	Green	Yellow	Yellow	Yellow	Yellow	Yellow

July 2013 → Approximate Time Dec 2014 →

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Supply chain aims to improve delivery performance and mitigate risks

- **Improve availability of products/reduce stock-outs, improve OTIF and reduce lead-time**
- **Increase visibility on supply chain**
- **Improve in-country supply chain capability**
- **Improve counterfeiting/theft/diversion avoidance**
- **Improve manufacturers quality**
- **Take an integrated approach with partners**
- **Build a lean, skilled and efficient supply chain team**

Upstream: The Rapid Supply Mechanism will address stock-outs leading to treatment disruptions

HIV: Responding to Stock-outs & Supplying Regular Orders

- Selected commonly used ARVs
- Rapid Supply to any GF PR in shortage
- Regular Supply to Cameroon, Côte d'Ivoire, Nigeria (+ potentially other PPM PRs)

TB: Market Shaping & Responding to Stock-outs

- Majority of Second Line Drugs
- Rapid Supply to any GF PR in shortage
- Regular Supply to any GF PR & potentially other countries (TBD)

IDA Facility,
Netherlands

IHS Facility,
Accra

IHS Facility,
Johannesburg

Manufacturers to be selected from ACT tender winners; locations indicative only

Low-volume Paediatric HIV: Market Shaping Only

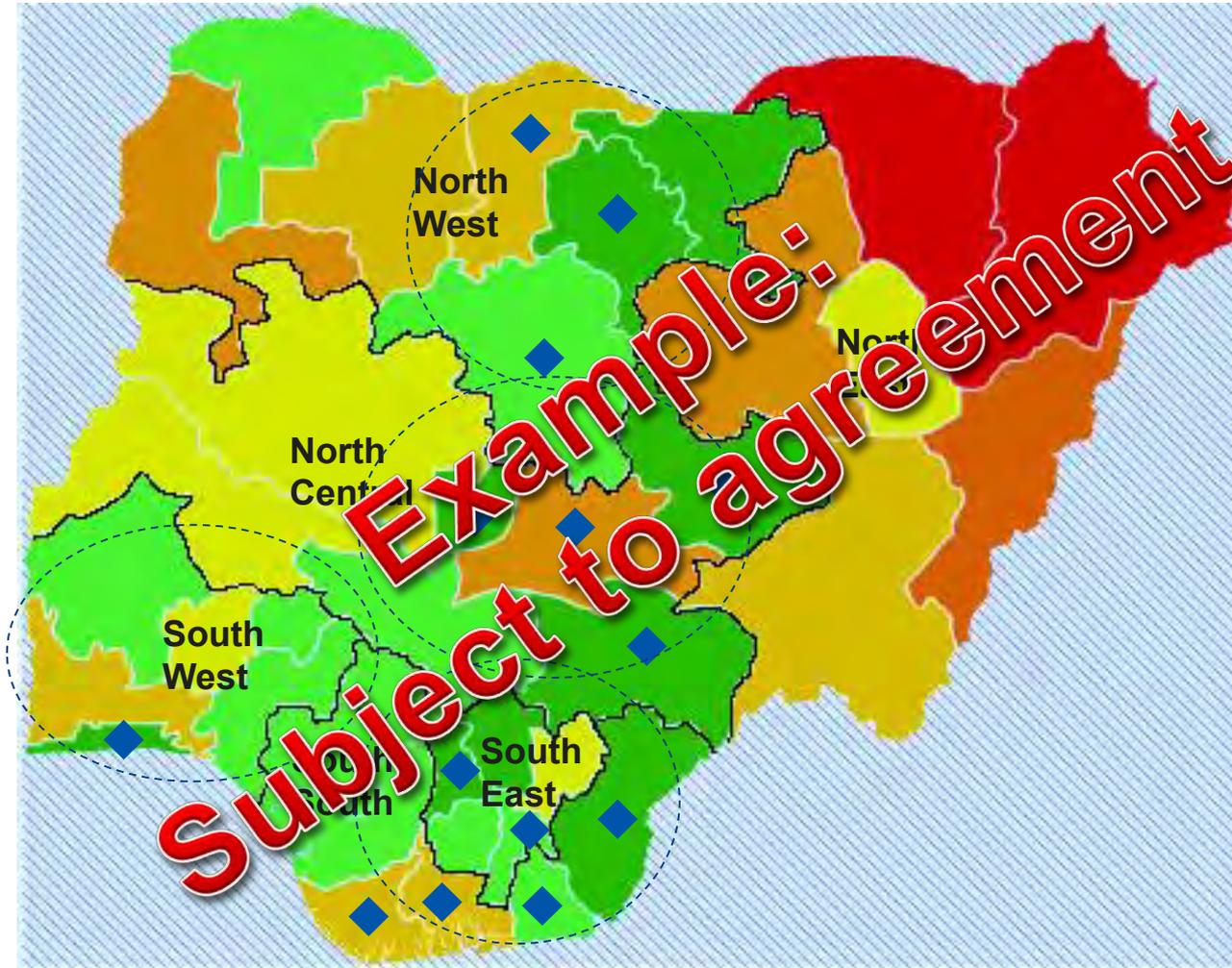
- Selected Paediatric ARVs where demand aggregation is needed to secure supply
- Regular Supply to any GF PR + other agencies (CHAI, UNICEF, ...)

Malaria: Stock-out Response Only

- Most commonly used ACTs
- Stock to be held by manufacturers, who will also supply regular orders as normal
- Rapid Supply to any GF PR in shortage

Downstream :- In country supply chain: example of Nigeria

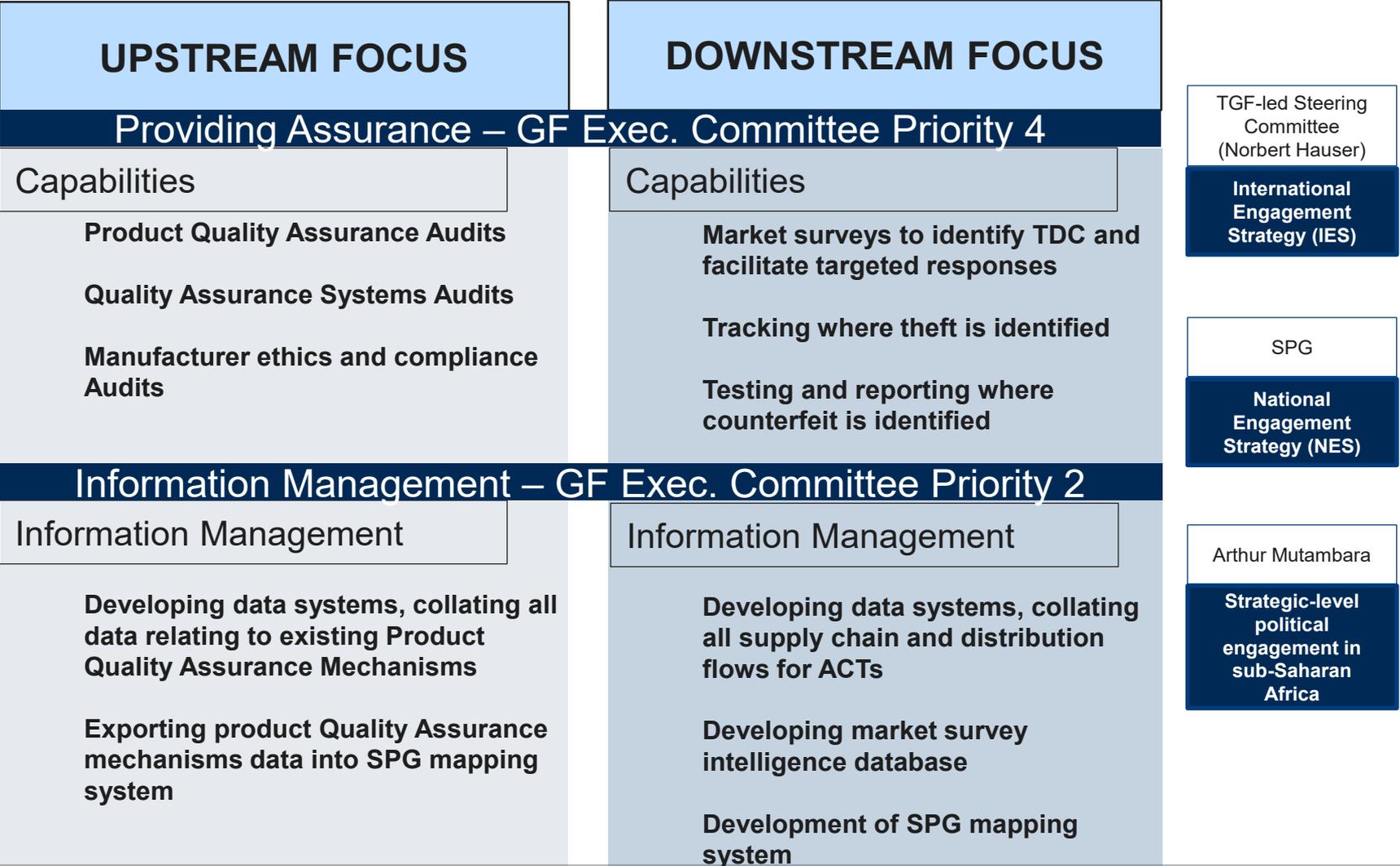
Program scope – 2014 to 2017 for 14 Focus States



- ◆ Lagos
- ◆ Abuja
- ◆ Plateau
- ◆ Nasarrawa
- ◆ Kaduna
- ◆ Rivers
- ◆ Cross River
- ◆ Benue
- ◆ Akwa Iborn
- ◆ Abia
- ◆ Anambra
- ◆ Bayelsa
- ◆ Kano
- ◆ Katsina

Sourcing Unit Special Projects Group (SPG)

Assuring Legitimate Supply Chain, Product Quality, and Detecting, Preventing and Responding to Theft, Diversion, and Counterfeiting of Medicines



Strengthening Partnerships – Exec. Committee Priority 5

-
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Systems and Tools

- **Comprehensive market intelligence**
 - **Upstream Active Pharmaceutical Ingredient and Formulation capability**
 - **Cost of goods sold transparency**
 - **Downstream supply chain**
- **Track and trace is up and running on ARVs, ACTs and available on LLINs in October**
- **100 Things as a precursor to a wider platform (Amazon)**
- **Tender and E-Procurement capability**
- **Rapid response mechanism**

A groundbreaking e-marketplace would enable to source aid products and commodities from multiple suppliers

Online marketplace

Buyers

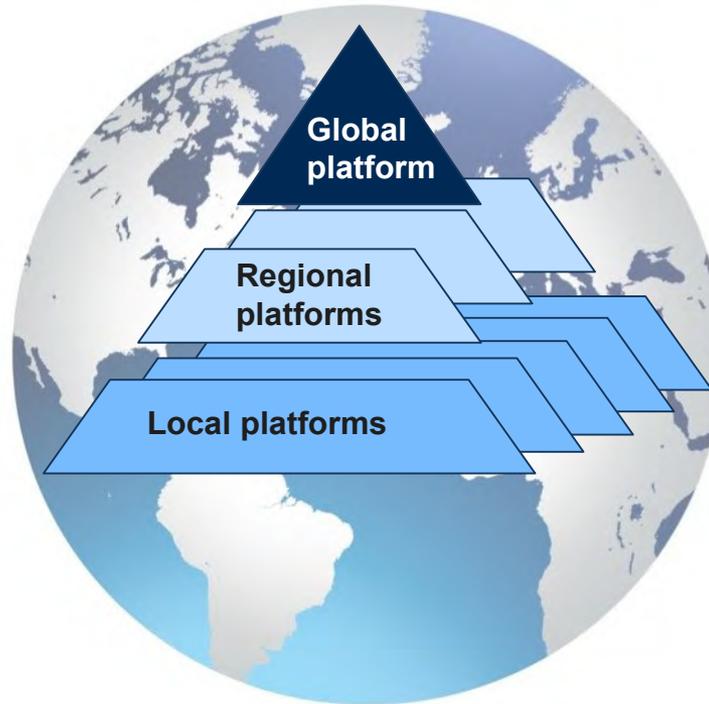
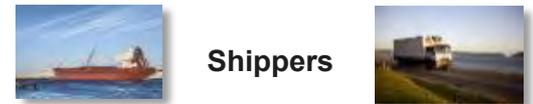
Recipients countries



Aid agencies



Suppliers



- An online marketplace where buyers and suppliers meet to buy and sell products and services
- Intended to Global Fund recipients at first, with the aim to spin it off as a self-sustained sourcing platform for aid

How are we evolving ?

Under our current strategy - *Maximized within our current strategic remit*

<p>\$1.2 - \$1.6Bn under control</p> <p>Pooled Procurement</p> <p>Mix of mature and new enrolments</p>	<p>Fragmented / Tail or Countries outside of pooled mechanisms</p>	<p>Countries Procuring with own or other donor funds</p>
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- This has created leverage for our spend within our existing remit
- Smaller countries or those who lack the scale for wider assistance do not benefit from this
- Countries with good procurement systems do not benefit from this
- Countries procuring with own funds do not benefit from this
- Pooled Procurement lacks a graduation mechanism as capability and capacity are built
- Regional approaches are very difficult

Under our future strategy

<p>Pooled Procurement</p>	<p>Fragmented / Tail or Countries outside of pooled mechanisms</p>	<p>Countries Procuring with own or other donor funds</p>
<p>>\$15B under control Market Place Exchange (M_aX)</p>		

- We are migrating to a model that facilitates governance and manages risk
- Increased leverage, access, partnering and accountability
- Creates a natural transition from a punitive “VPP”
- The ability to manage Quality
- The ability to create sufficient leverage for local manufacture
- Country level mentoring by TGF sourcing a key factor

Let's re-cap:- From 2013 To September 2014

Jan 2013

- Reactive procurement based on grant disbursement
- Spot tendering through PSA
- Minimal cross agency leverage
- Multiple negotiation processes
- Stock-outs and missed delivery windows
- Lack of standardised processes between Sourcing and PSM
- Wide discrepancy in prices between VPP and non VPP purchasing



September 2014

- Procurement based on improving forecast demand
- Long term, multi agency, collaborative contracts
- Single negotiation process
- A standardised project based approach.
- Contractually assured best price promulgated to all PRs and / or countries and partners that might benefit from leveraged, value based procurement.

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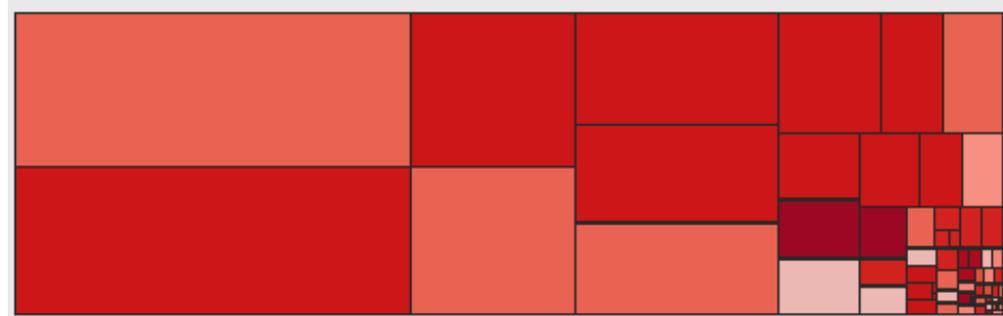
Global Fund Strategic Reviews in Procurement and Market Dynamics

Overview of UNITAID and Market Dynamics

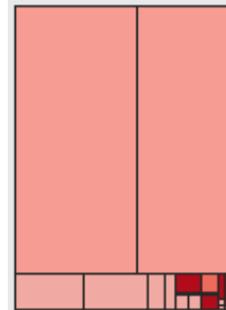
Philippe Duneton
Executive Director a.i.
Geneva
1 October 2014

Donor-Funded purchases of medicines by product formulation and pack size, 2012

HIV/AIDS



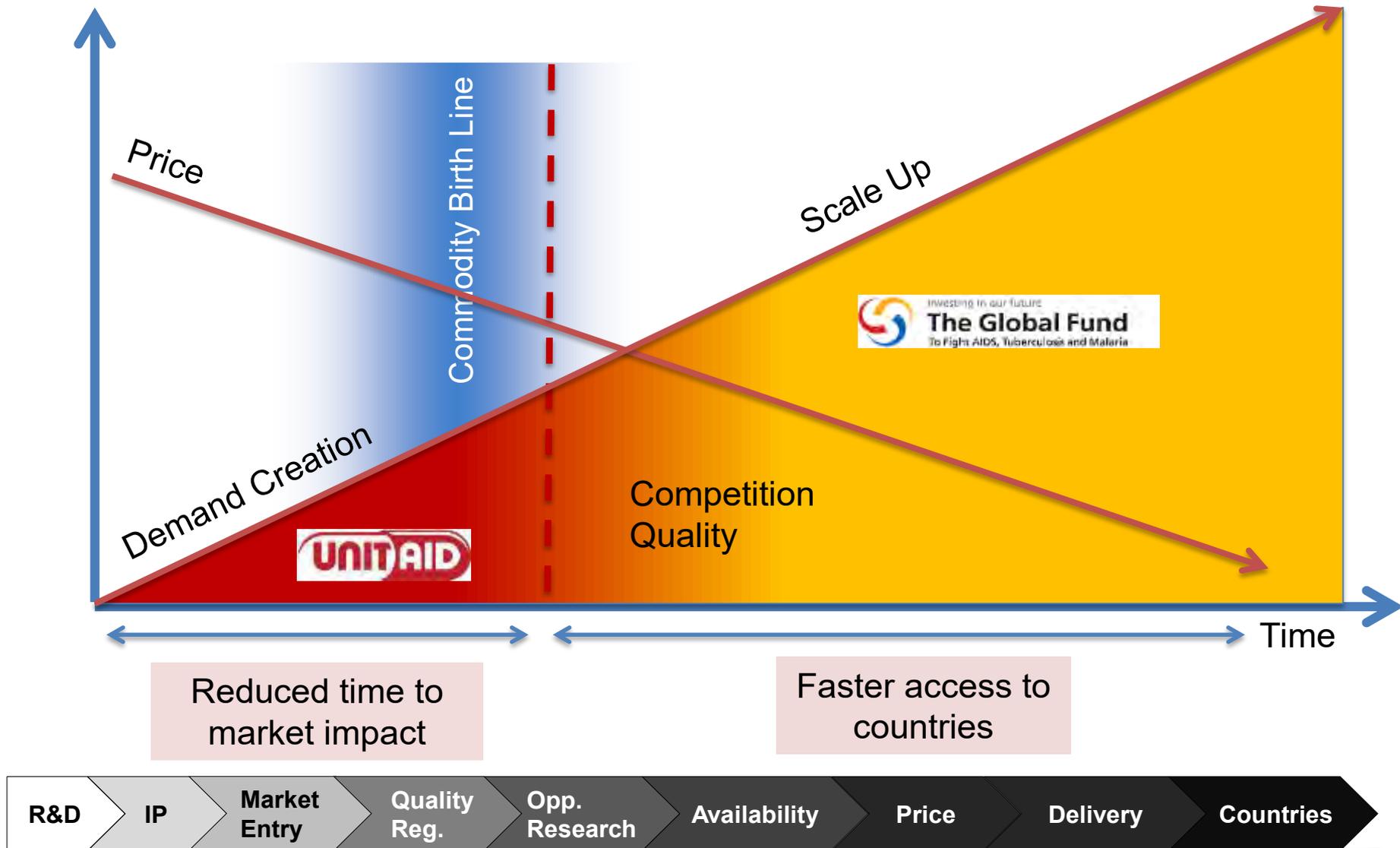
Malaria



Tuberculosis



UNITAID and GFATM



Aim of UNITAID - Global Fund

Joint collaboration

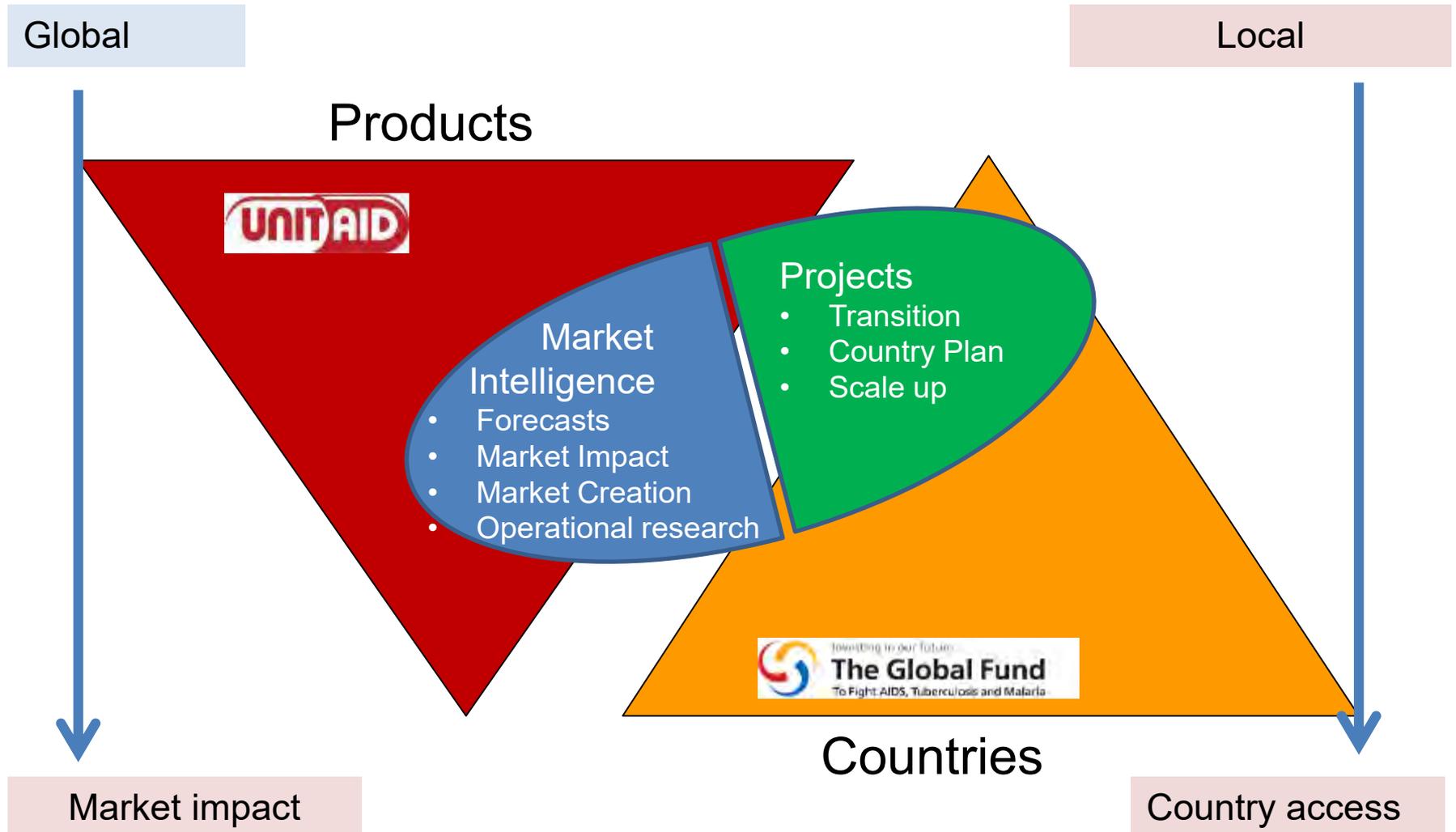
- **Ensure more rapid development and uptake of high-quality medicines and diagnostics** through market-shaping activities that increase access among underserved populations.
- **Promote simpler treatment**, including fixed-dose combinations and point-of-care diagnostics that improve adherence and reduce pill burden and opportunity costs for patients.
- **Improve the value for money** of donor investments by achieving greater market effect and public health impact.

Strategic Framework

UNITAID – The Global Fund

- Commitments of the two organizations
 - The assessment of needs and opportunities, together with the review of potential resource implication, key priorities and intervention activities for 2014
 - The development of a cooperation plan for 2015
 - Track implementation
 - Develop specific KPIs
 - Report to each Board on activities and achievements

UNITAID and GFATM



How UNITAID intervenes

UNITAID's role depends upon the particular circumstances in a given market:

- **Market catalyst:** identify and facilitate adoption and uptake of new and/or superior public health products;
- **Market creator:** provide incentives for manufacturers to produce otherwise unattractive products with low demand that yield little profit but substantial public health benefit to those in need; and
- **Market “fixer”:** address severe market inefficiencies (e.g. grossly inaccurate demand forecasts and excessive transaction costs) that contribute to low access to quality-assured public health products.

UNITAID Market Effects Framework

The Framework underpins every UNITAID intervention:



Five **categories** of 'market shortcomings':

Affordability - Availability - Quality - Acceptability - Delivery

Example **reasons** for market shortcomings

- Absence of market
- Lack of external grant funds when commercial incentives are insufficient
- Unbalanced market structure (e.g., monopsony/oligopsony)
- Structural & capacity issues along the supply chain
- Barriers to market entry & exit

UNITAID's Six Strategic Objectives

SO1: Increase access to simple, point-of-care (POC) **diagnostics** for HIV/AIDS, TB, and malaria

SO2: Increase access to affordable, adapted **paediatric medicines** to treat HIV/AIDS, TB, and malaria

SO3: Increase access to emerging medicines and/or regimens, as well as new formulations, dosage forms, or strengths of existing medicines that will improve the **treatment of HIV/AIDS and co-infections** such as viral hepatitis

SO4: Increase access to artemisinin-based combination therapies (ACTs) and emerging medicines, including paediatric formulations, that in combination with appropriate diagnostic testing will improve the **treatment of malaria**

SO5: Secure supply of second-line TB medicines, and increase access to emerging medicines and regimens that will improve **treatment of both drug-sensitive and multi drug-resistant TB**

SO6: Increase access to **preventives** for HIV/AIDS and malaria

Landscape Analysis
UNITAID
Dx
Meds
Prev

Market Forum
HIV
TB
Malaria

UNITAID MARKET DYNAMICS DASHBOARD (Updated August 2014)

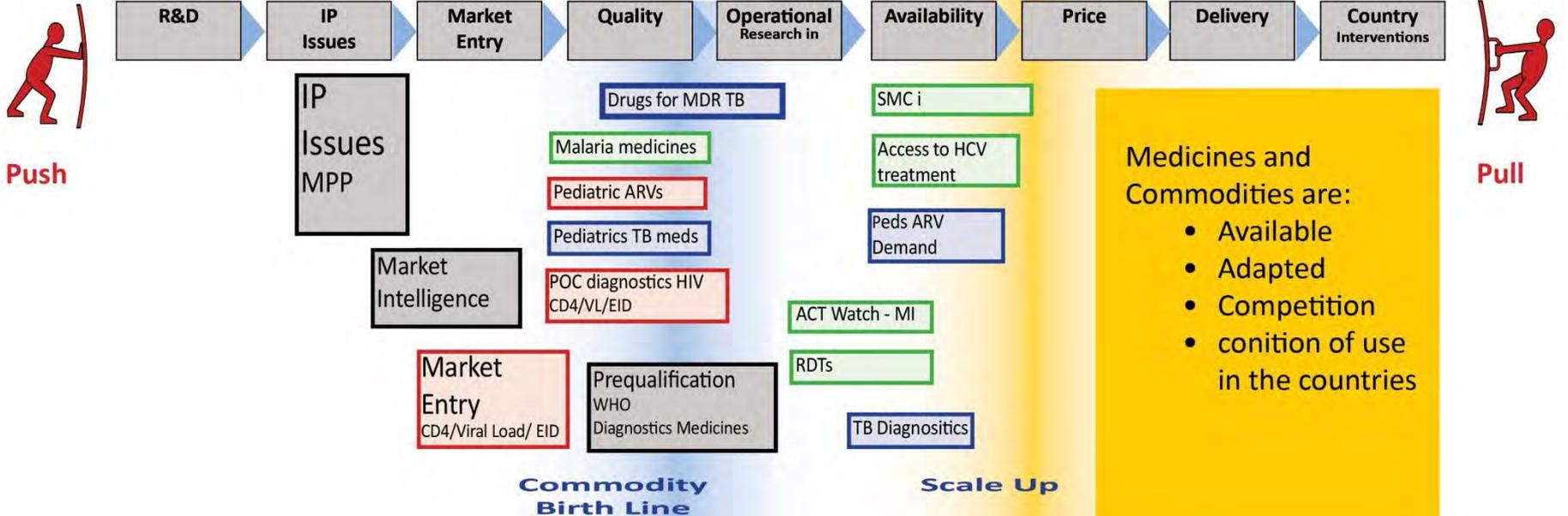
Disease Sub-type	Product Sub-type	Across Estimate (August 2014)	Current Market Shortcomings*					Opportunity for Intervention**	
			Availability	Quality	Accessability	Affordability	Delivery	Current Shortcomings** (August 2014)	Over next 4 years
M	Adult first-line	300k*	X	XX	XX	X	High	Med	
	Adult second-line	80k*	X	XX	XX	XX	High	High	
	Paediatric	200k*	XX	XX	XX	XX	High*	Med	
	Paediatric C co-infection	10k*	X	XX	X	XX	High	High	
	Adult diagnosis	100k*	XX	XX	XX	XX	High	High	
D	Early infant diagnosis (EID)	300k**	XX	XX	XX	XX	High*	High	
	CD4	<100k*	X	XX	X	X	Low*	Low	
	Viral load (VL)	<100k*	XX	XX	XX	XX	High*	High	
	Male circumcision	100k*	XX	X	XX	XX	High	Med	
	Female condoms	80k**	X	XX	XX	XX	Low	Low	
P	Microbicides	80k**	XX	XX	XX	X	Low	High	
	Pre-exposure prophylaxis (PrEP)	80k**	X	XX	XX	XX	Low	Low	
	Adult first-line	500k**	XX	XX	XX	XX	Low	Med	
	Adult second-line	170k**	XX	XX	XX	XX	Med*	High	
	Paediatric	10k**	XX	X	XX	XX	High*	High	
Tuberculosis	Adult diagnosis	100-150 Tn 100-150 Mln 15-20 5-10 2011**	X	XX	X	XX	Med*	High	
	Adult	<100 patients <100 patients**	X	XX	X	XX	Med*	High	
	Paediatric	<100 patients <100 patients**	X	XX	XX	XX	Med*	High	
	Diagnosis testing	800-1000 1000-1500 patients**	X	XX	X	XX	High*	High	
	LLNs	100k**	XX	X	X	XX	Low	Med	
Malaria	Indoor residual spraying (IRS)	80k**	X	XX	XX	X	Med	Med	

UNITAID
STRATEGY 2013-2016

Six
Strategic
Objectives

April 2013

Project Selection



Market Dynamics Dashboard

UNITAID MARKET DYNAMICS DASHBOARD (Updated October 2014)

M = Medicines D = Diagnostics P = Preventives	Product Sub-type	Access Estimate (October 2014)	Current Market Shortcomings*					Opportunity for Intervention***		
			Availability	Affordability	Quality	Acceptability/ Adaptability	Delivery	Composite severity of all current market shortcomings** (October 2014)	Current (October 2014)	Over next 4 years
M	Adult first-line	36% ¹	x	xx	--	xx	x	●	High	Med
	Adult second-line	NA ²	x	xx	--	xx	xx	●	High	High
	Paediatric	24% ³	xx	xx	--	xx	xx	●	High ⁴	Med
HIV/AIDS	Hepatitis C co-infection	NA ⁴	x	xx	x	xx	xx	●	High	High
	Adult diagnosis	50% ⁵	--	xx	x	xx	xx	●	High	High
	Early infant diagnosis (EID)	39% ⁶	xx	xx	xx	xx	xx	●	High ⁷	High
	CD4	<60% ⁷	x	xx	x	x	x	●	Low ⁸	Low
	Viral load (VL)	<30% ⁸	xx	xx	xx	xx	xx	●	High ⁹	High
	Male circumcision	16% ⁹	--	xx	x	--	xx	●	High	Med
	Female condoms	NA ¹⁰	x	xx	--	xx	xx	●	Low	Low
P	Microbicides	NA ¹¹	xx	--	--	xx	x	●	Low	High
	Pre-exposure prophylaxis (PrEP)	NA ¹²	--	x	--	xx	xx	●	Low	Low
	Adult first-line	66% ¹³	--	--	xx	xx	xx	●	Low	Med
M	Adult second-line	17% ¹⁴	xx	xx	xx	xx	xx	●	Med ¹⁵	High
	Paediatric	35% ¹⁵	xx	x	xx	xx	xx	●	High ¹⁶	High
D	Adult diagnosis	34% TB Dx 19% MDR-TB Dx 5-9% DST ¹⁶	x	xx	x	xx	xx	●	Med ¹⁷	High
M	Adult	<20% public <10% private ¹⁷	x	xx	xx	x	xx	●	Med ¹⁸	High
	Paediatric	<20% public <10% private ¹⁸	x	xx	xx	xx	xx	●	Med ¹⁹	High
D	Diagnostic testing	64% public Minimal private ¹⁹	x	x	xx	x	xx	●	High ²⁰	High
P	LINs	19% ²⁰	xx	x	x	x	xx	●	Low	Med
	Indoor residual spraying (IRS)	4% ²²	x	xx	xx	x	x	●	Med	Med

Opportunities for intervention assessed on a continuous basis via Landscapes, Market Fora outcomes & expert consultation

Dashboard presents:

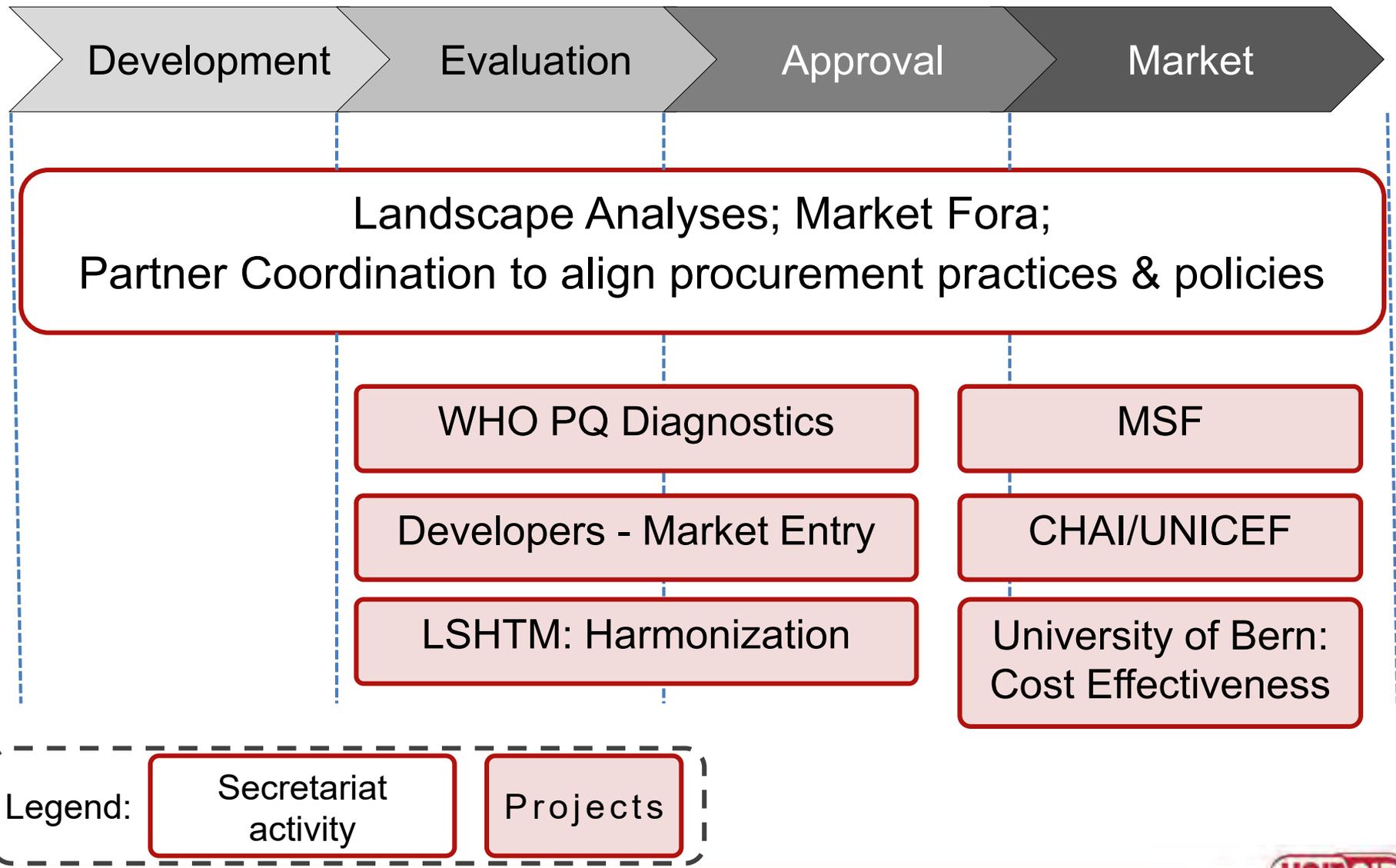
- **Severity** of current market shortcomings by type
- **Composite severity** of all shortcomings
- Level of current and future **opportunity for intervention**

M = Medicines D = Diagnostics P = Preventives	Product Sub-type	Access Estimate (October 2014)	Current Market Shortcomings*					Opportunity for Intervention***	
			Availability	Affordability	Quality	Acceptability/ Adaptability	Delivery	Composite severity of all current market shortcomings** (October 2014)	Current (October 2014)

Product Sub-type	Access Estimate (October 2014)	Current Market Shortcomings*						Opportunity for Intervention***	
		Availability	Affordability	Quality	Acceptability/ Adaptability	Delivery	Composite severity of all current market shortcomings** (October 2014)	Current (October 2014)	Over next 4 years
Adult diagnosis	50% ⁵	--	XX	X	XX	XX		High	High
Early infant diagnosis (EID)	39% ⁶	XX	XX	XX	XX	XX		High [†]	High
CD4	<60% ⁷	X	XX	X	X	X		Low [†]	Low
Viral load (VL)	<30% ⁸	XX	XX	XX	XX	XX		High [†]	High

- No POC viral load or early infant diagnosis marketed.
- Lab-based tests not optimal for resource-limited settings
- No competition yet in POC space.
- QA review of newer products slow. Lack of post-market QA.
- Inconsistent and costly national approval processes.

UNITAID's cross-cutting approach to investment in Dx



US\$ 116M in UNITAID investments for POC Diagnostics: Policy development, Quality Assurance, Market Entry & Scale-up



DxPO \$12.2M:
Quality Assurance



\$4.9M: Regulatory
Harmonization



\$55M to date:
- Country preparation
- Scale-up
- Market intelligence
- Market/PH Impact



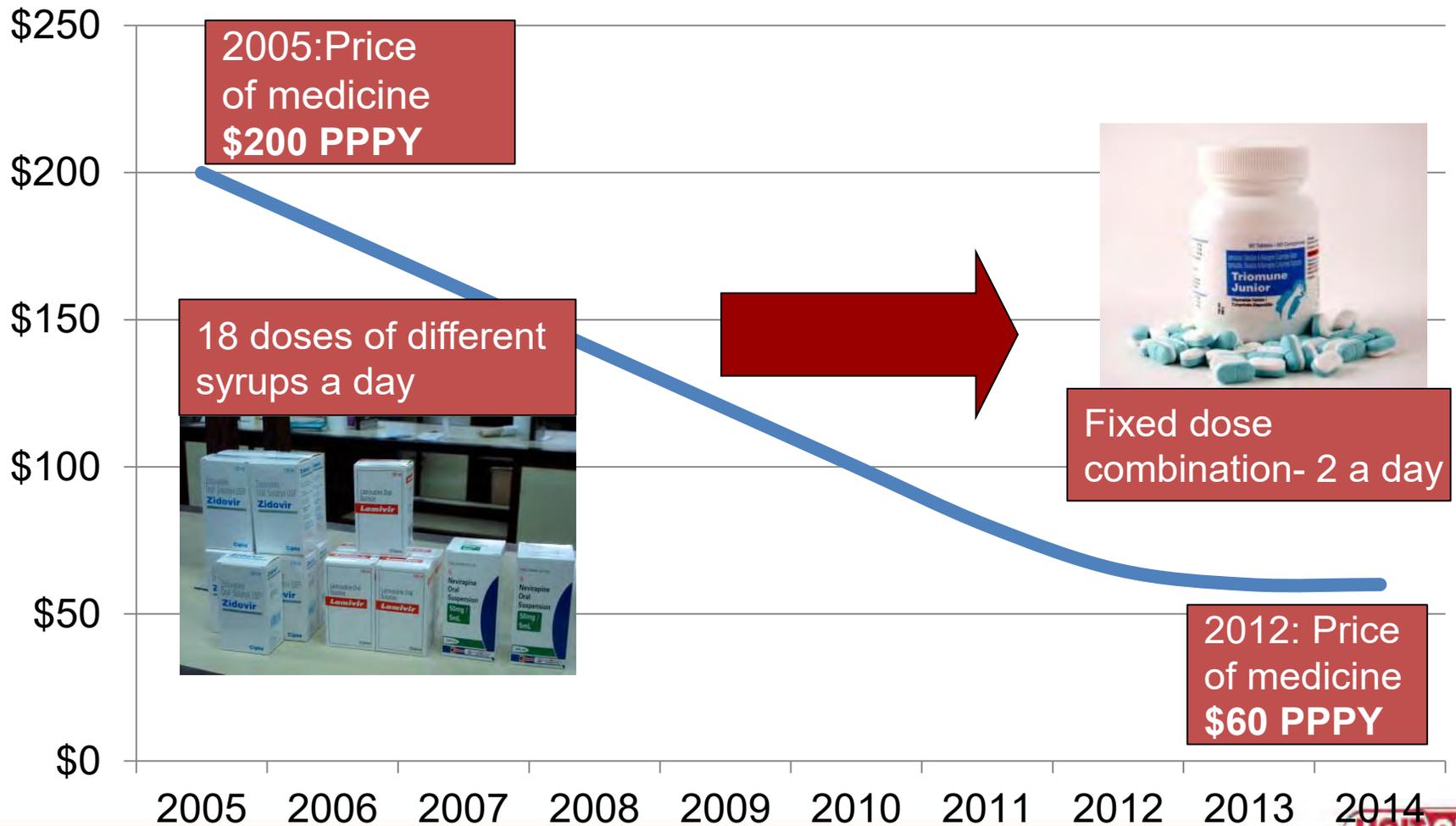
\$28.6M:
Demonstration
projects and Op.
Research

Market Entry

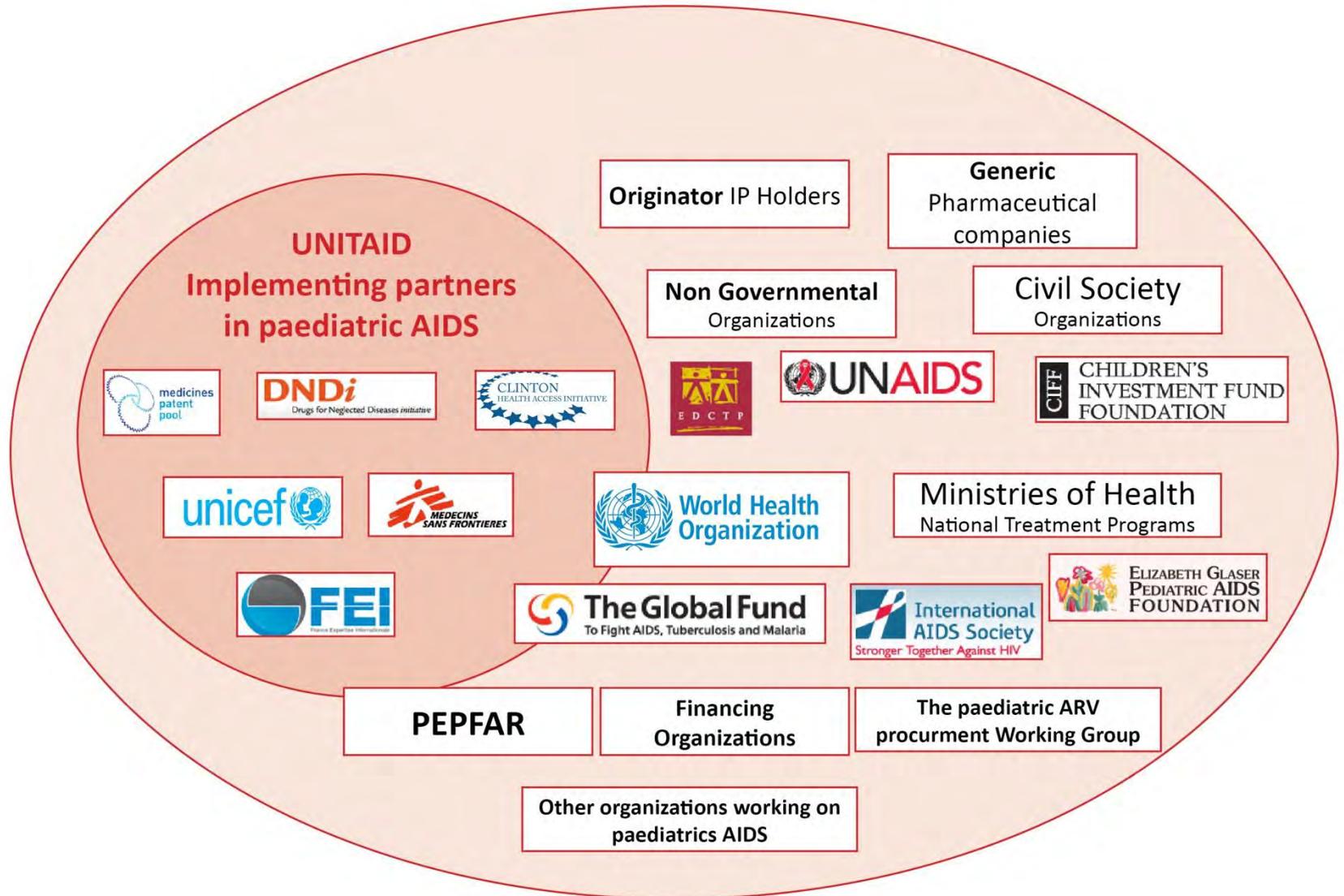
\$15M:
Market competition



Better products at lower prices



Stakeholders needed to increase access



Overview of UNITAID - and Market Dynamics



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Obatunde Oladapo

**PLAN Health Advocacy and Development
Foundation (PLAN Foundation)
Treatment Action Movement (TAM) – Nigeria
Civil Society for the Eradication of TB in
Nigeria
obatunde65@gmail.com
08037190628; 08128803611
skype: obatunde65**

Monday, October 13, 2014

**Turning the tide:
A beneficiary's
perspective on the
impact of the Global Fund**

*Being presentation delivered at the
Global Fund Sourcing and Market
Dynamics Strategic Review Meetings,
Geneva, Switzerland,
October 1 - 3, 2014*

Preamble

Nelson Mandela



“Our human compassion binds us the one to the other - not in pity or patronizingly, but as human beings who have learnt how to turn our common suffering into hope for the future.”

background

- HIV, Tuberculosis and Malaria continue to constitute major public health issues in Nigeria.
- The three diseases have huge negative socio-economic impact, for instance, contributing to reduction in productivity, school attendance and economic growth.

- HIV has exacerbated the TB burden in the world with the emergence of MDR-TB being a major consequence of the failure to adequately contain the disease.
- It is estimated that 3.14 million of Nigerians were living with HIV at the end of 2010 and 25% of adults with TB are also HIV positive.

- Nigeria remains one of the 22 high TB burden countries that account for about 80% of the world's TB. (*Global TB Report 2013*).
- Malaria cases alone account for 60% of outpatient visits to health facilities and about one-third of deaths of infants and children in the country. The entire population of the country, especially children under five years and pregnant women, are at risk of getting the disease.

- Looking back at the days when there was no access to antiretroviral treatment in Nigeria and today that over 600,000 are reputed to be on ARV treatment in the country, we cannot but say that we have come a long way in our efforts at ensuring that every man, woman or child living with HIV has access to life-saving ARV treatment.
- We didn't achieve this on a platter of gold!

- We couldn't have achieved this much without the political commitment from our government, the immense contributions of development partners, commitment and innovativeness of our healthcare workers, support of our communities, the sacrifices by and doggedness of treatment activists, as well as the cooperation of PLHIV, their support groups and their national network.



TREATMENT = LIFE
NO RETREAT ON AIDS

TREATMENT = LIFE
NO RETREAT ON AIDS

TREATMENT = LIFE
NO RETREAT ON AIDS

AHP NIGERIA

Man in white t-shirt holding a box of pills.

Woman in white t-shirt sitting at the table.

Man in white t-shirt sitting at the table.

Woman in white t-shirt sitting at the table.

Woman in white t-shirt sitting in the audience.

Woman wearing a green patterned headwrap sitting in the audience.

Woman in white t-shirt sitting in the audience.

Man in yellow t-shirt sitting in the audience.

Impact of the Global Fund: Personal Stories

**Obatunde
Oladapo:
from
adversity to
advantage**



- Before the advent of the Global Fund, access to ATM services were very low in the Nigeria.
- As a leader of PLHIV in the country I have witnessed the death of scores of my colleagues due to lack of access to treatment.
- Then we used to believe that home based care and support were exclusive of ARV treatment and vice versa.

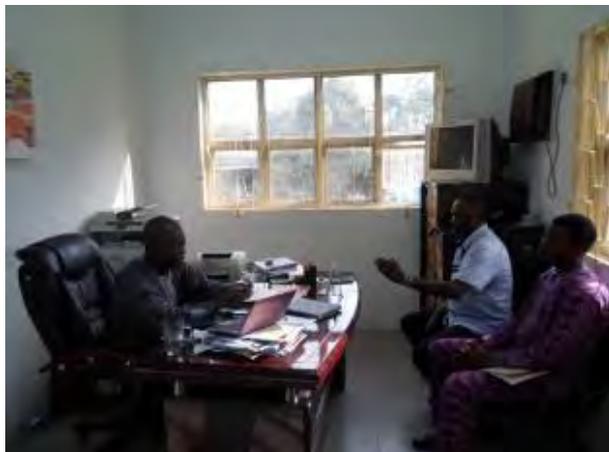
- The deaths of over 50% of our members that died were attributable to TB as well as other opportunistic infections arising from lack of access to ART.
- For many PLHIV, it was three diseases (AIDS, TB and Malaria) in one person! It was therefore not surprising that with the advent of the Global Fund, the quality of life and life expectancy of the average PLHIV has dramatically improved.

My journey

- I tested positive to HIV in July 2000 and went through a lot searching for the elusive and non-existent 'cure' which made me to fall into the hands of many fake cure claimants.
- I started ARV treatment in May 2002 at the UCH ARV treatment centre in Ibadan, Nigeria.
- Since then, I have not experienced any major illness.

- In 2000, I was reeling under the shock of learning of my HIV status in a period when little or nothing was known about living with HIV in a society where PLHIV and their families were experiencing debilitating and suffocating stigma and discrimination.
- In 2002, I was 'lucky' to access what can be likened to my first real HIV counseling session.

- This enabled me to co-found the Positive Life Association of Nigeria (PLAN), the pioneer membership organization of people living with HIV (PLHIV) in Oyo State, Nigeria.
- PLAN later transformed into PLAN Foundation, a major player in ATM responses in South-west Nigeria serving as Sub-Sub-Recipient on the Global Fund CSS project in Nigeria.



Advocacy visits to stakeholders under Global Fund CSS project with PLAN Foundation as SSR

- Key achievements of the CSS project include
 - Improved health seeking behaviour in communities.
 - Improvement in technical capacity for the implementing CBOs due to enhanced oversight and TA
 - Improvement recorded in the interrelationship between the community and facility components
 - Significant involvement and service uptakes have been recorded among the community members compared to periods preceding the implementation of community based CSS.
 - Effective advocacy to community gate keepers and other stakeholders helped in penetrating difficult areas.



Demand Generation activities by CBOs under Global Fund CSS project with PLAN Foundation as SSR

- I was founding member and National Secretary of Treatment Access Movement (TAM) – Nigeria, the Nigerian coalition of activists and advocates for access to treatment on HIV/AIDS, Tuberculosis and related diseases from 2005.
- I was elected as TAM's National Coordinator in 2012.
- I focus on treatment access, community engagement, mainstreaming disability into HIV/AIDS and SRH as well as stigma reduction and social research.



NO TO TYONEX!
PEOPLE WITH HIV ARE DYING



AFTER GLORIA, WHO IS NEXT?
ONYEBUCHI CHUKWU:
MINISTER OF DEATH!

NO TO TYONEX
TYONEX Nigeria Ltd. does not have WHO pre-qualification for products AYA
PLHIV are DYING!
KILLS ALL
TYONEX POSITIVE
PEOPLE





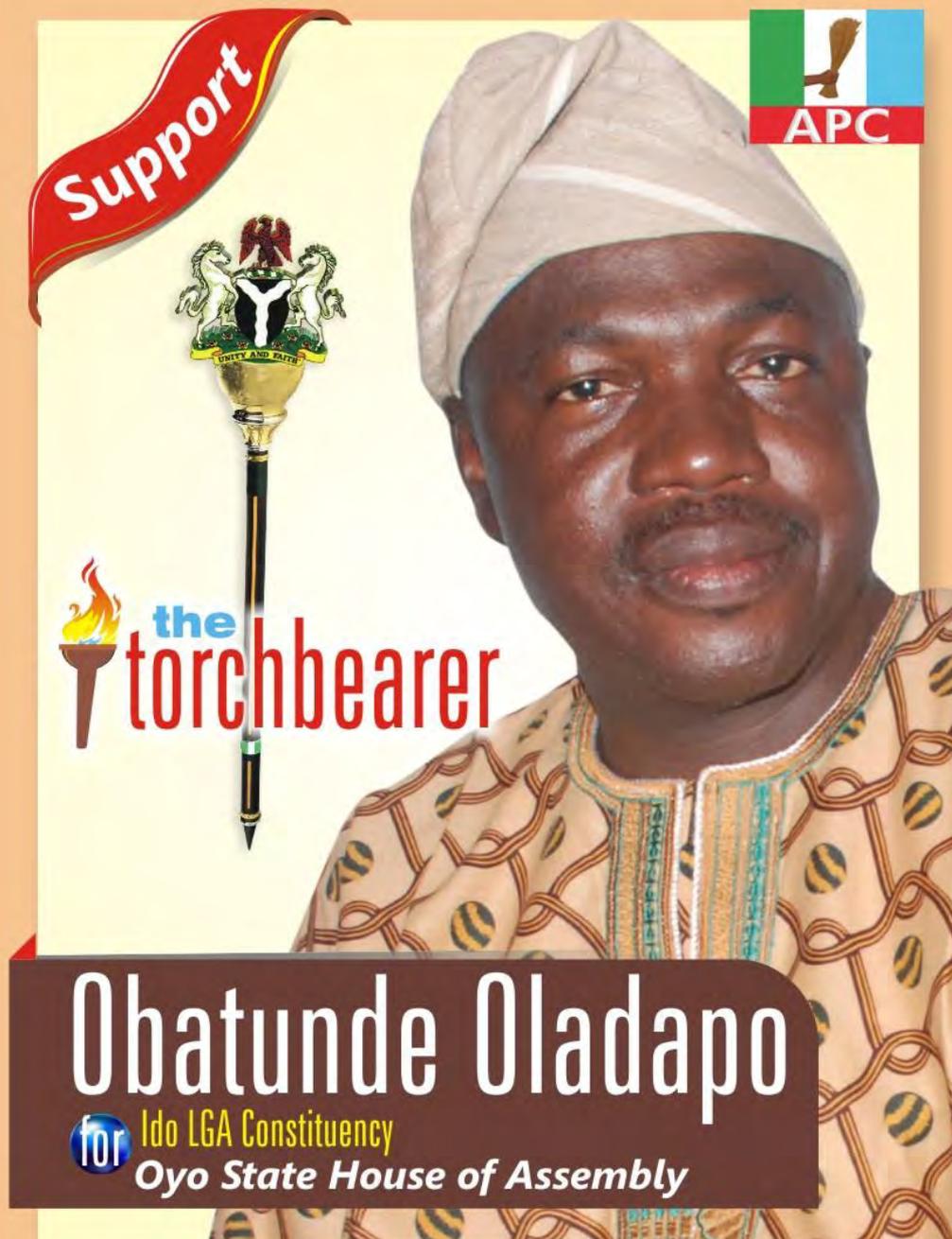
- I hold membership of various organizations and networks including
 - International AIDS Society (IAS)
 - International Union Against Tuberculosis and Lung Diseases (IUATLD)
 - International Alliance of Patients' Organizations (IAPO)
 - Global Health Council (GHC)
 - Global Network of People Living with HIV/AIDS (GNP+)
 - International Treatment Preparedness Coalition (ITPC)

- I served as Community Representative on the TB/HIV Core Group of the Stop TB Partnership from 2007 – 2009.
- I am National Secretary of Civil Society for the Eradication of Tuberculosis in Nigeria (TB Network)
- I am a Steering Group member of the African Community Advisory Board (AFRO CAB) which engages the pharmaceutical industry, government and other relevant stakeholders in addressing issues affecting access to quality HIV and TB-related treatment and care as well as ensuring that ethical measures are put in place for clinical trials for HIV and TB related drugs.



- I have authored and co-authored over 20 abstracts published and presented in national and international conferences on HIV and TB since 2002.
- Today, with my experience and insights on the need for making change in the world around me, I am aspiring to serve as a lawmaker believing that the lessons that I have learned for over a decade will help towards influencing a more caring government through people-centred legislations.

- Mission to influence legislation for fostering a society that protects, cares for and empowers the weak, marginalized and vulnerable.



A campaign poster for Obatunde Oladapo. The poster features a portrait of Obatunde Oladapo wearing a white traditional cap and a patterned shirt. In the top right corner is the APC logo, which consists of a green, white, and blue flag with a white exclamation mark and the letters 'APC' below it. A red ribbon with the word 'Support' in white is positioned in the top left. In the center, there is a torch with a flame, and above it is the Nigerian coat of arms featuring two horses and a shield with the motto 'UNITY AND FAITH'. Below the torch, the text 'the torchbearer' is written in blue and red. At the bottom, a dark brown banner contains the name 'Obatunde Oladapo' in large white letters, followed by 'for Ido LGA Constituency' in yellow and 'Oyo State House of Assembly' in white.

Support

APC

the torchbearer

Obatunde Oladapo
for Ido LGA Constituency
Oyo State House of Assembly

*Power has only one duty - to secure the social welfare of the People
- Benjamin Disraeli*

**Nasiru: saved
from the
precipice**

- Nasiru Mohammed was barely 2 years old and looking very ill, emaciated and weak when he was diagnosed with TB at the DOTS Clinic at Sabo, Ibadan, Nigeria.
- Apart from losing his father at an early age, Nasiru had also been abandoned by his mother, because she had lost hope of him surviving his prolonged illness.

**Nasiru at
the onset
of DOTS
treatment**



- A childless woman in the community was encouraged to take up the custody and care of Nasiru.
- Through the prompting of one of PLAN Foundation's Community Volunteers (CVs) his foster mother gave him the care that he had been missing after being abandoned. Nasiru was placed on GF funded pediatric DOTS treatment and has since successfully completed his treatment.

Nasiru after completing DOTS



L-R: Mrs. Ajayi, TBLS at Sabo DOTS Clinic; Abimbola Wintolu of PLAN Foundation (holding Nasiru Muhammed); and Nasiru's foster mother pose for photograph at Sabo DOTS Clinic, Ibadan North Local Government Area

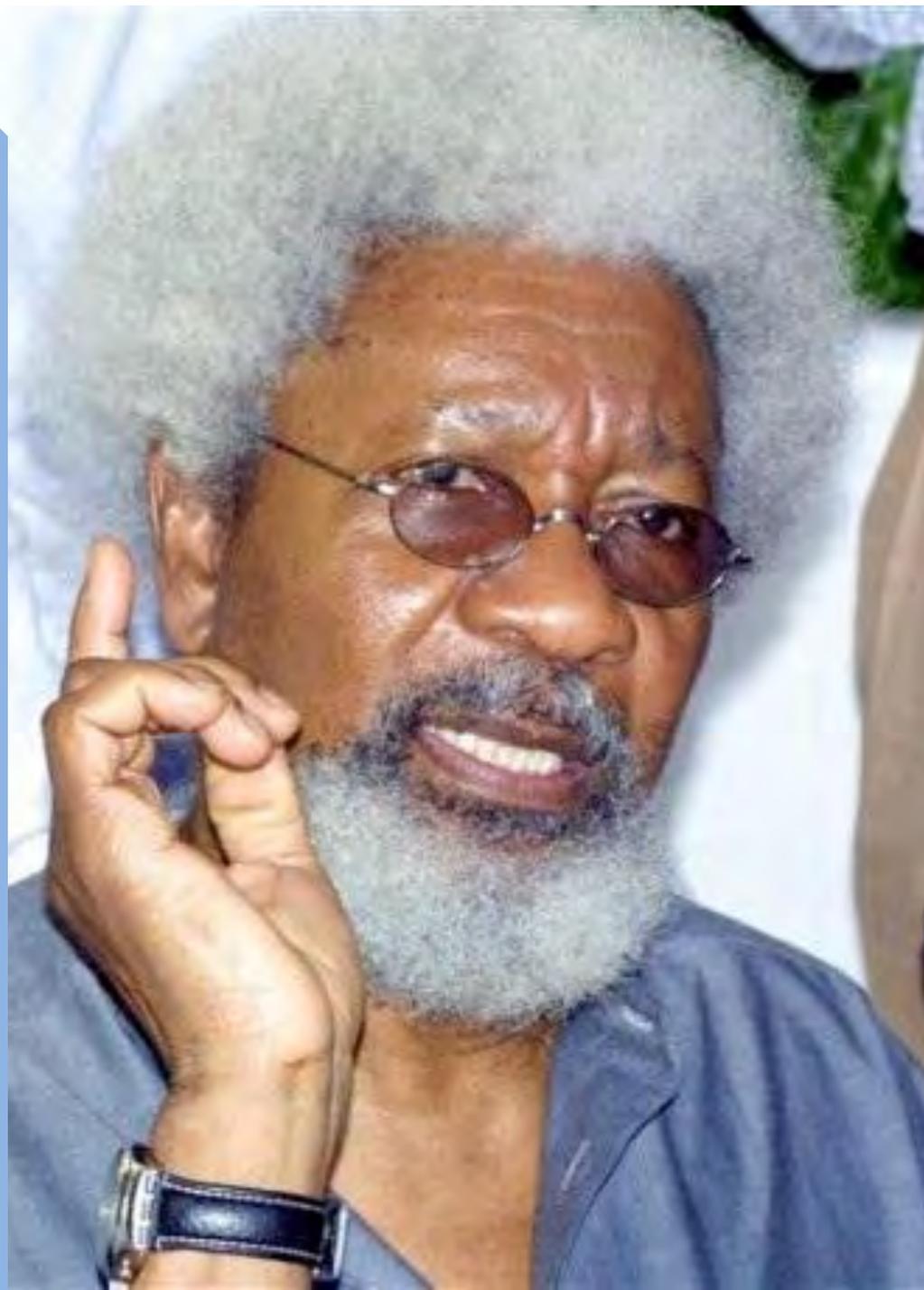
- Without the Global Fund, I and millions of other persons living with HIV and/or affected by TB in Nigeria and the world over would have been occupants of the grave today!



**but, where are
the gaps?**

"The greatest threat to freedom is the absence of criticism."

- Wole Soyinka



- Despite our achievements, we are not yet near, and neither are we moving towards the global targets of getting to zero.
- Therefore, we cannot afford to sit down, pat ourselves on the back and go to sleep as long as there are community people dying from TB, HIV and Malaria, children getting infected with HIV through their parents and millions more exist who do not have access to ATM services.



TO GET TO ZERO

MIND THE GAP

WE MUST CLOSE THE TREATMENT GAPS

beyond the figures...

- Overdependence on donors by several treatment programs.
- No reagents in many ARV clinics.
- Many ARV clinics have no provision for VL, CD4 count, LFT, etc.
- Being on ARV treatment without adequate monitoring is like embarking on journey while blindfolded.

- Debilitating stigma including self-inflicted stigma against PLHIV and persons affected by TB as well as KAPs.
- Punitive legislations by several African governments are posing great impediments to access to ATM services
- Huge gaps being left behind by the consistent withdrawal by international donors especially PEPFAR in countries like Nigeria. One in every ten persons living with HIV is a Nigerian!

**The way
forward**

- **There is need for establishing strong, effective, sustainable and enduring channels of effective communication and feedback involving donors, governments and civil society (including affected communities and KAPs) at all levels.**
- **This will go a long way in informing decisions in boardrooms and high-level meetings that have direct impact on the wellbeing of people in communities.**

- Governments need to demonstrate greater leadership and commitment in the ATM responses.
- The donor community needs to be awakened to the economic benefits of investing in the health and development of the people.

I hold the fervent belief that we have the duty, ability, resources, responsibilities and patriotic fervour to safeguard the health and wellbeing of all our people including men, women, children and vulnerable populations the world over.

**Whatever is
conceivable is
achievable!**



Thanks for listening!

Day 1 - Agenda

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Keynote Address

Daniel Camus

Chief Financial Officer

Finance Information Technology
Sourcing & Administration Div.



The Global Fund

To Fight AIDS, Tuberculosis and Malaria

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Sourcing Transformation across Health Products

Mariatou Tala Jallow
Martin Auton
Aziz Jafarov
Silas Holland
Lin (Roger) Li

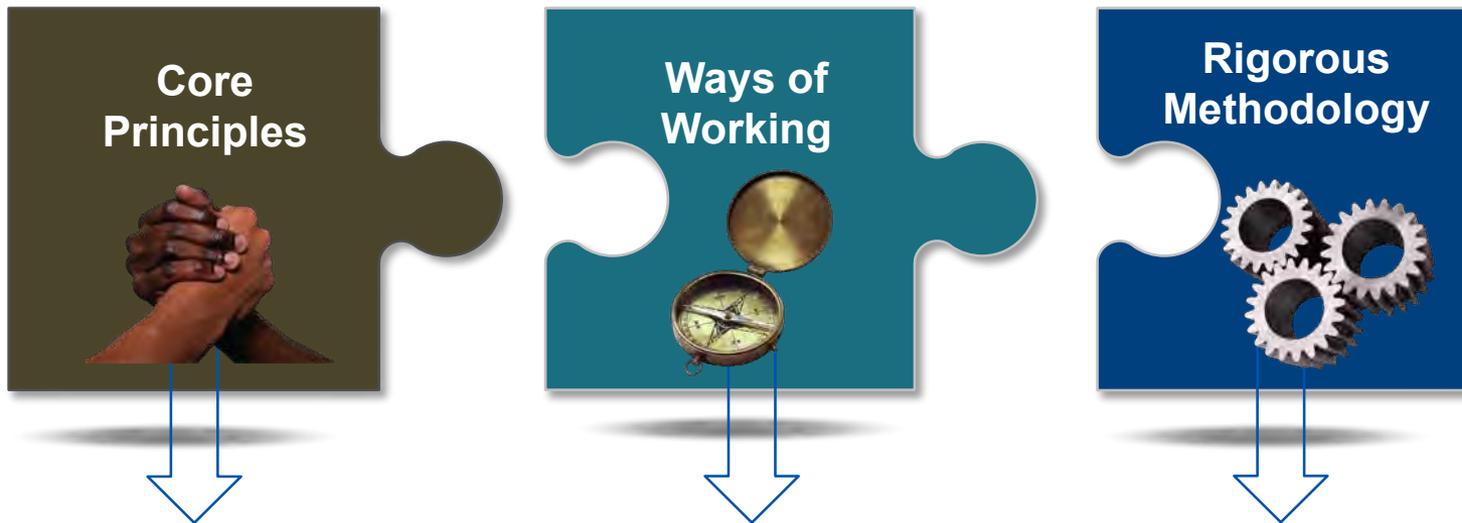
Today's Objective

To present and illustrate how **Global Fund Sourcing** translates a diverse set of information and relationships into cohesive strategies and effective, practical procurement plans



The Elements of Our Approach

Our approach is separated into three distinct elements.



An established set of values focused on increasing access to affordable products.

Moving at pace with the right resources and sponsorship. Where appropriate working with partners to increase value creation

A process to ensure we maximise value both before and after contract signature.

Our Core Principles and their Implementation

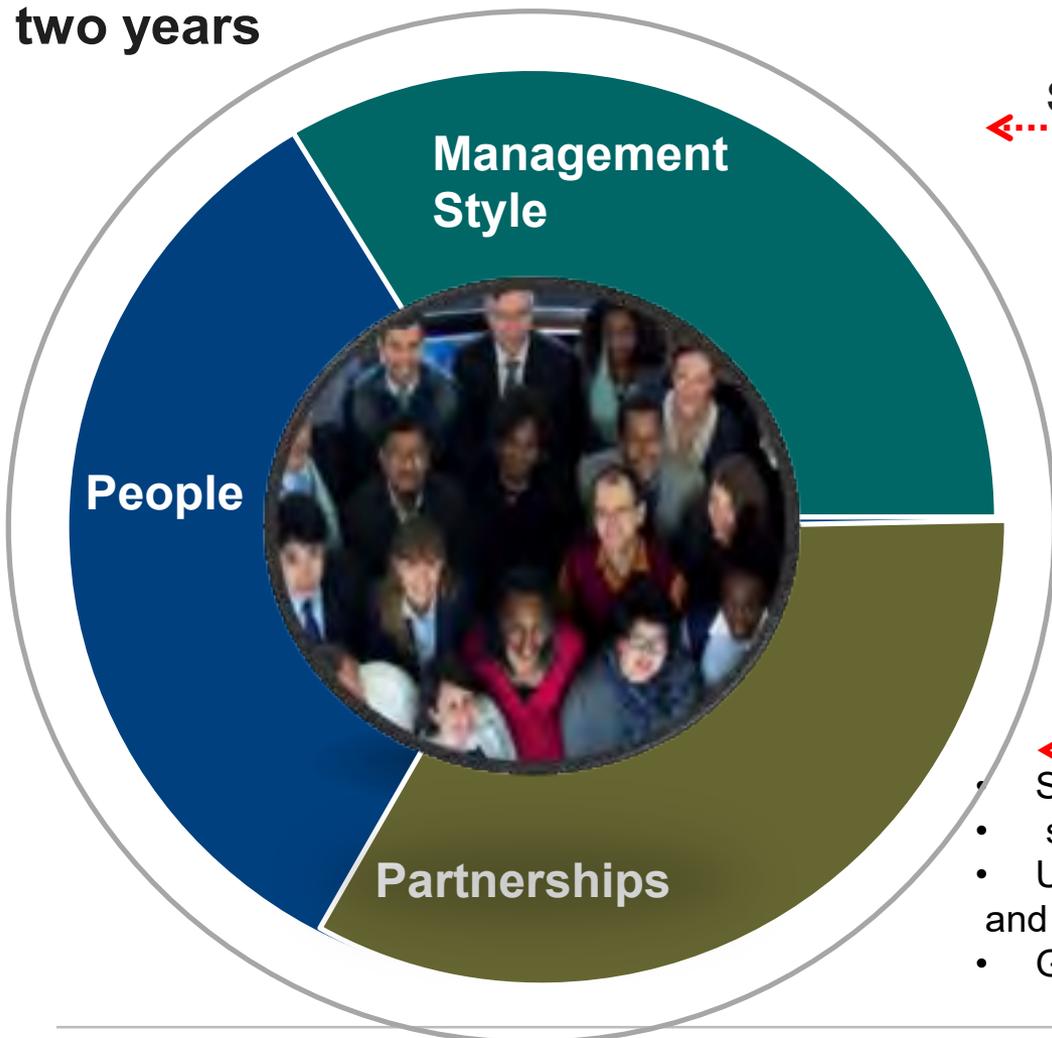


- 1. A focus on increasing the supply of affordable products to those in need and recognizing value added factors beyond price.**
Our evaluation processes consider a range of criteria and we provide the opportunity for other agencies and non-PPM PRs to access the framework prices achieved
- 2. Supporting new product innovation and market sustainability**
Our ARV tender is aligned to the WHO Guidelines and has provision for new entrants
- 3. A balanced approach to both originators and generic manufacturers.**
The market needs both types of supplier and our ACT strategy is structured accordingly.
- 4. Total transparency and integrity, zero tolerance of impropriety**
Committed volumes from LLIN suppliers under sanction were removed
- 5. Working more closely with suppliers and recognising their challenges.**
We are establishing collaborative projects with our suppliers
- 6. Encouraging local manufacture where ever possible.**
We have placed substantial business in Tanzania (LLIN) and Uganda (ACT)

New Ways of Working



Our ways of working have been clearly established over the past two years



Setting the Drumbeat

- Fast paced
- Objective measurement of performance
- Consensual and not directive
- Commercially orientated
-

Partnering where Appropriate

- Increasing leverage
- Access to specialist skills
- Supplier Collaboration

Growing our Capability

- Supported by experienced procurement specialists and increasing in-house capability
- Using best practice from both the public and private sector
- Growing our in house resource base



Our Methodology

A connected process to maximise value (which is not limited to purely cost)

UNDERSTAND



Going to the real places, meet the stakeholders and understanding the facts.

DESIGN



Defining a set of objectives based on findings and designing an approach to deliver them

ENGAGE



Designing tenders to meet our objectives

MANAGE



Working with suppliers to drive continuous improvement

Demand and Market Analysis

A structured, fact based diagnostic that evaluates 4 sets of criteria



The Product , Its Cost Structure and Market Dynamics

In depth analysis of API / FF; packaging and country specific requirements. Understanding of relative drivers, supply chain integrity and volatility



The Supply Base, Their Capabilities and Challenges

On site analysis with face to face discussions

Provides insight to supplier strategy, commitment and issues

UNITAID



Department
for International
Development



PEPFAR

The Demand Profile and Opportunities for Partner Alignment

Reliable and up to date demand forecast through PPM countries;

Coordination of demand across agencies; Partnering where objectives and legislative processes permit



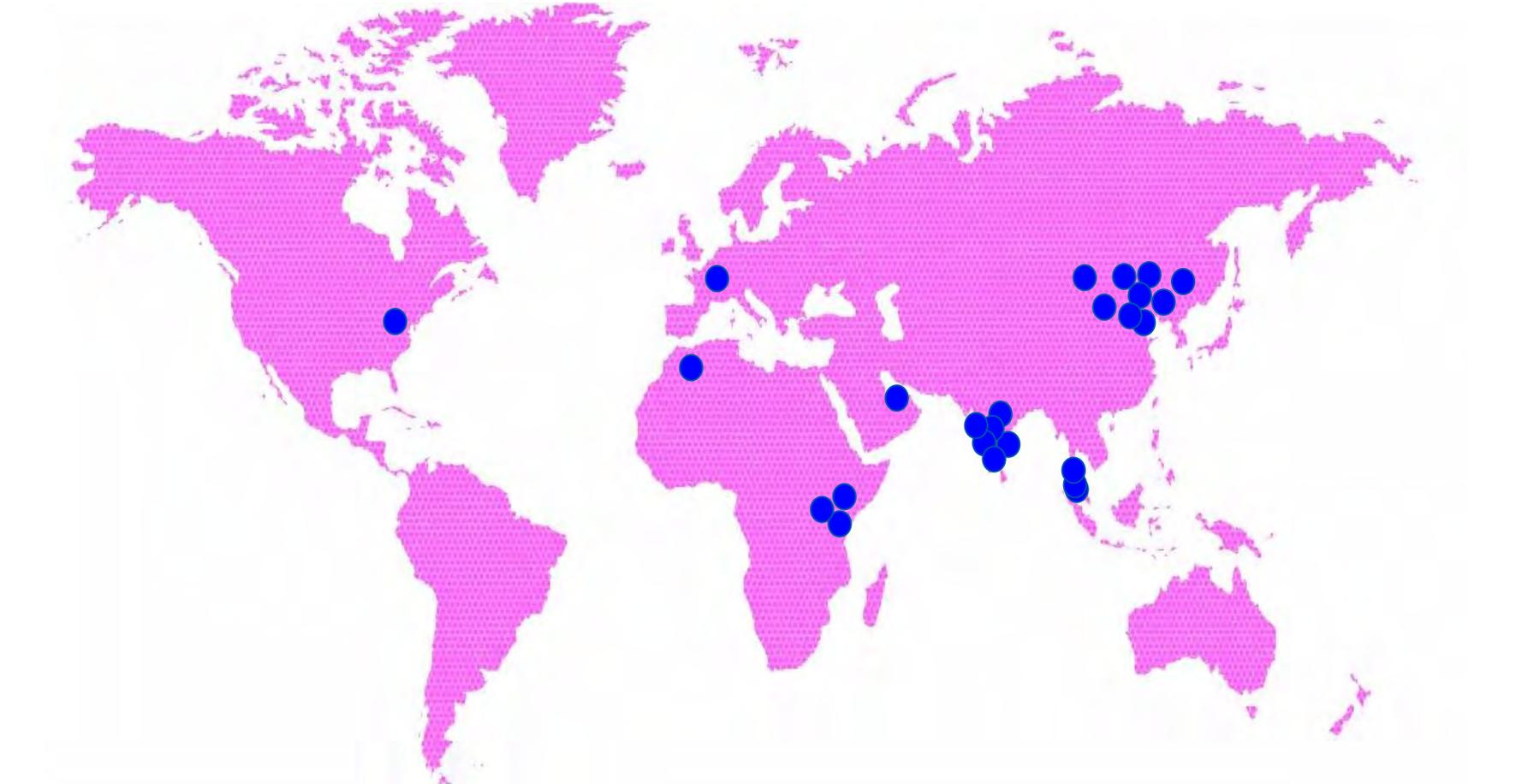
Historical Challenges and Future Direction

Learning from the past to avoid previous mistakes

Understanding the future development path to ensure our strategy is aligned

A Global Perspective.

**We have covered a lot of miles to get a comprehensive understanding:
Suppliers visited.**





Sourcing Transformation across Health Products

Illustrating the Approach:
Market Analysis

LLIN: The Manufacturing Process

Base Chemicals and Initial Mixing



LLIN: The Manufacturing Process

Impregnated net construction, extrusion and weaving



LLIN: The Manufacturing Process

Tailoring, Packaging and QA



LLIN – Better Understanding of the market

Our strategy included key elements learnt during our supplier visits and subsequent analysis



What we learnt	What we did
Stop start production in a labour intensive industry was driving up costs	Provided longer term contracts to optimise unit costs of production
Raw material costs were up to 50% of overall price	Designed a price protection mechanism to share risk between parties
Multiplicity of specifications was adding complexity and cost	Standardised wherever possible
Freight was a significant proportion of total landed cost	Geographically divided suppliers and encouraged local manufacture

ACT: The Journey 1: Bio-mass cultivation and storage

Industrial Enterprises



Family Businesses



ACT The Journey 2: Extraction

Large Scale



Small Scale

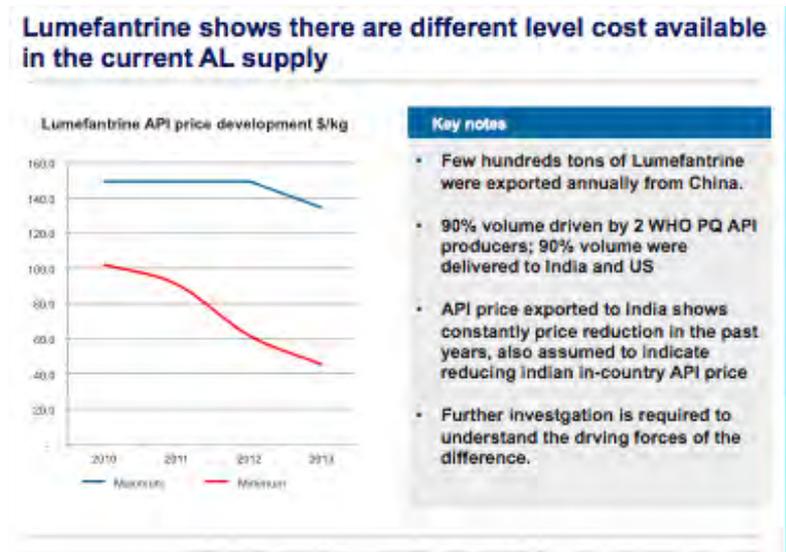
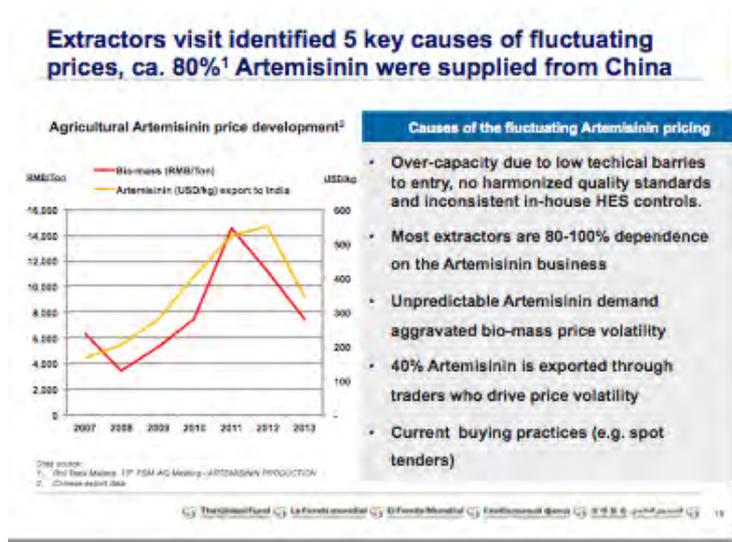


ACT The Journey 3: Formulation



ACT : The Analysis in Practice

We spoke to extractors and growers and assessed export data to understand the true nature of the cost build up and fluctuations.



We learnt that API price reductions were not being passed on and that AMFm pricing was artificially high owing to the externally developed price structure. We also learnt that as a commodity artemisinin pricing volatility is largely cyclical

Demand Side Analysis

Placing the spotlight on ourselves, our customers and partners to understand the problems from the demand perspective - our findings from ACT.

Limited capacity planning for manufacturers

Lack of supply chain integrity due to over commitment and under performance.

Lack of leverage by separating PPM and AMFm volumes

Limited transparency in co-payment allocation process

Complex administration processes

Short term planning causing instability in raw material pricing



**All these have been impacting Our Core Objective
AVAILABILITY OF PRODUCT**

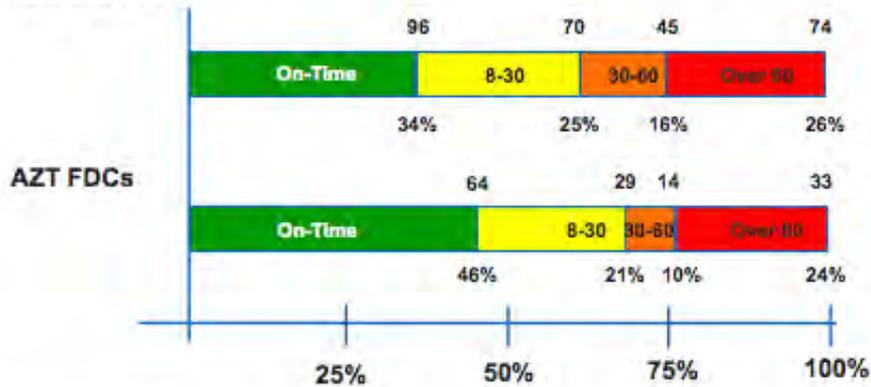
The Analysis in Practice: Delivery Performance

Poor delivery performance means that people who need treatment are not getting it. It has been caused by a variety of factors ----- and We will do something about it

Supplier Delivery Performance

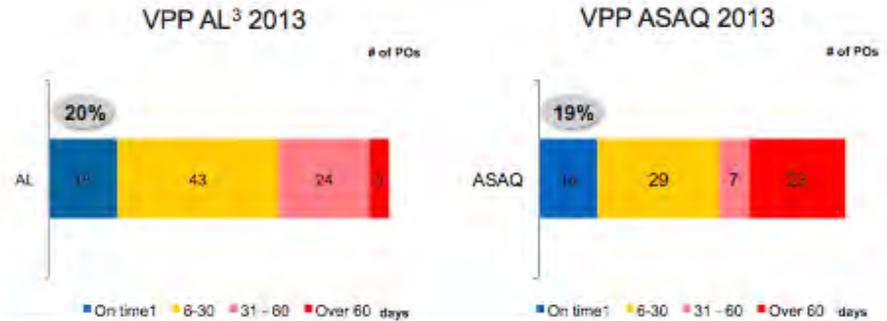
Supplier delivery performance has been poor. A statistic that has been made worse by current procurement processes.

TEE and TLE



2013 VPP¹ data shows very poor weighted average on-time² delivery at only ca. 20% (AL) and 19%(ASAQ)

Measured from vendor commit date



We strongly expect performance will improve with the new procurement strategy

1. Data source: PFSCM
 2. On-time is calculated based on "Vendor Promise date" against "Vendor into Millstone date" and late delivery within 6 days has been considered as on-time during this assessment.
 3. Including dispenser tablet, second tablet and tablet.



Sourcing Transformation across Health Products

Illustrating the Approach:
Strategy Definition &
Supplier Engagement

Previously

Our analysis suggest there was a great deal of activity with limited discernable output.

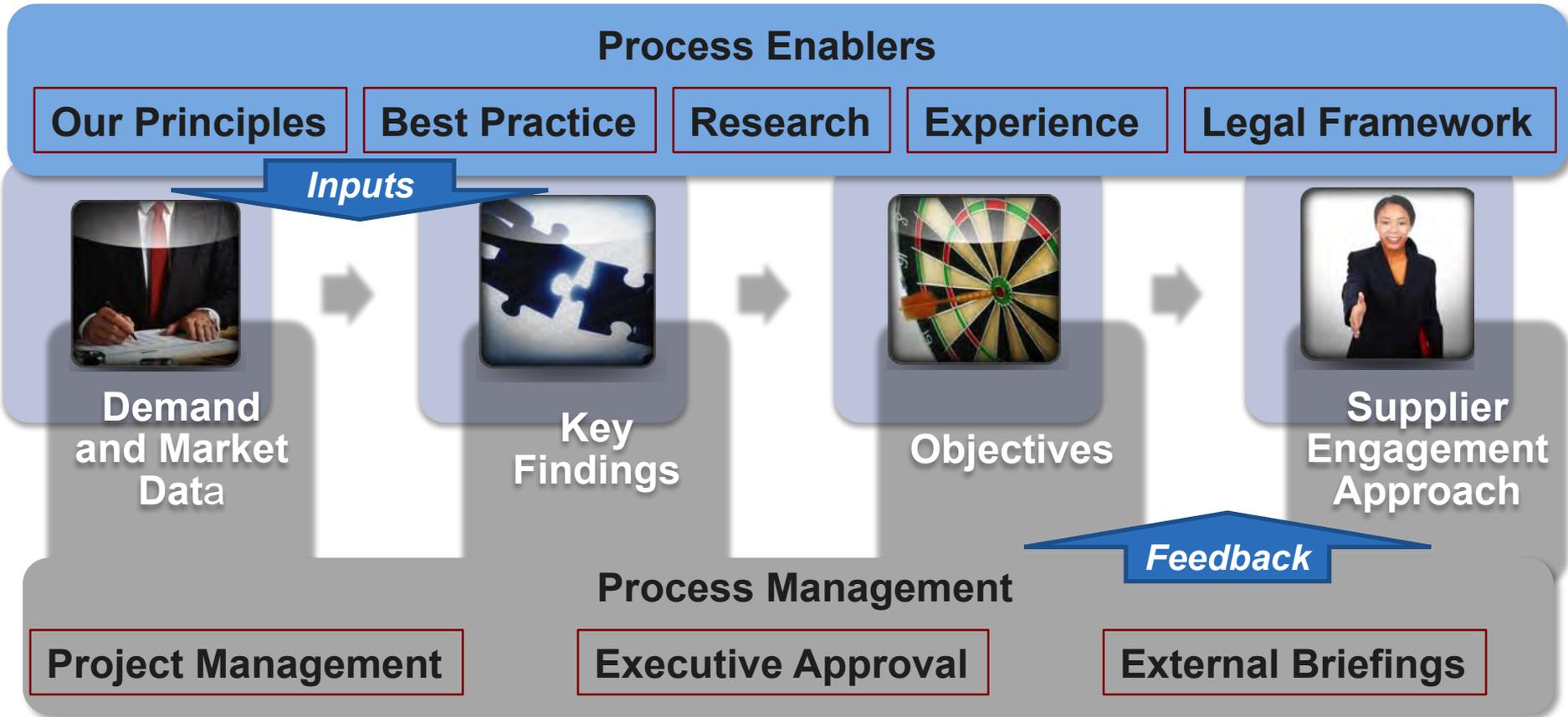


Inputs

Outputs

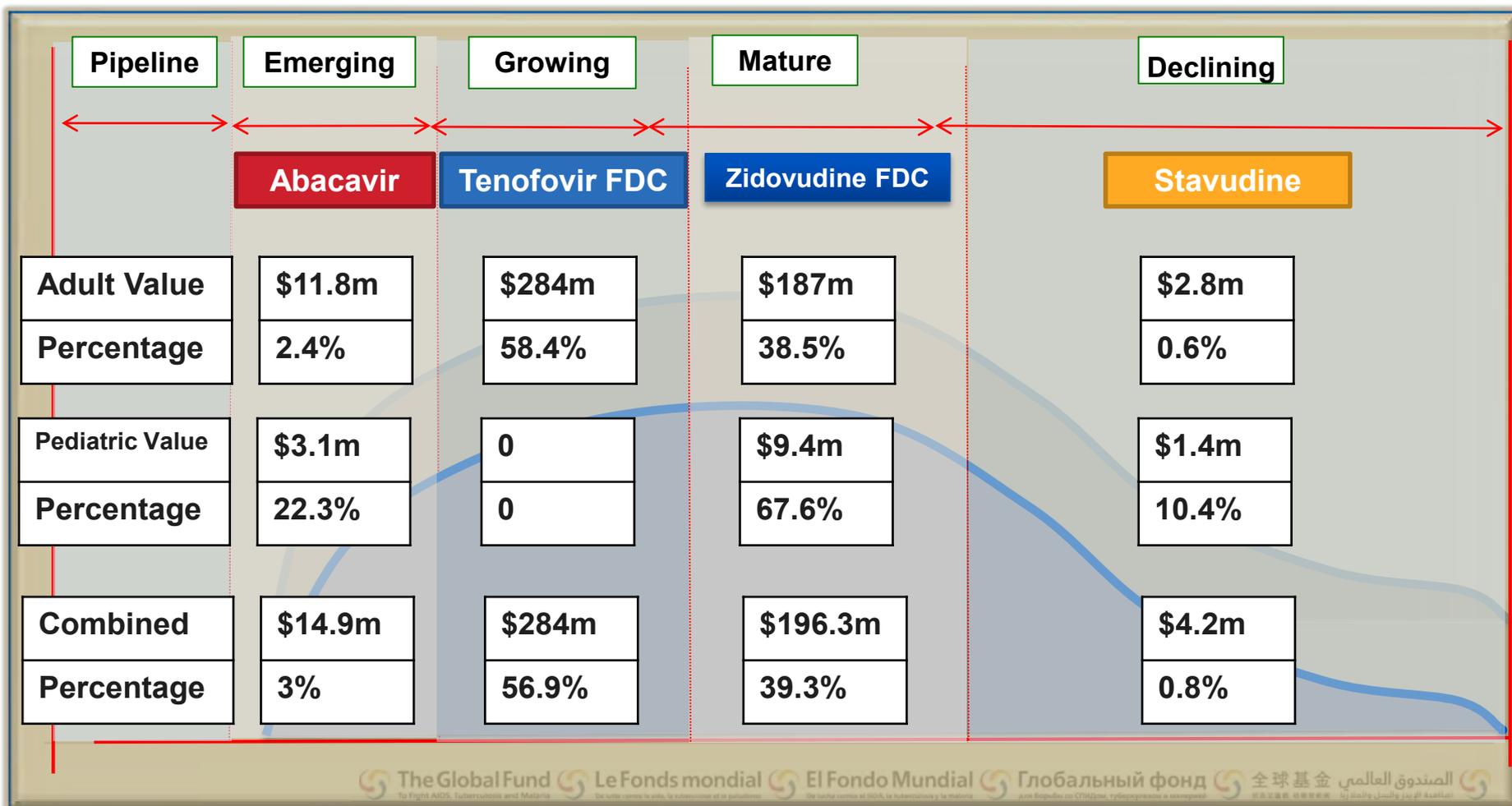
Strategy Definition: The New Approach

The new approach is supported by knowledge / information collated across sectors and permits feedback from stakeholders



Life Cycle Management in ARV

To meet all the objectives – a new approach was adopted for the ARV strategy based on product lifecycle



Other Examples on Supplier and Partner Engagement

- ***Viral Load Analysis:*** We are examining total cost of ownership and optimal contracting models
- ***ACT:*** We designed a strategy to accommodate the ‘Push’ dynamics of PPM and the ‘Pull’ dynamics of the Co-Payment mechanism.
- ***Rapid Supply Mechanism:*** to provide a short term solution to lack of supply chain integrity / stock-outs
- ***Malaria:*** We have commenced initial Consultations with RDT and IRS suppliers
- ***TB:*** Joint process improvement activity between GF and GDF looking at procurement process, forecasting and quantification

Supplier Engagement

Our tender structures and process combine common and separate elements across health products

Common Elements

- Openness and Transparency
- Legal Oversight
- Q+A Opportunity
- Competition Driven
- Open book costing
- Zero Sum (Where appropriate)
- Objective Evaluation
- Use of mathematical evaluation tools
- 2 Stage Process
- Fair and equal treatment for bidders
- Lobbying prohibited

LLIN



ACT



ARV



Separate Elements

- Type and level of Information requested
- Evaluation Criteria
- Commercial and Technical Weighting
- Evaluation algorithms
- Forms of contract
- Style of Collaboration
- Negotiation Processes
- Freight analysis

The LLIN Tender

Key Facts

Date:	Sept-Dec 2013
Value	\$250m per year
No of Products	50+
No of Bidders	13
Evaluation Criteria	9
Technical : Commercial Weighting	35% : 65%
Negotiation Medium	Telephone
Successful Bidders	10
Additional Elements	2 year contracts with committed volumes Price adjustment mechanism & protection

Results

**Savings of \$140m (8.7%)
through contract life.**

Support to local manufacture

**Product standardisation
through active demand
management**

**Pricing available to other
parties**

**New levels of trust and
understanding.**

The ACT Tender

Key Facts

Date:	Apr-Jun 2014
Value	\$130m per year
No of Products	20
No of Bidders	9
Evaluation Criteria	8
Technical : Commercial Weighting	40%: 60%
Negotiation Medium	Reverse Auction or Telephone
Successful Bidders	9
Additional Elements	ASAQ and AL separate evaluation 2 year contracts Combined PPM, CPM and RSM volumes

Results

- **Savings of \$100m (33%) over contract life**
- **Stabilising Artemisinin price through longer term demand.**
- **Encouraging investment in new products by recognising originators**
- **Implementation of measures to improve delivery**
- **Proved supplier capability to support RSM concept**

The ARV Tender

Key Facts

Date:	In progress
Value	\$600m per year
No of Products	120+
No of Bidders	TBA
Evaluation Criteria	9
Technical : Commercial Weighting	45% : 55%
Negotiation Medium	Collaborative Workshop
Successful Bidders	In evaluation
Additional Elements	2-3 year contracts Project based on type of collaboration

Results

**Watch this
space**



Sourcing Transformation across HIV, TB and Malaria

Illustrating the Approach:
Contract and Performance
Management

Contract and Performance Management

To ensure contract adherence and especially to maintain value creation we have implemented ongoing supplier performance measurement and different forms of collaborative working:

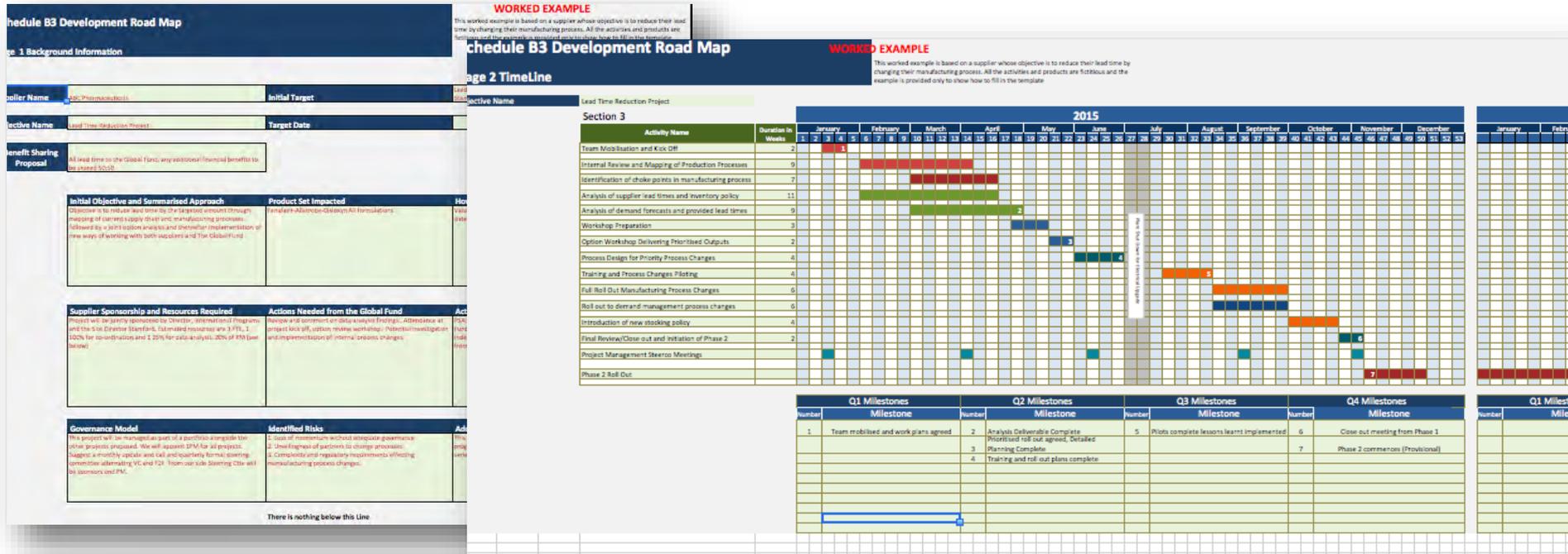
- **LLIN and ACT: We established collaborative projects and ongoing material cost review:**
 - *Price tracking has led to price reductions in polyester based nets*
 - *On going engagement on projects - recycling of nets; increased durability of nets; improved environment friendly production (use of wind mill or steam generated power).*

- **Performance indicators will be used to measure suppliers OTIF, and will be part of the reward / incentive scheme**

- **ARV : we will be forming strategic partnerships with selected suppliers based on a common development road map.**

The Development Road Maps in ARV

Our Development Road Maps are aligned to established best practice in the private sector



Bidders who want a strategic partnership will work with the Fund on a series of agreed projects to address issues identified in the tender



Sourcing Transformation across Health Products

Next Steps

TB: Strong Partnership with Stop TB/GDF to address challenges in TB market

- Improved forecasts and procurement predictability
- Harmonized data for increased visibility and accountability
- Strategic Revolving Stockpile and Rapid Supply Mechanism
- Coordinated country and manufacturer engagement
- Innovative approaches to enable MDR-TB scaleup



Some recent highlights

- ✓ **UK Department of International Development wins 2014 Chartered Institute of Purchasing and Supply Award for work undertaken with the Global Fund.**
- ✓ **USAID PEPFAR collaboration on HIV products including jointly hosting ARV Supplier Conference in Dubai, May 2014.**
- ✓ **UNITAID and the Global Fund announce Memorandum of Understanding for collaborative working August 2014.**
- ✓ **Spend under Global Fund direct management has increased from \$500m to >\$1.0bn in two years.**
- ✓ **US Congressional briefing on Global Fund / USAID collaboration, September 2014.**

Other activities we are engaging in going forward.

Beneath the headlines other activities will also be going on:

- 1. The implementation of ongoing ‘Supplier Business Standards’ management that may include self certification for ethics, labour, human rights and the environment.**
- 2. Development of strategies for raw materials including API that will involve engagement with Tier 2 suppliers.**
- 3. Engagement with specific governments to tax exempt ‘funded’ raw materials.**
- 4. Improving communication with PRs to support greater understanding of their responsibilities.**
- 5. Continuing to build our own capability.**

Next Steps: HIV Diagnostics and TB

- **Deep dives with all concerned partners into specific topics, pre-selected on a needs basis by the Global Fund, UNITAID and StopTB**
- **HIV diagnostics, a complex disparate landscape**
- **TB**

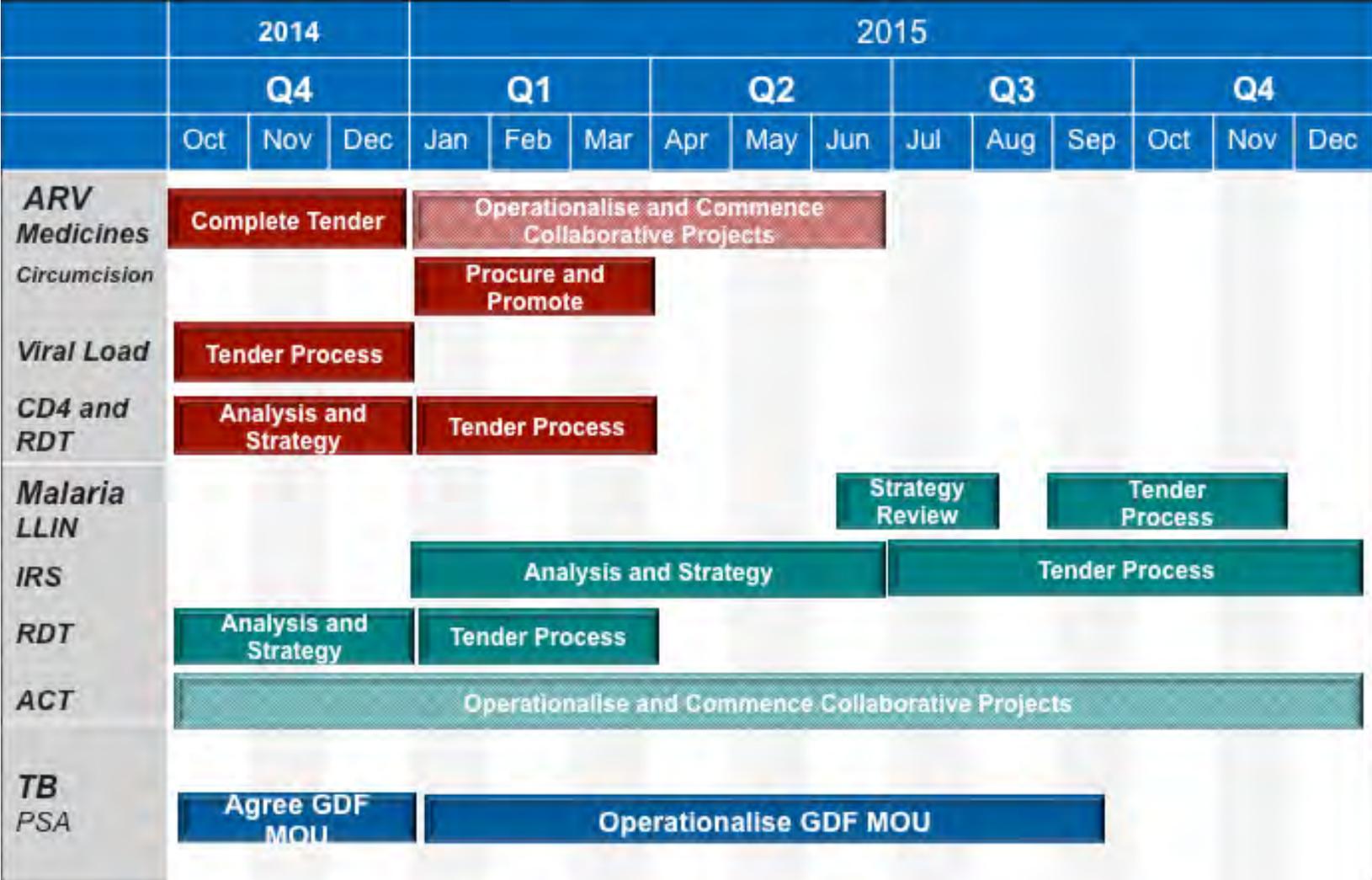
Challenges Remain

Which we recognise and are addressing.....

Identified Challenges

- The provision of accurate, timely data remains problematic
- Supplier relationship management is a new skill but we are learning fast
- We need to operationalize our day to day contract management quicker
- Supplier maturity is improving but has some way to go
- We are well aligned with partner agencies in certain areas but issues of 'turf' remain
- Not all PRs yet recognize their responsibility for adherence to schedules and procurement plans
- Providing most up to date information on P4I activities on the website

Our Overall Timeline



Questions?



With acknowledgements to PresentationPro for some graphics

Day 1 - Agenda

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A difficult day...



36%

On time and in full

37%

Of stolen, diverted or counterfeited drugs among ~700 vendors visited

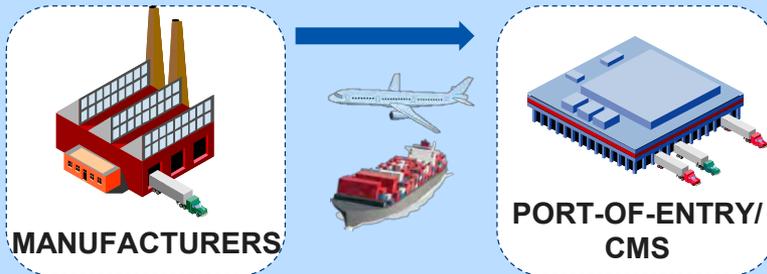
One out of three

countries reported stock-out with potential treatment disruption



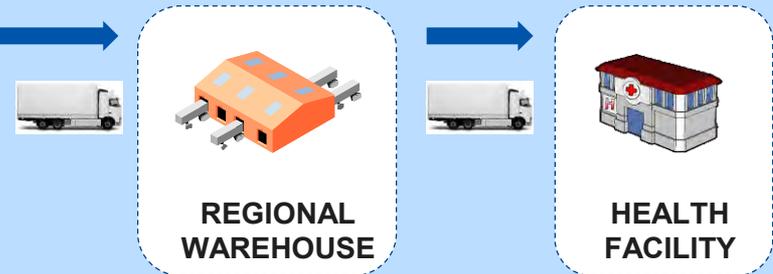
Supply Chain team is focusing on downstream supply chain, in-country supply chain and audit/compliance

1 Downstream supply chain (for Pooled Procurement Mechanism countries)



Improve and monitor supply chain performance for which Global Fund is accountable and has oversight (reduce lead time (OTIF), limit stock-outs, increase visibility on cost and footprint of supply chain and optimize where possible)

2 In-country supply chain



Support countries with financial, human and technical resources along with partners to strengthen public health in-country supply chains

3 Audit and compliance

- Monitor and support suppliers to achieve Good Manufacturing Practices
- Fight counterfeiting, theft and diversion via Joint Inter-Agency Task Force

1 Downstream supply chain team advises and leads change, engages with partners (manufacturer to port of entry/CMS)

Manage & improve performance (e.g OTIF)

- ✓ Monitor overall performance
- ✓ Identify areas for improvement
- ✓ Propose solutions

Tools/exercise

- *Traffic light*
- *Mapping of downstream*
- *Evaluate KPIs, suggest improved methodology*

Country Code	PQ	Product Group	Status	Forecasted delay	PSA predicted delivery date	TGF Forecasted delivery	Delay management
BJ	FPQ	ARV	Production	1	24/10/2014	25/10/2014	↑
DO	FPQ	ARV	Production	25	12/09/2014	07/10/2014	↔
NG	FPQ	ARV	Production	-6	20/01/2015	14/01/2015	↓
NI	FPQ	HRDT	Production	2	28/11/2014	30/11/2014	↔

Implement structural changes

- ✓ Rapid Supply Mechanism
 - *emergency response*
 - *new operational model to deliver goods faster*
- ✓ Freight Forwarding optimization / diversification
 - *Understand, manage change on country by country basis*

Engage with partners

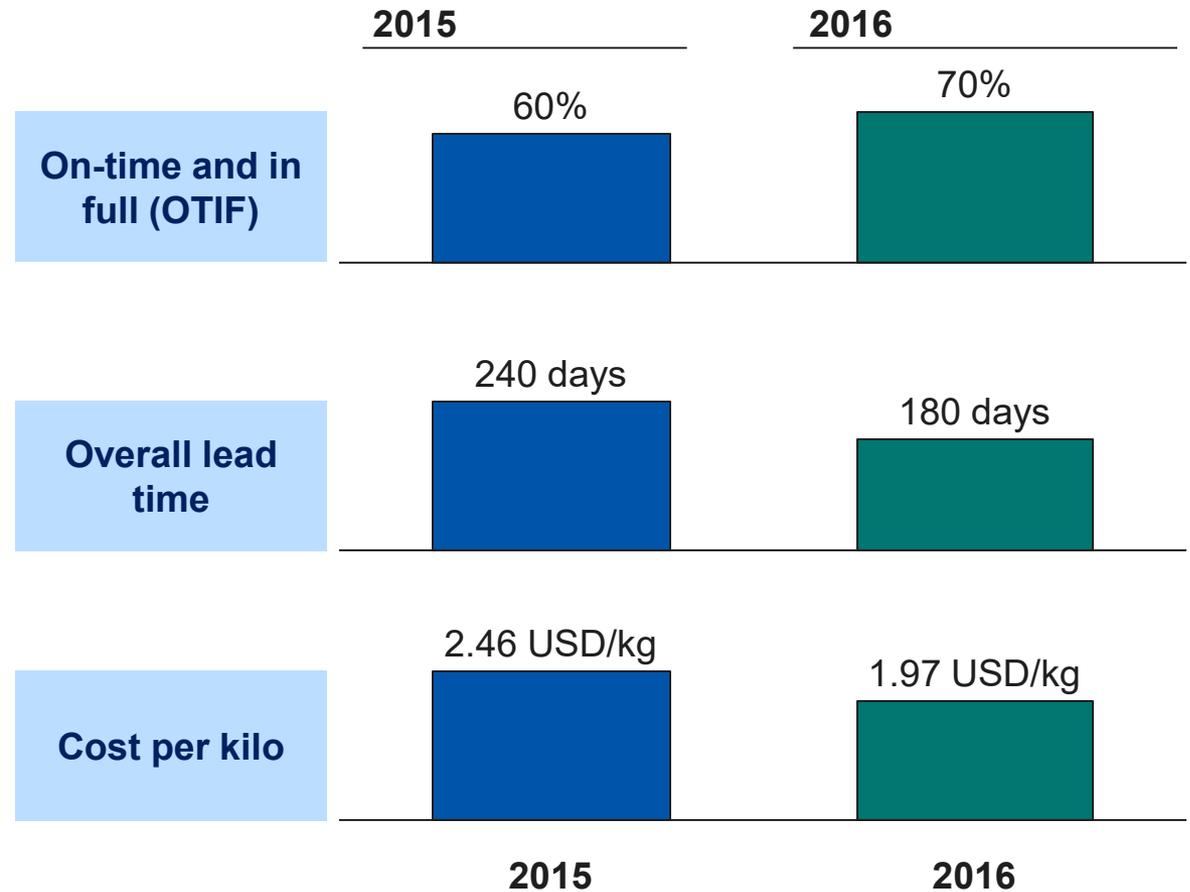
- ✓ Best practices
- ✓ Look for opportunities to collaborate
- ✓ Create lasting partnerships
- ✓ Create information sharing agreements
- ✓ Innovation Coalition

1 Downstream supply chain evaluate KPIs, suggest way forward

Approach

- Benchmark Global Fund performance against public and private sector peers
- Adapt metrics and methodology to Global Fund contingencies and business model
- Develop tools with Procurement Services Agents to have full visibility on performance and monitor it
- Address/help resolve bottlenecks to improve performance

Global Fund performance targets

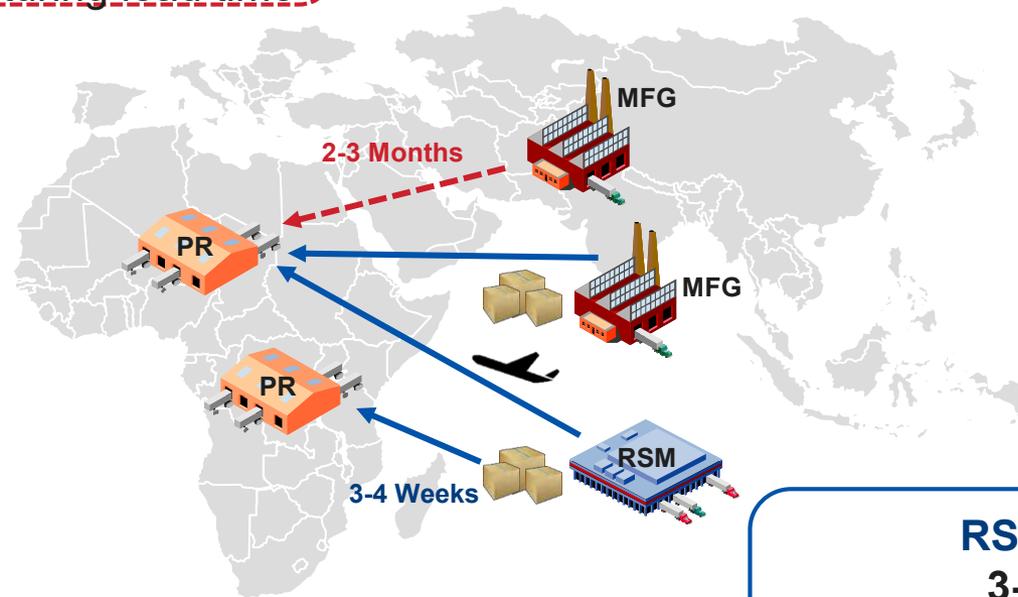


1 The Rapid Supply Mechanism will respond quickly to product shortages and prevent treatment disruption

Today: Months

2 – 3 months

Fastest emergency response including manufacturing lead time



RSM: Weeks

3-4 weeks

Target response time from manufacturer or distribution hub

1 For efficacy and risk management, different RSM solutions are being implemented by disease

	RSM Solution Selected	Status Update
HIV	Rotating stockpile to be built onto PPM, located in Ghana, managed by PFSCM	<ul style="list-style-type: none">Orders placed to stock hubAnticipated Go-Live Q4 2014 / Q1 2015
Malaria	Selected Manufacturers to maintain stock and provide rapid response to emergency orders	<ul style="list-style-type: none">Agreement reached with selected ACT manufacturersImplementation under way – Go-Live expected Q4 2014
TB	GF will contract with GDF to provide rapid response to emergencies from their rotating stockpile	<ul style="list-style-type: none">Agreed that UNITAID will pass stockpile to GDFDiscussion ongoing with GDF

1 The RSM for HIV is being implemented by PFSCM on GF's behalf and will act as an add-on to PPM

1



Stock the Hub

Product will be ordered and shipped to the Ghana hub (also used by PEPFAR). GF will provide working capital but PFSCM will own the stock.

2

Keep the Stock Fresh

Nigeria, Côte d'Ivoire & Cameroon will receive their regular PPM orders from the hub in order to keep the stock fresh. They will pay no more than at present.

3

Respond to Emergencies

When a PR has a stock shortage and the Country Team approves, the available buffer stock can be rapidly despatched from Ghana to wherever it is needed.

Pooled regular orders
(quarterly / bi-monthly)



HIS Pharmaceutical Grade Hub in Accra
Bonded facility

1 Selected manufacturers are currently implementing the RSM for Malaria, for availability from end-Q4 2014

Artesunate Amodiaquine

SANOFI 

Product available from Paris
within 10 days

Artemether Lumefantrine


Strides
ARCOLAB LIMITED

Product available from Bangalore
within 2 weeks

**GF has reached in-principle
agreement with three selected
ACT vendors**


CiplaQCi
ACCESS TO QUALITY AFFORDABLE MEDICINES

Product available from Kampala
within 1 week

2 Global Fund has started process to articulate its in-country supply chain strategy

What role should the Global Fund play in in-country supply chain and how to operationalize it?

Streams

1 Engage with Tier 1 and Tier 2 priority countries to strengthen supply chain

2 Become a Knowledge hub focal point with ad-hoc support and off-the-shelf resources

Support provided

- **Short term:** *diagnostic and roadmap*
 - Capability Maturity Assessment through the National Supply Chain Assessment
 - Roadmap definition for supply chain strengthening
 - Costing of the required effort
 - Support to embed effort in concept note
- **Medium term:**
 - Knowledge database of tools, expertise or documented initiatives around supply chain
 - Ad-hoc team support on in-country supply chain assessment and improvement

2 Typical supply chain areas of support

- Integrated Logistics and Transportation including Last Mile Delivery.
- Logistics Management Coordination and data management for Logistics Management Information Systems (LMIS)
- Distribution network optimization
- Supply chain governance and coordination
- Information collection mechanisms at point of supply / last mile
- Quality assurance
- Promoting operational research and sharing best practices

2 Weak supply chain: the need for change is clearly identified, understood and supported

The Nigerian Public Sector medicines supply chain is seriously compromised across all disease areas has numerous challenges.

- Mio USD of expired drugs for multiple years.
- Frequent stock-outs and poor availability of medicines at Health Facilities.
- State warehouses not at minimum Pharmaceutical standards.
- Last-Mile delivery is partial and inadequately funded.
- Lack of visibility / focus / capacity / reporting across all disease areas.
- Lack of basic logistics management control systems.
- Inefficiencies due to poor coordination/ integration/ harmonization

Non-Pharma Grade Facilities



There is a growing consensus amongst the Nigerian Government and Donor organisations that concerted action is needed to integrate the different supply chains and to deliver a structural change in performance.

- There is a shared recognition that the existing situation is not acceptable.
- There is a recognised opportunity to align and reinforce existing Strategic Plans through further Supply Chain Integration.
- **National ownership** is in place – “we are part of the process”, “ownership has been put in place from the start”.

Waste: Product Expiries



2 Clear Vision established for Supply Chain Integration

Vision:

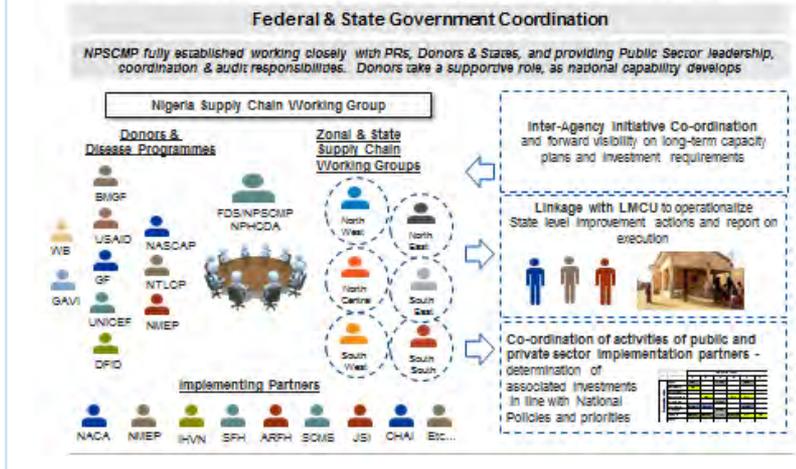
- **Improved patient access and availability of medicines** – through visibility, control and efficient Last Mile delivery.
- **Forge a tighter integration of National Pharmaceutical supply chains** between Federal & State, Donors, Public & Private Sector, and across commodities - HIV, Malaria, TB and by platform extension to Family Planning and Vaccines.
- Develop a **streamlined, cost effective** and ultimately more **sustainable National Pharmaceutical Supply Chain**.

Key Elements of the Vision:

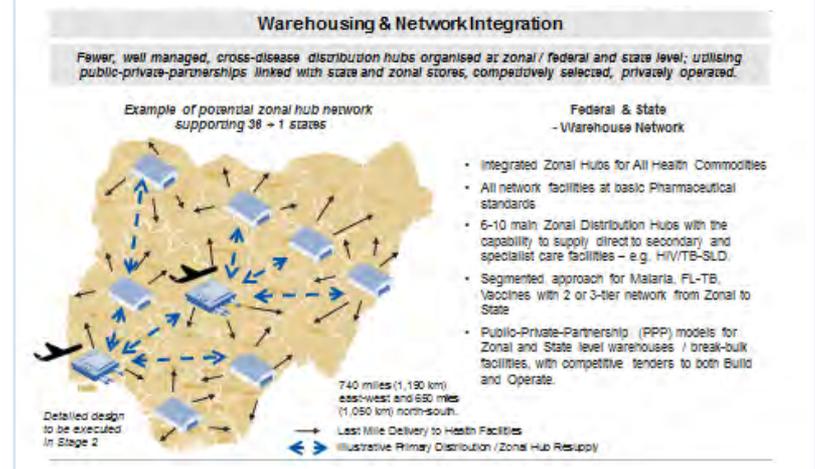
- Strengthening **Federal & State Government coordination**.
- **Public Private Partnerships** – for a network of 6-8 Zonal Hubs (Warehouses).
- **Integrated Logistics and Transportation** including **Last Mile Delivery**.
- Establishment of **Logistics Management Coordinating Units** at State level and deployment of LMIS tools.

2 Country engagement has led to a clear vision for the programme with strong in-country support ...

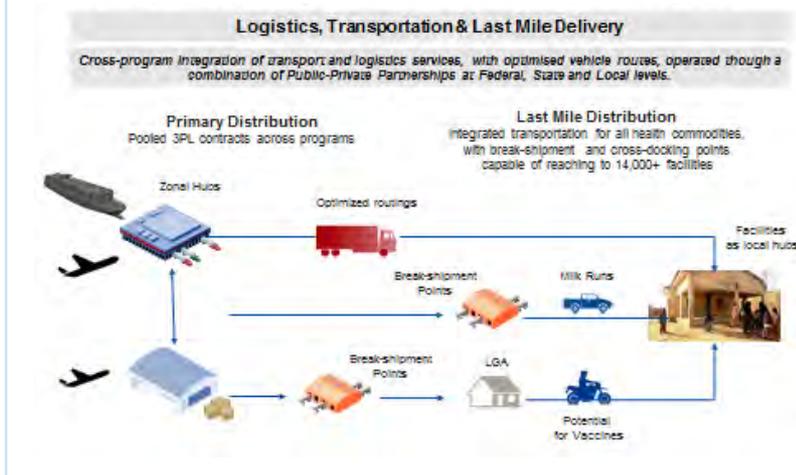
Strengthened Federal & State Government coordination



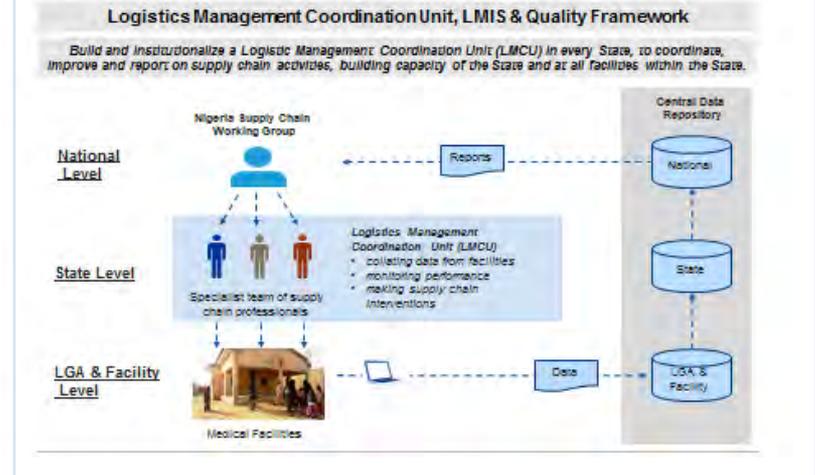
Network of integrated PPP Zonal Hubs



Integrated Logistics including Last Mile Delivery



Logistics Management Coordinating Units and LMIS



3 Objectives of the Joint Inter-Agency Task Force

- To **Detect, Respond, and Prevent the theft, diversion and falsification of Global Fund and USAID-funded medicines** by:
 - Conducting market surveys in focus countries
 - Protecting public health by identifying falsified medicines
 - Mitigate reputational risk and maintaining public trust
 - Developing and strengthening Global Fund Impact
 - Strengthening national systems by building capacity and harnessing cooperation within and between key drug regulatory and law enforcement agencies

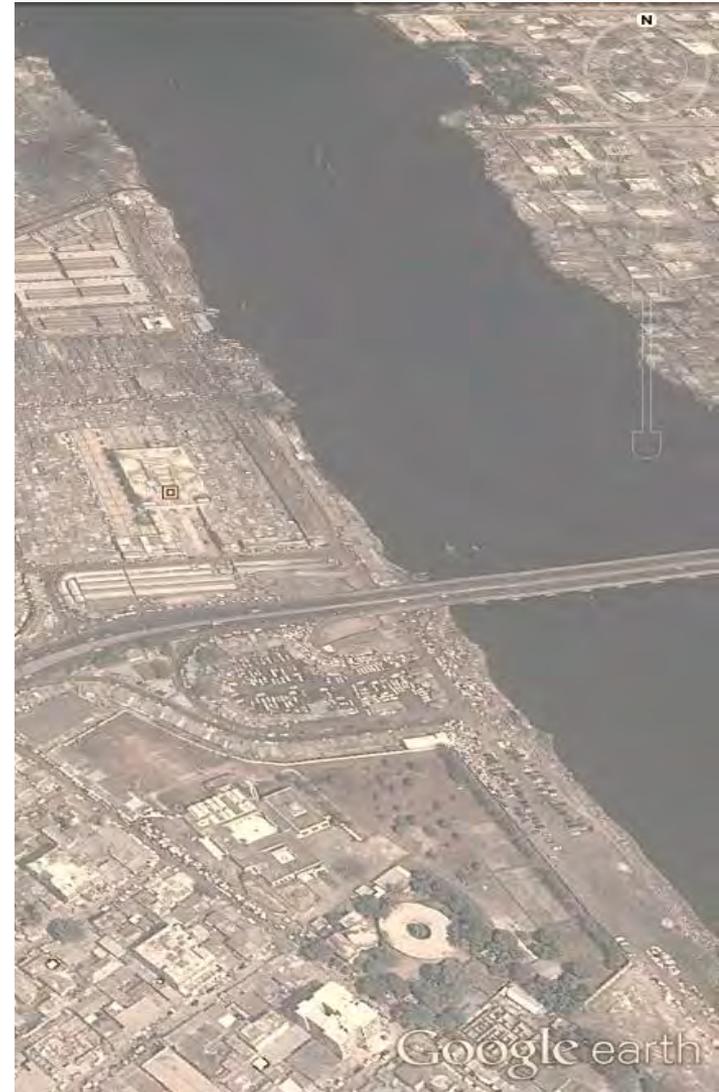
3 Joint Inter-Agency Task Force (JIATF) membership and partners

JIATF CORE MEMBERSHIP

- The Global Fund & OIG
- PMI & OIG
- UNDP & OAI

JIATF PARTNERS

- Interpol
- WHO
- National Drug Regulatory and Law Enforcement Agencies
- Drug Manufacturing Industry



3 Surveyed Countries



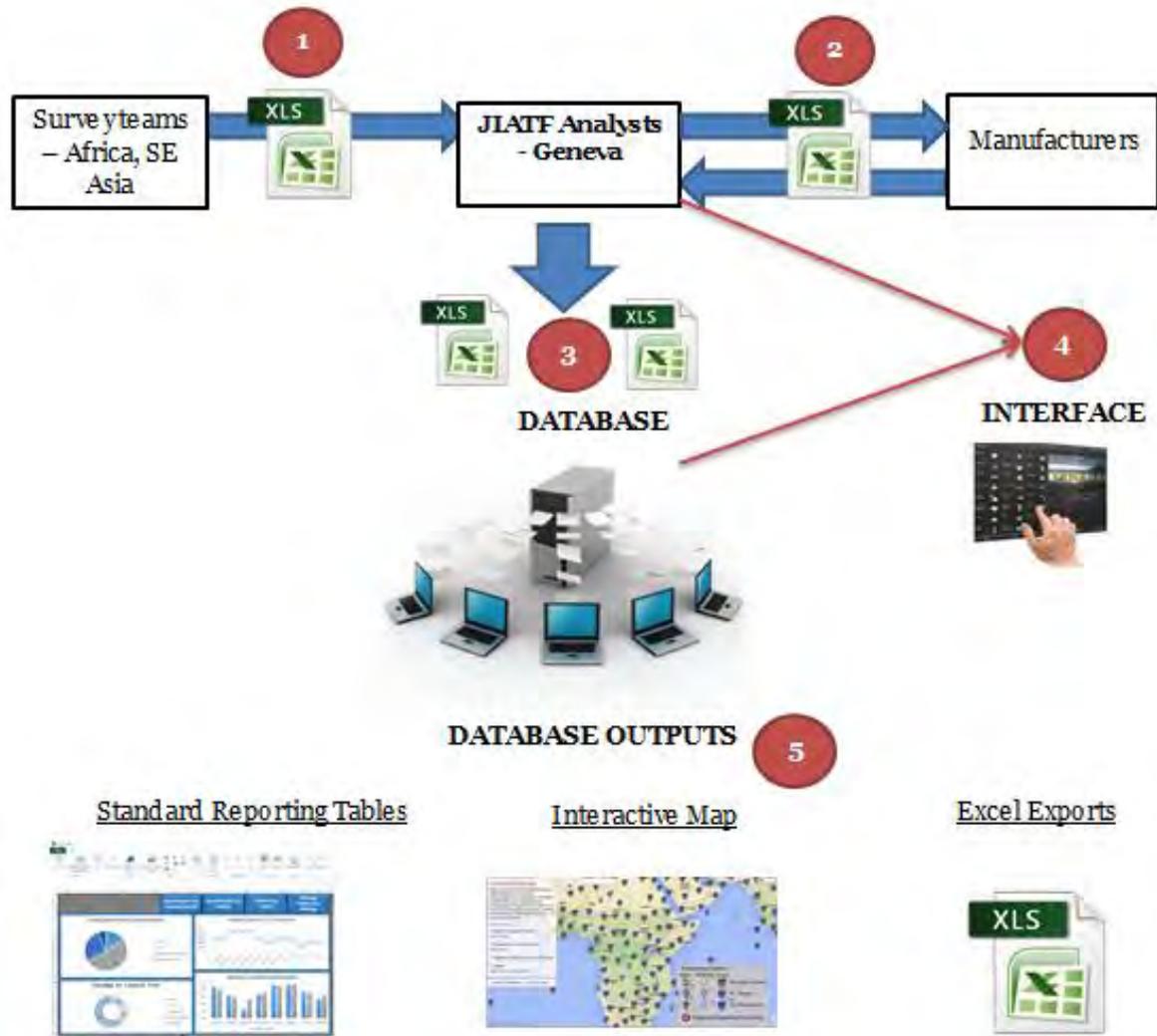
Countries Are Selected Based on a Variety of Factors, Including:

Global Fund High Impact Status

Known incidents or known risk of theft, diversion, and falsification

Global Fund funding for ACTs

3 Analysis and Mapping



3 Improving Global Fund Impact

- Supporting The Global Fund Secretariat: Facilitating focused responses. Enhanced traceability beyond the Central Medical Stores; Awareness Raising campaigns
- Proactively engaging with key manufacturers
- Introducing enhanced standardized anti-theft/anti-counterfeiting measures

3 Togo: Joint Enforcement Operation

GF-JIATF participated in a 5-day Interpol-coordinated operation with Interpol and Togolese National Authorities



3 National Engagement Strategy (NES)

MOUs

- Nigeria Economic and Financial Crimes Commission (EFCC)
- Malawi Anti-Corruption Bureau (ACB)
- Tanzania Food and Drug Authority (TFDA)



Capacity Building and Logistical Support

- Investigating Pharma Crime Training
- Intelligence Analysis Training
- Provision of Specialist Software and Computers

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Developing the E-Marketplace of the Future

Strategic Reviews Meetings

1 October 2014

- **Context of Global Fund Sourcing transformation**
- Setting the stage for a 21st century procurement approach
- Towards a global e-platform for Global Health

The Global Fund (GF) is broadly transforming its procurement approach in line with the 2012-2016 strategy

Since 2010-2011, the GF has been working to improve our operations and *demonstrate beyond a doubt that we are making the best investment for health impact*

As part of this, we have adopted a *new 2012-2016 strategy: “Investing For Impact”*

The new strategy includes:

- *Investing strategically* in areas with high potential for *impact* and *value for money*
- Providing funding in more *proactive*, more *flexible*, more *predictable* and more *effective* ways
- Becoming more *engaged* in *supporting* grant implementation success

In line with this strategy, the GF has launched a number of initiatives to *fundamentally rethink its approach to the procurement of goods and services, to deliver greater value for money & impact; collectively we call this “Procurement For Impact” (P4i)*

The objectives of the P4i effort are well aligned to the Global Fund's strategy...

The Global Fund will become the benchmark organisation in the sector for Sourcing and Procurement

Using simple, clear leading edge processes and tools designed by and for the organisation



Minimising waste and eliminating non value adding activities

With measurable performance in value and lives saved

Ensuring effective governance and watertight compliance

Building collaborative relationships with partner agencies suppliers and donors

... and the P4i effort will fundamentally change how the Global Fund works across the supply chain

Fundamentally changing the way we work across the supply chain to
increase access to products



Earlier involvement and closer collaboration with manufacturers

Improving our purchasing capability and changing our contracting models

Optimising the international supply chain to reduce cost and improve quality and efficiency

Better planning and scheduling to support continuity of supply

Delivering more products at the right time and place to more people

Current spend on procurement items is ~40% of total Global Fund disbursement

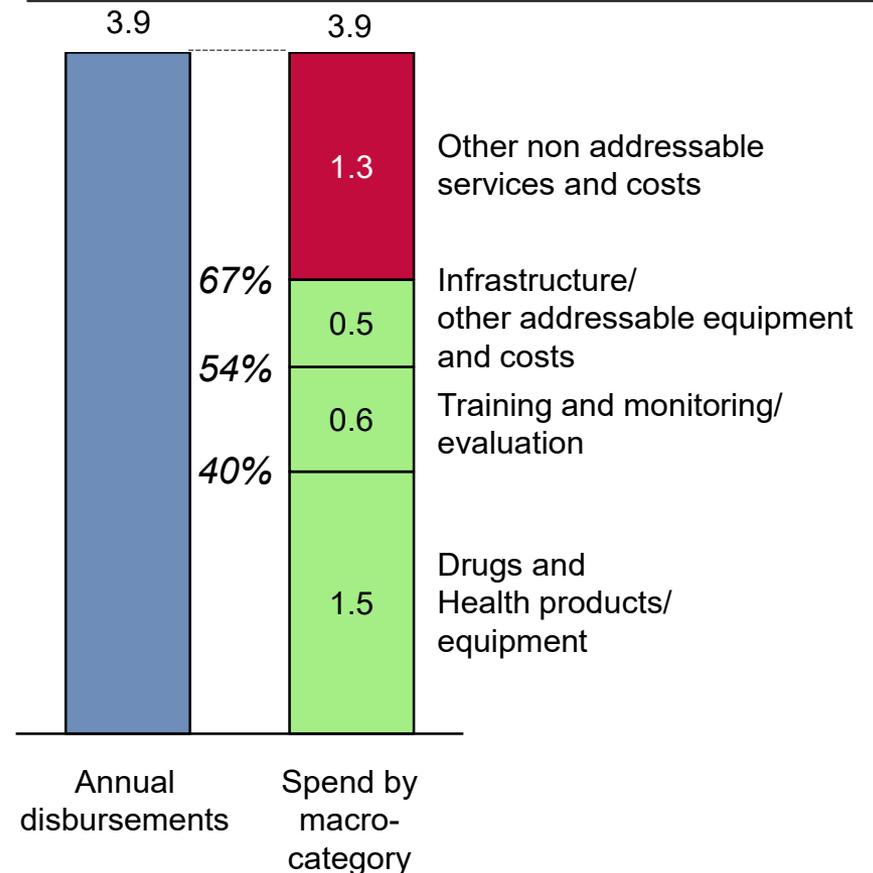
- Global Fund disbursed USD 3.9 bn in grants in 2013

- 40% for pharmaceuticals (e.g., ARVs, ACTs) and other health products (e.g., LLINs, lab equipment, rapid diagnostic tests)
- 27% for other addressable services and costs (e.g., project management, training) for centralized procurement

- Multiple purchase models exist for PRs

- Directly from manufacturers
- With support from Procurement Services Agents (PSAs)
- Leveraging the Pooled Procurement Mechanism (formerly the Voluntary Pooled Procurement) of the Global Fund

Global Fund spend on addressable commodities and services for centralized procurement USD billions, 2013



Agenda

- Context of Global Fund Sourcing transformation
- **Setting the stage for a 21st century procurement approach**
- Towards a global e-platform for Global Health

Global Health procurement must strategically evolve to accommodate countries' ownership...

From a trade-off model...

Despite savings and de-risking benefits, pooled procurement shows limitations

- Purchasing power and related **savings** through pooled orders
- **Mitigation of risk**
- **Better transparency**
- Increasing countries' **procurement and supply chain capacity**
- Call for **country ownership** and operational leeway
- Support for **local manufacturing**



To a virtuous model

Future model must provide market transparency while keeping countries owners and accountable for procurement operations

Market transparency and aggregation of volumes

Risk mitigation

Access to new markets for local manufacturers

Country fully autonomous and free for procurement



... and address gaps and limitations of current procurement approach



Global Health procurement market today...

- Akin to a crowded bazaar or physical marketplace with limited market intelligence and transparency
- Processes tend to be recurring and manual-intensive
- Limited visibility into lead-times, including shipping information
- Stakeholders have limited real-time connectivity
- Enrollment of country partners as primary stakeholders in the GF procurement marketplace



Our vision of Global Health procurement

A single technology platform to

- Provide buyers – countries and agencies – market power with a new tool at their disposal to source at cheaper price and with greatest range of options
- Eliminate information asymmetry and price variability
- Automate wherever possible through standardization and technology
- Shorten lead-times and make them more predictable
- Foster more of a community between stakeholders
- Limit human and financial resources required

Agenda

- Context of Global Fund Sourcing transformation
- Setting the stage for a 21st century procurement approach
- **Towards a global e-platform for Global Health**

A groundbreaking e-marketplace would enable to source Global Health products and services from multiple suppliers

Online marketplace

Buyers

Implementer countries



Aid agencies



Suppliers



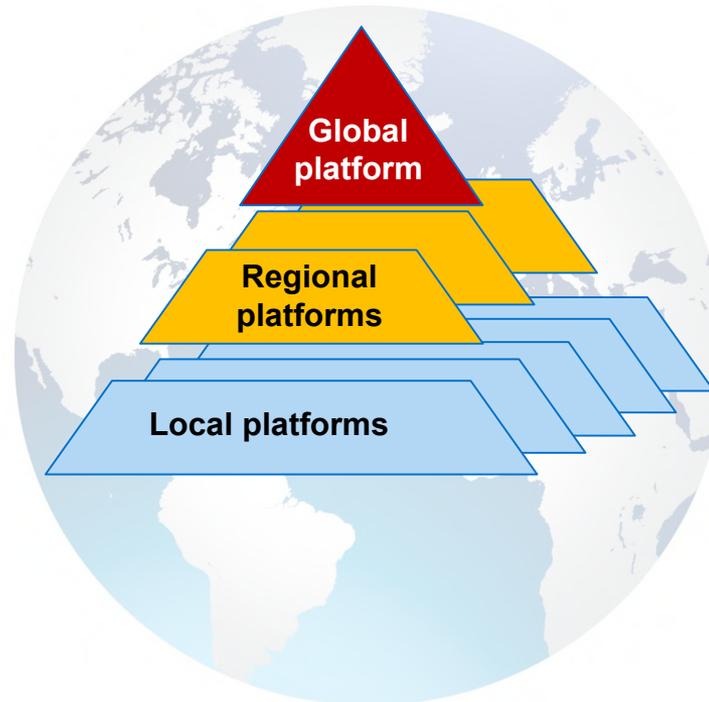
Manufacturers



Wholesalers/
Distributors



Shippers



- An online marketplace where buyers and suppliers meet to buy and sell products and services
- Intended to Global Fund implementers at first, with the aim to spin it off as a self-sustained sourcing platform for Global Health

This marketplace will be easy to use: it will offer visibility, predictability, and automation to reduce costly and time-consuming paperwork

Discover and search

You have access to...

Product catalogs from various qualified suppliers, with pre-negotiated prices and availability/delivery estimates

Search function that allows user to find best price, shortest lead-time, and highest quality

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One-click to submit an order...

Fill “shopping basket” with multiple items across categories

Get information on expected delivery timing, packaging,

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Submit a review to enhance the community-curated system



The e-marketplace shows numerous benefits, from savings to risk mitigation to increased country ownership...



Greater country ownership

- Provide countries freedom to **contemplate increasing market choices** of products and commodities and select the most favorable one under their terms
- **Provide countries full visibility on pricing**, enabling **optimal grant budgeting** and **benchmarking suppliers** according to countries' needs
- **Allow buyers to shape** the market through a pull model where they can input their desired specifications
- Create a continuous **capacity building and capability transference** of advanced procurement practices



Greater market transparency for buyer

- **Give full and real-time visibility** to buyers on global, regional and local catalogues of products and commodities
- **Generate substantial savings at global scale** thanks to aggregated volumes of purchase, enabling buyers to leverage purchasing power and negotiate better deals on direct and indirect products
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Greater supplier access to market

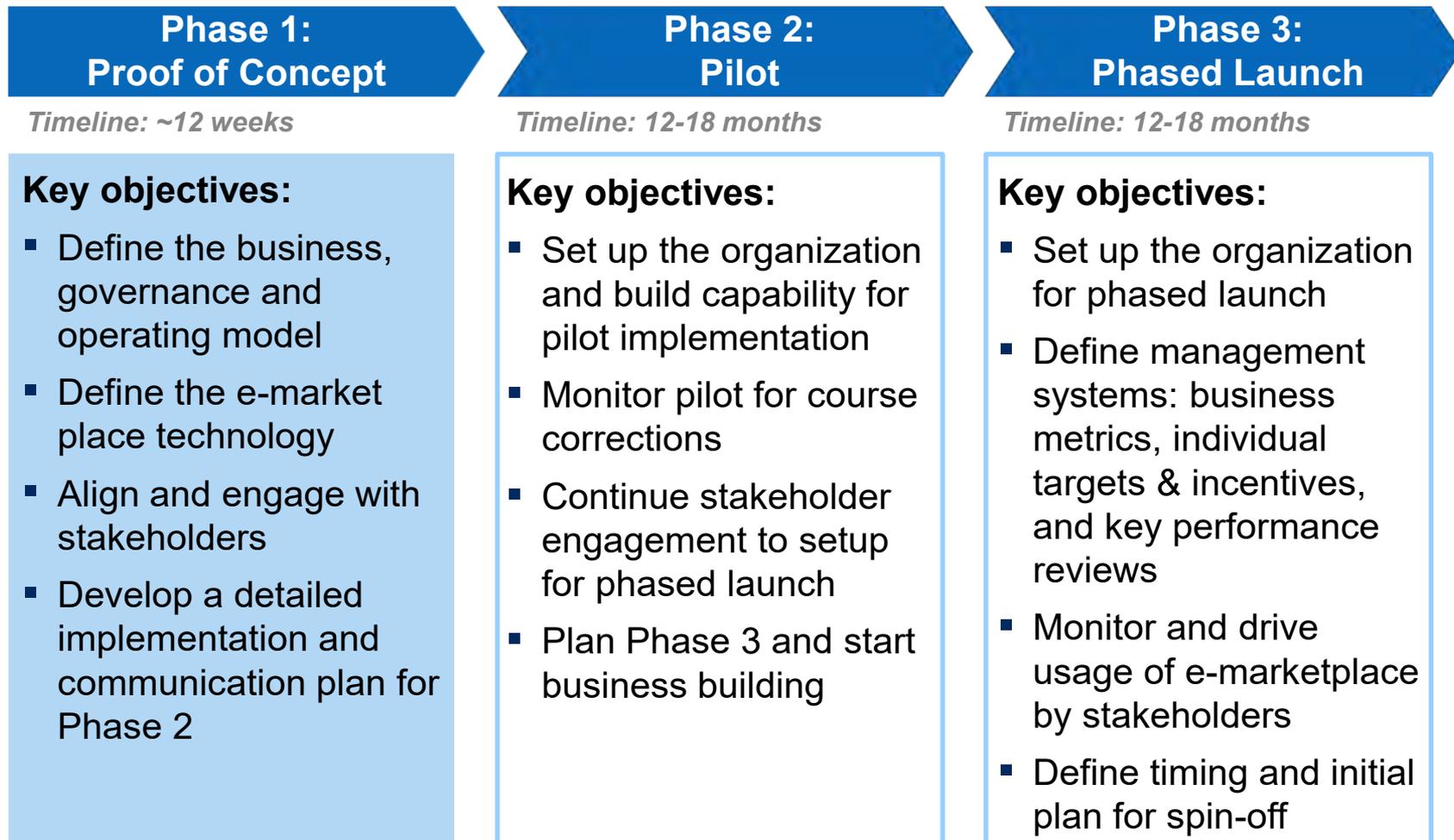
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Speedier and safer transactions

- **Automate transactions where possible, freeing up resources**
- **Reduce financial/fiduciary risk and transaction costs** through direct payment to suppliers from donors, without transiting through in-country third parties
- **Shorten up lead-times** and make them more predictable, **reduce administrative burden**

The overall e-marketplace project is planned over 3 phases, with imminent start of Phase 1



- **Gather in groups, discuss the e-marketplace and report to the plenary**
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Developing the E-Marketplace of the Future

Strategic Reviews Meetings

1 October 2014

- **Context of Global Fund Sourcing transformation**
- Setting the stage for a 21st century procurement approach
- Towards a global e-platform for Global Health

The Global Fund (GF) is broadly transforming its procurement approach in line with the 2012-2016 strategy

Since 2010-2011, the GF has been working to improve our operations and *demonstrate beyond a doubt that we are making the best investment for health impact*

As part of this, we have adopted a *new 2012-2016 strategy: “Investing For Impact”*

The new strategy includes:

- *Investing strategically* in areas with high potential for *impact* and *value for money*
- Providing funding in more *proactive*, more *flexible*, more *predictable* and more *effective* ways
- Becoming more *engaged* in *supporting* grant implementation success

In line with this strategy, the GF has launched a number of initiatives to *fundamentally rethink its approach to the procurement of goods and services, to deliver greater value for money & impact; collectively we call this “Procurement For Impact” (P4i)*

The objectives of the P4i effort are well aligned to the Global Fund's strategy...

The Global Fund will become the benchmark organisation in the sector for Sourcing and Procurement

Using simple, clear leading edge processes and tools designed by and for the organisation



Minimising waste and eliminating non value adding activities

With measurable performance in value and lives saved

Ensuring effective governance and watertight compliance

Building collaborative relationships with partner agencies suppliers and donors

... and the P4i effort will fundamentally change how the Global Fund works across the supply chain

Fundamentally changing the way we work across the supply chain to
increase access to products



Earlier involvement and closer collaboration with manufacturers

Improving our purchasing capability and changing our contracting models

Optimising the international supply chain to reduce cost and improve quality and efficiency

Better planning and scheduling to support continuity of supply

Delivering more products at the right time and place to more people

Current spend on procurement items is ~40% of total Global Fund disbursement

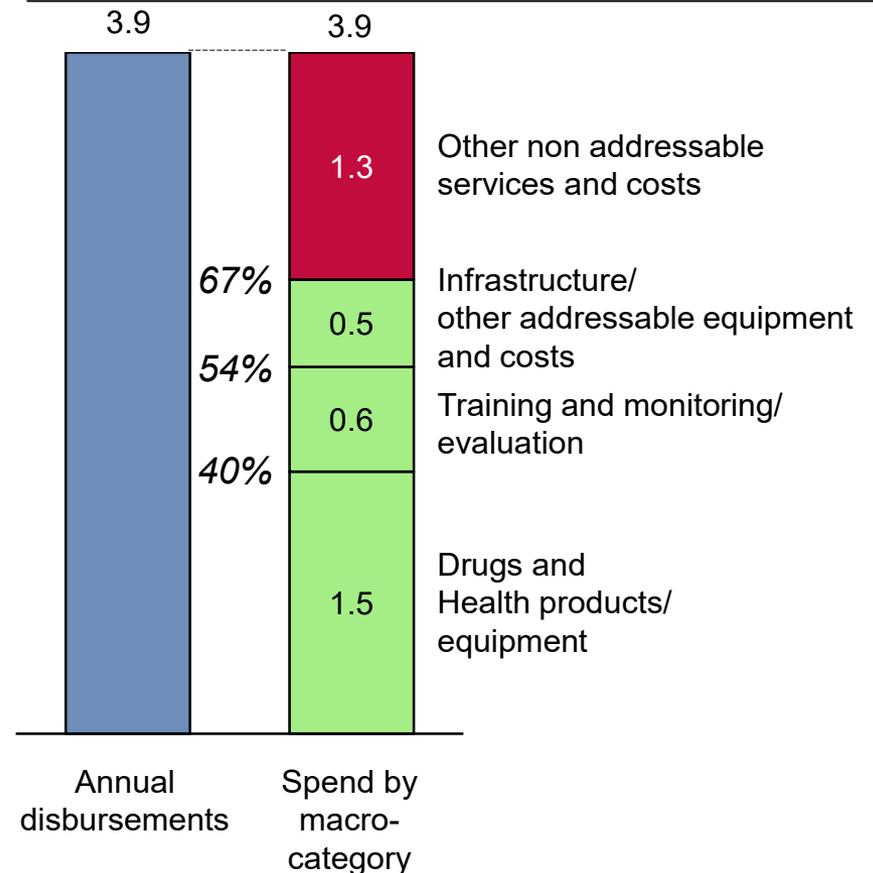
- Global Fund disbursed USD 3.9 bn in grants in 2013

- 40% for pharmaceuticals (e.g., ARVs, ACTs) and other health products (e.g., LLINs, lab equipment, rapid diagnostic tests)
- 27% for other addressable services and costs (e.g., project management, training) for centralized procurement

- Multiple purchase models exist for PRs

- Directly from manufacturers
- With support from Procurement Services Agents (PSAs)
- Leveraging the Pooled Procurement Mechanism (formerly the Voluntary Pooled Procurement) of the Global Fund

Global Fund spend on addressable commodities and services for centralized procurement USD billions, 2013



Agenda

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Global Health procurement must strategically evolve to accommodate countries' ownership...

From a trade-off model...

Despite savings and de-risking benefits, pooled procurement shows limitations with competing countries' interests

- Purchasing power and related **savings** through pooled orders
- **Mitigation** of fiduciary and operational **risk**
- **Better transparency** and oversight
- Increasing countries' **procurement and supply chain capabilities** and **capacity**
- Call for **country ownership** and operational leeway
- Support for **local manufacturing**



To a virtuous model

Future model must provide market transparency while keeping countries owners and accountable for procurement operations

Market transparency on benchmark costs and **aggregation of volumes**, leading to substantial savings

Risk mitigation through direct cash-to-suppliers transfers

Access to new markets for local manufacturers through single sourcing platform

Country fully autonomous and free for procurement operations



... and address gaps and limitations of current procurement approach



Global Health procurement market today...

- **Akin to a crowded bazaar or physical marketplace** with limited market intelligence and transparency, leading to sub-optimal purchase decisions, great price variability and wastage:
- Processes tend to be **recurring and manual-intensive**, leading to non-mission essential tasks and potential for errors/omissions
- **Limited visibility into lead-times, including shipping information** before and after the order is placed, making it difficult to plan
- Stakeholders **have limited real-time connectivity** which limits collaboration and best-practice sharing
- Enrollment of **country partners as primary stakeholders** in the GF procurement marketplace



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A single technology platform to

- **Provide buyers – countries and agencies – with a new tool at their disposal** to source at cheaper price and with greatest range of options though under their terms and strategy
- **Eliminate information asymmetry** and price variability giving all buyers the same and full view of product specifications and vendor performance
- **Automate wherever possible** through standardization and technology, freeing up resources for other work
- **Shorten lead-times** and make them more predictable
- **Foster more of a community between stakeholders**
- **Give buyers market power** with ability to access one single platform for procurement to place orders, provide reviews and quality scores
- **Limit human and financial resources** required

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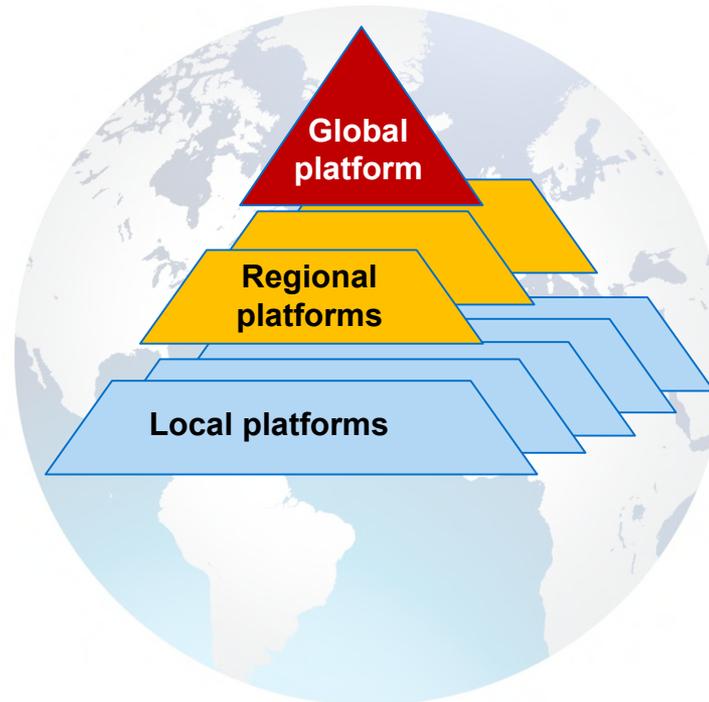
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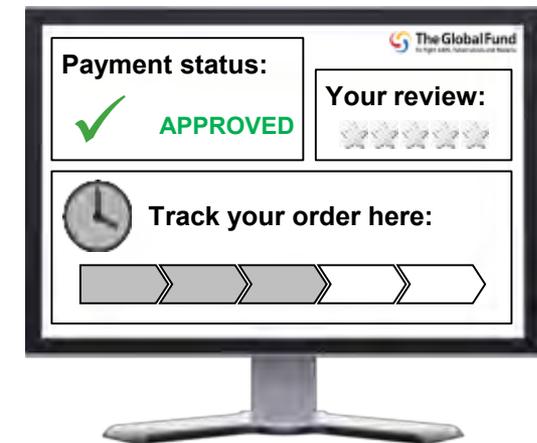
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- Create a continuous **capacity building and capability transference** of advanced procurement practices to countries



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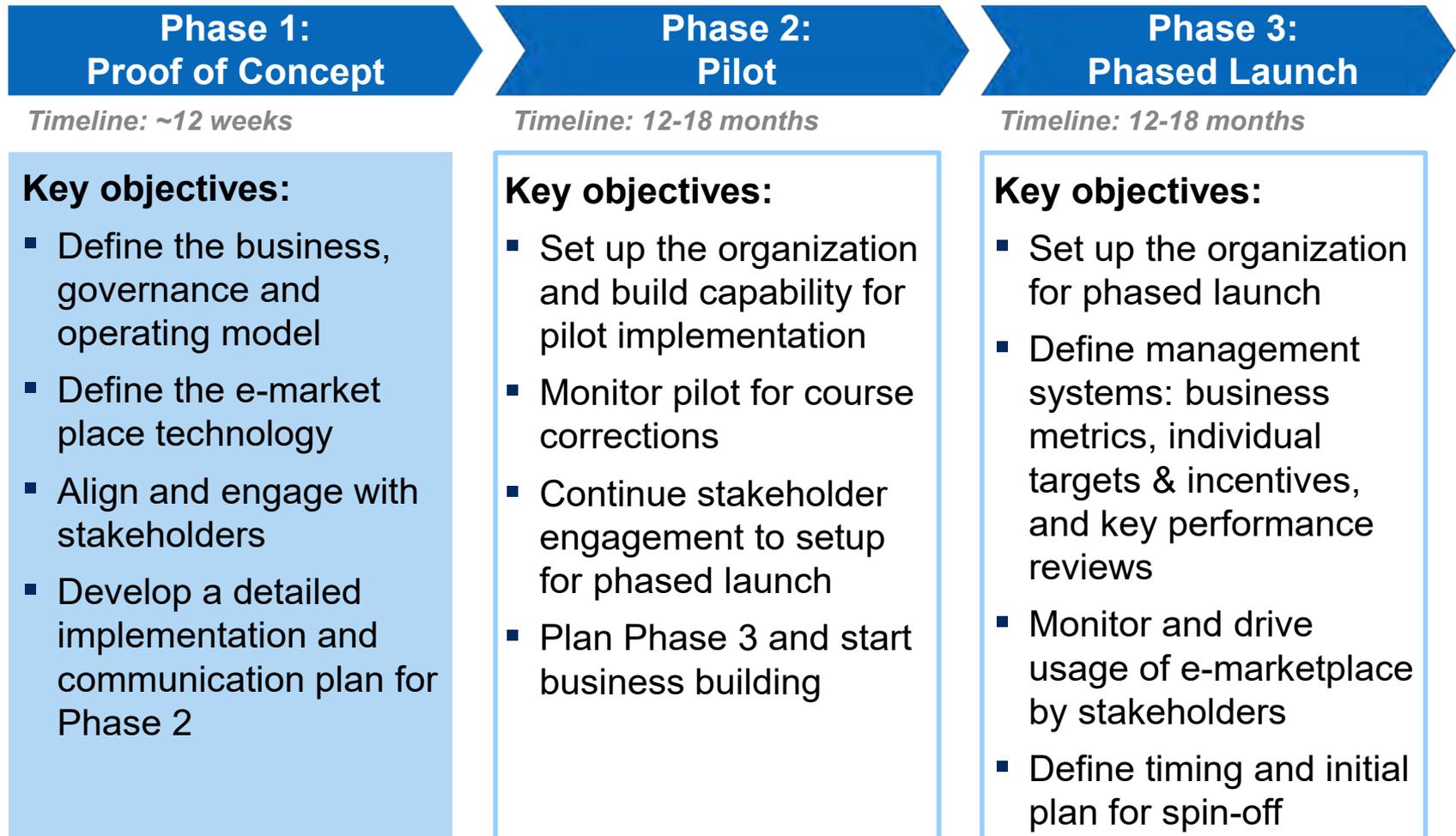
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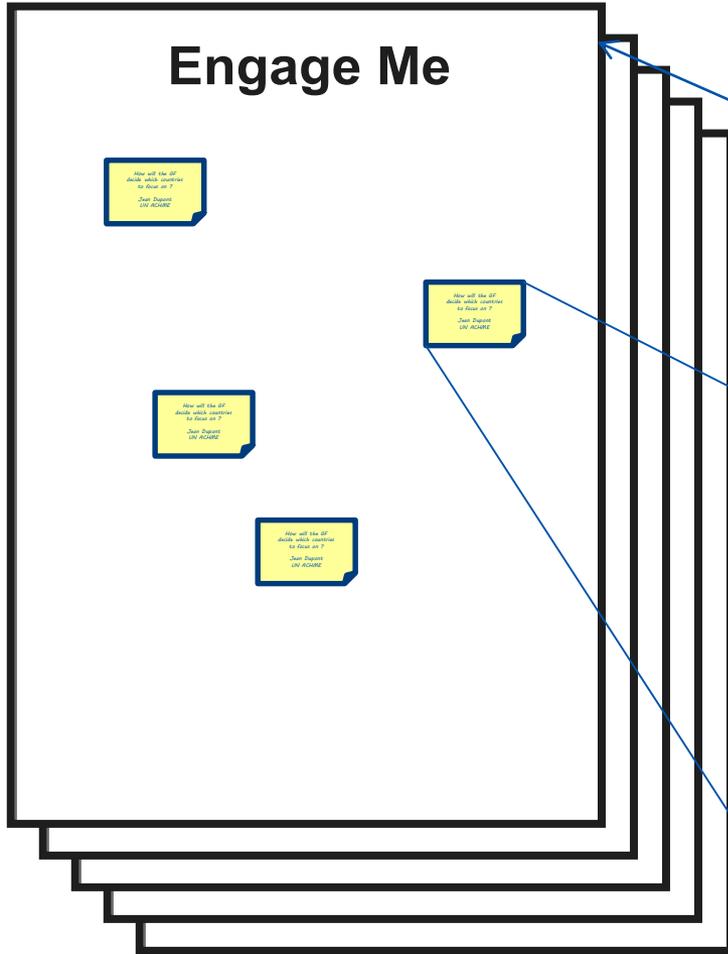


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Indicate how you wish to be involved



Desired involvement

Engage Me

Consult Me

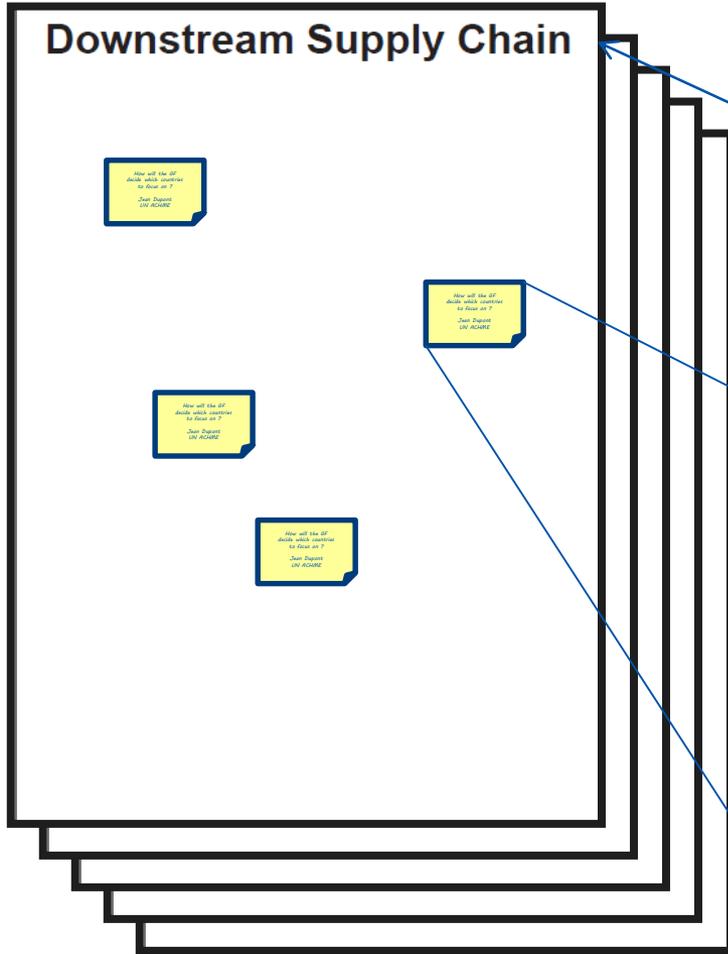
Keep me informed

Not a priority for me

I'd like to be actively involved in the e-marketplace

*Jean Dupont
UN ACME*

Feedback/ questions during the event



Feedback / questions
HIV
TB
Malaria
HIV Diagnostics
Downstream Supply Chain
In-Country Supply Chain
JIATF
e-Marketplace

How will the GF decide on which countries to focus?

*Rudolph Lingens
UN ACME*

Twitter feed

#Procurement4Impact

Prepare yourself for a live-feedback meeting



1. Login to your personal Twitter account
2. Tweet using [#procurement4impact](#)
3. Live feedback shows up on screen!



GF Strategic Reviews in Procurement and Market Dynamics Day 3 - TB

Starling Hotel, Geneva

3 October 2014

Day 3 - Agenda

Type	Time	Topic
●	08.30 – 08.55	Registration and Coffee
●	09.00 – 9.05	Welcome and Introduction
●	09.05 – 9.45	Update on the New Funding Model
●	09.45 – 10.30	Scene-setting <ul style="list-style-type: none"> • What's the big picture? (Stop TB) • TB Landscape and Market Forum Outcomes (UNITAID) • Challenges in TB from the Global Fund perspective (GF)
●	10.30 – 10.45	Coffee Break
●	10:45 – 11.45	Deep Dive Session – Challenge # 1 (Prioritization): Feedback on initial concept notes, including opportunities/challenges for joint TB/HIV notes
●	11.45 – 13.00	Deep Dive Session – Challenge # 2 (Demand) : In-country challenges in ensuring access to treatment for TB patients
●	13.00 – 14.00	Lunch
●	14.00 – 15.30	Deep Dive Session – Challenge # 3 (Supply): Challenges and vulnerabilities in the supply of TB medicines
●	15.30 – 15.45	Coffee Break
●	15.45 – 16.30	Summary and Actions; Feedback and Closing Remarks

Objectives and output

Objectives	<p>To develop a roadmap on how to support the acquisition and implementation of TB products better</p> <ul style="list-style-type: none">• Map out partners'/organizations' ongoing or planned (and funded) activities/initiatives• Identify any gaps/opportunities that can be realistically addressed in the short- to medium-term• Jointly agree on actions and deliverables
Output	<p>Rough road map against which Global Fund and other partners/organizations could work. This roadmap will serve to monitor progress at the next Global Fund Strategic Review on TB and HIV Diagnostics in 12-18 months.</p>

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NEW FUNDING MODEL

Mark Edington
Head, Grant Management Division
October 2014

Principles of the new funding model



The new funding model has been designed to bring the **Global Fund Strategy of 'Investing for Impact'** to life. The new model will improve the way the Global Fund assesses, approves, disburses, and monitors grants

Principles of the new funding model

- **Bigger impact:** focus on countries with the highest disease burden and lowest ability to pay, while keeping the portfolio global
- **Predictable funding:** process and financing levels become more predictable, with higher success rate of applications
- **Ambitious vision:** ability to elicit full expressions of demand and reward ambition
- **Flexible timing:** in line with country schedules, context, and priorities
- **More streamlined:** for both implementers and the Global Fund

Total funding from Global Fund is increasing

- **The total funds for allocation are 20% higher than what we have disbursed in the past.**
 - The total funds to be allocated to countries, available as of January 1, 2014 (including existing funds): **US\$ 14.8 billion**
 - Average implied funding level: **US\$ 3.7 billion per year**
 - This compares favorably vs. the average annual disbursement rates of **US\$ 3.2 billion**. However, this is less than the higher rate of disbursement in 2013 of **US\$ 3.9 billion**
- **In addition, the Global Fund will allocate:**
 - **US\$ 950 million** of incentive funding which will be awarded to ambitious programs that deliver impact in country
 - **US\$ 200 million** for new regional grants and **US\$ 91 million** to finish existing regional grants

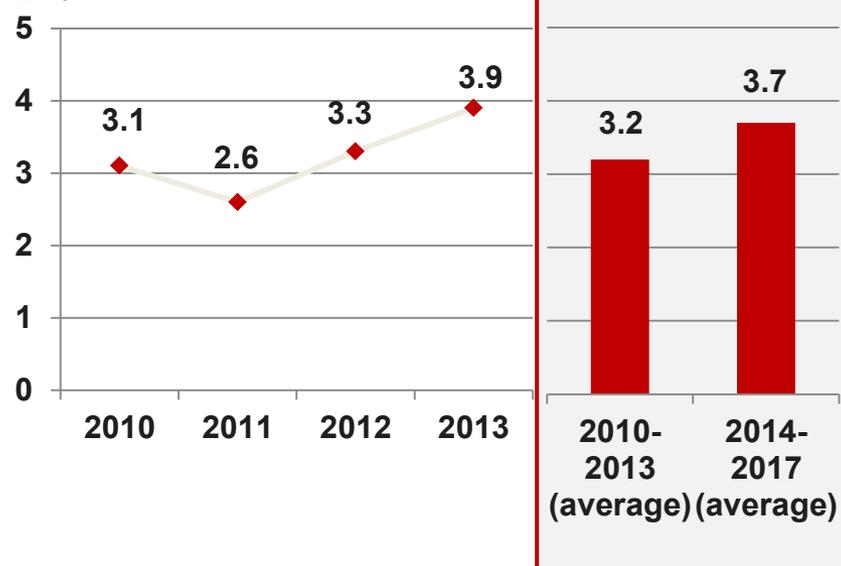
This represents US\$ 16 billion for countries

On average, most countries will receive more funds

- **On average, countries will receive more funds** from the Global Fund for this Replenishment period than they did in the past.
- In many countries, **funds from the Global Fund include (only) existing funds** that must be used for maximum impact
- **For many countries, 2013 was a peak year for GF disbursements** as the Global Fund 'unstuck' grants and a backlog of funds flowed to countries. This means that **there will be a decrease in funding compared to 2013 levels.**

Disbursements

US\$
in bn



Stronger resource prioritization is critical to achieving impact

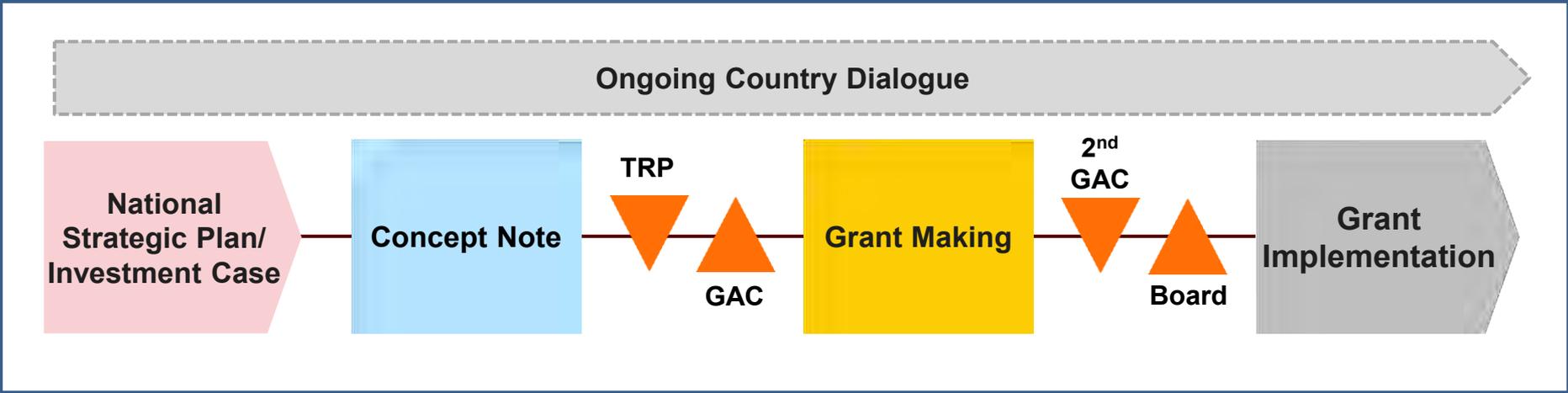
Resources available to countries

- Existing grants should be used as effectively as possible, ensuring that programs are regularly evaluated and grants reprogrammed when it makes sense for maximum impact
- Any additional funding should be harmonized with existing funding; disease programs should be viewed in a holistic manner
- Donor funding should be coordinated and aligned in-country to avoid duplication/inefficiencies

Strategic investment for maximum impact

- Funding requests are based on quality national strategies
- Resources are focused on targeting the right populations
- Decisions on the allocation of resources are based on evidence/data
- Costs can be driven down by optimizing procurement/supply chain

New funding model cycle



Key principles of country dialogue

Ongoing process to develop health strategies

- Develop NSP for the three diseases
- Strengthen health and community systems

Country-led process used to request Global Fund support

- Align funding request on NSP or investment case
- Produce a concept note that maximizes the impact of Global Fund resources

Open, inclusive and participatory process

- Matches involvement of stakeholders to the epidemic in the country
- Builds concept notes based on inputs of those most affected

Where should partners be involved in the new funding model?

Provide policy advice, technical support and capacity building in the following areas:

- Engaging and supporting key population involvement
- Understand epidemic with epi analysis and program reviews
- Strengthen national systems and capacities to implement with NSP development and review
- Shape investment strategies via concept note development and grant making
- Ensure investment impact via program monitoring

Grant Management and Procurement/Sourcing

The Global Fund's Procurement Department works closely with the Country Teams in Grant Management as a fundamental part of the grant making process to:

- work across the supply chain to increase access to products
- provide quicker responses and shorter lead times for procurements, where we have grant ready proposals coming to the Board for approval

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Improving Access for Quality-Assured TB Medicines & Diagnostics



Critical Vulnerabilities of TB Medicines Supply Chain

Dr Joël Keravec

GDF Manager

Global Fund Strategic Review – October 3rd, 2014



Outline

1. Highlights on key TB supply chain vulnerabilities
2. Looking forward: is the landscape changing?
3. How can partners address the remaining challenges?
4. Discussion / Q&A



Mapping Critical Vulnerabilities for TB Supply Chain

Key Challenges

1. In Country Planning / Preparation Phase



- ⇒ Country not adhering to WHO guidelines / product demand not standardized
- ⇒ Realistic planning based on treatment capacity targets + diagnostic (Xpert) projections
- ⇒ Late planning does not allow for standard delivery – disconnection between grants targets and capacity
- ⇒ Management support , information systems, monitoring and quantification systems are weak
- ⇒ Over reliance on emergency orders by countries through SRS

2. Lack of funding or complex & lengthy financial mechanisms have hampered processes



- ⇒ Delays in finalization of agreements with donors & lack of coordination in grants disbursement
- ⇒ Budget available not sufficient to cover the costs of the order or not secured / available at the time of the quote confirmation
- ⇒ Documentation required by the authority releasing the funds is not completed
- ⇒ Specific tenders for using government monies
- ⇒ Mandatory prepayment condition against public accountability for domestic funds use

3. Production based on a make to order paradigm increased lead time + hampered efficiency



- ⇒ Global demand still perceived as low and unpredictable with small fragmented orders & sub-optimal batch sizes
- ⇒ Limited planning and capacity allocation flexibility->long lead times
- ⇒ Few WHO PQP API manufacturers: WHO PQ process perceived as onerous and lengthy by suppliers
- ⇒ monopoly risk & API+FPP vertical integration risk
- ⇒ Higher Costs of FPP
- ⇒ Info systems not always optimized / integrated to serve procurement cycle and decrease LT

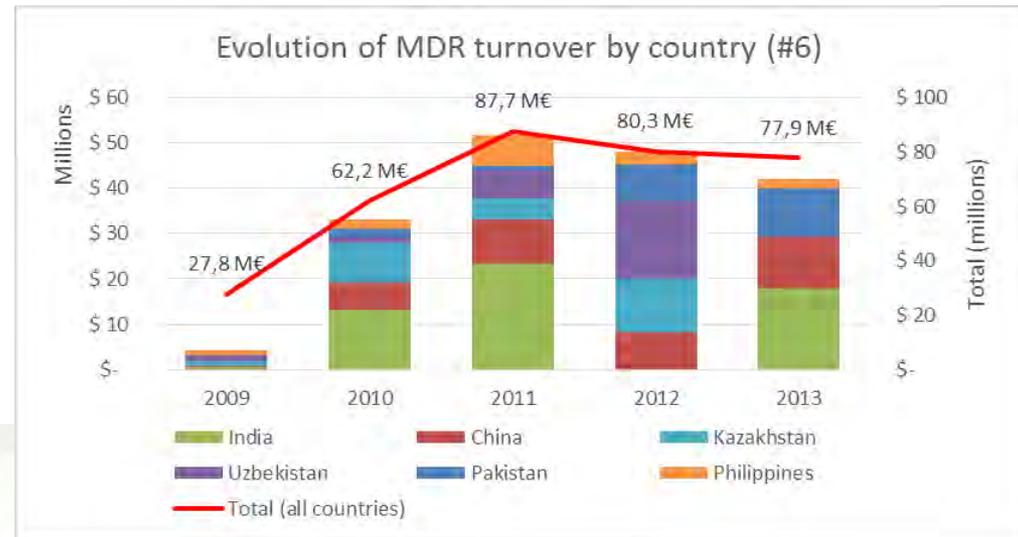
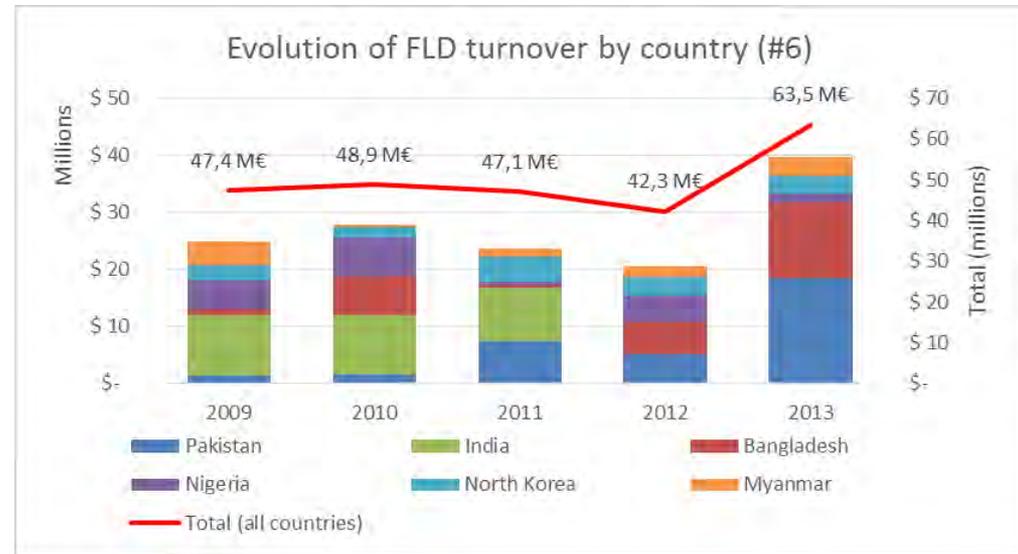
4. In country supply chain challenges remain with a lack of alignment of key actors



- ⇒ Procurement, Inventory and Distribution challenges
- ⇒ Minimum 75% remaining shelf life requirement by many countries in short shelf-life product settings (24 months)
- ⇒ Registration and importation:
- ⇒ Regulatory requirements are getting more complex, with several levels for approval:
- ⇒ WHO PQ products not recognized as SDRA approval => no mutual recognition of registration across regions => like USFDA, EU some other countries requirements don't allow for importation on waivers for NTPs

Turnover by country is very variable, and depends a lot on grants affectation with impact on the activity

- Turnover evolution from 2009 to 2013, for FLD and MDR – analysis on 6 countries
- Ranking is quite volatile from one year to another
 - Procurement fragmentation/lack of coordination
 - Financing issues/in-country management problems
 - Treatment capacity
- Countries exiting or requesting GDF services have a big impact on global activity and are not easy to predict



Current TB Supply Chain Process

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

NTP Procurement & Funding planning
12 to 24 months
75%

NTP Final Drug
Quantification
+ Payment
Mechanism



NTP funding
plan & request

NTP calculates
theoretical
drugs
requirements

NTP assess
stocks &
shelf life

NTP
surveillance
data collection:
enrollment
rates, etc

If Drugs in stock +
immediate payment



If late payment,
delayed PO =>
production

GDF supply chain = **1/4**
From 1 to **12 months**
25%

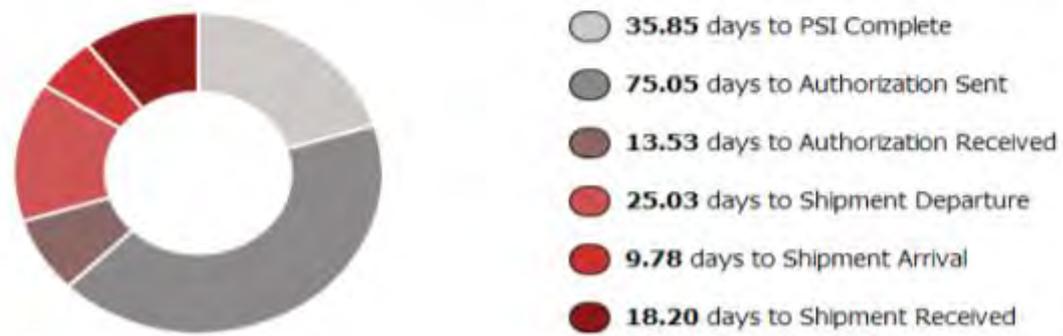


Country Profile Dashboard – Transparency on Lead Times Issues

Order Lead Times in Days from Order Initiation



Shipment Lead Times in Days from Order Placed with Suppliers



New: Supply Chain Process with Guarantee Fund and SRS



TB Drugs Supply Chain Vulnerabilities: Main Challenges and Priorities

- **< 3 eligible suppliers & limited production capacity :**
 - Paediatric formulations (FDCs), RH150/150mg, H300mg
 - Km, Cm, Cfz, Lnz, Pth, Trz
- **Short shelf life (24 months only):**
 - 100% of paediatric formulations (FDCs)
 - 2 out of 4 suppliers manufacturing adults FDCs
 - 40% of SLDs
- **Limited # of API suppliers:**
 - Km, Cm, Cfz, H,
- **Registration related issues:**
 - slow; limited quantities; complex NRA requirements
- **Focus on new drugs / paediatrics:**
 - 2 new anti-TB drugs entering the market in over 35 years
 - New paediatric formulations require support for early uptake by countries
- **How can we sustain the gains within IQA drugs market when countries transition from a donors funded market into domestic funding & not creating parallel procurement systems**

Key MDR-TB & SLDs challenges

- ✓ Lack of standardized regimens => DM complexity
- ✓ High variability in supply stability / suppliers basis
- ✓ Complex manufacturing processes for injectables
- ✓ Relatively small basis of IQA manufacturers (API+FFP)
- ✓ API impact on FFP cost estimated between 30 to 60%
- ✓ Limited competition for API and FFP with monopolistic situations & risk of vertical integration creating additional monopoly risks
- ✓ Risks of prices increase/risk premium
- ✓ Risks of counterfeit/substandard medicines



API Issues

- While having 2 or more suppliers for each of FPP, concerns remain of API monopoly and related supply risks:
 - While oral medicines normally have more than 1 quality API source, the situation with injectables is causing a concern due to either monopoly, low capacity or low quality of API
 - WHO PQP started prequalification of APIs, but only anti-5 DR-TB APIs are prequalified to date.
 - Additional risks of monopoly if FFP manufacturers would choose to use only PQd API (to avoid additional burden to submit APIMF – Active pharmaceutical ingredient master file to WHO PQP)

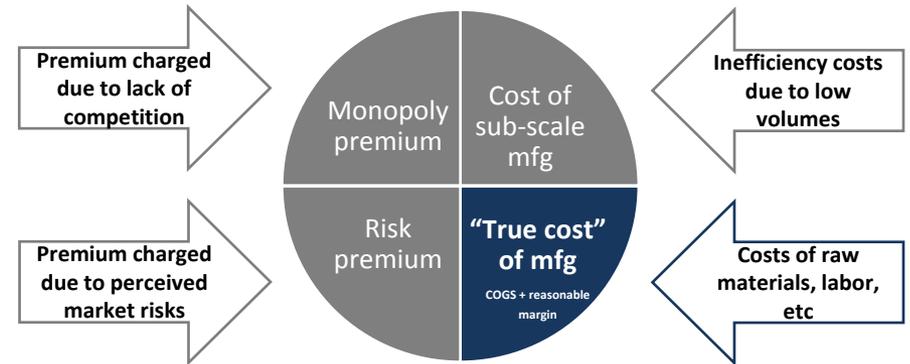
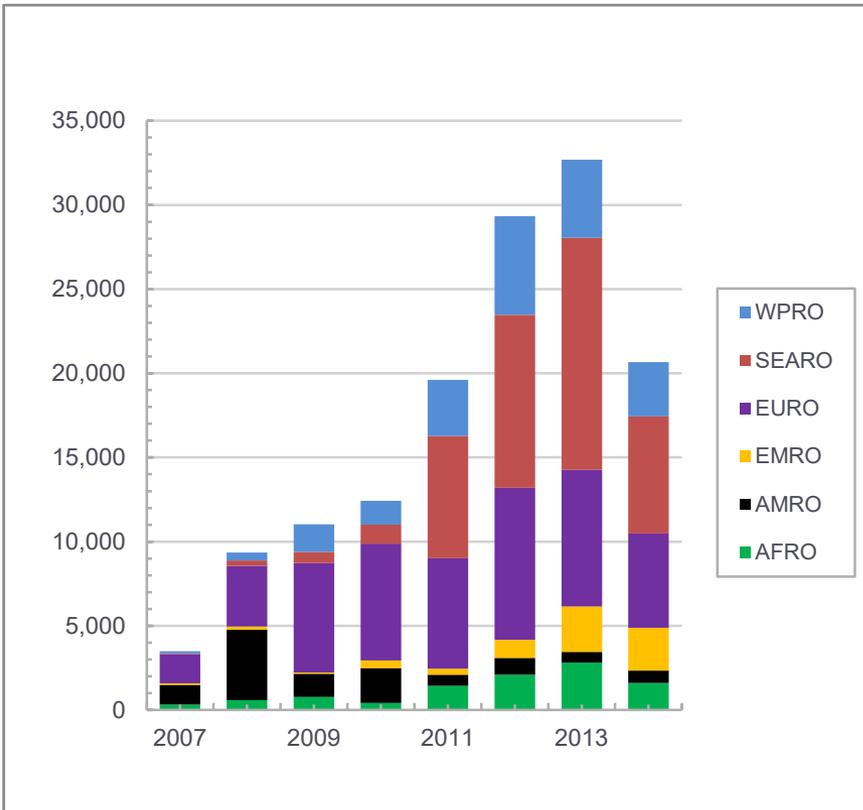


WHO List of Prequalified APIs for TB

Updated 01.10.2014

WHO reference number	INN	Applicant	Manufacturing site	Date of Prequalification
WHOAPI-078	Pyrazinamide	Calyx Chemicals & Pharmaceuticals Ltd	India	01-December-2011
WHOAPI-086	Isoniazid	Calyx Chemicals & Pharmaceuticals Ltd	India	07-December-2011
WHOAPI-028	Rifampicin	Lupin Ltd	India	08-May-2012
WHOAPI-158	Pyrazinamide	Anuh Pharma Ltd	India	12-July-2012
WHOAPI-093	Ethambutol (hydrochloride)	Lupin Ltd	India	10-October-2012
WHOAPI-040	Pyrazinamide	Lupin Ltd	India	10-October-2012
WHOAPI-106	Protionamide	Pen Tsao Chemical Industry Ltd	China	13-February-2013
WHOAPI-105	Etionamide	Pen Tsao Chemical Industry Ltd	China	23-April-2013
WHOAPI-177	Cycloserine	Shasun Pharmaceuticals Ltd	India	07-May-2013
WHOAPI-113a	Rifampicin	Sandoz Pvt Ltd	India	22-August-2013
WHOAPI-113b	Rifampicin	Sandoz Pvt Ltd	India	22-August-2013
WHOAPI-113c	Rifampicin	Sandoz Pvt Ltd	India	22-August-2013
WHOAPI-113d	Rifampicin	Sandoz Pvt Ltd	India	22-August-2013
WHOAPI-168	Isoniazid	Second Pharma Co Ltd	China	25-September-2013
WHOAPI-169	Capreomycin (sulfate)	Zhejiang Hisun Pharmaceutical Co Ltd	China	29-April-2014
WHOAPI-203	Levofloxacin	Zhejiang Langhua Pharmaceutical Co Ltd	China	17-July-2014

SLDs evolving landscape and remaining challenges



- **Volumes MDR TB drugs have increased to more significant levels in recent years**
- **The supplier base has shown promising growth in parallel**
- **Challenges and supply threats remain**

From GDF/CHAI joint SLDs landscape analysis, presented at GDF Strategic Advisory Committee Meeting, September 2014

Working towards improved SLD supply security (1)

#	SLDs	# Eligible suppliers, 2011	# Eligible suppliers, 2012	# Eligible suppliers, 2013	# Eligible suppliers, 2014	Manufacturer & QA status
1	Amikacin 500mg/2ml vial	2	2	4	4	Medochemie (SRA) Mylan (SRA) Cipla (WHO PQP) Pharmatex (SRA)
2	Capreomycin 1 g vial	1	1	3	2	Eli Lilly (FDA USA) until 2011 Akorn (FDA, USA) Vianex (SRA)
3	Cycloserine 250mg tablet	3	3	6	7	Aspen (WHO PQP, backup) Chao Centre (FDA USA, backup) Macleods (WHO PQP) Lupin (ERP) Dong-A (WHO PQP) Cipla (ERP) Biocom (WHO PQP, backup)
4	Ethionamide 250mg tablet	1	1	4	4	Macleods (WHO PQP) Cipla (WHO PQP) Lupin (WHO PQP) Microlabs (WHO PQP)
5	Kanamycin 1gr vial	1	2	2	2	Meiji (SRA) Panpharma (SRA)
6	Levofloxacin 250mg tablet	3	3	4	4	Cipla (WHO PQP) Hetero (ERP) Microlabs (WHO PQP) Macleods (ERP*)
7	Levofloxacin 500mg tablet	3	3	4	4	Cipla (WHO PQP) Hetero (WHO PQP) Microlabs (WHO PQP) Macleods (ERP)
8	Moxifloxacin 400mg tablet	2	2	4	5	Bayer (SRA) Cipla (WHO PQP) Hetero (WHO PQP) Macleods (ERP) Sandoz (ERP)
9	Ofloxacin 200mg tablet	1	1	3	4	Cipla (WHO PQP) Microlabs (WHO PQP) Macleods (WHO PQP) Remedica (SRA)

Working towards improved SLD supply security (2)

10	Ofloxacin 400mg tablet	2	2	2	3	Microlabs (WHO PQP) Remedica (SRA)
11	PAS acid granules	3	3	3	3	Jacobus (SRA)
	PAS sodium granules					Macleods (WHO PQP)
	PAS sodium powder					Olainfarm (WHO PQP/SRA)
12	Prothionamide 250mg tablet	1	2	2	3	Fatol (SRA) Microlabs (WHO PQP) Cadila (ERP)
13	Terizidone 250 mg capsule	1	1	1	1	Fatol (SRA)
14	Amoxi/Clavunate 875+125mg tablet	0	0	2	3	Medochemie (SRA) Reig Jofre (SRA) Microlabs (WHO PQP)
15	Amoxi/Clavunate 500+125 mg tablet	0	0	3	4	Remedica (SRA) Medochemie (SRA) Reig Jofre (SRA) Microlabs (WHO PQP)
16	Amoxi/Clavunate 250+125 mg tablet (+2 suppliers for suspension)				3	Remedica (SRA) Medochemie (SRA) Microlabs (WHO PQP)
17	Clarithromycin 500 mg tablet	0	0	2	2	Remedica (SRA) Medochemie (SRA)
18	Clarithromycin 250 mg tablet	0	0	2	2	Remedica (SRA) Medochemie (SRA)
19	Clofazimine 100 mg capsule	0	0	1	1	Novartis through Victoria Pharmacy (SRA)
20	Linezolid 600 mg tablet	0	0	2	2	Pfizer (SRA) Hetero (ERP)
21	Imipenem/Cilastatin 500mg + 500mg injectable, IV (vial/ampoule)	0	0	2	3	Panpharma (SRA) Labatec (SRA) Demo (SRA)

NOTE: backup supplier - approved, but either cannot produce large volumes and/or does not provide appropriate packaging (i.e. loose product only)

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

There are a few possible 'interim' result scenarios:

- 1 Early STREAM results, non-BDQ (end 2015/early 2016)
- 2 Interim END-TB findings from PIH/MSF/UTD (2016??)
- 3 Observational study for UNION short course (end 2016)

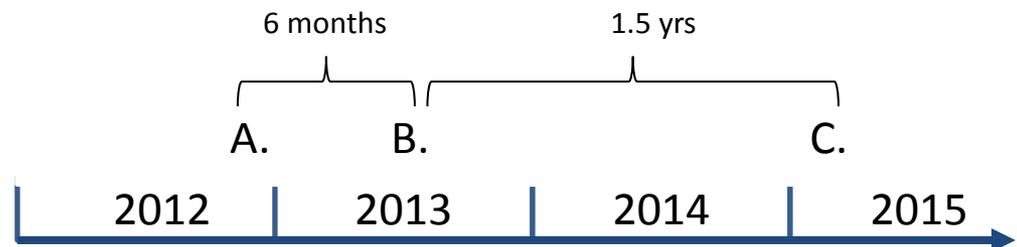


Positive results will influence some NTP decisions, but it will take time

- 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)

The Bedaquiline experience confirms this expectation:

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

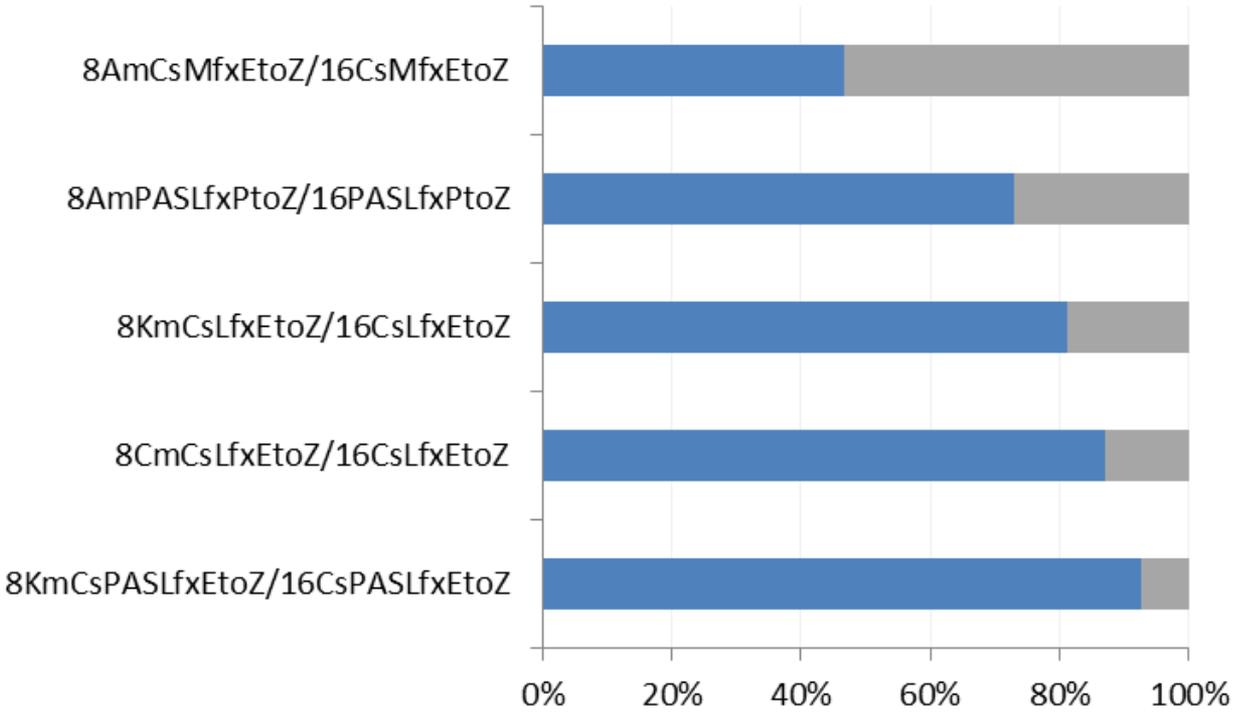


>12 drugs are indicated for standard MDR-TB therapy, 4 make up a majority of costs and are vulnerable to supply security risks

MDR-TB regimen costs driven by 4 MDR-TB medicines:

- Capreomycin
- Cycloserine
- PAS
- Kanamycin

⇒ **45-90% of cost per MDR-TB treatment**
(depending of regimen)

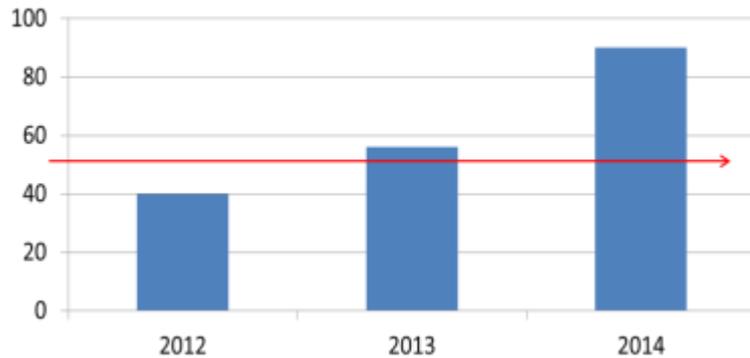


GDF prices. From GDF/CHAI joint SLD landscape analysis, GDF Strategic Advisory committee meeting, September 2014



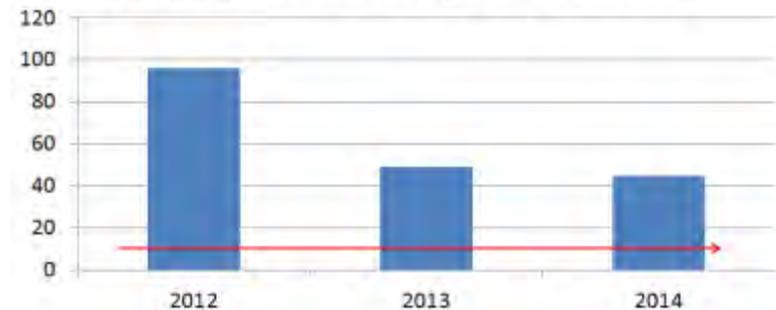
SLDs Supply Chain Vulnerabilities Mapping: Adopting a risk management approach (1)

Cycloserine Units, in million capsules



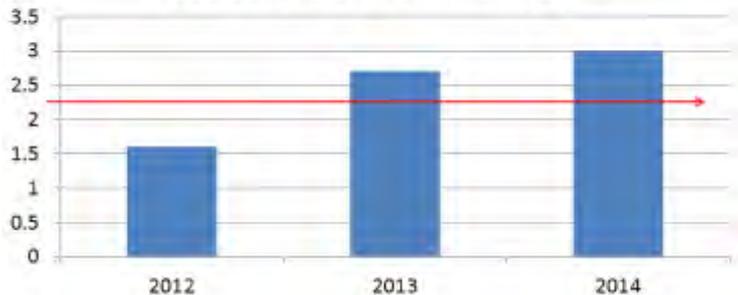
WHO PQ/ SRA / ERP	API	FDF in review	API in Review	
Macleods Dong A TCC Biocom	4	2	3	0

PAS Units, in million sachets, Na+Acid combined



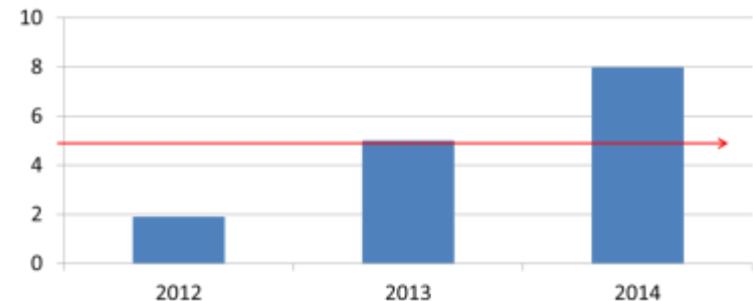
WHO PQ/ SRA / ERP	API	FDF in review	API in Review	
Jacobus Macleods OlainFarm	3	2	0	0

Capreomycin Units, in million vials



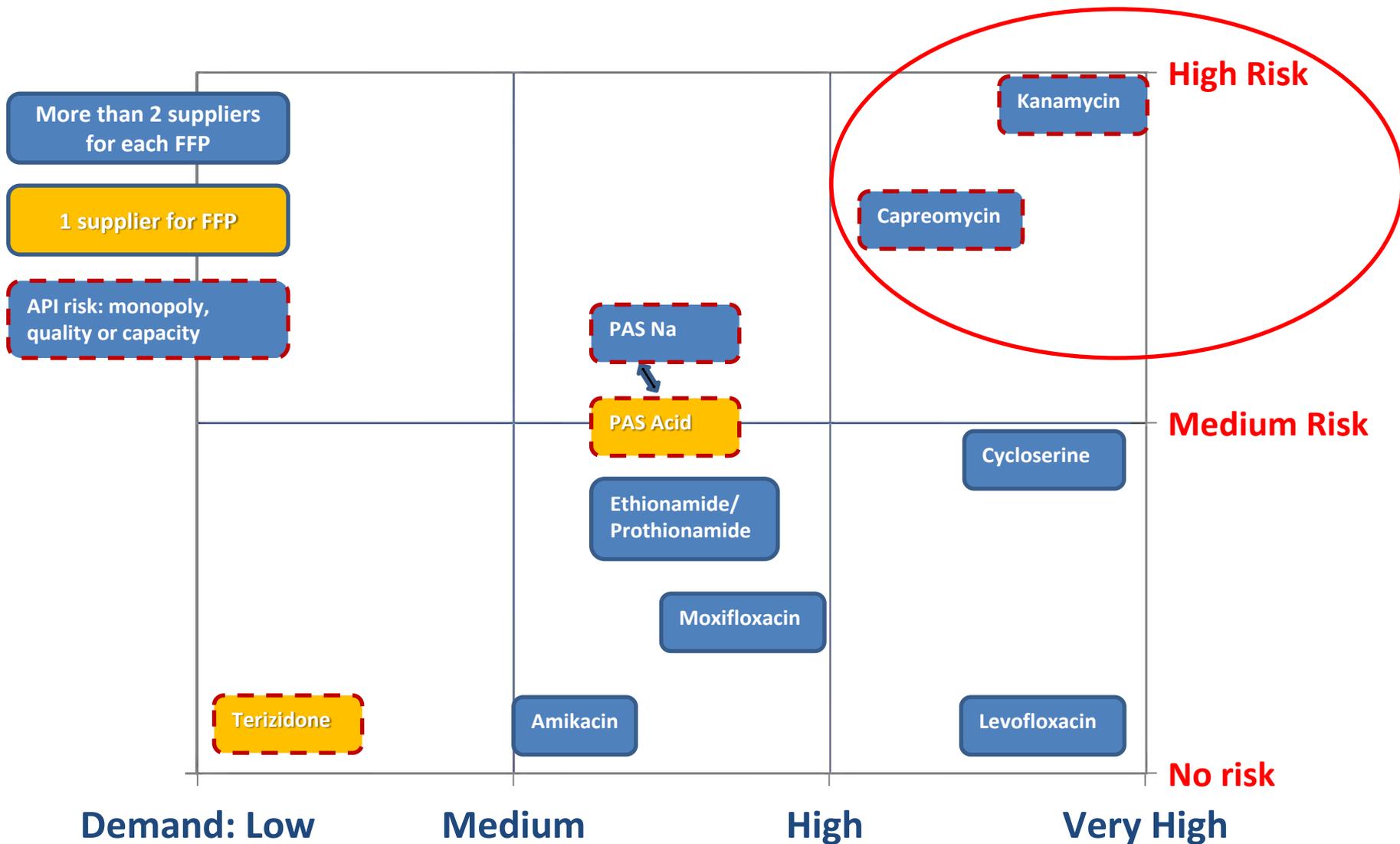
WHO PQ/ SRA / ERP	API	FDF in review	API in Review	
Akorn Vianex	2	1	5	1

Kanamycin Units, in million ampoules/vials



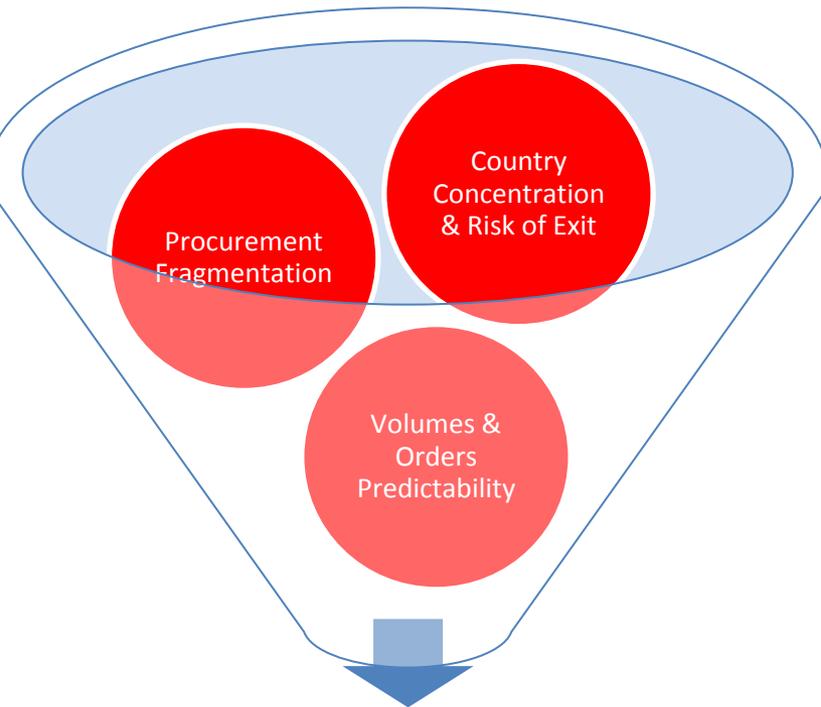
WHO PQ/ SRA / ERP	API	FDF in review	API in Review	
Meiji Panpharma	2	2	2	1

SLDs Supply Chain Vulnerabilities Mapping: Adopting a risk management approach (2)



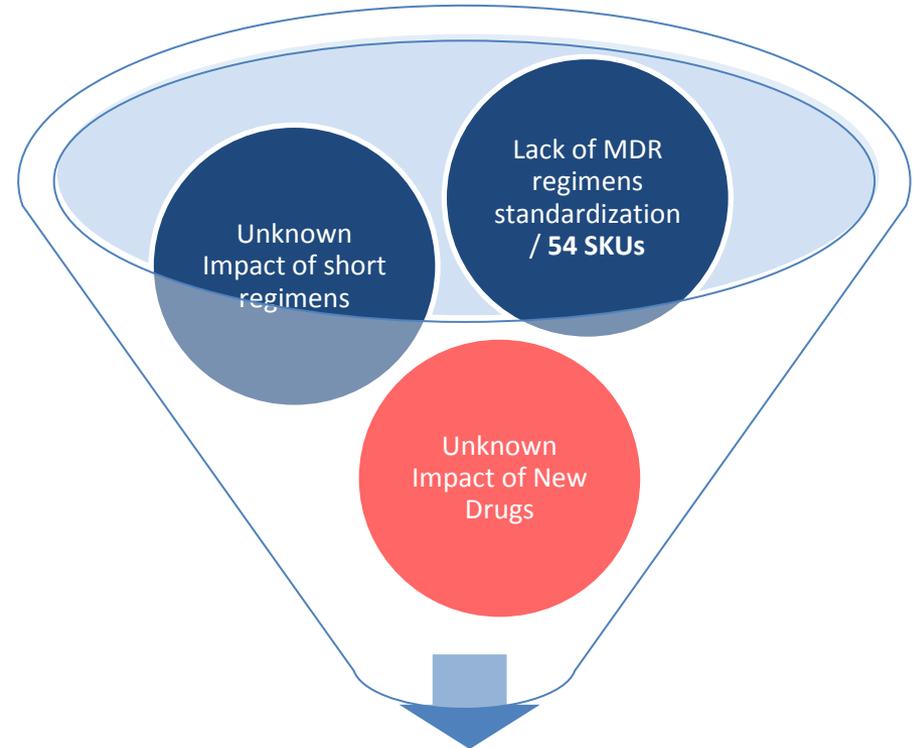
Addressing key SLDs challenges (1)

Demand versus supply issues



IMPROVED FORECAST MODEL
EARLY DATA MANAGEMENT / ORDERS PLANNING
FUNDING & DONORS COORDINATION TO AVOID DEMAND/SUPPLY FRAGMENTATION
PRODUCTION TO STOCK MODEL-STOCKPILES LEVERAGE
FINANCIAL FLEXIBILITY TO COUNTRIES

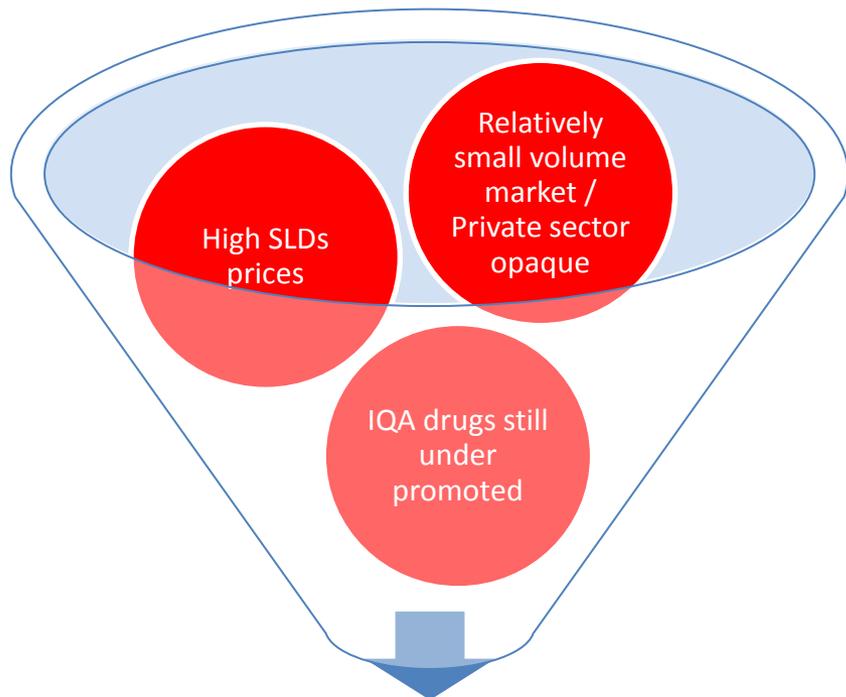
Complex MDR-TB treatments



SUPPORTING SCIENCE FOR NEW & EASIER TO MANAGE REGIMENS
ANTICIPATE / SUPPORT UPTAKE BY COUNTRIES

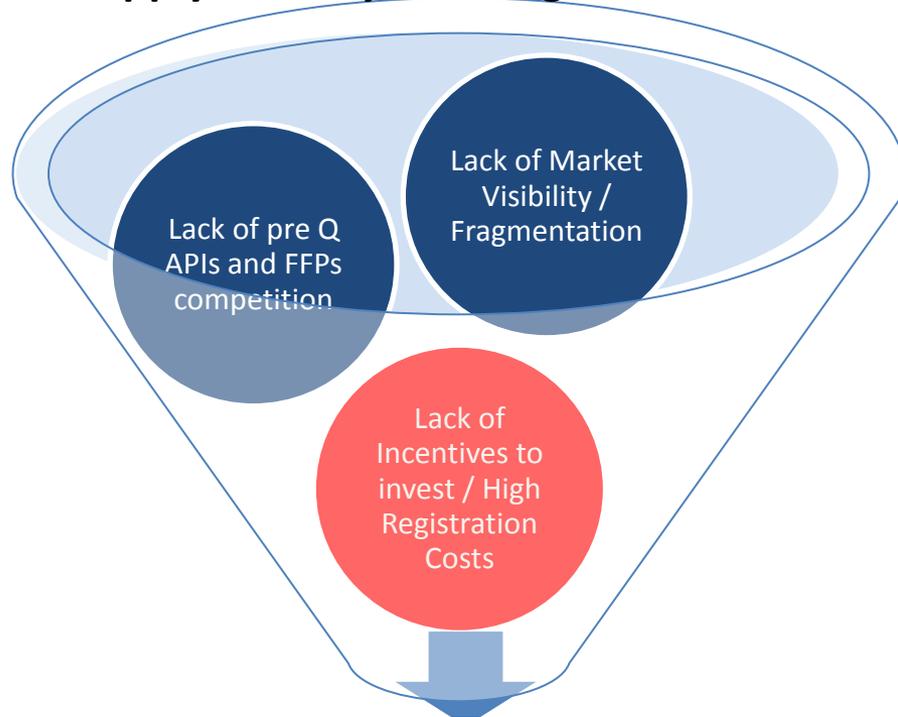
Addressing key SLDs challenges (2)

Overall Market has improved but is still limited



INVEST IN MARKET RESEARCH & DYNAMICS
MAP DRIVERS OF GROWTH AND CONSUMPTION TRENDS
MAP OUT SUPPLY SECURITY PER PRODUCT LINE /
MONOPOLIES / COMPETITION PATTERNS
INNOVATIVE FUNDING STRATEGIES
& AVAILABILITY

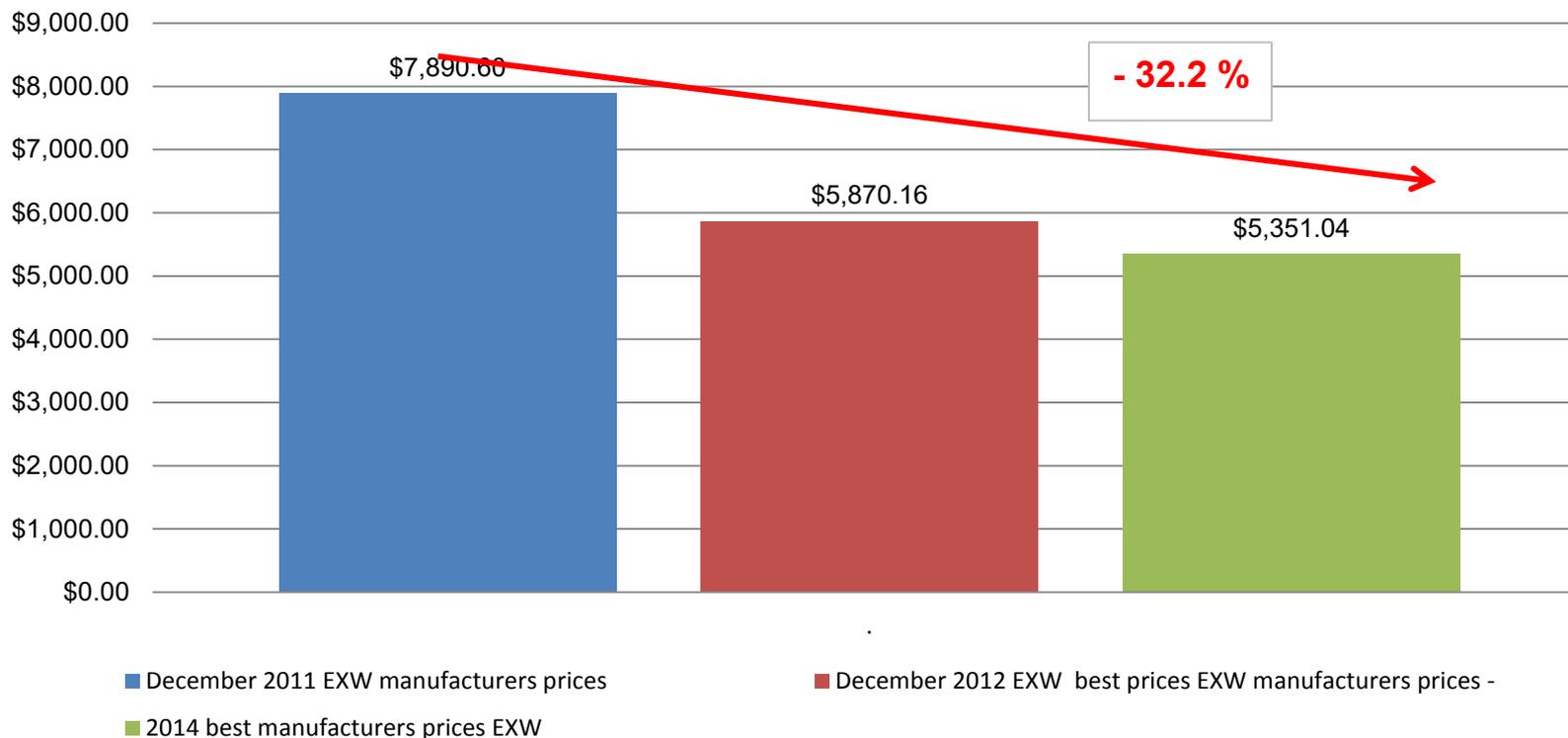
Supply Security Challenges remain



CONSOLIDATE ORDERS FOR ECONOMY OF SCALE
MONITOR COSTS / POTENTIAL PROCESSES
OPTIMIZATION / RISKS
LEVERAGE COODINATED & SPECIFIC MARKET
INTERVENTIONS WITH PRODUCT TARGETS FOR
INCREASED APIs & FFPs SOURCING

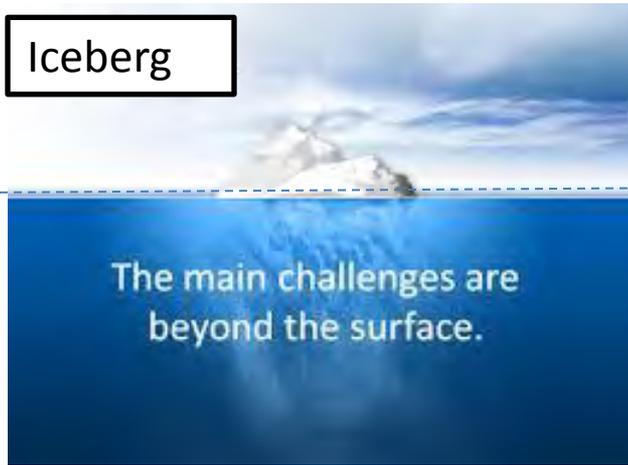


2011/2014 Change in Regimen costs: High end regimen cheapest suppliers 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS



SLDs Price Reduction versus SLDs Costs Reduction

Iceberg



Production cost

There are still savings to achieve



Supply cost



Distribution cost



Public Health cost

But by focusing on ExWorks Price mainly, are we really addressing the biggest challenges with the maximum leverage ?

Or shall we develop a more comprehensive analysis to assess transparently other costs drivers and identify more leverage ?

To evaluate the cost of a drug, not only in terms of procurement costs, but also in terms of cost impact on the health-care system and patient outcome

Till new standardized regimens are made available, GDF Operational model with additional partner's engagement can contribute to :

Total Cost of Ownership

Production cost

- API, excipient,...
- Manufacturing
- Administration / Export process

- Strengthening forecast to improve accuracy of demand
- Lean manufacturing to build stock instead of make to order model to cope with highly variable demand

Decrease cost by reaching lean manufacturing benefits

Supply cost

- GDF and PA Fee
- Freight cost
- PSI, Quality Control

- Improve transport strategy by rationalisation of delivery planning
- Enhance productivity through e-procurement

Decrease of transport and transaction costs

Distribution cost

- Custom clearance
- Storage and administration
- In country transport

- Improvement of lead times by delivering from stock and improve steadiness of deliveries

Better write off ratios and reduce countries safety stocks

Public Health cost

- Patient treatment / retreatment
- Patient lost

- Decrease time to access TB or MDR-TB treatments
- Reduce interruption of treatment due to stock out

• Reduce cost of retreatment / cost of drug resistance

Highlighting key interventions for linking Supply with Demand and manage production capacity / allocation

- Regular Forecast / Quarterly Data Collection for better predictability
 - ✓ Matrix analysis per region / per product (molecule stewardship / suppliers capacity monitoring) / partners linking strategy for maximizing impact
- Early Warning Stock-out System
- Flexible Procurement Fund and Global Strategic Stockpile
- Risk Management / Risk Based Approach
 - ✓ Engage stakeholders for concerted actions with suppliers towards commitment / capacity investment
 - ✓ Metrics and demand regular data sharing + capacity assessment allow better production planning
 - ✓ Balance short term (0-3 months) interventions (packaging ordering/shipment schedule/ labels ordering/ resources schedule allocation ...)
 - ✓ With long term (3-24 months) interventions like LT capacity planning/allocation, API schedule, regulatory changes, HR planning ...)
 - ✓ Address the risk of vertical integration / manufacturers (injectables) with potential monopoly or supply vulnerabilities – GDF working on new intervention model for API sourcing in cooperation with USAID & USP PQM

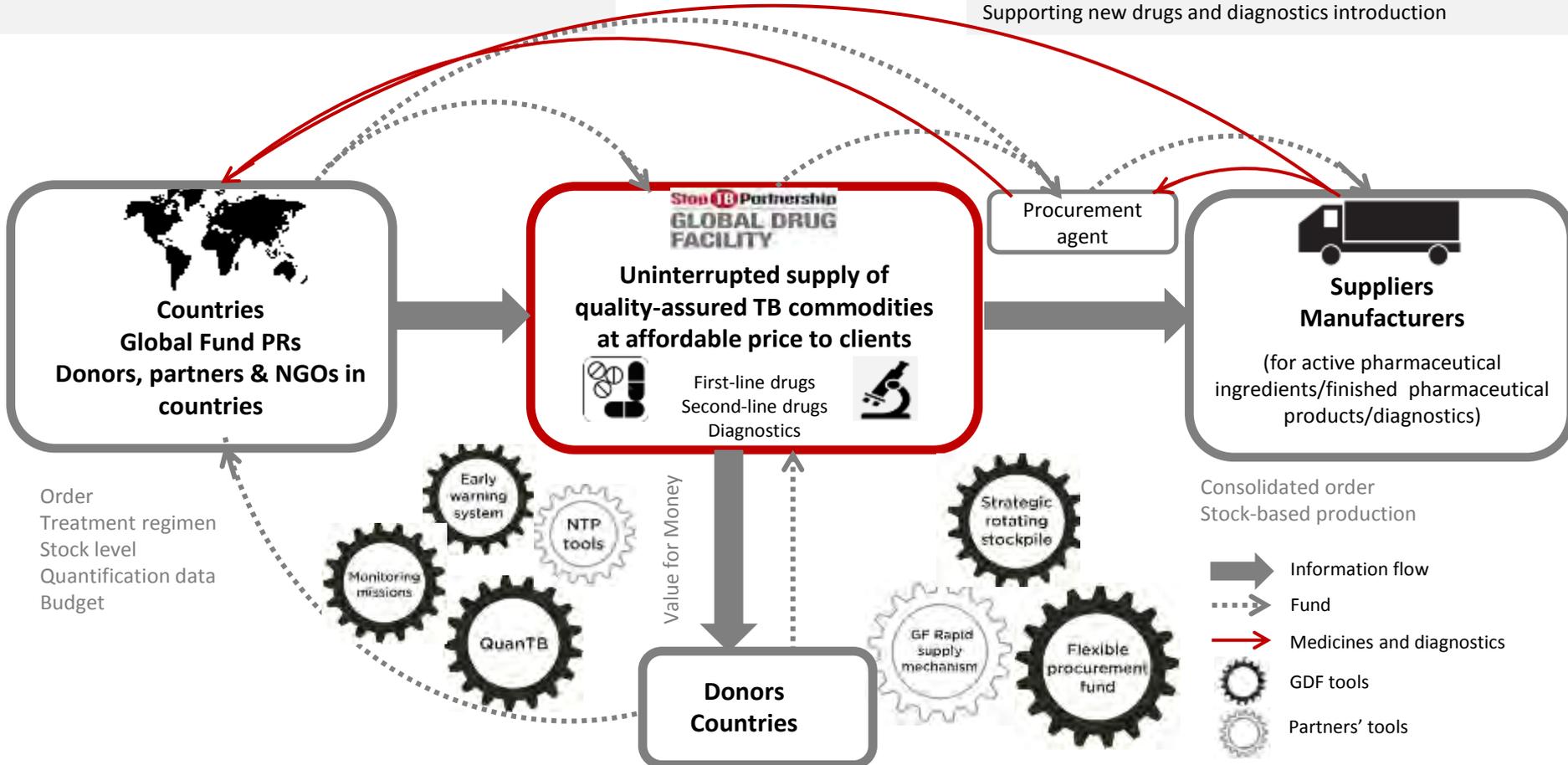


Country Support

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

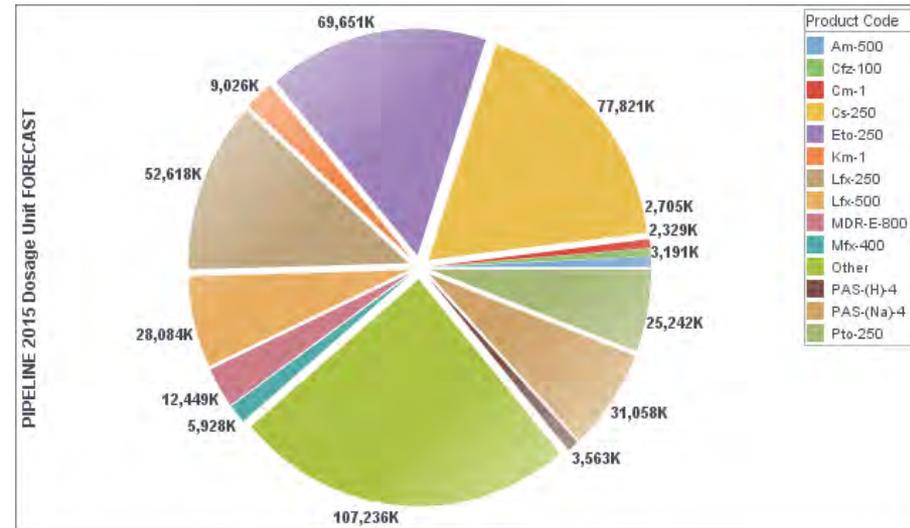
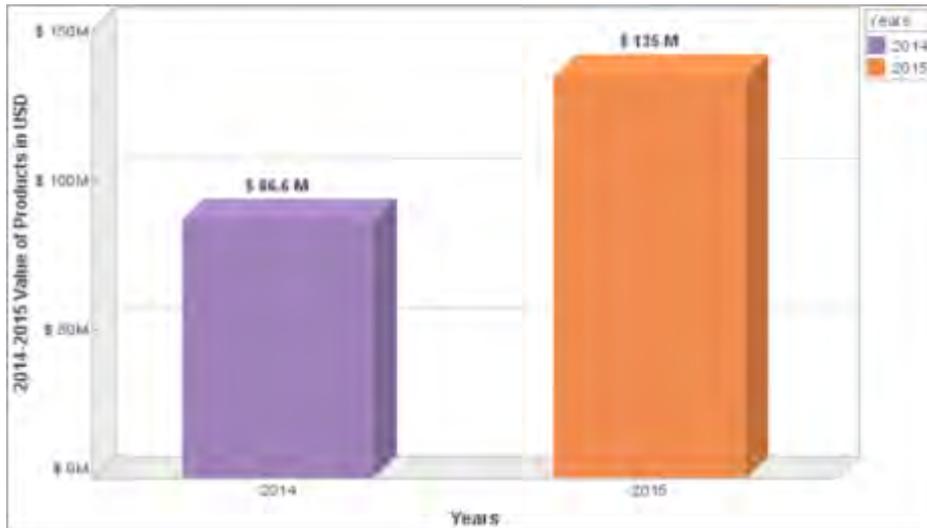
Evolve from Grant model toward Direct Procurement model
Foster closer/earlier interaction for GF NFM Order placement optimization by using advance ordering
GDF strategic stockpile to contemplate FLDs + SLDs
Financial flexibility
Quality Management

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

Progress on Forecast: Towards an holistic approach

Based on GDF order management system & data on quantities / products supplied:
 ⇒ New forecasting tool developed to support GDF operations & strategies
 ⇒ Impact on NTP planning, management of orders, suppliers' relations and market shaping

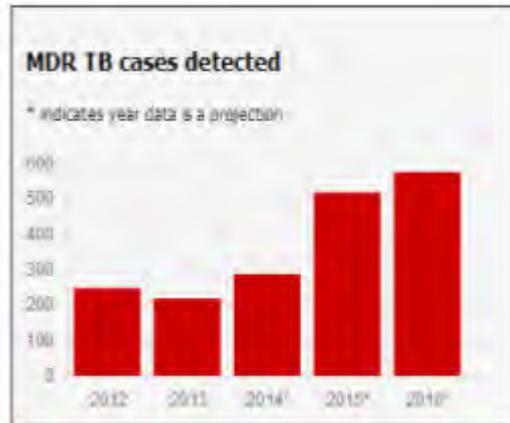
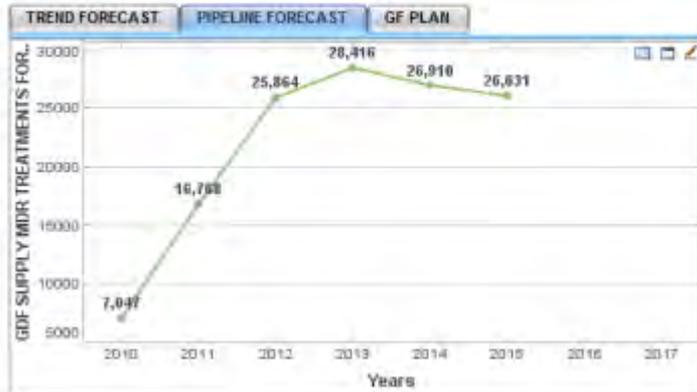


⇒ Additional data sources required to be fed into the forecasting tool regularly
 ⇒ Data Validation Processes



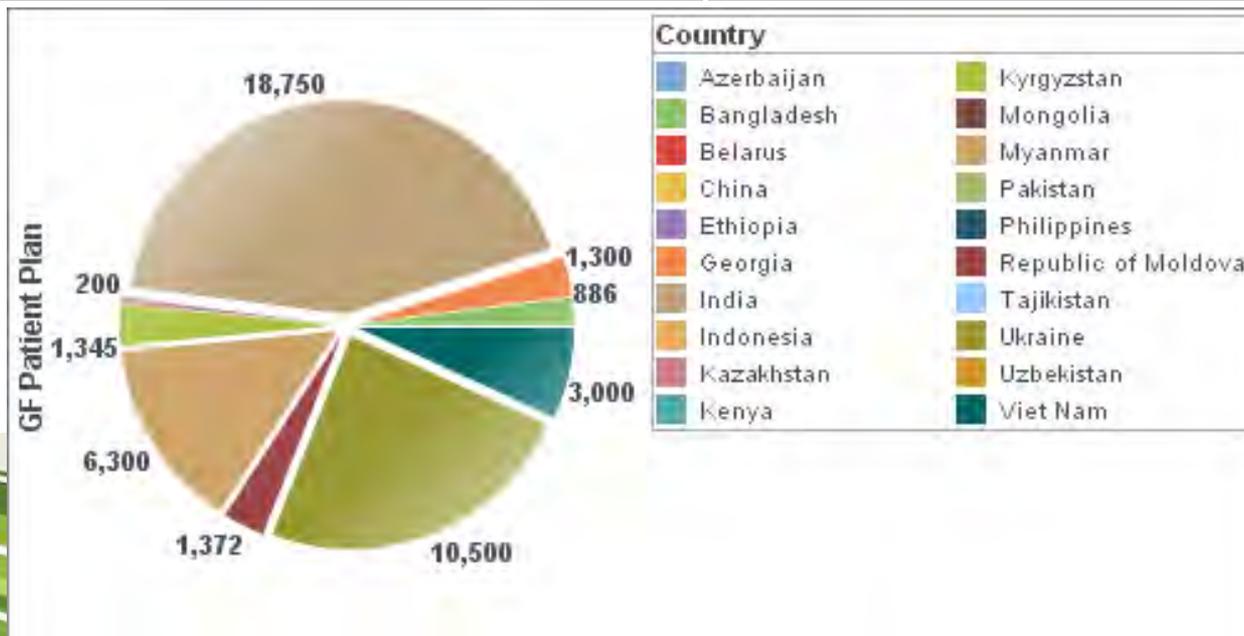
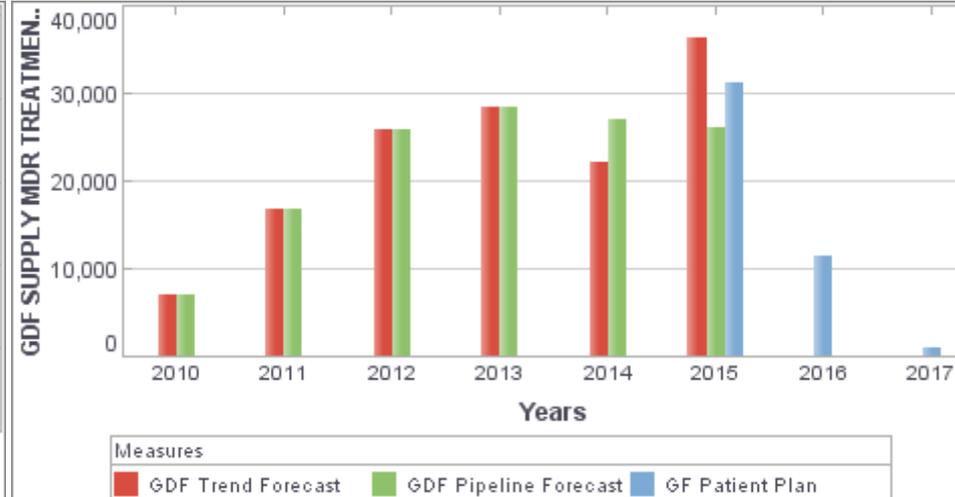
Forecast Visualization 1

Country Level and Global View



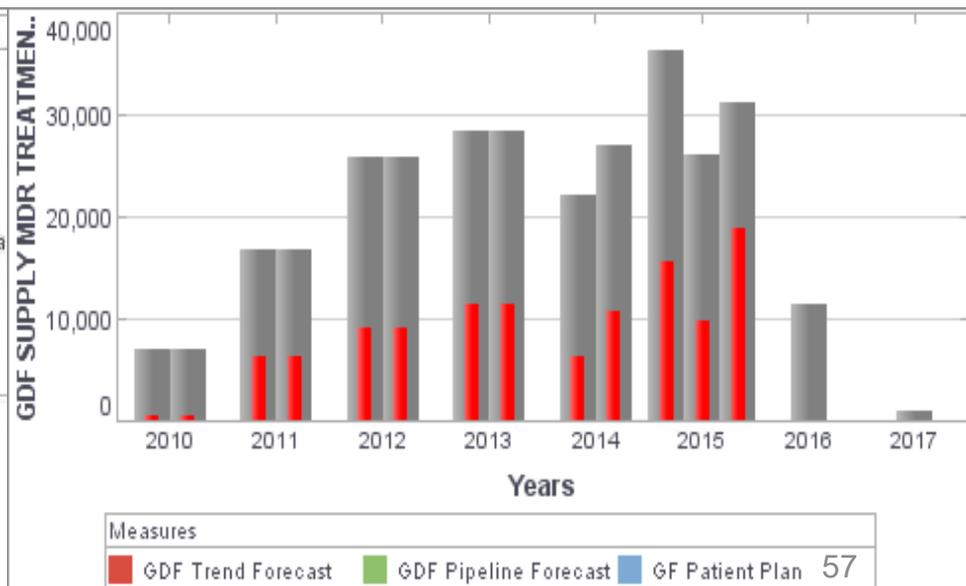
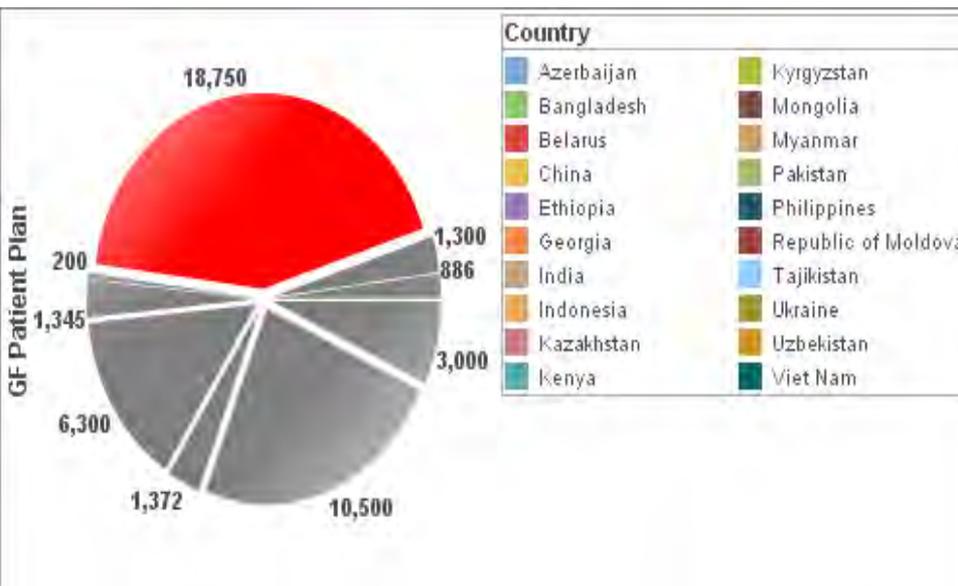
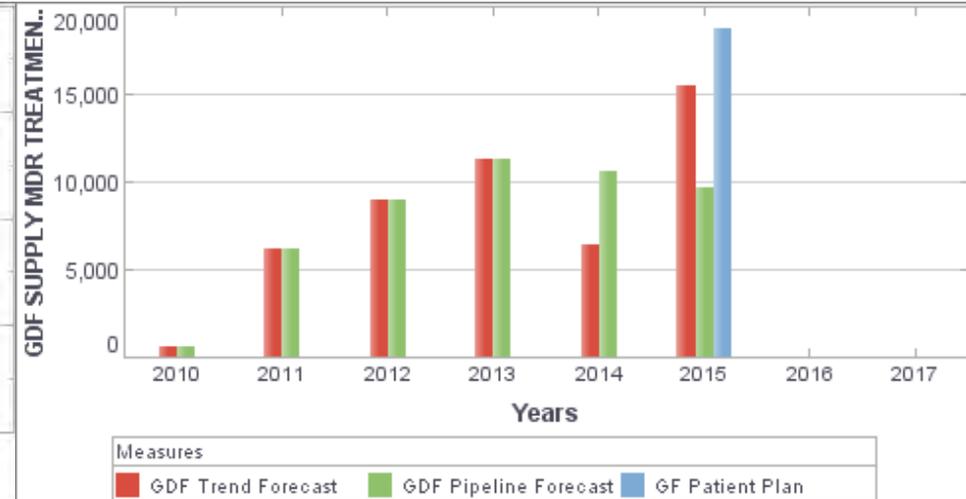
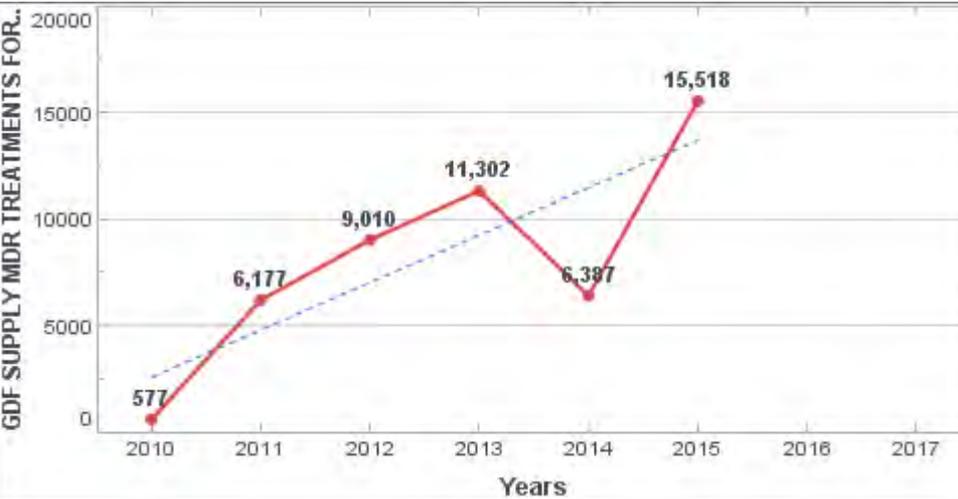
Forecast Visualization 2

Country Level and Global View



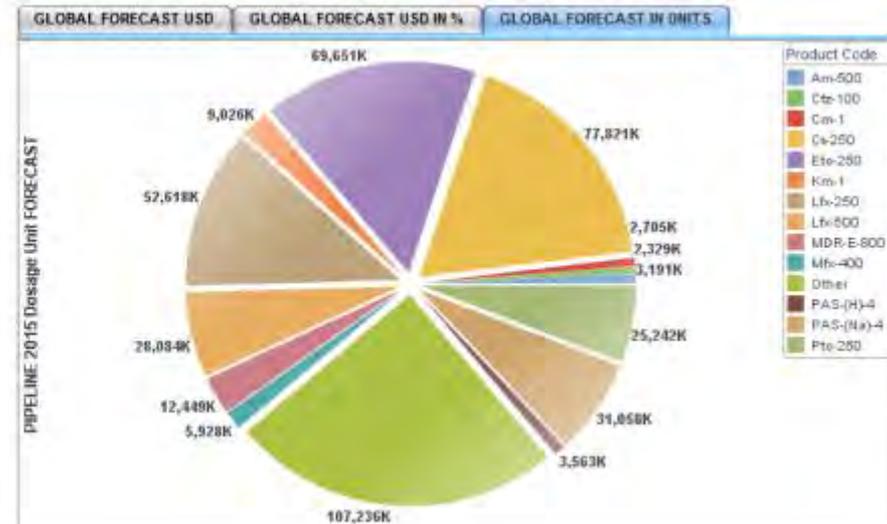
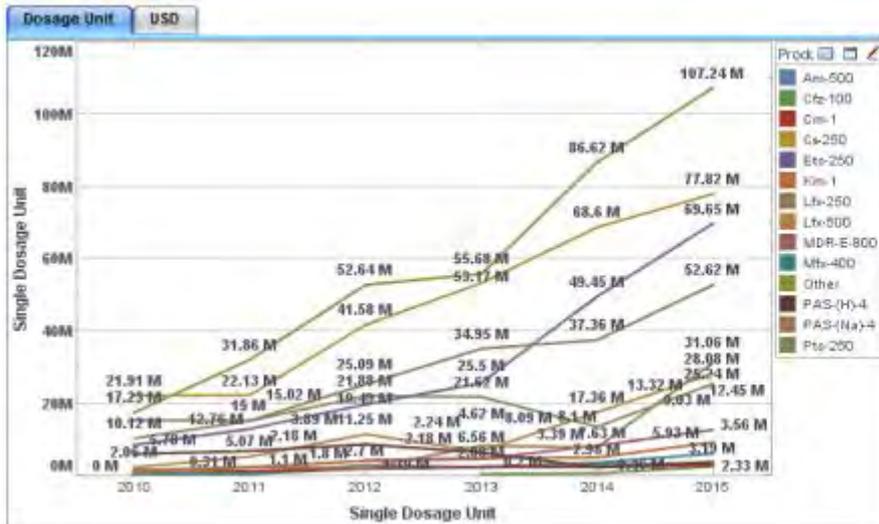
Forecast Visualization 3

High Impact Country Level : ex India



Forecast Visualization 4

Country Level and Global View



Discussion



keravecj@who.int

Challenges in TB from the Global Fund perspective



The Global Fund
To Fight AIDS, Tuberculosis and Malaria

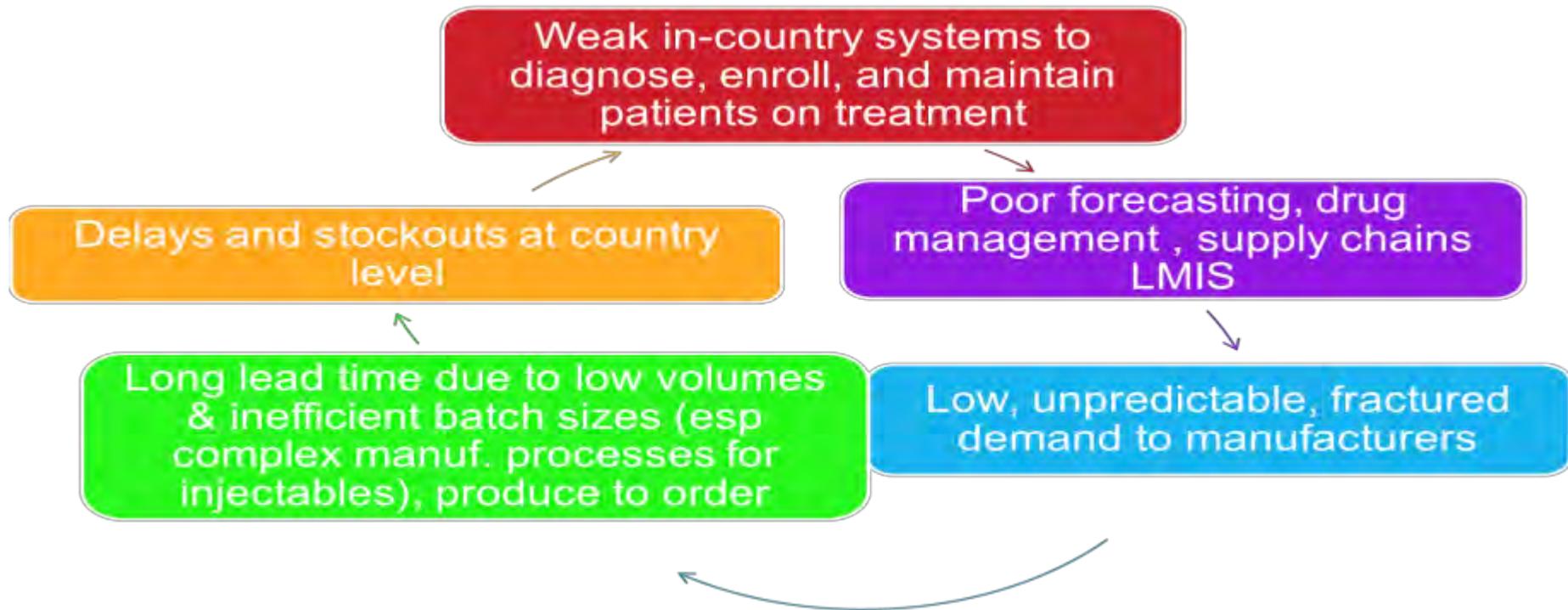
Supply Challenges: TB Drugs

Fractured global market

- Donor-funded (GF ~90%), non-donor-funded public MIC/ BRICS, private retail); relative influence of donors limited
- Drug choice, dosage, formulation
- Large benefits likely from growing IQA market and efforts to rationalize regimens/presentations

Small, unattractive MDR-TB and paediatric market: volatile demand, limited visibility, complex production = higher prices, long lead times, limited investment and new products

In-country delivery gap impacts global drug supply



Market shortcomings are on both the supply and demand side → supply side (interventions must be complemented by activities by other stakeholders and in-country implementers to increase diagnosis and treatment capacity, improve systems

TB Sourcing Strategy

- Improved forecasting and procurement predictability; new tools and rolling forecast of GF-funded TB drug demand
- Strengthened relationship with GDF as procurement platform for TB SLD
 - Clear roles, responsibilities, KPIs, accountability
 - Data transparency/harmonization with access to data on budgets, orders, shipments, tenders price
 - Rapid Supply Mechanism and Strategic Revolving Stockpile
 - Close engagement with HPM and Grant management
 - Extension of funding flexibilities to facilitate procurement
- Improved manufacturer & supply performance (coordinated GF/GDF country and manufacturer engagement) → Understanding of and action plan to address supplier challenges → greater SLD accessibility/affordability
- Innovative approaches with partners to enable MDR-TB scaleup

TB Deep Dive Challenges:

Prioritization

- How can NTPs, CCMs and PRs be further supported to quantify needs and gaps, and develop a clear, prioritized, and robust case to support investment in the right mix of TB diagnostic commodities and drugs?
- How can we ensure ambitious and realistic funding requests to the Global Fund?
- How can PRs use the opportunity of joint TB and HIV concept notes to strengthen in-country drug stocking, distribution and information systems in order to ensure uninterrupted supply to patients?

TB Deep Dive Challenges:

Demand

- How can NTPs, CCMs and PRs be further supported to deliver key TB services and make the best use of available funding for impact?

Supply

- How can better “value” be achieved in the donor-funded procurement and supply of TB medicines (“value” = supply chain, lead time, price, quality)?
- How do we encourage and support future innovation?

Mapping activities, gaps and opportunities

Purpose: Share and learn about ongoing initiatives
→ opportunities for collaboration/coordination →
joint agreement on gaps/opportunities → Action
plan and next steps

For each challenge, identify:

- Partner + funded activity/initiative + timeline
- Existing links/intersections with other projects
- Gaps and Opportunities

Mapping activities, gaps and opportunities

Challenge: Forecasting

Global Fund: PSM Plan Consolidation (ongoing)

GDF: QuanTB rollout and TOMS (ongoing)

MSH: Technical support to XX countries on quantification (through end 2015)

Gap: Single, consolidated global forecast of donor-funded demand for manufacturers

Day 3 - Agenda

Type	Time	Topic
●	08.30 – 08.55	Registration and Coffee
●	09.00 – 9.05	Welcome and Introduction
●	09.05 – 9.45	Update on the New Funding Model
●	09.45 – 10.30	Scene-setting <ul style="list-style-type: none"> • What's the big picture? (Stop TB) • TB Landscape and Market Forum Outcomes (UNITAID) • Challenges in TB from the Global Fund perspective (GF)
●	10.30 – 10.45	Coffee Break
●	10:45 – 11.45	Deep Dive Session – Challenge # 1 (Prioritization): Feedback on initial concept notes, including opportunities/challenges for joint TB/HIV notes
●	11.45 – 13.00	Deep Dive Session – Challenge # 2 (Demand) : In-country challenges in ensuring access to treatment for TB patients
●	13.00 – 14.00	Lunch
●	14.00 – 15.30	Deep Dive Session – Challenge # 3 (Supply): Challenges and vulnerabilities in the supply of TB medicines
●	15.30 – 15.45	Coffee Break
	15.45 – 16.30	Summary and Actions; Feedback and Closing Remarks

Challenge # 1: Prioritization

- How can NTPs, CCMs and PRs be further supported to quantify needs and gaps, and develop a clear, prioritized, and robust case to support investment in the right mix of TB diagnostic commodities and drugs?
- How can we ensure ambitious and realistic funding requests to the Global Fund?
- How can PRs use the opportunity of joint TB and HIV concept notes to strengthen in-country drug stocking, distribution and information systems in order to ensure uninterrupted supply to patients?

Deep dive – logistics – at tables

Observations, 5



Introduction, 5



Feedback, 20



Presentation, 15



Discussion, 15

Review of TB and TB/HIV Concept Notes: Opportunities and challenges

Eliud Wandwalo
Senior Disease Coordinator, TB

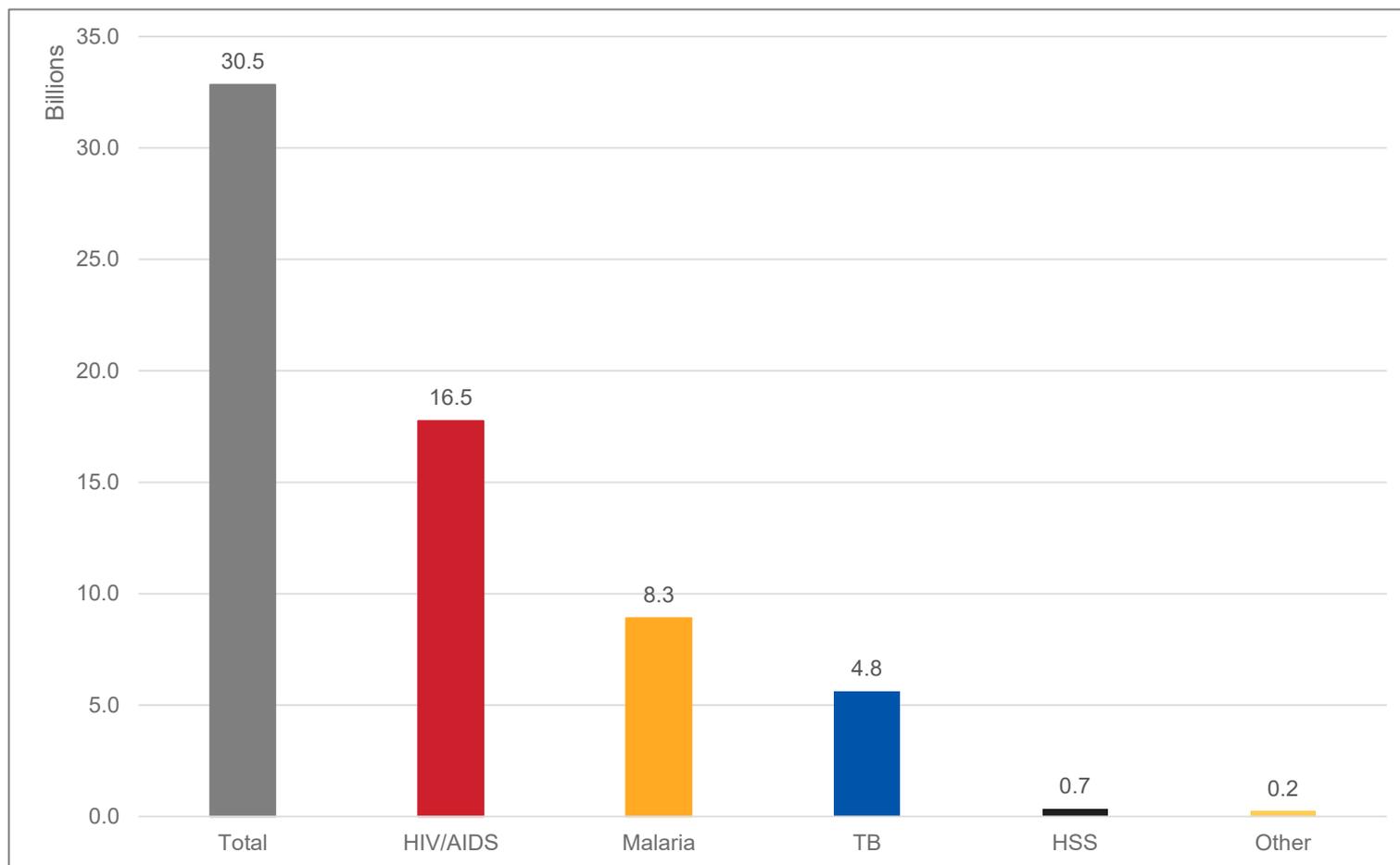
Content

-
- 1 GF TB Portfolio**
 - 2 Single Concept Note**
 - 3 Key lessons from windows 1&2**
-

Content

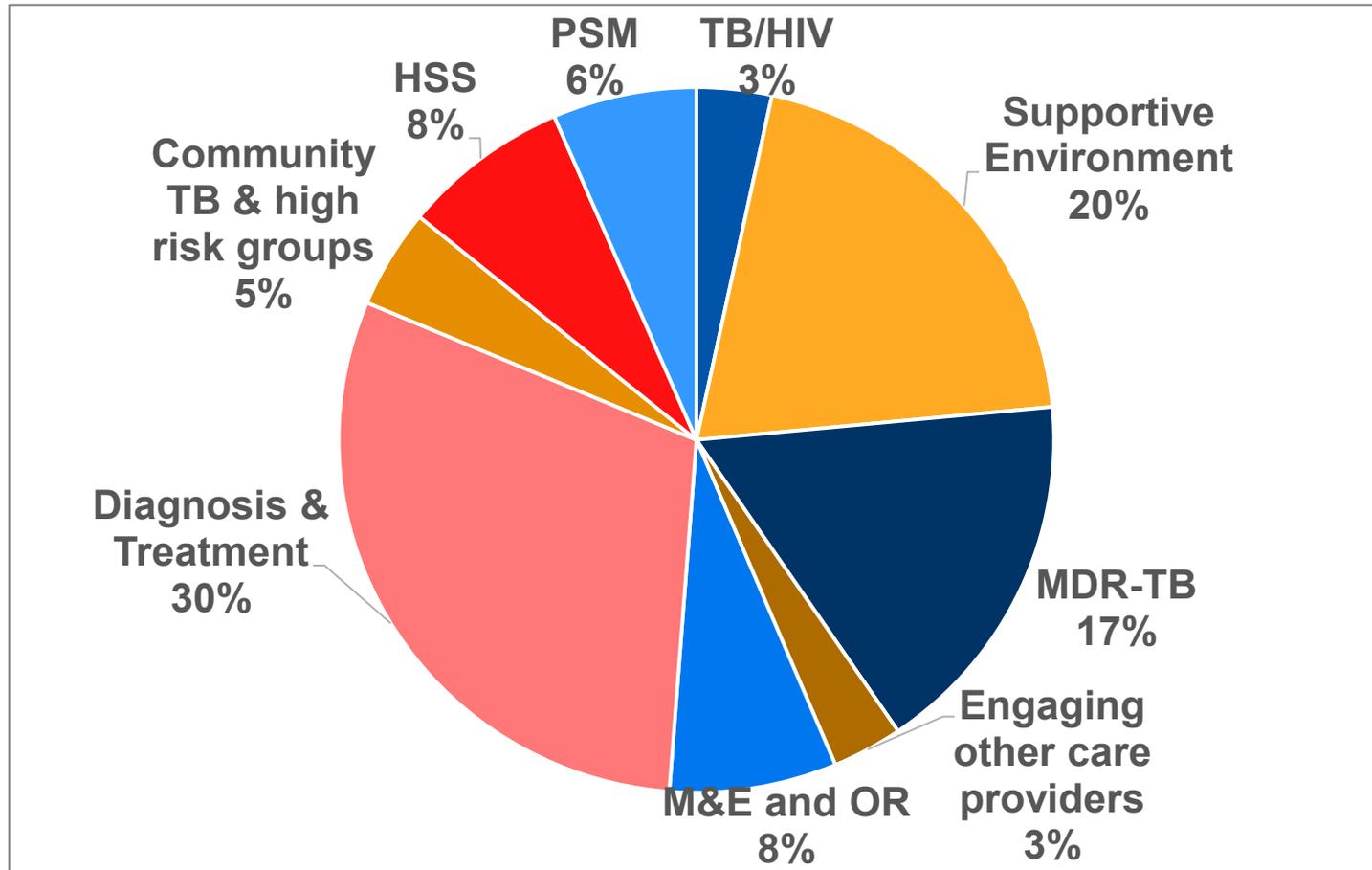
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- 1 GF TB Portfolio**
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-

Grant Portfolio 2002-2014



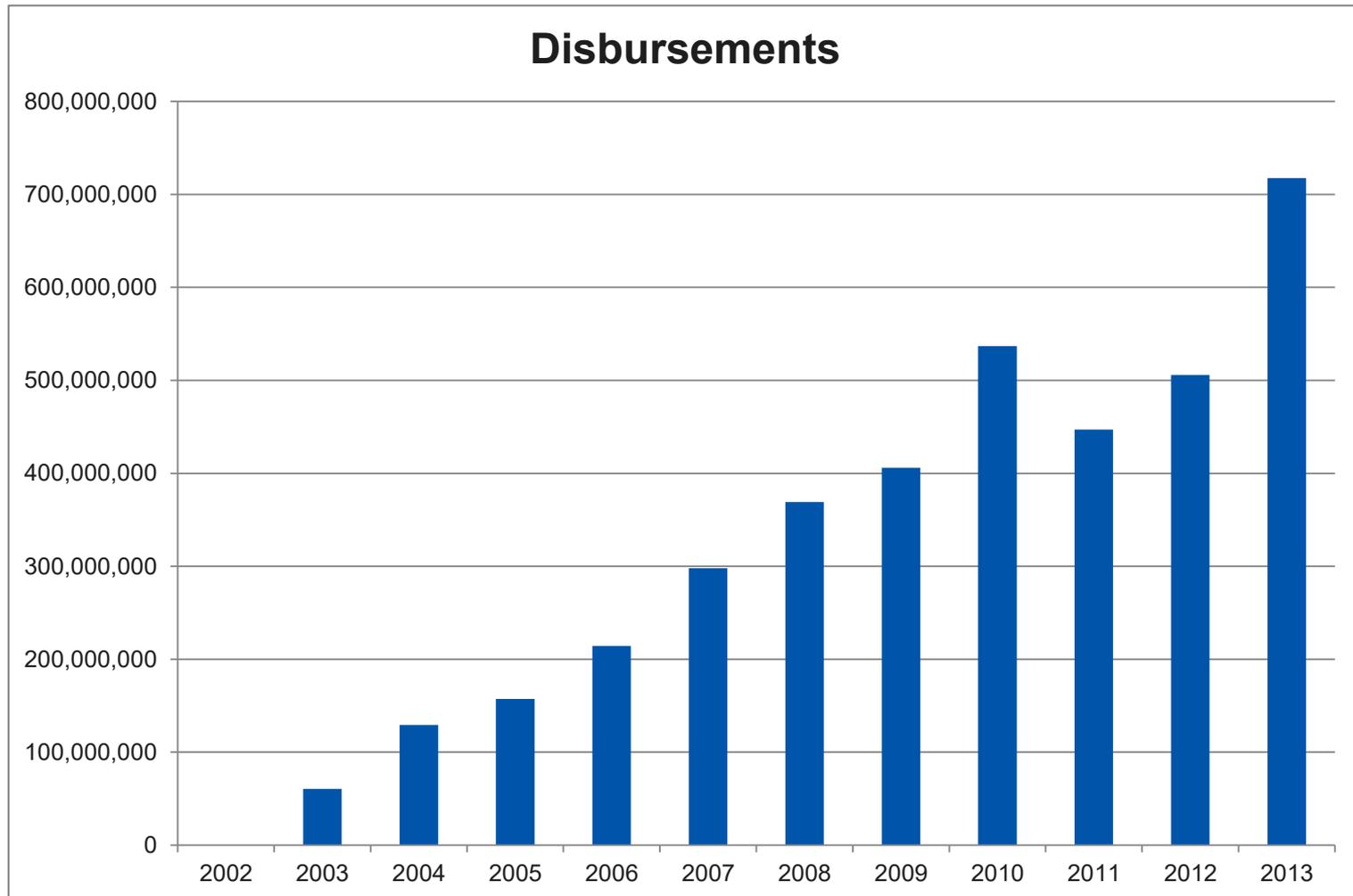
Global Fund reports,
2014

Cumulative Budget for TB services



Cumulative budget, as of 2013

Trends in TB Disbursements 2002-2013



Content

-
- 1 GF TB Portfolio
 - 2 Single Concept Note**
 - 3 Key Lessons from windows 1&2
-

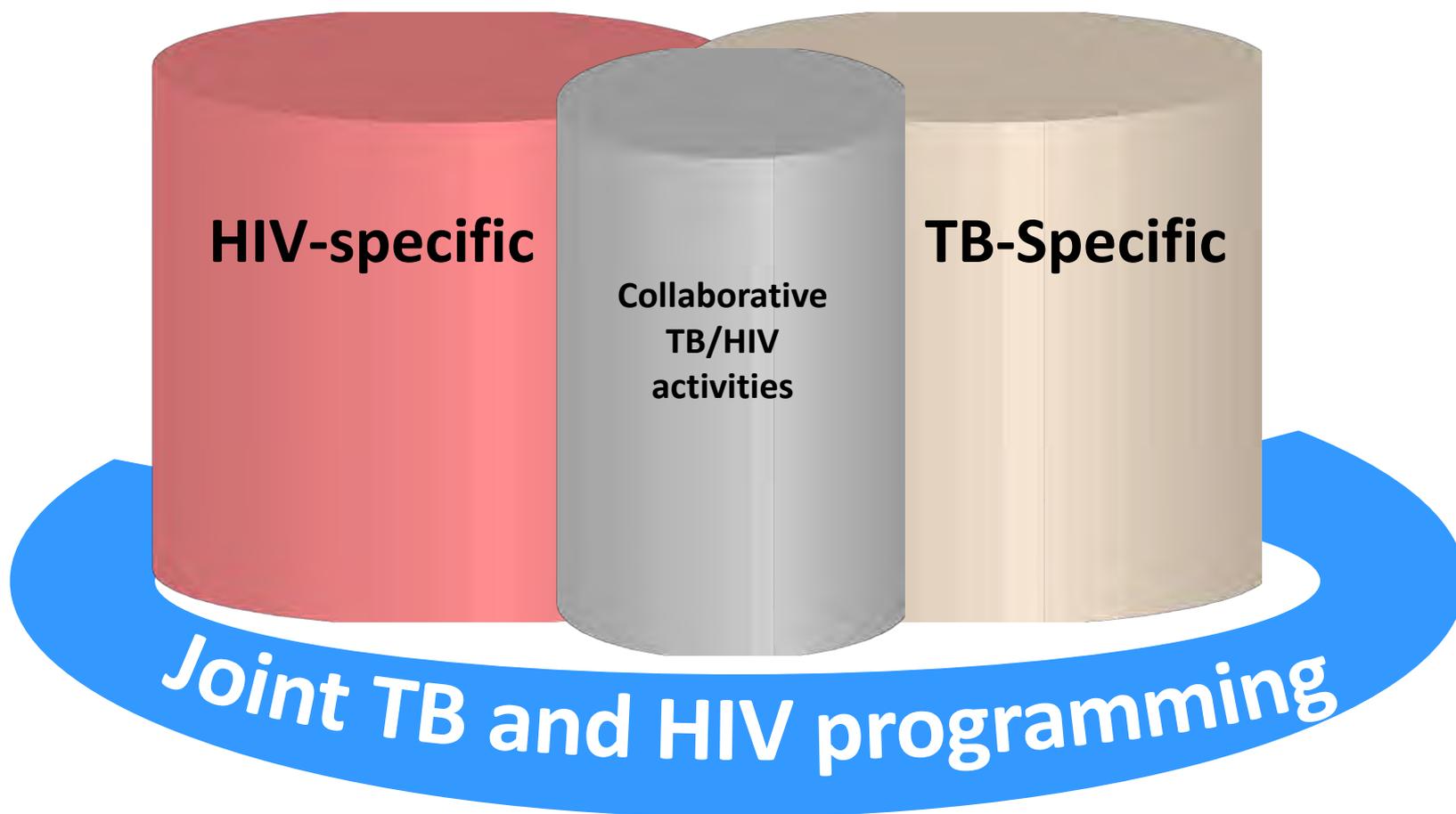
Joint TB and HIV applications

- In 2012, 1.1 million (13%) of 8.6 million people who developed TB worldwide were HIV-positive
- In the same year, 1.3 million died from TB, of which 320,000 were people living with HIV
- The highest rates of TB and HIV co-infection are in Africa, where 43 percent of TB patients had a positive HIV test result in 2012
- **Thailand: 12,000 people co-infected, 13% HIV among TB patients** (17th among 41)

Recognizing the importance of core TB-HIV collaboration services and the need for TB and HIV programs to work jointly, the Board's Strategy, Investment and Impact Committee decided that:

Countries with high co-infection burden of TB and HIV shall submit a single concept note that presents integrated and joint programming for the two diseases
(Global Fund Board Decision on Joint TB and HIV Concept Notes; Oct 2013)

Framework for joint programming and joint concept note



Areas of Joint Programming

Country analysis and planning

- Joint epidemiological and context analysis
- Harmonised national strategic plans
- Joint HIV and TB programme reviews

Management & supervision

- Regular liaison between HIV and TB programmes at all levels
- Joint or integrated supervision

Cross-cutting systems

- Optimizing the health system building blocks – human resources, information systems, PSM, laboratory, infrastructure, etc

Service delivery

- One-stop service
- Partially integrated
- Co-located/adjacent services

Opportunities: Alignment of Critical Components of the Health System

1. Health information systems
2. Health workforce
3. Financing
4. Procurement and supply chain management
5. Laboratory and diagnostic services

- **Goal:**
- **Integrated TB, HIV and other**



Better TB and HIV health outcomes

Opportunities: Alignment of Critical Components of the Health System

- **4. Procurement and supply chain management**
 - Integrated system for PSM
 - Harmonized forecasting
 - Purchase, storage and distribution of supply
 - Uninterrupted supply of drugs

- **5. Laboratory and diagnostic services**
 - Integrated lab plan development, aligned with national lab strategic plans
 - Common platform opportunities (e.g. Xpert)

It is not overloading programmes



Nor a big fish swallowing a small fish



Content

-
- 1 GF TB portfolio
 - 2 Single Concept Note
 - 3 Key lessons from Windows 1&2**
-

NFM update

- A total of 33 CN were reviewed by TRP/GAC by August
- 10 CN reviewed 1st window (June) and 23 in 2nd window (July)
- 6 were HIV, 3 TB, 4 TB/HIV, 12 Malaria, no HSS
- 23 recommended for grant making, value of USD 2.72 billion
- 9 sent for further iteration
- Window 3 (September), 33 CN submitted valued at USD 3.3 billion
- Window 4 (November), 80 CN registered valued at USD 4.43 billion
- In 2014 expecting 146 CN , representing 71% of total allocation

NFM Summary: TB & TB-HIV Submissions to Date

May		June		August	
TB	TB-HIV	TB	TB-HIV	TB	TB-HIV
	Haiti	Bangladesh	Thailand	Afghanistan	Chad
		Cambodia	Ukraine	Armenia	DRC
		Philippines	Zambia	Bhutan	India
		Thailand		Comoros	Multicountry Western Pacific
		Zimbabwe		Moldova	Nigeria
				Myanmar	Panama
				Pakistan	Rwanda
				Papua New Guinea	Viet Nam
				Sudan	
-	1	5	3	9	8
1		8		17	

Grand Total = 26

Key Lessons Learned

1

TB Care and Prevention: Prioritization TB case detection and the immediate treatment of all cases. Case detection targets still not ambitious

2

TB-HIV: full involvement of both TB and HIV programmes in CN development. Joint programming of TB and HIV beyond collaborative TB/HIV activities

3

MDR-TB: countries must be prepared to seriously address the issue, with an integrated approach, and equipped to close the gap between diagnosis and treatment. Improve quality of care

4

Community Based Approaches: Ensure linkages & alignment with health system including HIV. Ensure both CSS and service delivery. Contribute to both case detection and improved treatment outcomes

5

Key Affected Populations: Target KAPs explicitly with specific interventions, informed by existing in-country pilots and lessons learned.

1. TB Care & Prevention

- **Prioritization of interventions is still a challenge**
 - NSP and Concept Note
 - Basic services and scale-up
 - Basic services and MDR-TB scale-up
 - Lab services and new diagnostics
- **Case detection targets are still not ambitious**
 - Flattening/decreasing trends
 - TB estimates Vs prevalence survey results
 - Allocation and other sources including domestic funding
- **Innovative approaches to improve TB case detection not used**
 - PPM, inclusive of NGOs and private sector, community

2. MDR-TB

- **Integrated approach to MDR-TB care:** Balance between various interventions; case finding, diagnosis, treatment and adherence
- **Ambitious case detection targets** not balanced with case detection strategies, treatment capacity and quality of treatment
- **Gene-Xpert expansion** not linked to comprehensive laboratory plans
- Appropriate **model of MDR-TB care** is still a challenge: Decentralization of MDR-TB treatment
- **Quality of MDR-TB care:** Low treatment outcomes
- Countries are requesting or considering using **shorter regimen**

3. TB-HIV experience

- Requires the **full involvement of both TB and HIV programmes** in the development of joint concept notes
- Some CNs were **HIV-dominated**, with more data and epidemiological context than TB
- **Not simply TB-HIV activities**, but joint programming should leverage both TB and HIV to harmonize intervention to increase efficiency and impact (look holistically)
- TB-HIV joint programming not reflected in **budgeting of activities**
- **No concrete plans** beyond the narrative on further alignment in short, medium, and long term of TB and HIV strategies, policies and interventions

Your questions...

Challenge # 1: Prioritization

- How can NTPs, CCMs and PRs be further supported to quantify needs and gaps, and develop a clear, prioritized, and robust case to support investment in the right mix of TB diagnostic commodities and drugs?
- How can we ensure ambitious and realistic funding requests to the Global Fund?
- How can PRs use the opportunity of joint TB and HIV concept notes to strengthen in-country drug stocking, distribution and information systems in order to ensure uninterrupted supply to patients?

Day 3 - Agenda

Time	Topic
08.30 – 08.55	Registration and Coffee
09.00 – 9.05	Welcome and Introduction
09.05 – 9.45	Update on the New Funding Model
09.45 – 10.30	Scene-setting <ul style="list-style-type: none"> • What's the big picture? (Stop TB) • TB Landscape and Market Forum Outcomes (UNITAID) • Challenges in TB from the Global Fund perspective (GF)
10.30 – 10.45	Coffee Break
10:45 – 12.45	Deep Dive Session – Challenge # 1 (Prioritization): Feedback on initial concept notes, including opportunities/challenges for joint TB/HIV notes
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15.45 – 16.00	Coffee Break
16.00 – 16.20	Group Feedback
16.20 – 16.30	Summary and Actions; Closing Remarks

Challenges #2 and #3 – Demand and Supply

What are the short-, medium-, and long-term market shaping activities that Global Fund and partners should implement in order to address TB drug and diagnostic market challenges?

Scene-setting presentation: In-country challenges in ensuring access to treatment for TB patients

 **K N C V**
To eliminate TB



TUBERCULOSIS FOUNDATION





TB CARE I

GF Sourcing and Market Dynamics Strategic Reviews

*Deep Dive Session – Challenge # 2 (Demand):
In-country challenges in ensuring access to
treatment for TB patients*

Agnes Gebhard
KNCV TB Foundation

Geneva, 3-10-2014



In countries challenges quantification, forecasting, funding of TB drugs

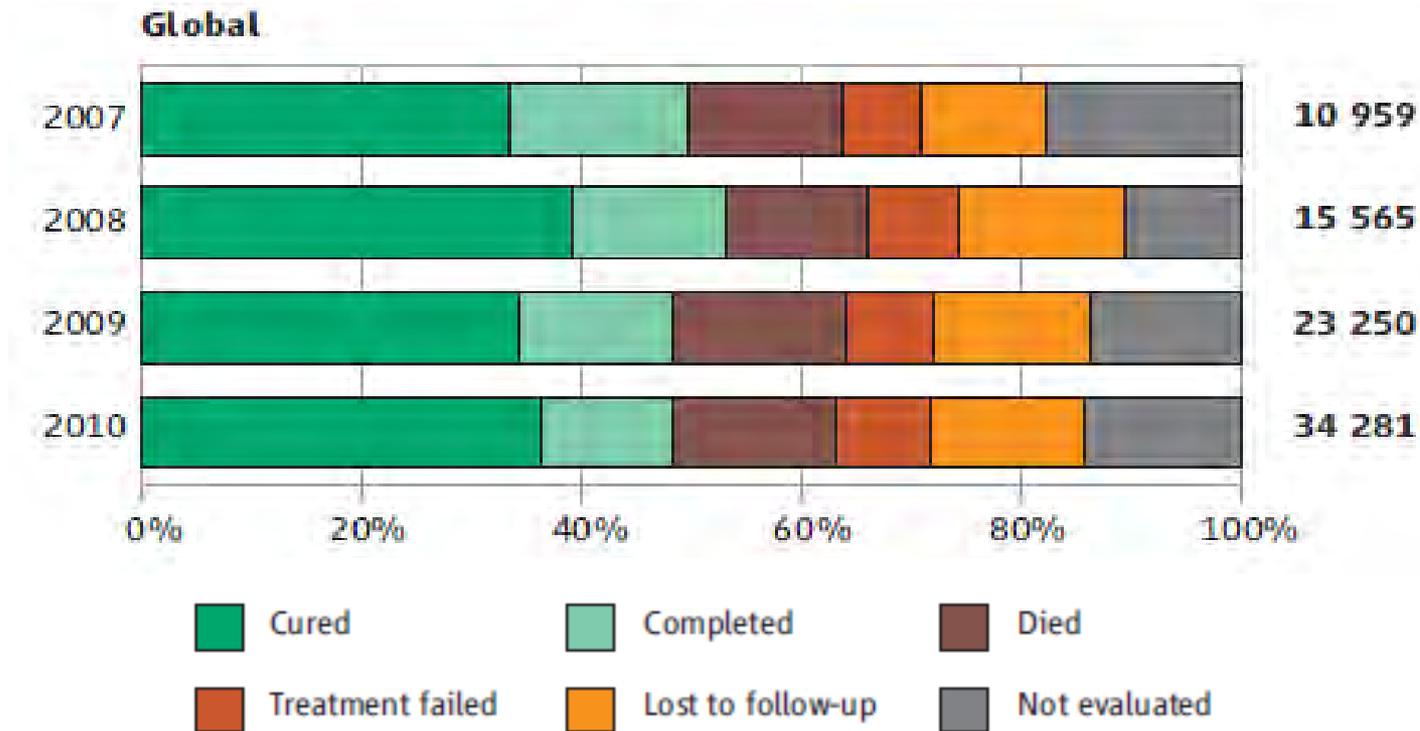
- Reliable information is needed on
 1. numbers of patients currently on treatment per regimen
 2. the number of patients expected to be diagnosed and enrolled on treatment over the coming years per regimen
 3. current stock positions and pipelines- LMIS, NTP and partners – all drug management systems
- Why is this information so difficult to generate, esp for SLD TB drugs ?



Number of patients currently on treatment

- The number of patients enrolled and currently continuing their treatment
 - Effectiveness of regimens
 - Quality of the health system (lab, drug PSCM)
 - Patient support mechanisms , management of side effects and co-morbidities
 - The quality of recording and reporting
 - Completeness and correctness of data

Effectiveness of treatment: outcome of MDR treatment 2007-2010 cohorts



➤ More effective and scalable treatment is needed

What do patients need to enrol & stay on treatment ?



- Information on their disease, reassurance
- Support in how to deal with stigma and self-stigma, grief, acceptance of diagnosis
- Information and guidance on medication, prevention of transmission to family / friends / others
- Support in understanding the consequences for income generation / education, finding solutions and possibilities for support
- Patient friendly regimen and excellent medical management (short, oral , not toxic regimen)

Health service tasks

- Treatment counseling, psych support
- Establishment of PS support network
- Appropriate treatment allocation
(guidelines and treatment councils, trained HWs etc)
- Uninterrupted supply of QA'ed drugs and daily intake with a trained treatment supporter (facility or home based, patient choice)
- Recognition and management of side effects
- Admission facilities for (initiation of treatment) SSE
- QA'ed lab services for monitoring of treatment

Application of R&R and data quality tools

- Quarterly interim cohort assessments at treatment centres
 - monitor of progress pt treatment
 - early identification of problems in service delivery
 - ensure data quality
- Electronic R&R tools: eTB manager, open MRS, Tibu
 - Challenge to integrate electronic R&R in daily work, essential for procurement and program management – **Needs strengthening**



Registered cases	
Suspect not on treatment	354
Confirmed Not on Treatment	6
Confirmed On Treatment	1,016
Transferring to another unit	9
Closed	1,781
Total	3,166
Validation Status	
Waiting validation	1,766
Pending	1



How to calculate the patients currently on treatment per regimen

Based on assumptions related to patient category , fi:

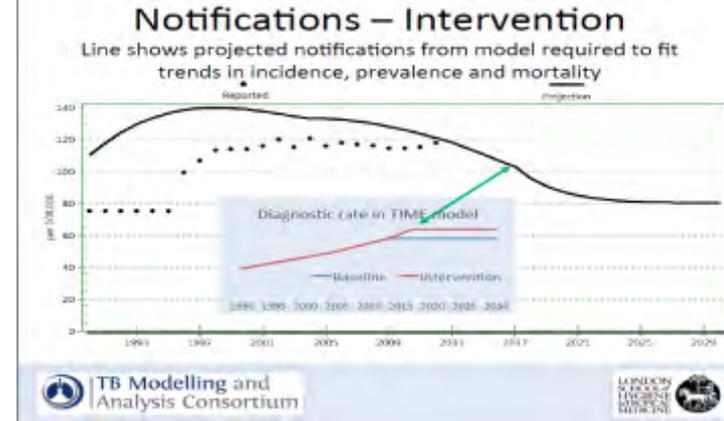
- Preventive treatment with Isoniazid only
- All new patients get Cat I treatment
- Children get Cat I or Cat III treatment (transition to pediatric drugs)
- PT patients get Cat II treatment (if not R resistant)
- MDR : different MDR regimens, duration is not fixed (not reported in WHO R&R format for PMDT – **missing link – now additional book keeping required**)
- Clinicians may decide differently (regimen, duration)



Expected number of TB patients diagnosed

Based on

- TB epidemiological trends (**prevalence surveys, modeling**)
- Impact of program developments, for instance:
 - Community awareness campaigns, health financing
 - Increasing access for children, PLHIV, prisoners, migrants
 - Engagement of all providers (private and public)
 - Changes in D algorithms (Chest X-ray, Xpert)
 - Risk group screening policies
- Partner collaboration/information



Expected number of MDR patients diagnosed

- DR epidemiology: need for up to date drug resistance surveys or cont. surveillance
- Laboratory network expansion, availability of tools, and tests (PSCM), maintenance, lab safety, quality assurance
- Tests speed : Xpert MTB/Rif 1 day, culture based DST 4-12 weeks
- Yield of diagnostic algorithms (not 100%):
 - Despite lower levels of MDR most MDR is found among new cases, testing only retreatment patients leads to delayed diagnosis and exclusion of significant numbers of patients
 - Testing for SL drug resistance at start of MDR treatment or at failure
 - Health worker adherence to algorithms



Introduction of Xpert in Vietnam

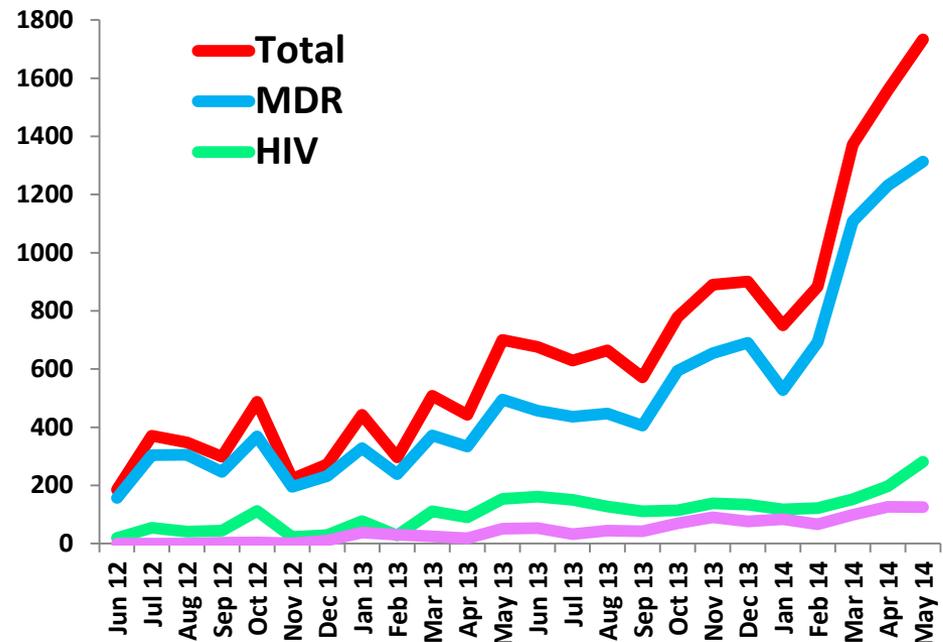
2012-2014

Xpert network

- 8 MDR-TB treatment centers, 1 satellite site & 3 districts
- 4 provinces with high HIV prevalence
- 1 Pediatric Hospital

In 2012:

- 17 GeneXpert systems installed and starting operations
- 962 NTP staff/technicians trained on Xpert MTB\RIF implementation



Acceptance by clinicians, trust in the technology, availability of SLD's once a diagnosis is made, location of the tool, name transportation systems, supplies



MDR Scenario - DST

DST coverage (all TB patients, including EPTB)

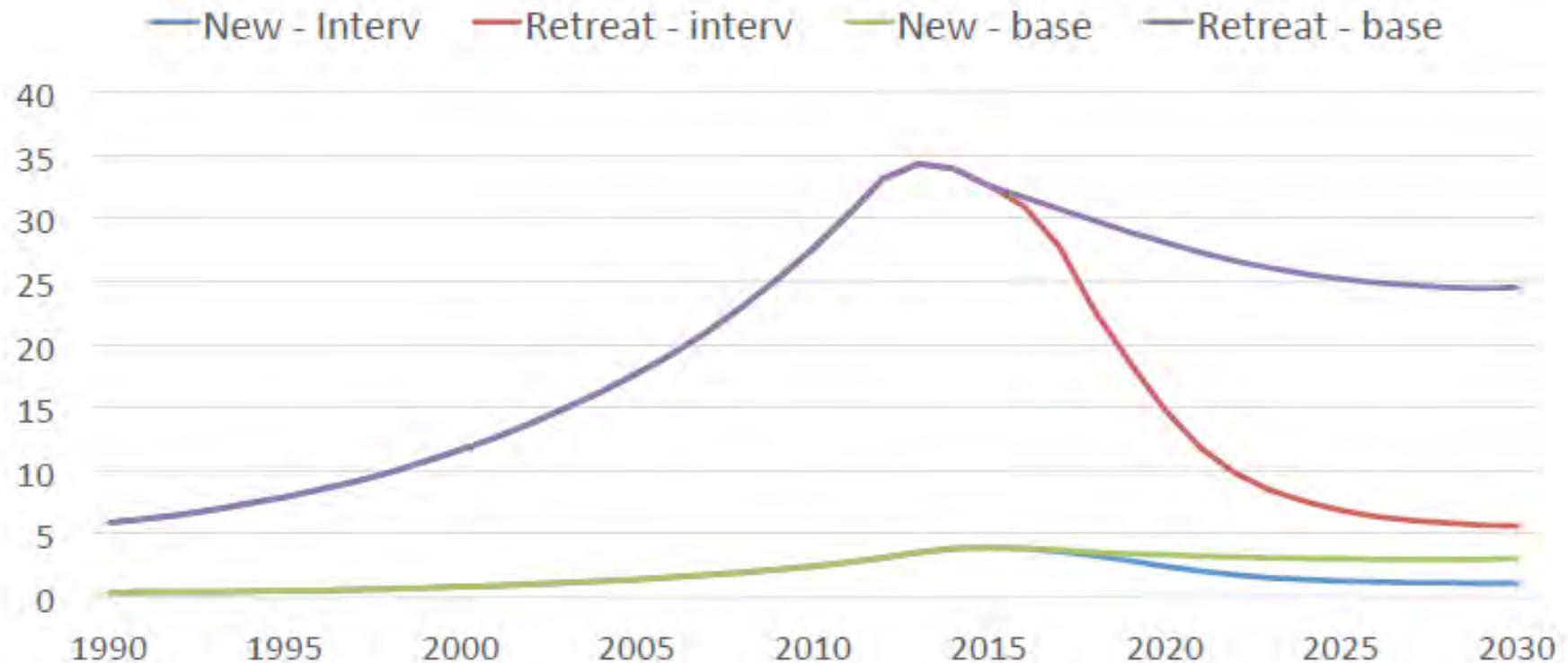


- Xpert based DST screening of all diagnosed pulmonary cases (at provincial level). Scaled up from 2015 onwards
- Includes an adjustment for sensitivity of Xpert test and estimated operational loss of patients during diagnostic process:
 - ~10% not receive results
- Improved cure rate (85% by 2017)
 - Bang regimen, and implementation of pre-XDR and XDR treatment (11% and 5%)



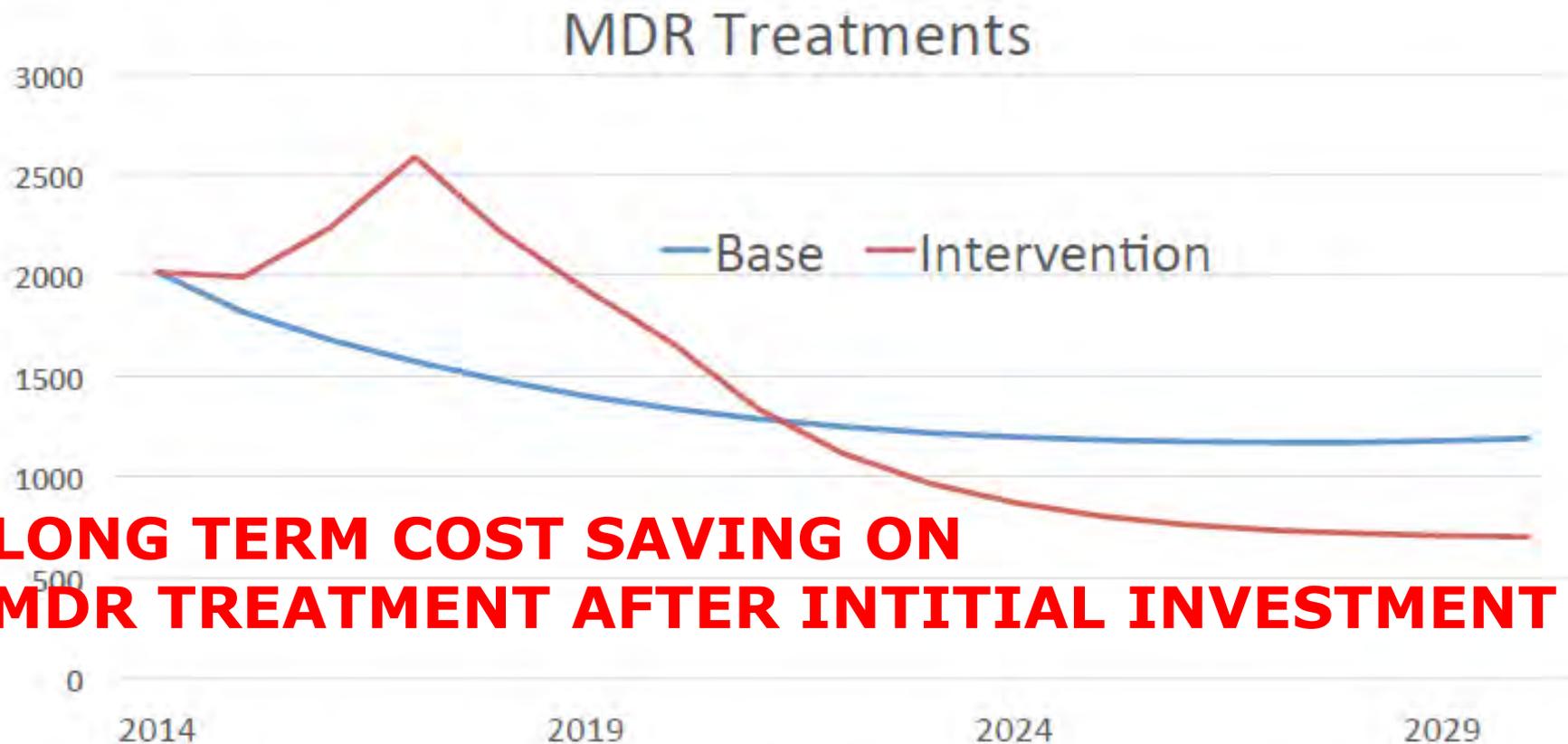
Change in prevalence of MDR

Change in % MDR among notified TB cases



Note: Numbers are approximation from TIME model fit

Number of MDR cases treated



**LONG TERM COST SAVING ON
MDR TREATMENT AFTER INITIAL INVESTMENT**

Note: Numbers are approximation from TIME model fit

Number of diagnosed MDR patients expected to be enrolled

- Partner collaboration/information
- Timely communication of test results
- Sufficient good quality medical treatment capacity
 - Trained staff, treatment council network, appropriate model of care, adequate backup admission capacity, guidelines and communication , infection control
- Availability of socio-economic support (legislation, systems, CSO etc.)
- Patient consent





Risk for transmission of resistant strains to patients and health workers

Expected regimens

Vietnam example 2015 - 2020:

- Preventive treatment: Isoniazid (adult/ped)
- Drugs susceptible TB - Cat I, Cat II (adult/ped)
- MDR TB:
 - Cat IVA
 - Cat IVB (till March 2015, start phase out)
 - 9 month regimen phase in from 3/2015
 - Individualized regimens with new drugs phase in from 3/2015



	2015	2016	2017	2018	2019	2020
Provinces under coverage	41	50	57	63	63	63
Estimated MDR suspects	18.333	17.634	16.920	16.235	15.577	14.946
% MDR-TB suspects screened	65%	75%	90%	100%	100%	100%
MDR-TB suspects to be tested	11.916	13.226	15.228	16.235	15.577	14.946
R-res among notified cases	4.151	4.031	3.868	3.675	3.488	3.311
R-res to be detected	2.429	2.721	3.133	3.307	3.139	2.980
% enrolled among detected	90%	91%	92%	93%	94%	95%
R-res to be enrolled	2.200	2.500	2.900	3.076	2.951	2.831
% 9 mos regimen/R-res	5%	20%	40%	60%	80%	83%
9 mos regimen	100	500	1.450	1.845	2.361	2.358
Long course regimen/standard	1.734	1.586	969	717	97	-
% Pre XDR	11,1%	11,1%	11,1%	11,1%	11,1%	11,1%
Pre XDR	243	275	320	341	328	314
% XDR	5,6%	5,6%	5,6%	5,6%	5,6%	5,6%
XDR	123	139	161	172	165	159



Access to funding

- Procurement planning should match funding cycles and vice versa – in case of donor dependency grant negotiations and grant disbursement problems may result in interruptions of drug supplies to patients
- Funding often not sufficient to fulfill the needs
- Procurement of IQA'ed drugs with domestic funds meets with difficulties (awareness, procedures, GDF)
- Mismatch of funding for scale-up of different PMDT components, esp laboratory network development and patient support

Planning targets driven by financial resources

INDICATOR	Indicator values				Estimated budget US\$			TOTAL
	BL 2012	2013	2014	2015	2013	2014	2015	
Percentage of population at risk with access to diagnosis and treatment of MDR TB in accordance with national guidelines	25%	28%	40%	55%	3.812.889	4.374.758	5.801.300	13.988.947

INDICATOR	Indicator values				Estimated budget US\$			TOTAL
	BL 2012	2013	2014	2015	2013	2014	2015	
Percentage of population at risk with access to diagnosis and treatment of MDR TB in accordance with national guidelines	25%	36%	49%	75%	6279927	7374247	10141214	23795388

Summary country challenges in ensuring access to treatment for TB patients

1. Insufficient diagnosis and notification of TB, (children, private sector, KAP)
2. Insufficient diagnostic capacity for MDR and XDR TB (new tools still needed)
3. Mismatch of diagnostic and treatment capacity during scale-up
4. Lack of DR TB treatment capacity, patient centred care and support
5. Lack of a short, effective, patient friendly, unified (M/XDR)TB regimen
6. Insufficiently reliable data on epidemiology (PS, DRS), diagnosis, continuation of treatment and regimens used - interoperability of systems (quarterly cohort assessment, eR&R systems, data dictionary , link to GDF EWS)
7. Finance for SLD and other essential PMDT treatment components not adequately secured
8. Implementation of projects sometimes contrary to the promotion of sustainability
9. Lack of priority or awareness of complexity of quality assurance of SL TB drugs, possibilities for GDF direct procurement from domestic sources



Demand streamlining and improving access to TB medicines

Andre Zagorski

GF Sourcing and Market Dynamics Strategic Reviews

October 3, 2014

Geneva, Switzerland



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SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

Deep Dive TB Market Dynamics and Supply Chain

Deep Dive Session - Challenge #2: Demand

- In-country challenges in ensuring access to treatment for TB patients



TB treatment challenges

- Long treatment regimens (for MDR-TB: longer than procurement cycles)
- Country's capacity to identify resistance patterns and perform individual DST may be limited
- Constantly changing regimens:
 - Changing WHO recommendations on daily dosages and regimens compositions
 - Duration of regimens (e.g. switch from 24 to 9 months may have dramatic impact on medicines management)
 - Phasing-in/phasing out of regimens (maybe several at once)
 - New medicines



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Access to TB medicines

Increasing Access to Products and Services



Demand for TB medicines

The kind of demand we all want:

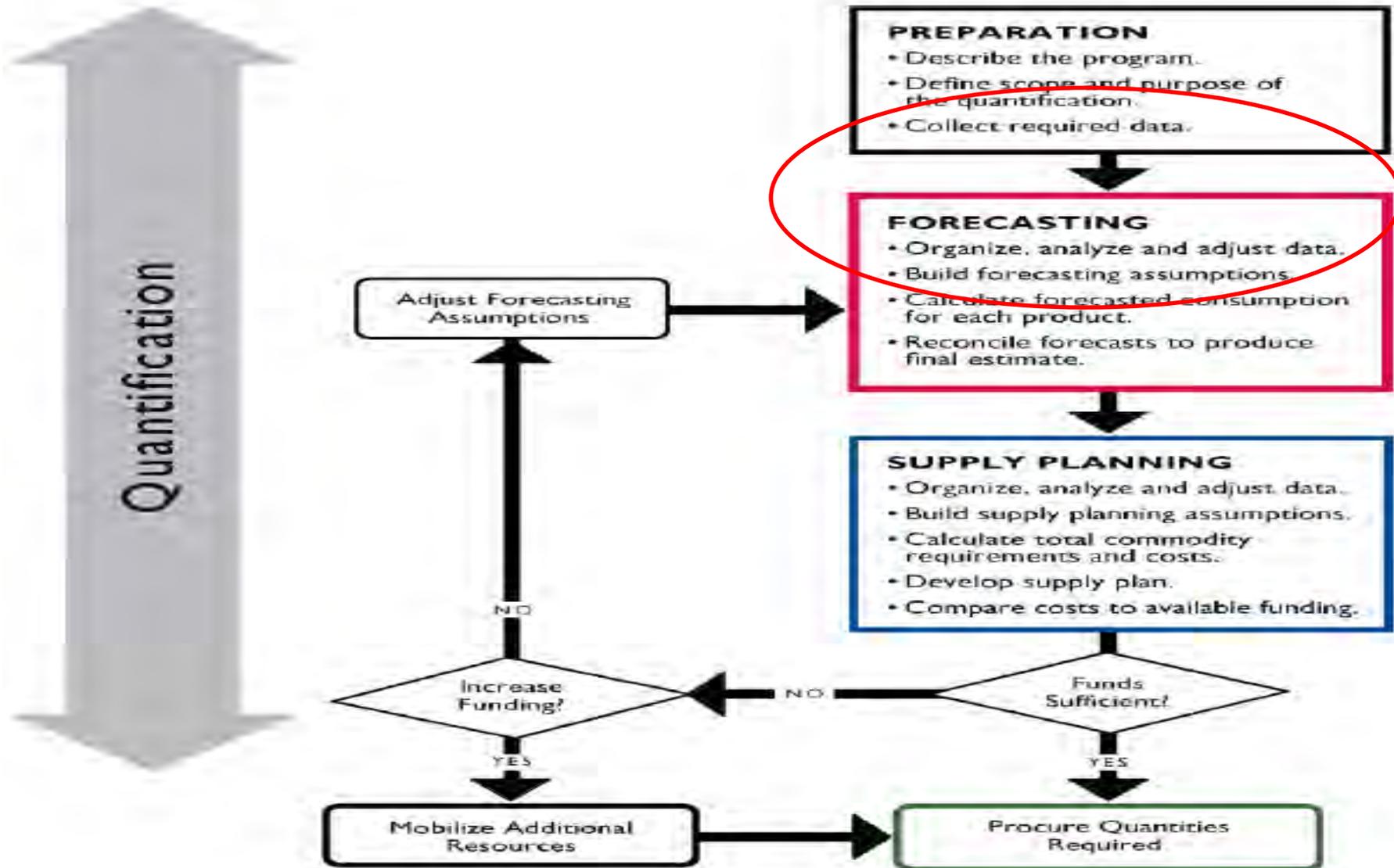
- Reliably forecasted and quantified: based on valid data and educated assumptions
- Matching TB program capacity to detect cases and provide all treatment services through to the outcomes
- Funded throughout the entire supply chain down to a patient
- Timely related to suppliers – according to known lead times (for the TGF funding decisions; for the GDF Global Forecasting and orders placement; etc.)
- Timely adjusted through a functional early warning system and related to suppliers (e.g. for GDF to adjust orders)
- Etc...



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Demand: The Quantification Process



Consensus on *Data dictionary for forecasting and quantification standardization and interoperability**

Technical Term	Description	Format	Example
Issuer			
Issuer	Issuer agency	String	TB statistics department of NTP
Forcecastdate	Date of making the forecast	Date (dd-mm-yyyy)	01/01/2014
IssuerStreetAddress	Street address	String	GDF street
IssuerCity	City	String	Earth city
IssuerState	State	String	Moon state
IssuerZipCode	Zip code	String	12345
IssuerCountry	Country name	Dropdown menu	World Heritage
IssuerEmail	Emailaddress	String	best.worker@home.org
Regimen			
RegimenComposition	Composition of the regimen	Dropdown menu	Kanamycin, Levofloxacin, etc
RegimenDuration	Number of months to complete the regimen	Numeric	20
MedicineName	Name of the active ingredient	Dropdown menu	Kanamycin
MedicineDosageForm	The physical form in which the medicine is to be administered	Dropdown menu	vial
MedicineStrength	Quantity of the active ingredient	Numeric	1000
DailyDosis	Number of medicine dosage forms used per day	Numeric	1
FrequencyPerWeek	Number of days per week that the daily dose is taken	Numeric	6
StartMonthOfMedicine	The number of the month in the regimen that this medicine is started	Numeric	1
StopMonthOfMedicine	Number of the month of the regimen that this medicine is stopped	Numeric	6
Enrollment			
StartMonth	The month of enrollment	Numeric	12
StartYear	The year for the month of enrollment	Numeric	2013
EnrolledPatients	Actual and expected patient enrollment during the defined month	Numeric	10
StillOnTreatmentperMonth	The number of patients still on treatment per month	Numeric	8%
StillOnTreatmentperQuarter	The percentage still on treatment per quarter at 6 months on treatment	Numeric	80%
Stock and Order			
Stockdate	The date the stock was taken	Date (dd-mm-yyyy)	08/10/2013
MedicineName	Name of the active ingredient	dropdown menu	Cycloserine
MedicineDosageForm	The physical form in which the medicine is to be administered	Dropdown menu	capsule
MedicineStrength	Quantity of the active ingredient	Numeric	250
ExpirationDate	Expiration date per medicine on stock	Date (dd-mm-yyyy)	09/09/2014
MedicineonStock	Number of medicines in stock	Numeric	1500
ExpectedReceivingDate	The date of expected delivery	Date (dd-mm-yyyy)	01/01/2015
MedicineonOrder	Number of medicines in stock	Numeric	8000

*In collaboration with The Project on e&mHealth interoperability; United Way Worldwide grant on behalf of Eli Lilly and Company Foundation ; managed by KNCV



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Early Warning System (EWS) for stock-outs

- Regular re-quantification, quarterly:
 - Updating medicines stock
 - Updating expected cases that became enrolled
 - Adjusting for attrition (up or down depending on TB indicators)
 - Adjusting medicines prices, supply chain costs
- Proper inventory management (monitoring of stock levels and reordering dates)
- User friendly quantification and EW tools with dashboards – such as ***QuanTB***



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Key challenge: Where are the data?

- Medicines: each product by batch and expiry date, stock on order
 - LMIS: are the numbers for CMS only or the entire country?
 - Could dispensation data be used for forecasting?
 - Are numbers matched with actual cases and regimens?
- WHO-type recording and reporting: are numbers of cases on treatment by regimen or by % of use of each medicine in regimen reported and available?
 - Data are available in treatment forms, but are not a part of quarterly reporting requirements
- Electronic R&R will greatly help: e.g. e-TB Manager, openMRS, TIBU, etc.



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The SIAPS logo consists of the word "SIAPS" in a bold, green, sans-serif font, followed by a stylized blue and green graphic of a person with arms raised in a celebratory or active pose.

Country X case: Challenges and solutions

April 2014 (start of QuanTB as quantification and EWS)

- Multiyear enrollment plan was approved by GF in 2012 based on expectations from GeneXpert implementation
- In 2013, Country X enrolled 65% of planned MDR-TB cases
- During Ramadan (July or August) and winter season (December and January) MDR-TB patient enrolment is usually reduced by 25%
- All MDR-TB cases reported by NTP in 2013 were diagnosed by GeneXpert: 39 machines as of April 2014, with additional 25 coming in September 2014
- Country planned 10 XDR-TB cases for 2013: 6 were diagnosed and enrolled, but 1 died and 2 were lost to follow, 3 patients on treatment in April 2014.
- Ten XDR-TB patients were planned for 2014; none enrolled by April 2014.
- All medicines have been procured and partly delivered



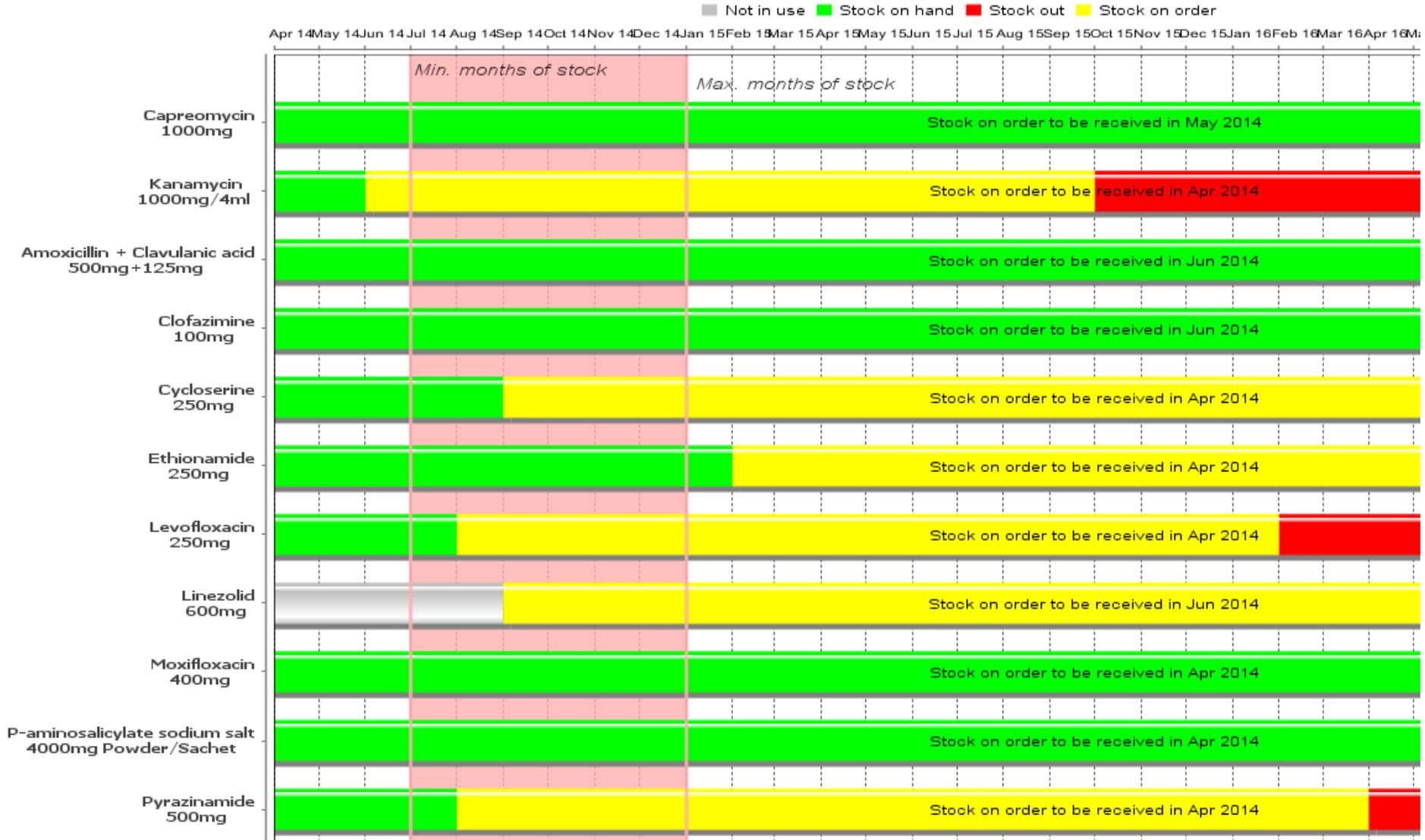
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QuanTB dashboard

Overstock and potential expiry: Capreomycin, Amoxicillin/Clavulanate, Clofazimine, Moxifloxacin and PAS

Reference date: Apr 1, 2014 Total enrolled cases: 863 Total expected cases: 910



Country X scenarios

Used QuanTB to:

- Create alternative regimens with overstocked medicines replacing those used in standard MDR-TB regimen
- Use QuanTB to play the scenarios and monitor medicines consumption by patients on each regimen
- Update planned cases distribution to alternative regimens
- Identify medicines and their quantities that require immediate adjustments in the GDF orders

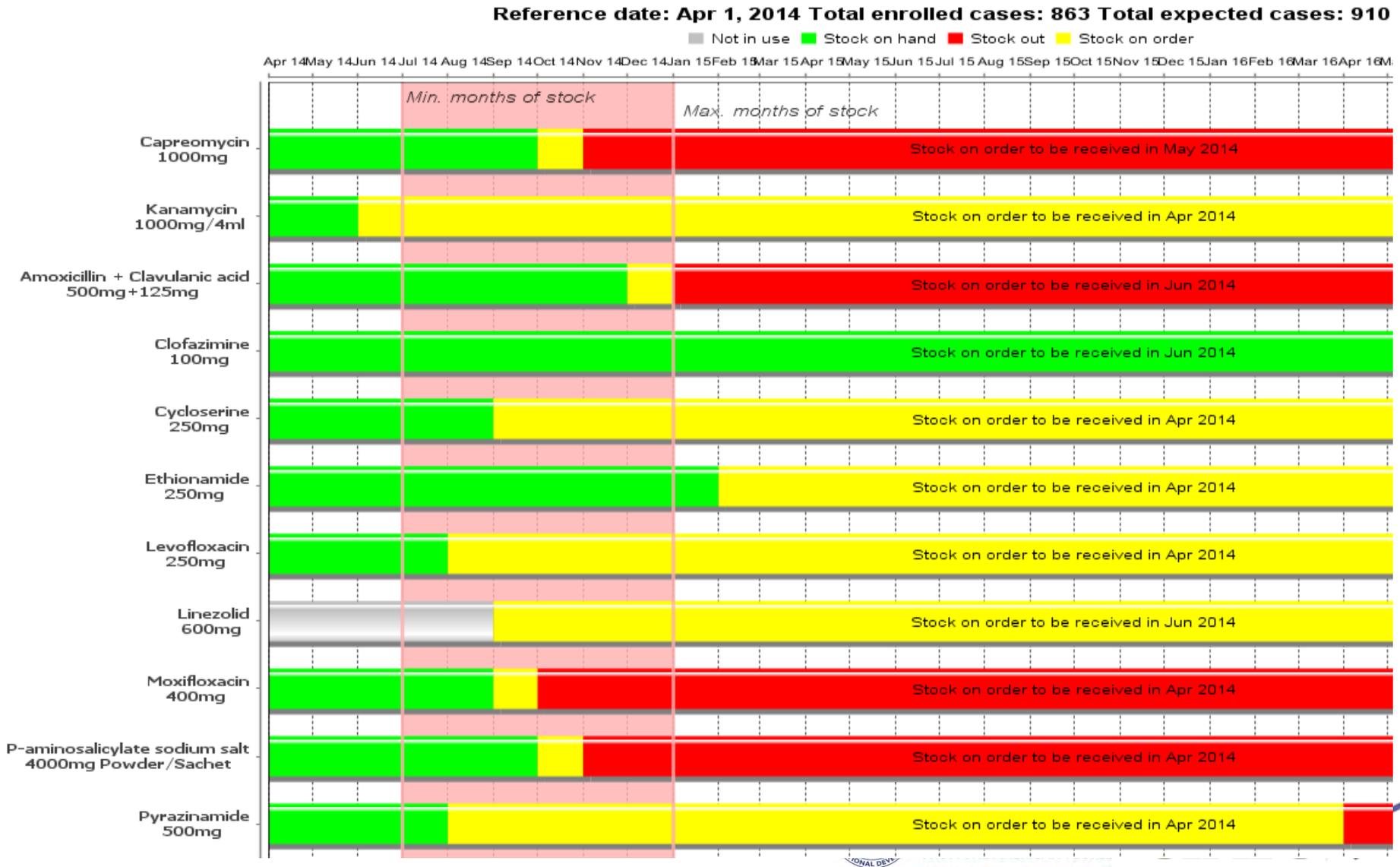


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Country X: QuanTB dashboard

Hypothetical scenario if country follows proposed approach:



Country X results

- Country worked with the GDF, WHO, and technical partners including in other countries:
 - Pending delivery of one product was postponed
 - Seven orders were cancelled
 - Shipments of nine SLD products were re-directed to other countries
- Country X saved medicines worth of \$ 899,976 USD from expiry and waste



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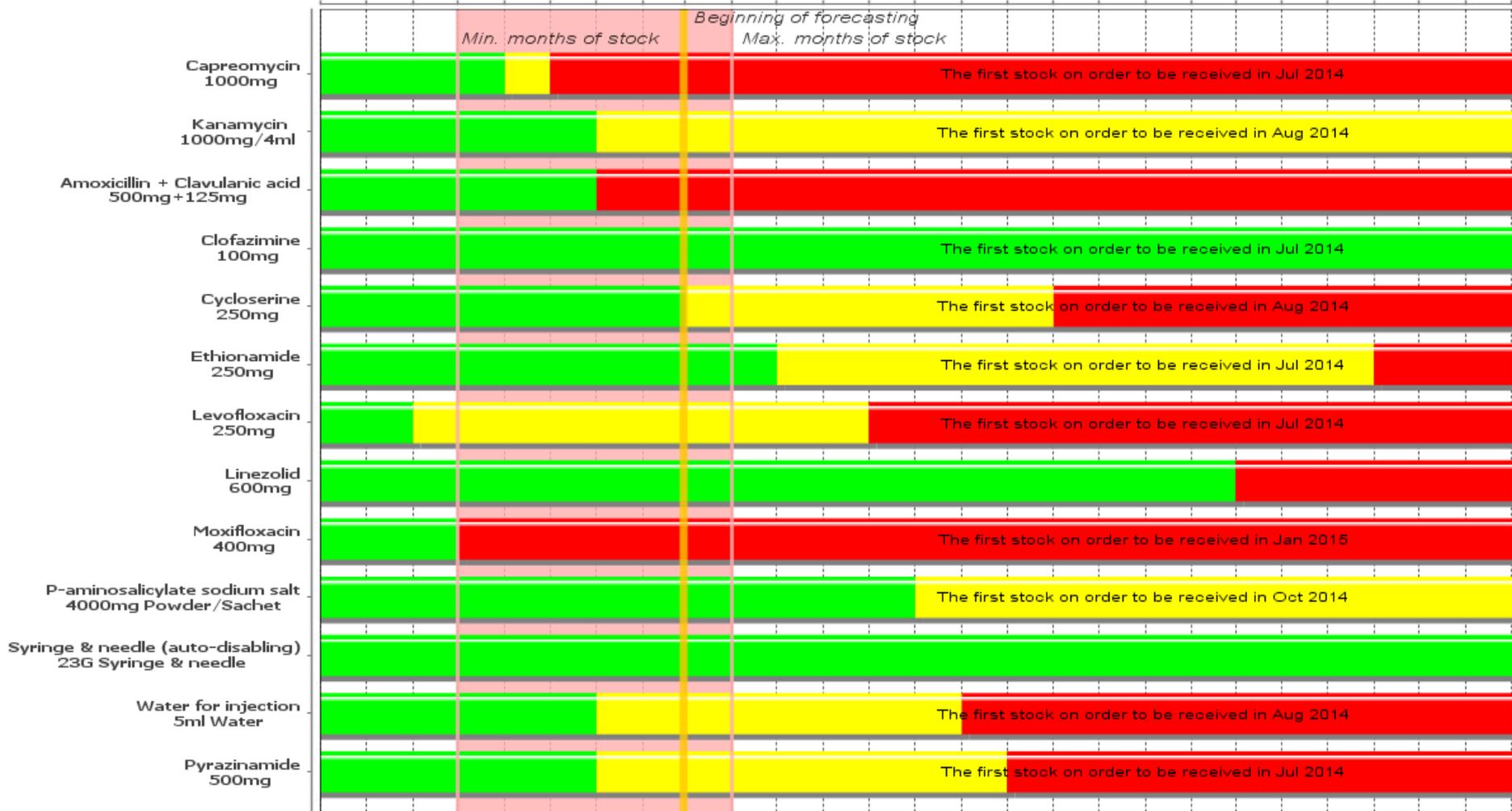
Country X: current situation

August 2014 QuanTB shows country is on track with medicines

Reference date: Jul 1, 2014 Total enrolled cases: 968 Total expected cases: 1,055

Not in use Stock on hand Stock out Stock on order

Jul 14 Aug 14 Sep 14 Oct 14 Nov 14 Dec 14 Jan 15 Feb 15 Mar 15 Apr 15 May 15 Jun 15 Jul 15 Aug 15 Sep 15 Oct 15 Nov 15 Dec 15 Jan 16 Feb 16 Mar 16 Apr 16 May 16 Jun 16 Jul 16 Aug 16



Summary

- All tools and guidance for the assessing supply chains and developing interventions to improve access are readily available from technical partners
- Quantification and early warning tools are available (for both country and global level) USE THEM
 - QuanTB now in version 2, can quantify for any complexity of regimens (multi-phased)
 - QuanTB is an effective early warning tool for stock-outs
 - QuanTB is the GDF tool of choice for monitoring missions and quarterly reporting to Global Forecasting and EWS
 - April 2014 – ten GF portfolio managers were trained in QuanTB



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Summary, cont.

- Key challenge for demand forecasting is lack of reliable data at the country level
 - WHO and donors should revise their recording and reporting recommendations and tools to ensure data collection and validation for demand forecasting, supply planning, and quantification
 - Technical partners in countries should invest in strengthening MIS for TB using standardized tool (e.g. Data dictionary for quantification)
 - GDF has developed interfaces and is developing channels for data collection and aggregation at the global level



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Discussion: Demand

- **Diagnosis:** Insufficient diagnosis and notification (children, private sector); mismatch between diagnostic and treatment scaleup
- **Keeping patients on (effective) treatment:** Non-patient centered care; ineffective regimens
- **Poor data quality:** Patient monitoring, program management
- **Budgets:** Insufficient or not readily available
- **Country-level quantification and forecasting:** Availability of accurate data for timely procurement planning

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Deep dive – logistics – in groups

Observations, 5



Introduction, 5



Feedback, 25



Presentation 15



Discussion, 40



Challenges #2 and #3 – Demand and Supply

What are the short-, medium-, and long-term market shaping activities that Global Fund and partners should implement in order to address TB drug and diagnostic market challenges?

Next Steps
